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Manuscript writing

Dr. Jayashree K, MD

Scientist -D

ICMR- National Institute of Epidemiology

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Session objectives



At the end of this session, you must have a basic understanding of how to do the following in your manuscript

- Organize the ideas logically and sequentially within a defined structure
- Furnish additional information before submission
- Articulate the content to deliver the message effectively



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Manuscript

- A document submitted for publication

Scientific manuscripts

- Original article
- Review
- Correspondence
- Perspective
- Editorial

Merriam-Webster dictionary



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Before we begin writing

- Product of the analysis
 - Tables and figures
- Key points and recommendations
 - Central 2 to 3 ideas
- Outline of the argument



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The IMRD structure

- **I**ntroduction
 - *Why did you start?*
- **M**ethods
 - *What did you do?*
- **R**esults
 - *What did you find?*
- **D**iscussion
 - *What does it all mean?*



Example

- Choose an original article of your choice
- My article for demo



Introduction

- Zooming in
- Background
- Knowledge gap
- Rationale
- Objectives



Public Health Action

International Union Against Tuberculosis and Lung Disease
Health solutions for the poor

VOL 10 NO 3 PUBLISHED 21 SEPTEMBER 2020

Impact and operational feasibility of TrueNat™ MTB/Rif under India's RNTCP

K. Jeyashree,¹ D. Shanmugasundaram,¹ K. Rade,² R. R. Gangakhedkar,³ M. V. Murhekar¹

Zooming in

Background

TB is the leading cause of death due to a single infectious agent.¹ In 2018, the estimated incidence of TB in India was 204 per 100 000 population,² with a mortality of around 31 per 100 000.¹ It has been estimated that a rapid and widely available diagnostic test for TB with sensitivity of $\geq 85\%$ for smear-positive and smear-negative cases, and a specificity of 97% can save ~400 000 lives annually.³

Sputum smear microscopy (SSM), which is the cornerstone of TB diagnosis in India, has several limitations, including low sensitivity.⁴ TrueNat™ MTB/Rif (Molbio Diagnostics, Verna, India) is a rapid molecular test launched by Molbio, a Make In India Company, as a commercial product for diagnosis of active TB. It is a portable, battery-operated, chip-based test which detects *Mycobacterium tuberculosis* (MTB) in approximately 1 h and rifampicin (RIF) resistance in another 40–60 min.

TrueNat MTB has high sensitivity (91.1%) and specificity (100%) compared with a composite reference standard consisting of smear and culture results, clinical treatment and follow-up, and radiology findings.⁵ There is high agreement (92.7%) between Xpert® MTB/RIF (Cepheid, Sunnyvale, CA, USA) and TrueNat in MTB detection.⁶ TrueNat had significantly higher sensitivity than Xpert (84.1% vs. 81%; $P < 0.001$).⁷ Compared to SSM, TrueNat has been shown to increase life expectancy by 0.39 years and was also found to be cost-effective.⁸ TrueNat is less resource-intensive than Xpert.^{7,9} Deploying TrueNat at point-of-care (POC) eliminates the need for sample transportation, as is required for Xpert thus adding cost benefit, besides detecting RIF resistance during the patient's first visit. The WHO's rapid evaluation of evidence, which is expected to inform the updated 2020 Consolidated Guidelines on TB, suggests that the accuracy of TrueNat is comparable to that of Xpert.¹⁰

Based on the evidence supporting the POC use of TrueNat, the Government of Andhra Pradesh, a state in India, introduced TrueNat under its Revised National Tuberculosis Control Programme (RNTCP) at TB unit (TU) level for TB diagnosis in October 2018. After almost a year of its deployment, we evaluated its impact on microbiologically confirmed TB case detection by comparing the case notification rate of microbiologically positive TB before (January–August 2018) and after (January–August 2019) the implementation of TrueNat under the RNTCP, and assessed the operational feasibility of deploying TrueNat at POC settings.

