TAS Best Practices Webinar December 12, 2019 Questions and Answers

Please find below questions submitted during the registration process and during the webinar itself and the related answers. The questions have been grouped into topic areas.

Diagnostics

- **Q: Are donated FTS provided for pre-TAS?** A: Yes. Country needs to write letter of request and pre-TAS plans (e.g., indicate which IUs meet criteria). FTS are also available for re-mapping.
- **Q: Would WHO provide donated FTS for surveillance?** A: Currently, FTS are donated for confirmation mapping, pre-TAS and TAS. However, WHO will discuss with the consortium responsible for donating FTS to determine if FTS could be donated for surveillance.
- **Q: How potent is the FTS kits kept from the time of production till they are been use in Africa for surveys?** A: The manufacture guarantees a 12-month shelf life in temperatures under 37° Celcius. WHO has asked the manufacturer to look into exploring whether the shelf life can be longer.
- **Q: How should FTS be stored?** A: They should be stored in a cool, dry place out of direct sunlight. Ambient temperature should be between 2-37° Celsius. Tests should not be frozen. Tests also should not be exposed to extreme heat for prolonged periods of time. Report any irregularities with the tests using the new form that will be posted on the NTD Toolkit website.
- **Q: What is timing to use positive control on diagnostic tests and why is it important?** A: Use of positive control ensures that between the manufacturing site and delivery, we can have confidence that the test is working correctly and able to detect circulating antigen. Positive control should be tested upon receipt of shipment in country, and because tests are not always used right away, programmes should also reassess positive control at survey implementation. It is only required to assess a few tests from each lot through positive control.
- **Q: Is it a best practice to have all people who will conduct TAS to train/refresh train on how to use correctly?** A: Yes, best practice is to train or retrain survey teams before every planned TAS implementation. In addition, developing a team of TAS trainers to build capacity and conduct field supervision is advised.
- **Q: Is there a way to assess technical effectiveness of lab techs during training?** A: National programmes can make an examination that techs would have to pass to be included in survey implementation. WHO does not have an examination, but is a good suggestion for WHO to develop a standardized way to assess competencies.
- **Q: Is there a time limit as how long you will open the FTS packs to when they are used to remain effective?** A: FTS should be used immediately upon opening.
- **Q: How relevant are FTS "scores" (1-3, depending on strength of blood) for national programs to be collecting and interpreting?** A: Decisions are made only on + or -. Scores are subjective unless automated by a device, which we do not yet have.

- **Q: Is there a way around night-time testing considering the discomfort from consumer perspective for the same?** A: Yes, for *Wuchereria bancrofti* areas, the FTS rapid diagnostic test can be used. For pre-TAS in *Brugia* spp. areas, night time testing for microfilaremia is still recommended as a rapid antigen test does not exist.
- **Q: Should we do re-test for Brugia Rapid test when we found the positive result then we do re-test and become negative?** A: See slide 44, no need to test more than 2 times.
- **Q: How to interpret the result if the first test of Brugia Rapid was positive but the second test was negative?** A: See slide 44, no need to test more than 2 times.
- **Q: Why are we repeating initial positive FTS result?** A: It was suggested given the experience of a few programmes when much higher than expected positive tests were encountered, when quality of the test or technician's skill was in question. This, as well as taking a photo, is seen as a best practice when possible. The alternative, if the results were unusual, would require a separate visit at another time to retest of sample of positive children to confirm the results. The expected number of positives after meeting eligibility criteria is low and retesting positives is considered a reasonable quality check.
- **Q: What possible errors would you suggest if after rerunning positive tests, all show negative during TAS? Do you think concomitantly using FTS and dried blood spots (DBS) will help resolve the errors suggested?** A: The FTS should be applied as the product insert and TAS training instructions. Reading the result too late can result in a false positive. DBS may add value. However, currently there are no decision-making thresholds or standardized interpretation of subsequent analysis of DBS.
- **Q: How to interpret if FTS is still positive after complete treatment?** A: Circulating filarial antigen can persist in the body for some time – interpretation may be as follows: a) current infection with viable adult worm or b) past infection with uncleared antigen of the dead adult worm
- **Q: FTS are not very user friendly, is there any possibility to make them more easy?** A: Please report any specific issues with the FTS and invalid results to WHO using the diagnostic reporting form available on the NTD Toolbox. This data helps WHO work with the manufacturers to address problems.

