Response to FT article and Twitter thread by Peter Foster

An article in FT Weekend on 18 April 2020, 'Muddled thinking punctures plan for British ventilator', includes multiple inaccurate and misleading claims about the UK's work to procure and manufacture ventilators in response to the COVID-19 public health emergency.

An opinion thread on Twitter by one of the article's authors contains further inaccurate claims and assertions.

A detailed rebuttal of the article and the associated Twitter thread can be found below.

First of all, the Government wishes to pay tribute to the manufacturers who, in just four weeks, have provided vital additional ventilators for patients at unprecedented speed, to the businesses and others who have responded to the Ventilator Challenge, working tirelessly, and to the public for staying at home, playing their part in protecting the NHS and saving lives.

The Government's strategy to increase ventilator capacity has always focused on three pillars: first, procuring more devices from existing manufacturers overseas; second, scaling up production of existing ventilator suppliers, and third, working with industry to design and manufacture new devices. It has also involved seeking specialist support in other areas including logistics, component and peripheral procurement, and technical expertise.

While during the course of this public health emergency the NHS has had spare ventilator capacity for Covid-19 patients, scientific modelling nonetheless suggested an urgent need for further capacity still. In response, and alongside wider work, the Ventilator Challenge was launched.

At present, two devices from the Ventilator Challenge are ready for use in hospitals, with the Penlon ESO2 device this week becoming the first newly-adapted device to receive approval from the regulator, the MHRA. A number of other devices are currently undergoing tests for regulatory approval.

The Cabinet Office has previously corrected inaccurate claims made by FT Weekend: our earlier response can be found here

Detailed rebuttal of claims made in the FT and on Twitter:

What emerged was a procurement effort which insiders say was plagued by disjointed thinking that sent off non-specialist manufacturers designing products that clinicians and regulators deemed unsuitable for treating Covid-19 patients.

This assertion neglects to mention that designing and manufacturing new devices was always only one pillar of the Government's strategy.

Non-specialist manufacturers were engaged alongside specialists because there was an urgent risk that NHS ventilator capacity would prove insufficient for the rapidly-growing demand, and that the other two pillars would not, by themselves, provide sufficient new ventilators to meet that growing demand.

In many cases, the non-specialist companies teamed up in consortia with medical technology firms who obviously have specialist knowledge. Senior and leading NHS clinicians and the regulator, the MHRA, have been intimately involved at every stage of the Ventilator Challenge. Through the testing phase, designers have received feedback on their designs. While it is the case that several designs have not yet received regulatory approval that is not to say they will not.

At the heart of the problem was that Britain does not produce sophisticated devices for intensive care units. But at the outset, the aim of the initiative was unclear: to boost production of existing designs or to try to reinvent the wheel with homegrown products.

This is inaccurate. As has been repeatedly made clear, the aim of the challenge has always been to do both.

The press release issued after the Prime Minister's call on 27 March said: 'The government has partnered a number of the UK's leading technology and engineering firms with smaller manufacturers to rapidly build existing, modified or newly designed ventilators at speed."

At the Downing Street Press Conference on 31 March, the Chancellor of the Duchy of Lancaster, Michael Gove, said: 'thanks to the dedication of existing medical supply companies and the ingenuity of our manufacturing base, we have existing models being produced in significantly greater numbers and new models coming on stream'.

The same point was made in a Cabinet Office press release issued on 16 April which said: 'Last month, the Prime Minister called on some of the biggest names in British manufacturing to help step up ventilator supplies, in order to save lives during this coronavirus pandemic. Following this, the government has partnered a number of the UK's leading technology and engineering firms with smaller manufacturers to rapidly build existing, modified or newly designed ventilators at speed.

As mentioned above, as part of the Challenge, several non-specialist companies have teamed up in consortia with those with specialist knowledge.

As business leaders prepared for a conference call with Boris Johnson…on March 16, industry experts issued warnings about what was realistic and desirable. Stephen Philipson, chief executive of manufacturers group Make UK, said British companies would be better placed to make proven models "under license".

No one was under any illusions at the time of launching the Challenge that producing new designs for domestic production would be anything other than a significant and exacting test.

Ventilators are highly complex medical devices requiring hundreds of individual components. That was precisely the point of issuing a public Challenge. Alongside new devices, the Challenge has pursued scaling up a number of existing, proven ventilators, including Smiths paraPac devices which are already in the NHS. And we are working with other companies, including Breas Medical, to further increase production of existing ventilators.

“They were at pains to stress, this needs to be simple designs – no ICU ventilators – and we’ve got to get them through basic regulatory approval,” said one person who was on the Prime Minister’s call with business leaders on 16 March.

