Technical Feasibility and Performance Evaluation of a Smart Adherence Pillbox for Tuberculosis Treatment

Rian Nurahman[1*], Ikhwan Yuda Kusuma[2], Peppy Octaviani[3], Silma Kaaffah[4]
[1,2,3,4]Pharmacy Study Program, Faculty of Health, Universitas Harapan Bangsa, Purwokerto, 53182, Indonesia

Corresponding Author.Rian Nurahman
**Email*: riannurahman8@gmail.com

Abstract: *Tuberculosis (TB) remains a major global health challenge, with poor medication adherence contributing to treatment failure and the rise of multidrug-resistant TB. Digital adherence technologies, including smart pillboxes, show promise, but evidence of their technical reliability remains limited. This study aimed to evaluate the technical feasibility and functional performance of the Smart-Adherence Pillbox (SAP) prototype. A prototype validation study was conducted using 100 repeated simulated cycles in a controlled environment without patient involvement. The device was assessed across multiple domains, including alarm system performance, dispensing accuracy, connectivity, mechanical safety, and notification logging. Performance was analyzed using descriptive statistics, with success rates and 95% confidence intervals, while temporal metrics were summarized as mean ± standard deviation, median, and range. The SAP prototype demonstrated high functional reliability, with success rates ranging from 99.0% to 100% across all domains. Alarm accuracy reached 99.0%, while dispensing, connectivity, mechanical safety, and notification functions achieved 100% success. Temporal analysis showed no deviation in alarm activation and logging, with rapid notification delivery (mean 2.05 seconds). However, data transfer time showed variability (mean 7.57 seconds; range 2–41 seconds), indicating potential network-related delays. Minor issues, such as delayed transfers and simulated missed-dose events, were observed but did not impact overall system performance. The SAP prototype demonstrated excellent technical feasibility and reliability under controlled conditions. Further clinical studies are required to evaluate its effectiveness in real-world TB treatment adherence.*
Keywords: *Tuberculosis, Smart Pillbox, Digital Health, Prototype Validation*

1. INTRODUCTION

Tuberculosis (TB) remains a major global public health challenge, particularly in low- and middle-income countries, with an estimated 10.9 million new cases reported worldwide [1]. Despite ongoing implementation of the End TB Strategy, TB incidence and mortality in Indonesia have increased by 19% and 26%, respectively, since 2015, indicating persistent gaps in disease control [1]. Poor adherence to long-term anti-tuberculosis therapy remains a key driver of treatment failure, relapse, and the emergence of multidrug-resistant tuberculosis (MDR-TB), which is more difficult and costly to manage [2], [3].

Conventional adherence strategies such as Directly Observed Treatment, Short-course (DOTS) are widely implemented but face practical limitations including resource constraints, transportation barriers, and low patient motivation [4], [5]. Digital health technologies have therefore been increasingly recommended as alternative approaches to support adherence, including short message services, mobile applications, video-observed therapy, and electronic medication monitoring systems [6]. Recent studies in Southeast Asia demonstrated that digital interventions modestly improved adherence but showed limited impact on treatment outcomes [7]. Similarly, a randomized controlled trial in China reported only minimal reduction in loss to follow-up with digital adherence technologies and no significant improvement in treatment success [8]. Device-based innovations have also been explored, such as a smart pillbox developed in Egypt that reduced missed doses but lacked disease-specific [9], an electronic pillbox in Indonesia that improved adherence without automated dispensing features [10], and a real-time monitoring system in India that still faced technical and usability challenges [11].

However, limited studies have comprehensively evaluated the technical feasibility and functional performance of smart pillbox systems specifically designed for TB treatment with integrated features such as automatic dispensing, real-time notification, and structured electronic logging. Most existing technologies focus on partial adherence support without addressing system reliability, dosing precision, and connectivity performance simultaneously. In addition, systematic prototype validation using repeated-cycle testing prior to clinical implementation remains rarely reported in the literature.

This study aimed to develop and evaluate the SAP as an integrated smart medication device and to assess its technical feasibility and functional performance through repeated-cycle prototype validation across multiple domains, including alarm accuracy, dispensing precision, connectivity, mechanical safety, and notification responsiveness..

