



Published By : the Indonesian Society
for Clinical Microbiology



Bacterial Filtration Efficiency (BFE) test of medical masks according to SNI 8489:2018: a literature review

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ABSTRACT

Background: The specifications of medical masks are different from those of non-medical masks although they may appear similar. Currently, the Indonesian Government through the Ministry of Health has made efforts to tighten supervision of the quality of medical mask products circulating in the community. Bacterial Filtration Efficiency (BFE) testing is one of the requirements for medical masks to obtain circulation permit from the Indonesian Ministry of Health. Medical masks can be considered good if they have a minimum bacterial filtration efficiency of 95%. If the percentage of BFE result is greater, then the ability of the mask to filter bacteria is also greater. This review aims to provide information on the performance of various types of medical masks through BFE testing and the relationship with the characteristics of the materials used.

Method: Relevant articles were obtained from PubMed, Science Direct, Research Gate, Google Scholar, and Springer databases and then filtered. Sixteen articles were reviewed and included in this study to achieve the study objective.

Result: There are various types of medical masks including surgical masks and N-95 respirator masks. One of the requirements for medical masks is the ability to filter or (BFE) test. Factors that affect the filtration ability of masks include the type of material used and the method of making the mask.

Conclusion: Testing the filtration efficiency of medical masks can be done through the Bacterial Filtration Efficiency (BFE) test. Good medical masks must have a minimum bacterial filtration efficiency of 95%.

Keywords: Medical masks, Bacterial Filtration Efficiency (BFE), SNI 8489 : 2018.

Cite This Article: Stevina, L., Tjampakasari, C.R. 2024. Bacterial Filtration Efficiency (BFE) test of medical masks according to SNI 8489:2018: a literature review. *Journal of Clinical Microbiology and Infectious Diseases* 4(1): 23-28. DOI: 10.51559/jcmid.v4i1.49

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Received: 2024-01-28

Accepted: 2024-04-12

Published: 2024-06-20

INTRODUCTION

The highly contagious Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) is the cause of the Covid-19 pandemic. It spreads quickly and has a high death rate. Airborne transmission through droplet nuclei is this infectious agent's main transmission route. Covid-19 can spread between individuals, especially within less than one meter. Using disposable medical masks is the strategy put into place globally to control the source of infection. The use of medical masks is considered necessary in addition to physical distancing measures.^{1,2}

Surgical and respirator masks (N-95 masks) are the two main types of medical masks.^{3,4} These mask types are classified based on the type and size of infectious particles that the masks can filter. The Indonesian Ministry of Health has currently tightened the supervision of

the quality and safety of medical masks; one of the strategies is applying the Bacterial Filtration Efficiency (BFE) test. The filtration efficiency of medical mask materials can be quantitatively determined using the BFE testing method. The BFE approach can yield results as high as 99.9%.⁵ In Indonesia, regulations on BFE testing refer to SNI 8489:2018 on the BFE testing method for medical masks using biological aerosols *Staphylococcus aureus*.⁶ With this regulation, the effectiveness of medical masks is expected to improve to provide maximum protection to prevent and control respiratory infections, including COVID-19.⁷

There are not many reviews of medical mask materials' filtration capabilities. This review aims to present data on the effectiveness of different kinds of medical masks using BFE testing and how those results relate to the properties of the materials employed.⁸

METHOD

The study's selection process was conducted in two stages. The first stage involved a literature search on online databases from January 2018 to April 2023. The second stage comprised the screening and evaluating relevant studies based on predetermined eligibility criteria. Only studies utilizing the BFE testing method on medical masks conforming to the SNI 8489:2018 standard were included. This research only included studies with relevant full-text articles that were accessible.

Five databases were explored: PubMed, Science Direct, Research Gate, Google Scholar, and Springer. Articles were selected based on eligibility criteria using keywords: "medical mask," "Bacterial Filtration Efficiency," and "SNI 8489:2018" until April 22, 2023. The articles are expected to provide insights into the

testing of BFE in medical masks. We obtained 228 articles from the databases, and after the screening and analysis, we used 16 relevant articles that can answer the research objective (Figure 1).

RESULT

The World Health Organization (WHO) recommends that elderly individuals or those with certain health conditions, such as patients with chronic respiratory diseases and immune disorders, wear medical masks in their daily activities. Several experimental studies have shown that medical masks can protect individuals from various respiratory infections or the possibility of transmitting infections to others (Figure 2). Medical masks circulating in the community must be certified according to international or national standards; the certification can be done through the BFE test. The test is useful to ensure that medical masks meet quality and safety standards, thus providing maximum protection to prevent and control respiratory infections, including COVID-19.

DISCUSSION

Medical Masks

Several experimental studies indicate that medical masks can protect individuals from various respiratory infections or the possibility of transmitting infections to others⁹. On June 24, 2020, the Indonesian Ministry of Health, through the spokesperson for COVID-19 handling, stated that if a virus carrier or an Asymptomatic Carrier (AC) who does not wear a mask has contact with vulnerable individuals who also do not wear masks, the likelihood of transmission could reach 100%. Meanwhile, if a sick person wears a mask and has close contact with a group of vulnerable individuals who do not wear masks, the potential for transmission can be reduced to 70%. If the sick person wears a mask and has close contact with a healthy individual who does not wear a mask, the transmission rate is around 5%. If both groups, the sick and healthy individuals, wear masks, then the potential for transmission is only about 1.5%.¹⁰

Not only does the use of masks suppress the spread and transmission of respiratory

