

DC CTSA Spring Regulatory Update & Hot Topics in Clinical and Translational Research

Beyond COVID-19: Challenges & Lessons Learned during a Pandemic

Challenges for Researchers During the Pandemic

Moderator: Hiromi Sanders, J.D., Ph.D.

Director, Research Integrity and Compliance
Office of the Vice President for Research
George Washington University

10:45 - 11:30 AM EST

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Beyond COVID-19: Challenges & Lessons Learned during a Pandemic

Challenges for Researchers During the Pandemic



**Federico M. Asch,
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Director, Cardiovascular Core Labs
Director, Cardiac Imaging Research
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Professor of Medicine, Department of Medicine
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Federico M Asch MD

Cardiovascular Core Laboratories and Cardiac Imaging

MedStar Health Research Institute



Scope of my Lab's Research Work

- Core Services
- Investigator-Initiated



Specific Challenges Due to the Pandemic

- Team Work disruption, well-being
- Patient enrollment challenges,
- Dynamics of our research sponsors



How were you able to get your research back up and running

- Old projects
- New Opportunities



What lessons did you learn?

- Risk Assessment Evaluation
- Prepare in advance
- Identify unique opportunities and shift of goals or plans



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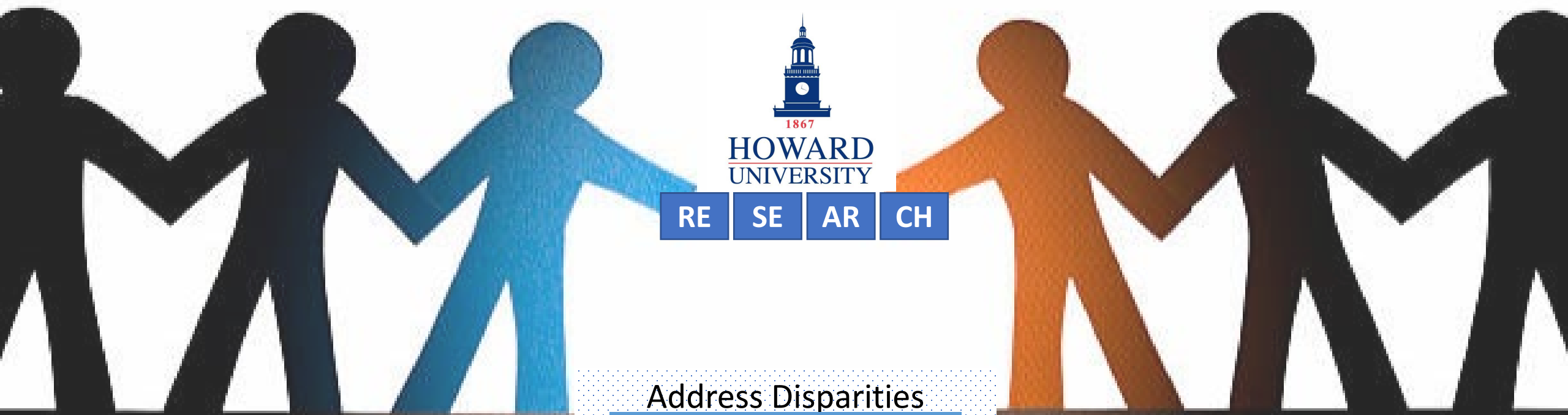
Beyond COVID-19: Challenges & Lessons Learned during a Pandemic

