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**EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB**

**JA2015 - GPSD [705038]**

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Project abstract

This project would contribute to the ultimate elimination of tuberculosis in the EU by utilising evidenced based interventions to ensure early diagnosis, improve integrated care and support community and prison outreach activities in low- and high-incidence countries. We aim to achieve this by bringing together several EU member states and jointly evaluating evidence based interventions, taking best practice approaches from countries where co-applicants have developed national strategic plans and providing a framework, in collaboration with ECDC, to support the adaptation and implementation of these measures. We will prioritise migrants, homeless persons, prisoners, problem drug users and those with multi-drug resistant tuberculosis.

Summary of context, overall objectives, strategic, relevance and contribution of the action

The E-DETECT Tuberculosis (TB) consortium is a European Commission co-funded group which brings together world leading TB experts in national public health agencies (Sweden, United Kingdom, the Netherlands, Italy and Romania), with industry (Delft diagnostics) and major academic centres (UCL, Karolinska, SMI, OSR, UNIBS). The composition of the consortium also reflects the incidence of TB in different European countries.

The overall objective of the consortium is to contribute to a decline, and the eventual elimination of TB, in the European Union (EU). Specific objectives include:

1. To ensure early diagnosis in vulnerable populations- defined as homeless individuals, Roma, those with a history of drug use within the community, and prisoners in two high-incidence European countries (Romania and Bulgaria). This will be done by an outreach mobile digital x-ray screening van equipped with automated x-ray reading equipment and rapid molecular diagnostics. (Work Package (WP) 5)

2. To evaluate approaches to consolidate migrant TB detection and improve European cross-border management by:
   • producing new feasibility data on early detection and care integration in individuals arriving via the Mediterranean sea in Italy using innovative molecular testing at immigration (WP6).
   • collating, analysing and evaluating multi country data on TB in migrants to low incidence countries to inform effective strategies for early diagnosis of active and latent TB in low incidence EU countries (WP6).

3. To support the development of action plans in member states by taking best practice approaches from countries where E-DETECT TB partners have developed national and international strategies and evidence from this project and providing a framework, in collaboration with ECDC, to support the adaptation and implementation of these measures across other EU member states (WP7).
Methods and means

Successful delivery of all programmes should contribute to a reduction in EU TB incidence; in particular:

• Outreach activity in Romania and Bulgaria is expected to lead to the early detection and treatment of active TB. Patients detected early and successfully treated will benefit from an increase in quality of life, including being able to return to the work place, and provide for dependents where required. Those prevented from being secondarily infected will each gain between 0.14 to 1.55 quality adjusted life years (estimate based on published TB quality of life studies in Europe). There will also be a projected increase of 10% in patients placed on treatment for TB and MDR TB (Multi-drug Resistant Tuberculosis) who would otherwise not have been found, and a consequent rise of 20% in those completing treatment due to better patient support. This has a cost implication for the health system, but also considerable benefits to the individuals by reducing premature mortality (from nearly 10% to under 5%) and to society in decreasing further spread substantially. Due to the high proportion (25%) of TB cases within the EU in Romania, a substantial impact of E-DETECT TB would be to accelerate the current slow decline.

• Implement and evaluate migrant TB detection in Italy and early diagnosis of active and latent TB in migrants in low incidence countries. In this setting, further decline of TB incidence can only be achieved by intervention in migrant populations who account for the majority of new TB notifications. Lessons would be identified that are applicable to low incidence countries with a high migrant TB burden in the EU. The screening of migrants immediately on arrival will have a direct effect of early diagnosis on the migrants we plan to screen in Italy leading to an increase in quality of life with an estimated gain of 0.05 quality adjusted life years per person diagnosed early and nearly 1 quality adjusted life year per case prevented. The work programme in Italy will help identify the optimal strategy for targeting vulnerable migrants arriving via the Mediterranean Sea, with particular emphasis on strengthening of cross-border interventions.

• Creating a database containing information on active and latent TB cases in migrants from low incidence countries. This will allow the identification of the best approach for screening all migrants and how this might best be targeted to the groups at highest risk. Appropriate screening in migrants successfully delivered in low-incidence countries will have a considerable impact on European TB trends. Particular outcomes from database analysis will include an understanding of which population sub-groups to screen, where and with which technology. Furthermore, the lessons learnt from analysis of the database generated by this study will be applicable to all EU Member States with a high TB burden in migrants, and eventually globally.
• Strengthening national TB programmes. Completion of this work stream should result in an improved understanding of the differences and commonalities of national TB strategies and action plans across the EU. Furthermore, it will lead to a better understanding of barriers and facilitators to implementing national TB action plans and thus the development of a document describing the best approach to develop novel, future strategies.

