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Wendy Diller

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As the digital revolution sweeps healthcare, traditional musculoskeletal companies are grappling with its value to their core businesses, but the answers are far from clear-cut. We asked Health Advances experts to assess the extent to which these companies are integrating AI into their business strategies and what the future holds.

▶ WENDY DILLER

The exhilaration combined with anxiety that accompanies the ongoing digital revolution in healthcare arouses different reactions in various subsectors. For traditionally conservative orthopedics and spine manufacturers, the impact to date has been largely confined to workflow efficiencies, and tweaks to their existing businesses. Less certain is how and when big data initiatives will lead to improved patient outcomes—and whether traditional manufacturers or new tech players that are comfortable managing huge volumes of data will take the lead.

These companies are weighing whether and how much to incorporate artificial intelligence (AI)-driven rapid-cycle innovation into their core businesses, and the extent to which AI will drive the value of their innovation going forward versus advances in traditional device design.

MedTech Strategist spoke with the following experts from Health Advances: Jeffrey Abraham, partner and co-leader of the digital health and healthcare IT practice, physical therapist by training; Brandon Wade, a vice president and co-leader of the firm's digital health and IT practice as well as the musculoskeletal (MSK) practice; and Masha Dumanis, a vice president, focusing on medtech and digital health, and co-leader of the MSK practice. (*The conversation has been edited for length and clarity.*)

MedTech Strategist: How are orthopedic and spine companies, and other big surgical instrument manufacturers, approaching digital health technologies?


BRANDON WADE

Brandon Wade: Interestingly, while their initial response is excitement, they always come back to the big questions today around business models. While direct revenues would be optimal, and this is starting to happen in some areas, many companies are starting to see indirect benefits from digital technologies. If digital tools enable companies to sell more implants or break into more practice settings and hospitals and drive preferential use, there is a strong belief that they can still create value for companies.


JEFFREY ABRAHAM

Jeffrey Abraham: All device companies face a ubiquitous question: what is their revenue generation strategy [for digital]—is it to make money continuing to focus on an acute or limited episode of care, or should they expand their role in the care continuum, moving into pre- and postsurgical and more holistic approaches to treatment?

Some of them are looking at becoming quasi-providers. We are seeing some transition to expanding relationships with patients that they did not have before—where they offered only products and now also provide a service. The question is, how far do they want to go? Do they want to stay focused on building products or do they want to provide care and services as well?

Wade: I don't see the traditional MSK players moving too far in that direction, frankly. They are not set up to do that. Orthopedics is always going to need implants. Companies will need to provide that. Some companies will move upstream slightly into pre-hab and presurgical planning, and downstream slightly in terms of managing the post-op and rehab period, but as far as evolving into disease management companies—I don't see them doing that. Others are better fit to do that and operate within a completely different set of practice areas and business models.

Future winners will be the companies that recognize that surgery in orthopedics can be both an art form, which surgeons believe it is, and something that can be improved with data. Companies that are investing strategically and have the tools that can nudge a surgeon in one direction or other when they have patients in their office and are deciding on the most appropriate procedures, that is really where data could impact surgery positively.

Making data accessible—that will not be done by traditional MSK companies.

Wade: No, it will not be. Where the big companies will play in the future is closer to where they are today, with some expansion, but big digital players are pioneering access to this data.

That said, medical device companies that can ingest huge amounts of data that can cut through the noise to drill down to something that enables physicians to improve patient outcomes in surgery will be winners. The companies that will lag in 10 years are those that continue to believe that surgery is just an art form and do not fully invest in data.


MASHA DUMANIS

Masha Dumanis: We do have a little disagreement, Brandon, in that while these companies may not be the best positioned right now, most of the large OEMs recognize that the paradigm is changing and that to capture downstream patients they need to go upstream. Whether that is through regenerative medicine, or digital tools, they need to broaden their horizons in terms of the funnel of patients so that they capture the patients more broadly.

These are not mutually exclusive, they are complimentary pathways, of course. What is unique about digital, however, is that while it is not easy to do well, it is more attainable than the graveyard of regenerative assets, for example. But today pre-hab and post-hab digital care relies on virtual physical therapy or remote patient monitoring. Companies are still figuring out how to integrate more into the care continuum.

Stryker, for example, acquired OrthoSensor [2021], which has a remote patient monitor motion sensor platform, a wearable. They have acknowledged that they are not sure what to do with it yet, but they are moving up- and downstream beyond just episodic care. Yes, implants are not going away, but companies' thoughts on capturing patients are evolving.

