Research protocol title: Delivering an Innovative Multi-disease Screening and Vaccination Tool to High-risk Migrant Populations (ISMiHealth)

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RESEARCH PROTOCOL

1. JUSTIFICATION

Migration is a significant, **complex, and growing global phenomenon** of critical importance to European countries[1]. Having good health is key for a smooth and prompt integration process into the host community[2]. However, heterogeneous socio-economic, cultural, and legal factors across European countries affect migrants' physical and psychological health and determine the availability, accessibility, acceptability, and quality of services in the new host environment[3]. **Unprecedented rises in migration** to and within the European Union (EU) in recent years have resulted in **numerous challenges for health services[4]**; also, in Spain where the foreign population represented in July 2020 11.2% of the total Spanish population[5]. The need for integrated programmes to deliver **effective and cost-effective services** to high-risk migrants is now a key step for the medical services within the EU[6].

Migrants may have particular health needs; they are **disproportionately affected by key infections**, including tuberculosis (**TB**), human immunodeficiency virus (**HIV**), hepatitis B virus (**HBV**) and hepatitis C virus (**HCV**) in Europe; and this has been associated with the incidence in the country of origin, socio-economic risk factors and other comorbidities on arrival to the host Europe[7]. A decline in TB incidence in most European countries in recent decades has slowed due to the re-emergence of TB in vulnerable populations, including migrants[7]. Overall, approximately 33% of TB cases in the EU were foreign-born in 2016 but there is considerable variation between countries[8]. In 2018, almost half of the new HIV cases (42%) within the EU occurred in the migrant population[9]and hepatitis B and C prevalence in migrants in Europe is estimated to be 6 and 2 times higher, respectively, than the general population[10]. In addition, a homogeneous strategy in European countries including Spain on **vaccines and preventable diseases** in migrant adult populations is still lacking[11]. And this will be particularly crucial for the COVID-19 vaccine strategy to elucidate if the national strategy will also explicitly include asylum seekers, refugees and undocumented migrants who should not be left behind in the fight against the COVID-19[12], but also to evaluate how the vaccination records will be registered and traced in the migrant mobile population. Similarly, certain **imported diseases**, only prevalent in migrant populations[13-16], are at risk of transmission in non-endemic areas under special circumstances (through transplants, blood-transfusion or congenitally)[15] and are potentially severe, particularly if there is a diagnosis delay, in immunosuppressed patients[16]. Finally, **female genital mutilation** is a neglected condition, with estimates about 38000 migrant women in some European countries[17]. In Spain, a study reported a profound lack of knowledge around the concept, typology, countries with a high prevalence of female genital mutilation and protocols of action for health professionals, who are then unable to identify and detect risk factors[18].

Health systems need to be prepared to respond to both immediate and long-term health needs of migrants with an **inter and multidisciplinary approach**, considering the migrants' backgrounds and the impacts of poverty and gender on health. The need for integrated programmes to **deliver more effective and cost-effective services to high-risk migrants is now a key step** for the medical services within European countries[6].

Accordingly, health systems are responsible for providing an efficient, economic, and affordable solution to be implemented at primary care and hospital level. However, primary care is usually the first contact point of the migrant population with the health system and therefore, these health facilities are key to guarantee the early detection of migrant health needs. It should be added post-migration transmission and complications of communicable diseases and other conditions prevalent in migrants could be prevented or reduced by enhanced screening and vaccination strategies focused on migrant populations[19].

Screening and vaccination policies may improve the communicable diseases and the female genital mutilation prevention, diagnosis, and treatment if the legal and policy environment is conductive. Screening all of these conditions may be beneficial either because there is a transmission risk through

community exposure, transplants, blood transfusion or congenitally or because severe complications and sequel may be prevented if the diseases are early identified[6].

Data on cost-effectiveness are scarce but suggest **moderate to high cost-effectiveness of migrant screening programmes depending on the migrant group and disease targeted**. Cost effectiveness studies evaluating **screening for TB in** migrant populations have shown a clear benefit of screening among high prevalence groups, close contacts of those with known TB, and migrants at entry if they originate from intermediate- or high-TB-incidence countries defined as >60/100000 and >120/100000, respectively[11]. These studies demonstrated that increased cost-effectiveness was associated with higher TB incidence in the country of origin, suggesting that programmes will be more cost-effective when targeting migrants from countries of origin with a high incidence TB. However, most TB screening programmes in Europe target asylum seekers and refugees and, therefore, miss other circulating migrant groups[11] that could be potentially targeted in other settings such as primary care. In addition, the average cost per patient of TB in Spain has been estimated to be 10,262€, with an estimation of the total cost in Spain during 2016 of around 40 million€[20]. This cost increases significantly when associated with patient admission and could be potentially everted if proper measures are established to improve the early detection of the disease.

Approaches such as **moving from routine HIV testing** from **sexual health and antenatal clinics to non-traditional settings (e.g., primary care)** to reduce the pool of undiagnosed HIV infections in the population have been recommended[21]. A recent health economics analysis has demonstrated that HIV screening in primary care in high HIV prevalence areas is cost effective[22] and pilot studies have demonstrated the feasibility and acceptability of implementing routine HIV and other communicable diseases screening tests among patients and healthcare professionals in primary care. **Implementation of targeted HBV and HCV screening programmes to increase early diagnosis and treatment is important to reduce the burden of chronic hepatitis B and C** among migrants[23], which has **also been demonstrated for Chagas disease**[24].

The **new guidelines from the European Centre for Disease Control and Prevention**[11] on infectious diseases screening and vaccination in new-arriving migrant populations and alongside country-specific guidelines, promote screening implementation at the primary care level[25]. In particular, ECDC guidelines **call for innovative approaches to multi-disease testing and vaccination** in high-risk migrants[11]. Nevertheless, how best to implement these new guidelines is not clear and there is an urgent need to explore country-specific implementation to assess effectiveness and cost-effectiveness[6].

Current migrant screening programmes across Europe are too narrow in focus, focusing mainly on active TB and mainly on asylum seekers and refugees[6]. Also, recommendations are often expert-opinion driven and rarely evidence-informed. In general, comparison of these strategies across countries or regions has been performed for single diseases, such as TB or hepatitis, but not comprehensively across all relevant conditions. In addition, the implementation of screening programmes requires coordination between health care providers, social services and policymakers and should include insights from diverse disciplines (Economics, Epidemiology, Clinical Practice, Psychology or Social science)[6]. In this regard, the **need for integrated programs of migrant health care, including screening and vaccination programmes**, has introduced a challenge to medical services within the EU[19].

The current value of a systematic screening at primary care level has not been properly evaluated and the practical implementation of screening programmes remains a challenge at primary care level[6], particularly when including imported diseases. In this regard, one of the main determinants of barriers that delay and decrease the detection rate of communicable diseases, generate health inequalities, increase morbidity and DALYs associated, and also increase the risk of transmission of disease within migrant communities is the **lack of expertise of health professionals in assessing the risk of communicable diseases** and other conditions in migrants including the epidemiological risk considering their individual differences (sex, age, epidemiological origin)[18]. This may combine to affect health outcomes of migrants, generating health inequities and sustaining disease transmission, and

consequently increasing the cost for health systems. Although migrant screening guidelines are becoming increasingly available, most of the screening strategies designed require the health professionals´ active commitment to navigate much deeper into the guidance until finding the epidemiological information on the country of origin that is needed for the individual-based risk assessment to take the appropriate screening decision. In many cases, **guidelines do not provide specific information by country of origin and a general recommendation is provided considering all migrants as a homogeneous group**. Therefore, in many settings, the screening programme is overestimating the population at risk, thereby wasting the scarce health resources of the health system - for example, low prevalence of HBV and HCV in most Latin American countries would not justify screening of these infections to migrants coming from these countries.

With the aim of improving patient care by strengthening medical decisions, there has been an outstanding development of clinical decision support systems in the last decade[26]. In such tools, the characteristics of an individual patient are matched to a computerized clinical staff knowledge base in patient-specific assessments and recommendations are then presented in electronic patient record (EPR) system to the clinical staff for decision. The decrease in consultation time, wrong diagnosis, and test duplication at primary care settings support the cost-effectiveness of implementing CDSS in screening[27].

Our research group has already developed an **innovative prototype digital software (CRIBMI)**[28]. This user-friendly and simple software was designed by the Barcelona Institute for Global Health (ISGlobal) in collaboration with the Jordi Gol Institute for Primary Care Research (IDIAP Jordi Gol) and the Fundació Clinic Recerca Biomédica (FCRB) and was tested in four primary care centres (PCCs) in Catalonia. In addition, this software was already **integrated into the EPR system** in Catalonia at primary care level (**eCAP**). The software uses routinely structured health data (country of origin, sex, and age) collected by the administrative staff of the health centre and registered in the EPR system, and **through simple algorithms, generates an automated screening decision support system** able to inform clinicians about screening on targeted conditions in migrants based on an individual risk- assessment. It currently includes eight conditions: 7 communicable diseases (HIV, HBV, HCV, TB, Chagas diseases, strongyloidiasis and schistosomiasis) and one key health condition (female genital mutilation)[29]. Data shows the digital tool is feasible to implement, acceptable to healthcare professionals and migrants, and well adapted to the primary care context[30], with data suggesting that the digital tool is improving the diagnosis of imported conditions but also other common communicable diseases in migrants when comparing it with a standard training programme[30].

The **aim** of this study is to implement and test **a digital tool that will use routine health data to perform an individualized risk assessment** (using a set of parameters: age, sex, country of origin) and it will provide recommendations for primary care health professionals in several health aspects: the screening of communicable diseases and female genital mutilation. This can better utilize scarce health care resources and at the same time, improve the knowledge of health professionals on migrant health conditions.

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2. HYPOTHESIS

Screening programmes for migrant-related diseases differ widely, and detailed descriptions of their effectiveness are currently lacking. Comprehensive data on the design and performance of screening programmes for both communicable diseases and female genital mutilation in migrant groups in Spain would enable opportunities for cross-regional sharing of information and homogenizing best practice.

Our hypothesis is that migrants´ overall health status may be improved by increasing the detection of certain infectious diseases and other conditions for which effective care is available. This can be achieved through a systematic screening of these conditions that can be facilitated by using innovative and digital solutions implemented in the routine health care.

3. OBJECTIVES

General objective: To develop an integrated and primary care based, communicable diseases and female genital mutilation screening programme for migrant populations in Spain in order to promote better health and integration.

Specific objectives:

Aim 1: To develop a Spanish consensus guidance on migrant screening recommendations based on existing European examination/screening programmes and on a consensus of a country-expert transdisciplinary national collaborative network.

Aim 2: To scale-up and validate a simple and user-friendly innovative digital tool that will be integrated into the local electronic patient record system of primary care in two different settings (Catalonia and Andalusia) and that aims to facilitate targeted screening to recently arrived migrants presenting for a routine appointment. This digital tool will support health professionals to follow best-practice recommendations; while considering patients' individual characteristics (country of origin, age, sex) and therefore specific risk factors.

4. STUDY DESIGN

This study will be developed into two sub-studies in order to accomplish the specific objectives.

4.1.1 Study 1 related to aim 1. Spanish consensus guidance on migrant screening recommendations

a. A comparative review and analysis of existing screening programmes will be performed across Catalonia and Andalusia. We will comprehensively review screening policies for migrants and the

access to these programmes in Spain, including: health care settings, type of migrants (asylum seekers/refugees/undocumented), diseases included, gender perspective (specific programmes for women), target higher-risk subgroups (e.g., immunosuppressed), access to treatment and follow-up (particularly for female genital mutilation) and inter-disciplinarity of the programmes.

b. A survey on migrant health screening strategies policies for migrants will be conducted targeting national experts to (i) assess what screening strategies for migrant on infectious diseases and female genital mutilation are being implemented; (ii) to provide the contact details from their National Ministry of Health experts, responsible of asylum seekers programmes, blood banks, national transplant organizations, and antenatal care units of Spain.

c. A report with the reviewed results will be developed and presented in two consensus workshops, one in Catalonia and one in Andalusia.

d. A consensus workshop with national experts will be carried out to establish which diseases will be included in the final screening algorithm and what will be defined as the screening criteria for each condition. The tentative elements to include are HIV, HBV, HCV, TB, selected parasitic infections and female genital mutilation. For most of the communicable diseases, the screening criteria will be fully aligned with the current ECDC screening guidelines and recommendations. The screening criteria used in the previous project (CRIBMI) will be reviewed and updated. In the previous project, HIV test was offered following ECDC recommendations to those individuals coming from countries with a prevalence >1%. HBV and HCV tests were offered (also following ECDC guidelines) to those individuals coming from countries with $\geq$2% prevalence. Strongyloidiasis and schistosomiasis tests were offered to those individuals coming from endemic areas, also defined in the ECDC guidelines. Chagas disease test was offered to those individuals coming from the 17 Chagas endemic countries. Nevertheless, active TB was screened in migrants from countries with an incidence >50/100000. Furthermore, exploring the risk of female genital mutilation was considered in all women between 15 and 50 age years-old that come from countries where this practice is frequent.

e. To measure the level of agreement with the recommendations a questionnaire based on a Linkert Scale of 5 points (1- Strongly disagree, 2- Disagree, 3- Neutral, 4- Agree and 5- Strongly agree) will be sent to the different experts invited to the workshops. The agreed recommendations by setting can be found in the supplementary files, Annex 1 for Catalonia's recommendations and Annex 2 for Andalusia's recommendations.

4.1.2 Study 2 related to aim 2. Operational implementation of a pilot screening programme using the ISMiHealth software and evaluation of its feasibility, impact, equity, and cost. The study will be registered in clinical.trials.gov

a. Study design and subjects.

A pragmatic cluster controlled randomised trial will be conducted in 41 PCCs of Catalonia and Andalusia to explore and assess the effectiveness of the digital tool ISMiHealth. In Catalonia, 35 PCCs will compose the sample size (see sample calculation below) and in Andalusia 7 centres will be selected to conduct the pilot study. See Annex 3 and 4 for the list of the participating centres. Eligible participants will be Health professionals working at the corresponding PCCs. Indirect participants will be migrant populations attended at Primary care (aged $\geq$14 years in Andalucía and $\geq$15 years in Catalonia), included in the definition of the targeted migrant population (people coming from countries in the geographic areas of Africa, Latin-America, Asia and Eastern Europe following the categorization of the UN Statistical Commission), that are attending the PCCs for any reason. No exclusion criteria will be set concerning the year of arrival to provide the screening recommendations except for active TB where a limit of five years since the arrival to the host country will be established. These criteria will be established since all the infections, except for active tuberculosis, are chronic infections and because a higher risk of such infections has also been seen in long term migrants.

b. Health centres selection, randomisation and masking.

Regarding the selection of the participating PCCs in Catalonia, the IDIAPJGol research team will find areas where there are referents with an interest in participating in the study. The list of PCCs belonging to these areas, where the referral to the reference laboratory is more feasible, will be provided. With this final list, we will proceed with the randomization stratified by area and by density of migrant population in the area (low, medium and high). For the selection of the PCCs in Andalusia, an IT committee of the Andalusian Health Service (SAS) will provide a list of the possible centres that could participate in the study and the randomization will be carried using the same stratification method mentioned previously. The randomization will be performed through a statistical software for each pair of selected health centres stratified by study area. Therefore, for each pair of PCCs, one PCC will be randomly selected to implement the screening programme through the ISMiHealth software, and it will be compared with the other PCC of the same area where the PCCs do follow the current practices in the routine care. However, one of the seven centres will not be paired, but will participate of the intervention. In both cases, health professionals will receive a training session on migrant health; the training contents will include for each condition, epidemiological aspects, diagnosis, treatment and the screening recommendation.

In addition, a group informed consent will be required to be signed by the Director or a responsible of each PCC where they will agree that their respective PCC will participate in the study.

c. Implementation strategy.

The implementation strategy designed will be carried out in three phases and using mixed methodology. For the study of the implementation process, three PCCs, per study setting (3 in Catalonia and 3 in Andalusia) will be selected by convenience from the intervention branch. In the pre-implementation phase, the local needs, resources, barriers, and facilitators will be assessed through the conduction of focus group (FG) discussions for professionals and the migrant population, with the aim of adapting the intervention to the contexts of each setting. FGs for professionals and migrants will be carried out separately. In the implementation phase, real-time monitoring of the strategy will be performed (by a data manager and a study coordinator from each PCC) in order to identify opportunities for improvement and optimization of the process. The technical monitoring will help identify errors in the implementation of the alerts in the EPR system, to be mitigated in real-time. In the post-implementation phase, participants´ opinions will be assessed through FG discussions and in-depth individual interviews (IDI) with health professionals, IDI with intervention PCC's directors, IDI with managers of the health care system, and IDI with migrant patients who have undergone any of the included screening tests during the study period. We aim to understand the vision of professionals participating in the intervention on aspects of utility, applicability, understanding and relevance of the alert system, as well as barriers and facilitators for the implementation of the alert system in the health information systems to the entire health care systems (Catalan Institute of Health and SAS). We also aim to understand the opinion of migrants regarding screening and referrals pathways derived from health care. Approximately 10 FGs and IDI will be conducted with health professionals, around 10 IDI will be done with PCC's directors/managers and up to 40 IDI will be carried out with migrant patients. These FG discussions and IDI will be carried out in the corresponding PCC and will last approximately 90 and 60 minutes respectively. Quantitative indicators will also be taken to evaluate the outcomes of the implementation. Additionally, an ad-hoc survey of the programme acceptance, targeting health professionals and a sample of migrants will be performed.

d. **Two sub-studies** regarding the topics of i) Female Genital Mutilation (see Annex 5) and ii) Health Data Collection (see Annex 6) will be carried out.

5. INTERVENTION

The implementation of the screening programme will be facilitated using a simple and user-friendly tool

that helps health professionals to follow best-practice recommendations while taking into account patients' individual characteristics: country of origin, age, sex. ISMiHealth set a series of rules that provide real-time prompts to health professionals on screening of infectious diseases and female genital mutilation for migrants.

In Catalonia, the digital tool has already been integrated to the EPR system (e-CAP), program shared by all PCCs that are part of the Catalan Institute of Health, as part of a pilot study. The 3 demographic variables (country of origin, age and sex) are routinely collected by the PCC´s administrative staff and documented in electronic medical records. Once the administrator collects these variables in the computer system, the tool will generate an alert that will be reflected once the patient's medical history is reopened. Therefore, when the migrant patient goes to the consultation with the health professional, the alert will appear containing the recommendations for screening of the different diseases/conditions. The data of the patients is not registered nor collected by the digital tool, it is only used to produce the alert.

In Andalusia, the digital tool will be integrated for the first time into the primary care EPR system (DIRAYA). Similar to what is described above for Catalonia, the alert will be generated from demographic data but, in this case, the information is centralized in the Database of Users (BDU) of the SAS. Each user in such BDU is uniquely identified by their Andalusian Health History Number (NUHSA). The tool will be linked to specific user data (NUHSA) to be able to apply the screening algorithm. Therefore, in this scenario the tool does not collect any personal data but use it to generate the alert.