Work performed during the reporting period

WP1 – Co-Ordination
Effective management of the E-DETECT TB consortium through a high-level monitoring of the project’s work progress, effective communication both internal and external (throughout the consortium with external organisations and with the EC) and adherence to the EC’s rules (contractual and financial).

WP2 - Dissemination
• Development of a dissemination plan (including details for internal and external dissemination, as well as timeline for all the activities planned)
• Branding visual identity
• Development of promotional tools as follows:
  o Website with periodic updates
  o Leaflet design and distribution
  o EDETECT Newsletter

• Development of promotional activities:
  o Close liaison with MoH and NTP in the countries where investigators work
  o Activation of two mailing list (internal and external)
  o Participation in scientific events and submission of scientific articles
  o Planning and implementation of the first webinar on screening among migrants
  o Development of a promotional and training video on the EDETECTTB (EDETECT) migrant screening activities
  o Development of the first full E-DETECT project promotional video

• Meetings:
  o Kick-off meeting in Luxemburg (2016)
  o First annual meeting in The Hague (2017)

• Training:
  o An active training course for pulmonologists on reading CAD4TB screening in Romania (2017)
  o Migrant screening training: development of a tutorial video on the screening activities among migrants to use in national and international events
  o Participation at international training activities: WHO/Europe Summer School and ESCMID postgraduate course and “WHO 2017 SONDALO TRAINING
COURSES: Implementing the WHO End TB strategy and the new vision of TB elimination: skills for managers and consultants”; 5th European Advanced Course in Clinical tuberculosis, Stockholm, 19 Sept 2017 (EACCTB)

- Peer learning events:
  - Work shadowing/study visit (28.Aug-01.Sep/2017) in London: a Romanian delegation (health care workers of the Bucharest’s Marius Nasta Institute and its NGO partner, ARAS) met London’s Find&Treat team and participated to group meetings and screening of homeless people in the Lincoln`s Inn Fields Park area.

WP3 - Evaluation
The evaluation work package is designed to broadly integrate other work packages by assessing progress towards meeting project objectives and drawing together key quantitative and qualitative analysis of all work packages. The key deliverable in this period was to develop an evaluation plan and to commission the external evaluation.

Activities
- Evaluation plan: This was developed and submitted as a deliverable and published on the E-DETECT TB website as a project output. This plan includes details of a process evaluation as well as effectiveness measures for the work packages generating primary data. In addition, a cost effectiveness evaluation is planned (see below)
- Commissioning external evaluation: A decision was taken following further review of the programme that the health economics team at UCL will be well placed to deliver this programme. Therefore a cost effectiveness evaluation of the key work packages will be undertaken. WP 4 – 6 are currently collecting data that will inform the effectiveness evaluation.
- Further outputs: This work package has also acquired data from ECDC that is complementary to the outputs of the programme and will allow the evaluation of TB in migrants. These data will be analysed and reported in due course. A paper describing the programme has been submitted for publication to the European Respiratory Journal.

WP4 – Outreach for Early Diagnosis

- Activities were mainly concentrated on the purchase of a truck and equipping it with x-ray equipment and GeneXpert equipment, turning it thus into a functioning mobile digital x-ray unit (MXU) for screening high risk populations in Romania. This appeared to be a great challenge due to many administrative reasons and suffered delays. Ind

The main output achieved so far and their potential impact and use by target group (including benefits)
WP2
• The website has been set up with constant uploads. Future steps are to increase the number of posts uploaded
• A webinar has taken place and two others are already planned. Future steps are to enlarge participation to future webinars.
• A peer-learning event with E-DETECT TB Partners and stakeholders took place and a return visit to Romania is being planned.

WP5
• A digital recording tool for TB screening activities was designed and finalised. The future steps are to use mobile technology to record patient information

WP6
• A survey and inventory of data sources was done. The future steps are the harmonization of TB screening data collection and analysis in line with E-DETECT TB objectives.
• The development of data sharing agreements, protocol and a database was done. The future steps are to set standards for data sharing not only between E-DETECT TB partner countries but also between other EU countries.

Achieved outcomes compared to the expected outcomes

We have made considerable progress in the project and achieved outcomes in relation to the screening of migrants in Italy. Similarly, we surveyed all national programmes in the EU to inform our policy engagement work package. Other work packages at different stages of development and largely on track except WP4. The overall management of the project including financial, dissemination and coordination activities are proceeding as planned. Compared to the original plan, delays largely relate to the difficulties in WP 4. This has affected expenditure as well as project deliverables. We have outlined our deliverables, due date, amended and reasons for any delay below.

