



Early Detection and Integrated Management of Tuberculosis in Europe

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Early diagnosis of tuberculosis

D5.1

Temporary migrant screening set up

WP 5–Migrant TB detection, prevention and treatment

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History of the changes

Version	Date	Released by	Comments
2	22-02-16	DANIELA MARIA CRILLO	<ul style="list-style-type: none"> - Background information on TB among migrants in South of Italy - Questionnaire in English, French and Arabic added in Appendix 1 - Management of the refusals: information sheet and patient's education - Description of E-DETECT TB App - D5.1 postponement's reason - CARE project implementation - English editing

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Key word list

Tuberculosis, Migrants, TB screening

Definitions and acronyms

Acronyms	Definitions
TB	Tuberculosis
LTBI	Latent Tuberculosis Infection
CARA	Centro Accoglienza per Richiedenti Asilo
CSPA	Centro Primo Soccorso e accoglienza
Usmaf	Uffici di sanità marittima, aerea e di frontiera
OSR	Ospedale San Raffaele
POC	Point of Care
CARE	Common Approach for Refugees and other migrants' health
INMP	National Institute for Health Migration and Poverty

1. Introduction

The scope of **work-package 5 (WP5) - Migrant TB detection, prevention and treatment**, is to establish a mechanism to ensure that health services delivering TB care are accessible to asylum seekers at the point of arrival.

The aim of deliverable **5.1-Temporary migrant screening set up** was to develop, in collaboration with local and national health and immigration authorities, a coordinated protocol of intervention within *a selected sample of CSPA centres and to identify the asylum seekers as a relatively stable population who offer the opportunity of screening and treatment interventions for both active TB and LTBI*.

1.1. General context

In recent years, there has been a surge in the number of asylum seekers arriving via the Mediterranean route, with an ever-increasing number of people arriving on Sicilian shores. It is estimated that 170,100 people arrived in Italy by sea in the year 2014, 153,842 in the year 2015 and more than 180,000 in the year 2016 (www.interno.gov.it). Italy is a country with a low incidence of TB cases, with incidence below 10 per 100,000[1]. Since 2009, more than 50% of cases reported each year (and most MDR TB cases) have occurred in foreign-born persons[1]. Although TB diagnosis and treatment are offered for free to all those who report to a public hospital (regardless of their legal resident status), symptomatic migrants tend to report late, increasing the chance of complications and TB transmission.

To date, little data has been published on the incidence of TB amongst migrant populations and the majority of reports available concern northern European countries, where the context is significantly different to the Mediterranean one in terms of features and number of arrivals.

Recently, Schepisi et al published data from three TB case finding interventions conducted at primary centres and mobile clinics for migrants and asylum seekers (performed at five different sites in Rome and one site in Milan, Italy) [2]. Out of a population of 6347 migrants screened over a 4 years' period (2009-2014) by verbal screening through a structured questionnaire, TB was diagnosed in 11 persons representing 0.17% of the screened population. A similar incidence rate was reported in the Italian guidelines [3] for TB screening among migrants published in 2010, which states that "*active TB screening yield (number of identified cases over 100,000 persons screened) is very low corresponding in mean to 272 cases per 100,000 persons-year*".

The data from TB notification system shows that between 2010 and 2013, 876 new TB cases were reported in Sicily (median 4.4 cases per 100,000 persons-year). TB incidence rate (4.4 cases per 100,000 persons-year) is almost doubled when compared to incidence rate reported in the decade 1999-2008 (2.6 cases per 100,000 persons-year)[4]. Since July 2015 local health authorities (Usmaf) in collaboration with Garibaldi Hospital in Catania have been carrying out the active TB case finding at the Port of Catania. From July 2015 until July 2016, 11,804 migrants have been screened at the point of arrival by means of a multi-step questionnaire. Eighty-eight (88) individuals resulted questionnaire-positive and out of them twenty-nine (29) were referred to further analysis. Eleven (11) TB cases were diagnosed by GeneXpert and culture (estimated incidence 93 per 100,000 person-year).

Italian data on TB screening among migrants is limited and therefore does not allow for an exhaustive evaluation of different screening approaches. Most of the case-finding interventions are performed in symptomatic migrants who report themselves to health centres or who visit outpatient clinics for unrelated medical conditions. Moreover, due to the low resource setting of the centres, case finding investigations for TB are rarely provided by local health services. Microbiological and radiological investigations of suspected cases, when performed, require authorized transport of this population to local hospital. CSPA and CARA in the south of Italy are well recognised patterns in migration routes[5] and focusing intervention in these

structures will allow early detection of infection and spread prevention. Therefore, we plan to implement a locally-based intervention in a selected sample of CARA.

