CMSS Presents:

Reflecting on Our Covid-19 Failures –
A New Vision for Integrated Registries

July 17, 2020 | 1:30 – 3:00 pm ET

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CMSS WEBINAR SERIES

Advancing Clinical Registries to Support Pandemic Treatment and Response

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Advancing Clinical Registries to Support Pandemic Treatment and Response

The series will address key questions related to the rapid development, deployment and implementation of Covid-19 focused clinical registries and clinical repositories by specialty societies and academia.

SUMMER 2020 | FREE TO ATTEND

About the Series:

- Made possible with funding from the Gordon and Betty Moore Foundation

- To foster collaboration between specialty societies and academia, we are grateful to collaborate with the Association of Academic Medical Colleges

Continue the Conversation:

- Use #COVIDRegistries when tweeting about the webinar series

- Follow @CMSSMed and visit CMSS.org for frequent updates

CMSS WEBINAR SERIES

Advancing Clinical Registries to Support Pandemic Treatment and Response

Today's Webinar:

Reflecting on Our Covid-19 Failures – A New Vision for Integrated Registries

Moderator:

Helen Burstin, MD, MPH, MACP
Chief Executive Officer
Council of Medical Specialty
Societies (CMSS)

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Division Director, Biostatistics and
Research Data Governance;
Center for Research and Analytics
(CENTRA), American Society of
Clinical Oncology

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Principal Scientist
Google

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FACS, FASCRS**
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College of Surgeons; Vice Chair and
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Los Angeles (UCLA)

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Executive Associate Division
Director, Division of
Pulmonary, Allergy, Critical Care,
and Sleep Medicine
President-Elect, Society for
Critical Care Medicine

# REFLECTING ON OUR COVID-19 FAILURES – A NEW VISION FOR INTEGRATED REGISTRIES

Clifford Ko

Professor of Surgery and Health Services, UCLA

Director, Quality Division, American College of Surgeons

The American College of Surgeons

- Largest surgeon membership organization (80,000+ members)

- 100+ year history – founded on principles of quality and education

- Quality Division: largest division in the ACS
  - ~3000 hospitals in the US participate in one or more American College of Surgeons Quality Programs.
  - 15 Accreditation/Verification Programs (e.g. Trauma Centers Program, Cancer Center).
  - Seven Clinical Registries (e.g. National Surgical Quality Improvement Program).
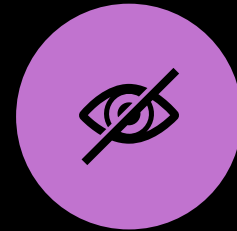
Why good data are essential
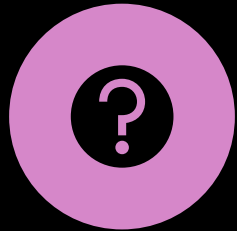
INFORMATION   INVESTIGATION   IMPROVEMENT   WITHOUT DATA, WE ARE BLIND   GARBAGE IN, GARBAGE OUT

At start of the pandemic…

○ International studies showed extremely poor surgical outcomes.

○ In the U.S., non-emergent operative care was triaged to conserve resources.

○ Many hospitals didn't know their CV-19 numbers nor outcomes – operative and non-operative.

○ Request to ACS: help organize data collection

○ ACS developed two things:
1. Put CV-19 variables into current registries (e.g. NSQIP, trauma)

2. Created a "basic" CV-19 registry

- Released April 2019
- All Covid patients (operative, non operative)
- Free
- Hospital-based (inpatients)
- Registrar collected
- IRB approved
- International
- Variables: Patient Demographics, Presenting Symptoms, Comorbidities, Treatments, Outcomes
- ~10,000 patients, 30 states

Good, however…
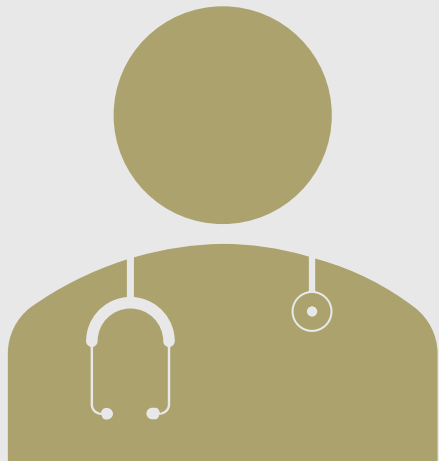
○ Are the data providing: (1) enough clinical care and epidemiologic information, (2) adequate for investigation, (3) helping us improve?

Not really, particularly if we agree the pandemic is ongoing (and worsening in some areas)

Issues to address:

- Why are we collecting? What are the questions being answered? What are the questions we will need to answer?

- Settings - community, hospital, combinations

- Collection - case identification/ascertainment, automation

- Variables – accuracy, standardization, parsimony, related to aims, adding things later?

- Analysis – Who? How? Coordination?

- Timeliness

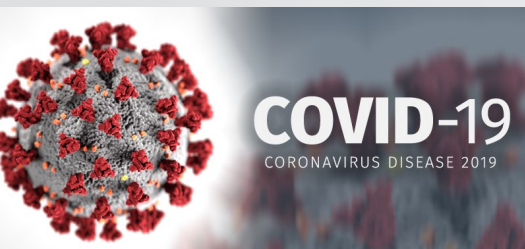- Integration/Merging of registries – what's possible?

Overarching Questions

1. If the pandemic is going to persist for awhile, what lessons (good and bad) have we learned in these past few months re: data collection, analysis, reporting, and actionable improvement?

2. What things can we do to do better?

Why ASCO?

