



Open flanks in the management of tuberculosis in Germany under the pressure of migration

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Abstract

To prevent transmission is the ultimate goal of any TB control strategy. So far, asylum seekers/immigrants are only actively screened for TB after arrival in Germany, if admitted to mass accommodation facilities. The current TB control strategy in Germany is assessed by a SWOT-analysis (strengths, weaknesses, opportunities and threats) including the impact of active case finding, environmental case finding (ECF) also known as contact tracing, passive case finding (PCF) and effective TB treatment. According to the number-needed-to-screen (NNS), asylum seekers from most countries and unaccompanied minors would have to be screened for active TB by a chest radiograph at entry independently of the type of accommodation. This would include children between 10 and 15 years of age and a follow-up for at least 3 to 5 years, with a denser follow-up in the first year. ECF and PCF only contribute little to a proactive reduction of the pre-patency period. The available data on the epidemiology and the NNS of TB in migrants are sufficient to come up with a more powerful control strategy for TB in migrants in Germany to close the existing open flanks. It is time for action.

Keywords Active case finding · Asylum seeker · Entry screening · Number-needed-to-screen · SWOT

Introduction

Germany is target for immigration and witnessed a steep increase of asylum seekers particularly since 2015. Health issues related to migration are several from acute diseases at entry into Germany, to medical care and follow-up of chronic conditions. A routine health check at immigration into Germany according to the German anti-infectious diseases act (Infektionsschutzgesetz, IfSG, §36) is mandatory only if the person is admitted to a mass accommodation facility. This includes a chest X-ray (CXR) from 15 years of age onwards. If entering the country by other routes and not being admitted to a mass accommodation facility, migrants do not get a routine health check or an obligatory CXR at entry. Children are seen by the public health service if entering school. Several federal states hand out health cards for individual care according to the German health insurance policy after immigration. Otherwise, the support act for asylum seekers applies

(Asylbewerberleistungsgesetz). Since the tuberculosis (TB) rate in Germany is low, most migrants come from countries with a higher TB burden. TB incidence in 2016 was 2.2/100,000 in Germans (German-born) vs 48/100,000 in foreign-born persons in Germany [1]. Different tools for the prevention, control and elimination of TB do exist: active case finding (ACF), environmental case finding (ECF, also known as contact tracing), passive case finding (PCF) and effective TB treatment. These tools, however, have a different impact on the prevention of spread of TB. German health policies and politics have to ask themselves how actively and proactively prevention and control of TB should be carried out in the current situation and how much residual risk of acquiring TB is acceptable for the population.

Methods

Based on accessible data on the epidemiology and knowledge on principles and practice of TB management in Germany, this work intends to delineate a clear strategy with maximum impact on reducing the risk of transmitting and spreading TB in Germany due to immigration from high or higher prevalent countries into Germany. The enhanced strategy suggested in

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this paper is developed along a SWOT analysis assessing strengths and weaknesses of the health care system and particularly the Public Health Care System in Germany. The opportunities to avoid transmission and to reduce the burden of TB are in contrast to the threats, if the current situation with several open flanks stays unchanged. The open flanks of the current strategy are stated after each section. The four tools—ACF, PCF, ECF and treatment—are compared in regard to their impact on the pre-patency period and the reduction of transmission. The term pre-patency period is derived from parasitology and means the period between onset of potential transmission to its end when the patient is isolated or comes down with the disease so that he cannot spread the infection any longer.

Current treatment costs for TB reach from up to 10,000€ for a drug-susceptible TB case to up to around 60,000€ for a multidrug-resistant or over 100,000€ extensively resistant case [2]. Indirect costs are about 6 to 7 times higher. A CXR costs about 3€ according to the health insurance plan and up to 20€ for non-insured patients (with the courtesy of Hofmann-Preiss, MD, Department of Radiology, University of Erlangen, Germany). Crude cost estimates are used for illustration purposes only, without claiming the level of a health economic analysis. Incidence data for Germany are from the Robert Koch-Institute and can be self-generated by the open-access platform “survnet” (www.rki.de/survnet, calculation June 12, 2018, Fig. 1). Other data such as the point prevalence of active TB for migrants of a given country of origin at arrival in Germany and the number-needed-to-screen (NNS) to detect one case of active TB were published recently and are used here [3, 4].

