

Original Research

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Corresponding author: Frank Fox; Email frank.fox@universityofgalway.ie.

Key Factors Impacting a Medical Ventilator Supply Chain During the COVID-19 Pandemic: Lessons for Pandemic Preparedness

Frank Fox PhD¹ , Jessica Hayes PhD¹, Barbara Whelan PhD², Dymna Casey PhD² and Máire Connolly PhD¹

¹University of Galway, Global Health, School of Health Sciences, Galway, Ireland and ²University of Galway, School of Nursing and Midwifery, Galway, Ireland

Abstract

Objectives: Future pandemics may cause more severe respiratory illness in younger age groups than COVID-19, requiring many more mechanical ventilators. This publication synthesizes the experiences of diverse contributors to Medtronic's mechanical ventilator supply chain during the pandemic, serving as a record of what worked and what didn't, while identifying key factors affecting production ramp-up in this healthcare crisis.

Method: In-depth, one-on-one interviews (n = 17) were held with key Medtronic personnel and suppliers. Template analysis was used, and interview content was analyzed for signals, initiatives, actions, and outcomes, as well as influencing forces.

Results: Key findings revealed many factors limiting ventilator production ramp-up. Supply chain strengths and weaknesses were identified. Political factors played a role in allocating ventilators and also supported production. Commercial considerations were not priority, but economic awareness was essential to support suppliers. Workers were motivated and flexible. Component shortages, space, production processes, and logistics were challenges. Legally based pressures were reported e.g., import and export restrictions.

Conclusion: Crisis response alone is not enough; preparation is essential. Coordinated international strategies are more effective than individual country responses. Supply chain resilience based on visibility and flexibility is key. This research can help public health planners and the medical device industry prepare for future healthcare crises.

Background

In the first wave of the COVID-19 pandemic, 34.6% of hospital admissions progressed to intensive care units (ICU), 18.5% of hospital admissions received mechanical ventilation, and up to 34% of COVID-19 patients in the ICU died,¹ leading to a surge in demand for ventilators,² with required estimates running up to a million to satisfy global needs.^{2–4} Medical device manufacturers were unable to satisfy this demand, precipitating a worldwide shortage.⁵ Governments, health authorities, international organizations such as the World Health Organization (WHO), and USA's Biomedical Advanced Research Development Authority (BARDA),⁶ all sought large numbers of ventilators, often competing with each other. Panic buying exposed weaknesses in public health procurement and allocation systems, and led to further distortions in worldwide supply chains.⁷ Medical device manufacturers were faced with the simultaneous challenges of urgent need for their products and pandemic-related constraints on production.

While worldwide demand for ventilators subsided as evidence on clinical management of COVID-19 cases emerged, future pandemics may have different characteristics with the potential to affect the population much more severely, making it imperative that we learn from the supply and demand experiences of this pandemic. For example, the 1918 influenza pandemic is estimated to have led to 50 million deaths and had a significantly higher young-adult mortality.⁸

This case study documents and synthesizes the experiences of diverse contributors to Medtronic's mechanical ventilator supply chain during the pandemic into a PESTLE framework, a pragmatic and familiar format enhancing preparedness by identifying key factors affecting production ramp-up in a healthcare crisis.

Case Study: Medtronic

Medtronic's plant in Mervue, Galway, Ireland produced a range of ventilators from portable models like the Puritan Bennett™ 560 to the Puritan Bennett™ 980, a critical care model, assembling and testing over 1500 components sourced from 100 companies in 14 countries. In pre-pandemic circumstances, around 200 high-end ventilators were produced weekly, and satisfying the huge pandemic demand was impossible. This necessitated the mobilization of

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organizational resources to manage the production and allocation of available ventilators. The team was tasked with increasing ventilator production 5-fold in an initiative known as the “Drive for 5,” posing challenges and requiring reorganization, additional workforce, and new and repurposed spaces, as well as replication of assembly/ testing facilities, process innovation/ changes, and subcontracting of process steps. It also required greater engagement with suppliers ensuring their capacities ramped up appropriately. Allocation of available ventilators necessitated engagement between leadership and pan-national organizations, governments and public health authorities, in a world where public health measures including travel restrictions, and export restrictions made such initiatives challenging. Shrinking air-freight capacity was a knock-on effect with most available transport capacity filled with personal protective equipment (PPE) and little availability to transport ventilators. In spite of this, production ramp-up from March 2020 to July 2020 saw the output of the Puritan Bennett™ 980 critical care ventilator rise from 200 to 1000 units per week with many lessons in crisis management learned.

Supply Chain Risk

The pandemic disrupted worldwide supply chains causing shortages in the availability of critical medical equipment, electronics, and raw materials. Medtronic’s CEO, Geoff Martha, spoke of supply chain difficulties for ventilators,⁹ and components. He referred to a ‘catastrophic explosion’ in the supply of trade packaging, semiconductors, and resins.¹⁰ This and prior events have led to a realization that such disruptions are no longer rare events but happen regularly, and need to be planned for.

