

**A STUDY TO ASSESS THE FEASIBILITY OF INNOVATIVE POINT OF
CARE DEVICE- AINA FROM THE PERSPECTIVE OF USER**

Dissertation Submitted to



The IIHMR University, Jaipur

For the partial fulfillment

for the award of the degree of Master of Business Administration (MBA)

In

Hospital and Health Management

By

Dr. Kartik Sharma

Under the Supervision and Guidance of

Dr. Dhirendra Kumar

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled ‘Study to assess the feasibility of innovative point of care device-AINA from the perspective of device operators’ is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

(Signature) Name of Student

Date

CERTIFICATE

This is to certify that Dr. Kartik Sharma in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management) from the IIHMR University, Jaipur has successfully completed her/his internship at WISH Foundation, Jaipur-Rajasthan during April 12, 2021 to June 19, 2021.

Place:
Date:

Preceptor/Head of the Organization
Name of the organization

CERTIFICATE

This is to certify that dissertation titled ‘Study to assess the feasibility of innovative point of care device-AINA from the perspective of device operators’ is a record of the research work undertaken by Dr. Kartik Sharma in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management) from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

Faculty Guide
IIHMR University, Jaipur

Date

School Dean
IIHMR University, Jaipur

Date

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Abbreviations

LEHS - Lords Education & Health Society

WISH -Wadhwani Initiative for Sustainable Healthcare

PHC - Primary Health Centre

NHM -National Health Mission

HWC -Health and Wellness Centre

Lab. -Laboratory

CPHC-Comprehensive Primary Health Care

POC - Point of Care

TAT -Turn Around Time

COVID 19 - Coronavirus Disease

TB - Tuberculosis

ISO - International Organization for Standardization

PoCD -Point of care devices

MIS - Management Information System

Acknowledgement

The success of any task would be incomplete without the expression to the people who made it possible. Hereby I take this opportunity to express my deep sense of gratitude to all this who have been Instrumental in successful completion of my dissertation in WISH/LEHS Foundation, Jaipur.

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Dr. Kartik Sharma

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CHAPTER 1

2.1 Introduction

India's is having more than 1.37 billion people. Approx. 70% of the total population lives in rural areas in India. To consider this population in respect to health services, government of India created various health centers setup at rural areas, like sub centers (SC's) , Community Health Centers (CHC's) and Primary Health Centers (PHC) under National Health Mission (NHM) which have two components NUHM and NRHM.

Each primary health Centre serves around 30,000 people. PHC is headed and managed by a medical officer in charge (MOIC). Also consists of few Para medical staff. It has a small pathology laboratory for routine diagnostic tests. Although there is a reasonable infrastructure for primary care, issues such as traffic and road shortages make it difficult for pregnant women and children to access health center services.

The Primary Health Center (PHC's) is the second level of the rural health care structure, which aims to provide integrated preventive and therapeutic health care to rural people, with an emphasis on prevention and promotion aspects.

In February 2018, the Government of India announced that it would create 150,000 HWC's by converting existing sub-centers (SC's) and PHCs to provide holistic primary care, and claiming it as one main out of two components of Ayushman Bharat Yojna. In particular, the report of the Primary Care work force of the Indian Government's Department of Health and Family Welfare points out that primary care is the only reasonable and effective path for addressing the universal health coverage. It also provides valuable information on what the health system needs for comprehensive primary health care (CPHC). It is basic to highlight here that quality services to address the growing burden of communicable and non-communicable disease at the last-mile are an important and integral part of the proposed primary healthcare delivery model. Given this mandate, the importance of integrating innovative point of care devices with tele-consultation units in the primary healthcare settings across India and that can be used by frontline healthcare workers at the last-mile can hardly be overemphasized.

Point-of-care (POC) testing is highly regarded as an effective and innovative method to manage diseases, especially in settings where resources available are very poor, primarily

to reduce wait times for diagnosis and start of treatment as early as possible. The POC test has many definitions, but all of them contain important elements of the Rapid Turnaround Time (TAT) that enable rapid diagnosis and provide results on the same day itself which provides a good decision making tool such as referrals and treatment decisions. It also enables patients to receive care outside traditional health facilities, while improving access to quality care in remote, underserved places.

