

Healthcare is undergoing a transition. With a renewed focus on patients and health outcomes, at-home care is in the spotlight again. For MedTech companies, it means new opportunities to create devices for patients and their caregivers to use at home, and to consider the convenience aspect of patient care.

# A more patient-centric approach





Healthcare is constantly evolving the best ways to support health, improve outcomes and lower cost. As part of this evolution, there has been a shift in where patients receive care. The site of care has changed over time from home visits by a family doctor, to care at a hospital by a medical team, to care at ambulatory clinics by healthcare providers. Now we are circling back, with patients once again receiving quality care in an at-home environment.

Focus on the patient has also shifted over time. Where early hospital visits provided a degree of hospitality and personalized care, in today's fast-paced world, that is not always possible. Lately, healthcare facilities have concentrated on operational efficiency so they can provide people with the best conventional care for the lowest cost

However, trends indicate that the healthcare ecosystem is moving toward a more patient-centric care model. This shift in focus—to access, experience and outcomes—means existing

procedures, devices and equipment need revisiting. What worked well in a clinical setting does not necessarily fit within the at-home setting.

For medical technology (MedTech) companies and others in the healthcare sector, it will be an adjustment. The technology and capabilities now exist to enable telehealth for routine check-ins and remote monitoring to support patients recovering from surgical procedures at home, but MedTech companies will need a new approach to product development, services and operations. Although the science and therapies may remain the same, how they are presented and delivered to patients and their caregivers must change to support at-home care models.

# Healthcare is trending—toward at-home care



Trends in the healthcare ecosystem indicate that some parts of patient care are shifting to the home setting. There is increasing pressure from payers and insurers to reduce the cost of medical care and increase the adoption of value-based care models. At the same time, the COVID-19 pandemic made it difficult to continue with traditional care models, prompting the widespread use of telehealth. Plus, patient and healthcare provider expectations are leaning toward at-home care, where the patient can be more comfortable, secure and confident, and enjoy a better quality of life. Furthermore, the consumerization of medical technology presents new prospects.

### Industry pressures make at-home care attractive

Healthcare costs are rising, particularly in the US where national healthcare spending is expected to reach \$6.8 trillion by 2030.¹ Furthermore, hospital bed capacity is limited. In the United States, for example, inpatient capacity nationally is currently at around 75%.² But simply building more capacity is no longer economically feasible. It is estimated to cost between \$1 million and \$3 million to build a new inpatient bed.³ Staffing shortages are also an issue. Early in 2022, U.S. Department of Health & Human Services data indicated that 19% of US hospitals are critically understaffed.⁴

Healthcare providers are also being required to adopt alternative payment models. The US Centers for Medicare & Medicaid Services (CMS) have introduced several value-based care models, where reimbursement is based on quality of care and outcomes, not quantity of treatments.<sup>5</sup> One of these is the End-Stage Renal Disease (ESRD) Quality Incentive Program, which links a portion of payments to the healthcare provider's performance.

Private payers are also pushing for the adoption of value-based models.<sup>6</sup> They see these models as

a way to manage risk, by having the healthcare provider make decisions that will lead to the best health outcomes for patients. Aetna and Fresenius Medical Care North America, for example, announced in 2021 that they would be extending their value-based agreement to treat patients with ESRD who are eligible to enroll in Medicare Advantage. And, more recently, Fresenius announced "partnerships with more than 1,000 nephrology providers as part of the new Kidney Care Choices (KCC) models first announced by the Centers for Medicare and Medicaid Services (CMS) in 2019, and formally beginning in 2022."

Beyond value-based payment models, the US government is also investigating the value of payment incentives for treatments such as home dialysis for Medicare beneficiaries. For patients who might not be aware that at-home care is an option, Fresenius Kidney Care informs them of the benefits of home dialysis (greater flexibility of treatment scheduling, fewer food restrictions, less medication and better adherence) and that they may qualify for Medicare benefits sooner if they choose at home care. 10

These industry pressures are leading healthcare sector stakeholders to look for ways to lower expenses and free up hospital capacity while still

improving patient outcomes. At-home care and therapy could help address each of these pain points.

## The pandemic has accelerated the adoption of virtual care

The COVID-19 pandemic also accelerated the shift to at-home and virtual care.