Results

From 2002 to 2008, the incidence of TB in Germany declined from 7692 cases steadily by around 500 cases per year in a total population of 82 million (Fig. 1). From 2008 to 2014, the decline faded and even reversed. In the year 2015, the incidence increased significantly by 1279 cases to 5768 cases total, a surplus of 28.5% in comparison to 2014. The figure for 2015 compares to 2005, 10 years back. In 2016, the numbers increased to 5960 and declined in 2017 (5504 cases). Diel et al. estimated the incidence figures for 2015 to 2019 based on the expected reactivation rate just on the numbers of asylum seekers having arrived in 2015 [5]. A best-case scenario estimated 10,090 (143 pulmonary MDR-TB cases), a worst-case scenario 19,031 (377 pulmonary MDR-TB cases) additional cases in the 5-year period ahead. As the number of asylum seekers decreased due to several reasons, the real number is expected to be lower than the best-case scenario with around 8000 excess cases, if migration movements stay at the present level until 2019. The total number of additional cases from 2008 to 2017 is around 18,000. Based on the direct and indirect cost estimates of Diel et al. from 2011 [2], the costs sum up to at least one billion Euros in 10 years.

The age distribution (Fig. 2) for the pulmonary TB cases in 2016 shows actually the overlap of three different distributions: The incidence of primary TB from birth to below 10 years of age with a substantial fraction of primary TB also in the age group 10–14 years and beyond, the high incidence of adult-type TB in young persons with foreign origin in contrast to a steadily increasing incidence by age in the ageing resident German-born population, but on a much lower level.

Fig. 1 Epidemiology and trend of TB notifications in Germany 2002–2017. Data derived from Survnet (www.rki.de/survnet). The circles mark the two turning points in 2009 and 2015. Prognosis due to Diel et al. 2016 [5] is indicated by pointed line. The dashed line marks the extrapolation, if no migration out of higher incidence countries into Germany would have occurred. The area between the dashed line and the actual line points out the excess cases (roughly 18,000 in 10 years).

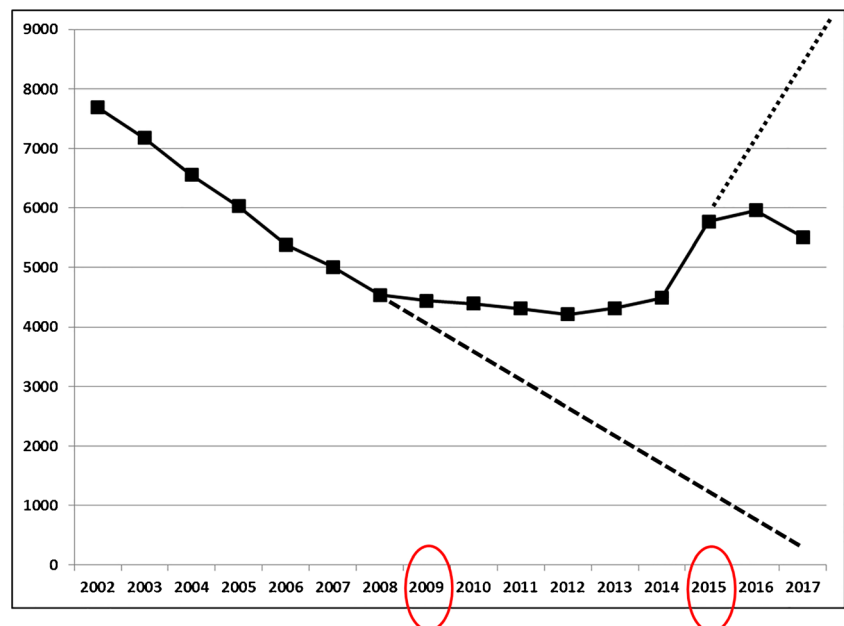
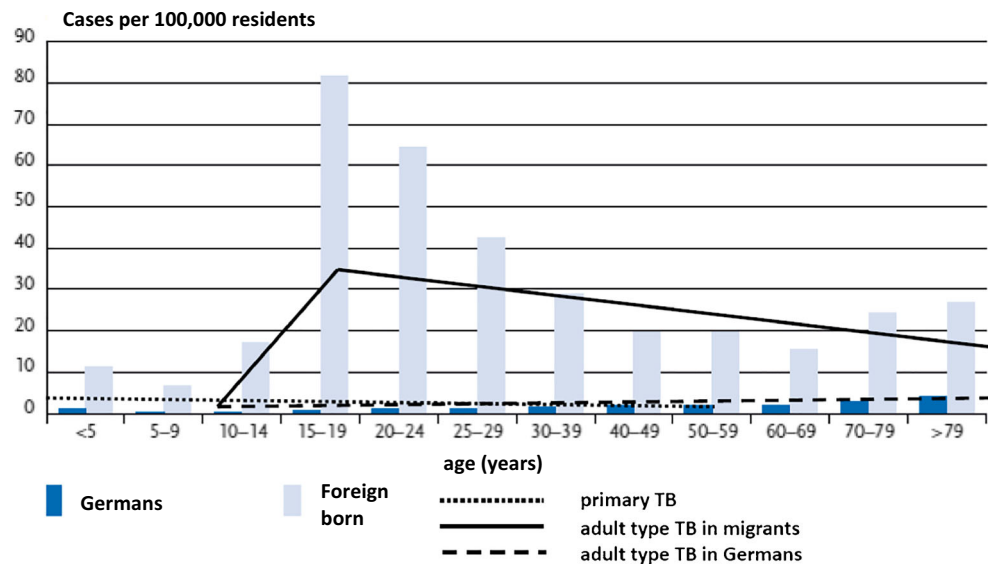


