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Impact of the COVID-19 pandemic: a perspective from industry

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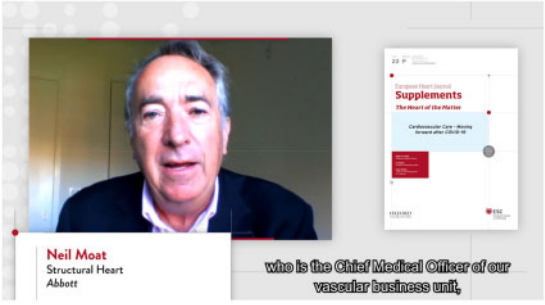
The global COVID-19 pandemic has led to unprecedented change throughout society.[1] As the articles in this supplement outline, all segments of the broader cardiovascular community have been forced to adapt, to change models of care delivery, and to evolve and innovate in order to deliver optimal management for cardiovascular patients. The medtech/device industry has not been exempt from such change and has been forced to navigate direct and indirect COVID-associated disruption, with effects felt from supply chain logistics to the entire product lifecycle, from the running of clinical trials to new device approvals and managing training, proctoring and congresses in an increasingly-online world.

This sea-change in circumstances itself has enforced the industry, in effect, to disrupt its own processes, models and activities. Whilst some of these changes may be temporary, many will endure for some time and some will doubtless become permanent; one thing is for sure: the healthcare ecosystem, including the medical device industry, will never look quite the same again. Although the pandemic has brought a short- to medium-term medical crisis to many countries, its role as a powerful disruptor cannot be underestimated, and may indeed prove to be a force for long-term good, given the accelerated innovation and rapid adaptation that it has cultivated.



Video 1 (Video is clickable in the HTML version).

Adaptation

As the healthcare sector has adapted its practices to accommodate the needs of patient care during the pandemic, so too has the medtech industry: not withstanding the disruptions encountered in manufacturing and supply chains

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owing to working restrictions, personnel being infected and/or requiring frequent testing, availability of raw materials and transport of product across borders, the changes in the practice of medicine have enforced widespread change. In addition, a large proportion of medtech employees have had to resort to remote working from home for much of the pandemic.

Diversion of healthcare resources to providing increased capacity for critical care and high-dependency units resulted in reduced or abolished elective procedural volumes for long periods in the early part of the pandemic; initially-divergent practices in different geographies have largely stabilized into accepted and aligned protocols,[2,3] and in combination with public health measures, this led to restoration of elective volumes to near-normal levels despite the continuing pandemic. However, the effect of the recent resurgence in case numbers in Europe and elsewhere has yet to be determined.

There have been unpredictable fluctuations in procedure volumes consequent on a variety of factors: the well-publicized fall in many emergency presentations such as acute myocardial infarction[4,5] resulted in a decline in percutaneous coronary intervention volumes, but this fall may have been buttressed, to some small extent, by deferral of coronary bypass surgeries. The preference for less invasive percutaneous procedures (where possible) for patients with cardiovascular disease, avoiding surgical intervention and subsequent need for critical care support, clearly enables earlier ambulation, shorter hospitalizations and therefore reduced bed occupancy. However, many patients suffering from valvular heart disease and heart failure have been denied interventions such as transcatheter valve replacements or repairs as these were deemed to be elective procedures. In two U.S. studies, this led to high levels of mortality in patients awaiting aortic valve interventions.[6,7] Guidance from the European Society of Cardiology and the European Association of Percutaneous Cardiovascular Interventions (EAPCI) has attempted to align patient needs with requirements for safety of both patients and caregivers, and address many of the uncertainties about who should be treated, how and with what urgency[2,3]; this was backed up in Europe by industry-supported unbranded initiatives to encourage patients not to delay or avoid medical contact when they suffered symptoms suggestive of myocardial infarction or critical limb ischaemia.

Medical affairs teams across the sector, usually involved with provision of information and education to doctors and allied professionals, driving engagement with key opinion leaders and facilitating non-commercial advisory panels to guide scientific strategy, had to demonstrate the ability to pivot rapidly to a virtual environment; in order to support these activities, and for the larger congresses that have continued on a variety of web-based platforms, considerable agility in the digital space has been required. Across the industry, all of these activities have continued seamlessly, with the reach (in particular) of educational content now able to engage more healthcare providers than before thanks to the ability to share content live and after-the-event online. Interestingly, many congresses have reported a substantial increase in registrations for their 'virtual' events compared with those for the prior live congresses, which may provide a new direction for such meetings—despite a perceived reduction in the opportunity for networking and face-to-face meetings.

There has also been understandable and considerable impact on clinical trials across the sector, with some geographies effectively suspending all non-COVID-related research; even where such embargos did not exist, reduction in elective case volumes exerted a similar impact. The consequent 'collateral damage' from the COVID-19 pandemic may yet result in delays to future device approvals, denying patients access to important and/or innovative therapies. For the trials that have continued, there remains the complexity of endpoint event adjudication moving forwards, of particular importance in the cardiovascular arena, as COVID-19 has been intricately linked with myocardial injury and oedema, heart failure, microthrombosis and endothelial inflammation/injury, as well as indirect myocardial injury consequent on systemic hypoxia from pulmonary involvement and as a result of multi-organ failure.[8,9] With this in mind, we have convened a panel of multi-specialty physician experts to assist our understanding and handling of this important phenomenon. However, there have also been some benefits for clinical research: the advent and acceptance of widespread remote consent, monitoring and event ascertainment, the acknowledgement and identification of barriers to representation of all socioeconomic and ethnic groups within trial populations, and the adoption of adaptive and pragmatic trial designs to enhance success, efficiency and generalizability of trials; to effect meaningful change in the way that trials are run and executed, these developments should be considered as a template for the future.[10]

Innovation

Across the broader medtech industry, huge efforts were mobilized to provide healthcare workers with the tools required to diagnose infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the coronavirus responsible for COVID-19 infection. Three different kinds of tests are generally used to diagnose such viral infections: in the acute phase of infection, molecular tests detect viral RNA and antigen tests denote presence of viral proteins; in the convalescent phase, antibody tests can detect IgM (early post-infective phase) or IgG (late convalescent phase). At the time of writing, a total of 283 different detection tests had received emergency use authorization from the FDA for use in the USA (221 molecular tests, 56 antibody tests, and 6 antigen tests), with varying capabilities, sample types and location of use (lab-based vs. point-of-care), representing an enormous redeployment of resources to combat a public health emergency. Our Diagnostics and Rapid Diagnostics divisions have gained approval for a variety of tests, all with proven sensitivity and specificity to detect infection >90% (*Table 1*); crucially, point-of-care tests are now becoming widely-available, reducing the burden on overstretched healthcare systems, and additionally providing added functionality with novel developments such as the NAVICA 'digital passport', allowing generation

Table 1 Summary of currently available Abbott tests for diagnosis of SARS-Cov-2/COVID-19

	Test name	US FDA EUA	CE Mark	Location	Sample type	Notes
Molecular	Abbott m2000 RealTime SARS-CoV-2 assay	18 March	20 March	Lab	NP swab	470 tests/day
	Alinity m SARS-CoV-2 assay	11 May	1 June	Lab	NP swab	1080 tests/day, results ≈2 h
	ID NOW COVID-19	27 March	16 September	POC	NP swab	Results ≤13 m
Serology	ARCHITECT i1000SR and i2000SR IgG	26 April	29 April	Lab	Blood test	100-200 test/h
	Alinity i SARS-CoV-2 IgG	11 May	14 May	Lab	Blood test	High volume
	AdviseDx SARS-CoV-2-IgM (ARCHITECT/Alinity)	12 October	17 August	Lab	Blood test	High volume
	Panbio COVID IgG/IgM rapid test	NA	14 April	POC	Fingerprick	Results 10-20 m
Antigen	BinaxNOW COVID-19 Ag Card	26 August	NA	POC	Nasal swab	Results 15 m + NAVICA app digital passport
	Panbio COVID-19 Ag rapid test	NA	18 August	POC	NP swab	Results 15 m

Tests are grouped by method (molecular/serology/antigen) with dates indicating relevant approvals in 2020.

CE Mark, Conformite Europeenne approval; Lab, lab-based testing; NP, nasopharyngeal; POC, point-of-care; US FDA EUA, US Food & Drug Administration emergency use authorization.

of a QR code on a smart device, similar to an airline boarding pass, to provide instant access to recent antigen testing results.

Just as the pandemic has driven this type of innovation, other device divisions have developed novel solutions to replace/augment in-person training or proctoring of new technologies: a variety of remote techniques, virtual training schemes and remote medical proctoring have enabled the continued launch and expansion of life-changing device technologies worldwide, without necessitating the in-person contact that such activities usually require. A number of novel technological platforms are emerging to facilitate and optimize the above 'remote' activities, including multichannel live transmission platforms and virtual reality technologies. Similar remote monitoring techniques have been adopted and expanded for device follow-up, enabling patients with heart failure, arrhythmias and chronic pain syndromes to benefit from ongoing care without the need to enter a hospital environment. For example, physician-directed management of heart failure patients using remote pulmonary artery pressure monitoring has been shown to be safe, effective, and to reduce heart failure hospitalizations,[11] and the reassessment of in-hospital use of continuous glucose monitoring systems has indicated reductions in need for staff-patient contact, especially important in patients suffering from COVID-19, and allows digital transmission of readings to a remote device.[12]

It is highly likely that remote follow-up (where feasible) and training may become the norm moving forwards, given the convenience and time efficiencies that have been observed for both the industry and the professionals it serves.

Evolution

As the industry has adapted to inevitable change, it is clear that the adaptations and innovations that have been embraced will lead to permanent metamorphosis. Digital transformations within the sector that may have previously suffered from inertia have accelerated rapidly with acquisition of new digital and virtual skillsets, and evolved companies to deliver better, more efficient ways of treating patients, providing services to healthcare professionals and managing clinical studies.

The wealth of remote data capture from both clinical trials and routine care that has started during the pandemic, alongside deployment of advanced analytics such as machine learning and artificial intelligence algorithms will lead to far better understandings of how we can personalize treatment for individual patients. We have recently published a white paper 'Beyond Intervention',[13] which highlights the potential synergies between novel technologies and data-driven techniques to generate concrete and actionable insights and drive the future of cardiovascular care. Such progress is likely to continue in tandem with long-term adoption of the observed positive adaptive and innovative developments from the crisis, resulting in a leaner and potentially unrecognizable sector in the future, with a more patient-tailored and -focused view that considers not just the point of device intervention, but the entire holistic patient care continuum.

Conclusion

Drivers for change may emerge from even the worst of crises, and the medtech industry, as a whole, has responded to the evolving needs and obstacles posed by the pandemic to continue delivering healthcare solutions from diagnosis to treatment, to follow-up and beyond for patients-in-need. Further, the ongoing digital and virtual transformations that COVID-19 has driven will no doubt enhance the industry's ability to continue to reach and support the

healthcare community in the future. These novel circumstances have facilitated the development and evolution of new forward-facing and patient-centric solutions to a rapidly changing environment that will endure long after the pandemic has passed.

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