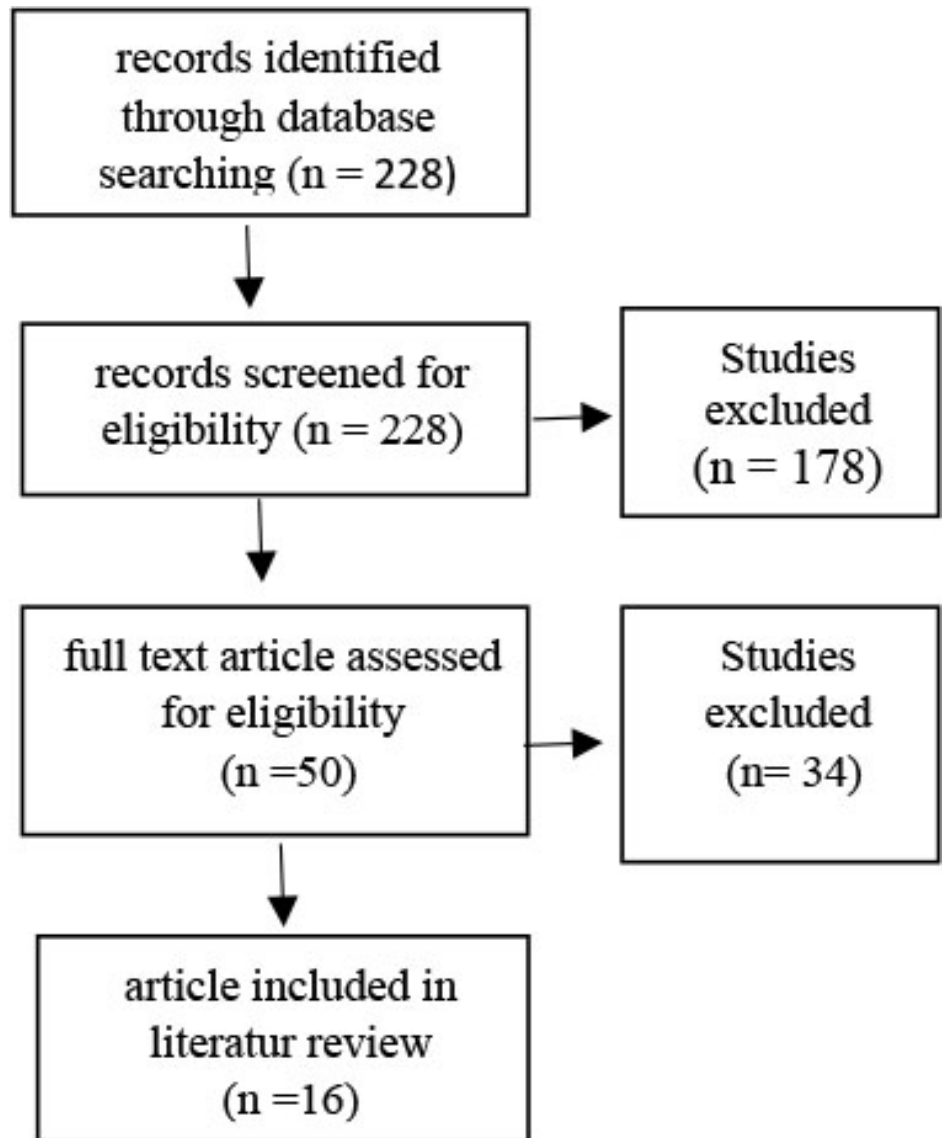


Figure 1. The study selection scheme

infections caused by viruses such as SARS-Cov-2, but it can also suppress transmission of other dangerous infections caused by bacteria such as Tuberculosis (TB) caused by *Mycobacterium tuberculosis*.^{11,12}

The two primary categories of medical masks are respirator masks (N-95 masks) and surgical masks. These mask types are categorized based on the various types and sizes of infectious particles that the masks can filter.

Surgical Mask

A Surgical mask protects the face area, including the mouth and nasal mucosa. Surgical masks have varying levels of capabilities. They are considered more effective in blocking large aerosols and droplets but less effective in blocking small

particles transmitted through sneezing or coughing¹³.

Surgical masks have a multi-layered structure with different functions. Generally, disposable surgical masks consist of three layers made from nonwoven fabric (Figure 3). Nonwoven fabric is made from polymers processed using heat, chemicals, and mechanics. There are two types of materials used for surgical masks: SMS (nonwoven spun-bond, melt-blown, and spun-bond) and SMMS (spun-bond, melt-blown, melt-blown, and spun-bond).¹⁴

Surgical mask filtration efficiency depends on several elements, such as the type of fiber used, the shape of the fiber cross-section, and the manufacturing process. High and medium barrier masks

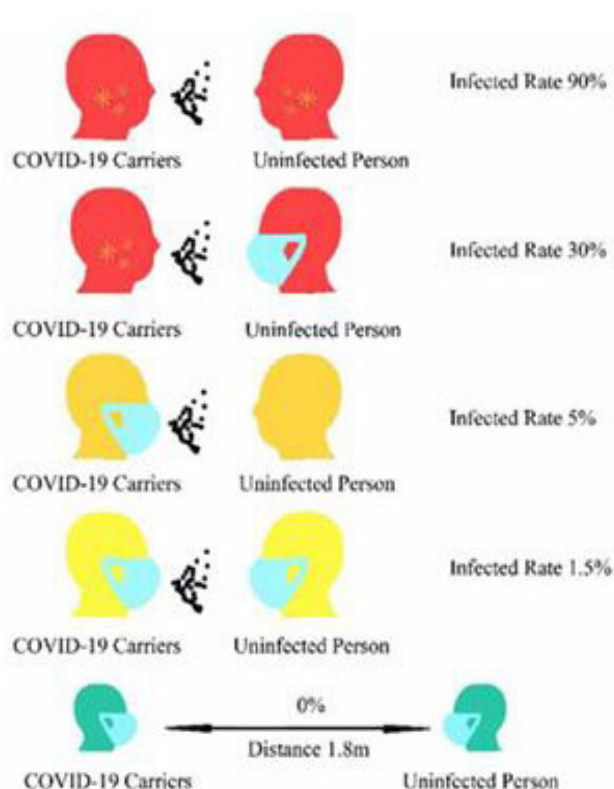


Figure 2. The infection rate when healthy people encounter COVID-19 carriers.¹⁰

have a BFE value of $\geq 98\%$, while low barrier masks have a BFE value of $\geq 95\%$.¹⁶

