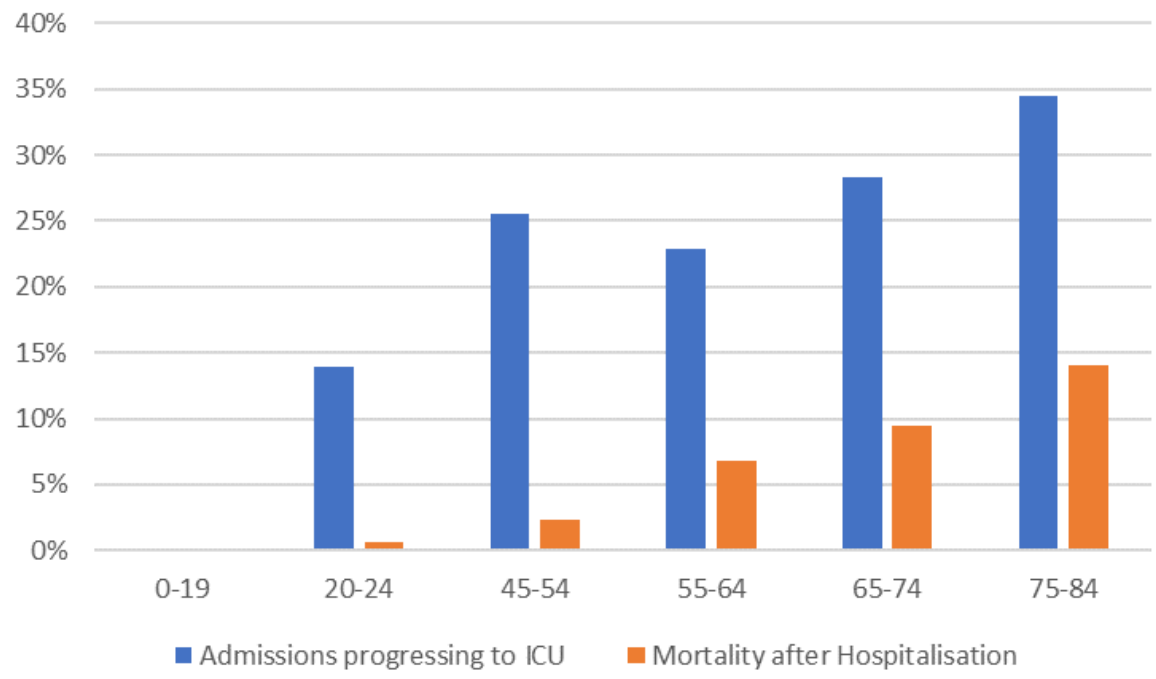
Coronavirus – The UK's Ventilator Exit Strategy

As the UK moves towards a more major lockdown, it's becoming apparent that this will not be a short-term disruption. Imperial College have published their modelling plans, on which the UK strategy has been based and it's clear there is no quick fix. The Coronacrisis looks set to be with us for the next twelve to eighteen months.

It's a hundred years since the Spanish flu pandemic, for which society had no medical solution. The result was that millions died around the world, as the best that medical science could do was to alleviate the symptoms of the dying. Since then, medical science has progressed to the point that people expect it to save them this time around. The unfortunate truth is that we have no drugs or vaccine available and it will probably be eighteen months before we do. Until then, all we can do to limit the spread is suppression, i.e. keeping people apart to reduce the number of infections.

Where we have made advances is in the technology to treat those who progress to secondary infections which are resulting in the death toll. Again, we have no pharmaceutical cure, but we can use ventilators on Intensive Care Units which can save many patients. Not all, as anyone with underlying health issues is likely to succumb. The following chart, based on US stats from Statista shows the percentage of patients who need intensive care after hospital admission, broken down for different age ranges. It also shows the mortality rate. If you are young or healthy, ventilators have a big effect on survival rate.

