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In-patient Tuberculosis (TB) Treatment in Armenia: Establishment of a Continuous Quality Improvement System

A Needs Assessment

Prepared for the Armenian Medical Fund

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ABBREVIATIONS

ACC	– Access and Continuity of Care
AIDS	– Acquired Immunodeficiency Syndrome
ALAT	– Alanine aminotransferase
AOP	– Assessment of Patients
ASAT	– Aspartate Aminotransferase
AUA	– American University of Armenia
BK	– Bacilli of Koch
CHSR	– Center for Health Services Research and Development
CJSC	– Closed Joint Stock Company
COP	– Care of Patients
DOT	– Directly Observed Treatment
DOTS	– Directly Observed Treatment Short course
DR-TB	– Drug Resistant Tuberculosis
DST	– Drug Sensitivity Test
DS-TB	– Drug Sensitive Tuberculosis
FCTC	– Framework Convention of Tobacco Control
GLD	– Governance, Leadership and Direction
HIV	– Human Immunodeficiency Virus
IPSG	– International Patient Safety Goals
ISTC	– International Standards for Tuberculosis Care
JCI	– Joint Commission International
MCI	– Management of Communication and Information
MDR-TB	– Multi-Drug Resistant Tuberculosis
MMU	– Medication Management and Use
MOH	– Ministry of Health
NRL	– National Reference Laboratory
NTCC	– National Tuberculosis Control Center
PCI	– Prevention and Control of Infection
PFE	– Patient and Family Education
PFR	– Patient and Family Rights
QPS	– Quality and Patient Safety
RA	– Republic of Armenia
SNCO	– State Non-Commercial Organization
SQE	– Staff Qualifications and Education
SS	– Sputum Smear
TB	– Tuberculosis
WHO	– World Health Organization
XDR-TB	– Extra-Drug Resistant Tuberculosis

EXECUTIVE SUMMARY

High-quality TB care provision is an important step toward improving patients' quality of life and decreasing TB morbidity and mortality. Introduction of international standards and guidelines for TB care provide opportunity to ensure access to high-quality TB services serving as a comparison benchmark for the national program's performance assessment. Assessment of adherence of diagnostic and treatment services to the standards is one of the important components for defining quality of provided care and later for developing quality improvement programs.

In 2016, the Center for Health Services Research and Development (CHSR) of the 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 Armenian Medical Fund implemented the In-patient Tuberculosis (TB) Treatment in Armenia: Establishment of Continuous Quality Improvement System project, during which it conducted a needs assessment of the NTCC's diagnostic and inpatient treatment services in the TB inpatient facility located in Abovyan city. The assessed facility is the largest TB hospital in the country that provides inpatient care to around 3,000 TB patients annually.

The study team (1) reviewed and summarized the literature on quality assessment of inpatient TB facilities, (2) qualitatively explored practices of healthcare professionals of NTCC and inpatient treatment experience of TB patients and their family members, (3) assessed the documentation, staff practices and environmental conditions of the NTCC's inpatient facilities using standardized checklists, (4) evaluated the compliance level of TB diagnostic and treatment practices with the internal policies and procedures, national and international guidelines and standards, and (5) made recommendations to the NTCC based on the findings for further improvement of TB diagnostic and treatment services.

The study showed that in practice there are several processes that are not standardized and consistent throughout the organization, because of either absence of relevant policies or lack of enforcement of existing ones. Moreover, the monitoring and follow-up mechanisms throughout

the organization are very weak; therefore, compliance with even existing policies is not achieved. More specifically:

- NTCC lacks relevant up-to-date policies for daily operation of the organization, including formal regulations for all the structural units of the organization, patients' rights and responsibilities, policies for patients' assessments, care delivery, medication management and use, patients' and family education, targeted policies on quality and patient safety, staff recruitment, appointment and evaluation, and in-service staff education.
- The overall understanding of quality and patient safety are very narrow in the NTCC, and the staff does not share the same vision and dedication to quality improvement.
- NTCC lacks the modern diagnostic infrastructure, including clinical laboratory and radiology to address safety risks within and outside the diagnostic areas. The laboratory facility needs major renovations and modernization to meet the local and national standards, laws and regulations.
- The organization does not adequately use all the data which they collect. Recording, reporting, documenting, and acting based on the data, as well as further analysis of the data is missing in several areas, including patient health, infection prevention and control, medication management and use, monitoring and evaluation.
- The staff education at NTCC is mainly informal or non-existent. The organization has no planned and systematic educational programs developed to improve the professional skills of the staff and the disease-related knowledge of patients and their family members.

The findings of the study suggest that interventions on two levels of the organization's operation are needed: structure-related improvements (development of policies, procedures, written documentations and establishment of modern infrastructures) and process-related improvements (actions towards improving the patient care processes). Furthermore, the hospital-wide organizational culture should undergo several changes to go in-line with the notion of healthcare quality and patient safety.

INTRODUCTION

Tuberculosis

Tuberculosis (TB) is an infectious bacterial disease caused by *Mycobacterium Tuberculosis* (BK, bacilli of Koch) that spreads through the air by coughing, sneezing, or talking.[1,2] The most commonly affected site is the lungs, but it can also affect other organs, especially in immune-suppressed persons. The symptoms include cough with thick, cloudy mucus or sputum, sometimes with blood for more than three weeks, fever, chills, night sweats, fatigue, muscle weakness, weight loss and in some cases shortness of breath and chest pain.[2,3] The disease may be expressed as pulmonary TB and extra pulmonary TB. The extra pulmonary is much less common than pulmonary.[1, 2]

According to the World Health Organization (WHO) in 2014 the level of incidence of TB was lower than the one in 2000 by 18% which was achieved by 1.5% annual average decrease of TB incidence. In the meantime, during 1990-2015 the death rate because of TB has fallen by 47% and the estimated number of lives saved due to TB diagnosis and treatment during 2000-2014 was 43 million.[3] Nevertheless, TB remains one of the major global public health problems and is a major cause leading to death (1.5 million deaths worldwide in 2014) along with the human immunodeficiency virus (HIV).[4] The estimated number of TB cases worldwide in 2014 was 9.6 million of which 12% (1.2 million) were estimated to be HIV positive.[4] More than 80% of active tuberculosis in the world falls on 22 low and middle income (high-burden) countries and more than 95% of TB death occur in those countries.[3–5]

Risk Groups

Men and women have equal chances to become infected with TB but men are more likely to develop TB disease.[6] Exposure to mycobacterium tuberculosis puts persons living with the Human Immunodeficiency Virus (HIV) at increased risk for mortality and greater severity of morbidity, because their immune system is depressed and they have a 26-31 times higher probability of developing active TB.[7] High risk groups include also migrant populations, the homeless, prisoners, orphans, people in hospices or psychiatry hospitals, people with medical problems such as occupational pulmonary diseases, diabetes mellitus, gastric and duodenal ulcer, people who had treatment experience with corticosteroids, cytostatics, radiotherapy, people

having contact with persons or animals suffering from pulmonary TB, and people working at schools, municipal services, public transport, catering and grocery stores.[2,8] There is consistent and strong epidemiological evidence that passive exposure to tobacco smoke are significantly associated with TB infection, disease, recurrent TB and TB mortality.[5,9]

After infection the risk of developing TB disease is the highest among children younger than 4 years old – then it decreases. Starting from the age 15-19 the risk substantially increases again, peaking between the ages of 20-30 years.[10] In 2014, 1 million childhood TB cases have been reported in the age span of 0-14 years and 140,000 of those cases ended up with death.[3] The risk for developing active TB and death because of TB increases among tobacco users with approximately 20% of world TB cases being attributed to tobacco use.[3]

Transmission and Disease Development

The spread of TB bacteria depends on several factors such as duration and intensity of exposure, related to the time of exposure of those without TB to infectious person with TB and the number and concentration of infectious persons, and the proportion of exposed persons who are more susceptible to TB.[11] About 30% of people who have close contact with an infectious person with TB become infected. Furthermore, 10% of TB-infected people develop TB disease throughout their lifetime and the risk is the greatest in the first two years after infection.[3] In most populations, approximately 95% of persons infected with TB enter a latent asymptomatic phase; these persons may develop TB disease later if the bacteria overcome the immune system of the individual. It is estimated that each person with active TB infects 10-15 people on average if not treated.[3]

Drug-Resistant TB

TB can be treated with five standard first-line anti-TB drugs.[1] Misuse or mismanagement[2] of these drugs may lead to drug resistant (DR) TB. DR-TB includes mono-resistant TB, polyresistant TB, multi-drug resistant TB (MDR-TB) and extensively drug resistant TB (XDR-

[1] First-line anti-TB drugs are isoniazid, rifampin, pyrazinamide, ethambutol and streptomycin (S).
[2] Misuse or mismanagement – drugs taken in a wrong combination, or fewer drugs taken than prescribed, or drugs taken in insufficient doses, or drugs taken for insufficient time.

TB). A mono-resistant TB case is a TB patient with a Drug Susceptibility Test (DST) result showing resistance to one first-line anti-TB drug. A poly-drug resistant TB case is a TB patient with DST results indicating resistance to several anti-TB drugs but not to both rifampicin and isoniazid. MDR-TB case is a patient with DST resistance to at least two of the most powerful first-line anti-TB drugs: isoniazid and rifampicin. XDR-TB is resistance of the bacteria to any fluoroquinolone drug in addition to isoniazid and rifampicin and at least one of three following injectable second-line drugs: capreomycin, kanamycin and/or amikacin. Patients with DR-TB can transmit DR-TB to others. Symptoms of drug-resistant and non-drug-resistant TB are the same.[2]

Treatment with second-line drugs is more expensive, less effective and more toxic.[12] Those infected with DR-TB are more likely to default in treatment, treatment success rates are lower and they are more likely to die due to their disease than those patients with regular TB. According to WHO in recent years, 3.3% of new TB cases and 20% of cases on retreatment have developed MDR-TB.[4] The estimated number of new MDR-TB cases in 2014 was 480.000 with the estimated number of deaths 190.000.[4] XDR-TB cases have been reported in 105 countries with the highest prevalence in Eastern European and central Asian countries.[4] High mortality rates and loss to follow-up among MDR-TB cases worldwide have resulted in achieving only 50% treatment success rate.[4] Approximately 37% of the estimated TB cases and 74 % of the estimated MDR-TB cases were either undiagnosed or underreported in 2014, thus leaving unknown the quality of TB diagnostic and treatment services for these groups of TB cases.[4]

Quality of Care and TB

The WHO defines quality of care as a conjunction of six dimensions: effectiveness, efficiency, accessibility, acceptability, equitability, and safety.[13] Best practice of care will try to address all these dimensions.[13] According to Donabedian, the quality of health care can be defined through two components: technical care (the result of application of science and technology of health care) and interpersonal interaction (agreement to social values and norms in health care context).[14] In the scope of quality assessment three main indicators of health care services have been suggested by Donabedian's framework, that are structure, process and outcome of health care.[15] Structural factors are characteristics of health care providers: their human, physician and

financial resources necessary for services' provision. Process factors encompass variety of activities between health care providers and patients. The outcome is defined as change in patients' health status attributable to the services provided.[14]

Another approach of defining quality of care is differentiation of roles and responsibilities.[13] The TB care Improvement Handbook identifies three perspectives of the concept of quality of TB care: perspective of a patient, service provider and health facility manager.[16] Service provider's perspective of quality incorporates capacities such as competence, confidence, being respectful, educating patients, application of TB 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.

Joint Commission International Accreditation Standards for Hospitals developed by the Joint Commission International (JCI) target to measure the quality of services being provided in the hospital in order to improve the performance and the outcomes of the hospital. The assessment of quality of service provided in the hospitals is conducted through functions, standards and measurable elements. The functions consist of various standards, whereas the standards consist of measurable elements. The measurable elements are to be assessed to judge upon the degree of compliance of hospital performance to the respective standard. The assessment of standards in its turn assist in evaluating the overall performance on the function level.

The Joint Commission International Accreditation Standards for Hospitals 4th 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.[17]

Introduction of international standards and guidelines for TB care have both provided opportunity to ensure access to high-quality TB services and served as a comparison benchmark

for the national program's performance assessment.[16,18] 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.[18]

High-quality TB care provision is an important step toward improving medical practice and patient outcomes to eventually decrease the disease incidence.[19,20] The improvement of the quality of TB services is possible through adherence to international standards adapted for the country.[16] Assessment of adherence of diagnostic and treatment services to the standards is one of the important components for defining quality of provided care and later for developing quality improvement programs.[16] The studies have shown that providers' non-adherence was mostly determined by being overburdened, by the lack of knowledge/skills, attitude and behavior, lack of materials/supplies, and other factors.[21–23]

The International Stop TB Strategy that aimed to drastically lessen the burden of disease worldwide by 2015 developed four major objectives to attain the goal.[4,24] Provision of universal access to high-quality diagnosis and treatment services was one of those objectives.[4,24] The new Global TB Strategy is the End TB Strategy targeting 95% and 90% decrease in the number of TB deaths and new cases respectively during 2015-2035 period.[25] The End TB Strategy still 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.[25]

The Government of Armenia has also joined the WHO End TB Strategy for 2016-2022 years.

TUBERCULOSIS IN ARMENIA

Burden

In Armenia, according to the 2014 estimates, the TB (excluding HIV/TB) incidence rate was 42 per 100,000 population and the TB mortality rate was 5.1 per 100,000 population including HIV-positive cases.[4] The estimated proportion of new MDR-TB cases is 9.4% and the proportion of retreated TB cases who develop MDR-TB is estimated to be 43% (Table 1).[4] Currently 3,800

people are estimated to be living with HIV/AIDS in Armenia. Among people aged 15-49, HIV prevalence is reaching 0.2%.

Out of 1,099 TB patients that were tested for HIV from 2002 to 2007, 1.8% of TB patients were reported to be co-infected with HIV in 2002, climbing to 3.1% in 2007.[26] Based on the 1,242 TB patients tested for HIV in 2010, the percent of co-infected persons with HIV dropped to 1.4% [27], but then started dramatically increase reaching 6.3% for 1,342 HIV-tested patients in 2014.[4]

Table 1. TB indicators for Armenia for 2014

Mortality (Excluding HIV+TB)	4.7 (3.9-5.5)* per 100.000
Prevalence (Includes HIV+TB)	55 (24-101)* per 100.000
Incidence (includes HIV+TB)	45 (40–50)* per 100.000
Incidence (HIV+TB only)	2.7 (2.4–3)* per 100.000
Case detection, all forms	98 (88–110)*%
New MDR-TB cases	9.4 (7–12)*%
Previously treated TB cases with MDR-TB	43 (38-49)*%
Treatment success rate among new smear-positive and relapse	81%
Treatment success rate among previously treated cases, excluding relapse	78%
RR-/MDR-TB cases started on second-line treatment in 2012	44%

* Uncertainty intervals

National Tuberculosis Control Center

The Government of Armenia's National TB Control Program (NTP) was established on December 4th, 2003 by the decree N° 1680. According to the decree N°337-A of March 27, 2014 the "Republican TB Dispensary" CJSC united with the "National TB Control Program" SNCO and consolidated into the "National TB Control Center" SNCO of RA (NTCC).

From 2006 to 2015 The NTP adhered to the International STOP TB strategy and the Global Plan to STOP TB to apply best practices for organizing prevention, detection and treatment efforts,

based on the WHO recommended Directly Observed Treatment Short-course (DOTS) strategy.[2, 3] In 2016 the National Program transited from the Stop TB Strategy to the End TB Strategy by updating the national strategy for TB control for 2016-2022 years to achieve the reduction of TB morbidity and prevent spread of TB.

Service delivery

From 2003 to 2014 in Armenia, TB services in the civilian sector were organized through health care facilities located in 10 marzes and Yerevan. These included two specialized TB dispensaries, providing inpatient care (the Republican TB Dispensary in Abovian and the City TB dispensary in Yerevan), 10 TB in-patient departments in general hospitals (with a total 518 TB hospital beds), and 72 TB outpatient centers/offices in polyclinics providing outpatient services.[28] During 2007-2014, the National Tuberculosis Control Program underwent optimization with regards to the structure, service, and resource allocation provision.

Currently the 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.

As a result of optimization, 72 outpatient TB centers in Yerevan and regional polyclinics were consolidated into 60 currently functioning outpatient TB centers. Ten TB in-patient departments in regional general hospitals were consolidated into 4 departments in Gyumri, Vanadzor, Kapan, and Goris (with a total 110 TB hospital beds). Two hospitals still provide inpatient services: one located in Yerevan city (with a total 48 TB hospital beds) that mainly serves Yerevan residents and another one located in Abovian city (with a total 300 TB hospital beds) that serves about 90% of all TB patients from Armenia: around 3,000 TB patients annually.

The National Reference Laboratory (NRL), which is located in the NTCC building, is an independent legal entity and performs microscopy, Drug Sensitivity Testing (DST) and culture growth. The NRL, together with 25 Level-I microscopy laboratories, comprises the network of TB laboratories in Armenia. The NRL is also responsible for quality assurance monitoring of all laboratories in the country.

Treatment

According to the National Standard of TB diagnosis and treatment, treatment for new regular pulmonary and extra-pulmonary TB cases is six months. The first phase of treatment is two months of intensive treatment with HRZE[3], usually at an in-patient TB care facility.[27] The second phase is four months of treatment with HR (Isoniazid (H), Rifampicin (R)). The treatment for relapsed regular TB cases is eight months – two months of intensive treatment with HRZES followed by HRZE (Streptomycin removed) for one month, followed by five months of treatment with HRE. If after this treatment the patient is still smear positive, the intensive phase treatment is extended for an additional month. The patients receive the continuous phase of treatment at their local TB outpatient centers. For those patients who live far from the local TB outpatient center, the rural health facilities (Medical Ambulatories and Village Health Points) provide TB care during this phase of treatment.[27] Rural health care nurses are responsible for monitoring patients' compliance with TB treatment, as well as visiting any patient that has missed their regular appointment with the health facility. During both intensive and continuous phases of treatment, directly observed treatment (DOT) is required. The responsibility for direct supervision of patients taking TB medication primarily falls on in-patient and out-patient health facilities. When necessary, nurses receive extra pay to stay on duty on Saturdays to conduct directly observed treatment for TB patients.

In 2009 the World Health Assembly resolution 62.15 urged member states "to achieve universal access to diagnosis and treatment of multidrug-resistant and extensively drug-resistant tuberculosis".[29] In 2010, Armenia was one of the first countries to present their adapted national TB control plan to WHO.[29]

[3] Isoniazid(H), Rifampicin(R), Pyrazinamide(Z), Ethambutol(E), Streptomycin(S)

Médecins Sans Frontières France (MSF France) initiated MDR-TB DOTS+ treatment in two districts of Yerevan (Malatia/Sebastia and Shengavit) as a pilot program in 2005 in collaboration with the Armenian Government. By the end of 2011 this program was expanded to cover the entire country, with an ongoing handover of this treatment program to the National TB Program.[27] A multidisciplinary team, which included doctors, nurses, social workers and psychologists, was formed to assist and encourage patients and to decide on treatment approaches as well as systematically conducts training sessions on TB infection and TB treatment related difficulties.

MDR TB patients are directly treated by TB physicians who have undergone specialized training for DR-TB management. The treatment for drug-resistant TB is complicated and varies widely depending on the response of the bacteria to the treatment and on side effects.[27] Treatment for DR-TB requires a minimum of 21-24 months or 18 months after the smear and the culture are negative. Before starting the treatment for DR-TB, biochemical and hematological tests are conducted for side-effects due to the medication and HIV testing is recommended since TB is an opportunistic disease for HIV. For these DR-TB patients, the intensive phase of treatment is provided in-patient TB departments. The continuous phase of treatment for these patients is provided in TB outpatient centers. All the marzes and Yerevan have TB outpatient centers that provide DR-TB services.[27]

Once the drug sensitivity test results are available, a specialized treatment plan is developed for each patient.[27] Based on their previous history of disease and treatment, 4-5 effective medications are chosen to begin the intensive treatment phase. Medications are administered twice a day, 6-7 days a week- initially, dosage is lower and is increased to full dosage within 3-14 days.[27]

STUDY OBJECTIVES

The Center for Health Services Research and Development (CHSR) of the 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 Armenian Medical Fund

launched the "In-patient Tuberculosis (TB) Treatment in Armenia: Establishment of Continuous Quality Improvement System" project, which started with an initial needs assessment to develop a multi-year plan for collaboration to strengthen the inpatient and outpatient TB care in Armenia. During the needs assessment we looked at the NTCC diagnostic and inpatient treatment services in the facility located in Abovian city.

The aim of the study was to develop a multi-year plan on how to turn the inpatient and diagnostic facilities into settings with modern mechanism of patient safety and quality assurance system for provided care through undertaking systematic measures to continuously improve NTCC operations and the quality of care it provides. The established quality assurance system will ensure that patients seeking health care will be protected from medical mistakes in care they receive and create a safe environment for the patients. During the first phase – the needs assessment – we assessed different aspects of NTCC's diagnostic and inpatient operations, including both clinical and administrative functions.

The specific objectives of the needs assessment were:

- To review and summarize the literature on quality assessment of inpatient TB facilities.
- To qualitatively explore practices of healthcare professionals of NTCC's diagnostic and inpatient facilities and inpatient treatment experience of TB patients and their family members.
- To assess the documentation, staff practices and environmental conditions of the NTCC, using standardized checklists.
- To assess the compliance level of TB diagnostic and treatment practices with the internal policies and procedures, national and international guidelines and standards.
- To make recommendations for establishing a Continuous Quality Improvement system at the NTCC.

The quality of provided services has been determined by the degree of compliance of the NTCC with the internal policies and procedures and national and international guidelines.

METHODS

Study Design

To evaluate the quality of diagnostic and treatment services in the hospital of the National Tuberculosis Control Center the CHSR research team used document review and qualitative research methods, including in-depth interviews and observations.

Study Participants

The CHSR identified key informants using purposive and convenient sampling methods to provide pertinent information for the assessment, based on key informants' experience and expertise in the inpatient TB center of NTCC. The research team recruited study participants purposively from the clinical departments and administrative structural units of the NTCC. In-depth interviews included the following 11 groups of key informants: 1) NTCC managers, 2) Heads of departments, 3) TB physicians and nurses, 4) TB patients and their family members 5) Laboratory staff, 6) Pharmacists, 7) Infection prevention and control, 8) Radiology, 9) Monitoring and evaluation, 10) Continuing education, and 11) Human resource management.

To recruit TB patients, who received their inpatient treatment in the inpatient treatment facility in Abovian city for the in-depth interviews, the research team cooperated with TB outpatient center physicians in Yerevan and Aragatsotn regions in Armenia.

The physicians of TB outpatient centers initially contacted the patients and after obtaining their agreement, passed the patients' information to the research team.

Study Instruments

The research team developed the study instruments based on the Joint Commission International Accreditation Standards for Hospitals, International Standards for TB Care, and WHO framework for conducting TB program reviews. The study instruments include:

1. Three document review checklists for
   - Policy review
   - Staff qualification review
   - Medical records

2. Twenty four in-depth interview guides for different groups of key informants
3. Five observation checklists for
   - TB patients admission, access and continuity of care
   - Laboratory
   - Medication storage management and use
   - Infection prevention and control
   - Kitchen and food storage

All the study instruments were developed in English, translated into Armenian, and pretested (Appendix 1). The items in all the study instruments were adapted from the Joint Commission International Accreditation Standards for Hospitals, International Standards for TB Care, and WHO framework for conducting TB program reviews.[17,30] These standards were divided into two main sections that include seven Patient Centered Functions and five Healthcare Organization Management Functions. In addition to seven Patient Centered Functions the research team developed the TB-Tobacco Control function using WHO recommendations for integration of TB and tobacco control measures.[31]

Patient Centered Functions

1. International Patient Safety Goals (IPSG)
2. Access and Continuity of Care (ACC)
3. Patient and Family Rights (PFR)
4. Assessment of Patients (AOP)
5. Care of Patients (COP)
6. Medication Management and Use (MMU)
7. Patient and Family Education (PFE)
8. TB-Tobacco Control (TBTC)

Healthcare Organization Management Functions

9. Quality Improvement and Patient Safety (QPS)
10. Prevention and Control of Infection (PCI)
11. Governance, Leadership and Direction (GLD)
12. Staff Qualifications and Education (SQE)

13. Management of Communication and Information (MCI)

All these functions have their specific standards, each of them consists of several measureable elements (Appendix 2).

Sampling, Data Collection and Analysis

Legal documents review

The document review was conducted to understand what are the formal documents regulating the hospital's daily practices related to TB treatment and diagnosis. In the frame of the document review, we looked at different policies and regulations - 16 legal documents. The internal policies included the Organizational Charter of the NTCC, Internal Disciplinary Rules of the organization, and internal regulations of different structural units. The research team also reviewed several guidelines and national regulations, such as Hand-Hygiene guideline, Waste and Expired Materials' Disposal Guideline, Methodological Guide for TB Infection Control, and National Standard for TB treatment.

Staff qualification documents review

During staff qualification documents review 20 personnel files, per each position of employees from all the departments, were reviewed along with the staffing plan of the organization. The aim of the staff qualification document review was to check the compliance of relevant experience, qualifications, credentials to the requirements of the position as determined in the job duties and responsibilities of the staff members.

Medical records review

Medical records review included 34 medical records and TB treatment cards of TB patients admitted for TB inpatient treatment at the NTCC. The medical record review checklists were entered into an excel database for further analysis. After the discharge the patients take their TB treatment cards to the outpatient TB cabinets. In order to review a full package of medical records per patient (medical history, TB treatment card, DR-TB treatment files), the research team chose a two-month-period prior to the actual review. All medical records of newly admitted TB patients during the period of March-April 2016 were sampled. In this case most of the

medical records contained all the necessary components. All those clinical departments, which did not admit new TB patients in the specified time period, were asked to provide whatever they had during 2016 (e.g., the Children TB department and Surgical TB department admit relatively smaller number of patients as compared to the other departments, this is why they might not have newly admitted patients for a specified time period). Two CHSR researchers reviewed the medical records.

In-depth interviews

The data collection included 40 in-depth interviews. All in-depth interviews were conducted by two CHSR research team members. Data collection during some interviews required involvement of both moderator and a note-taker. These roles were rotated among the researchers.

The study participants were categorized into three groups: 1) *administration* 2) *healthcare provider*, and 3) *TB patient/family member*.

Administration was represented by professionals involved in the administrative work of the hospital and the NTCC who were responsible for such activities as overall management of the organization, management of clinical services, human resources management, provision of continuing education efforts, monitoring and evaluation, coordination of medication management, infection prevention and control. *TB health care providers* were physicians and nurses with professional experience working in the inpatient unit of the NTCC. *TB patients/family members* were people who had finished the intensive phase of TB treatment in the hospital of the NTCC and were in the continuation phase of treatment in outpatient TB centers. In case of dealing with patients from Children TB department, the parents/caregivers were interviewed.

All the information from in-depth interviews was transcribed. The CHSR team used standard qualitative research techniques of heterogeneity and triangulation,[32] and analyzed the data using mixed – conventional inductive and directed deductive content analysis techniques.[33,34] The direct quotes provided in the boxes are abstracted from in-depth interviews.

Observations

Observations were conducted to explore several specific environmental conditions and daily practices of healthcare providers in terms of TB treatment and diagnosis using standardized checklists. Overall 21 observations were conducted. The information collected through the standardized checklists were entered into an electronic database after the fieldwork.

To evaluate the quality of diagnostic laboratory services the research team observed the daily practices in two laboratories providing different types of services. The laboratories have been chosen considering the ones that yield higher risks of health care-associated infections. The daily practices in the bacteriological/ microbiological laboratory (where the sputum is processed) and the clinical laboratory were observed. The assessment considered the degree of compliance of actual practices to bio-safety standards of TB laboratories, described in the WHO "Tuberculosis laboratory bio-safety manual."[35]

The research team conducted planned observations in the hospital and in the vicinity using a standardized observational checklist. The checklist aimed at assessing smoking practices as well as strategies implemented by the hospital to eliminate indoor smoking. Throughout the data collection the research team observed smoking practices of healthcare providers and patients/family members.

After obtaining all the information from the document review, in-depth interviews, and observations, the research team developed a single general checklist comprising of all the used and assessed standards, along with relevant measurable elements of those standards. Afterwards the data from different sources were transferred into that single checklist.

Based on the findings the scoring for all the standards were developed. The compliance with the standards was measured based on the extent to which the requirements represented by measurable elements were met. The maximum score of a standard was set to be ten. The research team evaluated the compliance of NTCC's daily practices with the requirements of the standards according to the findings.

To emphasize the strengths, weaknesses, opportunities, and threats of the hospital services and management, the CHSR/AUA research team applied the SWOT scheme for the analysis of the collected data considering the JCI standards.[36] The findings include a scoring table of each of the standards, and SWOT analysis for each of the standards, supported by direct quotes from the respondents.

To measure the overall performance of inpatients services of the NTCC for 13 assessed functions, the research team has calculated the 'function mean score' by developing a scoring system that identified the level to which the standards and scores of each function were met. The score ranges were defined using standard deviation principle calculated from the mean[37] of the minimum score equal to zero and maximum score equal to ten and were defined as function '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).

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 verbal informed consent (Appendix 4). 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)

The Joint Commission International Accreditation Standards for Hospitals identify several goals to be achieved and sustained to ensure improvements in patient safety within the healthcare facility. For the assessment of the diagnostic and treatment services of NTCC the section has been adapted for standards and measureable elements relevant to the Armenian context and to the hospital specialization. Eventually, three goals have been evaluated during the assessment. The goals are to assess whether patients in this health facility are identified correctly, communication improvement is done effectively, and the risk of health care-associated infections is reducing.

1.1 Identify patients correctly

According to the standard, processes are to be introduced to assure correct patient identification throughout the entire course of the hospital stay. Firstly, specific patient identifiers should be developed and continuously used whenever providing care or interventions to the patients. However, patient identification should not be merely done through locating the patient by the department or the room number. Rather the name, birth date, identification number, etc. should be used. Secondly, the policies should outline the acceptable ways of patient identification peculiar to the hospital. Thus, the processes should integrate practices related to patient identification described in policies/ regulations with the staff actual implementation of those.

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	**2.0**	**2.0**
2. Patients are identified before administering medication	**2.0**	**2.0**
3. Patients are identified before taking blood and other specimens for clinical testing	**2.0**	**2.0**
4. Patients are identified before providing treatment and procedures	**2.0**	**2.0**
5. Policies and procedures support consistent practice in all situations and locations	**2.0**	**0**
Total score	**10.0**	**8.0**

Strengths. The hospital has adapted several identifiers to distinguish the patient within the hospital, including the identification number, patient name/ surname, the number of the medical record, and the number of the treatment card (TB-01 form) that consequently accounts all TB

cases. Among all medical records reviewed, the patients' room numbers have not been indicated as a mean to locate the patient within the department, which satisfies the standard's requirement. For inviting patients to administer medication, take blood and other specimens for clinical testing, or to conduct procedures and treatment, healthcare providers call/identify patients by their names that were memorized or red from the medical records.

Weaknesses. The medical records had notes on the cover page indicating the department where the patient is hospitalized, which was done to identify the patients in the hospital. This practice contradicts the proposed standard. However, the main shortcoming associated with patient identification was the absence of uniform procedures. NTCC has no policies indicating the exact approaches of patient identification in specified situations. Therefore, at the point of care provision, patient identification and decisions related to it are left on individual health care providers, rather than being regulated by the hospital.

Opportunities. To achieve and sustain standardized practices regarding correct patient identification the organization should take action towards improving the accuracy of patient identification. The proposed actions encompass development of policies and procedures supporting standardized practices regarding correct patient identification and establishment of monitoring mechanisms to surveil implementation of those policies.

Threats. Given that improvements in accuracy of patient identification is mainly associated with formalization of accepted practices and will not propose major changes in health care professional practices, the research team did not identify specific threats.

1.2 Improve effective communication

Effective communication is essential to enhancing the patient safety. Among all possible communications means the one over the telephone is the most risky in terms of yielding the higher chances of miscommunication, especially if ordering tests or receiving the test results over the telephone. To avert the errors associated with frail communication the hospital should introduce respective policies describing safe modes of communication between staff members.

Measurable elements	Max. score	Obtained score

1. The complete verbal and telephone order or test results are written down by the receiver of the order or test result.	**3.0**	**2.0**
2. The verbal and telephone order or test result is read back by the receiver of the order or test result.	**3.0**	**2.0**
3. The order or test result is confirmed by the individual who gave the order or test result	**3.0**	**1.0**
4. Policies and procedures support consistent practice in verifying the accuracy of verbal and telephone communications.	**1.0**	**0**
Total score	**10.0**	**5.0**

Strengths. According to the observations and the medical records review, the test orders and test results were not communicated through telephone or verbally. The hospital has developed specific referral forms to order tests and have the test results returned in a written form. Physicians attach these written referral forms to the medical records of patients insuring comprehensive written communication that avoids verbal verifications.

Weaknesses. During the medical records review, the research team noticed that pages of the written referral forms were attached to the medical records inadequately resulting on easy-loss or fails to distinguish between patients records. Confirmation of orders or test results was not done systematically, but only in suspicious cases when physicians doubt about the reason of the order or the test results. The major weakness associated with these processes was the absence of relevant policies and procedures to support and assure consistency while implementing.

Opportunities. The reliable methods for documenting the test results should be introduced to the clinical staff. The policies have to identify the situations requiring confirmation of orders and test results and guide the most appropriate way of documenting it. The use of electronic databases can be considered as an alternative mode of information exchange enhancing the accuracy of the test orders and results communication.

Threats. Changes on the level of routine activities may trigger the clinicians' resistance. Not all physicians might feel comfortable ordering tests and reporting the results in the electronic format. Additional paper work related to transcribing the test results into the medical records, instead of having them simply attached to the medical records can also cause reluctance to change.

1.3 Reduce risk of health care-associated infections

This is an important step toward improving the patient safety. An integration of set of activities towards reduction of the risks of health care-associated infections combining the evidence-based practices and policies that would support and foster implementation of practices essential for reducing the risks of health care-associated infections.

Measurable elements	Max. score	Obtained score
1. The organization has adopted or adapted currently published and generally accepted hand-hygiene guidelines	**3.0**	**3.0**
2. The organization implements an effective hand-hygiene program.	**4.0**	**1.0**
3. Policies and/or procedures are developed that support continued reduction of health care–associated infections	**3.0**	**3.0**
Total score	**10.0**	**7.0**

Strengths. Using as a basis the WHO guidelines, the hospital has adopted its own hand-hygiene guideline, approved by the Ministry of Health of Armenia (MOH). The Infection prevention and control department implements activities focusing on proper hand-hygiene practices. To support continuous reduction of health care-associated infections the governance of the NTCC has established a council/board and has developed an action plan that guides the infection prevention and control activities within the organization. The action plan captures different facets of infection control activities that are planned to be implemented on a continuous basis.

Weaknesses. Considering that the Infection prevention and control department does not have a surveillance mechanism over the effectiveness of implemented activities against the infection risks, it is hard to judge whether or not the hand hygiene program is effective. In practice the hospital tends to conceal the cases of health care-associated infections with no reporting. Despite the guidelines and policies developed, the hospital staff does not share the common vision and understanding of activities targeted to reduce the risk of infections. It was repeatedly indicated by the study participants that the nursing and janitorial staff of the hospital are afraid of the infection prevention and control department specialists.

> *Everybody reports zero cases of healthcare-associated infections, otherwise they will be penalized.*
>
> **Administration**

Absence of monitoring mechanisms over the practices directed to reduce the risks of health care-associated infections, complicates assessment of whether these practices are appropriately implemented and the actions are truly effective in reducing the risks. The facility is lacking to have mechanisms to reinforce implementation of the existing policies.

Opportunities. Having all staff members oriented toward the infection risks reduction vision and practices is an essential step toward combating the health care-associated infections for NTCC. In addition to nicely formulated documentation, the facility administration need to strengthen and implement internal surveillance system and monitoring mechanism to facilitate integration and overall effectiveness of the program.

Threats. The hospital cannot truly fight the infection risks while not acknowledging those risks. The culture of not reporting the health care- associated infections' cases is deeply rooted in the hospital staff members.

2. Access to Care and Continuity of Care (ACC)

In the context of a single patient an integration of services, health care professionals, and care throughout the hospital altogether form a continuum of care, which is there to continuously satisfy patients' health needs, ensure coordination between various departments and settings and plan patients' discharge. The continuum is made up of three phases; admission, care and discharge/transfer while every next stage should be rationalized by the assessment findings of the previous stage. In case of Tuberculosis treatment scheme the discharge from the hospital is equalized with the transfer to other organization, as after intensive treatment phase patients are transferred to outpatient units for continuation of treatment.

2.1 Patients are admitted to receive inpatient care or registered for outpatient services based on their identified health care needs and the organization's mission and resources

The hospital should make sure that the hospitalized patients' health needs are matched with the hospital's mission and resources. The clue towards ensuring this match is the initial TB diagnosis driven from patients' timely and accurate screening.

Measurable elements	Max. score	Obtained score
1. Screening is initiated at the point of first contact within or outside the organization	**4.0**	**4.0**
2. Policies identify which screening and diagnostic tests are standard before admission	**3.0**	**1.5**
3. Patients are not admitted, transferred, or referred before the test results required for these decisions are available	**3.0**	**3.0**
Total score	**10.0**	**8.5**

Strengths. The admission department and the clinical departments have developed a fluent process of admitting patients through matching their health needs with the hospital mission and resources. The patients' flow in the hospital is organized in a way that at the point the patient has entered the admission department the team of TB physicians and narrow-specialists, including neurologists, physician of infectious diseases, dentist, ophthalmologist, dermatologist, otolaryngologist, cardiologist and etc. conduct screening to check if the patient has TB. If a patient is a TB suspect then based on the health complaints and the age, the patient is referred to a specific department: Pulmonary Drug Susceptible TB, Pulmonary Drug Resistant TB, Extra-pulmonary TB, Children TB, or Psychiatric TB. In departments, physicians or/and head nurses who are going to treat the patient later conduct initial assessment and order diagnostic procedures confirming TB.

The National Standard for TB diagnosis and treatment, approved by the MOH, includes complete list of the required laboratory and radiology testing.

TB suspected patients are kept in hospital until the final results of sputum testing are available. Only those patients who have bacteriologically or clinically confirmed TB are hospitalized for an inpatient treatment. The document review, IDIs and observations confirmed that the clinical staff precisely implement diagnostic procedures required for the patients' admission.

The patient is sent to our department with the medical record... We perform initial medical assessment, and do other things; take blood sample, urine sample for biochemical examination, the sputum examination, sonography, gastric lavage if the patient has some processes while does not produce sputum. Firstly, the emergent cases are hospitalized.

Healthcare provider 1

In case if the patient has approached the hospital by his/her initiative, then we shall organize the diagnostic procedures. It lasts approximately 7 to 8 days. Patients, stay in the Smear-negative department for 10 days. During these days we receive the laboratory analysis results according to which we decide if the patient is our or not. Until receiving the analysis results

the patient receives antibiotic therapy. If the patient does not show a dynamic to the treatment, it means that the patient does not have TB and the further antibiotic therapy is meaningless. If eventually it becomes clear that the patient indeed does not have TB, then he/she is sent to the respective clinic.

Healthcare provider 2

Weaknesses. Even though the National Standard identifies standard screening procedures required for the admission, the hospital has failed to develop its own policy that will capture the sequence of the required procedures for diagnosing TB.

Opportunities. Development of the policy describing the admission process along with the screening procedures required for the admission decision will more firmly guide the admission process.

Threats. Not identified.

2.2 The organization has a process for admitting inpatients and for registering outpatients

In addition to standardization of screening procedures and diagnostic tests that are to be performed prior to admission, the admission process itself including the patients' complete path in the NTCC till hospitalization should be standardized. The policies and procedures should describe each step of the patient route in advance to hospitalization as illustrated by the measurable elements below.

Measurable elements	Max. score	Obtained score
1. The inpatient admitting process is standardized	**2.0**	**2.0**
2. There is a process for admitting emergency patients to inpatient units	**2.0**	**2.0**
3. There is a process for holding patients for observation	**2.0**	**2.0**
4. There is a process for managing patients when bed space is not available on the desired service or unit or elsewhere in the facility	**2.0**	**2.0**
5. Written policies and procedures support the processes for admitting inpatients and registering outpatients	**1.0**	**0**
6. Staff are familiar with the policies and procedures and follow them	**1.0**	**0**
Total score	**10.0**	**8.0**

Strengths. All measurable elements describing the procedural aspects of admission process (admission of patients, admission of emergency patients, holding patients for observation, patients' management when bed spaces are not available) are implemented in a standardized fashion. All participants participated in the study described the same admission processes that are routinely done in the hospital. This information was also triangulated between different specialists from various departments.

…When a new patient is referred to us for the first time from the outpatient TB cabinet we send him to the registry, where 3 physicians perform screening to see if the patient is a TB suspect or no. If yes, the patient comes back to me for X-ray and other analysis. If I confirm TB suspicion… we hospitalize the patient, if needed. If we don't find TB, we refer the patient to the respective [based on disease localization] *department's head, for diagnosis and further treatment in the corresponding clinic.*

Healthcare provider 1

Patients are referred to the specialized departments from the admission. If a patient is referred to the department at late hours and needs immediate hospitalization, we admit him and conduct all necessary examinations later, in the morning: X-ray, blood, urine, sonography, ECG etc.

Healthcare provider 2

Bed spaces in the hospital are regulated by the departments' heads based on the patients flow: admission and discharge, usually without causing any problems. The management of emergency situations when bed space is not available on the desired service or unit in the facility the general approach would depend on health condition of the admitted patient: either sending patient home until bed spaces are available (if a patient's health condition is good enough) or adding a new bad (if a patient needs hospitalization immediate).

Usually we don't have such issue [insufficiency of bed space on the desired service or unit], *but even if such issue occur we will add new beds in the rooms.*

Healthcare provider 1

I cannot recall a case when the beds spaces have not been available. Even if such an issue arises, perhaps we will consider the patient health status, and if the patient's condition will be fair enough to send him back home, we will do that, until the space become available.

Healthcare provider 2

Weaknesses. Coherence of the stages of patient hospitalization is agreed upon the director, the heads of the departments and physicians and is simply based on verbal communication, instead of having formally documented grounds. Despite the consistent admission process across

different departments, there are no policies developed to guide it and make the staff members familiar with those policies.

> *All of these* [admission process] *has been an oral instruction/assignment. Our department has a regulation, though it does not include detailed indications on patients' admission and assessments.*
>
> **Healthcare provider**

Opportunities. Written policies and procedures guiding the process of patients' admission will specify the admission process and guide the actions in particular situations outlined in measurable elements.

Threats. As identified from the IDIs clinical staff has apathy towards importance of policies that would support their practices and guide their decision making.

2.3 At admission as an inpatient, patients and families receive information on the proposed care, the expected outcomes of care, and any expected cost to the patient of care

An important stage of the admission process is acquaintance of patient and family members with information related to care the patient will receive at the hospital. Health care providers are supposed to provide sufficient information on proposed care, expected outcomes, and financial issues associated with care such as patients will make insightful decisions.

Measurable elements	Max. score	Obtained score
1. The patient and family are provided with information at admission	**2.5**	**2.5**
2. The information includes information on the proposed care	**2.5**	**2.5**
3. The information includes information on the expected outcomes of care	**2.5**	**2.5**
4. The information include information on any expected costs to the patient or family	**2.5**	**2.5**
Total score	**10.0**	**10.0**

Strengths. From IDIs with patients and family members the research team learned that during the initial counseling patients and family members are provided with information about the disease they have, duration and course of proposed care, expected outcome if treating and not

treating the disease. Patients also are informed that care and treatment they are going to receive at the hospital are exempt of fees.

> *I was very anxious of it and was crying a lot. I was told that disease will leave if I take all the medicines, do not abandon the treatment, and eat appropriately. But if not doing all these, the disease won't leave. I was also told that 80% of treatment success depends on me. They* [healthcare providers] *gave me comprehensive information…*
> *…I was told that the disease is curable and I should not worry or be afraid of it.*
>
> **Patient/family member 1**
>
> *Physicians have told what I should expect after treatment. I haven't had unanswered questions.*
>
> **Patient/family member 2**

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

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

Cooperation of departments responsible for patient care provision at the full length of the patient's hospital stay (the admissions, emergency, diagnostic and treatment departments) form integrated and coordinated health care services. The leadership of the hospital and discrete departments should plan and assure provision of coordinated health care services collaboratively.