Respirator Mask

When shielding people from small, airborne particles, respirator or N-95 masks perform better than other types of masks, including surgical ones. The N-95 mask's initial "N" stands for "not resistant to oil." The number "95" indicates that while the mask cannot block gases and vapors, it can filter up to 95% of particles of sodium chloride (NaCl) that are between 0.1 and 0.3 microns in size.¹⁷ One kind of disposable FFR (Filtering Facepiece Respirator) mask is the N-95 mask. Healthcare professionals who directly handle cases with high infectious levels are advised to wear this type of mask. If used properly, this mask has a fit-face seal shape that protects the wearer from exposure to aerosols.¹⁸

The N-95 mask consists of four main layers: the inner layer, support layer, filter layer, and outer layer (Figure 4). The material used on the inside is synthetic polymer fiber or, known as nonwoven polypropylene material, which filters small

particles.¹⁹

The material used for the support layer of the N-95 mask is generally made of modacrylic material, a high-performance synthetic fiber that is fire-resistant, allowing it to blend with all types of fibers to enhance strength and comfort with excellent moisture management. In addition, there is also an electrostatic/electret/charge polypropylene melt-blown fabric in the middle layer of the N-95 mask that functions to filter viruses, bacteria, and other small particles. Spunbond is used to create the N-95 mask's outer and inner layers, while melt-blown is used to create the filter layer. The wearer's mouth and nose contours are fitted into the N-95 mask. This type of mask must be used correctly to minimize the entry of air-carrying hazardous particles from the sides of the mask. Wearing this mask for an extended period may cause discomfort or even difficulty in breathing.²⁰

Medical Mask Requirements

Standardized medical mask requirements can be used to determine the strength of mask materials and how effective the

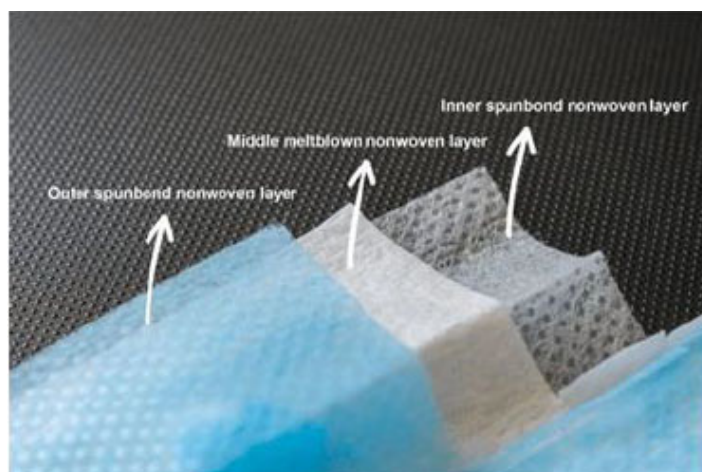


Figure 3. Three layers of material in medical masks.¹⁵

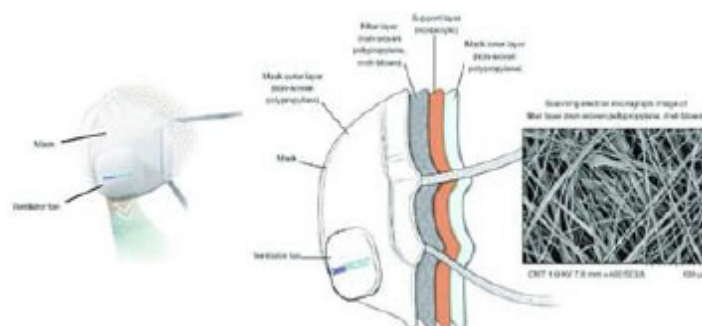


Figure 4. Respirator mask material layer.²¹

mask is in protecting the wearer from inhaling harmful particles in the air, thereby indicating the protection level they will receive when using the mask. The established medical mask requirements include testing:

a. Particle Filtration Efficiency (PFE)

