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Options For Medtechs In A Value-Based Care World

by Harry Liu

Driven by increasingly cost-conscious payers, health care is shifting from a volume-based model to “value-based care,” now the latest buzzword. In response, the medical device industry has started employing new commercial strategies.

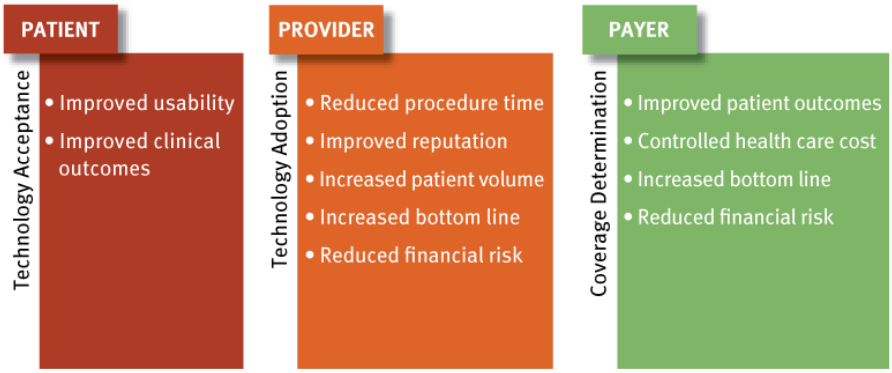
- Medtronic recently inked a value-based contract with Aetna. If patients switch from multiple daily insulin injections to Medtronic’s insulin pump and outcome targets are not met, Medtronic will rebate Aetna.
- On the surface, this type of agreement suggests that the device industry is entering an era of new commercial and reimbursement models. Or is this partnership an outlier? In either case, how should device companies adapt?
- So what? Market access + quality care + affordability is now the ubiquitous equation that health care solutions providers are seeking to calculate and leverage. For them, crucially, it is now a case of where do they fit and what options do they have if – or rather when – value-based care gains momentum?

Almost everyone has a definition of value and it's not likely that all definitions will be the same. To the question “What is value?” we would argue that it is the perceived worth of a product or service relative to the cost of purchasing that product or service. The sources of value often vary across different clients.

We cannot over-emphasize the importance of health care providers in product commercialization. The extent of a medical technology’s diffusion depends on the value it can generate for providers by reducing procedure time, enhancing one’s reputation and patient or procedure volume, improving operational efficiency and boosting the bottom line. (*See Exhibit 1.*) A hospital might wish to adopt a technology if it increases procedure throughput, operating

room utilization and stature among referring physicians and patients.

Exhibit 1



SOURCES: Rand Corp.; Frost & Sullivan

The sources of value for payers are different, and coverage determination by payers can make or break a product's commercialization strategy.

> ***Any viable commercialization strategy must focus on the two sources of value for payers: clinical outcome improvement and cost reduction.***

In the constant, unenviable tension payers face between ensuring patient access to advanced technologies and their fiduciary obligation to contain ever-expanding health care costs, any viable commercialization strategy must focus on the two sources of value for payers: clinical outcome improvement and cost reduction. Payers perceive little value in costly innovations that improve patient outcomes only marginally.

Private payers even differ from public payers in how they define value. Private payers focus more on the bottom line and public payers focus more on value from a societal perspective. The latter is frequently measured by quality-adjusted life years (QALY), an outcome that may make no economic sense to a private payer. If patients or providers really want a technology, payers may cover it, but only when patients or providers have the option to switch payers.

Acceptance by patients depends on whether a technology appeals to patients' values: better patient usability and improved clinical outcomes. Patients may not see value in a product feature that helps providers but does not improve usability or clinical outcomes for themselves. Yet experience tells us that patients have little influence on medical care decisions, which are often made by providers or payers, unless a consumer product is involved.

Solution-Based Commercial Models Are The Future

He who has the gold makes the rules: it is payers that drive the emergence of new commercial models. Device manufacturers have responded by offering solutions rather than just products. For example, when the Medicare program in the US implemented bundled payment models for total knee and hip replacements (TKR and THR), some manufacturers began offering implant-related services to help hospitals manage bundled payment risk and meet quality targets such as complication and hospital readmission rates. In the process of adapting to the new payment environment, two types of solutions emerge: provider-oriented solutions and payer-oriented solutions.

