INTEGRATION OF MINIMALIST IOMT IN HEALTH AND WELLNESS CENTRES: A FEASIBILITY STUDY

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in

Hospital and Health Management

By

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Under the Supervision & Guidance

of

Dr. Neetu Purohit

2022

DECLARATION

I hereby declare that this dissertation titled Integration of Minimalist IoMT in HWC-PHC: Cross sectional analytical study is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

Dr. Hardik Sankhla

Hardik Sankhla

CERTIFICATE

This is to certify that Hardik Sankhla in partial fulfilment of the requirements for the award of the degree of MBA (Hospital and Health Management) from the IIHMR University, Jaipur has successfully completed his internship at Enira Consulting Private Limited during March 22, 2022, to June 19, 2022.

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Director

Enira Consulting Private Limited

Place: Bhavnagar, Gujrat

Date: 28/ June/ 2022

CERTIFICATE

This is to certify that dissertation titled **Integration of Minimalist IoMT in Health and Wellness Centres: a feasibility study** is a record of the research work undertaken by **Hardik Sankhla** in partial fulfillment of the requirements for the award of the degree of **MBA (Hospital and Health Management)** from the **IIHMR University**, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific, and analytical.

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Dr Hardik Sankhla

Hardik Sankhla

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Abstract

Indian subcontinent is second most populous country on the globe, Healthcare system deals with heavy patient load, depleting quality of care, increasing cost of care, inequitable access and lack of healthcare workers. With a view to enable health system to operate in a decentralized diagnostic landscape, the study attempts to explore the possibilities of integration of need based minimalist IoMT diagnostic devices at the primary healthcare level, As part of methodology semi-structured interviews were conducted with the senior position bureaucrats of MoHFW, NHA and Niti Ayog, CEOs of renowned IoMT companies, senior manager, directors of community outreach and capacity building organisations.

Information gathered during these interviews was sorted into different themes across the study, that is understanding minimalist IoMT devices, market dynamics, policy analysis and health technology assessment. Results of health technology assessment was analysed to create integrated need based IoMT network at the HWCs.

The result of this study was that one-time cost of IoMT integration at the HWCs will be 2.45 times higher than the conventional existing setup with 16 percent reduction in the cost of diagnostics when HWCs are operating at minimum performance indicators as per IPHS guidelines 2022.

The main challenges in project deployment are hand-holding of different health-tech companies for unified healthcare interface, ensuring continues supply of consumables, capacity building of FLHWs at the HWCs and dealing poor network connectivity in remote regions.

1. Introduction

The covid-19 pandemic had unmasked gaps in the healthcare sector across the globe, with the Digital India initiative we are moving towards the complete digital transformation of the public as well as the private healthcare sector. Digital transformation is ray of hope for strengthening the healthcare system. (1) Digital health is utilisation of technology for improvement of individual's health and prevent disease as well, with digital health applications real-time population health data can be captured (2)

The Internet of Things (IoT) is one of the most propitious technology trend, and its possibilities have not yet been exhausted. Its applications range reach from B2C to B2B solutions, in different industry segment like healthcare, logistic and supply chain management, etc. IoT technology constitutes hardware, software, services, and connectivity. As there are numerous use cases of IoT devices, market power of specific use case is difficult to be established. (3,4)

The number of IoT devices have already surpassed the total number of population across the globe, in 2011, and by 2022, these devices are expected to be raised between 26 billion to 50 billion. (5)

This research work specifically focuses on the application of IoT devices in the healthcare industry, such IoT devices are termed Internet of Medical Things. The global Internet of Medical Things (IoMT) market size is expected to grow from 26.5 billion US dollars in 2021 to 94.2 billion US dollars by 2026, by compound annual growth rate (CAGR) of 29 percent. With a population of 1.38 billion, India in the Asia- Pacific region is the leading market of IoT devices in healthcare, GoI's Make in India initiative had boosted the growth of indigenous IoT devices, there are more than seven thousand health-tech start-ups in India now and their growth is tremendous. (6,7,8)

IoMT device industry is largely dominated by wearable devices, the most common features in the available wearable devices in market are pedometer, pulse-oximeter, sleep monitor and heart rate monitor, these wearable devices can be brought in form of wrist band and smart watches. Wrist band/ fitness band segment is dominated by One plus followed by Xaomi MI and Fastrack while smart watch segment is dominated by Noise followed by Samsung and Apple. (8,9,10)

This research work explores the possibilities of IoMT devices other than wearables, to integrate within public health infrastructure of India. The advantage of IoMT devices is that

they can be very minimalistic and offers an improved continuous, penetrating, healthcare ecosystem up to the last mile over the conventional healthcare setups. With the progress of time, the designs and technology is becoming easier and minimalist. (11,12,13)

IoMT integration will effectively reduce the cost of care as we can detect the impending diseases at a very early stage and effectively monitor the patient. (11)

There is a need for research in the field of IoMT devices so that healthcare system can offer better services to the masses in more economic and sustainable way. There is a need for policy assessment so that the found gaps can be addressed. (13)

Point of care consist of those devices, which are used close to the point where healthcare services are provided while personal care devices are utilised by the patient itself to track the healthcare records. (12)

1.1 Defining Minimalist IoMT

Minimalists is the ideology of "less is more" (14,15,16,17,18)

IoT device- is an amalgamation of electronic hardware, network connectivity, and software in any device, i.e., IoT is a seamlessly connected network of embedded objects/ devices, with identifiers, in which machine to machine communication without any human mediation is possible using standard & inter-operable communication protocols. (20)

IOMT- Blend of medical devices with IoT, The Internet of Medical Things (IoMT) is the collection of medical devices and applications that connect to healthcare IT systems through online computer networks. Medical devices equipped with network connectivity/ internet connectivity allow the machine to machine communication is the foundation of IoMT devices. (21)

Minimalist IoMT has a simple product design. As with the recent growth of IoT devices, consumers are heavily loaded with different smart wearable devices. Minimalism is smartly adding, only the essential features to the device, this results in a simple yet complete product design.

Minimalism is need based and customizable as per area specific population needs. Minimalist IoMT is devices with minimal required sensors, that have clinical feasibility & are powered by simple software and hardware integration. Such devices effectively reduce the physical appearance as well as operating cost of the device & deliver results equivalent to gold-standard devices.(14-21)

2. Review of Literature

Table 1- Review of literature

#	Author and year of publication	Title	Methodology	Findings	Place of study	Limitations
1	Razdan S, Sharma S 2021	Internet of Medical Things (IoMT): overview, emerging technologies, and case studies	Literature review	IoMT consist of Medical sensors with network connectivity and digital interface. IoMT solves major healthcare issues like shortage of human capital, long waiting time, raising demand as well as cost of care.	National College of Ireland, Dublin, Ireland	Information Bias & confounding bias
2	Swati Swayamsiddhaa & Chandana Mohanty 2020	Application of cognitive Internet of Medical Things for COVID-19 pandemic	Literature review	IoMT is a promising technology for rapid diagnosis, dynamic monitoring, tracking, and better treatment and control without spreading the virus to others.	KIIT University, Bhubaneswar	Information Bias & confounding bias

3	George Hatzivasilis 2019	Review of Security and Privacy for the Internet of Medical Things (IoMT)	Literature review	Per-patient cost for the medical institutions is reduced by the integration of IoMT Due to bringing your device concept, there is a security threat to the sensitive health record of users, there is a need for SOPs derived from best industry practices.	Santorini Island, Greece	Information Bias
4	Basatneh R, Najafi B, Armstrong D 2018	Health Sensors, Smart Home Devices, and the Internet of Medical Things: An Opportunity for Dramatic Improvement in Care for the Lower Extremity Complications of Diabetes	Literature review	Effective management of non-communicable diseases and reduction in the cost of care via the use of IoMT	Baylor College of Medicine, Houston	Information bias
5	Gulraiz J. Joyia, Rao M. Liaqat, Aftab Farooq, and Saad Rehman 2017	Internet of Medical Things (IOMT): Applications, Benefits and Future Challenges in Healthcare Domain	Literature review	This paper traces the challenges of the IoMT industry starting from the management of a	National University of Sciences and Technology, Islamabad, Pakistan	Information bias

				diversity of IoT devices, data collection, and management, security threats, and technical challenges on part of hardware and data integration.		
6	Carroll J 1997	Reconstructing minimalism	Literature review	Theory of less is more and human-centric product designing is essential for sustainable growth	Department of computer science Virginia tech, Blacksburg	Information bias
7	Cross J, Street A 2022	To Fail at Scale!: Minimalism and Maximalism in Humanitarian Entrepreneurship. Social Anthropology/Anthropologie social.	Literature review	Minimalism is new driving force for design thinkers and entrepreneur	University of Glasgow, Scotland	Information bias
8	MEITY 2019	IoT Policy Draft	Literature review	National centre of excellence for development of IoT devices.	MEITY	Information Bias
9	MEITY 2020	IoT Revised Policy Draft	Literature review	On part of IoMT's only remote	MEITY	Information Bias

				monitoring devices are considered, further policy development is needed No regulation of software as medical device		
10	Gerke S, Babic B, Evgeniou T, Cohen IG 2020	The need for a system view to regulate artificial intelligence/machine learning-based software as medical device.	Literature review	No regulations in India on software as medical device	University of Cambridge	Information bias
11	Ambade M, Sarwal R, Mor N, Kim R Subramanian S. 2022	Components of Out-of-Pocket Expenditure and Their Relative Contribution to Economic Burden of Diseases in India.	Cross-sectional descriptive study	INR 2711 is spent on diagnostics for outpatient department patients while 5337 is spent on diagnostics for indoor patient department This comes out to be 12 percent of the total healthcare expenses and 10 percent of total household income despite of	MoHFW	Information bias

				free diagnostics scheme by governmen t.		
1 2	Ayuningtyas D, Haq H, Utami R, Susilia S. 2021	Requestioning the Indonesia Government's Public Policy Response to the COVID-19 Pandemic: Black Box Analysis for the Period of January–July 2020	Cross-sectional descriptive study	Use of system's framework of policy analysis via collection of data by variety of sources.	Faculty of Public Health, Indonesia	Informati on bias
1 3	Angelis A, Lange A, Kanavos P. 2018	Using health technology assessment to assess the value of new medicines: results of a systematic review and expert consultation across eight European countries	Systematic review	Use of health technology assessment framework in deploymen t of new technology	LSE Health, London	Informati on bias

The above literature review enlightens the concept of minimalism in technology, it shows that digital health aided India's response towards covid-19 pandemic, IoMT industry showed rapid growth and acceptance among the masses post the inception of pandemic. Share of expanses on diagnostics is significant, despite the implementation of free diagnostics scheme by government of India, there are gaps in implementation of this scheme, IoMT's can be a ray of hope to solve this problem. There is need of research to understand the enablers and barriers for the integration of IoMT diagnostic devices within primary healthcare setup of India.

3. Research questions

How can minimalist IoMT devices created? Are there any gaps in government policies related to IoMT devices? How can IoMT devices be integrated in health and wellness centres of India?