Once the health professional accesses the digital tool, he/she will have to mark in a check-list produced by the tool, the diseases that the patient has already been screened. This information (the check-list) will be registered and will be protected on a server under a secured environment ensuring data protection policy. In addition, access to the primary care environment (DIRAYA) requires a prior identification by the healthcare professional on a private and secured connection.

Training sessions

Health professionals from both intervention and control centres will receive training sessions, targeting staff of the centres including nurses, medical doctors, and other technicians. The sessions will cover background information on each infection, including epidemiology, diagnostic tools, treatment available, particular aspects in high-risk groups such as immunosuppressed patients, data on cost-effectiveness, and screening recommendations for migrants.

Participants´ selection

Therefore, when an individual comes to the PCC for any reason, the health professional will receive a message, in the EPR system, inserted as a pending task assignment with a recommendation on the diseases that should be considered for screening, based on this person's background characteristics. The tool is also able to identify if a person had already a diagnosis of any of the conditions included in the algorithm (based on ICD-10, International Classification Diagnosis codes) or if a diagnostic test had been performed for any condition included in the program. In such cases, the automated electronic prompt does not appear for that condition. A pilot test will be conducted with 3 health professionals to assure the correct functioning of the tool. In the control centres, we will hold just training sessions with the same screening recommendations as for the intervention centres but will not initiate the tool/prompts onto the EPR system. When the patient comes to the PCC, health professionals will decide what diseases/conditions should be screened for according to the information received either through the digital software (intervention centres) or based on their knowledge on the epidemiological background of the diseases (control centres), which was included in the training programme. In any case, health professionals will be responsible for requesting a blood test or a chest radiography and/or the derivation to a specialist.

Participant´s selection for the feasibility and acceptability evaluation (focus group discussions, IDIs and survey)

In the pre-implementation phase, general practitioners (GP) and nurses from the selected PCCs will be invited by an electronic mail sent by a member of their PCC leadership team. Among those that express interest to participate, the research team will perform a selection based on personal characteristics (professional category, sex, age and time of contract with the Catalan Institute of Health for participants from Catalonia or the SAS for participants from Andalucía) in order to obtain discourse variability in the FG. In the post-implementation phase, PCCs will be selected in each geographical area where the study was carried out taking into account the findings of the previous study phase (real-time monitoring and survey to health professionals) and a consensus of the research team. Participant's selection will be performed in the selected PCCs. PCC's directors and managers of the healthcare system will be invited by an electronic mail sent by the study coordinator at their study area. GPs and nurses will be selected as explained above.

Migrant population will be selected by one GP in each PCC. In the pre-implementation phase, the GP will select his/her own patients based on the following characteristics: sex, age and geographical area of origin. In the post-implementation phase, the GP will select his/her own patients based on sex, age, geographical area of origin, if the person underwent screening for any of the conditions included in the intervention and screening results. Each GP will call his/her patients to explain the study and invite them to participate. Oral consent will be obtained in that phase and registered in patient clinical history followed by the written consent on the day of the FG discussion or IDI. Also, the research group will provide the participants with a short questionnaire to collect sociodemographic data such as, age, time residing in Spain, sex, education level, professional status, marital status, among others detailed in the document 'Information of the Patient'. All IDI and FG discussions will be conducted in the PCCs, the latter with 8 to approximately a maximum of 10 participants in each group.

For the survey of the programme acceptance, a list of possible candidates (sex and gender balanced) will be made for both groups, health professionals and migrant patients. The same member of the PCC leadership team that sent the invite to the GP and nurses for the FGs of the 6 participating PCCs will send an anonymous questionnaire via email or WhatsApp, using the secured LimeSurvey platform, to the chosen health professionals and migrant patients. Candidates will receive the invitation by email or message with a link to the anonymous survey and their access to it will represent their consent to participate.

6. STUDY PROCEDURES, TREATMENT AND CALENDAR OF THE STUDY.

In line with the existing national guidelines, active TB will be screened with chest radiography. If radiographic findings are compatible with TB, or if TB symptoms are present, the person should be immediately referred to a specialist for full diagnostic workup. For HIV testing, a standard HIV ELISA test will be performed. For HBV, the Australian antigen (HBsAg) and the IgG Core (IgG anti-HBc) serological test will be performed. For HCV, an IgG-HCV test will be performed. For Chagas disease, strongyloidiasis and schistosomiasis, a serological test will also be performed. All of them will be processed in the reference laboratory facility of the PCC, being all of them based on the commercial tests available in each hospital of reference. Finally, for female genital mutilation, a gynaecological physical examination will be performed and/or referral to a gynaecologist will be carried out if required. A preventive protocol will be applied for girls at risk of this practice.

In the case of a positive test result or diagnosis, the individuals will be referred to receive specialized care as appropriate.

7. DATA ANALYSIS

a. Sample size. For estimating the number of PCCs that will compose the sample in Catalonia, we have

considered that the mean migration rate in all settings is higher than 10%, then the achieved confidence level will exceed 95% when 32 centres or more are participating. A comparative analysis of the PCCs in relation to the migration density will be first performed to select the pairs of PCCs with more similar characteristics to assure the validity of the results.

b. Feasibility and acceptability analysis. IDIs and FGs will be conducted in the PCCs, the latter with 8 to approximately an estimated maximum of 10 participants in each group. Data will be collected through digital audio recording. All IDIs and FGs will be manually transcribed by one interviewer and field notes will be made during or after the IDI/FG discussion. A thematic content analysis will be performed to evaluate the data from each IDI/FG. It will consist of six phases: become familiar with the data, generate initial codes, search for themes, review themes, define final themes and write-up. In order to validate the data, the coding and final categories will be triangulated by the research team. To complement this analysis, the analysis of the survey of the programme acceptance will be carried out.

c. Analysis impact of the tool. The effectiveness of the tool will be evaluated and compared in each pair of PCCs, the intervention compared with the control group.

d. The **primary outcome** measure will be the increased detection rate of all aggregated conditions included in the study in the intervention-PCCs compared with the control-PCCs. Conditions: Chagas diseases, strongyloidiasis, schistosomiasis, HIV, viral hepatitis B, viral hepatitis C, active tuberculosis and female genital mutilation.

Secondary outcomes will be the proportion of **screening tests performed for each condition and other factors associated with having a higher screening rate, such as sex, age, immunosuppression status, being attended in an intervention centre, fulfilling the screening criteria, or coming from specific geographic areas**. All cases will be classified using pre-defined case definitions, including the number of diagnoses codified through the ICD-10 code, number of positive laboratory tests, and referrals to specialists. To analyse the effect of the intervention on the outcomes, a difference in differences approach will be performed using a generalized linear model. Intervention units will be compared before and after implementation with respect to the monthly diagnostic rate. Significant deviations between intervention and control centres before implementation will be suggestive of the main underlying assumption, parallel trends prior to implementation. Sandwich-robust standard errors will be clustered at the intervention level. For secondary outcomes, logistic regression models will be used to identify associations between the screening rate performed and socio-demographic, and, other health conditions, using area as a random intercept.

Study variables:

1. Sociodemographic characteristics of the Primary care health professionals: age, sex, primary care team (PCT)

2. Socio demographic characteristics of migrants: age, sex, country of origin, assigned PCT, assigned doctor

3. Characteristics of the PCT: intervention or control centre, number of professionals (GP and nurses), urban/rural centre, index of socioeconomic depravation (MEDEA), Standard Quality of Healthcare migration density, number of migrants with active status in the year of the implementation of the tool; number of migrants who did not visit any of the centres during the intervention; number of migrants with at least one visit during the intervention period

4. Variables related to the use of alerts: number of migrants with screening criteria for each condition, number of screening tests performed for each condition, date of entry/exit into the system, date of visits, referral to specialists

5. Laboratory or clinical variables: X-rays, serological or microbiology tests for the conditions studied (HIV, HBV, HDC, Chagas disease, strongyloidiasis, and schistosomiasis). In addition, other laboratory parameters will be included (hemogram, including haemoglobin, platelets, leucocytes, neutrophils, lymphocytes, and eosinophils, IgE, liver and renal function - creatinine, urea, AST, ALT, GGT, bilirubin, coagulation…)

6. Diagnostic variables: Diagnoses of each disease/condition (HIV, HBV, HCV, Chagas disease, strongyloidiasis, schistosomiasis and female genital mutilation) based in ICD 10 codes registered by health professionals in the last 10 years including the intervention period.

7. Drug related to the diseases included in the study (e.g., ivermectine for strongyloidiasis) prescribed during the intervention period.

8. Co-morbidities: Other diseases diagnoses based on ICD-10 codes registered by health professionals into the system in the last 10 years including the intervention period. The aim is to study the possible association of other diseases (diseases associated with immunosuppression, mental health conditions, cardiovascular and other diseases, other infectious diseases...) with the studied diseases/conditions. In addition, to carry out the cost-effectiveness study (an economic analysis that will be essential to achieve the second objective of the study) all parameters must be considered to adjust the model, including the comorbidities of the diseases.

9. Immunosuppression status: Here it will include the prescription and billing of immunosuppressive drugs in the last 10 years including the intervention period as well as ICD-codes on transplant, haematological diseases, cancer and related diagnoses, and autoimmune diseases in the last 10 years for determination of immunosuppression status.

