

Health Research Institute *Spotlight*



August 2016

Beyond the device: From producer to problem solver

The medical device industry is uniquely positioned to solve some of healthcare's most intractable problems. In the New Health Economy, device and diagnostics manufacturers are making new connections with health systems, healthcare providers, pharmaceutical companies and others to lower costs and improve the lives of patients.

The evolution of the medical device business model – from device maker to problem solver – is a direct response to an increasingly modular, plug-and-play health ecosystem defined by consumer needs and desires.¹ Medical device and technology manufacturers are striking large, multiyear deals with health systems and other healthcare providers. They are developing software while supplying data and insights to help hospitals meet growing quality requirements. Some are putting their fees partially at risk. The business model for medical products is changing as a result: half of the top

10 medical device manufacturers by revenue have rolled out service-based solutions to support their customers, independent of specific product offerings, according to an analysis by PwC's Health Research Institute (HRI).

Medtech's role in healthcare is changing in concert with an explosion of technological discovery, downward pressure on healthcare spending and a sharpened focus on value. As established healthcare organizations and new entrants respond to these changes, medical device and diagnostic companies

are serving as enablers, reaching across the ecosystem to offer services that engage patients in real-time, improve physician performance and demonstrate value beyond any one device, diagnostic or technology (see Figure 1).

To understand how the medical device and technology industry is changing its business model in key segments – including diagnostics, imaging and implants – HRI interviewed top executives at large medtech firms and analyzed recent organizational changes among the top 10 medical device companies

Figure 1: A comparison of established players and new entrants in medtech

Established players are expanding their portfolios to include service offerings, while new entrants are building consumer convenience into the development and design of their products and solutions.

Established Medical Device Companies



Historical emphasis on clinical technology used by providers



Recent shift to expanding beyond the device



Deeper pockets enable innovation through acquisition

New Entrants in Medtech



Development focuses on enabling clinical technology and at-home care



Service and broader solution offerings are ingrained in products



Subscription offerings provide revenue streams to support new product development

by revenue. HRI also interviewed CEOs representing some of the industry's new entrants to understand how these organizations are competing in the New Health Economy.

HRI found an industry adapting to profound changes in its customers' needs. Physicians and health systems are adjusting to new financial incentives and reimbursement models, particularly from the Centers for Medicare and Medicaid Services (CMS), and are eager for aid in meeting new requirements. Consumers desire convenient, mobile and user-friendly care. The medtech industry is using digital tools and services to pair these new consumer expectations with clinicians' needs to monitor health outcomes, analyze results of medical interventions and share that information quickly and efficiently with other providers, other devices and patients.

Helping customers meet new quality requirements

Medical device manufacturers are launching broad service offerings attuned to customer needs (see Figure 2). Data and information that document and analyze the delivery of healthcare has become as important to health systems and other healthcare providers as the devices and technology used to diagnose

and treat patients. New customer needs and incentives are opening up new opportunities for manufacturers.

Public and private insurers and providers are pushing forward with payment models that tie reimbursement to quality measures.² And recent changes to the way physicians are paid under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) put \$1.3 billion in Medicare incentive payments to physicians up for grabs.³ As a result, hospitals, health systems and physician practices – medtech's primary customer base – are looking for help in gathering quality data and meeting performance standards.

Stryker Performance Solutions – a division of Stryker focused on partnering with hospitals and other healthcare providers to improve quality outcomes, patient satisfaction and profitability – was not created to nudge physicians to use the company's implants over competing devices. Instead, the division, launched in 2009, began with consulting services built around Stryker's orthopedic products and grew to provide subscription-based data and analytics packages geared toward improving provider efficiency and patient health outcomes. As providers make the transition towards value-based care, there is a need for data analytics and solutions

for the entire episode of care, said Brian McCrone, vice president, Stryker Performance Solutions. "We wanted to become a broader partner to providers and physicians," McCrone told HRI.

In April, Stryker Performance Solutions launched JointCOACH, a web-based portal connecting joint replacement patients with their hospital care teams from surgery preparation through post-op recovery.⁴ The tool helps providers manage patients throughout the episode of care and delivers timely information to the patient about surgery preparation and expectations as well as rehabilitation activities once the patient leaves the hospital. This information allows care coordinators to monitor patients as they move through post-op care protocols, intervening on a timely basis to avoid readmissions, McCrone said.