WP1
• D1.1, MoU with ECDC, 02 August 2016. We are discussing the necessity to have an MoU with the ECDC
• MS9, Full collaboration with ECDC achieved, 02 August 2016. Dependent on D1.1 so pending for now
• D1.2, Interim report, 02 November 2017. This is delayed due to the submission of the amendment and the issues within WP4 taking place in parallel.
• D1.3, Final report, 02 May 2019, on time for now

WP2
• D2.1, Project leaflet, 02 August 2016, submitted
• D2.2, Website, 02 August 2016, submitted
• MS1, Project website designed and delivered, achieved
• D2.3, Dissemination plan, 02 November 2016, submitted
• D2.4, Policy brief early diagnosis and case holding of TB, 02 November 2016, submitted
• MS2, Development of dissemination plan, 02 November 2016, achieved.
• D2.5, Project video early diagnosis, 02 May 2018, on time for now
• D2.6, Training and peer-learning events, 02 March 2017, delayed to June 2017 and since submitted
• D2.7, Final dissemination report, 02 May 2019, on time for now
• D2.8, Layman version of the final report, 02 May 2019, on time for now

WP3
• D3.1, External evaluation for the project, 02 November 2016, submitted
• MS3, External evaluation for the project, 02 November 2016, achieved.
• D3.2, Outreach screening evaluation in Romania, 02 November 2016, to be delayed to M33 (02 February 2019). This is to allow for as much data to be collected as possible in Romania (WP4) before results are evaluated.
• D3.3, Migrant screening evaluation in Italy, 02 November 2018, to be delayed to M33 (02 February 2019). This is to allow for as much data to be collected as possible in Italy (WP5) before results are evaluated.

WP4
• MS4, Equipped mobile digital radiography in place and functioning, 02 November 2016, to be delayed to M12 (02 May 2017). This is a delay of 6 months which we cannot catch up in the other two years the project is running. We will do our outmost best to achieve more than the planned screening days per week and number of persons screened per day, but for the moment the number screened should be reduced from 25,600 to 19,200. Further delay accumulated which will be mitigated.
• MS5, Staff trained to implement the screening in Romania, 02 November 2016, achieved.
• D4.1, Feasibility screening in Bulgaria, 02 November 2018, on time for now

WP5
• D5.1, Temporary migrant screening set up, 02 October 2016, submitted. OSR needed more time to obtain the clearance for the project from the OSR ethical committee. Moreover, D5.1 was also delayed because of the time needed to obtain the necessary agreement in Sicily to have access to the project site and to discuss with local Sicilian authorities and partners (Red Cross, local hospital and USMAF) the protocol for the intervention and in particular the question to be adopted for the screening.
• MS6, Agreements reached and facilities set up for migrant screening in temporary centres, 02 October 2016, achieved.
• D5.2, Settled migrants screening set up, 02 November 2016, submitted. OSR needed the necessary time to discuss the protocol with the authorities in the Lombardia region in order to obtain an agreement on the protocol for data collection. Moreover extra time was also needed
Dissemination and evaluation activities carried out so far and their major results

Dissemination:
• Development of a dissemination plan (including details for internal and external dissemination, as well as timeline for all the activities planned)
• Branding visual identity
• Development of promotional tools as follows:
  o Website with periodic updates
  o Leaflet design and distribution
  o EDETECT Newsletter
• Development of promotional activities:
  o Close liaison with MoH and NTP in the countries where investigators work
  o Activation of two mailing list (internal and external)
  o Participation in scientific events and submission of scientific articles
  o Planning and implementation of the first webinar on screening among migrants
  o Development of a promotional and training video on the EDETECT TB (EDETECT) migrant screening activities
  o Development of the first full E-DETECT project promotional video
• Meetings:
  o Kick-off meeting in Luxemburg (2016)
  o First annual meeting in The Hague (2017)
• Training:
  o An active training course for pulmonologists on reading CAD4TB screening in Romania (2017)
  o Migrant screening training: development of a tutorial video on the screening activities among migrants to use in national and international events
  o Participation at international training activities: WHO/Europe Summer School and ESCMID postgraduate course and “WHO 2017 SONDALO TRAINING COURSES: Implementing the WHO End TB strategy and the new vision of TB elimination: skills for managers and consultants”; 5th European Advanced Course in Clinical tuberculosis, Stockholm, 19 Sept 2017 (EACCTB)
• Peer learning events:
  o Work shadowing/study visit (28.Aug-01.Sep/2017) in London: a Romanian delegation (health care workers of the Bucharest’s Marius Nasta Institute and its NGO partner, ARAS) met London’s Find&Treat team and participated to group meetings and screening of homeless people in the Lincoln’s Inn Fields Park area.
All the activities were accomplished according to schedule. There was active contribution from all Consortium members to the dissemination activities.