Pre-TAS

- **Q: What is the difference between Pre-TAS and TAS?** A: A: Pre-TAS is the sentinel and spot-check surveys that are conducted to determine eligibility for the transmission assessment surveys (TAS) which makes the decision whether or not to stop MDA. See intro slides.
- **Q: What are the criteria for programme to conduct pre-TAS and TAS?** A. See eligibility criteria slides 14-16.
- **Q: What are the basic requirements in preparation for pre-TAS and TAS?** A. See eligibility criteria slides 14-16.
- **Q: What are the indicators for pre-TAS?** A: See eligibility criteria slide 16.

- **Q: What guidelines are recommended in planning pre-TAS and TAS surveys?** A: See slide 9 WHO TAS guidance.
- **Q: How many times do you conduct pre-TAS and TAS?** A: Pre-TAS should be conducted ideally only once, followed by 3 successful TAS.
- **Q: What is the timing for conducting the pre-TAS and TAS survey from the last day of MDA?** A: Should conduct pre-TAS 6 months after the previous MDA round. TAS can be implemented once eligibility criteria are met.
- **Q: Are there training materials for preTAS and TAS available on WHO website or NTD Toolbox?** A: Yes. Facilitator's guide, learner's guide and PPT modules are available on WHO website and the NTD Toolbox. PPTs have been revised in English and French; can send a message to WHO Regional Office to get copies.
- **Q: For pre-TAS, what is the number of sites where night blood survey needs to be conducted?** A: At least one sentinel site and one spot-check site should be assessed per 1 million population in an implementation unit for pre-TAS.
- **Q: During pre-TAS, what are the criteria to select the village if baseline survey was not known?** A: Want to select sites that bias towards finding infection; expected high risk. Go to areas with highest baseline prevalence, or if there was any monitoring survey, go to community with positive results. Also, look at MDA coverage, and select site where had low coverage. Select site where other vector-borne diseases have high prevalence.
- **Q: During the pre-TAS, must all the old sites having an antigenic prevalence higher than 2% be re-evaluated?** A: Yes. Any sites that failed previous criteria can be used again.
- **Q: What should the maximum sample size per site for night blood survey?** A: No maximum, test at least 300 persons.
- **Q: What is actually the eligible population for pre-TAS? 5-50 years old or can be greater than 50 years old?** A: >5 years of age.
- **Q: Is there a plan to consider treatment of positives found in Pre-TAS even if EU passes to TAS1?** A: Positives should be treated in pre-TAS directly after they are found, regardless of whether pre-TAS or TAS passes. See slide 44.
- **Q: What happens between pre-TAS and TAS?** A: Reporting of results to WHO, technical review by RPRG, request for donated diagnostics and/or support for TAS implementation if needed.
- **Q: In the EPIRF there's no option for selecting Pre-TAS, is there a reason for that?** A: Yes, because pre-TAS is the same survey as sentinel and spot-check surveys.

Repeated Pre-TAS

- **Q: Concerning the failed Pre-TAS and TAS districts, are there any global updates and experiences?** A: The rate varies by country. At least 14 countries have failed a pre-TAS or TAS in at least 1 IU. Don't know the pre-TAS fail rate, but less than 5% have failed TAS overall.
- **Q: What are the considerations for sentinel and spot check site choices in re-pre-TAS / pre-re-TAS situations?** A: See slide 48-49 FAQs.

- **Q: Can a spot-check site be changed if it had >2% Ag or > 1% mf during the last survey?** A: If a spot-check was above the criteria during the last survey, e.g. ≥2% Ag or ≥1% Mf, it should be kept for the following survey as well.
- **Q: In a re-pre-TAS, how many sites need to be assessed? What is the role of traditional "sentinel site" in re-pre-TAS?** A: See slide 16 eligibility criteria. Sentinel sites shouldn't be surveyed again if they have already met the <1% or <2% criteria.
- **A: Results of a re-pre-TAS: Sentinel site = 0% and 2 or 3 control/spot-check sites have prevalence above 2%. What decision should be taken?** A: Implement 2 additional rounds of MDA then assess again.
- **Q: Is it necessary to conduct a pre-TAS after failing TAS1? Or we conduct MDA for 2 years and repeat TAS1 without pre-TAS?** A: Conduct a pre-re-TAS before moving to TAS1.
- **Q: For selecting sentinel and spot-check sites after failed TAS, do we need to select the same sentinel site, plus 2 spot-check sites?** A: For the pre-TAS after failed TAS, there is no need to include the sentinel site, since it was <2% Ag or <1% Mf in the first pre-TAS. Instead, two spot-check sites should be chosen.

