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Since the World Health Organization designated COVID-19 a pandemic on March 12th, Carilion Clinic has navigated the crisis to provide healthcare to our community in a safe environment. Although some clinical services were paused in an abundance of caution, the Infectious Diseases (ID) clinical section had to ramp up and mobilize a comprehensive plan to care for our community while safeguarding our workforce. Analogous to past pandemics, decisions needed to be made in real time as new data emerged on this novel virus, SARS-CoV-2 that was isolated on January 12, 2020. Carilion Clinic is fortunate to have several infectious diseases physicians with extensive clinical and research experience with other pandemics including H1N1 and HIV/AIDS.

Given that no cure or vaccine exists for this disease, it is imperative that our physicians keep up to date on experimental therapies that have either gained Emergency Use Authorization (EUA) see <https://www.phe.gov/> for additional information or are being evaluated in placebo controlled clinical research trials. Two promising experimental therapies were evaluated at Carilion Clinic before EUA designation: Remdesivir, a drug that blocks virus replication, and convalescent plasma to boost one's ability to fight the disease. At present, another agent that is directed against the inflammatory component of COVID-19 is being studied. The ID physicians review many clinical research opportunities and must make rapid decisions based on their scientific merit, risk/benefit profile and feasibility given our patient population.

In closing, the care and management of this pandemic is a vast undertaking of ID physicians working closely with our ID PharmDs who provide up to date therapeutic guidelines and our Infection Preventionists who work tirelessly to

keep our staff, patients and community safer through education and contact tracing. In addition, our collaboration with other clinical sections including pulmonary/ critical care, family and community medicine and the numerous clinical services has strengthened our response. Although we are several months away from an approved therapy and/or a vaccine, it is important that all of us do our part to stem this disease in our community.



Anthony Baffoe-Bonnie, MD
Medical Director, Infection
Prevention & Control



Dorothy Garner, MD
Interim Chief, Infectious Disease



HIGHLIGHT ON RUTH NDOLO, ED.D., MSN, CCRP

Ruth Ndolo, Clinical Research Nurse III for Infectious Disease, has been with Carilion Research and Development since September of 2016. In a typical year, she stays busy coordinating various clinical trials for flu, C. difficile, blood stream infections, and various other topics of interest for the Infectious Disease Division. However, we all know 2020 has not been a typical year! For the past 7 months, Ruth and her colleagues rapidly pivoted their efforts towards COVID-19 research and launched 3 critical studies under intense pressure. Because of their tireless commitment, Carilion Clinic was invited to participate in national COVID-19 studies such as the Mayo Clinic/FDA Convalescent Plasma Program, the Gilead Remdesivir Expanded Access Program, and a trial with GlaxoSmithKline for COVID-19 patients suffering from severe pulmonary disease. These programs are providing potentially life-saving options to our patients and bolstering Carilion Clinic's recognition as a research institution on a national level.



Ruth has a passion for education and research, leading her to obtain Master of Arts in Human Service, a Master of Science in Nursing, a Doctor of Education Leadership and Administration, and certification as a Clinical Research Professional. Ruth is an advanced Clinical Research Nurse and serves as a mentor to many of our junior team members. Carilion is fortunate to have such an accomplished and dedicated team member, constantly striving to improve outcomes in Infectious Disease through research. Please join us in expressing gratitude to Ruth and her ID colleagues for their tremendous fortitude and commitment to our patients.

RAP – RESEARCH ACCELERATION PROGRAM AWARDS & ANNOUNCEMENTS

Carilion Clinic funded 10 projects shown below through the Research Acceleration Program (RAP). This program, in its 16th round, offers funding for Carilion Clinic employees interested in pursuing clinical, biomedical or behavioral research projects. While all significant, innovative, and rigorous research proposals were welcomed, applicants were encouraged to submit research proposals in the following priority areas shown below. Twenty-four proposals across the three tiers were submitted. Of the projects selected for funding, several will be collaborations with our partner institutions, including Dr. Chitnavis' project with the Salem Veterans Administration and Dr. Bernier's project with a VTCSOM faculty member and medical student. In addition to clinical research, two collaborative projects will explore the use of virtual reality for surgical training (Dr. Thompson) with the Department of Computer Science, Virginia Tech and development of a novel biomarker (Drs. Shah and Mittal) for seizure induced neuronal injury with the Fralin Biomedical Research Institute. Congratulations to the awardees and we would like to thank all applicants for submitting a proposal.

