NYC Health

Testimony

of

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New York City Department of Health and Mental Hygiene

before the

New York City Council

Committee on Health

and

Committee on Hospitals

and

Committee on Land Use

on

Oversight-The Current State of Access to Hospitals and Healthcare

September 19th, 2022
City Hall Chamber
City Hall

Good afternoon, Chairs Schulman, Narcisse, and Salamanca, and members of the committees. I am Rishi Sood, Executive Director of the Health Care Access & Policy Unit at the New York City Department of Health and Mental Hygiene. Thank you for the opportunity to testify today. I am joined today by my colleagues from Health + Hospitals: Dr. Andrew Wallach, Ambulatory Care Chief Medical Officer, Dr. David Silvestri, Assistant Vice President of Emergency Management, and Mr. Manny Saez, Senior Assistant Vice President of Facilities. On behalf of the Administration, we thank you for the opportunity to speak today on the importance of hospital and healthcare access in New York City.

The Health Department believes access to quality healthcare should be available to all New Yorkers. In the past two and a half years, we have seen and experienced how important and essential access to healthcare is. Yet, social, economic, and geographic factors can often be barriers to receiving health services, especially for marginalized populations. Lack of access to healthcare is both a public policy issue and a moral one. We work together with other city agencies such as Health + Hospitals, community-based organizations and community healthcare providers to identify and respond to the barriers that prevent access to healthcare to ensure that all New Yorkers can receive the care that they need.

Over the last two and half years, the City has worked tirelessly to ensure equitable access to care was provided for all New Yorkers during the COVID-19 pandemic – from standing up a massive vaccine infrastructure to supporting the existing health care system, and ensuring distribution of available treatments. The City pursued a broad effort to address health disparities and serve communities hardest hit by COVID-19 focusing on the 33 Taskforce on Racial Inclusion and Equity – or TRIE – neighborhoods. We broke down language access barriers by bringing translators and translated materials to vaccine sites and partnering with community-based organizations to deliver critical health information to their communities in the languages they speak. We met people where they

were by deploying mobile vaccines via tents, vans, and buses to locations across the city where people live, work, dine, commute, learn, play, and even into their homes. And more recently the City increased capacity to ensure that New Yorkers have access to the medication needed to treat COVID-19 as soon as they test positive through telehealth services, same-day delivery and treatment vans.

The collaboration between public and private partners that exists in our COVID-19 response, extends to the work that the Health Department does every day to address the social and environmental factors that impact health. Specific to our work to address health care access, we engage with community healthcare providers to bolster their capacity to serve their neighborhoods. Our support for these providers helps to identify and address residents' health care needs and reduce health risk factors for both infectious and chronic diseases, provide technical assistance for telemedicine, and ensure providers receive adequate PPE to reduce their own risks especially during emergencies. Our engagement with the community involves collaborating with community partners to identify issues that lead to poor health outcomes, create response strategies, increase awareness of health information on infectious and chronic diseases, and ensure residents receive resources and services. Working with trusted partners in the community is an essential part of residents seeking healthcare services, dispelling misinformation and promoting positive health behaviors.

In addition, the Health Department works closely with other agencies and offices including the Mayor's Office of Immigrant Affairs, Health + Hospitals, and the Department of Homeless Services – as well as community-based health care providers – to provide services to immigrant populations. We work collaboratively to provide psychological first aid, emotional support services, health insurance enrollment, and to connect individuals and families to primary care appointments. In addition, the Health Department works closely with the Community Health Care Association of New York State, individual community health centers and networks, and other primary care

providers and stakeholders to ensure access to primary care services and continuity of care for all New Yorkers, particularly those who are low-income and/or uninsured. We continue to identify ways to improve coordination of the health care safety net during complex public health crises such as COVID-19 and MPV, as well as on an ongoing basis.

New York City's health care safety net is always in need of more resources but is strong, healthy, responsive, and available to all New Yorkers, regardless of insurance or immigration status. We recognize that health insurance provides a vital pathway to care and financial protection, particularly for more specialized care. As such, we work through our Office of Health Insurance Services to enroll New Yorkers into coverage through the New York State of Health Marketplace and provide enrollment assistance with both paper and web-based portal applications and renewals. Our staff are designated Certified Application Counselors (CACs), trained to provide education, outreach, and enrollment services from our health centers across the city. CACs help all New Yorkers, with a focus on people with lower income; Black, Latino and immigrant communities; and those who are medically vulnerable, to explore their health insurance options and to select a health plan and primary care provider that best fits their needs. In collaboration with other city agencies, we assist the older adult (65+) population and certified blind and certified disabled populations in NYC through education, outreach, and enrollment assistance for public health insurance programs. Additionally, CACs assist with applying for the Supplemental Nutrition Assistance Program (SNAP) benefits (food stamps) and refer individuals to other social service organizations as needed.

It is important to note that regulation of health care facilities, including hospitals, is conducted by the state, specifically the New York State Department of Health. Among other responsibilities, the State's Public Health and Health Planning Council reviews and makes decisions on Certificate of Need applications submitted by hospitals, home care agencies, and hospice facilities when they are looking to establish facilities, transfer

ownership of facilities, or make substantial changes "concerning major construction projects, service changes, and equipment acquisitions."

In the face of this landscape, the Health Department utilizes a multifaceted approach to support New Yorkers in accessing quality healthcare and we will continue to prioritize equity and access to ensure New Yorkers are getting the services and support they need. Thank you again to Chairs Schulman, Narcisse, and Salamanca for holding this hearing today. I am happy to answer any questions.

Oversight Hearing: The Current State of Access to Hospitals and Healthcare
Committees on Health, Hospitals, and Land Use
9/19/2022

Good morning Chairpersons Schulman, Narcisse, Salamanca, and members of the Committees on Health, Hospitals and Land use. I am Dr. Andrew Wallach, the Ambulatory Care Chief Medical Officer at New York City Health and Hospitals (Health + Hospitals) and a practicing primary care physician at Health + Hospitals / Bellevue. I am joined today by my colleagues, Dr. David Silvestri, Assistant Vice President of Emergency Management and a practicing emergency medicine physician at Health + Hospitals / Lincoln, and Mr. Manny Saez, Senior Assistant Vice President of Facilities. Thank you for the opportunity to testify regarding the work Health + Hospitals does to promote access to healthcare for all New Yorkers and to ensure its preparedness for emergencies. While Health + Hospitals is only one component of a much larger health care delivery system in our City, we are proud of what we do.

Health + Hospitals is the largest municipal health care system in the United States. Our mission is to deliver high-quality health services with compassion, dignity, and respect for all, regardless of insurance status or ability to pay. We provide essential inpatient, outpatient, and home-based services to more than one million New Yorkers every year in more than 70 locations across NYC's five boroughs. More than 60 percent of our patients identify as either Black/African American, Hispanic/Latinx, or Asian American/Pacific Islander. More than 70 percent of our patients are insured by Medicaid or have no insurance, including nearly 400,000 uninsured New Yorkers who would otherwise not have access to care.

Healthcare Access

Health + Hospitals offers high quality and affordable healthcare services at our eleven acute care sites, five post-acute care (skilled nursing) facilities, and through our Federally Qualified Health Centers (FQHCs), known as Gotham Health. Gotham Health has over 50 Community Health Centers throughout all five boroughs, allowing us to address the primary care needs of families and individuals in their own neighborhoods.

At both our hospital-based primary care practices and Gotham Health centers, we provide:

- Routine check-ups, preventive health screenings and immunizations for children and adults
- Chronic disease management, including for asthma, heart care and diabetes
- Adolescent health services
- Behavioral health services
- Diagnostic imaging services
- Women's health and maternity care services
- Well baby care and pediatric services
- Senior care and geriatric specialties
- Help with implementing lifestyle changes and other wellness goals

Health + Hospitals offers free language services 24 hours a day, 7 days a week, 365 days a year in over 200 languages and dialects. We translate key patient documents, such as consent forms and patient education materials, into the top languages spoken by limited English proficient (LEP) New Yorkers, who represent an estimated 30% of our patients.

In addition to our extensive physical footprint across New York City, I am also incredibly proud of our new telehealth and mobile services, which expand access to care and allow Health + Hospitals patients to receive their care where and how they need it.

For telehealth, we have several options, such as telephone appointments, video visits, and an online patient portal for patients to connect with our health care providers without coming into the doctor's office or hospital, all accessible via our MyChart system. For non-emergency urgent care services, we offer Virtual ExpressCare. Virtual ExpressCare was launched in 2020 to ensure convenient one-click access for patients seeking urgent care services to the most appropriate level of care where they were safest during the first wave of the COVID-19 pandemic – at home. Virtual ExpressCare is available 24/7 and allows patients to receive virtual care from a Health + Hospitals provider for common physical, mental, emotional, and behavioral health issues. We provide this service in over 200 languages, including American Sign Language, with in-screen interpretation services.

Virtual ExpressCare has become a nationally recognized leader for its COVID-19 treatment model that helps patients access treatment via telehealth and offering home delivery for antivirals and same- or next-day monoclonal appointments. Additionally, this summer we received funding to launch and integrate a new tele-behavioral health service into Virtual ExpressCare, and to create a tailored version of the new tele-behavioral healthcare service for New Yorkers experiencing homelessness.

We are also bringing care directly to New Yorkers. For New Yorkers experiencing homelessness, the Street Health Outreach and Wellness (SHOW) mobile units engage individuals where they are and provide vital health care and social services. The SHOW units have provided COVID-19 testing and vaccines, behavioral health care, and a host of other harm reduction and social services to well over 100,000 New Yorkers. In addition, our mobile Test to Treat program offers COVID-19 testing and Paxlovid distribution to thousands of New Yorkers via 30 mobile vans. To ensure deployments are reaching New Yorkers most in need, 75% of mobile Test to Treat locations have been established in neighborhoods the City's Taskforce on Racial Inclusion and Equity (TRIE) determined were hardest hit by the COVID-19 pandemic.

Emergency Planning

Hospitals play an essential role in planning for and responding to the needs of New Yorkers during any citywide emergency. Health + Hospitals has a history of preparing for, responding to, and recovering from a myriad of emergency events, including pandemics. While Health + Hospitals has been activated in response to the COVID-19 pandemic, we have had to concurrently respond to multiple other emergencies including coastal storms, winter storms, mass transit shut down, extreme heat, and most recently MPV. Health + Hospitals has maintained and even expanded operations throughout each emergency event and provided continuity of care to our patients and communities we serve.

Health + Hospitals uses an Incident Command System (ICS) to manage all disasters, emergencies and other incidents. The ICS is a national best practice for coordinating emergency response and allows for communication, coordination, and collaboration with other agencies. A Central Office Incident Management Team (IMT), embedded within the System's ICS, is responsible for coordinating emergency response across the health system. Once Health + Hospitals activates the ICS, internal and external notifications are made while information is gathered for situational awareness. Staff are assigned to their incident command roles, briefings are held providing the latest intelligence, and an incident action plan is developed for the first

operational period. This process repeats for each operational period throughout the activation. Similarly, for preparation and planning of an emergency, Health + Hospitals also utilizes the ICS. Trainings and exercises take place regularly where each facility tests components of the Emergency Operations Plan (EOP) to ensure operations and communication chains run smoothly.

In addition to its robust procedures to address an emergency as it unfolds, Health + Hospitals takes great efforts to ensure its preparedness well before disaster strikes. To ensure the safety of its patients and staff, Health + Hospitals has extensive plans in place in the event of weather, public health, or other catastrophic emergencies. Our emergency operations and response plans are developed to address "All Hazards," with specific Incident Response Annexes and Guides for high probability and high impact events which include coastal storms, extreme temperatures, and winter and summer weather events. Each of our sites is required to conduct training and exercises to test and evaluate their plans. Planned exercises and actual response activations are reviewed to identify gaps and areas for improvement.

Importantly, we do not work alone. Health + Hospitals works closely with the Mayor's Office and NYC Emergency Management (NYCEM) in all phases of emergency management including planning, mitigation, response, recovery, and training and exercises. Each year, Health + Hospitals participates in exercises with other agencies and led by NYCEM. While the intent of these exercises is to test plans and identify gaps, real-life activations also serve this purpose and allow for real time identification of gaps and resolution of issues. In addition, Health + Hospitals partners with other hospital systems in NYC through the Greater New York Hospital Association (GNYHA) to prepare for emergency events.

We are always striving to better serve our patients and make our system even stronger and better prepared for the next emergency.

Infrastructure

Health + Hospitals is committed to enhancing the resiliency of its facilities in order to mitigate future disasters, plan for future emergencies, and shore up our aging infrastructure. We're learning and building resiliency from COVID-19; shoring up facilities, increasing patient capacity, safeguarding long-term COVID-19 services, and supporting our staff. We have also learned and rebuilt after major hurricanes; sites that incurred flood damage after Hurricane Sandy made major improvement measures including moving critical infrastructure to higher floors, flood protection for our facilities, flood resistant infrastructure, investing in generators, electrical panels, HVAC systems, and other capital projects. In May, Health + Hospitals and the NYC Economic Development Corporation broke ground on a new flood protection system at NYC Health and Hospitals/Metropolitan in East Harlem. In October, Health + Hospitals will open the Ruth Bader Ginsburg Hospital at NYC Health and Hospitals/South Brooklyn Health campus, which will feature a new concrete flood wall and flood resilient infrastructure for power, heating, cooling, and water systems.

Over the next ten years, Health + Hospitals has significant infrastructure needs including IT, equipment, and capital improvements. This includes work specific to the COVID-19 response, green energy upgrades across the system, and work to improve the patient experience such as individual patient rooms, improved behavioral health settings, and renovated operating rooms and emergency departments. Infrastructure improvements are especially important to Health + Hospitals as a safety net provider: Our infrastructure is 17 years old on average, compared to an average of 9 years for other NYC hospitals. We have made significant investments to modernize

our facilities, and we are grateful to the Council, the Mayor, our Borough Presidents, and our Federal delegation for their crucial funding support. Hospital and health care infrastructure should be considered equally critical as roads and bridges, and we continue to engage on this topic at the city, state, and federal levels.

Closing

It is the mission of Health + Hospitals to deliver high quality health services with compassion, dignity, and respect to all, without exception. Every day, we work towards that mission and strive to continuously improve our services, and stay ready for the next challenge. Thank you to the committees for the opportunity to testify and for your continued support of Health + Hospitals. I look forward to our continued partnership and I am happy to answer any questions.

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MANHATTAN BOROUGH PRESIDENT MARK LEVINE TESTIMONY BEFORE THE CITY COUNCIL COMMITTEES ON HEALTH, HOSPITALS, AND LAND USE

September 19, 2022: Oversight: The Current State of Access to Hospitals and Healthcare

Good afternoon, Chairs Schulman, Narcisse, and Salamanca, and members of the Committees on Health, Hospitals and Land Use. My name is Mark Levine, and I am the Manhattan Borough President. I would like to thank Chairs Schulman, Narcisse, and Salamanca, and the members and staff of these committees for holding this important joint hearing on the current state of access to hospitals and healthcare.

New York is a proud home to America's largest public health care system, Health + Hospitals, as well as world class academic medical centers. However, as we have seen at length with the ongoing coronavirus pandemic, access to equitable health care is not a reality for every community in New York. The disparities in healthcare and hospital access are rooted in chronic underinvestment, as well as structural racism and classism. Especially as community health clinics struggle to stay open amidst rising rents, New York City must prioritize protecting and expanding access to community-based, quality, culturally responsive and affordable health care, as well as retaining and further advancing telemedicine opportunities for patients to tap into, so we can prevent loss of life and ensure New Yorkers can access the care they need to thrive.

Zoning, land use and public health have long been intertwined policy areas. In 1926, the Supreme Court's Village of Euclid v. Ambler Realty Co. decision supported local governments' ability to make zoning mandates to promote "health, safety, morals and the general welfare". The physical features of our built environments - from transportation to food access, from housing to hospitals and community health centers - are grounded in zoning and land use decisions.
As repeatedly shown by the ongoing COVID pandemic, hospital capacity and community health center access are resources we must continue to invest in and not all communities experience access equally. From 1998 to 2020, the Association for Neighborhood and Housing Development found that at least 18 hospitals have closed all their inpatient services in New York City, resulting in the loss of thousands of hospital beds with two-thirds of those closures occurring in the outer boroughs. As of September 2021, it was reported that there were at least 5 hospital beds for every 1,000 residents in Manhattan, with Queens experiencing only 1.8 per 1,000. However, Manhattan also lost key healthcare institutions as well in:

- St. Vincent's in Midtown (2007), once a major source of HIV/AIDS care that was later recommended for closure by the Berger Commission report to cut down on costs.

- St. Vincent's in Greenwich Village (2010), a hospital that once served patients as far back as the cholera epidemic in 1849 and was also a major source of HIV/AIDS care and site of LGBT advocacy. While there were once plans to work to preserve its urgent care and certain outpatient services, luxury buildings eventually took this hospital's place.
- Cabrini Medical Center in Gramercy (2008), a hospital focused on accessible, community based primary and acute care, and an early source of expert care for HIV/AIDS patients. The buildings were eventually converted into residences.
- North General Hospital in East Harlem (2010), once the largest private employer in Harlem with over 60% of the workforce living in the neighborhood.

Such closures mean that loss of good jobs to a neighborhood, and healthcare expertise and services close to a community. While public health infrastructure was once at the heart of zoning processes, we have moved away from grounding our planning in protecting and uplifting the public's health. We must ensure healthcare and public health principles are at the forefront of planning discussions and decisions. Chair Schulman has advocated fiercely and rightly about the need to find creative ways to add hospital capacity through the land use process and I look forward to working with her, Chair Narcisse and across all three of the committees represented today to ensure all New Yorkers have access to the healthcare they need and deserve, while ensuring current and future hospital designs and renovation plans can be adapted to prepare for surges of known and currently unknown health threats. We also must continue to ensure H&H Gotham FQHC clinic planning prioritizes areas with low healthcare access, in partnership with communities on the ground.

In response to the pandemic, our city has seen changes in how patients access healthcare as well. Increased use of telemedicine practices has given patients and providers more chances to connect on a wide range of healthcare needs. Patients deserve continued and increased access to quality telemedicine services. I'm glad to be partnering with Council Member Crystal Hudson on Int 0675-2022, a bill requiring the Department of Health and Mental Hygiene to develop a plan to improve the availability and accessibility of telemedicine services including making available portable monitoring and needed telehealth devices to patients (including for those without broadband access), and conducting outreach to patients and healthcare providers to provide information and to improve availability and of telemedicine services. I urge the City Council and Mayor to pass this legislation quickly.

Finally, I want to continue to thank our healthcare workers, centers, and hospitals. From COVID, to monkeypox, to polio, and to many, many other healthcare responses, NYC's healthcare workers have met every challenge with diligence and compassion. I know I can't know the toll this has taken on you and with hearings like today's, I look forward to learning more about where you see the most pressing needs and how our city can best empower and support you in your ongoing work for our neighbors. Thank you for everything you do.

CACF
Coalition For Asian American Children+Families

New York City Council
Committee on Health, Hospitals, and Land Use
September 19, 2022

Testimony of Medha Ghosh, MPH, Policy Coordinator
Coalition for Asian American Children and Families (CACF)

Good afternoon, my name is Medha Ghosh, and I am the Health Policy Coordinator at CACF, the Coalition for Asian American Children and Families. Thank you very much to Chair Schulman, Narcisse, and Salamanca for holding this hearing and providing this opportunity to testify.

Founded in 1986, CACF is the nation's only pan-Asian children and families' advocacy organization and leads the fight for improved and equitable policies, systems, funding, and services to support those in need. The Asian American Pacific Islander (AAPI) population comprises nearly 18% of New York City. Many in our diverse communities face high levels of poverty, overcrowding, uninsurance, and linguistic isolation. Yet, the needs of the AAPI community are consistently overlooked, misunderstood, and uncounted. We are constantly fighting the harmful impacts of the model minority myth, which prevents our needs from being recognized and understood. Our communities, as well as the organizations that serve the community, too often lack the resources to provide critical services to the most marginalized AAPI New Yorkers. Working with over 70 member and partner organizations across the City to identify and speak out on the many common challenges our community faces, CACF is building a community too powerful to ignore.

Nearly 19 million people reside in the New York City metropolitan area, and over 800 different languages are spoken. Because of New York's linguistic diversity, it is incredibly important to ensure language access. Language barriers are a huge obstacle faced by many folks in immigrant communities, and especially in the AAPI community. In New York City, the AAPI community has the highest rate of linguistic isolation of any group, as 46% have limited English proficiency (LEP), meaning that they speak English less than very well, according to a recent report from the New York City Department of Health and Mental Hygiene. Moreover, more than 2 in 3 Asian seniors in NYC are LEP, and approximately 49% of all immigrants in NYC are LEP.

Language barriers can prevent folks from accessing vital services like healthcare. Despite there being 76 language access policies targeting healthcare settings in New York, we have found that many LEP patients still report facing difficulties like being unable to find an interpreter that speaks their dialect or being unable to fill out paperwork because a translated version in their language does not exist. A lack of linguistically accessible services in healthcare settings can have grave consequences: 52% of adverse events that occurred to LEP patients in US hospitals were likely the result of communication errors, and nearly half of these events involved some form of physical harm.

