Medical history for preventine vaccination against COVID-19 – with mRNA-vaccine -
(Comirnaty® from BioNTech/Pfizer und Spikevax®, earlier known as COVID-19 Vaccine Moderna from Moderna)

Name, date of birth: _____

Address, zip code: _____

Email address, tel.: _____

Occupation: _____

Clinic/Ward/University/Department: _____

1. Do you currently have an acute illness with fever? **O yes** **O no**
2. Have you been vaccinated in the last 14 days? **O yes** **O no**
3. Have you already received a vaccination against COVID-19? If yes, when and which vaccine? **O yes** **O no**
   Date: _____ Vaccine: _____
   Date: _____ Vaccine: _____
   (Please bring your proof of vaccination to your appointment.)
4. In the event you have already received one COVID-19 vaccine dose: Did you develop an allergic reaction thereafter? **O yes** **O no**
5. Has it been reliably proven that you were infected with the novel coronavirus in the past? **O yes** **O no**
   If yes, when: _____
6. Do you have chronic diseases or suffer from immunodeficiency? **O yes** **O no**
   (e.g. due to chemotherapy, immunosuppressive therapy or other medications)
   If yes, which: _____
7. Do you suffer from a coagulation disorder or do you take blood-thinning medication? **O yes** **O no**
8. Do you have any known allergies? **O yes** **O no**
   If yes, which: _____
9. Have you ever shown symptoms of an anaphylactic reaction? **O yes** **O no**
10. Have you ever experienced allergic symptoms, high fever, fainting spells or other uncommon reactions following a previous different vaccination? **O yes** **O no**
    If yes, which: _____
11. Are you currently pregnant (if applicable: pregnancy week_____) or nursing? **O yes** **O no**

☐ **I have taken note of the contents of the information sheet and had the opportunity to have a detailed discussion with my practitioner administering the vaccine or with the COVID-19-Hotline (80-38777).**

☐ **I have no further questions andi consent to the recommended vaccine against COVID-19 with mRNA-vaccine.**

☐ **I have further questions** _____

☐ **I refuse the vaccine.**

After the vaccination, please go to the café lounge (gallery of the staff canteen) for approx. 15 minutes for medical supervision.

Aachen, _____

_____
Signature of the person to receive the vaccine

_____
Signature of the practitioner

1. Vaccination date: _____ Chargen-Nr. _____
2. Vaccination date: _____ Chargen-Nr. _____

INFORMATION SHEET for vaccination against COVID-19 (Corona Virus Disease 2019) – with mRNA vaccines – (Comirnaty® from BioNTech/Pfizer and Spikevax®, formerly COVID-19 Vaccine Moderna® from Moderna)

What is COVID-19?

Coronaviruses have been known for decades. As of the turn of the year 2019/2020, a novel coronavirus, SARS-Coronavirus-2 (SARS-CoV-2), which is the pathogen of COVID-19 (Corona Virus Disease 2019), has been circulating globally.

Frequent symptoms of COVID-19 include dry cough, fever, shortness of breath, as well as a temporary loss of smell and taste. A general feeling of being unwell accompanied by headaches and aching limbs, sore throat, and sniffles are also depicted. Patients less often report having gastrointestinal problems, conjunctivitis, and swelling of the lymph nodes. Consequential damage to the nerves or cardiovascular system as well as persisting courses of the disease are possible. Although the disease often runs a mild course and most patients fully recover, severe courses of the disease, for example with pneumonia, do occur as well and may result in death. Children and adolescents in particular usually have mild courses of the disease; severe courses are rare in this age group and usually occur with preexisting conditions.

In addition to avoiding an infection by observing the AHA + A + L rules (maintaining social distance, observing hygiene, masking in daytoday life, downloading the corona warning app, frequent ventilation), the vaccine offers the best possible illness protection.

Which vaccine is involved?

Several vaccines against COVID-19 are approved which are suitable for individual protection against COVID-19 and pandemic response. The mRNA COVID-19 vaccines discussed here (BioNTech/Pfizer's Comirnaty® and Spikevax®, formerly Moderna's COVID-19 Vaccine Moderna®) are genebased vaccines that are predicated on the same new type of technology. Additional mRNA vaccines are being tested, although they have not yet been approved.

mRNA (messenger RNA or ribonucleic acid) is the “blueprint” for each individual protein of the body and must not be confused with human genetic information – DNA. A “blueprint” for a single element of the virus (the socalled spike protein) is contained in the mRNA vaccines against COVID-19. The COVID-19 mRNA vaccines do not contain replicable vaccine viruses, which means that vaccinated persons cannot transmit vaccine viruses to other persons.

The mRNA contained in the vaccines is not incorporated into the human genome after vaccination, but is "read" after entering the cells (primarily in muscle cells at the vaccination site and in certain immune cells), whereupon such cells then produce the spike protein themselves. The spike proteins thus generated by the body of the vaccinated person are recognised as foreign proteins by the immune system; as a result, antibodies and immune cells are generated against the spike protein of the virus. This produces a protective immune response.

The mRNA contained in the vaccine is degraded in the body after a few days. At that point, virus protein (spike protein) is no longer produced.

How is the vaccine administered?

The vaccine is injected into the upper arm muscle. The vaccine must be administered twice. There should be 3 to 6 weeks (Comirnaty®) or 4 to 6 weeks (Spikevax®) between the 1st and 2nd vaccination. Manufacturers' guidance is that the vaccine used for the 2nd vaccination should be the same vaccine from the same manufacturer as was used for the 1st vaccination. An exception applies to persons for whom the COVID-19 vector vaccine Vaxzevria® from AstraZeneca was used for the 1st vaccination. For such persons, the Standing Committee on Immunisation at the Robert Koch Institute (STIKO) currently recommends that the 2nd vaccination be performed with an mRNA vaccine (Comirnaty® or Spikevax®) at least 4 weeks after the 1st vaccination with Vaxzevria®. The reason for this recommendation is the superior immune response after this socalled "heterologous vaccination series" (1st vaccination with Vaxzevria® followed by 2nd vaccination with Comirnaty® or Spikevax®) compared to the homologous vaccination series with Vaxzevria® (1st and 2nd vaccination with Vaxzevria®) according to current study results. According to these study results, the immune response after such heterologous vaccination series (1st vaccination with Vaxzevria® followed by 2nd vaccination with Comirnaty® or Spikevax®) is comparable to the immune response after two vaccinations with an mRNA vaccine (Comirnaty® or Spikevax ®). In addition, with the shorter vaccination interval in such heterologous vaccination series, complete immunization can be achieved in a shorter time frame. Study results also suggest that the side effects of such heterologous vaccination are comparable to those presented here below.

COVID-19 vaccination along with other vaccinations:

According to the recommendation of STIKO, COVID-19 vaccinations and other so-called killed vaccines (inactivated vaccines, which contain killed pathogens or only pathogen components, and which do not reproduce and cannot cause disease) can be administered simultaneously. This is especially true for influenza vaccination if there is an indication for vaccination against both influenza and COVID-19. In this case, the injection should be administered respectively indifferent limbs. IfCOVID-19 vaccines and influenza vaccines (including high-dose vaccines) are administered concurrently, it should be noted that vaccine reactions may occur more frequently than if administered separately. If different vaccines are used, the efficacy and safety generally correspond to those when respectively used alone.

Vaccination after proven infection

At this time, persons who have undergone infection with the novel coronavirus should receive only one dose of vaccine, unless they are immunocompromised. If the infection is accompanied by symptoms, vaccination should usually be given 6 months after the illness, but no earlier than 4 weeks afterward. In the event of an infection without symptoms, vaccination can occur no sooner than 4 weeks after the diagnosis. Even in cases where more than 6 months have passed since diagnosis, one dose of the vaccine is sufficient. According to STIKO, it is currently not possible to say if or when a 2nd vaccination is necessary in such persons at a later date. In persons in whom infection with the novel coronavirus has been reliably confirmed after the 1st vaccination, STIKO recommends that the 2nd vaccination be administered as a rule 6 months after recovery or following the diagnosis, but no earlier than 4 weeks thereafter. There is no evidence that vaccination poses a risk if one has had an infection in the past.

Booster vaccinations with mRNA vaccines (Comirnaty® or Spikevax®)

The STIKO recommends booster vaccination for persons over 70 years of age, for individuals working in nursing homes or other institutions caring for individuals with an increased risk of severe COVID-19 illness and who have direct contact with multiple clients, for staff in medical institutions who have direct patient contact and for individuals with impaired immune systems. The booster vaccination should use an mRNA vaccine no sooner than 6 months following completion of the primary vaccination. At present, booster vaccination is not advised for individuals who have suffered a proven SARS-CoV-2 infection either before or after the primary vaccination.

Currently only Comirnaty® is approved specifically for booster vaccinations. Approval is being sought for booster vaccination with Spikevax® at a lower dose; currently booster vaccination using Spikevax® in the usual dose is possible under the terms of the current approval.

Persons with severe immunodeficiency:
In such cases, the 3rd vaccine dose can be administered as early as 4 weeks after the 2nd vaccine dose as an optimisation of the primary vaccination series. The decision must be made on a case-by-case basis regarding booster vaccination at an interval of an additional approximately 6 months from the primary vaccination series. Persons within the household in close contact with persons having severe immunodeficiency should be offered a booster vaccination with an mRNA vaccine no earlier than 6 months after primary COVID-19 vaccination if the person with severe immunodeficiency has not responded or has not adequately responded to the COVID-19 vaccination.

Optimisation of the vaccine protection following primary vaccination with the Janssen® COVID-19 vaccine: Individuals who have received a vaccine dose using the Janssen® COVID-19 vaccine should receive an additional vaccination in order to optimise their vaccine protection, according to STIKO recommendations. Independent of age, these individuals should be offered an mRNA vaccine more than 4 weeks after the vaccination with the Janssen® COVID-19 vaccine. If a proven COVID-19 infection has developed subsequent to the Janssen COVID-19 vaccination, then no additional vaccinations are currently advised.

Over and above the current STIKO recommendations, booster vaccinations may be offered as a preventative measure to individuals over the age of 60, taking into account their individual circumstances and following assessment by a doctor. In addition, individuals who have received a comprehensive vaccination with a vector-vaccine may also be offered an additional vaccination as a preventative measure: this affects individuals who received 2 doses of the AstraZeneca Vaxzevria® vaccine or who received a single dose of a vector-vaccine after suffering a proven SARS-CoV-2 infection. All the above- named booster or supplementary vaccinations are achieved with a single dose of one of the two mRNA vaccines (Comirnaty® or Spikevax®) no sooner than 6 months after completion of the primary vaccination.

How effective is the vaccine?

The available COVID-19 mRNA vaccines are comparable in terms of efficacy as well as potential vaccine reactions and complications.

According to the current state of knowledge, complete vaccination with the COVID-19 mRNA vaccines is highly effective. In the licensing studies, the likelihood of individuals becoming ill with COVID-19 following full vaccination with (Comirnaty®) (over 16 year-olds) or (Spikevax®) (over 18 year-olds) was reduced by approximately 95% in comparison to unvaccinated individuals. Current studies looking into the protection against the Delta variant, which is presently predominant in Germany, show an efficacy of approx. 90% (Comirnaty®) and 80% (Spikevax®) against developing severe illness from the Delta variant; the protection against developing a mild illness is less for both of the vaccines. This means that if a person completely vaccinated with a COVID-19 vaccine comes into contact with the pathogen, there is a high probability that they will not become ill. How long this vaccine protection lasts is not yet known.

Vaccinating children and adolescents between the ages of 12 and 17:
In clinical trials, full vaccination with Comirnaty® in 12 to 15yearolds, and with Spikevax® in 12 to 17yearolds, demonstrated an efficacy of up to 100% with respect to a COVID-19 illness. For both mRNA vaccines, it should be assumed that efficacy is similarly high in relation to a severe COVID-19 illness.

Even if you or your child are vaccinated, it is necessary that you continue to observe the AHA + A + L rules and thus protect yourself and your surroundings. The reasons for this are that protection does not start immediately after vaccination and is also not equally present in all persons who were vaccinated. In addition, vaccinated persons can spread the virus (SARS-CoV-2), although the risk is significantly reduced compared to unvaccinated individuals.

Who should be vaccinated against COVID-19?

Comirnaty® and Spikevax® are approved for persons 12 years and older.

STIKO recommends vaccination against COVID-19 for persons 12 years of age and older. Both mRNA COVID-19 vaccines described here can be used for this age group.

Children and adolescents 12 to 17 years of age:
STIKO now generally recommends vaccination with mRNA vaccines for children and adolescents aged 12 years and older, that is, vaccination is no longer essentially limited to children and adolescents with certain preexisting conditions, since the benefits of vaccination outweigh the risks. For the benefits and risks of vaccination, see also "How effective is the vaccine?" above as well as "What types of reactions to the vaccine may occur after receiving the vaccine?" and "Are complications possible due to the vaccine?" below.

Pregnant and breastfeeding women and unvaccinated women of childbearing age:
STIKO recommends COVID-19 vaccination with mRNA vaccines for pregnant women as well, since pregnancy as such poses a risk factor for a severe COVID-19 course and since SARS-CoV-2 infections in pregnant women increase the risk for pregnancy complications. In addition, the mRNA vaccines protect very well against the COVID-19 disease during pregnancy, and according to current studies, serious side effects do not occur more frequently after vaccination during pregnancy. Unvaccinated pregnant women should receive the vaccine starting at the 2nd trimester (2nd trimester of pregnancy). If the pregnancy was established after the first vaccination had already taken place, the second vaccination should only be carried out starting at the 2nd trimester (2nd third of pregnancy). At this time, it is not clear whether vaccination of a pregnant woman can also provide protection for the baby. STIKO explicitly recommends the COVID-19 vaccination for women of childbearing age, especially those who wish to have children, in order to be protected in the 1st trimester (1st trimester of pregnancy) in the event of a future pregnancy. Close contacts of pregnant women should also be vaccinated against COVID-19 starting at the age of 12.

STIKO also recommends vaccination with mRNA vaccines for unvaccinated breastfeeding women. There is no evidence that COVID-19 vaccination during breastfeeding poses a risk to mother or child.

Who should not be vaccinated?

Children up to and including 11 years of age, for whom no vaccine is currently approved, should not be vaccinated.

Those suffering with an acute illness accompanied by a fever (38.5°C and higher) should only be vaccinated after recovery. However, a cold or slightly elevated temperature (below 38.5°C) is no reason to postpone vaccination. Those with a hypersensitivity to a substance of a vaccine should not be vaccinated – please inform the practitioner administering the vaccine if you have allergies prior to being vaccinated. Any person who had an immediate allergic reaction (anaphylaxis) after the 1st vaccination should not receive the 2nd vaccination.

How should I behave prior to and after receiving the vaccine?

An interval of at least 14 days from receiving other vaccines should be maintained; this does not apply to dead vaccines, especially not to influenza vaccination (see above). If you have fainted following a previous vaccination or other injection, have a tendency towards immediate allergies or have had other reactions, please inform the practitioner administering the vaccine. He/she can then potentially observe for an extended period after vaccination.

Prior to vaccination, please inform the doctor if you have a coagulation disorder or are taking anticoagulant medication. You can be vaccinated with simple precautions. Persons with an immune deficiency can receive the vaccine. However, vaccination may not be as effective in such persons. Please also tell the doctor prior to vaccination if you have allergies or have had an allergic reaction after a vaccination in the past. The doctor will clarify with you whether there is any reason not to have the vaccination.

It is advisable to avoid extraordinary physical stress and competitive sport in the first days after vaccination. In the event of pain or fever after the vaccination (see "What types of reactions to the vaccine may occur after receiving the vaccine?"), analgesic/antipyretic medication can be taken. You can consult with your family practitioner about this.

What types of reactions to the vaccine may occur after receiving the vaccine?

Following vaccination with the mRNA vaccines, local and general reactions can occur as an expression of the interaction of the body with the vaccine. These reactions occur most often within 2 days after the vaccination and rarely persist longer than 3 days. In older persons, most reactions are observed somewhat less often than in younger persons. The vaccination reactions are mostly pronounced to be mild or moderate and occur somewhat more frequently after the second vaccination.

Comirnaty®:

Frequently occurring reactions to the vaccine (in more than 10% of the persons) may be reported regardless of age:

Persons 16 years of age and older: The most frequently reported reactions to the vaccine in the approval studies were pain at the injection site (more than 80%), fatigue (more than 60%), headaches (more than 50%), muscle pain and chills (more than 30%), joint pain (more than 20%), fever, and swelling at the injection site (more than 10%).

Children and adolescents between 12 and 15 years of age: The most frequently reported vaccine reactions in the approval studies after administering Comirnaty® during the mostly 2-month observation period were pain at the injection site (more than 90%), fatigue and headaches (more than 70%), muscle pain and chills (more than 40%), joint pain and fever (more than 20%).

The following reactions to the vaccine were reported in less than 10% of the persons in the approval studies which include all study participants 12 years of age and older: Nausea and redness around the injection site occurred frequently (between 1% and 10%). Swelling of the lymph nodes, insomnia, pain in the vaccinated arm, malaise, itching at the injection site, and hypersensitivity reactions (e.g., generalized rash and itching) occurred occasionally (between 0.1 and 1%). Since vaccination was introduced, diarrhoea has also been reported very frequently (in 10% or more) and vomiting has been reported frequently (between 1% and 10%).

Spikevax®:
Frequently occurring reactions to the vaccine (in more than 10% of the persons) may be reported regardless of age:

Persons 18 years of age and older: The most frequently reported reactions to the vaccine in the approval studies were pain at the injection site (more than 90%), fatigue (70%), headache and muscle pain (more than 60%), joint pain and chills (more than 40%), nausea or vomiting (more than 20%), swelling or pain sensitivity of the lymph nodes in the armpits, fever, swelling and redness at the injection site (respectively more than 10%). A common rash as well as a rash, redness or hives at the injection site were frequently (between 1% and 10%) reported. Occasionally (between 0.1% and 1%), itchiness developed at the injection site.

Children and adolescents between 12 and 17 years of age: The most frequently reported reactions to the vaccine were pain at the injection site (more than 90%), headaches and fatigue (more than 70%), muscle pain (more than 50%), chills (more than 40%), swelling or tenderness of the axillary lymph nodes and joint pain (more than 30%), nausea or vomiting, swelling and redness at the injection site (more than 20%), and fever (more than 10%).

The following reactions to the vaccine were reported in less than 10% of persons (relating to all age groups 12 years and older): Frequently (between 1% and 10%), redness, rash, and hives occurred at the vaccination site, to some extent delayed, as well as a general rash. Occasionally (between 0.1% and 1%), itchiness at the injection site and dizziness occurred.

Are complications possible due to the vaccine?

Vaccine-related complications are consequences of the vaccine exceeding the normal extent of a vaccine reaction, which significantly impact the health of the vaccinated person. During the extensive clinical trials prior to approval, cases of acute facial paralysis were observed rarely (between 0.1% and 0.01%) after administering mRNA vaccines (Comirnaty®: 4 cases after administering the vaccine; Spikevax®: 3 cases after administering the vaccine and 1 case in the control group). In all cases, the facial paralysis subsided after a few weeks. Such facial paralyses may be causally related to the vaccination. Hypersensitivity reactions were observed in rare cases (between 0.1% and 0.01%): Hives or facial swelling after administering Comirnaty® and 2 cases of facial swelling after administering Spikevax®.

Since introducing the vaccine, anaphylactic reactions (immediate allergic reactions) have been reported in very rare cases. These occurred shortly after administering the vaccine and required medical treatment. Likewise, since the introduction of vaccination, very rare cases of myocarditis and pericarditis have been observed after administration of the mRNA vaccines. Such cases occurred mainly within 14 days of vaccination, more frequently after the 2nd vaccination, and more often in younger men. Some older persons or persons with preexisting conditions died. So far, several million doses of the mRNA-COVID-19 vaccines have been administered in Germany. The adverse reactions previously reported to the Paul Ehrlich Institute after vaccination with mRNA vaccines were mainly temporary local and general reactions. Anaphylactic reactions (immediate allergic reactions) have been reported very rarely after vaccination with the two mRNA vaccines. Cases of myocarditis or pericarditis have also occurred very rarely in children and adolescents as well as in adults: Predominantly male adolescents and young men were affected during the first 14 days after the second dose of vaccine, and the illnesses were mostly mild. As with all vaccines, in very rare cases an immediate allergic reaction up to and including shock or other previously unknown complications cannot be categorically precluded.

If symptoms occur following a vaccination, which exceed the aforementioned quickly passing local and general reactions, your family practitioner is naturally available for consultation. In the event of severe impacts, chest pain, shortness of

breath or palpitations, please seek immediate medical attention. There is also the option of reporting side effects yourself: https://nebenwirkungen.bund.de. In addition to this information sheet, your practitioner administering the vaccine will provide you with the opportunity to have a clarification discussion.

You can find additional information about COVID-19 and about the COVID-19 vaccine at

www.coronaschutzimpfung.de
www.infektionsschutz.de
www.rki.de/covid-19-impfen
www.pei.de/coronavirus

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