



Johns Hopkins Biocontainment Unit
Annual Report
FY 2022

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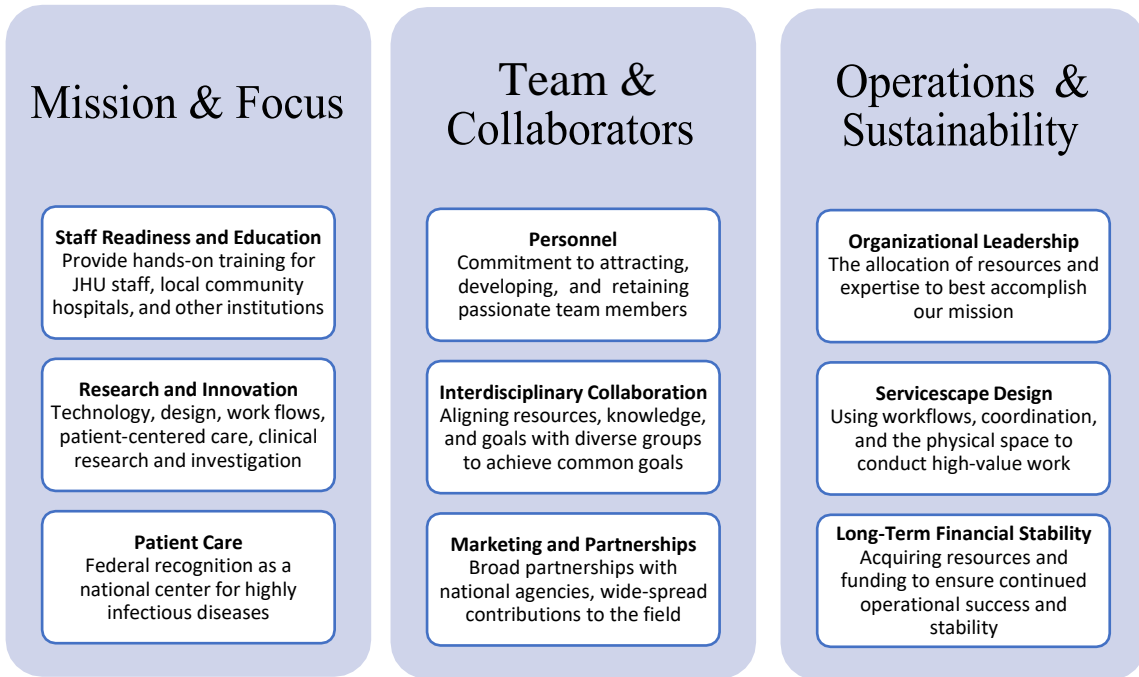
Performance Measure 1: Standards and Guidance

The [Johns Hopkins Biocontainment Unit \(BCU\)](#) is dedicated to patient care, safety, training, research and innovation in the context of highly infectious diseases. Established in the Spring of 2015 in response to the Ebola outbreak in West Africa, the JH BCU has become one of the premier highly infectious diseases units in the world. Shortly after its opening, the JH BCU was selected by the Office of the Assistant Secretary of Preparedness and Response (ASPR) to be the U.S. Region 3 Emerging Special Pathogens Treatment Center (RESPTC).

During the COVID-19 pandemic the BCU spearheaded a number of important clinical, operational, educational, and research initiatives. In addition to caring for the first COVID-19 patients at the Johns Hopkins Hospital, the BCU trained over 500 providers in the proper use of personal protective equipment (PPE) and designed a safety officer training program to keep frontline staff safe on COVID “biomode” units. The BCU team led the Johns Hopkins arm of the Adaptive COVID-19 Treatment Trial, a large multinational NIH study that showed the efficacy of remdesivir and baricitinib in the treatment of COVID-19. The BCU helped establish a biorepository that has elucidated critical aspects of SARS-CoV-2 pathobiology. The BCU helped to create the Johns Hopkins Precision Medicine Center of Excellence (PMCOE) for COVID-19 leading to comparative effectiveness analyses of therapeutics and the development of real-time prediction models now used by frontline clinicians around the world. On the regional front, the BCU hosted webinars and remote training sessions to help other health systems prepare for COVID.

On a national level, BCU team members helped to create and direct the Special Pathogens Research Network, advised the Secretary of HHS through membership on the National Biodefense Science Board and a pandemic influenza preparedness committee of the National Academy of Science, Engineering and Medicine, advised Governor Hogan on the Maryland state response to COVID-19, engineered the groundbreaking COVID-19 response of the National Basketball Association (NBA) and cared for the President when he became ill with COVID-19. The BCU worked closely with the National Emerging Pathogens Treatment and Education Center (NETEC) and the Office of the Assistant Secretary for Preparedness and Response (ASPR) to design the framework of a National Special Pathogens System. The BCU also worked with the Johns Hopkins Government Affairs team to educate congressional representatives about the importance of investment in pandemic preparedness, leading to a 5-year extension as the Region 3 RESPTC.

In the coming year, the BCU will continue to grow its education and research agenda to meet the needs of the Johns Hopkins Health System, the local community, the state of Maryland, and our national and international partners as we continue our fight against COVID-19 and prepare for future infectious disease outbreaks.



The BCU Team

Lisa Maragakis
Executive Director

Brian Garibaldi
Medical Director

Noreen Hynes
Associate Medical Director

Mark Romig
Associate Medical Director

Jade Flinn
Unit Director

Chad Bowman
Special Operations Response Team Coordinator (SORT): Lifeline Critical Care Transport