CACF

Coalition For Asian American Children+Families

In the summer of 2021, we conducted a rapid needs assessment in collaboration with the NYU Center for the Study of Asian American Health and the Chinese-American Planning Council. We surveyed over 1000 adults of Asian, Hispanic/Latinx, or Arab descent living in the metropolitan New York area to assess the current and ongoing needs of the community during the COVID-19 pandemic.

This study highlights the disproportionate impact that the COVID-19 pandemic has had on the New York Asian American community and demonstrates the importance of language access. Specifically, the study found 1 in 3 (34%) Asian American adults reported language barriers being a challenge during the pandemic. Furthermore, 27% of Asian American respondents indicated that they felt like they did not have regular access to timely, accurate information during the COVID-19 pandemic in their language. The study also shed light on the specific language barriers that Asian American folks were facing: Chinese, Korean, and Bangladeshi adults reported high rates of difficulty waiting for an interpreter, while Korean, Japanese and other Asian adults reported high rates of difficulty getting written materials in their preferred languages. Being unable to access vital COVID-19 information or health services can be a threat to one's livelihood, so ensuring language access for all New Yorkers must be prioritized. The full report with the findings from this study can be found here.

In response to this, CACF's campaign, "Lost in Translation" aims to ensure that New Yorkers have equitable access to linguistically and culturally responsive healthcare services. Over the past two years, CACF conducted quantitative and qualitative research to identify the key barriers that LEP New Yorkers face in healthcare settings and identify corresponding recommendations.

Our major recommendations for the LEP New Yorker community, which includes many members of the AAPI community, are as follows:

- Demand healthcare institutions collect more data on translation and interpretation services and service utilization
- Increase the number of languages for translated signage and forms, and ensure accuracy of translations by engaging community partners in a language review
- Ensuring accountability for language access complaints
- Create more opportunities to increase the number of practitioners who speak the languages of the communities they serve

Overall, we see a need for more intentional collaboration between the City and community-based organizations to better identify language access gaps in our communities and to find solutions that will have a direct positive impact on the wellbeing of our communities.

Thank you very much for your time.

Community Service Society

Powering a more equitable New York

Testimony of the Community Service Society of NY
Before the New York City Council Committees on Health, Hospitals, and Land Use

Oversight: The Current State of Access to Hospitals and Healthcare

September 19, 2022

The Community Service Society of New York (CSS) would like to thank the Committees on Health, Hospitals and Land Use for holding this hearing. The Community Service Society of New York (CSS) has been an unwavering voice for low-income New Yorkers for over 175 years. Our health programs help approximately 130,000 New Yorkers enroll in and use health insurance, negotiate medical billing, or otherwise access free or low-cost health care every year. We do this through a live-answer helpline and in partnership with over 50 community-based organizations (CBOs) throughout the City and State.

Our testimony describes the affordability crisis faced by patients in New York, and the gaps left by existing policies meant to help them. CSS suggests that the City Council consider taking a stronger role in monitoring hospital financial assistance policies and support statewide legislation that would improve access to hospital financial assistance, bar hospitals from placing liens on patients' homes or garnishing wages, and reallocate the State's indigent care pool funding to increase support for safety-net hospitals. The City Council could also consider participating in the rule-making process for the Health Equity Assessment Act.

Affordability Barriers Lead to Unequal Access to Care

All of New York's hospitals are non-profit charities that are required by law to offer financial assistance based on income. However, New Yorkers are still struggling with an affordability crisis that prevents them from getting the care they need. Since 2019, our Community Health Advocates program has identified a 64 percent spike in medical debt cases. A March 2022 poll of New Yorkers found that 38 percent of New Yorkers say that they are sacrificing health care because of costs, three in 10 have appealed or questioned a bill, and one in five have paid a bill they didn't think they owed for fear of being placed in

collections.[1] In the five boroughs, the proportion of people whose medical debt has been reported to collections agencies ranges from 2.9% in Manhattan to 6.1% in the Bronx.[2] There are significant racial disparities: in Manhattan, people who live in communities where most residents are people of color are 200% more likely to have medical debt on their credit reports than people in majority-white communities.

Table 1. Racial Disparities in Medical Debt Reported to Collections Agencies[3]

County	Share with Medical Debt in Collections	Communities of Color	Majority White Communities	Difference
Bronx	6.1%	6.2%	N/A	N/A
Kings	3.4%	4.4%	2.5%	178%
New York	2.9%	4.0%	2.0%	200%
Queens	3.8%	4.1%	3.0%	133%
Richmond	3.0%	3.7%	2.6%	142%

New York's hospitals respond inconsistently to patients who cannot afford their medical bills. CSS has issued a series of reports on consequences for patients who cannot pay their medical bills called Discharged Into Debt. Findings include:

- Over 53,000 New Yorkers were sued by hospitals between 2015 and 2020, including thousands who were sued at the height of the pandemic. The majority of these lawsuits were filed by a small subset of hospitals.[4]
- Hospital lawsuits are disproportionately filed against patients who live in low-income communities of color or communities.[5]
- In 2017 and 2018, hospitals placed over 2,400 liens on patients' primary homes.[6]

[1] CSSNY, "Financial Hardship, Avoiding Care: Results from a Statewide Survey," March 2022, https://www.cssny.org/news/entry/financial-hardship-avoiding-care-healthcare-affordability-survey
[2] Urban Institute, "Debt In America", accessed Sept. 16, 2022 at https://apps.urban.org/features/debt-interactive-map/?type=overall&variable=totcoll.
[3] Ibid.
[4] Amanda Dunker and Elisabeth Benjamin, "Discharged Into Debt: A Pandemic Update," Community Service Society of New York, Jan. 2021, https://www.cssny.org/publications/entry/discharged-into-debt-a-pandemic-update.
[5] Amanda Dunker and Elisabeth Benjamin, "Discharged Into Debt: Medical Debt and Racial Disparities in Albany County, Community Service Society of New York, March 2021, https://www.cssny.org/publications/entry/discharged-into-debt-medical-debt-and-racial-disparities-in-albany-county.
[6] Amanda Dunker and Elisabeth Benjamin, "Discharged Into Debt: Nonprofit Hospitals File Liens on Patients' Homes," Community Service Society of New York, November 2021, https://www.cssny.org/publications/entry/discharged-into-debt-nonprofit-hospitals-file-liens-on-patients-homes.

- A study of five hospitals revealed 1,600 instances of patients' wages being garnished, most of whom appear to work in low-wage jobs.[7]

Over the past few years, many of New York's hospitals have revisited their collection practices. Health & Hospitals and New York Presbyterian have voluntarily stopped suing patients. NYU, which took over the litigious Winthrop University Hospital, stopped it from suing more patients and withdrew approximately 3,000 past lawsuits. Several hospitals associated with the Northwell System have stopped suing patients, and the system announced in 2022 that it would no longer place liens on patients' homes or garnish their wages.

To prevent onerous medical debt collection practices, CSS urges the city and state to change laws and policies to streamline financial assistance. Under current State law, hospitals receive $1.1 billion annually in Indigent Care Pool funds for "uncompensated care" so long as they are in compliance with the hospital financial assistance law. But there are significant deficits between hospitals as to how much they provide in patient discounts and how much support they receive from the indigent care pool. One such measure is A8441/S7625, which would establish a "common" financial assistance application that must be used by all hospitals receiving ICP funds.

The allocation of ICP pool funds has also exacerbated state and city policy decisions regarding the planning and financing of health care resources in New York favor wealthier neighborhoods where patients can pay more directly.[8] Hospitals that serve communities with lower incomes are allowed to close instead of rewarded for providing health care even when their patients cannot pay. As a result, since 2003, 43 hospitals have closed around New York State, dropping the number of beds statewide from almost 74,000 in 2000 to just 53,000 in 2020. These hospital closures mostly occurred in poor neighborhoods where there were fewer patients who could pay – not fewer patients.[9] As a result, Manhattan has 534 beds per 100,000 residents, while Queens has just 144 (see Table 2). The neighborhoods that lost hospital beds are also the neighborhoods where more patients fell ill and died from COVID-

[7] Amanda Dunker and Elisabeth Benjamin, "Discharged Into Debt: New York's Nonprofit Hospitals Garnish Patients' Wages," Community Service Society of New York, July 2022, https://www.cssny.org/publications/entry/discharged-into-debt-new-yorks-nonprofit-hospitals-garnish-patients-wages.

[8] David Robinson, April 10, 2020, LoHud/USA Today, "Why NY hospital closures, cutbacks made COVID-19 pandemic worse," https://www.recordonline.com/news/20200410/why-ny-hospital-closures-cutbacks-made-covid-19-pandemic-worse. C. Campanile, "New York Has Thrown Away 20,000 Beds, Complicating Coronavirus Fight," New York Post, March 17, 2020, https://nypost.com/2020/03/17/new-york-has-thrown-away-20000-hospital-beds-complicating-coronavirus-fight/.

[9] Lena Afridi and Chris Walters, "Land Use Decisions Have Life and Death Consequences," Association for Neighborhood & Housing Development, April 10, 2020, https://anhd.org/blog/land-use-decisions-have-life-and-death-consequences.

19.[10] Patients at well-resourced hospitals in Manhattan have had significantly higher survival rates than those at safety-net hospitals that have been repeatedly underfunded due to hospital financing and health coverage policies.[11] Overall, Black and Hispanic/Latino people experienced a Covid-19 mortality rate 1.6 times as high as that of White people. [12]

Table 2. Hospital Beds Compared to COVID-19 Deaths in New York City's Five Boroughs

Borough	Beds per 100,000 People[13]	COVID-19 Deaths per 100,000 as of Sept. 2022[14]
Bronx	336	563
Brooklyn	214	521
Manhattan	534	351
Queens	144	545
Staten Island	234	519

Recommendations

Much of these structural financing and planning problems are established by state policies. The City Council should engage with State policymakers to ensure all hospitals treat patients with lower incomes the same way and make health equity concerns a meaningful part of the State's certificate of need process. It could also investigate how to use preferential tax treatment as a lever for making the health care system fairer for residents of New York City. CSS asks that the Council consider the following:

- The City could take a more proactive role in ensuring that all patients are able to access hospital financial assistance. That might include investigating the amount of public goods, such as the provision of financial assistance, provided by hospitals in

[10] A. Dunker and E. Benjamin, "How Structural Inequalities in New York's Health Care System Exacerbate Health Disparities During the COVID-19 Pandemic: A Call for Equitable Reform," Community Service Society of New York, June 2020, https://www.cssny.org/news/entry/structural-inequalities-in-new-yorks-health-care-system.
[11] Bryan Rosenthal et al., "Why Surviving the Virus Might Come Down to Which Hospital Admits You," The New York Times, July 1, 2020, https://www.nytimes.com/2020/07/01/nyregion/Coronavirus-hospitals.html.
[12] New York City Department of Health, https://www1.nyc.gov/site/doh/covid/covid-19-data.page.
[13] Rishi K. Wadhera et al., "Variation In Covid-19 Hospitalizations and Deaths Across New York City Boroughs," JAMA 2020 Jun 2; 323 (21): 2192-2195, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7191469/.
[14] New York City Department of Health, https://www1.nyc.gov/site/doh/covid/covid-19-data.page.

the City. Given the City's investment in Health & Hospitals, and the value of the preferential tax treatment those hospitals benefit from as non-profits, it has an interest in ensuring that all hospitals provide their fair share of health care to the City's low-income and minority populations.

- Submit a letter of support to the State legislature and Governor for A8441/S7625 to ensure that patients have equal access to financial assistance at all city hospitals. This bill would establish a "common" financial assistance application, increase eligibility for hospital discounts to 600% of the federal poverty level, and make other improvements to the state financial assistance law.
- Submit a letter of support to Governor Hochul asking her to sign S6522A/A7363A. This bill would prevent medical providers from securing a lien on a patient's home or garnishing a patient's wages when they when a medical debt judgment in court. Two major editorial boards[15] have urged the termination of this practice and seven in 10 New Yorkers support this bill.[16]
- Submit a letter of support to the State legislature and Governor for A6883/S5954, which would reallocate the State's indigent care pool funding to prioritize safety-net hospitals.
- The Health Equity Assessment Act passed the State legislature last session, which means hospitals participating in the certificate of need process will have to submit health equity assessments to the State. The law is currently in the rule-making process. The City could monitor this process and weigh in to make sure that the health equity assessments are conducted independently and result in meaningful community engagement in health planning decisions.

[15] Syracuse Post Standard Editorial Board, "NY should ban lines on patients' homes over medical debts," November 15, 2021, https://www.syracuse.com/opinion/2021/11/ny-should-ban-liens-on-patients-homes-over-medical-debts-editorial-board-opinion.html; Daily News Editorial Board, "Hospitals must stop placing liens on medical debtors' homes," November 14, 2021, https://www.nydailynews.com/opinion/ny-edit-hospital-liens-20211114-ypavmznqyrdvjgr7gwqgp23qqm-story.html

[16] CSSNY.

New York City Council

Committee on Health
Committee on Hospitals
Committee on Land Use

Hearing Testimony:
"The Current State of Access to Hospitals and Healthcare."

Andrew Title, Associate Vice President, Government Affairs
GREATER NEW YORK HOSPITAL ASSOCIATION

Chairs Schulman, Narcisse, and Salamanca and other members of the Committees on Health, Hospitals, and Land Use, my name is Andrew Title, Associate Vice President at the Greater New York Hospital Association (GNYHA). Thank you for the opportunity to testify today.

GNYHA represents every hospital and health system across the five boroughs. Our members believe health care is a human right and proudly take care of all New Yorkers, regardless of ability to pay, as part of their public and not-for-profit mission. They operate 62 acute care hospitals, which—unique among providers—are open 24/7 and deliver lifesaving care in New Yorkers' time of need. These hospitals provided 900,000 inpatient visits in New York City in 2020.[1] There is no substitute for the highly specialized inpatient services hospitals provide and are committed to maintaining.

But hospitals do so much more than that. They are, and always have been, community-based providers. GNYHA's New York City members provided 13 million outpatient visits in 2020. Many are the largest primary and specialty care providers in areas where access to physician offices is limited. In fact, hospitals and their ambulatory care networks provide the majority of health care services to Medicaid and Medicare beneficiaries and the uninsured.

This mirrors a national trend: health care delivery continues to shift from an inpatient hospital setting to an ambulatory setting as more medical procedures can safely take place in ambulatory settings[2] and increases in insurance coverage (including the Affordable Care Act and Medicaid expansion) provide individuals with enhanced health care access.[3] We believe the continued growth of ambulatory services benefits patients and communities by empowering people to seek care early rather than presenting at emergency departments with critical health issues.

GNYHA members understand that outreach and dialogue with our diverse communities is critical during this ongoing transition. They are working with community partners, hiring a diverse, culturally competent workforce, and investing in language access services. Hospitals regularly assess community health needs and design interventions through Community Service Plans to address them. They collect social needs data from patients and make referrals to appropriate community partners. Hospitals also regularly partner with community-based organizations to provide co-located services, determine eligibility for government benefit programs, and promote access to social services.

Any discussion of health care capacity would be incomplete without addressing the ongoing COVID-19 pandemic. New York City hospitals and their dedicated workforce were the first in the country to face the virus' horrific first wave and performed heroically. They led the largest mobilization of health care resources in history—rapidly stepping up bed capacity, coordinating with all levels of government and other hospitals ("load balancing"), mobilizing volunteers and staff, deferring non-urgent surgeries, and developing telehealth infrastructure. They saved thousands of lives. When the spring 2020 wave eased, GNYHA and our members conducted a media campaign urging New Yorkers not to delay health care services (particularly preventive care services) because of COVID-19. Hospitals, government, and clinicians have learned a great deal from the pandemic response through extensive after-action reviews. We are confident in their ability to ensure adequate resources, staff, and equipment during future emergencies by maintaining a flexible infrastructure.

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[1] 39% were covered by Medicaid and 34% by Medicare.

[2] The Delivery System Reform Incentive Payment Program (DSRIP), a State-Federal partnership that aimed to reduce avoidable hospital use by 25% over five years by boosting primary care, accelerated this shift.

[3] Uninsured individuals are more likely to skip preventative care and delay needed health care services. ("The Uninsured and the ACA," Kaiser Family Health Foundation, January 25, 2019.)

At the same time, however, as a result of the COVID-19 pandemic and the preexisting trends mentioned earlier, New York hospitals face severe financial challenges. Patient volume is down,[4] workforce shortages and burnout are making it harder to find staff, inflation is rampant, for-profit insurance companies are denying medically necessary care at unprecedented levels, and drug and medical device costs continue to rise. Perhaps most critically, government reimbursement doesn't come close to keeping up with costs: Medicaid pays hospitals around 63% of cost and Medicare pays around 80% of cost.[5] Hospitals therefore incur significant losses on every single Medicaid and Medicare beneficiary they treat. For safety net hospitals with very few commercially insured patients, that is a recipe for fiscal disaster. And while safety net providers receive billions in State subsidies, last-minute cash infusions make it difficult to plan for the future, invest in facilities, and attract and retain staff.

From 2013 to 2019, hospital inpatient discharges decreased by 8% while outpatient visits increased by 9%. We expect this trend to continue. It strengthens our belief that the best way improve access to health care is to invest in primary and community care. Hospitals must also maintain a flexible infrastructure to always be ready to respond to emergencies and complex health problems. Below are some ways to achieve these goals.

- *Continue improving and expanding outpatient care.* Research shows that most health problems are better managed in the ambulatory setting rather than a full-service hospital designed to treat acute illness that requires many more resources. Investing in outpatient care options is an efficient and effective way to ensure New Yorkers get the care they need.
- *Support the Medicaid program and safety net hospitals.* If we want to help hospitals maintain services, including their inpatient capacity, we need to reimburse them at an adequate level. Albany must finally correct this problem, which is the main cause of recent hospital closures nationally.[6] GNYHA will continue to advocate for fair Medicaid reimbursement and support for safety net hospitals.
- *Close the coverage gap.* The vast majority of New Yorkers are insured. The uninsured are split, roughly evenly, among Medicaid-eligible individuals that lack coverage because of enrollment barriers, people eligible for coverage through the Exchange who find it unaffordable, and undocumented immigrants barred from buying coverage. We support streamlining Medicaid enrollment and public education campaigns to encourage people to sign up, tax credits to make coverage more affordable, and expanding the Essential Plan to cover low-income undocumented immigrants.[7]
- *Address social determinants of health.* Hospitals play an important role in the health of their communities, but many other factors influence health outcomes, including education, housing, transportation, the strength and effectiveness of the social safety net, and systemic racism.

Thank you for the opportunity to testify on this critically important issue. GNYHA and our member hospitals are committed to working with the City Council to improve access to health care.

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[4] According to a GNYHA survey, inpatient discharges in May 2022 declined nearly 9% from January 2022 and emergency room volumes continue to be depressed.

[5] Outpatient rates are generally lower than inpatient rates.

[6] Along with 1199SEIU United Health Care Workers East, we successfully advocated for a 1% Medicaid reimbursement rate increase in the last State budget. However, this falls far short of the need.

[7] The last State budget took positive steps on coverage, granting Medicaid coverage for otherwise eligible senior citizens regardless of immigration status, extending Medicaid for new mothers; increasing Essential Plan eligibility to 250% of the Federal Poverty Level, eliminating premiums for low-income Child Health Plus (CHP) enrollees, and enhancing Medicaid coverage for dual eligible.

NYC Council Committees on Health, Hospitals, and Land Use
Oversight Hearing: The Current State of Access to Hospitals and Healthcare
September 19, 2022

The Community Health Care Association of New York State (CHCANYS) is grateful for the opportunity to provide written testimony to NYC Council Committees on Health, Hospitals, and Land Use. CHCANYS is the statewide primary care association representing New York's 70+ federally qualified health centers (FQHCs), also known as community health centers (CHCs).

Located in medically underserved communities, CHCs provide high quality primary care to everyone, regardless of ability to pay, insurance coverage, or immigration status. NYC's community health centers serve 1.2 million patients at 490 sites across the city. Community health centers are a vital safety net for quality affordable healthcare services for many New Yorkers who otherwise wouldn't have access to healthcare. Among NYC health center patients, 40% are Hispanic, 33% are Black, 17% are White, and 10% are other people of color.

The COVID-19 pandemic exacerbated the longstanding inequities that low-income communities and communities of color have experienced for generations. Due to the pervasive structural inequities that CHC patients regularly encounter, they are at the highest risk for severe negative health consequences resulting from a lack of access to health care and social support services. For New Yorkers who otherwise wouldn't have access to healthcare services due to being uninsured or underinsured, their immigration status, or they lack the ability to pay, community health centers provide timely, affordable, and high-quality health care services. However, more work needs to be done to advance health equity and ensure that all New Yorkers are connected to high quality comprehensive care.

