DISSERTATION
AT
JHPIEGO, NEW DELHI

A LANDSCAPE OF POINT OF CARE DIAGNOSTICS DEVICE FOR COMPREHENSIVE PRIMARY HEALTH CARE IN INDIA

BY

MISHRABA
PG/21/060

UNDER THE GUIDANCE OF

DR TUKARAM KHANDADE

PGDM (Hospital &Health Management) 2021-2023

International Institute of Health Management Research New Delhi

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NAME MISHRABA

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UNDER THE GUIDANCE OF

DR ANANDHI RAMACHANDRAN

International Institute of Health Management Research, New Delhi

Completion of Dissertation from respective Organization

This certificate is awarded to

Mishraba

In recognition of having successfully completed his/her internship in the department of

Digital Health and Innovation

And has successfully completed his/her Project on

A landscape of Point of Care Diagnostics devices for comprehensive primary Health care in India.

From

February 20th 2023 to May 19th 2023

At

Jhpiego

She comes across as a committed, sincere & diligent person who has a strong drive & zeal for learning.

We wish her all the best for future endeavors.

Training and Development

Dr Tukaram Khandade

Zonal Head -Human Resources

TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Miss Mishraba** student of Post Graduation Diploma in Hospital and Health Management(PGDM)from International Institute of Health Management Research, New Delhi has undergone internship training at **Jhpiego, India** from **February 20th 2023 to May 20th 2023**.

The candidate has successfully carried out the study designated to her during internship training and her approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish her all success in all his future endeavor

Dr Sumesh Kumar
Dean, Academics and Student Affairs
IIHMR, New Delhi

Dr. Anandhi Ramachandran
Professor, IIHMR New Delhi

Certificate of Approval

The following dissertation titled **"A Landscape of point of care diagnostic devices for Comprehensive Primary care in India "** at **"Jhpiego, India "** is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of **PGDM (Hospital & Health Management)** for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

Dissertation Examination Committee for evaluation of the dissertation.

Name	Signature
EKTA SAROHA	
Anandhi Ramachandran	

Certificate from Dissertation Advisory Committee

This is to certify that **Ms. Mishraba ,** a graduate student of the **PGDM (Hospital & Health Management)** has worked under our guidance and supervision. He/ She is submitting this dissertation titled " **A landscape of Point of Care Diagnostics devices for comprehensive primary Health care in India**" at "JHPIEGO INDIA" in partial fulfillment of the requirements for the award of the **PGDM (Hospital & Health Management).**

This dissertation has the requisite standard and to the best of our knowledge no part of it has beenreproduced from any other dissertation, monograph, report or book.

Dr. Anandhi Ramachandran
Professor, IIHMR New Delhi

Dr. Tukaram khandade
Lead Innovation, Jhpiego.

INTERNATIONAL INSTITUTE OF HEALTH MANAGEMENT RESEARCH, NEW DELHI

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled **A landscape of Point of Care Diagnostics devices for comprehensive primary Health care in India** and submitted by **Ms. Mishraba** Enrollment No. PG/21/060 under the supervision of **Dr. Anandhi Ramachandran & Dr. Tukaram Khandade** for award of postgraduate Diploma in Hospital and Healthcare Management of the institute carried out during the period from **February 20th 2023 to may 20th 2023** embodies my original work and has not formed the basis for the award of any degree, diploma associateship, fellowship, title in this or any other institute or other similar institution of higher learning.

Ms. Mishraba

FEEDBACK FORM

Name of the Student: Mishraba

Name of the Organization in Which Dissertation Has Been Completed: Jhpiego

Area of Dissertation: A landscape of Point of Care Diagnostics devices for comprehensive primary Health care in India

Attendance: 100%

Objectives achieved: Yes

Deliverables: 1. Landscaping document for Point of Care devices 2. Detailed report on analysis of landscape

Strengths: Sincerity, Punctuality, meeting the deadlines, willingness to learn

Suggestions for Improvement: NA

Suggestions for Institute (course curriculum, industry interaction, placement, alumni): NA

Signature of the Officer-in-Charge/ Organization Mentor (Dissertation)

Dr. Durbha Rohini Kumar

Date: 27/06/2023
Place: Delhi

FEEDBACK FORM

Name of the Student: Mishraba

Name of the Organization in Which Dissertation Has Been Completed: Jhpiego, New Delhi, India

Area of Dissertation: Lan A landscape of Point of Care Diagnostics devices for comprehensive primary Health care in India

Attendance: Complete

Objectives achieved: Yes, she has completed the literature search, Analysis, and report writing

Deliverables:
She has submitted the final report on the landscape study

Strengths:
She is good at understanding the digital health applications. She is focused person.

Suggestions for Improvement:
She needs to continue learning the analysis of the data. She needs to gain more understanding of drawing recommendations from the study results.

Suggestions for Institute (course curriculum, industry interaction, placement, alumni):
Besides internships, the institute may initiate a tie-up with industry players, through which the students after completion of elective modules (logistic management, NGO management, advocacy, etc) may be posted for one day at the industry to observe how it is done practically.

Dr. Tukaram Khandade

Signature of the Officer-in-Charge/ Organization Mentor (Dissertation)

Date: 28.6.2023

Place: Delhi

Acknowledgment

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Mishraba
PG/21/060

Table of Contents

Abstract

A landscape of Point of Care Diagnostics devices for comprehensive primary Health care in India. The rational of this study is currently not much information is available related to POC diagnostic devices for primary care level in India. Their availability, cost, services provided etc. need to be known so they could be easily integrated with existing workflow in the primary health care levels. This will provide a solution for reducing the cost of service and increase quality of care. Hence such information need to be identified as need of the hour. The aim of doing research on this topic is to explore the landscape of point of care devices available in India and to identify their suitability for adoption in the health and wellness centers and the expected outcome of this study is this landscaping review will provide an in-depth information of the type of point care devices available in the country, their features, and their suitability for adoption in the country. This would help the policy makers, and health care service providers to take decisions on utilization these POCs in for primary care in the country. Total 116 point of care diagnostic devices we have included in this study. The results shows that there are Among the 116 Devices 69 (59.48%) are handheld device, 44(37.93%) are portable, 2(1.72%) are wearable, and 1(0.86%) are benchtop device. 56(48.28%) are connected, 60(51.72%) are unconnected devices. Among 56 connected devices, 20 (36%) are mobile application based, 10(18%) are IoT devices, 7 (13%) are connected through web and mobile application, 5 (9%) are Bluetooth and Wi-Fi connected devices, 5 (9%) are connected through Bluetooth only and remaining are connected through LIS, USB, Wi-Fi, Pc etc.. 37 devices for physiological test, 21 are for general monitoring, 15 are for biochemical and 13 for urology test, 10 for Hematology, and remaining for other test. Among total 116 devices 48 (41.37%) are approved. Limitations of this study is Scarcity of literature related to POC's cost features etc and POCs adopted for PHC and HWC centers only.

List of Abbreviations

1.	AI- Artificial Intelligence
2.	CGM- Continuous glucose monitoring
3.	PCR- Polymerase Chain Reaction
4.	RT-PCR- Reverse transcription-polymerase chain reaction
5.	COVID-19 – Coronavirus Disease 2019
6.	SMBG- Self-monitoring blood glucose
7.	POCT - Point of care Testing.
8.	ER- Emergency Room.
9.	NCDs- Non-Communicable Diseases
10.	HbA1c- Glycated hemoglobin
11.	IoMT- Internet of Medical Things
12.	PCR- Polymerase Chain Reaction
13.	ELISA- Enzyme-linked immunosorbent assay
14.	POC- Point of care
15.	CVD- cardiovascular disease
16.	IoT- Internet of Things
17.	TB- Tuberculosis
18.	ICER- Incremental cost-effectiveness ratio
19.	DALY- Disability-adjusted life year
20.	MTB/RIF- Mycobacterium tuberculosis complex/resistance to rifampin
21.	HIV- Human immunodeficiency virus
22.	IP- Intellectual Property
23.	WIPO: World Intellectual Property Organization
24.	NGO- Non-Government Organization
25.	STI- Sexually Transmitted Infection
26.	RVF- Rapid Vertical Flow
27.	MAbs- Monoclonal Antibodies
28.	SARS-CoV-2- severe acute respiratory syndrome coronavirus 2.
29.	IgG- Immunoglobulin G.
30.	sIgA- secretory Immunoglobulin A
31.	ECL- electrochemical
32.	SERS- Surface-enhanced Raman scattering spectroscopy
33.	mHealth- Mobile device related health,
34.	INAA- Isothermal nucleic acid amplification
35.	LOAD- lab-on-a-disc (LOAD)
36.	PADs- Paper-based Analytical Devices
37.	SERS- Surface-enhanced Raman scattering
38.	MEMS- Micro electro-mechanical systems
39.	HCG- Human chorionic gonadotropin
40.	OPD- Out Patient Department

41.	WHO- World Health Organization
42.	TAT- Turnaround time
43.	HRMS- Human Resource Management System
44.	UP- Uttar Pradesh
45.	EMR- Electronic Medical Record
46.	MIS- Management Information System
47.	PPP- Public Private Partnership
48.	NIC- National Informatics Center
49.	ECS- Electronic Clearance Service
50.	MRMBS- Dr. Muthu Lakshmi Reddy Maternity Benefit Scheme
51.	ASHA- Accredited Social Health Activist
52.	ICD- International Classification of Disease
53.	GHMIS- Gujarat Hospital Management Information System
54.	GDP- Gross Domestic Products
55.	HWC- Health and Wellness Center
56.	SHC- Secondary Health Center
57.	PHC- Primary Health Center
58.	UPHC- Urban Primary Health Center
59.	AYUSH- Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy
60.	UHWC- Urban Health and Wellness Centre.
61.	MoHFW- Ministry of Health and Family Welfare
62.	ICT- Information and communication technology
63.	ENT- Ear, Nose, Throat
64.	TB- Tuberculosis
65.	AB- Ayushman Bharat
66.	ABHWC- Ayushman Bharat Health and Wellness Center
67.	PM-JAY- Pradhan Mantri Jan Arogya Yojana
68.	CPHC- comprehensive primary healthcare
69.	HR- Human Resource
70.	UHC- Universal Health Coverage
71.	PM-ABHIM- Pradhan Mantri Ayushman Bharat Health Infrastructure Mission
72.	CSS- Centrally Sponsored Scheme
73.	FC-XV- Fifteenth Finance Commission
74.	IPHS- The Indian Public Health Standard
75.	FRU- First Referral Units
76.	CHC- community health centres
77.	NRHM- National Rural Health Mission
78.	BMS- Basic Minimum Services
79.	SC- Sub Center
80.	ANM- Auxiliary nurse midwife
81.	SAMD- software as a medical devices

CHAPTER-1

INTRODUCTION

Introduction

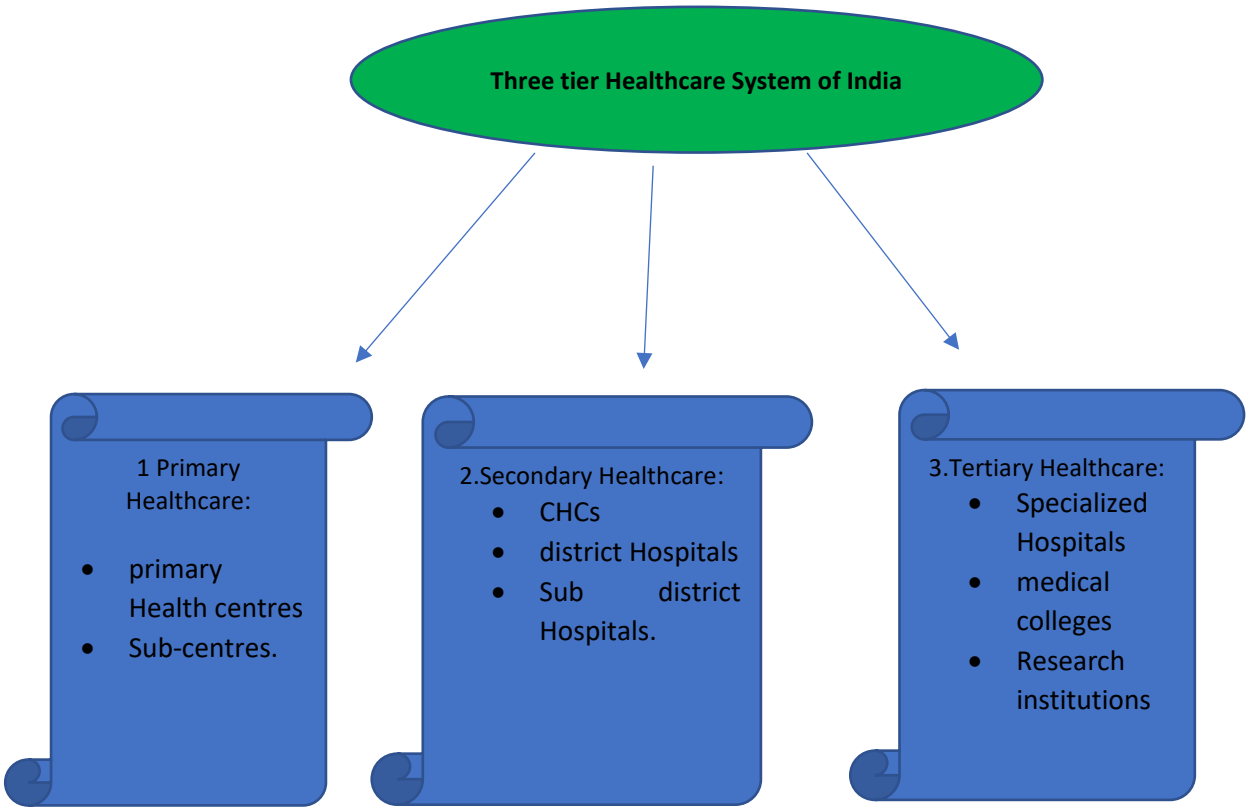
The Bhore Committee Report, often referred to as the Report on the Health Survey and Development Committee, was released in 1946 and is regarded as a foundational work for India from which the nation's current health policies and systems have evolved.[1]

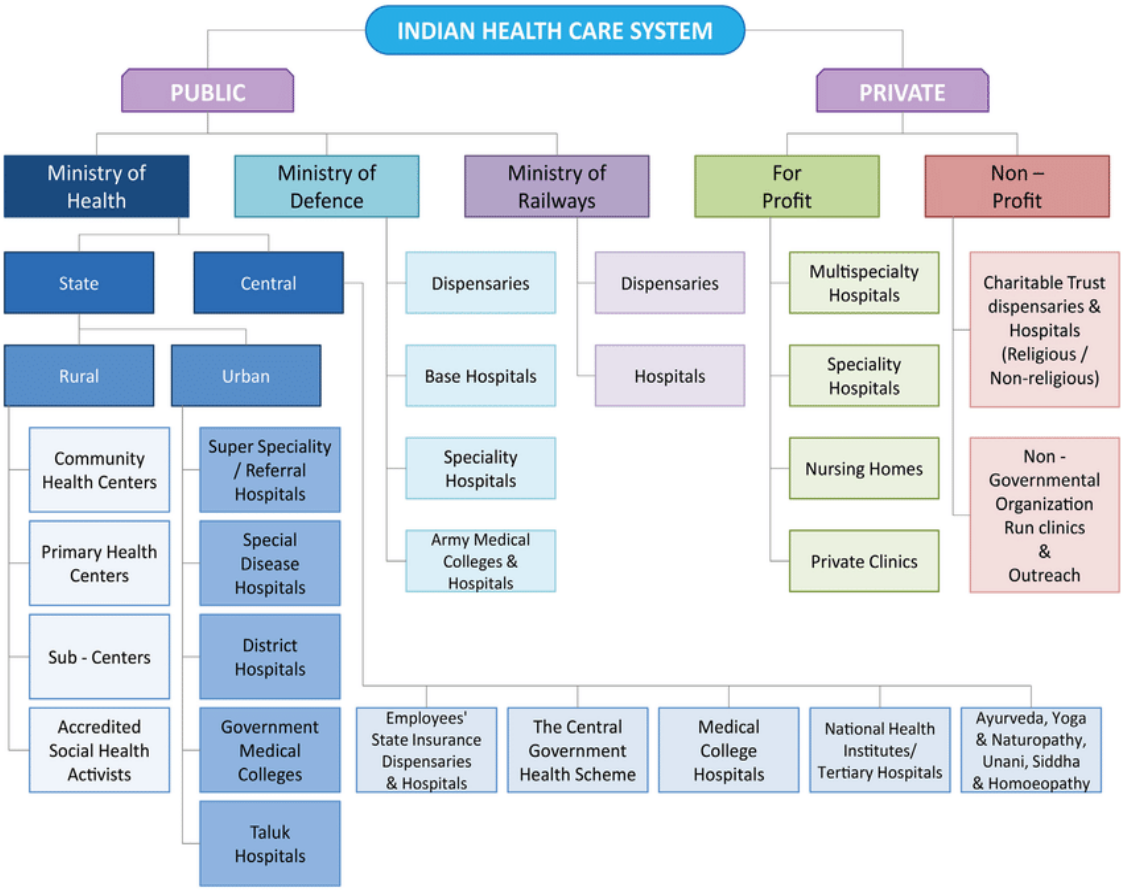
The three-tiered healthcare system was advocated in order to provide preventive and curative healthcare in both urban and rural areas, placing healthcare workers on government payrolls and reducing the need for private practitioners. These principles form the foundation of the current public health care systems. This was done to ensure that a person's capacity to get primary care would not be impacted by their socioeconomic situation. However, as a result of the need for high-quality care not being met by public health systems, private health-care systems evolved concurrently, continuously and progressively expanding the provision of private health-care services.[2]

