DIGITAL GOVERNANCE SYSTEM FOR ULTRASOUND DEVICES

A progressive step towards enhanced preventive healthcare access in India

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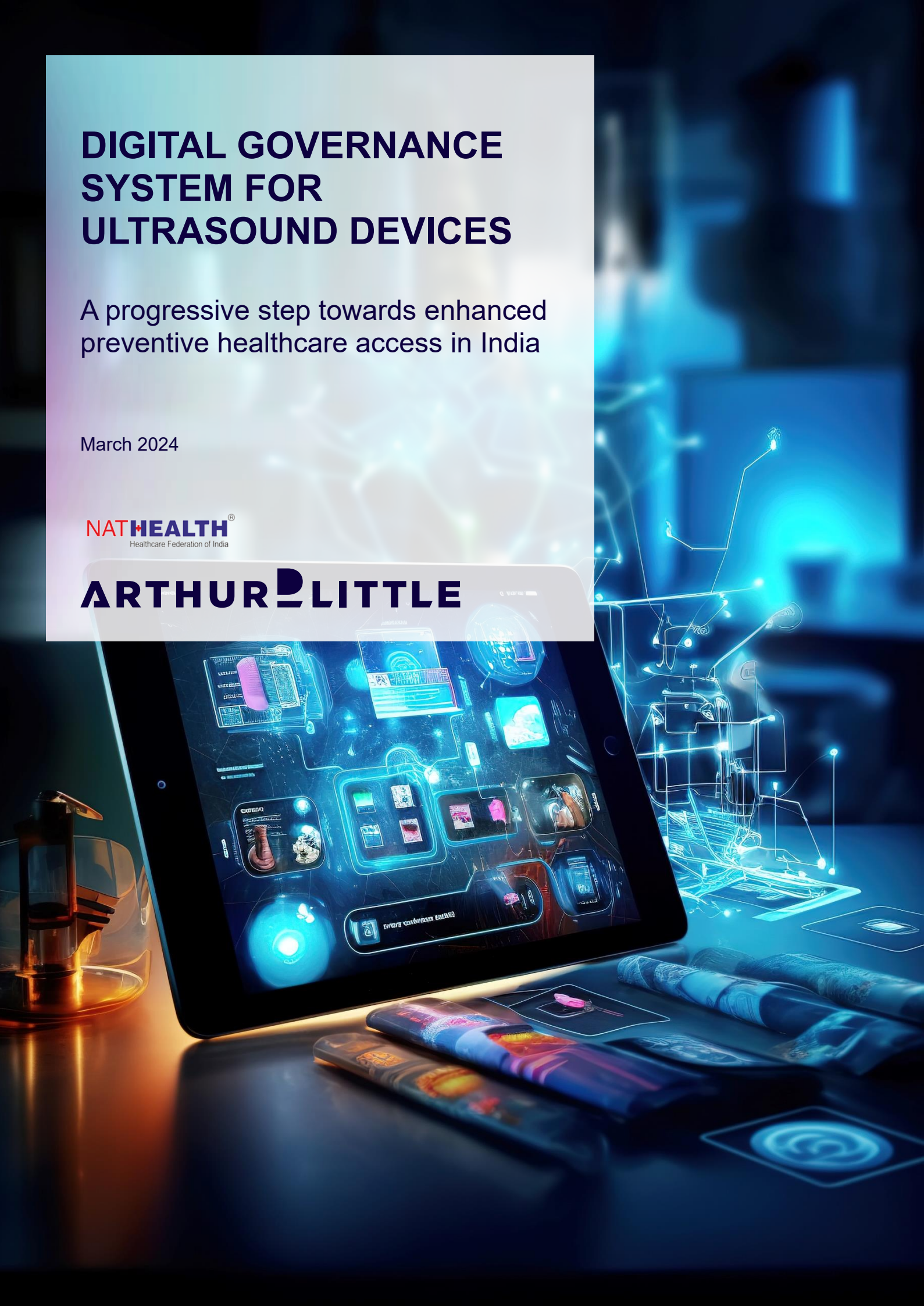
Healthcare Federation of India

ARTHUR D LITTLE



FOREWORD

In India, despite commendable advancements in healthcare, significant disparities persist in access, particularly evident in rural areas. While there has been progress in maternal health indicators, challenges endure, emphasizing the necessity for a more comprehensive and standardized healthcare delivery model. The burden of non-communicable diseases (NCDs) weighs heavily, impacting economic productivity and calling for proactive interventions.

Ultrasound technology emerges as a transformative force, offering real-time, high-resolution diagnostics and therapeutic capabilities. However, its adoption in India encounters numerous hurdles including limited awareness, regulatory complexities, and inadequate infrastructure. Although the existing regulatory framework is well-intentioned, its implementation falls short, leading to prolonged approval processes and unease among healthcare practitioners.

This report analyses the challenges in deeper penetration of ultrasound technology and proposes a Digital Governance System for Ultrasound Devices which is aligned with Ayushman Bharat Digital Mission (ABDM).

To ensure the robustness of data and coverage across the value chain, we involved key stakeholders including government officials, CXOs, diagnostic labs, hospitals, and radiologists. The findings of this report are based on the 90+ RTIs filed across 11 states and 80+ districts for circulars and applications pertinent to ultrasound devices over a specific period encompassing 6 months. 90+ state circulars related to procedural formalities and implementation guidelines across 11 states were analysed. Additionally, we conducted in-depth interviews of over 10 hours interacting with doctors, radiologist, pathology labs and government officials.

These insights emerging from the analysis of RTIs, circulars and interviews can prove to be particularly useful for the entire ecosystem to gain a systemic view of the status of ultrasound adoption and its evolution. The proposed Digital Governance System is set to transform healthcare accessibility, overcome regulatory obstacles, decrease the burden of non-communicable diseases (NCDs), provide better maternity and child healthcare, and establish India as a leader in health-tech innovation

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EXECUTIVE SUMMARY

India, amid commendable advancements in healthcare, grapples with disparities in access across states, particularly in rural areas. Despite progress in maternal health indicators, challenges persist, underscoring the need for a more comprehensive and uniform healthcare delivery model. The burden of non-communicable diseases (NCDs) looms large, affecting economic productivity and necessitating proactive interventions.

Ultrasound technology emerges as a transformative force, offering real-time, high-resolution diagnostics and therapeutic applications. However, its adoption in India faces several hurdles like limited awareness, regulatory complexities, and inadequate infrastructure. The existing regulatory framework, while well-intentioned, lacks in proper implementation, resulting in prolonged approval processes and apprehension among healthcare practitioners.

In response, a proposal for Digital Governance System for Ultrasound Devices is proposed—a solution aligned with the Ayushman Bharat Digital Mission (ABDM). This digital transformation aims to streamline ultrasound compliance, addressing regulatory inefficiencies and improving transparency. The envisioned system operates on a rule-based model, encompassing four interconnected modules focused on healthcare providers, equipment suppliers, provider operations, and device registries.