PFE is a test to measure the ability of medical masks to filter submicron particles or aerosols such as harmful smoke, dust, or other airborne particulate matter. The higher the PFE value of a mask material, the better its filtration ability is, which means that the higher the grade of the mask material used. Based on the standards set by the American Society for Testing and Material (ASTM), the particle size used for this test is 0.1 microns, with a minimum filtration efficiency of 95%.^{22,23}

b. Breathing Resistance

Breathing resistance can be tested to determine breathability (differential pressure). Breathing resistance is a test of the air permeability level of medical masks. This test measures the pressure difference on the mask material under

$$BFE = \frac{C - T}{C \times 100}$$

where

C is the mean of the total plate counts for the two positive control runs;
T is the total plate count for the test specimen.

Figure 5. BFE calculation formula.³⁰

Table 1. ASTM standard for medical face

Test	Level 1 (Low)	Level 2 (Moderate)	Level 3 (High)
BFE (Bacterial Filtration Efficiency) at 3.0 micron	≥95%	≥98%	≥98%
PFE (Particulate Filtration Efficiency) at 0.1 micron	≥95%	≥98%	≥98%
Breathing Resistance (mmH ₂ O/cm ²)	<4.0	<5.0	<5.0
Splash Resistance (mmHg)	80	120	160
Flame Spread	Class 1	Class 1	Class 1

certain humidity, temperature, and air flow conditions. The standard for medical masks for breathing resistance testing is below 49 Pascals/cm², while for non-medical masks, it must be below 100 Pascals/cm².^{22,24}

c. BFE

The filtering effectiveness of medical mask materials against bacterial penetration can be measured quantitatively using the BFE method. One crucial factor in assessing a mask's performance is its BFE. The percentage (%) represents mask materials' filtering efficiency in preventing aerosol passage.²²

BFE

Bacterial filtration efficiency is quantified using the BFE test procedure. This approach can determine filtration effectiveness up to a maximum of 99.9%. The filtration effectiveness of other porous medical items, such as sterile barrier systems, surgical garments, and linens,

can also be assessed using this testing technique. Medical mask efficacy is reported as a percentage (%).^{25,26}

Testing is carried out by subjecting bacterial aerosols to a sample—the mask—at a steady flow rate of 28.3 L/min, or 1 ft³/minute. This flow rate stays within a cascade impactor's operating parameters and the typical breathing range. The cascade impactor is a device used to determine the size of an aerosol particle. The testing should be performed with the challenge aerosol directed towards the inside of the medical mask. The aerosol droplets will be collected through the Andersen six-stage sampler, which allows for step-by-step analysis. When the aerosol is collected in the six-stage cascade impactor without the test specimen clamped in the test system, the results of the positive control plate are used to determine the delivery rate of the bacterial challenge at the time of testing. Throughout the test, the bacterial suspension must be continuously changed to get the right challenge level. Virus

aerosols are not used in this test as the virus would need a host cell to survive, making it more difficult.²⁷

BFE Testing Protocol

Before starting the test, the challenge bacteria, *Staphylococcus aureus* (ATCC 29213), are inoculated into 30 ml of tryptic soy broth and incubated in an incubator at 37 ± 2°C for 24 ± 2 hours. Next, dilutions are made using a series of dilutions in peptone water to achieve a concentration of approximately 5 × 10⁵ CFU/mL, which will be used in the test. The challenge bacterial inoculum is maintained at an average of 2200 ± 500 colonies or about 1.7 × 10³ to 3.0 × 10³ CFU per test or viable particle per test as required in EN 14683. The average particle size (Mean Particle size/MPS) in the bacterial challenge should also be maintained at 3.0 ± 0.3 μm, allowing for bacterial efficiency to be reported up to 99.9%.²⁸

The BFE testing is conducted following the SNI 8489:2018 standard that is specifically set for measuring the performance of medical masks. The mask samples to be tested are first clamped between the aerosol chamber (60 mm outer diameter and 60 mm long glass tube) and a six-stage cascade impactor (ACI) with a flow rate of 28.3 L/min. The medical mask samples to be tested should be at least 100 mm × 100 mm with a minimum test area of 49 cm², as required by SNI EN 14683. The testing is conducted by placing the inner part of the mask in contact with the aerosol bacteria that will be sprayed. Each sample is conditioned at a temperature of 21 ± 5 °C and a relative humidity of 85 ± 5% for at least 4 hours to achieve atmospheric equilibrium before testing.²⁹

Interpretation of BFE Results

The test is conducted as recommended in the testing method of SNI 8489:2018 and expressed in percentage (%), using the following formula (Figure 5).

