Second WHO consultation on the translation of tuberculosis research into global policy guidelines: meeting report, 15–16 March 2022
Acknowledgements

We acknowledge with gratitude the participants of this consultation, the Chairs and administrative personnel who made this meeting possible and productive. All the meeting participants contributed their time to the review of the final document; this support is also gratefully acknowledged.
## Abbreviations and acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>DST</td>
<td>drug susceptibility testing</td>
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<td>DS-TB</td>
<td>drug-susceptible tuberculosis</td>
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<td>DR-TB</td>
<td>drug-resistant tuberculosis</td>
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<td>GTB</td>
<td>Global Tuberculosis Programme</td>
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<td>IPC</td>
<td>infection prevention control</td>
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<td>TB</td>
<td>tuberculosis</td>
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<td>TPT</td>
<td>TB preventive therapy</td>
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<td>WHO</td>
<td>World Health Organization</td>
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**Background**

The Global Tuberculosis Programme of the World Health Organization (WHO/GTB) has the mandate to develop and disseminate evidence-based policy for tuberculosis (TB) prevention, diagnosis, treatment, and care. Regular review of evidence, and assessment of country needs for policy is part of its core function. In this regard, WHO organized a consultation assembling scientists, public health experts, partners, civil society, and countries to exchange views on emerging areas of need for global TB policy guidance to achieve the goals and targets of the WHO End TB Strategy.

The specific objectives of this consultation were:

I. to present on progress as well as plans to review WHO TB policy guidance (2022-23); and

II. to exchange views on emerging needs of Member States for policy guidance in the context of the current evidence landscape.

The expected outcome of this meeting is a report (herewith) summarizing current thinking and suggested actions aligned to these objectives

**Introduction**

After a welcome by Tereza Kasaeva, Matteo Zignol, Chair of the first day of the consultation, opened the meeting at 13:10 on 15 March, 2022. Dr. Zignol presented the programme of the meeting and the participants (Annexes 1 and 2) and gave a brief presentation on the architecture of WHO TB policy guidelines.

**Day 1: WHO TB policy guidance: current status, update plans and evidence gaps**

1.1 **Screening and prevention**

*Dennis Falzon, WHO*

Dennis Falzon presented WHO’s latest consolidated guidance on TB preventive treatment (TPT), TB infection prevention control (IPC) and TB screening, as well as the accompanying operational handbooks in the context of the current evidence landscape. Planned updates to TB IPC handbook and guidelines were shared, along with other developments on target product profiles for biomarkers and new data on digital adherence technologies relevant to existing policy.

The Chair opened the floor for discussion framed around (but not limited to) the following questions:

1. Are you aware of other ongoing research (trials, cohorts, epidemiological, or implementation research) that is due to be published shortly and that could influence our current recommendations on TB screening, TPT and IPC?

2. Do you agree with our proposed way forward? Are there other needs that countries have that we need to address? What else do you suggest?
Discussion:

Screening
- On screening, monitoring the adoption and implementation of the algorithms and tools recommended in the 2021 guideline is a priority, as well as generating new evidence so that vulnerable populations or age groups excluded from current recommendations can benefit from innovations (e.g., recommendation on use of chest radiography and Computer-aided Detection excludes individuals under 15 years due to lack of research evidence).
- On implementation, further studies are needed to evaluate the affordability and cost effectiveness of the newly recommended screening approaches to inform implementation and scale-up. Better assessment of the sensitivity and specificity of WHO's recommended four-symptom screening among high-risk groups, other than people with HIV is also needed.

