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Research article

APPROACHES TO ANALYZING EFFICIENCY OF RESPIRATORY PROTECTIVE EQUIPMENT AS A WAY TO REDUCE HEALTH RISKS DURING COVID-19 PANDEMIC

E.A. Shashina[1], T.S. Isiutina-Fedotkova[1], V.V. Makarova[1], O.A. Gruzdeva[1,2], O.V. Mitrokhin[1]

[1]I.M. Sechenov First Moscow State Medical University, Bldg. 2, 8 Trubetskaya Str., Moscow, 119991, Russian Federation
[2]Center for Hygiene and Epidemiology in Moscow, the Central Administrative District brunch, Bldg. 1, 17 Krasnogvardeiskii blvd., Moscow, 123317, Russian Federation

Use of respiratory protective equipment (RPE) has become the most significant way to prevent the coronavirus infection from its rapid spread.

Our research goal was to analyze efficiency of various RPE used by people during COVID-19 pandemic.

We made a review focusing on RPE manufactured and tested as per standards existing in different counties; we also analyzed the State Medical Equipment Register of the Federal Service for Surveillance in Public Healthcare as well as a market where respiratory protective equipment available to people was distributed.

RPE is quite variable as per such parameters as bacterial filtration efficiency, number of layers and quality of a material it is made of, being fit to a person's face (masks for children/adults), conditions for use (a time of use, whether a mask can be disinfected and used again, etc.). Data provided for customers when respiratory protective equipment is sold are rather scarce and controver sial (people do not understand what a mask name means and how efficiently it protects their respiratory organs). Respiratory protective equipment which is registered within the State Medical Equipment Register of the Federal Service for Surveillance in Public Healthcare accounts for only 24 % of the overall equipment sold to consumers. Taking into account variable and multiple properties of different masks, we developed a RPE classification basing on their efficiency when it comes down to protection from respiratory infections. FFP3/KN100/N99/N100 respirators are the most efficient ones. FFP2/KN95/N95/DS/DL2/KF94 respirators have average efficiency. FFP1 respirators and nonwoven medicals masks, II R, II, I type, and woven gauze masks have efficiency that is lower than average (RPE is mentioned in a descending order as per its efficiency). Low and extremely low efficiency was established accordingly for various non-medical masks (nonwoven, woven cotton, and synthetic ones) and face shields.

When RPE is manufactured and sold, there are no precise criteria for assessing its protective efficiency. There is either no unified approach to such concepts as «medical» and «non-medical» masks. Most respiratory protective equipment sold on the consumer market in Russia is not registered within the Russian State Medical Equipment Register of the Federal Service for Surveillance in Public Healthcare. Our classification allows working out a unified approach to providing data on respiratory protective equipment for consumers.

Key words: *pandemic, COVID-19, respiratory protective equipment, medical mask, non-medical mask, bacterial filtration efficiency, the State Medical Equipment Register, protective equipment market.*

Coronavirus infection pandemic that started in December 2019 in Wuhan, China's Hubei province, spread all over the world in 2020 and is now a global threat to the whole mankind [1]. According to WHO data, by February 10, 2021 106,555,206 confirmed COVID-19 cases were registered all over the world, including 2,333,446 deaths; in Russia, 4,012,710 cases and 78,134 deaths accordingly [2].

Efforts made by numerous scientists have yielded much desirable results as vaccines against COVID-19 have been created and allowed starting mass immunization among population. However, WHO experts predict that collective immunity to the virus will start to form only by the end of 2021 [3].

Since respiratory way and a direct contact are basic ways for COVID-19 contagion, non-

Ekaterina A. Shashina – Candidate of Medical Sciences, Associate Professor at the Common Hygiene Department (e-mail: shashina_e_a@staff.sechenov.ru; tel.: +7 (499) 248-51-55; ORCID: http://orcid.org/0000-0002-5294-6813).

Tatiana S. Isiutina-Fedotkova – Candidate of Medical Sciences, Associate Professor at the Common Hygiene Department (e-mail: isyutina-fedotkova_t_s@staff.sechenov.ru; tel.: +7 (499) 248-51-55; ORCID: https://orcid.org/0000-0001-8423-9243).