Mary Brown
Chair of BCU Drill Committee

Carrie Billman
Sr. Infection Control

Lindsay Bow
Infection Control Practitioner

Elaine Nowakowski
Infection Control Associate

Christopher Sulmonte
Administrative Director

Brandy Loveless
Nurse Super User: Adult ED Liaison

Brad Ensor
Administrative Manager

Performance Measure 2: Building Research Capability and Capacity

2.1 Notable Research Projects

2.1.1 JH-CROWN and the COVID-19 Precision Medicine Center of Excellence

The BCU helped to create the [Johns Hopkins Precision Medicine Center of Excellence \(PMCOE\) for COVID-19](#). The centerpiece of the PMCOE is the JH-CROWN registry (PI – Brian Garibaldi), a comprehensive database of over 15,000 hospitalized patients and 150,000 outpatients with COVID-19. The PMCOE described the clinical trajectory of COVID-19, developed real-time prediction models that are currently being used in frontline care, and conducted comparative effectiveness analyses for COVID-19 therapeutics including remdesivir and tocilizumab. Recently, the JH-CROWN team showed that pulse oximetry underestimates the incidence of hypoxemia in underrepresented minorities, which leads to a delay in recognition of eligibility for COVID-19 treatments. This study, among others, led to the FDA calling a special meeting with pulse oximeter manufacturers to urgently discuss ways to address the issue. The COVID-19 PMCOE also helped dozens of Johns Hopkins research teams develop and implement projects using JH-CROWN. To date, over 50 IRB-approved protocols have accessed JH-CROWN data, leading to dozens of important discoveries and manuscripts about COVID-19. The PMCOE has partnered with HCA Healthcare to form the CHARGE consortium, a group of 10 academic medical centers and AHRQ, who are working to analyze data from over 200,000 hospitalized COVID-19 patients to advance our understanding of COVID clinical trajectories and real-world therapeutic effectiveness.

2.1.2 Adaptive COVID-19 Treatment Trial (ACTT)

Noreen Hynes served as the Johns Hopkins Site principal investigator (PI) for the implementation of this multicenter, adaptive, international randomized, double-blind, placebo-controlled trial. The adaptive clinical trials model included four trial phases where different agents were studied in the inpatient setting for their effectiveness in reducing morbidity and decreasing hospital length of stay. ACTT primary trial data collected between 1 December 2020 and 13 April 2021 supported FDA approval of remdesivir (ACTT-1). Baricitinib combined with remdesivir for inpatient treatment in select patients was better than remdesivir alone (ACTT-2). Subsequent phases of the study demonstrated that interferon beta-1a plus remdesivir was not superior to remdesivir alone

among hospitalized patients (ACTT-3). Lastly, use of baricitinib plus remdesivir or dexamethasone plus remdesivir is similar in ventilation-free survival by day 29 after trial enrollment (ACTT-4). Since the closure of the ACTT trials, Dr. Hynes has participated in additional ongoing secondary analyses of the collected data and has co-authored several peer-reviewed journal articles (see Section 2.2 below).

2.1.3 Special Pathogens Research Network

Noreen Hynes serves as the Associate Lead of the State of the Science Working Group of the Special Pathogens Research Network (SPRN), the operational research arm of NETEC. Jade Flinn serves as the associate lead for the Internal Operations and Response Working Group of SPRN to build research capacity and develop educational and training resources related to rapid protocol implementation during high consequence infectious disease outbreaks.

2.1.4 Decontamination of Highly Infectious Waste

The BCU team used advanced pressure and temperature monitors to re-evaluate the steam sterilization process for Category A infectious waste on a biocontainment unit. With the data gathered from these newly purchased devices, the BCU team validated the use of super rapid biological indicators to confirm the successful decontamination of infectious waste. The team also reduced overall sterilization time by validating a higher within bag temperature target that leads to effective kill faster. Overall, these innovations led to a substantial streamlining of the waste handling process on the BCU. The BCU team has continued to provide waste management consultative advice to other biocontainment units throughout the country and world.

