Disaster Medicine and Public Health Preparedness

www.cambridge.org/dmp

Commentary

Cite this article: Emami A, Akbari A, Javanmardi F, *et al*. Designing a multicenter registry of COVID-19 and other respiratory infections in Fars, Iran. *Disaster Med Public Health Prep*. doi: https://doi.org/10.1017/dmp.2021.100.

Keywords:
COVID-19; Fars; Iran; registry; severe acute respiratory syndrome coronavirus 2

Corresponding author:
Amir Emami,
Email: Emami.microbia@gmail.com.

SDMPH
SOCIETY FOR DISASTER MEDICINE & PUBLIC HEALTH

Designing a Multicenter Registry of COVID-19 and Other Respiratory Infections in Fars, Iran

Amir Emami[1], Ali Akbari[2], Fatemeh Javanmardi[1], Mehrzad Lotfi[3], Mohsen Moghadami[4], Mehrdad Sharifi[5], Hamid Bakhtiari[6] and Farshad Falahati[7]

[1]Microbiology Department, Burn and Wound Healing Research Center, Shiraz University of Medical Sciences, Shiraz, Iran; [2]Department of Anesthesiology, School of Medicine, Shiraz University of Medical Sciences, Shiraz, Iran; [3]Department of Radiology, Namazi Hospital, Shiraz University of Medical Sciences, Shiraz, Iran; [4]Health Policy Research Center, Institute of Health, Shiraz University of Medical Sciences, Shiraz, Iran; [5]Emergency Medicine Department, Faculty of Medicine, Shiraz University of Medical Sciences, Shiraz, Iran; [6]Vice Chancellor for Health Affairs Center of Disease Control (CDC), Shiraz University of Medical Sciences, Shiraz, Iran and [7]Vice Chancellor for Treatment, Shiraz University of Medical Sciences, Shiraz, Iran

Abstract

Objective: A year after the emergence of a novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), as a new crisis in respiratory infections, there remain many uncertainties and unknowns about SARS-CoV-2 and the disease it causes, called *coronavirus disease* (*COVID-19*). Although COVID-19 is known as a respiratory disease, some atypical manifestations have been seen, different from those seen in other types of viral respiratory infections. This paper aims to describe designing, launching, and implementing a data collection system for all respiratory diseases, with a focus on SARS-CoV-2 from the onset of this pandemic.

Method: The current registry is designed in compliance with the standard Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines, along with the declaration of Helsinki principles.

Results: A respiratory disease registry, with an emphasis on COVID-19 and other co-infections, was developed. Data consisted of demographic, clinical, and supporting information about SARS-CoV-2 and other respiratory viral diseases.

Conclusion: It is hoped that the current data registry will facilitate patient evaluation and improve the outcomes of cases of respiratory infection defined by a particular condition, disease, or exposure. Moreover, the registry can harmonize data about the treatment, outcomes, and well-being of patients who receive care over time, and identify best practices.

Introduction

A year after the emergence of a novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), as a new crisis in respiratory infections, there remain many uncertainties and unknowns about SARS-CoV-2 and the disease it causes, called *coronavirus disease* (*COVID-19*). Even the mortality rate and rate of spread of infection across communities are debatable and unspecified.[1] Besides the plethora of management strategies and infection control policies from the World Health Organization (WHO) and Centers for Disease Control and Prevention, evidence-based studies are critical for better understanding the nature of the current outbreaks and how best to treat the patients. It is very important to diagnose the disease pattern, from asymptomatic to severe cases and, moreover, to identify high-risk individuals.[2]

Common symptoms have changed from first recognition of the disease until now. Although COVID-19 is known as a respiratory disease, some atypical manifestations have been seen, different from other types of viral respiratory infections.[3,4] Skin vesicular, cerebrovascular, neurological complications, dry eye, itching, and ocular involvement have been reported.[5–7] On the other hand, co-infections with COVID-19 and other respiratory viruses (eg, influenza viruses, adenoviruses) have been detected.[8] Exact information about positive cases with respiratory diseases, especially SARS-CoV-2, their symptoms, complications, and comorbidities are required to clarify the ambiguities of these viral infections.[9] Therefore, a comprehensive database registry would be helpful for specialists and health policy-makers to manage and control the disease and improve treatment. This paper is intended to explain design and implementation of a registry for data collection for all respiratory diseases, with a focus on SARS-CoV-2 from the onset of this pandemic.