Workforce Shortages Amidst Rising Patient Demand

Community health centers re-invest in the communities where they are located by hiring individuals who live in the communities they serve. However, CHCs are facing difficulty in maintaining delivery of services due to the COVID-19 pandemic exacerbating existing health care provider shortages. In the summer of 2021, CHCANYS surveyed CHCs on top workforce-related challenges and priorities and CHCs reported immediate staffing needs across occupations including Licensed Clinical Social Workers/Licensed Professional Counselors, Psychiatrists, Nurses, Family Physicians/Internal Medicine, Nurse Practitioners/Physician Assistants, Dental Providers, and Case Managers. CHCs also reported insufficient educational pipelines, uncompetitive wages, and high clinical/case load requirements as some of the reasons for recruitment and retention challenges.

Meanwhile, CHCs continue to take on new patients, many of whom may not have received care during the COVID-19 pandemic. CHCs are also performing outreach to reconnect returning patients to care to address their needs. CHCs are delivering more behavioral health visits as compared to before the pandemic. Additionally, many CHCs are stepping up in partnership with DOHMH to get asylees from the Texas border connected to a primary care home.

To ensure that CHCs can continue to provide quality accessible healthcare services for the underserved communities, there needs to be significant investment in healthcare workforce. Investments could include funding for existing workforce programs, developing new loan repayment programs for nursing

and behavioral health staff, especially in communities of color, expanding loan repayment programs for individuals living in medically underserved communities, and increasing workforce development opportunities in medically underserved communities and communities of color.

Telehealth Improves Access Challenges

Telehealth (audio visual and telephonic) has proven to be crucial to ensuring patients are able to receive care in a timely fashion. Telehealth has expanded access to healthcare services by decreasing barriers that would usually inhibit the ability to visit a provider, like lack of transportation, childcare issues, or time off from work. According to a recent survey by CHCANYS, CHCs are seeing fewer no shows for remote visits, especially for behavioral health visits, and CHCs predict that about 37% of patients will request remote visits over the next year. Today, about 25% of CHC visits occur via telehealth. Most of these visits are for behavioral health needs. For providers, the ability to deliver care through telehealth modalities is a much-welcomed flexibility. CHCs continually report that the ability to offer remote working options to their providers has increased their ability to recruit new providers who, without that option, would not be interested in working for the CHC.

The future of telehealth is uncertain. The State's enacted budget requires a lower payment for services delivered when both a provider and patient are at home, which is a model that has allowed CHCs to expand access to behavioral health services without cutting into the ability to provide medical visits in their physical clinic space. With lower payments, CHCs may not be able to continue their high caseloads of behavioral health visits, which already do not meet the demand for services.

The State's Pharmacy Benefit Carve Out Will Reduce Access to Care

The Federal Public Health Service Act 340B drug discount program was enacted in 1992 by Congress to allow safety net providers, including CHCs, access to pharmaceutical drugs at reduced costs and to reinvest the savings to expand access to health care in medically underserved communities. Community health centers rely on the savings generated through the 340B program to fund life-saving programs and initiatives that have no other funding sources. Many CHCs use 340B savings to provide access to free or low-cost drugs and support programs that are not funded by Medicaid. Much of the savings from the 340B program support care for the uninsured.

However, the 340B program is currently under threat due to the State's proposal to carve the Medicaid pharmacy benefit out of managed care and into fee-for-service, which would result in an annual $61M lost across NYC-based health centers. The pharmacy benefit carveout will cause unprecedented disruptions for the safety net community.

In 2021, the NYC Council adopted Res. 1529, calling on the New York State Legislature to pass, and the Governor to sign, S.2520/A.10960, legislation to protect New York State's safety net providers and Special Needs Health Plans by eliminating the Medicaid pharmacy carve-out. Again, we look to the NYC Council to protect community health centers by calling on the State to repeal the pharmacy benefit carve out.

A Looming Financial Crisis

As costs continue to rise across sectors, they have also risen sharply at CHCs. Many CHCs received COVID relief dollars from the federal government, which allowed them to increase wages to stave off some staff turnover and invest in programs to increase access to care, i.e. through telehealth expansion, creation of new access programs, testing and vaccination campaigns, opening of mobile clinics, pharmacy expansion, and more. However, that funding is set to sunset in spring 2023. The ending of federal COVID relief funding at the same time as inflation is rising across the sector (in wages, materials, and physical space) paints an unsettling future for CHCs. With the end of the federal grants, lower payments in telehealth, removal of the 340B benefit, and likelihood of individuals falling off Medicaid enrollment when the public health emergency ends, the ability for CHCs to continue to react nimbly to public health crises is threatened.

Conclusion

CHCANYS is thankful for the opportunity to submit this testimony to highlight the current state of access to healthcare at the City's CHCs. For questions or follow up, please contact Marie Mongeon, Senior Director of Policy, mmongeon@chcanys.org.

Testimony Submitted on behalf of CVHSA
Submitted to the New York City Council Committees on Health, Hospitals and Land Use

Addressing Inequities in Access to Hospital Care across New York City

More than two decades of hospital consolidation, downsizing and closures left some areas of New York City in an extremely vulnerable position when the COVID-19 pandemic hit in March of 2020. There simply were not enough hospital beds to serve desperately ill New Yorkers, especially in predominantly Black and Brown neighborhoods within Queens and Brooklyn. Queens, for example, had lost Mary Immaculate, St John's and Parkway hospitals, while Brooklyn lost Victory Memorial, St. Mary's and Long Island College Hospital (and more recently, mid-pandemic, all inpatient services at Kingsbrook Medical Center). Now is the time to reflect on the inequities in access to care that were so starkly revealed by the pandemic and draw lessons we New Yorkers should take away from this traumatic and tragic experience.

We commend the New York City Council Committees on Health, Hospitals and Land Use for seizing the moment to envision new ways of making the health delivery systems on which New Yorkers rely more responsive to and aligned with actual community needs. The question before us is this: What steps can New York City government take to make access to health care services more equitable through our city? We have three main recommendations:

1. New York City government must advocate for the needs of the most marginalized, medically-underserved New York City residents when health systems submit Certificate of Need (CON) applications to the state proposing mergers, acquisitions, downsizing, relocation or closure of health facilities in the city and when decisions are being made about allocation of state and federal funding support for health facilities.

2. New York City government must create and exercise its own health planning capacity and authority in order to preserve existing health facilities in medically-underserved areas and encourage future location of new health facilities in these areas, rather than in already well-served middle and upper-income neighborhoods.

3. Individuals, communities and boroughs within New York City must have a greater voice in holding the existing health delivery system accountable for meeting their needs and in reshaping the delivery system to better address health disparities and inequities.

New York City has been effectively missing in action while a group of four private health systems – NY Presbyterian, NYU Langone, Mount Sinai and Northwell – have been busy rearranging the health

delivery system on which we all rely to maximize their own market shares and revenues in commercially-insured areas of the city and adjacent suburbs, while watching safety-net hospitals close and leaving a disproportionate burden of indigent care to the public Health and Hospitals system. These systems must receive state approval for such changes through the Certificate of Need (CON) process. As a 2018 report published by the NY Health Foundation recounted, the CON process is non-transparent and fails to engage and listen to communities that would be affected by changes in their hospitals:

- The appointed 24-member body that reviews and votes on CON applications for proposed changes in health facilities, the state Public Health and Health Planning Council (PHHPC), is chaired by an executive of the state's largest health system, Northwell, and includes representatives of the very health systems it is supposed to be overseeing. Only this summer, after a protracted legislative effort by CVHSA members that included battles with the hospital-friendly Cuomo administration, was a second seat for a consumer representative on the council finally created and filled with a Hochul administration appointee who has expertise in Medicaid and medically-underserved communities.

- When CON applications for changes to hospitals and health facilities located with New York City come before the PHHPC, typically no one representing New York City shows up to provide comments on whether the proposed changes would be good or bad for the affected neighborhoods. The summary of proposed transactions produced by the NYS Department of Health to inform council members are also typically devoid of any reference to what city health officials might think about the proposal.

- The absence of city health officials in this crucial regulatory oversight arena is especially unfortunate because people who would be affected by proposed health facility changes are most often unable to raise their own voices to articulate concerns. PHHPC meetings are held on weekdays, and often in Albany, making it difficult for people to take time off work and travel to PHHPC meetings. Moreover, the agendas for the PHHPC committee meetings at which the public theoretically could provide comments are released less than one week in advance of the meetings, forcing health advocates to scramble to identify applications that are concerning, alert affected communities and then digest hundreds of pages of supporting materials in order to prepare comments. The CON process includes no requirement for public hearings for most transactions, and specifies a public hearing for hospital closings 30 days *after* the closure.

How can this sorry situation be changed? One important opportunity is coming up. Last year, CVHSA and our colleagues in the Health Care for All NY coalition succeeded in winning New York State legislative approval of the Health Equity Assessment bill (S1451A/A191A), sponsored by Senate Health Committee Chair Gustavo Rivera and Assembly Health Committee Chair Richard Gottfried, who aptly described it as "landmark" legislation. Signed into law in late December by Gov. Kathy Hochul, this new act amends the CON process and will for the first time require hospitals and most other health facilities to provide state health regulators with an independent assessment of how proposed transactions, such as reductions or elimination of services, are likely to affect medically-underserved people.

Rulemaking to implement the Health Equity Assessment Act is underway this fall, with proposed rules due out by December 1. There are many elements of this new law that would benefit from strong implementing rules, such as the method by which "meaningful engagement" of the affected community would be carried out. We have attached a recent letter from some of our organizations to NYS DOH officials identifying key priorities for these rules. We encourage your City Council committees to contact

the NYS DOH, if you have not already done so, and urge promulgation of strong rules that will help truly assess whether proposed health facility changes would improve or reduce access to services for medically-underserved New York City residents.

We further urge that the New York City Council fund the creation of capacity with city government, potentially at the city Department of Health or in an Office of Patient Advocate, as Councilmember Carlina Rivera has urged, to routinely review and prepare comments on CON applications as they are submitted to the NYS Department of Health. Such comments could be informed by outreach to affected communities and surveys or listening sessions with patients within medically-underserved groups. Such an office could also provide analysis of and comments on ways in which state indigent care funds could be more equitably distributed to ensure access to care for the most vulnerable patients.

We specifically urge that city government explore whether it is possible to regain Health Systems Agency (HSA) status and authority to provide official comments to the state DOH and PHHPC on CON applications submitted by health facilities located within the city. When the HSAs across the state and nation were defunded years ago, New York City did not provide the needed funds to continue this important function. Only one HSA now exists anywhere in the state– Common Ground Health in the Rochester region. However, we believe the authority for HSAs still exists within state law, as evidenced by state DOH summaries of CON applications that routinely say: HAS recommendation: N/A.

Further, we urge that the NYC DOH be given both legislative direction and budgetary support for creating a robust system of health planning that can, on an annual basis, predict the need for health care delivery capacity by borough and identify existing gaps in the delivery system. Citywide health planning could be strengthened and supported in gathering and analyzing data and patient experiences. Such a system would enable the city and state Departments of Health to prioritize approval of health facility transformation and capital improvement funding for projects that would fill identified gaps. It would also clearly communicate public need for additional or changed capacity by borough, providing a basis for evaluation of health facilities' Certificate of Need (CON) applications for proposed projects as to whether they would address identified gaps, exacerbate those gaps or, conversely, create additional capacity where it is not needed. It is possible that some funding support for such a citywide health planning effort might be available through the state's proposed creation of Health Equity Regional Organizations (HEROs) under its proposed Medicaid 1115 waiver.

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These comments are submitted on September 22, 2022, by CVHSA coordinator Lois Uttley on behalf of the organizations participating in Community Voices for Health System Accountability. These include the Center for Independence of the Disabled, the Children's Defense Fund, the Coalition for Asian American Children and Families, the Coalition to Save and Transform Mount Vernon Hospital, Community Catalyst's Hospital Equity and Accountability Project, the Community Service Society-NY, Empire Justice Center, March of Dimes, Medicaid Matters-NY, Metro NY Health Care for All, Neighbors to Save Rivington House, the New York Immigration Coalition, Schenectady Coalition for Healthcare Access and the StateWide Senior Action Council.

For further information, contact Lois Uttley, Senior Advisor, Hospital Equity and Accountability Project for Community Catalyst at luttley@communitycatalyst.org or 212.870.2010 (office, Monday through Thursday) or 518.281.4134 (cell).

July 28, 2022

John Morley, M.D.
Deputy Commissioner
Office of Primary Care and Health Systems Management
New York State Department of Health
Corning Tower, Empire State Plaza
Albany NY 12237

Dear Dr. Morley:

Many thanks for inviting a group of us to meet with you and your colleagues on July 18, as a follow up to our previous meeting. We greatly appreciate the opportunity to begin a conversation with you about rules implementing the state's Health Equity Assessment Act. We consider this new law to be an important step forward in reforming the state's Certificate of Need process to better incorporate consideration of health equity by assessing how proposed health facility transactions might affect medically-underserved New Yorkers. As promised, we have compiled for your consideration our top six priorities for interpretation of key elements of the law, along with some of our thinking about these elements.

1. **"The health equity impact assessment shall be prepared for the applicant by an independent entity…"**

    A. **Lack conflict of interest or bias on part of the independent entity:** We firmly believe that the assessment should be prepared by an independent entity that has no ongoing financial relationship with the applicant and is not involved in preparation of the pending Certificate of Need application to be considered. In other words, there must be no conflict of interest or bias toward the applicant on the part of the independent entity in its assessment of the likely impact of a transaction on medically-underserved people.

    B. **Demonstrated credentials to conduct such an assessment**: Further, such independent entity must have demonstrated credentials and experience in the assessment of access to health care for medically-underserved people, addressing health disparities and advancing health equity. Examples of such entities include schools of public health and non-profits such as the Arthur Ashe Institute for Urban Health or Common Ground Health. We would be happy to work with the Department to begin scoping out the required qualifications for

assessor agencies, develop a list of potential organizations that could meet such qualifications and outline the needed scope and process for such assessment.

C. **Potential role for the HEROs:** We noted your suggestion that the Health Equity Regional Organizations (HEROs) that might be created through the state's pending Medicaid 1115 waiver application could possibly play a role in the assessment process. We have two concerns about this idea. First, it is unclear at this juncture when those HEROs might become fully operational, and we think it's unlikely that would be before the Health Equity Assessment Act takes effect in June of 2023. Second, since hospitals, health systems and other providers would be partners in HEROs, they could unfairly influence any assessment that would be carried out by a HERO regarding proposed transactions involving those health systems. We do think HEROs could potentially play a role down the line in assembling and providing data and data analysis about the health status and needs of the population within their geographic regions, which could help inform an assessment performed by an independent entity. Another alternative would be to provide a role for the Social Determinants of Health Networks that will be comprised of community based organizations. But if they do play a role, it should not become an unfunded mandate for these already under-resourced organizations.

2. A health equity assessment is required if a transaction would result in "elimination or substantial reduction in a hospital service"

A. Elimination of a hospital service: We suggest that elimination of a hospital service be explicitly defined to include elimination of entire units of the hospitals -- such as labor and delivery, the emergency department, a dental clinic or a psychiatric or substance use treatment unit. These are precisely the type of reductions in access to care that most negatively affect medically-underserved New Yorkers, such as pregnant women living in rural areas who are forced to travel long distances for childbirth when local maternity units are closed; or people with low incomes who are left without timely, affordable dental care when hospitals eliminate their clinics. We are especially concerned that the Department has shifted review of proposed eliminations of such units to a "limited review" process that offers no opportunity for community engagement and never comes up for a public discussion at the Public Health and Health Planning Council (PHHPC).[1] We believe such transactions should be considered for full review and subjected to a health equity assessment. In our meeting, we requested a copy of the "limited review" policy and/or procedures guidelines. Would it be possible for the Department to share that with us?

We further urge that a health equity assessment be required when a hospital is eliminating all inpatient services and transforming a facility into a "medical village" or other type of outpatient or rehabilitation facility. We further urge the Department to seek reform of the "notice" process being used when a hospital plans to close entirely. The closure of an entire

[1] For example, Mount Sinai Beth Israel was allowed to close multiple units at the facility – including labor and delivery and cardiac surgery – through successive limited review CON applications for which no comments were sought from the affected local residents.

hospital can have devastating consequences for the medically-underserved people enumerated in the Health Equity Assessment Act, and should be subjected to full CON review and a health equity assessment. Perhaps the Department could include such a measure in its upcoming program bills that it submits to the Governor for her review as part of the FY24 budgeting process.

Finally, we urge that a health equity assessment be required for the elimination of a single service when the loss of that service would negatively affect one or more of the groups of medically-underserved people enumerated in the law. For example, a proposed hospital merger that would require one of the facilities to end abortion services or post-partum tubal ligations would negatively affect women and other people capable of pregnancy, especially those who have low incomes or who suffer discrimination because they are Black, Latinx or other racial/ethnic minorities. Similarly, elimination of gender-affirming surgery would negatively affect transgender patients, and elimination of cardiac surgery could disproportionately affect older patients with heart problems. For such patients, obtaining access to this care elsewhere might be challenging. Allowing hospitals to argue that only a small fraction of surgeries, or of gynecological care, is being eliminated, would potentially allow them to escape a needed health equity assessment.

B. **Substantial reduction of a hospital service:** We suggest that "substantial" be defined as a reduction of 20% or more of an individual service or category of services. Again, this is a place where how we count will matter. For example, elimination of pediatric or geriatric psychiatric services should not be counted as constituting only a small reduction in a hospital's psychiatric services. Similarly, re-locating an outpatient clinic site, such as the proposed relocation of Montefiore's Family Practice Clinic, may not appear to cause a reduction in services, but actually could have the effect of sharply reducing or eliminating access to those services for people where the clinic historically had been located.

3. **Exemption from a health equity assessment requirement for any establishment, merger or acquisition of a hospital "if it would not result in the elimination or substantial reduction, expansion, addition or change in location of a hospital service"**

We are concerned that CON applicants seeking approval for establishment, mergers or acquisitions of a hospital will be incentivized to declare that their transactions will not result in any changes to hospital services, in order to qualify for an exemption from the assessment requirements. Such an applicant could then a year or two later announce eliminations, reductions or changes in locations of services that actually had been planned from the start. While it appears that such changes would then require a new CON application, the merger of two facilities or the acquisition of a facility by a health system would then be so far along that it would be difficult or impossible to reconsider the merits of the original CON approval, with full knowledge of the planned elimination of or reduction in services. Here are some suggestions about how to avoid such "gaming" of the process:

A. **Conditions should be attached to applications exempted from review**. CON applicants seeking exemptions from the health equity assessment requirement must agree, as a condition of CON approval, that no services will be eliminated, reduced or relocated within a specified period of time (perhaps five years) following approval of the merger, acquisition or similar transaction.

B. **Exempted applications should receive limited life approvals with review after a period of time.** To guard against violations of such conditions, applicants given an exemption should receive a limited-life CON subject to review after a suitable period of time (perhaps at three years and five years) in the same way that ambulatory surgery CONs are now given limited life approvals subject to review concerning whether they have met targets for provision of Medicaid service and charity care.

C. **The state could explore such possibilities as requiring a performance bond or monetary pledge to guarantee maintenance of the services, or attaching penalties for violations of CON conditions.**

4. **"In considering whether and on what terms to approve an application, the Commissioner and the Council (PHHPC), as the case may be, shall consider the health equity impact statement."**

We would like to urge that the words "shall consider" in this sentence of the law be interpreted to require a proscribed process of evaluating the assessment and any steps that might be necessary to eliminate or reduce a negative impact on medically-underserved people. For example, the rules might say something like "NYS DOH staff, including the Office of Minority Health, must review the assessment and prepare proposed contingencies and conditions for attachment to any CON approval in order to address any identified negative impacts on medically-underserved people in the applicant's service area. When a CON application is being forwarded to the Council for consideration, the DOH summary of the application must include a review of key points of the assessment and any needed conditions to address negative impacts on medically-underserved people."

5. **"The health equity impact assessment shall include the meaningful engagement of public health experts, organizations representing employees of the applicant, stakeholders, and community leaders and residents of the applicant's service area."**

Meaningful engagement of community leaders and residents of the applicant's service area must be sufficiently robust to surface any likely negative impacts on medically-underserved people, as well as potential methods of addressing such impacts. We suggest that meaningful engagement procedures be specified in the rules, and potentially include such requirements:

A. **Meaningful engagement should be carried out through at least two of the following methods:** A community forum in the affected community at night or on a weekend, focus groups (in-person or virtual) with a representative sample of community residents, interviews with leaders of community-based non-profits familiar with the community's health needs and on-line surveys of community residents. Offering of virtual options would be important for those community members who suffer from chronic illness, have

Disabilities or are vulnerable older adults. All options should include measures to ensure participation by those residents for whom English is not their primary language, such as providing surveys in multiple languages and interpreters for community forums.