10. Minimum basic data set (CMBD) variables: hospitalization dates, primary diagnoses during hospitalizations, laboratory parameters during hospitalizations, drugs prescribed during hospitalization or outpatient units, cost associated or attributed to hospitalization, number of visits in outpatient units

e. Cost of the screening programme and the tool. The cost of the software tool will be evaluated and compared with the standard care (non-tool based), considering: 1. Costs associated with screening and subsequent treatment of diseases and their sequelae; 2. Cost-saving resources allocated to the screening programme in primary care will be estimated. Besides the prevalence estimates for each condition, the number of cases will be compared with the previous notification rates of the notifiable diseases and with other prevalence studies or registries, if any, for the rest of diseases. Finally, the software tool will be compared with other innovative ways of improving the operationalization of the screening programmes implemented in other countries, such as United Kingdom or Sweden.

f. Gender perspective. Results will also report gender inequalities concerning the access to screening programmes or differences in health professionals´ decision to screen specific female-related-conditions (e.g., female genital mutilation compared with TB or other communicable diseases).

g. Study limitations. The retrospective data collection can lead to inaccuracy or insufficient information of some variables. Also, underestimation of female genital mutilation cases might result due to less referral of potential affected patients to specialists. Recommendations are up to the healthcare worker to inform and the patient to accept it, therefore results may vary significantly by PCC. On the other hand, since the data of date of arrival to the country is not routinely collected at PCCs, it might not provide the adequate information to fulfil the active TB screening criteria proposed in the recommendations.

h. Other aspects. A business plan model will be developed including the integration of the software in an application programming interface (API) to facilitate and simplify the implementation and maintenance of the software and the registry of the evidence of modifications of the software in the

Property Management System Block Changes.

8. ETHICS

The study will be performed according to Ethical Principals of Medical Research (WMA Declaration of Helsinki, Fortaleza Brazil, October 2013) and following the International Ethical Guidelines for Biomedical Research. It will be carried out in accordance with the protocol and with the pertinent legal requirements: -Law 14/2007 of July 3rd on Biomedical Research, since this is a research project that does not involve medicines.

The study protocol will be submitted to the ethical committee of the Hospital Clinic, IDIAP Jordi Gol in Barcelona and the Provincial Research of Almería. The application will consider in both cases all ethical considerations, including those reflected in the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. No research will start until ethical approval of the new study protocol has been gained and the REA has received a scanned copy of all documents proving compliance with existing EU/national legislation on ethics.

The screening programme will only provide advice or recommendations to health professionals for screening and early detection of infectious diseases and female genital mutilation in migrant patients according to the current guideline recommendations that should be considered during the routine practice and that will be agreed during the workshop with experts and will be summarised in a consensus document. Therefore, it will be the health professional, the direct beneficiary, who will finally decide what tests should be offered to each individual as part of the clinical practice. Accordingly, an explicit written consent form from the migrant individual will not be necessary. However, an informed consent will be required from the Director or a responsible of each PCC agreeing to the participation of their respective primary care team.

Nonetheless, all individuals will be properly informed in compliance with relevant national and local regulations about the procedures and tests that are indicated in each case. As part of the routine health care, all patients being attended at those selected centres will be informed by the health professional about the diseases that should be screened according to their epidemiological background. Therefore, the person will be fully aware of the implications of different screening test results, including that some of the diseases are notifiable, while others are not. It will also be stressed that screening decision is voluntary and that not accepting the screening will in no way influence the care they will receive, or the assessment of the asylum rights or other resident permit criteria. Careful information, using translators as required, will be provided to all study subjects that cannot speak Spanish. As part of the standard health care, they will be informed that if there is a positive test or a diagnosis of any of the diseases, they will be treated or referred to a specialist as appropriate.

On the other hand, for the execution of the FG discussions the preselection of candidates, health professionals and migrants, will be performed by a member of the PCC leadership team and by a GP, respectively. After expressing interest and accepting to participate in the study, by e-mail for the group of professionals and giving their oral consent by phone for the migrant group, they will be summoned for the date of the FG. In each of the FG discussions, signatures in the individual informed consents will be collected after explaining the study and the participant information sheet.

Objection by participants/patients

To avoid any suspicion of coercion, this study follows the code of conduct in case of objection/resistance of (1) health professionals to follow the recommendations that the tool is providing, or (2) of the individuals to be tested for any of the conditions following the current guidelines recommendations. This code of conduct describes both verbal objection/resistance, and non-verbal or behavioural expressions of objection/ resistance. Behaviour needs to be interpreted as objection if it is different from, or more intense than, usual behaviour in routine care.

Potential impact of the research

This research project is not expected to have any possibly harmful impact on the individuals involved. If an individual is diagnosed with one of the diseases screened, he/she will be referred and treated as appropriate according to the routine care standard procedures of each centre.

9. DATA MANAGEMENT AND DATA PROTECTION

-The project involves handling personal data that are routinely collected in healthcare services. The Primary Care Information System (SISAP) will supervise the technical monitoring of the tool in the implementation phase of the study.

Data extraction. The data extraction process will be performed according to the principles established by the healthcare services, including the data protection policies in this regard. All processing of patients' personal data collected within the study will be conducted according to conventional confidentiality.

In the Catalan Institute of Health, data will be extracted from the electronic patient record system eCAP and pseudo-anonymized by IT staff of the System for the Development of Research in Primary Care (SIDIAP) Institute. The study variables will be pseudo-anonymized, with technical and functional separation, by a SIDIAP data manager. SIDIAP will be responsible for the data processing in Catalonia. Regarding SIDIAP source data, the strict SIDIAP security standards will be followed. Aggregated data will also be obtained via SIDIAP during the process of implementation of the tool in the Catalan Institute of Health with the sole objective of technical monitoring to identify alert errors and provide subsequent remediation.

In Andalusia, the data will be extracted by a specialized IT committee of the SAS Institution of the area involved in this project. The information will be extracted retrospectively and will include: 1) the check-list from the tool and 2) the demographic and clinical variables from the BDU. Then, the IT committee will link this information with the laboratory data of the reference hospital (Hospital de Poniente in Almeria) and will pseudo-anonymize the data. Thereafter, the biostatistician responsible for the data analysis will only have access to pseudo-anonymized data without personal or sensible information. Thus, the privacy of individuals will be protected.

In this regard, details on the health of migrants may have the consideration of sensitive data, as described in article 8 of Directive 95/46/EC (data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, data concerning health and sex life) and therefore such data will be aggregated when applicable (region will be provided instead of country of origin) to avoid the identification of the individuals. When applicable, specific authorization by the national data protection authority will be obtained.

Data processing and management. A data processing agreement will be undertaken with the Catalan Institute of Health/IDIAPJGoL and with Distrito Poniente de Almería, for the ownership and use of research data. Also, a plan for the ongoing custodial responsibilities for the research data at the conclusion of the project will be carried out, including recommendations for the disposal and destruction of the research data.

Concerning the data-management, the treatment, communication, and transfer of personal data of all participants will be adjusted in compliance with EU Regulation 2016/679 of the European Parliament and the Council of April 2, 2016 related to the people physical protection with regards to the processing of personal data and the free circulation of data, being binding as of May 25, 2018. All data analysis will be conducted on pseudo-anonymized data and no personal data or data that could potentially identify an individual will be included in the final report.

For the qualitative study, the manager of each PCT participating in the project or study coordinators will

send an email to the professionals (GPs, nurses, PCC directors and managers of the health system) and those who declare interest in participating will be selected to be part of the focus groups and/or IDIs. The migrants who will participate in the focus groups or IDI of the study will be invited in a visit or by telephone by their own doctor and will sign the consent form on the day of the focus groups. The qualitative study data will be obtained through the informed consents of the participants, in accordance with the provisions of articles 6.1 a) and 9.2 a) of the RGPD. In Catalonia, the audio recordings will be stored and secured in the local server of ISGlobal (VPN) where only participating investigators will have access to it. While in Andalucía the audio recordings will be stored in the UGRDrive, a high security storage service since it is a private cloud of the University of Granada (UGR). Only researchers of the UGR participating in the project will have access to these. In both settings, audio recordings will be erased after five years of completion of the study. No international data transfer will take place of the recordings made in the FG discussions and IDIs. For the survey of the programme acceptance, the secured LimeSurvey platform will be used as previously explained.

Pseudo-anonymized data will also be stored in ISGlobal's VPN and only participating investigators will have access to the data-base, and integrity and security of data will be maintained. In addition, a password will be requested to all researchers in order to access the data, registering any access. Also, a regular backup will be generated to avoid loss of information. An adequate documentation of data (metadata) -i.e., adding semantic descriptions, annotations, etc. will facilitate identification and support effective reuse of research data. Only encrypted data will be transferred to third parties and other countries, which in no case will contain information that can directly identify the participant (such as name, initials, address, social security number, etc.). In the event of such a transfer, it would be for the same purpose of the study described and would guarantee confidentiality.

If a transfer of encrypted data takes place outside the EU, either in entities related to the hospital where the patient is involved, to service providers or researchers working with us, the data of the participants will be protected by safeguards such as contracts or other mechanisms established by the data protection authorities.

In addition to the rights already provided for in the previous legislation (access, modification, opposition and cancellation of data, deletion in the new Regulation) participants can also limit the processing of data collected for the project that are incorrect, request a copy or be transferred to a third party (portability). In order to exercise these rights, the participants must contact the principal investigator of the study or the Data Protection Officer of ISGlobal via lopd@isglobal.org. Participants from the Catalan Institute of Health must contact the Data Protection Officer via dpd@ticsalutsocial.cat. Also, the participants have the right to contact the Data Protection Agency if they remain unsatisfied.

This project does not prevent advanced data usage. In accordance with the provisions of article 35 of the RGPD, the project does not meet the necessary characteristics that require the performance of an impact assessment.

Reutilization of data First, a standardized communications protocol to retrieve (meta) data by their identifier, free and universally implementable, will be generated, including a clear and accessible data usage license. After 10 years, all data will be eliminated and destroyed.

Data will be anonymously uploaded in the repository, and those records that may lead to the individual identification of the participants will be removed or grouped with the aim of keeping their identity hidden at all times. Likewise, the possibility of withdrawing all the individual information of a patient will be guaranteed when so expressed. The data will be stored in a repository created specifically for this purpose in the ISGlobal data centre in the Campus Mar (Carrer del Dr. Aiguader, 88), which requires prior appointment with IT staff and therefore only those responsible for computer security and researchers linked to the project will have access to them. A series of protocols are in place to test and maintain network security, and to provide access management policies for network drives, databases and remote access. The system is protected from power interruptions, with controlled access to authorized users

only.

The study does not involve biological samples.

10. FUNDING

The ISMiHealth project received funding (87.120,00€) from the Health Research Fund Call 2021 of The Ministry of Science and Innovation to support this study economically. Study investigators will not receive any personal compensation or extra salary for participating in this study.

11. RESULTS COMMUNICATION

The promoter and investigators commit to publish the results of the study in journal articles, other scientific publications and communications to congresses. Authorship in case of publication will be decided according to quantitative and qualitative input to the study. The principal investigator will be the first or last author of the articles.

12. SUPPLEMENTARY FILES

Annex 1. Screening recommendations for infectious diseases and FGM targeting the migrant population residing in Catalonia, Spain.

1. Población diana: Se ha definido como población diana del estudio a inmigrantes que procedan de países en África, Latino América, Asia y Europa del Este. Se utilizó la división geográfica de la Comisión de Estadística de las Naciones Unidas.
2. Virus de la inmunodeficiencia humana (VIH): Todas las personas deberían tener acceso a una prueba de VIH si lo solicitan, pero además se recomienda ofrecer el cribado a la población inmigrante procedente de áreas dónde la prevalencia de VIH es >1% si no se ha hecho una prueba de VIH con anterioridad.
3. Otras infecciones de transmisión sexual (ITS): Se recomienda pedir pruebas para sífilis y otras ITS basado en factores de riesgo. Por lo tanto, no se recomienda el cribado sistemático de sífilis y otras ITS ya que no hay evidencia del riesgo de exposición de una persona basándose en las variables: país de origen, edad y sexo.
4. Virus de la hepatitis B (VHB): Se recomienda realizar el cribado de VHB mediante la detección del antígeno australiano (HBsAg) y el anticuerpo contra el antígeno core (anti-HBc) a todos los inmigrantes procedentes de un área con prevalencia intermedia o alta de VHB (≥2%). *Además, se ofrecerá cribado de VHB a inmigrantes procedentes de Marruecos y Guinea Ecuatorial, aunque la prevalencia en estos países es <2%. Se ofrecerá pauta vacunal a las personas con un test serológico negativo.
5. Virus de la hepatitis C (VHC): Se recomienda realizar cribado de hepatitis C mediante el anticuerpo anti-VHC a todos los inmigrantes procedentes de áreas con una prevalencia de VHC ≥2%.
6. Tuberculosis (TB) activa: Se recomienda el cribado de TB activa utilizando radiografía de tórax a inmigrantes recién llegados (<5 años) procedentes de países con una incidencia >50 casos/100.000 habitantes. Si la persona tiene una radiografía previa, se debe valorar la situación antes de solicitar otra radiografía de tórax.
7. Infección tuberculosa latente (ITL): Se decidió que no se implementará el cribado de ITL en Cataluña ya que nunca se ha realizado un cribado de forma sistemática para la ITL en Atención Primaria (AP), además de que la mayoría de los centros de AP no tienen acceso a la prueba diagnóstica IGRA, la prueba más coste-efectiva para detectar la ITL. Aunque no se creará una alerta específica para la ITL durante el proyecto, se recomienda que en un futuro se promueva la formación para poder implementar está infección en programas de cribado llevados a cabo en AP.
8. Estrongiloidiasis: Se recomienda el cribado serológico de estrongiloidiasis a la población inmigrante procedente de países endémicos y si alguno de estos individuos está inmunosuprimido o tiene un potencial riesgo de ser inmunosuprimido en un futuro, se debería derivar a la unidad especializada del hospital de referencia y se debería realizar estudio de parásitos en heces.
9. Esquistosomiasis: Se recomienda el cribado serológico de esquistosomiasis a la población inmigrante procedente de países endémicos.
10. Enfermedad de Chagas: Se recomienda el cribado serológico de *T. cruzi* a la población inmigrante procedente de países endémicos.
11. Mutilación genital femenina (MGF): Se recomienda valorar el riesgo de MGF y detectar los casos en niñas y mujeres procedentes de países endémicos. Además, es necesario formar a los profesionales de la salud en competencia intercultural y en cómo abordar la temática en la consulta respetando la cultura de la mujer y de su familia.
12. Derivación: Personas diagnosticadas de alguna de las patologías incluidas en el programa de cribado deben ser derivadas a la unidad especializada del hospital de referencia.

Annex 2. Screening recommendations for infectious diseases and FGM targeting the migrant population residing in Andalusia, Spain.

1. Población diana: Se ha definido como población diana del estudio a inmigrantes que procedan de países en África, Latino América, Asia y Europa del Este. Se utilizó la división geográfica de la Comisión de Estadística de las Naciones Unidas.
2. Virus de la inmunodeficiencia humana (VIH): Se recomienda el cribado universal de VIH a todos los inmigrantes procedentes de un país incluido en la definición de población diana si no se ha hecho una prueba de VIH con anterioridad. Repetir prueba de VIH si la persona es diagnosticada con otra ITS y/o presenta otros factores de riesgo.
3. Otras infecciones de transmisión sexual (ITS): Se recomienda el cribado universal de sífilis a todos los inmigrantes procedentes de un país incluido en la definición de población diana si no se ha hecho una prueba de sífilis con anterioridad. Repetir prueba de sífilis si la persona es diagnosticada con otra ITS y/o presenta otros factores de riesgo.
4. Virus de la hepatitis B (VHB): Se recomienda realizar el cribado de VHB mediante la detección del antígeno australiano (HBsAg) y el anticuerpo contra el antígeno core (anti-HBc) a todos los inmigrantes procedentes de un área con prevalencia intermedia o alta de VHB (≥2%). *Además, se ofrecerá cribado de VHB a inmigrantes procedentes de Marruecos y Guinea Ecuatorial, aunque la prevalencia en estos países es <2%. Se ofrecerá pauta vacunal a las personas con un test serológico negativo.
5. Virus de la hepatitis C (VHC): En el contexto del plan para la eliminación de la hepatitis C en Andalucía, se recomienda el cribado universal de VHC a todos los inmigrantes procedentes de un país incluido en la definición de población diana.
6. Tuberculosis (TB) activa: Se recomienda el cribado de TB por Mantoux a inmigrantes asintomáticos recién llegados (<5 años) procedentes de países con una incidencia >50 casos/100.000 habitantes. Si el resultado es positivo o dudoso, realizar radiografía de tórax.
7. Infección tuberculosa latente (ITL): De acuerdo con el protocolo de actuación que se va a implementar en el Distrito Sanitario de Atención Primaria Poniente, se recomienda lo siguiente, a inmigrantes <35 años, procedentes de países con una incidencia >50 casos/100.000 habitantes, que se puedan tratar y que no tengan contraindicaciones para el tratamiento de la infección tuberculosa latente: i) Tratar si procede a las personas con resultados de Mantoux >20mm. ii) Realizar IGRA y tratar si procede a personas vacunadas con resultados de Mantoux de 5-19mm para inmigrantes del Magreb y África subsahariana y de 10-19mm para el resto de los inmigrantes incluidos en la población diana. *Además, se incluirán en la recomendación la población inmigrante procedente de Marruecos, aunque la incidencia en este país es <50 casos/100.000 habitantes y se considerará realizar IGRA y tratar si procede a personas vacunadas con resultados de Mantoux de 5-19mm.
8. Estrongiloidiasis: Se recomienda el cribado serológico de estrongiloidiasis a la población inmigrante procedente de países endémicos.
9. Esquistosomiasis: Se recomienda el cribado serológico de esquistosomiasis a la población inmigrante procedente de países endémicos.
10. Parásitos intestinales: Se recomienda el cribado de parásitos en heces en población inmigrante proveniente de países tropicales y sub tropicales, que hayan llegado en los últimos tres años al país o que hayan regresado de un viaje reciente a su país (visitando a amigos y familiares, VFR por sus siglas en inglés).
11. Enfermedad de Chagas: Se recomienda realizar el cribado serológico de *T. cruzi* en mujeres en edad fértil (15-45 años) y a personas inmunosuprimidas o en riesgo de inmunosupresión procedentes de países endémicos.
12. Mutilación genital femenina (MGF): Se recomienda valorar el riesgo de MGF y detectar los casos en niñas y mujeres procedentes de países endémicos. Además, es necesario formar a los profesionales de la salud en competencia intercultural y en cómo abordar la temática en la consulta respetando la cultura de la mujer y de su familia.

13. Derivación: Personas diagnosticadas de alguna de las patologías incluidas en el programa de cribado deben ser derivadas a la unidad especializada del hospital de referencia.

