

Tuberculosis Control Program Information System Specification

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1. Purpose

The purpose of the Information system is to provide tools for tracking and monitoring active cases of Tuberculosis in Montenegro. The system should encompass both clinical data and laboratory results in order to provide a complete overview of the prevalence of this condition in a given territory.

2. Objectives and Deliverables

The objective is to develop a user-friendly application, with a number of functionalities, including data collection in a physically distributed environment with clients located throughout the entire country. The system should provide a disconnected approach (offline mode) where clients periodically synchronize data with the central database (synchronization will not be used at present but will be implemented later).

The purpose of the information system is to provide analytical information about tuberculosis cases and their treatment in accordance with the specification defined by Euro TB.

The vendor is expected to deliver the following in the specified order:

- Application or group of applications that fulfill the given specification.
- User Documentation.

In specific, the Information system will consist of the following functionalities and features:

- Clinical data collection,
- Clinical data synchronization with the central database,
- Central clinical database overview, analysis and reporting,
- Laboratory results collection,
- Central laboratory results database overview, analysis and reporting,
- Data export in compliance with the Euro TB data specification.

3. Standards and requirements

3.1. Development tools and technologies used

The system should run under the Microsoft Windows platform, the central database should run under MS SQL Server 2005 or can be run under Windows platforms in case that database is not synchronized with local (regional) databases. Local/regional (if any) databases should work under Microsoft Access.

3.2. Hardware standards

Configuration under which software can be used as local database:

- Pentium D 2.4 GHz/512 MB RAM/80GB

Server (for future use with sync option):

- 1 x Pentium D 2.0 GHz/1GB/Ultra160 SCSI integrated

Vendors should indicate whether the configuration can be supported and what is the minimal configuration required.

3.3 Other requirements

- Local support provided – phone support provided on local/BCMS (Bosnian, Croatian, Montenegrin, Serbian) language
- Written manual on BCMS language provided as well as Help on local language within software
- After sale support provided within warranty period (software debugging problems only) – At least 2 years of after sale support provided (to be defined by possible separate contract)
- Initial training provided for minimum 5 people - immediately after software installation
- Warranty period minimum 1 year
- Delivery period should not exceed 60 days (development and installation) from day of signing of contract.

4. Functional Specification

4.1. Clinical data collection

The application should enable the registration of tuberculosis patients, as well as their admittance records and course of treatment, the facilities in which they undertook treatment and the doctors in charge. The application will be used by clinical staff in Special Hospital for Lung Diseases in Brezovik, where relevant data from referent health facilities is collected in paper form.

To enter the application the user must provide a valid username and password. Users should be able to change their passwords but not their usernames.

Upon entering the application the user should be notified of patients whose release date is within the following timeframe, patients whose release date has passed, and of messages sent from the program supervisor. The duration of this timeframe should be updatable by the program supervisor.

4.1.1. Medical facilities register

Medical facilities belonging to a certain region are to be defined through a central administrative application. The following data should be kept up-to-date:

- Municipality (to be chosen from dropdown list)
- Place (to be chosen from dropdown list)
- Address
- Telephone number
- Fax number
- E-mail address

4.1.2. Medical staff records

The application should allow record keeping for doctors treating tuberculosis patients in the country. The records should be searchable by first name, last name and id number.

The form should contain the following fields:

- First name
- Last name
- Identification number (unique)
- Places of employment (the form should provide a list of every medical facility in the country from which those the person is employed in, can be chosen)

4.1.3. Patient records

This is the central part of the application. The necessary data is gathered, in paper form and delivered to the SHLD Brezovik where it is entered into the system. Possibility of synchronizing with regional centers should be enabled.

The program should allow the preview of patient records and search by the following criteria:

- First name
- Last name
- ID number
- Case number
- Admittance date (period from - to)
- Medical facility.

The program should primarily enable the recording of patient data and the form should contain three separate sets of fields logically following the course of treatment:

I Part – Personal data

- Medical facility (to be chosen from a dropdown list)
- Case number
- First name
- Parent's name
- Last name
- ID number
- Country of birth (to be chosen from a dropdown list)
- Municipality of birth (to be chosen from a dropdown list)
- Place of birth (to be chosen from a dropdown list)
- Date of birth
- Age group
- Marital status
- Telephone number
- Citizenship (to be chosen from a dropdown list)
- Gender
- Address
 1. Country (to be chosen from a dropdown list)
 2. Municipality (to be chosen from a dropdown list)
 3. Place (to be chosen from a dropdown list)
 4. Street and number

- Level of education
- Job description
- Organization of employment.

II Part – Admittance data

- Diagnosis (to be chosen from a dropdown list)
- Site of disease (multiple choice checkbox list)
- Manner of diagnosis (single choice checkbox list)
- Patient type (single choice checkbox list)
- Medical history (multiple choice checkbox list, possibility to enter year)
- Risk factors (multiple choice checkbox list)
- Symptom duration
- Beginning of treatment date
- BCG inoculation (Yes/No field)
- Cavern (Yes/No field)
- Admittance date
- Attending doctor (to be chosen from a dropdown list)

III Part – Release data

- Hospitalization - multiple records containing the following fields:
 1. Medical facility (to be chosen from a dropdown list)
 2. Date
 3. Number of days in hospital
- Laboratory test results and anti-tuberculosis drug susceptibility – multiple records containing the following fields :
 1. Month
 2. Date
 3. Microscope (+ / - / NR / NE)
 4. Culture (+ / - / NR / NE)
 5. Drug susceptibility (HRZSE / O / NR / NE)
- Course of treatment - multiple records containing the following fields :
 1. Initial phase (number of months followed by HRZSE – e.g. 3HR)
 2. Secondary phase (number of months followed by HRZSE – e.g. 3HR)
- Number of house calls
- Number of contacts (total, examined, diagnosed)
- Treatment outcome (single choice checkbox list, possibility to enter date)
- Release date
- Attending doctor (to be chosen from a dropdown list based on the selected medical facility).

The first and second sets of fields are to be entered at the time of admittance while the third set is entered upon the patient's release.

In the third set of fields, initial laboratory test results and anti-tuberculosis drug susceptibility as well as hospitalization details might be provided on admittance.

While recording patient's data, the data should automatically be compared to existing patients records using two criteria – ID number or first name, last name and birth date combination Search should be as loose as possible – case insensitive and insensitive to culture specific letters.

Case records can be annulled in situations in which patients are misdiagnosed and the reason for cancellation must be provided. These records should not be deleted from the system and their preview must be allowed.

The admittance data can only be altered within a certain timeframe but not after the release data has been entered. Similarly the release data can also only be altered within a certain timeframe. The duration of these timeframes should be updatable by the program supervisor.

4.1.4. Data analysis and reporting

The application should provide two reports:

- Patient records exported in a Microsoft Access format (column definitions can be found in Appendix A),
- Summary case data export to Microsoft Word (column definitions can be found in Appendix B).

4.2. Clinical data synchronization with the central database

The application should enable data exchange between regional centers (that are going to be established in future) and the central database in SHLD Brezovik.

During this exchange patient records, medical staff records and changes in medical facility records are to be sent from regional centers (that are going to be to be established in future) to the central database in SHLD Brezovik. This exchange should only include new data or data modified since the last successful synchronization.

To enter the application the user must provide a valid username and password.

Upon entering the application the data pertaining to the last synchronization should be displayed. This data includes:

- The user who performed the synchronization,
- Synchronization date and time,
- The course of synchronization (time and action performed),
- Synchronization status (successful / unsuccessful).

The application should allow the user to view the synchronization history and to perform new data synchronization. During the synchronization process detailed information about the course of synchronization should be displayed. Upon completion the user should be notified about the synchronization status.

4.3. Central clinical database overview, analysis and reporting

This application is intended for use by the program supervisor and should give the user an overall view of system information in addition to the possibility of communication with regional centers and the modification of system data.

To enter the application the user must provide a valid username and password.

4.3.1. Medical facilities register

The medical facilities belonging to a certain region are defined through this application.

The form for the new medical facility should contain the following fields:

- Region (to be chosen from dropdown list)
- Commune (to be chosen from dropdown list)
- Place (to be chosen from dropdown list)
- Address
- Telephone number
- Fax number
- E-mail address.