B. **Sufficient advance notice of community engagement activities must be given**. We suggest that such notice should be carried out at least four weeks in advance, through multiple communications vehicles, including notices in local and/or ethnic newspapers, notice to local and state officials representing the area, posting of notices at the facility submitting the CON application and postings on the facility's website and social media. Such a notice should fully explain the proposed project, including spelling out whether services would be relocated, reduced or eliminated, and explain how residents of affected communities can provide comments. Notices should be provided in languages common in the service area.

C. Information and data about potential health equity impacts should be shared with community stakeholders for feedback and input. Any data identifying potential health impacts that is identified, collected or analyzed in initial stages of a health equity assessment should be shared with community leaders and residents for their feedback and suggestions.

6. **The assessment shall include identifying "the means of assuring effective communication between the applicant's hospital and health related service staff and people of limited English-speaking ability and those with speech, hearing or visual impairments."**

   These requirements are especially important for two groups of the medically-underserved people enumerated in the law: immigrants and people with disabilities. We urge the Department of work with the New York Immigration Coalition, Make the Road and other groups representing immigrant communities to determine oral and written standards for communities with people who have limited English proficiency. Similarly, we suggest the Department work with the Center for Independence of the Disabled (CIDNY) and the NY Association on Independent Living to determine standards for communication with people with disabilities.

We look forward to further discussion with you of these priorities, as well as other aspects of the statute for which we have suggestions (such as how to define various groups of medically-undeserved people enumerated in the law and guidelines for how hospitals can define their service areas). We hope you and your colleagues are also open to discussion of other CON reform measures that could better ensure community engagement in oversight and regulation of the health facilities on which they depend for their health care.

Sincerely,

Lois Uttley Community Catalyst	Elisabeth Benjamin Community Service Society NY	Lara Kassel Medicaid Matters NY
Arline Cruz Make the Road NY	Seungun Chun NY Immigration Coalition	Arthur Butler Schenectady Coalition for Healthcare Access

Testimony on Access to Hospitals and Healthcare in New York City
for the 19 September 2022 Joint Hearing
of the Committees on Health, Hospitals, and Land Use
of the Council of the City of New York

by

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Submitted 22 September 2022

I thank the chairs, the Hon. Lynn Schulman, the Hon. Mercedes Narcisse, and the Hon. Rafael Salamanca Jr., for convening this hearing, and I thank you for the opportunity to testify on these crucial topics. One indicator of their urgency, as I will describe, is that even before the COVID-19 pandemic, New York City had lost 4,400 hospital beds since the year 2000, an estimated 17 percent of the beds it had in 2000. And, tragically, one Brooklyn hospital closed last year, amid the continuing pandemic.

Background: My name is Deborah Socolar. I live in upper Manhattan where I grew up and I returned several years ago. I have a Masters in Public Health and have been working on issues of access to health care and health policy for over 35 years, in these arenas among others:

- first with the Boston Mayor's Committee on Access to Health Care;
- then for over 20 years at the Boston University School of Public Health (BUSPH), as a co-principal of the Access and Affordability Monitoring Project and then co-director of the Health Reform Program (www.healthreformprogram.org);
- in the community's fight to save its only hospital, in Quincy, Mass., where I used to live;
- as a longtime national board member of the Universal Health Care Action Network;
- most recently as an active member of the Kingsbrook Community Action Committee, trying to protect access to care and to save Kingsbrook Jewish Medical Center in East Flatbush; and
- as a member of several groups promoting prevention of COVID (including the People's CDC, VaxPlus, and Marked By COVID).

At the Boston University School of Public Health, I worked with Professor Alan Sager, a nationally-recognized expert on decades of urban hospital closings, addressing risks and predictors of closings in New York as well as Massachusetts and elsewhere. *But please note that my comments and views here are my own alone; I am not representing any organization.*

I applaud the Committees on Health, Hospitals, and Land Use for addressing urgent problems of inequities in access to care and hospitals, which predated the pandemic but were highlighted and exacerbated by it. I welcome this focus on what's needed to address access barriers now and to avoid future calamities -- and all the chairs' long-standing attention to inequitable distribution of health care and hospital capacity in New York City. I was grateful to hear the careful questions from all three committee chairs in Monday's hearing, and your insistence on the urgency of improving access to care in communities long underserved. And I greatly appreciate the thoughtful joint committee staff report.

These issues are likely to become very visible again in coming months. As federal pandemic relief funding ends, New York (like the nation as a whole) faces great risk of hospital closings, especially for facilities that largely serve poor and uninsured patients. Further, even if hospitalizations from acute COVID infection are declining, there is unpredictable need for hospital care -- for strokes, heart attacks, kidney problems, and more -- in patients weeks or months after their infection, amid the clearly growing need for chronic care in the still-expanding population with Long COVID.

My testimony will address in turn these four inter-connected topics:

- Hospital capacity in New York and in general
- An array of access concerns, including some in specific New York City communities and institutions, in brief
- The loss of Kingsbrook Jewish Medical Center in Brooklyn
- Several related state-level policy issues that ought to concern City Council members.

HOSPITAL CAPACITY

Your report justifiably highlighted the dangerously low hospital bed-to-population ratios in the outer boroughs, particularly Brooklyn and Queens, and how low those are compared to the national average.

In connection with these bed-to-resident ratios, it's worth also noting that

- **Bed tallies citywide that roughly match the United States' average are not enough**, not only because NYC hospitals draw patients from beyond the city, but also because **the U.S. ratio of beds to population is significantly low by international standards --** lower than in many other wealthy developed nations which, notably, provide health care to all and at lower cost. The U.S. has fewer hospital beds per thousand people than 28 other wealthy countries.
- **Brooklyn and Queens are this nation's second and fourth most-densely-populated counties**. (Among other consequences, as traffic is a huge challenge, distances to a hospital that might seem manageable elsewhere can be very hard to negotiate in NYC.)

Near the end, your report includes an important list of 18 hospital closings in NYC since 2003 --- documenting a tragic loss of community resources that the city has paid dearly for, especially during the peak of the pandemic. **That total should actually be 19 -- as it should also include the devastating closure in June 2021 of Kingsbrook Jewish Medical Center in East Flatbush in central Brooklyn** (which I'll discuss in some detail below).

It is also important to recognize that many beds are lost to hospitals' shrinkage of their inpatient capacity, as well as to closings. Last year, my long-time colleague at BUSPH, Prof. Sager, calculated these estimates, which reflect the impact of both closings and bed cuts:

- **From the year 2000 until the pandemic, NYC had lost 4,400 hospital beds, equal to 17 percent of the city's bed supply in 2000.**

- **Notably, in Brooklyn alone (even before the closing of Kingsbrook), about 1,600 hospital beds were lost between 2000 and the start of the pandemic -- equaling 24 percent of the borough's capacity in 2000.**

Hospitals nationwide have been cutting beds for decades, with the rationale that patient stays are getting shorter, many services are shifting to outpatient care -- and some assume that care outside the hospital is always cheaper. And as you know, New York State, under several governors, has promoted hospital closings, with the assumption that excess capacity causes this state's high costs, that closing hospitals is essential to save money, and that money should be spent in poorer communities on outpatient care rather than on hospital care.

These rationales, and the push to cut hospital capacity, must now be re-examined closely, in light of the lessons of the pandemic. They rest in part on mythology about costs, which time does not permit me to address here, except to note that the real incremental cost of an additional hospital recuperative day is likely very low in most cases (but issues of in-hospital infection risk now do weigh most strongly in favor of discharge, if circumstances for a patient at home are safe), and that there is little evidence that closings have in fact saved money.

In light of both the pandemic and prior losses of valuable community resources, please consider:

- **Both for the ongoing needs of underserved communities and to be prepared for disasters, we should assume that all existing hospital capacity is needed** (unless proven otherwise in a detailed needs assessment).
- Poor communities certainly do need more primary care and more outpatient specialty care -- but they should not be forced, in exchange, to forfeit hospital inpatient resources that are vital when people are very sick. **Richer communities are not forced to choose between inpatient and outpatient care, and poor communities should not, either**.
- **The pandemic vividly revealed the need for hospital standby capacity**. Suddenly, almost overnight, hospitals across New York, as you know, were having to care for hundreds of patients in hallways and converted conference rooms. We must not allow that situation to arise in a future calamity, whether a future pandemic, flood, or other disaster. Unless an institution is hoping for a big profit from sale of real estate, it costs very little to mothball unused beds (with enough heat to keep the pipes from freezing, pest control, and perhaps very occasional cleaning). So New York, both the city and state, need to address how to require and support the maintenance of some reserve capacity.
- The pandemic is painfully revealing the **risk of contagion in shared hospital rooms**. (See, for example, the work of Dr. Abraar Karan.) Though that should partly be addressed by more careful testing, I worry that in many hospitals and nursing homes, many patients in this pandemic may still not be getting treated in single rooms nor in rooms with negative air pressure. Yet in New York Certificate of Need applications for hospital construction projects, some hospitals upstate have recently told the NY Public Health Policy and Planning Commission (PHHPC) that the standard for hospital care should now be single-bedded rooms. Rather than allowing any more

hospitals to cut beds or close, should NYC perhaps be requiring them to use the space to convert to single rooms?

- As noted earlier, though hospitalizations from acute COVID infection are declining, we cannot yet project the need for **post-COVID hospitalizations** for strokes, heart attacks, and other problems that have been arising in COVID patients weeks or months after their infection.

I am glad that your thoughtful report highlighted staffing as well as licensed beds. Though I have just been addressing physical beds, clearly they will not be available if there are no caregivers to staff them. And as the New York State Nurses Association and National Nurses Union have often stressed, **improving staffing ratios is crucial to both retention and recruitment of nurses, as well as to the quality of care** for patients. **Understaffing is a vicious cycle** now greatly exacerbated by the loss of so many hospital workers to disability from Long COVID -- and even death -- as well as other factors including burnout from the intensity of pandemic care for two-plus years, especially in understaffed facilities.

RELATED ACCESS CONCERNS AND SPECIFIC COMMUNITIES

I will just briefly note several related and currently pressing issues of access to hospital care, and of health care resource inequities in New York City, and especially the outer boroughs.

* There is a massive ongoing issue of underfunding, understaffing, and inadequate quality of care at safety-net hospitals, both public and private. It's crucial to distribute Indigent Care Pool funds in ways that prioritize those hospitals that actually serve poor patients, as every other state does.

* The city and state have suffered for years from an ongoing loss of psych beds. This was worsened when many switched to COVID care. It's urgent to look into how many of those have been lost permanently.

- One example is that when the One Brooklyn Health system announced its plans for the Kingsbrook Jewish Medical Center in September 2020, it promised to keep the two psych units open there, including a very valuable geriatric psych unit. But I believe both of those have already been closed. OBH pleads that it could not find MDs to oversee the service. Why did neither the City nor the state step in, perhaps to assign an appropriate physician there to ensure that the units could survive?
- Also, attention should be paid to what has happened or is planned at Allen Psych, in a vital community hospital at the northern tip of Manhattan, which Columbia wished to convert largely to a facility to attract high-cost cardiac cases internationally. (This page on its "featured" services lists neither of those. https://www.nyp.org/allenhospital)

* Another issue is that at least some hospitals in the big private systems appear to be shifting their outpatient services and resources, reducing them even further in poorer communities, and building new capacity in wealthier areas.

- Please look at what is happening in the Bronx, where Montefiore plans to squeeze two FQHC sites into one inadequate space, moving many physicians to a less accessible location farther from longtime patients -- even as Montefiore builds up a concierge service in Hudson Yards.
- Similarly, poorer patients would suffer diminished access to care under Mount Sinai's plans to disperse the services now located at the New York Eye and Ear Infirmary.

* Regarding the threat of closings, consider also two near-misses:

- Closing or radical shrinkage of St. John Episcopal in Rockaway, which had been pushed by Gov. Cuomo's Health Dept. consultants, was averted -- but for how long? The hospital needs substantial support to upgrade services so that access can be maintained where travel to get care is already difficult.
- Also recently, the proposal (now stopped) for closings and cuts of inpatient capacity at two VA hospitals in NYC did not seem to draw much attention, even though other nearby hospitals could have become even more overloaded if those plans had proceeded.

KINGSBROOK HOSPITAL CLOSING

Kingsbrook Jewish Medical Center was part of the One Brooklyn Health (OBH) system, along with Brookdale Hospital and Interfaith. Last year, amid the ongoing pandemic, an outdated plan promoted by former Governor Cuomo was used to justify closing central Brooklyn's Kingsbrook Jewish Medical Center at the end of June. Kingbrook was the only private hospital in New York State among the nation's 50 "most racially inclusive" in a 2021 Lown Institute analysis.

OBH, and city and state officials who promoted the plan to close Kingsbrook, asserted that there would be no problem absorbing the inpatient volume served by Kingsbrook, whether at the two affiliated hospitals or elsewhere. But closing 200 beds at Kingsbrook was especially risky amid the pandemic, as many Brooklyn hospitals, despite having few COVID-19 cases, remained crowded.

As community advocates in the Kingsbrook Community Action Committee predicted, however, since the June 2021 closing of Kingsbrook, these communities in central Brooklyn have consistently suffered severe shortages of hospital capacity, particularly ICU capacity. Kingsbrook had 20 ICU/CCU beds, and, as I understand it, their closure was only partially offset by a very small expansion of ICU capacity at its affiliates. So OBH's remaining ICUs have been extremely busy -- as they were during much of 2020 and the first half of 2021, before Kingsbrook closed -- even as ICU occupancy elsewhere in the city has declined. Through 2022, I have in many (though not all) weeks, checked the weekly reports of ICU occupancy and bed availability as published in the New York Times, and have found

- During 2022 to date, in half the weeks or more (at least 18 of those first 37 weeks of the year), **the intensive care units at Brookdale, Interfaith, or both have been among the four ICUs in New York City with the highest occupancy rates**.

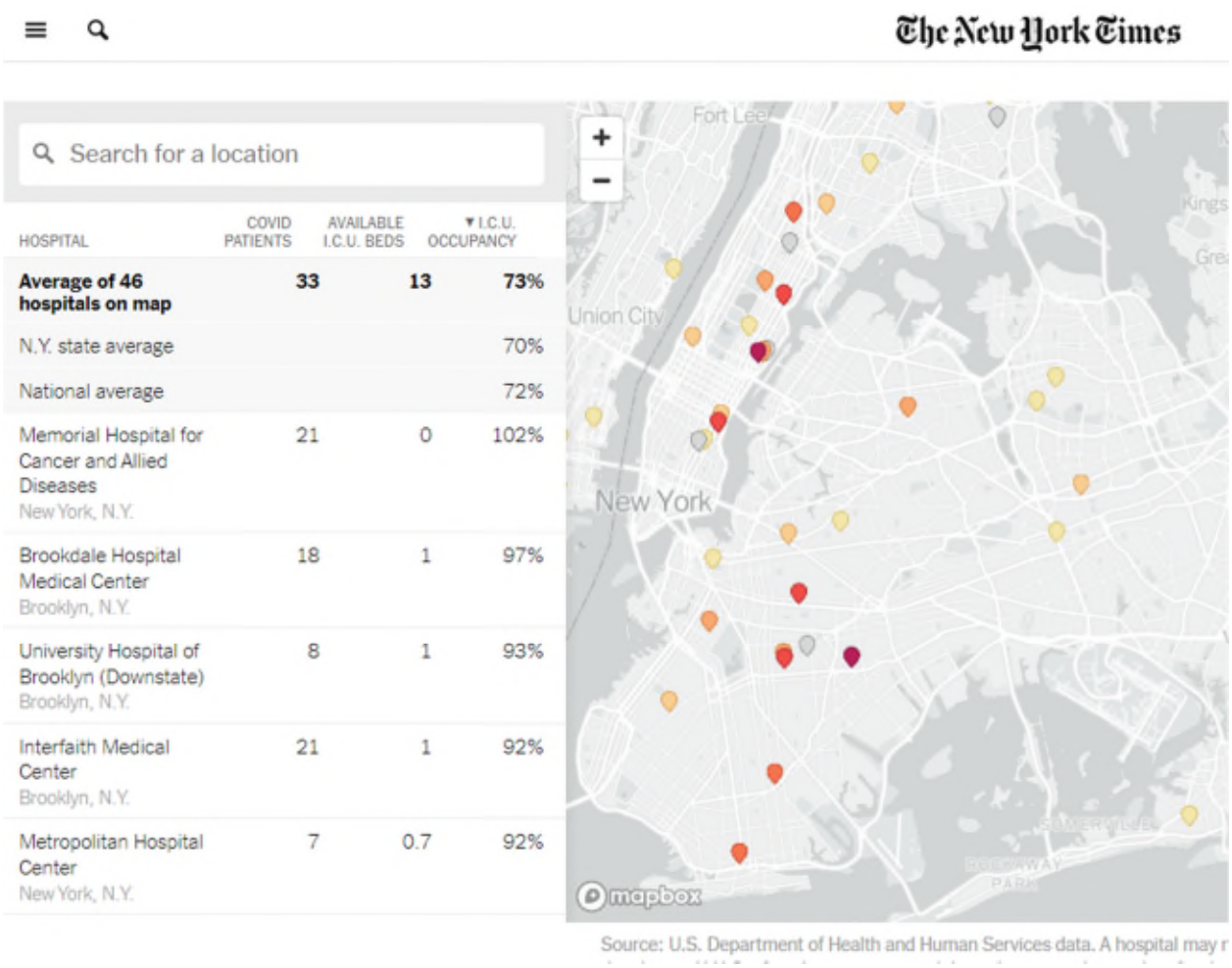
- For example, very recently**, in the week ending 25 August 2022, Brookdale had the second highest ICU occupancy percentage among NYC hospitals, and Interfaith was fourth highest.** (See map below, from https://www.nytimes.com/interactive/2020/us/covid-hospitals-near-you.html, accessed 29 August 2022.) Worse, central Brooklyn had the ICUs with the 2nd, 3rd, and 4th highest occupancy rates in the city -- Brookdale's ICU averaged 97% full; SUNY Downstate/University Hospital's ICU averaged 93% full; and Interfaith's ICU averaged 92% full.

- The table below compares ICU occupancy and bed availability (unoccupied beds) in early June 2021, before Kingsbrook closed, to two spot-checked weeks since then (including the recent week shown in the map), and shows **how ICU bed availability in Brooklyn has fallen**.

The downward spiral of neglect at Kingsbrook, and the aftermath of its closing, are discussed in this substantial piece, "After the Hospital Leaves Town" (in Crain's NY Business, by Maya Kaufman).

Patients and hospital workers aren't interchangeable cogs in a health care machine. Because people don't know where to go, cannot readily get to other hospitals, or don't trust unfamiliar caregivers, closing a hospital can mean that as much as 30 percent of its inpatient volume disappears.

Indeed, OBH had projected that its other two hospitals, would each attract only 15 percent of Kingsbrook's inpatient volume, while "other utilization will either be captured by other area hospitals or will not materialize."(See PHHPC 9/24/20, PDF pgs.9-10) State regulators irresponsibly accepted this as an adequate plan. After the closing, in Kingsbrook's emergency room, as patients needing admission were told they had to transfer, staff reported, some cried and some left, refusing transfer.



The New York Times

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HOSPITAL	COVID PATIENTS	AVAILABLE I.C.U. BEDS	▼I.C.U. OCCUPANCY
Average of 46 hospitals on map	**33**	**13**	**73%**
N.Y. state average			70%
National average			72%
Memorial Hospital for Cancer and Allied Diseases New York, N.Y.	21	0	102%
Brookdale Hospital Medical Center Brooklyn, N.Y.	18	1	97%
University Hospital of Brooklyn (Downstate) Brooklyn, N.Y.	8	1	93%
Interfaith Medical Center Brooklyn, N.Y.	21	1	92%
Metropolitan Hospital Center New York, N.Y.	7	0.7	92%

Source: U.S. Department of Health and Human Services data. A hospital may r

BROOKLYN ICU's, BEFORE AND SINCE KINGSBROOK'S JUNE 2021 CLOSING

Source: https://www.nytimes.com/interactive/2020/us/covid-hospitals-near-you.html (Accessed 6/9/21, 5/6/22, and 9/19/22)

	Intensive care unit occupancy %, average for week			**Available (unoccupied) ICU beds, average for week**		
	week ending **6/3/21**	week ending **4/28/22**	week ending **9/15/22**	week ending **6/3/21**	week ending **4/28/22**	week ending **9/15/22**
NY state average	*61%*	*72%*	*73%*			
National average	*70%*	*71%*	*73%*			
Brookdale - OBH	**92%**	**94%**	**98%**	**3**	**2**	**0.6**
NY Presbyterian Brooklyn Methodist	63%	88%	90%	17	4	3
Interfaith - OBH	**97%**	**92%**	**87%**	**0.4**	**1**	**2**
Coney Island	78%	84%	85%	11	6	6
Univ./SUNY/Downstate	75%	83%	82%	4	2	3
Maimonides	64%	59%	78%	25	27	12
NY Cmty Hosp. of Bklyn	92%	87%	78%	2	2	14
Kings County	69%	73%	77%	13	11	9
Woodhull	56%	68%	77%	8	8	6
Brooklyn Hosp. Ctr. - Downtown	67%	83%	72%	6	3	5
Wyckoff Heights	79%	71%	58%	6	7	10
Kingsbrook - OBH	**72%**	**----**	**----**	**6****	**----**	**----**
ICU beds avail. in 12 Brooklyn hospitals*				**101.4**	**73**	**70.6**

*NY Times omits Brooklyn hospitals of Mt. Sinai and NYU Langone systems, tallying them with Manhattan affiliates.

