



## Early Detection and Integrated Management of Tuberculosis in Europe

PJ-03-2015

Early diagnosis of tuberculosis

### D5.2

## Settled migrants screening set up

### WP 5–Migrant TB detection, prevention and treatment

<b>Due date of deliverable</b>	2 <sup>nd</sup> February 2017
<b>Actual submission date</b>	05 / 02/ 2017
<b>Start date of project</b>	3 May 2016
<b>Duration</b>	9 months
<b>Lead beneficiary</b>	OSR
<b>Last editor</b>	Alberto Matteelli
<b>Contributors</b>	UNIBS
<b>Dissemination level</b>	PU



*This project E-DETECT TB has received funding from the European Union's Health Programme (2014-2020) under grant agreement N°709624.*

## History of the changes

On the 20<sup>th</sup> of February 2017, the project officer Cinthia MENEL LEMOS requested the following revisions:

1. To include the voluntary basis of the testing, following the informed consent, describing how refusals will be registered and managed.
2. To provide more details on the current management of LTBI in the Province of Brescia: how many TST, IGRA, chest XR, treatments for LTBI were provided in the last 2 years.
3. To describe the roles and sharing of responsibilities of the partners of the network, based on the agreed protocols.
4. To provide details on questionnaire used in the digital data collection tool,
5. To describe compliance with confidentiality and personal data protection
6. To explain how the data collection tool is linked to the WP on link of existing databases on active and latent TB cases
7. To specify the link to the national surveillance system, and to explain how the application will be sustained after the end of the E-DETECT TB project

This is therefore the second version of the deliverable.

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## Definitions and acronyms

Acronyms	Definitions
TB	Tuberculosis
LTBI	Latent Tuberculosis Infection
CARA	Centro Accoglienza per Richiedenti Asilo, Centre for Accomodation of Asylum-seeker
CSPA	Centro Primo Soccorso e accoglienza, First Aid and Reception Centre
Usmaf	Uffici di sanità marittima, aerea e di frontiera
SPRARS	Sistema di Protezione per Richiedenti Asilo e Rifugiati, System of Protection of Asylum-seekers and Reefuges
CAS	Centri di Accoglienza Straordinaria, Emergency Reception Centres

### 1. Introduction

In low TB incidence countries, asylum seekers represent a population at increased risk of tuberculosis, particularly of reactivation tuberculosis. Compared with other recent immigrants, asylum seekers represent a relatively stable population and could benefit from screening and treatment interventions for latent tuberculosis infection (LTBI). Although policies may be in place, LTBI screening practices are scarcely implemented mainly due to poor standardisation, virtually non-existent monitoring capacity, and uncertainties on the cost-benefit ratio of the intervention.

A priority research topic is therefore measuring completion rates of screening and treatment practices for LTBI among asylum seekers under different circumstances. In particular, new information is needed on the feasibility, acceptability, and cost-effectiveness of LTBI screening and treatment programmatic conditions.

The scope of **work-package 5 (WP5)- Migrant TB detection, prevention and treatment**, is measuring the magnitude/significance of the TB threat in refugees and asylum seekers, and measuring completion rates of screening and treatment practices.

The aim of deliverable **5.2-Settled migrant screening set up** is to develop, in collaboration with local and national health and immigration authorities, a coordinated protocol of intervention for LTBI management in a selected sample of reception centres.

#### 1.1. General context

The unpredictable arrival on migrants at several ports of Sicily and other South of Italy shores represent a major challenge. Shortly after arrival, migrants who seek for asylum are transferred in reception centers in other Italian regions, where they remain until the asylum request is analysed and a decision is taken. This takes, approximately, 18 months.

Italy has developed a specific organization to host asylum seekers and refugees, by accomodating them in a network of SPRARS (Sistema di Protezione per Richiedenti Asilo e Rifugiati, System of Protection of Asylum-seekers and Reefuges) managed by civil society organizations. Because the reception capacity of the SPRARS network is insufficient to cover the needs of the large number of incoming immigrants, a second network of centers, the CAS (Centri di Accoglienza Straordinaria, Emergency Reception Centres), frequently represented by hotels, has been created with the function to accommodate immigrants until they can be received in the SPRARS.

During the stay in the reception centers, both SPRARS and CAS, asylum seekers are expected to undergo health screening process for TB and LTBI. However, implementation challenges exist, as protocols are demanding and resource intensive. Due to the absence of an information system, the extent of implementation of screening practiced and their effectiveness are currently unknown.

## 2. Methodological approach

Under this component of the E-DETECT project, we planned to measure the extent of implementation and effectiveness of management practices for LTBI in the province of Brescia, Lombardy Region. During 2015 and 2016 over 3,000 asylum seekers were resettled in this Province from the ports of arrivals in the South of Italy. We approached the Local Health Authorities to inform them about the E-DETECT project, obtained necessary authorization for the intervention, and mounted local collaborations for project activities.

Information on screening practices and results of the screening cascade is not available due to the absence of a data collection system. As part of the project and of the activities, we are creating a retrospective individual database on such information in 2015 and 2016, collecting data from several sources: the list of subjects eligible for the screening is provided by the Prefettura, data on TST screening from the Public Health Clinic for Immigrants, data on follow-up procedures for those with a positive test from the Pneumology Outpatient Clinic. Very preliminary results show that among 3,170 resettled refugees, 2,268 (71.5%) received a TST test. A positive test (> 10 mm) was obtained in 832 (35.4%) subjects.