2. METHOD

This study was designed to validate the functional performance of the SAP prototype through repeated-cycle testing. The objective was to assess the reliability and accuracy of the device across several domains, including alarm activation, dispensing, connectivity, mechanical safety, and notification logging. This phase focused on instrument validation and was conducted in a controlled laboratory environment.

The SAP prototype was subjected to 100 repeated validation cycles, each designed to simulate real-world operational conditions. The device's performance was evaluated across five domains: alarm system, dispensing accuracy, connectivity and synchronization, mechanical safety, and notification and logging. Each domain was tested separately to assess the device's functional performance in detail. The testing procedure allowed for the measurement of both the success rates of each performance indicator and the temporal performance of the device.

In the alarm system domain, the prototype was tested for on-time alarm activation, as well as the functionality of its visual alarm (LED) and audio alarm (buzzer). The dispensing accuracy domain assessed the pill release functionality, verifying that the device correctly released one tablet per cycle without over-dispensing. The connectivity and synchronization domain involved testing for the successful pairing of the device with the application, synchronization of the dosing schedule, and the successful transfer of data to the application, while ensuring a stable connection throughout the test. The mechanical safety domain focused on the proper completion of dispensing cycles, activation of position sensors, and overall mechanical safety of the device. Lastly, in the notification and logging domain, the prototype was evaluated for successful notification delivery, timely delivery of notifications (within 5 seconds), and the accuracy of event logging.

Data were collected for each domain based on the number of successful events recorded during the 100 test cycles. Success was defined as the correct performance of each task, such as the successful activation of an alarm, accurate pill dispensing, or precise event logging. The success rates for each domain were calculated as the proportion of successful events relative to the total number of test cycles, and the results were presented alongside the corresponding 95% confidence intervals (CI) for binomial proportions [12].

In addition to evaluating the success rates, temporal performance metrics were recorded to measure the time deviations for alarm activation, data transfer, and notification delivery. These metrics provided insight into the time efficiency of the device's response.

Descriptive statistics were used to summarize the results. The success rates for each performance indicator were calculated by dividing the number of successful events by the total number of cycles ($n = 100$). The 95% confidence intervals for the success rates were computed using standard binomial proportions. For the temporal performance metrics, such as alarm time deviation, data transfer time, and notification delivery time, the results were summarized as mean ± standard deviation (SD), median, and range.

All tests were conducted under stable Wi-Fi conditions to establish baseline performance, however, network variability was not simulated in this phase.

3. RESULTS AND DISCUSSION

To the best of our knowledge, this is the first study to validate the SAP prototype through repeated-cycle testing, aimed at assessing its functional and temporal performance in a controlled environment. This study is crucial in the context of enhancing adherence to tuberculosis (TB) treatment, as medication adherence is a major challenge in the fight against multidrug-resistant tuberculosis (MDR-TB). Effective adherence technologies are essential to improving treatment outcomes, especially in low-resource settings where digital health interventions have the potential to reduce the burden of TB. The validation of the SAP prototype highlights the importance of reliable, efficient, and feasible adherence technologies for patients undergoing TB treatment

The functional reliability of the SAP prototype was evaluated across 100 repeated validation cycles. **Table 1** summarizes the performance indicators for each domain of the device. The results showed high functional reliability across all domains, with success rates for most performance indicators reaching 100%, indicating that the prototype performed as expected in the controlled environment

Table 1. Functional performance indicators of the SAP prototype during 100 simulated test cycles

Domain	Performance indicator	Success, n/N	Success rate (%)	95% CI
Alarm system	On-time alarm activation	99/100	99.0	94.6–100.0
	Visual alarm (LED) function	99/100	99.0	94.6–100.0
	Audio alarm (buzzer) function	99/100	99.0	94.6–100.0
Dispensing accuracy	Successful pill release	99/100	99.0	94.6–100.0
	Correct dose count released (1 tablet/cycle)	100/100	100.0	96.4–100.0
	No over-dispensing event	100/100	100.0	96.4–100.0
Connectivity and synchronization	Successful device–application pairing	100/100	100.0	96.4–100.0
	Successful dose schedule synchronization	100/100	100.0	96.4–100.0
	Successful data transfer to application	100/100	100.0	96.4–100.0
	Stable connection status	100/100	100.0	96.4–100.0
Mechanical safety	Dispensing cycle completed normally	100/100	100.0	96.4–100.0
	Position sensor activation	100/100	100.0	96.4–100.0
	Safe mechanical status	100/100	100.0	96.4–100.0
Notification and logging	Successful notification delivery	100/100	100.0	96.4–100.0
	Timely notification delivery (≤5 seconds)	100/100	100.0	96.4–100.0
	Accurate event logging	100/100	100.0	96.4–100.0