Point-of-Care (POC) diagnostic devices are devices used to collect patient-specific clinical information in clinical and resource-constrained setups. The POC diagnostic device is used by healthcare professionals, patients and their families because of its user-friendly features. In developing countries like India, POC devices and tests play an important role in the healthcare system. Today, POC diagnostic devices are widely used and can be used for a variety of analyses. Its Facilities range from intensive care units to outpatient clinics and private care. As India is a country with limited medical resources and advancements, the availability of various POC diagnostic devices promises benefits and helps improve the health of most of the population.

We are also currently discussing the importance of POC diagnostic equipment in the fight against the COVID-19 pandemic. The country has a large resource gap with more than Millions of healthcare professionals. Nearly 60% of the existing workforce works in urban areas and 70% of India's population lives in rural areas. In this context, providing and maintaining health care facilities in rural areas with limited resources become much more difficult. POC devices have been used as a preparatory step for clinical diagnosis to reduce the burden on the advanced healthcare ecosystem.

Low cost is a major benefit provided by POC diagnostic devices as a large part of Indian population cannot afford traditional diagnostic methods which cost them high. The availability of POC diagnostic devices has increased management reliability through rapid analysis and has facilitated the penetration of POC diagnostic devices in the Indian markets as and the households. Seasonal infections such as influenza, dengue fever and malaria add to the already threatened diseases such as pneumonia, tuberculosis (TB), thyroid dysfunction and urinary tract infections. In addition, it most often occurs in rural areas, which make up the majority of the country's population. Therefore, existing diagnostic methods, such as advanced laboratory testing systems, need to be updated with

efficient POC tests that are fast, remotely accessible and very effective in terms of cost.

The key benefits of innovative remote patient monitoring are early and real-time disease detection, continuous monitoring of patients, prevention of further illness and premature death, lower hospital costs, shorter patient stays, and more accurate measurements, improves the effectiveness of medical services using communication technology, emergency medical care, services for patients with mobility impairments, emergency road traffic accidents and other injuries using non-invasive medical interventions to improve patient lives.

The POC diagnostic devices and technologies that are in the development phase in India that has tremendous potential to impact the clinical diagnostics scenario are also emphasized.

This study tries to identify the feasibility of integrating innovative point of care devices at the PHC level and gave an insight on the challenges and limitations associated in implementing innovative point of care devices at user end.

1.2 About the Device

AINA

AINA Device is a portable blood monitoring system that performs blood tests within minutes. It allows performing up to four types of screening tests on a single platform via tablet and smartphone. The AINA Blood Monitoring System offers a wide range of tests including Hemoglobin, HbA1c, Lipid profile and glucose tests on a single platform including immunological, enzymatic or chemical assays. AINA can detect and manage chronic diseases with the world's first smartphone-based diagnostic system.

In order to manage and control chronic diseases, when it is used by the AINA Blood Monitoring System is very:

- Safe and Reliable - Manufactured in a very high quality standard in an environment in accordance with ISO 1385
- Clinically proven – clinically validated at various reputed clinical setups across the

world.

- Mobile and Cloud Ready - Compatible with iOS and Android platforms. Ready for the integration of guaranteed and secured information technology.
- •Accurate and precise – performance at par with industry gold standard, laboratory and point-of-care equipment's.

The AINA Blood Monitoring System runs a full panel of metabolic tests to deliver lab-quality results in real time within minutes. This is complemented by Habits, a behavioral guidance application that makes it possible to improve individual disease management outcomes

AINA is available in two configurations: smartphone-based devices and portable tablet-based lab systems. By connecting AINA to your smartphone, you can use your smartphone as a diagnostic test device for point-of-care (POC) results.

In this study we tried to assess the feasibility of integrating innovative point of care device- AINA at the PHC level and gave an insight on the challenges and limitations associated in implementing it at user end. This Study also emphasizes the role that POC diagnostic devices can play in reducing the disease burden at District level.

CHAPTER 2

2.1 Review of literature

The point of care testing with the innovative devices at the rural setting can be a game changer in reducing the diseases burden for the diseases. Researchers suggested that the early diagnosis and treatment at the initial progress of disease decreases the chance of fatality. In 2015, a study was published explaining the agents, techniques and practices involved in the diagnosis of major diseases in five scenarios in India. Surrounding homes, communities, clinics, labs, and hospitals to understand how the tests are used and can be fitted into the health system and with what implications for the POC continuum.

In 2017, a study was conducted to shed light on the implementation of PoCD in primary care in rural Africa from a stakeholder perspective.

In 2017, another study was published explaining and reviewing recent advances in telemedicine and monitoring in both with contactless methods and contact. This review highlighted some issues in most healthcare systems.

A study conducted in 2020 aimed to focus on the phenomenon of POCD in the Indian healthcare system with updated information on the ongoing COVID-19 scenario. It also focuses on devices and technologies that are in the R&D phase across the country, which have great potential to improve clinical and diagnostic scenarios for the ongoing COVID-19 pandemic. . The study also discusses the means of using POC diagnostic devices and the future goals of technological advancements that can improve the state of healthcare and related fields in India

2.2 Research Question

Does implementation of the point of care device AINA at PHC across Rajasthan is feasible from operator's point of view?

2.3 Objectives

- To assess the feasibility of AINA device from the users perspective.
- To assess the challenges and limitations associated in at user end.

CHAPTER 3

METHODOLOGY

3.1 Study Design:

It was a mixed approach having both qualitative as well as quantitative component. There are 25 respondents from the HWC/PHC across Rajasthan where AINA device are installed. The study was done for a period of 2 months.

3.2 Sampling Technique:

Using purposive sampling of the operators from the 25 health center's where the device is installed based on the previous year MIS data across the various districts from Rajasthan.

3.3 Data collection procedure:

Data was collected through Phone call Interview of the device operators i.e. LT, GNM. Before collecting the data they were thoroughly explained about the purpose of the study.

3.4 Tool of analysis:

Analysis was done using the Microsoft Excel in which the qualitative question component was coded and then analyzed using the formulas. Followed by the results was depicted in the form of graphs and tabular form.

3.5 Data collection instrument: Structured interview having the questions based on parameters related to the use of device AINA across

3.6 Study population:

The study respondents were the operators of the Device AINA at the Health center's across the various districts from Rajasthan. The Data was collected by a structured interview based on the parameters related to the use of device and responses were submitted by the respondents from the Health center's across the District of Rajasthan.

Below is the list of Facilities that were covered:-

S.no	Facility	District
1.	HWC Sorsan	Baran
2.	HWC Dholam	
3.	HWC Bhajneri	Bundi
4.	PHC Jajawar	
5.	PHC Dugari	
6.	PHC Khandwa patta	Churu
7.	HWC Myala	
8.	PHC Richha	Dungarpur
9.	UPHC Needad	Jaipur I
10.	PHC Chacchlao	Jhalawar
11.	PHC Kanwara	
12.	PHC Dhanuri	Jhunjhunu
13.	PHC Padampura	
14.	HWC Kherulla	Kota
15.	PHC Barod	
16.	PHC Kotra deep singh	
17.	PHC Lakshaneeja	
18.	HWC badi sagthali	Pratapgarh
19.	PHC Ambirama	
20.	HWC Kankarwa	Rajsamand
21.	HWC Kuncholi	
22.	PHC Odda	
23.	HWC Kundali nadi	Sawai madhopur
24.	PHC Bhadoti	
25.	PHC Mandwa	Udaipur

Table 1: AINA device installed facilities list

3.7 Inclusion Criteria:

Operators from the Health center's that have point of care device – AINA installed.

3.8 Exclusion criteria:

Operators from the Health center's that do not have point of care device – AINA installed.

3.9 Ethical consideration:

Respondents were clarified about the purpose and importance of this study and answered questions. They had given clear consent to ensure the safety and security of the data collected. The data collected will be used for research purposes only.

CHAPTER 4

4.1 Result

Characteristics	Number (n=25)
Gender	
Male	23
Female	2
Education	
Graduation	25
Post-graduation	0
Above post-graduation	0
Marital status	
Married	10
Unmarried	15
Experience	
1-2 years of experience	5
2-4 years of experience	11
Above 4 years of experience	9