Provider-Oriented Solutions

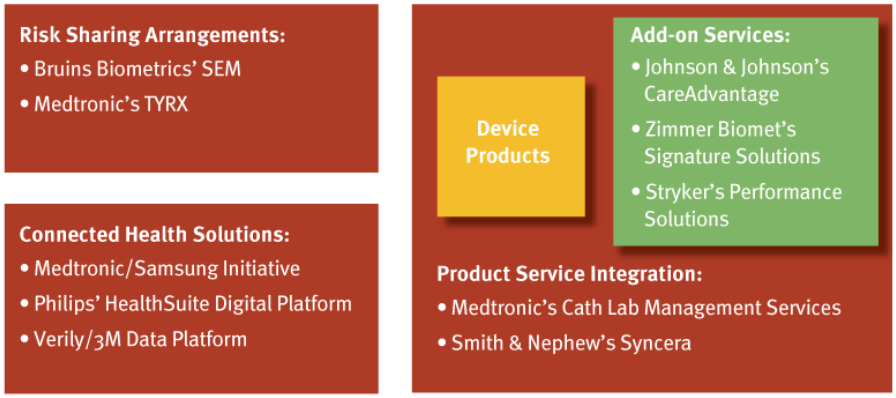
Facing the new payment models imposed by payers, providers are under pressure to control costs, meet quality targets, negotiate adequate payments, improve operating efficiency, maintain and raise their reputations, and increase patient volume. So solutions designed to help providers must address at least one of these imperatives.

Responding to the emerging needs of providers, many device companies started offering add-on services that may not tie to a specific product or device, such as patient engagement tools, data analytics and consulting services. (*See Exhibit 2*.) For example, *Stryker Corp.*, a company with annual sales in 2016 of $11.3 billion (39% in orthopedic products), recently acquired consultancies in orthopedics and now offers *Performance Solutions*.

This service targets physicians and hospitals and helps them succeed under new payment models through data analytics, care delivery standardization, quality improvement and profitability maximization. *Johnson & Johnson*, which has an annual revenue of $25.1 billion in its medical device segment in 2016 (37% in orthopedics), started offering its *CareAdvantage* program in early 2017, which helps providers develop care pathways in multiple therapeutic areas, engage patients, and improve the operational efficiency of operating rooms and the supply chain. (Also see "*J&J Ups The Tempo In The March Toward Value-based Health Care*" - In Vivo, 13 Feb, 2017.)

Another heavyweight in orthopedics, *Zimmer Biomet Holdings Inc.*, with a revenue of $7.7 billion in 2016, provides similar services, called *Signature Solutions*, but with an emphasis on patient engagement and education.

Exhibit 2



SOURCES: Rand Corp.; Frost & Sullivan

Another potential solution integrates services with devices. For example, the *Cath Lab Management Services* offered by *Medtronic PLC* currently serve nearly 140 hospitals worldwide. The services help hospitals manage cardiovascular suites, such as by providing medical technology and infrastructure; managing inventory, scheduling and operating room turnover; and developing care pathways. One key feature of the program is that it operates independently from Medtronic's cardiology device division: the catheter labs under management do not necessarily use Medtronic's products.

Smith & Nephew PLC's *Syncera* program is another example of integration of products and services, utilizing a low-cost model that operates under a separate brand name. The program offers to cost-conscious hospitals two clinically established implant devices – *Genesis II Total Knee System* and *Synergy & Reflection Total Hip System* – at cheaper prices. To lower costs, Syncera provides a package of services tied to the implants – helping hospitals set up infrastructure, evaluating inventory needs, connecting the system to an automated supply chain, training hospital staff and offering continuous technical support – rather than keeping a sales representative in the operating room.

Risk sharing is a prime example of value-based care. The payments to device companies are tied to patient outcomes. Bruin Biometrics LLC, a start-up company, produces a hand-held wireless scanner that detects sub-epidermal moisture (SEM) to assess tissue damage and helps caregivers or providers prevent the formation of pressure ulcers. The company has already signed risk-sharing agreements with providers in the UK. And given that Medicare does not pay for "never events" such as Stage 3 and 4 pressure ulcers, Bruin is eager to secure FDA approval and enter the US market.

Using similar arrangements, Medtronic is seeing rapid growth in its *TYRX* technology, a

bioabsorbable antibacterial envelope that can be used for cardiac implants or implantable neurostimulators. As of June 2017, 325 hospitals had adopted the technology and signed risk-sharing agreements with Medtronic.

Provider-oriented solutions also include digital platforms that connect consumer data, biometrics, imaging studies and medical records, which offer a range of capabilities for providers to manage their patient populations, implement interventions and monitor progress. These solutions can be implemented for various health care providers.

The most ambitious of these efforts is *Philips Healthcare*'s *HealthSuite Digital Platform*. It aims to build an open, cloud-based digital ecosystem to encompass various sources of patient information, alert providers to abnormal patient health status, facilitate interactions between patients and providers and among providers, and inform and guide managers in organizational and financial decisions. (Also see "*Philips Targets Bolt-On Deals That Meet Demand At The Point Of Care*" - In Vivo, 25 Sep, 2017.)

In 2015, Philips and Netherlands-based *Radboud University Nijmegen Medical Centre* collaborated to develop applications linked to the online community of type 2 diabetic patients. In 2016, Philips and Christus Health unveiled population health management initiatives to address the challenges associated with alternative payment models and improve patient population health.

