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Interoperable devices: Golden Opportunity for Smart Health Ecosystem

28 March 2019 | Features | By Pratheep PS

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The medical device industry is assured for steady growth, with the global annual sales forecast to rise by over 5% a year and reach nearly US$800 billion by 2030. These projections reflect the higher market demand for innovative new devices (like wearables) and also services (emerging health delivery models).

It has been estimated that with lifestyle diseases becoming more prevalent, the doors have unlocked for the huge potential in emerging markets – particularly China and India.

Paving the way for Medical Device Interoperability

In a bid to understand users more closely, manufacturers now, should indeed leverage data and also build intelligence within their products – it is gradually becoming an essential part of the new device value proposition. Data and analytics together allow companies to directly connect with users, placing prevention ahead of treatment and cure, and giving a greater control over individual care. To achieve all this & build a smart health eco-system, medical devices ought to be talking to one another and be 'interoperable'.

'Interoperability' is "the ability to exchange and use information through an electronic interface with another medical/nonmedical product, system, or device." - FDA

However, in the new medical device market, value of the device and data alone will not drive sales. Instead, it is solutions that bundle device, data, and real-time analytics that clinicians, health systems, and also payers will want to buy.

Layers of Interoperable Medical Devices Ecosystem

The idea of ‘connected care’ is all about promptly using interoperability for collaborating with the healthcare facilities whenever you are in the continuum. Hence, in such an ever-changing landscape, the interoperable ecosystem works in five layers. These layers can enhance the landscape further by creating an end-to-end enterprise strategy that provides for improved clinical workflows. Let us examine each level.

Data Sources – As patients and providers gradually accumulate data about single or multiple health events, they all combine to form the enormous source of data. It can range from simple body activity metrics that measure fitness and performance, to critical parameters that are relevant to emergency scenarios.

Monitoring Devices – Monitoring devices are placed to constitute the terminal end of the data capturing systems and also to transmit body vitals to a remote system. They are classified into two – native interoperable devices and non-interoperable devices. Majority of the existing connected medical devices falls under the category of non-native interoperable devices.

Health Data Gateway – The growth of opportunities in the healthcare industry has paved the way for many elements that allow transfer of data from the terminal monitoring devices to Personal Health Records (PHRs). Hence, the gateways serve as a crucial link in the entire healthcare ecosystem.

Data Systems – The fourth layer includes data systems along with the associated applications. Though leading medical device OEMs have already developed proprietary monitoring systems with varying degrees of interoperability, not all devices are compliant with interoperability standards.

Data Consumers – The current healthcare ecosystem is based on a curative care model. Hence, data consumers run the healthcare data collected within the PHRs through analytical tools and then generate insights for various purposes.

Data Establishing Digital Insights and Transformation

As per a 2014 report from EMC and the research firm IDC says that the volume of global healthcare data records was 153 exabytes in the year 2013. The report also projected an annual growth of 48% by 2020. Hence with the huge data, we are in the phase of multi-manufacturer devices, talking to each other and improving the safety and effectiveness of connectivity for the diverse array of medical information.

Looking at such statistics, the US Food and Drug Administration (FDA) has initiated guidance to promote design and also the development of interoperable medical devices, and also to assist the industry and FDA staff to identify the potential of this initiative.

But, does Interoperability really exist?

As mentioned earlier, modernizing healthcare organizations with technology, connecting medical devices, sharing patient data - are all ways to contribute to the continuum of patient care. Digital is a huge buzzword in the healthcare now, with technology playing as the catalyst for change.

As per a recent report by HIMSS Analytics, over 90 per cent of the hospitals use six or more types of devices that are integrated with EHRs (such as defibrillators, electrocardiographs, vital signs monitors, ventilators and infusion pumps) and only a third of hospitals actually integrate medical devices with EHRs today. Such a lack of interoperability creates significant sources of waste and risk to patient safety.

But are we really ready for the ‘change’?

It is true that the promise of digital health has been oversold in the healthcare space for so many years that there are many stakeholders who are, understandably, skeptical about its potential. Major challenges to adopting interoperability include:

- The diversity of data, functions, and systems can simultaneously exist in many states, leading to various hidden vulnerabilities.
- If we go function-by-function, task-by-task basis, there are two or more systems that can be incompatible or not fully integrated.
- Asynchronous evolution of interfaced or interdependent components, that is, legacy components.
- Device makers wish to preserve their proprietary systems.
- Hospitals fear the high cost and also the complexity of upgrading the technical integration.

Part of the reason for limited interoperability goes to the high cost as well as the complexity of medical device integration that

results from the lack of incentives for medical device and also to use open interfaces to establish interchangeable interoperability.

Challenges to Interoperability

In the new medical device market, the value of the device and data alone will not drive sales, instead, solutions that bundle device, data, and real-time analytics for improved decision-making and outcomes are able to deliver actionable information into the existing health information exchanges.

As a result, facilitating the interchange of data among medical devices and EHRs requires hospitals to invest significant resources in developing the custom interfaces and paying for middleware solutions.

Key considerations while implementing interoperability are:

1. **Standardization:** For seamless data transfer, the healthcare industry has defined specific standards, related to documentation, architecture, and so on. Although all these standards are available for free, many solutions and devices use the proprietary elements which in turn restricts the implementation process.
2. **Complex structure:** The advent of wireless technologies has compounded the complexity to develop interoperable systems. Standardization alone cannot guarantee the process. It is necessary to design with significant expertise for supporting the underlying clinical workflows at varying levels.
3. **Lack of resources:** Expertise in implementing healthcare workflows and integration of systems is required for efficient execution. However, healthcare organizations are facing an acute shortage of talent to perform such tasks.
4. **Regulatory and compliance issues:** There is a significant uncertainty about the exact regulatory requirements among the developers of interoperability services. There is no explicit government/private/self-regulatory definition. Moreover, the regulatory bodies are continually drafting new regulations for the upcoming technologies, thus complicating the problem.
5. **Data lifecycle management:** Ownership of the healthcare data is one of the most significant questions still left unanswered among all the groups. If we review the lifecycle of data, each group plays a different role in data generation and processing – with different rights and responsibilities. The current method of data lifecycle management also does not scale up to the rise in the volume of data.
6. **Cybersecurity management:** As the number of connected diagnostic devices and systems is increasing, the data generated is also accessed by a broader ecosystem. Hence, data privacy is being threatened by unauthorized access with minimal safeguards for data theft or leaks.

Connecting the Dots

Though interoperability challenges are many, opportunities are also not less. Healthcare organizations need a holistic look at data sharing strategies that span the full patient care continuum, to be able to deliver on those strategies. The future of care will be all about connecting the dots and sharing data along the value chain. The current healthcare ecosystem is based on a curative care model, which can be converted into a purely preventive care model, with the data-driven technology.

Who Will Lead the Way?

To drive faster adoption of medical device interoperability, incentives for various device companies, must be aligned with those of the other health care stakeholders, who reap the benefits of increased interoperability and adoption of standards. Infact, discussions with medical device industry leaders highlights the fact that although technology enable interoperability, market forces today do not create aligned incentives to produce devices with consistent modes for interoperability.

Providers accrue benefit from medical device interoperability at $33 billion, primarily due to productivity gains from improved workflow.

Collaborate and establish an ecosystem

In the current scenario, executing over both business and operating model choices will require capabilities from an expanded external network. While M&A activity are intended to build scale and diversify portfolio, the shift to services and intelligence should generate deal focused on corresponding capabilities, both within as well as outside the value chain. Medical device companies hence, need to institute a systemic process and identify strategic alliance partners along with san internal capability to effectively manage their ecosystem.

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