

## Clinical Audit on Diagnosis and Therapeutic Outcomes of Tuberculosis Patients in RNTCP / DOT Centers of Primary Health Care Settings

Dr. Mekkanti Manasa Rekha<sup>1\*</sup>, Dr. E.Maheswari Ph.D<sup>2</sup>

<sup>1</sup> Research Scholar in Department of Pharmacy Practice, M.S. Ramaiah University of Applied Sciences Bangalore, Karnataka, India. Email: manasarekharoyal@gmail.com

<sup>2</sup> Professor, Department of Pharmacy Practice, Faculty of Pharmacy, MS.Ramaiah University of Applied Sciences Bangalore Karnataka India. Email: drmanasarekharoyal@gmail.com

\*Corresponding Author: Dr. Mekkanti Manasa Rekha

### KEYWORDS

Clinical Audit, Primary health care settings, RNTCP, DOT, RNTEP Guidelines etc.,

### ABSTRACT

This clinical audit investigates the diagnosis and therapeutic outcomes of tuberculosis (TB) patients at RNTCP/DOT centers within primary healthcare settings; the study evaluates the adherence to RNTCP guidelines and the resulting therapeutic outcomes. Utilizing a descriptive, cross-sectional design, the audit spans from June 2022 to March 2023, covering four PHCs in North Bangalore. The study includes a sample size of 999 patients, focusing on adults diagnosed with TB and tracking their treatment and recovery. Key findings include a detailed demographic breakdown, with males constituting 52.35% and females 47.67% of the sample. The audit also identifies common co-morbidities, such as TB combined with diabetes mellitus (27.44%) and hypertension (20.27%). The audit highlights the efficiency of diagnostic processes, with a significant portion of patients undergoing necessary examinations and tests, including chest X-rays and sputum analysis. Treatment adherence and outcomes were assessed, revealing a high cure rate of 89.48%, but also noting challenges such as a 6.206% loss to follow-up and a 3.903% treatment failure rate. Gaps evolved in recording of body weight (81%), the follow up first 40%, second 15%, third 5%, physical examination 97% and chest x-ray 89% and documentation of findings with 95% where the health care professional didn't meet up their target level of performance, and the same followed up during the course of therapy for 9 months of period with minor deviations from target level of performance. The study underscores the importance of strict adherence to standardized treatment protocols like DOTS and the potential benefits of adjunctive therapies, such as corticosteroids for tubercular pleural effusion. The findings suggest areas for improvement in both diagnostic and treatment phases, aiming to enhance the quality of care and overall management of TB within community healthcare frameworks. This comprehensive audit provides valuable insights for optimizing TB management and improving patient outcomes in primary health care settings.

### 1. Introduction

The Clinical Audit on the diagnosis and therapeutic outcomes of tuberculosis patients at RNTCP/DOT centers in primary healthcare settings involves a thorough assessment of the diagnostic processes and treatment outcomes within these facilities [1]. This audit aims to evaluate the efficiency and effectiveness of TB diagnosis, adherence to treatment protocols such as those outlined by the Revised National TB Control Programme (RNTCP) which transformed later into RNTEP (Revised National Tuberculosis Elimination Programme) and the overall patient recovery and management outcomes. Conducting these audits allows healthcare providers to identify areas for improvement, ensure strict adherence to standardized treatment regimens like Directly Observed Treatment Short course (DOTS), and enhance the quality of care provided to tuberculosis patients [2,3]. This evaluation is crucial for optimizing patient outcomes, reducing adverse events, and ultimately improving the management of tuberculosis within the community healthcare framework, the diagnosis and therapeutic outcomes of tuberculosis (TB) patients at RNTCP/DOT centers in primary healthcare settings are critical components of TB management. Diagnosing TB is a complex process involving clinical evaluation, laboratory tests, and imaging studies [3,4,5]. As Delay in diagnosis can result in more severe disease progression and increased transmission within the community [6].

**Aim:** To Conduct Clinical Audit and to evaluate the health care provider's implementation of RNTCPs guidelines during the diagnosis and treatment outcomes of tuberculosis patients for the achievement of desired therapeutic outcomes.

