

# Increasing elderly population drives demand for home care and self-health management

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## Introduction:

Demographic trends show an increased percentage of people aged 65+ across the globe. This shift in the composition of the population is expected to put a great deal of pressure on societies' financial resources all over the world. This demographic which defines the 'ageing-in-place' philosophy is resulting in more nursing and personal care moving out of the hospitals and professional care institutions and into private individuals' homes. Since over 75% of healthcare costs are attributed to chronic diseases and an equal percentage of hospital readmissions can be prevented through proactive home management, home care solutions are vital. The adoption of self-health management has also increased owing to the large proportion of the population suffering from chronic conditions worldwide, wanting to engage and empower themselves in the management of their diseases.

As chronic diseases and aging increase worldwide, the global home medical devices market is likely to surpass around US\$ 312 billion by 2032. As the number of diabetic and hypertension patients grows, along with an increasing geriatric population and rising hospital traffic and costs, more patients are opting for home dialysis systems, which are expected to exceed \$42 billion by 2030. Moreover, oxygen-related home medical equipment is gaining popularity due to the significant rise in chronic obstructive pulmonary disease (COPD) worldwide. In addition, technological advances in home care medical devices contribute to the market's growth, such as smaller sizes, portability, and ease of access and more standardization in administration of care

Home-use medical devices are likely to become more popular amongst healthcare providers due to the shift towards patient-centered and proactive healthcare, enabling holistic disease management and improved clinical outcomes.

These devices provide patients with a safe, convenient, cost-effective and comfortable environment within their own homes. Home care device and their ecosystem are thus here to stay and grow.

With technological advancements such as sensors, Internet of Things (IoT), cloud computing, and artificial intelligence there is a call for cheaper, more inclusive, and more innovative healthcare solutions. Smart homecare, a home-based health service system, utilizes various technologies to access, manage and share health-related information dynamically, intelligently and in a user-friendly manner. By leveraging real-time data and connecting with various healthcare stakeholders, will be key to future healthcare solutions.

**The Internet of Medical Things (IoMT)**, has potential to comprehensively transform the traditional medical system, making healthcare more efficient, convenient, affordable, and personalized.

Designers and engineers will be required to play a crucial role in creating devices that empower individuals to take an active role in managing their health while ensuring safety, usability, and compliance with healthcare standards allowing healthcare providers to monitor patients' health remotely. This is especially important for managing chronic conditions and ensuring timely interventions in a near real time basis.

The growing popularity of home use medical devices has significant implications for their design and engineering. Several factors contribute to this trend, including advances in technology, the increasing focus on preventive healthcare, and the desire for more convenient and accessible healthcare options.

Here are some key impacts on the design and engineering needs of home use medical devices as we anticipate them.

## Home care environmental considerations:

Unlike the clinical setting, the home is an uncontrolled environment with additional hazards. Many of the well-defined healthcare risks – the spread of nosocomial infections, the development of resistant organisms, medication errors and device malfunctions – are also prevalent in home care. Consequently, care may be delivered under substandard conditions that may worsen the aforementioned risks.

Environmental considerations include a wide range of issues, from safety hazards associated with the macro-environment (such as geographic location of the house) to environmental concerns specific to

the home (as an example – Home construction and maintenance, unsafe home conditions), all of which can present a threat to patient and provider safety.

It is important to consider all these environmental issues when designing medical device technologies for patients receiving home care. Manufacturers are encouraged to consider the new international home healthcare standard IEC 60601-1-11:2015: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

### Engineering Considerations:

IoT Coupled with Advances in technology like low-power wireless communication technologies, embedded technologies and their integration with cloud and mobile technologies have led to the development of small form factor, wireless, body-wearable biomedical devices for health monitoring. This enables patient mobility and comfort and enables continuity of care from hospital to homes. Devices whether monitoring, diagnostics or therapeutics would be equipped with intelligence and self-managing capabilities and enable future systems to be able to autonomically handle several alarm conditions for efficient operation and would require less intervention by doctors and would reduce errors related to patient management.

As an example, today patient monitors have biomedical signal processing algorithms for detecting abnormal physiological conditions such as cardiac arrhythmias, apnea, low blood pressure, etc., and the monitor usually gives an audiovisual alert when such a condition is detected. The doctor usually intervenes when an alert is generated and either silences the system or takes corrective action to treat the patient. Apart from alerts generated by physiological conditions, other alerts are also generated to notify system status or malfunctions such as a low battery condition, sensor coming off the patient, etc. Since a doctor managing an ICU has to respond to alerts from several patients, it becomes an uphill task for the doctor to manage alerts, if the patient monitoring system does not have the capability to self-manage such alerts. In the future, ihome-use environments, could feature multiple devices connected to patients for monitoring multiple parameters. All this data could be shared with a back-end server or cloud platform which, leveraging AI-based solutions, would enable self-management by sensing or monitoring parameters from the device or system, and then analyzing the data to determine if corrective action is required.