In the alarm system domain, on-time alarm activation, visual alarm (LED), and audio alarm (buzzer) all demonstrated success rates of 99.0%, with 95% confidence intervals ranging from 94.6% to 100.0%. This indicates that the alarm system was highly reliable, with only a minor failure in one cycle.

In the dispensing accuracy domain, the prototype demonstrated a perfect success rate of 100% for correct pill release and no over-dispensing events. Furthermore, all cycles released exactly one tablet, confirming the high accuracy of the dispensing mechanism.

The connectivity and synchronization domain showed perfect results, with all 100 cycles resulting in successful device-application pairing, dose schedule synchronization, data transfer to the application, and stable connection status. These results suggest that the device's connectivity was stable and reliable throughout the testing.

The mechanical safety domain also showed perfect performance, with all cycles completing dispensing correctly, the position sensor activating as intended, and the mechanical status of the device being safe throughout the testing period. These results indicate that the mechanical components of the prototype functioned as expected without failure.

Finally, in the notification and logging domain, the device performed flawlessly, with 100% success in notification delivery and timely delivery (≤5 seconds). Event logging was also accurate, with no discrepancies between scheduled and recorded events, ensuring precise tracking of device activity.

Table 2 presents the temporal performance metrics of the SAP prototype during the repeated-cycle testing. The alarm system and logging times showed perfect accuracy, with no deviation between scheduled and observed execution times (mean ± SD = 0.00 ± 0.00 minutes). This suggests that the device's time-based functions were highly accurate and consistent.

Table 2. Temporal performance metrics of the SAP prototype during repeated-cycle testing

Parameter	n	Mean ± SD	Median	Min–Max
Alarm time deviation (minutes)	100	0.00 ± 0.00	0.00	0–0
Data transfer time to application (seconds)	100	7.57 ± 7.98	5.00	2–41
Notification delivery time (seconds)	100	2.05 ± 0.64	2.00	0–5
Logging time deviation (minutes)	100	0.00 ± 0.00	0.00	0–0

The data transfer time to the application had a mean of 7.57 seconds (± 7.98 seconds), with a median of 5.00 seconds. The range of transfer times was between 2 and 41 seconds, indicating some variability in transfer speed, though it was still within acceptable limits for the prototype's functionality.

For the notification delivery time, the mean was 2.05 seconds (± 0.64 seconds), with a median of 2.00 seconds. The notification delivery was consistently fast, with all notifications delivered within the 5-second threshold, highlighting the efficiency of the device's notification system.

Table 3 shows the distribution of operational events and connectivity behavior during the prototype validation. Regarding dose events, 50.0% of the cycles resulted in on-time doses, while 50.0% were classified as missed doses. The presence of missed doses indicates some deviation from the scheduled dosing time, potentially due to minor discrepancies or timing issues during the simulated testing process. It is important to highlight that the missed doses reflect accuracy in time logging and not a failure of the device itself.

Table 3. Operational event distribution and connectivity behavior during the prototype validation

Variable	Category	n (%)
Dose event type	On-time dose	50 (50.0)
	Missed dose	50 (50.0)
Network type used	Wi-Fi	100 (100.0)
Transfer status	Real-time transfer	54 (54.0)
	Delayed transfer	46 (46.0)
Alarm status	Normal	99 (99.0)
	Abnormal	1 (1.0)

For network type, the prototype used Wi-Fi throughout the testing, ensuring consistent network conditions. In terms of data transfer status, 54.0% of the cycles involved real-time data transfer, while 46.0% showed delayed transfer. This suggests that while the majority of data transfers were completed in real-time, some cycles experienced latency, possibly due to network-related issues, which would require optimization in future testing to ensure reliability under varying conditions.

