

EY US/AdvaMed Medtech CEO roundtable

26 August 2020



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The second EY US/AdvaMed Medtech CEO roundtable on 26 August 2020 convened senior representatives from some of medtech's biggest players for a wide-ranging discussion, overseen by participants from Ernst & Young LLP (EY US) and the industry's representative body AdvaMed. The conversation focused on medtech's response to the COVID-19 crisis and what the lasting impact of the disruption caused in 2020 will be. It followed the first EY US/AdvaMed Medtech CEO roundtable held on 4 August with smaller and emerging companies and forms part of a broader dialogue the firm is seeking to enable about how medtech and other industries can respond and reinvent themselves in the wake of the pandemic's challenges and opportunities.

Questions and topics

Moderated by **Jim Welch**, EY Global Medical Technology Leader, and **Scott Whitaker**, President and Chief Executive Officer of AdvaMed, the group's discussion focused on four key areas:

- ▶ What is the industry most proud of in 2020?
- ▶ What have been the biggest challenges during the pandemic?
- ▶ Which areas of disruption cause them the most concern as the world emerges from the first wave of the COVID-19 crisis?
- ▶ In what ways can the lessons learned during the pandemic help the industry build a better future?

The group offered a range of provocative insights around each of these points. Leading practice around specific challenges, such as go-to-market models, digital interactions with customers, training surgeons and other areas, may form the focus of future roundtables, which are part of EY US and AdvaMed's continuing efforts to widen and strengthen communications throughout the medtech ecosystem.

Medtech on the front lines

Scott Whitaker of AdvaMed opened the discussion by asserting that medtech can genuinely be proud of the way the industry has collectively mobilized to fight COVID-19, including in ways that are not recognized or appreciated by the wider public. Medtech has "been on the front lines from the absolute beginning," working with government officials to bring products to the market rapidly, from personal protective equipment (PPE) in the initial stages of the crisis, to scaling up ventilator production, before moving to address the need for diagnostics. As participant summarized, "we stepped up and saved the day."

The group agreed that collaboration between the industry's members has been a necessary and salutary part of this response. Competitors, who would usually "fight tooth and nail for contracts," came together in a "unified effort" to increase volume. When plants were shut down, medtech companies were able to help each other in "getting visibility across our supply dimensions". This level of "really powerful" collaboration, participants agreed, is not seen in all other industries. One participant described how his company had collaborated with internal and external companies to quintuple production levels and flatten the curve: while hospitals in Wuhan, Milan and New York City had approached ventilator capacity, in all other geographies excess capacity remained throughout the crisis. This pride in the industry's response to the pandemic, the group

noted, is justifiably also felt by companies focused on diagnostics. One participant commented on how well the diagnostics group coordinated to respond to the challenge and recalling that there wasn't a diagnostics group in the past, mentioned that other medtechs "really appreciate their role in the space."

Medtechs that have no direct role in fighting COVID-19 were also proud of their efforts as "silent warriors" throughout the crisis, keeping health care delivery going in the face of "incredible obstacles." One of the companies in the discussion serves patients with a mortality rate of roughly 1% per day; the company made significant efforts throughout the past months to keep supply chains open and to allow its patients to be treated in hospitals throughout the crisis. The industry can also take pride in the fact that it protected its workforce very well (something less evident in, for example, the retail sector, the group noted), despite the need for employees to stay on-site or in the field. With hospitals pivoting toward acute care management, clinical trial programs have been sidelined. As a result, some medtechs have given their clinical trial employees the freedom to redeploy within their institutions, and one participant noted his pride "that we enabled that activity and they took on that personal risk." One participant noted an internal survey indicating that 91% of employees felt both proud and safe throughout the crisis.

Supply chain challenges

One area in which the industry was forced to rethink its efforts during COVID-19's peak was the supply chain. As one participant commented, "you realize, as a company, that you're scaled for efficiency, not redundancy." When faced with the "tremendous" ramping up of demand in 2020, as the industry has been brought up against the lack of redundancy in its supply base, companies

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found themselves competing for the limited resources of their suppliers. In the diagnostics sector, for example, "we have very similar suppliers; as we all scale up, the limitations are

very much on raw materials." As this comment suggests, very low-tech basic items, such as swabs and pipettes, have been hard to deliver on the scale required. In the future, the industry will need a stronger understanding, perhaps enabled by digital technology and data, of how much scale redundancy its suppliers have and whether they can pivot toward greater production: "we have to figure out how we can do that better, maybe in a virtual environment."

The group agreed that major components have been much less problematic than minor components from a supply perspective, since major components have multiple suppliers. One participant reported that his company had "complete redundancy" around the

major components of the ventilators in the first part of 2020, but that it was struggling to source basic components, including even O-rings (basic mechanical gaskets widely used in assembly) and screws. With most medtechs having outsourced manufacturing to lower-cost geographies, often with specific areas of manufacturing confined to a single country, the national shutdowns precipitated by COVID-19 have threatened to completely cut off supply of certain components. Another risk arises if the supplier is diversified into other, non-medical sectors. This makes them "nonessential suppliers" in government terms, even if medtech companies are heavily reliant on them, and medtechs therefore "have to talk them into being essential."