And, of course, to Brandon's point, other companies, such as the Hinges and Kaias of the world, are addressing MSK in completely different ways and cutting out traditional players. They are not engaging with traditional orthopedic

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>
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surgeons or other caretakers the way traditional MSK OEMs have. We are still at the precipice of that transformation, and MSK OEMs are starting to notice these other players. They do not have upstream relationships right now, but they are starting to ask questions about whether there is a role for them in broader patient management.

Wade: Absolutely, MSK companies have moved upstream into close adjacencies, for example, sports med procedures before you move to implant—but I meant very upstream into this like population health and disease management.

Dumanis: Interestingly, there is not a perfect model for MSK management in a hybrid world right now. There are opportunities, however, and it still is to be seen who grabs those. The idea of an MSK medical home, which manages the patient over the course of their MSK disease process from an early stage, is an opportunity for "pay-viders." The traditional OEMs are not positioned today to be those players, but I would not discount that some of them are thinking about this.

Where are digital technologies gaining traction in orthopedics and spine surgeries?

Wade: Navigation has become standard of care for most neuro procedures but that is not the case for spine procedures yet. In spine surgery, the percentage of procedures done with navigation versus traditional imaging is still relatively low, less than 25% overall, and nowhere near comparable to neuro. Spine surgeons just do not believe they need it for procedures they do frequently. So, it will take time for navigation to become ubiquitous in spine surgery and require a subtle shift in the perception of orthopedics as an art form that does not need enabling technologies to one that can still be helped, even if more modestly.

Abraham: We may see more adoption of digital technologies in the post-acute phase of treatment. I don't know how much the traditional players will participate in this. If the surgery is elective, it makes sense for the manufacturer to go upstream, but if not, staying downstream is probably the best option. That's just the nature of these types of procedures.

I wouldn't say robotics is a digital technology necessarily, but given its connectivity and ability to extract data, it is related to the digital world. Is it a template for how companies could look at digital health technology?

Wade: I don't think robotics is the model for all digital, but neither does it stand alone and separate from the digital ecosystem. While the connectivity aspect of robotics is incredibly important, robots are commercialized and adopted like capital equipment and used as part of acute episodes of care. There is a concrete payment associated with use of a robot, even if it is only partial reimbursement. Therefore, it is similar to what these companies already know how to do.

Dumanis: In contrast, a lot of digital technologies are in uncharted territory in terms of business models. But the corollary to robotics is that there is potential to capture patient data and to coexist with the digital ecosystem.

Wade: Robotics is a capital equipment purchase. But it puts data in front of physicians and connects to presurgical planning software that loops right back to the robot. That will open physicians' minds to think about some of the more digital type technologies. It's very similar to how COVID-19 forced digital solutions into the hands of patients and physicians, particularly telehealth; we obviously saw a massive increase in that use, which has since dropped quite a bit, but we leveled out at a place that was fundamentally higher than where we were prior to COVID.

If they will not engage in building upstream businesses, how are the MSK companies thinking about working with upstream players that may be coming online? Some top surgeons have formed holistic practices—are they the exception rather than the rule?

Wade: Today, this is dictated by where their patients are coming to them from. If physicians are starting to explore some of these models that better prioritize which patients are appropriate for surgical procedures, it will be hard for these companies to ignore those pathways. Whether these companies help establish those

pathways, probably not, certainly not in the near term. They will come in once the patient comes into their offices. A lot of upstream care will happen well before a person is considered for a procedure.

The companies are following their customers. What about upstream innovations, like fall prediction technologies?

Wade: There are companies doing that and it is impactful and will move the broader industry in the right direction, but the players will be different than traditional MSK companies. There is no guarantee, after all, that the person who does not or does fall will go to a physician who uses your implants.

Predictive analytics for selecting appropriate patients for procedures are of increasing interest, particularly for spine surgery, given the difficulties of determining which patients are most likely to benefit from some of the most common procedures. Where do these technologies fit into the MSK companies' portfolios?

Wade: There is a spectrum of predictive analytics that is already being done today. Presurgical planning software helps determine implant sizes. It does not make recommendations but consists of algorithms that make it just a little more user friendly for physicians when they are doing presurgical planning. I don't know of any technologies that are approved as clinical decision support tools for patient or implant selection, but that is a real near-term opportunity for companies. The challenge is you are only as good as the data you are ingesting. And these companies operate only on the data that their platforms collect. Bigger companies have more procedures, more physicians, and more placements, so they capture more data and have a better chance to succeed here.

You are saying that start-ups in this space are at a disadvantage in that they do not have the same access to high-quality data.

Wade: Start-ups are doing incredibly novel things, but they unfortunately do not always have access to the right amount of data. As someone who evaluates companies in this space, it is really, really important to understand where companies are getting their data from and how big are their data sets, because their algorithms are dependent on those parameters.