Table 2 Background information of the respondents

4.1. A. Graphical depiction of the results obtained

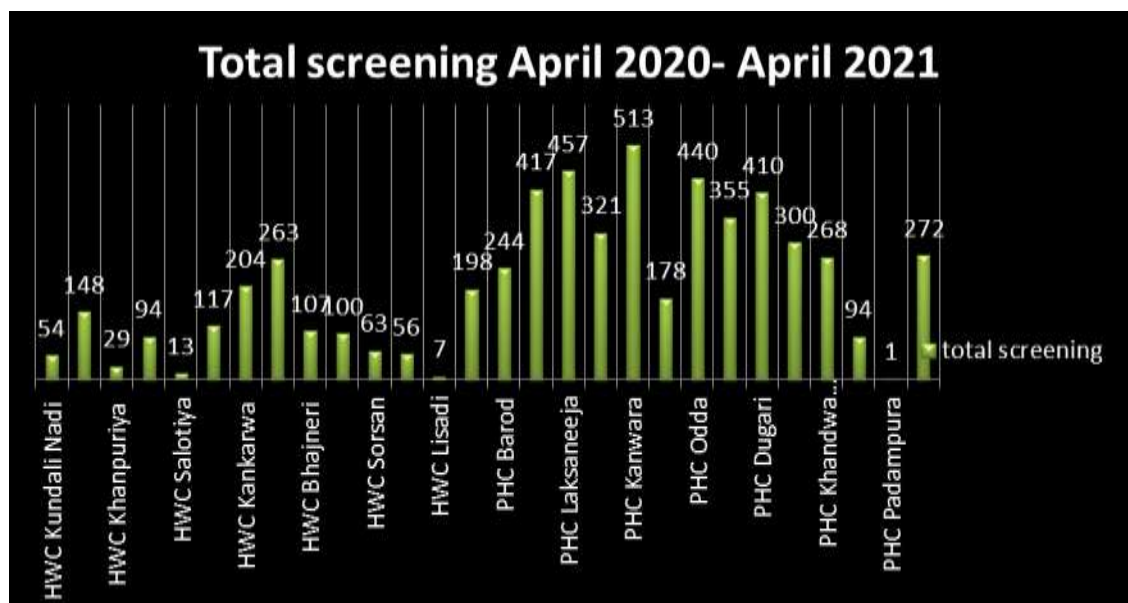


Figure -1: Patient screened by AINA device at PHC in Rajasthan

Figure 1 showing the number of test done as per the facilities across Rajasthan from the April 2020 to April 2021. The top five facilities with most number of tests across all the districts of Rajasthan were

PHC Kanwara, followed by PHC Laksaneeja , PHC Odda, PHC Kotradeep singh and PHC Dugari . While the lowest number of tests done from the April 2020 to April 2021 are at PHC Padampura and HWC Lisadi.

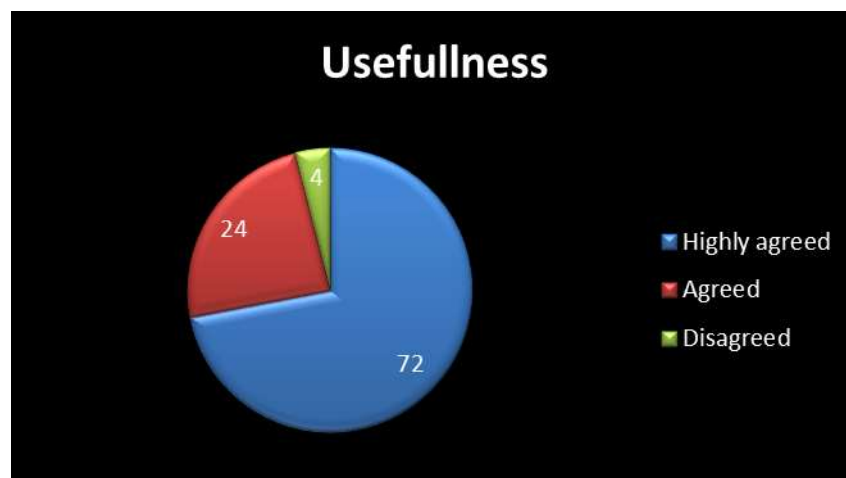


Figure 2: Usefulness of the AINA-device at Facility

Figure 2 showing the perception of the device operators towards the device usefulness at PHC and below level. An Overall 96 % device operator agreed and supports the fact that the AINA device is very useful at the facilities and only 4% disagreed that the AINA device are useful.