**Most of Kingsbrook's 20 ICU/CCU beds were still busy till June 2021, when OBH stopped admitting prior to closing.

IMPORTANT STATE POLICY CONCERNS

Several state policy matters are vital issues for the City Council to monitor and speak up about:

- As mentioned above, distribution of the ICP funds to support safety-net hospitals is crucial. Recent federal relief dollars and a large state appropriation this year could help support endangered facilities, but the funds need to be targeted to public and private safety-net facilities that serve Medicaid and uninsured patients. And there needs to be much greater transparency from the state about the use of those federal relief funds; other states have done much more to solicit public input on their use and to provide public information on how the relief has been distributed.
- The PHHPC currently claims its CON reviews do not have the power to address hospital closings. This needs to change! AM JoAnn Simon has long had a useful bill addressing issues related to hospital closings. I hope that she will refile it, and that Council members will support it.

In reality, New York needs a statewide moratorium on hospital closings and capacity cuts until the pandemic is clearly over -- and its impact has been carefully assessed. The governor should use her long-standing public health emergency powers to protect communities from Brooklyn and Far Rockaway to Buffalo against losing valuable hospital services. In 2021, Sen. Jamaal Bailey had a bill for a moratorium on hospital closings during pandemic -- a pandemic that continues.

Finally, it is vital to recognize that we cannot know the future impact on need for hospital care of the growing epidemic of Long COVID.

ALL HOSPITAL CAPACITY SHOULD BE ASSUMED NEEDED UNLESS PROVEN OTHERWISE.

New York has extraordinarily high hospital spending per person, with far too much money of it spent on enhancing highly specialized and lavish care for the well-insured. The state could and should, instead, mobilize money already available today to raise the floor for care of people now underserved, and to help finance vital primary care, save community hospitals, and provide needed care to all.

Thank you.

Personal Testimony to Save New York Eye and Ear Infirmary in East Village

The New York Eye and Ear Infirmary located on 2nd Ave and 14th St is the oldest specialty hospital in the Western Hemisphere. It has resided in its current location for over 150 years.

Mount Sinai plans to close that location, sell the property to a developer and use those proceeds to subsidize other money losing hospitals in its health system.

Moving New York Eye and Ear Infirmary out of its current location will deprive many thousands of patients from world class care at an accessible location.

We cannot let this happen.

Please stop Mount Sinai from moving forward with its plans to close and sell that historic and valuable healthcare institution.

Thank you.

Paul Lee, MD

President of the New York Eye and Ear Infirmary Alumni Association

Testimony of Richard S. Koplin, MD on the Imminent Closure of the New York Eye and Ear Infirmary (NYEEI)

New York City Council Joint Committees Hearing on Hospitals and Land Use
September 19, 2022

Good afternoon, I am Richard S. Koplin, MD, and I am writing as an advocate for the New York Eye and Ear Infirmary (NYEEI). I was trained at the NYEEI and have been an attending with offices at the institution for over 45 years. I remain an active clinician at the NYEEI and presently co-direct its Cataract Division. I was the first Director for Resident training in Ophthalmology at the New York Eye and Ear Infirmary (now of Mount Sinai), the founder and Director of the New York Eye Trauma Service (of the New York Eye and Ear Infirmary), and Founder and Director of the Bioengineering and Computer Science Division of the NYEEI, with inventions used world-wide. In all, I represent more than 25% of the institutions entire 200-year history. I believe I can speak authoritatively and accurately about the Infirmary's historic clinical training, teaching and research capabilities, the threats to its very existence, and its future potential.

Two hundred years ago, two esteemed New York City physicians acted on a vision --- one that was unique and would prove to be genius. They would establish a specialty ophthalmologic medical institution in New York City --- the first of its kind in the western hemisphere (prior to its founding the medical establishment frowned on specialty care). Their intent was to serve a growing community in need (1820). The founders, Drs. Kearny and Delafield, understanding early American medicine's needs --- especially in New York City, America's gateway city --- ignited the imagination of others around the nation and subsequently a dozen more specialty ophthalmic institutions were founded following our template.

The Infirmary has always served patients representing the melting pot that is New York City: including undocumented individuals, people of color, the ongoing immigrant population, union members, retirees, and many of those whose primary healthcare is covered through Medicare and Medicaid. As well, we have been the central referral resource for eye trauma to our police and fire departments. Proudly, the NYEEI trained the first black ophthalmologist (born a slave!) who attended the institution for eleven years in the mid-1850's. Ear, nose and throat services were added in the 1800's.

Unique to the Infirmary --- in spite of its departmental employment program --- the life-blood of the teaching and clinical services has historically been served by the voluntary staff. The same staff filling the operating rooms year after year. After stating emphatically (at the very first meeting with Mount Sinai when they assumed ownership) that they "cherished" the institution and would not fail its mandate, they have with mendacity and lack of transparency have begun, inexorably, to close the Infirmary.

I am writing to issue a clarion call to our community, its agencies, patients, politicians, health care planning agencies, the physician, nurses, and all the employees of the infirmary. Over the past four years, Mount Sinai closed our specialty emergency room, our laboratories, hobbled the voluntary staff and undercut their zeal to teach clinical ophthalmology to our residents and fellows.

Mount Sinai denies it is ;closing' the NYEEI, no matter that their machinations have been clouded by upper level's management obfuscation and lack of consistent clarity. (They have presented at least three plans --- even placing placards in the hospitals waiting area --- describing the "great changes" in store.)

Not once did Mount Sinai's leadership form a cohesive committee to look at the institutions challenges and possibilities. Instead, they authored 'town hall meetings,' where they continued to cloud their plans. Once it became clear that they did indeed plan to shutter the Infirmary and make off with the proceeds of a real estate sale they claimed that that NYEEI would live on, albeit spread among at least four venues (more perhaps) with no unifying campus. This would force both patients and attending staff to migrate around the lower part of town.

This absurd plan is NOT the New York Eye and Infirmary. It is Mounts Sinai's contrived view of a non - future for the NYEE and the result of mis-management at the highest levels, as well as a failure to involve the rank and file --- the backbone of the historic NYEEI program.

Mount Sinai accounting legerdemain, including close to $100 million dollars in losses at Beth Israel that was apparently covered none the less by government dollars and, as well, what losses we can glean from their sideways accounting for NYEEI suggests that their foray into gender reassignment surgery was a disaster. And still those of us still loyally attending the Infirmary and frustrated by Sinai's abuse of our interests in saving the institution, watch as they mismanage the operating rooms, accumulating further losses and, incredulously, chasing surgeons from the operating rooms.

This situation is untenable, and we are saying to the City Council that this situation is a bell weather: as medicine within large hospital systems comes under growing pressure as there is an increasing move to outpatient care, management will continue to compromise clinical services. Mount Sinai's mis-management of the NYEEI should not stand. The community must force Sinai's corporate mentality to serve our community of patients and physicians. To do this instead of ignoring us, they should have partnered with those of us who have made the Infirmary what it is --- or step aside as we invent the New York Eye and Infirmary for the 21st Century.

My name is Dr. Ronald Gentile. I am a well-known and respected retina and ocular trauma surgeon in New York City and operate at the New York Eye and Ear Infirmary (NYEEI). For over two hundred years, the NYEEI has provided world-class care to New Yorkers of every background and identity. Currently, the Infirmary services many patients who are from marginalized and underserved populations. I am here today to make the City Council aware of the plans by Mount Sinai to downsize, dismantle, and disaggregate the services of the NYEEI. I highly suspect these actions are an attempt for Mount Sinai to empty the current hospital and prepare for the sale of the buildings and land for financial gain. This will disproportionately affect this at-risk population by segregating clinic services to a largely inaccessible location removed from mass transit, expert faculty, and specialized diagnostic services. We must rally together to protect the historic building, quality healthcare, and the future of specialized care for all New Yorkers.

The NYEEI is an iconic institution with an important history intertwined with the city and country. Initially founded in 1820 by Doctors Edward Delafield and John Kearny Rodgers, the Infirmary was the first specialty clinic in the nation. It was also the first hospital to train and employ an African American Ophthalmologist. History at the NYEEI runs deep and includes Colonel William Few, a signer of the US Constitution. The building's architecture is also paramount to the historic character of the East Village. NYEEI's south campus was designed in the Richardson Romanesque Style by Robert Williams Gibson, who's other landmarked credits include the New York Botanical Garden Museum Building in the Bronx and St. Michael's Episcopal Church at Amsterdam Avenue and 99th Street. Allowing a mega corporate hospital system to sell the NYEEI building and land and potentially erect a luxury condominium in its place would be a disaster and disservice to the hundreds of thousands of people it currently services.

New York City is at a crossroad where healthcare, like many other services, are segregated into those who can afford it and those who cannot. The closing of the NYEEI follows a stark pattern of other facilities that have fallen-into and been replaced with a shell of what existed before, to benefit only those privileged to be involved in the lucrative real estate transaction. We implore the City Council to get involved and apply pressure to Mount Sinai to marshal its resources and act to the benefit of all New Yorkers to save the iconic NYEEI, protecting patients, practitioners, and our shared, collective history.

To: COMMITTEE ON HEALTH
Meeting of September 19, 2022

Written Testimony of Taras M. Czebiniak
Submitted Online

RE: **A Demand To End Human Rights Violations in New York City, Perpetuated by Mayor Eric Adams and the City Council, with Covid-19 Private and Public Worker Injection Mandates**

The purpose of this written testimony with supporting exhibits is to make it easy for future historians of New York City to confirm that you, the City Council, together with Mayor Eric Adams commit and perpetuate human rights violations here with your full personal knowledge and consent. There remains a legal mandate in New York City that all City workers, and all private workers, have received a Covid injection in order to earn a living (the "**Mandate**"). (*See* EXHIBIT 1: Emergency Executive Order No. 317, December 15, 2021.) The Mandate is inconsistent, hypocritical, dangerous, it goes against the global consensus against mRNA injection mandates, and it violates the Nuremberg Code established after examination of the Nazi atrocities of World War II.

You can no longer claim ignorance of, or deny your full complicity with, Human Rights Violations in New York City in 2022.

The City Council has the power to stop the human rights violations, but up until today, the Council has refused to stand against the Mayor, and the Council therefore stands against human rights.

1. The Mandate violates the fundamental human right of every New Yorker to choose his or her medical interventions, a right enunciated in the Nuremberg Code of August 1947. EXHIBIT 2 provides the relevant text of the Nuremberg Code. The threat of being fired from one's job, losing one's pension or retirement benefits, and any and all other methods of coercion and duress to force the Covid injection violate the Nuremberg Code -- period. The Nuremberg Code is clear, it is written in plain English, and it is accessible and understandable by every human citizen on each. One need not be an 'expert' of any kind to understand and demand the rights confirmed by the Nuremberg Code.

2. Private employers continue to block non-injected workers from working, and they threaten existing workers with an ultimatum to take the injection and return to the office, or else be fired. The Mayor has stated that he is not personally enforcing the private employer mandate. But New Yorkers remain unable to work or are forced into taking the injection, because the Mayor has merely deputized private employers who conduct the enforcement on his behalf. My personal friend was given an ultimatum to either permit Mayor Adams to violate her bodily autonomy and take a Covid injection, or else be fired. (*See* NEW YORK CITY COUNCIL, Testimony of Taras M. Czebiniak, online video of the proceedings of the September 9, 2022 meeting of the Committee on Civil Service and Labor, time index: 3 hours 44 minutes.) Large private employers will not violate standing law, regardless of a politician's promise not to enforce, therefore the Mandate remains pernicious to private workers and violates them. As another example, Goldman Sachs has dropped all of its Covid injection mandates – except in New York City and Lima, Peru. (*See* BLOOMBERG, August 30, 2022, *Goldman Lifts Most Vaccination Rules for Staff in Office*.) This is because only those cities still require Covid injection from employees where Goldman Sachs maintains offices. (Regarding the worker mandates in Lima, Peru, *see* ACTUALIDAD CIVIL, March 28, 2022, *A partir del 1 de abril, trabajadores deberán tener las tres dosis de la vacuna contra el covid-19*.)

3. The Mandate forces a medically dangerous intervention, that both government and pharmaceutical companies have provably lied about, for nearly 2 years. A recent study published in VACCINE confirms that the Covid mRNA injections, those most prevalent in the United States, carry a 1 in 800 rate of serious adverse events, defined by the Code of Federal Regulations (21 C.F.R. section 312.32(a)) as death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomaly, or birth defect. Neither the federal or city government, nor the pharmaceutical companies themselves, have disclosed these numbers. Consent to any medical procedure is not informed, as required by medical ethics, when material information is withheld, obfuscated, censored, and outright lied about by those in power. (EXHIBIT 3: VACCINE 40:40, 22 September 2022, pages 5798-5805, *Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults*.) Further, the authors of the VACCINE study confirm that both the federal FDA and Pfizer-BioNTech have the underlying data, but they refuse to release it to unbiased third parties to determine safety and efficacy. Finally, the German Health Ministry has confirmed that 1 in 5,000 Germans have experienced "serious side effects" from Covid injections.

4. Most other countries have long since ended their Covid injection mandates. Denmark has gone even further: Denmark no longer recommends Covid injections to anyone under 50 years without other health risks. The Danish Health Authority now recognizes that the Covid injections no longer have a benefit for individuals under 50. Not only are the injections not mandated, but they are not even recommended. (*See* EXHIBIT 4: Danish Health Authority, updated September 13, 2022, *Vaccination against covid-19*.) Mayor Adams is not a physician nor a public health official, and yet he claims to magically know more about Covid than virtually every other country on earth that has eliminated mandates and even recommendations to continue injecting.

5. The Mandate exempts celebrities and athletes and treats them differently from everyday New Yorkers. This policy which has absolutely no scientific or medical basis. The Mandate must end for all. On March 4, 2022, Mayor Adams exempted performing artists and their staff, as well as professional athletes and their staff, from the private sector Covid injection mandate. (EXHIBIT 5: Emergency Executive Order 62.) There is no study demonstrating any scientific or medical reason for exempting rich, elite artists and athletes from the mandate. The entire mandate itself constitutes a human rights violation, and the Mayor must immediately rescind the Mandate for all New Yorkers -- not just his rich buddies that he wants to rub elbows and have himself photographed with.

CONCLUSIONS

It is a **crime against humanity** to coerce under duress harmful medical interventions to individuals without their free, voluntary, and informed consent to the intervention.

Mayor Adams has directly and indirectly **violated the bodies of tens of thousands of New Yorkers** by maintaining his Covid injection requirement to earn a living in New York City, which is a human right.

The New York **City Council is complicit in crimes against humanity** through its inaction to rein in this dictatorial Mayor and return and restore proper representation to the citizens of New York City.

Historians will look upon the 2022 New York City Council and the Mayor with absolute horror. You are fully aware of your perpetuation of crimes against humanity, yet, you have done nothing to stop this. Today is the day for the Council to draft and pass legislation to END the Mayor's Covid injection mandate.

Best regards,
Taras M. Czebiniak
TarasMC@gmail.com

EXHIBIT 1

Emergency Executive Order No. 317, December 15, 2021

See attached.

THE CITY OF NEW YORK
OFFICE OF THE MAYOR
NEW YORK, N.Y. 10007

EMERGENCY EXECUTIVE ORDER NO. 317
December 15, 2021

WHEREAS, the COVID-19 pandemic has severely impacted New York City and its economy, and is addressed effectively only by joint action of the City, State, and Federal governments; and

WHEREAS, the state of emergency to address the threat and impacts of COVID-19 in the City of New York first declared in Emergency Executive Order No. 98, and extended most recently by Emergency Executive Order No. 296, remains in effect; and

WHEREAS, on October 29, 2021, U.S. Food and Drug Administration authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include children 5 through 11 years of age; and

WHEREAS, on November 26, 2021, New York State Governor Kathy Hochul issued Executive Order No. 11 to address new emerging threats across the State posed by COVID-19, finding that New York is experiencing COVID-19 transmission at rates the State has not seen since April 2020 and that the rate of new COVID-19 hospital admissions has been increasing over the past month to over 300 new admissions a day; and

WHEREAS, the recent appearance in the City of the highly transmissible Omicron variant of COVID-19 suggests an increased risk of reinfection; and

WHEREAS, 70% of City residents are fully vaccinated and mandating vaccinations at the types of establishments that residents frequent will incentivize vaccinations, increasing the City's vaccination rates and saving lives; and

WHEREAS, additional reasons for requiring the measures continued in this Order are set forth in Emergency Executive Order No. 316;

NOW, THEREFORE, pursuant to the powers vested in me by the laws of the State of New York and the City of New York, including but not limited to the New York Executive Law, the New York City Charter and the Administrative Code of the City of New York, and the common law authority to protect the public in the event of an emergency:

Section 1. I hereby direct that Emergency Executive Order No. 316, dated December 13, 2021, shall be superseded in its entirety by the provisions of section 2 of this Order.

§ 2. a. The program set forth in this section shall be known as the "Key to NYC" program.

b. I hereby order that, except as provided in subdivision c of this section, a covered entity shall not permit a patron, full- or part-time employee, intern, volunteer, or contractor to enter a covered premises without displaying proof of vaccination and identification bearing the same identifying information as the proof of vaccination. However, for a child under the age of 18 only proof of vaccination, and not additional idenfication, is required to be displayed.

c. I hereby order that the following individuals are exempted from this section, and therefore may enter a covered premises without displaying proof of vaccination, provided that such individuals wear a face mask at all times except when they are consuming food or beverages:

(1) Individuals entering for a quick and limited purpose (for example, using the restroom, placing or picking up an order or service, changing clothes in a locker room, or performing necessary repairs);

(2) A nonresident performing artist not regularly employed by the covered entity, or a nonresident individual accompanying such a performing artist, while the performing artist or individual is in a covered premises for the purposes of such artist's performance, except that a performing artist is not required to wear a face mask while performing;

(3) A nonresident professional or college athlete/sports team that is not based in New York City (i.e., not a New York City "home team"), or a nonresident individual accompanying such professional or college athlete/sports team, who enters a covered premises as part of their regular employment for purposes of the professional or college athlete/sports team competition, except that such athlete is not required to wear a face mask while playing in a competition;

(4) An individual 5 years of age or older who enters a covered premises to participate in a school or after-school program offered by any pre-kindergarten through grade twelve public or non-public school, the Department of Youth & Community Development (DYCD), or another City agency, except that Department of Education (DOE) and charter school students participating in high risk extracurricular activities must comply with the vaccination requirements for high risk extracurricular activities as described in the relevent Order of the Commissioner of Health and Mental Hygiene Order issued on December 10, 2021;

(5) An individual who enters for the purposes of voting or, pursuant to law, assisting or accompanying a voter or observing the election; and

(6) An individual who was younger than five years of age on December 13, 2021, until 45 days after such individual's fifth birthday.

d. I hereby direct each covered entity to develop and keep a written record describing the covered entity's protocol for implementing and enforcing the requirements of this section. Such written record shall be available for inspection upon a request of a City official as allowed by law.

e. I hereby direct each covered entity to:

(1) Maintain a copy of workers' proof of vaccination or, if applicable, a record of reasonable accommodation(s) as described in paragraph (2)(iv) of this subdivision; or

(2) Maintain a record of such proof of vaccination, provided that such record shall include:

(i) the worker's name; and

(ii) whether the person is fully vaccinated; and

(iii) for a worker who submits proof of the first dose of a two-dose vaccine, the date by which proof of the second dose must be provided, which must be no later than 45 days after the proof of first dose was submitted; and

(iv) for a worker who does not submit proof of COVID-19 vaccination because of a reasonable accommodation, the record must indicate that such accommodation was provided, and the covered entity must separately maintain records stating the basis for such accommodation and any supporting documentation provided by such worker; or

(3) Check the proof of vaccination before allowing a worker to enter the workplace and maintain a record of the verification.

For a non-employee worker, such as a contractor, a covered entity may request that the worker's employer confirm the proof of vaccination in lieu of maintaining the above records. A covered entity shall maintain a record of such request and confirmation.

Records created or maintained pursuant to this section shall be treated as confidential.

A covered entity shall, upon request by a City agency, make available for inspection records required to be maintained by this section, consistent with applicable law.

f. I hereby direct each covered entity to post a sign in a conspicuous place that is viewable by prospective patrons prior to entering the establishment. The sign must alert patrons to the vaccination requirement in this section and inform them that employees and patrons are required to be vaccinated. The Department for Health and Mental Hygiene ("DOHMH") shall determine the text of such sign and provide a template on its website that a covered entity may use. A covered entity may use the sign available online at

nyc.gov/keytoNYC, or use its own sign, provided its sign must be no smaller than 8.5 inches by 11 inches, with text provided by DOHMH in at least 14-point font.

g. For the purposes of this Order:

(1) "Contractor" means the owner or employee of any business that a covered entity has hired to perform work within a covered premise.