Other players also have connected health solutions initiatives. Medtronic and *Samsung Electronics Co. Ltd.* collaborate to develop applications for diabetes management and chronic pain management. Google's *Verily Life Sciences LLC* formed a joint venture with *3M Co.* to develop population health management technology.

Payer-Oriented Solutions

Solutions have also been developed for payers to help them control health care costs, improve patient outcomes and reduce financial risk. (*See Exhibit 3*.) Depending on the scope and focus, these solutions can be device-centric, disease-centric or patient-centric. An example of a device-centric solution is the value-based contract between Medtronic and *Aetna Inc.* on Medtronic's insulin pump. The final amount paid to Medtronic will depend on clinical outcomes of target diabetic patients. This type of solution involves use of a specific device. (Also see "*Medtronic's Deal With Aetna Heralds New Value-Based Era*" - In Vivo, 18 Sep, 2017.)

Back in 2015, Medtronic bought Diabeter, a Netherlands-based diabetes clinic and research center, to expand its capabilities in diabetes management, blurring the lines between device companies and providers. Such a move is a good example of manufacturer and provider integration. Medtronic's new-found capability allows it to approach a payer and say, "Look, we

have this new solution. We can manage your diabetic patients and you can pay us if these patients achieve pre-specified clinical outcomes." According to Medtronic's senior management, the company is planning to offer a solution for type 1 diabetic patients by the end of this year in the Texas area. Elsewhere, Verily Life Sciences and pharma company *Sanofi* are building a diabetes management platform that could potentially be offered as a diabetes solution to payers.

The greatest success story related to integrating a device company with providers is *Fresenius Medical Care AG & Co. KGAA*, which provides dialysis care for patients with end-stage renal diseases (ESRD); its initiative is essentially a disease-centric solution to Medicare. In 1996, long before the term, "value-based care," was coined, Fresenius USA Inc. merged with National Medical Care's North American dialysis businesses and formed the largest dialysis service provider and renal products manufacturer in the US. The company has had a spectacular run for more than 20 years and has created tremendous financial returns for shareholders.

Fresenius is also a pioneer in patient-centric solutions: as one of the 37 ESRD Seamless Care Organizations (ESCO, one type of accountable care organization) approved by the Medicare program, Fresenius is held accountable for the clinical and financial outcomes of all Medicare ESRD beneficiaries enrolled in its ESCO. This is patient-centric care, including services not related to renal replacement therapy. Digital platforms such as Philips' HealthSuite, if leveraged by providers, could potentially be another form of patient-centric solution for payers.

Exhibit 3

SOURCES: Rand Corp.; Frost & Sullivan

Lastly, an intriguing question is, "Can device companies be integrated with a payer in the future?" Although such a move seems inconceivable at present, we're closer to that model than we think. Fresenius' ESCO is prototypical of such a solution. The company is subject to financial

risk associated with medical care but managing such risks is what payers do. The ability to take on financial risk at the patient level would enable a device company to become an insurer.

What Options Are Available And How Should Companies Choose?

A number of value-based solutions are feasible in a value-based care world, but the key is to ensure that the adopted solution enhances the economics of a company's core competencies. If no value-based models can serve this purpose, it is not worth pursuing them in the first place. But if that is not the case, two questions arise.

- Whose value are we talking about? If companies are not able to please patients, providers and payers at the same time, they must identify the major barrier to successful commercialization and then laser focus on that barrier. Identifying the major barrier determines whether companies should use a provider-oriented solution or a payer-oriented solution.
- How do you select a specific value-based solution? We have identified two key determinants of such a choice: the scope of product offerings and the resources or capabilities available to a company. If we chart example solutions along these two dimensions, it becomes clear that because of their limited product portfolio, small companies do not have solutions in the upper left quadrant, large companies are mostly concentrated in the upper right and only large companies can offer payer-oriented solutions, given that they have more resources and better capabilities. (*See Exhibit 4*.) In other words, for companies with a single product and few resources, simple arrangements with providers may be more likely to succeed. Companies with resources and a range of products may be able to build disease-centric or even patient-centric solutions or product-service integration to gain a competitive advantage.