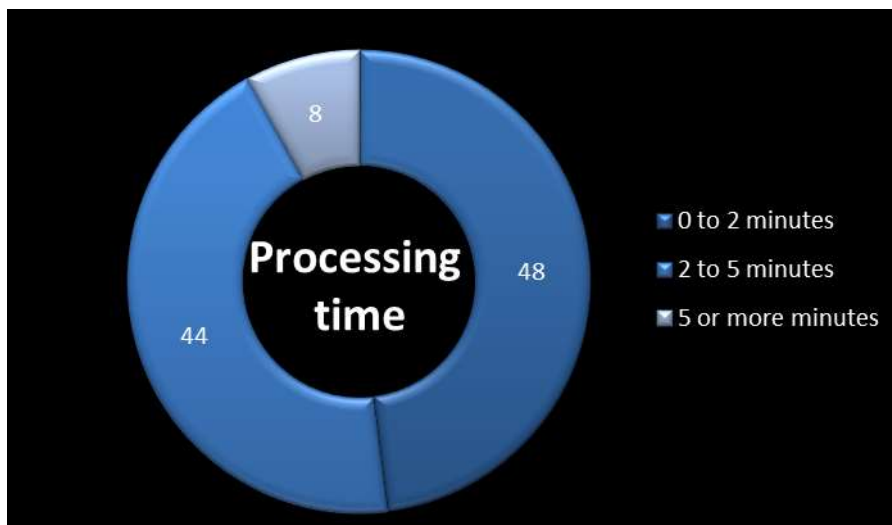


Figure 3: Processing time of device per testing

Figure 3 showing that when the AINA-Device operators were asked about the processing time of device per testing i.e. the time from the patient came and the test starts till the report generated , 48% operators responded that the device takes around 0-2 minutes per testing including the average of all tests. 44% said that the device takes around 2 to 5 minutes in testing and only 8 % said that the device takes 5 or more minutes while testing the patient.



Figure 4: Training requirement before use of device

In the above figure 4 it is showing the perception of the operators towards the required training before using the device. Approx. 88% says that only one session is enough to learn the process and use of the AINA device while no operator says that more than two sessions are required for the training and 12 agreed that 2 training sessions are needed to learn on how to operate the device.

DEVICE MANIPULATION



Figure 5: Required assistance for testing **Figure 6:** Perception towards handling and using device

Figure 5 and 6 showing the perception of the operators towards the use of device. All the AINA-Device operators' percepts that they do not require any assistance while using the device.

While when the operators asked about how much user friendly the device is in terms of manipulation on a rating from 1 to 10, none of the respondents gave below 4 rating i.e. they think that it's not difficult to use. 24 % respondents gave rating between 4 to 7 and 76 % of the operators gave rating 8 or above which can be noted as very easy to handle and use the AINA device.

Overall average rating given of perception towards handling and device usage is 8.27.

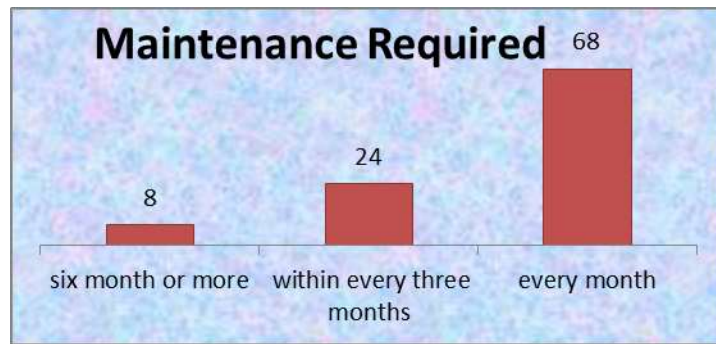


Figure 7: Maintenance required for AINA Device

The figure 7 shows the details about the maintenance required for the AINA Device. 68 % says that the maintenance for the AINA device is required every month, 24 % says maintenance required within 3 month and 8% says that the maintenance required or no after six month it also counts the no maintenance required.