4.3.2. System settings

System settings include timeframes in which patients should be released with the purpose of notifying appropriate regional centers of these cases in a timely fashion, as well as timeframes in which case data (entered upon admittance or release) can be altered, or can be annulled.

4.3.3. Messages

Software should enable the program supervisor to communicate important information to all or selected regional centers through the application.

The form should contain a list of all sent messages with detailed information about each one:

- Date
- Message subject
- Message text
- List of regional centers the message was sent to.

4.3.4. Patient records

Patient records are to be entered into the system in SHLD Brezovik. Option for entering patients records in some of the regional centers and then transferred to the central database within SHLD by the synchronization process, should be enabled for future use. New patient records are compared to existing patients records using two criteria – ID number or first name, last name and birth date combination.

The form should contain a list of all patients, and allow the user to browse through every one of their cases. Patient records should be searchable by:

- First name
- Last name
- ID
- Regional center.

4.3.5. Data analysis and reporting

The application should provide several reports:

- A synchronization report, which should contain a list of the last 10 synchronizations, including the last successful synchronization, for each regional center. For each item the commencement time and status (successful / unsuccessful) should be presented, so that the program supervisor can react in a timely fashion and contact the regional centers if necessary.

- Patient records exported in a Microsoft Access format (column definitions can be found in Appendix A),
- Summary case data exported to Microsoft Excel in the provided format,
- Patient records exported to Microsoft Excel in the format provided by Euro TB.

4.4. Laboratory results collection

The application should enable the recording of laboratory results for tuberculosis patients.

To enter the application the user must provide a valid username and password. Users should be able to change their passwords but not their usernames.

Upon entering the application the user should be notified of messages sent from the program supervisor.

4.4.1. Medical facilities register

Medical facilities belonging to a certain municipality are to be defined through a central administrative application. The following data should be kept up-to-date:

- Municipality (to be chosen from an dropdown list)
- Place (to be chosen from an dropdown list)
- Address
- Telephone number
- Fax number
- E-mail address.

4.4.2. Medical staff records

The application should allow record keeping for doctors treating tuberculosis patients in the country. The records should be searchable by first name, last name and id number.

The form should contain the following fields:

- First name
- Last name
- Identification number (unique)

Places of employment (the form should provide a list of every medical facility in the country)

4.4.3. Laboratory staff records

The application should allow record keeping for every staff member working in the laboratory. The records should be searchable by first name, last name and id number. Records should be maintained even after the staff member no longer works in the facility.

The form should contain following fields:

- First name
- Parent's name
- Last name
- Identification number (unique)
- Gender
- Date of birth
- Status (Active / Not active)

- Job description (to be chosen from a dropdown list)
- Level of education
- Number of years of employment in the laboratory
- Number of working hours per day
- Year of the last undertaken educational course.

4.4.4. Patient records

This is the central part of the application. Every test result is to be entered into the system and stored permanently, regardless of whether it is positive or negative.

The program should allow the preview of patient records and search by the following criteria:

- First name
- Last name
- ID number
- Case number
- Admittance date (period from - to).

The program should primarily enable the recording of patient data and the form should contain five separate sets of fields:

I Part – Patients personal data

- First name
- Parent's name
- Last name
- ID number
- Date of birth / Year of birth
- Gender
- Address
 1. Country (to be chosen from an dropdown list)
 2. Municipality (to be chosen from an dropdown list)
 3. Place (to be chosen from an dropdown list)
 4. Street and number
- Telephone number.

II Part – Admittance data

- Medical facility (to be chosen from a dropdown list)
- Attending doctor
 1. Name (to be chosen from a dropdown list)
 2. Medical facility department
 3. Phone number
 4. E-mail address
- Case number
- Specimen (single choice checkbox list)
- Patient type (single choice checkbox list)
- Testing grounds (single choice checkbox list)
- Specimen date
- Specimen taken by (single choice checkbox list with a corresponding dropdown list if a doctor or lab technician is selected)
- Admittance date.