Valentina V. Makarova – Candidate of Medical Sciences, Associate Professor at the Common Hygiene Department (e-mail: makarova_v_v@staff.sechenov.ru; tel.: +7 (499) 248-51-55; ORCID: http://orcid.org/0000-0002-7213-4265).

Olga A. Gruzdeva – Doctor of Medical Sciences, Chief Physician (e-mail: fguzmoscao@mail.ru; tel.: +7 (499) 256-71-15; ORCID: http://orcid.org/0000-0002-1244-1925).

Oleg V. Mitrokhin – Doctor of Medical Sciences, Professor, Head of the Common Hygiene Department (e-mail: mitrokhin_o_v@staff.sechenov.ru; tel.: +7 (499) 248-53-85; ORCID: http://orcid.org/0000-0002-6403-0423).

specific preventive activities become especially significant; such activities include social distancing, control over possible contacts with infected people, quarantine, isolation, and hand hygiene [4–7]. Use of respiratory protective equipment turned out to be among the most efficient protective actions against respiratory contagion with the virus [8, 9].

Basing on multiple studies, the World Health Organization issued recommendations on how to use face masks as the primary measure in fighting against COVID-19 spread. And in 2021 the WHO experts consider wearing face masks to be the most important activity that helps restraining and eliminating the pandemic; they note that it is necessary to wear a face mask indoors and outdoors in case it is impossible to keep a safe distance between people equal to 1 meter [10].

Basically, masks allow maintaining control over infection sources since they prevent the virus from spreading from one person to another thus reducing a risk that people might infect each other. Multiple research works, including those that involve mathematic modeling, show that even a slight decrease in individual transfer of the virus can result in a significant decrease in its spread among population [11–14].

Face masks wearing is among preventive activities that can be implemented rapidly and efficiently and require minimal costs. They should be easily available to the whole population and this availability is a key factor that influences provision of population with face masks.

Obligatory face masks wearing was introduced and is still valid in most Russian Federation (RF) regions according to the orders issued by the RF Chief Sanitary Inspector as well as by local authorities; face masks should be worn in public places, public transport, elevators, all objects where services to population are rendered, in public healthcare organizations, and educational establishments[1,2].

Besides, risks that biological threats might occur will persist in future (known microorganisms mutating and new ones occurring); therefore, an issue related to providing population with qualitative respiratory protective equipment will remain vital.

Our research goal was to analyze efficiency of respiratory protective equipment that people use during COVID-19 pandemic. To achieve this goal, we solved the following tasks:

– we accomplished a review of respiratory protective equipment (RPE) that is used as non-specific prevention measure during the pandemic;

– analyzed the State Medical Equipment and Organizations (Private entrepreneurs) Register of the Federal Service for Surveillance in Public Healthcare;

– analyzed the market where respiratory protective equipment available to people was distributed;

– developed RPE classification.

Data and methods. Respiratory protective equipment was examined and assessed as per Russian, interstate, European, Chinese, and American standards; sanitary rules and orders issued by the RF State Sanitary Service; methodical guidelines issued by the RF Public Healthcare Ministry, World Health Organization, and US Centers for Disease Control and Prevention regarding the coronavirus infection prevention and use of respiratory protective equipment during the pandemic.

Market offers made by different manufactures of respiratory protective equipment were analyzed using «Yandex Market», a service helping customers to select products or goods they needed.

Results and discussion. ***A review of respiratory protective equipment used as a non-specific prevention measure during the pandemic.*** People use a great variety of respiratory protective equipment during this pandemic.

Filtrating face half masks are respiratory protective equipment aimed at achieving very

[1] SR 3.1.3597-20. Prevention of the new coronavirus infection (COVID-19). *KonsultantPlus*. Available at: http://www.consultant.ru/document/cons_doc_LAW_353494/e4deaf074c290821400cfad27f87d23d667c4cfd/ (03.02.2021) (in Russian).

[2] On additional activities aimed at reducing risks of COVID-19 spread during a seasonal rise in morbidity with acute respiratory virus infections and flu: The Order by the RF Chief Sanitary Inspector issued on October 16, 2020. *Garant: information and legal database*. Available at: http://base.garant.ru/74811008/ (03.02.2021) (in Russian).

tight fitting with a face and protecting the respiratory organs both from solid and liquid aerosols. Respirators with a filtrating mask (FFP (the European Union), N (the USA), KN (China), DS/DL (Japan), and KF (South Korea)) are made of several layers (not fewer than 6), and these layers, as a rule, are non-woven polypropylene ones. A layer that is made via being blown out from melted material is the most significant one since fiber in such non-woven material can be arranged in a pile thus creating a three-dimensional net with 90 % porosity; it results in high air permeability [15]. Therefore, respirators allow achieving balance between filtration and air permeability. Respirators can be equipped with an exhale valve or be manufactured without it; they can be non-reusable (NR) or reusable ones (R).

Respirators from FFP1 category provide rather low-grade filtration. Respirators from FFP2/N95 and FFP3 categories are recommended by the WHO, the RF Public Healthcare Ministry and US Centers for Disease Control and Prevention (CDC) as personal protective equipment for medical workers who directly provide aid for patients with COVID-19 under conditions that involve virus aerosols formation in the air[3] [16, 17].

In Russia requirements to respirators are stipulated by the State Standard[4].

Face shields are protective screens made of transparent plastic; a shield looks like a plate that is rounded at its edges and can be fixed to a head. They are comfortable to wear and easy to clean, able to reduce autoinoculation due to not touching a person's face, they provide efficient protection from direct contacts with drops due to blocking initial forward movement of a liquid jet [18]. However, thrown out drops can move around a screen relatively easily and spread over a large area depending on ambient conditions [19].

The WHO recommends shields to be used in case face masks are not available; to provide comfortable communication between people when it is necessary to see a face of a person one is talking to; or they can be recommended to people who can't wear face masks due to various reasons (for example, mentally disabled people, people with development disorders, people suffering from deafness or hearing loss, and children as well) [10].

Criteria that allow defining a product as a medical one are approved on by the Eurasian Economic Commission[5]. The document stipulates that if a product is made by its manufacturer to be used in medical conditions to solve specific medical tasks it can be defined as a medical one. Otherwise, masks and respirators used to protect the respiratory organs cannot be defined as medical equipment and there are no unified regulatory requirements fixed for them. Such products are not subject to obligatory confirmation of their conformity with the existing standards[6].

A medical mask is protective equipment that covers the nose and the mouth and provides a barrier that minimizes direct transmission of infection agents between medical personnel and patients[7].

According to the WHO, medical masks are medical products; they belong to «personal protective equipment» category and are subject to obligatory certification [10]. In the USA

[3] Temporary methodical guidelines. Prevention, diagnostics, and treatment of a new coronavirus infection (COVID-19). Version 9 (26.10.2020). The RF Public Healthcare Ministry Publ., 2020, 235 p. (in Russian).

[4] GOST 12.4.294-2015. Personal respiratory protective equipment. Filtrating half masks for protection from aerosols. *KODEKS: an electronic fund for legal and reference documentation*. Available at: http://docs.cntd.ru/document/1200121996 (03.02.2021) (in Russian).

[5] On criteria allowing to define a product as a medical one within the Eurasian Economic Union: Recommendations issued by the EAEC Board on November 12, 2018 No. 25. *KODEKS: an electronic fund for legal and reference documentation*. Available at: http://docs.cntd.ru/document/551663485 (03.02.2021) (in Russian).

[6] Code of Federal Regulations (annual edition). Title 21 – Food and Drugs. Chapter I - food and drug administration, department of health and human services (continued). Subchapter H – Medical devices. Part 878 – General and plastic surgery devices. *U.S. Food and Drug Administration*. Available at: http://docs.cntd.ru/document/551663485 (03.02.2021).

[7] GOST 58396-2019. Medical masks. Requirements and testing procedures. *KODEKS: an electronic fund for legal and reference documentation*. Available at: http://docs.cntd.ru/document/1200163559/ (03.02.2021) (in Russian).

medical masks manufacturing is regulated according to the requirements fixed in the codified collection of the basic regulations and orders issued by the US Federal executive authorities[5].

In Russia it is conventional to divide masks into two types, I and II, depending on how efficiently they provide bacterial filtration[6]. Type II masks can be conditionally divided into two sub-types (II and IIR) depending on how resistant a mask is to sprays. Type I medical masks are used by patients in order to reduce risks of infection spread especially during epidemics and pandemics. Type II masks are predominantly used by qualified medical staff in operating rooms or other medical rooms with similar requirements to them. Type IIR masks are used by medical experts in laboratories or at production facilities where completely sterile conditions are required; they can also be used in operating rooms to provide antiseptic protection for a patient.

To make such masks, either non-woven SMS (spunbond / meltblown / spunbond) material or SS (spunbond / spunbond) material is used; or they can be made of cotton gauze. The latter variant is usually used to reduce contagion risks for population beyond medical organizations. Medical masks are non-reusable medical products and it is recommended to change them as frequently as every 2–3 hours[8].

The WHO recommends wearing medical masks in medical organizations in case there are no procedures involving aerosols formation. When considering an issue whether medical masks should be worn by people in everyday conditions, decision-makers should use an approach based on risk assessment procedures. Thus, medical masks are recommended to be worn by people who are older than 60 or people with concomitant diseases in case it is impossible to keep a safe 1-meter distance. They are also recommended to people who take care of or live together with people with assumed or confirmed COVID-19 diagnosis or in case they have to be in the same room with such people regardless of infection symptoms being apparent or absent [10].

Non-medical masks are sanitary-hygienic products made of various woven and non-woven materials.

According to the WHO requirements, non-medical masks are to be made of not fewer than 3 layers, the internal one being a hydrophilic material (for example, cotton or a mixed fabric containing cotton); the outer layer should be a hydrophobic material (for example, polypropylene, polyester, or their mixture) that can protect a carriers' nose or mouth from contaminants penetrating them; the middle layer should be a hydrophobic synthetic non-woven material, polypropylene for example, or cotton, that can enhance filtrating capacities or retain spray particles. Masks can be reused after being washed in water with a detergent under a temperature being not lower than 60 °C, and it should be done at least once a day [16].

Non-medical masks are recommended by the WHO to be used by people as a barrier aimed at reducing risks of contagion with respiratory infections; in case people should spend some time in a poorly ventilated room regardless of whether they can keep a safe distance or not; or they should be worn in the street in case it is impossible to keep a safe distance being at least 1 meter [10].

But at the same time, the US Centers for Disease Control and Prevention recommend wearing self-made and «manufactured» woven masks (being made of at least 2 layers) that are efficiently ventilated to all people who are older than 2 in order to protect themselves and people around during a pandemic; they also recommend wearing bandanas and headgears and wearing a scarf, ski mask or a balaclava over a woven mask during a cold season. Masks with valves are not recommended since contaminated air is exhaled into the ambient environment; respirators are either not recom-

[8] Methodical guidelines 3.1/3.5.0172/1-20. Recommendation on use of personal protective equipment (including reusable one) for different categories of citizens in case there are risks of COVID-19 contagion. Moscow, The Federal Service for Surveillance over Consumer Rights Protection and Human Well-being Publ., 2020, 17 p. (in Russian).

mended since they are subject to obligatory registration and are to be worn by medical personnel; shields are not recommended since their efficiency has not been properly examined [17].

To sum up all the properties described above, we can spot out the following groups of respiratory protective equipment:

Respirators: non-woven (polypropylene), non-sterile, for adults, 6–8-layered ones, with different sizes, with or without a valve.

Medical masks:

– non-woven (spunbond / meltblown), non-reusable ones with or without a bactericide layer: non-sterile 3-layered (Type I and II); sterile 4-layered (Type IIR with additional spray-resistant layer);

– woven cotton (gauze, gauze / madapollam), non-sterile: non-reusable, 4-layered; reusable, 5–10-layered.

Non-medical masks: 1–4-layered, non-sterile, for adults with different sizes / for children;

– non-woven (spunbond / meltblown) non-reusable;

– woven reusable: cotton (honeycomb fabric, gauze, coarse calico, calico); synthetic (neoprene, polyester / spandex).

Face shields: plastic ones, reusable, for adults / for children.

If assessed as per efficiency of filtration fixed by regulatory standards, respiratory protective equipment is distributed in the following way (Table 1).

Table 1

Respiratory protective equipment distributed as per filtrating efficiency

Mask type	Filtration efficiency in % standard given
FFP1/KN90 respirator*	not lower than 80[9] not lower than 94[10] not lower than 90[11]
FFP2/KN95/N95/DS/DL2/ KF94 respirator *	95[12] 94[13]
FFP3/KN100/N99/N100 respirator *	99[14] 97; 99[15]
Non-woven medical mask Type I**	not lower than 95[16]
Non-woven medical mask Type II and IIR**	not lower than 98[16]
Non-medical mask**	not lower than 70[17]

Note:

* means efficiency of filtration regarding aerosol particles sized 0.3 μm (NaCl particles);

** means bacterial filtration efficiency.

Analysis of respiratory protective equipment market in Russia. As we can see from the above review, masks differ as per their structure, number of layers and their density, efficiency, and mode of their use.

We examined marker offers made by different masks manufacturers using «Yandex Market», a popular service that helps consumers select goods or products. In December 2020 there were data on 838 various types of RPE being sold on the marker; most units were 3-layered ones (Table 2).

[9] National Institute for Occupational Safety and Health (NIOSH). NIOSH Guide to the Selection and Use of articulate Respirators. Department of Health and Human Services (DHHS) NIOSH publication number 96-101, 1996; EU Standard EN149: 2001+A1.

[10] Gost 12.4.294-2015. Personal respiratory protective equipment. Filtrating half masks for protection from aerosols.

[11] The Chinese standard GB 19083.

[12] National Institute for Occupational Safety and Health (NIOSH). NIOSH Guide to the Selection and Use of articulate Respirators. Department of Health and Human Services (DHHS) NIOSH publication number 96-101, 1996; GOST 12.4.294-2015. Personal respiratory protective equipment. Filtrating half masks for protection from aerosols; CEN, E., 2001. 149: 2001 norm: Respiratory protective devices-Filtering half masks to protect against particles Requirements, testing, marking. European Committee for Standardization; The Chinese standard GB 19083.

[13] The EU standard EN149: 2001+A1.

[14] National Institute for Occupational Safety and Health (NIOSH). NIOSH Guide to the Selection and Use of articulate Respirators. Department of Health and Human Services (DHHS) NIOSH publication number 96-101, 1996; GOST 12.4.294-2015. Personal respiratory protective equipment. Filtrating half masks for protection from aerosols; The EU standard EN149: 2001+A1

[15] The Chinese standard 19083; National Institute for Occupational Safety and Health (NIOSH). NIOSH Guide to the Selection and Use of articulate Respirators. Department of Health nd Human Services (DHHS) NIOSH publication number 96-101, 1996.

[16] GOST R 58396-2019. Medical masks.

[17] AFNOR. 2020. SPEC S76-001: Masque barrière. Guide d'exigenceminimales, de méthoded'essais, de confection etd'usage. Available at: https://masques-barrieres.afnor.org/home/telechargement (04.06.2020).

Table 2

Masks offered to consumers on «Yandex Market» web-site

Mask type	Number of layers						Total
	1	2	3	4	5	6	
Non-reusable	1	9	336	6	–	2	354
Reusable	12	192	96	6	28	5	339
Not specified	–	39	96	8	–	2	145
Total	13	240	528	20	28	9	838

We failed to find out what masks out of those offered on the site were medical ones since it was impossible to understand what manufacturers meant when they called their products «medical» or «non-medical» masks. They used a huge variety of descriptions such as *medical mask, protective medical mask, respirator, protective respirator, protective non-medical mask, hygienic mask, protective hygienic mask, hygienic common mask, gauze hygienic mask, protective mask, sanitary-hygienic mask,* etc.

Having analyzed the State Medical Equipment and Organizations (Private entrepreneurs) Register of the Federal Service for Surveillance in Public Healthcare that contained data on economic entities producing medical products, we established that there were 201 masks that were officially registered (taken as in December 2020). All the registered masks are divided into medical ones and respirators but a number of layers in them is not always specified (Table 3).

As we can see from data in tables 1 and 2, less than one quarter (24 %) of masks being sold on the market are officially registered by the Federal Service for Surveillance in the Public Healthcare and are allowed to be distributed on the RF territory.

Due to 2020 COVID-19 pandemic a simplified registration procedure was introduced at the initial stage in the process and it resulted in a drastic increase in number of registered masks (Table 4) 16 registration certificates were annulled by December 2020.

Therefore, our market analysis revealed that all the existing RPE types were being distributed on the market in Russia but data on the marketed products were rather controversial. Manufacturers rarely classify their products correctly (whether they are medical or non-medical ones); not all of them provide data on a registration certificate; a lot of manufacturers do not even give data on the structure and materials their RPE is made of. As a rule, any description contains data on only two properties: number of layers and whether RPE is non-reusable or reusable one. RPE is not always marked properly and marking does not confirm data stated in an advertisement for a product on the web-site.

Table 3

Masks registered in the State Medical Equipment Register *

Mask type	Number of layers							Total
	1	2	3	4	5	6	Not specified	
Non-reusable medical	2	21	107	24	3	2	32	191
Reusable medical	–	–	–	1		1	2	4
Respirators	–	–	–	–	2	–	4	6
Total	2	21	107	25	5	3	38	201

Note: * means that the analysis did not cover masks included into protective clothing sets and first-aid kits.

Table 4

Number of registration certificates issued and annulled over 2017–2020

Year	Certificates issued	Certificates for more than 1 type of masks	Certificates annulled
2017	5	1	0
2018	7	1	0
2019	3	2	0
2020	159	most	16

Respiratory protective equipment classification. Since RPE tends to have variable properties, it seems advisory to develop its classification.

Bearing in mind that RPE has different filtration efficiency, fitness to a face, number of layers, and can be made of different materials, and also taking into account recommendation issued by the WHO experts and the RF Public Healthcare Ministry, we suggest classifying RPE as per protection efficiency as follows (Table 5).

Table 5

RPE classification as per efficiency of protection from respiratory infections*

Protection efficiency		Respiratory protective equipment
High	Additional protection from virus aerosol	FFP3/KN100/N99/N100 respirators
Average		FFP2/KN95/N95/DS/DL2/KF94 respirators
Below average		FFP1respirators
	Medical masks: Non-woven, Type IIR Type II Type I Woven gauze masks	
Low	Non-medical masks: Non-woven, woven (cotton, synthetic) [1]	
Extremely low	Face shields[2]	

Note:

* means RPE is given in a descending order regarding its protective properties;

[1] means protective properties are directly proportionate to a number of layers in a mask provided it is used properly (proper duration of use, disinfection procedures for reusable masks are accomplished properly);

[2] means when they are worn separately, not combined with other RPE.

The suggested classification allows developing a unified approach to providing data on a product for a consumer especially when small lots are bought on retail market or in the Internet; these data should specify all the properties stipulated by the standards on product marking (material, number of layers, conditions of use, etc.) and protection efficiency of a product that is sold on the market.

Conclusions:

1. We have established that it is vital to develop precise criteria for determining protective efficiency when RPE is produced and sold.

2. It is necessary to develop a unified approach to «medical» and «non-medical mask» concept including situations when data are provided for a customer.

3. Only 24 % of all RPE being sold on the consumer market in the RF is officially registered within the State Medical Equipment and Organizations (Private entrepreneurs) Register of the Federal Service for Surveillance in Public Healthcare.

4. We have developed RPE classification as per efficiency of protection from respiratory infections; this classification takes into account filtration efficiency, fitness to a face, number of layers, a material a mask is made of, and recommendations issued by the WHO and the RF Public Healthcare Ministry

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