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National SOP for the use of dCXR for TB screening

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TB Think Tank Annual Meeting

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Presentation Outline

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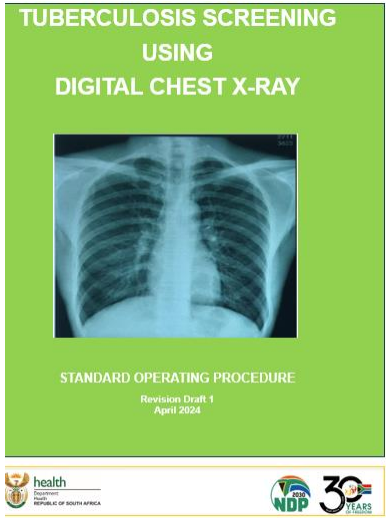
- SOP Goal and Purpose.
- Note on scope.
- DCXR TB screening Algorithms (Community and PHC).
- Key changes to note.
- A Note on Current Thresholds
- Next steps.
- Examples of High Priority Research Questions.



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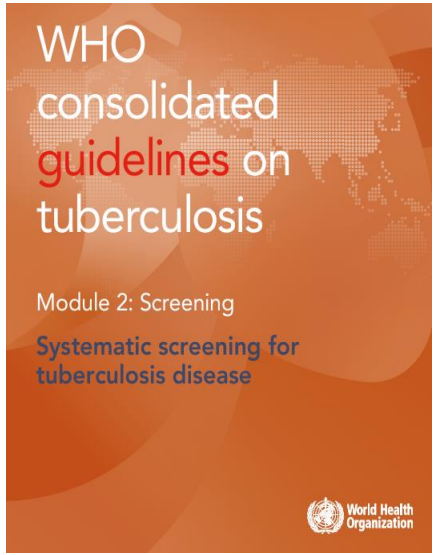
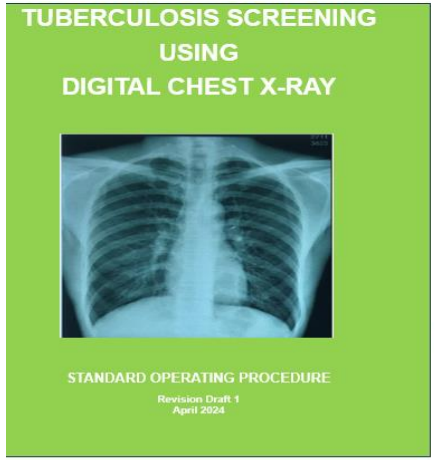
The Big Picture

VISION	**A world free of tuberculosis** – zero deaths, disease and suffering due to tuberculosis			
GOAL	**End the global tuberculosis epidemic**			
INDICATORS	**MILESTONES**		**TARGETS**	
	2020	**2025**	**SDG 2030**	**END TB 2035**
Reduction in number of TB deaths compared with 2015 (%)	35%	75%	90%	95%
Reduction in TB incidence rate compared with 2015 (%)	20% (<85/100 000)	50% (<55/100 000)	80% (<20/100 000)	90% (<10/100 000)
TB-affected families facing catastrophic costs due to TB (%)	Zero	Zero	Zero	Zero

Background

- While digital chest x-ray with artificial intelligence (dCXR+AI) has the potential to be a powerful tool for TB screening, its use in SA to date has not been standardized.
- The Finding Missing People with TB (FMP) Task Team sought to develop a national standardized SOP for the use of dCXR+AI for TB screening in targeted community settings and Primary healthcare clinics (PHCs).
- Through an extensive consultative and evidence-gathering process, a Standard Operating Procedure (SOP) has been developed with standard algorithms.





SOP Goal and Purpose

Goal

- to standardise the use of dCXR+AI technology for TB screening in South Africa to improve TB case-finding.

Purpose

- to outline inclusion and exclusion criteria for TB screening by dCXR+AI in community and PHC settings.
- to provide management and referral recommendations based on screening information and dCXR+AI results.

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A Note on Scope

- While this SOP focuses only on dCXR+AI for TB screening, it does not prevent the use of dCXR+AI results as an additional diagnostic tool for TB diagnoses.
- Given the numerous clinical elements to consider, dCXR+AI results in diagnosis are too numerous and complex to outline in an SOP.
- Therefore, dCXR+AI as a diagnostic tool is not covered in this SOP.

