SB0840_FAV_LifeSpan_COVID-19 Response Act of 2022.
Uploaded by: Danna Kauffman
Position: FAV

LIFESPAN NETWORK

Keeping You Connected…Expanding Your Potential…
In Senior Care and Services

TO: The Honorable Delores G. Kelley, Chair
Members, Senate Finance Committee
The Honorable Jim Rosapepe

FROM: Danna L. Kauffman
Pamela Metz Kasemeyer

DATE: March 3, 2022

RE: **SUPPORT** – Senate Bill 840 – *COVID-19 Response Act of 2022*

On behalf of the LifeSpan Network, the largest and most diverse senior care provider association in Maryland representing nursing facilities, assisted living providers, continuing care retirement communities, medical adult day care centers, senior housing communities and other home and community-based services, we **support** Senate Bill 840.

Among other provisions, Senate Bill 840 contains a provision on page 12 regarding the use of temporary nursing assistants employed in nursing homes. At the beginning of the COVID-19 pandemic, the federal Centers for Medicare & Medicaid Services (CMS) issued multiple waivers of federal regulations to alleviate staffing shortages. The CMS QSO-21-17-NH memorandum, revised on May 10, 2021, states:

> *To help nursing homes address staffing shortages during the pandemic, CMS provided a blanket waiver for the nurse aide training and certification requirements at 42 CFR §483.35(d) (except for requirements that the individual employed as a nurse aide be competent to provide nursing and nursing related services at 42 CFR §483.35(d)(1)(i)), specifically to permit nurse aides to work for longer than four months without having completed their training. This waiver allows facilities to employ individuals beyond four months, in a nurse aide role even though they might have not completed a state approved Nurse Aide Training and Competency Evaluation Programs (NATCEP). The individual could continue to work as long as the nursing home ensured that the nurse aide could demonstrate competency in skills and techniques needed to care for residents. CMS is not ending the current nurse aide waiver. However, we are clarifying how federal regulations can be applied to nurse aides working under the blanket waiver, and help enable these individuals to become certified nurse aides (CNAs).*

At this time, it is estimated that approximately 2,000 individuals are practicing under the designation of temporary nursing assistants. These individuals have worked tirelessly throughout this pandemic to provide care to residents of nursing homes under the close supervision of licensed individuals. We strongly believe that these individuals should be provided "credit" for the work that they have performed

over the last two years and that a process should be implemented to allow these hours to be applied to satisfy required training hours to be fully certified. As you know, Maryland faces a workforce shortage, especially in the areas of direct care. In particularly, nursing homes have struggled to recruit and maintain staff. Maryland must "think outside the box" and implement innovative approaches to bolster the workforce. We strongly believe that developing a program to assist these individuals in becoming certified at a faster pace is beneficial to the industry and the residents cared for by them.

For more information call:
Danna L. Kauffman
Pamela Metz Kasemeyer
410-244-7000

HFAM Testimony SB 840.pdf
Uploaded by: Joseph DeMattos
Position: FAV

TESTIMONY BEFORE THE
SENATE FINANCE COMMITTEE
March 2, 2022
Senate Bill 840: COVID-19 Response Act of 2022
Written Testimony Only

POSITION: FAVORABLE

On behalf of the members of the Health Facilities Association of Maryland (HFAM), we appreciate the opportunity to express our support for Senate Bill 840. HFAM represents over 170 skilled nursing centers and assisted living communities in Maryland, as well as nearly 80 associate businesses that offer products and services to healthcare providers. Our members provide services and employ individuals in nearly every jurisdiction of the state.

Senate Bill 840 establishes and alters requirements related to COVID-19, including requirements related to planning by institutions of higher education, home health agencies, nursing homes, and assisted living programs, the provision of coverage by the Maryland Medical Assistance Program, the Maryland MyIR Mobile immunization record service, and reporting by the Maryland Department of Health (MDH).

Senate Bill 840 provides for important medical treatments for Marylanders in need subject to budget availability. The legislation also provides for ongoing generalized testing associated with the COVID-19 pandemic and requires MDH, in partnership with others, to undertake planning going forward – hopefully moving from a pandemic to endemic COVID-19. In addition, there are important provisions on vaccination rates and outreach to at-risk and diverse communities.

We will note relative to the required COVID testing and testing planning portions of SB 840 that such plans will occur not just as a result of MDH directives, but in conjunction with federal requirements and ideally in public-private partnerships. Skilled nursing and rehabilitation centers continue to spend millions of dollars per year on employee testing. Obviously, these centers were not spending this money on testing prior to the pandemic. Nor are these expenses underwritten by Medicare or Medicaid.

Finally, and the primary reason for our support, Senate Bill 840 requires the Maryland Board of Nursing (MBON) establish a Geriatric Nursing Assistant Apprenticeship Program—an approach that is, in a way, already temporarily happening as a result of the pandemic and federal emergency rules. We have been working closely on this issue with Maryland Board of Nursing (MBON) Executive Director Karen Evans, Delegate Ariana Kelly, and other stakeholders.

Early on in the pandemic, the federal government waived federal nursing assistant training and certification requirements. The federal government, through the Centers for Medicare and Medicaid Services (CMS), has authority over this process, but state approval is also required. Under this waiver, many states permitted an eight-hour online emergency temporary nursing assistant (TNA) course. The American Health Care Association/National Center for Assisted Living (AHCA/NCAL) created a free online course and continues to

offer it for those wishing to become TNAs. **Here in Maryland, 3,137 participants have successfully taken the 8-hour TNA training as of February 24, 2022.**

Graduates of the course who demonstrate competency are allowed to work as TNAs in healthcare settings in Maryland as long as the national public health emergency (PHE) exists and for up to 120 days after the emergency ends. Under the current rules, those who have been working as TNAs throughout the COVID-19 pandemic will be required to start their training from scratch in order to continue working after the federal public health emergency. For those working in long-term care settings in Maryland, this means they will be required to satisfy all of the Geriatric Nursing Assistant (GNA) requirements including taking the full training program and pass the GNA certification examination.

We have been working with Karen Evans and MBON on a certification pathway that would take into consideration the experience of a TNA and allow them to sit for the state certification exam after attestation that their experience and on-the-job training during the pandemic has been sufficient.

Senate Bill 840 is incredibly helpful in this work because it provides a framework for MBON to appropriately credential and retain the temporary nursing assistants that want to continue working, and perhaps more importantly, it will establish a permanent framework for supporting other apprentice innovations in Maryland skilled nursing and rehabilitation centers even as we move beyond the COVID-19 pandemic.

There is at least one Maryland nursing home that augmented the 8-hour online training with a three-day (24-hour total) training before a temporary nursing assistant took the full 100-hour training program. Under the current federal public health emergency, such an approach is allowed. However, this approach would not be allowed in the absence of a federal emergency unless MBON formalizes it. Under the provisions of SB 840 and other initiatives being considered this session, MBON would be empowered to undertake this vital approach to retaining emergency TNAs and growing our licensed workforce.

Maryland faces a historic and dramatic shortage of licensed healthcare professionals. The Board of Nursing reported that 40,000 individuals licensed by the Board did not renew their license in 2021. And, we have all read of and perhaps experienced some aspects of “The Great Resignation” across various industries.

The current workforce crisis pre-dates the pandemic and the pressures of the pandemic dramatically worsened the workforce shortage. The most recent Omicron surge of COVID-19 proved to us yet again that there is no individual hospital, nursing home, or physician’s office workforce – there is one singular healthcare workforce in Maryland. It is shorthanded, and we are all drawing upon it.

Going forward the length of this workforce crisis will be measured in years and not months. As we navigate forward, we must create pathways that ensure we have enough healthcare professionals to continue caring for Marylanders in need.

For these reasons, we request a favorable report from the Committee on Senate Bill 840.

Submitted by:
Joseph DeMattos, Jr.
President and CEO
(410) 290-5132

SB 840 - COVID-19 Response Act of 2022.pdf
Uploaded by: Justin Hayes
Position: FAV

COMPTROLLER of MARYLAND
Serving the People

Peter Franchot
Comptroller

TESTIMONY OF COMPTROLLER PETER FRANCHOT

Support – Senate Bill 840 – COVID-19 Response Act of 2022
Finance Committee
March 2, 2022

Chair Kelley, Vice Chair Feldman, and members of the Committee, it is my pleasure to provide testimony in **support** of **Senate Bill 840 – COVID-19 Response Act of 2022.** I would like to thank Senator Rosapepe for sponsoring this important legislation, and the Committee for providing the opportunity for my testimony to be heard.

As the coronavirus evolves, so must our strategies. I support a vaccine passport outlined in Senate Bill 840, because it's time for people who follow best practices and science — a vast majority of our state by any measure — to be able to return to their daily lives and routines. We cannot continue in this climate where the small percentage of the unvaccinated determine the course of life for the overwhelming majority of people who did the right thing and got vaccinated.

Despite all efforts to counter misinformation about vaccines, the reality is that even though a small minority of Maryland adults remain unvaccinated, these unvaccinated individuals perpetuate unnecessary challenges and have allowed variants such as omicron to develop at faster rates.

Vaccine passports would require people to provide proof of vaccination before entering public spaces such as restaurants, retail spaces, concert venues and fitness facilities. Valid credentials that would be recognized as having "passport status" include Centers for Disease Control and Prevention records, a digital photo of CDC documentation or a certificate from MD MyIR Mobile.

Vaccine passports not only encourage people to do the right thing, but they also could mitigate even more negative impacts to households and Maryland's economy. For the reasons stated above, and the safety of all Marylanders, I respectfully request a favorable report for Senate Bill 840. Thank you for your time and consideration.

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SB 840_mgoldstein_fav 2022.pdf
Uploaded by: Mathew Goldstein
Position: FAV

Secular Maryland secularmaryland@tutanota.com

March 02, 2022

SB 840 - SUPPORT

COVID-19 Response Act of 2022

Dear Chair Kelley, Vice-Chair Feldman, and Members of the Finance Committee,

Secular Maryland favors laws that push back against contagious diseases that injure and kill. Mobile vaccine passports protect us all by providing incentive to get vaccinated. They give businesses and service providers the confidence of knowing they are providing a safe setting for their clientele and employees. They give citizens more confidence that it is safe to be employed at indoor locations shared with others. They give customers more confidence to purchase goods and services at local indoor providers instead of purchasing online for delivery or postponing their purchases. They facilitate international travel.

This bill also defends against the dangers that contagious disease pose at institutions of higher education, home health agencies, nursing homes, and assisted living programs. It provides state support for testing, contact tracing, case management, treatment, urgent care, and care resource coordination. It addresses ongoing shortages of medical staff. It requires reporting vaccinations to IMMUNET. Enacting this bill will enable the state to more effectively battle and manage COVID-19 and other contagious diseases.

Respectfully,
Mathew Goldstein
3838 Early Glow Ln
Bowie, MD

SB 840- COVID-19 Response Act of 2022- Letter of S

Uploaded by: Nicole Stallings

Position: FAV

Maryland
Hospital Association

March 2, 2022

To: The Honorable Delores G. Kelley, Chair, Senate Finance Committee

Re: Letter of Support – Senate Bill 840 – COVID-19 Response Act of 2022

Dear Chair Kelley:

On behalf of the Maryland Hospital Association's (MHA) 60 member hospitals and health systems, we appreciate the opportunity to support Senate Bill 840. This week marks the second year since Maryland hospitals saw their first COVID-19 patients. Last year, MHA supported Senate Bill 741 to establish COVID-19 testing, contact tracing, and vaccination protocols to combat the ongoing pandemic. However, as the recent delta and omicron surges have shown, we are not out of the woods. Additional measures are needed to ensure appropriate prevention and response in the future.

SB 840's response plan, vaccination, and treatment provisions are critical as hospitals continue to care for their communities. MHA appreciates the consideration of hospital-adjacent urgent care centers, as our experience demonstrates the importance of alternative sites to decant lower acuity patients from crowded hospital emergency departments.

If an urgent care center is adjacent to a hospital, we support clearly distinguishing the unregulated urgent care center from the regulated hospital. The Health Services Cost Review Commission (HSCRC) requires separate entrances and explicit signage to denote any unregulated building on a hospital campus, including an urgent care center. The bill language reinforces the intent that these services are considered unregulated.

We acknowledge additional clarification may be necessary to ensure SB 840 accounts for federal laws and requirements, including the Emergency Medical Treatment and Labor Act (EMTALA) and corresponding Centers for Medicare & Medicaid Services regulations.

The COVID-19 pandemic continues to test the strength of our state's public health system. The support offered in this legislation to shore up our state's systems for response plans, vaccination, treatment, and alternate care sites will help to speed our recovery and see our way through this unprecedented public health emergency.

For these reasons, we urge a ***favorable*** report.

For more information, please contact:
Nicole Stallings, Chief External Affairs Officer and SVP, Government Affairs & Policy
Nstallings@mhaonline.org

2022 MCHS SB 840 Senate Side.pdf
Uploaded by: Robyn Elliott
Position: FAV

Maryland Community Health System

Committee: **Senate Finance Committee**

Bill: **Senate Bill 840 - COVID-19 Response Act of 2022**

Hearing Date: **March 2, 2022**

Position: **Support**

Maryland Community Health System supports *Senate Bill 840 – COVID-19 Response Act of 2022*. The bill provides for a comprehensive framework to guide the State's ongoing response to COVID-19. As our state returns to "normal", it is important that we keep our public health infrastructure intact to ensure that we continue to see a decline in our COVID-19 rates. The bill focuses on the multi-prong strategy to ensure Maryland has effective testing, vaccination, and treatment programs. As a network of federally qualified health centers focused on providing services to the underserved, we appreciate the bill's focus on ensuring the state's COVID-19 efforts reach every community in our state.

We ask for a favorable report. If we can provide any additional information, please contact Robyn Elliott at relliott@policypartners.net.

Clinical Laboratory Ready Reserve--Testimony for M

Uploaded by: Jonathan Cohen

Position: FWA

Keep Maryland's Testing Labs Ready for Future Pandemics

Testimony of Jonathan Cohen*
SB 840 COVID-19 Response Act of 2022
Senate Finance Committee
March 2, 2022

I am Jonathan Cohen, President & CEO of 20/20 GeneSystems in Gaithersburg. Since the start of the pandemic our clinical lab has conducted nearly a quarter million PCR tests for Marylanders. We have contracts with both the Montgomery County Department of Health and the Maryland Department of Health and conduct testing at schools in Montgomery, Charles, Dorchester, St. Mary's, Caroline, and Wicomico Counties.

I am here this afternoon to recommend an amendment to the SB 840 (see bottom) that would help testing labs maintain readiness for future variants or pandemics.

With Omicron fading across the country, demand for Covid testing is falling too. Clinical laboratories that rushed to respond to the pandemic, to get their COVID-19 testing up and running, to scale-up to meet demand, are left wondering, "what should we do with our excess capacity?" We should think twice before we let it fade.

Before COVID hit the US, many labs did not have the tools and infrastructure the nation needed to respond to the pandemic. Many small- and medium-sized businesses invested hundreds of thousands of dollars in state-of-the art automation, robotics, and software systems while recruiting and training skilled personnel to run tests and meet 12–24-hour turnaround demands.

What should labs do with this testing infrastructure that may soon be gathering dust? Without coordination and support from government, many of these laboratories will have to make the rational decision to sell unused equipment and decrease capacity—leaving the nation unprepared for new variants or future pandemics.

Today's clinical laboratory infrastructure is almost unrecognizable from what existed in the first weeks of the pandemic. South Korea quickly scaled to 20,000 tests per day just a few weeks after their first confirmed COVID-19 infection. But it took the US four months to reach this per capita equivalent of 130,000 tests per day. We know that more testing earlier in the pandemic would have changed the course of our early response and saved lives.

While stockpiling may be appropriate for certain medical supplies and countermeasures such as therapeutics, it doesn't work for sophisticated high-throughput laboratory platforms that require ongoing maintenance, tuning, and upkeep nor does it address the need to quickly recruit and train skilled lab testing personnel.

Maryland should establish and maintain a "Clinical Laboratory Ready Reserve" to guard against atrophy and ensure that there is national capacity to ramp up a coordinated lab testing response quickly after a new infectious disease outbreak or bioterror attack. The lab reserve would be a state supported network of Maryland based diagnostic labs participating on a voluntary basis.

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* *Jonathan Cohen is CEO of 20/20 GeneSystems, Inc. a Gaithersburg, MD based clinical lab that has conducted nearly a quarter-million PCR tests for Marylanders since the start of the pandemic. He can be reached at jcohen@2020gene.com 240-453-6343*

Reserve labs would be incentivized to maintain "in reserve" excess testing equipment and to keep their personnel up to date and trained to respond to new outbreaks. This model is in line with ideas offered by experts, including former FDA Commissioner Scott Gottlieb, who have suggested that the government offer subsidies to community labs that maintain, in good operating condition, more testing capacity than they need to meet current demands. It is supported by the National Independent Laboratory Association.

Creating a reserve network of well-prepared clinical labs will help ensure that we are not again caught flat footed and blind to the next pandemic.

# # # # #

Proposed Amendment to SB 840:

One page 6, after line 17 insert:

(6) A PLAN TO INCENTIVIZE AND REMUNERATE CLIA LICENSED LABORATORIES LOCATED IN THE STATE TO MAINTAIN IN RESERVE THE RESOURCES REQUIRED TO RAPIDLY SCALE UP TESTING IF NEEDED IN RESPONSE TO NEW COVID-19 VARIANTS, PANDEMICS, DISEASE OUTBREAKS OR BIOTERRORISM ATTACKS IN THE STATE INCLUDING, WITHOUT LIMITATION,

(I) LABORATORY TESTING EQUIPMENT AND FACILITIES, AND

(II) LABORATORY PERSONNEL, WHETHER FULL TIME, PART-TIME, OR ON-CALL, WHO PERIODICALLY TRAIN, PRACTICE, AND DRILL TO RAPIDLY RESPOND TO EMERGENCIES REQUIRING A SURGE IN CLINICAL LABORATORY TESTING

SB0840_FWA_MedChi, MDAAP_COVID-19 Response Act of

Uploaded by: Pam Kasemeyer

Position: FWA

MedChi

The Maryland State Medical Society
1211 Cathedral Street
Baltimore, MD 21201-5516
410.539.0872
Fax: 410.547.0915
1.800.492.1056
www.medchi.org

Maryland Chapter
American Academy of Pediatrics
Speaking for Maryland Kids!

TO: The Honorable Delores G. Kelley, Chair
Members, Senate Finance Committee
The Honorable Jim Rosapepe

FROM: Pamela Metz Kasemeyer
J. Steven Wise
Danna L. Kauffman
Christine K. Krone

DATE: March 2, 2022

RE: **SUPPORT ONLY IF AMENDED** – Senate Bill 840 – *COVID-19 Response Act of 2022*

On behalf of the Maryland State Medical Society and the Maryland Chapter of the American Academy of Pediatrics, we submit this letter of **support** for Senate Bill 840, **only if the legislation is amended**.

Senate Bill 840 is an emergency bill that includes a number of requirements for action by the Maryland Department of Health, Medicaid, assisted living, home health agencies, nursing homes and higher education institutions relative to Maryland's COVID-19 response. MedChi and MDAAP have no objection to these COVID-19 provisions. However, there are three new initiatives included in the bill and outlined below that are not COVID-19 specific policies and that either have the potential for significant unintended consequences and/or require more careful consideration. MedChi and MDAAP are opposed to these provisions.

<u>Pharmacists Administration of Vaccines:</u>

Senate Bill 840 removes the current sunset on a pharmacist's authority to administer vaccines to minors age 3 and older without a prescription. Pharmacist administration of vaccines to children was addressed through legislation enacted last year (Senate Bill 736/House Bill 1040) that authorized the administration for two years and required a comprehensive study of issues relative to vaccine access by children, including the impact on well child visit rates. Removing the sunset provisions enacted negates the study and removes the ability of the State to determine whether current pharmacist authorization should be continued, modified, or permanently sunset based on the findings of the study. Senate Bill 840 should be amended to remove these provisions and retain the statutory structure enacted in 2021, pending the outcome and evaluation of the study.

<u>Expansion of Scope of Practice for Pharmacists and Pharmacy Technicians:</u>

Senate Bill 840 provides an expansion of scope for pharmacists and a significant expansion of scope for pharmacy technicians. These scope of practice expansions create significant risks for patient safety, given adverse reactions and other patient safety issues associated with delegation of vaccine administration and permitting unauthorized refills of prescriptions,

The provisions of concern include:

- Deletion of the administration of the flu vaccine from the list of actions precluded from delegation by a pharmacist.
- Including in the definition of "direct supervision" the ability to supervise via technology, therefore supervision does not need to be on site.
- Broadening the circumstances/provisions under which a prescription can be refilled without authorization from the prescriber.
- Increasing the number of days from 14 days to a 30-day supply that a pharmacist can renew a prescription that is not authorized and from 30 days to 90 days under a state of emergency.
- Very limited training requirements for a pharmacy technician to whom a pharmacist can delegate administration of vaccines.

These provisions should be deleted from the legislation, given the patient safety and over-utilization concerns and the fact that they are not tied to COVID-19 specific initiatives.

Emergency Medical Facilities:

Senate Bill 840 proposes a new section of law that defines "hospital-adjacent urgent care center" and addresses their authority to set rates and receive reimbursement on an unregulated basis. While MedChi and MDAAP do not have a position on this provision, it is not COVID-19 related and should be evaluated independently from a legislative initiative that is focused on COVID -19 response. This section should be removed from the legislation.

MedChi and MDAAP support the COVID-19 related provisions of this legislation, however that support is contingent on the adoption of amendments that remove the provisions outlined above.

For more information call:
Pamela Metz Kasemeyer
J. Steven Wise
Danna L. Kauffman
Christine K. Krone
410-244-7000

Testimony840.pdf
Uploaded by: Agne Pack
Position: UNF

This is a lengthy bill with a lot of issues rolled into one. These issues should have been addressed maybe separately and preferably par our founding fathers in both chambers. The most difficult part of this bill is on page 16 where caregiver for a child is not defined. Are we to think any random adult can be deemed a “caregiver” as long as they show up to a pharmacy technician and be vaccinated with a vaccine that is not FDA approved, at most the vaccines are emergency pushed through with little to no attention given to any adverse reactions and if these reactions may ultimately be worse than the flu like symptoms for the majority of the population. According to the Vaccine Adverse Events Reporting System, the best tool we have so far and clearly underfunded and underutilized as scrutiny goes to rushing ineffective vaccines and endless boosters with unknown consequences for a mild flu, there have been 33,740 reported deaths from the covid vaccines. These are only the reported ones. It is not popular to say anything against these when in places such as this Capitol and at a time such as a Senate Bill hearing we should be able to discuss adversities for citizens of a free country. There have been 1,134,482 adverse event reports in VAERS as of this hearing. 157 just in 2022 reported in MD aged 3 -18. Only time will tell what will happen further in symptoms of those already being experimented on. Dr. Scott Gottlieb the former head of FDA and director of Pfizer has delayed trials in shots for kids under 5 due to their low covid cases as they are not symptomatic. Masks were already cruel for children. Vaccines that are untested and unending with boosters are downright inhumane, especially if as like TrueCare24’s quality assurance fiasco with MD’s state correctional facilities and other such vulnerable populations are targeted. Such as in this bill’s proposed “caregiver” defined authority. It took 6 months and whistleblowers to have quality of vaccines known and then corrected, much less what symptoms there may be in the future most especially for the next generation of Marylanders. Such atrocious proposed bills seem to be targeting most especially the vulnerable, and most especially with vaccines that are not of quality which clearly did not meet the immunization practices as mentioned in lines 23 through 24 of this bill. Does this bill target vulnerable young orphans? I personally was coerced into taking the vaccine to keep my job, and the only thought I could muster as I was in the ER with arm paralysis which comes and goes was that this goes fairly well against the Hippocratic Oath and what medicine stands for; “ I will respect the privacy of my patients, for their problems are not disclosed to me that the world may know. Most especially must I tread with care in matters of life and death. If it is given me to save a life, all thanks. But it may also be within my power to take a life; this awesome responsibility must be faced with great humbleness and awareness of my own frailty. Above all, I must not play at God. I will remember that I do not treat a fever chart, a cancerous growth, but a sick human being, whose illness may affect the person's family and economic stability. My responsibility includes these related problems, if I am to care adequately for the sick. I will prevent disease whenever I can, for prevention is preferable to cure. I will remember that I remain a member of society, with special obligations to all my fellow human beings, those sound of mind and body as well as the infirm.”
Page 16 Lines 4-8 are problematic: “For a vaccination administered under paragraph (2) or (3) of this 5 subsection, if the authorized prescriber is not the individual’s primary care provider or if 6 the vaccination has not been administered in accordance with a prescription, document at 7 least one effort to inform the individual’s primary care provider or other usual source of 8 care that the vaccination has been administered”

Page 16 Lines 19-20 are problematic: “A pharmacist may 20 ORDER AND administer a vaccine to an individual who is at least 3 years old”
Page 16 Line 22 is problematic: “The vaccine is approved by the U.S. Food and Drug Administration”
Page 16 Line 23 -25 are problematic: “The vaccination is ordered and administered in accordance with the 24 Centers for Disease Control and Prevention’s Advisory Committee on Immunization 25 Practices immunization schedules”

SB 840 A. Phillips Oppose.pdf
Uploaded by: Amanda Phillips
Position: UNF

SB 840

Oppose

Dear members of the Finance and Budget and Taxation committee,

I am submitting my written testimony regarding SB 840 *COVID–19 Response Act of 2022.*

There are far too many issues packed into this bill. In no particular order, here are my concerns:

- **Repealing, reenacting, adding:** The first 3 pages are confusing
- **Incentivizing Vaccines:** By now, everyone is fully aware there are many places to receive vaccines across the state, as 90% of Marylanders are vaccinated. Walmart announces Covid vaccines over the loudspeaker and every pharmacy has covid vaccines available here signage. We shouldn't need to incentivize anyone to get additional booster; its common knowledge and there are many locations to receive a vaccine for those interested.
- **Vaccine Passports:** I'm against any form of vaccine passport. Its discriminating access to individuals based on personal health choices.
- **Emergency Act extended to 2023:** We are no longer in a state of emergency; its time to lift restrictions, contact tracing, and other emergency measures, not extend them another year. Case rates state wide are down to 500 per day, out of 6 million Marylanders. Omicron cases make up 95% of all cases.

I request unfavorable report.

Respectfully,

Amanda Phillips

St. Mary's County, district 29A

Andreas N. Mayr letter to MD.pdf
Uploaded by: ANDREAS MAYR
Position: UNF

March 1, 2022

TO whom it may concern -

As a lifelong resident of the state of Maryland I vote NO to the following two bills -

SB 0839 - MD Voluntary COVID -19 Vaccine Passport by Senator Rosapepe

SB 0840 - COVID - 19 Response Act of 2022

I, Andreas N. Mayr, a registered voter and tax payer of Maryland, **do not support** these two bills.

Forcing or coercing someone in any way to take a vaccine or any medication violates the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. The first of its ten points begins as follows:

"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, overreaching, 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 code of ethics must be upheld in any civilized country.

The COVID-19 vaccines were not tested for long-term effects and thus were and are experimental. Each person should choose whether to take the vaccine or not. Future vaccines may have similar experimental natures or may be carefully tested. Regardless, each person must have the right to accept or refuse the vaccine without any coercion, or penalty.

Andreas N. Mayr
8856 Horseshoe Lane
Potomac, MD 20854

Testimony.pdf
Uploaded by: Ann Brown
Position: UNF

“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, overreaching, 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.”

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Vote No for Covid Passport .pdf
Uploaded by: Anna Zambotti
Position: UNF

Forcing or coercing someone in any way to take a vaccine or any medication violates the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. The first of its ten points begins as follows:

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This code of ethics must be upheld in any civilized country. The COVID-19 vaccines were not tested for long-term effects and thus were and are experimental. Each person should choose whether to take the vaccine or not. Future vaccines may have similar experimental natures or may be carefully tested. Regardless, each person must have the right to accept or refuse the vaccine without any coercion, or penalty.

Medical or religious discrimination: People decline COVID-19 vaccines for medical reasons or sincerely held ethical, moral, or religious beliefs. The valued and valuable ethical and legal traditions of the United States and Maryland are clear that it not acceptable to discriminate on the basis of medical condition/disability or on the basis of religion/religious belief.

Weakening of medical privacy: Doctor/medical practitioner-patient confidentiality is legally protected and essential for a myriad of reasons, and the privacy & protection of medical records is also important. The COVID-19 passports and other COVID requirements erode or remove these legal protections.

Future implications: COVID passports set the groundwork for a two-tiered society, in which persons who have received vaccinations may

live normal lives (including work, schooling, right to assembly, and access to various services) and persons who have not received vaccinations are denied those rights. Do we want to live in such a society? Recall history, our worst moments and our greatest achievements! Does it not always go badly when one group is dehumanized and denied rights based on a physical or religious characteristic? Are we not proudest of those movements which restore those rights?

Right to bodily integrity: Everyone has the right to bodily integrity, which includes the right to decline medical interventions. There is some serious philosophical inconsistency among the legislation under consideration this session. Bills to expand access to abortion and to enshrine abortion in Maryland law are under debate, underpinned by a 'my body, my choice' argument. Persons who wish to decline COVID vaccines are not being offered the same respect for 'my body, my choice'! You can't have it both ways! (The correct way of looking at this is: A woman has the right to bodily integrity and autonomy over her own body. The developing baby in her womb is someone else's body. Everyone has the right to maintain bodily integrity by declining medical interventions to which they do not give informed consent apart from coercion.)

Potential for Misuse of the MyIR Mobile app: Like any app, this one is subject to technological failure and hacking. Let's use caution before mandating it. Additionally, while it is currently being used and proposed to track vaccination records, its use could easily be expanded to illegal and unjust overreaching surveillance of American citizens by the government and the development of a Communist-style social credit system

SB840_AnnetteNelson_UNFAV.pdf
Uploaded by: Annette Hibbert Nelson
Position: UNF

SB840 UNFAV Annette Nelson

March 1, 2022

Dear Members of the Senate Finance Committee,

Throughout the Covid-19 pandemic I have been incredibly impressed with how our state, and specifically Montgomery County where I live, have handled the crisis. We have responded with measured, calm, scientific approaches to the situation: shutting down to give us some time to learn about this new virus and support our hospitals, opening back up when things are more settled, requiring masks which clearly help to stop the spread, etc. Our leaders have done a wonderful job with these tough decisions and should be very proud of their efforts.

However, I strongly oppose a vaccine passport. A digital passport does not help us prevent the spread of Covid. The vaccines are a helpful tool people can choose to use, but they do not stop the spread of Covid. According to the CDC website:

The Omicron variant spreads more easily than the original virus that causes COVID-19 and the Delta variant. **CDC expects that anyone with Omicron infection can spread the virus to others, even if they are vaccinated or don't have symptoms.**

And

Scientists are still learning how effective COVID-19 vaccines are at preventing infection from Omicron. Current vaccines are expected to protect against severe illness, hospitalizations, and deaths due to infection with the Omicron variant. **However, breakthrough infections in people who are vaccinated are likely to occur.** People who are up to date with their COVID-19 vaccines and get COVID-19 are less likely to develop serious illness than those who are unvaccinated and get COVID-19.
Source:
https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html

Though it is anecdotal evidence, I have personally known about 47 people since November 2021 that have tested positive for Covid. Surprisingly, they were all vaccinated and most were recently boosted. And in every case, they caught it from another vaccinated person, not an unvaccinated person. Thanks to the vaccine they had a mild case, but they did still contract it and spread it to others around them.

If we spend the money to create a digital passport for the state of Maryland, we are wasting critical funds that could be used for other projects. Having a passport will not stop the spread of Covid. We will have sick, vaccinated people allowed to enter businesses, while healthy unvaccinated or those with natural immunity will not be able to.

Another issue with SB840 is allowing pharmacists and pharmacy technicians to vaccinate children ages 3 and older with all vaccines. This is not the first time the idea has been considered. I actually testified against a similar bill that would do this a few years ago. My point then was that pharmacies are overworked. They need to be able to focus on their incredibly important job of filling prescriptions correctly. In my testimony I quoted this article from the New York Times, https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html "How Chaos at Chain Pharmacies is Putting Patients at Risk." This article is from January 2020. The situation that was dire then can only have gotten worse now. A representative from the AMA was also present at this hearing and did not support the bill because we need doctors involved in these important wellness checks for our children. Many parents will skip a wellness check, but make sure to get their child vaccinated. If we allow pharmacists to give these childhood vaccines, we will likely end up with children missing critical wellness checks with their pediatricians.

While I understand the rationale behind this bill, it is simply not going to help stop the spread of Covid and it is not safe for young children to receive vaccines at overburdened pharmacies. Please oppose SB840.

Thank you for your time,
Annette Nelson, Silver Spring, MD

SAE./No.200/January 2022

Studies in Applied Economics

A LITERATURE REVIEW AND META-ANALYSIS OF THE EFFECTS OF LOCKDOWNS ON COVID-19 MORTALITY

Jonas Herby, Lars Jonung, and Steve H. Hanke

Johns Hopkins Institute for Applied Economics,
Global Health, and the Study of Business Enterprise

A Literature Review and Meta-Analysis of the Effects of Lockdowns on COVID-19 Mortality

By Jonas Herby, Lars Jonung, and Steve H. Hanke

About the Series

The *Studies in Applied Economics* series is under the general direction of Prof. Steve H. Hanke, Founder and Co-Director of The Johns Hopkins Institute for Applied Economics, Global Health, and the Study of Business Enterprise (hanke@jhu.edu). The views expressed in each working paper are those of the authors and not necessarily those of the institutions that the authors are affiliated with.

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Abstract

This systematic review and meta-analysis are designed to determine whether there is empirical evidence to support the belief that "lockdowns" reduce COVID-19 mortality. Lockdowns are defined as the imposition of at least one compulsory, non-pharmaceutical intervention (NPI). NPIs are any government mandate that directly restrict peoples' possibilities, such as policies that limit internal movement, close schools and businesses, and ban international travel. This study employed a systematic search and screening procedure in which 18,590 studies are identified that could potentially address the belief posed. After three levels of screening, 34 studies ultimately qualified. Of those 34 eligible studies, 24 qualified for inclusion in the meta-analysis. They were separated into three groups: lockdown stringency index studies, shelter-in-place-order (SIPO) studies, and specific NPI studies. An analysis of each of these three groups support the conclusion that lockdowns have had little to no effect on COVID-19 mortality. More specifically, stringency index studies find that lockdowns in Europe and the United States only reduced COVID-19 mortality by 0.2% on average. SIPOs were also ineffective, only reducing COVID-19 mortality by 2.9% on average. Specific NPI studies also find no broad-based evidence of noticeable effects on COVID-19 mortality.

While this meta-analysis concludes that lockdowns have had little to no public health effects, they have imposed enormous economic and social costs where they have been adopted. In consequence, lockdown policies are ill-founded and should be rejected as a pandemic policy instrument.

Acknowledgements

The authors thank Line Andersen, Troels Sabroe Ebbesen, Nicholas Hanlon, and Anders Lund Mortensen for their research assistance.

The authors also with to thank Douglas Allen, Fredrik N. G. Andersson, Jonas Björk, Christian Bjørnskov, Joakim Book, Gunnar Brådvik, Kristoffer Torbjørn Bæk, Ulf Gerdtham, Daniel B. Klein, Fredrik Charpentier Ljungqvist, Christian Heebøl-Nielsen, Martin Paldam, Jonas Ranstam, Spencer Ryan, John Strezewski, Roger Svensson, Ulf Persson, Anders Waldenström, and Joakim Westerlund for their comments.

Key Words: COVID-19, lockdown, non-pharmaceutical interventions, mortality, systematic review, meta-analysis

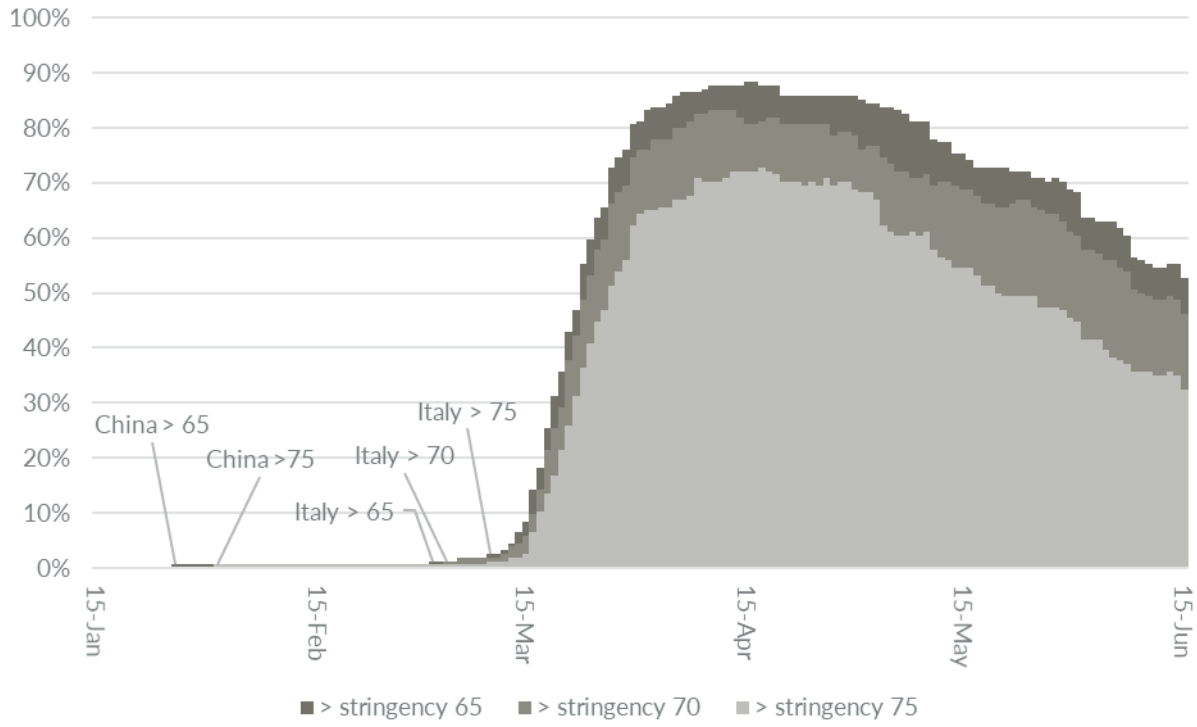
JEL Classification: I18; I38; D19

1 Introduction

The global policy reaction to the COVID-19 pandemic is evident. Compulsory non-pharmaceutical interventions (NPIs), commonly known as "lockdowns" – policies that restrict internal movement, close schools and businesses, and ban international travel – have been mandated in one form or another in almost every country.

The first NPIs were implemented in China. From there, the pandemic and NPIs spread first to Italy and later to virtually all other countries, see Figure 1. Of the 186 countries covered by the Oxford COVID-19 Government Response Tracker (OxCGRT), only Comoros, an island country in the Indian Ocean, did not impose at least one NPI before the end of March 2020.

Figure 1: Share of countries with OxCGRT stringency index above thresholds, January - June 2020



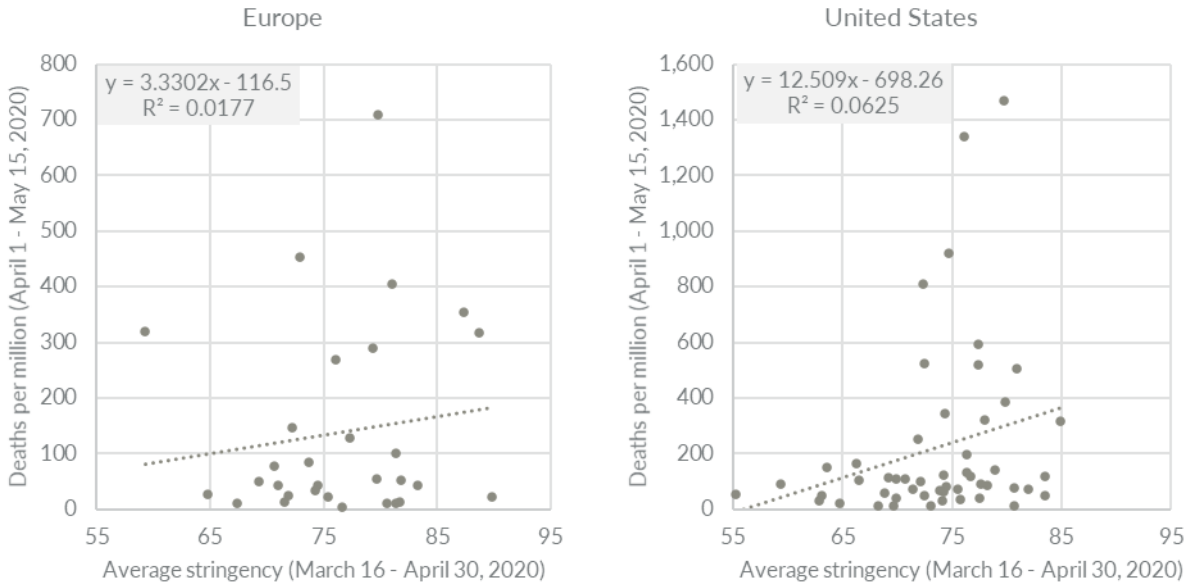
Comment: The figure shows the share of countries, where the OxCGRT stringency index on a given date surpassed index 65, 70 and 75 respectively. Only countries with more than one million citizens are included (153 countries in total). The OxCGRT stringency index records the strictness of NPI policies that restrict people's behavior. It is calculated using all ordinal containment and closure policy indicators (i.e., the degree of school and business closures, etc.), plus an indicator recording public information campaigns.
Source: Our World in Data.

Early epidemiological studies predicted large effects of NPIs. An often cited model simulation study by researchers at the Imperial College London (Ferguson et al. (2020)) predicted that a

suppression strategy based on a lockdown would reduce COVID-19 mortality by up to 98%.[1] These predictions were questioned by many scholars. Our early interest in the subject was spurred by two studies. First, Atkeson et al. (2020) showed that "across all countries and U.S. states that we study, the growth rates of daily deaths from COVID-19 fell from a wide range of initially high levels to levels close to zero within 20-30 days after each region experienced 25 cumulative deaths." Second, Sebhatu et al. (2020) showed that "government policies are strongly driven by the policies initiated in other countries," and less by the specific COVID-19-situation of the country.

A third factor that motivated our research was the fact that there was no clear negative correlation between the degree of lockdown and fatalities in the spring of 2020 (see Figure 2). Given the large effects predicted by simulation studies such as Ferguson et al. (2020), we would have expected to at least observe a simple negative correlation between COVID-19 mortality and the degree to which lockdowns were imposed.[2]

Figure 2: Correlation between stringency index and COVID-19 mortality in European countries and U.S. states during the first wave in 2020



Source: Our World in Data

[1] With R0 = 2.4 and trigger on 60, the number of COVID-19-deaths in Great Britain could be reduced to 8,700 deaths from 510,000 deaths (-98%) with a policy consisting of case isolation + home quarantine + social distancing + school/university closure, cf. Table 4 in Ferguson et al. (2020). R0 (the basic reproduction rate) is the expected number of cases directly generated by one case in a population where all individuals are susceptible to infection.

[2] In addition, the interest in this issue was sparked by the work Jonung did on the expected economic effects of the SARS pandemic in Europe in 2006 (Jonung and Röger, 2006). In this model-based study calibrated from Spanish flu data, Jonung and Röger concluded that the economic effects of a severe pandemic would be rather limited—a sharp contrast to the huge economic effects associated with lockdowns during the COVID-19 pandemic.

Today, it remains an open question as to whether lockdowns have had a large, significant effect on COVID-19 mortality. We address this question by evaluating the current academic literature on the relationship between lockdowns and COVID-19 mortality rates.[3] We use "NPI" to describe *any government mandate which directly restrict peoples' possibilities*. Our definition does *not* include governmental recommendations, governmental information campaigns, access to mass testing, voluntary social distancing, etc., but *do* include mandated interventions such as closing schools or businesses, mandated face masks etc. We define *lockdown* as any policy consisting of at least one NPI as described above.[4]

Compared to other reviews such as Herby (2021) and Allen (2021), the main difference in this meta-analysis is that we carry out a systematic and comprehensive search strategy to identify all papers potentially relevant to answer the question we pose. We identify 34 eligible empirical studies that estimate the effect of mandatory lockdowns on COVID-19 mortality using a counterfactual difference-in-difference approach. We present our results in such a way that they can be systematically assessed, replicated, and used to derive overall meta-conclusions.[5]

2 Identification process: Search strategy and eligibility criteria

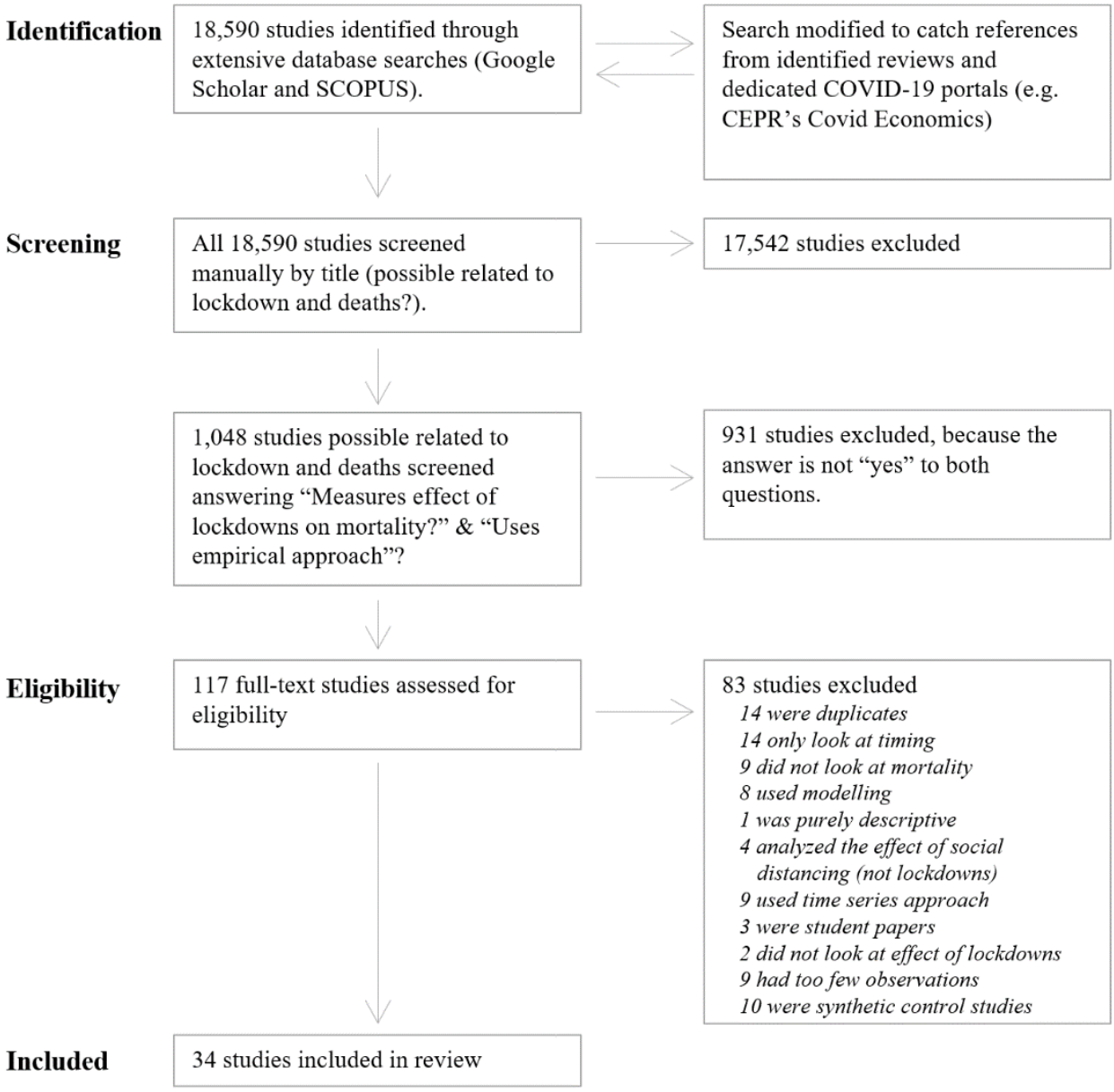
Figure 3 shows an overview of our identification process using a flow diagram designed according to PRISMA guidelines (Moher et al. (2009). Of 18,590 studies identified during our database searches, 1,048 remained after a title-based screening. Then, 931 studies were excluded, because they either did not measure the effect of lockdowns on mortality or did not use an empirical approach. This left 117 studies that were read and inspected. After a more thorough assessment, 83 of the 117 were excluded, leaving 34 studies eligible for our meta-analysis. A table with all 83 studies excluded in the final step can be found in Appendix B, Table 8.

[3] We use "mortality" and "mortality rates" interchangeably to mean COVID-19 deaths per population.

[4] For example, we will say that Country A introduced the *non-pharmaceutical interventions* school closures and shelter-in-place-orders as part of the country's *lockdown.*

[5] An interesting question is, "What damage lockdowns do to the economy, personal freedom and rights, and public health in general?" Although this question is important, it requires a full cost-benefit study, which is beyond the scope of this study.

Figure 3: PRISMA flow diagram for the selection of studies.



Below we present our search strategy and eligibility criteria, which follow the PRISMA guidelines and are specified in detail in our protocol Herby et al. (2021).

2.1 Search strategy

The studies we reviewed were identified by scanning *Google Scholar* and *SCOPUS* for English-language studies. We used a wide range of search terms which are combinations of three search strings: a disease search string ("covid," "corona," "coronavirus," "sars-cov-2"), a government

response search string[6], and a methodology search string[7]. We identified papers based on 1,360 search terms. We also required mentions of "deaths," "death," and/or "mortality." The search terms were continuously updated (by adding relevant terms) to fit this criterion.[8]

We also included all papers published in *Covid Economics*. Our search was performed between July 1 and July 5, 2021 and resulted in 18,590 unique studies.[9] All studies identified using SCOPUS and Covid Economics were also found using Google Scholar. This made us comfortable that including other sources such as VOXeu and SSRN would not change the result. Indeed, many papers found using Google Scholar were from these sources.

All 18,590 studies were first screened based on the title. Studies clearly not related to our research question were deemed irrelevant.[10]

After screening based on the title, 1,048 papers remained. These papers were manually screened by answering two questions:

1. Does the study measure the effect of lockdowns on mortality?
2. Does the study use an empirical *ex post* difference-in-difference approach (see eligibility criteria below)?

Studies to which we could not answer "yes" to both questions were excluded. When in doubt, we made the assessment based on reading the full paper, and in some cases, we consulted with colleagues.[11]

After the manual screening, 117 studies were retrieved for a full, detailed review. These studies were carefully examined, and metadata and empirical results were stored in an Excel

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[6] The government response search string used was: "non-pharmaceutical," "nonpharmaceutical," "NPI," "NPIs," "lockdown," "social distancing orders," "statewide interventions," "distancing interventions," "circuit breaker," "containment measures," "contact restrictions," "social distancing measures," "public health policies," "mobility restrictions," "covid-19 policies," "corona policies," "policy measures."

[7] The methodology search string used was: ("fixed effects," "panel data," "difference-in-difference," "diff-in-diff," "synthetic control," "counterfactual" , "counter factual," "cross country," "cross state," "cross county," "cross region," "cross regional," "cross municipality," "country level," "state level," "county level," "region level," "regional level," "municipality level," "event study."

[8] If a potentially relevant paper from one of the 13 reviews (see eligibility criteria) did not show up in our search, we added relevant words to our search strings and ran the search again. The 13 reviews were: Allen (2021); Brodeur et al. (2021); Gupta et al. (2020); Herby (2021); Johanna et al. (2020); Nussbaumer-Streit et al. (2020); Patel et al. (2020); Perra (2020); Poeschl and Larsen (2021); Pozo-Martin et al. (2020); Rezapour et al. (2021); Robinson (2021); Zhang et al. (2021).

[9] SCOPUS was continuously monitored between July 5th and publication using a search agent. Although the search agent returned several hits during this period, only one of them, An et al. (2021), was eligible according to our eligibility criteria. The study is not included in our review, but the conclusions are in line with our conclusions, as An et al. (2021) conclude that "The analysis shows that the mask mandate is consistently associated with lower infection rates in the short term, and its early adoption boosts the long-term efficacy. By contrast, the other five policy instruments— domestic lockdowns, international travel bans, mass gathering bans, and restaurant and school closures—show weaker efficacy."

[10] This included studies with titles such as "COVID-19 outbreak and air pollution in Iran: A panel VAR analysis" and "Dynamic Structural Impact of the COVID-19 Outbreak on the Stock Market and the Exchange Rate: A Cross-country Analysis Among BRICS Nations."

[11] Professor Christian Bjørnskov of University of Aarhus was particularly helpful in this process.

spreadsheet. All studies were assessed by at least two researchers. During this process, another 64 papers were excluded because they did not meet our eligibility criteria. Furthermore, nine studies with too little jurisdictional variance (< 10 observations) were excluded,[12] and 10 synthetic control studies were excluded.[13] A table with all 83 studies excluded in the final step can be found in Appendix B, Table 8. Below we explain why these studies are excluded.

2.2 Eligibility criteria

Focus on mortality and lockdowns

We only include studies that attempt to establish a relationship (or lack thereof) between lockdown policies and COVID-19 mortality or excess mortality. We exclude studies that use cases, hospitalizations, or other measures.[14]

Counterfactual difference-in-difference approach

We distinguish between two methods used to establish a relationship (or lack thereof) between mortality rates and lockdown policies. The first uses registered cross-sectional mortality data. These are *ex post* studies. The second method uses simulated data on mortality and infection rates.[15] These are *ex ante* studies.

We include all studies using a counterfactual difference-in-difference approach from the former group but disregard all *ex ante* studies, as the results from these studies are determined by model assumptions and calibrations.

Our limitation to studies using a "counterfactual difference-in-difference approach" means that we exclude all studies where the counterfactual is based on forecasting (such as a SIR-model) rather than derived from a difference-in-difference approach. This excludes studies like Duchemin et al. (2020) and Matzinger and Skinner (2020). We also exclude all studies based on interrupted time series designs that simply compare the situation before and after lockdown, as

[12] The excluded studies with too few observations were: Alemán et al. (2020), Berardi et al. (2020), Conyon et al. (2020a), Coccia (2021), Gordon et al. (2020), Juranek and Zoutman (2021), Kapoor and Ravi (2020), Umer and Khan (2020), and Wu and Wu (2020).

[13] The excluded synthetic control studies were: Conyon and Thomsen (2021), Dave et al. (2020), Ghosh et al. (2020), Born et al. (2021), Reinbold (2021), Cho (2020), Friedson et al. (2021), Neidhöfer and Neidhöfer (2020), Cerqueti et al. (2021), and Mader and Rüttenauer (2021).

[14] Analyses based on cases may pose major problems, as testing strategies for COVID-19 infections vary enormously across countries (and even over time within a given country). In consequence, cross-country comparisons of cases are, at best, problematic. Although these problems exist with death tolls as well, they are far more limited. Also, while cases and death tolls are correlated, there may be adverse effects of lockdowns that are not captured by the number of cases. For example, an infected person who is isolated at home with family under a SIPO may infect family members with a higher viral load causing more severe illness. So even if a SIPO reduces the number of cases, it may theoretically increase the number of COVID-19-deaths. Adverse effects like this may explain why studies like Chernozhukov et al. (2021) finds that SIPO reduces the number of cases but have no significant effect on the number of COVID-19-deaths. Finally, mortality is hierarchically the most important outcome, cf. GRADEpro (2013)

[15] These simulations are often made in variants of the SIR-model, which can simulate the progress of a pandemic in a population consisting of people in different states (Susceptible, Infectious, or Recovered) with equations describing the process between these states.

the effect of lockdowns in these studies might contain time-dependent shifts, such as seasonality. This excludes studies like Bakolis et al. (2021) and Siedner et al. (2020).

Given our criteria, we exclude the much-cited paper by Flaxman et al. (2020), which claimed that lockdowns saved three million lives in Europe. Flaxman et al. assume that the pandemic would follow an epidemiological curve unless countries locked down. However, this assumption means that the only interpretation possible for the empirical results is that lockdowns are the only thing that matters, even if other factors like season, behavior etc. caused the observed change in the reproduction rate, Rt. Flaxman et al. are aware of this and state that "our parametric form of R_t assumes that changes in Rt are an immediate response to interventions rather than gradual changes in behavior." Flaxman et al. illustrate how problematic it is to force data to fit a certain model if you want to infer the effect of lockdowns on COVID-19 mortality.[16]

The counterfactual difference-in-difference studies in this review generally exploit variation across countries, U.S. states, or other geographical jurisdictions to infer the effect of lockdowns on COVID-19 fatalities. Preferably, the effect of lockdowns should be tested using randomized control trials, natural experiments, or the like. However, there are very few studies of this type.[17]

Synthetic control studies

The synthetic control method is a statistical method used to evaluate the effect of an intervention in comparative case studies. It involves the construction of a synthetic control which functions as the counter factual and is constructed as an (optimal) weighted combination of a pool of donors. For example, Born et al. (2021) create a synthetic control for Sweden which consists of 30.0% Denmark, 25.3% Finland, 25.8% Netherlands, 15.0% Norway, and 3.9% Sweden. The effect of the intervention is derived by comparing the actual developments to those contained in the synthetic control.

We exclude synthetic control studies because of their inherent empirical problems as discussed by Bjørnskov (2021b). He finds that the synthetic control version of Sweden in Born et al. (2021) deviates substantially from "actual Sweden," when looking at the period before mid-March 2020, when Sweden decided not to lock down. Bjørnskov estimates that *actual Sweden* experienced

[16] Several scholars have criticized Flaxman et al. (2020), e.g. see Homburg and Kuhbandner (2020), Lewis (2020), and Lemoine (2020).

[17] Kepp and Bjørnskov (2021) is one such study. They use evidence from a quasi-natural experiment in the Danish region of Northern Jutland. After the discovery of mutations of Sars-CoV-2 in mink – a major Danish export – seven of the 11 municipalities of the region went into extreme lockdown in early November, while the four other municipalities retained the moderate restrictions of the remaining country. Their analysis shows that while infection levels decreased, they did so before lockdown was in effect, and infection numbers also decreased in neighbor municipalities without mandates. They conclude that efficient infection surveillance and voluntary compliance make full lockdowns unnecessary, at least in some circumstances. Kepp and Bjørnskov (2021) is not included in our review, because they focus on cases and not COVID-19 mortality. Dave et al. (2020) is another such study. They see the Wisconsin Supreme Court abolishment of Wisconsin's "Safer at Home" order (a SIPO) as a natural experiment and find that "the repeal of the state SIPO impacted social distancing, COVID-19 cases, or COVID-19-related mortality during the fortnight following enactment." Dave et al. (2020) is not included in our review, because they use a synthetic control method.

approximately 500 fewer deaths the first 11 weeks of 2020 and 4,500 fewer deaths in 2019 compared to *synthetic Sweden*.

This problem is inherent in all synthetic control studies of COVID-19, Bjørnskov argues, because the synthetic control should be fitted based on a long period of time before the intervention or the event one is studying the consequences of – i.e., the lockdown Abadie (2021). However, this is not possible for the coronavirus pandemic, as there clearly *is* no long period with coronavirus before the lockdown. Hence, the synthetic control study approach is *by design* not appropriate for studying the effect of lockdowns.

Jurisdictional variance - few observations

We exclude all interrupted time series studies which simply compare mortality rates before and after lockdowns. Simply comparing data from before and after the imposition of lockdowns could be the result of time-dependent variations, such as seasonal effects. For the same reason, we also exclude studies with little jurisdictional variance.[18] For example, we exclude Conyon et al. (2020b) who "exploit policy variation between Denmark and Norway on the one hand and Sweden on the other" and, thus, only have one jurisdictional area in the control group. Although this *is* a difference-in-difference approach, there is a non-negligible risk that differences are caused by much more than just differences in lockdowns. Another example is Wu and Wu (2020), who use all U.S. states, but pool groups of states so they end with basically three observations. None of the excluded studies cover more than 10 jurisdictional areas.[19] One study is a special case of the jurisdictional variance criteria (Auger et al. (2020). Those researchers analyze the effect of school closures in U.S. states and find that those closures reduce mortality by 35%. However, all 50 states closed schools between March 13, 2020, and March 23, 2020, which means that all difference-in-difference is based on maximum 10 days. Given the long lag between infection and death, there is a risk that Auger et al.'s approach is an interrupted time series analysis where they compare United States before and after school closures, rather than a true difference-in-difference approach. However, we choose to include this study, as it is eligible under our protocol Herby et al. (2021).

Publication status and date

We include all *ex post* studies regardless of publication status and date. That is, we cover both working papers and papers published in journals. We include the early papers because the knowledge of the COVID-19-pandemic grew rapidly in the beginning, making later papers able to stand on the shoulders of previous work. Also, in the early days of COVID-19, speed was

[18] A jurisdictional area can be countries, U.S. states, or counties. With "jurisdictional variance" we refer to variation in mandates across jurisdictional areas.

[19] All studies excluded on this criterion are listed in footnote 12.

crucial which may have affected the quality of the papers. Including them makes it possible to compare the results of early studies to studies carried out at a later stage.[20]

The role of optimal timing

We exclude papers which analyze the effect of early lockdowns in contrast to later lockdowns. There's no doubt that being prepared for a pandemic and knowing when it arrives at your doorstep is vital. However, at least two problems arise with respect to evaluating the effect of well-timed lockdowns.

First, when COVID-19 hit Europe and the United States, it was virtually impossible to determine the right timing. The World Health Organization declared the outbreak a pandemic on March 11, 2020, but at that date, Italy had already registered 13.7 COVID-19 deaths per million. On March 29, 2020, 18 days after the WHO declared the outbreak a pandemic and the earliest a lockdown response to the WHO's announcement could potentially have an effect, the mortality rate in Italy was a staggering 178 COVID-19 deaths per million with an additional 13 per million dying each day.[21]

Secondly, it is extremely difficult to differentiate between the effect of public awareness and the effect of lockdowns when looking at timing because people and politicians are likely to react to the same information. As Figure 4 illustrates, all European countries and U.S. states that were hit hard and early by COVID-19 experienced high mortality rates, whereas all countries hit relatively late experienced low mortality rates. Björk et al. (2021) illustrate the difficulties in analyzing the effect of timing. They find that a 10-stringency-points-stricter lockdown would reduce COVID-19 mortality by a total of 200 deaths per million[22] if done in week 11, 2020, but would only have approximately 1/3 of the effect if implemented one week earlier or later and no effect if implemented three weeks earlier or later. One interpretation of this result is that lockdowns do not work if people either find them unnecessary and fail to obey the mandates or if people voluntarily lock themselves down. This is the argument Allen (2021) uses for the ineffectiveness of the lockdowns he identifies. If this interpretation is true, what Björk et al. (2021) find is that information and signaling is far more important than the strictness of the lockdown. There may be other interpretations, but the point is that studies focusing on timing cannot differentiate between these interpretations. However, if lockdowns have a notable effect, we should see this effect regardless of the timing, and we should identify this effect more correctly by excluding studies that exclusively analyze timing.

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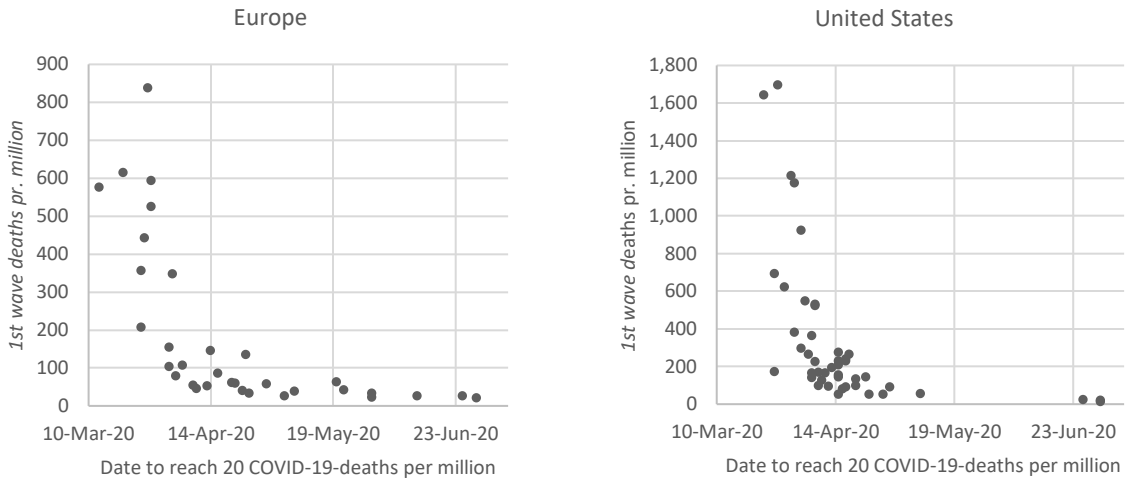
[20] We also intended to exclude studies which were primarily based on data from 2021 (as these studies would be heavily affected by vaccines) and studies that did not cover at least one EU-country, the United States, one U.S. U.S. state or Latin America, and where at least one country/state was not an island. However, we did not find any such studies.

[21] There's approximately a two-to-four-week gap between infection and deaths. See footnote 29.

[22] They estimate that 10-point higher stringency will reduce excess mortality by 20 "per week and million" in the 10 weeks from week 14 to week 23.

Figure 4: **Taken by surprise. The importance of having time to prepare**



Comment: The figure shows the relationship between early pandemic strength and total 1st wave of COVID-19 death toll. On the X-axis is "Days to reach 20 COVID-19-deaths per million (measured from February 15, 2020)." The Y-axis shows mortality (deaths per million) by June 30, 2020.
Source: Reported COVID-19 deaths and OxCGRT stringency for European countries and U.S. states with more than one million citizens. Data from Our World in Data.

We are aware of one meta-analysis by Stephens et al. (2020), which looks into the importance of timing. The authors find 22 studies that look at policy and timing with respect to mortality rates, however, only four were multi-country, multi-policy studies, which could possibly account for the problems described above. Stephens et al. conclude that "the timing of policy interventions across countries relative to the first Wuhan case, first national disease case, or first national death, is not found to be correlated with mortality." (See Appendix A for further discussion of the role of timing.)