These risks to supply chains occur in several broad areas including supply and demand, processes, and controls. This research categorizes risks into strategic, tactical, and operational categories, and are viewed through lenses including PESTLE analysis,¹¹ and supply chain risk assessment,¹² as shown in Figure 1. This research focusses on strategic and tactical knowledge levels.

Supply Chain Disruption Management and Resilience

Supply chain resilience is key to mitigating these risks. While many definitions of supply chain resilience exist,^{12–15} the definition used here is, “the capacity of an enterprise to survive, adapt and grow in the face of turbulent change.”¹⁶ Achieving supply chain resilience requires a deep knowledge of the risks facing it. This research contributes knowledge to this effort by assembling the pandemic ramp-up experiences of key Medtronic personnel and suppliers, creating deeper understanding, and supporting decisions in areas such as sourcing components, collaboration, and supplier development, as well as location strategy, and efficiency versus redundancy issues.

Medical device supply chain vulnerabilities in planning, forecasting, production, and delivery were previously reported by McKinsey and Company,¹⁷ where end-to-end supply chain visibility proved elusive. Previous studies identified issues due to competition with other industries for commonly-used electronic components as well as competition within the medical device industry for unique components such as oxygen sensors.¹⁸ Excessive demand was also reported in other work,^{2,10,18–20} with solutions such as collaboration with third parties,¹⁸ and easing of regulatory restrictions documented. Contingency contracts having potential to help in future crises by maintaining surge capacity in normal times were reported,¹⁸ as was the necessity of allocation by medical need.¹⁸ Business and production models such as global



Figure 1. Supply chain knowledge hierarchy pyramid (Adapted from Christopher and Peck¹¹).

sourcing, single sourcing, hyper-specialization, and geographical concentrations also came under scrutiny. Import and export restrictions were also reported as problematic.²¹ This research builds on previous work with a detailed interview-based PESTLE structured case study widely understood in both practical business environments and in research. It synthesizes the experiences of both the focal company and its suppliers and seeks unique insights based on their relationships and perspectives.

It documents how the supply chain and production ramp-up was achieved through interviews with key Medtronic personnel, and referenced documents, media interviews, and published literature. It identifies bottlenecks e.g., long lead times, customized components, and electronics as well as documents the approach taken to bolster the available workforce. It identifies strengths and weaknesses such as the benefits of long-standing relationships with key suppliers and strains caused by long distances. It brings these elements together as key findings. This study provides a timely analysis of factors impacting medical device production which will prove useful in developing strategies facilitating efficient and effective supply lines for future pandemics.

Method

Study Design

A retrospective case study approach was used, capturing the participants’ experiences through in-depth interviews. A descriptive approach documents how Medtronic ramped up its production capacity, identifying the factors which influenced the supply chain. This approach aimed to build a more general explanation of how this was achieved using thematic analysis. PESTLE themes¹¹ are typically used to gather and analyze information about forces acting on a business, identify key issues, and develop mitigating strategies,²² (see Table 2), hence providing an easily-understood structure familiar to both academics and managers.^{23,24}

Interview Participants

Seventeen (n = 17) individual interviews were conducted with personnel outlined in Table 1. Four scoping interviews (n = 4) were conducted with senior Medtronic personnel to identify others who

Table 1. Participants' roles in Medtronic (** = scoping interviews)

Medtronic personnel interviewed	Medtronic suppliers interviewed
**Research & Development Sustaining Manager	Purchasing and Supply Chain Manager (Supplier)
**Supply Chain Manager	General Manager (Component supplier)
**Vice President Operations	General Manager (Component supplier)
**Mervue Site Manager	
Senior Supply Chain Purchasing Supervisor	
Human Resources Site Manager	
Principal R&D Sustaining Engineer	
Site Quality Manager	
Government Affairs Manager	
President Respiratory Interventions	
Ramp-up Manager	
Legal Affairs and Intellectual Property Counsel	
Vice President International Relations	
Senior Supply Chain Planning Manager	

could contribute. Additional interviews were conducted with Medtronic personnel (n = 10) and Medtronic suppliers (n = 3).

Ethical approval

Ethical approval was granted under REC application 2022.08.005, by the Research Ethics Committee in the University of Galway, issued October 3, 2022. Participants were given a detailed information leaflet and ample time to study this before consenting.

Data Collection

Participants consented to an individual, semi-structured interview. Five interviews were held in person and the remaining 12 using Zoom and Microsoft Teams. Interviews ranged from 30 to 60 minutes between October 2022 and March 2023. Interviews were audio-recorded and additional notes were taken to facilitate follow-up questions.

Data Analysis

Interviews were transcribed using Word Transcribe with manual checking. Transcriptions were imported into NVIVO 14 (Lumivero, Denver, CO, USA),²⁵ for data organization and retrieval. A variation of thematic analysis known as template analysis was used.²⁶ The a-priori codes used in the initial template analysis codes were political, economic, social, and technical, as well as legal/ ethical, and environmental, derived from PESTLE.¹¹ Sub-themes were added as necessary.