Prevention
- If trials on TPT for contacts of people with drug-resistant TB (DR-TB) [(VQUIN (adults and adolescents) and TB CHAMP (children)] show positive signal and policy recommendations are made, countries need to be supported to rapidly scale up new interventions, including by providing guidance on appropriate service delivery options.
- For people with HIV, updating TB policy recommendations on co-administration of antiretroviral therapy and short course TPT remains a priority.
- For pediatric population, updating recommendations on the use of short course TPT regimens among very young children remains a priority in the context of available and upcoming evidence both among HIV infected and uninfected people: this includes three months of weekly rifapentine plus isoniazid regimen (3HP) and one month of daily rifapentine plus isoniazid (1HP) regimen. Data from current study (anticipated in 2023) and availability of water dispersible, functionally scored rifapentine can transform care for children.
- On implementation, better tests for TB infection and tests that can accurately predict which individuals will progress to TB disease after infection can help improve the scale up of TPTs. Better characterization of the duration of protection of the new TPT options, and policy guidance on the value of repeated courses of the several types of TPTs in high transmission settings and/or for very high-risk groups is needed. Further research on patient preference on TPT options can help inform policy and improve acceptability.
- On TPT research, participants highlighted the importance of longer-term research to develop treatment options that do not contain isoniazid or rifampicin, to reduce drug-induced toxicity as well as drug-to-drug interaction with antiretroviral therapy (especially considering the move towards long-acting drug delivery approaches for people with HIV).

IPC
- On infection control, better guidance for employers and patients on when people on TB/MDR-TB treatment can return to the workplace safely is needed to help ensure a return to life as normal, and to reduce catastrophic costs for patients and their families from loss of employment.
1.2 : Diagnostics
*Nazir Ismail, Global TB Programme, WHO*

Nazir Ismail presented the 2021 policy updates on TB diagnostics, the 2022 policy statement on use of alternative interferon-gamma release assays for the diagnosis of TB infection, as well as new developments in other relevant WHO norms and standards such as WHO’s first catalogue of mutations of *Mycobacterium tuberculosis* genome complex and the update to the target product profiles on the minimum and optimal performance of diagnostic tests for drug susceptibility testing at the peripheral levels.

Dr. Ismail reminded participants that WHO/GTB has shifted to making class-based recommendations for diagnostics, to allow for better competition in the market and provide Member States with potentially more options suited to their context. Although current policy work is mainly focused on TB disease with Nucleic Acid Amplification Tests, and to some degree biomarker tests as the primary tools, there is emerging recognition that TB is a continuum from infection to disease. Additional disease manifestations such as subclinical TB are now important areas for research and molecular, biomarker and host-based diagnostics are emerging and need to be shaped for impact. Planned policy guidance updates (2022/2023), evidence landscape, as well as pending policy and implementation gaps were presented. This includes consolidated guidelines on TB infection and next-generation sequencing for comprehensive drug susceptibility testing (DST). In addition, the introduction of a critical concentration for pretomanid DST is planned.

The Chair opened the floor for discussion framed around (but not limited to) the following questions:

1. Are there any further critical evidence gaps or upcoming studies?
2. What further guidance/updates should we consider to enhance the implementation of global TB policy guidance in these areas?
3. Are there any initiatives we could consider to direct new areas for research?

**Discussion:**
- Equitable access to rapid DST before new drugs are introduced is key to optimize care for patients and for antibiotic stewardship – this is especially relevant considering new recommendations for the treatment of DR-TB using regimens with new drugs such as pretomanid. Operational research into “pre-diagnostic loss to follow-up” and “pre-treatment loss to follow-up” can contribute towards closing the diagnostic gap, and improving health outcomes.
- Engagement with manufacturers/developers to encourage the development and optimization of microtiter plate development is a high priority in overcoming the impending bottleneck for multi-drug DST, particularly for monitoring population level resistance to anti-TB drugs. Genomic sequencing can be used in the interim for drug-resistance surveillance and to allow the detection of drug-resistance, at the reference laboratories where the technology may be available.
- Accurate non-sputum-based test for TB detection is a key priority, especially for children. Lack of validated biomarker(s) in non-sputum samples continues to be a challenge in operationalizing this vision. Better training, characterization of quality assurance and more research to improve sensitivity of existing biomarker tests such as LF-LAM may help expand its broader use.
- Development of affordable and easy to use integrated diagnostic platforms with other airborne pathogens should also be explored to reduce delay in diagnosis. The discussions on disease severity biomarkers to guide treatment are summarized in session 1.3.
1.3 Treatment