3 The empirical evidence

In this section we present the empirical evidence found through our identification process. We describe the studies and their results, but also comment on the methodology and possible identification problems or biases.

3.1 Preliminary considerations

Before we turn to the eligible studies, we present some considerations that we adopted when interpreting the empirical evidence.

Empirical interpretation

While the policy conclusions contained in some studies are based on statistically significant results, many of these conclusions are ill-founded due to the tiny impact associated with said statistically significant results. For example, Ashraf (2020) states that "social distancing

measures has proved effective in controlling the spread of [a] highly contagious virus." However, their estimates show that the average lockdown in Europe and the U.S only reduced COVID-19 mortality by 2.4%.[23] Another example is Chisadza et al. (2021). The authors argue that "less stringent interventions increase the number of deaths, whereas more severe responses to the pandemic can lower fatalities." Their conclusion is based on a negative estimate for the squared term of *stringency* which results in a total negative effect on mortality rates (i.e. fewer deaths) for stringency values larger than 124. However, the stringency index is limited to values between 0 and 100 by design, so the conclusion is clearly incorrect. To avoid any such biases, we base our interpretations solely on the empirical estimates and not on the authors' own interpretation of their results.

Handling multiple models, specifications, and uncertainties

Several studies adopt a number of models to understand the effect of lockdowns. For example, Bjørnskov (2021a) estimates the effect after one, two, three, and four weeks of lockdowns. For these studies, we select the longest time horizon analyzed to obtain the estimate closest to the long-term effect of lockdowns.

Several studies also use multiple specifications including and excluding potentially relevant variables. For these studies, we choose the model which the authors regard as their main specification. Finally, some studies have multiple models which the authors regard as equally important. One interesting example is Chernozhukov et al. (2021), who estimate two models with and without national case numbers as a variable. They show that including this variable in their model alters the results substantially. The explanation could be that people responded to national conditions. For these studies, we present both estimates in Table 1, but – following Doucouliagos and Paldam (2008) – we use an average of the estimates in our meta-analysis in order to not give more weight to a study with multiple models relative to studies with just one principal model.

For studies looking at different classes of countries (e.g. rich and poor), we report both estimates in Table 1 but use the estimate for rich Western countries in our meta-analysis, where we derive common estimates for Europe and the United States.

Effects are measured "relative to Sweden in the spring of 2020"

Virtually all countries in the world implemented mandated NPIs in response to the COVID-19 pandemic. Hence, most estimates are relative to "doing the least," which in many Western countries means relative to doing as Sweden has done, especially during the first wave, when Sweden, do to constitutional constraints, implemented very few restrictions compared to other western countries (Jonung and Hanke 2020). However, some studies *do* compare the effect of doing something to the effect of doing absolutely nothing (e.g. Bonardi et al. (2020)).

The consequence is that some estimates are relative to "doing the least" while others are relative to "doing nothing." This may lead to biases if "doing the least" works as a signal (or warning)

[23] We describe how we arrive at the 2.4% in Section 4.

which alters the behavior of the public. For example, Gupta et al. (2020) find a large effect of emergency declarations, which they argue "are best viewed as an information instrument that signals to the population that the public health situation is serious and they act accordingly," on social distancing but not of other policies such as SIPOs (shelter-in-place orders). Thus, if we compare a country issuing a SIPO to a country doing nothing, we may overestimate the effect of a SIPO, because it is the sum of the signal *and* the SIPO. Instead, we should compare the country issuing the SIPO to a country "doing the least" to estimate the *marginal* effect of the SIPO.

To take an example, Bonardi et al. (2020) find relatively large effects of doing *something* but no effect of doing *more*. They find no extra effect of stricter lockdowns relative to less strict lockdowns and state that "our results point to the fact that people might adjust their behaviors quite significantly as partial measures are implemented, which might be enough to stop the spread of the virus." Hence, whether the baseline is Sweden, which implemented a ban on large gatherings early in the pandemic, or the baseline is "doing nothing" can affect the magnitude of the estimated impacts. There is no obvious right way to resolve this issue, but since estimates in most studies are relative to doing less, we report results as compared to "doing less" when available. Hence, for Bonardi et al. we state that the effect of lockdowns is zero (compared to Sweden's "doing the least").

3.2 Overview of the findings of eligible studies

Table 1 covers the 34 studies eligible for our review.[24] Out of these 34 studies, 22 were peer-reviewed and 12 were working papers. The studies analyze lockdowns during the first wave. Most of the studies (29) use data collected before September 1st, 2020 and 10 use data collected before May 1st, 2020. Only one study uses data from 2021. All studies are cross-sectional, ranging across jurisdictions. Geographically, 14 studies cover countries worldwide, four cover European countries, 13 cover the United States, two cover Europe and the United States, and one covers regions in Italy. Seven studies analyze the effect of SIPOs, 10 analyze the effect of stricter lockdowns (measured by the OxCGRT stringency index), 16 studies analyze specific NIP's independently, and one study analyzes other measures (length of lockdown).

Several studies find no statistically significant effect of lockdowns on mortality. For example, this includes Bjørnskov (2021a) and Stockenhuber (2020) who find no significant effect of stricter lockdowns (higher OxCGRT stringency index), Sears et al. (2020) and Dave et al. (2021), who find no significant effect of SIPOs, and Chaudhry et al. (2020), Aparicio and Grossbard (2021) and Guo et al. (2021) who find no significant effect of any of the analyzed NIP's, including business closures, school closures and border closures.

Other studies find a significant negative relationship between lockdowns and mortality. Fowler et al. (2021 find that SIPOs reduce COVID-19 mortality by 35%, while Chernozhukov et al.

[24] The following information can be found for each study in Table 2.

(2021) find that employee mask mandates reduces mortality by 34% and closing businesses and bars reduces mortality by 29%.

Some studies find a significant positive relationship between lockdowns and mortality. This includes Chisadza et al. (2021), who find that stricter lockdowns (higher OxCGRT stringency index) increases COVID-19 mortality by 0.01 deaths/million per stringency point and Berry et al. (2021), who find that SIPOs increase COVID-19 mortality by 1% after 14 days.

Most studies use the number of official COVID-19 deaths as the dependent variable. Only one study, Bjørnskov (2021a), looks at total excess mortality which – although is not perfect – we perceive to be the best measure, as it overcomes the measurement problems related to properly reporting COVID-19 deaths.

Several studies explicitly claim that they estimate the actual causal relationship between lockdowns and COVID-19 mortality. Some studies use instrumental variables to justify the causality associated with their analysis, while others make causality probable using anecdotal evidence.[25] But, Sebhatu et al. (2020) show that government policies are strongly driven by the policies initiated in neighboring countries rather than by the severity of the pandemic in their own countries. In short, it is not the severity of the pandemic that drives the adoption of lockdowns, but rather the propensity to copy policies initiated by neighboring countries. The Sebhatu et al. conclusion throws into doubt the notion of a causal relationship between lockdowns and COVID-19 mortality.

Table 1: Summary of eligible studies

1. Study (Author & title)	2. Measure	3. Description	4. Results	5. Comments
Alderman and Harjoto (2020); "COVID-19: U.S. shelter-in-place orders and demographic characteristics linked to cases, mortality, and recovery rates"	COVID-19 mortality	Use State-level data from the COVID-19 Tracking Project data all U.S. states, and a multivariate regression analysis to empirically investigate the impacts of the duration of shelter-in-place orders on mortality.	Find that shelter-in-place orders are - for the average duration - associated with 1% (insignificant) fewer deaths per capita.	
Aparicio and Grossbard (2021); "Are Covid Fatalities in the U.S. Higher than in the EU, and If so, Why?"	COVID-19 mortality	Their main focus is to explain the gap in COVID-19-fatalities between Europe and the United States based on COVID-deaths and other data from 85 nations/states. They include status for "social events" (ban on public gatherings, cancellation of major events and conferences), school closures, shop closures "partial lockdowns" (e.g. night curfew) and "lockdowns" (all-day curfew) 100 days after the pandemic onset in a country/state. None of these interventions have a significant effect on COVID-19 mortality. They also find no	Find no effect of "social events" (ban on public gatherings, cancellation of major events and conferences), school closures, shop closures "partial lockdowns" (e.g. night curfew) and "lockdowns" (all-day curfew) 100 days after the pandemic onset.	In the abstract the authors states that "various types of social distance measures such as school closings and lockdowns, and how soon they were implemented, help explain the U.S./EUROPE gap in cumulative deaths measured 100 days after the pandemic's onset in a state or country" although their estimates are insignificant.

[25] E.g. Dave et al. (2021) states that "estimated case reductions accelerate over time, becoming largest after 20 days following enactment of a SIPO. These findings are consistent with a causal interpretation."

1. Study (Author & title)	2. Measure	3. Description	4. Results	5. Comments
		significant effect of early cancelling of social events, school closures, shop closures, partial lockdowns and full lockdowns.		
Ashraf (2020); "Socioeconomic conditions, government interventions and health outcomes during COVID-19"	COVID-19 mortality	Their main focus is on the effectiveness of policies targeted to diminish the effect of socioeconomic inequalities (economic support) on COVID-19-deaths. They use data from 80 countries worldwide and include the OxCGRT stringency as a control variable in their models. The paper finds a significant negative (fewer deaths) effect of stricter lockdowns. The effect of lockdowns is insignificant, when they include an interaction term between the socioeconomic conditions index and the economic support index in their model.	For each 1-unit increase in OxCGRT stringency index, the cumulative mortality changes by -0.326 deaths per million (fewer deaths). The estimate is -0.073 deaths per million but insignificant, when including an interaction term between the socioeconomic conditions index and the economic support index.	
Auger et al. (2020); "Association between statewide school closure and COVID-19 incidence and mortality in the U.S."	COVID-19 mortality	U.S. population-based observational study which uses interrupted time series analyses incorporating a lag period to allow for potential policy-associated changes to occur. To isolate the association of school closure with outcomes, state-level nonpharmaceutical interventions and attributes were included in negative binomial regression models. Models were used to derive the estimated absolute differences between schools that closed and schools that remained open. The main outcome of the study is COVID-19 daily incidence and mortality per 100000 residents.	State that they adjust for several factors (e..g percentage of state's population aged 15 years and 65 years, CDC's social vulnerability index, stay-at-home or shelter-in-place order, restaurant and bar closure, testing rate per 1000 residents etc.), but does not specify how and do not present estimates.	All 50 states closed schools between March 13, 2020, and March 23, 2020. Hence, all difference-in-difference is based on maximum 10 days, and given the long lag between infection and death, there is a risk that their approach is more an interrupted time series analysis, where they compare United States before and after school closures, rather than a true difference-in-difference approach. However, we choose to include the study in our review as it - objectively speaking - lives up to the eligibility criteria specified in our protocol.
Berry et al. (2021); "Evaluating the effects of shelter-in-place policies during the COVID-19 pandemic"	COVID-19 mortality	The authors use U.S. county data on COVID-19 deaths from Johns Hopkin and SIPO data from the University of Washington to estimate the effect of SIPO's. They find no detectable effects of SIPO on deaths. The authors stress that their findings should not be interpreted as evidence that social distancing behaviors are not effective. Many people had already changed their behaviors before the introduction of shelter-in-place orders, and shelter-in-place orders appear to have been ineffective precisely because they did not meaningfully alter social distancing behavior.	SIPO increases the number of deaths by 0,654 per million after 14 days (see Fig. 2)	The authors conclude that "We do not find detectable effects of these policies [SIPO] on disease spread or deaths." However, this statement does not correspond to their results. In figure 2 they show that the effect on deaths is significant after 14 days. Looks at the effect 14 days after SIPO's are implemented which is a short lag given that the time between infection and deaths is at least 2-3 weeks.
Bjørnskov (2021a); "Did Lockdown Work? An Economist's Cross-Country Comparison"	Excess mortality	Uses excess mortality and OxCGRT stringency from 24 European countries to estimate the effect of lockdown on the number of deaths one, two, three and four weeks later. Finds no effect (negative but insignificant) of (stricter) lockdowns. The author's specification using instrument variables yields similar results.	A stricter lockdown (OxCGRT stringency) does not have a significant effect on excess mortality.	Finds a positive (more deaths) effect after one and two weeks, which could indicate that other factors (omitted variables) affect the results.
Blanco et al. (2020); "Do Coronavirus Containment Measures Work? Worldwide Evidence"	COVID-19 mortality	Use data for deaths and NPIs from Hale et al. (2020) covering 158 countries between January and August 2020 to evaluate the effect of eight different NPIs (stay at home, bans on gatherings, bans on public	When using the naïve dummy variable approach, all parameters are statistically	Run the same model four times for each of the different NPIs (stay at home-orders, ban on meetings, ban on public events and mobility restrictions). These NPIs were often introduced almost simultaneously so there is a high risk of

1. Study (Author & title)	2. Measure	3. Description	4. Results	5. Comments
		events, closing schools, lockdowns of workplaces, interruption of public transportation services, and international border closures. They address the possible endogeneity of the NPIs by using instrumental variables.	insignificant. On the contrary, estimates using the instrumental variable approach indicate that NPIs are effective in reducing the growth rate in the daily number of deaths 14 days later.	multicollinearity with each run capturing the same underlying effect. Indeed, the size and standard errors of the estimates are worryingly similar. Looks at the effect 14 days after NPIs are implemented which is a fairly short lag given the time between infection and deaths is 2-3 weeks, cf. e.g. Flaxman et al. (2020), which according to Bjørnskov (2020) appears to be the minimum typical time from infection to death).
Bonardi et al. (2020); "Fast and local: How did lockdown policies affect the spread and severity of the covid-19"	Growth rates	Use NPI data scraped from news headlines from LexisNexis and death data from Johns Hopkins University up to April 1st 2020 in a panel structure with 184 countries. Controls for country fixed effects, day fixed effects and within-country evolution of the disease.	Find that certain interventions (SIPO, regional lockdown and partial lockdown) work (in developed countries), but that stricter interventions (SIPO) do not have a larger effect than less strict interventions (e.g. restrictions on gatherings). Find no effect of border closures.	Find a positive (more deaths) effect on day 1 after lockdown which may indicate that their results are driven by other factors (omitted variables). We rely on their publicly available version submitted to CEPR Covid Economics, but estimates on the effect of deaths can be found in Supplementary material, which is available in an updated version hosted on the Danish Broadcasting Corporation's webpage: https://www.dr.dk/static/documents/2021/03/04/managing_pandemics_e3911c11.pdf
Bongaerts et al. (2021); "Closed for business: The mortality impact of business closures during the Covid-19 pandemic"	COVID-19 mortality	Uses variation in exposure to closed sectors (e.g. tourism) in municipalities within Italy to estimate the effect of business closures. Assuming that municipalities with different exposures to closed sectors are not inherently different, they find that municipalities with higher exposure to closed sectors experienced subsequently lower mortality rates.	Business shutdown saved 9,439 Italian lives by April 13th 2020. This corresponds to a reduction of deaths by 32%, as there were 20,465 COVID-19-deaths in Italy by mid April 2020.	They (implicitly) assume that municipalities with different exposures to closed sectors are not inherently different. This assumption could be problematic, as more touristed municipalities can be very different from e.g. more industrialized municipalities.
Chaudhry et al. (2020); "A country level analysis measuring the impact of government actions, country preparedness and socioeconomic factors on COVID-19 mortality and related health outcomes"	COVID-19 mortality	Uses information on COVID-19 related national policies and health outcomes from the top 50 countries ranked by number of cases. Finds no significant effect of any NPI on the number of COVID-19-deaths.	Finds no significant effect on mortality of any of the analyzed interventions (partial border closure, complete border closure, partial lockdown (physical distancing measures only), complete lockdown (enhanced containment measures including suspension of all non-essential services), and curfews).	
Chernozhukov et al. (2021); "Causal impact of masks, policies, behavior on early covid-19 pandemic in the U.S."	Growth rates	Uses COVID-deaths from the New York Times and Johns Hopkins and data for U.S. States from Raifman et al. (2020) to estimate the effect of SIPO, closed nonessential businesses, closed K-12 schools, closed restaurants except takeout, closed movie theaters, and face mask mandates for employees in public facing businesses.	Finds that mandatory masks for employees and closing K-12 schools reduces deaths. SIPO and closing business (average of closed businesses, restaurants and movie theaters) has no statistically significant effect. The effect of school closures is highly sensitive to the	States that ”our regression specification for case and death growths is explicitly guided by a SIR model although our causal approach does not hinge on the validity of a SIR model.” We are uncertain if this means that data are managed to fit an SIR-model (and thus should fail our eligibility criteria).

1. Study (Author & title)	2. Measure	3. Description	4. Results	5. Comments
			inclusion of national case and death data.	
Chisadza et al. (2021); "Government Effectiveness and the COVID-19 Pandemic"	COVID-19 mortality	Uses COVID-19-deaths and OxCGRT stringency from 144 countries to estimate the effect of lockdown on the number of COVID-19-deaths. Find a significant positive (more deaths) non-linear association between government response indices and the number of deaths.	An increase by 1 on "stringency index" increases the number of deaths by 0.0130 per million. The sign of the squared term is negative, but the combined non-linear estimate is positive (increases deaths) and larger than the linear estimate for all values of the OxCGRT stringency index.	The author states that "less stringent interventions increase the number of deaths, whereas more severe responses to the pandemic can lower fatalities." However, according to their estimates this is not correct, as the combined non-linear estimate cannot be negative for relevant values of the OxCGRT stringency index (0 to 100).
Dave et al. (2021); "When Do Shelter-in-Place Orders Fight Covid-19 Best? Policy Heterogeneity Across States and Adoption Time"	COVID-19 mortality	Uses smartphone location tracking and state data on COVID-19 deaths and SIPO data (supplemented by their own searches) collected by the New York Times to estimate the effect of SIPO's. Finds that SIPO was associated with a 9%–10% increase in the rate at which state residents remained in their homes full-time, but overall they do not find an significant effect on mortality after 20+ days (see Figure 4). Indicate that the lacking significance may be due to long term estimates being identified of a few early adopting states.	Finds no overall significant effect of SIPO on deaths but does find a negative effect (fewer deaths) in early adopting states.	Find large effects of SIPO on deaths after 6-14 days in early adopting states (see Table 8), which is before an SIPO-related effect would be seen. This could indicate that other factors rather than SIPO's drive the results.
Dergiades et al. (2020); "Effectiveness of government policies in response to the COVID-19 outbreak"	COVID-19 mortality	Uses daily deaths from the European Centre for Disease Prevention and Control and OxCGRT stringency from 32 countries worldwide (including U.S.) to estimates the effect of lockdown on the number of deaths.	Finds that the greater the strength of government interventions at an early stage, the more effective these are in slowing down or reversing the growth rate of deaths.	Focus is on the effect of early stage NPIs and thus does not absolutely live up to our eligibility criteria. However, we include the study as it differentiates between lockdown strength at an early stage.
Fakir and Bharati (2021); "Pandemic catch-22: The role of mobility restrictions and institutional inequalities in halting the spread of COVID-19"	COVID-19 mortality	Uses data from 127 countries. combining high-frequency measures of mobility data from Google's daily mobility reports, country-date-level information on the stringency of restrictions in response to the pandemic from Oxford's Coronavirus Government Response Tracker (OxCGRT), and daily data on deaths attributed to COVID-19 from Our World In Data and the Johns Hopkins University. Instrument stringency using day-to-day changes in the stringency of the restrictions in the rest of the world.	Find large causal effects of stricter restrictions on the weekly growth rate of recorded deaths attributed to COVID-19. Show that more stringent interventions help more in richer, more educated, more democratic, and less corrupt countries with older, healthier populations and more effective governments.	Finds a larger effect on deaths after 0 days than after 14 and 21 days (Table 3). This is surprising given that it takes 2-3 weeks from infection to death, and it may indicate that their results are driven by other factors.
Fowler et al. (2021); "Stay-at-home orders associate with subsequent decreases in COVID-19 cases and fatalities in the United States"	COVID-19 mortality	Uses U.S. county data on COVID-19 deaths and SIPO data collected by the New York Times to estimate the effect of SIPO's using a two-way fixed-effects difference-in-differences model. Find a large and early (after few days) effect of SIPO on COVID-19 related deaths.	Stay-at-home orders are also associated with a 59.8 percent (18.3 to 80.2) average reduction in weekly fatalities after three weeks. These results suggest that stay-at-home orders	Finds the largest effect of SIPO on deaths after 10 days (see Figure 4), before a SIPO-related effect could possibly be seen as it takes 2-3 weeks from infection to death. This could indicate that other factors drive their results.

1. Study (Author & title)	2. Measure	3. Description	4. Results	5. Comments
			might have reduced confirmed cases by 390,000 (170,000 to 680,000) and fatalities by 41,000 (27,000 to 59,000) within the first three weeks in localities that implemented stay-at-home orders.	
Fuller et al. (2021); "Mitigation Policies and COVID-19–Associated Mortality — 37 European Countries, January 23–June 30, 2020"	COVID-19 mortality	Uses COVID-19-deaths and OxCGRT stringency in 37 European countries to estimate the effect of lockdown on the number of COVID-19-deaths. Find a significant negative (fewer deaths) effect of stricter lockdowns after mortality threshold is reached (the threshold is a daily rate of 0.02 new COVID-19 deaths per 100,000 population (based on a 7-day moving average))	For each 1-unit increase in OxCGRT stringency index, the cumulative mortality decreases by 0.55 deaths per 100,000.	
Gibson (2020); "Government mandated lockdowns do not reduce Covid-19 deaths: implications for evaluating the stringent New Zealand response"	COVID-19 mortality	Uses data for every county in the United States from March through June 1, 2020, to estimate the effect of SIPO (called "lockdown") on COVID-19 mortality. Policy data are acquired from American Red Cross reporting on emergency regulations. His control variables include county population and density, the elder share, the share in nursing homes, nine other demographic and economic characteristics and a set of regional fixed effects. Handles causality problems using instrument variables (IV).	Find no statistically significant effect of SIPO.	Gibson use the word "lockdown" as synonym for SIPO (writes "technically, government-ordered community quarantine")
Goldstein et al. (2021); "Lockdown Fatigue: The Diminishing Effects of Quarantines on the Spread of COVID-19 "	COVID-19 mortality	Uses panel data from 152 countries with data from the onset of the pandemic until December 31, 2020. Finds that lockdowns tend to reduce the number of COVID-19 related deaths, but also that this benign impact declines over time: after four months of strict lockdown, NPIs have a significantly weaker contribution in terms of their effect in reducing COVID-19 related fatalities.	Stricter lockdowns reduce deaths for the first 60 days, whereafter the cumulative effect begins to decrease. If reintroduced after 120, the effect of lockdowns is smaller in the short run, but after 90 days the effect is almost the same as during first lockdown (only app. 10% lower).	There is little documentation in the study (e.g. no tables with estimates).
Guo et al. (2021); "Mitigation Interventions in the United States: An Exploratory Investigation of Determinants and Impacts"	COVID-19 mortality	Uses policy data from 1,470 executive orders from the state–government websites for all 50 states and Washington DC and COVID-19-deaths from Johns Hopkins University in a random-effect spatial error panel model to estimate the effect of nine NPIs (SIPO, strengthened SIPO, public school closure, all school closure, large-gathering ban of more than 10 people, any gathering ban, restaurant/bar limit to dining out only, nonessential business closure, and mandatory self-quarantine of travelers) on COVID-19 deaths.	Two mitigation strategies (all school closure and mandatory self-quarantine of travelers) showed positive (more deaths) impact on COVID-19-deaths per 10,000. Six mitigation strategies (SIPO, public school closure, large gathering bans (>10), any gathering ban, restaurant/bar limit to dining out only, and nonessential business	Only conclude on NPIs which reduce mortality. However, the conclusion is based on one-tailed tests, which means that all positive estimates (more deaths) are deemed insignificant. Thus, in their mortality-specification (Table 3, Proportion of Cumulative Deaths Over the Population), the estimate of all school closures (.204) and mandatory self-quarantine of travelers (0.363) is deemed insignificant based on schools CI [.029, .379] and quarantine CI [.193, .532]. We believe, these results should be interpreted as a significant increase in mortality, and that these results should have been part of their conclusion.

1. Study (Author & title)	2. Measure	3. Description	4. Results	5. Comments
			closure) did not show any impact (Table 3, "Proportion of Cumulative Deaths Over the Population).	
Hale et al. (2020); "Global assessment of the relationship between government response measures and COVID-19 deaths"	COVID-19 mortality	Uses the OxCGRT stringency and COVID-19-deaths from the European Centre for Disease Prevention and Control for 170 countries. Estimates both cross-sectional models in which countries are the unit of analysis, as well as longitudinal models on time-series panel data with country-day as the unit of analysis (including models that use both time and country fixed effects).	Finds that higher stringency in the past leads to a lower growth rate in the present, with each additional point of stringency corresponding to a 0.039%-point reduction in daily deaths growth rates six weeks later.	
Hunter et al. (2021); "Impact of non-pharmaceutical interventions against COVID-19 in Europe: A quasi-experimental non-equivalent group and time-series"	COVID-19 mortality	Uses death data from the European Centre for Disease Prevention and Control (ECDC) and NPI-data from the Institute of Health Metrics and Evaluation. Argues that they use a quasi-experimental approach to identify the effect of NPIs because no analyzed intervention was imposed by all European countries and interventions were put in place at different points in the development of the epidemics.	Finds that mass gathering restrictions and initial business closures (businesses such as entertainment venues, bars and restaurants) reduces the number of deaths, whereas closing educational facilities and issuing SIPO increases the number of deaths. Finds no effect of closing non-essential services and mandating/recommending masks (Table 3)	Finds an effect of closing educational facilities and non-essential services after 1-7 days before lockdown could possibly have an effect on the number of deaths. This may indicate that other factors are driving their results.
Langeland et al. (2021); "The Effect of State Level COVID-19 Stay-at-Home Orders on Death Rates"	COVID-19 mortality	Estimates the effect of state-level lockdowns on COVID-19 deaths using multiple quasi-Poisson regressions with lockdown time length as the explanatory variable. Does not specify how lockdown is defined and what their data sources are.	Finds no significant effect of SIPO on the number of deaths after 2-4, 4-6 and 6+ weeks.	They write that "6+ weeks of lockdown is the only setting where the odds of dying are statistically higher than in the no lockdown case." However, all estimates are insignificant in Table C. Looks as if lockdown duration may cause a causality problem, because politicians may be less likely to ease restrictions when there are many cases/deaths.
Leffler et al. (2020); "Association of country-wide coronavirus mortality with demographics, testing, lockdowns, and public wearing of masks"	COVID-19 mortality	Use COVID-19 deaths from Worldometer and info about NPIs (mask/mask recommendations, international travel restrictions and lockdowns (defined as any closure of schools or workplaces, limits on public gatherings or internal movement, or stay-at-home orders) from Hale et al. (2020) for 200 countries to estimate the effect of the duration of NPIs on the number of deaths.	Finds that masking (mask recommendations) reduces mortality. For each week that masks were recommended the increase in per-capita mortality was 8.1% (compared to 55.7% increase when masks were not recommended). Finds no significant effect of the number of weeks with internal lockdowns and international travel restrictions (Table 2).	Their "mask recommendation" category includes some countries, where masks were mandated (see Supplemental Table A1) and may (partially) capture the effect of mask mandates. Looks at duration which may cause a causality problem, because politicians may be less likely to ease restrictions when there are many cases/deaths.
Mccafferty and Ashley (2021); "Covid-19 Social Distancing Interventions by Statutory Mandate and Their Observational	Other	Use data from 27 U.S. states and 12 European countries to analyze the effect of NPIs on peak morality rate using general linear mixed effects modelling.	Finds that no mandate (school closures, prohibition on mass gatherings, business closures, stay at home	

1. Study (Author & title)	2. Measure	3. Description	4. Results	5. Comments
Correlation to Mortality in the United States and Europe"			orders, severe travel restrictions, and closure of non-essential businesses) was effective in reducing the peak COVID-19 mortality rate.	
Pan et al. (2020); "Covid-19: Effectiveness of non-pharmaceutical interventions in the united states before phased removal of social distancing protections varies by region"	COVID-19 mortality	Uses county-level data for all U.S. states. Mortality is obtained from Johns Hopkins, while policy data are obtained from official governmental websites. Categorizes 12 policies into 4 levels of disease control; Level 1 (low) - State of Emergency; Level 2 (moderate) - school closures, restricting access (visits) to nursing homes, or closing restaurants and bars; Level 3 (high) - non-essential business closures, suspending non-violent arrests, suspending elective medical procedures, suspending evictions, or restricting mass gatherings of at least 10 people; and Level 4 (aggressive) - sheltering in place / stay-at-home, public mask requirements, or travel restrictions. Use stepped-wedge cluster randomized trial (SW-CRT) for clustering and negative binomial mixed model regression.	Concludes that only (duration of, see comment in next column) level 4 restrictions are associated with reduced risk of death, with an average 15% decline in the COVID-19 death rate per day. Implementation of level 3 and level 2 restrictions increased death rates in 6 of 6 regions, while longer duration increased death rates in 5 of 6 regions.	They focus on the negative estimate of duration of Level 4. However, their implementation estimate is large and positive, and the combined effect of implementation and duration is unclear.
Pincombe et al. (2021); "The effectiveness of national-level containment and closure policies across income levels during the COVID-19 pandemic: an analysis of 113 countries"	COVID-19 mortality	Uses daily data for 113 countries on cumulative COVID-19 death counts over 130 days between February 15, 2020, and June 23, 2020, to examine changes in mortality growth rates across the World Bank's income group classifications following shelter-in-place recommendations or orders (they use one variable covering both recommendations and orders).	Finds that shelter-in-place recommendations/orders reduces mortality growth rates in high income countries (although insignificant) but increases growth rates in countries in other income groups.	
Sears et al. (2020); "Are we #stayinghome to Flatten the Curve?"	COVID-19 mortality	Uses cellular location data from all 50 states and the District of Columbia to investigate mobility patterns during the pandemic across states and time. Adding COVID-19 death tolls and the timing of SIPO for each state they estimate the effect of stay-at-home policies on COVID-19 mortality.	Find that SIPOs lower deaths by 0.13- 0.17 per 100,000 residents, equivalent to death rates 29-35% lower than in the absence of policies. However, these estimates are insignificant at a 95% confidence interval (see Table 4). The study also finds reductions in activity levels prior to mandates. Human encounter rate fell by 63 percentage points and nonessential visits by 39 percentage points relative to pre-COVID-19 levels, prior to any state implementing a statewide mandate	In the abstract the authors state that death rates would be 42-54% lower than in the absence of policies. However, this includes averted deaths due to pre-mandate social distancing behavior (p. 6). The effect of SIPO is a reduction in deaths by 29%-35% compared to a situation without SIPO but with pre-mandate social distancing. These estimates are insignificant at a 95% confidence interval.

1. Study (Author & title)	2. Measure	3. Description	4. Results	5. Comments
Shiva and Molana (2021); "The Luxury of Lockdown"	COVID-19 mortality	Uses COVID-19-deaths and OxCGRT stringency from 169 countries to estimate the effect of lockdown on the number of deaths 1-8 weeks later. Finds that stricter lockdowns reduce COVID-19-deaths 4 weeks later (but insignificant 8 weeks later) and have the greatest effect in high income countries. Finds no effect of workplace closures in low-income countries.	A stricter lockdown (1 stringency point) reduces deaths by 0,1% after 4 weeks. After 8 weeks the effect is insignificant.	
Spiegel and Tookes (2021); "Business restrictions and Covid-19 fatalities"	COVID-19 mortality	Use data for every county in the United States from March through December 2020 to estimate the effect of various NPIs on the COVID-19-deaths growth rate. Derives causality by 1) assuming that state regulators primarily focus on the state's most populous counties, so state regulation in smaller counties can be viewed as a quasi randomized experiment, and 2) conducting county pair analysis, where similar counties in different states (and subject to different state policies) are compared.	Finds that some interventions (e.g. mask mandates, restaurant and bar closures, gym closures, and high-risk business closures) reduces mortality growth, while other interventions (closures of low- to medium-risk businesses and personal care/spa services) did not have an effect and may even have increased the number of deaths.	In total they analyze the lockdown effect of 21 variables. 14 of 21 estimates are significant, and of these 6 are negative (reduces deaths) while 8 are positive (increases deaths). Some results are far from intuitive. E.g. mask recommendations increases deaths by 48% while mask mandates reduces deaths by 12%, and closing restaurants and bars reduces deaths by 50%, while closing bars but not restaurants only reduces deaths by 5%.
Stockenhuber (2020); "Did We Respond Quickly Enough? How Policy-Implementation Speed in Response to COVID-19 Affects the Number of Fatal Cases in Europe"	COVID-19 mortality	Uses data for the number of COVID-19 infections and deaths and policy information for 24 countries from OxCGRT to estimate the effect of stricter lockdowns on the number of deaths using principal component analysis and a generalized linear mixed model.	Finds no significant effect of stricter lockdowns on the number of fatalities (Table 4).	Groups data on lockdown strictness into four groups and lose significant information and variation.
Stokes et al. (2020); "The relative effects of non-pharmaceutical interventions on early Covid-19 mortality: natural experiment in 130 countries"	COVID-19 mortality	Uses daily Covid-19 deaths for 130 countries from the European Centre for Disease Prevention and Control (ECDC) and daily policy data from the Oxford COVID-19 Government Response Tracker (OxCGRT). Looks at all levels of restrictions for each of the nine sub-categories of the OxCGRT stringency index (school, work, events, gatherings, transport, SIPO, internal movement, travel).	Of the nine sub-categories in the OxCGRT stringency index, only travel restrictions are consistently significant (with level 2 "Quarantine arrivals from high-risk regions" having the largest effect, and the strictest level 4 "Total border closure" having the smallest effect). Restrictions on very large gatherings (>1,000) has a large significant negative (fewer deaths) effect, while the effect of stricter restrictions on gatherings are insignificant. Authors recommend that the closing of schools (level 1) has a very large (in absolute terms it's twice the effect of border quarantines) positive	Their results are counter intuitive and somewhat inconclusive. Why does limiting very large gatherings (>1,000) work, while stricter limits do not? Why do recommending school closures cause more deaths? Why is the effect of border closures before 1st death insignificant, while the effect of closing borders after 1st death is significant (and large)? And why does quarantining arrivals from high-risk regions work better than total border closures? With 23 estimated parameters in total these counter intuitive and inconclusive results could be caused by multiple test bias (we correct for this in the meta-analysis), but may also be caused by other factors such as omitted variable bias.

1. Study (Author & title)	2. Measure	3. Description	4. Results	5. Comments
			effect (more deaths) while stricter interventions on schools have no significant effect. Required cancelling of public events also has a significant positive (more deaths) effect. We focus on their 14-38 days results, as they catch the longest time frame (their 0-24 day model returns mostly insignificant results).	
Toya and Skidmore (2020); "A Cross-Country Analysis of the Determinants of Covid-19 Fatalities"	COVID-19 mortality	Uses COVID-19-deaths and lockdown info from various sources from 159 countries in a cross-country event study. Controls for country specifics by including socio-economic, political, geographic, and policy information. Finds little evidence for the efficacy of NPIs.	Complete travel restrictions prior to April 2020 reduced deaths by -0.226 per 100.000 by April 1st 2021, while mandatory national lockdown prior to April 2020 increased deaths by 0.166 by April 1st 2021. Recommended local lockdowns reduced deaths but results are based on one observation. Partial travel restrictions, mandatory local lockdowns and recommended national lockdowns did not have a significant effect on deaths.	The study looks at the lockdown status prior to April 2020 and the effect on deaths the following year (until April 1st 2021). The authors state this is to reduce concerns about endogeneity but do not explain why the lockdowns in the spring of 2020 are a good instrument for lockdowns during later waves are.
Tsai et al. (2021); "Coronavirus Disease 2019 (COVID-19) Transmission in the United States Before Versus After Relaxation of Statewide Social Distancing Measures"	Reproduction rate, Rt	Uses data for NPIs that were implemented and/or relaxed in U.S. states between 10 March and 15 July 2020. Using segmented linear regression, they estimate the extent to which relaxation of social distancing affected epidemic control, as indicated by the time-varying, state-specific effective reproduction number (Rt). Rt is based on death tolls.	Finds that in the 8 weeks prior to relaxing NPIs, Rt was declining, while after relaxation Rt started to increase.	Their Figure 1 shows that Rt on average increases app. 10 days before relaxation, which could indicate that other factors (omitted variables) affect the results.

Note: All comments on the significance of estimates are based on a 5% significance level unless otherwise stated.

It is difficult to make a conclusion based on the overview in Table 1. Is -0.073 to -0.326 deaths/million per stringency point, as estimated by Ashraf (2020), a large or a small effect relative to. the 98% reduction in mortality predicted by the study published by the Imperial College London (Ferguson et al. (2020). This is the subject for our meta-analysis in the next section. Here, it turns out that -0.073 to -0.326 deaths/million per stringency point is a relatively modest effect and only corresponds to a 2.4% reduction in COVID-19 mortality on average in the U.S. and Europe.

4 Meta-analysis: The impact of lockdowns on COVID-19 mortality

We now turn to the meta-analysis, where we focus on the impact of lockdowns on COVID-19 mortality.

In the meta-analysis, we include 24 studies in which we can derive the relative effect of lockdowns on COVID-19 mortality, where mortality is measured as COVID-19-related deaths per million. In practice, this means that the studies we included estimate the effect of lockdowns on mortality or the effect of lockdowns on mortality growth rates, while using a counterfactual estimate.[26]

Our focus is on the effect of compulsory non-pharmaceutical interventions (NPI), policies that restrict internal movement, close schools and businesses, and ban international travel, among others. We do not look at the effect of voluntary behavioral changes (e.g. voluntary mask wearing), the effect of recommendations (e.g. recommended mask wearing), or governmental services (voluntary mass testing and public information campaigns), but only on mandated NPIs.

The studies we examine are placed in three categories. Seven studies analyze the effect of stricter lockdowns based on the OxCGRT stringency indices, 13 studies analyze the effect of SIPOs (6 studies only analyze SIPOs, while seven analyze SIPOs among other interventions), and 11 studies analyze the effect of specific NPIs independently (lockdown vs. no lockdown).[27] Each of these categories is handled so that comparable estimates can be made across categories. Below, we present the results for each category and show the overall results, as well as those based on various quality dimensions.

Quality dimensions

We include quality dimensions because there are reasons to believe that can affect a study's conclusion. Below we describe the dimensions, as well as our reasons to believe that they are necessary to fully understand the empirical evidence.

- *Peer-reviewed vs. working papers*: We distinguish between peer-reviewed studies and working papers as we consider peer-reviewed studies generally being of higher quality than working papers.[28]

- *Long vs. short time period*: We distinguish between studies based on long time periods (with data series ending *after* May 31, 2020) and short time periods (data series ending at or before May 31, 2020), because the first wave did not fully end before late June in the U.S. and Europe. Thus, studies relying on short data periods lack the last part of the first wave and may yield biased results if lockdowns only "flatten the curve" and do not prevent deaths.

[26] As a minimum requirement, one needs to know the effect on the top of the curve.
[27] The total is larger than 21 because the 11 SIPO studies include seven studies which look at multiple measures.
[28] Vetted papers from CEPR Covid Economics are considered as working papers in this regard.

- *No early effect on mortality*: On average, it takes approximately three weeks from infection to death.[29] However, several studies find effects of lockdown on mortality almost immediately. Fowler et al. (2021) find a significant effect of SIPOs on mortality after just four days and the largest effect after 10 days. An early effect may indicate that other factors (omitted variables) drive the results, and, thus, we distinguish between studies which find an effect on mortality sooner than 14 days after lockdown and those that do not.[30] Note that many studies do not look at the short term and thus fall into the latter category by default.

- *Social sciences vs. other sciences*: While it is true that epidemiologists and researchers in natural sciences should, in principle, know much more about COVID-19 and how it spreads than social scientists, social scientists are, in principle, experts in evaluating the effect of various policy interventions. Thus, we distinguish between studies published by scholars in social sciences and by scholars from other fields of research. We perceive the former as being better suited for examining the effects of lockdowns on mortality. For each study, we have registered the research field for the corresponding author's associated institute (e.g., for a scholar from "Institute of economics" research field is registered as "Economics"). Where no corresponding author was available, the first author has been used. Afterwards, all research fields have been classified as either from the "Social Science" or "Other.""[31]

We also considered including a quality dimension to distinguish between studies based on excess mortality and studies based on COVID-19 mortality, as we believe that excess mortality is potentially a better measure for two reasons. First, data on total deaths in a country is far more precise than data on COVID-19 related deaths, which may be both underreported (due to lack of tests) or overreported (because some people die *with* – but not *because of* – COVID-19). Secondly, a major purpose of lockdowns is to save lives. To the extend lockdowns shift deaths *from* COVID-19 *to* other causes (e.g. suicide), estimates based on COVID-19 mortality will overestimate the effect of lockdowns. Likewise, if lockdowns save lives in other ways (e.g. fewer traffic accidents) lockdowns' effect on mortality will be underestimated. However, as only one

[29] Leffler et al. (2020) writes, "On average, the time from infection with the coronavirus to onset of symptoms is 5.1 days, and the time from symptom onset to death is on average 17.8 days. Therefore, the time from infection to death is expected to be 23 days." Meanwhile, Stokes et al. (2020) writes that "evidence suggests a mean lag between virus transmission and symptom onset of 6 days, and a further mean lag of 18 days between onset of symptoms and death."

[30] Some of the authors are aware of this problem. E.g. Bjørnskov (2021a) writes "when the lag length extends to three or fourth weeks, that is, the length that is reasonable from the perspective of the virology of Sars-CoV-2, the estimates become very small and insignificant" and "these results confirm the overall pattern by being negative and significant when lagged one or two weeks (the period when they cannot have worked) but turning positive and insignificant when lagged four weeks."

[31] Research fields classified as social sciences were economics, public health, management, political science, government, international development, and public policy, while research fields not classified as social sciences were ophthalmology, environment, medicine, evolutionary biology and environment, human toxicology, epidemiology, and anesthesiology.

of the 34 studies (Bjørnskov (2021a)) is based on excess mortality, we are unfortunately forced to disregard this quality dimension.

Meta-data used for our quality dimensions as well as other relevant information are shown in Table 2.

Table 2: Metadata for the studies included in the meta-analysis

1. Study (Author & title)	2. Included in meta-analysis	3. Publication status	4. End of data period	5. Earliest effect	6. Field of research	7. Lockdown measure	8. Geographical coverage
Alderman and Harjoto (2020); "COVID-19: U.S. shelter-in-place orders and demographic characteristics linked to cases, mortality, and recovery rates"	Yes	Peer-review	11-Jun-20	n/a	Economics (Social science)	SIPO	United States
Aparicio and Grossbard (2021); "Are Covid Fatalities in the U.S. Higher than in the EU, and If so, Why?"	Yes	Peer-review	22-Jul-20	n/a	Economics (Social science)	Specific NPIs	Europe and United States
Ashraf (2020); "Socioeconomic conditions, government interventions and health outcomes during COVID-19"	Yes	WP	20-May-20	n/a	Economics (Social science)	Stringency	World
Auger et al. (2020); "Association between statewide school closure and COVID-19 incidence and mortality in the U.S."	Yes	Peer-review	07-May-20	>21 days	Medicine (Other)	Specific NPIs	United States
Berry et al. (2021); "Evaluating the effects of shelter-in-place policies during the COVID-19 pandemic"	Yes	Peer-review	30-May-20	8-14 days	Public policy (Social science)	SIPO	United States
Bjørnskov (2021a); "Did Lockdown Work? An Economist's Cross-Country Comparison"	Yes	Peer-review	30-Jun-20	<8 days	Economics (Social science)	Stringency	Europe
Blanco et al. (2020); "Do Coronavirus Containment Measures Work? Worldwide Evidence"	No	WP	31-Aug-20	8-14 days	Economics (Social science)	Specific NPIs	World
Bonardi et al. (2020); "Fast and local: How did lockdown policies affect the spread and severity of the covid-19"	Yes	WP	13-Apr-20	<8 days	Economics (Social science)	Specific NPIs	World
Bongaerts et al. (2021); "Closed for business: The mortality impact of business closures during the Covid-19 pandemic"	Yes	Peer-review	13-Apr-20	8-14 days	Management (Social science)	Specific NPIs	One country
Chaudhry et al. (2020); "A country level analysis measuring the impact of government actions, country preparedness and socioeconomic factors on COVID-19 mortality and related health outcomes"	Yes	Peer-review	01-Apr-20	n/a	Anesthesiology (Other)	Specific NPIs	World
Chernozhukov et al. (2021); "Causal impact of masks, policies, behavior on early covid-19 pandemic in the U.S."	Yes	Peer-review	03-Aun-20	n/a	Economics (Social science)	Specific NPIs	United States
Chisadza et al. (2021); "Government Effectiveness and the COVID-19 Pandemic"	Yes	Peer-review	01-Sep-20	n/a	Economics (Social science)	Stringency	World
Dave et al. (2021); "When Do Shelter-in-Place Orders Fight Covid-19 Best? Policy Heterogeneity Across States and Adoption Time"	Yes	Peer-review	20-Apr-20	Finds no effect	Economics (Social science)	SIPO	United States
Dergiades et al. (2020); "Effectiveness of government policies in response to the COVID-19 outbreak"	No	WP	30-Apr-20	n/a	Management (Social science)	Stringency	World
Fakir and Bharati (2021); "Pandemic catch-22: The role of mobility restrictions and institutional inequalities in halting the spread of COVID-19"	No	Peer-review	30-Jul-20	<8 days	Economics (Social science)	Stringency	World

1. Study (Author & title)	2. Included in meta-analysis	3. Publication status	4. End of data period	5. Earliest effect	6. Field of research	7. Lockdown measure	8. Geographical coverage
Fowler et al. (2021); "Stay-at-home orders associate with subsequent decreases in COVID-19 cases and fatalities in the United States"	Yes	Peer-review	07-May-20	<8 days	Public Health (Social science)	SIPO	United States
Fuller et al. (2021); "Mitigation Policies and COVID-19–Associated Mortality — 37 European Countries, January 23–June 30, 2020"	Yes	WP	30-Jun-20	n/a	Epidemiology (Other)	Stringency	Europe
Gibson (2020); "Government mandated lockdowns do not reduce Covid-19 deaths: implications for evaluating the stringent New Zealand response"	Yes	Peer-review	01-Jun-20	Finds no effect	Economics (Social science)	SIPO	United States
Goldstein et al. (2021); "Lockdown Fatigue: The Diminishing Effects of Quarantines on the Spread of COVID-19 "	Yes	WP	31-Dec-20	<8 days	International Development (Social science)	Stringency	World
Guo et al. (2021); "Mitigation Interventions in the United States: An Exploratory Investigation of Determinants and Impacts"	Yes	Peer-review	07-Apr-20	n/a	Social work (Social science)	Specific NPIs	United States
Hale et al. (2020); "Global assessment of the relationship between government response measures and COVID-19 deaths"	No	WP	27-May-20	n/a	Government (Social science)	Stringency	World
Hunter et al. (2021); "Impact of non-pharmaceutical interventions against COVID-19 in Europe: A quasi-experimental non-equivalent group and time-series"	No	Peer-review	24-Apr-20	<8 days	Medicine (Other)	Specific NPIs	Europe
Langeland et al. (2021); "The Effect of State Level COVID-19 Stay-at-Home Orders on Death Rates"	No	WP	Not specified	Finds no effect	Political Science (Social science)	Other	United States
Leffler et al. (2020); "Association of country-wide coronavirus mortality with demographics, testing, lockdowns, and public wearing of masks"	Yes	Peer-review	09-May-20	n/a	Ophthalmology (Other)	Specific NPIs	World
Mccafferty and Ashley (2021); "Covid-19 Social Distancing Interventions by Statutory Mandate and Their Observational Correlation to Mortality in the United States and Europe"	No	Peer-review	12-Apr-20	Finds no effect	Ophthalmology (Other)	Specific NPIs	Europe and United States
Pan et al. (2020); "Covid-19: Effectiveness of non-pharmaceutical interventions in the united states before phased removal of social distancing protections varies by region"	No	WP	29-May-20	n/a	Environment (Other)	Specific NPIs	United States
Pincombe et al. (2021); "The effectiveness of national-level containment and closure policies across income levels during the COVID-19 pandemic: an analysis of 113 countries"	No	Peer-review	23-Jun-20	n/a	Health Science (Social science)	SIPO	World
Sears et al. (2020); "Are we #stayinghome to Flatten the Curve?"	Yes	WP	29-Apr-20	Finds no effect	Economics (Social science)	SIPO	United States
Shiva and Molana (2021); "The Luxury of Lockdown"	Yes	Peer-review	08-Jun-20	15-21 days	Government (Social science)	Stringency	World
Spiegel and Tookes (2021); "Business restrictions and Covid-19 fatalities"	Yes	Peer-review	31-Dec-20	<8 days	Management (Social science)	Specific NPIs	United States
Stockenhuber (2020); "Did We Respond Quickly Enough? How Policy-Implementation Speed in Response to COVID-19 Affects the Number of Fatal Cases in Europe"	Yes	Peer-review	12-Jul-20	n/a	Evolutionary Biology and Environment (Other)	Stringency	Europe
Stokes et al. (2020); "The relative effects of non-pharmaceutical interventions on early	Yes	WP	01-Jun-20	n/a	Economics (Social science)	Specific NPIs	World

1. Study (Author & title)	2. Included in meta-analysis	3. Publication status	4. End of data period	5. Earliest effect	6. Field of research	7. Lockdown measure	8. Geographical coverage
Covid-19 mortality: natural experiment in 130 countries"							
Toya and Skidmore (2020); "A Cross-Country Analysis of the Determinants of Covid-19 Fatalities"	Yes	WP	01-Apr-21	n/a	Economics (Social science)	Specific NPIs	World
Tsai et al. (2021); "Coronavirus Disease 2019 (COVID-19) Transmission in the United States Before Versus After Relaxation of Statewide Social Distancing Measures"	No	Peer-review	15-Jul-20	<8 days	Psychiatry (Social science)	Specific NPIs	United States

Note: Research fields classified as social sciences were economics, public health, health science, management, political science, government, international development, and public policy, while research fields not classified as social sciences were ophthalmology, environment, medicine, evolutionary biology and environment, human toxicology, epidemiology and anesthesiology.

Interpreting and weighting estimates

The estimates used in the meta-analysis are not always readily available in the studies shown in Table 2. In Appendix B Table 9, we describe for each paper how we interpret the estimates and how they are converted to a common estimate (the relative effect of lockdowns on COVID-19 mortality) which is comparable across all studies.

Following Paldam (2015) and Stanley and Doucouliagos (2010), we also convert standard errors[32] and use the precision of each estimate (defined as 1/SE) to calculate the precision-weighted average of all estimates and present funnel plots. The precision-weighted average is our primary indicator of the efficacy of lockdowns, but we also report arithmetic averages and medians in the meta-analysis.

In the following sections, we present the meta-analysis for each of the three groups of studies (stringency index-studies, SIPO-studies, and studies analyzing specific NPIs).

4.1 Stringency index studies

Seven eligible studies examine the link between lockdown stringency and COVID-19 mortality. The results from these studies, converted to common estimates, are presented in Table 3 below. All studies are based on the COVID-19 Government Response Tracker's (OxCGRT) stringency index of Oxford University's Blavatnik School of Government (Hale et al. (2020)).

The OxCGRT stringency index neither measures the expected effectiveness of the lockdowns nor the expected costs. Instead, it describes the stringency based on nine equally weighted parameters.[33] Many countries followed similar patterns and almost all countries closed schools,

[32] Standard errors are converted such that the t-value, calculated based on common estimates and standard errors, is unchanged. When confidence intervals are reported rather than standard errors, we calculate standard errors using t-distribution with ∞ degrees of freedom (i.e. 1.96 for 95% confidence interval).

[33] The nine parameters are "C1 School closing," "C2 Workplace closing," "C3 Cancel public events," "C4 Restrictions on gatherings," "C5 Close public transport," "C6 Stay at home requirements," "C7 Restrictions on internal movement," "C8 International travel controls" and "H1 Public information campaigns." The latter, "H1

while only a few countries issued SIPOs without closing businesses. Hence, it is reasonable to perceive the stringency index as continuous, although not necessarily linear. The index includes recommendations (e.g. "workplace closing" is 1 if the government recommends closing (or work from home), cf. Hale et al. (2021)), but the effect of including recommendations in the index is primarily to shift the index parallelly upward and should not alter the results relative to our focus on mandated NPIs. It is important to note that the index is not perfect. As pointed out by Book (2020), it is certainly possibly to identify errors and omissions in the index. However, the index is objective and unbiased and as such, useful for cross-sectional analysis with several observations, even if not suitable for comparing the overall strictness of lockdowns in two countries.

Since the studies examined use different units of estimates, we have created common estimates for Europe and United States to make them comparable. The common estimates show the effect of the average lockdown in Europe and United States (with average stringencies of 76 and 74, respectively, between March 16th and April 15th, 2020, compared to a policy based solely on recommendations (stringency 44)). For example, Ashraf (2020) estimates that the effect of stricter lockdowns is -0.073 to -0.326 deaths/million per stringency point. We use the average of these two estimates (-0.200) in the meta-analysis (see Table 9 in Appendix B for a description for all studies). The average lockdown in Europe between March 16th and April 15th, 2020, was 32 points stricter than a policy solely based on recommendations (76 vs. 44). In United States, it was 30 points. Hence, the total effect of the lockdowns compared to the recommendation policy was -6.37 deaths/million in Europe (32 x -0.200) and -5.91 deaths/million in United States. With populations of 748 million and 333 million, respectively the total effect as estimated by Ashraf (2020) is 4,766 averted COVID-19 deaths in Europe and 1,969 averted COVID-19 deaths in United States. By the end of the study period in Ashraf (2020), which is May 20, 2020, 164,600 people in Europe and 97,081 people in the United States had died of COVID-19. Hence, the 4,766 averted COVID-19 deaths in Europe and the 1,969 averted COVID-19 deaths in the United States corresponds to 2.8% and 2.0% of all COVID-19 deaths, respectively, with an arithmetic average of 2.4%. Our common estimate is thus -2.4%, cf. Table 3. So, this means that Ashraf (2020) estimates that without lockdowns, COVID-19 deaths in Europe would have been 169,366 and COVID-19 deaths in the U.S. would have been 99,050. Our approach is not unproblematic. First of all, the level of stringency varies over time for all countries. We use the stringency between March 16th and April 15th, 2020 because this period covers the main part of the first wave which most of the studies analyze. Secondly, OxCGRT has changed the index over time and a 10-point difference today may not be exactly the same as a 10-point difference when the studies were finalized. However, we believe these problems are unlikely to significantly alter our results.

Public information campaigns," is not an intervention following our definition, as it is not a mandatory requirement. However, of 97 European countries and U.S. States in the OxCGRT database, only Andorra, Belarus, Bosnia and Herzegovina, Faeroe Islands, and Moldova – less than 1.6% of the population – did not get the maximum score by March 20, 2020, so the parameter simply shifts the index parallelly upward and should not have notable impact on the analyzes.

Table 3 demonstrates that the studies find that lockdowns, on average, have reduced COVID-19 mortality rates by 0.2% (precision-weighted). The results yield a median of -2.4% and an arithmetic average of -7.3%. Only one of the seven studies, Fuller et al. (2021), finds a significant *and* (relative to the effect predicted in studies like Ferguson et al. (2020)) substantial effect of lockdowns (-35%). The other six studies find much smaller effects. Hence, based on the stringency index studies, we find little to no evidence that mandated lockdowns in Europe and the United States had a noticeable effect on COVID-19 mortality rates. And, as will be discussed in the next paragraph, the fifth column of Table 3 displays the number of quality dimensions (out of 4) met by each study.

Table 3: Overview of common estimates from studies based on stringency indexes

Effect on COVID-19 mortality	**Estimate (Estimated Averted Deaths / Total Deaths)**	**Standard error**	**Weight (1/SE)**	**Quality dimensions**
Bjørnskov (2021)	-0.3%	0.8%	119	3
Shiva and Molana (2021)	-4.1%	0.4%	248	4
Stockenhuber (2020)*	0.0%	n/a	n/a	3
Chisadza et al. (2021)	0.1%	0.0%	7,390	4
Goldstein et al. (2021)	-9.0%	3.8%	26	2
Fuller et al. (2021)	-35.3%	9.1%	11	2
Ashraf (2020)	-2.4%	0.4%	256	2
Precision-weighted average (arithmetic average / median)	**-0.2% (-7.3%/-2.4%)**			

Note: The table shows the estimates for each study converted to a common estimate, i.e. the implied effect on COVID-19 mortality in Europe and United States. A negative number corresponds to fewer deaths, so -5% means 5% lover COVID-19 mortality. For studies which report estimates in deaths per million, the common estimate is calculated as: (COVID-19 mortality with "common area's" policy) / (COVID-19 mortality with recommendation policy) -1, where (COVID-19 mortality with recommendation policy) is calculated as ((COVID-19 mortality with "common area's" policy) - Estimate x Difference in stringency x population). Stringencies in Europe and United States are equal to the average stringency from March 16th to April 15th 2020 (76 and 74 respectively) and the stringency for the policy based solely on recommendations is 44 following Hale et al. (2020). For the conversion of other studies see Table 9 in appendix B.

** It is not possible to calculate a common estimate for Stockenhuber (2020). When calculating arithmetic average / median, the study is included as 0%, because estimates are insignificant and signs of estimates are mixed (higher strictness can cause both lower and higher COVID-19 mortality).*

We now turn to the quality dimensions. Table 4 presents the results differentiated by the four quality dimensions. Two studies, Shiva and Molana (2021) and Chisadza et al. (2021), meet all quality dimensions. The precision-weighted average for these studies is 0.0%, meaning that lockdowns had no effect on COVID-19 mortality. Two studies live up to 3 of 4 quality dimensions (Bjørnskov (2021a) and Stockenhuber (2020)). The precision-weighted average for these studies is -0.3%, meaning that lockdowns reduced COVID-19 mortality by 0.3%. Three studies lack at least two quality dimensions.[34] These studies find that lockdowns reduce COVID-19 mortality by 4.2%. To sum up, we find that the studies that meet at least 3 of 4 quality measures find that lockdowns have little to no effect on COVID-19 mortality, while studies that

[34] In fact, the working papers by P. Goldstein et al. (2021), Fuller et al. (2021) and Ashraf (2020) all lack exactly two quality parameters.

meet 2 of 4 quality measures find a small effect on COVID-19 mortality. These results are far from those estimated with the use of epidemiological models, such as the Imperial College London (Ferguson et al. (2020).

Table 4: Overview of common estimates split on quality dimensions for studies based on stringency indexes

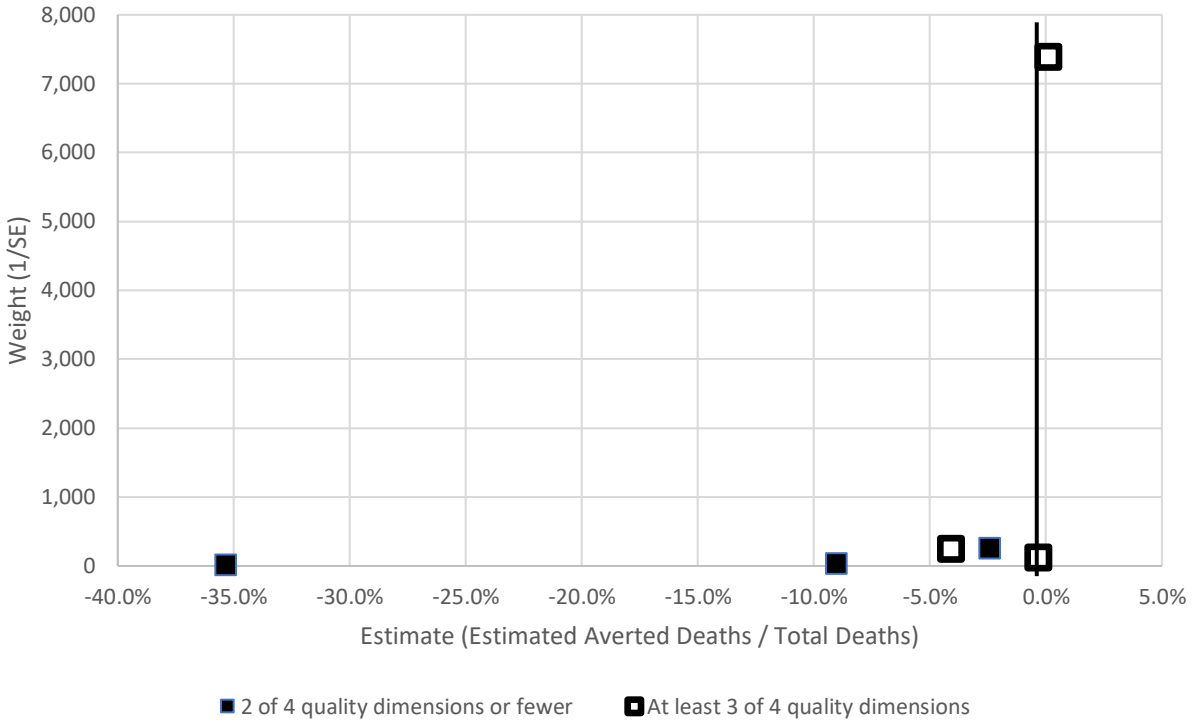
Values show effect on COVID-19 mortality	Precision-weighted average*	Arithmetic average	Median
Peer-reviewed vs. working papers			
Peer-reviewed [4]	0.0%	-1.1%	-0.2%
Working paper [3]	-4.2%	-15.6%	-9.0%
Long vs. short time period			
Data series ends after 31 May 2020 [6]	-0.1%	-8.1%	-0.2%
Data series ends before 31 May 2020 [1]	-2.4%	-2.4%	-9.0%
No early effect on mortality			
Does not find an effect within the first 14 days (including n/a) [5]	-0.2%	-8.3%	-2.4%
Finds effect within the first 14 days [2]	-1.9%	-4.7%	-4.7%
Social sciences vs. other sciences			
Social sciences [5]	-0.1%	-3.1%	-2.4%
Other sciences [2]	-35.3%	-17.7%	-17.7%
4 of 4 quality dimensions [2]	**0.0%**	**-2.0%**	**-2.0%**
3 of 4 quality dimensions [2]	**-0.3%**	**-0.2%**	**-0.2%**
2 of 4 quality dimensions or fewer [3]	**-4.2%**	**-15.6%**	**-9.0%**

*Note: The table shows the common estimate as described in Table 3 for each quality dimension. The number of studies in each category is in square brackets. * The precision-weighted average does not include studies where no common standard error is available, cf. Table 3.*

Figure 5 shows a funnel plot for the studies in Table 3, except Stockenhuber (2020), where common estimate standard errors cannot be derived. Chisadza et al. (2021) has a far higher precision than the other studies (1/SE is 7,398 and the estimate is 0.1%)[35], and there are indications that the estimate from Fuller et al. (2021) (the bottom left) is an imprecise outlier.[36] Figure 5 The plot also shows that the studies with at least 3 of 4 quality dimensions are centered around zero and generally have higher precision than other studies.

[35] Excluding Chisadza et al. (2021) from the precision-weighted average changes the average to -3.5%.
[36] Excluding Fuller et al. (2021) from the precision-weighted average only marginally changes the average because the precision is very low.

Figure 5: Funnel plot for estimates from studies based on stringency indexes



Note: The figure displays all estimates and the precision of the estimate defined as one over the standard error. Studies where standard errors are not available are not included. Studies which live up to at least 3 of 4 quality dimensions are marked with white, while studies which lives up to 2 of 3 quality dimensions or less are marked with black. The vertical line illustrates the precision-weighted average.

Overall conclusion on stringency index studies

Compared to a policy based solely on recommendations, we find little evidence that lockdowns had a noticeable impact on COVID-19 mortality Only one study, Fuller et al. (2021), finds a substantial effect, while the rest of the studies find little to no effect. Indeed, according to stringency index studies, lockdowns in Europe and the United States reduced only COVID-19 mortality by 0.2% on average.

In the following section we will look at the effect of SIPOs. The section follows the same structure as this section.

4.2 Shelter-in-place order (SIPO) studies

We have identified 13 eligible studies which estimate the effect of Shelter-In-Place Orders (SIPOs) on COVID-19 mortality, cf. Table 5. Seven of these studies look at multiple NPIs of which a SIPO is just one, while six studies estimate the effect of a SIPO vs. no SIPO in the United States. According to the containment and closure policy indicators from OxCGRT, 41 states in the U.S. issued SIPOs in the spring of 2020. But usually, these were introduced after implementing other NPIs such as school closures or workplace closures. On average, SIPOs

were issued 7½ days after *both* schools and workplaces closed, and 12 days after the first of the two closed. Only one state, Tennessee, issued a SIPO before schools and workplaces closed. The 10 states that did not issue SIPOs all closed schools. Moreover, of those 10 states, three closed some non-essential businesses, while the remaining 7 closed all non-essential businesses. Because of this, we perceive estimates for SIPOs based on U.S.-data as the marginal effect of SIPOs on top of other restrictions, although we acknowledge that the estimates may capture the effects of other NPI measures as well.

The results of eligible studies based on SIPOs are presented in Table 5. The table demonstrates that the studies generally find that SIPOs have reduced COVID-19 mortality by 2.9% (on a precision-weighted average). There is an apparent difference between studies in which a SIPO is one of multiple NPIs, and studies in which a SIPO is the only examined intervention. The former group generally finds that SIPOs *increase* COVID-19 mortality *marginally*, whereas the latter finds that SIPOs *decrease* COVID-19 mortality. As we will see below, this difference could be explained by differences in the quality dimensions, and especially the time period covered by each study.