On the one hand, Stryker Performance Solutions is putting some of its fees at risk, based on its ability to help hospitals achieve financial savings during an episode of care, McCrone said. On the other hand, this is an area of opportunity as more providers participate in CMS's Bundled Payment for Care Improvement (BPCI) program, in which participating organizations will be held accountable by the federal agency based on how much they charge for care and how well the

Figure 2: Half of the top medical device companies offer solutions independent of their devices

PwC's Health Research Institute analyzed the top ten medical device companies by 2014 revenues. These top players are broadening the scope of their product offerings and moving toward solutions.

Of the top 10 medical device companies...



5 out of 10

Offer **customized solutions** independent of their product offerings



7 out of 10

Have undergone organizational changes reflecting a shift toward **services-based offerings**



10 out of 10

Provide **training and educational resources**

Sources: PwC Health Research Institute analysis of company websites and financial reports; EvaluateMedTech "World Preview 2015, Outlook to 2020," October 2015.

patient responds. Bundled payments require active patient communication, management and documentation to succeed. Medical device and technology firms are bringing these critical capabilities to their customers.

Medtech's play in the cloud

Nowhere in the medtech industry is the power of the cloud better exemplified than in the imaging segment. Imaging systems have grown steadily less invasive and less time-intensive while becoming more user-friendly and mobile. Still, captured images often remain difficult to access across clinical practices. Accuracy issues have plagued radiology departments, especially in high-traffic, all-night locations.⁵ These challenges are where the cloud comes into play: medtech manufacturers are using the cloud to boost accessibility and to improve the accuracy of readings by combining machine learning with physician expertise.

GE Healthcare's cloud platform is improving clinical workflow by providing customers with easy access to images and preventing duplicate tests. Evren Eryurek, software chief technology officer at GE Healthcare, told HRI that the technology helps physicians get back to the primary task of treating patients. "Doctors want to spend more time with patients, not more time doing data entry," said Eryurek. By using the cloud's machine learning technology, physicians can spend less time doing spot analyses and computations. The cloud's applications use deep learning algorithms to increase the accuracy of image readings, and help physicians read and extract insights more effectively.

With one platform, physicians can access patient data and improve knowledge-sharing with colleagues, potentially leading to improved outcomes. Citing an internal research project, Eryurek said that expansive, mobile access to imaging in radiology is helping to improve the accuracy of readings. During the project, one health system found that accuracy readings in its emergency department

trended downward overnight, toward the end of a shift. The system used a network of radiologists in the cloud – including colleagues just waking up in other parts of the world – for second opinions. As a result, it "saw a huge uptick in terms of the care they provided and the insights provided," Eryurek said.

On-demand data

Many healthcare providers are pushing care out into the community and closer to their customers' homes in order to control costs while improving satisfaction levels. HRI survey data shows that two-thirds of consumers are interested in receiving care from a healthcare provider at home, and several health systems and start-ups are experimenting with home-based models and mobile technologies to better serve key population segments, such as frail and elderly patients.⁶ Research also shows that home-based care can be more effective, and less costly, than inpatient services.⁷ Medical device companies are driving this trend by developing products intended for use outside of the hospital's four walls, including mobile apps for patient engagement, at-home diagnostic tests and wearable sensors for remote patient monitoring.

"People don't want to go to the hospital," said Rannny Kellogg, president and CEO of Omron Healthcare, Inc., a heart health and wellness medtech firm. "Many patients are treated at the hospital because that's the way it was done in the past, not because it's more effective." Omron offers solutions, such as wrist and upper arm blood pressure monitors, which allow patients to receive clinical level care in the comfort of their own homes, on the go, or wherever they choose. Adoption of health monitoring tools is increasing; between 2013 and 2015, the number of patients being remotely monitored grew by 63% from 3 million to 4.9 million.⁸ The percentage of physicians accessing medical device data on a mobile device nearly doubled between 2010 and 2014, increasing from 11% to 20%, according to HRI survey data.⁹

To increase the impact of remote monitoring, patient data – and more

importantly, analysis of what the data suggest about the health of a patient – must be easily accessible to caregivers. Medical device companies are using biosensors and wearable tracking devices to collect patient data remotely, leading to real-time, actionable insights. These insights can help physicians and caregivers prevent complications and hospitalizations, keeping patients healthier and costs down.