## 2. Objectives

1. To Improve diagnosis and management of adults with tuberculosis
2. To Identify areas of non-adherence to RNTCP Guidelines and develop action plans to resolve them.

## 3. Methodology

A Descriptive, Cross-Sectional, Diagnostic Clinical Audit of TB patients was done from June 2022 to March 2023. All medical records were undertaken from four PHCs with RNTCP/DOT centers located in North Bangalore (RT Nagar area (Cholanayakanahalli, Sulthan palya, Hebbal), Herohalli, Devanahalli, Yelahanka.

**Method of Collection of Data:** The newly admitted cases in RNTCP/DOT centers of PHCs located in the north Bangalore (RT Nagar area (Cholanayakanahalli, Sulthan palya, Hebbal), Herohalli, Devanahalli, Yelahanka. The audit was performed based on the RNTEP Staff regarding the standard diagnostic and treatment criteria and Patient Data is collected through medication therapy chart review of patients maintained in the nursing station of PHC.

**Data Analysis:** Data were recorded anonymously from each TB patient's medical records and checklist at PHCs. information included related to symptoms suggesting TB , age; sex; weight; and the types and dosages of drugs prescribed treatment with broad-spectrum antibiotics Based on the documented clinical, physical and laboratory evidence, the diagnosis of each patient physical examinations x-ray tests and laboratory findings and their results was compared with the diagnostic criteria and treatment guidelines specified in National Tuberculosis Elimination Programme (NTEP) guidelines India.

## 4. Results and Discussion

Table No:1 Gender wise distribution of patients (n=999)

Gender wise distribution of Patients	Number (n)	Percentage (%)
Males	523	52.35
Females	476	47.67
<b>Total</b>	<b>999</b>	

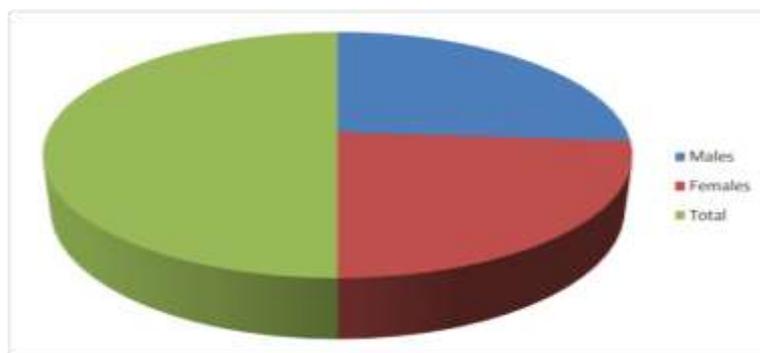


Figure 1. Gender Wise Distribution of patients

Table No:2 Literacy wise distribution of study population(n=999)