CHALLENGES WHILE USING THE DEVICE

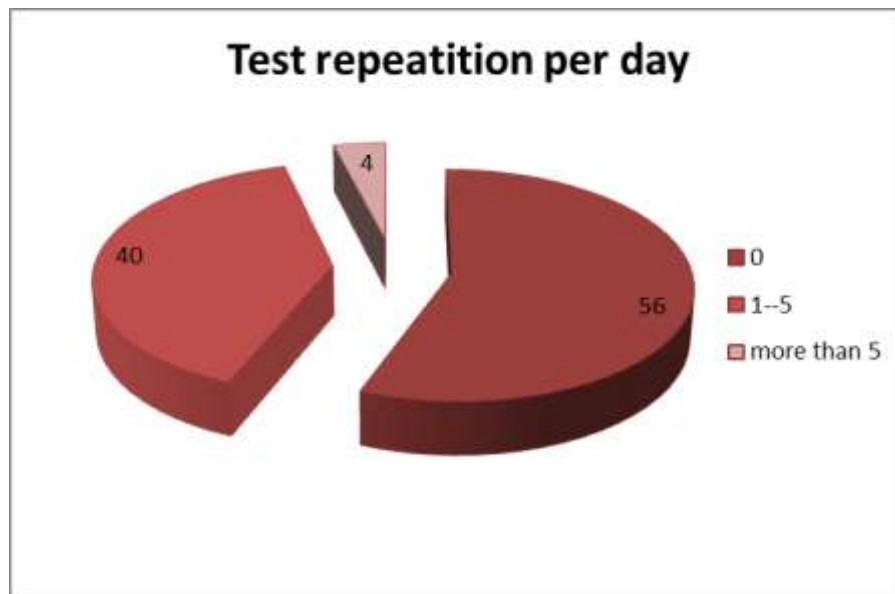


Figure 8: Test Repeat per day due to error

Figure 8 and 9 shows the challenges the operators faced while using the device 56 % of the respondents says that they have not faced any error or they do not have to repeat test till now. 40 % have repeated test 1 to 5 times per day and only 4 % says that they repeated five or more times per day

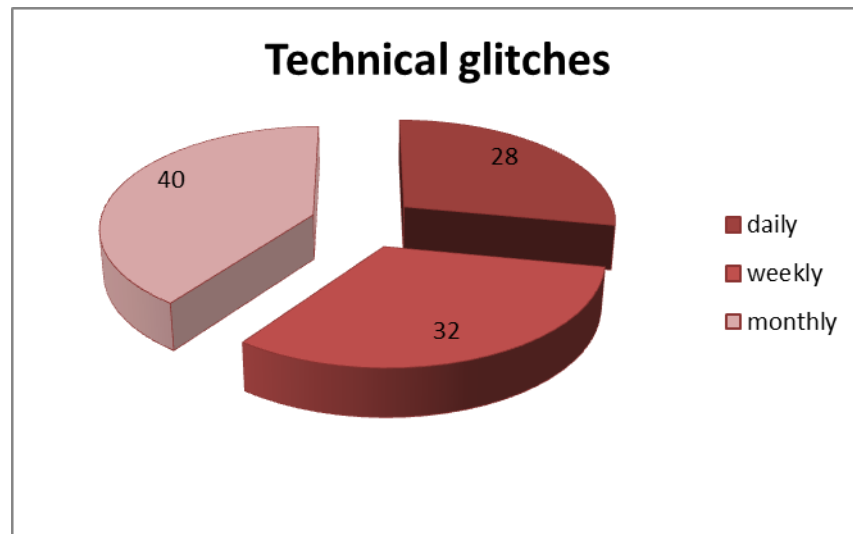


Figure 9: Technical glitches (network, connectivity, process error)

28% face the technical glitches like slow processing of the device, network issues and connectivity issues daily, 40 % faces glitches monthly or they haven't faced any glitches till now while 32 % faces those glitches weekly.

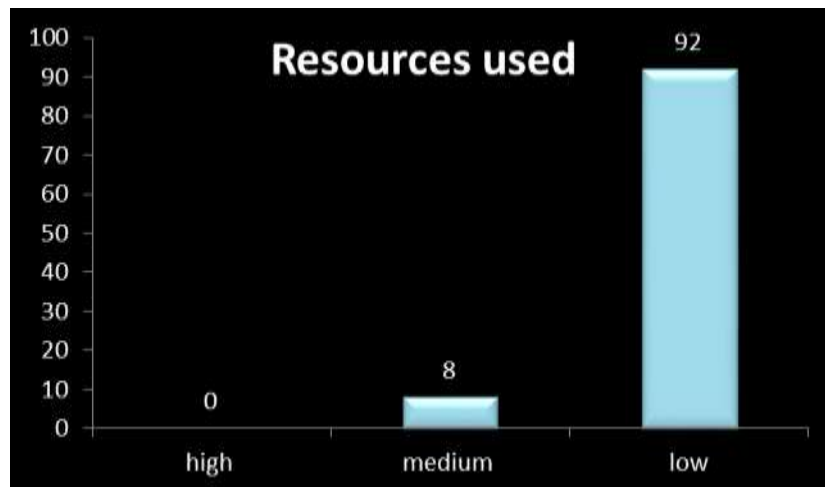


Figure 10: Resources used for testing compared to the other device

The figure 10 shows the results based on the resources used in comparison to the other devices on which same tests are done. 92 % of the operators responded that the resources required are low in comparison to the other devices. While 8% said that the resources used are quite few or low and no one said that the resources are high in comparison to the other devices.



