



**Surveillance of COVID-19 in Patients with Type 1 Diabetes**

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## **1. Background and Rationale**

The ongoing outbreak of the novel respiratory disease, Coronavirus 2019 (COVID-19), recognized in December 2019, has become a significant threat to global health (1).

As of April 03, 2020, more than 1 million cases of confirmed COVID-19 have been documented globally, with over 55,000 deaths worldwide. In the U.S. as of this date, there are over 257,000 confirmed cases with more than 6000 deaths. Although individuals of any age can be infected by COVID-19, individuals with pre-existing medical conditions, such as diabetes and heart disease, appear to be more vulnerable to becoming severely ill with the virus (2-4). Initial data from COVID-19 cases, recently reported by the American Diabetes Association, show that individuals with uncontrolled diabetes are more likely to have worse outcomes. Specifically, for individuals with Type 1 Diabetes (T1D), a chronic autoimmune disorder where the pancreas does not produce the insulin required to control blood sugar levels, an infection may lead to severe adverse outcomes such as Diabetic Ketoacidosis (DKA), and other serious complications or death (5, 6).

Given the lack of data and the urgent nature of this evolving health issue, we plan to implement a surveillance mechanism for this at-risk population of individuals with T1D. Understanding and cataloging clinical characteristics of individuals with T1D who may have contracted COVID-19 will be essential for preparing management strategies for this vulnerable population. The results from this study will be used to understand etiology and potential outcomes in COVID-19 patients, as well as inform clinical quality improvement activities.

The T1D Exchange seeks to implement a population health surveillance study that will collect, securely store, and aggregate non identifiable patient data on suspected or confirmed COVID-19 cases among patients with T1D.

## **2. Study Objective**

Aim 1: To conduct a population health surveillance of individuals with T1D who are suspected or confirmed to have contracted COVID-19.

Aim 2: To estimate the rate of COVID-19 infection among individuals with T1D

Aim 3: To estimate the rates of adverse outcomes, such as DKA, among COVID-19 positive, presumed positive, or suspected cases in the T1D population.

## **3. Research Design and Study population**

This study will be a cross-sectional survey completed by clinicians providing care to patients with T1D and suspected or confirmed COVID-19 cases. The study population will include all de-identified patients with T1D who have tested positive, are a presumed positive for, or are suspected of contracting COVID-19. Electronic health records from January 2020 onwards from participating clinic sites will be used in this study.

#### **4. Survey tool**

The online REDCap survey tool will be used at each participating clinic site by the clinician to report non identifiable patient health data. The reporting clinician will extract relevant information on required variables using data from electronic medical records and/or other relevant sources of documentation being used at clinic sites. The main variables of interest will be as follows.

##### *4.1 Primary variables of interest*

- Presenting symptoms
- Age (in years)
- Gender
- Race/Ethnicity
- Insurance type
- Duration of T1D diagnosis
- Diabetes management (use of diabetes technology for managing blood sugar levels)
- Comorbidities
- Relevant health behaviors (such as smoking or vaping)

#### **5. Statistical Analysis**

Aim 1: Descriptive statistics will be used to summarize survey data. Summary statistics, including frequency and percentage for categorical variables, will be calculated for all patient-related and clinical characteristics, such as age categories, gender, diabetes device usage, and comorbidities.

Aims 2 and 3: De-identified data will be used to estimate the rate of COVID-19 among patients with T1D, as well as rates of adverse events for suspected or confirmed COVID-19 patients with T1D, such as DKA.

#### **6. T1D Population Health Benefits**

- I. The results of the study will build evidence for ongoing Quality Improvement efforts in clinics to respond to the COVID-19 global pandemic.
- II. The results can provide guidance of different clinical presentations and outcomes for patients with T1D and COVID-19.
- III. The results of the study will be shared broadly with the clinical community to improve population health.
- IV. The study will address a missing information gap regarding critical information on the clinical impact of COVID-19 in patients living with T1D.

## **7. General Considerations**

### *7.1 Adverse Events*

As this is a non-treatment and non-intervention study, no patient identifiable data will be collected as part of the study. Risks to participants is very limited. All study data will be kept strictly confidential and only accessible to trained research staff and qualified researchers.

### *7.2 Protections Against Risk*

The study team considers the confidentiality of any patient data to be of the utmost importance. All staff at the study center will maintain strict confidentiality regarding data collected. No record with personally identifiable information regarding the participant will be collected, and all information will be stored securely. Information from this study will be released only in aggregate form, which will not identify any participant individually.

### *7.3 Potential Benefits of the Proposed Research to Subjects and Others*

Researchers believe that the risks of participating in this study, which are very limited considering no identifiable data will be collected, are outweighed by the benefits of the knowledge that may be gained.

## **8. References**

1. Li Q, Guan X, Wu P, Wang X, Zhou L, Tong Y, et al. Early Transmission Dynamics in Wuhan, China, of Novel Coronavirus-Infected Pneumonia. *The New England journal of medicine*. 2020 Mar 26;382(13):1199-207. PubMed PMID: 31995857.
2. Garnier-Crussard A, Forestier E, Gilbert T, Krolak-Salmon P. Novel Coronavirus (COVID-19) Epidemic: What Are the Risks for Older Patients? *Journal of the American Geriatrics Society*. 2020 Mar 12. PubMed PMID: 32162679.
3. Chan KW, Wong VT, Tang SCW. COVID-19: An Update on the Epidemiological, Clinical, Preventive and Therapeutic Evidence and Guidelines of Integrative Chinese-Western Medicine for the Management of 2019 Novel Coronavirus Disease. *The American journal of Chinese medicine*. 2020 Mar 13:1-26. PubMed PMID: 32164424.
4. Li LQ, Huang T, Wang YQ, Wang ZP, Liang Y, Huang TB, et al. COVID-19 patients' clinical characteristics, discharge rate, and fatality rate of meta-analysis. *Journal of medical virology*. 2020 Mar 12. PubMed PMID: 32162702.
5. Badawi A, Ryoo SG. Prevalence of Diabetes in the 2009 Influenza A (H1N1) and the Middle East Respiratory Syndrome Coronavirus: A Systematic Review and Meta-Analysis. *Journal of public health research*. 2016 Dec 9;5(3):733. PubMed PMID: 28083520. Pubmed Central PMCID: 5206772.

6. Yang JK, Lin SS, Ji XJ, Guo LM. Binding of SARS coronavirus to its receptor damages islets and causes acute diabetes. *Acta diabetologica*. 2010 Sep;47(3):193-9. PubMed PMID: 19333547. Pubmed Central PMCID: 7088164.