ABSTRACT BOOK

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SOA-04-C1 TPT: old and new regimens

SOA-04-1033-31 High treatment completion rates using a three-month isoniazid-rifampicin regimen during a community-wide latent TB screening and treatment campaign on Cu Lao Cham Island, Viet Nam

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Background and challenges to implementation: Viet Nam’s UNGA HLM commitment includes a target for treating 291,500 people for latent TB infection (LTBI) between 2018-2022. The current LTBI treatment regimen in Viet Nam is nine months of isoniazid for adults (≥15 years), posing a major challenge for LTBI treatment adherence and completion.

Intervention or response: As part of the TB REACH-fund SWEET-TB project, a population-level TB screening campaign was conducted on the island of Cu Lao Cham in January 2019. Over 90% of the island’s 2,026 residents were screened for LTBI (tuberculin skin test ≥10mm). After ruling out TB disease by chest X-ray screening and Xpert testing, 435 adults had normal liver enzymes and were considered eligible for treatment with daily rifampicin and isoniazid for 3 months (3HR). 377 (86.7%) of these people were started on the shorter regimen. Four local commune health officers and two community health workers supported the provision of LTBI treatment, which included weekly adverse event monitoring.

Results and lessons learnt: Among the 377 adults started on 3HR, 337 (89.4%) have successfully completed treatment or are in the final month of treatment and are expected to complete the full regimen. 13 individuals (3.7%) experienced adverse events (AEs); no episodes of hepatotoxicity were recorded. The most common side effects were itching (61.5%), fatigue (38.4%), numbness (23.1%) and muscle pain (15.4%). Of the people who discontinued 3HR treatment early, 29 (7.7%) were elective discontinuations, 10 (2.7%) were due to side effects, and 1 (0.2%) person moved away from Cu Lao Cham island.

Conclusions and key recommendations: People with LTBI who were treated with 3HR had high treatment completion rates and low rates of AEs. These data sug-
gest that 3HR can be safely administered at the population-level and that follow-up care can be managed by the existing health system.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiating treatment with 3HR</td>
<td>377</td>
<td></td>
</tr>
<tr>
<td>Treatment Completed</td>
<td>337</td>
<td>(89.4%)</td>
</tr>
<tr>
<td>Stopped early: adverse effect</td>
<td>10</td>
<td>(2.7%)</td>
</tr>
<tr>
<td>Stopped early: patient decision</td>
<td>29</td>
<td>(7.5%)</td>
</tr>
<tr>
<td>Stopped early: moved</td>
<td>1</td>
<td>(0.2%)</td>
</tr>
</tbody>
</table>

[3HR Treatment Outcomes]

**SOA-04-1034-31 Weekly rifapentine and isoniazid for tuberculosis prevention in China: a randomised controlled study**

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**Background:** Preventive treatment for individuals at the highest risk of tuberculosis progressing to an active disease is vital in the successful control of TB. For preventive TB treatment, it is a challenge to balance the potential long-term benefit and immediate risk of therapy-related adverse events. Three-month, once-weekly rifapentine and isoniazid may be a promising regimen to shorten preventive tuberculosis treatment in the high-risk population of China.

**Methods:** In this open-label, randomized clinical trial, eligible silicotic participants were assigned to the rifapentine/isoniazid group and observation group with a sample size ratio of 1:1, according to stratified randomization by silicosis categories. All were followed up for 37 months after enrollment. The efficacy, safety, and completion rate of the regimen were evaluated in this silicotic population in China.

**Results:** We screened 1,227 adults with silica exposure or silicosis; 513 were finally enrolled and assigned to the rifapentine/isoniazid (n=254) or observation group (n=259). Median age was 57 years-old, median body mass index was 23.5 kg/m², all subjects were males, and none had human immunodeficiency virus. Twenty-eight went twenty-eight cases with flu-like systemic drug reactions, nine led to hospitalization. Five subjects (2.1%) experienced hepatotoxicity.

**Conclusions:** Weekly rifapentine/isoniazid regimen was effective in preventing tuberculosis in the silicotic population in China; however, it was not well tolerated based on the unsatisfactory completion rate and decreased protection against tuberculosis.

Trial registration: www.clinicaltrials.gov (NCT02430259)

**SOA-04-1035-31 Direct supportive supervision results in improved isoniazid preventive therapy implementation in the Nigerian Military HIV programme**

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**Background and challenges to implementation:** Isoniazid preventive therapy (IPT) is recommended for tuberculosis (TB) prevention amongst people living with HIV (PLHIV) and other persons at high risk of TB. The Nigerian military HIV program had been facing numerous challenges since 2015, in increasing IPT uptake among its HIV clients, with a coverage rate of only 5% in fiscal year (FY) 2016. These challenges include; unstructured distribution and requisition system, healthcare providers’ oversight to initiate clients on IPT, myths about the intervention, poor recording and reporting of IPT.

**Intervention or response:** Between October 2016 and September 2017 (FY2017), the program worked in conjunction with other U.S. government agencies to address supply chain bottlenecks, which increased coverage to approximately 9% of eligible PLHIV in FY2017. Seeking additional improvements, in May 2018, the program embarked on IPT specific “direct supportive supervision” (DSS). With this, most of the 27 comprehensive sites under the Nigerian military program sites were visited to conduct root cause analysis, and mentorship to address barriers to IPT initiation. In addition, there was introduction of IPT monitoring tool, sticker-reminders on clients’ folders, and bi-weekly IPT uptake data collection and collation.

**Results and lessons learnt:** DSS implementation led to increased IPT uptake, (Fig. 1) from monthly uptake of 360 clients in May 2018 to a monthly uptake of 3,392 clients in September, 2018.

The total achievement, from the beginning of DSS in May 2018 to September 2018 (8,116 clients), represented 78% of the total number of patients on IPT for the year, and Grade 3 or 4 adverse events (7.9%), the completion of rifapentine/isoniazid was 54.7%. Of the 26 (10.8%) cases with flu-like systemic drug reactions, nine led to hospitalization. Five subjects (2.1%) experienced hepatotoxicity.

**Conclusions:** Weekly rifapentine/isoniazid regimen was effective in preventing tuberculosis in the silicotic population in China; however, it was not well tolerated based on the unsatisfactory completion rate and decreased protection against tuberculosis.

Trial registration: www.clinicaltrials.gov (NCT02430259)