Total subjects	Literates	Illiterates
999	684	315
100%	68.47%	31.53%

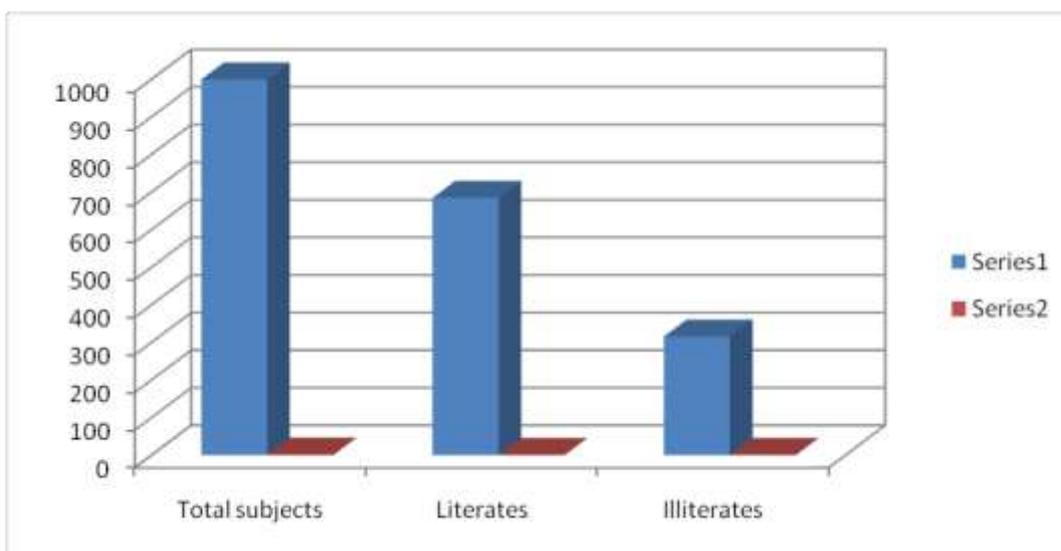


Figure 2 Literacy wise distribution of study population

Table No: 3 Age wise distribution of patients

Age wise distribution of patients	Males Number (n)	Percentage (%)	Females Number (n)	Percentage (%)
18 -30	148	28.29	122	25.63
31-40	197	37.66	164	34.45
41-50	63	12.04	88	18.48
51-60	57	10.89	41	8.613
61-70	42	8.030	29	6.092
71-80	14	2.676	28	5.882
81-90	2	0.382	3	0.630
91-100	0	0	1	0.210
<b>Total</b>	<b>523</b>	<b>52.35</b>	<b>476</b>	<b>47.67</b>

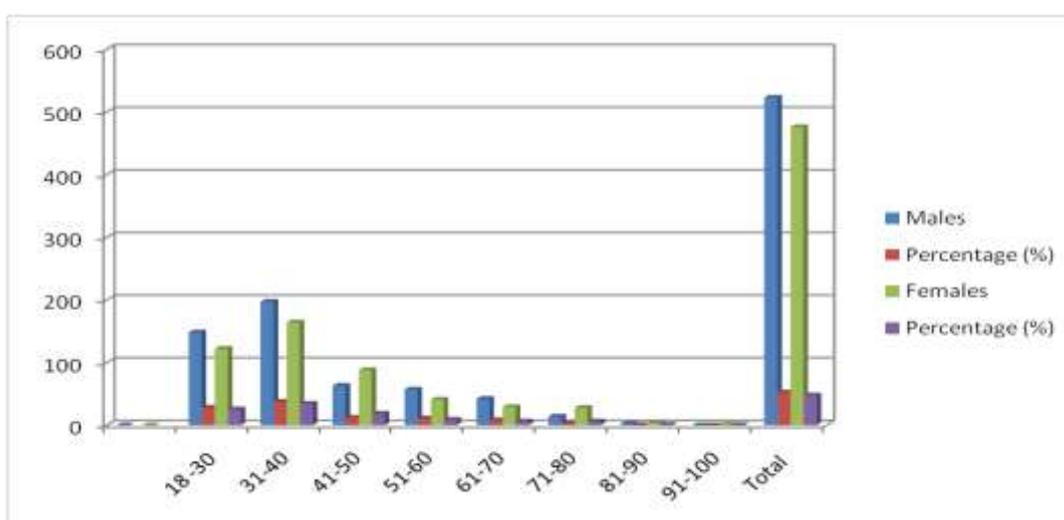


Figure 3. Age wise distribution of patients

Table No: 4 Co-morbidities

Status of co morbidity	Number	Percentage
<b>TB+ DM</b>	222	27.44
<b>TB+Bronchitis</b>	36	4.449
<b>TB+ HTN</b>	164	20.27
<b>TB+ DM+ HTN</b>	152	18.78
<b>TB+Hypothyroidism</b>	41	5.067
<b>TB+Hyperthyroidism</b>	22	2.729
<b>TB+ DM+ HTN+ hyperthyroidism</b>	11	1.359
<b>TB+ DM+ HTN+ hypothyroidism</b>	14	1.730
<b>TB+ DM+ Hypothyroidism</b>	16	1.977
<b>TB+ DM+ hyperthyroidism</b>	9	1.112
<b>TB+MI</b>	2	0.247
<b>TB+ Stroke</b>	4	0.494
<b>TB+Epilepsy</b>	2	0.247
<b>TB+ HTN+ Hypothyroidism</b>	7	0.865
<b>TB+ HTN+ hyperthyroidism</b>	5	0.618
<b>TB + Asthma</b>	42	5.191
<b>TB+ COPD</b>	21	2.595
<b>TB + Asthma+COPD</b>	39	4.820
<b>Total</b>	<b>809 out of 999 total population</b>	<b>80.98 out of 100 percent</b>
<b>DM=Diabetes mellitus,HTN=Hypertension,MI= Myocardial infarction</b>		