TAS

- **Q: What is the difference between pre-TAS and TAS?** A: Pre-TAS is the sentinel and spot-check surveys that are conducted to determine eligibility for the transmission assessment surveys (TAS) which makes the decision whether or not to stop MDA. See intro slides.
- **Q: What guidelines are recommended in planning pre-TAS and TAS surveys?** A: See materials referenced in slide 9.
- **Q: How many times do you conduct pre-TAS and TAS?** A: Pre-TAS should be conducted ideally only once, followed by 3 successful TAS.
- **Q: What is the time gap between TAS1, TAS 2, TAS 3?** A: After passing TAS1, national programme recommended to repeat TAS every 2-3 years. Criteria for being acknowledged as elimination as a public health problem is passing a final TAS no sooner than 4 years after MDA has stopped.

TAS Planning

- **Q: What are the basic requirements in preparation for pre-TAS and TAS?** A. See eligibility criteria slides 14-16 and review the TAS preparation checklist.
- **Q: What are the criteria for programme to conduct pre-TAS and TAS?** A: See eligibility criteria slides 14-16.
- **Q: What is the timing for conducting the pre-TAS and TAS survey from the last day of MDA?** A: Should conduct pre-TAS 6 months after the previous MDA round. TAS can be implemented once eligibility criteria are met.
- **Q: When an Evaluation Unit passes pre-TAS, what is the initial step to begin TAS?** A: Complete and submit the TAS Eligibility and Planning form to WHO, obtain resources for implementation, request FTS.

- **Q: Can the TAS survey be conducted just a week after the pre-TAS?** A: This is possible, but the recommendation is for the TAS Eligibility and Planning form to be filled and submitted for technical review by the RPRG.
- **Q: After 5 MDAs >65% coverage, can a country stop MDA while waiting for TAS? Sometimes TAS are postponed due to insecurity or budget reasons.** A: This is not advisable. Make every effort to complete the pre-TAS and TAS surveys within a year from the last MDA round and plan for an additional round before knowing the results of the TAS. It is better to continue MDA than to have inconsecutive distributions, assuming security is good enough to implement MDA.
- **Q: Should a district eligible for TAS not be planned for MDA as is presented by certain actors?** A: MDA should be planned even when going for TAS so that in the case pre-TAS or TAS fails, MDA can be delivered annually.
- **Q: What are the implications for delaying TAS and how long may they be delayed without impacting the ability to meet elimination as a public health problem criteria?** A: Delaying TAS may delay the ability to detect resurgence and need for restarting MDA. In addition, if TAS is delayed, it will take longer for a country to meet the validation criteria.

TAS Implementation

- **Q: Should an EU in TAS consist of 1 million, or should it be same as IU?** A: The smaller the EU, the better. Programs should take into consideration resources available. Maximum population can be up to 2 million, but this isn't encouraged.
- **Q: Why USAID is asking country to select EU with population not above 500,000 for TAS?** A: USAID follows evolving guidance and best practices from WHO. Best practices are to have smaller size EUs, as they better reflect true mean incident infection than larger EUs. Larger EUs could mean that 'hotspots' of ongoing transmission are at greater risk of being missed.
- **Q: Are there training materials for preTAS and TAS available on WHO website or NTD Toolbox?** A: Yes. Facilitator's guide, learner's guide and PPT modules are available on WHO website and the NTD Toolbox. PPTs have been revised in English and French; can send a message to WHO Regional Office to get copies.
- **Q: Is there a way to assess technical effectiveness of lab techs during training?** A: Can make an examination, that techs would have to pass to be included in survey implementation. WHO does not have an examination, but is a good suggestion for WHO to develop a standardized way to assess competencies.
- **Q: Is there a standard supervision form to use for surveys in field?** A: Yes, as part of checklist and job aids created, which are available on the NTD Toolbox. The Toolbox has links to job aids with standard supervision form for TAS; these standard tools can be adapted to country situation and pre-TAS.
- **Q: During the survey, if the survey team needs to move on to choose extra sites from the SSB, does the team choose in order from the SSB or can the team just go to the site closest to the team? A:** Need to start with first on SSB list and work down.

