

ASCO[®] Registry

ASCO Survey on COVID-19 in Oncology (ASCO) Registry

Study Schema – 8.23.2021

Rationale

The COVID-19 Pandemic is presenting a unique opportunity to capture information on how a disease outbreak affects delivery of high-quality cancer care. ASCO is providing the means for the oncology community to submit data that will inform both current cancer care and provide information to help guide decision-making for future disease outbreaks. While other entities have launched COVID-19 cancer registries, ASCO has extensive relationships with the entire cancer care community, particularly private practices that may be caring for the majority of cancer patients with COVID-19. ASCO's registry collects information about patients undergoing treatment for cancer and with confirmed SARS-CoV-2 infection based on a positive test. Unlike other registries, ASCO's registry collects follow-up information on both SARS-CoV-2 infection and cancer outcomes at 30-day intervals for the first 90 days, 90-day intervals up to one year, and at 18- and 24-months after a positive SARS-CoV-2 test.

Project Objectives:

- Capture and describe cancer and SARS-CoV-2 infection status at SARS-CoV-2 confirmed infection, during acute SARS-CoV-2 infection phase, and for lingering SARS-CoV-2 infection symptoms and sequelae (as relevant), as well as cancer and SARS-CoV-2 infection outcomes for patients who are either 1) undergoing active cancer treatment, 2) disease-free and within 12 months of surgical resection, or 3) receiving palliative care only at participating cancer practices/institutions. Data collected will include treatment approaches, cancer status, changes to cancer treatment plans in patients with confirmed SARS-CoV-2 infection, status of SARS-CoV-2 infection (e.g., severity of symptoms, need for ventilator, hospitalization, recovered, long-term symptoms and sequelae, etc.) and status of cancer (e.g., cancer progression, treatment-related changes/modifications, etc.).

Project Deliverables:

- Periodic Reports on Patient Population, Estimates of Disease Severity, Treatment Modifications, and Clinical Outcomes Among Patients – for participating sites and publicly accessible on ASCO websites for the oncology community
- Abstract(s) and Manuscript(s) for Submission to Peer-Reviewed Journals
- Deidentified data for use by ASCO-approved external researchers

Research Objectives:

Objective 1: Describe the distribution of symptoms and severity of SARS-CoV-2 infection among patients with cancer (on active treatment, on adjuvant treatment within 12 months after surgical resection, or on palliative care only) who have a positive SARS-CoV-2 test result

- **Objective 1.1:** Describe distribution of symptoms and severity of SARS-CoV-2 infection stratified according to demographic characteristics, including age, cancer type, cancer

extent, race, ethnicity, geography, type of therapy received, smoking status, comorbidities, etc.

- **Objective 1.2:** Identify characteristics independently associated with severity of SARS-CoV-2 infection in cancer patients.

Objective 2: Examine SARS-CoV-2 infection outcomes (ongoing; receiving supplemental oxygen; hospitalized, not in ICU; hospitalized in ICU; placed on ventilator; death due to COVID-19 disease complications; recovered; long-term symptoms and sequelae), receipt of SARS-CoV-2 vaccine, and cancer outcomes (stable, responding to treatment, progressed, delayed treatment, treatment discontinued, and death)

- **Objective 2.1:** Stratify patients with SARS-CoV-2 viral infection according to characteristics described in Objective 1.1 to examine whether any of the characteristics are independently associated with COVID-19 and/or cancer outcomes
- **Objective 2.2:** Examine the relationship between SARS-CoV-2 viral infection outcomes and cancer outcomes and whether SARS-CoV-2 viral infection outcomes are independently associated with cancer outcomes

Objective 3: To describe effects of the COVID-19 pandemic on cancer practices in the U.S., including changes in staffing and resource availability, prioritizations for patient care, modification of interactions between care providers and patients (including use of telemedicine), and modification of research-related interactions with trial participants and study sponsors (including use of telemedicine and local healthcare facilities for research visits and/or data collection)

Eligibility Criteria:

The registry will collect data about patients with a cancer diagnosis who have a confirmed SARS-CoV-2 infection and are being treated at participating cancer practices/institutions within the United States.

