

2020 Spring Regulatory Update and Hot Topics in Clinical Research

COVID-19: The Virus, Preparedness in the time of Crisis, and Clinical Research

POST-KEYNOTE PANEL ON COVID-19
10:15am – 11:45am



Children's National Hospital and Research Institute COVID-19 Response

Roberta L. DeBiasi, MD, MS

Chief, Division of Pediatric Infectious Diseases

Children's National Hospital and Research Institute

Professor, Pediatrics and Microbiology, Immunology and Tropical Medicine

The George Washington University School of Medicine



Children's National®

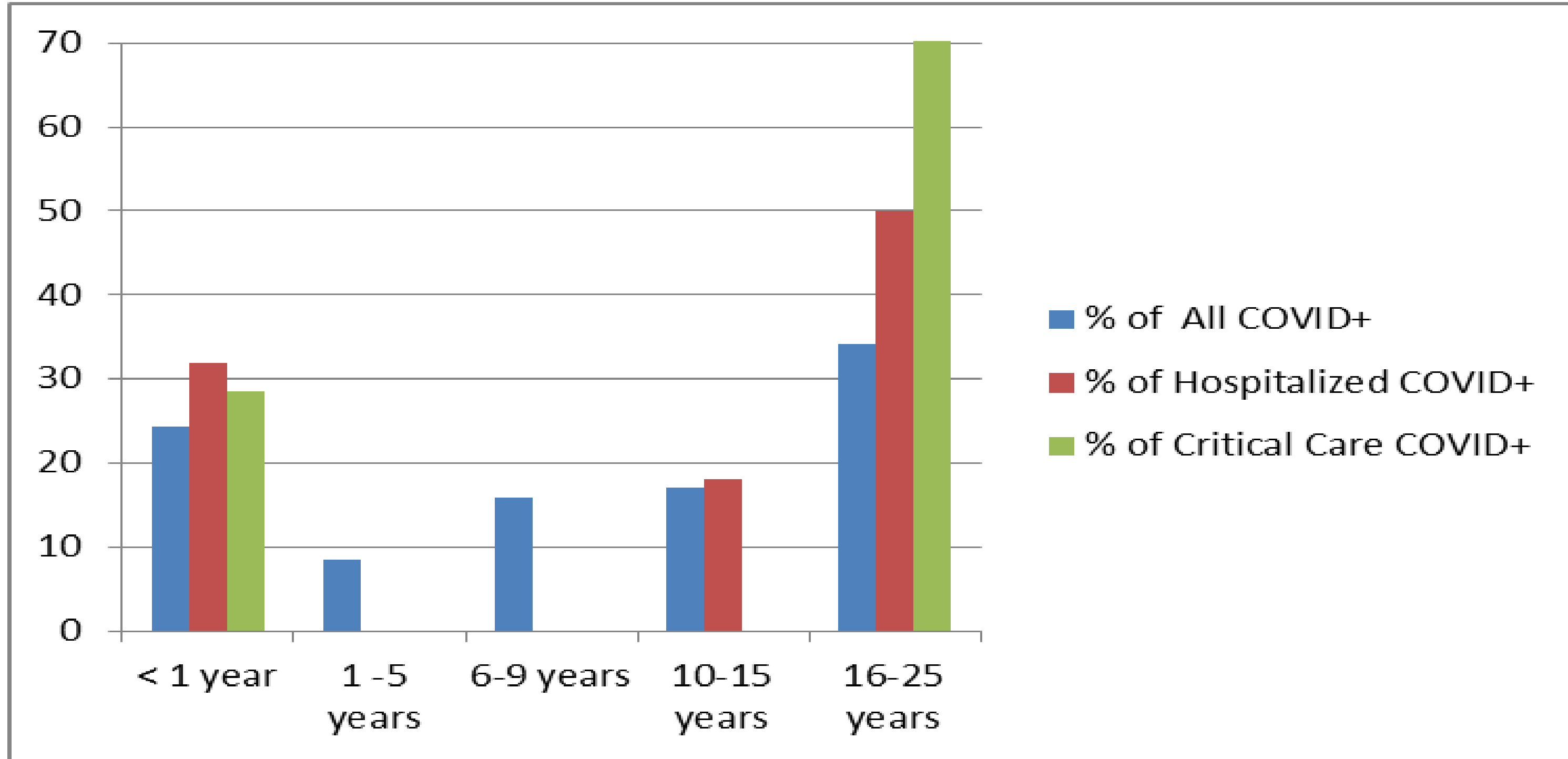
Daily Dashboard – Through 4.20.20

	Global	US	NYC	Region (MD/VA/DC)
Cases	2.4 million	772,000	250,000	24,000
Percent Increase	+4% Rate decreasing (Peak +13%- 3 wks ago)	+3.4% Rate decreasing Peak +60%- 4 wks ago	+2.4% Rate decreasing Peak +125%- 4 wks ago	+5% Rate decreasing Peak +30% 3 weeks ago
Hospitalizations		81,000	56,000	4600
Percent Increase		+2.6% Lowest	+2.5% Lowest	+6% Falling
Deaths	165,000	42,000	18,300	921
Percent Increase	+3%	+4%	+4%	+4%
Case Fatality Rate	6.9%	5.3%	7.4%	3.8%
Rate Change	No change	No change	+0.1	No change

CNH COVID – as of 4.20.20 (Excludes Popup Testing Site)

- 104 SARS-CoV-2 positive
 - 30 required hospital admission;
 - 22 Special Isolation Unit – SIU
 - 8 Pediatric Intensive Care Unit (PICU)
- Age range= 4 weeks – 25 years
- 50% Female/50% Male
- Underlying Conditions in approximately 45% overall and 57% of admitted
 - Resp: Asthma (23% overall, 15% admissions)
 - Heme/Onc: Stem Cell Transplantation, B cell ALL; HgbSS
 - Endocrine: Type 2 Diabetes; Endocrine Disorder
 - Neuro: Static Encephalopathy, Microcephaly, Global Devel Delay
 - Cardiac: ASD/PFO (one Trisomy 21)
 - Obesity
 - Rheumatologic: Lupus

CNH COVID Cases and Hospitalization– Age Distribution



Frontline Heroes: Pediatric ICU nurses caring for first young adult patient: proning an adult patient



Children's National.

