Design innovation and manufacturing challenges in the time of COVID-19.

Antonio Andreoni* and Dan Hill**

**UCL Institute for Innovation and Public Purpose, University College London.*

***UCL Institute for Innovation and Public Purpose and Vinnova, Sweden*

Within months the COVID-19 pandemic has impressed a dramatic impact on societies and economies around the world. Responses to the crisis have revealed sharp differences in terms of the economic resilience of countries, the social contracts between people and their governments, and the readiness of their institutions, especially their health systems. Some countries have found themselves better prepared to coordinate their response and leverage a wide range of capabilities across their ecosystem of hospitals, universities, testing labs, and manufacturing enterprises.

During the first wave of the global outbreak, ventilators and essential protective equipment were in shortage in countries like the United Kingdom (UK) and Italy, and the fast growing global high demand made clear that unprecedented responses were necessary. Governments set up several mission-oriented challenges around which public and private actors across the national ecosystem were asked to identify and coordinate a response. While important successes have been achieved, the design and manufacturing journeys presented significant and unexpected challenges.

At the aftermath of the pandemic, in the UK the National Health System (NHS) had only 8.000 ventilators, with epidemiologist models suggesting the need for 30.000 in a matter of weeks. The UK Government launched the *Ventilator Challenge UK Consortium* in March 14. The consortium included leading industrial, technology and engineering businesses from across the aerospace, automotive and medical sectors. Companies in these sectors rely on similar technology platforms, flexible supply chains made of highly specialised suppliers and coherent design capabilities for all product systems. These companies work with ecosystems as much as products.

The High Value Manufacturing Catapult took a coordination role, especially in the investigation of a range of design options and specifications for a Rapidly Manufactured Ventilator System developed by clinicians and the Medicines and Healthcare products Regulatory Agency. In normal time this investigation process takes months, if not years, given the complex interdependencies between design solutions, technological readiness and manufacturability challenges, along the entire innovation and production chains.

In a time of crisis, the rapid scaling up of design solutions present even more challenges. Fighting against time, along parallel and competing projects, different companies (often with non-medical specialised design capabilities) partnered to develop a prototype within weeks. While many companies attempted to develop completely new design solutions, one group built on product architectures and proven design solutions. Many of those who pursued a 'start-from-scratch ' approach underestimated the fact that the safety of the device is not simply a design property. Rather, it depends on how the device is manufactured, on the quality management and appropriateness of the product design innovation in meeting the clinical need. Guiding this process by enabling smart shortcuts and shared insights, without generalised assumptions clouding invention, is a delicate balancing act. The traditional approach of calls and challenge prizes does not tend to lead to the intense collaboration required in such situations (it typically generates competition instead), nor does the existing positioning of the innovation funding agency tend to be close enough to the rapidly moving front-lines in order to learn and guide.

Equally, a novel virus means a constantly-changing context. In April, new clinical needs emerged making a number of initial design solution unsuitable. COVID-19 patients tend to suffer from rapid fluid build-up in the lungs, thus ventilators must allow for frequent drainage. In some cases a number of medical ventilators had to be sent back to manufacturing facilities for retrofitting, leading to delays. The production ramp-up centred ultimately around two design solutions – i.e. Penlon Prima ES02 device and the paraPAC plus. The consortium managed to increase the combined capacity of Penlon and Smiths from 50 and 60 ventilators per week, to 100-200 per day. By 5 July the consortium concluded after delivering 13.347 ventilators to the NHS.

In Italy, in late March, an alternative design response to the shortage of ventilators came from bottom-up. Doctors at the Policlinico Sant'Orsola in Bologna, seized the opportunity of doubling the existing stock of ventilators by designing a circuit through which one device could be used to ventilate two people at the same time. This would have remained simply an idea, if the industrial ecosystem in the Emilia Romagna Region had not been able to produce in only three days a functioning prototype of a "double ventilator". The biomedical district in Mirandola has developed design capabilities in medical device starting from disposables, to complex haemodialysis machines. These devices are critical product system including flow and fluidic systems, sensors and embedded software, valves and filtration systems. Given their complex architecture, integration capabilities and product design modularisation are critical.

