Exovent: an accelerated innovation journey in 2020

2020 was an exceptional year for the Exovent team. It has been an unusual year for everyone with a global pandemic disrupting life, while putting enormous strain on the NHS. This backdrop created an environment and an imperative for innovation that is unique within the 21st Century, leading to extraordinary achievements in the areas of vaccines and ventilators at a time when much of the world's population and businesses have been adapting to online interaction. We describe the innovation journey for Exovent, a negative pressure ventilation support device developed in record time by a UK charity with a small volunteer team of clinicians and engineers, working alongside the UK's largest privately owned aerospace & defence company, Marshall ADG.

How did it start – the power of Facebook

The original idea came from Dave McKeown, a civil engineer in Cornwall working for the Environment Agency on flood defences. As the pandemic gathered momentum in March 2020, Dave asked himself what he could do to protect his family if the NHS was overwhelmed. After discarding several possibilities, he came up with a modern lightweight version of an iron lung using a wooden enclosure over the chest. He realised it could be built in large numbers quickly and cheaply, so on the 19th March he wrote to the Cabinet Office asking for support to turn the idea into reality. Although there was no reply to his letter, that same day an unknown person shared it on a Facebook post that was circulated widely amongst doctors and beyond. Suddenly Dave found himself being contacted by anaesthetists, critical care specialists, surgeons and engineers, all keen to turn his idea into reality. The Exovent team was born and had its first call the very next day.

Rapid proof of concept

Driven by the urgent potential need for the device, the pace of work was intense, often with multiple daily calls, working late into the evening and weekends. Within days, several of the team had built working prototypes at home based on plywood boxes, drysuit neck seals, vacuum cleaners and simple control systems, proving that a powerful system could be produced easily. All the time the Exovent network was expanding, broadening the team's strengths and capabilities; everyone was working with other disciplines with no hierarchy. Most fitted the activity around their day jobs, including NHS clinicians who would join meetings after long days working in hospital. Early on the team moved from phone calls to Zoom meetings.

Developing a professional system

The team needed partners to help turn the Exovent system into reality. Progress came at the end of March when Warwick University High Value Manufacturing Catapult was introduced to Exovent who, in turn, introduced Marshall ADG. Using specifications provided by the Exovent team, Marshall ADG set about creating a system. With accelerated design control processes allowing parallel engineering and development activity, they produced the first system within three weeks, and a week later a fully working second iteration incorporating design improvements from Exovent clinicians. On the 29th April Professor Anil Patel, a consultant anaesthetist at the Royal National Throat Nose and Ear Hospital, UCLH became the first Exovent team member to test the unit.

Ups and downs

Early on it became clear that the UK Ventilator Challenge covered only positive pressure ventilators, so fast track support was unavailable. The team continued undeterred because they believed that the benefits of negative pressure ventilation are not limited to COVID-19, but may be indicated for patients with a variety of acute and chronic respiratory diseases. By reducing the

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Figure 1. Professor Anil Patel in an Exovent

Figure 2. The Marshall-Exovent

work of breathing, increasing the surface area for gas exchange, and preserving right ventricular output, negative pressure can not only help the deteriorating patient but recovering patients too, with potential benefits to weaning and recruitment, although much work needs to be done to substantiate these aspirations [1]. The focus, therefore, moved to full medical device approval and it was clear that we lacked the specific skills necessary to navigate the medical device approval process. Coincidentally, Michael Rose, a product management specialist in the medical device industry filled the gap at just the right moment.

Medical device approval and clinical trials

Under normal circumstances it takes over three years for a medical device to gain approval. Exovent plan to achieve this in half that time, producing an approved device by September this year. In 2020 there were additional complications, Brexit uncertainty and replacement of the Medical Devices Directive with the more complicated and challenging Medical Device Regulations. After much analysis of the regulations and examination of all the predicate negative pressure devices, we now believe that approval can be achieved without the need for a clinical trial, albeit with extensive documentation. We also needed a manufacturer on board for submission, and are delighted that this will be Portsmouth Aviation.

Once the system has achieved regulatory approval, Exovent will conduct clinical trials as part of our post-market clinical follow-up plan. This should provide data to extend the use of the system to patients with a wider range of respiratory disorders. Much of the planning for these trials has already been completed by clinicians at the University of Southampton Hospital under the leadership of Professor Mike Grocott. This is a major undertaking, and Exovent will be applying for grants from a number of funding sources.

Summary

It took six weeks from concept to a fully functioning negative pressure ventilator that could have been produced in large quantities had the UK faced a major shortage of ventilators during the COVID-19 peak. Ultimately that was not needed, but the work highlighted the benefits of negative pressure ventilation; it is more physiological than positive pressure ventilation and allows the patient to remain conscious throughout, making it ideal for low-income countries where access to sophisticated medical care is difficult. The Exovent team are committed to delivering an approved UK-manufactured system in record time, and are working with teams around the world to help them develop their own versions. We want everyone that needs breathing support to have access to it.

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References

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