Fuad Mirzayev, Global TB Programme, WHO

Fuad Mirzayev presented the evolution of WHO policy guidelines in TB treatment and supportive tools over the past 25 years. Recent updates to WHO policy guidance for treatment of drug-susceptible TB (DS-TB) and the scope of the ongoing GDG on treatment of DR-TB were presented. The ongoing pipeline of clinical and operations research projects was presented. Other recently issued (non-guideline) norms and standards to shape the TB treatment field on dosage optimization of first line medicines for DS-TB treatment, as well as clinical outcomes and pharmacokinetics of first line drugs in people < 18 years of age being treated for DS-TB were presented. Furthermore, perspectives of Unite4TB consortium and PAN-TB collaboration platform to accelerate the Phase II testing of new TB regimens was presented. Progress update in the development of a Global individual patient data platform for DR-TB treatment (DR-TB IPD) was also shared.

The Chair opened the floor for discussion framed around (but not limited to) the following questions:

1. Are there any critical evidence gaps that we should highlight, promote and stimulate research in that area?
2. Are there any emerging needs in the TB treatment policies, derivative operational guidance and other normative documents?

Discussion:

- On DS-TB treatment, while there is potential to shorten the duration of treatment with dose optimized rifapentine and fluoroquinolones (e.g., TBTC study 31), there is less evidence for rifamycin based regimens. Programmes need support with standardizing treatment decision making related to shorter DS-TB treatment options, and the IPD platform can help build data to support optimization of this new approach. Further research on standardizing the stratification of TB patients into subgroups based on severity/factors predictive of clinical outcomes remains essential for the comparison of treatment regimens and for prioritizing the optimization of treatment for people with severe disease (e.g., children with disseminated TB or severe meningitis).
- On DR-TB treatment, reducing drug-toxicity for patients remains a priority. In this context, effectively defining the exact place of the new 6 months all-oral regimen versus the 9–11-month regimen can support patient centred programmatic implementation.
- Considering that there are many other short course regimens in the clinical pipeline with different drug compositions, it may be useful to consider identifying the optimal number of drugs and which ones are the most important for safe and effective treatment (e.g., to build evidence on the added value of pretomanid and delamanid).
- Participants highlighted that further studies on universal /Pan-TB regimens need to be complemented with the development of DST for monitoring resistance.
- On implementation, equitable and rapid access to DST for fluoroquinolones remains key to reduce delay in diagnosis. To improve health outcomes and antibiotic stewardship, person-centered approaches to care - such as social, psychological and economic support, as well as training healthcare workers to improve their confidence in DR-TB management and financing the TB response so it is free at the point of care are essential.
- Provision of cost-effectiveness data on regimens, particularly when there is more than one type of intervention for the same indication, is needed to support decision making by programmes. Advocacy on fair pricing for drugs such as rifapentine is needed to scale up the implementation of new recommendations.
Session 2: WHO TB policy guidance: current status, update plans and evidence gaps

2.1 Child and Adolescent TB

*Kerri Viney, Global TB Programme, WHO*

Kerri Viney opened her presentation by outlining some of the latest epidemiological data on the burden of TB in children and adolescents. She highlighted the significant challenges in case detection and access to TPT for children and adolescents. The impact of the ongoing COVID-19 pandemic was also discussed, highlighting that it has had a differential impact on children when compared to adults.

She discussed the most recent updates to WHO guidance on the management of TB in children and adolescents following on from the meeting of a WHO convened Guideline Development Group held in May-June 2021. New recommendations and associated research gaps signaled in WHO Rapid Communication on the management of TB in children and adolescents were presented. Updated consolidated guidelines and an associated operational handbook will be published by WHO in the coming weeks and will contain detailed information on the new recommendations as well as implementation guidance. Ongoing studies that are poised to inform future policy update were presented.

The Chair opened the floor for discussion framed around (but not limited to) the following questions:

1. Are there any additional critical evidence gaps or upcoming studies?
2. What strategies should WHO/GTB use to encourage investment in paediatric TB research and development, and to shorten paediatric TB research and development timelines to improve global policies on TB care?
3. What strategies should WHO/GTB employ to enhance the implementation and evaluation of global TB policy guidance for these age groups?