Jeyashree K, Shanmugasundaram D, Rade K, Gangakhedkar RR, Murhekar MV. Impact and operational feasibility of TrueNat™ MTB/Rif under India's RNTCP. *Public Health Action*. 2020 Sep 21;10(3):87–91.

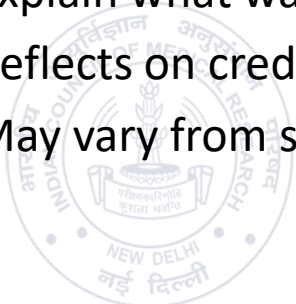
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Methods

- Explain what was done in simple terms
- Reflects on credibility and reliability
- May vary from study to study

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Methods

Provide key information

- Study settings
- Study design
- Operational definitions
- Sampling strategy
- Sample size
- Study procedures
- Data management (collection, analysis)
- Human participants protection



Methods

METHODS

Study settings

Andhra Pradesh, a state in southern India, is divided into 13 districts, and is home to a population of over 49 million, 70% of which resides in rural areas. The state has a sex ratio of 996 females per 1000 males and a literacy rate of 67.4%. Under the RNTCP, designated microscopy centres (DMCs) are the most peripheral units delivering TB care where TB diagnosis and treatment is available. At the next level, TUs oversee the DMCs and report to the district TB centres, which in turn report to the State TB centre. Diagnosis and treatment for TB is offered free of cost under the RNTCP. Besides the public healthcare system, patients can also avail of TB care from the private sector.

SSM is available from the level of DMCs and upwards. Cartridge-based nucleic acid amplification test

Study design

We compared TB case notification rates before and after the implementation of TrueNat using programmatic data from RNTCP.

Data accuracy checking

Before extracting data for analysis, we evaluated the accuracy and consistency of the data reported across all recording and reporting formats under RNTCP in the years 2018 and 2019 (Table 1). We randomly selected 10% of the TrueNat sites ($n = 25$). A data extraction form consisting of variables to be tallied across and within the reporting formats was prepared using Open Data Kit (ODK) for tablet-based data collection.

Impact of TrueNat deployment at POC for TB diagnosis

We used the following monthly RNTCP reports to extract data from January to August 2018 and January to August 2019: 1) Annexure M (monthly report on SSM), 2) TrueNat reports (report on TrueNat testing), and 3) CBNAAT reports (report on CBNAAT testing) (Supplementary Table S1). We compared the number of presumptive TB cases tested, and the number of microbiologically positive TB cases detected before and after TrueNat implementation. The period between October to December 2018 was not considered for analysis, as the sites were transitioning from SSM to TrueNat.

Operational feasibility

We interviewed laboratory technicians (LTs) and Senior TB Laboratory Supervisors (STLSs) at the 25 TUs using a semi-structured questionnaire to collect information about operational issues in TrueNat implementation. The operational feasibility was broadly assessed under the following domains: initiation of TrueNat testing in the centre, logistics, sample preparation and testing, training, time required for TrueNat testing, reporting, waste disposal, breakdown and troubleshooting.

Data analysis

Data accuracy checking

The data points generated from laboratory/culture and drug susceptibility testing (CDST) registers were considered as reference points against which other records were evaluated. For 2018, the agreement was quantified in two comparisons: 1) laboratory/CDST register vs. monthly laboratory register summary; and 2) laboratory/CDST register vs. Annexure M. For 2019, the agreement was quantified by comparing laboratory/CDST register and TrueNat monthly reports.

Impact on TB case notification rate

Case notification rate was operationally defined as the number of TB cases notified per 100 000 population within the RNTCP over a specific time period.¹¹ The total number of presumptive cases tested and the proportion of microbiologically positive cases among these were compared between January–August 2018 and January–August 2019. We used interrupted time series analysis (ITSA) to measure the impact of TrueNat on the detection of positive TB cases. We hypothesised a priori that the introduction of TrueNat would produce a level change in the number of TB cases detected.¹² We proposed a regression equation with 1) time elapsed since the beginning of the study period (January 2018), and 2) dummy variable identifying a given time point as pre- or post-implementation as independent variables and 3) the number of positive cases detected as the outcome variable. Since in most of the count data models, variance tends to be greater than mean (over-dispersion), we used negative binomial regression instead of Poisson to adjust the standard error. The incidence rate ratio (IRR) and its 95% confidence intervals (CIs) were calculated to indicate the additional yield of positive cases after introduction of TrueNat. Data were analysed using Stata v14.0 (StataCorp, College Station, TX, USA; 2015).