Pre-COVID Expertise Emerging Infectious Diseases

- Children's National has track record as leader in emerging infectious disease
 - 2003 Anthrax response
 - 2014- present: Designated Ebola Treatment Center
 - Centers for Disease Control recognition and pediatric expertise
 - HHS funding to maintain preparedness for Ebola and Highly Contagious Respiratory Viruses
 - **Special Isolation Unit**
 - 2015 – present: Congenital Zika Program
 - 2016 - present: Acute Flaccid Myelitis Taskforce/International Working Group
 - 2018-present : Pediatric Lyme
- Active Pandemic Emergency Plan
 - Planning/preparations for many years around pandemic emergencies
 - Plan reviewed annually and as needed to address situations like COVID-19.

COVID -19 Monitoring and Mobilization Phases

December 2019 – February 2020

- Infection Control, Infectious Diseases and hospital leadership work closely to monitor emerging infectious threats and maintain preparedness
- Closely followed China outbreak since emergence Dec 2019 – February 2020
- Activated Incident Command Structure March 2020
 - Daily Task Force Call, Daily Steering Committee call
- First patient March 15th
- Continuously monitor and implement recommendations from World Health Organization, CDC, White House Task Force and other federal agencies
- Proactively update policies and procedures to ensure the safety of our patients, staff, and visitors in the community.

Guiding Principles

- 1. Keep our staff safe
- 2. Keep our patients safe
- 3. Managing surge of potential volumes for our community



Clinical Care and Operations

- PPE and Supply Chain:
 - Actively manage all supply chain closely
 - Patient care supplies, , PPE, Equipment/Ventilators, Pharmaceuticals .
 - Monitor PPE inventory and burn rates– ensure reserve for surge needs
 - PAPR
 - PPE Conservation:
 - Guidelines for PPE conservation mode – extended wear, cohorting as per CDC guidelines
 - N95 UV sterilization
 - Universal Precautions

Personal Protective Equipment and Isolation Precautions



Special Precautions

Questions? Contact Infection Control at x5053 or email infectioncontrol@childrensnational.org

PERSONAL PROTECTIVE EQUIPMENT:

- ✓ Gown
- ✓ Gloves
- ✓ Eye Protection (face shield, goggle, etc)
- ✓ N95 or PAPR

HAND WASHING:

- ✓ Alcohol- based sanitizer or wash with soap and water

PATIENT PLACEMENT/STAFFING:

- ✓ Private room preferred
- ✓ Designated staff only
- ✓ Essential caregivers only
- ✓ Full time monitoring of the room
- ✓ Round on patient last

ENVIRONMENTAL MEASURES:

- ✓ Use hospital approved disinfectant to clean and disinfect once daily or more often as needed.
- ✓ Upon transfer/discharge
 - ✓ thoroughly cleaned by EVS or trained unit staff

VISITATION:

- ☐ Per Hospital Visitation Policy

PATIENT CARE EQUIPMENT:

- ✓ Single-use or disposable equipment preferred
- ✓ Dedicated reusable equipment for the patient preferred
- ✓ Thoroughly disinfect reusable equipment upon removing from the room
- ☐ Other: _____

PATIENT TRANSPORT:

- ✓ Only transport for medically necessary purposes

Sequence for Donning and Doffing of Personal Protective Equipment

Donning

Step 1. Gather Appropriate PPE



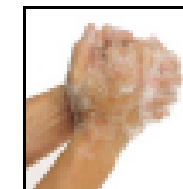
Step 2. N95/PAPR AND Face Shield On



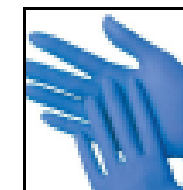
Step 3. Gown On



Step 4. Gel/Wash Hands

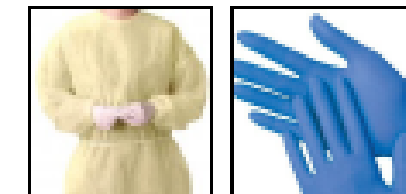


Step 5. Gloves On

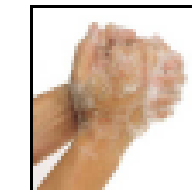


Doffing

Step 1. Gown and Gloves Off



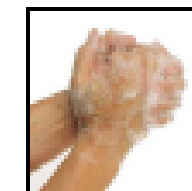
Step 2. If Needed, Gel/Wash Hands



Step 3. Face shield, N95/PAPR Off



Step 4. Gel/Wash Hands



Children's National

Questions? Call Infection Control at extension 5053

Surge Planning Regional Approach

- Strategies:
 - CNH is a 323 bed hospital, of these 143 are critical care beds and 106 negative pressure rooms.
 - Surge capacities calculated and coordinated using modeling
 - Regionalization of Pediatric Care : Inter-facility contracts as needed
 - Expansion to provide COVID+ Young Adults (21-29 years of age) patient care
 - Frees up Adult Ventilated Beds , Additional HCW Supply
- Working closely with District of Columbia Hospital Association, as well as DC, MD , VA DOH
 - Identification of projected surge volume based on modeling
 - DOH Consultant regarding surge planning
 - Liaison to DOH / National Guard to begin this week

Screening Visitors and Staff

- Purposeful reductions in visitors – limit one per patient
 - Cancellations of elective surgeries
 - Conversion of in person visits to telehealth visits
- All patients, visitors and employees screened upon entry into building
 - Symptom Screen
 - Temperature screen
 - System to re-direct if screen positive
- Cloth Mask Program for distribution to patient families
 - Donations/Philanthropy