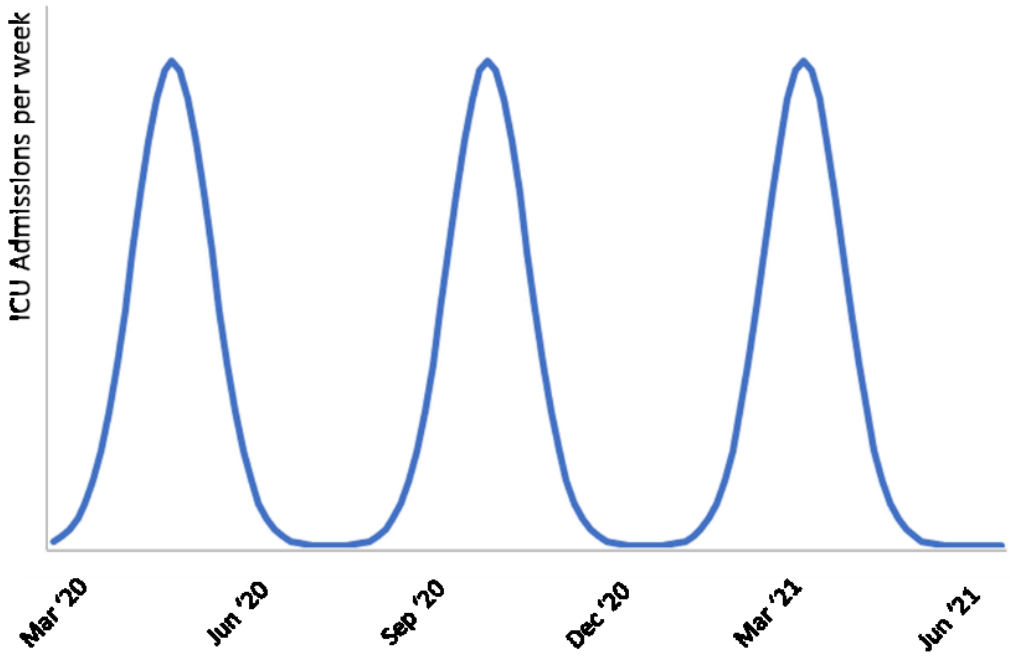


The problem is that no healthcare system has enough of them. One of the cornerstones of the UK (and most other countries') strategies is to acquire as many as quickly as possible. In the meantime, we need to suppress the growth of infections by locking down society. Unless we do that, cases will grow and the healthcare system will be overwhelmed. That is what happened with Spanish flu. At

the height of the epidemic, it was reported that in Boston, horse drawn wagons patrolled the streets looking for the abandoned dead. That is not a vision that any modern day politician wants to face.

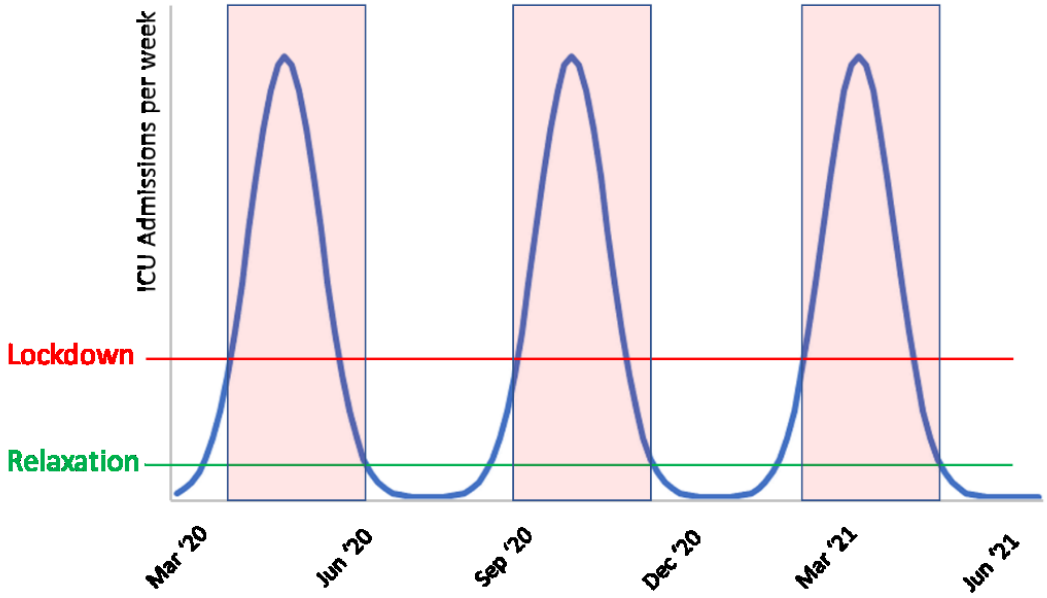
While suppression by isolation slows down infection and hospital admission rates, the flip side is that it also locks down the economy. At the point where we have a vaccine, cure, or have accepted the consequences of mass mortality and acquired immunity, it is important that life gets back to business as usual. We also need enough essential services operating throughout to maintain everyday services – food, energy, water, healthcare, essential transport and communications. That needs a balancing act which minimises the lockdown periods and maximises the number of jobs which can continue. Sectors like travel, High Street retail and hospitality will almost all shut down. Conversely, home delivery, healthcare and supermarkets may need to recruit. Many major manufacturing businesses will be hit, as we stop buying cars and construction slows down. The challenge is to ensure that although dormant, they can be resurrected.