Table 5: Overview of estimates from studies based on SIPOs

Values show effect on COVID-19 mortality	**Estimate (Estimated Averted Deaths / Total Deaths)**	**Standard error**	**Weight (1/SE)**	**Quality dimensions**
Studies where SIPO is one of several examined interventions and not (as) likely to capture the effect of other interventions				
Chernozhukov et al. (2021)	-17.7%	14.3%	7	4
Chaudhry et al. (2020) *	0.0%	n/a	n/a	2
Aparicio and Grossbard (2021)	2.6%	2.8%	35	4
Stokes et al. (2020)	0.8%	11.1%	9	3
Spiegel and Tookes (2021)	13.1%	6.6%	15	3
Bonardi et al. (2020)	0.0%	n/a	n/a	1
Guo et al. (2021)	4.6%	14.8%	4	3
Average (median) where SIPO is one of several variables	2.8% (0.5%/0.8%)			
Studies where SIPO is the only examined intervention and may capture the effect of other interventions				
Sears et al. (2020)	-32.2%	17.6%	6	2
Alderman and Harjoto (2020)	-1.0%	0.6%	169	4
Berry et al. (2020)	1.1%	n/a	n/a	2
Fowler et al. (2021)	-35.0%	7.0%	14	2
Gibson (2020)	-6.0%	24.3%	4	4
Dave et al. (2020)	-40.8%	36.1%	3	3
Average (median) where SIPO is the only variable	-5.1% (-19.0%/-19.1%)			
Precision-weighted average (arithmetic average / median) for all studies	**-2.9% (-8.5%/0.0%)**			

*Note: * Chaudhry et al. (2020) does not provide an estimate but states that SIPO is insignificant. We use 0% when calculating the arithmetic average and median. Chaudhry et al. (2020) and Berry et al. (2021) do not affect the precision-weighted average, as we do not know the standard errors.*

Table 6 presents the results differentiated by quality dimensions. Four studies (Chernozhukov et al. (2021), Aparicio and Grossbard (2021), Alderman and Harjoto (2020) and Gibson (2020))

meet all quality dimensions but find vastly different effects of SIPOs on COVID-19 mortality. The precision weighted average of the four studies is -1.0%. Four studies meet 3 of 4 quality dimensions. They overall find that SIPOs *increase* COVID-19 mortality, as the precision-weighted average is positive (3.7%). The five studies that meet 2 of 4 quality dimensions or fewer[37] find a substantial reduction in COVID-19-mortality (-34.2%). This substantial reduction seems to be driven by relatively short data series. The latest data point for the three studies which find large effects of lockdowns (Sears et al. (2020), Fowler et al. (2021), and Dave et al. (2021)) are April 29, May 7, and April 20, respectively. This may indicate that SIPOs can delay deaths but not eliminate them completely. Disregarding these studies with short data series, the precision-weighted average is -0.1%.

Table 6: Quality dimensions for studies based on SIPOs

Values show effect on COVID-19 mortality	Precision-weighted average*	Arithmetic average	Median
Peer-reviewed vs. working papers			
Peer-review [10]	-2.4%	-7.9%	-0.5%
Working paper [3]	-12.0%	-10.5%	0.0%
Long vs. short time period			
Data serie ends after 31 May 2020 [6]	-0.1%	-1.4%	-0.1%
Data serie ends before 31 May 2020 [7]	-25.9%	-14.6%	0.0%
No early effect on mortality			
Finds effect within the first 14 days [9]	-2.0%	-10.0%	-1.0%
Does not find an effect within the first 14 days (including n/a) [4]	-10.3%	-5.2%	0.0%
Social sciences vs. other sciences			
Social sciences [12]	-2.9%	-9.2%	-0.5%
Other sciences [1]	n/a	0.0%	0.0%
4 of 4 quality dimensions [4]	-1.0%	-5.5%	-3.5%
3 of 4 quality dimensions [4]	3.7%	-5.6%	2.7%
2 of 4 quality dimensions or fewer [5]	-34.2%	-13.2%	0.0%

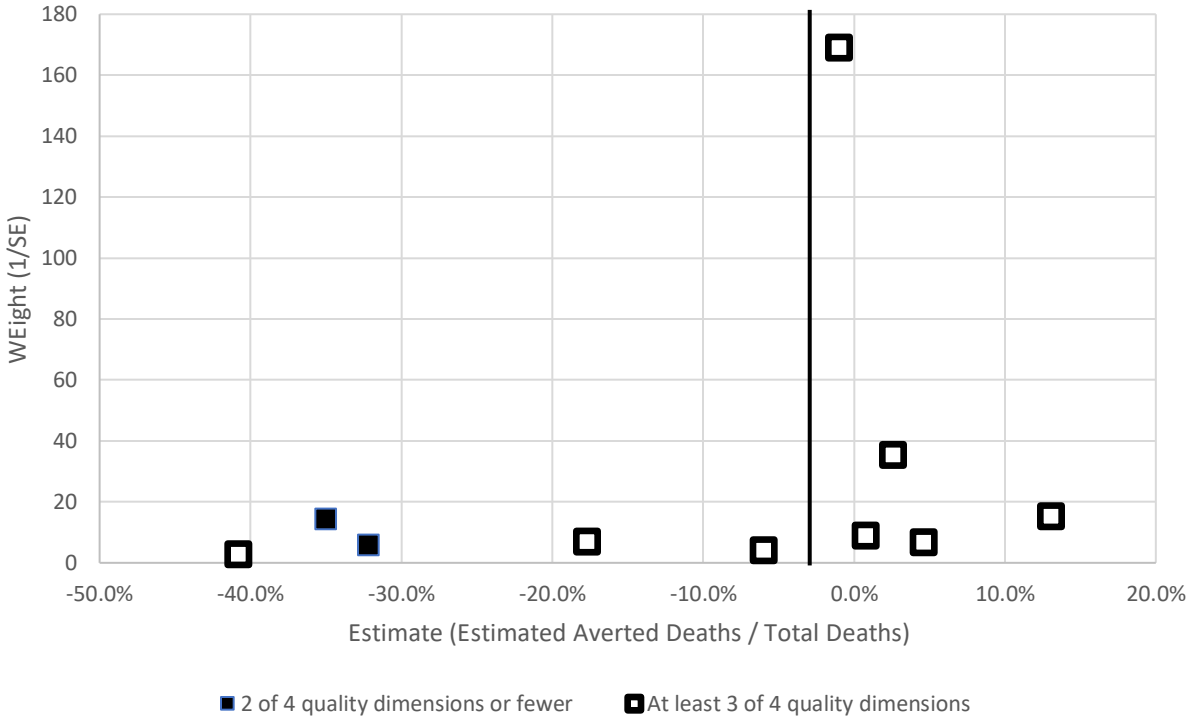
*Note: The table shows the common estimate as described in Table 5 for each quality dimension. The number of studies in each category is in square brackets. * The precision-weighted average does not include studies where no common standard error is available, cf. Table 5.*

Figure 6 shows a funnel plot for the studies in Table 5, except Chaudhry et al. (2020) and Berry et al. (2021), where common standard errors cannot be derived. Sears et al. (2020) stands out with a precision far higher than those of the other studies. But generally, the precisions of the studies are low and the estimates are placed on both sides of the zero-line with some 'tail' to the

[37] Bonardi et al. (2020) only meet one quality dimension (social science).

left.[38] Figure 5 also shows that four of eight studies with at least 3 of 4 quality dimensions find that SIPOs *increase* COVID-19 mortality by 0.8% to 13.1%.

Figure 6: Funnel plot for estimates from SIPO studies



Note: The figure displays all estimates and the precision of the estimate defined as one over the standard error. Studies where standard errors are not available are not included. Studies which live up to at least 3 of 4 quality dimensions are marked with white, while studies which lives up to 2 of 4 quality dimensions or less are marked with black. The vertical line illustrates the precision-weighted average.

Overall conclusion on SIPO studies

We find no clear evidence that SIPOs had a noticeable impact on COVID-19 mortality. Some studies find a large negative relationship between lockdowns and COVID-19 mortality, but this seems to be caused by short data series which does not cover a full COVID-19 'wave'. Several studies find a small positive relationship between lockdowns and COVID-19 mortality. Although this appears to be counterintuitive, it could be the result of an (asymptomatic) infected person being isolated at home under a SIPO can infect family members with a higher viral load causing more severe illness.[39] The overall effect measured by the precision-weighted average is -2.9%. The result is in line with Nuzzo et al. (2019), who state that "In the context of a high-impact

[38] This could indicate some publication bias, but the evidence is weak and with only 13 estimates, this cannot be formally tested

[39] E.g. see Guallar et al. (2020), who concludes, "Our data support that a greater viral inoculum at the time of SARS-CoV-2 exposure might determine a higher risk of severe COVID-19."

respiratory pathogen, quarantine may be the least likely NPI to be effective in controlling the spread due to high transmissibility" and World Health Organization Writing Group (2006), who conclude that "forced isolation and quarantine are ineffective and impractical."[40]

In the following section, we will look at the effect found in studies analyzing specific NPIs.

4.3 Studies of specific NPIs

A total of 11 eligible studies look at (multiple) specific NPIs independently or simply lockdown vs. no lockdown.[41] The definition of the specific NPIs varies from study to study and are somewhat difficult to compare. The variety in the definitions can be seen in the analysis of non-essential business closures and bar/restaurant closures. Chernozhukov et al. (2021) focus on a combined parameter (the average of business closure and bar/restaurant closure in each state), Aparicio and Grossbard (2021) look at business closure but not bar/restaurant closure, Spiegel and Tookes (2021) examine bar/restaurant closure but not business closure, and Guo et al. (2021) look at both business closures and bar/restaurant closures independently.

Some studies include several NPIs (e.g. Stokes et al. (2020) and Spiegel and Tookes (2021)), while others cover very few. Bongaerts et al. (2021) only study business closures, and Leffler et al. (2020) look at internal lockdown and international travel restrictions). Few NPIs in a model are potentially a problem because they can capture the effect of excluded NPIs. On the other hand, several NPIs in a model increase the risk of multiple test bias.

The differences in the choice of NPIs and in the number of NPIs make it challenging to create an overview of the results. In Table 7, we have merged the results in six overall categories but note that the estimates may not be fully comparable across studies. In particular, the lockdown-measure varies from study to study and in some cases is poorly defined by the authors. Also, there are only a few estimates within some of the categories. For instance, the estimate of the effect of facemasks is based on only two studies.

Table 7 illustrates that generally there is no evidence of a noticeable relationship between the most-used NPIs and COVID-19. Overall, lockdowns and limiting gatherings seem to increase COVID-19 mortality, although the effect is modest (0.6% and 1.6%, respectively) and border closures has little to no effect on COVID-19 mortality, with a precision-weighted average of -0.1% (removing the imprecise outlier from Guo et al. (2021) changes the precision-weighted average to -0.2%). We find a small effect of school closure (-4.4%), but this estimate is mainly driven by Auger et al. (2020), who – as noted earlier – use an "interrupted time series study"

[40] Both Nuzzo et al. (2019) and World Health Organization Writing Group (2006) focus on quarantining infected persons. However, if quarantining infected persons is not effective, it should be no surprise that quarantining uninfected persons could be ineffective too.

[41] Note that we – according to our search strategy – did not search on specific measures such as "school closures" but on words describing the overall political approach to the COVID-19 pandemic such as "non-pharmaceutical," "NPIs," "lockdown" etc.

approach and may capture other effects such as seasonal and behavioral effects. The absence of a notable effect of school closures is in line with Irfan et al. (2021), who – based on a systematic review and meta-analysis of 90 published or preprint studies of transmission in children – concluded that "risks of infection among children in educational-settings was lower than in communities. Evidence from school-based studies demonstrate it is largely safe for young children (<10 years of age) to be at schools; however, older children (between 10 and 19 years of age) might facilitate transmission." UNICEF (2021) and ECDC (2020) reach similar conclusions.[42]

Mandating facemasks – an intervention that was not widely used in the spring of 2020, and in many countries was even discouraged – seems to have a large effect (-21.2%), but this conclusion is based on only two studies.[43] Again, our categorization may play a role, as the larger mask-estimate from Chernozhukov et al. (2021) is in fact "employee facemasks," not a general mask mandate. Our findings are somewhat in contrast to the result found in a review by Liu et al. (2021), who conclude that "fourteen of sixteen identified randomized controlled trials comparing face masks to no mask controls failed to find statistically significant benefit in the intent-to-treat populations." Similarly, a pre-COVID Cochrane review concludes, "There is low certainty evidence from nine trials (3507 participants) that wearing a mask may make little or no difference to the outcome of influenza-like illness (ILI) compared to not wearing a mask (risk ratio (RR) 0.99, 95% confidence interval (CI) 0.82 to 1.18). There is moderate certainty evidence that wearing a mask probably makes little or no difference to the outcome of laboratory-confirmed influenza compared to not wearing a mask (RR 0.91, 95% CI 0.66 to 1.26; 6 trials; 3005 participants)" (Jefferson et al. (2020)).[44] However, it should be noted that even if no effect is found in controlled settings, this does not necessarily imply that mandated face masks does not reduce mortality, as other factors may play a role (e.g. wearing a mask may function as a tax on socializing if people are bothered by wearing a face masks when they are socializing).

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[42] UNICEF (2021) concludes, "The preliminary findings thus far suggest that in-person schooling – especially when coupled with preventive and control measures – had lower secondary COVID-19 transmission rates compared to other settings and do not seem to have significantly contributed to the overall community transmission risks." Whereas, ECDC (2020) conclude, "School closures can contribute to a reduction in SARS-CoV-2 transmission, but by themselves are insufficient to prevent community transmission of COVID-19 in the absence of other nonpharmaceutical interventions (NPIs) such as restrictions on mass gathering," and states, "There is a general consensus that the decision to close schools to control the COVID-19 pandemic should be used as a last resort. The negative physical, mental health and educational impact of proactive school closures on children, as well as the economic impact on society more broadly, would likely outweigh the benefits."

[43] Note again, that we – according to our search strategy – did not search on the specific measures such as "masks," "face masks," "surgical masks" but on words describing the overall political approach to the COVID-19 pandemic such as "non-pharmaceutical," "NPIs," "lockdown" etc. Thus, we do not include most of the studies in mask reviews such as Liu et al. (2021) and Jefferson et al. (2020).

[44] Lipp and Edwards (2014) also find no evidence of an effect and – looking at disposable surgical face masks for preventing surgical wound infection in clean surgery – conclude, "Three trials were included, involving a total of 2113 participants. There was no statistically significant difference in infection rates between the masked and unmasked group in any of the trials." Meanwhile, Li et al. (2021) – based on six case-control studies – conclude, "In general, wearing a mask was associated with a significantly reduced risk of COVID-19 infection (OR = 0.38, 95% CI: 0.21-0.69, I^2 = 54.1%).

Only business closure consistently shows evidence of a negative relationship with COVID-19 mortality, but the variation in the estimated effect is large. Three studies find little to no effect, and three find large effects. Two of the larger effects are related to closing bars and restaurants. The "close business" category in Chernozhukov et al. (2021) is an average of closed businesses, restaurants, and movie theaters, while that same category is "closing restaurants and bars" in Spiegel and Tookes (2021). The last study finding a large effect is Bongaerts et al. (2021), the only eligible single-country study.[45]

As a final observation on Table 7, studies with fewer quality dimensions seem to find larger effects, but the pattern is not systematic.[46]

Table 7: Overview of estimates from studies of specific NPIs

	Lockdown (complete/ partial)	Facemasks/ Employee face masks	Business closure (/bars & restaurants)	Border closure (/quarantine)	School closures	Limiting gatherings	Quality dimensions
Chernozhukov et al. (2021)		-34.0%	-28.6%				4
Bongaerts et al. (2021)			-31.6%				2
Chaudhry et al. (2020)*	0.0%			0.0%			2
Toya & Skidmore (2021)	0.5%			-0.1%			3
Aparicio & Grossbard (2021)			-1.3%		0.5%	0.8%	4
Auger et al. (2020)					-58.0%		2
Leffler et al. (2020)	1.7%			-15.6%			2
Stokes et al. (2020)			0.3%	-24.6%	-0.1%	-6.3%	3
Spiegel & Tookes (2021)		-13.5%	-50.2%			11.8%	3
Bonardi et al. (2020) *	0.0%			0.0%			1
Guo et al. (2021)			-0.4%	36.3%	-0.2%	5.7%	3
Precision-weighted average	**0.6%**	**-21.2%**	**-10.6%**	**-0.1%**	**-4.4%**	**1.6%**	
Arithmetic average	**0.6%**	**-23.8%**	**-18.6%**	**-0.7%**	**-14.4%**	**3.0%**	
Median	**0.3%**	**-23.8%**	**-14.9%**	**0.0%**	**-0.1%**	**3.2%**	
4 of 4 quality dimensions	**n/a [0]**	**-34.0% [1]**	**-2.9% [2]**	**n/a [0]**	**0.5% [1]**	**0.8% [1]**	
3 of 4 quality dimensions	**0.5% [1]**	**-13.5% [1]**	**-21.5% [3]**	**0.0% [3]**	**-0.1% [2]**	**5.6% [3]**	
2 of 4 quality dimensions or fewer	**1.7% [2]**	**n/a [1]**	**-31.6% [2]**	**-15.6% [2]**	**-58.0% [1]**	**n/a [1]**	

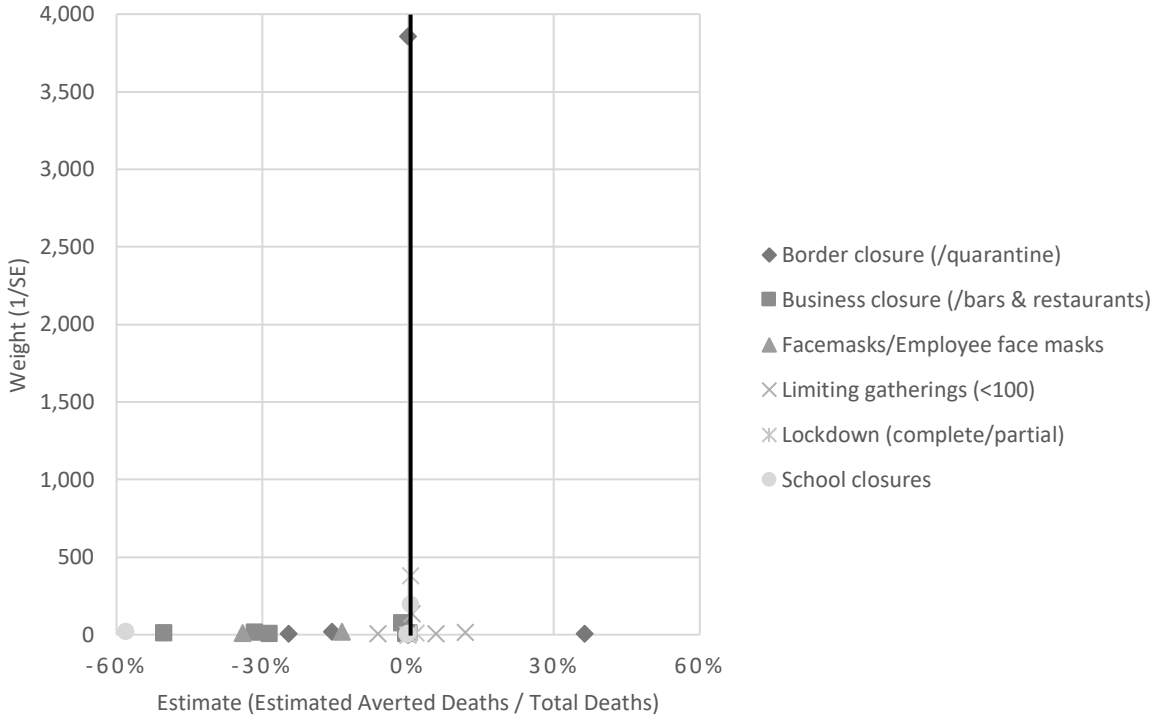
*Note: * It is not possible to derive common estimates and standard errors from Chaudhry et al. (2020) and Bonardi et al. (2020). Chaudhry et al. (2020) states that the effect of the various NPIs is insignificant without listing the estimates and standard errors. Bonardi et al. (2020) states that partial or regional lockdowns are as effective as stricter NPIs but does not provide information to calculate common estimates. Instead, we assume the estimate is 0% when calculating arithmetic average and median, while the estimates are excluded from the calculation of precision-weighted averages because there are no standard errors.*

[45] Bongaerts et al. (2021) (implicitly) assume that municipalities with different exposures to closed sectors are not inherently different, which may be a relatively strong assumption and could potentially drive their results.

[46] We saw with SIPOs that studies based on short data series tended to find larger effects than studies based on short data series. This is also somewhat true for studies examining multiple specific measures. If we focus on studies with long data series (>May 31st, 2020), the precision-weighted estimates are as follows (average for all studies in parentheses for easy comparison): Lockdown (complete/partial): 0.5% (0.6%), Facemasks/Employee face masks: -21.2% (-21.2%), Business closures (/bars & restaurants): -8.1% (-10.6%), Border closures (/quarantine): -0.1% (-0.1%), School closures: 0.5% (-4.4%), Limiting gatherings: 1.4% (1.6%).

Figure 7 shows a funnel plot for all estimates in Table 7, except Chaudhry et al. (2020) and Bonardi et al. (2020), where common standard errors cannot be derived. Two estimates from Toya and Skidmore (2020) stands out with a precision far higher than those of other studies, and estimates are placed with some 'tail' to the left, which could indicate some publication bias, i.e. reluctance to publish results that show large positive (more deaths) effects of lockdowns. The most precise estimates are gathered around 0%, while less precise studies are spread out between -58% and 36%. The precision-weighted average of all estimates across all NPIs is -0.6%.

Figure 7: Funnel plot for estimates from studies of specific NPIs



Note: The figure displays all estimates except two (se text in figure) of specific NPIs and the precision of the estimate defined as one over the standard error. Studies where standard errors are not available are not included.

Overall conclusion on specific NPIs

Because of the heterogeneity in NPIs across studies, it is difficult to draw strong conclusions based on the studies of multiple specific measures. We find no evidence that lockdowns, school closures, border closures, and limiting gatherings have had a noticeable effect on COVID-19 mortality. There is some evidence that business closures reduce COVID-19 mortality, but the variation in estimates is large and the effect seems related to closing bars. There may be an effect of mask mandates, but just two studies look at this, one of which one only looks at the effect of employee mask mandates.

5 Concluding observations

Public health experts and politicians have – based on forecasts in epidemiological studies such as that of Imperial College London (Ferguson et al. (2020) – embraced compulsory lockdowns as an effective method for arresting the pandemic. But, have these lockdown policies been effective in curbing COVID-19 mortality? This is the main question answered by our meta-analysis.

Adopting a systematic search and title-based screening, we identified 1,048 studies published by July 1st, 2020, which potentially look at the effect of lockdowns on mortality rates. To answer our question, we focused on studies that examine the actual impact of lockdowns on COVID-19 mortality rates based on registered cross-sectional mortality data and a counterfactual difference-in-difference approach. Out of the 1,048 studies, 34 met our eligibility criteria.

Conclusions

Overall, our meta-analysis fails to confirm that lockdowns have had a large, significant effect on mortality rates. Studies examining the relationship between lockdown strictness (based on the OxCGRT stringency index) find that the average lockdown in Europe and the United States only reduced COVID-19 mortality by 0.2% compared to a COVID-19 policy based solely on recommendations. Shelter-in-place orders (SIPOs) were also ineffective. They only reduced COVID-19 mortality by 2.9%.

Studies looking at specific NPIs (lockdown vs. no lockdown, facemasks, closing non-essential businesses, border closures, school closures, and limiting gatherings) also find no broad-based evidence of noticeable effects on COVID-19 mortality. However, closing non-essential businesses seems to have had some effect (reducing COVID-19 mortality by 10.6%), which is likely to be related to the closure of bars. Also, masks may reduce COVID-19 mortality, but there is only one study that examines universal mask mandates. The effect of border closures, school closures and limiting gatherings on COVID-19 mortality yields precision-weighted estimates of -0.1%, -4.4%, and 1.6%, respectively. Lockdowns (compared to no lockdowns) also do not reduce COVID-19 mortality.

Discussion

Overall, we conclude that lockdowns are not an effective way of reducing mortality rates during a pandemic, at least not during the first wave of the COVID-19 pandemic. Our results are in line with the World Health Organization Writing Group (2006), who state, "Reports from the 1918 influenza pandemic indicate that social-distancing measures did not stop or appear to dramatically reduce transmission […] In Edmonton, Canada, isolation and quarantine were instituted; public meetings were banned; schools, churches, colleges, theaters, and other public gathering places were closed; and business hours were restricted without obvious impact on the epidemic." Our findings are also in line with Allen's (2021) conclusion: "The most recent research has shown that lockdowns have had, at best, a marginal effect on the number of Covid-19 deaths." Poeschl and Larsen (2021) conclude that "interventions are generally effective in

mitigating COVID-19 spread". But, 9 of the 43 (21%) results they review find "no or uncertain association" between lockdowns and the spread of COVID-19, suggesting that evidence from that own study contradicts their conclusion.

The findings contained in Johanna et al. (2020) are in contrast to our own. They conclude that "for lockdown, ten studies consistently showed that it successfully reduced the incidence, onward transmission, and mortality rate of COVID-19." The driver of the difference is three-fold. First, Johanna et al. include modelling studies (10 out of a total of 14 studies), which we have explicitly excluded. Second, they included interrupted time series studies (3 of 14 studies), which we also exclude. Third, the only study using a difference-in-difference approach (as we have done) is based on data collected before May 1st, 2020. We should mention that our results indicate that early studies find relatively larger effects compared to later studies.

Our main conclusion invites a discussion of some issues. Our review does not point out *why* lockdowns did not have the effect promised by the epidemiological models of Imperial College London (Ferguson et al. (2020). We propose four factors that might explain the difference between our conclusion and the view embraced by some epidemiologists.

First, people respond to dangers outside their door. When a pandemic rages, people believe in social distancing regardless of what the government mandates. So, we believe that Allen (2021) is right, when he concludes, "The ineffectiveness [of lockdowns] stemmed from individual changes in behavior: either non-compliance or behavior that mimicked lockdowns." In economic terms, you can say that the demand for costly disease prevention efforts like social distancing and increased focus on hygiene is high when infection rates are high. Contrary, when infection rates are low, the demand is low and it may even be morally and economically rational not to comply with mandates like SIPOs, which are difficult to enforce. Herby (2021) reviews studies which distinguish between mandatory and voluntary behavioral changes. He finds that – on average – voluntary behavioral changes are 10 times as important as mandatory behavioral changes in combating COVID-19. If people voluntarily adjust their behavior to the risk of the pandemic, closing down non-essential businesses may simply reallocate consumer visits away from "nonessential" to "essential" businesses, as shown by Goolsbee and Syverson (2021), with limited impact on the total number of contacts.[47] This may also explain why epidemiological model simulations such as Ferguson et al. (2020) – which do not model behavior endogenously – fail to forecast the effect of lockdowns.

Second, mandates only regulate a fraction of our potential contagious contacts and can hardly regulate nor enforce handwashing, coughing etiquette, distancing in supermarkets, etc. Countries like Denmark, Finland, and Norway that realized success in keeping COVID-19 mortality rates relatively low allowed people to go to work, use public transport, and meet privately at home during the first lockdown. In these countries, there were ample opportunities to legally meet with others.

[47] In economic terms, lockdowns are substitutes for – not complements to – voluntary behavioral changes.

Third, even if lockdowns are successful in initially reducing the spread of COVID-19, the behavioral response may counteract the effect completely, as people respond to the lower risk by changing behavior. As Atkeson (2021) points out, the economic intuition is straightforward. If closing bars and restaurants causes the prevalence of the disease to fall toward zero, the demand for costly disease prevention efforts like social distancing and increased focus on hygiene also falls towards zero, and the disease will return.[48]

Fourth, unintended consequences may play a larger role than recognized. We already pointed to the possible unintended consequence of SIPOs, which may isolate an infected person at home with his/her family where he/she risks infecting family members with a higher viral load, causing more severe illness. But often, lockdowns have limited peoples' access to safe (outdoor) places such as beaches, parks, and zoos, or included outdoor mask mandates or strict outdoor gathering restrictions, pushing people to meet at less safe (indoor) places. Indeed, we do find some evidence that limiting gatherings was counterproductive and increased COVID-19 mortality.

One objection to our conclusions may be that we do not look at the role of timing. If timing is very important, differences in timing may empirically overrule any differences in lockdowns. We note that this objection is not necessarily in contrast to our results. If timing is very important relative to strictness, this suggests that well-timed, but very mild, lockdowns should work as well as, or better than, less well-timed but strict lockdowns. This is not in contrast to our conclusion, as the studies we reviewed analyze the effect of lockdowns compared but to doing very little (see Section 3.1 for further discussion). However, there is little solid evidence supporting the timing thesis, because it is inherently difficult to analyze (see Section 2.2 for further discussion). Also, even if it can be empirically stated that a well-timed lockdown is effective in combating a pandemic, it is doubtful that this information will ever be useful from a policy perspective.

But, what explains the differences between countries, if not differences in lockdown policies? Differences in population age and health, quality of the health sector, and the like are obvious factors. But several studies point at less obvious factors, such as culture, communication, and coincidences. For example, Frey et al. (2020) show that for the same policy stringency, countries with more obedient and collectivist cultural traits experienced larger declines in geographic mobility relative to their more individualistic counterpart. Data from Germany Laliotis and Minos (2020) shows that the spread of COVID-19 and the resulting deaths in predominantly Catholic regions with stronger social and family ties were much higher compared to non-Catholic ones at the local NUTS 3 level.[49]

Government communication may also have played a large role. Compared to its Scandinavian neighbors, the communication from Swedish health authorities was far more subdued and embraced the idea of public health vs. economic trade-offs. This may explain why Helsingen et

[48] This kind of behavior response may also explain why Subramanian and Kumar (2021) find that increases in COVID-19 cases are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States. When people are vaccinated and protected against severe disease, they have less reason to be careful.

[49] The NUTS classification (Nomenclature of territorial units for statistics) is a hierarchical system for dividing up the economic territory of the EU and the UK. There are 1215 regions at the NUTS 3-level.

al. (2020), found, based on questionnaire data collected from mid-March to mid-April, 2020, that even though the daily COVID-19 mortality rate was more than four times higher in Sweden than in Norway, Swedes were less likely than Norwegians to not meet with friends (55% vs. 87%), avoid public transportation (72% vs. 82%), and stay home during spare time (71% vs. 87%). That is, despite a more severe pandemic, Swedes were less affected in their daily activities (legal in both countries) than Norwegians.

Many other factors may be relevant, and we should not underestimate the importance of coincidences. An interesting example illustrating this point is found in Arnarson (2021) and Björk et al. (2021), who show that areas where the winter holiday was relatively late (in week 9 or 10 rather than week 6, 7 or 8) were hit especially hard by COVID-19 during the first wave because the virus outbreak in the Alps could spread to those areas with ski tourists. Arnarson (2021) shows that the effect persists in later waves. Had the winter holiday in Sweden been in week 7 or week 8 as in Denmark, the Swedish COVID-19 situation could have turned out very differently.[50]

Policy implications

In the early stages of a pandemic, before the arrival of vaccines and new treatments, a society can respond in two ways: mandated behavioral changes or voluntary behavioral changes. Our study fails to demonstrate significant positive effects of mandated behavioral changes (lockdowns). This should draw our focus to the role of voluntary behavioral changes. Here, more research is needed to determine how voluntary behavioral changes can be supported. But it should be clear that one important role for government authorities is to provide information so that citizens can voluntarily respond to the pandemic in a way that mitigates their exposure.

Finally, allow us to broaden our perspective after presenting our meta-analysis that focuses on the following question: "What does the evidence tell us about the effects of lockdowns on mortality?" We provide a firm answer to this question: The evidence fails to confirm that lockdowns have a significant effect in reducing COVID-19 mortality. The effect is little to none.

The use of lockdowns is a unique feature of the COVID-19 pandemic. Lockdowns have not been used to such a large extent during any of the pandemics of the past century. However, lockdowns during the initial phase of the COVID-19 pandemic have had devastating effects. They have contributed to reducing economic activity, raising unemployment, reducing schooling, causing political unrest, contributing to domestic violence, and undermining liberal democracy. These costs to society must be compared to the benefits of lockdowns, which our meta-analysis has shown are marginal at best. Such a standard benefit-cost calculation leads to a strong conclusion: lockdowns should be rejected out of hand as a pandemic policy instrument.

[50] Another case of coincidence is illustrated by Shenoy et al. (2022), who find that areas that experienced rainfall early in the pandemic realized fewer deaths because the rainfall induced social distancing.

6 Appendix A. The role of timing

Some of the included papers study the importance of the timing of lockdowns, while several other papers only looking at timing of (but not on the inherent effect of) lockdowns have been excluded from the literature list in this review. There's no doubt that being prepared for a pandemic and knowing when it arrives at your doorstep is vital. However, two problems arise with respect to imposing early lockdowns.

First of all, it was virtually impossible to determine the right timing when COVID-19 hit Europe and the United States. The World Health Organization declared the outbreak of a pandemic on 11 March 2020, but at that date Italy had already registered 13.7 COVID-19-deaths per million (all infected before approximately 22 February, because of the roughly 18 day gap between infection and death, c.f. e.g.. Bjørnskov (2021a)). On 29 March 2020, 18 days after WHO declared the outbreak a pandemic and the earliest a lockdown response to WHO's announcement could have an effect, the death toll in Italy was a staggering 178 COVID-19-deaths per million with an additionally 13 per million dying each day.

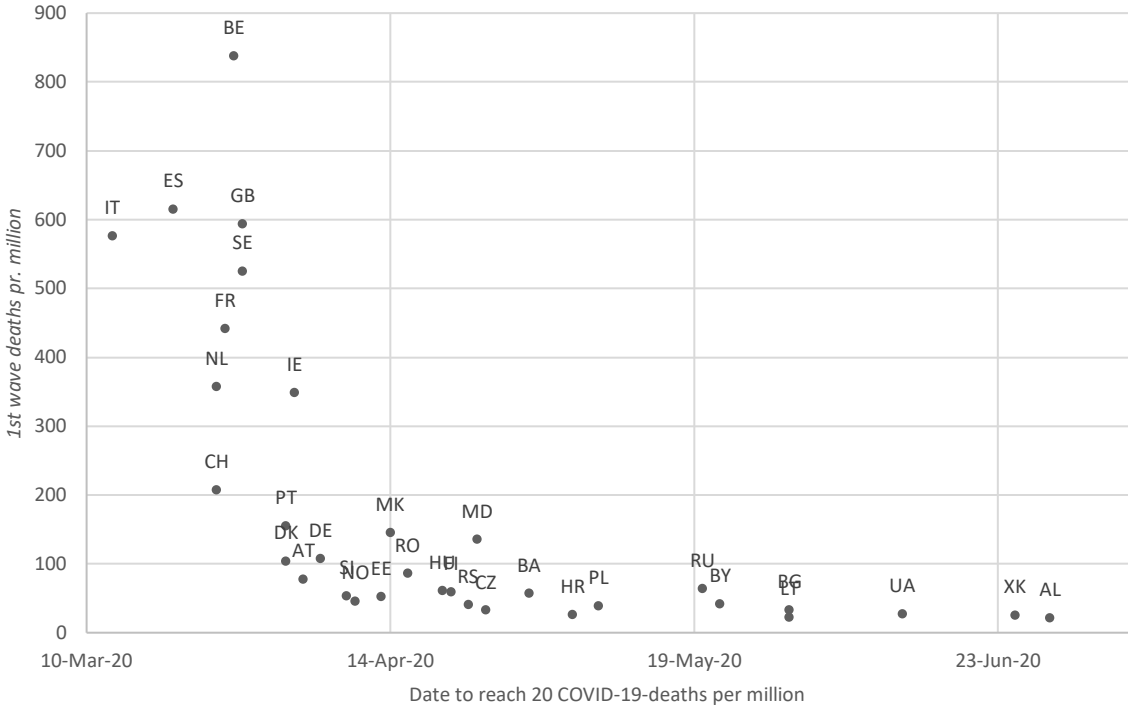
There are reasons to believe that many countries and regions were hit particularly hard during the first wave of COVID, because they had no clue about how bad it really was. This point is illustrated in Figure 8 (and Figure 9), which show that countries (and states), which were hit hard and early, experienced large death tolls compared to countries where the pandemic had a slower start. Björk et al. (2021) and Arnarson (2021) show that areas with a winter holiday in week 10 and – especially – week 9 were hit hard, because they imported cases from the Alps *before* they knew the pandemic was wide spread at the ski resorts. Hence, while acting early by warning citizens and closing business may be an effective strategy; this was not a feasible strategy for most countries in the spring of 2020.

The second problem is that it is extremely difficult to differentiate between the effect of public awareness and the effect of lockdowns. If people and politicians react to the same information, for example deaths in geographical neighboring countries (many EU-countries reacted to deaths in Italy) or in another part of the same country, the effect of lockdowns cannot easily be separated from the effect of voluntary social distancing or, use of hand sanitizers. Hence, we find it problematic to use national lockdowns and differences in the progress of the pandemic in different regions to say anything about the effect of early lockdowns on the pandemic, as the estimated effect might just as well come from voluntary behavior changes, when people in Southern Italy react to the situation in Northern Italy.

We have seen no studies which we believe credibly separate the effect of early lockdown from the effect of early voluntary behavior changes. Instead, the estimates in these studies capture the effects of lockdowns *and* voluntary behavior changes. As Herby (2021) illustrates, voluntary behavior changes are essential to a society's response to an pandemic and can account for up to 90% of societies' total response to the pandemic.

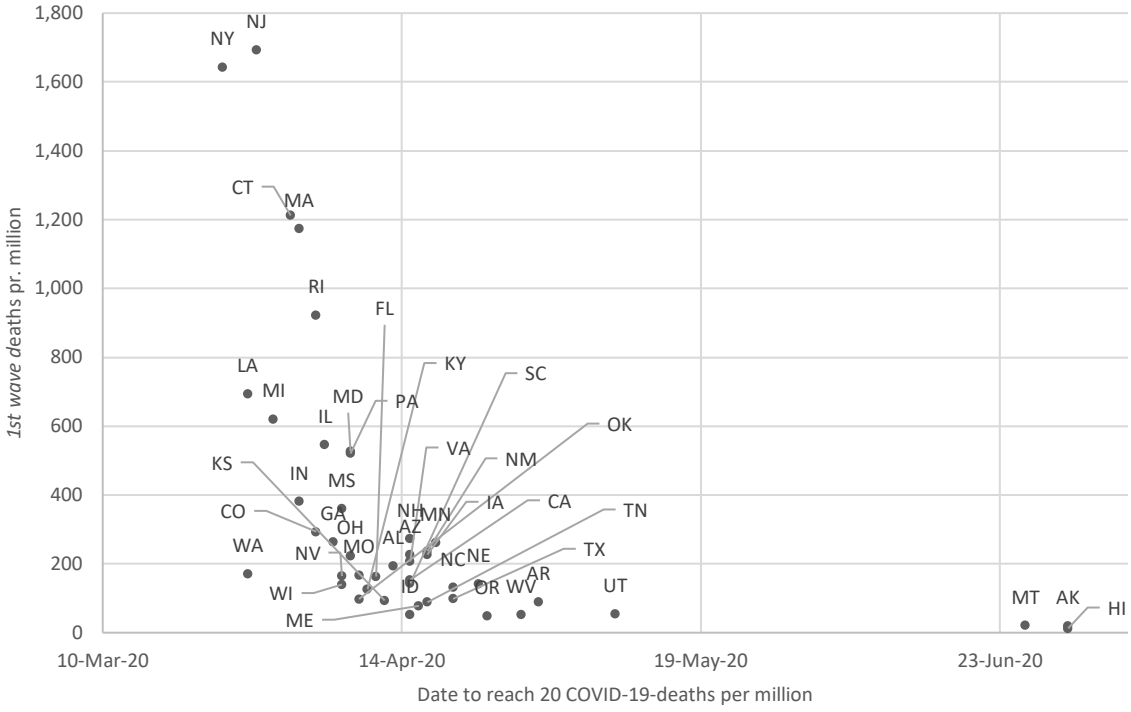
Including these studies will greatly overestimate the effect of lockdowns, and, hence, we chose not to include studies focusing on timing of lockdowns in our review.

Figure 8: Taken by surprise. The importance of having time to prepare in Europe



Description: European countries with more than one million citizens.
Source: Our World in Data

Figure 9: Taken by surprise. The importance of having time to prepare in U.S. states



Description: U.S. states with more than one million citizens.
Source: Our World in Data

7 Appendix B. Supplementary information

7.1 Excluded studies

Below is a list will the studies excluded during the eligibility phase of our identification process and a short description of our basis for excluding the study.

Table 8: Studies excluded during the eligibility phase of our identification process

1. Study (Author & title)	2. Reason for exclusion
Alemán et al. (2020); "Evaluating the effectiveness of policies against a pandemic"	Too few observations
Alshammari et al. (2021); "Are countries' precautionary actions against COVID-19 effective? An assessment study of 175 countries worldwide"	Is purely descriptive
Amuedo-Dorantes et al. (2020); "Timing is Everything when Fighting a Pandemic: COVID-19 Mortality in Spain"	Duplicate
Amuedo-Dorantes et al. (2021); "Early adoption of non-pharmaceutical interventions and COVID-19 mortality"	Only looks at timing
Amuedo-Dorantes, Kaushal and Muchow (2020); "Is the Cure Worse than the Disease? County-Level Evidence from the COVID-19 Pandemic in the United States"	Duplicate
Amuedo-Dorantes, Kaushal and Muchow (2021); "Timing of social distancing policies and COVID-19 mortality: county-level evidence from the U.S."	Only looks at timing
Arruda et al. (2021); "ASSESSING THE IMPACT OF SOCIAL DISTANCING ON COVID-19 CASES AND DEATHS IN BRAZIL: AN INSTRUMENTED DIFFERENCE-IN-	Social distancing (not
Bakolis et al. (2021); "Changes in daily mental health service use and mortality at the commencement and lifting of COVID-19 'lockdown' policy in 10 UK sites: a regression	Uses a time series approach
Bardey, Fernández and Gravel (2021); "Coronavirus and social distancing: do non-pharmaceutical-interventions work (at least) in the short run?"	Only looks at timing
Berardi et. Al. (2020); "The COVID-19 pandemic in Italy: policy and technology impact on health and non-health outcomes"	Too few observations
Bhalla (2020); "Lockdowns and Closures vs COVID–19: COVID Wins"	Uses modelling
Björk et al. (2021); "Impact of winter holiday and government responses on mortality in Europe during the first wave of the COVID-19 pandemic"	Only looks at timing
Bongaerts, Mazzola and Wagner (2020); "Closed for business"	Duplicate
Born, Dietrich and Müller (2021); "The lockdown effect: A counterfactual for Sweden"	Synthetic control study
Born, Dietrich and Müller (2021); "The lockdown effect: A counterfactual for Sweden"	Duplicate
Bushman et al. (2020); "Effectiveness and compliance to social distancing during COVID-19"	Social distancing (not
Castaneda and Saygili (2020); "The effect of shelter-in-place orders on social distancing and the spread of the COVID-19 pandemic: a study of Texas"	Uses a time series approach
Cerqueti et al. (2021); "The sooner the better: lives saved by the lockdown during the COVID-19 outbreak. The case of Italy"	Synthetic control study
Chernozhukov, Kasahara and Schrimpf (2021); "Mask mandates and other lockdown policies reduced the spread of COVID-19 in the U.S."	Duplicate
Chin et al. (2020); "Effects of non-pharmaceutical interventions on COVID-19: A Tale of Three Models"	Uses modelling
Cho (2020); "Quantifying the impact of nonpharmaceutical interventions during the COVID-19 outbreak: The case of Sweden"	Synthetic control study
Coccia (2020); "The effect of lockdown on public health and economic system: findings from first wave of the COVID-19 pandemic for designing effective strategies to cope	Only looks at timing
Coccia (2021); "Different effects of lockdown on public health and economy of countries: Results from first wave of the COVID-19 pandemic"	Too few observations
Conyon and Thomsen (2021); "COVID-19 in Scandinavia"	Synthetic control study
Conyon et al. (2020); "Lockdowns and COVID-19 deaths in Scandinavia"	Too few observations
Dave et al. (2020); "Did the Wisconsin Supreme Court restart a COVID-19 epidemic? Evidence from a natural experiment"	Synthetic control study
Delis, Iosifidi and Tasiou (2021); "Efficiency of government policy during the COVID-19 pandemic"	Do not look at mortality
Dreher et al. (2021); "Policy interventions, social distancing, and SARS-CoV-2 transmission in the United States: a retrospective state-level analysis"	Do not look at mortality
Duchemin, Veber and Boussau (2020); "Bayesian investigation of SARS-CoV-2-related mortality in France"	Uses modelling
Fair et. Al. (2021); "Estimating COVID-19 cases and deaths prevented by non-pharmaceutical interventions in 2020-2021, and the impact of individual actions: a retrospective	Uses modelling
Filias (2020); "The impact of government policies effectiveness on the officially reported deaths attributed to covid-19."	Student paper
Fowler et al. (2021); "Stay-at-home orders associate with subsequent decreases in COVID-19 cases and fatalities in the United States"	Duplicate
Friedson et al. (2020); "Did California's shelter-in-place order work? Early coronavirus-related public health effects"	Duplicate
Friedson et al. (2020); "Shelter-in-place orders and public health: evidence from California during the COVID-19 pandemic"	Synthetic control study
Fuss, Weizman and Tan (2020); "COVID19 pandemic: how effective are interventive control measures and is a complete lockdown justified? A comparison of countries and	Do not look at mortality
Ghosh, Ghosh and Narymanchi (2020); "A Study on The Effectiveness of Lock-down Measures to Control The Spread of COVID-19"	Synthetic control study
Glogowsky et al. (2021); "How Effective Are Social Distancing Policies? Evidence on the Fight Against COVID-19"	Only looks at timing
Glogowsky, Hansen and Schächtele (2020); "How effective are social distancing policies? Evidence on the fight against COVID-19 from Germany"	Duplicate
Glogowsky, Hansen and Schächtele (2020); "How Effective Are Social Distancing Policies? Evidence on the Fight Against COVID-19 from Germany"	Duplicate
Gordon, Grafton and Steinshamn (2021); "Cross-country effects and policy responses to COVID-19 in 2020: The Nordic countries"	Do not look at mortality
Gordon, Grafton and Steinshamn (2021); "Statistical Analyses of the Public Health and Economic Performance of Nordic Countries in Response to the COVID-19 Pandemic"	Too few observations
Guo et al. (2020); "Social distancing interventions in the United States: An exploratory investigation of determinants and impacts"	Duplicate
Huber and Langen (2020); "The impact of response measures on COVID-19-related hospitalization and death rates in Germany and Switzerland"	Duplicate
Huber and Langen (2020); "Timing matters: the impact of response measures on COVID-19-related hospitalization and death rates in Germany and Switzerland"	Only looks at timing
Jain et al. (2020); "A comparative analysis of COVID-19 mortality rate across the globe: An extensive analysis of the associated factors"	Do not look at mortality
Juranek and Zoutman (2021); "The effect of non-pharmaceutical interventions on the demand for health care and mortality: evidence on COVID-19 in Scandinavia"	Too few observations
Kakpo and Nuhu (2020); "Effects of Social Distancing on COVID-19 Infections and Mortality in the U.S."	Social distancing (not
Kapoor and Ravi (2020); "Impact of national lockdown on COVID-19 deaths in select European countries and the U.S. using a Changes-in-Changes model"	Too few observations
Khatiwada and Chalise (2020); "Evaluating the efficiency of the Swedish government policies to control the spread of Covid-19."	Student paper
Korevaar et al. (2020); "Quantifying the impact of U.S. state non-pharmaceutical interventions on COVID-19 transmission"	Do not look at mortality
Kumar et. Al. (2020); "Prevention-Versus Promotion-Focus Regulatory Efforts on the Disease Incidence and Mortality of COVID-19: A Multinational Diffusion Study Using	Do not look at mortality
Le et al. (2020); "Impact of government-imposed social distancing measures on COVID-19 morbidity and mortality around the world"	Uses a time series approach
Liang et al. (2020); "Covid-19 mortality is negatively associated with test number and government effectiveness"	Not effect of lockdowns
Mader and Rütternauer (2021); "The effects of non-pharmaceutical interventions on COVID-19-related mortality: A generalized synthetic control approach across 169 countries"	Synthetic control study
Matzinger and Skinner (2020); "Strong impact of closing schools, closing bars and wearing masks during the Covid-19 pandemic: results from a simple and revealing analysis"	Uses modelling
Mccafferty and Ashley (2020); "Covid-19 Social Distancing Interventions by State Mandate and their Correlation to Mortality in the United States"	Duplicate
Medline et al. (2020); "Evaluating the impact of stay-at-home orders on the time to reach the peak burden of Covid-19 cases and deaths: does timing matter?"	Only looks at timing

1. Study (Author & title)	2. Reason for exclusion
Mu et al. (2020); "Effect of social distancing interventions on the spread of COVID-19 in the state of Vermont"	Uses modelling
Nakamura (2020); "The Impact of Rapid State Policy Response on Cumulative Deaths Caused by COVID-19"	Student paper
Neidhöfer and Neidhöfer (2020); "The effectiveness of school closures and other pre-lockdown COVID-19 mitigation strategies in Argentina, Italy, and South Korea"	Synthetic control study
Oliveira (2020); "Does' Staying at Home'Save Lives? An Estimation of the Impacts of Social Isolation in the Registered Cases and Deaths by COVID-19 in Brazil"	Social distancing (not
Palladina et al. (2020); "Effect of Implementation of the Lockdown on the Number of COVID-19 Deaths in Four European Countries"	Uses a time series approach
Palladina et al. (2020); "Effect of timing of implementation of the lockdown on the number of deaths for COVID-19 in four European countries"	Duplicate
Palladino et al. (2020); "Excess deaths and hospital admissions for COVID-19 due to a late implementation of the lockdown in Italy"	Uses a time series approach
Peixoto et al. (2020); "Rapid assessment of the impact of lockdown on the COVID-19 epidemic in Portugal"	Uses modelling
Piovani et. Al. (2021); "Effect of early application of social distancing interventions on COVID-19 mortality over the first pandemic wave: An analysis of longitudinal data from 37	Only looks at timing
Reinbold (2021); "Effect of fall 2020 K-12 instruction types on CoViD-19 cases, hospital admissions, and deaths in Illinois counties"	Synthetic control study
Renne, Roussellet and Schwenkler (2020); "Preventing COVID-19 Fatalities: State versus Federal Policies"	Uses modelling
Siedner et al. (2020); "Social distancing to slow the U.S. COVID-19 epidemic: Longitudinal pretest–posttest comparison group study"	Duplicate
Siedner et al. (2020); "Social distancing to slow the U.S. COVID-19 epidemic: Longitudinal pretest–posttest comparison group study"	Uses a time series approach
Silva, Filho and Fernandes (2020); "The effect of lockdown on the COVID-19 epidemic in Brazil: evidence from an interrupted time series design"	Uses a time series approach
Stamam et al. (2020); "IMPACT OF LOCKDOWN MEASURE ON COVID-19 INCIDENCE AND MORTALITY IN THE TOP 31 COUNTRIES OF THE WORLD."	Uses a time series approach
Steinegger et al. (2021); "Retrospective study of the first wave of COVID-19 in Spain: analysis of counterfactual scenarios"	Only looks at timing
Stephens et al. (2020); "Does the timing of government COVID-19 policy interventions matter? Policy analysis of an original database."	Only looks at timing
Supino et al. (2020); "The effects of containment measures in the Italian outbreak of COVID-19"	Uses a time series approach
Timelli and Girardi (2021); "Effect of timing of implementation of containment measures on Covid-19 epidemic. The case of the first wave in Italy"	Only looks at timing
Trivedi and Das (2020); "Effect of the timing of stay-at-home orders on COVID-19 infections in the United States of America"	Only looks at timing
Umer and Khan (2020); "Evaluating the Effectiveness of Regional Lockdown Policies in the Containment of Covid-19: Evidence from Pakistan"	Too few observations
VoPham et al. (2020); "Effect of social distancing on COVID-19 incidence and mortality in the U.S."	Do not look at mortality
Wu and Wu (2020); "Stay-at-home and face mask policies intentions inconsistent with incidence and fatality during U.S. COVID-19 pandemic"	Too few observations
Xu et al. (2020); "Associations of Stay-at-Home Order and Face-Masking Recommendation with Trends in Daily New Cases and Deaths of Laboratory-Confirmed COVID-19 in	Do not look at mortality
Yehya, Venkataramani and Harhay (2020); "Statewide Interventions and Coronavirus Disease 2019 Mortality in the United States: An Observational Study"	Only looks at timing
Ylli et al. (2020); "The lower COVID-19 related mortality and incidence rates in Eastern European countries are associated with delayed start of community circulation Alban	Not effect of lockdowns

7.2 Interpretation of estimates and conversion to common estimates

In Table 9, we describe for each study used in the meta-analysis how we interpret their results and convert the estimates to our common estimate. Standard errors are converted such that the t-value, calculated based on common estimates and standard errors, is unchanged. When confidence intervals are reported rather than standard errors, we calculate standard errors using t-distribution with ∞ degrees of freedom (i.e. 1.96 for 95% confidence interval).

Table 9: Notes on studies included in the meta-analysis

1. Study (Author & title)	2. Date Published	3. Journal	4. Comments regarding meta-analysis
Alderman and Harjoto (2020); "COVID-19: U.S. shelter-in-place orders and demographic characteristics linked to cases, mortality, and recovery rates"	26-Nov-20	Transforming Government: People, Process and Policy	We use the 1% effect noted by the authors in "We find that the natural log of the duration (in days) that the state instituted shelter-in-place reduces percentages of mortality by 0.0001%, or approximately 1% of the means of percentages of deaths per capita in our sample. The standard error is calculated on basis of the t-value in Table 3.
Aparicio and Grossbard (2021); "Are Covid Fatalities in the U.S. Higher than in the EU, and If so, Why?"	16-Jan-21	Review of Economics of the Household	We use estimates from Table 3, model 5. For each estimate the common estimate is calculated as (difference in COVID-19 mortality with NPI)/(difference in COVID-19 mortality without NPI)-1, where (difference in COVID-19 mortality with NPI) is 237.89 (Table 2 states that deaths per million is 406.99 in U.S. and 169.10 in Europe) and (difference in COVID-19 mortality without NPI) is estimated as exp(ln(difference in COVID-19 mortality with NPI)-estimate).
Ashraf (2020); "Socioeconomic conditions, government interventions and health outcomes during COVID-19"	1-Jul-20	ResearchGate	It is unclear whether they prefer the model with or without the interaction term. In the meta-analysis, we use an average of -0.326 (Table 3, without) and -0.073 (Table 6, with) deaths per million per stringency point (i.e. -0.200). The common estimate is the average effect in Europe and United States respectively calculated as (Actual COVID-19 mortality) / (COVID-19 mortality with recommendation policy) -1, where (COVID-19 mortality with recommendation policy) is calculated as ((Actual COVID-19 mortality) - Estimate x Difference in stringency x population). Stringencies in Europe and United States are equal to the average stringency from March 16th to April 15th 2020 (76 and 74 respectively) and the stringency for the policy based solely on recommendations is 44 following Hale et al. (2020).

1. Study (Author & title)	2. Date Published	3. Journal	4. Comments regarding meta-analysis
Auger et al. (2020); "Association between statewide school closure and COVID-19 incidence and mortality in the U.S."	1-Sep-20	JAMA	Estimate that school closure was associated with a 58% decline in COVID-19 mortality and that the effect was largest in states with low cumulative incidence of COVID-19 at the time of school closure. States with the lowest incidence of COVID-19 had a −72% relative change in incidence compared with −49% for those states with the highest cumulative incidence.
Berry et al. (2021); "Evaluating the effects of shelter-in-place policies during the COVID-19 pandemic"	24-Feb-21	PNAS	The estimated effect of SIPO's, an increase in deaths by 0,654 per million after 14 days (significant, cf. Fig. 2), is converted to a relative effect on a state basis based on data from OurWorldInData. For states which did implement SIPO, we calculate the number of deaths without SIPO as the number of official COVID-19 deaths 14 days after SIPO was implemented minus 0,654 extra deaths per million. For states which did not implement SIPO, we calculate the number of deaths with SIPO as the number of official COVID-19 deaths 14 days after March 31 2020 plus 0,654 extra deaths per million. We use March 31 2020 as this was the average date on which SIPO was implemented in the 40 states which did implement SIPO. Using this approximation, the effect of SIPO's in the U.S. is 1,1% more deaths after 14 days. Common standard errors are not available.
Bjørnskov (2021a); "Did Lockdown Work? An Economist's Cross-Country Comparison"	29-Mar-21	CESifo Economic Studies	We use estimates from Table 2 (four weeks). Common estimate is calculated as the average of the effect in Europe and United States, where the effect for each is calculated as (ln(policy stringency) - ln(recommendation stringency)) x estimate.
Blanco et al. (2020); "Do Coronavirus Containment Measures Work? Worldwide Evidence"	1-Dec-20	World Bank Group	The study is not included in the meta-analysis, as it looks at the effect of NPIs on growth rates and does not include an estimate of the effect on total mortality.
Bonardi et al. (2020); "Fast and local: How did lockdown policies affect the spread and severity of the covid-19"	8-Jun-20	0	Find that, world-wide, internal NPIs have prevented about 650,000 deaths (3.11 deaths were prevented for each death that occurred, i.e. 76% effect). However, this effect is for any lockdown including a Swedish lockdown. They do not find an extra effect of stricter lockdowns and state that "our results point to the fact that people might adjust their behaviors quite significantly as partial measures are implemented, which might be enough to stop the spread of the virus." Hence, whether the baseline is Sweden, which implemented a ban on large gatherings early in the pandemic, or the baseline is "doing nothing" can affect the magnitude of the estimated impacts. Since all Western countries did something and estimates in other reviewed studies are relative to doing less – and, hence not to doing nothing, we report the result from Bonardi et al. as compared to "doing less." Hence, for Bonardi et al. we use 0% as the common estimate in the meta-analysis for each NPI (SIPO, regional lockdown, partial lockdown, and border closure (stage 1, stage 2 and full) because all NPIs are insignificant (compared to Sweden's "doing the least"-lockdown).
Bongaerts et al. (2021); "Closed for business: The mortality impact of business closures during the Covid-19 pandemic"	14-May-21	PLOS ONE	Business shutdown saved 9,439 Italian lives by 13th 2020. This corresponds to 32%, as there were 20,465 COVID-19-deaths in Italy by mid April 2020.
Chaudhry et al. (2020); "A country level analysis measuring the impact of government actions, country preparedness and socioeconomic factors on COVID-19 mortality and related health outcomes"	1-Aug-20	EClinacal-Medicine	Finds no effect of partial border closure, complete border closure, partial lockdown (physical distancing measures only), complete lockdown (enhanced containment measures including suspension of all non-essential services), and curfews. In the meta-analysis we use a common estimate of 0%, as estimates and standard errors are not available.
Chernozhukov et al. (2021); "Causal impact of masks, policies, behavior on early covid-19 pandemic in the U.S."	1-Jan-21	Journal of Econometrics	The study looks at the effect of NPIs on growth rates but does include an estimate of the effect on total mortality at the end of the study period for employee face masks (-34%), business closure (-29%). and SIPO (-18%), but not for school closures (which we therefore exclude). In reporting the results of their counterfactual, they alter between "fewer deaths with NPI" and "more deaths without NPI." We have converted the latter to the former as estimate/(1+estimate) so "without business closures deaths would be about 40% higher" corresponds to "with business closures deaths would be about 29% lower."
Chisadza et al. (2021); "Government Effectiveness and the COVID-19 Pandemic"	10-Mar-21	MDPI	The common estimate is the average effect in Europe and United States respectively calculated as (Actual COVID-19 mortality) / (COVID-19 mortality with recommendation policy) -1, where (COVID-19 mortality with recommendation policy) is calculated as ((Actual COVID-19 mortality) - Estimate x Difference in stringency x population). Stringencies in Europe and United States are equal to the average stringency from March 16th to April 15th 2020 (76 and 74 respectively) and the stringency for the policy based solely on recommendations is 44 following Hale et al. (2020). In the meta-analysis we use the non-linear estimate, but the squared estimate yields similar results.
Dave et al. (2021); "When Do Shelter-in-Place Orders	3-Aug-20	Economic Inpuiry	The study looks at the effect of SIPO's on growth rates but does include an estimate of the effect on total mortality after 20+ days for model 1 and 2 in Table 7. Since model 3, 4 and 5 have estimates

1. Study (Author & title)	2. Date Published	3. Journal	4. Comments regarding meta-analysis
Fight Covid-19 Best? Policy Heterogeneity Across States and Adoption Time"			similar to model 2, we use an average of model 1 to 5, where the estimates of model 3 to 5 are calculated as (common estimate model 2) / (estimate model 2) x estimate model 3/4/5.
Dergiades et al. (2020); "Effectiveness of government policies in response to the COVID-19 outbreak"	28-Aug-20	SSRN	The study is not included in the meta-analysis, as it looks at the effect of NPIs on growth rates and does not include an estimate of the effect on total mortality.
Fakir and Bharati (2021); "Pandemic catch-22: The role of mobility restrictions and institutional inequalities in halting the spread of COVID-19"	28-Jun-21	PLOS ONE	The study is not included in the meta-analysis, as it looks at the effect of NPIs on growth rates and does not include an estimate of the effect on total mortality.
Fowler et al. (2021); "Stay-at-home orders associate with subsequent decreases in COVID-19 cases and fatalities in the United States"	10-Jun-21	PLOS ONE	The study looks at the effect of SIPO's on growth rates but does include an estimate of the effect on total mortality after three weeks (35% reduction in deaths) which is used in the meta-analysis.
Fuller et al. (2021); "Mitigation Policies and COVID-19–Associated Mortality — 37 European Countries, January 23–June 30, 2020"	15-Jan-21	Morbidity and Mortality Weekly Report	For each 1-unit increase in OxCGRT stringency index, the cumulative mortality decreases by 0.55 deaths per 100,000. The common estimate is the average effect in Europe and United States respectively calculated as (Actual COVID-19 mortality) / (COVID-19 mortality with recommendation policy) -1, where (COVID-19 mortality with recommendation policy) is calculated as ((Actual COVID-19 mortality) - Estimate x Difference in stringency x population). Stringencies in Europe and United States are equal to the average stringency from March 16th to April 15th 2020 (76 and 74 respectively) and the stringency for the policy based solely on recommendations is 44 following Hale et al. (2020).
Gibson (2020); "Government mandated lockdowns do not reduce Covid-19 deaths: implications for evaluating the stringent New Zealand response"	18-Aug-20	New Zealand Economic Papers	We use the two graphs to the left in figure 3, where we extract the data from the rightmost datapoint (I.e. % impact of county lockdowns on Covid-19 deaths by 1/06/2020). We then take the average of the estimates found in the two graphs, because it is unclear which estimate the author prefers.
Goldstein et al. (2021); "Lockdown Fatigue: The Diminishing Effects of Quarantines on the Spread of COVID-19 "	4-Feb-21	CID Faculty Working	We convert the effect in Figure 4 after 90 days (log difference -1.16 of a standard deviation change) to deaths per million per stringency following footnote 3 (the footnote says "weekly deaths," but we believe this should be "daily deaths"), so the effect is e^-1.16 − 1 = −0.69 decline in daily deaths per million per SD. We convert to total effect by multiplying with 90 days and "per point" by dividing with SD = 22.3 (corresponding to the SD for the 147 countries with data before March 19, 2020 - using all data yields similar results) yielding -2.77 deaths per million per stringency point. The common estimate is the average effect in Europe and United States respectively calculated as (Actual COVID-19 mortality) / (COVID-19 mortality with recommendation policy) -1, where (COVID-19 mortality with recommendation policy) is calculated as ((Actual COVID-19 mortality) - Estimate x Difference in stringency x population). Stringencies in Europe and United States are equal to the average stringency from March 16th to April 15th 2020 (76 and 74 respectively) and the stringency for the policy based solely on recommendations is 44 following Hale et al. (2020).
Guo et al. (2021); "Mitigation Interventions in the United States: An Exploratory Investigation of Determinants and Impacts"	21-Sep-20	Research on Social Work Practice	We use estimates for "Proportion of Cumulative Deaths Over the Population" (per 10,000) in Table 3. We interpret this number as the change in cumulative deaths over the population in percent and is therefore the same as our common estimate.
Hale et al. (2020); "Global assessment of the relationship between government response measures and COVID-19 deaths"	6-Jul-20	medRxiv	The study is not included in the meta-analysis, as it looks at the effect of NPIs on growth rates and does not include an estimate of the effect on total mortality. They ascertain that "sustained over three months, this would correspond to a cumulative number of deaths 30% lower," however this is not a counterfactual estimate and three months goes beyond the period they have data for.
Hunter et al. (2021); "Impact of non-pharmaceutical interventions against COVID-19 in Europe: A quasi-experimental non-equivalent group and time-series"	15-Jul-21	Eurosurveillance	The study is not included in the meta-analysis, as they report the effect of NPIs in incident risk ratio which are not easily converted to relative effects.

