Specifications for Point-of-Care *TB Tests*
Expert Opinion Check from TB Field Practitioners

Analysis Report

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The Expert Opinion Check

Objective:

To better identify the medical needs encountered in TB field practices, in order to define the intended use a new POC diagnostic test for active TB should have.

Opinion Check Format:

- Questionnaire composed of a mix of open, semi-open and ranking questions for a total of 21 questions and addressing:
  - Context of practice of the participant
  - Gaps in current diagnostics tools
  - Intended use of a new TB POC test
  - Population needed to be targeted by a new TB POC test
  - Appropriate specimen sample type desired

- Answers and comments were captured over individual phone interviews

The Expert Opinion Check

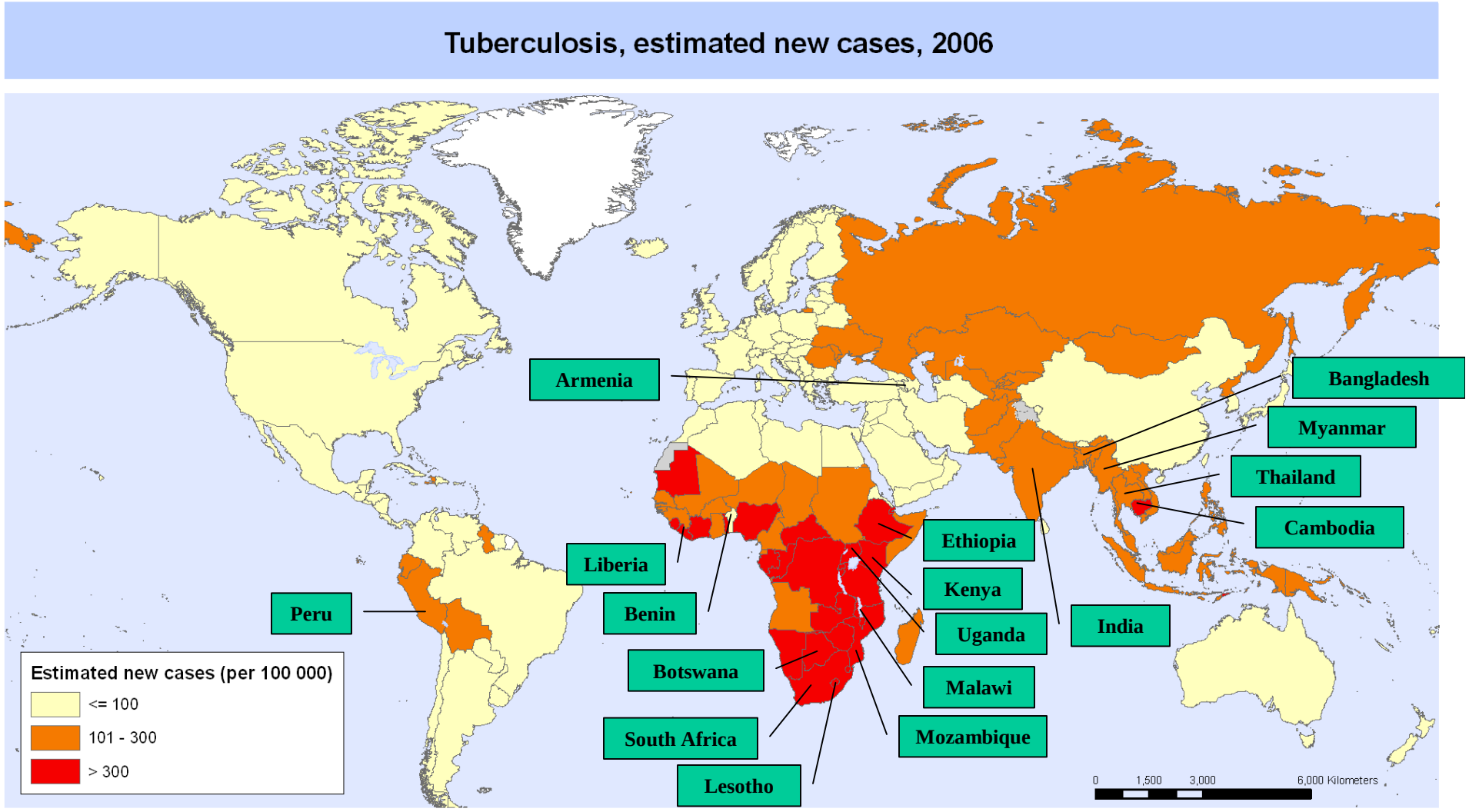
Contact Methodology

- Over 75 email invitations were sent out to participate in the opinion check
- 30 invites did respond and participated in answering the Questionnaire
- Opinions from all participants were collected through phone interviews (approx 45 min each)
- All phone interviews were done between Jan 30th Feb 24th 2009

Surveyed Group

- An heterogeneous group composed of TB practitioners involved at all levels of care, together with professionals in charge of TB programs at national level or working in a research institution
- 30 participants were surveyed from 17 different countries of practice

Participants Country Distribution



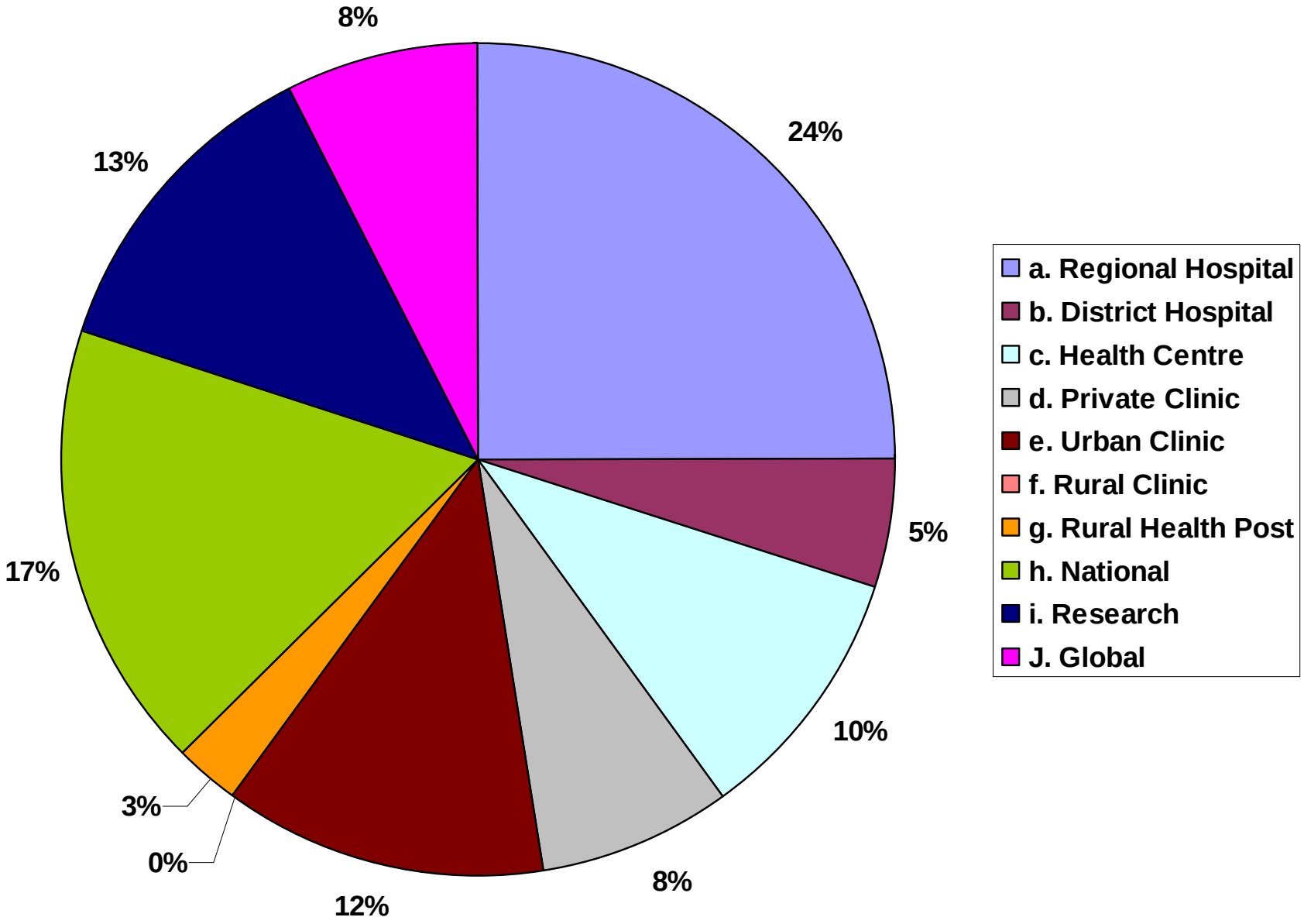
The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization
Map Production: Public Health Information and Geographic Information Systems (GIS)
World Health Organization