Fig. 2 Age distribution of the pulmonary TB incidence in Germany in 2016 stratified by origin [1]



The age group 10–14 years is highlighted since this is the age when the so-called adult-type TB with potential transmission starts to occur, particularly in populations with early exposure and primary infection in early childhood [6–8].

Strengths

Environmental case finding and inpatient treatment until transmission is banned

Around 419 municipal and county health departments have the governance of the TB management in general and ECF in particular (Table 1). When an index case is detected, the public health services (PHS), general practitioners and paediatricians are involved to find and detect further cases; the latter two professions mainly for testing children. If the index case is not the primary case, it is important to track and find the primary case. CXR and indirect methods such as the tuberculin testing, the interferon-g release assay (IGRA), or the Tspot are used. Any case of an actual TB-infection and active TB, whether primary or adult-type, are looked for. In subjects from high-prevalence countries, the CXR is more important than indirect tests. How comprehensive and extensive the ECF should be and how fast a CXR is recommended is well documented [9]. Treatment of TB is predominantly started after admission to a hospital or to one of the specialized centres at least in case of a resistant mycobacterium. Patients should be discharged only after transmission is no longer possible. Directly observed therapy (DOT) should be carried out by the PHS, but only a few services in big cities have the capacities to do so.

Open flank: hesitation in using CXR more widely, TB competence within PHS.

Weaknesses

Resources in the PHS, fraction of new cases diagnosed by PCF, incomplete or too slow sterilization

PHS in Germany are insufficiently financed and supported by federal and state ministries and county administrations (Table 1). Due to the lack of resources, only big city health departments can provide a DOT service. Otherwise, this function has to be outsourced implying issues such as additional costs and required know-how. PCF actually means the clinical situation, in which a patient has contact with the health care system and TB is part of the differential diagnosis. TB is finally confirmed as the cause of the actual disease. In PCF, the awareness and the competence of the physician are crucial. In primary TB, the bacterial load is low (paucibacillar) in contrast to often polybacillary adult-type TB. This impacts on timely diagnosis, confirmation and phenotypically resistance testing. In 2016, 75% of all incident TB cases in Germany were diagnosed via PCF [1], in the migrant population up to 50% [1, 10]. The time to diagnosis and the pre-patency period is longer in PCF than in ACF. The immediate treatment objective is the elimination of the pathogen and by this ending infectivity of the individual patient (“sterilization”). It is important to also re-evaluate stringently newly treated patients early on and eventually adjust the treatment if sterilization is delayed. Discharge criteria are key and obviously related to the health care system in place.

Open flanks: PHS support, TB awareness and competence of doctors and the entire health care system, competence in treatment, directly observed therapy (DOT), discharge criteria (non-infectivity).

Table 1 SWOT-analysis of the current German TB strategy

	Strengths	Weaknesses
Internal	Public health services - county, state and federal level - 419 municipal/county health departments - governance of TB-management - contact tracing (ECF) - DOT (where available) - surveillance/tracing of treatment defaulters Ambulatory and inpatient care - CXR-capacity - hospitalization, specialized centres - ambulatory treatment	Public health care financing/support - DOT services lacking - DOT delegation to other services Passive case finding (PCF) - fraction in migrants too high - pre-patency periods long Treatment - re-evaluation and adjustment in time - discharge management
External	Active case finding (ACF) as stronghold - independently of accommodation and mode of entry (also in the self-interest of the migrants) - adjustment according to prevalence in country of origin: -- NNS by CXR e.g. up to 1:3500 -- CXR from 10 to 12 years onwards -- CXR-FU: 6 months, 1 year, 2 years, 3 years, 4 years, 5 years	Political complacency, neglect - unwillingness to consolidate the strategy - free movement within the European Union Incomplete treatment - disappearance of migrants - treatment default—lacking adherence - §39 of Social Care Act (SGB V) refinancing of inpatient costs
	Opportunities	Threats

