



COVID-19 Evidence Accelerator Collaborative

Lab Meeting #22

Thursday, November 5, 2020, 3 - 4:00 pm ET

Call Summary

Overview of Lab Meeting 22

The November 5, 2020 lab meeting focused on using the oncology workstream to evaluate real-world data associated with oncology patients with COVID-19. First, Dr. Harpreet Singh of the Food and Drug Administration's Oncology Center of Excellence (FDA/OCE) introduced the meeting objectives. Next, there were presentations by representatives from Syapse, Flatiron Health, COVID-19 Cancer Consortium, TERA-VOLT, and ASCO around the current research in this area. This was then followed by a presentation introducing Project Post-COVIDity including a group of presentations from Health Catalyst and COTA focused on projects related to the FDA/OCE effort to use RWD to develop a longitudinal understanding of the impact of COVID-19 on patients with cancer.

Introduction to the Oncology Workstream

Harpreet Singh, FDA/OCE

- Early in the pandemic the Oncology community recognized a need to understand the impact of COVID-19 on cancer patients, a particularly vulnerable population.
- Bringing together a group to explore data and understand the impact of Covid on these populations. Some questions considered:
 - Natural history of COVID
 - Impact of health care system changes on the course of cancer therapies
 - Mortality, treatment, & outcomes of COVID patients with cancer
- Registry Component of Workstream – Collecting and analyzing data from registries to inform some of these questions.
 - Syapse
 - Flatiron Health
 - CCC19
 - TERA-VOLT
 - ASCO
- Long Haulers Working Group

- Once recovered from COVID, it may not be the end of the patient's journey. What does that mean for COVID patients with cancer?

Overview of Current Status on Available Data

FDA (OCE) & Syapse COVID-19 & Cancer Initiative

Thomas Brown, Syapse

- **Data Sources & Approach:** Data from health systems (Electronic Medical Records (EMRs), Physician Order Entries (CPOE), Hospital-Based Cancer Registries, etc.), reference labs, and external sources (SEER, Social Security Death Index (SSDI), Digitized Obituary Data).

Patterns of Diagnosis & Care for Patients with Early Breast Cancer during the COVID-era using an EHR-derived de-identified dataset

Shrujal Baxi, Flatiron Health

- Conducting a retrospective observational study using electronic health record data from the Flatiron Health network
 - Exploring patterns of diagnosis and treatment in patients with early breast cancer during the COVID era (Feb. 2020 – June 2020), benchmarked to a population diagnosed in a pre-COVID time period (June 2019-November 2019)
 - Will look at the impact of COVID on how we are taking care of patients holistically
- **Preliminary Findings (Note: Data not yet mature so it is too early to draw firm conclusions. It takes about 6 months to enable true comparison between time periods.):**
 - With data through August 2020, there was a drop in the number of early breast cancer diagnoses from April 2020 – May 2020 compared to a six month period in 2019
 - The percentage of patients receiving surgery as their first treatment modality decreased from the pre-COVID era (78.8%) to the COVID era (63.5%) and more patients received systemic therapy first during the COVID-era (Feb. 2020 – June 2020)
 - Further analyses are needed to adjust for key clinical factors that underpin treatment decisions (e.g., stage, biomarker status). Flatiron will present final results after conducting in-depth analyses and evaluating the entire treatment course for patients diagnosed with early breast cancer during the pandemic

COVID-19 & Cancer Consortium

Petros Grivas, University of Washington, Fred Hutchinson Cancer Research Center, Seattle Cancer Care Alliance

- 124 participating institutions across US, Canada & Spain

- **Results (Note:** Association in these data does not equal causation and remains hypothesis-generating considering inherent selection and confounding biases)
 - Identify risk factors associated with 30-day all-cause mortality
 - Age (older), sex (male), race (black vs white), history of smoking, ≥ 3 medical comorbidities, ECOG PS ≥ 2 (vs 0)
 - Progressive cancer
 - Recent anti-cancer therapy within 3 months
 - Hematologic vs. solid tumor
 - Multiple (vs. one) malignancies
 - 30-day all-cause mortality associated with anti-Covid19 therapy exposure as below:
 - Remdesivir alone was significantly associated with *lower* 30-day all-cause mortality vs other anti-Covid19 therapy
 - High-dose systemic corticosteroids alone were not significantly associated with *lower* 30-day all-cause mortality vs other anti-Covid19 therapy
 - Standardized Mortality Ratio (SMR)
 - Chemo given within 2 weeks, Chemo & IO given within 2 weeks, Targeted Therapy given between 1 and 12 months prior to Covid19 – associated with higher standardized mortality ratios
 - Endocrine Therapy given within 2 weeks – associated with lower standardized mortality ratio
- **Current Status & Future Plans**
 - Registry currently has 5,617 patients; we continue robust QA/QC of the dataset
 - Ongoing and future projects – thrombotic complications, geriatric populations, prostate cancer & ADT, etc.
 - Recently added Mexico, Argentina, Colombia & seeking to expand further to Central & South America
 - Updated analysis will be conducted very soon to assess validation of results