4. General Objective-

To create a IoMT device framework for the health and wellness centres

5. Specific Objective-

- To understand the extent of possible minimalism of IoMT devices.
- To identify and analyse the gaps in the policies laid by Government of India in the field of IoMT devices via Systems framework of policy analysis
- To assess IoMT devices in light of Health Technology Assessment Framework.
- To create a IoMT device virtual framework for the health and wellness centres.

6. Methodology

6.1 Type of study- Cross sectional descriptive study

6.2 Duration of study- February 2022- June 2022

6.3 Selection of IoMT-

6.3.1 Inclusion criteria- IoMT must a Point of care device

6.3.2 Exclusion criteria- All the personal care devices are excluded from the study.

6.4 Respondents of the study-

- Senior officials of IoMT companies
- Subject matter experts from NHA, MoHFW, NITI Ayog, NHSRC, Heath technology assessment cell and other policy planning agencies
- Subject matter experts from the community outreach agencies

6.5 Type of data- Mixed

- Primary data from IoMT companies
- Secondary data from Government policies on IoMT and their implementation

6.6 Method of data collection- Semi- Structured interviews and review of records

6.7 Data Analysis Plan

Medical devices and medical specialties mentioned in the latest IPHS guidelines for health and wellness centres was considered in the study. (22) Market research followed screening of minimalist IoMT devices was done followed by structured interviews with the senior officials of leading health- tech companies & start-ups. (23,24,25) Shortlisted technologies were evaluated through Health technology assessment framework and Strength and weakness analysis will be done based on the interview with senior officials of the respective company/ start-ups and comments of subject matter experts on the devices. And all the technologies will be graded based on this analysis. (26,27,28) All the policies and schemes of the Indian government were screened, and gap analysis will be done, subject matter experts from NHA, ABDM, MoHFW, MEITY, and NITI Ayog will be interviewed for the latest initiatives, and found gaps in policies will be discussed with them. (29) For this study, system's framework of public policy analysis by Easton was used, all the policies will be screened through this framework and policy gaps will be identified from secondary research as well as on-ground analysis with the help of subject matter experts will be added in the analysis. (30,31,32) Based on the market research integrated network of IoMT devices was proposed and cost benefit analysis will be done. (33,34)

7. Results-

7.1 Extent of possible minimalism of IoMT devices

Minimalism with proved Sensitivity is found in mercury sphygmomanometer to digital sphygmomanometer, stethoscope turned into single headed digital stethoscope upgraded with single lead ECG probe, mercury thermometers evolved to non-contact infrared thermometers, invasive haemoglobinometers and glucometers evolved into non-invasive near infrared spectroscopy devices and ophthalmoscope entirely transformed to ML backed AI engine with advance image processing. Rest of the devices are still using conventional gold standard technology but have effectively reduced their size and added digital interface and connectivity via Bluetooth or wi-fi.

As per the subject matter experts and senior super specialist following are the gold standard devices available in the market devices available in HWCs and minimalist IoMT technologies available in market with their percent Sensitivity-

Table 2- Gold standard technology V/s minimalist technology

Equipment	**Gold standard**	**Sensitivity**	**HWCs Infrastructure**	**Minimalist technology**	**Sensitivity**
Sphygmomanometer	Mercury Sphygmomanometer	99%	Digital/ Analogous Sphygmomanometer	Digital Sphygmomanometer	99%
Stethoscope	Dual Head Stethoscope	99%	Single Head Clinical Stethoscope	Digital tubeless stethoscope	99%
Weighing Scale	Digital Weighing Scale	99%	Analogous/ Digital Weighing Scale	Digital Adult Weighing Scale	99%
Baby Weighing Scale	Digital Baby Weighing Scale	99%	Analogous/ Digital Baby Weighing Scale	Digital Baby Weighing Scale	99%
Thermometer	Mercury Thermometer	99%	Digital thermometer/ Infrared laser thermometer	Infrared laser thermometer	97%
Haemoglobinometer	Auto Analyser	99%	Digital Haemoglobinometer	Non-invasive Digital Haemoglobinometer- Near-infrared Spectroscopy	94%
Glucometer	Digital Glucometer	99%	Digital Glucometer	Photo-Spectrometry method	95%
Direct Ophthalmoscope	Binocular Ophthalmoscope	99%	Binocular Ophthalmoscope	Software as medical device solutions	94%
Snellen Chart	Autorefractor	99%	Snellen Chart	Autorefractor	99%
Pulse Oximeter	Arterial blood gas analyser	99%	Digital Pulse Oximeter	Digital Pulse Oximeter	99%
ESR Analyser	Automated ESR Analyzer	99%	Automated ESR Analyzer	Automated ESR Analyzer	99%
3 Part Haematology analyser	Automatic 3 Part Haematology analyser	99%	Automatic 3 Part Haematology analyser	3 Part Haematology analyser	99%
Biochemistry analyser	Automatic Biochemistry analyser	99%	Automatic Biochemistry analyser	Automatic Biochemistry analyser	99%
Rapid Card Test- (Falciparum and Vivax)	Microscopy	99%	Rapid Card Test- Malaria	Rapid Card Test- Malaria	99%
Rapid Card Test- Urine Pregnancy test	hCG in blood	99%	Rapid Card Test- UPT	Rapid Card Test- UPT	99%

Despite of gold standard nature of Mercury- Sphygmomanometer and Thermometer, now they are not used in healthcare facilities due to bio-hazardous nature of mercury. (85,86)

7.2 Policy assessment via System's framework of policy analysis

The policies laid by government of India, lacks guidelines on software as medical devices, there are implementation gaps across the nation like lack of technical skills in frontline healthcare workers to operate smartphones as well as IoMT devices, health-tech industry is not ready for unified healthcare interface as majority of companies have internal APIs and resistance to data sharing, lack of registered doctors on Ayushman bharat medical registry (22 thousand) across the nation and interoperability issues while using unified healthcare interface. Nascent stage of personal data protection bill halts the utilization of historical healthcare records present in hospitals. It was also observed that senior doctors don't attend e- Sanjeevani OPDs, instead of them junior resident doctors attend OPDs, this leads to compromising quality of care. On ground implementation challenges like lack of technical skills in Asha and ANM workers to feed data on different healthcare applications, outdated hardware of smartphones, applications getting crashed and Asha workers changes sim cards very frequently, males the implementation of these policies difficult. The main challenges in project deployment is ensuring continues supply of consumables, capacity building of FLHWs at the HWCs and dealing poor network connectivity in remote regions.

7.3 IoMT device assessment in light of Health Technology Assessment

54 products were assessed via health technology assessment framework, out of these 35 percent products have internal API integration, all of the devices have automated diagnosis system baked by machine learning engine, this leads to difficult interoperability during integration. 58 percent IoMT devices don't have FDA certification, which is gold standard across the globe. Logy.AI is software as medical device which offers ophthalmologic diagnostics in the lowest market rate, but their integration with IoMT network can be challenging due to lack of policy framework on software as medical devices.

Out of 54 IoMT products 12 IoMT's were included into final integrated system, 26 IoMT products can be considered as second option while 21 were found incompetent for integration reason being internal APIs, high cost of product and testing.

Segregation of products- Green signifies most feasible product, yellow coloured products can be considered if supply of most feasible product is hampered while red signifies least feasible product. With further technical development in the field of API integration red coloured products can be most feasible. (Table 3-14)The feasibility of product is determined by the API integration status and price of the test.

Table 3- HTA- Digital Sphygmomanometer

#		Sphygmomanometer Digital/ Analogous											
	Product	**Technology**						**Economic**			**Organisational**		**Social**
		Technology used	**API Integration**	**Connectivity**	**Result Interpretation**	**Sensitivity**	**Battery life**	**Cost per device**	**Cost per test**	**AMC**	**Training**	**Portability**	**Clinical Validity**
1	Writzo	Silicon-based microelectromechanical systems (MEMS)	Open	Wi-Fi and Wired	Yes- ML backed AI	95%	4 hours	4592	-	Yes	Yes	Yes	CDSCO
2	E-med Tel	Silicon-based microelectromechanical systems (MEMS)	Open	Wi-Fi and Wired	Yes- ML backed AI	95%	4 hours	4578	-	Yes	Yes	Yes	CDSCO
3	Health Cubed	Silicon-based microelectromechanical systems (MEMS)	Open	Wi-Fi and Wired	Yes- ML backed AI	95%	5 hours	4527	-	Yes	Yes	Yes	CDSCO FDA CE
4	Medongo	Silicon-based microelectromechanical systems (MEMS)	**Internal**	Wi-Fi and Wired	Yes- ML backed AI	95%	12 hours	4450	-	Yes	Yes	Yes	CDSCO
5	Braun Exact fit 5	Silicon-based microelectromechanical systems (MEMS)	**Internal**	Bluetooth	Yes- ML backed AI	90%	No battery	5292	-	No	With quick start guide	Yes	FDA CE CDSCO
6	Omron HEM 7120	Silicon-based microelectromechanical systems (MEMS)	**Internal**	Bluetooth	Yes- ML backed AI	90%	Wired	1749	-	No	With quick start guide	Yes	FDA CE CDSCO
7	Inbody Upload Pressurized Automatic BPBIO320	Air pressure sensors	**Internal**	Wi-Fi and Wired	Yes- ML backed AI	97%	Wired	**116894**	-	Yes	Yes	No	FDA CE

Health cubed Digital Sphygmomanometer is shortlisted on the part of its lowest cost among the shortlisted IoMT products.

Table 4- HTA: Digital Stethoscope

#		Single Head Clinical Stethoscope											
	Product	**Technology**						**Economic**			**Organisational**		**Social**
		Technology used	**API Integration**	**Connectivity**	**Result Interpretation**	**Sensitivity**	**Battery life**	**Cost per device**	**Cost per test**	**AMC**	**Training**	**Portability**	**Clinical Validity**
1	Writzo	Acoustic sensor with ECG	Open	Wi-Fi and Wired	Yes- ML backed AI	95%	4 hours	15,670	-	Yes	Yes	Yes	CDSCO
2	E-med Tel	Acoustic sensor	Open	Wi-Fi and Wired	Yes- ML backed AI	95%	4 hours	13,670	-	Yes	Yes	Yes	CDSCO
3	Health Cubed	Acoustic sensor	Open	Wi-Fi and Wired	Yes- ML backed AI	95%	5 hours	13,257	-	Yes	Yes	Yes	CDSCO
4	Medongo	Acoustic sensor	Internal	Wi-Fi and Wired	Yes- ML backed AI	95%	12 hours	13,260	-	Yes	Yes	Yes	CDSCO
5	Chesto	Acoustic sensor	Open	Wi-Fi, Bluetooth	Yes- ML backed AI	92%	12 hours	11,000	-	Yes	Yes	Yes	CDSCO
6	Littman 3M	Acoustic sensor	Internal	Bluetooth	Yes, ML backed AI	99%	12 hours	29,000	-	No	No	Yes	FDA CE CDSCO
7	HD FonoDoc	Acoustic sensor	Internal	Bluetooth	No	89%	2 Hours	21,252	-	Yes	No	Yes	CDSCO

Chesto Digital Stethoscope is shortlisted on the part of its lowest price among the shortlisted IoMT products as well as most innovative design.