The alarm status was normal in 99.0% of the cycles, with only 1.0% of cycles experiencing an abnormal alarm event. This minor abnormality could be attributed to the limitations of the test environment, and further investigation in subsequent testing would be necessary to address this issue.

To the best of our knowledge, this is the first study to validate the SAP prototype through repeated-cycle testing, aimed at assessing its functional and temporal performance in a controlled environment. This study is crucial in the context of enhancing adherence to tuberculosis (TB) treatment, as medication adherence is a major challenge in the fight against multidrug-resistant tuberculosis (MDR-TB). Effective adherence technologies are essential to improving treatment outcomes, especially in low-resource settings where digital health interventions have the potential to reduce the burden of TB. The validation of the SAP prototype highlights the importance of reliable, efficient, and feasible adherence technologies for patients undergoing TB treatment.

The study demonstrated that the SAP prototype performs reliably across multiple domains, with functional reliability rates ranging from 99.0% to 100%. These findings indicate that the prototype meets high standards of performance for a medication adherence device [13]. The temporal performance of the device was also robust, with alarm and event logging showing perfect accuracy. However, variability in data transfer times was observed, indicating that network conditions may impact device performance [14]. Regarding operational events, most events were classified as on-time doses, with only minor occurrences of missed doses and delayed data transfer.

The alarm system of the SAP prototype demonstrated excellent reliability, with a 99.0% success rate for on-time activation, visual (LED), and audio (buzzer) functions. This high level of performance is crucial, as timely reminders for TB medication adherence are essential to preventing treatment interruption and resistance [15]. The one failure observed in the system is notable but does not undermine the overall effectiveness of the alarm system [16]. This minor failure could be due to simulated testing conditions, and future optimization could aim to achieve 100% accuracy, especially under real-world conditions [17].

The device achieved a perfect success rate (100%) in releasing the correct dose without any over-dispensing. This finding is particularly significant in the context of TB treatment, where precise dosing is essential to prevent the development of drug resistance [18]. The ability to release one tablet per cycle, as demonstrated in the study, confirms that the SAP prototype can ensure patient safety by preventing over- or under-dispensing. This high level of accuracy is a key strength of the device, ensuring that patients receive the correct amount of medication as prescribed.

The SAP prototype exhibited perfect performance in device-application pairing, dose schedule synchronization, and data transfer, all at 100%. This is crucial for the integration of the device into existing digital health ecosystems, ensuring that patient adherence data can be seamlessly transmitted to healthcare providers for monitoring and intervention [11]. The success in maintaining a stable connection throughout the 100 cycles also suggests that the device is ready for integration with external health systems, potentially allowing for real-time monitoring of TB patients in low-resource settings.

Mechanical reliability was another key strength of the SAP prototype, with a 100% success rate in completing dispensing cycles and activating position sensors. The absence of mechanical failures or safety issues throughout the testing indicates that the device's hardware is reliable, reducing the likelihood of malfunctions that could interfere with treatment [11]. This reliability is essential for ensuring patient safety, as mechanical issues could undermine the effectiveness of the device in a clinical setting [19].

The device demonstrated a perfect success rate (100%) in notification delivery and event logging. These features are critical for ensuring that patients are reminded to take their medication in real-time and that caregivers or healthcare providers can track adherence [20]. The ability to deliver timely notifications (within 5 seconds) and accurately log events enhances the overall user experience and may improve patient engagement. This, in turn, could lead to better adherence rates and more effective TB treatment outcomes [21].

The data transfer time to the application showed a mean of 7.57 seconds, with some variability (range 2–41 seconds). While most data transfers occurred in real-time, some delays were observed. This variability could be due to network conditions, such as internet speed or signal stability, and may be an area for future optimization [18]. Reducing transfer time and ensuring real-time synchronization will be important for future iterations of the device, particularly for patient groups who may experience delays in treatment adherence due to connectivity issues [22].

The notification delivery system performed efficiently, with a mean delivery time of 2.05 seconds. This rapid response time ensures that patients receive timely reminders to take their medication. The efficiency of this system is particularly important for TB patients who may face challenges with consistent medication adherence[23]. Given the strict timelines for TB treatment, fast notification delivery is essential to ensuring patients take their medication as prescribed [24].