Intelligent algorithms and decision trees are used to decide if a management action is necessary and then to arrive at the most effective decision to act on the inputs. The execution engine then acts in a feedback loop to manage the device or system, or to suggest actions for healthcare staff, minimizing the need for user intervention.

### User friendly design:

Trends over the past two decades have shown an increase in post-market events attributable to design issues and often related to the complex user interface. Factors that impact competence in operating these devices include literacy, dexterity, vision, hearing, learning ability, memory, training, experience and language barriers. For instance, the labeling on the device may be too small for users with weak eyesight or may contain unrecognizable symbols. The buttons on the console may be too small for some users. These and other concerns need to be addressed when providing a safe and ergonomic design for the home use device. Home use medical devices need to be user-friendly, catering to individuals with varying levels of technical expertise and medical knowledge.

To overcome challenges related to the use of these devices, it is important to understand how people interact with technology and the impact of the user interface design. Efficient methods of ensuring the involvement of home device end-users in usability studies is essential and their experiences must be effectively utilized in device design.

Leverage human-centered design principles with an emphasis in understanding the needs and preferences of end-users. This approach ensures that the devices align with the lifestyle and expectations of the individuals using them.

Intuitive interfaces, clear instructions, and simplified designs are crucial to ensuring that users can operate the devices confidently.

### Portability:

Home-use devices often need to be compact and portable to fit seamlessly into the home environment. An important aspect to consider here is that not all medical devices stay at home. People who work or when they travel, may take their device with them. This encourages regular use and enables users to take the devices with them if necessary. With a reduction in the physical footprint of home use devices, integration with other systems will also be made easier and efficient. This will require the device to be efficient in power management, along with small form factor for point-of-care use. Furthermore, electronics based medical devices should be able to operate seamlessly across multiple geographies that sustain a variety of electrical connections and output voltages

For a patient who requires dialysis 4 to 5 times a week, going to workplace or traveling outdoors should not be a barrier. A home hemodialysis machine that is relatively compact, portable and that can be used in an unassisted manner (with prior device education and training) is the perfect solution to encourage more patients to treat themselves and gives them full freedom to travel and choose the location of treatment. That is where solutions from NxStage Medical and others have made a difference. Similarly due consideration must be given to ancillary equipment. For example, oxygen concentrators and other respiratory care devices must not be bulky and should allow for space constraints in urban dwellings.

### Easy maintainability, calibration and upgrades:

Home use devices may require routine maintenance for continued optimal performance. Devices should be designed for easy maintenance, and upgrades should be straightforward. This helps extend the lifespan of the devices and ensures that users can benefit from ongoing advancements in technology. Thus, device maintenance includes adaptive (e.g. keeps pace with the changing environment), perfective (e.g. improve performance), corrective (e.g. corrects discovered problems), or preventive (e.g., corrects latent faults in the product before they become operational faults).

Designing home-use devices to eliminate the need for calibration or having minimal steps that the user needs to perform to calibrate the device makes it user-friendly and encourages users to use the device comfortably and confidently in homecare setting.

### Internal enterprise value chain implications

#### **Raw material sourcing, manufacturing considerations and quality control/ assurance considerations**

Specific raw material needs: Home care devices may require specialized materials, such as medical-grade plastics and antimicrobial coatings, to comply with health and safety standards. Ensuring that raw materials meet regulatory requirements contributes to the overall quality and safety of the devices. Looking at the large number of suppliers, manufacturers may need to diversify their supplier base to mitigate risks associated with dependence on a single source and may need to navigate complex international supply chains, considering factors like tariffs, shipping delays, and geopolitical issues. Sourcing of raw Material components through certified suppliers will become essential towards optimizing incoming inspections.

Forecasting is crucial to meet the demand for home care devices, as these products may experience quicker changes to market demands. Trunk stock planning and visibility is another area that will have a significant impact on the planning process. Furthermore, tracking and maintaining automatic replenishments of ancillary supplies (e.g., oxygen cylinders, reagents, masks, filters etc.) will be a tricky challenge. In most cases this will be a DSD (Direct-Store-Delivery) or Service-to-Cash type of a model with complex demand variations. This will be like what is seen in today in the beverage industry while restocking vending machines. Given these complexities, the number of Home Healthcare Supply Management organizations will grow exponentially.