2.2 Research Dissemination

2.2.1 Publications

1. Gupta S, Wang W, Hayek SS, Chan L, Mathews KS, Melamed ML, Brenner SK, Leonberg-Yoo A, Schenck EJ, Radbel J, Reiser J, Bansal A, Srivastava A, Zhou Y, Finkel D, Green A, Mallappallil M, Faugno AJ, Zhang J, Velez JCQ, Shaefi S, Parikh CR, Charytan DM, Athavale AM, Friedman AN, Redfern RE, Short SAP, Correa S, Pokharel KK, Admon AJ, Donnelly JP, Gershengorn HB, Douin DJ, Semler MW, Hernán MA, Leaf DE; STOP-COVID Investigators. Association Between Early Treatment With Tocilizumab and Mortality Among Critically Ill Patients With COVID-19. *JAMA Intern Med.* 2021 Jan 1;181(1):41-51. doi: 10.1001/jamainternmed.2020.6252. Erratum in: *JAMA Intern Med.* 2021 Apr 1;181(4):570. PMID: 33080002; PMCID: PMC7577201 (*BTG is a site co-investigator for STOP COVID).
2. Garibaldi BT*, Wang K, Robinson ML, Zeger SL, Bandeen-Roche K, Wang MC, Alexander GC, Gupta A, Bollinger R, Xu Y. Comparison of Clinical Improvement of Treatment With or Without Remdesivir Among Hospitalized Patients With COVID-19. *JAMA Open Network.* 2021 Mar 1;4(3):e213071. doi: 10.1001/jamanetworkopen.2021.3071. PMID: 33760094 * corresponding author (JH-CROWN Registry).
3. Wongvibulsin S, Garibaldi BT, Antar AR, Wen J, Wang MC, Gupta A, Bollinger R, Xu Y, Wang K, Betz JF, Muschelli J, Roche KB, Zeger SL, Robinson ML. Development of Severe COVID-19 Adaptive Risk Predictor (SCARP), a calculator to predict severe disease or death in hospitalized patients with COVID-19. *Ann Intern Med.* 2021 Mar 2. doi: 10.7326/M20-6754. Online ahead of print. PMID: 33646849 (JH-CROWN Registry).
4. Brenner DS, Liu GY, Omron R, Tang O, Garibaldi BT, Fong TC. Diagnostic accuracy of lung ultrasound for SARS-CoV-2: a retrospective cohort study. *Ultrasound J.* 2021 Mar 1;13(1):12. PMID: 33644829.
5. Garfinkel E., Lopez, S., Troncoso, R., Jr, Leon, D., Hubble, H., Bowman, C., & Margolis, A. (2021). A Critical Care Transport Program's Innovative Approach to Safety During the Coronavirus Disease 2019 Pandemic. *Air medical journal*, 40(2), 112–114. <https://doi.org/10.1016/j.amj.2020.12.002>
6. Garibaldi BT, Chisolm MS, Berkenblit GV, Feller-Kopman D, Stephens RS, Stewart RW, Wright SM. Review of the published literature to characterise clinical excellence in COVID-19 care. *Postgrad Med J.* 2021 May
7. Minhas AS, Gilotra NA, Goerlich E, Metkus T, Garibaldi BT, Sharma G, Bavaro N, Phillip S, Michos ED, Hays AG. Myocardial Work Efficiency, A Novel Measure of Myocardial Dysfunction, Is Reduced in COVID-19 Patients and Associated With In-Hospital Mortality. *Front Cardiovasc Med.* 2021 Jun 14;8:667721. doi: 10.3389/fcvm.2021.667721. PMID: 34195234; PMCID: PMC8236710.26:postgradmedj-2021-140002. doi: 10.1136/postgradmedj-2021-140002. Epub ahead of print. PMID: 34039705.
8. Scully EP, Schumock G, Fu M, Massaccesi G, Muschelli J, Betz J, Klein EY, West NE, Robinson M, Garibaldi BT, Bandeen-Roche K, Zeger S, Klein SL, Gupta A. Sex and Gender Differences in Testing, Hospital Admission, Clinical Presentation, and Drivers of Severe Outcomes From COVID-19. *Open Forum Infect Dis.* 2021 Aug 31;8(9):ofab448. doi: 10.1093/ofid/ofab448. PMID: 34584899; PMCID: PMC8465334.
9. Burnim MS, Wang K, Checkley W, Nolley EP, Xu Y, Garibaldi BT. The Effectiveness of High-Flow Nasal Cannula in Coronavirus Disease 2019 Pneumonia: A Retrospective Cohort Study. *Crit Care Med.* 2021 Sep 22. doi: 10.1097/CCM.0000000000005309. Epub ahead of print. PMID: 34637419.
10. Mehta HB, An H, Andersen KM, Mansour O, Madhira V, Rashidi ES, Bates B, Setoguchi S, Joseph C, Kocis PT, Moffitt R, Bennett TD, Chute CG, Garibaldi BT, Alexander GC; National COVID Cohort Collaborative (N3C). Use of Hydroxychloroquine, Remdesivir, and Dexamethasone Among Adults Hospitalized With COVID-19 in the United States : A Retrospective Cohort Study. *Ann Intern Med.* 2021 Oct;174(10):1395-1403. doi: 10.7326/M21-0857. Epub 2021 Aug 17. PMID: 34399060; PMCID: PMC8372837.
11. Menez S, Moledina DG, Thiessen-Philbrook H, Wilson FP, Obeid W, Simonov M, Yamamoto Y, Corona-Villalobos CP, Chang C, Garibaldi BT, Clarke W, Farhadian S, Dela Cruz C, Coca SG, Parikh CR; TRIKIC Consortium. Prognostic Significance of Urinary Biomarkers in Patients Hospitalized With COVID-19. *Am J Kidney Dis.* 2021 Oct 16:S0272-6386(21)00920-3. doi: 10.1053/j.ajkd.2021.09.008. Epub ahead of print. PMID: 34710516; PMCID: PMC8542781.
12. Garibaldi BT*, Wang K, Robinson ML, Betz J, Alexander GC, Andersen KM, Joseph CS, Mehta HB, Korwek K, Sands KE, Fisher AM, Bollinger RC, Xu Y. Real-World Effectiveness Of Remdesivir In Adults Hospitalized With Covid-19: A Retrospective, Multicenter Comparative Effectiveness Study. *Clin Infect Dis.* 2021 Dec 15:ciab1035. doi: 10.1093/cid/ciab1035. Epub ahead of print. PMID: 34910128; PMCID: PMC8754724.*corresponding author

13. Andersen KM, Bates BA, Rashidi ES, Olex AL, Mannon RB, Patel RC, Singh J, Sun J, Auwaerter PG, Ng DK, Segal JB, Garibaldi BT, Mehta HB, Alexander GC; National COVID Cohort Collaborative Consortium. Long-term use of immunosuppressive medicines and in-hospital COVID-19 outcomes: a retrospective cohort study using data from the National COVID Cohort Collaborative. *Lancet Rheumatol*. 2022 Jan;4(1):e33-e41. doi: 10.1016/S2665-9913(21)00325-8. Epub 2021 Nov 15. PMID: 34806036; PMCID: PMC8592562.
14. Robinson ML, Morris CP, Betz J, Zhang Y, Bollinger RC, Wang N, Thiemann DR, Fall A, Eldesouki RE, Norton JM, Gaston DC, Forman M, Luo CH, Zeger SL, Gupta A, Garibaldi BT*, Mostafa HH*. Impact of SARS-CoV-2 variants on inpatient clinical outcome. *MedRxIV*, in press.
<https://www.medrxiv.org/content/10.1101/2022.02.02.22270337v1>. *contributed equally.
15. Sadoff J, Gray G, Vandebosch A, Cárdenas V, Shukarev G, Grinsztejn B, Goepfert PA, Truyers C, Van Dromme I, Spiessens B, Vingerhoets J, Custers J, Scheper G, Robb ML, Treanor J, Ryser MF, Barouch DH, Swann E, Marovich MA, Neuzil KM, Corey L, Stoddard J, Hardt K, Ruiz-Guiñazú J, Le Gars M, Schuitemaker H, Van Hoof J, Struyf F, Douoguih M; ENSEMBLE Study Group*. Final Analysis of Efficacy and Safety of Single-Dose Ad26.COV2.S. *N Engl J Med*. 2022 Feb 9. doi: 10.1056/NEJMoa2117608. Epub ahead of print. PMID: 35139271. (*BTG is a member of the Ensemble adjudication committee).
16. Grein JD, Garland JA, Arguinchona C, Frank MG, Garibaldi BT, Grindle A, Hewlett A, Kline S, Levine CB, Mehta A, Mukherjee V, Sauer LM, Searle EF, Vanairsdale S, Vasa A. Contributions of the Regional Emerging Special Pathogen Treatment Centers to the US COVID-19 Pandemic Response. *Health Secur*. 2022 Apr 27. doi: 10.1089/hs.2021.0188. Epub ahead of print. PMID: 35483049.
17. Billman CL, Flinn J, Gadala A, Bowman C, McIlquham T, Sulmonte CJ, Garibaldi BT. Creating a Safety Officer Program to Enhance Staff Safety During the Care of COVID-19 Patients. *Health Secur*. 2022 Apr 28. doi: 10.1089/hs.2021.0182. Epub ahead of print. PMID: 35483094.
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21. Wang Z, Bowring MG, Rosen A, Garibaldi BT, Zeger S, Nishimura A. Learning and Predicting from Dynamic Models for COVID-19 Patient Monitoring. *Statist. Sci*. 37 (2) 251 - 265, May 2022. <https://doi.org/10.1214/22-STS861>
22. Andersen KM, Joseph CS, Mehta HB, Streiff MB, Betz JF, Bollinger RC, Fisher AM, Gupta A, LeMaistre, Robinson ML, Xu Y, Ng DK, Alexander GC, Garibaldi BT*. Intermediate dose versus standard dose thromboprophylaxis in hospitalized COVID-19 patient: A retrospective cohort study. *Res Pract Thromb Haemost*. 2022;6:e12753. <https://doi.org/10.1002/rth2.12753>. *corresponding author
23. National Academies of Science, Engineering, and Medicine (Hynes NA as expert consultant and committee member): “Addressing Issues of Vaccine Distribution and Supply Chains to Advance Pandemic and Seasonal Influenza Preparedness and Response.” The study examines supply chain and distribution challenges related to vaccines and vaccinations during the COVID-19 response and explores their implications for pandemic and seasonal influenza. The study is at the request of the Office of Global Affairs, U.S. Department of Health and Human Services. The study output <https://www.nationalacademies.org/our-work/addressing-issues-of-vaccine-distribution-and-supply-chains-to-advance-pandemic-and-seasonal-influenza-preparedness-and-response>
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- Colombo CJ, Levine CB, Jain MK, Maves RC, Marcone VC, Grossberg R, Hozayen S, Burgess TH, Atmar RL, Ganesan A, Gomez CA, Benson CA, Lopez de Castilla D, Ahuja N, George SL, Nayak SU, Cohen SH, Lalani T, Short WR, Erdmann N, Tomashek KM, Tabas P. Temporal improvements in COVID-19 outcomes in hospitalized adults: A post hoc observational study of remdesivir group participants in the Adaptive COVID-19 Treatment Trial. *Ann Intern Med* 2022; 175(12):IN PRESS
26. Hynes NA, Meyers D. Agents of Infection and Principles of Transmission. In Boulton ML, Wallace RB (eds). *Maxcy-Rosenau-Last: Public Health and Preventive Medicine*, 16th Ed. New York, NY: McGraw-Hill, 2022