- **Q: If the TAS survey team has tested all schools plus all extra schools indicated with SSB, and haven't met sample size, what should the team do?** A: Report data as is, seek consultation through WHO to discuss findings.
- **Q: How can the endemic communities be involved in TAS?** A: Endemic communities can be involved in mobilization of survey populations, registration of survey participants, and communication of results and next steps.

TAS Methodology

- **Q: What is the epidemiological basis of selecting a particular cut off of antigenemia to consider as TAS pass/fail?** A: These cut-offs were selected based on historical evidence and correlation between Ag and Mf in communities.
- **Q: How can we calculate sample builders' results using by hand?** A: Follow the instructions in the TAS manual, specifically using Tables A.5.1 or A.5.2.
- **Q: During TAS which is the best one, community based or school based? why?** A: It depends how you define best. Each has advantages. A community survey should be done when school enrollment is less than 75%. Community surveys are just as good as a school-based survey and may require more effort to reach selected communities.
- **Q: Sometimes MDA does not get to hard to reach areas with LF. How do we then use TAS in such areas?** A: All areas within an EU are eligible for assessment and included in the sampling frame (must have a chance to be selected). Teams would be required to access these hard to reach areas if selected.
- **Q: Each TAS might not have the same individuals; hence whether sampling strategy might have an effect on results of TAS?** A: TAS is not designed to follow the same cohort of infected individuals. TAS provides a cross-sectional estimate of recent infection and determines whether prevalence is above or below a threshold.
- **Q: Can you divide an EU after TAS1 for subsequent TAS surveys?** A: Absolutely, especially if there's evidence to suggest should break into smaller units. Encourage national programmes to look at spatial distributions and determine if there's a risk of a hot spot. In that case, consider breaking into smaller units for TAS2 and TAS3.
- **Q: Why does TAS have only 2 category results like pass or fail. Can't we make TAS result very low, medium and very high?** A: Any other outcome doesn't provide a clear decision.
- **Q: How can the sensitivity of TAS be optimized in detecting residual hotspots for LF transmission?** A: Currently no guidelines exist. However, having smaller size EUs, better formation of EUs, and revisiting schools with positive children in future TAS could help detect hotspots.
- **Q: Are there any other methods for assessment of LF disease to be used instead of TAS?** A: Currently, the pre-TAS followed by TAS1, 2 and 3 are the only methods recommended for programmatic decision making. These are also the criteria by which a programme will be held when assessing achievement of elimination of LF as a public health problem.

TAS Results and Follow Up

- **Q: How do you follow-up on positives found during TAS?** A: Treat the individual. May follow the algorithm in the TAS manual on page 77.
- **Q: According to the TAS manual, positive test results should be followed up with a night blood smear. This is the common practice in Indonesia for Brugia-endemic EUs. It wasn't clearly described in the manual for Bancrofti EU. However, in your presentation, the follow up for positive and invalid results is treatment for both Brugia and Bancrofti EU.** A: Since not all programs follow up positive antigen or antibody results with a night blood smear, best practice is to be conservative and treat any positive or indeterminant results.
- **Q: In TAS2 or TAS3, how do we deal with positives, do we treat them? them only or who else needs treatment? and for how long?** A: Treat the individuals. Target these areas for ongoing surveillance. Areas surveyed that exceed 2% Ag can be targeted for treatment.
- **Q: What is the intervention suggested for EUs which passed TAS, but had sampled villages/schools with more than 2 positives?** A: Treat positive individuals, target the communities for surveillance, consider further investigation of the community to determine whether targeted treatment is warranted. This is an opportunity to consider breaking up EU for TAS2/3 and focus ongoing surveillance activities in that area to see if it is a hot spot. In addition, use what's available in TAS manual on following up positive TAS children.
- **Q: What to do with an IU where more than 2% of people are found positive during an operational research in an EU which qualifies for TAS3?** A: For any situations with operational research results, notify and seek advice from WHO.
- **Q: What happens in EUs that pass TAS3?** A: EUs should be congratulated, and national programs should inform those areas that they have fulfilled one of the criteria for elimination of LF as a public health problem. The EUs should then be transitioned to surveillance, although we recognize that there is a lack of standardized guidance from WHO on surveillance. 16 countries have been validated as having eliminated LF as a public health problem, and so we can learn from their practices and lessons learned. WHO is currently considering health facility-based testing, conducting LF-specific surveys in high risk areas, or including LF indicators in any routine surveys for other programs which requires collaboration with MOH. Xenomonitoring is also a potential approach.