III Part – Microscopy result

- Specimen suitability(Yes/No field)
- Acid resistant bacteria (to be chosen from a dropdown list)
- Supervising doctor (to be chosen from a dropdown list)
- Date
- Note.

IV Part – Culture result

- Plating date
- Identified bacteria (single choice checkbox list)
- Test result (to be chosen from a dropdown list)
- Supervising doctor (to be chosen from a dropdown list)
- Date
- Note.

V Part – Drug susceptibility

- Plating date
- Test result for each of the 5 drugs – HRZSE (+ / - / NR / NE)
- Supervising doctor (to be chosen from a dropdown list)
- Date
- Note.

The first and second set of fields are entered at the time of admittance while the third, fourth and fifth sets are entered when the test results are final.

While recording patient's data, the data should automatically be compared to existing patients records using two criteria – ID number or first name, last name and birth date combination.

The application should allow entering test results for staff members, so as to enable the tracking of any case of disease within the laboratory itself.

4.4.5. Data analysis and reporting

The application should provide two reports:

- Summary case data (report definition will be provided as soon as possible).
- Detailed report for multi-resistant patients with their test results history.

4.5. Central laboratory results database overview, analysis and reporting

This application is intended for use by the program supervisor and should give the user an overall view of system information in addition to the possibility of communication with laboratories and the modification of system data.

To enter the application the user must provide a valid username and password.

4.5.1. Medical facilities register

The medical facilities belonging to a certain region are defined through this application.

The form for the new medical facility should contain the following fields:

- Region (to be chosen from an dropdown list)
- Municipality (to be chosen from an dropdown list)
- Place (to be chosen from an dropdown list)
- Address
- Telephone number
- Fax number
- E-mail address.

4.5.2. Patient records

Patient records are to be entered into the system in laboratory. New patient records are compared to existing patients records using two criteria – ID number or first name, last name and birth date combination.

The form should contain a list of all patients, and allow the user to browse through every on of their cases. Patient records should be searchable by:

- First name
- Last name
- ID
- Laboratory.

4.5.3. Data analysis and reporting

The application should provide one report:

- A report containing patients with positive laboratory test results, not found in the clinical database, and vice versa, patients in the clinical database with positive test results not found in the laboratory test results database.

5. Non Functional Specification

5.1. Offline work and synchronization

Due to current conditions concerning Internet connectivity in Montenegro both the application for Clinical data collection as well as the one for Laboratory results collection should work in offline mode. Only the small segments of data (i.e. changes in data) should be transferred through the internet by means of the synchronization process. The client applications should be able to work with modem internet connections.

5.2. Scalability

The information system design should allow for the possibility of subsequent inclusion of regional centers and laboratories without a significant performance hit.

5.3. Security

The information system database will store sensitive personal data concerning patients (including HIV test results) which can be subject to all kinds of abuse and discrimination. Bearing this in mind, special attention should be given to security issues. In addition to restricted access to the application through both Windows operating system and application password protected users, sensitive data should be encrypted, and in such form stored in local databases, transferred through the internet, and stored in the central database.

APENDIX A. Column definition for data export to Microsoft Access

Number	Number
Medical facility	Text
Last name	Text
First name	Text
Commune	Text
Gender	Text
Age group	Text
Date of birth	Date
Personal ID number	Text
Job description	Text
Patient type	Text
Risk group	Text
Previous medical history	Text
Pulmonary tuberculosis	YES/NO
Extra-pulmonary tuberculosis	YES/NO
Cavern tuberculosis.	YES/NO
Extra-pulmonary localization	Text
Microscopy results before therapy	Text
Culture results before therapy	Text
Microscopy results after initial phase	Text
Culture results after initial phase	Text
Microscopy results after therapy	Text
Culture results after therapy	Text
Drug susceptibility	Text
Other diagnostics	Text
Symptoms duration	Number
Beginning of treatment date	Text
Course of treatment - Initial phase	Text
Course of treatment - Secondary phase	Text

Admittance date	Date
Release date	Date
Treatment outcome	Text
Number of days in hospital (total)	Number
Number of contacts - total	Number
Number of contacts - examined	Number
Number of contacts - diagnosed	Number
Number of house calls	Number
Notes	Text