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CXO'S GUIDE DOCUMENT FOR INTEGRATING WEARABLES WITH TELEHEALTH PLATFORMS

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INTRODUCTION

According to a survey report published by Accenture in HIMSS 18, the consumer use of wearables in the US for health purposes has grown from 9% in 2014 to 33% in 2018. The study also found that this rapid growth was fueled by consumers' demand for wearables to play a more active role in managing their health.

The benefits of integrating wearables with Electronic Medical Records (EMR) was also highlighted in a recent report from BCC Research, which predicts the global market for wearable medical devices to grow from $8.8 Billion in 2018 to $30 Billion by 2023. The report suggests that the three primary benefits of wearable medical devices include the ability of a physician to remotely monitor their patients, make informed decisions with continuous biometric data, and expand the reach of patient care to geographically isolated areas.

Large telehealth companies are currently partnering with fitness tracking and smart-watch brands, to address the early adopter market. For example, American Well's Apple Heart Study uses data collected from Apple Watch to identify irregular heart rhythms, including those from potentially serious heart conditions such as atrial fibrillation. The impact of having wearables in mid-sized to large telehealth platforms are further discussed in Section 1 of this document.

There are design challenges in building a wearable medical device platform in terms of hardware, software, EMR, analytics, privacy, and AI. These challenges are discussed in Section 2 of this document.

Integration of a wearable system to a telehealth platform can be a complex process and has additional regulatory challenges in terms of hardware, network, privacy, database, and EMR. These additional regulatory challenges have been discussed in Section 3 of this document.

IMPACT OF WEARABLE IN TELEHEALTH

Patient Retention

One of the biggest challenges for CXOs of telehealth platforms is patient retention. A study by netsolutions.com identifies patient engagement and retention as one of the top five challenges for telehealth platforms today. Adding a wearable device can be a strategy to mitigate this risk since there is a strong interest among consumers in using wearable devices. A survey report by BCC found that currently, 16% of these consumers report using wearable sensors to track health, but 48% would consider using it in the future. For people aged 55+, only 6% are using wearable devices, but 36% say they would consider using a wearable. Similarly, in the age group of 36-55, only 15% use, but 50% would consider use in the future.

Rock Health's 'Digital Health Consumer Adoption 2018' report found that wearable use is shifting towards managing health conditions. The use of wearables to manage a diagnosis increased by 10% from the previous year, while the use of wearables to monitor physical activity went down by 10%. The increased adoption rate of wearables in health care can be best utilized in the remote monitoring of patients.

Cost of delivery

CXOs of telehealth platforms could also reduce individual cost of care by introducing wearable medical devices into their platforms. The drastic cost saving in delivery of care pathways will be due to avoiding in-hospital patient monitoring costs as well as avoiding medical procedures thanks to early detection of chronic conditions. A 2017 study by researchers at the IQVIA Institute for Human Data Science projected annual savings of more than $7 billion to the US health care system through the use of mHealth tools such as apps and wearables for patients suffering from chronic diseases.
The biggest reduction in the cost of delivery of care will be in the elderly care segment, by eliminating the cost of continuous monitoring by caregivers such as nurses and physicians. In a 2016 report, Frost & Sullivan estimates this market size to be about US$5 Billion.

Increased Profit

CXOs can position a wearable medical device as a strategy for revenue growth. Continuous monitoring of biometrics with wearable medical devices can aid the management of chronic cardiovascular and respiratory conditions. Currently, the lack of proper management of these two conditions alone causes 40 million annual deaths (Frost & Sullivan, 2018). Telehealth companies focusing on these two areas of care will immediately profit from high adoption rates. In a 2016 report, Frost & Sullivan estimates this market size to be about US$25 Billion.
In the US alone more than 3.5 million seniors are turning 65 every year, and 90% of them have at least one chronic condition (Frost & Sullivan, 2018). Telehealth companies working in older and geriatric patients, will immediately profit by addressing the requirements of this market.
CXOs of telehealth companies working with insurance providers could implement remote monitoring platforms thereby generating additional revenue through savings from reduced treatment costs and hospital stays. One of the largest and oldest health insurance companies in the US, John Hancock, is already moving away from selling traditional life insurance towards policies that record the exercise activities and biometric data of its customers using wearables such as Fitbit or Apple Watch.