Sharon Dowell, MBBS

Associate Professor of Internal Medicine

Howard University





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RE | SE | AR | CH

Address Disparities

HURAED

EMRAC

TTT

Specific Challenges Due to the Pandemic



Recruitment

Consent

Patients had limited broadband access

Study
Procedures

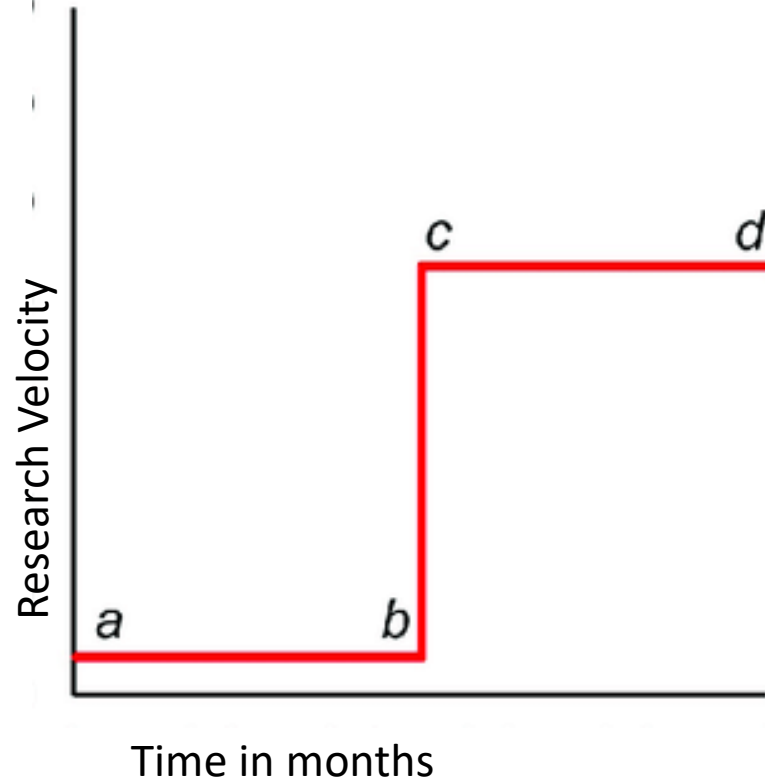
Follow-up

Research Rebound

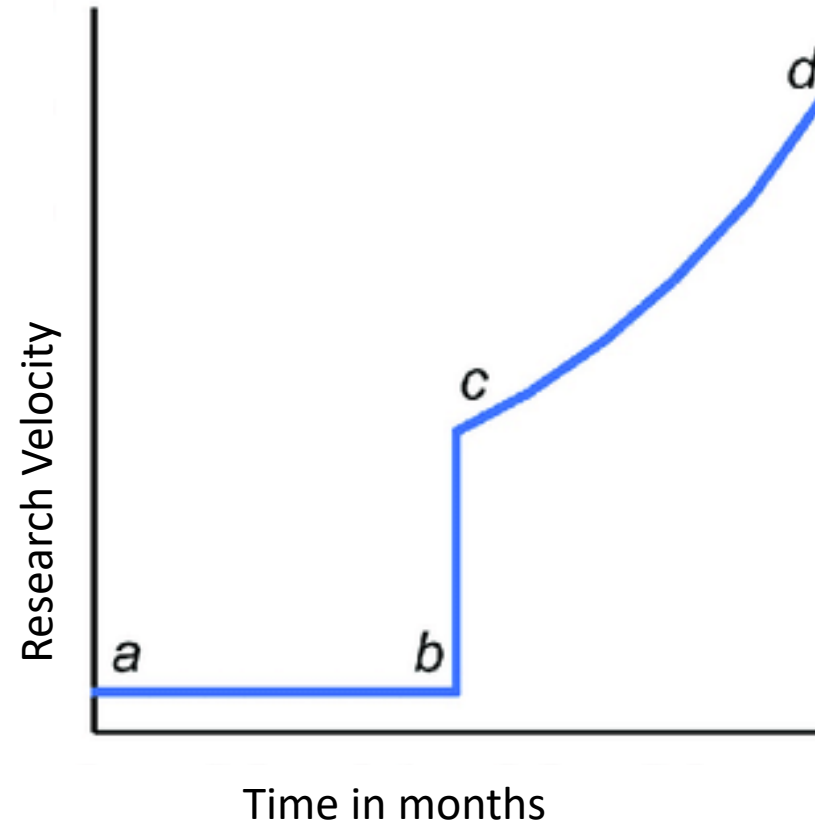


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TTT, HURAEDs, Clinical trials



New questions about health equity and telemedicine in RA



Lessons Learned



- If we have critical momentum, we can influence change
- For low-risk studies, virtual consent is an option
- Not everything can be done virtually
- Disparities in Telehealth/tele-research exist
- The importance of collaboration and a diverse team
- There is always a question that needs an answer

Thank You

HU Rheumatology Research Team

Gail Kerr (MD)

Mercedes Quinones (MD)

Tara Jamshidi (MD)

Micayla Wilson (RC)

Haja Kamara (RC)

Dermatology Collaboration with Ginette Okoye (MD)

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Jill P Smith, MD

Professor of Medicine

Georgetown University &

DC Veterans Affairs Medical Center



Challenges with Clinical Research Work

- Bench to Bedside translation clinical trials:
 - Phase 1 clinical trial is subjects with nonalcoholic steatohepatitis NASH (NCT04152473)- Enrollment started January 2020
 - The patients eligible for this clinical trial with metabolic syndrome & obesity were the same population at high risk for COVID
 - The IRB protocol was approved at 2 sites (Georgetown & the VA hospital)- but research at the VAMC closed completely during COVID
 - Getting subjects to come to the hospital for screening & consenting & participation in the trial was difficult

Solutions for Clinical Research

- Submitted an IRB protocol modification to be able to consent subjects by telephone
- Established an account with LabCorp to draw routine lab tests and to perform Biometrics so subjects could visit a LabCorp close to their home and not have to risk coming to the hospital.
- Obtained approval to FedEx investigational medication to subjects' homes
- Obtained approval from the VAMC to recruit subjects from the VA and treat them at the CRU at Georgetown University.
- Cost: In order to cover the extra cost of PPE for staff, LabCorp account etc: I submitted an application for PA-18-591: Administrative Supplements to Existing NIH Grants and Cooperative Agreements- it was funded

Challenges with Bench Research due to Pandemic

Laboratory research: Molecular Biology, animal preclinical studies, Graduate student thesis projects.

- Projects were delayed due to some Core facilities like Histology being closed.
- Had to develop & submit a plan for the times and numbers staff would be in lab.
- Weekly COVID tests were required and daily COVID building access done
- Difficulty teaching grad students laboratory skills when the laboratory was closed and there was social distancing.

Solutions for Continuation of Bench Research

- Spent time writing new grants and manuscripts
- Revised animal projects and treatment dosing schedules to have less time in the facility
- Lab meetings were changed to virtual ZOOM weekly meetings
- Some animal colonies were not maintained – other investigators had to euthanize animals

What lessons did you learn?

PROS

- Patients like telephone consenting for research studies
- Patients enjoyed the flexibility and safety of having bloodwork done at a small lab close to home rather than risk coming to the hospital

CONS

- For teaching students / residents, face to face learning and hands- on research cannot be replaced with virtual learning