World Health Organization

Health Care Structure Level

Overall Participant Experience



Suspected TB Populations Seen

• Children <15 yrs were treated in the majority of the settings.

• The 1/3 of the participants able to estimate the % of suspected patients <15 yrs, mentioned that this group represented > 20% of all suspected cases in their setting.

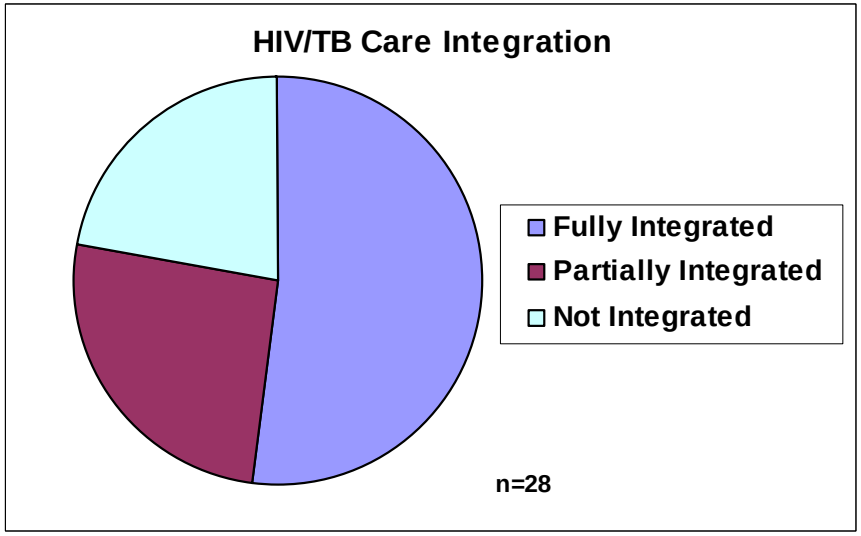
• 3/4 of the participants able to estimate the % suspected TB cases presenting with HIV co-infection reported this group as representing >25% of suspected cases.

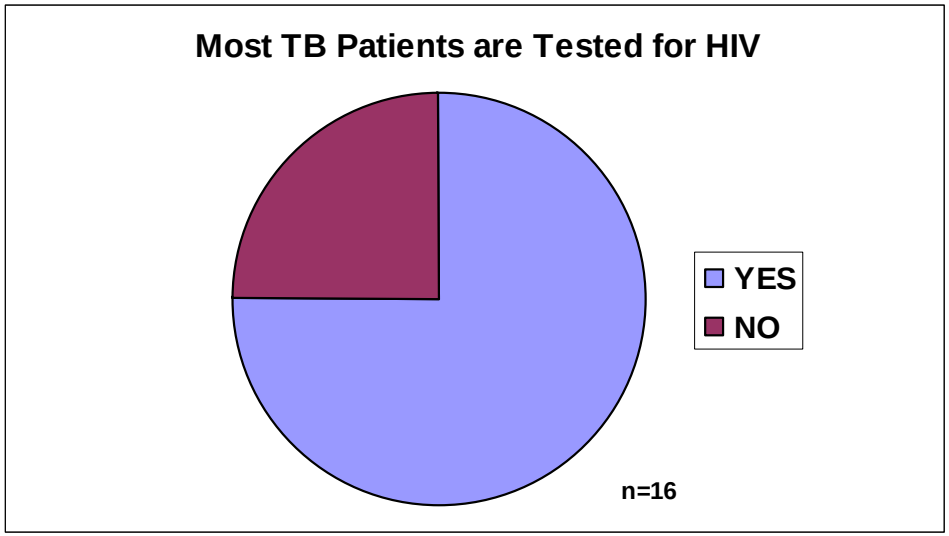
• 80% of the participants able to estimate the % suspected TB cases presenting with EPTB reported this group as representing >20% of all suspected cases.

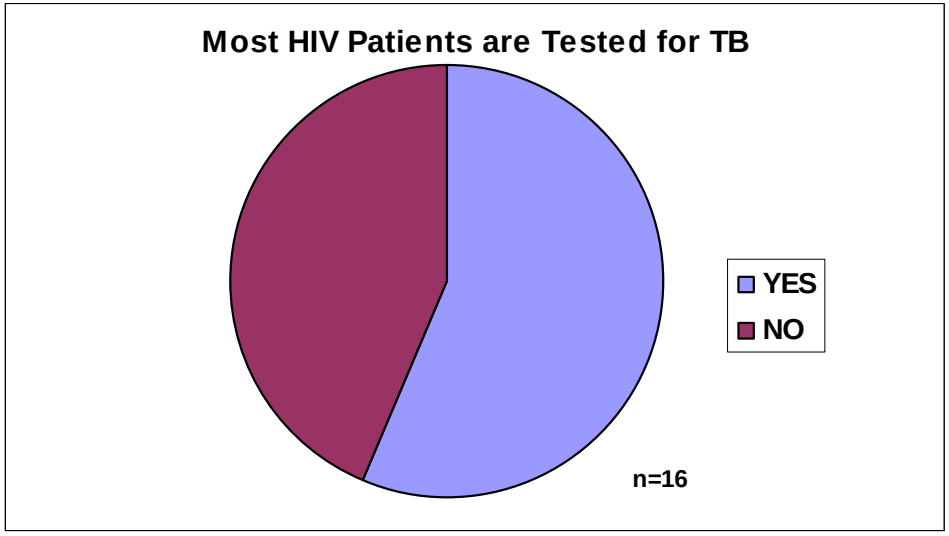
• Less than a third of the respondents were able to provide data on drug resistance, primarily due to the lack of technical means available in the country.

