Improving TB Preventative Treatment Adherence through STAMP System: A Pilot Study Among Household Contacts of TB Patients in High-Burden Areas under the Karnataka Health Promotion Trust

Population: Household Contacts of TB patients registered at KHPT
Project timeline: May 2023 to February 2024

Introduction

Medication adherence is a critical component in the effective management of tuberculosis (TB), particularly among household contacts (HHC) of TB patients. Ensuring consistent and timely medication intake is vital for preventing the spread of TB and improving patient outcomes. However, maintaining high levels of adherence remains a challenge, especially in community-based settings.

This study, funded by the JEET project under the Karnataka Health Promotion Trust (KHPT), was designed to evaluate the effectiveness of the STAMP (Support for Treatment Adherence Medication Protocol) system in enhancing medication adherence among HHC of TB patients. The STAMP system, with its automated reminders and tracking system, represents an innovative approach to addressing the challenges of medication adherence.

The study aimed to assess whether STAMP could address the challenges of non-adherence more effectively than current practices. This study also aimed to provide insights into the potential scalability of STAMP as a tool for broader public health interventions. By comparing STAMP with other existing medication adherence techniques, this study sought to contribute valuable data to the ongoing efforts to enhance TB preventative treatment protocols in high-burden areas.

In comparison with the conventional self-reported adherence techniques, STAMP not only reminds patients to take their medication but also logs their adherence data in real time, allowing healthcare workers to intervene promptly if a dose is missed. This study aims to assess STAMP's effectiveness relative to the conventional method (Control Group), providing valuable insights into its potential for broader application in TB treatment protocols.

Project

The Karnataka Health Promotion Trust (KHPT) undertook a project focused on enhancing medication adherence among Household Contacts (HHC) of Tuberculosis (TB) patients through the use of STAMP (Support for Treatment Adherence Medication Protocol). This initiative was implemented in the areas coming under Yeshwantpur TU and Abbigere TU targeting HHC registered under the respective health centers. The primary goal was to compare the effectiveness of STAMP against conventional methods of medication intake (Control Group).

Project Objectives

● 　Improve Medication Adherence: Enhance adherence to TB preventative treatment among HHC through automated reminders and tracking.
● 　Evaluate the Effectiveness of STAMP: Compare adherence rates between HHC using STAMP and those using conventional medication strips.
● 　Support Public Health Goals: Contribute to the overall TB control efforts by ensuring higher adherence to preventative therapy.

STAMP

The system consists of a back-end database and a smart front-end medication dispensing unit, where

- A tabletop medication dispenser, which is pre-loaded with cartridges that contain 7 days of medication. (Each HHC will be given two cartridges)
- At the designated medication time, the dispenser beeps audibly.
- If the patient presses the dispense button, the medication is dispensed and an SMS with the date and time stamp, unique identification number, and dispenser status is sent to the STAMP system's backend servers.
- If the patient does not press the dispense button, the alert escalation protocol proceeds through its hierarchy (until the medication dispensing button is pressed)

Escalation protocol
- An SMS is sent to the patient's designated mobile number 2 hours past the medication time
- An automated voice call is made to the patient's designated mobile number 4 hours past
- the medication time
- An SMS is sent to the caregiver's designated mobile number 6 hours past the medication time
- At 8 hours past the designated medication time, the system flags the patient's file in the app on KHPT HCW's phone. Then the HCW can contact the person and remind them to take the medicine.
- If HCW intervention is required more than twice in a row, a home visit is suggested by the system.

METHODOLOGY

The study was conducted in areas of Abbigere TU and Yeshwantpur TU, high-burden areas for TB, where the Karnataka Health Promotion Trust (KHPT) has been actively engaged in TB control efforts. The study population consisted of household contacts (HHC) of TB patients registered at the Yeshwantpur and Abigere Health Center. The setting provided a real-world environment to assess the effectiveness of the STAMP device in a community with significant public health challenges related to TB.

Study Population
The study included two groups of HHC:
- **Group A:** Consisting of 50 HHC who used the STAMP device for medication adherence.
- **Group B:** Consisting of 92 HHC who followed conventional methods, taking medication directly from strips.

Data Collection and Analysis Methods
Enrollment of Index patients, HHCs started from May 2023 to September 2023, and the course completion of TPT was till March 2024.

- **Implementation:**
- STAMP devices were distributed to the STAMP user population, and the STAMP cartridges were refilled with medicines every 14 days.
- Conventional medication strips were provided to the control group participants once a month.

- **Data Collection:**

- For Group A (STAMP users): Adherence was monitored through STAMP device logs, which recorded each instance of medication intake along with corresponding timestamps.
- For Group B (Control Group): Adherence was self-reported, with data collected by retrieving empty pill blisters at the end of each month.

❖ **Analysis:**

● Adherence rates between the two groups were compared using both quantitative and qualitative data.

● Quantitative analysis focused on adherence percentages, while qualitative interviews were conducted to gather feedback from participants on their experiences with STAMP and conventional methods.

● The analysis also included a comparative assessment of the reasons for non-adherence between the two groups.

Ethical Approvals and Consent Considerations

Ethical approval for the study was obtained from the Institutional Ethics Committee (IEC) of Shetty's Hospital, Bangalore. The study was conducted in compliance with ethical standards, ensuring that the rights and well-being of all participants were protected. Informed consent was obtained from all participants before their inclusion in the study. Participants were thoroughly briefed about the study's objectives, procedures, potential risks, and benefits. Special considerations were made to ensure that participants understood their right to withdraw from the study at any point without any consequences to their healthcare services. The JEET, KHPT team facilitated the ethical approvals and ensured that all consent procedures were properly documented and adhered to throughout the study.

Results:

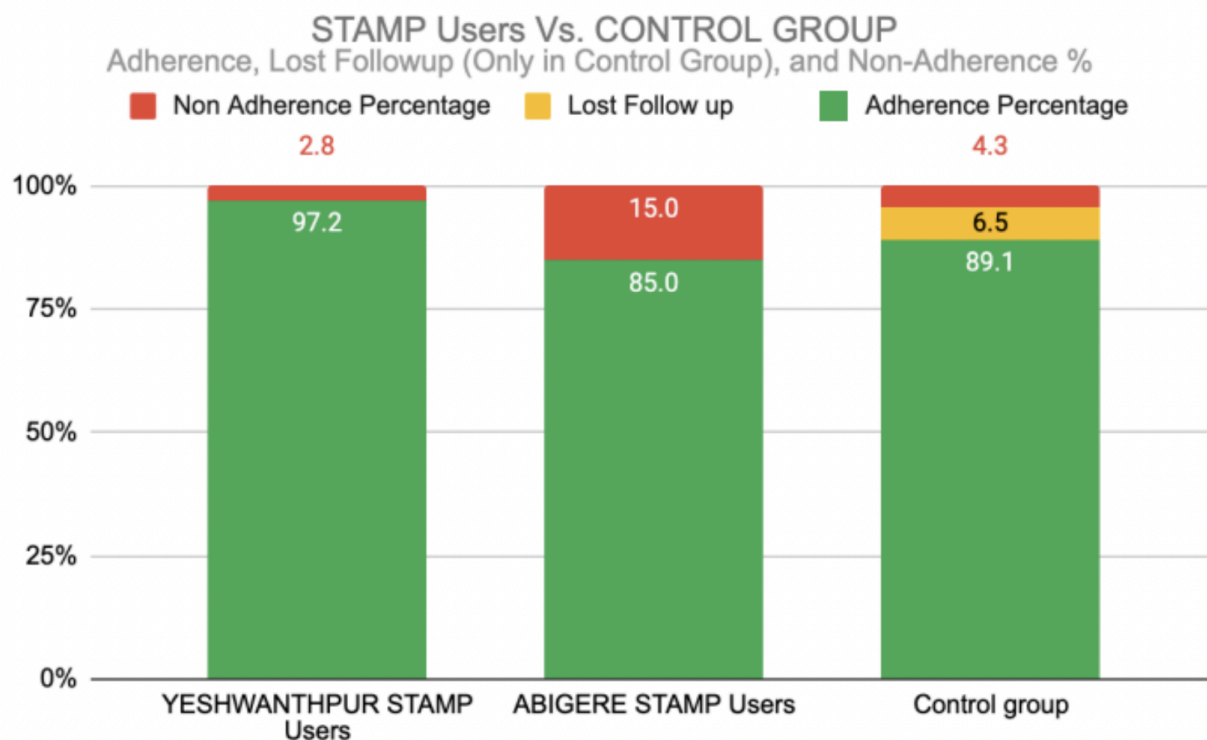**Comparative analysis of the Control Group and STAMP users**

Fig 1: Comparison of adherence, non-adherence, and lost to follow-up rates between the Control Group and STAMP users. The table demonstrates that STAMP users at both Yeshwantpur and Abigere centers had no lost follow-up cases, highlighting the effectiveness of the STAMP device's real-time monitoring.

The comparative analysis of medication adherence revealed a significant improvement in outcomes among STAMP users compared to the control group, particularly in preventing cases from being lost to follow-up. The control group demonstrated an adherence rate of 89.1%, with a non-adherence rate of 4.3% and a lost to follow-up rate of 6.5%. It is important to note that the control group's adherence data were self-reported, which may introduce recall or social desirability biases, potentially affecting the accuracy of the adherence rates.

In contrast, STAMP users showed stronger performance. STAMP users in the Yeshwantpur center achieved an impressive adherence rate of 97.2%, with no cases being lost to follow-up and a non-adherence rate of just 2.8%. Whereas, STAMP users in Abigere achieved an adherence rate of 85.0% with no cases lost to follow-up and a non-adherence rate of 15.0%.

The absence of cases lost to follow-up among all STAMP users strongly highlights the effectiveness of real-time monitoring provided by STAMP. The automated reminders, combined with timely interventions by healthcare workers (HCWs), ensured consistent patient engagement. This real-time tracking allowed HCWs to focus on targeted non-adherence cases, enabling prompt support and reducing missed doses.

Moreover, an analysis of non-adherence among STAMP users revealed that 7.79% of the missed doses were related to delays in healthcare worker responses. If these cases had been addressed promptly, the adherence rate among STAMP users would have exceeded 95%, clearly surpassing the control group.

These results underscore the value of STAMP's real-time monitoring in maintaining high levels of adherence and preventing cases from being lost to follow-up, demonstrating its potential to significantly improve TB treatment outcomes.

STAMP therefore reduced non-adherence and drop-outs from 10.9% to 2.8% (a nearly 75% improvement) in the Yeshwantpur block.

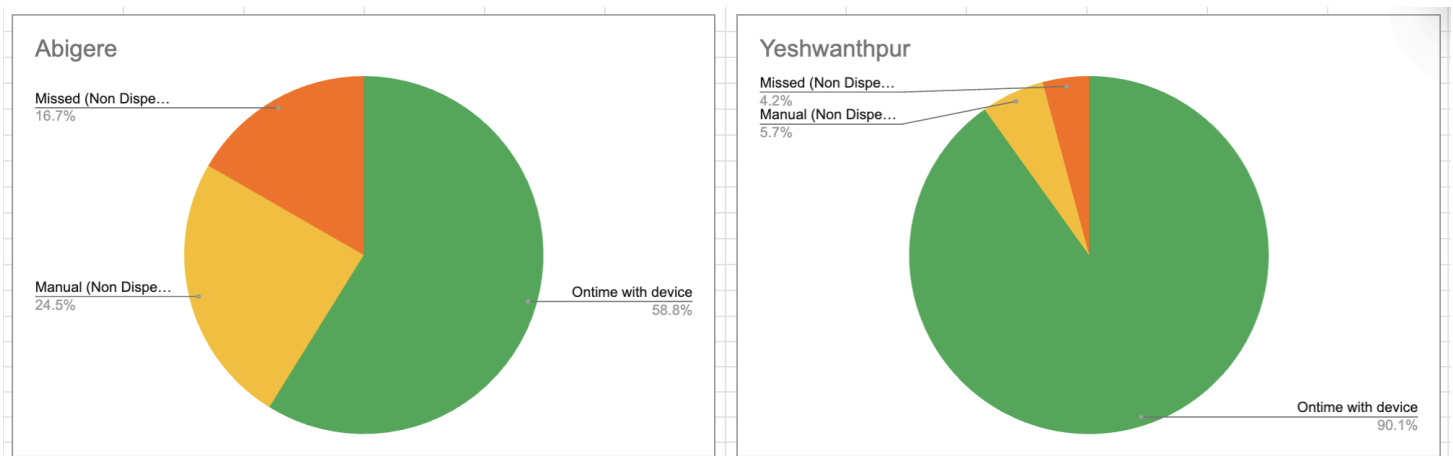**The overall adherence and non-adherence of STAMP Users:**

Fig 2:   Adherence rates at Abigere and Yeshwanthpur centers: The data shows notable differences, likely due to varying HCW engagement. Abigere had a 58.8% on-time adherence rate, with 24.5% manual dispensing and 16.7% missed doses. In contrast, Yeshwanthpur, with stronger HCWship, achieved 92.7% on-time adherence, 5.9% manual dispensing, and just 4.3% missed doses, underscoring the impact of HCWship on adherence.