2. Methodological approach

The analysis of data collected by the Catania Prefecture and the consultation of the public and local health authorities led to the identification of two lines of action:

- 1) The implementation of the Usmaf initiative “TB on port” by giving an on-spot tool for active TB diagnosis: GeneXpert Omni (Cepheid).
Rationale: empowering the real-time active TB detection at point of arrival (Port of Catania), avoiding the need for transport to local hospitals, which entails government directed police escort and support. OSR will provide: the GeneXpert Omni, once available; GIV cartridges for sputum analysis; local staff training on the GIV, Ultra and Omni expert laboratory procedures.
- 2) The implementation of an active case finding strategy in a selected CARA centre in Sicily.
Rationale: targeting the population within the CSPA and the CARA centres will allow an accurate screening of individuals whose point of arrival is not monitored by Usmaf and who therefore have yet to receive TB screening. It will additionally allow health personnel to monitor and screen the cases that develop TB during the stay in the centre. The active approach of this initiative will ensure an early identification of cases and avoid the incidence of individuals falling critically ill and reporting themselves to the health authorities when the disease is in an advanced stage.

3. Summary of activities and research findings

3.1. Screening strategies set up

Identification of lines of action:

- 1) Implementation of the Usmaf initiative “TB on port”,
- 2) Implementation of an active case finding strategy in a selected CARA centre in Sicily

3.1.1 TB on port implementation

In accordance with the Italian Ministry of Health and with local authorities, the team will contribute and provide assistance to the initiative “TB on port” carried out in the port of Catania by the Sicilian government and the Italian MoH. This initiative screens for TB cases in migrants who arrive directly at the quayside. Screening time will be extended from 1 year to 1.5 years to allow for a minimum of 10 months of continuous use of the Xpert OMNI platform, which will be available next September.

3.1.2 Active case finding in CARA centre

The strategies for conducting the active screening of TB cases at CARA and CSPA have been widely discussed between WP5 partners and the local health authorities. All those arriving at the centres will be offered the opportunity to participate in a voluntary screening by completing a questionnaire provided (in different languages and with the support of an interpreter if necessary). Refusal to participate in the initiative will not impact a person’s eligibility for the other services available. In addition, information will be provided on the main symptoms of TB disease and individuals will be encouraged to contact the local health centres (Red Cross outpatient service) should these symptoms present themselves.

Based on the score obtained in the questionnaire, health personnel will be able to quickly identify those with suspected pulmonary TB. This will prompt the collection of sputum on site and the performance of a rapid test using GeneXpert. Individuals identified as MTB positive will be immediately transferred for treatment initiation and further testing at the infectious disease service of the Garibaldi Hospital in Catania. Agreement with the general director of the Garibaldi Dr Santonocito, the head of the Infectious Diseases department Prof. Caccopardo and the head of the emergency service Dr Pintaudi, has been reached to provide a fast-track hospitalization for detected cases.

3.2. Active TB screening tools

3.2.1 Questionnaire

Trained medical staff will verbally carry out the screenings with the use of a structured questionnaire. The questionnaire (appendix A) has been drafted following the WHO[6] and the ECDC[7] recommendations. It will collect information including individuals' personal data, date of arrival in the centre, past medical history, past TB history and risk factors for TB (including HIV/AIDS). Symptoms suggestive of TB, such as cough, fever, haemoptysis, night sweats and weight loss will be also recorded. WP5 partners have agreed that a sputum sample will be requested if at least one of the above-mentioned symptoms is present. This strategy will also allow the evaluation of each symptom's sensitivity and specificity for active TB disease in migrant population. The questionnaire is available in three languages (English, French, and Arabic) and the support of an interpreter will be available when requested. The three vehicles languages cover over 90% of the spoken languages of the migrant population within the centre.

3.2.1.1 Ethics committee

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

3.2.2 EDETECT APP

As a part of **D5.8- Development of an effective, digital recording tool for CPSA and CARA residents**, we plan/propose to substitute the paper questionnaire with a digital recording tool. The use of a digital tool to perform active TB screening will allow the standardization of the TB screening practice and the possibility to record and share all the patient's information in a common database which, once adequately evaluated, could be shared by different CARA and CSPA centres. APP contents have been widely discussed amongst WP5 partners. The design of the APP has been subcontracted. Selection of the subcontractor has been performed. A preliminary App containing all the information needed for active TB screening has been already designed. After revision by all the WP5 partners it was found that this preliminary APP will greatly benefit from the adding of a second track for LTBI screening.

Edetect app is a mHealth system which includes:

-a Phone application. This is a touch screen icon-based application for Android smartphone designed and developed following the WHO guidelines for active TB and LTBI screening. The app is available in English, and is structured in five modules. To record information, a user can click on the relevant icons or take photos. The application additionally allows the user to verbally record and save any further comments if necessary. At the end of the questionnaire all data collected is automatically sent via network to the Medical Unit. If the app-user is out of cellular network coverage, it is still possible to use the application and store the data locally until

an area with network coverage is reached. The phone would then synchronize and send the details of the questionnaire to the medical unit based in the referral hospital.

-Medical Unit. This is a java-based software system hosted inside a referral hospital. The system receives all information registered by the phone application and allows clinical staff to monitor the data collected.

-Data Exportation system. All data collected will be directly exported into an Excel database for scientific and epidemiological purposes.

When GeneXpert OMNI will be available, Edetect App and GeneXpert OMNI technology will provide a complete point of care (PoC) in the CARA, CSPA centers allowing evidence-based standardized screening data collection and microbiological analysis on the spot.

4. Conclusions and future steps

The implementation of active TB screenings for the migrant population in Sicily was fully achieved on time (the deadline was postponed to M8 as requested by the ethical committee to approve the project and to set up the process). Active TB screening at CARA of Mineo started on schedule in November 2016. We have at present already screened around 1600 subjects.

We are in contact with staff working on the CARE project (Common Approach for Refugees and other migrants' health) Dr Valentina Marchese (INMP, National Institute for Health Migration and Poverty), which is following WP6 (Tracking and monitoring health status) of CARE projects. Currently the CARE project is not implemented from a practical standpoint at CARA in Mineo, where our action is now focusing. Red Cross is responsible for Health care services and organisation in Mineo centre, and Italian Red Cross is an also one of the partners of the CARE project. Dr Cirillo is part of the group, headed by Istituto Nazionale Migrazione e Povertà (Italian main partner of the CARE) responsible for establishing a consensus panel for next Italian guideline on TB screening among migrants. The first meeting will take place in March (annex 2). During this meeting, we will discuss the implementation of CARE interventions in the CARA centres in Sicily and how to best integrate the data collected during Edetect screening intervention and CARE USB medical recording tool (WP6).

5. References

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- [2] M. S. Schepisi, G. Gualano, P. Piselli, M. Mazza, D. D'Angelo, F. Fasciani, A. Barbieri, G. Rocca, F. Gnolfo, P. Olivani, M. Ferrarese, L. R. Codecasa, F. Palmieri, and E. Girardi, “Active Tuberculosis Case Finding Interventions Among Immigrants, Refugees and Asylum Seekers in Italy,” *Infect. Dis. Rep.*, vol. 8, no. 2, p. 6594, 2016.
- [3] “AGGIORNAMENTO DELLE RACCOMANDAZIONI PER LE ATTIVITÀ DI CONTROLLO DELLA TUBERCOLOSI ‘Gestione dei contatti e della tubercolosi in ambito assistenziale’.” [Online]. Available: http://www.salute.gov.it/imgs/c_17_pubblicazioni_1221_allegato.pdf. [Accessed: 15-Apr-2016].
- [4] C. Mammina, C. Bonura, M. Barchitta, A. Quattrocchi, M. Palermo, and A. Agodi, “Tuberculosis surveillance in Sicily, Italy,” *Epidemiol Prev*, vol. 38, 2014.
- [5] A. Barbieri, G. Cannella, L. Deotti, and M. Peca, “Migratory Routes from Sub-Saharan Countries to Europe SUMMARY, MEDU Medici per i Diritti Umani.”
- [6] WHO, “Systematic screening for active tuberculosis,” 2013.
- [7] ECDC, “Guidance on tuberculosis control in vulnerable and hard-to-reach populations,” 2016.