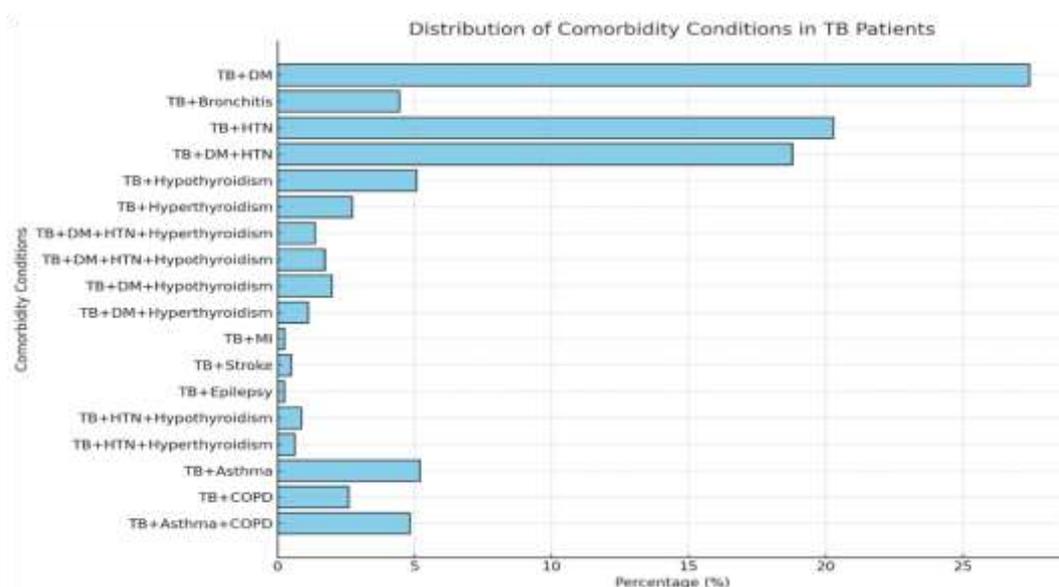


Figure 4. Distribution of Comorbidity in TB Patients

Table No: 5 Social Statuses(n=999)

Social habits	Number (n)	Percentage (%)
Alcoholic	97	32.65
Smoking	102	34.34
Alcoholic+smoking	77	25.92
Tobacco chewing	21	7.070
<b>Total</b>	<b>297 out of 999 total population</b>	<b>29.72 out of 100 percent</b>

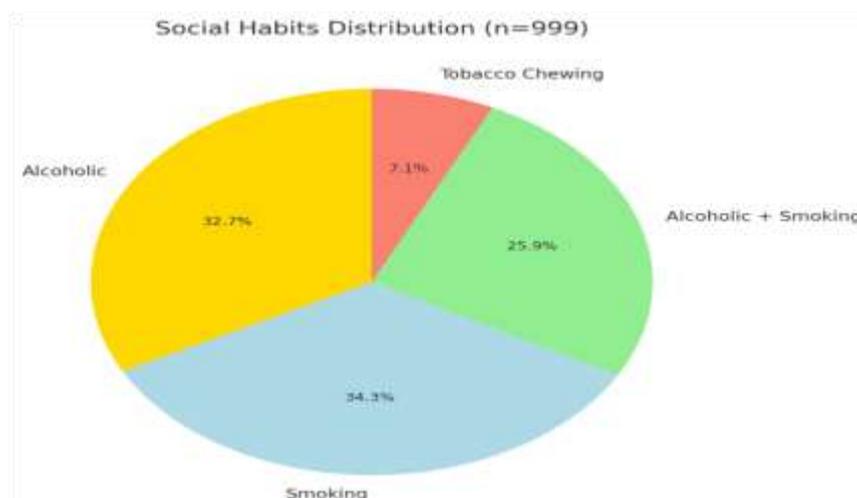


Figure 5. Social Status of patients

Table No: 6 Newly Diagnosed tuberculosis patients by PHC's (n=999)