- National medical emergency → Opportunity for ASCO to assist the oncology community by gathering information

- Critical need to capture and analyze data on clinical care

- Objectives:
    - Analyze distribution of symptoms and severity of COVID-19 among people with cancer
    - Examine impact of COVID-19 on cancer treatment and outcomes
    - Document adaptations of cancer care to the pandemic

Patients of Interest

- Confirmed COVID-19 Diagnosis <u>and</u>

- In active anti-cancer treatment
  - Initiating treatment for new diagnosis
  - Clinically evident cancer receiving anti-cancer treatment
  - Disease-free, but receiving any type of adjuvant therapy within 1 year after surgical resection
  - Clinically evident cancer receiving supportive care only
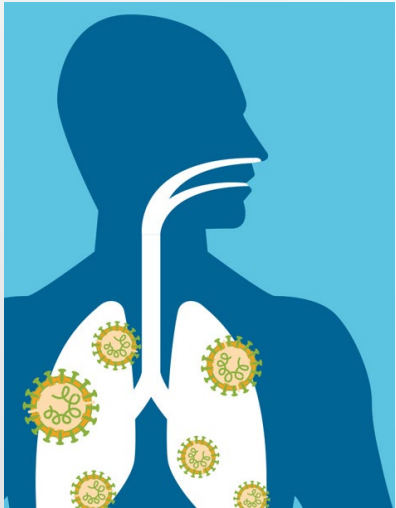
Practice Expectations

- Execute agreement with ASCO
  - Option to use central IRB review

- Complete survey about practice changes

- Provide baseline information on patients with cancer and COVID-19
  - Medical history and risk factors
  - Cancer status and treatment plan at time of COVID-19 diagnosis
  - COVID-19 diagnosis, symptoms and treatments

- Provide updates about COVID-19 and cancer outcomes and treatment changes over time
  - No consent from patients required
  - Limited dataset, using patient zip code and date of birth to link follow-up data

Data Collection

ASCO Registry

ASCO Survey on COVID-19 in Oncology Registry

This REDCap data capture form is for collecting data on cancer patients with active cancer and those being treated in the adjuvant setting. It should be used for submitting data on cancer patients who has had a confirmed case of COVID-19, and for follow-up information on patient outcomes.

Tips on data entry:

- Complete the information as accurately as possible.
- **Follow-up data will be linked to baseline data using zip codes and patient's date of birth so accuracy in these fields is especially important.**
- ICD-10 codes for cancer diagnosis are preferred to accurately categorize cancer types.
- Some information may not be known (e.g., certain dates of clinical events). Do your best to approximate when an exact date is unknown.
- Avoid using the "back" button on your browser: data will be entered twice.
- If you need to submit an amended form, contact CENTRA@asco.org with subject "ASCO Registry: amended form."

Please contact CENTRA@asco.org if you have any problems with the data capture instruments

We can only accept data from practices that have a Data Use Agreement with ASCO. Data entered without a Data Use Agreement will be immediately deleted from the registry.

If your practice does not have a signed data use agreement with ASCO to contribute to the ASCO Registry, please contact centra@asco.org.

Please enter the PIN code that was provided to your practice for patient data entry:

- Sought input from collaborator from Saudi Arabia with experience from MERS outbreak June 2015 (Dr. Abdul-Rahman Jazieh)
- REDCap forms completed as survey
- Two options:
  - Submit data directly to ASCO database
    - ASCO will de-identify data and provide practice's data back to practices for their own use
  - Collect data locally using "cloned" REDCap project
    - Practices send or upload data to ASCO at monthly intervals
- Forms can be found online:
 - https://www.asco.org/asco-coronavirus-information/coronavirus-registry

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ASCO Registry Overview

- Opened April 10

- Information through 7.16.2020

- Enrolled: 41 practices in 23 states
  - Continuing to accrue practices: 100+ interested
  - Targeting outreach to hotspot areas

- Approximately 175 patients (excluding those collected in local REDCap instances)

ASCO Registry

- ○ Enrolled practices
- ● Contributing data

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Inferences and Availability
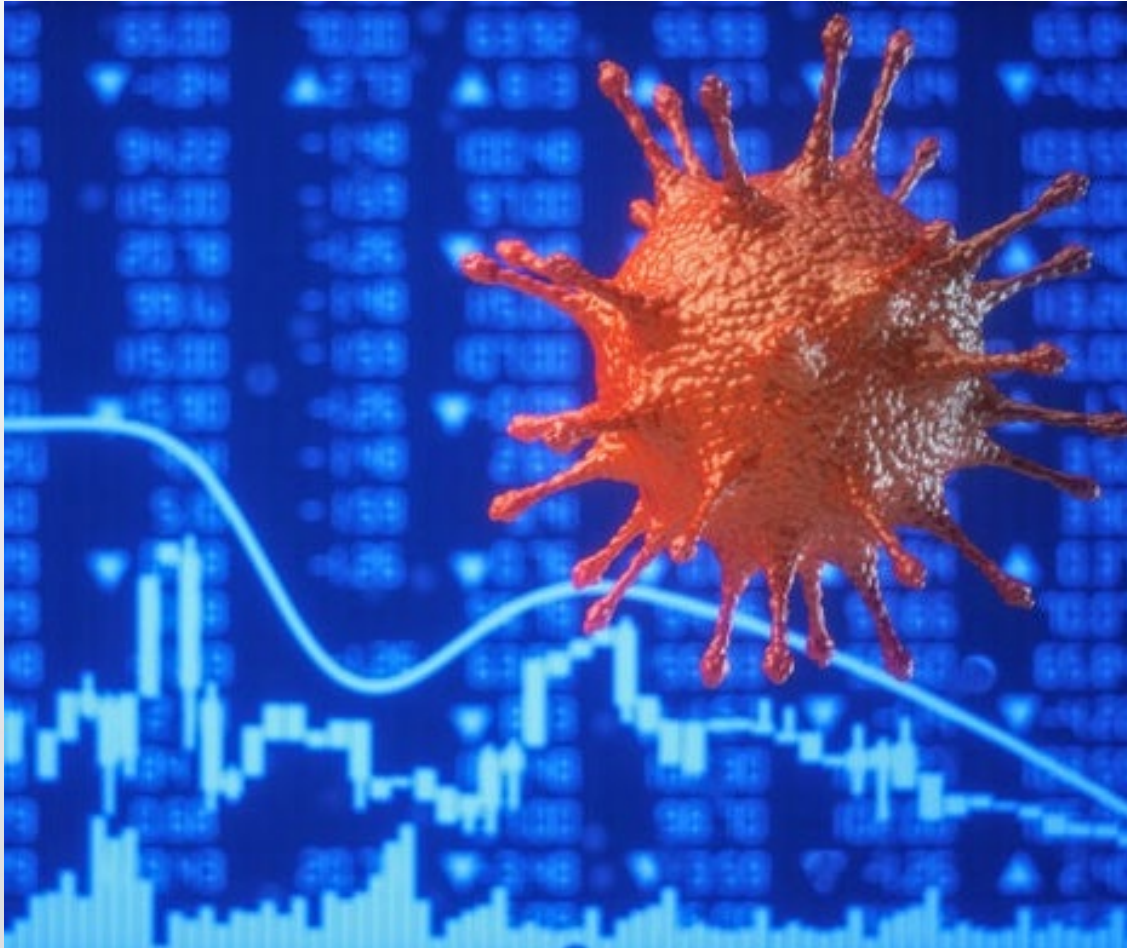
- Steering Group formed to provide guidance
  - Use of data
  - Changes to data collected
  - Analyses to perform in short and long term

- Plan to release reports periodically starting in early September

- Data will be made available to external researchers in 2021

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Coordination and Potential Collaborations

American Society of Hematology
- Data from patients with hematologic malignancies, collection by physicians at single point in time

COVID-19 and Cancer Consortium (CCC19) Registry
- De-identified data collected at the physician level
- One-time submission with option for follow-up data

COVID-19 in patients with thoracic malignancies (TERAVOLT)
- Global consortium

St. Jude's
- Global consortium for COVID-19 in childhood cancers

Other countries/regions
- Brazil
- Mexico
- Saudi Arabia
- European registry for neuroendocrine neoplasms

Thanks to Participating Practices

- AIS - Cancer Center - Bakersfield (CA)
- Augusta University (GA)
- Baptist Clinical Research Institute (TN)
- Baptist Health Madisonville (KY)
- The Cancer Team - Bellin Health (WI)
- CarolinaEast Medical Center (NC)
- CMH/OHSU Knight Cancer Center (OR)
- Emory University (GA)
- Florida Cancer Specialists and Research Institute (FL)
- Florida Precision Oncology, a Division of 21st Century Oncology (FL)
- Fox Chase Cancer Center (PA)
- Gene Upshaw Memorial Tahoe Forest Cancer Center (CA)
- Good Samaritan Hospital (OR)
- Goshen Center for Cancer Care (IN)
- Great Lakes Cancer Management Specialist (MI)

- Greater Baltimore Medical Center (MD)
- Hartford Healthcare Cancer Institute (CT)
- Helen Diller Family Comprehensive Cancer Center, University of California, San Francisco (CA)
- Hematology Oncology Associates of Central New York (NY)
- Illinois Cancer Care (IL)
- Lakeland Hospitals (FL)
- Levine Cancer Institute, Atrium Health (NC and SC)
- LifeBridge Health, Inc. (MD)
- Michiana Hematology Oncology (IN)
- Nebraska Cancer Specialists (NE)
- Nebraska Hematology-Oncology (NE)
- NorthShore University Health System (IL)
- Oncology Hematology Care, Inc. (OH)
- Penn Medicine Lancaster General Health - Ann B Barshinger Cancer Institute (PA)
- Penn Medicine Princeton Oncology (NJ)

- PIH Health (CA)
- Sarah Cannon Research Institute at HealthONE (CO)
- Sarah Cannon Research Institute/Florida Cancer Specialists & Research Institute, LLC (FL)
- Sarah Cannon Research Institute/MidAmerica Oncology Associates, LLC (KS)
- Sarah Cannon Research Institute/Tennessee Oncology, PLLC (TN)
- Tufts Medical Center (MA)
- University of Kansas Medical Center (KS)
- The University of North Carolina at Chapel Hill (NC)
- The University of Pennsylvania (PA)
- Virginia Cancer Institute (VA)
- Virginia Cancer Specialists (VA)

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Enrolled practices as of July 16, 2020