India has a three-tiered healthcare system consisting of primary, secondary, and tertiary levels of care. Here's an introduction to each of these tiers:

The primary or initial point of contact for the three-tier healthcare system are the sub-centers that provide services to a population of 3000-5000 persons.[3]

The Primary Health Centres (PHC) established in rural and urban areas for a population of 30,000 in plains and 20,000 in hilly and tribal regions are then connected to the sub-centers. Plain areas, where Community Health Centres (C.H.C.) are put up as the initial point of referral for Primary health centres, are home to every 1,20,000 people. In mountainous, tribal parts of India, the second tier of the public health system provides care to every 80,000 people. The third tier of healthcare and tertiary care are provided by the First Referral Units (F.R.U.s), which are created at the district or sub-district levels and provide 24-hour healthcare services.[4]


Three tier Healthcare System of India
1 Primary Healthcare:
primary Health centres
Sub-centres.
2.Secondary Healthcare:
CHCs
district Hospitals
Sub district Hospitals.
3.Tertiary Healthcare:
Specialized Hospitals
medical colleges
Research institutions



Sources: https://www.drishtiias.com/daily-updates/daily-news-editorials/public-health-system-in-india

Sub centre: The community's first and furthest-reaching point of contact with the primary healthcare system. In plain areas with 5000 people and in hilly, difficult-to-reach, tribal areas with 3000 people, a sub-centre (SC) is built. Each SC shall have a minimum of one auxiliary nurse midwife (ANM)/female health worker and one male health worker. [3]

Primary health centre (PHC): The primary health centre (PHC), which is established in plain regions with a population of 30 000 and in hilly/difficult-to-reach/tribal areas with a population of 20 000, serves as the first point of contact between the village community and the medical officer. PHCs were created to provide integrated curative and preventive healthcare to rural residents, with an emphasis on the preventive and promotive components of care. PHCs are created and run by the state governments in compliance with the Minimum Needs Programme (MNP)/Basic Minimum Services (BMS) Programme.[3]

community health centres (CHCs): Community health centres (CHCs) are established and maintained by the State Government under the MNP/BMS programme in areas with a population of 120 000 as well as in hilly, challenging-to-reach, and tribal areas with a population of 80 000. Four medical professionals, including a surgeon, physician, gynaecologist/obstetrician, and paediatrician, as well as 21 paramedical and

support employees, are the absolute minimum that a CHC must have on staff.It has a labour room, an operating room, an X-ray room, and lab equipment. It also has 30 beds. It serves as a referral centre for PHCs in the area and offers obstetric care and specialist consultations in addition to doing both of those things.[4]

First referral units: A fully functioning first referral unit (FRU) may only be defined as an existing facility that is outfitted to provide 24-hour services for emergency obstetric and new-born care, in addition to any emergencies that any hospital is expected to provide. District hospitals, subdivisional hospitals, and CHCs are included in this.

It should be emphasised that in order to be classified as a FRU, a facility must satisfy three requirements:

i. urgent obstetric care, including caesarean sections and other surgical treatments;

ii. A facility with a 24-hour blood storage facility;

iii. care for small, ill new-borns.

First Referral Units (FRU) offers a full range of family planning services, safe abortion services, treatment of STI/RTI, the availability of blood storage units, and referral transport services. It also offers caesarean section, newborn care, emergency care for sick children, and a full range of family planning services. From 940 in 2005 to 2996 in 2020, there will be a significant increase in the number of FRUs (upto 31.12.2020).[5]

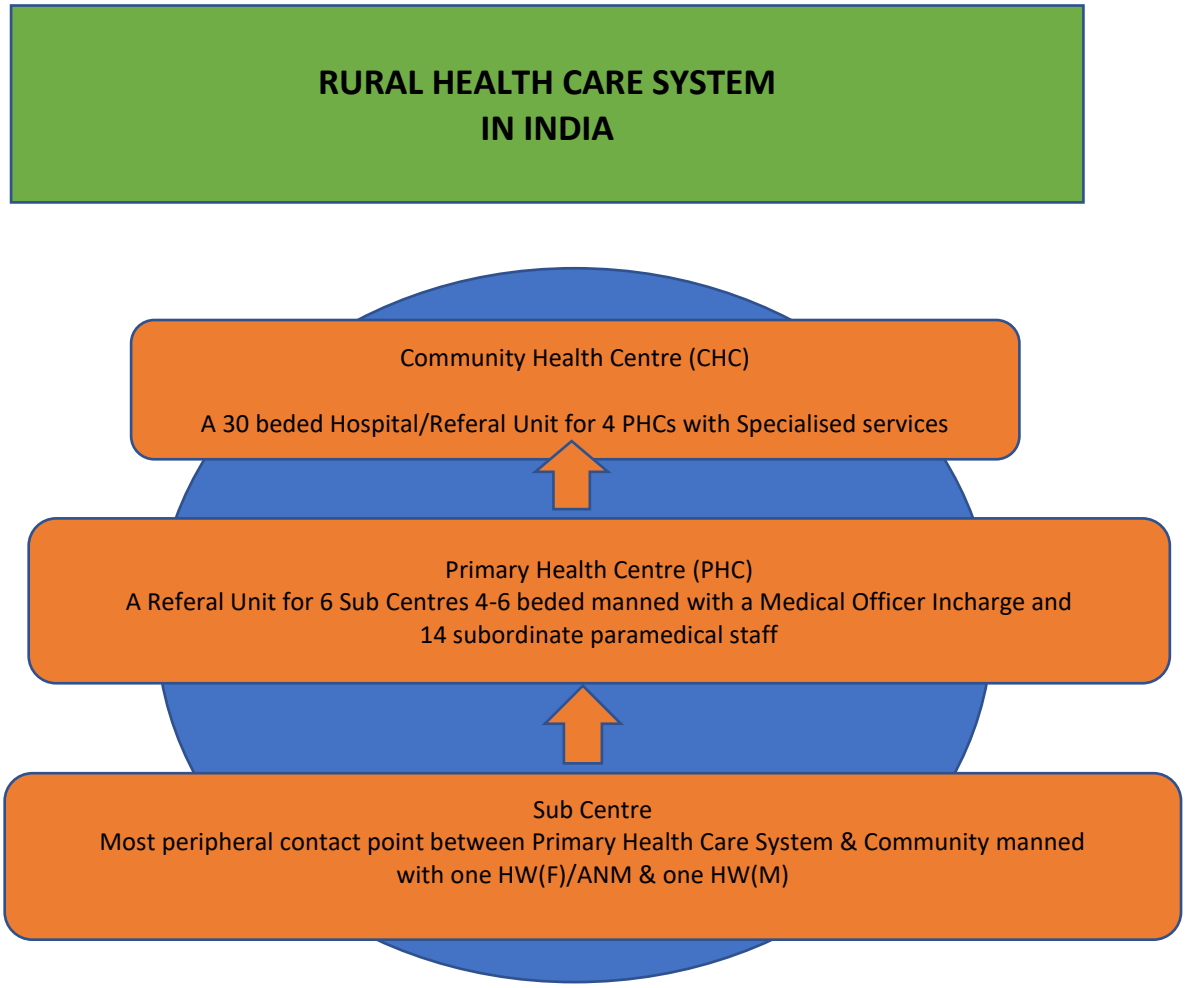
Centre	**Population Norms**	
	Plain Area	**Hilly/Tribal/Difficult Area**
Sub-Centre	5000	3000
Primary Health Centre	30,000	20,000
Community Health Centre	1,20,000	80,000

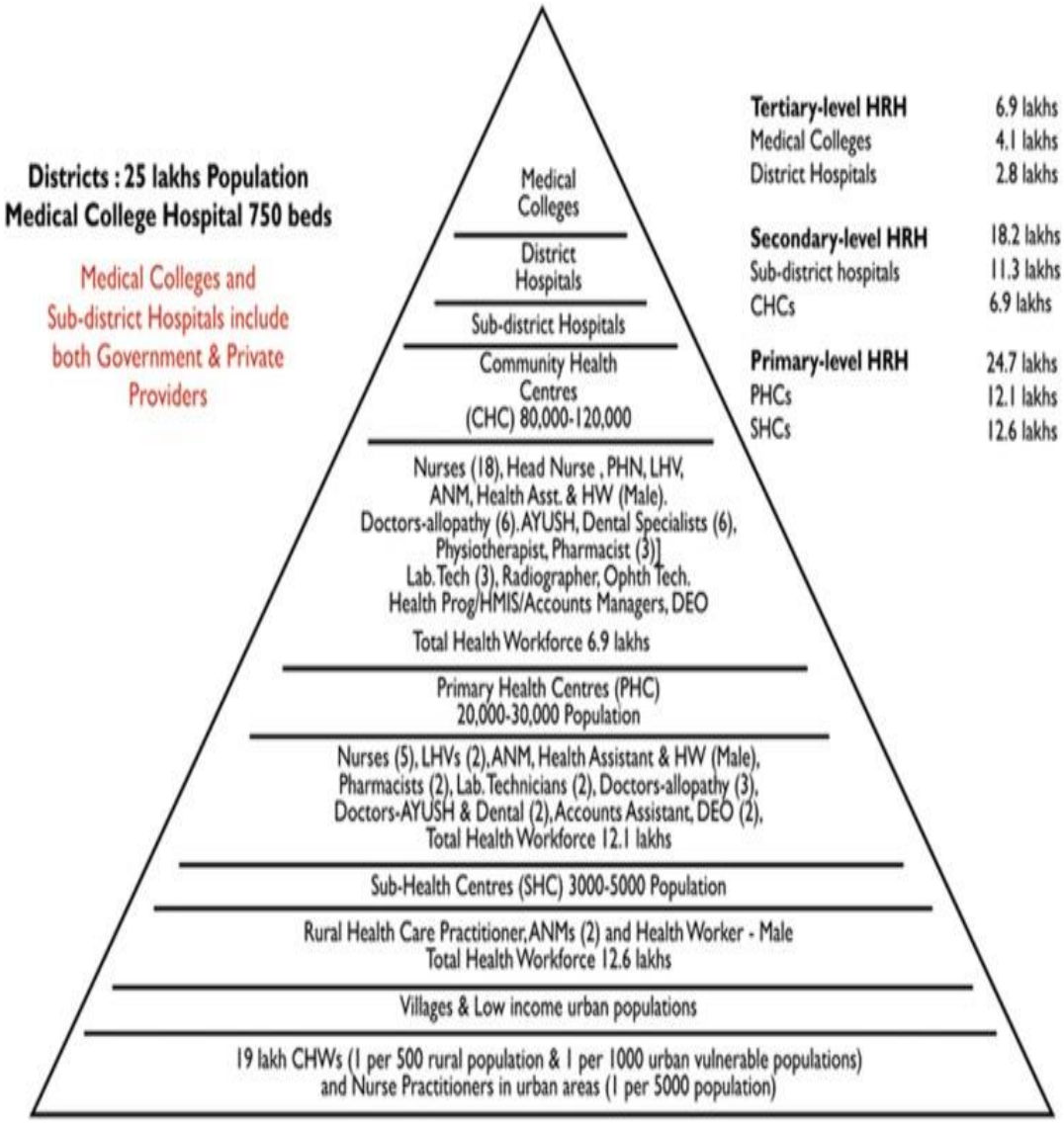
NUMBER OF SUB-CENTRES, PHCs, CHCs FUNCTIONING IN RURAL & URBAN AREAS OF INDIA					
Sub centres		**PHCs**		**CHCs**	
Rural	Urban	Rural	Urban	Rural	Urban
157935	3894	24935	6118	5480	584

Source: Rural Health Statistics (2021-202)

NUMBER OF SUB DIVISIONAL HOSPITAL, DISTRICT HOSPITAL & MEDICAL COLLEGES FUNCTIONING ALL OVER INDIA		
Sub District Hospital	**District Hospital**	**Medical Colleges**
1275	767	315

Source: Rural Health Statistics (2021-202)





Source: National Rural Health Mission, Ministry of Health and Family Welfare, Government of India

The Indian Public Health Standard (IPHS) norms' schematic design shows how they allocate resources for each level of care and determine how the infrastructure for providing healthcare is distributed.

XV-Finance Commission: With the goal of providing Comprehensive Primary Health Care close to the community, the Fifteenth Finance Commission (FC-XV) suggested funding to give support for diagnostic infrastructure in Sub-Health centres, PHCs, and Urban PHCs. This will improve primary care services that include preventive, promotional, basic curative, rehabilitative, and palliative care at the community level. With the purpose of bolstering the primary healthcare system, the Health Funds through

Local Government issued as part of the Union Budget 2021–22 has suggested grants of Rs. 70,051 Crores through local government over the course of five years (2021–2026).[6]

Pradhan Mantri Ayushman Bharat Health Infrastructure Mission (PM-ABHIM) intends to overcome significant gaps in public health infrastructure, particularly in primary care and critical care facilities in both urban and rural areas, with an investment of Rs. 64,180 crores. It has some Central Sector components and is a Centrally Sponsored Program. The Centrally Sponsored Scheme (CSS) Components provide assistance for the construction of the infrastructure for Sub-Health Centres, Urban Health and Wellness Centres, Support for Block Public Health Units, Integrated District Public Health Labs, and Critical Care Hospital Blocks.[6]

Debate on UHC and CPHC

In the international discussion of healthcare, universal health coverage (UHC) and comprehensive primary healthcare (CPHC) are two key ideas. They have some significant differences even though both aim to improve healthcare outcomes and access. In India, the debate over UHC and CPHC primarily focuses on how to increase access to high-quality healthcare services while addressing the underlying social and economic determinants of health. Promoting health, preventing disease, and providing balanced health care are important obstacles to achieving universal health coverage in India, and they need for new public policies, strategies, and programmes across various industries. The time has come to establish and implement a multisectoral strategy to accomplish sustainable development goals. (7)

Universal Health Coverage

Promoting, restoring, and/or maintaining the population's health is the major goal of every healthcare system.A way for a healthcare system to accomplish this objective is through UHC. Everyone must have access to the necessary healthcare as part of the UHC without experiencing financial hardship. Everyone has access to necessary, high-

quality healthcare services thanks to UHC, which also guarantees financial risk protection. (8)

The drive to achieve UHC is based on the World Health Organisation (WHO) Constitution of 1948, which declared health to be a fundamental human right. In 2005, members of the WHO signed a resolution urging countries to plan and advance the conversion of national healthcare systems to UHC. In the WHO studies from 2008 and 2010, population coverage, service coverage, and cost coverage were emphasised as the three components of UHC. The 2012 United Nations resolution urged governments to take action to provide accessible healthcare. The WHO, World Bank, and other international institutions suggest UHC as the best strategy for meeting the universally applicable health-related Sustainable Development Goals (SDG).(8)

UHC benefits on Population Level

The Ministry of Health and Family Welfare (MoHFW) implemented National Rural Health Mission, later renamed National Health Mission (NHM), to strengthen public health infrastructure, human resource capacity, and service delivery in both rural and urban areas. This was done to address health inequalities and improve health outcomes. Some of the other significant programmes, like as Mission Indradhanush and Janani Suraksha Yojana, etc are also complimented NHM.(9)

Source: (3) https://nhm.gov.in/WriteReadData/l892s/8414158732157009810 9.pdf

UHC Features

- Reduce Diseases Burden
- Preventing , Managing and controlling non Communicable Diseases
- Ensuring access to care
- Expanding Human Resources
- Correcting regional imbalances and reducing inequity

- Resources Augmentation
- Leveraging Digital Technology
- Increasing access to medicines

CPHC

On the other hand, comprehensive primary healthcare places a strong emphasis on giving people and communities access to a wide range of healthcare services at the primary level of care. This includes easily accessible, reasonably priced, and curative, promotional, and rehabilitative services. (10)

Key Elements of CPHC

Delivering CPHC through HWCs is a challenging endeavour since it necessitates a paradigm shift throughout the entire health system. HWC operationalization needs a number of inputs.(10)

1. Continuum of Care- Telehealth
2. Medcines and Expanding Diagnostics
3. Financing/Provider Payment Reforms
4. Robust IT System
5. Community Mobilisation and Health Promotion
6. Partnerships for Knowledge implementation
7. Expanding HR and Multitasking
8. Expended Service Delivery

In recent years, India has been actively pursuing both comprehensive primary healthcare (CPHC) and universal health coverage (UHC). Although the nation has made great strides in improving access to healthcare and increasing health outcomes, there is still a long way to go before universal coverage and comprehensive treatment are achieved.