Type of TB	Number of medical records reviewed		
	Number	Percentage	Total
Smear-negativePTB	201	20.12	20.12
Smear-positivePTB	326	32.63	32.63
EPTB	472	47.24	47.24
<b>Total</b>	<b>999</b>	<b>100</b>	<b>100</b>

**TB, tuberculosis;PTB, pulmonaryTB; EPTB,extra-pulmonaryTB.**

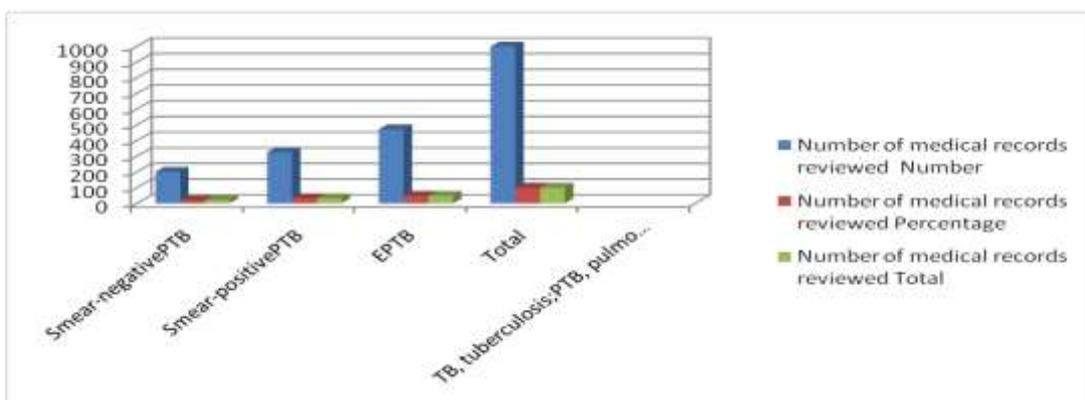


Figure 6. Newly Diagnosed tuberculosis patients by PHC's

Table No: 7 Representing the clinical audit indicators, criteria with target level performances

Sl. No	Indicators	Criteria	Target level of performance (%)
1.	Notification	Case notified	999
2.	Historydocumentation	TB symptoms assessed	999
		LMP1/UPT2	340
		Medication side effects assessed	673
3.	Pre-pregnancy counselling	Casereferred	62
4.	Examinations	Weight recorded	999
		Visual acuity	999
		Colour vision	999
		Respiratory rate recorded	999
		SP023recorded	999
		Lung findings	472
		Other findings	527
5.	Investigations	BaselineIX4**	999
		CBNAAT	999
		CXR done and documented	472
		SputumAFB5x1,x2,x3	472
		SputumMTB C&S6	472
		LFT7X2/52taken	862
		LFTX2/52reviewed	862
		MTBC&Straced	999
6.	Pharmacist referral	Casereferred	999
7.	Medications	Anti-TB continued	999
8.	Surveillance	Appointmentx6/12given	999



Figure 7. Representing the clinical audit indicators,crietria with target level performances

Table 8: Representing the clinical audit indicators, criteria with target level performances with Percentage

Sl. No	Indicators	Criteria	%									
			0	1	2	3	4	5	6	7	8	9
1.	Notification	Case notified	100									
2.	History documentation	Were TB symptoms assessed	100	100	98	98	95	95	98	97	90	98
		LMP1/UPT2	34.03	30.61	29.09	33.05	32.08	22.09	24.06	31.09	35.06	38.04
		Medication side effects assessed			4.457	17.83	11.88	15.15	21.84	30.61	48.15	54.9
3.	Pre pregnancy counselling	Case referred	36.26	36.26	36.26	36.26	36.26	36.26	36.26	36.26	36.26	36.26
4.	Examinations	Weight recorded	100	100	100	60	30	80	80	85	90	90
		Visual acuity	100	70	60	90	90	80	90	90	80	85
		Colour vision	100	60	30	72	70	80	98	90	90	90
		Respiratory rate recorded	100	70	65	72	68	84	90	94	94	90
		SPO2 recorded	100	90	87	84	94	92	90	86	90	84
	Lung findings	Positive finding*	100	90	80	79	98	90	90	93	95	98
		Normal finding	78	90	98	74	80	89	90	90	96	98
Not recorded		87	71	-	-	-	-	-	-	-	-	
5	Investigations	Baseline IX4**	100	100	100	100	100	100	100	100	100	100
		CXR done and documented	100	-	-	62	-	-	56	-	-	-
		Sputum AFB5 x1,x2,x3	100	100	100	90	82	71	40	-	86	-
		Sputum MTB C&S6	100	100	100	90	84	62	33	-	72	-
		LFT X2/52 taken	100	-	98	-	96	-	82	80	-	-
		LFT X2/52 reviewed	100		98		95		80		78	
		MTB C&S traced	100	88	90	95	90	87	97	96	98	90