(2) "Covered entity" means any entity that operates one or more covered premises, except that it shall not include pre-kindergarten through grade twelve (12) public and non-public schools and programs, houses of worship, childcare programs, senior centers, community centers, or as otherwise indicated by this Order.

(3) "Covered premises" means any of the following locations, except as provided in subparagraph (iv) of this paragraph:

(i) **Indoor Entertainment and Recreational Settings, and Certain Event and Meeting Spaces** including indoor portions of the following locations, regardless of the activity at such locations: movie theaters, music or concert venues, adult entertainment, casinos, botanical gardens, commercial event and party venues, museums, aquariums, zoos, professional sports arenas and indoor stadiums, convention centers and exhibition halls, hotel meeting and event spaces, performing arts theaters, bowling alleys, arcades, indoor play areas, pool and billiard halls, and other recreational game centers;

(ii) **Indoor Food Services**, including indoor portions of food service establishments offering food and drink, including all indoor dining areas of food service establishments that receive letter grades as described in section 81.51 of the Health Code; businesses operating indoor seating areas of food courts; catering food service establishments that provide food indoors on its premises; and any indoor portions of an establishment that is regulated by the New York State Department of Agriculture and Markets offering food for on-premises indoor consumption. The requirements of this Order shall not apply to any establishment offering food or drink exclusively for off-premises or outdoor consumption, or to a food service establishment providing only charitable food services, such as soup kitchens; and

(iii) **Indoor Gyms and Fitness Settings**, including indoor portions of standalone and hotel gyms and fitness centers, gyms and fitness centers in higher education institutions, yoga/Pilates/barre/dance studios, boxing/kickboxing gyms, fitness boot camps, indoor pools, CrossFit or other plyometric boxes, and other facilities used for conducting group fitness classes.

(iv) "Covered premises" do not include houses of worship or locations in a residential or office building the use of which is limited to residents, owners, or tenants of that building.

(4) "Identification" means an official document bearing the name of the individual and a photo or date of birth. Examples of acceptable identification include but are not limited to: driver's license, non-driver government ID card, IDNYC, passport, and school ID card.

(5) "Indoor portion" means any part of a covered premises with a roof or overhang that is enclosed by at least three walls, except that the following will not be considered an indoor portion: (1) a structure on the sidewalk or roadway if it is entirely open on the side facing the sidewalk; and (2) an outdoor dining structure for individual parties, such as a plastic dome, if it has adequate ventilation to allow for air circulation.

(6) "Nonresident" means any individual who is not a resident of New York City.

(7) "Patron" means any individual 5 years of age or older who patronizes, enters, attends an event, or purchases goods or services within a covered premise.

(8) "Proof of vaccination" means proof of receipt of a full regimen of a COVID-19 vaccine authorized for emergency use or licensed for use by the U.S. Food and Drug Administration or authorized for emergency use by the World Health Organization, not including any additional recommended booster doses, except that for children who are 5 years of age or older as of December 13, 2021, but younger than 12 years of age, "proof of vaccination" means proof of receipt of at least one dose of such a vaccine until January 28, 2022, after which time it shall mean proof of receipt of a full regimen of such vaccine. Such proof may be established by:

(i) A CDC COVID-19 Vaccination Record Card or an official immunization record from the jurisdiction, state, or country where the vaccine was administered or a digital or physical photo of such a card or record, reflecting the person's name, vaccine brand, and date administered; or

(ii) A New York City COVID Safe App (available to download on Apple and Android smartphone devices);

(iii) A New York State Excelsior Pass;

(iv) CLEAR's digital vaccine card; or

(v) any other method specified by the Commissioner of Health and Mental Hygiene as sufficient to demonstrate proof of vaccination.

(9) "Worker" means an individual who works in-person in New York City at a workplace in New York City. Worker includes a full- or part-time staff member, employer, employee, intern, volunteer or contractor of a covered entity, as well as a self-employed individual or a sole practitioner.

Worker does not include an individual who works from their own home and whose employment does not involve interacting in-person with co-workers or members of the public. Worker also does not include an individual who enters the workplace for a quick and limited purpose.

(10) "Workplace" means any location, including a vehicle, where work is performed in the presence of another worker or member of the public.

h. I hereby direct that each instance that a covered entity fails to check an individual's vaccination status shall constitute a separate violation of this section.

i. I hereby direct the City's Commission on Human Rights to publish guidance to assist covered entities in complying with this section in an equitable manner consistent with applicable provisions of the New York City Human Rights Law.

j. I hereby direct, in accordance with section 25 of the Executive Law, that staff from any agency designated by the Commissioner of Health and Mental Hygiene shall enforce the directives set forth in this section.

k. (1) I hereby direct that any person or entity who is determined to have violated the requirements of the Key to NYC program shall be subject to a fine, penalty and forfeiture of not less than $1,000. If the person or entity is determined to have committed a subsequent violation of this section within twelve months of the initial violation for which a penalty was assessed, such person or entity shall be subject to a fine, penalty and forfeiture of not less than $2,000. For every violation thereafter, such person or entity shall be subject to a fine, penalty and forfeiture of not less than $5,000 if the person or entity committed the violation within twelve months of the violation for which the second penalty was assessed. This section may be enforced pursuant to sections 3.05, 3.07, or 3.11 of the Health Code and sections 558 and 562 of the Charter.

(2) I hereby suspend: (i) Appendix 7-A of Chapter 7 of Title 24 of the Rules of the City of New York to the extent it would limit a violation of this section to be punished with a standard penalty of $1,000 or a default penalty of $2,000; and (ii) section 7-08 of such Chapter 7 and section 3.11 of the Health Code, to the extent such provisions would limit the default penalty amount that may be imposed for a violation of this section to $2,000.

(3) Notwithstanding the foregoing, this subdivision shall not apply until December 27, 2021 with respect to proof of receipt of a second dose of a two-dose vaccine.

l. Covered entities shall comply with further guidelines issued by DOHMH to further the intent of this section and increase the number of vaccinated individuals in the City.

m. I hereby order that section 20-1271 of the Administrative Code of the City of New York is modified by adding the following provision to the definition of "just cause:" Notwithstanding any provision of this chapter, a fast food employer shall be deemed to

have just cause when a fast food employee has failed to provide proof of vaccination required by an emergency executive order issued in response to the COVID-19 pandemic and shall not be required to follow progressive discipline procedures prior to terminating the employee, provided that the employee shall have 30 days from the date when the employer notified the employee of the requirement to submit such proof and the employee shall be placed on leave following such notification until such proof is provided. This provision shall not excuse the employer from the responsibility to provide a reasonable accommodation where required by law.

§ 3. This Emergency Executive Order shall take effect immediately.

Bill de Blasio,
MAYOR

EXHIBIT 2

Nuremberg Code, August 1947

1. The voluntary consent of the human subject is absolutely essential.

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

Source: https://www.ushmm.org/information/exhibitions/online-exhibitions/special-focus/doctors-trial/nuremberg-code

EXHIBIT 3

Scientific Journal VACCINE, volume 40, issue 40, September 22, 2022

Serious Adverse Events of Special Interest Following mRNA Covid-19 Vaccination in Randomized Trials in Adults

See attached.

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Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults

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Serious adverse events
Adverse events of special interest
Brighton Collaboration
Coalition for Epidemic Preparedness Innovations
Safety Platform for Emergency vACcines

ABSTRACT

Introduction: In 2020, prior to COVID-19 vaccine rollout, the Brighton Collaboration created a priority list, endorsed by the World Health Organization, of potential adverse events relevant to COVID-19 vaccines. We adapted the Brighton Collaboration list to evaluate serious adverse events of special interest observed in mRNA COVID-19 vaccine trials.

Methods: Secondary analysis of serious adverse events reported in the placebo-controlled, phase III randomized clinical trials of Pfizer and Moderna mRNA COVID-19 vaccines in adults (NCT04368728 and NCT04470427), focusing analysis on Brighton Collaboration adverse events of special interest.

Results: Pfizer and Moderna mRNA COVID-19 vaccines were associated with an excess risk of serious adverse events of special interest of 10.1 and 15.1 per 10,000 vaccinated over placebo baselines of 17.6 and 42.2 (95 % CI −0.4 to 20.6 and −3.6 to 33.8), respectively. Combined, the mRNA vaccines were associated with an excess risk of serious adverse events of special interest of 12.5 per 10,000 vaccinated (95 % CI 2.1 to 22.9); risk ratio 1.43 (95 % CI 1.07 to 1.92). The Pfizer trial exhibited a 36 % higher risk of serious adverse events in the vaccine group; risk difference 18.0 per 10,000 vaccinated (95 % CI 1.2 to 34.9); risk ratio 1.36 (95 % CI 1.02 to 1.83). The Moderna trial exhibited a 6 % higher risk of serious adverse events in the vaccine group: risk difference 7.1 per 10,000 (95 % CI –23.2 to 37.4); risk ratio 1.06 (95 % CI 0.84 to 1.33). Combined, there was a 16 % higher risk of serious adverse events in mRNA vaccine recipients: risk difference 13.2 (95 % CI −3.2 to 29.6); risk ratio 1.16 (95 % CI 0.97 to 1.39).

Discussion: The excess risk of serious adverse events found in our study points to the need for formal harm-benefit analyses, particularly those that are stratified according to risk of serious COVID-19 outcomes. These analyses will require public release of participant level datasets.

1. Introduction

In March 2020, the Brighton Collaboration and the Coalition for Epidemic Preparedness Innovations partnership, Safety Platform for Emergency vACcines (SPEAC), created and subsequently updated a "priority list of potential adverse events of special interest relevant to COVID-19 vaccine trials." [1] The list comprises adverse events of special interest (AESIs) based on the specific vaccine platform, adverse events associated with prior vaccines in general, theoretical associations based on animal models, and COVID-19 specific immunopathogenesis. [1] The Brighton Collaboration is a global authority on the topic of vaccine safety and in May 2020, the World Health Organization's Global Advisory Committee on Vaccine Safety endorsed and recommended the reporting of AESIs based on this priority list. To our knowledge, however, the list has not been applied to serious adverse events in randomized trial data.

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0264-410X/

We sought to investigate the association between FDA-authorized mRNA COVID-19 vaccines and serious adverse events identified by the Brighton Collaboration, using data from the phase III randomized, placebo-controlled clinical trials on which authorization was based. We consider these trial data against findings from post-authorization observational safety data. Our study was not designed to evaluate the overall harm-benefit of vaccination programs so far. To put our safety results in context, we conducted a simple comparison of harms with benefits to illustrate the need for formal harm-benefit analyses of the vaccines that are stratified according to risk of serious COVID-19 outcomes. Our analysis is restricted to the randomized trial data, and does not consider data on post-authorization vaccination program impact. It does however show the need for public release of participant level trial datasets.

2. Methods

Pfizer and Moderna each submitted the results of one phase III randomized trial in support of the FDA's emergency use authorization of their vaccines in adults. Two reviewers (PD and RK) searched journal publications and trial data on the FDA's and Health Canada's websites to locate serious adverse event results tables for these trials. The Pfizer and Moderna trials are expected to follow participants for two years. Within weeks of the emergency authorization, however, the sponsors began a process of unblinding all participants who elected to be unblinded. In addition, those who received placebo were offered the vaccine. These self-selection processes may have introduced nonrandom differences between vaccinated and unvaccinated participants, thus rendering the post-authorization data less reliable. Therefore, to preserve randomization, we used the interim datasets that were the basis for emergency authorization in December 2020, approximately 4 months after trials commenced.

The definition of a serious adverse event (SAE) was provided in each trial's study protocol and included in the supplemental material of the trial's publication. [2–4] Pfizer and Moderna used nearly identical definitions, consistent with regulatory expectations. An SAE was defined as an adverse event that results in any of the following conditions: death; life-threatening at the time of the event; inpatient hospitalization or prolongation of existing hospitalization; persistent or significant disability/incapacity; a congenital anomaly/birth defect; medically important event, based on medical judgment.

In addition to journal publications, we searched the websites of the FDA (for advisory committee meeting materials) and Health Canada (for sections of the dossier submitted by sponsors to the regulator). [5] For the FDA website, we considered presentations by both the FDA and the sponsors. [6] Within each of these sources, we searched for SAE results tables that presented information by specific SAE type; we chose the most recent SAE table corresponding to the FDA's requirement for a safety median follow-up time of at least 2 months after dose 2.

For each trial, we prepared blinded SAE tables (containing SAE types without results data). Using these blinded SAE tables, two clinician reviewers (JF and JE) independently judged whether each SAE type was an AESI. SAE types that matched an AESI term verbatim, or were an alternative diagnostic name for an AESI term, were included as an AESI. For all other SAE types, the reviewers independently judged whether that SAE type was likely to have been caused by a vaccine-induced AESI, based on a judgment considering the disease course, causative mechanism, and likelihood of the AESI to cause the SAE type. Disagreements were resolved through consensus; if consensus could not be reached, a third clinician reviewer (PW) was used to create a majority opinion. For each included SAE, we recorded the corresponding Brighton Collaboration AESI category and organ system. When multiple AESIs could potentially cause the same SAE, the reviewers selected the AESI that they judged to be the most likely cause based on classical clinical presentation of the AESI.

We used an AESI list derived from the work of Brighton Collaboration's Safety Platform for Emergency vACcines (SPEAC) Project. This project created an AESI list which categorizes AESIs into three categories: those included because they are seen with COVID-19, those with a proven or theoretical association with vaccines in general, and those with proven or theoretical associations with specific vaccine platforms. The first version was produced in March 2020 based on experience from China. Following the second update (May 2020), the WHO Global Advisory Committee on Vaccine Safety (GACVS) adopted the list, and Brighton commenced a systematic review process "to ensure an ongoing understanding of the full spectrum of COVID-19 disease and modification of the AESI list accordingly." [7] This resulted in three additional AESIs being added to the list in December 2020. The subsequent (and most recent fourth) update did not result in any additional AESIs being added to the list. [1].

We matched SAEs recorded in the trial against an expanded list of AESIs created by combining Brighton's SPEAC COVID-19 AESI list with a list of 29 clinical diagnoses Brighton identified as "known to have been reported but not in sufficient numbers to merit inclusion on the AESI list." [7] Sensitivity analysis was used to determine whether use of the original versus expanded list altered our results.

Risk ratios and risk differences between vaccine and placebo groups were calculated for the incidence of AESIs and SAEs. We excluded SAEs that were known efficacy outcomes (i.e. COVID-19), consistent with the approach Pfizer (but not Moderna) used in recording SAE data. The Pfizer study trial protocol states that COVID-19 illnesses and their sequelae consistent with the clinical endpoint definition were not to be reported as adverse events, "even though the event may meet the definition of an SAE." [8] For unspecified reasons, Moderna included efficacy outcomes in their SAE tables, effectively reporting an all-cause SAE result. Because we did not have access to individual participant data, to account for the occasional multiple SAEs within single participants, we reduced the effective sample size by multiplying standard errors in the combined SAE analyses by the square root of the ratio of the number of SAEs to the number of patients with an SAE. This adjustment increased standard errors by 10 % (Pfizer) and 18 % (Moderna), thus expanding the interval estimates. We estimated combined risk ratios and risk differences for the two mRNA vaccines by averaging over the risks using logistic regression models which included indicators for trial and treatment group.

We used a simple harm-benefit framework to place our results in context, comparing risks of excess serious AESIs against reductions in COVID-19 hospitalization.

3. Results

Serious adverse event tables were located for each of the vaccine trials submitted for EUA in adults (age 16 + for Pfizer, 18 + for Moderna) in the United States: Pfizer-BioNTech COVID-19 vaccine BNT162b2 (NCT04368728) [2,9,10] and Moderna COVID-19 vaccine mRNA-1273 (NCT04470427). [3,11,12] (Table 1).

3.1. Reporting windows and serious adverse events

Moderna reported SAEs from dose 1 whereas Pfizer limited reporting from dose 1 to 1 month after dose 2. Both studies

Table 1
Data sources for phase III trials.

Trial	Data cutoff date	Journal articles	FDA sources	Health Canada sources
Pfizer trial in ages 16 and above (NCT04368728)	14 Nov 2020 (supported Dec 2020 EUA)	Aggregate data only	**Table 23 in sponsor briefing document**	**Table 55 in sponsor document C4591001 Final Analysis Interim Report Body**
Moderna trial in ages 18 and above (NCT04470427)	25 Nov 2020 (supported Dec 2020 EUA)	Table S11 in publication	Table 27 in sponsor briefing document	**Table 14.3.1.13.3 in sponsor document mRNA-1273-P301 Unblinded Safety Tables Batch 1 (DS2)**

Note: bolded font indicates dataset chosen for analysis; EUA = Emergency Use Authorization.

reported all data at the time of data cutoff (14 Nov 2020 for Pfizer, 25 Nov 2020 for Moderna). 17 SAEs that were efficacy endpoints were removed from the Moderna trial (16 "COVID-19" SAEs and 1 "COVID-19 pneumonia" SAE). One such efficacy endpoint meeting the definition of a SAE was removed from the Pfizer trial ("SARS-CoV-2 test positive" SAE).

The Pfizer trial exhibited a 36 % higher risk of serious adverse events in vaccinated participants in comparison to placebo recipients: 67.5 per 10,000 versus 49.5 per 10,000; risk difference 18.0 per 10,000 vaccinated participants (95 % compatibility[1] interval 1.2 to 34.9); risk ratio 1.36 (95 % CI 1.02 to 1.83). The Moderna trial exhibited a 6 % higher risk of SAEs in vaccinated individuals compared to those receiving placebo: 136 per 10,000 versus 129 per 10,000; risk difference 7.1 per 10,000 (95 % CI −23.2 to 37.4); risk ratio 1.06 (95 % CI 0.84 to 1.33). Combined, there was a 16 % higher risk of SAEs in mRNA vaccine recipients than placebo recipients: 98 per 10,000 versus 85 per 10,000; risk difference 13.2 (95 % CI −3.2 to 29.6); risk ratio 1.16 (95 % CI 0.97 to 1.39). **(**Table 2**)**.

3.2. Serious adverse events of special interest

Regarding whether each SAE type was included on the SPEAC derived AESI list, agreement between the two independent clinician reviewers was 86 % (281/325); 40 of the 44 disagreements were resolved through consensus, and only four disagreements necessitated a third clinician reviewer. **Supplemental** Table 1 includes a full list of included and excluded SAEs across both trials.

In the Pfizer trial, 52 serious AESI (27.7 per 10,000) were reported in the vaccine group and 33 (17.6 per 10,000) in the placebo group. This difference corresponds to a 57 % higher risk of serious AESI (RR 1.57 95 % CI 0.98 to 2.54) and a risk difference of 10.1 serious AESI per 10,000 vaccinated participants (95 % CI −0.4 to 20.6). In the Moderna trial, 87 serious AESI (57.3 per 10,000) were reported in the vaccine group and 64 (42.2 per 10,000) in the placebo group. This difference corresponds to a 36 % higher risk of serious AESI (RR 1.36 95 % CI 0.93 to 1.99) and a risk difference of 15.1 serious AESI per 10,000 vaccinated participants (95 % CI −3.6 to 33.8). Combining the trials, there was a 43 % higher risk of serious AESI (RR 1.43; 95 % CI 1.07 to 1.92) and a risk difference of 12.5 serious AESI per 10,000 vaccinated participants (95 % CI 2.1 to 22.9). **(**Table 2**)**.

Of the 236 serious AESIs occurring across the Pfizer and Moderna trials, 97 % (230/236) were adverse event types included as AESIs because they are seen with COVID-19. In both Pfizer and Moderna trials, the largest excess risk occurred amongst the Brighton category of coagulation disorders. Cardiac disorders have been of central concern for mRNA vaccines; in the Pfizer trial more cardiovascular AESIs occurred in the vaccine group than in the placebo group, but in the Moderna trial the groups differed by only 1 case. **(**Tables 3 and 4**)**.

[1] A compatibility interval is identical to a confidence interval, but relabeled to emphasize that it is not a Bayesian posterior interval (as is improperly suggested by the "confidence" label).[13,14].

3.3. Sensitivity analysis

As a sensitivity analysis, we restricted the serious AESI analysis to those AESIs listed in SPEAC's COVID-19 AESI list (i.e. separating out Brighton's list of 29 clinical diagnoses "known to have been reported but not in sufficient numbers to merit inclusion on the AESI list.") This reduced the total number of AESIs across the two trials by 48 (35 vaccine group, 13 placebo group). There was still a higher risk of serious AESI when limited to the SPEAC COVID-19 AESI list, but the magnitude of the excess (in both relative and absolute terms) was smaller than when using the larger AESI list. **(Supplemental** Table 2**)**.

3.4. Harm-benefit considerations

In the Moderna trial, the excess risk of serious AESIs (15.1 per 10,000 participants) was higher than the risk reduction for COVID-19 hospitalization relative to the placebo group (6.4 per 10,000 participants). [3] In the Pfizer trial, the excess risk of serious AESIs (10.1 per 10,000) was higher than the risk reduction for COVID-19 hospitalization relative to the placebo group (2.3 per 10,000 participants).