Thanks to ASCO Volunteers and Staff
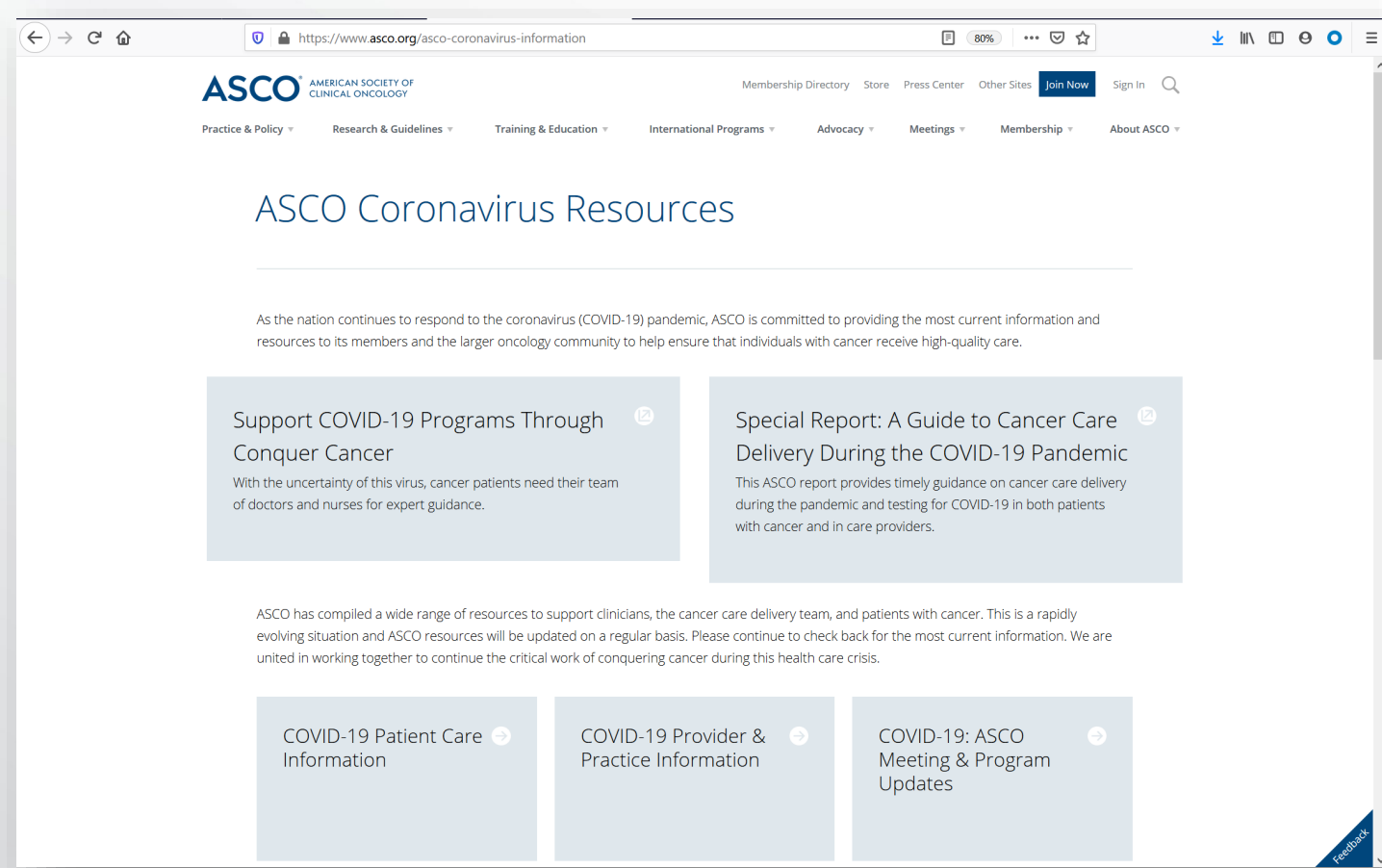
www.asco.org/asco-coronavirus-information

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- Kathryn F. Mileham, MD, FACP
- Grzegorz S. Nowakowski, MD
- Alexander I. Spira, MD, PhD, FACP
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- Andrea S. Clay
- Gina Grantham

Why a COVID-19 Registry?

- Our members:
  - The Society of Critical Care Medicine encompasses a diverse multi-professional workforce in more than 100 countries dedicated to excellence and consistency in the practice of critical care

- Our patients
  - Critically ill and injured patients require timely and high quality life-sustaining care throughout the course in the ICU: **Right Care, Right Now**

- Our mission
  - To secure the highest quality care for all critically ill and injured patients

We Failed Once – Never Again!

An infection wipes out an entire village in northeastern China
(3000 BC, "Hamin Mangha")

Plague of Athens: 430 BC (killed 100K in ancient Greece)
Plague of Justinian: 541-542 AD (killed 10% of the world's population)
The Black Death: 1346-1353 (killed 50% of Europe's population)
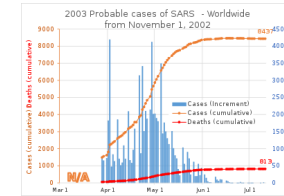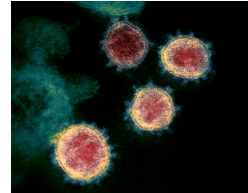Great Plague of London: 1665-1666 (100K deaths, 15% of London)

Influenza pandemic: 1889-1890 (1M deaths)
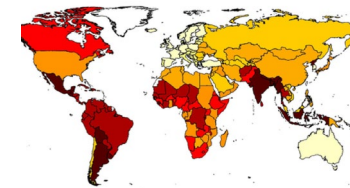Spanish flu pandemic: 1918-1920 (100M deaths)
Asian flu pandemic: 1957-1958 (1.1M deaths)
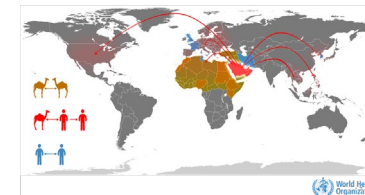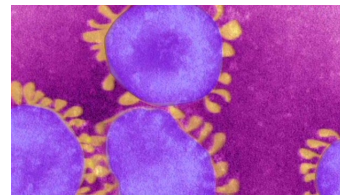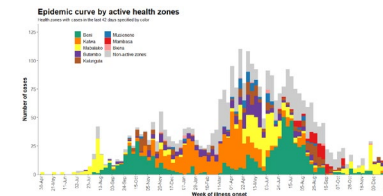
We Failed ~~Once — Never~~ Again!
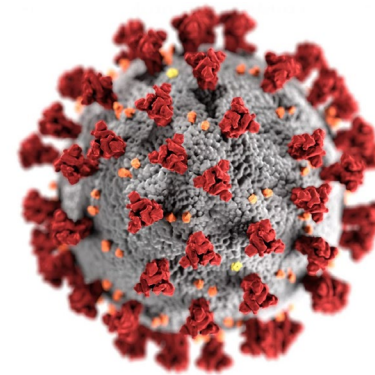
2003: SARS-CoV-1

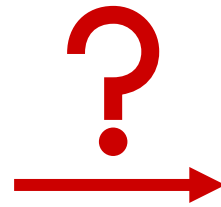2009: H1N1 Influenza
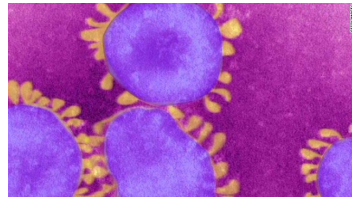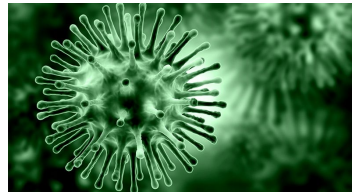
2012: MERS

2014: Ebola

Never Again!