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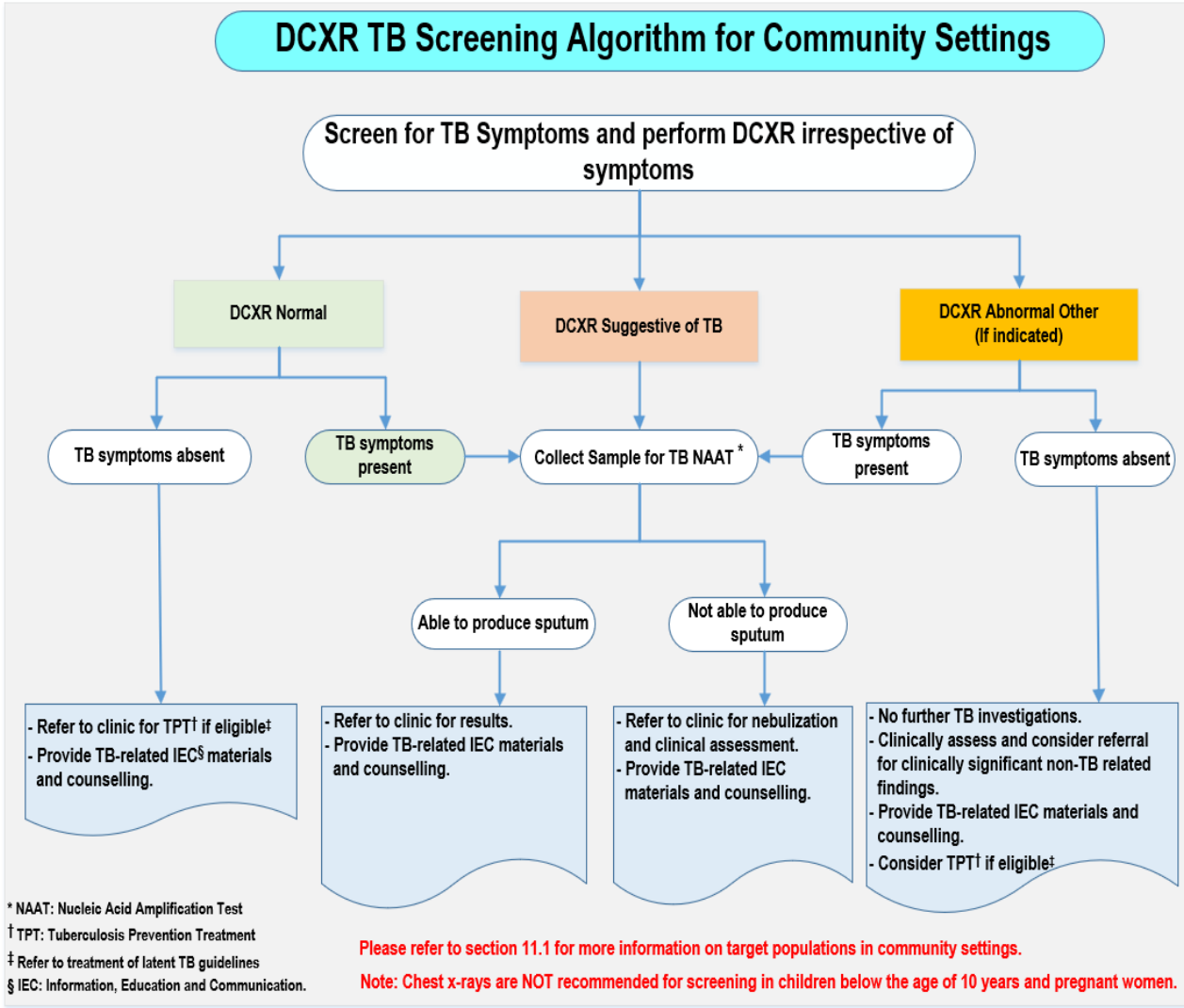
Community algorithm

- All people attending targeted community screening events will be screened by dCXR unless pregnant, <10 years of age, or currently on TB treatment.
- Community units will target populations that are less likely to present to clinics, including working-aged men, migrant populations, miners/ex-miners, the homeless, substance users, people in congregant settings, and those with poor healthcare access.
- NHLS data and geo-spatial mapping will also be used to help identify TB hotspot areas.
- Throughput will be improved by asking medical history and detailed contact information after participants screen positive by dCXR or symptoms screen.

