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Mobilizing MedTech for mHealth

Market trends and potential opportunities

Executive summary

The MedTech industry has met its next growth engine — mHealth. By harnessing the exponential power of mobile technologies, data, and analytics, mHealth is anticipated to disrupt traditional health care delivery models and drive innovation across the care continuum. While mHealth's disruptive potential may up-end traditional MedTech business models, it may also be the mechanism for transformative growth and a way out of the "commoditization" funnel in which many MedTech companies are trapped

Many new market entrants, particularly high-tech companies, are developing innovative mHealth solutions in response to a growing demand for consumer control and engagement. Collaborations are proliferating, enabling participants to test new business models, leverage innovation, and create adjacent and transformational opportunities. MedTech companies — collectively and individually — likely will need to mobilize their resources and capabilities to help offset competitive threats and realize mHealth's potential.

Obstacles to mHealth adoption remain, especially in developed markets such as the United States. Among these are lack of physician reimbursement incentives, and concerns about systems and data interoperability, privacy and data security, building patient-consumer trust, and inconsistent regulatory guidance. Efforts are underway to help break down these barriers. Still, behavioral changes by both consumers and providers also may be needed after these barriers are addressed to fully realize mHealth's potential benefits.

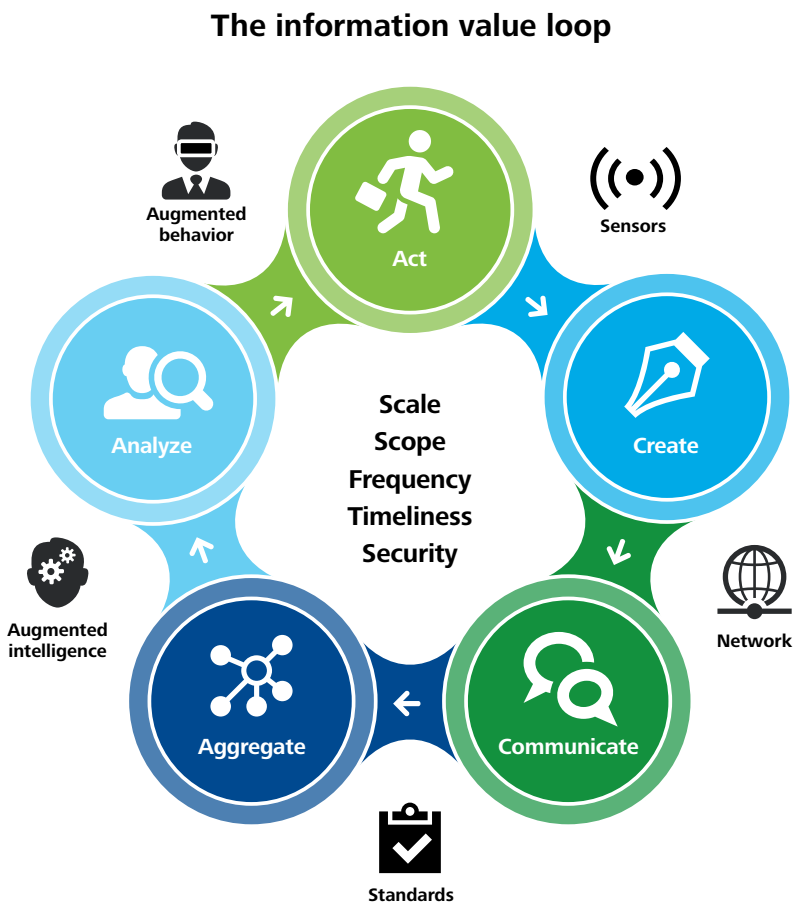
MedTech companies have the potential to benefit from innovation driven by mHealth solutions, but they should be thorough and deliberate when determining ways to capitalize on specific opportunities. Companies should decide whether to embrace mHealth at the corporate, business unit, or product level and identify ways to help create value for shareholders across the information value loop. In addition, it's important for MedTech companies to determine which capabilities they should build versus partner for or purchase. Fortunately, the evolving mHealth ecosystem offers an increasing array of organizations they can collaborate with to help create meaningful solutions along the patient journey and help position themselves for growth and sustainable advantage.

What is mHealth?

mHealth is the utilization of mobile technologies to provide health-care-related solutions across the patient journey. It is a component of Connected Health, in which sensors, networks, standards, augmented intelligence and consumer behavior are helping create opportunities to impact and improve the patient journey. mHealth aims to empower patients with information and management of their own health; promote outcomes improvement through enhanced decision-making; help reduce costs and increase access throughout the system, and supply data for predictive modeling of at-risk populations.

The global mHealth market was an estimated $10.5 billion in 2014 and is expected to grow 33.5 percent annually between 2015 and 2020.[1] mHealth solutions span applications (apps), smart devices (wearable and non-wearable), aggregation platforms, and analytics, creating business models across the "information value loop" (Figure 1). Many MedTech companies own a piece of this loop, often in sensor technologies. However, unless companies design solutions that link all of the pieces, mHealth's value to the health care system is likely to remain limited.