Longer term, the industry will need to accommodate the ongoing reality of travel restrictions between countries and even between US states: "a new wave of complications is coming to travel, and we need to redefine the SOPs [standard operating procedures]." The industry may need to bring some manufacturing capacity back to the US or Europe to safeguard the supply base. This may be particularly relevant if there are political pressures to localize production, "whether it's Virginia saying 'we want Made in America' ventilators or Germany doing the same." In terms of political pressures, participants noted that the crisis has sharply increased dialogue between companies' supply chain and government affairs units, with "constant two-way discussion" now the norm between these groups. Looking ahead, medtech will need to proactively confront future supply chain challenges by understanding and addressing the pain points that emerged during 2020.

Facing a future of financial pressures and patient fears

The group emphasized two key concerns about the health care landscape emerging in the wake of the pandemic. First, the crisis will bring a financial burden to hospitals and health care systems, which will feel "long-lasting cost effects." For example, hospitals will need to "clean and sterilize like never before," creating a nontrivial additional time and cost pressure on daily protocols. Into 2021, participants expect to see constrained expenditure on the part of health care systems.

Second, patients remain the industry's primary concern. Many patients have been "really scared" by the messaging during the past few months. One participant described how even just watching a TV movie can expose individuals to six repetitions of a CDC advertisement warning patients with serious chronic conditions to stay home. "We've done a good job of scaring the heck out of people," participants noted; but, at this point, the frightening message risks becoming counterproductive: people still need to go in for health care. "What patients view as elective may not be elective," another participant agreed. The group argued that the terminology used by CMS needs to be better. Elective surgeries for patients who otherwise have a high mortality risk should be called "urgent" rather than "elective," for example.

Patients' fear of engaging with their health care providers threatens not only immediate health consequences but also medtech's ability to execute on the clinical trial programs necessary for ongoing innovation.

Nevertheless, another participant observed, the public health messaging is correct in an important respect. Patients with health risks shouldn't be visiting hospitals and risking nosocomial infections if there is a safe and effective virtual platform to offer safer, cheaper and more efficient triage and treatment from home. People with acute conditions need to be in hospitals, but "other things should be done through team collaboration tools!" This comment emphasized another important key theme of the discussion: the pivot to digital interactions.

The digital future began in 2020

One of the few "blessings amid so many sufferings from COVID-19," participants noted, has been the "enormous pivot to digital health." Medtech, showing "an agility sometimes not attributed to our industry," has moved rapidly to adapt to a virtual environment. One participant noted that their company's strategy for 2025 focuses on getting people onto digital health platforms, and this effort has been greatly accelerated in the past few months.

One participant described his company's "three- to five-year plan" to move activities onto the cloud. "Now we're doing it all this year," this participant concluded, a comment echoed throughout this discussion (and across the wider conversation about the impact of 2020 on digital acceleration in health care). "In the last three months, we've run faster than in the last three years," another participant agreed, describing their company's rapid adoption of digital tools: "this is going to massively accelerate the utilization of medicine and our interaction with customers."

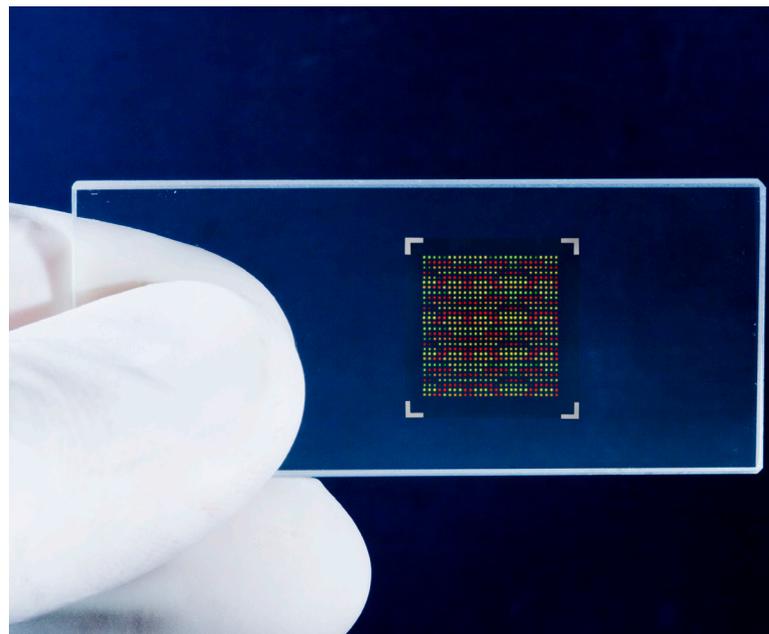
The attitude of those customers has radically changed, with provider groups embracing "telehealth to levels never done before." Provider groups have moved towards 50% to 80% use of digital rather than real-world channels, up from 5% to 15% before 2020. One participant suggests that the peak use levels of telehealth will not be sustained but that, going forward, we may see levels of 50% to 70%, "like France." One participant, whose company is focused on oncology, observed that all treatment planning has moved remotely. This will translate to not only safer interactions but also faster and more efficient interactions in terms of clinical activity, sales and interactions with patients: "patient interaction with health care systems is going to change too; that's going to stay, and it's going to be a more efficient system long term."