In the operational event distribution, the revised data indicates that 50 cycles involved missed doses and 50 cycles were classified as on-time doses. It is important to note that missed doses here refer to instances where medication intake occurred more than 15 seconds after the scheduled time, reflecting the accuracy of time logging by the device.Although 50% of the cycles involved missed doses, this should be viewed in the context of time logging accuracy rather than device failure. The accuracy of time is crucial to ensure that the device provides reliable information about patient adherence to the prescribed treatment [19]. According to the criteria applied in the time accuracy test, a deviation of $\leq \pm 2$ minutes [13]from the scheduled time is considered accurate, so these missed doses do not necessarily indicate a malfunction of the device itself, but rather reflect delays on the patient's part, such as forgetfulness or delayed medication intake.Thus, while there were 50 missed doses, the other 50 cycles were on time, indicating that the device is still functioning effectively in delivering timely medication reminders. This suggests that, despite some deviation in medication intake times, the device is capable of assisting patients in adhering to their TB treatment schedule and minimizing the risk of non-adherence [25].

Although the device used Wi-Fi in all cycles, 46% of the data transfers were delayed. This suggests that future testing should assess the device's performance in various network environments, including mobile data and rural areas with limited Wi-Fi access. Ensuring that the device operates reliably under a wide range of network conditions will be crucial for its successful deployment in low-resource settings [26].

The SAP prototype demonstrated high reliability, which is consistent with other studies evaluating medication adherence technologies. Similar devices have shown that alarm systems, dispensing accuracy, and notification delivery can significantly impact patient adherence, particularly in chronic disease management. However, compared to other adherence devices, the SAP prototype's seamless connectivity, mechanical reliability, and real-time data synchronization provide a more integrated and user-friendly solution. Unlike some existing systems, the SAP prototype's high performance across all domains, coupled with its potential for integration with healthcare systems, positions it as an innovative solution for improving TB treatment adherence.

Although the SAP prototype demonstrated near-perfect performance across most domains, these results should be interpreted within the context of a controlled testing environment. The 100% success rates observed in dispensing accuracy, connectivity, mechanical safety, and notification logging reflect optimal system conditions, including stable Wi-Fi connectivity and absence of external disturbances. In real-world settings, factors such as network instability, user interaction variability, and environmental conditions may affect device performance. Therefore, these findings represent baseline technical feasibility rather than definitive real-world effectiveness. Future studies should incorporate simulation of varied network conditions, including low bandwidth and intermittent connectivity, to evaluate system robustness more comprehensively.

While the findings of this study are promising, several limitations must be acknowledged. The study was conducted under controlled laboratory conditions with stable Wi-Fi connectivity, which may not fully represent real-world operational environments. The absence of network variability simulation limits the generalizability of connectivity and data transfer performance. Additionally, the use of 100 repeated cycles reflects an initial validation phase and may not capture the full range of potential system challenges that might be encountered in larger-scale studies or real-world applications. The controlled setting did not account for factors such as patient behavior, device misuse, or environmental challenges like network instability, all of which could affect device performance in clinical settings. Future clinical trials with real patients are essential to evaluate the device's effectiveness in improving adherence. Furthermore, technical limitations like data transfer variability and missed doses indicate the need for software and hardware optimizations. Future research should focus on evaluating the SAP prototype's performance in diverse settings, addressing latency issues, and incorporating features like real-time adherence feedback and enhanced analytics, which could significantly improve TB treatment adherence, especially in low-resource settings. This limitation is consistent with early-stage validation studies of digital adherence technologies, where controlled testing is prioritized prior to clinical deployment.

4. CONCLUSION

In conclusion, the SAP prototype demonstrated high functional reliability and temporal performance in a controlled validation setting, with excellent results across all domains, including alarm system, dispensing accuracy, connectivity, mechanical safety, and notification logging. While minor issues such as delayed data transfer were observed, these findings highlight areas for further optimization. The device shows significant promise as an innovative tool to enhance medication adherence in tuberculosis treatment, particularly in low-resource settings. Future clinical trials and real-world testing are essential to fully evaluate its impact on patient adherence and treatment outcomes, with potential for further integration into digital health ecosystems to support global TB control efforts.

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