Through the Ministry of Health, the Indonesian government has established a policy requiring medical masks to meet the SNI 8489:2018 standard. Based on the BFE parameter, medical masks are classified into three levels as shown in Table 1. Type I masks have a BFE ≥ 95% and Type II and III masks have a BFE ≥

98%.^{31,32}

By identifying the value of BFE, the ability of medical masks to prevent or reduce the spread of pathogenic bacteria and other harmful microorganisms that spread through the air can be determined. Proper and widespread mask testing can make it easier for the public to access high-quality masks, especially when needed. With an increasing number of standardized medical masks, it is expected that it can help prevent further pathogen spread. Good personal protective equipment will not only protect the user but also healthy individuals from the risk of potential bacterial hazards. According to SNI 8489:2018, medical masks must also undergo several different types of testing, depending on the type of mask.

Mandatory testing, in addition to Bacterial Filtration Efficiency (BFE) testing, includes Particulate Filtration Efficiency (PFE), Breathing Resistance (Differential Pressure), Splash Resistance, and Flame speed. All testing must be carried out on the final product during mask manufacturing.^{33,34}

Although BFE testing only focuses on testing against bacteria, it also plays an important role in assessing the defense of a mask material against viral pathogens. Determining the protection against viruses can be done through the Viral Filtration Efficiency (VFE) method with aerosol testing in the form of Bacteriophage OX174 or viruses (MS2 has a diameter of about 27 nm).³⁵ However, to date, based on regulations of the FDA (Food and Drug Administration) which state that medical masks including surgical masks which have at least three layers of filtration can prevent the entry of harmful particles in the air, medical masks that have passed the BFE test are considered to be able to filter virus particles effectively. For example, virus particles such as SARS-CoV-2 have a size range of 0.06 to 0.14 microns. However, patients transmit the virus in droplet form with a size range of 3.5 to 10.0 microns; so, these particles can still be filtered using medical masks.^{36,37}

CONCLUSION

Implementing health protocols, including standardized medical masks, is an effort to prevent and reduce the transmission of

COVID-19 in the community. There are various medical masks, including surgical and respirator masks (N-95 masks). Factors that affect the filtration capability of masks include the type of materials used and the manufacturing methods. The efficiency of filtration in medical masks can be tested through BFE testing. A good medical mask should have a minimum bacterial filtration efficiency of 95%.

The testing of BFE in medical masks according to SNI 8489:2018 is crucial, especially in the context of respiratory disease prevention. This applies not only during the COVID-19 pandemic but also to the dissemination of other respiratory pathogens such as Influenza and Tuberculosis. Information regarding the bacterial filtration efficiency of medical masks is paramount in preventing the transmission of these diseases.

The weakness of this study lies in the research timeframe, which extends only until April 2023, this may not encompass recent studies or the latest developments in medical mask technology. This indicates the need for literature review from recent studies or medical mask standardization technology updates. This is intended to ensure the suitability and relevance of the journal's findings within a more contemporary context.

DISCLOSURES

Funding

Not available.

Conflict of Interest

There is no conflict of interest.

Author Contribution

LS and CRT involved in conceiving, designing, and supervising the manuscript. LS and CRT conduct the study. LS and CRT analyses the data. All authors prepare the manuscript and agree for this final version of manuscript to be submitted to this journal.

Ethical Approval

Not applicable.

ACKNOWLEDGMENTS

We thank Department of Microbiology, Faculty of Medicine, Master's Program In

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