Home care devices often require adherence to strict quality standards and regulatory guidelines. Manufacturers must implement robust quality control measures to ensure product safety and efficacy along with rigorous testing protocols and certification processes to guarantee that home care devices meet industry and regulatory standards. A greater adoption of FMEA (Failure Mode Effect Analysis) to determine severity, risk, and occurrence of several device failure modes will be essential to mitigate risks, through a thorough understanding of cause and effect of failures. This is

especially critical in the case of Class 2B devices such as incubators, dialysis machines, blood bags etc. Quality control and compliance must also meet the jurisdiction control requirements in terms of restrictions on the country of origin of the raw material components or adherence to country specific product labelling requirements

Distributed manufacturing might become essential to address high volume demand and reduce product distribution costs by leveraging CMOs (Contract Manufacturing Organizations) near dense patient demographic locations. This will further increase the challenges associated with demand transparency, inventory tracking, and CMO collaboration. Furthermore, with the increasing trend of incorporating smart technologies into homecare devices (IoT, connectivity, data monitoring), manufacturers need to integrate these technologies seamlessly into their production processes.

### Outbound Logistics/ Distribution:

Efficient outbound logistics are crucial for ensuring that homecare devices reach customers on time and without damage, which is essential for the health and well-being of patients. Proper outbound logistics management will ensure optimized transportation, packaging, distribution and inventory carrying costs. This is important for maintaining competitiveness and profitability in the homecare device business. A lot of thought needs to go into designing secure packaging, labelling and handling, to maintain the integrity of the products during transportation, delivery and usage. Efficient return logistics for defective or damaged products is essential for maintaining customer trust and providing effective customer support, which is where companies like Amazon can bring a lot of value. Outbound logistics are critical in managing international shipments, dealing with customs regulations, and ensuring smooth cross-border movements.

### Sustainability considerations:

The trend towards sustainable and eco-friendly materials may impact the choice of raw materials and manufacturing processes. Due consideration must be given to the need to implement effective waste management practices, especially if the devices involve disposable components.

### Customer support and post market surveillance:

Post-market surveillance is crucial for monitoring the safety and performance of homecare devices after they have been released into the market. Compliance with regulatory requirements for post-market surveillance is essential to ensure that any emerging risks or concerns are promptly addressed. Robust customer support systems are essential for addressing user queries, troubleshooting issues, and providing assistance with device usage and adverse events. Leveraging technologies like OTA for software upgrades, logistic management for device recalls, and UID tracking for effective complaint handling ensures a strong post-market surveillance process. If a home care device or its consumables are found to be defective, unsafe, or non-compliant, a recall may be necessary to mitigate risks to users. Establishing a robust adverse event reporting system is essential for the prompt identification and reporting of any adverse events related to home care devices or consumables. This combined with a well-defined process for investigating reported adverse events and implementing corrective actions is crucial to address safety concerns and prevent recurrence.

Implementing anti-counterfeiting measures in consumables involves using authentication technologies, such as QR codes, holograms, or RFID to verify the authenticity of the product. Ensuring the security of the supply chain is essential to prevent counterfeit consumables from entering the market. This involves collaboration with trusted suppliers and rigorous quality control measures.

Manufacturer should ensure condition-based monitoring, which involves using advanced technologies to monitor the device's performance in real-time, detect any deviations from normal functioning and take preventive and corrective actions as needed to ensure safety and effectiveness in product use.

Maintaining comprehensive documentation and timely reporting to regulatory authorities is crucial to demonstrate compliance and ensure ongoing market authorization.

**Device pricing and distribution:** Efficient production processes and cost-effective materials can contribute to lowering production costs, allowing for competitive pricing. Understanding the market

demand and analyzing the competitive landscape is essential. Pricing should be competitive enough to attract customers. The distribution network plays a vital role in the accessibility of home care devices. The pricing strategy should consider the costs associated with distribution, including transportation, warehousing, and any commissions for distributors.

If home care devices come with additional services or warranties, these should be factored into the overall pricing strategy. Seamless integration with e-commerce platforms will be required for users to buy home care devices, easily reorder consumables, replacement parts, or accessories directly through the platforms.

Establish robust supply chain management systems to ensure a steady and reliable supply of consumables. Consider partnerships with local pharmacies or online platforms for convenient ordering and delivery.

### Improving Pricing outcomes through Generative AI:

**Pricing optimization:** Generative AI can help decide on the best price of the home care devices by analyzing historical data, current market trends, and customer willingness to pay. This dynamic pricing model enables MedTech companies to adapt quickly to market changes. Once deployed – and as companies collect more data over time – a fine-tuned custom large language model continues to learn and adjust strategies based on the new and changing trends it identifies.

