COVID-19 Protocol
May 2021

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1. General aspects

The data and studies carried out to date show that COVID-19 affects more severely those over 65 years of age with previous cardiovascular pathology (mainly hypertension and heart failure) and to a lesser extent those with chronic respiratory pathology and diabetes. Mortality increases with age. A study carried out in China shows that mortality is 3.6%, in the 60-69 age group 8% in the 70-79 age group and 14.8% in the over-80 age group.

The main mechanism of transmission of this virus, according to the information available, is by direct contact with respiratory droplets larger than 5 microns (Flügge), which do not remain suspended in the air and are deposited between 1 and 2 metres; through hands, surfaces and objects contaminated with these secretions, followed by contact with the mucous membrane of the mouth, nose or eyes. Nosocomial transmission has also been described in health centres. Close contact takes place in social health centres, so prevention and control measures to prevent infection are of great importance.

The following infection prevention and control recommendations are based on the current scenario in which COVID-19 infection develops and on the latest available information, taking into account that the main objective is to protect the population group most vulnerable to COVID-19 infection.

The aim of this protocol is to implement homogeneous measures that guarantee that all partners of the consortium establish preventive measures when carrying out actions (e.g. installation of technological devices, follow-up visits) in the homes of the participants, and in any clinical/rehabilitative centres, within the framework of the PROCare4Life project. This protocol takes into account the application of the instructions and protocols established by the local health authorities and their updating.

2. Justification

Participants are in a situation of vulnerability to COVID-19 infection for various reasons:

- They usually present basic pathology or comorbidities.
- They tend to be older adults.
- They have close contact with other people (their carers) and other co-habitants.
- They spend a lot of time in closed environments and with equally vulnerable populations.
3. General measures in Home Visits

3.1 PERSONNEL who visit participants’ homes

Obligations

It will be ensured that all personnel visiting a home have specific and up-to-date information and training on the measures to be implemented (e.g. adequate hand washing as the main measure of prevention and control of infection; use of hydro alcoholic gel; steps to put on and take off protective equipment properly, etc.) in each participation site.

In addition, each entity will guarantee the correct supply of materials, providing personnel:

- Surgical masks. Morning and afternoon working day will be delivered two, morning working day only one.
- Disposable gloves. Sufficient number to use a different pair of gloves with each user and that there is a spare in case of accidental breakage.
- Hydro-alcoholic solution.
- Protective glasses.
- Plastic bags for waste disposal.
- Spray with virucidal solution to spray the shoes just at the moment of entering the home.
- Disposable gowns/clean jackets with which to cover street clothes.

On the first day that personnel go to a home, they will inform the participant and family about the new COVID-19 protection regulations in accordance to local context updated regulations (see Appendix I).

Recommendations for ProCare4Life Personnel

General preventive hygiene measures

- It is essential to reinforce personal hygiene measures in all areas of work and against any exposure scenario. To this end, the necessary means will be provided so that the personnel of the PROCare4Life project can clean themselves properly following the following recommendations:
- Hand hygiene is the main measure for the prevention and control of infection (with soap and water for at least 20 seconds and more recommended for 40 seconds or with hydro alcohol). Hand hygiene should be carried out before putting on personal protective equipment and after its removal, as well as before and after each home visit.
- Gloves must always be changed with each participant and hand hygiene must be carried out after removing them and before putting on new ones.
- Once the gloves have been disposed of, the personnel will put them in a bag that they will close and throw away in the rubbish when they leave the house. They will carry bags to dispose of the waste individually.
- Personnel will cover their nose and mouth with a handkerchief when coughing and sneezing, and dispose of it in one of the plastic bags they will take with them for this purpose and which they will throw away outside the home. If tissues are not available, use the inside of the elbow to avoid contaminating the hands.
- Avoid touching eyes, nose or mouth.
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• Avoid touching eyes, nose or mouth.

• Avoid jewellery, rings, bracelets, etc.

• Wear hair tied up so as not to touch face, avoid using creams on face.

• If personnel wears glasses, disinfect the glasses.

• Keep a physical distance of 2 metres as much as possible (even if wearing a mask).

• It is important to stress the importance of adapting information and training to the measures that the Ministry of Health updates, which requires continuous monitoring.

• Ideally, go to the home visit with a negative PCR test, or instead a serological/rapid test (consult the corresponding risk prevention department).

Preventive material hygiene measures

• Have equipment users (participants) and maintenance personnel follow all recommendations outlined by health authorities to reduce the risk of transmission of VOC-19, including proper hand washing, use of appropriate hand sanitizer, use of face masks as well as the provision of appropriate PPE.

• Consult the equipment manufacturer for instructions on cleaning the equipment. Equipment instructions are expected to include validated cleaning and disinfection or sterilization procedures.

• Do not use disinfectants, including atomised floggers, sprays or other types of cleaning agents, on any component of electrical equipment made of any type of material: plastic, insulation, paint, metal, etc. unless specifically instructed to do so by the manufacturer of the electrical equipment.

• Among the recommendations, it is normally advisable to moisten (not soak) a lint-free cloth (microfiber) with hot water containing a pinch of soap, clean extremely gently and then dry the device.

Preventive measures when visiting homes

In Public Transport:

• The use of a mask is compulsory.

• When travelling by bus, public transport, metro or train, keep a safe distance from fellow travellers (whenever possible).

• In the case of public buses, the driver will ensure that the capacity is controlled and that interpersonal distance is respected.

In the street:

• It is compulsory to wear a mask on the street.

• Keep interpersonal distance when walking in the street.
Specific steps to be followed by PROCare4Life personnel

- The greeting will be cordial, but without touching or kissing the participant or the relative, neither when arriving nor when leaving.
- Personnel, upon arrival at the home and at the doorway, will disinfect the sole of her/his shoes with virucidal spray, wash her/his hands with water and soap for at least 20 seconds (or hydro alcohol), put on gloves, a gown or jacket that isolates the outside of his street clothes and protective glasses. S/he will collect the material needed and leave any bag/backpack at the entrance of the house. A mask will be worn at all times. Just before touching any device or surface in the house, personnel will protect gloves with hydro-alcoholic gel.
- As a general rule, touch objects as little as possible.
- If at any time it is necessary to write something down, personnel will use their pen and the participant their own.
- Personnel will wash work clothes every day (we recommend washing at 60 to 90 degrees or at 40 degrees in a long programme with an oxygenated detergent).

Order of placement and removal of PPE

<table>
<thead>
<tr>
<th>Placement of PPE</th>
<th>Removal of PPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Mask always on</td>
<td>1. Mask (it is not necessary to change it at home, we recommend one in the morning and one in the afternoon, in case of reduced working hours only one per working day)</td>
</tr>
<tr>
<td>2. Hand hygiene</td>
<td>2. Hydro alcohol in the gloves</td>
</tr>
<tr>
<td>3. Disinfect soles with virucidal spray</td>
<td>3. Remove protective glasses</td>
</tr>
<tr>
<td>4. Putting on gloves</td>
<td>4. Remove protective jacket</td>
</tr>
<tr>
<td>5. Putting on a protective jacket</td>
<td>5. Remove gloves</td>
</tr>
<tr>
<td>6. Putting on protective glasses</td>
<td>6. Disinfect your hands immediately after removing your gloves, after the removal of the PPE</td>
</tr>
<tr>
<td>7. Hydro alcohol on hands with gloves before starting any activity</td>
<td></td>
</tr>
</tbody>
</table>

3.2 PARTICIPANTS with Home Visits

- All participants to be visited by PROCare4Life personnel must be provided with a mask. As far as possible, an attempt will be made to maintain interpersonal safety distance.
- If there is family or a caregiver in the home they should maintain the same preventive measures, i.e. wear a mask, wash their hands and maintain safe distance.
- Participants must advise if they or any family member/caregiver has had recent COVID-19 symptoms. Disinfection and ventilation of rooms in which the ProCare4Life personnel will make installations is expected.
- Participants must allow the use of the toilet for personnel if needed.
4. **General measures in Centres**

### 4.1 PERSONNEL who visit a ProCare4Life Partner Centre

- At entrance all PROCare4Life personnel will disinfect their hands with hydro alcohol and the soles of their shoes on the mats with virucidal.
- Personnel will wash their hands and if handling anything, will put on gloves.
- The greeting will be cordial, but without touching or kissing the participants, their partner or relatives, neither when arriving nor when leaving.
- Personnel will avoid touching their faces.
- At the end of the visit, gloves will be removed and/or hands washed with soap and water or hydro alcoholic solution.
- Used gloves and mask used during the day will be discarded and hands washed with soap and water before leaving the centre.
- Wash used clothing (60-90 degree wash recommended).
- Follow the recommendations in the section ‘Preventive Measures for General Hygiene’.

### 4.2 PARTICIPANTS who attend a ProCare4Life Partner Centre

- Rehabilitation groups will include an adequate number of participants in relation to the space available, so that interpersonal safety distance can be maintained.
- Sealed groups have been designed to reduce the number of interactions with different people as much as possible and thus avoid the spread of infection. It will also facilitate the traceability and identification of the people who maintain contact. Space and timetables have been organised in such a way that the different groups do not have contact with each other. This type of group is called a “bubble” to make it easier to understand and refer to it.
- Bubble groups: the same times are kept, on the same days of the week; the people attending are always the same and the same therapist (as far as possible). In such a way that the risk of contagion is limited to people who are in the same therapeutic group.
- Bubble groups will also include participants’ companions who will be waiting in the corresponding waiting rooms.
- To avoid contact between the different groups, maps of the premises have been drawn up with authorised movement flows, waiting areas and defined treatments. In this way, two differentiated common areas meet the capacity requirements according to the interpersonal distances involved. Zone 2, which contains a waiting room and adjoining toilets, will be used by the groups at the entrance to the premises. These groups will remain in zone 2 until the group that had previously entered leaves the premises. When this happens, the group waiting to receive their therapy will move to Zone 1, which will be disinfected after the previous group uses it. Zone 1 consists of a waiting room and bathrooms. This way the two groups will not cross and it will give enough time for the areas to be disinfected.
- In order to avoid contact between the therapy groups, the therapists will organise the exit in such a way that interpersonal distance can be maintained in the waiting areas and corridors. Once the distance between the rooms is assured, the therapist will allow the users to leave.
- Participants must leave the room when indicated without delay.
- The therapy rooms (tables, chairs and the required utensils) will be disinfected after the passage of each group.

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5. Actions in case of confirmation or contact with COVID-19

5.1 PERSONNEL CONFIRMED or IN CONTACT with COVID-19

The following considerations will be taken into account for personnel who come into contact with a person with suspected or actual COVID-19 disease, or a potentially infected environment:

• Casual contact with a possible, probable or confirmed case of COVID-19: personnel will be removed from their role in PC4L in accordance with local guidelines of the Occupational Risk Prevention Services and their local medical practitioner.

• The individual will follow their local medical practitioners’ and local public health guidelines relative to quarantine and diagnostic testing before resuming their position.

5.2 PARTICIPANTS CONFIRMED or IN CONTACT with COVID-19

• Participants with symptoms of a possible respiratory infection such as cough, fever or shortness of breath must inform the Centre.

If the ProCare4life personnel are made aware that a participant is confirmed of having acute COVID-19 infection, all visits and contact with the patient will be delayed until it is confirmed that the participant is no longer contagious.

5.3 ACTION on COVID-19 contacts/cases among PROCare4Life Personnel

• It is important to identify all personnel who are dealing with probable, possible or confirmed cases of COVID-19 infection. To this end, a record should be made of all personnel who come into contact with participants.

• By virtue of the local protocols (Appendix I) when there has been close contact between personnel presenting symptoms compatible with COVID-19 or a confirmed case, they will be removed from service and the case will be referred either to the Occupational Risk Prevention Service or to their NHS doctor.

• Personnel with symptoms of a possible respiratory infection, such as cough, fever or shortness of breath, should avoid going to their workplace or making home visits and should inform their direct supervisor, who will provide instructions.

• Personnel with symptoms must remain at home and consult the health services/prevention/mutual services by telephone so that an individualised assessment can be made and the situation verified and the Temporary Disability (TI) managed if necessary.

• In the event that a worker presents symptoms of acute respiratory infection, the occupational risk prevention services should indicate the performance of a laboratory diagnostic test for SARS-CoV-2 in accordance with the local “Procedure(s) for action in cases of infection by the new Coronavirus (SARS-CoV-2)“.

• If the case is classified as probable or confirmed, it will be necessary to identify all persons (personnel, participants, families, caregivers, etc.) who may have had close contact with the person while having symptoms, as defined in the aforementioned local “Procedure for action in cases of infection by the new Coronavirus (SARS-CoV-2)“.
6. Most easily affected workers

- The health service of the Occupational Risk Prevention Service must evaluate the presence of personnel who are particularly sensitive to SARS-CoV-2 coronavirus infection, establish the nature of the worker’s special sensitivity and issue a report on prevention, adaptation and protection measures. To this end, it shall take into account the existence or non-existence of conditions that allow the work to be done without increasing the risk inherent in the health condition of the individual.

- Any especially sensitive individual personnel must explain their condition as a particularly sensitive person to the human resources manager.

- The WHO provides information for high risk population groups:
  - Diabetes
  - Cardiovascular disease (including hypertension)
  - Severe chronic liver disease
  - Chronic Lung Disease
  - Chronic kidney disease
  - Immunodeficiency
  - Cancer in the active treatment phase
  - Pregnancy
  - Over 60 years old

7. Personal Protective Equipment

In accordance with local provisions, protective equipment must be certified on the basis of Regulation (EU) 2016/425 on personal protective equipment, which is evidenced by the CE conformity marking.

On the other hand, when products such as gloves or masks are intended for medical use in order to prevent a disease in the participant, they must be certified as medical devices (MP) in accordance with the local provisions which regulates them.

The same product, for which a double purpose is required, must simultaneously comply with both legislations. This is the case of gloves or masks for dual use.

In general, the recommendation is to use disposable PPE, or if this is not the case, that they can be disinfected after use, following the manufacturer’s recommendations. PPE must be chosen in such a way as to guarantee maximum protection with minimum discomfort for the user, and for this purpose it is critical to choose the size, design or size that is adequately adapted to the user.

The correct placement of PPE is essential to avoid possible routes of entry of the biological agent; equally important is their removal to avoid contact with contaminated areas and/or dispersion of the infectious agent.

The following is a description of the PIDs that might be necessary, as well as the characteristics or aspects of them that may be noteworthy in the work environment in question. This is not a description of all the PID that could protect against a biological risk, but those indicated in the case of potentially exposed personnel in the handling of people with symptoms of coronavirus infection. The evaluation of the risk of exposure will make it possible to specify the need for the most appropriate type of protection.

1. Respiratory protection

In order to avoid contagion, possible, probable or confirmed cases should wear surgical masks. Surgical masks must comply with the standard UNE-EN (14683:2019+AC: 2019). Putting on a surgical mask for a person with respiratory symptoms is the first protective measure for the worker.

The respiratory protection generally recommended for healthcare personnel who may be in contact less than 2 metres with cases under investigation or confirmed cases is a self-filtering FFP2-type mask or half-mask fitted with a P2 particle filter. In case of a shortage of protective equipment, medical personnel may also use surgical masks in combination with other preventive measures. Furthermore, our partners are not investigated or confirmed cases.

Protective screens (which must comply with the UNE-EN 140:1999 standard) must be cleaned and disinfected after use. To do so, the manufacturer’s recommendations must be strictly followed and in no case should the user apply his own methods of disinfection as the effectiveness of the equipment may be affected.

Respiratory protection equipment must be removed last, after removal of other components such as gloves, gowns, etc.

2. Protective Gloves

Protective gloves must comply with the UNE-EN ISO 374.5:2016 standard.

In care activities and in laboratories, the gloves used are disposable since the associated tasks require dexterity and do not admit other types of thicker gloves.

However, it is important to note that in any other activity that does not require as much dexterity, such as cleaning and disinfecting surfaces that have been in contact with symptomatic persons, thicker, more tear-resistant gloves may be chosen.
3. Eye and face protection
Eye protection should be worn when there is a risk of eye contamination from splashes or drops (e.g. blood, body fluids, secretions and excretions).

Eye protectors certified according to the UNE-EN 166:2002 standard for protection against liquids may be integral goggles against drops or face shields against splashes (both, field of use 3), where what is evaluated is the airtightness of the protector (in the case of integral goggles) or the coverage area of the protector (in the case of face shields).

When it is necessary to use more than one piece of personal protective equipment together, compatibility between them must be ensured. This is particularly important in the case of simultaneous respiratory and eye protection, so that their airtightness and therefore their ability to protect is not impaired.

4. Placement and removal of PPE
As indicated above, PPE should be selected to ensure adequate protection according to the form and level of exposure and that this is maintained during the work activity. This must be taken into account when placing the various PPE in such a way that they do not interfere with and alter the specific protective functions of each piece of equipment. In this respect, the manufacturer’s instructions must be respected.

After use, it must be assumed that the PPE and any protective elements used may be contaminated and become a new source of risk. Therefore, an inappropriate removal procedure may lead to user exposure.

Consequently, a detailed and predefined placement and removal sequence for all equipment must be developed and implemented and monitored.

PPE should be placed before the start of any activity likely to cause exposure and removed only after it is out of the exposure area.

PIDs must be prevented from being a source of contamination, for example by leaving them on surfaces in the environment once they have been removed.

To access information from the WHO on the placement and removal of PPE, please visit: https://www.who.int/csr/resources/publications/PPE_EN_A1sl.pdf

5. Disposal or decontamination
After removal, disposable PPE should be placed in the appropriate disposal containers

6. Storage and maintenance
PPIs must be stored properly, following the instructions given by the manufacturer, so as to avoid accidental damage to or contamination of the equipment.
How to Handwash?

WASH HANDS WHEN VISIBLY SOILED! OTHERWISE, USE HANDRUB

Duration of the entire procedure: 40-60 seconds

0. Wet hands with water;
1. Apply enough soap to cover all hand surfaces;
2. Rub hands palm to palm;
3. Right palm over left dorsum with interlaced fingers and vice versa;
4. Palm to palm with fingers interlaced;
5. Backs of fingers to opposing palms with fingers interlaced;
6. Rotational rubbing of left thumb clasped in right palm and vice versa;
7. Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;
8. Rinse hands with water;
9. Dry hands thoroughly with a single use towel;
10. Use towel to turn off faucet;
11. Your hands are now safe.

World Health Organization
Patient Safety
A World Alliance for Safer Healthcare
SAVE LIVES
Clean Your Hands

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The 7-day incidence for Germany has increased sharply since mid-February 2021 and is well above 100/100,000 population. Since mid-April, the increase had initially weakened, and since the beginning of calendar week 17, the numbers have decreased. The number of counties with a 7-day incidence above 100/100,000 population remains very high. The 7-day R-value is below 1.

In the last week, the 7-day incidence decreased in all age groups. COVID-19-related outbreaks mainly affect private households, but also occupational settings as well as kinder gardens and schools. In contrast, the number of outbreaks in nursing homes and homes for the elderly has decreased.

The increase in the number of patients requiring intensive care currently appears to have been halted. According to current knowledge, all vaccines now available in Germany provide excellent protection against the disease.

As of May 9, 2021, 268,787 vaccine doses have been administered in Germany. This means that 7,813,381 people (9.4% of the total population) have now been fully vaccinated. In total, 27,286,227 people (32.8%) have received at least one vaccine dose.

All personnel involved in installing the ProCare4life system or who needs to interact with the ProCare4Life participants will be vaccinated (both doses), will have been recently had SARS-COV2 infection or a recent (<48h) negative rapid antigen SARS-COV2 test. They also respect the distancing and hygiene rules as well as the use of individual protective devices like wearing a medical face mask or a FFP2 mask.

The associations will take all the necessary protection measures to ensure that we are adequately protecting staff and partners from those risks to their health or safety that cannot be avoided or sufficiently limited by adopting organisational measures, technical measures and, ultimately, individual protection measures. All the above measures shall be taken simultaneously if the working conditions so require.

The Ministry of Health reported on Wednesday 28/04/21 a reduction of new hospitalized cases although the overall picture remains at a challenging level. From the analysis of data relating to the period 19-25 April a reduction in the weekly incidence is observed (146/100.000 inhabitants) and Rt index is stable below 1. Based on the different trends between Italian regions the DM of the 30 April defines the specific restrictions for each region according to four level of emergency, as follows: red area, indicating high number of cases; orange area, indicating medium number of cases, yellow area, with low level of cases and white area with no cases. At the moment (3 may 2021) 15 regions are yellow, 5 are orange, 1 is red and none is white. Lombardy is a yellow area meaning that several limitations are applied as follows:

• the movements can take place without any limit on the national territory for proven work reasons, situations of need, health reasons (also to assist people in need) or with green certification COVID-19*; between other white or yellow regions there are no displacement limits
• it is possible to visit relatives or friends from 5 AM to 22 PM in a maximum of 4 people
• in the presence of infectious symptoms it is mandatory to stay at home
• public businesses, commercial activities, catering and accommodation have no limitations even if they are required to comply with the distancing, hygiene rules and to use individual protective devices.
• restaurants can only serve tables outdoors and in the time slot from 5 AM to 22 PM
• activities that take place in closed and crowded places are prohibited (nightclubs, discos, parties)
• the presence of the public at competitive events is not allowed (football and other games)
• exhibitions and congresses in presence will be allowed from 15 June but they will have to respect specific protocols
• in any workplace it is mandatory to observe the rule of the distancing and hygiene and to use individual protective devices.

Green certification COVID-19: certification is obtained in one of the following situations:
• have completed vaccination (from no more than six months)
• be cured of COVID with cessation of isolation (from no more than six months)
• have a negative rapid or molecular antigen test (for no more than 48 hours)

We suggest that the person visiting the participant’s home is in possession of Green Certification COVID-19, she/he respects the distancing, and hygiene rules and uses individual protective devices.

Italian government website for monitoring the COVID-19 pandemic:
www.salute.gov.it/portale/nuovocoronavirus/dettaglioContenutiNuovoCoronavirus.jsp

PORTUGAL

During the outbreak of pneumonia by the new Coronavirus – COVID-19 the Portuguese government has been taking all necessary public health measures to protect the entire population. The analysis of the evolution of the outbreak is constant and implementation of new measures will be carried out whenever necessary.

General behavior guidelines were enacted, in which all people must adopt the following rules:
• Social distancing
• Frequent hand washing
• Mandatory use of mask
• Respiratory etiquette

In order to prevent the spread of the virus and the possibility of contagion, all services should take hygiene and sanitization measures according to the indications of the Directorate-General for Health, with specific recommendations for various sectors of activity.

Context:
• Since the beginning of the epidemic a total of 819,210 cases and 16,814 deaths have been reported.
• On 25th March 2021 it was also reported a total of 31,948 positive people, a total of 15,035 people in surveillance, 695 people were hospitalized in non-intensive wards, while 154 people were hospitalized in intensive care units and 9 deaths per day have been reported.
• The Ministry of Health reported on Tuesday 25/3/21 an incidence of 77.6 new cases per 100,000 population and a R(t) of 0.91.
• Following the COVID-19 vaccination strategy in Portugal, 1,434,044 doses administered, being 460,863 the number of people with the full vaccination regimen.

Context: Torres Vedras

Torres Vedras has a population of 78,530 people, of which currently 63 are positive for SARS-CoV-2 and 196 people are in surveillance.

Last January 2021, the country had a very sharp rise in cases, so the government declared the lock down for the whole country. Recently, some services started opening, declaring that it would be slow and contained to avoid a new infections. On 17th March, 2021 new measures were approved:
• Resume of in person teaching activities for children pre-school, 1st cycle of basic education and leisure activity centers for these ages;
• Reopening of establishments of non-essential goods exclusively in a home delivery or provision of goods at the door of the establishment regimen;

• Restaurants and similar only in take away;

• Ban on moving between municipalities except for work or health reasons between 24th of March and 2nd of April;

• Social or family gatherings, both in public and private spaces, open or closed, are no allowed;

• Teleworking whenever possible.

In accordance with the COVID-19 vaccination strategy in Portugal, we are now vaccinating:

• Front-line staff in the health and social-health care field (people who are at greater risk of exposure because they carry out direct care activities with COVID-19 patients, as well as because they are more likely to have contact with a person with SARS-CoV-2 infection).

• Other health, social-health care personnel

• Older adults

• People with a higher risk of develop a severe form of COVID if infected

Context: CNS

• Currently the direction of CNS, according to the indications of the local Health Protection Agency, recommends attending members follow all the hygienic and social distance measures. All staff and users that were admitted previous to 19th of January are vaccinated. All staff is tested every month.

Potential consequences

• Difficulties in the implementation of PROCare4Life system due to mobility restriction and health recommendations. Since most participants are older adults, many are afraid to go to the center to participate in a study or that researchers visit them at home for this purpose.

Possible solutions

• As more people are vaccinated, if the number continues to decrease, we will be more confident to accept participants.

https://covid19.who.int/region/euro/country/pt

References:


ROMANIA

In Romania, from 3 January 2020 to 10 of May 2021, there have been 1.2 million confirmed cases of COVID-19 with 28.903 deaths, reported to WHO.

As of 10 May 2021, 2,366,308 vaccine doses have been administrated to the Romanian population. Since Nov-Dec 2020 until March, the number of COVID patients and deaths related to COVID stared to increase. Bucharest is still one of the most affected counties of Romania, with an incidence of people getting infected with the SARS-COV2 virus higher than 3/1000 (see image 3) until March 2021. Since mid-April, number of COVID cases started to decrease, almost all cities in Romania entering in the “green scenario”.

Context: Bucharest

Bucharest is one of the most affected cities in Romania by the COVID pandemic. Since the start of the pandemic, 180,024 total cases of COVID infections were confirmed. Since mid-April, the number of COVID-cases started to decline, and Bucharest is now in the “green scenario”. Given the evolution of the COVID-19 infections, in Romania, restrictions are still in order, according to the current in force legislation (Government Decision. No. 293/2021, Law no. 55/2020). Therefore, all personnel responsible for installing the ProCare4life system will comply with the legislation in force (rules may differ from city to city, and from a period of time to another). Until the 3rd of May, Bucharest was in the “red scenario” (all shops were closed at 21:00 from Monday to Thursday, and at 18:00 from Friday to Sunday, cinemas, schools, theatres, universities were closed, restaurants and gyms were closed inside and no one was allowed to walk outside their homes after 22:00 PM (Monday-Thursday) and after 20:00 (Friday to Sunday).
Since the 4th of May, cinemas, theatres, gyms, restaurants are now opened (can allow 30% of their total capacity), but must close at 21:00 PM, and people are allowed to walk outside their home until 22:00 PM from Monday-Sunday. Maximum 6 people are allowed to gather in family meetings.

Romanian legislation can be consulted in the following links:

http://legislatie.just.ro/Public/DetaliiDocument/227953
http://legislatie.just.ro/Public/DetaliiDocumentAfis/239080

Context: UHB

Since the 3rd wave of COVID infections started, more severe cases of COVID patients are hospitalized. More patients which were previously hospitalized with neurological diseases are now also infected with the new coronavirus, which makes the treatment and management more complicated. Few intra-hospitalization coronavirus infections were also reported.

The neurology department of UHB has 28 beds reserved for COVID patients. Moreover, due to safety concerns, the total number of beds which can be used for hospitalization of non-covid patients in the neurology department was also reduced (~48 beds, compared with before the pandemic ~100 beds).

Doctors (including the personnel participating to the ProCare4Life project) are working extra shifts in the COVID department (usually 1 week/month). Wards in the neurology & emergency department are filling due to the high number of infected persons.

All personnel involved in installing the ProCare4life system or who need to interact/meet the ProCare4life participants will be vaccinated (both doses), will have been recently had SARS-COV2 infection or a recent (<48h) negative rapid antigen SARS-COV2 test. Moreover, all personnel who have symptoms compatible with SARS-COV2 infection will be isolated according to Romanian regulation and given medical attention as needed.

SPAIN

The Ministry of Health, within the framework of the Plan for the transition to a new normality, of 28 April, published the Strategy for diagnosis, surveillance and control in the transition phase of the COVID-19 pandemic, of 6 May 2020, which has been transferred to the BOE by Order SND/404/2020, of 11 May, on measures for epidemiological surveillance of SARS-CoV-2 infection during the transition phase towards a new normality, which regulates the obligations and procedures for obtaining and communicating information for epidemiological surveillance in relation to COVID-19 infection.

- COVID-19 OCCUPATIONAL CONTACT AND CASE MANAGEMENT PROCEDURE FOR LABOUR RISK
9. ANNEXES

9.1 PERSONNEL Confirmed or IN CONTACT with COVID-19

In accordance with the local provisions on the Prevention of Occupational Risks on Individual Protection Equipment, as well as the company’s action protocol for exposure to Covid 19:

On behalf of ProCare4Life’s Partner

Mr. /Ms. ___________________________ with D.N.I. No. ___________________________

with job position ___________________________

accepts the delivery of the following Personal Protection Equipment approved and with the corresponding CE marking, which are marked with an “X”.

<table>
<thead>
<tr>
<th>Material</th>
<th>Quantity</th>
<th>Delivered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gloves</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical mask</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protective glasses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disposable bags</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydro alcoholic gel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydro alcoholic spray</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wipes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hand towel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protective jacket</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The receiver of the equipment acknowledges that s/he has been informed of its use in accordance with the local Protocol of Action against Covid 19, and that s/he has received the necessary training for its correct use, and furthermore accepts the commitment:

• To use the equipment as long as it accesses the areas and zones obliged to do so.
• To consult any doubt about its correct use, as well as to take care of its correct state of use and conservation.
• Store it at the end of the working day in a suitable place for this purpose.
• Report any loss or damage to the equipment and request a new one from immediate.

In order to ensure compliance with workers’ obligations in terms of risk prevention, as by local worker statutes, failure by workers to comply with this duty in terms of risk prevention shall be considered at breach of duty for the purposes of the ProCare4Life project.

Signed: ___________________________ Date: ___________________________
9.2 CLOSE CONTACT

Local prevention services logo

Mr. /Ms. ___________________________ Participant number: ___________________________

National ID Number: ___________________________

specialist in occupational medicine of the prevention service: ___________________________

informs that:

Mr./Ms. ___________________________ National ID Number: ___________________________

fulfils the criteria to be considered as a close contact of a possible, probable or confirmed case of coronavirus occurring in the company of ___________________________

Following the criteria of the Procedure of action against cases of infection by the new coronavirus (SARS-CoV-2) and the Procedure of action against occupational risks of the new coronavirus (SARS-CoV-2) of the Ministry of Health, s/he must carry out home quarantine for 14 days, starting from the day ___________________________

the date on which the contact occurred. This person will maintain, as indicated, passive monitoring at home. If during this time s/he develops symptoms and the clinical situation allows it, s/he has been advised to immediately self-isolate at home and contact primary care services.

Place: ___________________________ Date: ___________________________

Signature: ___________________________
9.3 MOST EASILY AFFECTED WORKERS

Local prevention services logo

Mr./Ms. [Name]  Participant number: [Number]
National ID Number: [ID]
specialist in occupational medicine of the prevention service: [Name]

informs that:

Mr./Ms. [Name]  National ID Number: [ID]

complies with the criteria of the local Ministry of Health's Procedure for Occupational Risk Actions against the New Coronavirus (SARS-CoV-2), and is to be considered a working person with special sensitivity in relation to the SARS-CoV2 coronavirus infection, without the possibility of adaptation of the workplace, adequate protection to avoid contagion or relocation to another job free of risk of exposure in [Company].

For all these reasons, the worker should be temporarily disabled.

Place: [Place]  Date [Date]
Signature: [Signature]
9.4 Laws on the prevention of occupational hazards

GERMANY

There are two legislative decisions that seem to be of importance in this case. On the one hand, there is the Occupational Safety and Health Act “Occupational Health and Safety Act of August 7, 1996 (BGBl. I p. 1246), as last amended by Article 1 of the Act of December 22, 2020 (BGBl. I p. 3334).” The Occupational Health and Safety Act (ArbSchG) regulates all matters and basic obligations relating to the protection of employees in the workplace. This includes health protection, the design of work and rooms as well as compliance with legally defined working hours. This also includes dealing with hygiene and risks due to the threat of illness. Here is the link to the original document:

www.gesetze-im-internet.de/arbschg/BJNR124610996.html

Here is the link to the official english version: www.gesetze-im-internet.de/englisch_arbschg/

On the other hand, there are legal regulations for dealing with infectious diseases and their prevention. Infection Protection Act of July 20, 2000 (BGBl. I p. 1045), as last amended by Article 1 of the Act of May 28, 2021 (BGBl. I p. 1174).” The Act on the Prevention and Control of Infectious Diseases in Humans (Infection Protection Act - IfSG) regulates the prevention and control of infectious diseases and aims to prevent human diseases and to detect infections at an early stage and prevent their further spread. To this end, the IfSG specifies which diseases (and which laboratory diagnostic evidence of pathogens) must be reported in the event of suspicion, illness or death. In addition to general regulations, various sections of the IfSG cover, among other things, early detection, epidemiological surveillance, prevention of communicable diseases (such as protective vaccinations), control of communicable diseases, for example with protective measures, and protection against infection in certain facilities. In addition, this also includes legal requirements regarding water for human consumption, health requirements for personnel handling food, activities with pathogens, etc. This also includes the prevention of occupational hazards with regard to communicable diseases.

Here is the link to the original document: www.gesetze-im-internet.de/ifsg/BJNR104510000.html

Unfortunately, there is no official version of this law in English. These two pieces of legislation together form the comprehensive occupational hazard prevention laws in Germany.

ITALY

Risk Assessment is an obligation for all Employers. To simplify the drafting of the document numerous circulars have been issued by the Ministry of Labor, by the Ministry of the Interior, by the Higher Institute for Occupational Health and Safety and by the Conference State / Regions.

The Legislative Decree 81/08 does not determine precise rules regarding the form of the document risk assessment, however, the Employer has specific duties regarding the complete assessment of all risks to the safety and health of workers.

Employer will have to elaborate in the drafting of the document and more precisely:

- draw up a report on the assessment of risks for safety and health at work, in the which are the estimation criteria specified;
- identifying prevention and protection measures to eliminate risks or, if not, introduce measures to reduce them;
- identify individual protection devices;
- identify workers exposed to potential risks;
- plan the measures deemed appropriate to ensure the improvement over time of the levels of safety;
- the employer must also take into account visitors and contractors, the public and people who frequent workplaces and who normally don’t they know the risks of work.

The Risk Assessment Document is therefore configured as a supporting operational estimation tool of the organization of Corporate Security, as well as a tool capable of identifying what is connected the activation of the necessary procedures and the implementation of organizational and / or structural interventions.
Main rules on safety at work

Accident prevention

Decree of the President of the Republic 302/1956

Legislative Decree 242/1996: implementation of Community directives concerning the improvement of the safety and health of workers on the workplace

Council Directive 89/391: the implementation of measures aimed at promoting the improvement of workers' safety and health at work

Legislative Decree 66/2000: modification of title VII “Protection from carcinogens”.

Legislative Decree 81/2008: Implementation of art. 1 of the law of 3 August 2007 on the protection of safety and health of workers in the workplace

Accident prevention

Decree of the President of the Republic 303/1956: General rules for occupational hygiene

Decree of the President of the Republic 962/1982: Implementation of Directive (EEC) no. 78/610 related to protection health of workers exposed to monomer vinyl chloride


Law 1203/1957: Ratification and execution of the following international agreements signed in Rome on 25 March 1957:

• Treaty establishing the European Atomic Energy Community and annexed acts;
• Treaty establishing the European Economic Community and annexed acts;
• Convention relating to certain institutions common to the European Communities.


Ministerial Decree 16/01/1992: Definition of cases of reduction in the frequency of visits to the environments by the competent doctor.

Personal protective equipment


Ministerial Decree 02/05/2002: Criteria for the identification and use of personal protective equipment.

PORTUGAL

Concerning the safety and health of workers at work and minimum health and safety requirements for the use by workers of personal protective equipment at the workplace, there are two specific laws debating these subjects (Government Decision no. 1048 of 09/08/2006 and LAW no 319 of 14 July 2006). They can be consulted using the following links:

www.inspectamuncii.ro/documents/66402/267275/Law+319+on+2006.pdf/43ef9465-6bf5-44c4-b912-3f7fa74ecee8

www.inspectamuncii.ro/documents/66402/267275/GD+1048+on+2006+%281%29.pdf/837d3307-2546-452c-9226-1e48c5c0804e

ROMANIA

Concerning the safety and health of workers at work and minimum health and safety requirements for the use by workers of personal protective equipment at the workplace, there are two specific laws debating these subjects (Government Decision no. 1048 of 09/08/2006 and LAW no 319 of 14 July 2006). They can be consulted using the following links:

www.inspectamuncii.ro/documents/66402/267275/Law+319+on+2006.pdf/43ef9465-6bf5-44c4-b912-3f7fa74ecee8

www.inspectamuncii.ro/documents/66402/267275/GD+1048+on+2006+%281%29.pdf/837d3307-2546-452c-9226-1e48c5c0804e

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under the Grant Agreement No. 875221.
Article 29 of Law 31/1995 of 8 November. Workers’ obligations in the field of risk prevention.

1. It shall be the responsibility of each worker to ensure, according to his possibilities and by complying with the preventive measures adopted in each case, his own safety and health at work and that of other persons who may be affected by his professional activity because of his acts and omissions at work, in accordance with his training and the instructions of the employer.

2. Workers shall, in accordance with their training and on the instructions of their employer, in particular:
   a. Make appropriate use, in accordance with their nature and the foreseeable risks, of the machines, apparatus, tools, dangerous substances, transport equipment and, in general, any other means by which they carry out their activity.
   b. Use the protective means and equipment provided by the employer correctly, in accordance with the instructions received from the employer.
   c. Not to put out of operation and to use correctly the existing safety devices or those that are installed in the means related to their activity or in the workplaces where it takes place.
   d. Inform immediately their direct superior and the workers designated to carry out protection and prevention activities or, where appropriate, the prevention service, of any situation which, in their opinion, involves a risk to the safety and health of the workers.
   e. Contribute to the fulfilment of the obligations established by the competent authority in order to protect the safety and health of workers.
   f. Cooperate with the employer to ensure that working conditions are safe and do not pose risks to the safety and health of workers.

3. Non-compliance by workers with the obligations in the area of risk prevention referred to in the previous paragraphs shall be considered a labour non-compliance for the purposes of Article 58.1 of the Workers’ Statute or a misdemeanour, where applicable, in accordance with the provisions of the corresponding regulations on the disciplinary regime of public officials or statutory personnel in the service of the public administrations. The provisions of this section shall also be applicable to the participants of the cooperatives whose activity consists of providing their work, with the details established in their Internal Regulations.