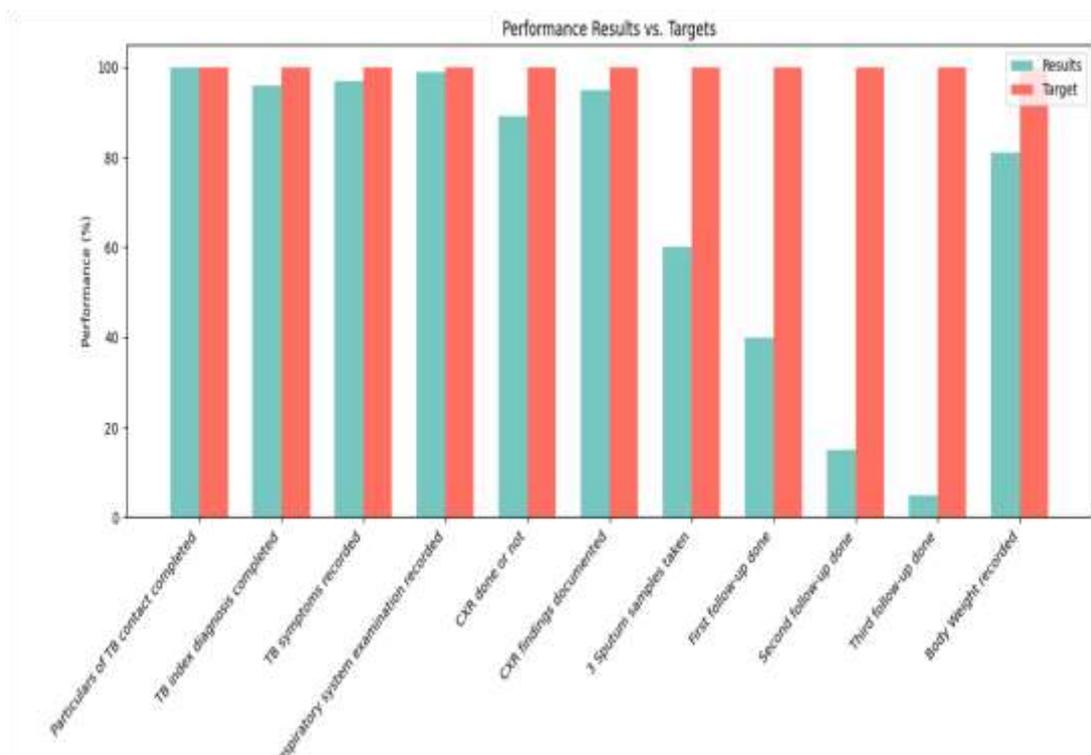


Figure 8: Representing the clinical audit indicators, criteria with target level performances with Average mean percentage

Table No:9 Treatment Outcome Categories

Treatment outcome	Number (N)	Percentage (%)
Curied	894	89.48
Loss to follow up	62	6.206
Died	4	0.400
Failed	39	3.903
<b>Total</b>	<b>999</b>	<b>100</b>