DESIGNING CHALLENGES

A recent BCC Report predicts that the US wearable medical devices market will grow from $2.8 Billion in 2018 to $9.1 Billion in 2023 at a CAGR of 26.3%. This market will primarily be fragmented between medical device manufacturers who are privately labeling their platform and large telehealth platforms building their own wearable medical devices. CXOs of a telehealth platform aiming to develop their own wearable medical device will need to meet the regulatory standards of medical device manufacturers in design and manufacturing of the devices and associated software platforms. The sub-sections below explain in detail the various designing challenges pertinent to the design, development, manufacture and sale of wearable medical devices.

QMS

CXOs of a telehealth platform aiming to build their own wearable medical device will need to build a quality management system (QMS). The QMS is the first step towards getting FDA approval as a medical device and ensures that the manufacturer is following good manufacturing practices (GMP).
The most widely accepted standard for wearable medical devices is ISO 13485 (Latest iteration: ISO 13485:2016). ISO 13485:2016 has evolved from and supersedes multiple earlier standards and documents:

1. EN 46001:1997 - Specification for application of EN ISO 9001 to the manufacture of medical devices
2. EN 46002:1997 - Specification for application of EN ISO 9002 to the manufacture of medical devices
3. ISO 13485:1996 and 2003 - earlier iterations of the standard, and,
4. ISO 13488:1996 - Quality systems. Medical devices.

Software and App

CXOs of a telehealth platform aiming to build their own wearable medical device will also have to implement the international standard IEC 62304 for developing medical device software and managing software life cycle processes. IEC 62304 can be used as a benchmark to comply with regulatory requirements from both US and EU markets. The general requirements under this standard include implementing a QMS, building a software risk management strategy and having a software safety classification.
Meeting the IEC 62304 standards is more challenging in the case of wearable medical devices compared to mHealth platforms, since they have software both at the device level (i.e., firmware) and at the app level.

EMR

CXOs of a telehealth platform aiming to integrate or build their own wearable medical device will have to implement additional Electronic Medical Records (EMR) modules pertaining to clinical, diagnostics, workflow and financial. If the CXO is privately labeling a wearable medical device, they should ensure that the original equipment manufacturer (OEM) adhere to their current EMR standards. The EMR typically operates within an open framework such as FHIR/HL7 framework (https://www.hl7.org/fhir/device.html). However other EMR framework such as EN 13606 (part of CEN's TC/251) is quite popular in the EU. Also, sometimes adherence to further EHR architecture standards like ISO 18308 is required.

Predictive Analytics

CXOs of a telehealth platform aiming to build their own wearable medical device, as well as build their own analytics and dashboard should adhere to ISO 13485:2016 guidelines. However, if the analytics engine claims to make medical diagnoses then this is classified as a software as a medical device (SAMD) system and has to be approved by the FDA. The regulatory guidelines for SAMD are proposed by International Medical Device Regulators Forum (IMDRF) Software as a Medical Device Working Group (WG) in the document numbered - IMDRF/SaMD WG/N41FINAL:2017. Similar guide documents are available for EU in European Commission updated MEDDEV 2.1/6.

The major challenge for CXOs in integrating wearable medical devices in telehealth platforms is understanding the multi-tier regulatory landscape, and then meeting the requirements within a fixed budget and timeframe. The regulatory requirements span across the safety and reliability of the device, secure storage, and sharing of the medical data and its clinical interpretation. The sub-sections below explain in detail the various regulatory requirements pertinent to wearable medical devices.

Hardware

The medical device will need to meet all the directives of a consumer grade electronic product which includes,

1. FCC Certifications – Nearly every electronics device radiates unintentional electromagnetic emissions and must be reviewed to comply with FCC Title 47 Part 15 sub-part B before it can be advertised or sold in the US market. If the device is transmitting data wirelessly to a phone or a cloud the device must be reviewed to comply with FCC Title 47 Part 15 Sub-part C (intentional radiator). Wearable medical devices often have built-in Bluetooth or ZigBee modules, that are regulated under FCC Title 47 Part 15 Sub-part B 15.239 deals which deals with the FM bands.
2. Bluetooth® SIG Certifications –To use Bluetooth® protocols the device will need to have Bluetooth SIG authorization. One can accelerate the certification process by using pre-certified Bluetooth® modules at the design stage.
3. NRTL Safety Certification – Electronic devices generally have additional safety certifications like those granted by a Nationally Recognized Testing Laboratory (NRTL) laboratory. NRTL laboratories are recognized by the Occupational Safety and Health Administration (OSHA) to test product safety standards. Examples of NRTL laboratories are companies like Underwriters Laboratories Inc. (UL), MET Laboratories, Inc. (MET) and TUV Rheinland of North America (TÜV) provide additional safety testing. UL provides a series of testing relevant to wearable medical devices including UL EMC Testing, UL 60601-1 for testing general safety requirement for medical electrical equipment. MET provides a series of testing relevant to wearable medical devices including, Medical Device Safety Testing, Medical Device EMC Testing, IEC 60601-1 Testing, Laser Safety Testing, and Battery Testing & Certification.

