

## **Masks and Covid-19**

### *Opinion of the French National Academy of Medicine*

*March 22, 2020*

In the context of the current Covid-19 pandemic, many health care professionals exposed to infected patients or contact persons report serious difficulties in accessing masks.

These reports are surprising because the production of masks is not subject to the high constraints that apply to, for example, vaccines or antiviral drugs.

This Opinion of the National Academy of Medicine was prepared by its Covid-19 scientific monitoring unit set up on 16 March 2020.

After a historical reminder of the stocks of masks in France over the last two decades, it makes recommendations on the current management of the mask shortage and to prevent it from recurring in the future.

#### **Constitution and use of the State's stock of masks in France (2005-2011)**

Since 2001, as part of the preparedness plans for large-scale threats (smallpox, biotox, radiation...), the French state has built up strategic stocks in order to protect the health of the population (antibiotics, vaccines, antivirals, needles, iodine tablets, antidotes...).

In 2005, during the avian influenza epizootic and the pandemic threat linked to the H5N1 virus, even though there was no vaccine or antiviral drug available, the French state built up stocks of masks.

Even if their effectiveness is limited, these masks would, in the event of an epidemic, meet the expectations of health professionals, numerous other professionals and the general public, as there would be no other means of prevention or treatment available.<sup>1</sup>

Two types of masks have been acquired: surgical (or anti-projection) masks, which are medical devices, and CE label respirators FFP2 masks, which are not medical devices but which, because of their aerosol filtration capacity, have a higher effectiveness than surgical masks in protecting exposed caregivers<sup>2</sup>.

---

<sup>1</sup> This opinion has been drafted by the special monitoring team on Covid 19 epidemic of Académie Nationale de Médecine: Patrick Berche, Jeanne Brugère-Picoux, Yves Buisson (President), Anne-Claude Crémieux, Gérard Dubois, Didier Houssin (Secretary), Dominique Kérouedan and Christine Rouzioux.

<sup>2</sup> Santé Publique France, Expert assessment on stockpile strategy to cope with the possibility of pandemic flu, 2019, p. 21

Surgical masks have a long shelf life before expiry. In contrast, the manufacturers have set the shelf life of FFP2 masks at five years, due to the gradual weakening of the electrostatic charge that contributes to the filtration effect of this type of mask.

In September 2009, when the "flu pandemic" plan was updated, the doctrine on the use of these masks had been updated by the Committee for the Fight against Influenza placed under the General Directorate of Health (DGS): surgical masks are intended for patients; FFP2 masks are intended for the most exposed professionals, in particular healthcare professionals. Between 2005 and 2009, a stock of surgical masks and FFP2 masks was gradually built up by the State, on shared financing (50%/50%) between the State and the Disease Assurance ("*Assurance Maladie*"). In 2005, in order to allow the creation of these stocks of FFP2 masks, the State had encouraged, through the launch of public contracts, the establishment of a French industrial fabric for the production of masks, with a few companies (Bacou-Dalloz, Macopharma, Paul Boyer, Thuasne...).

Until 2007, the constitution and management of these stocks were ensured by the Ministry of Health (DGS). From 2007 onwards, these stocks were managed by the Establishment for preparation for health emergencies (*Etablissement pour la préparation aux urgences sanitaires EPRUS*), a newly created institution under the supervision of the Ministry of Health.

In April 2009, when the influenza pandemic caused by the H1N1 virus broke out, the stocks held in France<sup>3</sup> were 1 billion surgical masks (100% of the estimated need) and 700 million FFP2 masks (80% of the estimated need). These needs were estimated by taking into account the size of the target populations, the probable duration of the pandemic and the conditions of use of the masks (in particular, the average time a mask is worn).

The value of surgical masks stock was €40 million in January 2009 and €32 million in May 2010. The value of the stock of FFP2 masks was €182 million in January 2009 and €219 million in May 2010.<sup>4</sup>

Indeed, during the H1N1 pandemic, surgical masks were released from these stocks for use, whereas due to the low level of concern among healthcare professionals and the population, there was little need to mobilise the stock of FFP2 masks.