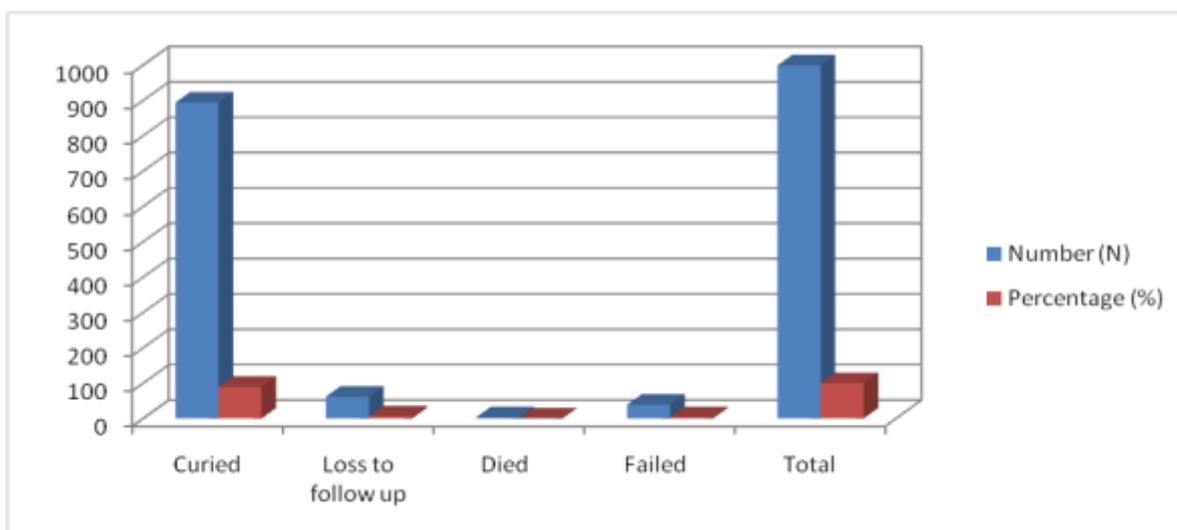


Figure 9 Treatment Outcome Category

## **5. Discussion**

The clinical audit of tuberculosis patients at RNTCP/DOT centers in primary healthcare settings highlights significant achievements and areas needing improvement in TB management. The high cure rate of 89.48% demonstrates the effectiveness of the current treatment protocols. However, challenges such as the 6.206% loss to follow-up and 3.903% treatment failure rate as mentioned in table no.10 indicate the need for enhanced strategies to improve patient adherence and treatment efficacy. The audit emphasizes the critical role of rigorous diagnostic processes and adherence to the RNTCP guidelines in achieving favorable therapeutic outcomes. The inclusion of corticosteroids in managing tubercular pleural effusion shows promise in improving patient recovery rates. Additionally, addressing co morbid conditions and social habits, which affect nearly 81% and 29.72% of the patient population respectively, is essential for comprehensive TB care. Gaps evolved in recording of body weight (81%), the follow up first 40%,second 15%,third 5% ,physical examination 97% and chest x-ray89% and documentation of findings with 95% where the health care professional didn't meet up their target level of performance as mentioned in numbers in table no 7 and table no 8, and the same followed up during the course of therapy for 9 months of period with minor deviations from target level of performance mentioned in detail in table no 9 .Overall, this audit provides valuable insights into the current state of TB management in primary healthcare settings. It underscores the necessity of continuous monitoring, adherence to standardized protocols, and the implementation of innovative strategies to enhance patient outcomes. By addressing the identified gaps and leveraging the strengths of the current system, healthcare providers can significantly improve the management and control of tuberculosis within the community.

## **6. Conclusion**

The Present Study showed the health care professionals are well adhered to the present RNTEP guidelines there are minor gaps identified during the audit which were addressed and further rectified with clinical pharmacist timely reports and interventions.

### **Permissions / Approvals:**

The present study got the approvals from District Tuberculosis Office from the Office of the Project Coordinator (TB) Bangalore, ACE Independent Ethics committee DCGI Reg. No.: ECR/141/Indt/KA/2013/RR-19 DHR Reg. No.: EC/NEW/IND/2021/KA/0005 and MS.Ramaiah University of Applied Sciences, Bangalore, Karnataka, India.