Operational feasibility

The operational issues faced by LTs and STLSs were given as frequencies and percentages or medians and interquartile ranges.

Ethics statement

As the study involved secondary data analysis of data obtained using record review, ethics approval was not sought. The data collected did not have any identifiers and confidentiality was ensured.

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Results

- Present the study findings
- Tables, Figures, Images
 - Title, footnote, abbreviations
 - Colour & Resolution
- No interpretations or comments



Results

RESULTS

Data accuracy

The average accuracy of 2018 data reported was 96.4% (range 77.0–100.0) when data in laboratory/CDST registers were compared with those in the monthly laboratory summary (Table 2). Data accuracy was 94.9% (range 77.0–100.0) when data in the laboratory/CDST registers were compared with Annexure M. In 2019, data accuracy was 90.9% (range 48.7–100.0), when data in CDST/ laboratory register were compared with TrueNat monthly report.

Impact assessment

In the 193 TUs studied, a total of 245989 presumptive cases were tested using SSM during January–August 2018, of which 25726 (10.5%; range 8.9–13.1) tested positive. During January–August 2019, of the total 185435 presumptive cases, 32876 cases were

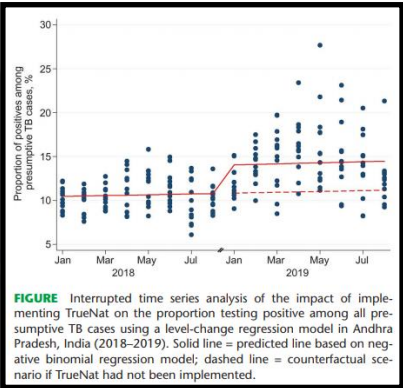


TABLE 2 Accuracy of data on presumptive TB cases tested as recorded in the RNTCP records and reports in 25 selected TB Units in Andhra Pradesh, India, 2018 and 2019

	Presumptive TB cases, n (%)				Positives, n (%)	
	2018		2019		2018	2019
	Laboratory register vs. monthly laboratory summary	Laboratory register vs. Annexure M	Laboratory register vs. monthly TrueNat report	Laboratory register vs. monthly laboratory summary	Laboratory register vs. Annexure M	Laboratory register vs. monthly TrueNat report
Date accuracy						
100%	6 (24.0)	3 (12.0)	3 (12.0)	13 (52.0)	14 (56.0)	10 (40.0)
95–99%	15 (60.0)	16 (64.0)	9 (36.0)	4 (16.0)	5 (20.0)	7 (28.0)
90–94%	1 (4.0)	1 (4.0)	7 (28.0)	3 (12.0)	2 (8.0)	3 (12.0)
<90%	3 (12.0)	5 (20.0)	6 (24.0)	5 (20.0)	4 (16.0)	5 (20.0)

RNTCP = Revised National TB Control Programme; TB = tuberculosis.

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Discussion

- Summary of findings
- Interpret and infer
- Compare
- Strengths & Limitations
- Conclusions
- Recommendations



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Discussion

summary

Interpret and infer

DISCUSSION

Our analysis of data on 431 424 presumptive TB cases tested under RNTCP in Andhra Pradesh, India, indicated that TrueNat improved case notification rates by 30%. The programmatic implementation of TrueNat was operationally feasible.

The overall accuracy of the data reported was satisfactory. This reflects on the quality of the training of the LTs/STLs and the monitoring and evaluation methods used in the programme. However, six sites reported <90% data accuracy in TrueNat recording and reporting. This could have been due to the delay in making logistics such as new registers and reporting formats available to the TrueNat sites, because of which LTs made informal entries in the existing laboratory register or maintained additional records to capture this information. This practice could have led to erroneous reporting. This emphasises the need for uniform recording and reporting mechanisms to be used at all TrueNat sites. LT-generated reports could also be validated by machine-generated reports from the TrueNat device.

