LESSONS LEARNED ON THE MANAGEMENT OF VENTILATORS. A VIEW FROM SPAIN.

Clearing House for Medical Equipment (COVID-19)
Meeting on ventilators. 29 June 2020

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THE HEALTH SYSTEM IN SPAIN

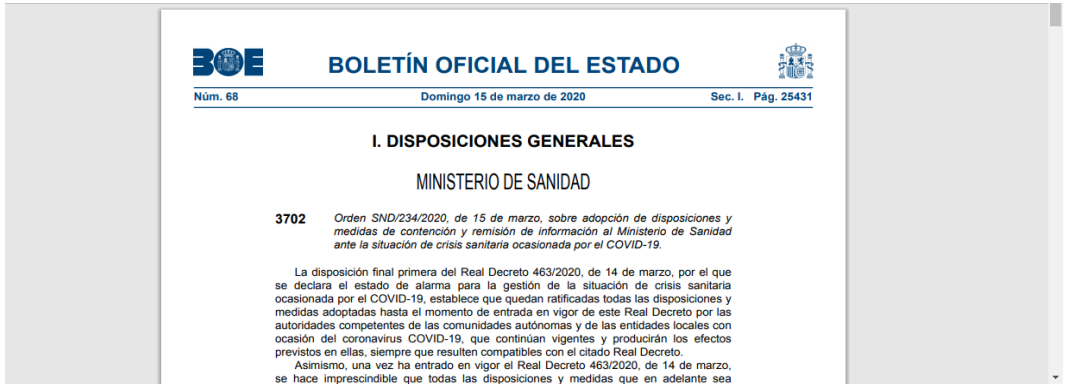
The Health System in Spain is coordinated by the Ministry of Health though fully managed by the **17** existing Health **Regional Governments**.

Particularities of some specific areas are to be considered, such as 3 peripheral areas: Balearic islands, and Melilla and Ceuta (two territories located in the African continent) and also one ultra-peripheral region: Canary Islands.

GOBIERNO DE ESPAÑA MINISTERIO DE SANIDAD

IDENTIFICATION OF NEEDS

In order to gather the necessary information from the Health Regional Governments, a Ministerial Mandate was published on March 15th. Among the data requested, a mandatory declaration of number of invasive mechanical ventilators pooled by Regions and also sorted by Health Centre for both private and public institutions dealing with covid19 patients was requested. Data should be submitted by March 20th and modifications should also be communicated.



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I. DISPOSICIONES GENERALES

MINISTERIO DE SANIDAD

3702 *Orden SND/234/2020, de 15 de marzo, sobre adopción de disposiciones y medidas de contención y remisión de información al Ministerio de Sanidad ante la situación de crisis sanitaria ocasionada por el COVID-19.*

La disposición final primera del Real Decreto 463/2020, de 14 de marzo, por el que se declara el estado de alarma para la gestión de la situación de crisis sanitaria ocasionada por el COVID-19, establece que quedan ratificadas todas las disposiciones y medidas adoptadas hasta el momento de entrada en vigor de este Real Decreto por las autoridades competentes de las comunidades autónomas y de las entidades locales con ocasión del coronavirus COVID-19, que continúan vigentes y producirán los efectos previstos en ellas, siempre que resulten compatibles con el citado Real Decreto.

Asimismo, una vez ha entrado en vigor el Real Decreto 463/2020, de 14 de marzo, se hace imprescindible que todas las disposiciones y medidas que en adelante sea

Permanent contact with the Health Regional Government representatives was key to establish the needs.

INITIAL ACTIONS TAKEN AT OUTBREAK

- Identify the available stock at national distributors warehouses.
- Check the availability of manufacturers and local distributors to supply ventilators in a short time.
- Establish contact with manufacturers and suppliers who could provide CE-marked ventilators complying with WHO specifications to be provided immediately or in a short period. Offers received complying with these criteria were sent to a group of experts from the Anaesthesiology and Internal Medicine Societies to check clinical appropriateness for covid patients.
- Contacts with national manufacturers to explore the possibility to increase production of ventilators. An increase of production of emergency and transport ventilators with advanced features from a national manufacturer was key for a quick supply when devices bought abroad could not be obtained immediately. A relevant number of these ventilators is currently being stored for strategic stockpiling.

DISTRIBUTION OF VENTILATORS

Ventilators purchased or received as donations were distributed by the MoH to the Regional Governments according to the needs reported. Then the Health Regional Governments assigned the ventilators to the health centres in their territories according to their needs.

Feedback from the Regional Governments regarding the need for ventilators was received and when there was no further need for supply, those devices where reassigned to other regions in need for them.

In order to monitor the needs and distribute the ventilators received, the information regarding ICU admissions was revised and updated daily, according to the data on covid published daily by the Ministry of Health (MoH) and the official population data, both pooled and by region,.

Assignment criteria applied depending on the phase of pandemia and type and number of ventilators to be distributed:

- At least 1 device to be delivered to each region, when feasible
- Accumulated ICU admissions/10,000 inhabitants
- % accumulated ICU admissions from total ICU admissions
- ICU admissions in the last 7 days/100,000 inhabitants.
- Geographical proximity and business relation to regions with a high Total ICU admissions/10,000 inhabitants rate.
- Consideration to the particularity of peripheral and ultra-peripheral regions.

DIFFICULTIES ENCOUNTERED

- Usual manufacturers and local distributors could not supply adequate covid19 ventilators in a short time.
- We needed to get ventilators with no further delay and the only ones available were mainly manufactured in China.
  - Though we chose CE-marked ventilators and were offered short delivery periods, even immediate deliveries, supply times agreed were not met or only partial deliveries reached.
  - Post-marketing and maintenance service was not available in our country or in any European country for most of the devices we could get from Chinese manufacturers.
  - When manufacturers were questioned for spare components, fungible and periods of warranty, we discovered that their supply could not be guaranteed and periods of warranty were unclear.
- Devices acquired in USA could not be delivered due to US Government Customs restrictions imposed.

LESSONS LEARNED

- Need to review the availability and grade of update and appropriateness of existing ICUs ventilators and need for replacement.
- Promote and increase national production of mechanical ventilators, if available.
- When devices must be purchased outside the EU, apart from the CE mark certificate, agreements should consider some important aspects such as:
  - Closed delivery dates subject to agreed penalties if unmet.
  - Clear warranty periods as established in their Operator/User manuals approved by their correspondent Notified Bodies.
  - Warranty of supply for components and fungibles and identification of brand-matching components.
  - Training on the use and operation of these devices needs to be sought well in advance.
  - Availability of post-marketing and maintenance service.

Thank you for your attention.

Keep safe!!