Table 5- HTA: Digital Weighing Scale (Adult)

#	Product	Digital Weighing Scale (Adult)											
		Technology						Economic			Organisational		Social
		Technology used	API Integration	Connectivity	Result Interpretation	Sensitivity	Battery life	Cost per device	Cost per test	AMC	Training	Portability	Clinical Validity
1	Dr. Trust	Pressure sensors	**Internal**	Bluetooth	No	99%	360 Days	1,299	-	No	No	Yes	FDA CE CDSCO
2	Mi	Pressure sensors	**Internal**	Bluetooth	No	99%	360 Days	1,999	-	No	No	Yes	FDA CE CDSCO
3	Real me	Pressure sensors	**Internal**	Bluetooth	No	99%	360 Days	1,999	-	No	No	Yes	FDA CE CDSCO
4	Actofit	Pressure sensors	Open	Bluetooth	No	99%	360 Days	5,400	-	No	No	Yes	CDSCO
6	Omron	Pressure sensors	**Internal**	Bluetooth	No	99%	360 Days	9,999	-	No	No	Yes	FDA CE CDSCO
7	Fitbit Aria	Pressure sensors	**Internal**	Bluetooth	Yes, ML backed AI	99%	360 Days	11,094	-	No	No	Yes	FDA CE CDSCO
8	Health cubed	Pressure sensors	Open	Bluetooth	Yes, ML backed AI	99%	360 Days	1,134	-	Yes	No	Yes	CDSCO

Health cubed digital weighing scale is shortlisted on the part of its lowest price among the shortlisted IoMT products.

Table 6- HTA: Digital Weighing Scale (Baby)

#		Digital Weighing Scale (Baby)											
	Product	Technology						Economic			Organisational		Social
		Technology used	API Integration	Connectivity	Result Interpretation	Sensitivity	Battery life	Cost per device	Cost per test	AMC	Training	Portability	Clinical Validity
1	Helyxon	Pressure sensors with growth monitoring module	Open	Wi-Fi	Yes, ML backed AI	99%	Wired	4,500	-	Yes	Yes	No	CDSCO
2	Omron Karada	Pressure sensors with growth monitoring module	Internal	Bluetooth	Yes, ML backed AI	99%	365 days	9,499	-	No	No	Yes	FDA CE CDSCO

Helyxon digital weighing scale for babies is shortlisted on the part of its lowest price among the shortlisted IoMT products.

Table 7: HTA: Digital Thermometer

#		Digital thermometer											
	Product	**Technology**						**Economic**			**Organisational**		**Social**
		Technology used	**API Integration**	**Connectivity**	**Result Interpretation**	**Sensitivity**	**Battery life**	**Cost per device**	**Cost per test**	**AMC**	**Training**	**Portability**	**Clinical Validity**
1	Health Cubed I.R. Thermometer FR400 Bluetooth	Infrared sensors	Open	Bluetooth	Yes, ML backed AI	99%	6 Months	1,135	-	Yes	Yes	Yes	CDSCO
2	Helyxon	Touch sensitive probe	Open	Bluetooth	Yes, ML backed AI	99%	6 Months	2,499	-	Yes	Yes	Yes	CDSCO
3	Writzo	Infrared sensors	Open	Bluetooth	Yes, ML backed AI	99%	6 Months	1,355	-	Yes	Yes	Yes	CDSCO

Health Cubed I.R. Thermometer FR400 Bluetooth is shortlisted on the part of it's lowest price. None of the products are rejected as all the shortlisted products have open API integration.

Table 8- HTA: Digital Haemoglobinometer

#		Digital Haemoglobinometer											
	Product	**Technology**						**Economic**			**Organisational**		**Social**
		Technology used	**API Integration**	**Connectivity**	**Result Interpretation**	**Sensitivity**	**Battery life**	**Cost per device**	**Cost per test**	**AMC**	**Training**	**Portability**	**Clinical Validity**
1	Eze check	Near-infrared Spectroscopy-Occlusion spectroscopy	Open	Bluetooth	Yes, ML backed AI	94%	8 hours	1,47,000	7	Yes	Yes	Yes	CDSCO ISO
2	HaemoCue	Narrow spectrum Photometry	Open	Bluetooth	Yes, ML backed AI	97%	12 hours	27,000	23	Yes	Yes	Yes	CDSCO FDA CE
3	Writzo	Broad spectrum photometry	Open	Bluetooth	Yes, ML backed AI	97%	12 hours	24,150	16	Yes	Yes	Yes	CDSCO
4	E-Medtel	Narrow spectrum Photometry	Open	Bluetooth	Yes, ML backed AI	97%	12 hours	27,500	22	Yes	Yes	Yes	CDSCO FDA CE
5	Medongo	Broad spectrum photometry	**Internal**	Bluetooth	Yes, ML backed AI	97%	12 hours	24,220	17	Yes	Yes	Yes	CDSCO
6	Health Cubed	Broad spectrum photometry	Open	Bluetooth	Yes, ML backed AI	97%	5 hours	24,150	17	Yes	Yes	Yes	CDSCO CE FDA

Eze check Haemoglobinometer is shortlisted on the part of its non-invasive nature of test and very low cost of test with instant results. Eze check is already engaged with government of Odisha, for mass anaemia screening, with more incoming data their Sensitivity of results will improve.

Table 9- HTA: Digital Glucometer

#	Product	Digital Glucometer											
		Technology						Economic			Organisational		Social
		Technology used	API Integration	Connectivity	Result Interpretation	Sensitivity	Battery life	Cost per device	Cost per test	AMC	Training	Portability	Clinical Validity
1	Roche-Sugar View	Photo-Spectrometre method	Open	Bluetooth	Yes, ML backed AI	95%	-	10	6	Yes	Yes	Yes	CDSCO FDA CE
2	Medongo	Amperometry method	**Internal**	Bluetooth	Yes, ML backed AI	97%	12 hours	22,109	22	Yes	Yes	Yes	CDSCO
3	Writzo	Amperometry method	Open	Bluetooth	Yes, ML backed AI	97%	4 hours	21,794	24	Yes	Yes	Yes	ISO
4	Cooye	Amperometry method	Open	Bluetooth	Yes, ML backed AI	97%	12 hours	1600	32	No	No	Yes	CDSCO
5	E-medtel	Amperometry method	Open	Bluetooth	Yes, ML backed AI	97%	4 hours	21,850	26	Yes	Yes	Yes	ISO
6	Health Cubed	Amperometry method	Open	Bluetooth	Yes, ML backed AI	97%	5 hours	21,850	7.3	Yes	Yes	Yes	CDSCO FDA
7	Eze check	NIR spectroscopy	Open	Bluetooth	Yes, ML backed AI	90%	8 hours	1,47,000	14	Yes	Yes	Yes	CDSCO ISO

Roche Sugar view is shortlisted on the part of very low device cost as well as per teat cost, colour cards can be used multiple times.

Table 10- HTA: Digital Ophthalmoscope

#		Digital Ophthalmoscope											
	Product	**Technology**						**Economic**			**Organisational**		**Social**
		Technology used	**API Integration**	**Connectivity**	**Result Interpretation**	**Sensitivity**	**Battery life**	**Cost per device**	**Cost per test**	**AMC**	**Training**	**Portability**	**Clinical Validity**
1	Bubitech	Binocular ophthalmoscopy	Open	Wi-Fi	Yes, ML based AI	95%	12 hours	**1,20,000**	-	Yes	Yes	Yes	FDA CDSCO CE
2	Allyn iExaminer	Binocular ophthalmoscopy	**Internal**	Wi-Fi	No	92%	-	7,099	-	No	Yes	Yes	CDSCO FDA
3	Logy.AI	Digital Image scanning	Open	Wi-Fi, Bluetooth, NFC	Yes, ML based AI	94%	-	-	1	Yes	Yes	Yes	CDCSO

Logy.AI is shortlisted on the part of very low cost of testing, Logy.AI is a Software based medical device, with incoming data it's Sensitivity will improve.

Table 11- HTA: Pulse-Oximeter

#	Product	Pulse-Oximeter											
		Technology						Economic			Organisational		Social
		Technology used	API Integration	Connectivity	Result Interpretation	Sensitivity	Battery life	Cost per device	Cost per test	AMC	Training	Portability	Clinical Validity
1	Writzo	SpO2 Probe	Open	Wi-Fi and Wired	Yes- ML backed AI	95%	4 hours	950	-	Yes	Yes	Yes	CDSCO
2	E-med Tel	SpO2 Probe	Open	Wi-Fi and Wired	Yes- ML backed AI	95%	4 hours	999	-	Yes	Yes	Yes	CDSCO
3	Health Cubed	SpO2 Probe	Open	Wi-Fi and Wired	Yes- ML backed AI	95%	5 hours	928	-	Yes	Yes	Yes	CDSCO FDA CE
4	Medongo	SpO2 Probe	Internal	Wi-Fi and Wired	Yes- ML backed AI	95%	12 hours	1200	-	Yes	Yes	Yes	CDSCO
5	Helyxon	SpO2 Probe	Open	Bluetooth	Yes- ML backed AI	95%	Wired	2499	-	Yes	Yea	No	CDSCO
6	Nelcor	SpO2 Probe	Open	Wi-fi- Wired	Yes- ML backed AI	95%	Wired	74,000	-	Yes	Yes	No	CDSCO FDA CE

Health cubed Pulse-Oximeter is shortlisted on the part of it's lowest cost of device.

Table 12- HTA: ESR Analyser

#		ESR Analyser											
	Product	**Technology**						**Economic**			**Organisational**		**Social**
		Technology used	**API Integration**	**Connectivity**	**Result Interpretation**	**Sensitivity**	**Battery life**	**Cost per device**	**Cost per test**	**AMC**	**Training**	**Portability**	**Clinical Validity**
1	Siemens Epoc	Micro ESR	Open	Wi-Fi and Wired	Yes- ML backed AI	95%	4 hours	4,00,000	33	Yes	Yes	No	CDSCO FDA CE
2	Medongo	Micro ESR	**Internal**	Wi-Fi and Wired	Yes- ML backed AI	95%	12 hours	60,000	42	Yes	Yes	No	CDSCO

Siemens Epoc system is shortlisted on the basis of open nature of API, although with product development ESR analysers can be upgraded with open API interface.