2.2.2 Presentations, Workshops, and Seminars

Regional

- 2021 COVID Data Repositories Curated by Hopkins: Resources for Observational Research and Data Science. Medical Grand Rounds, Johns Hopkins Hospital, Baltimore, MD (delivered via Zoom, co-presented with Chris Chute)
- 2021 Treating COVID-19: The race to save lives. Johns Hopkins Medicine Dean's Symposium (delivered via Zoom) The JH-CROWN Registry. MD Health IT Appreciation Forum. Maryland Department of Health (delivered via Zoom)
- 2021 Flying the Plane While Improving It – Learning from COVID-19 Patient Data in Close to Real Time. Shanxi Bethune Hospital, China (delivered via Zoom)
- 2021 Hynes NA. Basics of Preparedness and Response to Meet Chemical and Biological Weapons Threats. Presentation in “Chemical & Biological Weapons: Science, Public Health, and Policy (PH180.630.60). JHU Bloomberg School of Public Health
- 2021 Vaccines in, Masks Off: It's Time to Go Back to “Normal” – Pro-Con debate with Gregory Shrank. Point-Counterpoint Conference XL. Maryland Committee on Trauma (delivered via Zoom).
- 2021 How do you prepare for a highly infectious disease? [Hopkins on the Hill at Home](#) (delivered via Zoom). Using Informatics to Advance Use, Safety, and Effectiveness of COVID-19 Medical Products. Hopkins Summer Internship Program (delivered via Zoom).
- 2021 **Hynes NA.** The Pandemic of the Century: Making Sense of the Madness. Presentation in “Biothreat Agents and Emerging Infectious Diseases” at Georgetown University, School of Medicine, Graduate School.
- 2021 COVID-19: Treatments, variants and outlook for the pandemic. Cosmos Club Special Event (delivered via Zoom).
- 2021 Johns Hopkins Congressional Briefing on COVID-19 (delivered via Zoom to congressional staffers on Capitol Hill)
- 2021 The COVID-19 Pandemic: Insights from the frontlines. Keynote Address, Journey of Healthcare Transformation during Pandemic, JHAH/JHI Multidisciplinary Conference, Saudi Arabia (delivered via Zoom).
- 2021 Breakthrough Infections. Journey of Healthcare Transformation during Pandemic, JHAH/JHI Multidisciplinary Conference, Saudi Arabia (delivered via Zoom).
- 2021 The JH-CROWN Registry: COVID-19 ICTR Town Hall, The Johns Hopkins Hospital, Baltimore, MD (delivered via Zoom).
- 2022 Learning from COVID-19 Patients in Real Time. The [Johns Hopkins Pandemic Data Initiative Forum](#), Baltimore, MD (delivered via Zoom).

- 2022 Learning from COVID-19 Patients in Real Time. The Johns Hopkins Women’s Board (delivered via Zoom).
- 2022 Learning from COVID-19 Patients in Real Time. Shanxi Bethune Hospital, Shanxi, China (delivered via Zoom).
- 2022 **Hynes NA:** Monkeypox Vaccines – the Science and Use. Webinar sponsored by the HHS Region III STD-HIV Prevention Training Center.
- 2022 **Hynes NA:** Smallpox vaccines and their use for smallpox and monkeypox. Presentation in “Special Topics in Vaccine Science (PH.223.867). JHU Bloomberg School of Public Health
- 2022 BCU Presents: Ebola Vaccine rVSVΔG-Zebov GP (Ervebo™) for BCU NETEC Providers. (delivered via Zoom)
- 2022 Monkeypox: A briefing for JHU Leadership (delivered via Zoom)
- 2022 Monkeypox vaccines. Delivered via webinar sponsored by HHS Region III HIV/STD Prevention Training Center at Baltimore.

National

- 2021 Building the plane while flying it: Developing a research infrastructure during a changing pandemic. The Society of Thoracic Surgeons International Conference (delivered via Zoom).
- 2021 Entering the Lion’s Den: Conquering the COVID Unknown. The Society of Thoracic Surgeons International Conference (delivered via Zoom).
- 2021 The JHM COVID-19 Experience. Pulmonary Grand Rounds, Norwalk Hospital, NJ (delivered via Zoom).
- 2021 Health Executive Leadership Network (HELN) Forum on COVID-19 (delivered via Zoom).
- 2021 Using Informatics to Advance Use, Safety, and Effectiveness of COVID-19 Medical Products. Webinar on COVID-19 informatics hosted by Johns Hopkins and the FDA (delivered via Zoom)
- 2021 Pilot survey of HLIU staff attitudes about host genomics – prior to COVID. National Ebola Emerging Special Pathogens and Treatment Center (NETEC) Annual Conference, Atlanta, GA. (delivered via Zoom)
- 2021 **Hynes NA.** Ebola Vaccine rVSVΔG-ZEBOV-GP (Ervebo™) for Biocontainment Unit Providers. National Ebola Emerging Special Pathogens and Treatment Center (NETEC) (delivered via Zoom)
- 2021 Decision Making Challenges Evolving Crisis Standards of Care & Ongoing Lessons from COVID-19: A workshop Series. National Academies of Sciences, Engineering and Medicine (delivered vis Zoom).
- 2021 The future of big data in the response to public health emergencies: Lessons learned from the COVID-19 pandemic. IEEE/CHASE 2021 Conference on Connected Health Applications, Systems, and Engineering Technologies. Washington, DC.

International

- 2021 COVID-19 Update, Citigroup Leadership, Baltimore, MD (delivered via Zoom)
- 2021 Battling COVID-19: The Johns Hopkins COVID-19 Precision Medicine Center of Excellence. McMaster International Review Course in Internal Medicine (MIRCIM). Krakow, Poland (delivered via Zoom).
- 2021 Learning from experience: real world evidence for COVID-19 therapeutics from the USA. Educational session

- for European physicians, sponsored by Gilead. Switzerland (delivered via Zoom).
- 2021 The role of antiviral therapy in the management of hospitalised patients with COVID-19 – a focus on real-world evidence. 14th International Symposium on Antimicrobial Agents and Resistance (ISAAR), Korea (delivered via Zoom).
- 2021 The multifaceted approach to COVID-19 management, with a focus on antiviral therapy. 14th International Symposium on Antimicrobial Agents and Resistance (ISAAR), Korea (delivered via Zoom).
- 2021 The real-world effectiveness of COVID-19 therapeutics. Society of Infectious Disease of Argentina Conference Symposium (delivered via Zoom).
- 2021 **Hynes NA** (expert consultant and committee member). “Addressing Issues of Vaccine Distribution and Supply Chains to Advance Pandemic and Seasonal Influenza Preparedness and Response”. Study output: <https://www.nationalacademies.org/our-work/addressing-issues-of-vaccine-distribution-and-supply-chains-to-advance-pandemic-and-seasonal-influenza-preparedness-and-response>
- 2021 **Hynes NA**. COVID-19 Impacts and Response Panel Discussion. Southeast Asia Multilateral Biosecurity Dialogue (Virtual Meeting with Singapore, Malaysia, Indonesia, Thailand, Philippines, and USA. Sponsor: Defense Threat Reduction Agency, US Department of Defense. (by Zoom)8/15/22 **Hynes NA**.
- 2021 **Hynes NA**. Expert panel on Monkeypox. Webinar delivered by Zoom with international attendees. Sponsor: JHU Bloomberg School of Public Health
- 2021 Applying Precision Medicine to COVID-19. Pacific Rim Health Innovations Conference. Sun Yat-sen University, Guangzhou, China (delivered via Zoom).

2.3 National Special Pathogens System

The BCU was invited to serve on a special committee convened by NETEC and the Office of the Assistant Secretary for Preparedness and Response (ASPR) to develop a National Special Pathogens System (NSPS). The goal of the committee was to design a roadmap to improve the US' ability to respond to an infectious disease threat over the next 5-years. The 6-month committee engagement produced a report for ASPR that will help guide future funding programs and collaborations between NETEC, ASPR, and the regional treatment centers including the BCU. The NSPS is set to rollout in 2023, with the Regional Emerging Special Pathogen Treatment Centers (RESPTCs) as the tier A facilities in the new system.

Performance Measure 3: Workforce and Training

3.1 BCU Team Training

Training is at the heart of BCU team activities as the program emphasizes and highlights teamwork and healthcare worker safety. As the COVID-19 pandemic continued to limit the ability to return to quarterly in-person training, innovations in team engagement and remote education were developed including “Just-In-Time” (JIT) BCU PPE videos and Zoom webinars offering continuing education credits. Additionally, the BCU team continues to exercise their activation readiness through simulation, and through real-world events like the initial response to Mpox.



3.2 JIT BCU PPE Videos

The BCU team developed short videos featuring BCU personal protective equipment (PPE) donning and doffing. The goal of the JIT BCU PPE videos is to address knowledge and skill gaps in PPE donning and doffing. They supplement in-person JIT PPE demonstrations by providing a self-paced visual refresher of the critical steps of the donning and doffing process. As an easily deployable resource, the JIT BCU PPE videos are sent to BCU team members during times of heightened activation risk and used as a visual primer for newcomers prior to their first donning and doffing experience.



3.3 BCU Presents

“BCU Presents” is a recurring virtual presentation of a topic related to high consequence infectious disease, disaster/emergency management, or bio-security. The presentation is followed by moderated Q&A with audience members who include BCU team members and JHH hospital employees. Experts have presented on COVID-19 vaccines, Ebola clinical care, mask efficacy against droplet spread, and rapid response research during a pandemic.

In October 2021, our associate medical director Noreen A. Hynes, MD, MPH, provided our team members with information about the recently FDA-approved vaccine for Ebola virus. She presented data on the efficacy, safety profile, and recommendations associated with the Ebola vaccine, Ervebo, to assist healthcare workers with their own decision-making when presented with the opportunity to receive the inoculation. This was the first BCU Presents event to offer contact hours for registered nurses through the Institute of Johns Hopkins Nursing.

3.4 Activation Readiness: Operation Twisted Tail

In collaboration with external partners including the National Emerging Special Pathogens Training and Education Center (NETEC), the BCU drilled the activation processes including team notifications, readiness capacity, and shared decision-making.