Research Rigor

Recruitment used purposive sampling initially, followed by snowball sampling, reaching a broad range of participants across the Medtronic organization. The interviewer assessed that data adequacy had been reached after 17 interviews as no new content was forthcoming. The interviews were informed by a topic guide mitigating interviewer bias. This engendered trust in the process

Table 2. PESTLE theme guidelines

Political	Experiences recounted in the interviews relating to effects generated by the political branch of government and related bodies; This includes political support, legislative initiatives supporting pandemic related production, direct pressures exerted by politicians, and public statements by political figures, as well as political diplomacy at local, national, or international levels. It also includes participants' ideas on political initiatives which could support industries' response to future health crises.
Economic	Experiences recounted in the interviews relating to effects generated by economic factors including financial stability, capital availability, price inflation, or deflation, as well as price pressures, cash flow, government financial supports through taxation, or other support measures.
Social and Motivational	Experiences recounted in the interviews relating to effects of social and motivational issues including attitudes to the pandemic, demographic profiles of at-risk groups, and potential workforce.
Technical	Experiences recounted in the interviews relating to more technical aspects of the ventilator ramp-up including general supply chain issues such as component availability, sourcing issues, human resources, and logistics, as well as process improvement.
Legal and Ethical	Experiences recounted in the interviews relating to legal and ethical matters influencing the ramp-up including legislative barriers and facilitators to import and export, mandatory requirements and use of existing legislation, movement control orders, and social distancing restrictions, as well as ethical issues around the equitable allocation of available resources, particularly ventilators.
Environmental	Experiences recounted in the interviews relating to environmental matters influencing the ramp-up. This relates more to the organizational environment rather than the ecological environment.

and fostered forthright interviews. Some triangulation was achieved between the interview data using publicly available interviews and other Medtronic documentation. The in-depth interview method followed COREQ guidelines for qualitative research,²⁷ Roller's guidance for in-depth interviews,²⁸ and Yin case study guidelines.²⁹ The data was managed in NVIVO 14 (Lumivero, Denver, CO, USA).

Results

Summary of key Finding

Spikes in demand for ventilator consumables as early as January 2020 signaled the coming demand for ventilators and the need for a production ramp-up. Medtronic's *Drive for 5* started in March 2020. Governments and others rushed to source ventilators and simultaneously implemented initiatives supporting ventilator production. Humanitarian considerations took precedence over economic considerations, with an everything-goes investment attitude. Capacity constraints and shortages were experienced in workforce, space, components, and transportation, requiring investment and innovation in processes, and enhanced collaborations. Medtronic's organizational strength and the close involvement of senior leadership were key.