Annex 3. Participating PCCs in the setting of Catalonia

Regions within the Autonomous Community of Catalonia	Primary Care Centers
Costa de Ponent	CAP Esparreguera
	CAP Gavà-1
	CAP Molí Nou
	CAP Gornal
	CAP Sant Andreu de la Barca
	CAP Gavà-2
	CAP Camps Blancs
	CAP Sant Les Planes
	CAP Can Vidalet
	CAP El Castell
	CAP Florida Sud
	CAP Florida Nord
Lleida	CAP Lleida Rural Sud
	CAP Alfarràs - Almenar
	CAP Ponts
	CAP Almacelles
	CAP Artesa de Segre
	CAP Alcarràs
Tarragona	CAP El Morell
	CAP Tàrraco
	CAP Sant Pere i Sant Pau
	CAP La Canonja/Bonavista
	CAP Constantí
	CAP Jaume I
	CAP Sant Salvador/Els Pallaresos
	CAP Torreforta
	CAP El Salou
Terres de l'Ebre	CAP Deltebre
	CAP Gandesa
	CAP Baix Ebre
	CAP Amposta
	CAP Sant Carles de la Ràpita
	CAP El Temple
	CAP L'Ametlla de Mar – El Perelló
	CAP Ulldecona – La Sènia

Annex 4. Participating PCCs in the setting of Andalusia

Region within the Autonomous Community of Andalusia	Primary Care Centers
Almería	Centro de Salud Aguadulce Sur
	Centro de Salud Adra
	Centro de Salud El Ejido Norte
	Centro de Salud Roquetas Sur
	Centro de Salud La Mojonera
	Centro de Salud Puebla de Vícar
	Centro de Salud Roquetas Norte

Annex 5. Protocol Substudy: Barriers and enablers for the detection of Female Genital Mutilation among migrant women at Primary Health Care

Principal investigator of sub-study: Stella Evangelidou

Co-investigators: Rou Sánchez, Carme Saperas, Carolina Calero, Bombo Ndir, Alessandra Queiroga, Emma Zucchelli, Alba Cuxart, Angeline Cruz

Setting: Primary care centres in Catalonia and local civil society organizations/Non-Governmental Organizations that work with migrant populations

1. JUSTIFICATION

Over 200 million girls and women worldwide are estimated to be living with the effects of female genital mutilation (FGM), which can cause several physical, mental and sexual health complications (1). Women who have undergone FGM often delay or do not seek help when they experience health problems that may be linked to the procedure because of several reasons, such as shame, lack of access or affordability, normalization of certain health-related symptoms, lack of confidence in healthcare providers (2). On the other hand, women who do seek care for particular medical problems may not be aware about the complications of FGM and therefore, they may not disclose their experience of FGM to the care provider (2).

Primary health care providers play an important role in supporting girls and women living with FGM, and improving their health and well-being (1). Providing care and treatment requires not only understanding women's needs at all levels but also providing adequate information so that they can make informed decisions (2). It is essential that healthcare providers communicate and discuss women's health and FGM status with them in a sensitive and non-judgmental manner, although this discussion can be challenging for both parts (2).

Within the framework of the ISMiHealth project, which contributes to the screening and detection of migrant women who have suffered FGM, the research team identified the need to further investigate the health needs of these women and their perceptions about the way FGM is currently approached in Spain. Relevant recommendations on how to address this topic and a training course for healthcare providers will be carried out by a group of experts.

This study intends to contribute towards the development of culturally sensitive screening methods of FGM that can be integrated into the ISMiHealth digital tool, so that healthcare providers can identify

those women who may have been victims of FGM and address their health needs. By improving the types of questions in the existing tool and the way they are structured and worded, this will allow practitioners to start talking about FGMs in a respectful and trustful manner with their patients.

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2. Care of women and girls living with female genital mutilation: a clinical handbook. Geneva: World Health Organization; 2018.

3. Ethical considerations in research on female genital mutilation. Geneva: World Health Organization; 2021.

2. OBJECTIVES

The main objective of this study is to understand the barriers and enablers that migrant women, who are at risk or have survived FGM, encounter when disclosing their related health needs at primary care.

Specific objectives:

I. To explore the belief systems around FGM among women who come from areas where the practice is prevalent. This includes insights on the cultural relevance and social norms associated with FGM.

II. To examine the extent to which the health needs of this population group of women are met at primary health care, and the barriers encountered when seeking health care.

III. To explore healthcare professionals´ perceptions on the detection barriers and enablers of FGM at primary health care.

3. STUDY DESIGN

The sub-study will be developed parallel to the overall project, including the following stages:

I**. A Working group** with regional experts will provide advice and guidance throughout the study. It consists of medical doctors, community representatives, anthropologists, a psychologist and global health researchers. The medical doctors and the anthropologists will provide basic training on the thematic at the 35 primary care centres (PCCs) included in the ISMiHealth project.

II. A literature review on existing FGM screening methods worldwide and on the health needs of women who have survived FGM.

II. A qualitative study will be conducted in 5 PCCs, local Non-Governmental Organizations (NGOs) or civil society organizations that work with migrant populations in Catalonia. At each site, one focus group (FG) discussion with women from countries where the practice is prevalent, and 5 individual in-depth interviews (IDIs) with women victims of FGM will take place. Each FG discussion will have an estimated maximum of 10 participants. In total 5 FGs and 25 IDIs will be conducted by the research team. The PCCs, NGOs or civil society organizations will be selected at convenience level. Participants will be selected using purposive strategy methods based on the community work network at each site. The sessions will be held in Spanish, English or French based on participants´ preference.

Exclusion criteria will be:

- Individuals under 18 years of age.
- Individuals who cannot speak any of the language of the focus groups.
- No consent to participate.

Before each FG and IDI, the women will need to sign the informed consent form and the form on voice rights transfer. Informed consent will be gained through discussion between members of the research team and potential participants. The discussion will be supported by written participant information sheets (PIS), which, along with the informed consent form, will be translated into languages relevant to the study population. We will use the PIS to detail the nature of the research, our objectives, and any risks involved with participation. The right to decline to participate, or to withdraw consent at any stage of the research will be explicitly stated on both the PIS and in discussion with potential participants. All study information (including information sheets and consent forms) will be explained orally. The opportunity will be given for participants to ask any questions about the scope of the research, or their rights as participants during the consent process.

Data collection

Data will be collected using topic guides which will be developed by the principal investigator and research team.

Data will be recorded with audio-recorders. No sensitive information will be collected and data and quotes from the interview will be anonymized.

Confidentiality

We will de-identify data during the interview process, names will not be recorded or asked for, besides those provided in the signing of consent forms.

All audio and written recordings will be de-identified and anonymised during transcription. Audio recordings will be deleted after five years of completion of the study.

III. **A short survey** designed on LimeSurvey and RedCap platforms will be distributed to healthcare providers with the view to capture the factors that may inhibit and facilitate the detection of FGM during their clinical practice. The survey will be distributed to health professionals (primary care doctors, pediatricians, nurses and social workers) of PCCs through different institutions and professional associations, such as, Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAPJGol), Societat Catalana de Medicina Familiar i Comunitària (CAMFiC), Associació d'Infermeria Familiar i Comunitària de Catalunya (AIFiCC),Societat Catalana de Pediatria, Col·legi de Metges de Girona (COMG) and Sociedad Española de Medicina de Familia y Comunitaria (semFYC). Candidates will receive the invitation to participate via an online link to the survey and their access to it will represent their consent to participate.

The survey will include some profile information of the individual and their workplace, followed by several questions regarding their knowledge about FGM and possible consequences, barriers and facilitators when addressing FGM in their clinics, the importance of detecting or addressing the topic, prior education on FGM and training needs.

4. DATA ANALYSIS

For the analysis of the qualitative data collected by the FGs and IDIs, transcription and coding will be performed by members of the research team, led by early-career researchers who will receive required training and Co-Investigators' dedicated support. Anonymised audio recordings and written accounts/field notes will be transcribed into Word documents, with transcription, coding and analysis being facilitated by NVivo software.

A thematic content analysis will be performed and the NVivo software will be used for this purpose. The process for the collected data from each FG discussion and IDIs consists of the following steps: verbatim transcription, familiarization with transcripts, codification, categorization of coded segments, theme generation, triangulation, final results and write-up. For validation purposes, theme generation will be triangulated by at two independent researchers.

For the analysis of the quantitative data collected from the survey with professionals´ perspectives, the statistical software STATA will be used to generate frequencies and inferential statistics.

5. ETHICS

The study will be performed according to Ethical Principals of Medical Research (WMA Declaration of Helsinki, Fortaleza Brazil, October 2013) and following the International Ethical Guidelines for Biomedical Research. It will be carried out in accordance with the protocol and with the pertinent legal requirements: -Law 14/2007 of July 3rd on Biomedical Research, since this is a research project that does not involve medicines.

The study protocol will be submitted as a sub-study of the project "Delivering an Innovative Multi-disease Screening and Vaccination Tool to High-risk Migrant Populations (ISMiHealth)" already approved by the ethical committee of the Hospital Clinic, the IDIAP Jordi Gol in Barcelona and the Provincial Research of Almería. The application will consider in both cases all ethical considerations, including those reflected in the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. No research will start until ethical approval of the new study protocol has been gained and the REA has received a scanned copy of all documents proving compliance with existing EU/national legislation on ethics.

The preselection of candidates to be invited to participate in the FGs and IDIs will be performed by a member of the PCC research team or by a general practitioner, respectively. Candidates can also be contacted through members of local civil society organizations or Non-Governmental Organizations (NGOs). After expressing interest and accepting to participate in the study, giving their oral consent by phone or physically for the migrant group, they will be informed of the date of the FG or IDI. In each of the FG discussion or IDIs, signatures in the individual informed consents will be collected after explaining the study and the participant information sheet.

Potential impact of the research

This research project is not expected to have any possibly harmful impact on the individuals involved. If an individual has been detected with FGM or any associated health problem, she will be referred and treated as appropriate according to the routine care standard procedures of each centre.