This is simply incorrect. No minister or official on the call on 16 March said that designs needed to be simple, nor that they were not looking for ICU ventilators.

The first formal specification published by the Medicines and Healthcare products Regulatory Agency (MHRA) on March 20, [specified] the “intended purpose” of the device was for ‘short-term stabilisation for a few hours’ extendable to 24 hours “in extremis”.

This quote is misleading and misses key qualifications. As NHS England’s Chief Commercial Officer, Emily Lawson, specified on the Prime Minister’s call with business leaders on 16 March, the devices will ‘need to be able to operate 24/7’.

The specification published on 20 March by MHRA outlined ‘clinical requirements based on the consensus of what is “minimally acceptable” performance in the opinion of the anaesthesia and intensive care medicine professionals and medical device regulators. It made clear that these devices were for ‘the initial care of patients requiring urgent ventilation’. The specification ‘proposed these ventilators would be for short-term stabilisation for a few hours, but this may be extended up to 1-day use for a patient in extremis as the bare minimum function. Ideally it would also be able to function as a broader function ventilator which could support a patient through a number of days, when more advanced ventilatory support becomes necessary.

“The initial focus . . . was very much on novel designs, not scaling up existing designs,” said a person familiar with the internal deliberations. “But questions were then raised about why we were trying to reinvent safety-critical devices. This should not have been a job for non-specialists.

Response:

This is incorrect. The Government’s strategy has always been focused on three pillars: procuring more devices from overseas; scaling up production of existing ventilator manufacturers; and designing and producing new devices.

This strategy has been based on NHS clinical need, with experts and NHS clinicians – including those from the regulator, the MHRA – involved in

shaping it. This is why, as part of the Ventilator Challenge, the Government paired Penlon, an existing UK manufacturer of high spec ventilators, with High Value Manufacturing Catapult, Ford, a number of UK-based F1 teams and Siemens, in order to scale up their production. In just four weeks the newly adapted Penlon ESO2 has received regulatory approval and is being delivered to the NHS frontline to save lives.

Claim:

The government spin is the clinical need changed, but the reality is that it was always misguided to think you could develop and create these ventilators', an insider with direct knowledge of the process said.

Response:

It is correct, responsible and only right that the Government ensures that what it procures meets clinical need, and that this is kept under constant review.

Clinical experience of COVID-19, both in the UK and other countries, has inevitably grown rapidly over the last month. It is now clear that there are additional requirements for mechanical ventilators to support the effective critical care of patients.

Claim:

Two out of the UK's three main ventilator makers told the Financial Times their contact with government officials only began in mid-March, around the same time as the general appeal.

Response:

Throughout this public health emergency, the NHS has always had spare ventilator capacity for patients. The NHS has been liaising with suppliers since February and the Ventilator Challenge has involved work with manufacturers around the clock to increase ventilator supply.

Designing, manufacturing and gaining regulatory approval for ventilators usually takes years. That so much progress has been made in such a short time underlines the incredible efforts made by industry. The first devices from the Ventilator Challenge have already received regulatory approval and been delivered to the NHS frontline. Over the past six weeks the government has increased ventilator capacity by thousands. This means that 10,600 ventilators are now available to NHS patients across the country, with hundreds being delivered each week and many more on order.

The author made further claims on a twitter thread.

But the question soon arises – WHAT should those manufacturers build? Do we build from scratch? "Reinvent the wheel' so to speak? Or tool up/expand what existing capacity we have? Or seek to make stuff under licence? This is the BIG question…."

That was never, and is not now, the question. The Government pursued all avenues under the three pillars of its strategy, as outlined above. Given the unprecedented scale of the COVID-crisis, it sought both to scale up existing manufacture and build new designs.

And the answer comes on March 16 when @BorisJohnson does a conference call with all of the top industrial bosses. They want something simple, non-ICU that can be mass produced – as an insider on the call tells us.

This is simply incorrect. No minister or official on the conference call on the 16 March said that designs needed to be simple, or that they were not looking for ICU ventilators.

But when the regulator publishes the first formal "spec" for the new ventilators it is need super-simple [sic]. The "intended purpose" is that these vents should work for a "few hours" and "in extremis."

This is misleading. The very document that the author quotes makes clear that '1-day use' is the 'bare minimum function'. This is visible within the tweet itself. Further detail is provided in response to a claim above.

The author then questions what he calls the Government insistence that 'this was all done with the advice of both top doctors AND the regulators' He goes on to ask: 'What about the Regulators – the MHRA – what did they think?'. He quotes 'insiders' to suggest that 'there was push-back about the utility of these basic vents, the damage they would cause, and their utility in weaning patients back to health'

This is particularly confused. The MHRA – the regulator – published the very specification that the author quotes above. Their logo is visible in the graphic which he himself tweeted.