When we surveyed patients in 2020, still in the early days of the COVID-19 pandemic, 58% said that they would be more interested in options for getting treatment without visiting a healthcare provider's office or a hospital—even after the pandemic has abated. Similarly, 62% of healthcare providers thought patients will be more interested in homeadministration of treatment, such as by a visiting nurse who comes to their home.<sup>11</sup>

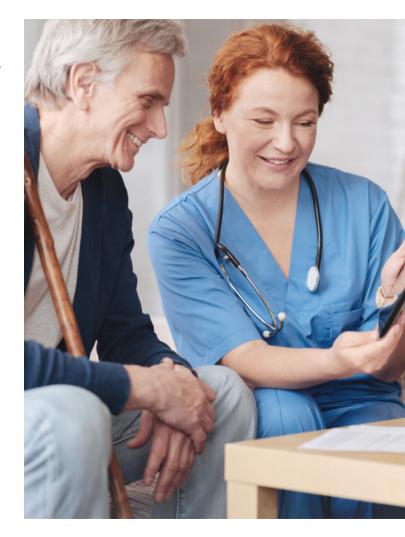
said that they would be more interested in options for getting treatment without visiting a healthcare provider's office or a hospital—even after the pandemic has abated.

In that same survey, nearly half of patients reported that they are now getting treatment at home instead of going to their healthcare provider's office. Video conference calling, for example, grew from 20% of patients using it before the pandemic to 37% using it during COVID-19. Furthermore, 44% of patients started using new devices or apps to help manage their conditions, and of those patients, 90% said that they wanted to keep using them.<sup>12</sup>

The pandemic also shifted the perceived value of at-home care in the eyes of healthcare providers. Sixty-five percent of healthcare providers said they now value self-administration methods for patients and allowing increased treatment at home (auto-injectors, for example, or on-body devices), more than they did pre-COVID-19.<sup>13</sup>

### Patients expect personalized care that fits their lives

Across all industries, including healthcare, people have growing expectations of their service providers. Because they can order consumer goods and groceries 24/7 and have them delivered to their homes, they expect other services to be similarly available where and when they choose. In short, they expect all services to be personalized,



convenient, timely and affordable—and that goes for healthcare too.

Our 2021 Health and Life Sciences Experience Survey revealed that people appreciate technology solutions. Respondents reported that in the last year they have used mobile apps (20%) and wearables (19%) to help manage their health. What's more, 8% reported that they have used remote patient monitoring to track symptoms or a condition, with data shared with a medical professional. And 8% used digital therapeutics. Virtual consultations were also valued by our survey respondents, with 22% feeling confident about their virtual healthcare appointment.<sup>14</sup>

A US national survey of telehealth found that people are increasingly comfortable using telemedicine.

"The use of telehealth services surged during the COVID-19 pandemic. A 2020 study found that telehealth usage during the initial COVID-19 peak (March to April 2020) increased from less than 1% of visits to as much as 80% in places where the pandemic prevalence was high." 15



For years, patients have been growing more and more concerned about hospital-acquired infections (transmitted by direct or indirect contact, or by air). This is another issue that came to the forefront during the height of COVID-19. Our survey of healthcare providers revealed that 66% of providers switched some of their patients to a different therapy driven by a fear of side effects or the impact of treatment on their risk of COVID-19.<sup>16</sup>

Affordability is also a factor that can have far-reaching consequences for people's health. When asked about what they had done when they could not afford care, 17% of our respondents reported that they had delayed treatment or medication; 12% skipped an appointment with a medical provider; and 11% declined treatment or medication.<sup>17</sup>

## The humanization of medical technology is driving change

Technology is constantly evolving as well. People now have access to sophisticated technology for their personal use—computers, laptops, tablets, smartphones and other devices—which affords them access to virtual doctors' visits. Connected devices can be used for diagnostic, treatment and monitoring purposes. Consumer wearable devices, for example, can monitor glucose, heart rate, physical activity, sleep or weight. They can also connect to smartphones and health apps for real-time reporting.

In fact, there are now entire ecosystems of solutions powering the connected home. In some cases, multiple devices work in concert to support and measure a patient's progress. Smart watches, smart phones and smart scales, virtual assistants like Amazon's Alexa; smart home products like Google's Nest; and smart medical devices provide data that can help paint a complete picture of the patient. All these things are easy to use by patients and give healthcare providers new insights to inform their care decisions. They are also disrupting the MedTech landscape.<sup>18</sup>

At-home care benefits patients, providers and payers



Some forward-thinking MedTech companies are already recognizing the advantages of at-home solutions. For patients, devices that enable at-home care can make treatment considerably more convenient and comfortable. But there are advantages for healthcare providers and payers, too.