To understand how ventilators and ICU beds help, you need to understand the dynamics of the pandemic, which are explained in the Imperial College paper.



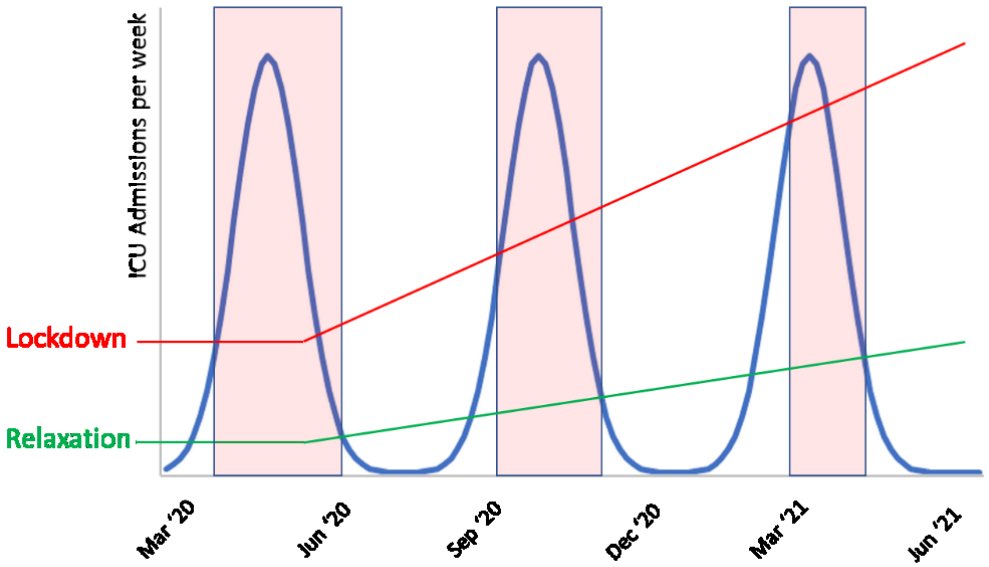
The graph above shows the predicted pattern if we use lockdown to suppress the spread of infection and reduce the number of hospital admissions. In each cycle, infections peak, resulting in increased numbers of people requiring admission to intensive care units (ICUs). As normal, daily activity stops and people isolate themselves, the infection rate slows and admissions fall. At that point, lockdown can be relaxed, life starts to return to normal and the cycle repeats itself. (The dates shown are guesses. No country has yet entered the reinfection stage, so we don't know how long each cycle will last.)

The main tool that a Government has to manage this is the point at which they impose a lockdown and how long it remains in place. As has happened in the UK, it can be done in stages. Leaving schools open means more people can continue to work, which helps the economy. The following diagram shows how that works:



Lockdown is triggered when it looks as if the growth in admissions will result in ICUs becoming full. The Imperial report sets that at 200 new admissions per week. The Lockdown then stays in place until ICU usage falls to 25% of available beds. That corresponds to the red "Lockdown" and green "Relaxation" lines above. The pink boxes represent the duration of each Lockdown. If you relax restrictions too early, then the infection rate may start to rise again immediately, leading to semi-permanent lockdown. The aim of this approach is to keep as many people alive as possible. If the number of patients needing an ICU exceeds the number of beds, then Governments and doctors will need to make the difficult decision of who gets treatment and who dies. That's something they all want to avoid.

That is where the ventilator strategy kicks in. The most effective way to change the duty cycle of Lockdown and Relaxation, reducing the time that everyone stays at home, it to increase the number of ICU beds, which means acquiring many more ventilators. The diagram below illustrates the basic concept:



This is vastly simplified to demonstrate the point. If we can start to increase the number of ICU beds from early summer, we can postpone the start of the next suppression lockdown, because more people can be admitted and treated each week. The 25% relaxation point signalling the end of lockdown also comes correspondingly earlier. As we add more ICU beds, each cycle of lockdown becomes shorter, letting people get back to work faster. It won't be life as normal; people will still be asked to work from home and public meetings will be discouraged. But it helps the economy to keep going and reduces the amount of money the Government has to pour into providing life support for business. In theory, if we had enough ICU beds we could just let the virus take its course, but that brings other challenges.

Having enough ICU beds won't stop deaths. As we saw at the start, there is still a mortality rate. This is a pandemic and one of the consequences is that hundreds of thousands of people in the UK will probably die prematurely. However, it is a strategy that should help to minimise that number, whilst keeping the economy alive for the long term.

I'll come to the issues of producing more ventilators in a minute, but before that I need to stress that simply delivering a lot of ventilators is only one part of the solution. They are the critical path component, not least because so few companies can make them. By themselves they have little value. We need to support each one with the rest of the equipment that makes up a full respiratory ICU, from beds to all of the associated monitoring equipment and infrastructure. To do that at scale means looking at this outside the current hospital paradigm and working out how to deploy them en masse. If you allocate 20 sq metres for each ICU bed, then you could fit around 5,000 into the Excel conference centre in London; 10,000 into the NEC in Birmingham and another 15,000 into major regional exhibition halls around the country. The prospect of serried ranks of ICU beds in barn-like structures may feel anathema to our concept of healthcare, but these are buildings with space, good access, transport links and nearby accommodation for the tens of thousands of staff that will be needed to work there. Once you have worked out a model for a group of 100 ICU beds it can be replicated again and again. This is all about mass production healthcare – the Kwikfix approach to intensive care.

The other imperative is to train enough people to provide medical and nursing care and maintenance. The 40,000 medical students in training should be co-opted, but that will only be a start. Many of those who have recently been laid off from the hospitality industry will need to join them. Training needs to be directed solely to the tasks of running an ICU and should already be starting. Politicians have already made the wartime references, with reminders of how many Spitfires we could build in a week. To support 30,000 or more new ventilators we will need people to stand up and volunteer. There are already voices protesting that this will not be possible, because we don't have a Plan B. Except we do have a Plan B: it's letting more patients die. Which means we have no alternative other than do all we can to make this work.

Which brings me to the question of procuring those ventilators. Matt Hancock has said that the government is launching "a call to arms for a drive to build the ventilators and other equipment the NHS will need. We now need any manufacturers to transform their production lines to make ventilators. We cannot make too many." Speaking on Sky News, he added that: "If you produce a ventilator, we will buy it. No number is too high."

BEIS – the Department for Business, Energy and Industrial Strategy has been spearheading the Government's drive to getting more ventilators. They've set up a survey, asking manufacturers and component supplier to let them know if they can help, and have been asking companies who can to

call them. That's fine, but to put things in perspective, Penlon, one of the UK major suppliers of ventilators, only has the capacity to make around 750 each year.

I've spent my working life in technology design, manufacture and data analytics. I want to see us get those 30,000 extra ventilators, but I have some concerns about the strategy. Every other country is after ventilators, so we're unlikely to acquire them outside the UK, necessitating a home-grown approach. If we want to get them fast, there are two obvious ways to attempt to hit the target of 30,000 ventilators which we should pursue.

