STUDY REPORT

Identifying 'turning points' for successful innovations during Covid-19

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Summary

*This study as was commissioned by UCL Research and Enterprise Bronze Aquamarine 5.3 / Sapphire 3B between 5 and 29 May 2020 as part of efforts towards "…*Developing a strategy for the emergent industries and research opportunities inspired by the COVID-19 pandemic period." *The approach used was to analyze known successful innovations and attempt to establish the critical turning points in their narratives and develop interventions around them. This study used the UCL Ventura breathing aid as a case study.*

1.0 Introduction

What happens when the trends, assumptions and usual trajectories for translation of research knowledge are upended by global and local events? Phenomena that at a much broader level alter the dynamics between anything from social norms and behaviours, interactions within and between economies to relationships between economic actors? The COVID-19 pandemic is no doubt such a phenomenon and this case study explores the background, process, content and context of interactions between engineers, clinicians, industrialists and regulators, among others, in the successful development and delivery of health technologies. The recent UCL Ventura breathing aid changed the speed and shape of innovation, and this study explores how and why. The question that this study seeks to answer and draw lessons from is: ***what were the critical factors that enabled the UCL Ventura project to be rapidly progressed to market, why were these successful in this instance and might they be replicable in other innovations?***

2.0 Background

The COVID-19 pandemic has had pervasive impact on health systems, the industrial landscape, commodity markets and prices, geopolitics, poverty, social welfare and many other aspects of global economics. The pandemic has on the one hand simultaneously tested various aspects of our deeply interconnected societies, resulting in delayed, sluggish, inadequate and at times impotent responses to the pandemic, and on the other hand inspired rapid scientific and technological responses that would have seemed impossible before. Indeed, if there is a silver lining that has visibly emerged from the pandemic, it is recognition of the important, yet often hidden role that different academic disciplines play in generating and providing tools for dealing with societal challenges[1]. From provision of personal protective equipment (PPE), rapid development and supply of breathing aids, ventilators and drug therapies, to insights feeding into social distancing guidance and rapid response measures to keep communities fed – medical science and engineering inputs in particular have been suddenly placed centre stage, for all to see and appreciate. From fields as diverse as epidemiology, behavioural science, chemistry,

[1] https://blogs.ucl.ac.uk/steapp/tag/coronavirus/

data science, molecular biology, pharmaceutical sciences, communication, civil, chemical and biomedical engineering, among thousands of others, the pandemic has provided a chance to see the great contributions that the millions of people working in these fields make to our lives. Paradoxically, a less (economically) globalized world like the one that we see emerging from the effects of COVID-19 seems to have the power to accelerate technological progress even more and (hopefully) dampen the global economic effects of COVID-like pandemics in the future. The COVID-19 pandemic will likely also accelerate innovations in biotech, telemedicine, online learning, and remote work based on the accelerated turnarounds in development, testing and regulatory approval during this prolonged, crisis-driven period.

Health technologies and innovations are often slow to reach patients and many COVID-19-related innovations took place against a backdrop of a much observed gap between the promise of scientifically proven health interventions and their successful implementation[2] in the real world of a wide variety of contexts[3]. Could the COVID-19 pandemic be fundamentally changing the shape and nature of knowledge translation from research to practice or is it simply accelerating trends that were under the radar prior to the pandemic? Guided by the question - *what were the critical factors that enabled the Ventura project to be rapidly progressed to market, why were these successful in this instance and might they be replicable in other innovations?* - this study deploys a framework combining innovation systems[4][5] (IS) and knowledge systems (KS), to identify and analyse barriers and bridges in the translation of academic, clinical and industrial evidence[6] into health products. In doing this, the study looks at, among others, actors, institutions, networks, knowledge generation and diffusion, and creation of synergies within and across these components.

