

# Ventilator safety in use: proposal

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Patient Safety Learning has been briefing key leaders in parliament and across the healthcare system in the UK and globally on matters in relation to patient safety and Covid 19.

We have recently engaged with experts and colleagues to seek their views on the human factors/ergonomics issues regarding the design and development of ventilators to meet urgent demand.

## Procurement of new ventilators in the UK

Manufacturers are currently being actively encouraged to respond by designing and delivering extra ventilators. We understand that manufacturers without any history of providing ventilators are also being asked to step up to support this crisis, not just established manufacturers of these products. Priority is being given to the fast delivery of safe product.

The UK Department of Health and Social Care has been, according to press coverage in the Health Service Journal 'weighing up whether manufacturers could come up with new designs, issuing specifications for a "minimally acceptable" rapidly manufactured ventilator system (RMVS). I include this specification as Appendix 1 and reflections on the major points in the RMVS spec where HFE expertise is needed as Appendix 2

## Risk to patient safety

These experts are concerned that there will be risk to patient safety with the speed of manufacture, where there are already safety issues relating to multiple designs and ways of using these products, different requirements for training and with the proposed relaxation of standards.

This is about not just the equipment but about the people who use it, especially those using it who may be inexperienced or untrained in the use of ventilator and also using ventilators whilst wearing protective PPE.

There is a risk that moving at speed and developing non-standard ventilators with manufacturers with little previous experiences and to reduced standards, we are designing a system than has numerous points of failure and built-in cumulative risk for patients.

Should ventilators fail to be safe in use, we may not realise it, as these patients are all so sick that deaths will probably be attributed to their disease.

A risk that has been raised at last the end of last week has been to adapt systems to ventilate multiple patients. They tried this in Italy. This was the strong reaction at international level <https://www.aarc.org/joint-statement-guidance-document-on-multiple-patients-per-ventilator/>

## The need is great and the timescale is short

This means a full Human factors ergonomics development and usability testing process is unlikely to be feasible. But we have connections with ergonomists and clinicians working in this area who have committed to collaborate and come up with input to make these ventilators as safe as possible. Some of these ergonomists and clinicians have tried to make contact to highlight their concerns and offer their support. They have had no response either from manufactures or those leading the procurement.

Human factors and usability professionals want to ensure any product, particularly with relation to the safety, are usable and error tolerant. It will be necessary to consider overall ALARP issues (As Low as Reasonably Practicable). This principle is that the residual risk shall be reduced as far as reasonably practicable.

### Perfection is the enemy of the good

Use current knowledge; bring in committed recognised experts and fast track the development of safe ventilators. Action is needed now.

In the last 48 hours human factors and ergonomics experts including clinicians have identified requirements and proposed actions:

### Share current knowledge and expertise

Share the usability testing from current manufacturers for the user interface/ use specifications for already approved ventilators.

### Ensure ventilator safety in use

Contribute to this fast development of ventilators with specialist human factor/ergonomics and clinical input including:

- a) Safety in use is included in specification and procurement
- b) Current knowledge of best practice and risk informs ventilator design and use
- c) Ventilators can be used safely by staff
- d) Patient needs are included in the design brief

Proposals include:

- a) Developing a set of user requirements
- b) Human engineering and user trials with hazard identification
- c) HF requirements must be included in procurement

Please see the attached driver diagram for more details.

And in the medium to long term, learn from and ensure that healthcare systems demand and drive standardisation in medical devices for safety in use.

### 'Minimally acceptable' rapidly manufactured ventilator system

The UK Department of Health and Social Care has been, according to press coverage in the Health Service Journal 'weighing up whether manufacturers could come up with new designs, issuing specifications for a "minimally acceptable" rapidly manufactured ventilator system (RMVS). Its specifications included:

- *Ventilators must be reliable and able to keep working 100% of the time for at least 14 days.*
- *They should be small and light enough to fix to a hospital bed, but robust enough to survive falling from bed to floor.*
- *The machines must be able to provide both mandatory ventilation – breathing on behalf of the patient – as well as a pressure support mode that assists those who can breathe independently to some extent.*
- *The machine should be able to sense when a patient stops breathing and switch from the assisted breathing mode to a mandatory setting.*
- *Ventilators will have to connect to hospital gas supplies and will also need at least 20 minutes of backup battery in case of mains power failure. The batteries should be swappable in case of a longer outage, or a patient transfer that could last two hours.*
- *Buried at the end of the government's specification document is a warning that requiring backup batteries will mean 30,000 large batteries being sourced quickly. The government admits it will "need the advice of an electronic engineer with military/resource-limited experience before specifying anything here. It needs to be got right first time."*
- *All of the ventilator's parts need to be detachable so they can be disinfected manually.*
- *They must also be fitted with an alarm that alerts medical staff in case of a fault or some other interruption or inadequacy of oxygen supply.*
- *Doctors must be able to monitor the ventilator's performance, for instance the oxygen percentage it is providing, via clear displays.*
- *Operating the machine must be intuitive, requiring no more than 30 minutes of training for a medical professional who already has some ventilator experience. Some of the instructions should also be included on the external labelling.*
- *Specifications include the ability to support a range of 10 to 30 breaths per minute, rising in increments of two, with the settings adjustable by medical professionals. They should also be able to change the ratio of the length of time for inhalations to exhalations.*
- *The document includes a minimum for the amount of oxygen the ventilator should be able to pump into a patient's lungs. Tidal volume – the amount of air someone inhales during a normal breath – is typically about six or seven millilitres per kilogram of body weight, or about 500ml for someone weighing 80kg (12 stone 8lb). The minimum requirement for a RMVS is a single setting of 450. Ideally, it could move on a spectrum between 250 and 800 in increments of 50, or be set to a ml/kg setting.*
- *The average proportion of oxygen in the air is 21%. The ventilator should offer 50% and 100% at the very least and ideally 30% to 100%, rising in increments of 10 percentage points.*
- *The Medicines and Healthcare Products Regulatory Agency (MHRA) is the UK body that approves medical equipment for use. It will have to give the green light to any ventilators used in the Covid-19 response. Manufacturers must show their supply chain is contained within the UK, to ensure no disruption in the event that cross-border freight movements are interrupted. The supply chain must also be transparent so that the MHRA can ensure suitability of parts.*
- *Ventilators must meet certain existing standards for MHRA approval. However, the DHSC said it was considering whether these can be "relaxed" given the urgency of the situation.'*

## Major points in the RMVS spec where HFE expertise is needed

1. **Yellow:** Portability and stability of location/attachment for use – both for carrying/securing and physical interface with controls
2. **Blue:** Usability
  - a. Instructions for use – should be based on quick task analysis to try and identify as many ways of ‘getting it wrong’ and putting in barriers to error
  - b. Testing when wearing PPE, tired, poor vision etc.

### **Miscellaneous**

3. Could be floor standing.
4. Could be small and light enough to mount on patient bed with orientation independent functioning.
5. *Should be as robust as possible. For example, it may be dropped from bed height to floor.*
6. It must be intuitive to use for qualified medical personnel, but these may not be specialists in ventilator use.
  - a. Must not require more than 30 minutes training for a doctor with some experience of ventilator use.
  - b. Must include Instructions for Use.
  - c. Instructions for use should be built into the labelling of the ventilator, e.g. with ‘connect this to wall’ etc.
  - d. Must include clear labelling of all critical functions and controls using standard terms, pictograms and colours that will be readily recognised by UK healthcare staff.
8. Must not be excessively cumbersome so that it would impede hospital operations or prevent easy movement within hospital premises.

### **Testing**

4. Usability testing at both prototype and final production stages will be required. This should be done as a short Formative Usability Test to ISO62366 (this can be done in a day) in a realistic environment if possible. The user will be wearing complex protective clothing which includes: Eye goggles (in addition to spectacles if worn), Face shield, Plastic apron, Surgical gown, Two layers of gloves, usually nitrile nonhanded small, medium, large variants, Gloves are donned in layers and sticky taped onto sleeves of gown in between layers
5. The user must be able to instantly see the settings selected and be able to easily operate all controls while dressed in protective gear. They may be required to remain so clothed and operating the ventilator for a number of hours without breaks.

### **Unknown issues**

4. If monitoring can be done by another machine it could be left out of the ventilator, but essential parameters must be available to the clinician.