#### Benefits of at-home care

- Lower costs compared to inpatient care.<sup>19</sup>
- Providers get earlier detection of side effects due to remote monitoring, continuous assessment and real time reporting.<sup>20</sup>
- Patients have improved outcomes for some treatments.21
- Convenience for patients and caregivers to avoid in-person visits.<sup>22</sup>
- Better experiences for patients, with scheduling that suits them, care that minimizes the impact on their daily lives, greater comfort and more agency over their own health.<sup>23</sup>

#### **Examples of devices used at home**

The types of devices used for at-home care vary widely. Here are a few current examples:

MedTech	Solution
NxStage <sup>24</sup>	NxStage, from Fresenius Medical Care, provides a portable hemodialysis system that has been cleared for home use in the United States. The company reveals that the machine was specifically designed for patients to use in their homes. It is also portable, allowing patients to travel and bring their treatment supplies with them.
FreeStyle Libre <sup>25</sup>	Abbott's FreeStyle Libre is a continuous glucose monitoring device that combines a small sensor on the upper arm and a smartphone app or reader to track blood glucose levels. Its continuous monitoring gives patients and healthcare providers better insights into diabetes management.
CUVITRU <sup>26</sup>	Takeda's CUVITRU is a primary immunodeficiency infusion treatment that patients can self-administer at home. A patient's healthcare team determines the number of infusion sites, how much CUVITRU to infuse at each site, how fast to infuse it and how often—and trains the patient to administer it.
Inspire <sup>27</sup>	Inspire is an obstructive sleep apnea treatment that offers an unobtrusive alternative to a continuous positive airway pressure (CPAP) machine. It is a small device placed inside the body during an outpatient procedure that the patient can then control at home with a remote control.
SWIFT Ray 1 <sup>28</sup>	The SWIFT Ray 1, from Canadian startup Swift Medical, is an imaging device for wound care that can be attached to a smartphone camera. Patients recovering from surgery can use the device to take images of their surgical site to scan for signs of infection, bacterial colonization, tissue compromise, perfusion, inflammation or blood oxygen levels. Data from the device can be integrated into electronic healthcare records, keeping the patient's medical chart up to date.

# The challenges of at-home care



MedTech companies investigating the opportunities of at-home devices for the first time have many things to consider. There are some examples of clinical solutions that have successfully transitioned to the home setting.

However, generally, at-home care is not as straightforward as simply recreating a hospital room at home. Instead, care needs to be designed for patients and caregivers specifically for the home environment.

#### The home environment is not a hospital

Often, a MedTech company's first instinct might be to repurpose existing clinical machines for at-home care. This can work as a stop-gap in some situations, perhaps when combined with a bridging connectivity solution, but it is not going to offer the best long-term advantage.

Existing clinical devices are designed to be used by trained clinicians. Often complex and multifunctional, they are not meant to be operated by the patient or an at-home caregiver. Also, this approach can lead to the home being turned into a clinical setting—with equipment, consumables. supplies and medical waste. This is an added burden for patients who would need to order supplies and manage inventory, medical waste and delivery schedules.

Furthermore, it can result in significant stigma for the patient. With medical delivery and waste removal trucks coming and going, neighbors might become aware of a person's medical condition. And it might reduce a patient's desire to socialize or entertain in their home with friends. and family. This, in turn, can affect their mental and social health.

Inventory management could also be an issue. For a patient needing dialysis, they might need to order a three-month supply of consumables like dialysate bags, tube sets and dialyzers. This can equate to an entire bedroom that must be devoted to storing and managing supplies.





#### New healthcare provider models

At-home care also requires entirely new models of service and operations for healthcare providers. Home visits mean additional training and education. There is an increased administration load, despite the potential for lower reimbursement and less time with patients.

For instance, nephrologists are not trained in home therapy as part of their medical training. As such. they are unfamiliar with the environment and often do not trust patients to manage their care at home (although, ironically, most nephrologists would choose home therapy if they required dialysis themselves).

#### Technical challenges

The technical challenges begin with device connectivity and cost. At home, each patient needs a dedicated device, whereas in a hospital or clinic setting devices can be shared. Device and data security is also more of a challenge when devices are used outside of a restricted environment

In a home care setting, the people using the devices often lack digital platform experience. While clinical solutions are designed for trained professionals, at home patients include seniors, many with declining mobility, eyesight and cognitive abilities, and those with limited technical savvv.

There is the option of teaching patients and caregivers to use existing clinical devices. But designing solutions for them that are easy to use means lower risk and superior reporting back to healthcare providers.

#### **Regulatory requirements** and risk adversity

When it comes to adopting innovative technology in a highly regulated environment, risk adversity is a key challenge. MedTech manufacturers must be prepared to meet a wide range of region-specific regulatory restrictions. Although manufacturers are familiar with requirements for current medical technology, introducing the use of devices at home adds a new level of complexity.

In recent years, payers in Europe have been increasing their scrutiny of new therapies as increasingly highcost drugs come to the market. France, for example, controls pharmaceutical pricing and spending by setting the maximum price for new products.<sup>29</sup> And while the United States does not have the same cost constraints as the single-payer health systems, it too faces heightened pressures to lower costs in order to afford innovative therapies.

There is also risk associated with meeting patient needs and understanding their ability to operate medical equipment in a home environment. And proving patient safety if medical devices are altered to better fit within the home setting.

#### Infrastructure and education

For devices to be used at home, patients and caregivers will need training in both the operation of the equipment and procedures around therapy delivery. This includes safe use of the devices, as well as reporting of vitals and therapy information. For example, the amount of dialysate used; time and duration of the therapy: and the patient's weight, blood pressure and temperature.

Sterilization is another important issue. At clinics and hospitals, staff have experience with creating and maintaining sterile environments. This is an especially challenging step for patients undergoing at-home infusions. With pets and dander, homes generally do not meet the same level of hygiene.

This is an area that will require a different mindset for healthcare providers (used to their own environment, staffing and control of the schedule) and MedTech manufacturers. At home, with the patient in charge. a new model and infrastructure is required.

For incumbent MedTech manufacturers, developing this new mindset might be daunting. Designing truly patient-specific solutions with a long lead time might be seen as too costly and unnecessary because highly functioning products are already available—patients just need to learn to use them.<sup>30</sup>

#### Competitors in the space

Legacy MedTech manufacturers will be competing with startups and technology companies that are more agile and able to respond with products that meet consumer expectations. Startups are less

encumbered by traditional mindsets and are capable of building innovative solutions that could disrupt the sector.

Technology companies like Apple and Google already have a range of devices in the home, plus a consumer mindset, powerful brand recognition and trust. In some ways, this puts them ahead of those companies just entering the sector.

MedTech companies that also provide care services will be competing with retailers like CVS, which is bringing kidney health home.<sup>31</sup> With trusted patient relationships through the pharmacy business. CVS is not a competitor to discount.

However, MedTech companies have the advantage of broadly understanding the regulatory environment, while consumer companies and startups are less knowledgeable in this area. Plus, they already have market share, recognition and potential investments to succeed over startups. And they can shift their mindset

# Seeding at-home care success



MedTech companies that want to create devices for at-home use need to set themselves up for success. We recommend adopting four foundational principles:

#### **Rethink development** approaches

Change is inevitable. Companies need to rethink traditional product development approaches to MedTech solutions if they want to see wide-spread adoption. It is not enough to simply repurpose the current clinical solutions in their product portfolio. They need to be willing to shed legacy mindsets and beliefs to get there.

#### Put patients at the center of design

Companies must build their solutions around the patient's needs—physical, cognitive, emotional, social and aspirational as providers introduce supporting care models. This might mean redesigning machines for ease of use, technical support and repair at home. Remember, machines should fit in the home environment (size) and maintain the patient's desire to receive care in the home. setting (design and usability).32

#### Incorporate connectivity

Using Internet of Things (IoT) devices or adding connectivity to existing devices can enable real-time monitoring of patient health. It also removes the burden of patients having to report data themselves. And improves the accuracy of collected data.

#### Plan for iust-in-time

Consider how to support MedTech products at home for continued success and sustainable care. From the delivery of consumables and removal of waste to predictive and proactive device maintenance. companies that can provide an Amazon-like experience will have the advantage with consumers and healthcare providers. 5G high speed data transmission will enable last mile connectivity.

As the healthcare sector moves ahead with at-home care, there are numerous opportunities for MedTech companies to lead the way. Devices that are easy to use and fit within a patient's home environment will benefit us all. They will spur growth for MedTech manufacturers, enable healthcare providers to offer better, more personalized care, and reduce costs for payers. Best of all, they will advance access, experiences and outcomes to improve quality of life for patients.

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