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AMERICAN SOCIETY OF CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

SESSION 5: Learning Rapidly to Improve the Conduct of Cancer Clinical Research Beyond the COVID-19 Pandemic

Insights Derived from Real World Clinical Data

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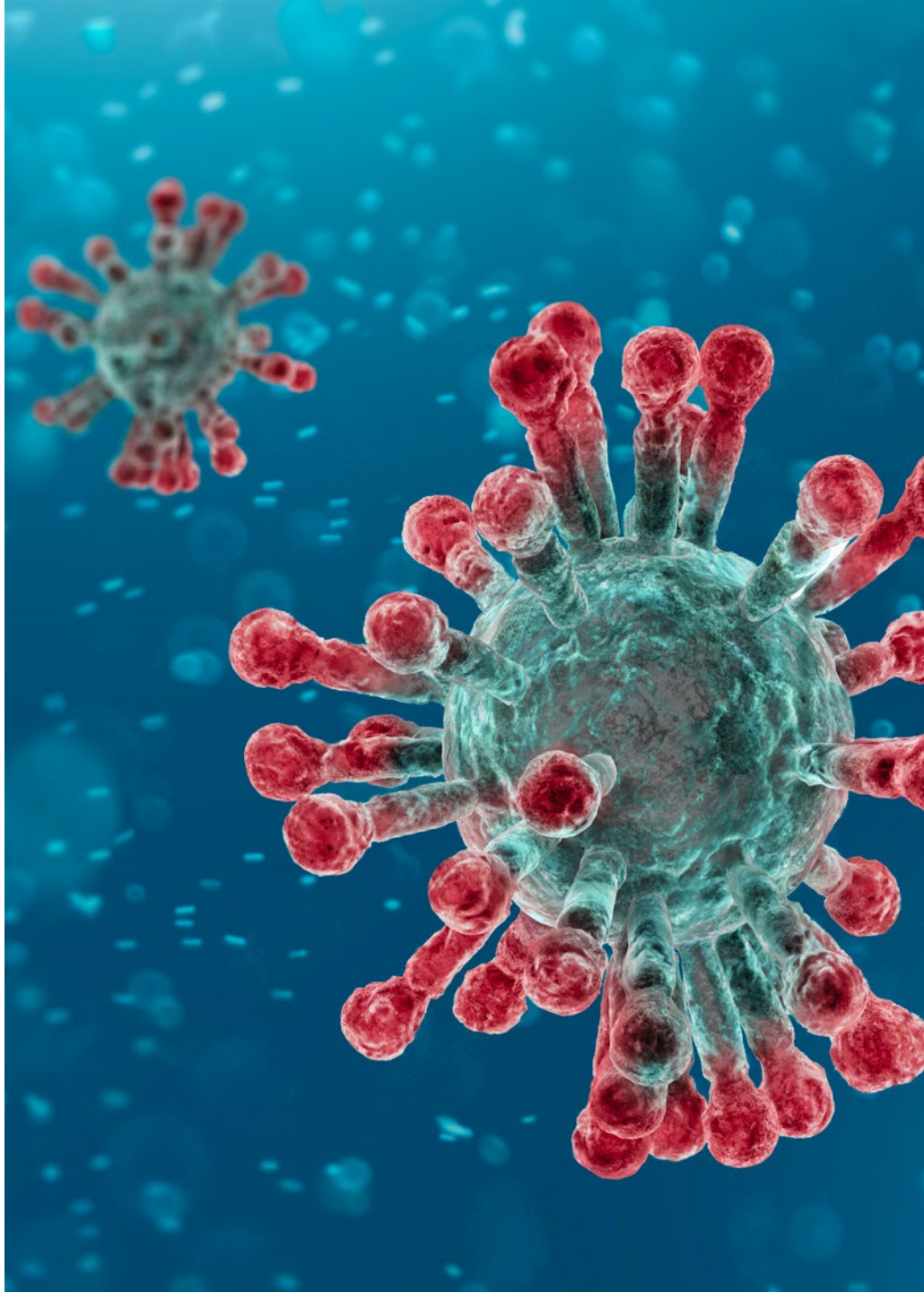


National Academies Workshop on Cancer Care and Cancer Research in the Context of the COVID-19 Pandemic

July 27, 2021

COVID & Cancer registries

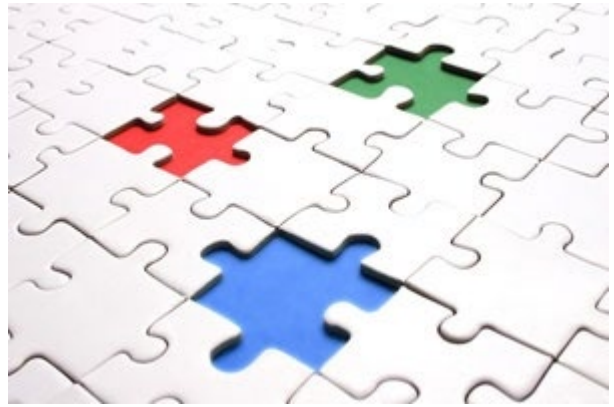
- Rapid development
  - Expedited process for data collection and database construction
- Lacking patient consent
- Diverse populations across registries
- Data collection calendar
- ASCO COVID-19 registry
  - “Limited” dataset
  - Patients with active cancer (or receiving adjuvant therapy for <12 mos)
  - Longitudinal design
  - Practice-based study