Compare

TrueNat positivity observed in our analysis (14.4%) was lower than the positivity reported earlier (18.1%).⁷ This difference may be attributed to the programmatic conditions under which the current evaluation was conducted, as against the experimental, controlled situations in which the earlier assessment had been done (using staff trained for the purpose under rigorous monitoring).

CONCLUSIONS

Deployment of TrueNat can significantly improve TB case detection as compared to SSM. While some minor issues are to be anticipated in the initial stabilisation period, proper logistics planning, manpower management and an inbuilt external quality assurance mechanism can help successfully integrate TrueNat as a

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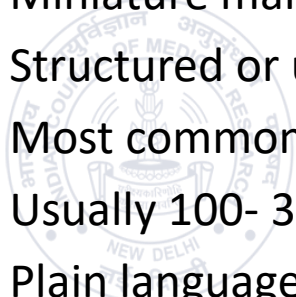


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Abstract or Summary

- Miniature manuscript
- Structured or unstructured
- Most commonly read
- Usually 100- 350 words long
- Plain language summary



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Abstract or Summary

Background: The Revised National Tuberculosis Control Programme (RNTCP) in Andhra Pradesh, India, introduced TrueNat™ MTB/Rif, a rapid molecular test for detecting *Mycobacterium tuberculosis* (MTB) and rifampicin (RIF) resistance at 193 TB units (TUs) in October 2018. We evaluated its impact on TB diagnosis and assessed the operational feasibility of its deployment at point-of-care (POC) settings.

Methods: We compared the number of presumptive TB cases tested and the number (proportion) of microbiologically positive before (January–August 2018) and after (January–August 2019) the deployment of TrueNat. We interviewed laboratory technicians and Senior TB Laboratory Supervisor from 25 randomly selected TUs to assess operational feasibility.

Results: In 2018, 10.5% (range 8.9–13.1) of 245,989 presumptive cases tested were positive. In 2019, of the 185,435 presumptive cases tested, 13.7% (range 9.6–18.9) were positive. The proportion of presumptive TB cases in whom MTB was detected using TrueNat was 14.4% (range 10.0–21.2). TrueNat significantly increased case detection (incidence rate ratio [IRR] 1.30; 95%CI 1.15–1.46), yielding an additional 18 TB cases per 100,000 population. Laboratory technicians became comfortable in performing TrueNat after a median of 10 tests (interquartile range 5–17.5). Invalid reports declined from 6.8% to 3.6%.

Conclusion: The deployment of TrueNat as POC diagnostic test improved case detection and was operationally feasible under RNTCP.

Jeyashree K, Shanmugasundaram D, Rade K, Gangakhedkar RR, Murhekar MV. Impact and operational feasibility of TrueNat™ MTB/Rif under India's RNTCP. *Public Health Action*. 2020 Sep 21;10(3):87-91.

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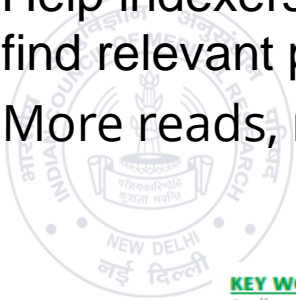


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Keywords

- Help indexers and search engines find relevant papers
- More reads, more citation



KEY WORDS

Andhra tuberculosis programme; point-of-care; presumptive TB; molecular diagnosis; operational research; India



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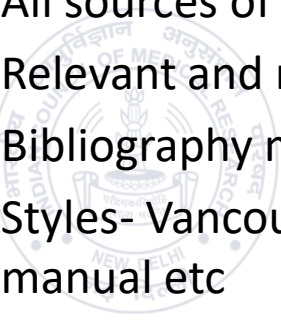
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References