- Among them, half of the settings had a DR-TB rate > 3%

TB/HIV Integration

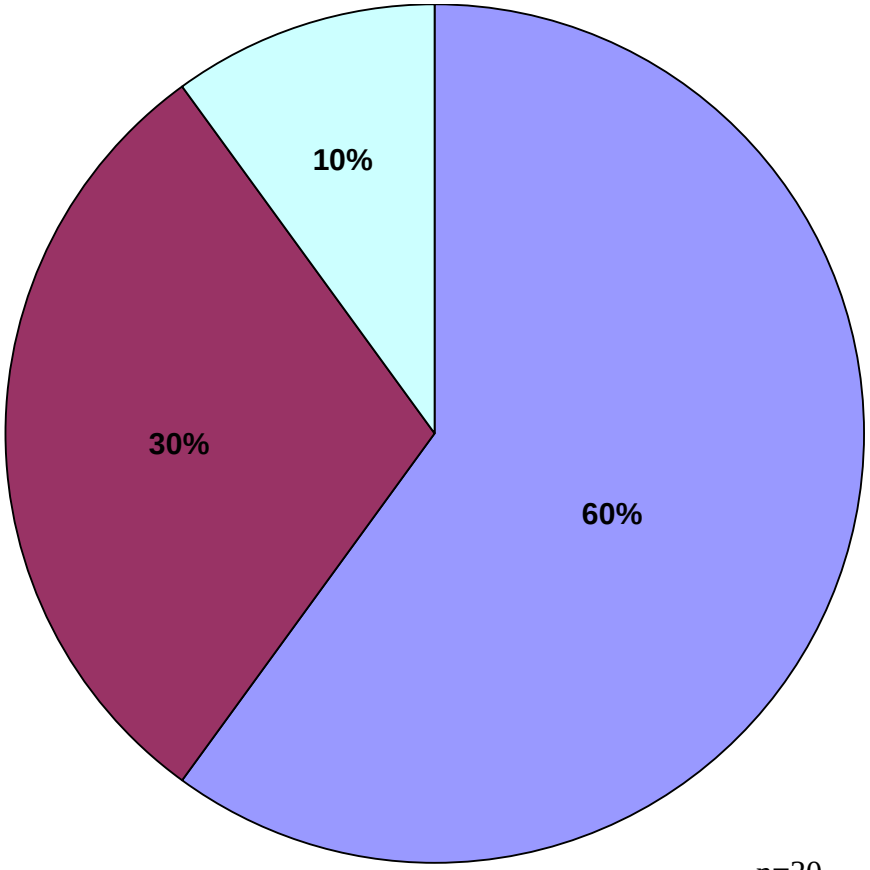






Expectections from a POC TB Test

Participant Interpretation of "Point-of-care"



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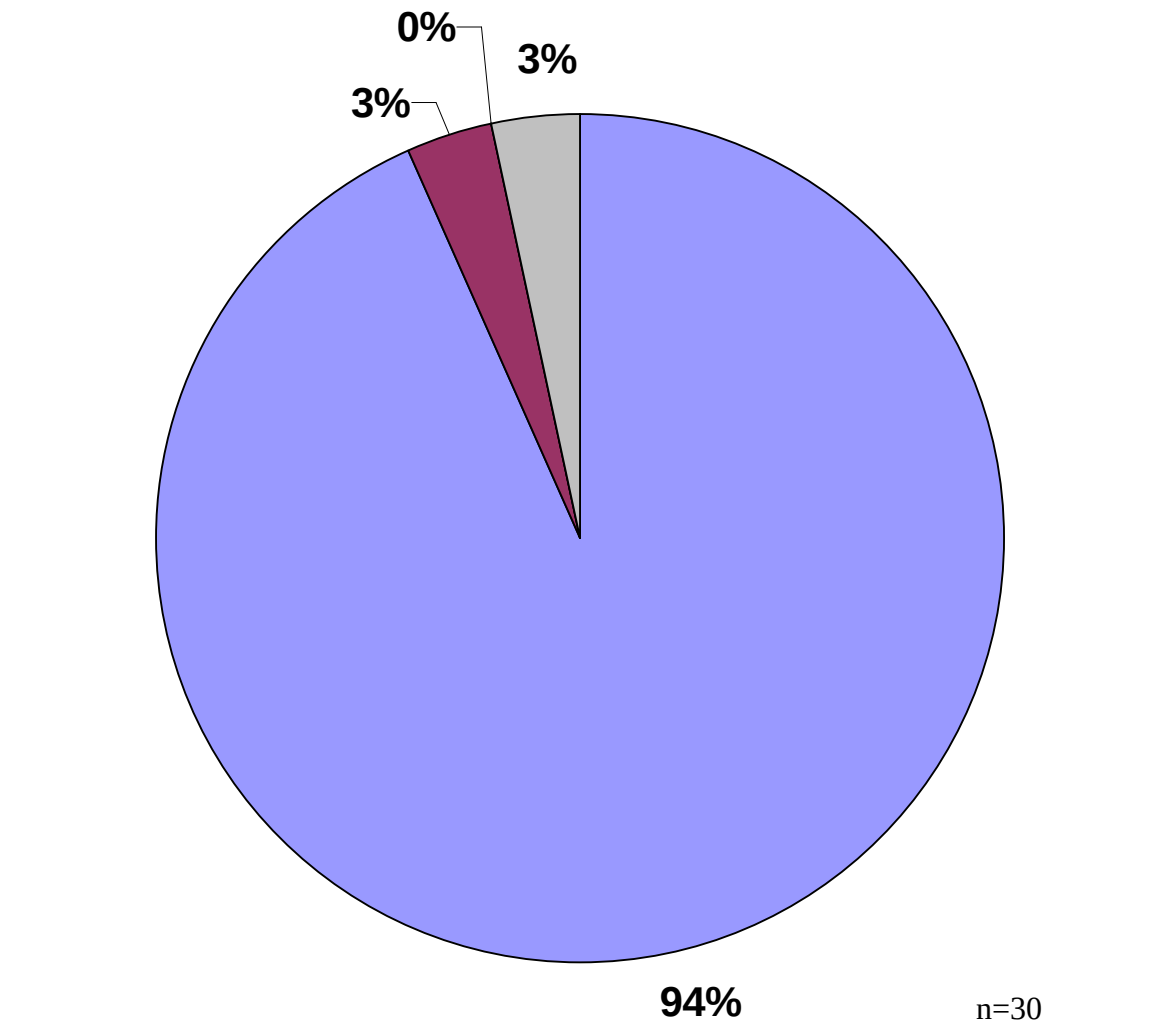
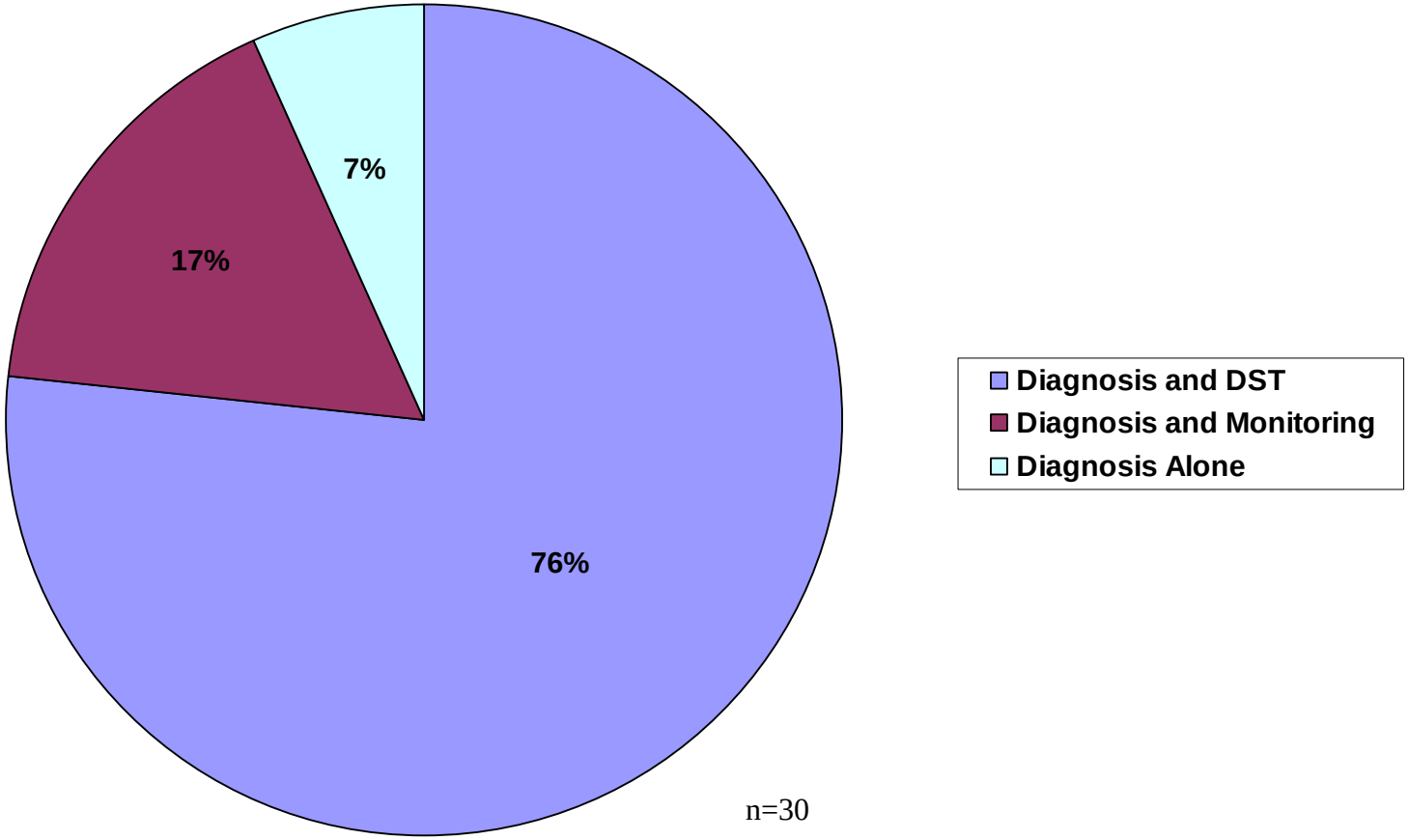
- a. at point of care where you treat the patients.
- b. at point of collection of samples where the patients can be seen by community health worker.
- c. anywhere else? Please complete with your own definition.