Laboratory Response

- Implemented rapid in house testing early on (3 hour turnaround)
 - Patient testing and Symptomatic Employee Testing
 - >1500 patients tested to date
 - Ramped up to include preoperative testing – selected high risk
 - Expanding for all admissions and majority of preoperative
- Implemented drive up/walkup site for ambulatory patient referrals for testing
 - Currently >750 tested in community
 - Important trends in community rates of positivity
- Serologic testing coming on-line soon
 - Important for recovery phase

CNH COVID-19 Testing and Isolation Algorithm

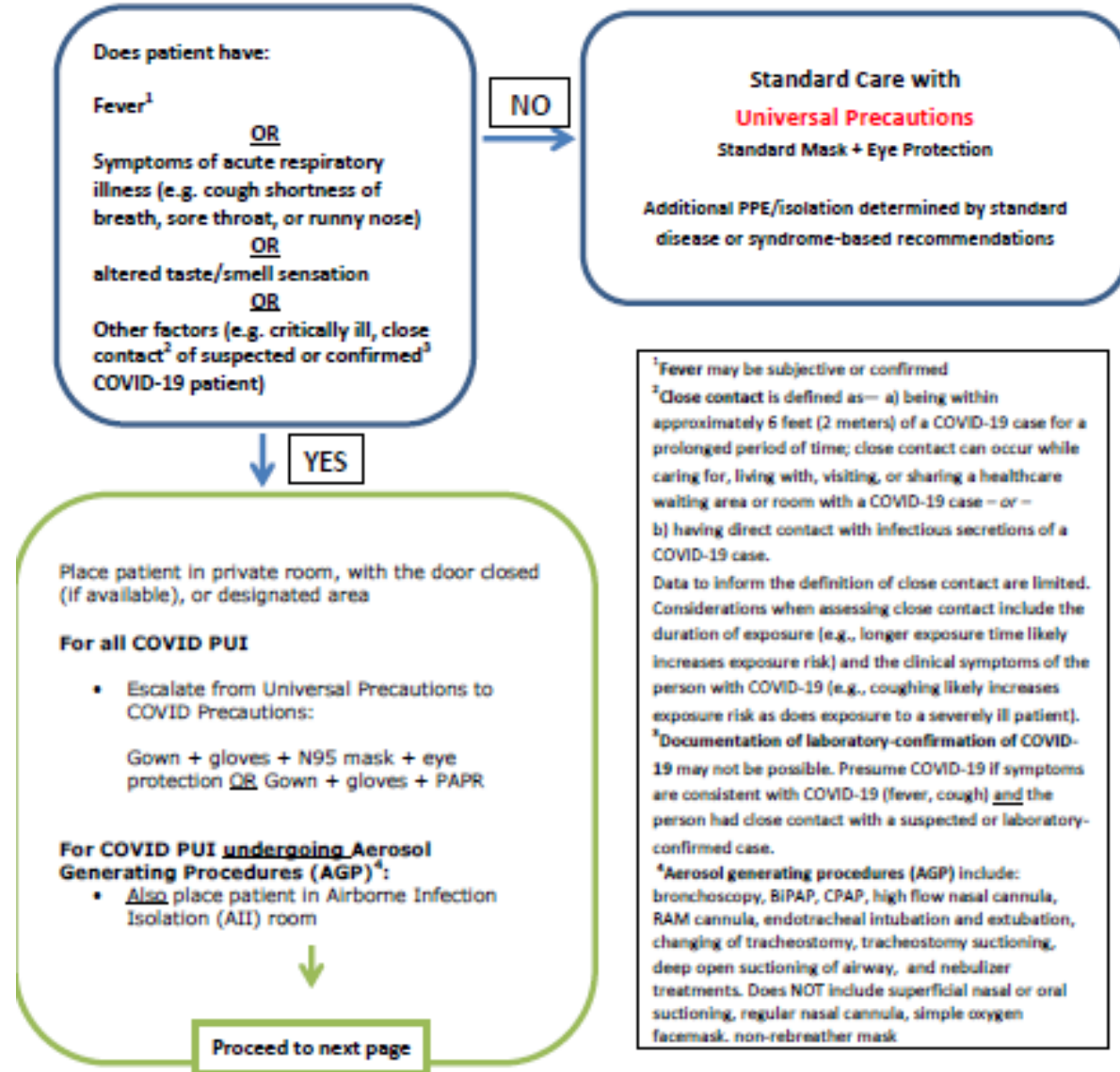
3

Testing and Isolation Algorithm for COVID-19 Persons Under Investigation (PUI) Division of Infectious Diseases; Update 4/17/20