Table 13- HTA: 3 Part Haematology Analyser

#		3 Part Haematology Analyser											
	Product	**Technology**						**Economic**			**Organisational**		**Social**
		Technology used	**API Integration**	**Connectivity**	**Result Interpretation**	**Sensitivity**	**Battery life**	**Cost per device**	**Cost per test**	**AMC**	**Training**	**Portability**	**Clinical Validity**
1	Writzo	Auto cell counter	Open	Wi-Fi and Wired	Yes- ML backed AI	95%	4 hours	1,75,000	15	Yes	Yes	No	CDSCO
2	E-med Tel	Auto cell counter	Open	Wi-Fi and Wired	Yes- ML backed AI	95%	4 hours	1,89,000	13	Yes	Yes	No	CDSCO
3	Health Cubed	Auto cell counter	Open	Wi-Fi and Wired	Yes- ML backed AI	95%	5 hours	1,43,000	10	Yes	Yes	No	CDSCO FDA CE
4	Medongo	Auto cell counter	Internal	Wi-Fi and Wired	Yes- ML backed AI	95%	12 hours	2,10,672	12	Yes	Yes	No	CDSCO

Table 14- HTA: Biochemistry Analyser

#		Biochemistry Analyser											
	Product	**Technology**						**Economic**			**Organisational**		**Social**
		Technology used	**API Integration**	**Connectivity**	**Result Interpretation**	**Sensitivity**	**Battery life**	**Cost per device**	**Cost per test**	**AMC**	**Training**	**Portability**	**Clinical Validity**
1	Writzo	Reagent based processing	Open	Wi-Fi and Wired	Yes- ML backed AI	95%	4 hours	1,25,000	15	Yes	Yes	No	CDSCO
2	E-med Tel	Reagent based processing	Open	Wi-Fi and Wired	Yes- ML backed AI	95%	4 hours	1,67,000	13	Yes	Yes	No	CDSCO
3	Health Cubed	Reagent based processing	Open	Wi-Fi and Wired	Yes- ML backed AI	95%	5 hours	1,50,000	10	Yes	Yes	No	CDSCO FDA CE

Health Cubed Biochemistry analysers are shortlisted on part of lowest per test cost.

7.4 IoMT device virtual framework for the health and wellness centres

Table 15- Price comparison of Government infrastructure & IoMT integrated infrastructure

Before Implementation			**After Implementation**		
Government			**Shortlisted IoMT**		
Medical Devices	**Price of equipment**	**Price / Test (INR)**	**IoMT product name**	**Price of equipment**	**Price / Test (INR)**
Sphygmomanometer Digital/ Analogous	1500	-	Health Cubed Sphygmomanometer	4527	-
Single Head Clinical Stethoscope	1600	-	Chesto Digital Stethoscope	11000	-
Analogous/ Digital Weighing Scale	500	-	Health Cubed Digital Weighing Scale	1134	-
Analogous/ Digital Baby Weighing Scale	1200	-	Helyxon Digital Baby Weighing Scale	4500	-
Digital thermometer/ Infrared laser thermometer	165	-	Health Cubed I.R. Thermometer FR400 Bluetooth	1,135	-
Haemoglobinometer	500	10	Eze check	147000	6
Digital Glucometer	1400	13	Roche- Sugar view	10	6
Direct Ophthalmoscope	2500	15	Logy. AI	-	1
Digital Pulse Oximeter	10000	0.03	Health Cubed Pulse Oximeter	928	-
Automated ESR Analyzer	30500	30	Siemens Epoc	400000	33
Automatic 3 Part Haematology analyser	156000	12	Health Cubed Haematology analyser	1,43,000	10
Automatic Biochemistry analyser	44200	12	Health Cubed Biochemistry analyser	1,50,000	10
Total price of equipment	**250065**			**863234**	
Total price of test if all the tests are done as per minimum IPHS standard (67800 test/ year) (Except ophthalmology) (Table 24)		**5222634**			**4407000**
Total price ophthalmologic test if all the tests are done as per minimum IPHS standard (2080 test/ year) (Table 24)		**31200**			**2080**
Net cost of diagnostic test		**5253834**			**4409080**

With the integration of 12 IoMT devices the network of IoMT integration is feasible with 2.45 times higher one-time installation cost, while after installation this device network will reduce the cost of diagnostics by 16 percent. It will take 15.4 years to break-even the cost of installation if the HWCs will run at minimum performing standards. With more research and development and hand holding sessions with the companies who have internal APIs, cost of testing and technology deployment can further be reduced.

The integration of IoMT devices at the health and wellness centres was found feasible.

8. Discussion

8.1 IoMT and Minimalism

IoMT devices are blend of medical devices with Internet of Things (IoT) devices, So, IoMT is the collection of medical devices and applications that connect to healthcare IT systems through online computer networks. Machine to Machine communication and close integration with medical sensors formulates the foundation of IoMT devices. Minimalism refers to a design idea of 'less' is 'more', the origin of minimalism in technology can be traced back to 1980s when technologies were novel & complex, back than people started working on ease of use and learning. This theory started to evolve by observing the end-user, utilizing the tech, concept of minimalism becomes physical size reduction with addition of multiple functions in a single technology. Now, minimalism refers to iteration of design to the simplest extent, minimally required hardware, customizable as per need of end-user and with futuristic outlook. So, Minimalist IoMT devices have simpler design then existing products, they offer multiple functions and are customizable as per need. (14-21)

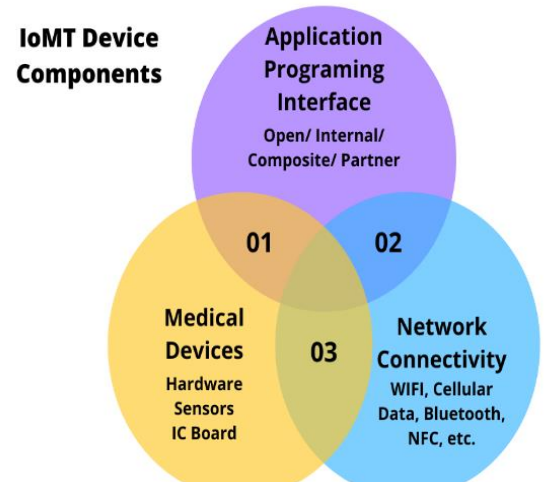

Figure 1- Components of IoMT

Since the launch of Start-up India initiative, India has witnessed tremendous growth in health-tech industry, it is growing with compound annual growth of thirty-nine percent, it will reach fifty billion US dollars by 2023. IoMT devices other than wearables have seen expedited growth since 2020, due to onset of Covid-19 pandemic, which led to fast paced growth of remote monitoring devices and teleconsultation services. The

growth of this market is further expedited by launch of National Digital Health Mission. (35,36)

Integration of IoMT devices in public healthcare infrastructure digitally transform and modernize the existing infrastructure. In line of Ayushman Bharat Digital Mission, IoMT integration will be crucial step, it will enable government to capture health data from the point of care. Health system will become more responsive and automated. (35)

8.2 Market dynamics of IoMT industry in India

To understand any market, it is extremely essential to understand the influence of external factors on the market, PESTLE analysis facilitate understanding of broader business environment and also helps in strategic thinking. (36)

Significance of political factors- Politics lays deep impact on the prolong sustainability, growth, and profitability of IoMT industry. The political environment comprises multiple factors- India is led by same political party since 2014, policies are focused on inclusion of private sector in national economy as well public-private partnerships in developing and implementing policies. Launch of policies like Start-up India initiative, Digital India, UPI, make in India laid the development of indigenous start-ups. In health-tech sector this is fuelled by launch of National Digital Health Mission. (37)

The setbacks for healthcare field are most of the policies in India are reactive in nature instead of responsive & Indian bureaucracy and project implementing agents lacks technical expertise. Sudden onset of Covid-19 pandemic unmasked the gaps in policies and gave a right reason to formulate responsive policies. (38)

Significance of economic factors- India is in growth segment of lifecycle, there is very high competition from developed nations like China. The generalize growth of economy as well as health-tech sector in India are encouraging factors for industry development and growth. Government of India attracted private investments towards the National digital health mission, and it laid a strong foundation for the growth of Industry. Further Government is providing economic support to start-ups with disruptive and scalable ideas via various grants and fellowships schemes. (39)

The setback in economic factors is high cost of research and development and high market price of IoMT devices. This is further enhanced by high inflation rate of India.

Significance of social factors- The health-tech industry is highly concentrated in Tier I and Tier II cities instead Tier III, Tier IV and marginal communities. Concentration and reach highly depends on the literacy rate and network coverage of any area. Development of online communities and social entrepreneurs have changed perception towards entrepreneurs, this turned everyone into design thinker. Perceived fear and susceptibility towards healthcare condition acted as an enabling sentiment towards IoMT market growth. (40)

The setback in social factors is inequitable distribution of literacy as well as network coverage within nation and high variety of dialect and regional languages in India.

Significance of technological factors- Increased access of internet as well as introduction of UPI are principal factors towards adoption of digital health, India is at verge of launching 5G technology. Introduction of 5G enabled technology in India initiated back in 2020, with the enhanced internet speed real time monitoring of patient will be possible. (41)

The setback in technology factors is the lack of technical skills in the bureaucrats as well as project implementing agents with Infrastructure in rural areas is not as technologically enabled as urban areas.

Significance of environmental factors- the environment is favourable for the growth of health-tech industry as a whole, including IoMT device markets. Post- covid-19 pandemic, perception towards continues monitoring as well as remote monitoring changed in a positive fashion. National lockdown imposed due to covid-19 pandemic acted as enabling factor, Policies laid by government of India laid foundation for the development of new entrepreneurs. (42)

The setback in the environmental factor is lack of technical skills in the project implementation agents.

Significance of legal factors- As India is in early growth phase of industry lifecycle, the legal framework is liberal while registering as start-up while there is prolong process proving clinical validity from government of India as well as international bodies. India is still in initial phase implementation of personal data security laws. (43)

Setback in the legal factors is lack of understanding of personal data protection bill and lack of access towards international agencies and patent laws for the clinical validity of technology. (9-10)

PESTLE analysis can describe the market dynamics of IoMT devices based on the comments of subject matter experts. As shown in Table 16

8.3 Pestle analysis of IoMT market-

Table 16- PESTEL analysis of IoMT

	P	E	S	T	E	L
	Political	**Economic**	**Social**	**Technology**	**Environment**	**Legal**
Enabler	Politically stable situation since 2014	Fast paced growth of health tech	Development of digital payment methods and low terrif of internet connections up to the grassroots.	Increased access to internet with the growth of cell phone industry.	Raised participation of private sector in Indian economy.	Expedited process of registration of MSMEs and DIIP (Department of Industrial Policy and Promotion)
	Focus of policies towards development of private sector.					
	Launch of Start-up India initiative back in 2016, followed by launch of Make in India program & National digital health mission in 2020.	Policies to grant economic support to newly launched start-ups- Atal Innovation Mission, MSME grants, start-up research grants, and etc.	Increased penetration of technical education in the Tier III and Tier IV cities.	Increased access to venture capitals with growth of technology.	Growth of remote monitoring solutions in response to national lockdown due to covid-19 pandemic.	
			Development of social entrepreneurs			
			Positive perception towards entrepreneurs in society			
Disabler	Responsive nature of policies instead of visionary productive policies.	High cost of technology & capacity development	Increased poverty due to de-monetization followed by onset of covid-19 pandemic.	Inequitable concentration of network coverage and technology.	Geographic and demographic differences across Indian subcontinent.	Exhaustive CDCSO (Central Drugs Standard Control Org.) & FDA approval process
	Lack of capacity building in bureaucracy	High cost of IoMT devices	Cultural diversity: 22 national languages and more than 19,500 regional mother tongues.		Lack of technical skills in the front-line health workers	
	Lack of retention in bureaucracy	Lack of expenditure for CROs				

8.4 Attempts towards minimalism

To understand minimalism in health-technology and evolution of IoMT, Theranos case study is highly crucial, within the duration of ten years from the point of foundation of company till 2014, Theranos became unicorn company, gained market presence all over the globe.

