

CARE for COVID-19: A Checklist for Documentation of Coronavirus Disease 2019 Case Reports and Case Series

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ABSTRACT

Coronavirus disease 2019 (COVID-19) is a new, rapidly spreading pandemic that can lead to a life-threatening disease. Accurate and transparent COVID-19 case reports provide systematic clinical observations supporting researchers designing clinical trials and clinicians delivering health care. The checklist described here is designed to systematically and accurately capture data from case reports and case series for documentation on COVID-19. It is aligned with the CARE guidelines, available from the EQUATOR (Enhancing the QUALity and Transparency Of health Research) Network.

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is a viral infection with severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2), first detected in December 2019 in Wuhan, China.¹ COVID-19 spread as a pandemic throughout the world, with more than 9 million confirmed cases and more than 470,000 deaths worldwide as of June 23, 2020.² The widespread and sometimes fatal outcome of this pandemic necessitates the acquisition of reliable knowledge about this disease. Much of the early evidence has come from case reports and case series.³⁻¹⁰ Prospective clinical research trials and reviews on COVID-19 have begun; however, the clinical observations of patients captured in accurate and transparent COVID-19 case reports provide systematic clinical observations supporting researchers designing clinical trials and clinicians delivering health care. This information will gather important observations across different fields of medicine treating different patients with different treatment approaches as well as the frequency and types of adverse events and complications. In 2013 and 2017 the CARE Group published the health research reporting guideline for case reports,^{11,12} which has been adopted and adapted by many medical fields.^{13,14}

DOCUMENTATION CHECKLIST CARE FOR COVID-19

We present here a documentation checklist for the elaboration of COVID-19 case reports (Table 1). This checklist is designed to systematically and accurately capture data from case reports and case series for documentation on COVID-19 and is aligned with the CARE¹⁵ guidelines; this and other health research reporting guidelines are available from the EQUATOR¹⁶ (Enhancing the QUALity and Transparency Of health Research) Network. This checklist aims to support the collection of important clinical information as generally given in the items 5, 6, 8, 9, and 10 of the CARE Guideline Checklist.¹¹ The checklist has been elaborated by 3 members of the CARE Group and represents a tool for

clinicians and researchers who want to present new information with importance for the medical community.

Guideline Development

For elaboration of this guideline, data from clinical and scientific literature (eg, ^{1,3-10,17,18}) and from current research projects (eg, NCT04331509, NCT04333407, NCT04291053, NCT04344171, NCT04323332, DRKS00021145¹⁹) were screened and included in the elaboration of the checklist. Items were especially included if they represent a special characteristic of the patient regarding risk, diagnostic certainty, and severity of the disease. This checklist is compatible with the Lean European Open Survey on SARS-CoV-2 (LEOSS; <https://leoss.net>), the publicly funded European COVID-19 registry. As the disease has different grades of severity and complications (Figure 1), additional items ask to give details about the patient's course in the intensive care unit.

The item collection was done by 1 author (PGW) and checked by 2 others (GSK, DR). After completion, the checklist was sent out to several researchers and physicians in charge of patients with COVID-19. Feedback from these experts was included in the revision of the checklist. The checklist was then sent out in English and in translations (German, Portuguese, and Spanish) to physicians in charge of patients with COVID-19. Their feedback was included in another revision of the current checklist. The checklist is currently available in English, German, Portuguese, Russian, and Spanish (see supplemental material to this article available at www.thepermanentejournal.org/files/2020/20.127supp.pdf).

How to Use This Checklist

This checklist can be used to achieve a more complete documentation and description of patients with COVID-19, including therapeutic treatment with off-label conventional medicine or complementary and alternative therapies. In case reports and case series mentioning new therapeutic interventions, additional information may be necessary such as TIDieR (template for intervention description and replication),²⁰ a guideline designed

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to clarify therapeutic interventions that is available from the EQUATOR¹⁶ Network.

For the preparation of a COVID-19 case report or case series, follow the structure of the CARE guideline checklist.¹¹ For the details about the patient information, use this CARE for COVID-19 checklist to include all important items. Judge for yourself whether all the items of this list are applicable to your report and use those that are applicable.

Improvement of This Checklist and Future Outlook

Although more than 2000 articles about COVID-19 are already displayed in MEDLINE, the knowledge about this disease is still growing rapidly. Future progress in diagnosis and treatment of this disease will lead to a more precise description about the main symptoms, rarer symptoms, classification of disease stages, complications, pathophysiology, immune processes, interventions, long-term outcomes, and ethical issues related to it. We tried to implement the current knowledge from the literature and signs and symptoms from clinicians into this checklist while leaving it lean and clear for easy use. The checklist might therefore expand or change over time to account for the change in our knowledge of COVID-19 and potential therapeutic interventions.

We hope this checklist will help to build up a well-funded evidence base in this disease, and it might become an example for new emerging diseases in the future. ❖

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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Authors' Contributions

Paul Georg Werthmann, MD, created the item collection checklist and wrote the first draft of the article. David Riley, MD, and Gunver Sophia Kienle, MD, checked the item collection checklist and revised and contributed to the article. All authors read and approved the final version of the article.

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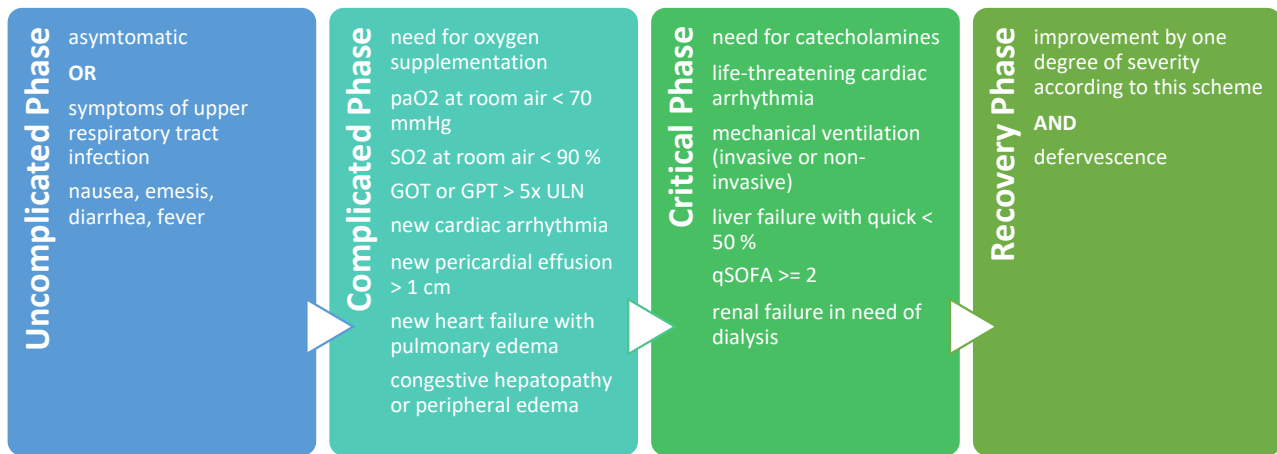


Figure 1. Stages of COVID-19 disease according to LEOSS. Reprinted with permission of Vehreschild et al.¹⁹

COVID-19 = coronavirus disease 2019; LEOSS = Lean European Open Survey on SARS-CoV-2 (severe acute respiratory syndrome-coronavirus 2); GOT = glutamic-oxaloacetate transaminase (now called aspartate aminotransferase); GPT = glutamic-pyruvic transaminase (now called alanine aminotransferase); paO₂ = arterial partial pressure of oxygen; qSOFA = quick Sepsis Related Organ Failure Assessment; SO₂ = oxygen saturation; ULN = upper limit of normal.

Table 1

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Checklist for Case Documentation of COVID19 Patients

Documentation if available / if applicable:

	Key Data	Additional Data
Patient Data	<ul style="list-style-type: none"> • Age • Gender • Weight and height (BMI) • Concomitant diseases (with severity) especially pre-existing conditions that increase the risk of a severe course of COVID19: <ul style="list-style-type: none"> ○ Arterial hypertension ○ Cardiovascular disease ○ Chronic lung disease ○ Chronic liver disease ○ Chronic kidney disease ○ Diabetes mellitus ○ Cancer ○ Immunocompromising diseases or treatments (immunodeficiencies, immunosuppressants, cytostatics, cortisone, ...) • Smoking (specify pack years or frequency) • Regular medication, especially <ul style="list-style-type: none"> ○ ACE inhibitors ○ Calcium antagonists ○ Statins ○ Steroids ○ Non-steroidal anti-inflammatory drugs (NSAIDs) ○ Calcineurin/mTor inhibitors ○ Anti-TNF-alpha inhibitors ○ other immunosuppressants ○ Chemotherapy ○ Anticoagulants 	<ul style="list-style-type: none"> • <i>Occupation</i> • <i>Ethnicity</i> • <i>Mobility (restricted? bedridden?)</i> • <i>Living environment (e.g., senior citizens' residence, facility for the disabled)</i>
Infection	<ul style="list-style-type: none"> • Known contact with an infected person? • Presumed date of infection • Onset of symptoms 	<ul style="list-style-type: none"> • <i>Travel history</i> • <i>Exposure and exposure risks</i>
COVID19 Testing	<ul style="list-style-type: none"> • Location of specimen collection (e.g., throat swab) • Test date • Test result 	<ul style="list-style-type: none"> • <i>Type of test:</i> • <i>L- or S-strain</i> • <i>Highest viral load</i> • <i>lowest PCR cycles</i> • <i>Antibody titer</i> • <i>Other Tests: Influenza A/B</i>
Clinical COVID19 symptoms Describe complaints in detail during the course	<p>Name all known symptoms indicate their severity (e.g. mild, moderate, severe) and describe their course.</p> <ul style="list-style-type: none"> • Fever (grade, duration, course) • Delirious, confused, disorientated • Fatigue / Exhaustion (how much limited by this?) • Cough • Hoarse voice • Sore throat • Sputum • Shortness of breath • Headache • Aching limbs • Chills • Loss of smell / taste 	<ul style="list-style-type: none"> • Nausea/vomiting • Nasal congestion • Diarrhea • Abdominal pain • Chest pain • Skin symptoms

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	Indication of the stage of disease at first presentation (see figure below)	
Vital signs Describe pathological findings in detail and during the course	<ul style="list-style-type: none"> Respiratory rate O₂ saturation 	<ul style="list-style-type: none"> RR Pulse paO₂ paCO₂
Imaging/ diagnostics (if applicable)		<ul style="list-style-type: none"> Thoracic x-ray, CT, ultrasound Echocardiography Evidence of vascular events, thrombosis or embolism
Lab Describe pathological findings in detail	<ul style="list-style-type: none"> CRP GOT/AST GPT/ALT GGT Bilirubin Creatine Leukocytes Lymphocytes Platelets Prothrombin time (PT) Partial thromboplastin time (PTT) 	<ul style="list-style-type: none"> IL-6 PCT Ferritin IL-2 LDH D-dimers plasma fibrinogen Troponin Lipase Blood type
Therapeutic measures for COVID19	Application Yes/No, specify preparation if yes <ul style="list-style-type: none"> Antivirals Antibiotics Anticoagulants Steroids Immunoglobulins Beta blockers and/or anti-arrhythmics Tocilizumab Plasmapheresis 	<ul style="list-style-type: none"> Application with duration (days, precise reference to disease findings), dosage (see above), application form
	For treatment in intensive care units <ul style="list-style-type: none"> Catecholamines (with duration in days) Invasive / non-invasive ventilation (with duration in days) ECMO and comparable procedures Cardiac assist device 	

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Experimental and complementary medical therapies	<ul style="list-style-type: none"> • Detailed description of the medications / applications / measures / recommendations (e.g., diet, exercise, lifestyle changes) • Dosage, frequency and application form • Start time and end time • Changes during the course 	
Clinical course, outcome, follow-up	<ul style="list-style-type: none"> • Duration <ul style="list-style-type: none"> ▪ of symptomatic course ▪ of hospital stay ▪ of stay in intensive care unit ▪ of ventilation • Clinical signs, vital signs, laboratory parameters during the course • Duration of the individual phases of the disease (see figure below) • Outcome <ul style="list-style-type: none"> ▪ Healthy, still symptomatic, deceased • Follow-up <ul style="list-style-type: none"> ▪ Lung function after the disease? ▪ Any other persistent symptoms? 	<ul style="list-style-type: none"> • <i>Imaging during the course</i>
Intensive care data	<ul style="list-style-type: none"> • Intensive care diagnosis (e.g., acute lung failure (ARDS), kidney failure, multiple organ failure, shock) • First values after intubation of <ul style="list-style-type: none"> ▪ SO₂, RR, pulse, PaO₂, PaCO₂, ▪ PEEP, Pmax, frequency, FiO₂ • Worst values of <ul style="list-style-type: none"> ▪ GOT/AST, GPT/ALT, GGT, bilirubine, creatine, lipase, leukocytes, lymphocytes, platelets, troponin, CRP, IL-6, PCT, ferritin, IL-2, LDH, D-dimers ▪ SO₂, RR, pulse, PaO₂, PaCO₂, ▪ PEEP, Pmax, frequency, FiO₂ ▪ SOFA score • Proven super-infection (bacterial, fungal) 	

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