**Protocol**

**concerning the new coronavirus identified in 2020**

**(Detection, identification and reporting)**

1. **Pathogen**

Coronaviruses are single-stranded RNA viruses enveloped in a lipid shell. They can cause sickness to humans as well as several animal species, typically including birds and mammals such as camels, cats and bats. Coronaviruses are zoonotic, i.e., they can be transmitted from animals to humans: the in-depth epidemiological studies in the Y2003 SARS coronavirus revealed that the pathogen was transmitted from civet cats whereas MERS-CoV was shown to have been transmitted from camels to humans. At present, there are seven coronaviruses known to be capable of causing human infections and illness. The severity of coronavirus infections vary significantly from simple flu to more serious respiratory diseases. There are four human coronaviruses that generally cause mild or moderate symptoms in the upper respiratory tract while the Middle East respiratory virus (MERS-CoV) and SARS coronavirus are so severe that they may cause life-threatening respiratory diseases as well. (The human diseases caused by the SARS-coronavirus were eliminated by the epidemiology measures taken in 2003.)

Investigating the causes of the pneumonia epidemic in Wuhan in late 2019, scientists identified a virus from the Beta Coronavirus family, **currently known as 2019-nCoV Wuhan coronavirus**, which is genetically closest to the SARS coronavirus. This newly-emerged virus was identified through a new-generation sequencing procedure from samples of patients with the Wuhan pneumonia epidemic and from direct virus cultures. The electro-microscopic images reveal the pathogen’s characteristic crown-like morphology.

**2. Source of infection:** currently unknown. The common epidemiological connections of the initial cases to the Wuhan seafood and live animal market make it highly likely that an animal available there may have had a role as a zoonotic source in the outbreak of the epidemic, but the exact species is currently unknown. The human-to-human transmission of the new Wuhan coronavirus has been confirmed: **Humans** can be a source of infection. To the best of our current knowledge, human-to-human transmission occurs when there is close contact (e.g., infections have occurred through exposure in the healthcare system, family or common household).

**3. Manner of transmission:** The human-to-human transmission of the new Wuhan coronavirus (2019-nCoV) has been confirmed. Coronaviruses are typically transmitted via close contact, in particular through respiratory droplets and the infected secreta.

**4. Incubation period:** according to the current data, 7 days on average (2-12 days).

**5. Key symptoms**: according to our current knowledge, the disease is associated with high temperature, cough, laboured respiration and radiological variances characteristic of pneumonia. The disease may be manifested with mild, moderate and severe symptoms, including severe pneumonia, ARDS, sepsis and septic shock.

**6. Duration of pathogenicity:** unknown.

**7. What to do with the patient:**

**7.1. Reporting:**

After classification, the therapist (e.g., General Practitioner, physician of outpatient clinic, ambulance physician) must immediately report via phone all patients meeting the following case definitions (case under investigation, probable case, confirmed case) to the epidemiology department of the relevant county government office, while individuals under inpatient care must be reported directly to the public health division of the relevant county government office. Out of office hours, the case must be reported via the hotline of the county government office. The public health associate of the regional office will immediately inform the public health division of the relevant county government office.

Having evaluated the information, the public health associate of the county government office will immediately report the case with the personal identification data to the Epidemiology and Infection Control Division of the National Public Health Center (NPHC), or, out of office ours, to the NPHC hotline. The NPHC will forward the data to the WHO. *(The WHO expects its member states to report probable and confirmed cases within 24 hours of their classification.)*

The **data collection form**, which is compiled based on the data requested by the WHO, **must be filled out with the available data and submitted within 24 hours** to the NPHC’s Epidemiology and Infection Control Division at jarvany.titkarsag@nnk.gov.hu. If laboratory data are also available, the updated data collection form must be submitted again. The data collection form must also be updated in the event of any information of other fundamental changes.

**1.1.7. Classification of cases**

**7.1.1.1.** **Suspected case / Case under investigation**

**A.** Patients with severe acute respiratory infection (SARI), who also demonstrate high temperature (≥38°C) and coughing, and their condition justifies hospitalization

**AND**

Patients whose clinical condition cannot be fully explained by other reasons (immune-compromised persons may demonstrate atypical clinical pictures, too)

**AND** at least one of the following:

* The patient travelled to or stayed in Wuhan (Hubei Province, China) within 14 days prior to the onset of the disease, or
* The patient is a healthcare professional attending to patients with severe acute respiratory syndrome of unknown etiology.

**B.** Persons with acute respiratory disease (regardless of the severity of the clinical picture),

**AND** at least one of the following:

* Persons who had close contact with a probable or confirmed case of a syndrome caused by the new Wuhan coronavirus during the 14-day period before the onset of their disease; or
* Persons who visited or worked at the Wuhan (Hubei Province, China) live animal market during the 14-day period before the onset of their disease; or
* Persons who, during the 14-day period before the onset of their disease, worked at or visited a healthcare institution where new Wuhan coronavirus infection cases were reported.

 **Close contacts** are defined as family members or healthcare professionals who provided care for, or stayed for over 15 minutes in the immediate environment of a probable or confirmed case, in a closed space during the occurrence of the symptoms. The definition includes any person who lives together, has visited or has stayed in the same room for over 15 minutes with a probable or confirmed case during the occurrence of the patient’s symptoms.

**7.1.1.2. Probable case**

Suspected cases with dubious results from their 2019-nCoV lab test or with a positive result from their pan-coronavirus test.

**7.1.1.3. Confirmed case**

Any person whose infection by the new Wuhan coronavirus has been confirmed by laboratory tests.

**7.2. Isolation: obligatory.** **Probable and even suspected cases must be isolated.**

**Isolation in hospitals is obligatory.** Until further notice, the patient must be directed to the National Institute of Haematology and Infectology - South Pest Hub Hospital (DPC), where they can be properly isolated and cared for.

**7.2.1. Infection control, precautionary and safety regulations in patient care**

Considering what we know so far of the new Wuhan coronavirus and the transmission of coronaviruses in general, the infection control practice recommended for healthcare institutions to prevent the spread of the new coronavirus is similar to the infection control practice applied to prevent the severe acute respiratory syndrome (SARS).

Infection prevention guideline in healthcare:

1. Early detection and isolation
2. Infection control, precautionary and safety regulations in patient care
3. Disinfection of the environment and equipment
4. Education of healthcare professionals and visitors
5. Provide material and personnel conditions

***A. Early detection and isolation***

- Based on the clinical symptoms and medical history, it is necessary to detect suspected cases of infection early, and immediately isolate such patients. When establishing the medical history, it is highly important to thoroughly interview the patient.

- **If a suspected case of infection is identified, the patient must immediately be isolated**. Persons under investigation of the infection or patients with probable and/or confirmed coronavirus infection must be placed in a well-ventilated, well-equipped, separated (single-bed) hospital room. If there are no separate rooms available, cohort isolation is also possible but the beds must be at least one metre away from each other. The room’s door must be kept closed. If the conditions are provided, probable and/or confirmed cases of new coronavirus infections must be placed in rooms with negative pressure (i.e,, lower than the environment).

- If the health professionals attending to a new coronavirus patient start to demonstrate respiratory symptoms within 14 days after their last contact with the case, then such health professionals must immediately inform the hospital hygiene service of their symptoms.

***B. Infection control, precautionary and safety regulations in patient care***

In addition to the basic (standard) precautionary and safety regulations, the additional precautionary and safety regulations related to the prevention of diseases transmitted via droplet infection and direct or indirect contact must also be observed in all suspected (under investigation), probable and confirmed cases of the new coronavirus infection. The rules of respiratory isolation must be observed during interventions involving aerosol production.

 *Key rules from the list of basic (standard) precautionary and safety regulations mentioned above:*

* Apply the appropriate hand hygiene practice in compliance with the “five hand hygiene principles”, strictly observing each element during patient care.
* Personnel working in the isolation room must wear personal protective equipment, i.e., face masks (surgical masks), gloves (disposable) and coats (long-sleeved, disposable).
* If their condition allows for it, patients are also recommended to wear a surgical mask.
* Personnel not involved in the patient’s care are not allowed to enter the room, the number of other hospital staff (including cleaners) must also be limited. All personnel involved in the patient’s care must be registered.
* As possible, the use of disposable equipment is strongly recommended in the care of the patient. Non-disposable equipment must be disinfected/sterilized according to the manufacturer’s requirements.
* The environment in the hospital room must be regularly disinfected. After the patient left, the hospital room must be subjected to a final disinfection.
* The patient’s bed linen and other textile items must be collected in a bag with an “infectious” label on it.
* Patients are not allowed to leave the room unless justified.
* If their exit is justified (the patient is transported for an examination or to another institution, etc.,), the patient must wear a face mask (surgical mask). The staff transporting the patient must also use protective equipment and disinfect their hands. The ward/department conducting the examination must be informed in advance so that the examination room could be cleaned and disinfected before the patient arrives.
* Visitors must be registered before entering the hospital room, they must also wear protective gear and disinfect their hands.

*Key rules from the list of precautionary and safety regulations to prevent respiratory transmission mentioned above:*

* You must use safety glasses or face protectors when attending to patients who have respiratory symptoms and need close contact for their care since the patient’s coughing and sneezing may generate droplet-like secreta.
* In order to ensure a full mouth-nose-eye protection during interventions involving aerosol production (e.g., intubation, extubation, bronchoscopy, tracheal suction, mechanical and positive-pressure ventilation), healthcare workers must wear safety glasses, face protectors and respirator masks (FFP3 meeting the N95 – EN 149 standard) in addition to wearing (disposable) gloves and long-sleeved water-repellent protective clothes.
* As possible, interventions involving aerosol production should be conducted in a separate, well-ventilated hospital/examination room. The intervention must be performed by as few staff members as possible.

***C. Disinfection of the environment and equipment***

**The environment must be subjected to regular and final disinfection with virucide.** Coronaviruses have a lipid shell so most one-phase (cleaning, disinfecting) substances are effective against them.

***D. Education of healthcare professionals and visitors***

- Staff and visitors must be taught the proper hand hygiene, respiratory hygiene, coughing etiquette and the correct use of individual protective equipment. The particular healthcare institution is responsible for such education.

***E. Provide the material conditions***

- The basic (standard) precautionary and safety regulations and the rules to prevent infections transmitted by droplets and contact cannot be constantly observed unless **the healthcare workers always have a sufficient amount of** the necessary (disposable and other) **equipment available.** The particular healthcare institution is responsible for providing such equipment.

**Additional rules and recommendations for healthcare services providing basic and specialist inpatient care:**

- It is justified to wear a surgical mask and regularly ventilate the examination room when attending to patients with respiratory symptoms.

- It is obligatory to wear a surgical mask, disposable gloves and coat when attending to a patient suspected to have a new Wuhan coronavirus infection.

- With regard to the necessary care, the use of other protective equipment may also be justified (see above: infection control, precautionary and safety regulations).

- You must apply the appropriate hand hygiene practice in compliance with the “five hand hygiene principles”, strictly observing each element during patient care.

- Early detection is key, based on the symptomatology, the potential travel history and/or other relevant information (e.g., travels of a family member).

- The patient should not use public transport. Instead, they should individually be taken to the hospital by car or, if necessary, by ambulance, while wearing a surgical mask.

- Environment and equipment (e.g., patient examination table, stethoscope, thermometer, other non-disposable items) disinfection rules must be observed throughout the care of the patient.

- If the examination is conducted in the patient’s home, the physician must bring the above protective equipment and alcohol-based hand disinfectant for themselves. They must also make sure that the generated hazardous waste is correctly collected and disposed of.

**Additional rules and recommendations for the ambulance transport of patients suspected to have the new Wuhan coronavirus infection:**

**-** Patients suspected to have the new Wuhan coronavirus infection must not be transported together with other patients (unless the other patient is also suspected to have the new Wuhan coronavirus infection). The receiving institution must be informed in advance so that they could prepare for the patient.

- Strict hand hygiene with alcohol-based disinfectant and the application of individual protective gear is required, including face masks (surgical masks), gloves (disposable) and coats (long-sleeved, disposable).

- When transporting the patient, the ambulance driver must also wear a surgical mask. While transporting the patient, the transporters must not touch their face, nose, eyes, hair, contact lenses. They must not eat, drink and smoke, either.

- It is recommended to perform all necessary interventions using disposable equipment. The applied non-disposable equipment must be disinfected/sterilized according to the manufacturer’s requirements.

- Interventions involving aerosol production (e.g., intubation, tracheal suction) must be performed under full mouth-nose-eye protection, so healthcare workers must wear safety glasses, face protectors and respirator masks (FFP3 meeting the N95 – EN 149 standard) in addition to wearing (disposable) gloves and long-sleeved water-repellent protective clothes.

- The ambulance car must have a proper size collective bin for the hazardous waste generated.

- After the transport is completed, the ambulance car and its entire equipment must be disinfected with virucide. The staff performing the disinfection must wear protective equipment. The completion of the disinfection must be documented.

- If the staff members attending to a new coronavirus patient start to demonstrate respiratory symptoms within 14 days after their contact with the case, then such staff members must immediately inform their employer of their symptoms.

**7.3. Microbiological examination:** Obligatory. As laid out in the laboratory sampling regulations, deeper respiratory tract samples / respiratory secreta samples and blood/serum samples must be submitted to the NPHC’s Respiratory Viruses National Reference Laboratory for a direct evaluation and/or serological testing.

**8. What to do in the patient’s environment**

**8.1. Identify all persons who contacted the patient**: It is obligatory to identify all persons who had a close contact with the patient during the persistence of the symptoms. This procedure is performed by the epidemiology department of the regional government office territorially responsible according to the patient’s Hungarian address/residence, in cooperation with the relevant county government office’s public health division if necessary.

**Close contact:**

Family member or healthcare professional who provided care for, or stayed for over 15 minutes in the immediate environment of a probable or confirmed case, in a closed space.

**8.2. Microbiological screening for epidemiological interest:** not necessary.

**8.3. Epidemiological observation:** Any asymptomatic person who had close contact with a probable or confirmed new Wuhan coronavirus case while the patient had symptoms, must be placed under epidemiological observation in order to immediately detect any potential occurrence of the high temperature and respiratory symptoms characteristic of the disease.

In the course of the epidemiological investigation, the territorially competent regional government office’s epidemiology department will identify the persons (including healthcare workers) who had close contact with a probable or confirmed new Wuhan coronavirus case while the patient had symptoms, and place them under epidemiological observation for 14 days. Contacts may be isolated in their homes. The officials of the authority will check on the symptoms of the persons under epidemiological observation in the form of daily phone calls.

If the symptoms occur within 14 days after the contact, the newly-detected patient must also be considered a “patient under evaluation”, regardless of the severity of their diseases, and processed accordingly.

**8.4. Post-exposure prophylaxis: -**

**8.5. Research of infection source:** obligatory

**8.6. Exploration of transmitting media:-**

**9. Prevention:**If you travel to China, you are recommended to avoid any contact with people who cough or have a high temperature and pay an increased attention to your personal hygiene. You should avoid markets selling live animals and if you are not wearing protective equipment, avoid direct contact with live animals in the area effected by the epidemic. Avoid consuming raw or insufficiently heat-processed animal products. Tourists are recommended to get information on the current occurrence and characteristics of the disease. If you experience symptoms in your upper respiratory tract, contact your General Practitioner/therapist and inform the healthcare workers involved in your care about your travel history.

The above protocol was compiled based on the recommendations and guidelines issued by the World Health Organization and the European Centre for Disease Prevention and Control. If there is a change in the recommendations of international organizations, the protocol will be updated.