Innovation

During Times of Change

Contents

JOHNS HOPKINS
INDIA INSTITUTE

A Year Like No Other

Dr. Amita Gupta, Jane McKenzie-White, & Dr. Robert Bollinger, CCGHE Leadership Team

One year ago we were bracing for what we feared to be coming: a novel corona virus in the same family as the deadly and highly contagious SARS virus from 2003. With the last severe pandemic dating back more than a century, the world was overdue for a new disease that would test capacity of leadership, science, public health, hospitals, and healthcare personnel.

The severity and longevity of the pandemic have profoundly altered us all. At CCGHE, the Infectious Diseases physicians among us have been at the frontlines of patient care on the COVID unit at Johns Hopkins Hospital. Others have been marshalled into operating mobile testing sites and conducting contact tracing in Baltimore. Our amazing and dedicated team in India shuttered research while ensuring that participants had enough medication to get through the country's national lockdown. And, like teams across the globe, ours relocated operations of our robust research center into their home offices, living rooms, basements, and kitchen tables, where they have remained cheerfully Zooming since March 15, 2020.

> "The worst circumstances have a way of bringing out the best in people."

Our core mission is to find innovative ways to improve the outcomes for patients who have infectious diseases—whether COVID, tuberculosis, or HIV. It's been a challenging year, but the worst circumstances have a way of bringing out the best in people. We are enormously proud of the work we do, and we are grateful for the dedicated people who make it happen.

Remote

Control

The CCGHE team is close and highly collaborative. While conducting operations remotely has posed challenges at times, our morning Zoom rally at 9:00 each morning kept us connected and caffeinated.

COVID-19

Response & Research

On the Frontline

CCGHE recognizes the contributions of our infectious diseases healthcare providers and staff who are at the forefront of the COVID-19 pandemic response at Johns Hopkins Medicine.

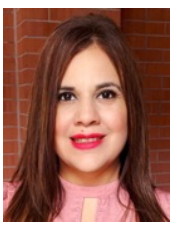
Robert Bollinger, MD, MPH
COVID-19 inpatient care provider at Johns Hopkins Hospital, and helped establish daily COVID-19 symptom screening for Johns Hopkins Medicine employees

Larry Chang, MD, MPH
COVID-19 inpatient care provider at Johns Hopkins Hospital, and a panel member of the Johns Hopkins Novel Coronavirus Research Compendium and Reddit Science Discussion Series Team

Kelly Dooley, MD, MPH, PhD
COVID-19 inpatient care provider at Johns Hopkins Hospital, and Deputy Director of the COVID-19 Clinical Research Center, overseeing all COVID-19 outpatient research

Katheen Page, MD
COVID-19 inpatient care provider at Johns Hopkins Hospital, and advises Baltimore City on testing and vaccinating the city's undocumented Latino community. Also directs a large mobile testing and vaccine site targeting the Latino community

Maunank Shah, MD, PhD
COVID-19 inpatient care provider at Johns Hopkins Hospital

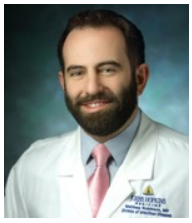


Alejandra Florez-Miller
Working with Dr. Page at the mobile testing site for Baltimore's undocumented Latino community

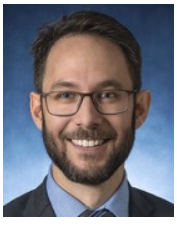
Amita Gupta, MD, MHS
COVID-19 inpatient care provider at Johns Hopkins Hospital, and part of the team that developed a prediction model for patients at risk of severe disease or death

Natasha Chida, MD, MSPH
COVID-19 inpatient care provider at Johns Hopkins Hospital, developed Johns Hopkins' monthly COVID ID Grand Rounds, is Medical Editor for IDSA's COVID-19 Real Time Learning Network

Yukari Manabe, MD
COVID-19 inpatient care provider at Johns Hopkins Hospital, and is assessing new diagnostic tests that return quicker, more accurate results



Matthew Robinson, MD
COVID-19 inpatient care provider at Johns Hopkins Hospital, and developed a tool now used throughout Hopkins to predict COVID outcomes and help prioritize care and allocate scarce resources



Jeffrey Tornheim, MD, MPH
COVID-19 inpatient care provider at Johns Hopkins Hospital

Ana Cervantes
Working with Dr. Page at the mobile testing site for Baltimore's undocumented Latino community

Unlocking the Promise of

Precision Medicine

The COVID-19 pandemic has created often unmanageable volumes of patients requiring acute care for a disease that's never been previously seen. Early on, clinicians were observing that severe COVID disease and death are more prevalent among patients who are elderly and/or who have certain underlying health conditions. There were little data about what factors contributed to those poor outcomes, and what therapies are effective. Drs. Brian Garibaldi (Pulmonary and Critical Care), Scott Zeger (former Provost and Chair of Biostatistics), and Amita Gupta were tapped to establish the Precision Medicine Center of Excellence for COVID-19 to begin to identify patient-tailored care solutions. Drs. Matt Robinson and Bob Bollinger from the CCGHE were also enlisted to help support the COVID Precision Medicine Center's work. This center is the newest of 17 precision medicine centers throughout the Johns Hopkins Health System.

Systemwide Patient Data Repository and Severe COVID Risk Calculator

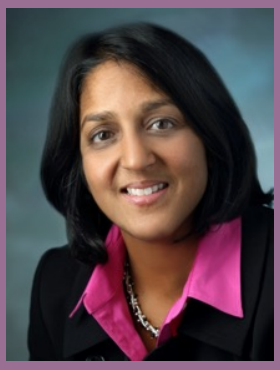
The first effort of the Center was to establish a COVID-19 data registry (JH-CROWN) from patient records across 5 of the Hopkins-affiliated hospitals—Johns Hopkins Hospital, Bayview Medical Center, Howard County General Hospital, Sibley Memorial Hospital, and Suburban Hospital. Garibaldi, Gupta, Robinson and colleagues then analyzed the data to identify specific health factors that predict the likelihood that a patient admitted with COVID-19 will progress to severe disease or death within 7 days. "We identified a few readily measurable demographic and clinical factors that, when assessed on admission to the hospital, can predict if someone has a 5% or a 90% risk of developing severe disease or dying from COVID-19" says Dr. Gupta. "It's incredibly useful information to have when communicating with patients and families and for informing resource allocation in the hospital."

Published Findings:

Patient Trajectories Among Persons Hospitalized for COVID-19: A Cohort Study

Garibaldi BT, Fiksel J, Muschelli J, Robinson ML, Rouhizadeh M, Perin J, Schumock G, Nagy P, Gray JH, Malapati H, Ghobadi-Krueger M, Niessen TM, Kim BS, Hill PM, Ahmed MS, Dobkin ED, Blanding R, Abele J, Woods B, Harkness K, Thiemann DR, Bowring MG, Shah AB, Wang MC, Bandeen-Roche K, Rosen A, Zeger SL, Gupta A. Annals of Internal Medicine. 2020 Sep 22. doi: 10.7326/M20-3905. Epub ahead of print. PMID: 32960645; PMCID: PMC7530643.

The Johns Hopkins Precision Medicine
Center of Excellence for COVID-19
https://bit.ly/3c8UYy5



Dr. Amita Gupta

Dr. Matthew Robinson

Dr. Bob Bollinger

"We identified a few readily measurable demographic and clinical factors that, when assessed on admission to the hospital, can predict if someone has a 5% or a 90% risk of developing severe disease or dying from COVID-19."

Dr. Amita Gupta

Precision Medicine

Continued

Dr. Matthew Robinson

"As healthcare providers, we know what information we need to deliver high quality care. As researchers, we are in a position to look critically at what's possible and meet the need. Applying research to practical use in improving patient care is tremendously gratifying."

Published Findings:

Development of Severe COVID-19 Adaptive Risk Predictor (SCARP), A Calculator to Predict Severe Disease or Death in Hospitalized Patients with COVID-19

Wongvibulsin S, Garibaldi BT, Antar AAR, Wen J, Wang MC, Gupta A, Bollinger R, Xu Y, Wang K, Betz JF, Muschelli J, Bandeen-Roche K, Zeger SL, Robinson ML. Ann Intern Med. 2021 Mar 2. doi: 10.7326/M20-6754. Epub ahead of print. PMID: 33646849.

Smart Tool for Patient-Tailored COVID Clinical Projections

Building on the initial risk prediction findings, Dr. Matthew Robinson applied artificial intelligence computer learning tools to make an even more powerful tool. With a team of colleagues in precision medicine, biostatistics, and data science, he designed and developed an adaptive clinical tool that predicts patient-tailored clinical trajectories, which was validated using data from the JH-CROWN registry. The Severe COVID-19 Adaptive Risk Predictor Prediction Model (called SCARP) provides clinicians with real-time, evidence-based projections about a patient's risk for severe disease or death within the next 24 hours and next 7 days of hospitalization. SCARP is a smart tool that continuously adjusts with changing clinical factors. In other words, it updates an individual patient's 1 and 7 day risk scores, based on data entered at the bedside into Hopkins' patient medical records system. SCARP's forecasting provides advance notice for positioning treatments, ICU beds, and other resources, and it provides information critical to patient and family communications and decision making. SCARP is felt to be so useful, that it is now fully integrated into the Johns Hopkins Health System electronic medical records system (EPIC).