6. DATA MANAGEMENT AND DATA PROTECTION

Concerning the data-management, the treatment, communication, and transfer of personal data of all participants will be adjusted in compliance with EU Regulation 2016/679 of the European Parliament and the Council of April 2, 2016 related to the people physical protection with regards to the processing of personal data and the free circulation of data, being binding as of May 25, 2018. All data analysis will be conducted on pseudo-anonymized data and no personal data or data that could potentially identify an individual will be included in the final report.

Data extraction. The data extraction process will be performed according to the principles established by the healthcare services, including the data protection policies in this regard. All processing of patients' personal data collected within the study will be conducted according to conventional confidentiality.

Data processing and management. Migrants who will participate in the FG discussions or IDIs of the study will be invited in a visit or by telephone by their own doctor or they will be recruited through civil society organizations/NGOs working with migrant populations, and they will sign the consent form on the day of the FGs or IDI.

They will be requested to answer some questions related to socio-demographic data (i.e., sex, age or country of birth among other, see document 'Information of the Patient' attached) with a statistical purpose of the analysis of the participants of the FG. No name or personal data will be registered. The questionnaire will be identified with a code and only researchers from the study will have access to these data.

The qualitative study data will be obtained through the informed consents of the participants, in accordance with the provisions of articles 6.1 a) and 9.2 a) of the RGPD. Digital audios will be stored and secured in the local server of ISGlobal (VPN), where only participating investigators will have access to it. These will be erased after five years of completion of the study. No international data transfer will take place of the recordings made in the FG discussions.

Transcriptions of the audios and questionnaires will be stored in ISGlobal's VPN and only participating investigators will have access to the data-base, and integrity and security of data will be maintained. In addition, a password will be requested to all researchers in order to access the data, registering any access. Also, a regular backup will be generated to avoid loss of information. An adequate documentation of data (metadata) -i.e., adding semantic descriptions, annotations, etc. will facilitate identification and support effective reuse of research data. Only encrypted data will be transferred to third parties and other countries, which in no case will contain information that can directly identify the participant (such as name, initials, address, social security number, etc.). In the event of such a transfer, it would be for the same purpose of the study described and would guarantee confidentiality.

In addition to the rights already provided for in the previous legislation (access, modification, opposition and cancellation of data, deletion in the new Regulation) participants can also limit the processing of data collected for the project that are incorrect, request a copy or be transferred to a third party (portability). In order to exercise these rights, the participants must contact the principal investigator of the study or the Data Protection Officer of ISGlobal via lopd@isglobal.org. Participants from the Catalan Institute of Health must contact the Data Protection Officer via dpd@ticsalutsocial.cat. Also, the participants have the right to contact the Data Protection Agency if they remain unsatisfied.

This project does not prevent advanced data usage. In accordance with the provisions of article 35 of the RGPD, the project does not meet the necessary characteristics that require the performance of an impact assessment.

Reutilization of data First, a standardized communications protocol to retrieve (meta) data by their identifier, free and universally implementable, will be generated, including a clear and accessible data usage license. After 10 years, all data will be eliminated and destroyed.

Data will be anonymously uploaded in the repository, and those records that may lead to the individual identification of the participants will be removed or grouped with the aim of keeping their identity hidden at all times. Likewise, the possibility of withdrawing all the individual information of a patient will be guaranteed when so expressed. The data will be stored in a repository created specifically for this purpose in the ISGlobal data centre in the Campus Mar (Carrer del Dr. Aiguader, 88), which requires prior appointment with IT staff and therefore only those responsible for computer security and researchers linked to the project will have access to them. A series of protocols are in place to test and maintain network security, and to provide access management policies for network drives, databases and remote access. The system is protected from power interruptions, with controlled access to authorized users only.

The study does not involve biological samples.

7. FUNDING

The ISMiHealth project received funding (87.120,00€) from the Health Research Fund Call 2021 of The Ministry of Science and Innovation to support this study economically. Study investigators will not receive any personal compensation or extra salary for participating in this study.

8. RESULTS COMMUNICATION

The promoter and investigators commit to publish the results of the study in journal articles, other scientific publications and communications to congresses. Authorship in case of publication will be decided according to quantitative and qualitative input to the study. The principal investigator will be the first or last author of the articles.

Annex 6. Protocol Substudy: The perception of migrant populations about health data collection in Catalonia

Principal investigator of sub-study: Ana Requena Méndez

Co-investigators: Daniel Kwakye, Chiara Chillè, Alba Cuxart, Angeline Cruz, Stella Evangelidou, Manu Krishna

Setting: Primary care centres in Catalonia and local civil society organizations/Non-Governmental Organizations that work with migrant populations

1. JUSTIFICATION

The rapid increase in migration in recent years has brought to light the need to develop migrant and refugee-sensitive healthcare systems. Aspects such as poverty, ethnicity, gender, discrimination and persecution, risk factors linked to the migration journey and the difficulty of integration into the new community, need to be taken into account to provide targeted, efficient and effective healthcare to refugee and migrant populations and to inform policy-making and planning of the health services (1).

This awareness has highlighted the need to strengthen health information systems and incorporate health variables of refugees and migrants into national datasets (1). The integration of key elements of data relating to refugees and migrants (for example, the country of birth, length of residence, and migration history) into existing data collection systems allows the disaggregation by migratory status, which is useful to better understand the health needs of this population and implement tailored interventions (1,2).

However, data collection systems working with sensitive data involve safety and privacy concerns (1). Many refugees and migrants may be cautious in sharing sensitive data about their status.

This may stem from the fear of being stigmatized or discriminated against or, for subgroups such as irregular migrants, the fear of being deported as a result of the misuse of information.

Within the framework of the ISMiHealth project, in which the collection of migrants' variables is key to performing an individualized risk assessment, the research team saw the need to investigate the perception of migrants about data collection and health indicators of the migrant population. This includes their thinking on the quality, quantity, and usefulness of data collection, giving the variable of

the 'country of origin' higher recognition - an extremely important variable for identifying specific risk factors of the migrant (especially concerning infectious diseases), but today rarely included in the data routinely collected by the host country's health system.

BIBLIOGRAPHY

1. World Health Organization. Collection and integration of data on refugee and migrant health in the WHO European Region. Copenhagen: WHO Regional Office for Europe; 2020.

2. Bozorgmehr K, Biddle L, Rohleder S, Puthoopparambil SJ JR. What is the evidence on availability and integration of refugee and migrant health data in health information systems in the WHO European Region? (Health Evidence Network (HEN) synthesis report 66). Copenhagen: WHO Regional Office for Europe; 2019.

2. HYPOTHESIS

A more detailed and targeted migrant health data collection system is a useful tool to better understand the health needs of migrant populations and to strengthen disease surveillance and response capacities at national and cross-border levels. However, given the sensitivity of such data, refugees and migrants may be cautious about sharing information. There are ethical concerns regarding the collection of data and the potential for stigmatization and discrimination.

Our hypothesis is that a better understanding of how the collection of personal health data is viewed and experienced by migrant communities, and whether or not migrants are comfortable with the collection of such data, can provide important information to improve the approach to migrant data collection and consequently the care provided.

3. OBJECTIVES

The aim of this study is to better understand the needs, insights and comfortableness of migrants around the collection of data in healthcare centres in order to be able to improve the process of data collection and care.

Specific objectives:

Aim 1: Identify the main migrant health indicators routinely registered in the electronic patient record systems of European countries, including those indicators for addressing the vulnerabilities of migrant populations.

Aim 2: Assess the perception of migrant and refugee populations in Catalonia about the health data that is collected in terms of quantity, quality, and usefulness but also in terms of respect to human integrity, protection of human rights, or discriminatory aspects.

4. STUDY DESIGN

The sub-study will be developed parallel to the overall project, including the following stages:

I. A literature review and analysis of the migrant health indicators used in the health information systems including those indicators for addressing the vulnerabilities of migrant populations.

II. A survey among health professionals from different European countries to inquire about the variables and indicators that are collected and registered in the electronic patient record (EPR) system.

The survey will be distributed to healthcare providers at primary care level and specialists through the network of the Study Group on Infections in Travellers and Migrants of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID). Candidates will receive the invitation to participate via an online link to the survey, designed on LimeSurvey platform, and their access to it will represent their consent to participate.

The survey will include some profile information of the individual and their workplace, followed by several questions regarding the presence and features of the digital EPR systems, the migrant indicators that are routinely collected in the health information systems, the data protection policy regarding these indicators and the possibility of linking these data with other datasets containing migrant indicators (See Annex 6).

III. A qualitative research study to assess their perception on the data collection process, whether or not they feel comfortable about disclosing sensitive variables (such as country of birth, time of arrival in the host country, legal status, reason for migration, ever resided abroad, or sociodemographic data) and perceived stigma around it. This will be carried out through the organization of 26 focus group (FG) discussions with migrant populations, of an estimated maximum of 10 people each. 4 FGs will be held in Spanish (2 with males and 2 with females), 4 will be held in French (2 males and 2 females), 4 in English (2 males and 2 females), 2 in Russian (1 males and 1 females), 2 in Malayalam (1 males and 1 females), and 10 in Arabic (5 males and 5 females).

Participants' selection and FG discussions will be carried out through different primary care centres (PCC) in Catalonia or local Non-Governmental Organizations (NGOs) or civil society organizations that work with migrant populations. The FG discussions will be carried out either at the same PCCs or at the office of the NGOs or civil society organizations by the research team members. Participants will be selected using purposive strategy methods based on the community work network at each PCC. Different participant profiles in terms of duration of stay in the host country will be included. The criteria for the composition of the groups will be age, gender, time of stay in the country and language.

