THEMATIC MEETING ON VENTILATORS: LESSONS LEARNT AND PREPAREDNESS

Meeting report

Monday 29 June 2020

On Monday 29 June, the Clearing House for medical equipment (COVID-19) held a meeting with Member States' and associated countries' contact points on mechanical ventilators (lessons learnt and preparedness).

1. LESSONS LEARNT ON VENTILATORS DURING THE COVID-19 CRISIS

The first presentation focused on the **lessons learned from the CCH perspective**. The COVID-19 pandemic outbreak has revealed that mechanical ventilators are crucial in the clinical management of COVID-19 patients and that they can be in shortage.

The CCH's main messages were as follows:

- ✓ Ventilators have always been used in Intensive Care Units (ICU) context. With the Covid19 crisis, it was shown even more how essential they are.
- ✓ During the crisis, shortages were mainly due to exponential short term demand, a volatile market situation and availability issues concerning components and accessories.
- ✓ Even with industry's increase of production, this was not sufficient to meet the very high demand, and therefore recourse was made to derogation procedures.

The European Society of Intensive Care Medicines presented the **lessons learnt from the use of ventilators in clinical/healthcare (ICU settings)** based on the clinicians' experience on the front line.

Their main messages were as follows:

- ✓ One important measure was to separate COVID-19 patients from flu patients, to protect other patients and healthcare workers.
- ✓ Ventilators save lives. They are used to buy time, because there is still no treatment for COVID-19 patients. However, if not properly used, they can damage patients' lungs.

Therefore the ventilators used must be "adequate" and must be used by specialised health professionals who are competent to do so.

- ✓ Beyond ventilators themselves, the availability of other ICU devices, such as infusion pumps and patient monitors is also essential in Intensive Care Units.
- ✓ Qualified and specialised ICU staff to properly use ventilators and other ICU devices is crucial. However, there is currently no harmonised European training, which makes mobility within the EU difficult. The need for Intensive Care Medicine (ICM) will grow over the next years. Regarding a future pandemic, an appropriate strategy is needed when it comes to the necessary ICU staff and it should include specialist intensive nurses.
- ✓ The experience of 'Sleeping ICUs' could be extended. These are fully operational healthcare settings with complex invasive ventilators and all the other needed ICU devices to be ready in times of crisis.

The following presentation focused on a Member State's experience **facing increased needs of ventilators:**

The presenters' messages were as follows:

- ✓ The country saw an enhancement of the manufacturing capacity, particularly increasing the production of already certified ventilators, as they understood that there was a real need to have a national or European production.
- ✓ National derogations on ventilators were one of the chosen measures but mainly applied to models of ventilators that were previously certified.
- ✓ They ran clinical investigations on ventilators prototypes. However, these were used only if there was no alternative, only for COVID-19 patients.
- ✓ To identify the needs, data was published by the different regions. Invasive ventilators were specifically requested.
- ✓ There was a lack of devices and suppliers of CE-marked ventilators.
- ✓ The Ministry of Health was able to provide the regional governments medical devices, which can be distributed to local healthcare centers.

2. PREPAREDNESS

The second block of the meeting focused on the preparedness approach for a possible second wave of the virus. The Commission and the EU have striven to assist Member States/countries in the provision of mechanical ventilators during the crisis through various instruments. The Joint Procurement Agreement and RescEU are two tools at EU level that can be used to be better prepared for future pandemics.

DG SANTE presented **the Joint Procurement Agreement (JPA)**, specifically for ventilators.

The main messages were as follows:

- ✓ The JPA tool is designed for preparedness purposes, and is not suitable to address immediate crisis responses. However, due to the pandemic outbreak, this instrument was used during the crisis.
- ✓ Member States use the framework contracts negotiated for them by the European Commission; each Member State has equal access to the market and companies are interested in answering calls.
- ✓ It should be noted that JPA is a very specific legal framework, and does not concern only the EU; Norway, Iceland, UK, Liechtenstein are also involved.
- ✓ The European Commission made all possible efforts to act quickly, and draft contracts were sent to the companies within four working days.
- ✓ Through this procedure, offers for 100.000 CE-marked ventilators were identified. While delivery periods were originally much longer, delivery time has now come down to weeks, due to a stabilising market.

DG ECHO subsequently delivered a presentation on **RescEU (physical and virtual stockpiling)**.

The main messages were as follows:

- ✓ The RescEU instrument is part of the Civil Protection Mechanism, which aims to strengthen civil protection to have better preparedness for civil disaster.
- ✓ The European Commission's role is to coordinate the response and help Member States on financial matters. It was already activated in the past for fires and medical emergencies.

- ✓ If national capacities are overwhelmed, it is possible to ask other Member States for help, and when many MS are in the same situation, RescEU can be activated.
- ✓ RescEU should be intended as a safety net, and does not replace stockpiling at Member State level.

CONCLUSIONS

The objectives of the meeting were threefold: 1) Ensure a common understanding of the challenges on the use of ventilators for COVID-19 patients in the EU (lessons learnt on the use of ventilators/on the use of different types of ventilators/when/by whom – and how these lessons can be used to better prepare in case of a second wave; 2) Come to a joint understanding of the current situation on demand and supply of mechanical ventilators, of their components/accessories in the EU and of the remaining needs; and 3) Identify the most suitable options and instruments at EU level both in times of crisis preparedness and when facing crisis.

During the meeting, some important messages were shared with participants, and there were also some answers to these questions:

- yes, ventilators save lives. Yet, if the right material is not available or if it is not properly used by trained professionals, ventilators can damage patients: intensive Care Unit (ICU) professionals identify the availability of qualified staff (intensivist nurses and doctors) as a key concern;
- the medical devices industry has ramped up production and there is availability: Member States can now purchase invasive ventilators through the Joint Procurement but few are doing so. Ventilators are not in shortage anymore, but there is still pressure on accessories (tubes, etc.);
- in view of a possible next wave, attention was drawn to the fact that half of seasonal flu patients in ICUs also need invasive ventilation. This could come on top of patients from a second COVID-19 wave.
- Lastly, the good practice of 'sleeping' ICU units ("reserve units") could be extended.

From the meeting itself and from the subsequent exchanges there seems to be a continuous interest in exchanging information, learning from each other and preparing for the future in general and on the issue of ventilators. Ventilators are crucial devices to treat COVID-19 patients and in the preparedness phase a careful analyses of their capacity is of crucial importance.