Evaluation
- Data to inform evaluation being collected
- Evaluation plan completed and submitted
- Evaluation work package contributing to project meetings and activities
- Overview of the project submitted to the European Respiratory Journal
Work package

Work Package 1: Coordination of the project

Start month: 1
End month: 36
Work Package Leader: UCL

Financial and contractual management: The ERIO Project Manager will ensure the day-to-day management of the financial, administrative and contractual aspects of the project by:

- Liaising with the EC on behalf of the Coordinator and the Consortium;
- Administering the EU grant by appropriately allocating funds between partners and activities in accordance with the Grant Agreement and the decisions taken by the Consortium.
- Coordinating the submission of Interim and Final reports to the EC. The ERIO Project Manager will be in charge of obtaining financial statements (Form C) from each of the partners, and certificates on financial statements (CFS) when required.
- Advising the consortium members on the Third Health Programme financial rules.
- The ERIO Project Manager will ensure that the Consortium Agreement (CA) is maintained and updated throughout the duration of the Project. E-DETECT TB CA will set out in detail the rights, responsibilities, and liabilities of participants to each other and towards the EC. The management of knowledge and intellectual property will be determined and regulated within the CA.
- The ERIO Project Manager will provide advice on IPR matters (management of authorship, ownership, access rights) and protection and licensing supported by UCL Business.
- The ERIO Project Manager will advise the partners in relation to their contractual obligations and will ensure that Amendments to the Grant Agreement are submitted in accordance with the Third Health Programme rules.

1.2 - Communication within and outside the Consortium: A project web site will be set up and maintained by UCL-TB. The secure portion of this (only accessible by partners) will be maintained and manned by ERIO. This will enable on-line entry, display and transfer of results to be available to all participants and it will also serve as repository of project’s internal documents (e.g. contractual documents, reporting templates and instructions, deliverables classified as Confidential or Restricted, etc.). Appropriate project management tools/communication systems (e.g. e-mailing list, Dropbox, Google+, video conferences) will be set up in order to ensure the smooth flow of communication within the Consortium. The UCL project management team will liaise with partner UNIBS on dissemination strategy (WP2) through regular tele/videoconferencing and allowing administrative access to the web site for necessary changes. ERIO will facilitate communication with the EC. The public portion of the website will serve as main contact point for external users and will include general information and updates on the progress made by E-DETECT TB. The web site will contain a ‘contact us’ portal for interested stakeholders to pose questions to the consortium.
1.3 - Monitoring and Reporting: Interim reports: The ERIO Project Manager, in collaboration with the Coordinator, will monitor progress of the project in terms of achievement of objectives and resource consumption through internal 6 monthly reports delivered by all partners. All partners will provide the following information:

- description of work carried out over the 6 months
- achievements reached during the 6 months (e.g. deliverables, milestones, publications)
- planned achievements in the following 3 - 6 months
- resource usage per WP

Customised templates will be drafted and relevant instructions circulated to partners. Information will be then collated by the ERIO Project Manager, reviewed and analysed by the Coordinator and reported to the Steering Committee (SC) [governing decision making body in charge of the direction of the project] which in turn will propose and ensure that corrective actions are implemented. The SC consists of the coordinator, WP leads and management team and they will meet every 6 months. The SC will interact with External Advisory Board, Data Governance group as described in detail in section 7 of Annex

Work Package 2: Dissemination
Start month: 1
End month: 36
Work Package Leader: UNIBS

Dissemination strategy: This task will provide partners with detailed guidance for dissemination across all work packages at local/national level and extensive database of interested parties. The main target groups for dissemination are: national TB programmes, city TB control programmes, clinicians, nurses, civil society activists, national parliaments, health departments, and European decision makers (MEPs). The task should produce an overall project dissemination strategy and one local dissemination strategy per partner across all work packages. The UCL project management team (WP1) will liaise with collaborate with UNIBS on dissemination strategy through regular tele/videoconferencing and allowing administrative access to the web site for necessary changes.

2.2 Branding and visual identity: A visual identity will be developed in order to give the recognition of the project and to support the communication and dissemination of the project’s results. Outputs will include a logo, visuals, toolkit for users & designers.

2.3 Promotional tools: We will develop and use a traditional set of communication tools for promoting the results including:
- Project website – as mandated by the EC, E-DETECT TB will develop it as the main communication channel with the stakeholders involved in the project and with the outside world. Through the website, all project partners will interact with stakeholders, will provide updates on the results and it will interact with similar initiatives at EU level. The main language of the website is English. Based on the information obtained from the stakeholders’ assessment needs, the website could be upgraded in any other relevant language;
- Social media - We will utilise university and partner organization existing social media accounts, for example, by creating an E-DETECT TB hashtag in Twitter to reach a wider audience than possible with a new account.
- Leaflets (printed & digital) - will present the project and its objectives, expected results and the partnership. The leaflet will be produced in English and translated in partners’ languages (with the support of project partners)
- Power point presentation – a standard E-DETECT TB presentation will be developed and updated during the project. It aims to present the project, its objectives, its (expected)/results and to be used by partners as base of their presentations in different events organised by the project and in their active involvement in external events.
- Articles - to be included in existing newsletters and in specialised academic journals. . All WPs will be expected to produce scientific articles for publication. These articles will be widely disseminated with the support of members in the consortium.
- Videos – a video will be developed with support of all partners to communicate the project to healthcare workers and other stakeholders.

2.4 Promotional activities
- In consortium member countries, the partners in each country will liaise closely with their Ministry of Health (MoH) and NTP. All the investigators already have good links with their MoH We will produce policy briefs based on the results of the study to communicate.
- We will use mailing lists and events (internal newsletter and thematic newsletters), dedicated mailings, presentations at internal events.
- Presentations at external conferences, events and webinars: including the ECDC/WHO Europe programme managers meeting, Union Europe Region conference, European Respiratory Society Conference and other TB relevant events in Europe.
- Publication of news and announcements on online TB portals and websites. Partners will contribute by representing the project at events as speakers and by writing articles for newsletter and magazines and in the development of the materials listed above.

2.5 Meetings (Lead: UCL)
- The projects kick-off meeting will be held in Luxembourg as directed in guide for applicants’ that the EU project officer (or other representative) wi

Work Package 3: Evaluation
Start month: 1
End month: 36
Work Package Leader: UCL

Structure, Process, Outputs and Outcome Evaluation (Lead: UCI for internal evaluation plan; external independent assessor through competitive tender for the external evaluation
• The external partner will undertake a comprehensive evaluation of this project by analysing the data collected using the indicators in each work package and report these to the project steering committee, and to the EC.
• This will utilise a framework based on the structure, process, outputs & outcome model.
• A detailed evaluation plan will be agreed with the successful contractor

3.2 We will develop a detailed epidemiological and economic analysis plan to investigate the drivers, determinants, and interventions that would allow the control of tuberculosis in our target populations and therefore in each country and the EU.

3.3 Evaluating Mobile Outreach in vulnerable populations in Romania and Bulgaria. A detailed evaluation protocol will be developed with the following tasks:
• undertake a baseline cross sectional survey of active TB in the target population
• collect information on the number of people eligible for screening and number screened.
• collect comparable risk factor information on those screened as that collected in the baseline cross sectional survey and link this to the radiology information system (RIS) enabling measurement of the prevalence of CAD4TB radiographic changes of TB in different risk groups.
• compare CAD4TB data with human reading results and using GeneXpert data assess the prevalence of PCR confirmed Mtb and rifampicin resistance to be measured and compared with liquid culture based testing.
• Collect information on whether referred patients attended their appointments and what dates and type of supervision was given for treatment. This will be linked to national surveillance information to determine treatment completion.
• Analysis of risk factors using logistic regression to assess the hypothesis that passively identified cases are more likely to be smear positive on diagnosis than actively identified cases and to compare treatment outcomes in passively and actively identified cases after controlling for potential confounders.
• Undertake an economic evaluation of the programme to assess value for money

3.5 Migrant Screening in low incidence countries (Lead: UCL with INMI, KNCV and KI). A detailed evaluation protocol will be developed. We will
• Undertake descriptive statistical analysis of the pooled data sets on active and latent TB from WP6 and WP7 to determine uptake by site of screening, country of origin and immigration status.
• Calculate the overall prevalence of active and latent TB in migrants and stratify this by country of origin, place of screening and immigration status.
• Develop multivariable statistical analysis to determine the factors associated with high uptake and high yield.
• Undertake an economic analysis to determine which strategy offers the best value.