CXR, chest X-radiograph; *DOT*, directly observed therapy; *ECF*, environmental case finding or contact tracing; *FU*, follow-up; *NNS*, number-needed-to-screen; *PCF*, passive case finding

Opportunities

Active case finding and a comprehensive proactive control strategy

The objective of active case finding (ACF) is to prevent transmission proactively and therefore to find cases with adult-type TB as soon as possible. The method used is the CXR. Screening at entry into Germany, screening from an age onwards when adult-type TB can be expected, active follow-up after entry according to a roster such as 6 months, 1 year, 2 years, and 3 years for instance, are options (Table 1). Currently, only migrants from 15 years of age onwards admitted to a mass accommodation facility at entry are actively screened (§36 IfSG), but an increasing number of migrants come independently to Germany to join family members already in Germany. At present around 50–74% of prevalent TB cases in migrants are detected by ACF with a declining trend [1, 10]. The NNS is lower, the higher the incidence and prevalence in the country of origin is. Unaccompanied minor asylum seekers under 18 years of age (UMA) have the lowest NNS known so far (Table 2). The cost-benefit ratio acceptable for the NNS has to be decided. Even in a NNS of 1:3434 as in migrants from Syria [4], ACF by a CXR at entry is cost-effective given the costs of a CXR of 3–20€, the direct costs of a drug-susceptible TB case of around 10,000€, indirect costs of around 60,000€ and the risk of infecting four additional cases on average with potentially four times the costs on top for four secondary cases. The duration and the costs for treatment of TB are tremendous, which puts most control strategies into a favourable cost-benefit ratio.

Table 2 illustrates my suggestion for a risk-stratified approach. According to the NNS, current Syrians above 15 years of age would be screened at entry into Germany independently of type of accommodation. For countries of origin with a lower NNS such as Somalia, Ethiopia, Eritrea, Pakistan, Afghanistan, and UMA, all would be screened at entry independently of the type of accommodation including children between 10 and 15 years of age and followed-up for at least 3 to 5 years, with a denser follow-up (FU) in the first year (e.g. after 6 months). Questions beyond those remain such as a higher cost-benefit ratio of the NNS for countries with a high prevalence of MDR/XDR-TB, e.g. migrants from Middle and Eastern European Countries or even eastern European countries of the European Union (EU).

Open flanks: NNS cut-off, age-limit in §36 IfSG, migrants not admitted to mass accommodation facilities, follow-up screening.

Threats

Political complacency and neglect, incomplete TB treatment

The current political climate is worrisome in the regard that migration-related issues around TB are dealt with complacency or even neglected on several levels. Besides proper public health care and avoiding transmission, it is also in the interest of asylum seekers to detect active TB early. Burden of disease for TB in migrants is considerable (Fig. 1, Table 2) and spillovers to other migrants or even the resident population are possible. Several downstream issues have been highlighted in this paper so far. Paediatric TB as an early indicator of

Table 2 Suggested strategy to close the open flanks in prevention and control of TB in Germany

Origin	Point prevalence ¹ per 100,000	NNS	Entry screening independent of entry pathway	Screening in 10- < 15-year-old children	Follow-up screening up to 3 to 5 years
UMA ²		94	+	+	+
Somalia	1871	146 ³	+	+	+
Ethiopia	1037	~ 180	+	+	+
Eritrea	822	216 ³	+	+	+
Pakistan	616	729 ³	+	+	+
Afghanistan	161	~ 1000	+	+	+
Syria	48	3434 ³	+	–	–
Germany	2.2. vs 48 ⁴		Ref.	Ref.	Ref.

¹ According to [3]

² Data from the Health Department Frankfurt/Main (personal communication)

³ According to [4]

⁴ TB incidence 2.2/100.000 in Germans vs 48/100, 000 in foreigners in Germany in 2016 [1]

UMA, unaccompanied minor asylum seeker; NNS, number-needed-to-screen

increased transmission is rising in Germany [1]. Also in children it is crucial to treat according to a resistance profile. In this regard, ECF has an impact by gathering data (anti-biogram) on the primary case [9]. Children tolerate TB drugs better than adults in general which is an asset for the ready use of post-exposure prophylaxis and pre-emptive therapy especially in young children given the high manifestation index and the increased case fatality.

By treating TB patients effectively, the source of the infection is eradicated and by this, a spin-off for public health is achieved. In 2016, 22.8% of TB patients in Germany did not complete their treatment [1]. The fraction is highest in adolescents and young adults mainly migrants, the age groups with the most diverse contact pattern. Recently, the Robert Koch-Institute showed that cases detected by ACF have the highest default rate [11]. Isolation, inpatient care, and follow-up are important in this regard and a challenge at the same time given the long treatment duration. The health insurers undermine inpatient care by not refunding costs via §39, SGB V, the German Social Care Act, Book V, because they are allowed to decide post hoc how long inpatient care was indicated in their opinion.

Open flanks: Open evidenced-based discussion and strategy development, reluctance of health insurers to pay for inpatient costs (post hoc).

Discussion

The available data on TB and its epidemiology in current Germany are sufficient for decision making and no excuse by not having sufficient data can be accepted. However, a priori questions have to be answered such as how flexible and proactive Germany wants to be? How epidemiologically sensitive the approach should be? Should the prevalence of

drug resistance in the country of origin be taken into account for deciding the upper margin of the NNS? Due to which regard, action should be orientated? Should the resident population, the gatherings of migrants in mass accommodation facilities or the individual subject have the highest priority? Given the exposure during migration and turmoil periods before departure from the country of origin into consideration, the risk for active TB is increased in general. The current political environment renders an open discussion around TB and appropriate control measures a difficult issue.

Since TB is still a disease with profound consequences such as damage to the lungs with impairment of lung function, social stigma, fact of transmissibility which implies fear, long duration of therapy and treatment with potentially serious side effects, particular care and scrutiny by authorities and PHS is indicated. The fact that the resident population is accepting the migrants with all consequences, utmost care should be taken to keep additional costs down and to prevent spillovers into the resident population. However limited the events in this regard are, they do occur and the risk is real. Most events, however, do not reach the public. A publication bias by insufficient publications in number by public health services in Germany is a fact and should be changed urgently. Obviously, migrants transmit the disease after arrival primarily within peers and peers from the same community [12] or within mass accommodations [13]. In adults, the contact pattern is important. Particularly at risk for disease are children, since they are more susceptible (manifestation index). Latent TB infection (LTBI), not in the context of a recently documented exposure, is not a priority within mass events and has only recently been in discussion as target for pre-emptive treatment or post-exposure prophylaxis [14].

ACF is regarded as the most efficient measurement to shorten the pre-patency period and finally reduce

transmission. At present, only around 50–74% of cases in asylum seekers are diagnosed by ACF in Germany [1, 10]. This fraction is declining and too low and should be increased urgently. To achieve this, several means within ACF are possible: First of all the screening by CXR at entry into Germany and into mass accommodations according to §36 IfSG has to be comprehensive. There were doubts that in the crisis of 2015, not all refugees were screened. Secondly, all migrants from countries with a higher incidence than Germany have to be screened regardless of type of accommodation or pathway to Germany. The county health service in Leer, Lower Saxony, recently reported a case of a 23-year-old Eritrean woman, who arrived with her 8-year-old son to join her husband already a resident in Germany [12]. Since she was entering Germany on an individual basis, she was not admitted to a mass accommodation and therefore did not get a routine health check and CXR at entry into Germany. Her medical history post hoc revealed that she had a cough with intermittent haemoptysis already at entry, infected five other Eritreans already residents and having been tested negative at entry and her own son, before she was diagnosed herself with TB after 1 year in Germany.

It is well documented that children from high prevalence countries and infection earlier in life can transmit TB to others. This starts around 10 years of age. Only one case with a pulmonary cavity at 8 years and one case at 9 years of age have been reported in the literature [6–8]. Pre-pubertal girls are more often afflicted than boys. In this regard, §36 IfSG is not flexible enough and also the reform of the IfSG in 2017 did not take an amendment into consideration in this regard. The lower age limit can be debated, but should be lower than 15 years by any means for high-prevalence countries. UMA below 15 years of age are prevalent and have a diverse contact pattern and a particularly long pre-patency period before being diagnosed with adult-type TB.