As medical device companies develop solutions to meet this real-time data need, physicians must parse an increasingly large set of data inputs. Medical device company executives repeatedly told HRI that one unsolved issue remains physician trust in data received from remote devices. Devices from companies such as Vital Connect Inc., a biosensor and data management device and technology firm, can generate clinical-grade data, which help ease physician concerns. Physicians also face the challenge of managing large quantities of data, Nersi Nazari, Vital Connect's chairman and CEO, told HRI. "It is essential that clinically validated analytics are available to assist doctors. Physicians are asking: 'Where are the analytics to help me understand and act on all of this data?'"

Designing for consumer demand

Across device segments, the medtech industry is recognizing the need to make products more consumer-centric. In the cardiology space, manufacturers such as Medtronic and St. Jude Medical have created miniature pacemakers designed to reduce the risk of major complications and infections. Companies such as Boston Scientific Corporation and Biotronik have designed pacemakers that are safe for use in MRIs. Manufacturers are just beginning to uncover the potential of 3D printing, experimenting with replacements made from patients' own cells.

Medical device and technology executives interviewed for this report emphasized the importance of incorporating the consumer perspective into product design, including making medical technology and

devices easier to operate (see Figure 3). “A big barrier to wide adoption of connected health is typically that the devices are scary and ugly and remind you that you’re going to die,” Robert Kaul, founder, president and CEO of Cloud DX, a health monitoring and wearables company, told HRI. Kaul said the driving force behind Cloud DX’s Vitaliti device was to create “a Star Trek-style user experience that makes you want to use these tools.”¹⁰ While the Vitaliti device isn’t yet marketed to the public, components of the device – like a rapid HIV diagnostic test – will be submitted for FDA approval soon, Kaul said.

Created through a partnership with Stanford University for the Qualcomm Tricorder XPrize contest, the Vitaliti solution is comprised of four wireless devices that connect to a mobile app, allowing patients to access results quickly. The solution uses blood, urine and saliva tests to diagnose 19 conditions, including COPD, atrial fibrillation, mononucleosis and sleep apnea. The degree of instant gratification, combined with two-way video conferencing and text messaging through the Vitaliti platform, are features

that will appeal to consumers, Kaul said. The innovation demonstrates the shift manufacturers are making toward non-invasive, convenient diagnostics.

Proteus Digital Health seeks to improve patient outcomes through better medication adherence and compliance. Pharmacists, on a physician’s order, are able to co-encapsulate the Proteus ingestible sensor with a patient’s prescribed medication. This ingestible sensor is a component of Proteus’s Discover offering and is roughly the size of a grain of sand. When swallowed, the sensor transmits a signal to a patch worn by the patient and communicates the data to the cloud. There, the data – which also includes physiological information – are analyzed by software and delivered back to the patient through his or her mobile device. With the patient’s permission, the information is also delivered to physicians through a web portal.