In August 2021, the BCU participated in a national tabletop exercise, Operation Twisted Tail, that included coordination and communication of multiple patient transfers originating from the University of Nebraska's National Quarantine Unit. Operation Twisted Tail exercised the coordination across the 10 US emerging special pathogen treatment centers to distribute 20 patients infected with Nipah virus. As a result of the evaluation measurements made in real-time during drill notification, the JH BCU's capacity would have allowed for not only multiple patient admissions but also specialty care for Nipah virus, specifically neurocritical care treatment. Internal preparedness plans also resulted in a method of clear communication pathways utilizing Microsoft Teams Chat and strengthened collaboration between the NCCU, Neuroradiology, and neurosurgery teams to increase clinical care capacity that can be provided on an activated BCU.

3.5 Activation Readiness: Mpox

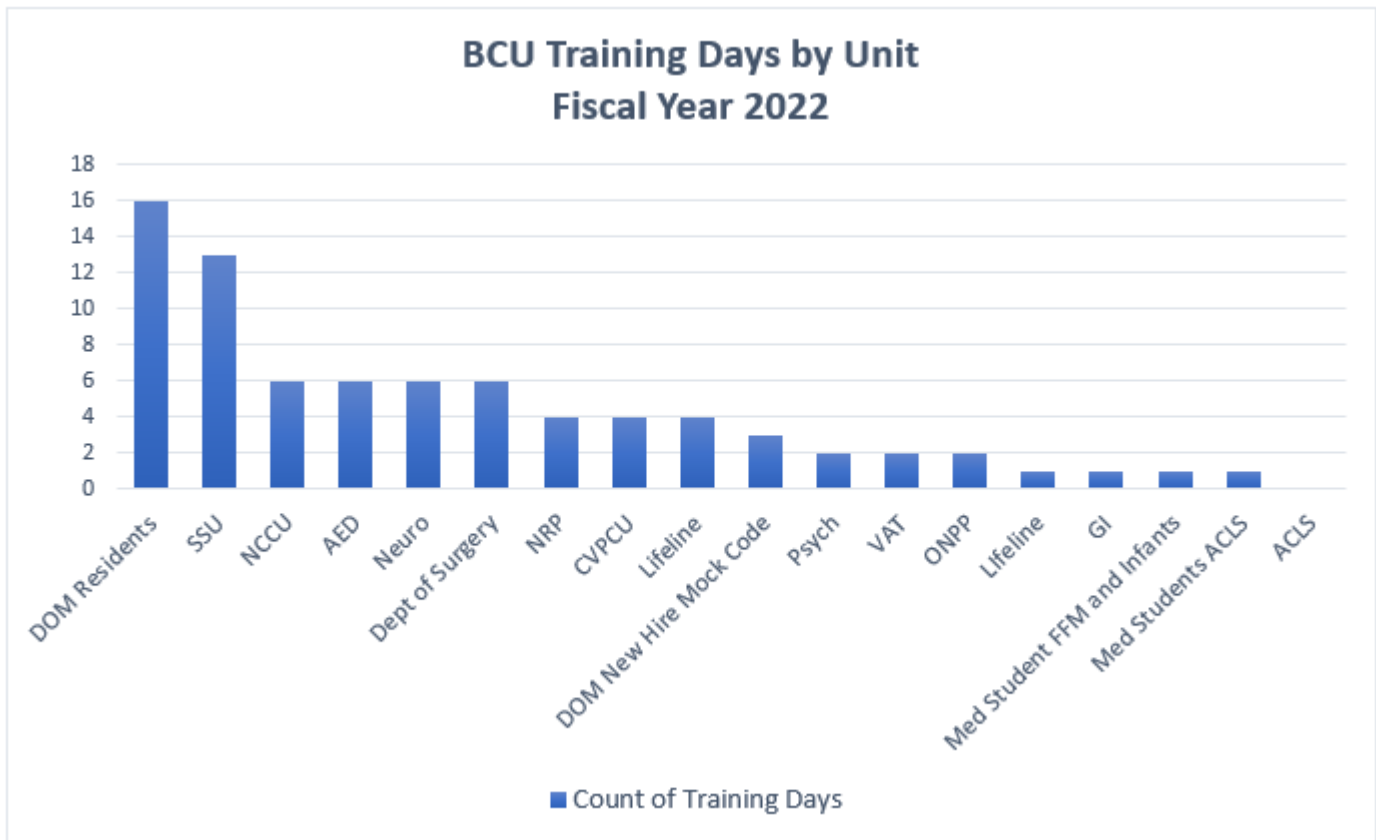
The BCU team exercised activation procedures in both November 2021 and May 2022 to care for patients infected with the Mpox virus. In November 2021, the BCU team was engaged by the Maryland State Health Department to assess the ability to quarantine an individual who tested positive for Mpox virus after travel to Nigeria. Activation readiness procedures were implemented and measured between 14 November and 05 December 2021 to admit a single adult. The JH BCU was ready to activate and receive the individual within an 8 hour timeframe from notification. After action items identified during Operation Twisted Tail in August were updated to include a greater emphasis on developing a new staff symptom monitoring system to implement during activation.

During the beginning weeks of the current Mpox outbreak, the BCU team responded to early cases of European and South American reports of monkeypox by evaluating the BCU's capacity to care for multiple infected patients who require hospitalization. The initial concerns of this outbreak revolved around waste management, as guidelines at the time recommended Category A waste management. The operational and infection control needs for this type of waste management warrant BCU activation. However, the outbreak's West African strain de-escalated the need for BCU intervention since that strain is not classified as a Category A agent. The BCU team evaluated the first confirmed Mpox patient in the JHH ED in July 2022 and worked with HEIC and the Department of Medicine to care for the patient on the hospitalist service. Once the decision was

made to care for Mpox patients in standard airborne isolation rooms, the BCU pivoted to a support role to clinical units throughout JHH including PPE training and bedside consultation.

3.6 Training Space

During times of inactivation, the BCU space on Osler 8 is an ideal training space for clinical teams. Throughout FY22, the BCU accommodated more than 90 dates for groups to hold skills days, training stations, and classes. Approximately 30% of available calendar dates are reserved for non-BCU groups and all groups are welcome to utilize the BCU’s high fidelity manikin in their curriculum. Through these shared learning opportunities, the BCU is able to recruit new team members and provide added value to the education and training mission of the hospital.