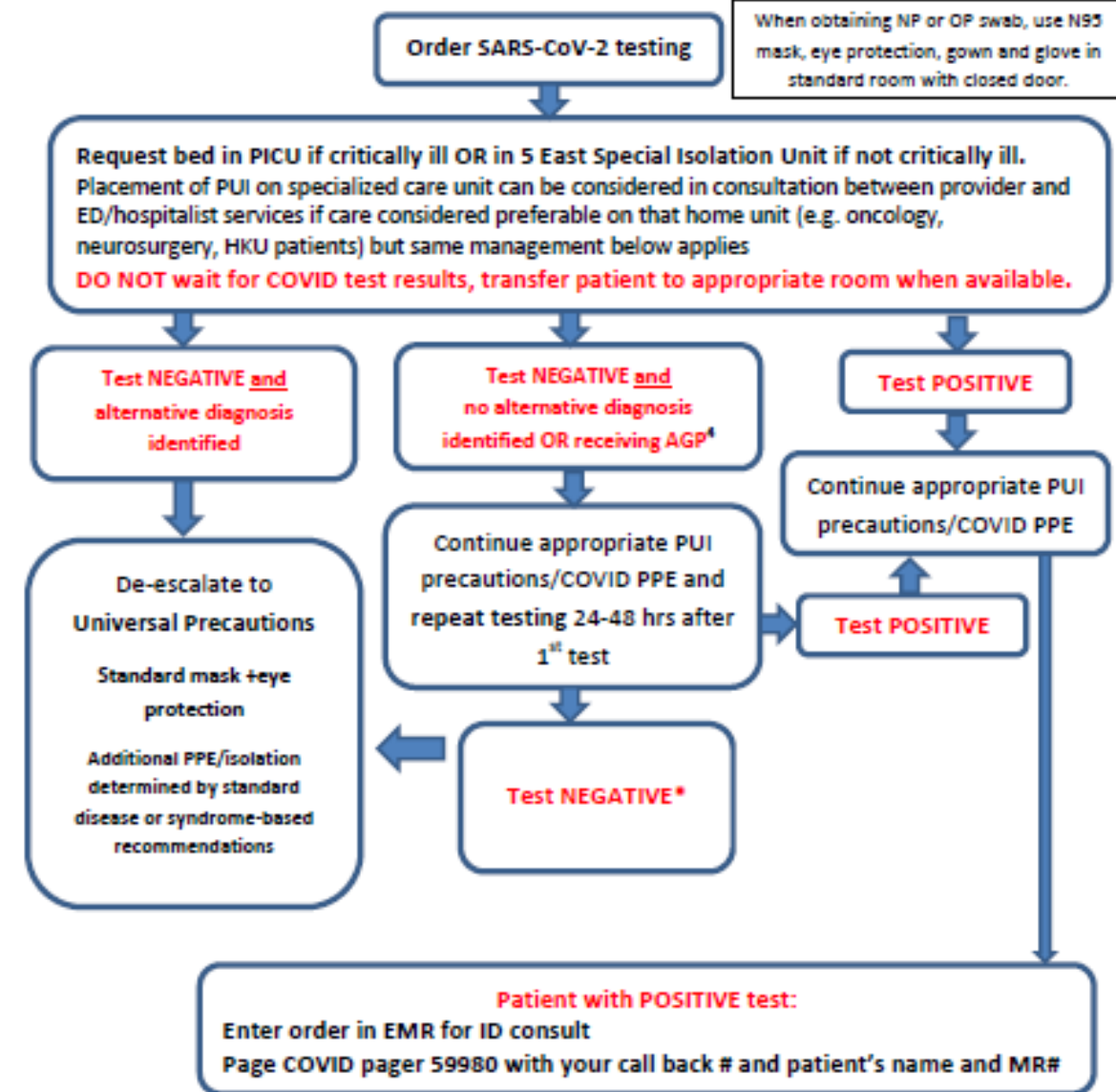
NOTE:

1. Please obtain complete history and exam to best assess risk of COVID-19
2. For all clinical encounters, regardless of PUI status, use minimum of **Universal Precautions** (Standard Mask + Eye Protection)
3. Asymptomatic surgical/anesthesia patients being tested simply for pre-op/pre-procedure clearance (designated procedures) are not considered PUI. Symptomatic patients should be evaluated as PUI.

At the time of initial patient encounter:



For PUI Being Admitted to the Hospital*: Continue admission under appropriate COVID PUI precautions



- * A negative test never completely rules out COVID-19: If test negative and high clinical suspicion, maintain COVID precautions and consult ID
- Ideally patient remains on PICU or 5E until discharge or until 14 days after admission, unless clinical matters such as specialty care dictate otherwise- please contact Infection Control before moving patient
- *Some patients meet PUI criteria after admission. Patient can remain in same room with COVID PPE being used while awaiting test results. Follow testing protocol on this page. If SARS-CoV-2 test is positive, move patient to 5E or PICU

Telehealth

- Rapid conversion of outpatient new and follow-up visits to telehealth visits via Zoom platform
 - 70 % of all ambulatory visits via telehealth
 - Increase from <50 providers to >800 providing telehealth nearly overnight
- Patient and Staff safety
- High customer satisfaction and improved access
- Good rates of reimbursement achieved
- Landscape may have changed for post-COVID era

Occupational Health

- Marked expansion of OH role and staffing
- Clear guidance to employees and managers regarding immediate reporting of employee symptoms
- Clear guidance prohibiting symptomatic workers from reporting to work
- Email contact occupational health – return of call to staff same day with disposition (e.g. testing, home quarantine).
- Implemented in-house testing for employees
- Developed algorithm to be deployed by expanded team of nurses
- Wellness initiatives
 - Meditation, Child/Elder care solutions

Human Resources

- Contingency workforce plans to include assumptions of a reduced workforce
- Managing family medical leave and vacation time.
- Telecommuting options/expanded and encouraged
- Applying for ADA Exclusions from care of COVID+ patients

Communication/Education

- COVID-19 Intranet Hub
 - <http://intranet.childrensnational.org/departments/clinical-support/infection-control/Pages/Coronavirus.aspx>
 - FAQs expanded daily for staff.
 - Online training for staff on appropriate utilization of personal protective equipment, isolation procedures, etc
- Town Halls three times per week for staff and managers and targeted groups (Leadership, IC, ID, Lab, HR)
- Community Education – CIN / Primary care network
 - FAQ's for families and patient/family communication
 - Hot line
 - Ensure tight communication with our Community physicians education and operational guidance

COVID Countermeasures/Treatments

- Clinical care algorithms for experimental therapies
 - Hydroxychloroquine/Azithromycin
 - Tocilizumab
 - Remdesivir
 - Convalescent Plasma Program
 - <https://childrensnational.org/departments/pathology-and-laboratory-medicine/blood-donor-center/convalescent-plasma-program>

Convalescent Plasma Program

Share:     

Children's National Hospital is accepting donors who have recently recovered from COVID-19 infection. When a person recovers from an infection, they have antibodies that are primed to fight the infection. These antibodies, which can be seen in convalescent plasma, may help other patients who are acutely ill with COVID-19. Currently, there is no specific treatment that exists for the virus, which is why convalescent plasma is being used.