**Demand forecasting:** Depending on the scope and usage of home care devices, customer demand may hold steady or fluctuate significantly. This complicates a manufacturer's ability to accurately forecast and implement timely and realistic price structures. As generative AI models evolve, they will get better at forecasting customer demand based on historical and real-time data, considering nuanced customer, product, and geographic characteristics, such as seasonality. Companies can use these insights to adjust pricing strategies, helping MedTech companies prepare for changing demand.

### As a Service Model

Transitioning home care devices to a service model involves offering not just the product itself but a comprehensive solution that addresses ongoing needs and provides added value to consumers. Here are some thoughts to consider for implementing a service model for home care devices:

Consider a subscription services that include regular maintenance, updates, and access to additional features or services. This model provides a steady stream of revenue and encourages customer loyalty. Implement remote monitoring capabilities in the home care devices to allow for real-time data collection. This enables proactive support, timely interventions, and personalized assistance based on individual needs and provide this as a pay by use service for patients and healthcare professionals.

Use data analytics and AI to predict when a device might require maintenance or replacement parts. Proactively addressing issues can reduce downtime for users and improve overall satisfaction.

Provide ongoing training and educational materials to users, caregivers, and healthcare professionals. This ensures that they fully understand how to use the devices effectively and optimally.

Integrate telehealth features into the home care devices, allowing users to connect with healthcare professionals for remote consultations. This adds a layer of medical support to the service offering.

Tailor the service model to the specific needs of individual users. This could include personalized health plans, device settings, and support services based on user profiles and health conditions.

Offer regular software updates to enhance device functionality, improve security, and introduce new features. Keeping the devices up-to-date ensures that users continue to receive value from their investment.

Foster a community around your home care devices, facilitating discussions, knowledge-sharing, and peer support. This not only enhances the user experience but also provides valuable insights for ongoing improvements.

Design the service model to be scalable and adaptable to evolving user needs. As users' health conditions change, the service should be flexible enough to accommodate new requirements.

Adopting a service-oriented approach, home care device providers can not only sell products but also establish long-term relationships with users, improving health outcomes and creating a sustainable business model

### Device leasing as a financing option

One aspect of the affordability of home use devices is the price point which might make outright purchase an unsuitable option for many of the home use patients. Leasing of the device may also be a very effective option to reduce the upfront cost impact and distribute the burden with a time-based payment scheme. This will however need to have congruence of the payers, the provider and the patient. Furthermore, enterprise leasing solutions with support for flexible payment models, and integration of 3<sup>rd</sup> Party Business Services will be required to help mature this option further for the Device Manufacturers.

### Future of Homecare devices:

Miniaturization of various components, including microprocessors and nanotechnology, will make possible advances to many types of medical devices used outside formal health care settings. Some of the devices will be embedded in common household objects, such as a biosensing chip in a toothbrush that will check blood sugar and bacteria levels; smart bandages made of fiber that will detect bacteria or a virus in a wound and then recommend appropriate treatment; and smart T-shirts that will monitor the wearer's vital signs in real time. Novel handheld devices may provide new capabilities for home health care, such as skin surface mapping, an imaging technology that will track changes in moles to detect malignancies; biosensors that will perform as portable laboratories; and alternative input devices such as eye blinks (electromyography) or brain activity (electroencephalography) that will facilitate hands-free device control, which will be especially useful for people with limited use of their hands (e.g., people with paralysis or arthritis).

The advancement of technology-driven innovations paves the way for more holistic home care. While there are obvious benefits offered by networked medical devices, this evolving technology raises new safety issues that must be considered when using these in a home care environment.

### Technology Shaping the Home Care Industry:

Traditionally, medical devices have been designed to operate in a stand-alone manner. However, recent years have seen a growth in their ability to communicate information, allowing them to be interoperable with other systems. Technological advancements have led to migration of medical devices into home care setting and has enabled remote patient monitoring as an excellent growth strategy for medical device companies. Several players have integrated the internet of things (IoT) with medical devices, which facilitate patient-provider communication. At-home technologies such as wearable devices and Telemedicine have been widely adopted thanks to the built-in connectivity of medical devices through mobile applications, cloud services, and machine-to-machine connections.

Here are [Top 10 technology trends](#) that are impacting the Home care industry.

When implemented, these At-Home Digital Healthcare Tools may enhance chronic disease management, improve access to care, promote affordability, and deliver individualized service. As an example, medical devices with cameras and smart sensors can be used to track patient movements and behaviors, monitor vital signs, detect falls in the home. Monitors can collect and transmit a variety of data to remote healthcare providers, eliminating the need to visit a clinic or to call in.