### **Two main lines of action were identified:**

- 1) Creating a network of all SPRARS and CAS in the Province of Brescia to make a common plan for standardization of screening practices.  
The network is coordinated by UNIBS, and linked to the health settings where screening and treatment activities take place: namely, the Brescia screening center where initial LTBI screening is implemented, and the outpatient TB clinic, where asylum seekers with a positive screen are referred for management.
- 2) Creating a new system for data recording of screening and treatment practices for LTBI in asylum seekers. We planned to develop and introduce a digital tool in order to create a centralized database with information that allow to measure effectiveness of implemented activities.

## 3. Activities

### 3.1. Current LTBI screening and treatment practices in the Province of Brescia

LTBI screening and treatment policy and practices for asylum seekers in the province of Brescia were reviewed.

Asylum seekers are expected to be systematically screened for LTBI using the Tuberculin Skin test (TST) administered through the Mantoux technique at one public screening center. Testing is conducted on voluntary basis, following verbal informed consent. In the unlikely event of refusal, testing may be offered once again after some time. In current practice, refusals are not registered (registration of refusal is planned to be collected by the App system implemented by the project, see below).

Persons with a reaction of 10 mm or more are referred to the Pneumology clinic for further management.

At the Pneumology clinic referred asylum seekers with a positive TST test are further screened with an interferon gamma release assay (IGRA).

Those who have a positive test receive a Chest-way.

Those who have a chest X-ray results with no abnormalities are prescribed treatment of LTBI using isoniazid daily for 6 months.

Treatment is monitored by the Pneumology clinic

### 3.2 Network of hosting centers and screening and treatment centres

A census of hosting centers for asylum seekers in the Province of Brescia was performed in collaboration and under the mandate of the Prefecture that has jurisdiction over these centers. Approximately 80 SPRARS and CAS are present in the Province

Representatives of all the centers were invited to three meetings where the nature of the project was explained and the bases for collaboration were discussed and, eventually, agreed.

Several informative and educational meetings were organized and implemented with small groups of centers. The nature, objectives and activities of the project were discussed with the people in charge at the screening center and the Pneumology clinic where data collection will be implemented. Agreement protocols were created.

The roles and responsibilities of the partners of the network were defined as described below:

- SPRARS and CAS: registration in the App of demographic information and implementation and registration in the App of symptomatic screening of active TB disease
- Spedali Civili, Public Health Clinic for Immigrants: implementation and registration in the App of TST results and clinical evaluation
- Spedali Civili, Pneumology Outpatient Clinic: implementation and registration in the App of IGRA and Chest X-ray results, as well as data on preventive treatment prescription, initiation and completion
- University of Brescia, Clinic of Infectious and Tropical Diseases: coordination of the project and data management, including maintenance and protection of the database; implementation and registration in the App of diagnostic and treatment procedures for active TB disease

### 3.3. Digital data collection tool

As a part of **D5.8- Development of an effective, digital recording tool for CPSA and CARA residents**, a digital recording tool was developed, to be implemented in the Province of Brescia. The APP structure has been widely discussed among WP5 partners, and was developed with full consistency with the information required by the database being developed as part of WP6.

Specifically, the questionnaire collects information on the presence or absence of the following symptoms (active disease screening):

- Cough for more than 2 weeks
- Fever for more than 7 days
- Haemoptysis
- Night sweats
- Weight loss

The App is identical to what described under product D5.1 as far as active disease screening and management is concerned. However, for the current deliverable, the section on screening and treatment of LTBI was added. The final design of the App containing all the information needed for LTBI screening and treatment has been completed. The development of the APP has been subcontracted after careful selection of the subcontractor. At the same time the structure of the back-office was also agreed upon, and the agreement for hosting the database at UNIBS was stipulated. UNIBS will coordinate data analysis.

Data entered in the App are immediately encrypted in the cloud service of the Google Firebase Platform. From the platform, data can be decrypted and downloaded into a back-office by authorized staff (data manager only) using a password. The back-office, that contains sensitive information, is stored in the server of the Institute of Infectious and Tropical Diseases, and is protected with the standard level of security ensured by all databases of the Institution.

The structure of the App has been discussed with the health workers in all SPRAS and CAS of the province, that will be in charge of demographic data entry and registration of TB symptoms. The App has also been discussed with health officers at the screening health site and the Pneumology clinic that will enter clinical data.

The APP for LTBI screening and management is expected to be introduced into practice in the month of March 2017.

No link with the national surveillance system could be established, as Italy has no current national surveillance system to capture information on TB and LTBI screening activities for refugees and asylum seekers.

We are in continuous dialogue with regional and national authorities informing them on the nature and the results of the project, and advocating for the adoption of the system at the expiration of the project itself. However, there is no certainty of continuation of data collection at regional and national level that will depend on the results of the project and on political decision. Clearly, this project increases the probability that the Region and the Country will ever have a data collection system in this area.

### 3.4 Ethics committee

The study entitle **EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB** (WP5 Migrant TB detection, prevention and treatment) presented at San Raffaele Institute Ethic Commission (protocol number 709624) the 25th October 2016 was approved the 10th November 2016. Informed written consent will be obtained from each subject before data collection.

## 4. Conclusions and future steps

Set up of a data collection tool for LTBI screening and treatment in settled migrant population is fully achieved on time (deadline postponed to M9). Data collection of asylum seekers hosted in over 80 SPRARS and CAS in the Province of Brescia is ready to start in March 2017.