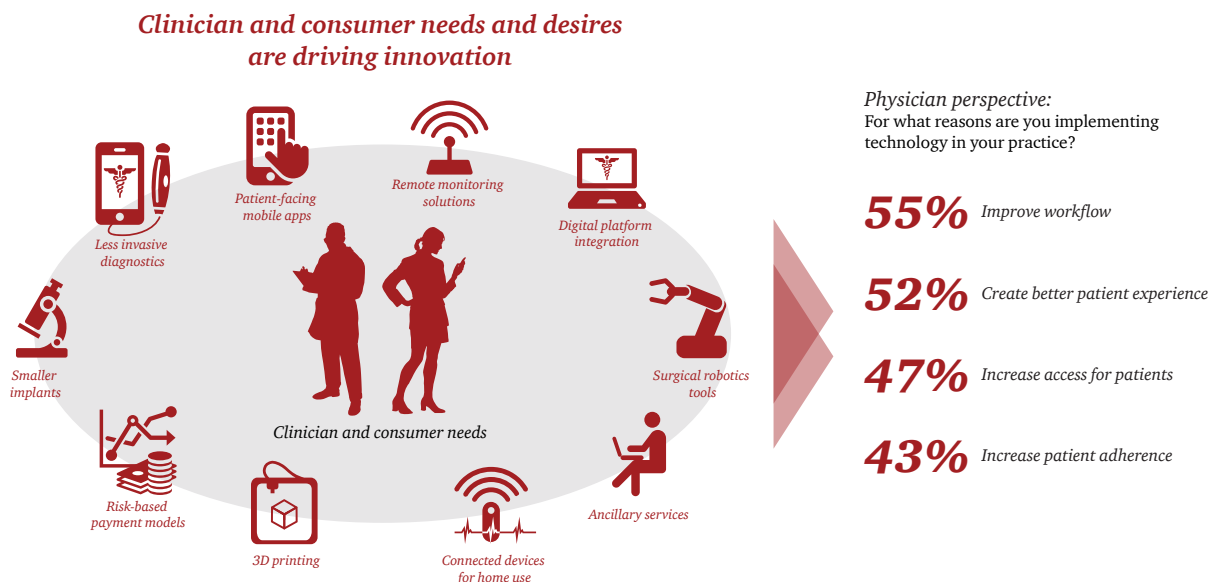
Andrew Thompson, co-founder and CEO at Proteus, told HRI that a patient’s “life flow” – as opposed to a physician’s work flow – is the first priority. “If patients don’t like these products and don’t find

them easy to use, they won’t use them, and none of the data will be available to providers,” said Thompson. Proteus is one example of a medtech company using the patient experience as the starting point for innovation. “We’re working from the patient back into the system,” Thompson said. “Patients are a core part of our business model.”

The Proteus Discover platform is sold to health systems as a software license, which provides access to the patient- and physician-facing applications, along with the system analytics. The health system pays on a monthly, per patient basis. Thompson said Proteus’s early customers are health systems with risk-based models. “The reason why the technology industry in the last two decades has created trillions of dollars of value is because tech companies have started to collaborate and put consumers at the center of their business models, and build solutions,” he said. “They don’t work to optimize their own piece of the solution, and then tell the consumer to go figure it out. That approach, in healthcare, represents a massive opportunity for new value.”

Figure 3: Customer needs are driving medtech companies into new areas of innovation

Clinicians and consumers are demanding more from the devices and technology they use, spurring innovation by manufacturers. In parallel, physicians are looking to new technology to improve workflow as well as patient satisfaction and outcomes.



Source: PwC Health Research Institute clinician survey, 2015

Recommendations

Decide whether to offer solutions or discrete products. New entrants are building robust, customer-centric services into their commercialization models. Established players that choose to broaden their offerings to become solutions-based must examine the opportunities for value-based contracting in specific product segments, and understand changing customer needs among hospital systems and other providers. Manufacturers who decide not to become solutions companies still should focus on building the customer and patient perspective into product design efforts.

Make new connections across the healthcare ecosystem. Medtech companies are well positioned to alleviate some of the health industry's pain points. Insurers and health systems are struggling to improve quality and lower costs, physicians are looking for help managing the onslaught of incoming data and consumers are looking for ease and convenience in their healthcare experiences. Manufacturers should consider partnering with other players, traditional or new, to gain the capabilities necessary to meet their customers' needs.

Prepare to enter into value-based contracts and assume risk for outcomes. Medical device manufacturers have a unique opportunity to help healthcare providers fulfill value-based contracts with insurers and government payers. Medtech firms providing solutions that cover episodes of care and fill gaps in the patient journey must listen to their customers and monitor new developments in the health insurance sector to create services aligned with changing needs.

Develop devices with the capability to feed data back to providers. Medical device makers should integrate their data and insights into physician workflows. These devices, such as diagnostics, monitoring systems or imaging technologies, should be easy to adopt for all stakeholders as more care moves out of traditional delivery centers, such as hospitals. Physicians will view devices that deliver data as well as automated, relevant and actionable insights as far more valuable than devices that do not.