The study evaluated medication adherence using the STAMP device at two centers: Abigere and Yeshwanthpur, categorizing outcomes by timeliness of medication dispensation, the necessity for manual adherence, and instances of missed doses.

The Yeshwanthpur center demonstrated higher rates of on-time medication dispensation with fewer instances of manual intervention and missed doses. Meanwhile, in the Abigere center, while a significant portion of doses was dispensed on time with the STAMP device, there were some instances where patients manually adhered to their medication regimen. Additionally, a portion of doses was missed. This suggests that further education on device usage, comprehensive training, and more consistent follow-up could enhance adherence outcomes.

These findings suggest a difference in patient adherence behaviors between the two centers. The lower adherence at Abigere points to the need for enhanced training and follow-up to ensure more consistent engagement with the device. Improving education and support across all centers would further optimize STAMP's effectiveness in promoting medication adherence.

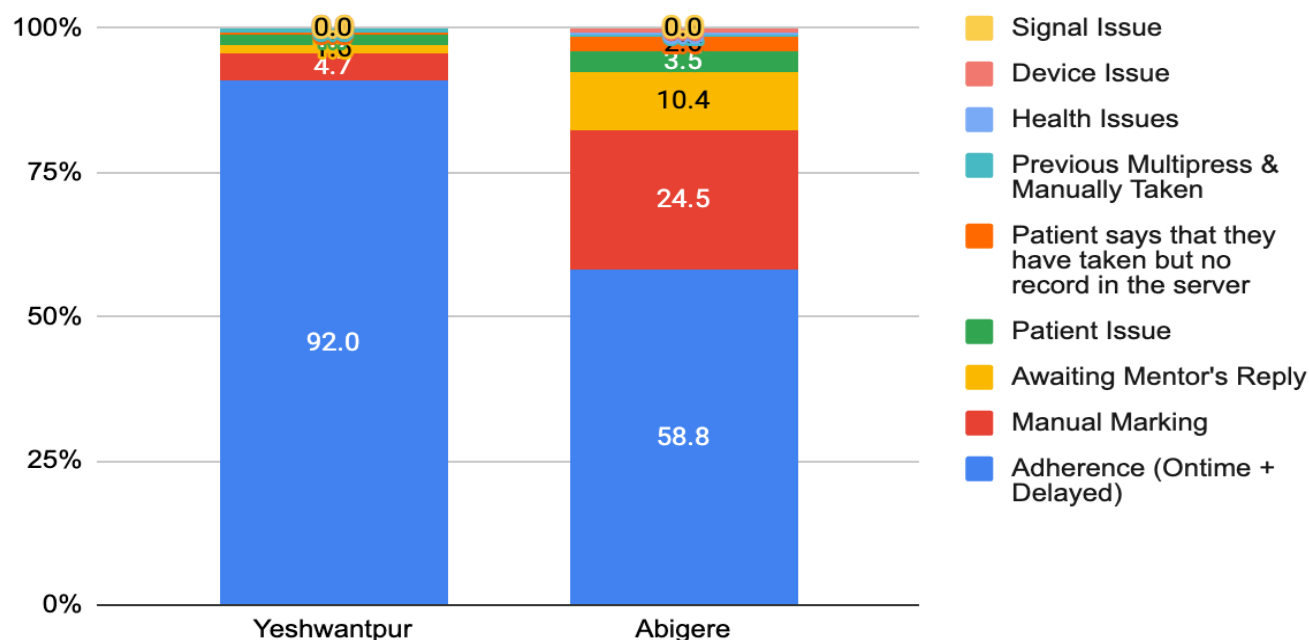**Adherence and Non-Adherence Analysis with Reasons**

Fig 3: Percentage distribution of adherence and non-adherence reasons by center.

The adherence data from the Yeshwantpur and Abigere centers presents a stark contrast, highlighting significant differences in medication management and compliance. Yeshwantpur shows a high STAMP device-recorded adherence rate of 92.04%, significantly outperforming Abigere, which has STAMP device-recorded adherence rate of 58.78%. This suggests that patients in Yeshwantpur are more consistent in taking their medication on time, whereas Abigere may face challenges in ensuring regular adherence.