- All sources of information referred
- Relevant and recent
- Bibliography management
- Styles- Vancouver, Harvard, Chicago manual etc
- Software



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References

References and In-text citations



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Sputum smear microscopy (SSM), which is the cornerstone of TB diagnosis in India, has several limitations, including low sensitivity.⁴ TrueNat™ MTB/Rif

References

- 1 Bernal JL, et al. Interrupted time series regression for the evaluation of public health interventions: a tutorial. *Int J Epidemiol* 2016; 46(1): 348–355.
- 2 Central TB Division, Ministry of Health and Family Welfare, Government of India. India TB report, 2019. New Delhi, India: MoHFW, 2019.
- 3 Keeler AE, et al. Reducing the global burden of tuberculosis: the contribution of improved diagnostics. *Nature* 2006; 2: 49–58.
- 4 Ngabonziza JCS, et al. Diagnostic performance of smear microscopy and incremental yield of Xpert in detection of pulmonary tuberculosis in Rwanda. *BMC Infect Dis* 2016; 16(1): 660.

Jeyashree K, Shanmugasundaram D, Rade K, Gangakhedkar RR, Murhekar MV. Impact and operational feasibility of TrueNat™ MTB/Rif under India's RNTCP. *Public Health Action*. 2020 Sep 21;10(3):87–91.



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Organizing the ideas within the structure

Argument matrix

- A framework that
 - Respects the structure of the various sections
 - Develops few ideas (2 or 3) logically and sequentially
- Used to prepare the outline of the manuscript



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Argument matrix template

Ideas	Intro	Methods	Results	Discussion	Limitations	Conc	Recs
Idea #1							
Idea #2							
Idea #3							

1. Direction used to construct the ideas developed
(Follow this in the preparation to remain logical)



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Argument matrix template

Ideas	Intro	Methods	Results	Discussion	Limitations	Conc	Recs
Idea #1	↓	↗	↓	↗	↓	↗	↓
Idea #2	↓	↗	↓	↗	↓	↗	↓
Idea #3	↓	↗	↓	↗	↓	↗	↓

2. Direction that the paper will follow
(That is what the reader will see)



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Optional sections

- **Highlights**
 - List key messages from your research
 - Bullet points (5 to 6)
- **Research in context**
 - What was already known?
 - What your study adds?
- **Graphical abstract**



Highlights

Profile of and expenditure on morbidity and hospitalizations among elderly—Analysis of a nationally representative sample survey in India



Highlights

- 30.3% elderly had suffered an ailment and 8% had atleast one hospitalisation episode.
- Private sector was more commonly utilised than the public sector for hospitalisation of elderly.
- Pro-rich distribution of hospitalizations observed; overall, in rural and urban elderly.
- Urban elderly were spending more on hospitalisations compared to rural counterparts.
- Across wealth quintiles, expenditure on hospitalisations for women was lesser than for men.

Jeyashree K, Abdulkader RS, Kathirvel S, Chinnakali P, Kumar A. Profile of and expenditure on morbidity and hospitalizations among elderly—Analysis of a nationally representative sample survey in India. Archives of Gerontology and Geriatrics. 2018 Jan 1;74:55-61.



Research in context

Burden of dengue infection in India, 2017: a cross-sectional population based serosurvey

Research in context

Evidence before this study

We searched PubMed for estimates of seroprevalence of dengue infection in India on Dec 6, 2018, using the search terms "dengue", "seroprevalence" and "India". We identified 43 publications, of which eight reported seroprevalence of dengue infection. A systematic review and meta-analysis, which included seven of these studies, reported the seroprevalence of dengue in India as 56.9% (95% CI 37.5–74.4). Age-specific seroprevalence was reported by three studies. These studies reported that by the age of 9 years, 47.6–73.4% of children have developed antibodies against dengue. These studies were done on a conveniently selected sample or were limited to a few cities and hence the results could not be generalised. In this context, we did a cross-sectional survey among individuals aged 5–45 years to estimate the age-specific seroprevalence of dengue in India.