Figure 1: mHealth solutions create business models across the "information value loop" that can help improve the patient journey

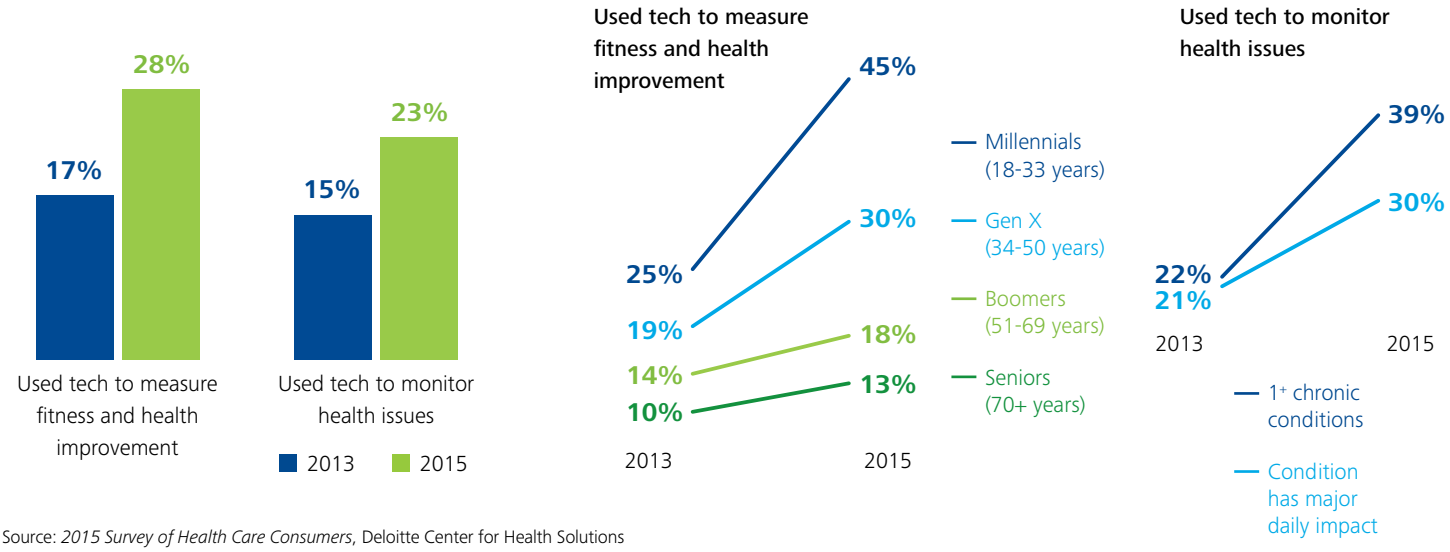


Source: *Next-generation "smart" MedTech devices*, Deloitte Center for Health Solutions, 2015

mHealth's impact on the patient journey

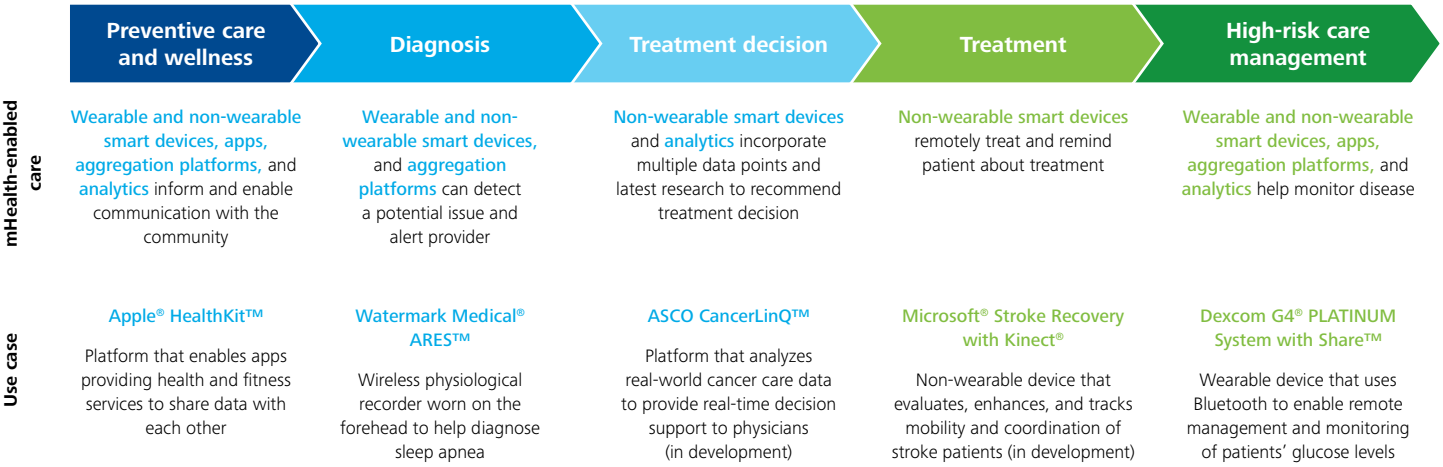
Consumers using technology to manage their health (Figure 2) are the "pull" force propelling many mHealth opportunities. As consumer and physician adoption rates for mHealth and other technology solutions continue to rise, and new uses emerge, the patient journey experience across the spectrum of preventive care and wellness, diagnosis, treatment decision, treatment, and high-risk care management is expected to evolve (Figure 3).