The SCARP effort has just been published, and it marks the quickest timeline from research to implementation across all of Johns Hopkins' 17 Precision Medicine Centers of Excellence. Robinson's work hasn't gone unnoticed. He was recently honored with the Johns Hopkins 2020 Clinician Scientist Career Development Award, and the SCARP tool is garnering attention from clinicians around the world seeking a more tailored approach to COVID-19 patient care. Additionally, the FDA has approached him about potentially using its crowdsourced CURE-ID platform to help identify which COVID-19 therapies are showing the greatest promise. CURE-ID is an internet-based case study repository in which members of the clinical community report new uses of existing drugs for difficult-to-treat infectious diseases. With SCARP's capability of taking thousands of data points, crunching them rapidly, and returning patient-tailored care options, there is certainly no shortage of applications.

According to Dr. Robinson, "As healthcare providers, we know what information we need to deliver high quality care. As researchers, we are in a position to look critically at what's possible and meet the need. Applying research to practical use in improving patient care is tremendously gratifying."

Precision Medicine

Continued

COVID-19 Treatment Outcomes among Minority Populations

A randomized clinical trial demonstrated that use of the drug remdesivir was associated with a shorter inpatient stay for hospitalized COVID patients. However, the benefit of prescribing remdesivir in the community setting outside of clinical trials is not clear. In addition, COVID-19 is having a disproportionate and devastating impact on risk of infection, hospitalization, and death among Black and Latino communities in the U.S. However, since a small percentage of participants in the remdesivir clinical trial were Black or Latino, it is also important to confirm that remdesivir is being prescribed for, and is equally beneficial in, all COVID patients. Therefore, the Hopkins COVID Precision Medicine team is conducting a retrospective study of remdesivir use that analyzes data from Black and Latino patients in the JH-CROWN registry.

"Treatments that are effective in one slice of the population don't necessarily help everyone," says Dr. Bollinger. "Our job as physicians is to provide patients with care that gives them the best chances for quick and full recovery. Our job as researchers is to figure out exactly what that involves for each individual patient. Our goal is to optimize treatment outcomes for all patients, especially for patients from communities most affected by COVID-19."

Dr. Bob Bollinger

"Treatments that are effective in one slice of the population don't necessarily help everyone. Our job as physicians is to provide patients with care that gives them the best chances for quick and full recovery. Our job as researchers is to figure out exactly what that involves for each individual patient."

Published Findings:

Comparison of Time to Clinical Improvement With vs Without Remdesivir Treatment in Hospitalized Patients With COVID-19

Garibaldi BT, Wang K, Robinson ML, Zeger SL, Bandeen-Roche K, Wang MC, Alexander GC, Gupta A, Bollinger R, Xu Y. JAMA Netw Open. 2021 Mar 1;4(3):e213071. doi: 10.1001/jamanetworkopen.2021.3071. PMID: 33760094.

Medical records from 1,972 COVID-19 patients were analyzed for mortality and clinical improvement

Rapid COVID Diagnostics

Dr. Yuka Manabe

Dr. Matt Robinson

Dr. Kathleen Page

A new disease poses rapidly evolving challenges for care providers. Recognizing a need for accurate, reliable, rapid, and accessible diagnostic tests, NIH established the Rapid Acceleration of Diagnostics (RADx) initiative "to promote development, commercialization, and implementation" of COVID testing technologies as well as strategies that enhance access to testing among those most in need. CCGHE faculty have taken on 2 RADx efforts.

Evaluating Rapid Testing Technologies

The standard COVID test is the polymerase chain reaction, or PCR test, which detects COVID RNA to confirm the presence of disease. It's highly accurate and sensitive, but it's an expensive process that can take days to return results. Drs. Yuka Manabe and Matt Robinson are evaluating the sensitivity of COVID antigen tests, which instead pick up specific proteins from the surface of the virus and can return results rapidly. Study participants get the standard nasal pharyngeal swab and a PCR test, and they also get a less invasive intra-nasal swab and provide a saliva sample. The testing platforms are then compared. The goal of the the study is to answer questions about the role that rapid antigen testing can play in identifying COVID quicker and easier, thereby mitigating community spread and getting patients into care quickly.

Customized Testing Strategies for Baltimore's Latino Community

Nationally, Latinos have been disproportionately affected by COVID. Within the Johns Hopkins Health System, for example, the COVID positivity rate between March 11 and May 25, 2020 was 43% among Latinos, compared to 18% among Blacks and 9% among Whites. To address the disparities, Centro SOL, led by Dr. Kathleen Page, partnered with the Johns Hopkins Medicine Office of Diversity, Inclusion and Health Equity, several community-based organizations that serve Latinos, media outlets, and local officials to develop outreach strategies to expand access to free testing. Approaches include a mobile testing site, a bilingual hotline to link patients to testing services, and support for the JH Emergency Department to provide timely delivery of results to Spanish-speaking patients and rapidly link them to aftercare and social services. Support is also provided for the health department contact investigation team, and a team of bilingual clinicians to facilitate complex communications with patients and families. Finally, a weekly, bilingual "Ask Your Doctor" Facebook live session is held to answer community questions about COVID-19. The team is evaluating testing uptake, positivity rates, household contacts tested, and characteristics of testers stratified by approaches and by campaign exposure. This effort leverages lessons learned from the ongoing JHHS Latino COVID-19 response, our team's experience developing campaigns in partnership with community members to enhance HIV testing among Latinos, and a mature network of local partners

Above, team members register people seeking COVID-19 testing at the mobile clinic

Changing Course to

COVID-19

When COVID arrived in Baltimore, Dr. Kathleen Page sprung into action to provide testing services and outreach to Baltimore's Latino immigrant community. This is a role she knows well, serving as Co-Director of Baltimore's Centro SOL, an organization that promotes equity in health and opportunity for Latinos through clinical care, research, education, and advocacy at Johns Hopkins in active partnership with the Latino community.

Dr. Page has long provided community health screenings and services to Baltimore's Latino community, but making the leap to screening for a highly contagious disease, with no cure, and with which many people who are infected don't have symptoms, was no small feat. Additionally, restrictive immigration policies have created conditions in which people don't feel safe seeking healthcare services without risking deportation.

"There is no shortage of challenges," Page notes. "At the beginning it was was getting the testing site up and running, training staff, and ensuring their safety. Our amazing team didn't hesitate when asked to staff the mobile testing site. In the colder months we have had to ensure that we can safely provide the same services indoors."

The team offers testing and then contacts people with results within 48 hours. Upon being tested, people are offered critical public health information about isolation and other precautions for keeping their contacts safe.

Dr. Page noted the impact of community partnership: "Our longstanding work in health services and advocacy has helped encourage people to seek testing. We also have a great partner in Father Bruce Lewandowski at the Sacred Heart of Jesus parish, who has graciously provided space for us to serve the community. 3,500 people have been screened for COVID and referred into care, as needed, so we know our team is meeting a vital need in the community. "

Dr. Kathleen Page

"3,500 people have been screened for COVID.

Our amazing team didn't hesitate when asked to staff the mobile testing site."

India's Mental Health

Outcomes

Dr. Nishi Suryavanshi

Dr. Nikhil Gupte

Dr. Gauri Dhumal

Smita Nimkar

Mental Health Outcomes among Health Care Professionals Involved in the Treatment and Care of COVID-19 Patients in India

Frontline healthcare workers are under tremendous pressure in their role as COVID patient care providers. With shortages of personal protective equipment and other resources in India, providers have also faced a prolonged period of increased personal risk to themselves and their families. The pandemic's toll on mental health among clinical care providers hasn't been well documented, so Drs. Nishi Suryavanshi, Nikhil Gupte, and team launched a study to characterize the impact. The team is conducting a structured survey among healthcare professionals working in flu clinics and hospital COVID-19 units in Maharashtra. The team seeks to characterize the severity of symptoms associated with depression and anxiety, understand the specific factors having an impact on mental health, and assess the pandemic's impact on quality of life for healthcare workers. The results could help guide the development of tailored interventions that improve mental health in the short- and long-term.

Study Team: Nishi Suryavanshi, Nikhil Gupte, Abhay Kadam, Smita Nimkar, Gauri Dhumal

Pandemic Planning in Pune

The COVID-19 pandemic presented challenges for research teams around the world conducting clinical trials. The experience with tuberculosis studies underway at the Byramjee Jeejeebhoy Government Medical College-Johns Hopkins University Clinical Research Site (BJGMC-JHU CRS) in Pune, India, required swift action, agility, and innovation in ensuring that study participants continued to receive lifesaving care in the midst of a national lockdown.

The WHO has prioritized TB preventive therapy, including for household contacts of people with multidrug-resistant tuberculosis (MDR-TB), as a key strategy for controlling the TB epidemic. One study to prevent MDR-TB among household contacts of confirmed cases underway at the BJGMC-JHU CRS is a multinational, phase 3, randomized clinical trial to assess therapies for preventing confirmed or probable active TB in high-risk household contacts.