Exclusion criteria will be:

- Individuals under 18 years of age.
- Individuals who cannot speak any of the language of the focus groups.
- No consent to participate.
- There will be no exclusions based on gender nor ethnicity.

All participants in the focus group will need to sign the informed consent form and the form on voice rights transfer. Informed consent will be gained through discussion between members of the research team and potential participants. The discussion will be supported by written participant information sheets (PIS), which, along with the informed consent form, will be translated into languages relevant to the study population. We will use the PIS to detail the nature of the research, our objectives, and any risks involved with participation. The right to decline to participate, or to withdraw consent at any stage of the research will be explicitly stated on both the PIS and in discussion with potential participants. All study information (including information sheets and consent forms) will be explained orally. The opportunity will be given for participants to ask any questions about the scope of the research, or their rights as participants during the consent process.

Data collection

Data will be collected using topic guides which will be developed by the principal investigator and research team.

Data will be recorded with audio-recorders. No sensitive information will be collected and data and quotes from the interview will be anonymized.

Confidentiality

We will de-identify data during the interview process, names will not be recorded or asked for, besides those provided in the signing of consent forms.

All audio and written recordings will be de-identified and anonymised during transcription. Audio recordings will be deleted after five years of completion of the study.

5. DATA ANALYSIS

Transcription and coding will be performed by members of the research team, led by early-career researchers who will receive required training and Co-Investigators' dedicated support. Anonymised audio recordings and written accounts/field notes will be transcribed into Word documents, with transcription, coding and analysis being facilitated by NVivo software.

A thematic content analysis will be performed to evaluate the data from each FG discussion.

The process for the collected data from each FG consists of the following steps: verbatim transcription, familiarization with transcripts, codification, categorization of coded segments, theme generation, triangulation, final results and write-up. In order to validate the data, the coding and final categories will be triangulated by the research team.

For the analysis of the quantitative data collected from the survey with professionals´ perspectives, the statistical software STATA will be used to generate frequencies and inferential statistics.

6. ETHICS

The study will be performed according to Ethical Principals of Medical Research (WMA Declaration of Helsinki, Fortaleza Brazil, October 2013) and following the International Ethical Guidelines for Biomedical Research. It will be carried out in accordance with the protocol and with the pertinent legal requirements: -Law 14/2007 of July 3rd on Biomedical Research, since this is a research project that does not involve medicines.

The study protocol will be submitted as a sub-study of the project "Delivering an Innovative Multi-disease Screening and Vaccination Tool to High-risk Migrant Populations (ISMiHealth)" already approved by the ethical committee of the Hospital Clinic the IDIAP Jordi Gol in Barcelona and the Provincial Research of Almería. The application will consider in both cases all ethical considerations, including those reflected in the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. No research will start until ethical approval of the new study protocol has been gained and the REA has received a scanned copy of all documents proving compliance with existing EU/national legislation on ethics.

The preselection of candidates to be invited to participate in the FGs will be performed by a member of the PCC research team, by a general practitioner or by members of NGOs or civil society organizations. After expressing interest and accepting to participate in the study, giving their oral consent by phone or physically for the migrant group, they will be informed of the date of the FG. In each of the FG discussions, signatures in the individual informed consents will be collected after explaining the study and the participant information sheet.

Potential impact of the research

This research project is not expected to have any possibly harmful impact on the individuals involved.

7. DATA MANAGEMENT AND DATA PROTECTION

Concerning the data-management, the treatment, communication, and transfer of personal data of all participants will be adjusted in compliance with EU Regulation 2016/679 of the European Parliament and the Council of April 2, 2016 related to the people physical protection with regards to the processing of personal data and the free circulation of data, being binding as of May 25, 2018. All data analysis will be conducted on pseudo-anonymized data and no personal data or data that could potentially identify an individual will be included in the final report.

Data extraction. The data extraction process will be performed according to the principles established by the healthcare services, including the data protection policies in this regard. All processing of patients' personal data collected within the study will be conducted according to conventional confidentiality.

Data processing and management. Migrants who will participate in the focus groups of the study will be invited in a visit or by telephone by their own doctor or they will be recruited through civil society organizations working with migrant populations, and they will sign the consent form on the day of the FGs.

They will be requested to answer some questions related to socio-demographic data (i.e., sex, age, or country of birth among others, see document 'Information of the Patient' attached) with a statistical purpose of the analysis of the participants of the FG. No name or personal data will be registered. The questionnaire will be identified with a code and only researchers from the study will have access to these data.

The qualitative study data will be obtained through the informed consents of the participants, in accordance with the provisions of articles 6.1 a) and 9.2 a) of the RGPD. Digital audio recordings will be stored and secured in the local server of ISGlobal (VPN), where only participating investigators will have access to it. These will be erased after five years of completion of the study. No international data transfer will take place of the recordings made in the FG discussions.

Transcriptions of the audios and questionnaires will be stored in ISGlobal's VPN and only participating investigators will have access to the database, and integrity and security of data will be maintained. In addition, a password will be requested to all researchers in order to access the data, registering any access. Also, a regular backup will be generated to avoid loss of information. An adequate documentation of data (metadata) -i.e., adding semantic descriptions, annotations, etc. will facilitate identification and support the effective reuse of research data. Only encrypted data will be transferred to third parties and other countries, which in no case will contain information that can directly identify the participant (such as name, initials, address, social security number, etc.). In the event of such a transfer, it would be for the same purpose of the study described and would guarantee confidentiality.

In addition to the rights already provided for in the previous legislation (access, modification, opposition and cancellation of data, deletion in the new Regulation) participants can also limit the processing of data collected for the project that are incorrect, request a copy or be transferred to a third party (portability). In order to exercise these rights, the participants must contact the principal investigator of the study or the Data Protection Officer of ISGlobal via lopd@isglobal.org. Participants from the Catalan Institute of Health must contact the Data Protection Officer via dpd@ticsalutsocial.cat. Also, the participants have the right to contact the Data Protection Agency if they remain unsatisfied.

This project does not prevent advanced data usage. In accordance with the provisions of article 35 of the RGPD, the project does not meet the necessary characteristics that require the performance of an impact assessment.

Reutilization of data First, a standardized communications protocol to retrieve (meta) data by their identifier, free and universally implementable, will be generated, including a clear and accessible data usage license. After 10 years, all data will be eliminated and destroyed.

Data will be anonymously uploaded in the repository, and those records that may lead to the individual identification of the participants will be removed or grouped with the aim of keeping their identity hidden at all times. Likewise, the possibility of withdrawing all the individual information of a patient will be guaranteed when so expressed. The data will be stored in a repository created specifically for this purpose in the ISGlobal data centre in the Campus Mar (Carrer del Dr. Aiguader, 88), which requires prior appointment with IT staff and therefore only those responsible for computer security and researchers linked to the project will have access to them. A series of protocols are in place to test and maintain network security, and to provide access management policies for network drives, databases, and remote access. The system is protected from power interruptions, with controlled access to authorized users only.

The study does not involve biological samples.

8. FUNDING

The ISMiHealth project received funding (87.120,00€) from the Health Research Fund Call 2021 of The Ministry of Science and Innovation to support this study economically. Study investigators will not receive any personal compensation or extra salary for participating in this study.

9. RESULTS COMMUNICATION

The promoter and investigators commit to publish the results of the study in journal articles, other scientific publications and communications to congresses. Authorship in case of publication will be decided according to quantitative and qualitative input to the study. The principal investigator will be the first or last author of the articles.

Annex 6. Online questionnaire

QUESTIONNAIRE 1: MIGRANT INDICATORS IN HEALTH INFORMATION SYSTEM

Background information

My name is _____ and I am a medical student at the University of Barcelona. I am currently working on my MSc thesis project on "The perception of migrant populations about health data collection in Catalonia". This project is supported by the study group for Infections in Travellers and Migrants (ESGITM) of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) and coordinated by Dr. Ana Requena-Méndez, researcher at the Barcelona Institute for Global Health (ISGlobal) in Barcelona.

The aim of this project is to explore what type of migrant indicators are routinely collected or registered in the health information systems at primary care level in European countries.

For this purpose, we have developed a short online survey. The survey contains questions regarding the health information systems in your country and will not take more than 2 minutes to be completed. Additional information about the study can be found in the attached Study Protocol.

We would greatly appreciate if we could have a couple of minutes of your time to answer this short survey.

Many thanks for your time.

Profile information:

1. Name _____
2. Profession
   - Primary Care doctor
   - Specialist
   - Primary Care nurse
   - Other _____
3. Type of primary care centre

Rural	Urban
Public	Private
Health centre	Migrant examination centre

4. Name of the Centre _____
5. City, county _____
6. Country _____

Questionnaire:

1. Does you centre/hospital have a digital electronic patient record (EPR) system?
   - YES
   - NO

2. How is this EPR implemented in your country?
   - Country level (the same EPR for the whole country)
   - Regional/county/state level
   - Local level

3. Is this EPR system manually registering socio-demographic information for new users?

Yes,

No, it is imported from another database containing demographic information

4. Is there any migrant indicator regarding the origin routinely registered in the EPR?
   YES
   NO

5. What type of indicators are included (multiple options available)?
   Migrant /non-migrants
   Country of birth
   Nationality

6. Are there any other migrant indicators collected?
   YES
   NO

7. What type of indicators?
   Type of migrant: Asylum seeker/refugeed/labour migrant…),
   Last country of residence
   Date of arrival to the country
   Language
   Need of interpreter

8. What other migrant indicators are included?

   _____

9. If you have any comment or suggestion, we would be glad to hear from you: