POST-COVID-19 FUNCTIONAL STATUS SCALE MANUAL

Version 2, July 2020

Manual to the Post-COVID-19 Functional Status Scale for physicians and study personnel – including corresponding structured interview and assessment tools

Introduction

Post-acute care of patients with Coronavirus disease 2019 (COVID-19) will become particularly relevant after having addressed the surge of infections in the acute care settings. It is anticipated that an infection with Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) may have a major impact on physical, cognitive, mental and social health status in the long run, also in patients with mild disease presentation. Given the heterogeneity of COVID-19 in terms of clinical and radiological presentation, it is pivotal to have a simple tool to monitor the course of symptoms and their impact on the functional status of patients. An easy and reproducible instrument to identify those patients suffering from slow or incomplete recovery would help guiding pondered use of medical resources and will also standardize research efforts.

A scale to quantify current functional outcome in COVID-19 patients

The post-COVID-19 functional status (PCFS) scale (**Table 1**) focuses on relevant aspects of daily life during follow-up after the infection. The scale is intended to help users becoming aware of current functional limitations in COVID-19 patients, whether or not as a result of the specific infection, and to objectively determine this degree of disability. As such, the scale is not meant to replace other relevant instruments for measuring quality of life, tiredness or dyspnoea, but is developed to use as an additional tool for evaluating the ultimate consequences of COVID-19 on functional status. This will aid in demarcating effective and ineffective COVID-19 therapies on functional outcomes in an experimental setting, as well as pave the road for value-based healthcare.

Recently, our group proposed an ordinal scale for assessment of patient-relevant functional limitations following an episode of venous thromboembolism (VTE): the post-VTE functional status (PVFS) scale (Boon GJAM et al. 2020, Thromb Res; Klok FA et al. 2019, Thromb Res). This scale was

developed after literature review and discussion with both international experts via a Delphi analysis and with patients via focus groups. As a result, good-to-excellent inter-observer agreement of scale grade assignment between self-reported values and independent raters was achieved. A slightly adapted scale for COVID-19 could be of great use to determine functional recovery, beyond binary outcomes such as mortality, in these patients (Klok et al. 2020, ERJ).

General Instructions

Characteristics of the PCFS scale

The scale is ordinal, has 6 steps ranging from 0 (no symptoms) to 5 (death, D), and covers the entire range of functional outcomes by focusing on limitations in usual duties/activities either at home or at work/study, as well as changes in lifestyle. The scale grades are intuitive and can easily be grasped by both clinicians and patients.

Timing

The post-COVID-19 functional status is intended to be assessed 1) at the time of discharge from the hospital, 2) in the first weeks after discharge to monitor direct recovery, e.g. at 4 and 8 weeks post-discharge, and 3) 6 months after a COVID-19 diagnosis to assess the degree of persistent disability. Providing a reference value (pre-COVID-19 grade) is optional and will allow to measure the change in status. To measure this pre-COVID-19 functional status, the functional status assessment should refer to the status 1 month prior to the infection. While inquiring the patient on the pre-COVID-19 grade, it is recommended to ask multiple questions to ascertain the change in functional outcome. Assessment of the pre-COVID-19 functional status should be preceded by the first assessment of the current functional status.

Procedure

The post-COVID-19 functional status scale can be assessed by either medical experts or trained interviewers during a short structured interview, or may be self-reported by the patient. Assigning the

appropriate PCFS scale grade by the patient him or herself can be done by using the patient questionnaire (**Table 2**) and a simple flowchart (**Figure 1**). In the setting of clinical trials, using the structured interview is recommended as it is designed to further reduce subjectivity and bias between raters.