Research

- Building centralized de-identified institutional database with validated data
 - Lab, clinical, demographic
- CTSA – Wiki to catalogue COVID-focused projects, assist with resource management, encourage collaborations
 - Genetics
 - T cell therapies
 - Fetal/Maternal interface, neurodevelopmental outcomes
 - Diagnostics – rapid POC
- Working with Government Affairs partners to identify federal appropriations to support COVID research

The Path Ahead

- Potential Challenges
 - Financial Implications to the institution
 - Lost revenue
 - Maintaining Supply Chain and managing PPE inventory
 - Contingencies if surge of patients > planned surge
 - Contingencies if large proportion of workforce on medical leave due to illness
 - Maintaining safety of staff/employees as recovery phase is implemented (3 phases)
 - Utilizing serologic and molecular testing

Measures to Minimize the Spread and Impact of COVID-19 at GW



Marcia A. Firmani, Ph.D., MSPH, MT(ASCP)MB^{CM}

firmanim@gwu.edu

Strategies to Minimize Spread

- All students instructed to leave campus for remainder of semester following spring break (March 16 – March 21)
- All on-campus classes were converted to an online format starting March 23, 2020
- Contingency Plans developed and approved for spring and summer and fall contingencies are being finalized
- Numerous conferences, workshops, programs, etc. have been cancelled or moved to online formats if possible
- All GW-related business travel was cancelled. If non-GW travel occurred, individuals were asked to self-quarantine for 14 days

Spring Modifications

- All on-campus courses converted to an online format starting on March 23, 2020 and continuing for spring semester
- Programs that have courses that cannot be taught online have moved courses around when possible
- May graduation (GW, schools and programs) was cancelled
 - Many schools and divisions will hold a virtual “graduation”
 - All students have been invited to attend the May 2021 graduation

Summer Modifications

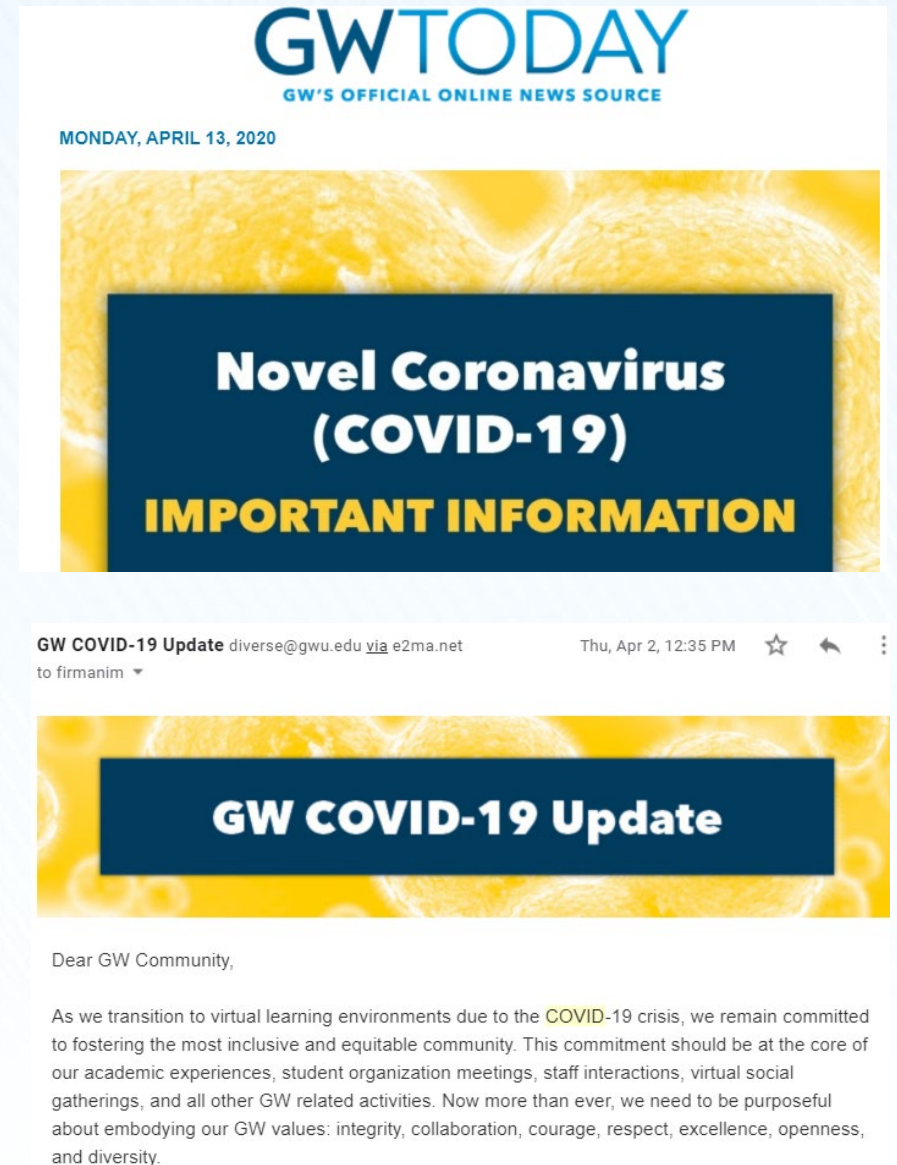
- All courses moved to online format
- On-campus students not coming back to campus in summer
- On-campus summer programs either cancelled, postponed, or modified to an online format