Annex 1



Nom _____ Date: _____

Données personnelles

Date de naissance _____ Sexe: F M

Pays d'origine _____ BHPHone _____

Famille oui non Scariabion oui non

nBchdenBA

nBchdenBA de TB oui non Enquête annexe _____ConBacTB oui non Enquête annexe _____GroAeAe oui non MoiA de groAeAe _____CigareBBeA
oui non :co:
oui non DrogCe
oui non DiabGBeA
oui non VIH
oui non CBre ma:adieA
oui non

DEPISTAGE DES SYMPTOMES

ToCE
oui non figDre
oui non CrachaBA AangCino:enBeA
oui non SCeCrA nocBCrneaA
oui non PerBe de PoidA
oui non Co:ecBion dC crachaB
oui non

!NOME% _____ **!BADGE** _____ **DATE: %** _____ %

PERSONAL DATA

!
 DaG: Cf aEEiI:!:iB IGaIL _____ **S:x:** F M M M
 DaG: Cf BiEGh _____

CCHBGEL _____ **PhCB:** _____

FaAiIL L:F M BC M **EdHcaGiCB** L:F M BC M

MEDICAL HISTORY

PE: iCHF TB L:F:M BC:M If L:F L:aE _____

TB CCBGacG L:F:M BC:M If L:F L:aE _____

PE: gBaBcL L:F:M BC:M If L:F ACBGh _____



SACKiBg
L:F:M BC:M



Alcohol
L:F:M BC:M



IDU
L:F:M BC:M



Diab:G:F
L:F:M BC:M



HIV
L:F:M BC:M



OGh:EF
L:F:M BC:M

TB SYMPTOMS SCREENING


CCHgh
L:F:M BC:M


F:I:E
L:F:M BC:M


Ha:ACDGLFiF
L:F:M BC:M


NighG Fw:aGF
L:F:M BC:M


W:ighG ICFF
L:F:M BC:M


SDHGHA CCII:cGiCB
L:F:M BC:M

المعلومات الشخصية

تاریخ المیلاد _____ يوم الوصول الى ايطاليا _____
 جنس ♂ ♀ الهاتف _____ البلد _____
 الدراسة نعم لا العائلة نعم لا

التاريخ الطبي

السنة _____	نعم <input type="checkbox"/> لا <input type="checkbox"/>	مرض السل في الماضي	
السنة _____	نعم <input type="checkbox"/> لا <input type="checkbox"/>	معرفة شخص مصاب بمرض السل	
الشهر _____	نعم <input type="checkbox"/> لا <input type="checkbox"/>	الحمل	
 التدخين	<input type="checkbox"/> لا <input type="checkbox"/> نعم	 الكحول	 تعاطي المخدرات
 مرض السكر	<input type="checkbox"/> لا <input type="checkbox"/> نعم	 HIV	 اخر

اعراض السل

 السعال	<input type="checkbox"/> لا <input type="checkbox"/> نعم	 الحمى	<input type="checkbox"/> لا <input type="checkbox"/> نعم	 البلغم الدموي	<input type="checkbox"/> لا <input type="checkbox"/> نعم
 التعرق ليلا	<input type="checkbox"/> لا <input type="checkbox"/> نعم	 فقدان الوزن	<input type="checkbox"/> لا <input type="checkbox"/> نعم	 جمع البلغم	<input type="checkbox"/> لا <input type="checkbox"/> نعم

Annex 2

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Il Direttore Generale

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Trasmessa via mail

Oggetto: Linee guida per il contrasto della tubercolosi tra gli immigrati in Italia – designazione esperti panel per la ReNIP.

L’Istituto Nazionale per la promozione della salute delle popolazioni Migranti e per il contrasto delle malattie della Povertà - INMP ha avviato, una specifica attività finalizzata all’elaborazione di linee guida clinico-organizzative sulla tutela della salute e l’assistenza socio-sanitaria alle popolazioni migranti.

Per la realizzazione di tale attività, ha sottoscritto, in data 3 luglio 2015, un Accordo di collaborazione con l’Istituto Superiore di Sanità, in ragione dell’esperienza maturata nell’ambito del Sistema Nazionale Linee Guida, e con la Società Italiana di Medicina delle Migrazioni, in quanto impegnata anche a sostenere le buone pratiche nell’assistenza ai migranti, sia a livello nazionale sia locale (attraverso i Gruppi territoriali Immigrazione e Salute - GrIS).

Tra gli argomenti prioritari da affrontare con le linee guida, è stato individuato – mediante consultazione dei principali stakeholder dell’Istituto – il tema della tubercolosi. Su questo argomento, nel giugno 2008 è stata tenuta a Roma una *Consensus Conference* che ha coinvolto un gruppo qualificato di esperti, le cui raccomandazioni sono state recepite dal Ministero della Salute nel documento di indirizzo “*Politiche efficaci a contrastare la tubercolosi negli immigrati da paesi ad elevata endemia tubercolare*” (2010). Tale documento rappresenta una base

Istituto Nazionale per la promozione della salute delle popolazioni Migranti e per il contrasto delle malattie della Povertà (INMP)
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