Theranos's Edison machine claimed to conduct more than 200 diagnostic tests from a single drop of blood via fingertip prick, Theranos offered these test in less than half price of diagnostic laboratory empanelled on Medicaid and Medicare. This disruption led to expedited fund raising of over 900 million US dollars and partnering with largest pharmaceutical retail store chain 'Walgreens'. Theranos plans to democratize diagnostic industry by self-prescribed diagnostic test from nearest pharmacy retail store without any doctor's prescription. This idea will save millions of US dollars of US health department. (44,45)

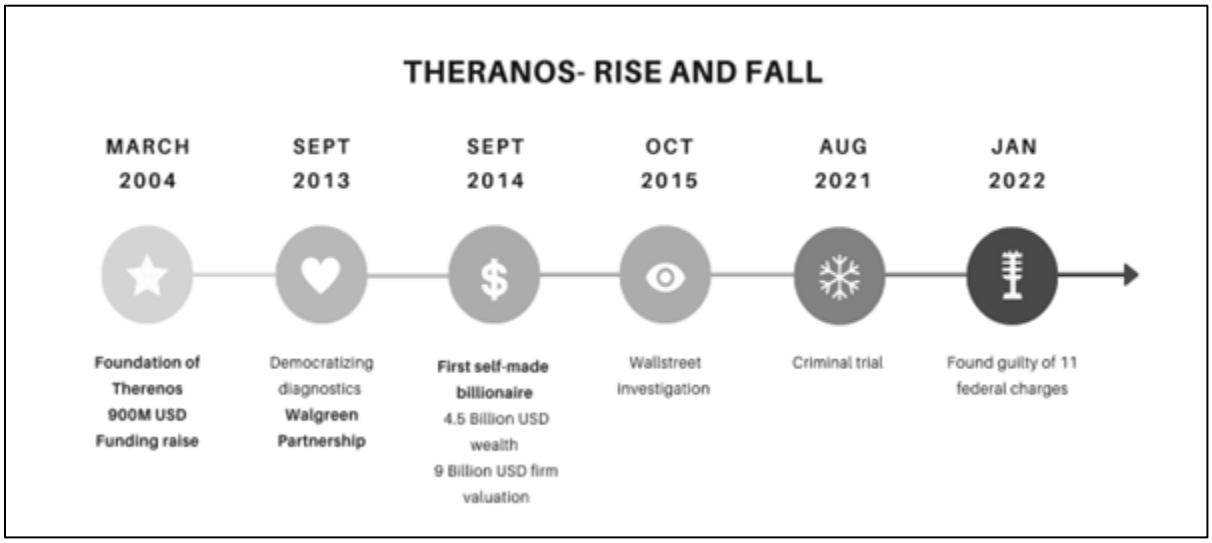

Figure 2 Rise and Fall of Theranos

The decline of Theranos began after the Wall Street investigation in 2015, leading to cancelation of deals with pharmaceutical chain Walgreen and criminal trail in 2021.

8.4.1 Competitive analysis of Theranos-

Abbott's I Stat Blood Analyser, is FDA approved IoMT, POC device that can produce results in less than 2 minutes, it was launched back in 2011, Theranos's disruptive- democratic vision, moved market towards their Edison machine, despite strong clinical foundation of Abbott's I Stat Blood Analyser. (45)

8.4.2 Problems and learnings from Theranos case study

Despite of high marketing and accelerated growth of the firm- Theranos desperately failed. The main causes of failure were associated with the false claims about products without backing of any clinical validation from FDA. Theranos was accused of misleading the investors and malpractice. During external audit their diagnostic test were found to be inaccurate, they were using third party blood analysers instead of their trademark Edison machine. From fingerpick sample they were doing only single diagnostic test and claiming it for all the tests. At last they have not shared any peer-reviewed study with the scientific community, this kept secrecy hinted wall street to initiate investigation. (46)

One of the major reason of their failure was, their inability to onboard subject matter experts from the scientific community, instead of this, they onboarded veteran senior officials from military and politics in their advisory panel and board of directors. (45)

8.5 Policy analysis-

This study explores the policies of government of India, revolving around health-tech industry and digital health- that can impact the market of IoMT devices, their utilization and their integration within public healthcare system of India.

System's framework of policy analysis is being utilised for analysis of concerned policies. System's framework is given by David Easton- this model gives emphasis on Inputs, Process and Outputs. Inputs are *demands and desires* of the population of any region/ nation & support is what population requires on the base of their feedback on the policies.

Process starts from situation analysis, brainstorming on solutions, policy formulation and ends on policy implementation; Process involves coordination of different ministries and departments, political will and work of bureaucracy and implementing agents. After the process decision on policy is being taken and in output, we get expected results out of the interventions and in outcome we get positive and negative feedbacks of beneficiaries. (30,31,32)

In the case of healthcare industry- Morbidity and Disease prevention is the input, while process is policies implemented on ground and at last output is better health outcomes of general population. (47)

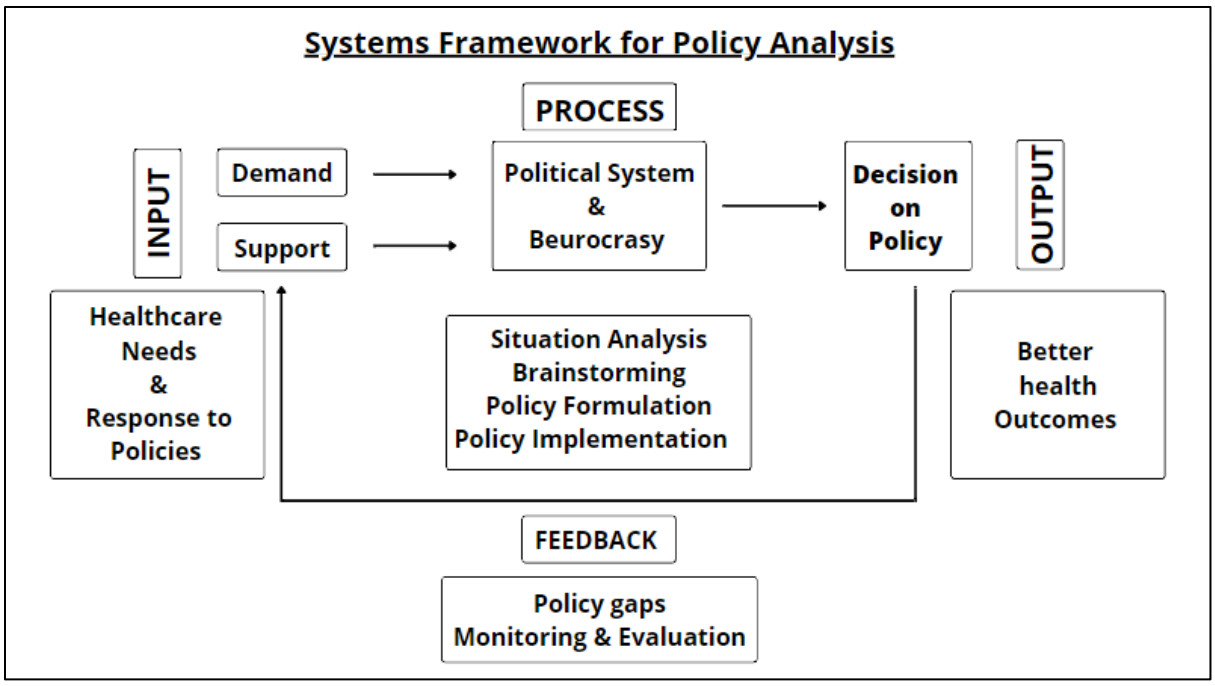

Figure 3 Systems framework of public policy in the field of healthcare

Systems framework of policy analysis is used to analyse different policies by Government of India revolving around digital health, digital transformation and scope of IoMT device integration. Data collected from structured interviews of senior officials and subject matter experts was inculcated to define the feedback and responses of concerned policy. (30,31,32)

Ayushman Bharat Digital Mission, E-Sanjeevani, Different data entry applications for ASHA and ANM workers across the nation, are analysed via systems framework of policy analysis-

8.5.1 Ayushman Bharat Digital Mission (ABDM)

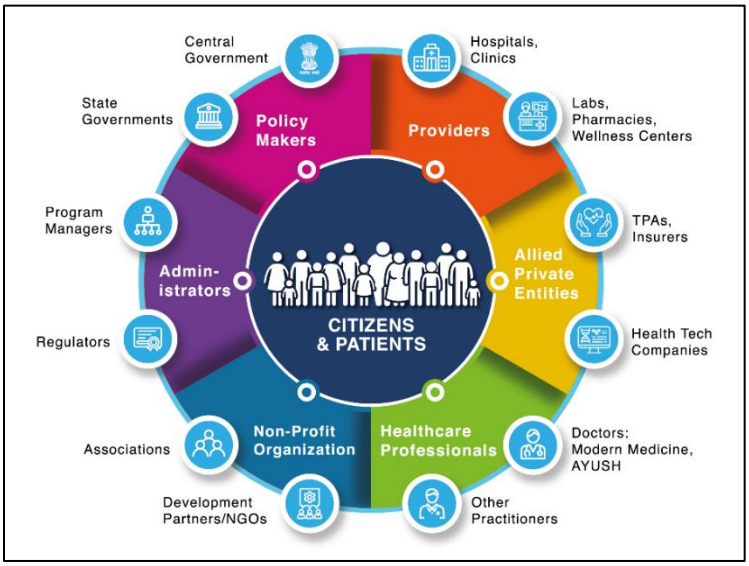

Figure 4- ABDM Framework

Ayushman Bharat Digital Mission was launched on 15th August 2020, as a pilot in six union territories and following successful pilot ABDM was launched nationally in September 2021. ABDM aims to create Universal Healthcare Interface and generate Ayushman Bharat Health Account for all the Indians, this won't be possible without integration with existing

government policies and private players. To facilitate this NHA has launched the ABDM sandbox to test technology and products on ABDM. (48,49,50)

To pave the pathway towards ABDM, National Health policy 2017, lays founding stone followed by lunch of National Health Stack 2017 and National Digital Health Blueprint 2019.

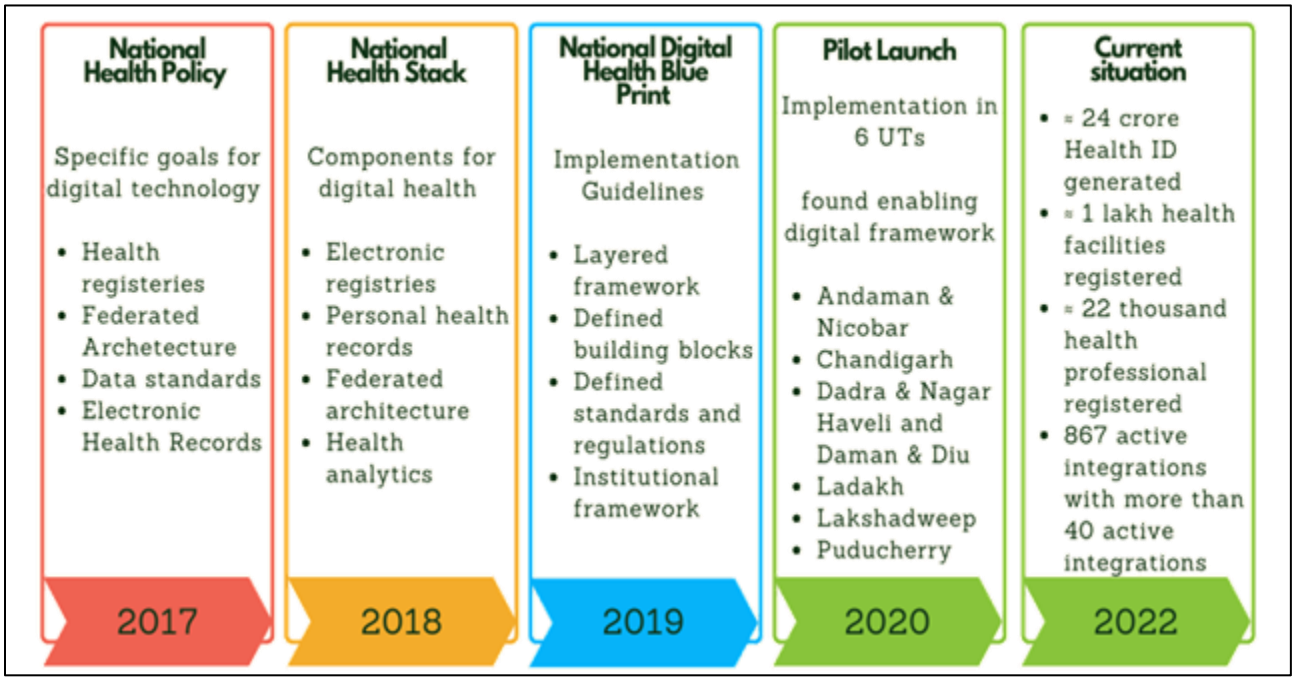

Figure 5- ABDM Timeline & Achievements

Table 17- System's Framework for Policy Analysis: ABDM

Input	**Increased digital access** • *Increasing its digital access* through internet connectivity to more than 95 percent of villages, more than 60 percent population consumes the internet daily and the average data consumption per month is 14 GB. The success of digital health services like e-Sanjeevani, Cowin, and Arogya Setu with a combined download of more than 60 crore. Digital services like Aadhar, eKYC, UPI transactions, and Digilocker further facilitated the implementation of ABDM. **Infrastructure deficit and reach of healthcare** • India is the second-most populous country, India's doctor-population ratio is 1:834, assuming 80 percent availability of registered allopathic doctors and 565,000 Ayurvedic, Unani, Siddha, and homeopathic doctors. There are 1,301,319 allopathic doctors, 289,000 dentists and 565,000 Ayush doctors. These 13 lakh allopathic doctors cater to the 1.3 billion population of India. Out of these 13 lakh doctors, only 3.71 lakh doctors have any medical specialty. (51,52) • Despite surpassing the WHO standard of 1 doctor on 1000 individuals, the healthcare facilities are highly concentrated in urban areas as compared to rural. India witness 5.2 million medical errors per annum, this accounts for a lack of continuous care mechanism, under the supervision of a specialist doctor. (53) • Indian healthcare infrastructure is highly dominated by private care providers, Out-of-pocket private payments make up 75% of the total expenditure on healthcare.

	Only one-fifth of healthcare is financed publicly. An average Indian's out-of-pocket (OOP) health expenses are ₹2,494, which is twice the government spending of ₹1,261. The insurance coverage in India is around 40%, which makes the situation more serious. (54) **Flow of Information in government system** • Healthcare is a highly dynamic field; we can't predict what will happen next. Health is a matter of state government, As said by lead in National Health Authority (NHA)- it takes a minimum of 1.5 months to capture healthcare data of any sub-centre and report is . The Healthcare system cannot be responsive, unless until policies are planned and implemented as per the real-time ground-level situation. (55) • The government of India had launched multiple policies for public welfare, the average individual doesn't know where to consult/ whom to consult- there is a lack of a unified interface that can track all the previous treatments undertaken by the patient. • Digital technology offers a solution to create universal health interface, store and process data, and bring out public-private partnerships for better health outcomes. (1) • Covid-19 pandemic flared the need of digital transformation in the nation. (2)
Process	• Technology integration- within digital interface of ABDM- to create unified healthcare interface • Creation of national healthcare registry • Creation of ABHA
Output	• 24 crore ABHA generated • 22 thousand health care professionals registered • 867 undergoing integration over ABDM's sandbox • 40 functional integrations- 16 government applications and 24 private sector applications
Feedback	As per lead at NHA • Lack of technical skills in front-line healthcare workers to operate applications • The majority of Private digital healthcare services have internal API • Intellectual property right concerns • Validation of healthcare professionals- lack of healthcare practitioners registered on the platform • Interoperability issues between different service providers
Response	• **NHA-ABDM-UHI- Git Hub Community-** Contribute to the creation of a universal health interface on github.com (56) • **ABDM Sandbox-** Sandbox is a framework that allows technologies or products to be tested in the contained environment in compliance with ABDM standards. (57,58) • **ABDM open database-** To promote academic as well as policy research, population data will be live updated on this platform. (58)

According to leader of ASHA union, CEO of renowned private community outreach and training agency of India, majority of frontline healthcare workers lacks technical skills to operate point of care devices and handle smart phones, poor network connectivity is very common in remote areas with extensive power cuts. Different ASHA unions are protesting for timely delivery of incentives and face corruption at different levels of government.

While majority of health-tech companies uses internal API to protect intellectual property rights.

The statistics shows that only 22 thousand doctors have registered themselves on National healthcare registry out of massive total of 13 thousand doctors, this is 1.6 percent of total allopathic doctors of India. (59)

According to lead at NHA Headquarters and NHA Haryana, there are interoperability issues between different service providers registered over sandbox. The main reasons being incompetent APIs, service delivery mechanism and conflict of interest among different service providers.

8.5.2 E-Sanjeevani

As part of space technology for social welfare ISRO launched first telemedicine services of the country via satellite signals. E-Sanjeevani is advanced version of program launched by ISRO.

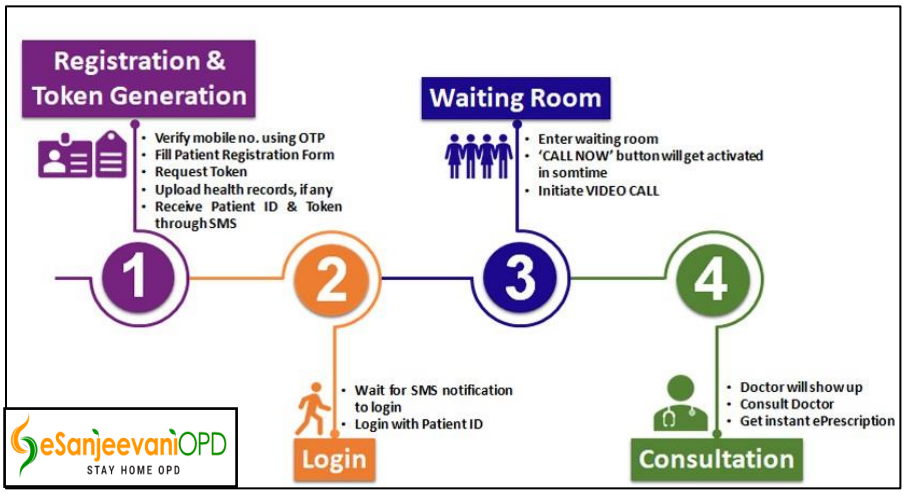

Figure 6- Process of e-Sanjeevani

E- Sanjeevani is flagship teleconsultation service launched by Ministry of Health and Family Welfare (MoHFW) & Ministry of Electronics and Information Technology (MeitY) in November 2019 to tackle with increasing cases of Covid-19 global pandemic. Till now E-Sanjeevani catered its services to more than 3 crore teleconsultations, 333014 hours 17 minutes worth of teleconsultation hours, with average waiting time of ≈8 minutes and 2.5 minutes average consultation time for each case. (60)

E-Sanjeevani is free of cost service offered to all the individuals of nation, it also offers speciality consultations and days of availability of specialist doctors varies over the Indian states.

Table 18- System's Framework for Policy Analysis: e- Sanjeevani

<table>
<tr><td>Input</td><td colspan="2">Infrastructure deficit and reach of healthcare
• India is the second-most populous country, India's doctor-population ratio is 1:834, assuming 80 percent availability of registered allopathic doctors and 565,000 Ayurvedic, Unani, Siddha, and homeopathic doctors. There are 1,301,319 allopathic doctors, 289,000 dentists and 565,000 Ayush doctors. These 13 lakh allopathic doctors cater to the 1.3 billion population of India. Out of these 13 lakh doctors, only 3.71 lakh doctors have any medical specialty.
• Despite surpassing the WHO standard of 1 doctor on 1000 individuals, the healthcare facilities are highly concentrated in urban areas as compared to rural. (51-53)
• India witness 5.2 million medical errors per annum, this accounts for a lack of continuous care mechanism, under the supervision of a specialist doctor. (61)

National lockdown due to covid-19 pandemic
• Global pandemic house arrested the entire globe, this significantly flared the utilization of medical services via use of teleconsultation portal.

Increased client engagement via digital consultation applications
• According to CEO of large teleconsultation platform service- Doctors like being showcased on digital platform, majority of such services works on aggregator business model. (1)</td></tr>
<tr><td>Process</td><td>For Teleconsultation
• Register with your mobile number
• Fill registration form
• Upload health records if any
• Receive token ID and token through SMS
• Join call with SMS notification
• Consult doctor
• Instant e- Prescription/ referral</td><td>For doctors
• Empanel government doctors
• Generate roaster with department of health and family welfare
• Share login links
• Tele consult patients/ Follow-up</td></tr>
<tr><td>Output</td><td colspan="2">• More than 3 crore OPDs done till date
• 2291 hubs with 33297 spokes
• 1.10 Lakh patient use this service daily
• Super-speciality services available- ENT, Ophthalmology, Orthopaedics and General medicine
• Collaboration with Old age homes and prisons
• Collaboration with ABDM to generate ABHA and longitudinal health records (60)</td></tr>
<tr><td>Feedback</td><td colspan="2">• As per senior volunteer and subject matter expert at NHA, Senior doctors don't attend their E-Sanjeevani OPD, Junior resident doctors are commonly seen instead of them.
• According to lead at NHA and subject matter experts, need of IoMT Point of care devices at remote healthcare facilities will bridge the gap of specialist access.</td></tr>
<tr><td>Response</td><td colspan="2">IoMT integration at public healthcare facilities
• Different health-tech companies have piloted IoMT integration with different state governments.

Rapid growth of teleconsultation market in India
• 1315 million US dollars in 2021 to reach 6220 million by 2027
• CAGR- 22 percent (62)</td></tr>
</table>

8.5.3 Different applications for ASHA and ANM workers

Figure 7- Distribution of smartphones to ASHA workers- Karnataka Government

Different departments of health and family welfare and women and child development had launched various applications across the nation as an effort to collect health data at the grass root level. In order to facilitate data collection via these applications different state governments have distributed smartphones to ASHA and ANM workers. 159790 ASHA workers and 223762 aanganwadi workers (AWW) received smartphones from different state governments. 865577 smartphones were distributed to ANM workers under the Poshan Tracker scheme of Ministry of women and child development.

Table 19- Infrastructure in different states (63-71)

State	Number of units distributed	Beneficiary
Maharashtra	2070	ASHA
Uttar Pradesh	80000	ASHA
Uttar Pradesh	1,23000	AWW
Telangana	720	ASHA
Karnataka	35000	ASHA
Andhra Pradesh	42000	ASHA
Himachal Pradesh	All, Incentive given 8k	ASHA
Bihar	100762	AWW

According to lead of large community outreach and training agency, state governments are trying to collect healthcare data from the point of care at the remote sub-centres and public health centres, via different applications.

8.5.3.1 Some of the renowned applications by respective state governments

(Public/ Public Private Partnership)

Table 20- Renowned Applications for FLHWs (71-82)

Application Name	Purpose/ Program name	State	Remarks
Asha Soft	Forms- RCH, ANMOL, JSY, etc. Payments, Appraisals	Rajasthan	Best application award
Poshan tracker	Poshan Abhiyan	GoI	Protest against the slow working of application
Asha Pay	Forms- RCH, ANMOL, JSY, etc. Payments, Appraisals	Haryana	Application installation mandatory with new sim card (30GB Monthly data)
MDM 360	Tracking of daily targets and location of ASHA workers	Haryana	Protest against the application due to privacy concerns
Asha disease profile	EHR creation	Telangana	40 tablets distributed, low rating of application, 4G- post-paid connection given to ASHA workers
mSakhi	Digitalise and supervise the work of ASHA	Uttar Pradesh	mHealth interventions require initial and recurring costs, with the mSakhi program costing INR 10,280 and INR 4,680 per ASHA, respectively. Application found user- friendly
Integrated AAA app	Integration of data of MoHFW and WCD to streamline the works of ASHA, ANM and AWW	Rajasthan	Functional in Jhalawar and Sikar district of Rajasthan by Antara Foundation
House to house surveillance	Tracing symptoms of covid, TB, DM, BP and Asthma	Punjab	Department of health, Punjab is paying INR4/ form and additional 5000/ month for this exercise 21500 ASHA workers in Punjab and 15000 don't have smartphones

Table 21- System's Framework for Policy Analysis- Applications for FLHWs

Input	**Flow of Information in government system** • Healthcare is a highly dynamic field; we can't predict what will happen next. Health is a matter of state government, As said by lead in National Health Authority (NHA)- it takes a minimum of 1.5 months to capture healthcare data of any sub-centre and report is . The Healthcare system cannot be responsive, unless until policies are planned and implemented as per the real-time ground-level situation. • The government of India had launched multiple policies for public welfare, the average individual doesn't know where to consult/ whom to consult- there is a lack of a unified interface that can track all the previous treatments undertaken by the patient. (51-53) • Digital technology offers a solution to create universal health interface, store and process data, and bring out public-private partnerships for better health outcomes. • Covid-19 pandemic flared the need of digital transformation in the nation. (63) **National lockdown due to covid-19 pandemic** • Global pandemic house arrested the nation, for the purpose of door-to-door surveillance, delivery of essential medicines and commodities ASHA workers lead the government's ante- covid drive at grass roots. To facilitate the entire process ASHA workers used different mobile applications. (83,84)
Process	• Planning of application • Preparation of questionnaire • Digital technology offers a solution to create universal health interface, store and process data, and bring out public-private partnerships for better health outcomes. • Covid-19 pandemic flared the need of digital transformation in the nation.
Output	• Streamlined health monitoring at the grass root level • Scrutiny of incentivization
Feedback	*As per the ASHA union leader* • Lack of technical skills to handle smartphones • Poor network coverage- ASHAs have to go to nearest cities to upload the data In few applications on .jpeg file take half hour to upload • Distributed smartphones were of sub-standard quality and protective cases were not distributed along with smartphone • Applications are of very large size- frequent application crash • ASHA workers changes sim cards very frequently, so it is difficult to manage their accounts
Response	***As per CEO of community outreach and training organization- Training sessions are designed in a way to address all the operational issues*** • Hands on training on application • Training invitation sent via Chief district medical officer's office • Transport and lunch facility for ASHA workers or travelling allowance and dearness allowance to be distributed • At least two days training sessions must ***As per lead at community outreach and research organisation*** • Application's user interface is simplified and in local language • Open API to integrate with other services • Local data storage to surpass poor network connectivity

8.5.4 Challenges in above policies-

As per system's framework of public policy analysis challenges in deployment of IoMT in public health spaces are social, organisational, technical and economic-

Social challenges in the implementation of project- Training of frontline health workers to operate IoMT devices at the HWCs and during community outreach activities. Gaps in Internet connectivity in the remote areas. Organisational challenges in the implementation of project- Ensuring continuum of care via maintaining supply chain of consumables at the HWCs, dissatisfaction with the voluntary nature of work in ASHA workers leads to frequent instances of strikes. Nascent condition of personal data protection bill makes the ownership of sensitive healthcare information sceptical. Technical challenges in implementation of project- lack of companies with open APIs and gaps in acceptance of newly deployed technology. Economic challenges like high cost of technology deployment.

8.6 Technology utilization at HWC-PHC

Primary healthcare centres (PHC) are the first point of contact between doctor and community, under Pradhan Mantri Ayushman Bharat Jan Arogya Yojna (PMJAY), existing PHCs are developed as Health and wellness centres (HWC). HWCs are upgraded version of PHCs with emphasis on health and wellness, by promoting AYUSH system of medicine and additional common area for yoga and exercises. According to the Indian public health standards guidelines for PHC-HWC 2021, health and wellness centres provide following services which require any type of diagnostic technology- (21)

Table 22- Services and Infrastructure at PHC- HWC

Service	Nature of service	Diagnostic device
Emergency	Essential	• Sphygmomanometer • Stethoscope
Outdoor Patient Department *ANC, NCD screening, Diagnosis and follow up & referral*	Essential	• Sphygmomanometer • Weighing Scale • Infantometer • Baby Weighing Scale • Stethoscope • Thermometer • Haemoglobinometer • Glucometer
Ophthalmology *Diagnosis of cataract, glaucoma and refractive errors*	Desirable	• Ophthalmoscope- Direct & Indirect • Snellen Chart
Indoor Patient Department	Essential	• Weighing Scale • Pulse Oximeter
Diagnostics		
CBC- Hb, TLC, DLC, Platelet count, ESR, Blood Group	Essential	• 3 Part Haematology analyser • ESR Analyser • Hemoglobinometer
Lipid Profile, S. VLDL, S.HDL, S. LDL, S. Uric acid, Glycosylated haemoglobin (HbA1C), Serum Calcium		• Biochemistry analyser
Peripheral Smear- Malaria P. Falciparum and P. vivax	Essential	• Rapid Card Test- (Falciparum and Vivax)
Screening test for G6PD enzyme deficiency	Essential	• Glucometer
Human chorionic gonadotropin (HCG) (Urine test for pregnancy)	Essential	• Rapid Card Test- Urine Pregnancy test
Stool culture Throat Swab for Diphtheria Stool for hanging drop for Vibrio Cholera	Essential	• Microscopy

The HWCs are equipped with conventional devices, this study explores the integration of IoMT devices in place of above devices.

On screening of different e-commerce websites, Enira consulting and NHA data base following products were found and out of those IoMT products are shortlisted for further health-technology assessment, during this screening personal care IoMT are excluded and point of care devices are included, who possess clinical validity from any validatory authority in the field of healthcare.

Table 23- Market Study of IoMT

Medical Devices	**Number of Personal care companies**	**Number of Point of care companies**	**Number of IoMT device companies**
Sphygmomanometer Digital/ Analogous	-	38	7
Single Head Clinical Stethoscope	-	201	7
Analogous/ Digital Weighing Scale	909	-	8
Analogous/ Digital Baby Weighing Scale	-	69	2
Digital thermometer/ Infrared laser thermometer	76	-	3
Haemoglobinometer	83	33	5
Digital Glucometer	2	51	5
Binocular Ophthalmoscope	-	9	1
Digital Pulse Oximeter	-	337	4
Automated ESR Analyzer	-	596	4
Automatic 3 Part Haematology analyser	-	326	4
Automatic Biochemistry analyser	-	204	4

8.7 Health technology assessment (HTA)

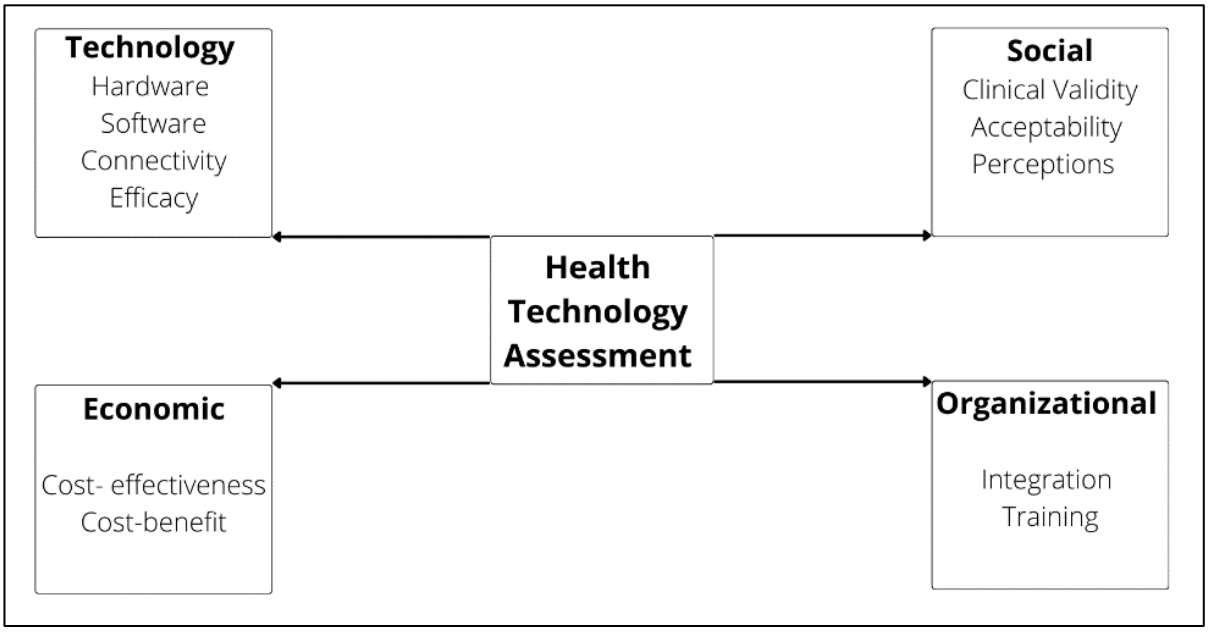

Figure 8- Health technology assessment framework in light of IoMT devices

HTA model is systematic approach to evaluate healthcare technology from the perspective of technical, economic, social, and organizational factors. This model is utilized for the purpose of informing policy makers about feasibility of concerning technology. (26,27,28)

In this study, healthcare technologies are screened with the lens of HTA, combined with experts opinion and existing ongoing projects and success of technology in healthcare is determined, to analyze the technical, economic, social and organizational feasibility of health-tech products. From technology point of view this study explores the technical feasibility via determining the type of technology used, type of API integration, connectivity of device, type of result interpretation- if it is automated that is backed by ML backed AI or it is connected tele-consultation, Sensitivity of device and battery life. Economic assessment explores the cost of deployment of technology- that is cost of device and cost per test and annual maintenance contract. For social assessment, it is well established with of policies and emerging healthcare needs that perception towards IoMT has changed and for ethics, clinical validity is crucial. Organizational assessment traces the diffusion of concerned technology within the organization- to trace this capacity building of end user is crucial. The most technically, economically, socially and easily diffusible products are marked green while not feasible products are marked red while rest of the products that can be considered are colored yellow. Reason of being not feasible is in bold font. (26,27,28)

Shortlisted IoMT companies are requested to quote their per test prices as per minimum performing standards for health and wellness centers. (Table 23, Table 3-24)

5.8 Calculation of number of patients per year-

Table 24- Minimum standards at PHC-HWC (23)

Number of diagnostic test done/ day (in case of auto-analyser)	200 test
Number of patients to ophthalmologist & optometrist/ day	40 patients
Ophthalmologist consultation days in year	52 days
Number of functional days in week	6.5 days
Number of functional days in year	339 days
Number of diagnostic test done/ year (in case of auto-analyser)	**67,800 test**
Number of patients to ophthalmologist & optometrist	**2080 patients**

5.9 Government rates for the following diagnostic test- (22,23)

Table 25- Price of equipment (government) & Price per test

Medical Devices	**Price of equipment**	**Price / Test (INR)**
Sphygmomanometer Digital/ Analogous	1500	-
Single Head Clinical Stethoscope	1600	-
Analogous/ Digital Weighing Scale	500	-
Analogous/ Digital Baby Weighing Scale	1200	-
Digital thermometer/ Infrared laser thermometer	165	-
Haemoglobinometer	500	10
Digital Glucometer	1400	13
Direct Ophthalmoscope	2500	15
Digital Pulse Oximeter	10000	0.03
Automated ESR Analyzer	30500	30
Automatic 3 Part Haematology analyser	156000	12
Automatic Biochemistry analyser	44200	12

IoMT companies quoted prices as per the patient load mentioned in table-10, depending on the nature of API integration, price of IoMT device, Sensitivity, connectivity, results interpretation availability, Sensitivity of IoMT, battery life, presence of annual maintenance contract (AMC), Training module availability, portability, and clinical validity- most feasible IoMT is shortlisted. The following details can be found in table number 3 to table number 14.

In most of the cases, IoMT having most suitable economic feasibility is preferred while devices having internal API are rejected despite of economically feasible nature.

8.8 Characteristics of feasible IoMT for integrated network at HWCs.

With the above Health technology assessment (Table 3-14) it is clear that feasible IoMT's must have **open API integration** instead of internal. Open API integration enables all the IoMT's to easily integrate over a common unified application. According to Senior consultant at NHA, to surpass the complexities of intellectual property rights, companies sign non-disclosure agreement with each other and NHA itself, followed by detailed **hand holding sessions**.

All the CEOs and senior managers have common point of view on the **simple and data savvy light user interface** in native languages to facilitate the frontline healthcare workers even in remote areas with poor network connectivity.

Hands on training module are part of package along with **annual maintenance contract**.

Devices must have **clinical validity** certification by central drugs standard control organisation (CDSCO). Certification with Food and Drug Administration, USA (FDA) and Conformité Européenne from European union (CE) are desirable.

Battery powered devices are desirable, as most of the remote locations deals with frequent power cuts.

India is a developing country, so **technology deployment and maintenance cost** is of prime importance, so these cost must be lower then rest of the competitors in market, in above tables 3-14, it was found that one-time cost technology is high but the cost of each test is significantly reduced.

Details of feasible technologies can be found in table-15.

9. Conclusion-

9.1 Minimalism in IoMT

Digital integration and Minimalism in IoMT devices enable them to form a unified healthcare interface, they have open API integration, they are simple in design, technologies like hemoglobinometers, glucometers, digital applications to detect ophthalmic disorders have shown economic minimalism while digital stethoscope has shown structural minimalism.

The most advance benefit with minimalistic technology is, they can be modulated as per the requirement of the case.

9.2 Economic analysis

Table 26- Economic Analysis

	Pre intervention	**Post intervention**
Cost of infrastructure	**250065**	**863234**
Net cost of diagnostic test as per minimum IPHS 2022 performance guidelines	**5253834**	**4409080**

The one lime cost of IoMT integration at the health and wellness centres will be 2.45 times higher than the conventional setup. The cost incurred on diagnostic test done at HWC-PHC with minimum performance standards, 16 percent reduction in the cost is seen. It will take 15 years and 31 days to break even this additional cost, if the health and wellness centre operates as per minimum performance indicators.

9.3 Cost benefit analysis-

The advantage with IoMT devices is creation of longitudinal health records, within purview of Ayushman Bharat Digital Mission, majority of IoMT devices are portable in nature and mass level community screening is possible with this intervention. This leads to early diagnosis and reduces out of pocket expanses on hospitalization.

10. Challenges

- Social challenges in the implementation of project- Training of frontline health workers to operate IoMT devices at the HWCs and during community outreach activities. Gaps in Internet connectivity in the remote areas.
- Organisational challenges in the implementation of project- Ensuring continuum of care via maintaining supply chain of consumables at the HWCs, dissatisfaction with the voluntary nature of work in ASHA workers leads to frequent instances of strikes. Nascent condition of personal data protection bill makes the ownership of sensitive healthcare information sceptical.
- Technical challenges in implementation of project- lack of companies with open APIs and gaps in acceptance of newly deployed technology.
- Economic challenges like high cost of technology deployment.

11. Future prospects-

Adoption of value-based insurance models, development of doctor-less diagnosis via IoMT network at the HWC level and home delivery of medicines as part of unified healthcare interface.

12. Recommendations-

- To setup national centre of excellence for AI in healthcare- draft regulatory framework for software as medical devices
- Mandatory hands-on training of frontline health workers on the IoMT devices and setup of common achievable vision.
- Setup of unified data collection application with open APIs- Digital health annuity model- so that IoMT technology can be tested on mass scales.
- Promotion of ABDM sandbox for universal healthcare interface
- Collaboration with state doctor's unions and medical council of India to create national medical registry.

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Annexure

Interview Questionnaire 1

Subject matter experts, community outreach organisations and bureaucrats

Introduction of project

Part A- Introduction

Name	
Age-	
Sex-	
Number of years of experience	
Company name	
Designation	

Part B- Technical Round

Question	**Probe**
Does POC network of IoMT devices is possible at primary healthcare centres?	

What are the policies related to IoMT integration within public health infrastructure.	
What are the gaps in policy implementations	
How it is possible?	If yes. Features of IoMT- Connectivity, Data interpretation, clinical validity, AMC, battery life, cost per test or per device, manufacturing capacity, capacity building.
Why not possible	If No
What are the major challenges	Social, political, economic, and technical challenges
What can be a ideal minimalist IoMT device	Technical and economic specifications

Interview Questionnaire 2

Clinicians/ specialist doctors

Introduction of project

Part A- Introduction

Name	
Age-	
Sex-	
Number of years of experience	
Company name	
Designation	
Clinical speciality	

Part B- Technical round

Question	**Probe**
Does POC network of IoMT devices is possible at primary healthcare centres?	

How it is possible?	If yes. Features of IoMT- Connectivity, Data interpretation, clinical validity, AMC, battery life, cost per test or per device, manufacturing capacity, capacity building.
Why not possible	If No
What are the major challenges	Social, political, economic, and technical challenges
What is gold standard device used in your speciality	Technical specifications of technology used and sensitivity of the test.

Interview Questionnaire 3

Senior officials of IoMT companies

Introduction of project

Part A- Introduction

Name	
Age-	
Sex-	
Number of years of experience	
Company name	
Designation	

Part B- Technical Round

Question	**Probe**
What are the possible use cases of IoMT device	

What are the differences with the gold standard devices	Technical and product design specifications- sensitivity and usability
What is the nature of API	Internal/ Open
How do you interpret recorded health data	ML backed AI engine/ manual/ Teleconsultation
What is the Battery life	
Do you need internet connectivity to use the IoMT	Yes/No
What is the cost per device and cost per test	As per minimum patient load at HWC according to IPHS guidelines 2022
Do you provide training	Virtual/ Hands-on/ Paper book
How do you position your product in terms of minimalist IoMT	Reduced size/ cost/ operations

Details of Respondents

Sector	**Organisation name**	**Number of interviewee**
Health tech companies (24 Companies) CEO, Senior Managers, CTO & COO	Health cubed	2
	Medongo	1
	Writzo	1
	E-med Tel	1
	Helyxon	1
	Omron	1
	Barun	1
	Inbody	1
	Chesto	1
	Litmann	1
	HD Fono Doc	1
	Dr Trust	1

	MI	1
	Realme	1
	Actofit	1
	Fitbit	1
	Haemocue	1
	Roche	2
	Ezecheck	1
	Bulbitech	3
	Allyn	2
	Logy.AI	1
	Nelcor	1
	Siemens	2
Government organisations (Policy lead, Consultants, OSD, Secretary, Executive, Add. CEO)	Ministry of health and family welfare	3
	Niti Ayog	3
	NHA HQ	2
	NHA Haryana	1
	Health technology assessment (ICMR)	1
	Department of health and family welfare- Government of Delhi	2
Community outreach and training organisations	Artist	1
	Digiswasthya	1
Senior clinicians (General practitioner, CDMO)	Navjeevan Hospital, Mumbai	2
	Distrct CDMO- East Delhi, South Delhi)	2