Box 1: UCL's life-saving breathing aid – in a nutshell

The UCL-Ventura breathing aid, a low-flow Continuous Positive Airway Pressure (CPAP) device, is now being deployed to treat coronavirus patients in more than 60 NHS hospitals across the UK, including London, Belfast, Glasgow, Hull, Newcastle, Liverpool, Manchester and Norwich. The background to this feat is that with the coronavirus pandemic spreading to nearly every country in the world, the number of hospital patients needing respiratory support has been unprecedented. It is not easy for manufacturers to quickly make huge numbers of extra ventilators, resulting in an imbalance in supply and demand for the necessary equipment to provide this support. Clinical evidence emanating from China and Italy was also highlighting operational and effectiveness challenges facing mechanical ventilators. To alleviate this problem, a team of engineers and clinicians from UCL and Formula One engine maker Mercedes-AMG HPP, pulled off the task of moving from reverse-engineering an original product and producing a new design, through testing and regulatory approval to full-scale production in under 10 days. This machine, similar

[2] https://bmjopen.bmj.com/content/4/6/e005548
[3] https://www.sciencedirect.com/science/article/pii/S0033350619302951
[4] file:///Users/macadmin/Downloads/JHOM-04-2016-0061.pdf
[5] Malerba, F. (2002), "Sectoral systems of innovation and production", Research Policy, Vol. 31 No. 2, pp. 247-264.
[6] Chatterji, A.K., Fabrizio, K.R., Mitchell, W. and Schulman, K.A. (2008), "Physician-industry cooperation in the medical device industry", Health Affairs (Millwood), Vol. 27 No. 6, pp. 1532-1543.

to those commonly used to treat sleep apnea, is non-mechanical, simpler and cheaper to make, and can support patients with severe breathing problems, freeing up mechanical ventilators for the most critically ill.

All the details required to make the device are available for manufacturers and humanitarian agencies to download at no cost from covid19research.uclb.com/product/ucl-cpap, a research licensing website developed by UCL Business (UCLB) to disseminate technologies designed to help in the fight against the pandemic. As of 30 May 2020, these designs had been downloaded by more than 1,800 teams from 105 countries around the world and 20 teams have manufactured prototypes for testing in Brazil, Bulgaria, Canada, Colombia, Kenya, Germany, India, Iran, Mexico, Russia, South Africa and the USA.

3.0 Conceptual and methodological framework

In seeking to unpack processes, content and contexts surrounding the breathing aid innovation, this study made a deliberate choice to focus on the coming together (implementation) of engineering, industrial and clinical actors and regulatory institutions in response to the unprecedented and pervasive challenge posed by the COVID-19 pandemic. This study sought to understand the background, process, content and context of the dynamic partnership that successfully carried out the task of conceiving an idea and delivering the non-invasive breathing aid to the health system within 10 days. The decision to focus on interactions, networks and dynamics between actors, organisations and institutions is rooted in a conceptual understanding of how national, regional and sectoral innovation systems work and evolve. Numerous previous studies[7] demonstrate that relationships, power dynamics and incentive systems are key to understanding why innovation occurs in some contexts and not others[8]. While, this short study was not the place to offer full insight into how innovation systems and key associated concepts can or cannot shed light on the development of UCL Ventura breathing aid, exploring these concepts in a full study could be of great interest for academia, policy and practice. Bringing together the above, the conceptual framework below was developed to guide the study.

[7] Consoli, D. and Mina, A. (2009), "An evolutionary perspective on health innovation systems", Journal of Evolutionary Economics, Vol. 19 No. 2, pp. 297-319.
[8] Bleda, M. and Del Río, P. (2013), "The market failure and the systemic failure rationales in technological innovation systems", Research Policy, Vol. 42 No. 5, pp. 1039-1052

