INTERNATIONAL COVID-19 CLINICAL EVALUATION REGISTRY: HOPE-COVID 19.

(Health Outcome Predictive Evaluation for COVID 19)

HOPE PROJECT MD.

PROTOCOL VERSION 5.2, APPENDIX

ENGLISH VERSION. NCT04334291

HOPE COVID-19. Inclusion criteria

Patients discharged (deceased or alive), after any in hospital admission, from any hospital center with a confirmed diagnosis or a COVID-19 high suspicion.

There are no exclusion criteria, except for the patient's explicit refusal to participate.

CONFIRMED CASES

- **Confirmed**, COVID -19 case: Positive result to high-throughput sequencing or real-time reverse transcriptase polymerase-chain-reaction (PCR) assay for pharyngeal and nasal swab samples if their attending physician team consider it a true positive.
- **High suspicion**, COVID -19 case: If their attending physician team consider them highly likely to have presented the infection because compatible signs or symptoms together with any other finding (imaging, etc..) or with inconclusive PCR/other positive test type.

DATABASE VARIABLES AND EVENTS DEFINITION.

As recorded in www.HopeProjectMD.com.

Any technical or scientific question (24/7): support@hopeprojectmd.com

GENERAL DATA

- **GENDER (MALE, FEMALE):** as the patient defines himself or if such information was not available, according to the relevant administrative documents.
- **RACE(CAUCASIAN/LATIN/BLACK/ORIENTAL/OTHER):** as the patient defines himself or if such information is not available, according to the relevant administrative documents or physician judgment.
- **HEALTH_PROFESSIONAL:** If the *patient* serves as physician, nurse, auxiliary or as other health professional position.
- **WEIGHT(KG):** At the admission time.
- **HEIGHT(CM):** At the admission time.

- **BORN(DATE):** official data.
- **ONSETSYMPTOMS(DATE):** as reported by the patient himself or medical estimation (clear clinical history dating).
- **HOSPITAL ADMISSION (DATE):** The day of admission. In the case they were various admissions, the index admission would be considered the closer to the COVID19 test positive date.
- **ADMISSION ICU (DATE):** Intensive care unit (or similar) admission, during index admission.
- **ICUDISCHARGE_DATE:** During index admission.
- **DISCHARGE_DATE:** Regarding the index admission.
- **LASTFOLLOWUPDATE:** last follow up. It will be considered as such the death date and for survivors, office or phone follow up after discharge, is strongly recommended.

CLINICAL PROFILE

- **HYPERTENSION_(YES/NO):** If stated in clinical history and/or the patient receives medication for that purpose.
- **DISLIPEMIA_(YES/NO):** If stated in clinical history and/or the patient receives medication for that purpose.
- **DM(1/2/NO):** If stated in clinical history and/or the patient receives medication for that purpose (ADA criteria).
- **OBESITY YES/NO**: If stated in clinical history or assessed by medical team. Considering as cutoff a BMI>30.
- **CURRENTSMOKER(YES/NO/EX):** If stated in clinical history and/or reported by the patient himself.
- **RENALINSUF. YES/NO:** If stated in clinical history and/or the patient receives medication for that purpose, considering as such Cr. clearance < 30ml(min.
- **KNOWNALLERGIES:** recorded as such in the medical history. State it, please.
- **ANYLUNGDISEASE (1COPD,2RESTRICTIVE,3ASMA,4INTERSTICIAL,5 OTHER): If** stated in clinical history and/or the patient receives medication for that purpose.
- **ANYHEARTDISEASE_YES/NO:** If stated in clinical history and/or the patient receives medication for that purpose.
- **MAINHEARTDISEASE_(CORONARY/VALVE/HEARTFAILURE/MYOPATHY/ARRHYTHMIAS/COMBINED):** according the attending physician criteria. Ie A 67 yo. gentleman with a previous myocardial infarction (CORONARY) or moderate aortic stenosis (VALVE) or paroxysmal atrial fibrillation (ARRHYTHMIAS). Two of them (COMBINED).
- **ANYCEREBROVASCULARDISEASE(YES/NO):** ie. Previous stroke or Transient ischemic attack. If stated in clinical history and/or the patient receives medication for that purpose.
- **CONECTIVEDISEASE_YES/NO:** If stated in clinical history and/or the patient receives medication for that purpose.
- **LIVER DISEASE(YES/NO):** If stated in clinical history and/or the patient receives medication for that purpose.
- **ANYCANCER_YES/NO:** Any oncologic condition (acute, chronic or already solved).
- **TYPEOFCANCER (LUNG,BREAST,PHARYNX-LARYNX,INTESTINE COLON,GENITOURINARY,BLOOD-LEUK-LINPH,SKIN,VARIOUS):** As classified in the

medical records. If more than one condition or unknown oncologic disease type, please check Various.

- **ANYIMMUNOSUPRESSIONCONDITION(YES/NO):** Regarding the moment of admission. If stated in clinical history and/or the patient receives medication with that effect (steroid high doses, chemotherapy, immunosuppressants).
- **PERIFERALVESSELDISEASE_YES/NO:** If stated in clinical history and/or the patient receives medication for that purpose.
- **OTHERRELEVANTANTECEDENT:** please state the other antecedents (tuberculosis, type of arrhythmias, Parkinson, etc..) present in the clinical records.
- **DEPENDENCYLEVEL(NONE/PARTIALLYDEPENDENT/TOTALLYDEPENDENT):** Upon researcher's judgment.
- **HOME OXIGEN THERAPY (YES/NO):** As stated in clinical history or reported by patient.
- **PREVIOUSASPIRIN(YES/NO):** As stated in clinical history or reported by patient, at the time of admission.
- **OTHERANTIPLATELET(YES/NO):** As stated in clinical history or reported by patient. (if dual antiplatelet therapy, check both previous aspirin and other antiplatelet fields).
- **ORALANTICOAGL(YES/NO):** As stated in clinical history or reported by patient. Please make sure to state the reason in OTHERRELEVANTANTECEDENT and if the patient is on vitamin K inhibitors or direct oral anticoagulants (DOACs) in OTHERPREVIOUSTREATMENT.
- **TYPE OF ANTICOAGULANT (AVK/DOAC).**
- **ACEI/ARB(YES/NO):** As stated in clinical history or reported by patient. ACEI (angiotensin-converting enzyme inhibitors)/ ARB (Angiotensin II receptor blockers).
- **BETABLOCKERS(YES/NO):** As stated in clinical history or reported by patient.
- **BETAGONISTINHALED(YES/NO):** As stated in clinical history or reported by patient.
- **GLUCORTICOIDSINHALED(YES/NO**): As stated in clinical history or reported by patient.
- **DVITAMINSUPLEMENT BENZODIACEPINES(YES/NO):** As stated in clinical history or reported by patient.
- **ANTIDEPRESSANT(YES/NO):** As stated in clinical history or reported by patient.
- **OTHERPREVIOUSTREATMENT:** importantly, please state the other drugs as recorded in the clinical records (antidiabetic drugs, anti-inflammatory, chemotherapy, etc..).

AT ADMISSION/EMERGENCY ROOM ASSESSMENT VARIABLES

- **ASYMPTOMATIC(YES/NO):** As stated in clinical history or reported by patient, in the emergency room or office. The patient was admitted because something else (laboratory or imaging results). State it in **OTHERRELEVANTFINDINGS,** see below.
- **DISPNEA (NO/MILD/MODERATE/SEVERE):** As stated in clinical history or reported by patient, upon the medical team judgement.
- **TAQUIPNEA (>22 per minute, YES/NO):** Tachypnea considered as > 22 breaths per minute, as recorded in clinical history.
- **FATIGUE(YES/NO):** As stated in clinical history or reported by patient.
- **HIPO/ANOSMIA (YES/NO):** As stated in clinical history or reported by patient.

- **DISGEUSIA(YES/NO):** As stated in clinical history or reported by patient.
- **SORETHROAT(YES/NO):** As stated in clinical history or reported by patient.
- **FEVER (YES/NO):** As stated in clinical history or reported by patient. Usually considered -thermometered- as > 38ºC (100.4 F).
- **MAXTEMPDURINGADMISSION:** in Celsius degrees.
- **COUGH(YES/NO):** As stated in clinical history or reported by patient.
- **VOMITING(YES/NO):** As stated in clinical history or reported by patient.
- **DIARRHEA(YES/NO):** As stated in clinical history or reported by patient.
- **MYALGIAORARTHALGIA(YES/NO):** As stated in clinical history or reported by patient.
- **02SAT<92%(YES/NO):** Oxygen saturation at admission. As stated in clinical history, measured by transcutaneous pulsioximetry.
- **ELEVATEDDDIMER(YES/NO):** As defined by local laboratory cutoff levels. Suggested (≥0.5mg/L).
- **ELEVATEDPROCALCITONIN(YES/NO):** As defined by local laboratory cutoff levels. Suggested (≥0.5ng/ml).
- **ELEVATEDPCR(YES/NO):** As defined by local laboratory cutoff levels. Suggested (≥10mg/L).
- **ELEVATED TN (YES/NO):** As defined by local laboratory cutoff levels. Both (cardiac) troponin I and T are acceptable. Suggested > 99th percentile.
- **ELEVATEDTRANSAMINASES(GPTAND/ORGOT)YES/NO:** As defined by local laboratory cutoff levels. Suggested (≥40 U/L).
- **ONSETNALEVELS(mEq/L):** As measured (first determination).
- **TOTALONSETLEUCOCYTESCOUNT(/Ul):** As measured (first determination).
- **TOTALONSETLinphoCYTESCOUNT(/Ul):** As measured (first determination).
- **ONSEThemoglobin(gr/dl):** As measured (first determination).
- **TOTALONSETplateletCOUNT(/uL):** As measured (first determination).
- **ONSETCREATININELEVELS(mg/dL):** As measured (first determination).
- **ONSETARTERIALBLOODGASph:** As measured (first determination).
- **ONSETARTERIALBLOODGASPa02(mmHG):** As measured (first determination).
- **ONSETARTERIALBLOODGASPaC02(mmHG):** As measured (first determination).
- **ONSETARTERIALBLOODGAS02SATURATION(%), AIR ROOM:** As measured (first determination).
- **ANYCHESTRXABNORMALITY(NO/UNILATERAL/BILATERAL):** As stated in clinical history or reported by patient.
- **OTHERRELEVANTFINDINGS:** Please state them, ie neurologic or cutaneous findings. Whatever clinically relevant or unusual. This refers to test results as well, If available. IL6 levels, ie.

DURING IN HOSPITAL STAY

- **COMMENTSDURING ADMISION:** Please state them, ie neurologic or cutaneous findings. Whatever clinically relevant or unusual.
- **RESPIRATORYINSUFFICIENCYADMISSION(YES/NO):** as determined by the attending medical team, usually requiring 02 supplements. Reported in the clinical history as such.

- **HEARTFAILUREADMISSION(YES/NO):** typical symptoms and signs, as determined by the attending medical team, usually requiring specific medical or other treatment. Reported in the clinical history as such.
- **RENALFAILURE(YES/NO):** as determined by the attending medical team, usually requiring specific medical or other treatment. Reported in the clinical history as such, usually when an acute increase in serum creatinine levels ≥0.3 mg/dl within 48 hours or an increase in serum creatinine levels≥1.5 times of the baseline level is demonstrated.
- **UPPERRESPIRAROTYTRACTINFECTIONDATA(YES/NO):** as determined by the attending medical team, usually requiring specific medical or other treatment. Reported in the clinical history as such.
- **PNEUMONIA(NO/UNI/BILATERAL):** as determined by the attending medical team, usually requiring specific medical or other treatment. Reported in the clinical history as such. As suggestion, it should be considered as an acute respiratory disorder characterized by the existence of cough and at least one of new-onset chest signs, fever for more than 4 days, dyspnea and/or tachypnea and supported by radiologic signs, with uni or bilateral involvement, assessed by chest X-ray or CT imaging, if available.
- **SEPSIS(YES/NO):** as determined by the attending medical team, usually requiring specific medical or other treatment. Reported in the clinical history as such.
- **SYSTEMICINFLAMATORYREPONSESYNDROME(YES/NO):** as determined by the attending medical team, usually requiring specific medical or other treatment. Reported in the clinical history as such.
- **ANYRELEVANTBLEEDING(YES/NO):** as determined by the attending medical team, usually requiring specific medical or other treatment. As classified in BARC bleeding score 2,3 and 5 types. Reported in the clinical history as such.
- **HEMOPTYSIS(YES/NO):** as determined by the attending medical team, usually requiring specific medical or other treatment. Reported in the clinical history as such.
- **EMBOLICEVENT(YES/NO):** as determined by the attending medical team, usually requiring specific medical or other treatment. Reported in the clinical history as such.
- **RASH/CUTANEOUS INVOLVEMENT.** Any abnormal cutaneous data. Please elaborate in **COMPLICATIONSDESCRIPTION.**
- **COMPLICATIONSDESCRIPTION:** When a complication/event or death is present, please elaborate.
- **DEATH(DATE).**
- **DEATHCAUSE:** Considering as such the main cause (respiratory, neurological, cardio, sepsis or sirs, combined), according the local medical team criteria. Please elaborate the death circumstances in the **COMPLICATIONSDESCRIPTION** field. If sudden or unknown cause, please, state it.
- **02DURINGADMISSION(YES/NO):** any kind of oxygen supplement during in hospital stay.
- **HIGHFLOWNASALCANNULA(YES/NO):** any kind of High-flow nasal cannula oxygenation, providing PEEP.
- **NOINVASIVEMECHANICALVENTILATION(YES/NO):** any kind of mechanical ventilation, with respirator, without intubation, during in hospital stay.
- **INVASIVEMECHANICALVENTILATION(YES/NO):** Mechanical ventilation through orotracheal intubation.
- **DAYSONMECHANICALVENTILATION,** regarding invasive ventilation.

- **PRONEDURINGADMISSION(YES/NO):** If performed, in any moment during in hospital stay (ICU or ward).
- **VASOACTIVE SUPPORT.** Use of any vasoactive/inotrope during inhospital stay.
- **ECMO OR SIMILAR SUPPORT(YES/NO):** Any moment during in hospital stay. Ecmo, or other type of ventricular assist devices, including intraortic balloon pump. Please detail further in **RELEVANTCOMMENTS,** below.
- **USEOFCORTICOIDSDURINGADMISSION(YES/NO).** Any moment during in hospital stay.
- **Glucocorticoids start date.**
- **USEOFCLOROQUINEORSIMILARDURINGADMISSION(YES/NO).** Any moment during in hospital stay.
- **USEOFANTIVIRALDRUGSDURINGADMISSION(YES/NO):** Any moment during in hospital stay. We consider as antiviral mainly lopinavir y ritonavir. If you use a different one (ie. Oseltamivir, remdesivir, please state it in **RELEVANTDRUGSDURINGADMISSION,** below.
- **Antiviral Start date.**
- **USEOFINTERFERONORSIMILARDURINGADMISSION(YES/NO):** Any moment during in hospital stay.
- **USEOFTOCILIZUMABORSIMILARDURINGADMISSION(YES/NO):** Any moment during in hospital stay.
- **TOCILIZUMAB Start date.**
- **USEOFANTIBIOTICS(AZITRO/BETALAC)YES/NO:** Any moment during in hospital stay.
- **RELEVANTDRUGSDURINGADMISSION:** please record specific (Ej.Remdesivir, Ivermectina, …) treatment (Antiviral, antibiotic,….) and antithrombotic treatment during in stay.
- **ACEi/ARBs* during inhospital stay (YES/NO):** If the patient receives during his/her hospital stay this type of drugs.
- **ANTICOAGULATION DURING IN HOSPITAL STAY (NONE/PROPHYLACTIC/PARENTERAL/AVK OR DOAC).** Select the main anticoagulant treatment received during in hospital stay for the patient.
- **RELEVANTCOMMENTS:** Any important comments about the patient and his stay or discharge.
- **DISCHARGEANTIPLATELET:** Yes or no.
- **DISCHARGECLACEI/ARBS:** Yes or no
- **DISCHARGEANTICOAGU(YES/NO):** yes or no. Please state the type (aVK, DOAC..) in DISCHARGE MEDS.
- **DISCHARGE MEDS**: Specify discharge complete medical treatment.
- **DISCHARGEDIAGNOSIS:** As stated in discharge report.
- **COVID19_CONFIRMED(RNA+)YES/NO:** Positive result to high-throughput sequencing or real-time reverse transcriptase polymerase-chain-reaction (PCR) assay for pharyngeal and nasal swab samples if their attending physician team consider it a true positive.
- **COVID16HIGHSUSPICION(NORNA+ORNOTTESTED)YES/NO:** If the attending physician team consider the patient highly likely to have presented the infection

because compatible signs or symptoms together with any other finding (imaging, etc..) or with inconclusive PCR/other positive test type.

- **ALIVE(YES/NO):** discharged alive.
- **DISCHARGETO(HOME/LOWLEVEHEALTCAREFCILITY-HOSPICE/DEATH):** Discharge destiny (home, medicalized hotel or hospice-residence or death).

SCIENTIFIC COORDINATION: Iván J. Núñez-Gil, MD, PhD. Carlos Macaya, MD, PhD. Vicente Estrada, MD, PhD.

SCIENTIFIC COMMITTEE AND LIST OF PARTICIPATING HOSPITALS: Available updated at www.HopeProjectMD.com.

COORDINATOR CENTRE: HOSPITAL CLINICO SAN CARLOS, MADRID, SPAIN.

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