Figure 2: Use of digital tools and mobile tech for health improvement and monitoring is on the rise, especially among younger consumers and those with chronic conditions



Source: *2015 Survey of Health Care Consumers*, Deloitte Center for Health Solutions

Figure 3: mHealth's impact on the patient journey



Source: Deloitte Consulting LLP analysis as of July 2015; Deloitte Consulting LLP is not endorsing any of the products or solutions illustrated.

mHealth helps drive innovation

We anticipate that increasing mHealth development and adoption are likely to disrupt traditional health care delivery models and spur innovation across the care continuum. Among the diseases and conditions most likely to be addressed by mHealth innovative solutions are diabetes, cardiovascular disease (CVD), chronic obstructive pulmonary disease (COPD), and asthma (Figure 4).

Investments by established MedTech firms are indicative of increasing confidence in mHealth's adoption and its commercial value. Among notable 2014 deals:

- St. Jude Medical acquired CardioMems, manufacturer of a wireless heart failure implantable, for $350+ million. The acquisition is expected to accelerate growth in St. Jude's cardiovascular business.[2]
- Medtronic acquired Corventis for more than $150 million and combined Corventis' wearable technology with its Cardiocom cardiac home health monitoring offering to develop the Seeq Mobile Cardiac Telemetry System.[3]
- Stryker acquired SurgiCount for $120 million. Stryker integrated SurgiCount's safety sponge mobile system and compliance software into its perioperative care product portfolio ($16M in sales in 2013).[4]

"Only 14% of diabetic patients in America meet the control target of their blood sugar levels, blood pressure, and cholesterol levels. Digital patient support will improve healthcare and health outcomes. It will not solve all of our problems, but medicines alone are not enough to treat chronic diseases."[5]

— Eddie Chan, Global Head of Customer Solutions and Innovation, Sanofi, Speaking at the Eyeforpharma Conference in Barcelona, March 24-26, 2015

Figure 4: mHealth solutions are more likely to be developed and adopted for diabetes, CVD, COPD, and asthma

	Most prevalent chronic diseases						
Disease characterization	Diabetes	CVD	COPD	Asthma	Alzheimer's disease	Cystic fibrosis	Arthritis
US disease prevalence	21M[6]	86M[8]	15M[9]	25M[11]	5.1M[12]	30K[13]	53M[15]
Total cost of treatment	$245B[7] ($12k pp)*	$196B[8] ($2.3k pp)*	$32B[10] ($2.1k pp)*	$56B[11] ($2.2k pp)*	$226B[12] ($44k pp)*	$0.5B* ($16k pp)[14]	$81B[15] ($1.5k pp)*
Preventable through lifestyle changes*	Yes	Yes	Yes	No	Maybe	No	No
Disease likely to require provider monitoring*	Yes	Yes	Yes	Maybe	Yes	Yes	No
mHealth solutions' ability to help diagnose, treat, or manage disease*	High	High	High	High	Medium	Low	Low

Chronic diseases most likely to be addressed by mHealth solutions

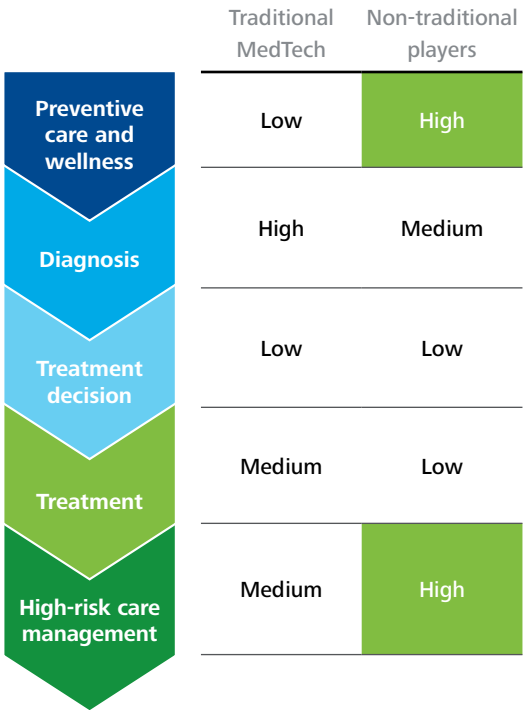
Note: * Deloitte Consulting LLP analysis as of July 2015

New entrants — in particular, high-tech companies — tend to be the dominant innovators across mHealth product types as they provide solutions that help engage patients. These companies, rich in consumer engagement experience and data analytics, may challenge MedTech companies and other market players for the lion's share of mHealth revenues as they offer solutions along the patient journey (Figure 5).