Medical Decisions to be Influenced



Preferred Combination of Test Analyses Among Diagnosis, DST and Treatment Monitoring



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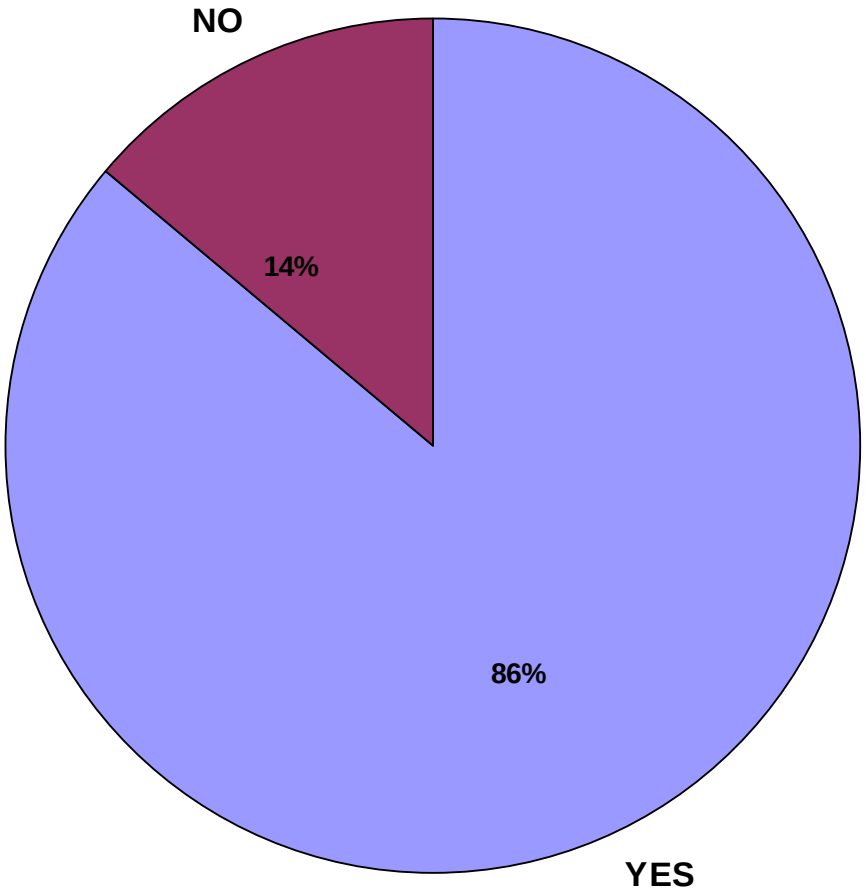
The vast majority of participant would preferred a test which combines Dx and DST if feasible

