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# **An Epidemiological Investigation on the Prevention of Respiratory Infectious Diseases by wearing Mask correctly**

## **Program**

**Program No: 2020-KZLXB-01**

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**Research Unit (Seal) : Fuwai Yunnan Cardiovascular Hospital**

**Research time: June 2020 to August 2020**

## Program outline

<b>Research title</b>	An Epidemiological investigation on the Prevention of Respiratory Infectious Diseases by wearing Mask correctly
<b>Population</b>	Those who are 7 years old or above, have the ability of autonomous behavior and language expression, are willing to take the test.
<b>Research center</b>	Responsible organization: Research site 1: Kunming Research site 2: Shizong Research site 3: Luliang Research site 4: Luoping Research site 5: Beijing Research site 6: Yuncheng Research site 7: Jinzhong Research site 8: Taizhou
<b>Research purpose</b>	To explore the relationship between the transmission of respiratory diseases and the correct wearing of masks, as well as the factors affecting the correct wearing of masks, an investigation and intervention study will be carried out. <b>1. Investigate the proportion of people who wear masks correctly.</b> Subgroup analysis: age, sex, education level. <b>2. Is the effectiveness of the direct injection method not inferior to that of the hood method?</b> Is the false positive rate or false negative rate of direct injection acceptable? <b>3. Can the adhesive strip above the mask effectively improve the protection rate?</b> If the efficiency is significantly increased after the use of adhesive tape (such as $\geq 95\%$ ), is there no need to change the hood test? <b>4. Is "surgical mask + tape" a more effective measure?</b>
<b>Research design</b>	<b>1. Overall design:</b> This study uses the methods of cross-sectional survey and chance sampling. <b>2. Sign the Informed Consent Form.</b> <b>3. Investigation on the basic situation of personnel:</b> The gender, age and

education level of the subjects were analyzed as the factors influencing whether the mask was worn correctly or not.

#### **4. Investigation on the types and duration of wearing masks:**

1) The types and duration of masks worn by the subjects were recorded as the basis of stratified statistics.

2) Mask suitability testing:

(1) Visual inspection

whether the mask is close to the face with obvious gaps.

(2) Breathing test

whether it can blow the cotton wool under the eyes when the subject taking a deep breath.

(3) Spray test

The FT-30 qualitative fitness test system of 3M company was used to test the suitability and correctness of wearing mask.

In the spray test, all subjects underwent a sensitivity test to prove their ability to smell the bitterness of the reagent, and then were randomly divided into a hood group and a direct spray group.

##### **The process is as follows:**

**1. Sensitivity test:** the subjects will not wear a mask, but put on a hood, open their mouth to breathe, and extend their tongue properly. Spray the sensitivity reagent (the diluent of the fitness test reagent) 10 times and ask the subjects if they feel bitter, and if they have, record it. If there is no feeling, spray 10 more times to see if there is a feeling. If you need to spray another 10 times, record the subjects' sensation during 20 or 30 times of spray. If there is no feeling for 30 times of spray and the test is over, the subject is not suitable for the test method. The subjects took off the hood and drank water to make the bitterness disappear.

**2. After drinking water to eliminate bitterness, sensitive subjects will be randomly divided into hood group and direct spray group.**

**3. The process of the hood group:**

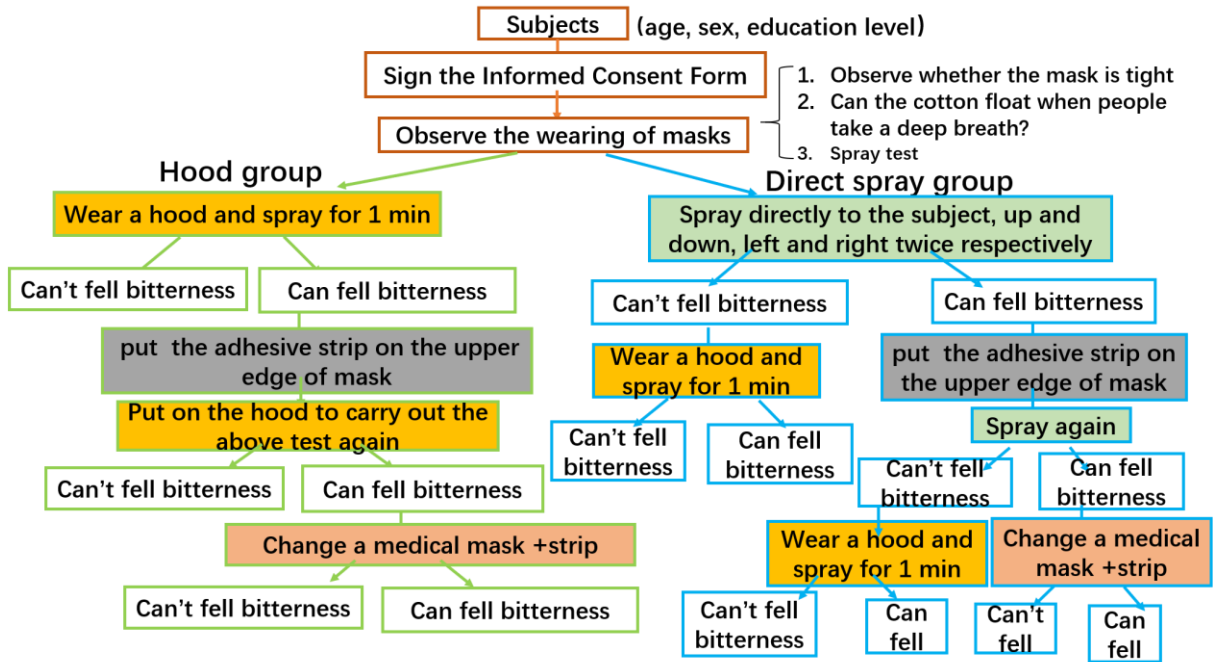
	<ol style="list-style-type: none"> <li>1) The subject wears a mask and a hood, opens his/her mouth to breathe, and sticks out his/her tongue properly. Using the fitness test reagent to spray into the hood, the number of sprays should be the same as that of the sensitivity test.</li> <li>2) Record whether the subject feels bitterness, if there is no feeling, the test is over. If there is a sensation, put the adhesive strip on the upper edge of the subject's mask and put on the hood to carry out the above fitness test again. Observe and record whether the subjects have adverse reactions, and if so, stop the operation immediately.</li> <li>3) Record whether the subject feels bitterness, if not, the test is over. If there is any sensation, ask the subject to change to a medical surgical mask, and put an adhesive strip on the upper edge of the mask, and put on the hood to carry out the above fitness test again.</li> </ol> <p><b>4. The process of direct spray group:</b></p> <ol style="list-style-type: none"> <li>1) The subject wears a mask and his/her tongue sticks out properly. The suitability test reagent is used to spray directly to the subject from the top, bottom, left side and right side twice respectively, and the subject can stop the spray as soon as he/she smells bitterness.</li> <li>2) Record whether the subject feels bitterness, if not, let the subject puts on the hood, carry out the fitness test again and record the results.</li> <li>3) If the subject feels bitterness, stick the adhesive strip on the upper edge of the subject's mask and perform the direct spray test again. Record whether the subject feels bitterness, if not, ask the subject to put on the hood, carry out the fitness test again and record it. If there is a feeling, ask the subject to change to a medical surgical mask and put an adhesive strip on the upper edge of the mask, then conduct the direct spray test again, and record the test results.</li> </ol>
<p><b>Selection criteria</b></p>	<ol style="list-style-type: none"> <li>1) Healthy people with autonomous behavior ability and language expression ability who are older than or equal to 7 years old, Persons under the age of 18 need to obtain the consent of their legal guardians;</li> </ol>

	<p>2) The subjects and / or their legal guardians have the ability to understand the contents of the study and to participate in all the research processes with the subjects;</p> <p>3) People who volunteered to take part in the study;</p> <p>4) There was no respiratory infection in nearly one month.</p>
<b>Exclusion criteria</b>	<p>1) People with a history of allergies, including those who are allergic to pollen, dust mites, etc;</p> <p>2) People with any history of drug allergy;</p> <p>3) People who have participated in the experiment are not allowed to participate in this study for the second time;</p> <p>4) Pregnant women;</p> <p>5) The healer after COVID-19 's infection;</p> <p>6) After questioning, it was found that the subjects were the factors that affected the study, such as dysosmia, or those who had decreased olfactory ability due to disease, or facial paralysis, which affected the judgment of the test;</p> <p>7) Those who are participating in clinical trials of other drugs / devices;</p> <p>8) Subjects with poor compliance or unwilling to cooperate with the operation as required;</p> <p>9) The researchers believe that any other situation that may affect the evaluation of the study.</p>
<b>Elimination standard</b>	<p>1) Subjects with incomplete information collection;</p> <p>2) Subjects who have participated in the experiment twice (if the first data collection is available, the second data is excluded).</p>
<b>Related reagent information</b>	<p>Common name: Trinitrophenol</p> <p>Production unit: 3M company</p> <p>Specification: 55ml</p> <p>Active ingredient: 2, 4, 6- trinitrophenol</p> <p>Other ingredients: water dilution</p>
<b>Research end point</b>	<p>Collect survey data with sufficient sample size.</p>

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<b>Sample size consideration</b>	In order to objectively reflect the overall situation of the subjects, it is necessary to cover many ages and educational levels of men and women.
<b>Research duration</b>	Each subject participated in the study for about 5-6 minutes, and the total duration of this study was about 3 months.
<b>Statistical analysis</b>	Results were statistically analyzed by SPSS software.

## Research flow chart



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## **1、 Purpose and significance**

The purpose of this study was to explore the relationship between the transmission of respiratory diseases and the correct wearing of masks, as well as the factors affecting the correct wearing of masks. The research is beneficial to the prevention of respiratory diseases and moves the barrier of prevention and control forward. It is of great significance to COVID-19 's practical prevention and control.

## **2、 Research design**

### **(1) Overall design:**

#### 1、 Selection methods

This study uses the methods of cross-sectional survey and chance sampling.

#### 2、 Sign the informed consent form.

#### 3、 Investigation on the basic situation of personnel

The gender, age and education level of the subjects were analyzed as the factors influencing whether the mask was worn correctly or not. This study is an anonymous survey and does not collect personal information other than the subjects' names and the above-mentioned information.

#### 4、 Investigation on the types of wearing masks

The types of masks worn by the subjects were recorded as the basis of stratified statistics.

#### 5、 Mask suitability testing:

(1) Visual inspection: whether the mask is close to the face with obvious gaps.

(2) Breathing test: whether it can blow the cotton wool under the eyes when the subject taking a deep breath.

(3) Spray test: The FT-30 qualitative fitness test system of 3M company was used to test the suitability and correctness of wearing mask.

In the spray test, all subjects are required to undergo a sensitivity test to prove their ability to smell the bitterness of the reagent, and then will be randomly divided into a hood group and a direct spray group, as shown in the flow chart. For the specific operation of FT-30 qualitative suitability testing equipment, see Attachment 1.

#### 6、 If the subject wears the mask incorrectly, correct the way the mask is worn.

A、 Training participants who wear the mask incorrectly on the correct way to wear masks



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(1) Demonstrate the correct way to wear disposable medical masks:

1) wash your hands and check the validity and packaging of the mask. 2) the side of the nose clip is facing up and the dark face is facing outward. If there is no color difference, it is judged from the fold of the mask, and the downward part of the fold is on the outside. 3) pull the wrinkles up and down, cover the mouth, nose and jaw with a mask, and wrap the whole chin. 4) the fingertips of both hands are gradually moved outward to the medial contact pressure nose clip. 5) when taking off the mask, one hand hooks it off at the place where the mask is tied.

(2) The correct way to wear an N95 mask:

1) Face the mask without a nose clip so that the nose clip is above the mask, hold the mask on your face and hold it against your chin. 2) pull the upper headband over the top of the head and place it above the top of the head. 3) pull the lower headband over the top of the head and place it under the back of the neck and the ear. 4) place your fingers in the middle of the metal nose clip, press inward and move your fingertips along both sides of the nose clip until the nose clip is completely pressed into the shape of the bridge of the nose. Squeezing the mask nose clip with only one hand may affect the tightness of the mask. 5) the user must check the closeness of the mask to the face and cover the mask with both hands to avoid affecting the position of the mask on the face. You can inhale quickly. If air leaks from the bridge of the nose, you should re-adjust the nose clip according to step 4. If the air leaks from the edge of the mask, the headband should be readjusted. If a good fit cannot be obtained, repeat steps 1) to 4). If you do not feel the leak, you should wear it well.

B、 Check the tightness again after correcting the way the mask is worn.

(1) The liquid spraying experiment verifies the correctness of the mask wearing after correcting the wearing mode.

Ask the subjects to wash their mouths with unified mineral water. After a 1-2 minute rest, there is no difference in the mouth, and then use FT30 qualitative fitness testing equipment to test the suitability of the mask to see if the subjects smell peculiar smell or bitter taste in the mouth.

After all the studies are completed, the research team will provide the subjects with a new medical aseptic mask.

### **3、 Statistical analysis**

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The results were analyzed by SPSS software.

#### **4、 Subject protection**

The subjects should take this test of their own free will, and they can withdraw from the test at any time for any reason, and will not cause any adverse effect on the subjects. Before participating in the study, the subjects or minor subjects' legal guardians will be fully informed of the informed consent of this study and sign the informed consent form.

##### **1、 Protection of the rights and interests of minors and children with amblyopia**

If the subjects are under 18 years old (excluding 18 years old) to participate in this test, the school will seek the consent of the legal guardian (parents) on behalf of the school, and the medical staff can also demonstrate the testing process by video. after letting the minors know and fully understand, if they agree to the test, they and the guardian need to sign and agree to participate.

##### **2、 Subject information confidentiality**

This test will not collect any personal privacy-related information of the subjects, does not involve the disclosure of the subjects' personal identity information (for example, name or address), and will not infringe upon the subjects' privacy. The medical data from the subjects and the records of participating in this trial will be submitted to the research party and kept in a secure repository to control the data. The personal data of the subjects collected during the test may be transmitted to Fuwai Hospital of the Chinese Academy of Medical Sciences, located at 167 Beilishi Road, Xicheng District, Beijing. The results of this study will be used for experimental reports, article publication and policy research.

#### **5、 The scientific research ability of the research unit**

Yunnan Fuwai Hospital is a public third-class specialized hospital jointly built by Fuwai Cardiovascular Hospital of Chinese Academy of Medical Sciences and Yunnan Provincial Government, which integrates medicine, teaching and research. It is also the only third-class cardiovascular hospital in southwest China. It has been approved Yunnan Cardiovascular Disease Clinical Medical Center, National Arrhythmia intervention Engineering and Technology training Base, and national postdoctoral research station. National New Drug Clinical Phase I observation Base, Kunming Medical University doctorate and Master's degree Award Point, Yunnan Heart failure diagnosis and treatment Innovation team, Yunnan pacing

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patient follow-up platform, Yunnan Atrial Fibrillation cryoablation collaboration Network, Yunnan Hypertension Prevention and Control Center, Cardiovascular Disease Rehabilitation Center.

At present, the hospital has been approved a number of construction projects, such as the national project to improve the ability of diagnosis and treatment of difficult diseases, Yunnan Clinical Medical Center, Yunnan Heart failure Innovation team and so on. Access to external support funds of nearly 200 million yuan. At the same time, our hospital has also been approved to become a national medical device and drug clinical trial institution, actively carrying out clinical research work. At the same time, the hospital actively declared all kinds of scientific research projects at all levels. Nearly three years after its establishment, the hospital was newly approved to preside over 22 scientific research projects at all levels, with a scientific research funding of 4.95 million yuan. Under the leadership of the leaders of various disciplines, his team completed 24 innovative technologies in our hospital, including the first case in the world, the first case in southwest China, and the first case in Yunnan Province, including magnetic levitation left heart assist device, aortic arch covered stent system to repair the dissection of the arch, total thoracoabdominal aortic replacement under normal temperature and off-pump, and continuous coronary artery bypass grafting and intracavitary repair of abdominal aortic aneurysm at the same time. Simultaneous endovascular repair of complex aortic dissection and coronary stent implantation, and simultaneous PDA occlusion and external windowing for thoracic aortic aneurysm.

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## Attachment 1

### Operating rules for FT-30 qualitative suitability testing equipment (bitterness)

#### (1) Application:

It is used to test the facial fitness of tight-fitting respiratory protector to the wearer, it is suitable for all dust masks / masks and gas masks / masks equipped with particulate pre-filter cotton.

#### (2) Reagent ingredients:

water, sodium chloride, Denatoniumbenzoate

#### (3) Note:

Denatoniumbenzoate is a very bitter chemical, so be careful not to let children come into contact with it.

If there are signs of contamination in the reagent, pour the reagent away immediately.

According to the OSHA regulations of the US Occupational Safety and Health Administration, the tested person should be informed of the composition of the test reagent before the fitness test, and the test object will be exposed to a fine spray of the reagent during the test.

If crystallization occurs in the reagent, tighten the opening of the reagent bottle, soak it in warm water, or shake hard to dissolve the crystal.

The 3M TMFT-30 qualitative fitness testing equipment (bitterness) meets the relevant provisions of OSHA respiratory protection standard 29CFR1910.134 for fitness testing.

#### (4) Preparation:

1. Put the hood on the collar, align the center of the window of the hood with the round hole on the collar, and tighten the rope on the hood and tie the knot.

2. Pour about 1 teaspoon # 1 reagent into the # 1 sprayer.

3. Pour the same amount of # 2 reagent into the # 2 sprayer.

4. Tighten the lid of the reagent bottle immediately.

#### (5) Sensitivity test:

The purpose of the sensitivity test is to determine whether the subject can feel the reagent used. The sensitive reagent is the diluent of the reagent used in the suitability test. The subjects are not allowed to eat, drink (except water) or chew gum 15 minutes before the test.

1. Don't wear a mask, put on a hood.

2. Adjust the position of the hood so that there is a distance of more than 10 centimeters between the subject's face and the window of the hood.

3. Subjects are asked to open their mouths to breathe and stick out their tongues properly.

4. Remove the # 1 sprayer nozzle seal cover, insert the nozzle into the round hole in the window, compress the airbag and spray 10 times. The airbag should be completely flattened each time it is sprayed, and then allow it to expand completely. The sprayer must be in a vertical position with the airbag facing down.

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5. Ask the subject if he or she feels bitterness, and if so, record the subject's feeling of bitterness during 10 sprays.

6. If there is no feeling, spray 10 more times to see if the subjects feel. If you need to spray 10 more times, record that the subjects feel the spray 20 or 30 times.

7. If there is still no feeling after 30 times of spray, the test is over, indicating that the subject should choose other fitness test methods.

8. Take off the hood and let the taste disappear from the subjects' mouths. Drinking water can help the taste disappear.

(6) Fitness test:

1. After the subjects put on the mask and wear the mask correctly, the facial tightness test is performed to ensure the closeness.

2. Use the # 2 sprayer and spray once.

3. After spraying, the subjects are asked to do the following actions

a. Normal breathing---standing posture, normal breathing rate, do not speak.

b. Take a deep breath---stand up, take a slow, deep breath, and be careful not to exhale too much.

4. Whenever the subject feels bitter, it means that the mask does not fit well with the subject's face, and stop the fitness test.

5. The fitness test is repeated after the subjects readjusted or wore a new mask. If it tastes bitter again, it means the subjects need other types of masks.

6. If the subjects do not feel bitter all the time, it means that the mask is suitable for the subjects' face and can be worn.

7. Regularly check the sprayer, if there is a blockage, remove the blockage phenomenon, repeat the fitness test.

(7) Inspection equipment includes:

#1 sprayer (sensitivity test) 1

#2 sprayer (fitness test) 1

spray nozzle spare parts 2 sets

#2 fitness test reagent one bottle

(8)、 Equipment cleaning:

After each inspection, or after at least 4 hours of use, pour out the reagent in the sprayer. **Never pour the remaining reagents back into the original bottle.** Wash the sprayer with warm water to prevent the nozzle from clogging and air-drying. Wipe the inside of the hood with a wet towel or paper towel to remove aerosols deposited on it. For mask type masks, you can wipe the mask with 3MTM mask wipes 504 after each fitness test.

**Attachment 2**

**Inspection record of qualitative suitability of close-fitting mask**

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Fitness test time:

Inspection equipment:

Serial number	Gender	Age	Culture	Type and duration of mask					Mask suitability test			Sensitivity test	Hood group	Direct spray group	
				General medical masks	Medical surgical masks	Medical protective masks	Particulate matter protective mask	Warm cloth mask	Visual inspection	Breathing test	Spray test				

Note: qualitative suitability test: according to whether the bitter taste is felt, it is recorded as-not felt, + as felt.

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Inspection record of qualitative suitability of close-fitting mask

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Fitness test time:

Inspection equipment:

Serial number	Gender	Age	Culture	Hood group				Direct spray group							
				Can't fell	Can fell:	Can fell	Can fell	Can't fell:	Can fell	Can fell:	Can fell	Can fell:	Can fell		
					Strip									Call fell: Medical mask+strip	Wear a hood

Note: qualitative suitability test: according to whether the bitter taste is felt, it is recorded as-not felt, + as felt.