**Discussion:**

- On screening and diagnosis, the research community and WHO, should work on optimizing the yield from respiratory and non-respiratory samples in children to allow for more accurate diagnosis of both DS-TB and DR-TB. Evaluation of Computer Aided Detection software with pediatric disease patterns is also needed to optimize and assess the utility of this tool in young children.
- On prevention, a lack of data on the optimal daily dosage of rifapentine for young children continues to pose problems. Discussions on TPT for children are summarized in session 1.1.

- On treatment, the translation of the new recommendation on a 4-month regimen to treat children with non-severe DS-TB into practice is important, but countries will need support on defining non-severe TB in children, as well as in scaling up access to chest radiography, supplemented with capacity building and training. Furthermore, participants noted that a lack of age-appropriate formulations has created a disproportionate challenge in treating DR-TB.
- On implementation and access, optimization of models of care remains critical to improve case detection and TPT uptake. Identifying and addressing other barriers to health care access such as
household literacy and better contact screening strategies may pave the way to earlier access to care. Development of a composite indicator to monitor progress in child and adolescent TB at the national and sub-national levels may accelerate efforts towards the targets of the political declaration of the United Nations High-Level meeting on ending TB. Better estimation of the burden of TB infection and disease in children and adolescents can promote the scale up of nationally and locally tailored interventions.

- On the topic of future research, the purposeful inclusion of children and adolescents in clinical trials, across different geographic settings remains key to allow for generalizability of research findings. Operationalizing this requires that the TB research community resolve any confusion around the definition of the age of a child or adolescent (for example, these definitions could be based on the clinical disease spectrum rather than the age cut offs used for surveillance and reporting purposes). The impact of SARS-CoV-2 infection on the development of TB in children and adolescents should be studied further.

### 2.2 TB comorbidities and vulnerable populations

*Kerri Viney, Global TB Programme, WHO*

Kerri Viney opened her presentation by defining priority drivers for TB and risk factors for poor treatment outcomes among persons with TB, including alcohol use disorders, diabetes, HIV infection, malnutrition and smoking, as well as mental health. Member states have already committed to strengthen integrated care for TB, HIV, diabetes, smoking cessation, substance use, malnutrition and mental health disorders through the respective UN High-Level Meeting political declarations on HIV, TB and NCDs. However, despite the existence of WHO guidelines on TB and these comorbidities and risk factors, countries have been slow to scale-up action to address TB comorbidities, with the exception of HIV-associated TB. To translate these commitments into action, WHO/GTB is developing a Framework for Collaborative Action on TB and Comorbidities, which builds on the experience of the WHO Policy on Collaborative TB/HIV Activities and which will aim to establish and strengthen collaboration across health programmes and across sectors to deliver people-centred services for people with TB and comorbidities. The development of the Framework has been informed by a review of policy uptake on TB and comorbidities, interviews with TB-comorbidity survivors as well as a consultation with countries to assess the barriers and enablers for scaling up joint action. Throughout 2022-2023 WHO will be consolidating and reviewing its recommendations and guidelines for the management of TB and various comorbidities. WHO/GTB’s work on vulnerable populations other than children and adolescents was also presented. Ongoing studies that may shape policies on co-management of TB and comorbidities were presented.

The Chair opened the floor for discussion framed around (but not limited to) the following questions:

1. Are you aware of new evidence that is due to be published shortly and that could influence our current recommendations on TB and diabetes, TB and undernutrition, and TB and HIV?
2. What further guidance/updates should we consider to enhance the implementation of global TB policy guidance for people with TB and comorbidities and vulnerable populations?
3. What support is needed or available to accelerate translation of global TB policy guidance for people with TB and comorbidities and vulnerable populations into practice?

**Discussion:**

- Participants welcomed WHO/GTB’s plans to consolidate the various recommendations/guidelines on the management of TB and comorbidities, and the development of the Framework for Collaborative Action on TB and Comorbidities, including the focus on person-centered care to address comorbidities and multi-morbidity in TB. The ongoing evidence review by WHO on TB and hepatitis B/C co-infection was acknowledged as a welcome advance in this area.

- On research, the inclusion of people with co-morbidities in ongoing studies on TB screening, prevention, diagnosis, and treatment across all age groups is essential to address pending evidence gaps for policy, especially for conditions where there is scant evidence such as co-management of alcohol and tobacco dependence. Development of standardized study protocols with clarifications on relevant sub-populations and endpoints can help build high-quality evidence for policy.

- On implementation, future development of the operational handbook on TB and comorbidities needs to consider several issues. For example, it may be logistically challenging to provide fully integrated care at the primary healthcare level due to a lack of capacity to manage drug-drug interactions or toxicities.

- Considering the broader determinants of TB comorbidities and also TB in vulnerable populations, a multisectoral lens to the response, including through joint programming across health programmes or other sectors is key. The success of joint programming in TB/HIV, as well as current efforts to co-manage TB and COVID-19 can provide lessons on how partners and programmes can galvanize action to scale up collaborative action on TB and comorbidities. TB vulnerability mapping at the national and sub-national levels can support prioritization and implementation of relevant actions.

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### 2.3 TB social protection and associated disability

**Ernesto Jaramillo, Global TB Programme, WHO**

Achieving End TB targets requires the provision of person-centred TB care and prevention services within the broader context of universal health coverage, and multisectoral action and accountability to address the broader social and economic determinants and consequences of TB.

Ernesto Jaramillo presented how current WHO TB guidance approaches social protection/patient support to address vulnerabilities of people affected by TB. Also presented was on how current approaches can be further strengthened in the context of the goals and milestones of the End TB Strategy. Research gaps on various aspects of TB and social protection were presented in the context of emerging needs for policy. WHO/GTB’s plans to repackage existing WHO recommendations and guidance on patient support into a TB social protection guidance, as well as plans for a development of a policy guidance on managing TB associated disability were shared.

The Chair then opened the floor for discussion framed (but not limited to) the following questions:
1. What policy areas in TB social protection are missing in this agenda?

2. What is the most effective/efficient approach suggested to address the challenges to improve current policy approach to social protection?

3. What is the most effective/efficient approach suggested to further develop the evidence for a policy approach to TB-associated disability?

**Discussion:**

- An intervention by a discussant highlighted pertinent research gaps and approaches for developing evidence for policy. During this intervention, WHO/GTB was encouraged to develop and use an indicator for measuring progress and for promoting accountability of social protection coverage, in addition to catastrophic cost surveys. To increase the uptake of social protection measures by NTPs, participants encouraged WHO/GTB to compile case studies of best practices to promote programmatic learning across countries. Impact assessment of social protection measures is also critical to help build evidence for action and decision making (e.g., identifying various risk groups for support, costing and effectiveness studies, etc.).
- On TB associated disabilities, evidence is needed to better characterize who is at risk, the determinants, the types of care needed, and outcomes of people post-TB treatment completion. Addressing this issue comprehensively requires multisectoral collaboration both on aspects of prevention, as well as care (e.g., palliative care, social or psychological support, pulmonary rehabilitation, etc.). Considering the gaps in evidence, situational assessment and prioritization of research needs for global TB policy making were suggested. Randomized trials may help build high-quality evidence for policy, and other studies that can expand understanding of predictors of chronic disease post-TB are also needed. In the interim, WHO should explore the possibility of developing an interim guidance to at least support countries in preventing TB associated disabilities.

**2.4 TB and COVID-19**

*Dennis Falzon, Global TB Programme, WHO*

Dennis Falzon presented on the impact of the COVID-19 pandemic on TB services, provided information related to commonly asked questions on the co-management of TB and COVID-19, and described WHO/GTB’s efforts to support national TB programmes during the pandemic: This includes monitoring the impact of the COVID-19 response on TB notification (monthly); issuing guidance on maintaining TB services in the context of the COVID-19 pandemic; and sharing case studies of programmatic innovations to address emerging challenges in TB prevention and care in the context of the pandemic. Finally, the ongoing review of evidence on “the association of SARS-CoV-2 infection and TB disease with unfavorable treatment outcomes” was presented.