Acceptability of a 2-3 Test-algorithm for Treatment Initiation



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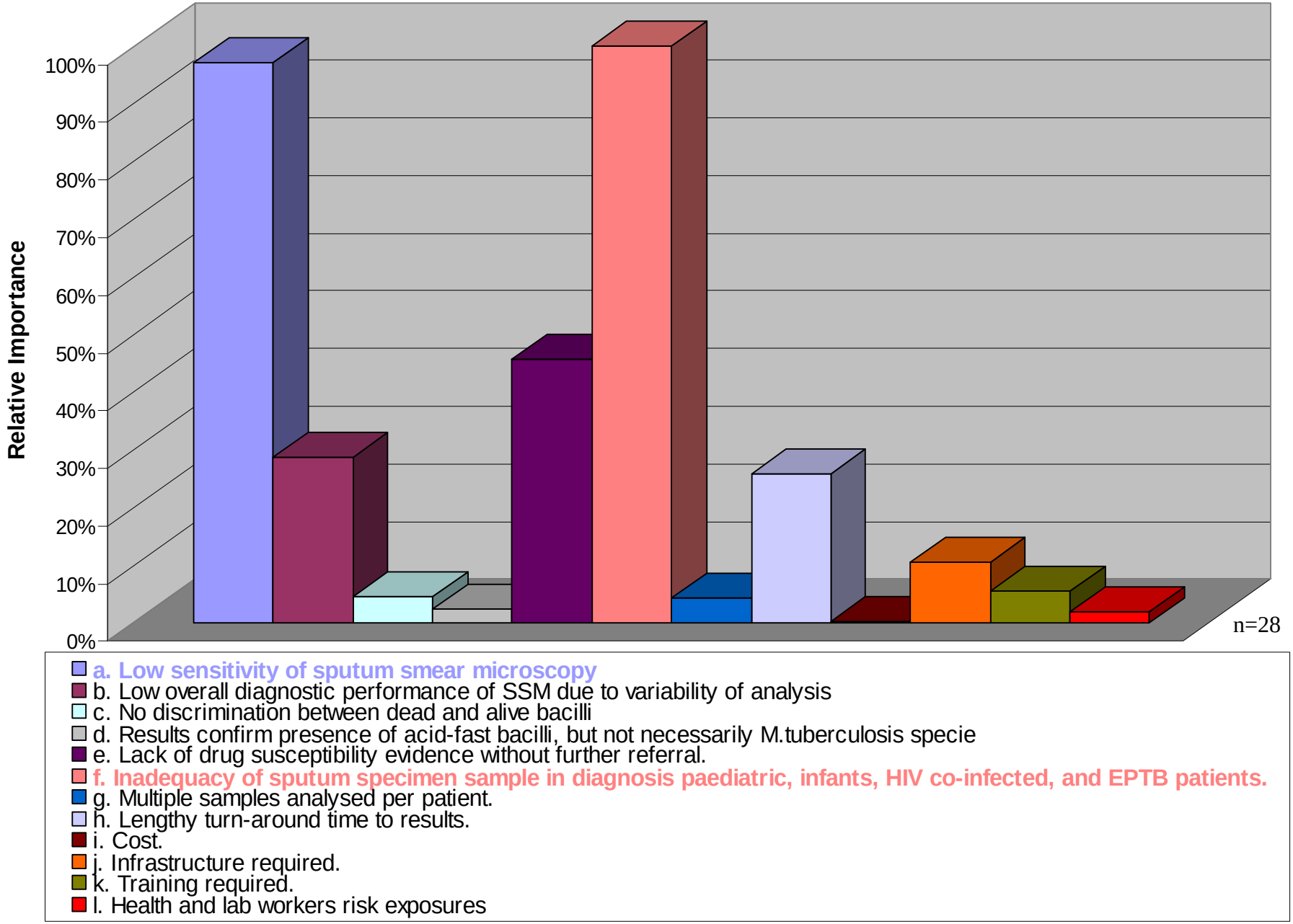
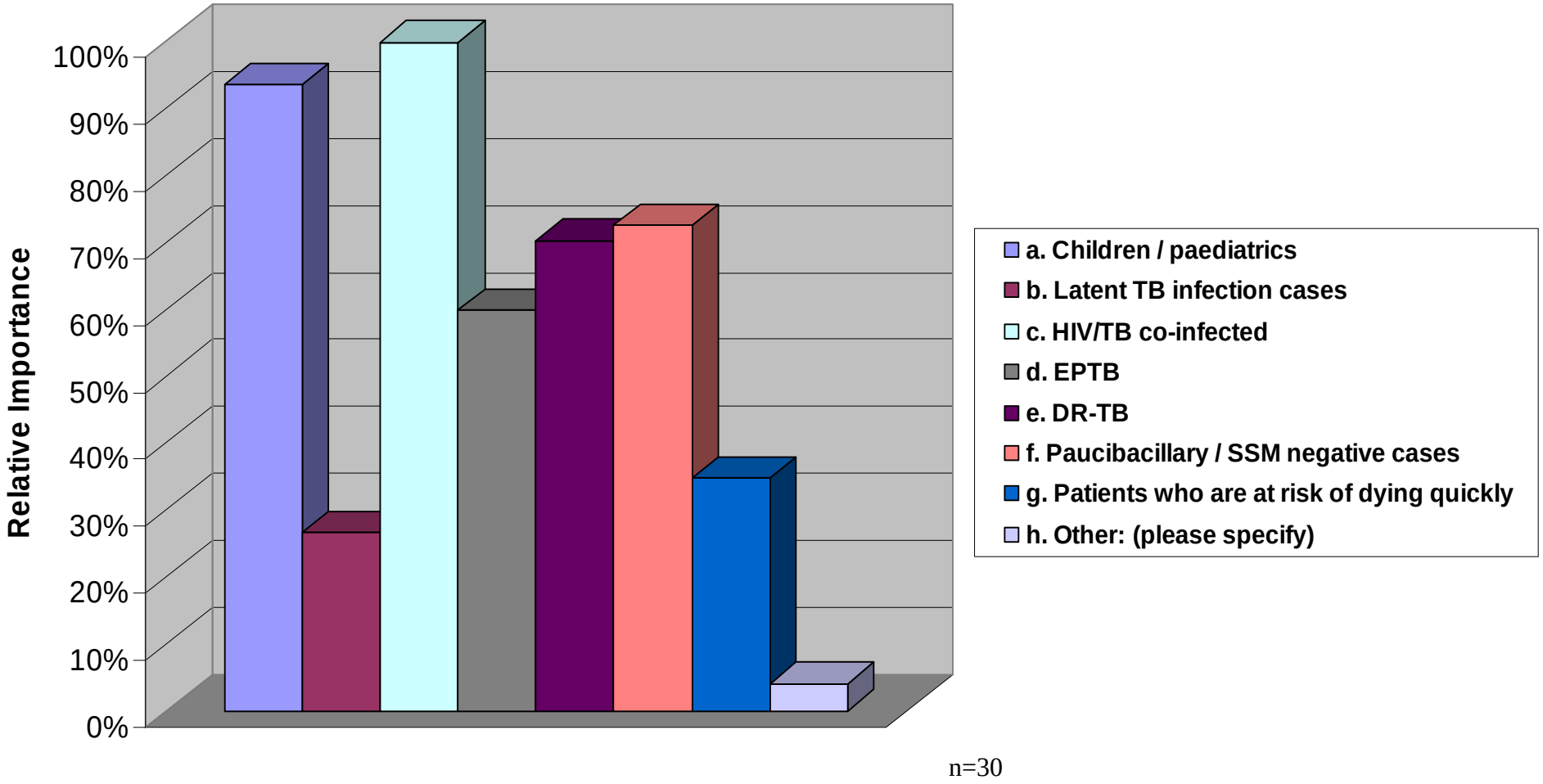
Current Gaps
Faced by Participants

Current Gaps in TB Diagnostics



Populations Essential to Diagnose in Addition to Non-HIV Adults



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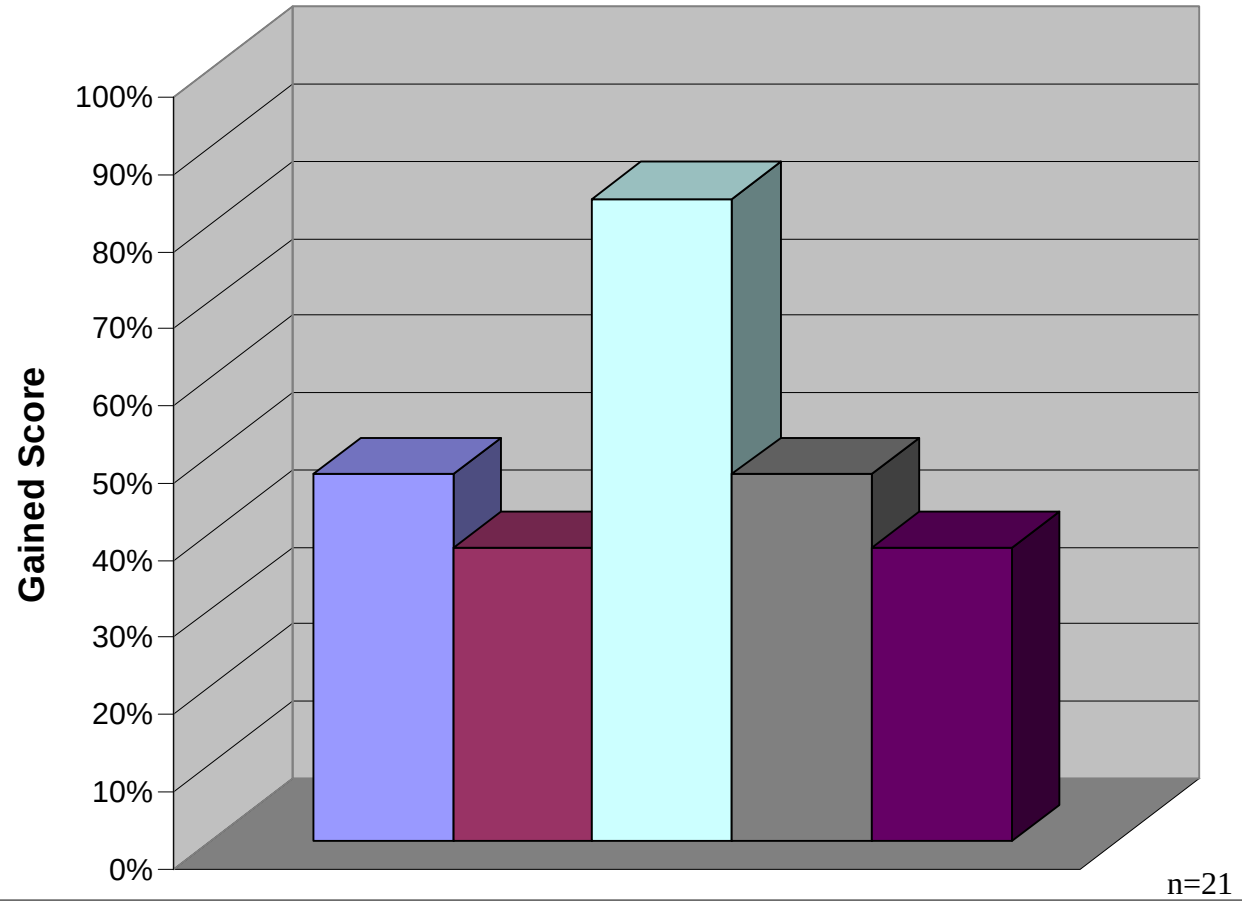
Ranking Test Options - Specification Trade-offs