Collaborating to transform care delivery

As these comments suggest, a key part of the digital transformation in 2020 has been the willingness of customers and other stakeholder groups to collaborate with the industry. The attitude of customers and hospital systems "in terms of data access and sharing, has flipped overnight." While IT staff in hospitals prior to the pandemic "weren't confrontational exactly, now there is real receptivity; the speed is so different." Another participant agreed that prior to the crisis, providers were skeptical about medtech companies offering digital platforms to capture and use data; whereas today, they are using remote testing and remote monitoring eagerly. In short, "customers are helping us transform what care looks like," not just in the acute settings but all the way across the care continuum.

Jim Welch, EY Global Medical Technology Leader, noted another theme that has surfaced in sessions the firm has conducted with provider groups. These stakeholders have emphasized that they have a real appetite and need for medtechs to come to them with new ideas but also that they "want the industry to come in together, not separately." This emphasizes the importance of medtech maintaining the collective response it has mounted during 2020.

The willingness to collaborate has been demonstrated not just between medtech companies but also between the industry and its hospital and health care system customer base. Another participant also praised the FDA's role in helping the industry to mitigate the impacts of COVID-19, noting the way the regulator had granted Emergency Use Authorizations for new products, including one issued in under 24 hours. This participant cited the "remarkable" evolution of the industry's relationship with its regulator over the past eight years.



Beginning to live with COVID-19: restarting operations in the “yellow phase”

Overall, participants agreed on the need now to move the collective effort away from the overwhelming focus on COVID-19 to the challenge of helping patients more generally. “We have to stay on top of this,” one participant summarized, but at the same time, “it’s too easy for people to go back to worrying about the next wave.” The number of people dying as a result of being scared away from treatment channels (in part by the aggressive public health messaging) will probably exceed the total number of deaths from COVID-19. Cancer diagnosis rates, for example, were down 30% in June, and this threatens to become a long-lasting burden on society.

Participants also concurred that a new normal for operations needs to be found in this so-called “yellow phase,” with the reopening of schools being an important part of this. The reopening of schools will “create a chaos wave,” disrupting anew the productive virtual working practices individuals and companies have evolved over the past few months. The crisis has brought home to one participant that “we are more dependent on the communities in which we operate than I was previously aware of; we’re going to have to keep the awareness of that, as schools go back.” One participant observed that making this new transition is going to require medtechs to make demands of their employees comparable to those placed on them by the initial stages of the crisis: “we’re going to have to ask folks to work like they did in the first 12 to 14 weeks.”

The broader question for the industry and for society now, another participant observed, is: “how do we start to live with COVID-19?” Among other things needed to enable this transition are a scaling-up of diagnostics efforts and a positive attitude shift in the wider community. At present, the public conversation reveals “public discomfort with risk.” For all the good the industry is doing in the diagnostics space, for example, “all we hear about is the few misses.” Diagnostics needs to be at the forefront as societies enter the “return and recover phase,” built on mass testing with a focus on reducing risk and slowing transmission.

Building the business models for a changed future

Participants agree that as medtech moves forward into the next phase, the big question is about the long-term business model change, and how companies want to move this change sustainably into a new era. This will involve building flexibility into operations. The industry has seen that “people can work very well virtually,” so “what does that mean for the environment going forward?” as one participant asked. Another participant emphasized that while digital is going to be a big part of the future, companies must also ensure that “we can still get together physically and see each other’s body language; that stuff is important for new employees and for the culture of a company.”

Yet, while rebuilding and maintaining physical operations is clearly going to remain necessary into the future, medtech also needs to double down on its digital pivot, especially on how it engages with its customers. In the past, “medical device sales has always been a contact sport.” But, whereas a year ago, “inviting a customer to a virtual demo would have been insulting,” now companies are doing just this every day, and customer interactions and expectations have changed as a result: “the days of going in and expecting customers to give us a couple of hours are over,” this participant argued. Short, focused, often virtual conversations may increasingly become the norm, allowing clinicians to focus more on patients rather than spending time with medtechs.

This kind of shift means building new business models and accepting the major cultural and philosophical shift they imply. As one participant says, now the “conventional way of thinking is a big obstacle for us as an industry” and “thinking that we’re going back, as an industry, could be a mistake.” Completing the digital pivot successfully means addressing the “very clear gap in the talent we have versus the talent we need.” This is not just a question of bringing in additional tech expertise: it’s the broader question of having people who can think differently “and go out there in different ways,” in areas such as sales, training, education and product support. The companies that grasp these necessary shifts to SOPs and focus on becoming the trusted partners of the future can gain significant advantages in trust and access. In the meantime, “post-COVID-19, companies that scramble back to how things used to be are going to be the losers.”

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US SCORE no. 10392-201US
CSG no. 2008-3576323

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