Manual marking, where doses are recorded manually rather than through the device, is markedly higher in Abigere (24.50%) compared to Yeshwantpur (4.71%). This discrepancy indicates a potential issue

with device usage or patient engagement in Abigere, necessitating further investigation and possible intervention to improve adherence rates.

The reasons for missed doses have been analyzed in detail. Notably, the category "Awaiting HCW's Reply" is significantly higher in Abigere (10.44%) than in Yeshwantpur (1.59%). This category is critical as it may represent doses that were taken but not yet confirmed due to pending communication from healthcare workers. The delay in information sharing by healthcare workers may have led to some instances of adherence being underreported, indicating the need for enhanced communication processes.

Other factors contributing to missed doses include patient-related challenges, discrepancies between patient-reported intake (Manual Marking) and server records, as well as occasional health or device-related issues. These factors were more common in one of the KHPT blocks, contributing to its lower adherence rate. However, these issues could be controlled through better installation process, guidance, training, and monitoring, which would help improve adherence outcomes in centers like Abigere.

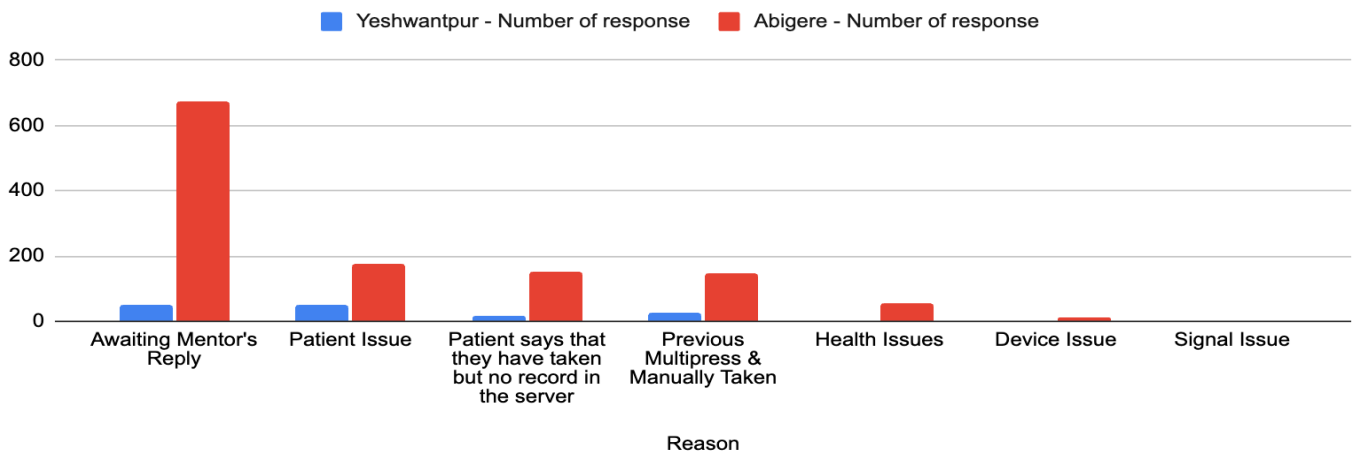**Comparison of Missed Medicine Analysis between Two Blocks:**

Fig 4: Comparison of missed medicine reasons between Yeshwantpur and Abigere centers.

The missed medicine analysis for Yeshwantpur and Abigere provides insights into the differing factors contributing to non-adherence between the two locations. Yeshwantpur had 3,643 instances, while Abigere had a larger sample size of 5,667 instances, offering a more comprehensive look at the challenges faced in each center.

In Abigere, 11.9% of missed doses were due to awaiting a mentor's (LTBI coordinators who were working Abbigere and Yaswantpur TU) reply, a significantly higher percentage compared to the 1.4% observed in Yeshwantpur. This suggests that delayed responses from healthcare workers in Abigere could be a key area to address in improving medication adherence.

Patient-related issues, such as forgetting to take medication or being out of town without pre-dispensing, were responsible for 1.4% of missed doses in Yeshwantpur, while in Abigere, these issues accounted for 3.1% of missed instances. This indicates that patient engagement or adherence challenges are more prominent in Abigere.

Both centers reported cases where patients claimed to have taken their medication, but no record was found in the server (0.5% in Yeshwantpur and 2.7% in Abigere).