Participants on study routinely receive enough medication to last until their next scheduled clinical visit. With visits cancelled due to India's national lockdown, and with recovery from COVID-19 likely to be prolonged, the team needed to find alternate ways to distribute medication. Mail delivery was not an option and asking research participants to pick up medication from the CRS or at designated locations within the community was deemed too risky. With the lockdown imminent, the team was under considerable pressure to develop and implement a plan to deliver enough medication to participants. While it might appear fairly straightforward, there were considerable logistical and safety issues to address:

- Specific measures were planned for, and the team notified participants of what to expect.
- Online prescriptions were sent to the pharmacist for filling.
- Personal protective equipment (PPE)—including gloves, N-95 masks, and hand sanitizer—was provided for staff going into the field. The team decided to use glasses/goggles and helmets rather than full PPE kits, because of the optics. There is considerable stigma associated with disease, and teams presenting to households in such gear could cause problems for participants in their communities.
- Online training was provided on safe use and disposal of PPE.
- The BJGMC Dean provided a letter to outreach counselors that granted them authority to travel during the lockdown.
- Each Outreach Counselor was assigned a specific route to reach participants, and a "drop and run" protocol was implemented in order to minimize personal interactions.
- The day before the drop, participants were contacted by the Outreach team, and phone screenings were conducted to assess COVID-19 related symptoms.

The planning that went into ensuring participants for one study were provided for during a health emergency served as a template for other studies at the BJGMC-JHU CRS. Clear communication with study participants inspired further confidence in the team's commitment to their health and wellbeing.

Dr. Vidya Mave

Dr. Nishi Suryavanshi

Dr. Nikhil Gupte

Dr. Sandesh Patil

Savita Kanade

Dr. Natasha Chida

"Sharing lessons from research and clinical care—across institutions and disciplines—informs improvements in patient care. It's central to Johns Hopkins' mission."

318 Participants per session, on average

3,100+ Subscribers

Right, Drs. Michael Melia, Kathleen Page, Natasha Chida, and Damani Piggott discuss the disparate impact of COVID-19 by race and ethnicity

Making the Rounds

Medical Grand Rounds, during which physicians discuss clinical issues and research, are a core methodology of inpatient care and medical education. Developed by Drs. Natasha Chida and Michael Melia, who lead the Johns Hopkins Infectious Diseases Fellowship Program at Johns Hopkins, ID COVID-19 Grand Rounds was established early on as a virtual seminar series to help build knowledge about research and patient care as it emerges. It has been wildly successful.

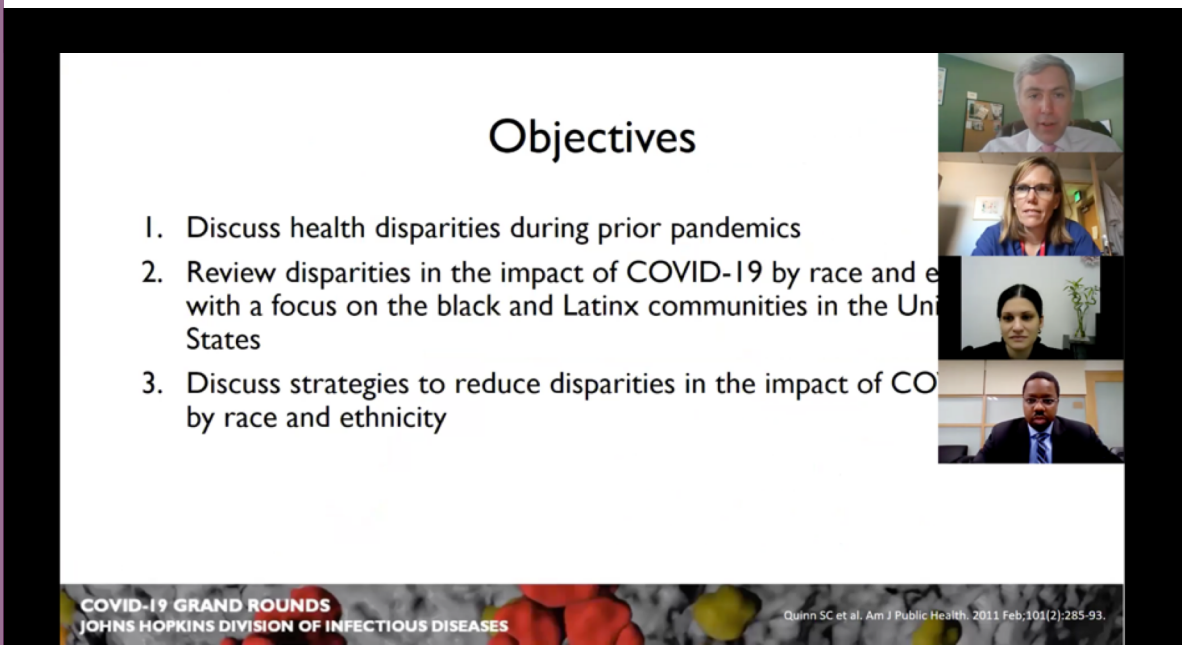
First convened April 7, 2020 as a weekly series through June, it was subsequently convened twice in July and went monthly as of August. A wide range of topics covered by top experts from around the world has drawn a large and faithful following that traditional in-person Grand Rounds does not afford.

Topics have ranged from diagnostics, therapeutics including Remdesivir and the controversial use of chloroquine/hydroxychloroquine, the role of convalescent plasma in recovery, vaccine development, ICU outcomes, achieving herd immunity, multisystem inflammatory syndrome in children, the impact of COVID by race and ethnicity, antibodies, the efficacy of protective measures like masking and social distancing, public health policy for reopening schools, and the science about long-term effects of COVID.

Drs. Chida and Melia have built a library of timely information about COVID-19 in a rapidly changing landscape. As Chida notes, "Sharing lessons from research and clinical care—across institutions and disciplines—informs improvements in patient care. It's central to Johns Hopkins' mission."

10,600+ Unique visitors

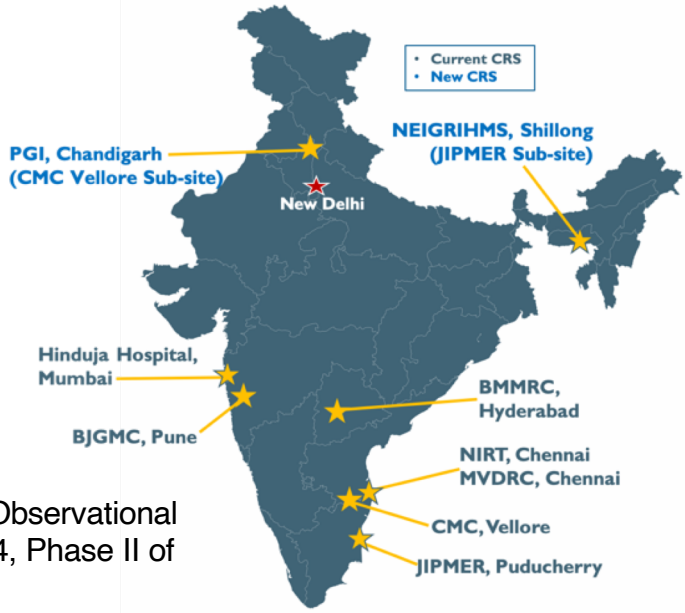
Archived online: https://bit.ly/2KBcgZh



New Efforts to Tackle

Tuberculosis

Tackling TB



One of CCGHE's primary areas of research is to improve care and long-term outcomes for people with tuberculosis (TB). We launched several new and exciting efforts in 2020 that build on our long-standing work.

RePORT India

While we have participated in the Regional Prospective Observational Research in Tuberculosis (RePORT) consortium since 2014, Phase II of this important effort was launched during 2020.

Background

The mission of RePORT International is to advance TB science globally, with emphasis on translational research to provide new tools for TB control. India's countrywide consortium (RePORT India):

- Advances regional TB science in India, towards fulfilling the TB strategic goals of the country;
- Strengthens TB research capacity and infrastructure; and
- Fosters research collaboration within India and with other countries focused on research that can lead to clinically important biomarkers, vaccines, drugs, and diagnostics.

Partnerships

RePORT International supports countrywide consortia in India, Brazil, South Africa, China, Indonesia, and the Philippines for the purpose of conducting basic and clinical research to identify clinically important TB biomarkers, which are basically signals in the body that raise flags about a change in disease or that one is likely to occur. Research is also conducted on promising vaccines, therapeutic drugs, and diagnostics. The partnerships comprise in-country and U.S research institutions. Since 2014, Dr. Amita Gupta has served as the U.S. Chair for RePORT India, which represents the largest program of all participating countries.

Bilateral Support

RePORT India is supported with bilateral funding from the Government of India's (GOI) Department of Biotechnology (DBT) and the U.S. National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS), and Office of AIDS Research (OAR). CRDF Global administers and oversees the funding from the U.S. government.

CCGHE participates in 2 RePORT India Research Partnerships

- Bhagawan Mahavir Medical Research Center (BMMRC) I University of Texas
- **Byramjee Jeejeebhoy Government Medical College (BJGMC) I National Institute for Research in Tuberculosis (NIRT) I Johns Hopkins University**
- Christian Medical College-Vellore (CMC-Vellore) I University of California-San Francisco (PGI Subsite)
- **PD Hinduja Hospital I Johns Hopkins University**
- Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER) I Boston Medical Center I Boston University I Rutgers University (NEIGRIHMS Subsite)
- Prof. M. Viswanathan Diabetes Research Centre (MVDRC) I University of Massachusetts I NIRT International Centre for Excellence in Research (ICER)

Tackling TB

Continued

RePORT India Phase I (2014-2020)

The objective for the first phase was to provide data and specimens to biomarker researchers and collaborators to better understand the prognosis of TB disease in India and how it progresses from TB exposure to active disease among 2 cohorts of patients: those who have active TB disease, and those who are household contacts (HHCs) of an active case of TB. To support the research, the RePORT India consortium established a Central TB Sample Biorepository at the National Institute of Research in Tuberculosis (NIRT) in Chennai, and a Statistical/Data Management Center at the Society for Applied Studies-Centre for Health Research and Development (CHRD) in New Delhi. Pharmaceutical Product Development, LLC (PPD) was contracted to provide technical support.

RePORT India Phase II (2020-2025)

Leveraging the data, specimens, infrastructure and scientific partnerships established in Phase I, RePORT India will focus on five specific scientific aims in Phase II:

1. Evaluate Novel Diagnostics & Biomarkers of Diverse States of Infection
2. Identify Markers of Lung Injury Associated with Unfavorable TB Treatment Outcomes
3. Identify Markers of Treatment Response
4. Identify Mechanisms of Protection against TB in Exposed Persons
5. Identify Immunologic Markers of Persons at Highest Risk of Progress of Latent TB Infection to TB

RePORT India will also assess cross-cutting epidemiologic and COVID-19 related aims.

In addition to the Phase I cohorts of confirmed TB cases and their household contacts, Phase 2 introduces a new study cohort of people who are suspected but not confirmed to have TB.

CCGHE plays a central role in facilitating scientific collaboration and coordination both internationally and across the India consortium. Dr. Amita Gupta is a member of the Executive Leadership Group for RePORT International, and Dr. Nikhil Gupte is lead Biostatistician. Dr. Bob Bollinger is the U.S. Protocol Chair for the RePORT India Phase II Common Protocol, and CCGHE staff and faculty serve in coordination and working group leadership roles.

47 publications from our 2 RePORT India research partnerships, including these high impact findings

Baseline IL-6 is a biomarker for unfavorable tuberculosis treatment outcomes: a multi-site discovery and validation study. Mave V, Kadam D, Gaikwad S,, et al (*Submitted: American Journal of Critical Care Medicine*)

Measuring tuberculosis drugs in hair in adults and children as a tool to monitor exposure and outcomes. Mave V, Kadam D, Gaikwad S, et al. Int J Tuberc Lung Dis. 2021 Jan 1;25(1):52-60. doi: 10.5588/ijtld.20.0574. PMID: 33384045.

Tuberculosis preventive treatment should be considered for all household contacts of pulmonary TB patients in India. Paradkar M, Padmapriyadarsini C, Jain D, et al. *PLOS One*. 2020 July 29;15(7):e0236743. PMID: 32726367; PMCID: PMC7390377.

Whole genome enrichment approach for rapid detection of Mycobacterium tuberculosis and drug resistance-associated mutations from direct sputum sequencing Soundararajan L , Kambli P , Priyadarshini S et al. Tuberculosis (Edinb). 2020 Mar;121:101915. doi: 10.1016/j.tube.2020.101915. Epub 2020 Feb 20. PMID: 32279871.

Transcriptomic profiles of confirmed pediatric tuberculosis patients and exposed household contacts identifies tuberculosis disease, infection, and response to treatment among Indian patients. Tornheim JA, Madugundu A, Paradkar M et al. J Infect Dis. 2019 Dec 4. pii: jiz639. doi: 10.1093/infdis/jiz639. [Epub ahead of print]. PMID: 31796955.

Delamanid central nervous system pharmacokinetics in tuberculous meningitis in rabbits and humans Tucker EW, Pieterse L, Zimmerman MD et al. Antimicrob Agents Chemother. 2019 Sep 23;63(10). pii: e00913-19. doi: 10.1128/AAC.00913-19. Print 2019 Oct. PMID: 31383662; PMCID: PMC6761520.

Sub-therapeutic rifampicin concentration is associated with unfavourable tuberculosis treatment outcomes. Ramachandran G, Padmapriyadarsini C, Gaikwad S et al. Clin Infect Dis. 2019 May 10. pii: ciz380. doi: 10.1093/cid/ciz380. [Epub ahead of print]. PMID: 31075166.

Effect of diabetes mellitus on the pharmacokinetics and pharmacodynamics of tuberculosis treatment. Alfarisi O, Mave V, Gaikwad S et al. Antimicrob Agents Chemother. 2018 Oct 24;62(11). pii: e01383-18. doi: 10.1128/AAC.01383-18. Print 2018 Nov. PMID: 30126955; PMCID: PMC6201087.

2020 RePORT India Annual Meeting in Mumbai

Tackling TB
Continued

New in 2020

PARTHISA: Pregnancy Associated Immune Responses to TB and HIV in India and South Africa

Expanding on our growing portfolio of work on the immunology of pregnancy and tuberculosis and HIV, this study will look for immunologic signatures that can signal latent TB infection and active disease. We will compare these markers in both HIV positive and negative pregnant and post-partum women, and we will compare placental cells in pregnant women with no evidence of infection or diseases, active TB disease, and latent TB infection, in order to learn more about immunologic responses during pregnancy and suppression of tuberculosis.

Study Team: Jyoti Mathad, Amita Gupta, Ramesh Bhosale, Shilpa Naik, Neetal Nevrekar, Vandana Kulkarni, Nishi Suryavanshi, Mallika Alexander, Neeta Pradhan, Neil Martinson

HATHI Trial: Reducing Alcohol Use among People with Tuberculosis and HIV in India

This 5-year study will enroll 450 patients, half with tuberculosis and half with HIV/TB coinfection, and will assess whether treatment that integrates cognitive behavioral therapy and motivational enhancement therapy is more effective in mitigating alcohol abuse and improving treatment outcomes. The study is being conducted at DY Patil Hospital and BJGMC in Pune.

Study Team: Amita Gupta, Geetanjali Chander, Nishi Suryavanshi, Arjun Kakrani, Dr. Gaikwad, Jonathan Golub, David Dowdy, Prasad Bogam, Nikhil Gupte, Vidya Mave, Gauri Dhumal

CATALYST Trial: Studying Safer, Shorter Course, More Effective Treatments among Children with Drug-Resistant Tuberculosis

CATALYST is a multi-national trial being conducted in India, South Africa, and Philippines. The BJGMC-JHU clinical research site Pune will enroll HIV+/- children under the age of 15 who have confirmed or diagnosed drug-resistant TB. The current standard treatment is lengthy (9-11 months) and has significant side effects, thus this study is assessing new formulations that are child-friendly.

Study Team: Mandar Paradkar, Aarti Kinikar, Nishi Suryavanshi, Amita Gupta

Our research team in Pune, India, is among few groups worldwide to focus on the immunological changes associated with pregnancy and post-partum stages of life.