Syndrome Definitions..
Data Points..
Central IRB..
Legal Agreements..

Never Again!

VIRUS COVID-19 Registry
A COVID-19 REGISTRY OF CURRENT ICU AND HOSPITAL CARE PATTERNS
Society of Critical Care Medicine
The Intensive Care Professionals
DISCOVERY
The Critical Care Research Network

?

VIRUS COVID-19 Registry
A COVID-19 REGISTRY OF CURRENT ICU AND HOSPITAL CARE PATTERNS

Society of
Critical Care Medicine
The Intensive Care Professionals

DISCOVERY
The Critical Care Research Network

2020
- Learning from those earlier failures, SCCM Discovery began creating C2D2, the Critical Care Data Dictionary, to harmonize critical data definitions for rapid deployment and data collection.
- We sought to automate data collection wherever possible, using middleware for direct capture of the data points from Electronic Health Records (EHR).
- We planned to organize hundreds of 'sleeping nodes' of academic and community hospitals across all 10 HHS regions, to be activated for data collection within hours of an event.
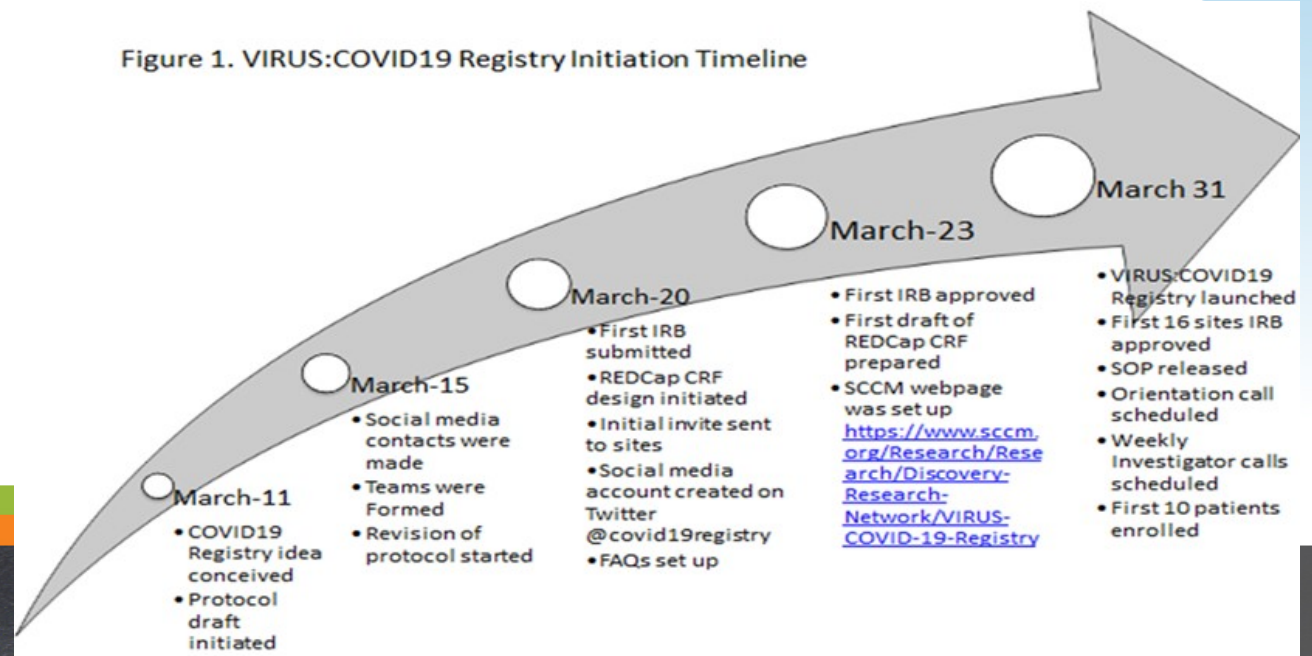
Project Description

- VIRUS is a cross-sectional, observational study and registry of adult and pediatric patients who were admitted to a hospital with COVID-19 confirmed disease or high clinical suspicion
- Only de-identified data collected and used for analysis
- Data collection for patients hospitalized after January 2020

- https://www.sccm.org/Research/Research/Discovery-Research-Network/VIRUS-COVID-19-Registry
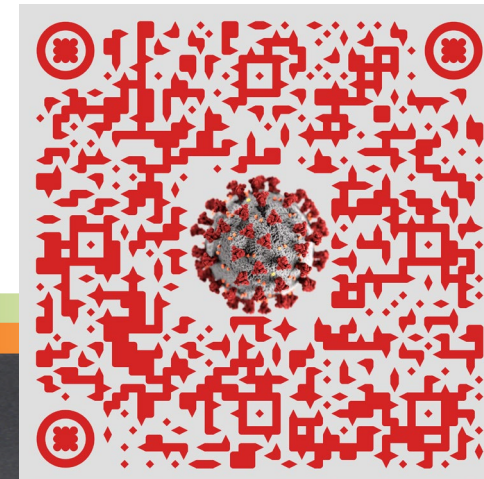
Project Inception

- We optimized the scope of SCCM Discovery C2D2 workgroup and rapidly deployed the VIRUS COVID-19 Registry
  - Plans and opportunity to participate were shared through email and social media channels
  - Within one week, 170+ sites signed up worldwide (140+ USA)
- After all research/legal/administrative approvals, data collection started at the first 10 sites on 3/31/2020