Additionally, previous multipress and manually taken doses accounted for 0.7% in Yeshwantpur and 2.6% in Abigere. Health-related issues accounted for 0.1% of missed doses in Yeshwantpur and 1.0% in Abigere. Device-related issues were minimal, appearing only in Abigere, affecting 0.2% of missed doses. Neither center reported signal issues as a factor in missed medication.

The analysis of the reasons for missed medication doses showed that at Yeshwantpur, the main causes were waiting for the mentor's reply and patient-related issues, while problems with device functionality were minimal. In Abigere, a large percentage of missed doses also resulted from waiting for the mentor's response. This indicates that timely replies from healthcare workers could have prevented many of these missed doses, and improved adherence rates significantly.

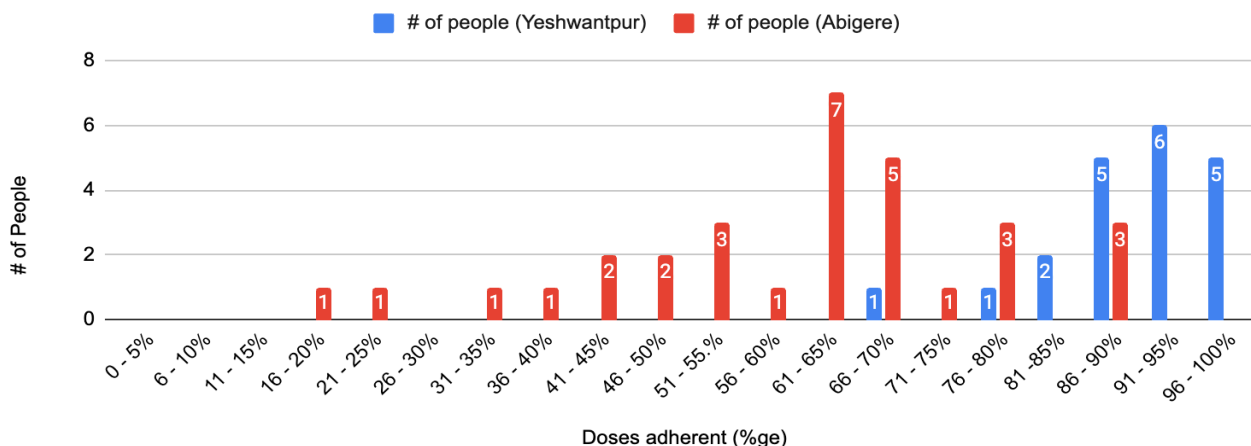**Centerwise Patient Adherence Percentage from May 2023 to February 2024.**

Fig 5: Centerwise Patient Adherence Percentage from May to February 2024: The table presents the distribution of patient adherence to prescribed doses across two centers (A and B).

The table presents the distribution of patient adherence to prescribed doses across two centers (A and B). The adherence is categorized into percentage ranges, with the number of patients from each center falling within each range shown. Yeshwantpur exhibits higher adherence overall, with 11 patients achieving 86-100% adherence, whereas Abigere shows a more varied distribution, with a higher concentration of patients in the 61-70% range. No patients in either center had adherence levels below 20%, indicating a baseline of moderate adherence.

The adherence analysis for patients across Yeshwantpur and Abiggere from May to February (2024) reveals distinct differences in medication adherence patterns.

At Yeshwantpur, the majority of patients exhibited high adherence rates, with 16 patients (84.2%) achieving an adherence level of 81% or higher. Specifically, 5 patients reached 96-100% adherence, while 6 patients fell within the 91-95% adherence range. Only one patient had an adherence level between 66-80%, indicating that Yeshwantpur had consistently high adherence rates among its participants.

Whereas Abigere displayed more variation in adherence. While no patients in Abigere achieved adherence above 91%, the majority of patients (55.5%) had adherence rates ranging from 41% to 70%.

Seven patients had adherence between 61-65%, and 5 patients were in the 66-70% range. Notably, Abigere had more patients with lower adherence, with some even falling below 50%, indicating potential challenges in maintaining consistent medication adherence.

This discrepancy highlights the need for improved healthcare worker engagement at Abigere to address the lower adherence rates. Providing healthcare workers with adequate training and resources can equip them to better engage with patients, monitor adherence more effectively, and offer timely interventions. Strengthening the capacity of healthcare workers through targeted training could play a critical role in improving medication compliance and ensuring better health outcomes for patients.