The Two arms of AB

The Indian government unveiled the Ayushman Bharat Programme (ABP). It is divided into two components: Health and Wellness Centres (HWCs), which will offer comprehensive primary health care (PHC) services to the entire population; and Pradhan Mantri Jan Arogya Yojana (PMJAY), which will make hospitalization services

at secondary and tertiary level health facilities more accessible to the bottom 40% of the population.. (11)

PMJAY: In 2018, the Indian government unveiled the Pradhan Mantri Jan Arogaya Yojana (PMJAY), a national Publicly Funded Health Insurance (PFHI) programme. With an annual insurance of about Rs 5 Lakhs per family, PMJAY aims to provide coverage for 500 million people. As a strategy for universal health coverage, PMJAY claims to be the largest government-funded health programme in the world and has sparked debate on a worldwide scale. The former national and state-specific PFHI systems in India had a ten-year track record of ineffective financial protection. (12)

The PMJAY is a step in the right way because it gave the poorest 40% of the population insurance coverage. Comprehensive hospitalization coverage for secondary and tertiary care is offered by PMJAY.(13)

AB-HWC

Since independence, India's primary healthcare system has advanced, and both urban and rural areas are now supported by an advanced network of nearly 200,000 Government Primary Health Care Facilities (GPHCFs). The present GPHCFs provide a limited range of services as a result of a number of issues, occasionally including a provider shortage.. As a result, the mother and child health services are significantly underutilised and excluded from the GPHCFs in India. In India, primary health care (PHC) needs are either met by higher level government facilities (which raises a subsidiarity issue) or by private providers (which results in out-of-pocket expenses, or OOPE). Neither of these options is ideal for a healthy healthcare system. In February 2018, the Indian government unveiled the Ayushman Bharat Programme.(11)

In an effort to move from selective health care towards a more comprehensive range of services covering preventive, promotive, curative, rehabilitative, and palliative care for all ages, the Ayushman Bharat - Health and Wellness Centers (AB-HWCs) were introduced under the Ayushman Bharat Program. It intends to convert 1.5 lakh sub-centers and primary health centres into health and wellness centres (HWCs). (13)

The AB-HWCs Project is a collection of numerous changes covering all facets of the healthcare systems, including service delivery, human resource management, financing, drugs and diagnostics, community involvement, and ownership and governance. (10)

Services

The services' expansion has been planned out in phases. HWCs have started by implementing screening, prevention, control, and management of both chronic communicable diseases like leprosy and tuberculosis as well as non-communicable disorders. (10)

1. Prenatal and postpartum care.

2. Services for newborn and infant healthcare

3. Services for pediatrics and adolescent medical treatment.

4. Services for family planning, contraception, and other reproductive healthcare

5. National Health Programmes: Communicable Disease Management

6. General outpatient care for minor illnesses and acute uncomplicated illnesses as well as management of common communicable diseases

7. Chronic communicable diseases including TB and leprosy as well as non-communicable diseases screening, prevention, control, and management

8. Essential dental care

9. Treatment of Common ENT and Ophthalmic Issues

10. Services for palliative and elderly care

11. Medical Emergency Services

12. Mental health condition screening and basic management

E health

E-Health is a term used recently to describe medical procedures aided by electronic systems and web-based communications. The term can refer to a variety of services on the cutting edge of both information technology and medical (14).

- **Components of E health (14)**
- Electronic medical records make it simple for doctors, specialists, care teams, and pharmacies to share patient information.

- Telemedicine: All physical and psychological assessments that don't require a patient to visit a professional are included in telemedicine. When this service is effective, patients travel less to see a specialist or, conversely, the specialist's catchment area is larger.

- Consumer health informatics, often referred to as citizen-oriented information delivery, recognises that both healthy individuals and patients seek to learn about medical issues.
- Health knowledge management (or the distribution of information targeted towards specialists): A few examples of health knowledge management include an analysis of the most recent medical articles, best practise suggestions, or epidemiological tracking.

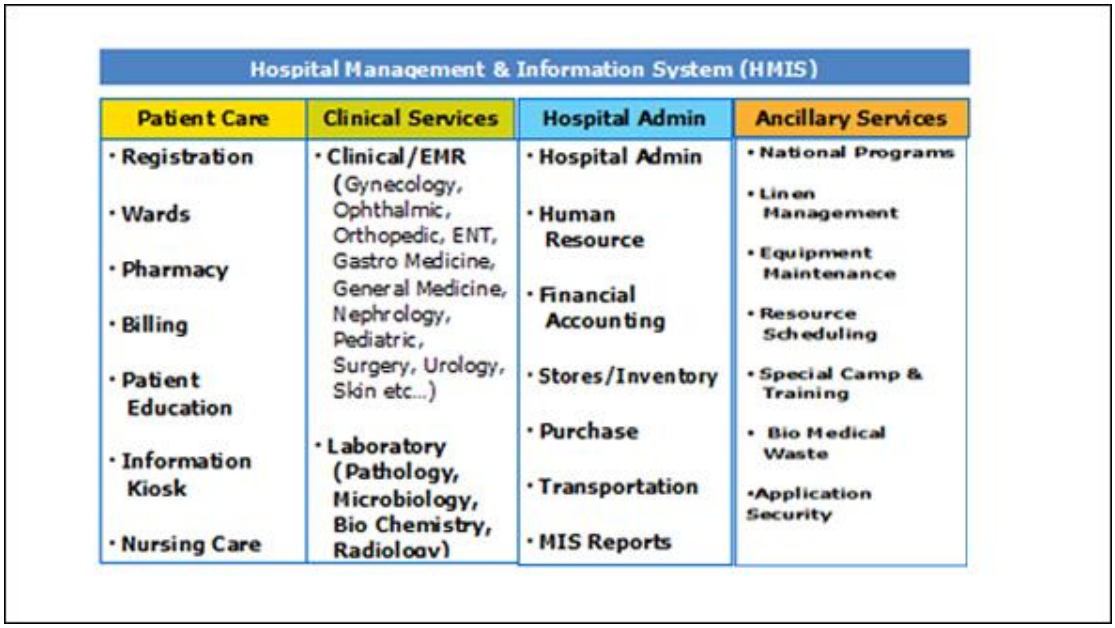
- Virtual healthcare teams: Are made up of medical professionals that communicate and share patient data electronically (for transmural treatment).

- mHealth: Mobile health, also known as mHealth, is the use of mobile devices to gather aggregate and patient-level health data, to disseminate healthcare knowledge to practitioners, researchers, and patients, to track patients' vital signs in real-time, and to directly deliver care (through mobile telemedicine).

- - To handle massive amounts of heterogeneous data, medical research makes use of eHealth Grids, which offer powerful processing and data management capabilities.
- Healthcare Information Systems: Systems for managing patient data, employee schedules, appointments, and other administrative chores related to health are referred to as healthcare information systems. Depending on the criteria used, it may or may not be considered that these jobs are eHealth-related; regardless, they interact with the majority of eHealth implementations because of the intricate link between administration and healthcare at health care providers.

Services:

The various services provided through GHMIS are as follows (15)



Use cases (15)

Administrators and Medical Superintendents:

- A statewide holistic view of hospital operations.
- Monitoring of pre-defined health indicators and management information system
- Exception reporting-based decision support via alerts and triggers
- Monitoring national programme effectiveness and identifying areas for improvement.

Point of Care Devices:

Point-of-care (POC) testing is carried out when a patient is being examined to gather particular clinical data and parameters. POC has numerous definitions, but they all describe the same idea: fast test data collecting so that the patient can start getting the right care as quickly as feasible. Medical professionals, patients, and their families all use POC diagnostic equipment because of how user-friendly they are. The turnaround time is ultimately shortened (TAT) as a result.

India and other emerging nations struggle to acquire pricey, highly automated, and sophisticated tools. These instruments require routine maintenance by qualified

specialists, which raises the overall cost of diagnosis and eventually burdens the patient as the end-user. Because to this, both patients and professionals are unable to access cutting-edge medical technologies.

WHO has established "ASSURED" standards for POC tests in environments with limited resources.
The ASSURED recommendations specify the functions that all PoCT devices ought to have.

> Affordable for individuals at risk of infection; Sensitive with few false negatives; Specific with few false positives; User-friendly with few procedures required; Rapid & Robust with quick turnaround and no requirement for chilled storage, Delivered to end users, Equipment-free ,no complex equipment
> [16]

Devices that meet the mentioned requirements could therefore be used in the Indian healthcare system.

Classification of POC Diagnostic Devices

There are many different types of equipment that are utilised in POC settings, such as disposable kits like fast assay dipsticks, reusable handheld tools like glucose monitoring kits, and multipurpose tabletop tools that are mostly used in laboratories. The POC diagnostic devices range in complexity from simple to complicated systems, and many of them have multiplex functionality built in. Depending on their use and sensitivity requirements, POC diagnostic devices may produce qualitative, semi-quantitative, or quantitative data. Rapid test pads and dipsticks are examples of POC diagnostic tools that only need to apply a sample once to produce results; other tools, however, involve sample processing, handling, and result interpretation procedures.

The Classification of POC devices according to their characteristics

- Operation: Devices used for fundamental medical operational purposes on clinics, OPDs, and labs are included in operational POC.

- Utility : Devices according to their intended use, such as in clinics or the field
- Sampling: Devices used to collect bodily samples for follow-up research or diagnostic purposes
- Result Reporting : Devices on the basis of their mode of their result generation.
- Cost : Devices based on their price.
- Analysis: Devices based on the output they generate from the diagnostic procedures they carry out.[17]

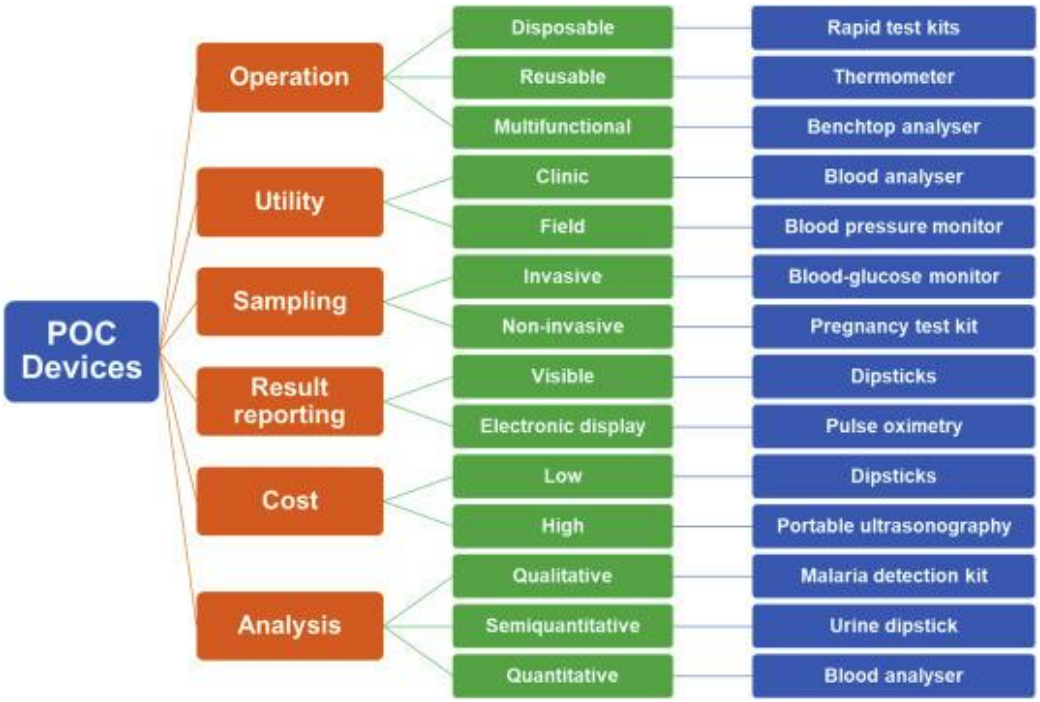


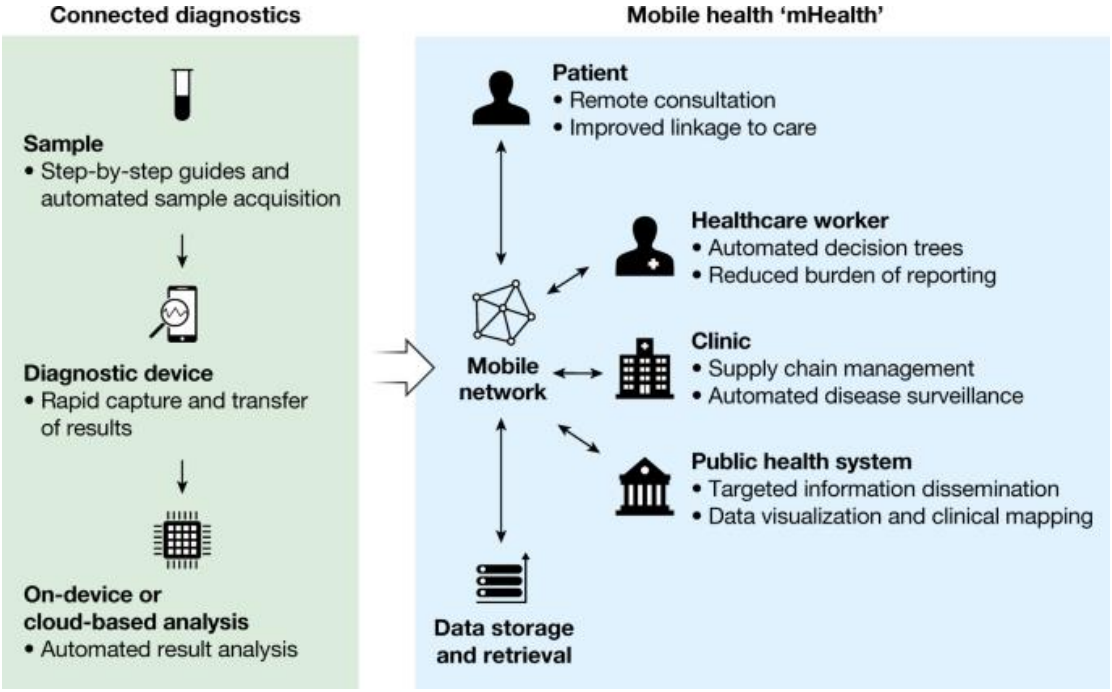
Image source : https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7280827/#:~:text=There%20are%20a%20variety%20of,mostly%20used%20in%20the%20laboratories. [17]

Diagnostic services:

In order to offer patients with high-quality care, healthcare professionals must be able to accurately detect, identify, and monitor diseases. This capability also enables the development of effective treatment plans and the evaluation of the efficacy of care interventions.[18]

What are connected diagnostics?

In order to increase the precision, effectiveness, and accessibility of medical diagnostic technologies and data, connected diagnostics are diagnostic systems that have been digitalized to adapt and integrate with the larger health care ecosystem.
For instance, connected diagnostics can be handheld diagnostics with internet connectivity, laboratory surveillance networks, mobile-based health applications, and more.
Connected diagnostics can be made accessible as global public goods, such as open-source digital health tools or free services that can be used, customized, and applied in many settings. They could also be bought and set up for local use commercial systems.[17]



Source: https://rdcu.be/c67Ty

Non connected point of care diagnostics devices:

Point-of-care diagnostics are medical tests that can be performed at or near the site of patient care, without requiring the use of a centralized laboratory.
Point-of-care diagnostics that are not wirelessly connected to a central database or a healthcare practitioner are referred to as non-connected.[19]

CHAPTER 2

Review of literature

Review of literature

1. **Chao Wang et al. (2021), Point-of-care diagnostics for infectious diseases:** From methods to devices, the objective of the review study is to provide the insight and ways to improve POC diagnostics in the future for the treatment of infectious diseases and to help stop and contain pandemics like COVID-19. The POC diagnostics have a number of benefits over labor- and time-intensive traditional diagnostic techniques, including faster diagnostic speed, improved sensitivity and specificity, cheaper cost, more efficiency, and the capacity for on-site detection. The creation of associated POC equipment and POC detection methods is essential for achieving POC diagnostics and should be given top priority. In this review, several POC detection techniques for the diagnosis of infectious diseases were first briefly discussed. These techniques included electrochemical biosensors, fluorescence biosensors, surface-enhanced Raman scattering (SERS)-based biosensors, colorimetric biosensors, chemiluminescence biosensors, and magnetic biosensors. The latest developments in POC device development, including lab-on-a-chip (LOC), lab-on-a-disc (LOAD), microfluidic paper-based analytical devices (PADs), lateral flow devices, miniaturized PCR devices, and isothermal nucleic acid amplification (INAA) devices, were then carefully examined.

2. Christopher S Wood et al.(2019), Taking connected mobile-health diagnostics of infectious diseases to the field, The use of mobile devices, their components, and related technologies in healthcare is known as "mHealth," or mobile health. Access to care and guidance for patients has already improved. It now offers unique techniques to detect, track, and control infectious diseases as well as ways to boost the effectiveness of the healthcare system when used in conjunction with internet-connected diagnostic tools. Here, this paper looks at the potential of these technologies and talk about the difficulties in making use of their potential to improve patient access to testing, assist in their treatment, and enhance the capacity of public health authorities to track outbreaks, put response plans into place, and evaluate the effects of interventions globally.

Keywords: internet-connected diagnostic tools, mHealth.

3. Junjie Liu et al.(2018), Point-of-care testing based on smartphone: The current state-of-the-art (2017–2018), Due to cost and equipment availability issues, particularly in places with limited resources, smartphone-based point-of-care testing (POCT) is quickly becoming a viable alternative to the traditional laboratory-based diagnostic testing.. In this study, we selected liquid biopsy samples (blood, urine, sweat, saliva, and tears) as the benchmark for categorizing smartphone-based POCT devices since they contain a variety of disease-related indicators. The evolution of smartphone-based POCT devices over the previous two years (2017–2018) was thoroughly examined, and their relative benefits and downsides were evaluated. The development of POCT indicates how important and urgent the various technological and economic requirements are. The

prevalence of high-quality, reasonably priced smartphone-based POCT devices, as well as the characteristics of the biosensors (paper-based sensor, flexible device, microfluidic chip, etc.) now utilized in POCT, were outlined, along with suggestions for future research.

Keywords: Microfluidic chip, Liquid biopsy samples, Biosensor, Smartphone-based point-of-care testing (POCT).

4. Aditya Narayan Konwar et al(2020), diagnostic devices in the Indian healthcare system with an update on COVID-19 pandemic, The traditional clinical diagnostic process is time-consuming and expensive because it calls for expensive, high-end equipment, a skilled technician to operate it and interpret the results, among other factors. The adoption of POC diagnostic tools is still in its early stages, despite the fact that the medical facilities in the Indian healthcare system have undergone significant advancements. This review describes the limitations to the use of POC diagnostic tools currently employed in clinical settings. Emphasis is placed on the devices and technologies that are now undergoing research and development across the nation and have the potential to significantly improve clinical diagnostics and the identification of the continuing COVID-19 epidemic. This article also discusses the effects of deploying POC diagnostic equipment and the long-term goals for technological development that could eventually improve the status of India's healthcare system and related industries.

Keywords: Point-of-care (POC) diagnostic gadget.

5. Dionysios C. Christodouleas et al.(2018), From Point-of-Care Testing to eHealth Diagnostic Devices (e Diagnostics), The initial purpose of point-of-care devices was to enable medical testing by healthcare professionals at or close to the point of care. While some point-of-care devices enable medical self-testing at home, they are unable to fully meet the expanding diagnostic requirements of the eHealth systems being developed in many nations. To enable remote patient monitoring, a number of user-friendly, network-connected diagnostic instruments for self-testing are required. This Perspective identifies point-of-care technologies that could result in the creation of new devices and underlines the crucial qualities of diagnostic devices for eHealth settings. Also, it presents the best cases of straightforward point-of-care tools that have been utilized to analyze untreated biological material.

Keywords: Network-connected diagnostic instruments, Remote patient monitoring, eHealth, Point-of-care devices.

6. Kaichen Xu et al. (2019), Toward Flexible Surface-Enhanced Raman Scattering (SERS) Sensors for Point-of-Care Diagnostics, In-depth research is done on the most recent developments in flexible substrate-based SERS diagnostic devices. An introduction to the cutting-edge SERS technology comes after a brief description of the enticing idea of point-of-care diagnostics. After that, the emphasis shifts from traditional rigid substrate-based SERS to the recently developed flexible SERS technology. In the main part of the paper, the three most recent categories of flexible SERS substrates—actively adjustable

SERS, swab-sampling strategy, and in situ SERS detection approach—are highlighted. Furthermore, offered are additional promising flexible SERS methods. Flexible SERS substrates can be included into portable Raman spectroscopes for point-of-care diagnostics, which are likely to enter the worldwide market and households as next-generation Wearable sensors in the near future due to their low cost, batch production, and ease of operation.

Keywords: Wearable sensors, in situ SERS, swab-sampling strategy, point-of-care diagnostics, Surface-enhanced Raman scattering (SERS) spectroscopy.

7. Subrata Mondal et al. (2020), Wearable Sensing Devices for Point of Care Diagnostics, This paper provides a comprehensive overview of current developments in smart wearable biosensors with a focus on applications in point-of-care diagnostics. The present analysis additionally highlights the deployment in clinical trials, validation, and a rigorous comparison of already accessible commercial devices. The problems and potential outcomes for scientists and engineers working in the developing interdisciplinary field are discussed in the work's conclusion.

Keywords: Smart wearable biosensors, ambulant monitoring , signaling processes, smart wearable sensing systems.

8. Eiichi Tamiya et al. (2023), Point-of-Care Diagnostic Biosensors to Monitor Anti-SARS-CoV-2 Neutralizing IgG/sIgA Antibodies and Antioxidant Activity in Saliva, in this study , they examined the levels of neutralizing IgG and secretory IgA (sIgA) antibodies in saliva produced in response to the SARS-CoV-2 vaccine. Three weeks after the first vaccination, eight months after the second, and one month after the third, a total of 19 samples of saliva and serum were taken throughout the course of a ten-month period. Following immunization, the antibody levels ranged from 81 to 15,000 U/mL in the blood, 3.4 to 330 U/mL in the saliva, and 58 to 870 ng/mL in the saliva. After the second immunization, there was a significant rise in salivary IgG levels. sIgA levels also demonstrated an upward trend. A link with changes in serum IgG levels was found, suggesting the potential for routinely evaluating vaccine effectiveness using saliva. Both the antioxidant activity assessment based on luminol electrochemical (ECL) and the electrochemical immunosensor assay created in this study based on the gold-linked electrochemical immunoassay may be carried out using portable instruments, making them helpful for individual-based diagnosis utilizing saliva samples.

Keywords: Gold-linked electrochemical immunoassay, electrochemical immunosensor assay, luminol electrochemical (ECL), SARS-CoV-2 vaccine, neutralising IgG and secretory IgA (sIgA).

9. John F. Alderete et al. (2023), Point-of-Care Diagnostic for Trichomonas vaginalis, the Most Prevalent, The MedMira Rapid Vertical Flow (RVF®) Technology test cartridge with a membrane that incorporates a Vertical procedural/reagent control line (referred to as CVL) and spotted with 1 g of a 72.4-kDa truncated variant of -actinin termed

ACT::SOE3 was used to create a point-of-care diagnosis for this STI. Antibodies present in the sera of people with trichomoniasis specifically target this protein for diagnostic purposes. A positive reaction to the test spot is seen with serum antibodies to ACT::SOE3. With the help of monoclonal antibodies (MAbs) made against ACT::SOE3, the specificity of ACT::SOE3 was discovered. The identification of both ACT::SOE3 and the CVL is demonstrated by the addition of negative control serum with MAb 67B reactive to ACT::SOE3. Only people with positive sera were ACT::SOE3 antibody reactive, which allowed for the detection of the spot and the CVL. Only individuals with positive sera had ACT::SOE3-reactive antibodies that could identify the spot and the CVL. Negative control sera only detected the presence of the CVL and were unresponsive to ACT::SOE3. Significantly, ACT::SOE3 was found in the positive patient sera spiked with whole blood, demonstrating proof-of-principle for POC use. Last but not least, packaged cartridges kept in desiccant packs at 37 °C for a year produced findings with both positive and negative human sera that were identical. The reliability of this novel POC serodiagnostic for this STI is demonstrated by our findings.

10. Diana-Gabriela Macovei et al. (2022), Point-of-care electrochemical testing of biomarkers involved in inflammatory and inflammatory-associated medical conditions, Recent studies have demonstrated that identifying and tracking biomarkers linked to inflammatory-related illnesses including cancer, neurological diseases, viral infections, or regular physical activity can actually improve the standard of medical care and the quality of patients' lives. This review focuses on the most recent developments in bioanalysis of both specific and inflammatory-associated biomarkers, which are present in a variety of diseases like neoplasia, severe neurological disorders, viral infections, and routine physical activity. It also gives a state-of-the-art overview of the most recent electrochemical (bio)sensors for the detection of inflammation-related biomarkers. The potential for point-of-care testing to enhance healthcare administration is also explored.

Keywords: Neoplasia, Inflammatory-associated biomarkers, Electrochemical sensors, Biomedical analysis, Point-of-care testing instruments, Biomarkers.

11. Arpana Parihar et al. (2023), Internet-of-medical-things integrated point-of-care biosensing devices for infectious diseases: Traditional laboratory-based diagnostics for microorganisms like bacteria and viruses require large, expensive experimental equipment and trained workers, which restricts their application in environments with little resources. The biosensors-based point-of-care (POC) diagnostics have demonstrated enormous potential to identify microbial infections quickly, affordably, and easily. The design and manufacture of POCT devices for the detection of microbiological pathogens, such as bacteria, viruses, fungus, and parasites, were covered in the present review. They include primarily microfluidic-based technologies, smartphone and Internet-of-things (IoT) and Internet-of-Medical-Things (IoMT) integrated systems, and current advancements in electrochemical techniques and integrated electrochemical platforms. Also, a briefing on the commercial biosensors that are available for the detection of microbial infections will be provided. Finally, the difficulties encountered in the manufacture of POC biosensors as well as anticipated developments in the field of biosensing have been reviewed. In order

to better prepare for existing and upcoming pandemics and to avert social and economic losses, integrated biosensor-based platforms with the IoT/IoMT typically collect data to track the community spread of infectious diseases.

Keywords: Pathogenicity, microbial diseases, Biosensors-based point-of-care (POC) diagnostics, Microfluidic integrated biosensors, Transducers including electrochemical and optical,multiplexed analyte detection , Internet-of-things (IoT) and Internet-of-Medical-Things (IoMT)

12. Benjamin Heidt et al. (2020) Point of Care Diagnostics in Resource-Limited Settings: A Review of the Present and Future of PoC in Its Most Needed Environment

This research looks at the value chain of PoC devices and the barriers that prevent them from reaching the market and exerting a benefit to the patient. It looks at the different domains of research, market, and usage, and how each of these domains can be further subdivided into subdomains. It also looks at the importance of connecting all stakeholders, such as research groups, companies, healthcare professionals, as well as governments and NGOs, to enable IP considerations and licenses to be negotiated to everyone's benefit. It also looks at the importance of a multidisciplinary team for market introduction, the need for funding and incentives for valorization, the need for appropriate device characteristics, and the need for collaboration between academia and industry. Finally, it looks at the importance of IP considerations and the role of the World Intellectual Property Organization (WIPO) Research consortium. However, there are many barriers along the way. For example, there can be funding problems that prevent the design of a prototype, or intellectual property considerations that prevent market access. Additionally, there are logistical shortcomings, collaboration considerations, and quality control and assurance issues that can all prevent a device from being successful. Therefore, it is important to connect all stakeholders, such as research groups, companies, healthcare professionals, as well as governments and NGOs, in order to ensure that the device is successful. This can help to prevent leaks in the pipeline and ensure that the device is able to reach the market and benefit patients.

Keywords: World Intellectual Property Organization (WIPO), IP considerations (Intellectual Property), NGO (Non-Government Organization).

13.Tobias Miesle et al. (2020)Frugal Innovation for Point-of-Care Diagnostics Controlling Outbreaks and Epidemics: The research explained frugal innovation as the creation of affordable, uncomplicated, and user-friendly devices to meet the needs of settings that have limited resources. Since POC diagnostics for controlling outbreaks and epidemics must be accessible, quick, and easy to use, frugal innovation can be especially helpful in this area. The study analyzes a number of case studies of frugal innovation in the creation of POC diagnostics for limiting epidemics and outbreaks. The creation of a low-cost Ebola virus diagnosis, a portable, affordable HIV viral load monitor, and a rapid malaria diagnostic test are some examples of these case studies. According to the article, cost-effective innovation can have a number of advantages, such as better patient outcomes,

more patients having access to diagnostics in settings with limited resources, and lower healthcare expenditures. Yet, there are obstacles to inexpensive innovation as well, including financing restrictions, legal barriers, and the requirement for stakeholder participation. The article's overall conclusion is that frugal innovation could improve the design of POC diagnostics for limiting epidemics and outbreaks. To address the issues with frugal innovation, however, and to guarantee that these diagnostics are trustworthy and effective in identifying and managing outbreaks and epidemics in resource-constrained contexts, more research and development is required.

Keywords: Epidemics, Rapid malaria diagnostic test, HIV viral load monitor, Ebola virus, frugal innovation, Point-of-care (POC) diagnostics

14. David J Lee et al. (2019) Rapid, point-of-care diagnosis of tuberculosis with novel Truenat assay Cost-effectiveness analysis for India's public sector: Examines the cost-effectiveness of using the Truenat assay, a quick and portable molecular diagnostic test, for TB diagnosis in India's public sector. In the context of India's national TB control programme, the authors evaluate the cost-effectiveness of employing the Truenat assay in comparison to other diagnostic methods, such as smear microscopy and Xpert MTB/RIF. They calculate the incremental cost-effectiveness ratio (ICER) of each diagnostic instrument and the cost per disability-adjusted life year (DALY) avoided using a decision-analytic model. The findings demonstrate that the Truenat assay, with an ICER of US$40 and US$323 per DALY averted, respectively, is more affordable than smear microscopy and Xpert MTB/RIF. The Truenat assay also has the potential to accelerate diagnosis and treatment initiation, which would improve patient outcomes and lessen the spread of TB. The Truenat assay, according to the authors, is a promising diagnostic tool for the detection of tuberculosis in India's public sector. It has the potential to enhance patient outcomes and lessen the prevalence of the disease there.

Keywords: point-of-care diagnostic tests, decision-analytic model, disability-adjusted life year (DALY), incremental cost-effectiveness ratio (ICER), Xpert MTB/RIF, smear microscopy, India's national TB control program , molecular diagnostic test, Truenat assay.

15. Rajat Vashistha et al. (2018)Futuristic biosensors for cardiac health care: an artificial intelligence approach: Advances in artificial intelligence (AI) and machine learning have opened up new possibilities for creating novel predictive methods for clinical use, including cardiac diseases. IoT constitutes wearable biosensors along with telemedicine for preventive health activities and remote medical help, along with the continuous monitoring of patients for chronic cardiac ailments. The combination of biosensors and AI in cardiac healthcare may totally alter how doctors identify and treat heart disease. For example, real-time monitoring of a patient's cardiac activity can be provided via biosensors, allowing medical personnel to spot problems early and adjust treatment as needed. The article "Futuristic biosensors for cardiac health care: an artificial intelligence approach," in conclusion, perhaps sheds light on the potential of biosensors and AI in cardiac healthcare. To create efficient technologies that can enhance the diagnosis and treatment of cardiac disease, further research in this area is required.

Keywords: cardiovascular diseases (CVDs),stroke, Artificial Intelligence, POC cardiac diagnosis, cardiac scorecard, lasso logistic regression approach, biomarker, logistic regression coefficients, IoT, Wearable biosensors, Telemedicine, AI algorithms.

16. Sutapa Bandyopadhyay Neogi et al. (2020) Diagnostic accuracy of point-of-care devices for detection of anemia in community settings in India: Researchers evaluated the diagnostic efficacy of point-of-care tools for identifying anaemia in community settings in order to address this problem. Distinct point-of-care devices—portable instruments that can swiftly measure a range of health factors, including haemoglobin levels—were used in the study to test the blood of participants. The outcomes of the laboratory-based tests, which are regarded as the gold standard for identifying anaemia, were then contrasted with those of the point-of-care tests. The point-of-care devices were found to have great diagnostic accuracy for identifying anaemia, with sensitivity and specificity rates exceeding 95%, according to the researchers. This indicates that the tools could correctly distinguish between those who had anaemia and those who did not. The study also discovered that the point-of-care tests were affordable, simple to use, and didn't require any training. These findings have important ramifications for bettering anaemia diagnosis and treatment in community settings, especially in resource-constrained regions where access to laboratory-based diagnostics may be restricted.