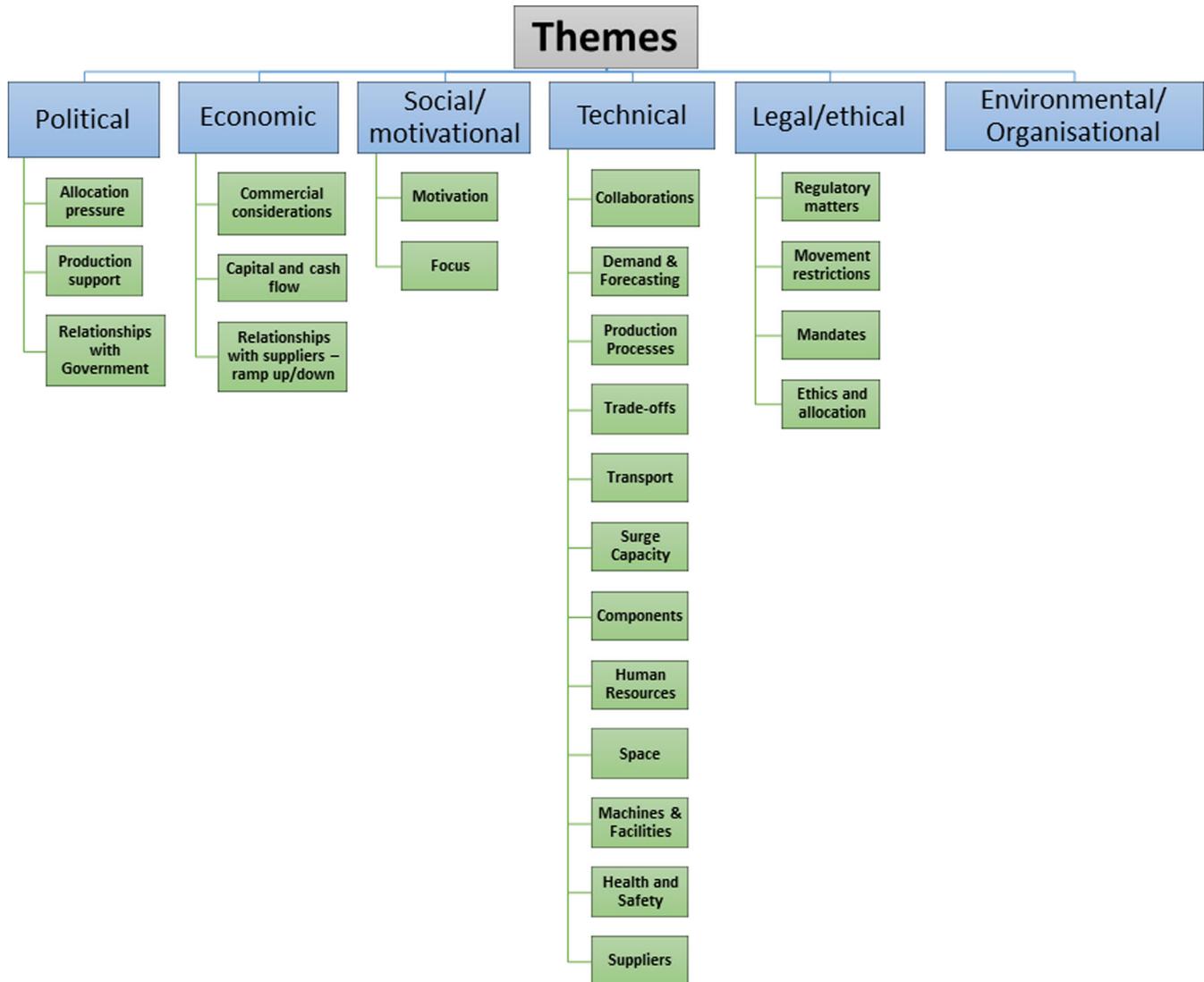


Figure 2. Top level themes (blue) and sub-themes (green).

Thematic Analysis Using PESTLE

Interview data were coded to PESTLE themes and sub-themes added (Figure 2)²⁶. Organizational factors were prevalent, and the environmental theme focusses on these. Key participants' quotations are listed in Table 3.

Political theme

Three major political factors impacting the ramp-up were identified.

- 1) Allocation pressures: Governments applied pressure to influence the allocation of the limited number of ventilators.
- 2) Production support: Political influence supported production by facilitating flexible enforcement of movement restrictions allowing workers to travel to work and removing barriers to the movement of ventilator components which was otherwise restricted.
- 3) Relationships with governments: Relationships were initially strained due to shortages and competition for devices. Broader understanding of the complexity of ventilator production developed among the parties during the pandemic leading to better cooperation.

Economic theme

The group identified 3 recurring economic matters:

- 1) Cash flow and capital availability: Ramp-up was costly and required collaboration between Medtronic and its suppliers. Rapid capital investment was facilitated, and cash-flow allowances were made.
- 2) Commercial considerations: Humanitarian rather than commercial considerations drove decisions.
- 3) Impact of relationships with suppliers including ramp-down matters: Long-standing relationships were key in responsive supplier engagement. Ramp-down was difficult for suppliers and led to uncertainty within Medtronic.

Social/motivational/focus themes

Strong motivation and sense of purpose were reported i.e., producing life-saving ventilators.

- 1) Singular focus: The sharp organizational focus on ventilator production was beneficial to the ramp-up effort. However, the commitment level was not considered sustainable long-term.