Table 1. Data items included in the acute respiratory distress syndrome (ARDS) registry

Demographic and Identification Data	Name, Family name, Father name, National ID, Gender, Birth Date, Age, Phone number, Occupation, Education, Nationality, Ethnicity, Address, Case type (confirmed, probable), Job, Having relatives with this disease and the relations, Being passenger and origin, Pregnancy status (and gestational week), Postpartum status (and pregnancy outcome, delivery date, test for baby, result of baby test, method of baby test), Infant < 1 year (birthweight, gestational outcome
Onset and Admission	Onset date of first/earliest symptom, Admission date at this facility, Time of admission, Transfer from other facility (name and date of admission), Travel in the 14 days prior to first symptom onset (date and place), Contact with animals, raw meat, or insect bites in the 14 days prior to symptom onset (type of animal)
Signs and Symptoms in Admission	History of fever, Cough, Sputum, Bloody sputum/hemoptysis, Sore throat, Runny nose (rhinorrhea), Ear pain, Wheezing, Chest pain, Muscle aches (myalgia), Joint pain (arthralgia), Fatigue/malaise, Shortness of breath (dyspnea), Lower chest wall in drawing, Headache, Altered consciousness/confusion, Seizures, Abdominal pain, Vomiting/nausea, Diarrhea, Conjunctivitis, Sweating, Vertigo, Chills, Palpitation, Skin rash, Skin ulcers, Lymphadenopathy, Bleeding (hemorrhage), Site of bleeding, Loss of sense of smell and taste, Eye (dry and itchiness)
Signs and Symptoms During Hospitalization	Temperature, Heart rate, Respiratory rate, Systolic blood pressure, Diastolic blood pressure, Severe dehydration, Sternal capillary refill time > 2 seconds, Oxygen saturation, Ventilator dependent
Comorbidities	Chronic cardiac disease (including congenital heart disease not hypertension), Hypertension, Chronic pulmonary disease (not asthma), Asthma (physician diagnosed), Chronic kidney disease, Liver disease (moderate, severe, or mild), Chronic neurological disorder, Malignant neoplasm, Chronic hematologic disease, AIDS/HIV, Obesity, Diabetes with/without complications, Rheumatologic disorder, Dementia, Malnutrition, Smoking
Pathogen Testing	Influenza (type), Coronavirus (type), RSV, Adenovirus, Other respiratory infections diagnosis (type), Clinical pneumonia, Type of collected biospecimen (eg, nasal swap, sputum), Date, Laboratory test method (PCR, culture, other), Results (+/-), detected pathogen
Assessment (Daily)	Date, ICU admission, FiO_2, SaO_2, PaO_2 at time of FiO_2, PaO_2 sample type, PCO_2 (from same blood gas record as PaO_2), pH, HCO_3, Base excess, AVPU alert, AVPU verbal, AVPU pain, AVPU unresponsive, Glasgow coma score, Richmond Agitation-Sedation Scale (RASS), Riker Sedation-Agitation Scale (SAS), Systolic blood pressure, Diastolic blood pressure, Mean arterial blood pressure, Urine flow rate, Non-invasive ventilation (eg, BIPAP, CPAP), Invasive ventilation, Extracorporeal life support (ECLS), High-flow nasal cannula oxygen therapy, Dialysis/hemofiltration, Any vasopressor/inotropic support (if yes, type), Neuromuscular blocking agents, Inhaled nitric oxide, Tracheostomy inserted, Prone positioning, Other intervention or procedure
Laboratory	Date, Laboratory name, Hemoglobin, WBC count, Lymphocyte count, Neutrophil count, Hematocrit, Platelets, APTT/APTR, PT, INR, ALT/SGPT, LDH, Total bilirubin, AST/SGOT, Glucose, Blood urea nitrogen (BUN), Lactate, Creatinine, Sodium, Potassium, Mg, Troponin, Potassium, Procalcitonin, CRP, Blood group, FBS, Troponin, IgG, IgM, ESR
Imaging	Chest x-ray, Presence of infiltrates, CT scan, Results of CT
Complications	Viral pneumonitis, Bacterial pneumonia, ARDS (and severity), Pneumothorax, Pleural effusion, Cryptogenic organizing pneumonia (COP), Bronchiolitis, Meningitis/encephalitis, Seizure, Stroke/cerebrovascular accident, Congestive heart failure, Endocarditis/myocarditis/pericarditis, Cardiac arrhythmia, Cardiac ischemia, Cardiac arrest, Bacteremia, Coagulation disorder/Disseminated intravascular coagulation, Anemia, Rhabdomyolysis/myositis, Acute renal injury/acute renal failure, Gastrointestinal hemorrhage, Pancreatitis, Liver dysfunction, Hyperglycemia, Hypoglycemia, Other
Treatment and medication	ICU admission, Total ICU duration, Date of ICU admission and discharge, Oxygen therapy, Non-invasive ventilation, Invasive ventilation, Invasive ventilation total duration, Prone ventilation, Inhaled nitric oxide, Inserted tracheostomy, Extracorporeal support, Renal replacement therapy (RRT) or dialysis, Inotropes/vasopressors (start and end date), Other intervention or procedure, Antiviral agent (type of medication), Antibiotic (type of medication), Corticosteroid (route, type, and dose), Antifungal agent, Others
Outcome	Date, Outcome type (discharged alive, hospitalization, transfer to other facility, death, palliative discharge), Ability to self-care at discharge, Post-discharge treatment, Oxygen therapy, Dialysis/renal treatment, Other intervention or procedure, Transferred facility name
Financial part	General bill, Cost of ICU bed, Cost of general bed, Cost of radiology services, Cost of human sources, Cost of drugs, Cost of consuming materials, Cost of laboratory test