Research addressing addiction in our region

Engagement of rural participants in the clinical research process

Utilization of telemedicine in the execution of a clinical research study

Management of high-risk patients (e.g. patients with serious chronic disease, multiple comorbid conditions, significant psychosocial challenges) to increase engagement in self-care and prevent ED visits and hospital admissions

Methods for reducing overutilization of high-volume, low-value clinical services

RAP 16 AWARDS

TIER I

- Chitnavis, M., Defining the Prevalence of Asymptomatic Colonization of Clostridium difficile Among Patients with Inflammatory Bowel Disease
- Aziz, S., Development of home-based Pulmonary rehabilitation program using activity tracking devices with focus on self-efficacy
- Bernier, C., Evaluation of Dyspnea through Education and Implementation of the Bedside Lung Ultrasound in Emergency (BLUE) Protocol by Roanoke Valley Advanced Life Support Paramedics,
- Apel, P., Can Telehealth Replace In-Person Occupational Therapy after Hand Surgery? A Noninferiority Study
- Shah, A., Mittal, S. Study of neurofilament light chain (NfL) as a biomarker for seizure induced neuronal injury – A translational approach

TIER II

- Bernier, C., Treatment of subacute and chronic extremity pain with fascial distortion model (FDM) in the emergency department
- Phillips, M., Combination topical 5-fluorouracil 5% / calcipotriene 0.005% cream for treatment of in-situ and superficially invasive squamous cell carcinoma of the skin
- Thompson, J., The Virtual Loupe: A Pilot Study Demonstrating the Use of Mixed Reality in Surgery
- Epling, J., Targeting Health Service Overuse in Primary Care: A Preliminary Study

TIER III

- Mierisch, C., What Factors Affect the Likelihood of Developing New Long-Term Opioid Prescription Filling Behavior Arising in the Fifteen Months After Surgery

CONVALESCENT PLASMA AND COVID-19

To date, no Food and Drug Administration (FDA) approved treatment or vaccine exists for COVID-19. That said, many experimental treatments are being explored in randomized clinical trials and/or through Emergency Use Authorization (EUA). Interestingly, one experimental treatment for COVID-19 is nearly 100 years old and was investigated for the Spanish flu in 1918. More interestingly, the therapy is derived from previously infected COVID-19 individuals that are on their way to recovery.

Many patients that have been infected with COVID-19 generate antibodies to ward off the ensuing infection. Antibodies are produced by your immune system to fight infections like viruses and may provide protection against a recurrence. It is for this fact that the transfer of these antibodies to a newly diagnosed COVID-19 patient may provide protection. The therapy is known as convalescent plasma. Carilion Clinic participated in a convalescent plasma national access program with the Mayo Clinic. In addition to the infusion of convalescent plasma, patient demographic and acute care resource utilization was collected to assess outcomes. Although additional studies are necessary to show that convalescent plasma has a positive effect on outcome, the FDA issued an (EUA) on August 23, 2020 based on the scientific data to date.



STORAGE AND PROGRAMS ACCELERATING RESEARCH COLLABORATIONS

Testimonial from a SPARC Client: Nathan Everson, PharmD, BCIDP

“The pharmacy residency program at Carilion conducts over 20 research projects a year driven by resident and student learners. Many of these projects will be presented at national conferences and several will go onto publication each year. Our pharmacy research curriculum has incorporated residents into data diving and performing their own statistics for years using various electronic methods. We have now been able to move on from under-performing programs to SPARC. SPARC has given us a new set of tools to not only allow the resident to have higher powered software in the form of SAS VIYA, but also allows the entire research team to collaborate in the same webspace. Whereas much of our feedback was retrospective for resident research development, SPARC will allow preceptors to collaborate and evaluate resident research in real time in the most critical portion – data evaluation and statistical analysis. SPARC gives the flexibility we’ve sorely needed with the web-based application and limited need for software installation. We can work together much more efficiently and effectively, especially at the distances required over the next year or two.”

NATIONAL COVID COHORT COLLABORATIVE (N3C)

Carilion Clinic has recently joined the National COVID Cohort Collaborative (N3C). The N3C is a partnership with the National Center for Advancing Translational Science (NCATS) supported Clinical and Translational Science Awards (CTSA) Program hubs and the National Center for Data to Health (CD2H), see link <https://ncats.nih.gov/n3c>. As part of this collaboration, Carilion Clinic will be providing limited datasets from our electronic medical records pertaining to COVID-19. The goal of this program is to harmonize electronic health records from multiple academic medical centers to allow the clinical and research community to study COVID-19 and potentially use the information to identify effective interventions. Carilion Clinic will utilize its TriNetX alignment for data transfer. For more information about the data and process see this PowerPoint from Johns Hopkins University, the central IRB for this program: <https://ictr.johnshopkins.edu/wp-content/uploads/Chute-N3C-07292020.pdf>. If you are interested in using this data for a research project, contact Francis Farrell fxfarrell@carilionclinic.org or Mattie Tenzer, mmtenzer@carilionclinic.org.

OCPD AND R&D 2020-2021 RESEARCH SERIES

The Office of Continuing Professional Development and the Research & Development department have partnered to develop and offer the **2020-2021 Research Series** for faculty and staff at Carilion Clinic, Virginia Tech Carilion School of Medicine, and Radford University Carilion.

This series is intended to provide guidance and education on the research process across the organization with sessions that focus on foundational research practices and principles. This 6-session introductory series is aimed at novice-intermediate level researchers and will be complemented with a catalog of archived sessions to help support those embarking on their first research journeys.