Table 3. Participant quotations from interview transcripts

Theme	Selected quotations	Participant
Political: allocation pressure	<i>"We had demands at the highest levels of government to conform, right. And that includes the big international organization like UN and UN OPS, WHO, a variety of others, and World Bank, etc."</i>	15
Political: allocation pressure	<i>"On the UN side, the UN was fighting with it itself. The people that you think were the most enlightened, you know, had the most information like UNOPS and World Bank, were fighting with each other for the same reasons that governments fight. They're just simply a reflection of, you know, say the Irish Government versus the French Government."</i>	15
Political: production support	<i>"I was working closely with the department of Foreign Affairs and with the various embassies where our suppliers were impacted. Ireland was fantastically responsive with getting in touch with host governments through their embassies and ensuring that the letters we had created to say that this supplier is part of the Medtronic ventilator business and therefore is exempt from lockdown laws... got them out."</i>	7
Political: relationships with governments and other bodies	<i>"People understand drugs; they do not understand medical devices. They don't understand the technologies. No one knew what a ventilator was, coming into this thing."</i>	15
Political: relationships with governments and other bodies	<i>"The point is our IP decision, our intellectual property was in my view, the most daring and the most appreciated by the global community. Even the impact of this has been incredibly large from a recognition of Medtronic standpoint. So, I cannot possibly over-state to you how many thanks I've received from the major global organizations, how much they thought of that decision."</i>	15
Economic: cash flow and capital availability	<i>"Basically we were giving directions to Galway to ramp up as fast as they could to make as many as they could, and they were coming to us to say that in order to do that we will need to do X investment either in Galway or with our suppliers, or hire this many people, or train this many people. They were letting us know what this required; it was sort of a philosophy of well everything goes: if you need it to ramp, we'll do it."</i>	10
Economic: cash flow and capital availability	<i>"We'll shorten credit terms, you know - We'll pay you quicker. You know, those were the kind of things that made a huge, actually a huge difference. However, scaling a business up needs a lot of cash, but actually by just shortening those credit terms, that really helped us with that scale up."</i>	17
Economic: commercial considerations	<i>"I can absolutely say that for us, the commercial aspect wasn't considered, not even once. The cost of producing the ventilators went up significantly - (15 - 20% overnight, just on the transportation costs). Material costs started to go up very quickly after that. We didn't increase the cost of the ventilators. There was no commercial consideration whatsoever, not once. I think actually, I'm not sure we'd get the same response again."</i>	4
Economic: commercial considerations	<i>"We obviously made good money in that time frame. Now we didn't increase prices. We didn't do anything to try and capitalize on it around that level, just naturally volume went up, and we made good money in that time frame. Because the time frame was so short and because we're down now, I wouldn't want to do a calculation on what we've actually lost, although we did well in that 1 year, 6- month period or whatever."</i>	14
Economic: relationships with suppliers	<i>"The 1 critique I would have for Medtronic was that the carpet was pulled out from underneath us pretty quickly on the downside."</i>	11
Economic: relationships with suppliers	<i>"But yeah, the peel down was hard, I think, because they had slightly lost a grip on how much new stuff is in the system. That's the kind of stuff that we'd be disappointed with in the partnership. Yeah, it still is a partnership. It's still a very strong partnership."</i>	17
Economic: relationships with suppliers	<i>"Maybe we could have done better, we fell off a cliff in terms of coming down the other side when you talk about ramp-down. I just wonder if we could have, from a planning perspective, have a bit more visibility there and not put our suppliers under so much pressure at the back end of it."</i>	12
Social and motivational	<i>"The mission was very key, the Medtronic mission to alleviate pain, restore health, and extend life was very much the focus, so you can say your quality department ramped up and increased in size, yes but every operator on that floor already had a heightened focus."</i>	8
Social and motivational	<i>"From a cultural perspective it was a team that was all moving in the 1 direction, and that's not always the case where people have their own agendas and their own silos. It just felt like normal thinking went out the window. That sounds like a warm, fluffy thing. For me, it was very much the fact that everybody pulled in the one direction."</i>	12
Technical: transport	<i>"Air freight reduced by a very significant amount very quickly; there was pretty hard rules about PPE going on the plane first."</i>	2
Technical: surge capacity	<i>"Doubling was quite straightforward for us because it just meant O.K., we need to get a lot of extra staff in, we need to put night shift on, and effectively, we need the same number of machines."</i>	17
Technical: surge capacity	<i>"I think having a mature supply base with many suppliers who have been with us for a long time. We understand how each other thinks. Sometimes it can be, you know, it can be fashionable. Just put it out to tender every 2 years and move it around to get the lowest price, but there's a lot of benefits to having deep relationships as well."</i>	12
Technical: suppliers	<i>"There are too many Mom & Pop shops, and this is across the business. What I discovered was that when they did an acquisition, they bought over a vent design, they brought over the incumbent suppliers with them, and never managed to get the bandwidth to take a consolidate approach."</i>	2
Technical: suppliers	<i>"Lots of daily calls with maybe 8 or 9 suppliers and weekly calls with other ones, and sometimes we would be tier 3 in, tier 4 deep trying to resolve things blocked in the chain."</i>	12
Technical: demand spike	<i>"We very soon realized that no matter how many we made, it wouldn't fill the demand so we kind of just converted that to Galway to make as many to ramp up, as quickly as they could, and for them to tell us how long it would take and what it would take to do that."</i>	10

(Continued)

Table 3. (Continued)