It is also well documented that immigrants into western countries carry the highest risk for active TB within the first 3 to 5 years after immigration [5]. Whether the risk is similarly high in this period or steadily decreasing, is in debate at present. The latter is more plausible, however. The current control policy so far does not take TB manifestation beyond entry into consideration. A report from the Federal Public Health Department of Lower Saxony (NLGA) shows that 44 out of 85 cases in 2016 were missed at the entry screening and diagnosed thereafter [10]. Therefore, a FU screening is strongly warranted. The time intervals and the length of FU can be debated. The X-ray burden, however, cannot be an argument any longer, given the low radiation dose for a CXR today. My risk-stratified approach is straight forward; details such as the exact lower age limit for ACF and frequency of FU can be debated.

In regard to ECF, it is important to re-emphasize the age onset of adult-type disease in children. If the index case is

not transmissible since it is e.g. a child under 10 years of age or any person with primary TB and no cavity, the primary case with a cavity has to be elucidated by ECF. This knowledge is crucial for day to day work in public health and paediatrics [9]. In contrary, if the index case is the primary case (e.g. an adult with a cavity) only secondary or co-primary cases are looked for. The term “transmissible TB” was identical with “open TB” in German language and terminology so far. Recently, the Robert Koch-Institute changed nomenclature and currently classifies all cases as “open TB”, if mycobacteria can be detected. However, key for transmission is the aerosol and aerosol is only generated, in case of a cavity [15]. It is well documented that a cavity is more important than the microbiological finding per se [16]. Obviously, there is no tuberculosis without tuberculous mycobacteria, but a cavity is the precondition to form an aerosol and transmit the bacteria. Therefore, the CXR and if suspicious or inconclusive, a computer tomography of the lung, is the stronghold for public health-related investigations in regard to transmissibility. The negative predictive value of the indirect methods such as Mantoux, IGRA or Tspot becomes sufficiently high 8 to 12 weeks after last exposure. Of high value is a well-documented negative finding before exposure in case a subject converts.

PCF so far does not seem to be a sole option or an alternative to ACF for Germany, since the time lag to attend a doctor is more pronounced in migrants and the level of suspicion for TB too low in health care professionals in Germany. To improve this, training and awareness are needed. The impact of PCF on lowering the pre-patency period and transmission is doubtful.

Germany has world leading centres for TB research and treatment, but only a minority of patients is treated in specialized centres. It is a MUST to concentrate patients at least with resistant variants in specialized hospitals [17]. Regardless of where the treatment takes place, a fast elimination of the pathogen is a good surrogate that the treatment is effective and transmissibility resolved besides the lower risk for secondary resistance. Initial inpatient treatment is crucial in a migrant population. Discharge management, however, is an issue and health insurances in Germany frequently do not cover the costs, if the treatment extends beyond several weeks. Via the health insurance act (§39, SGB V) insurance companies refrain from refunding costs to hospitals. Unfortunately, they are allowed to do this post hoc. As consequence, hospitals get under pressure to discharge patients without finally resolved transmissibility, at least for drug-susceptible TB. The national guideline differentiates between drug-susceptible and non-susceptible TB in this regard [17]. This is counterproductive for disease control and prevention since there is no compensatory system in place, which can guarantee no transmission to others (threat). Action is needed to guarantee care in this regard. Given the overall low incidence of TB in Germany, inpatient care should be afforded. DOT is an issue as well

since no commonly and generally available public health resources do exist which can assure DOT. DOT would be a precondition for early discharge besides non-transmissibility. Only some PHS in big cities with specialized TB services have outreach teams with sufficient power. A fraction of 22.8% of TB patients with no completion of their therapy is by far too much [1], in spite of a WHO's target of 10%, a shame for Germany.

Conclusions

The available data on epidemiology and NNS of TB in migrants are sufficient to come up with a more powerful, evidenced-based control strategy for TB in Germany to close the existing flanks. A clear operative strategy is needed in regard to ACF and ECF. A comprehensive screening by CXR from about 10 years of age onwards at any entry with FU screenings according to the NNS is essential. To improve PCF, training and awareness is needed. Insufficient TB treatment in hospitals and in outpatients can have a detrimental backlash onto public health. The utmost should be done to avoid this, however, difficult in a moving population. In synopsis, however, all suggested measurements are feasible and should be implemented without hesitation. The epidemiological curve warrants it. "Danger (really) breads on too much confidence". The German citizen and taxpayer does not deserve this.

Compliance with ethical standards

Competing interests The author declares that he has no competing interests.

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