Measurable elements	Max. score	Obtained score
1. The leaders of services and settings design and implement processes that support continuity and coordination of care, including those identified in the intent statement	**6.0**	**6.0**
2. Established criteria or policies determine the appropriateness of transfers within the organization	**4.0**	**0**
Total score	**10.0**	**6.0**

Strengths. The leaders of all settings do coordinate provision of care and ensure continuity of care for patients while they are moving through departments. Study participants especially emphasized communication within the diagnostic and clinical departments, qualifying it as the most ubiquitous one.

> *We mainly deal with the diagnostic departments, as our department is totally separate from the others. We are mainly connected with the radiology and laboratory departments. Each*

morning we start our work from 5-minute briefing, discuss the issues, works to be done and each of us process to their work.

Healthcare provider

Weaknesses. Implementation of processes to support continuity and coordination of care is based on verbal agreements only. In spite of daily implemented practices, the hospital has failed to establish policies that would identify the appropriateness of transfers within the organization, and characterize the roles and responsibilities of each of the health practitioner involved in assuring the continuity of care.

Opportunities. Formalization of transfers within the hospital could be achieved through development of criteria or policies that will define the appropriateness of transfers and eventually guide the process.

Threats. The fact that the hospital staff perceives that oral agreements are appropriate for implementation of processes might hinder the development and application of relevant policies. This may result in overall reluctance to formalization of processes.

2.5 There is a policy guiding the discharge of patients

The discharge of patients is to be regulated by the internal policies that are developed as so to capture the clinical indications for discharge.

Measurable elements	Max. score	Obtained score
1. Patients are discharged based on their health status and needs for continuing care	**3.0**	**3.0**
2. The patient's readiness for discharge is determined by the use of relevant criteria or indications that ensure patient safety	**3.0**	**3.0**
3. Patient are discharged according to their needs	**3.0**	**3.0**
4. Organization policy guides the process for patients being permitted to leave the organization during the planned course of treatment on an approved pass for a defined period of time	**1.0**	**0**
Total score	**10.0**	**9.0**

Strengths. The discharge from the hospital implies that the intensive treatment phase has finished, the patient has achieved health goals, and needs in continuing care (continuation phase of TB treatment) are identified. From the document review the research team identified that patients' discharge is regulated by the National Standard of TB diagnosis and treatment which identifies the indicators of discharge and brings forth the conditions when patient's discharge should be organized. The indicators include outcomes of TB treatment that are determined by the reassessment findings. Patients are discharged only if their health status strictly satisfies the discharge criteria of the TB treatment. If the patients' health status does not meet the criteria for discharge, normally the treatment regimen is extended.

> *In case of BK+* [sputum smear positive] *patients the sputum examination results serve as a basis for discharge plan... While in case of BK-* [sputum smear negative] *patients, if the patient health status allows and if the patient does not have complains, we discharge him in order for him to start the continuation phase.*
>
> **Healthcare provider**

Weaknesses. Even though the National Standard of TB diagnosis and treatment is the only nationwide document that has a legal force to guide TB care in Armenia, still the need in adapting the organization-level policies guiding patients' discharge is topical. Furthermore, the hospital has not specified conditions or restrictions for leaving the hospital during the hospitalization.

Opportunities. Given the specialization of the hospital and the nature of TB disease, the conditions of leaving the hospital should be very clearly stated and be evident to all patients. The NTCC should develop a policy which will put the conditions or restrictions of leaving the hospital into a legal field.

Threats. As far as the standard will be concerned with formalization of already existing practices, no factor will threaten implementation of the standard.

2.6 The clinical records of inpatients contain a copy of the discharge summary

The medical record of discharged patients should contain the copy of the discharge summary written by the qualified individual at the patients' discharge.

Measurable elements	Max. score	Obtained score
1. A discharge summary is prepared at discharge by a qualified individual	**3.0**	**2.0**
2. The summary contains follow-up instructions	**3.0**	**3.0**
3. A copy of the discharge summary is placed in the patient record	**3.0**	**3.0**
4. Policy and procedure define when the discharge summary must be completed and in the record	**1.0**	**0**
Total score	**10.0**	**8.0**

Strengths. Discharge summaries are always written by the managing physicians who are qualified for preparing the summaries. During the medical record review the research team has examined medical records of discharged patients, which, as required, contained the copies of discharge summaries. The summaries included indications for patients' transfer to the continuation phase of TB treatment.

Weaknesses. During medical records review the research team has found a discharge summary of a patient who yet had to be discharged 2-3 days later. It means that this particular discharge summary was prepared in advance and might not depict the patients' very final health condition. No policies and procedures defining conditions of how the discharge summary should be completed exist in the hospital.

Opportunities. A defined and clearly stated process of preparing the discharge summary supported by the relevant policy will guide this process and promote adherence by the clinical staff members.

Threats. The absence of policies and procedures defining conditions of how the discharge summary should be completed might trigger medical error during the patients' discharge.

2.7 The discharge summary of inpatients is complete

The discharge summary should be written comprehensively covering the information on reasons for admission, diagnosis and comorbidities; significant physical and other findings; performed

diagnostic and therapeutic procedures; medications; patient's condition/status at the time of discharge; follow-up instructions.

Measurable elements	Max. score	Obtained score
1. The discharge summary contains reason for admission, diagnoses, and comorbidities	**1.5**	**1.5**
2. The discharge summary contains significant physical and other findings	**1.5**	**1.5**
3. The discharge summary contains diagnostic and therapeutic procedures performed	**1.5**	**1.5**
4. The discharge summary contains significant medications, including discharge medications	**1.5**	**1.5**
5. The discharge summary contains the patient's condition/status at the time of discharge	**2.0**	**2.0**
6. The discharge summary contains follow-up instructions	**2.0**	**2.0**
Total score	**10.0**	**10.0**

Strengths. The medical record review showed that the discharge summaries completed for the discharged inpatients contained information on admission, diagnoses, and comorbidities; significant physical and other findings; diagnostic and therapeutic procedures performed; medications; patient's condition/status at the time of discharge; follow-up instructions.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

2.8 The receiving organization is given a written summary of the patient's clinical condition and the interventions provided by the referring organization

Patients who are transferred to the continuation phase of treatment shall also take the summary which includes the clinical condition, patient's status, provided procedures, and the indications for the continuing care.

Measurable elements	Max. score	Obtained score
1. Patient clinical information or a clinical summary is transferred with the patient	**2.5**	**2.5**
2. The clinical summary includes patient status	**2.5**	**2.5**

3. The clinical summary includes procedures and other interventions provided	**2.5**	**2.5**
4. The clinical summary includes the patient's continuing care	**2.5**	**2.5**
Total score	**10.0**	**10.0**

Strengths. Patient's discharge from the inpatient treatment is the same stage of treatment as the transfer to the outpatient unit, as far as the continuation phase of treatment automatically proceeds the inpatient treatment phase. The transfer summaries which are basically the same as the discharge summaries include the necessary information mentioned in the measurable elements. The copy of discharge summary that is transferred through the patients to the receiving organizations (i.e. outpatient TB cabinet) serves as a transfer summary.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

3. Patients and Family Rights (PFR)

The hospital is supposed to identify patients and family rights within the hospital and establish an environment where patients and families will be notified of their rights and will be able to act accordingly. Through the hospital's recognition of patients and family rights the clinical staff will learn how to protect and promote those rights and will learn their own roles in accordance with the policies of the hospital. The hospital should define the scopes of families' involvement in the decision making process for the patient care. Obtaining an informed consent should be integrated in the patient rights protection and promotion activities and the clinical staff should be educated on skills necessary for obtaining an informed consent.

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

An understanding of patient and family rights should be hospital-widely overspread from leaders to clinical staff members. Firstly, the leaders should recognize patients and family rights and acknowledge their own roles in those rights' protection. Secondly, the leadership of the hospital should convey this vision to all staff members and have all staff members educated on their responsibilities to collaboratively protect patient and family rights. On the other hand, family

members and patients should be notified of their rights to participate in care related decisions i.e. to further protect their rights. And finally, policies and procedures should cover all aspects, roles and responsibilities involved in the patients and family rights protection.

Measurable elements	Max. score	Obtained score
1. The organization's leaders work collaboratively to protect and to advance patient and family rights.	**2.0**	**0**
2. The leaders understand patient and family rights as identified in laws and regulations and in relation to the cultural practices of the community or individual patients served.	**2.0**	**1.0**
3. The 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.	**2.0**	**2.0**
4. Staff members are knowledgeable about the policies and procedures related to patient rights and can explain their responsibilities in protecting patient rights.	**2.0**	**0**
5. Policies and procedures guide and support patient and family rights in the organization.	**2.0**	**0**
Total score	**10.0**	**3.0**

Strengths. During IDIs, nearly all clinical staff members highlighted their respect towards patient and family rights and their prerogative to choose what healthcare related information is to be provided to family or others and under what circumstances, despite the absence of formally introduced practices. In the DR-TB department, due to coordination of TB care by the MSF France and their oral instruction provided to the department staff members, staff signs contracts and obtains patients' written consents before initiating the treatment.

Family members of children have right to know what is done with their child. We sign a contract with the DR-TB patients in contrast to the DS-TB. We assure implementation of patients' rights through our daily work with the patients.

Healthcare provider 1

Patients know their rights very well and we try to do our best to have them feeling good...

Healthcare provider 2

Weaknesses. The hospital leadership put insufficient emphasis on importance of patient and family rights. As a result the organization has no hospital-wide policies and procedures, enforcing practices directed to protect patient and family rights. Even activities coordinated by

MSF France in the DR-TB department are not considered by the hospital leaders as an example for developing actions toward promotion of patient and family rights hospital-wide.

In other than the DR-TB departments, promotion of patient and family rights is done either a little, based on clinicians' personal understanding of the issue at the level of oral communication or is not done at all.

Opportunities. Development of policies and procedures describing patient and family rights promotion in the hospital will serve as a basis for creating an environment respecting patients and family rights. In the frames of newly developed policies and procedures the hospital leadership and the clinical staff should be educated on the principles of patient and family rights protection and promotion. This in its turn will lead to having all staff members acknowledging their roles in patients and family rights promotion and actual implementation of processes described in the policies and procedures.

Threats. Adding new responsibilities to existing ones may in the beginning cause staff resistance to performing new duties. However, if the hospital leadership will achieve and maintain a common understanding of patient and family rights, these processes will gradually become a routine.

3.2 Care is respectful of the patient's need for privacy.

The clinical staff members should be aware of the patients' desired degree of privacy by directly questioning them. Not only this will build trust and strengthen the communication between the two, but also will further promote respect toward patients' privacy throughout the hospital stay, more specifically during the clinical interviews, examinations, procedures and treatments.

Measurable elements	Max. score	Obtained score
1. Staff members identify patient expectations and needs for privacy during care and treatment.	**5.0**	**3.5**
2. A patient's expressed need for privacy is respected for all clinical interviews, examinations, procedures/ treatments, and transport	**5.0**	**3.5**
Total score	**10.0**	**7.0**

Strengths. All interviewed clinicians appeared to be respecting and satisfying patients' needs for privacy. Clinical interviews are conducted privately. From IDIs with former patients and their family members the research team found that for performing clinical interviews the patients have been invited to the physicians' rooms, and only there all communications with patients were held.

> *Physician has not been talking about my disease in the presence of other people, we were talking privately in his/her medical room only.*
>
> **Patient/Family member**

Weaknesses. However, patients shared also their negative experience of non-respect of their privacy, particularly during the psychological counseling. To some of the patients the counseling was offered in the presence of others in the general area of the patients' room, with directly violating the patients' privacy during care provision.

> *The psychological counseling was not organized very well. The counseling was done in my room, in the presence of other patient. The psychologist came for another patient and just offered services to me, but I felt no confidence during the whole process thus was not satisfied.*
>
> **Patient/Family member**

Opportunities. All healthcare providers should be thoroughly educated on importance of respecting patients' needs for privacy. Healthcare providers should also be trained on when and how the patients' privacy should be maintained.

Threats. Not identified.

3.3 Children, disabled individuals, the elderly, and other populations at risk receive appropriate protection

The hospital should have defined the vulnerable populations and take the responsibility of protecting the rights of those vulnerable groups. Staff member should be clearly aware of those vulnerable groups and should acknowledge their roles in protecting the rights of those patients when providing care to them. The vulnerable population can include children, disabled individuals, and the elderly and other populations at risk.

Measurable elements	Max. score	Obtained score
1. The organization identifies its vulnerable patient groups.	**3.0**	**1.5**

2. Children, disabled individuals, the elderly, and others identified by the organization are protected.	**3.0**	**3.0**
3. Staff members understand their responsibilities in the protection processes.	**4.0**	**0**
Total score	**10.0**	**4.5**

Strengths. The National Standard for TB diagnosis and treatment lists the high-risk patient groups that need provision of high-risk services. The national law of TB diagnosis and treatment states that all individuals are guaranteed with free of charge TB diagnostic and treatment services covered by the state budget. This law applies to all patient groups including vulnerable patients. The National Standard of TB diagnosis and treatment also identifies the socially vulnerable patients who should receive treatment through home visits. The disabled individuals or the patients who cannot walk and only stay at home are guaranteed with home treatment, again, covered by the state budget. Therefore, children, disabled individuals, the elderly and other groups are protected by the national law of TB diagnosis and treatment and receive all necessary services.

Weaknesses. Document review did not identify any internal hospital-specific definition of vulnerable patients groups that require additional efforts for their rights' protection. The leadership of the hospital has failed to highlight the importance of knowing those groups. During the IDIs the clinical staff members either could not consistently enumerate the vulnerable groups or did not know if such groups do exist. Vulnerability was not perceived in its social terms rather co-morbidities that are known to influence the TB treatment outcomes were frequently confused with indicators of vulnerability.

There are no vulnerable groups as such. Those patients who have family members that can be infected with TB are vulnerable.

Healthcare provider 1

The vulnerable groups include the patients with diabetes, AIDs, ulcer diseases, professional conditions…. Children are a vulnerable group, those who have a TB diseased contact person at their households.

Healthcare provider 2

Vulnerable [the interviewee meant patients with co-morbid conditions] *patients groups do not need protection. Patients with AIDs need attention. Of course attention towards other patients is also important. For me there is no difference between* [TB] *patients....*

Healthcare provider 3

Opportunities. Recognition of vulnerable groups in the form of policies and procedures and staff awareness of those groups will result in safer environment during care and treatment where vulnerable patients' rights will be protected.

Threats. Even though all population groups including vulnerable patients groups are ensured to receive TB diagnosis and treatment services, clinicians who are not aware of those vulnerable groups may not acknowledge their special needs during care and treatment provision.

3.4 Patient information is confidential

The information obtained from the patient to understand patient's health needs for planning care are to be maintained confidentially. The hospital is responsible to develop policies guiding how the patient information will be kept confidential and to implement procedures to ensure staff members' adherence to the policies. Staff members and patients should be knowledgeable on policies describing confidentiality of patient information and be aware of the situations when the information can be released with the prior patients' permission to do so.

Measurable elements	Max. score	Obtained score
1. Patients are informed about how their information will be kept confidential and about laws and regulations that require the release of and/or require confidentiality of patient information.	**5.0**	**2.5**
2. The organization respects patient health information as confidential	**5.0**	**4.0**
Total score	**10.0**	**6.5**

Strengths. Almost all patients participated in the IDIs reported that during treatment they were informed that their personal and health information will be kept confidential and will not be communicated to other people. This information was triangulated with healthcare providers, who perceive the confidentiality as an intrinsic part of medicine.

I was told, that everything [health-related and personal information] *is confidential and if I won't anybody to know about my disease, no one will know about it.* **Patient/Family member** *The confidentiality is assured. It is the matter of the medical ethics.* **Healthcare provider**

Weaknesses. Some of the healthcare providers appeared to be not fully practicing confidentiality protection in terms of not necessarily notifying patients about how their personal and health-related information will be protected. Patients will not acknowledge any violation, unless they know what to expect from the healthcare providers.

> *I did not have issues with confidentiality. But no one has told me that the information* [related to me and my health] *will be kept confidential.*
>
> **Patient/Family member**

During clinical interviews the healthcare providers haven't covered the legal aspects of confidentiality protection. Some of the clinical staff members tended to parallelize the general understanding of patient information confidentiality with a particular aspect of HIV/AIDs confidentiality protection.

> *We are especially cautious when working with the patients with AIDS. We try to maintain the confidentiality on 100%, as we know that we should not speak about that disease* [HIV/AIDS].
>
> **Healthcare provider**

The process of immediate case notification: sharing with the policlinics information on newly diagnosed TB patients, to refer his/her relatives to TB check-ups, is contrary to information confidentiality protection. This notification automatically reveals health related information to third parties, including family and neighbors.

> *When I got to know that I have TB, right next day my whole family already knew that.*
>
> **Patient/Family members**

Opportunities. Development of policies and procedures based on respective laws and regulations will strengthen the grounds of health information confidentiality protection and will create a common understanding of the health information confidentiality concept on the whole. The healthcare providers should be educated to implement practices maintaining the confidentiality of patient information.

Threats. Not identified.

3.5 The organization supports the patient's right to respectful and compassionate care at the end of life

The hospital should acknowledge the unique needs of dying patients for respectful and compassionate care and respect those needs by providing treatment of primary and secondary symptoms, pain management, satisfying patient's and family's psychological, social, emotional, religious and cultural needs.

Measurable elements	Max. score	Obtained score
1. The organization recognizes that dying patients have unique needs	**5.0**	**2.5**
2. The organization's staff respect the right of dying patients to have those unique needs addressed in the care processes	**5.0**	**2.5**
Total score	**10.0**	**5.0**

Strengths. During the IDIs the health care professionals expressed strong empathy towards the patients receiving the end of life care.

Weaknesses. Clinical staff takes care of dying patients merely based on their own perception of how the end of life care should be organized. During the IDIs clinicians emphasized different approaches used while taking care of dying patients, which confirms the fact that the hospital has failed to develop a uniform means of approaching the dying patients' needs.

This [the end of life care] *is a painful topic. We* [clinical staff] *surely notify the family members about the severity of patient's condition and inform about possible outcomes. We can never tell that the patient is going to die, and we should not talk to patients about such issues. Perhaps from the psychological perspective it is wrong but we try to cheer the patient up by all the means we have.*

Healthcare provider 1

We [clinical staff] *mainly works on the direction of alleviating the pain of dying patients.*

Healthcare provider 2

Opportunities. Development of a uniform mechanism of satisfying dying patients special needs will not only lead to standardization of care but will also help to alleviate the psychological stress that clinicians experience while working with those patients.

Threats. Not identified.

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

At the admission for an inpatient treatment the patient and family members should be provided with an information (in the written form) on their rights and responsibilities associated with their hospitalization. The information is to be provided in an understandable manner and when necessary should be substituted with other effective communication means.

Measurable elements	Max. score	Obtained score
1. Information about patient rights and responsibilities is provided in writing to each patient	**4.0**	**2.0**
2. The statement of patient rights and responsibilities is posted or otherwise available from staff at all times.	**3.0**	**1.5**
3. The organization has a process to inform patients of their rights and responsibilities when written communication is not effective or appropriate.	**3.0**	**3.0**
Total score	**10.0**	**6.5**

Strengths. In contrast to other patients, DR-TB patients are consistently provided with information on their rights and responsibilities in a writing form (2 copies of contract are signed and one is placed in patients' medical records). The DR-TB patients are getting informed of their rights and responsibilities when signing the contract agreeing for an inpatient treatment at the hospital. The information on rights and responsibilities is provided both orally and in a writing form. To be admitted for an inpatient treatment, the DR-TB patients should necessarily sign the contract.

The nurses hold conversation with patients and sign a contract with the patient, where all rights and responsibilities are described. The nurses on shift present all these information during the conversation. This is later registered in the special journal. Patients are notified not to smoke, drink and vituperate.

Healthcare provider

Weaknesses. No information on rights and responsibilities in either written or oral form is provided to the patients other than DR-TB department.

Opportunities. Taking an example of DR-TB department the leadership of the hospital can integrate the practices used at the DR-TB department in all remaining departments by adapting all writing forms to the specific departments' context. The clinical staff members of remaining

departments can be trained on the procedures of informing patients on their rights and responsibilities in a consistent manner.

Threats. Not identified.

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

Patients should grant informed consent before their hospitalization. The process of obtaining the informed consent from the patients should be clearly described in the policies and procedures as according to laws and regulations. And the designated staff should be accordingly trained on informing, obtaining and documenting the consent.

Measurable elements	Max. score	Obtained score
1. The organization has a clearly defined informed consent process described in the policies and procedures	**3.0**	**0**
2. Designated staff are trained to implement the policies and procedures	**4.0**	**1.0**
3. Patients give informed consent consistent with the policies and procedures	**3.0**	**0**
Total score	**10.0**	**1.0**

Strengths. MSF France has informally trained DR-TB department physicians, nurses and the social workers on obtaining patient's informed consent. However this training was not based on policies and procedures.

Weaknesses. During document review the research team could not identify any policy that guides the process of informed consent, in any department, including DR-TB department.

Opportunities. The process of informed consent should be clearly defined in policies and regulations for all departments. All clinical staff should be trained on implementing of those policies.

Threats. Not identified.

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

The hospital should have developed processes to guide the situations when the informed consent is obtained from people other than the patient. This may happen if the patient does not have mental or physical ability to make decision related to care, the patient is a child or because of the cultural issues, when the decision should be made by the other person.

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

Strengths. In DR-TB department, whenever the written consent is inappropriate for the patient the patients' guardian signs the contract and grants the consent for hospitalization.

Weaknesses. The processes of obtaining informed consent from individuals other than patients is implemented only in DR-TB department. The hospital hasn't developed formalized processes to guide the situations of obtaining informed consents from people other than the patients.

Opportunities. Along with the introduction of processes on obtaining consent for hospitalization the hospital should address the situations (by developing relevant policies) when the consent is to be obtained from people other than patients. The hospital has separate departments for children and for patients with psychiatric disorders. Each of departments can develop its own informed consent process as supported by the respective policies and procedures.

Threats. Not identified.

3.9 Informed consent is obtained before surgery, anesthesia, use of blood and blood products, and other high-risk treatments and procedures

The patients and family permission should be obtained before undertaking procedures requiring additional consent such as surgical or invasive procedures, anesthesia, use of blood and blood products high-risk procedures and treatments. This consent should be as informative as described in the 3.8, first measurable element.

Measurable elements	Max. score	Obtained score

1. Consent is obtained before surgical or invasive procedures	**2.5**	**0**
2. Consent is obtained before anesthesia (including moderate and deep sedation)	**2.5**	**0**
3. Consent is obtained before the use of blood and blood products	**2.5**	**0**
4. Consent is obtained before other high-risk procedures and treatments	**2.5**	**0**
Total score	**10**	**0**

Strengths. Not identified.

Weaknesses. The hospital did not identify a list of situations (neither the ones listed in the measurable elements, nor some other situations) when an additional informed consent is required.

Opportunities. The policies and procedures should list all procedures performed in the hospital that require an additional consent.

Threats. Not identified.

4. Assessment of Patients (AOP)

Patients' admission to the hospital is based on the assessments to be conducted in order to identify whether the patients' health needs are going to be met if hospitalized. Patients' health-related data collection during the interviews, the analysis of those data and the development of the treatment regimen form the patient assessment process. Patient assessment is done collaboratively involving different health professionals from different departments and settings. Continuously throughout the treatment the patients should be reassessed to check if the health needs are satisfied in the hospital and to make adjustments in the treatment regimen. Reassessment data should continuously support and justify the treatment the patient is receiving in the hospital.

4.1 All patients cared for by the organization have their health care needs identified through an established assessment process

Established process should guide the patient assessment which is done to identify patient health care needs. The policies should describe all information to be acquired during the assessment and define the ones that are to be documented.

Measurable elements	Max. score	Obtained score
1. Organization policy and procedure define the assessment information to be obtained for inpatients	**5.0**	**2.0**
2. Organization policy identifies the information to be documented for the assessments	**5.0**	**2.0**
Total score	**10.0**	**4.0**

Strengths. The NTCC is a mono-specialty hospital, thus the health care needs there are common and are identified through a homogenous assessment process with the same assessment tests to be performed. The content of the medical records that are approved by the MOH, guide the assessment process in terms of outlining the information that should be gathered during the clinical interviews and be documented.

Weaknesses. Except the medical records, in the hospital there are no policies that define what assessment information should be collected and documented.

Opportunities. The assessment information gathering during clinical interviews will be structured if being guided by the relevant policies and procedures.

Threats. Not identified.

4.2 The organization has determined the minimum content of assessment, based on applicable laws and regulations and professional standards

To determine the patients' health needs that have approached the hospital, they should undergo the minimum assessments that are standard for the hospital to decide if the patient matches to the hospital mission and resources.

Measurable elements	Max. score	Obtained score
1. The minimum content of assessments is defined for each clinical discipline that performs assessments and specifies the required elements of the history and physical examination	**4.0**	**4.0**
2. Only qualified individuals permitted by licensure, applicable laws and regulations, or certification perform the assessment	**4.0**	**4.0**
3. The minimum content of assessments performed in inpatient settings is defined in policies	**2.0**	**0**
Total score	**10.0**	**8.0**

Strengths. The National Standards of TB diagnosis and treatment identifies the minimum content of assessments that should be conducted to diagnose TB. According to the Standard, three sputum smear examinations and an X-Ray examination are required. The standard lists additional procedures that can be provided to diagnose TB. Staff qualification review showed that all practicing physicians have qualification to do so, including the licensure and certifications. IDIs with healthcare providers of different departments (DS, DR, Children, and Psychiatry TB departments) confirmed that all patients admitted to the hospital undergo a defined set of examinations.

Evaluation of assessments and reassessments was done through comparison of the actual practices with the requirements outlined in the International Standards for TB Care 2014. According to the healthcare providers, adult pulmonary TB suspects who are capable of producing sputum undergo sputum examinations; culture, GenXpert, and polymerase chain

reaction (PCR). Those children who are able to produce sputum undergo sputum examinations and those who are not capable of producing sputum undergo bronchoscopy for microbiological examination. Initial diagnostic method for patients at risk of drug resistance or HIV is GenXpert. When patients are referred to the extra-pulmonary TB department for diagnostic purposes, the biological specimen biopsied from the affected site is sampled and analyzed. This examination refers to both adults and children. Among patients who are sputum smear negative but their clinical conditions are strongly suggestive of TB, undergo double assessment and initiate the antibiotic therapy.

Weaknesses. The hospital does not have policies describing the minimum content of assessments required for diagnosing TB. The minimum content of assessments for children TB suspects is not specified even in the National Standard for TB diagnosis and treatment, while the NTCC proposes to add it in the future edition of the National Standard.

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

Threats. Not identified.

4.3 Each patient's initial assessment(s) includes an evaluation of physical, psychological, social, and economic factors, including a physical examination and health history

Through an initial assessment patients should be evaluated for physical, psychological, social and economic conditions. In addition, health history should be gathered and physical examination should be performed.

Measurable elements	Max. score	Obtained score
1. All inpatients have an initial assessment that includes a health history and physical examination consistent with the requirements defined in hospital policy	**4.0**	**2.0**
2. Each patient receives an initial psychological assessment as indicated by his or her needs	**3.0**	**1.0**
3. The initial assessment results in an initial diagnosis	**3.0**	**3.0**
Total score	**10.0**	**6.0**

Strengths. After referring the patient to a respective department, physicians and nurses collaboratively perform initial assessment that encompasses physical assessments and acquisition of health history. After initial assessment physicians conclude the initial diagnosis which is yet to be confirmed by the sputum examinations. The initial diagnosis is documented in the medical record. During the IDIs healthcare providers indicated that patients who need psychological counseling, receive it.

> *During the patients' counseling we sometimes feel that they* [patients] *need a psychological help, thus we invite him/her* [the psychologist].
>
> **Healthcare provider 1**
>
> *If the physician finds it necessary for patient to have a psychological counseling, he/she organizes it.*
>
> **Healthcare provider 2**

Patients shared their diverse experience with regards to the psychological services. Some of the patients were satisfied and grateful to the psychologist for helping them to combat the disease.

> *During the hospital stay the psychologist has worked a lot with me. She has brought me back from the death threshold. The physician invited the psychologist for me.*
>
> **Patient/Family member**

Weaknesses. The process of initial assessment is not supported by the hospital policies and is merely guided by an oral indication. Though some patients receive professional psychological support, the psychologist's services are not uniformly and necessarily offered to all patients. The need for such service is determined solely by the managing physicians and not by the psychologist, which is prone of misidentification of patients' actual needs in those services. Moreover, the organization has no certain methodology/instrument developed to be used by the physicians to identify TB patients psychological needs. Some patients had bad insights regarding the psychological services they received during the treatment.

> *The psychological counseling was not organized very well. The counseling was done in my room, in the presence of other patient. The psychologist came for another patient and just offered services to me, but I felt no confidence during the whole process thus was not satisfied.*
>
> **Patient/Family member**

Opportunities. In addition to the TB-related indicators, psychological assessment per patients' needs should be performed to have an initial assessment results depicting the patient's condition

holistically. Because only psychologist can professionally assess the patients' psychological needs, the psychologist should be a part of initial assessment. If for some reason physicians are the ones who should determine the patients' needs in psychological services, then a certain methodology/instruments should be developed. The policies and procedures should guide implementation of psychological assessment and documentation of assessment findings. Meantime, the staff retention, recruitment program which is also yet to be developed should be ready to substitute healthcare professionals to support the continuity of patient care.

Threats. Not identified.

4.4 The patient's medical needs are identified from the initial assessments and recorded in the clinical record

The initial assessment that results in an initial diagnosis uncovers the medical needs that should be written in the patient medical record. The stages of patient's medical needs identification should be guided by the relevant policies.

Measurable elements	Max. score	Obtained score
1. The patient's medical needs are identified by the initial assessment, documented health history, physical exam, and other assessments performed based on the patient's identified needs.	**4.0**	**4.0**
2. The identified medical needs of the patient are documented in the patient's clinical record	**4.0**	**4.0**
3. Policies and procedures support consistent practice in all areas.	**2.0**	**0**
Total score	**10.0**	**8.0**

Strengths. The medical needs are identified once the TB diagnosis is confirmed. The medical needs are also driven from the initial assessments' findings, the health history, physical and other assessments that have been conducted. Medical record review showed that patients' medical needs are documented in all reviewed medical records, in the form of proposed treatment.

Weaknesses. Despite the constant conduct of the initial assessments and medical needs' identification, the hospital does not have policies and procedures to guide those stages of patients stay in the hospital.

Opportunities. The medical needs' identification will be formalized once policies and procedures are developed to guide and standardize the process.

Threats. Not identified.

4.5 Assessments are completed in the time frame prescribed by the organization

The appropriate time frames should be established for all types of assessment that are conducted within the hospital. The compliance to the established timeframes should be regularly monitored.

Measurable elements	Max. score	Obtained score
1. Appropriate time frames for performing assessments are established for all settings and services	**5.0**	**0**
2. Assessments are completed within the time frames established by the organization	**5.0**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. The document review didn't identify any document that covers information on timeframes for performing assessments. Healthcare providers emphasized the pointlessness of having the timeframes, as they do their job as quick as possible.

> *We organize the assessment immediately, in order not to keep the patients waiting. If everybody do their work, it won't be necessary to have the processes written. If everybody do their work fair enough, nothing else will be needed.*
>
> **Healthcare provider**

Opportunities. Developing and establishing timeframes for performing assessments in all settings and services, along with the training of the clinical staff on its importance and advantages, will form a common vision among the hospital staff for more coordinated activities.

Threats. The healthcare providers might be dissatisfied with new frames guiding their work causing resistance to change.

4.6 Assessment findings are documented in the patient's record and readily available to those responsible for the patient's care

All medical assessment findings should be documented in the patient medical record or other easily accessible locations. Timely documentation of all assessment findings is essential for assuring an on-going monitoring of the patient's health condition and rationalizing the reassessments. It is necessary to have the patient's medical assessment findings documented within 24 hours after hospitalization. All assessment-related entries should be accessible to all practitioners responsible for the patient care.

Measurable elements	Max. score	Obtained score
1. Assessment findings are documented in the patient's record	**4.0**	**4.0**
2. Those caring for the patient can find and retrieve assessments as needed from the patient's record or other standardized accessible location	**3.0**	**3.0**
3. Medical assessments are documented in the patient's record within 24 hours of admission	**3.0**	**3.0**
Total score	**10.0**	**10.0**

Strengths. During the medial record review the research team found that the assessment findings have been documented in all reviewed medical records where the assessment information was found in a uniform location, making it easy to complete and retrieve by the different practitioners involved in the patient care. In all medical records the first assessment results were dated within first 24 hours of hospitalization.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

4.7 All patients are reassessed at intervals based on their condition and treatment to determine their response to treatment and to plan for continued treatment or discharge

The reassessments are core for understating the patient's response to treatment, for redesigning the treatment regimen and planning the discharge. The reassessments should be conducted within the defined intervals and should be flexible to patient's immediate health needs. The reassessments done by the physicians are integral part of their daily work. The acute patients require daily reassessments including the weekends.

Measurable elements	Max. score	Obtained score

1. Patients are reassessed to determine their response to treatment	**2.0**	**2.0**
2. Patients are reassessed to plan for continued treatment or discharge	**2.0**	**2.0**
3. Patients are reassessed at intervals based on their condition and when there has been a significant change in their condition, plan of care, and individual needs or according to organization policies and procedures	**2.0**	**2.0**
4. A physician reassesses patients at least daily, including weekends, during the acute phase of their care and treatment	**2.0**	**2.0**
5. Reassessments are documented in the patient's record	**2.0**	**2.0**
Total score	**10.0**	**10.0**

Strengths. IDIs with healthcare providers from different departments showed that the reassessments are performed routinely and are deemed as an intrinsic part of their daily work. Two types of reassessments are conducted in the hospital to monitor the patients' response to treatment: the daily and planned reassessments.

Firstly we orient based on the patient's clinical picture: the complaints lessen, the weight increases, the temperature decreases. Secondly, we orient based on the sputum smear examination results. We monthly do sputum culture, and microscopy. Thirdly, we consider the X-ray study results. The planned X-ray examination is done on the third month of the treatment.

Healthcare provider 1

The dynamic against the treatment is determined by the patient's clinical conditions, temperature gauging and objective screening.

Healthcare provider 2

Planned reassessments are important for assessing the overall dynamic to TB treatment and are conducted continuously. The planned reassessments are conducted according to the National Standard and international standards of TB treatment and also guided by the patients' health conditions. Based on the reassessments findings the decision is made to discharge/transfer the patient to the outpatient treatment.

According to the standard, the sputum smear examination [reassessment] *should be done at the beginning of the 2nd month…*

Healthcare provider 1

The reassessments are planned based on the patient's clinical condition.

Healthcare provider 2

Regular visits and examination of the patients are an integral part of physician's daily responsibilities in the hospital. 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.

> *Every morning and evening we measure the patient's temperature. The information on what has been done during the shift is transferred* [orally and written] *to other shift health professionals.*
>
> **Healthcare provider**

During the medical record review the research team checked the presence of notes of daily and planned reassessments in the sampled medical records. All medical records reviewed contained information on reassessments and their findings, making possible to track the patient course of treatment.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

4.8 Medical, nursing and other individuals and services responsible for patient care collaborate to analyze and to integrate patient assessments

The information on patient health status, obtained from the reassessments should be analyzed and integrated collaboratively with all clinicians responsible for the patient care (physicians, nurses and others).

Measurable elements	Max. score	Obtained score
1. Patient assessment data and information are analyzed and integrated	**5.0**	**5.0**
2. Those responsible for the patient's care participate in the process	**5.0**	**5.0**
Total score	**10.0**	**10.0**

Strengths. During the patient care provision all healthcare providers directly involved in the patient care process analyze the patient's health information received from the patient's reassessments and use that information to monitor the dynamic over the treatment and if needed integrate the data to modify the treatment and care plan. The analysis and integration of assessment data and information may eventually result in prolongation of treatment regimen,

early discharge or even in shift of treatment regimen, for instance from DS-TB treatment to DR-TB treatment. Managing physicians, heads of the departments and senior nurses participate in this process.

In the department we have two physicians. We discuss and analyze together all reassessment information. **Healthcare provider 1** *On a specific weekday all physicians of the department discuss all our patients.* **Healthcare provider 2** *Firstly, the treating physician analyzes the findings and then discusses with the head of the department.* **Healthcare provider 3**

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

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

The laboratory services provided in the hospital should meet the served population's and the healthcare professionals' needs. The laboratory services should meet local and national standards, laws and regulations.

Measurable elements	Max. score	Obtained score
1. Laboratory services meet applicable local and national standards, laws, and regulations	**5.0**	**0**
2. Adequate, regular, and convenient laboratory services are available to meet needs	**5.0**	**1.0**
Total score	**10.0**	**1.0**

Strengths. The laboratory department provides regular services as the department operates regularly. The services provided by the laboratory department are convenient for the hospital.

Weaknesses. The quality of laboratory services provided in the hospital do not comply with local and national standards of proper laboratory practices. The services provided by the laboratory are not adequate as the laboratory itself do not meet the necessary bio-safety

standards. Repeatedly healthcare providers from different departments have expressed their dissatisfaction with the quality and the scopes of services provided by the clinical laboratory.

Opportunities. The laboratory needs full reconstruction and renovation to satisfy requirements and to provide adequate services.

Threats. The improvements in the laboratory department require huge financial resources. The lack of financial resources will hinder improvements in laboratory services.

4.10 A laboratory safety program is in place, followed and documented

The laboratory safety program that is planned to be coordinated by the organization's safety management program should address the safety risks for laboratory and other staff, which will be designed in accordance with the degree of risks and hazards of the laboratory.

Measurable elements	Max. score	Obtained score
1. A laboratory safety program addresses potential safety risks in the laboratory and other areas outside the laboratory where laboratory services are provided	**2.0**	**0**
2. The program is part of the organization's safety management program and reports to the organization safety structure at least annually and when any safety events occur	**2.0**	**0**
3. Written policies and procedures address the handling and disposal of infectious and hazardous materials	**2.0**	**2.0**
4. Laboratory staff are oriented to safety procedures and practices	**2.0**	**0**
5. Laboratory staff receive education for new procedures and newly acquired or recognized hazardous materials	**2.0**	**2.0**
Total score	**10.0**	**4.0**

Strength. The hospital has guidelines describing the handling and disposal of infectious and hazardous materials. The laboratory and other clinical staff are periodically educated on new procedures and newly acquired hazardous materials. The education is provided by the specialists of the Infection prevention and control program.

The epidemiologist trains us about new procedures and newly acquired hazardous materials
Healthcare provider

Weaknesses. The laboratory department does not have a formal safety program that will address the potential safety risks within and outside the laboratory. During the IDIs with the laboratory

staff, the research team found that already familiar safety risks are controlled merely by avoiding the practices that are prone to causing those risks. The laboratory is ought to take reactive steps against the safety risks, as far as the preventive measures are not always available or implemented. The laboratory staff is not oriented to the safety procedures and practices and the only thing left is to assure their security on their own, based on their own perception of the safety.

> *We try to assure our security. We don't feel confident about the safety practices and procedures.*
>
> **Healthcare provider**

Opportunities. Development and integration of laboratory safety program will address the safety risks for staff members within and outside the laboratory. Implementation of program should be supported by the staff members that are appropriately oriented to the safety program and safety procedures. The laboratory staff should be evaluated on how well they have understood the newly taught practices.

Threats. Integration of a new program with new duties and responsibilities might cause staff members' reluctance**.**

4.11 Individuals with proper qualifications and experience administer the test and interpret the results. Laboratory results are available in a timely way as defined by the organization

The organization should define responsibilities of each of the laboratory's staff members. The supervisory and technical staff should have appropriate training, experience and skills as defined by the position requirement and should be given work assignments as related to their professional trainings, experience and skills. The laboratory should be staffed as appropriate for providing laboratory services.

Measurable elements	Max. score	Obtained score
1. Those individuals who perform testing and those who direct or supervise testing are identified	**2.0**	**2.0**
2. Staff with proper qualifications and experience administer tests	**2.0**	**2.0**
3. Staff with proper qualifications and experience interpret tests	**2.0**	**2.0**
4. Supervisory staff have proper qualifications and experience	**2.0**	**2.0**
5. The organization has established the expected report time for results	**1.0**	**0**

6. Laboratory results are reported within a time frame to meet patient needs	**1.0**	**0**
Total score	**10.0**	**8.0**

Strengths. The staff qualification review showed that all laboratory staff who supervise laboratory services, administer, interpret laboratory tests have proper qualification and experience.

Weaknesses. In the laboratory there are no timeframes established to guide the reporting of test results. The laboratory staff performs and reports the test results guided by an internally agreed schedule, considering the workload and the urgency of patients' needs. During the IDIs with laboratory staff it was found that reporting of test results can be delayed because of various issues such as non-operation of equipment, not-availability of materials necessary to perform certain test, etc.

As far as the exhaust fan does not operate, we stopped doing some of the tests. But in order to administer the remaining tests and to prepare the sputum smears we take the sputum samples to the NRL, and use their exhaust. At times, the NRL staff do not have time to immediately help us and the sputum smears are delayed in NRL. We do this at expense of our time, work. All of these [additional steps to do] *influence the quality of the sputum and result in delays in reporting of test results.*

Healthcare provider 1

The process of buying the laboratory materials through the tender delays our work a lot. Sometimes, when the tender results are announced lately, we end up running out of the necessary reagents, and accordingly we do not do the respective tests.

Healthcare provider 2

Opportunities. Establishment of timeframes for reporting the test results will lead to provision of coordinated laboratory services.

Threats. The laboratory capacities should be appropriate to assure constant reporting of the test results within defined timeframes. The financial resources are needed to equip the department with required amenities to avoid delays in test performances and reporting of results.

4.12 All equipment used for laboratory testing is regularly inspected, maintained and calibrated and appropriate records are maintained for these activities

The laboratory should have a "laboratory equipment management program" that is responsible for selecting and acquiring, identifying and inventorying, inspecting, testing, calibrating and maintaining the equipment, monitoring and acting on equipment hazard notice, recalls, reportable incidents, problems and failures, and documenting the management program activities.

Measurable elements	Max. score	Obtained score
1. There is a laboratory equipment management program and it is implemented	**3.0**	**1.0**
2. The program includes selecting and acquiring equipment	**1.0**	**1.0**
3. The program includes inventorying equipment	**1.0**	**1.0**
4. The program includes inspecting and testing equipment	**1.0**	**1.0**
5. The program includes calibrating and maintaining equipment	**1.0**	**1.0**
6. The program includes monitoring and follow-up	**1.0**	**0**
7. All testing, maintenance, and calibration of equipment are adequately documented	**2.0**	**1.0**
Total score	**10.0**	**6.0**

Strengths. The activities associated with equipment management such as selecting and acquiring equipment, inventorying, inspecting and testing are periodically carried out. All activities are implemented by the hospital engineer, and only calibration is done by a contracted company. The calibration center is responsible for calibration of laboratory equipment and the hospital engineer documents the equipment calibration results.

Weaknesses. The laboratory does not have a formal equipment management program to guide activities associated with the equipment management. Activities that are periodically performed are not supported by any plan or written document, but rather are carried out based on an oral indication. Responsibilities associated with implementation of these activities are not defined. Given the absence of formal equipment management program, the monitoring and follow-up of implemented activities are not organized either. The testing and maintenance of equipment are not documented.

Opportunities. A formal equipment management program should be developed to frame and coordinate already existing activities.

Threats. Not identified.

4.13 Essential reagents and other supplies are regularly available and evaluated to ensure accuracy and precision of results

The laboratory should implement processes to assure continuous availability of essential reagents and supplies that are necessary for performing tests to meet the patients' needs. The identified essential reagents and supplies should be maintained in conditions that are accordant with the manufacturer's recommendations. Reagents should be continuously evaluated to ensure accuracy and precision of laboratory test results. All reagents and supplies should be labeled as described in written guidelines.

Measurable elements	Max. score	Obtained score
1. Essential reagents and supplies are identified	**2.0**	**2.0**
2. Essential reagents and supplies are available, and there is a process to address when reagents are not available	**2.0**	**1.0**
3. All reagents are stored and dispensed according to manufacturer's directives or packaging instructions	**2.0**	**2.0**
4. The laboratory has and follows written guidelines for evaluation of all reagents to provide for accuracy and precision of results	**2.0**	**1.0**
5. All reagents and solutions are completely and accurately labeled	**2.0**	**2.0**
Total score	**10.0**	**8.0**

Strengths. All reagents and supplies that are required for performing essential tests are identified. During the laboratory observation the research team found that all reagents are labeled accurately and stored appropriately as recommended by the manufacturers' requirements, in the refrigerator or at room temperature. Not systematically but the laboratory personnel evaluates the reagents through performing control tests and checking whether the results fit in the reference ranges or not.

We check if after using the specific reagent the analysis results fit to the reference ranges or not. If yes, then the reagent's quality is satisfactory. In the biochemical laboratory we document control analysis results, whereas in the microbiological we do not.

Healthcare provider 1

We store the reagents according to the manufacturers' recommendations.

Healthcare provider 2

Weaknesses. During the IDIs the research team found that the laboratory has a shortage of necessary reagents and supplies, because of the financial constraints and the tendering process. The procedure of purchasing materials through a tender at times delays the supply which eventually results in shortage of necessary reagents. In case of the shortages, the laboratory either supplies the reagents from other TB laboratories, or does not perform the respective tests. The hospital does not have guidelines that describe the evaluation of laboratory reagents. The processes that are directed to evaluation of reagents are decided based on oral indications.

Opportunities. The hospital should develop a process to continuously assure the laboratory with necessary reagents, thus to perform the full spectrum of tests. Development of written guidelines on reagents' and supplies' evaluation will formalize the procedure and result in implementation of these processes.

Threats. The quality of test results performed in the laboratories will suffer unless the appropriate mode of reagent evaluation is integrated into daily practices.

4.14 Established norms and ranges are used to interpret and to report clinical laboratory results

The tests' reference ranges that are specific to the laboratory should be established for the laboratory. The "normal" reference ranges should be included in the medical records along with the test results.

Measurable elements	Max. score	Obtained score
1. The laboratory has established reference ranges for each test performed	**3.0**	**3.0**
2. The range is included in the clinical record at the time test results are reported	**3.0**	**3.0**
3. Ranges are reviewed and updated as needed	**4.0**	**3.0**
Total score	**10.0**	**9.0**

Strengths. All tests conducted in the laboratory have established reference ranges. Along with the test results, the reference ranges are also reported and attached in the medical records.

Weaknesses. The review and the update of the test results are not done regularly. The laboratory uses the ranges that are written in the instructions shits of the reagents.

> *We perform an examination on 20-30 healthy people in the hospital, to identify and update the reference ranges specific to the hospital. We haven't had a case of not matching the reference range to the one mentioned in the instruction, that is why we mostly use the ranges written in the instruction.*
>
> **Healthcare provider**

Opportunities. The laboratory should develop a formal process of reviewing and updating the reference ranges.

Threats. The absence of formal process of reviewing and updating the reference ranges can eventually lead to misinterpretation of test results.

4.15 A qualified individual(s) is responsible for managing the clinical laboratory service or pathology service

The laboratory director should be a qualified individual with possessing all required trainings, expertise and experience as according to law and regulations. The director's responsibilities include daily supervision of laboratory activities, ensuring trainings and supply management and development and implementation of according policies and practices.

Measurable elements	Max. score	Obtained score
1. The clinical laboratory, and other laboratory services throughout the organization, are under the direction and oversight of one or more qualified individuals	**2.0**	**2.0**
2. Responsibilities for developing, implementing, and maintaining policies and procedures are defined and carried out	**2.0**	**2.0**
3. Responsibilities for administrative oversight are defined and carried out	**2.0**	**2.0**
4. Responsibilities for maintaining quality control programs are defined and carried out	**2.0**	**1.0**
5. Responsibilities for monitoring and reviewing all laboratory services within and outside the laboratory are defined and carried out	**2.0**	**2.0**
Total score	**10.0**	**9.0**

Strengths. The laboratory director possesses all prerequisites (as defined in the department regulation) for being appointed for that position. During the document review the research team found that the responsibilities associated with developing, implementing and maintaining

policies and procedures are defined in the laboratory department regulation. The regulation elaborates the director's responsibilities regarding the administrative oversight of the laboratory services. The regulation includes responsibilities related to the quality control related activities. According to the regulation the director's responsibilities enclose monitoring and reviewing all laboratory services within and outside the laboratory.

Weaknesses. As far as the laboratory does not have a formal quality control program, the responsibilities associated with implementation of activities directed to quality control are not in the scopes of a program.

Opportunities. Not identified.

Threats. Not identified.

4.16 Quality control procedures are in place, followed, and documented

The pledge of high-quality pathology and clinical laboratory services is the presence of quality control program. The quality control program should encompass activities such as validation of test methods, daily surveillance of test results, rapid correction of deficiencies, and documentation of results and corrective actions.

Measurable elements	Max. score	Obtained score
1. There is a quality control program for the laboratory	**2.0**	**0.5**
2. The program includes the validation of test methods	**2.0**	**0**
3. The program includes the daily surveillance of test results.	**2.0**	**0.3**
4. The program includes rapid correction of deficiencies	**2.0**	**0.5**
5. The program includes the documentation of results and corrective actions.	**2.0**	**0**
Total score	**10.0**	**1.3**

Strengths. In the biochemical laboratory of the laboratory department an external and internal quality assurance systems are implemented. In scopes of the internal quality assurance system the laboratory tests undergo quality assurance tests through control serums, twice a weak.

Whenever a deficiency is detected a quality assurance action plan algorithms are used for different test methods to identify and correct the deficiency in the biochemical laboratory. In clinical, bacteriological, cytological, histological laboratories for the quality assurance purposes, physicians monitor the performance of laboratory assistants, and if doubt the results, send the samples for double analysis in an external laboratory.

Weaknesses. All actions performed in the biochemical laboratory in the frames of quality assurance program are not documented. In the remaining four laboratories, clinical, bacteriological, cytological, histological no proper quality assurance systems are integrated as the relevancy of activities performed in four above listed laboratories to quality assurance conduct is questionable.

Opportunities. A quality control program for laboratory services will be a pledge for continuous quality improvement and will eventually result in establishing high-quality laboratory services.

Threats. Not identified.

4.17 Laboratory access

The laboratory entrance should be identifiable with an international biohazard warning symbol and sign. The department should identify individuals who are authorized and unauthorized to enter the laboratory area. The entrance to the laboratory should be restricted to ones who are not permitted 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**	**1.5**
2. Only authorized persons are allowed to enter the laboratory's working areas.	**2.0**	**0**
3. Children are not authorized or allowed to enter the laboratory's working areas.	**2.0**	**0**
4. The name, telephone number of the laboratory manager are placed at the entrance to the laboratory.	**2.0**	**0.5**
5. The rules of entering and exiting the laboratory are placed at the entrance to the laboratory	**2.0**	**0**
Total score	**10.0**	**2.0**

Strengths. The international biohazard warning symbol is displayed at the entrance to the laboratory area. The name of the laboratory director and managers are placed at the entrance to the laboratory.

Weaknesses. The bio-safety levels are not displayed at the entrances to laboratories. The laboratory department is not visually protected from unauthorized entries to the area. The entrance area of the laboratory department does not restrict the entry of children. Because of the absence of a warning sign restricting entry to the laboratory, patients and visitors easily access the general and working areas of the laboratories. Healthcare providers from different departments indicated that patients bring their sputum samples for reassessments to the microbiological laboratory, and enter without properly wearing the protective equipment. Study participants explained this practice by insufficiency of nursing staff and negligence of laboratory staff to prohibit such practice.

Sometimes it is difficult to control the patient's entry to the department. Often patients bring their sputum sample to the laboratory, without wearing a respirator or even without properly closing the sputum container. And the justification is that all nurses are busy in the respective TB department.

Healthcare provider 1

The respective department who allow patients to take the sputum on their own, do have free nurses. On the other hand, if laboratory staff do not accept the sputum sample brought by the patient, the patient would complain and this would not repeat.

Healthcare provider 2

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

Opportunities. The laboratory department director should more effectively control the entry area and protect it from unauthorized accesses by developing policies and restrictions that are evident to all staff, patients and visitors. The laboratory department administration telephone numbers should be placed at the entrance, along with the rules for entering and exiting the laboratory.

Threats. Accessing the laboratory area without properly maintaining the rules for entering and exiting it poses a major risk of infection transmission between staff and patients.

4.18 Personal protective equipment

The laboratory personnel should wear personal protective equipment whenever working in the laboratory. For the sake of personal protection and minimizing the risks of infection transmission the personnel should not perform non-work-related activities while in the laboratory.

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.	**2.0**	**2.0**
2. Protective clothing is worn and laundered appropriately as according to the biosafety standards	**2.0**	**1.0**
3. Personnel wash hands after any overt contamination, after completing work and leaving the laboratory.	**2.0**	**1.5**
4. Hand washing stations with automated taps, soap, paper towels and dispensers are located at the entrance to laboratory working areas.	**1.0**	**0.7**
5. Laboratory personnel do not eat, drink, smoke, apply cosmetics and handle contact lenses in the laboratory.	**1.0**	**1.0**
6. Food and drink are not stored in the laboratory working areas.	**1.0**	**1.0**
7. Mobile telephones are not used in the laboratory	**1.0**	**0.5**
Total score	**10.0**	**7.7**

Strengths. In both laboratories observed, staff wore laboratory clothing while performing the laboratory manipulations. The laboratory staff wore gloves whenever working with sputum, blood samples, 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. The used gloves were collected in a special pocket which was taken away from the laboratory as soon as full.

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. In the clinical laboratory a dispenser for paper towels was located next to the hand-washing station. During the observation no one from staff eat, drink, smoke,

apply cosmetics and/or handle contact lenses in the working areas. Food and drinks were not stored in the working areas.

Weaknesses. The laundering of laboratory clothing was done by the staff at home violating the bio-safety standards. Observations confirmed that the laboratory workers reuse the gloves explaining it as a mean to thrift with justification that the type of procedures they performed with reused gloves pose no risk for infection. Laboratory staff was entering and exiting the working areas without washing the hands. They used mobile phones covered with a cellophane coating as an infection control method.

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 educated on safety practices and adequate personal protection.

Threats. Not appropriate management of potentially contaminated and infectious items such as laboratory clothing, reused glows, and cell phone pose a huge risk of transmitting the infection outside of the laboratory and even outside of the hospital.

4.19 Procedures

To comply with bio-safety standards the personnel should perform procedures in a way to prevent infection risks.

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**	**1.8**
2. Mouth pipetting is not done and needles and syringes are not used as substitute for pipetting.	**2.0**	**2.0**
3. No materials are placed in the mouth, and labels are self-adhesive	**2.0**	**2.0**
4. Written documentation that may be removed from the laboratory is protected from contamination.	**2.0**	**0**
5. Standard operating procedures for all processes are developed and used	**2.0**	**2.0**
Total score	**10.0**	**7.8**

Strengths. The bacteriological laboratory works in a way to avoid generation of aerosols and droplets. Staff never uses mouth pipettes and never place materials in the mouths. They also never use needles and syringes as substitutes for pipettes. Labeling and notes on the flasks are done only using markers In the microbiological laboratory, the standard operating procedures are developed and the National Standards are available and used.

Daily sputum specimen transfers from microbiological laboratory to the National Reference Laboratory (NRL) and back are done with the respect of records, using for each sample the unique ID, request form (TB-05), and response form (TB-06).

Weaknesses. In the microbiological laboratory the exhaust fan, aimed to prevent generation of aerosols and droplets, was broken. To avoid risk of aerosol generation and infection transmission the laboratory staff avoids preparing the specimens. They take the sputum to the neighboring (100 meters away) National Reference Laboratory (NRL) to have the sputum specimens prepared there, using the NRL equipment. Prepared specimens are brought back and further tested in the clinical laboratory of the hospital. Paper documents are exchanged between the laboratories and other departments with no respect for contamination.

Opportunities. The hospital should provide necessary equipment for implementing microbiological manipulations without triggering infections risks. All paper documents' exchange have to be protected from contamination.

Threats. Lack of financial resources for purchasing new equipment might trigger infection risks increase.

4.20 Work areas and design

The work areas in the laboratory should be divided into "functionally clean" and "potentially contaminated" ones with the restricted access to there. The laboratory should be clean, neat and all equipment and materials that are not used should be removed from the work areas. It should be designed properly to assure protection of staff from aerosols that might be generated while performing microbiological procedures.

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**	**0.7**
2. Access to the clean areas and the contaminated areas must be controlled and enforced by the laboratory's manager.	**1.0**	**0.3**
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**	**0.5**
6. Laboratory doors have a glass window and fire rating.	**1.5**	**0.7**
7. Laboratory has reliable and adequate electricity supply	**1.5**	**0.3**
Total score	**10.0**	**5.5**

Strengths. The bacteriological laboratory was designed in a way to have a conventional division of work areas that were clean, neat and free of unused equipment and materials. During the observation, whenever the spill occurred it was immediately decontaminated. UV lamps were available in both laboratories observed. Ventilation was assured primarily through open windows. The doors of both laboratories were self-closing and had glass windows.

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 because were made of wood. Moreover, the laboratory staff reported that the electricity supply is not reliable in both laboratories and might cause fire at any time.

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, and reliable electricity supply.

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

4.21 A radiation safety program is in place, followed and documented

The hospital should implement a radiation safety program which will be there to address the radiation safety risks among staff and patients. The radiation safety program should report to the safety structure of the hospital, ensure patients and staff safety while performing the radiation studies, and orient the staff to safety practices.

Measurable elements	Max. score	Obtained score
1. A radiation safety program is in place that addresses potential safety risks and hazards encountered within or outside the department	**2.0**	**2.0**
2. The safety program is part of the organization's safety management program and reports to the organization safety structure at least annually and when any safety events occur	**2.0**	**0**
3. Written policies and procedures address compliance with applicable standards, laws, and regulations	**2.0**	**0**
4. Written policies and procedures address handling and disposal of infectious and hazardous materials	**2.0**	**2.0**
5. Identified radiation safety risks are addressed by specific processes or devices that reduce safety risks (such as lead aprons, radiation badges and the like)	**2.0**	**2.0**
Total score	**10.0**	**6.0**

Strengths. The Radiology and Diagnostic imaging department has implemented a list of practices to address the radiation safety risks: the walls of the radiology cabinet are lined with barium, the doors are lined with lead, physicians wear special protective coats and the patients wear protective gears with lead layers. The findings of annual assessment of background radiation are documented indicating whether deviations have been detected or not. The hospital has a manual addressing the handling and disposal of infectious and hazardous materials. .

Weaknesses. The Radiology and Diagnostic imaging department does not have a formal radiation safety program as the department does not have written policies and procedures guiding

the processes related to radiation safety assurance. The activities implemented to address the safety risks are not integrated in the overall safety program of the hospital and the department does not report on the activities implemented to the safety program.

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.

4.22 Individuals with proper qualifications and experience perform diagnostic imaging studies, interpret the results and report the results. Radiology and diagnostic imaging study results are available in a timely way as defined by the organization

The hospital should identify radiology and diagnostic imaging department staff members by their job descriptions and responsibilities. Individuals who perform imaging studies, interpret study results and supervise the department's routine activities should be identified. All identified staff members should have appropriate training, experience and skills for implementing work assignments. The department should be staffed adequately to satisfy patients' needs. The diagnostic and imaging study results are reported within defined timeframes to meet patients' and clinical staff needs.

Measurable elements	Max. score	Obtained score
1. Those individuals who perform diagnostic and imaging studies or direct or supervise the studies are identified	**2.0**	**2.0**
2. Staff with proper qualifications and experience perform diagnostic and imaging studies	**2.0**	**2.0**
3. Staff with proper qualifications and experience interpret study results	**1.0**	**1.0**
4. Properly qualified staff verify and report the results of studies	**1.0**	**1.0**
5. Supervisory staff have proper qualifications and experience	**2.0**	**2.0**
6. The organization has established the expected report time for results	**1.0**	**0**
7. Radiology and diagnostic imaging study results are reported within a time frame to meet patient needs	**1.0**	**0.5**
Total score	**10.0**	**8.5**

Strengths. Assessment of the Radiology and Diagnostic imaging department staff members' personal 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 The department specialists reported that the department staff are working in a way to provide the results of studies as soon as possible in order not to keep patients waiting.

> *We organize the studies immediately as patient has been referred to us. Thus, the patient will not wait long.*
>
> **Healthcare provider**

Weaknesses. The radiology department does not have timeframes for reporting the radiology imaging study results.

Opportunities. Established and followed timeframes for reporting the imaging study results will lead to standardization of the department services and will help to avoid delays in the patient care process.

Threats. Unless the timeframes are developed for imaging studies results reporting deviation from the expected timeframes will not be controlled, as the department staff will work collaboratively to meet the set timeframes.

4.23 All equipment used to conduct radiology and diagnostic imaging study is regularly inspected, maintained and calibrated and appropriate records are maintained for these activities

In the scope of the radiology and diagnostic imaging equipment management program the department should organize selection and acquisition; inventorying; inspection and testing; calibration and maintenance of the equipment; and monitor implementation of the aforementioned activities.

Measurable elements	Max. score	Obtained score
1. There is a radiology and diagnostic imaging equipment management program, and it is implemented	**1.5**	**1.0**
2. The program includes selecting and acquiring equipment	**1.5**	**1.0**
3. The program includes inventorying equipment	**1.5**	**1.0**
4. The program includes inspecting and testing equipment	**1.5**	**1.5**
5. The program includes calibrating and maintaining equipment	**1.5**	**1.5**
6. The program includes monitoring and follow-up	**1.5**	**0**
7. There is adequate documentation of all testing, maintenance and calibration of equipment	**1.0**	**0**
Total score	**10.0**	**6.0**

Strengths. The hospital has officially contracted an outsource center to provide services related to diagnostic equipment management. The center from the Mergelyan Institute is responsible for examinations of equipment and performing annual inspections, testing, calibration and maintenance of equipment. Selection, acquiring, and inventorying of equipment is done collaboratively by the technician and the radiology department specialist.

Weaknesses. The Radiology and Diagnostic imaging department does not have a formal radiology and diagnostic imaging equipment management program that is guided by the hospital regulations. The hospital does not have a formal schedule guiding all activities related to the equipment management. The findings of the equipment management activities are not documented in the hospital. And as there is no formal program, the monitoring and follow-up are not organized either.

Opportunities. An equipment management program will shape the activities that are to be conducted to manage the equipment as listed in the table while the monitoring and follow-up plan will monitor over the implementation of the program.

Threats. Not identified.

4.24 A qualified individual(s) is responsible for managing the radiology and diagnostic imaging services

The radiology and diagnostic imaging department director is a qualified individual with respective trainings, expertise and skills. The director takes the responsibility for supervision of department activities and provided services.

Measurable elements	Max. score	Obtained score
1. Radiology and diagnostic imaging services are under the direction of one or more qualified individuals	**2.0**	**2.0**
2. Responsibilities for developing, implementing, and maintaining policies and procedures are defined and carried out	**2.0**	**0**
3. Responsibilities for administrative oversight are defined and carried out	**2.0**	**0**
4. Responsibilities for maintaining quality control programs are defined and carried out	**2.0**	**0**
5. Responsibilities for monitoring and reviewing all radiology and diagnostic imaging services are defined and carried out	**2.0**	**0**
Total score	**10.0**	**2.0**

Strengths. The head of the radiology and diagnostic imaging department who directs the department's services is a qualified individual.

Weaknesses. The department does not have a regulation describing the activities conducted in the department and defining the responsibilities for implementing, and maintaining policies and procedures. The job description of department director only captures responsibilities that are associated with clinical duties while the responsibilities associated with administrative oversight, implementation of activities directed to quality control and monitoring and reviewing radiology and diagnostic imaging services are not stated. Administrative activities are implemented based on personal understanding and indications made by the superior staff.

> *I control physicians' daily work, analyze the complicated cases, and organize the department's general work.*
>
> **Healthcare provider**

Opportunities. All responsibilities for developing, implementing, and maintaining policies and procedures, performing the administrative oversight, maintaining quality control programs, monitoring and reviewing all radiology and diagnostic imaging services should be defined either in the department's regulation or in the job description of a responsible person.

Threats. Not identified.

4.25 Quality control procedures are in place, followed, and documented

The radiology and diagnostic imaging department should have a quality control program and through defined processes bolster the quality of services provided in the department. The processes that should be implemented include validation of test methods, daily surveillance of imaging results, rapid correction when a deficiency is identified, and testing of reagents and solutions.

Measurable elements	Max. score	Obtained score
1. There is a quality control program for the radiology and diagnostic imaging services, and it is implemented	**2.0**	**0**
2. Quality control includes validating test methods	**2.0**	**0**
3. Quality control includes daily surveillance of imaging results	**2.0**	**2.0**
4. Quality control includes rapid correction when a deficiency is identified	**2.0**	**2.0**

5. Quality control includes testing reagents and solutions	**2.0**	**0**
Total score	**10.0**	**4.0**

Strengths. The department routinely implements processes targeted to maintaining quality of services being provided: the department's head evaluates the physicians' performance through checking the quality of imaging studies performed, a private organization which is responsible for equipment maintenance, performs rapid corrections whenever identified.

Weaknesses. The department does not have a formal quality control program regulated by documents or policies. However, the appropriateness and relevancy of described evaluation to the quality control procedures are questionable. The validation of test methods, testing of reagents and solutions are not included in the actions aiming to improve the quality of services.

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 quality control activities and share a common understanding of quality improvement.

5. Care of Patients (COP)

Patients' care should be planned based on the assessment findings and collaboratively with physicians, nurses, pharmacists and other health care practitioners. All healthcare providers involved in development of a patient's care plan should acknowledge their roles as defined by their qualifications, knowledge, skills, experience, hospital policies and personal job descriptions.

Patients' care consists of several phases; planning and delivery of health care services, monitoring of the response to treatment, redesign of the planned care, completion of care and planning of the follow-up. All these phases should be performed to attain the principle function of the hospital that is TB treatment. Throughout the hospitalization, care should be accessible to

all patients admitted for TB treatment, it should be responsive to high-risk patients and should capture the food and nutritional aspects of treatment.

5.1 Policies and procedures and applicable laws and regulations guide the uniform care of all patients

Through direct coordination, the leadership of the hospital should assure the uniformity of care between patients within a single department and patients in different departments. Patients with the same health issues should be assured to receive the same quality of care. Respective policies and procedure should guide uniform provision of services across the settings. In general, uniformity of care considers the following aspects (a-e):

a) Access to appropriate care and treatment by qualified practitioners does not depend on the day of the week or time of day.
b) Acuity of the patient's condition determines the resources allocated to meet the patient's needs.
c) The level of care provided to patients (for example, anesthesia care) is the same throughout the organization.
d) Patients with the same nursing care needs receive comparable levels of nursing care throughout the organization.

Measurable elements	Max. score	Obtained score
1. The organization's leaders collaborate to provide uniform care processes	**3.0**	**3.0**
2. Policies and procedures guide uniform care and reflect relevant laws and regulations	**2.0**	**0**
3. Uniform care is provided that meets requirements a) through e)	**5.0**	**5.0**
Total score	**10.0**	**8.0**

Strengths. The leadership of the hospital takes actions to supervise provision of care and keep it uniform across the patients, physicians and departments.

Firstly I do clinical rounds. If I don't have enough time to daily meet each and every patient, I try to visit all departments and talk to patients that are most in need. I guide all physicians similarly, assuring their uniform performance.

Administration

According to the national law the TB diagnosis and treatment services are covered by the state budget expanding to all population groups in all health care units, therefore the financial aspect of accessibility to uniform care is assured (a). Throughout the day patients are under the supervision of qualified physicians and nurses (b). Acuity of patient condition is always

respected while planning the resource allocation (c). The level of care is uniform in all departments (d). Nursing services may vary per nurse's personal characteristics however the basic nursing duties are performed similarly (e).

The acuity of patient condition is considered for planning the financial resource and other [human] *resource allocation. When the physician evaluates the patient condition, the personnel approach of taking care of patients' changes. Resource allocation is based on evaluation results and patient's complaints.* **Healthcare provider 1** *From nurse to nurse, based on their personal peculiarities the practices may alter. However there are accepted norms of practices, procedures (injecting technique, working with gloves, blood draw from veins and etc.) that are always the same, thus it does not influence the quality of services.* **Healthcare provider 2**

Weaknesses. Processes targeted to assuring uniform care are implemented based on internal agreements and personal initiatives of the leadership staff. No written document was found to guide those processes. Except the national law highlighting the country-wide uniformity of TB care the hospital has not adapted internal policies and procedures that would reflect the relevant law.

Opportunities. Policies and procedures should be developed to formalize and guide the actions towards ensuring the uniformity of care.

Threats. Not identified.

5.2 There is a process to integrate the care provided to each patient

Integrated and coordinated care is a pledge for efficient care process, effective use of human resources and increased likelihood for success. The leadership of different departments in conjunction with the leadership of the hospital should apply different means to support integration and coordination of TB care services.

Measurable elements	Max. score	Obtained score
1. Care planning is integrated and coordinated among settings, departments, and services	**4.0**	**4.0**
2. Care delivery is integrated and coordinated among settings, departments, and services	**4.0**	**4.0**

3. The results or conclusions of any patient care team meetings or other collaborative discussions are written in the patient's record.	**2.0**	**2.0**
Total score	**10.0**	**10.0**

Strengths. For TB patients the treatment regimen is planned collaboratively with physicians and heads of the departments, and for DR-TB patients the care is planned collaboratively within the DR-committee. Several processes are implemented to support coordination and integration of care. The hospital leadership organizes meetings and discussions in different formats: 5-minute briefings, DR-meetings and discussion of acute cases. Five-minute briefings are led by the director of the hospital and separately by the clinical head of the hospital. During 5-minute briefings led by the clinical head, the urgent patient cases are discussed, to collaboratively plan and monitor care delivery. During DR-meetings the DR-committee plans the treatment regimens for newly admitted DR-TB patients and discusses the treatment dynamics of the hospitalized ones. During the admission process, acute cases are collaboratively discussed to plan proposed care for new patients. Internal communications between physicians, heads of treating and diagnostic departments, admission department and the clinical head are strongly facilitated, to assure continuous integration and coordination of patients care planning and delivery. The hierarchy grounded in the hospital is considered as one of the means for care coordination.

> *In the hospital we have a hierarchy that ensures the coordination. Within a department, the nurse supervises the janitorial staff, the physicians supervises the nurses, and finally the department head supervises the physicians. Now we have a new position, a head nurse who is supposed to supervise all nurses of the hospital.*
>
> **Healthcare provider**

Medical records review showed that the conclusions of collaborative discussions have been filled in by the specialists who were responsible for those conclusions and proved that collaborative efforts used to plan and deliver patient care in the hospital.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

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

Patients' TB treatment regimen is planned and modified according to the assessments and reassessments findings to adapt the treatment to patients' health needs' dynamics. Ideally, the treatment regimen should be planned in a most optimal way to achieve the best possible outcome in a shortest period. Planned treatment regimen along with the patient care goals and procedures performed are written up in the patients' medical records. In case of changes in the planned care, the modified goals of care and the modified regimen should be also included in the patients' medical records. All new entries are preferably to be written by the specialists who are making those health-related decisions.

Measurable elements	Max. score	Obtained score
1. The care for each patient is planned by the responsible physician, nurse, and other health professionals within 24 hours of admission as an inpatient	**2.0**	**2.0**
2. The planned care is individualized and based on the patient's initial assessment data	**2.0**	**2.0**
3. The planned care is documented in the record in the form of measurable progress (goals)	**1.0**	**1.0**
4. The anticipated progress (goals) is updated or revised, as appropriate, based on the reassessment of the patient by the health care practitioners	**1.0**	**1.0**
5. The care planned for each patient is reviewed and verified by the responsible physician with a notation in the progress notes	**1.0**	**1.0**
6. The care provided for each patient is written in the patient's record by the health professional providing the care	**1.0**	**1.0**
7. Procedures performed are written into the patient's record	**1.0**	**1.0**
8. The results of procedures performed are written into the patient's record	**1.0**	**1.0**
Total score	**10.0**	**10.0**

Strengths. Care for each patient is planned by the treating physician along with the head of the department. In specific cases briefings (*see more in Care of Patients section, 5.2*) can be organized to plan patient care. The TB treatment regimen is planned within several days of hospitalization, as soon as the smear and culture tests results become available (up to 6 weeks), which complies with the TB-related requirement of initiating the treatment. Medical record review confirmed that patient care is planned only after the analysis results are available as the diagnoses and treatment plans dated later than the analysis results' release dates.

For TB treatment, measurable goals are not specified and documented for each patient separately, since, in general, TB treatment has unique goals to be achieved (TB treatment positive outcomes); cured, treatment completed or treatment success. The treatment regimens are modified or extended by the treating physicians based on the reassessment findings and are documented in the medical records.

All medical records reviewed contained the concurrent history of care the patients have received, with daily notes capturing the treatment progresses and/or drawbacks as well as the list of all procedures that have been performed along with the findings, laboratory test results and summaries of radiology and diagnostic imaging studies' findings. All entries in the medical records were made by the physicians responsible for the patient care and were annotated with their signatures.

Weaknesses. Not identified.
Opportunities. Not identified.
Threats. Not identified.

5.4 Those permitted to write patient orders write the order in the patient record in a uniform location

Writing orders for services as laboratory testing, administration of medication and etc. is closely related to daily care provision to patients. The organization should decide how and which orders should be documented and where.

Measurable elements	Max. score	Obtained score
1. Orders are written when required and follow organization policy	**2.5**	**1.5**
2. Diagnostic imaging and clinical laboratory test orders include a clinical indication/rationale when required for interpretation	**2.5**	**2.0**
3. Only those permitted to write order do so	**2.5**	**2.5**
4. Orders are found in a uniform location in patient records	**2.5**	**2.5**
Total score	**10.0**	**8.5**

Strengths. The orders are written whenever a certain service is required for the patient to be provided. The hospital has developed and put into a use specific referral forms for laboratory,

diagnostic imaging studies in which the orders for particular tests are written. Only treating physicians write the orders and attach them into uniform location of the medical record.

Weaknesses. The hospital does not have an internal policy defining conditions for writing the orders. Diagnostic imaging and clinical laboratory test orders do not include a clinical indication/rationale, but given the mono-specialty of the hospital, this does not pose high risk for misinterpretation as far as the scopes of sputum reassessments and diagnostic imaging studies are evident and are uniform throughout the hospital. The hospital does not formally specify the mode of placing the order: verbal or written; does not specify individuals who are permitted or prohibited to make orders for services, and does not define the location in patient records where the orders should be placed.

Opportunities. To formalize the procedure of placing the orders the hospital should develop a policy that will define the acceptable mode of placing the order for each of the tests conducted in the hospital, indicate for which tests the rationale should be written along with the order, define the conditions for permitting specific healthcare providers to make orders and indicate the location in the medical record or elsewhere, where the orders should be kept.

Threats. Not identified.

5.5 Policies and procedures guide the care of high-risk patients and the provision of high-risk services

The hospital should have policies and procedures defining how care should be organized for patients with communicable disease and immune-suppressed patients; patients on dialysis; frail, dependent and elderly patients; young, dependent children and patients receiving chemotherapy.

Measurable elements	Max. score	Obtained score
1. The care of immune-suppressed patients is guided by appropriate policies and procedures	**2.0**	**1.5**
2. The care of patients on dialysis is guided by appropriate policies and procedures	**2.0**	**1.5**
3. The care of frail, dependent elderly patients is guided by appropriate policies and procedures	**2.0**	**1.5**

4. The care of young, dependent children is guided by appropriate policies and procedures	**2.0**	**2.0**
5. The care of patients receiving chemotherapy or other high-risk medications is guided by appropriate policies and procedures	**2.0**	**1.5**
Total score	**10.0**	**8.0**

Strengths. The National Standard for TB diagnosis and treatment enumerates the list of high-risk patient groups for provision of high-risk services. The hospital organizes care of patients with high-risk conditions listed in the National Standard including immune-suppressed patients, patients on dialysis, frail, dependent elderly patients and other patients not included in the list of the National Standard, who need high-risk procedures. The hospital has a separate department for children, where care of young, dependent children is managed and guided by the departmental regulation.

Weaknesses. The hospital provides high-risk services to TB patients without having a certain list of conditions requiring those services.

Opportunities. Development of internal policies describing the high-risk groups needing high-risk services and organization of care for them will formalize this aspect of anti-tuberculosis treatment provision and will assure protection of high-risk patients.

Threats. Not identified.

5.6 A variety of food choices, appropriate for the patient's nutritional status and consistent with his or her clinical care, is regularly available. Food preparation, handling, storage, and distribution are safe and comply with laws, regulations, and current acceptable practices

The food should be regularly available for the patients. Food preparation, handling, storage and distribution should be organized as such the risk of contamination, and spoilage is minimized and it is safe and complaint to the laws and regulations. Food distribution should be timely.

Measurable elements	Max. score	Obtained score
1. Food or nutrition for the patients is regularly available	**3.0**	**3.0**
2. Food is prepared in a manner that reduces risk of contamination and spoilage	**3.0**	**0.5**

3. The distribution of food is timely	**2.0**	**2.0**
4. Practices meet applicable laws, regulations, and acceptable practices.	**2.0**	**0**
Total score	**10.0**	**5.5**

Strengths. Food is regularly provided to the patients, according to an internally decided schedule. All patients of the hospital receive food three times a day. Psychiatry TB department' patients, receive food four times a day, per medical indication. The hospital has developed a schedule for distributing food to all departments in timely manner and the kitchen adheres to that schedule.

Weaknesses. During the observation of kitchen area the research team found that during preparation, handling, and distribution, the food was at risk of contamination. The environmental conditions and kitchen utensils need renovation. During observation the research team noticed insects in the area where food was prepared and distributed.

Opportunities. The kitchen has to be completely renovated to meet the applicable standards and regulations. The hospital's administration has plans to close the kitchen area and contract an external food service provider.

Threats. Financial constraints may limit the capacities of renovating the kitchen area. Food prepared in inappropriate sanitary conditions can get contaminated and result in health complications both among staff and patients.

6. Medication Management and Use (MMU)

Throughout the TB treatment course the medication management and use is one of the most essential stages that encompasses systemic and organizational processes to assure patients with anti-tuberculosis treatment. Medication management and use is concerned with the organization and management, selection and procurement, storage, ordering, distribution of medication and administration and monitoring of medication therapies.

6.1 Medication use in the organization complies with applicable laws and regulations and is organized to meet patient needs

Effective and efficient management of medication is essential for the patient care and should be organized jointly with the pharmaceutical specialists, the healthcare providers and the managerial staff. Medication management evaluation should consider the processes of medications selection and procurement, storage, ordering and transcribing, administration and monitoring, including errors and near misses, identification of any educational needs and consideration of new evidence-based practices. The medication management and use and all organizational processes associated with it should be guided by relevant laws and regulations.

Measurable elements	Max. score	Obtained score
1. There is a plan or policy or other document that identifies how medication use is organized and managed throughout the organization	**2.5**	**0**
2. All settings, services, and individuals who manage medication processes are included in the organizational structure	**2.5**	**2.5**
3. Policies guide all phases of medication management and medication use in the organization	**2.5**	**0**
4. There is at least one documented review of the medication management system within the previous 12 months	**2.5**	**0**
Total score	**10.0**	**2.5**

Strengths. The hospital has a separate department "Medication planning and management" for carrying out activities related to the medication management and use. All pharmacists, physicians and nurses who are involved in the medication management and use processes are included in the staffing plan of the hospital.

Weaknesses. The hospital has failed to develop any plan or policy that will guide the process of medication management and use within the hospital. The phases of medication management and medication use are not defined for the hospital. The research team could not identify any document describing the review of the medication management processes conducted ever. In fact, the hospital does not conduct a formal review of the medication management processes.

Opportunities. A plan or policy for the medication planning and management department guiding the medication management and medication use processes will formalize the activities carried out in the department. The plan or policy should identify all phases of the medication

management and use process, which will shape the duties of the department. The plan or policy should outline how and when the review of the medication management system should be organized.

Threats. Development of policies will not cause a threat, as it will merely summarize the activities that are routinely conducted in the department, however implementation of review of the medication management system may cause reluctance as staff might be dissatisfied with a new surveilling body.

6.2 Supervision of the pharmacy or pharmaceutical service. There is a method for overseeing the organization's medication use

Medication management is organized and supervised by the licensed, certified and trained pharmacist. This specialist is the one responsible for immediate supervision of selection and procurement, storage, ordering and transcribing of medication and close participation in medication administration, and monitoring processes. The organization should implement processes to monitor medication use throughout the organization and protect medication from loss or theft from the places were the medication is stored or dispensed.

Measurable elements	Max. score	Obtained score
1. An appropriately licensed, certified, and trained individual supervises all activities	**2.5**	**2.5**
2. The individual provides supervision for medication management	**2.5**	**2.5**
3. There is a method for overseeing medication use in the organization	**2.5**	**2.5**
4. Medications are protected from loss or theft throughout the organization	**2.5**	**2.5**
Total score	**10.0**	**10.0**

Strengths. The individual who supervises the medication management system activities has appropriate license, certification and training. Activities associated with the department oversight of medication use include identification of departments' medication needs, monitoring of expiration dates and stocks of medications, ordering the necessary amounts of medications, maintenance of the medication buffer stock for the departments and the hospital, distribution of medication to different departments, organization of an extra provision of medications and etc. IDIs and the observation showed that throughout the hospital medications are protected from loss or theft.

In the hospital medications' storehouse of controlled medications is protected with alarm system, with internal and external bars. The entrance is protected with double doors that are always locked. The storehouse is opened only for staff and only if some medication is needed to be taken out of there.

Administration

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

6.3 The organization can readily obtain medications not stocked or normally available to the organization or for times when the pharmacy is closed

The hospital should implement processes to address the shortages of medications normally available or medications that are not stocked in the hospital. The hospital should ensure availability of medication when the pharmacy is closed or when the medication supply is stopped.

Measurable elements	Max. score	Obtained score
1. There is a process to approve and to procure required medications not stocked or normally available to the organization	**4.0**	**2.0**
2. There is a process to obtain medications at times the pharmacy is closed or medication supply is locked	**4.0**	**4.0**
3. Staff understand the processes	**2.0**	**2.0**
Total score	**10.0**	**8.0**

Strengths. The medical planning and management department, aside from the general procurement, has a process of an "urgent tender" to immediately procure medications that are not available in the hospital. The hospital pharmacy (guided by the medication planning and management department) distributes the weekly stock of necessary medications to the departments accounted for the number of patients and the treatment regimens and keeps the 20% buffer stock there. If extra amount of medications is needed, the specific department in collaboration with the medication planning and management department procures the necessary amounts from the stock house of the hospital.

The processes of obtaining not stocked medications or distributing medications to the departments are conducted collaboratively with all staff of the medication planning and

management department and healthcare professionals of departments, and all the staff understand these processes.

Weaknesses. Along with the established regulatory mechanisms of medication purchase and distribution, some IDI participants stressed an alternative method practicing in the hospital for obtaining medication or supply by bypassing the tendering process and violating the law. One of the key informants reported that sometimes the department is forced to buy the supply without a tender, because the order they put in the previous tender rejected due to, high prices or other reasons.

> *Just recently the X-ray reagents have been rejected in the last tender, so I was urged to bypass the tender and just buy the reagents we needed. It is a violation but the hospital cannot operate without performing X-ray - the major diagnostic procedure. And it is not our fault that the reagents have not been purchased during the last tender.*
>
> **Administration**

The department staff feel uncomfortable in procuring supplies through the process of bypassing the tender and violating the law.

Opportunities. The hospital leadership should develop a more reliable mechanism of obtaining not stocked supplies, particularly when an urgent order is being rejected during the tender. It will ensure operation in the frames of law.

Threats. Not identified.

6.4 Medications are properly and safely stored

Medication should be stored appropriately for maintaining the product stability, considering the applicable laws and regulations. The medication storage areas, including the storehouses, procedure rooms within the departments and the pharmacies are regularly inspected as defined in the hospital policies. Furthermore, the policies should define the conditions of bringing medications to the hospital by patients themselves.

Measurable elements	Max. score	Obtained score
1. Medications are stored under conditions suitable for product stability	**2.5**	**2.0**

2. Controlled substances are accurately accounted for according to applicable laws and regulations	**2.5**	**2.5**
3. All medication storage areas are periodically inspected according to hospital policy to ensure medications are stored properly	**2.5**	**2.0**
4. Organization policy defines how medications brought in by the patient are identified and stored	**2.5**	**0**
Total score	**10.0**	**6.5**

Strengths. The assessment showed that the hospital storehouse complied with the WHO standards of TB medication management: temperature was maintained as suggested by the standard within 15-25^{0}C. The storehouse had acceptable sanitary conditions. Medications were kept in closed shelves avoiding the direct sunlight and were organized so that the expiration dates and the medication names were easy to read. The shelves were arranged one meter apart from each other. The storehouse had an air conditioner, ventilator and a window that can be opened to assure appropriate ventilation. The medications needing lower temperatures were kept in the refrigerator. The containers of medicines were not stacked one on top of another, and the boxes were not stored on the floor of the storehouse.

Controlled substances are managed immediately by the head pharmacist of the hospital in collaboration with the respective instances, according to the national laws and regulations. Within the hospital a special committee is formed to monitor the management of controlled substances to which the head pharmacist is accountant.

Weaknesses. At the time of the assessment the moisture of the storehouse was out of control due to the absence of functional hygrometer. The level of humidity in the rooms was evaluated subjectively by the staff according to presence or absence of molds on the walls.

Inspection of the medication storage areas in the hospital is organized merely by the head pharmacist's personal initiative and is not guided by the policies of the hospital. Even though in the practice it is prohibited to bring in any type of medications to the hospital, the hospital has failed to develop a policy that will state the respective permissions and/or limitations.

Opportunities. The hospital should ensure that all conditions required for maintaining the product stability are respected and are regularly checked. A policy should guide the process of inspecting the storehouses for medications proper storage. The hospital should clearly define conditions when patients can bring medications. This written information can be provided to patients when obtaining consents for the treatment.

Threats. Not identified.

6.5 Emergency medications are available, monitored and safe when stored out of pharmacy

The hospital should ensure accessibility and availability of emergency medications in locations when they will be needed.

Measurable elements	Max. score	Obtained score
1. Emergency medications are available in the units they will be needed or readily accessible within the organization to meet emergency needs	**5.0**	**5.0**
2. Organization policy defines how emergency medications are stored, maintained, and protected from loss or theft	**5.0**	**0**
Total score	**10.0**	**5.0**

Strengths. The emergency medications are available in the procedural rooms of the hospital and readily accessible as those rooms are located in all departments and are adjacent to the patient care areas.

Weaknesses. The hospital does not have a policy describing how emergency medications should be stored, maintained and protected from loss or theft.

Opportunities. The hospital should develop a policy guiding the process of management of emergency medications thus to formalize these processes.

Threats. Not identified.

6.6 The organization has a medication recall system

The hospital should have developed processes to implement identification, retrieval, return and destroy of medication that have been recalled by the manufacturer or supplier. These processes should be guided by the hospital policies.

Measurable elements	Max. score	Obtained score
1. There is a medication recall system in place	**2.5**	**2.5**
2. Policies and procedures address any use of medications known to be expired or outdated	**2.5**	**1.5**
3. Policies and procedures address the destruction of medications known to be expired or outdated	**2.5**	**1.5**
4. Policies and procedures regarding medication recall system are implemented	**2.5**	**1.5**
Total score	**10.0**	**7.0**

Strengths. During the IDI the participant described that expired or outdated medications are written-off the hospital through the written-off certificate and are stocked in a separate location for later to organize the destruction of medications. The destruction of medication is done by a contract organization.

Weaknesses. The hospital does not have policies regarding how the medications known to be expired or outdated should be used or destructed in the hospital. The medication recall related processes are conducted through internal agreements rather than being guided by respective documentation.

Opportunities. Relevant policies should be developed to formalize the existing procedures related to the medication recall process.

Threats. The medication recall processes should be implemented in a standardized and formalized fashion, otherwise not properly managed expired or outdated medications can cause medication errors.

6.7 Prescribing, ordering, and transcribing are guided by policies and procedures

The hospital should develop policies and respective procedures to support safe medication prescription, ordering and transcription. Furthermore, the policies should address measures against illegible prescriptions. All medications prescribed to the patient should be listed in the patient medical record and be available to health professionals responsible for patient care.

Measurable elements	Max. score	Obtained score
1. Policies and procedures guide the safe prescribing, ordering, and transcribing of medications in the organization	**3.3**	**2.0**
2. Policies and procedures address actions related to illegible prescriptions and orders	**3.3**	**0**
3. Patient records contain a list of current medications taken prior to admission, and this information is made available to the pharmacy and the patient's health care practitioners	**3.4**	**1.0**
Total score	**10.0**	**3.0**

Strengths. The uniformity of procedures that are routinely implemented throughout the hospital support safe prescribing, ordering and transcribing of medications. Prescription of medications to be administered in scopes of the treatment regimen is organized by the treating physicians along with the heads of the departments. The prescribed medications are verified by senior healthcare providers such as clinical head of the hospital and other experienced physicians. In most of the cases, during the whole inpatient treatment one treatment regimen with a specific list of medications to be administered are prescribed, ordered and transcribed into medical records. For each of the patient the orders are made mainly in the scope of the treatment regimen and only symptomatic treatment medications can be added in the process of treatment. Given the narrowness of the list of medications that can be prescribed to the TB patients the safe transcribing is also itself guaranteed. The nature of inpatient treatment minimizes the medication errors and ensure the safe medication administration.

Weaknesses. The hospital neither has policies guiding the safe prescribing, ordering, and transcribing of medications nor document guiding those processes. No policies and procedures are developed targeting illegible prescriptions or orders. In addition, only half of the reviewed medical records contained information of medications taken prior to the admission to the hospital.

Opportunities. The hospital should develop policies on safe prescribing, ordering, and transcribing of medications, on illegible prescriptions and orders. The process of writing up the list of medications taken prior to the admission should be formalized through development of a relevant policy.

Threats. Not identified.

6.8 Medications prescribed and administered are written in the patient's record

Patients' medical records include all medications that have been prescribed and records on each dose administered. In case if daily administration of medication is documented in a different form, then it should be inserted in the medical records.

Measurable elements	Max. score	Obtained score
1. Medications prescribed or ordered are recorded for each patient	**3.3**	**3.3**
2. Medication administration is recorded for each dose	**3.3**	**3.3**
3. Medication information is kept in the patient's record or inserted into his or her record at discharge or transfer	**3.4**	**2.0**
Total score	**10.0**	**8.6**

Strengths. All medical records reviewed contained the lists of prescribed anti-TB medications along with other medications for symptomatic treatment. The TB treatment cards (TB-01 form) is designed to include information on daily administration of each dose of DS-TB patients. For DR-TB patient's daily dose administration is recorded in TB treatment files. All TB treatment cards and treatment files reviewed have been fully filled in, thus each dose of medications administered is recorded.

Weaknesses. Not all reviewed discharge/transfer summaries contained information on medications administered during the hospitalization.

Opportunities. Hospital leadership should enforce transcribing medications administered also into discharges/transfers summaries.

Threats. Not identified.

6.9 A system is used to dispense medications in the right dose to the right patient at the right time and in a safe and clean environment

To minimize errors during distribution and administration, the medication should be given to patients in the most ready-to-administer forms. Medication dispensing should be accurate, timely and consistent throughout the different settings and should be organized in a clean and safe area.

Measurable elements	Max. score	Obtained score
1. There is a uniform medication dispensing and distribution system in the organization	**2.0**	**2.0**
2. Medications are dispensed in the most ready-to-administer form	**2.0**	**2.0**
3. The system supports accurate dispensing	**2.0**	**2.0**
4. The system supports timely dispensing	**2.0**	**2.0**
5. Medications are dispensed in clean and safe areas with appropriate equipment and supplies	**2.0**	**1.0**
Total score	**10.0**	**9.0**

Strengths. In all departments medications are distributed in a uniform manner: the head nurses distribute the medications into named kits before bringing the medications into the procedure rooms. In the procedure rooms the nurses invite patients by calling patients' names and provide personal kits containing the prescribed medications in the most ready-to-administer forms. The kits in which the medications are dispensed vary from department to department (plastic cups, pockets), while the system of medication distribution as a whole is uniform. Bedridden patients and children who cannot come to the procedure rooms on their own are provided with daily doses at beds. Observation of medication dispensing showed that the processes are organized in a way to support accurate and timely dispensing. In the procedural rooms of the recently renovated departments (DS-TB, DR-TB, and Children TB) medications are dispensed in a clean and safe environment.

Weaknesses. The procedural rooms of the departments that have not been renovated since the building construction (Extra-pulmonary TB, Psychiatric TB) have very poor conditions. In these departments proper cleaning and safety for medications distribution is impossible to respect.

Opportunities. The inappropriate procedural rooms along with the respective departments should be renovated to maintain required environmental conditions, be clean and safe for medication dispensing.

Threats. Financial constraints might threaten an implementation of the standard.

6.10 The organization identifies those qualified individuals permitted to administer medications

Individuals who are authorized to administer medications should be identified by job descriptions. Otherwise the hospital should place limits on medication administration and monitor that only the ones who are authorized administer medication to patients.

Measurable elements	Max. score	Obtained score
1. The organization identifies those individuals, by job description or the privileging process, authorized to administer medications	**3.4**	**3.4**
2. Only those permitted by the organization and by relevant licensure, laws and regulations administer medications	**3.3**	**3.3**
3. There is a process to place limits, when appropriate, on the medication administration of individuals	**3.3**	**0**
Total score	**10.0**	**6.7**

Strengths. Through the departmental regulations, the responsibilities associated with the medication administration are formally assigned to the department nurses. The procedural nurses and the nurses on shifts are responsible for administering medications to patients as according to the physicians' prescriptions, and the senior nurses of departments are responsible for organization of medication administration process. Given that the departmental regulations define the minimum necessary qualifications for the senior nurse, the procedural nurse and the nurse on shifts, the licensure, laws and regulations for medication administration are defined respectively.

Weaknesses. Despite clear assignment of responsibilities of medication administration to nurses, the hospital has failed to state the limits on individuals, who should not administer medications.

Opportunities. The hospital should identify those situations when individuals should not administer medications to patients, thus to advance the safety of medication administration to a higher level.

Threats. Not identified.

6.11 Medication administration includes a process to verify the medication is correct based on the medication order

Safe medication use is achieved when medication administration, the dosage, routes of administration are verified with prescription. Furthermore, medication administration should be timely and the medical records should contain notes on administered doses.

Measurable elements	Max. score	Obtained score
1. Medications are verified with the prescription or order	**2.0**	**2.0**
2. The dosage amount of the medication is verified with the prescription or order	**2.0**	**2.0**
3. The route of administration is verified with the prescription or order	**2.0**	**2.0**
4. Medications are administered on a timely basis	**2.0**	**2.0**
5. Medications are administered as prescribed and noted in the patient's record	**2.0**	**2.0**
Total score	**10.0**	**10.0**

Strengths. The nurses are informally responsible for verification of medications before the administration. While distributing medications into the named patients' kits the head nurses verify the name, the dosage of medication and the route of administration with the physicians' prescriptions. Throughout the hospital the anti-TB medications are distributed at the same daytime, 10AM. For each dose administered marks in the TB-01 form and the treatment files are made.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

6.12 Medication effects on patients are monitored

Considering the minimum duration of the hospitalization for TB treatment, it is especially essential to monitor the effects of medications. The blood count, liver functions, renal functions, the medications' effect on patients' symptoms as well as the adverse reactions should be closely monitored. If necessary, theses parameters should be used to adjust the treatment regimen. Documentation of observed effects is an integral part of monitoring, and the policies should guide how recording and reporting of observed medication effects should be organized.

Measurable elements	Max. score	Obtained score
1. Medication effects on patients are monitored, including adverse effects	**2.5**	**1.2**
2. The monitoring process is collaborative	**2.5**	**2.5**
3. The organization has a policy that identifies those adverse effects that are to be recorded in the patient's record and those that must be reported to the organization	**2.5**	**0**
4. Adverse effects are documented in the patient's record as required by policy	**2.5**	**1.0**
Total score	**10.0**	**4.7**

Strengths. In the hospital medication effects, including the adverse effects are monitored routinely in collaboration with the Scientific Center of Drug and Medical Technology Expertise. Physicians, nurses and laboratory services work collaboratively to monitor the medication effects; medical records include reassessment findings that are done to monitor the organs' functions.

When modifying the treatment plan we are guided by the patients' health conditions and also adverse reactions. If the patient has adverse effects, we terminate the treatment for a while.
Healthcare provider 1

Ones in a month we check the aspartate amino transferase/ alanine amino transferase, and if needed, we prescribe hepatoprotective medications.
Healthcare provider 2

We track the adverse effects in collaboration with the scientific center of drug and medical technology expertise. They provide checklists and we distribute them to physicians. But we don't have a database to enter the information on adverse effects and to use it later on.
Administration

Besides, all the patients' treatment files in the DR-TB department contain a special form to track the adverse effects of anti-TB medications.

Weaknesses. The National Standard does not include activities targeted to monitor the adverse effects, and the hospital has failed to develop a policy regarding how the information related to adverse effects is to be documented and reported. The collection of data on adverse effects is currently organized by one of the pharmacists of the hospital through his/her own initiative. Only 12% of all medical records reviewed by the research team contained information about the adverse effects occurred during inpatient treatment. Though the DR-TB patients' treatment files contain special form for tracking the adverse effects of anti-TB medications, those forms were not completed in a consistent manner.

Opportunities. Given the duration of TB treatment and toxicity of anti-TB medications, especially second line drugs for MDR treatment it should be a priority for the hospital to monitor the medications effects, including the adverse effects. The hospital should develop policies describing the adverse effects that should be documented and reported. Also, the hospital may collect and use the data on adverse effects of medications for internal purposes such as analyzing the data and integrating them into researches of the hospital. Having developed form for tracking adverse effects of anti-TB medication in the DR-TB department may serve a basis to transfer this experience to all the other clinical units.

Threats. Not identified.

6.13 Medication errors, including near missed, are reported through a process and time frame defined by the organization

The hospital should develop its own definitions of medication errors and near misses and thus establish a system of recording and reporting of medication errors and near misses that occur. The definitions should be developed jointly by all specialists involved in the medication management process. This system should be accountant to quality and patient safety program (which is yet to be developed) and to individuals powerful enough to take actions in response to the system reports. The main focus of this monitoring system should be prevention of medication errors and near misses, thus education and trainings should be provided to staff members for preventive purposes.

Measurable elements	Max. score	Obtained score
1. A medication error and near miss are defined through a collaborative process	**2.5**	**0**

2. Medication errors and near misses are reported in a timely manner using an established process	**2.5**	**0**
3. Those accountable for taking action on the reports are identified	**2.5**	**0**
4. The 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. Neither the hospital has developed definitions of medication errors and near misses, nor does it have processes in response to the occurred errors. That is to say, the medication errors and near misses are not defined, reported in the hospital and not data are used to improve the medication use processes.

Opportunities. The hospital should introduce a system which will take actions to monitor the medication errors and near misses, including recording and reporting. This system should include all settings of the hospital and share the common understanding of importance of acknowledging the medication errors and near misses for improving the overall medication use processes.

Threats. The medication use process will not be improved, unless the whole hospital staff perceive the importance of acknowledging the medication errors and near misses, recording and reporting them.

7. Patient and Family Education (PFE)

In long term therapies patient and family education is essential to improving adherence to treatment, and thus to achieving better outcomes. Patient and family education should normally start from the educational needs assessment and later be routinely conducted whenever patient and family interact with physicians and nurses. Education provided should be considerate of learning preferences, beliefs, cultural values, reading and learning skills. Education should aim to explain and support treatment process and guide in making health related decisions.

7.1 The organization provides education that supports patient and family participation in care decision and care processes

The hospital should have a developed education plan that corresponds to hospital mission, provided services and targeted population. In the hospital a uniform structure should be established, according to which the education is to be provided in all settings. The hospital leadership is responsible to take actions to assure effective provision of educational services by appointing an education coordinator or education committee that will train the staff members to educate patients in an organized fashion.

Measurable elements	Max. score	Obtained score
1. The organization plans education consistent with its mission, services, and patient population	**3.4**	**0**
2. There is an established structure or mechanism for education throughout the organization	**3.3**	**0**
3. The education structure and resources are organized in an effective manner	**3.3**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. The hospital does not have an established education plan taught to patients and family members. In some settings the education provision is more patient driven instead of being initiated by the healthcare providers. During the IDIs with healthcare providers a controversial attitude regarding the education provision was found. According to one of the healthcare providers, education should be provided in the primary settings rather in the hospital. In contrast to this, some healthcare professionals stressed that provision of education is the hospital's immediate responsibility and having education materials would be a plus for the healthcare providers and patients.

Some of the healthcare providers considered that mere notification about disease is enough for patients to make knowledgeable decisions regarding care. During the IDIs the healthcare providers tended to justify their inaction by the low education level of population and putting the guilt away from themselves.

In the hospital the educational activities with patients should not be done. Whenever the patient ask questions, we answer. We don't put people in a line in the corridor and read lectures to them. People are different. If one is adequate and not stupid we explain to him/her

and family that before sputum conversion they should try not to kiss each other. Much depends on educational level of patients… I don't really know if it is my responsibility or not [to educate patients], *but how can I tell nothing* [about the disease] *to my long term patient?!*

Healthcare provider 1

Patient's education starts in the hospital admission. We notify the patient what is going to happen with him/her in the hospital, while trying to make the patient feel positively about the treatment.

Healthcare provider 2

We don't have a specific education program. We just notify about the disease. Sometimes, the educational materials need to be provided to patients [the hospital does not have education materials for patients].

Healthcare provider 3

We are not supposed to educate family. We may just talk to them if needed, but education is not included in our responsibilities.

Healthcare provider 1

Opportunities. The hospital should develop an educational program consistent with its mission, services, and patient population. The program should have a specific structure and should be consistently throughout the organization. The hospital leadership should allocate adequate resources to have the education program organized effectively. Well counseled patients might better adhere to TB treatment, resulting in decreased rates of lost to follow-up after intensive phase of TB treatment.

Threats. Healthcare providers might be reluctant to having new responsibilities added to their work. However, if having the program organized effectively the time constraints might not hinder implementation of the education program.

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

Prior to educating patients and family about TB healthcare providers should firstly identify educational needs of patients and family thus to make sure that the education program that is provided on the level that best fits the patient's and family's educational capacities. The knowledge gained through the program should assist patients and family in making health related decisions and support the treatment. Identified education needs should be documented in the medical records in a uniform location, and be accessible to different health care professionals thus to foster collaboration between health care specialists in continuous provision of education to patients.

Measurable elements	Max. score	Obtained score
1. The educational needs of the patient and family are assessed	**3.4**	**0**
2. Educational needs assessment findings are recorded in the patient's record	**3.3**	**0**
3. There is uniform recording of patient education by all staff	**3.3**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. Healthcare providers around the hospital do not assess the patients and families' education needs.

> *We don't have a tool for educational needs assessment. Everything is based on oral communication. We talk to them, explain and they understand whatever we tell.*
>
> **Healthcare provider**

Opportunities. In scopes of the education program that is yet to be introduced, the hospital should implement education needs assessment and document the findings. This will help to personalize the education to the level of patient's and family's educational capacities and to achieve better outcomes in learning.

Threats. Implementation of needs assessments will add new work for the healthcare providers, and this can trigger their reluctance in performing it.

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

To make the education program more targeted the program should be considerate of patients' and family's ability and willingness to learn. This is determined by the factors such as beliefs and values, educational level and language, emotional barriers and motivations, physical and cognitive limitations, and willingness to receive information. The assessment findings should be documented in the medical records.

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	**3.4**	**0**

• Physical and cognitive limitations • The patient's willingness to receive information		
2. The assessment findings are used to plan the education	**3.3**	**0**
3. The assessment findings are documented in the patient's record	**3.3**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. The healthcare providers do not assess patients and family on the matter of beliefs, values, literacy, educational level, language, emotional barriers, motivations, physical and cognitive limitations and willingness to receive information.

Opportunities. Along with the education needs assessment, the assessment of patients' and family's ability and willingness to learn should be performed. These information should be used while planning the education program.

Threats. Implementation of these assessments will add new work for the healthcare providers, and this can trigger their reluctance in performing it.

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 and food, nutritional guidance, pain management. Patients and families receive adequate information about the illness, proposed treatment(s), and health care practitioners so that they can make care decisions.

Topics related to patient care should be necessarily taught in the frames of the education program. The education program should include:

- 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
- about proper diet and nutrition
- pain management
- TB-related topics

Measurable elements	Max. score	Obtained score
1. Patients are informed of these points, as relevant to their condition and planned treatment	**2.0**	**2.0**

• 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. Patients know the identities of the physicians or other practitioners responsible for their care	**1.0**	**1.0**
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	**2.0**	**1.0**
4. As related to the care provided, patients and families are educated about proper diet and nutrition	**1.0**	**0.5**
5. 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, DOTs, importance of regular medical assessment, importance of contact investigation	**4.0**	**2.0**
Total score	**10.0**	**6.5**

Strengths. In spite of the fact that during IDIs patients and family members could not specifically list what information was provided to them about the disease and the proposed care during inpatient treatment, they seemed to be satisfied with whatever they have been informed of. Probably because when inquired the healthcare providers necessarily and exhaustively answer to the patients' questions. During the interviews patients avoided indicating the names of their treating clinicians, but it was clear to the interviewers that all patients knew the identities of health providers responsible for their care.

I was told, that disease is curable and I should not be afraid of it [disease]. *I was concerned about my condition and was crying a lot. If something was not clear, I was asking and clarifying from the physicians. I was told that if I take the medications, do not interrupt the treatment, eat good enough, disease will leave. But if not, I won't heal. They also told that 80% of treatment success depends on me. I was also told that if I won't take medication as prescribed and when feeling better would stop taking them, the disease will become untreatable.*

Patient/Family member 1

Healthcare providers have told about TB transmission routes. They answered to all my questions. We talked about TB symptoms, the HIV test, and contact persons screening. My physician told about the importance of drug administration and also mentioned the adverse effects of some medications.

Patient/Family member 2

Weaknesses. Given the absence of formal and structured education program, the content of education provided to patients varies per healthcare providers and across the hospital. The existing education is more patient-driven and is not initiated by the healthcare providers.

There is no specific list of topics to educate patients. It depends on the patients' needs.

Healthcare provider 1

If they [patients and families] *ask, we respond, but not the opposite.*

Healthcare provider 2

Opportunities. All topics listed in the table should be included in the education program and necessarily taught to patients and families. Healthcare providers throughout the hospital should be trained to uniformly educate patients and families.

Threats. Implementation of the structured education program might be time consuming for the healthcare providers and they might refuse to conduct it properly.

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

To ensure better comprehension of education received, the educators should implement various techniques such as verification of whether patients and families understood the topics covered, encouragement of patients and families to be active and ask questions and also provision of written materials.

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**	**0**
2. Those who provide education encourage patients and their families to ask questions and to speak up as active participants	**3.3**	**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**	**0**

Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. The healthcare providers did not indicate any means they use to verify that patients and families received and understood the information provided. Rather physicians assess the level of percept during the next conversations.

> *We do not assess. Our patients stay here for a long period. We notify them and later during the conversations it becomes clear whether or not they have understood us.*
>
> **Healthcare provider**

Different physicians have reported that they do not specifically encourage patients to be active and ask questions. In general, physicians are more inclined to answer questions than to initiate discussions. The hospital does not provide written materials to patients and families to support the information they receive.

> *We don't provide educational materials. The education is merely based on oral communications…*
>
> **Healthcare provider**

Opportunities. The healthcare providers should be notified to necessarily verify if patients and families have understood the provided information. They should encourage patients and families to actively participate in the education program. During the IDIs, healthcare providers pointed the importance of written materials in facilitating and promoting patients and their family members for better understanding.

> *Previously we used to have some materials for HIV-TB patients but now we don't have. The NTCC used to have booklets about TB and patients reading those were approaching us with specific questions. Working this way was much easier.*
>
> **Healthcare provider**

Threats. Financial constraints associated with continuously having written educational materials might result on increasing rates of patients, who drop out from the continuation phase of the TB treatment.

> *… there is a need to provide educational materials to patients. Family education is very important as you never know whether patients will be adherent to treatment after the discharge.*

Healthcare provider

7.6 Health professionals caring for the patient collaborate to provide education

The education should be provided collaboratively and the clinical staff should acknowledge the collaboration in order to make the program more effective. Those persons who provide education have to be knowledgeable of the content of the program and possess good commination skills to deliver it. The time allocated for the education program should be adequate to cover the entire program.

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**	**1.5**
4. Those who provide education have the communication skills to do so	**2.5**	**2.5**
Total score	**10.0**	**9.0**

Strengths. All physicians who have provided education to the interviewed patients and families were characterized as knowledgeable individuals with good communication skills. During the IDIs, the patients and family members reported that education is provided collaboratively with nurses and physicians.

Weaknesses. During the IDIs physicians complained on the scarcity of time for educating patients and families and all healthcare providers interviewed believed that providing detailed information to patients and families about the disease is irrational.

…We have 10-15 patients and one [healthcare provider] does not have enough time to educate all patients with all details. We are overloaded with paper work. Till 1AM we write up the medical records. We don't even have time to go for the clinical rounds... There are patients who ask very detailed questions. We cannot explain whole medicine to them. There is no need to talk about too detailed things, it is time consuming.
Healthcare provider

Opportunities. The education program should be structured in a way that healthcare providers will have adequate time to fully implement it.

Threats. Not identified.

8. TB-Tobacco Control (TBTC)

Studies show significant association between smoking habits and risk of development of pulmonary tuberculosis.[5,9] Smoking results in almost 2-fold increase in the risk of TB infection. It also affects the mortality from TB.[5] A case-control study conducted by Alcaide et al. showed a dose-response relationship between tobacco smoking and risk of developing active pulmonary TB based on the amount of cigarettes consumed per day.[9] These results suggest that anti-smoking campaigns may have a positive impact on the reduction of incidence of pulmonary TB infection.[9]

8.1 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
4. There are "No Smoking" signs visible from outside of the building and on the entrance door.	**2.0**	**0**
5. There are "No Smoking" signs in the entrance lobby of the building.	**2.0**	**1.5**
6. There is "No Smoking" sign inside the building.	**2.0**	**0.5**
7. There are warning signs of financial (and other) penalties.	**2.0**	**0**
8. In general, the existing "No Smoking" signs are clearly visible.	**2.0**	**1.5**
Total score	**10.0**	**3.5**

Strengths. There are "No Smoking" signs in the main entrance lobby of the hospital and in some places (near the entrance) inside the building. Those signs are visible.

Weaknesses. The "No Smoking" signs are absent from outside of the building, as well as from the entrance doors of the hospital. There are no warning signs on financial and other penalties either. The existing "No Smoking" signs inside the building are not evenly distributed throughout the hospital. In those areas where the patients' and visitors' flow is high, the "No Smoking" signs are non-existent.

Opportunities. To comply with the requirements of the national regulations, there is need to place appropriate "No Smoking" signs from outside of the building, on the entrance doors of the hospital, as well as in all those areas where smoking might be practiced.

Threats. Not identified.

8.2 Availability of smoking related functional items and policies in the areas where smoking is prohibited.

According to the WHO Framework Convention on Tobacco Control (FTCC), functional items related to tobacco smoking (such as ashtrays) should be eliminated in the healthcare organizations.

Measurable elements	Max. score	Obtained score
1. There are no ashtrays in the no-smoking-areas.	**2.0**	**0**
2. There are no cigarette vendors or vending machines inside the building	**1.0**	**1.0**
3. There are no ashtrays and lighters with tobacco logotypes in the hospital.	**1.0**	**1.0**
4. Policy and/or procedure guides elimination or limitation of smoking	**2.0**	**1.0**
5. Smoking limitation policy and/or procedure applies to patients	**1.0**	**1.0**
6. Smoking limitation policy and/or procedure applies to families	**1.0**	**1.0**
7. Smoking limitation policy and/or procedure applies to visitors	**1.0**	**1.0**
8. Smoking limitation policy and/or procedure applies to staff	**1.0**	**1.0**
Total score	**10.0**	**7.0**

Strengths. There are no cigarette vendors or vending machines and ashtrays and lighters containing tobacco logotypes inside the hospital building. Based on the national law of the RA on the limitation of tobacco distribution, consumption and use, the NTCC director has placed an order restricting smoking practices on the whole territory of the NTCC. This order applies to staff of the NTCC, patients, families and visitors.

Weaknesses. Despite the order and formal grounds restricting smoking practices, the NTCC failed to actually address the smoking practices, as several functional items indicative of

smoking practices have been observed in the NTCC. The research team noticed several cases when ashtrays were present in the hospital. Moreover, those ashtrays were used by the personnel of the hospital – both administrative and clinical.

Opportunities. The functional items related to smoking should be eliminated from the hospital. Implementation of developed policies should be more effectively enforced throughout the NTCC among staff members, patients, families, and visitors.

Threats. Removing ashtrays will not directly guarantee smoke free environment inside the hospital. Therefore targeted actions towards prohibiting smoking inside the hospital should be undertaken.

8.3 Presence of proofs related to tobacco-free environment

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 hospital, since those items might advertise and provoke smoking.

Measurable elements	Max. score	Obtained score
1. There is no tobacco smoke in no-smoking-areas.	**3.4**	**0**
2. There is no smoker in the vicinity area.	**3.3**	**0**
3. There are no tobacco leftovers in the no-smoking-areas in the building.	**3.3**	**0**
Total score	**10.0**	**0**

Strengths. Not identified

Weaknesses. During data collection the research team noticed smokers, tobacco leftovers and has been exposed to second-hand smoke for several times in different locations: in the physicians' rooms, in patient areas, in the corridors of the building. There were smokers in areas which were not clearly defined as smoking areas, such close to the different entrances of the building.

Opportunities. In order to succeed in the elimination of smoking in the hospital a responsible person/unit should undertake comprehensive actions; such as discouraging people to smoke, reporting violations, enforce financial and other penalties. The patients and visitors should be informed that the hospital is a smoke-free area, and thus any smoking not be practiced.

Threats. Lack of commitment as well as recognition of the problem is a potential threat.

9. Quality Improvement and Patient Safety (QPS)

The following section thoroughly describes quality improvement and patient safety. Quality improvement and patient safety seek to change the overall organizational culture and to demonstrate sustainable improvements. The approach described in this section involves leading and planning quality improvement and patient safety program, designing new clinical and managerial processes, measuring the effectiveness of those processes, analyzing the obtained data, as well as implementing and sustaining changes leading to improvement.

9.1 Those responsible for governing and managing the organization participate in planning and measuring a quality improvement and patient safety program

According to the standard, leadership and planning are key factors that play essential role in terms of quality improvement and patient safety initiatives. The governing body of the organization and clinical and managerial leaders are the ones responsible for planning and leadership. They are responsible to develop and maintain the organizations approach and commitment to quality improvement and patient safety. According to JCI the leadership of the organization should develop the quality and patient safety plan, and shape the overall quality culture of the organization. Being accountable for the quality and patient safety in the organization, the governing body not only approves the quality and patient safety plan, but also receives and acts on different reports regarding quality improvement and patient safety program.

Measurable elements	Max. score	Obtained score
1. The organization's leadership participates in developing the plan for the quality improvement and patient safety program	**2.5**	**0**
2. The organization's leadership participates in measuring the quality improvement and patient safety program.	**2.5**	**0**
3. The organization's leadership establishes the oversight process or mechanism for the organization's quality improvement and patient safety program.	**2.5**	**0.5**
4. The organization's leadership reports on the quality and patient safety program to governance.	**2.5**	**0**

Total score	**10**	**0.5**

Strengths. Though there is no formal quality improvement and patient safety program established in the NTCC, some related activities, however, are carried out by different other units. For example, there is Infection prevention and quality control department, which is doing infection prevention activities. There is also a group of clinicians (called commission), including heads of departments, and the head physician, who gather periodically to discuss various difficult cases related to TB diagnosis and treatment. The establishment of the commission was initiated by the leadership of the hospital. The functions of this commission resemble the oversight process for quality improvement and patient safety.

Weaknesses. Since there is no quality improvement and patient safety program in the organization, none of the listed above requirements represented by the measureable elements are met. Moreover, the understandings of quality and patient safety in NTCC are very narrow. The perception of quality is limited to just infection prevention. The inherited culture of the hospital 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 organization towards improvement and already existing non-systematic elements of quality improvement may serve as a ground to establish a quality improvement and patient safety system in the organization. The establishment of the quality improvement and 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 quality improvement program. It becomes more obvious while considering that there is no universal understanding and commitment to quality accepted all over there organization, at least by the majority of the staff. Another threat to develop and establish a quality improvement and patient

safety program is the lack of appropriately trained staff sharing a mutual vision towards quality and patient safety.

9.2 Quality improvement and patient safety information is communicated to staff.

Another important component of quality improvement program is the regular communication of information to the staff of the hospital. This communication should be done regularly using effective channels. According to the standard such channels are newsletters, storyboards, staff meetings, and human resource processes. The communicated information can represent different aspects of the quality improvement programs, such as recently completed improvements, progress in meeting the IPSGs, results of adverse events analysis, benchmarking data, etc.

Measurable elements	Max. score	Obtained score
1. Information on the quality improvement and patient safety program is communicated to staff.	**5.0**	**2.5**
2. The communications are on a regular basis through effective channels.	**5.0**	**2.5**
Total score	**10.0**	**5.0**

Strengths. Though there is no formal quality improvement and patient safety program at place, however, the information about the existing quality improvement activities are communicated to the staff. There is an internally accepted process of communication. It primarily involves the heads of the departments and the head nurse of the hospital. They are the ones, who participate in the meetings and are given the new information. Later on, they are supposed to share the information accordingly in their departments among the physicians and nurses. For example, if there is a new policy regarding the disposal of hazardous materials, or hand hygiene, the infection prevention department organizes a presentation of the new policy for the heads of the departments and the head nurse. Afterwards, it is expected that the new information will reach the frontline clinicians through the heads.

Weaknesses. The major limitation of the approach to communicate new information to the staff at NTCC is that there is no follow-up mechanism to ensure that the information has reached the clinicians, and that the new requirements/recommendations/ are correctly practiced in reality. The effectiveness of the communication channels is questionable. In some cases the frontline clinicians find this type of communication acceptable and effective, but there are cases, when the clinicians think that it enlarges the gap between managerial staff and the clinicians.

…We ourselves are not aware what is discussed in the reality. We do not participate in the meetings. Only the head of the department is in contact with the administration. They organize some meetings, and we are never participating. I have never been involved in any 5minutka [a short daily meeting about everyday activities with the head of the hospital]. *I am informed about new approaches from our head.*

Healthcare provider

Opportunities. Instead of an internal non-formal mechanism to share information about quality improvement initiatives, a more comprehensive approach can be adopted. The quality improvement program should contain separate section on how to communicate quality and patient safety related information to the staff. Having meetings or organizing trainings, which involve only the heads of the departments, is not enough. There is a separate administrative unit in the organization called as Information flow management unit. This unit could play an essential role in designing effective communication channels using new information technologies. For example, it would be easier to reach the whole staff to share with them updated policies, practice guidelines, different announcements, progress reports etc. via emails, than assigning this task to the heads of the departments. Another important aspect is whether the communicated information reached the target audience or not. For this reason a follow-up mechanism should be created.

Threats. Improvement of the effectiveness of communication channels requires modernization of the working style. The lack of appropriately trained staff to redesign communication channels is one of the potential threats.

9.3 The organization designs new and modified systems and processes according to quality improvement principles.

Quality improvement is a continuous process, which requires to design new processes and to redesign the old ones. It is recommended to use authoritative sources while dealing with designing and redesigning of the processes. Those sources include applicable laws and regulations, clinical practice guidelines, national standards and norms and other sources of information.

Measurable elements	Max. score	Obtained score
1. Quality improvement principles and tools are applied to the design of new or modified processes.	**3.4**	**0**
3. Measures are selected to evaluate how well the newly designed or redesigned process operates.	**3.3**	**0**

4. Measurement data are used to evaluate the ongoing operation of the process.	**3.3**	**0.3**
Total score	**10.0**	**0.3**

Strengths. There is a separate monitoring and evaluation unit in the organization, which develops several reports on TB related situation in Armenia using the existing measurement data. This unit could be involved in introducing quality improvement principles and tools in practice. Another strength is that the process of TB treatment in Armenia is guided by the National TB treatment guideline, which makes it easier to standardize the clinical care process.

Weaknesses. There is lack of awareness on quality improvement principles and tools all over the hospital. The staff has not been trained to use the quality improvement principles in practice. There is no systematic approach to evaluate any newly introduced approach or process related to TB hospital care. Regarding the selection of measures for evaluation of the newly designed or redesigned processes, there is complete absence of any formal structured evaluation mechanism of TB treatment processes within the hospital.

Opportunities. Though the notion of healthcare quality is perceived in a quite narrow manner in the hospital, there is potential infrastructure within the organization, which can initiate the introduction of quality improvement principles in practice. Engaging the monitoring and evaluation unit in the selection of measures to evaluate the newly designed processes in terms of TB hospital treatment is an area to pay attention to. They should play a key role in the selection of measures to evaluate how the newly designed processes operate. Another opportunity is to train the staff regarding quality improvement principles and tools to start using those principles and tools in designing and redesigning clinical care processes. Finally, there is a huge amount of country-level data related to TB treatment in the organization which can be used for evaluation purposes.

Threats. Meeting the requirements of the standard is linked with expansion of job responsibilities and duties of the relevant staff, which, in turn, requires more time commitment. In this sense, there might be potential resistance to change to integrate new job duties into the practice.

9.4 Clinical practice guidelines, clinical pathways, and/or clinical protocols are used to guide clinical care.

The standardization of clinical care processes, reduction of risks within care processes, provision of clinical care in a timely, effective manner, as well as consistently delivering high-quality care using evidence-based practice are emphasized by JCI as goals of health care organizations. Clinical practice guidelines and clinical protocols are among widely accepted tools for developing, as well as for standardizing clinical care processes. JCI recommends clinical practice guidelines and protocols to be:

a) selected from among those applicable to the services and patients of the organization (mandatory national guidelines are included in this process, if present);
b) evaluated for their relevance to identified patient populations;
c) adapted when needed to the technology, drugs, and other resources of the organization or to accepted national professional norms;
d) assessed for their scientific evidence;
e) formally approved or adopted by the organization;
f) implemented and measured for consistent use and effectiveness;
g) supported by staff trained to apply the guidelines or pathways; and
h) periodically updated based on changes in the evidence and evaluation of processes and outcomes.

Measurable elements	Max. score	Obtained score
1. On an annual basis, clinical leaders determine at least five priority areas on which to focus the use of guidelines, clinical pathways, and/or clinical protocols.	**2.5**	**0**
2. The organization follows the process described in a) through h) of the intent in implementing clinical practice guidelines, clinical pathways, and/or clinical protocols.	**2.5**	**1.0**
3. The organization implements clinical guidelines and a clinical pathway or clinical protocol for each identified priority area.	**2.5**	**0**
4. Clinical leaders can demonstrate how the use of clinical practice guidelines, clinical pathways, and/or clinical protocols has reduced variation in processes and outcomes.	**2.5**	**0**
Total score	**10.0**	**1.0**

Strengths. TB hospital care in the NTCC is guided by the national TB treatment guideline. The latter encompasses all the components of the TB treatment in Armenia, including the hospital care. There are also other practice guidelines used in the hospital: e.g. hand hygiene guideline, guideline on the disposal of hazardous materials, etc. The mentioned guidelines are approved

and recommended by the Ministry of Health of the RA, and the hospital does not have a separate process of adapting those guidelines; they are just following them.

Weaknesses. There is no process of annually selecting priority areas to target by the clinical guidelines or protocols. This is not done in the hospital level. There is no process going on as described by JCI before implementation of clinical guidelines and protocols. Those are not assessed for their relevance, scientific evidence, are not formally approved or adopted by the organization, implemented and measured for consistent use and effectiveness, etc. Since there are no priority areas selected by the organization, respectfully no appropriate guidelines and protocols are implemented to target those areas. There is no practice of clinical leaders to demonstrate how the use of clinical practice guidelines, clinical pathways, and/or clinical protocols has reduced variation in processes and outcomes.

Opportunities. Identification of several clinical priority areas will serve as a basis for developing and implementing more relevant and focused clinical practice guidelines and protocols to guide the clinical care process. The experience of using several practice guidelines will be an asset in this context.

Threats. Not identified.

9.5 The organization's leaders identify key measures in the organization's structures, processes, and outcomes to be used in the organization wide quality improvement and patient safety plan.

Collecting data is an essential component of any quality improvement and patient safety initiative. For designing and implementing evidence based quality improvement program there is need to continuously collect data on the organization's structures, processes and outcomes. In the situation of limited resources it is impossible to obtain data on every aspect of the organization. This is why the organization's leaders should identify several important measures for collecting data. The organization's leaders are responsible for making the final selection of key measures to be included in the organization's quality activities. Besides selecting measures to include in the quality and patient safety activities, the leaders of the organization should also decide:

a) the process, procedure, or outcome to be measured;
b) the availability of science or evidence supporting the measure;
c) how measurement will be accomplished;
d) how the measures fit into the organization's overall plan for quality measurement and patient safety;
e) the frequency of measurement.

Measurable elements	Max. score	Obtained score
1. The organization's leaders identify targeted areas for measurement and improvement.	**3.4**	**1.0**
2. The measurement is part of the quality improvement and patient safety program.	**3.3**	**0**
3. The results of measurement are communicated to the oversight mechanism and periodically to the organizational leaders and the governance structure of the organization.	**3.3**	**0**
Total score	**10.0**	**1.0**

Strengths. Though there is no quality improvement and patient safety program at place, the organization's leaders are aware that there are areas for improvement and have identified some of those areas for themselves.

First of all continuous nursing education needs to be improved. This is, perhaps, one of the most serious problems we have. We need to significantly improve the nurse institute in our hospital. We cannot fire all the nurses and replace them with new ones, however keeping the things as they are results in downturn. Another issue relates to the building conditions of some of our departments: extra-pulmonary TB department, psychiatric TB department, and the clinical laboratory. We understand that this is our problem and something needs to be done.

Administration

Weaknesses. There is no practice of systematically selecting areas for measurement and improvement for the purposes of quality improvement and patient safety in the organization. Since there is no formal quality improvement and patient safety program, and there is no process

of selecting measures to target in the quality improvement program, the ME 2 and ME 3 become not applicable.

Opportunities. Since the leadership of the hospital recognizes some of the problematic issues in the hospital, there are opportunities to systematize and prioritize those issues making them measures to target in quality improvement and patient safety program.

Threats. Selection of the corresponding measures and the collection of data on those measures require not only time and dedication, but also appropriate knowledge and skills to use that data. The latter might serve as an obstacle in collecting data about selected key measures.

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

To be able to make use of the collected data, it needs to be aggregated and analyzed. People involved in data analysis should be competent to manage the data and to have skills in data analysis using different statistical tools. After analyzing the data it needs to be reported to the ones, who are responsible to take action based on the results. Data analysis plays essential role in quality improvement program, and provides useful feedback to the decision making bodies.

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

Strengths. There is monitoring and evaluation unit in the organization which deals with data analysis. The staff working in this department analyzes the data transforming it into useful information. They develop different reports, make presentations on the findings.

Weaknesses. The major weakness in this context is that the monitoring and evaluation unit of the NTCC analyses only nationwide TB situation. Hospital wide assessments are not conducted. The reports and presentations they develop are related to TB situation all over the country. They do not deal with hospital-level quality related issues.

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 monitoring and evaluation unit to include specific hospital-related quality measures in their daily activities.

Threats. Newly added job duties demand more time commitment. The latter might threaten the expansion of functions of monitoring and evaluation unit.

9.7 The analysis process includes comparisons internally, with other organizations when available, and with scientific standards and desirable practices.

According to JCI the primary goal of analysis process is to draw comparisons. It is recommended to make comparisons in several ways, including internal comparisons, external comparisons with other organizations, with accepted standards, as well as with desirable practices.

Measurable elements	Max. score	Obtained score
1. Comparisons are made over time within the organization.	**2.5**	**2.5**
2. Comparisons are made with similar organizations when possible.	**2.5**	**0**
3. Comparisons are made with standards when appropriate.	**2.5**	**0**
4. Comparisons are made with known desirable practices.	**2.5**	**0**
Total score	**10.0**	**2.5**

Strengths. The organization prepares periodic reports of their activities, and they include comparisons within the organization over time in those reports.

Weaknesses. Drawing external comparisons, is not practiced in NTCC, whether with other similar organizations, or with other standards and desirable practices.

Opportunities. On the basis of the existing practice it will be feasible to start comparing the obtained data with similar organizations, other standards and practice guidelines.

Threats. In order to be able to meet the requirements of the standard the functions of monitoring and evaluation unit need to be expanded to draw different internal and external comparisons. This will require more time commitment, which might serve as a potential obstacle to expand the functions of monitoring and evaluation unit.

9.8 The organization uses a defined process for identifying and managing sentinel events.

Based on JCI recommendations the healthcare organizations should have their own operational definition of sentinel events. It is recommended to include at least the following situations while defining such events:

a) unanticipated death unrelated to the natural course of the patient's illness or underlying condition (for example, suicide);
b) major permanent loss of function unrelated to the patient's natural course illness or underlying condition;
c) wrong-site, wrong-procedure, wrong-patient surgery;
d) infant abduction or infant who was sent home with the wrong parents.

In case if a sentinel event occurs, it should be assessed thoroughly and a root-cause analysis should be performed, based on which the organization might modify some processes and take actions to prevent further occurrence of similar events.

Measurable elements	Max. score	Obtained score
1. The hospital leaders have established a definition of a sentinel event that at least includes a) through d) found in the intent statement.	**2.5**	**0**
2. The organization conducts a root cause analysis on all sentinel events in a time period specified by the hospital's leaders.	**2.5**	**0**
3. Events are analyzed when they occur.	**2.5**	**0**
4. Hospital leaders take action on the results of the root cause analysis.	**2.5**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. There is no operational definition of a sentinel event at NTCC. Correspondingly no root cause analysis is done, thus no 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 of 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.

10. Prevention and Control of Infection (PCI)

The main goal of infection prevention and control activities in any healthcare organization is the reduction of acquiring and transmitting infections among patients, healthcare providers, staff and others involved in the care process. Though the infection prevention and control programs vary among different organizations depending on the organizations scope, focus, patient population and provided services, however effective infection prevention and control programs have several things in common: identified leaders, trained staff, relevant policies and procedures, staff education and overall coordination all over the organization.

10.1 One or more individuals oversee all infection prevention and control activities. This individual(s) is qualified in infection prevention and control practices through education, training, experience, or certification.

JCI recommends having a special infection prevention and control program corresponding to the size and complexity of the organization. The program should have its own qualified staff with appropriate education; training; experience; and certification or licensure.

Measurable elements	Max. score	Obtained score
1. One or more individuals oversee the infection prevention and control program.	**10.0**	**10.0**
Total score	**10.0**	**10.0**

Strengths. The organization has a separate unit for infection prevention and control, called Nosocomial infection and quality control department. The department has its own staff with appropriate qualifications, carrying out the daily activities of the department.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

10.2 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.

Infection prevention and control activities are multidimensional and involve different departments of the hospital – both clinical and administrative. In order to coordinate the infection prevention activities, as well as to ensure consistent approach all over the hospital, JCI recommends having a special coordinating mechanism. The latter can be represented by a committee, a small working group or a task force. Their responsibilities may vary from developing criteria for healthcare-associated infections, to selecting data collection methods, or designing a reporting process. According to JCI, no matter what type of coordination mechanism the hospital chooses, it is very important to include physicians and nurses in it.

Measurable elements	Max. score	Obtained score
1. There is a designated mechanism for the coordination of the infection prevention and control program.	**2.0**	**2.0**
2. Coordination of infection prevention and control activities involves physicians.	**1.6**	**1.6**
3. Coordination of infection prevention and control activities involves nurses.	**1.6**	**0**
4. Coordination of infection prevention and control activities involves infection prevention and control professionals.	**1.6**	**1.6**
5. Coordination of infection prevention and control activities involves housekeeping.	**1.6**	**0**
6. Coordination of infection prevention and control activities involves others based on the size and complexity of the organization.	**1.6**	**1.6**

Total score	**10.0**	**6.8**

Strengths. Besides special structural unit dedicated to quality control, there is also coordinating mechanism for infection control activities. That mechanism is called Infection control committee, and consists of different specialists: physicians, laboratory representatives, engineer, managerial leaders, epidemiologists, etc. Nosocomial infection and quality control department has developed an action plan which guides their daily activities. Establishment of the quality control committee was one of the actions proposed by the mentioned above action plan. The committee gathers once a month or upon necessity. The committee is responsible for organization, coordination and evaluation of infection control activities.

Weaknesses. The coordination of infection prevention and control activities does not include nurses and representative from housekeeping.

Opportunities. Since there is an already existing system of infection prevention along with a coordination mechanism, it would be feasible to expand the existing committee to involve a nurse and a housekeeping representative.

Threats. The hospital's predominantly vertical management style, where the role of nurses is underestimated, might serve as an obstacle to include nurses and housekeepers in the quality control committee, considering the fact that the vast majority of the committee members are head physicians.

10.3 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.

In order to implement effective infection prevention program, it is important to use current scientific evidence, as well as accepted practice guidelines and applicable laws and regulations to guide infection prevention activities.

Measurable elements	Max. score	Obtained score
1. The infection prevention and control program is based on current scientific knowledge.	**2.5**	**1.0**

2. The infection prevention and control program is based on accepted practice guidelines.	**2.5**	**2.5**
3. The infection prevention and control program is based on applicable laws and regulations.	**2.5**	**2.5**
4. The infection prevention and control program is based on standards from national or local agencies for sanitation and cleanliness.	**2.5**	**2.5**
Total score	**10.0**	**8.5**

Strengths. Currently accepted practice guidelines, applicable laws and regulations, as well as standards from local and international agencies are applied in the infection control program. Since the accepted practice guidelines are based on the scientific knowledge, we may assume that scientific knowledge is also used. In the action plan of the quality control department all the legal documents, which serve as a basis for the proposed actions, are listed. The organization also uses different practice guidelines related to infection prevention developed by the Ministry of Health.

> *…The infection prevention and control activities in our hospital are based on national standards and international norms.*
>
> **Administration**

Weaknesses. The importance of using available scientific knowledge in designing quality control activities is not emphasized. When asked about what is the basis of the infection prevention and control program, the scientific knowledge is not among the answers, whereas the laws and regulations, other practice guidelines are emphasized.

Opportunities. On the basis of the existing quality control program, it would be feasible to start reviewing the available scientific evidence behind quality control activities internationally and incorporate it into daily practice.

Threats. Lack of time to commit to scientific literature review could be a potential challenge.

10.4 The organization's leaders provide adequate resources to support the infection prevention and control program

In order to carry out the proposed infection prevention and control activities in an effective way, the program should be appropriately staffed, and adequate resources need to be dedicated to it. Besides having adequate staffing and resources, it is important to collaborate with information management systems. The latter supports the program in data analysis, interpretation, as well as in presentation of findings.

Measurable elements	Max. score	Obtained score
1. The infection prevention and control program is adequately staffed as approved by the leadership.	**3.4**	**3.4**
2. The organization's leaders allocate adequate resources for the infection prevention and control program.	**3.3**	**3.3**
3. Information management systems support the infection prevention and control program.	**3.3**	**0**
Total score	**10.0**	**6.7**

Strengths. The infection prevention and control unit is properly staffed with adequate job distribution among the staff members. The program is assured with necessary resources.

> *We are supplied with all the resources we need: respirators, gloves, disinfectants, etc. Some of those resources are provided by our donor, the rest are purchased by the hospital.*
>
> **Administration**

Weaknesses. There is no collaboration with information flow management unit in terms of data analysis, interpretation, and presentation of findings.

Opportunities. The collaboration between infection prevention infrastructure and information flow management needs to be formalized to fulfill the requirement of the standard.

Threats. Not identified.

10.5 The organization designs and implements a comprehensive program to reduce the risks of health care–associated infections in patients and health care workers.

A comprehensive infection prevention and control program should focus on all the sides in the process of provision of healthcare services. Both - the patients and service providers should be targeted by the program. To ensure consistency in infection prevention and control activities, the program should be guided by corresponding policies and procedures. Besides that, the infection prevention and control program should conduct continuous surveillance over the infection rates to determine the endemic rates, as well as to establish and periodically modify risk-reduction goals.

Measurable elements	Max. score	Obtained score
1. There is a comprehensive program and plan to reduce the risk of health care–associated infections in patients.	**2.0**	**2.0**
2. There is a comprehensive program and plan to reduce the risk of health care–associated infections in health care workers.	**2.0**	**2.0**
3. The program includes systematic and proactive surveillance activities to determine usual (endemic) rates of infection.	**2.0**	**1.0**
4. The program is guided by appropriate policies and procedures.	**2.0**	**2.0**
5. Risk-reduction goals and measurable objectives are established and regularly reviewed.	**2.0**	**0**
Total score	**10.0**	**7.0**

Strengths. The Nosocomial infection and quality control department at NTCC has developed internal regulation for their department, which guides their daily activities. They also have a special action plan including the list of activities planned to reduce infection risks among patients and health care workers. The infection prevention and control program involves surveillance activities targeting different predetermined zones at high risk of infection in the hospital. According to a specific schedule of the program different samples are taken from various parts of the hospital to perform several microbiological examinations. The time interval of each of the examination is defined by the program. The results of those examinations are presented to the nosocomial infection and quality control department immediately after identification/recording. Besides their action plan, there are also several regulations, according to which the infection prevention and control program is engaged in periodic assessments of the health status of healthcare workers aiming at reducing the risk of health-care associated infection among the staff. There is a special commission consisting of different specialists responsible for performing those assessments.

Weaknesses. The data obtained from the microbiological examinations of samples from high risk zones is not analyzed thoroughly to determine endemic rates of infection. The infection control specialists notify about the results to the responsible bodies of each of the selected high risk zones only in case if they find something that needs to be corrected. The hospital has no defined and acceptable endemic rate of infection.

> *Our result needs to be 0 in terms of endemic rate of infection. Otherwise we will be fined/penalized.*
>
> ***Administration***

Another weakness is that the infection control program has no risk-reduction goals and measurable objectives.

Opportunities. Since periodically samples are collected for microbiological examinations of samples collected from high risk zones in terms of infections, it would be technically feasible to aggregate and thoroughly analyze that data including time series analysis.

Threats. Potentially increased workload of the infection prevention and control specialists, as well as lack of knowledge and skills in data analysis may serve as potential threats to fulfilling the requirements. Besides, the overwhelming culture of fear of being penalized for having any healthcare associated infections in the hospital might hinder the establishment of appropriate reporting procedures.

10.6 All patient, staff, and visitor areas of the organization are included in the infection prevention and control program.

Since infections can access the hospital form variety of people (patients, their family members, staff, volunteers, visitors and others) all the areas where these individuals are found should be targeted by the activities of the infection prevention and control program.

Measurable elements	Max. score	Obtained score
1. All patient care areas of the organization are included in the infection prevention and control program.	**3.4**	**3.4**
2. All staff areas of the organization are included in the infection prevention and control program.	**3.3**	**3.3**
3. All visitor areas of the organization are included in the infection prevention and control program.	**3.3**	**3.3**

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

Strengths. The organization has formally identified all the zones, where the infection risk is high. The infection prevention and control program involves activities targeting all those zones. The patient care areas, staff areas, as well as the visitor areas are included in the infection prevention and control program.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

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

The provision of healthcare services is associated with infection risks both to the patients, and to the staff. It is very important for hospitals to review and measure the processes with high infection risks, and to implement corresponding policies and procedures to reduce those risks.

Measurable elements	Max. score	Obtained score
1. The organization has identified those processes associated with infection risk.	**3.4**	**3.4**
2. The organization has implemented strategies to reduce infection risk in those processes.	**3.3**	**3.3**
3. The organization identifies which risks require policies and or procedures, staff education, practice changes, and other activities to support risk reduction.	**3.3**	**3.3**
Total score	**10.0**	**10.0**

Strengths. The infection prevention and control activities in NTCC are based on the TB infection control nationwide guideline, which is approved by the Ministry of Health of the RA and contains all the required and recommended activities for infection prevention. It also contains the high risk processes, as well as strategies to minimize the risk of infection. Besides the mentioned methodological guideline, the high risk processes are emphasized by the infection prevention action plan of the hospital. Besides identifying the high risk processes, and implementing strategies to reduce the infection risks, the infection prevention and control unit also organizes different workshops and training for the staff on infection prevention topics.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

10.8 There is a policy and procedure in place that identifies the process for managing expired supplies and defines the conditions for reuse of single-use devices when laws and regulations permit.

Most materials used in the provision of healthcare services have their specific expiry date. After expiry the manufacture does not guarantee effectiveness, sterility and safety of the material. Using materials past the expiry date might be linked with infection risks. JCI recommends healthcare organizations to have a special policy targeting the use expired supplies. The policy should not only be implemented, but also monitored.

Measurable elements	Max. score	Obtained score
1. There is a policy and procedure consistent with national laws and regulations and professional standards in place that identifies the process for managing expired supplies.	**3.4**	**3.4**
2. The policy is implemented.	**3.3**	**3.3**
3. The policy is monitored.	**3.3**	**0**
Total score	**10.0**	**7.7**

Strengths. The infection prevention and control department has developed and implemented a policy on expired medical supplies' management. The policy is based on the nationwide guideline on expired medical supplies management, developed by the Ministry of Health of the RA. The infection prevention and control department has trained the heads of the departments and the head nurse on expired supplies' management.

Weaknesses. The policy is not monitored properly. Despite the fact that the heads of the departments and the head nurse have been trained on expired supplies' management, there is no follow-up process to identify how the policy works in practice.

We have trained the heads of the departments, and the head nurse. The rest is their responsibility. If something goes wrong, it is their fault.

Administration

Opportunities. Since there are infection prevention and control, as well as monitoring and evaluation infrastructures in the hospital, it will be feasible to expand the frames of their collaborative activities to include monitoring over the policy of expired supplies.

Threats. Increased work load resulting from expansion of job responsibilities can cause resistance to change among the infection prevention and monitoring specialists.

10.9 The organization has a policy and procedure on the disposal of sharps and needles.

The inappropriate disposal of sharps and needles can pose a major risk to safety in hospitals. This is why it is recommended to have a special policy implemented, which will address all the steps in the process of sharps' and needles' safe disposal.

Measurable elements	Max. score	Obtained score
1. Sharps and needles are collected in dedicated, puncture-proof containers that are not reused.	**3.4**	**3.4**
2. The hospital disposes of sharps and needles safely or contracts with sources that ensure the sharps containers are disposed of in dedicated hazardous waste sites or as determined by national laws and regulations.	**3.3**	**3.3**
3. The disposal of sharps and needles is consistent with infection prevention and control policies of the organization.	**3.3**	**3.3**
Total score	**10.0**	**10.0**

Strengths. The organization uses a practice guideline on safe disposal of hazardous medical materials, including sharps and needles. The guideline was developed by the Ministry of Health of the RA and goes in line with other infection prevention policies implemented in the NTCC.

Weaknesses. Not identified

Opportunities. Not identified.

Threats. Not identified.

10.10 Gloves, masks, eye protection, other protective equipment, soap, and disinfectants are available and used correctly when required.

Hand hygiene, barrier techniques, such as wearing masks, gloves, protective equipment, as well as surface disinfectants are important tools for infection prevention and control. It is recommended for healthcare organizations to identify all the situations and processes, in which using the mentioned barrier techniques and disinfectants are required. Having those processes identified is not enough: the staff should be educated to perform proper hand hygiene and use barrier techniques.

Measurable elements	Max. score	Obtained score
1. The organization identifies those situations for which gloves and/or masks or eye protection are required.	**2.5**	**2.5**
2. Gloves and/or masks or eye protection are correctly used in those situations.	**2.5**	**0**
3. The organization identifies those situations for which hand washing and hand disinfection or surface disinfecting procedures are required.	**2.5**	**2.5**
4. The organization has adopted hand-hygiene guidelines from an authoritative source.	**2.5**	**2.5**
Total score	**10.0**	**7.5**

Strengths. There are several documents (internal regulation, practice guidelines, methodological guidelines) which guide the infection prevention and control activities in the NTCC. In those documents the organization has identified the situations requiring masks, gloves, and/or eye protection. There is a separate guideline for hand hygiene and it is used all over the organization. All those guidelines and policies are either approved by the Ministry of Health, or go in line with their requirements. Besides that, the organization provides trainings on hand hygiene and use of barrier techniques for infection prevention and control.

We periodically organize different trainings and educational workshops for the heads of departments and head nurses. Later on they pass the information to their staff.

Administration

Weaknesses. During observations, the research team came across many situations when the masks, respirators, and gloves were not used properly. More specifically, the healthcare providers were not always wearing respirators while going to potentially TB infected areas. Moreover, in the visitors' and patients' waiting areas the healthcare providers could be wearing surgical masks, instead of appropriate respirators, or wearing respirators incorrectly. Since the general approach towards infection prevention and control is blaming, some of the healthcare providers use respiratory protection only when they see some administration representatives.

…Whenever they [meaning the physicians and nurses in the clinical departments] *see us, they immediately wear their respirators in order not to be blamed for not wearing it….* **Administration**

Opportunities. Since the infection prevention and control unit trains the head physicians and head nurses on proper hand hygiene and barrier techniques for infection prevention and control, it will be feasible to come up with a comprehensive strategy to include the remaining staff in the training program.

We need to increase the awareness and the use of personal protection techniques among the healthcare providers and the patients. They do not adequately perceive the risk of getting infected **Administration**

Besides, a systematic follow-up mechanism will be useful in sustaining the practice changes. The general approach towards improving the situation should not be punitive, and blaming as it is currently. Otherwise the things will remain as they are.

Threats. More efforts will be needed to train all the staff and to conduct follow up activities. This will require more time commitment, which can serve as a potential obstacle.

10.11 The organization tracks infection risks, infection rates, and trends in health care–associated infections.

The main goal of infection prevention and control unit is to decrease the risk of health care associated infections in the hospital. In reaching this goal, the healthcare organizations are recommended to track healthcare associated infection risks, rates and trends, as well as to use that information for improvement of infection prevention activities. The obtained information can also be used to compare it with similar data from other relevant organizations.

Measurable elements	Max. score	Obtained score
1. Health care–associated infection risks are tracked.	**3.4**	**0**
2. Health care–associated infection rates are tracked.	**3.3**	**0**
3. Health care–associated infection trends are tracked	**3.3**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. The organization does not track the risks, rates and trends of healthcare associated infections. Having healthcare associated infections recorded can cause troubles to the organization. The overall approach towards tracking healthcare associated infections is hiding.

> *Everyone* [other hospitals] *reports 0 healthcare associated infections. Otherwise they will be punished and fined…*
>
> *…There is no data to compare with. No one shows any data. The situation is worse in other places.*
>
> **Administration**

Opportunities. The overall approach towards reporting healthcare-associated infections needs to be modified. The organizational culture needs to be changed from hiding/blaming to an open culture of learning from failures. This transition requires comprehensive interventions across the organization. Along with making that transition happen, the organization should start tracking the healthcare-associated infection risks, rates, and trends.

Threats. Resistance to change, lack of appropriate knowledge and skills might be potential threats in making the proposed above organization-wide transition.

10.12 The results of infection prevention and control measurement in the organization are regularly communicated to leaders and staff.

A good communication is essential in infection prevention and control activities. The organization's leaders, both clinical and administrative, as well as the medical staff and the nursing staff should be informed about the results of infection prevention and control activities.

Measurable elements	Max. score	Obtained score
1. Measurement results are communicated to medical staff.	**3.4**	**2.0**
2. Measurement results are communicated to nursing staff.	**3.3**	**2.0**
3. Measurement results are communicated to management.	**3.3**	**3.3**
Total score	**10.0**	**7.3**

Strengths. The information on infection prevention and control activities is circulated among the medical, nursing, and management representatives during formal meetings and everyday

informal meetings. Usually the infection prevention and control unit organizes meetings and workshops for the heads of the departments and the head nurses. Afterwards, the heads of the departments and the head nurses are responsible to circulate the obtained information among the corresponding staff. The managerial staff is also involved in the communication mechanism. The results of infection prevention activities are directly reported to the leadership of the hospital.

Weaknesses. Though the results are communicated to the heads of the departments and the head nurses, the other frontline clinicians are not contacted directly. Besides, since there is no follow-up mechanism, no one knows what kind of information the clinicians (physicians and nurses) received.

We get information on infection prevention and control practices from the clinical practice guidelines and from the head of our department. We personally are not informed what is discussed during the meetings in the reality, because we never participate in those meetings. Previously we were participating in the meetings. We were feeling some boredom then. However, now I understand how important those meetings were.

Healthcare provider 1

I am not well aware on the infection prevention and control activities. I am getting some information from the head of our department.

Healthcare provider 2

Opportunities. A mechanism to directly engage the frontline physicians and nurses in communication about infection prevention activities can potentially improve the situation.

Threats. Resistance to change the established practice might be a potential obstacle in engaging the clinicians and nurses into the communication.

10.13 The organization provides education on infection prevention and control practices to staff, physicians, patients, families, and other caregivers when indicated by their involvement in care.

For the infection prevention and control program to be effective, it should emphasize education of staff, patients, their families, and visitors on infection prevention and control practices. Besides ongoing educational activities it is important to educate the new staff as a part of their orientation. The education on infection prevention and control practices needs to be refreshed periodically, or at least when there is a change in relevant policies and procedures.

Measurable elements	Max. score	Obtained score
1. The organization provides education about infection prevention and control to all staff and other professionals.	**3.4**	**2.0**
2. The organization provides education about infection prevention and control to patients and families.	**3.3**	**2.0**
3. All staff are educated on the policies, procedures, and practices of the infection prevention and control program.	**3.3**	**2.0**
Total score	**10.0**	**6.0**

Strengths. The infection prevention and control activities at NTCC target all the staff and other professionals. There are trainings and workshops on infection prevention and control practices, policies and procedures, which are designed to reach all the staff. Those trainings and workshops initially involve only the heads of the departments and the head nurses, who are later on responsible to pass the obtained information to their staff.

Educating the patients and family members on infection prevention practices is mainly done by the physicians during everyday work. The physicians include topics related to infection prevention in their counseling. They inform about infection control practices not only their patients, but also their family members and caregivers.

Weaknesses. Though the educational activities are designed to reach all the staff, however those do not directly focus on all the members of the staff. The trainings involve only the heads of the departments and the head nurses, which are later on responsible to educate their staff. There are no follow-up mechanisms to track whether the education reached the frontline clinicians or not, and whether it is practiced or not.

Education of the patients and their families is the responsibility of the physicians, and the topics to cover are not formally defined. Each of the physicians has his/her own working style, and since educating the patient is the individual responsibility of physicians, there might be variation from physician to physician.

…We might serve 10-15 patients per day, practically not having time to properly educate all of them. Some patients might ask very detailed questions and we cannot educate them on the whole medicine. There is no need to go into all the details.

... It would be unrealistic to think that the patients' families will not have any questions. Usually the families ask us question and we answer them, wherever they have questions.

Healthcare provider 1

…We do not deal with education of families. We might give them some advices; however we do not have such responsibilities.

There is no list of defined topics to cover in educating the patients. All depends on the patients' individual needs.

Healthcare provider 2

Opportunities. A mechanism need to be established to directly engage the frontline clinicians and nurses in educational programs on infection prevention and control practices.

Threats. Increase workload resulting in resistance to change might be a problem in establishing the mentioned above mechanism.

11. 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 all over the organization.

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

Each healthcare organization should have an entity responsible for the oversight of the operations. A special document should describe the responsibilities of this entity, as well as the ways how its performance and the performance of the organizational leaders are evaluated.

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.	**2.5**	**2.5**
2. Governance responsibilities and accountabilities are described in the documents.	**2.5**	**2.5**
3. The documents describe how the performance of the governing entity and managers will be evaluated and any related criteria.	**2.5**	**0**
4. There is an annual documented performance evaluation of governance.	**2.5**	**0**
Total score	**10.0**	**5.0**

Strengths. The organization's governance structure is described in its organizational charter, which is approved by the Ministry of Health of the RA. The document describes the organization's goals and objectives, as well as the responsibilities and accountabilities of the Governance.

Weaknesses. There are no documents describing how the performance of the governing body will be evaluated, and no performance evaluation of the governance is documented.

Opportunities. 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.

11.2 Those responsible for governance approve and make public the organization's mission statement.

The healthcare organization should have its mission approved by the governance. The mission should be available to the public.

Measurable elements	Max. score	Obtained score
1. Those responsible for governance approve the organization's mission.	**5.0**	**0**

2. Those responsible for governance make public the organization's mission.	**5.0**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. The mission of the organization is identified neither in its organizational charter, nor in any other formal document. Thus there are no activities to make it publicly available.

Opportunities. 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. Not identified.

11.3 Those responsible for governance approve the policies and plans to operate the organization.

The organizations governance should approve all the policies, strategic and management plans, which are needed for daily functioning of the hospital.

Measurable elements	Max. score	Obtained score
1. Those responsible for governance approve the organization's strategic and management plans and operating policies and procedures.	**5.0**	**5.0**
2. Those responsible for governance approve organization strategies and programs related to health care professional education and research and then provide oversight of the quality of such programs.	**5.0**	**5.0**
Total score	**10.0**	**10.0**

Strengths. All the documents related to the organization daily operation, as well as programs related to the professional education of the healthcare providers is approved by the governance of the hospital.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

11.4 Those responsible for governance approve the budget and allocate the resources required to meet the organization's mission.

The budgeting and allocation of resources should be done by the governance of the healthcare organization.

Measurable elements	Max. score	Obtained score
1. Those responsible for governance approve the organization's capital and operating budget(s).	**5.0**	**5.0**
2. Those responsible for governance allocate the resources required to meet the organization's mission.	**5.0**	**5.0**
Total score	**10.0**	**10.0**

Strengths. According to the 2666-Ա (17.11.2016) order of the Minister of Health of the RA the authorized governing body (կառավարման լիազոր մարմին) of the NTCC is the Ministry of Health of the RA, which approves the annual budget of the organization. Further resource allocation within the organization is done by the leadership of the hospital.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

11.5 Those responsible for governance appoint the organization's senior manager(s) or director(s).

The organization's director/manager is defined by the governance, which is also responsible for the performance evaluation of the senior management.

Measurable elements	Max. score	Obtained score
1. Those responsible for governance appoint the organization's senior manager.	**3.3**	**3.3**
2. Those responsible for governance evaluate the performance of the organization's senior manager.	**3.4**	**0**
3. The evaluation of the senior management is performed at least annually.	**3.3**	**0**
Total score	**10.0**	**3.3**

Strengths. The director of NTCC is appointed by the authorized governing body – the Ministry of Health of the RA.

Weaknesses. No assessments are conducted in NTCC to evaluate the performance of the senior management.

We don't have any mechanism on paper to evaluate the performance of senior management.
Administration

Opportunities. Periodic assessments of the performance of senior management should be incorporated into practice to be able to understand the effectiveness of performance of the senior management, as well as to introduce new managerial approaches for improvement.

Threats. Considering the fact that performance assessments are not practiced at NTCC at all, it would be challenging to introduce such assessments. The old management style is well rooted in the hospital and it would be very hard to make the administration recognize the importance of performance evaluations in all the levels of the organization, including senior management.

11.6 A senior manager or director is responsible for operating the organization and complying with applicable laws and regulations.

The healthcare organization daily functions need to be coordinated by a qualified senior manager. Starting from procurement of essential supplies, financial management, to maintenance of physical facility, fit in frames of senior manager's responsibilities. To fulfill those responsibilities the senior manager of the organization cooperates with the other managers of the hospitals.

Measurable elements	Max. score	Obtained score
1. The senior manager or director manages the organization's day-to-day operations, including those responsibilities described in the position description.	**2.0**	**2.0**
2. The senior manager or director recommends policies to the governing body.	**2.0**	**2.0**
3. The senior manager or director ensures compliance with approved policies.	**2.0**	**2.0**
4. The senior manager or director ensures compliance with applicable laws and regulations.	**2.0**	**2.0**
5. The senior manager or director responds to any reports from inspecting and regulatory agencies.	**2.0**	**2.0**

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

Strengths. NTCC director manages daily operations of the hospital and is the one, who serves as a linkage between the governing body and the hospital itself. Other managers make the director informed about the situation in the hospital through regular reports. The director recommends policies to the governing body, ensures that the practice corresponds to the approved policies, applicable laws, and regulations, and responds to any reports from inspecting and regulatory agencies.

…The clinical practice all over the hospital has to be consistent with the adopted policies, laws, and regulations. We ensure the consistency through conducting clinical rounds every day. Even if I do not have time to meet each and every patient during those rounds, I try to go to each clinical department at least once a day. The departments receive guidance related to their daily operations directly from me.

Administration

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

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

The staff recruitment, retention, as well as development programs should be uniform all over the organization. JCI particularly emphasizes the importance of staff retention and development, since those have a long term effect. It is essential to have a program to attract the qualified staff to stay in the organization. The leaders of the organization should collaborate to develop uniform processes for recruiting, retaining and developing the staff. With this regards already accepted and published guidelines could be useful.

Measurable elements	Max. score	Obtained score
1. There is a planned process for staff recruitment.	**2.5**	**0.5**
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**	**1.0**
4. The planning is collaborative and includes all departments and services in the organization.	**2.5**	**0**

Total score	**10.0**	**1.5**

Strengths. The standard process of hiring new employees in the organization complies with the Labor Code of the RA.

> *There are three main ways to hire new employees: competition, director's appointment, or by announcement. When the director tells us that we should hire the person, the Human Resources department writes the order for the new employee with 3 months of probation period.*
>
> **Administration**

The continuing education efforts all over the organization are coordinated by director's advisor on scientific and educational affairs. The medical and administrative staffs of the organization regularly participate in different trainings and workshops in both - local and international levels. The leadership of the organization also plans to come up with continuing education initiatives for nurses.

> *To fulfill the educational needs of our nurses we plan to develop a system, which will give the nurses opportunity to expand their knowledge and advance their skills. We have done some preliminary evaluations of the nurses' knowledge based on which we are now developing an educational program for them.*
>
> **Administration**

Weaknesses. Though the process of hiring new staff is standard, there is no planned comprehensive staff recruitment process in the NTCC. The organization has developed a document called internal disciplinary regulations, which somehow relates to staff recruitment issues, but is not specific to NTCC. The document just follows the Labor Code of the RA. There are no specific domains on planning staff recruitment activities across the organization. Moreover, this document has been developed by the previous administration, and has not been modified despite major structural changes all over the organization. NTCC 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 organization, however, the

nurses do not fit in those programs. The planning of the educational activities is not collaborative and does not include all the services.

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 hospital should be considered. Besides, 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 potentially hinder development of such plans.

11.8 Medical, nursing, and other leaders of clinical services plan and implement an effective organizational structure to support their responsibilities and authority.

Having an effective organizational structure is essential to effectively carry out daily responsibilities of the hospital. The chosen organizational structure should correspond to the size and complexity of the organization, as well as support good communication between professionals and help in oversight of the quality of services.

Measurable elements	Max. score	Obtained score
1. There is an effective organizational structure(s) used by medical, nursing, and other leaders to carry out their responsibilities and authority.	**2.5**	**2.5**
2. The structure(s) is appropriate to the organization's size and complexity.	**2.5**	**2.5**
3. The organizational structure(s) and processes support professional communication.	**2.5**	**2.5**
4. The organizational structure(s) and processes support oversight of the quality of clinical services.	**2.5**	**0**
Total score	**10.0**	**7.5**

Strengths. The organization has a strict hierarchical structure, where everyone is aware on the subordination order, which in turn, helps to carry out everyday responsibilities.

The head of the department is superior to the physicians, the physicians are superior to the nurses, and the nurses are superior to the midwives and so on.

Healthcare provider

The structure is appropriate to the organization's size and complexity. Currently the space available in the hospital is sufficient to serve the hospital's patient population.
Besides the mentioned predominantly hierarchical structure, there are also some working groups/commissions/committees focusing on different hospital wide issues, including infection prevention activities, staff health status assessments, and providing consultation to difficult cases. These working groups support professional communication among the personnel.

Weaknesses. Since the hospital has no measureable standards for quality, and no program for quality improvement of the provided services, the oversight mechanism is also absent.

Opportunities. Structure and processes of quality improvement should be developed further, to be able to support the oversight of the quality of services.

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

11.9 Directors recommend space, equipment, staffing, and other resources needed by the department or service.

The leaders of the departments inform the senior leaders about the special needs of their departments in terms of human, space, and material resources. The senior leaders later on make recommendations about those issues. The senior leaders should have process to respond to shortages of resources.

Measurable elements	Max. score	Obtained score
1. Directors recommend space needed to provide services.	**2.0**	**2.0**
2. Directors recommend equipment needed to provide services.	**2.0**	**2.0**
3. Directors recommend the number and qualifications of staff needed to provide services.	**2.0**	**2.0**
4. Directors recommend other special resources needed to provide services.	**2.0**	**2.0**
5. Directors have a process to respond to resource shortages.	**2.0**	**2.0**
Total score	**10.0**	**10.0**

Strengths. The organizational charter of the NTCC defines the frames of the director's responsibilities. According to it, the director can recommend human, space, equipment, and other material resources needed in the provision of healthcare services.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

11.10 Directors recommend criteria for selecting the department or service's professional staff and choose or recommend individuals who meet those criteria.

In order to ensure that the staff employed in the organization can meet the needs of the patient population, the directors should develop criteria for the selection of the relevant staff. While developing those criteria they can cooperate with human resource department and other departments involved in staffing processes.

Measurable elements	Max. score	Obtained score
1. The director develops criteria related to the needed education, skills, knowledge, and experience of the department's professional staff.	**5.0**	**0**
2. The director uses such criteria in selecting or recommending professional staff.	**5.0**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. The director of the organization is not involved in developing criteria related to the needed education, skills, knowledge and experience of the professional staff. *(See more in Staff Qualification and Education section)* Moreover, there is no criterion about those issues at all. Everything is based on so called common sense:

> *Of course I* [a person without nurse education] *cannot go and work as a nurse.*
>
> **Administration**

Opportunities. Since there is a functioning human resource management infrastructure within the organization it would be feasible to collaboratively develop criteria related to the education, knowledge, skills, and experience of the professional staff of the departments.

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

11.11 Directors provide orientation and training for all staff of the duties and responsibilities for the department or service to which they are assigned.

According to JCI the directors of healthcare organizations should ensure that the whole staff is aware of their duties and responsibilities by having completed a formal orientation program.

Measurable elements	Max. score	Obtained score
1. The director has established a documented orientation program for department staff.	**5.0**	**0**
2. All department staff have completed the program.	**5.0**	**0.5**
Total score	**10.0**	**0.5**

Strengths. There is no documented orientation program for the staff, however there is a procedure of introducing the job duties and responsibilities of the department, and the particular employee during the process of hiring:

> *When we decide to hire someone for a particular position, and if s/he meets the corresponding requirements, an employment contract is prepared containing all the job duties and responsibilities. Later on the primary supervisor of that particular position introduces all the other details to the employee.*
>
> **Administration**

Weaknesses. The absence of a documented orientation program is a major weakness. Without having a formal orientation program, the administration cannot ensure consistency in its approach of introducing the job responsibilities to the employees.

Opportunities. Since there is already an existing process of introducing job duties and responsibilities to the new employees, it would be feasible to systematize and document that process.

Threats. Developing a formal orientation program and documenting the completion of the program by the staff will be a time consuming task. It might result in an increased workload and a resistance to change already existing practice.

12. Staff Qualifications and Education (SQE)

A coordinated and uniform process in essential in recruiting, appointing and evaluating relevant staff in healthcare organizations. The staff in the healthcare organization should have opportunities for personal and professional advancement. The standards described below discuss processes related to staff qualifications and education.

12.1 The organization uses a defined process to ensure that clinical staff knowledge and skills are consistent with patient needs and the non-clinical staff's knowledge and skills are consistent with the organization's needs.

In order to hire qualified staff members, who are capable to carry out their job responsibilities, the healthcare organizations should have a process to match the position requirements with the qualifications of the potential staff member. In that case s/he will be able to consistently meet the patients' and the organization's needs over time.

For purposes of matching position requirements with the candidate's qualifications, it is recommended to perform an initial evaluation to understand whether or not s/he can perform the proposed tasks. Besides this initial evaluation it is recommended to have process of on-going evaluation of the clinical staff members. It will help to understand their on-service educational needs. It is also recommended to have at least one documented annual evaluation of each clinical staff member.

Measurable elements	Max. score	Obtained score
1. The organization uses a defined process to match staff knowledge and skills with patient/organization's needs.	**2.0**	**0**
2. New staff members are evaluated at the time they begin their work responsibilities.	**2.0**	**0**
3. The department or service to which the individual is assigned conducts the evaluation.	**2.0**	**0**
4. The organization defines the frequency of ongoing staff evaluation.	**2.0**	**0**
5. 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**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. There is no process of matching clinical staff knowledge with patient needs. No evaluations are conducted for the clinical staff members.

We [hospital administration] *do not conduct initial evaluations. We do not have any tests for that. We just consider their certificates/diplomas as proofs about their knowledge and skills.*

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 at all, 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.

12.2 Organization leaders define the desired education, skills, knowledge, and other requirements of all staff members. There is documented personnel information for each staff member.

The organization's leaders should define all the requirements related to education, knowledge and skills for all the staff members. The healthcare organization should have records containing information about the education, experience, and qualification of all staff members. Those records should be standardizes and up to date.

Measurable elements	Max. score	Obtained score
1. The desired education, skills and knowledge are defined for staff.	**3**	**1.0**
2. Personnel information is maintained for each staff member.	**1.0**	**1.0**
3. Personnel files contain the qualifications of the staff member.	**1.0**	**1.0**
4. Personnel files contain the job description of the staff member when applicable.	**1.0**	**1.0**
5. Personnel files contain the work history of the staff member.	**1.0**	**1.0**
6. Personnel files contain the results of evaluations.	**1.0**	**0**
7. Personnel files contain a record of in-service education attended by the staff member.	**1.0**	**1.0**
8. Personnel files are standardized and kept current.	**1.0**	**1.0**
Total score	**10.0**	**7.0**

Strengths. Some of the organizational units at the NTCC have developed internal regulations for guiding their daily practices. Those internal regulations contain requirements on the desired education and experience of some of the personnel, specifically the head of the department, physicians, nurses and midwives. Besides those internal regulations, there are some job

descriptions developed for some of the positions containing educational and experience requirements.

The human resource management unit of the NTCC maintains personal files for all the staff members – both clinical and non-clinical. Those personal folders capture information about the qualification of the staff member, job description, work history, records about in-service trainings. Those files are standard, and are regularly updated whenever necessary.

Weaknesses. The described above internal regulations were developed before major structural organization-wide changes. After those changes some of the departments have changed their names and functions. However, those internal regulations have remained the same. Besides, not all of the organizational units have their regulations. Depending on the working style of the heads of the departments, some departments managed to develop internal regulation, while others – not.

The personnel files do not contain information about evaluation, because evaluations, as such, are not practiced in the NTCC.

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 internal regulations for different organizational units need to be updated. New regulations need to be developed for those organizational units, which do not have any regulations. After establishing a process of staff members' evaluation, the results from those evaluations can be easily included in the personnel folders of the staff members.

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

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

In order to be able to adequately meet the patients' needs, the knowledge and skills of the staff should be updated periodically. The healthcare organizations should design ongoing in-service and other training programs to meet staff's educational needs. JCI recommends using and integrating different data sources to develop educational programs. The healthcare organizations should also define which staff needs continuing education, how this education should be monitored, etc. The staff's educational progress should be documented and kept in the personnel folders.

Measurable elements	Max. score	Obtained score
1. The organization uses various sources of data and information, including the results of quality and safety measurement activities, to identify staff education needs.	**2.5**	**0.5**
2. Education programs are planned based on these data and information.	**2.5**	**0**
3. Organization staff are provided ongoing in-service education and training.	**2.5**	**0.5**
4. The education is relevant to each staff member's ability to meet patient needs and/or continuing education requirements.	**2.5**	**0.5**
Total score	**10.0**	**1.5**

Strengths. The administration of the hospital tries to understand the gaps in nurse education and skills through random checks in the clinical departments. They plan to use that information later on while designing continuing education program for nurses.

I am doing random visits to clinical departments. …I try to understand differences in nurse practice between different departments, as well as to identify the drawback and problematic areas that need to be corrected. Based on that we want to educate our nurses.

Administration

Many of the staff members at NTCC, both administrative, and clinical, participate in different trainings in local and international levels. Most of the hospital physicians have participated in such trainings. The administration of the hospital tries to engage as many physicians in trainings as possible:

The physicians undergo trainings very often. We try to organize the process so that the ones, who have never participated in international trainings, are given priority. And with logic they [physicians] *sequentially participate in trainings abroad. As for the local trainings, there are different trainings, and our physicians take part in those as well.*

Administration

We participate in different trainings about TB treatment. When we come back from those trainings, we usually share the new information with our colleagues.

Healthcare provider

Nurses of the Drug Resistant (DR) TB department are also extensively involved in trainings, since the "Médecins Sans Frontières" (MSF), involved in DR TB treatment, organizes different trainings for them. Nurses from other departments also participate in trainings, predominantly local, though not as often as physicians and DR TB department nurses.

Weaknesses. Though the staff of NTCC 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 NTCC links its staff to those trainings. NTCC has 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 nursing staff, and later to use that information to design the continuing educational program for nurses. 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.

12.4 The organization provides a staff health and safety program.

In order to maintain the health, satisfaction, as well as productivity of the staff JCI recommends having a special program for staff health and safety. The program includes periodic health assessments for the staff, medical counseling, treatment and referral.

Measurable elements	Max. score	Obtained score
1. The organization's leaders and staff plan the health and safety program.	**3.4**	**3.4**
2. The program is responsive to urgent and non urgent staff needs through direct treatment and referral.	**3.3**	**3.3**

3. There is a policy on the evaluation, counseling, and follow-up of staff exposed to infectious diseases that is coordinated with the infection prevention and control program.	**3.3**	**3.3**
Total score	**10.0**	**10.0**

Strengths. There is a special program for staff health and safety in the NTCC. The program is based on several documents, including governmental decrees and internal hospital-wide regulations. Staff health assessments are included in the action plan of the infection prevention and control department. The mentioned above documents define the frequency of the assessments, specifies the narrow medical specialists involved in health assessments, as well as the staff members that should undergo those assessments.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

12.5 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.

The medical and nursing staff of hospitals should be qualified to provide safe and high quality healthcare services to patients. Those are the ones responsible for patient care and its outcomes. This is why hospitals have high accountability to hire only qualified medical and nursing staff. For this reason it is recommended to have standard procedures for gathering and maintaining required credentials of the staff, as well as verifying the obtained information on credentials of the staff.

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.	**3.4**	**3.4**
Total score	**10.0**	**6.7**

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:

> *We do not have any procedure to verify the credentials. To decide whether they* [the staff member] *have the required qualifications we look at their diplomas of higher education. Since they bring state diplomas/certificates, we do not check the validity/accuracy of those documents.*
>
> **Administration**

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 really qualified to do so.

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

12.6 Leadership makes an informed decision about renewing permission for each medical staff member to continue providing patient care services at least every three years.

According to JCI recommendations healthcare organizations should have a process of reviewing the files medical staff members at least once in three years to ensure that the staff members are licensed, not compromised by disciplinary actions of licensing and certifying organizations. It is done to understand whether there are enough bases to expand the privileges or duties and responsibilities of the staff members. In order to carry out the mentioned review, the organization should define the individuals and mechanisms, as well as the criteria used for the review. All the results of this process should be documented.

Measurable elements	Max. score	Obtained score
1. There is a process described in policy for the review of each medical staff member's credential file at uniform intervals at least once every three years.	**3.4**	**0**

2. Designated individuals make an official decision to renew permission for each medical staff member to continue to provide patient care services in the organization.	**3.3**	**0**
3. The renewal decision is documented in the staff member's credential file.	**3.3**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

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

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

Threats. The development and implementation of the mentioned above process of 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.

13. Management of Communication and Information (MCI)

Communication of information plays an important role in the provision of healthcare services. Throughout the whole process of patient care the healthcare organizations highly rely on different sources and types of information. Organizations leaders should be able to manage all the information just like the other resources. The information should be used to improve patient outcomes, as well as overall performance of the organization.

13.1 The organization informs patients and families about its care and services and how to access those services.

According to JCI recommendations healthcare organizations should provide complete information about healthcare services provided by the organization to the patients and their family members. This information helps in building trusting communication between the organization and the patients and their family members. It is also important to provide information about alternative sources of care in case if the needed services are not in the scope of the hospital's functions.

Measurable elements	Max. score	Obtained score
1. Patients and families are provided information on the care and services provided by the organization.	**4**	**4**
2. Patients and families are provided information on how to access services in the organization.	**4**	**4**
3. Information on alternative sources of care and services is provided when the organization cannot provide the care or services.	**2**	**2**
Total score	**10.0**	**10.0**

Strengths. After patients are admitted to the hospital, the head of the department assigns the patient a particular physician, who is responsible for the entire course of hospital treatment for that patient. The physician provides counseling to the patient and the family members. All the information related to treatment is communicated to them during that counseling. *(See more in Access and Continuity of Care section, 2.3)* If during the initial assessments it turns out that the patient's needs are out of the scope of the hospital services, they are referred to other healthcare organizations.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

13.2 Communication is effective throughout the organization.

Ensuring effective communication throughout the organization is one of the important tasks that the leadership should accomplish. It refers to communication between different structural units, between clinical departments, between healthcare professionals and patients/families, etc. Effective communication also means that the information should be up-to-date and communicated in a timely manner.

Measurable elements	Max. score	Obtained score

1. The leaders ensure processes are in place for communicating relevant information throughout the organization in a timely manner.	**5.0**	**5.0**
2. The leaders communicate the organization's mission and appropriate policies, plans, and goals to all staff.	**5.0**	**5.0**
Total score	**10.0**	**10.0**

Strengths. There are several established processes in the daily operation of the NTCC ensuring effective communication throughout the organization. Meetings, clinical rounds, discussions in the central medical committee (*see more in Quality and Patient Safety section, 8.1*) all aim at communicating necessary information throughout the organization. The administration of the hospital organizes meetings which include the heads of all structural units. New information, organization's policies, plans and goals, as well as issues related to daily functioning of the hospital, are discussed in those meetings. The heads of department later pass this information to the staff of their departments. Besides, in the beginning of the working day there are clinical rounds in the departments, where the head of the department and the medical director of the hospital participate. Those rounds help to understand what is going on in the clinical units.

There are clinical rounds every day. We talk to the patients, provide short counseling during those rounds.

Healthcare provider

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

13.3 The leaders ensure that there is effective communication and coordination among those individuals and departments responsible for providing clinical services.

According to JCI in order to integrate and coordinate patient services, the leaders should develop a culture emphasizing cooperation and communication. For that reason the leaders can use both formal (standing committees, joint teams, etc.) and informal (newsletters, posters) channels to promote communication. Besides, there should be established regular communication methods between the governance and the hospital management.

Measurable elements	Max. score	Obtained score
1. Leaders ensure effective and efficient communication among clinical and nonclinical departments, services, and individual staff members.	**5.0**	**5.0**
2. Leaders foster communication in the delivery of clinical services.	**3.0**	**3.0**

3. There are regular communication channels established between governance and management.	**2.0**	**2.0**
Total score	**10.0**	**10.0**

Strengths. The leadership of the organization has established several committees and working groups, which function in different areas, such as infection prevention and control, staff health assessments, counseling to patients, etc. Those groups consist of representatives of different structural units, both clinical and non-clinical. While working together, there is consistent flow of information between group members, which support communication. The mentioned above central medical committee together with other functions also provides counseling to patients and their family members, which means that the leaders foster communication in the delivery of clinical services. Regarding communication between governance and management, there is a process of trimester reporting, which means that NTCC prepares reports on TB situation (including treatment) and sends those reports to its donors and to the Ministry of Health, which is the authorized governing body of NTCC.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified

13.4 Information about the patient's care and response to care is communicated among medical, nursing, and other health care practitioners during each staffing shift and between shifts.

In order to have a smooth process in the provision of healthcare services it is important to ensure that information about patients health status, provided services, as well as the patients response to care are communicated among healthcare specialists involved in treatment. The communication can be done it different ways: written, verbal, and oral.

Measurable elements	Max. score	Obtained score
1. There is a process to communicate patient information among the health care practitioners on an ongoing basis or at key times in the care process.	**2.5**	**2.5**
2. Information communicated includes the patient's health status.	**2.5**	**2.5**
3. Information communicated includes a summary of the care provided.	**2.5**	**2.5**

4. Information communicated includes the patient's progress.	**2.5**	**2.5**
Total score	**10.0**	**10.0**

Strengths. There are regular discussions on an everyday basis between healthcare providers involved in patient care. Besides those discussions, all the new information about patient's health status, new treatment, and patient progress, etc. are kept in the patient records, so that each new healthcare provider is well informed about the procedures carried out before.

There are regular discussions among the physicians. The main topic of those discussions is treatment dynamics, decisions whether or not to do specific examinations, whether or not to modify the treatment.

Healthcare provider 1

We regularly make entries in the patients' records, and periodically update those records. Only the physicians involved in patient care are involved in this process.

Healthcare provider 2

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified

13.5 The patient's record(s) is available to the health care practitioners to facilitate the communication of essential information.

Patients' records are an important communication tool. To be able to make use of those records it is important to keep them up-to-date and available for during the entire course of treatment. JCI recommends healthcare organizations to have policy which defines those healthcare practitioners who have access to the patients' records to ensure confidentiality of patient information.

Measurable elements	Max. score	Obtained score
1. Policy establishes those health care practitioners who have access to the patient's record(s).	**2.0**	**0**
2. The record(s) is available to those practitioners who need it for the care of the patient.	**4.0**	**4.0**
3. The record(s) is up to date to ensure communication of the latest information.	**4.0**	**4.0**
Total score	**10.0**	**8.0**

Strengths. All the patients receiving treatment at NTCC have their records. The records are available for all the current patients, and those practitioners who need it for care, can easily use the information from those records. The physician providing care to the patient makes entries periodically. Whenever there is a new medication introduced, or a referral is made for a lab test, or there is a change in patient progress, etc. the physician makes notes in the record.

> *We make new entries in the patients' records very often. Whenever something is written there, it means you can trust it and base your actions on it.*
>
> **Healthcare provider**

Weaknesses. Though only the physicians directly involved in the care process and make entries in those records, there is no policy to prevent unauthorized access to the records. Moreover, the hospital staff fails to recognize the importance of maintaining patient's information confidential.

> *We have no policy to protect unauthorized access to the patient's records. On the other hand, who should be interested to access those records other than physicians?*
>
> **Healthcare provider**

Opportunities. Considering the fact that the requirements of the standard related to the practice are fulfilled, there is a potential to develop a policy establishing those healthcare practitioners who have access to the patients records.

Threats. Absence of the policy to prevent unauthorized access to the records might cause violation of patient information confidentiality. Lack of recognition of the importance of the policy might be a potential threat to develop one.

13.6 Information related to the patient's care is transferred with the patient.

Sometimes the patients are transferred from one clinical department to another. In order to ensure a smooth transfer process as well as continuity of care JCI recommends including a summary of patient care information in the transferred records. The summary should contain information on the reason of admissions, significant findings, diagnosis made, procedures performed, medications and other treatments administered, as well as the patient's status at the transfer.

Measurable elements	Max. score	Obtained score
1. The patient's record or a summary of patient care information is transferred with the patient to another service or unit in the organization.	**4.0**	**4.0**
2. The summary contains the reason for admission.	**1.0**	**1.0**

3. The summary contains the significant findings.	**1.0**	**1.0**
4. The summary contains any diagnosis made.	**1.0**	**1.0**
5. The summary contains any procedures performed.	**1.0**	**1.0**
6. The summary contains any medications and other treatments.	**1.0**	**1.0**
7. The summary contains the patient's condition at transfer.	**1.0**	**1.0**
Total score	**10.0**	**10.0**

Strengths. During the review of the medical records the research team identified that whenever there was a transferred patient a transfer summary was attached to the clinical record containing information on the reason of admissions, significant findings, diagnosis made, procedures performed, medications and other treatments administered, as well as the patient's health status at the transfer.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified

13.7 Information privacy and confidentiality are maintained.

The healthcare organizations should address the issues of data security and confidentiality very carefully. They might deal with very sensitive data, and it is recommended to have a comprehensive policy addressing the balance between data sharing and data confidentiality.

Measurable elements	Max. score	Obtained score
1. There is a written policy for addressing the privacy and confidentiality of information that is based on and consistent with laws and regulations.	**2.5**	**0.5**
2. The policy defines the extent to which patients have access to their health information and the process to gain access when permitted.	**2.5**	**0**
3. The policy is implemented.	**2.5**	**0**
4. Compliance with the policy is monitored.	**2.5**	**0**
Total score	**10.0**	**0.5**

Strengths. The issues of data security and confidentiality are somehow addressed by the internal disciplinary regulations of the NTCC. There is a small part in that document stating that the staff should respect confidentiality and data security of their job-related activities.

Weaknesses. The document indicated above was developed during the previous administration, and requires updating since several structural changes of the organization have been made after its development. Besides, even in the current version the issues of privacy and confidentiality are not addressed comprehensively. The policy does not define the extent to which patients have access to their health information and the process to gain access when permitted. The policy is never monitored.

The clinicians have their own perception of information security and confidentiality, which may vary from clinician to clinician:

We do not provide any information about patients to the third parties. Even the nurses sometimes may not be fully aware of the situation. **Healthcare provider 1**
Whenever we identify a new infectious TB case we immediately inform the corresponding primary care facility to organize diagnostic procedures for the immediate family members of the patient. Besides, if the identified patient is a student, we also inform the corresponding educational institution. So the patient's health status cannot be kept confidential. **Healthcare provider 2**

Opportunities. A new comprehensive policy addressing data privacy and confidentiality of information should be developed to meet the requirement of the standard. Along with the development of the policy a monitoring mechanism should also be established.

Threats. Lack of recognition of the importance of the mentioned above policy might be a potential obstacle in its development.

13.8 Records and information are protected from loss, destruction, tampering, and unauthorized access or use.

The organization should ensure that the data and information are protected at all times. The patient records should be kept in areas where only authorized people can have access to. The archived information should be protected from heat, water, fire, etc. The protective processes refer to electronically stored information, too.

Measurable elements	Max. score	Obtained score

1. Records and information are protected from loss or destruction.	**5.0**	**0**
2. Records and information are protected from tampering and unauthorized access or use.	**5.0**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. The records and information are not protected from loss or destruction. There are no processes to protect the information from tampering and unauthorized access. During the data collection the research team discovered that in the past the archive of the NTCC suffered from a heavy rain, and several archived document were damaged as a result.

> *Our archive is in very poor conditions. It is very humid, which is very dangerous and increases the risk of TB infection. In the past it was damaged by a heavy rain, and some information was also damaged.*
>
> **Administration**

Opportunities. Because of the past experience with records damage the organization has increased recognition of importance of ensuring protection of data from loss and destruction. This can serve as a basis for establishing corresponding procedures for data protection.

Threats. Increased workload of the specialists involved in the process might be a potential threat to establishing the proposed processes. Besides, financial issues might also hinder the advancement of data protection.

13.9 The organization initiates and maintains a clinical record for every patient assessed or treated.

Each patient receiving treatment in the healthcare organization should a clinical record, which is unique to the patient. The organization should be able to easily locate the patient with its special identifier.

Measurable elements	Max. score	Obtained score
1. A clinical record is initiated for every patient assessed or treated by the organization.	**5.0**	**5.0**
2. Patient clinical records are maintained through the use of an identifier unique to the patient or some other effective method.	**5.0**	**5.0**
Total score	**10.0**	**10.0**

Strengths. Clinical records review showed that the organization establishes clinical records for all the patients receiving treatment in the hospital. Those records contain ID numbers which are unique for each patient.

Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified

13.10 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.

JCI recommends that the healthcare organization have a predetermined content of clinical records of the patients. The records should contain sufficient information to identify the patients, to support the diagnosis, to justify the treatment, and to document the results.

Measurable elements	Max. score	Obtained score
1. The specific content of patient clinical records has been determined by the organization.	**2.0**	**0**
2. Patient clinical records contain adequate information to identify the patient.	**2.0**	**2.0**
3. Patient clinical records contain adequate information to support the diagnosis.	**2.0**	**2.0**
4. Patient clinical records contain adequate information to justify the care and treatment.	**2.0**	**2.0**
5. Patient clinical records contain adequate information to document the course and results of treatment.	**2.0**	**2.0**
Total score	**10.0**	**8.0**

Strengths. Review of the clinical records confirmed that the process of maintaining the patients' records is consistent all over the organization. The records contain necessary information for identifying the patient, supporting the diagnosis, justifying the treatment, and documenting the results. *(See more in the Assessment of Patients section, 4.4)*

Weaknesses. NTCC does not have a predetermined specific content for the patients' medical records. They use the standard form approved by the Ministry of Health. The standard for currently in use does not have information on many important issues in terms of TB, including TB related risk factors such as migrant work.

Opportunities. NTCC can improve patients' records by developing forms specific to TB type, and population groups, and include information related to TB risk factors.

Threats. Developing a new form requires time resources, and will increase the workload of the specialists involved in its development. It might result is resistance to change.

13.11 Every patient clinical record entry identifies its author and when the entry was made in the record.

According to JCI recommendations while making entries in the patients clinical records the author and the date of entry should be identified.

Measurable elements	Max. score	Obtained score
1. The author can be identified for each patient clinical record entry.	**5.0**	**5.0**
2. The date of each patient clinical record entry can be identified.	**5.0**	**5.0**
Total score	**10.0**	**10.0**

Strengths. All the entries made in the clinical records contained the authors and the date when the entry was made.

Weaknesses. Not identified.

Opportunities. Not identified.

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				8.0	
1.2 Improve effective communication			5.0		
1.3 Reduce risk of health care-associated infections				7.0	
Function mean score	**6.7**				

- In all stages of hospitalization, patients are identified appropriately with continuous use of several identifiers at different points of care provision. However, the patients' identification practices need to be supported with development of relevant policies and procedures.

- The hospital should take steps to improve the effectiveness of communication of patient health-related information.
- The hospital has human resources for implementing programs for the health care-associated infections' risks reduction. Building up on these grounds will lead to strengthening and making the activities for infection risks reduction more targeted.

The hospital achieved 67% performance for IPSG function by meeting specific standards satisfactory or partially. The overall function was graded as **almost satisfactorily performed**. On the level of assessed standards for this function the hospital 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 Patients are admitted to receive inpatient care or registered for outpatient services based on their identified health care needs and the organization's mission and resources				8.5	
2.2 The organization has a process for admitting inpatients and for registering outpatients				8.0	
2.3 At admission as an inpatient, patients and families receive information on the proposed care, the expected outcomes of care, and any expected cost to the patient of care					10
2.4 The organization designs and carries out processes to provide continuity of patient care services in the organization and coordination among health care practitioners			6.0		
2.5 There is a policy guiding the discharge of patients				9.0	
2.6 The clinical records of inpatients contain a copy of the discharge summary				8.0	
2.7 The discharge summary of inpatients is complete					10
2.8 The receiving organization is given a written summary of the patient's					10

clinical condition and the interventions provided by the referring organization					
Function mean score				**8.7**	

- For all patients in the hospital the set of screening and diagnostic tests are initiated at the time of their first contact with physicians. The results of the screening define further treatment and care-related decisions.
- At admission, patients and family receive information on details regarding the TB treatment and the consequences of treatment/withdrawal.
- The hospital established processes that promote and support the continuity and coordination of TB care within different settings and services. Verbally set up criteria are used to determine those processes.
- The hospital lacks relevant policies to guide and standardize the patient stay in the hospital and to define the degree of patients' transfers between various settings within the hospital.
- For all patients the hospital organizes the discharge following the National Standard of TB diagnosis and treatment. Based on the assessment of the patient using the defined set of health criteria, physicians determine when the patient has to be discharged and referred to continuing outpatient treatment facility with all necessary documents, including discharge summary and follow-up instructions.

The hospital achieved 87% performance for ACC function by meeting specific standards fully, satisfactory, or partially. The overall function was graded as **satisfactorily performed**. On the level of assessed standards for this function the hospital required some 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 organization is responsible for providing processes that support patient and family rights during care		3.0			
3.2 Care is respectful of the patient's need for privacy.				7.0	
3.3 Children, disabled individuals, the elderly, and other populations at risk receive appropriate protection			4.5		

3.4 Patient information is confidential			6.5		
3.5 The organization supports the patient's right to respectful and compassionate care at the end of life			5.0		
3.6 All patients are informed about their rights and responsibilities in a manner and language they can understand			6.5		
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		1.0			
3.8 The organization establishes a process, within the context of existing law and culture, for when others can grant consent		2.0			
3.9 Informed consent is obtained before surgery, anesthesia, use of blood and blood products, and other high-risk treatments and procedures	0				
Function mean score	**3.9**				

- The National law for TB diagnosis and treatment in Armenia protects TB patient and family rights for receiving free care regardless of TB type, severity and treatment duration. Hospital physicians and leaders work to protect and advance the patient rights, primarily by maintaining confidentiality of treatment. Physicians verbally inform patients and their families about their rights. Only MDR TB department has established written policies and procedures that guide and support patient rights by informed patient consent and signed agreement to undergo treatment. Policies and procedures for other departments are verbally established. A written document specifically describing patient rights at the hospital does not exist.
- The privacy of care is given high priority at the hospital. Staff members are respectful and act accordingly to maintain patient health information confidential.

The National law lists the high-risk patient groups that need provision of high-risk services. These vulnerable groups include children, disabled individuals, and elderly and other populations at risk; for example, disabled individuals or the patients who cannot walk and only stay at home

are guaranteed with home treatment, again, covered by the state budget. However, staff members fail to understand their responsibilities to protect the vulnerable groups.

- The hospital failed to develop a formal respectful and compassionate end-of-life care for dying patients.
- The hospital performs successfully in informing patients of their illness and proposed treatments. However, uniformly informing patients and family of their rights and responsibilities is neglected; consent for an inpatient treatment, consent from people other than patients, and/or other procedures that require an additional consent are not obtained.
- All processes related to promotion and protection of patient and family rights have lacked policies and procedures that would formalize the existing practices.

The hospital achieved 39% 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 hospital 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 All patients cared for by the organization have their health care needs identified through an established assessment process			4.0		
4.2 The organization has determined the minimum content of assessment, based on applicable laws and regulations and professional standards				8.0	
4.3 Each patient's initial assessment(s) includes an evaluation of physical, psychological, social, and economic factors, including a physical examination and health history			6.0		
4.4 The patient's medical needs are identified from the initial assessments and recorded in the clinical record				8.0	

4.5 Patient assessments are completed in the time frame prescribed by the organization	0				
4.6 Assessment findings are documented in the patient's record and readily available to those responsible for the patient's care					10
4.7 All patients are reassessed at intervals based on their condition and treatment to determine their response to treatment and to plan for continued treatment or discharge					10
4.8 Medical, nursing and other individuals and services responsible for patient care collaborate to analyze and to integrate patient assessments					10
4.9 Laboratory services are available to meet patient needs, and all such services meet applicable local and national standards, laws, and regulations		1.0			
4.10 A laboratory safety program is in place, followed and documented			4.0		
4.11 Individuals with proper qualifications and experience administer the test and interpret the results. Laboratory results are available in a timely way as defined by the organization				8.0	
4.12 All equipment used for laboratory testing is regularly inspected, maintained and calibrated and appropriate records are maintained for these activities			6.0		
4.13 Essential reagents and other supplies are regularly available and evaluated to ensure accuracy and precision of lab results				8.0	
4.14 Established norms and ranges are used to interpret and to report clinical laboratory results				9.0	
4.15 A qualified individual(s) is responsible for managing the clinical laboratory service or pathology service				9.0	
4.16 Quality control procedures are in place, followed, and documented		1.3			
4.17 Laboratory access		2.0			

4.18 Personal protective equipment				7.7	
4.19 Procedures for patient assessment				7.8	
4.20 Work areas and design			5.5		
4.21 A radiation safety program is in place, followed and documented			6.0		
4.22 Individuals with proper qualifications and experience perform diagnostic imaging studies, interpret the results and report the results. Radiology and diagnostic imaging study results are available in a timely way as defined by the organization				8.5	
4.23 All equipment used to conduct radiology and diagnostic imaging study is regularly inspected, maintained and calibrated and appropriate records are maintained for these activities			6.0		
4.24 A qualified individual(s) is responsible for managing the radiology and diagnostic imaging services		2.0			
4.25 Quality control procedures are in place, followed, and documented for patient assessments			4.0		
Function mean score	**6.1**				

- All patients undergo an internally established assessment process which leads to identification of their health care needs. The hospital follows the minimum content of assessment to diagnose TB as defined by laws and regulations. However, the hospital does not have policies guiding what assessment information should be collected and documented and does not have policies adapted from the laws and regulations on minimum content of the assessment. Patient's psychological assessment is not uniformly organized for all patients.
- Patients' medical needs are identified collaboratively with different healthcare providers. The identified medical needs and all assessment findings are documented in the medical records.
- There is no pre-defined timeframe in which patient assessment should be completed and documented in the patient's record. However the intervals of reassessments are well defined and strictly maintained across departments: patients are reassessed at appropriate intervals, as determined by the patient's health status and response to treatment. Findings from patient reassessment are documented in the clinical records.

- The hospital laboratory infrastructure and services are failing to meet applicable local and national standards, laws, and regulations. It is also lacking to have programs toward safety, equipment management, and quality control.
- The laboratory is staffed with qualified individuals for administering and interpreting laboratory tests and with qualified individual for supervising laboratory services.
- The laboratory is successful in performing procedures as collecting, identifying, handling, and safely transporting and disposing of specimens. However, there is a lack of established timeframe in which results of the tests should be reported to physicians responsible for patient care and procedures highlighting continuous evaluation of essential reagents, review and update of established norms and ranges.
- The laboratory equipment is inspected and maintained on a regular basis by the local technical staff while calibration performed by a contracted company. However, there are no written documents to outline rules and quality control procedures with respect to equipment inspection, maintenance, calibration, or validation of test results. Moreover, some essential laboratory equipment is out of function for a long time and because of that the sputum smear testing is done outside, in the National Reference Laboratory leading to delays for testing, results reporting and quality complaints.
- The supplies are in adequate quantity, and maintained according to their date of expiration. However, from time to time the laboratory experiences a shortage of necessary reagents and supplies, because of the financial constraints and the tendering process.
- The radiology and diagnostic imaging services are regularly available to meet patients' needs and are consistent with applicable local and national standards, laws, and regulations. However, the department does not have written policies and procedures guiding the processes related to radiation safety assurance and timeframes for reporting radiology and diagnostic imaging study results.
- As for radiology services, there is a lack of established programs towards radiation safety, radiology and diagnostic imaging equipment management, and quality control.
- The radiology and diagnostic imaging department also is staffed with individuals qualified to administer and interpret the X-ray imaging and with individuals qualified to supervise the department's services. However, the responsibilities associated with quality control of the department's services are not part of the job responsibilities for the department director.

The hospital achieved 61% performance for ACC function by meeting specific standards fully, 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 hospital required several 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 Policies and procedures and applicable laws and regulations guide the uniform care of all patients				8.0	
5.2 There is a process to integrate the care provided to each patient					10
5.3 The care provided to each patient is planned and written in the patients' record. Procedures performed are written into the patient's record					10
5.4 Those permitted to write patient orders write the order in the patient record in a uniform location				8.5	
5.5 Policies and procedures guide the care of high-risk patients and the provision of high-risk services				8.0	
5.6 A variety of food choices, appropriate for the patient's nutritional status and consistent with his or her clinical care, is regularly available. Food preparation, handling, storage, and distribution are safe and comply with laws, regulations, and current acceptable practices			5.5		
Function mean score	**7.1**				

- Following the National law for TB diagnosis and treatment clinical and managerial leaders at the hospital collaboratively provide uniform care to all TB patients across departments. Regular inter-departmental meetings, 5-minutes briefings, integrated patient records, and the

assignment of the patient's physician and nurses as their "care managers" are the principal techniques used to achieve coordination of care.

- Heads of departments for drug-susceptible patients and DR-committee for drug-resistant patients in collaboration with the treating physicians produce plans for a patient's care as soon as the smear and culture tests results become available. Plans are revised consistent with changes in the patient's condition and qualified individuals document all results, performed procedures and care provided to patients in the medical records.
- There is no uniform, established process for making orders for services such as laboratory testing, administration of medication, etc, which can be communicated either verbally or in writing. The hospital failed to develop specific operational procedures to guide orders or services, and define the location in patient records where the orders should be placed.
- Clinical staff in the hospital provides services to high-risk patient groups guided by the National Standard for TB diagnosis and treatment and verbally. The hospital has a separate department for children, where care of young, dependent children is managed and guided by the departmental regulations. However, specific policies and procedures to guide the care of vulnerable patients do not exist.
- The hospital has a kitchen that provides food to patients according to internal schedule: three times a day. However, the kitchen physical conditions and the food preparation equipment appeared to be in poor state and not concordant with acceptable practices. This might pose additional risk for food cross contamination.

The hospital achieved 71% performance for PFR function by meeting specific standards fully, satisfactory or partially. The overall function was graded as **satisfactorily performed**. On the level of assessed standards for this function the hospital required some 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 Medication use in the organization complies with applicable laws and regulations and is organized to meet patient needs		2.5			

6.2 Supervision of the pharmacy or pharmaceutical service. There is a method for overseeing the organization's medication use					10
6.3The organization can readily obtain medications not stocked or normally available to the organization or for times when the pharmacy is closed				8.0	
6.4 Medications are properly and safely stored			6.5		
6.5 Emergency medications are available, monitored and safe when stored out of pharmacy			5.0		
6.6 The organization has a medication recall system				7.0	
6.7 Prescribing, ordering, and transcribing are guided by policies and procedures		3.0			
6.8 Medications prescribed and administered are written in the patient's record				8.6	
6.9 A system is used to dispense medications in the right dose to the right patient at the right time				9.0	
6.10 The organization identifies those qualified individuals permitted to administer medications			6.7		
6.11 Medication administration includes a process to verify the medication is correct based on the medication order					10
6.12 Medication effects on patients are monitored			4.7		
6.13 Medication errors, including near missed, are reported through a process and time frame defined by the organization	0				
Function mean score	**6.2**				

- Medication management processes in the hospital are regulated by verbally established policies. No document on policies/procedures guides the phases of medication management and use, and no processes and the implemented practices are evaluated for appropriateness and quality.
- The hospital has "Medication Planning and Use" department supervised by licensed, certified and trained pharmacists who is responsible for medication management, use, and protection

from loss or theft. This department successfully ensures timely procurement of medications not stocked in the hospital, availability of emergency medications in all clinical units of the hospital and safe and proper storage of medications in the storehouses.

- The medication dispensing and distribution system at hospital is uniform. One treatment regimen with a specific list of medications is prescribed to be administered by the treating physicians and the heads of the departments. Throughout the hospital qualified individuals, permitted by job description, administer medications to patients after verifying with prescriptions to assure correct doses to correct patients at correct time. Each dose administered is noted in the medical record. However, all the processes of prescription, ordering, administration and documentation of medications are established verbally with no written policies and procedures for support.
- The hospital has developed a medication recall system which addresses the use of expired or outdated medications. However, these processes are conducted through internal agreements rather than respective documentation.
- Medications effects, including the adverse effects are monitored routinely in collaboration with the Scientific Center of Drug and Medical Technology Expertise. Though the DR-TB department treatment files contain a special form to track the adverse effects of anti-TB medications, the records are incomplete. The hospital fails to practice and to develop a policy to systematically document, track, report, monitor, and analyze adverse effects.
- The hospital has failed to define and acknowledge any medication error including near misses that should be tracked in the hospital.

The hospital achieved 62% performance for PFR function by meeting specific standards fully, 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 hospital 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 organization provides education that supports patient and family	0				

participation in care decision and care processes					
7.2 Each patient's educational needs are assessed and recorded in his or her record	0				
7.3 The patient's and family's ability to learn and willingness to learn are assessed	0				
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 and food, nutritional guidance, pain management. Patients and families receive adequate information about the illness, proposed treatment(s), and health care practitioners so that they can make care decisions.			6.5		
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	0				
7.6 Health professionals caring for the patient collaborate to provide education				9.0	
Function mean score	**2.6**				

- The hospital has failed to develop a uniform education plan that will be delivered to patients and families in a consistent manner. The healthcare providers educate patients and their families on TB-related topics without being guided by a structured program and educational materials and merely motivated by their common sense and by patients demand.
- Healthcare providers do not assess any of patient and family educational needs, ability and willingness to learn, and/or degree of comprehension of received education.
- All healthcare providers who are there to educate patients, are knowledgeable of the subject that is to be taught, however their counseling skills are not well developed and they more inclined to answer questions than to initiate discussion. Some health providers even believe that providing detailed information to patients and families about the disease is irrational.

The hospital achieved 26% performance for PFR function by meeting one specific standard satisfactory, another partially and the rest not meeting at all. The overall function was graded as **minimally performed**. On the level of assessed standards for this function the hospital required major improvements.

8. 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)
8.1 Availability of "No Smoking" signs			3.5		
8.2 Availability of smoking related functional items and policies in the areas where smoking is prohibited				7.0	
8.3 Presence of proofs related to tobacco-free environment	0				
Function mean score	**3.5**				

- The "No Smoking" signs are placed in some areas of the NTCC though they are not evenly distributed in the NTCC. Statements on financial and other penalties for illegible smoking practices are absent in the areas with high patients and staff flow.
- The NTCC has set formal grounds to eliminate smoking practices among staff, patients, families and visitors. However, the functional items and proofs associated with smoking are still present in the NTCC that undermines the effectiveness of smoking elimination program.

The hospital achieved 35% performance for TBTC function by meeting one specific standard satisfactory, one hardly partially and one not meeting at all. The overall function was graded as **partially performed**. On the level of assessed standards for this function the hospital required several improvements.

9. 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)
9.1 Those responsible for governing and managing the organization participate in planning and measuring a quality improvement and patient safety program.		0.5			

9.2 Quality improvement and patient safety information is communicated to staff.			5.0		
9.3 The organization designs new and modified systems and processes according to quality improvement principles.		0.3			
9.4 Clinical practice guidelines, clinical pathways, and/or clinical protocols are used to guide clinical care.		1.0			
9.5 The organization's leaders identify key measures in the organization's structures, processes, and outcomes to be used in the organization wide quality improvement and patient safety plan.		1.0			
9.6 Individuals with appropriate experience, knowledge, and skills systematically aggregate and analyze data in the organization.					10
9.7 The analysis process includes comparisons internally, with other organizations when available, and with scientific standards and desirable practices.		2.5			
9.8 The organization uses a defined process for identifying and managing sentinel events.	0				
Function mean score	**2.5**				

- There is no formal quality improvement and patient safety program established in the NTCC. Some related activities, however, could be categorized as "QPS activities". They are carried out by a group of clinicians called "central medical commission" that includes the heads of departments and the head physician, who gather periodically to discuss various difficult cases related to TB diagnosis and treatment. Results of these quality improvement activities later communicated to the clinical staff by the heads of the departments and the head nurse. But the organization has no follow-up mechanism to ensure that the information has reached the clinicians, and that the new requirements/recommendations/ are correctly practiced in reality.
- Understandings of quality and patient safety as well as a quality improvement principles and tools in NTCC are very narrow. The perception of quality is limited to just infection prevention. The inherited culture of the hospital is a blaming and hiding one, where talking about the drawbacks, weaknesses and areas for improvement is not an accepted practice.

- There is no systematic approach to evaluate any newly introduced methods or process related to TB hospital care and no practice of systematically selecting areas for measurement and improvement for the purposes of quality improvement and patient safety in the organization. However, the organization leaders are aware that there are areas for improvement, and they have identified one of those areas: continuous education for nurses.
- Inpatient care in the NTCC is guided by the national TB treatment guideline and supported by some other practice guidelines approved and recommended by the Ministry of Health of the RA. The hospital blindly follows those guidelines and has no mechanisms for the adaption.
- There is monitoring and evaluation unit in the organization, dealing with national data analysis. They develop different reports and make presentations on the findings related to TB situation all over the country. This unit does not conduct hospital - wide assessments that can contribute to defining the areas for quality improvement and patient safety.
- The organization has periodic reports of their activities. This helps to define improvement in the quality of care by including comparisons within the organization over time. However, no external comparisons ever made – neither with other organizations, nor with acceptable practice standards.
- NTCC has no operational definition for "sentinel events", resulting on absence of its root cause analysis and actions to be taken.

The hospital achieved 25% performance for QPS function by meeting majority of specific standards minimally and others fully, partially, or not meeting at all. The overall function was graded as **minimally performed**. On the level of assessed standards for this function the hospital required major improvements.

10. 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)
10.1 One or more individuals oversee all infection prevention and control activities. This individual(s) is qualified in infection prevention and					10

control practices through education, training, experience, or certification.					
10.2 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.				6.8	
10.3 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.				8.5	
10.4 The organization's leaders provide adequate resources to support the infection prevention and control program			6.7		
10.5 The organization designs and implements a comprehensive program to reduce the risks of health care–associated infections in patients and health care workers.				7.0	
10.6 All patient, staff, and visitor areas of the organization are included in the infection prevention and control program.					10
10.7 The organization identifies the procedures and processes associated with the risk of infection and implements strategies to reduce infection risk.					10
10.8 There is a policy and procedure in place that identifies the process for managing expired supplies and defines the conditions for reuse of single-use devices when laws and regulations permit.				7.7	
10.9 The organization has a policy and procedure on the disposal of sharps and needles.					10
10.10 Gloves, masks, eye protection, other protective equipment, soap, and disinfectants are available and used correctly when required.				7.5	

10.11 The organization tracks infection risks, infection rates, and trends in health care–associated infections.	0				
10.12 The results of infection prevention and control measurement in the organization are regularly communicated to leaders and staff.				7.3	
10.13 The organization provides education on infection prevention and control practices to staff, physicians, patients, families, and other caregivers when indicated by their involvement in care.			6.0		
Function mean score	**7.5**				

- The NTCC hospital has a comprehensive infection control program operating by special organizational unit called "Nosocomial infection and quality control" and coordinated by the Infection control committee aiming at reducing infection risks among patients and healthcare workers. This program is based on Armenian laws and regulations, currently accepted practice guidelines, and standards from local and international agencies, but not much on current scientific knowledge.
- The infection control program identifies and establishes the infection types, infection sites and associated devices to minimize the incidence of nosocomial infections. It implements strategies and procedures to also minimize the risk of infection among the staff. However the data collected is not analyzed thoroughly to determine endemic rates of infection, the risks, rates and trends of healthcare associated infections are not tracked and the available results not systematically reported to the responsible bodies.
- The organization uses appropriate policies on infection prevention and control, such as policies on hand hygiene, on managing expired supplies, on the disposal of sharps and needles. However the policies are not monitored and actions are not followed-up properly.
- The staff at NTCC is oriented to the policies, procedures, and practices of the infection control program through formal and informal meetings and workshops. The orientation is based on transferring the knowledge to the heads of clinical departments and to the head nurses. Other frontline clinicians are not contacted directly. No follow-up mechanism on information dissemination is applied.

- Physicians provide informal education regarding the prevention of infection to patients and their families. As the topics and the scope of the provided information are not formally defined, the quality of such education varies and greatly depends on a physician working style.

The hospital achieved 75% performance for PCI function by meeting majority of specific standards fully or satisfactorily, others partially or not meeting at all. The overall function was graded as **satisfactorily performed**. On the level of assessed standards for this function the hospital required some improvements.

11. 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)
11.1 Governance responsibilities and accountabilities are described in bylaws, policies and procedures, or similar documents that guide how they are to be carried out.			5.0		
11.2 Those responsible for governance approve and make public the organization's mission statement.	0				
11.3 Those responsible for governance approve the policies and plans to operate the organization.					10.0
11.4 Those responsible for governance approve the budget and allocate the resources required to meet the organization's mission.					10.0
11.5 Those responsible for governance appoint the organization's senior manager(s) or director(s).		3.3			
11.6 A senior manager or director is responsible for operating the organization and complying with applicable laws and regulations.					10.0
11.7 Organization leaders ensure that there are uniform programs for the recruitment, retention, development, and continuing education of all staff.		1.5			

11.8 Medical, nursing, and other leaders of clinical services plan and implement an effective organizational structure to support their responsibility & authority				7.5	
11.9 Directors recommend space, equipment staffing, and other resources needed by the department or service.					10.0
11.10 Directors recommend criteria for selecting the department or service's professionals and choose/ recommend individuals who meet those criteria.	0				
11.11 Directors provide orientation and training for all staff of the duties and responsibilities for the department or service to which they are assigned.		0.5			
Function mean score	**5.3**				

- The organizational charter of the NTCC, approved by the Ministry of Health of the RA, describes its governance structure, the organization goals and objectives, and the responsibilities and accountabilities of the Governance. However it does not include the mission of the organization to communicate it to the public.
- All the policies and plans to operate the organization, the budget and resources required, and the educational programs for the staff are approved by the governance of the hospital – the Ministry of Health.
- The organization has a strict hierarchical structure, where everyone is aware on the subordination order, which in turn, helps to carry out everyday responsibilities. The senior management ensures the compliance of the daily operations of the organization to the applicable national laws and regulations. But the hospital has no standards for measuring the quality of services and has no tool to evaluate and document the performance of senior management.
- The director of NTCC is appointed by the Ministry of Health of the RA. The director can recommend human, space, equipment, and other material resources needed in the provision of healthcare services, but he is not involved in developing criteria related to the needed education, skills, knowledge and experience of the professional staff. There is no criterion about those issues at all and no uniform programs for the recruitment, retention, development and continuing education for all the staff.

- There is no documented orientation program for the staff, but there is a procedure of introducing the job duties and responsibilities of the department, and the particular employee during the process of hiring.

The hospital achieved 53% performance for GLD function by meeting specific standards fully, satisfactorily, 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 hospital required several improvements.

12. 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)
12.1 The organization uses a defined process to ensure that clinical staff knowledge and skills are consistent with patient needs and the non-clinical staff's knowledge and skills are consistent with the organization's needs.	0				
12.2 Organization leaders define the desired education, skills, knowledge, and other requirements of all staff members. There is documented personnel information for each staff member.				7.0	
12.3 Each staff member receives ongoing in-service and other education and training to maintain or to advance his or her skills and knowledge.		1.5			
12.4 The organization provides a staff health and safety program.					10.0
12.5 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.			6.7		
12.6 Leadership makes an informed decision about renewing permission for each medical staff member to continue providing patient care services at least every three years.	0				
Function mean score	**4.2**				

- There are no uniform processes in place for recruiting, evaluating, and appointing staff in the organization and matching clinical staff knowledge with patient needs. As for other staff members, there is no formal assessment and evaluation of clinical staff performance.
- Some of the organizational units at the NTCC have developed internal regulations for guiding their daily practices. Those internal regulations contain requirements on the desired education and experience for the heads of the departments, physicians, nurses and midwives. Besides those internal regulations, there are some job-descriptions developed for some of the positions containing educational and experience requirements. However, the existing regulations were developed before major structural changes in the NTCC, and are currently not relevant. Besides, not all of the units have developed internal regulations.
- Many of the staff members at NTCC, both administrative, and clinical, participate in different trainings in local and international levels. Most of the hospital physicians have participated in such trainings. However, no formal assessments using systematic approach are carried out to identify the educational needs of the staff and the organization has no formalized on-service educational program for the staff.
- All the required documents capturing the education and licensure of staff members are gathered and kept in the personnel folders, but there is no mechanism to verify those credentials.
- Organization has failed to develop the process of reviewing, projections or planning, or changes in staffing plans and it has no designated individuals to make an official recommendation about renewal decision of the clinical staff to continue providing patient care services.
- There is a special program for staff health and safety in the NTCC. The program is based on several documents, including governmental decrees and internal hospital-wide regulations.

The hospital achieved 42% performance for SQE function by meeting specific standards fully, satisfactorily, 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 hospital required several improvements.

13. MANAGEMENT OF COMMUNICATION AND INFORMATION (MCI)					
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 The organization informs patients and families about its care and services and how to access those services.					10.0
13.2 Communication is effective throughout the organization.					10.0
13.3 The leaders ensure that there is effective communication and coordination among those individuals and departments responsible for providing clinical services.					10.0
13.4 Information about the patient's care and response to care is communicated among medical, nursing, and other health care practitioners during each staffing shift and between shifts.					10.0
13.5 The patient's record(s) is available to the health care practitioners to facilitate the communication of essential information.				8.0	
13.6 Information related to the patient's care is transferred with the patient.					10.0
13.7 Information privacy and confidentiality are maintained.		0.5			
13.8 Records and information are protected from loss, destruction, tampering, and unauthorized access or use.	0				
13.9 The organization initiates and maintains a clinical record for every patient assessed or treated.					10.0
13.10 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.				8.0	
13.11 Every patient clinical record entry identifies its author and when the entry was made in the record.					10.0
Function mean score	**7.9**				

- The patients and families are informed about the care and services the organization provides. They receive all the relevant information during the initial counseling by TB physicians.
- By having several committees and working groups functioning in areas of infection prevention and control, staff health assessments, and counseling to patients, the leadership of the organization has established and ensured effective communication in the hospital daily operations through meetings, clinical rounds, and discussions, including the regular discussions on an everyday basis between healthcare providers involved in patient care.
- All the patients receiving treatment at NTCC have their records accessible 24 hour for health practitioners involved in patient care management. These records completed by the healthcare providers include sufficient information to support TB patients' diagnosis, course of treatment, and its results, clearly indicating the authors and the date of data entry. The records are transferred with the patients clearly indicating the patient's health status at the transfer. However, the patient records do not include specific information on many important issues in terms of TB such as TB related risk factors.
- The patients' records and information are not protected from loss or destruction. There is no policy to prevent unauthorized access to the records, and the hospital staff fails to recognize the importance of maintaining patient's information confidential. The issues of privacy and confidentiality are not addressed comprehensively within the organization.

The hospital achieved 79% performance for MCI function by meeting majority of specific standards fully, others satisfactorily, minimally, or not meeting at all. The overall function was graded as **satisfactorily performed**. On the level of assessed standards for this function the hospital required some improvements.

RECOMMENDATIONS

The main recommendations that derived from the Quality Assessment of Diagnostic and Inpatient Treatment Services of the National Tuberculosis Control Center 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 such as development of policies, procedures, written documentations 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:

- Improve the accuracy of patient identification process through development of policies and procedures to formalize and standardize the patient identification process. Establish monitoring mechanisms to surveil an implementation of these policies.
- Advance the effectiveness of communication of patients' health-related information while placing and documenting orders/ tests results by confirmation of orders and test results and by the use of electronic databases. The policies should be developed to support and guide all stages of communication of patient health-related information between staff members.
- Improve the processes related to the access and continuity of care through development of policies and criteria standardizing patient stay in the NTCC.
- Orient NTCC staff members towards the infection risks reduction vision and practices to combat the health care-associated infections. Strengthen internal surveillance system and monitoring mechanisms to improve the overall effectiveness of infection prevention and control program.
- Involve the frontline clinicians in educational programs on infection prevention and control more extensively. Specific follow-up mechanisms should be developed to make sure that the disseminated information has reached the target.
- Develop infection prevention and control activities that will involve tracking and thoroughly analyzing the risks, rates, and trends of healthcare-associated infection. The endemic rates of healthcare-associated infections should also be defined.

- Formally and systematically monitor the infection prevention policies and activities with systematically applied corresponding actions.
- Implement uniform and systematic training of patients and families on infection prevention and control activities. For this reason a specific list of topics to cover should be developed and used during the counseling sessions.
- Develop a written document describing patient and family rights at the hospital. Develop policies and procedures for all clinical departments of the NTCC that will guide and support patient rights by informed patient consent and signed agreement to undergo treatment.
- Advance patient and family rights protection with appropriately informing patients and families of their rights and responsibilities by implementing a uniform informed consent process, obtaining consent for inpatient treatment from people other than patients and obtaining consent for high-risk procedures.
- Develop policies and procedures that will guide all processes pertaining to patient and family rights protection and promotion.
- Establish an environment of respect and compassion and develop policies and procedures guiding the care of vulnerable patients and patients receiving end-of-life care.
- Develop specific policies and processes to protect the patient's medical records from loss, destruction, and unauthorized access.
- 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.
- Improve and standardize patients' assessment process by setting timeframes for implementation of assessments and reporting the diagnostic laboratory test results.
- Reconstruct and renovate the laboratory that failed to meet applicable local and national standards, laws and regulations. Establish laboratory equipment management, quality control and laboratory safety programs in the NTCC Laboratory department. Develop policies and procedures that will outline the rules and quality control procedures with respect to equipment inspection, maintenance, calibration or validation of test results.
- Assure the NTCC laboratory with functioning laboratory equipment and appropriate amounts of essential reagents to advance the quality of laboratory services.

- Develop policies and procedures guiding the processes of radiation safety assurance in the Radiology and Diagnostic Imaging department and standardize performing the imaging studies through setting timeframes for reporting radiology and diagnostic imaging study results.
- Establish radiology and diagnostic equipment management, quality control and radiation safety programs in the NTCC Radiology and Diagnostic Imaging department.
- Define the responsibilities associated with administrative oversight of the NTCC Radiology and Diagnostic Imaging department.
- Develop operational procedures to guide the process of placing orders/services, and define the locations in patient records where the orders should be documented.
- Modify the forms of patient records to include specific information on several important issues in terms of TB risk factors.
- Develop policies and procedures guiding the medication management and use. The policies will also describe the processes that are to be implemented to evaluate the appropriateness and quality of medication management and use processes.
- Develop written policies and procedures that will guide and support medication prescription, ordering, administration and documentation processes, and the medication recall system.
- Develop policies describing the medication adverse effects that should be documented, tracked, reported, monitored and analyzed. The respective policies should be enforced throughout the hospital. The collected data are proposed to be used for the purposes such as analysis and integration into internal researches of the NTCC.
- Define and acknowledge the medication errors, including the near misses that should be tracked in the NTCC. Introduce a system which will take actions to monitor the medication errors and near misses, including recording and reporting. This system should include all settings of the hospital and share the common understanding of importance of acknowledging the medication errors and near misses for improving the overall quality of medication use processes.
- Advance the patients and family education process by developing a uniform, structured education program consistent with mission, services and patient population of the NTCC. Allocate adequate resources to the conduct of an effective education program for all patients.

- Perform educational needs assessment and adapt the delivery of education program to the patients' needs, ability and willingness to learn. Implement evaluation of effectiveness of the education program delivery through assessment of patients' degree of comprehension of received education.
- Establish a formal comprehensive quality improvement program, which will incorporate into it 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 the NTCC 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 hospital-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 hospital-level evaluations along with their other functions. This should include comparing hospital-level data with similar data from other organizations, as well as with acceptable practices.
- Develop clear operational definitions of "sentinel events" and "medical errors" relevant to their practice areas. Root cause analysis and other techniques of analyzing such events should be incorporated into the daily practice.
- Developed and at least annually carry out systematic evaluation of the senior management performance.
- Define clearly and share with the public the mission of the NTCC.
- 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.

- Introduce a formal orientation program for the staff consistent throughout the organization.
- Establish formal processes to evaluate the educational needs of the staff. Based on that evaluation, develop a formal on-service educational program for the staff.
- Advance the smoking elimination practices as guided by the policies of the NTCC. Place more "No Smoking" signs throughout the NTCC along with the statements of financial and other penalties for smoking practices in the restricted areas. Actively reinforce the smoking elimination program by restricting the use of smoking-related functional items and taking actions on detected smoking-related proofs.