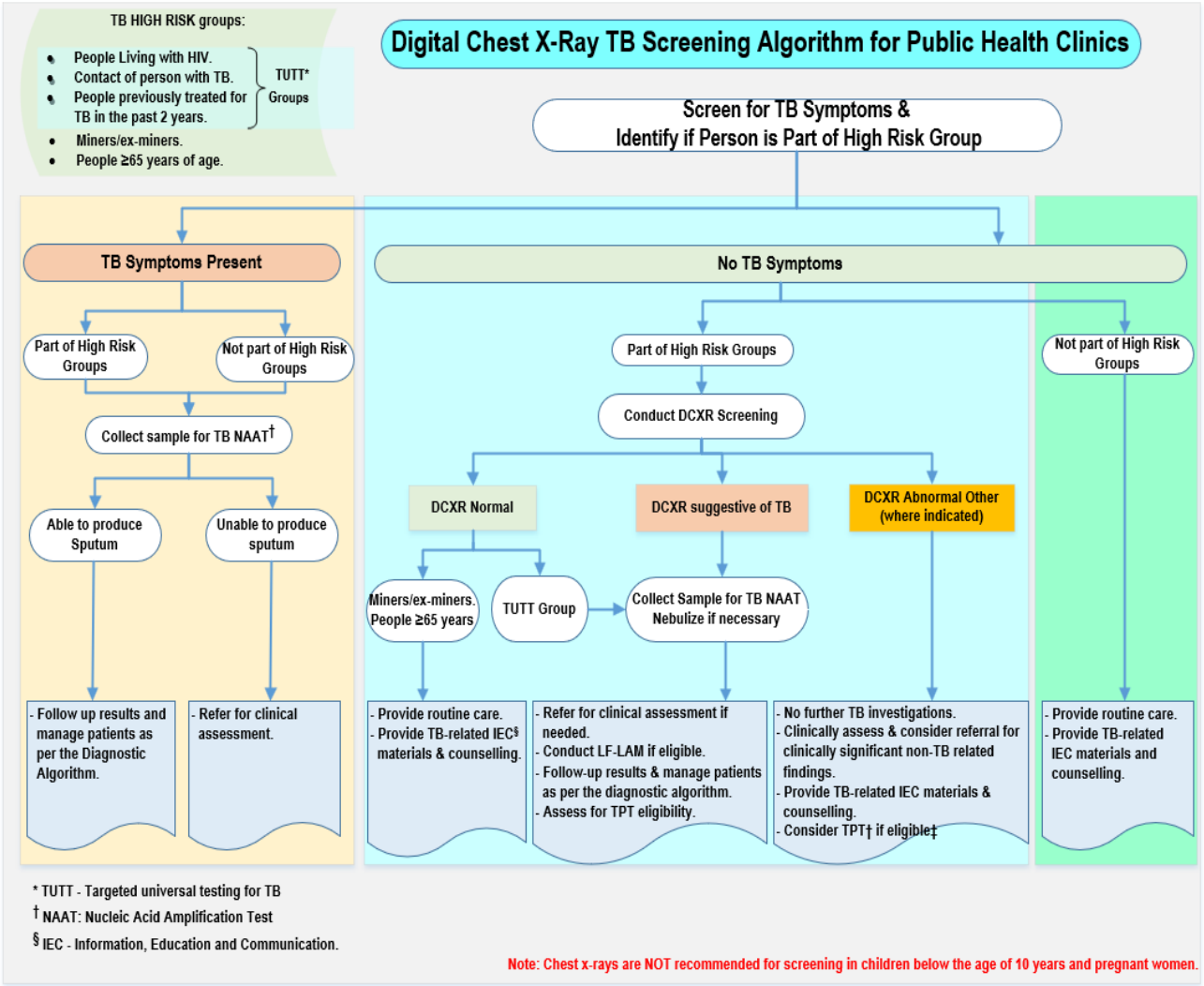


PHC algorithm

- Populations to be screened by dCXR in PHCs include Targeted Universal Test and Treat (TUTT) groups as well as people ≥65 years, miners and ex-miners.

- TUTT groups will continue to be tested by TB NAAT (e.g. Xpert ultra) regardless of symptoms and dCXR result; however, data on TUTT groups without symptoms will be further analysed to determine if each group still requires TB testing following a normal dCXR result.

- People with diabetes who do not meet other high-risk criteria are not currently prioritised for dCXR as there is no evidence to support increased dCXR+AI screen-positivity in this population in South Africa.



Next Steps

- The SOP has been reviewed by NDOH and is undergoing a final stage of editing and circulation.
- Screening and referral forms are being updated to align with the new algorithms and data fields in the systems used to input dCXR-related data are also undergoing revision to align with algorithms.
- The FMP Task Team leads are working with the TB Think Tank Secretariat to develop an ethics application for high-priority research questions to facilitate additional data collection by implementing agencies.

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A Note on Current Thresholds

- Work by AHRI identified that different versions of AI software may necessitate different thresholds (Fehr et al, *NPJ*, 2021).
- E.g. In rural KZN, a threshold of 20 in CAD4TB version 7 was equivalent to a threshold of 60 in CAD4TB version 5.
- The current CAD4TB v. 7 threshold has been lowered to 20 in 5 mobile units to test the appropriate threshold across settings. These data, once analyzed, will inform current recommendations.
- QURE.AI maintains a threshold of 0.50 in all qXR versions to date.

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Examples of High Priority Research Questions

- Ability to rule out TB disease in TUTT groups with no symptoms and normal chest x-rays.
- Sensitivity and specificity of dCXR+AI in children <10 years of age.
- Increased efficiency in PHCs among high-risk populations with TB symptoms.
  - Reduce testing demands when dCXR is normal.
  - Speed up diagnosis when dCXR is TB suggestive.

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Acknowledgments and Appreciation

- All stakeholders that contributed to the development of this SPO and Algorithms.
- These include but are not limited to:
  - ✓ WHO, Global Fund, USAID, CDC, Gates Foundation
  - ✓ DoH Clusters.
  - ✓ THINK Tank Exco.
  - ✓ District Support Partners funded by (PEPFAR, USAID and CDC).
  - ✓ Sub Recipients funded by the Global Fund.

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Thank you!

Important Note:
From today to 31st December 2035

Total Months to go: **139 months**	Total Weeks to go: **605 weeks**
Total Days to go: **4239 days**	Total Hours to go: **101,725 hours**
Total Minutes to go: **6,103,552 minutes**	Total Seconds to go: **366,213,167 seconds**