Other organizations — among them, health care providers, telecommunications companies, and non-profits — are also engaging in mHealth solutions. Mature MedTech companies likely will need ready access to players across the solution spectrum as they build knowledge and relationships. Health care information security professionals might look to data security and privacy practices in the financial services industry as models for mHealth applications.

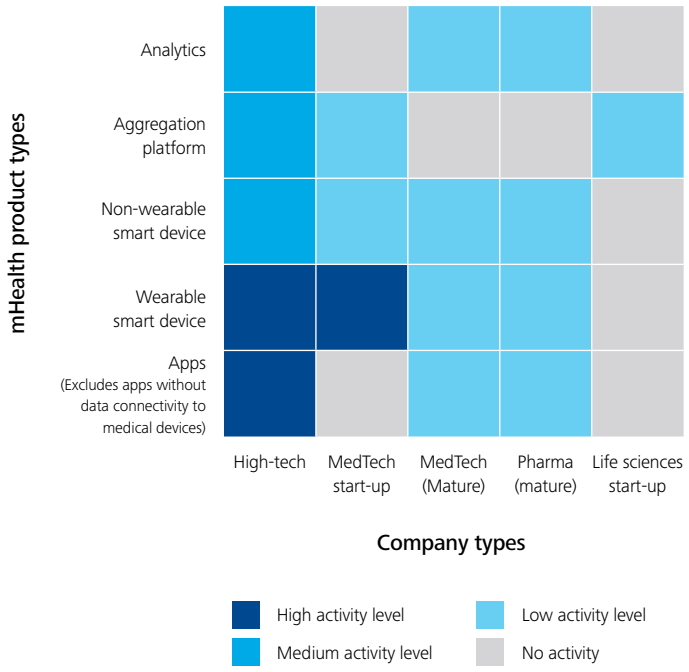
Figure 5: New entrants are providing mHealth solutions along the patient journey and across the product spectrum

mHealth activity along the patient journey



Source: Deloitte Consulting LLP Analysis as of July 2015

New mHealth solutions activity (by company and product type)



Source: Deloitte Consulting LLP Analysis as of July 2015 based on 200+ distinct solutions

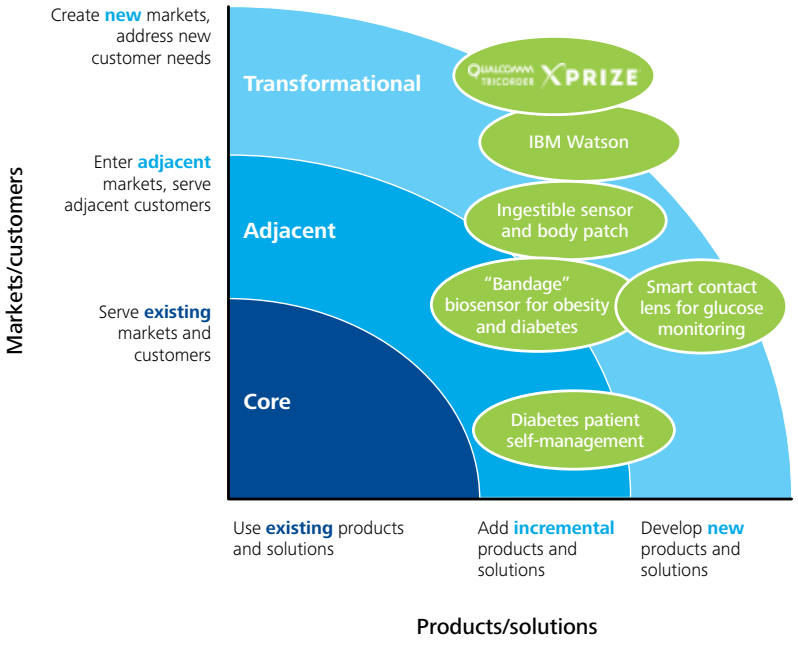
Opportunities for collaboration

Collaborations among mHealth players are proliferating, enabling participants to test new business models; leverage their individual and combined capabilities to bring innovative solutions to market; enhance the patient experience; create adjacent and transformational opportunities; and increase the likelihood of technical and commercial success. Moving forward, collaborations are likely to be robust and varied, with each organization bringing sector-specific experience and capabilities that may include the following:

- Traditional MedTech — Regulatory and reimbursement experience; clinical trial expertise; deep knowledge of product usage and customer needs
- Traditional pharma — Patient outcomes and health care economics; deep knowledge of payer needs and reimbursement; clinical trials and regulatory experience
- High-tech companies — Consumer engagement experience; data management and advanced analytics; technology and innovation expertise
- MedTech start-ups — Innovative MedTech solutions; quick organizational alignment and execution
- Wireless service providers — Collection, storage, and retrieval of large data sets; wireless technology and data transfer infrastructure; telecommunications regulatory experience
- Providers — Patient care coordination and planning; patient privacy management; disease monitoring data and adherence
- Payers — Disease monitoring and adherence; health care economics