Patients in one of the four categories are eligible:

1. Patients with a new cancer diagnosis and in the process of cancer staging and/or receipt of initial cancer therapy
2. Patients with clinically evident cancer receiving anti-cancer treatment,
3. Patients who are disease free, but receiving any type of adjuvant therapy within 1 year following surgical resection (including hormonal treatments), and
4. Patients with clinically evident cancer receiving supportive care only.

Statistical Considerations and Reporting

ASCO's Center for Research and Analytics (CENTRA) has created an online data dashboard (<https://www.asco.org/asco-coronavirus-information/coronavirus-registry/covid-19-registry-data-dashboard>) that is routinely updated. The ASCO Registry Dashboard summarizes data in the overall cohort and includes an interactive mechanism to stratify by patient characteristics, such as cancer types and extent, age, race, ethnicity, gender, smoking status, SARS-CoV-2 infection symptoms, and comorbidities. Reports or publications will also include cancer treatment delay and discontinuation of cancer treatments including surgery, radiation, and drug-based therapies, due to the patient's SARS-CoV-2 infection and to other factors, with stratification by other variables as described above. Changes in practices' patterns of care, staffing, resources, and interactions with patients will also be evaluated and summarized.

As there is no hypothesis testing planned, there is no required sample size and providing repeated reports, with cumulative information, will not affect validity of results. Confidence intervals will be provided where appropriate to demonstrate precision of estimates.

IRB Review

Prior to launch of the ASCO Registry in April 2020, ASCO received approval from the WCG Institutional Review Board (IRB):

“We determined this study is exempt from IRB review because it does not meet the definition of human subject as defined in 45 CFR 46.102. Specifically this study will [*sic*] deidentified data in the form of limited data sets from the participating clinics and institutions and you will enter into Data Use Agreements, and you will not otherwise interact with the patients.”

ASCO asked WCG IRB to rereview the August 2021 updates, and WCG IRB reaffirmed the determination of the study as exempt. The WCG IRB letters are available on the ASCO Registry website. ASCO encourages practices to rely on the WCG IRB review. If local IRB approval is necessary, the review must be completed before the practice can execute the data use agreement (DUA) with ASCO.

Practice Expectations (*Refer also to study calendar in Appendix.*)

- Review study schema, data collection elements, and WCG IRB determination.
- Complete practice contact information (link available at the ASCO Registry website) and download the DUA. In the interest of prompt data reporting, ASCO will only entertain DUA revisions related to the local site contact information.
- Contact CENTRA@ASCO.org to express interest in participation and execute DUA with ASCO.
- Access web address provided by ASCO for data entry and select practice name from the drop-down list of practices that have executed a DUA.
- Complete initial and follow-up data entry forms. Follow-up data includes information on SARS-CoV-2 and cancer treatment and outcomes. Ideally, data entry will be done routinely. During short-term follow-up, ASCO requests case updates at 30-, 60-, and 90- -day intervals, unless a patient has died or left the practice. ASCO requests long-term follow-up at 6-, 9-, 12-, 18-, and 24-month intervals, unless a patient has died or left the oncology practice. Where necessary, practices should attempt to obtain information from inpatient hospitalizations.
 - Data includes:
 - Limited patient identifiable data, including home zip code, practice zip code, and date of birth
 - Demographics (e.g., gender, race, ethnicity, type of cancer, and comorbidities)
 - SARS-CoV-2 infection status (e.g. symptoms, sequelae, treatments, vaccination status, and outcomes)
 - Cancer status (e.g., treatment plans, any changes to treatment plans, and response to treatments)
 - ASCO encourages practices to create a local standard operating procedure (SOP) to arrange systematic data entry. Retrospective data could be retrieved from the EHR using the ICD-10-CM diagnosis code U07.1 ([created by the Centers for Disease Control and Prevention \(CDC\) on March 18, 2020](#)). Previous ICD-10-CM codes were 1) Coronavirus, as cause of disease classified elsewhere B97.29, 2) Coronavirus NEC B34.2, and 3) SARS-associated coronavirus J12.81. The coding system for laboratory and clinical test results

(LOINC) has also established several [codes for tests for the COVID-19 virus: SARS Coronavirus 2](#).

- ASCO has created a [Registry Patient Tracker](#) to help practices maintain a local record of patient cases entered into the registry and due dates for data updates.
- Practices may have to contact the hospital for information regarding an inpatient admission.
- ASCO provides participating sites with a practice-based stipend following completion of the Practice Changes Survey and completion of initial and at least one follow-up form submitted 30 or more days after the date of the first form submission for a patient. Initial case-based stipends are paid to a practice after the first 30-day update is provided for the patient case. ASCO will provide second per-case stipends for completed registry cases that have data entered at 12-, 18-, and 24-month updates.
 - For patients who are initially enrolled in the Registry as cancer-free and receiving any type of adjuvant therapy within 1 year following surgical resection (including hormonal treatments), please continue to enter data on them for 18- and 24-month updates after positive SARS-CoV-2 test. Even though they would be outside the 12-month period mentioned in the initial eligibility criteria, we would like their data for the full 24 months.
- For patients who have a second positive SARS-CoV-2 test, please treat this as a NEW SARS-CoV-2 infection. This will reset the timing of their data entry criteria. In other words, a second positive test brings them back to SARS-CoV-2 infection and cancer updates at 1, 2, 3, 6, 9, 12, 18, and 24 months after the second infection time. The second infection serves as a new infection qualifying event. We would like to have data on the patient through 24 months after the last confirmed coronavirus infection. In these cases, ASCO will not pay a second initial per-case payment, but will provide the second per-case payment at their final 24-month data update.

Participating practices are listed on the [ASCO Registry webpage](#). Practices may withdraw from the registry at any time.

Please contact CENTRA@ASCO.org for additional information or questions.

The ASCO Registry is supported by Conquer Cancer's [COVID Impacts Cancer Fund](#).

Appendix A – Study Calendar and Timelines

Study Calendar for Patients in ASCO Survey on COVID-19 in Oncology Registry

This schedule is intended to ensure consistent reporting across practices. It is important for practices to follow the schedule as close as possible because deviations may impact the quality of data in the registry and accuracy of inferences. However, ASCO acknowledges that adjustments may need to be made for some practices.

Phase	Initial Entry	Short term Follow-up			Long-term Follow-up
	Initial at time of SARS-CoV-2 infection*	1 month** after SARS-CoV-2 infection	2 months after SARS-CoV-2 infection	3 months after SARS-CoV-2 infection	6, 9, 12, 18, and 24*** months after SARS-CoV-2 infection
Initial Entry:					
Initial Clinical and Demographic Information	●				
SARS-CoV-2 infection Symptoms, and Treatment	●				
Cancer Diagnosis, Status, and Treatment	●				
Short Term Follow-up					
SARS-CoV-2 infection Update		●	●	●	
Cancer Status Update		●	●	●	
Long Term Follow-up					
SARS-CoV-2 infection Long-term Update					●
Cancer Long-term Update					●

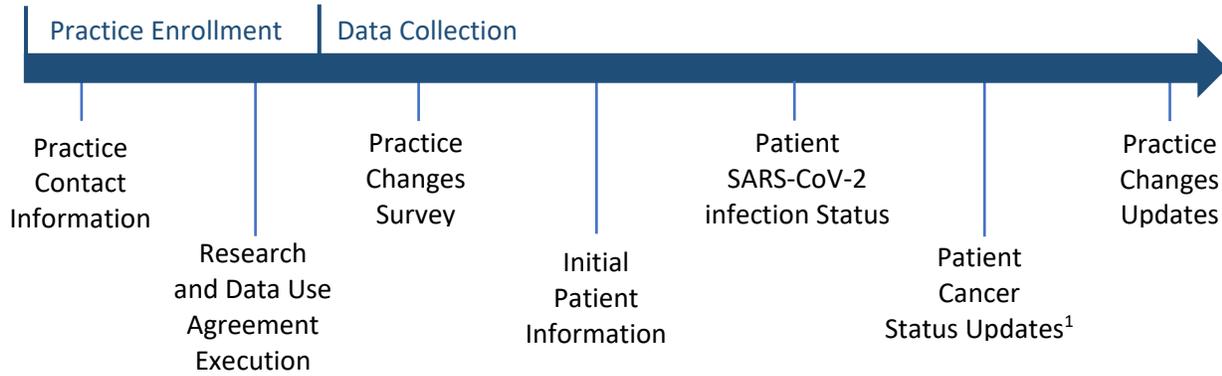
*If patient is deceased at the time of initial form submission or leaves practice prior to 30 days, a practice should complete a patient update form at any time to receive the initial per-case payment for the case in that month.