The first to is get existing manufacturers to make more. You start that by ordering them and then finding out what they need to do to increase their production tenfold. Reliable ventilators, which you can deploy in tens of thousands, which work largely autonomously, are complicated beasts. They involve hundreds of electronic, electrical and mechanical components. Around 85% are probably standard parts available off the shelf, but the rest are specialised or custom products which typically have long lead times. To have any hope of getting large quantities of those you probably need to parachute in a procurement manager for each one. In many cases you may need to bring new suppliers on stream to acquire the volumes you need and for some others you may need to bring in an engineering team to redesign the component so it can be manufactured locally.

Production should be less of a problem. There are plenty of specialist assembly companies who can help, but they will need to reproduce manufacturing jigs, program assembly equipment, build additional test stations and train their staff. It is not an insurmountable problem if you throw enough resource at it and it has the advantage of being relatively low risk. Ventilator manufacturers may not be happy with this approach. If they sell 30,000 ventilators this year, they may never sell another one after that. But that's something the Government needs to sort out. We should ensure that a company that is trying to save lives has a future.

The second approach is to design a new ventilator from scratch and mass produce it. At first sight that seems counterintuitive, but there is a logic to it. Most medical device companies are not vastly inventive. Having developed a product which works, each new model tends to have fairly minor innovative steps. There's a good commercial reason for this, which is that all of these products need to go through stringent regulatory testing. Changing the way they work makes that risky and expensive. As a result, the basic technology in many of them is probably similar to what it was ten years ago and uses components which had already been around for ten years at that stage. If you were to start from scratch today you would probably do it differently, taking advantage of the major advances in technology over the last two decades. The other advantage is that a new design can be developed for mass production by a wide range of manufacturers. Very often the technology going into a medical device is chosen to suit that company's current production line, which may limit their technology choice and also make it more difficult to transfer production to a different manufacturer.

The UK has some of the world's leading medical technology design consultancies, developing products for major brands around the world. They include a cluster based around Cambridge, including Cambridge Consultants, Plextek, Sagentia and TTP. A consortium based around these could well bring us a robust, reliable ventilator design that could be produced in volume. It is a higher risk strategy and would need the Government to waive many of the normal regulatory procedures to get it deployed in time to be effective. That is another risk, which is far from trivial.

These are both good, valid strategies and we should probably do both, as it's not a high cost if one fails – we still have a second strand. My concern is that BEIS may be being guided by other voices with vested interests.

There was a report this week from the High Value Manufacturing Catapult claiming that five design companies have been asked to write a specification and the best one will be chosen by PA Consulting. The Government currently has a policy of funding development through competitions, typically run by Innovate UK. This feels like a rerun of that approach. It doesn't chime with the current imperative, which needs a cooperative effort which pools the best available talent. This should not be treated like an Innovate UK competition, but a collaborative national effort.

Yesterday (Friday 20th March) BEIS published a specification for a "rapidly manufactured ventilator system", with the intention of acquiring 30,000 units. Nothing indicates whether this is the "winner" of the process reported by the High Value Manufacturing Catapult, or an amalgam of inputs. It's a good overview, with some very pragmatic requirements, such as:

- It must be intuitive to use for qualified medical personnel, but these may not be specialists in ventilator use,
- It must not require more than 30 minutes training for a doctor with some experience of ventilator use, and
- Instructions for use should be built into the labelling of the ventilator, for example, with 'connect this to wall' etc.

These imply that BEIS realises that many of the people using it will have minimal background experience. The specification is obviously a little rushed, as it includes the statement "Need the advice of an electronic engineer with military/resource limited experience before specifying anything here. It needs to be got right first time." However, it's honest and has a sensible section on unknown issues. It does need a section on data capture, as it will be important to collect and process patient information as well as ventilator performance. The specification currently only talks about data display, not data capture and connectivity. If we are going to win the battle against coronavirus it needs to be evidence-based, so the more information we capture and analyse, the better chance we have. Today, each ICU is generally staffed with one experienced ICU nurse. That's not going to be possible with this rapid expansion - we will have one skilled nurse in charge of a number of general and recently trained nurses. Even simple analytics may help to support these newly trained nurses and allow a greater ratio of skilled to apprentice nurses, as well as helping with predictive and preventative maintenance. But is should not impose a burden on getting these devices shipped.

