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HOW TO EVALUATE THE EFFECTIVENESS AND PROTECTION FROM BIOLOGICAL AGENTS OF A RESPIRATOR?

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Presentation: CP 12

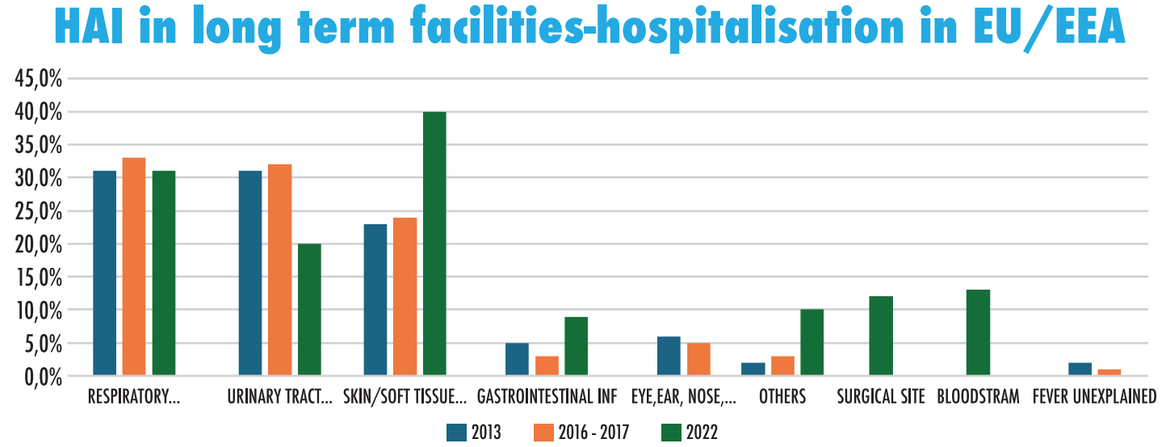
BACKGROUND

This study sums up evidence base on the benefits on the use a specific respirator ARES BIO BARRIER MASK abbreviated as “BBM”, certified in compliance with Regulation (UE) 425/2016 to protect against biological agents of group 2 and 3 (Directive 2000/54/EC of the European Parliament and of the Council on the protection of workers from risks related to exposure to biological agents at work) for health and safety protection.

European legislation is very protective towards workers' health and obliges the employer to make efforts in providing PPE for the specific risk as well as providing the best available technology.

There is strong evidence that respiratory pathogens are transmitted predominantly via aerosol.

The use of respirator also help to cull HAI (Healthcare Associated Infection). Pathogen deeps in the lug. Lower respiratory infections (LRIs) cause a substantial mortality, morbidity and economic burden.



(https://platform.who.int/mortality/themes/theme-details/topics/topic-details/MDB/respiratory-infections)
https://www.ecdc.europa.eu/en/publications-data/PPS-HAI-AMR-acute-care-europe-2022-2023
https://www.ecdc.europa.eu/en/all-topics-z/healthcare-associated-infections-long-term-care-facilities/surveillance-and-disease-3

Until now, there was no PPE tested and certified to protect respiratory tracts against biological agents so we developed both methodology to test with micro-organism and PPE named BBM (Bio Barrier Mask).

FFP2 and FFP3 (EN 149) respirators are certified to protect from aerosol of chemical nature and dusts, and tests are performed using sodium chloride (NaCl) and paraffin oil and NOT using micro-organisms

METHODS

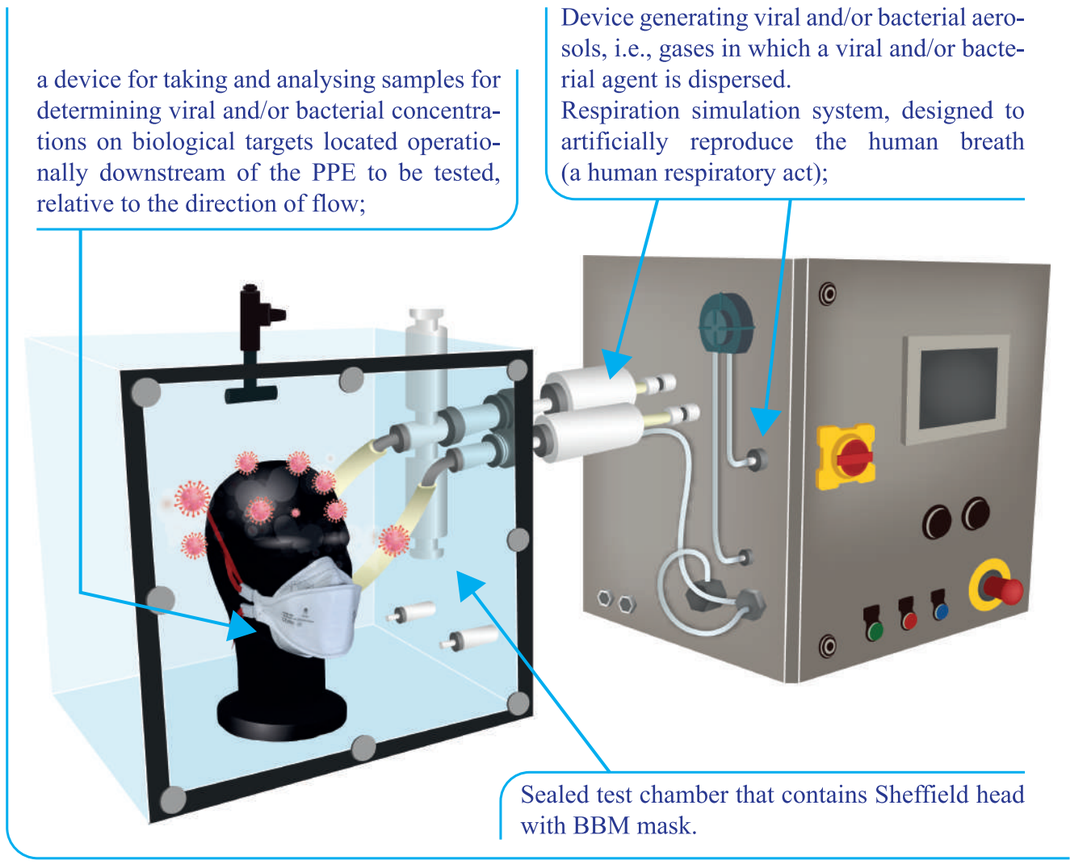
Develop of an equipment, system for testing filtering half mask (respirator) and filter to evaluate their protective efficacy against biological agents, for example pathogens such as bacteria, fungi, viruses, etc.

It is known to use PPE for respiratory tract in health environments in order to protect against biological agents which may be in aerosol form coming from breaths of other subjects present in a confined environment and/or possible concentration in the air of the biological agents.

Outside health facilities this personal protective equipment is also of growing and current use, in particular to prevent and/or contain the spread of biological agents of an epidemic or pandemic nature and that are highly contagious, for example when one is an epidemic or pandemic and/or in other activities wherein it is necessary to protect the respiratory tract of an operator from these agents.

This system or assemblies of test equipment are designed to reproduce, inside a controlled test environment, with high level concentration of a virus, the conditions and methods of use of PPE to be tested simulated human respirator and reproducing the correct wearing of the PPE itself.

A test system of the type described above typically comprises:



In use, the generator device generates aerosol containing the pathogen and feeds it inside the test chamber.

The aerosol containing virus (Bacteriophage MS2) (0,024 µm) is breathe in by the Sheffield head via the simulation system.

The sampling and analysis device samples, with a predetermined frequency, samples of aerosol from a position fluidically downstream of the PPE to convey them to one or more biological targets, which are successively analysed so as to assess the protection provided by the PPE via the degree of retention of the pathogenic agents on the same.

RESULTS and CONCLUSION

The purpose is to produce a system for testing PPE for the respiratory tract that is highly reliable and inexpensive, develop and manufacture a specific bidirectional barrier respirator (BBM) to protect against microorganism in order to provide protection for those exposed or potentially exposed to biological agents.

Viral concentration upstream (head or eye) / concentration downstream = % filtering efficiency.

Lower pathogen concentration inside the respirator, major protection provided by respirator.

The size profile of the microbial agent is important but is not the only one that determines passage or non-passage through the barrier device such as the respirator. Very important is the combination of different layer of fabrics and the fit.

If we evaluate the respirator's test using Bacteriophage MS2, it is clear that specific protection using micro-organism tested respirators provides protection for operator/worker/patient/family members and reduces transmissibility. The employer complies with regulations requiring the use of risk-specific devices and reduces costs to the administration because workers protecting themselves do not get sick and do not incur occupational disease claims.

DETAIL INFORMATION

FFP3

- EN149:2009+A1:2009 (Filtering half mask to protect against particles)
- Test performed with chemical agents (NaCl and paraffin oil)
- EN14683 (Medical Device)

Ares BBM

- Test performed with aerosol of microrganism for each production batch
- Protection form virus, bacteria, parasites, fungi
- Certification for the protection against biological agents
- Biohazard pictogram
- EN149:2009+A1:2009 (Filtering half mask to protect against particles)
- Test performed with chemical agents (NaCl and paraffin oil)
- EN14683 (Medical Device)

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Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC)