QuEST Global Point of View

Interoperable Medical Devices:
Has Covid-19 Brought the Right Opportunity to Build a Smart Healthcare Ecosystem?

As the Covid-19 pandemic sweeps around the world, the world is waking up to a new normal. A few countries are exiting from lockdown, others introducing more stringent lockdown, and yet others relying on the resilience of their health care systems to bring in changes that can predict and preempt such catastrophes in the future. Healthcare systems and all related products and services are being urged to adapt to this new world wherein the old ways of working are more or less obsolete. Just like the Coronavirus that changes parts of their genetic code as part of their lifecycle, our healthcare ecosystem needs to 'mutate' at pace and scale.

Prior to the pandemic, the medical devices industry was 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 reflected the higher market demand for innovative new devices (like wearables) and also services (emerging health delivery models). The current situation has only catalyzed this growth. Moody's Investor Services recently published a report expecting the overall growth of the Medical device market to drop to 2-4% for the next 12-18 month period:

"We expect a pullback in consumption in the first half of the year followed by a moderate recovery, assuming global efforts to arrest the spread of coronavirus are successful," - says Scott Tuhay, Moody's Vice President.

Paving the way for medical device interoperability

In a bid to understand users more closely, medical device manufacturers should now 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 these companies to connect directly with users, placing prevention ahead of treatment and cure and giving a greater control over individual healthcare. In order to achieve all this and to build a smart healthcare ecosystem for the future, 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, clinicians, health systems and payers will want to buy complete solutions that bundle device, data, and real-time analytics.

Layers of interoperable medical devices ecosystem

The idea of 'connected care' is all about promptly using interoperability for collaborating with various healthcare facilities when inside the continuum. In a dynamic 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.

1. **Data Sources** – As patients and providers gradually accumulate data about single or multiple health events, they combine to form an 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.
2. **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-native interoperable devices. Majority of the existing connected medical devices fall under the category of non-native interoperable devices.
3. **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.

4. **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.
5. **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

According to a 2014 report from EMC and research firm IDC, 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 inflow, 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, and sharing patient data -- are all ways to contribute to the continuum of patient care. Digital is a huge buzzword in healthcare now, with technology catalyzing the change.
A recent report by HIMSS Analytics states that 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. This lack of interoperability creates significant sources of waste, and poses serious 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 technical integration.

Part of the reason for limited interoperability goes is the high cost as well as the complexity of medical device integration that results from the lack of incentives for medical devices, and also to use open interfaces to establish interchangeable interoperability.

Challenges to interoperability

In the emerging medical devices market, the value of the device and data alone will not drive sales. Only complete solutions that bundle device, data, and real-time analytics for improved decision-making and outcomes will be able to deliver actionable information to 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, restrict 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 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 healthcare data is one of the most significant questions still left unanswered among all the groups involved. 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 the challenges for interoperability are many, the opportunities it can bring along are huge. Healthcare organizations need to take a holistic look at data sharing strategies that span the entire patient care continuum to be able to deliver on those strategies. The future of healthcare 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 data-driven technology.

Who will lead the way?

In order to drive faster adoption of medical device interoperability, incentives for various device manufacturers must be aligned with those of the other healthcare stakeholders, who reap the benefits of higher interoperability and adoption of standards. In fact, discussions with medical device industry leaders highlight the fact that although technology enables interoperability, market forces today do not create aligned incentives to produce devices with consistent modes for interoperability. Today, Providers accrue benefits from interoperability to the tune of $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 Mergers & Acquisitions (M&A) are intended to build scale and diversify portfolio, the shift to services and intelligence should generate deals focused on corresponding capabilities, both within as well as outside the value chain. Hence, medical device companies need to institute a systemic process and identify strategic alliance partners along with building internal capability to effectively manage their ecosystem.

Accelerating interoperability with QuEST

QuEST Global focuses on delivering a comprehensive set of solutions for the medical devices industry that spans the complete value chain -- building cost-effective models for emerging markets and boosting new product development, all the while ensuring top quality. With keen interest on R&D and product development, regulatory compliance, verification/validation services and post-market support, our team has co-engineered modern and holistic medical devices used by millions of people across the world today.

With over 1000 engineers and 15 years of experience in building safety-critical devices, QuEST is a trusted thinking partner in solving your interoperability challenges -- be it migration of your existing devices to interoperability compliant standards (E.g.: ISO/IEEE 11073) or architecting interoperable systems ground up.

We have delivered significant outcomes like reducing product recall rates by 30% and accelerated time to market by 20% for global leaders in the industry, and have also enabled them to breathe new life into their existing products.

About QuEST Global

For more than 20 years, QuEST Global has aimed to be a trusted global product engineering and lifecycle services partner to many of the worlds' most recognized companies in the Aero Engines, Hi-Tech, Aerospace & Defense, Transportation (Auto and Rail), Power and Industrial, Oil & Gas and Medical Devices industries. With a global presence in 15 countries, 67 global delivery centers, and 12,800+ personnel, QuEST Global believes that it is at the forefront of the convergence of the mechanical, electronics, software and digital engineering innovations to engineer solutions for a safer, cleaner world. QuEST Global's deep domain knowledge and digital expertise aim to help its clients accelerate product development and innovation cycles, create alternate revenue streams, enhance consumer experience and make manufacturing processes and operations more efficient.

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