Supporting TB preventive therapy for clients accessing DSD during COVID-19

CQUIN DSD and COVID-19 webinar series
26 May 2020

- Please type your name, organization and email address in the chat box and select “All panelists and attendees”
  - If you would like to join the CQUIN-COVID WhatsApp group, please also add your telephone number 😊
- Please ask questions to the panelists in the “Q&A”
CQUIN DSD and the COVID-19 response webinar series

- Tuesdays since 31 March at 12N Abidjan/2PM Joburg/3PM Nairobi
- [https://cquin.icap.columbia.edu/cquin-covid-webinars/](https://cquin.icap.columbia.edu/cquin-covid-webinars/)
- Multi-Sectoral Interventions to Ensure Uninterrupted Access to ART During COVID-19 Lockdowns (Recorded May 19, 2020)
- Updates on Policy and Practice Adaptations from Sierra Leone and Zambia (Recorded May 12, 2020)
- The Provision of Family Planning Services During COVID-19 – Considerations for DSD (Recorded May 5, 2020)
- Updates on Policy and Practice Adaptations from Ministries of Health (Recorded April 28, 2020)
- Perspectives of Recipients of Care During the COVID-19 Pandemic (Recorded April 21, 2020)
- Responding to COVID-19: Adaptations to Facility-Based DSD Models (Recorded April 14, 2020)
- DSD and the COVID-19 Response: Making the DSD Connection (Recorded April 7, 2020)
- DSD and the COVID-19 Response (Recorded March 31, 2020)
Housekeeping

1. Use the Q&A section to ask questions to all the panellists
2. Use the “chat” and select “All panellists and attendees” to discuss with the group and/or for any logistics challenges
3. Please note you are muted – so “raise your hand” if you would like to be unmuted
Why are we talking TPT and DSD?

1. Push to increase TPT uptake
2. Scale-up of differentiated ART delivery models

BUT WHAT IS HAPPENING NOW THAT WE ARE IN THE COVID-19 PANDEMIC?

- Clients have less frequent clinical visits and may be excluded for accessing TPT.
- DSD models for clinically stable clients may provide an opportunity to make sure clients have initiated and completed TPT successfully.

Source: Adapted from Tomlinson, IAS 2019

<table>
<thead>
<tr>
<th>Started TPT in FY17</th>
<th>Completed TPT in FY18</th>
<th>Complete TPT in FY19 (target)</th>
<th>Complete TPT in FY20 (target)</th>
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22 PEPFAR-Supported Countries

Source: Adapted from Tomlinson, IAS 2019
Key questions when considering TPT and differentiated ART delivery models

1. Should TPT completion be part of eligibility criteria for stability to access differentiated ART delivery for clinically stable clients?

2. Can the duration of TPT refill be adapted to align with the ART refill and facilitate integration within differentiated ART delivery for clinically stable clients?

3. Can the TPT refill duration be aligned for all members on TPT in a group differentiated ART delivery model for clinically stable clients?

http://differentiatedservicedelivery.org/Guidance
Today’s agenda

• Ensuring access to TB preventive therapy during COVID-19, Blessina Kumar, CEO, Global Coalition of TB Activists (10 mins)

• TPT surge sites in Zambia: Aligning TPT with 6MMD ART dispensation, Khunga Morton, Chief TB Pharmacist, Ministry of Health (TB Unit) (5 mins)

• TPT and DSD in Uganda, Josen Kiggundu, National Technical Advisor for DSD, Ministry of Health Uganda (5 mins)

• PEPFAR guidance and data on TPT within HIV programmes during COVID-19, Dr Teeb Al-Samarrai, Senior Technical Advisory for TB/HIV, Office of the Global AIDS Coordinator (S/GAC), USA (5 mins)

• Panel discussion

• Q&A, discussion and wrap up
Ensuring access to TB preventive therapy during COVID-19

Blessina Kumar
Global Coalition of TB Activists
26 May 2020
<table>
<thead>
<tr>
<th>Year</th>
<th>WHO</th>
<th>WHO &amp; Union</th>
<th>WHO &amp; UNAIDS</th>
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<td>1993</td>
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Isoniazid preventive therapy recommended for PLHIV and child contacts since 1993.
TPT and HIV - Situation before COVID-19
In 2018 …

- Total 65 countries reported data. 16/38 high TB or TB/HIV burden countries
- **1.8 million** PLHIV started IPT

**350,000 children < 5 years** started TPT, or 27% of ~1.3 million children estimated to be eligible (up 20% from 2017)

**79,000 people ≥5 years** started TPT (down 30% from 2017)
TPT and HIV- Situation before COVID-19

WHO Guidelines for TPT- 2020 (options)

1. 3HP
   - Once-weekly isoniazid (INH or H) plus rifapentine (P) for 12 weeks, total 12 doses for adults, adolescents and children above 2 years of age.