This report provides 5 key imperatives for the implementation of the Digital Governance System for Ultrasound Devices:

1. **Uniformity in communication:** It is essential that the Ministry of Health and Family Welfare (MoHFW) makes very clear communication to all the state governments to bring uniformity in understanding of the guidelines of governing Acts pertaining to compliances for sale, use, transport and record-keeping of USG devices

2. **Digitization of the process:** Adoption of digital technologies is imperative in today's world. A central digital registry of all devices should be created by providing each device a unique ID to track them throughout their lifecycle. This will help in efficiently monitoring the usage of ultrasound across all devices and arrest malpractices. A digital registration process is needed to upload documents and track application. Digital patient records should be made accessible in integration with ABDM. This initiative will enhance efficiency, uniformity, and transparency across all states. Consequently, it is poised to improve the ease of doing business, and attract investments in MedTech sector. Consequently this will help in achieving the objectives of the "Make in India" initiative.

3. **Deemed approval to accelerate the process:** Deemed approval of the application for sale, renewal, transport and demonstration should be introduced. This will bring accountability and the ownership to the responsible stakeholders. This will reduce the long and inconsistent waiting times for approvals. This will develop a conducive environment for ease of doing business.

4. **Data driven decision making:** Decisions should be taken based on data-driven approach instead of perception-based approach. This will result in more informed decision making effective planning and better governance.

5. **Push-pull for deeper penetration of ultrasound:** Push needs to be created for more awareness about ultrasound devices and their use cases. Demonstrations of these devices should be allowed uniformly across the country to ensure widespread understanding and knowledge dissemination. Moreover, there should be awareness campaigns about the benefits of using ultrasound in the early diagnosis of diseases and preventive healthcare reducing the NCD burden and providing better maternal and child healthcare.

By addressing these imperatives, the successful implementation of the Digital Governance System for Ultrasound Devices can be ensured, contributing to a more inclusive, transparent, and technologically advanced healthcare ecosystem in India.

OVERVIEW OF HEALTH OUTCOMES IN INDIA

India has witnessed remarkable advancements in the health outcomes of its citizens, with life expectancy at birth rising from 47.7 years in 1970 to 69.6 years in 2020, according to the World Health Organization (WHO). This is a result of the advancement of science & technology, supportive government schemes and funding, increased public expenditure on health and higher awareness of the human body.

However, the progress is not uniform across states. As health is a state matter, there are notable differences in delivery models, insurance schemes, and the adoption of the latest technology across states. The problem becomes more peculiar as we move to deeper parts of the country where around 65% of the population resides. These rural areas still face challenges in terms of accessibility to quality healthcare and diagnostic services. This makes universal health coverage a distant dream for India.

The Ministry of Health has made many strides in improving the health infrastructure in India with initiatives under Ayushman Bharat. These schemes aim to shift from selective health care to a more comprehensive range of health services and ensure universal access to a broader range of primary healthcare services spanning preventive, promotive, curative and rehabilitative care for all ages.

Maternal Health Indicators

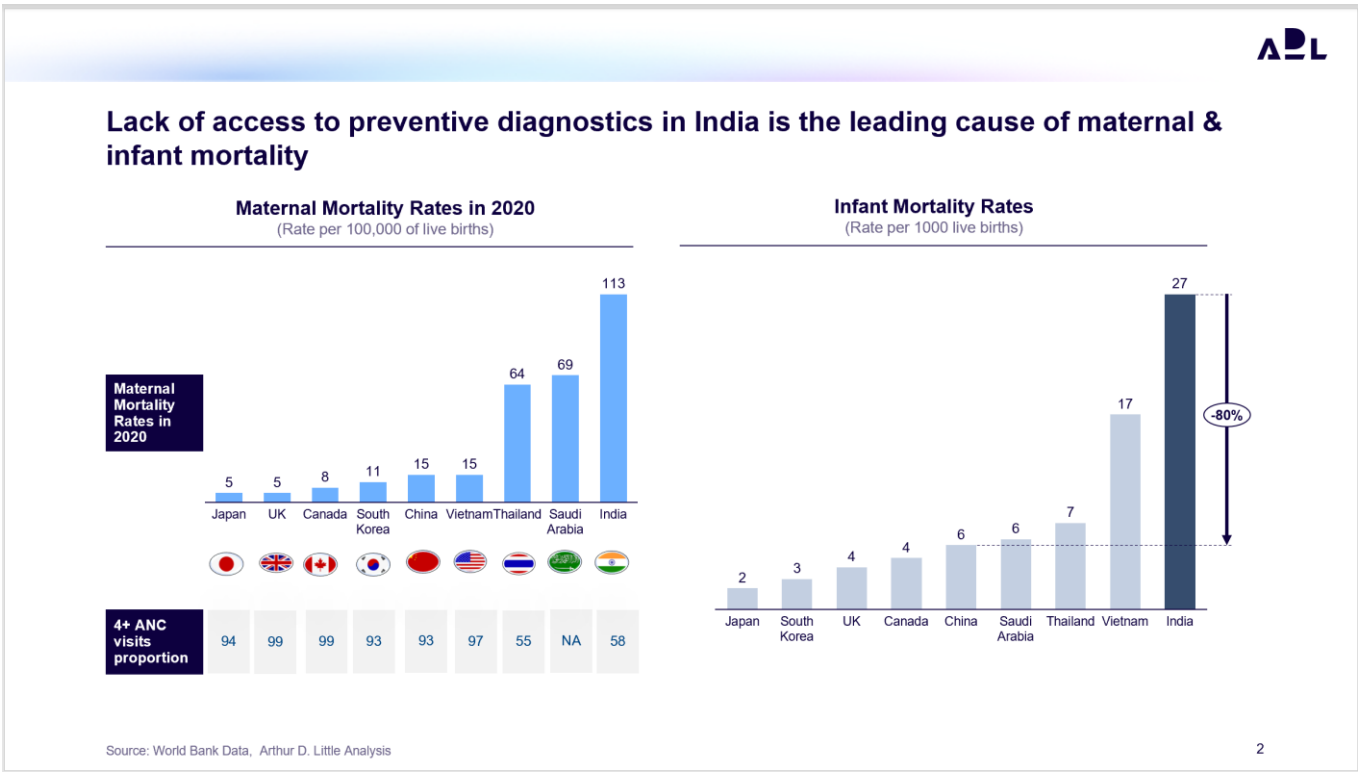
India has made remarkable strides in reducing maternal mortality, with a 22% reduction since 2013. The Maternal Mortality Rate (MMR) stood at 113 per 100,000 live births in 2020 showcasing the government's effective strategic approach to expanding infrastructure, capacity, and various initiatives.

Despite these advancements, India still has a substantial journey ahead to meet the WHO's target maternal mortality rate of 70 and align with economies of similar stature. India has the opportunity to progress towards the very low MMRs seen in developed nations such as Japan, the UK, Canada, and South Korea, which typically range between 5 and 11 as shown in Figure 1. Even among developing countries in Asia like China, Vietnam, and Thailand, where rates fall between 15 and 64, there is a positive trend that India can aspire to emulate and surpass.

Moreover, WHO advises a minimum of four antenatal care (ANC) visits for an optimal care routine during pregnancy. India faces a challenge in achieving this standard, as only 58% of pregnant women in the country receive the recommended minimum of four ANC visits Moreover, only 21% of women in India have access to complete ANC, highlighting a significant portion of pregnant women who are unable to access adequate prenatal services. In addition, 22% of pregnant women had their first visit only during the fourth or fifth month of pregnancy opposed to the suggested visit in first trimester. According to National Family Health Survey (NFHS)- 5, the rate of four or more ANC visits varies significantly across the states, ranging from 21% to 93% across different states.

The maternal mortality rate can be improved through enhanced preventive healthcare and improved access to diagnosis, particularly in the realm of antenatal care for women.

Figure 1



In terms of infant mortality, India has one of the highest rates among developing countries, with 27 deaths per 1000 live births. India has a significant opportunity to aim for the remarkably low infant mortality rates observed in developed nations such as Japan, South Korea, the UK, and Canada, typically ranging between 2 and 4. Even in developing nations like China and Thailand, where infant mortality rates are 6 and 7 respectively, there is a promising benchmark for India to strive towards and potentially surpass as shown in Figure 1.

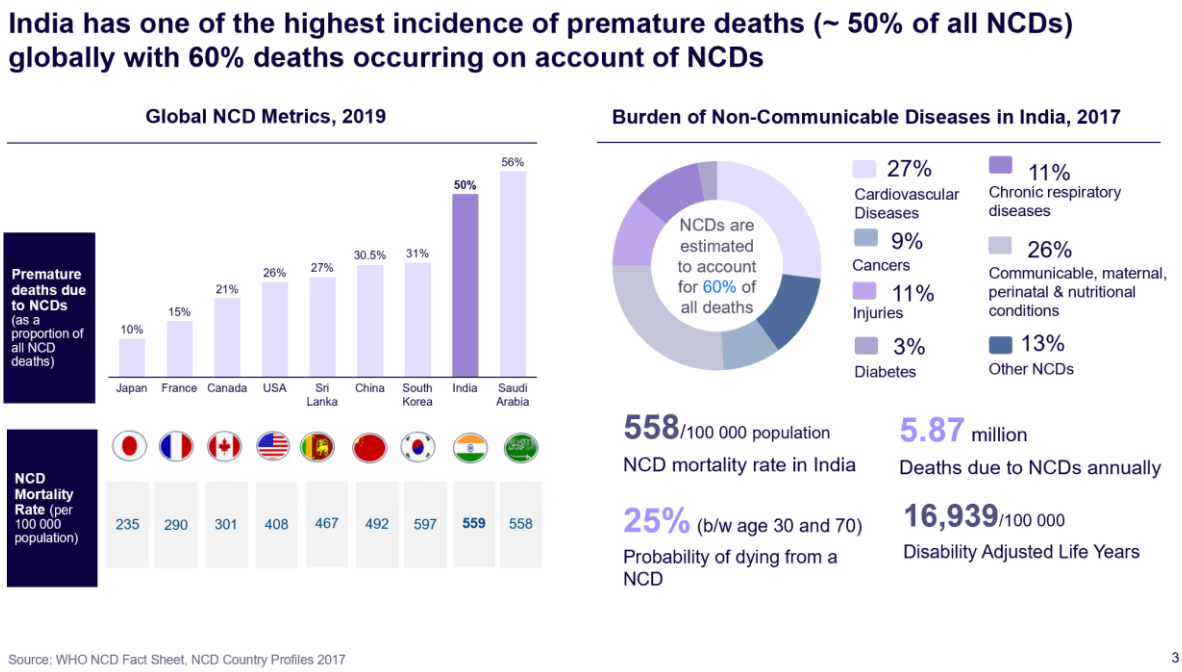
Predominant causes of infant mortality in India include premature birth, neonatal complications, malnutrition, and infectious diseases like pneumonia. Studies emphasize that women receiving comprehensive prenatal care are 16% less likely to experience stillbirth and 24% less likely to give birth prematurely.

Recognizing the integral role of maternal health as a key indicator, the government places a high priority on improving antenatal care and maternal mortality rates through initiatives like Ayushman Bharat. Integrating ongoing efforts such as Reproductive Child Health (RCH) and Pradhan Mantri Jan Arogya Yojana (PM-JAY) with diagnostic technology emerges as a critical strategy to ensure the viability of foetuses and enhance overall maternal health outcomes. This comprehensive approach underscores the government's commitment to achieving better health outcomes for mothers and infants across the nation.

Burden of Non-Communicable Diseases

Non-communicable diseases (NCDs) have emerged as the primary global cause of death, posing a growing public health challenge for 21st-century India. NCDs are a significant burden on India's healthcare system as they account for 60% of all the deaths in the country. India contends with a high NCD mortality rate of 558 per 100,000 people (higher than many other countries), resulting in an estimated 5.87 million annual deaths attributed to NCDs, according to the World Health Organization (WHO). Alarmingly, a majority of these deaths occur prematurely (between ages 30 and 70) and are preventable with early and accurate diagnosis. NCDs are predicted to account for 75% of all deaths in India by 2030, despite government interventions.

Figure 2



Studies indicate that NCD treatment significantly impacts the financial stability of affected families. Households dealing with NCDs face an average out-of-pocket expenditure (OOPE) of INR 13,170, more than twice as high as non-NCD expenditure. Furthermore, 27% of households experience catastrophic health expenditure (CHE) at public facilities, with even higher rates at private facilities. Macroeconomic studies suggest that every 10% increase in NCDs hampers yearly economic growth by 0.5% due to productivity losses. As India stands on the brink of the full impact of this dual health burden, projections indicate an economic output loss of $3.55 trillion by 2030.

26,585 INR
Avg. Annual OOPE on treatment

16,939/100 000
Disability Adjusted Life Years

47% of households
Catastrophic Health Expenditure

In response, the World Health Organization recommends early detection of NCDs for timely intervention, aligning with the "Global Action Plan for the prevention and control of NCDs 2013-2020."

India has taken a proactive stance by being the first country to adopt the National Action Plan, aiming to reduce global premature deaths from NCDs by 25% by 2025.

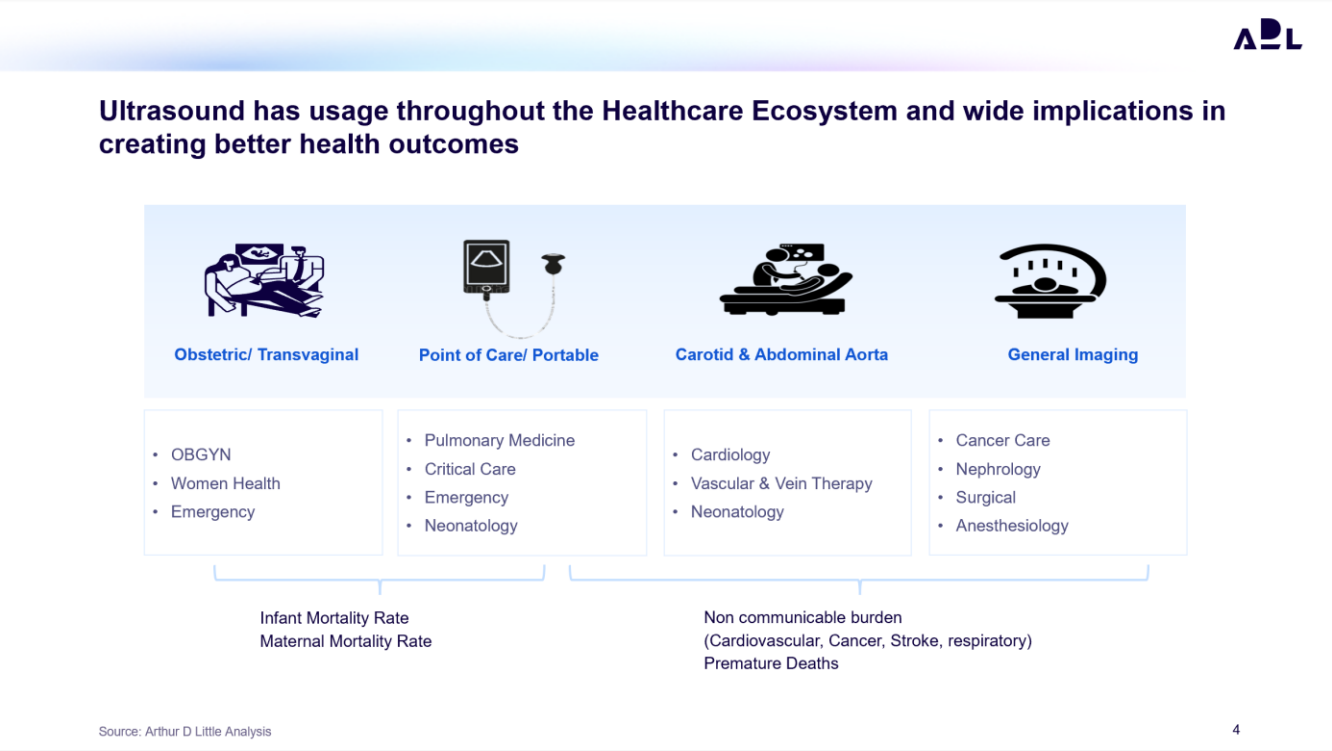
NEED OF DIAGNOSTIC DEVICES – ULTRASOUND TECHNOLOGY

To effectively improve maternal care and combat the escalating burden of NCDs a shift towards preventive care is imperative. Key to this strategy is the utilization of diagnostic devices which play a pivotal role in early disease detection and prevention, thereby reducing healthcare expenses and improving overall quality of life. Early diagnosis of NCDs can reduce the cost of curative and OPD care on NCDs which account for around 85% of total healthcare expenditure, hence resulting in USD 100 billion boost to India's GDP.

Use Cases of Ultrasound Technology

Ultrasound, a well-established non-invasive diagnostic tool, employs high-frequency sound waves to generate real-time images with exceptional resolution and detail, fundamentally transforming modern medicine for over half a century. Its versatility is evident in obstetrics and gynaecology, where it visualizes the developing foetus and monitors growth. In radiology, ultrasound aids in diagnosing liver, kidney, and gallbladder conditions, as well as assessing blood flow in veins and arteries. Additionally, it plays a crucial role in cardiology, evaluating heart health and blood vessels.

Figure 3



Beyond diagnostics, ultrasound has found applications in various therapeutic modalities such as high-intensity focused ultrasound (HIFU) and therapeutic ultrasound. Portable ultrasound technology has revolutionized accessibility, particularly in remote areas and confined spaces where traditional equipment may be impractical. Technological advancements have enabled portable ultrasounds deliver high-quality imaging comparable to traditional equipment, with Point of Care Ultrasound (POCUS). 96% of indications can be diagnosed using a POCUS with the same accuracy as compared to a conventional USG. Studies proved a kappa coefficient of correlation between 0.7 to 0.85 when comparing POCUS to traditional ultrasound, reinforcing its reliability and efficacy in diverse medical settings

International Case Studies of Ultrasound Industry

Global Medical Imaging is estimated to be a huge USD 20 billion industry, of which ultrasound has the highest share at 31%. Ultrasound is estimated to grow from USD 6 billion to USD 8 billion market by the end of 2027 with a CAGR of 3.4%. This growth in the market is driven by the increasing prevalence of cancer & cardiovascular diseases, government initiatives, rapid technological advancements, increasing adoption of preventive healthcare and disease screening programs and strategic collaborations.

The bigger burden of non-communicable diseases is driving government initiatives to improve preventive healthcare through investment and flexible regulatory frameworks. The improved efficiency and invention of portable devices have rapidly driven the adoption of imaging in healthcare.

Various developed nations have embraced ultrasound technology for preventive healthcare, with Canada emerging as one of the leaders in the ultrasound market. In 2020, Canada's ultrasound devices market reached USD 177 million, projected to escalate to USD 254 million by 2028 at a 5.0% CAGR. This growth is propelled by supportive government initiatives, technological advancements, an ageing population, and increased adoption of point-of-care solutions. Notably, Canada allocated USD 1.03 billion in public funds for advanced medical imaging research and development between 1998 and 2011, anticipating the demand generated by an ageing population susceptible to chronic diseases. Point-of-care ultrasound (POCUS) received specific training within formal healthcare programs, emphasizing its role in emergencies and remote settings, complementing rather than replacing conventional ultrasound.

South Korea boasts a substantial ultrasound devices market, valued at USD 167 million in 2020, poised to reach USD 239 million by 2028 with a 4.9% CAGR. The Korean government actively supports the industry through the "grow through innovation plan". Less stringent regulations for lower-risk devices further foster growth. Disease conditions in South Korea, driven by an ageing population and high obesity rates, contribute to the increasing demand for ultrasound technology. The country has established a robust manufacturing base for ultrasound devices, featuring contributions from industry leaders such as GE Healthcare, Siemens, Samsung Medison, DRGEM, Listem, and Macrovision.

Ultrasound Penetration in India

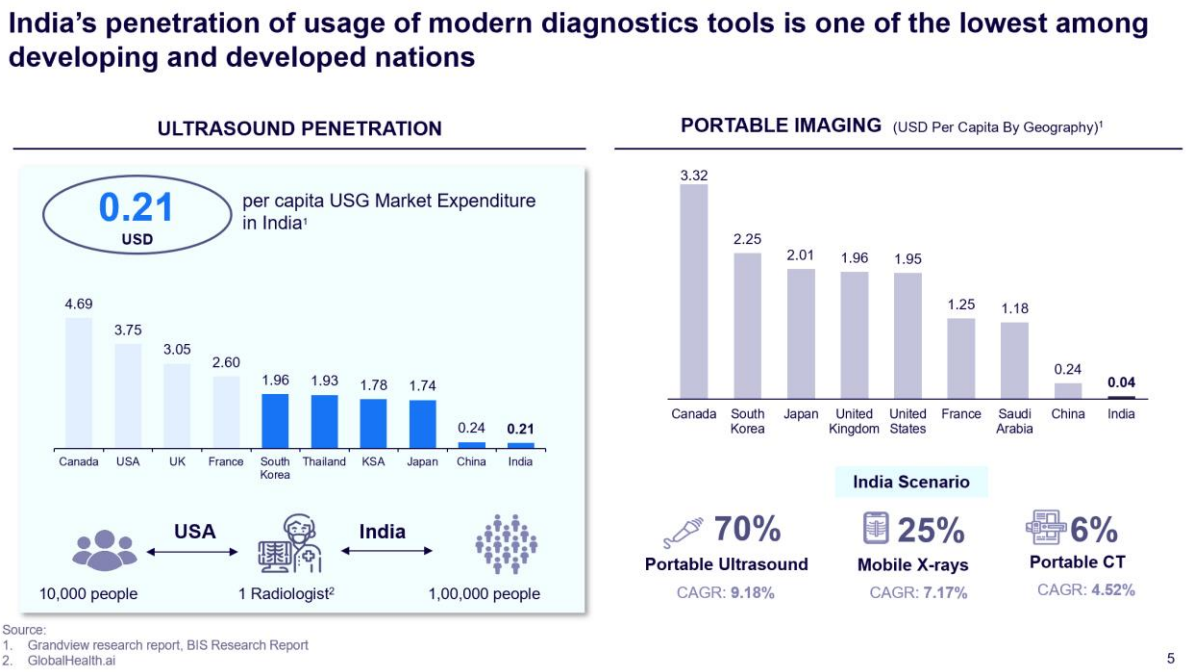
The ultrasound market in India has experienced impressive growth and is currently valued at USD 282 million. Portable ultrasound dominates the portable imaging market, representing 70% and is expected to witness a CAGR of 9.18%. Similarly, mobile X-rays and portable CT contribute around 25% and 6% of the portable imaging market, with growth rates of 7.17% and 4.12% respectively.

However, India's ultrasound market still lags behind other nations by a considerable margin. Per capita ultrasound spending in India is a mere USD 0.21, which pales in comparison to countries of similar economic stature. For instance, Canada's highest expenditure stands at USD 4.69 per capita, approximately 22 times higher than India's. Even in Asia, countries like Thailand and South Korea allocate USD 1.93-1.96 per capita to ultrasound, around 9 times India's expenditure, highlighting a significant discrepancy.

Furthermore, the per capita expenditure on portable imaging in India is just USD 0.04, which is considerably lower than countries like Canada and China. For instance, Canada's per capita expenditure is USD 3.32, approximately 83 times more than India's, while China allocates USD 0.24 per capita, around 6 times higher than India's spending.

This substantial gap in spending underscores the challenge of accessibility to ultrasound services in India, with only 30% of Indian hospitals equipped with ultrasound facilities. Addressing this issue is imperative to ensure broader access to crucial medical imaging services across the country.

Figure 4



Some of the reasons behind the weak penetration are:

Lack of awareness: There is a general lack of awareness regarding the benefits and importance of ultrasound technology in healthcare diagnostics. This contributes to low demand and adoption rates.

Cumbersome regulatory environment: The regulatory framework surrounding medical devices and technologies, including ultrasound machines, is complex and cumbersome. This may hinder the smooth entry and operation of ultrasound services, deterring potential providers from investing in the market

Lack of skilled professionals: The availability of skilled professionals, such as radiologists and ultrasound technicians, is crucial for the effective utilization of ultrasound technology. However, there is a shortage of such trained personnel, which limits the scale and quality of ultrasound services. Currently, there is only 1 radiologist for 1 lac people in India in contrast to the USA where there are 10 radiologists for 1 lac people

Limitations in infrastructure: Inadequate infrastructure, including the lack of proper facilities and equipment in healthcare institutions, poses a significant barrier to the widespread adoption of ultrasound technology. Without the necessary infrastructure, the usage of ultrasound services becomes challenging, particularly in remote or underserved areas.

CASE FOR DIGITAL GOVERNANCE

Regulatory initiatives to curb misuse of ultrasound technology in India

The effective utilization of ultrasound technology for positive outcomes relies heavily on a robust regulatory system. Misuse of ultrasound devices, particularly during pregnancy to determine the gender of the foetus, has become a major concern in India, leading to a disproportionate number of sex-selective abortions in favour of male children. This phenomenon is rooted in societal biases that prioritize men over women and is driven by a range of economic, cultural, religious, and emotional factors. To prevent such misuse and promote safe practices, it is imperative that a comprehensive regulatory framework be established to govern the use of ultrasound devices.

Government of India has taken various steps to eliminate gender-biased sex selection, which includes regulating the use of ultrasound and addressing the underlying issue of gender discrimination. Beti Bachao- Beti Padhao Yojana, PCPNDT Act, Balika Samridhi Yojana were some initiatives under this cause. In 1994, the Pre-Natal Determination Techniques Act (PNDT) was passed to limit usage of pre-natal tests for specific genetic conditions and banned sex determination. The act was later revised in 2003 to become the Pre-Conception and Pre-Natal Determination Techniques Act (PC-PNDT), which expanded its scope to include pre-conception techniques and ultrasound technology. The act mandates registration of genetic counselling centers, labs and clinics to ensure presence of ultrasound equipment at authorised locations only. It also requires submission and maintenance of patient records for inspection.

Challenges in implementation of regulations governing ultrasound

Various challenges have been identified in the implementation of regulations governing ultrasound

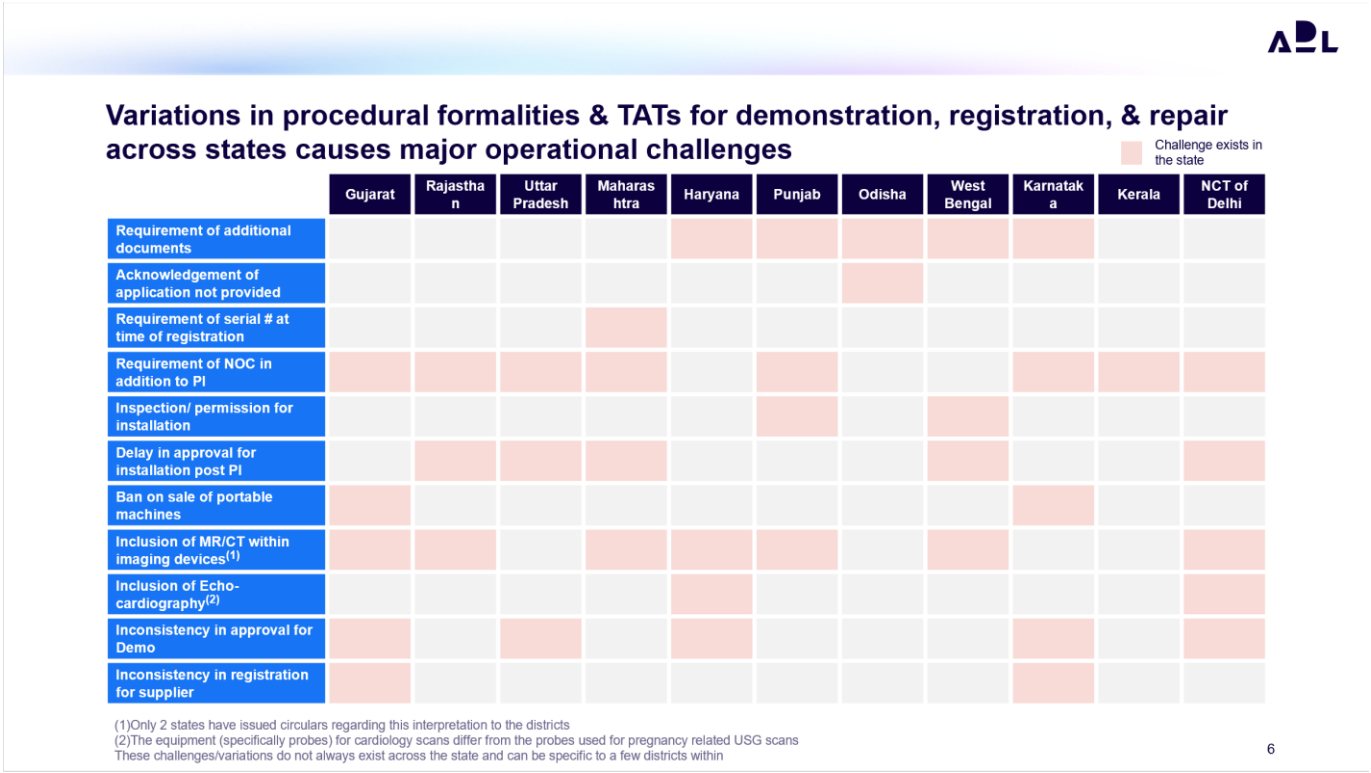
1. Ambiguity in interpretation & deviations from central guidelines

The execution was left up to the state which led to inconsistent implementation due to misinterpretations. The guidelines for implementation vary greatly from district to district, leading to ambiguity around issues such as required documents for registration, the authority responsible for approval, obtaining NOCs, timelines for prior notification, approval for demonstrations, and the use of portable ultrasound devices. From Figure 5, it seen that

- There are variations at 2-3 steps in the registration process observed in circulars for 7 states
- The interpretations of “imaging equipment” differ across states - 7 states include MRI/CT & Echo cardiography under the purview of the act
- 2 states (Gujarat and Karnataka) have banned the sale of portable equipment (allowed as per central guidelines)

The sale of portable imaging devices is banned in many states and all other states mandate the use of portable equipment only in the registered center. This eliminates the purpose of portable devices in the first place. This acts as a major impediment in leveraging portable ultrasound at point of care in remote areas of the country.

Figure 5



Variations in procedural formalities & TATs for demonstration, registration, & repair across states causes major operational challenges

Challenge exists in the state

	Gujarat	Rajasthan	Uttar Pradesh	Maharashtra	Haryana	Punjab	Odisha	West Bengal	Karnataka	Kerala	NCT of Delhi
Requirement of additional documents					■	■	■	■	■		
Acknowledgement of application not provided							■				
Requirement of serial # at time of registration				■							
Requirement of NOC in addition to PI	■	■	■	■		■			■	■	■
Inspection/ permission for installation						■		■			
Delay in approval for installation post PI		■	■	■				■			■
Ban on sale of portable machines	■								■		
Inclusion of MR/CT within imaging devices(1)	■	■		■	■	■		■			■
Inclusion of Echo-cardiography(2)					■						■
Inconsistency in approval for Demo	■		■		■				■		■
Inconsistency in registration for supplier	■								■		

(1)Only 2 states have issued circulars regarding this interpretation to the districts
(2)The equipment (specifically probes) for cardiology scans differ from the probes used for pregnancy related USG scans
These challenges/variations do not always exist across the state and can be specific to a few districts within

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2. Variations in procedural formalities & TATs across states

The applicants are unaware of the timeline of the approval to plan their activities as the process does not follow a stipulated deadline and there are no means to track the progress. It is estimated that the turnaround time (TAT) could range anywhere between 90 days to 720 days.

- Registration & procurement take 3 different routes with TAT varying from 90 to 180 days (TAT as per central guidelines is 90 days)
- 1-2 years of TAT for renewal of the approval certificate in most states, while repair and end-of-life guidelines are inconsistent
- Irregular guidelines, 30 days TAT for demonstration and permission denied in some states

3. Increasing criminalization of doctors and rising fear amongst practitioners of using ultrasound

Non-adherence to any of the constantly changing non-uniform guidelines could result in seizing the device, sealing the registered center or even de-licensing and criminalization of doctors.

- 68% of the total cases are due to non-maintenance of records while cases under communication of sex of fetus constitute only 15%
- There are 3158 ongoing cases with 617 convictions & 145 license suspensions
- 8/36 states have 0 ongoing cases while states like Rajasthan have 753 – however higher prosecution is not translated into better SRB or missing girl child numbers
- As of 2020, there were a total of 3,158 ongoing cases of which 68% were only due to clerical errors. This is creating fear among medical practitioners to include ultrasound at their place of work

4. Manual processes lacking end-to-end visibility

All the registered centers need to submit hard and/or soft copies of patient records on a quarterly basis and maintain them for the next 2 years. Given the scale of the number of scans done in a hospital, this task requires several work hours of manual efforts.

- Manual record-keeping processes and lack of data consolidation increases operational burden on centers and leave opportunities for misuse
- Online mechanism for application in 18 states/UT with frequent functional challenges

Need for digital governance

The existing regulatory landscape has hindered private sector involvement in enhancing ultrasound penetration. Expanding the reach of ultrasound in diagnostics necessitates a revision of the restrictive regulatory pathways that impede the establishment and sale of additional private imaging/diagnostic facilities. To facilitate this, digital systems can serve as a pivotal tool in crafting a standardized and transparent regulatory framework, while also mitigating the risk of human error or bias.

The digital platform functions as a potent instrument for monitoring and curbing malpractices, while simultaneously simplifying business operations for medical professionals. This transparent and data-rich platform enhances implementation efficiency by facilitating officials' ability to detect malpractices and apprehend offenders. By transitioning manual processes into a streamlined digital workflow, considerable time and effort can be conserved, ambiguities resolved, and overall business operations for both medical practitioners and equipment suppliers can be enhanced.

Opportunity for Digital Health by Integrating with ABDM

The digital transformation of regulatory processes of ultrasound poses a significant opportunity to increase the adoption of digital health in India. The government has taken many strides to move ahead on this path by launching Ayushman Bharat Digital Mission (ABDM). ABDM aims to provide a strong IT infrastructure backbone to develop a robust digital health ecosystem in India. This ecosystem would comprise patients, healthcare professionals, facilities and health-tech companies. A digital connection within these components enables e-consultations, secured online access to digital health records, creates a central registry of all healthcare professionals & facilities and develops an open protocol network for various digital health services. It aims to create digital highways to bridge the gap between various stakeholders in the healthcare system.

National Health Authority (NHA), the responsible body for ABDM implementation, has taken many measures to increase its adoption. It launched the Digital Health Incentive Scheme (DHIS) to accelerate the onboarding of health facilities like hospitals and clinics by providing financial incentives up to Rs 4 crores. It is also taking various initiatives to promote awareness about digital health benefits to scale up the creation and linking of digital health records.

In addition to these, the digitalization of regulatory processes has the potential to multiply the scale of adoption. This transformation eliminates the roadblocks for regulatory compliance for all the stakeholders involved providing them sufficient incentives to switch to the digital ecosystem. Onboarding of all the diagnostic centers, clinics, and genetic laboratories triggers the cycle of adoption down to the patients. This integration could be a critical step to initiate large-scale adoption within the diagnostic sector of healthcare.

In the context of ultrasound, the implementation of ABDM emerges as a compelling opportunity for digital governance. Specifically, the monitoring of ultrasound device usage on patients can be facilitated by linking medical reports to unique ABHA IDs. Furthermore, ABDM can serve to establish a comprehensive repository of devices, thereby enhancing tracking capabilities. Further elaboration on these concepts is delineated within the rule-based governance system outlined in the recommendations of this report.

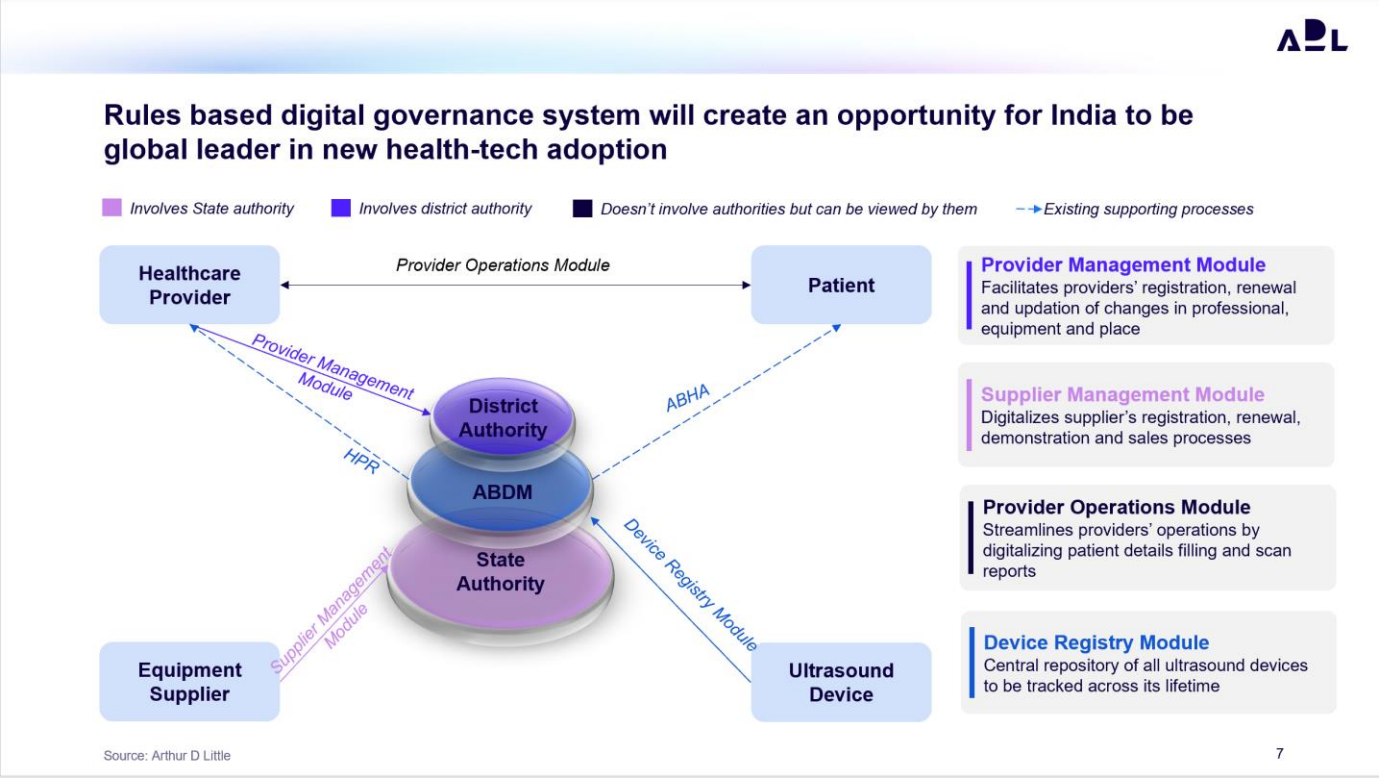
E-GOVERNANCE AS A SOLUTION

For the regulations to meet their purpose, digitalization of the implementation is the most attractive and feasible solution. E-governance has been a recent trend in transforming the way that governing bodies function in various ministries. The Ministry of Environment, Forest, and Climate Change (MoEFCC) launched the PARIVESH portal for online submission and monitoring of the applications filed by the proponents for obtaining Environment, Forest, Wildlife, and CRZ Clearances from Central, State, and district-level authorities. Atomic Energy Regulatory Board (AERB) developed the e-LORA platform to transform the licencing process of radiation applications online. These e-governance solutions proved to considerably improve the efficiency and transparency of the regulatory processes. Even in the health sector, the Reproductive & Child Health (RCH) department of MoHFW undertook the initiatives of ANMOL and RCH portal to effectively track ANC visits and pregnancy health.

Recommendations

Rules-Based Digital Governance System

A rules-based digital governance system will create an opportunity to eliminate the inefficiencies in the implementation of ultrasound regulations and enhance health-tech adoption. In this system, all the processes mentioned in the act are mapped under four modules associated with relevant stakeholders.



1. **Healthcare provider management module-** This module facilitates all the regulatory approval processes required by the owner of ultrasound equipment. It involves registration and renewal of centers through digital platform. A single checklist is to be provided based on which the applicants can upload the required documents. Through the portal, they can track the status of their application. The applicants can also update their certificate in the event of buying new equipment, repairing or end-of-life of old ones, change in medical professionals or change of address of the registered center.

The district authority can review all the applications in a single window. After the stipulated timeline (90 days), if the application is not reviewed by the authority, it can be deemed to be approved. This feature of auto-approval can be introduced to enforce authorities to strictly abide by the stipulated turnaround times (TAT).

Additionally, a credibility score can be associated with each of the applicants which assesses their compliance from the time they obtain their registration. This score could be used in times of renewal to simplify the process or during sales or criminal prosecutions as a metric of trustworthiness.

2. **Equipment supplier management module-** This module supports the equipment supplier in registration and renewal of their regulatory certificate. Further, it also facilitates demonstration of the devices before sale by uploading self-declaration by both parties to not commit any malpractices. This eliminates the long waiting times and inconsistent procedural norms for demos.

   This module can also digitize the entire regulatory process to facilitate sales of the device which includes verifying the buyer, providing prior intimation before the sale of equipment and regularly submitting sales records to the authorities. It would put a stop to the manual cumbersome process of maintaining and submitting hardcopies of sales records every 3 months.

3. **Provider operation module-** This module streamlines the operations at clinics/diagnostic centers while improving patient records transparency to authorities. At the center, the patient can be directly linked to their ABHA/ Aadhaar number to connect every patient to the digital health ecosystem. This will ease the physical maintenance of these records and eliminate the scope for clerical errors. The results of the pregnancy scans can be uploaded to the online portal to create a central registry of all patient records which could be monitored by the authorities in real time.

   All patient data (Medical history, scans, reports, interventions) is to remain protected under the data privacy laws and thus only ABDM will have access to that data. With upcoming technology, the upgradation of all equipment with the capability to auto-upload scans of a patient on the shared network can be explored.

4. **Device registry module-** The final leg of the digital system is to create and maintain a central registry of all the ultrasound devices in the country and track their status across its lifecycle. A unique device ID needs to be created and linked to each of the ultrasound equipment. Device ID keeps track of any changes done in any of the above-mentioned modules. Purchase of new equipment or repair/end-of-life of existing equipment updated in the healthcare provider management module are reflected in the central registry through this device ID. The location of the device can be fetched through the registered location of the center for conventional devices and use GPS tracker for portable devices. Provider operator module links the patient scans with the device which was used in scanning. This creates a central repository of all the devices with their location and usage readily available for the authorities to monitor at all times. ABDM plays a crucial role in maintaining the registry and integrating the data from the modules.

The role of each stakeholder in the proposed modules is mapped in a matrix for clear role definitions

Stakeholder Engagement Matrix

User Stakeholder who will use the module for compliances

Approver Stakeholder with the authority to approve/reject the user's applications

Monitor Stakeholder with the authority to view the data captured in the module

Modules	Stakeholders				
	Healthcare Provider	Equipment Supplier	District Authority	State Authority	Central Authority/ ABDM
Provider Management Module	User	-	Approver	Monitor	
Supplier Management Module	-	User	-	Approver	Monitor
Provider Operations Module	User	-			Monitor
Device Registry Module	-	-	-	Monitor	

Note: To maintain the data privacy of the users and the patients (captured in the center operations module) the authority to access and view this data lies only with the required personnel in State, MoHFW & ABDM. The approver is only given access to the data required for decision making.

Source: Arthur D Little

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Impact of proposed changes

The proposed recommendations to digitalize ultrasound compliance have several potential benefits:

1. **Uniformity in process implementation:** The proposed recommendation to digitalize ultrasound compliance has a significant impact in bringing uniformity in process implementation thus improving compliances & ease of doing business in the healthcare sector. Digitization of compliance leads to uniform implementation across states/districts eliminating the ambiguities & redundancies

2. **Higher efficiency and better monitoring:** The feature of auto approvals reduces the turnaround time for obtaining the certificate significantly and provides a defined timeline for the buyer to plan activities accordingly. Credibility scores will incentivize centers to comply with regulations. It provides effective oversight mechanisms for implementing bodies thus improving efficiency of implementation and decision-making for the authorities. All proposed modules have the functionality for monitoring by state/center authorities in an efficient manner

3. **Facilitating the attainment of ABDM goals:** It furthers ABDM's digital health objectives via the introduction of a digital device registry module and integration of the system with current components of ABDM. The introduction of a device registry module which could later be scaled to all medical devices in the country makes the digital ecosystem more holistic. Digitalizing the regulatory process ensures all the relevant stakeholders are onboarded onto the digital ecosystem and improves its adoption

4. **Better monitoring:** It ensures the effective identification of culprits of sex-selective abortions using the aggregated data and the connected ecosystem of devices and centers. Digitised record keeping and maintenance enable easy tracking of discrepancies through improved transparency. Linking of all records & devices under ABDM will provide easy tracking of device usage & patient scans and hence identify malpractices. States can intervene in required cases. This also provides scope for performance-linked incentives for better-performing districts/DAAs in the future

5. **Reduction of NCD burden:** E-governance is expected to increase penetration of ultrasound technology which can be used in preventive healthcare and early diagnosis of diseases. This can lead to a reduction of the NCD burden in India. Overall, it increases penetration of affordable diagnostics in the country creating an opportunity for India to be global leader in new health-tech adoption

6. **Access to data:** Additionally, the data aggregated by the digital system is of critical importance in this data-driven world. This can unlock many opportunities through use cases in machine learning, pregnancy tracking, device improvement and compliance records. The live location of the device, scan results, patient IDs, time of scan, etc. provide a solid database to track pregnancy and identify malpractices. A repository of patient scans can be used for training AI algorithms for improving diagnosis and patient outcomes. The data could be leveraged to identify pregnancy-related complications and other genetic disorders in the fetus using AI/ML on the pregnancy scan and other genetic marker data. Repair frequency and device lifetime can be used as metrics to gauge and improve the durability of the device. Live location of all devices- traditional and portable helps to suggest the nearest scanning availability in emergency situations

KEY IMPERATIVES

Five key imperatives have been proposed for implementing the Digital Governance System for Ultrasound Devices:

1. **Uniformity in communication:** It is essential that the Ministry of Health and Family Welfare (MoHFW) makes very clear communication to all the state governments to bring uniformity in understanding of the guidelines of governing Acts pertaining to compliances for sale, use, transport and record-keeping of USG devices

2. **Digitization of the process:** Adoption of digital technologies is imperative in today's world. A central digital registry of all devices should be created by providing each device a unique ID to track them throughout their lifecycle. This will help in efficiently monitoring the usage of ultrasound across all devices and arrest malpractices. A digital registration process is needed to upload documents and track application. Digital patient records should be made accessible in integration with ABDM. This initiative will enhance efficiency, uniformity, and transparency across all states. Consequently, it is poised to improve the ease of doing business, and attract investments in MedTech sector. Consequently this will help in achieving the objectives of the "Make in India" initiative

3. **Deemed approval to accelerate the process:** Deemed approval of the application for sale, renewal, transport and demonstration should be introduced. This will bring accountability and the ownership to the responsible stakeholders. This will reduce the long and inconsistent waiting times for approvals. This will develop a conducive environment for ease of doing business

4. **Data driven decision making:** Decisions should be taken based on data-driven approach instead of perception-based approach. This will result in more informed decision making effective planning and better governance

5. **Push-pull for deeper penetration of ultrasound:** Push needs to be created for more awareness about ultrasound devices and their use cases. Demonstrations of these devices should be allowed uniformly across the country to ensure widespread understanding and knowledge dissemination. Moreover, there should be awareness campaigns about the benefits of using ultrasound in the early diagnosis of diseases and preventive healthcare reducing the NCD burden and providing better maternal and child healthcare

By addressing these imperatives, the successful implementation of the Digital Governance System for Ultrasound Devices can be ensured, contributing to a more inclusive, transparent, and technologically advanced healthcare ecosystem in India.

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