Initially when … concerns were pushed up the chain, the reply came back "that's what the customer wants". Which begs a question. WHO was the customer? Not the docs. Not the regulator. Not the patients. The only answer that fits, is the Government. The politicians. EESH

This is entirely untrue and absurd. The specification was published by the MHRA. The ventilators are sought for the NHS.

It takes time for the penny to drop in Whitehall and the Cabinet Office – but by April 10, check out the "amended" spec that says "the greater proportion of devices" for treating coronavirus would need to be capable of supporting "spontaneous breathing modes."

On the Prime Minister's call with business leaders on 16 March, Emily Lawson, NHS England's Chief Commercial Officer, outlined 'the absolute clinical specifics of what these machines need to be able to do', which included that they 'need to have both mandatory and spontaneous breathing modes so that as people start to breathe for themselves the machine recognises and responds to that.

The result is that the Bluesky consortium – which HAD BUILT to spec is canned

on April 11. And others like the ‘Oxvent’ scheme (another low-spec effort) is paused. Insiders tell us that quite possibly none of these ‘hackathon’ designs will get approval

As Cabinet Office officials made clear on the Prime Minister’s call with business leaders on 16 March, this “will be an iterative process….Some [designs] will not pass the clinical standards that we need of reliability and so on and so forth”.

The Government has always been led by NHS clinical need, and the best available medical and scientific evidence. When that advice evolves, the Government has responded accordingly: support was halted, for example, for the production of the BlueSky device on the advice of clinical experts – specifically following a review by the Technical Design Authority, including NHS Clinicians and the MHRA.

the government did change tack in the face of medical and scientific pressure and (mercifully) it was spared its blushes because ventilator capacity held up, clinicians used more (non-invasive) CPAP and (probably) more deaths happened in community.

We have been consistently clear that we have sought to increase both invasive and non-invasive capacity as part of the overall strategy, as set out by the Chancellor of the Duchy on 4 April at the Downing Street daily briefing. That is why the Government has also worked to increase CPAP availability with the University Colleges of London and Mercedes partnership, demonstrating the Challenge’s broad efforts to meet a range of clinical needs.

As a side note, this kind of treatment PISSSES PEOPLE OFF. My inbox is full of people who daren’t speak on record but are SEETHING at the way they were treated. People who worked 20-hour days for weeks; gave freely of their time, energy and spirit for nothing.

This is a huge national effort so, unfortunately, we are unable to respond to these claims without further details. It was always likely that as part of this Challenge some designs would not succeed but the Government recognises the tremendous efforts made by so many towards a shared goal of protecting the NHS and saving lives.

The government may look to try and find an outlet for these ventilators in other places – but you have to ask, if they’re not fit for UK patients (and we’ll see if any can get clearance) why would they work for poorer countries?

All ventilators from the Ventilator Challenge must undergo stringent safety testing by the regulator, the MHRA. This work is led by a panel of expert clinicians. It is incorrect to imply that ‘not fit’ devices would ever be used on patients from any country.

Because guess, a device that keeps you alive, that breathes for you IS flipping complicated. How hard can it be? Damn hard. It’s parts mustn’t catch fire in a high-oxygen environment. It’s software must anticipate a patients breathing. If it freezes, you may die’. This continues – ‘This was OBVIOUS AT

THE OUTSET’.

This was indeed obvious at the outset and was made clear on the Prime Minister’s call on 16 March. Emily Lawson, NHS England’s Chief Commercial Officer, said then that the devices ‘need to be able to operate 24/7. They need to have a failsafe in case of fire. They need to provide oxygen and air at specified concentration, at set volume and to not exceed a set pressure. They need to be able to provide positive pressure at the end of exhaling, at a pressure set by the clinician. They need to have both mandatory and spontaneous breathing modes so that as people start to breathe for themselves the machine recognizes and responds to that’.

What worries me is if this “how hard can it be?” principle is applied to testing, to PPE procurement etc. The government needs to show some HUMILITY. It needs to LISTEN TO PEOPLE WHO KNOW STUFF. I think this is a clear example of where it did not.

This is untrue. As the Prime Minister made clear on his call to business leaders on 16 March, what business was being asked to do was a ‘huge undertaking’. This was acknowledged from the very outset. The suggestion that Government is not listening to people ‘who know stuff’ is entirely misplaced. There have been daily ‘meetings’ on the Ventilator Challenge bringing together ministers, officials and advisers with procurement experts, clinicians and the regulator. This was to ensure that the latest clinical and regulatory advice was being followed and to drive delivery, address obstacles and find solutions. While the difficulties have been immense, the Government is truly grateful for the tireless dedication and application shown by so many companies and individuals.