Despite this finding on the use of masks during the H1N1 pandemic, the Senate Inquiry Report concluded that, in the face of a serious and unknown virus, reluctance to wear masks would fall and that "absolute criticism of this effective means of protection should be avoided"<sup>5</sup>.

### **Doctrine of use and stocking strategy of masks between 2011 and 2015**

Despite the estimated number of deaths linked to the pandemic due to the H1N1 virus in 2009 (approximately 200,000 worldwide)<sup>6</sup>, the judgements made on the management of the flu

---

<sup>3</sup> Report to the French Assemblée Nationale (N°2698) (Jean-Christophe Lagarde, Jean-Pierre Door) on The influenza vaccination campaign. 2009: an experience for the future. Audion de Thierry Coudert, Director of l'Etablissement pour la préparation aux urgences sanitaires (EPRUS), p. 195

<sup>4</sup> Report of the Commission of Inquiry into the role of pharmaceuticals in the Government's handling of influenza A (H1N1) (François Autain, Alain Milon), p.23

<sup>5</sup> Ibid. p. 136

<sup>6</sup> F.S. Dawood et al, Estimated global mortality associated with the first 12 months of 2009 pandemic influenza A H1N1 virus circulation: a modelling study, *The Lancet, Infectious Diseases*, 2012, 12, 9, p. 687-695

pandemic due to the H1N1 virus were rather that WHO and many States, including France, had done too much, particularly with regard to the acquisition of vaccines.

These judgements may have influenced the attitude of scientific bodies and public authorities with regards continuing the preparation for the risk of a pandemic linked to an emerging virus with respiratory tropism.

Following the health crisis caused by the H1N1 virus, several developments were observed, with changes in the government's attitude towards its stocks, particularly of masks.

A slight change first occurred in the doctrine on the use of masks, following the opinion of the High Council of Public Health (HCSP) dated 1 July 2011<sup>7</sup>. Referring to the preventive effectiveness of both surgical masks and FFP2 type masks, "in the context of a high risk such as SARS",<sup>8</sup> this opinion recommended that :

- The surgical mask is worn by sick people, particularly in the healthcare setting;
- The FFP2 mask is made available to healthcare professionals being in a high-risk care situation on a patient's respiratory system (intubation; tracheal suctioning; nasopharyngeal sampling; physiotherapy; etc...);
- The FFP2 mask is worn by the patient's family or friends;
- The FFP2 mask is made available to exposed healthcare professionals (in the case of a highly pathogenic respiratory agent, for healthcare workers at risk of airborne transmission of the agent during an act involving direct contact with a suspect or confirmed case or on entering a room where there is a suspect or confirmed case, regardless of the mode or place of practice)<sup>9,9</sup>;
- The surgical mask, and no longer the FFP2 mask, is recommended for professionals (other than healthcare professionals) in counter activity.<sup>10</sup>

This advice indicated that the stock should therefore be composed of both types of masks, provided information for the calculation of the sizing, including the permanent stock, and suggested ways to avoid a supply disruption<sup>11</sup>.

In the aftermath of the H1N1 flu pandemic and in order to draw lessons from it, the revision of the "pandemic flu" strategic plan<sup>12</sup> also led to the development of a new strategy for health-related products stockpiling.

Based in particular on the HCSP's opinion of 1 July 2011, this new strategy also concerned masks.

In the framework of this strategy, led by the General Secretariat for Defence and National Security, in conjunction with the ministries concerned, several changes have been made **from 2013 onwards**. These were analysed in a report by the Senate Finance Committee in 2015<sup>13</sup>.

---

<sup>7</sup> Haut Conseil de la santé publique, Opinion on the strategy to be adopted concerning the stockpile Status of breathing masks, July 1st, 2011

<sup>8</sup> Ibid. p. 2

<sup>9</sup> Ibid. p. 4

<sup>10</sup> Ibid. p.4

<sup>11</sup> Ibid. p. 5

<sup>12</sup> Secrétariat général de la défense et de la sécurité nationale, Plan national de prévention et de lutte « Pandémie grippale », N°850, Octobre 2011

One important change, with regard to masks, was that **"the national stock of masks managed by EPRUS would be limited to surgical protective masks, while the stockpiling of masks for the protection of health personnel (in particular FFP2 masks for certain high-risk procedures) was now the responsibility of employers"**.<sup>14</sup>

These shifts resulted in

- The non-renewal of certain stocks that had reached their expiry date, linked in particular to the transfer of responsibility for building up certain stocks from the State to various employers in the health sector, in particular health establishments or medico-social establishments, in the case of FFP2 protective masks intended for their staff;<sup>15</sup>
- The smoothing of target stock acquisitions<sup>16</sup>;
- A reorganization of the State's storage logistics between the central platform in Vitry-le-François and the zonal platforms;
- A distinction between "strategic" stocks managed by the State at the national level and "tactical" resources located in health facilities with SAMU/SMUR, with a view to "ensuring an early response while awaiting the mobilization, if necessary, of strategic stocks".
- The acquisition of tactical resources was now the responsibility of the health establishments, financed by MIGAC credits;<sup>17</sup>
- EPRUS support for the management of the resources of the Regional Health Agencies and health establishments, particularly with a view to maintaining and renewing their "tactical" stocks.

It can be assumed that an instruction (interministerial circular?) indicated to private health professionals, heads of health establishments and managers of establishments in the medico-social sector that it was their responsibility to have stocks of FFP2 masks for the protection of professionals likely to be exposed.

This evolution of the doctrine of use of masks and their stocking strategy has resulted in a strong decrease in stocks since 2010.<sup>18</sup>

It should be noted that "the composition and distribution of these stocks constituting sensitive data", the special rapporteur of the Senate Finance Committee limited himself, in 2015, to an analysis of the evolution of the general value of the State's stocks. The value of these stocks rose from 982 million euros at the end of 2010 to 416

---

<sup>13</sup> Rapport d'information n°625 du Sénat (Francis Delattre) sur l'Établissement de préparation et de réponse aux urgences (EPRUS), 15 juillet 2015

<sup>14</sup> *Ibid.* p. 33

<sup>15</sup> *Ibid.* p.35

<sup>16</sup> Circulaire interministérielle du 21 août 2013 relative au dispositif de stockage et de distribution des produits de santé des stocks stratégiques de l'Etat pour répondre à une situation sanitaire exceptionnelle

<sup>17</sup> Rapport d'information n°625 du Sénat (Francis Delattre) sur l'Établissement de préparation et de réponse aux urgences (EPRUS), 15 juillet 2015, p. 33

<sup>18</sup> *Ibid.* p. 34

million euros in 2015. The projected expenditures for the government health stock was 33 million euros per year between 2016 and 2018.<sup>19</sup>

In the same Senate report, regarding the evolution of the strategic stocks of the State concerning Health, a Senator recalled that: "in periods when no pandemic is raging, such a tool always seems too expensive but, in times of crisis, it is judged that it is not powerful enough"<sup>20</sup>.

### **Stocks of masks (2016-2020) and their management during the covid-19 epidemic**

An important change in the governance of State stocks occurred on 1 May 2016, when the InVS, the INPES and the EPRUS were brought together in a single institution: Santé Publique France (SPF).

of inventories, particularly of masks. In a chapter on inventories in preparation for pandemic influenza in 2018, mention is made of barrier measures and the "constitution of a stock of surgical masks"<sup>21</sup>. No information is provided on the level of inventories, nor on the funding committed. FFP2 masks are not mentioned. No mention is made of any possible support provided by SPF for the stockpiling of FFP2 masks by health facilities, medico-social institutions and private health professionals.

**As the acquisition of FFP2 masks is now the responsibility of these employers (health facilities, medico-social institutions, liberal health professionals), the question arises as to whether, in all professional places in the health sector, the acquisitions necessary for pandemic preparedness have been made satisfactorily and renewed?**

In this context, according to the testimonies mentioned in the introduction, the outbreak of the Covid-19 epidemic in February 2020 revealed a shortage of masks, in particular FFP2. The health authorities, faced with this situation and with a view to managing the shortage as well as possible, asked for advice in March 2020:

- The HCSP's opinion, issued on 14 March 2020, regarding the policy of nationalizing the wearing of masks, specifies the list of invasive acts and maneuvers justifying the wearing of FFP2 mask (not yet public)<sup>22</sup>;
- The opinion of the French Society of Hospital Hygiene, dated 4 March 2020, specifies the indications for wearing surgical and FFP2 masks<sup>23</sup>;
- That of the Société Française d'Hygiène Hospitalière of 14 March 2020, regarding the conditions for extending the wearing or reuse of surgical and FFP2 masks for healthcare professionals, takes into account "the need to take into account the availability of masks"<sup>24</sup>. It concludes that reuse should be avoided, that the duration of

---

<sup>19</sup> *Ibid.* p. 34

<sup>20</sup> *Ibid.* p. 68

<sup>21</sup> Santé Publique France, Annual report 2018, p. 35

<sup>22</sup> Haut conseil de la santé publique, Avis relatif à la politique de rationalisation du port du masque, 14 mars 2020

<sup>23</sup> Société Française d'Hygiène Hospitalière, Avis précisant les indications des ports des masques chirurgicaux anti-projection et des masques de protection filtrant de type FFP, 4 mars 2020

<sup>24</sup> Société Française d'Hygiène Hospitalière, Avis quant aux conditions de prolongation du port ou de réutilisation des masques chirurgicaux et des masques FFP2 pour les professionnels de santé, 14 mars 2020, p. 2

use can be extended up to 4 hours for a surgical mask and up to 8 hours for an FFP2 mask, and that the use of other types of masks is not recommended.

## **Recommendations of the National Academy of Medicine**

### **Management of mask shortage**

In the current situation of a shortage of masks for healthcare professionals, the allocation of masks available in France must give priority to the most exposed professionals, i.e. healthcare professionals.

Among healthcare professionals, the allocation of available FFP2 masks must go:

- **as a priority, to healthcare professionals carrying out the procedures most at risk of virus transmission** (intubation/extubation, mechanical ventilation with an "open" expiratory circuit or non-invasive mechanical ventilation, tracheal suctioning, physiotherapy, aerosol therapy, bronchial fibroscopy, nasal or nasopharyngeal sampling, autopsy). These procedures must be performed by a health professional equipped with an FFP2 type mask and not a surgical anti-projection mask;

- **then, to professionals in health care institutions in charge of care or in close contact with people who are ill** because of Covid-19 or people suspected of being ill; - and to health professionals (doctors, nurses, assistant nurses, ambulance drivers, etc.) in close contact with people suspected of being ill with Covid-19, in the private sector care, in medical-social institutions the or at home.

For the most exposed healthcare professionals, only FFP2 type masks, offering a certain filtration capacity and a certain degree of tightness, can reduce the risk of contamination. Surgical splash-proof masks do not provide this protection, whether they are made of fabric or paper, even if they are washed or disinfected.

Health care and social care facilities, faced with the shortage of FFP2 masks, should not produce local guidelines which, by deviating from national guidelines, could lead to a false sense of security, particularly for those carers exposed during the most high-risk procedures.

### **Prevention of mask shortages:**

In order to avoid such shortages in the future, the strategy for storing masks, particularly FFP2 type masks, should be reviewed so that the State can build up a strategic stock of this type of mask, which might be mobilized urgently from the national platform or zonal platforms, and which might be sized and renewed in order to cover needs during the first weeks of an epidemic. This sizing must take into account all the target populations identified in the framework of the doctrine on the use of these masks.

Without relieving health establishments, medico-social establishments and professionals in the liberal sector of their responsibility towards their staff, this storage of masks by the State will make it possible to better respond to a large-scale epidemic, such as the pandemic at Covid-19. This new storage strategy will make it possible to better cope in circumstances in which the seriousness of the epidemic would make it necessary to extend the use of FFP2 masks to professionals in continuity of activity in counter, reception or security positions, or to intensify barrier measures by encouraging wider use of surgical anti-projection masks in the general population.

This new storage strategy will help maintain production capacity for these masks on national territory. The storage of surgical anti-projection masks and FFP2 type masks, as part of the preparation for a pandemic with an emerging virus with respiratory tropism, must finally be closely and regularly monitored by Parliament in order to ensure transparent monitoring of the evolution of mask stocks by nature and quantity.