Keywords: Anemia, Point of care Tools

17. Nora Engel at al. In the article "Barriers to Point of Care Testing in India and South Africa,": the challenges and impediments to putting point-of-care (POC) testing into practice in healthcare settings in India and South Africa are examined. The paper outlines the potential advantages of POC testing, including better patient outcomes, quicker access to healthcare services, and shorter diagnostic turnaround times. However, the authors also point out a number of obstacles to the widespread use of POC testing in South Africa and India, including a lack of infrastructure, inadequate money, and regulatory difficulties.

The lack of infrastructure to facilitate POC testing, particularly in rural and distant locations, is one of the major issues mentioned in the article. Inadequate power supplies, inconsistent internet connections, and inefficient transportation networks are a few examples of problems that might make it challenging to move and maintain POC testing equipment. The authors point out that insufficient financing is another obstacle to the application of POC testing, in addition to infrastructural constraints. This covers funds for new POC tests' creation and validation as well as for tools, instruction, and maintenance. The use of POC testing is also noted to be significantly hampered by regulatory issues. The authors add that bringing new POC tests to market frequently requires major regulatory hurdles to be cleared, which may cause a delay in their accessibility by patients and healthcare professionals. Overall, the article offers insightful information about the obstacles to POC testing implementation in South Africa and India. The authors hope that

by outlining these hurdles, governments, healthcare professionals, and other stakeholders would engage in conversation and be inspired to take action to remove these barriers and enhance access to POC testing in these nations.

Keywords: Point-of-care (POC) testing , Turnaround Time

18. **Rachael V. Dixon et al. (2021) Microneedle-based Devices for Point-of-care Infectious Disease Diagnostics:** The authors examine the drawbacks of present methods for diagnosing infectious diseases, including the requirement for specialized equipment, trained workers, and lengthy and expensive procedures. They contend that by providing a quick, easy, and affordable option for identifying infectious diseases, microneedle-based technologies have the ability to solve these constraints. Small, minimally invasive devices called microneedle-based devices can be used to collect blood samples for examination. The presence of infectious agents can then be determined in this blood using a variety of diagnostic methods, such as PCR or ELISA. The portability, simplicity of use, and ability to deliver quick results are just a few benefits that the authors note for using microneedle-based instruments to diagnose infectious diseases. They also go over the possibility of using these tools in environments with limited resources, when access to diagnostic testing performed in labs can be restricted. The scientists note that ther e are still a number of issues that need to be resolved before microneedle-based devices can be extensively used for infectious illness diagnostics, despite the potential advantages they may provide. These difficulties include the requirement for additional validation studies to show its diagnostic efficacy as well as the necessity for advancements in device production and design. Overall, the study offers a thorough analysis of the state of microneedle-based diagnostic tools for infectious diseases and underlines their potential to enhance point-of-care diagnosis and management of infectious disorders.

Keywords: Microneedle-based devices, Point-of-care diagnosis, PCR, ELISA

19. **Sandeep Kumar et al. (2021), Aspects of Point-of-Care Diagnostics for Personalized Health Wellness**: Examines how point-of-care (POC) diagnostics may help to advance personalized health and wellbeing. The authors contend that rather than emphasizing disease prevention, conventional healthcare approaches have placed a greater emphasis on treating illnesses once they manifest. They contend that POC diagnostics, which allow for early identification and individualized therapies for a variety of medical diseases, have the power to alter this paradigm. In the article, numerous examples of POC diagnostics for individualized health and wellbeing are discussed, including wearable sensors for tracking bodily activity and biomarkers and mobile apps for tracking and managing chronic illnesses. The authors also point out some of the major issues that need to be resolved in order to promote the broad use of POC diagnostics for individualized health and wellness. These difficulties include making POC tests accurate and reliable,

assuring their use and accessibility for patients, and dealing with regulatory and payment problems. The authors are upbeat about POC diagnostics' potential to advance individualised health and wellness despite these difficulties. They contend that POC diagnostics could be crucial in encouraging a move towards more proactive, preventative healthcare approaches and in empowering people to take a more active part in controlling their own health. Overall, the article offers a useful overview of POC diagnostics' potential for promoting individualised health and wellbeing and identifies some of the major issues that need to be resolved in order for them to be widely used in healthcare settings.

Keywords: Point-of-care (POC) diagnostics, Personalized health, Wearable sensors, Biomarkers, chronic illnesses.

20. Shikha Jain et al. (2021) Internet of Medical Things (IoMT)-Integrated Biosensors for Point-of-Care Testing of Infectious Disorders: The possibility of combining biosensors with the Internet of Medical Things (IoMT) for infectious disease point-of-care testing (POCT) is explored in this article. The authors contend that by providing remote monitoring, real-time data collecting, and decision support, the IoMT has the potential to revolutionise healthcare. They assert that it is feasible to develop extremely sensitive, focused, and portable diagnostic tools that can be utilised for point-of-care (POC) testing of infectious diseases by merging biosensors with IoMT devices. The article discusses a number of biosensor integrations with IoMT devices for point-of-care (POC) testing of infectious diseases, including wearable sensors for tracking infection-related biomarkers, smartphone-based platforms for capturing and analysing infectious agents, and biosensors integrated with cloud-based platforms for real-time monitoring and data analysis. The authors also point out some of the major issues that need to be resolved in order to promote the broad use of IoMT-integrated biosensors for point-of-care (POC) diagnostics of infectious illnesses. These difficulties include guaranteeing the precision and dependability of biosensors, dealing with concerns about data security and privacy, and making sure that these technologies are inexpensive and available to the communities who most require them. The potential of IoMT-integrated biosensors for POC detection of infectious illnesses is still optimistically seen by the scientists in spite of these difficulties. They claim that these technologies could aid in addressing some of the persistent issues that have impeded successful infectious disease management, such as the need for quick diagnosis and treatment and limited access to laboratory facilities.

Keywords: Cloud-based platforms, Infection-related biomarkers, Wearable sensors,remote monitoring, Point-of-care testing (POCT), Internet of Medical Things (IoMT), Biosensors

21. **Zhang Z et al. (2022) Advanced Point-of-Care Testing Methods for Human Acute Respiratory Virus Detection:** Discusses the most recent advancements made in point-of-care testing methods for human acute respiratory viruses. The difficulties with typical laboratory-based testing for respiratory viruses are discussed by the authors, including the

need for specialist personnel and equipment, lengthy turnaround times, and difficult sample preparation requirements. They contend that by delivering quick and precise results in a decentralized environment, point-of-care testing technologies have the ability to solve these difficulties. The article discusses a number of cutting-edge point-of-care testing innovations created for the detection of human acute respiratory viruses, including biosensors, antigen assays, and nucleic acid amplification tests. The writers go over each technology's advantages and disadvantages as well as prospective uses in various clinical scenarios. The authors also point out some of the major issues that must be resolved to allow for the widespread use of cutting-edge point-of-care testing methods for the identification of human acute respiratory viruses. Assuring the precision and dependability of these tests, creating testing infrastructure that is both affordable and accessible, and incorporating new technologies into current healthcare systems are some of these obstacles. Overall, the article provides a thorough summary of the most recent developments in point-of-care testing methods for detecting human acute respiratory viruses and highlights some of the major difficulties and opportunities these methods present. The authors contend that these technologies have the potential to revolutionize the diagnosis of respiratory viruses and enhance patient outcomes, and that maximizing this potential will require sustained research and development in the field.

Keywords: Point-of-care testing, Acute respiratory viruses, Turnaround times, Biosensors, Antigen assays, and Nucleic acid Amplification tests.

22. KV Giriraja et al. (2020) Clinical Validation of Integrated Point-of-Care Devices for the Management of Non-Communicable Diseases

The article emphasises the growing prevalence of NCDs, such as diabetes, cardiovascular disease, and chronic respiratory diseases, as well as the demand for better care of these illnesses. The use of point-of-care devices, which can quickly and accurately assess a variety of biomarkers, has the potential to enhance the management of NCDs by facilitating early diagnosis, disease progression monitoring, and individualised treatment, according to the author.

The point-of-care devices for testing cholesterol, blood pressure, glycated haemoglobin (HbA1c), blood glucose, and other parameters are discussed in the article. In order to assure the accuracy and dependability of these devices, the author outlines the clinical validation tests that have been carried out on them.

The article additionally addresses the costs, requirements for learning, and data management issues that come with integrating point-of-care devices into clinical practise. In order to overcome these obstacles and guarantee the successful integration of point-of-care devices into clinical practice, the author emphasises the necessity of a collaborative strategy involving healthcare practitioners, patients, and device makers.

Overall, the study offers a thorough analysis of point-of-care tools now available for the treatment of NCDs, showing their potential advantages and outlining the difficulties that must be solved before they can be successfully implemented in clinical settings.

23. **Gerald J Kost et. al (2021), Public Health Education Should Include Point-of-Care Testing**: Lessons Learned from the Covid-19 Pandemic The COVID-19 pandemic has brought attention to the value of POCT in public health, the authors note in the opening statement. Diagnostic procedures that can be carried out on-site or close to the location of patient treatment, such as a clinic or doctor's office, as opposed to a centralized laboratory, are referred to as POCTs. The literature on the application of POCT in public health is then reviewed in the article. The authors point out that POCT has been successfully implemented in a number of contexts, including ERs, primary care offices, and community health centers. It has been demonstrated that the use of POCT enhances patient outcomes, lowers costs, and boosts patient satisfaction. The article then goes into detail on POCT's contribution to the COVID-19 epidemic. The authors contend that public health education should include POCT as a crucial element, particularly in the context of pandemic preparedness. The authors argue that POCT need to be included in public health education programs in their conclusion. They point out that doing this will call for collaboration between experts in public health, medical staff, and decision-makers. Additionally, they mention that POCT implementation will be difficult due to factors like cost, quality assurance, and training. Yet, they contend that POCT should be a significant part of public health education because the advantages exceed the drawbacks.
24. Keywords: POCT,ER

25. **Stefan Pleus et al. (2022) Self-Monitoring of Blood Glucose as an Integral Part in the Management of People with Type 2 Diabetes Mellitus,** The first section of the article discusses the prevalence and effects of type 2 diabetes mellitus, highlighting that it is a serious global public health issue. The evidence regarding the advantages and restrictions of SMBG in the therapy of type 2 diabetes mellitus is then reviewed by the author. According to Authors, there is some debate in the research regarding the ideal timing and frequency of SMBG. While some studies have indicated no significant differences between different monitoring frequencies, others have suggested that more frequent monitoring may be related with better glycemic management. The expense, the requirement for appropriate training and education, and the possibility of measurement inaccuracy are some of the potential difficulties and restrictions of SMBG that the author also considers. Despite these difficulties, the author comes to the conclusion that SMBG is a crucial management tool for persons with type 2 diabetes mellitus and should be regarded as a crucial component of their care.

Keywords: hypoglycemia, SMBG.

26. Shalini Sehgal et al. (2022) Diagnostic Tools for COVID-19, this report opens by underlining the urgent need for reliable and efficient diagnostic tools. The authors then discusses the many categories of diagnostic techniques that are accessible, including testing based on nucleic acids, antigen tests, and antibody tests. Reverse transcription-polymerase chain reaction (RT-PCR) assays are currently regarded as the gold standard for diagnosing COVID-19, according to the authors. But the author also considers the drawbacks of these tests, namely the chance of false negatives and the demand for specialised labs with qualified staff. After that, the author discusses the potential benefits and drawbacks of antigen and antibody testing, noting that while they might be quicker and more convenient than nucleic acid-based tests, they might also be less sensitive or specific. The document "Diagnostic Tools for COVID-19" offers a helpful summary of the many diagnostic methods available for identifying COVID-19, as well as their benefits and drawbacks. Given that the virus still poses a serious public health risk, the paper's focus on the necessity of precise and trusted testing is particularly notable.

Keywords: Testing based on nucleic acids, Antigen tests, Antibody tests. Reverse transcription-polymerase chain reaction assays

27. **Mukul Sharma et al. (2022) Advances in the Diagnosis of Leprosy,** A review of the most recent developments in leprosy diagnosis has been found in the paper "Advances in the Diagnosis of Leprosy." The authors start by tracing the development of leprosy diagnosis from its earliest instances to the present. The various techniques currently employed to diagnose leprosy, such as clinical diagnosis, histological analysis, and bacterial index measures, are then covered. The creation of molecular methods for identifying the Mycobacterium leprae bacteria, which is the source of the disease, is one of the significant developments in leprosy diagnosis that the study highlights. The polymerase chain reaction (PCR), which enables quick and precise diagnosis even in situations when only minor numbers of bacteria are present, has shown to be particularly helpful for this purpose. The creation of molecular methods for identifying the Mycobacterium leprae bacteria, which is the source of the disease, is one of the significant developments in leprosy diagnosis that the study highlights. The polymerase chain reaction (PCR), which enables quick and precise diagnosis even in situations when only minor numbers of bacteria are present, has shown to be particularly helpful for this purpose. The authors also go over the significance of diagnosing and treating leprosy as soon as possible because delays in care can result in impairment and permanent nerve damage. They emphasize how important it is for community health professionals to spot potential leprosy cases and recommend them for additional testing and care. The remaining obstacles in leprosy diagnosis are discussed in the report,

including the lack of a conclusive diagnostic test and the need for better access to diagnostic instruments in rural and underdeveloped areas. The authors contend that carrying out more research and development in this field is essential to lowering the incidence of leprosy globally. Overall, "Advances in the Diagnosis of Leprosy" offers a thorough analysis of the condition of leprosy diagnosis at the present time, highlighting the advancements that have been made recently and the issues that still need to be resolved. The well-researched report offers insightful information to those involved in leprosy research, healthcare, and policymaking.

Keywords: Histological analysis, Bacterial index measures ,Mycobacterium leprae bacteria

28. **Arfan Ahmed et al. (2022) The Effectiveness of Wearable Devices Using Artificial Intelligence for Blood Glucose Level Forecasting or Prediction:** Systematic Review, It intends to evaluate the efficacy of wearable technology that makes use of artificial intelligence (AI) to forecast or predict blood glucose levels. The opening of the paper emphasizes the rising prevalence of diabetes and the need of blood glucose monitoring in treating the condition. The author then goes through how wearable technology that makes use of AI may be able to enhance blood glucose control by making more precise and timely forecasts of blood glucose levels. The paper offers a thorough overview of the studies that have looked into the viability of wearable technology that employs AI for blood glucose forecasting or prediction. The author found a total of 15 studies that satisfied the inclusion criteria after searching four significant scientific databases. The review's research made use of a range of wearable devices, including wristbands, smartwatches, and continuous glucose monitoring (CGM) systems. The review found that the majority of the studies reported positive results, with the wearable devices demonstrating good accuracy in predicting blood glucose levels. The review also noted that some studies reported challenges with data reliability and device usability, which may affect the overall effectiveness of the devices. The paper concludes with a discussion of the limitations of the studies included in the review and suggests areas for future research.

29. Nikos Mitro et al. (2023) AI-Enabled Smart Wristband Providing Real-Time Vital Signs and Stress Monitoring, The beginning of the paper emphasises the rising popularity of wearable health monitoring technology as well as the potential advantages of applying artificial intelligence to improve the precision and efficacy of these devices. The author goes on to explore the difficulties in real-time monitoring of stress and vital signs as well as wearable technology's potential to solve these problems. The paper's literature review part offers a thorough overview of the research that have looked into the use of wearable technology for in-the-moment monitoring of stress and vital signs. The author found a total of 22 studies that satisfied the inclusion criteria after searching the top scientific databases. The review's research made use of a range of wearable gadgets, including wristbands, patches, and smartwatches.

According to the review, the majority of research showed promising findings, and wearable technology showed good accuracy in monitoring stress and vital signs. The evaluation also made notice of some studies' reports of issues with data dependability, device usability, and privacy worries, all of which may have an impact on the devices' general efficacy.

30. **Delshi Howsalya Devi et al. (2023) 5G Technology in Healthcare and Wearable Devices: A Review,** The introduction to 5G technology, its features, and its potential advantages in healthcare is the first section of the study. The author goes on to discuss other healthcare applications, where 5G technology has a big potential. The first use highlighted is telemedicine, in which 5G technology can aid by enabling high-quality, real-time video consultations between healthcare professionals and patients. The author talks about how telemedicine could lead to lower healthcare expenditures, better patient outcomes, and more widespread access to medical treatment. In the following application, 5G technology is used to gather and transmit patient data in real-time for remote patient monitoring. The author emphasizes the advantages of remote patient monitoring, including the quicker identification of medical problems, fewer re-admissions to the hospital, and better patient outcomes. The possible drawbacks of remote patient monitoring are also covered by the author, including the requirement for secure and dependable data transfer and the fusion of diverse data sources. The application of wearable technology in healthcare and the possible effects of 5G technology on wearable technology are also covered in the study. The author examines the different kinds of wearable technology and its possible uses in healthcare, including monitoring medication adherence, vital signs monitoring, and exercise tracking. The author also examines some of the potential drawbacks of employing wearable technology in the medical field, including data security and privacy issues. The paper's overall finding is that 5G technology has the power to transform healthcare by providing real-time, high-quality healthcare services and enhancing patient outcomes. The author also discusses some of the potential difficulties that could arise when using 5G technology to the healthcare industry, including the requirement for secure and dependable data transfer and the integration of diverse data sources.