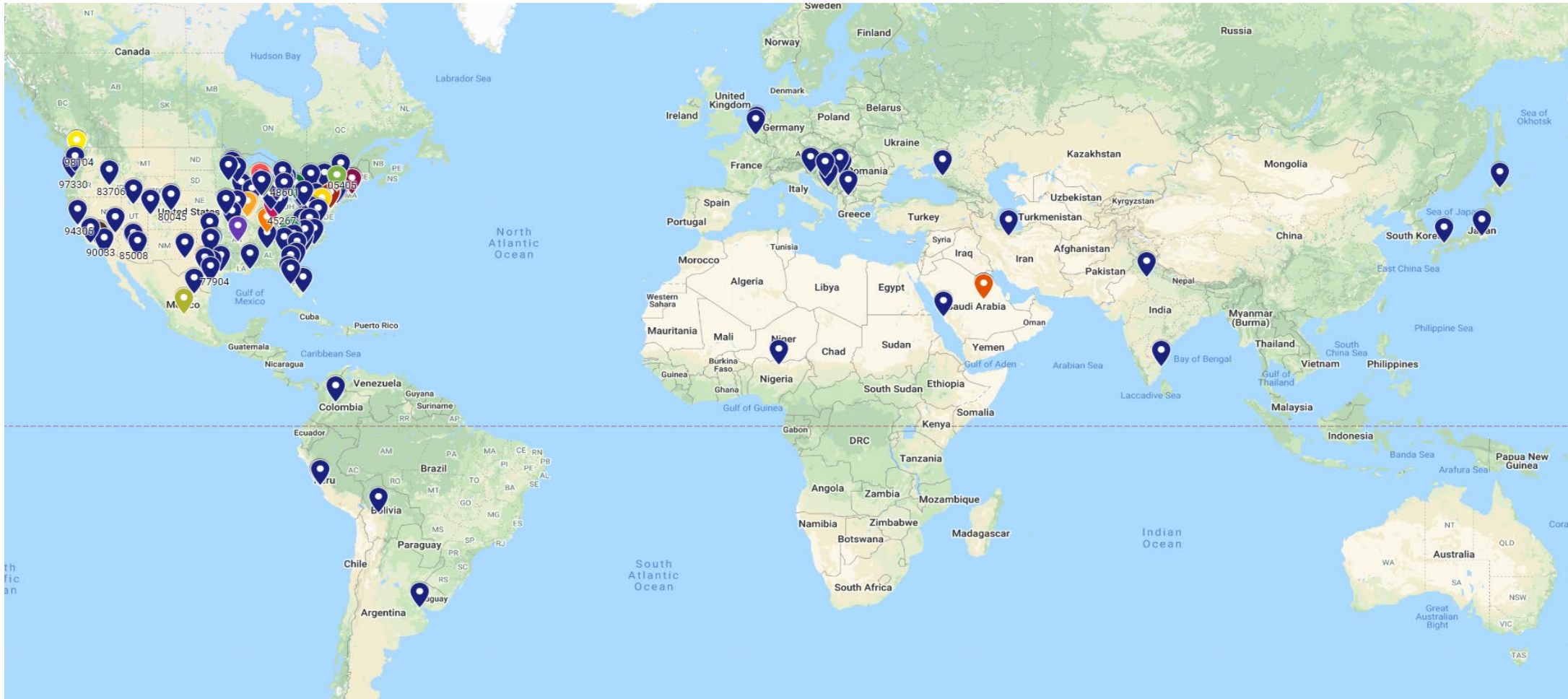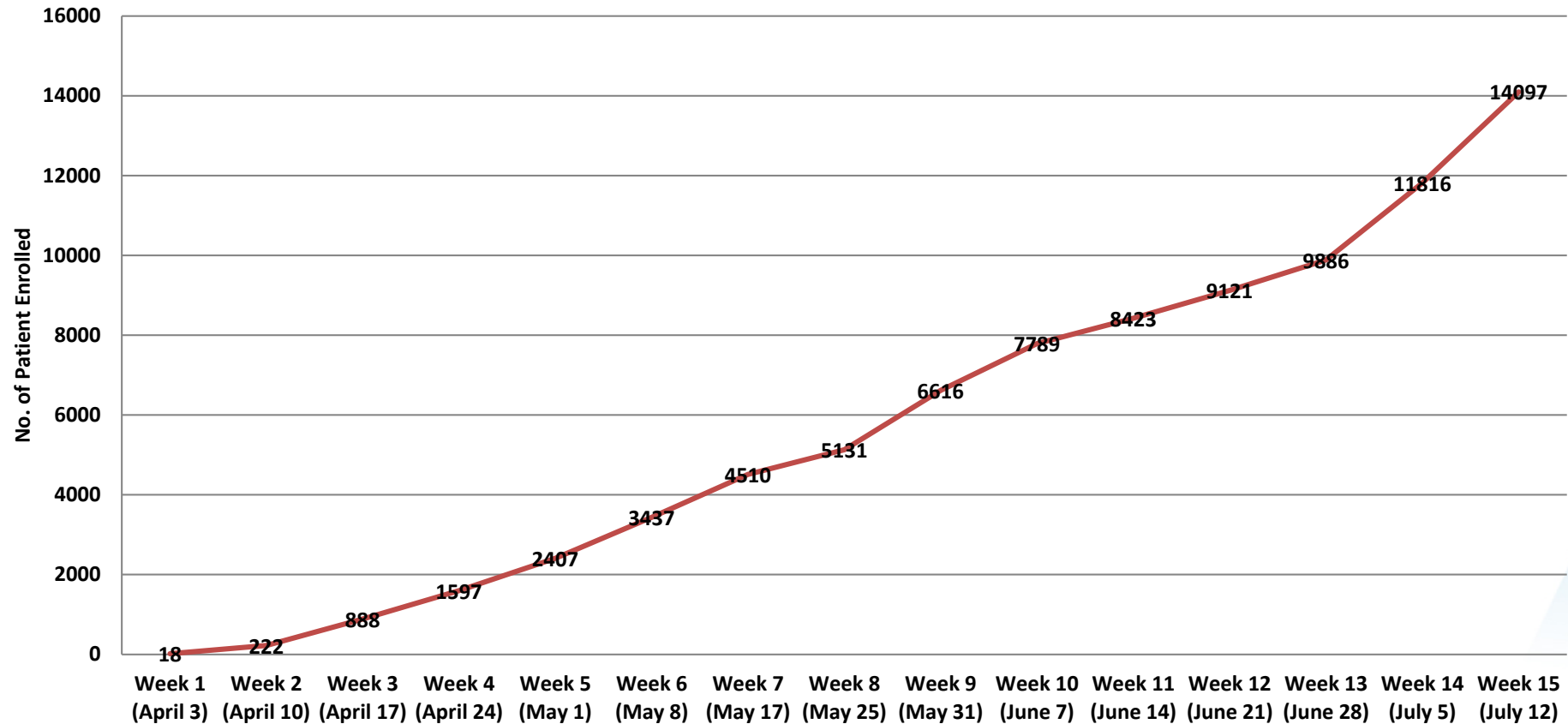Figure 1. VIRUS:COVID19 Registry Initiation Timeline