3.7 HHS Region III Special Pathogen Training and Education Program (Previously Maryland Education Program)

The Maryland Education and Special Pathogen Training Program initially started in FY18 in partnership with the Maryland Department of Health. The initial 2-year \$800,000 grant, supported the development of a statewide education and preparedness program focused on frontline healthcare facilities. These hospitals are the largest designation in the state, and are required to identify, isolate, and inform state stakeholders of potential patients with high consequence pathogens. They are also required to provide care for such patients in their facility for up to 24 hours. In order to provide this training, the BCU, in partnership with the Bloomberg School of Public Health, created a one-day frontline training course that could be performed at any facility. The course includes an overview of high consequence pathogen terminology and case studies, an overview of personal protective equipment, and simulation of basic clinical skills that frontline staff will use in most encounters. The training course started its full rollout in May 2018 and, as of October 2022, trained over 200 frontline staff at almost 24 locations around the state.

Following expanded baseline funding entering FY23, the program was renamed the HHS Region III Special Pathogen Training and Education Program. In its new format the program will expand to support hospitals throughout the entire region as well as other federal entities such as Veterans Administration hospitals. The program is already on track this year to complete sessions at 10 new facilities and training close to 100 frontline staff.



3.8 BCU Staff

The BCU team has elevated 2 of its core team members to more senior positions. Jade Flinn was promoted to Coordinator of Central Programs within the Department of Medicine's Nursing Administration and was named as the Unit Director of the Biocontainment Unit. During COVID-19, Jade's role expanded beyond Nurse Educator to include unit operational preparedness and response. In Jade's new role, she will represent the JH BCU as a subject matter expert in special pathogen program operational readiness at regional and national forums.

Christopher Sulmonte is the Administrative Director of the Johns Hopkins Biocontainment Unit (JHBCU) at The Johns Hopkins Hospital. He is also the Program Director of the Region III Special Pathogen Training and Education Program. Chris has coordinated the JH BCU operations over the last five years. He led the development and rollout of the Special Pathogen Training and Education Program which provides free, onsite, hands-on training to help prepare frontline facilities throughout HHS Region III for special pathogen response. Chris has also taken on a leadership role at NETEC as the technical co-lead of education and outreach to frontline and assessment hospitals. Chris has a bachelor's of science in Chemistry from Boston College and a Master of Health Administration from the Johns Hopkins University Bloomberg School of Public Health.

3.9 Personnel Spotlight



Currently completing the residency portion of his Master's in Healthcare Administration at Johns Hopkins Bloomberg School of Public Health, Brad is the new administrative manager of the BCU. In his role, Brad's focus will involve monitoring monthly finances for the BCU, improving standard operating procedures, and improving activation readiness workflows.

Performance Measure 4: Patient Medical Transport and Care Delivery

4.1 Patient Care in the BCU

The BCU team continues to diversify the clinical teams who would care for patients admitted with a high consequence pathogen. In collaboration with Kent Allen Stevens, Chief of the Division of Acute Care Surgery, the preparation and needs to safely provide a range of surgical interventions within the Osler 8 space have been refocused. Jose Suarez, Medical Director of the Neurocritical Care Unit, has involved a multi-disciplinary team including faculty representatives from the Neurosurgery and Neuroradiology teams, the Encephalitis Center, and Neurocritical Care clinical leadership to explore the possibilities of providing neuro-diagnostic and neuromonitoring on the Biocontainment Unit.

Recruitment of nurses and respiratory therapists continues to result in a more diverse team including greater representation across surgical, medical, psychiatric, pediatric, and oncology departments. The strategic recruitment across the entire hospital aims to build a true team staffing model with varied experience and expertise to not only provide quality patient care but to also reduce the impact on any single unit during BCU activation.



4.2 Special Operations Response Team

LIFELINE's Special Operations Response Team (SORTeam) has continued to set the standard for highly infectious disease transports. Established in response to the 2014 Ebola outbreak and partially funded through the BCU, the SORTeam is nationally recognized as a critical care transport team specializing in highly infectious disease transports. Lifeline and the SORTeam have continued to participate and train with the BCU and HEIC to further develop their protocols and procedures in the packaging, transport, and admission of a patient needing biocontainment care. Additionally, the SORTeam represents those highly specialized and intensively trained patient transport clinicians on the NETEC EMS Biosafety Workgroup as subject matter experts (SME) and maintains an active presence in the NETEC EMS Biosafety Forum. SORTeam Biosafety Workgroup SMEs contributed to the development of the NETEC Special Pathogens Operational Readiness Self-Assessment for Emergency Medical Services (SP-ORSA EMS). This tool was designed to assist EMS/patient transport agencies in assessing their readiness to safely isolate, assess, and manage patients suspected or confirmed to have Ebola virus disease or other emerging pathogens.

4.3 Autoclave Optimization

The BCU team has recently published and presented a poster on the methods developed to validate the efficacy of the 2 autoclaves housed in the BCU. The autoclaves inactivate potentially infectious waste during unit activation. The newest development in the autoclave validation process includes the use of in-bag temperature and pressure monitors that record and transmit real-time trends during an autoclave cycle. With this new tool, the team was able to develop modified autoclave cycles that achieve sufficient within bag temperatures to inactivate Category A pathogens such as Ebola. Using these updated protocols, the BCU team validated the use of super rapid biological indicators that result after a 24 minute incubation period. As a result of these validation changes, autoclave cycles and waste management processes have been modified to not only be effective but also efficient in waste throughput. The BCU team's autoclave validation processes can be found in *Applied Biosafety*. A poster was also presented at the annual conference of the American Society of Microbiology in June, 2022 in Washington DC.





Lindsay Bow and Jade Flinn presenting at the American Society of Microbiology Conference. Washington D.C. (June 2022)

Performance Measure 5: Communication and Coordination

5.1 Collaboration with the National Emerging Special Pathogen Training and Education Center (NETEC)

FY22 saw increased collaboration between the BCU and NETEC. Multiple members of the core team became part of nationwide working groups addressing special pathogen education, operations, and research needs. Additionally, each of these working groups developed new national metrics for determining special pathogen capacity and capability. In total, the Johns Hopkins BCU was a part of all 8 working groups, including Long Term Care, Infection Control, and Frontline Patient Care & Operations.



Performance Measure 6: Monitoring and Evaluation

6.1 Tours

In FY22, the BCU hosted visitors from local, regional, national and international partners. Audiences included students, nurses, physicians, hospital executives, federal agencies, and county health departments. Below is a partial illustration of tours from the past year. Now that in-person meetings are once again possible, the volume of tours has started to increase back to pre-pandemic levels.