For any type of data collection, raters are encouraged to base their assessments on the *ability* of the patient to perform the activity rather than whether the patient actually performs the activity currently. This prevents overestimation of the severity of symptoms in patients who have chosen to abandon or who simply never performed certain activities in the course of a COVID-19 diagnosis**.**

General description of each scale grade

Grade 0 reflects the absence of any functional limitation. Grades 1 and 2 correspond to a condition for which usual duties/activities could be carried out, defined as any activity that patients undertake on a monthly basis or more frequently, either at home or at work/study. Importantly, this includes sports and social activities. Specifically, *Grade 1* is reserved for patients with some symptoms, which however do not prohibit or limit doing any usual activities. Grade 2 is reserved for patients who are able to independently perform all usual activities but at a lower intensity, sometimes combined with mild limitations in participation in usual social roles.

Grade 3 accounts for moderate functional limitations that force patients to structurally modify usual activities, reflecting the inability to perform certain activities which, therefore, need to be taken over by others. Those patients may require assistance in instrumental activities of daily living (iADL), e.g. managing basic household chores, community mobility, shopping for groceries or necessities, or participation in usual social roles is restricted.

Grade 4 describes those patients with severe functional limitations who require assistance with activities of daily living (ADL), not necessarily administered by a certified nurse. It should be indicated that assistance with some ADL activities, e.g. using the toilet, managing routine daily hygiene and functional mobility, is essential. Participation in usual social roles is likely restricted.

The death of a patient is recorded in grade D, and is mainly relevant in the setting of clinical research and quality control.

Structured interview to the post-COVID-19 functional status scale

The structured interview in the setting of clinical trials facilitates the objective assignment of patients to scale grades. Information should be ideally obtained primarily from the patient and/or a close friend or caregiver (proxy) who is familiar with the daily routine of the patient. If the patient lacks insight into some questions or if responses are inconsistent, it may be helpful to interview a caregiver or relative independently. The standardized questions cover 5 sections corresponding to the separate levels of disability (**Table 1**). However, it is encouraged to ask questions beyond those stated to ensure that the patient has grasped the meaning of the question and to further clarify their responses. Additionally, it is recommended to adapt the interviewing strategy according to the patient's status and his/her answers. Open questions can be a great way to start the interview, during which some key information will be obtained useful to score the patients. Later, more targeted or even closed questions can help to make a clear distinction between adjacent grades.

Table 1: The post-COVID-19 Functional Status (PCFS) Scale

PCFS scale grade + description		Section of the structured interview
0	**No functional limitations** No symptoms, pain, depression or anxiety.	Symptom checklist
1	**Negligible functional limitations** All usual duties/activities at home or at work can be carried out at the same level of intensity, despite some symptoms, pain, depression or anxiety.	Symptom checklist
2	**Slight functional limitations** Usual duties/activities at home or at work are carried out at a lower level of intensity or are occasionally avoided due to symptoms, pain, depression or anxiety.	Participation in usual social roles *(independently able to perform all duties/activities, even if occasional adjustment in tempo or frequency is needed)*
3	**Moderate functional limitations** Usual duties/activities at home or at work have been structurally modified (reduced) due to symptoms, pain, depression or anxiety.	Instrumental ADL; participation in usual social roles *(inability to perform certain duties/activities which are taken over by others)*
4	**Severe functional limitations** Assistance needed in activities of daily living due to symptoms, pain, depression or anxiety: nursing care and attention are required.	Constant care; basic ADL; instrumental ADL; participation in usual social roles
D	**Death**	-

Structured interview to the Post-COVID-19 Functional Status Scale

INSTRUCTIONS

Please mark the appropriate boxes and respond to all questions. Check for consistency as you proceed, responses to later questions may suggest revision to earlier responses. Limitations or symptoms may vary over time, *the measurement concerns the average situation of the past week (except for when assessed at discharge, in that case it concerns the situation of the day of discharge).* The corresponding PCFS scale grade is provided in the column besides each specific response. In case two grades seem to be appropriate, the patient will be assigned to the highest grade with the most limitations.