a. Similar performance to SSM, sputum-based, but more rapid and more accessible

b. 90% sensitivity, 95% specificity, diagnosing active pulmonary TB, only in HIV negative adults

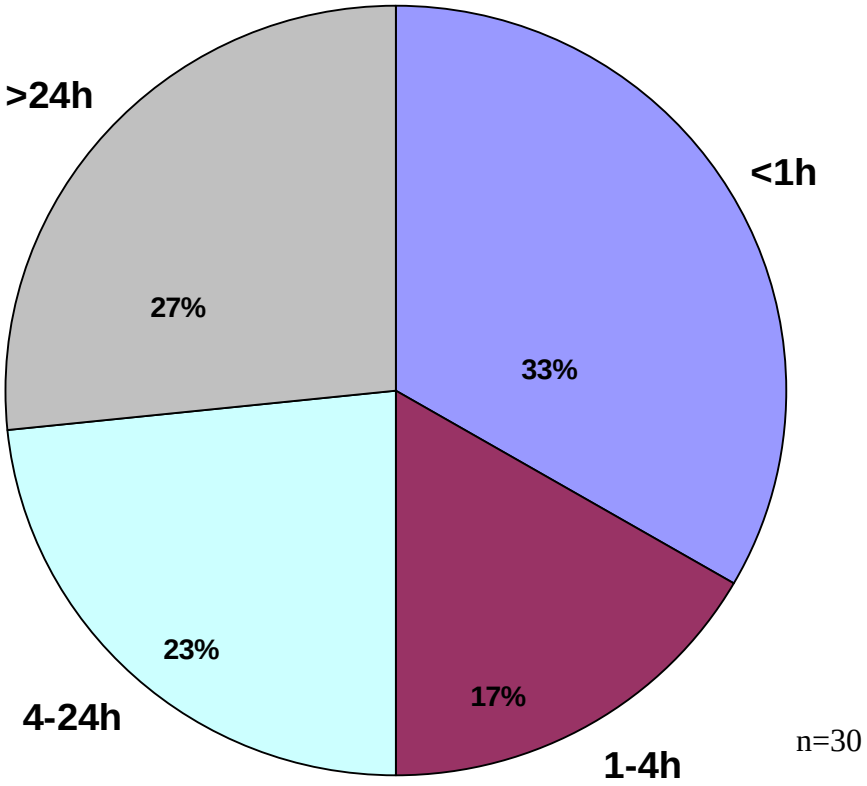
c. 75% sensitivity, 95% specificity, diagnosing active pulmonary TB, irrespective of the HIV status and age

d. 60% sensitivity, 95% specificity, diagnosing active pulmonary and EPTB, irrespective of the HIV status and age

e. 60% sensitivity, 95% specificity, diagnosing active pulmonary, irrespective of the HIV status and age, and inlcluding DST information

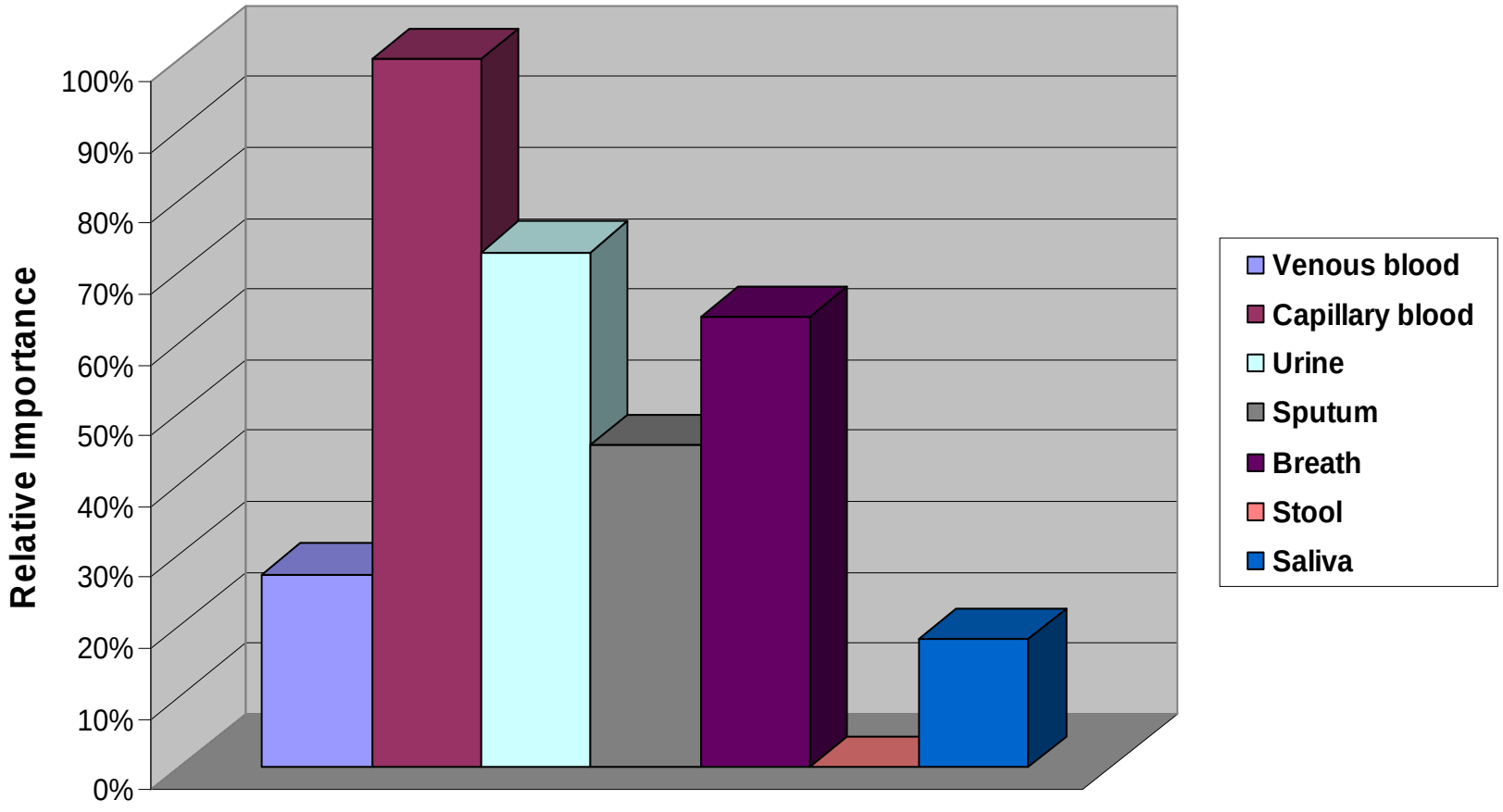
The Use of a Future TB POC Test

Acceptable Turn-Around Time
for a POC TB Test



- Strong agreement among participants to have the Dx test result available to the patient on the same day of sample collection (same visit)
- If DST is also performed by the test, its result could take a bit longer