Such collaborations are helping boost companies' abilities to leverage innovation and create new opportunities (Figure 6). For example, traditional pharma company Novartis' eye care division, Alcon, has in-licensed GoogleX's "smart lens" technology for optical medical uses. (This arrangement is now part of a subsidiary of Alphabet, Inc.) One application allows diabetic patients to manage their condition via a smart contact lens which is designed to measure tear fluid in the eye and connects wirelessly with a mobile device.[16] In an example of a provider and high-tech company collaboration, the Mayo Clinic and Gentag are developing wearable biosensors focused on managing diabetes and obesity. The small bandage communicates via a closed-loop diabetes management system and allows researchers to monitor movement and develop treatments for obesity and related conditions.[17]

Figure 6: Creating adjacent and transformational opportunities through innovation



Source: Deloitte Consulting LLP analysis as of July 2015; Framework leverages insights from Doblin.
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Common barriers to adoption

Despite mHealth's potential, barriers to adoption remain, especially in developed markets such as the United States. Efforts are underway to help break down common barriers, which include lack of physician reimbursement incentives, and concerns about systems and data interoperability, privacy and data security, building patient-consumer trust, and inconsistent regulatory guidance.[18]

Lack of reimbursement incentives. Without clear economic impact on patient outcomes, mHealth solutions tend to face an uncertain reimbursement environment. Likely reimbursement coverage varies across the patient journey spectrum. For example, we anticipate there is low likelihood of physician or payer approval for mHealth utilization in Preventive Care and Wellness — physicians in Accountable Care Organizations (ACOs) may be more likely to support mHealth due to expected improvements in patient outcomes, but payers are likely to need evidence of patient behavior changes that would help save costs in the long term. We expect there is uncertain likelihood of physician or payer approval in the areas of Diagnosis and Treatment Decision — physician skepticism is generally high for solutions making diagnosis claims due to inconsistent accuracy, and payers likely will need evidence of efficacy and value over existing protocols. Moving up the spectrum, we anticipate there is increased likelihood of physician or payer approval for Treatment or High-risk Care Management. Physicians are more likely to be interested in mHealth solutions that help manage chronic conditions, while some payers are beginning to show confidence in certain solutions, as illustrated by the 2013 reimbursement approval for WellDoc's BlueStar diabetes management program.[19]

The Department of Health and Human Services' (HHS) efforts to transition from traditional fee-for service (FFS) reimbursement — which does not incentivize providers to take advantage of mHealth solutions — to value-based care (VBC) is likely to impact mHealth reimbursement as providers and payers focus on improving outcomes and lowering costs.[20] We anticipate the projected timing to address reimbursement challenges to be five or more years, as business models probably will need to change, from the set-up and organization of care delivery to the way providers are being paid.

Systems and data interoperability. Universal health data exchange protocols have not been adopted to help improve the ability of health care IT systems to work together to exchange information. Mitigating initiatives include engagement of the Office for the National Coordinator for Health Information Technology (ONC) to help define common standards and protocols and the Healthcare Information Management and Systems Society's (HIMSS) development of an Interoperability Roadmap. We anticipate the projected timing to reduce this barrier should be three to five years, as businesses will need the right incentives to share their data.

Privacy concerns and data security. The permeability of digital technologies has permitted widely publicized unauthorized access, impacting patient and provider confidence. Among mitigating efforts is California Assembly Bill 658, signed into law in 2013, which extends consumer medical information privacy protection to mobile apps.[21] We anticipate the projected timing to reduce this barrier likely will be three to five years.

Building patient and consumer trust. Most consumers are wary of sharing personal health data without fully understanding how and where it will be used. Physicians are calling for a vetted "app formulary"[22] which may also end up helping generate consumer trust in mHealth solutions. We anticipate the projected timing to build patient and consumer trust may be three to five years.

Inconsistent regulatory guidance. There is increasing pressure to regulate mHealth's data security, as growing mobile medical device connectivity raises the likelihood of data breaches, sabotage, or even loss of device control. In addition, exposure of patient data can place patient privacy at risk from hackers, while many patients are increasingly concerned about how their information is aggregated and used by health care companies. However, lack of clarity on regulations and oversight jurisdiction, and conflicting legislative messages are contributing to industry confusion.

mHealth's complex ecosystem has resulted in an increased number of regulatory agencies overseeing its development and application. The Food and Drug Administration (FDA) currently does not regulate mHealth apps that are not medical devices, as mobile apps that simply track certain behaviors (e.g., a pedometer) pose a low risk to the public.

The FDA's February 2015 guidance on mobile medical apps states the agency's intent to exercise enforcement discretion on mobile apps that fit certain categories.[23] The FTC is targeting mHealth app marketers for misleading or fraudulent claims[24] and the Office for Civil Rights (OCR) is enforcing HIPAA privacy rules and increasing compliance audits.[25] Meanwhile, ONC is advocating for a public-private partnership to develop common policies for data security and device interoperability.[26] The Federal Communications Commission (FCC) has created a task force, Connect2HealthFCC, which explores the intersection of broadband, advanced technology, and health. The task force serves as an umbrella for all FCC activities to help enable a healthier America.[27] Through the Rural Health Care Program, the FCC provides funds to increase broadband connectivity to improve the quality of health care available to patients in rural communities.[28]

From a provider perspective, the lack of validation for mobile device claims may discourage physicians from leveraging the data from mHealth devices and recommending the devices to their patients. Many physicians are calling for formal certification, review mechanisms, and a vetted "app formulary" so they can confidently prescribe apps to patients in the future.[30] Finally, since many mHealth apps rely upon real-time, crowd-based feedback through social media (which companies can leverage for user experience and marketing information), companies should think about how to comply with adverse events and regulatory requirements when leveraging social media.

Among industry actions to help clarify and standardize regulatory guidance, The App Association is working with HHS to update HIPAA guidance documents for mobile health.[31] We anticipate the projected timing to address this regulatory challenge is likely to be one to three years.

FDA guidance on medical devices[29]

According to a February 2015 guidance, the FDA intends to exercise enforcement discretion on mobile apps that fit the following categories:

- Provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment
- Provide patients with simple tools to organize and track their health information
- Provide easy access to information related to patients' health conditions or treatments (beyond providing an electronic "copy" of a medical reference)
- Are specifically marketed to help patients document, show, or communicate to providers potential medical conditions
- Perform simple calculations routinely used in clinical practice
- Enable individuals to interact with Personal Health Record (PHR) systems or Electronic Health Record (EHR) systems
- Meet the definition of Medical Device Data Systems.

In order to overcome the above-mentioned barriers to mHealth adoption and fully realize the technology's potential benefits, behavioral changes by both consumers and providers may be needed after these barriers are addressed. In the case of providers, changes are likely to occur given the shift towards value-based care and the increased adoption of care delivery outside traditional settings. The situation tends to be more complex with consumers. Looking at pharma as an example, getting patients to comply with their treatment regimen has often been a challenge, even after years of incentives and programs. The good news is that data from the Deloitte Center for Health Solutions *2015 Survey of Health Care Consumers* indicates that 74 percent of surveyed consumers with major chronic conditions are very interested or somewhat interested in monitoring technologies for health issues.[32] That said, only 47 percent of those who are interested have actually used technology to monitor their health issue, which illustrates there is still a gap to close.[33]

Potential implications and opportunities for MedTech

mHealth's disruption of the care continuum may trigger substantial implications and opportunities for the MedTech industry across the care continuum (Figure 7). Further, since mHealth enables the provision of care outside traditional settings such as hospitals and physician offices, it will likely drive associated growth in alternate delivery systems such as home- and community-based care.

However, companies should be thorough and deliberate when identifying ways to capitalize on potential opportunities. Important considerations include:

1. **Make a strategic decision on whether to embrace mHealth** and whether this will be driven at the corporate, business unit, or product line level. A MedTech company's mHealth strategy, technology, and information should be coordinated to enable a consistent experience for patients and providers. Furthermore, mHealth solutions should be cost-effective and fit within the existing health care system workflow to encourage provider adoption. The MedTech company should, therefore, identify where in the information value loop it is most likely to monetize its mHealth solution.

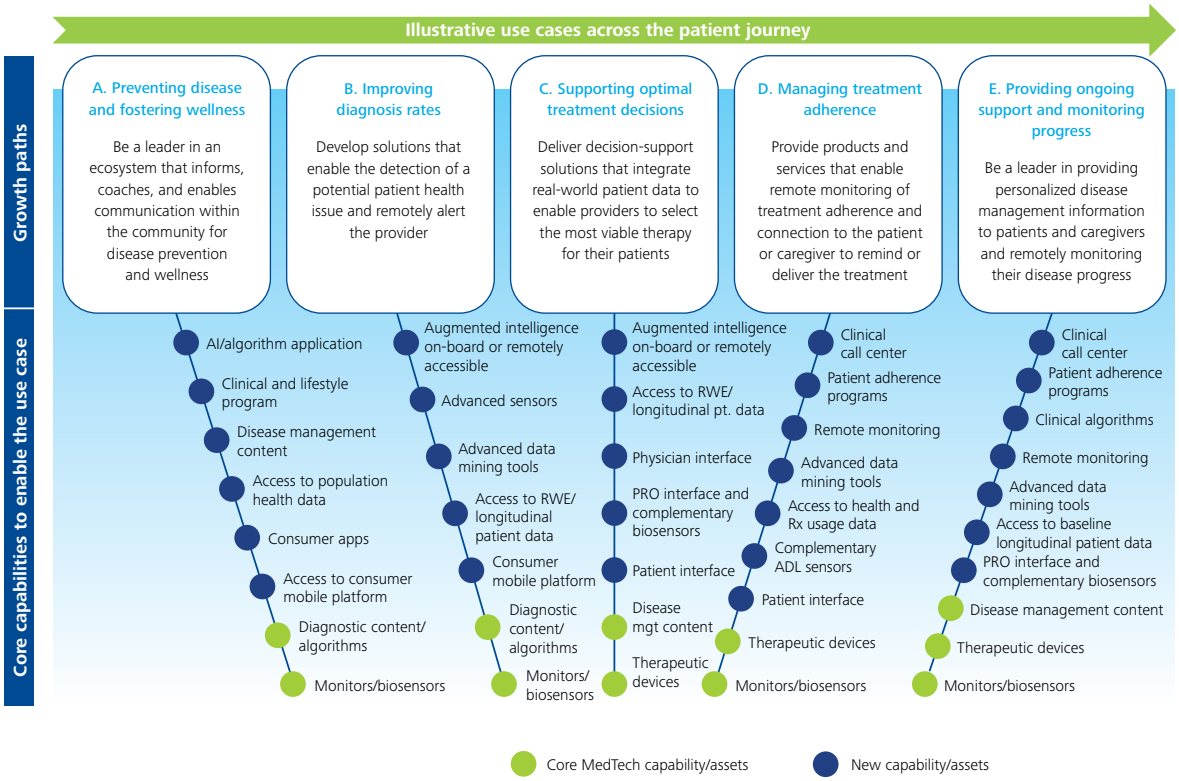
The growth path a MedTech company decides to pursue will help determine the core capabilities it needs to obtain the desired use case. These capabilities can be developed internally or through acquisitions and collaborations. Not all capabilities in a single growth path are required for effectiveness; however, the company should promptly assess whether they are needed and, if so, whether they should become a core competency (Figure 8).

Figure 7: mHealth's disruption of the care continuum carries potential implications and opportunities for MedTech companies

	Care continuum			
	Prevention and wellness	Chronic care	Acute care	Ambulatory post-acute
US annual estimated cost	Undefined	>$1T[35]	$936B[36]	$586B[36]
Current mHealth adoption	**Present and growing**	**Present and growing**	**Still in infancy**	**Present and growing**
Disruptive mHealth technology examples	• Innovative wearable devices • Sensor-enabled predictive analytics • Population management tools	• Remote monitoring • Non-wearable devices; ingestibles • Sensor-enabled predictive analytics • Population management tools	• Continuous remote monitoring • Real-time care updates	• Continuous remote monitoring • Self-administered biometric devices
Potential MedTech implications	• Disintermediated Dx procedures	• Disintermediated Dx procedures • Replacement of select Tx devices • Shift in home care solutions	• Disintermediated Dx procedures • Replacement of select Tx devices • Replacement of equipment	• Disintermediated Dx procedures • Shift in home care solutions

Source: Deloitte Consulting LLP analysis as of July 2015

Figure 8: Illustrative MedTech growth path use case



Notes: The blue dots represent industry segments that could be a part of a MedTech company's play should the growth be prioritized and are not intended to imply that any one blue dot is required to play in the space.
Source: Deloitte Consulting LLP Analysis

2. **Target the diseases** for which the organization wants to leverage mHealth solutions and identify how these solutions can provide value in the patient journey through data/results from studies that show these solutions work in real populations to help change behavior, engage patients, and improve outcomes. Such an approach is vital to drive patient adoption, provider acceptance, and reimbursement for commercial effectiveness. Also, it is important to remember that the adoption of mHealth solutions does not automatically or immediately translate into improved outcomes. It is important, therefore, to identify what motivates people to change behaviors in ways that can impact their health in the long run.

3. **Collaborate with other organizations** aligned on a similar patient experience vision. This can provide a mechanism to bring mHealth solutions to patients while leveraging innovation, technical competencies, and commercial and regulatory expertise.

4. **Expand the scope of regulatory awareness beyond the FDA.** Multi-agency oversight is likely to become the new norm as the FTC, FCC, OCR, and others become more involved in the creation and enforcement of mHealth regulations.

5. **Leverage mHealth for emerging markets.** This may enable collaboration among MedTech companies and other organizations to develop innovative solutions that can address patient access challenges while helping improve health outcomes in a cost-effective manner.

mHealth in emerging markets

Some of the barriers to mHealth adoption in developed markets may take a back seat to potential opportunities in emerging markets, where mHealth addresses specific challenges while enhancing health outcomes (Figure 9).