Fall Contingency Plans

- Several plans being developed that include:
 - Continue teaching online
 - Starting classes late for some programs to allow international students to travel once travel restrictions are lifted
 - Limiting the number of students in classrooms
 - Requiring appropriate PPE (face masks)
 - Social distancing required in classrooms and conference rooms
 - Cleaning all high-touch areas
 - Moving to fully online format after Thanksgiving break if necessary
 - Some programs doing temperature checks prior to entering classroom

Information Dissemination

- All-school emails being sent out with COVID-19-related information regularly
- Emails for specific subsets being distributed through the schools and/or departments
 - Information for faculty regarding courses and dates
 - Information for specific students, such as those in clinical rotations



Dissemination of Information

- Town Hall meetings
 - Several town hall meetings carried out via teleconferencing (i.e., webex) to discuss information about the virus
 - Numerous Q/A sessions
- GW Health Resource Page
- COVID-19 Wellness Resources

COVID-19: GW Health Updates

We have developed this resource page and a daily digest email to minimize the number of emails our providers and staff are getting daily. By going to this page, you will be able to access the latest information in your area in real time and will try to minimize blast emails for urgent information.



Welcome to the COVID-19 GW Health Resource Page. The clinical and administrative teams throughout our system (at the GW Medical Faculty Associates, the GW Hospital, and the GW School of Medicine and Health Sciences) have developed policies and protocols in response to the COVID-19 pandemic. We are including documents that have been sent to the community starting (date) and we are frequently revising them as the COVID-19 situation evolves. When using the documents, we *caution you to be mindful of the date the*

The GWell Center for Healthcare Professionals

Mission & Population

Resources

Future Plans

News

[Resources](#) » COVID-19 Wellness Resources

COVID-19 Wellness Resources

Clinical Impact

- Students in clinical programs with no direct patient contact are allowed to continue their clinical rotations
 - All voluntary direct patient contact is restricted
- Students in clinical programs with direct patient contact were not allowed to continue clinical rotations in spring
- Students allowed to go back to clinical rotations (after June 29) but will not interact with COVID-19 patients

Clinical Impact

- Students not able to complete required clinical rotations
 - Many clinical facilities across the U.S. suspended student rotations
- Programs have developed alternate formats (i.e., virtual simulations), expedited clinical rotations, or postponed rotations
- Lack of PPE and tests
- Various COVID-19 tests developed for research use but many are testing different aspects of infection
- May delay some student's program of study
 - Incomplete or in progress grades

COVID-19 Research Impact

- Pros
 - Many questions that need answers
 - Numerous qualified scientists and clinicians
 - COVID-19-related funding opportunities
- Cons
 - All projects working with human samples, animals, or biohazardous materials need to be approved (IRB, IACUUC, IBC) prior to implementation
 - Committees convening emergency meetings to get projects approved
 - Lack of PPE and tests to carry-out some projects
 - Time needed to get approvals, funding and appropriate samples

Thank-you





Cohorts and COVID-19 – Challenges and Opportunities

Seble Kassaye, MD, MS

Associate Professor

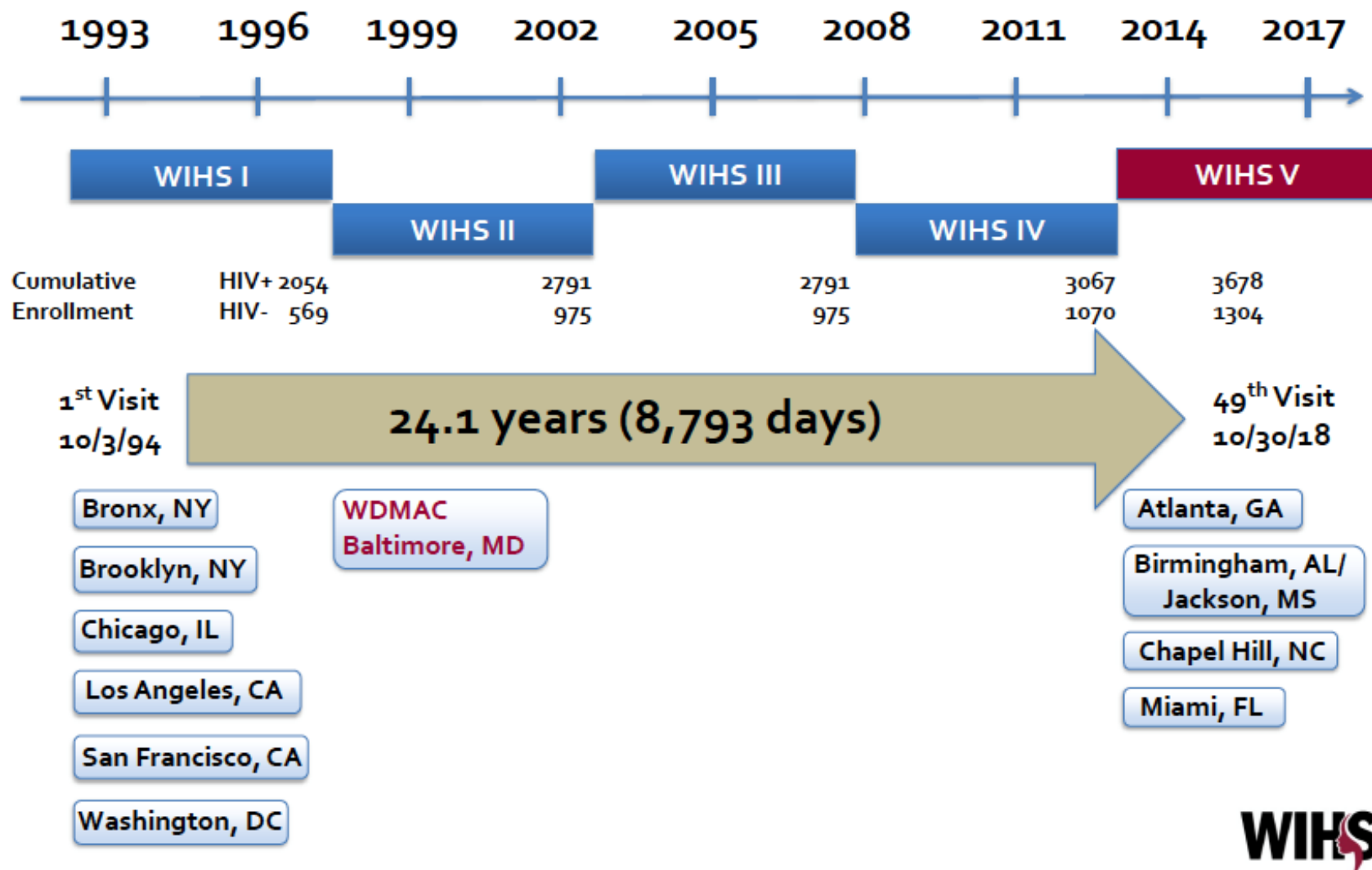
Division of Infectious Diseases and Travel Medicine