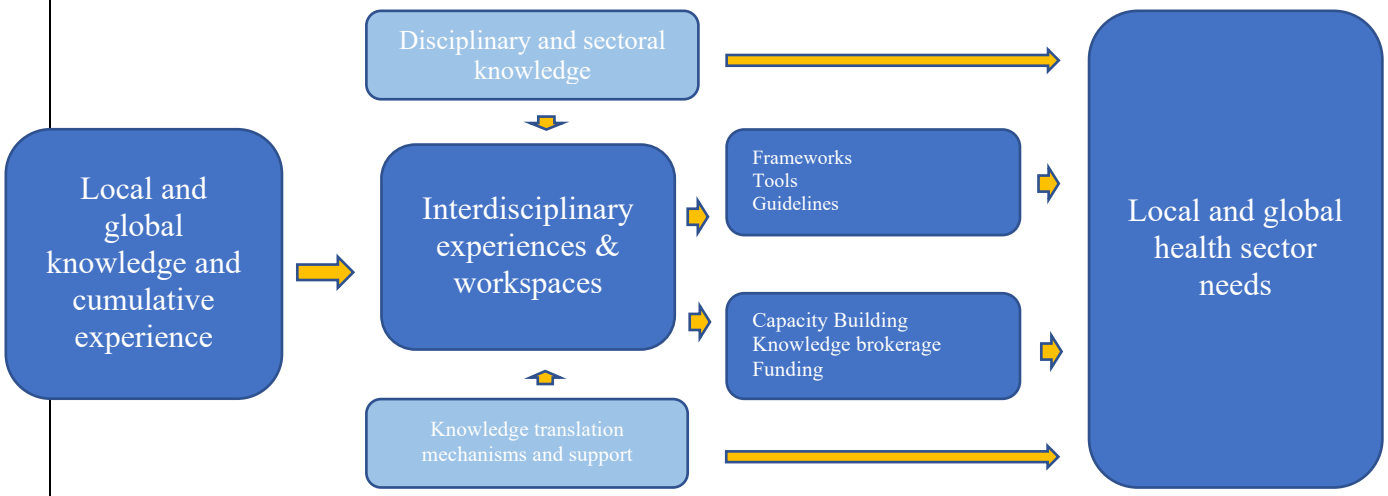

Fig 1: Conceptual framework for analysis of knowledge translation for the UCL Ventura Covid-19 breathing aid innovation
Adapted from Tumilowicz et al. (2018)

Key[9]:
Components of the framework can be analysed singly for qualitative and quantitative aspects. Connections, alignment, coherence and synergies between the components also important to measure and evidence

4.0 Methods

Guided by the main research question and conceptual underpinnings, this study gathered primary evidence through interviews with key UCL engineers, clinicians and management staff who were involved in or are knowledgeable about the project. The interviews, which were guided by an open-ended checklist, were conducted between 15 May and 26 May via Microsoft Teams (see Annex 1), with interviews lasting approximately one hour each. All interviewees consented to having the interviews recorded, which allowed the researcher to be able to go through the recordings and auto-generated transcripts later to analyse and draw out emerging themes using an approach encompassing content and thematic analysis. A total of 7 key informants were interviewed. As part of the study, the researcher also had two meetings with Celia Caulcott, Michael Reynier and Martin Davies; attended a seminar on the CPAP at the Royal Academy of Engineering, presented by Rebecca Shipley and Andy Cowell (Mercedes) on 19 May; and received input from UCL STEaPP colleagues Joanna Chataway, Jenny Bird and Ana Rita Pinho.

[9] Alison Tumilowicz et al (2018) https://academic.oup.com/cdn/article/3/3/nzy080/5129139

4.1 Interview questions

The interviews with key informants were guided by a checklist which sought insights on a number of issues relating to how choices were made on the innovation pathway to pursue; how and why different participants were involved; critical steps and factors in the progression of the innovation; broad lessons that can be drawn from this innovation for other research and enterprise activities in UCL; suggestions of other UCL cases that could be studied as part of the process of identifying 'turning points' for successful innovations during and beyond the COVID-19 pandemic.

5.0 Findings

This study identified a number of critical factors that coalesced to result in an unprecedentedly successful response to the oxygen therapy challenge ushered in by COVID-19. As alluded to in Box 1, data from China and Italy was showing that continuous positive airways pressure (CPAP) devices could help patients by keeping them off invasive mechanical ventilation, but there were problems in the UK at **three** fundamental levels, **firstly** that CPAPs were not on the NHS care pathways, **secondly** that CPAP ventilation was **not a priority**[10] for Her Majesty Government's ventilator challenge in which the Prime Minister had asked companies to help manufacture, design and build thousands of NHS ventilators in the fight against COVID-19[11], and **thirdly**, that the above notwithstanding, there were insufficient devices in the UK. These challenges were couched in the backdrop of a rapidly advancing pandemic, with a 'surge' expected in London over the Easter weekend (10 – 13 April). The UCL team of engineers and clinicians and industrial partner Mercedes-AMG High Performance Powertrains drew on their individual and collective expertise and networks to take a series of decisive actions which resulted in a successful navigation of the challenges above[12]. Box 1 above, Fig 2 and Fig 3 below, capture the key developments, enabling factors and a 'dramatis personae' in this journey.

