Lessons and risks of medical device deployment in a global pandemic

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See Online for appendix

COVID-19 has challenged health-care systems in an unprecedented manner. As recorded deaths exceed 2 million worldwide, countries continue to grapple with policies that balance health care and economic stresses. Strategic international coordination and cooperation remain haphazard. Here we reflect on our experiences in delivering a non-invasive respiratory support device that highlights the need for a more responsive, harmonised approach.

Countries with restricted technological or manufacturing capacities depend heavily on imports to maintain health-care delivery. In early 2020, self-interest took hold, with nearly 80 countries imposing restrictions on the export of medical supplies.[1] Available equipment was often sold at hugely inflated prices, as unscrupulous manufacturers sought to profit, and more prosperous countries were prepared to outbid others to secure scarce resources, such as ventilators and personal protective equipment.[2] These issues disproportionately exposed low-income and middle-income countries (LMICs) and some of the most vulnerable of the global population to poor COVID-19 health outcomes.

In conjunction with Mercedes HPP (Brixworth, UK), the Formula 1 engine manufacturer, we produced a simple, purely mechanical non-invasive respiratory support device to deliver continuous positive airway pressure. Within a month of conceiving the idea in mid-March, 2020, we achieved regulatory approval and delivered 10 000 UCL-Ventura devices to the UK National Health Service.[3]

The device is relatively cheap and quick to manufacture, simple to use, reliable, and only requires an adequate oxygen supply. We released designs and manufacturing instructions through a zero-cost license to bona fide governments, universities, health-care organisations, and companies worldwide. Legal liabilities for manufacture and in-country regulation were transferred to the licensee. We published a comprehensive, multilingual package of clinical, training, technical, and regulatory support.[4] Blueprints were downloaded by 1884 teams across 105 countries. 20 consortia worldwide are now manufacturing devices or assembling UK-made components and tooling available at cost and deploying them clinically. We are also working with individual charities to supply devices and consumables on a non-profit basis (appendix).

Governments and international organisations have mostly failed to offer a clear path or strategic direction to facilitate distribution to, or deployment in, LMICs. The UK regulator—the Medicines and Healthcare products Regulatory Agency (MHRA)—has provided invaluable guidance to in-country regulators. With our support, teams in individual countries have generally had to develop their own ad hoc solutions.

Throwing a solution at a medical problem will not work in isolation. Location-specific need and infrastructure must be carefully considered to allow the intervention to be used effectively and safely. For example, our device requires an adequate oxygen supply, health-care worker training, and either supply of consumables or facilities for safe sterilisation and re-use. Detailed guidance on priority medical devices was not published by WHO until Nov 20, 2020.[6] The focus of this guidance was on high-end invasive and non-invasive respiratory support devices that would not be usable or affordable by many countries. Given that the occurrence of a global pandemic was not a case of if but when, why was no such document pre-prepared, considering the heterogeneity of clinical settings, devices, manufacturers, and regulators? We found the WHO processes unwieldy and unresponsive. If such a role falls outside their remit, who then should take responsibility?

The international regulatory landscape is fragmented. Usual regulatory processes are non-feasible within the urgent timescales of an international crisis. The MHRA streamlined their processes, maintaining an emphasis on safety standards, and provided invaluable guidance in advance of our submission that facilitated rapid authorisation. Bar some notable exceptions, we found regulators in other countries were bureaucratic and tardy. Could recommendations from regulators of high international standing—such as the MHRA, who have pivoted to emergency processes—be adopted, with addenda related to location-specific issues such as electrical power fluctuations and operability in varied climates? An allegation of colonialism is perhaps inevitable, but is the alternative of delay, silos, reinvention,

avoidable errors, and unforeseen variability beneficial to vulnerable populations in LMICs during a pandemic?

A global health crisis response that must reach the most vulnerable people lies at odds with the commercial pressures of medical manufacturers and export markets, let alone governments imposing trade embargoes or outbidding poorer countries.[8] A collaborative altruistic approach does not come naturally in academia.[9] Our non-profit approach has engendered trust, enabling us to build new partnerships spanning health care, industry, academia, government, and regulators at speed. Such consortia should form a critical bedrock to accelerate rapid product development, manufacture, clinical testing, and approvals. Close multidisciplinary interaction, clear identification of clinical need and suitability, prospective regulatory advice, and active governmental cooperation and funding support are vital. University College London (London, UK) and Mercedes HPP took on the not insignificant risk of providing major seed funding with no guarantee of reimbursement. We were also fortunate to access corridors of governmental power, to have the conviction and weight of argument to overcome initial doubts and resistances, and to secure the necessary financial support. Our inability to access these levers at a global level made international deployment a bigger challenge. There needs to be a process to support and guide appropriate innovation.

Coherent strategies for the distribution of equipment, drugs, and consumables to LMICs are essential but must be developed in tandem with understanding of local clinical environments, cultures, and training programmes. Governments and international organisations have a critical part to play in streamlining their processes, and ensuring a suitable infrastructure for innovation, regulation, and deployment. We have a moral imperative to do better to support global populations.

RJS sits on the board of trustees of the International Medical Education Trust 2000. DB, TB, and MS report that the UK Department of Health and Social Care commissioned 10 000 UCL Ventura devices. RH reports grants from the Wellcome Trust and the National Institute of Health Research, outside the work described here, and is an honorary expert member of the WHO Respiratory Support Expert Panel, the WHO Clinical Data Platform Advisory Panel, the WHO LMIC Covid-19 Platform Trial Group, and the USAID/STAR/UCSF Technical Advisory Group for Covid in LMICs. DAL reports personal fees from GlaxoSmithKline and Griffols, and personal fees from Griffols, outside the work described here. MS reports grants and advisory board fees from NewB, grants from the Defence Science and Technology Laboratory, speaking fees to their institution from Amormed, advisory borad fees to their institution from Biotest, General Electric, Baxter, Roche, and Bayer, research grants from Critical Pressure and Apollo Therapeutics, and honoraria from Shionogi, outside the work discussed here. CE declares no competing interests.

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