Preferred Specimen Sample-Types



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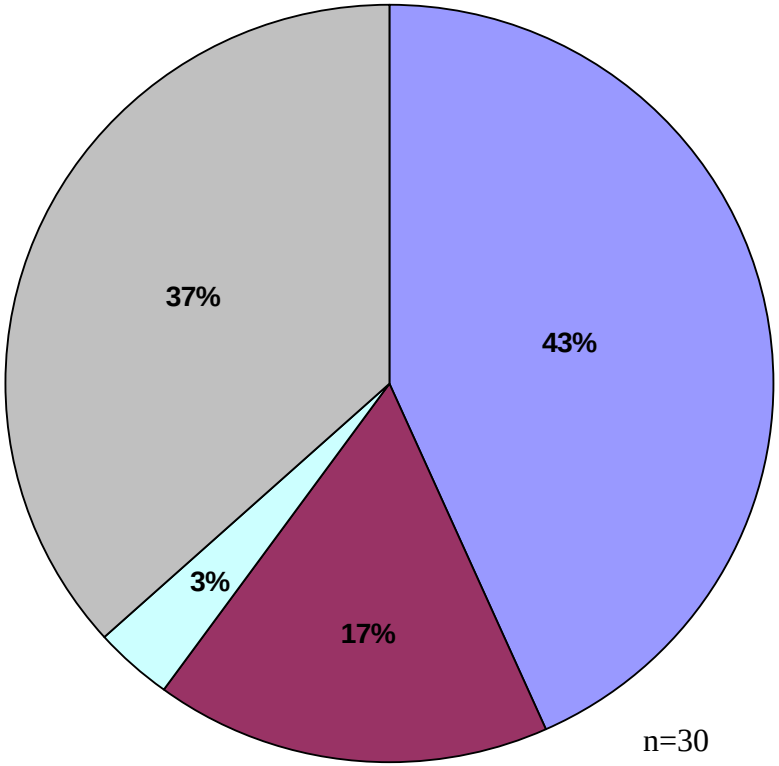
Categories of Health Workers Expected to Use a TB POC Test



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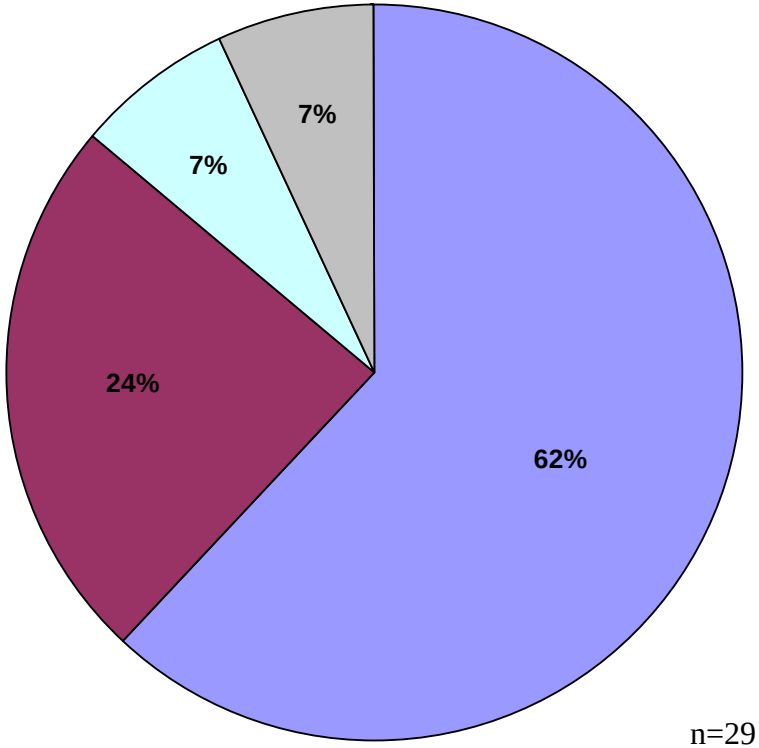
- a. Lab Staff
- b. Nurses
- c. Medical Doctors
- d. Community Health Workers

Feasibility of Nurses and/or CHW to Perform the POC Test



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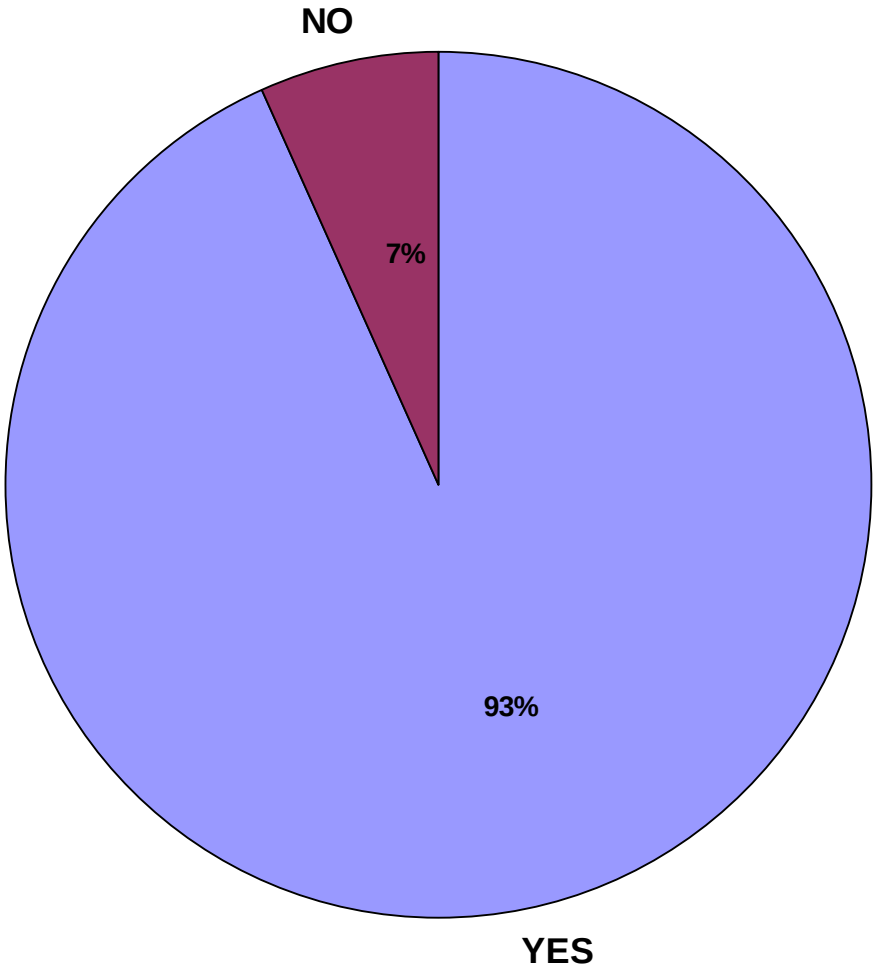
- Reasonable
- Difficult
- The only way
- NA