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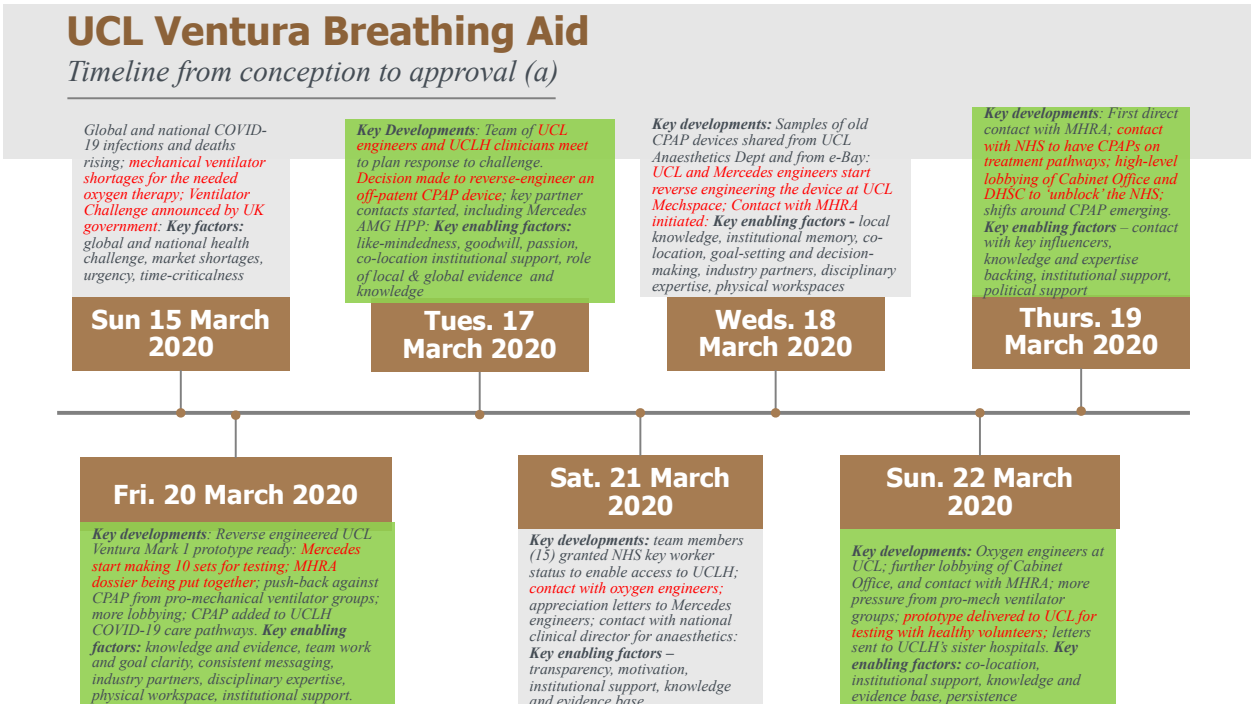
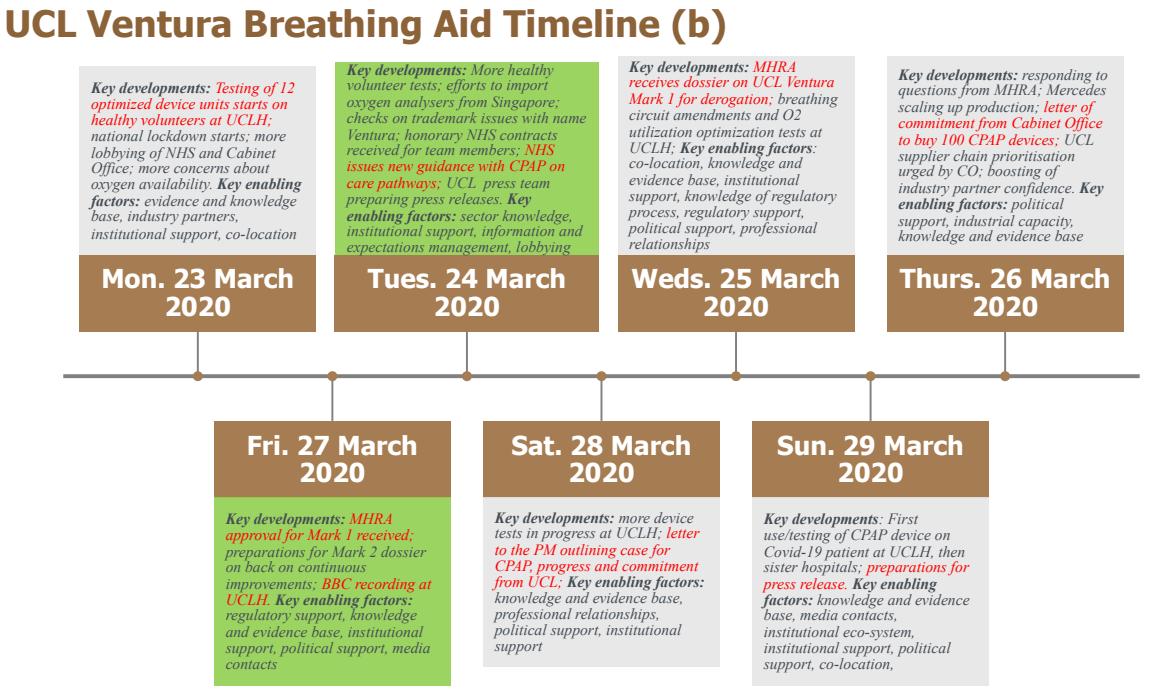
10 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879382/RMVS001_v4.pdf

