



NIH Collaboratory

*Rethinking Clinical Trials*®

Health Care Systems Research Collaboratory

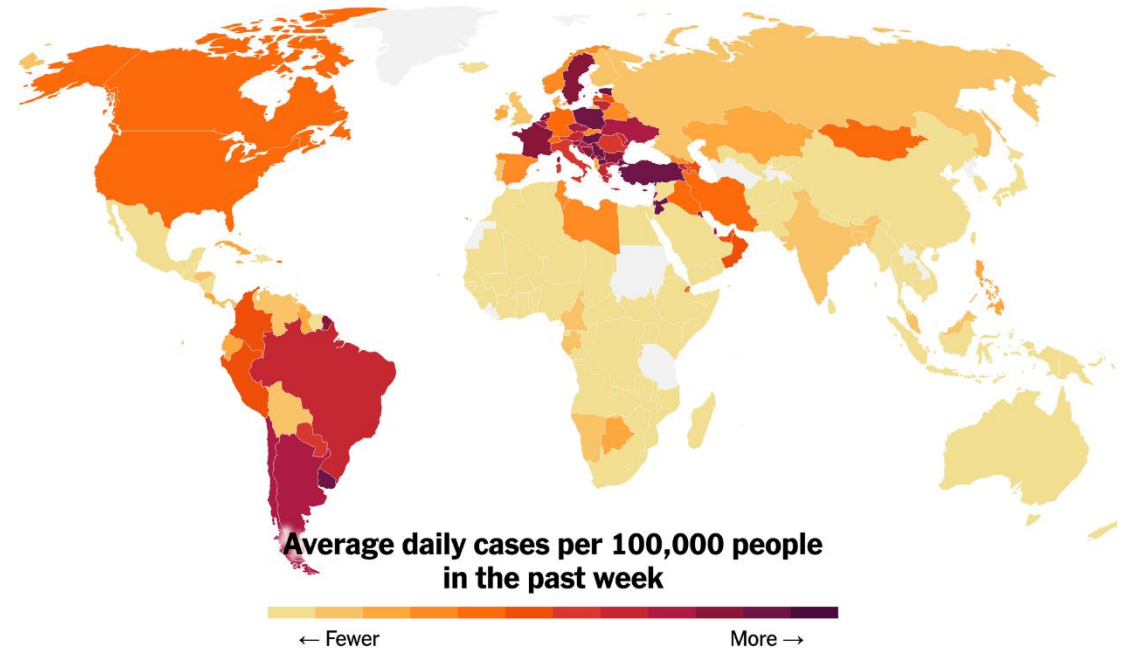
# High-Level Overview: Impact of COVID-19 on Collaboratory Projects

Emily O'Brien, PhD



# Background

- COVID-19 has considerably disrupted clinical research activities
  - Changes in care-seeking behavior
  - Altered research environments
- Pragmatic clinical trials may offer novel ways to adapt to such disruptions



# Goal

Understand the specific impacts of COVID-19 on pragmatic clinical trials that were ongoing at the time of the pandemic's onset.

# How Did We Gather Information?

- Survey of 14 Demonstration Projects in June 2020
  - 7 trials in implementation phase
  - 4 trials in pilot phase
  - 3 completed trials
- Core and Steering Committee calls April-July 2020
- Issues Tracker



# What We Learned

# Delay Was Most Common Effect

- Staff re-allocation
- Health system reprioritization
- Suspension of some services
- Switch to telehealth delivery
- Study modifications



# Potential Effect on Study Outcomes

- Anticipated increases in rates of hospitalization and death
- Statistical impacts for stepped-wedge trials
- Missed ongoing care visits → missing follow-up data

# Adaptations to Interventions & Implementation Plans

- Most common adaptation: shift from in-person interactions to virtual
- Adjustments in statistical analysis plans where applicable
- Modified enrollment schedules



# Stakeholders Supporting Demonstration Project Intervention Adaptation

Agency stakeholders	Collaboratory stakeholders	Health system stakeholders	Trial team stakeholders
<ul style="list-style-type: none"> <li>Funding agency leadership</li> <li>NIH Program Officer</li> </ul>	<ul style="list-style-type: none"> <li>Biostatistics and Study Design Core</li> <li>Electronic Health Records Core</li> <li>Health Care Systems Interactions Core</li> <li>Ethics and Regulatory Core</li> <li>Coordinating Center</li> </ul>	<ul style="list-style-type: none"> <li>Health system managers, clinic liaisons, site healthcare providers, and site support staff</li> <li>Non-study team members from research institutions for refinement of at-home study procedures and to understand ongoing implications of COVID-19</li> <li>Practice leadership</li> <li>Nursing leadership</li> <li>IT leadership</li> <li>Provider organization leadership</li> </ul>	<ul style="list-style-type: none"> <li>Trial steering committee and executive committee members</li> <li>Trial stakeholder panel for review of intervention messages regarding COVID-19</li> <li>Intervention experts to develop virtual intervention</li> <li>Biostatistician</li> <li>Data and safety monitoring board</li> </ul>

# Changes to Research Environment

- Staffing effects
- Changes in IRB permissions for research initiation
- Travel and group assembly restrictions (training impacts)
- Decreased provider referrals to specialty care
- Increased telehealth delivery
- Lasting impacts on availability of research funding?

# Benefits Described

- Sites and staff showed adaptability
- Ability to reach a wider population through virtual intervention delivery
- Renewed commitment to trial from partners



# What We Did

# Coordinating Center Support

- Core consultations with individual projects
- Sharing of challenges and solutions among projects
- Created COVID 19 Issues Tracker
  - Tracking and following up on issues
- Documenting lessons learned to share with research community

# Summary & Next Steps

- Some trials affected more than others
- All trials resumed in 2020
  - Continued flexibility needed
  - Increased communication with stakeholders
- Continue to track issues and consult as needed
  - Preparing publication