The shortage of ventilators also led to innovative design solutions along different therapeutic lines, namely the increasing use of Continuous Positive Airway Pressure (CPAP) devices. Differently from ventilators, CPAP machines deliver oxygen via a mask and do not require intubation. A team at the University College London (UCL) launched the *UCL Ventura Initiative* for breathing aids in March. Working in collaboration with industry partners Mercedes-AMG High Performance Powertrains, and relying on direct access to clinicians at the UCL Hospital, the Ventura Initiative led to the production of 10.000 devices in 1 month and over 1900 open-licences across 105 countries. The original design from 1992 entailed a purely mechanical device controlled simply by rotary valves to alter oxygen concentration and flow rate. While the product was much simpler than a ventilator, the UCL team could have not been able to scale up the CPAP without an industrial partner. The reverse engineering process relied on computer-aided design and computational fluid mechanics simulators, normally used for Formula 1 engine design. Design improvements were constrained by the availability of consumables, later manufactured by Intersurgical. The product design effort had also to face an implementation challenge, determined by the limited supply of oxygen in British hospitals. The Ventura team modelled oxygen flows to each floor and bed area of the UCL hospital, hence designed an integrated product-system-therapy solution.

For protective equipment presenting simple product design like disposable masks, design capabilities were mainly required in developing robust and highly automated production technologies and processes capable to deliver high volume production over long periods. In Italy the shortage of masks, for example, was addressed by a leading packaging machinery company called *IMA spa.* In this case, responding to the call from the Italian government, the company was able to design a streamlined and highly flexible production line – *IMA Face 400* – capable to produce (and package) between 200 and 400 masks a minute. The design of 25 machines capable to satisfy national demand was led by an agile task force leveraging both internal design and organisational capabilities, as well as a network of specialised contractors capable to provide components despite lockdown restrictions A resilient supply chain was critical in finding the most appropriate process and product system design solutions.

The context of such technologies is accessed via different design disciplines, such as the triumvirate of interaction design, service design and strategic design. Taking a multidisciplinary approach, building on the engineering but adding richer forms of design capability, may have unlocked a richer set of other solutions. Such solutions could be more immediately effective, cheaper, faster to deploy, easier to use for both medical staff and patient, and with a sensitivity to cultural diversity necessary in such contexts. Engineering-led approaches do not tend to get at these aspects. Equally, strategic design would ensure that broader insights would be generated; such as how the efficiency-oriented 'just-in-time' supply chain and procurement logics have come to dominate healthcare in the first place, particularly in the UK. These broader questions can be addressed by design, and are crucial to building true resilience, or at least learning from a crisis. But they are unlikely to emerge from a Ventilator Challenge led by a High-Value Manufacturing Catapult. As is often the case, an all-too-simplistic focus on science, technology and engineering develops blindspots about the more ambiguous, yet equally productive, aspects of culture, policy and politics. Whilst ventilators needed to produced, and quickly, the broader question of why ventilators were not there in the first place also needs addressing. That is not an engineering problem, but it can be addressed by different forms of design.

Several lessons have been learned from different design and manufacturing solutions that emerged during the pandemic. The pandemic has ultimately revealed how the development and diffusion of design capabilities in the health sectors is at the core of both the innovation ecosystem, and the choices we have made about the everyday infrastructures that comprise healthcare. In both cases, forms of design can help improve the resilience of societies and economies in the time of crisis. Part of this design challenge concerns solutions that are functionally appropriate and affordable. A further design challenge would address the broader policy contexts that produce—or diminish—such resilient solutions in the first place. Developing this richer set of design capabilities, well beyond engineering, can generate health technologies tuned to people and place, allowing us to address both the short-term and long-term emergencies we now face.