11 https://eandt.theiet.org/content/articles/2020/03/rival-companies-work-together-to-manufacture-medical-ventilators/

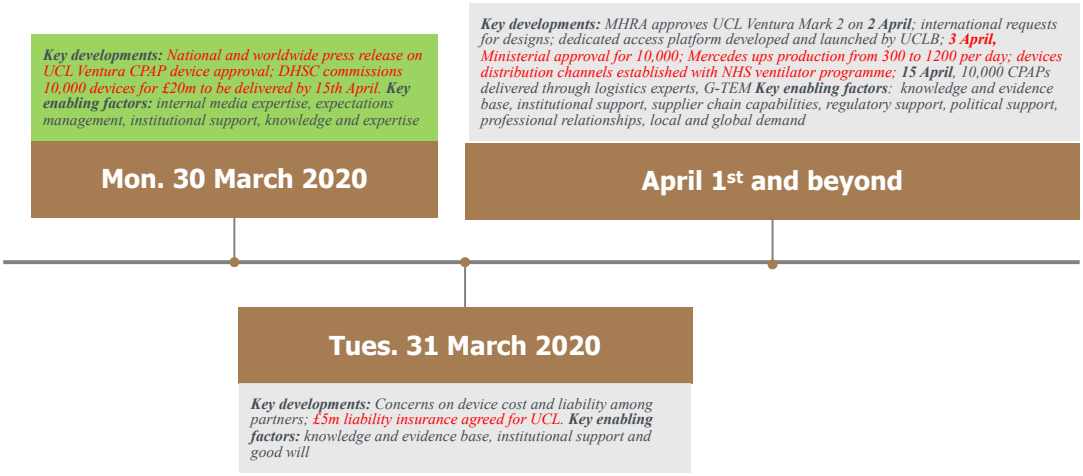
12 https://eandt.theiet.org/content/articles/2020/03/reverse-engineered-breathing-aid-gets-swift-regulatory-nod/

Fig 1: UCL Ventura breathing aid innovation timeline





UCL Ventura Breathing Aid Timeline (c)



Seven key moments in **green** – representing crowning moments for preceding processes and charting of course for succeeding steps (source: author, with input from respondents)

The timeline above highlights **7 key moments**, sparked off by the team's choice on 17 March to reverse-engineer an off-patent device, the Respironics WhisperFlow, that had been used in the NHS for decades. In the coming days, this enabled the device to be quickly approved for use by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA)[13]. It is without doubt, however, that this venture would not have been possible without the constellation of both engineering, clinical and other embedded as well as overarching issues which the team had to deal with, prepare for and resolve. To reflect on a few, while CPAPs were not on the NHS treatment care pathways, hospitals and trusts had the leeway to use them and the project team leveraged their knowledge of this window to garner the support of UCLH executives to have CPAPs in the hospital's care pathways as a first step. The co-location of UCL engineers and clinicians allowed resolution of operational and performance challenges with the CPAP to take place rapidly, for example reducing oxygen utilisation by 70%, which was an important step in the backdrop of national medical oxygen[14] shortages. The push-back from pro-mechanical ventilator groups was an on-going battle which the team dealt with by producing and deploying engineering and clinical evidence to support the important role of CPAPs. The team directed its passion and expertise towards solving the unravelling health challenge, thus unsurprisingly, when the Cabinet Office offered their support for CPAPs on 26 March, they noted that '*whilst this device does not meet the published specification, the ventilation challenge team have agreed to look at it as is fulfils a complimentary clinical purpose'.* Meanwhile the foresight to apply for key-worker status for non-UCLH partners was an inspired act of getting ready for the impending lockdown which was going to curtail