FY22 Number of Tours: 17

Johns Hopkins Pharmacy Department

Johns Hopkins Microbiology Department

Johns Hopkins Bloomberg School of Public Health Epidemiology Program

Health Minister of France

Johns Hopkins Nursing School

Johns Hopkins Bloomberg School of Public Health Occupational Health Program

Congressional Office of Maryland, Virginia, Georgia, and West Virginia



6.2 BCU in the News

- 08/23/2021 Winning in Medicine: Victories Large and Small- Even when times are tough, there's still hope. Anamnesis. Medscape Podcast hosted by Amy Faith Ho.
- 11/29/2021 Omicron is new, but the old advice to protect yourself still applies. (NBC News)
- 12/07/2021 Live appearance on [Yahoo Finance](#) (online news program –100 million international viewers monthly).
- 12/08/2021 Fact Check-Debate about mask-wearing hots up again as England brings back some COVID-19 restrictions (Reuters)
- 12/21/2021 How should you be wearing masks as coronavirus cases surge? (WTOP News)
- 01/04/2022 Live appearance on [Yahoo Finance](#) (online news program –100 million international viewers monthly).
- 01/05/2022 Omicron Biocontainment Unit medical director: Kids ‘should be wearing masks in schools right now,’ doctor says (Yahoo News)
- 01/12/2022 Fact Check-Satirical video claiming that masks don’t work against COVID and that vaccines are a population tool taken seriously on social media (Reuters)
- 01/14/2022 How many times can you reuse a mask before replacing it? (MSN)
- 01/19/2022 I planned a trip to a country the CDC labeled 'Do not travel'. Should I cancel? (Lonely Planet)
- 01/19/2022 Study Supports Use of Remdesivir for COVID-19 Patients on Low-Flow Oxygen or No Oxygen (News Wise)
- 01/21/2022 Experts: COVID-19 hospitalization data drives public, private decision-making (WBAL)
- 03/03/2022 Face masks expired? How to tell, plus why you should hold onto them despite easing restrictions (CNN)
- 03/25/2022 Hopkins experts cautiously optimistic over state of COVID-19 pandemic (WBAL)
- 04/09/2022 Many Americans can now get a 4th COVID shot – but should they wait? (FOX)
- 04/22/2022 Maryland not the only state seeing rising COVID-19 metrics (WBAL)
- 04/22/2022 What Is 'One-Way Masking'—And How Can It Protect You From COVID? (Health Magazine)
- 05/20/2022 'Masking Is A Really Good Idea': Hopkins Experts Urge Caution As COVID-19 Cases Surge Again (CBS Baltimore)
- 05/24/2022 Monkeypox Medicine Is Here—but There’s a Catch (Daily Beast)
- 05/31/2022 [Pulse Oximeters Are Less Accurate Among Black, Hispanic and Asian Covid-19 Patients: Devices flag low oxygen levels more reliably in white patients, according to study.](#) The Wall Street Journal.

- 5/31/2022 [Faulty oxygen readings delayed Covid treatments for darker-skinned patients, study finds](#). STAT news (online story).
- 06/02/2022 [Faulty pulse oximeter readings delayed life-saving treatments for Black COVID-19 patients, research finds](#). Insider (online story).
- 06/05/2022 [Inaccurate pulse oximeter measurements delayed COVID treatment for people of color](#). NPR's Weekend Edition. (radio broadcast).
- 06/07/2022 [Study: Ineffective blood oxygen readers have endangered Black and Latino Covid patients](#). NBC News (online story).
- 06/17/2022 [Racial, ethnic biases in pulse oximetry accuracy may have delayed COVID-19 treatment for some](#). Healio News (online story).
- 06/29/2022 [The problem with pulse ox](#). ACP Hospitalist (online story).
- 07/02/2022 [Flawed oxygen readings may be behind Covid-19's toll on people of color](#). Politico Magazine (online story).
- 08/28/2022 [Did a flawed pandemic tool lead to more deaths among Blacks, Hispanics? N.J. docs call for answers](#). New Jersey.com (online story).



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6.3 Financial Sustainability

FY22 saw the continuation of Congressional support for Regional Emerging Special Pathogen Treatment Centers (RESPTCs) throughout the United States, including the Johns Hopkins BCU. The BCU program entered FY22 with a budget of \$1,260,000 which included supplemental COVID funding to support relevant initiatives throughout the region as well as \$600,000 funding to continue to support operational preparedness within the BCU. Entering FY23, Congress approved an increase of permanent baseline funding of the BCU program from \$600,000 to \$1,200,000. Entering FY23, the BCU will have a budget of \$1,381,000.

This year saw continued and strengthened collaboration with the Government Affairs team to develop a strategy of education and exposure to critical congressional offices on the importance and relevance of the BCU. Over the past year, we hosted congressional staff and members during training and exercises in an effort to keep hospital preparedness on the forefront of prioritized funding. In addition, the BCU and government affairs team, along with members of NETEC, visited congressional offices virtually on multiple occasions to advocate for continued funding. This led to a discussion not only with Maryland delegates, but other states within the region with funding appropriation roles in Delaware, West Virginia, and Pennsylvania. As of October 2022, Congress has approved the expansion of baseline funding for the current regional biocontainment units from \$600,000 to \$1,200,000. In addition, Congress has allocated funding to expand the Regional Treatment Center Network with the aim of expanding the program nationally over the next five years.

6.4 Future Activities

The BCU has continued to demonstrate its value to our local, regional, and federal partners over the last year. We are poised to grow the BCU into a Center for Special Pathogens that will better reflect our tripartite mission of patient care, research and education. The pivot to a Center model will allow us to successfully compete for federal funding beyond our current HHS designation as a regional treatment center and expand the scope of our activities as we look to tackle infectious disease threats beyond SARS-CoV-2. We are excited to take on larger roles within NETEC and as part of the national conversation on preparedness for future infectious disease threats. We look forward to continued discovery about the pathobiology and clinical trajectory of COVID-19 through our collaboration with the Hopkins COVID PMCOE and our partnerships with the NIH and the Special Pathogens Research Network. We are also excited to refocus our efforts on preparing for other infectious disease outbreaks that we might encounter beyond COVID, as we participate in the rollout of the National Special Pathogens System.