Thoracic Cancers International COVID-19 Collaboration

Marina Chiara, TERA-VOLT

- Registry to capture details on thoracic cancer patients with a confirmed COVID-19 infection, including:
 - Demographic & clinical information
 - Cancer diagnosis & prior treatment details
 - COVID-19 diagnosis & course of illness
 - Lab & radiology findings at COVID diagnosis
 - Clinical outcomes
- **Baseline Demographics**
 - **Region**
 - Europe – 74%
 - N. America – 23%

- **Median Age** – 68 (60% >65 years old)
- **Males** – 58%
- **White** – 73%
- **Current or Former Smoker** – 78%
- **ECOG PS**
 - 0 – 23%
 - 1 – 38%
 - >= 2 – 26%
- **Oncological Treatment**
 - Chemotherapy, Target Therapy, Immunotherapy, Chemo-Immuno, No Treatment
 - More patients that received chemotherapy or no treatment (in last 3 months) died than recovered from COVID.

ASCO Survey on COVID-19 Oncology Registry

Liz Garrett-Mayer, American Society of Clinical Oncology (ASCO)

- **Goal:** Capture & analyze practice changes and outcomes of cancer patients with confirmed COVID-19 from participating practices & institutions for 12 months.
- **Eligibility:** Patients with confirmed COVID-19 & either active cancer treatment OR cancer free for <1 year *and* on adjuvant therapy.
- **Key Data Elements:**
 - Risk factors & demographics
 - COVID-19 symptoms, treatments & long-term outcomes
 - Cancer status at baseline, changes to treatment plans, & cancer outcomes
 - Pandemic impacts on practice patterns, care implementation, & resources
- **Data:**
 - From 57 practices across the United States:
 - ~700 patients so far
 - Practice-level changes in cancer delivery
 - Geospatial analysis with other cancer, COVID, socioeconomic datasets
- **ASCO Registry Data Dashboard**
 - Shows information on patients in registry so far

Project Post COVIDity

Donna Rivera, FDA/OCE

- **Background**
 - Need to rapidly develop evidence-based information to characterize & treat patients with COVID-19, especially those in vulnerable populations such as those with cancer.
 - Clinical trials for COVID-19 therapeutics exclude cancer patients, RWD can help inform clinical decisions and design of clinical trials for oncology drugs.

- Regulatory research opportunity to conduct RWD studies that assist FDA in characterizing the patient population with cancer and COVID-19.
- **Objective**
 - To develop a longitudinal understanding of the impact of COVID on patients with cancer post infection, including the impact of infection on treatment initiation or delay, regimen selection and therapeutic utilization potential adverse sequelae, and outcomes.
- **Aims**
 1. Characterize baseline cohort of patients with COVID & cancer (type, age, sex, race/ethnicity, geographic region, type of cancer therapy, potential risk factors).
 2. Characterize longitudinal outcomes of patients with COVID & cancer, including cardiac, neurologic, thrombotic, and renal complications.
 3. Describe safety of immunotherapies patients who have recovered from COVID and are being treated with immune checkpoint inhibitors, including analysis of each cancer site, sequelae, treatment patterns, and outcomes.
- **Lessons Learned from Friends of Cancer Research Real World Evidence Pilot Project on NSCLC**
 - Standardizing definitions across datasets
 - Data quality
 - Variance in methodological approaches
 - Importance of sensitivity analysis
 - Collective effort for the common good
 - RWD is complex & required careful analysis
- **Parallel Analysis Methods**
 - Creating standardized nomenclature
 - Consider potential outcomes & treatment patterns
- **Next Steps**
 1. Establish interest among collaborative group
 2. Address cohort feasibility
 3. Discuss feasibility results
 4. Assess the need to update data table intermittently
 5. Begin analytical discussions to decide on threshold for study start
 6. Initiate longitudinal analysis through the RU EA oncology workstream

Health Catalyst: Project Post-COVIDity Update

Elizabeth Eldridge, Health Catalyst

- 16 health systems, de-identified EMR structured data
- Identified cohort using MAR and ICD codes
- Patients with Cancer & COVID receiving IO administration (5 specified)
 - Temporality of Selected IO Administration
 - Any history of IO prior to COVID diagnosis (n=193), within 3 months prior to COVID diagnosis (n = 125), within 4 weeks prior to COVID diagnosis (n = 95)

- Any IO administration, IO administration within +/- 90 days of COVID diagnosis (n = 164)
- Mixed timing of IO administration around COVID-19 diagnosis & mix of how clinicians document malignancies using ICD codes
 - Requires additional data cleaning considerations
 - Data lag is a barrier to data exploration

COTA: Project Post-COVIDity Update

Drew Belli, COTA

- **Collaboration Overview**
 - Working through data acquisition & curation of outpatient population with active cancer diagnosis & COVID testing.
 - Patient populations representing Northeast, Southeast, and Southcentral United States.
- **Current Status**
 - 400 patients with cancer who have also been diagnosed with COVID-19
 - **Note:** Preliminary numbers, expected to increase.
 - Most common cancers include breast, multiple myeloma, & lung
- **Challenges**
 - Data aggregation challenges including varying HER documentation and site-specific testing practices
- **Next Steps:** Identify cohort(s) of interest.