[13] https://theconversation.com/coronavirus-inside-story-of-how-mercedes-f1-and-academics-fast-tracked-life-saving-breathing-aid-136028
[14] https://blogs.worldbank.org/health/oxygen-all-during-covid-19-coronavirus-and-beyond

team members' movements. The lockdown itself was turned into an opportunity to harness underutilised capacity at Mercedes. Careful engagements with the media and management of expectations was also key, allowing the team to align extensive media coverage[15] of the CPAP on Monday March 30th with among others, device approval by MHRA, Cabinet Office commitment to buy 100 devices and emerging COVID-19 patient clinical data. Meanwhile, other key moments include 20 March, when UCLB were asked to sense-check whether the Philips/Respironics patent had lapsed or not. This was confirmed with a patent agent at Barker Brettell; and 6 April when a dedicated on-line access platform for the UCL Ventura designs/manufacturing instructions went live. Work began on the platform on 3 April.

Fig 3: A 'dramatis personae' for the UCL breathing aid innovation

Actors		Key roles
Partners/Disciplines	**Individuals**	
UCL Engineers - UCL Institute of Healthcare Engineering & UCL Mechanical Engineering,	Prof Rebecca Shipley, Prof Tim Baker, Dr Tom Peach, Mr Tom Rushton, Mr Peter Weston, Mr James Weaver	Engineering knowledge, interdisciplinary working space, project leadership and management, knowledge of industrial partners, knowledge and navigation of political, regulatory and media terrains
UCL MechSpace		Physical space for fast tracking design and prototype manufacture.
UCL Alumni	Jamie Robinson, Alex Blakesley and Ismail Ahmad	Used skills and commercial software (Mashoom) developed by Robinson during his degree to manage and store the computer designs that would underpin the production process.
University College London Hospital Clinicians	Prof Mervyn Singer (UCLH Critical Care) Prof David Lomas (UCL Vice Provost Health) Dr David Brealey (UCLH Critical Care)	Clinical expertise, internal champion/influencer, local and global clinical knowledge and networks, knowledge brokerage and intermediation, co-located product testing and optimisation facilities
UCL Project Management, Legal and	Ian Galloway (TOPS) Weng Sie Wong (UCLB)	Experience and agile contracts, regulatory, legal

[15] https://www.bbc.co.uk/news/health-52087002

Contracts Support and Advice	Georgie Cade, Alice Hardy and Marilyn Aviles (UCL IHE)	and business case support, internal media liaison
Mercedes AMG HPP (Formula 1)	Andy Cowell (Managing Director) Ben Hodgkinson (Lead Mechanical Engineer)	Design and manufacturing capabilities, supplier chain networks
Other key partners	G-TEM (logistics and distribution) Oxford Optronix (oxygen analysers) LifeRacing (oxygen analysers) Avon Protection (breathing circuits) Intersurgical (breathing circuits) MHRA (UK regulation authority) Cabinet Office (Gareth Rhys Williams Government Chief Commercial Officer) UCL Partners (Lord Ajay Kakkar)	Value chain and networks, technical expertise, political and regulatory support, product purchase commitment, securing supplier chain prioritisation for the CPAP

The Figures above have been produced by the author from a synthesis of inputs, insights and reflections from the respondents. Other key data sources include – 'inside story of how Mercedes F1 and academics fast-tracked life-saving breathing aid' (Clare Elwell, 16 April, 2020)[16]; 'the NHS guidance for the role and use of non-invasive respiratory support in adult patients with COVID19 (confirmed or suspected)' (NHS, 6 April, 2020[17]); the UK Intensive Care National Audit and Research Centre (ICNARC) report of 27 March 2020, which showed that half of COVID-19 patients were in receipt of "basic respiratory support" (predominantly CPAP) (ICNARC Report, 27 March, 2020)[18]. What is represented above could be summed up in the words of one of the key actors who described this as '**the case of how a group of passionate, like-minded people, with no disciplinary egos, worked well together, unencumbered by bureaucracy'.** The following section presents some of the key lessons from this project.