SCALE ASSESSMENT

Name / ID patient	
Date of COVID-19 diagnosis	__ __ / __ __ / __ __ __ __
Date of assessment of the PCFS scale	__ __ / __ __ / __ __ __ __
Setting	At discharge ☐ Outpatient visit at 4 weeks ☐ Outpatient visit at 8 weeks ☐ Outpatient visit at 6 months ☐ Other (specify) ☐ _____
Respondent(s)	Patient ☐ Patient and another person ☐ Only another person ☐ Specify _____
Rater	Physician ☐ Study personnel ☐

STRUCTURED INTERVIEW

1. SURVIVAL	**Corresponding PCFS scale grade if the answer is 'YES'**
1.1 Has the patient died after the COVID-19 diagnosis?	**D**

2. CONSTANT CARE Explanation: meaning someone else needs to be available at all times. Care may be provided by either trained or an untrained caregiver. The patient will usually be bedridden and may be incontinent.	**Corresponding PCFS scale grade if the answer is 'YES'**
2.1 Do you require constant care?	**4**

3. BASIC ACTIVITIES OF DAILY LIVING (ADL) Explanation: assistance includes physical assistance, verbal instruction, or supervision by another person. It may be considered *essential* when there is a need for physical help (by another person) with an activity or for supervision, or the patient needs prompting or reminding to do a task. The need for supervision for safety reasons should be due to *objective danger* that is posed, rather than 'just in case'.	**Corresponding PCFS scale grade if the answer is 'YES'**
3.1 Is assistance essential for eating? (Eating without assistance: food and implements may be provided by others)	**4**
3.2 Is assistance essential for using the toilet? (Using toilet without assistance: reach toilet/commode; undress sufficiently; clean self; dress and leave)	**4**
3.3 Is assistance essential for routine daily hygiene? (Routine hygiene includes only washing face, doing hair, cleaning teeth/fitting false teeth. Implements may be provided by others without considering this as assistance)	**4**
3.4 Is assistance essential for walking? (Walking without assistance: if absolutely necessary, able to walk indoors or around house or ward, may use any aid, however not requiring physical help or verbal instruction or supervision from another person)	**4**

4. INSTRUMENTAL ACTIVITIES OF DAILY LIVING (iADL) Explanation: assistance includes physical assistance, verbal instruction, or supervision by another person. It may be considered *essential* when there is a need for physical help (by another person) with an activity or for supervision, or the patient needs prompting or reminding to do a task. The need for supervision for safety reasons should be due to *objective danger* that is posed, rather than 'just in case'.	**Corresponding PCFS scale grade if the answer is 'YES'**
4.1 Is assistance essential for basic household chores which are important for daily life? (E.g. preparing a simple meal, doing the dishes, take out the garbage; exclude chores that do not need to be done every day)	**4**
4.2 Is assistance essential for local travel? (Local travel without assistance: the patient may drive or use public transport to get around. Ability to use a taxi is sufficient, provided the patient can manage to call and instruct the driver)	**4**
4.3 Is assistance essential for local shopping? (The patient is not able to buy groceries or necessities by him or herself)	**3**

5. PARTICIPATION IN USUAL SOCIAL ROLES Explanation: this section concerns impairment in fulfilment of major social roles (not social or financial circumstances).	**Corresponding PCFS scale grade if the answer is 'YES'**
5.1 Is adjustment essential for duties/activities at home or at work/study because you are unable to perform these yourself (e.g. resulting in a change in the level of responsibility, a change from full-time to part-time work or a change in education)? (Work refers to both paid employment and voluntary work. Special arrangements which allow someone to return to work, even though normally he/she wouldn't be able to work, should be considered as adjustment of work.)	**3**
5.2 Do you occasionally need to avoid or reduce duties/activities at home or at work/study or do you need to spread these over time (while you are basically able to perform all those activities)?	**2**
5.3 Can you no longer take good care of loved ones as before? (Taking good care includes babysitting, looking after your partner, parents, grandchildren or dependent others.)	**3**
5.4 Since the COVID-19 diagnosis, have there been problems with relationships or have you become isolated? (These problems include communication problems, difficulties in relationships with people at home or at work/study, loss of friendships (increase in) isolation, etc.)	**3**
5.5 Are you restricted in participating in social and leisure activities? (Comprising hobbies and interests, including going to a restaurant, bar, cinema, going for walks, playing games, reading books, etc.)	**2**