Theme	Selected quotations	Participant
Technical: machines and other facilities	<i>"The thing that took the longest was the capital equipment. You know, that's the thing that you couldn't waste any time on getting because equipment is a big expense. It's not always off the shelf."</i>	17
Technical: production processes	<i>"When we were put to the pin of our collar and there was a real need to reduce cycle times. It was a real discussion around process improvements that could help get vents out to customers quicker. So we had a number of tests that we were able to reduce for testing the integrity of the device, and the duration they spent in the rooms was challenged, reduced, and remains reduced."</i>	3
Technical: quality	<i>"We didn't drop our standards - if anything we tightened our standards because we knew the risks of new employees; they add extra risks because they have to go through learning curves. So we have a very rigorous training program for new operators on the production line: for example, they go through a series of phases before they are finally signed off to work independently. Operators were watching other operators work. People who were very shy normally were confident enough to go to another operator and say - Hey you might be doing it a little bit wrong; can I give you a hand to do that a little bit better, or keep an eye out for this, keep an eye out for that; all of a sudden you had multiple eyes everywhere - everybody watching."</i>	8
Technical: collaborations	<i>"The collaboration that existed at the beginning of and during COVID was really positive but harnessing it was challenging."</i>	4
Technical: collaborations	<i>"For the significantly technical elements of the supply chain, you had to expand what was there - there was no point asking someone else to produce a PSOL for a vent overnight, where the solution had taken almost 10 years of design plus probably another 5 years to fine-tune a process to produce it. There were heat-treatment processes, machining processes, annealing processes that were crucial to the performance of the ventilator, and you just couldn't stand them up overnight."</i>	4
Technical: human resources	<i>"People were absolutely fantastic in how they responded - very flexible - extremely flexible and helpful."</i>	6
Technical: human resources	<i>"I think a good thing COVID has shown, is the flexibility of workers. Now we're going with the hybrid model in Medtronic, and they saw that even people working from home can be very efficient. I believe the business was surprised by what you achieved. They never expected to deliver so much in 1 year."</i>	16
Technical: components	<i>"Historically across medical devices in general and ventilators too, but also pacemakers and heart-valves, all of the products that are developed - (historically [supply chain] that haven't been a focus) have been more focused on innovation, the new critical need, then figure out how to make it later, which lends itself to having global customized components that are made specifically to go into the device, as opposed to thinking from the very beginning to design for manufacturability."</i>	10
Technical: components	<i>"One of the challenges will be where you have single source components and if those single source components are from a Mom & Pop shop, yeah that's where your big risk is."</i>	5
Legal: regulatory matters	<i>"Suddenly all those regulatory requirements and extensive regulatory reviews fell away - the FDA from my perspective did seem to accept that the manufacturer would do due diligence and the review was in a week instead of many months."</i>	7
Ethics and allocation	<i>"We realized very soon that we weren't going to have enough to fill the demand at all and that it was going to be a matter of allocating what we had. I think we pretty quickly, probably in March, pulled together some of our own internal Medtronic clinical affairs team, partnering with some people that were working on databases to show COVID prevalence and death rates."</i>	10
Environmental/Organizational	<i>"People confuse taking a chance with cutting corners and that's not what it is. So, I think he empowered everybody and that came through (the plant manager) as well. He really empowered everybody to think outside the box and make it; if it doesn't work out or if someone makes a mistake and doesn't do something, put your hand up straight away and you know, I think everybody was encouraged."</i>	12

Technical themes

The technical theme refers largely to participant experiences relating to aspects of the ramp-up including components, sourcing, logistics, and process improvement. Several sub-themes were identified.

- 1) *Collaborations and the Puritan Bennett™ 560 specification release*: Releasing the Puritan Bennett™ 560 design specification was seen as innovative and ambitious and built good faith with the public, and improved relationships with bodies such as the WHO and United Nations. It proved educational to others regarding the complexity of medical devices and their regulatory system. However, as knowledge of the COVID-19 disease developed, the Puritan Bennett™ 560 was of limited use in the treatment of severely ill patients, despite Medtronic expending significant resources to facilitate collaborative production. The many collaboration offers proved difficult to organize and harness

effectively, and participants felt that efforts might have been better spent on Medtronic's own production.

- 2) *Demand and forecasting*: Early signals of the demand surge included demand for consumables such as tubes and filters. Uncoordinated ordering and demand by governments dominated the initial phases of COVID-19. Demand could not be satisfied, and allocation was required.
- 3) *Quality*: Quality remained a top priority for Medtronic during the ramp-up, and the influx of inexperienced operators and suppliers required heightened vigilance. Medtronic's 'Quality begins with me' initiative was an asset.
- 4) *Production processes*: Several production process innovations were implemented and retained including change management, burn-in times, and component paint/ colors. Participants suggested many process changes impossible to execute during the ramp-up, but should be considered now, including electronic signatures, component testing at source, and electronic purchase orders.

- 5) *Trade-offs*: In normal circumstances, optimization trade-offs are often necessary e.g., lean thinking versus inventory, local sourcing versus globalization, and single source versus multiple sources. Medtronic's existing lean initiatives were generally helpful during the ramp-up. Multiple manufacturing facilities would not be practical given the historically small market size. However, participants suggested that localization at distribution centers may help shorten the supply chain i.e., delivery of a generic ventilator to distribution centers.
- 6) *Transport*: Air freight capacity significantly reduced due to passenger fleets being grounded and most available capacity from Asia used for PPE during the first wave.
- 7) *Surge capacity*: Initial doubling of capacity was straightforward was made easier by the slowdown in other industries. Manufacturing space was acquired using contract manufacturers. Medtronic was not fully aware of their suppliers' surge capacity pre-pandemic, and this took time to establish and incorporate into planning.
- 8) *Components*: Electronics, computer chips, proportional solenoid valves, and castings were identified as key components limiting the ramp-up. Long lead times, complexity, and specialization were characteristics of these key components. The most effective pathway to increased production was to support existing suppliers rather than developing new sources.
- 9) *Human resources*: Recruiting staff were eased through the availability of skilled and experienced people from production lines within Medtronic and externally, through pandemic related layoffs. Engagement of an employment agency was productive. Communication between human resources and personnel was more difficult due to social distancing etc., necessitating innovations such as remote interviews. Ramp-down, although it was predicted, was difficult and procedurally onerous.
- 10) *Manufacturing space*: Space was a constraint exacerbated by social distancing, resolved by engaging a contract manufacturer. The relationship with the contract manufacturer was more collaborative than usual.
- 11) *Machines and other facilities*: Capital equipment purchases were not significant for Medtronic but were for suppliers and had long lead times. Suppliers felt that Medtronic's involvement in the purchases could slow things down, due to formalities such as sign-off.
- 12) *Health and safety*: While health and safety remained the priority, COVID-19 introduced new risks where close contact between staff members was unavoidable.
- 13) *Suppliers*: Medtronic's considerable number of smaller suppliers was acknowledged as a risk. Relationships were reported as strong, with visibility increasing during the ramp-up. Financial support, trust and cooperation were key. Senior Medtronic leadership intervened to resolve issues e.g., the supply of electronic chips.

