The ASH Research Collaborative Data Hub COVID-19 Registry for Hematologic Malignancy Protocol

Date: March 26, 2020

A. Introduction
The ASH Research Collaborative (ASH RC) seeks to launch a Hematologic Malignancy and COVID-19 Surveillance Registry to provide near real-time observational data summaries to clinicians on the front line of the COVID-19 pandemic. The COVID-19 Surveillance Registry will capture high-level de-identified data on all malignant hematology patients regardless of recovery or active treatment status. Data will be entered via a web-based data collection tool by a clinician or other health care provider. Data will be analyzed, and observations reported, in aggregate form on ASH RC’s public facing website. The primary purpose of the registry is to publicly report near real-time observational data summaries and is not intended for research purposes.

B. COVID-19 Registry for Hematologic Malignancy Overview

Background and Significance
The COVID-19 pandemic is an evolving healthcare crisis in the United States and around the world. COVID-19 has unique implications for patients with blood diseases. Patients with hematologic malignancy are at markedly increased risk of infection as a direct consequence of their blood disease and the powerful immunosuppression caused by contemporary treatments for these diseases. Early published evidence suggests that cancer patients, and potentially even cancer survivors, may be uniquely susceptible to morbidity and mortality from COVID-19. However, existing data is limited and may not be generalizable to patients with hematologic malignancies. There is an urgent need to rapidly collect and disseminate surveillance data on the natural history of patients with COVID-19 and hematologic malignancies. Already, clinicians are being required to make difficult decisions regarding when to continue versus decrease or delay cancer treatment in order to mitigate the risk of death from COVID-19 without informative data. The ASH RC Data Hub is well positioned to lead an international initiative to provide near real-time observational data for clinicians who urgently need real time data as they determine the best course of treatment with their patients.

Project Goals:
1. To create an international de-identified observational surveillance registry for outcomes of patients with COVID-19 and hematologic malignancy.
2. To provide expedient public reports of aggregated data on the outcomes of patients with COVID-19 and hematologic malignancy in order to facilitate clinical decision making.

C. Methods

Patient Inclusion Criteria and Data Capture
Standard course of care data will be captured through a web-based data collection form to allow physicians or other healthcare providers to enter information for any person who tested COVID-19 positive and has previously been, or is currently diagnosed with, a hematologic malignancy. The data collection form will link to a secure database where providers enter de-identified patient information. See appendix 1 for the data collection form. The online data collection form has been designed to capture only essential information on the hematologic disease, recent treatments for the hematologic disease, and severity and outcome of their infection with SARS-CoV-2. To minimize burden on
healthcare workers, the online data collection form is designed to take less than five minutes to complete.

Data will be entered by healthcare providers (reporters) on a voluntary basis at his or her workplace in a private setting. Reporters will establish a login so they can return to complete data entry for patients as more information is available. Reporters are able look up previously submitted patients used a de-identified code developed by the data collection tool and the patient’s age category and sex if previously entered. No additional interventions will be necessary.

Patients (and/or family members) will not be recruited to participate due to concerns about data reliability and duplicate data entry.

IRB/HIPAA
Data will not be collected for research purposes and data captured meets HIPAA Safe Harbor De-identification requirements. No identifiable patient information will be collected. This protocol is being submitted for IRB review and request for a non-Human Subjects Research determination because the Registry:

- Meets the definition of HIPAA de-identification.
- Creates a code for each patient at the reporter level that is generated by the data entry tool at the point of data entry. Only the reporter will know who the patient is and their corresponding code.
- The reporter may look up a patient to complete additional data entry based on the code and other demographic information maintained by the reporter, and ASH RC will have no mechanism to identify individual patients.
- Anyone involved with data analysis will not have access to any patient identifiers.

Obtaining a non-Human Subjects Research determination will greatly facilitate the speed and efficiency of implementation and subsequent data collection.

Compensation
Data entry is voluntary, and no compensation is provided to reporters who enter data.

Oversight
Registry program clinical experts will provide leadership and subject matter expertise and will work closely with operations staff to design and execute the registry. A registry task force of 3-5 individuals will serve as a convening group review data analysis prior to public posting. The task force will consist of the registry program leaders and 1-3 individuals with malignant hematology, bio epidemiology, and/or biostatistical expertise. The registry task force will report to the Data Hub Oversight Group.

Data Security, Analyses and Reporting
Although no protected health information (PHI) will be collected, all data will be securely stored. Security measures include physical and network access controls, HR and business operations SOPs, encrypted data transmissions and storage, user access controls and activity logging, system monitoring for abnormality events, and active third-party penetration testing.

Data analysis will be performed and reported on the ASH RC public facing website with simple descriptive statistics on a weekly basis or more frequent, if needed. Since all data entered are de-identified, no PHI will be reported.

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1 Risk of COVID-19 for patients with cancer, Hanping Wang, Li Zhang, Published:March 03, 2020DOI:https://doi.org/10.1016/S1470-2045(20)30149-2