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### **References:**

- [1] World Health Organization. Global tuberculosis report 2014. Geneva: World Health Organization; 2014. Available from: <http://apps.who.int/iris/handle/10665/137094>
- [2] Ministry of Health Malaysia. Clinical Practice Guidelines for Management of Tuberculosis Third edition. Putrajaya: MaHTAS. 2012: 1-49
- [3] Escreet BC, Cowie RL. Criteria for the diagnosis of pulmonary tuberculosis. S Afr Med J. 1983;63(22): 850-854
- [4] Limb C, Fowler A, Gundogan B, Koshy K, Agha R. How to conduct a clinical audit and quality improvement project. Int

J Surg Oncol (N Y). 2017;2(6):e24. doi:10.1097/ IJ9.0000000000000024

- [5] Mathioudakis A, Rousalova I, Gagnat AA, Saad N, Hardavella G. How to keep good clinical records. *Breathe (Sheff)*. 2016;12(4): 369-373.doi:10.1183/20734735.018016
- [6] Williams G, Alarcon E, Jittimane S, Walusimbi M, Sebek M, Berga E, Villa TS. Guidance for the implementation of best practice for the care of patients with tuberculosis. *Int J Tuberc Lung Dis*. 2008;12(3): 19.
- [7] Disease Control Division (TB/ Leprosy Sector) Ministry of Health Malaysia.National strategic plan for tuberculosis control (2016 – 2020).Putrajaya: Ministry of Health Malaysia; 2016:1-28
- [8] 8. World Health Organization. Treatment of tuberculosis: guidelines for national programmes (fourth edition). Geneva: World Health Organization; 2010.Available from: <https://www.who.int/tb/ publications/2010/9789241547833/en/>
- [9] World Health Organization. Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis. Geneva: World Health Organization; 2014. Monitoring Treatment Response. Available from: [https://www.who.int/ tb/publications/ pmdt\\_companion handbook/en/](https://www.who.int/ tb/publications/ pmdt_companion handbook/en/)
- [10] National Department of Health South Africa. National Tuberculosis Management Guideline. South Africa: Directorate of TB DOTS Strategy Coordination. 2014: 11-70
- [11] Bangwal r. Clinical pharmacist interventions on miliary koch’s patient with antitubercular therapy-induced hepatotoxicity and psychosis: a rare case report. *Asian j pharm clin res*. 2023;16(12):1-3.
- [12] Keena M, Chawla G, Sonika U, Abrol N, Hiremath S, Meena VK. Indian tubercular belly: A prospective study of 140 patients of abdominal tuberculosis and their outcomes. *Journal of Family Medicine and Primary Care*. 2022 Jun 1;11(6):2423-30.
- [13] Nizami MohdA, Tabassum S, Iffath n. bulletin on the adverse drug event (ade) prompted by the anti- tubercular therapy (att) [Internet]. 2018. Available from: [https://www.semanticscholar.org/paper/BULLETIN-ON-THE-ADVERSE-DRUG-EVENT-\(ADE\)-PROMPTED-Nizami Tabassum/5359ae8f51330342ef4b90d2c05503b6a765d0d4](https://www.semanticscholar.org/paper/BULLETIN-ON-THE-ADVERSE-DRUG-EVENT-(ADE)-PROMPTED-Nizami Tabassum/5359ae8f51330342ef4b90d2c05503b6a765d0d4)
- [14] Veeraraghavan V, Srinivasan K. Alcohol use, mental disorder comorbidity and personality factors as a reason for anti-tubercular drug discontinuation in a tertiary health care centre in south India–A pilot study. *Alcoholism and Drug Addiction/Alkoholizm i Narkomania*. 2021 Apr 1;34(2):111-8.
- [15] Dubba S, SAYANA SB, VaDithya M, SRAVAN KUMAR M, SRIDHAR I, KUMAR MR. Role of Corticosteroids in Tubercular Pleural Effusion: A Prospective Interventional Study from a Tertiary Care Teaching Hospital, Telangana, India. *Journal of Clinical & Diagnostic Research*. 2022 Aug 1;16(8).
- [16] Dhanvij PA, Joshi RA, Kalantri S. Delay in diagnosis of tuberculosis in patients presenting to a tertiary care hospital in rural central India. *J MGIMS*. 2009 Sep;14(2):56-63.
- [17] Jou R, Chuang PC, Wu YS, Yan JJ, Luh KT. Drug-resistant Mycobacterium tuberculosis, Taiwan. *Emerging Infectious Diseases*. 2006 May;12(5):871.
- [18] Metcalfe JZ, O’Donnell MR, Bangsberg DR. Moving beyond directly observed therapy for tuberculosis. *PLoS medicine*. 2015 Sep 15;12(9):e1001877.