March-11
- COVID19 Registry idea conceived
- Protocol draft initiated

March-15
- Social media contacts were made
- Teams were Formed
- Revision of protocol started

March-20
- First IRB submitted
- REDCap CRF design initiated
- Initial invite sent to sites
- Social media account created on Twitter @covid19registry
- FAQs set up

March-23
- First IRB approved
- First draft of REDCap CRF prepared
- SCCM webpage was set up https://www.sccm.org/Research/Research-Network/Discovery-Research-Network/VIRUS-COVID-19-Registry

March 31
- VIRUS:COVID19 Registry launched
- First 16 sites IRB approved
- SOP released
- Orientation call scheduled
- Weekly Investigator calls scheduled
- First 10 patients enrolled

VIRUS COVID-19 Registry
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DISCOVERY

DISCOVERY
The Critical Care Research Network

Data Elements

REDCap®

Data Collection Instrument	Day 0 (1)	Day 1 (2)	Day 2 (3)	Day 3 (4)	Day 4 (5)	Day 5 (6)	Day 6 (7)	Day 7 (8)	Day 8 (9)	Day 9 (10)	Day 10 (11)	Day 11 (12)	Day 12 (13)	Day 13 (14)	Day-14 (15)	Day-21 (16)	Day-28 (17)
Core Data I (Inclusion, Testing, Trials, Location, Admin)	✔																
Core Data II (Demographics, Symptoms, Premeds, History, Diagnosis)	✔																
Core Data III (Microbiology, Misc Tests)	✔																
Core Data IV (Daily- Imaging, MV)	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
Core Data V (Daily- Processes of Care, VAP Bundle)	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
Core Data VI (Daily-Fluid, Vasopressors, Other Meds)	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
Core Data VII (Outcomes)																	✔
Enhanced Data 1 (Daily-Vitals, Neuro exam & Labs)	✔	✔	✔	✔				✔								✔	✔
Enhanced Data 2 (Daily SOFA, PELOD, Events)	✔	✔	✔	✔				✔								✔	✔
Full Data A (APACHE II)		✔															
Full Data B (Cardiac Echo, ECG)	✔	✔	✔	✔				✔									
FEMA Data Z (ONLY for Co-venting patients)	✔																
Pediatrics Data P (FSS, PRISM)	✔	✔															

Site Recruitment

Subject Enrollment in Registry

VIRUS Weekly Enrollment as of July 12, 2020

Line chart showing "No. of Patient Enrolled" (y-axis, 0 to 16000) versus week (x-axis):

- Week 1 (April 3): 18
- Week 2 (April 10): 222
- Week 3 (April 17): 888
- Week 4 (April 24): 1597
- Week 5 (May 1): 2407
- Week 6 (May 8): 3437
- Week 7 (May 17): 4510
- Week 8 (May 25): 5131
- Week 9 (May 31): 6616
- Week 10 (June 7): 7789
- Week 11 (June 14): 8423
- Week 12 (June 21): 9121
- Week 13 (June 28): 9886
- Week 14 (July 5): 11816
- Week 15 (July 12): 14097

DISCOVERY
The Critical Care Research Network

VIRUS Dashboard

Who sought help
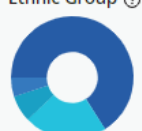
Gender
- 53% Male
- 47% Female

13% Missing

Race
- 53% White Caucasian
- 28% Black or African American
- 2% Asian American
- 1% American Indian or Alaska Native
- 1% East Asian
- 1% West Asian (Arabic)
- 1% Mixed
- 13% Other

17% Missing

Ethnic Group
- 66% Non Hispanic
- 22% Hispanic
- 7% Unknown
- 5% Not Specified

23% Missing

Top 5 Signs and Symptoms Experienced by Patients
64%	Dyspnea/Shortness of Breath
63%	Fever
49%	Cough - Dry
35%	Myalgia Or Fatigue
20%	Diarrhea

59% Missing

Top 5 Comorbidities
55%	Hypertension
32%	Diabetes (DM)
21%	Obesity
14%	Chronic Kidney Disease
12%	Coronary artery disease

What type of support have patients received

Mechanical Ventilation
29%
N: 8284

Non-invasive Ventilation
11%
N: 8284

High-flow Nasal Oxygen (HFNO2)
15%
N: 8284

Dialysis
7%
N: 7586

Extracorporeal Membrane Oxygenation (ECMO)
2%
N: 6616

What happened to the patients (outcome)

Mechanical Ventilation Duration
9 days (Median)
25th-75th %ile: 5-16 days
N: 1977
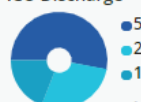
ICU Length of Stay
7 days (Median)
25th-75th %ile: 3-15 days
N: 2742