Potential Areas of Improvement

The Management and Clinical Leadership at the NTCC are urged to develop written policies and procedures corresponding to the national laws and regulations and to define standards of care to which the organization wants to hold its health professionals accountable. The policies should identify appropriateness of transfers and characterize the roles and responsibilities of each of the health practitioner involved in those processes i.e. to ensure the continuity and coordination of care.

The NTCC does not have a formal Continuous Quality Improvement (CQI) infrastructure and program. It is recommended that a CQI Program be officially established at the NTCC (at both inpatient and outpatient levels) along with strengthening those existing infrastructures that are linked to quality. The responsibilities of planning, coordinating, and implementing the CQI program should be allocated to a multidisciplinary team of health professionals who will report to the Management and Clinical Leadership; there might be a need for hiring properly trained health professionals with CQI expertise.

The NTCC needs to develop a modern diagnostic infrastructure, including laboratory and radiology, to meet local and international standards, laws and regulations. Strengthening of diagnostic services requires financial resources, technical equipment and human resource trainings to implement newly adapted processes. The hospital leadership should establish a safety program that will address safety risks within and outside the diagnostic areas. The regulation of this safety structure should describe the planned processes to assure the safety.

It is recommended that the NTCC inpatient services continue improvement of medical records and increase data collection and analysis activities in order to further study the relationship between health care delivery and patient outcomes. The mentioned activities would straighten the monitoring of patient-level data. More specifically, the following areas might be targeted for action:

- ✓ Aggregation and critical analysis of patient-level data that are currently collected to identify areas for improving care.
- ✓ Establishing mechanisms to follow-up infection prevention activities tracking infection risks, rates, and trends in healthcare associated infections.
- ✓ Collection of data on patient health, including psychological and functional status before treatment and at different intervals during TB treatment, including during the continuation phase of treatment, and at the completion of treatment.
- ✓ Enhancement of methods used to analyze data in order to account risk factors including, but not limited to TB infection, all the treatment outcomes and relapses, and development of MDR/XDR TB.

The research team discovered that the health providers in almost all functional areas at the NTCC lacked appropriate continuous professional development opportunities. It is recommended that the NTCC improves the quality of its training programs by identifying the training needs and developing an action plan for meeting those needs.

The results of this needs assessment will help to develop a multiyear plan for establishing a CQI system at the NTCC.

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APPENDIX 1. List of Assessed Functions and Standards

1. **International Patient Safety Goals (IPSG)**
    - 1.1. Identify patients correctly.
    - 1.2. Improve effective communication.
    - 1.3. Reduce risk of health care-associated infections.

2. **Access and Continuity of Care (ACC)**
    - 2.1. Patients are admitted to receive inpatient care or registered for outpatient services based on their identified health care needs and the organization's mission and resources.
    - 2.2. The organization has a process for admitting inpatients and for registering outpatients.
    - 2.3. At admission as an inpatient, patients and families receive information on the proposed care, the expected outcomes of care, and any expected cost to the patient of care.
    - 2.4. The organization designs and carries out processes to provide continuity of patient care services in the organization and coordination among health care practitioners.
    - 2.5. There is a policy guiding the discharge of patients.
    - 2.6. The clinical records of inpatients contain a copy of the discharge summary.
    - 2.7. The discharge summary of inpatients is complete.
    - 2.8. The receiving organization is given a written summary of the patient's clinical condition and the interventions provided by the referring organization.

3. **Patients and Family Rights (PFR)**
    - 3.1. The organization is responsible for providing processes that support patients' and families' rights during care.
    - 3.2. Care is respectful of the patient's need for privacy.
    - 3.3. Children, disabled individuals, the elderly, and other populations at risk receive appropriate protection.
    - 3.4. Patient information is confidential.
    - 3.5. The organization supports the patient's right to respectful and compassionate care at the end of life.
    - 3.6. All patients are informed about their rights and responsibilities in a manner and language they can understand.
    - 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.
    - 3.8. The organization establishes a process, within the context of existing law and culture, for when others can grant consent.
    - 3.9. Informed consent is obtained before surgery, anesthesia, use of blood and blood products, and other high-risk treatments and procedures.

4. **Assessment of Patients (AOP)**
    - 4.1. All patients cared for by the organization have their health care needs identified through an established assessment process.
    - 4.2. The organization has determined the minimum content of assessment, based on applicable laws and regulations and professional standards.
    - 4.3. Each patient's initial assessment(s) includes an evaluation of physical, psychological, social, and economic factors, including a physical examination and health history.

4.4. The patient's medical needs are identified assessments and recorded in the clinical record.
4.5. Assessments are completed in the time frame prescribed by the organization.
4.6. Assessment findings are documented in the patient's record and readily available to those responsible for the patient's care.
4.7. All patients are reassessed at intervals based on their condition and treatment to determine their response to treatment and to plan for continued treatment or discharge.
4.8. Medical, nursing and other individuals and services responsible for patient care collaborate to analyze and to integrate patient assessments.
4.9. Laboratory services are available to meet patient needs, and all such services meet applicable local and national standards, laws, and regulations.
4.10. A laboratory safety program is in place, followed and documented.
4.11. Individuals with proper qualifications and experience administer the test and interpret the results. Laboratory results are available in a timely way as defined by the organization.
4.12. All equipment used for laboratory testing is regularly inspected, maintained and calibrated and appropriate records are maintained for these activities.
4.13. Essential reagents and other supplies are regularly available and evaluated to ensure accuracy and precision of results.
4.14. Established norms and ranges are used to interpret and to report clinical laboratory results.
4.15. A qualified individual(s) is responsible for managing the clinical laboratory service or pathology service.
4.16. Quality control procedures are in place, followed, and documented.
4.17. Laboratory access.
4.18. Personal protective equipment.
4.19. Procedures.
4.20. Work areas and design.
4.21. A radiation safety program is in place, followed and documented.
4.22. Individuals with proper qualifications and experience perform diagnostic imaging studies, interpret the results and report the results. Radiology and diagnostic imaging study results are available in a timely way as defined by the organization.
4.23. All equipment used to conduct radiology and diagnostic imaging study is regularly inspected, maintained and calibrated and appropriate records are maintained for these activities.
4.24. A qualified individual(s) is responsible for managing the radiology and diagnostic imaging services.
4.25. Quality control procedures are in place, followed, and documented.

5. Care of Patients (COP)

5.1. Policies and procedures and applicable laws and regulations guide the uniform care of all patients.
5.2. There is a process to integrate the care provided to each patient.
5.3. The care provided to each patient is planned and written in the patients' record.
5.4. Those permitted to write patient orders write the order in the patient record in a uniform location.

5.5. Policies and procedures guide the care of high-risk patients and the provision of high-risk services.
5.6. A variety of food choices, appropriate for the patient's nutritional status and consistent with his or her clinical care, is regularly available. Food preparation, handling, storage, and distribution are safe and comply with laws, regulations, and current acceptable practices.

6. Medication Management and Use (MMU)

6.1. Medication use in the organization complies with applicable laws and regulations and is organized to meet patient needs.
6.2. Supervision of the pharmacy or pharmaceutical service. There is a method for overseeing the organization's medication list and medication use.
6.3. The organization can readily obtain medications not stocked or normally available to the organization or for times when the pharmacy is closed.
6.4. Medications are properly and safely stored.
6.5. Emergency medications are available, monitored and safe when stored out of pharmacy.
6.6. The organization has a medication recall system.
6.7. Prescribing, ordering, and transcribing are guided by policies and procedures.
6.8. Medications prescribed and administered are written in the patient's record.
6.9. A system is used to dispense medications in the right dose to the right patient at the right time and in a safe and clean environment.
6.10. The organization identifies those qualified individuals permitted to administer medications.
6.11. Medication administration includes a process to verify the medication is correct based on the medication order.
6.12. Medication effects on patients are monitored.
6.13. Medication errors, including near missed, are reported through a process and time frame defined by the organization.

7. Patient and Family Education (PFE)

7.1. The organization provides education that supports patient and family participation in care decision and care processes.
7.2. Each patient's educational needs are assessed and recorded in his or her record.
7.3. The patient's and family's ability to learn and willingness to learn are assessed.
7.4. Patient and family education includes the following topics, related to the patient's care: the safe use of medications, the safe use of medical equipment, potential interactions between medications and food, nutritional guidance, pain management, and rehabilitation techniques.
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.
7.6. Health professionals caring for the patient collaborate to provide education.

8. TB-Tobacco Control (TBTC)

8.1. Availability of "No smoking" signs.
8.2. Availability of smoking related functional items and policies in the areas where smoking is prohibited.
8.3. Presence of proofs related to tobacco-free environment.

9. Quality Improvement and Patient Safety (QPS)

9.1. Those responsible for governing and managing the organization participate in planning and measuring a quality improvement and patient safety program

9.2. Quality improvement and patient safety information is communicated to staff.

9.3. The organization designs new and modified systems and processes according to quality improvement principles.

9.4. Clinical practice guidelines, clinical pathways, and/or clinical protocols are used to guide clinical care.

9.5. The organization's leaders identify key measures in the organization's structures, processes, and outcomes to be used in the organization wide quality improvement and patient safety plan.

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

9.7. The analysis process includes comparisons internally, with other organizations when available, and with scientific standards and desirable practices.

9.8. The organization uses a defined process for identifying and managing sentinel events.

10. Prevention and Control of Infection (PCI)

10.1. One or more individuals oversee all infection prevention and control activities. This individual(s) is qualified in infection prevention and control practices through education, training, experience, or certification.

10.2. 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.

10.3. 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.

10.4. The organization's leaders provide adequate resources to support the infection prevention and control program.

10.5. The organization designs and implements a comprehensive program to reduce the risks of health care–associated infections in patients and health care workers.

10.6. All patient, staff, and visitor areas of the organization are included in the infection prevention and control program.

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

10.8. There is a policy and procedure in place that identifies the process for managing expired supplies and defines the conditions for reuse of single-use devices when laws and regulations permit.

10.9. The organization has a policy and procedure on the disposal of sharps and needles.

10.10. Gloves, masks, eye protection, other protective equipment, soap, and disinfectants are available and used correctly when required.

10.11. The organization tracks infection risks, infection rates, and trends in health care–associated infections.

10.12. The results of infection prevention and control measurement in the organization are regularly communicated to leaders and staff.

10.13. The organization provides education on infection prevention and control practices to staff, physicians, patients, families, and other caregivers when indicated by their involvement in care.

11. Governance, Leadership, and Direction (GLD)

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

11.2. Those responsible for governance approve and make public the organization's mission statement.

11.3. Those responsible for governance approve the policies and plans to operate the organization.

11.4. Those responsible for governance approve the budget and allocate the resources required to meet the organization's mission.

11.5. Those responsible for governance appoint the organization's senior manager(s) or director(s).

11.6. A senior manager or director is responsible for operating the organization and complying with applicable laws and regulations.

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

11.8. Medical, nursing, and other leaders of clinical services plan and implement an effective organizational structure to support their responsibilities and authority.

11.9. Directors recommend space, equipment, staffing, and other resources needed by the department or service.

11.10. Directors recommend criteria for selecting the department or service's professional staff and choose or recommend individuals who meet those criteria.

11.11. Directors provide orientation and training for all staff of the duties and responsibilities for the department or service to which they are assigned.

12. Staff Qualifications and Education (SQE)

12.1. The organization uses a defined process to ensure that clinical staff knowledge and skills are consistent with patient needs and the non-clinical staff's knowledge and skills are consistent with the organization's needs.

12.2. Organization leaders define the desired education, skills, knowledge, and other requirements of all staff members. There is documented personnel information for each staff member.

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

12.4. The organization provides a staff health and safety program.

12.5. 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.

12.6. Leadership makes an informed decision about renewing permission for each medical staff member to continue providing patient care services at least every three years.

13. Management of Communication and Information (MCI)

13.1. The organization informs patients and families about its care and services and how to access those services.

13.2. Communication is effective throughout the organization.

13.3. The leaders ensure that there is effective communication and coordination among those individuals and departments responsible for providing clinical services.

13.4. Information about the patient's care and response to care is communicated among medical, nursing, and other health care practitioners during each staffing shift and between shifts.

13.5. The patient's record(s) is available to the health care practitioners to facilitate the communication of essential information.

13.6. Information related to the patient's care is transferred with the patient.

13.7. Information privacy and confidentiality are maintained.

13.8. Records and information are protected from loss, destruction, tampering, and unauthorized access or use.

13.9. The organization initiates and maintains a clinical record for every patient assessed or treated.

13.10. 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.

13.11. Every patient clinical record entry identifies its author and when the entry was made in the record.

APPENDIX 2. Study Instruments

In-Depth Interview guide for Continuing education department staff

1. Could you please describe the provision of opportunities for staff personal development and continuing education in the NTCC? To what extent the process is uniform throughout the organization?

2. How do you identify the staff education needs? What internal and/or external sources are used for staff education needs identification?

3. How the education programs for staff are planned? What information is used as a basis for the education programs?

4. What resources do you provide for staff in-service education and training? Where are the in-service education and trainings organized?

5. Please describe how the time allocated for in-service education is adequate for provision of education and trainings? What proportion of staff participates in the education and training opportunities?

In-Depth Interview guide for the Human resource manager

General

1. Could you please describe the general process of staff recruitment? What is the process of evaluation of new staff qualifications? How do you ensure a uniformity of processes throughout the organization?

2. What is the process of individuals' appointment to the staff? What is the process for staff retention? To what extent the process is uniform throughout the organization?

3. Please describe the process of verification of all credentials (education, licensure, knowledge, etc.) of the individuals who begin providing services to patients? At what stage of an individual appointment is the verification conducted? With what source are the credentials verified?

4. When new clinical staff members are first evaluated? Who conducts this evaluation? What is the defined frequency of ongoing clinical staff evaluation? How do you document the evaluations results?

5. What is the process of matching clinical staff knowledge and skills with patient needs? How do you match nonclinical staff knowledge and skills with the requirements of the position?

6. How is staff health and safety organized? How do you plan staff health and safety program? How do you react to urgent and non-urgent staffs' health and safety needs? How staff healthy and safety data are communicated to quality and safety program?

Nursing staff

7. Now please describe the procedure of gathering the credentials of nursing staff members? How the information on licensure, education, training and experience are usually verified? With what sources do you verify the credentials?

8. How do you check the validity and completeness of the credentials of contract nurses? What credentials are used for assigning nursing staff member to the specific work? Could you please describe the extent to which the process of identification of job responsibilities and making clinical assignments is consistent with the relevant laws and regulations?

Ongoing M&E of medical staff

9. How do you review an ongoing professional practice and safety of patient services provided by each medical staff member? How do you communicate the results to the medical staff members? What is the frequency of this process?

10. What do you use as a benchmark for comparison of ongoing professional practice evaluation results? How the analyses of already known complications are used in this evaluation?

In-Depth Interview guide for a managerial leader (1)

Care of patients

1. Please describe the mechanism for ensuring uniform provision of care processes in the hospital throughout the organization?

2. How does the acuity of the patient's condition influence the resource allocation to meet the patient's need? How similar is the level of care provided to patients throughout the hospital? How do you ensure comparability of provided nursing care throughout the organization?

3. How do you ensure integration and coordination of settings, departments, services in care planning? What techniques and/or tools are used to foster integration and coordination of settings, departments, services in planning care for patients? *(For example, team-delivered care, integrated patient records, etc.)*

4. How do you ensure integration and coordination of settings, departments and services in care delivery?

Quality improvement and patient safety

5. Please describe how the design of new processes or redesign of existing processes is organized? ***Probe:*** What methods are applied to the design of new or modified processes? How do you apply quality improvement principles and tools to the design of new or modified processes?

6. What measurements are used to evaluate the newly designed or redesigned processes operation? How do you evaluate operation of the newly designed or redesigned processes?

7. Please tell what guides clinical care in the hospital? ***Probe****:* What practice guidelines are used to guide clinical care?

8. What improvements in quality and safety do you plan and implement?

9. How do you document achieved and sustained improvements?

10. What processes/ stages does the risk management program include? ***Probe:*** Risk identification, risk prioritization, risk reporting, risk management, investigation of adverse events, and management of related claims.

11. How analysis of risk reduction processes' results are used to review the high-risk processes?

12. How do you receive information on results of infection prevention and control measurement? How do you use the measurement data you receive?

In-Depth Interview guide for a managerial leader (2)

Management of communication and information

1. How do you ensure the communication throughout the organization to be in a timely manner? How do you communicate the organization's mission and appropriate policies, plans, and goals to all staff?

2. What do you do to ensure effective and efficient communication among clinical and nonclinical departments, services, and individual staff members?

3. What do you do to promote communication in the delivery of clinical services? How do you ensure that the policy on information privacy and confidentiality is maintained?

4. What are the communication channels between governance and management?

Governance of the organization

5. What mechanism exists for those responsible for governance to approve or disapprove of the organization's mission? How often a review of organization's mission is done?

6. How does the mission of the organization reach the public? How can the public get to know the mission of the organization?

7. What mechanism exists to approve organization's strategic and management plans and operating policies?

8. What is the mechanism of approving organization strategies and programs related to health care professional education and research? Who is responsible for provision of oversight of the quality of such programs?

9. How do those responsible for governance approve the organization's budget? How they allocate the resources required to meet the organization's mission?

10. How do the persons responsible for governance appoint the organization's leader? Who appoints the organization's senior managers? What criteria are used while appointing him/her?

11. How is the performance of the organization's senior managers evaluated? Who evaluates the performance of the organization's senior manager? How often an evaluation of the senior management is performed?

12. What is the mechanism of approving the organization's plan for quality and patient safety? What is the response action to the reports of the quality and patient safety program?

In-Depth Interview guide for a managerial leader (3)

Leadership of the organization

1. Who manages the organization's day-to-day operations? What are the daily responsibilities of the director? How does the director manage the organization's day-to-day operations?

2. Who recommends policies to the governing body? How does the organization's director ensure compliance with approved policies?

3. How does the organization's director ensure compliance with laws and regulations? How important is this part in director's job/ responsibilities.

4. How does the organization's director respond to any reports from inspecting and regulatory agencies?

5. How is decision on needed space to provide a service made? Who is responsible for recommending space needed to provide services? Who is responsible for recommending equipment needed to provide services? How decision on needed equipment is made?

6. How is decision on the number and qualifications of staff made? Who is responsible for recommending the number and qualifications of staff?

7. Who is responsible for recommending other special resources needed to provide services? How does the responsible person respond to resource shortages?

8. What are the criteria related to needed education, skills, knowledge, and experience of the department's professional staff? Who develops those criteria? What are the criteria for professional staff selection and recommendation?

9. How is the department staff orientation program developed? Which departments have completed the program (if any)?

In-Depth Interview Guide for Heads of departments

1. Could you please describe how is the continuity of care *(integrated system of services, health care practitioners and levels of care)* and coordination of care services among different health practitioners supported? For instance, between emergency services provision and inpatient admission; between diagnostic and treatment services; between surgical and nonsurgical treatment services.

2. Please tell how do you support patients' and their family participation in care decision and care processes? Describe the education provided to patients and family to support their participation in care decisions and care processes? To what extent is this education of patients and family consistent with the hospital mission, services and patient population?

3. Describe the mechanism of patient and family education provision throughout the organization? How would you comment on the effectiveness of structure and resources of education?

4. How do you understand patient and family rights? On what is your understanding of patient and family rights is based? *(laws and regulation)* What do you undertake to protect and advance patient and family right?

5. What are the vulnerable patients groups identified by the organization? How do you perceive your responsibility in protecting these vulnerable patients *(children, disabled individuals, the elderly and others)*?

6. How do you check the level of compliance with information privacy and confidentiality with the policy?

7. Let's talk about the mechanism employed to ensure maintenance of a policy concerning information security and data integrity. Please describe that mechanism. How do you monitor the level of compliance with information security and data integrity with the policy?

8. How do you ensure that patient care is up-to-date? What sources are used to update practice?

9. How do you ensure that the clinical education is up-to-date?

10. How do you ensure that the research done in the hospital is up-to-date?

11. How do you ensure that the information supporting management is up-to-date?

12. Please describe the extent to which you are familiar with the concepts and methods of quality improvement? In what quality improvement and patient safety process have you participated in?

Prevention and control of infection

13. Who develops an infection prevention and control program? Who are included in the infection prevention and control program?

14. How do you receive information on results of infection prevention and control measurement?

15. To what extent are you familiar with the policies, procedures, and practices of the infection prevention and control program?

16. 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?

In-Depth Interview guide for the NTCC Infection and Quality Control specialist (*TB and other infections*)

1. Please describe what workplace and administrative infection-control measures are implemented in the NTCC. What infection-control plan does the facility have? What mechanism for the coordination of the infection prevention and control program do you have and who are involved in that (physicians, nurses, infection prevention and control professionals, housekeeping, others)?

2. What is the basis of current infection prevention and control program? Please describes how the national standards, current scientific knowledge and the accepted practice guidelines are used in infection control program?

3. What do you think about adequacy of allocated resources to infection prevention and control program?

4. How the information management system supports the infection prevention and control program? (for tracking risks, rates, and trends)

5. How do you control and reduce the risk of health-care associated infections in patients? **Probe:** Please describe the plan that the organization has developed with regards to infection prevention in patients.

6. How do you control and reduce the risk of health-care associated infection in health care workers? ***Probe:*** Please describe the plan that the organization has developed with regards to infection prevention in health care workers.

7. How the usual (endemic) rates of infections are determined?
   Probe: What systematic surveillance activities do you implement to track the rates of infections?

8. Are there any policies and procedures on how the program must target infection risks? Please describe the established risk reduction goals and measurable objectives? How often are they reviewed?

9. What strategies have you implemented to reduce infection risks (policies or procedures, staff education, practice change, and/or other activities)

10. How you assure the uniformity of cleaning, disinfection, and sterilization throughout the hospital? How these processes are coordinated?

11. Please describe the organization's policy on the management of expired supplies? How the organization monitors the policy of management of expired supplies.

12. Please describe how the sharps and needles are disposed? To what extent the disposal is consistent with the national laws and regulations? To what extent the disposal is consistent with the policies and procedures of the hospital?

13. Let's now talk about wearing of gloves, masks, respirators and other protection means such as hand washing and hand disinfection or surface disinfecting procedures. Are those situations defined by the organization formally? Where the guidelines were adopted from

14. Please describe how the leadership of the infection prevention and control program is included in the organization's quality and patient safety program's oversight mechanism.

15. Please describe how health-care associated infection risks, rates, and trends are tracked and how infection prevention and control activities are measured? What infections are targeted by these measurements?

16. Please describe how do you apply information of infection risks, rates, and trends? How the processes are reviewed based on infection risks, rates, and trends?

17. What is the desired level of infection risk in the organization? What is done to meet that level?
    Probe: How the processes are reviewed to meet that level? What are some examples of activities or processes that have been redesigned at NTCC in order to reduce infection risk?

18. Please describe how the health-care associated infections' rates are compared with other TB hospitals? Which are the best standards of infection rates the hospital compares its rates with? Which organizations are they compared with

19. Let's now talk about how monitoring results are communicated to medical, nursing and management staff. Please describe how the organization provides education about infection prevention and control program.
    Probe: Who are included in the program? To what extend are patients and their families are included in the program?

20. How you educate the staff about new policies, procedures and practices for infection prevention and control and inform the staff about significant trends in infection data?

In-Depth Interview guide for Monitoring and Evaluation department specialist

1. Let's talk about the organization's structures, processes, outcomes, which need to be measured and improved. Are those areas identified?

2. Please describe how this measurement is integrated in the quality improvement and patient safety program?

3. How you are getting informed about the results of the measurement? How often the results are communicated to you and to the governance of the organization?

4. Please list and describe the prioritized key measures from the clinical areas to be used for the organization wide quality improvement and patient safety plan. How do you substantiate your decision of selecting those clinical measures?
   Probe: How do you use science and evidence to support your decision?

5. What is your approach in the measurement of the clinical areas?
   Probe: Do you obtain information about structure, processes and outcomes from the clinical areas? How do you evaluate the effectiveness of improvements in clinical areas?

6. Please list and describe the prioritized managerial areas to be used for the organization wide quality improvement and patient safety plan? How do you substantiate your decision of selecting those managerial areas?
   Probe: How do you use science and evidence to support your decision?

7. What is your approach in the measurement of the management areas?
   Probe: Do you obtain information about structure, processes and outcomes from the management areas? How do you evaluate the effectiveness of improvements in the managerial areas?

8. What is your contribution in identification of measures in each International Patient safety Goals (IPSG)?
   How the effectiveness of improvements is assessed? What data are used for assessment? How you use the obtained measurement data.
   Probe: How that data are transformed into useful information?

9. Please list and describe who participates in this process? What qualifications and experience do they have?

10. How data are analyzed? What statistical tools and techniques are used for data analysis? How and to whom the results of analysis are communicated.
    Do you compare the results you get with the past results? What about comparing with results from other organizations, different standards, regulations, and known desired practices?

11. How do you validate the collected data?

12. Let's now talk about sentinel events. Please describe what the organization's definition of sentinel events is. How you analyze the sentinel events?
    Probe: What kind of analysis tools do you use? What about root cause analysis?

13. Please describe in which cases you analyze the events. How do you use the results of analysis?

14. What types of adverse levels, patterns, or trends are analyzed intensely?
    Probe: What additional efforts do you pay when adverse levels, patterns, or trends occur?

15. Please describe how you analyze:
    - Confirmed transfusion reactions
    - Adverse drug events
    - Significant medical errors
    - Discrepancies between preoperative and postoperative diagnoses
    - Adverse events or patterns of adverse events during sedation and anesthesia use

16. What other events do you analyze?

17. What types of events do you report? ***Probe:*** How do you define what to report and what – not?

18. What is the definition of near misses in this hospital? Please describe how near misses are reported and how data are used to reduce near-miss events. ***Probe:*** What is the process of reporting near misses?

19. Please describe how the information on patient is communicated among health care practitioners? What is the general process of information communication?
    What kind of patient data is included in the communicated information? (Health status, summary of provided care, patients' progress)

20. To what extend the up-to-date patients' records are available? What is you experience with regards to this? ***Probe:*** How accessible are those records for the clinicians who need it for providing care

21. How up-to-date is the information in the patients' records?

22. Please describe how the records and information are protected from:
    - loss or destruction
    - tampering and unauthorized access and use

23. What is the process of initiating a clinical record for assessed and treated patients?

24. How you ensure that only authorized individuals have access to patients' clinical records and can make entries in patient clinical records.

In-Depth Interview guide for the NTCC pharmacist

Medication management and use

1. Please describe the mechanism of the medication use oversight throughout the NTCC? How the organization oversees the medication list in the hospital? What is the source of the anti-TB medicines?

2. How do you track the delivery, receipt and movement of medicine or supplies? How do you document that information?

3. What procedures are established to ensure hospital regular receipt of medicines and supplies? How often are supplies received? Who determines what supplies are needed and places the order? How are orders for anti-TB medicines calculated? How are quantities of buffer or safety stocks calculated?

4. How do you organize approval of medication not stocked or readily available if needed? How do you organize procurement of such medication? What principle of stock rotation do you have in place?

5. What are the buffer or safety stocks of anti-TB medicines? How long should the buffer stock last (for example, 3 months)? Have there been any medicine stock-outs during the past year? If so, which medicines were affected, and for how long? What was the reason for the stock-outs? (For example, determine whether the incorrect amount was ordered, or deliveries arrived late from the regional or central store, or whether some medicines expired.)

6. According to what policy the medicine storage is organized? Are stored medicines sampled and tested regularly, how often? How is the inspection in the medication storage areas organized?

7. How do you monitor the expiry dates of medication and supplies? What is the procedure for handling expired anti-TB medicines?

8. Please tell what medication recall system do you have in place? How the process of identification is organized? How the retrieval of medication is organized? How the return or destroying of medication is organized? Please describe how the policies and procedures concerning medication recall system are implemented?

9. Could you describe the processes applied to protect the medication from loss or theft? How does the organization account for control substances? What guides the process? To what extent it is consistent with the applicable laws and regulations?

10. What is done with medicines from patient kits that are not used? Are kits of medicines for treating individual patients available? How are they supplied?

11. Please tell what first-line anti-TB medicines are available at the hospital?

12. What second-line anti-TB medicines are available?

13. What anti-TB medicines are available for children? What pediatric formulation do you have? Are pediatric formulations available, or are adult tablets broken in half for children?

14. What emergency medications are available? How the emergency medication can be accessed in the units where they could be needed?

15. Please describe the extent to which medication dispensing and distribution is different from patient to patient? How do you ensure and reinforce accuracy of medication dispensing? How do you ensure and reinforce timeliness of medication dispensing?

16. Please describe the process of tracking medication effects and adverse effects? How do you track medication effects and adverse effects? How the process of monitoring the medication effects on patients is organized? Who are involved in the process?

17. How are the adverse reactions from second line medicines managed? What medicines are available for managing the adverse effects? What is the cost of these medicines, who pays for that? How the care providers are trained on the use of such medication? (MDR TB)

18. What mechanism exits for reporting the adverse reactions to the national center responsible for pharmacovigilance? (MDR TB)

19. When a medication is added to the list, what is the process or mechanism of monitoring the drug usage? How do you monitor unanticipated adverse events?

20. Please tell what is the organization's definition of medication errors? How you report the medical errors? Who is responsible for taking action on the reporting? How the information of medical errors reports is used in the organization?

Prevention and control of infection

21. How do you receive information on results of infection prevention and control measurements?

22. To what extent are you familiar with the policies, procedures, and practices of the infection prevention and control program?

23. 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?

In-Depth Interview guide for the NTCC Radiology and Diagnostic imaging department specialist

1. Please tell what general mechanism (radiation safety program) exists and how does it address the safety risks and hazards within and outside the department?

2. How the radiation safety program collaborates with the organization's safety management program? What is the process of reporting and in what situations the radiology safety program reports to the safety structure? What is the frequency of reporting to the safety structure?

3. Please describe the extent to which you are familiar with the safety procedures and practices? How confident you are in performing the safety procedures and practices?

4. How do you usually learn about the new procedures and hazardous materials employed in the hospital? How would you describe the usefulness and completeness of information you receive?

5. What is the defined timeframe for reporting radiology and diagnostic imaging study results? What is the actual time of reporting radiology and diagnostic imaging study results?

6. What processes and procedures exist for management of the radiology and diagnostic imaging equipment? How are those processes implemented? How is the equipment for radiology and diagnostic imaging inspected and tested?

7. How is the equipment and supplies maintained and calibrated? How do you monitor and what is the frequency of checking and follow-up on equipment and supplies?

8. What are the main responsibilities of the radiology and diagnostic imaging department director? Who is responsible for development, implementation and maintenance of the policies and procedures regarding the radiology and diagnostic imaging services? How are the responsibilities carried out?

9. What are the responsibilities of the administrative oversight of the radiology and diagnostic imaging services? How are those responsibilities carried out?

10. Who is responsible for maintenance of the quality control programs regarding the radiology and diagnostic imaging services? How are those responsibilities carried out?

11. What are the responsibilities of monitoring and reviewing all the radiology and diagnostic imaging services? How are the responsibilities carried out?

Prevention and control of infection

12. How do you receive information on results of infection prevention and control measurements?

13. To what extent are you familiar with the policies, procedures, and practices of the infection prevention and control program?

14. 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?

In-Depth Interview guide for the NTCC laboratory Physician/Technician

1. How does the laboratory safety program address safety risks and what are the responsibilities of laboratory safety program within and outside of the laboratory?

2. How is the laboratory safety program associated with the organization's safety management program? How does the laboratory safety program report to the organizations safety structure? What is the frequency of reporting to the safety structure?

3. How familiar are you with the laboratory safety procedures and practices? How confident are you in performing safety procedures and practices?

4. How have you been trained on a respiratory protection program and proper use and fitting of respirators?

5. How do you get acquainted to new safety procedures and newly acquired or recognized hazardous materials?

6. Let's now talk about your everyday practices. How much time does it take to report laboratory result?

7. How is the laboratory equipment management program implemented? What processes does it include? How are laboratory equipment inspected, maintained and calibrated and how it documented?

8. How does the laboratory evaluate all the reagents, to provide accuracy and precision of results?

9. In what cases the "normal" ranges of laboratory results are reviewed and updated? How often are the "normal" ranges of the laboratory results reviewed and updated?

In-Depth Interview guide for the NTCC laboratory Director

1. What are the responsibilities for developing, implementing and maintaining policies and procedures regarding laboratory services? How these responsibilities are carried out?

2. What are the responsibilities regarding administrative oversight of clinical laboratory services? How are the responsibilities regarding administrative oversight of the clinical laboratory service carried out?

3. What are the responsibilities for maintaining quality control programs? How are the responsibilities regarding maintenance of quality control carried out?

4. By what means do you control access to the laboratory?

5. What are the responsibilities for monitoring and reviewing all laboratory services within and outside the laboratory? How are the responsibilities for monitoring and reviewing all laboratory services within the laboratory carried out?

6. How do you receive information on results of infection prevention and control measurement?

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? How often are educational programs conducted to train the staff on significant trends in infection data?

In-Depth Interview guide for Pulmonary Drug Sensitive TB Department physicians

Access and Continuity of care

1. Could you please describe the general process of inpatient admission? What are the policies regarding the process of admitting inpatients?

2. Describe the process of emergency patients' admission to inpatient units? What are the policies regarding emergency patients' admission to inpatient unit?
   What mechanism do you use to prioritize patients with immediate needs?

3. What is the process for holding patients for observation? What are the policies regarding the process of holding patients for observation? How do you follow those policies? When is the screening of a patient initiated?

4. How do you manage new admitted patients when bed spaces are not available?

Assessment of patients

5. What Lab tests are conducted to diagnose patients suspected of having pulmonary TB and are capable of producing sputum?

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

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

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

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

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

11. How is the response to treatment monitored in patients with pulmonary tuberculosis?

12. If the sputum smear is positive at the completion of the initial phase, when should the next sputum microscopy is performed?

13. Based on what the plan for continued treatment is developed?

14. What are the intervals between reassessments? How is that interval determined? What is the frequency of reassessment of your patients during intensive phase of their care and treatment?

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

Staff qualification and education (*applicable only to newly admitted staff members*)

16. As a new staff member how confident do you feel in the organization, department, unit you are assigned to and about your job responsibility?

17. What in-service education and trainings do you receive to maintain or to advance your skills and knowledge?

18. How relevant is the provided education to your ability to meet patient needs?

19. How often do you receive evaluation of the quality and safety of your services provided to patients?

Care of patients

1. Who plans care for each patient? After admission as an inpatient when is care for each patient planned? How is the care plan different from patient to patient? What data do you use to plan care for patients?

2. How is the planned care for patients reviewed and verified? How do you monitor the provision of care?

3. How is the process of treatment and care updated or revised? When (in which case) is the process of treatment and care updated or revised?

4. How are the medications verified to ensure that the correct medication is used? How is the patients adherence to the treatment regimen monitored?

5. If the treatment is interrupted or discontinued, how are the factors leading to it addressed?

6. In order to promote adherence, improve quality of life and relieve suffering, what kind of approach is adopted to treat patients?

7. What treatment regimen is prescribed for the initial (intensive) phase to patients who have not been treated previously and do not have other risk factors for drug resistance?

8. Which drugs are administered for the initial phase? For how long are these drugs administered?

9. Is Isoniazid preventive therapy (IPT) administered to those whose contact investigation did not identify anyone with active TB?

10. Are fixed-dose combinations (FDCs) of anti-TB medications used? Are patient kits used?

11. For patients with HIV and tuberculosis who have profound immunosuppression what is the first treatment of choice?

12. 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?

13. 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?

14. Patients with HIV infection who do not have active TB infection, how are they treated for presumed latent TB infection?

15. 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 guide for Pulmonary Drug Resistant TB Department physicians

Access and Continuity of care

1. Could you please describe the general process of inpatient admission? What are the policies regarding the process of admitting inpatients?

2. Describe the process of emergency patients' admission to inpatient units? What are the policies regarding emergency patients' admission to inpatient unit?
   What mechanism do you use to prioritize patients with immediate needs?

3. What is the process for holding patients for observation? What are the policies regarding the process of holding patients for observation? How do you follow those policies? When is the screening of a patient initiated?

4. How do you manage new admitted patients when bed spaces are not available?

Assessment of patient

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

6. Which patients are considered for drug susceptibility testing? What is the initial diagnostic test performed for patients at risk for drug resistance?

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

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

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

10. What is the general process of HIV testing and counseling for TB suspects and drug sensitive/resistant TB patients?

11. Who initiates and maintains antiretroviral therapy (ART) for HIV– positive drug-resistant TB patients?

12. How is the response to treatment monitored in patients with pulmonary drug-resistant TB tuberculosis?

13. If the sputum smear is positive at the completion of the initial phase, when should the next sputum microscopy be performed?

14. Based on what the plan for continued inpatient treatment or discharge for outpatient treatment is developed?

15. What are the intervals between reassessments? How is that interval determined? What is the frequency of reassessment of your patients during intensive phase of their care and treatment?

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

Staff qualification and education (*applicable only to newly admitted staff members*)

17. As a new staff member how confident do you feel in the organization, department, unit you are assigned to and about your job responsibility?

18. What in-service education and trainings do you receive to maintain or to advance your skills and knowledge?

19. How relevant is the provided education to your ability to meet patient needs?

20. How often do you receive evaluation of the quality and safety of your services provided to patients?

Care of patients

1. Who plans care for each patient? After admission as an inpatient when is care for each patient planned? How is the care plan different from patient to patient? What data do you use to plan care for patients?

2. How is the planned care for patients reviewed and verified? How do you monitor the provision of care?

3. How are patents who have bacteriological confirmed drug resistant TB treated? How are patents who have suspected drug resistant TB treated?

4. Which drugs are used during the intensive phase for 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?

5. How is the process of treatment and care updated or revised? When (in which case) is the process of treatment and care updated or revised?

6. How are the medications verified to ensure that the correct medication is used? How is the patients adherence to the treatment regimen monitored?

7. If the treatment is interrupted or discontinued, how are the factors leading to it addressed?

8. In order to promote adherence, improve quality of life and relieve suffering, what kind of approach is adopted to treat patients? How the adherence to treatment is ensured among drug-resistant TB patients?

9. Is Isoniazid preventive therapy (IPT) administered to those whose contact investigation did not identify anyone with active TB?

10. Are fixed-dose combinations (FDCs) of anti-TB medications used? Are patient kits used?

11. For patients with HIV and tuberculosis who have profound immunosuppression what is the first treatment of choice?

12. 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?

13. 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?

14. Patients with HIV infection who do not have active TB infection, how are they treated for presumed latent TB infection?

15. 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 guide for Extra-pulmonary TB Department physicians

Access and Continuity of care

1. Could you please describe the general process of inpatient admission? What are the policies regarding the process of admitting inpatients?

2. Describe the process of emergency patients' admission to inpatient units? What are the policies regarding emergency patients' admission to inpatient unit?
   What mechanism do you use to prioritize patients with immediate needs?

3. What is the process for holding patients for observation? What are the policies regarding the process of holding patients for observation? How do you follow those policies? When is the screening of a patient initiated?

4. How do you manage new admitted patients when bed spaces are not available?

Assessment of patients

5. What procedures are used to establish the diagnosis of extra-pulmonary TB? Are histopathology tests commonly used?

6. For suspected tuberculosis meningitis which test is used for rapid diagnosis?

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

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

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

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

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

12. How is the response to treatment monitored in patients with extra-pulmonary tuberculosis?

13. If the analyses still TB positive at the completion of the initial phase, when should the next microscopy be performed?

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

15. Based on what the plan for continued treatment or discharge is developed?

16. What are the intervals between reassessments? How is that interval determined? What is the frequency of reassessment of your patients during intensive phase of their care and treatment?

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

Staff qualification and education (*applicable only to newly admitted staff members*)

18. As a new staff member how confident do you feel in the organization, department, unit you are assigned to and about your job responsibility?

19. What in-service education and trainings do you receive to maintain or to advance your skills and knowledge?

20. How relevant is the provided education to your ability to meet patient needs?

21. How often do you receive evaluation of the quality and safety of your services provided to patients?

Care of patients

1. Who plans care for each patient? After admission as an inpatient when is care for each patient planned? How is the care plan different from patient to patient? What data do you use to plan care for patients?

2. How is the planned care for patients reviewed and verified? How do you monitor the provision of care?

3. How are patients who have bacteriological confirmed drug resistant TB treated? How are patents who have suspected drug resistant TB treated?

4. Which drugs are used during the intensive phase for 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?

5. How is the process of treatment and care updated or revised? When (in which case) is the process of treatment and care updated or revised?

6. How are the medications verified to ensure that the correct medication is used? How is the patients adherence to the treatment regimen monitored?

7. If the treatment is interrupted or discontinued, how are the factors leading to it addressed?

8. In order to promote adherence, improve quality of life and relieve suffering, what kind of approach is adopted to treat patients? How the adherence to treatment is ensured among drug-resistant TB patients?

9. Is Isoniazid preventive therapy (IPT) administered to those whose contact investigation did not identify anyone with active TB?

10. Are fixed-dose combinations (FDCs) of anti-TB medications used? Are patient kits used?

11. For patients with HIV and tuberculosis who have profound immunosuppression what is the first treatment of choice?

12. 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?

13. 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?

14. Patients with HIV infection who do not have active TB infection, how are they treated for presumed latent TB infection?

15. 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 guide for Children TB Department physicians

Access and Continuity of care

1. Could you please describe the general process of inpatient admission? What are the policies regarding the process of admitting inpatients?

2. Describe the process of emergency patients' admission to inpatient units? What are the policies regarding emergency patients' admission to inpatient unit?
   What mechanism do you use to prioritize patients with immediate needs?

3. What is the process for holding patients for observation? What are the policies regarding the process of holding patients for observation? How do you follow those policies? When is the screening of a patient initiated?

4. How do you manage new admitted patients when bed spaces are not available?

Assessment of patients

5. What standard operating procedures or guidelines do you use for childhood TB?

6. What Lab tests are conducted to diagnose children suspected of having pulmonary TB and are capable of producing sputum?

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

8. What types of diagnostic examinations are done for children suspected of having intrathoracic tuberculosis?

9. Are contacts of children with TB investigated?

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

11. What is the initial diagnostic test performed for children who have HIV risks? What is the initial diagnostic test performed on children who are seriously ill (with other diseases)?

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

13. Who initiates and maintains antiretroviral therapy (ART) for HIV– positive children with TB?

14. How is the response to treatment monitored in children capable of producing sputum with pulmonary tuberculosis? What are the intervals between reassessments? How is that interval determined? What is the frequency of reassessments of your patients during acute phase of their care and treatment?

15. If the sputum smear is positive at the completion of the initial phase, when should the next sputum microscopy is performed?

16. How is the response to treatment monitored in children not capable of producing sputum? What are the intervals between follow-ups? How is that interval determined? What is the frequency of follow-ups of your patients during acute and continuation phases of their care and treatment?

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

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

19. Based on what the plan for continued treatment or discharge is developed?

Staff qualification and education (*applicable only to newly admitted staff members*)

20. As a new staff member how confident do you feel in the organization, department, unit you are assigned to and about your job responsibility?

21. What in-service education and trainings do you receive to maintain or to advance your skills and knowledge?

22. How relevant is the provided education to your ability to meet patient needs?

23. How often do you receive evaluation of the quality and safety of your services provided to patients?

Care of patients

1. Who plans care for each child? After admission as an inpatient when is care for each patient planned? How is the care plan different from a child to child? What data do you use to plan care for children?

2. How is the planned care for children reviewed and verified? How do you monitor the provision of care?

3. How is the process of treatment and care updated or revised? When (in which case) is the process of treatment and care updated or revised?

4. How are the medications verified to ensure that the correct medication is used? How is the children's adherence to the treatment regimen monitored?

5. If the treatment is interrupted or discontinued, how are the factors leading to it addressed?

6. In order to promote adherence, improve quality of life and relieve suffering, what kind of approach is adopted to treat children?

7. Which treatment regimens are used to treat childhood TB? Are they aligned with WHOs' recommendations?

8. Are fixed-dose combinations (FDCs) available for pediatric use? Do they include the appropriate associations and doses? Is Isoniazid available for pediatric use?

9. Is Isoniazid preventive therapy (IPT) administered to children?

10. What is the procedure for managing a child suspected of having drug-resistant TB? How it is different from procedures of adults?