Work Package 4: Outreach for early diagnosis and strengthen care integration in vulnerable populations in Eastern Europe
Start month: 1
End month: 36
Work Package Leader: KNCV

4.2: Training of the staff to implement the screening activities: including a kick-off meeting in Romania and further training in London
4.3: Screening of the vulnerable populations (project months 7-30). Selection of populations, settings and cities will be guided by data from the TB surveillance system on the prevalence in risk groups, settings and geographical areas.
4.4: Quality control with possible adaptation of the diagnostic methods and algorithm. This includes quality control procedures to assess the CAD4TB method through double reading by Romanian radiologists/chest physicians and Dutch experts and bacteriological quality control
4.5: Strengthened care integration in vulnerable populations in Romania: Develop, agree and implement on the pathway and point of care for referred cases and treat TB patients in the screening programme under the conditions of the NTP Romania. In addition, peers will support the diagnosed patients to complete treatment successfully.
4.6: Implement a pilot screening in Sofia/Bulgaria: We will organise a kick-off meeting in Bulgaria to share screening practices in Romania, UK and the Netherlands. We will implement a pilot screening in high-risk settings in Sofia/Bulgaria for one week and evaluate it in WP 3.
4.7: Project support: External consultants will support the service quarterly in the first operational year with on-site assistance and every half year in the second operational year. There will be an interim meeting with stakeholders and external consultants (including representatives of the Bulgarian NTP programme) will take place in Romania after 6-9 months to discuss progress, achievements and challenges. A final meeting will take place after completing two years of screening, to discuss results, evaluate the screening and prepare the final report.

Roles and responsibilities:
- The Romanian NTP is responsible for the purchase of the van and the equipment.
- The Romanian and Bulgarian NTPs are responsible for implementation of the screening.
- KNCV and UCL are responsible for technical assistance in the training, screening and quality control. NTPR, KNCV and UCL are jointly responsible for the operational research, project evaluation and reporting.
A sustainability plan in Romania will be developed during the implementation phase, which will run beyond the end of the project.

Work Package 5: Migrant TB detection, prevention and treatment
Start month: 1
End month: 36
Work Package Leader: OSR

The scope of this work-package is to establish: 1) a mechanism to ensure that health services delivering TB care are accessible to refugees at the point of arrival
and provided in a primary health care embedded, patient-centred, culturally-sensitive manner, following established ethical principles for screening for infectious diseases and based on respect of human rights; 2) to identify the asylum seekers represent another population at increased risk of tuberculosis, particularly of reactivation tuberculosis. The latter population is relatively stable and offer the opportunity of screening and treatment interventions for both active TB and LTBI. Although policies may be in place, TB screening practices are scarcely implemented mainly due to poor standardisation of screening practices, virtually non-existent monitoring capacity, and uncertainties on the cost-benefit ratio of the intervention. This WP will measuring the magnitude/significance of the TB threat in refugees and asylum seekers, and will measure completion rates of screening and treatment practices. In particular, the project will bring essential new information on the feasibility, acceptability, and cost-effectiveness of a program for active case finding and treatment of TB and systematic testing and treatment of latent TB infection in migrants. Moreover, it will provide a model for effective cross-border interventions from TB prevention and care among highly mobile populations.

5.1: Development, in collaboration with local and national health and immigration authorities, of a coordinated protocol for intervention in a selected sample of CPSA centres (lead partners: OSR, UNIBS, INMI). Finalise the selection of centres according to the logistics. M1-3

5.2: Planning and implementation of a training program for project medical and administrative personnel to familiarise with the project tools (lead partner OSR, INMI) M3-5

5.3 Provision of systematic testing and treatment for active TB in refugees at CPSA centres using questionnaire, medical evaluation, and GeneXpert examination of the sputum in individuals with signs and symptoms (lead Partner OSR, UNIBS, Local partners, Stop TB Italy). M 6-18

5.4 Data collection and evaluation (Lead partner INMI, UNIBS) M12-30

5.5: Development, in collaboration with local and national health and immigration authorities, of a coordinated protocol for intervention in a selected sample CARA centres (lead partners: OSR, local collaborators, INMI, STOP TB Italy, UNIBS) M1-5

5.6 Provision of systematic testing and treatment for active TB and latent tuberculosis infection (LTBI) in asylum seekers at CARA centres. Testing for TB will be based on chest X-ray and symptoms screening, followed by GeneXpert evaluation of abnormal findings. Testing for LTBI will be performed using IGRA tests. Treatment of TB will be based on standard regimens, while that of LTBI will be based on short, rifamycin based regimens M 6-30

5.7 Design and implementation of a system to empower CARA residents through health promotion and education. (Lead partners: UNIBS, OSR).

5.8 Development of an effective, digital recording tool for CPSA and CARA residents to provide a denominator to assess the intervention. The tool will allow recording of information on screening and treatment activities and results. (Lead partners: UNIBS, OSR, INMI)

5.9 Develop a system for transfer of information between Italy and final destination countries. This will include achieving a deeper understanding about current flows of migrants from point of arrival to final destination countries in the context of recent agreements on immigrant accommodation in Europe. This will be achieved via Early Warning Response System (EWRS) or the new WHO platform for transfer of confidential data by national TB programmes (Lead: OSR)
5.10 Development of an effective way of communicating to policy-makers, other stakeholders and civil society project results, in order to create a constructive and inclusive enviro

Work Package 6: Multi country latent and active TB in migrants databases

Start month: 1
End month: 36
Work Package Leader: KI

Pooled multi-country database on LTBI screening yield, linkage to care, and incidence of reactivation among immigrants.

The following activities will be undertaken:

• The work will start with a stakeholder meeting with representatives of relevant services and authorities from the respective country to discuss the practical, managerial and legal implications of standardising recording, reporting and registration required for the creation of the LTBI database.
• A steering group will be established for overseeing the development and running of the database with representatives from each participating country.
• Data from each module will be collated at national level, anonymised and transferred, via secure file upload into the Farr Safe Haven, a robust infrastructure at UCL certified according to international and national information security standards (ISO/IEC 270001 and NHS IG Toolkit). Although the data will not contain identifiable data, we will use the safe haven for storage of individual level data where there may be a small risk of deductive disclosure. Data transfer will occur annually.
• The data manager will work with the study steering group to develop network of key data providers and stakeholders, and understand existing data collection programmes. In the next phase, stakeholder meetings including representatives of LTBI screening centres, LTBI treatment centres and national surveillance centres will discuss the practical, managerial and legal implications of standardizing recording, reporting and registration required for the creation of the LTBI database and agree on: The core minimum dataset; Case definitions; Exact methodologies for data linkage; Meta data for each file; Data transfer protocols and frequency; Standardised reporting through web interface
• This will be followed by data collection and collation at national level, international level and analysis and reporting. The analysis will follow the logic of the three modules outlined in section 5.3.2. and involve the following elements: No of peopled screened; % screened positive; % started on treatment; % completing treatment; Determinants of screening, positive screen, treatment initiation and treatment completion; Reactivation rate, and risk factors for reactivation (beyond project period)

Pooled multi-country database on digital radiography and laboratory findings from screening for active TB among immigrants, with information on results of human reading, CAD4TB reading, and bacteriological test results. The following activities will be undertaken:
• Stakeholders meeting and establishment of a steering group. Due to with the activities under 6.1. It is anticipated that a joint meeting can be organized to cover both activities and it be explored if a joint steering group for both sub-projects can be established.
• Data from each module will be collated at national level, anonymised and transferred, via secure file upload into to the Farr Safe Haven
• Data collection and collation at national level, international level and analysis and reporting. The analysis will follow the logic of the three modules outlined in section 5.3.2. and involve the following elements: No screened, % screened positive based on radiologist assessment, % positive bacteriology, % diagnosed with TB, TB notification rate, agreement between CAD4TB screening results and results of human reading

Work Package 7: Strengthening national TB programmes
Start month: 1
End month: 36
Work Package Leader: DH PHE

1. A survey amongst TB control programme leads will be carried out to get information about the development and implementation of national TB action plans and strategies across the EU/EEA. This survey, to inform further work, will be led by PHE in collaboration with UCL, KNCV, KI and ECDC and WHO. The tasks will include:
   • Development of a questionnaire based on a review of previously tools.
   • A small pilot of the questionnaire with experts and finalising survey tool.
   • Administering the survey and ensuring a high response rate through reminders
   • Collection, collation and analysis of data and summary of results
2. A policy review: We will systematically review national/international policies and guidelines, as well as peer-reviewed TB policy research papers relevant to EU/EEA Member States to summarise current policies and best practice. The tasks will include
   • Collect and collate guidelines, strategy, policy documents and published literature.
   • Collect and collate other relevant information pertaining to policy and strategies (including website materials, and relevant public health reports).
   • Provide a summary document of current regional, national/international policies and gaps
3. An expert meeting with national TB programme leads and other TB experts will be convened to review the evidence from European-wide survey and the policy review and present a proposal for a targeted priority-based approach to overcome barriers in countries and support the development and implementation of strategies. The tasks will include
   • Secure the venue, accommodation and invitation to relevant experts
   • Set up the structure, agenda and convene the meeting
   • Define consensus on key questions using an iterative Delphi process
• Write up a report with summary and recommendations for approval of the expert group
4. TB strategy prioritisation, action and support plan: The findings of the survey, policy review and expert consensus will be used to inform a practical step-by-step TB strategy prioritisation, action and support document. The tasks will include
• Draft the document based on expert recommendations and other available evidence.
• Circulate the draft among experts and other stakeholders to inform the final draft.
• Publish the plan for road testing.
• Producing a toolkit for implementation of outreach, screening of migrants, follow up of LTBI, strengthening of national TB programmes
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Layman version of the final report
UNIBS
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)
Expected on: 03/05/2020
Mandatory deliverable This is a short (e.g. 10 pages) version of the final report, written for the interested public as a target group and includes the executive summary.