[16] https://theconversation.com/coronavirus-inside-story-of-how-mercedes-f1-and-academics-fast-tracked-life-saving-breathing-aid-136028
[17] https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/specialty-guide-NIV-respiratory-support-and-coronavirus-v3.pdf
[18] file:///Users/macadmin/Downloads/ICNARC%20COVID-19%20report%202020-03-27.pdf.pdf

5.1 Key lessons

What emerges consistently at the different stages depicted in the timeline, among others, is

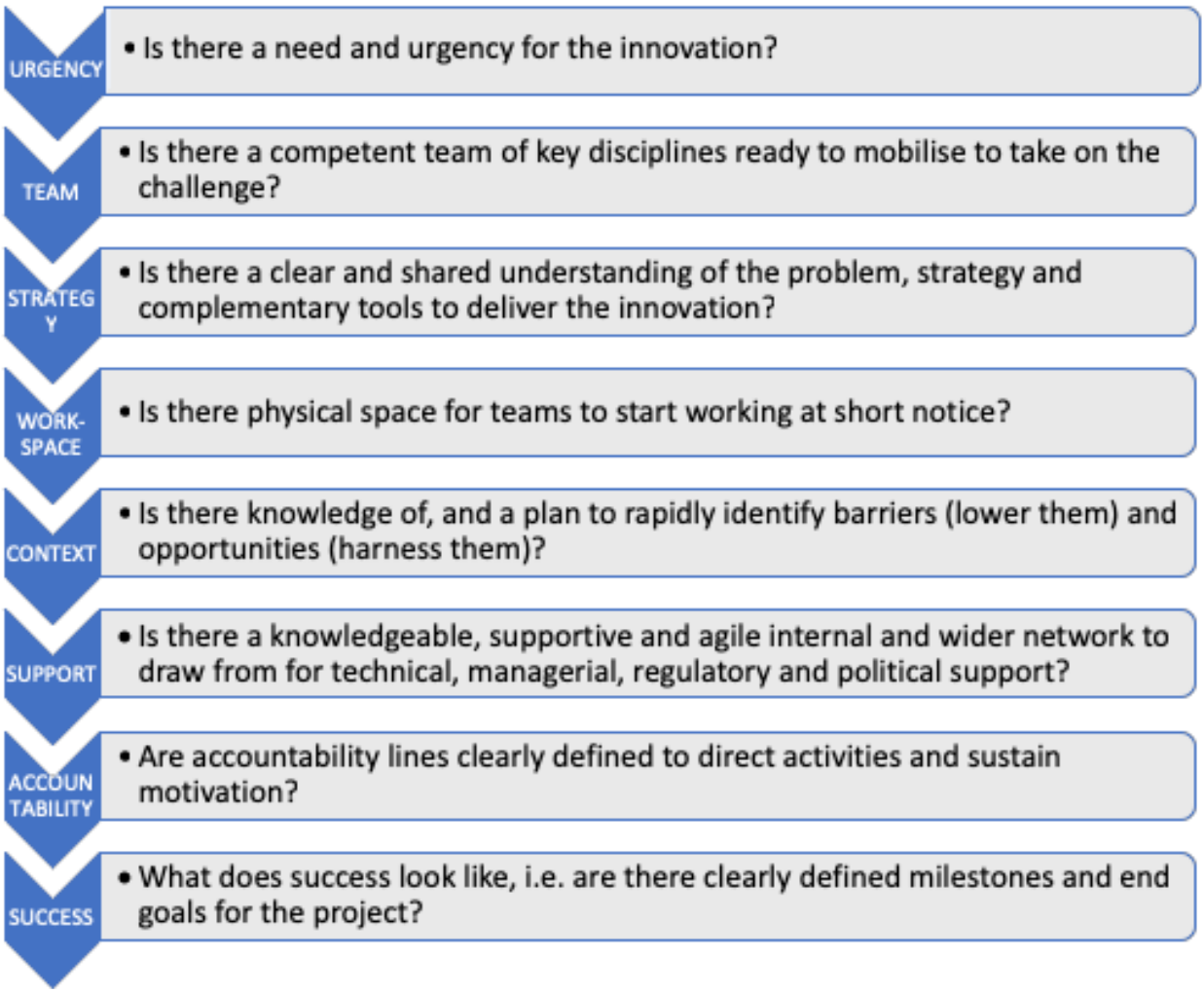
1. the importance of local and global bodies of knowledge and evidence in shaping innovation pathway choices,
2. the importance of context-relevant and timely data in garnering support for work-in-progress,
3. ability to work in and across disciplines, with professionalism and mutual respect
4. the importance of investing in, operationalising and optimising interdisciplinary workspaces
5. having institutional support from dedicated, experienced and incentivised professionals,
6. the importance of agile and supportive institutional systems for decision-making and financing
7. the importance of prior relationships, proximity and strong ties among collaborators,
8. the importance of knowledge of key influencers and networks beyond academia
9. the importance of clear goals, trust and lines of accountability
10. the importance of knowledgeable innovation intermediaries
11. the importance of internal and external media capabilities and contacts
12. the importance of identifying and leveraging opportunities to lower barriers to success of an innovation, for example re-engineering existing products

Many of these key factors are already part of the UCL culture and community of partners, as exemplified by the success of this breathing aid case. Some factors to reiterate among those highlighted in the figures and key lessons above, is the importance of having champions or **high-level influencers** within the University. For example, UCL VP (Health) David Lomas' role was noted as a key game changer within UCL, NHS and the political arena. Another key lesson both internally and externally is about ensuring having adequate **disciplinary representation** in decision-making structures. The importance of disciplines working together in an environment of **trust, valuing each other and mutual respect** is amply demonstrated by this case. Engineers alone without medics (and vice versa) would not have been successful in this case, neither would these two together without the contributions of legal, business and media minds, among others. How the team resolved the **regulatory framework** challenges is another lesson from this study, and as underscored by one respondent, '*a major differentiator between CPAP and Dyson, who haven't got their device to market (yet)'*. Meanwhile, the value of **UCL alumni** and their contribution to knowledge translation opportunities is also amply demonstrated by this case.

5.2 Rapid innovation check list

Drawing from the above sections, the following 8-point checklist is proposed as a 'tool' for gauging whether a new initiative 'has what it takes' to move fast through innovation':

Fig 4: Rapid innovation checklist



Source: Proposed by author from study findings

The checklist above (as was the conceptual framework earlier, Fig 1) is presented in a linear fashion merely for analytical simplicity. In practice, and as revealed by the case study, there is rapid interaction and shifting within and between the different stages.

6.0 Other cases to study

The lessons from this case study offer a good opportunity for a careful study of other UCL research and enterprise efforts to glean detailed lessons on how to make innovations

successful and impactful. Adopting a challenge-led or challenge-oriented innovation perspective, it is proposed that an innovation and knowledge ecosystems approach be adopted in looking at such case studies, analysing internal and external factors and their connections, as revealed by the CPAP device case study.

Some of the potential case studies suggested by interviewees include:

- UCL biobank
- Covid-19 vaccine research
- CPAP breathing hood/face mask (submitted for approval on 05.06.2020)
- Oxygen monitor (MHRA approved on 03.06.2020)
- Dyson/Airbus ventilators

7.0 Conclusion

What were the critical factors that enabled the Ventura project to be rapidly progressed to market, why were these successful in this instance and might they be replicable in other innovations? This study has unpacked the unprecedented interplay between critical socio-economic, technological, institutional, individual and political factors in responding to the complex and rapidly evolving societal challenge posed by the COVID-19 pandemic. It is not imaginable that the success realised in progressing the CPAP device from idea to market in less than two weeks would have been possible without the perfect storm of multiple factors which formed the background and foreground for this successful partnership. Being an 'unknown' disease helped people to be open to change in the treatment pathways. These changes 'in pathways' are usually a lot more difficult to implement in cases where clinicians have been doing the same thing for many years, and there is no urgency to change. It is more difficult to embed innovation in such settings. As one respondent observed … '*we were lucky to have the right people with the right skills at the right time. Going forward, we need a deliberate and institutionalised match-making function'*. The success may not be exactly reproducible in other contexts but there are many lessons to take forward for UCL about the ways in which teams and people can be brought together to address critical needs . Put in another way, **UCL and partners' capabilities** (the right people/skills at the right time) enabled rapid response. This is a demonstration of the value of investment in a certain type of **interdisciplinary capability and approach** to research. Rapid and agile project support pathways should be available to facilitate **challenge-relevant inter-disciplinary work** through availing physical spaces and other necessary incentives. Studying more cases, successful and unsuccessful ones, will be useful for informing appropriate reconfigurations of existing systems.

Annex 1: Study Interviewees (15 – 26 May, 2020)

Respondent	Date Interviewed
Prof Clare Elwell	15 May
Prof Rebecca Shipley	18, 21 & 26 May
Weng Sie Wong	18 May
Prof Tim Baker	18 May
Prof David Lomas	18 May
Ian Galloway	20 May
Prof Mervyn Singer	22 May