Added value of this study

Our study indicates a heterogeneous seroprevalence in different geographical regions in India with high level of

dengue transmission in northern, western, and southern geographical regions, whereas low transmission was observed in northeast and eastern regions. In all regions, younger children had higher force of infection corresponding to suboptimal immunity in this age group. Our serosurvey also generated data about profile of dengue serotype specific neutralising antibodies in a subsample. In eastern and northeastern regions, where dengue seroprevalence was low, most of the infections were monotypic in nature; whereas in northern, western, and southern regions, most dengue infections were multitypic in nature.

Implications of all the available evidence

Evidence on seroprevalence of dengue infection would be useful for making informed decisions about the introduction of upcoming dengue vaccines in the country.

Murhekar MV, Kamaraj P, Kumar MS, Khan SA, Allam RR, Barde P, Dwivedi B, Kanungo S, Mohan U, Mohanty SS, Roy S. Burden of dengue infection in India, 2017: a cross-sectional population based serosurvey. The Lancet Global Health. 2019 Aug 1;7(8):e1065-73.



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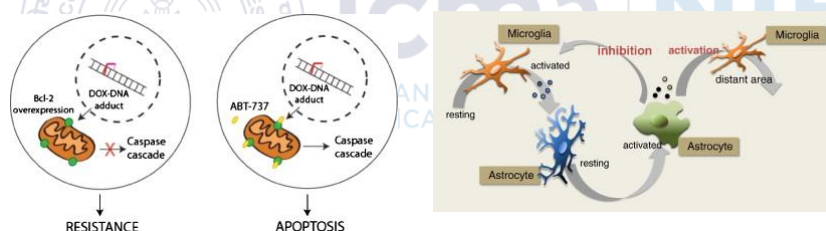
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Graphical abstract

- Single, concise, pictorial and visual summary of the main findings



Ugarenko M, Nudelman A, Rephaeli A, Kimura KI, Phillips DR, Cutts SM. ABT-737 overcomes Bcl-2 mediated resistance to doxorubicin–DNA adducts. Biochemical pharmacology. 2010 Feb 1;79(3):339-49.

Liu W, Tang Y, Feng J. Cross talk between activation of microglia and astrocytes in pathological conditions in the central nervous system. Life sciences. 2011 Aug 1;89(5-6):141-6.



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The special case of thesis

- Dissertation - an extended, usually written treatment of a subject
- A dissertation embodying results of original research and substantiating a specific view *especially*: one written by a candidate for an academic degree

Merriam-Webster dictionary



Manuscript Vs Thesis

Manuscript

- Voluntary/Mandatory
- Can be primary research or reviews, perspectives etc
- Led by the first author
- Contributions from all authors
- Timelines
- Bound by journal guidelines

Thesis

- Mandatory for PG/doctoral degree
- Always primary research
- Led by the resident/ scholar
- Mentored by the guide/ supervisor
- Timelines
- Bound by university guidelines
- Thesis as a manuscript



Writing a manuscript Vs thesis

- Word limit and length
- Target audience
 - Thesis committee
 - Peers/ experts/ community
- Structure and sections

Basic principles of scientific writing are similar

Session objectives

At the end of this session, you must have a basic understanding of how to do the following in your manuscript/thesis

- ☐ Organize the ideas logically and sequentially
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Additional information

- Title page
- Cover letter
- Funding
- Conflicts of interest
- Author contributions
- Appendices
- Supplementary files
- Acknowledgement



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Title Page

- Title
- Authors
 - Addresses, affiliations, qualifications
- Corresponding Author
- Word count
- Key words
- Short running title



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- Table of contents
- List of abbreviations, tables, figures



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VOL 10 NO 3 PUBLISHED 21 SEPTEMBER 2020

Impact and operational feasibility of TrueNat™ MTB/Rif under India's RNTCP

K. Jeyashree,¹ D. Shanmugasundaram,¹ K. Rade,² R. R. Gangakhedkar,³ M. V. Murhekar¹

<http://dx.doi.org/10.5588/pha.20.0004>

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Methods: We compared the number of presumptive TB cases tested and the number (proportion) of microbiologically positive before (January–August 2018) and after (January–August 2019) the deployment of TrueNat. We interviewed laboratory technicians and Senior TB Laboratory Supervisor from 25 randomly selected TUs to assess operational feasibility.