Final report
UCL
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)
Expected on: 03/05/2020
Mandatory deliverable This report describes the project implementation and the results achieved. This will include annexes on the kick-off and steering committee minutes, internal evaluation plan and half-year report, progress report for each WP.

Project video-early diagnosis
UCL
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)
Expected on: 03/05/2018
This report will be based on a film produced and available online. The video will only address early TB diagnosis and case holding.

Final dissemination report
UNIBS
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)
Expected on: 03/04/2020
This will provide the final dissemination and exploitation report and action plan for succession.
Outreach screening evaluation in Romania
UCL
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)
Expected on: 03/10/2019
Evaluation report on outreach screening in Romania

Migrant screening evaluation in Italy
UCL
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)
Expected on: 03/07/2019
Evaluation report on migrant screening in Italy

Feasibility screening in Bulgaria
KNCV
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)
Expected on: 03/10/2019

Temporary migrant screening completed and available for analysis
OSR
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)
Expected on: 03/09/2018
Completed screening and data ready for temporary migrants

Asylum seekers screening completed and available for analysis
OSR
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)
Expected on: 03/11/2018
Completed screening and data ready for settled migrants
Databases populated with records from each participating country

UCL

EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)

Expected on: 03/03/2018

This will ensure that data are gathered from countries

Data analysis report on latent TB in Europe, mobile x-ray and migrant screening

UCL

EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)

Expected on: 03/04/2020

Analysis on each work package undertaken. Analysis to include work on latent TB in Europe, mobile x-ray screening and migrant screening.

Survey of national TB control plans/policy

DH PHE

EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)

Expected on: 03/12/2017

Survey of existing national TB control action plan and policy

Expert meeting to develop a framework for TB action plans

DH PHE

EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)

Expected on: 03/01/2019

Expert consensus meeting to agree a framework and template for national TB action plans

Prioritisation Document on TB action plans and toolkit production

DH PHE
Document outlining strategy and action plan development which can be used by EU member states to develop their action plan for TB control. Will include toolkit for implementation of outreach, screening of migrants, follow up of LTBI, strengthening of national TB programmes.

Undocumented migrants screening available for analysis

Survey on Italian regional TB/LTBI screen policy in Italy finalized

MoU with ECDC

Interim report

Mandatory deliverable This report describes the activities carried out,
milestones and results achieved in the first half of the project. This will include
annexes on the kick-off and steering committee minutes, internal evaluation
plan and half-year report, progress report for each WP.

External evaluation plan for the project
UCL
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN
EUROPE: E-DETECT TB (E-DETECT TB)
Published on: 16/05/2018
Structure, Process, Output and Outcomes evaluation plan developed

Policy review of action plans for TB
DH PHE
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN
EUROPE: E-DETECT TB (E-DETECT TB)
Published on: 10/04/2018
Analysis of published TB control action plans and policy documents

Training and peer-learning events
UCL
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN
EUROPE: E-DETECT TB (E-DETECT TB)
Published on: 01/03/2018
This report will summarise activities in relation to educational exchange visits
between partners and include active case finding, migrant screening and
package of training for dissemination. This deliverable is also due at M18 and
M29

Temporary migrant screening set up
OSR
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN
EUROPE: E-DETECT TB (E-DETECT TB)
Published on: 01/03/2018

Settled migrants screening set up
OSR
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN
Settled migrant screening set up

Data pooling agreement on latent TB in Europe

KI
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)
Published on: 01/03/2018
Agreement to pool data by all participating countries

Protocol for data transfer agreed

KI
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)
Published on: 01/03/2018
This will provide a report on the development of data transfer protocol

Database created to host latent TB data

UCL
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)
Published on: 01/03/2018
This will report the creation of a project database to share data between countries

Project leaflet

UNIBS
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)
Published on: 13/02/2017
A leaflet to promote the project must be produced at the beginning.

dissemination plan

UNIBS
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)
Published on: 13/02/2017
This report will present the exploitation and dissemination plan (including local/national strategies)

Policy brief-early diagnosis and case holding of TB
UNIBS
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)
Published on: 13/02/2017
Policy Briefs for Stakeholders on outlining key issues to improve on early diagnosis and case holding of TB that this project will address

Web site
UCL
EARLY DETECTION AND INTEGRATED MANAGEMENT OF TUBERCULOSIS IN EUROPE: E-DETECT TB (E-DETECT TB)
Published on: 17/10/2016
Mandatory deliverable. also has confidential parts. Each project must have a dedicated web-site / web-pages. This can have a public part and another one accessible only to the applicants.