Georgetown University

April 21, 2020



WIHS Timeline



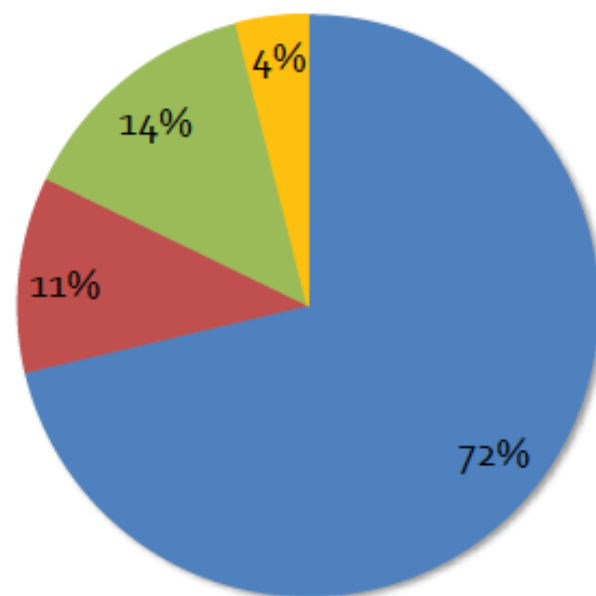
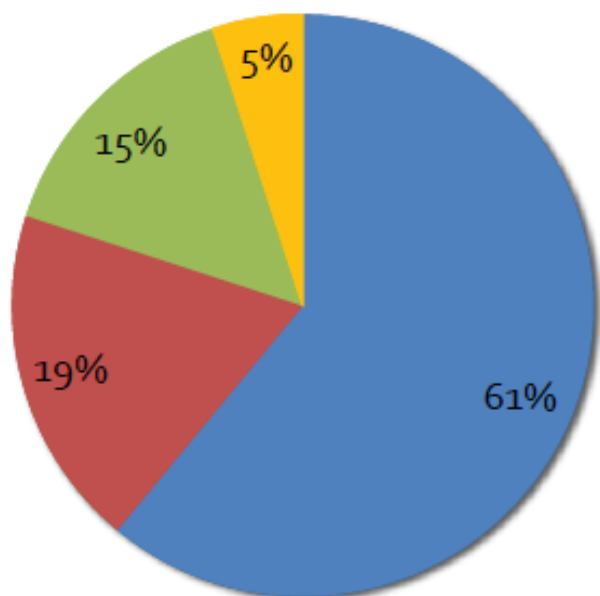
Longstanding national observational cohort study



Race/Ethnicity among HIV+ Women: U.S. & WIHS

*Diagnoses of HIV Infection, U.S.**

WIHS Active HIV+ Participants



■ Black/African American
■ White

■ Hispanic/Latina
■ Multiple Races / Other

* Data from the *Centers for Disease Control and Prevention*; includes diagnoses of HIV infection among adult and adolescent females (n=7,402), by race/ethnicity in 2015.



MWCCS AIMS



Aim 1. Cardiovascular disease in the setting of HIV

- structural changes – Echo
- clinical endpoints – CAD/MI/Stroke

Aim 2: Pulmonary and Sleep Aims - influence of HIV infection on lung function and sleep quality

- PFTs
- Sleep studies

Aim 3: Neurocognitive impairment – risks and modifiers

Aim 4: Biology of Aging

Aim 5: Cancer – risk factors for AIDS and non-AIDS related malignancies

Aim 6: Psychosocial contributions to health outcomes (HIV-related and unrelated)

Aim 7: Health Disparities - effect of neighborhood characteristics on HIV-related outcomes and comorbidities