CXOs of a telehealth platform aiming to build their own wearable medical device will also have to list their devices with the FDA according to 21 CFR Part 807. This will most often require them to adhere to FDA's Class II device premarket notification requirement 21 CFR Part 807 Subpart E (also known as 510(k)). CXOs often get their application reviewed by an 'Accredited Person' to accelerate the review process. FDA accredited 12 organizations to conduct a primary review of 670 types of devices. By law, FDA must issue a final determination within 30 days after receiving a recommendation from an 'Accredited Person'.

In order to potentially sell the wearable medical device in California, the device will also need to comply with California (USA): Electronic Waste Recycling Act (EWRA) act. EWRA is a comprehensive system for the reuse, recycling, and proper and legal disposal of covered electronic devices.
In order to potentially sell the wearable medical device in Canada, the device will also need to comply with IC requirements for RF exposure in accordance with RSS GEN Issue 3.
In order to potentially sell the wearable medical device in the European Union (EU) the device will also need to comply with the Restriction of Hazardous Substances (RoHS). RoHS, also known as Directive 2002/95/EC, originated in the European Union and restricts the use of specific hazardous materials found in electrical and electronic products (known as EEE). All applicable products in the EU market after July 1, 2006, must pass RoHS compliance. In addition, the product will need to have a declaration of conformity with regard to the EU Directive 1999/5/EC to apply the CE-marking as a non-medical fitness tracker or have a declaration of conformity with regard to the EU Directive Medical Devices Directive 93/42/EEC EC to apply the CE-marking as a medical device. The choice of EU Directive depends on the intended purpose of the use and according to the data supplied by the manufacturer on the labeling, in the instructions and/or in promotional materials.

Network Protocols

CXOs of a telehealth platform integrating a wearable medical device will have to ensure network security. This can be most efficiently implemented by adhering to an NRTL safety certification such as UL 2900-1 standard for software cybersecurity for the network-connectable product. UL 2900-2-1 was developed over a number of years with input from the American National Standards Institute (ANSI) and has now been adopted by the FDA as a standard. The additional regulatory requirement that the telehealth platform might be subjected to includes IEC TR 80001-2-2 Edition 1.0 2012-07 (or AAMI ANSI IECTIR 80001-2-2:2012) for risk management for IT Networks incorporating medical devices. Also, vulnerability disclosures requirement such as IEC ISO29147 First edition 2014-02-15 or HIMSS/NEMA Standard HN 1-2013 can also be implemented.

Data Security

CXOs of a telehealth platform integrating a wearable medical device will have to implement additional HIPAA compliance training programs to lower their risk of regulatory action under HIPAA Title II. Employing an external consultancy or a training group with particular expertise in wearable medical devices to conduct these programs is often the most cost-effective solution. The HHS Office for Civil Rights (OCR), which enforces HIPAA, extended the breach notification rule and its enforcement to healthcare organizations not covered by HIPAA, including vendors of electronic health records (EHRs) and EHR-related systems.
If the CXOs of a telehealth platform chooses to privately label the wearable medical device platform, they need to produce a contract that imposes specific safeguards on the PHI that the medical device manufacturer uses or discloses. If the HIPAA Privacy Rule is violated under false pretenses, the penalties can be up to a $100,000 fine and up to 10 years in prison. Covered entities and individuals who intentionally obtain or disclose PHI in violation of the HIPAA Privacy Rule can be fined up to $50,000 and receive up to one year in prison. HIPAA Title II lays out certain administrative requirements that covered entities must have in place. These requirements include the following,
1. A privacy official must be appointed who is responsible for developing and implementing policies and procedures at a covered entity.
2. Employees, including volunteers and trainees, must be trained on policies and procedures.
3. Appropriate administrative, technical and physical safeguards must be maintained to protect the privacy of PHI in a covered entity.
4. A process for individuals to make complaints concerning policies and procedures must be in place at a covered entity.
5. If PHI is disclosed in violation of its policies and procedures, a covered entity must mitigate, to the furthest extent actionable, any harmful effects.
The CXOs of a telehealth platform integrating a wearable medical device in Europe will also have to take additional General Data Protection Regulation (GDPR) regulations into considerations.

Device Labelling

CXOs of a telehealth platform aiming to build their own wearable medical device will also have to consider device labeling and marking on packages. In the case of FDA, the labeling rules are summarized in 21 CFR Part 801 directive for device labeling, 21 CFR Part 801.15 directive for the use of symbols, 21 CFR Part 820 directive for GMP, and 21 CFR Part 1010 for General Electronic Products. Similarly, labeling rules have to be individually followed for FCC, Bluetooth® SIG and, NRTL Safety Certifications.
In order to potentially sell the wearable medical device in the European Union (EU), the device will need to comply with the CE-marking labeling requirement as mentioned in 93/42/EEC EC. This includes requirements such as the logo has to be a minimum of 5mm in height (unless specified differently in the directive) and remain proportional to the original logo.

The higher cost of new wearable medical devices and lack of favourable reimbursement policies are somewhat inhibiting the rapid growth of wearable medical devices. Although certain glucose monitoring wearables, drug, and insulin delivery systems, and pain management devices are reimbursed in the US, there are large numbers of wearables that measure heart rate and track fitness levels that receive no reimbursement. In November 2018, the CMS (Centers for Medicare and Medicaid Services) issued its final 2019 Physician Fee Schedule and Quality Payment Program, which increased reimbursement for connected care services that enable remote monitoring services with the new CPT (Current Procedural Terminology) codes for Chronic Care Remote Physiologic Monitoring.
The new CPT codes are:

- CPT code 99453: “Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on the use of equipment.”
- CPT code 99454: “Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, every 30 days.”
- CPT code 99457: “Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month.
- CPT 99457: This allows remote patient monitoring services to be performed not only by the physician or qualified healthcare professional but also by “clinical staff”, such as registered nurses and medical assistants.

CXOs of Telehealth companies that primarily focus on insurance reimbursement models and want to immediately implement a wearable medical device in their platform, should actively seek out remote monitoring devices for weight, blood pressure, pulse oximetry, respiratory flow rate. CloudDX and Fora Care have currently built integrable software platforms that can be used with these CPT codes, and have multiple wearable medical devices that comply with the requirements

CASE STUDIES

Apple is the most sold wearable medical device manufacturer in the world, courtesy its Apple Watch. Apple shipped a total of 46.2 million wearables in the year 2018. Here are two case studies about the adoption of Apple Watch and Health and its relevance in Telehealth.

The Apple Heart Study combines the video chat capabilities of American Well, with the wearable medical device capabilities of Apple Watch towards early detection of irregular heart rhythms. In addition to checking the reliability of the system in predicting heart conditions, the study is also designed to fine-tune a potential care pathway that combines telemetry with wearable medical devices for early detection and management of chronic heart conditions. Preliminary results show that wearable technology can safely identify heart rate irregularities that subsequent testing confirmed to be atrial fibrillation, a leading cause of stroke and hospitalization in the United States. Participants connect by video with a physician using technology from American Well. Based on this study we strongly recommend that CXOs of telehealth platforms should emphasize on designing and testing a multi-modal care pathway for chronic disease management that best suits the need of their patient population before launching their final product.

A recent study published in The Journal of the American Medical Association (JAMA) identified multiple reasons why the Apple Health Records available on iPhones may accelerate adoption of Personal Health Records (PHR). This survey conducted by a team of researchers at the University of California, San Diego found that patients are positive towards using Health Records features. The Health Records app uses the widely accepted FHIR (Fast Healthcare Interoperability Resources) standard for transferring electronic medical records, therefore is it inter-operable with electronic health records available in most U.S. hospital systems. Given this study, CXOs of telehealth platforms should perform similar studies to ensure that they have optimized the ease of use of the mobile app and dashboard for the patient, in addition to focusing on the accuracy and reliability of the device itself.

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