4. Comparison with FDA reviews

In their review of SAEs supporting the authorization of the Pfizer and Moderna vaccines, the FDA concluded that SAEs were, for Pfizer, "balanced between treatment groups," [15] and for Moderna, were "without meaningful imbalances between study arms." [16] In contrast to the FDA analysis, we found an excess risk of SAEs in the Pfizer trial. Our analysis of Moderna was compatible with FDA's analysis, finding no meaningful SAE imbalance between groups.

The difference in findings for the Pfizer trial, between our SAE analysis and the FDA's, may in part be explained by the fact that the FDA analyzed the total number of participants experiencing any SAE, whereas our analysis was based on the total number of SAE events. Given that approximately twice as many individuals in the vaccine group than in the placebo group experienced multiple SAEs (there were 24 more events than participants in the vaccine group, compared to 13 in the placebo group), FDA's analysis of only the incidence of participants experiencing any SAE would not reflect the observed excess of multiple SAEs in the vaccine group.

A more important factor, however, may be that FDA's review of non-fatal SAEs used a different analysis population with different follow-up windows. The FDA reported 126 of 21,621 (0.6 %) of vaccinated participants experienced at least one SAE at data cutoff compared to 111 of 21,631 (0.5 %) of placebo participants. In contrast, our analysis found 127 SAEs among 18,801 vaccine recipients versus 93 SAEs among 18,785 placebo recipients. [15] While summary results for the population we analyzed was provided in a table, FDA did not report an analysis of them. The substantially larger denominators in FDA's analysis (5,666 more participants) reflect the fact that their analysis included all individuals receiving at least one dose (minus 196 HIV-positive participants), irrespec-

Table 2
Serious adverse events.

Trial	Total events (events per 10,000 participants)[a] Vaccine	Placebo	Risk difference per 10,000 participants (95 % CI)[e]	Risk ratio (95 % CI)[e]
Serious adverse events				
Pfizer[b]	127 (67.5)	93 (49.5)	18.0 (1.2 to 34.9)	1.36 (1.02 to 1.83)
Moderna[c,d]	206 (135.7)	195 (128.6)	7.1 (−23.2 to 37.4)	1.06 (0.84 to 1.33)
Combined[f]	333 (98.0)	288 (84.8)	13.2 (-3.2 to 29.6)	1.16 (0.97 to 1.39)
Serious adverse events of special interest				
Pfizer	52 (27.7)	33 (17.6)	10.1 (-0.4 to 20.6)	1.57 (0.98 to 2.54)
Moderna	87 (57.3)	64 (42.2)	15.1 (-3.6 to 33.8)	1.36 (0.93 to 1.99)
Combined[f]	139 (40.9)	97 (28.6)	12.5 (2.1 to 22.9)	1.43 (1.07 to 1.92)

[a] Denominators for Pfizer were 18,801 in the vaccine group and 18,785 in the placebo group, and for Moderna were 15,185 in the vaccine group and 15,166 in the placebo group.
[b] Pfizer excluded efficacy outcomes from its SAE table (COVID-19 illnesses and their sequelae meeting the definition of an SAE). However, at least one SAE appears to have been inadvertently included, which we removed from our calculations (“SARS-CoV-2 test positive”: 0 vaccine group; 1 placebo group).
[c] Moderna included efficacy outcomes in its SAE table (COVID-19 illnesses and their sequelae meeting the definition of an SAE). We removed efficacy SAEs outcomes that could be identified: “COVID-19” and “COVID-19 pneumonia.” Lacking access to participant level data, SAEs that were sequelae of serious COVID-19 could not be identified and therefore remain included in this analysis.
[d] “All SAEs” for Moderna was calculated using the “Number of serious AEs” row in Moderna’s submission to FDA.[11].
[e] Standard errors used to estimate 95% CIs were inflated by the factor $\sqrt{}$[#SAE]/[#patients with SAE] to account for multiple SAE within patients.
[f] The combined risk differences and risk ratios were computed from the fitted logistic regression models and so may not exactly equal comparisons computed from the first two columns.

Table 3
Serious AESIs, Pfizer trial.

Brighton category	Vaccine	Placebo	Vaccine events per 10,000	Placebo events per 10,000	Difference in events per 10,000	Risk ratio
Association with immunization in general						
Anaphylaxis	1	1	0.5	0.5	0.0	1.00
Association with specific vaccine platform(s)						
Encephalitis/encephalomyelitis	0	2	0.0	1.1	−1.1	0.00
Seen with COVID-19						
Acute kidney injury	2	0	1.1	0.0	1.1	N/A
Acute liver injury	0	1	0.0	0.5	−0.5	0.00
Acute respiratory distress syndrome	2	1	1.1	0.5	0.5	2.00
Coagulation disorder	16	10	8.5	5.3	3.2	1.60
Myocarditis/pericarditis	2	1	1.1	0.5	0.5	2.00
Other forms of acute cardiac injury	16	12	8.5	6.4	2.1	1.33
Subtotal	39	28	20.7	14.9	5.8	1.39
Brighton list of 29 clinical diagnoses seen with COVID-19						
Abscess	4	1	2.1	0.5	1.6	4.00
Cholecystitis	4	2	2.1	1.1	1.1	2.00
Colitis/Enteritis	1	1	0.5	0.5	0.0	1.00
Diarrhea	1	0	0.5	0.0	0.5	N/A
Hyperglycemia	1	1	0.5	0.5	0.0	1.00
Pancreatitis	1	0	0.5	0.0	0.5	N/A
Psychosis	1	0	0.5	0.0	0.5	N/A
Subtotal	13	5	6.9	2.7	4.3	2.60
Total	**52**	**33**	**27.7**	**17.6**	**10.1**	**1.57**

tive of the duration of post-injection follow-up time. In contrast, our analysis was based on the study population with median follow-up $\geq$ 2 months after dose 2 (minus 120 HIV-positive participants), of which 98.1 % had received both doses. [2,17] The FDA’s analysis of SAEs thus included thousands of additional participants with very little follow-up, of which the large majority had only received 1 dose.

4.1. Comparison with post-authorization studies

Although the randomized trials offer high level evidence for evaluating causal effects, the sparsity of their data necessitates that harm-benefit analyses also consider observational studies. Since their emergency authorization in December 2020, hundreds of millions of doses of Pfizer and Moderna COVID-19 vaccines have been administered and post-authorization observational data offer a complementary opportunity to study AESIs. Post-authorization observational safety studies include cohort studies (which make use of medical claims or electronic health records) and disproportionality analyses (which use spontaneous adverse event reporting systems). In July 2021, the FDA reported detecting four potential adverse events of interest: pulmonary embolism, acute myocardial infarction, immune thrombocytopenia, and disseminated intravascular coagulation following Pfizer’s vaccine based on medical claims data in older Americans. [18] Three of these four serious adverse event types would be categorized as coagulation disorders, which is the Brighton AESI category that exhibited the largest excess risk in the vaccine group in both the Pfizer and Moderna trials. FDA stated it would further investigate the findings but at the time of our writing has not issued an update. Similarly, spontaneous-reporting systems have registered serious adverse reactions including anaphylaxis (all COVID-19 vaccines), thrombocytopenia syndrome among premenopausal females (Janssen vaccine), and myocarditis and pericarditis among younger males (Pfizer and Moderna vaccines). [19,20].

Using data from three postmarketing safety databases for vaccines (VAERS, EudraVigilance, and VigiBase), disproportionality studies have reported excess risks for many of the same SAE types as in

Table 4
Serious AESIs, Moderna trial.

Brighton category	Vaccine	Placebo	Vaccine events per 10,000	Placebo events per 10,000	Difference in events per 10,000	Risk ratio
Association with specific vaccine platform(s)						
Bell's Palsy	1	0	0.7	0.0	0.7	N/A
Encephalitis/encephalomyelitis	1	0	0.7	0.0	0.7	N/A
Seen with COVID-19						
Acute kidney injury	1	3	0.7	2.0	−1.3	0.33
Acute liver injury	1	0	0.7	0.0	0.7	N/A
Acute respiratory distress syndrome	7	4	4.6	2.6	2.0	1.75
Angioedema	0	2	0.0	1.3	−1.3	0.00
Coagulation disorder	20	13	13.2	8.6	4.6	1.54
Generalized Convulsions	2	0	1.3	0.0	1.3	N/A
Myelitis	0	1	0.0	0.7	−0.7	0.00
Myocarditis/pericarditis	4	5	2.6	3.3	−0.7	0.80
Other forms of acute cardiac injury	26	26	17.1	17.1	0.0	1.00
Other rash	1	1	0.7	0.7	0.0	1.00
Rhabdomyolysis	0	1	0.0	0.7	−0.7	0.00
Single Organ Cutaneous Vasculitis	1	0	0.7	0.0	0.7	N/A
Subtotal	65	56	42.8	36.9	5.9	1.16
Brighton list of 29 clinical diagnoses seen with COVID-19						
Abscess	1	0	0.7	0.0	0.7	N/A
Arthritis	3	1	2.0	0.7	1.3	3.00
Cholecystitis	4	0	2.6	0.0	2.6	N/A
Colitis/Enteritis	6	3	4.0	2.0	2.0	2.00
Diarrhea	2	1	1.3	0.7	0.7	2.00
Hyperglycemia	1	0	0.7	0.0	0.7	N/A
Hyponatremia	1	1	0.7	0.7	0.0	1.00
Pancreatitis	2	0	1.3	0.0	1.3	N/A
Pneumothorax	0	1	0.0	0.7	−0.7	0.00
Psychosis	1	1	0.7	0.7	0.0	1.00
Thyroiditis	1	0	0.7	0.0	0.7	N/A
Subtotal	22	8	14.5	5.3	9.2	2.75
Total	**87**	**64**	**57.3**	**42.2**	**15.1**	**1.36**

the present study. [21–23] For example, a study using VAERS and EudraVigilance comparing the disproportionality of adverse event reports between the influenza vaccine versus the mRNA COVID-19 vaccines reported excess risks for the following Brighton AESIs: cardiovascular events, coagulation events, hemorrhages, gastrointestinal events, and thromboses. [22] While CDC published a protocol[24] in early 2021 for using proportional reporting ratios for signal detection in the VAERS database, results from the study have not yet been reported. [25] Among self-controlled case series, one reported a rate ratio of 1.38 (95 % CI 1.12–1.71) for hemorrhagic stroke following Pfizer vaccine, [26] another reported 0.97 (95 % CI 0.81–1.15), [27] while a cohort study[28] reported 0.84 (95 % CI 0.54–1.27).

5. Discussion

Using a prespecified list of AESI identified by the Brighton Collaboration, higher risk of serious AESI was observed in the mRNA COVID-19 vaccine group relative to placebo in both the Pfizer and Moderna adult phase III trials, with 10.1 (Pfizer) and 15.1 (Moderna) additional events for every 10,000 individuals vaccinated. Combined, there was a risk difference of 12.5 serious AESIs per 10,000 individuals vaccinated (95 % CI 2.1 to 22.9). These results raise concerns that mRNA vaccines are associated with more harm than initially estimated at the time of emergency authorization. In addition, our analysis identified a 36 % higher risk of serious adverse events in vaccinated participants in the Pfizer trial: 18.0 additional SAEs per 10,000 vaccinated (95 % CI 1.2 to 34.9). Consistent with the FDA evaluation, our analysis found no clear difference in SAEs between groups in the Moderna trial.

Results between the Pfizer and Moderna trials were similar for the AESI analysis but exhibited substantial variation in the SAE analysis. Caution is needed in interpreting this variation as it may be substantially explained by differences in SAE recording practices in the trials rather than differences in actual vaccine harm profiles. For reasons that are not documented in the trial protocol, Moderna included efficacy outcomes in its SAE tabulations, while Pfizer excluded them. As a result, Moderna's SAE table did not present a traditional SAE analysis but rather an all-cause SAE analysis. The FDA analysis of the Moderna trial presented an all-cause SAE analysis, which estimates total vaccine effects on SAEs, including effects transmitted via effects on COVID-19. It did not however present a traditional SAE analysis with efficacy endpoints removed, which attempts to estimate only the direct effects on SAEs. While our analysis attempted to perform a traditional SAE analysis by excluding efficacy SAEs (serious COVID-19 and its sequelae), our effort was hindered because we did not have access to patient level data. Easily recognizable efficacy SAEs ("COVID-19", "COVID-19 pneumonia," and "SARS-CoV-2 test positive") could be removed, but many participants who experienced a COVID-19 SAE likely experienced multiple other SAEs (e.g. pneumonia, hypoxia, and thrombotic events) which could not be identified and therefore remain included in our analysis. Of 17 total efficacy SAEs (16 "COVID-19" and 1 "COVID-19 pneumonia") removed from our analysis of the Moderna trial, 16 were in the placebo arm. As a consequence, the background SAE risk (risk in absence of COVID-19) would be overestimated by the Moderna placebo group, resulting in underestimation of the actual risk of SAEs and AESIs attributable to the vaccine in the Moderna comparisons as well as in the combined analysis. Access to patient-level data would allow adjustments for this problem.

Rational policy formation should consider potential harms alongside potential benefits. [29] To illustrate this need in the present context, we conducted a simple harm-benefit comparison using the trial data comparing excess risk of serious AESI against reductions in COVID-19 hospitalization. We found excess risk of serious AESIs to exceed the reduction in COVID-19 hospitalizations in both Pfizer and Moderna trials.

This analysis has the limitations inherent in most harm-benefit comparisons. First, benefits and harms are rarely exact equivalents, and there can be great variability in the degree of severity within both benefit and harm endpoints. For example, intubation and short hospital stay are not equivalent but both are counted in "hospitalization"; similarly, serious diarrhea and serious stroke are not equivalent but both are counted in "SAE." Second, individuals value different endpoints differently. Third, without individual participant data, we could only compare the number of individuals hospitalized for COVID-19 against the number of serious AESI events, not the number of participants experiencing any serious AESI. Some individuals experienced multiple SAEs whereas hospitalized COVID-19 participants were likely only hospitalized once, biasing the analysis towards exhibiting net harm. To gauge the extent of this bias, we considered that there were 20 % (Pfizer) and 34 % (Moderna) more SAEs than participants experiencing any SAE. As a rough sensitivity calculation, if we divide the Pfizer excess serious AESI risk of 10.1 by 1.20 it becomes 8.4 compared to a COVID-19 hospitalization risk reduction of 2.3; if we divide the Moderna excess serious AESI risk of 15.1 by 1.34 it becomes 11.3 compared to a COVID-19 hospitalization risk reduction of 6.4.

Harm-benefit ratios will be different for populations at different risk for serious COVID-19 and observation periods that differ from those studied in the trials. Presumably, larger reductions in COVID-19 hospitalizations would have been recorded if trial follow-up were longer, more SARS-CoV-2 was circulating, or if participants had been at higher risk of serious COVID-19 outcomes, shifting harm-benefit ratios toward benefit. Conversely, harm-benefit ratios would presumably shift towards harm for those with lower risk of serious COVID-19 outcomes--such as those with natural immunity, younger age or no comorbidities. Similarly, waning vaccine effectiveness, decreased viral virulence, and increasing degree of immune escape from vaccines might further shift the harm-benefit ratio toward harm. Large, randomized trials in contemporary populations could robustly answer these questions. Absent definitive trials, however, synthesis of multiple lines of evidence will be essential. [30,48,49].

Adverse events detected in the post-marketing period have led to the withdrawal of several vaccines. An example is intussusception following one brand of rotavirus vaccine: around 1 million children were vaccinated before identification of intussusception, which occurred in around 1 per 10,000 vaccinees. [31] Despite the unprecedented scale of COVID-19 vaccine administration, the AESI types identified in our study may still be challenging to detect with observational methods. Most observational analyses are based on comparing the risks of adverse events "observed" against a background (or "expected") risk, which inevitably display great variation, by database, age group, and sex. [32] If the actual risk ratio for the effect was 1.4 (the risk ratio of the combined AESI analysis), it could be quite difficult to unambiguously replicate it with observational data given concerns about systematic as well as random errors. [33–35].

In addition, disproportionality analyses following COVID-19 vaccination also have limitations, particularly with respect to the type of adverse events seen in our study. The majority of SAEs that contributed to our results are relatively common events, such as ischemic stroke, acute coronary syndrome, and brain hemorrhage. This complicates signal detection because clinical suspicion of an adverse vaccine reaction following an event commonly seen in clinical practice will be lower than for SAEs like myocarditis.[50] For this reason, clinical suspicion leading to the filing of an individual case safety report--may be far less common in the post-authorization setting than in the trials. At the same time, heightened awareness about COVID-19 vaccine SAEs can result in under and overreporting. Public health messages assuring vaccine safety may lower clinical suspicion of potential causal relationships, whereas messages about potential harms can conversely stimulate reports that otherwise may not have been made. These factors can lead to bias both directions, further complicating interpretation. In contrast to these problems, in the randomized trials used in this analysis, all SAEs were to be recorded, irrespective of clinical judgment regarding potential causality.

Although our analysis is secondary, reanalyses of clinical trial data have led to the detection of adverse events well after the market entry of major drugs such as rofecoxib and rosiglitazone. [36,37] Our analysis has an advantage over postmarketing observational studies in that the data are from blinded, placebo-controlled randomized trials vetted by the FDA, which were matched against a list of adverse events created before the availability of the clinical-trial results and designed for use in COVID-19 vaccine trials.

Our study has several important limitations. First, Pfizer's trial did not report SAEs occurring past 1 month after dose 2. This reporting threshold may have led to an undercounting of serious AESIs in the Pfizer trial. Second, for both studies, the limited follow up time prevented an analysis of harm-benefit over a longer period. Third, all SAEs in our analysis met the regulatory definition of a serious adverse event, but many adverse event types which a patient may themselves judge as serious may not meet this regulatory threshold. Fourth, decisions about which SAEs to include or exclude as AESIs requires subjective, clinical judgements in the absence of detailed clinical information about the actual SAEs. We encourage third party replication of our study, with access to complete SAE case narratives, to determine the degree to which these decisions affected our findings. For additional sensitivity analyses, such replication studies could also make use of other AESI lists, such as those prepared by FDA, [38–41] CDC, [24], Pfizer, [42], or a *de novo* AESI list derived from a list of COVID-19 complications understood to be induced via SARS-CoV-2's spike protein. [43,44].

A fifth important limitation is our lack of access to individual participant data, which forced us to use a conservative adjustment to the standard errors. The 95 % CIs[13,14] calculated are therefore only approximate because we do not know which patients had multiple events. Finally, as described above, in the Moderna analysis, the SAEs that were sequelae of serious COVID-19 could not be identified and therefore remain included in our calculations. Because the vaccines prevent SAEs from COVID-19 while adding SAE risks of their own, this inclusion makes it impossible to separately estimate SAEs due to the vaccine from SAEs due to COVID-19 in the available Moderna data, as must be done to extrapolate harm-benefit to other populations. These study limitations all stem from the fact that the raw data from COVID-19 vaccine clinical trials are not publicly available. [45,46].

We emphasize that our investigation is preliminary, to point to the need for more involved analysis. The risks of serious AESIs in the trials represent only group averages. SAEs are unlikely to be distributed equally across the demographic subgroups enrolled in the trial, and the risks may be substantially less in some groups compared to others. Thus, knowing the actual demographics of those who experienced an increase in serious AESI in the vaccine group is necessary for a proper harm-benefit analysis. In addition, clinical studies are needed to see if particular SAEs can be linked to particular vaccine ingredients as opposed to unavoidable consequences of exposure to spike protein, as future vaccines could then be modified accordingly or sensitivities can be tested for in advance. In parallel, a systematic review and meta-analysis using individual participant data should be undertaken to address questions of harm-benefit in various demographic subgroups, particularly in those at low risk of serious complications from COVID-19. Finally, there is a pressing need for comparison of SAEs and harm-benefit for different vaccine types; some initial work has already begun in this direction. [47].

Full transparency of the COVID-19 vaccine clinical trial data is needed to properly evaluate these questions. Unfortunately, as we approach 2 years after release of COVID-19 vaccines, participant level data remain inaccessible. [45,46].

Author contributions

All authors had full access to all of the data in the study (available at https://doi.org/10.5281/zenodo.6564402), and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: All authors.
Acquisition of data: Doshi.
Analysis and interpretation: All authors.
Statistical analysis: Jones, Greenland.
Drafting of the manuscript: Fraiman, Doshi.
Critical revision of the manuscript for important intellectual content: All authors.

Data availability

All of the data in the study is available at https://doi.org/10.5281/zenodo.6564402

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Ethical review statement

This research was confirmed to be Not Human Subjects Research (NHSR) by University of Maryland, Baltimore (HP-00102561).