Legal and ethical

Widespread import and export restrictions were overcome with the intervention of Medtronic's government affairs department. Mandates e.g., the USA's Defense Production Act, were useful allowing Medtronic prioritize ventilator production and to empower suppliers. Problematic movement control orders were

alleviated by Medtronic's government affairs department's interventions. Regulatory restrictions were relaxed e.g., Emergency Use Authorization, a form of self-regulation, was available for ventilators and other innovations in the US. Ethical fair-share allocation was widely reported.

Environmental/ organization

A dedicated project team, assembled from the wider organization and including senior leadership, was productive. Participants reported on the benefits of senior leadership interventions in the supply chain. A culture of innovation and calculated risk taking was encouraged by senior leadership. A mixture of new and highly experienced personnel with innovative ideas positively influenced the decision-making process.

Discussion

Learnings emerged in all of the PESTLE themes and are discussed by theme below:

Political Learnings

Attempts by individual organizations to secure ventilators were ineffective. The findings from the interviews encourage coordinated international efforts based on clinical need and the recipients' ability to utilize the ventilators – the latter limited by infrastructure and the availability of trained staff. There was widespread criticism of the excessive ordering and subsequent oversupply of ventilators,^{19,30} although this aspect should not create a false understanding of the threat. A future virus could severely affect a wider and younger population, whereas COVID-19 largely spared the young and healthy. Alternative scenarios should be simulated to enhance preparedness. Investment and political support will be required to underpin preparedness initiatives.

The WHO, BARDA, and Europe's Health Emergency Preparedness and Response Authority (HERA) have roles here and each has published crisis preparedness strategies.^{31–34} Engagement between ventilator manufacturers and these bodies to implement preparedness strategies should be a priority.

Political influence to support medical device production was key. These initiatives can be evaluated and replicated in future crises.

Economic Learnings

Medtronic saw a spike in ventilator sales and revenue during the initial stages of COVID-19 and subsequently a significant fall-off in ventilator revenue. Humanitarian considerations took precedence over commercial matters. This led to the release of design specifications allowing others to produce ventilators. Some participants reported that the ramp-up had negative economic consequences for them and that the response to future crises might be different. For example, a future severe pandemic may be better served by higher end ventilators however, the same approaches to IP release may not be as effective for these ventilators due to their increased complexity.

The prospect of manufacturers being unable or unwilling to finance a ramp-up in a future health crisis needs consideration. Scenario planning of various influenza and other pandemics as well as estimation of their ventilator requirements, and likely market responses, would facilitate better planning and preparedness.

Social/Motivational Learnings

The highly motivated workforce was essential. However, the level of commitment was not sustainable long-term and repeated crisis scenarios might elicit different responses. Public support is not guaranteed. Preparedness planning should incorporate these behavioral factors. Within Medtronic, the singular focus on ventilators was productive, as distractions disappeared and traditional barriers to production reduced.

Technical Learnings

This section is the core of production - people, raw materials, suppliers, and transport, processes, machines, space, etc. All areas felt pressure. Initial ramp-up was straightforward as key players had spare capacity and supply chains held sufficient product. Subsequent steps-up were more difficult requiring flexibility, visibility, and heavy investment. While there was proactive work in Medtronic on single-source suppliers and other vulnerabilities pre-pandemic, there was low visibility into the supply chain's surge capacity. The application of supply chain analysis frameworks addressing critical attributes such as component complexity, lead times, and specialization appears necessary.

Legal and Ethical Learnings

Legal hurdles to production were quickly overcome. Legal mandates were invoked to support production. Flexibility was required to negotiate these and was facilitated by Medtronic's government affairs department initiatives e.g., intervening with public authorities.

Environmental/ Organizational Learnings

Medtronic's organizational strength was positive, through capital resources, workforce, and market position, as well as senior personnel interventions. It cannot be assumed that critical suppliers in future scenarios will possess these strengths.

The study highlighted clear limits in the organization's ability to respond to the crisis-led demand for ventilators indicating that crisis preparation is essential. Developing political strategies including needs-led, cooperative sourcing of medical devices and components, and legislative preparation for lockdown and import/export exceptions. Economic preparation requires investment in supplier capacity where the impacts of both ramp-up and ramp-down should be considered. Workforce preparation can be achieved with flexibility measures such as cross-training. These initiatives feed into supply chain resilience, visibility, and flexibility.