11. For patients with HIV and tuberculosis who have profound immunosuppression what is the first treatment of choice? Is this applicable for children?

12. 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?

13. As a prophylaxis for other infections, do children with TB and HIV receive other than HIV/TB drugs? If yes, what drugs do they receive?

14. Patients with HIV infection who do not have active TB infection, how are they treated for presumed latent TB infection?

15. Is Isoniazid preventive therapy (IPT) offered to children living with HIV after active TB disease has been ruled out? Are children living with HIV screened for TB each time they visit a health facility?

Additional general questions for In-Depth Interviews with physicians (1)

Quality improvement and patient safety

1. Do you have quality improvement and patient safety program in the hospital? How is the information on the quality improvement and patient safety program communicated to you? What is the frequency of communication? What are the channels of communication?

2. To what extent a training programs for physicians matches your role in the quality improvement and patient safety program? How is the training integrated in your regular work assignments?

Prevention and control of infection

3. How do you receive information on results of infection prevention and control measurements?

4. To what extent are you familiar with the policies, procedures, and practices of the infection prevention and control program?

5. 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?

Management of communication and information

6. How would you assess the effectiveness of the organizational structure in carrying out your responsibilities?

7. How would you evaluate the role of the medical, nursing and other leaders of this hospital in
   - Supporting good communication between professionals;
   - Jointly plan and develop policies that guide the delivery of clinical services;
   - Oversee the quality of patient care.

8. How the organizational structure is appropriate to the organization's size and complexity?

9. How is the information on patient communicated among health care practitioners? What is the general process of information communication: electronic databases, paper records?

10. What does the communicated information about patients include? (Health status, summary of provided care, patients' progress)

11. What is your opinion regarding the availability of the patients' records to the health care practitioners, needed for the care of patients?

12. How up-to-date is the information in the patients' records?

13. How are records and information protected from loss or destruction?

14. How are records and information protected from tampering and unauthorized access and use? How do you ensure that only authorized individuals have access/can make entries to patients' clinical records?

15. What is the process of initiating a clinical record for assessed and treated patients?

16. How are the entries in the patient's record corrected and overwritten?

Additional general questions for In-Depth Interviews with physicians (2)

Patient and family education

1. 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?

2. 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)

3. How do you verify that the information provided to patients (*children*) and family is understood?

4. What topics are covered during education of patients (*children*) and families? What goals underlie their 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

5. How do you reinforce patients and their families' participation in the education?

6. What learning sources are used to provide education for patients (*children*) and family?

7. 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?

8. How would you evaluate adequacy of time for provision of education?

9. How are patients (*children*) educated about proper diet and nutrition?

10. How are patients (*children*) educated about pain management?

11. How are patients (*children*) educated about rehabilitation techniques?

12. How is a professional psychological counseling (if any) for patients (*children*) organized?

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?
    What do you know about the policies and procedures related to patient rights? What is your responsibility in protecting patient rights?

Patients and family rights

14. 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?

15. How is the privacy of a patient respected for all clinical interviews, examinations, procedures, and treatments? How are issues concerning patient's need for privacy during clinical interviews, examinations, procedures, and treatments, dealt with at the hospital?

16. What do you think about confidentiality of the patient's health information?
    Do you have policies and procedures for obtaining informed consent (*assent*) regarding the planned care from the patient (*parent*)? If yes, to what extent is the informed consent (*assent*) obtained from the patient (*parent*) consistent with the policies and procedures?

17. How were you trained to obtain patient informed consent (*assent*)? How do you ensure that the patient (*parent*) understands the consent (*assent*)?

18. In which situations do you obtain a separate informed consent (*assent*) other than the planned care consent form? What is the list of procedures that require separate consent (*assent*)? 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.

19. How do you inform patients of their rights and responsibilities?

20. 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)?

21. How were you trained to undertake the role of supporting patients and promoting family participation in the care process? How have you been trained on the relevant policies and procedures of your hospital?

22. How do you perceive the unique needs of dying patients? What do you think about the rights of dying patient?

Interview guides for patients and family

1. Could you please tell what information have you received at admission as an inpatient? When have you been told about your condition and diagnosis?

2. What have you been told about planned care/ treatment and expected/unexpected outcomes?

3. How would you comment on demonstrated attitude of respect toward your needed privacy during clinical interviews, examinations, procedures/treatments and transport?

4. How did you learn about the way the information you gave will be kept confidential?

5. How would you evaluate the adequacy of provided information on your condition? On proposed care?

6. How would you evaluate the adequacy of information provided about the likelihood of success or possible problems related to recovery?

7. How would you evaluate the adequacy of information about possible results of non-treatment?

8. What type of information on infection control and prevention have you received?

9. How many professionals were providing education? How do they provide education? How would you evaluate them, their knowledge about the subject?

10. How would you evaluate the communication skills of the individuals who were providing education in TB?

11. Could you tell the topics you been educated on during an inpatient treatment:

- 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
- DOTs
- importance of regular medical assessment
- importance of contact investigation

Medication Storage, Management and use

Availability of emergency medications in the hospital	**Yes**	**No**	**Comments**
1. Emergency medications are available in the units they will be needed			
2. Emergency medications are accessible if needed			
Medications storage conditions	**Yes**	**No**	**Comments**
3. Is the temperature of the area between 15 – 25 °C?			
4. Is the humidity of the area more than 60%?			
5. Are medicines exposed to direct sunlight?			
6. *Inspect some of the tablets:* are the colors of the medicines appropriate?			
7. Has the color faded?			
8. Are the tablets crumbling, or do they smell unusual?			
9. Have medicines been organized on the shelves so that it is easy to read the product's name and expiry date?			
10. Does air circulate in the storage area?			
11. Is there an air conditioner?			
12. Are there windows that can be opened?			
13. Is there an exhaust fan?			
14. Are there spaces between the shelves?			
Management and security of anti-TB medicines and supplies	**Yes**	**No**	**Comments**
15. Has a lock been installed on the door of storage room?			
16. Does staff use the lock?			
17. If there are windows, can they be locked *(if no window put N/A in the comments)*			
18. Have bars been installed to prevent access?			
19. Are medicines stored on the floor of the storage area?			
20. Are containers of medicines stacked one on top of other?			
21. Are there any insects, rodents or other pests in the storage area?			
22. Is there potential for stock to be destroyed by rain or floods?			
23. Is there a fire extinguisher with a valid expiry date?			
24. Is the fire extinguisher easily accessible?			
25. Has staff been trained to use the fire extinguisher?			
26. Is stock rotated using the first expiry, first out (FEFO) principle? *Inspect a few kits to ensure that FEFO is being followed*			
27. Are kits of medicines used to treat individual patients? ***If yes***			
1. Do they contain fixed-dose combination (FDC) blister packs?			
2. Are the kits easy to access on the shelf or in the storage area?			
3. Are syringes and other supplies (for example, sterile water for injections) included in the kits for retreatment patients?			
4. Are kits adjusted for a patient's weight?			
5. Are patients' names listed on the outside of the kits?			
6. Is the shortest expiry date for all the medicines listed on the outside of kit?			
Area where the medications are prepared and dispensed	**Yes**	**No**	**Comments**
28. Is area clean and safe?			
29. Are medications dispensed in the most ready-to-administer form?			

30. Before administration, are medications verified with prescription or order?			
31. Is the dosage/amount of medication aligned with prescription or order?			
32. Is the route of administration verified with prescription or order?			

Infection Prevention and Control activities

*Observe all areas included in **infection surveillance, prevention and control program (ISPCP)*** *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 %)*	**Yes**	**No**	**Comments**
1. All patients' care areas are included in the ISPCP			
2. All staff care areas are included in the ISPCP			
3. All visitors' areas are included in the ISPCP			
4. HIV-positive people and other at-risk patients separated from TB patients and people suspected of having TB			
Ventilation system in the facility	**Yes**	**No**	**Comments**
5. Is there Local exhaust ventilation (enclosing devices and exterior devices)?			
6. Is there General ventilation (e.g., single-pass system, recirculation system)?			
7. Is there Natural ventilation (*for low-risk procedures it is sufficient)*			
8. Is the ventilation available for all rooms?			
9. Are there Air-cleaning methods (e.g., high efficiency particulate air [HEPA] filtration and ultraviolet germicidal irradiation [UVGI])?			
10. Are the Air-cleaning methods available in high-risk areas? 1. Isolation rooms			
2. Sputum-induction rooms			
3. Bronchoscopy			
4. Surgical suites			
5. Autopsy suites			
11. Are surgical masks available in the facility?			
12. Do the patients use surgical masks?			
13. Do the visitors use the surgical masks *(If yes, specify in the comments section % of use)*			
14. Do the health-care workers use surgical masks during contacts with patients? *(If yes, specify in the comments section % of use)*			
15. Are respirators available in the facility? *(If yes, specify in the comments section the type of respirators)*			
16. Do the visitors use the respirators *(If yes, specify in the comments section % of use)*			
17. Do the health-care workers use respirators during contacts with patients? *(If yes, specify in the comments section % of use)*			
18. Staff members included in the respiratory-protection program: 1. Physicians			

2. Nurses			
3. Administrators			
4. Laboratory personnel			
5. Contract staff			
6. Construction or renovation staff			
7. Janitorial staff			
8. Maintenance or engineering staff			
9. Transportation staff			
10. Dietary staff			
11. Students			
Sterilization *Check the sterilization and cleaning guidelines of the hospital.Observe bronchoscopes, surgical supplies and other invasive or noninvasive patient care equipment cleaning, disinfection and sterilization process.*	**Yes**	**No**	**Comment**
19. *Whether <u>Bronchoscopes</u> cleaning and sterilization process includes:*			
1. ***Cleaning*** *Mechanically clean internal and external surfaces, including brushing internal channels and flushing each internal channel with water and a detergent or enzymatic cleaners (leak testing is recommended before immersion)*			
2. ***Disinfecting*** *Immerse bronchoscope in high-level disinfectant (or chemical sterilant) and perfuse disinfectant into all accessible channels, such as the suction/biopsy channel and air/water channel and expose for a time recommended for specific products*			
3. ***Rinsing*** *Rinse the bronchoscope and all channels with sterile water, filtered water (commonly used with AERs) or tap water (i.e., high-quality potable water that meets federal clean water standards at the point of use)*			
4. ***Drying*** *Rinse the insertion tube and inner channels with alcohol, and dry with forced air after disinfection and before storage*			
20. Is the process consistent with the guidelines?			

Preventing the Transmission of Mycobacterium tuberculosis in laundry and linen management process	**Yes**	**No**	**Comments**
21. The receiving area for contaminated textiles is maintained at negative pressure compared with the clean areas of the laundry. (*In accordance with AIA construction standards in effect during the time of facility construction*)			
22. Laundry areas have hand-washing facilities and products and appropriate personal protective equipment available for workers			
23. Textiles or fabrics are not left in machines overnight			
24. Contaminated textiles and fabrics are handled with minimum agitation to avoid contamination of air, surfaces, and persons			
25. Bag or otherwise contain contaminated textiles and fabrics at the point of use.			
26. Pre-rinse contaminated textiles or fabrics are not sorted in patient-care areas			
27. Leak-resistant containment for contaminated textiles and fabrics are used			
28. Bags or containers for contaminated textiles with labels are identified with color coding, or other alternative means of communication as appropriate			
29. Laundry bags are closed before tossing the filled bag into the chute			
Preventing transmission of infection	**Yes**	**No**	**Comments**
30. Sharps and needles are in dedicated, puncture-proof containers			
31. Sharps and needles are not reused			
From the hospital guidelines define the situations in which masks, eye protection, gowns or gloves are required 32. Gloves, masks, eye protection are correctly used in defined situations			
From the hospital guidelines define hand washing and hand disinfection procedures. 33. Hand washing procedures are performed correctly			
Observe the areas where hand washing and disinfecting procedures are required 34. Soap, disinfectants, towel are located in the required areas			

TB patients' Admission, Access, and Continuity of care processes

Admission	**Yes**	**No**	**Comments**
Observe the first screening of the patients. 1. Screening is initiated at the point of first contact within the organization.			
2. Patients are admitted after test results require that			
3. Patients are referred after test results require that			
4. Inpatient admission process is standard.			
5. The initial medical assessment is conducted within the first 24 hours.			
Observe during the initial assessment of the patient. 6. Whether Initial assessment includes:			
1. Health history collection			
2. Physical examination			
3. Psychological assessment			
4. Social and economic assessment			
5. Appropriate time frames for performing assessments are established for all settings and services.			
6. The findings of all assessments performed outside the organization are reviewed and/or verified at the time of admission to inpatient status.			
Access and continuity of care	**Yes**	**No**	**Comments**
Observe medication administration process 7. Patients are identified before administering medication.			
8. Patients are identified before providing treatment and procedures.			
Observe taking of blood and other specimens 9. Patients are identified before taking blood and other specimens for clinical testing.			
10. Speciment taking hygiene guidelines that have been adapted are implemented.			
11. The complete test results are written down by the receiver of the test result.			
12. 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)*			
13. Are the guidelines for establishing the diagnosis of TB available in the health facility?			
14. Are the standard operating procedures or guidelines on childhood TB available at the health facilities visited?			
15. Are there any training materials about implementing activities?			

Laboratory

Standards	**Yes**	**No**	**Comments**
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: 1. Goggles			
2. Full-face piece respirator			
3. Face shield			
4. Other splatter guard *(specify)*			
9. Respirators are stocked for personal protection. *Surgical masks are not respirators, are not certified as such and do not offer significant protection to personnel performing aerosol-producing diagnostic tests for TB*			
10. Masks are used as personal protective equipment in the laboratory			
11. Protective laboratory clothing is worn at all times while staff is working in the laboratory.			
12. Protective clothing is worn outside the laboratory area (For example, in canteens, coffee rooms, offices, libraries, staff rooms and toilets).			
13. Laboratory coats and gowns are stored separately from personal clothing.			
14. Clean gowns and used gowns are stored in different areas of the laboratory.			
15. Facilities for storing outer garments and personal items are provided outside work areas.			
16. Laboratory coats and gowns laundering are done at home.			
17. Gowns are worn during work in a high risk of TB laboratory.			
18. Gloves are worn for <u>all</u> procedures that involve direct contact, or may involve accidental contact, with sputum, blood, body fluids and other potentially infectious materials.			
19. After use, gloves are removed aseptically.			
20. 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.*			
21. Personnel wash their hands after any overt contamination.			

22. Personnel wash their hands after completing work with infectious materials.			
23. Personnel wash their hands before leaving the laboratory's working areas.			
24. Is standard safety equipment <u>available</u> in the laboratory? 1. Hand-washing station near the exit (automated or hands-free taps are recommended).			
2. A dispenser for paper towels is near the sink			
3. First aid kits			
25. Is standard safety equipment <u>used</u> in the laboratory? 1. Hand-washing station, hands-free taps, and dispenser for paper towels			
2. Spill kits			
3. First aid kits			
26. Some people eat in the laboratory			
27. Some people drink in the laboratory			
28. Some people apply cosmetics in the laboratory			
29. Some people handle contact lenses in the laboratory			
30. Facilities for eating and drinking, and for rest, are provided outside work areas			
31. Food or drink sometimes stored in the laboratory's working areas.			
32. Some people wore open-toed footwear in the laboratory.			
33. Mobile telephones are used in the laboratory.			
34. All procedures are performed in a way as to minimize or prevent the formation of aerosols and droplets.			
35. Mouth pipetting is done in the laboratory.			
36. Sometimes materials are placed in the mouth.			
37. All labels used in the laboratory are self-adhesive.			
38. The use of needles and syringes is limited.			
39. Sometimes needles and syringes are used as a substitute for pipetting.			
40. Written documentation that may be removed from the laboratory is protected from contamination.			
41. The laboratory is divided into "functionally clean" and "potentially contaminated" areas. (*The clean areas reserved for administrative and preparatory work*).			
42. Access to the clean areas is controlled and enforced by the laboratory's manager.			
43. Access to the contaminated areas is controlled.			
44. Laboratory doors have a glass window panel.			
45. Laboratory doors have appropriate fire ratings.			
46. Laboratory doors are self-closing.			
47. The laboratory has a reliable and adequate electricity supply.			
48. Separate autoclaves are used to sterilize solutions or glassware (clean materials).			

49. Infectious and non-infectious waste is separated.			
50. Autoclaves decontaminate infectious waste.			
51. Emergency laboratories are available during normal hours.			
52. Emergency laboratories are available after normal hours.			
53. Identified essential reagents are available.			
Check conditions under which the reagents are stored. 54. All reagents are stored according to manufacturers' directives or packaging instruction.			
55. *Check* how *the reagents are dispensed:* 1. All reagents are dispensed according to manufacturers' directives or packaging instructions.			
2. All reagents and solution are completely and - accurately labeled with chemical name			
3. All reagents and solutions are labeled with hazard marking (WHO-TB)			
Directional airflow with 6–12 air exchanges per hour; Directional airflow refers to air flowing from clean areas towards areas where aerosols maybe generated 56. Is the airflow appropriately directed?			
57. Are the smears prepared in a Class I or II biological safety cabinet?			
58. Are the smears stained in a Class I or II biological safety cabinet?			
59. *Observe whether sputum is collected in* 1. Well ventilated areas in the building			
2. Outside the building			
60. Are sputum-collection containers: 1. Wide-mouthed			
2. Sterile			
3. Clear			
4. Leak-proof			
5. Have a screw lid			
61. Are specimens labeled with patient information?			
62. Are specimens labeled with test?			
63. Are specimens labeled with date?			
64. Are specimens labeled with time of collection?			
65. Are specimens labeled with date of collection?			
66. Are specimens labeled with authorized requester?			
67. Does the laboratory receive sputum specimens from an outpatient clinic or facility?			
68. Prior to transport, are specimens kept in a cool place, preferably a refrigerator at 4°C?			
69. If travel time is greater than one hour, are cold boxes used during the transportation?			
70. If storage and transport of specimen exceeds 3 days, is cetylpyridinium chloride added to the specimen?			

71. The basic packaging system for local surface transport of all specimens consists of three layers.			
72. Are the following environmental conditions checked daily? *Review the laboratory's infrastructure and environmental conditions:* 1. Room temperature			
2. Freezer			
3. Incubator			
4. Water bath			
5. Electricity supply			
6. Management of waste			
7. General maintenance			
8. Safety			
73. Are national laboratory guidelines and standard operating procedures for sputum processing available and used?			
74. Is a laboratory-specific biosafety manual prepared and adopted as policy (Biosafety in Microbiological and Biomedical Laboratories)?			
75. Is the biosafety manual available and accessible. (BMBL)			
76. Environmental controls are in place: 1. Through Local exhaust ventilation in <u>all</u> rooms			
2. Through General ventilation in <u>all</u> rooms			
3. Through High efficiency particulate air (HEPA) filtration			
4. Through Ultraviolet germicidal irradiation (UVGI)			

Kitchen and Food storage

Food and nutrition	**Yes**	**No**	**Comments**
1. Food or nutrition for the patients is regularly available			
2. Food is prepared in a manner that reduces risk of contamination and spoilage			
3. Food is stored in a manner that reduces risk of contamination and spoilage			
4. Nutrition products are stored according to manufacturer recommendations			
5. The distribution of food is timely			

Documents review checklists

Human resource department/ Staff qualification review

Standard Measurable element	Document name	Yes	No	Comments
1. Individuals performing testing are identified				
2. Individuals directing or supervising testing are identified				
3. Staffing of the laboratory is sufficient to perform tests during all hours of operation and for emergencies				
4. Staff administering tests have proper qualification				
5. Staff administering tests have proper experience				
6. Staff interpreting test results have proper qualification				
7. Staff interpreting test results have proper experience				
8. Supervisory staff of the laboratory have proper qualifications				
9. Supervisory staff of the laboratory have proper experience				
10. The clinical laboratory are under the direction and oversight of one or more qualified individuals				
11. Staffing of radiology and diagnostic imaging department is sufficient to perform, interpret and report studies during all hours of operation and for emergencies				
12. Supervisory staff of radiology and diagnostic imaging department have qualifications				
13. Supervisory staff of radiology and diagnostic imaging department have experience				
14. Individuals performing diagnostic and imaging studies/ direct/ supervise the studies are identified				
15. Radiology and diagnostic imaging services are under the direction of one or more qualified individuals				
16. Staff performing diagnostic and imaging studies have proper qualifications				
17. Staff performing diagnostic and imaging studies have proper experience				
18. Staff interpreting diagnostic and imaging studies have proper qualifications				

19. Staff interpreting diagnostic and imaging studies have proper experience				
20. Qualified staff verify and report the results of studies				
21. Anesthesia services (including moderate and deep sedation) are under the direction of one or more qualified individuals				
22. A qualified individual monitors the patient during the period of sedation and documents the monitoring				
23. A qualified individual documents the monitoring				
24. Pre-anesthesia and pre-induction assessment is conducted by a qualified individual				
25. One or more individuals oversee the infection prevention and control program				
26. The individual(s) is qualified in infection prevention and control practices through education, training, experience, or certification.				
27. The infection prevention and control program is adequately staffed as approved by the leadership				
28. Individuals with appropriate clinical or managerial experience, knowledge, and skills participate in aggregation and analysis of data				
29. An appropriately licensed pharmacist, technician, or other trained professional supervises the pharmacy or pharmaceutical service.				
30. The organization identifies those individuals, by job description or the privileging process, authorized to administer medications				
31. 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				
32. Human Resources department has a recruitment plan that is developed collaboratively with department directors				
33. Human Resources department's recruitment plan that is updated annually				
34. The Human Resources department has a retention plan that is developed collaboratively with department directors				

35. The Human Resources department's retention plan is updated annually				
36. A staffing plan is developed, based on the organization's strategic plan and the department's scope of services				
37. The plan describes the methods used to ensure an adequate number and mix of staff				
38. Staffing levels are based on appropriate utilization/ workload information which is recorded periodically (e.g. daily patient census)				
39. Organization defines the desired education, skills, knowledge and other requirements for all staff members				
40. Each staff member not permitted to practice independently has a job description				
41. Job descriptions are current according to hospital policy				
42. 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				
43. There is at least one documented evaluation of nonclinical staff members each year or more frequently as defined by the organization				
44. 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)*				
45. Personnel files contain 1. the qualifications of the staff member				
2. the job description of the staff member when applicable				
3. the work history of the staff member				
4. the results of evaluations				
5. a record of in-service education attended by the staff member				
46. Personnel files are standardized and kept current				
47. There is a written plan for staffing the organization				
48. The number of staff are identified in the plan using a recognized staffing method				
49. Types of staff are identified in the plan using a recognized staffing method				

50. Desired qualifications of staff are identified in the plan using a recognized staffing method				
51. The plan addresses the assignment and reassignment of staff				
52. The plan addresses the transfer of responsibility from one individual to another				
53. All credentials on file (education, licensure, registration, among others) are current and updated as required				
54. The renewal of decision on permission for each medical staff member to continue to provide patient care services is documented in the staff member's credential file				
55. Information from the professional practice evaluation (evaluation of the quality and safety of the patient service provided) process is documented in the medical staff member's credentials file and other relevant files				
56. Licensure, education, training, and experience of nursing staff are documented				
57. There is a record maintained of the credentials of every nursing staff member				
58. Information from the review of nursing staff performance process is documented in the nurse’s credentials or other file				
59. Licensure, education, training, and experience of other health care professionals are documented when relevant				
60. There is a record maintained of the credentials of other health professional staff member				
61. The record contains copies of any required license, certification, or registration				
62. The information from the review process is documented in the health professional's file				
63. The organization policy defines evaluation and annual review of each medical staff member				
64. The ongoing professional practice evaluation and annual review of each medical staff member are accomplished by a uniform process				

Policy review

Standard Measurable element	Policy name	Yes	No	Comments
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. Policy describes how the patients are identified for provision of treatments and procedures				
6. Policies describe the process how to ensure: 1. correct site				
2. correct procedure				
3. and correct patient				
7. Policies and procedures are developed to support continued reduction of health care–associated infections				
8. Policies identify screening and diagnostic tests standard before admission				
9. Written policies and procedures describe the processes for admitting inpatients				
10. Established criteria or policies determine the transfers within the organization				
11. Policy and procedure define when the discharge summary must be completed				
12. Law and regulations identify patient and family rights				
13. Policies and procedures guide and support patient and family rights in the organization				
14. Policies and procedures support and promote patient and family participation in care processes				
15. Policies and procedures clearly define informed consent process				
16. The organization defines how a general consent is documented in the patient’s record				

17. Policies and procedures indicate who may grant consent when the patient is unable to do so				
18. Policies and procedures describe how patients' health information is protected and how breaches of confidentiality are dealt with				
19. Policies and procedures include a list of high-risk procedures and treatments for which consent is required				
20. Organization policy and procedure define the assessment information to be obtained for inpatients				
21. Organization policy identifies the information to be documented for the assessments				
22. The minimum content of assessments performed in inpatient settings is defined in policies				
23. Policies and procedures describe how Patients medical needs are defined				
24. Policies and procedures describe how Patients nursing needs are defined				
25. Policies and procedures describe how Patients medical needs should be documented				
26. Policies define time frames for performing assessments for all settings and services				
27. The organization has established the expected report time for laboratory test results				
28. Written policies and procedures address the handling and disposal of infectious and hazardous materials				
29. Written policies and procedures address compliance of radiation safety program with applicable standards, laws, and regulations				
30. The organization has established the expected report time for radiology and diagnostic imaging results				
31. Policies and procedures guide 1. the care of immune-suppressed patients				
2. the care of patients on dialysis				
3. the care of frail, dependent elderly				
4. the care of young, dependent children				

5. the care of patients receiving chemotherapy or other high-risk medications				
6. preparation of food in a manner that reduces risk of contamination and spoilage				
7. storage of food in a manner that reduces risk of contamination and spoilage				
8. storage of enteral nutrition products in accordance with the manufacturers recommendations				
9. timeliness of food distribution				
Anesthesia services				
32. Policies and procedures guide the planning of care of patients undergoing moderate and deep sedation				
33. Sedation policies and procedures identify 1. documentation required for the care team to work and to communicate effectively				
2. special consent considerations				
3. frequency and type of patient-monitoring requirements				
4. special qualifications or skills of staff involved in sedation process				
5. availability and use of specialized equipment				
34. Established criteria are developed for the recovery from sedation				
35. Established criteria are developed for the discharge from sedation				
36. Policy and procedure address the minimum frequency of monitoring during anesthesia				
37. Policy and procedure address the type of monitoring during anesthesia				
Medication management				
38. The plan/ policy/other document identify organization of medication use throughout the organization				
39. The plan/ policy/other document identify medication management throughout the organization				

40. Policies guide all phases of medication management and medication use in the organization				
41. Policy defines 1. storage of medications				
2. maintenance of medications				
3. protection of medication from loss or theft				
42. Policies and procedures address 1. any use of medications known to be expired or outdated				
2. the destruction of medications known to be expired or outdated				
3. actions related to illegible prescriptions and orders				
43. Policies and procedures guide 1. the safe prescribing of medications in the organization				
2. the ordering of medications in the organization				
3. transcribing of medications in the organization				
44. Policy identifies those adverse effects that are to be recorded in the patient's record				
45. Policy identifies those adverse effects that must to be reported to the organization				
46. Policy or procedure defines medication errors				
47. Policy or procedure defines near misses				
48. Policy or procedure defines timeframe for reporting medication errors and near misses				
49. Policy or procedure defines timeframe for reporting near misses				
50. Policy defines identification and storage of medications brought in by the patient				
51. Organization policy defines storage and control of sample medications				
52. Policy describes management of medications to prevent loss or theft				
53. Policy describes accounting of controlled substances according to laws and regulations				
54. Policy/procedure defines "sentinel event"				

55. Definition of sentinel elements include at least 1. Unanticipated death unrelated to the natural course of the patient's illness or underlying condition (ex. suicide)				
2. Major permanent loss of function unrelated to the patient's natural course illness or underlying condition				
3. Wrong-site, wrong-procedure, wrong-patient surgery				
Prevention and control of infection				
56. Policy and procedure consistent with national laws and regulations and professional standards identify the process for managing expired supplies (IV fluids, catheters, sutures and the like)				
57. Policies and procedures for equipment cleaning and sterilization in the central unit are based on manufacturer's recommendations and current practice				
58. Laundry department policies and procedures include infection prevention practices				
59. Policies and procedures are written for kitchen sanitation				
60. Policy guides provision of vaccinations and immunizations for staff				
61. Policy guides the 1. evaluation of staff exposed to infectious diseases				
2. counseling follow-up of staff exposed to infectious diseases				
3. follow-up of staff exposed to infectious diseases				
62. Policy and procedures describe hand hygiene guidelines. *References used (e.g. WHO, US CDC, JCI) should be cited on the procedure and dated*				
63. Policies and procedures outline steps that are taken when shortages occur, e.g. of drugs or staff				
64. Policy and/or procedure guides elimination or limitation of smoking				
65. Smoking limitation policy and/or procedure applies to 1. patients				
2. families				
3. visitors				
4. staff				

66. Policy describes 1. evaluation of staff exposed to infectious diseases				
2. counseling of staff exposed to infectious diseases				
3. follow-up of staff exposed to infectious diseases				
67. Policy and regulations define required credentials for each medical staff member				
68. Policy describes process for the review of each medical staff member's credential file				
69. Policy/procedure lists the required contents of personnel files				
70. Policy establishes those health care practitioners who have access to the patient's record(s)				
71. A written policy addresses the privacy and confidentiality of information				
72. The abovementioned policy is based on and consistent with laws and regulations				
73. The policy defines the extent to which patients have access to their health information				
74. The policy defines the process of patients' gaining access to health information				
75. A written policy addresses information security, including data integrity				
76. The abovementioned policy is consistent with laws or regulations				
77. Policy includes levels of security for each category of data and information are identified				
78. Policy describes the process of retention of patient clinical records, other data and information				
79. The policy describes expected confidentiality and security of the retention process provides				
80. Records, data, and information are destroyed appropriately				
81. Policy determine the format and location of entries				
82. Policy determine specific content of patient clinical record				
83. Those authorized to have access to the patient clinical record are identified in organization policy				

84. Those authorized to make entries in the patient clinical record are identified in organization policy				
Governance and and management				
85. The organization's governance structure is described in the written documents				
86. Those responsible for governance and managing are identified by title or name				
87. Governance responsibilities and accountabilities are described in the documents				
88. The documents describe how the performance of the governing entity and managers will be evaluated and any related criteria				
89. There is an annual documented performance evaluation of governance				
90. Organization plans describe the care and services to be provided				
91. There is at least one documented review of the medication management system within the previous 12 months				
92. The organization identifies those situations for which gloves and/or masks/or respirators are required				
93. The organization identifies those situations for which hand washing and hand disinfection or surface disinfecting procedures are required				
94. The organization has adopted hand-hygiene guidelines from an authoritative source				
95. Appropriate time frames for performing assessments are established for all settings and services				

Laboratory and Radiology

Standard Measurable element	Document name	Yes	No	Comments
1. Laboratory services meet applicable local and national standards, laws, and regulations *Check the presence of certificate*				
2. There is a laboratory equipment management program				
3. All testing, maintenance, and calibration of equipment are documented				
4. Essential reagents and supplies are identified				
5. The laboratory has written guidelines for evaluation of all reagents				
6. Procedures describe the process of 1. ordering of tests				
2. collection of specimens for tests				
3. identification of specimens for tests				
4. transport of specimens				
5. storage of specimens				
6. preservation of specimens				
7. receipt of specimens				
8. tracking of specimens				
7. The laboratory has established reference ranges for each test performed				
Laboratory register				
8. All smear examinations performed in the laboratory have been recorded in the laboratory register (previous month)				
9. The following fields have been included in the register and have been completed for newly diagnosed and registered patients: 1. date the specimen was received				
2. name of the patient				
3. address of the patient				
4. name of the referring facility				
5. reason for sputum-smear microscopy				
6. results				

7. basic management unit and TB laboratory register number				
10. Each patient has at least two (or three) results from the sputum-smear examination				
Radiology department				
11. Radiology and diagnostics imaging services meet applicable local and national standards, laws, and regulations *Check the presence of certificate*				
12. Quality control program for the radiology and diagnostic imaging services is documented				
13. Quality control program includes 1. validation of test methods				
2. daily surveillance of imaging results				
3. rapid correction when a deficiency is identified				
4. testing reagents and solutions				

Medical records review checklist

Clinical records	Yes	No	Comments
1. Patient clinical records are maintained through the use of an identifier unique to the patient or some other effective method			
2. Patient clinical records contain adequate information to identify the patient			
3. Patient clinical records contain adequate information to support the diagnosis			
4. Patient clinical records contain adequate information to justify the care and treatment			
5. Patient clinical records contain adequate information to document the course and results of treatment			
6. The author can be identified for each patient clinical record entry			
7. The date of each patient clinical record entry can be identified			
8. Clinical records contain the completed summary list per organization policy *(check the respective policy first)*			
9. The clinical summary includes: 1. patient status (SS+ or SS-)			
2. procedures			
3. other interventions provided			
4. patient's continuing care needs			
10. Patient's record contains: 1. the identity of the individual providing the information to the patient and family			
2. consent is documented, by signature or record of verbal consent			
3. identified medical needs of the patient			
4. assessment findings			
5. medical assessments are documented within 24 hours of admission			
6. reassessments and findings			
7. laboratory reference ranges are included in the clinical record at the time test results are reported			
8. planned care (in the form of measurable progress goals)			

9. care provided for each patient; written by the health professional providing the care			
10. diagnostic imaging test orders; include a clinical indication/rationale when required for interpretation			
11. clinical laboratory test orders; include a clinical indication/rationale when required for interpretation			
12. procedures to establish the diagnosis of TB are clearly described			
13. results of performed procedures			
14. list of current medications taken prior to admission			
11. Orders are found in a uniform location in patient records			
12. Medications prescribed or ordered are recorded for each patient			
13. Educational needs assessment findings are recorded in the patient's record			
14. This assessment findings are documented: 1. Patients beliefs and values			
2. Education level and language			
3. Emotional barriers and motivations			
4. Physical and cognitive limitations			
5. Willingness to receive information			
15. There is uniform recording of patient education by all staff			
16. A copy of the discharge summary is placed in the patient record			
17. Those caring for the patient can find and retrieve assessments as needed from the patient's record or other standardized accessible location			
Discharge summary	**Yes**	**No**	**Comments**
18. Medication information is kept in record at discharge or transfer			
19. The discharge summary contains 1. follow-up instructions			
2. reason for admission			
3. diagnoses			
4. comorbidities			

5. significant physical and other findings			
6. diagnostic and therapeutic procedures performed			
7. significant medications, including discharge medications			
8. patient's condition/status at the time of discharge			
20. A discharge summary is prepared at discharge by a qualified individual			
Transfer summary	**Yes**	**No**	**Comments**
21. Patient clinical information or a clinical summary is transferred with the patient			
22. The records of transferred patients contains 1. documentation or other notes as required by the policy of the transferring organization			
2. note the reason(s) for transfer			
3. note any special conditions related to transfer			
4. documentation of any change in patient condition or status during transfer			
5. documentation or other notes as required by the policy of the transferring organization			
23. The transfer summary contains 1. the reason for admission			
2. the significant findings			
3. any diagnosis made			
4. any procedures performed			
5. any medications and other treatments			
6. patient's condition at transfer			
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.*	**Yes**	**No**	**Comments**
24. TB treatment cards include : 1. information on referrals			

2. information on HIV care			
3. information on date and results of HIV test			
4. information on beeng a migrant worker			
5. information on anti-retroviral treatment			
6. information on the date when co-tremoxazole preventive therapy started			
7. information on dates of radiography and results			
8. complete patient addresses or information where to locate the patient is provided.			
25. Information from the TB treatment register and the laboratory register has been correctly recorded on the TB treatment card.			
26. Medication administration is recorded for each dose			
27. Medication information is kept in the patient's record			
28. Administered medications are noted in the patient's record			
29. Adverse effects of treatment are reported on the TB treatment card			
TB treatment register	**Yes**	**No**	**Comments**
30. Childhood TB cases have been recorded in the TB treatment registers			
31. Patients are entered in the TB treatment register in numerical and chronological order, starting with 1 at the beginning of the calendar year			
32. 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.*			
33. Correct TB registration numbers have been recorded in the laboratory register			
34. The diagnosis and results of follow-up sputum examinations have been recorded accurately in the TB treatment register			
35. 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.*			

36. Sputum follow-up examinations are done on time *Every month during the intensive phase of treatment*			
37. Positive sputum results are entered in red ink in the TB treatment register			
38. For all patients who completed their treatment, treatment outcomes and their corresponding dates are written in the TB treatment register *Review the TB treatment register for the quarter of the previous year that corresponds to the current quarter*			
39. Definitions of treatment outcomes are aligned with the definitions established by the WHO			
40. Patients HIV status is recorded in the TB treatment register			
41. Patients migrant worker status is recorded in the TB treatment register			

APPENDIX 3. IRB Approval

American University of Armenia | Հայաստանի Ամերիկյան Համալսարան

February 8, 2016

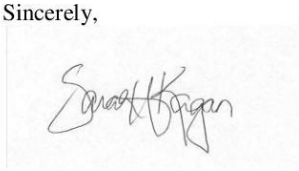
PRINCIPAL INVESTIGATOR: Varduhi Petrosyan, MS, PhD
CO-INVESTIGATOR: Nune Truzyan, DVM, MPH, Lusine Musheghyan, MA, MPH, Zaruhi Grigoryan, BSc, MPH, Hratchia Lylozian, MD
TITLE: Quality assessment of the Republican Tuberculosis Dispensary diagnostic and treatment services
PROTOCOL #: AUA-2016-002

Varduhi Petrosyan, MS, PhD
Via Email: vpetrosi@aua.am

Dear Dr. Petrosyan,

The above referenced protocol was reviewed and approved by the 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 February 8, 2016. This study will be due for continuing review on or before February 8, 2017. 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 skagan@nursing.upenn.edu with a copy to skagan@aua.am and auairb@aua.am, should you have any questions about the information in this letter. Thank you.

Sincerely,



Sarah H. Kagan PhD, RN
Chair, AUA IRB
Adjunct Professor, AUA
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APPENDIX 4. Consent Forms

American University of Armenia
Institutional Review Board #1
School of Public Health

Consent Form for In-Depth Interview with physicians in the NTCC

Title of Research Project: Quality assessment of the National Tuberculosis Control Center (NTCC) diagnostic and inpatient treatment services.

Hello, my name is _____ I am a researcher at the Center for Health Services Research and Development at the American University of Armenia. Our center in collaboration with the National TB Control Center conducts a study to assess the quality of TB diagnostic and treatment services provided by the NTCC. The findings of the study will be used to give recommendations to the hospital for further improvements in the services' provision.

You are invited to participate in this study to share your expertise and experience on daily practices in the NTCC. Your knowledge and opinion is extremely important for us. Your participation in this study is completely voluntary. Your decision to participate or refusal to do so will have no consequences on you and on your work and position. During the interview you may refuse to answer any question or stop the interview at any time. The information you provide during the interview will pose **no risk** for you and will not leave consequences on your work and position. Instead, the NTCC staff and TB patients will **benefit** from the program, as the information you provide will be anonymously used for an impartial assessment of the hospital, for identification of consistencies and deviations from the standards and will be used for further improvements in your daily practices and your work environment.

The information you provide will not be accessible to any person other than the research team and will be used only for the research purposes without revealing your identity including your name, position. To ensure your privacy any information that could enclose your personality will be destroyed upon the completion of the data collection. The notes and final report will not contain any information that could lead to identification of your personality.

The interview will last approximately 40-45 minutes. If you give your permission we will tape record our interview and take notes during the interview to make sure not to lose any comment you will make. If no, we will only take notes with your permission.

In future you can contact the coordinator of this study Nune Truzyan by (060) 61 25 91, if you have any other questions regarding this study. If you feel you have not been treated fairly or think you have been hurt by joining the study you should contact Dr. Kristina Akopyan, the Human Subject Protection Administrator of the American University of Armenia (060) 61 25 61.

American University of Armenia
Institutional Review Board #1
School of Public Health

Consent Form for In-Depth Interview with nurses in the NTCC

Title of Research Project: Quality assessment of the National Tuberculosis Control Center (NTCC) diagnostic and inpatient treatment services.

Hello, my name is _____ I am a researcher at the Center for Health Services Research and Development at the American University of Armenia. Our center in collaboration with the National TB Control Center conducts a study to assess the quality of TB diagnostic and treatment services provided by the NTCC. The findings of the study will be used to give recommendations to the hospital for further improvements in the services' provision.

You are invited to participate in this study to share your expertise and experience on daily practices in the NTCC. Your knowledge and opinion is extremely important for us. Your participation in this study is completely voluntary. Your decision to participate or refusal to do so will have no consequences on you and on your work and position. During the interview you may refuse to answer any question or stop the interview at any time. The information you provide during the interview will pose **no risk** for you and will not leave consequences on your work and position as provided information will not be identifiable by either senior or other staff members at the NTCC. Instead, the NTCC staff and TB patients will **benefit** from the program, as the information you provide will be anonymously used for an impartial assessment of the hospital, for identification of consistencies and deviations from the standards and will be used for further improvements in your daily practices and your work environment.

The information you provide will not be accessible to any person other than the research team and will be used only for the research purposes without revealing your identity including your name, position and workplace. To ensure your privacy any information that could enclose your personality will be destroyed upon the completion of the data collection. The notes and final report will not contain any information that could lead to identification of your personality.

The interview will last approximately 40-45 minutes. If you give your permission we will tape record our interview and take notes during the interview to make sure not to lose any comment you will make. If no, we will only take notes with your permission.

In future you can contact the coordinator of this study Nune Truzyan by (060) 61 25 91, if you have any other questions regarding this study. If you feel you have not been treated fairly or think you have been hurt by joining the study you should contact Dr. Kristina Akopyan, the Human Subject Protection Administrator of the American University of Armenia (060) 61 25 61.

American University of Armenia
Institutional Review Board #1
School of Public Health

Consent form for In-Depth Interviews with the patients of NTCC and their family members

Title of Research Project: Quality assessment of the National Tuberculosis Control Center (NTCC) diagnostic and inpatient treatment services.

Hello, my name is _____I am a researcher at the Center for Health Services Research and Development at the American University of Armenia. Our center in collaboration with the National TB Control Center conducts a study to assess the quality of TB diagnostic and treatment services provided by the NTCC. The findings of the study will be used to give recommendations to the hospital for further improvements in the services' provision.

You and other TB patients and family members are invited to participate in the study to share your experience of inpatient treatment including admission process, privacy/confidentiality issues, and adequacy of information and education received.

Your participation in this study is completely voluntary. Your decision to participate or refusal to do so will have no consequences on future provision of any type of health care services to you. During the interview you may refuse to answer any question or stop the interview at any time. The information you provide during the interview will pose **no risk** for you. Moreover, the NTCC staff and TB patients will benefit from the program, as the information you provide will be anonymously used for further improvements in NTCC daily practices and work environment.

The information you provide will not be accessible to any person other than the research team and will be used only for the research purposes without revealing your identity and the identity of your doctor. To ensure your privacy any information that could enclose you or your doctor personality will be destroyed upon the completion of the data collection. The notes, final report will not contain any information that could lead to identification of the identities.

The interview will last approximately 40-45 minutes. If you give your permission we will tape record our interview and take notes during the interview to make sure not to lose any comment you will make. If no, we will only take notes with your permission.

In future you can contact the coordinator of this study Nune Truzyan by (060) 61 25 91, if you have any other questions regarding this study. If you feel you have not been treated fairly or think you have been hurt by joining the study you should contact Dr. Kristina Akopyan, the Human Subject Protection Administrator of the American University of Armenia (060) 61 25 61.

Consent Form for Observation in the NTCC facilities

Hello, my name is ____ I work for the Center for Health Services Research and Development of the American University of Armenia. Our center in collaboration with the National TB Control Center conducts a study to assess the quality of TB diagnostic and treatment services provided by the NTCC. The findings of the study will be used to give recommendations to the hospital for further improvements in the services' provision.

In scope of this program our research team interviews NTCC staff, reviews the hospital documents and observes different sites in the hospital. We will observe different facilities of the hospital, including yours. During the observation we will make notes in the checklist. The notes will not contain any personal information of any of the staff member. Do you agree if we observe these facilities?

Thank you.