Tackling TB

Continued

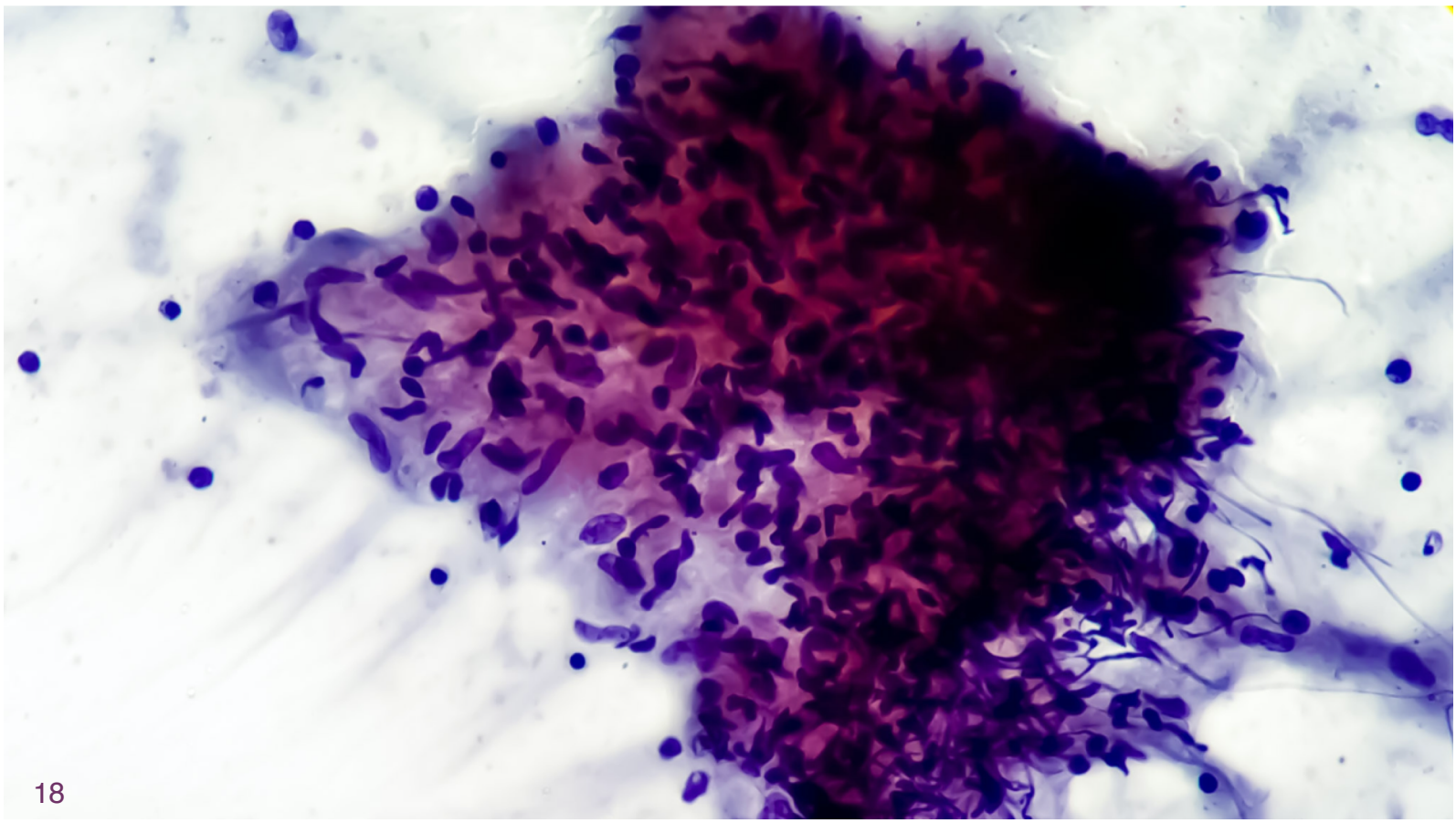
New in 2020

RePORT: Nanopore Biosensor for Leveling MTB Antigens in Blood

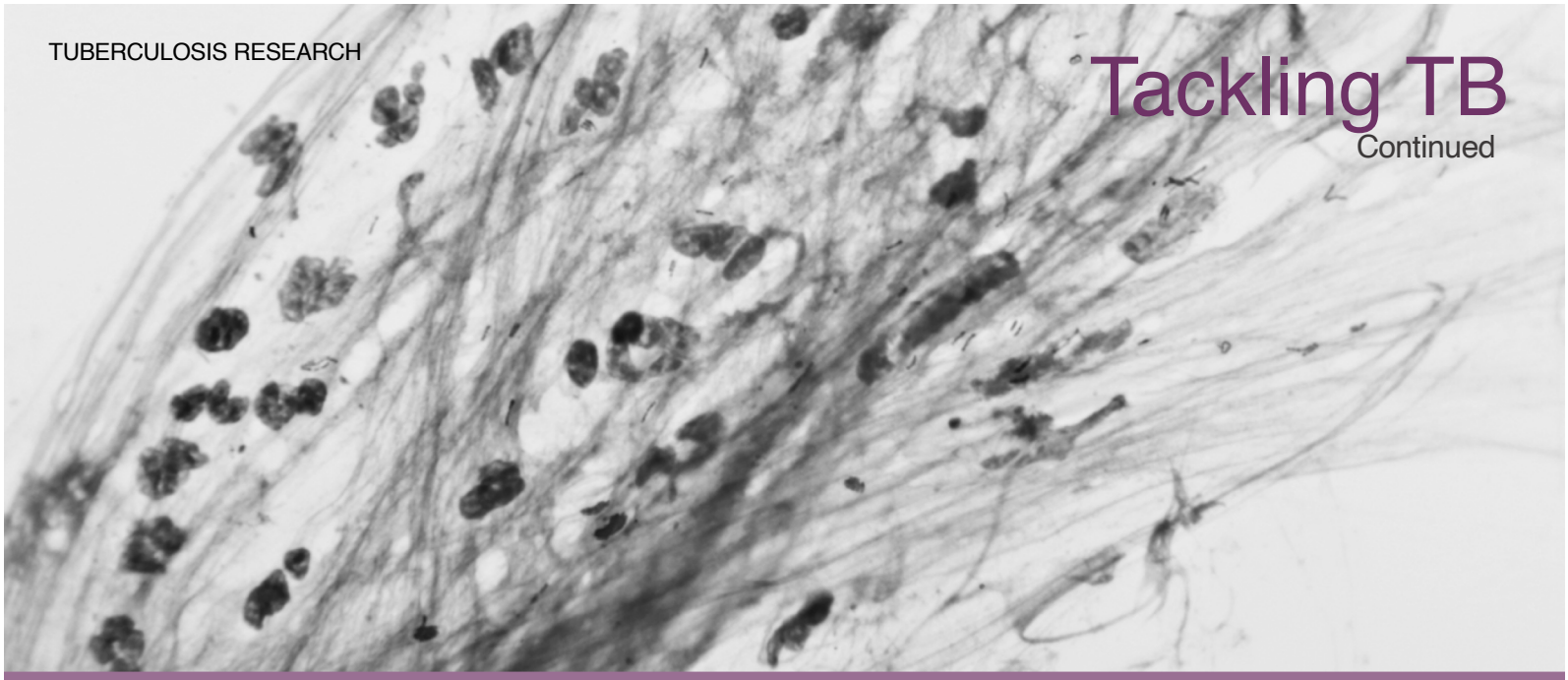
It's challenging to get useful sputum samples from TB patients, and current TB diagnostic tests lack sensitivity to other kinds of samples. Moreover, standard TB diagnostics involve mass-spectrometry, which requires expensive equipment. For this study, our team is validating a nanopore sequencing platform to look for two specific biomarkers that we previously identified to be associated with TB for a potential diagnostic test, and we are looking at the platform for its potential to monitor medication response. Nanopore sequencing is more cost effective approach for resource limited settings with high TB burden. **Study Team:** Tony Hu**,** Bob Bollinger, Amita Gupta, Nikhil Gupte, Mandar Paradkar, Sanjay Gaikwad, Vidya Mave, Vandana Kulkarni

Multicenter Study to Evaluation the Diagnostic Accuracy of a Stool Processing Kit Combined with Xpert MTB/RIF Ultra for Pediatric Diagnosis Using Microbiological Confirmation on Respiratory Samples as the Reference Standard

Most diagnostics tests for tuberculosis require sputum, and collecting quality samples from young children is not an easy undertaking for clinical staff. Our team is assessing the accuracy of a new diagnostic test for pediatric tuberculosis and drug-resistant TB that analyzes stool samples and is less invasive for diagnosing children. **Study Team:** Mandar Paradkar, Amita Gupta, Samyra Cox, Vandana Kulkarni, Nikhil Gupte



Tackling TB
Continued



New in 2020

RePORT: Identification of Biomarkers that Can Predict Progression from Latent TB Infection to Active Tuberculosis Disease

The current tests for tuberculosis lack sensitivity needed to accurately detect infection that hasn't yet progressed to active disease. Thus, there is a high rate of false-negative results, and people who have been exposed are not receiving the preventive care they need. We are assessing a proteomic platform that can simultaneously measure multiple biosignatures that point to TB infection in people who are contacts of confirmed TB patients.

Study Team: Mandar Paradkar, Robert Bollinger, Amita Gupta, Vidya Mave, Vandana Kulkarni, Nikhil Gupte, Shri Vijay Balayogendra Shivakumar, Akshay Gupte

RePORT: Pharmacokinetic Assessment of MDR-TB Drugs in the Treatment of TB Meningitis

This study is being conducted in South Africa, China, and India. Our RePORT teams at BJGMC and PD Hinduja Hospital and Medical Research Center are measuring TB drug concentrations in stored plasma and cerebral-spinal fluid samples to develop a model that describes second-line drug disposition and penetration, and that can identify biomarkers of greater survival for tuberculosis-meningitis co-infection.

Study Team: Jeff Tornheim, Kelly Dooley, Amita Gupta, Camilla Rodriguez, Sandesh Patil, Prena Chawla, Neeta Pradhan, Vidya Mave, Shri Vijay Bala Yogendra Shivakumar

Tackling TB
Continued


Dr. Vidya Mave


Dr. Jonathan Golub

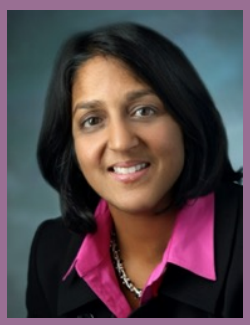

Samyra Cox


Dr. Sachin Atre


Dr. Akshay Gupte


Dr. Nikhil Gupte


Dr. Nishi Suryavanshi


Dr. Amita Gupta

Some health factors—like diabetes, and alcohol and tobacco use—correlate strongly with TB relapse.

New in 2020

TB Aftermath Aims to Identify Effective Approach for Recovery Follow-Up

In India, tuberculosis disease relapse following treatment is common. In fact, the rate of TB among patients who have already recovered from the disease is 60 times the national average for new cases. Following up with recovered patients and their household contacts for TB is a strategy proposed by India's National Tuberculosis Elimination Program to aid in finding active cases in the community, but more evidence is needed to guide implementation. Thus, for this 5-year trial, the Indo-JHU research partnership will assess two methods of active TB case finding to determine which approach is most effective, has the best potential for scale-up, and demonstrates the most cost effective return on investment.

Drs. Vidya Mave and Jonathan Golub are leading the JHU effort, and the study team includes Sachin Atre, Abhay Kadam, Samyra Cox, Akshay Gupte, Nikhil Gupte, Nishi Suryavanshi, and Amita Gupta. The study is being conducted in partnership with colleagues at DY Patil Medical College and Research Centre in Pune, and it will be run in four Pune TB Units of India's National Tuberculosis Elimination Program: Sahakarnagar, YCM, Khed, and Paud. Case findings will be conducted either through household visits or through telephone screenings, and participants reporting symptoms will be tested and referred into care, as necessary. Because some health factors—including diabetes, and alcohol and tobacco use—correlate strongly with TB relapse, participants will be screened for tobacco and alcohol use and will receive a rapid blood sugar diagnostic test.

TB is a devastating disease that can cause debilitating and life-long damage to the lungs. This study will help identify the most effective strategy for India's national TB program to prevent recurrence and community spread.