Comparison of key Findings With Prior studies

This research used the PESTLE framework and its outcomes confirm and expand on 4 main medical device supply chain vulnerabilities reported by McKinsey and Company,¹⁷ namely, in planning, and forecasting, as well as production, and delivery. End-to-end visibility proved elusive if not impossible. Forecasting was reported as heavily dependent on historical demand. In sourcing of both raw material and components, monitoring of tier-1 suppliers was patchy and little information was available on deeper tiers. This was compounded by single source suppliers for critical components. Participants attributed this to medical device production having typically been optimized for stability and regulatory compliance with the effects of limiting production

acceleration and distribution. Delivery and logistics were widely reported as constrained with movement controls and lack of air-freight capacity. This study reported mixed results from its collaboration efforts where the initial rush of collaboration offers proved difficult to harness and limited success was reported. Nevertheless, significant achievements were reported by participants in duplicating production systems for simpler devices and specific complex components.

Other findings confirmed those of previous studies,¹⁸ and provided further specifics on issues of competition with other industries for commonly-used electronic components as well as competition within the medical device industry for unique components such as oxygen sensors. Little excess capacity existed and accordingly, significant investment was required from Medtronic.¹⁸ Excessive demand was also noted in other work.^{2,10,18-20} with solutions such as collaboration with third parties,¹⁸ and easing of regulatory restrictions documented.

Improved demand prediction, coordination between companies and governments, regulatory relief, and improved information technology, as well as knowledge of surge capacity were identified as targets for improvement.¹⁷ As suggested in this research, contingency contracts with potential to help in future crises by maintaining surge capacity in normal times were also noted elsewhere,¹⁸ as was the necessity of allocation by need.¹⁸ Similar to prior studies, business models also arose as issues with global sourcing, single sourcing, and manufacturing specialization detailed. Innovations in product development and certification were mirrored in other manufacturers.²¹

Conclusion

This case-study documents the ventilator supply chain ramp-up experiences of Medtronic staff and suppliers during the COVID-19 pandemic and organizes the results in a PESTLE framework, interpreted through key findings and learnings.

The study exposed factors unique to the production of medical devices including the lack of third party awareness of the complexity of manufacturing and regulatory perspectives. This lack of understanding led to pressure for the release of ventilator designs and intellectual property without the knowledge required to achieve quality production and to achieve regulatory compliance. It showed the need for a political understanding of medical device supply chains and incorporating this knowledge into decision making processes around movement control and import/export restrictions. The findings highlighted the importance of collaborative work with suppliers and outside the supply chain with third parties such as contract manufacturers. Also highlighted was visibility into the supply chain which developed during the crisis and how long-term trust relationships with suppliers bore fruit. Organizational adaptability and flexibility underpinned the ramp-up and supported the human resource needs. Vulnerabilities such as single-source suppliers and geographically dispersed suppliers were exposed, supporting an organizational shift to more crisis-proof supply chains.

The key lessons learned from this study are the futility of an *everyone-for-himself* national strategic approach with a solution necessitating a pan-national sourcing and allocation approach for scarce medical devices. The study showed the outsized impact of pandemic-related component supply problems combined with the dire need for critical medical devices. It highlighted the limited capacity of a response-led approach to satisfy crisis demand and the necessity for preparation and scenario planning. The limited

capacity of a response-led approach was due mainly to a lack of public and political understanding of the technical and regulatory complexity of medical device production.

Impact

This work contributes to future pandemic preparedness by documenting and analyzing the experiences of a critical medical device manufacturer, providing learnings on critical supply chain and production strategies during the crisis and highlighting barriers and facilitators to satisfying the pandemic demand-spike. It documents forces acting both in support of and hindering the ramp-up. It reveals the economic effects throughout the supply chain and highlights difficulties experienced by suppliers particularly in complex, specialized components. It highlights the need for coordinated and sustained international efforts to maintain capacity in preparation for future health crises. This can contribute towards execution of international pandemic preparedness strategies such as those of HERA and BARDA.

Limitations of This Research

While this research documents and synthesizes Medtronic's ramp-up experiences, largely agreeing with prior studies, it remains a single case-study and only cautious generalizations are possible. The interview method has limitations including selection and confirmation bias.²⁹ These effects were mitigated by selecting across a range of disciplines within Medtronic and outside suppliers. With the broad range of expertise among the interviewees, it was challenging to bring this diverse information and documentation together. The PESTLE themes were useful but alone, it is insufficient to tell the full story of the ramp-up as became apparent with the data analysis requiring sub-themes, based on recurring ideas in the interview transcripts. While generalizations are difficult, many of the findings of this study have been supported by prior work.^{5,17,18,21,35,36}

Supplementary material. To view supplementary material for this article, please visit <https://doi.org/10.1017/dmp.2024.55>

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Abbreviations. COREQ, Consolidated Criteria For Reporting Qualitative Research; BARDA, Biomedical Advanced Research Development Authority; HERA, Health Emergency Preparedness and Response Authority; ICU, Intensive Care Units; IP, Intellectual Property; PPE, Personal Protective Equipment; REC, Research Ethics Committee; UN, United Nations; WHO, World Health Organization

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