6. SYMPTOM CHECKLIST Explanation: these can be any symptoms or problems reported by the patients or found on physical examination. Symptoms include but are not limited to: dyspnoea, pain, fatigue, muscle weakness, memory loss, depression and anxiety.	**Corresponding PCFS scale grade if the answer is 'YES'**
6.1 Do you report symptoms through which usual duties/activities need to be avoided, reduced or spread over time?	**2**
6.2 Do you report any symptoms, resulting from COVID-19, without experiencing functional limitations?	**1**
6.3 Do you have problems with relaxing or do you experience COVID-19 as a trauma? ('Trauma' is defined as: suffering from intrusive memories, flashbacks or avoidance responses, associated with having experienced COVID-19.)	**1**

Assigning a grade on the post-COVID-19 functional status scale

The overall rating is simply the poorest functional status indicated by the patient's answers (the highest grade corresponds with the most limitations). If a respondent has no limitations or symptoms, then the appropriate scale grade is 0.

Final PCFS scale grade: _____

What was your PCFS scale grade *before* COVID-19? _____

Measure the impact of COVID-19 on your life yourself: manual to the Post-COVID-19 Functional Status Scale for patients

To indicate and discuss your current functional status, you can use the flowchart (**Figure 1**) and the patient questionnaire (**Table 2**), both belonging to the post-COVID-19 functional status scale. This PCFS scale covers the entire range of functional outcomes by focusing on limitations in usual duties/activities either at home or at work/study, as well as changes in lifestyle. Sports and social activities are also included in this. Limitations or symptoms may or may not be directly linked to COVID-19 and may have been present for a longer time period. They may vary over time, *the measurement concerns the average situation of the past week (except for when assessed at discharge, in that case it concerns the situation of the day of discharge).*

You can assign yourself to the appropriate PCFS scale grade by following the steps of the flowchart and by ticking the right box in the table. In case two grades seem to be appropriate, always choose the highest grade with the most limitations. Together with your treating physician you can coordinate when and how often you should measure your functional status. The treating physician will compare these results with normal recovery after the infection. In case of slow or incomplete recovery, the physician will indicate whether additional diagnostic tests are necessary, or treatment could be started.

Figure 1: Flowchart for patient self-report of the Post-COVID-19 Functional Status Scale

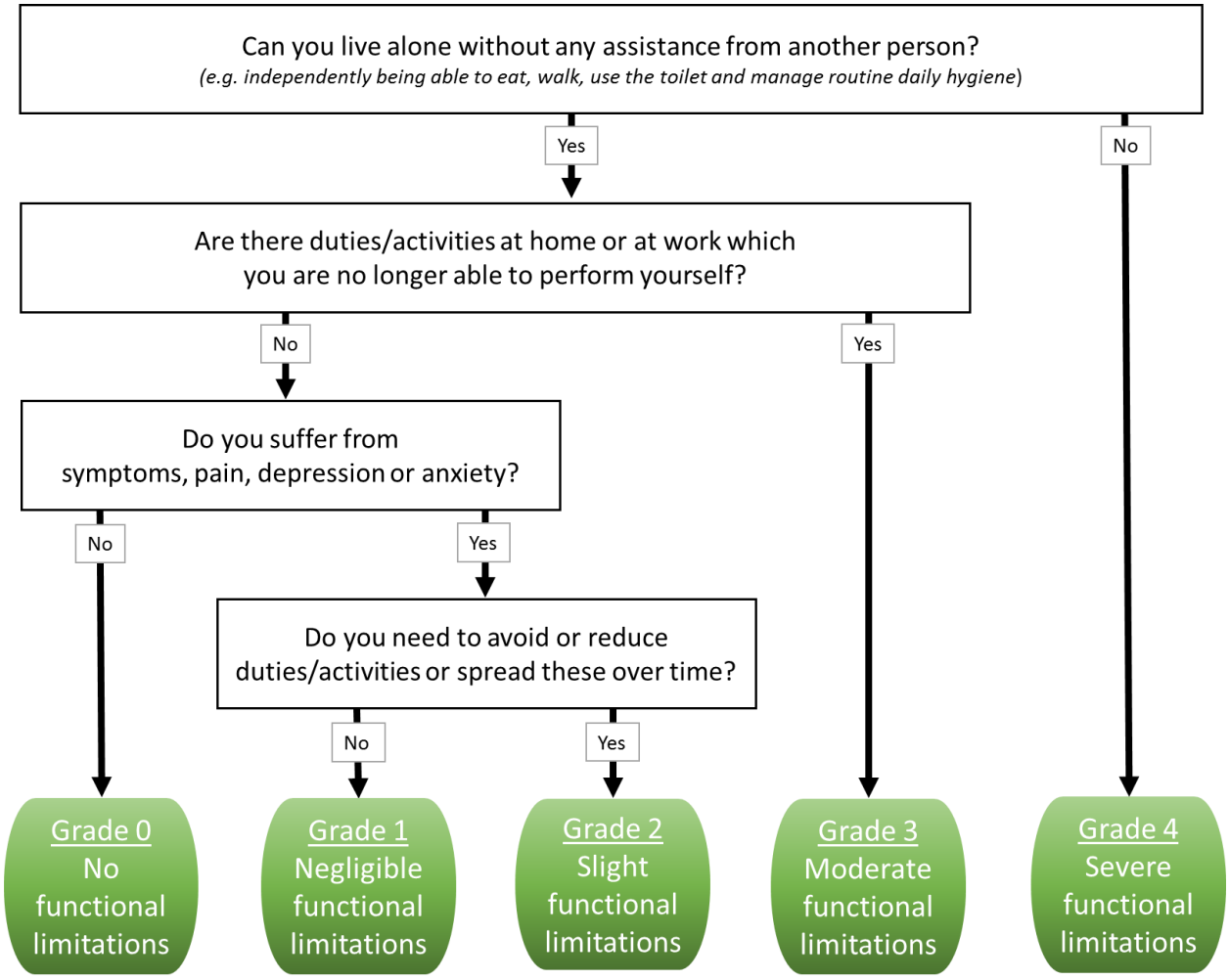

Table 2: Patient questionnaire for patient self-report of the Post-COVID-19 Functional Status Scale

How much are you currently affected in your everyday life by COVID-19? **Please indicate which one of the following statements applies to you most.** *Please tick only one box at a time.*		**Corresponding PCFS scale grade if the box is ticked**
I have no limitations in my everyday life and no symptoms, pain, depression or anxiety.	☐	0
I have negligible limitations in my everyday life as I can perform all usual duties/activities, although I still have persistent symptoms, pain, depression or anxiety.	☐	1
I suffer from limitations in my everyday life as I occasionally need to avoid or reduce usual duties/activities or need to spread these over time due to symptoms, pain, depression or anxiety. I am, however, able to perform all activities without any assistance.	☐	2
I suffer from limitations in my everyday life as I am not able to perform all usual duties/activities due to symptoms, pain, depression or anxiety. I am, however, able to take care of myself without any assistance.	☐	3
I suffer from severe limitations in my everyday life: I am not able to take care of myself and therefore I am dependent on nursing care and/or assistance from another person due to symptoms, pain, depression or anxiety.	☐	4