31. Zhiyong Deng et al. (2023) Smart Wearable Systems for Health Monitoring

The authors examine many wearable device types and their potential uses in healthcare, including smartwatches, fitness trackers, and smart clothing.

The introduction to smart wearable devices, their features, and their potential advantages in healthcare is the first section of the study. Following that, the author explores a number of healthcare applications where smart wearable devices can have a big influence. Health monitoring is the first application that is covered. Wearable technology may gather and transmit vital indications including heart rate, blood pressure, and body temperature. The author focuses on the advantages of health

monitoring, including the earlier diagnosis of illnesses, better patient outcomes, and lower healthcare expenses. The next application under discussion is activity monitoring, in which wearable technology can record physical activity such steps done, calories burned, and distance travelled. The prospective uses of activity monitoring are examined by the authors, including fitness tracking, therapy, and geriatric care. The application of smart wearable technologies to control chronic diseases like diabetes and hypertension is also covered in the study. The author emphasizes the potential advantages of wearable technology in the management of chronic diseases, including greater patient self-management, fewer hospitalizations, and better drug adherence. Overall, the article draws the conclusion that smart wearable technologies, by providing real-time, continuous monitoring of vital signs, physical activity, and chronic illness management, have the potential to transform healthcare.

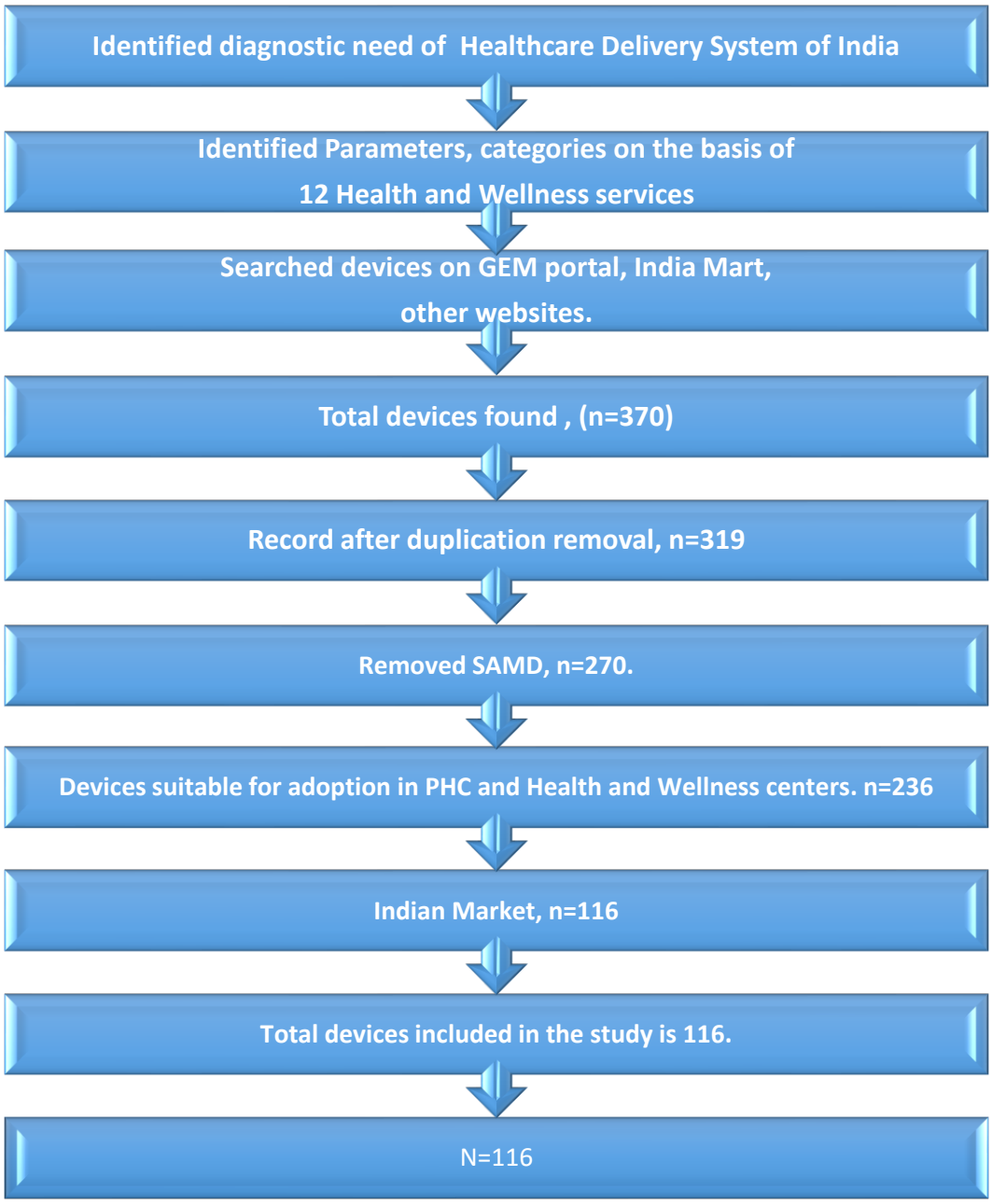
Keywords: Geriatric Care

CHAPTER-3

METHODOLOGY

Methodology

This study is an external desk research. In this study, we collected data from different authentic sites such as GEM Portal, India Mart, Amazon, and other reputable e-commerce websites. Firstly, we searched and recorded n = 370 point-of-care diagnostic devices. After removing duplicate devices, we were left with 319 devices. We then excluded SAMDs that are not suitable for Indian primary care. In the end, a total of 116 point-of-care diagnostic devices were recorded, which are available in the Indian market and suitable for adoption in primary healthcare and Health and Wellness Centers in India.



Rational of the study;

Currently not much information is available related to POC devices for primary care level in India. Their availability, cost, services provided etc need to be known so they could be easily integrated with existing workflow in the primary health care levels. This will provide a solution for reducing the cost of service and increase quality of care. Hence such information need to be identified as need of the hour.

Objective of the study -

To explore the landscape of point of care devices available in India and to identify their suitability for adoption in Primary Health Centre, the health and wellness centers.

Data Type : Secondary data
Data source: GEM Portal, India Mart, Amazon, other Ecommerce websites.
Data collection tool & method: Literature reports & websites
Study design – cross-sectional.
Study Duration: 3months (Feb 2023 –May 2023)
Geography – India

Search terms: point of care device, diagnostic devices, primary healthcare, health and wellness centers.

Inclusion criteria – 4 categories POC, PHC, India made and India make (permission to sell out), For profit and not for profit.
Exclusions criteria –

- Devices which are only used in secondary and tertiary care hospital.
- SAMD (software as a medical devices)

sample size – 116 POC Diagnostic Devices. Searched till no incremental gain
Limitations –

- Scarcity of literature related to POC's cost features etc.
- POCs adopted for PHC and HWC centers only.
- Can not generalize the results, because market is growing day by day.

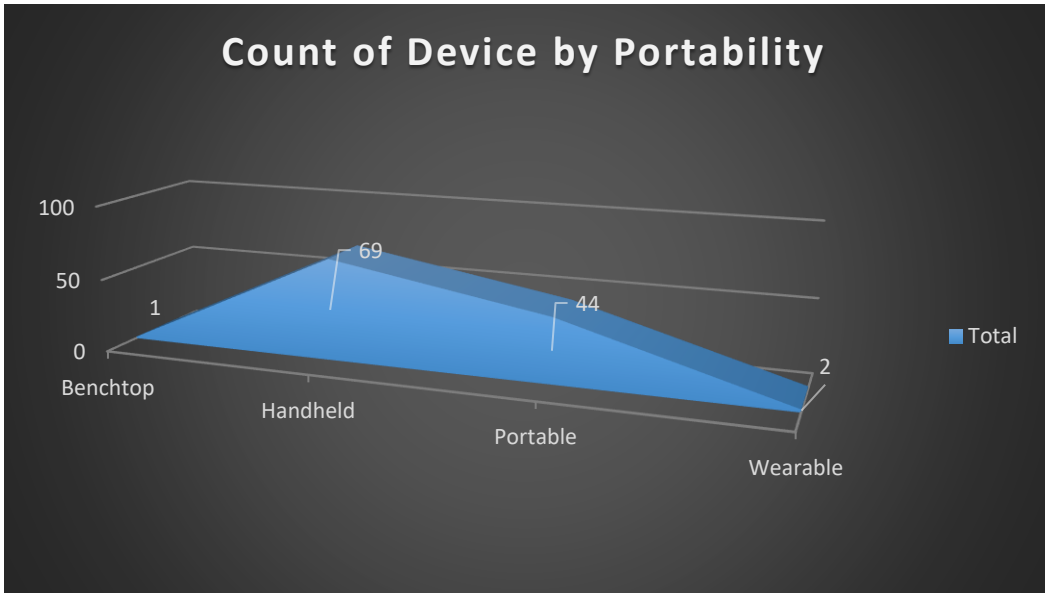
Expected Outcome
This landscaping review will provide an in-depth information of the type of point care devices available in the country, their features, and their suitability for adoption in the country. This would help the policy makers, and health care service providers to take decisions on utilization these POCs in for primary care in the country.

CHAPTER- 4

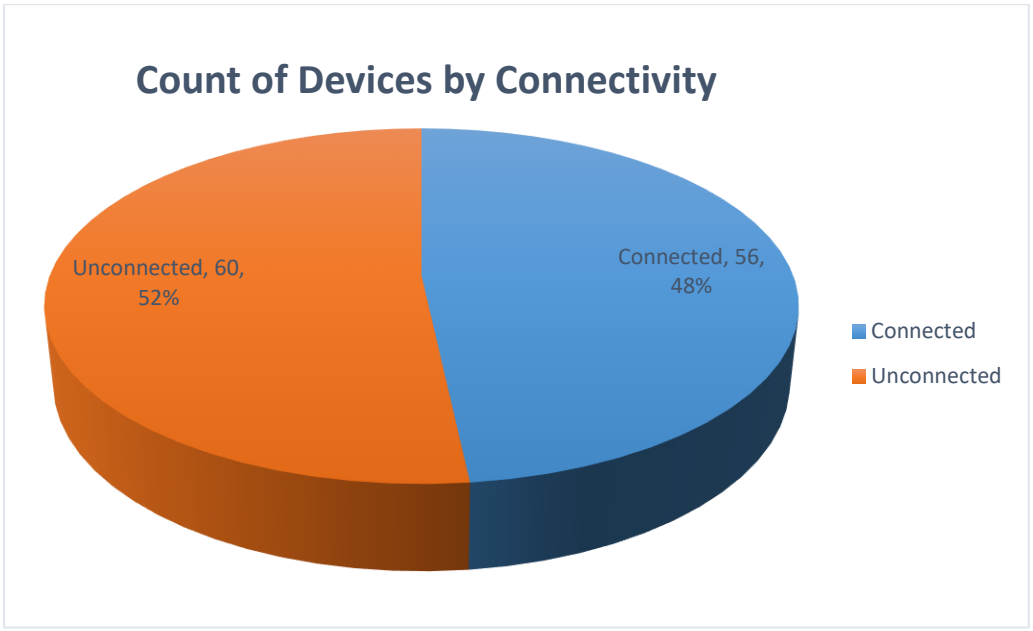
RESULT

Results:

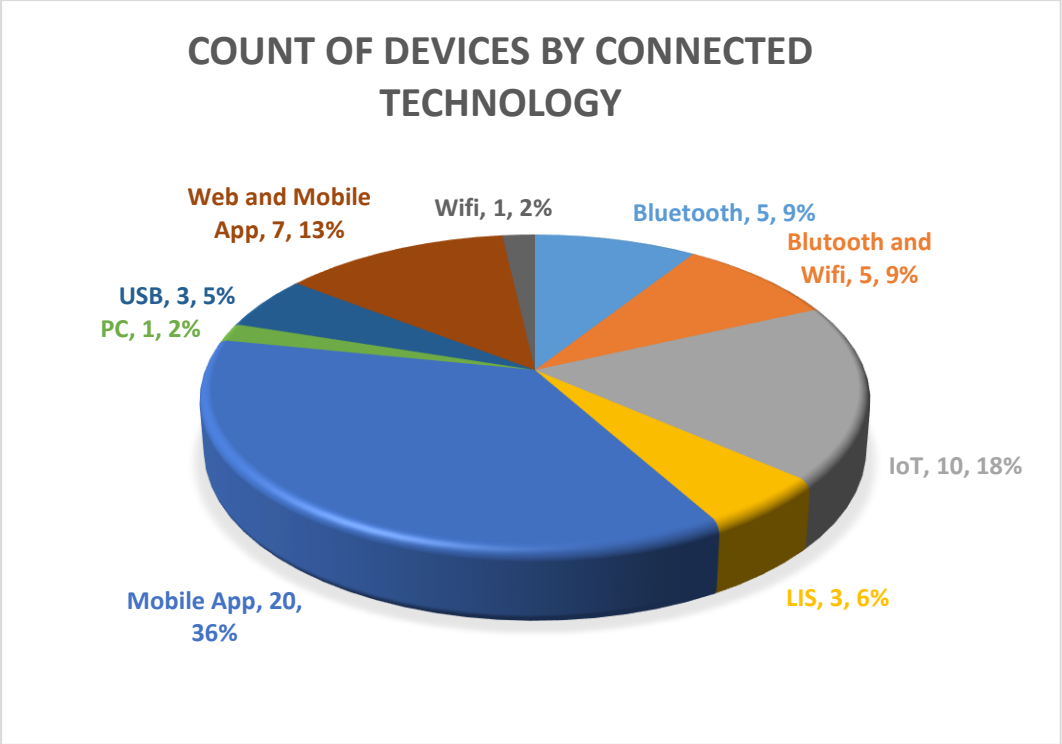
Devices List: Total 116



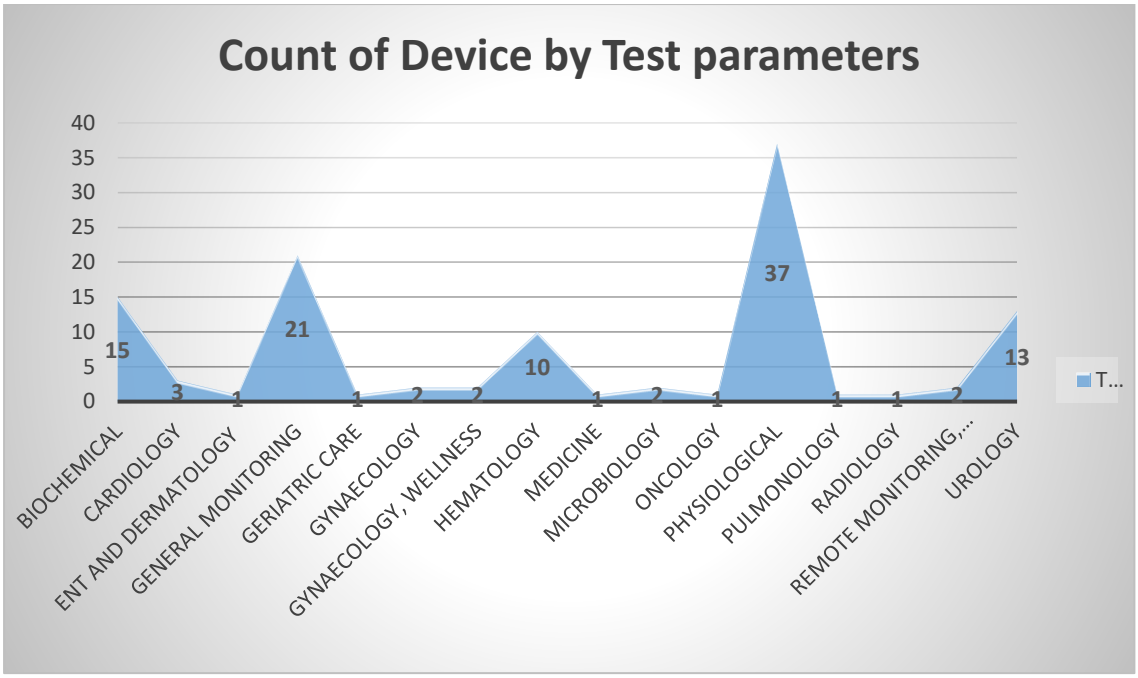
Portability: Among the 116 Devices 69 (59.48%) are handheld device, 44(37.93%) are portable, 2(1.72%) are wearable, and 1(0.86%) are benchtop device.