Acceptability of a Purely *Qualitative* Result



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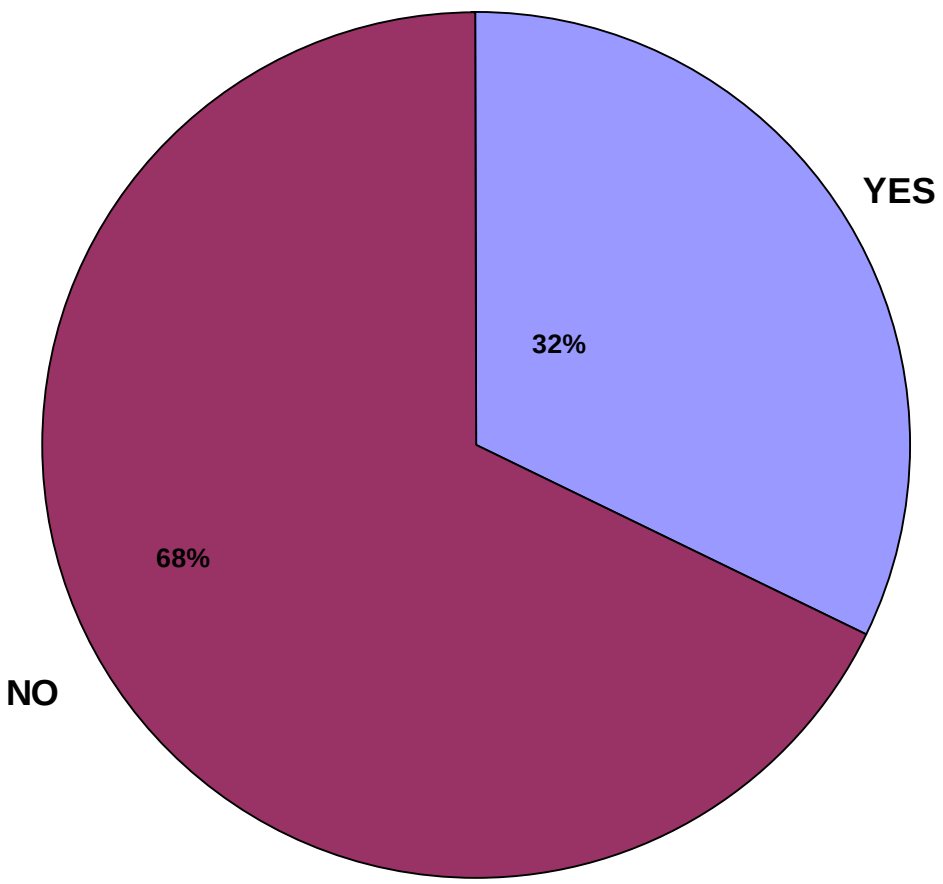
Potential Impact of a *Quantitative* or *Semi-quantitative* TB POC Test on Patient Treatment



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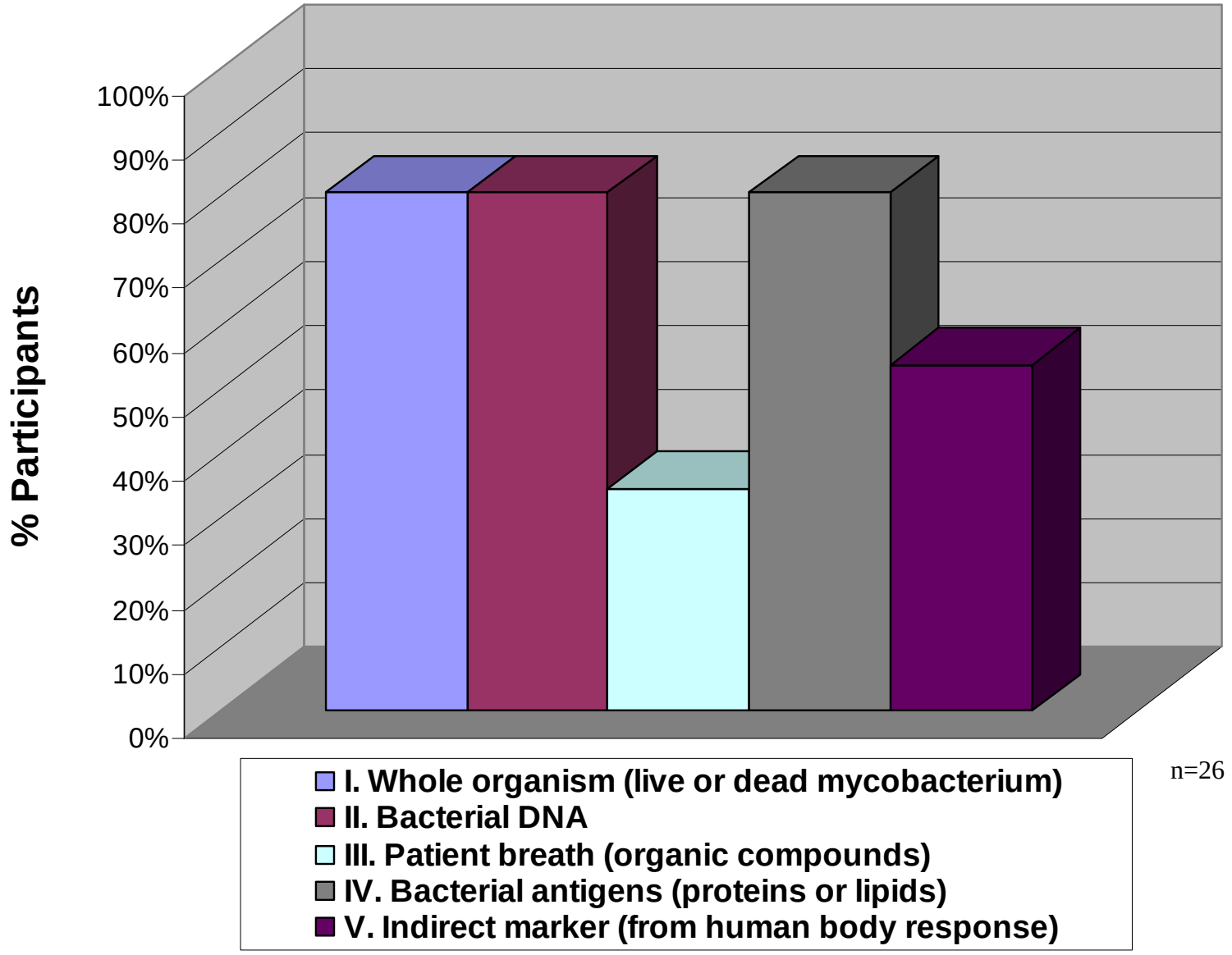
Willingness to Rely on Various Detection Methods



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In Summary

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Main Conclusions

- The POC test should be used at the place where patients are treated
- The POC tests should enable to communicate the result to the patient on the day of collection (could be longer if also provides DST)
- The POC tests should be designed in a way that nurse and/or CHW could use it
- The POC test should allow direct treatment initiation and ideally also provide DST information
- The POC test should be qualitative and a YES/NO answer is sufficient
- The POC test should be adapted to non-invasive samples, either capillary blood, urine or breath
- The POC test must be able to diagnose active TB in HIV/TB co-infected and children, followed in importance by paucibacillary, DR-TB and EPTB
- The POC test should aim to be adapted to a broader population (HIV, children) rather than super high sensitivity in a restricted population

In a Nutshell…

The POC test should AT LEAST diagnose active pTB in ALL patients, be used by nurses or CHW where patients are treated and allow results from capillary blood, urine or breath samples in less than a day with a confidence level not lower than 75% and preferably also give DST information .

Acknowledgements

Many thanks to all participants surveyed for their generous time and active contribution to this Opinion Check.
Many of them took special care to gather information and feedback from their colleagues, organizing internal discussion among their team, which has drastically enriched the data collection.

A special thank you to Mrs Martine Guillerm who contributed significantly to the questionnaire design and allow the capture of the data by holding all the phone interviews.

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