**Discussion:**

Participants welcomed WHO/GTB actions on TB and COVID-19, and discussed if guidance will be issued on how to prevent drug-drug interactions between Paxlovid and rifamycin- or bedaquiline-containing TB regimens.
Conclusions and way forward

Finally, participants reflected on the need to prioritize the policy-relevant research gaps that keep coming up in these meetings and to find a way to support their implementation, and that such research should include people of all age groups and relevant vulnerabilities and consider acceptability and feasibility of interventions and the impacts of interventions on equity, gender issues and human rights. The post-pandemic context makes this more important.

Where there is low certainty of evidence in guidelines, WHO was encouraged to make more efforts to advocate for research implementation to increase the strength of the recommendations. In the interim, generalized evidence synthesis using both trial and non-trial data may be used to address evidence gaps. On the presentation of guidelines, in addition to the knowledge sharing platform, participants highlighted the value of infographics to simplify the message.

Tereza Kasaeva and Matteo Zignol thanked the participants and emphasized WHO’s commitment to convening regular fora to share WHO/GTB policy development plans. The Chair closed the meeting at 16:50.
Annex 1. Meeting agenda

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<td>13:00–13:10</td>
<td>Welcome and Introductions</td>
<td>Tereza Kasaeva Matteo Zignol</td>
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**Session 1: WHO TB policy guidance: current status, update plans and evidence gaps [Part 1]**

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<tr>
<th>13:10–13:20</th>
<th>Architecture of TB policy development</th>
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<tr>
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<td><em>Matteo Zignol</em></td>
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**13:20–15:55**

- **TB screening and prevention:** Dennis Falzon
  - Discussants: Mike Frick, Lindiwe Mvusi
- **TB diagnosis:** Nazir Ismail
  - Discussants: Daniela Cirillo, Rumina Hasan
- **TB treatment:** Fuad Mirzayev
  - Discussants: Gerry Davies, Rafael Laniado-Laborin

**15:55–16:00**

Summary of Day 1

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<td>13:00–13:10</td>
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**Session 2: WHO TB policy guidance: current status, update plans and evidence gaps [Part 2]**

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<th>13:10–15:50</th>
<th>Child and adolescent TB: Kerri Viney</th>
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<td><em>Discussants: Chishala Chabala, Tiara Pakasi</em></td>
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**13:10–15:50**

- **Child and adolescent TB:** Kerri Viney
  - Discussants: Chishala Chabala, Tiara Pakasi
- **Comorbidities and vulnerable populations:** Kerri Viney
  - Discussants: Srinath Satyanarayana, Mohammed Yassin
- **TB social protection and TB associated disability:** Ernesto Jaramillo
  - Discussants: Delia Boccia (social protection), Jeremiah Mukwa Chakaya (TB-associated disability)

**15:50–16:00**

Summary and way forward

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<td>Tereza Kasaeva Chair</td>
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Annex 2. Participants list

1. **Helen Ayles**  
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2. **Draurio Barreira**  
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7. **Gerry Davies**  
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9. **Patricia Hall**  
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10. **Anthony Harries**  
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11. **Rumina Hasan**  
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WHO/GTB

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41. Matteo Zignol, Unit Lead, PCI
42. Farai Mavhunga, Unit Lead, VCC
43. Dennis Falzon, Team Lead, PCI
44. Nazir Ismail, Team Lead, PCI
45. Fuad Mirzayev, Team Lead, PCI
46. Annabel Baddeley, VCC
47. Annemieke Brands, VCC
48. Nebiat Gebreselassie, PCI
49. Ernesto Jaramillo, VCC
50. Avinash Kanchar, PCI
51. Cecily Miller, PCI
52. Kerri Viney, PCI
53. Sabine Verkuijl, VCC
54. Tiziana Masini, VCC