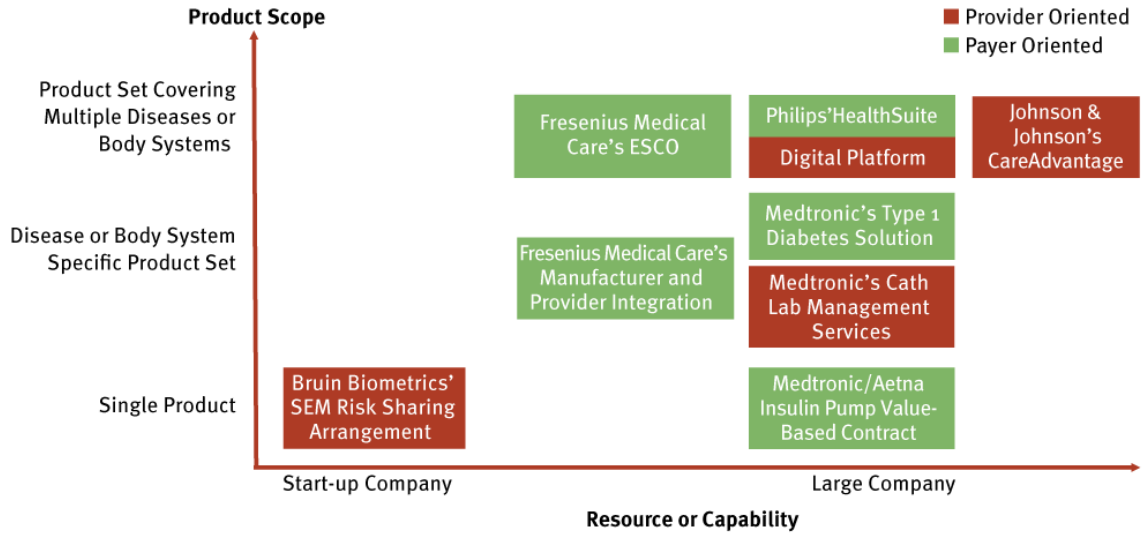
Take the example of Bruins Biometrics' SEM risk-sharing arrangement. The product mainly helps providers because pressure ulcer prevention may not be reimbursed by payers. The outcome, pressure ulcers, can be easily measured and observed in a relatively short time-period. Bruins is a small start-up company and does not have resources to launch initiatives like add-on services, product service integration or manufacturer/provider integration. A risk-sharing arrangement with nursing homes or hospitals would make economic sense.

In contrast, a large company like Medtronic might enter risk-sharing arrangements with providers or payers as illustrated by its contract with Aetna on insulin pumps. Moreover, Medtronic has resources and capabilities to integrate with providers, and they can be offered to payers as a solution for type 1 diabetes patients. Philips' HealthSuite Digital Platform offers a solution to providers and to payers if the company collaborates or integrates with providers.

Value-based contracting and risk sharing are contracting tools that may be used in all solutions,

although risk sharing is a solution in its own right. For example, Johnson & Johnson's CareAdvantage program has a risk-sharing option for its Orthopedic Episode of Care component. Essentially, any contract tied to outcome or performance with providers or payers can be considered a value-based contract. Typically, value-based contracting with a payer requires a large scale to be economically viable due to high costs of implementing and monitoring a contract. In contrast, a value-based contract with a provider may be much smaller in terms of the amount of money at stake.

Exhibit 4:



SOURCES: Rand Corp.; Frost & Sullivan

Despite all the promising value-based commercial models, companies should be cautious in executing them, especially regarding integrating with providers. Vertical integration may not work as expected. Back in the early 1990s, pharmaceutical company *Merck & Co. Inc.* acquired Medco Containment Services Inc., a leading pharmacy benefit manager, for $6 billion. Sensing Merck must be on to something, several pharmaceutical companies followed suit. The results were not as expected, and most of these acquisitions failed; Merck spun off Medco in 2003 after an unsuccessful decade-long "marriage."

Nevertheless, Fresenius Medical Care has succeeded spectacularly. One reason may be that Fresenius gained a dominant position in the dialysis market. A cautious approach would be to pilot test on a small scale and expand after ironing out all the kinks.

The Value-Based Train Has Left The Station But There Is Still Time

Despite the hype in recent years, value-based care is still in its infancy. Most health care is still fee-for-service based. Medicare, for example, aims to spend 50% of its payments on alternative

payment (non-fee-for-service) models and 90% of its payments will be linked to quality metrics by 2018. However, it remains to be seen, how much impact these reforms will have on the device industry, given that the evidence for the effectiveness of these models is not robust.

Consider the example of Smith & Nephew's Syncera. The program was designed to target the 5% to 10% of hospitals whose decisions on implants are driven more by administration than by surgeons. However, the program is far from reaching its original goal, due mainly to the delay in implementing Medicare's Comprehensive Care for Joint Replacement program. The company remains committed to Syncera, but it is currently fine-tuning the program to expand its scope. New value-based models are, in its words, "slowly emerging."

While payers are increasingly engaged in cost-cutting initiatives, a counter-force is at play: providers need to attract patients by offering state-of-the-art technologies. Value-based care may align the goals of various stakeholders and will stimulate new types of innovations that are value oriented. With value-based tools and commercial models available for deployment, device companies have the potential to become more innovative and grow a stronger market presence.

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