Abraham: The Digital Medicine Society [DiME] has a framework, which it calls the V-3, for verification, analytical validation, and clinical validation. Small sample sizes may be useful for verification and analytical validity, but convincing clinicians to adopt a digital technology to use for decision-making requires an entirely different amount of data. To get that data, you have to "own the patient," which means going upstream and engaging with them.

Healthcare systems are potential sources of this upstream data. They also have innovative strategies for collaborating and partnering around data-sharing in ways that they would never have done in the past. As they take strategic views about maximizing the value of their data, including sharing it with external vendors, has it impacted how they interact with medical device companies?

Wade: There's precedent for how technology companies work with healthcare systems to mutually benefit from data, but it's largely on the operational side of things. At a minimum, hospitals are increasingly pushing for integration of data science tools. There are a host of companies that will help medical device companies integrate into the hospital's clinical and operational software, including the electronic health records, clinical documentation, revenue cycle management, and PACS systems.

But do the medical device companies get feedback data?

Wade: Healthcare system data is of course heavily regulated. The companies could get back de-identified data, which they can use to improve their algorithms. The hospitals benefit from access to that data, as well. Eventually, these efforts may be able to move the needle on patient outcomes, but that remains to be seen.

Several MSK players are exploring ways to leverage their capital equipment to be the "eyes" in the OR, which can provide live reporting of when a procedure starts, when anesthesia starts, and when the procedure ends, among a whole host of additional data. This can help in planning use of the surgical suite. That kind of information is starting to be collected and shared through traditional enabling technologies like navigation platforms and robotic systems.

Is that a business, though, and if so, who benefits from it either clinically or financially? Who keeps the data?

Wade: There is value to extracting, analyzing, and interpreting data, but it depends on how much investment is made and what the expectations for it are. There are administrative, operational, and workflow advantages, which are going to be first. Farther out are clinical use cases that will drive and improve clinical outcomes but those will require a lot more data.

I would like to believe that the healthcare systems and physicians who are starting to collect data on that will over time slightly

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>
> —Jeffrey Abraham

shift the odds of success for procedures. That will be hard though because success rates for some of these procedures are already high and there is a lot of noise in the data.

Abraham: People overestimate the monetary value of the data that they have. Monetization should have a lower priority. If that is one of the main reasons you are collecting data, reconsider because data-sharing is very complex and there are companies for whom it is not a side dish but a core business. That does not mean companies' data has no value, but it's a matter of how much you invest in it to make it salable versus the return.

What will a successful MSK company look like in two years? Five years? Ten years?

Wade: I'll say that in two years, it will look like more of the same, which is not bad. In five years, honestly, it will also be more of the same, although more companies will have digital landing pages, enabling technologies and acquisitions of novel start-ups with computer-assisted surgical technologies under their belt. Will there be an MSK company that truly breaks out of the acute and near-acute setting to go far up- or downstream? Probably not in five years. There will likely be more interesting new digital companies trying to tackle MSK with various solutions and creating a secondary market.

Abraham: I'm a bit more optimistic about 10 years. In 10 years, as a PT, I will be able to tell if a patient is a likely candidate for a knee replacement, or whatever procedure, and use sensors to evaluate them and share that data with their doctors. We will have more objective measures to inform patient care. And that data will help to inform patients about when they should get the surgery. It may lead to slightly more aggressive treatment. I see digital playing a key role in the diagnostic and treatment paradigm, especially in the academic centers of excellence.

How do you as consultants evaluate these opportunities and what do you recommend to clients?

Wade: A lot of what we do is level set. Many stakeholders within these companies are still looking for that big direct revenue on the scale of an implant or on the scale of a drug. And that's just not possible for a lot of digital. If something looks more like a device that is enhanced by digital, I think the price points in the direct revenue can still be there. But if it's purely digital, really teasing out what value can be created, direct if possible, if not indirect, and then, obviously, the strategic value is important as well.

These are not simple and easy conversations to have because the audience is skeptical and, at the same time, they think it's going to create more value than it does today. With all that said, we are hearing across the industry a general belief that this is the right direction that we should be moving in.

Is there a business in adding sensors to implants?

Wade: I think that's yet to be proven. There's a whole host of data that could be collected and sensors are getting deeper, but the algorithms and how you're cutting the data and what data you're looking at—that is really where the potential upside will be. The big, big question: what's that going to look like moving forward? Could we be in a world where every implant has a sensor on it? Absolutely. Sensor technology pricing will come down. That coupled with the data proving to be valuable could shift us in that direction. MTS

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