Endnotes

1. PwC Health Research Institute, "The coming plug-and-play health ecosystem," December 2015. (<https://www.pwc.com/us/en/health-industries/assets/pwc-health-research-institute-the-coming-plug-and-play-health-ecosystem-essay-dec-2015.pdf>)
2. PwC Health Research Institute, "Healthcare's alternative payment landscape," October 2015. (<http://pwchealth.com/cgi-local/hregister.cgi/reg/pwc-hri-alternative-payments-2015.pdf>)
3. PwC Health Research Institute, "MACRA: Payments tied to big changes in quality reporting," June 2015. (<http://pwchealth.com/cgi-local/hregister.cgi/reg/pwc-hri-MACRA-MIPS-merit-based-incentive-payment-system.pdf>)
4. Press release, "Stryker's Performance Solutions Announces JointCOACH™ Engagement Platform Designed to Educate and Navigate Patients Through the Entire Episode of Joint Replacement Care," May 9, 2016. (<https://www.strykerperformancesolutions.com/articles/jointcoach-press-release>)
5. Krupinski, E. A., Berbaum, K. S., Caldwell, R. T., Scharz, K. M., & Kim, J, "Long Radiology Workdays Reduce Detection and Accommodation Accuracy," *Journal of the American College of Radiology*, September 2010. (<http://doi.org/10.1016/j.jacr.2010.03.004>)
6. PwC Health Research Institute, "Primary care in the New Health Economy: Time for a makeover" November 2015. (<https://www.pwc.com/us/en/health-industries/our-perspective/primary-care-report-new-health-economy-2015.html>)
7. Smith S, Brick A, O'Hara S, and Normand C, "Evidence on the cost and cost-effectiveness of palliative care: A literature review" *European Association for Palliative Care, Sage journals*, July 9, 2013. (<http://pmj.sagepub.com/content/28/2/130.full>)
8. Fagerberg J and Kurkinen L, Berg Insight AB, "mHealth and Home Monitoring Product Sheet," Berg Insight's M2M Research Series, December 2015 and June 2014. (<http://www.berginsight.com/ReportPDF/ProductSheet/bi-mhealth7-ps.pdf> and <http://www.berginsight.com/ReportPDF/ProductSheet/bi-mhealth6-ps.pdf>)
9. PwC Health Research Institute, "Healthcare delivery of the future: How digital technology can bridge time and distance between clinicians and consumers," November 2014. (<https://www.pwc.com/us/en/health-industries/top-health-industry-issues/assets/pwc-healthcare-delivery-of-the-future.pdf>)
10. Cloud DX's Vitaliti device is a finalist in the Qualcomm Tricorder Xprize, a contest that will award \$10 million to a company that develops a handheld device, a la Star Trek's Tricorder, that can accurately diagnose at least 13 health conditions, and capture five real-time health vitals. The Xprize winner will be announced in early 2017.

About this Research

This report is based on research conducted between May 2016 and August 2016. HRI conducted interviews with executives from leading medical device companies as well as medical technology firms emerging as new entrants. HRI also conducted an analysis of the top 10 medical device organizations by 2014 global revenue. In addition, HRI analyzed premarket approval data as published by the FDA's PMA database.

About the PwC Health Research Institute

PwC's Health Research Institute (HRI) provides new intelligence, perspectives and analysis on trends affecting all health related industries. The Health Research Institute helps executive decision makers navigate change through primary research and collaborative exchange. Our views are shaped by a network of professionals with executive and day-to-day experience in the health industry. HRI research is independent and not sponsored by businesses, government or other institutions.

Acknowledgements

Evren Eryurek, Software Chief Technology Officer, GE Healthcare

Robert Kaul, Founder, President and CEO, Cloud DX

Randy Kellogg, President and CEO, Omron Healthcare

Brian McCrone, Vice President, Stryker Performance Solutions

Nersi Nazari, Chairman and CEO, Vital Connect

Helen Routh, Head of Integrated Solutions and SVP Strategy & Innovation, Philips

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