ICU Discharge
- 53% Discharged Alive
- 28% Deceased
- 19% Data is Pending

N: 3722

Hospital Length of Stay
7 days (Median)
25th-75th %ile: 4-14 days
N: 7545

Hospital Discharge
- 80% Discharged Alive
- 20% Deceased

N: 7545

Discharged Alive to
- 50% Home, without assistance
- 11% Home, with home health
- 10% Long-term care facility
- 7% Subacute rehabilitation
- 4% Other
- 3% Hospice
- 1% Other hospital (overflow)

N: 6066

15% Missing

Strategy for Dissemination

For dissemination, SCCM has a comprehensive dissemination plan

- VIRUS dashboard

- Publications and member facing articles

- Collaborative news releases and webcast to critical care community   and beyond

- Social media campaigns

- Dissemination through the Critical Care Societies Collaborative
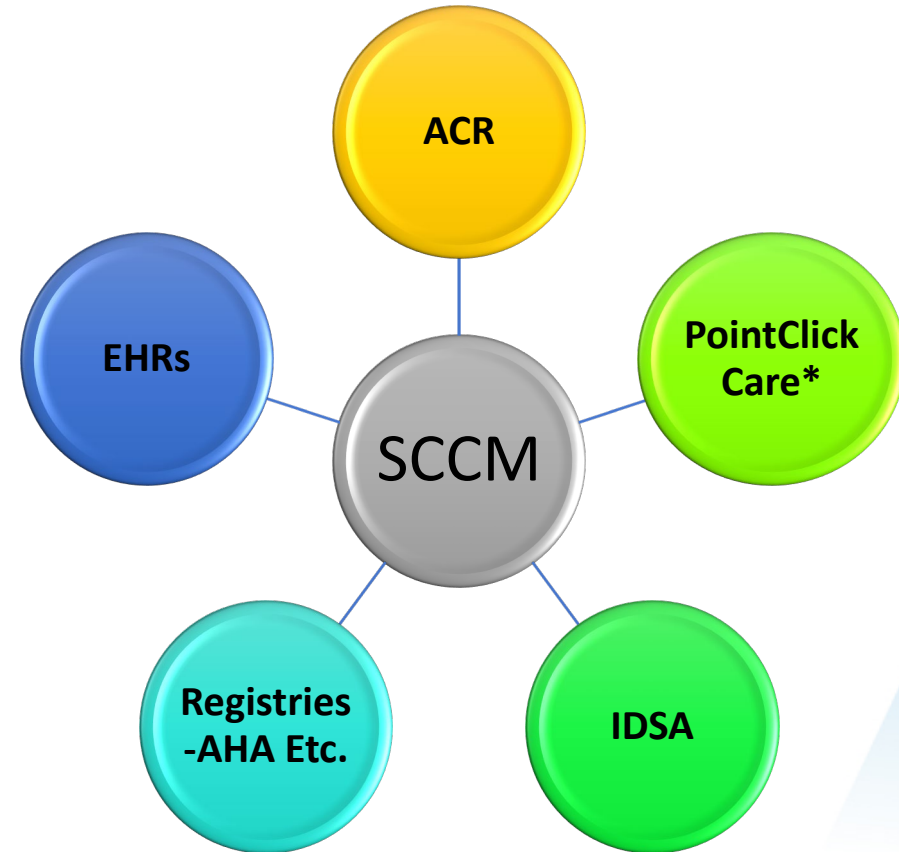
PointClickCare: Data on long term care and nursing home facilities

ACR

PointClick Care*

EHRs

SCCM

Registries -AHA Etc.

IDSA

Current Status

The Society of Critical Care Medicine Discovery Network Viral Infection and Respiratory Illness Universal Study (VIRUS) provides an example of a rapidly deployed, international, pandemic registry that seeks to provide near real-time analytics and information regarding intensive care treatments and outcomes for patients with Covid-19

- Dashboard - https://sccmcovid19.org/
- Cohort Explorer - under development
- Ancillary Studies – 68 proposals received
- Collaborations completed – ACR, PointClickCare
- Manuscripts – 1 published, 2 in development/review

Methodology

Critical Care Explorations

OPEN

The Viral Infection and Respiratory Illness Universal Study (VIRUS): An International Registry of Coronavirus 2019-Related Critical Illness

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Lessons Learned

Early Buy-in !!

Strategies that work:

- ✓ Meaningful collaboration, data harmonization
- ✓ Strong social media presence / networking
- ✓ Rapid IRBs approval /DUAs signing
- ✓ A daily reminder to focus on the goals of the registry—ICU practices, physiology, and outcomes for patients with COVID-19

Challenges:

- ➢ Resource limitations (project and study sites)
- ➢ Scope creep
- ➢ Political barriers to participation/data harmonization

Funding & Collaboration

The Discovery VIRUS COVID-19 Registry is funded by the Gordon and Betty Moore Foundation. With additional support from Mayo Clinic Ventures, the VIRUS Registry was able to secure funding from Janssen Research & Development to support VIRUS Registry infrastructure and critical seed funding to additional sites for data automation and data entry.

Thank you to all our partners and collaborators:

- Mayo Clinic

- Lyntek Medical

- nference

- American College of Radiology – VIRUS Imaging Partner

- PointClickCare Technologies – Providing de-identified patient data for nursing and long term care facilities

VIRUS COVID-19 Registry
A COVID-19 REGISTRY OF CURRENT ICU AND HOSPITAL CARE PATTERNS

Society of Critical Care Medicine — The Intensive Care Professionals
DISCOVERY — The Critical Care Research Network

Contact US

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#SCCMDiscovery

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DISCOVERY — The Critical Care Research Network

Society of Critical Care Medicine — The Intensive Care Professionals

Perspectives on how technology can move the field forward

Michael Howell, MD, MPH
Principal Scientist, Google

Questions & Answers

Please submit all questions through the question box.

Summary & Evaluation

- Thank you to all our panelists.

- A recording of the webinar will be available on the CMSS website in the coming weeks.

- Please compete a short evaluation following the webinar.

- For more information, contact info@cmss.org.