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Langeland et al. (2021); "The Effect of State Level COVID-19 Stay-at-Home Orders on Death Rates"	5-Mar-21	Culture & Crisis Conference	The study is not included in the meta-analysis, as it looks at the effect of NPIs on odds-ratios and does not include an estimate of the effect on total mortality.
Leffler et al. (2020); "Association of country-wide coronavirus mortality with demographics, testing, lockdowns, and public wearing of masks"	26-Oct-20	ASTMH	Their "mask recommendation" includes some countries, where masks were mandated and may (partially) capture the effect of mask mandates. However, the authors' focus is on recommendation, so we do interpret their result as a voluntary effect - not an effect of mask mandate. Using estimates from Table 2 and assuming NPIs were implemented March 15 (8 weeks in total by end of study period), common estimates are calculated as 8^est-1.
Mccafferty and Ashley (2021); "Covid-19 Social Distancing Interventions by Statutory Mandate and Their Observational Correlation to Mortality in the United States and Europe"	27-Apr-21	Pragmatic and Observational Research	The study is not included in the meta-analysis, as it looks at the effect of NPIs on peak mortality and does not include an estimate of the effect on total mortality.
Pan et al. (2020); "Covid-19: Effectiveness of non-pharmaceutical interventions in the united states before phased removal of social distancing protections varies by region"	20-Aug-20	medRxiv	The study is not included in the meta-analysis, as the cluster the NPIs (e.g. SIPO, mask mandata amd travel restricions are clustered in Level 4).
Pincombe et al. (2021); "The effectiveness of national-level containment and closure policies across income levels during the COVID-19 pandemic: an analysis of 113 countries"	4-May-21	Health Policy and Planning	Policy implementations were assigned according to the first day that a country received a policy stringency rating above 0 in the OxCGRT stay-at-home measure. As the value 1 is a recommendation "recommend not leaving house," we cannot distinguish recommendations from mandates, and, thus, the study is not included in the meta-analysis.
Sears et al. (2020); "Are we #stayinghome to Flatten the Curve?"	6-Aug-20	medRxiv	Find that SIPOs lower mortality by 29-35%. We use the average (32%) as our common estimate. Common standard errors are calculated based on estimates and standard errors from (Table 4) assuming they are linearly related to estimates.
Shiva and Molana (2021); "The Luxury of Lockdown"	9-Apr-21	The European Journal of Develepment Research	The estimate with 8 weeks lag is insignificant, and preferable given our empirical strategy. However, they use the 4-week lag when elaborating the model to differentiate between high- and low-income countries, so the 4-week lag estimate for rich countries is used in our meta-analysis. Common estimate is calculated as the average of the effect in Europe and United States, where the effect for each is calculated as (policy stringency - recommendation stringency) x estimate.
Spiegel and Tookes (2021); "Business restrictions and Covid-19 fatalities"	18-Jun-21	The Review of Financial Studies	We use weighted average of estimates for Table 4, 6, and 9. Since authors state that they place more weight on the findings in Table 9, Table 9 weights by 50% while Table 4 and 6 weights by 25%. We estimate the effect on total mortality from effect on growth rates based on authors calculation showing that estimates of -0.049 and -0.060 reduces new deaths by 12.5% 15.3% respectively. We use the same relative factor on other estimates.
Stockenhuber (2020); "Did We Respond Quickly Enough? How Policy-Implementation Speed in Response to COVID-19 Affects the Number of Fatal Cases in Europe"	10-Nov-20	World Medical & Health Policy	When calculating arithmetic average / median, the study is included as 0%, because estimates in Table 6 are insignificant and signs of estimates are mixed (higher strictness can cause both fewer and more deaths). We don't calculate common standard errors.
Stokes et al. (2020); "The relative effects of non-pharmaceutical interventions on early Covid-19 mortality: natural experiment in 130 countries"	6-Oct-20	medRxiv	We use estimates from regression on strictness alone (Right panel in Table "Regression results, policy strictness. Baseline is "policy not introduced within policy analysis period" in "Additional file"). We use the average of 24 and 38 days from model 5. There are 23 relevant estimates in total (they analyze all levels within the eight NPI measures in the OxCGRT stringency index). We calculate the effect of each NPI (e.g. closing schools) as the average effect in all of U.S./Europe. This is done by calculating the effect for each state/country based on the maximum level for each measure between Mar 16 and Apr 15 (e.g. if all schools in a state/country are required to close (school closing level 3) the relevant estimate for that state/level is -0.031 (average of -0.464 and 0.402). We assume all NPIs are effective for 54 days (from March 15 to June 1 minus 24 days to reach full effect). Standard errors are converted to common standard errors following the same process (this approach is unique for Stokes, as our general approach is not possible).

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Toya and Skidmore (2020); "A Cross-Country Analysis of the Determinants of Covid-19 Fatalities"	1-Apr-20	CESifo Working Papers	It is unclear how they define "lockdown." They write that "many countries [...] imposed lockdowns of varying degrees, some imposing mandatory nationwide lockdowns, restricting economic and social activity deemed to be non-essential," and since all European countries and all states in the U.S. imposed restrictions on economic (closing unessential businesses) and/or social (limiting large gatherings) activity, we interpret this as all European countries and all U.S. states had mandatory nationwide lockdowns. The effect of recommended lockdowns is set to zero in the meta-analysis, as only one country was in this lockdown category (i.e. too few observations, cf. eligibility criteria). The estimate for complete travel closure is -0.226 COVID-deaths per 100,000. Hence, if all of Europe imposed complete travel closure, the total effect would be -0.266 * 748 million (population) * 10 (100,000/1,000,000) equal to 1,690 averted COVID-19 deaths. However, according to OxCGRT-data European countries only had complete travel bans (Level 4: "Ban on all regions or total border closure") in 11% of the time between March 16 and April 15, 2020. So the total effect is 1,690 * 11% = 194 averted deaths. During the first wave 188,000 deaths in Europe was related to COVID-19 (by June 30, 2020), so the total effect is approximated to -0.1% in Europe and, following the same logic, 0% in U.S., where no states closed their borders completely. We use the average, -0.05%, in the meta-analysis. The estimate for mandatory national lockdown is 0.166 (>0) COVID-deaths per 100,000. Since all European countries (and U.S. states) imposed lockdowns, the total effect is 1,241 (553) extra COVID-19 deaths corresponding to 0.7% (0.4%). We use the average of Europe and the U.S., 0.5%, in the meta-analysis. Calculations of the effect of "Mandatory national lockdown" follow the same logic, but we assume 100% of Europe and United States have had "Mandatory national lockdown."
Tsai et al. (2021); "Coronavirus Disease 2019 (COVID-19) Transmission in the United States Before Versus After Relaxation of Statewide Social Distancing Measures"	3-Oct-20	Oxford academic	The study is not included in the meta-analysis, as they report the effect of NPIs on Rt which are not easily converted to relative effects.

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covid_bill.pdf
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Democrats insisted that all forms of voter ID were racist. They called voter verification "Jim Crow of the 21st century" and "Jim Crow 2.0." What are Democrats saying about Covid Passports? Isn't this another example of government overreach?

Covid Passports are an infringement on citizens rights and should be voted down.

With two years of data collection, we are learning from Johns Hopkins University that lock-downs didn't work:

> https://sites.krieger.jhu.edu/iae/files/2022/01/A-Literature-Review-and-Meta-Analysis-of-the-Effects-of-Lockdowns-on-COVID-19-Mortality.pdf
>
> "After three levels of screening, 34 studies ultimately qualified. Of those 34 eligible studies, 24 qualified for inclusion in the meta-analysis. They were separated into three groups: lock-down stringency index studies, shelter-in-place-order (SIPO) studies, and specific NPI studies. An analysis of each of these three groups support the conclusion that lock-downs have had little to no effect on COVID-19 mortality."

And, earlier studies warn of the deoxygenation of N95 masks for long periods of usage:

> https://scielo.isciii.es/pdf/neuro/v19n2/3.pdf

masks.pdf
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Neurocirugía
2008 19: 121-126

Preliminary report on surgical mask induced deoxygenation during major surgery*

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Summary

***Objectives*. This study was undertaken to evaluate whether the surgeons' oxygen saturation of hemoglobin was affected by the surgical mask or not during major operations.**

***Methods*. Repeated measures, longitudinal and prospective observational study was performed on 53 surgeons using a pulse oximeter pre and postoperatively.**

***Results*. Our study revealed a decrease in the oxygen saturation of arterial pulsations (SpO_2) and a slight increase in pulse rates compared to preoperative values in all surgeon groups. The decrease was more prominent in the surgeons aged over 35.**

***Conclusions*. Considering our findings, pulse rates of the surgeon's increase and SpO_2 decrease after the first hour. This early change in SpO_2 may be either due to the facial mask or the operational stress. Since a very small decrease in saturation at this level, reflects a large decrease in PaO^2, our findings may have a clinical value for the health workers and the surgeons.**

KEY WORDS: Surgery. Surgical Mask. Oxygenation. Operation. Oxygen saturation. Facemask.

Comunicación preliminar sobre desoxigenación inducida por la mascarilla quirúrgica durante la cirugía de larga duración

Resumen

***Objetivos*. Este estudio se realizó para determinar si la saturación de oxígeno del cirujano se afectaba por el uso de la mascarilla, durante intervenciones de larga duración.**

Métodos. Se hizo un estudio longitudinal y prospectivo en 53 cirujanos con medidas de la hemoglogina realizadas con un oxímetro para medir la saturación del pulso arterial. Se hicieron estudios antes y después de la operación.

***Resultados*. Nuestro estudio puso de manifiesto una disminución de la saturación de oxígeno de las pulsaciones arteriales (SpO_2) y un ligero aumento de las pulsaciones en comparación con el estado preoperatorio en todos los grupos de cirujanos. La disminución era mayor en el grupo de edad superior a los 35 años.**

***Conclusiones*. Según nuestros hallazgos, el ritmo del pulso aumenta y la concentración de SpO_2 disminuye después de la primera hora de la operación. Este cambio temprano de SpO_2 puede deberse a la mascarilla o al estrés de la intervención. Puesto que un ligero descenso en la saturación a este nivel refleja una mayor disminución de la PaO_2, nuestros datos pueden tener un valor clínico para la salud del personal sanitario y para los cirujanos.**

PALABRAS CLAVE: Cirugía. Oxigenación. Operación. Saturación de oxígeno. Mascarilla.

Introduction

Soon after the introduction of surgical masks by Mikulicz[5] in 1897, their usage in the operating theatre became a standard practice. Although there appears to be a shift from a patient-protective standpoint to a healthcare worker-protective standpoint in recent years, it is generally accepted that operating theatre staff has to wear surgical masks and change it partway through long procedures (4 hr or more)[6].

Surgeons in the operating room frequently experience physical discomfort, fatigue, and possibly even deterioration of surgical judgment and performance. Although considerable information exists about the effects of ambient environment on both mental and physical performance, the final "personal" environment for the surgeon beneath the surgical mask is often very inadequately conditioned

Recibido: 13-03-07. Aceptado: 6-06-07

*The work was done in the surgical theaters of Kirikkale University, Faculty of Medicine and Fatih University, Faculty of Medicine

despite the universal air-conditioning standard of operating theaters. Thus they either wear masks improperly or refrain from using them altogether. As it is known that heat and moisture trapping occur beneath surgical masks, it seems reasonable that some of the exhaled CO_2 may also be trapped beneath them, inducing a decrease in blood oxygenation.

"Normal blood O_2 saturation" is usually defined as a fractional saturation of 90 to 97.5%, which corresponds to an arterial oxygen partial pressure of 13.3 to 13.7 kPa, if there are no other hemoglobin species, apart from oxy- and reduced hemoglobin. A pulse oximeter can detect the oxygen saturation of hemoglobin quickly, in an accurate, and reliable way. Pulse oximeters combine oximetry and plethysmography to measure arterial oxygen saturation, noninvasively. According to Lambert Beer Law, oxygenated and reduced hemoglobin absorb red and infrared light differently. Oxyhemoglobin absorbs more infrared light, while reduced hemoglobin absorbs more red light. The ratio of absorptions at the red and infrared wavelengths is analyzed by oximetry to give the oxygen saturation of arterial pulsations[4].

The primary focus of this study was to measure the surgeons' oxygenation status while they were engaged in their daily routine activities of major operations.

Materials and methods

53 surgeons from both sexes, employed at university hospitals, 24 to 54 years old, non-smokers and without any chronic lung disease were studied by pulse oximetry before and after the course of an operation. They were hemodynamically stable, breathing room air and standing throughout the operations.

The groups were formed according to the duration of the operations:

I. Duration of the operations was up to 60 minutes,

Ia: group wearing mask (n=5)

Ib: group of surgeons who did not wear mask during primary care operations with duration of less than 30 minutes (n=9)

II. Duration of the operations was in between 60-120 minutes (n=25).

III. Duration of the operations was in between 120-180 minutes (n=23).

IV. Duration of the operations was in between 180-240 minutes (n=20).

In order to estimate whether age has any effect on oxygen saturation of hemoglobin and pulse rate, surgeons were also divided into two age groups according to the median age: Surgeons under the age of 35 (**n=25**) and surgeons over the age of 35 (**n=28**). The surgeon age could not be used as a covariate in regression analysis due to sparsity of the data.

Disposable sterile one-way surgical paper masks (Surgical Face Mask SLM/B, Sterilife, Yozgat, Turkey) were used and the mask position did not vary during the procedures (never below the nose). The same pulse oximeter with a reusable clip type finger probe (Cardiocap/5, Datex-Ohmeda, Helsinki, Finland) was used to measure the blood O_2 saturation during the study. Participants were encouraged to speak and behave in their usual manner throughout the operation. To eliminate the effect of dehydration over a several hour case on both pulse rate and O_2 saturation, the surgeons were allowed after every hour to drink water through a straw. For all measurements, finger probe was applied to the second finger of the right hand. The study was performed for over a 3-month period extending from March to May, while the operating room ambient temperature varied from 18 to 20°C, and the relative humidity from 35 to 40%.

Just before the operation, oxygen saturation and pulse rate values were recorded. At the end of the operation, pulse oximeter was applied again and the values were recorded. As the sham group, same surgeons were individually reassessed in the following days before and after exactly the same periods (between preoperational and post operational measurements) while they were standing in the operating room with their sterile gowns as an observer, not performing surgery and not wearing masks to obtain the pre control and post control values.

Paired and unpaired Student's t test were employed when comparing two groups such as pre and post operational values. The differences between the groups -more than two- were statistically evaluated using Kruskal-Wallis analysis of variance and than post hoc Dunn's test. Data are expressed as mean ± standard error of mean (S.E.M.). Conditions were considered to be statistically significant when $p<0.05$.

Results

When the values for oxygen saturation of hemoglobin were compared, there were statistically significant differences only between preoperational and post operational values (Fig. 1). As the duration of the operation increases, oxygen saturation of hemoglobin decreases significantly. Neither preoperational values, nor the post operational values in themselves were different among the groups. In the group of surgeons who did not wear masks during primary care operations with duration of less than 30 minutes, preoperational saturation values were 97.6±0.2 while post operational values decreased to 96.3±0.3 ($p=0.0006$).

When preoperational and post operational pulse rates were compared, it was observed that pulse rate increased after the operations, and there was a statistically significant

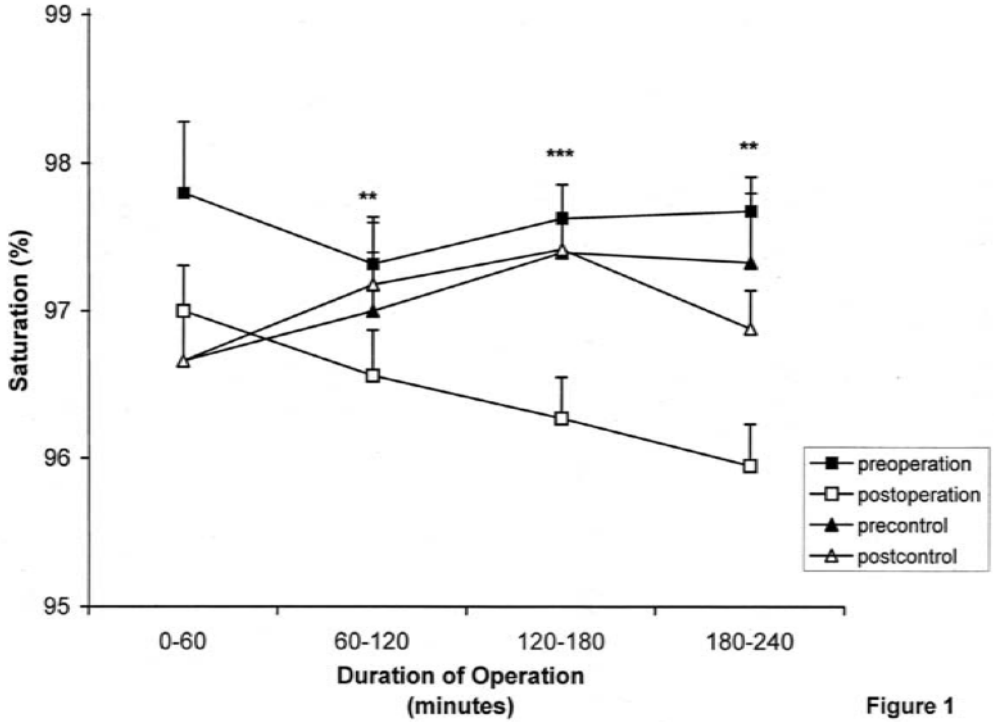

Figure 1. *The changes in the oxygen saturation of hemoglobin by the duration of surgical operations. Data are expressed as mean ± S.E.M.of n surgical operations. There were statistically significant differences only between preoperational and post operational values. ** p<0.01, *** p<0.0001*

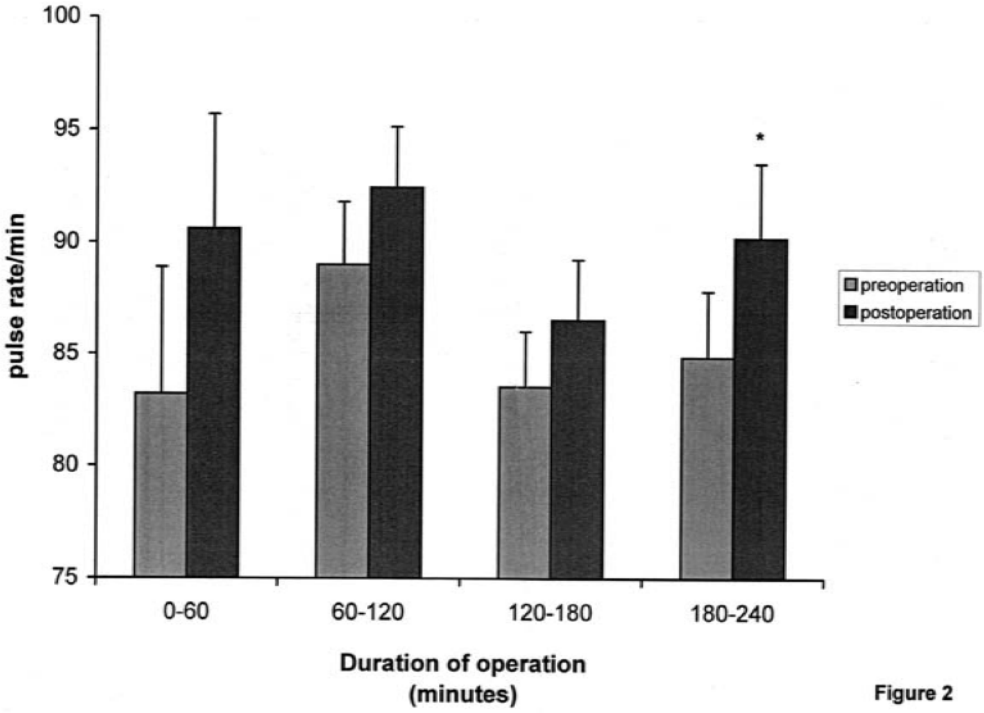

Figure 2: *The changes in pulse rates by the duration of surgical operations. Data are expressed as mean ± S.E.M. of n surgical ope-rations. There was a statistica-lly significant difference only in the group in which operation duration was 180-240 minutes. * p<0.05.*

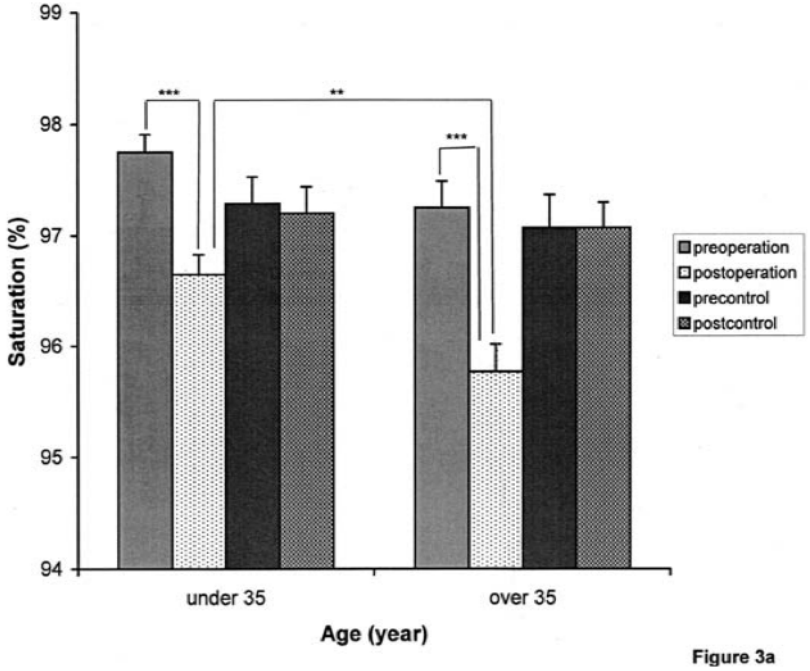

Figure 3a

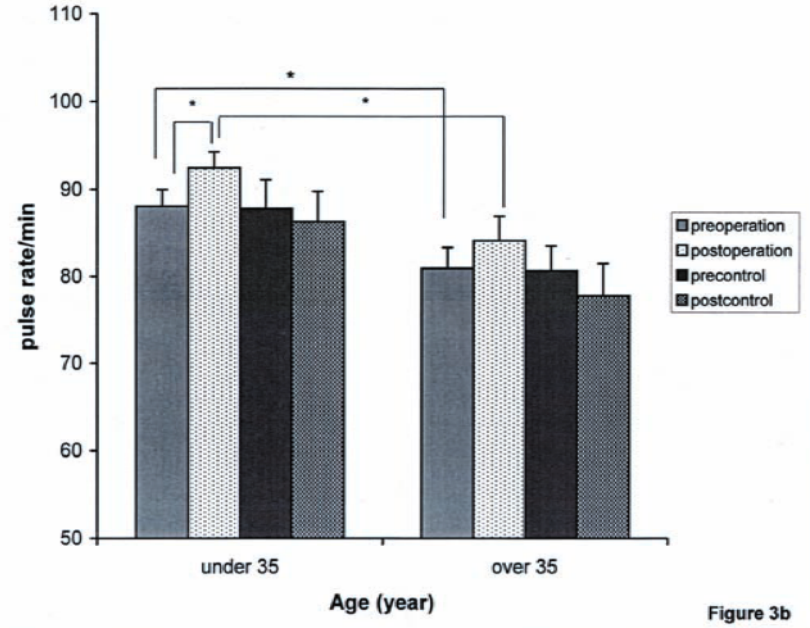

Figure 3b

Figure 3. a: *Effect of age on oxygen saturation of hemoglobin. ** $p<0.01$, * * * $p<0.0001$.*
*b: Effect of age on pulse rates. * $p<0.05$.*

difference only in the group in which operation duration was 180-240 minutes (p=0.02) (Fig. 2). Neither preoperational values, nor post operational values in themselves were different in the groups.

There was not any statistically significant difference between pre control and post control values of pulse rates and oxygen saturations (SpO_2) of the same surgeons, without facial masks while not performing surgery (Fig 1).

Oxygen saturation of hemoglobin decreased significantly after the operations in both age groups (p<0.0001). The post operational decrease was more prominent in surgeons over 35 when compared to the surgeons under 35 (p=0.0073) (Fig. 3 a).

It was observed that pulse rate decreases by age. Both preoperational and post operational pulse rates were significantly different between the two age groups (p=0.0287

and p=0.0124 respectively) (Fig 3 b). Under the age of 35, pulse rate increases significantly after the operations (p=0.0207).

Discussion

Although decrease in both mental - physical performance and accuracy may sometimes be overcome by the motivation of the surgeon, increased fatigue is common in lengthy operations. The increased endogenous heat production of the surgeon, as well as many aspects of the operating room situation -even the close environment beneath the surgical mask- may also negatively affect the working condition of the surgeon. Surgical masks may impose some measurable airway resistance, but it seems doubtful if this significantly increases the process of breathing. Although it might have appeared to be likely that hypoxemia results from the increased CO_2 content of the inspired air[1] due to the exhaled CO_2 getting trapped beneath the surgical face mask; there has been no controlled study concerning with the effect of surgical masks on the level of blood oxygenation. In this study we have measured the oxygen saturation of arterial pulsations (SpO_2) by a pulse oximeter and found a statistically significant decrease in the blood O_2 saturation level of the surgeons post operationally, which is not due to prolonged standing or stress.

Pulse oximetry, nowadays considered as a standard of clinical care, is a non-invasive method used to measure arterial oxygen saturation with a clinically acceptable accuracy. Since pulse oximeters cannot be calibrated by the user, their performances had been evaluated under both normal (good perfusion, saturation within a normal range and no interfering substances or extraneous factors) and adverse conditions. Despite some performance limitations in the settings of carboxyhemoglobinemia, motion artifact, presence of intravascular dyes, change in systemic vascular resistance, hypotension, nail polish, vasoconstriction, and anemia[2,7], it has been shown that age, gender, weight, body temperature, hemoglobin concentration and pulse pressure have little effect on the accuracy of pulse oximeters in detecting hypoxemia[8]. The majority of pulse oximeters have an absolute mean error of less than 1.0% when compared to in vitro saturation measurements[3,9]. Pulse oximeters are limited by their software so as not to give a saturation reading greater than 100%, and this limits the potential for positive errors and makes bias and precision calculations difficult to interpret in this high range. As the sigmoid shape of the blood oxygen dissociation curve flattens out at this high saturation levels (>90%) and since even a very small decrease in saturation at this level reflects a large decrease in PaO_2; our findings may have a clinical value for the health worker-surgeon: The surgeon's post operational blood O^2 saturation level is decreased more than 1% although the variability of the saturation sensors is less than 1%. It is thought that after a very short time the barrier function of the surgical face mask is gone[6]. Thus it is hard to believe that these masks serve as a reducer of oxygen uptake, but they may be acting as a psychological restriction over spontaneous breathing of the active surgeon.

Considering our findings, this is the first clinical investigation reporting a decrease in blood O_2 saturation and an increase in pulse rates of the surgeons after the operations due to surgical mask usage. This change in SpO_2 may be either due to the facial mask or the operational stress, since similar changes were observed in the group performing surgery without a mask. However, it cannot be decided whether stress plays any role on the late changes, namely pulse rate increase and SpO_2 level decrease; since surgeons are not allowed to perform major surgery without a facial mask in most institutions. In order to better elucidate the effects of stress, a randomized control study should have been conducted in a more controlled environment with different sorts of workers from different gender who are or are not used to wearing face masks on (such as anesthesiologists, nurses) also working the same durations. Thus, it is important not to generalize the results of this preliminary study, and further studies involving measurement of gas tensions over time, both from blood and from samples obtained under the mask (in order to show a presumed build-up of CO_2 under the mask) have to be carried out to elucidate this issue.

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Neurocirugía
2008; 19: 121-126

Beder, A.; Büyükkoçak, Ü.; Sabuncuoğlu, H.; Keskil, Z.A.; Keskil, S.: Preliminary report on surgical mask induced deoxygenation during major surgery. Neurocirugía 2008; 19: 121-126.

Corresponding author: Prof. Dr. Semih Keskil, M.D., Ph.D. Fethiye Sokak No: 4/6. Gazi Osman Pasa. 06700 Ankara Turkey.

Export.pdf
Uploaded by: Brian Davies
Position: UNF

Dear sir or ma'am,
Forcing or coercing someone in any way to take a vaccine or any medication violates the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. The first of its ten points begins as follows:

"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, overreaching, 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 code of ethics must be upheld in any civilized country. The COVID-19 vaccines were not tested for long-term effects and thus were and are experimental. Each person should choose whether to take the vaccine or not. Future vaccines may have similar experimental natures or may be carefully tested. Regardless, each person must have the right to accept or refuse the vaccine without any coercion, or penalty.

I have taken the liberty of adding a few additional ideas you may consider using in your testimony below:

Medical or religious discrimination: People decline COVID-19 vaccines for medical reasons or sincerely held ethical, moral, or religious beliefs. The valued and valuable ethical and legal traditions of the United States and Maryland are clear that it not acceptable to discriminate on the basis of medical condition/disability or on the basis of religion/ religious belief.

Weakening of medical privacy: Doctor/medical practitioner-patient confidentiality is legally protected and essential for a myriad of reasons, and the privacy & protection of medical records is also important. The COVID-19 passports and other COVID requirements erode or remove these legal protections.

Future implications: COVID passports set the groundwork for a two-tiered society, in which persons who have received vaccinations may live normal lives (including work, schooling, right to assembly, and access to various services) and persons who have not received vaccinations are denied those rights. Do we want to live in such a society? Recall history, our worst moments and our greatest achievements! Does it not always go badly when one group is dehumanized and denied rights based on a physical or religious characteristic? Are we not proudest of those movements which restore those rights?

Right to bodily integrity: Everyone has the right to bodily integrity, which includes the right to decline medical interventions. There is some serious philosophical inconsistency among the legislation under consideration this session. Bills to expand access to abortion and to enshrine abortion in Maryland law are under debate, underpinned by a 'my body, my choice' argument. Persons who wish to decline COVID vaccines are not being offered the same respect for 'my body, my choice'! You can't have it both ways! (The correct way of looking at this is: A woman has the right to bodily integrity and autonomy over her own body. The developing baby in her womb is someone else's body. Everyone has the right to maintain bodily integrity by declining medical interventions to which they do not give informed consent apart from coercion.)

Potential for Misuse of the MyIR Mobile app: Like any app, this one is subject to technological failure and hacking. Let's use caution before mandating it. Additionally, while it is currently being used and proposed to track vaccination records, its use could easily be expanded to illegal and unjust overreaching surveillance of American citizens by the government and the development of a Communist-style social credit system. Please review the work of Reggie Littlejohn to learn more about this.

With all sincerity,
Brian Davies

March 1-SB 840 testimony.pdf
Uploaded by: Brian Finglass
Position: UNF

March 1, 2022

To the Honerable Committee members:

Re: My testimony regarding SB 840

Dear Honorable Committee Members,

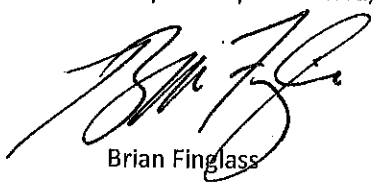
I am a 63 year old lifelong Maryland resident. I have never been involved politically in my life, but the events of the last 2 years have me very concerned with the loss of freedom, privacy and general rights in the name of public health. Therefore, I feel compelled to get involved and speak out.

I am opposed to any form of health document that will be utilized in any way to restrict participation in the full access to society. This is wrong in so many ways.

- It will serve to divide families, friends, communities and society as a whole. This should be rejected by our public leaders.
- Medical information should be 100% private. I do not want my personal medical information shared with anyone or any machine...only by myself to the doctor of my choosing.
- I feel that the push for digital tracking is the first step towards a society where all of our mobility and transactions are tracked with the associated complete loss of privacy. This has chilling implications and would lead to a society in which we would not have the freedom and privacy that I have enjoyed for my 63 years.

Please do not move forward with this legislation.

Respectfully submitted,



Brian Finglass

SB 840 letter - McDougall - Combined.pdf
Uploaded by: Clifford McDougall
Position: UNF

Senator Rosapepe

Senator King

Senate Finance Committee

Regarding: SB 840 – I Oppose this Bill

Finance Committee,

I am a concerned father and longtime MD resident. I work in Data Center technology and our personal medical data will not be safe with this proposed centralized vaccine passport. This bill was passed last year as an emergency use authorization and should be ended now - not extended further.

The pandemic is over. This bill is all over the map having regulations for qualification of qualifications for employment in nursing, testing centers, and pharmacies. All these things should be considered separately with careful debate – not thrown together in an emergency measure that no longer applies.

Most alarming is that Pharmacists are not doctors but are being granted authority to give vaccines to 3-year-olds. Vaccines should be given after informed consent and consultation with parents and the Pediatrician. We should not be incentivizing people to get vaccines (D.5) but promoting careful consideration regarding individual health history. Pharmacists are already too busy to give proper post shot care or respond to adverse reactions.

The most egregious part of this bill is letting pharmacists, or their technicians administer vaccines to children. It lowers the age from 11 to 3 years old. There is no mention of requirement for parental consent. This should only be administered by a pediatrician familiar with the child's health history after the parent received full informed consent as to the risks these vaccines present to children who are at effectively no risk of dying from COVID.

I strongly oppose this bill and ask you to vote no and prevent it from moving forward.

Thank you,

Cliff McDougall

For more information watch

https://stopvaxpassports.org/webinar-vaccine-passports-gateway-to-mass-surveillance/

STOP VAX PASSPORTS!

NEWS RELEASE: CPDC and WRWF Issue Letters to Congressional Leaders: Stop Vaccine Passports

For Immediate Release

August 26, 2021

CONTACTS:

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Media@HamiltonStrategies.com,

For *Women's Rights Without Frontiers*
Reggie Littlejohn, 310.592.5722
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Beth Harrison, 610.584.1096, ext. 105,
or Deborah Hamilton, ext. 102

CPDC and WRWF Issue Letters to Congressional Leaders: Stop Vaccine Passports

Action Needed to Stop Vaccine Passports not only by the federal government, but also by any state or local government, or by businesses, schools, or commercial enterprises

WASHINGTON, D.C.—The *Committee on the Present Danger: China*, *(*CPDC*)* and *Women's Rights Without Frontiers* (WRWF) today issued letters to Republican members of the U.S. House and Senate calling on these leaders to take every opportunity to speak out against vaccine mandates and passport platforms used to track American's vaccine status to enable or deny access to public venues including grocery stores, restaurants, and even organ transplants, and to support legislation being introduced to defend the civil liberties of Americans who have already recovered from the Covid-19 virus, or those who for whatever reason have declined to get the shots.

A recent National Republican Senatorial Committee fundraising appeal sent August 8 promised Republican leaders would support efforts to stop vaccine mandates and passports now being pushed in New York City and being considered by additional states and cities.

Earlier in August, the Stop Vaccine Passports Task Force sponsored by the Committee on the Present Danger: China and Women's Rights Without Frontiers issued President Biden an Open Letter signed by human rights activists and defenders of the Constitution. President Biden has already mandated vaccines for federal workers, and a similar mandate is looming for the armed forces, as well.

NYC Mayor Bill de Blasio's discriminatory executive order denies unvaccinated citizens access to public facilities and businesses without proof of vaccination. With the advent of formal FDA approval of the Pfizer vaccine on Monday, Aug. 23, President Biden called on businesses and institutions to rapidly move to mandate vaccines for employees and consumers alike.

As we explained in our letter to President Biden and congressional leadership and in a webinar hosted in July, "***the digital platform used by vaccine passports can provide the same totalitarian functionality as that used by the Chinese "Social Credit System." The risks of such a system being abused to deprive the American people of their liberties, livelihoods and possibly even their lives are too great to allow it, or even its precursors, to be introduced here."***

China has instituted a "Social Credit System" that gives it totalitarian control over every person in the nation. This platform tracks and integrates the following aspects of every individual: medical history, social media posts, bank accounts, credit cards, shopping history, internet search history, residence, place of employment, criminal history, facial and gait recognition, network of relationships, religious activities, participation (or the lack thereof) in the "Xi-Jinping thought" app, and real-time physical location.

All this information is fed into a central database and used to issue a "social credit score." Citizens are rewarded or punished, based on these scores. Those with a high score are able to participate freely in society. Those with a low score cannot travel, borrow money, may be fired from their jobs, and may be unable to get their children into school. Those with very low scores, such as political dissidents, can be cut off from credit card use, a big problem in China's increasingly cashless society. Dissidents can be found (and potentially disappeared) in minutes, along with their networks of relationships.

While it may begin with only carrying digital information regarding whether an individual is vaccinated, the rest of the functionality of the Chinese Social Credit System can be integrated into the "Vaccine Passport" system in a matter of minutes. Whether such digital documentation is governmentally issued or produced by corporate sponsors, the practical effect will be to provide a platform that, in the wrong hands, could usher in totalitarianism in the United States.

Today's Stop Vax Passports Task Force letter to Republican members of the U.S. House and Senate calls on these elected leaders to:

- Translate that commitment into legislation by **co-sponsoring a bill that would stop vaccine passports** such as Senator Cruz's "No Vaccine Passports Act" and supporting House bills like Representative Clay Higgins' "Employee Rights and Freedom Act" and Representative Diana Harshbarger's "No Vaccine Passports for Americans Act."

- Utilize every available media platform to educate the public about your determination to stop these totalitarian measures. We fear that your constituents are not hearing about your leadership role in preserving their constitutional rights.

On Monday, former U.S. Secretary of Housing and Urban Development Ben Carson warned on Newsmax, ***"The mandating of vaccines could shape a terrible future. The really important thing here is for us to recognize that this is America that we're living in," Carson said. "This is a place where people came so that they could be free. And the whole concept of mandates, no matter how wonderful you think they are, are opening the door to something that could be pretty terrible in the future."***

* * *

To interview representatives of the Committee on the Present Danger: China, contact Media@HamiltonStrategies.com,
Beth Harrison, 610.584.1096, Ext. 105
or Deborah Hamilton, Ext 102.

To interview Reggie Littlejohn,
contact reggielittlejohn@gmail.com, 310.592.5722.

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‹ D.C. joins Maryland, Virginia in vaccine mandate for government workers
› Former Professor of Ethics Dr. Julie Ponesse provides essential lesson on courage and integrity

9739
signatures

CLICK HERE TO SIGN THE PETITION

STATE GOVERNMENT POLICIES ABOUT VACCINE REQUIREMENTS (VACCINE PASSPORTS)

Read The CDC Disclaimer

VAERS COVID Vaccine Adverse Event Reports

Reports from the Vaccine Adverse Events Reporting System. Our default data reflects all VAERS data including the "nondomestic" reports.

All VAERS COVID Reports **US/Territories/Unknown**

1,134,982 Reports
Through February 18, 2022

24,402
DEATHS

133,057
HOSPITALIZATIONS

120,552
URGENT CARE

175,921

DOCTOR OFFICE VISITS

9,262

ANAPHYLAXIS

14,157

BELL'S PALSY

4,142

Miscarriages

12,511

Heart Attacks

34,448

Myocarditis/Pericarditis

44,512
Permanently Disabled

5,725
Thrombocytopenia/
Low Platelet

27,811
Life Threatening

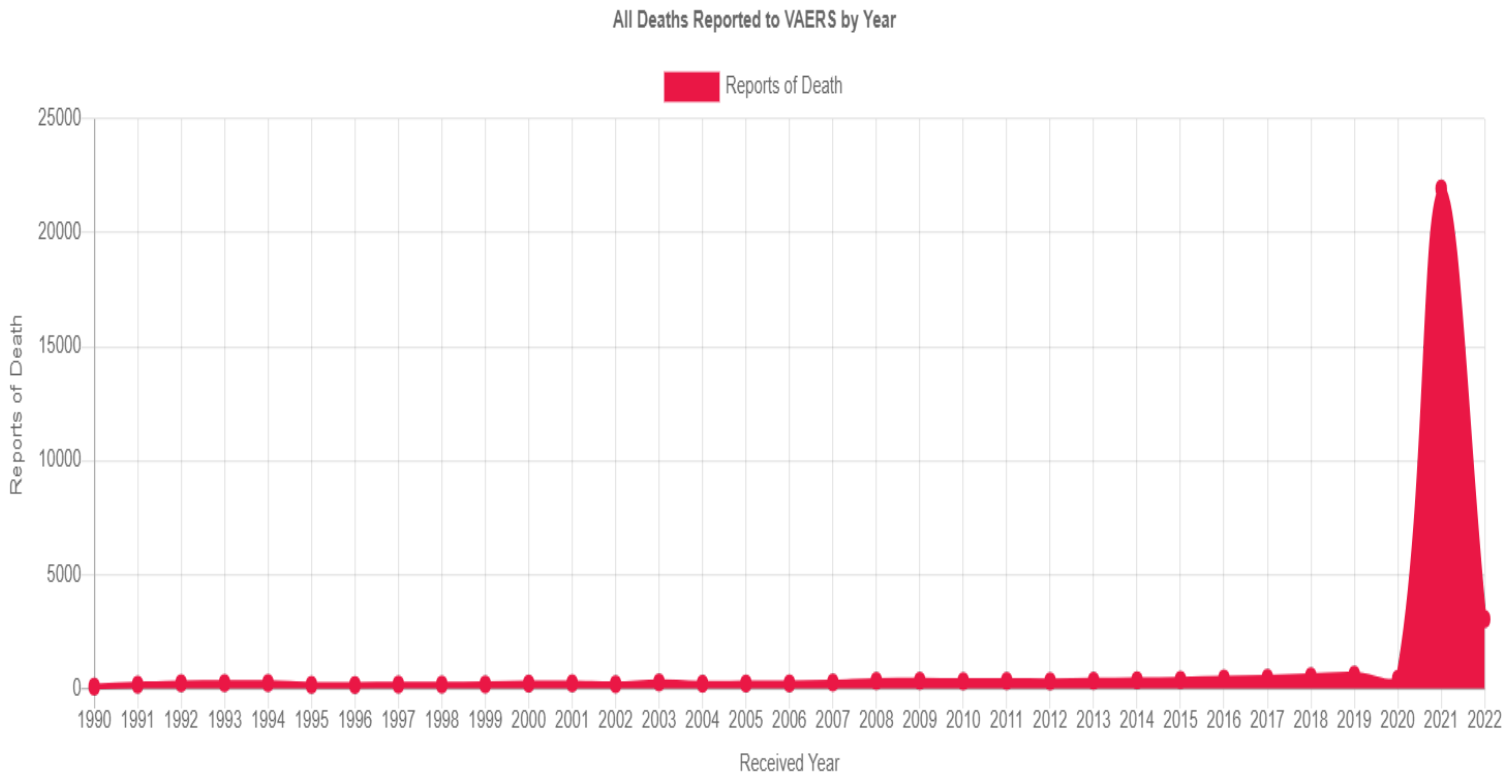
40,123
Severe Allergic Reaction

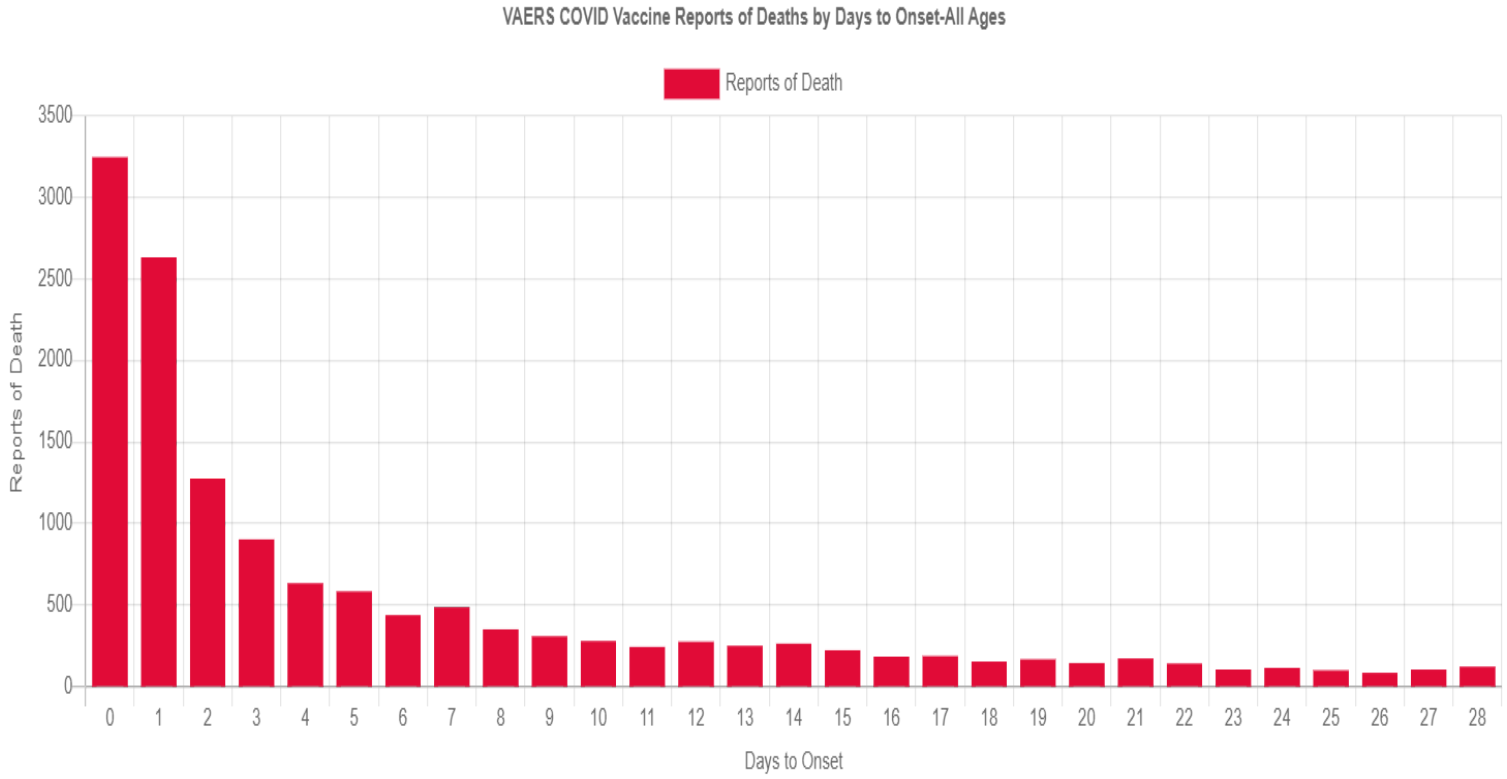
12,566
Shingles

Read COVID Child Reports

Read All VAERS COVID Reports

Read All VAERS Reports





Questions? Comments? Bugs?

info@openvaers.com

Due to the high volume of inquiries, please be patient with response times.

AND PLEASE read the FAQ first.

OpenVAERS is a private organization that posts publicly available CDC/FDA data of injuries reported post-vaccination.
Reports are not proof of causality.

SB840 UNFAVORABLE.pdf
Uploaded by: Crystal Kijesky
Position: UNF

SB840- **UNFAVORABLE**

March 1, 2022

Senators,

I oppose SB840. Even the basic premise- that pharmacists can give vaccines to children in the store- is rife for so many things to go wrong.

My children have a relationship with their pediatrician who specializes in their care. They have special training to see specifically what children are able to receive as far as their growth goes because it is such a specialized field.

Children are developing daily and any sort of changes need to be monitored. I have children with special conditions that the thought of a pharmacists giving them a vaccines would be awful.

They suffer from allergies and a heart condition that were not know until later in their lives.

Having vaccines administered in the pharmacists office would have meant emergency room follow up care after vaccine issues because there would be no recourse or follow up with the pharmacist. Which then would require a pediatric visit anyway after a vaccines issue follow up.

Getting records to the pediatrician afterwards would be a nightmare for follow up care and future information with their primary pediatrician.

Also, how many vaccine dosing issues have their been even in the covid 19 vaccines administration alone at pharmacies for young people? Many. Can you imagine trying to keep administration of doses straight with multiple vaccines?

Pharmacists are busy enough trying to consult with patients on specific medicines they administer. They usually have less than a minute for consultations. Adding yet *another* very important task of vaccine administration for children doe not seem like it is wise for children nor pharmacists.

I am **opposed** to SB840 and I ask you give it an **UNFAVORABLE** review.

Sincerely,

Crystal Kijesky

Covid 19 testimony.pdf
Uploaded by: Cynthia Feldman
Position: UNF

To Whom It May Concern:

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, overreaching, 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 code of ethics must be upheld in any civilized country.

The COVID-19 vaccines were not tested for long-term effects and thus were and are experimental. Each person should choose whether to take the vaccine or not. Future vaccines may have similar experimental natures or may be carefully tested. Regardless, each person must have the right to accept or refuse the vaccine without any coercion, or penalty.

Furthermore, there are many religious and conscience objections to taking this kind of inoculation. I submit this testimony as part, but not the entire reason, to the numerous reasons that compel me to be wholly against it.

Cynthia Feldman

Maryland Bill 840 - Vaccine Passports (Strong Oppo

Uploaded by: Dale Miller

Position: UNF

This notification is to provide my **strong opposition** to Maryland Senate Bill 840 which would require colleges, schools, and institutions to develop plans and goals to monitor, prevent, mitigate, and track via contact tracing the spread and Covid-19 vaccination for Maryland residents. The bill also develops a vaccination mobile app to voluntary provide proof of an individual's Covid vaccination status and to access venues where proof of Covid-19 vaccinations is required for entry. This bill is an incremental unilateral government assault on our personal freedoms granted by the U.S. Constitution. Even with consideration for a religious, medical, or immunity exemption, it is unconscionable the Maryland assembly would consider (even voluntary) Covid-19 vaccination passports. Regardless of your vaccination status, citizens should be concerned with this unprecedented breach of freedom. It always begins as a "temporary" or "voluntary" measure before removed to "mandated." We have watched our freedoms and liberties trampled (2 weeks to flatten the curve, closed schools, lockdowns, no religious worship, virtual learning, restrictions on visiting nursing homes, mask mandates, vaccine mandates to participate in activities) for the past 2 years.

This is mind bogging from the common-sense standpoint and makes NO sense from the science standpoint. Vaccine passports are immoral, unconstitutional, and a massive authoritative overreach. How does this fulfill social justice to force someone to be medicated against their will? Medical coercion is a human rights violation. Medical experimentation on non-consenting subjects has been recognized as a crime since the formulation of the Nuremberg Code. *What's next?* Separating the vaccinated from the unvaccinated? Vaccine passports to attend school, employment, church, eat at restaurants? This sounds like history repeating itself.

We have seen the Government require vaccine mandates/passports for employment and participation in normal societal activities. This would economically destroy the Maryland economy and small businesses. The Supreme Court blocked President Biden's vaccine mandate on large businesses, called the plan a "blunt instrument, and noted the mandate is "no 'everyday exercise of federal power.' It is instead a significant encroachment into the lives -- and health -- of a vast number of employees." The Supreme Court stated further vaccinations "cannot be undone at the end of the workday," adding that "a school-based mandate imposes irreversible medical treatment that extends far beyond the threshold of the school door." Furthermore, 17 states have passed legislation banning COVID-19 vaccine requirements for school attendance. In addition, the majority of states including the District of Columbia are dropping mask mandates. And the Maryland Assembly is considering vaccine passports? Are you kidding me?

Medical science is proving vaccine mandates useless and irrational. Martin Kulldorff, a Harvard Medical School professor/biostatistician and epidemiologist, said research showing that natural immunity offers exponentially more protection than vaccines mean vaccine passports are both unscientific and discriminatory, since they disproportionately affect working class individuals. There is simply no historical parallel for governments attempting to restrict the movements of healthy people over a respiratory virus in this manner. The argument that mandating vaccination is a public health issue for protection falls apart when considering the following. Maryland legislation must reflect these realities.

- COVID vaccinations do not prevent infection or spread of the virus as noted by CDC Director Dr. Rochelle Walensky.
- COVID-vaccinated individuals carry the same viral load when symptomatic as unvaccinated individuals.
- More than 15 studies show the natural immunity to SARS-CoV-2 is broader, more durable, and longer-lasting than any of the shots on the market today.
- Documented long-term health impacts (including myocarditis, stroke, and reproductive harms) on youth in light of the minimal risk of infection/spread/hospitalization.
- The World Health Organization have noted that children and adolescents tend to have milder disease compared to adults, so unless they are part of a group at higher risk of severe COVID-19, the priority should be to fully vaccinate older people, those with chronic health conditions and health workers.
- Peer-reviewed research shows that children have virtually zero risk of hospitalization and death from the COVID-19 virus. Conversely, according to Pfizer's own study trial data, the chance of death in children from the Pfizer vaccine is 107 times higher than death due to COVID.

- Parents and school administrators should never allow the government to force a medical procedure on children, especially when they have a minuscule risk of hospitalization and death from COVID.

Thank you for the opportunity to provide my comments on Maryland Bill 840.

Dale Miller

Daniela DOrazio Testimony SB0839 0840 .pdf
Uploaded by: Daniela D’Orazio
Position: UNF

Unfavorable Testimony, SB839 Maryland Voluntary COVID-19 Vaccine Passport

Chair Kelley, Vice Chair Feldman and committee members:

My name is Daniela DOrazio and I am Romanian American citizen that loves freedom.

I strongly oppose SB 839 and SB 840 because both bills reflects **discrimination, government control, surveillance and an attack on one's physical and mental health.**

SB839 is setting up a wholly new passport system in the declining days of the covid outbreak. This action is contrary to the movement of the entire country and some European countries.

Bill sponsor Senator Rosapepe was the United States Ambassador of Romania. I am surprised that Sen. Rosapepe would bring a bill to this respected body that has the dangers this bill presents. Has he forgotten how easily a population can be controlled by an oppressive government and how difficult it is to bring freedom back to that population? I grew up in Communist Romania and was shot at twice during the Revolution, so I understand how valuable freedom is.

The risks and problems with this proposal are so numerous they overwhelm.

Let's say that COVID-19 vaccine passport is a voluntary thing **than why is the state involved? Is it because when the state wants it to be required, or MANDATED it will have the full structure already there and ready to go?**

As a survivor of Communism, **I ask you to mandate freedom and not vaccine passports**. **Our medical information should be private and not used to divide and segregate the population into vaccinated and unvaccinated.**

Moreover, Covid is NO longer a threat but we do have a pandemic of mental illness. Eight students in Montgomery County MD died to suicide, overdose and homicide in the last two months, yet thankfully no child died of Covid in two years. Please spend our tax dollars on mental health treatment and not useless passports and contact tracing for a now endemic virus.

My Covid recovered husband was forced to get vaccinated to keep his job. Hours after vaccination he spiked a 103 fever,crucial migraine and **was referred immediately to the emergency room with stroke symptoms**. **The next Covid shot could kill him.**

School children are in constant fear of getting traced and missing 5 to 10 days of school with no academic support and therefore add additional anxiety and depression that could lead to suicide.

Covid is NO longer a threat but WW3 is knocking in our doors so Please retract both bills right here right now and make history as a Senator that gave people freedom of choice over one's own body without external domination or duress in the last days on potential peace on earth.

This nation felt strongly enough about the privacy of our individual health information that the federal government set up prohibitions via HIPPA laws that prevent those in medicine from sharing our health information. But, we are okay with handing this same information over to app companies who already abuse other personal information data collection privileges?

Companies that make covid testing and vaccinations are heavily benefitting from widespread government mandates and contracts while people are dying from vaccine side effects or lost of jobs if chose to not bee part of this experimental injection.

SB 839 and SB 840 is an attack on our freedom and privacy I respectfully ask to oppose it.

Respectfully,

Daniela D'Orazio

vaccine passport objections.pdf
Uploaded by: Dean Harding
Position: UNF

Dear Legislators,

We don't trade essential liberty for temporary safety! This principle must be understood and enforced by all government officials or they will enslave the very people they are supposed to protect and serve.

All the recent covid policies failed, taking away peoples' rights. Let's admit our mistakes and learn from them. Let's not move forward down the same path. The people already distrust the government more than ever. Do you think they are asking you for more restrictions? Do you think they are asking for a system that can tell them where they can go and what they can do? Do you think they want to have to carry "papers please" or a mobile phone in order to get access to goods and services? Who is asking for this vaccine passport? It's not the citizens. It seems more in alignment with the World Economic Forum's Great Reset plan and the big players exploiting the CVID crisis.

The revolt is all around you. Can you not see it? Can you not see the people rising up and saying we're not going to take it anymore?

The vaccine mandates are being forced upon us to give vaccine passport systems a purpose. There is no need for a
vaccine passport system without vaccine mandates. Vaccine passport systems are nothing more than digital human
control systems. The US goverment has already asked Mitre corporation to build a vaccine passport system.
Since these systems take away freedom, the government needs some type of big scare (like a pandemic) to justify them.
Vaccine passport systems are simply another type of social credit score system in disguise (like the one China deployed).
This is all
part of the globalist World Econonic Forum's Great Reset plan, which defines the next version of how humans will live
(A New World Order, the next version of human slavery). If you want to keep your freedom, it is up to all of us to
speak out NOW against vaccine mandates and vaccine passports. Once vaccine passports are instituted, they will gradually
be adapted to enforce other mandates in society. There will be no way to stop it. Imagine having to own and carry a
mobile phone in public, having a digital tattoo or microchip in your skin so that you can show your vaccine passport
and get permission to do things! That's where we are heading unless we all do something to stop it. This is already
being implemented throughout other test countries. Mass protests and revolts are occurring (but the mainstream media
isn't showing that).

In order to sneak vaccine passports into public acceptance, we will call them "voluntary" to make them sound harmless. But this is just a trick because to take away peoples freedom. You need to build the core infrastructure behind the peoples back without them knowing it. Otherwise, they would never accept it. That's what

this bill will do. It will open the authoritarian doors wider. It will start the process. It will begin building the infrastructure. It will train the brainwashed people to comply because they don't know any better and blindly trust their government. It's your job to protect the people from these con games.

Besides the above, I also strongly believe in the principles below.

Forcing or coercing someone in any way to take a vaccine or any medication violates the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. The first of its ten points begins as follows:

“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, overreaching, 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 code of ethics must be upheld in any civilized country. The COVID-19 vaccines were not tested for long-term effects and thus were and are experimental. Each person should choose whether to take the vaccine or not. Future vaccines may have similar experimental natures or may be carefully tested. Regardless, each person must have the right to accept or refuse the vaccine without any coercion, or penalty.

Medical or religious discrimination: People decline COVID-19 vaccines for medical reasons or sincerely held ethical, moral, or religious beliefs. The valued and valuable ethical and legal traditions of the United States and Maryland are clear that it not acceptable to discriminate on the basis of medical condition/disability or on the basis of religion/religious belief.

Weakening of medical privacy: Doctor/medical practitioner-patient confidentiality is legally protected and essential for a myriad of reasons, and the privacy & protection of medical records is also important. The COVID-19 passports and other COVID requirements erode or remove these legal protections.

Future implications: COVID passports set the groundwork for a two-tiered society, in which persons who have received vaccinations may live normal lives (including work, schooling, right to assembly, and access to various services) and persons who have not received vaccinations are denied those rights. Do we want to live in such a society? Recall history, our worst moments and our greatest achievements! Does it not always go badly when one group is dehumanized and denied rights based on a physical or religious characteristic? Are we not proudest of those movements which restore those rights?

Right to bodily integrity: Everyone has the right to bodily integrity, which includes the right to decline medical interventions. There is some serious philosophical inconsistency among the legislation under consideration this session. Bills to expand access to abortion and to enshrine abortion in Maryland law are

under debate, underpinned by a ‘my body, my choice’ argument. Persons who wish to decline COVID vaccines are not being offered the same respect for ‘my body, my choice’! You can’t have it both ways! (The correct way of looking at this is: A woman has the right to bodily integrity and autonomy over her own body. The developing baby in her womb is someone else’s body. Everyone has the right to maintain bodily integrity by declining medical interventions to which they do not give informed consent apart from coercion.)

Potential for Misuse of the MyIR Mobile app: Like any app, this one is subject to technological failure and hacking. Let’s use caution before mandating it. Additionally, while it is currently being used and proposed to track vaccination records, its use could easily be expanded to illegal and unjust overreaching surveillance of American citizens by the government and the development of a Communist-style social credit system. Please review the work of Reggie Littlejohn to learn more about this.

Sincerely,

Dean Harding

SB840UNFAV.pdf
Uploaded by: Denee Daly
Position: UNF

SB#840

UNFAV

March 2, 2022

Submitted by: Denee Daly, Life long Maryland resident

I oppose SB#840 Covid-19 Response Act of 2022. There is so much in this bill I oppose.

I oppose a vaccine passport by Maryland IR Mobile by any design and by any provider. This infringes on my medical privacy and the medical privacy of my family. We have already experienced first hand the division, discrimination and other harms that occur at the hands of identifying people and allowing or restricting their movement, as well as granting or denying equal access to jobs and education based on vaccination status. It cannot be financed, otherwise supported or allowed to continue.

In addition, there are many issues with giving pharmacists and their assistants the authority to vaccinate children 3 and older, let alone without parental consent. These are private decisions to be made by parents in consultation with trusted medical professionals.

For these, and other reasons, I oppose SB840.

Thank you

Petro_Testimony_SB0840_20220302.pdf
Uploaded by: Ed Petro
Position: UNF

Petro Testimony SB0840
02-March-2022

This testimony is to share my unfavorable views of SB0840: COVID-19 Response Act of 2022 and ask that the Senate vote to NOT pass this legislation.

Forcing or coercing someone in any way to take a vaccine or any medication is immoral and violates international statutes, specifically the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. The first of its ten points begins as follows:

"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, overreaching, 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 code of ethics must be upheld in any civilized country. The COVID-19 vaccines were not tested for long-term effects and thus were and still are experimental. Each person should have the option to choose whether to take the vaccine or not. Regardless, each person must have the right to accept or refuse the vaccine without any coercion or penalty.

Medical or religious discrimination: People decline COVID-19 vaccines for medical reasons or sincerely held ethical, moral, or religious beliefs. The valued and valuable ethical and legal traditions of the United States and Maryland are clear that it is not acceptable to discriminate on the basis of medical condition/disability or on the basis of religion/religious belief.

Weakening of medical privacy: Doctor/medical practitioner-patient confidentiality is legally protected and essential for a myriad of reasons, and the privacy & protection of medical records is also important. The COVID-19 passports and other COVID requirements erode these legal protections.

Future implications: COVID passports set the groundwork for a two-tiered society, in which persons who have received vaccinations may live normal lives (including work, schooling, right to assembly, and access to various services) and persons who have not received vaccinations are denied those rights. Do we want to live in such a society? Recall history, our worst moments and our greatest achievements! Does it not always go badly when one group is dehumanized and denied rights based on a physical or religious characteristic? Are we not proudest of those movements which restore those rights?

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womb is someone else's body. Everyone has the right to maintain bodily integrity by declining medical interventions to which they do not give informed consent apart from coercion.)

Potential for Misuse of the MyIR Mobile app: Like any app, this one is subject to technological failure and hacking. Let's use caution before mandating it. Additionally, while it is currently being used and proposed to track vaccination records, its use could easily be expanded to illegal and unjust overreaching surveillance of American citizens by the government and the development of a Communist-style social credit system. Please review the work of Reggie Littlejohn to learn more about this.

Little Justification for Mandating Vaccinations: If the COVID-19 vaccinations are as effective as advertised, then everyone who has been vaccinated can be assured of protection against the virus. The virus has spread via both vaccinated and unvaccinated persons. Those who have chosen to be protected, have been vaccinated. Requiring a 'vaccination passport' will not add to the protection of vaccinated persons; it will only serve as a Yellow Star to single-out those who choose to follow their conscience about vaccinations. This singling-out will yield no value to society, but only make some individuals clear targets for discrimination and derision.

Thank you for considering my testimony. I ask that the Senate vote to NOT pass SB0840: COVID-19 Response Act of 2022.

Sincerely,

Ed Petro
Ijamsville, Maryland

SB840_ElizabethStanford_Unfav.pdf
Uploaded by: Elizabeth Kampororo
Position: UNF

SB840
UNFAV
Elizabeth Stanford

I am writing to register strong opposition to SB 840/HB 1084.

Vaccine passports are illegal, based on HIPAA and Nuremburg Code violations, divisive, discriminatory and irrelevant. Furthermore, this vaccine---designed for emergency use---does not thwart or diminish the transmission of COVID-19. (Please click on the following link to view a Harvard study which shows that increases in covid cases are not related to vaccination in 68 countries and 2947 US counties.
https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8481107/)

Most citizens have been inoculated to assuage fear when, in reality, their protection against COVID-19 has not transferred to the Omicron variant. Quite frankly, the unfounded pressure to "get the vaccine" is unconscionable. Medical decisions are private matters between each patient and their doctor.

If the purpose of the vaccine passport is to corral COVID-19 and minimize the spread, the vaccine has proven ineffective with the Omicron variant, as I stated previously. Given that the vaccine is not curbing the spread of COVID-19, proof of vaccination would be irrelevant.

It is disconcerting to think that our state leaders want to coerce pharmacists into doubling as pediatricians, assuming the moral liability for mass scale injections without having comprehensive patient history on any one recipient. Pharmacists are not qualified to assess a child's readiness for vaccination. Requiring pharmacists to administer a large ongoing volume of vaccinations without proper training is an undeniable setup for large scale disaster. Proposing adequate backup from a pharmacy technician as young as seventeen years old---a child themselves---with a total of six weeks of training is outrageous!

This bill is not in the best interest of the health and well-being of your constituents. Please vote no.

testimony opposing SB 840- 2022.pdf
Uploaded by: Emily Tarsel
Position: UNF

Emily Tarsell, LCPC, LCPA

2314 Benson Mill Road
Sparks, Maryland 21152
March 2,2022

Oppose SB 840

Chairwoman Kelley and Committee Members, I am Emily Tarsell, a mother, therapist and founder of Health Choice Maryland, a grassroots non profit with hundreds of Members across the state. We are united by our belief in our right to health choice, informed medical consent, parental rights and science based information for informed medical decisions. SB 840 is an egregious assault on all of these.

SB 840 piggybacks on a former bill with emergency use authorizations created last year at a time when we had a pandemic.There is no need to extend emergency measures now to 2024. T**he pandemic is over and EU authorizations have long expired across the state.**

Last year, the rationale for letting pharmacists give some childhood vaccines as a **temporary measure,** was based on the contention that visits to pediatricians declined due to the pandemic so pharmacists might pick up the slack. But SB840 wants to extends that authority for a pharmacist **and their assistants** to now **ORDER** vaccination for children as young as 3 and it does not state a requirement for written informed parental consent.

Busy pharmacists will not know the child's health history and don't have the time or training to treat children. Furthermore vaccination rates among children in Maryland have been and continue to be among the highest in the nation at 93% [1] which is near prepandemic levels. So doctor's are meeting the need. Pharmacists do not need to fill that role and parents, not pharmacists, should call the shots.

With COVID 19 gone, it is time to let go of the proliferation of sites, providers, authorizations, tests and promotions to get an **experimental** Covid 19 shot which is not only unnecessary but according to attached recent public health data has negative efficacy over time and weakens immunity with increased doses. Data **clearly show that the vaccinated have a higher rate of Omicron infection than the unvaccinated and one's vulnerability greatly increases after the second dose. Proof of vaccination is therefore meaningless which is why vaccine passports have been withdrawn worldwide.**

Please veto SB 840 - an unnecessary, reckless, divisive and costly bill. Please protect our children and restore some sanity.