Challenges faced:

Delayed Mentor Responses: In Abigere, a significant portion of missed doses (11.9%) was due to healthcare workers awaiting mentor replies. This delay prevents timely intervention and patient follow-up, impacting adherence.

To address these challenges, we have provided healthcare workers with a comprehensive video tutorial and a user manual. These resources are designed to improve their understanding of device functionality and adherence tracking, ensuring smooth operations and better support for patients.

DISCUSSION:

The KHPT TB TPT project, implemented from May 2023 to February 2024 in the Yeshwantpur Block, successfully demonstrated the significant impact of the STAMP device on medication adherence among household contacts (HHC) of TB patients.

The comparative analysis of medication adherence between STAMP users at the Yeshwantpur and Abigere centers, alongside the control group, demonstrates the effectiveness of STAMP in improving adherence rates and preventing loss of follow-up. STAMP showed superior performance, particularly in preventing lost to follow-up cases and promptly identifying patients and centers that needed additional support.

The Yeshwantpur center achieved an impressive adherence rate of 97.2%, while the Abigere center reported an adherence rate of 85.0%. Despite these differences, the absence of cases lost to follow-up across both STAMP user groups underscores the device's role in maintaining consistent patient engagement through real-time monitoring and timely interventions.

The analysis of missed medicine reasons revealed that at Yeshwantpur, awaiting the mentor's reply and patient issues were the primary contributors to missed doses, with minimal issues related to device functionality. In Abigere, a significant proportion of missed doses were due to awaiting the mentor's reply. This suggests that with prompt responses from healthcare workers, a substantial portion of these missed doses could have been avoided, further improving adherence rates.

Overall, STAMP significantly improved adherence compared to the control group, which had an adherence rate of 89.1% and higher instances of lost follow-up cases. Enhancing training, support, and communication processes could further optimize the device's effectiveness, particularly in areas where adherence challenges persist.

The project's findings underscore the effectiveness of STAMP in enhancing medication adherence and supporting preventative TB treatment protocols. Future efforts should focus on addressing the identified challenges, improving HCW training, monitoring and exploring scalable solutions to extend the benefits

of STAMP to a broader population. Continued engagement and user support are essential for optimizing STAMP's impact on public health outcomes.

Challenges:

One of the main challenges encountered during the project was the change in healthcare workers at Abigere, which led to inconsistencies in monitoring medication adherence. The new healthcare workers were not fully familiar with STAMP or its operational requirements, leading to delays in addressing missed doses and reduced overall adherence. This shift in personnel without adequate training impacted the effectiveness of adherence interventions and created challenges in accurately tracking patient adherence.

To overcome such challenges, it is essential to provide comprehensive and continuous training to healthcare workers, especially when there are staff changes. Adequate training ensures that new staff can seamlessly integrate into the workflow, enabling them to use STAMP effectively and provide timely interventions. Additionally, regular monitoring by administrators, coupled with timely countermeasures, can help address any issues related to adherence tracking and ensure that patients receive the necessary support to maintain their medication schedules.

Another challenge of the project was the STAMP dispenser's use of a single slot in a medicine cartridge for all the household contacts. This configuration made it challenging to separate and identify individual adherence within the family, as missed doses could not be attributed to specific individuals. This limitation potentially impacted the accuracy of adherence tracking and the effectiveness of targeted interventions.

In response to this issue, Sundaram Medical Devices Pvt Ltd, the manufacturer of the STAMP device, has developed a new version called the Multi-User STAMP (MU STAMP). The MU STAMP allows up to five individuals to use a single device, with each person's medication adherence tracked and recorded separately. This innovation aims to enhance the accuracy of adherence monitoring and provide more precise data for healthcare workers to support TB preventative treatment protocols. Future studies should consider incorporating the MU STAMP to further improve the outcomes of preventative TB treatment adherence initiatives.

Recommendations

1.   **Comprehensive Administrator Training, HCW Training, and User Training**: Develop more comprehensive training materials and support systems for users.
2.   **Expand Usage of STAMP Devices**: Consider scaling up the use of STAMP to other blocks, health centers, and other diseases.

ABBREVIATIONS:
HCW - Health Care Worker
HHC - Household contacts
IEC - Institutional Ethics Committee
KHPT - KARNATAKA HEALTH PROMOTION TRUST
MU - Multiple users
STAMP - Support for Treatment Adherence Medication Protocol
TB - Tuberculosis
TPT - TB Preventative therapy