ASCO® Registry

Phase	Initial Entry	Short term Follow-up			Long-term Follow-up
	Initial at time of COVID-19 diagnosis[1]	1 month after COVID-19 diagnosis	2 months after COVID-19 diagnosis	3 months after COVID-19 diagnosis	6, 9 and 12 months after COVID-19 diagnosis
Initial Entry: At time of COVID-19 diagnosis					
Initial Clinical and Demographic Information	•				
COVID-19 Diagnosis Symptoms, and Treatment	•				
Cancer Diagnosis, Status, and Treatment	•				
Short Term Follow-up					
COVID-19 Status Update		•	•	•	
Cancer Status Update		•	•	•	
Long Term Follow-up					
COVID-19 Long-term Update					•
Cancer Long-term Update					•

Electronic health records as a source of research data

- Registries and other data sources (e.g., claims or EHR database) are populated by clinical data in medical record.
- Oncology practice data focuses on collection of data for management of cancer
- Key data elements may not be included in patient record
  - Comorbidities and other risk factors
  - COVID19 Symptoms
  - Anti-covid treatments and duration of treatments



Implications for data quality

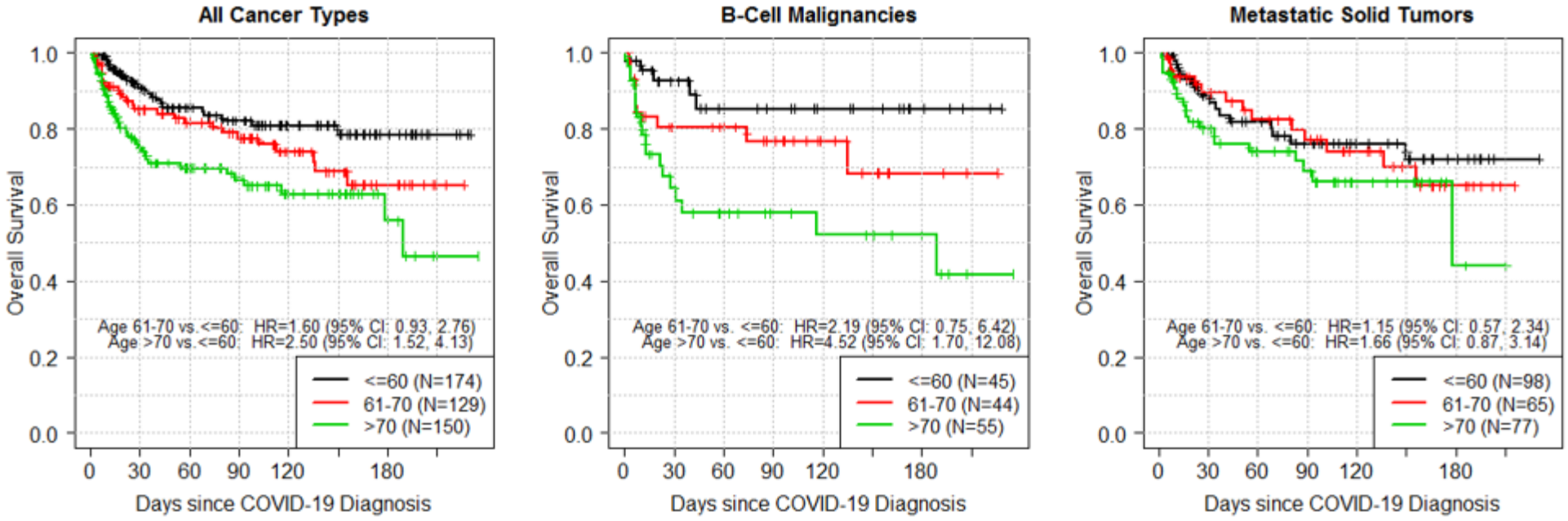
- Variability of data availability and entry by site
- Completeness of follow-up
- Source verification may be impossible
- Under-representation of other relevant health information in datasets
- Potential lack of representation across geographic regions

Key component for valid inferences: Design of study and analytic plans

- Planning and rigor required for each analysis
- Requires pre-specification of research objectives and methods
- Topics to consider:
  - Identification of relevant patient population
  - Control of potential bias
  - Matching and/or accounting for confounding
  - Immortal time bias
  - Definition and measurement of endpoints
  - Handling missing data
  - Differential follow-up
  - Cohort (or seasonal) effects
  - Power to detect clinically meaningful effects
- Missing data and biases limits potential inferences

Despite challenges, evidence emerges!

Figure 1. Overall survival by age in all patients (left; p = 0.001), patients with B-cell malignancies (center; p=0.002), and patients with metastatic solid tumors (right; p=0.40)



Mileham et al., ASCO Annual Meeting 2021, Abstract #6509