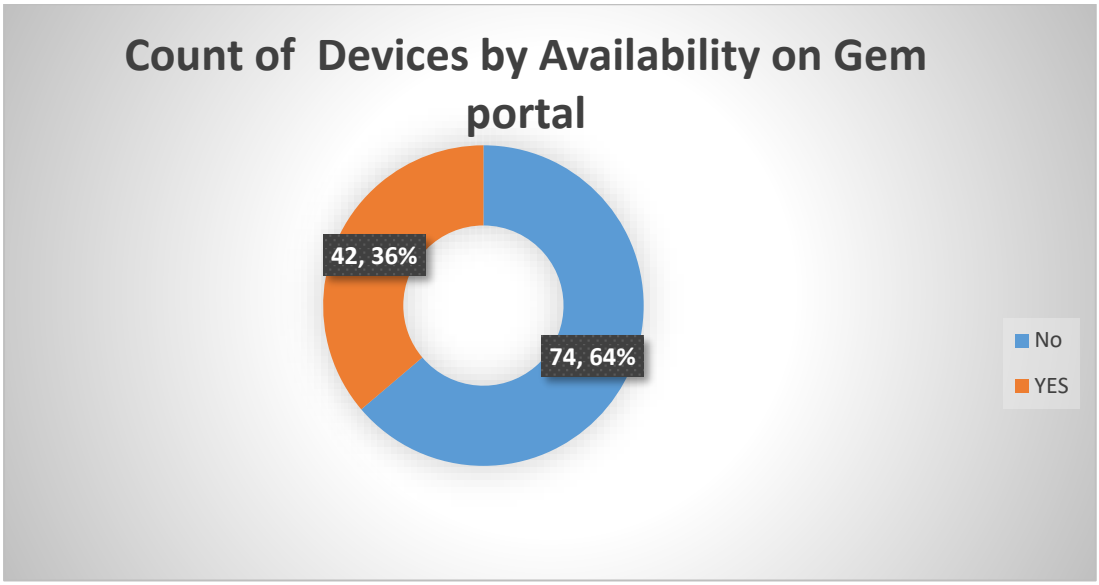
Count of devices by Connectivity: Among 116 devices 56(48.28%) are connected , 60(51.72%) are unconnected devices.



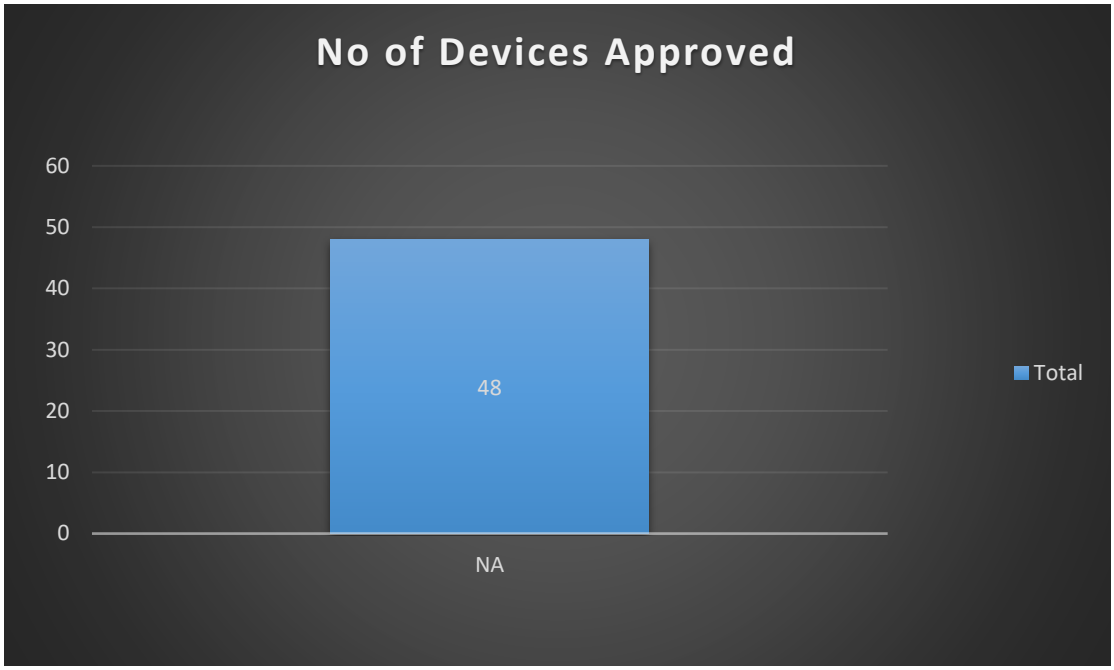
Count of devices by connected technology: Among 56 connected devices , 20 (36%) are mobile application based, 10(18%) are IoT devices, 7 (13%) are connected through web and mobile application, 5 (9%) are Bluetooth and Wi-Fi connected devices, 5 (9%) are connected through Bluetooth only and remaining are connected through LIS, USB, Wi-Fi, Pc etc..



Count of Devices by Test Parameters: Among 116 devices , 37 devices for physiological test , 21 are for general monitoring, 15 are for biochemical and 13 for urology test, 10 for Hematology , and remaining for other test.



Devices Available on Government e Marketplace (GeM Portal) : 42(36%) devices are available on Gem portal and 74(64%) are not available on Gem portal.



Among total 116 devices 48 (41.37%) are approved .

CHAPTER-5
DISCUSSION

Discussion:

The healthcare system in India is a rare instance of budgetary restrictions, a diverse population, and various healthcare needs. POC diagnostic tools precisely meet the needs of the circumstance, healthcare professionals, patients, and the rural populace. POC tests are also growing more sophisticated, with the possibility to integrate lab on a chip technology that can multitask and improve the timely effectiveness of patient care. [17]

According to the results, it is evident that in the Indian market, the majority of point-of-care (POC) diagnostic devices are handheld, while only a few are benchtop devices. In terms of integration, approximately half of the devices are connected or integrated. The most commonly used technologies in these devices include mobile applications, IoT, Bluetooth, and Wi-Fi. Some devices also utilize USB, LIS, and PC connections.

The results also indicate that the majority of POC devices are designed for physiological tests, general monitoring, biochemical tests, and hematological tests. There are relatively fewer devices available for other tests such as cardiology, urology, oncology, and radiology.

When it comes to certification, around 41.37% of POC devices have been approved by ISO and other organizations.

CHAPTER-6
CONCLUSION

Conclusion:

In this paper, we discuss different categories of POC diagnostic devices. The difference between connected and unconnected devices is only 4%. This indicates that the Indian market offers a good variety of connected POC devices, which can facilitate the flow of primary healthcare in India. Although we are aware that portable and handheld POC Diagnostic devices which has connectivity may require some training, this training can be provided by facilitators. By using these POC diagnostic devices, healthcare provider can easily and promptly provide diagnostics and treatments, which will undoubtedly improve patient satisfaction. If healthcare providers receive fast results, they can initiate treatment within an hour. As we know, the golden hour is crucial in emergency patient care. By using such devices in emergency or life-threatening situations, healthcare providers can save more lives, thus improving the quality and efficiency of primary healthcare and health and wellness centers in India. This will also help meet the healthcare needs of India.

CHAPTER-7
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ANNEXURE

S.No	Device	Manufacture /Brand Name	Model Name	Type (Handheld/ Portable)	Product Approval	Connectivity	Connectivity Technology	Combined test parameter	Specific Parameter Tested	Availability on Gem Portal (Yes/ No)
1	Baby height measuring mat	VSILKR	(SLK 20B)	Portable	NA	Unconnected	NA	Physiological	For measuring the length or height of new borns, infants and small children in laying down position as a part of Monitoring the baby growth and anthropometry	YES
2	Baby Weighing Scale	Ace	BS 30	Portable	ISO	Unconnected	NA	Physiological		No
3	Bilirubinometer	AMIGO	(BJ20 NEONATAL JAUNDICE meter)	Handheld	European CE, 98/79/EC (Doe), ISO 9001 & ISO 13485	Unconnected	NA	Hematology	Transcutaneous Non Invasive Bilirubinometer is used to test transcutaneous concentration of bilirubin correlative with serum bilirubin concentration	YES
4	Bilirubinometer	Korrida	Korrida Jaundice meter	Handheld	NA	Unconnected	NA	Biochemical	Bilirubin Analysis	No

5	Blood Pressure Monitor	NISCOMED	NISCOMED ABlood PressureM-50	Handheld	ISO: 13485 ,ISO: 9001, IEC 60601-1	Connected	USB	Geriatric Care	Blood Pressure Monitoring	Yes
6	Blood Pressure Monitor	NISCOMED	Niscomed PW-201	Handheld	NA	Unconnected	NA	Medicine	Blood Pressure Monitoring	Yes
7	Blood Pressure Monitor	Remedi	Remedi Nova (cpw34)	Handheld	CDSCO	Unconnected	NA	General Monitoring	Blood Pressure Monitoring	Yes
8	BNP Fast Test Kits	Accurex	AccuDX CQ NT-Pro BNP (25 Tests)	Handheld	CE,ISO,GMP	Unconnected	NA	Cardiology	BNP Level in Blood	No
9	Body Composition Monitor	Advin	Advin Body Fat Scale	Portable	NA	Unconnected	NA	General Monitoring	Body Fat	No
10	Body Composition Monitor	Sansui Electronics Pvt Ltd	NA	Portable	NA	Connected	IoT	Physiological	It helps track various body metrics such as, Body Weight, BMI, Body Fat(%), Body Water(%), Skeletal Muscle(%), Bone(%), Protein(%), Muscle(%), Visceral Fat Index, Subcutaneous Fat, Lean Body Mass, Body Age, Somatotype, BMR and AMR.	NO
11	Body Composition Monitor	Actofit	Smart Scale Pro Max	Portable	NA	Connected	Mobile App	General Monitoring	Body Composition Monitoring	No
12	Cervix Screen Liquid based Ctylogy Kit (Sample Collection)	Biopro	Cervix Screen LBC	Handheld	NA	Unconnected	NA	Oncology	Cervical Sample collection for Cytologocal Examination (In vitro Diagnosis)	No

13	CQ Analyzer Box	Accurex Biomedical Pvt. Ltd	Accurex AccuDx CQ Analyser Box	Portable	NA	Unconnected	NA	Hematology	Near patient critical care quantitative analyzerInstant quantitative analyzer for cardiac bio-marker & sepsis	NO
14	CTG machine	Care Nx Innovations Private Limited	Fetosense Wireless NST Machine	Portable	NA	Connected	IoT		Fetal Heart Monitoring/Cardiotocography/NST	No
15	CTG Machine	dr diazR	NA	Portable	Product certification EU-CE,Four digit number of notified body If product is EU-CE certified 9052 , CE-9052	Unconnected	NA	Physiological	For recording and analyzing the Fetal Heart Rate (FHR) and contractions of uterus during antepartum and intrapartum period	yes
16	Diagnostic Spirometer	RMS	Helios 401	Portable	NA	Connected	USB	Physiological	Pulmonary Function Test PFT Device, Desktop Spirometer, Diagnostic Spirometer	No
17	ECG Machine	Atom	Atom ECG v2.0	Portable	CE	Connected	Mobile App	Cardiology	ECG	No
18	ECG Machine	BPL	CARDIART 108T DIGI	Portable	European CE, G11019020007, IEC-60601-1-2:2001 , IS - 13450 /	Unconnected	NA	Physiological	ECG Machine is primary equipment to record ECG signal with interpretation which is required for recording and analyzing the	YES

					IEC60601-1-2005				waveforms with software.	
19	ECG Machine	BPL	Cardiart 9108	Portable	NA	Unconnected	NA	Physiological	easy viewing of patient demographics and real time ECG data option	YES
20	ECG Machine	Express Diagnostics Private Limited	ET-U12	Portable	CE and ISO certified	Connected	Mobile App	Physiological	The innovative concept of Tele ECG met with yet more innovation of easily wearable belt, this will ensure the accurate placement of ECG electrodes and eliminates the human error, online opinion facilities provides best in class diagnosis round the clock.	no
21	ECG Machine	Recorders & Medicare Systems	MAXIMUS 24	Portable	European CE, 2074 dt 19-1-22, ISO 13485 and ISO 9001	Unconnected	NA	Physiological	EEG (Electro Encephalogram) Machine is used to detect problems in the electrical activity of the brain that may be associated with certain brain disorders	YES
22	ECG Machine	Nasan Medical Electronics Private Limited	MBNAS0029	Portable	NA	Connected	IoT	Physiological	PC based ECG Machine with DSP Technology	NO

23	ECG Machine	Allengers	NEUROPLOT EEG Machine - Allengers Global	Portable	NA	Unconnected	NA	Physiological	Allengers Neuroplot test systems are designed using state-of-the-art technology and Recording & Monitoring of electrical activities of the brain and to investigate and locate seizure origin.	NO
24	ECG Machine	MEDICAIDUR	NMX-64	Portable	ISO 13485 and ISO 9001	Unconnected	NA	Physiological	Portable bluetooth enabled EEG (Electro Encephalogram) Machine Machine is used to detect problems in the electrical activity of the brain that may be associated with certain brain disorders	YES
25	ECG Machine	Sanket Life	SanketLife-Proplus	Portable	ISO	Connected	Mobile App	Cardiology	ECG	No
26	ECG Machine	SURGI HUB	SURGI HUB 11080	Portable	IS - 13450 / IEC60601-1-2005, CE 181911502 04/08/2020	Unconnected	NA	Physiological	ECG Machine is primary equipment to record ECG signal with interpretation which is required for recording and analyzing the waveforms with software.	YES
27	ECG Machine	RMS	VESTA 101	Portable	CE3777, ISO 13485, IS -	Unconnected	NA	Physiological	record ECG signal with interpretation	Yes

					13450 / IEC60601-1-2005					
28	Fetal Doppler	Accusre	Accusure Fetal Doppler	Handheld	ISO, CE	Unconnected	NA	Gynaecology, Wellness	FHR Display and Sound Hearing	No
29	Fetal Doppler	ASKP Solutions	AD 5650	Handheld	ISO, CE	Unconnected	NA	Gynaecology, Wellness	FHR Display	No
30	Fetal Doppler	Mukerji & Banerjee Surgical Private Limited	Care Touch Fetal Doppler	Portable	NA	Unconnected	NA	Physiological	fetal heart rate Monitoring	NO
31	Fetal Doppler	Janitri	Keyar Mini	Handheld	NA	Connected	IoT	Gynaecology	Baby's Heartbeat listen and measure	No
32	Fetal Monitor	Janitri	Keyar CM	Portable	NA	Connected	IoT	Gynaecology	Fetal Monitoring	No
33	Fever Watch	Helyxon	Fever Watch Pro	Handheld	NA	Connected	Mobile App	Physiological	Temperaure Monitoring	No
34	Glucometer	Health ARX technology Pvt. Ltd (BeatO)	Abbott sensor continuous glucose monitor	Handheld	ISO	Connected	Mobile App	Biochemical	Blood glucose level	No
35	Glucometer	Ambitech	AmbiTech Elizy Glucometer	Handheld	CDSCO	Unconnected	NA	Biochemical	Blood glucose level	Yes
36	Glucometer	Health ARX technology Pvt. Ltd (BeatO)	BeatO curve glucometer with Type C or micro USB	Handheld	ISO	Connected	Mobile App	Biochemical	Blood glucose level	No
37	Glucometer	Health ARX technology	BeatO smart glucometer with 3.5 mm Jack	Handheld	ISO	Connected	Mobile App	Biochemical	Blood glucose level	No

		Pvt. Ltd (BeatO)								
38	Glucometer	Dr Morepen	BG-03	Handheld	NA	Unconnected	NA	Biochemical	Blood glucose level	No
39	Glucometer	Health ARX technology Pvt. Ltd (BeatO)	Contour plus one (Blutooth Glucometer)	Handheld	ISO	Connected	Mobile App	Biochemical	Blood glucose level	No
40	Glucometer	Control D	Control D Glucometer	Handheld	CE	Unconnected	NA	Biochemical	Blood glucose level	Yes
41	Glucometer	Gluco Care Sense	MDT RBS Kit Glucometer	Handheld	CE	Unconnected	NA	Biochemical	Blood glucose level	Yes
42	Glucometer	POCT	PSG10	Handheld	CDSCO	Unconnected	NA	Biochemical	Blood glucose level	Yes
43	Glucometer	Sinocare	Safe- Accu	Handheld	FDA,CE	Unconnected	NA	Biochemical	Blood glucose level	Yes
44	Glucometer	NISCOMED	Sure Screen	Handheld	CE	Unconnected	NA	Biochemical	Blood glucose level	Yes
45	Glucometer	Ultrahuman	Ultrahuman M1 Continuous Glucose Monitor	Handheld	NA	Connected	IoT	Biochemical	Blood glucose level	NO
46	Glucometer	Accurex	Xpress Glucometer Kit	Handheld	CE,ISO,GMP	Unconnected	NA	Biochemical	Blood glucose level	No
47	HbA1c Analyzer	Accurex	Xpress A1C meter Strips	Handheld	CE,ISO,GMP	Unconnected	NA	Biochemical	HbA1c Analysis	No
48	Health Kiosk	HAL CLOUD CLINICR	BASIC	Portable	CE (EU)	Connected	Web and Mobile App	Physiological	10 Non invasive health parameters, Doctor consultation platform with health record.	YES
49	Health Kiosk	BLUEBAILEYR	BLUEBAILEY STANDARD HEALTH CHECKUP	Portable	CE(EU),US FDA	Connected	Web and Mobile App	Physiological	40+ Non invasive & Invasive health parameter & Tests. 12 lead ECG, stethoscope,	YES