Telehealth platforms can provide reminders to people at home, to take medications, measure their blood pressure, perform physical therapy, or schedule follow-up appointments.

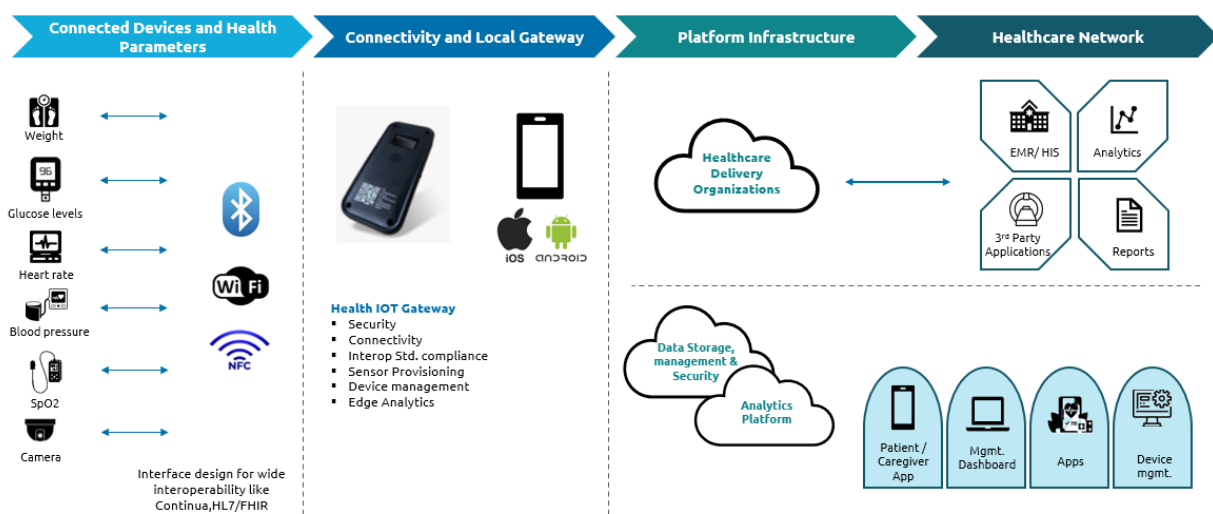
Smart home solutions like a handheld ultrasound that connects to a smartphone can allow patients to self-scan, send the image to their provider, and have a consultation, and the data can even be integrated into their electronic medical records.

Assistive robots for home care may address challenges like caregiver shortage and social isolation by providing companionship and assistance. Such examples include Socially Assistive Robots (SARs),

robotic companions, nursing robots, and sanitation robots. Innovations like robotic devices and VR headsets enable remote neurorehabilitation, facilitating faster recovery and guided exercises for stroke patients.

There is a growing need for AI personalized solutions including chatbots, predictive analytics, and NLP models. AI-powered wearable devices like smartwatches and fitness trackers are already equipped with AI algorithms capable of tracking vital signs, sleep patterns, and physical activity.

IoT-enabled home care devices can transmit data to the cloud, allowing healthcare providers to remotely monitor patients in real time. AI algorithms can analyze this data to provide immediate feedback, enabling timely interventions and adjustments to treatment plans. AI algorithms can process and analyze vast amounts of data generated by IoT devices. This analysis can yield personalized insights into individual health trends, helping users and healthcare professionals make informed decisions about lifestyle changes, treatment adjustments, or preventive measures. This will enable care being delivered more efficiently from homes, reduce hospitalization and rehospitalizations, enable more proactive disease management and enable larger patient numbers to be managed effectively by limited number of clinicians.



Leveraging IoT technology, the devices enable the creation of interconnected ecosystems where various devices and applications work together seamlessly and stay interactive. The product companies and service providers will be using it for continuing with their services even after the product has been actually sold.

IoT sensors in medical devices can collect data on usage patterns and device performance. AI algorithms can predict potential issues or malfunctions, allowing for proactive maintenance and reducing the risk of device failure while the devices are being used from homes.

### Data engineering:

In the context of supporting homecare intelligently for independent living, there is a requirement for several types of data to be continuously captured, analysed, and stored using the diverse types of technologies like cloud, mobile platforms, etc. to name a few. Data from demographic data, personal health data, behavioural/activity data to environmental data needs to be fetched to build in the correlation. All these types of data can now be collected using either automated, embedded systems with sensor technologies. This data is crucial for effective and efficient management and treatment; for example, shared health-related data between different hospitals and departments can help clinicians make real-time decisions on patients' health and treatment options providing for personalized treatment plans for individual patients.