SERIES SCHEDULE

Navigating the Carilion System - Andrea Bidanset, MHA, CCRP – Clinical Trials Director, R&D

- Tuesday, September 15, 2021 7:00 am – 8:00 am (Online via Zoom)
- Thursday, September 24, 2020 12:00 pm-1:00 pm (Online via Zoom)

Compliance, Data Safety, & Legal - Allison McKell, PhD, MPH - Research Compliance Specialist & Brenda Manning, JD, CHC, CHPC - Privacy Director

- Tuesday, November 17, 2021 7:00 am – 8:00 am (Online via Zoom)
- Thursday, November 19, 2020 12:00 pm-1:00 pm (Online via Zoom)

Institutional Review Board Overview - Carley Emerson, MS, CIP, CCRP – Director, IRB & Brooke Blevins, MHA, CIP - Regulatory Affairs Administrator, IRB

- Tuesday, January 19, 2021 7:00 am – 8:00 am (Online via Zoom)
- Thursday, January 21, 2021 12:00 pm-1:00 pm (CRMH 13th Floor Conf Room and Zoom)

Data Management - Mattie Tenzer, MS – Director, Health Analytics Research Team

- Tuesday, March 16, 2021 7:00 am – 8:00 am (Online via Zoom)
- Thursday, March 25, 2021 12:00 pm-1:00 pm (CRMH 13th Floor Conf Room and Zoom)

Investigator Initiated Multisite Studies – Vera Hollen, MA – Grants Management Administrator

- Tuesday, April 20, 2021 7:00 am – 8:00 am (Online via Zoom)
- Thursday, April 29, 2021 12:00 pm-1:00 pm (CRMH 13th Floor Conf Room and Zoom)

Statistics 101 - Alex Hanlon, PhD - Director, Center for Biostatistics and Health Data Science

- Tuesday, May 18, 2021 7:00 am – 8:00 am (Online via Zoom)
- Thursday, May 13, 2021 12:00 pm-1:00 pm (CRMH 13th Floor Conf Room and Zoom)

PI Competencies - Anita Kablinger, MD, CPI, FAAP, FAPA, FACRP - Program Director Clinical Trials Research, Dept. of Psychiatry and Behavioral Medicine

- Tuesday, July 20, 2021 7:00 am – 8:00 am (Online via Zoom)
- Thursday, July 22, 2021 12:00 pm-1:00 pm (CRMH 13th Floor Conf Room and Zoom)

NEW EMPLOYEES

Brooke Fuhrey, Clinical Research Coordinator I - Supporting the Aortic Center & Research and Development

Brooke Fuhrey is a new Clinical Research Coordinator that will be supporting research in the Aortic Center and Research & Development. Brooke graduated from Pennsylvania State University in 2018 with a B.S. in Health Policy and Administration, minoring in Kinesiology. She is an internal transfer, most recently working in Carilion's Orthopaedic Department as a Clinical Patient Liaison.

Mary Frazier, Clinical Research Assistant – Supporting the Orthopaedic Hand Clinic

Mary Frazier is a new Clinical Research Assistant that will be supporting Dr. Peter Apel's research in the Orthopaedic Hand Clinic. Mary graduated from Virginia Tech in 2017 with a B.S. in microbiology. For her undergraduate research, Mary developed an optimum cultivation efficiency and a system for genetic manipulation of an anaerobic hyper thermophilic methane-producing archaebacteria. Before coming to Carilion, Mary worked for two years as a medical scribe at Lewis Gale Physicians in the Orthopaedics & Sports Medicine clinic.

Joshua Edwards, Clinical Research Assistant – Supporting the Orthopaedic Hand Clinic

Joshua Edwards is a new Clinical Research Assistant that will be supporting Dr. Peter Apel's research in the Orthopaedic Hand Clinic. Joshua is a recent graduate from Virginia Tech where he earned his B.S. in biological sciences and minored in leadership and social change. While completing his undergraduate education, Joshua worked as a medical scribe in an emergency department and as a CNA at a local rehabilitation facility.



iTHRIV UPDATES:

Upcoming Workshops and general information: <https://portal.ithriv.org/#/home>

NIH Proposal Development <https://portal.ithriv.org/#/resource/726> *The session is full but if interested please put your name on the waiting list for potential future sessions.*

Data Science for the Biomedical Sciences <https://portal.ithriv.org/#/resource/1350> *Space is limited, sign up today.*

 *Please help us continue our support for clinical and translational research by citing our grant number in relevant publications: National Center for Advancing Translational Science of the National Institutes of Health Award UL1TR003015/ KL2TR003016. Thank you.*

RESOURCE LINKS: CLICK ON KEYWORD BELOW

[Research and Development](#)

[Human Research Protections Office](#)

[CITI](#)

[Health Analytics Research Team](#)

[TriNetX](#)

[iTHRIV](#)

[PRIS3M Online IRB Submission System](#)

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