									Octoscope & Dermascope to assist Doctor consultation	
50	Health Kiosk	HOPSR	HK-B1	Portable	CE,US FDA	Connected	Web and Mobile App	Physiological	10 Non invasive health parameters, Doctor consultation platform with health record.	YES
51	Health Kiosk	HOLDENR	holden	Portable	CE(EU),US FDA	Connected	Web and Mobile App	Physiological	10 Non invasive health parameters, Doctor consultation platform with health record.	YES
52	Health Kiosk	PHOENIX MICROSYSTEM SR	PHXHLTH2302	Portable	CE (EU)	Connected	Web and Mobile App	Physiological	40+ Non invasive & Invasive health parameter & Tests. 12 lead ECG, stethoscope, Octoscope & Dermascope to assist Doctor consultation	yes
53	Health Kiosk	CLOUDSPITALUR	SAK03	Portable	CE (EU)	Connected	NA	Physiological	Basic verison with 12 lead ECG, stethoscope, Octoscope & Dermascope to assist doctor consultation	YES
54	Health Kiosk	SWAYAM	Swayam - B-Plust	Portable	CE(EU),US FDA	Connected	Web and Mobile App	Physiological	40+ Non invasive & Invasive health parameter & Tests. 12 lead ECG, stethoscope, Octoscope & Dermascope to assist Doctor consultation.	Yes

55	Health Kiosk	YOLO HealthR	YOLO HEALTHATM ADVANCE - 2020	Portable	CE(EU),US FDA	Connected	Web and Mobile App	Physiological	40+ Non invasive & Invasive health parameter & Tests. 12 lead ECG, stethoscope, Octoscope & Dermascope to assist Doctor consultation.	YES
56	Health Monitor	Aabo	aabo-x6	Handheld	CE,CDSCO	Connected	Blutooth and Wifi	General Monitoring	Multiple Parameters (Like: Temperature, Glucose, Oxygen, ECG,PR, Blood Pressure)	No
57	Health Monitor	HealthCube	AgeWell Health Monitor	Portable	NA	Connected	IoT	Physiological	Can check blood pressure, oxygen saturation, ECG, respiratory rate and temperature	NO
58	Health Monitor	Turtle Shell technologies Pvt Ltd	Dozee Health Monitoring Device	Handheld	CE certified	Connected	Mobile App	Physiological	Dozee tracks health vitals like heart rate, respiration, sleep, HRV and myocardial performance index.	NO
59	Heart Rate Monitor	Nivia	DG 567	Wearable	NA	Unconnected	NA	General Monitoring	Heart rate Monitoring	No
60	Heart Rate Monitor	Nexus	Heart Rate Monitoring Alere Heart Check System, for Personal	Handheld	NA	Unconnected	NA	General Monitoring	Cardiac Monitor	No

61	Hemoglobinometer	United Scietific and surgicals	Hemoglobin meter	Benchtop	ISO	Unconnected	NA	Hematology	Hemoglobin Analysis	No
62	Hemoglobinometer	Labtronics	113P	Handheld	FDA, CE, NSIC	Unconnected	NA	Hematology	Hemoglobin Analysis	No
63	Hemoglobinometer	AccuSureR	Accusure, HB 101	Handheld	US FDA, Certification number and date, 2018-2-25416 Dated 25.01.2020, ISO 9001 & ISO 13485	Unconnected	NA	Hematology	Haemoglobin Analysis	YES
64	Hemoglobinometer	Hemocue	Hemocue Hb 201+	Handheld	NA	Unconnected	NA	Hematology	Hemoglobin Analysis	No
65	Hemoglobinometer	Ozone	Ozone Semi Automatic Ozocheck HemoSimple Hemoglobin Analyzer HB Meter	Handheld	NA	Unconnected	NA	Hematology	Hemoglobin Analysis	No
66	Hemoglobinometer	Biosense	Smart Hemoglobin Monitor Hbcheck	Handheld	NA	Connected	Blueto oth	Hematology	Hemoglobin Analysis	No
67	Hemoglobinometer	Wrig Nanosystems	Truehb Hemoglobin meter Kit	Portable	CDSCO	Unconnected	NA	Haematology	Hemoglobin Analysis	No

68	Hemoglobinometer	Accurex	Urit-12	Handheld	CE,ISO,GMP	Unconnected	NA	Haematology	Hemoglobin Analysis	No
69	Hepatitis C Virus (HCV)	xamin	HCV Rapid Test Device	Handheld	EU-CE (IVD) 5008	Unconnected	NA	Microbiology	To provide diagnosis of Hepatitis C Virus infection	YES
70	Infrared Thermometer	Putex	Putex Handheld Infrared Thermometer	Handheld	NA	Unconnected	NA	General Monitoring	Temperaure Monitoring	Yes
71	Infrared Thermometer	Walnut Medical	Thermosure	Handheld	NA	Unconnected	NA	Physiological	Temperaure Monitoring	Yes
72	Mobile Lab	AccusterR	Portable Compact Static Lab	Portable	98/79/EC	Connected	Blueto oth			yes
73	Multi Parametric POC Testing Device	EzeRx	EzeCheck	Handheld	CDSCO, ISO, IEC	Connected	IoT	General Monitoring	Multiple Parameters (Like: Creatine, Oxygen saturation, glucose, bilirubin, Hb)	No
74	Portable Pragnency Care Kit	Care Mother	AnandiMaa	Portable	NA	Connected	IoT		Pregnancy Remote Monitoring	No
75	Pulse Oximeter	GB International	Pulse Oximeter	Handheld	ISO	Unconnected	NA	General Monitoring	SPO2 and Pulse	No
76	Pulse Oximeter	MokkoMotto	Abs based battery operated Oled display biosensor based Pulse Oximeter	Handheld	CE, FCC, BIS	Unconnected	NA	General Monitoring	Pulse, SPO2 Monitoring	Yes
77	Pulse Oximeter	ASKP Solutions	AD 5700	Handheld	ISO,CE	Unconnected	NA	General Monitoring	SPO2 and Pulse	No

78	Pulse Oximeter	DC Medicare	DC Medicare PL-1133	Handheld	ISO	Unconnected	NA	Physiological	Pulse, SPO2,RR Monitoring	Yes
79	Pulse Oximeter	Pine	Fingertip Pulse Oximeter	Handheld	NA	Unconnected	NA	General Monitoring	SPO2 and Pulse	No
80	Pulse Oximeter	LIVCURE SURGICAL PRIVATE LIMITED	MB020321LIVCURE10	Handheld	NA	Unconnected	NA	Physiological	A small, lightweight Device used to Monitor the amount of oxygen carried in the body	YES
81	Pulse Oximeter	BIODevices	OXYZEN Elite	Handheld	NA	Unconnected	NA	Physiological	Pulse rate, Saturation % & Perfusion Index Display	NO
82	RDT Reader	CTK- Alta	Alta- RTR- 1	Portable	NA	Connected	USB	Microbiology	RDT reading	No
83	Sleep,Activity Tracker	Aabo	aaboRing	Handheld	CE	Connected	Blueto oth	General Monitoring	Sleep, Stress, Activity Tracker	No
84	Sleep,Activity Tracker	Ananta Medisystems	Yh-600b Pro	Portable	NA	Connected	IoT	Physiological	SPO2, Pulse Rate, Airflow Waveform, Snore, CPAP Pressure, Wrist Movement (Sleep / Awake), Thoracic / Abdominal Respiratory Effort, Body Position	NO
85	Smart Band	SKG Enterprise	M4 Fitness Band	Wearable	NA	Connected	Mobile App	General Monitoring	Heart rate Monitoring and sleep Monitor	No
86	Smart Health Briefcase	Yolo	Health Box	Portable	FDA, CE	Connected	Mobile App	Remote Monitoring, Telemedicine	Multiple Parameters (Like: Blood Pressure, Temperature, Glucose,Hb, etc)	No
87	Smart Health Briefcase	Remedi	Remedi Nova Portable Telemedicine Kit	Handheld	CDSCO	Connected	Mobile App	Remote Monitoring, Telemedicine	Multiple Parameters (Like: Blood Pressure,	No

									Temperature, Glucose,Hb, etc)	
88	Spirometer	Clarity	Spirotech	Handheld	NA	Unconnected	NA	Pulmonology	Spirometry	No
89	Stadiometer	Rohit Enterprises	214cm Height MeasuringScale	Portable	NA	Unconnected	NA	Physiological	Height Measuring	No
90	Stadiometer	Indosurgicals	Height Measuring Scale	Portable	NA	Unconnected	NA	Physiological	Height Measuring	No
91	Stadiometer	Maa International	Mid 11	Portable	NA	Connected	Wifi	Physiological	Height Measuring	No
92	Stethoscope	Aabo	aaboOne- AI Powered Smart Stethoscope	Handheld	CE,CDSCO	Connected	Mobile App	General Monitoring	Auscultation	No
93	Stethoscope	Global Trade Links	Double Sided Ayu Devices Bluetooth Stethoscope, Black, Single Piece Tunable	Handheld	NA	Connected	PC	General Monitoring	Patient Monitoring	Yes
94	Stethoscope	Indosurgicals	ll-SS	Handheld	NA	Unconnected	NA	General Monitoring	Auscultation	No
95	Stethoscope	AyuDevices	AyuLynk	Handheld	NA	Connected	Blutooth and Wifi	General Monitoring	Heart and Lung Sound Monitoring	No
96	Stethoscope	AyuDevices	AyuSynk 2 Pro	Handheld	NA	Connected	Blutooth and Wifi	General Monitoring	Heart and Lung Sound Monitoring	No
97	Stethoscope	AyuDevices	AyuSynk 2+	Handheld	NA	Connected	Blutooth and Wifi	General Monitoring	Heart and Lung Sound Monitoring	No

98	Thermometer	Jain Laboratory Instruments Pvt. Ltd	MBJ1300	Handheld	NA	Unconnected	NA	Physiological	measure body temperature manually.	YES
99	Thermometer	PROACTIVER	thermometer PO-10	Handheld	EU-CE	Unconnected	NA	Physiological	For oral, rectal and armpit/axilla temperature measurement	YES
100	Ultrasound Machine	PhilipsR	(Philips Lumify)	Handheld	Equipment should be European CE / US FDA/BIS/ISO Certified- yes	Unconnected	NA	Physiological	Ultrasonography	YES
101	Ultrasound Machine	BPL	BPL Portable UltraSound	Portable	ISO 9001 & ISO 13485	Unconnected	NA	Radiology	Radiological Diagnosis of various conditions	Yes
102	Uric Acid Analyzer	Accurex	Beneckeck Plus	Handheld	CE,ISO,GMP	Unconnected	NA	Urology	Uric Acid meter	No
103	Urine Analyzer	Accurex	Accurex Xpress ACR Urine Analyzer	Handheld	NA	Connected	Blueto oth	Urology	Urine analysis	No
104	Urine Analyzer	BioGenix	BI-400	Portable	NA	Connected	LIS	Urology	Urine analysis	Yes
105	Urine Analyzer	Sinduri Biotec	SB 600 TS Urine Analyzer	Handheld	CE	Unconnected	NA	Urology	Urine analysis	No
106	Urine Analyzer	Arkray	UA120	Handheld	NA	Unconnected	NA	Urology	Urine analysis	No
107	Urine Analyzer	UriScan	UriScan Pro	Portable	NA	Connected	LIS	Urology	Urine analysis	Yes
108	Urine Analyzer	Urit	Urit 31	Handheld	CE, ISO	Connected	Blueto oth	Urology	Urine analysis	No
109	Urine Analyzer	Biogeny	URIT-50	Portable	CDSCO		LIS	Urology	Urine analysis	Yes

110	Urine Analyzer	Neodocs	Wellness Care Kit, Maternal care Kit	Handheld	ISO	Connected	Mobile App	Urology	Multiple Parameters (Like: Protein, UTI, Ketones, Glucose,etc)	No
111	Urine Analyzer	Neodocs Healthcare Pvt. Ltd	CKD	Handheld	ISO 13485-2016	Connected	Mobile App	Urology	Urine analysis	No
112	Urine Analyzer	Neodocs Healthcare Pvt. Ltd	E201	Handheld	ISO 13485-2016	Connected	Mobile App	Urology	Urine analysis	No
113	Urine Analyzer	Neodocs Healthcare Pvt. Ltd	UD201-Parent	Handheld	ISO 13485-2016	Connected	Mobile App	Urology	Urine analysis	No
114	Urine Analyzer	Neodocs Healthcare Pvt. Ltd	W201- Parent	Handheld	ISO 13485-2016	Connected	Mobile App	Urology	Urine analysis	No
115	Vitals and ECG Monitoring System	Agatsa	Multivital-2.0	Handheld	ISO	Connected	Mobile App	General Monitoring	Vitals	No
116	Wireless Visual investigation Device	Aabo	aaboScope ENT and Skin Investigation	Handheld	CE, FDA	Connected	Blutooth and Wifi	ENT and Dermatology	Visual investigation in ENT and Dermatology	No

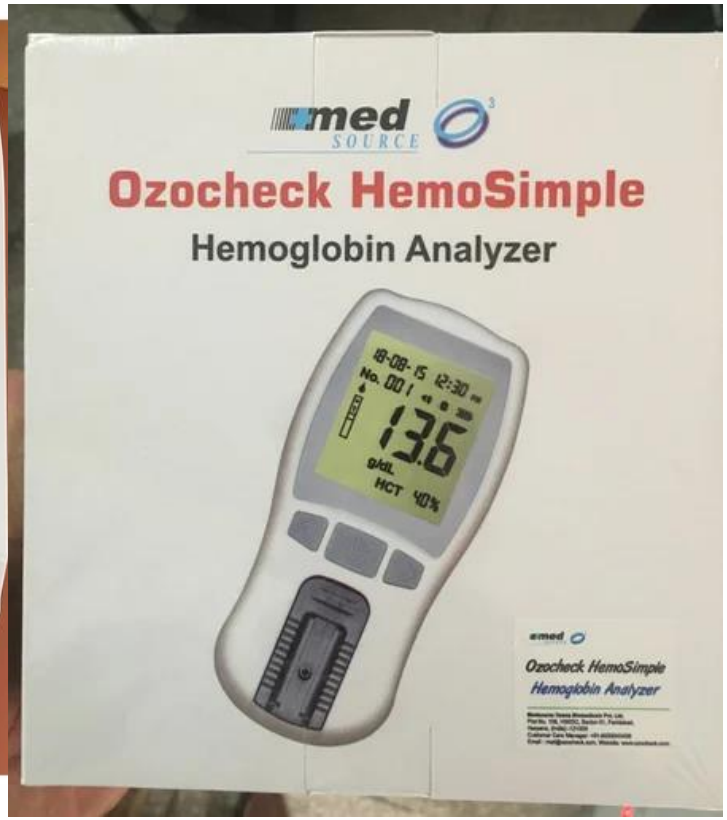
EXAMPLES


Pulse oximeter
SpO2 (%)
100
99
90
PR (bpm)
120
81
50
PI%:2.3
Unmute


beurer
36.7


ANANTA MEDISYSTEMS
PolyWatch
00:02:34
CPAP: 0.0
FL
CR
SN
96
Spo2(%)
79
PR(bpm)


Urine Strip Analyzer


med SOURCE
Ozocheck HemoSimple
Hemoglobin Analyzer
13.6
HCT 40%


SMART BRACELET
A Partner To Monitor Your Health
02:00
06:14
6/24 Thu
23450
M4


142
2.0MHz
bpm
2.0MHz


epoc Host
Pat ID 45231313164652165
26-Sep-17 10:29:00
Gases+
Chem+
Meta+
pH 7.40
pCO2 42.1 mmHg
pO2 101.5 mmHg
pH(T) 7.39
pCO2(T) 43.9 mmHg
pO2(T) 107.7 mmHg
cHCO3- 23 mmol/L
BE(ecf) 1 mmol/L
cSO2 98.5 %
epoc Readers
Rdr1702 (01702)
Tools View Help
epoc


ACCUREX
LIFETIME WARRANTY
XPRESSGLUCO
BLOOD GLUCOSE MONITORING SYSTEM
Accurate Result
Fast Test
Portable Device
FOR SELF-TEST
105
mg/dl
25