Figure 11: Perception of operators towards accuracy of the AINA-device

In figure 11 it can be seen that 84 % operation percepts that the AINA- device accuracy is more than 90 % while testing and 16 % operators thinks that the device accuracy is between 70 to 90 percent. None of the respondents thinks that its accuracy is below 70 %.

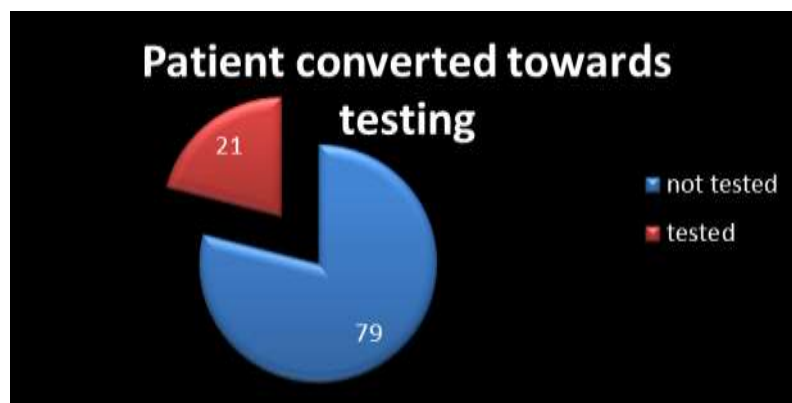


Figure 12: Patient percentage converted to testing by AINA devices daily

Figure 12 showing that out of the daily OPD patients 21 % tested daily with the AINA devices while 79 % did not get tested with AINA device. The count of patients tested daily with AINA device increases in some facilities on 9th day of every month from 21 % to up to 40-45 % as the pregnant lady screening increase on day 9.

4.2 Discussion

Study by Engel, N., Ganesh, G., Patil, M. et al. suggests that there are many diagnostic delays that interfere with the continuity of POC. Conventional rapid tests are not currently available because they have not translated into rapid treatment decisions or may warrant shorter turnaround times, thus completely reducing their potential. While this study resulted that more than 92% of test execution times were found to be less than 5 minutes.

Various studies have done for the accuracy of AINA device which suggests that the device accuracy is more than 90 % in comparison with the other methods of testing in view with that study; this study suggests that more than 84 % people responded that the device accuracy is more than 90 %.

A Study by Aditya Narayan Konwar, Vivek Borse, et al suggests that TATA Elxi has developed a glucose monitoring device. It is easy-to-use, portable, and very convenient for people that need continuous blood glucose level monitoring this study gives an account on that operators gave an average 8.27 rating to use which shows that it is very easy to use add on to that 100 % operators support the statement by responding that they do require any assistance while using the device. Also the resource requirement is very low responded by approx. 92 % operators.

A study by Tivani P. Mashamba-Thompson, Ngcwalisa A. Jama, Benn Sartorius, Paul K. Drain, Rowan M. Thompson et al showed that 11 key stakeholders were involved in the study and all stakeholders found that the main benefit of the point of care diagnostic devices as it enables access to healthcare diagnostic services for rural patients. Stakeholders believe that existing POC diagnostic services can meet the needs of patients. In contrast to the study, this study also suggests that more than 96 % operators agreed that the AINA-device is really useful at PHC.

CHAPTER 5

5.1 Recommendation

Despite the fact that the use of AINA-device at PHC level helps in decreasing the patient loads at district hospital the device makers need to incorporate few changes to resolve the issues like technical glitches.

In few devices it is found that in the months of summer season due to temperature increase there is a variation or error seen in the devices, operator's needs to have look on that. The device can be placed at ac rooms where the temperature can be maintained in contrast to summer season.

The device need maintenance like cleaning within 15-20 days as the optical lens becomes dusty and results in variations of the test value manufacturers need to account the issue. Manufacturers can organize virtual training on how to clean and maintain the device so that the results won't get affected.

5.2 Limitation and strength

This study is the first primary care study to investigate the perceptions of rural health care providers in Rajasthan regarding the major barriers associated with the diagnostic process. This information will help develop and implement health innovations that can improve service delivery in rural areas.

The study was carried out in the lockdown period due to corona virus second wave in Rajasthan so it was not feasible to interview the operators in person or at the site.

The study was carried out during the time of handing over of PHC to GOVT. of Rajasthan that resulted towards less interest in participation of the operators.

This study only based on the perception towards the AINA- device of the device operators at the facilities.

CHAPTER 6

Conclusion

The effectiveness of point of care AINA device for better patient outcomes, including improved access to diagnosis and treatment, has been demonstrated. Increasing access to POC diagnostic devices, such as AINA device, is one of the global medical priorities in resource-constrained environments with restricted access to lab infrastructure. Our results highlight the feasibility and key challenges in implementing POC diagnostic services at the HWC/PHC/CHC level. A better implementation of POC diagnostics in these contexts requires ideas, perspective and collaboration among POC stakeholders to overcome the above obstacles.

To ensure the success of Point of care testing surveys or programs, test developers, policy makers, and funders must account for the everyday ground realities and challenges to overcome the barriers of POC testing programs.

REFERENCES

1. Engel, N., Ganesh, G., Patil, M. et al. Point-of-care testing in India: missed opportunities to realize the true potential of point-of-care testing programs. BMC Health Serv Res 15, 550 (2015). <https://doi.org/10.1186/s12913-015-1223-3>
2. Engel N, Ganesh G, Patil M, Yellappa V, Pant Pai N, et al. (2015) Barriers to Point-of-Care Testing in India: Results from Qualitative Research across Different Settings, Users and Major Diseases. PLOS ONE 10(8): e0135112. <https://doi.org/10.1371/journal.pone.0135112>
3. Vikram thaploo, Apollo, Essence of Point-of-Care Diagnostic Testing (POCT) in Remote Healthcare in India; Published on July 20, 2017. Available from <https://www.linkedin.com/pulse/essence-point-of-care-diagnostic-testing-poct-remote-india-thaploo>
4. Aditya Narayan Konwar, Vivek Borse, Current status of point-of-care diagnostic devices in the Indian healthcare system with an update on COVID-19 pandemic, Sensors International, Volume 1, 2020, 100015, ISSN 2666-3511, <https://doi.org/10.1016/j.sintl.2020.100015>.
5. Mashamba-Thompson TP, Jama NA, Sartorius B, Drain PK, Thompson RM. Implementation of Point-of-Care Diagnostics in Rural Primary Healthcare Clinics in South Africa: Perspectives of Key Stakeholders. Diagnostics (Basel). 2017;7(1):3. Published 2017 Jan 8. [doi:10.3390/diagnostics7010003](https://doi.org/10.3390/diagnostics7010003)
6. Geoffrey C. E. Herd, Samarina M. A. Musaad; Point-of-Care Testing in Rural and Remote Settings to Improve Access and Improve Outcomes: A Snapshot of the New Zealand Experience. *Arch Pathol Lab Med* 1 March 2021; 145 (3): 327–335. doi: <https://doi.org/10.5858/arpa.2020-0104-RA>
7. Goodridge D, Marciniuk D. Rural and remote care: Overcoming the challenges of distance. *Chron Respir Dis*. 2016;13(2):192-203. [doi:10.1177/1479972316633414](https://doi.org/10.1177/1479972316633414)
8. Anticona Huaynate, C.F., Pajuelo Travezaño, M.J., Correa, M. et al. Diagnostics barriers and innovations in rural areas: insights from junior medical doctors on the

frontlines of rural care in Peru. BMC Health Serv Res 15, 454 (2015).
<https://doi.org/10.1186/s12913-015-1114-7>

9. Pai NP, Vadnais C, Denkinger C, Engel N, Pai M. Point-of-care testing for infectious diseases: diversity, complexity, and barriers in low- and middle-income countries. PLoS Med. 2012;9(9):e1001306. doi: 10.1371/journal.pmed.1001306. Epub 2012 Sep 4. PMID: 22973183; PMCID: PMC3433407.