Methods

Study Design and Setting

Based on standards for disease registries, the development of the registry program was done in several steps: (1) definition of the target population, (2) diagnosis of infected cases, (3) data gathering and appropriate related checklists, (4) data storage program, (5) assessing the quality of data, and, finally, (6) data analysis and reporting outputs. The current registry is designed in compliance with the standard Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines, along with the declaration of Helsinki principles.[10,11] The current registry is approved by the ethical committee at Shiraz University of Medical Sciences, approval IR.SUMS.REC.1399.022.

The entire process is in consultation with scientific committees, including microbiologists, infectious disease specialists, radiologists, anesthesiologists, neurologists, cardiologists, emergency medicine, pharmacologists, and biostatisticians. This committee is responsible for providing protocols, supervising the data access, quality assessment of data, and managing the reports and outputs. Moreover, launching a biobank related to prevalent viral infections (such as COVID-19) and accompanying information has recently been added to the current registry. Detailed information about included variables is provided in Table 1.

Inclusion and Exclusion Criteria

In order to manage the infected patients, the admission criteria were divided into 4 levels, based on the severity of disease and

Table 2. Inclusion and admission criteria

Level 1 Severe Cases	• Have COVID-19 symptoms • $PO_2 < 80\%$ • Respiratory rate > 30% • Lung infection > 50% • Hemodynamic disorders • Loss of consciousness • Multi-organ dysfunctions • Fraction of inspired oxygen (FIO_2) < 100%
Level 2 Mild Cases	• Have COVID-19 symptoms • $PO_2 < 85\%$ • Respiratory rate > 30% • Lung infection > 50% • Hemodynamic disorders
Level 3 Moderate Cases	• Have COVID-19 symptoms • $85\% < PO_2 < 90\%$ • Respiratory rate > 30% • No lung infection • No hemodynamic disorders
Level 4 Isolation at Home	• No symptoms of COVID-19, but positive qRT-PCR test • $PO_2 > 90\%$ • Respiratory rate < 24% • No lung infection • No hemodynamic disorders

treatment requirements, and patient location (hospitalized in 3 levels of centers or isolated at home). Characteristics of included patients are provided in Table 2. The definitions of the hospital ratings are as follows:

Level 1

Referral and tertiary hospitals: Several medical teams and specialists, including expert health care workers in respiratory diseases, pulmonary department; more intensive care unit (ICU) beds are provided in these centers and allocated for severe patients.

Level 2

General hospitals: These centers are one of the multifunctional hospitals in Fars Province. Based on the WHO guidelines, some departments and wards are allocated for COVID-19 patients and changed to infectious disease. Mildly ill patients were admitted to these centers.

Level 3

Designated hospitals: These centers are prepared for the admission of patients in case of an increasing trend in the current outbreak. New trained medical staff care for moderately ill patients.

Level 4

Isolation: These patients isolate at home, rest, and implement health care protocols. Their status is screened and followed by the Medical Care Monitoring Center; if in need of special care, they will be moved to one of the centers described previously.

Readmission Criteria

Although the second presentation of the disease has been reported rarely, following the pandemic, some cases in our region are seen readmitted in our centers. In general, re-presentation of the respiratory symptoms in our study means individuals recovered after being infected and confirmed for COVID-19 once before and later admitted again with the recent crisis guideline criteria.

Discussion

This paper described the rationale and fundamentals of launching a respiratory disease registry, with an emphasis on COVID-19 and other co-infections, with data consisting of demographic, clinical, and supporting information about SARS-CoV-2 and other respiratory viruses and diseases. Although this new virus is from a known family of viruses (Coronaviridae), due to ambiguous points about complications and symptoms of this virus with respect to the previous coronavirus infections (SARS-CoV, MERS-CoV), prior insights were insufficient. Therefore, a comprehensive database will be helpful to support researchers and clinicians for a better understanding of the disease and proper treatments.[12]

As of March 1, 2021, COVID-19 has affected 217 countries and territories with more than 114 million confirmed cases around the world. In Iran, there have been more than 1.6 million total cases and over 60 000 deaths. Based on the current registry, data such as the following will be provided: total tests, confirmed cases, final status, readmissions, laboratory data, underlying diseases, risk factors, and complications.