Conflicts of interest

JF, JE, MJ, SG, PW, RK: none to declare. PD has received travel funds from the European Respiratory Society (2012) and Uppsala Monitoring Center (2018); grants from the FDA (through University of Maryland M-CERSI; 2020), Laura and John Arnold Foundation (2017-22), American Association of Colleges of Pharmacy (2015), Patient-Centered Outcomes Research Institute (2014-16), Cochrane Methods Innovations Fund (2016-18), and UK National Institute for Health Research (2011-14); was an unpaid IMEDS steering committee member at the Reagan-Udall Foundation for the FDA (2016-2020) and is an editor at The BMJ. The views expressed here are those of the authors and do not necessarily reflect those of their employers.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2022.08.036.

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EXHIBIT 4

Danish Health Authority, *Vaccination against covid-19*

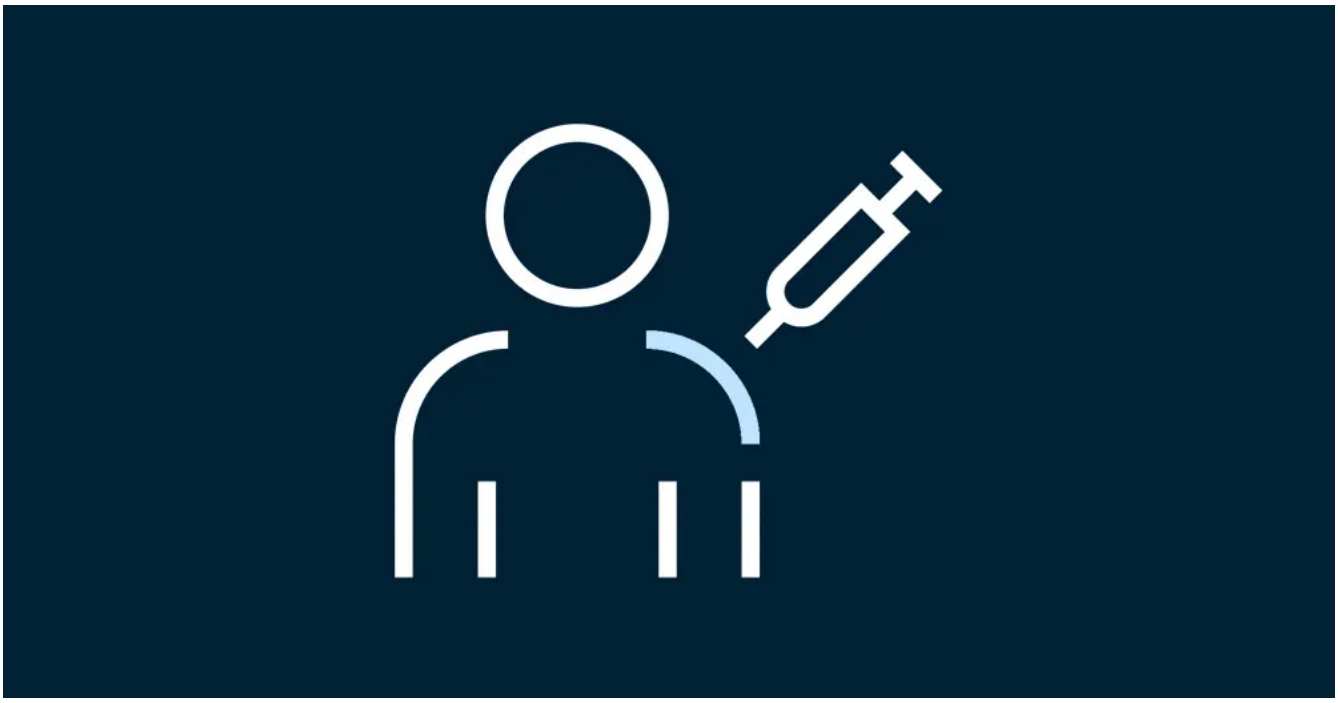
See attached.

DANISH HEALTH AUTHORITY

COVID-19

Vaccination against covid-19

The Danish Health Authority expects that the number of covid-19 infections will increase during autumn and winter. Therefore, we recommend vaccination of people aged 50 years and over as well as selected risk groups. Read more about the autumn vaccination programme here.



With the autumn vaccination programme, we aim to prevent serious illness, hospitalisation and death. The risk of becoming severely ill from covid-19 increases with age. Therefore, people who have reached the age of 50 and particularly vulnerable people will be offered vaccination. We expect that many people will be infected with covid-19 during autumn and winter. It is therefore important that the population remembers the guidance on how to prevent infection, which also applies to a number of other infectious diseases.

> See the guidance here: Prevent being infected with covid-19

On this page, you can read who will be offered vaccination, which vaccines we plan to use and when the programme will begin.

Q&A about vaccination

Who will be offered vaccination against covid-19?

People aged 50 years and over will be offered vaccination.

People aged under 50 who are at a higher risk of becoming severely ill from covid-19 will also be offered vaccination against covid-19.

Staff in the healthcare and elderly care sector as well as in selected parts of the social services sector who have close contact with patients or citizens who are at higher risk of becoming severely ill from covid-19 will also be offered booster vaccination against covid-19.

In addition, we recommend that relatives of persons at particularly higher risk accept the offer of vaccination to protect their relatives who are at particularly higher risk.

Why do we need to re-vaccinate?

We have achieved very high population immunity in Denmark. This is due both to the high adherence to the vaccination programme and to many people previously having been infected with covid-19. However, we expect that this immunity will gradually decrease over time. In addition, we know that covid-19 is a seasonal disease and that the number of infections are expected to increase during autumn and winter. We expect that a large part of the population will become infected with covid-19 during the autumn, and we therefore want to vaccinate those having the highest risk so that they are protected from severe illness if they become infected.

When will I be offered vaccination?

Nursing home residents and people aged 85 and over will be offered vaccination from mid-September. For others, the vaccination programme against covid-19 will begin on 1 October 2022.

I have a specific disease or condition – will I be offered vaccination?

People aged under 50 who are at higher risk of becoming severely ill are recommended vaccination against covid-19. This may, for example, be people who have a severely impaired immune system.

> Read more here

Will i get an invitation for vaccination?

If you are offered vaccination based on your age, you will receive an invitation in e-Boks/mit.dk. You will be offered vaccination against covid-19, influenza and pneumococci. For nursing home residents, there will be a special offer of local vaccination without appointment.

If you are in the target group for vaccination based on your illness/condition or your work, you will not receive an invitation. When the programme starts on 1 October, you can instead either:

- Fill in a solemn declaration and booking an appointment for vaccination on www.vacciner.dk. If you are in doubt about whether you are in the target group for vaccination, you can fill in a guiding questionnaire, which is also available on www.vacciner.dk, and then book an appointment if you are in the target group.
- Talk to your doctor, who can set up a vaccination process at www.vacciner.dk for you with the vaccines you are offered. You can then book an appointment yourself. In some cases, your doctor will be able to vaccinate you immediately.

If you are a healthcare professional or elderly care worker or employed in selected parts of the social services sector, your workplace can inform you about whether they offer vaccination of their staff.

Why are people aged under 50 not to be re-vaccinated? +

The purpose of the vaccination programme is to prevent severe illness, hospitalisation and death. Therefore, people at the highest risk of becoming severely ill will be offered booster vaccination. The purpose of vaccination is not to prevent infection with covid-19, and people aged under 50 are therefore currently not being offered booster vaccination.

People aged under 50 are generally not at particularly higher risk of becoming severely ill from covid-19. In addition, younger people aged under 50 are well protected against becoming severely ill from covid-19, as a very large number of them have already been vaccinated and have previously been infected with covid-19, and there is consequently good immunity among this part of the population.

It is important that the population also remembers the guidance on how to prevent the spread of infection, including staying at home in case of illness, frequent aeration or ventilation, social distancing, good coughing etiquette, hand hygiene and cleaning.

Variant-updated vaccines

What does it mean that a vaccine is variant updated? +

The Danish Health Authority will offer variant-updated mRNA vaccines in the autumn vaccination programme. These vaccines have been approved by the European Medicines Agency.

The vaccination, which will be offered during autumn/winter 2022-2023, consists of a variant-updated vaccine. The influenza vaccines are updated every year, and the covid-19 vaccines have likewise also been updated to target the Omicron variant more effectively.

The variant-updated vaccines have been adapted to the variant that is dominant in society.

What side effects do the vaccines have?

All vaccines cause side effects, including the covid-19 vaccines. In general, the side effects are mild and transient, and we consider the vaccines to be very safe and highly documented.

Studies of the variant-updated vaccines have shown that the side effects do not differ from those seen in connection with the vaccines we have previously used in Denmark.

Mild side effects

Most people will experience pain at the injection site. Other common side effects include fatigue, headache, pain in muscles and joints, chills, a slight fever as well as redness and swelling at the injection site. These are generally signs that your body's immune system is reacting as it should to the vaccine. You do not need to call your doctor if you experience these known and transient side effects. If you are among those who do not experience side effects, you should not worry that the vaccine is not working, because it will regardless of whether you experience side effects.

We know from other vaccines that almost all side effects occur within the first six weeks of vaccination. It is very rare for them to occur later than this. Both Danish and European medicines agencies monitor the vaccines closely after they have been approved both in relation to how well they work and how many side effects they cause.

However, there is a difference in how well the immune system of older and younger people responds to vaccines. Elderly people will typically have poorer-responding immune systems, and they will therefore typically experience fewer side effects.

Rare side effects

In rare cases, severe immediate allergic reactions (anaphylaxis) may occur, which may be caused by, for example, allergy to the additives in the vaccine. If you have previously had a severe allergic reaction immediately after being vaccinated or after being injected with a medicinal product, you should contact your doctor before being vaccinated against covid-19. If you have a known allergy to macrogols/PEG/polyethylene glycol, you should not be vaccinated with the mRNA vaccines.

Vaccination of children against covid-19

Children and adolescents rarely become severely ill from the Omicron variant of covid-19.

From 1 July 2022, it was no longer possible for children and adolescents aged under 18 to get the first injection and, from 1 September 2022, it was no longer possible for them to get the second injection.

A very limited number of children at particularly higher risk of becoming severely ill will still be offered vaccination based on an individual assessment by a doctor.

Should I be vaccinated?

Can I tolerate being vaccinated?

Can I tolerate being vaccinated?

Situations in which you should not be vaccinated

You should not be vaccinated against covid-19 if you have:

- A known, ascertained allergy to the vaccine (for example an immediate allergic reaction (anaphylaxis) in connection with the first injection)
- A known allergy to one of the excipients in the vaccine

Situations in which you should postpone vaccination

- You are acutely ill with a fever above 38°. You can be vaccinated if you only have a slight fever or light infections such as a common cold. However, you should always consider whether you might have covid-19 in this connection.
- You have covid-19 or suspect that you have covid-19.
- You have had covid-19 within one month before vaccination.
- You have been tested due to suspicion of covid-19 or because you are a close contact of an infected person.
- You are to undergo surgery within one week before or after vaccination.

Situations in which you should consult a doctor before being vaccinated

- You have been informed that there is a suspicion of allergy to macrogol/PEG/polyethylene glycol.
- You have previously had an immediate allergic reaction (anaphylaxis) after vaccination or after injection of another medicinal product.
- You have previously repeatedly had an immediate allergic reaction (anaphylaxis) after ingestion of other medicinal products (for example laxatives, stomach acid drugs).
- You have mastocytosis (a rare disease of the body's mast cells).

Situations in which you can be vaccinated

Most people tolerate the vaccine well. You can be vaccinated even if:

- You are waiting for the result of a covid-19 test
- You have developed a skin rash after taking other medicinal products (for example penicillin, ibuprofen).
- You cannot tolerate or experience discomfort from strong pills (for example painkillers).
- You have experienced common, known side effects after the first injection of the vaccine.
- You are allergic to foods (for example eggs, shellfish, nuts).
- You are allergic to insecticides, latex or the like.

- You have pollen allergy/hay fever, allergy to animals or asthma eczema.
- You are undergoing fertility treatment.
- You have received another vaccine (for example against influenza or pneumococci) on the same day/recently.
- You are a cancer patient and are undergoing treatment
- You have an impaired/weakened immune system1
- A family member has had an allergic reaction after vaccination.
- You do not want to consume products made from pigs.
- You have previously had treatment with botox.
- You are on ordinary blood-thinning medication.
- You have previously had a blood clot or there is a tendency to blood clots in your family.

[1]People with impaired/weakened immune system may have a poorer effect of the vaccine and should pay special attention to following

> The Danish Health Authority's guidance on how to prevent infection

Need further advice?

Healthcare professionals can contact Statens Serum Institut or the regional pharmacovigilance units/side effect managers.

CanI be vaccinated if I am ill?

If you have a fever of 38 degrees or more or have an acute severe infection such as pneumonia, your vaccination must be postponed.

You can be vaccinated if, for example, you only have a slight fever or a light infection such as a common cold, but you must always consider whether you may have covid-19.

Publications, etc.

Please click on the arrow to view our current publications, etc. on COVID-19 vaccination.

vaccination COVID-19

EXHIBIT 5

Emergency Executive Order 62, March 4, 2022

See attached.

THE CITY OF NEW YORK
OFFICE OF THE MAYOR
NEW YORK, N.Y. 10007

EMERGENCY EXECUTIVE ORDER NO. 62
March 24, 2022

WHEREAS, the COVID-19 pandemic has severely impacted New York City and its economy, and is addressed effectively only by joint action of the City, State, and Federal governments; and

WHEREAS, the state of emergency to address the threat and impacts of COVID-19 in the City of New York first declared in Emergency Executive Order No. 98, issued on March 12, 2020, and extended most recently by Emergency Executive Order No. 46, issued on February 28, 2022, remains in effect; and

WHEREAS, this Order is given because of the propensity of the virus to spread person-to-person, and also because the actions taken to prevent such spread have led to property loss and damage; and

WHEREAS, athletes and performing artists frequently conduct their work at venues both inside and outside of the City, without regard to their residence in the City, and their work benefits the City's economic recovery from the pandemic, often attracting large numbers of visitors to the City; and

WHEREAS, New York City athletic teams have been, and continue to be, at a competitive disadvantage because visiting teams can field unvaccinated players, and this competitive disadvantage has negatively impacted, and continues to negatively impact, New York City teams' success, which is important to the City's economic recovery and the morale of City residents and visitors; and

WHEREAS, additional reasons for requiring the measures continued in this Order are set forth in my prior Emergency Executive Order No. 50, issued on March 4, 2022;

NOW, THEREFORE, pursuant to the powers vested in me by the laws of the State of New York and the City of New York, including but not limited to the New York Executive Law, the New York City Charter and the Administrative Code of the City of New York, and the common law authority to protect the public in the event of an emergency:

Section 1. I hereby direct that section 1 of Emergency Executive Order No. 59, dated March 19, 2022, is extended for five (5) days.

§ 2. I hereby order that section 3 of Emergency Executive Order No. 50, dated March 4, 2022, is amended to read as follows.

§ 3. I hereby direct that:

a. Covered entities that had been covered by the Key to NYC program shall continue to require that a covered worker provide proof of vaccination, unless such worker has received a reasonable accommodation. Covered entities shall continue to keep a written record of their protocol for checking covered workers' proof of vaccination and to maintain records of such workers' proof of vaccination, as described in subdivisions d and e of section 2 of Emergency Executive Order No. 317, dated December 15, 2021.

b. Records created or maintained pursuant to subdivision a of this section shall be treated as confidential.

c. A covered entity shall, upon request by a City agency, make available for inspection the records required to be maintained by this section, consistent with applicable law.

d. For the purposes of this Section:

(1) "Covered entity" means any entity that operates one or more "covered premises," except that "covered entity" does not include pre-kindergarten through grade twelve (12) public and non-public schools and programs, houses of worship, childcare programs, senior centers, community centers.

(2) "Covered premises" means any of the following locations, except as provided in subparagraph (iv) of this paragraph:

> **(i) Indoor Entertainment and Recreational Settings, and Certain Event and Meeting Spaces**, including indoor portions of the following locations, regardless of the activity at such locations: movie theaters, music or concert venues, adult entertainment, casinos, botanical gardens, commercial event and party venues, museums, aquariums, zoos, professional sports arenas and indoor stadiums, convention centers and exhibition halls, hotel meeting and event spaces, performing arts theaters, bowling alleys, arcades, indoor play areas, pool and billiard halls, and other recreational game centers;
>
> **(ii) Indoor Food Services**, including indoor portions of food service establishments offering food and drink, including all indoor dining areas of food service establishments that receive letter grades as described in section 81.51 of the Health Code; businesses operating indoor seating areas of food courts; catering food service establishments that provide food indoors on its premises; and any indoor portions of an establishment that is regulated by the New York State Department of Agriculture and Markets offering food for on-premises indoor consumption; and

(iii) Indoor Gyms and Fitness Settings, including indoor portions of standalone and hotel gyms and fitness centers, gyms and fitness centers in higher education institutions, yoga/Pilates/barre/dance studios, boxing/kickboxing gyms, fitness boot camps, indoor pools, CrossFit or other plyometric boxes, and other facilities used for conducting group fitness classes.

(iv) "Covered premises" does not include houses of worship or locations in a residential or office building the use of which is limited to residents, owners, or tenants of that building.

(3) "Covered worker" means an individual who works in-person in the presence of another worker or a member of the public at a workplace in New York City. "Covered worker" includes a full- or part-time staff member, employer, employee, intern, volunteer, or contractor of a covered entity, as well as a self-employed individual or a sole practitioner.

"Covered worker" does not include:

(i) an individual who works from their own home and whose employment does not involve interacting in-person with co-workers or members of the public;

(ii) an individual who enters the workplace for a quick and limited purpose;

(iii) a performing artist, or an individual accompanying such performing artist, while the performing artist is in a covered premises for the purpose of such artist's performance; or

(iv) a professional athlete, or an individual accompanying such professional athlete or such athlete's sports team, who enters a covered premises as part of their regular employment.

(4) "Proof of vaccination" means proof of receipt of a full regimen of a COVID-19 vaccine authorized for emergency use or licensed for use by the U.S. Food and Drug Administration or authorized for emergency use by the World Health Organization, not including any additional recommended booster doses. Such proof may be established by:

(i) A CDC COVID-19 Vaccination Record Card or an official immunization record from the jurisdiction, state, or country where the vaccine was administered, or a digital or physical photo of such a card or record, reflecting the person's name, vaccine brand, and date administered; or

(ii) A New York City COVID Safe App (available to download on Apple and Android smartphone devices); or

(iii) A New York State Excelsior Pass; or

(iv) CLEAR's digital vaccine card; or

(v) Any other method specified by the Commissioner of Health and Mental Hygiene as sufficient to demonstrate proof of vaccination.

(5) I hereby order that section 20-1271 of the Administrative Code of the City of New York is modified by adding the following provision to the definition of "just cause:" Notwithstanding any provision of this chapter, a fast food employer shall be deemed to have just cause when a fast food employee has failed to provide proof of vaccination required by an emergency executive order issued in response to the COVID-19 pandemic and shall not be required to follow progressive discipline procedures prior to terminating the employee, provided that the employee shall have 30 days from the date when the employer notified the employee of the requirement to submit such proof and the employee shall be placed on leave following such notification until such proof is provided. This provision shall not excuse the employer from the responsibility to provide a reasonable accommodation where required by law.

e. An individual who meets the requirements of subparagraph (iii) or (iv) of section 3(d)(3) of this Order shall be exempt from the Order of the Commissioner of Health dated December 13, 2021, relating to requiring COVID-19 vaccination in the workplace.

§ 3. I hereby direct the Fire and Police Departments, the Department of Buildings, the Sheriff, and other agencies as needed, to enforce the directives set forth in this Order in accordance with their lawful authorities, including Administrative Code sections 15-227(a), 28-105.10.1, and 28-201.1, and section 107.6 of the Fire Code. Violations of the directives set forth in this Order may be issued as if they were violations under Health Code sections 3.07 and 3.11, and enforced by the Department of Health and Mental Hygiene or any other agency.

§ 4. This Emergency Executive Order shall take effect immediately and shall remain in effect for five (5) days unless it is terminated or modified at an earlier date.

Eric Adams
Mayor

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: ANDREW WALLACH

Address: AMBULATORY CARE CHIEF MEDICAL OFFICER

I represent: NYC HEALTH + HOSPITALS

Address: _____

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: RISHI SOOD

Address: Executive Director, Health Care Access + Policy

I represent: DOHMH

Address: _____

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: 9.19.22

(PLEASE PRINT)

Name: (Dr.) David Silvestri, Assistant Vice President Emergency Management

Address: 50 Water St. Medical Director, Utilization Management + Transitional Care

I represent: _____

Address: _____

Please complete this card and return to the Sergeant-at-Arms

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: 9/19/22

(PLEASE PRINT)

Name: Andrew Title

Address: _____

I represent: Greater New York Hospital Association

Address: _____

Please complete this card and return to the Sergeant-at-Arms

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: 9/19/22

(PLEASE PRINT)

Name: Manuel Sanz, PhD. Senior Asst. VP, H+H

Address: 55 Water St

I represent: _____

Address: _____

Please complete this card and return to the Sergeant-at-Arms