Thank you.
Emily Tarsell

[1] https://worldpopulationreview.com/state-rankings/vaccination-rates-by-state

Here are the 10 states with the highest rates of vaccination:

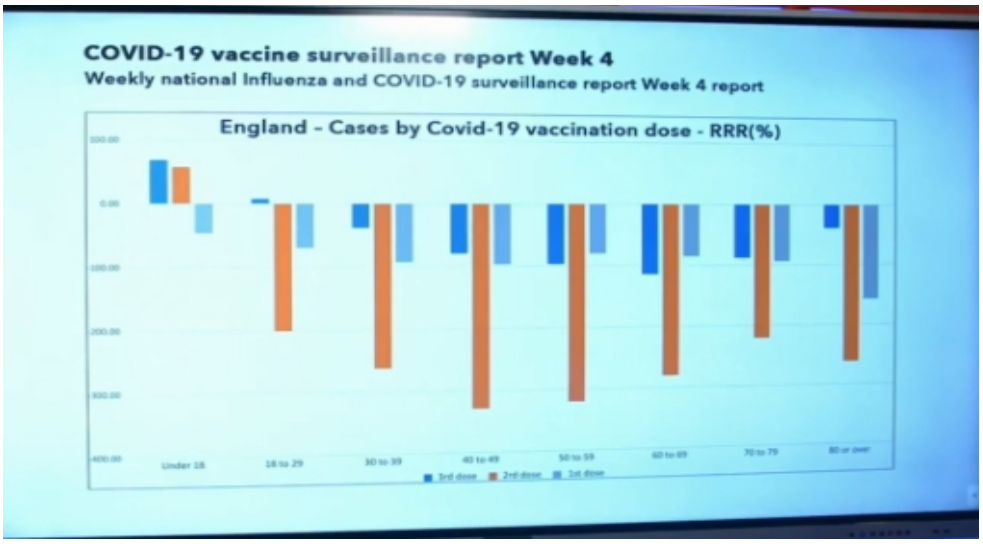
1. Maryland (0.93%)
2. Vermont (0.92%)
3. Louisiana (0.88%)
4. Nevada (0.88%)
5. Pennsylvania (0.88%)
6. Connecticut (0.87%)
7. South Dakota (0.87%)
8. North Carolina (0.86%)
9. Montana (0.86%)
10. New Jersey (0.86%)

Vaccination Rates by State 2022

Week	Unvaccinated			1 Dose		
	No. tested positive by PCR	Population	Age-standardised case rate per 100,000 with 95% confidence intervals	No. tested positive by PCR	Population	Age-standardised case rate per 100,000 with 95% confidence intervals
18 December - 24 December 2021	5,594	1,006,025	**540.82** (518.55 - 563.08)	1,860	357,752	**780.31** (733.17 - 827.45)
25 December - 31 December 2021	9,496	998,045	**958.52** (926.37 - 990.68)	3,387	348,727	**1,409.70** (1,347.89 - 1,471.51)
01 January - 07 January 2022	9,105	988,033	**923.27** (893.85 - 952.70)	3,066	341,481	**1,393.46** (1,325.60 - 1,461.32)
08 January - 14 January 2022	3,601	979,617	**412.77** (390.36 - 435.18)	1,093	340,151	**543.98** (497.93 - 590.03)

The above table is taken from that recently published by Public Health Scotland. It compares positive cases of Omicron per 100,000 among those who are Unvaccinated and those who were Vaccinated. **It clearly shows that the vaccinated have a higher rate of Omicron infection than the unvaccinated.**

The chart below is from recent data from the UK. It shows the rate by age category of Omicron cases in the vaccinated depending on the number of COVID vaccine shots received. The bar graphs show sequential doses in the order 3rd dose, 2nd dose, 1st dose.
It clearly shows not only waning efficacy but actual NEGATIVE efficacy. That means that **one is more likely to get Omicron if one is vaccinated and vulnerability greatly increases after the second dose.** There is some benefit initially in the under 18 group because they just got it. But that benefit will also likely wane and actually make the recipient more vulnerable to the variant as suggested by the other data.


COVID-19 vaccine surveillance report Week 4
Weekly national Influenza and COVID-19 surveillance report Week 4 report
England – Cases by Covid-19 vaccination dose - RRR(%)
100.00
0.00
-100.00
-200.00
-300.00
-400.00
Under 18
18 to 29
30 to 39
40 to 49
50 to 59
60 to 69
70 to 79
80 or over
3rd dose
2nd dose
1st dose

Opposing SB840.pdf
Uploaded by: Eszter Szabo
Position: UNF

OPPOSE Senate Bill 840

Eszter Szabo
7608 Cayuga Avenue, Bethesda, MD 20817
March 1, 2022

This Bill would extend Covid19 response in the state till the end of 2023 which is no longer necessary since Covid19 is over. This bill is asking for institutions of higher education with residence halls for students to establish a CV19 security plan with perpetual screening and testing of healthy students. In the name of safety, which is an undefined scientific category, it would require students be tested. We would be using EUA testing kits on a population that is not at risk of CV19 where the spread of CV19 is minimal. This bill is also unnecessarily asking for specific goals to be set to safely reopen schools, which have already been opened and being kept open safely in Maryland. Overall, we should be returning to sound medical practice which is testing of symptomatic people via medical doctors ordering tests when their patients need them. More testing of asymptomatic for CV19 is not necessary. This bill would also require various health departments to create other artificial testing goals to achieve, the funding of which is a waste of taxpayers' resources.

The bill is requesting to establish a strategy to increase vaccination amongst the unvaccinated and incentivize eligible individuals to receive a third dose of CV19 vaccine. Since CV19 is over and the CV19 vaccine is not protective of the latest variant, Omicron, this is only a moneymaking proposition transferring funds to the public health administration profession for creating policies, targets, monitoring, etc. and the pharmaceutical companies who market the tests, masks and vaccines. There are treatments for CV19 so vaccines are not anymore essential. We better allow medical doctors treat patients with CV19.

The MyIR digital vaccine passport is discriminatory, allows segregation of society and encourages employers to hire/fire based on a health choice regarding a vaccine. Everyone's health choice is private information; we shouldn't base access to basic needs on this choice.

As far as allowing pharmacists to order and inoculate children age 3 and over with CV19 EUA vaccine without parental consent, this is dangerous and a serious breach of parental rights. Pharmacists are not doctors or nurses. Pharmacists have a lot of responsibilities, adding this to their busy schedule is not a good idea. Recently I received a medication from my pharmacy which my doctor prescribed. At home when I wanted to take the medication, I noticed that the information didn't contain instruction on how many tablets to take per day. Since I couldn't reach the pharmacy nor my doctor, I needed to find the information myself on the internet. This was a simple case. What if a busy pharmacist is administering a vaccine to a 3-year-old? Any small mistake can cause serious harm for that child.

Please vote against this bill with a mish-mash of various items included that would all need to be debated separately and not in one bill as submitted here.

SB 840 Against.pdf
Uploaded by: Gwenn Murray
Position: UNF

SB 840 Against

Gwenn Murray

706 Cypress Road

Severna Park, MD 21146

I oppose SB-840 COVID–19 Response Act of 2022 use of vaccine passport technology, known as Maryland MyIR Mobile because it will enable Maryland to become a Covid passport state. This technology, promoted by Big Tech and Big Pharma, will facilitate government overreach which is inappropriate in a free society. This technology also has the very real potential to impact many aspects of life for all citizens in Maryland. With the implementation and utilization of vaccine passports, individual privacy will be compromised. Additionally, it is a precursor to digital identity which will facilitate a digital surveillance apparatus for the government. <u>As a result, vaccine passports and digital id's can force compliance in any area of life.</u>

If you accept vaccine passports, you are essentially giving consent to what may come as a result of its implementation. As a country that was founded on freedom and individual rights, should we NOT be legislating tools that can very easily be used to take away the very rights and freedoms that we cherish as American citizens.

Opposing Bills SB0839 and SB0840.docx.pdf
Uploaded by: Hind Walker
Position: UNF

Good day to all,

I am writing as a Maryland resident of Carroll County to request these two bill be withdrawn as soon as possible because they infringe upon my individual liberties and those of my family.
To Everyone,

SB 839- The bill proposes using mobile technology to implement an immunization record "service" called MyIR. This vaccine passport would display COVID 19 vaccination status allegedly for admission to certain venues.
It would furthermore use tax payer money to develop and promote this outrageous and unnecessary "service".

https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/sb0839

Why I oppose this bill:

1.One's medical information is one's own business and should not be used to discriminate and segregate citizens based on vaccine status.
2. No business should be discriminating who can or cannot use their service based on COVID or other vaccination status especially vaccines that are still only Emergency Use Approved.
3.The CDC itself has said that the vaccinated can both get and spread COVID virus. Many unvaccinated people have natural immunity which is cross protective, enduring and a benefit to the public.
4.One's medical information should be protected information but we have seen repeatedly that "protected" information can be hacked.
5.Vaccine passports have been withdrawn across the globe. They are unnecessary and represent a violation of personal freedom, privacy and health choice.
6.Public funding would be used to develop and market an unecessary program which lays the foundation for chilling government tracking, surveillance, divisiveness and control.

SB 840-
This bill was originally passed last year as Emergency Use Authorization that was supposed to expire at the end of this year. This bill extends to 2024 emergency use authorizations that are no longer required! Furthermore it expands the authority and reach of administrators regarding testing, contact tracing and protocols in multiple settings to "control" COVID 19, a virus that no longer exists! The bill is allegedly to be able to reopen schools, colleges and workplaces which are already open.

But there are even more egregious things in this sweeping bill which talks about the vaccine passport structure mentioned in SB839 as though it were already law. The bill talks about incentivizing vaccine uptake of ANY CDC recommended vaccine now or in the future. How can

we possibly know if that is a good idea when we don't know what the risks and benefits might be? And every parent should be outraged that the bill wants to allow a PHARMACIST (or his delegated assistant) to have the authority to ORDER and ADMINISTER a vaccine to a child 3 or older and does not even require parental informed consent!

There is more in this egregious bill that is way too broad and includes everything from qualifications for an apprentice geriatric nurse assistant to rates for an Urgent Care Center. What have these things got to do with each other?
https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/sb0840

Why I oppose this bill:

1. We oppose any vaccine passport as our medical information should be private and not used to divide and segregate the population into vaccinated and unvaccinated.
2. Vaccine passports have been withdrawn globally
3. Pharmacies are not doctor's offices and pharmacists (and their assistants) are not doctors. They should not have the authority to ORDER and vaccinate our children even more so without parental or guardian informed consent.
4. This bill was originally intended to expire by the end of 2022 and it should expire. It was an emergency use bill intended for a pandemic which has passed. The authorizations given in the original bill should expire as intended.
5. The bill is a mishmash of all kinds of unrelated things from listing the qualifications for certain practictioners to rates for an urgent care center to tracking, testing and funding for a virus that no longer exists. Each of these things should be considered separately with thoughtful debate, not thrown together in a bill that is too far reaching.

I came to this country for freedom and equality. I am saddened and worried about the government over-reach that has been taking place over the past 2 years. This started our because of Covid and is now continuing for no valid reason. This has to stop

testimony_against_SB0840.pdf
Uploaded by: J Laird
Position: UNF

Whether you are in favor of vaccinations or not, people should not be required to have a foreign substance injected into their body to live normal lives. If the vaccines are very effective, then those vaccinated have nothing to fear from the unvaccinated.

Forcing or coercing someone in any way to take a vaccine or any medication violates the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. The first of its ten points begins as follows:

"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, overreaching, 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 code of ethics must be upheld in any civilized country. The COVID-19 vaccines were not tested for long-term effects and thus were and are experimental. Each person should choose whether to take the vaccine or not. Future vaccines may have similar experimental natures or may be carefully tested. Regardless, each person must have the right to accept or refuse the vaccine without any coercion, or penalty.

Medical or religious discrimination: People decline COVID-19 vaccines for medical reasons or sincerely held ethical, moral, or religious beliefs. The valued and valuable ethical and legal traditions of the United States and Maryland are clear that it not acceptable to discriminate on the basis of medical condition/disability or on the basis of religion/religious belief.

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Right to bodily integrity: Everyone has the right to bodily integrity, which includes the right to decline medical interventions. There is some serious philosophical inconsistency among the legislation under consideration this session. Bills to expand access to abortion and to enshrine abortion in Maryland law are under debate, underpinned by a 'my body, my choice' argument. Persons who wish to decline COVID vaccines are not being offered the same respect for 'my body, my choice'! You can't have it both ways! (The correct way of looking at this is: A woman has the right to bodily integrity and autonomy over her own body. The developing baby in her womb is someone else's body. Everyone has the right to maintain bodily integrity by declining medical interventions to which they do not give

informed consent apart from coercion.)

Potential for Misuse of the MyIR Mobile app: Like any app, this one is subject to technological failure and hacking. Let's use caution before mandating it. Additionally, while it is currently being used and proposed to track vaccination records, its use could easily be expanded to illegal and unjust overreaching surveillance of American citizens by the government and the development of a Communist-style social credit system. Please review the work of Reggie Littlejohn to learn more about this.

Maryland-OPPOSE SB840-COVID-19 Response Act of 202
Uploaded by: Jacquelin Zubko-Cunha
Position: UNF

OPPOSE

SB 840 COVID-19 Response Act of 2022

Jacquelin Zubko-Cunha, Gaithersburg, MD

I am writing to OPPOSE SB 840. This bill is massive and too broad in scope. The varied articles, amendments, and changes all bundled together make these bills extremely confusing for constituents, even experienced legislative advocates. Above all the current science and metrics we have do not indicate the necessity for these kind of expensive and restrictive plans through 2023.

I am particularly concerned about the “temporary emergency” measures becoming permanent policy at the expense of my kids. Allowing pharmacists to vaccinate children ages 3+ indefinitely is dangerous and unnecessary. Pharmacists agree their work environment is too chaotic to do this safely. It is unconscionable and negligible that they can give vaccines to children under virtual supervision and only 6 hours of training. This set up puts children at undue risk. Pediatricians also recognize that children need comprehensive medical care. Vaccination decisions should be made by parents with their child’s pediatricians.

The budgetary and economic impact is also sure to be exorbitant. Language such as “incentivizing any future vaccines recommended by the CDC” is overly broad and raises concerns about the long-term vision of this legislation. Not to mention the ethics behind bribery and coercion.

Finally, vaccine passports are raised in these bills yet again, even with stand-alone passport legislation on the table. “Voluntary” vaccine passports are discriminatory and are not supported by science or the public.

Written testimony for HB0840. .pdf
Uploaded by: Jaime Brooke
Position: UNF

Written testimony for HB0840.
Jaime Brooke

I am a registered democrat living in West Laurel (20707), and I oppose HB0840.

I am strongly opposed to this bill for many reasons, but mainly the fact that it deals with starting a digital V passport for the state of Maryland. This is not only a violation of privacy, but a huge expense that I feel is not necessary. There are so many other areas where this money could be going: keeping our children safer and well prepared in schools, environmental initiatives, housing/community initiatives for impoverished neighborhoods (especially for youth and young mothers). Also, the Maryland Health Department had a breach/data was compromised just recently this year. I do not feel comfortable with my health information (and especially my vaccination status) on my phone. I know it says "optional", but we know that this can open doors that shouldn't be opened. A passport will do nothing to stop the spread of Covid (we know this now). This will lead to healthy unvaccinated individuals who are not carrying the virus, or have natural immunity from a previous infection will be discriminated against like they have been over the last year. New York, who has a passport system is now dropping the passport. We need to follow the science and protect the privacy and health decisions of Marylanders.

Medical decisions have always been private, and respected. This should remain. Please VOTE NO on HB0840.

Thank you,

Jaime Brooke
6605 Weaver Court
Laurel, MD 20707

oppose SB0840.pdf
Uploaded by: James Elbourn
Position: UNF

SB840 – WITHDRAW!

Hello, please withdraw this bill. Once again, this is un-American. My medical status is my business. This bill originally was an emergency use bill, and should expire this year since there is no longer a state of emergency.

Thank you.

Sincerely,

James Elbourn
D33

SB840 UNFAVORABLE OPPOSE Helms, James Jr.pdf
Uploaded by: James Helms Jr
Position: UNF

UNFAVORABLE/OPPOSE

SB0840

James Helms Jr

Capitol Heights, MD

I oppose the passing of SB0840. Many individuals choose not to be vaccinated for religious reasons. While I assume that the majority of this bill's supporters are innocent of any malicious motives, a passport system for vaccines posses a serious threat to those who declined the vaccine. It could potentially become a form of "Jewish Star" to point out the "others" or those who are noncompliant with the dominant worldview of the times. In fact, many who declined vaccination are members of devout Jewish sects and practices. Given the metrics, I do not see an emergency that justifies the risks involved with this bill.

SB840.pdf
Uploaded by: Janet Stann
Position: UNF

Vaccines administered by pharmacists and pharmacy tech to children as young as 3 years old have so many risks of something going wrong. Pharmacists are stretched thin on time consulting and administering medicines, I cannot see how adding another huge responsibility to their shoulders is safe for children.

testimony_against_SB0840.pdf
Uploaded by: jasraj joglekar
Position: UNF

Whether you are in favor of vaccinations or not, people should not be required to have a foreign substance injected into their body to live normal lives. If the vaccines are very effective, then those vaccinated have nothing to fear from the unvaccinated.

Forcing or coercing someone in any way to take a vaccine or any medication violates the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. The first of its ten points begins as follows:

"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, overreaching, 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 code of ethics must be upheld in any civilized country. The COVID-19 vaccines were not tested for long-term effects and thus were and are experimental. Each person should choose whether to take the vaccine or not. Future vaccines may have similar experimental natures or may be carefully tested. Regardless, each person must have the right to accept or refuse the vaccine without any coercion, or penalty.

Medical or religious discrimination: People decline COVID-19 vaccines for medical reasons or sincerely held ethical, moral, or religious beliefs. The valued and valuable ethical and legal traditions of the United States and Maryland are clear that it not acceptable to discriminate on the basis of medical condition/disability or on the basis of religion/religious belief.

Weakening of medical privacy: Doctor/medical practitioner-patient confidentiality is legally protected and essential for a myriad of reasons, and the privacy & protection of medical records is also important. The COVID-19 passports and other COVID requirements erode or remove these legal protections.

Future implications: COVID passports set the groundwork for a two-tiered society, in which persons who have received vaccinations may live normal lives (including work, schooling, right to assembly, and access to various services) and persons who have not received vaccinations are denied those rights. Do we want to live in such a society? Recall history, our worst moments and our greatest achievements! Does it not always go badly when one group is dehumanized and denied rights based on a physical or religious characteristic? Are we not proudest of those movements which restore those rights?

Right to bodily integrity: Everyone has the right to bodily integrity, which includes the right to decline medical interventions. There is some serious philosophical inconsistency among the legislation under consideration this session. Bills to expand access to abortion and to enshrine abortion in Maryland law are under debate, underpinned by a 'my body, my choice' argument. Persons who wish to decline COVID vaccines are not being offered the same respect for 'my body, my choice'! You can't have it both ways! (The correct way of looking at this is: A woman has the right to bodily integrity and autonomy over her own body. The developing baby in her womb is someone else's body. Everyone has the right to maintain bodily integrity by declining medical interventions to which they do not give

informed consent apart from coercion.)

Potential for Misuse of the MyIR Mobile app: Like any app, this one is subject to technological failure and hacking. Let's use caution before mandating it. Additionally, while it is currently being used and proposed to track vaccination records, its use could easily be expanded to illegal and unjust overreaching surveillance of American citizens by the government and the development of a Communist-style social credit system. Please review the work of Reggie Littlejohn to learn more about this.

MD Bills.pdf
Uploaded by: Jeff Wall
Position: UNF

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Jeff Wall

SB840-INFO-Pharmacy Chaos.pdf
Uploaded by: Jenna Butler
Position: UNF

How Chaos at Chain Pharmacies Is Putting Patients at Risk

Pharmacists across the U.S. warn that the push to do more with less has made medication errors more likely. “I am a danger to the public,” one wrote to a regulator.

Published Jan. 31, 2020Updated Oct. 13, 2021

Video by Jeremy M. Lange For The New York Times

For Alyssa Watrous, the medication mix-up meant a pounding headache, nausea and dizziness. In September, Ms. Watrous, a 17-year-old from Connecticut, was about to take another asthma pill when she realized CVS had mistakenly given her blood pressure medication intended for someone else.

Edward Walker, 38, landed in an emergency room, his eyes swollen and burning after he put drops in them for five days in November 2018 to treat a mild irritation. A Walgreens in Illinois had accidentally supplied him with ear drops — not eye drops.

For Mary Scheuerman, 85, the error was discovered only when she was dying in a Florida hospital in December 2018. A Publix pharmacy had dispensed a powerful chemotherapy drug instead of the antidepressant her doctor had prescribed. She died about two weeks later.

The people least surprised by such mistakes are pharmacists working in some of the nation's biggest retail chains.

In letters to state regulatory boards and in interviews with The New York Times, many pharmacists at companies like CVS, Rite Aid and Walgreens described understaffed and chaotic workplaces where they said it had become difficult to perform their jobs safely, putting the public at risk of medication errors.

They struggle to fill prescriptions, give flu shots, tend the drive-through, answer phones, work the register, counsel patients and call doctors and insurance companies, they said — all the while racing to meet corporate performance metrics that they characterized as unreasonable and unsafe in an industry squeezed to do more with less.

"I am a danger to the public working for CVS," one pharmacist wrote in an anonymous letter to the Texas State Board of Pharmacy in April.

"The amount of busywork we must do while verifying prescriptions is absolutely dangerous," another wrote to the Pennsylvania board in February. "Mistakes are going to be made and the patients are going to be the ones suffering."

[Read how you can protect yourself against medication errors.]

State boards and associations in at least two dozen states have heard from distraught pharmacists, interviews and records show, while some doctors complain that pharmacies bombard them with requests for refills that patients have not asked for and should not receive. Such refills are closely tracked by pharmacy chains and can factor into employee bonuses.

Michael Jackson, chief executive of the Florida Pharmacy Association, said the number of complaints from members related to staffing cuts and worries about patient safety had become "overwhelming" in the

past year.

CVS Health ranks eighth on the Fortune 500 list and has nearly 10,000 pharmacies across the United States.Jeenah Moon for The New York Times

The American Psychiatric Association is particularly concerned about CVS, America's eighth-largest company, which it says routinely ignores doctors' explicit instructions to dispense limited amounts of medication to mental health patients. The pharmacy's practice of providing three-month supplies may inadvertently lead more patients to attempt suicide by overdosing, the association said.

"Clearly it is financially in their best interest to dispense as many pills as they can get paid for," said Dr. Bruce Schwartz, a psychiatrist in New York and the group's president.

A spokesman for CVS said it had created a system to address the

issue, but Dr. Schwartz said complaints persisted.

Regulating the chains — five rank among the nation's 100 largest companies — has proved difficult for state pharmacy boards, which oversee the industry but sometimes allow company representatives to hold seats. Florida's nine-member board, for instance, includes a lawyer for CVS and a director of pharmacy affairs at Walgreens.

Aside from creating potential conflicts of interest, the industry presence can stifle complaints. "We are afraid to speak up and lose our jobs," one pharmacist wrote anonymously last year in response to a survey by the Missouri Board of Pharmacy. "PLEASE HELP."

Officials from several state boards told The Times they had limited authority to dictate how companies ran their businesses. Efforts by legislatures in California and elsewhere have been unsuccessful in substantially changing how pharmacies operate.

A majority of state boards do not require pharmacies to report errors, let alone conduct thorough investigations when they occur. Most investigations focus on pharmacists, not the conditions in their workplaces.

In public meetings, boards in at least two states have instructed pharmacists to quit or speak up if they believe conditions are unsafe. But pharmacists said they feared retaliation, knowing they could easily be replaced.

The industry has been squeezed amid declining drug reimbursement rates and cost pressures from administrators of prescription drug plans. Consolidation, meanwhile, has left only a few major players. About 70 percent of prescriptions nationwide are dispensed by chain

drugstores, supermarkets or retailers like Walmart, according to a 2019 Drug Channels Institute report.

CVS garners a quarter of the country's total prescription revenue and dispenses more than a billion prescriptions a year. Walgreens captures almost 20 percent. Walmart, Kroger and Rite Aid fall next in line among brick-and-mortar stores.

In statements, the pharmacy chains said patient safety was of utmost concern, with staffing carefully set to ensure accurate dispensing. Investment in technology such as e-prescribing has increased safety and efficiency, the companies said. They denied that pharmacists were under extreme pressure or faced reprisals.

"When a pharmacist has a legitimate concern about working conditions, we make every effort to address that concern in good faith," CVS said in a statement. Walgreens cited its confidential employee hotline and said it made "clear to all pharmacists that they should never work beyond what they believe is advisable."

Errors, the companies said, were regrettable but rare; they declined to provide data about mistakes.

The National Association of Chain Drug Stores, a trade group, said that "pharmacies consider even one prescription error to be one too many" and "seek continuous improvement." The organization said it was wrong to "assume cause-effect relationships" between errors and pharmacists' workload.

The specifics and severity of errors are nearly impossible to tally. Aside from lax reporting requirements, many mistakes never become public because companies settle with victims or their families, often requiring

a confidentiality agreement. A CVS form for staff members to report errors asks whether the patient is a “media threat,” according to a photo provided to The Times. CVS said in a statement it would not provide details on what it called its “escalation process.”

A CVS form for pharmacy staff members to report errors asks whether the patient is a “media threat.”

The last comprehensive study of medication errors was over a decade ago: The Institute of Medicine estimated in 2006 that such mistakes harmed at least 1.5 million Americans each year.

Jonathan Lewis said he waited on hold with CVS for 40 minutes last summer, after discovering his antidepressant prescription had been refilled with another drug.

Mr. Lewis, 47, suspected something was wrong when he felt short of breath and extremely dizzy. Looking closely at the medication — and turning to Google — he figured out it was estrogen, not an antidepressant, which patients should not abruptly quit.

“It was very apparent they were very understaffed,” Mr. Lewis said, recalling long lines inside the Las Vegas store and at the drive-through when he picked up the prescription.

Pharmacists have written to state regulatory boards about their safety concerns.

Too Much, Too Fast

The day before Wesley Hickman quit his job as a pharmacist at CVS, he worked a 13-hour shift with no breaks for lunch or dinner, he said.

As the only pharmacist on duty that day at the Leland, N.C., store, Dr.

Hickman filled 552 prescriptions — about one every minute and 25 seconds — while counseling patients, giving shots, making calls and staffing the drive-through, he said. Partway through his shift the next day, in December 2018, he called his manager.

Wesley Hickman, who now runs an independent pharmacy, left a job at CVS because of conditions he described as unsafe.Jeremy M. Lange for The New York Times

“I said, ‘I am not going to work in a situation that is unsafe.’ I shut the door and left,” said Dr. Hickman, who now runs an independent pharmacy.

Dr. Hickman felt that the multitude of required tasks distracted from his most important jobs: filling prescriptions accurately and counseling patients. He had begged his district manager to schedule more pharmacists, but the request was denied, he said.

CVS said it could not comment on the “individual concerns” of a former employee.

With nearly 10,000 pharmacies across the country, CVS is the largest chain and among the most aggressive in imposing performance metrics, pharmacists said. Both CVS and Walgreens tie bonuses to achieving them, according to company documents.

Editors’ Picks

[Sarah Polley Is OK With Oversharing]

[Feb. 17, 2022]

[‘The Batman’ Review: Who’ll Stop the Wayne?]

Nearly everything is tracked and scrutinized: phone calls to patients, the time it takes to fill a prescription, the number of immunizations given, the number of customers signing up for 90-day supplies of medication, to name a few.

The fact that tasks are being tracked is not the problem, pharmacists say, as customers can benefit from services like reminders for flu shots and refills. The issue is that employees are heavily evaluated on hitting targets, they say, including in areas they cannot control.

In Missouri, dozens of pharmacists said in a recent survey by the state board that the focus on metrics was a threat to patient safety and their own job security.

“Metrics put unnecessary pressure on pharmacy staff to fill prescriptions as fast as possible, resulting in errors,” one pharmacist wrote.

Of the nearly 1,000 pharmacists who took the survey, 60 percent said they “agree” or “strongly agree” that they “feel pressured or intimidated to meet standards or metrics that may interfere with safe patient care.” About 60 percent of respondents worked for retail chains, as opposed to hospitals or independent pharmacies.

Surveys in Maryland and Tennessee revealed similar concerns.

The specific goals are not made public, and can vary by store, but internal CVS documents reviewed by The Times show what was expected in some locations last year.

Staff members were supposed to persuade 65 percent of patients picking up prescriptions to sign up for automatic refills, 55 percent to

switch to 90-day supplies from 30-day, and 75 percent to have the pharmacy contact their doctor with a “proactive refill request” if a prescription was expiring or had no refills, the documents show.

Prescriptions at Dr. Hickman's pharmacy. When he worked at CVS, he said, longtime patients sometimes signed up for automatic refills as a favor to help him meet corporate metrics.Jeremy M. Lange for The New York Times

Pharmacy staff members are also expected to call dozens of patients each day, based on a computer-generated list. They are assessed on the number of patients they reach, and the number who agree to their requests.

Representatives from CVS and Walgreens said metrics were meant to provide better patient care, not penalize pharmacists. Some are related to reimbursements to pharmacies by insurance companies and the government. CVS said it had halved its number of metrics over the past 18 months.

But dozens of pharmacists described the emphasis on metrics as burdensome, and said they faced backlash for failing to meet the goals or suggesting they were unrealistic or unsafe.

“Any dissent perceived by corporate is met with a target placed on one’s back,” an unnamed pharmacist wrote to the South Carolina board last year.

In comments to state boards and interviews with The Times, pharmacists explained how staffing cuts had led to longer shifts, often with no break to use the restroom or eat.

“I certainly make more mistakes,” another South Carolina pharmacist wrote to the board. “I had two misfills in three years with the previous

staffing and now I make 10-12 per year (that are caught)."

Much of the blame for understaffing has been directed at pressure from companies that manage drug plans for health insurers and Medicare.

Acting as middlemen between drug manufacturers, insurers and pharmacies, the companies — known as pharmacy benefit managers, or P.B.M.s — negotiate prices and channel to pharmacies the more than $300 billion spent on outpatient prescription drugs in the United States annually.

The benefit managers charge fees to pharmacies, and have been widely criticized for a lack of transparency and applying fees inconsistently. In a letter to the Department of Health and Human Services in September, a bipartisan group of senators noted an "extraordinary 45,000 percent increase" in fees paid by pharmacies from 2010 to 2017.

While benefit managers have caused economic upheaval in the industry, some pharmacy chains are players in that market too: CVS Health owns CVS Caremark, the largest benefit manager; Walgreens Boots Alliance has a partnership with Prime Therapeutics; Rite Aid owns a P.B.M., too.

Walgreens draws nearly 20 percent of the United States' total prescription revenue.Jeenah Moon for The New York Times

The Pharmaceutical Care Management Association, the trade group representing benefit managers, contends that they make prescriptions more affordable, and pushes back against the notion that P.B.M.s are responsible for pressures on pharmacies, instead of a competitive

market.

Pharmacists have written to state regulatory boards about their safety concerns.

Falling Through the Cracks

Dr. Mark Lopatin, a rheumatologist in Pennsylvania, says he is inundated with refill requests for almost every prescription he writes. At times Dr. Lopatin prescribes drugs intended only for a brief treatment — a steroid to treat a flare-up of arthritis, for instance.

But within days or weeks, he said, the pharmacy sends a refill request even though the prescription did not call for one. Each time, his office looks at the patient's chart to confirm the request is warranted. About half are not, he said.

Aside from creating unnecessary work, Dr. Lopatin believes, the flood of requests poses a safety issue. "When you are bombarded with refill after refill, it's easy for things to fall through the cracks, despite your best efforts," he said.

Pharmacists told The Times that many unwanted refill requests were generated by automated systems designed in part to increase sales. Others were the result of phone calls from pharmacists, who said they faced pressure to reach quotas.

In February, a CVS pharmacist wrote to the South Carolina board that cold calls to doctors should stop, explaining that a call was considered "successful" only if the doctor agreed to the refill.

"What this means is that we are overwhelming doctor's office staff with

constant calls, and patients are often kept on medication that is unneeded for extended periods of time," the pharmacist wrote.

CVS says outreach to patients and doctors can help patients stay up-to-date on their medications, and lead to lower costs and better health.

Dr. Rachel Poliquin, a psychiatrist in North Carolina who says she constantly gets refill requests, estimates that about 90 percent of her patients say they never asked their pharmacy to contact her.

While Dr. Poliquin has a policy that patients must contact her directly for more medication, she worries about clinics where prescriptions may get rubber-stamped in a flurry of requests. Then patients — especially those who are elderly or mentally ill — may continue taking medication unnecessarily, she said.

The American Psychiatric Association has been trying to tackle a related problem after hearing from members that CVS was giving patients larger supplies of medication than doctors had directed.

While it is common for pharmacies to dispense 90 days' worth of maintenance medications — to treat chronic conditions like high blood pressure or diabetes — doctors say it is inappropriate for other drugs.

For example, patients with bipolar disorder are often prescribed lithium, a potentially lethal drug if taken in excess. It is common for psychiatrists to start a patient on a low dose or to limit the number of pills dispensed at once, especially if the person is considered a suicide risk.

But increasingly, the psychiatric association has heard from members that smaller quantities specified on prescriptions are being ignored,

particularly by CVS, according to Dr. Schwartz, the group's president.

CVS has created a system where doctors can register and request that 90-day supplies not be dispensed to their patients. But doctors report that the registry has not solved the problem, Dr. Schwartz said. In a statement, CVS said it continued to "refine and enhance" the program.

Dr. Charles Denby, a Rhode Island psychiatrist, said CVS ignored his explicit directions not to dispense 90-day supplies of medication to patients.Tony Luong for The New York Times

Even after he began stamping the instructions on prescriptions, he said, CVS would tell him the "baldfaced lie" that his patients were asking for 90-day supplies. Dr. Denby's D.E.A. number has been redacted.Tony Luong for The New York Times

Dr. Charles Denby, a psychiatrist in Rhode Island, became so concerned by the practice that he started stamping prescriptions, "AT MONTHLY INTERVALS ONLY." Despite those explicit instructions, Dr. Denby said, he received faxes from CVS saying his patients had asked for — and been given — 90-day supplies.

Dr. Denby, who retired in December, said it was a "baldfaced lie" that the patients had asked for the medication, providing statements from patients saying as much.

"I am disgusted with this," said Dr. Denby, who worries that patients may attempt suicide with excess medication. "There are going to be people dead only because they have enough medication to do the deed with."

'We Already Have Systems in Place'

Alton James never learned how the mistake came about that he says killed his 85-year-old mother, Mary Scheuerman, in 2018.

He knows he picked up her prescription at the pharmacy in a Publix supermarket in Lakeland, Fla. He knows he gave her a pill each morning. He knows that after six days, she turned pale, her blood pressure dropped and she was rushed to the hospital.

Mary Scheuerman died in December 2018 after taking a powerful chemotherapy drug mistakenly dispensed by a Publix pharmacy. Her son said she was supposed to have received an antidepressant.

Mr. James remembers a doctor telling him his mother's blood had a toxic level of methotrexate, a drug often used to treat cancer. But Mrs. Scheuerman didn't have cancer. She was supposed to be taking an antidepressant. Mr. James said a pharmacy employee later confirmed that someone had mistakenly dispensed methotrexate.

Five days after entering the hospital, Mrs. Scheuerman died, with organ failure listed as the lead cause, according to medical records cited by Mr. James.

The Institute for Safe Medication Practices has warned about methotrexate, listing it as a "high-alert medication" that can be deadly when taken incorrectly. Mr. James reported the pharmacy's error to the group, writing that he wanted to raise awareness about the drug and push Publix, one of the country's largest supermarket chains, to "clean up" its pharmacy division, according to a copy of his report provided to The Times.

Trexall, a brand name for the drug methotrexate, can be used to treat cancer.

The company acknowledged the mistake and offered a settlement, Mr. James wrote, but would not discuss how to avoid future errors, saying, "We already have systems in place."

Last September, Mr. James told The Times that Publix wanted him to

sign a settlement agreement that would prevent him from speaking further about his mother's death. Mr. James has since declined to comment, saying that the matter was "amicably resolved."

A spokeswoman for Publix said privacy laws prevented the company from commenting on specific patients.

It can be difficult for patients and their families to decide whether to accept a settlement.

Last summer, CVS offered to compensate Kelsey and Donavan Sullivan after a pediatrician discovered the reflux medication they had been giving their 4-month-old for two months was actually a steroid. To be safely weaned, the baby had to keep taking it for two weeks after the error was discovered.

"It was like he was coming out of a fog," Mrs. Sullivan recalled.

Kelsey and Donavan Sullivan with their son, Finnegan. Last year, a CVS mistakenly dispensed a steroid for the baby in place of reflux medication. Nina Robinson for The New York Times

The couple, from Minnesota, are still considering a settlement but haven't agreed to anything because they don't know what long-term consequences their son might face.

The kinds of errors and how they occur vary considerably.

The paper stapled to a CVS bag containing medication for Ms. Watrous, the Connecticut teenager with asthma, listed her correct name and medication, but the bottle inside had someone else's name.

Directions on the prescription for Mr. Walker, the Illinois man who got ear drops instead of eye drops from Walgreens, were clear: "Instill 1

drop in both eyes every 6 hours." He later saw the box: "For use in ears only."

In September, Stefanie Davis, 31, got the right medicine, Adderall, but the wrong dose. She pulled over on the interstate after feeling short of breath and dizzy with blurred vision. The pills, dispensed by a Walgreens in Sun City Center, Fla., were each 30 milligrams instead of her usual 20. She is fighting with Walgreens to cover a $900 bill for her visit to an emergency room.

Fixes That Fall Short

State boards and legislatures have wrestled with how to regulate the industry. Some states have adopted laws, for instance introducing mandatory lunch breaks or limiting the number of technicians a pharmacist can supervise.

But the laws aren't always followed, can be difficult to enforce or can fail to address broader problems.

The National Association of Chain Drug Stores says some state boards are blocking meaningful change. The group, for instance, wants to free up pharmacists from some tasks by allowing technicians, who have less training, to do more.

It also supports efforts to change the insurance reimbursement model for pharmacies. Health care services provided by pharmacists to patients, such as prescribing birth control, are not consistently covered by insurers or allowed in all states. But it has been difficult to find consensus to change federal and state regulations.

While those debates continue, some state boards are trying to hold

companies more accountable.

For Mrs. Sullivan's infant to safely wean off the high-dose steroid he was given by mistake, he had to keep taking it for two weeks after the error was discovered.Nina Robinson for The New York Times

Often when an error is reported to a board, action is taken against the pharmacist, an obvious target. It is less common for a company to be scrutinized.

The South Carolina board discussed in November how to more thoroughly investigate conditions after a mistake. It also published a statement discouraging quotas and encouraging "employers to value patient safety over operational efficiency and financial targets."

California passed a law saying no pharmacist could be required to work alone, but it has been largely ignored since taking effect last year, according to leaders of a pharmacists' union. The state board is trying to clarify the law's requirements.

In Illinois, a new law requires breaks for pharmacists and potential penalties for companies that do not provide a safe working environment. The law was in response to a 2016 Chicago Tribune investigation revealing that pharmacies failed to warn patients about dangerous drug combinations.

Some states are trying to make changes behind closed doors. After seeing results of its survey last year, the Missouri board invited companies to private meetings early this year to answer questions about errors, staffing and patient safety.

CVS and Walgreens said they would attend.

Research was contributed by Susan C. Beachy, Jack Begg, Alain

SB840-INFO-Pharmacy Gave Children Wrong Shot Dose.
Uploaded by: Jenna Butler
Position: UNF

Virginia Pharmacy Gave Wrong COVID Vaccine Dosage to Children 5-11

Ted Pharmacy In Loudoun County can no longer provide COVID-19 vaccines after health officials say more than 100 children were given the wrong dosage

By Cory Smith, News4 Reporter • Published November 10, 2021 • Updated on November 10, 2021 at 8:39 pm

NBC Universal, Inc.

The health department in Loudoun County began administering COVID-19 shots to children ages 5 to 11. News4's Justin Finch reports what parents in the area need to know.

A pharmacy in Loudoun County, Virginia, gave the wrong COVID-19 vaccine dosage to some children, worrying parents and leading health officials to send out a warning to families Wednesday.

Ted Pharmacy, located in a building on Stone Carver Drive in Aldie, admitted to giving children 5-11 a dose of the vaccine meant for people 12 years and older. The Virginia Department of Health said about 112 children in Loudoun County are affected.

Dasha Hermosilla told News4 a pharmacist at Ted Pharmacy gave her daughter, 7-year-old Gryffin Fahle, a diluted dose of the vaccine for people 12 and older, which comes in a vial with a purple cap, not the orange cap of the vaccine meant for younger children.

She said the pharmacist told them it was OK. But a simple Google search later confirmed Hermosilla's fear that it was not.

"Nothing says that you can change a purple to an orange," Hermosilla said. "I had this pit in my stomach that, like, what did they just do to my daughter?"

Hermosilla wasn't the only parent asking that question. Another mom sent News4 a screengrab of a Facebook conversation in which the pharmacy admitted to the mistake and apologized for the "inconvenience."

"The way they have dealt with individuals is really, like, 'Oh, it's no big deal,'" Hermosilla said. "There are dozens and dozens of families out there that don't even know that this is an issue."

State health officials told parents the Virginia Board of Pharmacy has opened an investigation, but the agency would neither confirm nor deny that when News4 inquired.

After News4's interview with Hermosilla, the Loudoun County Health Department released an alert about the pharmacy's error.

"The pharmacy who administered the Pfizer COVID-19 vaccination to your child last week has been removed from both state and federal COVID-19 vaccination programs," Loudoun County Department of Health Director David Goodfriend said in the letter.

The health department said parents of affected children should first consult with their child's pediatrician to decide the best course of action.

If a lower dosage of the vaccine meant for people 12 and older is given to younger children, parents can wait 21 days to restart the correct COVID-19 vaccine series, according to the Centers for Disease Control and Prevention.

Parents can either wait the 21 days or proceed with getting the second dose as scheduled, ensuring it is the correct vaccine with the orange cap, the county health department said.

Health officials also said parents should watch for side effects of the vaccine, such as fever, chills, fatigue and pain or redness at the injection site and call their pediatrician if their child has prolonged or more serious side effects.

Goodfriend said in the letter that Ted Pharmacy relinquished the rest of its COVID-19 vaccines to the health department.

Below is the full statement a spokesperson for Virginia's Board of Pharmacy gave News4:

Virginia's Board of Pharmacy (BOP) takes seriously the mission of the Department of Health Professions which is to ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public.

It is important to note under Virginia law 54.1-2400.2, Virginia's health regulatory boards, including the Board of Pharmacy (BOP), are not at liberty to confirm nor deny whether an investigation into a possible violation of a law or regulation is or is not underway.

Should an investigation reveal there is probable cause to believe a law

or regulation was broken an Informal Conference or a Formal Hearing before the board may be held for consideration of possible disciplinary action. The Board's findings of fact and resulting actions are contained in a Board Order that becomes a matter of public record available online on the Board of Pharmacy's website under License Lookup and Recent Case Decisions.

BOP licenses and regulates approximately 75,000 practitioners and entities; inspects pharmacy facilities; manages practitioner and patient registration for the use of medical cannabis and regulates the state's five pharmaceutical processor permit holders.

SB840-INFO-Shots Given Incorrectly.pdf
Uploaded by: Jenna Butler
Position: UNF

Half of All New Federal Vaccine Cases Allege Injury From Shots Given Incorrectly

By Jodie Fleischer, News4 I-Team Reporter, Rick Yarborough and Jeff Piper • Published May 1, 2018 • Updated on May 2, 2018 at 7:05 pm

An I-Team review found half of all the new federal vaccine injury cases allege “shoulder injury resulting from vaccine administration,” or SIRVA, and have little or nothing to do with what was in the syringe. Jodie Fleischer reports.

After months of questioning by the News4 I-Team, two federal agencies have vowed to study injuries from vaccines alleged to have been given incorrectly.

An I-Team review found half of all the new federal vaccine injury cases allege “shoulder injury resulting from vaccine administration,” or SIRVA, and have little or nothing to do with what was in the syringe.

Both the Centers for Disease Control and the Health Resources and Services Administration previously told the I-Team there were no comprehensive studies of SIRVA underway, despite the relevant information being filed into thousands of court cases alleging that injury. The influx of new SIRVA cases has further hampered an already backlogged court system riddled with delays.

Those cases allege the shots were administered incorrectly — usually too high on the arm — but the I-Team found the program has no mechanism to notify the shot-giver of the injury he or she likely caused. Thus, they would have no reason to seek additional training.

'The Most Excruciating Pain I've Ever Had'

Ann Wyborski didn't think twice when her OB-GYN suggested she get her flu shot in 2013. She was nine months pregnant at the time.

"They swabbed the whole area," she told the News4 I-Team. "But as soon as [the needle] went in I said, 'That's too high.'"

Wyborski says by the time she got to her car, she struggled to put on her seatbelt. She couldn't type on her keyboard at work or do anything around the house.

"It was a throbbing constant pain — the most excruciating pain I've ever had," she said.

About a week later she went into labor and gave birth to her baby boy. She had trouble nursing and even holding him.

"I realized there was a massive problem because I had just had major surgery and I was crying about the pain in my arm, not from my C-section," she said.

She went to her doctor and an orthopedic specialist, but they didn't know what was causing her pain. They even sent her to physical therapy, which Wyborski says worsened her condition.

She was suffering from SIRVA.

"The person administered the shot in the wrong spot, is basically what happens — usually too high on the arm," explained Renee Gentry, who runs the Vaccine Injury Law Clinic at George Washington University.

Gentry says SIRVA has become so common; it's now covered under the

National Vaccine Injury Compensation Program — a nearly $3.7 billion trust fund created and run by the federal government to take care of victims with catastrophic reactions to vaccines.

"Vaccines have been an extraordinary contribution to society," said Gentry, "but they're not magic. They are pharmaceuticals, and anyone can react to them."

To keep companies developing and producing vaccines, the government took on the liability back in the late 1980s, protecting vaccine-makers and those who give the shots from being sued.

The Vaccine Court

Instead, these cases go through a special vaccine court inside the U.S. Court of Federal Claims.

In a traditional lawsuit, the victim would usually have to show negligence, not just that the vaccine caused the injury within a certain timeframe.

More than 80 percent of all compensation awards in the vaccine court are negotiated settlements, which allows the government to include language stating it has not concluded, based on the review of the evidence, that the vaccine caused the injury.

A $0.75 tax on every shot given funds the vaccine compensation. Since the program started, about 6,000 victims have received nearly $4 billion.

"It has good intentions and it means well, it's just not being implemented correctly," said Martha Toomey, a parent of a vaccine-

injured child.

It took Toomey more than a decade to get compensated after her son, Jeffrey, started having seizures within 24 hours of getting a vaccine. She says he ended up with a traumatic brain injury and a lifetime of health problems.

"There are a lot of words in the English language," said Toomey, "but I can't think of anything that would describe that kind of hell."

Hers is the kind of family the Vaccine Court was designed to help, but the program now has five times the number of cases it had in 2011, and Congress has never increased the number of judges allowed to hear them.

"Right now, the earliest available hearing date is in 2020," said Gentry.

The U.S. Department of Health and Human Services declined the I-Team's request for an on-camera interview.

But after a month of questioning, the agency finally acknowledged half of all the new cases filed in the court last year were not vaccine reactions — they were SIRVA cases.

"It's frustrating, I think, for everyone involved in it, because it's preventable," said Gentry.

‘You Can't Make Informed Decisions If You Don't Have The Information’

And the I-Team discovered no one keeps data on how often SIRVA happens, where it's happening or even which shot-givers caused the injury. So they're never told to improve their technique, which Wyborski

calls ridiculous. She says a temporary nurse from her doctor's office gave her the shot.

"Once an injury happens, they need to follow up and make sure that person doesn't continually injure more people," Wyborski said.

In a statement to the News4 I-Team, HHS admitted it "does not track or monitor this data" — despite the info being filed in to the record with every vaccine court case.

"Somebody at HHS has to say, 'I'm going to take control of this and I'm going to fix it,'" said Toomey, who also serves on a vaccine advisory commission, which recommended Congress double the number of judges for the program in 2016.

HHS has asked for increased funding for the program each year but told the I-Team "as to the allocation of the requested funding, this is a question for the Congress."

"Yes, Congress should look at this," Maryland Sen. Chris Van Hollen told the I-Team.

Van Hollen pointed out that the benefits of getting vaccines still far outweigh the risks, but he says SIRVA is definitely something federal agencies should be tracking.

"We need to collect the data," said Sen. Van Hollen, "because you can't make informed decisions if you don't have the information to start with."

A review by the News 4 I-Team found the Vaccine Injury Compensation Program has paid 575 SIRVA patients more than $76 million while doing

little to fight the problem.

"If you don't inform the people who are doing it wrong, they're not going to learn to do it right," said Van Hollen.

Shot-Givers Aren't Told About Injuries They Likely Caused

The Health Resources and Services Administration is the HHS agency that oversees this program.

A HRSA spokesperson told the I-Team a confidentiality provision in the program prohibits the agency from notifying the vaccine administrator of the corresponding SIRVA case.

Because they are protected from liability, the shot-giver is not a party to the lawsuit, so each SIRVA victim would have to give written consent to allow them to be told about the vaccine injury they likely caused.

When the I-Team asked what's being done to combat the drastic rise in SIRVA cases, HRSA suggested contacting the Centers for Disease Control and Prevention. (Read our entire exchange of questions and answers with HRSA here.)

The CDC says the increase in the number of SIRVA cases could be because more people are getting shots or because more people are aware of SIRVA and reporting it.

Each state decides which medical professionals are allowed to administer vaccines and the training required; some have relaxed their rules over time to make vaccines readily accessible to the public.

The CDC has launched an educational campaign on the correct way to administer shots. They're supposed to be given in the deltoid muscle,

the thick part of the upper arm, but not too close to the shoulder.

In January, a representative from the CDC's Immunization Safety Office told the I-Team it had no comprehensive data on SIRVA occurrences and no immediate plans to do any further investigation.

He had conducted a partial study of voluntary reports submitted to a separate system called VAERS, the Vaccine Adverse Event Reporting System. The CDC found most of the SIRVA injuries reported happened after vaccines were administered at pharmacies or stores but cautioned that that system doesn't verify the injury or identify its cause.

Just last week, the CDC told the I-Team it will now work together with HRSA to conduct an epidemiologic review of the SIRVA claims in the Vaccine Injury Compensation Program, which they're hoping to complete by the end of 2019.

"I think it needs to be fixed," said Wyborski, who got a settlement from the program for her pain and suffering, medical costs, and lost wages.

She says no amount of money is worth what she went through.

"I spent over 18 months in excruciating pain," she said. "You can't get that back."

Reported by Jodie Fleischer, produced by Rick Yarborough, and shot and edited by Jeff Piper.

SB840_Jennifer-Rauhofer_Unfavorable.pdf
Uploaded by: Jennifer Rauhofer
Position: UNF

SB840
COVID Response Act of 2022
Jennifer Rauhofer
Unfavorable

I am writing as a concerned parent who is opposed to this bill. Allowing pharmacists to vaccinate children is reckless as children's immunization schedules are complicated as compared to adults. They should only be receiving vaccinations from a trained medical professional who is aware of their history and health. Why are there so many bills attempting to let other professionals vaccinate children?

I urge you to pull this bill to protect children and allow parents to have a relationship with their pediatrician to get the best outcome for our children.

SB0840 Jessica Helms OPPOSE.pdf
Uploaded by: Jessica Helms
Position: UNF

OPPOSE SB0840

I OPPOSE SB0839. This bill is unnecessary, costly, and discriminatory. DC, Montgomery County, and other places nearby have tried to implement something similar only to rescind it later. The use of a vaccine passport discriminates against minorities, religious peoples, and those with medical issues. It also hurts small businesses. While it might be “optional” now, what’s the prevent it from becoming mandatory later? I OPPOSE SB0840. I also don’t think overworked pharmacists need more to do. Let kids get their shots with their pediatricians.

Thank you,

Jessica Helms

623 Elfin Ave

Capitol Heights, MD 20743

585-610-6119

SB 840.pdf
Uploaded by: Jill Kapper
Position: UNF

Hello,

I’m writing in regards to SB 840. I oppose any vaccine passport as our medical information should be private and not used to divide and segregate the population into vaxxed and unvaxxed. Pharmacies are not doctor's offices and pharmacists (and their assistants) are not doctors. They should not have the authority to ORDER and vaccinate our children even more so without parental or guardian informed consent. Vaccine passports have been withdrawn across the globe. They are unnecessary and represent a violation of personal freedom, privacy and health choice. This bill was originally intended to expire by the end of 2022 and it should expire. It was an emergency use bill intended for a pandemic which has passed. The authorizations given in the original bill should expire as intended. The bill is a mishmash of all kinds of unrelated things from listing the qualifications for certain practictioners to rates for an urgent care center to tracking, testing and funding for a virus that no longer exists. Each of these things should be considered separately with thoughtful debate, not thrown together in a bill that is too far reaching. Lastly, I oppose this bill because many vaccines, including COVID-19, don’t prevent infection or transmission. We can’t implement a vaccine passport for a vaccine that doesn’t prevent transmission or infection. The CDC itself has said that the vaccinated can both get and spread the COVID virus. This makes no sense. Common sense and logic must be used by those in positions to protect American citizens and their rights. I urge you to do just that by voting NO!

I appreciate you hearing my concerns and feel free to reach out with any questions.

-Jill

Document 3 (3).pdf
Uploaded by: John Roswell
Position: UNF

John C. Roswell

6357 Old Washington Road

Elkridge, MD. 21075

3/01/2022

SB0840

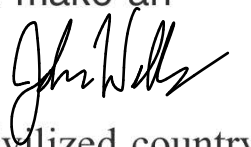
This proposed law if passed will be a bureaucratic waste of time. The vaccines do not prevent the spread of covid. As examples Governor Hogan's wife caught it and even though Prime Minister Trudeau of Canada was vaccinated 3 times he also caught it. Eventually herd immunity may happen which will more likely happen from the omicron strain after effect than from vaccines and all this unnecessary fear of covid 19 will go away.

John C. Roswell

IMG_2548.pdf
Uploaded by: John Wells
Position: UNF

Forcing or coercing someone in any way to take a vaccine or any medication violates the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. The first of its ten points begins as follows:

"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, overreaching, 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 code of ethics must be upheld in any civilized country.

The COVID-19 vaccines were not tested for long-term effects and thus were and are experimental. Each person should choose whether to take the vaccine or not. Future vaccines may have similar experimental natures or may be carefully tested. Regardless, each person must have the right to accept or refuse the vaccine without any coercion, or penalty.

SB840_Sharpe_UNfav.pdf
Uploaded by: Julie Sharpe
Position: UNF

SB840_SHARPE_unfav

Dear Senators.

I have concerns about vaccine passports; this bill assumes them and builds upon them.

We know that a vaccine passport might be a convenience, as long as the promised security of our private information is maintained. It is hard to be sure: Maryland Health Department data was compromised earlier this year. Hopefully that won't happen again.

But there are other issues that are more concerning. If Maryland institutes a vaccine passport, for now, it is about covid; this bill allows for future boosters to be added on. We might be fine with the original intention of the passport and with the vaccines it was originally designed to record. But how many boosters are enough? The Washington Post reported that booster effectiveness declined substantially after four months, suggesting the need for additional boosters. Israel is finding a fourth dose insufficient against Omicron. So we might have been fine with the first two or three but not want to get another.

Or what if there are other adult vaccines that become required but that we don't want to take? This bill allows any future CDC approved vaccine to be added to it. If I don't comply, will my passport go invalid? Will I then be compelled to receive the shots for the sake of maintaining my ability to function in a world we created by setting up this system in the first place?

Or will anyone who doesn't comply be relegated to the "other" tier of society?

What about passports for our kids? There are reasons many parents have been reluctant to sign up their kids for these new covid vaccines. There is a reasonable caution since we don't know, we can't possibly know, the long term effects until sufficient time has passed. So parents wait. Unless there is a passport system and our kids must be signed up. Coercion like this does not feel entirely about health, though.

My sister lives in Manhattan. She recently ate at a restaurant where her husband and she were asked for their papers. They showed them, but she said it felt wrong. Normalizing showing our proof of vaccination feels like an echo of a cautionary dystopian novel, not a preferred progressive future.

A passport system that can potentially compromise private information, that has an open ended number of requisite vaccines, and which compels parents to make a choice that is maybe against their better judgement is not a system we should institute in Maryland.

A vaccine passport system is a bad idea. Vote no for 840.

Vaccine Bills Testimony.pdf
Uploaded by: Justin Foster
Position: UNF

Forcing or coercing someone in any way to take a vaccine or any medication violates the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. The first of its ten points begins as follows:

“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, overreaching, 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 code of ethics must be upheld in any civilized country. The COVID-19 vaccines were not tested for long-term effects and thus were and are experimental. Each person should choose whether to take the vaccine or not. Future vaccines may have similar experimental natures or may be carefully tested. Regardless, each person must have the right to accept or refuse the vaccine without any coercion, or penalty.

Signed,
Justin J. Foster

Justin Foster

Type text here

Opposition to SB 840.pdf
Uploaded by: Justin Kuk
Position: UNF

To Finance Committee Members:

I am writing to urge you to reject SB 840. The bill not only contains the same COVID-19 vaccine passport provisions as SB 839, but it also requires the use of taxpayer money to promote and incentivize vaccination. While the MyIR Mobile App is currently a voluntary system, it is an inappropriate function of the government to contribute to regulating access to venues, events, and services based on vaccination status. Standardizing a COVID-19 vaccine passport system is a state-sponsored endorsement of COVID-19 vaccine mandates and discrimination.

Many states have already prohibited such vaccine passports and I believe that Maryland would be wise to oppose this bill. Cities that implemented vaccine passport systems, such as New York City, were not able to slow the spread of COVID during the Omicron wave. Even if implemented with good intentions, the vaccine passport systems are not an effective mitigation measure.

Beyond that, they will segregate our society based on vaccination status, which will have the unintended consequence of segregating our society based on race and class. Even if it is not its intention, this bill will have a disparate impact on black, brown, and lower-class Marylanders and prevent them from fully participating in community life. That is a step backward that our state cannot support.

Finally, I believe that this bill is a violation of the principles of medical freedom laid out established in the Nuremberg Code in 1947 after the terrible acts that took place at the hands of the Nazi regime in the name of science. The first of ten points begins as follows: “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, overreaching 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.”

Even if the MyIR Mobile App is a voluntary program, it is still a form of state-sponsored coercion that is attempting to make it more difficult for individuals to make a free choice regarding vaccination. Many people have legitimate religious, philosophical, medical, scientific, and logical reasons why they do not want to participate in a mass vaccination experiment in which the potential long-term side effects are unknown.

SB 840 also requires the Maryland Department of Health to submit a plan to the legislature which must include items such as measures to increase vaccination rates among the unvaccinated, even though many of these individuals have made an informed consent decision to remain unvaccinated or may have superior immune protection in the form of natural immunity. At this point, virtually everyone is aware of the COVID-19 vaccine and boosters. It is not a prudent use of taxpayer money to continue to promote and incentivize vaccine uptake.

Finally, bill also allows pharmacists to delegate vaccine administration to pharmacy technicians who have completed a six-hour training course. This is not adequate training for vaccine administration when adverse events can occur, even if the rates of adverse events are low. Finally, the Maryland Medical Assistance Program provides

Medicaid benefits. The provisions of this bill lay the groundwork for discrimination against unvaccinated individuals who rely on Medicaid for their health coverage, as these people would be excluded from these incentives.

I do not believe that it would be wise for the legislature to support SB 840. We have seen during this pandemic that people are voting with their feet and leaving areas that have already experimented with vaccine passport systems, such as California and New York, for states where individual freedom and autonomy are respected and protected. A Maryland with a vaccine passport system is a weaker Maryland, a more totalitarian Maryland, a more segregated Maryland, and a more divided Maryland. As leaders of this state, I call on you to reject SB 840 and protect the freedom of all Marylanders.

Sincerely,

Justin Kuk
Baltimore, Maryland

SB840_Fisher_UNF.pdf
Uploaded by: Kara Fisher
Position: UNF

SB840: COVID-19 Response Act of 2022

UNFAV

Kara Fisher

Dear Chair, Vice Chair and Senate Finance Committee:

I ask you to oppose SB 840 including a vaccine passport system.

A system like this is **unnecessary**. It will be an expensive proposition to design, test and implement a digital system and marketing plan. There is no need for any business or organization to see a mobile vaccine record.

A system like this is **discriminatory** against those who will not have the means to acquire a mobile phone or share this data via a mobile device.

A system like this is **risky** as it puts aggregated confidential medical information in one place where it could be vulnerable to hackers.

In addition to opposing the digital vaccine passport, I feel it is **inappropriate for poorly-trained pharmacy techs to vaccinate toddlers** as this bill proposes.

Thank you.

Kara Fisher

District #19

Rockville, MD

Please oppose SB839 and SB840.pdf
Uploaded by: Karen McCullough
Position: UNF

3/1/2022

RE: Please oppose SB839 and SB840

Hello, please oppose SB839 and SB840. The idea of a vaccine passport is discriminatory and a waste of money. The concept that our government would spend money on a passport when 70% of high school students in Baltimore can't read above a 5th grade level is ridiculous. This really shows the priority of the government in Maryland. The passport won't stop the spread of the virus and could potentially allow vaccinated people who have the virus to spread a virus while health unvaccinated and those who have natural immunity would be discriminated against similar to what black people fought and died to overcome in this country. I guess we will soon see "Vaccinated" and "Unvaccinated" bathrooms soon.

Furthermore, how on earth is a pharmacy technician qualified after 6 weeks of training to know the contraindications of administering vaccines to my child without knowing their health history. Pediatricians are trained to properly access risk factors and pharmacist are not. It is absolutely unbelievable that government officials feel they should be making laws like this that they hold no one liable when something goes wrong, and EVERYTHING falls on the parent. The pharmaceutical company isn't held liable do the 1986 National Childhood Vaccine Injury Act, the doctors, pharmacist, government will all have immunity when something goes wrong and a child is serious harmed and/or dies.

I am a Maryland citizen and will be watching this bill closely and voting accordingly in the next election. I will also be deciding if I want to live in a state (where I contribute my taxes to) where its government believes that carrying around a passport to prove that I have injected drugs in my system is synonymous with living in the "land of the FREE".

Regard

Karen

MD Covid 19 response bill SB0840 letter.pdf
Uploaded by: Kathleen Shoemaker
Position: UNF

3/1/2022

Dear Maryland General Assembly,

I oppose the MD Senate bill SB0840. I oppose ANY regulations related to Covid 19 that take away any citizen's rights. It is not right when a bill:

1) **will REMOVE a citizen's right to body integrity:**
   [Everyone has the right to maintain bodily integrity by declining medical interventions to which they do not give informed consent apart from coercion.]

2) **will UNDERMINE medical or religious exemptions:**
   [Forcing or coercing someone in any way to take a vaccine or any medication violates the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. People decline COVID-19 vaccines for medical reasons or sincerely held ethical, moral, or religious beliefs. The valued and valuable ethical and legal traditions of the United States and Maryland are clear that it not acceptable to discriminate on the basis of medical condition/disability or on the basis of religion/religious belief.]

3) **will establish a SEPERATIST PRECEDENT:**
   [COVID passports set the groundwork for a two-tiered society, in which persons who have received vaccinations may live normal lives (including work, schooling, right to assembly, and access to various services) and persons who have not received vaccinations are denied those rights.]

4) **will WEAKEN each citizen's medical privacy:**
   [First, the websites/apps used to hold these passports will be easy prey for hackers to steal medical and personal information. Second, Doctor/medical practitioner-patient confidentiality is legally protected and essential for a myriad of reasons, and the privacy & protection of medical records is also important. The COVID-19 passports and other COVID requirements erode or remove these legal protections.]

For these reasons (and more), I implore you to not pass this bill. Sincerely,

Kathleen Shoemaker
8308 Painted Rock Road, Columbia MD 21045

SB 840.pdf
Uploaded by: Kathy Jaggers
Position: UNF

Senate Bill 840

Forcing someone in any way to take any medication violates the Nuremburg Code established in 1947. It emphasizes voluntary consent and the free power of choice without any **constraint or coercion.**

The ethical and legal traditions of Maryland have long countered discrimination based on medical condition and religious belief. They must continue to do so. We must not violate doctor/patient confidentiality and medical privacy. These would be seriously eroded with any kind of covid passport or other requirements.

Everyone has the right to bodily integrity. Those who are willing to destroy an unborn child which is its own person are on the other hand saying that persons must accept, under pain of joining an underclass, a medical procedure for which he or she does not give informed consent.

A vaccine passport is a further step in the direction of Communist style surveillance and the Chinese social credit system. Why protest the invasion of Ukraine when Maryland government proposes its own invasion of privacy and bodily integrity?

Anti Vax Mandate (1).pdf
Uploaded by: Kristin Treacy
Position: UNF

Forcing or coercing someone in any way to take a vaccine or any medication violates the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. The first of its ten points begins as follows:

“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, overreaching, 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 code of ethics must be upheld ion any civilized country.

SB0840.pdf
Uploaded by: Laura Gallo
Position: UNF

SB0840

UNFAV

Laura Gallo

I strongly oppose the creation of an electronic vaccine passport and allowing any vaccines to be administered without parental informed consent.

SB840 Oral Testimony.pdf
Uploaded by: Laura Hartman
Position: UNF

SB840 Oral Testimony

Hello, I am a lifelong resident of Maryland and am here with you today out of sheer terror as it relates to this bill.

I have two boys age 12 and 14 and under no circumstance would I ever consider making them part of a medical experiment. And in a democracy that is my right.

There have been thousands of calls and emails from concerned Maryland parents all around the state, to Senator Rosapepe to remove this bill, yet here we are.

As a mother who has been blessed with two healthy boys, why would I consider risking their short or long-term health for a vaccine that does not reduce transmission or infection? Why wouldn't I instead take the risk of getting a respiratory illness that is treatable and 99.8% survivable? That's not a selfish question. My husband and I thought long and hard about what would be best for our community, our friends, our parents, our children. Because we weren't sure, we waited.

Boys have a 1 in 50 chance of Myocarditis from the vaccine. Myocarditis in not treatable-it weakens the heart muscle and there is no turning back for these boys.

Here are some questions for you:

1. Why do we need the State Department of Education to be involved with my family's medical decisions? Are they knocking education out of the park and have free time?
2. Why are we still sticking with the narrative that the covid vaccines are good for us?
    a. As of last week, according to the CDC,VAERS has 1.9M reported adverse effects and 24k deaths directly attributed to the vaccine.
3. Why does the State believe that we should still be encouraging vaccination when it does not stop transmission or infection rates?
4. Why are will still ignoring the early treatment protocols that have saved hundreds of thousands of lives and only mandating vaccination?

This bill is riddled with coercion, enticement and it circumvents the traditional doctor/ patient relationship. The scariest part is this: With this bill, we completely take that right away from parents and give it to pharmacists who have no training, who are not more qualified than my doctor, are not equipped to handle adverse events, and have no systems in place to mitigate mistakes or risks.

Where there is risk, there must be choice. I implore you to vote NO on this bill.

OPPOSE.pdf
Uploaded by: Laura Kuhl
Position: UNF

OPPOSE Vaccine Passport Bills and Threats to Children Two Bills, both sponsored by Senator Rosapeppe should be withdraw	

n or defeated! Oppose SB 839 and SB 840

SB 839- The bill proposes using mobile technology to implement an immunization record

"service" called MyIR. This vaccine passport would display COVID 19 vaccinati on status allegedly for admissio n to certain venues. It would

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payer
money to
develop
and
promote
this
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us and
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ary
“service”.
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ite/Legislation/Details/sb0839

Why we oppose this bill:

1.One's medical information is one's own business and should

not be used to discriminate and segregate citizens based on vaccine status.
2. No business should be discriminating who can or cannot use their service

based on COVID or other vaccination status especially vaccines that are still only Emergency Use Approved.

3.The CDC itself has said that the

vaccinate
d can
both get
and
spread
COVID
virus.
Many
unvaccin
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people
have
natural
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which is
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protective
, enduring

and a benefit to the public. 4.One's medical informati on should be protected informati on but we have seen repeatedl y that "protecte d"

informati
on can be
hacked.
5.Vaccine
passports
have
been
withdraw
n across
the globe.
They are
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ary and
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freedom, privacy and health choice. 6.Public funding would be used to develop and market an unecessa ry program which lays the foundatio

n for chilling governm ent tracking, surveillan ce, divisivene ss and control.

SB 840- This bill was originally passed last year as

Emergency Use Authorization that was supposed to expire at the end of this year. This bill extends to 2024 emergency use authorizations that are no

longer required! Furthermore it expands the authority and reach of administrators regarding testing, contact tracing and protocols in

multiple settings to "control" COVID 19, a virus that no longer exists! The bill is allegedly to be able to reopen schools, colleges and workplac es which

are already open.

But there are even more egregious things in this sweeping bill which talks about the vaccine passport structure mentione

d in SB839 as though it were already law. The bill talks about incentivizing vaccine uptake of ANY CDC recommended vaccine now or in the

future. How can we possibly know if that is a good idea when we don't know what the risks and benefits might be? And every parent should be

outraged that the bill wants to allow a PHARMACIST (or his delegated assistant) to have the authority to ORDER and ADMINISTER a vaccine

to a child 3 or older and does not even require parental informed consent!

There is more in this egregious bill that is way too broad and includes

everythin
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qualificati
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to rates
for an
Urgent
Care
Center.
What
have
these
things
got to do

with each other?
https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/sb0840

Why we oppose this bill:

1. We oppose

any vaccine passport as our medical informati on should be private and not used to divide and segregat e the populatio n into vaxxed and

unvaxxed
.
2.
Vaccine
passports
have
been
withdraw
n globally
3.
Pharmaci
es are not
doctor's
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pharmaci
sts (and
their

assistant s) are not doctors. They should not have the authority to ORDER and vaccinate our children even more so without parental or

guardian informed consent. 4. This bill was originally intended to expire by the end of 2022 and it should expire. It was an emergency use bill intended for a

pandemic which has passed. The authorizations given in the original bill should expire as intended. 5. The bill is a mishmash of all

kinds of unrelated things from listing the qualificati ons for certain practictio ners to rates for an urgent care center to tracking, testing and funding

for a virus that no longer exists. Each of these things should be considered separately with thoughtful debate, not thrown together in a bill

that is too far reaching.	

Dear Finance Committee-2.pdf
Uploaded by: Lelane Schmitt
Position: UNF

Dear Finance Committee,

I am writing as a long-time Maryland resident to ask you to oppose SB840. I am greatly concerned with the many things it addresses. First and foremost, there should be no covid vaccine mandates/passports. The CDC has made a clear statement that the covid vaccines do not stop transmission. And recent numbers tell us that covid cases have dropped dramatically and are reported to continue doing so. Clearly, there is no longer reason for "controlling" the covid virus. This bill also speaks to giving authority to pharmacists to administer vaccines to children without parental consent. Since when are children able to make medical decisions for themselves? My children certainly never were. And I've always relied on the advice of my children's doctors regarding medical procedures, not a pharmacist who has no way of knowing the ins and outs of my children's health. I am especially concerned that this one bill covers so many unrelated topics. Why on earth would they all be combined into one bill? That's ridiculous. It sure seems like the supporting senators want to sneak many things past us constituents. Not at all good governing behavior!

Please please do not allow this bill to move forward!

Thank you.

Lelane Schmitt
March 1, 2022

sb0840.pdf
Uploaded by: Linda Adlum
Position: UNF

I oppose bill SB0840 for the following reasons:

I firmly oppose mandatory COVID vaccines, Vaccine Passports and tracking and tracing apps.

I should have the free choice to determine if I want a COVID shot. Neither government nor private corporations have the right to force me to have a so-called “Vaccine Passport.” Nor should an app that contains my private medical information and that tracks and traces my movement be permitted.

Vaccine passports and other COVID requirements erode or remove legal protections of doctor-patient confidentiality and privacy and protection of medical records. Business should not discriminate who can or cannot use their service using an individual's private medical record. Digital vaccine passport information can be "hacked".

Vaccine passports discriminate and segregate citizens based on vaccine status. Persons who have received vaccinations may live normal lives (including work, schooling, right to assembly, and access to various services) and persons who have not received vaccinations are denied those rights - even medical treatment!

The Covid vaccines are experimental and have not been tested for long term effects. Mandating vaccines to force or coerce someone in any way to take a vaccine or any medication violates the 1947 Nuremberg Code. Everyone has the right to bodily integrity and autonomy, which includes the right to decline medical interventions.

Mandating vaccines ignores natural immunity which is enduring and a benefit to the public.

Vaccine passports have been withdrawn globally. They are unnecessary and represent a violation of personal freedom, privacy and medical choice.

Misuse of digital vaccine passports could easily be expanded to illegal and unjust overreaching surveillance of American citizens by the government, tracking, surveillance, divisiveness and control, and the development of a Communist-style social credit system. Digital vaccine passports presents a serious threat to freedom. My private medical decisions regarding a COVID shot or other vaccine should not determine whether I can leave my home, work, shop, dine or worship.

Pharmacies are not doctor's offices and pharmacists (and their assistants) are not doctors. They should not have the authority to ORDER and vaccinate our children even more so without parental or guardian informed consent.

This bill was originally intended to expire by the end of 2022 and it should expire. It was an emergency use bill intended for a pandemic which has passed. The authorizations given in the original bill should expire as intended.

The bill is a mishmash of all kinds of unrelated things which should be considered separately with thoughtful debate, not thrown together in a bill that is too far reaching.

SB840ROSAPEPE:32.pdf
Uploaded by: Linda Diefenbach
Position: UNF

SB840 - UNFAVORABLE! This is another horrible long rambling bill. This bill contains not only the same COVID-19 vaccine passport provisions as SB839, it also requires the use of taxpayer dollars to promote and incentivize vaccination ie market vaccines for the drug companies.

It requires the Maryland Department of Health to submit a plan to the legislature which must include items such as measures to increase vaccination rates among the unvaccinated, even though many of these individuals made informed consent decision to be unvaccinated, recommendations to incentivize vaccination among people receiving benefits from the Maryland Medical Assistance Program and a strategy to incentivize individuals to receive a third COVID-19 vaccine dose and any future CDC recommended vaccines.

This bill also permanently allows pharmacists to order and administer vaccines to individuals who are at least 3 years old. It also authorizes pharmacy technicians to give vaccines. Do the pharmacists and technicians know these people's medical histories as a family doctor would? NO! Even with the corresponding training programs as provided by the bill, pharmacists and pharmacy technicians still lack the knowledge and experience of trained medical providers such as physicians and nurses who administer vaccines. This is irresponsible!

The Maryland Medical Assistance Program provides Medicaid benefits. The provisions of this bill lay the groundwork for discrimination against unvaccinated people who rely on Medicade for their health coverage. These individuals would be excluded from these incentives.

Each person at this point is aware of the COVID-19 vaccine, it's dangers and lack of efficacy. The people of Maryland do not need their government to make sure they take the vaccine or booster. This is an individual decision and no one should be coerced, bribed, threatened, intimidated or mandated to take this vaccine. THIS WRETCHED BILL MUST BE STOPPED!

Linda Diefenbach
6742 Deer Spring Ln.
Middletown, MD 21769

Against Vaccine Passports.pdf
Uploaded by: Lourdes Corso
Position: UNF

Forcing or coercing someone in any way to take a vaccine or any medication violates the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. The first of its ten points begins as follows:

"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, overreaching, 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 code of ethics must be upheld in any civilized country.

The COVID-19 vaccines were not tested for long-term effects and thus were and are experimental. Each person should choose whether to take the vaccine or not. Future vaccines may have similar experimental natures or may be carefully tested. Regardless, each person must have the right to accept or refuse the vaccine without any coercion, or penalty.

Very truly yours,

Lourdes Corso
12601 Orchard Brook Terrace
Potomac, MD 20854
(301) 251-6318
Corsojohn@aol.com

testimony regarding SB0839 and SB0840.pdf
Uploaded by: Marco Colombini
Position: UNF

Date: 3/1/2022

Citizen: Professor Marco Colombini

I am very much against vaccine passports. Although one can call them voluntary, in fact, they are a mechanism of coercion. The first of the ten points of the Nuremberg Code begins as follows: "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, overreaching, or other ulterior form of constraint or coercion…"** No matter how one spins it, these proposed bills SB0839 and SB0840, facilitate and encourage the use of vaccine passports to limit the normal activities of unvaccinated individuals.

As a Biophysicist, I read the peer reviewed literature. There is no question that the current vaccines being urged on Marylanders are experimental. They use technology never before used in vaccines. There has not been time for long-term testing, for obvious reasons. There are serious problems with these vaccines as demonstrated by clinical research in many labs all over the world and by reports collected by VAERS . Thus, not only is it unethical to coerce anyone to inject a foreign substance into their body but that substance could be harmful making the coercion even more unethical.

Finally, when a person has taken a vaccine that is effective at reducing morbidity and mortality, that person should feel safe enough not to expect others to also be vaccinated. Vaccine passports seriously erode the basic freedoms of those who choose not to be vaccinated.

SB 840 Unfavorable.pdf
Uploaded by: Margaret Montuori
Position: UNF

SB 840 Unfavorable
Margaret Montuori
7901 Deepwell Dr.
Bethesda, MD 20817

Once again Maryland state senators are proposing a bill that is deceptively vague and therefore should be withdrawn. What is “Establishing and altering certain requirements” and what are the “certain urgent care centers”? These phrases tell the taxpayer ABSOLUTELY NOTHING.

The only reason why people are being asked about their vaccine status is because the federal health emergency was recently renewed. Otherwise HEPA prohibits such health inquiries because health status is no one’s concern other than that of the individual, their family and their physician. Why the health emergency was extended is nonsensical. Nationwide the blue states have almost simultaneously withdrawn their mask and vaccine mandates. Red states stopped buying into these protocols last year with tremendous socioeconomic success! Globally, nations around the world are withdrawing their mask and vaccine mandates and passport schemes. WHY? Not because of science, because governments including the U.S. federal agencies and the federal, state and local governments never truly investigated the science, but because citizens, parents, healthcare professionals and businesses are standing up for the truth. Covid-19 was a hoax except for the elderly and those with comorbidities. Covid-19 was created with the purpose of negatively affecting western societies, including the United States, by decimating their economies, crippling child development and education, eradicating small businesses, increasing crime, fragmenting families, neighborhoods and churches. The money that the U.S. government has spent for Covid is staggering and has turned out to be an unfathomable waste.

Maryland taxpayers do not need to pay for state overreach into different institutions regarding Covid vaccine status nor does the state need to extend medical authority outside of what the individual dictates.

After watching the bills and testimonials this legislative session, I have witnessed the constant begging for money from the taxpayer for the most inconsequential and ludicrous schemes. At this point in time ANYTHING for Covid is a waste of tax dollars. Omicron, zenacron, larry moe and curlycron are attenuated derivatives of the original flu. The public can survive them. The number of people who passed from the regular flu in 2021 is similar to the number that passed from Covid. We don’t need to invest in a medical fact of life. The state of Maryland does not need mobile units, vaccine mandates, vaccine passports or lists regarding the public’s immunization status. The CDC’s information on Covid, which should have been a reliable source, has either been all over the map or simply published lies. They couldn’t be trusted, Maryland legislators can’t be trusted. Stop all Covid related legislative schemes!

SB0840 Testimony - Stoklosa.pdf
Uploaded by: Margaret Stoklosa
Position: UNF

Dear Committee Members,

Please OPPOSE SB0840 for the following reasons:

1. On the last estimate, 3 out of 4 Americans either had COVID overtly or are vaccinated and did not contract it (or maybe did but it did not present overtly). The other ¼, probably made up mostly of children, already had a COVID infection but it was mild enough to not even present. There is no need to micromanage SARS-CoV-2 at this point.
2. Vaccine passports would funnel money away from other programs that are more vital, such as early treatment. Collectively, there is an abundance of research that supports various therapeutic agents. Let's put money towards this – how about just focusing on this.
3. Vaccine passports are onerous for businesses to implement. This is precisely the reason they have been voted down in many jurisdictions. Small businesses are still trying to recover from the shutdowns – let's funnel money to support them.
4. Incentivizing vaccines is considered coercion. I am honestly surprised that this type of behavior is allowed at the state level and that lawmakers think this is acceptable. There is plenty of research supporting adverse effects of COVID vaccines – remember these are still experimental and not FDA-approved for those under 16. Please take a look at this study that documents increasing rates of autoimmune conditions due to vaccination. https://onlinelibrary.wiley.com/doi/full/10.1111/imm.13443.
5. Marketing a vaccine passport requires state funds – those can be used elsewhere for other supportive programs.
6. Pharmacists and pharmacy techs should not be vaccinating children. They are not qualified to assess and discuss adverse reactions or provide follow-up care if appropriate. They should be focusing on accuracy with drug dispersal, which continues to be an issue. That is not even relevant for COVID as these vaccines are not FDA approved for those under 16. Why is this even in this bill?
7. There is nothing in this bill about supporting those with long-COVID and inappropriate immune response in spite of vaccination. Where will that be addressed?
8. By the way, there is not state declared emergency for COVID any longer. We should be discussing recovery efforts.

There is no need for a vaccine passport system in Maryland and the response to COVID in this bill is a little late. I'd like to see more public health guidance and support on how to live healthfully, perhaps expanding access to nutritious food.

As a taxpayer, I oppose this bill and ask you to do the same.

Thank you,
Margaret Stoklosa
803 Main St
Gaithersburg, MD 20878

Testimony ‘passports’.pdf
Uploaded by: Marianne Sibal
Position: UNF

I totally reject any medical “passport” for Covid and all other medical reasons because they are easily manipulated, forged, and are potentially vehicles of private data abuse, either nefarious or politically misguided. It will increase the desire of people to try to circumvent it leading to unproductive legal actions.
There is no need for this action. It would be onerous and a hardship for many. The lack of nimbleness of such cumbersome legislation would restrict honest citizens from exercising Constitutional Freedoms as the ability to keep ahead of public health is unattainable when it comes to the unpredictable, as is quite evident looking at the past two years of events in New York City for example. It is shameful that so many people suffered the loss of freedoms and jobs because an illegal mandate that has now been lifted. Who will make up the financial and psychological losses caused by the shortsighted rush to control a virus which has mutated beyond its initial concern?
No, to any health “passport”. No, to this bill.
Sincerely,
Marianne Sibal

2021 Natural Immunity.pdf
Uploaded by: Mark Meyerovich
Position: UNF

One-year sustained cellular and humoral immunities of COVID-19 convalescents

Jie Zhang[1,9], Hao Lin[1,9], Beiwei Ye[1,9], Min Zhao[2,9], Jianbo Zhan[3,9], Shaobo Dong[4], Yaxin Guo[1], Yingze Zhao[1], Min Li[1], Sai Liu[1,5], Hangjie Zhang[1], Wenling Xiao[1,5], Yuanyuan Guo[1], Can Yue[1,6], Danni Zhang[1], Mengjie Yang[1], Jing Zhang[1], Chuansong Quan[7], Weifeng Shi[7], Xinxue Liu[8], Peipei Liu[1], Yongzhong Jiang[3], Guizhen Wu[1]*, George F. Gao[1,2,6]*, William J. Liu[1,5]*

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[3]Hubei Provincial Center for Disease Control and Prevention, Wuhan 430079, China.

[4]Macheng Center for Disease Control and Prevention, Huanggang 438300, China.

[5]College of Laboratory Medicine and Life Sciences, Wenzhou Medical University, Wenzhou 325035, China.

[6]Savaid Medical School, University of Chinese Academy of Sciences, Beijing 100049, China.

[7]Key Laboratory of Etiology and Epidemiology of Emerging Infectious Diseases in Universities of Shandong, Shandong First Medical University & Shandong Academy of Medical Sciences, Taian 271016, China.

[8]Oxford Vaccine Group, Department of Paediatrics, University of Oxford, Oxford OX3 9DU, UK.

[9]These authors contributed equally

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Summary: SARS-CoV-2-specific humoral and T-cell immune memory are present within ~95% and ~90% convalescents, respectively, until 1-year, with durable NAb, $CD8^+$ and $CD4^+$ T cells, but declined IgG and IgM from 6 to 12 months.

Abstract

Background: The longitudinal antigen-specific immunity in COVID-19 convalescents is crucial for long-term protection upon individual re-exposure to SARS-CoV-2, and even more pivotal for ultimately achieving population-level immunity. To better understand the features of immune memory in individuals with different disease severities at one year post-disease onset we conducted this cohort study.

Methods: We conducted a systematic antigen-specific immune evaluation in 101 COVID-19 convalescents, who had asymptomatic, mild, moderate, or severe disease, through two visits at months 6 and 12 post-disease onset. The SARS-CoV-2-specific antibodies, comprising NAb, IgG, and IgM, were assessed by mutually corroborated assays, i.e. neutralization, enzyme-linked immunosorbent assay (ELISA), and microparticle chemiluminescence immunoassay (MCLIA). Meanwhile, the T-cell memory against SARS-CoV-2 spike, membrane and nucleocapsid proteins was tested through enzyme-linked immunospot assay (ELISpot), intracellular cytokine staining (ICS), and tetramer staining-based flow cytometry, respectively.

Results: SARS-CoV-2-specific IgG antibodies, and also NAb can persist among over 95% COVID-19 convalescents from 6 months to 12 months after disease onset. At least 19/71 (26%) of COVID-19 convalescents (double positive in ELISA and MCLIA) had detectable circulating IgM antibody against SARS-CoV-2 at 12m post-disease onset. Notably, the percentages of convalescents with positive SARS-CoV-2-specific T-cell responses (at least one of the SARS-CoV-2 antigen S1, S2, M and N protein) were 71/76 (93%) and 67/73 (92%) at 6m and 12m, respectively. Furthermore, both antibody and T-cell memory levels of the convalescents were positively associated with their disease severity.

Conclusions: SARS-CoV-2-specific cellular and humoral immunities are durable at least until one year after disease onset.

Keywords: SARS-CoV-2, COVID-19, neutralizing antibody, T cells, disease severity

Introduction

The ongoing severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) pandemic has now lasted over one and a half years, resulting in over 229 million coronavirus disease 2019 (COVID-19) cases with 4.7 million deaths (https://covid19.who.int/), and remains a tough challenge for global health [1]. The characteristics of viral pathogeneses and immune responses during acute and convalescent phases of COVID-19 have been widely studied [2-4]. In response to SARS-CoV-2 infection, adaptive immunity, including antibodies, T cells against the virus, is generated [5]. SARS-CoV-2-specific T-cell responses are associated with milder disease in individuals with acute and convalescent COVID-19 [6,7], and neutralizing antibodies (NAbs) contribute to protective immunity against a second infection with SARS-CoV-2 in various animal models [8], indicating protective roles for antigen-specific antibodies and T cells in COVID-19 [9]. This immune memory among the COVID-19 convalescents is crucial for long-term protection upon individual re-exposure to this virus, and even more pivotal for ultimately achieving population-level immunity and interrupting disease transmission, together with the global usage of vaccines.

Here we conducted a systematic antigen-specific immune response evaluation in 101 convalescents of asymptomatic, mild, moderate or severe COVID-19 cases at 6 and 12 months post-disease onset. The SARS-CoV-2-specific antibodies, comprising NAb, IgG, and IgM, were assessed by mutually corroborated in neutralization assay, enzyme-linked immunosorbent assay (ELISA), and microparticle chemiluminescence immunoassay (MCLIA). Moreover, the T-cell memory against SARS-CoV-2 spike (S), membrane (M), and nucleocapside (N) proteins was tested through enzyme-linked immunospot assay (ELISpot), intracellular cytokine staining (ICS), and tetramer staining-based flow cytometry, respectively. This study will expand knowledge of the immune features and their persistence in convalescents recovering from COVID-19 of differing severities.

Materials and methods

Sample collection

We recruited a total of 101 COVID-19 convalescent patients from Macheng, Hubei Province, China, with two visits in July 2020 and January 2021. A total of 28 healthy controls (HC) who had neither been infected with SARS-CoV-2 nor vaccinated against COVID-19 were recruited at Chinese Center for Disease Control and Prevention (Fig. 1, Supplementary Table 1). Venous blood was collected from each participant, and sera and peripheral blood mononuclear cells (PBMCs) were isolated. Isolated PBMCs were frozen in cell stock solution containing 90% fetal bovine serum (FBS) with 10% dimethylsulfoxide, and stored in liquid nitrogen for later use. Serum samples were preserved at −80^{o}C until use in testing.

Detection of SARS-CoV-2-specific antibodies

SARS-CoV-2-specific IgG and IgM were assessed by ELISA and MCLIA, respectively [10-13]. NAb titer were measured via a live-virus neutralizing assay in Vero E6, as described previously [14]. Sample preparation was performed in a biosafety level-2 (BSL-2) laboratory, and the virus neutralization assay was conducted in a BSL-3 laboratory (Supplementary file 1).

Peptide pools design and culture of PBMCs *in vitro*

Totally, 271 15- to 18-mer SARS-CoV-2 peptides overlapped by 10 amino acids spanning the entire of S, M and N proteins were designed. For *in vitro* PBMC culture, the S1, S2, M and N peptide pools, recombinant IL-7 and IL-2 were added to PBMCs. PBMCs were cultured in a 24-well plate at a density of 3×10^{6} cells/well for 9 days, with half of the cultured medium replaced every three days.

Enzyme-linked immunospot (ELISpot) assay

IFN-γ-secreting T cells were detected with human IFN-γ ELISpot assay kits (BD Corp, USA), as described previously [15] (Supplementary file 1). The results are expressed as spot-forming cells (SFCs) per 10^{6} PBMCs, counted using an ELISpot Reader System (CTL Corp., USA).

Tetramers staining

HLA-A*1101 tetramers complexed with SARS-CoV-2-specific peptides M23 (M171-180, ATSRTLSYYK) and N25 (N362-370, KTFPPTEPK) were generated in our laboratory as described previously for the preparation of other HLA class I tetramers [16]. *In vitro* cultured PBMCs were harvested, washed twice with FACS buffer, and then stained with antibodies on ice for 30 min. After the final wash, the cells were re-suspended and immediately analyzed by flow cytometry.

Statistical analysis

Statistical analyses were conducted with GraphPad Prism 8, R, and SAS. The difference between groups was examined by a Wilcoxon matched-pairs signed rank test or Mann-Whitney U-test as appropriate. The comparison of categorical variables was examined by a chi-square test or Fisher' s exact test as appropriate. Correlations were assessed using a Spearman's Rank correlation coefficient (*r*). Simple linear regression was used to evaluate the impact of disease severity on immune indexes. The statistical significance was set as follows: ns, not significant; * $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$; All tests were two tailed.

Results

Anti-SARS-CoV-2 antibodies persist in COVID-19 convalescents at 6m and 12m

From July 2020 to January 2021, 101 documented COVID-19 convalescent patients responded to the recruitment during their recovery from disease onset for 6 months (denoted as 6m, n=81) to 1-year (denoted as 12m, n=74) with 57 successfully followed up among them (Fig. 1). We measured anti-RBD IgG and IgM levels in the sera of all COVID-19 convalescents visited at 6m and 12m post-disease onset, and in healthy controls, by ELISA and MCLIA (Table 1). There was no significant difference in the percentage of IgG-positive subjects between those followed-up at 12m and 6m. However, the IgG levels were both significantly lower at 12m ($P<0.0001$ for ELISA and $P=0.0011$ for MCLIA, Fig. 2A and B, Supplementary Fig. 1). Similarly, the IgM antibody levels at 12m also

decreased significantly compared to 6m (P=0.0004 for ELISA and P=0.0067 for MCLIA, Fig. 2C and D, Supplementary Fig. 1). We also calculated the percentage of the convalescents with double positive results from both antibody detection methods (double-positive). IgG and IgM antibodies against SARS-CoV-2 S protein RBD were not detectable in any of the healthy controls with either ELISA or MCLIA.

In addition to quantifying SARS-CoV-2-binding antibodies, we also measured NAbs with live virus neutralization assay in a BSL-3 laboratory. The percentages of convalescents with detectable SARS-CoV-2 NAb were high at both 6m (95%) and 12m (99%), with no significant difference (Table 1). And also no significant difference of the SARS-CoV-2 NAb titers was observed between 6m and 12m (Fig. 2E). Among the 57 participants who provided consecutive samples, 28 (49%) had unchanged NAb titers at 12m compared with 6m (Fig. 2F), (Fig. 2G), 27 (47%) had decreased titers and 2 (4%) had increased titers (Fig. 2H) (Supplementary Fig. 2). No SARS-CoV-2-specific NAb was detected in healthy controls (Fig. 2E).

The relationship assessment between SARS-CoV-2 IgG, IgM levels and the NAb titers showed positive correlations between any two of the three antibody indicators, which confirmed reliability of the methods and the authenticity of the results (Fig. 2I-L, and Supplementary Fig. 3). We also analyzed the maintenance of IgG and IgM levels in COVID-19 convalescents from 6m to 12 based on different disease severities during their acute phase. The level of IgG antibody trended lower at 12m than that at 6m post-disease onset in mild, moderate, or severe cases (Fig. 2M, N). The IgM antibody level significantly decreased at 12m in mild or moderate cases (Fig. 2O, P). However, there was no significant decreasing in the NAb levels between 6m and 12m of convalescents (Fig. 2Q). Furthermore, to assess a possible correlation between anti-SARS-CoV-2 antibodies among convalescents and their disease severity, we converted the severity variable to a rank variable and performed a univariate linear regression. All the relationships between disease severity and IgG, IgM, or NAb levels showed statistically significant fittings; thus, disease severity has an important impact on the humoral immune memory among COVID-19 convalescents (Fig. 2R-V). And this may also indicate that stronger humoral responses were induced at the acute phase in more severe cases.

Overall T-cell memory is sustained in most COVID-19 convalescents at 12m

The SARS-CoV-2-specific T-cell immunity in COVID-19 convalescent patients were detected by utilizing both freshly isolated PBMCs (*ex vivo*) and 9-days cultured PBMCs (*in vitro*). PBMCs in the IFN-γ ELISpot assay were tested under the stimulation of four pools of overlapping peptides spanning the SARS-CoV-2 S protein (divided into S1 and S2), M protein and N protein. In the *ex vivo* ELISpot detection, only the median of M protein responding T cells at 12m (median: 28 spot-forming cells (SFCs)/10^6 PBMCs; IQR: 0, 103 SFCs/10^6 PBMCs) is above the cutoff (20 SFCs/10^6 PBMCs), which is significantly higher than that at 6m (median: 10 SFCs/10^6 PBMCs; IQR: 0, 28 SFCs/10^6 PBMCs) (Fig. 3A).

We also conducted the *in vitro* expansion of PBMCs for 9 days under the stimulation of the same four antigens. After the expansion, the percentages of convalescents with positive T-cell responses to S1, S2, M protein and N protein at 6m were not differ significantly from their respective percentages at 12m. The percentages of convalescents with positive T-cell responses to at least one of the SARS-CoV-2 antigen peptide pools were 93% and 92% at 6m and 12m, respectively (Table 2). This suggests that robust memory T-cell responses could persist for at least 1 year among most COVID-19 convalescents. We also compared the T-cell memory to peptide pools of different antigens. M and N peptide pool-specific T-cell responses were significantly higher compared with S1 or S2 peptide pool-specific responses (Fig. 3B). Interestingly, we observed T-cell responses to SARS-CoV-2 in healthy controls as well (S1: 7/28(25%), S2: 10/28(36%), M: 8/28(29%) and N: 10/28(36%) which may reflect cross reactivity to common cold coronaviruses in the population.

To evaluate the impact of disease severity on virus-specific T-cell memory, we compared the T-cell response intensities among patients who recovered from COVID-19 cases of differing clinical severity (asymptomatic, mild, moderate, and severe). The response in subjects who had asymptomatic cases was lower than that in subjects who had more severe symptoms, these differences were significant at 6m (mild, P=0.0123; moderate, P=0.0045; and severe, P=0.0115) and the trend continued at 12m (Fig. 3C). We also converted the severity variable to a rank variable and performed

a univariate linear regression, considering the healthy controls as the lowest rank in this analysis. T-cell memory of the convalescents against different protein peptide pools, both at 6m and 12m, showed a relatively good fit with disease severity, indicating an increasing trend for T-cell memory in convalescent patients with increasing disease severity (Fig. 3D-G).

The T-cell memory against S protein was significantly correlated with antibody responses at 12m. Correlations were also observed among the S1- and S2-specific T-cell responses with antibody levels (Fig. 3H-P). No relationship was observed between the anti-SARS-CoV-2 antibodies and the T-cell responses to other viral antigens, i.e. M and N proteins (Supplementary Fig 4).

Both SARS-CoV-2-specific $CD4^+$ and $CD8^+$ T cells are durable in convalescents.

We also performed ICS followed by flow cytometry with PBMCs from 12 convalescents at 6m and 12m to further investigate the features of SARS-CoV-2-specific memory T cells, such as the multiple-cytokine-secreting SARS-CoV-2-specific $CD4^+$ and $CD8^+$ T cells across timepoints (Fig. 4A and Supplementary Fig. 5). The percentages of different $CD4^+$ or $CD8^+$ T-cell subsets secreting IFN-γ, IL-2, and TNFα with the stimulation of SARS-CoV-2 antigen peptide pools were not significantly different between 6m and 12m in convalescents (Fig. 4B, C). The proportions of single-, double-, and triple-cytokine-secreting T cells tended to be stable between 6m and 12m for both $CD4^+$ and $CD8^+$ T cells. In detail, single-cytokine-secreting IFN-γ^+IL-2^-TNFα^- and double-cytokine-secreting IFN-γ^+IL-2^-TNFα^+ $CD4^+$ T cells accounted for most of the SARS-CoV-2-specific $CD4^+$ T cells (Fig. 4D, E), while single-cytokine-secreting IFN-γ^+IL-2^-TNFα^- and IFN-γ^-IL-2^+TNFα^- and double-cytokine-secreting IFN-γ^+IL-2^-TNFα^+ $CD8^+$ T cells accounted for most of the virus-specific $CD8^+$ T cells. SARS-CoV-2-specific T cells targeting different virus proteins showed very similar cytokine secretion profiles (Supplementary Fig. 6 and 7).

To investigate the memory phenotypes of SARS-CoV-2-specific $CD4^+$ and $CD8^+$ T cells, CCR7 and CD45RA expressions on IFN-γ-secreting T cells was investigated and the percentages of naïve ($CD45RA^+CCR7^+$), central memory ($CD45RA^-CCR7^+$), effector memory ($CD45RA^-CCR7^-$), and effector ($CD45RA^+CCR7^-$) subsets were determined. The results demonstrate that both virus-specific

$CD4^+$ and $CD8^+$ T-cell groups were mainly composed of effector memory T cells, and no significant differences were observed across the two timepoints, i.e., at 6m and 12m, for each subset (Fig. 4F, G).

HLA-A*1101/epitope tetramer-based characterization of memory $CD8^+$ T cells among the COVID-19 convalescents

After evaluating T-cell responses to overall antigen peptide pools, we investigated the single epitope-specific T cells within COVID-19 convalescents. Based on results of overlapping peptide-stimulating IFN-γ ELISpot assays performed with PBMCs from COVID-19 convalescent individuals at 6m, two overlapping peptides (nCoV-M23 and nCoV-N25) were identified as the antigenic regions that stimulated T cells to secrete IFN-γ. We predicted potential $CD8^+$ T-cell epitopes within these regions and identified two HLA-A*1101-restricted epitopes M23 (ATSRTLSYYK) and N25 (KTFPPTEPK) derived from the M and N proteins, respectively (Supplementary Fig. 8). Subsequently, we prepared HLA/peptide tetramers comprising these two epitopes bound to the HLA-A*1101 molecules. Using PBMCs from four HLA-A*1101^+ COVID-19 convalescents recovered for 6m, M23 tetramer-positivity was detected in 0.32%–3.63% of the $CD8^+$ T cells, and epitope N25-specificity was detected in 0.83%–2.37% (Fig. 4H and J). Furthermore, we tested the SARS-CoV-2-specific T cells in Participant 16 with HLA-A*1101 restriction at two time points (6m and 12m), using the HLA-A*1101/M23 tetramer. The percentage of M23 tetramer-specific $CD8^+$ T cells at 12m (0.52%) was lower than that at 6m (3.63%) post-disease onset (Fig. 4I). The alignment of the M23 and N25 peptide amino acid sequences with other human coronaviruses and SARS-CoV-2 variants of concern (VOC) showed that the amino acids of these two peptides are conserved in SARS-CoV and the current SARS-CoV-2 VOC, but not in other human coronaviruses (Fig. 4K). Thus, the T-cell responses determined herein are SARS-CoV-2-specific and not influenced by cross-reactivity with common cold coronaviruses.

Discussion

With the continuous unabated pandemic of SARS-CoV-2, as one of the newly emerging viruses infecting humans [17], the prophylactic interventions, especially the accelerated vaccine inoculation were promoting in various countries with the goal of achieving herd immunity among the population. The attainment of protective population-level immunity requires the induction of long-term immunological memory by SARS-CoV-2 infection or vaccination, as this is crucial for protection upon virus re-exposure and reduction of human-to-human transmission. Thus, the longitudinal assessment of humoral and cellular immune memory against this newly emerging virus among convalescents is critical. Herein, we present a comprehensive longitudinal analysis of SARS-CoV-2-specific humoral and T-cell responses in COVID-19 convalescents who provided follow-up samples at 6m and/or 12m post-symptom onset, conducted using mutually corroborating methods.

The anti-SARS-CoV-2 antibody titers in convalescents were durable. The percentages of NAb-positive COVID-19 convalescents were both above 95% at 6m and 12m post-infection, without a significant decline in NAb titer over time. The IgG against spike RBD, as determined by ELISA and MCLIA, also persisted among nearly 95% patients at 12m post-infection. This finding is in line with previous reports on the relatively stable humoral immunity within the COVID-19 convalescent individuals for up to 6-8 months [18-20]. However, our study found an even higher percentage of convalescents who were positive for anti-SARS-CoV-2 antibodies, supported by the consistency among three different antibody detection methods (NAb, ELISA IgG and MCLIA IgG). Some previous studies have shown clear decay of SARS-CoV-2 NAb and IgG responses in the first several months post-infection [21-23]. Although a significant IgG level decline was also detected among the convalescents in our study, the percentage of IgG-positive individuals was sustained between 6m and 12m. In addition, the SARS-CoV-2 NAb titers of the convalescents did not differ significantly between 6m and 12m. Considering the declining trend in NAb titer among over 40% (27/57) of the convalescents, evaluating the durability of establishing humoral immunity through SARS-CoV-2 infection needs further observation.

Wheatley et al. found that S-specific IgM fit a two-phase decay (before and after 70 days) in the convalescent time period, through a mixed-effects modelling approach, with a more rapid early decay ($t_{1/2}$=55 days) followed by a slower decay ($t_{1/2}$= 118 days) in late convalescence [23]. In our study, approximately a quarter of the convalescents had anti-SARS-CoV-2 IgM (ELISA and MCLIA double-positive) at 12m. No participants in our study reported reinfection during their convalescent phase. A certain proportion (13%) of individuals who were positive for SARS-CoV IgG had IgM antibodies was also reported among the population in Wuhan, Hubei province, China [20]. Thus, the long-term persistence of anti-S IgM among some of our convalescents may be linked to a certain feature of COVID-19, the mechanism for which needs further investigation.

Post-infection antigen-specific memory T-cell responses are diverse among individuals [24, 25]. Herein, one of our major findings is that the cellular immunity established following acute SARS-CoV infection is maintained for at least 12 months in most convalescents. More than 90% of the convalescents showed T-cell responses to at least one SARS-CoV-2 antigen peptide pool when *in vitro*-cultured PBMCs were used, although the intensities of the T-cell responses were diverse and had a high heterogeneity between individuals.

Disease severity during the acute virus infections plays a pivotal role in the level of antibody and T-cell immune memory among convalescents [25]. One study on COVID-19 convalescents indicated that anti-S IgG titers and memory B cells percentages were higher in hospitalized cases compared with non-hospitalized cases at 120 days post-disease onset [19]. Meanwhile, T-cell responses tended to be lower following asymptomatic SARS-CoV-2 infection than following symptomatic infection [26, 27]. Here, we found a significant linear correlation between patient disease severity during the acute phase and immune memory against SARS-CoV-2, comprising both antibody and T-cell responses. As proposed by Long et al, temperate T-cell responses in asymptomatic patients may clear the virus before they reach higher levels during acute infection, and this may be sufficient to allow reinfection with the virus [28].

Our data demonstrate that SARS-CoV-2-specific humoral immunity is present within ~95% of convalescents and T-cell memory against at least one viral antigen is measurable among ~90% of subjects at 12m post-infection. From 6m to 12m post-infection, anti-SARS-CoV-2 IgG and IgM levels show a declining trend, but the levels of NAb and $CD8^+$ and $CD4^+$ T cells against SARS-CoV-2 are durable. These findings are encouraging in relation to the longevity of immune memory against this novel virus and indicate that these sustained immune components, which persist, among most SARS-CoV-2-infected individuals, may contribute to protection against reinfection.

NOTES

Author contributions

W.J.L., G.F.G. and G.W. designed and supervised the study. Jie Z., S.D., M.L., C.Y., Jianbo Z. and Y.J. collected the samples. Jie Z., M.L., B.Y. and M.Z. conducted the experiments. Y.Z., S.L., H.Z., W.X., Y.G., D.Z., M.Y., Jing Z. and P.L. provided technical support and experimental assistance. Jie Z., H.L., M.Z., Y.G., X.L. and W.J.L. analyzed and interpreted data. Jie Z., M.Z., H.L. and W.J.L. wrote the initial draft of the manuscript. All authors contributed intellectually and approved the manuscript.

Ethics

This study was approved by the Ethics Committee of National Institution for Viral Disease Control and Prevention, China CDC (Ethical approval No. IVDC2020-021). Written informed consent was obtained from all participants.

Funding:

The study was supported by the National Natural Science Foundation of China (82161148008, 81621091 and 81971501), the Major Special Projects for Infectious Disease Research of China (2018ZX10101002-005) and CAMS Research Units of Adaptive Evolution and Control of Emerging Viruses (2018RU009). W.J.L. is supported by the Excellent Young Scientist Program of the National Natural Science Foundation of China (81822040). G.F.G. is a leading principal investigator of the National Natural Science Foundation of China Innovative Research Group (81621091).

Declaration of interests

The authors declare no competing interests.

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Tables

Table 1. SARS-CoV-2-specific antibody in COVID-19 convalescents at 6 or 12 months post-disease onset.

Methods[a]	Group[a]	Case Number	Positive Number	Positive Proportions （%）	95% CI[c]	*P* value[d] （6m VS 12m）
Neutralization	HC	28	0	0	NA	
	6m	81	77	95	(88, 99)	
	12m	74	73	99	(93, 100)	0.42
MCLIA-IgG	HC	28	0	0	NA	
	6m	81	79	98	(91, 100)	
	12m	74	70	95	(87, 99)	0.60
MCLIA-IgM	HC	28	0	0	NA	
	6m	81	51	63	(52, 74)	
	12m	74	38	51	(39, 63)	0.19
ELISA-IgG	HC	28	0	0	NA	
	6m	81	78	96	(90, 99)	
	12m	74	71	96	(85, 99)	0.98
ELISA-IgM	HC	28	0	0	NA	
	6m	81	42	52	(40, 63)	
	12m	74	26	35	(24, 47)	0.05
IgG[e]	HC	28	0	0	NA	
	6m	81	78	96	(90, 99)	
	12m	74	70	95	(87, 99)	0.90
IgM[e]	HC	28	0	0	NA	
	6m	81	32	40	(29, 51)	
	12m	71	19	26	(16, 37)	0.09

[a]Neutralization: cutoff: neutralizing antibody titer >3; MCLIA: Microparticle chemiluminescence immunoassay, cutoff: S/CO>1; ELISA: Enzyme-linked immunosorbent assay, cutoff: IgG >0.19, IgM>0.105.

[b]HC: Healthy control; 6m: 6 months post disease onset; 12m: 12 months post disease onset.

[c]95% CI: 95% Confidence Interval.

[d]Chi square test was performed and the corresponding *P* value was listed (α=0.05).

[e]Double-positive, i.e., positive results from both an ELISA and MCLIA.

Table 2. Percentages of COVID-19 convalescents with positive T-cell responses to SARS-CoV-2[a]

Peptide pool[b]	Group[c]	Case Number[d]	Positive Number	Positive Proportions (%)	95% CI[e]	*p* value[f]	
S1	HC	28	7	25	(11, 45)	6m VS HC	<.0001
	6m	76	53	70	(58, 80)	12m VS HC	<.0001
	12m	73	57	78	(67, 87)	6m VS 12m	0.2467
S2	HC	28	10	36	(19, 56)	6m VS HC	0.0124
	6m	76	48	63	(51, 74)	12m VS HC	0.0027
	12m	73	50	68	(57, 79)	6m VS 12m	0.4926
M	HC	28	8	29	(13, 49)	6m VS HC	<.0001
	6m	76	67	88	(79, 94)	12m VS HC	<.0001
	12m	73	60	82	(71, 90)	6m VS 12m	0.3048
N	HC	28	10	36	(19, 56)	6m VS HC	<.0001
	6m	76	66	87	(77, 94)	12m VS HC	<.0001
	12m	73	60	82	(71, 90)	6m VS 12m	0.4322
SARS-CoV-2	HC	28	20	71	(51, 87)	6m VS HC	0.0026
	6m	76	71	93	(85, 98)	12m VS HC	0.0081
	12m	73	67	92	(83, 97)	6m VS 12m	0.7019

[a]T-cell responses to SARS-CoV-2 were tested by enzyme-linked immunospot assay (ELISpot) with *in-vitro*-cultured PBMCs, the evaluation criteria were as follows: if negative-control wells had < 20 SFCs/10^6 PBMCs, positive responses were defined as having ≥ 40 SFCs/10^6 PBMCs; otherwise, positive responses were defined as having results at least twice that of the negative control.

[b]S1&S2: Spike protein (S) were divided into S1 and S2 pools according to the natural split site.

[c]HC: Healthy control; 6m: 6 months post disease onset; 12m: 12 months post disease onset.

[d]Five recovered patients at 6m and one at 12m had insufficient PBMCs for ELISpot.

[e]95% CI: 95% Confidence Interval.

[f]Chi square test was performed and the corresponding *P* value was listed (α=0.05).

Figure legends

Fig. 1 Participant characteristics and flow chart of immune memory detection.

A total of 101 COVID-19 convalescent patients were enrolled in two visits within Macheng, Hubei, China. The two visits were conducted in month 6 (n=81) and month 12 (n=74) of the convalescent period. Across the two visits, 57 of these subjects were followed up longitudinally. Three individuals clinically diagnosed with SARS-CoV-2 but lacking nucleic acid diagnostic confirmation were later confirmed by our study as being negative for SARS-CoV-2-specific antibody and T-cell responses; they were excluded from our analyses. Sera were used to measure the titer of SARS-CoV-2-specific antibodies via ELISA, MCLIA and neutralization assays. Whereas PBMCs were used to determine the T-cell memory responses through ELISpot, ICS and tetramer staining assays.

Fig. 2 Humoral immune responses in COVID-19 convalescents.

A-**E**, NAb, IgG, and IgM antibodies of COVID-19 convalescent donors at month 6 (6m, red; n=81) and month 12 (12m, blue; n=74) post-disease onset and of healthy controls (HC, gray; n=28) were detected by virus neutralization assay, ELISA, and MCLIA. **F**-**H**, NAb titers changes in the 57 longitudinally followed up convalescents at 6m and 12m with sustaining (**F**), declining (**G**), or increasing (**H**) trends. The thickness of the line represents different number ranges of convalescent donors. **I**-**L**, Correlation between NAb titers and IgM/IgG levels at 6m and 12m. **M**-**Q**, Changes of NAb, IgG and IgM antibody titers at 6m or 12m in asymptomatic (Asym), Mild (Mild), Moderate (Mod), or Severe (Sev) convalescents. **R**-**V**, The influence of disease severity on SARS-CoV-2-specific antibodies among the convalescents by a univariate linear regression. The distance between each point on the abscissa (x-axis) was considered to be equal and was used as an independent variable for simple linear regression. R^2 represents the goodness of fit. *P*-values were calculated based on the slope of the curve. A Mann-Whitney U-test was used for (**A**-**E**) and a Wilcoxon matched-pairs signed rank test was used for (**M**-**Q**). Correlations in (**I**-**L**) were assessed using a Spearman's Rank correlation coefficient (*r*). A simple linear regression (**R**-**V**) was used to evaluate the impact of

disease severity on antibodies. Two-tailed *P* values were calculated. * $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$.

Fig. 3 Memory T-cell responses against to SARS-CoV-2 as detected by ELISpot.

A, Memory T-cell responses of COVID-19 convalescent donors at month 6 (6m, red; n=78) and month 12 (12m, blue; n=74) post-disease onset and of healthy controls (HC, gray; n=28) were detected by *ex vivo* ELISpot using freshly isolated PBMCs under the stimulation with the corresponding peptide pool. Medians with interquartile ranges data are presented. **B**, After a 9-day *in vitro* expansion, memory T-cell responses from convalescent patients at 6m (n=76) or 12m (n=73), or from HC (n=28), were detected by ELISpot. "&" and "#" symbols indicate a significant difference with the S1 or S2 peptide pool, respectively. **C**, Memory T-cell responses in HCs and convalescents with different COVID-19 disease severity. Asym (6m, n=8; 12m, n=6); Mild (6m, n=36; 12m, n=36); Mod (6m, n=23; 12m, n=25); Sev (6m, n=9; 12m, n=6). **D-G**, Univariate linear regression fitting plot of disease severities vs T-cell responses, with HC considered as the lowest rank in the analysis. **H-P**, The correlation between T-cell memory against S (sum of S1 and S2), S1, and S2 proteins and antibody responses at 12m post-infection. A Mann-Whitney U-test was used for (**A**) and (**C**), a Wilcoxon matched-pairs signed rank test was used for (**B**). A simple linear regression (**D-G**) was used to evaluate the impact of disease severity on T-cell responses. Correlations in (**H-P**) were assessed using a Spearman's Rank correlation coefficient (r). Two-tailed P-values were calculated. *P<0.05; **P<0.01; ***P<0.001.

Fig. 4 Functional characterization of SARS-CoV-2-specific memory T cells.

A, Gating strategies for multiple cytokine analyses in $CD4^+$ (left) and $CD8^+$ (right) T cells. **B**, **C**, Percentages of SARS-CoV-2-specific T cells secreting IFN-γ, IL-2, and/or TNFα among the total T cells at month 6 (6m, red) and month 12 (12m, blue) post-COVID-19. **D**, **E**, The constitution ratios of

T cells secreting IFN-γ, IL-2, and/or TNFα in virus-specific $CD4^+$ or $CD8^+$ T cells. **F**, **G**, Phenotypic memory analysis of IFN-γ-secreting $CD4^+$ and $CD8^+$ T cells. **H**, Examples of SARS-CoV-2-specific $CD8^+$ T cells stained by HLA-A*1101 tetramers complexed to either the peptide M23 or the peptide N25 with cultured PBMC cells at 6m post-infection. The controls were stained with an irrelevant tetramer. **I**, HLA-A*1101/Peptide tetramer staining with cultured PBMCs cells from the same participant at 6m and 12m post-infection. **J**, Mean percentage of SARS-CoV-2-specific $CD8^+$ T cells positive for HLA-A*1101/M23 (n=4) or HLA-A*1101/N25 (n=4) in COVID-19 convalescent patients at 6m post-infection. **K**, Alignment of the M23 and N25 peptide amino acid sequences with other human coronaviruses and VOCs. Data are presented as mean ± SEM. The Wilcoxon matched-pairs signed rank test was used for comparison. Two-tailed *P* values were calculated. * $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$.

Figure 1

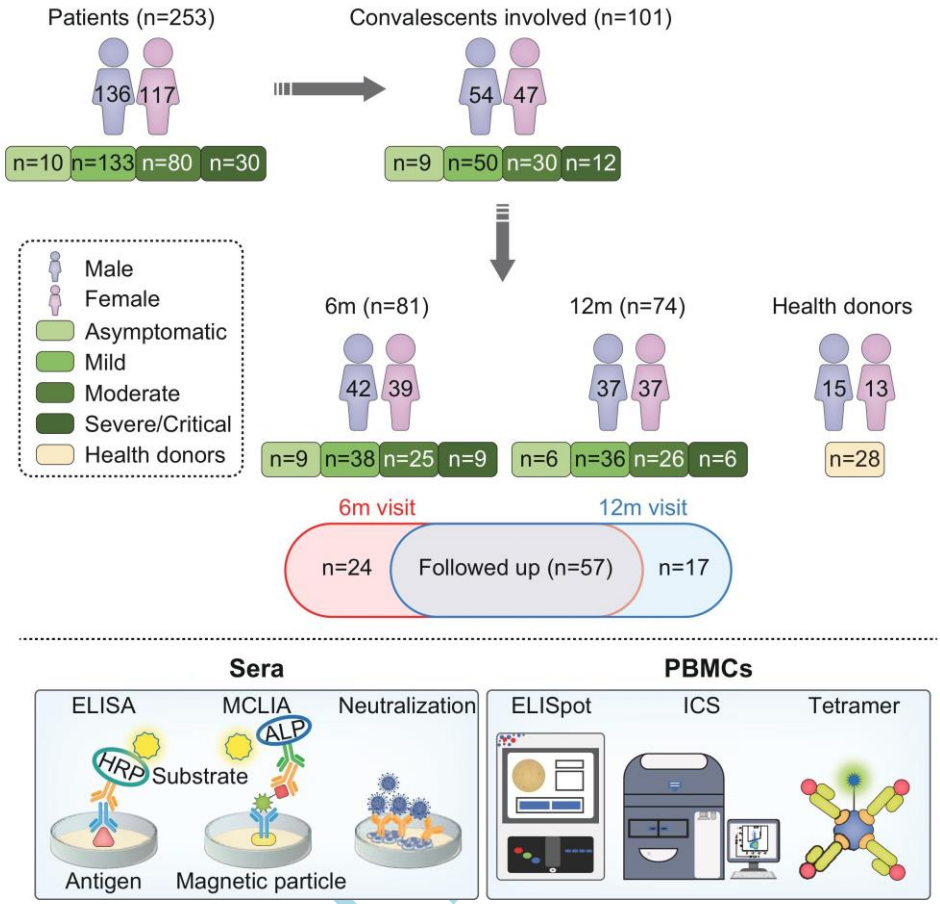


Figure 2

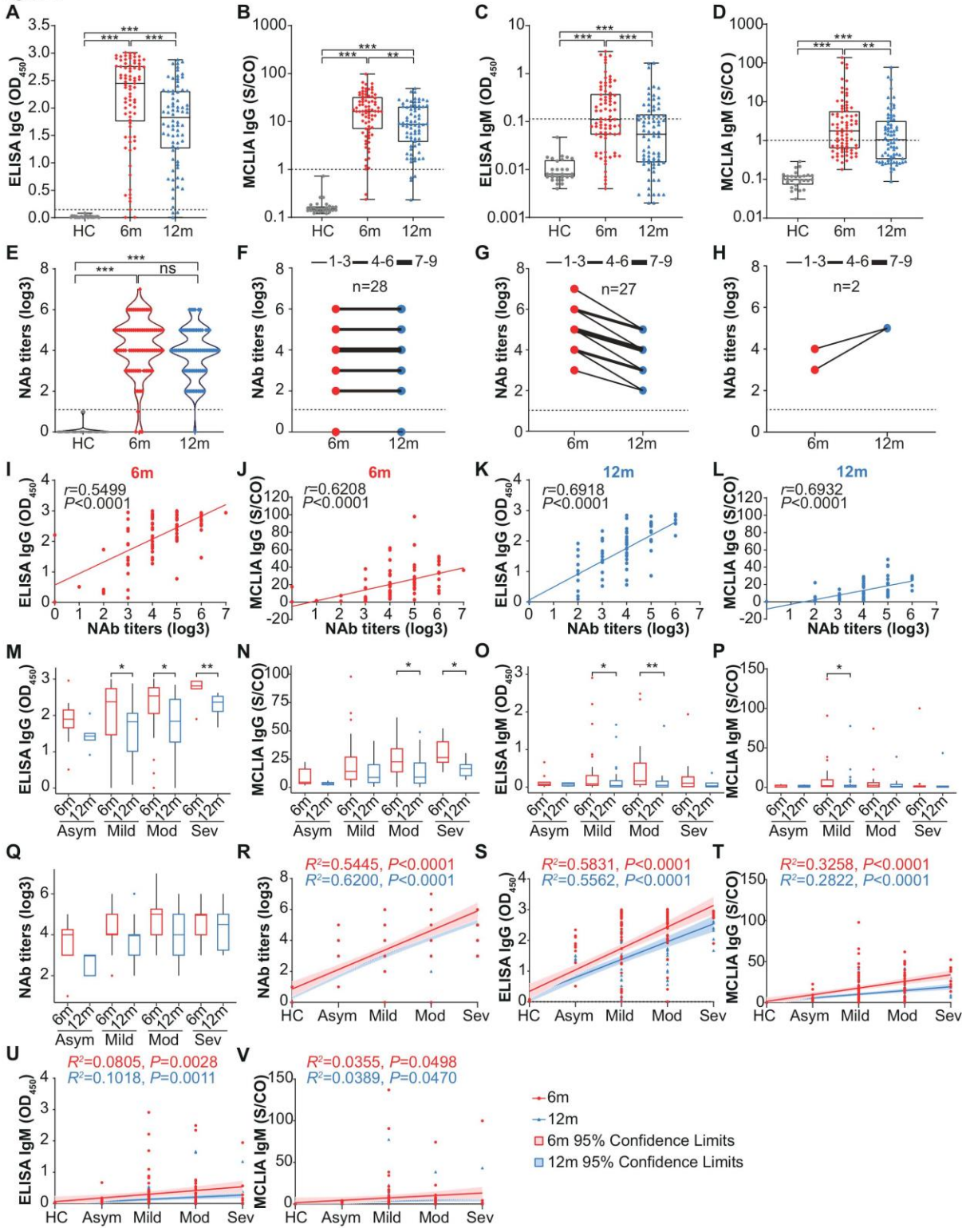


Figure 3

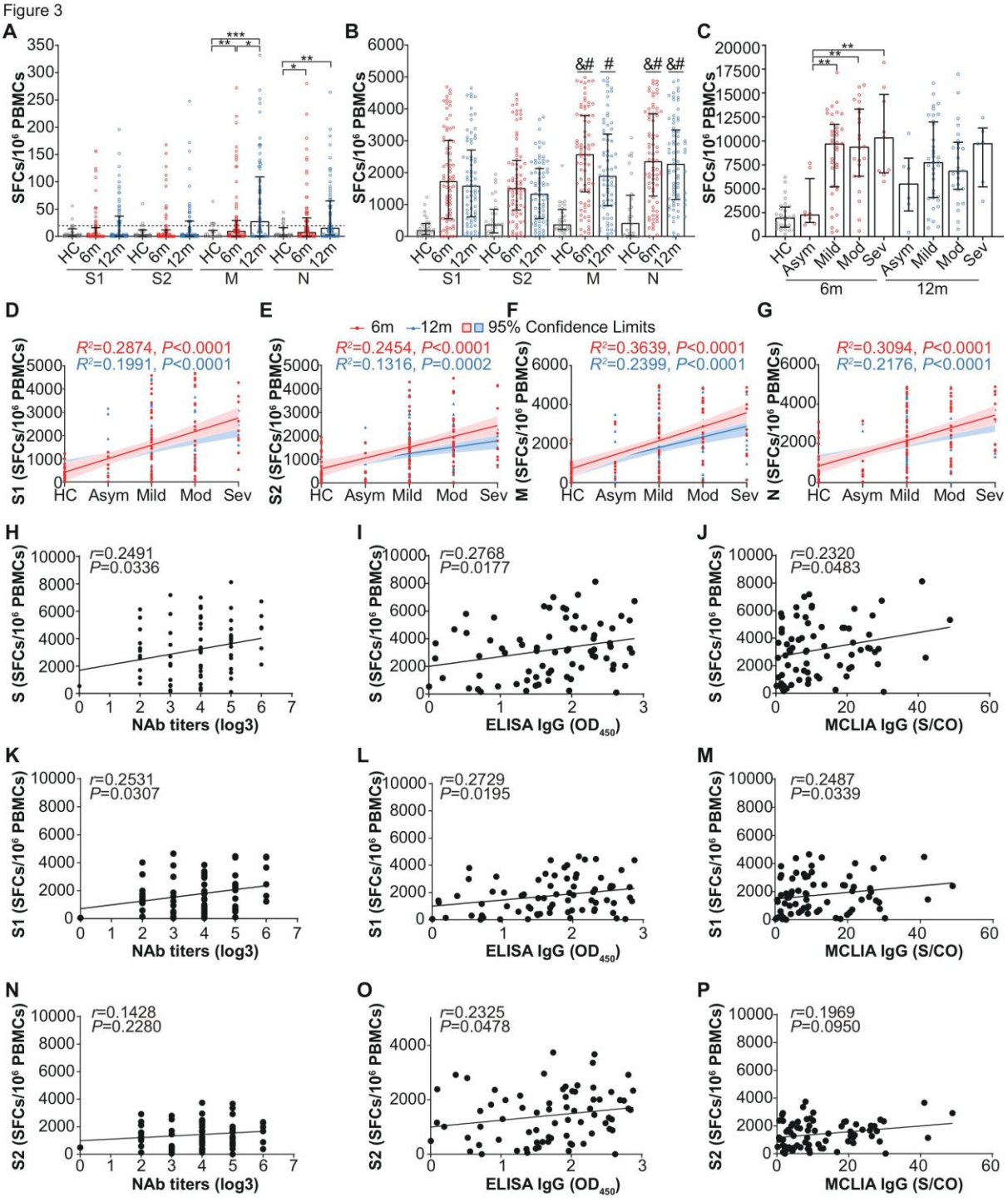
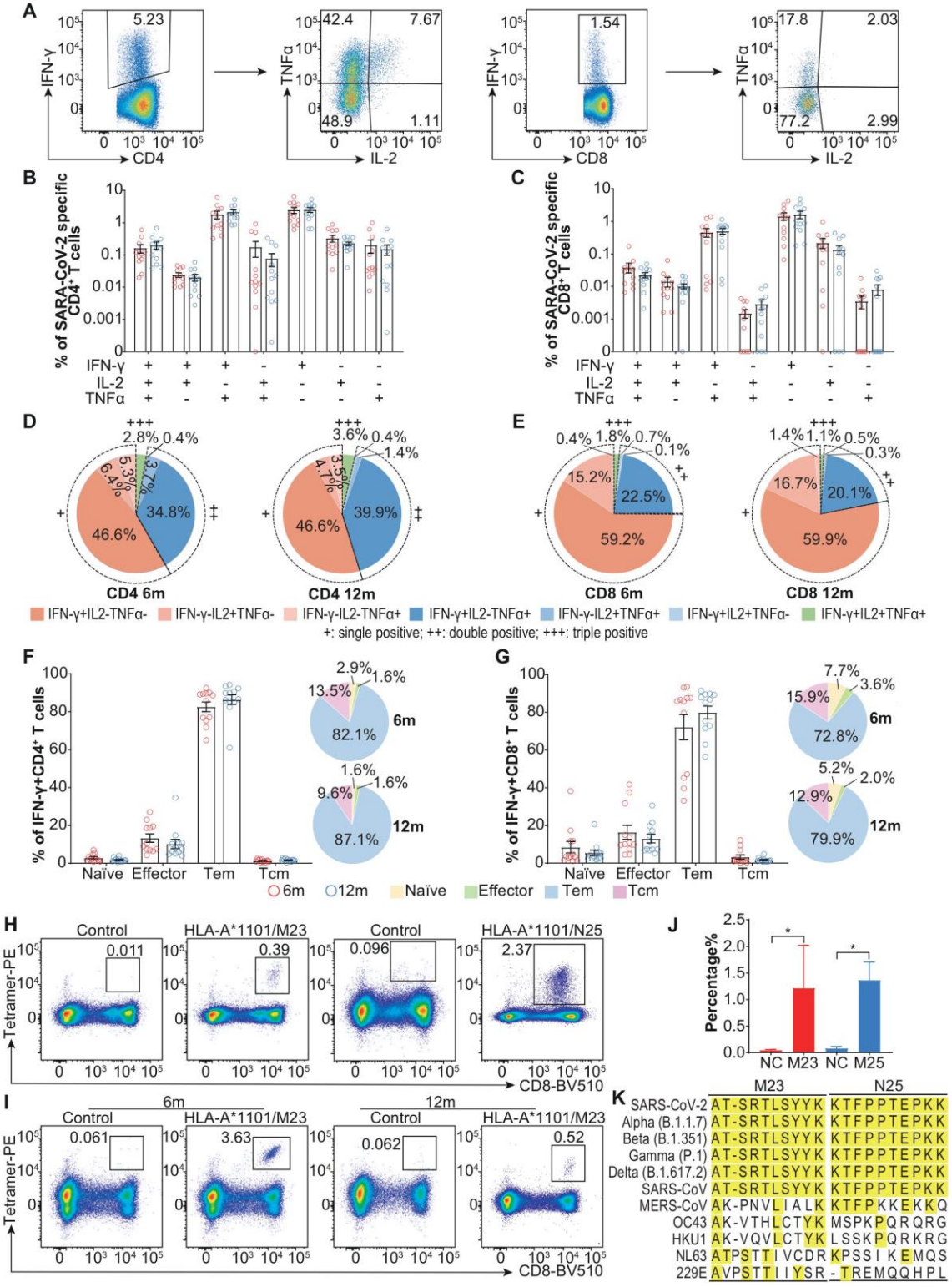


Figure 4



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Vaccination before or after SARS-CoV-2 infection leads to robust humoral response and antibodies that effectively neutralize variants

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Current coronavirus disease 2019 (COVID-19) vaccines effectively reduce overall morbidity and mortality and are vitally important to controlling the pandemic. Individuals who previously recovered from COVID-19 have enhanced immune responses after vaccination (hybrid immunity) compared with their naïve-vaccinated peers; however, the effects of post-vaccination breakthrough infections on humoral immune response remain to be determined. Here, we measure neutralizing antibody responses from 104 vaccinated individuals, including those with breakthrough infections, hybrid immunity, and no infection history. We find that human immune sera after breakthrough infection and vaccination after natural infection broadly neutralize SARS-CoV-2 (severe acute respiratory coronavirus 2) variants to a similar degree. Although age negatively correlates with antibody response after vaccination alone, no correlation with age was found in breakthrough or hybrid immune groups. Together, our data suggest that the additional antigen exposure from natural infection substantially boosts the quantity, quality, and breadth of humoral immune response regardless of whether it occurs before or after vaccination.

INTRODUCTION

Severe acute respiratory coronavirus 2 (SARS-CoV-2) is the causative agent of the ongoing coronavirus disease 2019 (COVID-19) pandemic. Globally, cases continue to increase despite worldwide vaccination campaigns (*1*). Numerous safe and effective vaccines have been developed that effectively reduce the risk of infection, severe disease, and death including BNT162b2 (Pfizer), mRNA-1273 (Moderna), and Ad26.COV2.S (Janssen) (*2*, *3*). However, variants of concern (VOCs) with differing levels of increased transmissibility and resistance to existing immunity have sequentially emerged, spread widely, and receded over time since the beginning of the pandemic (*4*–*7*). Several studies have shown that antibody responses from the initial wave of vaccines in early 2021 have waned over the 6 months after vaccination, possibly contributing to an increase in breakthrough infections (*8*–*12*). Booster vaccine doses were first approved in Israel in July 2021 and have since been more widely adopted in other countries to address these concerns despite the concern that booster campaigns may divert much needed vaccine doses away from lower-income countries (*13*).

Vaccination after recovery from natural SARS-CoV-2 infection, or "hybrid immunity," has been reported to substantially increase both the potency and breadth of humoral response to SARS-CoV-2 (*14*, *15*). However, current studies on breakthrough infection occurring after vaccination have focused on identifying susceptibility factors such as virus neutralizing titer before infection (*16*). The impact of breakthrough infection on the neutralizing antibody response and how this compares with the response elicited by hybrid immunity remains unclear; we therefore undertook the present study to directly address this gap in knowledge.

RESULTS

Cohort and study design

We recruited a total of 104 participants (Table 1) consisting of 31 fully vaccinated individuals with polymerase chain reaction (PCR)–confirmed breakthrough infections, 31 individuals with one (6 individuals) or two vaccine (25 individuals) doses after recovery from COVID-19 (hybrid immunity), and 42 fully vaccinated individuals with no history of COVID-19 or breakthrough infection (Fig. 1A). Ninety-six participants received BNT162b2, six received mRNA-1273, and two received Ad26.COV2.S. Serum samples were collected from each of the participants, which were then tested for 50% effective antibody concentrations (EC_{50}) by enzyme-linked immunosorbent assay (ELISA) and 50% live SARS-CoV-2 neutralizing titer with focus reduction neutralization tests ($FRNT_{50}$) against early lineage strain SARS-CoV-2 (WA1) and clinical isolates of three VOCs: Alpha (B.1.1.7), Beta, (B.1.351), and Delta (B.1.617.2). We performed additional antibody-dependent cellular phagocytosis (ADCP) experiments to evaluate any functional differences in the antibody response of each group.

We first analyzed the hybrid immunity of participants who received only a single vaccine dose compared with those who had received two doses (fig. S1). All measures of antibody levels, ADCP, and live virus neutralization revealed no significant difference between these two groups. For this reason, we combined these samples into a single group containing participants with both one and two vaccine doses after natural infection, which we henceforth refer to as the hybrid immune group.

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Table 1. Cohort demographics. IQR, interquartile range; N/A, not applicable.

Characteristic		Vaccine only	Hybrid immunity	Breakthrough
		***N* = 42**	***N* = 31**	***N* = 31**
Sex				
	Female—*N* (%)	35 (83.3)	19 (61.3)	24 (77.4)
	Male—*N* (%)	7 (16.7)	12 (38.7)	7 (22.6)
Age (years)				
	Median [range]	40 [23–74]	50 [23–73]	38 [24–63]
Critical time periods (days)—median [IQR]				
	Latest vaccine dose to blood draw	24 [17.25–35.75]	25 [17.5–34]	N/A
	PCR positivity to blood draw	N/A	N/A	35 [23–48.5]
	PCR positivity to first vaccine dose	N/A	289 [124–334.5]	N/A
	Second vaccine dose to PCR-positive	N/A	N/A	139 [81.5–201.5]
	Days between vaccine doses	21 [21–22]	22 [21–25]	21 [21–23]
Vaccine type—*N* (%)				
	BNT162b2 (Pfizer)	42 (100)	25 (80.6)	29 (93.5)
	mRNA-1273 (Moderna)	0 (0)	5 (16.1)	1 (3.2)
	Ad26.COV2.S (Janssen)	0 (0)	1 (3.2)	1 (3.2)

Antibody levels after breakthrough infection, hybrid immunity, and vaccination alone

ELISA geometric mean titer (GMT) EC_{50} values for SARS-CoV-2 spike-specific antibodies were significantly elevated in both the breakthrough (2.5-fold, $P = 0.005$) and hybrid immune (3.6-fold, $P < 0.0001$) groups compared with vaccination alone, but we saw no significant difference between the breakthrough and hybrid groups (Fig. 1B). A similar trend was seen for EC_{50} values specific for the spike receptor-binding domain (RBD) (Fig. 1B). We additionally confirmed that none of the vaccine-only participants exhibited reactivity against the nucleocapsid (N) protein, supporting lack of previous infection, whereas the breakthrough and hybrid immune groups were 68 and 48% N-responsive, respectively (Fig. 1B). Opsonization with hybrid immune and breakthrough sera also induced phagocytosis of spike protein–coated particles in an ADCP assay significantly more than vaccination alone but not compared with each other (Fig. 1C). The levels of immunoglobulin G (IgG) and IgA antibodies specific to RBD protein displayed a similar trend to the total EC_{50} levels with significant increases for hybrid immunity and breakthrough compared with vaccination alone but not compared with each other (Fig. 1D). RBD-specific IgM values were notably low and did not differ significantly between groups. Consistent with previous reports (*17*), spike-specific antibody levels correlated negatively with age among vaccine-only participants. In contrast, neither the breakthrough nor hybrid immune group recapitulated this correlation, displaying no significant age-related trend (Fig. 1E).

Neutralizing antibody titers against SARS-CoV-2 and the VOCs

We next quantified the functional activity of participants' immune sera by comparing their neutralization titers against early (WA1) SARS-CoV-2 and selected VOCs. Against all viruses, the trend mirrored that of the antibody EC_{50} levels, with the vaccine-only group $FRNT_{50}$ titers significantly lower than both breakthrough and hybrid immunity, which were comparable with each other (Fig. 2A). The $FRNT_{50}$ GMTs of hybrid immune group participants were 10.8-, 16.9-, 32.8-, and 15.7-fold higher than vaccination alone for WA1, Alpha, Beta, and Delta variants, respectively, whereas breakthrough group participants were 6.0-, 11.8-, 17.0-, and 8.5-fold higher than vaccination alone, respectively, all with $P < 0.0001$. Among vaccine group participants, neutralization of the Beta variant was significantly reduced compared with WA1, whereas the difference seen for the hybrid immune and breakthrough groups was not significant (fig. S2).

In addition to eliciting immunity with greater breadth (Fig. 2A), the serum antibody potency across the breadth of VOCs tested was greater for both hybrid immune and breakthrough groups, as measured by an increase in the ratio of variant neutralization over WA1 $FRNT_{50}$ values against Alpha and Beta for the hybrid immune and breakthrough groups and against Delta for the hybrid immune group (Fig. 2B and fig. S3). Breakthrough and hybrid immune participants grouped more tightly and displayed variant neutralizing titers closer to that of WA1 (Fig. 2, C to E).

Quality of the neutralizing antibody response

We also found that hybrid immunity was associated with a remarkable improvement in the proportion of spike-specific antibodies that were also neutralizing. WA1 neutralizing titers correlated with spike-specific antibody levels for all three groups, but the hybrid immune and breakthrough groups correlated more strongly (Fig. 3A). To analyze the efficiency of sera at neutralizing a given virus strain, we determined a neutralizing potency index by calculating the ratio of

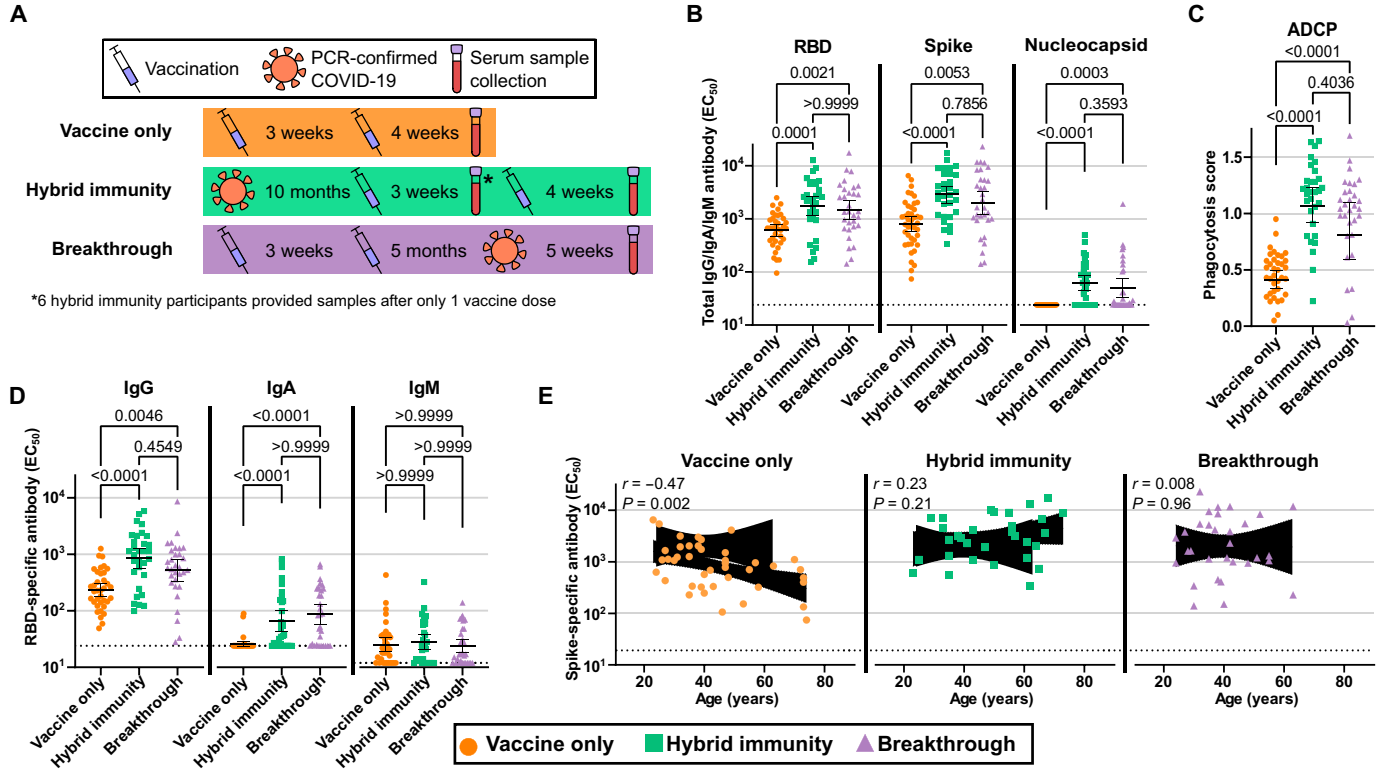

Fig. 1. Antibody levels after breakthrough infection, hybrid immunity, and vaccination alone. (**A**) Schematic depicting the order and approximate time scale of vaccination and natural infection for each group. The blue syringe indicates a dose of vaccine, the orange virus particle indicates PCR-confirmed natural infection with SARS-CoV-2, and the purple-capped vial indicates serum collection. The asterisk (*) indicates that 6 (of 31) hybrid immune participants provided serum samples after only a single vaccine dose. (**B**) IgG/IgA/IgM inverse fold-dilution EC_{50} values for sera specific to RBD, full-length spike, and nucleocapsid proteins measured by ELISA. (**C**) ADCP scores. (**D**) RBD-specific EC_{50} values for IgG, IgA, and IgM class antibodies measured by ELISA. (**E**) Correlation between spike-specific EC_{50} values and participant age. Error bars in (B) and (D) indicate the geometric mean with the 95% confidence interval, whereas error bars in (C) indicate the arithmetic mean with the 95% confidence interval. *P* values in (B) to (D) were calculated with two-tailed Kruskal-Wallis test with Dunn's multiple comparison correction. Scatterplots in (E) depict the simple linear fit of age and log-transformed EC_{50} values with 95% confidence bands along with the Spearman's rank correlation coefficient and two-tailed *P* value.

neutralizing titer ($FRNT_{50}$) to spike binding EC_{50} values (*18*). The index expresses a ratio of fold-serum-dilution with 50% neutralization potency to fold-serum-dilution 50% spike binding capacity or a relative neutralizing antibody–to–total antibody ratio for a given subject's serum. The neutralizing potency index was significantly higher among hybrid immune and breakthrough participants than after vaccination alone (Fig. 3B). Last, we found that the relationship between age and total antibody levels also extends to neutralizing titer; vaccine-only participants displayed a clear negative correlation with age, whereas the hybrid immune and breakthrough participants showed no such correlation (Fig. 3C). No association was seen between reported sex and neutralizing titer for any of the groups (Fig. 3D).

DISCUSSION

Overall, our results show that SARS-CoV-2 infection before or after vaccination gives a significantly larger boost to the neutralizing antibody response compared with two doses of vaccine alone. The potency and breadth of the antibody response appear to improve concomitantly. It has been well established that natural infection alone provides short-lived protection from infection (*17*), showing the importance of vaccination, regardless of infection history. Because vaccination protects against severe disease and death (*19*), it is safer for individuals to be vaccinated before rather than after natural infection.

The negative correlation between age and neutralizing antibody levels after vaccination alone is an effect that has been previously identified (*20*). The relationship between age and antibody levels after natural infection is markedly more complex, with a peak in antibody levels seen between the ages of 60 and 80 (*21*). The exact reasons for this association remain to be determined, but one hypothesis is that the greater disease severity among individuals of advanced age leads to an overall greater humoral response (*18*). These two opposing trends may obscure any age dependence of antibody levels in the present study among patients with humoral responses resulting from both vaccination and natural infection.

Recent studies have suggested that the humoral response continues to develop long after vaccination, with memory B cells at late time points after vaccination showing improved quality and breadth compared with early time points (*14*, *15*, *22*). Our data cannot separate the contribution of mixed boosting due to the combination of vaccination with natural infection from the contribution of ongoing memory B cell development during the time between first antigen exposure and most recent boosting, whether from vaccination or breakthrough infection. Future studies with individuals who have been vaccinated and boosted may be able to distinguish between these possibilities, and an early study suggests that booster vaccination

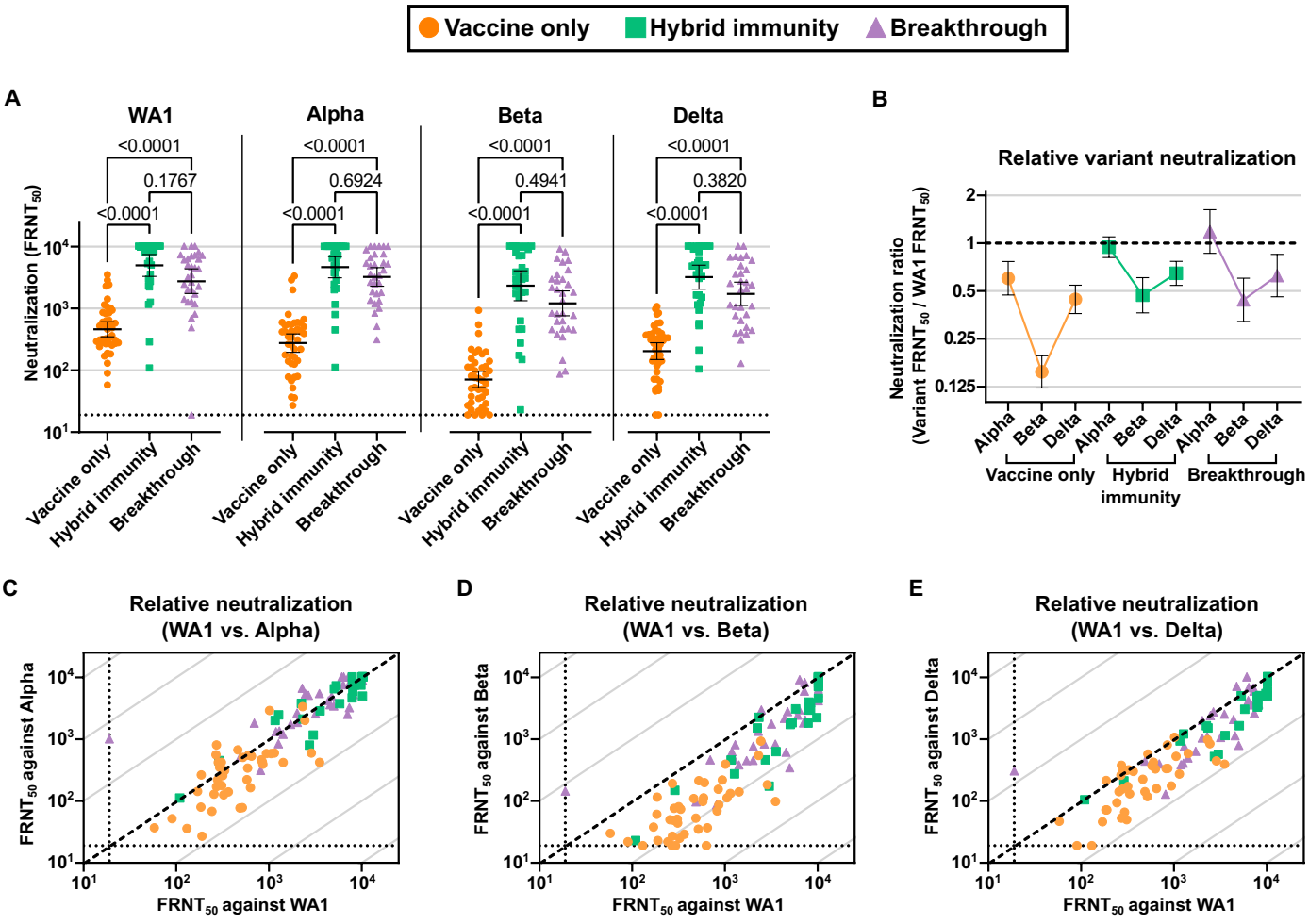

Fig. 2. Neutralizing antibody response after breakthrough infection, hybrid immunity, and vaccination alone. (**A**) Neutralizing antibody titers determined by focus-forming assay with clinical isolates of the original strain of SARS-CoV-2 (WA1), Alpha, Beta, and Delta variants. (**B**) The ratio of Alpha, Beta, and Delta variant neutralization to WA1 neutralization. WA1 neutralizing titer versus Alpha (**C**), Beta (**D**), and Delta (**E**) variant neutralizing titer. The dotted line indicates equal neutralization. Error bars in (A) and (B) indicate the geometric mean with the 95% confidence interval. *P* values in (A) were two-tailed and calculated with the Kruskal-Wallis method with Dunn's multiple comparison correction.

8 months after a second dose leads to improved overall Delta variant neutralizing titers by 6- to 12-fold (*23*). This appears consistent with the 8.5- and 15.7-fold improvements against the Delta variant for the breakthrough and hybrid immune groups, respectively, compared with two vaccine doses alone. This suggests that the magnitude of improvement for booster vaccinations may be similar to those seen with combined vaccination and natural infection, including hybrid immunity with a single dose of mRNA vaccine. This would point to the importance of the memory B cell compartment in generating a robust and variant cross-neutralizing humoral response. Although this study focuses on the humoral response, it is known that the cellular response by T cells plays an important role in responding to SARS-CoV-2 vaccination and infection (*24*).

COVID-19 vaccines using mRNA technology, including BNT162b2 and mRNA-1273, are the most commonly administered vaccines in the United States, where this study took place, and most of this study's participants received the BNT162b2 vaccine. However, some participants received the Ad26.COV2.S adenovirus-based vaccine. The majority of hybrid immunity research has focused on mRNA vaccination, but research on adenovirus vaccine hybrid immunity has shown similar improvements to neutralizing titers and variant cross-neutralization (*25*). While this study was not designed to compare the effectiveness of different vaccination technologies, we do not anticipate any substantial effect due to differences in vaccine types.

Vaccination is highly effective at preventing the most severe outcomes from COVID-19 and should be provided regardless of previous infection status and age. A single dose of vaccine may provide sufficient protection for many individuals with previous SARS-CoV-2 infection. Vaccine availability remains limited in many regions, and the shortest path to broad global immunity may be to prioritize administering at least one vaccine dose to as many individuals as possible with a confirmed history of SARS-CoV-2 infection.

MATERIALS AND METHODS

Study design

The purpose of this study was to directly compare the humoral immune response among individuals who received COVID-19 vaccines either

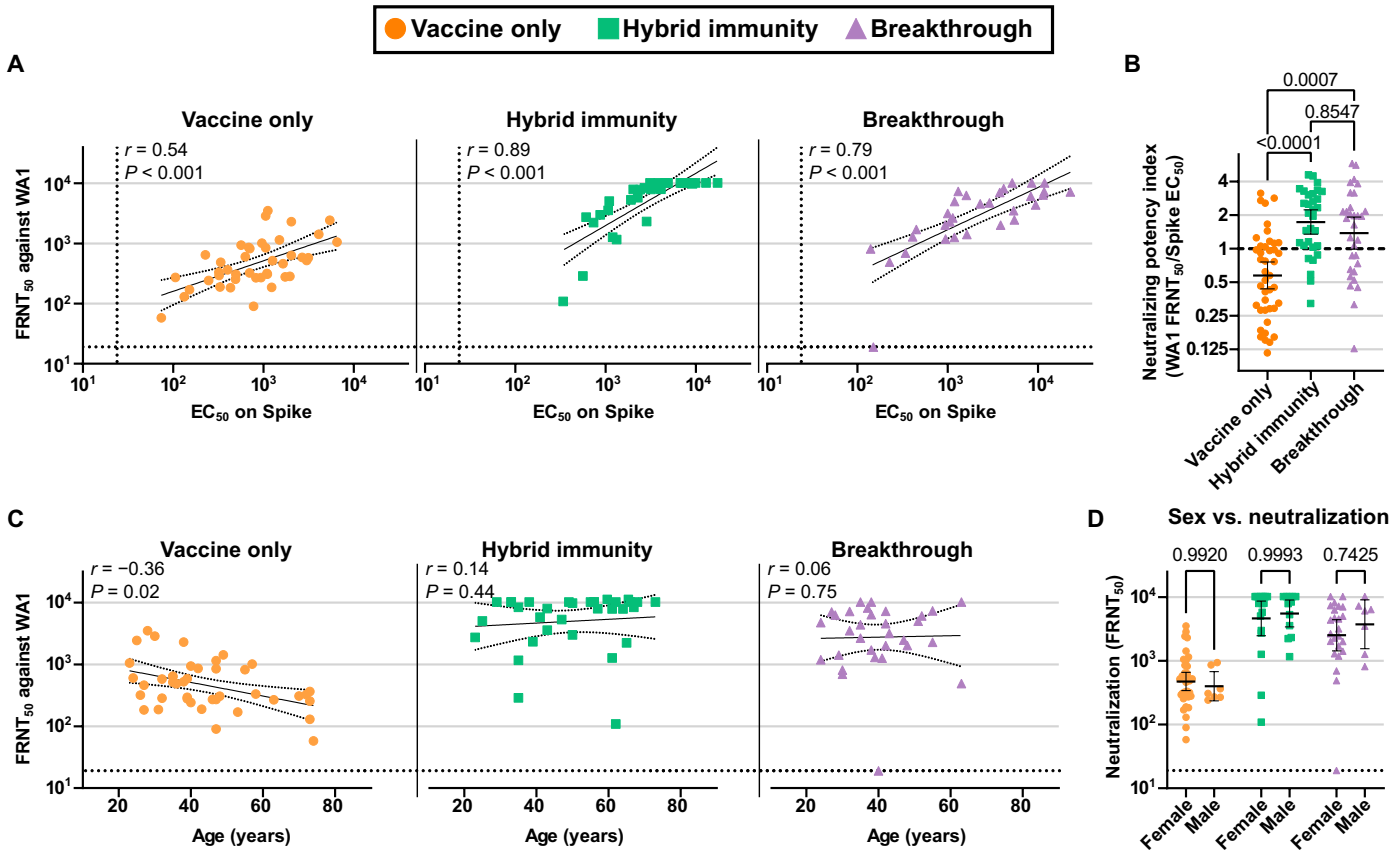

Fig. 3. Neutralizing efficiency and correlation with age. (**A**) Correlation between spike-specific EC_{50} values and WA1 neutralizing titers. (**B**) Serum-neutralizing potency index was calculated as the ratio of WA1 neutralizing titer to spike-specific EC_{50} values. (**C**) Correlation between age and WA1 neutralizing titers. (**D**) WA1 neutralization by sex. Error bars in (B) and (D) indicate the geometric mean with the 95% confidence interval. *P* values in (B) were two-tailed and calculated with the Kruskal-Wallis method with Dunn's multiple comparison correction. *P* values in (D) were two-tailed and calculated using a two-way analysis of variance (ANOVA) with the Šidák multiple comparison correction. Scatterplots in (A) depict the simple linear fit of log-transformed $FRNT_{50}$ versus log-transformed EC_{50} values with 95% confidence bands. Scatterplots in (C) depict the simple linear fit of log-transformed $FRNT_{50}$ versus age with 95% confidence bands. Correlations in (A) and (C) show Spearman's rank correlation coefficients and two-tailed *P* values.

before or after naturally acquired SARS-CoV-2 infection. Serum samples were collected from participants, which were analyzed using ELISAs, FRNTs, and measurement of ADCP. Study participants were selected for inclusion on the basis of a history of both vaccination and previous SARS-CoV-2 infection. Vaccinated controls with no history of previous infection were selected on the basis of sex, age, days between vaccine doses, and the time period since the most recent vaccination.

Cohort selection and serum collection

Health care workers at Oregon Health & Science University (OHSU) were recruited and enrolled in the study belonging to three groups: vaccine-only, hybrid immunity, and breakthrough infection. Written informed consent was obtained at the time of enrollment, and study approval was obtained from the OHSU institutional review board (IRB no. 00022511). Vaccine-only participants were fully vaccinated, defined as having received two doses of BNT162b2 or mRNA-1273, or one dose of Ad26.COV2.S. Serum samples were collected at least 14 days after the final vaccine dose. Hybrid immune participants had a history of PCR-confirmed diagnosis of COVID-19 at least 10 days before vaccination with at least one dose of BNT162b2, mRNA-1273, or Ad26.COV2.S, and serum samples were collected at least 10 days after the final vaccine dose. Breakthrough participants were fully vaccinated as defined for the vaccine-only group at least 10 days before PCR-confirmed diagnosis of COVID-19, and serum samples were collected at least 10 days after the date of diagnosis. Sera were obtained by collecting 4 to 6 ml of whole blood in a BD Vacutainer Plus plastic serum tube, which was centrifuged at 1000*g* for 10 min before serum was aliquoted and stored at −20°C. Hybrid immune and breakthrough infection participants were selected on the basis of availability, whereas vaccine-only participants were selected to most closely match the average sex, age, and time since most recent vaccination (or infection for breakthrough) of the other two groups. Participants in these cohorts are previously described (*20*, *26*).

Enzyme-linked immunosorbent assays

ELISAs were performed as previously described (*20*). In 96-well plates (Corning Incorporated, EIA/RIA High Binding, reference no. 359096). Plates were coated with 100 µl per well of the following proteins at 1 µg/ml in phosphate-buffered saline (PBS) and incubated overnight at 4°C with rocking: SARS-CoV-2 RBD (produced in

Expi293F cells and purified using Ni-NTA chromatography), full-length SARS-CoV-2 spike (Recombinant Spike, SARS-CoV-2 stabilized protein, produced in Expi293F cells, BEI resources no. NR-52724), and nucleocapsid (SARS-CoV-2 Nucleocapsid-His, insect cell-expressed, SinoBio catalog no. 40588-V08B, item no. NR-53797, and lot no. MF14DE1611). Plates were washed three times with 0.05% (v/v) Tween 20 in PBS (wash buffer) and blocked with 150 µl per well and 5% nonfat dry milk powder in wash buffer (blocking buffer) at room temperature (RT) of about 20°C for 1 hour with rocking. Breakthrough and control sera were aliquoted and frozen in dilution plates and then resuspended in blocking buffer; sera were diluted and added to ELISA plates 100 µl per well (6 × 4-fold dilutions from 1:50 to 1:51,200), except for IgM (6 × 3-fold dilutions from 1:25 to 1:6075). Sera were incubated for 1 hour at RT before plates were filled three times with wash buffer. Secondary antibodies were added to plates at 100 µl per well depending on the intended readout: goat anti-human IgG/IgA/IgM–horseradish peroxidase (HRP) at 1:10,000 (Invitrogen, reference no. A18847), anti-human IgA-HRP at 1:3000 (BioLegend, reference no. 411002), mouse anti-human IgG-HRP clone G18-145 at 1:3000 (BD Biosciences, reference no. 555788), and goat anti-human IgM-HRP at 1:3000 (Bethyl Laboratories, reference no. A80-100P). Plates were incubated, protected from light with secondary antibody at RT for 1 hour with rocking, and then filled three times with wash buffer before the development with *o*-phenylenediamine dihydrochloride (Thermo Fisher Scientific, no. 34005) according to the manufacturer's instructions. The reaction was stopped after 25 min using an equivalent volume of 1 M HCl; optical density was measured at 492 nm using a CLARIOstar plate reader. Normalized A_{492} values were calculated by subtracting the average of negative control wells and dividing by the 99th percentile of all wells from the same experiment. A dilution series of positive control serum was included on each plate to verify appropriate performance of the assay.

Cell culture

Vero E6 monkey kidney epithelial cells (CRL-1586) were obtained from the American Type Culture Collection (ATCC) and maintained in tissue culture-treated vessels in Dulbecco's modified Eagle's medium, 10% fetal bovine serum (FBS), 1% nonessential amino acids (NEAAs), and 1% penicillin-streptomycin (PS) (complete media) under tissue culture conditions (TCCs) of 100% relative humidity, 37°C, and 5% CO_2. THP-1 (ATCC, TIB-202) human monocyte cells were obtained from ATCC and maintained in suspension culture in tissue culture–treated vessels in Roswell Park Memorial Institute medium (RPMI-1640) supplemented with 10% FBS, 1% NEAA, and 1% PS (THP-1 media).

SARS-CoV-2 growth and titration

SARS-CoV-2 isolates USA-WA1/2020 [lineage A] (NR-52281), USA/CA_CDC_5574/2020 [lineage B.1.1.7—alpha] (NR-54011), hCoV-19/South Africa/KRISP-K005325/2020 [lineage B.1.351—beta] (NR-54009), and hCoV-19/USA/PHC658/2021 [lineage B.1.617.2—delta] (NR-55611) were obtained from BEI Resources. Viral stocks were propagated as previously described (*5*). Subconfluent Vero E6 cells were infected at a multiplicity of infection of 0.05 in a minimal volume (0.01 ml/cm^2) of Opti-MEM + 2% FBS (dilution media) for 1 hour at TCC, and then additional complete media (0.1 ml/cm^2) was added and incubated for 24 hours at TCC. Culture supernatant was centrifuged for 10 min at 1000*g* and frozen at −80°C in aliquots. Titration was performed on clear 96-well tissue culture plates containing 70 to 90% confluent (at the time of infection) Vero E6 cells. Dilutions (8 × 10-fold) were prepared in dilution media, and 30 µl per well of diluted virus was incubated with the cells for 1 hour at TCC before further addition of Opti-MEM, 2% FBS, and 1% methylcellulose (overlay media) and incubation for 24 hours at TCC. Plates were then fixed by soaking in 4% formaldehyde in PBS for 1 hour and then removing from the biosafety level three facility following institutional biosafety protocols. Cells were permeabilized in 0.1% bovine serum albumin and 0.1% saponin in PBS (perm buffer) for 30 min and then with polyclonal anti–SARS-CoV-2 alpaca serum (Capralogics Inc.) (1:5000 in perm buffer) overnight at 4°C. Plates were washed three times with 0.01% Tween 20 in PBS (focus wash buffer) and then incubated for 2 hours at RT with 1:20,000 anti-alpaca-HRP (Novus, no. NB7242). Plates were filled three times with focus wash buffer and then incubated with TrueBlue (SeraCare, no. 5510-0030) for 30 min or until sufficiently developed for imaging. Well images were captured with a CTL ImmunoSpot Analyzer and counted with Viridot (1.0) in R (3.6.3) (*27*). Viral stock titers in focus-forming units (FFU) were calculated from the dilution factor and volume used during infection.

Focus reduction neutralization test

FRNT assays were carried out as previously described (*5*). Duplicate 5 × 4.7-fold (1:10 to 1:4879) serial dilutions of participant sera were prepared in 96-well plates. An equal volume of dilution media containing about 50 FFU of SARS-CoV-2 or variant was added to each well (final dilutions of sera, 1:20 to 1:9760) and incubated for 1 hour at TCC. Virus-serum mixtures were used to infect Vero E6 cells in 96-well plates as described above in the titration assay. Each plate contained 16 virus-only control wells, one for each serum dilution series. Fixation, development, and counting of FRNT plates were carried out as described above in the titration assay. Percent neutralization values were calculated for each well as the focus count divided by the average focus count of virus-only control wells from the same plate.

Antibody-dependent cellular phagocytosis

ADCP assay was adapted from a protocol described previously (*28*). Biotinylated RBD was incubated at 1 µg/ml with fluorescent neutravidin beads (Invitrogen, F8775) for 2 hours at RT; beads were washed twice with 1% bovine serum albumin in PBS (dilution buffer) and resuspended at a final dilution of 1:100 in dilution buffer. In a 96-well plate, 10 µl of resuspended bead solution was incubated with 10 µl of diluted serum from study participants for 2 hours at 37°C. After serum pretreatment, 2 × 10^4 THP-1 cells were added to each well in 80 µl of THP-1 media and incubated overnight in TCC. The following morning, 100 µl of 4% paraformaldehyde was added to each well and incubated at least 30 min at RT before analysis on a CytoFLEX flow cytometer (Beckman Coulter). Samples were mixed for 3 s before analysis, and samples were injected until at least 2500 cell events were recorded per sample. Phagocytosis scores are reported as the product of percent bead-positive cells and mean fluorescence intensity of bead-positive cells and then divided by 10^6 for presentation. Three replicate experiments were performed for each participant serum sample, the average of which was used for further analysis. The gating strategy with representative data is presented in fig. S4.

Statistical analysis

$FRNT_{50}$ and EC_{50} values were calculated by fitting percent neutralization or normalized A_{492} values to a dose-response curve as previously

described (*5*). Final $FRNT_{50}$ values below the limit of detection (1:20) were set to 1:19. Final EC_{50} values below the limit of detection of 1:25 for N, Spike, RBD, IgG, and IgA were set to 1:24, and values below 1:12.5 for IgM were set to 1:12. Aggregated EC_{50} and $FRNT_{50}$ values were analyzed and plotted in GraphPad Prism (9.2.0). Dot plots of EC_{50} and $FRNT_{50}$ values were generated on a log-transformed axis with error bars showing the geometric mean and 95% confidence interval. Phagocytosis score and neutralization ratio were plotted on a linear axis with error bars showing the arithmetic mean and 95% confidence interval. *P* values for dot plots were two-tailed and calculated using the Kruskal-Wallis test with Dunn's multiple comparison correction. *P* values for reported sex versus neutralization were two-tailed and calculated by group using a two-way ANOVA with the Šidák multiple comparison correction. Scatterplots were prepared by first log-transforming $FRNT_{50}$ and EC_{50} data and then performing simple linear fitting and plotting the 95% confidence bands. Correlations were calculated using Spearman's correlation, and two-tailed *P* values were calculated for the 95% confidence interval.

SUPPLEMENTARY MATERIALS

www.science.org/doi/10.1126/sciimmunol.abn8014
Figs. S1 to S4
MDAR Reproducibility Checklist

View/request a protocol for this paper from *Bio-protocol*.

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Acknowledgments: We acknowledge the study participants for contributions, the OHSU COVID-19 serology study team and the OHSU occupational health department for recruitment and sample acquisition, and the OHSU clinical laboratory under the direction of D. Hansel and X. Qin for SARS-CoV-2 testing and reporting. Flow cytometry experiments were performed with support from the OHSU Flow Cytometry Shared Resource. **Funding:** This study was funded by a grant from the M. J. Murdock Charitable Trust (to M.E.C.), an unrestricted grant from the OHSU Foundation (to M.E.C.), the NIH training grant T32HL083808 (to T.A.B.), OHSU Innovative IDEA grant 1018784 (to F.G.T.), and NIH grant R01AI145835 (to W.B.M.). **Author contributions:** Conceptualization: T.A.B., M.E.C., F.G.T. Cohort recruitment: T.A.B., Z.L.L., D.S., B.W., H.C.L., D.X.L., W.B.M., M.E.C. Experimental design: T.A.B., F.G.T. Laboratory Analysis: T.A.B., S.K.M., G.G. Statistical analysis: T.A.B. Data visualization: T.A.B., J.-Y.L. Funding acquisition: T.A.B., W.B.M., M.E.C., F.G.T. Supervision: W.B.M., M.E.C., F.G.T. Writing - original draft: T.A.B. Writing - review and editing: T.A.B., W.B.M., M.E.C., F.G.T. **Competing interests:** The authors declare that they have no competing interests. **Data and materials availability:** All data needed to evaluate the conclusions in the paper are present in the paper or the Supplementary Materials.

Submitted 21 December 2021
Accepted 19 January 2022
Published First Release 25 January 2022
Final published 18 February 2022
10.1126/sciimmunol.abn8014

Science Immunology

Vaccination before or after SARS-CoV-2 infection leads to robust humoral response and antibodies that effectively neutralize variants

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Sci. Immunol., 7 (68), eabn8014. • DOI: 10.1126/sciimmunol.abn8014

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Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study

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Summary

Background The SARS-CoV-2 delta (B.1.617.2) variant is highly transmissible and spreading globally, including in populations with high vaccination rates. We aimed to investigate transmission and viral load kinetics in vaccinated and unvaccinated individuals with mild delta variant infection in the community.

Methods Between Sept 13, 2020, and Sept 15, 2021, 602 community contacts (identified via the UK contract-tracing system) of 471 UK COVID-19 index cases were recruited to the Assessment of Transmission and Contagiousness of COVID-19 in Contacts cohort study and contributed 8145 upper respiratory tract samples from daily sampling for up to 20 days. Household and non-household exposed contacts aged 5 years or older were eligible for recruitment if they could provide informed consent and agree to self-swabbing of the upper respiratory tract. We analysed transmission risk by vaccination status for 231 contacts exposed to 162 epidemiologically linked delta variant-infected index cases. We compared viral load trajectories from fully vaccinated individuals with delta infection (n=29) with unvaccinated individuals with delta (n=16), alpha (B.1.1.7; n=39), and pre-alpha (n=49) infections. Primary outcomes for the epidemiological analysis were to assess the secondary attack rate (SAR) in household contacts stratified by contact vaccination status and the index cases' vaccination status. Primary outcomes for the viral load kinetics analysis were to detect differences in the peak viral load, viral growth rate, and viral decline rate between participants according to SARS-CoV-2 variant and vaccination status.

Findings The SAR in household contacts exposed to the delta variant was 25% (95% CI 18–33) for fully vaccinated individuals compared with 38% (24–53) in unvaccinated individuals. The median time between second vaccine dose and study recruitment in fully vaccinated contacts was longer for infected individuals (median 101 days [IQR 74–120]) than for uninfected individuals (64 days [32–97], p=0·001). SAR among household contacts exposed to fully vaccinated index cases was similar to household contacts exposed to unvaccinated index cases (25% [95% CI 15–35] for vaccinated *vs* 23% [15–31] for unvaccinated). 12 (39%) of 31 infections in fully vaccinated household contacts arose from fully vaccinated epidemiologically linked index cases, further confirmed by genomic and virological analysis in three index case–contact pairs. Although peak viral load did not differ by vaccination status or variant type, it increased modestly with age (difference of 0·39 [95% credible interval –0·03 to 0·79] in peak $\log_{10}$ viral load per mL between those aged 10 years and 50 years). Fully vaccinated individuals with delta variant infection had a faster (posterior probability >0·84) mean rate of viral load decline (0·95 $\log_{10}$ copies per mL per day) than did unvaccinated individuals with pre-alpha (0·69), alpha (0·82), or delta (0·79) variant infections. Within individuals, faster viral load growth was correlated with higher peak viral load (correlation 0·42 [95% credible interval 0·13 to 0·65]) and slower decline (–0·44 [–0·67 to –0·18]).

Interpretation Vaccination reduces the risk of delta variant infection and accelerates viral clearance. Nonetheless, fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts. Host–virus interactions early in infection may shape the entire viral trajectory.

Funding National Institute for Health Research.

Introduction

While the primary aim of vaccination is to protect individuals against severe COVID-19 disease and its consequences, the extent to which vaccines reduce onward transmission of SARS-CoV-2 is key to containing the pandemic. This outcome depends on the ability of

Lancet Infect Dis 2022; 22: 183–95

Published Online October 28, 2021 https://doi.org/10.1016/S1473-3099(21)00648-4

This online publication has been corrected. The corrected version first appeared at thelancet.com/infection on November 2, 2021

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Research in context

Evidence before this study

The SARS-CoV-2 delta variant is spreading globally, including in populations with high vaccination coverage. While vaccination remains highly effective at attenuating disease severity and preventing death, vaccine effectiveness against infection is reduced for delta. Determining the extent of transmission from vaccinated delta-infected individuals to their vaccinated contacts is a public health priority. Comparing the upper respiratory tract (URT) viral load kinetics of delta infections with those of other variants gives insight into potential mechanisms for its increased transmissibility. We searched PubMed and *medRxiv* for articles published between database inception and Sept 20, 2021, using search terms describing "SARS-CoV-2, delta variant, viral load, and transmission". Two studies longitudinally sampled the URT in vaccinated and unvaccinated delta variant-infected individuals to compare viral load kinetics. In a retrospective study of a cohort of hospitalised patients in Singapore, more rapid viral load decline was found in vaccinated individuals than unvaccinated cases. However, the unvaccinated cases in this study had moderate-to-severe infection, which is known to be associated with prolonged shedding. The second study longitudinally sampled professional USA sports players. Again, clearance of delta viral RNA in vaccinated cases was faster than in unvaccinated cases, but only 8% of unvaccinated cases had delta variant infection, complicating interpretation. Lastly, a report of a single-source nosocomial outbreak of a distinct delta sub-lineage in Vietnamese health-care workers plotted viral load kinetics (without comparison with unvaccinated delta infections) and demonstrated transmission between fully vaccinated health-care workers in the nosocomial setting. The findings might therefore not be generalisable beyond the particular setting and distinct viral sub-lineage investigated.

Added value of this study

The majority of SARS-CoV-2 transmission occurs in households, but transmission between fully vaccinated individuals in this setting has not been shown to date. To ascertain secondary transmission with high sensitivity, we longitudinally followed index cases and their contacts (regardless of symptoms) in the community early after exposure to the delta variant of SARS-CoV-2, performing daily quantitative RT-PCR on URT samples for 14–20 days. We found that the secondary attack rate in fully vaccinated household contacts was high at 25%, but this value was lower than that of unvaccinated contacts (38%). Risk of infection increased with time in the 2–3 months since the second dose of vaccine. The proportion of infected contacts was similar regardless of the index cases' vaccination status. We observed transmission of the delta variant between fully vaccinated index cases and their fully vaccinated contacts in several households, confirmed by whole-genome sequencing. Peak viral load did not differ by vaccination status or variant type but did increase modestly with age. Vaccinated delta cases experienced faster viral load decline than did unvaccinated alpha or delta cases. Across study participants, faster viral load growth was correlated with higher peak viral load and slower decline, suggesting that host–virus interactions early in infection shape the entire viral trajectory. Since our findings are derived from community household contacts in a real-life setting, they are probably generalisable to the general population.

Implications of all the available evidence

Although vaccines remain highly effective at preventing severe disease and deaths from COVID-19, our findings suggest that vaccination is not sufficient to prevent transmission of the delta variant in household settings with prolonged exposures. Our findings highlight the importance of community studies to characterise the epidemiological phenotype of new SARS-CoV-2 variants in increasingly highly vaccinated populations. Continued public health and social measures to curb transmission of the delta variant remain important, even in vaccinated individuals.

vaccines to protect against infection and the extent to which vaccination reduces the infectiousness of breakthrough infections.

Vaccination was found to be effective in reducing household transmission of the alpha variant (B.1.1.7) by 40–50%,[1] and infected, vaccinated individuals had lower viral load in the upper respiratory tract (URT) than infections in unvaccinated individuals,[2] which is indicative of reduced infectiousness.[3,4] However, the delta variant (B.1.617.2), which is more transmissible than the alpha variant,[5,6] is now the dominant strain worldwide. After a large outbreak in India, the UK was one of the first countries to report a sharp rise in delta variant infection. Current vaccines remain highly effective at preventing admission to hospital and death from delta infection.[7] However, vaccine effectiveness against infection is reduced for delta, compared with alpha,[8,9] and the delta variant continues to cause a high burden of cases even in countries with high vaccination coverage. Data are scarce on the risk of community transmission of delta from vaccinated individuals with mild infections.

Here, we report data from a UK community-based study, the Assessment of Transmission and Contagiousness of COVID-19 in Contacts (ATACCC) study, in which ambulatory close contacts of confirmed COVID-19 cases underwent daily, longitudinal URT sampling, with collection of associated clinical and epidemiological data. We aimed to quantify household transmission of the delta variant and assess the effect of vaccination status on contacts' risk of infection and index cases' infectiousness, including (1) households with unvaccinated contacts and index cases and (2) households with fully vaccinated contacts and fully vaccinated index cases. We also compared sequentially sampled

URT viral RNA trajectories from individuals with non-severe delta, alpha, and pre-alpha SARS-CoV-2 infections to infer the effects of SARS-CoV-2 variant status—and, for delta infections, vaccination status—on transmission potential.

Methods

Study design and participants

ATACCC is an observational longitudinal cohort study of community contacts of SARS-CoV-2 cases. Contacts of symptomatic PCR-confirmed index cases notified to the UK contact-tracing system (National Health Service Test and Trace) were asked if they would be willing to be contacted by Public Health England to discuss participation in the study. All contacts notified within 5 days of index case symptom onset were selected to be contacted within our recruitment capacity. Household and non-household contacts aged 5 years or older were eligible for recruitment if they could provide written informed consent and agree to self-swabbing of the URT. Further details on URT sampling are given in the appendix (p 13).

The ATACCC study is separated into two study arms, ATACCC1 and ATACCC2, which were designed to capture different waves of the SARS-CoV-2 pandemic. In ATACCC1, which investigated alpha variant and pre-alpha cases in Greater London, only contacts were recruited between Sept 13, 2020, and March 13, 2021. ATACCC1 included a pre-alpha wave (September to November, 2020) and an alpha wave (December, 2020, to March, 2021). In ATACCC2, the study was relaunched specifically to investigate delta variant cases in Greater London and Bolton, and both index cases and contacts were recruited between May 25, and Sept 15, 2021. Early recruitment was focused in West London and Bolton because UK incidence of the delta variant was highest in these areas.[10] Based on national and regional surveillance data, community transmission was moderate-to-high throughout most of our recruitment period.

This study was approved by the Health Research Authority. Written informed consent was obtained from all participants before enrolment. Parents and caregivers gave consent for children.

Data collection

Demographic information was collected by the study team on enrolment. The date of exposure for non-household contacts was obtained from Public Health England. COVID-19 vaccination history was determined from the UK National Immunisation Management System, general practitioner records, and self-reporting by study participants. We defined a participant as unvaccinated if they had not received a single dose of a COVID-19 vaccine at least 7 days before enrolment, partially vaccinated if they had received one vaccine dose at least 7 days before study enrolment, and fully vaccinated if they had received two doses of a COVID-19 vaccine at least 7 days before study enrolment. Previous literature was used to determine the 7-day threshold for defining vaccination status.[11–13] We also did sensitivity analyses using a 14-day threshold. The time interval between vaccination and study recruitment was calculated. We used WHO criteria[14] to define symptomatic status up to the day of study recruitment. Symptomatic status for incident cases—participants who were PCR-negative at enrolment and subsequently tested positive—was defined from the day of the first PCR-positive result.

Laboratory procedures

SARS-CoV-2 quantitative RT-PCR, conversion of ORF1ab and envelope (E-gene) cycle threshold values to viral genome copies, whole-genome sequencing, and lineage assignments are described in the appendix (pp 13–14).

Outcomes

Primary outcomes for the epidemiological analysis were to assess the secondary attack rate (SAR) in household contacts stratified by contact vaccination status and the index cases' vaccination status. Primary outcomes for the viral load kinetics analysis were to detect differences in the peak viral load, viral growth rate, and viral decline rate between participants infected with pre-alpha versus alpha versus delta variants and between unvaccinated delta-infected participants and vaccinated delta-infected participants.

See Online for appendix

We assessed vaccine effectiveness and susceptibility to SARS-CoV-2 infection stratified by time elapsed since receipt of second vaccination as exploratory analyses.

Statistical analysis

To model viral kinetics, we used a simple phenomenological model of viral titre[15] during disease pathogenesis. Viral kinetic parameters were estimated on a participant-specific basis using a Bayesian hierarchical model to fit this model to the entire dataset of sequential cycle threshold values measured for all participants. For the 19 participants who were non-household contacts of index cases and had a unique date of exposure, the cycle threshold data were supplemented by a pseudo-absence data point (ie, undetectable virus) on the date of exposure. Test accuracy and model misspecification were modelled with a mixture model by assuming there was a probability p of a test giving an observation drawn from a (normal) error distribution and probability $1-p$ of it being drawn from the true distribution.

The hierarchical structure was represented by grouping participants based on the infecting variant and their vaccination status. A single-group model was fitted, which implicitly assumes that viral kinetic parameters vary by individual but not by variant or vaccination status. A four-group model was also explored, where groups 1, 2, 3, and 4 represent pre-alpha, alpha, unvaccinated delta, and fully vaccinated delta, respectively. We fitted a correlation matrix between

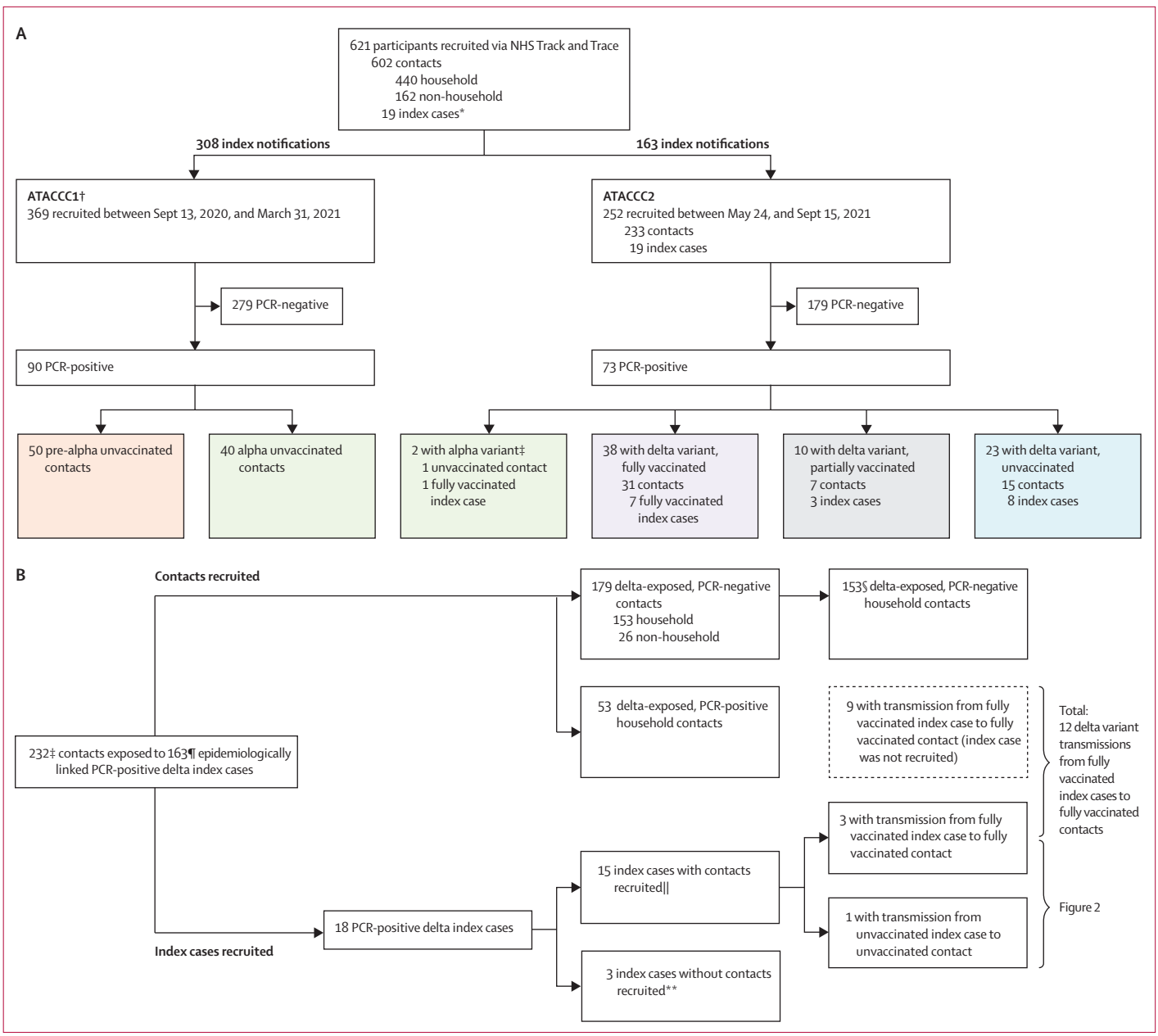


Figure 1: **Recruitment, SARS-CoV-2 infection, variant status, and vaccination history for ATACCC study participants**
(A) Study recruitment and variant status confirmed by whole-genome sequencing (ATACCC1 and ATACCC2 combined). (B) ATACCC2: delta-exposed contacts included in secondary attack rate calculation (table 1) and transmission assessment (table 2). NHS=National Health Service. *All index cases were from ATACCC2. †All contacts. ‡The two earliest PCR-positive cases from the ATACCC2 cohort (one index case and one contact) were confirmed as having the alpha variant on whole-genome sequencing (recruited on May 28, 2021). This alpha variant-exposed, PCR-positive contact is excluded from figure 1B. §One PCR-negative contact had no vaccination status data available and one PCR-negative contact's index case had no vaccination data available. ¶Vaccination data were available for 138 index cases of 163. ||The contacts of these 15 index cases are included within the 232 total contacts. **These three index cases without contacts are only included in the viral load kinetics analysis (figure 3) and are not included in tables 1 and 2.

participant-specific kinetic parameters to allow us to examine whether there is within-group correlation between peak viral titre, viral growth rate, and viral decline rate. Our initial model selection, using leave-one-out cross-validation, selected a four-group hierarchical model with fitted correlation coefficients between individual-level parameters determining peak viral load and viral load growth and decline rates (appendix p 5). However, resulting participant-specific estimates of peak viral load (but not growth and decline rates) showed a marked and significant correlation with age in the exploratory analysis, which motivated examination of models where mean peak viral load could vary with age. The most predictive model overall allowed mean viral

load growth and decline rates to vary across the four groups, with mean peak viral load common to all groups but assumed to vary linearly with the logarithm of age (appendix p 5). We present peak viral loads for the reference age of 50 years with 95% credible intervals (95% CrIs). 50 years was chosen as the reference age as it is typical of the ages of the cases in the whole dataset and the choice of reference age made no difference in the model fits or judgment of differences between the groups.

We computed group-level population means and within-sample group means of log peak viral titre, viral growth rate, and viral decline rate. Since posterior estimates of each of these variables are correlated across groups, overlap in the credible intervals of an estimate for one group with that for another group does not necessarily indicate no significant difference between those groups. We, therefore, computed posterior probabilities, *pp*, that these variables were larger for one group than another. For our model, Bayes factors can be computed as *pp*/(1–*pp*). We only report population (group-level) posterior probabilities greater than 0·75 (corresponding to Bayes factors >3) as indicating at least moderate evidence of a difference.

For vaccine effectiveness, we defined the estimated effectiveness at preventing infection, regardless of symptoms, with delta in the household setting as 1 – SAR (fully vaccinated) / SAR (unvaccinated).

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Sept 13, 2020, and Sept 15, 2021, 621 community-based participants (602 contacts and 19 index cases) from 471 index notifications were prospectively enrolled in the ATACCC1 and ATACCC2 studies, and contributed 8145 URT samples. Of these, ATACCC1 enrolled 369 contacts (arising from 308 index notifications), and ATACCC2 enrolled 233 contacts (arising from 163 index notifications) and 19 index cases. SARS-CoV-2 RNA was detected in 163 (26%) of the 621 participants. Whole-genome sequencing of PCR-positive cases confirmed that 71 participants had delta variant infection (18 index cases and 53 contacts), 42 had alpha variant infection (one index case and 41 contacts), and 50 had pre-alpha variant infection (all contacts; figure 1A).

Of 163 PCR-positive participants, 89 (55%) were female and 133 (82%) were White. Median age was 36 years (IQR 26–50). Sex, age, ethnicity, body-mass index (BMI) distribution, and the frequency of comorbidities were similar among those with delta, alpha, and pre-alpha infection, and for vaccinated and unvaccinated delta-infected participants, except for age and sex (appendix pp 2–3). There were fewer unvaccinated females than males (p=0·04) and, as expected from the age-prioritisation of the UK vaccine roll-out, unvaccinated participants infected with the delta variant were significantly younger (p<0·001; appendix p 3). Median time between exposure to the index case and study enrolment was 4 days (IQR 4–5). All participants had non-severe ambulatory illness or were asymptomatic. The proportion of asymptomatic cases did not differ among fully vaccinated, partially vaccinated, and unvaccinated delta groups (appendix p 3).

No pre-alpha-infected and only one alpha-infected participant had received a COVID-19 vaccine before study enrolment. Of 71 delta-infected participants (of whom 18 were index cases), 23 (32%) were unvaccinated, ten (14%) were partially vaccinated, and 38 (54%) were fully vaccinated (figure 1A; appendix p 3). Of the 38 fully vaccinated delta-infected participants, 14 had received the BNT162b2 mRNA vaccine (Pfizer–BioNTech), 23 the ChAdOx1 nCoV-19 adenovirus vector vaccine (Oxford–AstraZeneca), and one the CoronaVac inactivated whole-virion vaccine (Sinovac).

It is highly probable that all but one of the 233 ATACCC2 contacts were exposed to the delta variant because they were recruited when the regional prevalence of delta was at least 90%, and mostly 95–99% (figure 1B).[10] Of these, 206 (89%) were household contacts (in 127 households), and 26 (11%) were non-household contacts. Distributions of age, ethnicity, BMI, smoking status, and comorbidities were similar between PCR-positive and PCR-negative contacts (appendix p 4). The median time between second vaccine dose and study recruitment in fully vaccinated contacts with delta variant infection was 74 days (IQR 35–105; range 16–201), and this was significantly longer in PCR-positive contacts than in PCR-negative contacts (101 days [IQR 74–120] *vs* 64 days [32–97], respectively, p=0·001; appendix p 4). All 53 PCR-positive contacts were exposed in household settings and the SAR for all delta variant-exposed household contacts was 26% (95% CI 20–32). SAR was

	Total	PCR positive	PCR negative	SAR (95% CI)	p value
Contacts					
All	231	53	178	23 (18–29)	NA
Fully vaccinated	140	31	109	22 (16–30)	0·16
Unvaccinated	44	15	29	34 (22–49)	..
Partially vaccinated	47	7	40	15 (7–28)	NA
Household contacts					
All	205	53	152	26 (20–32)	NA
Fully vaccinated	126	31	95	25 (18–33)	0·17
Unvaccinated	40	15	25	38 (24–53)	..
Partially vaccinated	39	7	32	18 (9–33)	NA

χ^2 test was performed to calculate p values for differences in SAR between fully vaccinated and unvaccinated cases. One PCR-negative contact who withdrew from the study without vaccination status information was excluded. NA=not applicable. SAR=secondary attack rate.

Table 1: **SAR in contacts of delta-exposed index cases recruited to the ATACCC2 study**

	All household contacts (n=204)*	Fully vaccinated contacts (n=125)		Partially vaccinated contacts (n=39)		Unvaccinated contacts (n=40)	
		PCR positive (n=31)	PCR negative (n=94)	PCR positive (n=7)	PCR negative (n=32)	PCR positive (n=15)	PCR negative (n=25)
Fully vaccinated index cases (n=50)	69	12	31	1	8	4	13
Partially vaccinated index cases (n=25)	35	7	12	3	10	3	0
Unvaccinated index cases (n=63)	100	12	51	3	14	8	12

Non-household exposed contacts (n=24, all PCR negative) were excluded. One PCR-negative household contact who withdrew from the study without vaccination status information was excluded. One PCR-negative household contact who could not be linked to their index case was also excluded. *The rows below show the number of contacts exposed to each category of index case.

Table 2: **Comparison of vaccination status of the 138 epidemiologically linked PCR-positive index cases for 204 delta variant-exposed household contacts**

not significantly higher in unvaccinated (38%, 95% CI 24–53) than fully vaccinated (25%, 18–33) household contacts (table 1). We estimated vaccine effectiveness at preventing infection (regardless of symptoms) with delta in the household setting to be 34% (bootstrap 95% CI –15 to 60). Sensitivity analyses using a 14 day threshold for time since second vaccination to study recruitment to denote fully vaccinated did not materially affect our estimates of vaccine effectiveness or SAR (data not shown). Although precision is restricted by the small sample size, this estimate is broadly consistent with vaccine effectiveness estimates for delta variant infection based on larger datasets.[9,16,17]

The vaccination status of 138 epidemiologically linked index cases of 204 delta variant-exposed household contacts was available (figure 1B, table 2). The SAR in household contacts exposed to fully vaccinated index cases was 25% (95% CI 15–35; 17 of 69), which is similar to the SAR in household contacts exposed to unvaccinated index cases (23% [15–31]; 23 of 100; table 2). The 53 PCR-positive contacts arose from household exposure to 39 PCR-positive index cases. Of these index cases who gave rise to secondary transmission, the proportion who were fully vaccinated (15 [38%] of 39) was similar to the proportion who were unvaccinated (16 [41%] of 39). The median number of days from the index cases' second vaccination to the day of recruitment for their respective contacts was 73 days (IQR 38–116). Time interval did not differ between index cases who transmitted infection to their contacts and those who did not (94 days [IQR 62–112] and 63 days [35–117], respectively; p=0·43).

18 of the 163 delta variant-infected index cases that led to contact enrolment were themselves recruited to ATACCC2 and serial URT samples were collected from them, allowing for more detailed virology and genome analyses. For 15 of these, their contacts were also recruited (13 household contacts and two non-household contacts). A corresponding PCR-positive household contact was identified for four of these 15 index cases (figure 1B). Genomic analysis showed that index–contact pairs were infected with the same delta variant sub-lineage in these instances, with one exception (figure 2A). In one household (number 4), an unvaccinated index case transmitted the delta variant to an unvaccinated contact, while another partially vaccinated contact was infected with a different delta sub-lineage (which was probably acquired outside the household). In the other three households (numbers 1–3), fully vaccinated index cases transmitted the delta variant to fully vaccinated household contacts, with high viral load in all cases, and temporal relationships between the viral load kinetics that were consistent with transmission from the index cases to their respective contacts (figure 2B).

Inclusion criteria for the modelling analysis selected 133 participant's viral load RNA trajectories from 163 PCR-positive participants (49 with the pre-alpha variant, 39 alpha, and 45 delta; appendix p 14). Of the 45 delta cases, 29 were fully vaccinated and 16 were unvaccinated; partially vaccinated cases were excluded. Of the 133 included cases, 29 (22%) were incident (ie, PCR negative at enrolment converting to PCR positive subsequently) and 104 (78%) were prevalent (ie, already PCR positive at enrolment). 15 of the prevalent cases had a clearly resolvable peak viral load. Figure 3 shows modelled viral RNA (ORF1ab) trajectories together with the viral RNA copy numbers measured for individual participants. The E-gene equivalent is shown in the appendix (p 2). Estimates derived from E-gene cycle threshold value data (appendix pp 5, 7, 9, 11) were similar to those for ORF1ab.

Although viral kinetics appear visually similar for all four groups of cases, we found quantitative differences in estimated viral growth rates and decline rates (tables 3, 4). Population (group-level) estimates of mean viral load decline rates based on ORF1ab cycle threshold value data varied in the range of 0·69–0·95 $\log_{10}$ units per mL per daxes 4; appendix p 10), indicating that a typical 10-day period was required for viral load to decline from peak to undetectable. A faster decline was seen in the alpha (*pp*=0·93), unvaccinated delta (*pp*=0·79), and fully vaccinated delta (*pp*=0·99) groups than in the pre-alpha group. The mean viral load decline rate of the fully vaccinated delta group was also faster than those of the alpha group (*pp*=0·84) and the unvaccinated delta group (*pp*=0·85). The differences in decline rates translate into a difference of about 3 days in the mean duration of the decline phase between the pre-alpha and delta vaccinated groups.