Tackling TB
Continued

New in 2020

Vaccine Trial: A Multicenter Phase II/III Double-blind, Randomized, Placebo Controlled Study to Evaluate the Efficacy and Safety of VPM1002 in the Prevention of Tuberculosis (TB) Recurrence in Pulmonary TB Patients after Successful TB Treatment in India

Although there is a vaccine for TB that's generally given at birth in high burden countries, it has been in use for 100 years, and it's not terribly effective. To meet the need, Serum Institute of India Pvt Ltd developed a new recombinant vaccine candidate for preventing recurrence of TB in recovered patients. Preclinical data and previous clinical studies of this vaccine show promising results, and JHU-India clinical research partnership is now conducting a Phase II/III trial to determine the vaccine's safety and efficacy.

Under the leadership of Dr. Vidya Mave, 2,000 people who have recovered from TB following treatment will be enrolled in the study in Pune, India. Participants have several scheduled follow up visits, where samples are taken to gauge immune response and to closely monitor for any side effects. The data will then be analyzed for efficacy and strains associated with recurrence, and immunological differences will be compared.

A new, more effective TB vaccine would save countless lives globally each year. We look forward to reporting the findings of this important research.

147 participants
were enrolled in 2 tuberculosis therapy trials to shorten treatment for children & adults

Shortening the Course

Dr. Vidya Mave

"India assumes the world's largest burden of tuberculosis, and the treatment is prolonged and difficult . . . Our team is proud to have contributed to findings that shorten treatment, and we are grateful to the families who participated in this important effort."

New in 2020: Findings from 2 TB Trials

During the 2020 Union Conference on Lung Health, the World Health Organization (WHO) and the U.S. Centers for Disease Control and Prevention announced important findings about two trials conducted at the JHU-India Clinical Research that shorten the length of treatment. These findings will change the WHO's current treatment guidelines.

SHINE Trial Offers Shorter Course TB Treatment in Children

Led by Drs. Vidya Mave and Aarti Kinikar, the Shortened Treatment for Minimal Tuberculosis in Children (SHINE) Trial compared a 4-month drug combination to the current standard 6-month treatment for children with drug-susceptible TB. The clinical trial site enrolled 86 participants and found that the shortened course offered the same results with no difference in adverse events. Shortening the course will help with medication adherence, as TB therapy is expensive, requires a burdensome number of pills, and is associated with drug toxicity.

Dr. Mave weighed in on the team's findings: "India assumes the world's largest burden of tuberculosis, and the treatment is prolonged and difficult—particularly for children. Our team is proud to have contributed to findings that shorten the length of treatment, and we are grateful to the families who participated in this important effort."

The study team included Drs. Priyanka Richur and Mandar Paradkar, and Savita Kanade, Sadaf Inamdar, and Aparna Nijampurkar.

Study 31/A5349: Four Month Course of Daily TB Treatment Is as Effective as 6-Months in Adults

In another important finding, the CDC announced the results of a Phase 3 trial that found that a daily regimen of a drug combination administered to adults over 4-months is as effective as the current 6-month standard of care. And, with no difference in adverse events, the shortened treatment is just as safe.

Study 31/A5349 enrolled more than 2,500 participants from clinical sites in 13 countries, including the JHU-India Clinical Research Site in Pune, India, where 61 participants were enrolled. The study represents the largest drug-susceptible TB treatment trial ever conducted by CDC or NIAID.

Study team members in this landmark study included Dr. Vidya Mave, Dr. Sanjay Gaikwad, Dr. Nishi Suryavanshi, Dr. Neetal Nevrekar, Dr. Sandesh Patil, Vandana Kulkarni, Neeta Pradhan, Savita Kanade, Sadaf Inamdar, Sameer Khan, and Smita Nimkar.

Tackling TB

Continued

New in 2020

Women's Health Education Seminar Convened for Multi-drug Resistant TB Survivors in Pune, India

Tuberculosis affects women more severely in their reproductive years than during any other time of life. TB is a known cause of infertility, menstrual irregularity, and pregnancy loss, and undernutrition places women at increased risk of death and disease relapse. In India, stigma and discrimination, depression, and poverty keep women from accessing lifesaving healthcare.

In an effort to promote health and wellness among multi-drug resistant TB survivors, the team at the BJGMC research site in Pune convened a woman's health seminar that offered sessions on reproductive health, mental health, and nutrition, and opportunities for attendees interact and share their experiences. Convened in December by Dr. Nishi Suryavanshi, Savita Kanade, and colleagues, with support from the Arun and Elisabeth Shenoy Foundation, 25 adolescent and young women MDR-TB survivors and their mothers attended this community seminar.

Reproductive Health Session

Following an overview and ice-breaker activity, Dr. Neetal Nevrekar, a gynecologist on the Indo-JHU research team, presented the first session on reproductive health. She provided information about menstruation and cycle, and symptoms that are associated with a need for health consultation such as heavy bleeding, infection, and irregularity. Dr. Nevrekar reviewed good practices for vaginal hygiene, as well as issues pertaining to ovulation, Polycystic Ovary Syndrome, family planning, pregnancy care, reproductive health in the context of tuberculosis, and the importance of social and community health as well as physical and psychological health. Participants were very engaged in the question and answer session, seeking information about missed periods, optimal cycle duration, premenstrual syndrome, stress, illness, weight, when to seek healthcare, and resuming sexual activity after completing TB treatment.

Mental Health Session

The session on mental health issues was presented by guest speakers, Dr. Sneha Karmani, Consultant Psychiatrist, from Aditya Birla Memorial Hospital and Manisha Wahi, Clinical Psychologist, from Dr. DY Patil University. The session focused on dealing with stress and the importance of mental health to physical health and wellbeing. Issues addressed included why and when to seek mental health care, medications that can help with symptoms of anxiety and depression, how to discuss mental health with family and friends, and how physical exercise plays a role in mental health. Some participants shared emotional experiences of accepting TB disease, the burden of taking 10-12 tablets per day, coping with injection pain, medication side effects, stigma, and the mental stress associated with the diagnosis of MDR-TB.

Dr. Nishi Suryavanshi

Savita Kanade

Dr. Neetal Nevrekar

Tackling TB
Continued

Women's Health Education Seminar for Multi-drug Resistant TB Survivors (Continued)

Many expressed a need for counselling and mental health services in the Government TB programme. Participants also shared that family counselling services (particularly with in-laws) in the Government TB programme could help destigmatize TB and help family members understand and be supportive during treatment. Citing a need for peer support, a few participants offered to work as peer counsellors with the site.

Nutrition Session

The final session of the day was presented by Dr. Pooja Paur, Dietician at "Just for Hearts" Healthcare Institute, who addressed the components of a healthy diet. Specifically, she discussed the benefits of protein, iron, calcium, and B12 and the foods that wholesome meals should include. Dr. Paur also emphasized the importance of fruits and vegetables and the benefits that healthy foods add to TB therapy.

Following the educational sessions, a lunch was convened during which participants shared their thanks for the session and for the support that they had received from the staff during India's national COVID lockdown. Site Community and Outreach Coordinator Savita Kanade conducted an empowerment exercise, and attendees received gifts for their participation. Closing out the day, Site Counsellors Prasanna Sahoo and Meena Chivate gave a vote of thanks.

"Community education seminars are an important part of our work," notes Dr. Suryavanshi. "We strive to provide opportunities for people to feel less alone, to feel acknowledged, and to be empowered as a partner in treating disease and overall health and well-being."

This educational programming was supported through the generosity of the Arun and Elisabeth Shenoy Foundation

Advancing the Science Behind

HIV Care

2020 Grant Award: Advancing the Science Behind

HIV Care

Network Trial Impact: Select Findings

PROMISE: Continuing antiretroviral therapy after delivery significantly reduces adverse events for post-partum women

REPRIEVE: A daily statin drug can help prevent major adverse cardiovascular events in people living with HIV

MULTI-OCTAVE: Targeted genotyping can help identify appropriate third-line antiretroviral therapy among patients who have drug-resistant HIV

TB APPRISE: The drug commonly used to prevent TB in HIV+ pregnant women is associated with a higher rate of adverse pregnancy events

BRIEF TB: A shortened one-month course of a new combination therapy to prevent TB in HIV+ patients is just as effective as 9-months of the standard therapy

REMEMBER: A drug combination commonly used to prevent TB in people with advanced HIV/AIDS offers no benefit over using just one drug, and the one drug regimen may actually be safer

Continuing our decades of work on HIV, the JHU-India research partnership was awarded a 7-year grant from the NIH to conduct research in India under two of the premier international HIV clinical trials networks: the Adult Clinical Trials Group (ACTG) and International Maternal, Pediatric, Adolescent Clinical Trials (IMPAACT).

This grant is the third NIH-funded HIV Clinical Trial Unit under which our team has conducted research. Co-led by Dr. Amita Gupta, the Johns Hopkins-India-Baltimore Clinical Trials Unit (JHUBI-CTU) is a partnership comprising trial sites in Baltimore and Pune. The research evaluates the safety and efficacy of new therapies for HIV and other diseases, including TB, that complicate HIV treatment, and/or that are associated with more severe disease. Since 2004, the India clinical trial site at BJGMC in Pune has participated in 24 multinational network trials, providing important contributions to HIV and TB clinical science and improvements in care.

This decades-long partnership is one of few internationally that focuses on HIV in pregnant and postpartum women. The unique physiological changes that occur during this time are not well characterized, and there is little data about the safety and efficacy of standard treatments that are routinely administered to HIV+ pregnant women. Our research advances safe and effective HIV care for pregnant women and infants.