Based on previous experiences on registry data analysis, it was found that having a registry is crucial for pandemic diseases since it may help in designing infection control protocols, managing the transmission mode, identifying epidemiological changes, and recognizing disease patterns to improve treatment in order to save human lives.[13,14] Research studies are essential for this outbreak, especially since no one is assured of SARS-CoV-2 immunity. It is hoped that the current data registry will evaluate and improve the outcomes of this infectious respiratory disease and infected cases defined by a particular condition, complication, and presentation. Moreover, in a specific insight, we can harmonize data about the treatment, outcomes, and well-being of patients who receive care over time. Several research papers have been derived from this registry, which were very useful for managing the disease and codification of guidelines.[5,15–17]

Conclusion

An electronic registry system for patients with respiratory infections focused on COVID-19 was developed in Fars Province, southwest of Iran. This registry should help researchers and policy-makers, as well as clinicians, collect reliable and up-to-date information on respiratory infections.

Conflict(s) of Interest. The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this paper.

References

1. **Wiersinga WJ, Rhodes A, Cheng AC, *et al.*** Pathophysiology, transmission, diagnosis, and treatment of coronavirus disease 2019 (COVID-19): a review. *JAMA*. 2020;324(8):782-793.
2. **Sohrabi C, Alsafi Z, O'Neill N, *et al.*** World Health Organization declares global emergency: a review of the 2019 novel coronavirus (COVID-19). *Int J Surg.* 2020;76:71-76.
3. **Moriyama M, Hugentobler WJ, Iwasaki A.** Seasonality of respiratory viral infections. *Annu Rev Virol.* 2020;7(1):83-101.
4. **Cheng MP, Papenburg J, Desjardins M, *et al.*** Diagnostic testing for severe acute respiratory syndrome-related coronavirus 2: a narrative review. *Ann Intern Med.* 2020;172(11):726-734.
5. **Keshavarzi A, Mohammadi AA, Ayaz M, *et al.*** Cutaneous vesicular of COVID-19 in two burn patients. *World J Plast Surg.* 2020;9(3):331-338.
6. **Emami A, Javanmardi F, Keshavarzi A, Pirbonyeh N.** Hidden threat lurking behind the alcohol sanitizers in COVID-19 outbreak. *Dermatol Ther.* 2020;33(4):e13627.

7. **Lawrenson JG, Buckley RJ.** COVID-19 and the eye. *Ophthalmic Physiol Opt.* 2020;40(4):383-388.
8. **Konala VM, Adapa S, Gayam V, *et al.*** Co-infection with Influenza A and COVID-19. *Eur J Case Rep Intern Med.* 2020;7(5):001656.
9. **Yuen K-S, Ye ZW, Fung SY, *et al.*** SARS-CoV-2 and COVID-19: the most important research questions. *Cell Biosci.* 2020;10(1):1-5.
10. **von Elm E, Altman DG, Egger M, *et al.*** The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Ann Intern Med.* 2007;147(8):573-577.
11. **Harriss D, Atkinson G.** Ethical standards in sport and exercise science research: 2016 update. *Int J Sports Med.* 2015;36(14):1121-1124.
12. **Khorrami F, Shahi M, DavariDolatabadi N, *et al.*** Implementation of regional COVID-19 registry in Hormozgan (RCovidRH), Iran: rationale and study protocol. *Med J Islam Repub Iran.* 2020;34(1):676-683.
13. **Dandachi D, Geiger G, Montgomery MW, *et al.*** Characteristics, comorbidities, and outcomes in a multicenter registry of patients with HIV and coronavirus disease-19. *Clin Infect Dis.* 2020;epub:ciaa1339. doi: 10.1093/cid/ciaa1339.
14. **Ciminelli G, Garcia-Mandicó S.** COVID-19 in Italy: an analysis of death registry data. *J Public Health.* 2020;epub:fdaa165. doi: 10.1093/pubmed/fdaa165.
15. **Emami A, Javanmardi F, Akbari A, *et al.*** Survival rate in hypertensive patients with COVID-19. *Clin Exp Hypertens.* 2021;43(1):77-80.
16. **Emami A, Javanmardi F, Akbari A, *et al.*** Characteristics of deceased patients with COVID-19 after the first peak of the epidemic in Fars Province, Iran. *Infect Ecol Epidemiol.* 2020;10(1):1781330.
17. **Emami A, Fadakar N, Akbari A, *et al.*** Seizure in patients with COVID-19. *Neurol Sci.* 2020;41(11):3057-3061.