2. 1HP
   - A daily dose of isoniazid plus rifapentine for one month for adolescents and children above 12 years of age.

Both these regimens (3HP and 1HP) can also be given to PLHIV.

3. 3HR
   - Daily rifampicin (R) plus isoniazid for 3 months for adults and children. The regimen can also be given to PLHIV who are on rifampicin-friendly ART regimen. Child friendly formulations are available in several countries.

4. 6H/9H/36H
   - Either daily isoniazid for 6 months for adults and children, or daily INH for 9 months for adults and children, or daily INH for 36 months for PLHIV in high TB transmission settings.

5. 4R
   - Daily rifampicin for 4 months for adults and children.

H- Isoniazid
P- Rifapentin
R- Rifampicin

Not fully adopted and implemented yet.
GCTA quick survey of challenges-

- Public transport facilities are unavailable
- Drugs
- Treatment disruption for certain most vulnerable groups
- Nutrition support challenges and mitigation suggestions
- Challenges arising due to re-routing of health staff to combat COVID19
- Disruption of access due people avoiding crowded health facilities

Countries
- India
- Nepal
- Indonesia
- Thailand
- Cambodia
- South Africa
- Eswatini
- Kenya
- Cameroon
- Cote D’Ivore
- Nigeria
- Uganda
- Mozambique
- Ukraine
Key challenges

• Services interrupted- lock down, OPD closed, ART centers closed
• Access to diagnosis, treatment, counseling etc.
• Increased stigma
• Reverse Migration
• Disruptions in supply chain – Generics, API
• Focus diverted
• Fund availability
Recommended way forward

Advocacy – The TPT options need to be integrated within existing—or new—care systems

- From IAS: integrate TPT into differentiated service delivery (DSD) models of HIV care. (www.differentiatedservicedelivery.org)

- Think about when • where • who • what – for TB screening, TPT initiation, TPT refills, adherence support, and TPT completion.

When advocating for TPT think beyond access to the pills—ask for TPT to be delivered within people-centered systems. For example, call for TPT scale-up to be linked to DSD.

Slide borrowed from Mike Frick, TAG
Example:
The ZNNP+ Experience in Zimbabwe

• Creating demand for TPT uptake by PLHIV through community sensitization meetings, trainings, and dialogues.
• Identifying gaps in TPT provision through community monitoring of TPT services at health facilities to check on service provision.
• Establishing and strengthening support systems among PLHIV to enhance TPT uptake and adherence, including putting TPT into DSD models.
  – Includes training: expert patients; Community ART Refill Group (CARG) leaders; PLHIV support group leaders.
• Engaging duty bearers on what can be done to improve TPT uptake.

“"I am in a Community ART Refill Group and I hope we will be allowed to collect our TPT as a group so that we can monitor ourselves on adherence."
—CARG member trained by ZNNP+

Slide borrowed from Esnath Manhiri at ZNNP+
Everyone has a right to access the highest available standard of TB prevention

- For TB preventive therapy, this means short-course regimens based on either rifapentine (3HP, 1HP) or rifampicin (3HR, 4R).
- These rifamycin-based TPT regimens are shorter than isoniazid preventive therapy (IPT), have better adherence, are easier to complete, and have less liver toxicity. They’ve been studied and used in a wide range of settings.
- The “IPT only” era is over! (But, IPT is still important for certain populations e.g., kids with HIV on lopinavir-ritonavir).

No more excuses not to use rifapentine-based TPT, especially 3HP

Slide borrowed from Mike Frick, TAG
If prevention is a public good, then TPT regimens must be considered public goods

- Sanofi has tried to patent 3HP fixed-dose combinations for adults and children, filing patents in nearly 70 countries.
- BUT: rifapentine and isoniazid were each discovered decades ago. Rifapentine is off patent and isoniazid was never patented. 3HP was developed mostly with public funding.
- A simple combination of two decades-old drugs isn’t innovation and doesn’t deserve a patent.
- Civil society has fought back: DNP+ and Ganesh Acharya filed pre-grant patent oppositions in India; activists in Thailand followed soon after.
- Now civil society is calling on Sanofi to withdraw their patent applications and abandon their patents where already granted.

Slide borrowed from Mike Frick, TAG
Acknowledgements:

Avinash Kanchar, WHO Geneva
Mike Frick, TAG
GCTA – ‘How to Protect Ourselves from TB’- Brochure
WHO Civil Society Task Force

www.gctacommunity.org
Thank you!!
TPT surge sites in Zambia: Aligning TPT with 6MMD ART dispensation

Morton Khunga
Ministry of Health, Zambia
26 May 2020
TPT and HIV in Zambia

Before COVID-19

• Conducting TPT in all the ART facilities across the country but concentration was in the surge sites
  – Plan was to satisfy these facilities and move to another round of sites (mainly based on stock availability)
  – Response was very good from the facilities and we had support from partners
  – Appointments (of about 1-3 months) for refills were based on a number of factors such as availability of drugs, how stable the patient is etc.
  – Numbers of initiations were going up
  – We had commodities on order with EDD confirmed under GF and USAID
TPT and HIV in Zambia

After COVID-19

• The country has continued to offer TPT to the persons at risk of TB during the COVID 19 response

• “Given the guidance on 6MMM for ART, We should align the TPT prescription to the ART.”

• If a patient has taken 1 month of TPT give addition INH for 5 months, If another patient has been on TPT for 2 months give additional TPT for 4 months

• Only TPT surge sites should continue to recruit new patients on TPT, the rest will need to focus on TPT completion for the patients already on TPT
Effects of COVID19 on Weekly TPT Surge Initiations

Before COVID19

Amidst COVID19

Wk1  Wk2  Wk3  Wk4  Wk5  Wk6  Wk7  Wk8  Wk9  Wk10  Wk11  Wk12  Wk13
Feb 20  Mar 20  Apr 20
549  725  1,316  1,964  1,476  1,989  2,976  2,155  1,860  1,695  1,200
500  1,000  1,500  2,000  2,500  3,000  3,500
Key challenges

- Physical distancing measures and national quarantine measures are interrupting treatment support
- More focus on COVID-19 and less attention on other disease areas including TPT
- HCWs fear to attending to patients
- Patients would fear to present to a facility in fear of COVID
- 6MMD implies entails stock piling of TPT commodities
- M and E related
- Procurement and supply chain related (on the next slide)
Key challenges

• Procurement and supply management related risks

“........................At this moment in time, we are experiencing **reduced manufacturing capacity by our suppliers** due to the lockdown situation in the countries where medicines are manufactured. At the same time, we are **facing disruptions in flight operations, caused by delays and cancellations of flights** due to COVID-19 related control measures at origin and destination countries. The accumulation of these bottlenecks is leading to **overall delays in the supply chain**..........................”

“...............Lastly, we may also ask you to **accommodate some flexibilities** given the current situation, especially with regards to remaining shelf life requirements, **splitting shipments for partial deliveries**, etc.”

-GDF-
Next steps

• Continue providing TPT while responding to COVID-19

• Continue to support the TPT surge sites by providing adequate stocks to meet their targets

• All patients on TPT to be given enough supplies to complete the course

• Patients being supported with adequate information
  • Telephonic counselling should need arise

• TB Situation room – overall aim is to monitor and spur the TB response amidst the COVID-19 pandemic
  • TPT Coverage is one of the indicators being tracked

• Continue following up with procurements
TPT and DSD in Uganda

Dr. Josen Kiggundu
Senior Program Officer - DSD
Ministry of Health, Uganda
26 May 2020
TPT and HIV in Uganda

Before COVID-19 (1)

Regimen for TPT
• 6H:
  – Daily Isoniazid for 6 months (IPT).
  – Daily Q-TIB for 6 months.
• 3HP:
  – Weekly Isoniazid and Rifapentine for 3 months (3HP)
  – Recommended for patients > 2 years.
  – To start next year

Eligibility for TPT
• PLHIV ≥one year of age with no signs and symptoms of TB;
• HIV-positive children <5 years with a history of TB contact who have no signs and symptoms of active TB disease, *irrespective of previous TPT*
TPT and HIV in Uganda Before COVID-19 (2)

• TPT integrated in all DSD approaches
• TPT initiated by a clinician regardless of DSD approach
  – TPT initiated at the health facility for all recipients of care (RoC) RoC receiving ART services through facility based individual management (FBIM), facility based groups (FBG), fast track drug refills (FTDR) and community client led ART delivery (CCLAD)
  – For RoC enrolled onto community drug distribution points (CDDPs), TPT initiated from the CDDP during the clinicians visit.
• Patient education about side effects and when to return to the facility emphasized
• TPT and ART refills aligned
  – 1 month refill for both ART and TPT at TPT initiation
  – Later monthly for more intense approaches (FBIM and FBG) and MMRs for less intense approaches (FTDR, CDDP and CCLAD)
• Clinical monitoring for RoC on TPT done at every clinical encounter regardless of DSD approach
• SOP on providing IPT in DSD models developed
TPT by DSD model
March 2020

- N=725,758 on ART
- 14% on TPT
- Range from 8% in CDDP to 17% in FBIM
TPT and HIV in Uganda

After COVID-19

- 3 months refills provided, including at TPT initiation
- RoCs empowered with information on side effects, dangers signs and are encouraged to return to facility whenever they observe any danger sign
- RoC monitored through phone calls
- ART and TPT refills provided at closest health facility, regardless of registration
- FBGs temporarily suspended
Key challenges

• Clinical monitoring due to COVID lockdown

• Documentation of TPT services provided to visitors

• Increased loss to follow up
Next steps

- Assess impact of COVID-19 on ART and TPT service delivery
- Conduct a CQUIN funded study to understand the factors associated with IPT completion among RoC on ART/IPT aligned multi-month refills by DSD model
PEPFAR TB/HIV Guidance in Response to COVID-19

CQUIN DSD & COVID-19 Webinar Series (ICAP, IAS, ITPC)

Teeb Al-Samarrai, MD MS
Office of the Global AIDS Coordinator
May 26, 2020
A triple threat: COVID-19, HIV, TB

COVID-19 (As of May 25, 2020)
• 5,449,135 confirmed cases worldwide
• 345,721 deaths

HIV
• ~38 million people living with HIV worldwide (2018)
• 770,000 deaths (2018),
• ~251,000 deaths among HIV/TB (2019)

TB
• 1.5 billion infected, 10 million become ill
• ~1.5 million deaths (2019)

COVID-19 and TB in PLHIV

- Both respiratory diseases with diverse manifestations
  - Environmental factors play a role in transmission
  - Host factors and comorbidities impact presentation and severity of disease
- Uncertainties remain regarding impact and clinical presentation of COVID-19 among PLHIV
- Limited data on latent or active TB susceptibility to COVID-19 and disease severity
- Potential protection from BCG
  - Clinical trial enrolling health care workers in South Africa, Australia, Netherlands
PEPFAR COVID Guidance: MMD

• Accelerate and scale up MMD dispensing of ARVs, TB medications, and TPT for all, including children
• TPT remains a core HIV service
  – For newly initiating patients, a full course of TPT (INH or 3HP) should be dispensed
  – For PLHIV already on TB or TPT regimens, ensure remaining doses are provided to complete fill course of treatment
• ARV & TB visits and medication dispensing should be aligned
• Ensure that adverse event monitoring can be done via telephone, SMS, or electronically
Expanding Decentralized Drug Distribution

- Medication dispensation preferably outside of facilities in decentralized distribution
  - Community or private pharmacies
  - Home deliveries
  - Pop-up pharmacies
  - Automated lockers
  - Community ARV distribution through schools, FBOs, KP sites
COVID-19 Impact on TPT Uptake

- Declines in case finding and patients presenting to facilities
- TB Programs and staff diverted to COVID-19 response
- TB diagnoses decreased
- TPT scale-up significantly impacted
- Adopted MMD and/or DSD for TB and/or TPT (DR, Haiti, Kenya, Lesotho, Mozambique, Namibia, Rwanda, South Africa, Tanzania, Uganda, Vietnam, Zambia, Zimbabwe)
- High risk of INH stock-out limit MMD (Eswatini, Mozambique, Uganda, Vietnam)
- Discussions regarding expanding MMD and DSID for TB (Ethiopia)
COVID Impacts on TB/HIV Supply Chain

- All HIV commodities with 1 month delay
- ARV manufacturers (largely based in India) reporting sufficient ingredients (API) to continue production of formulations, TLD and other ARVs however orders are delayed by ~4 weeks
- Orders of essential medicines, including TPT arriving on-time (range: early by 132 days to delay of 70 delays)
- 3HP delays in shipments
  - **Sanofi** (Italy): reduced capacity due to movement restrictions;
  - **McLeods** (India): manufacturing is halted due to India lock down
  - Delayed submission of Validation Reports to Global Fund and GHSC-QA as part of the QA contingency to approve their manufacturing capacity
  - ERP-2 approval of the FDC requires pre-shipment testing
Additional Resources

Thank you

For questions, please email: ifz8@cdc.gov
Discussion and Q&A
Thank you

- DSD & COVID-19 resources:
  - [bit.ly/DSDCOVID](bit.ly/DSDCOVID)
  - [https://cquin.icap.columbia.edu/network-focus-areas/covid-19/](https://cquin.icap.columbia.edu/network-focus-areas/covid-19/)
  - [http://itpcglobal.org/resources/](http://itpcglobal.org/resources/)

- Details of the past and future webinars in this series can be found at [https://cquin.icap.columbia.edu/cquin-covid-webinars/](https://cquin.icap.columbia.edu/cquin-covid-webinars/)