Results: In 2018, 10.5% (range 8.9–13.1) of 245,989 presumptive cases tested were positive. In 2019, of the 185,435 presumptive cases tested, 13.7% (range 9.6–18.9) were positive. The proportion of presumptive TB cases in whom MTB was detected using TrueNat was 14.4% (range 10.9–17.3). TrueNat significantly increased

TrueNat MTB has high sensitivity (91.1%) and specificity (100%) compared with a composite reference standard consisting of smear and culture results, clinical treatment and follow-up, and radiology findings.⁵ There is high agreement (92.7%) between Xpert® MTB/RIF (Cepheid, Sunnyvale, CA, USA) and TrueNat in MTB detection.⁶ TrueNat had significantly higher sensitivity than Xpert (84.1% vs. 81%; $P < 0.001$).⁷ Compared to SSM, TrueNat has been shown to increase life expectancy by 0.39 years and was also found to be cost-effective.⁸ TrueNat is less resource-intensive than Xpert.^{7,9} Deploying TrueNat at point-of-care (POC) eliminates the need for sample transportation, as is required for Xpert thus adding cost benefit, besides detecting RIF resistance during the patient's first visit. The WHO's rapid evaluation of evidence, which is expected to inform the updated 2020 Consolidated Guidelines on TB, suggests that the accuracy of TrueNat is comparable to that of Xpert.¹⁰

Based on the evidence supporting the POC use of TrueNat, the Government of Andhra Pradesh, a state

AFFILIATIONS

- 1 Indian Council of Medical Research (ICMR)-National Institute of Epidemiology, Chennai, India
- 2 World Health Organization India Country Office, New Delhi, India
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KEY WORDS

Andhra tuberculosis programme; point-of-care; presumptive TB; molecular diagnosis; operational research; India

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Plagiarism

- Recommended before submission

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Session objectives

At the end of this session, you must have a basic understanding of how to do the following with reference to your manuscript/thesis

- ☐ Organize the ideas logically and sequentially
- ☐ Furnish additional information before submission
- ☐ Articulate the content to deliver the message effectively

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Tips for making your writing clearer

- Use simple, specific and necessary words
- Use consistent terminology; avoid synonyms
- Use inclusive, non-offensive language
- Use precise word order
- Avoid passive voice
- Be mindful of sentence length and structure



Scientific language editing

- Spell check
- Grammar
- Sentence structure
- Punctuation



Formatting guidelines

- Font style and size
- Indent and Spacing
- Heading style
- Paragraphs

Follow standard formatting styles as recommended by university or the journal eg. American Psychological Association (APA) style 7th edition



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The six “s” of scientific writing

1. Simple
2. Short
3. Structured
4. Sequential
5. Strong
6. Specific

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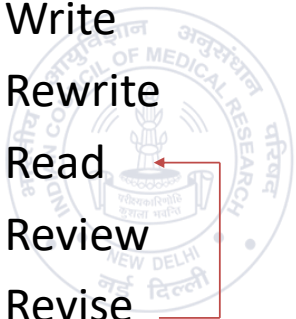
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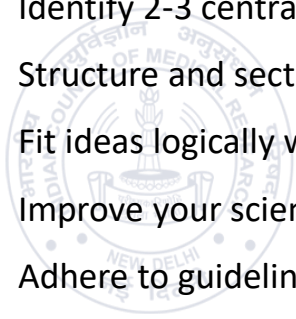
Review drafts

- Write
- Rewrite
- Read
- Review
- Revise
- Submit



Take home messages

- Identify 2-3 central messages
- Structure and sections- **IMRD**
- Fit ideas logically within structure- **Argument matrix**
- Improve your scientific writing style
- Adhere to guidelines
- Write, review, revise





Thank you