Our team members serve on international scientific committees that set priorities for research, and they lead the design and implementation of large multinational trials. The Clinical Trial Site at BJGMC has participated in several landmark trials that changed global standards for patient care. The renewal of this funding allows important HIV research to continue and is a testament to the impact of our work is having for improved HIV care.

JHMI Press Release: Grants, Management Roles Keep Johns Hopkins A Leader In HIV/AIDS Clinical Trial Research. 2020-12-08
https://bit.ly/3kwItyo

New in 2020: Sentinel Research Network of IeDEA: A Prospective Cohort among People Living with HIV

The JHU-India research team has embarked on a large effort to capture and analyze data among people living with HIV in low and middle income countries (LMICs) as part of our collaboration with the International epidemiology Databases to Evaluate AIDS consortium. The consortium is establishing a Sentinel Research Network that will implement studies focused on cardiovascular health, mental health and substance abuse, and liver disease. There currently is very limited data from LMICs about HIV and noncommunicable disease comorbidities and mental health problems, and what the impact is on access to HIV treatment and disease outcomes. As a participating IeDEA site, JHU-India research partnership in Pune will collect longitudinal clinical and mental health data for a shared international repository that can be tapped for studies on cardiovascular risk factors and enrollment in HIV care, prevalence of substance abuse and mental health issues and their association with treatment outcomes, and prevalence of liver diseases and what the specific causes are.

Study Team: Dr. Vidya Mave, Smita Nimkar

New in 2020: Prevalence of Risk Factors for Lung Cancer and Barriers for Tobacco Cessation among People Living with HIV

Lung cancer is among the leading causes of cancer deaths in people living with HIV, who develop lung cancer at an earlier age and who, evidence suggests, develop the disease after lower exposures than the general population. Although there are higher rates of smoking among people with HIV, there are other factors, like immunosuppression and inflammation, that could contribute. With the world's third largest HIV+ population, India is acutely affected. This study has several aims: (1) To assess the prevalence of lung cancer risk factors among people with HIV, including smoking and use of smokeless tobacco, TB, COPD, and pneumonia; (2) To characterize use of tobacco products, assess attitudes, behaviors and barriers to quitting, and identify preferred cessation strategies; and (3) To assess whether lung screenings can motivate HIV patients to quit.

Study Team: Dr. Vidya Mave, Dr. Jonathan Golub, Dr. Jessica Elf, Dr. Akshay Gupte, Dr. Nishi Suryavanshi, Smita Nimkar, Dr. Gauri Dhumal, Ivan Marbaniang

Improving Therapy Selection for HIV Care

HIVASSIST

Dr. Maunank Shah

New Strategies in Clinical Guideline Delivery: Randomized trial of online, interactive decision-support versus guidelines for HIV treatment selection by trainees Ramirez JA, Maddali MV, Nematollahi S, Li JZ, Shah M. Clin Infect Dis. 2020 Mar 25:ciaa299. doi: 10.1093/cid/ciaa299. Epub ahead of print. PMID: 32211758.

News Article: HIV-ASSIST Uses Algorithms in Appropriate ART-Regimen Selection. Contagion Live. March 30, 2020. https://bit.ly/3c59pRS

www.hivassist.com/

HIV is now a chronic disease that's increasingly managed by primary care providers. Yet surveys of primary care programs suggest that less than half offer dedicated training in HIV medicine. With more than 30 FDA-approved antiretroviral (ARV) drugs from 7 different classes, clinicians are faced with a formidable number of possible antiretroviral therapy (ART) combinations.

Selecting the best ART regimen for individual patients can be time consuming and intimidating. There are complex and cascading factors to consider when making ARV selections. Drug interactions and side effects, comorbidities, resistance mutations, viral load, dosing frequency, patient adherence to treatment, and other issues present complex considerations for care providers.

Developed by Dr. Maunank Shah and colleagues, HIV-ASSIST is an online clinical decision support tool that guides primary care providers in making appropriate ART selections. The tool integrates the latest HIV clinical care guidelines and considers individual patient factors. Care providers enter patient-specific clinical information such as comorbidities, comedications, CD4 cell count, and HIV treatment history, as well as virus-specific attributes, including genotype, HIV viral load, and tropism. HIV-ASSIST then ranks all possible drug combinations. The lower the weighted score, the more likely the combination is to both suppress the virus and be tolerable for the patient to take. The tool saves providers time, and it ensures that appropriate therapies are selected for individual patients.

The tool was validated in a randomized study. Trainees who used HIV-ASSIST were found to be significantly more likely to select appropriate antiretroviral combinations than those who used care guidelines alone.

In 2020, HIV-ASSIST became a registered non-profit company, HIV ASSIST, Inc., and Dr. Shah launched a continuing medical education series through Clinical Care Options.

Using Mobile Health to Improve HIV Care

Connection & Retention

New in 2020: Leveraging mHealth and Peers to Engage African-Americans and Latinos in HIV Care (LEAN)

African Americans represent 12% of the population but account for 43% of people living with HIV in the U.S., and they are less likely to receive antiretroviral therapy. In Baltimore City, African Americans accounted for 78% of all new HIV infections in 2016. Similarly, HIV rates among Latinos are 3 times higher than among Whites, and Latinos are at high risk for delays in diagnosis and linkage to care. Because delays in HIV care are associated with more severe disease and death, it's critically important that people living with HIV get connected to health services early and stay engaged in care.

Health departments have traditionally focused on linkage to care, while clinics have mostly been responsible for retention of patients in their practice. Under current Baltimore City Health Department protocols, linkage officers do not follow up with patients after linking them to a clinic. While many HIV clinics have retention protocols, they vary widely, ranging from simple automatic reminder calls to systematic review of patients to identify those who have fallen out of care. Evidence suggests that increased contact with the clinic can improve retention in care but may not be enough, particularly for people living in poverty and in unstable housing conditions. Thus, patients who don't follow up with continuing appointments are identified as out of care. Re-engaging patients is challenging: linkage officers do not have ongoing relationships with patients, and contact information is often out of date.

In a study funded by the Patient-Centered Outcomes Research Institute (PCORI), Drs. Kathleen Page and Larry Chang and Jane McKenzie-White are evaluating whether the use of an evidence-based mobile health (mHealth) strategy that leverages 2 smart phone applications, developed by emocha Health, are more effective than standard methods of keeping patients engaged in care. One app is tailored for patient supporters (including linkage officers, patient navigators, nurses) that helps facilitate communication on issues related to HIV care, viral load, appointment scheduling, transportation to care, and patient requests. The other app is tailored for patients to facilitate their engagement in care through appointment reminders and health-related text messaging. The assessment will focus on whether patients achieve viral suppression after 12 months in the study, and whether they are still engaged in care. Currently, the BCHD Linkage to Care program and three HIV clinics are participating in the effort—Baltimore City Health Department, the Bartlett Specialty Practice at Johns Hopkins Hospital, and the THRIVE clinic at University of Maryland, Baltimore-Midtown.

The target enrollment for this 5-year study is 500 patients, who are randomized to receive either the current standard of care, or the smart-app intervention. Due to COVID, enrollment has been slow—the study was halted from April through mid-June 2020. However, 108 participants are now enrolled, and we anticipate that those numbers will increase substantially.

Dr. Kathleen Page

Dr. Larry Chang

Jane McKenzie-White

Note: emocha Health was established in 2014. The platform is licensed mobile health software created by Jane McKenzie White, Miquel Sitjar, and Drs. Bob Bollinger and Larry Chang.

Journey to India

Dr. Amita Gupta

"With support from University leadership, we are able not only to expand our own work, but also to foster faculty collaboration and student engagement across all of Johns Hopkins."

Learn More:
https://bit.ly/3qXeUrA

2020 marked an exciting turning point in the expansion of our work in India, with efforts to establish a university-wide Johns Hopkins University India Institute operationalized after years of planning. Led by Drs. Amita Gupta and David Peters, a Strategic Working Group conducted a landscape analysis and concept planning and presented findings to University Provost Dr. Sunil Kumar. With his enthusiastic support, the Institute has launched as an initiative within the Office of the Provost.

JHII will support a network of research centers in India and provide additional programming, including training, scholarships, education, research grants, and more. Drs. Gupta and Peters are Co-Chairs of the newly-formed JHII Faculty Steering Committee, and an Executive Advisory Board is being formed. The University established official business entities in country and is in the process of hiring staff to coordinate India-focused efforts across all schools within the University. JHII established a virtual seminar series in partnership with Hopkins at Home and convened the first of a series of faculty Town Halls designed to build community, ascertain needs, and promote partnership. A survey of 257 faculty at Hopkins revealed that 140 had worked in India, and 80 are actively working there currently. More than 200 were keen to work in India and interested in interdisciplinary grants and operational support to conduct research, training, and education programs with Indian partners.

Additional priorities of JHII are the establishment of the Center for Excellence in Infectious Diseases Research in Pune and the Center for Excellence in Child and Maternal Health in Kolkata. The first initiative is headed by our group and makes permanent the infrastructure we have built over decades of research. Through JHII's convening of faculty across the school, new partnerships with State governments of Maharashtra, Andhra Pradesh, Madhya Pradesh as well as new public-private partnerships are being formalized.