Homecare IoT devices collect a multitude of patient health data and environmental data. Hence, it is important for data collection devices to get informed consent from patients before starting data collection to comply with data privacy regulations and guidelines. This can be achieved by obtaining consent from the patient during the registration process where the type of data collected, and storage methods are informed to the patient and a consent is obtained.



## Connectivity and integration:

The design of home medical devices must support remote monitoring capabilities. Integration with smartphones and other smart devices allows for data sharing, remote monitoring, and real-time feedback. This connectivity enhances the overall user experience and provides healthcare professionals with valuable data for monitoring patient health. Therefore, device interoperability and adherence to standard data formats are essential for seamlessly connecting home care devices with various backend self-managing and information systems. This will leverage the power of data to build autonomous healthcare systems in the future.

Moreover, data interoperability with EHRs and EMRs is also crucial to ensure proper data storage and data ownership. Here, health data acquired through homecare sensors are stored in the HER and moved to EMR for further analysis from the care provider interface.

For lasting success, device manufacturers should collaborate with healthcare providers to integrate home care devices into broader health management programs. This can include regular check-ins, consultations, and a more holistic approach to patient care.

## Network communication:

The quality and speed of the network are imperative for positive outcomes in home care. Faster network connectivity enables better care from home - reducing the strain on hospitals and allowing for better, more reliable sharing of data. For instance, when it comes to the home care industry, the 5G network opens up possibilities for better point-of-care diagnostics, more reliable home monitoring and even faster data transfers between care staff, hospitals and care managers or providers.

Elderly living in more rural areas will also have access to better technology via the internet, meaning there are no delays in care, wherever they are living.

## Data security and privacy:

Given the sensitive nature of health data, designers and engineers must prioritize robust security measures to protect user information and maintain patient privacy. IoT based home devices are vulnerable to security threats and identifying potential security breaches is crucial. Implementing robust encryption protocols to protect sensitive health information is the key both in rest and transit. Several Regulations and Acts exist to protect the health-related data of individuals. For example, in the USA, the Health Insurance Portability and Accountability Act (HIPAA) helps to mandate the adoption of Federal privacy protections for individual health data. Similarly, in other countries, such as the UK, the General Data Protection Regulation (GDPR) help to mandate the proper collection and processing of personal information, with one of the strictest provisions regarding privacy and security. In addition to health-related devices, the increasing popularity of mobile and cloud computing necessitates regulation and compliance checks for mobile applications and cloud-based services used in clinical settings. This includes determining whether software used in clinical and wellness applications should fall under Software as a Medical Device (SaMD) provisions

## Compliance to safety and regulatory compliance needs:

Designers must adhere to regulatory standards and compliance requirements specific to medical devices' design. Ensuring that devices meet safety, performance and quality standards is crucial to gaining approval for home use environment. In the US compliance with 21CFR Parts 801,803, 807,812, 814 &820 will be considered essential. Similarly, compliance with UDI requirements as well as e-MDR and GDPR for traceability and data protection will be required given the global distributed nature of the patient community

## Affordability and accessibility:

Designing cost-effective devices is essential to make them accessible to a broader population. This involves optimizing manufacturing processes, materials, and technologies to keep the overall cost of the devices reasonable. One point to note here is the fact that an off-label or used device market could mushroom in many parts of the world especially in regions with high levels of poverty. Such a

market would not only pose a risk to the user but also result in a lot of chain of custody and traceability challenges for the device manufacturer in case of recalls

### Continuous learning through Machine Learning

Machine Learning algorithms enable continuous improvement of AI models over time. As more data becomes available, these algorithms can refine their predictions, leading to better accuracy and more effective personalized insights. However, a challenge exists in the adoption of AI due to the complexity and inconsistency of regulatory processes, including the lack of guidance for the approval and validation of these devices and technologies for clinical use and care. Moreover, different levels of approval can be applied to regulate data accessibility in healthcare that may appear inconsistent or incongruent with potential healthcare benefits. There may also be complexities associated with the regulation of technologies that utilize AI or ML, such as the 'blackbox' nature of these technologies and the issue of how sensitive health data is collected and used. A balance will eventually evolve between technological innovations and regulations to ensure the safety of the users and bringing of value-based health care outcomes.

Thus, there will be the need for Explainable AI which refers to the use of techniques that help users of AI technology to comprehend the decision-making process of AI systems. It is important for AI systems, especially in healthcare setups to be explainable, to ensure that users trust the technology and understand where it could possibly go wrong or may require additional analysis to be done by clinician.

### How could technology companies like Google and Amazon provide value in home care market:

Companies like Amazon and Google are likely to play a significant role in the home care device market, given their expertise in technology, data analytics, and consumer-centric services.

They can serve as marketplaces where consumers can purchase home care devices and also access a variety of related services, apps, and subscriptions. Their smart home systems could be leveraged to connect home care devices and provide an integrated system. Amazon is setting up initiatives to transform pharmacy, the medical supply chain, health insurance, and care delivery. Amazon is leveraging its delivery power to penetrate the medical supplies distribution space and using its massive employee base to explore telehealth .

When it comes to helping the elderly live more independently, home companions like Amazon Alexa and Google Home have been praised as a solution for everything from companionship to helping take medication on time. These companies possess robust data analytics capabilities and AI technologies which can be utilized alongside their health cloud platform to offer personalized insights, predictive analytics, and health monitoring features. This enhances the functionality of home care devices and other wearables.

Apple is using its popular consumer-facing products, like the Apple Watch and iPhone, to forge partnerships with payers, health systems, and clinical researchers. Apple has been enhancing the number of health-related features accessible on its Watch to establish the wearable as a clinical tool for medical research.

Microsoft, along with Amazon and Google is asserting dominance in the healthcare cloud market with its strength in data storage and analytics including addressing interoperability aspects with EHR/EMR,

Amazon and Google can enable formation of partnerships with healthcare providers, MedTech companies, and insurance companies to create comprehensive health and wellness ecosystems. This could involve sharing health data securely and integrating their services into broader healthcare initiatives. Amazon and Google both have a global presence, allowing MedTech companies to expand their influence in the home care device market across various regions. They can facilitate the dissemination of technology and healthcare solutions on a global scale.

## Challenges to ensure safety and effectiveness of the solution:

### Payment models

With the 'uberisation' of healthcare and the shift towards patient-centered care models, insurance coverage and reimbursement policies for homecare are expected to improve. However, traditional fee-for-service payment models incentivize volume of care rather than outcome of care. This will affect the adoption of homecare technology and services by both clinicians and patients as the model focuses more on payment based on services delivered rather than the quality of outcome of care. This may also incentivize the deployment of costly homecare technologies without necessarily considering their value.

Therefore, homecare device manufacturers, insurance agencies and healthcare providers need to explore better payment models, like episode-of-care payment models that focus on quality of care while also ensuring fair reimbursement to all stakeholders (payers and healthcare providers). Improved payment models and reimbursement policies should help healthcare providers envision positive returns on their investment.

### Usability and patient preferences

Improved usability plays a crucial role in adoption of homecare technology among patients and their immediate family members (caregivers). This ensures seamless navigation and utilization of homecare technology with limited medical knowledge. The key to successful integration lies in designing solutions that seamlessly connect with existing supporting devices and environments, facilitating a user-friendly experience.

### Patient safety

Common patient safety risk in home care setups include misuse of devices, infection control and lack of education among patients and family caregivers. This brings in the need for laborious processes like initial safety assessment, risk identification and implementation of mitigation strategies at the patient end before setting up a home-care environment. This may hinder the adoption of homecare technology by patients and healthcare providers.

### Challenges in data security:

Healthcare providers are entrusted with safeguarding vast amounts of personal health information, including health monitoring data, medical histories, treatment plans and billing details. Owing to the sensitive and confidential nature of personal health information and considering the penalties and legal ramifications associated with data breaches, healthcare premises mostly do not want the data to leave their premises. This poses a major challenge towards the adoption of home care technology.

Data security challenges can be mitigated by adopting robust security measures for data access, transfer and processing. Hence, it is essential that manufacturers invest in data security practices like transport layer security, data encryption, security audits, risk assessment and regulatory compliance that will help convince healthcare organizations to trust the safety of these devices.

### Interoperability challenges

Home care technologies often operate within a fragmented ecosystem where different devices and platforms use different data formats and protocols. This makes it difficult to achieve data interoperability between home care devices and EHRs. Moreover, integration of modern home care technologies with outdated infrastructure and legacy systems can pose a great threat to the adoption of home care technologies by healthcare providers.

### Regulatory compliance

Navigating regulatory hurdles presents significant challenges for the implementation and adoption of home care technology. Compliance with complex regulations such as HIPAA and GDPR adds administrative burden and costs, while varying interoperability standards hinder seamless data exchange between home care technologies and existing healthcare systems. Additionally, medical device regulatory clearance (FDA, EU-MDR etc.) and strict data security regulations pose challenges towards development and implementation of home care technology.

## Device labeling:

The focus of device labeling should be the end users. Labeling information should be tailored based on the expected user's skill level including what the user will see, hear and feel with devices' use.

If in-house expertise is not available, manufacturers should consult experts when designing user material. Consumer material, whether in electronic or booklet must include all information for safe installation, use, storage, servicing, and maintenance of the device to be provided to the user.

For instance, a prefilled syringe allowing a patient to administer a measured dose of medication at home could help treat or prevent a specific disease when used correctly. If used incorrectly, a number of adverse effects may occur, such as injury from improper handling of the needle or an incomplete dose of medication. To avoid such scenarios, it's good to design labels with clear instructions on how to correctly handle and use the device along with other necessary information.

FDA's Home Use Device Initiative: The FDA's Home Use Device initiative provides resources and information about medical products used in home care setting, as well as information about the agency's home use initiative to improve the safe use of medical devices in the home. FDA takes proactive steps to assure safety, quality and usability of devices labeled for home use, as well as to provide more information for home care recipients and caregivers to support their safe use.

## Home use challenges:

Easy availability and accessibility of consumables such as test strips, cartridges, or disposable parts can be challenging. Maintaining a steady stock is crucial to avoid interruptions in device usage. Consumables can contribute significantly to the overall cost of using home care devices and thus affordability is key along with extend of insurance coverage.

There have been many instances of patient harm from untrained or improper use of at-home devices. Medication errors can occur when changing infusion pumps or skin injuries when the electrodes from a cardiac monitor are applied incorrectly. Fatalities can occur if a home ventilator alarm fails to activate or goes unheard, or if the venous needle becomes dislodged during use of a hemodialysis machine. Some home care devices and their consumables may have specific storage requirements (e.g., temperature, humidity). Ensuring proper storage conditions is crucial for maintaining the effectiveness of the devices and consumables.

Lack of comprehensive training and educational resources for users can result in improper device usage, misinterpretation of results, or neglect of essential device maintenance practices. As more and more patients and health systems embrace and expand various remote monitoring and hospital-at-home initiatives, users must be adequately trained on proper handling and usage of devices. Incorrect handling can lead to inaccurate results or device damage. Providing training materials in multiple languages and addressing literacy levels is important to ensure that users can understand and follow instructions effectively.

Device failure or malfunction can occur unexpectedly. Ensuring the reliability of home care devices is critical, and addressing any recurring issues promptly is essential. Implementing predictive maintenance strategies may require advanced monitoring capabilities and data analytics. Integrating these features into devices and ensuring they are user-friendly leveraging IoT platforms is the key.

Implement remote monitoring capabilities in devices to track usage patterns and detect potential issues in real-time. This allows for proactive support and timely interventions. Design devices with a user-friendly interface, incorporating features that minimize the risk of user error. Consider ergonomic design principles to enhance ease of use. Provide regular software updates to address bugs, improve device performance, and introduce new features. Users should be informed and encouraged to install updates to ensure optimal functionality.

## Conclusion

### Empowering home-based healthcare: Overcoming challenges for future success

In conclusion, in home smart solutions will become a critical for fulfilling the needs of the ever-growing ageing population and with an increasing number of chronic diseases amongst this population.

They need targeted and efficient healthcare delivery within the comfort of one's own home. This will enable proactive, personalized and patient empowered care which will eventually enable significant reduction in hospitalization/rehospitalization especially among the chronically ill population who account for significant portion of overall healthcare expenses.

While user-centric design, affordability, new-age technologies, and excellent data analytics drive successful deployment, obstacles such as effective operating and reimbursement models, data privacy concerns, interoperability needs, and regulatory ambiguity impede widespread acceptance among stakeholders' home care devices play an important role in improving clinical outcomes through value-based and patient-centered care delivery. To reach their full potential, coordinated efforts are required to strengthen the payment and regulatory landscape, as well as the implementation of strong data security and interoperability measures. These challenges, when overcome, may promote the adoption of home care devices, ushering in a new era of empowered, proactive, and personalised home-based healthcare.

Additionally manufacturing of home care devices demands a comprehensive approach that encompasses raw material selection, supply chain management, planning and procurement strategies, quality control measures, technological integration, sustainability considerations, regulatory compliance, and post-market surveillance. Manufacturers need to stay adaptable and responsive to changes in the market and regulatory landscape to ensure the success of their home care device manufacturing processes

A well-thought-out pricing strategy for home care devices should consider a combination of production costs, market dynamics, distribution networks, and consumer perceptions to ensure competitiveness and profitability. Establish robust supply chain management systems to ensure a steady and reliable supply of consumables. Consider partnerships with local pharmacies or online platforms for convenient ordering and delivery.

## About Sogeti

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