Failed TAS

- **Q: Concerning the failed Pre-TAS and TAS districts, are there any global updates and experiences?** A: The rate varies by country. At least 14 countries have failed a pre-TAS or TAS in at least 1 IU. Don't know the pre-TAS fail rate, but less than 5% have failed TAS overall.
- **Q: What becomes of an EU which having passed TAS twice fails a third TAS**? A: Consult WHO, perhaps re-survey with smaller EUs, and/or implement targeted MDA.
- **Q: When should you resume MDA after fail?** A: As soon as possible.
- **Q: Besides conducting MDA after TAS failure, what else should be done?** A: Review checklist that available, to investigate reasons why. WHO recommends enhanced MDA – for example, revisit social mobilization messages, and conduct an assessment for reasons why the TAS

failed. TAS failure is often related to insufficient coverage, but areas with high baseline often take more rounds to bring prevalence down. Microplanning has been used by vaccination programs and has also shown to be valuable for IDA. Vector control is feasible in some settings, specifically helpful in areas of malaria, where same vector.

STH TAS

- **Q: Is there a way to do community-based clusters for STH TAS, or only methodology for school-based surveys?** A: Programs can collect stools in community-based TAS (not just school-based).
- **Q: Could you also do SCH sampling during that survey?** A: Yes; programs can measure intestinal SCH with Kato-Katz that are already being used in the STH TAS, and could add diagnostics to assess urinary SCH. That said, the program needs to consider the value of this addition, given the focal nature of SCH.

Other

- **Q: Will there be any discussion on iTAS?** A: If the programme feels that adding oncho data to the TAS is beneficial, then include. The iTAS methodology is still in the operational research phase.
- **Q: Is molecular xenomonitoring an accepted tool to use independently for Pre-TAS or TAS?** A: Currently programme decisions are made only on microfilaremia (mf) and antigen (Ag) [or antibody (Ab) in *Brugia* spp. areas].
- **Q: What is the WHO perspective on using EDC?** A: Use it when resources are available – it's better than paper-based data collection. See slide 36.
- **Q: What are the opportunities of setting up surveillance with STH programs in co - endemic districts?** A: Take any such opportunity to set up integrated surveillance.
- **Q: Do you think in hard to reach areas, infections can be reduced?** A: Yes, we have data from areas in countries such as Papua New Guinea and Timor Leste that show that infection has been reduced, even in very difficult to reach areas.
- **Q: What disposition to take in a context of high mobility of the population?** A: See slide 51.
- **Q: What does IDA mean?** A: IDA stands for Ivermectin+DEC+Albendazole and is a three-drug regimen recommended for use in certain LF-endemic areas. See the WHO Alternative MDA Regimens to Eliminate LF guidelines for more information.
- **Q: Supply chain management and drug procurement may affect the survey. How do we tackle the same?** A: Requests for FTS should be submitted to WHO as soon as possible, allowing for at least 12 weeks from cleared request to delivery, not including customs clearance.
- **Q: What to do in post-validation surveillance?** A: Post-validation surveillance should be specific to the setting of the country, taking advantage of existing platforms for surveillance that could include LF. WHO is monitoring ongoing operational research to identify tools, new diagnostic tests and standardized methods that have potential for use in post-validation research.

Programs will also have to respond to surveillance results, which may include testing and treatment, additional investigations or groups for targeted treated.

- **Q: When to start dossier preparation, after clearing TAS3 in all EUs or any single EU?** A: Dossier preparation can begin anytime – the earlier, the better. Data gathering and archiving should start as soon as possible. Programme managers should consider preparation of the data for the dossier and narrative sections as soon as all endemic IUs have completed TAS1.
- **Q: TAS results from west Africa?** A: We didn't have time to discuss regional or individual country results in this presentation.
- **Q: Why LF can't be cured?** A: Some damage due to infection can't be reversed. It's the chronic effect of that irreversible damage that can be managed to prevent suffering.