Additionally, we expanded research operations into new space just a short walk from BJGMC and Sassoon hospitals, one of our main research partners. The facility houses a new conference room, office space, and pharmacy to accommodate the growing research enterprise. With support from the Ujala Foundation, we worked with a nonprofit business consulting firm to develop a strategic plan for an expanded Pune clinical research center and laboratory that will position the Center of Excellence to serve as a hub-and-spoke model and that will include new partners such as the Indian Institutes of Science Education and Research (IISER).

These efforts will foster greater collaborations between Indian institutions and Johns Hopkins. According to Dr. Gupta, "With support from University leadership, we are able not only to expand our own work, but also to foster faculty collaboration and student engagement across all of Johns Hopkins. We are thrilled to be the driving force behind this exciting initiative."

JOHNS HOPKINS
INDIA INSTITUTE

2020 by the

Numbers

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Press Releases about Our Work

25
New Research Awards

18
COVID-19 Grand Rounds Presentations

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116
Media Placements

$7.6 Million
2020 Grant Awards

CCGHE in the

News

116 News Appearances

Our team of infectious disease experts was consulted by the news media throughout the year. Here are a few of the highlights.

The New York Times

U.S. Coronavirus Cases Surpass 9 Million with No End in Sight by Mitch Smith, Simon Romero and Giulia McDonnell Nieto del Rio. 2020-10-29. *Larry Chang*

The Northeast Held the Virus in Check. Now Cases Are Inching Up Again. 2020-10-09. *Larry Chang*

Models Project Sharp Rise in Deaths as States Reopen. 2020-05-04. *Larry Chang*

The Covid-19 Riddle: Why Does the Virus Wallop Some Places and Spare Others? 2020-05-03. *Bob Bollinger*

As Businesses Resurface After State Shutdowns, So Does Divisiveness. 2020-05-01. *Larry Chang*

The Washington Post

A flag football league provides Maryland high school players their competitive fix. 2020-10-09. *Kathleen Page*

A new deal could ease Venezuela's humanitarian crisis. The international community must get behind it. 2020-07-02. *Kathleen Page*

BBC RADIO WORLD SERVICE

UK coronavirus death toll is now the highest in Europe. 2020-05-05. *Bob Bollinger*

Associated Press

Funeral industry concerned about guidance, protective gear. 2020-04-24. *Natasha Chida*

U.S. News & World Report

Hispanic Americans Being Hit Hard By COVID-19. 2020-06-29. *Kathleen Page*

Do Anti-Inflammatories Like Ibuprofen Aggravate Coronavirus? 2020-03-20. *Larry Chang*

New York

Trump Briefly Leaves Hospital for Drive-by Photo Op With Supporters. 2020-10-04. *Amita Gupta*

Why Antibody Tests May Not Be the Answer. 2020-04-16. *Natasha Chida*

AFP

Venezuela's official virus data is 'absurd': HRW and Johns Hopkins. 2020-05-27. *Kathleen Page*

TIME

Could the Coronavirus Topple Nicolas Maduro's Regime in Venezuela? 2020-03-20. *Kathleen Page*

TODAY.com

Is it safe to go to a nail salon now? What experts want you to know. 2020-06-09. *Natasha Chida*

C-SPAN

Dr. Robert Bollinger on the Coronavirus Pandemic 2020-06-12. *Bob Bollinger*

Los Angeles Times

A Notre Dame celebration was reckless, but can it teach us about COVID-19 spread? 2020-11-14. *Larry Chang*

Is bringing back sports during coronavirus realistic or safe? We asked the experts. 2020-04-08. *Larry Chang*

ALJAZEERA

Venezuela health system 'grossly unprepared' for COVID-19 crisis. 2020-05-26. *Kathleen Page*

USA TODAY

Across US, a 'tale of two cities' as some embrace reopening amid coronavirus and others remain wary. 2020-05-08. *Larry Chang*

News
Continued

THE BALTIMORE SUN

We started weeping in April, and we haven't stopped': Baltimore's Latino community racked by coronavirus. 2020-11.24. *Kathleen Page*

As Ravens welcome family in stands in preparation for fans, public health experts urge caution. 2020-09-29. *Larry Chang*

Latinos disproportionately hurt by coronavirus in Maryland, Baltimore and among Johns Hopkins patients. 2020-05-12. *Kathleen Page*

BNN Bloomberg

COVID victims are forced into filthy warehouses in Venezuela. 2020-08-24. *Kathleen Page*

What Would It Take to Lift Coronavirus Restrictions? Experts Weigh In. 2020-03-25. *Larry Chang*

THE HUFFINGTON POST

Shocking Draft US Report Sees 200,000 COVID-19 Cases, 3,000 Deaths Daily By June. 2020-05-05. *Larry Chang*

Are temperature checks effective in stopping corona virus spread? 2020-04-27. *Natasha Chida*

Slate

Why Did Florida Avoid a Coronavirus Disaster? 2020-05-21. *Larry Chang*

FOX NEWS

Coronavirus: Is herd immunity possible and if so, what's the threshold? 2020-06-04. *Bob Bollinger*

Coronavirus live blog: Infectious disease expert Dr. Bob Bollinger answers your questions. 2020-04-10. *Bob Bollinger*

Johns Hopkins deploys mobile health app to assist frontline health workers. 2020-04-02. *Bob Bollinger*

POLITICO

Battling Information Chaos in a Public Health Crisis. 2020-12-09. *Natasha Chida*

Rising coronavirus cases among Latinos alarm public health experts. 2020-06-18. *Kathleen Page*

CNN EN ESPAÑOL

¿Cómo se hace el conteo de enfermos y muertos en la Universidad Johns Hopkins? 2020-04-21. *Kathleen Page*

El murciélago y su relación con los virus. 2020-04-21. *Kathleen Page*

CNBC

'Every part of the country' still at risk — ex-FDA chief urges US to stay united in coronavirus fight. 2020-04-09. *Bob Bollinger*

We need to expand access to rapid coronavirus testing and contact tracing: Johns Hopkins' Dr. Bollinger. 2020-04-08. *Bob Bollinger*

The Christian Science Monitor

Want to end state lockdowns? Send in the coronavirus detectives. 2020-04-21. *Bob Bollinger*

Medscape NEWS

Comparing COVID-19, Flu Death Tolls 'Extremely Dangerous' 2020-05-14. *Natasha Chida*

4 Johns Hopkins Press Releases

- **Grants, Management Roles Keep Johns Hopkins A Leader In HIV/AIDS Clinical Trial Research. 2020-12-08. *Amita Gupta***
- **Johns Hopkins Researchers Publish COVID-19 'Prediction Model' 2020-09-23. *Amita Gupta***
- **International Johns Hopkins Study Says Broad Measures Needed to Prevent TB Spread in India. 2020-08-06. *Amita Gupta, Mandar Paradkar***
- **Study Shows Mobile Health, Video Technology, Influence Behavior of Affected Populations. 2020-07-09. *Nishi Suryavanshi, Bob Bollinger***

Peer-Reviewed Research

Publications

Tocilizumab for the treatment of COVID-19 among hospitalized patients: A matched retrospective cohort analysis

Ignatius EH, Wang K, Karaba A, Robinson M, Avery RK, Blair P, Chida N, Jain T, Petty BG, Siddiqui Z, Melia MT, Auwaerter PG, Xu Y, Garibaldi BT. Open Forum Infect Dis. 2020 Dec 28;8(1):ofaa598. doi: 10.1093/ofid/ofaa598. PMID: 33537364; PMCID: PMC7798657.

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Podany AT, Leon-Cruz J, Hakim J, Supparatpinyo K, Omoz-Oarhe A, Langat D, Mwelase N, Kanyama C, Gupta A, Benson CA, Chaisson RE, Swindells S, Fletcher CV; AIDS Clinical Trials Group A5279 Team. J Antimicrob Chemother. 2020 Nov 26:dkaa470. doi: 10.1093/jac/dkaa470. Epub ahead of print. PMID: 33241266.

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Peer-Reviewed Research

Publications

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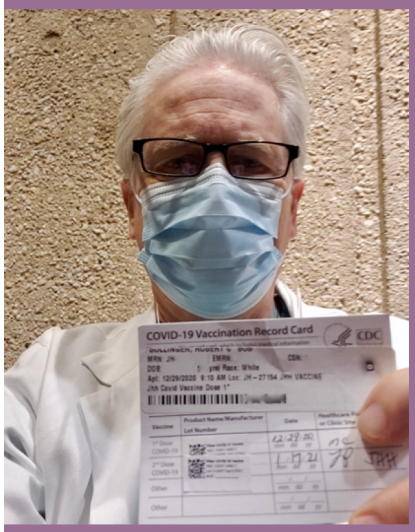
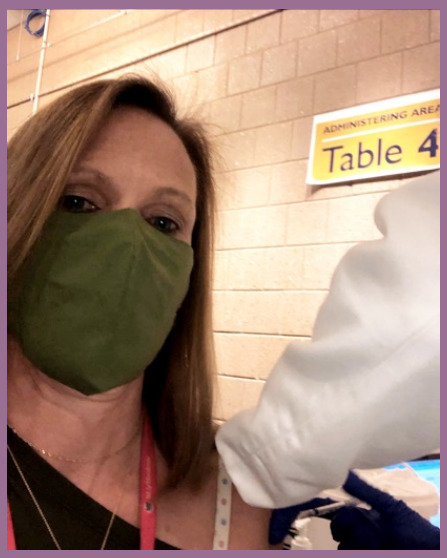


An Ounce of Prevention

CCGHE team members responsible for patient care eagerly rolled up their sleeves to be vaccinated. We look forward to gathering again.



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