Aim 8: Support career development of new and young investigators



Women's HIV Cohort Study

HIV infection and Treatment Among Women of Reproductive Age

STAR cohort: **S**tudy of **T**reatment **A**nd **R**eproductive outcomes

NICHD, R01HD101352

MPI: Alcaide, Kassaye, Golub, Rana, Sheth, Westreich



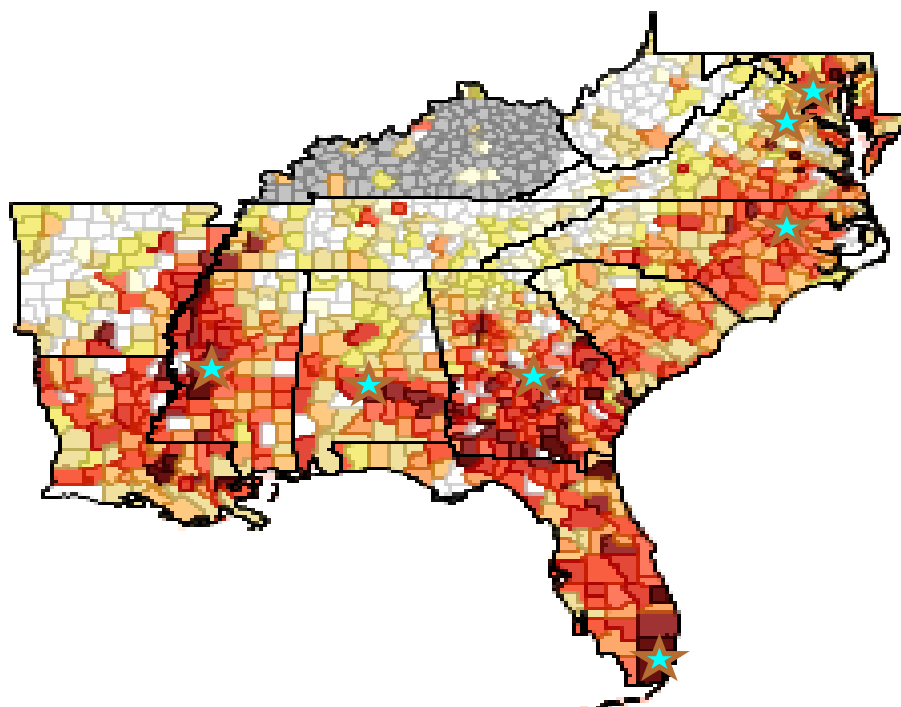
Anandi Sheth
Emory




Aadia Rana
UAB
Mississippi



Maria Alcaide
U Miami



AIDS*Vu*  0 - 40 41 - 60 61 - 100 101 - 130 131 - 160 161 - 200 201 - 260 261 - 340 341 - 510 511+



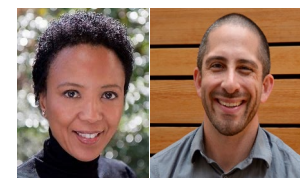
WHCS Enrollment Sites co-located with MWCCS sites are in areas with high HIV prevalence among women (rates per 100,000 adult women)



Elisabeth
Golub
JHU
Data
Center



Seble Kassaye
Georgetown
DC



Ada Adimora, Daniel
Westreich
UNC

Challenges related to COVID-19

- Delays in study implementation
 - Delayed study start up and enrollment
 - Parent studies
 - Junior investigator funded studies – KL2, DC CFAR pilots with fixed end dates
- Delays in Agreements
 - External signatures for agreements due to competing interests
 - MTA
 - sIRB

Opportunities related to COVID-19

- Existing cohorts
 - Opportunities for observational and behavioral research
 - Rapid approval of multi-site survey-based study
- Existing grants
 - Opportunities to propose application of biomarker studies from cancer immunotherapies to COVID-19 for supplemental funding
- Existing research personnel and external consultants
 - Ability to propose participation in multi-site clinical and observational studies related to COVID-19, and design monitoring systems

Critical Elements

- Highly responsive research administrative and University services
- Access to existing cohorts
 - Innovation in survey implementation
 - Ensuring privacy – phone/video/web-based surveys
 - Technology
- Access to patients with COVID-19
 - Biosafety concerns/PPE
- Access to exposed individuals for prevention studies
- Space considerations
 - Access
 - Safety



Thank you!!

Celia J. Maxwell, M.D., FACP, FIDSA

Associate Dean for Research
College of Medicine
Howard University

Howard University

- This pandemic resulted in dramatic changes to the educational experience as well as to campus life, including the closure of the campus to all but critically essential personnel only; as the University sought to preserve the health and safety of our students, faculty and staff through social distancing.
- The University, with Board support, immediately transitioned to online learning so that the education provided to our students would not be compromised and telework for staff so that University operations could continue.
- Realizing past several weeks has been stressful to our students, faculty and staff, telehealth mental health services and an Emotional-Support Help Line are available 24 hours a day, seven days a week, for as long as necessary.

Howard University and Howard University Hospital

Information delivered using:

- *HU Communications* - University Communication emails
- Video conferencing via online meeting platforms

Howard University Hospital

- HUH has proudly served the D.C. community for more than 150 years.
- To help minimize COVID-19 exposure, HUH has postponed all non-essential events to decrease the exposure for our patients and staff.
- HUH has changed its entrance policy to a "ZERO Visitor's" policy, only allowing patients to enter the facility

Howard University Hospital

- The hospital is responding to the challenge of an anticipated surge in patient admissions during this crisis. In preparation, HUH has erected a new triage tent on the grounds of the main hospital in Northwest Washington, DC, streamlining the triage process to rapidly identify and isolate patients that enter the facility exhibiting flu-like symptoms.
- The triage tent will expand the capabilities of the HUH emergency room. It will be equipped with independent bays where medical staff can triage, or evaluate, patients for symptoms and treatments inside the main hospital. The tent system ensures that hospital staff and patients maintain proper social distancing while patients get the appropriate treatment they need.

Howard University Hospital

- HUH has an ample number of beds in this isolated unit dedicated to patients who test positive for COVID-19. As well as, negative pressure rooms onsite for its COVID-19 patients.
- Currently, HUH does not test for COVID-19 at its in-house laboratory. All COVID-19 tests are outsourced. However, we are researching the feasibility of conducting onsite COVID-19 testing.
- HUH is working closely with OCHA, D.C. Health and Adventist HealthCare to stay abreast of available resources if there is an expected influx of patients due to COVID-19.

Howard University Hospital

- Speaking daily with local officials to ensure that the hospital is provided with the most up-to-date information, guidelines and current policies surrounding COVID-19.
- HUH is closely monitoring supply chains, personal protective equipment usage, and staffing levels in response to an expected COVID-19 surge and sharing this information with city officials
- Howard University Hospital is ready to be a part of the solution to help the DMV get through these trying times.