** ASCO provides a practice-based stipend after a practice has entered initial data and at least one follow-up form submitted 30 or more days after the date of the initial data for a patient. ASCO also provides an initial per-case stipend for each case, following initial data and an update at least 30 days later.

*** ASCO provides a second per-case stipend for all cases that have updates provided at 12, 18, and 24 months after SARS-CoV-2 infection, unless the patient has died or left the practice.

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Registry Schedule for Participating Practices



¹Patient SARS-CoV-2 infection and cancer status updates should be entered every 30 days for first 90 days, every 90 days for 12 months, and at 18 and 24 months, unless the patient has died or left the practice. If a patient has a second positive SARS-CoV-2 infection, they should restart the data entry process as a new infection.

³Practice Changes Survey updates may be requested periodically.

Appendix B – Study Stipends

- ASCO provides practices with a practice-based stipend at the time of initial data entry that includes completion of
 - Practice Changes Survey
 - Initial entry for the first patient and at least one follow-up form submitted 30 or more days after the date of the initial form submission
- ASCO provides an initial per-case stipend for each patient entered once the practice has completed
 - Initial entry for SARS-CoV-2 infection
 - Update 30 or more days after initial entry
- ASCO provides a second per-case stipend for each case after the practice has
 - Provided updates at (or as soon as possible near) 12, 18, and 24 months after initial SARS-CoV-2 infection, except in cases where the patient
 - does not come in for treatment at a relevant reporting time OR
 - has died or left care of the oncology practice.

Examples of Cases for Second Per-Case Stipend:

	Initial Data	30 Days	Initial Per-Case?	60 Days	90 Days	6 Months	9 Months	12 Months	18 Months	24 Months	Second Per-Case?
A	✓	✓	Y	✓	N/A	N/A	✓	✓	✓	✓	Y
B	✓	✓	Y	✓	✓	✓	✓	✓	N/A	✓	Y
C	✓	✓	Y	✓	✓	✓	✓	✓	X	✓	N
D	✓	✓	Y	✓	✓	✓	✓	✓	✓ + death		Y
E	✓	✓	Y	✓	✓	✓	✓	N/A	N/A	N/A	N

- Case A – Patient is not seen at practice from the 80th day through 8 months, so updates are not provided at 90 days and 6 months. Practice provides updates at 12, 18, and 24 months.
 - Practice is paid initial AND second per-case stipends.
- Case B – Practice provides all updates during initial year. Practice provides update at 12 months. Patient is not seen at practice during months 13-23, and practice indicates on 24-month update that the patient did not have data at 18 months. Practice provides final 24-month update.
 - Practice is paid initial AND second per-case stipends.
- Case C – Practice provides all updates during initial year. Practice saw the patient during months 13-23, but did not provide 18-month update. Practice provides 24-month update.
 - Practice is paid ONLY initial per-case stipend. A practice must provide updates at 12, 18, and 24 months after COVID-19 diagnosis to receive a payment.
- Case D – Practice provides all updates during initial year and at 12 months. Patient dies at 16 months. Practice indicates at 18 months that patient has died.
 - Practice is paid initial AND second per-case stipends.

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- Note: This scenario would be paid the same if the practice indicates that the patient will no longer be treated at the practice.
- Case E – Practice provides initial and 30-day follow-up and continues updates through 6 months. At 9 months, the practice indicates that patient has died OR indicates that patient has transferred to another oncology practice.
 - Practice is paid only initial per-case stipend. To be eligible for second payment, practice must have data to enter, beginning at 12 months.