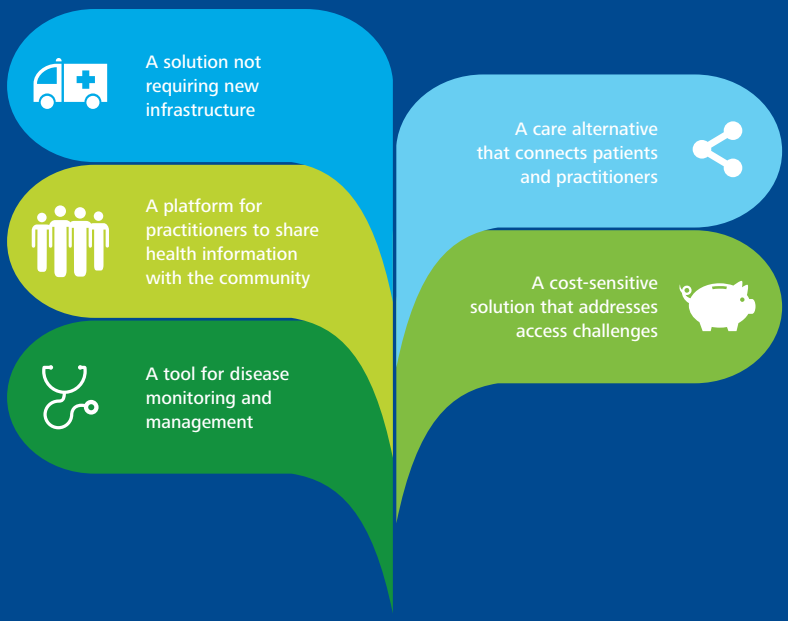
While the Disability-Adjusted Life-Year (DALY) burden of infectious diseases in emerging markets has dropped 30 percent from 2000 to 2012, the prevalence of non-communicable diseases has risen by almost 20 percent. Cancer, diabetes, and cardiovascular disease (CVD) now comprise ~40 percent of non-communicable disease burden in emerging markets.[37]

Patient access challenges in emerging markets — a shortage of health care workers, insufficient health care infrastructure capacity, and high out-of-pocket (OOP) consumer expenditures — can impede traditional health care solutions. Yet, emerging markets tend to be primed for mHealth innovation, due to unmet needs, lower barriers to entry, and less entrenched competition. Also, mHealth innovation in emerging markets can flourish and spread to disrupt developed markets.

Increasing mobile penetration in emerging markets is anticipated to be a key enabler of mHealth effectiveness. LTE networks in developing countries will reach the majority of their population by 2019 and 60 percent by 2020. The mobile subscription penetration rate for developing countries reached 45 percent in 2014 and is expected to rise to 56 percent by 2020.[39]

Our research of more than 25 unique solutions in emerging markets involving more than 45 organizations indicates that, to date, mHealth solutions have been delivered to Latin America, Sub-Saharan Africa, Middle East, China, and India. Most of the solutions in emerging markets involve collaborations (e.g., with a telecommunications partner) and focus on apps for community empowerment and preventive care/wellness. (Community empowerment is specific to emerging markets: It covers platforms that equip health care professionals with timely data to help monitor and manage the health of local communities.) Collaborations are more likely to be effective if objectives are aligned with national and local health priorities, the competencies and resources required for the mHealth solution are scalable, and there is long-term planning.

Figure 9: Emerging markets may present a more welcome adoption environment for mHealth



Source: Deloitte Consulting LLP Analysis as of July 2015

"We have a crisis — not only in the United States but around the world — around healthcare. Universally, we need to decrease costs, increase quality, and increase access or reach. One of the ways we can do that is by using mobile technology."[38]

— Rick Cnossen, Director, Worldwide Health IT Office, Intel, Cnossen interview during the mHealth Summit Europe 2014

Conclusion

mHealth is the next growth engine for the MedTech industry. MedTech companies have the potential to benefit from innovation driven by mHealth solutions, but they should be thorough and deliberate when determining ways to capitalize on specific opportunities. Companies should decide whether to embrace mHealth at the corporate, business unit, or product level and identify ways they can help create value for shareholders across the information value loop. In addition, it's important for MedTech companies to determine which capabilities they should build versus partner for or purchase. Fortunately, the evolving mHealth ecosystem offers an increasing array of organizations they can collaborate with to help create meaningful solutions along the patient journey and help position themselves for growth and sustainable advantage.

Glossary

Connected health: Leveraging technology to integrate health care delivery by connecting patients and practitioners; improving delivery and management of care outside the hospital; and improving care management in population health. Includes Remote Patient Monitoring (RPM), Electronic Health Records (EHR), TeleHealth, and tools for provider education.

Mobile health (mHealth): The utilization of mobile technologies to provide health-related solutions across the patient journey. Excludes Electronic Health Records (EHR), TeleHealth, and tools for provider education.

Analytics: A mobile technology solution capable of performing complex data analysis through sophisticated algorithms and/or referencing empirical studies. Often also has aggregation-platform capabilities to pull in data from multiple sources to be analyzed.

Aggregation platform: A mobile technology solution that automatically aggregates data from multiple sources to make the range of data accessible in one central location.

Non-wearable smart device: mHealth-enabled device that does not require a user to wear it for a continuous period of time.

Wearable smart device: mHealth-enabled device that requires a user to wear it for a continuous period of time.

App device/data connectivity enabled or required: Mobile phone or tablet application that is capable of or requires a connection to another data source/device for automatic upload of data.

App no device/data connectivity: Mobile phone or tablet application that only allows manual data input and cannot connect automatically to other data sources/devices.

Endnotes

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