ECFS surveillance of COVID-19 infection and outcomes in people with CF

Case report form

SARS-Cov-2 infection in patients with Cystic Fibrosis **Data collection form**
Centre/Institute: ……
Physician: ……Phone: ….....
e-mail: ……

PATIENT DEMOGRAPHICS	
Does this patient have an ECFSPR ID number Yes [ ] No [ ]	
If **YES** please enter the ECFSPR ID number here: ……..	If **NO**, please answer the following demographic questions for the patient: Sex [F] [M] Age at time of COVID-19 infection (years) Country of residence *CFTR* genotype Variant on first allele Variant on second allele Pancreatic insufficiency Yes [ ] No [ ]

PRE-INFECTION DATA			
Weight (kg)	**Height** (cm)		
Number of pulmonary exacerbations during the previous 12 months ……			
Bacterial respiratory infection status during the previous 12 months			
Pseudomonas aeruginosa	None [ ]	Intermittent [ ]	Chronic [ ]
Achromobacter species	None [ ]	Intermittent [ ]	Chronic [ ]
Staphylococcus aureus	None [ ]	Intermittent [ ]	Chronic [ ]
Stenotrophomonas maltophilia	None [ ]	Intermittent [ ]	Chronic [ ]

MRSA	None [ ]	Intermittent [ ]	Chronic [ ]
Burkholderia cepacia complex bacteria	None [ ]	Intermittent [ ]	Chronic [ ]
Nontuberculous mycobacteria	None [ ]	Intermittent [ ]	Chronic [ ]

Aspergillus colonisation during the previous 12 months Yes [ ] No [ ]

Allergic bronchopulmonary aspergillosis (ABPA) requiring treatment during the previous 12 months Yes [ ] No [ ]

FEV1 (average of the last 3 tests)

…… litres (L)

Was the patient receiving oxygen therapy prior to SARS-Cov-2 infection?
Yes [ ] No [ ]

Was the patient receiving noninvasive positive-pressure ventilation (NIPPV) prior to SARS-Cov-2 infection?
Yes [ ] No [ ]
If yes, specify whether NIPPV was CPAP [ ] or BPAP [ ]

Comorbidities
Diabetes Yes [ ] No [ ]
If yes:

- Treated with daily insulin [ ]
- Treated with oral hypoglycaemic agents [ ]
- Only dietary advice [ ]
- Therapy unknown [ ]

Chronic liver disease Yes [ ] No [ ]

Arterial hypertension Yes [ ] No [ ]

Other comorbidities () ……

Organ transplantation
None []
Lung [ ]
Liver [ ]
Kidney [ ]
Other organs [ ]
Year of latest transplant……. (yyyy)

Chronic CF maintenance therapy

Inhaled Antibiotics	Yes [ ]	No [ ]
Oral antibiotics	Yes [ ]	No [ ]
Azithromycin	Yes [ ]	No [ ]
Oral steroids	Yes [ ]	No [ ]
If yes, mean daily dose greater of equal to 4 mg/day	Yes [ ]	No [ ]
Inhaled steroids	Yes [ ]	No [ ]
CFTR modulators	Yes [ ]	No [ ]

Immunosuppressive therapy Yes [ ] No [ ] Type of immunosuppressant ……
Antivirals (ongoing) Yes [ ] No [ ] Type of antiviral drug …….
NSAID (chronic use) Yes [ ] No [ ]
Mucoactive drugs (DNase, hypertonic saline, mannitol) Yes [ ] No [ ]
Angiotensin- Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) Yes [ ] No [ ]

Other treatments (specify)…….

Did the patient receive an influenza vaccination?
Yes [ ] No [ ]
If yes, specify date
…….(mm yyyy)

SARS-COV-2 INFECTION DATA

Documented COVID Contact Yes [ ] No [ ]
If yes
[ ] Living/traveling in epidemic area
[ ] Close contact* with a confirmed or probable case of SARS-Cov-2 infection
[ ] Presence in a healthcare facility where SARS-Cov-2 infections have been managed
[ ] No clear contact history

* Close contact is defined as:
- Health care associated exposure, including providing direct care for novel coronavirus patients, e.g. health care worker, working with health
- Care workers infected with novel coronavirus, visiting patients or staying in the same close environment of a novel coronavirus patient
- Direct exposure to body fluids or specimens including aerosols.
- Working together in close proximity or sharing the same classroom environment with a novel coronavirus patient.
- Traveling together with novel coronavirus patient in any kind of conveyance.
- Living in the same household as a novel coronavirus patient

Onset date of first symptoms …../…../…. (dd/mm/yyyy)

Symptoms

Fever	Yes [ ]	No [ ]
Fatigue	Yes [ ]	No [ ]
Increased cough	Yes [ ]	No [ ]
Increased dyspnoea	Yes [ ]	No [ ]
Chest tightness	Yes [ ]	No [ ]
Wheezing	Yes [ ]	No [ ]
Increased sputum production	Yes [ ]	No [ ]
Pulmonary exacerbation	Yes [ ]	No [ ]
Haemoptysis	Yes [ ]	No [ ]
Acute rhinitis (runny nose)	Yes [ ]	No [ ]

Pharyngitis (sore throat)	Yes [ ]	No [ ]
Conjunctivitis	Yes [ ]	No [ ]
Acute anosmia (loss of smell)	Yes [ ]	No [ ]
Acute ageusia (loss of taste)	Yes [ ]	No [ ]
Diarrhoea	Yes [ ]	No [ ]
Myalgia/Arthralgia (muscle aches/joint pain)	Yes [ ]	No [ ]
Headache	Yes [ ]	No [ ]
Vomiting / Nausea	Yes [ ]	No [ ]
Abdominal pain	Yes [ ]	No [ ]

Other Yes [ ] No [ ]
Please specify:……

Documented respiratory viral co-infections
Was pathogen testing done during this illness period? Yes [ ] No [ ]

Respiratory viruses

Influenza A/B	Yes [ ]	No [ ]	Not investigated [ ]
Other Coronavirus	Yes [ ]	No [ ]	Not investigated [ ]
Metapneumovirus	Yes [ ]	No [ ]	Not investigated [ ]
RSV	Yes [ ]	No [ ]	Not investigated [ ]
Rhino/Enterovirus	Yes [ ]	No [ ]	Not investigated [ ]
Adenovirus	Yes [ ]	No [ ]	Not investigated [ ]

Other virus (please specify) ……

Mycoplasma pneumonia detected Yes [ ] No [ ] Not investigated [ ]
Other non-viral co-infection (specify) ……

SARS-Cov2 positive result
Specify results for biospecimens tested:

- Nasal/NP swab date performed…../…../…. (dd/mm/yyyy) positive [ ] negative [ ]
- Throat swab date performed…../…../…. (dd/mm/yyyy) positive [ ] negative [ ]
- Combined nasal/NP+throat swab date performed…../…../…. (dd/mm/yyyy) positive [ ] negative [ ]
- Sputum date performed…../…../…. (dd/mm/yyyy) positive [ ] negative [ ]
- BAL date performed…../…../…. (dd/mm/yyyy) positive [ ] negative [ ]
- ETA date performed…../…../…. (dd/mm/yyyy) positive [ ] negative [ ]
- Urine date performed…../…../…. (dd/mm/yyyy) positive [ ] negative [ ]
- Feces/rectal swab date performed…../…../…. (dd/mm/yyyy) positive [ ] negative [ ]

Other Specify: _____

Hospitalisation Yes [ ] No [ ]
If yes, number of days ……..

Intensive Care Unit Yes [ ] No [ ]
If yes, number of days ……..

COVID-19 Severity[1]

Mild **[ ]**
Patients without pneumonia or cases of mild pneumonia

Severe **[ ]**
Patients who suffered from shortness of breath, respiratory frequency ≥ 30/minute, blood oxygen saturation ≤93%, PaO2/FiO2 ratio <300, and/or lung infiltrates >50% within 24–48 hours

Critical **[ ]**
Patients who suffered respiratory failure, septic shock, and/or multiple organ dysfunction or failure

Haemogasanalysis (blood gas) at worst moment during infection
On room air [ ] On oxygen [ ] …….(l/min)
pH
pCO2 (mmHg)
pO2 (mmHg)
Base excess (BE) mEq/L (mmol/L)
Lactates (mmol/L)
HCO3 (mEq/L)
FiO2 (%)

Peak CRP value (mg/L)
Peak white cell count ($x10^9$/L)

Was CT performed? Yes No
If yes, which abnormalities were present?.....

Did this patient have any other notable investigation findings that might be specific or important for CF patients?
…….

What pharmacological treatments did the patient receive for COVID-19?

Anti-viral therapy Yes [ ] No [ ]
Type of anti-viral drug(s):
Ribavirin:……..
Lopinavir/Ritonavir:……..
Interferon alpha/beta:……..
Neuraminidase inhibitor:……..
Other, specify:……..

Additional IV antibiotic therapy Yes [ ] No [ ]
Type of additional IV antibiotic(s): ……..
Drug 1:……..
Drug 2:……..
Drug 3:……..
Drug 4:……..
Drug 5:……..

Anti-inflammatory biologic therapy – Tocilizumab Yes [ ] No [ ]

Systemic steroids Yes [ ] No [ ]

Hydroxychloroquine/Chloroquine Yes [ ] No [ ]

Azithromycin Yes [ ] No [ ]

Additional oral antibiotics Yes [ ] No [ ]

Antifungal agent Yes [ ] No [ ]

Vitamin C Yes [ ] No [ ]

Anakinra Yes [ ] No [ ]

Other therapies (specify):……..

Were any of the above treatments given as part of a formal registered clinical trial?
Yes [ ] No [ ]

Did the patient receive oxygen therapy Yes [ ] No [ ]

Did the patient receive respiratory support (specify type and duration):
Non-invasive ventilation (BIPAP, CPAP): Yes [ ] No [ ] Duration (days).....
High flow nasal canula oxygen therapy: Yes [ ] No [ ] Duration (days).....
Extra corporeal life support (ECLS): Yes [ ] No [ ] Duration (days).....

Did the patient have complications? Yes [ ] No[ ]
Renal insufficiency
Sepsis
Multi-organ failure
CF exacerbation
Bacterial pneumonia
Pneumothorax
Pleural effusion
ARDS

Other complications relevant to CF: ……

Was the patient pregnant during the COVID-19 illness? Yes [ ] No [ ]
If yes, were there any notable remarks regarding the pregnancy?

Outcome of the disease (tick one):

Discharged alive from COVID-19 care [ ] …../…../…. (dd/mm/yyyy)
Hospitalization [ ] …../…../…. (dd/mm/yyyy)
Transfer to other facility [ ] …../…../…. (dd/mm/yyyy)

Death	[ ] …../…../…. (dd/mm/yyyy)
Palliative discharge	[ ] …../…../…. (dd/mm/yyyy)
Unknown	[ ] …../…../…. (dd/mm/yyyy)
Ongoing at time of case submission	[ ]

If patient was discharged alive, what is the patient's ability to self-care at discharge versus before illness?

Same as before illness	[ ]
Worse	[ ]
Better	[ ]
N/A	[ ]

Post-discharge treatment:
Oxygen therapy? Yes [ ] No [ ] Not applicable [ ]

Date of negative SARS-CoV2 swab (if known)
Specify results for biospecimens tested:

- Nasal/NP swab date performed…../…../…. (dd/mm/yyyy) positive [ ] negative [ ]
- Throat swab date performed…../…../…. (dd/mm/yyyy) positive [ ] negative [ ]
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- Urine date performed…../…../…. (dd/mm/yyyy) positive [ ] negative [ ]
- Feces/rectal swab date performed…../…../…. (dd/mm/yyyy) positive [ ] negative [ ]

Other Specify: _____

References

[1] The Novel Coronavirus Pneumonia Emergency Response Epidemiology Team. The Epidemiological Characteristics of an Outbreak of 2019 Novel Coronavirus Diseases (COVID-19) — China, 2020[J]. China CDC Weekly, 2020, 2(8): 113-122. http://www.ourphn.org.au/wp-content/uploads/20200225-Article-COVID-19.pdf.