Large scale reuse of FFP2 and N95[1] masks

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Synthesis: this document proposes the *reuse* of FFP2 masks on a large scale thanks to the pre-existing sterilization and decontamination infrastructure in France. This initiative aims to avoid the amplification of the Covid-19 health crisis due to a shortage of masks for medical personnel, which would lead to additional contamination from the medical personnel themselves.

Within a week, this initiative would allow the reuse of **1 million masks per day** for a cost of less than 4€ per mask from the first masks treated. The cost would probably be **less than 1€ per mask** if the operation is carried out on a large scale.

A process for the reuse of masks must meet two health requirements: (a) no cross-contamination of successive wearers and (b) the mask retains its filtering properties despite successive reuse.

During the week of March 23, 2020, **two separate processes** for the re-use of masks were validated, each by **two independent organizations**. These two processes each allow a very large number of masks to be handled within a very short period of time.

The CDC (see note 19) has already identified a dozen protocols. These protocols vary according to several criteria: cost, risk, ease of implementation, number of possible reuses, etc. The feasibility and risk control of a protocol for reusing FFP2 masks on a very large scale is therefore a certainty to date (see note 24).

I call for the immediate implementation of a collection system for used FFP2 masks. If FFP2 masks are not properly collected after use, there will be no possibility for reuse after all.

I call on ANSM and ANSES to authorise, immediately and provisionally[2], the two processes already identified for the reuse of masks, and to gradually adjust its position as these processes are refined by the actors executing such initiatives themselves.

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[1] N95 is the USA's norm. FFP2 is Europe's norm.

[2] The reuse of FFP2 masks only makes sense in situations of shortage. As soon as France again has a substantial stock of new FFP2 masks, of the order of one billion masks, the reuse of these masks should stop.

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The Problem

China has managed to increase its mask production to 200 million units per day (see note 1) however, the production of medical grade masks - N95 or FFP2 - remains limited to 600,000 units per day, a figure that is largely insufficient for the Chinese population. The weakest link in the supply chain seems to be, as mentioned above, the production of non-woven textiles, as a difficult and highly specialised production process is required. Actors specialised in the production of machines that produce the relevant non-woven textiles, such as the German company Reicofil (see note 2), do not seem to be able to significantly increase the number of machines producing these textiles in less than 6 months.

Moreover, the recall on March 28th 2020 of **600,000 defective FFP2 masks** delivered by China to the Netherlands (cf. note 12) confirms that the rapid increase in production is very difficult; the problem seems to be precisely linked to the very high demands of the non-woven textile manufacturing process.

Unless alternative solutions are put in place very quickly, medical services will be short of masks, which will increase mortality in two ways: lack of access to care and accidental over-contamination via the medical staff themselves. In normal situations, production capacity is sufficient to meet the current consumption of this equipment, which is therefore normally single-use.

In addition, critical industrial players, such as drug manufacturing or the food industry, are also in urgent need of FFP2 masks to maintain their production lines.

In regards to the reuse of masks, unfortunately, the usual methods (see note 4) for sterilising medical equipment are inappropriate for masks, either because they are insufficient to inactivate pathogens or because they reduce the filtering capacity of the mask (chemicals such as alcohol, autoclave, beta and gamma ionising radiation at 1kGy).

However, solutions for the reuse of FFP2 masks were found in March 2020, and have already been approved by the authorities in various countries. In particular, the FDA indicates (see note 19) that it is not necessary to prove the effectiveness of a sterilization and decontamination protocol on SARS-CoV-2 but that a class of pathogens more resistant than SARS-CoV-2 can be used for these validations.

FFP2 mask collection

The first urgency is to set up the collection of FFP2 masks. The following process is proposed:

1. Wearers of FFP2 masks **must not wear make-up**. Initial tests (see note 15) show that up to 30% of the masks are non-reusable because of make-up if staff are not informed.
2. Masks used during procedures that generate aerosol elements should be discarded.
3. Masks contaminated with blood or body fluids should be discarded.

At the end of shift, staff place the FFP2 mask eligible for decontamination in a IMW (Infection Medical Waste) cardbox box - possibly a box- provided for this purpose.

It is important to **avoid airtight containers** as they complicate the sterilization or decontamination operations that follow.

1. The cardbox box must be reserved exclusively for FFP2 masks.
2. The cardbox box must be marked with a highly visible letter **P** indicating FF**P**2.

3. The cardbox box must be marked with a highly visible **H** (**h**ospital) to indicate a hospital or clinical facility, or alternatively with a highly visible **U** (factory[3]) to indicate a facility that does not treat patients.

Why not include surgical masks? The reuse of surgical masks seems possible, but it is also possible that the sterilization processes are different, as these masks are not made from the same materials as the FFP2 masks. If surgical masks are collected, marking with the letter **G** (sur**g**ery) is recommended.

Why this choice of letter? The choice of marking should be unambiguous, even if the letters are misoriented (e.g. avoid confusion C vs U).

Will it also be necessary to collect masks that have already been reused? Yes, it will. Initial tests show that masks may be decontaminated up to 30 times. It is therefore essential to collect those as well. However, the masks will be marked during reconditioning under sterile conditions to ensure that masks that have reached their life limit are discarded. This operation is entrusted to the reconditioning line.

Ethylene oxide sterilization of FFP2 masks

This process has already been validated by two separate organizations, in the USA and in France (see notes 13, 14 and 26).

Ethylene oxide sterilization has been known and used since the 1940s. The literature is abundant, and the process is already used for the sterilization of medical devices that do not tolerate ionizing radiation or temperature rise.

The envisaged process (see notes 13 and 14) already demonstrates that FFP2 masks can be reused **at least once** while preserving all the barrier properties of the masks. Tests are currently underway to determine the number of acceptable sterilization cycles for ethylene oxide.

Is the virus eradicated? Yes, the virus is eradicated.

Are other sources of contagion (e.g. microbes) treated? Yes, other sources of contagion (e.g. microbes) are treated.

Ethylene oxide is carcinogenic, is it dangerous for mask wearers? No, it is not. The sterilization facilities considered for ethylene oxide sterilization have vacuum chambers to ensure complete degassing of the masks. These facilities also have sensors to validate an extremely strict and already standardized level of residue removal.

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[3] *"**u**sine"* means "factory" in French.

Is there a risk for medical personnel? No, there is not. However, a fit test must always be carried out. If the mask does not seal properly, the mask must be discarded.

Hydrogen peroxide vapor decontamination of FFP2 masks

This process has already been validated by two separate organizations in the USA (see notes 1 and 13). This process has been approved by the FDA for immediate use (see note 17). This protocol has also been deployed on a large scale (see note 25).

Decontamination using hydrogen peroxide vapor is a process that has been known and mastered for years (see notes 5 and 6). This process is already used in the most critical medical laboratories, such as the P4 Inserm Jean Mérieux laboratory in Lyon (see note 7), which treats viruses and other pathogens considered to be the most dangerous in the world.

According to players specialising in the hydrogen peroxide steam decontamination sector, the decontamination capacities already available in France are fully capable of immediately decontaminating 1 million FFP2 masks in France per day.

The process developed by Duke University (see note 1) shows that decontamination is effective on a 6-log factor, i.e. **elimination of 999,999 per 1,000,000 pathogens**. It also shows that N95 masks (US equivalent of FFP2 in Europe) can undergo up to **30 decontamination cycles** without loss of filtering or mechanical properties.

Is the virus eradicated? Yes, SARS-CoV-2 is a relatively "fragile" pathogen. Hydrogen peroxide vapor decontamination is extremely effective against this type of pathogen.

Are other sources of contagion (e.g. microbes) treated? Yes, microorganisms, especially bacteria, are also eliminated. Hydrogen peroxide vapor has a very wide range of action.

What is the difference between decontamination and sterilization? Decontamination eliminates pathogens at a ratio of 999,999 per 1,000,000. Sterilization eliminates all pathogens. Decontamination offers a very high level of sanitary safety but is not absolutely perfect.

Is hydrogen peroxide dangerous for mask wearers? No, it is not. The process used ensures complete degassing without residue. The Duke study (see note 1) even indicates that the masks have no particular smell after decontamination.

Is there a risk for medical personnel? Doctors equipped with perfectly sterile protective equipment already die (see note 11) from accidental contamination. Zero risk already does not exist under "normal" conditions. If a choice has to be made between very good (999,999/1,000,000) but imperfect decontamination, or no mask (or the reuse of contaminated

masks, which is already practised today), the risk calculation is obviously in favour of decontamination of the latter.

Proposed solution

To realize an initiative of this type one would have to implement, in descending order of priority:

A. a dedicated collection process for all medical masks so that they are no longer thrown away - and thus the possibility of reuse is lost.
B. a process for sterilization and decontamination of masks.
C. a process for reconditioning (packaging) the masks after decontamination.

All these steps can be implemented within a few days in an emergency situation and will require appropriate regulatory adjustments.

The probability of success of such an operation is very high today. The scientific results are from highly respected teams, and the proposed procedure leverages a decontamination process that is already widely used in France and around the world.

This document is not intended to cover the technical details of the two processes considered.

Costs and capacities

According to initial estimates, medical masks can be reprocessed at a cost of less than €4 per mask, and the immediate capacity of the French actors indicates that at least 1 million masks per day can be immediately envisaged.

The costs of putting a mask back into service can be broken down as follows:

1. Collection, transport and consolidation. Estimation: less than 0.10€ / mask.
2. The treatment
    a. EtO sterilization of masks. Estimation: less than 0.1€ / mask.
    b. H2O2 decontamination of the masks. Estimation: less than 3€ / mask (see note 21).
3. Sorting and reconditioning of masks. Estimation: less than 0.5€ / mask.

The main logistic constraint is the availability of appropriate cleanrooms with the necessary surface to practice decontamination (for H2O2) and consequent reconditioning of masks (for EtO and H2O2). Two French companies, ArianeGroup and FM Logistic (cf. note 9) have already given an agreement in principle for the implementation of such a system - an agreement naturally conditional to prior validation of the processes by the French authorities.

Other processes for reusing FFP2 masks

The RIVM in the Netherlands (see note 17) has also validated a plasma H2O2 process that allows the reuse of FFP2 masks. However, this process seems less favourable to a mass treatment than the two processes presented above and requires a lot of handling. The FDA has approved the same protocol up to two cycles (see note 18). However, tests performed by MGH (see note 20) suggest that the H202 plasma protocol will not be reliable beyond 1 cycle. The position of the MGH is therefore to keep the H2O2 plasma protocol as a solution of last resort, and limited to 1 cycle.

A protocol of heat treatment at 121C for 15min has also been validated in the Netherlands (see note 22 and 23). Filtration tests indicate that 5 cycles can be obtained.

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Annexes

Notable players

- Agence nationale de sécurité sanitaire de l’alimentation, de l’environnement et du travail (ANSES) - https://www.anses.fr/
- Agence Nationale de Sécurité du Médicament (ANSM) - https://ansm.sante.fr/
- Ionisos - https://www.ionisos.com/
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