Earlier this week the Guardian reported that "More than 60 manufacturers have been sent a blueprint for making up to 20,000 ventilators", which may or may not have been this specification, or a precursor. Companies named as being involved included Rolls-Royce, Airbus and Land-Rover, with later announcements adding JCB, Honda and even a Formula One team. All companies which I suspect have been lobbying hard to be involved, as they see this as a lifeline.

However, the Government needs to be hard-headed about this decision – it is not about supporting companies which are threatened by the current situation, but about saving lives by mass producing effective ventilators as quickly as possible. By all means put support packages in place for industries in trouble, but don't let that cloud the decision of how to get our ventilators.

I'm fortunate in that I can continue to work at home during this period, as are many others involved in engineering development. Many of us have experience which may be relevant and would like to know how best to help, albeit aware that effective development is often best achieved by small teams. It does feel that specialist technology organisations with direct experience, such as the IET and Cambridge Wireless should be closely involved in providing advice to this project, but I've not

seen that happening. Hence my concern that large industrial interests may be influencing Government policy. Getting these ventilators delivered is the only priority - it has nothing to do with supporting industries in trouble. We need to be focused on saving lives and getting 30,000 Intensive Care Units up and running. 30,000 ventilators is not high volume – consumer electronics manufacturing considers a million to be relatively low volume. But ventilators are highly specialised devices, requiring companies who are experienced in that type of medical device design and bringing designs to market, not ones who subcontract electronic design out to others, as the automotive industry does.

I am sure there is much going on which is not public, simply because the most important thing right now is to get things done. Equally I would like to be sure that the best advice is being used and that the only consideration is how to get thirty thousand ventilators manufactured and in use, along with the trained staff to support them, without decisions being sullied by the survival plans of manufacturers, however large and vocal they may be. If they can contribute, please include them, but make sure every decision is evidence based. To put it bluntly, this is a life and death decision.

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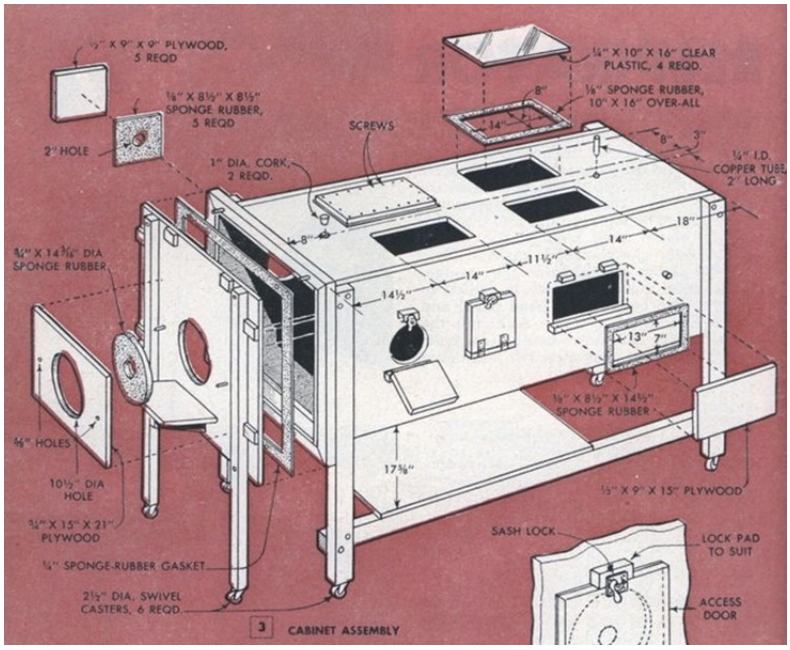
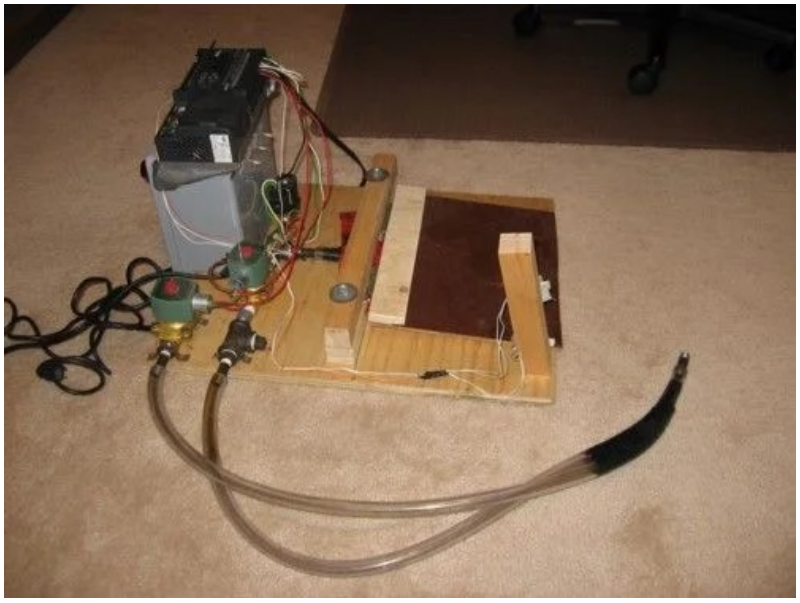
There is a third way, but not one that is probably a serious alternative. It is very definitely Plan C. That is to appeal to the design community to develop their own. It's not a new idea – back in 1952, Popular Mechanics magazine published a design for a DIY Iron Lung made out of plywood.



I've no idea how many people followed the instructions and had one sitting in their basement for the next emergency. I suspect there may have been a few constructed, if only to keep unruly kids in.

The Avian Flu pandemic in 2007 saw another DIY project for a ventilator constructed using commonly available components. The project, called the Pandemic Ventilator, was meant to be used as a ventilator of last resort during a possible avian (bird) flu pandemic. It carried the codicil

that “the prototypes presented are not fully functional devices and have had no safety testing done. A ventilator is a potentially hazardous device and should only be operated by a trained and certified respiratory therapist. Anyone using this information to build or use a device agrees to waive any and all liability.” The lack of comments on the original post suggests this may have had even fewer followers than the wooden lung.



This time around, numerous maker groups, with the benefit of advances in 3D printing are rushing in with designs. Unfortunately, experience of these projects is that they’re rarely designed for manufacture, usability or reliability and need to go through multiple generations of development until they are robust and reliable. Designing a working prototype and designing a product to be mass manufactured and reliable are very different things. For example, valves on ventilators may operate every five seconds, which means half a million operations each month. Very few of us have designed components with that level of reliability, and it isn’t easy. But if a ventilator is not reliable, supporting it will require more staff, not fewer. So as far as ventilators are concerned, we are likely to do best by concentrating on professional approaches. There is a telling post from an anaesthetist on the Open Source COVID 19 Medical Supplies page thanking contributors for their enthusiasm but asking them to temper it with some thought of actual clinical utility.

Make magazine has just published an excellent overview of “Plan C” initiatives to develop open source ventilators and other products. Robot builder Gui Cavalcanti, who is one of the organisers of the Open Source Covid-19 group acknowledges the challenge. He started a ventilator project, but realised that there were even more problems beyond ventilators, and has shifted the group’s focus in that direction. I suspect that is where many of us would be best employed. We can probably help more by concentrating on the lower profile requirements.

There are a growing number of groups starting to organise the engineering community – amongst them Helpful Engineering, Project Open Air and 1 million ventilators. COVIDbase curates a list of projects and news and there is even a COVID accelerator. The world has a global community of engineers and manufacturing experts who are about to find themselves with more time on their hands than usual, wondering how they may be able to play a part. We need to work out how best to

utilise that experience without generating more noise which distracts overworked medics. As the crisis develops, I'll update this article, so please let me know if there are initiatives I'm missing.

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