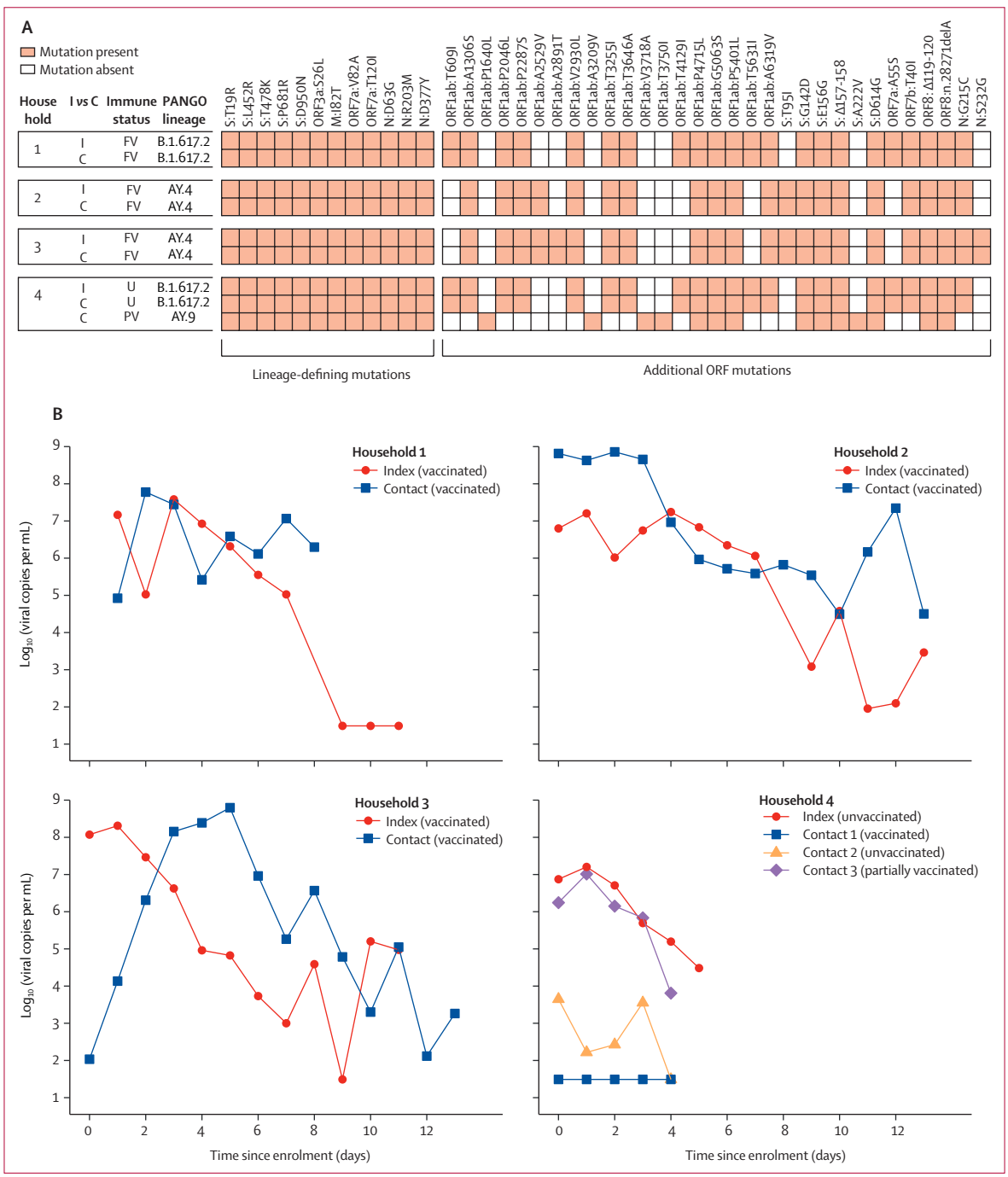
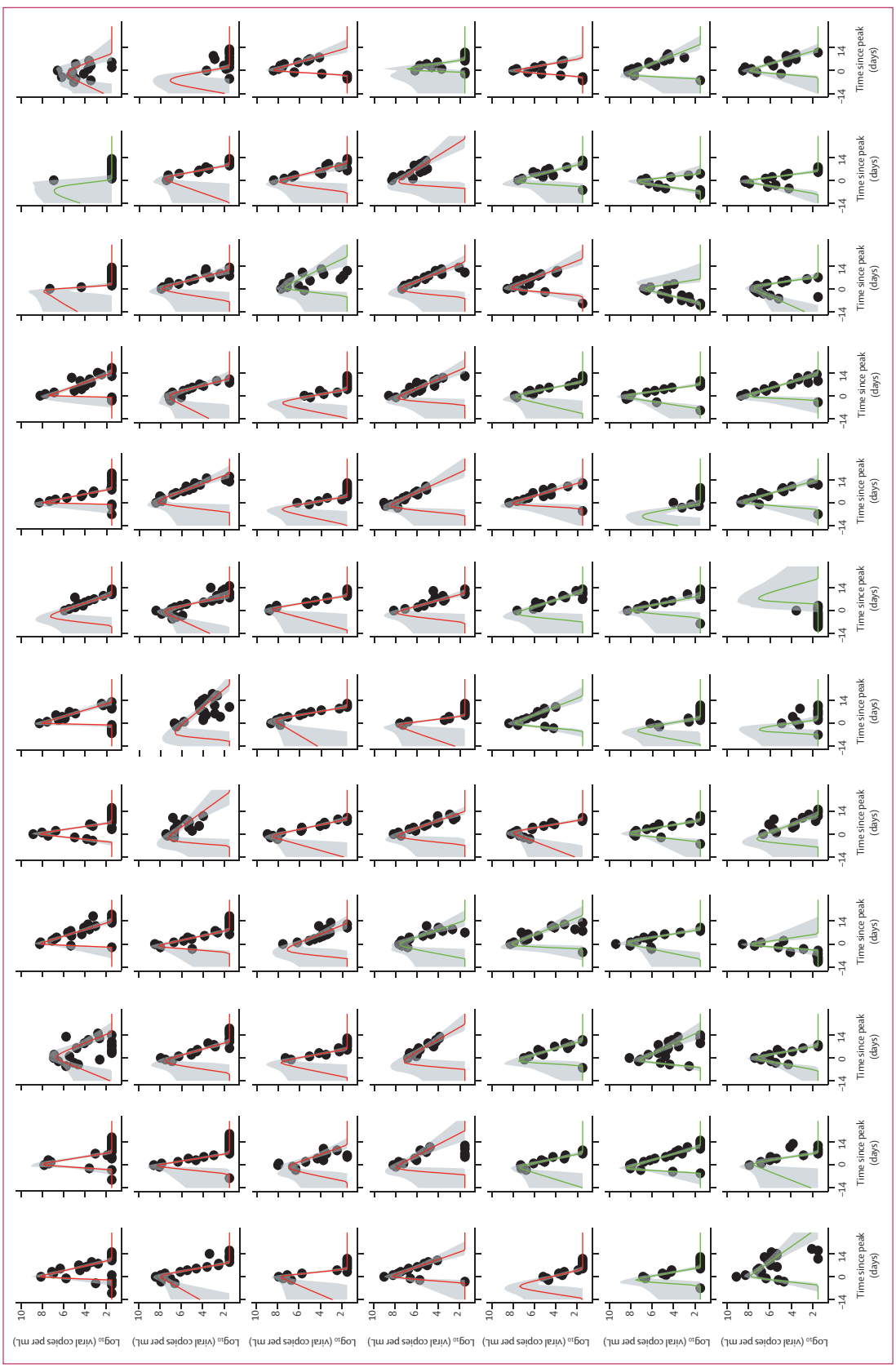


Figure 2: **Virological, epidemiological, and genomic evidence for transmission of the SARS-CoV-2 delta variant (B.1.617.2) in households**
(A) Genomic analysis of the four households with lineage-defining mutations for delta[18] and additional mutations within ORFs displayed to give insight into whether strains from individuals within the household are closely related. Lineages AY.4 and AY.9 are sub-lineages of delta. (B) Viral trajectories and vaccination status of the four index cases infected with the delta variant for whom infection was detected in their epidemiologically linked household contacts. All individuals had non-severe disease. Each plot shows an index case and their household contacts. Undetectable viral load measurements are plotted at the limit of detection ($10^{1\cdot49}$). C=contact. I=index case. FV=fully vaccinated. ORF=open reading frame. PV=partially vaccinated. U=unvaccinated.

Viral load growth rates were substantially faster than decline rates, varying in the range of 2·69–3·24 $\log_{10}$ units per mL per day between groups, indicating that a typical 3-day period was required for viral load to grow from undetectable to peak. Our power to infer differences in growth rates between groups was more restricted than for viral decline, but there was moderate evidence (*pp*=0·79) that growth rates were lower for



(Figure 3 continues on next page)

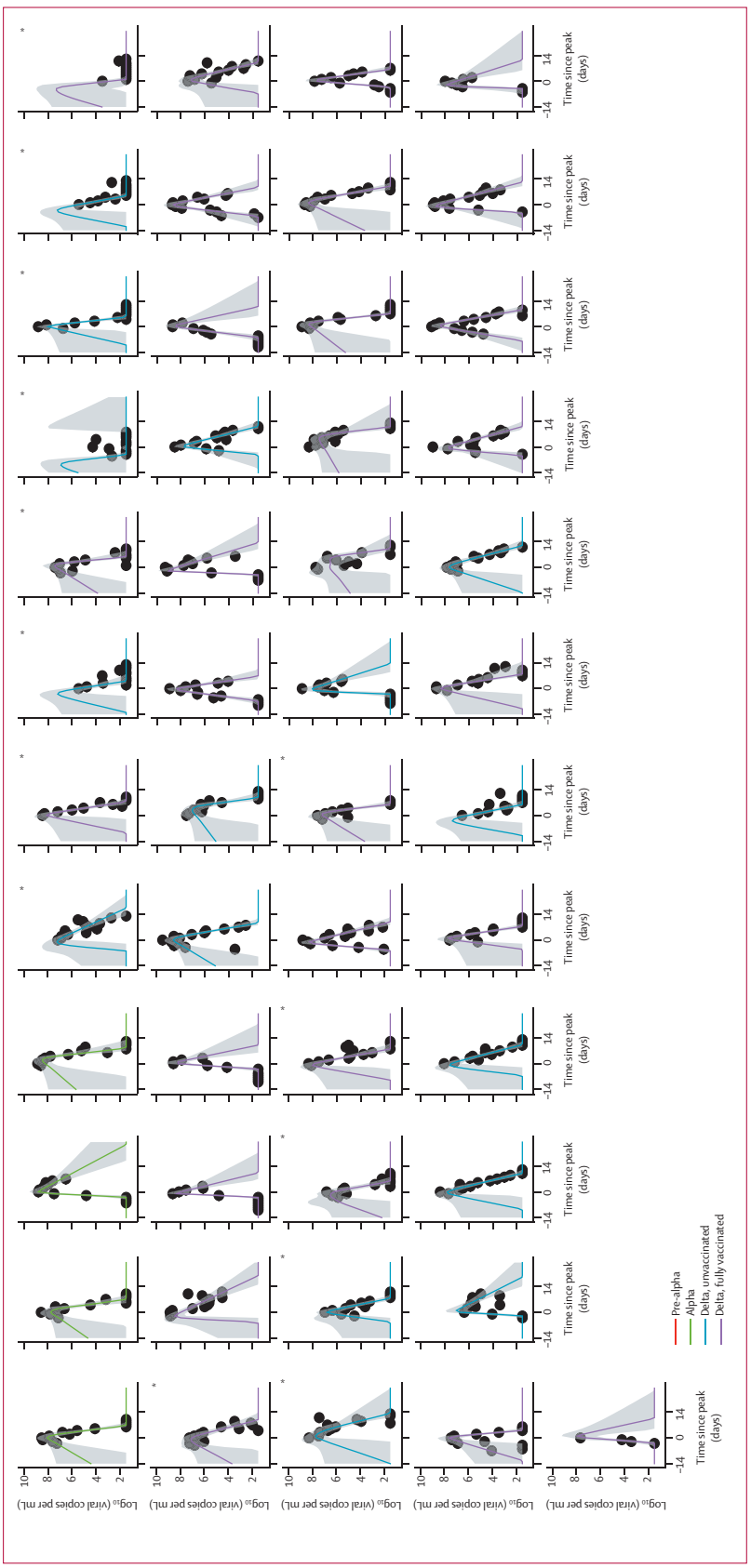


Figure 3: **ORF1ab viral load trajectories from 14 days before to 28 days after peak for 133 participants infected with pre-alpha or alpha variants (uncaccinated), or the delta variant (vaccinated and unvaccinated) variants**
Black circles are measured values, with the first datapoint for each participant being taken to the day of enrolment. Plots are rooted on the day of peak viral load for each participant, denoted as day 0 on the x-axis. Curves show the model posterior median estimate, with a 95% credible interval shading. 133 infected participants, comprising 114 contacts and 19 index cases. *Index cases.

	VL growth rate (95% CrI), log_{10} units per day	Posterior probability estimate is less than pre-alpha	Posterior probability estimate is less than alpha	Posterior probability estimate is less than delta (unvaccinated)	Posterior probability estimate is less than delta (fully vaccinated)
Pre-alpha (n=49)	3·24 (1·78–6·14)	..	0·44	0·27	0·21
Alpha (n=39)	3·13 (1·76–5·94)	0·56	..	0·32	0·25
Delta, unvaccinated (n=16)	2·81 (1·47–5·47)	0·73	0·68	..	0·44
Delta, fully vaccinated (n=29)	2·69 (1·51–5·17)	0·79	0·75	0·56	..

VL growth rates are shown as within-sample posterior mean estimates. Remaining columns show population (group-level) posterior probabilities that the estimate on that row is less than an estimate for a different group. Posterior probabilities are derived from 20 000 posterior samples and have sampling errors of <0·01. VL=viral load. CrI=credible interval.

Table 3: **Estimates of VL growth rates for pre-alpha, alpha, and delta (unvaccinated and fully vaccinated) cases, derived from ORF1ab cycle threshold data**

	VL decline rate (95% CrI), log_{10} units per day	Posterior probability estimate is larger than pre-alpha	Posterior probability estimate is larger than alpha	Posterior probability estimate is larger than delta (unvaccinated)	Posterior probability estimate is larger than delta (fully vaccinated)
Pre-alpha (n=49)	0·69 (0·58–0·81)	..	0·07	0·21	0·01
Alpha (n=39)	0·82 (0·67–1·01)	0·93	..	0·60	0·16
Delta, unvaccinated (n=16)	0·79 (0·59–1·04)	0·79	0·40	..	0·15
Delta, fully vaccinated (n=29)	0·95 (0·76–1·18)	0·99	0·84	0·85	..

VL decline rates are shown as within-sample posterior mean estimates. Remaining columns show population (group-level) posterior probabilities that the estimate on that row is less than an estimate for a different group. Posterior probabilities are derived from 20 000 posterior samples and have sampling errors of <0·01. VL=viral load. CrI=credible interval.

Table 4: **Estimates of VL decline rates for pre-alpha, alpha, and delta (unvaccinated and fully vaccinated) cases, derived from ORF1ab cycle threshold data**

those in the vaccinated delta group than in the pre-alpha group.

We estimated mean peak viral load for 50-year-old adults to be 8·14 (95% CrI 7·95 to 8·32) log_{10} copies per mL, but peak viral load did not differ by variant or vaccination status. However, we estimated that peak viral load increases with age (*pp*=0·96 that the slope of peak viral load with log[age] was >0), with an estimated slope of 0·24 (95% CrI –0·02 to 0·49) log_{10} copies per mL per unit change in log(age). This estimate translates to a difference of 0·39 (–0·03 to 0·79) in mean peak log_{10} copies per mL between those aged 10 years and 50 years.

Within-group individual participant estimates of viral load growth rate were positively correlated with peak viral load, with a correlation coefficient estimate of 0·42 (95% CrI 0·13 to 0·65; appendix p 8). Hence, individuals with faster viral load growth tend to have higher peak viral load. The decline rate of viral load was also negatively correlated with viral load growth rate, with a correlation coefficient estimate of –0·44 (95% CrI –0·67 to –0·18), illustrating that individuals with faster viral load growth tend to experience slower viral load decline.

Discussion

Households are the site of most SARS-CoV-2 transmission globally.[19] In our cohort of densely sampled household contacts exposed to the delta variant, SAR was 38% in unvaccinated contacts and 25% in fully vaccinated contacts. This finding is consistent with the known protective effect of COVID-19 vaccination against infection.[8,9] Notwithstanding, these findings indicate continued risk of infection in household contacts despite vaccination. Our estimate of SAR is higher than that reported in fully vaccinated household contacts exposed before the emergence of the delta variant.[1,20,21] The time interval between vaccination and study recruitment was significantly higher in fully vaccinated PCR-positive contacts than fully vaccinated PCR-negative contacts, suggesting that susceptibility to infection increases with time as soon as 2–3 months after vaccination—consistent with waning protective immunity. This potentially important observation is consistent with recent large-scale data and requires further investigation.[17] Household SAR for delta infection, regardless of vaccination status, was 26% (95% CI 20–32), which is higher than estimates of UK national surveillance data (10·8% [10·7–10·9]).[10] However, we sampled contacts daily, regardless of symptomatology, to actively identify infection with high sensitivity. By contrast, symptom-based, single-timepoint surveillance testing probably underestimates the true SAR, and potentially also overestimates vaccine effectiveness against infection.

We identified similar SAR (25%) in household contacts exposed to fully vaccinated index cases as in those exposed to unvaccinated index cases (23%). This finding indicates that breakthrough infections in fully vaccinated people can efficiently transmit infection in the household setting. We identified 12 household transmission events between fully vaccinated index case–contact pairs; for three of these, genomic sequencing confirmed that the index case and

contact were infected by the same delta variant sub-lineage, thus substantiating epidemiological data and temporal relationships of viral load kinetics to provide definitive evidence for secondary transmission. To our knowledge, one other study has reported that transmission of the delta variant between fully vaccinated people was a point-source nosocomial outbreak—a single health-care worker with a particular delta variant sub-lineage in Vietnam.[22]

Daily longitudinal sampling of cases from early (median 4 days) after exposure for up to 20 days allowed us to generate high-resolution trajectories of URT viral load over the course of infection. To date, two studies have sequentially sampled community cases of mild SARS-CoV-2 infection, and these were from highly specific population groups identified through asymptomatic screening programmes (eg, for university staff and students[23] and for professional athletes[24]).

Our most predictive model of viral load kinetics estimated mean peak $\log_{10}$ viral load per mL of 8·14 (95% CrI 7·95–8·32) for adults aged 50 years, which is very similar to the estimate from a 2021 study using routine surveillance data.[25] We found no evidence of variation in peak viral load by variant or vaccination status, but we report some evidence of modest but significant (pp=0·95) increases in peak viral load with age. Previous studies of viral load in children and adults[4,25,26] have not used such dense sequential sampling of viral load and have, therefore, been restricted in their power to resolve age-related differences; the largest such study[25] reported a similar difference between children and adults to the one we estimated. We found the rate of viral load decline was faster for vaccinated individuals with delta infection than all other groups, and was faster for individuals in the alpha and unvaccinated delta groups than those with pre-alpha infection.

For all variant vaccination groups, the variation between participants seen in viral load kinetic parameter estimates was substantially larger than the variation in mean parameters estimated between groups. The modest scale of differences in viral kinetics between fully vaccinated and unvaccinated individuals with delta infection might explain the relatively high rates of transmission seen from vaccinated delta index cases in our study. We found no evidence of lower SARs from fully vaccinated delta index cases than from unvaccinated ones. However, given that index cases were identified through routine symptomatic surveillance, there might have been a selection bias towards identifying untypically symptomatic vaccine breakthrough index cases.

The differences in viral kinetics we found between the pre-alpha, alpha, and delta variant groups suggest some incremental, but potentially adaptive, changes in viral dynamics associated with the evolution of SARS-CoV-2 towards more rapid viral clearance. Our study provides the first evidence that, within each variant or vaccination group, viral growth rate is positively correlated with peak viral load, but is negatively correlated with viral decline rate. This finding suggests that individual infections during which viral replication is initially fastest generate the highest peak viral load and see the slowest viral clearance, with the latter not just being due to the higher peak. Mechanistically, these data suggest that the host and viral factors determining the initial growth rate of SARS-CoV-2 have a fundamental effect on the trajectory throughout infection, with faster replication being more difficult (in terms of both peak viral load and the subsequent decline of viral load) for the immune response to control. Analysis of sequentially sampled immune markers during infection might give insight into the immune correlates of these early differences in infection kinetics. It is also possible that individuals with the fastest viral load growth and highest peaks contribute disproportionately to community transmission, a hypothesis that should be tested in future studies.

Several population-level, single-timepoint sampling studies using routinely available data have found no major differences in cycle threshold values between vaccinated and unvaccinated individuals with delta variant infection.[10,27,28] However, as the timepoint of sampling in the viral trajectory is unknown, this restricts the interpretation of such results. Two other studies longitudinally sampled vaccinated and unvaccinated individuals with delta variant infection.[23,29] A retrospective cohort of hospitalised patients in Singapore[29] also described a faster rate of viral decline in vaccinated versus unvaccinated individuals with delta variant, reporting somewhat larger differences in decline rates than we estimated here. However, this disparity might be accounted for by the higher severity of illness in unvaccinated individuals in the Singaporean study (almost two-thirds having pneumonia, one-third requiring COVID-19 treatment, and a fifth needing oxygen) than in our study, given that longer viral shedding has been reported in patients with more severe illness.[30] A longitudinal sampling study in the USA reported that pre-alpha, alpha, and delta variant infections had similar viral trajectories.[24] The study also compared trajectories in vaccinated and unvaccinated individuals, reporting similar proliferation phases and peak cycle threshold values, but more rapid clearance of virus in vaccinated individuals. However, this study in the USA stratified by vaccination status and variant separately, rather than jointly, meaning vaccinated individuals with delta infection were being compared with, predominantly, unvaccinated individuals with pre-alpha and alpha infection. Moreover, sampling was done as part of a professional sports player occupational health screening programme, making the results not necessarily representative of typical community infections.

Our study has limitations. First, we recruited only contacts of symptomatic index cases as our study recruitment is derived from routine contact-tracing notifications. Second, index cases were defined as the first household member to have a PCR-positive swab, but we cannot exclude the possibility that another household member might already have been infected and transmitted

to the index case. Third, recording of viral load trajectories is subject to left censoring, where the growth phase in prevalent contacts (already PCR-positive at enrolment) was missed for a proportion of participants. However, we captured 29 incident cases and 15 additional cases on the upslope of the viral trajectory, providing valuable, informative data on viral growth rates and peak viral load in a subset of participants. Fourth, owing to the age-stratified rollout of the UK vaccination programme, the age of the unvaccinated, delta variant-infected participants was lower than that of vaccinated participants. Thus, age might be a confounding factor in our results and, as discussed, peak viral load was associated with age. However, it is unlikely that the higher SAR observed in the unvaccinated contacts would have been driven by younger age rather than the absence of vaccination and, to our knowledge, there is no published evidence showing increased susceptibility to SARS-CoV-2 infection with decreasing age.[31] Finally, although we did not perform viral culture here—which is a better proxy for infectiousness than RT-PCR—two other studies[27,32] have shown cultivable virus from around two-thirds of vaccinated individuals infected with the delta variant, consistent with our conclusions that vaccinated individuals still have the potential to infect others, particularly early after infection when viral loads are high and most transmission is thought to occur.[30]

Our findings help to explain how and why the delta variant is being transmitted so effectively in populations with high vaccine coverage. Although current vaccines remain effective at preventing severe disease and deaths from COVID-19, our findings suggest that vaccination alone is not sufficient to prevent all transmission of the delta variant in the household setting, where exposure is close and prolonged. Increasing population immunity via booster programmes and vaccination of teenagers will help to increase the currently limited effect of vaccination on transmission, but our analysis suggests that direct protection of individuals at risk of severe outcomes, via vaccination and non-pharmacological interventions, will remain central to containing the burden of disease caused by the delta variant.

Contributors

AS, JD, MZ, NMF, WB, and ALal conceptualised the study. AS, SH, JD, KJM, AK, JLB, MGW, ND-F, RV, RK, JF, CT, AVK, JC, VQ, EC, JSN, SH, EM, TP, HH, CL, JS, SB, JP, CA, SA, and NMF were responsible for data curation and investigation. AS, SH, KJM, JLB, AC, NMF, and ALal did the formal data analysis. MAC, AB, DJ, SM, JE, PSF, SD, and ALac did the laboratory work. RV, RK, JF, CT, AVK, JC, VQ, EC, JSN, SH, EM, and SE oversaw the project. AS, SH, JD, KJM, JLB, NMF, and ALal accessed and verified the data. JD, MZ, and ALal acquired funding. NMF sourced and oversaw the software. AS and ALal wrote the initial draft of the manuscript. AS, JD, GPT, MZ, NMF, SH, and ALal reviewed and edited the manuscript. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

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Declaration of interests

NMF reports grants from UK Medical Research Council, UK National Institute of Health Research, UK Research and Innovation, Community Jameel, Janssen Pharmaceuticals, the Bill & Melinda Gates Foundation, and Gavi, the Vaccine Alliance; consulting fees from the World Bank; payment or honoraria from the Wellcome Trust; travel expenses from WHO; advisory board participation for Takeda; and is a senior editor of the *eLife* journal. All other authors declare no competing interests.

Data sharing

An anonymised, de-identified version of the dataset can be made available upon request to allow all results to be reproduced. Modelling code will also be made publicly available on the GitHub repository.

Acknowledgments

This work is supported by the National Institute for Health Research (NIHR200927), a Department of Health and Social Care COVID-19 Fighting Fund award, and the NIHR Health Protection Research Units (HPRUs) in Respiratory Infections and in Modelling and Health Economics. NMF acknowledges funding from the MRC Centre for Global Infectious Disease Analysis and the Jameel Institute. PSF and MAC are supported by the UK Dementia Research Institute. JD is supported by the NIHR HPRU in Emerging and Zoonotic Infections. MGW is supported by the NIHR HPRU in Healthcare Associated Infections and Antimicrobial Resistance. GPT is supported by the Imperial NIHR Biomedical Research Centre. We thank all the participants who were involved in the study, Public Health England staff for facilitating recruitment into the study, the staff of the Virus Reference Department for performing PCR and sequencing assays, and the Immunisations Department for assisting with analysis of vaccination data. We also thank Kristel Timcang, Mohammed Essoussi, Holly Grey, Guilia Miserocchi, Harriet Catchpole, Charlotte Williams, Niamh Nichols, Jessica Russell, Sean Nevin, Lulu Wang, Berenice Di Biase, Alice Panes, Esther Barrow, and Lauren Edmunds for their involvement in logistics, conducting data entry, or quality control; and the Molecular Diagnostics Unit at Imperial College London, in particular Lucy Mosscrop, Carolina Rosadas de Oliveira, and Patricia Watber, for performing RNA extraction, quantitative RT-PCR, and preparing samples for sequencing.

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Oppose SB 840.pdf
Uploaded by: Mark Meyerovich
Position: UNF

Oppose SB 840

This bill requires the use of taxpayer money to promote and incentivize vaccination. It requires the Maryland Department of Health to submit a plan to the legislature which must include items such as measures to increase vaccination rates among the unvaccinated, recommendations to incentivize vaccination among people receiving benefits from the Maryland Medical Assistance Program, and a strategy to incentivize individuals to receive a third COVID-19 vaccine dose and any future CDC-recommended vaccines.

The bill has similar provisions to increase COVID-19 testing. Have you not heard that CDC does not recommend universal case investigation and contact tracing?
https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/prioritization.html
As Covid-19 vaccination does not prevent transmission or infection and targets an obsolete variant, there is no good reason to universally promote the vaccines. In fact, they do not work in children, and thus present all risk and no benefit.
https://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1

The bill would also promote vaccination irrespective of natural immunity, but in fact, the natural immunity is more effective than vaccination alone.
https://www.reuters.com/business/healthcare-pharmaceuticals/prior-covid-infection-more-protective-than-vaccination-during-delta-surge-us-2022-01-19/
https://www.medrxiv.org/content/10.1101/2021.08.19.21262111v1.full-text

The decision whether to take any vaccine must be a private, voluntary decision between healthcare providers and patients based on the individual risk/benefit profile of each patient, not on government incentives. Collecting and using this information in a broadly available system abolishes any medical privacy one could hope for.

The Maryland Medical Assistance Program provides Medicaid benefits. The provisions of this bill lay the groundwork for discrimination against unvaccinated people who rely on Medicaid for their health coverage, as these individuals would be excluded from these incentives.

By this point, everyone is aware of the COVID-19 vaccine, and it has been made widely available. The people of Maryland do not need their government to make sure they take the COVID-19 vaccine or booster. Is the booster required because the original vaccine failed to work as promised? So, whom does this bill benefit or protect?

Please oppose bill SB 840. There is no justification for spending on such a program with questionable benefits, the program that discriminates based on medical information, violates medical privacy, risks exposure of sensitive information, and increases costs for everyone.

No to Vaccine Passports.pdf
Uploaded by: Mary McNamara Hugo
Position: UNF

March 1, 2022

TO whom it may concern -

As a lifelong resident of the state of Maryland I vote NO to the following two bills -

SB 0839 - MD Voluntary COVID -19 Vaccine Passport by Senator Rosapepe

SB 0840 - COVID - 19 Response Act of 2022

I, Mary McNamara Hugo, a registered voter and tax payer of Maryland, **do not support** these two bills.

VOTE NO.

Mary McNamara Hugo
8528 Horseshoe Lane
Potomac, Maryland 20854

Matthew McBride - OPPOSED SB 840 - COVID-19 Respon
Uploaded by: Matthew McBride
Position: UNF

Matthew McBride, MPH, MSHI
2215 227th Street
Pasadena, MD 21122

I am opposed to OPPOSED SB 840 - COVID-19 Response Act of 2022

I have worked in health care public policy for 25 years. This has included four years with the United State Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR), the federal pandemic response authority. At HHS/ASPR I served on the H1N1 pandemic response and the 2014 Ebola response. I wrote the H1N1 pandemic after-action report, which consolidated all federal pandemic response knowledge in preparation for the next pandemic (i.e., COVID). During Ebola I was the HHS point of contact for all US hospitals and physicians seeking patient treatment information and working with CDC to develop treatment and infection safety protocols.

SB 840 - COVID-19 Response Act of 2022 will not be effective and I stand in opposition to this bill.

Anti Vax Mandate.pdf
Uploaded by: Maureen Reim
Position: UNF

Forcing or coercing someone in any way to take a vaccine or any medication violates the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. The first of its ten points begins as follows:

“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, overreaching, 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 code of ethics must be upheld ion any civilized country.

Attorney_ COVID vaccines given to family, includin

Uploaded by: Megan Montgomery

Position: UNF

Attorney: COVID vaccines given to family, including small kids, instead of flu shots

Newscast recording

By Jill Lyman and Gray News staff

Published: Oct. 8, 2021 at 5:53 PM EDT

EVANSVILLE, Ind. (WFIE/Gray News) - Members of an Indiana family who went to get flu shots, including two children, were accidentally given adult doses of the Pfizer coronavirus vaccine, their attorney said.

They said it happened Monday at a Walgreens pharmacy, WFIE reported.

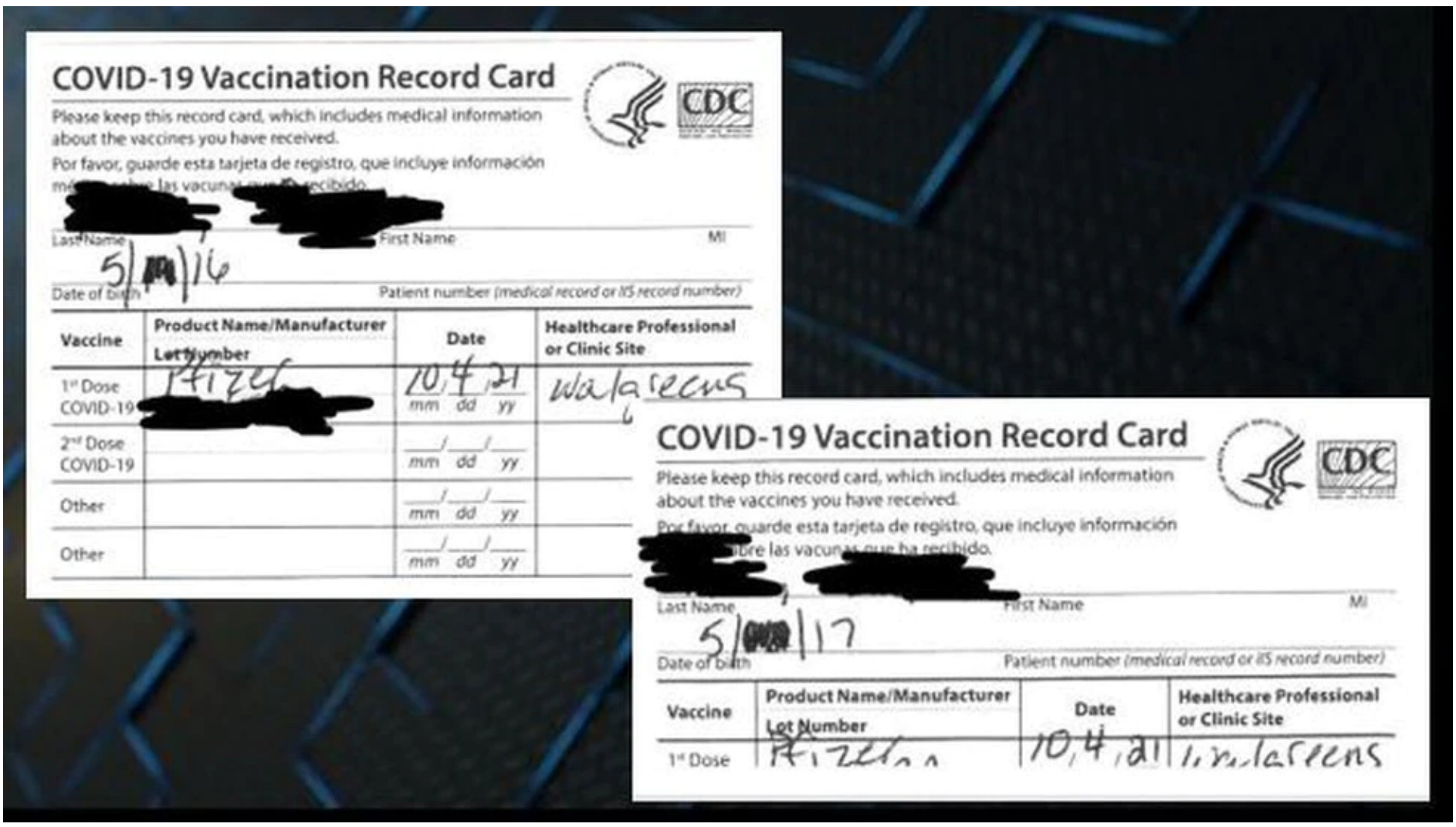
The family of four includes two adults and children who are 4 and 5 years old.

The Pfizer-BioNTech vaccine is only approved for people ages 12 and older. The companies are seeking approval for use in children ages 5 to 11 with the U.S. Food and Drug Administration.

They show children born in 2016 and 2017 were given a vaccine shot.

The family said they left the pharmacy thinking they had received their flu shots, but a Walgreens employee later called them and said they had made a mistake. The attorney said the cards were then issued since the coronavirus vaccine had been given.

Tuley said the children have been taken to a pediatric cardiologist, and the family was told both are showing signs of heart issues.



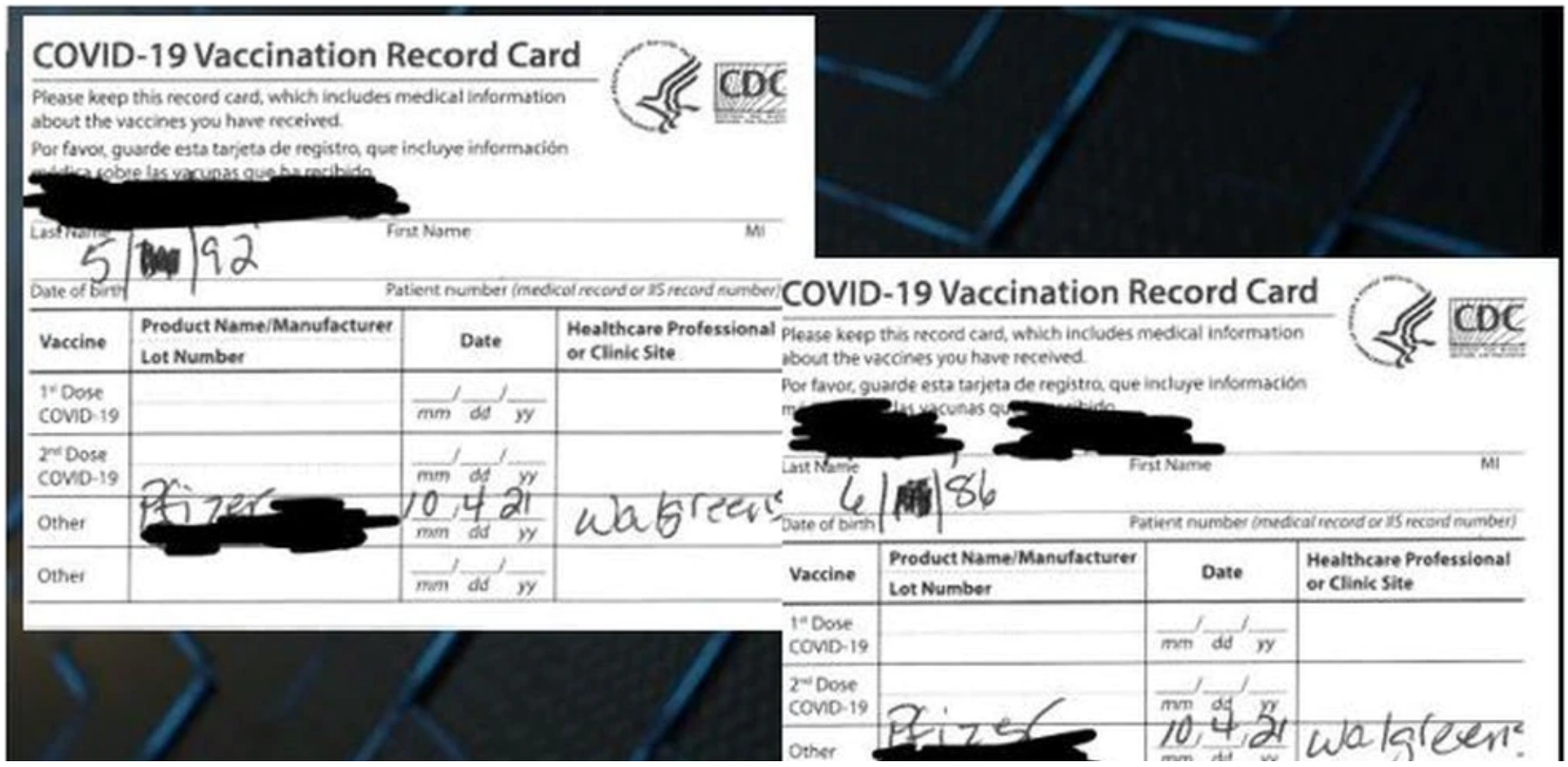
The family's attorney, Daniel Tuley, shared what he says are the vaccination cards given to the family by Walgreens. Pictured are the children's cards. (Daniel Tuley)

The family said the younger child has been sick with a fever and a cough.

On Monday, Walgreen's sent the following statement:

"Due to privacy laws, we cannot comment on specific patient events. However, in general, such instances are rare and Walgreens takes these matters very seriously. In the event of any error, our first concern is always our patients' well-being. Our multi-step vaccination procedure includes several safety checks to minimize the chance of human error, and we have reviewed this process with our pharmacy staff in order to prevent such occurrences."

Last year, the U.S. Department of Health and Human Services **used emergency powers due to the pandemic.** The directive allows pharmacists in all 50 states to give vaccines, like flu shots, to children 3 and older.



How to Make Immunizations a Pharmacy Profit Center

Uploaded by: Megan Montgomery
Position: UNF

How to Make Immunizations a Pharmacy Profit Center

March 15, 2019

When Beverly Schaefer became one of the first pharmacists to administer flu shots in 1996, she could never have guessed that twenty years later she'd be administering nearly thirteen thousand immunizations per year.

Schaefer says her pharmacy was the first in the U.S. to offer mass immunizations administered by a pharmacist, and the reason she pioneered the idea came down to a business problem. She had turned down a contract from a major payer and all at once she lost 300 patients. Searching for a way to retain their business even while they were getting their prescriptions somewhere else, she ordered the flu vaccine and posted a sign on her door.

"We were hoping to do 300 flu shots the first year," she said. "We did 1,200. The biggest problem is that we had to go to the bank twice a day because we had so many tens and twenties in the till."

At that time they gave the shots out of a backroom with a table and a couple of chairs. When people came in to get the shots, they kept asking what else the pharmacy was going to offer back there. "It was like a light bulb went off," Schaefer said. "What people want is access to healthcare." Now her pharmacy, Katterman's Sand Point Pharmacy, has become a true immunization destination, offering 28 vaccines year-round. They account for nearly 20 percent of her business and 30 percent of her profit.

"If you want to add profit to your bottom line, increase the number of immunizations that you're doing," Schaefer said. "Every single immunization that you do adds to your bottom line. There are no

exceptions."

Marty Feltner, director of immunization services for Kohll's Pharmacy, also pioneered immunization in his home state of Nebraska. As the first pharmacy in the state to offer immunizations, Kohll's has become the immunization leader in the region. "It's another added component to bring in another revenue stream," Feltner said. "When you look at pharmacies today, they're pretty much breakeven pharmacies. So in order to be positive, as far as revenue stream, you've got to think outside the box." Among its eight locations, Kohll's administers 50,000 to 80,000 flu immunizations per year.

Both Katterman's and Kohll's specialize in travel immunizations, which in itself has been a boon for business. People travel from hours away to get travel shots from their pharmacies. Around half of Schaefer's total immunization revenue comes from travel vaccines.

They both believe immunizations have become essential to compete in today's world, especially as a way to differentiate from online and mail-order pharmacies that are capturing more and more of the market share. "You know that [Bezos] family that sends boxes to every house every day across the country?" Schaefer said, whose pharmacy is in Seattle, the location of Amazon's headquarters. "They have to come to my store to get travel immunizations. Because you can't do that by mail. So why not offer a service that mail order will never be able to compete with?"

A Golden Opportunity

Around 100 million Americans get the flu shot every year, which produces around $4 billion to $5 billion in revenue. That's just influenza. Each year, the national chain pharmacies and big-box stores battle to snatch up patients to their immunization programs with aggressive marketing and significant discounts.

Yet the immunization market is still largely untapped. A 2017 report from the Centers for Disease Control and Prevention stated that vaccination rates have a long way to go to meet the *Healthy People 2020* goals. And pharmacies can be the prime beneficiaries of this growing demand. Surveys show that patients find pharmacies to be more accessible and convenient than physicians' offices and health clinics. And the majority of people in the U.S. now prefer getting vaccinated at the pharmacy, according to
a survey by PrescribeWellness.

Many independent pharmacies have already caught on to this trend. The 2018 *NCPA Digest* shows 70 percent of pharmacies offering immunizations. However, that number includes pharmacies that only offer the flu shot. Another estimate says less than a quarter of independents offer immunizations beyond influenza. And the flu shot is only the tip of the immunization iceberg. There's a glacial immunization opportunity beyond influenza waiting to be uncovered. For example, flu shots bring in roughly $20 of profit a pop. Compare that to meningococcal group B vaccine at $48, human papillomavirus at $50, and hepatitis B at $80, according to one estimate. An independent pharmacy in Louisiana earned nearly $6,000 in profit from only 70 shots of hep B in the first year of offering the vaccine.

"If you want to add profit to your bottom line, increase the number of immunizations that you're doing. Every single immunization that you do adds to your bottom line. There are no exceptions."

Multiple pharmacy experts say pharmacies that offer expanded immunizations can expect a minimum $40K per year in additional revenue, but more likely closer to $90K. One independent pharmacy in Oklahoma gave 1,800 vaccines in one year, earning $40K in pure profit. Another independent pharmacy in Pennsylvania averaged more than 700 immunizations in its second year, resulting in more than $16K in profit.

"You do two or three new consultations a day, your profit on just those consultations could potentially pay for that pharmacist just to be there that day," Feltner said. "There are times where we'll get five or seven consultations in one day and have profitability of three or four hundred dollars on just that one-hour appointment depending on the patient's travel designation."

Schaefer said the least amount of profit you'll ever make on a vaccine is $15 to $20. You essentially get paid twice, once for the product and once for the service itself. "How many prescriptions do you make fifteen to twenty dollars on?"

Immunizations also provide additional business benefits to indirectly increase revenue and profitability. "What we're finding is that pharmacies and pharmacists who are engaging in immunizations are being approached for other patient care activities," said Mitch Rothholz, chief strategy officer for the American

Pharmacists Association (APhA). “Coming in for immunizations is an opportunity to talk about other healthcare services they might need that the pharmacy can provide.”

That has been true in Feltner’s experience, especially for the shingles vaccine, which is suffering shortages because demand is so high. “You’re going to have lots of patients come into the pharmacy who may not be a regular customer and by offering the service you get them in the door,” he said. “If we say we offer the shingles vaccine, we may be able to transfer their prescription business over to our pharmacy just by having an immunization program. It just opens more doors.”

A broad and lasting benefit, immunizations move your pharmacy in the direction the profession is headed: from medication-focused to patient-focused care. “It’s a demonstration of pharmacists as a healthcare provider,” Rothholz said. “Because pharmacists are trying to move and expand their services into a more quality patient care delivery activity versus just providing a product. Pharmacists’ value to patients and the healthcare team is recognized when patients receive the appropriate medication or healthcare service and achieve the optimal benefit from those services.”

The addition of patient-centered services not only sets you up to survive the future of pharmacy, it also helps nurture patient loyalty. It’s one of the few opportunities pharmacists have to meet face-to-face with patients. “You’ll have a patient for life once you start immunizing,” Feltner said. “It’s been a very rewarding experience.”

Easy as 1, 2, 3

Many pharmacies don’t offer immunizations because the thought of an immunization program is overwhelming. After all, it’s a whole new addition that requires you to spend time and money ordering and storing new inventory, marketing new services, and most importantly, fitting it into your already busy workflow.

But Feltner and Schaefer said the difficulty of offering immunizations is a major misconception that keeps too many pharmacies away. In fact, adding an immunization program is really easy, they said.

You simply treat immunizations like prescriptions. When someone asks for an immunization, your process follows just as if they handed you a prescription. You give them a consent form, enter their insurance info, ring them up, and when they get to the front of the queue, the pharmacist brings them to

the consultation room and administers the vaccine. “Doing an immunization takes about as much time as filling a new prescription,” Schaefer said. “It’s like entering a new patient.”

Vaccines are ordered from your primary wholesaler (or possibly direct from the manufacturer) and stored in your refrigerator with your insulins and other refrigerated medicine, or they’re stored in your freezer. In other words, they fit right in alongside all your other prescription medicines.

But the only way to make the integration seamless is to utilize your employees well. Every part of the process should be conducted by technicians except for reviewing the documentation and administering the vaccine, which doesn’t take more than a couple of minutes of the pharmacist’s time. If you have a pharmacist who’s a recent graduate, consider letting them take the reins. “They’ve been trained in college to do this,” Schaefer said. “Give it to the youngest one and let them be in charge of it if you trust them.”

Feltner suggests starting out slow, with the flu, shingles, and pneumonia vaccines, and working your way up from there. “You can get a vaccine program up and running very, very quickly,” he said. He and Schaefer both grew their immunization programs gradually, adding vaccines to their repertoire as patients requested them. She suggests trying to expand your program by 10 percent each year, which she promises is achievable. Eventually you may grow your pharmacy into a complete immunization destination. “It just has a way of continuing to grow if you’re doing a good job at it,” she said.

Before you get started, reach out to other health providers and public health staff in your community, Rothholz said. “Identify what are their and their patients’ needs and challenges related to immunizations that your pharmacy could help address.”

Six Steps to Get Your Program Off the Ground

1. Check laws and regulations
2. Get trained and certified
3. Talk to other providers to get buy-in, discover needs, and establish a CPA if necessary
4. Prepare the pharmacy: create a private space, train staff, order supplies, and put a sign on the door
5. Establish workflow
6. Market the service

Potential Challenges

The biggest obstacle to getting an immunization program off the ground will likely be the legal aspect. Although every state allows pharmacists to administer vaccines, scope of authority varies widely. “The variability in what pharmacists can administer is typically dependent upon the age of the patient, the type of antigens or vaccine, and some other procedural modifications,” Rothholz said.

In many states, you have to establish standing protocols or collaborative practice agreements to be able to vaccinate. Most states require pharmacists to complete training on pharmacy-based immunizations. Pharmacies and pharmacists can check with their state pharmacy association or state board of pharmacy to identify the requirements and restrictions related to immunizations before getting started, Rothholz said.

If you need an agreement or protocol, Schaefer recommends coming up with a plan to approach a provider. Choose your provider carefully, maybe starting with the health department. And when you go to make your case, make it all about the patient. “Always, always take the high road,” she said. “It’s about giving patients easy access to preventive care.”

Another potential hurdle you’ll want to be ready for is billing. Coverage for vaccines in pharmacies varies from plan to plan, including some under Medicare Part B and others through Part D. Some plans cover the total cost of the vaccine, others require a copay, and others don’t cover it at all. If a vaccine is not covered under the patient’s pharmacy benefit, Feltner and Schaefer have the patient pay out-of-pocket and self-submit the claim to their medical insurance. However, pharmacies can enroll as a mass-immunization provider and be compensated at the same level as physicians and other providers under Medicare Part B, Rothholz said.

For pharmacies feeling overwhelmed by the thought of starting a program, there are all kinds of resources to help. Start with the APhA’s certification program, which has trained more than 340,000 pharmacists. “The program is now considered the gold standard for pharmacy-based immunizations. It’s updated, it’s in line with CDC recommendations, it’s reviewed by immunization experts, and it’s recognized by individuals outside of the profession for its quality and content,” Rothholz said. In addition, APhA provides access to products and resources to keep up with current recommendations and vaccine information.

For clinical and logistical resources, visit the Immunization Action Coalition (IAC) website (*www.immunize.org*), which provides protocols, vaccine information statements, consent forms, and a host of other free documents as well as complete guidelines for offering immunizations at the pharmacy. Further resources for everything you need can be found from the APhA, CDC, and the Advisory Committee on Immunization Practices (ACIP).

More Than Profit

One of Feltner's favorite parts of immunizations is the opportunity they provide to interact with patients. It's one of the few things that frees him from behind the counter to get that personal touch.

Same goes for Schaefer. "Doing an immunization, it's a very intimate and private moment," she said. "You actually get to know these patients in a different way than you do transacting over the counter."

Immunizations live in that sweet spot of pharmacy practice where healthier patients and a healthier business meet. Research overwhelmingly shows that when pharmacies vaccinate, uptake increases, outcomes improve, and healthcare costs decrease.

"The more often we vaccinate, the more chances we have to decrease disease," Feltner said. "And that's the whole goal is to vaccinate as many people as we can. And it's a great feeling as a pharmacist to immunize someone against a potentially deadly disease."

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20 Tips to Make Your Immunization Program a Profit Center

Maximize your profit by increasing immunization sales with smart strategies from pharmacy owners who have been doing it for decades. Independent pharmacy owner Beverly Schaefer and director of immunization services Marty Feltner provide tens of thousands of immunizations every year, and their independent pharmacies have become immunization destinations. Use these tips compiled from their expertise and current research to get most money from your immunization program.

1. Start the Conversation

Starting the conversation is the most important part of increasing immunizations, Schaefer said. “There’s lots of topics that you can choose to start a conversation about immunization—travel, staying healthy, new vaccines. Even if people don’t do it right then, it plants a seed in their brain. And it gets word-of-mouth going.”

2. Put a Sign on the Door

For Schaefer, a simple sign is the first and most important step in marketing your services. This has been her single most successful strategy for increasing immunizations. On the sign, list all the immunizations you offer. “When we did this, people were totally amazed that we were doing all these shots,” she said.

3. Educate Patients

According to the CDC, education remains the largest barrier to immunization coverage. Simply informing patients about the preventable diseases and the vaccines that prevent them is an easy way to increase immunization rates. Use in-store signage, brochures from manufacturers, bag inserts, or a conversation.

4. Make Specific Recommendations

Asking the right patients about the right vaccines will give you a higher conversion rate. That involves identifying eligible patients and recommending the specific vaccine to them directly. For example, if the patient is over 50, simply let them know: Nearly 40 percent of people who have had chickenpox will get shingles. Offer to give them the vaccine right then and there.

5. Target Flu Shot Patients

Patients who get the flu shot have already shown an openness to immunizations, which means they’ll be much more inclined to accept further vaccines, according to a 2018 study published in Psychological Science in the Public Interest (PSPI). When patients come in for flu shots, have them fill out an intake form and ask about the last time they received other recommended vaccines.

6. Make Strong Recommendations

The PSPI study also discovered that a strong recommendation from the provider is the single most powerful way to motivate someone to get vaccinated. Instead of asking if they would like the vaccine, tell them they're eligible and that they can get it before they leave the pharmacy.

7. Identify Eligible Patients

Most pharmacy systems allow you to create an alert for patients when their profile matches a vaccine need, which most often is based on age. Feltner relies on his employees to know which patients to look for and when to recommend vaccines. "The big key is to delegate and to train your staff on how to recognize someone who is eligible," he said. "Train your staff. Train your staff. Train your staff."

8. Utilize Entire Staff

After a visit to a national chain, Feltner realized how effective it is to have every single staff member, no matter their role, ask patients if they've gotten a vaccine. The store's cashier asked every patient at checkout if they had gotten the flu shot. If they said no, she directed them to the pharmacy. "I thought that was eye opening," he said. "That's part of the whole idea of delegating to your entire staff."

9. Zero Copay Tactic

This trick has been wildly successful for Feltner: He keeps track of which insurance and government plans offer patients a zero copay for a vaccine. Any time his staff sees a patient with one of those plans, they make the recommendation and let the patient know the vaccine is completely free. At that point, it's an easy sell.

10. Co-administration

Co-administering vaccines can also cause an uptick in vaccinations. Patients will be much more likely to receive multiple immunizations if they get them all in one stop rather than returning at another time. As long as the vaccines don't have contraindications, you can safely administer multiple vaccines in one

visit. Also consider ordering combination vaccines that contain multiple vaccines in one shot, which are even more convenient for patients and reduce your storage costs.

11. Offsite Events

“Pharmacists who are successful in immunizations are not limiting provision of vaccines to the walls of their practice,” said Mitch Rothholz, chief strategy offer at APhA.“They’re going out to businesses and doing immunizations in the community, whether it be an event or in private businesses.” Offsite events not only generate money from vaccines given at the event, they’re also a perfect opportunity to recruit new patients to your pharmacy for good. Good offsite opportunities include school systems, health fairs, local businesses, assisted-living communities, apartment-complex communities, police departments, churches, and colleges.

12. Employer Partnerships

A huge source of immunization revenue for Feltner’s practice site is corporate partnerships. He’s developed relationships with several corporations who send their employees overseas. All of those employees go to Kohll’s Pharmacy for travel immunizations, which usually involve multiple vaccines.

13. On-Air Advertising

Go live on the radio or TV and give flu shots. “Just make it fun,” Feltner said. “The big thing I tell pharmacists is make it fun. Then you’re having fun immunizing and preventing disease.”

14. Helping with Costs

The second biggest barrier to immunizations, according to the CDC, is cost. The agency recommends pharmacies consult with local and state public health vaccination programs to learn about publicly funded programs that could help patients with the cost of vaccines. You can also enroll in the Vaccines for Children Program, which provides pharmacies federally purchased vaccines to fully vaccinate eligible children.

15. Offer Coupons

Take a page from the national chain pharmacies and big-box stores. Give patients a small voucher or coupon to your front end when they get an immunization from you. The profit you earn from them will outweigh the gift.

16. Fax Physicians

After immunizing a patient, Schaefer sends a fax to the provider. The fax includes the entire list of vaccines she offers, with an X next to the vaccine she administered. That way, the physician will know every vaccine she offers and can refer patients to her in the future.

17. Word-of-Mouth

If you offer a top-notch immunization program, your patients and physicians will do the advertising for you. Both Schaefer and Feltner attributed their most successful marketing to word-of-mouth. In fact, Schaefer spends zero dollars on advertising.

18. Answering Machine

Use your answering machine to highlight your immunization services. “When you call my store, it’s ‘Hello, you’ve reached Katterman’s pharmacy, your immunization destination,’” Schaefer said. “That way they’re thinking about immunizations whether they want to or not.”

19. Incentivize Your Pharmacists

Schaefer said the high margins on immunizations allow you to pay a bonus to your pharmacists for each immunization they administer. For an immunization that earns $20, let your pharmacists take two to five bucks of that to give them extra motivation.

20. Travel Tricks

Travel vaccinations come with their own bag of tricks—all of which genuinely help the health of patients.

- Hold a consultation with patients to ask where they're going, review their immunization history, and offer them everything they'll need.
- Use Travax, an online resource, to identify every vaccine a patient will need for the area they're visiting.
- Create a "travel checklist" with OTC items patients may need for the trip, which they can purchase in your front end.
- Compile a section in the front end dedicated solely to travel products and walk your patient through it after each consultation. Schaefer said it's not uncommon for patients to spend an extra one to two hundred dollars on her OTC travel products.
- Put a sign on your front door: "Are you traveling out of the country? Have you had your hep A, yellow fever, and typhoid shots?"
- If a patient comes in asking for a specific travel vaccination, ask where they're traveling. You may be able to offer additional immunizations or travel products.
- Get a standing order or collaborative practice agreement to administer prescription travel medicine, like antimalarial drugs.

From the Magazine

This article was published in our quarterly print magazine, which covers relevant topics in greater depth featuring leading experts in the industry. Subscribe to receive the quarterly print issue in your mailbox. All registered independent pharmacies in the U.S. are eligible to receive a free subscription.

Read more articles from the March issue:

- How CPESN networks break pharmacies into the lucrative side of healthcare
- A classic retail tactic that boosts front-end sales
- Is pharmacist prescribing authority on the rise?
- This pharmacy dramatically expanded its business through telepharmacy
- How to hire the best people for your pharmacy

SB840 Flyer.pdf
Uploaded by: Megan Montgomery
Position: UNF

OPPOSE SB840/HB1084

Prevent Unintended Harm to Maryland's Children

PROTECT THE PARENT-DOCTOR-PATIENT RELATIONSHIP

BEST HEALTH OUTCOMES

The best health outcomes for children occur when the parent and the physician work as a team and consider health history, precautions and contraindications before making any medical decisions. Children are not vaccinated like adults and have a very complicated recommended schedule, receiving multiple shots at once.

TRAINING

Pediatricians are specifically trained to assess children for vaccine appropriateness and readiness. Immunizations are pharmaceutical products that come with warnings, precautions, and contraindications. A child must be properly assessed prior to administration to reduce risk for serious harm and/or death. A pharmacist does not have this training.

LIABILITY

The Federal 1986 National Childhood Vaccine Injury Act removed liability from vaccine makers as well as the provider that administers the vaccine. Pharmacists have not been properly trained in assessment for childhood vaccines and will not be liable for mistakes leaving children at risk.

PHARMACIES ARE CHAOTIC

Pharmacies have a reputation for being chaotic. Pharmacist's jobs are harder than ever as so many people are on multiple pharmaceutical products. It is dangerous to have pharmacists stop filling a prescription every time they have to give shots. A toddler should not be assessed for vaccine appropriateness in the middle of a crowded Walmart.

IMPROPER INJECTIONS

SIRVA (Shoulder Injury Related to Vaccine Administration) Injuries are on the rise since pharmacies started giving immunizations. A skyrocketing number of cases have been compensated by the Federal Government as people are getting their immunizations outside of the the doctor's office.

lovemarylandpac.org

SB840 UNFAV Love Maryland PAC.pdf
Uploaded by: Megan Montgomery
Position: UNF

SB840: COVID-19 RESPONSE ACT OF 2022
UNFAV
Love Maryland PAC

Dear Chair Kelley, Vice Chair Feldman, and Distinguished Members of the Finance Committee,

Our organization is very concerned about this bill and its potential impacts on the safety of children in our state and citizens that get prescriptions filled at pharmacies.

This bill in part received an unfavorable report from this committee last year (HB530) and that was with a minimum age of 9. 9-year-old children are bigger physically which minimizes their risk of injury and able to sit for a vaccination without restraint. Lowering the minimum age to 3-years-old only makes the bill more concerning and dangerous. This is a bill that the Trump administration pushed hard during the pandemic. It has no place here in Maryland.

- Young children are not vaccinated like adults. They have a complicated "recommended" schedule by the CDC that requires an assessment to determine actual vaccine appropriateness. Issues such as allergies, diagnoses (autoimmunity, immune system dysfunction, immune system suppressing drugs), current health status, and previous adverse reactions to vaccinations are just some of the things that pediatricians consider before determining what vaccine a child should have in a visit. They do not go by a checklist. At well-visits, pediatricians perform a full physical examination and have the child's entire medical and vaccination history, which they use to determining vaccine appropriateness. Pharmacists do not have this expertise.

- No one is liable if a pharmacist gives an inappropriate vaccine, or if they administer it incorrectly into a tiny 3-year-old arm. The Federal 1986 National Childhood Vaccine Injury Act removed liability from vaccine makers as well as the provider that administers the vaccine.

- If this bill were to become law, many children would never go to see the pediatrician again. Pediatric well visits include a thorough physical exam and screenings for physical, mental and developmental milestones. These screenings allow referrals to help children who are showing signs of developmental struggles or other health diagnoses. This is a particularly worrisome reality for our BIPOC children in Maryland, and children who come from homes without adequate socioeconomic resources- they very families who need the support of a pediatrician the most and who can least afford to handle a vaccine injury.

- Last year, the New York Times profiled the chaos that is occurring in American pharmacies. It is dangerous to have pharmacists stop filling a prescription every time a child gets in line for vaccinations. This article can be found here: https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html I have also attached several other articles highlighting vaccination issues at pharmacies to this testimony.

- SIRVA (Shoulder Injury Related to Vaccine Administration) injuries have increased since people have started getting vaccines in pharmacies. This is a huge risk for a 3-year-old child who will not sit still and has a very small arm.

- Pharmacies want to give more vaccines to increase revenue. Per the attached article by pbahealth, “If you want to add profit to your bottom line, increase the number of immunizations that you’re doing.” Schaefer said. “Every single immunization that you do adds to your bottom line. There are no exceptions.” Currently, Pharmacists at major retail pharmacies, have quotas for the number of flu shots they must give and they are offered bonus incentives from their employers. Children’s healthcare must be based on examination, assessment, and diagnosis… not quotas and bonuses.

- This bill goes a step further than previous bills before this body by also allowing pharmacy technicians to vaccinate very young children **with only 6 hours of training**. This is dangerous. People who go into pharmacy practice are smart enough to choose clinical care specialties, but instead chose a profession where they do not have to do direct patient care. They certainly did not choose pediatrics. A pharmacy technician does not have the training that a pediatric nurse has. It often takes 2-3 pediatric nurses to vaccinate a 3-year-old child.

We respectfully ask the Committee for another Unfavorable Report.

Megan Montgomery

Chair

Love Maryland PAC

Silver Spring, MD

Virginia pharmacy gives 112 kids wrong doses of CO

Uploaded by: Megan Montgomery

Position: UNF

NEWS

Virginia pharmacy gives 112 kids wrong doses of COVID vaccine

By Lee Brown

November 12, 2021 3:55pm Updated

Authorities confiscated the remaining amount of vaccines and ordered the pharmacy to inform the families of those who had been vaccinated.

CQ-Roll Call, Inc via Getty Imag

At least 112 Virginia children were given wrong doses of COVID-19 vaccines after a local pharmacy tried to make up for not having the new shots for kids, according to local officials.

Ted Pharmacy in Aldie "incorrectly administered" partial doses of adult vaccines to the kids — likely either not fully protecting them or even giving them too much, the Loudoun County Health Department said.

"Because they did not have the children's formulation they used the adult formulation but only gave a third of the amount to the children," the health department's director, David Goodfriend, told the Washington Post.

"Our understanding from Ted Pharmacy is they were trying to do a workaround, which is not authorized," he said.

"If it doesn't all go in, or it goes into the body but doesn't go into the muscle, or you didn't draw it up exactly to the [correct] line, there's a chance you might get too little vaccine," he said.

"There's also a chance it could have given too much," he admitted.

Ted Pharmacy is located in Aldie, Virginia.

Facebook

The Loudoun County Health Department released a statement informing parents of the potential incorrect dosage administered to children who received their vaccine from Ted Pharmacy.

dpa/picture alliance via Getty I

Authorities confiscated all of the pharmacy's remaining coronavirus vaccines and ordered it to contact the families who'd received the shots. They were also sent guidance from the Centers for Disease Control and Prevention (CDC) to still get their second shot in three weeks as planned, or to even restart the two-shot series after that time.

The alarm was only raised by "a good observant parent" who noticed the shots came from vials with the wrong color cap.

Dasha Hermosilla told Fox 5 that she noticed her 7-year-old daughter getting the vaccine with a purple cap — meant for those age 12 and older — rather than the new younger kids' one with an orange cap.

Authorities confiscated the remaining amount of vaccines and ordered the pharmacy to inform the families of those who had been vaccinated.

Bloomberg via Getty Images

“I would have never done this if I knew they were giving the adult reformulated vaccine. Absolutely not,” said Hermosilla.

“I should’ve pushed her to show me the vial of orange which she didn’t have and then I should’ve left.”

The board of pharmacy told Fox 5 that it was unable to reveal if there is an investigation into a possible violation of law or regulation.

Ester Megally, who is listed in corporate filings as an owner of Ted Pharmacy, did not comment when reached by phone Thursday by the Washington Post.

“It’s a working day for us now, and we are a little bit busy. I’m sorry,” she told the paper.

FILED UNDER , COVID VACCINE , PHARMACY , VACCINES , VIRGINIA 11/12/21

Testimony.pdf
Uploaded by: Melissa Burns
Position: UNF

SB839/SB840
UNFAVORABLE
Melissa Burns

I thank you for the work you do for the citizens of our state. I ask you to oppose these proposed bills in order to preserve our rights and those of future generations. These bills, if passed, can be slippery slopes to the degradation of our rights as Americans as protected by both our state and national constitutions. Thank you for your consideration and the work you do to protect the rights of Marylanders.

SB 839:

Why I oppose this bill:

1.One's medical information is one's own business and should not be used to discriminate and segregate citizens based on vaccine status. Vaccines are not safe for everyone and individuals need to have complete control over their medical decisions. I have several family members who have vaccine injuries and can no longer receive vaccines. It is discriminatory to segregate these individual in various societal situations.
2. No business should be discriminating who can or cannot use their service based on COVID or other vaccination status especially vaccines that are still only Emergency Use Approved.
3.The CDC itself has said that the vaccinated can both get and spread COVID virus. Many unvaccinated people have natural immunity which is cross protective, enduring and a benefit to the public.
4.One's medical information should be protected information but we have seen repeatedly that "protected" information can be hacked.
5.Vaccine passports have been withdrawn across the globe. They are unnecessary and represent a violation of personal freedom, privacy and health choice.
6.Public funding would be used to develop and market an unnecessary program which lays the foundation for chilling government tracking, surveillance, divisiveness and control.

SB 840:

Why I oppose this bill:

1. I oppose any vaccine passport as our medical information should be private and not used to divide and segregate the population into vaxxed and unvaxxed.
2. Vaccine passports have been withdrawn globally.
3. Pharmacies are not doctor's offices and pharmacists (and their assistants) are not doctors. They should not have the authority to ORDER and vaccinate our children even more so without parental or guardian informed consent.

4. This bill was originally intended to expire by the end of 2022 and it should expire. It was an emergency use bill intended for a pandemic which has passed. The authorizations given in the original bill should expire as intended.
5. The bill is a combination of all kinds of unrelated things, from listing the qualifications for certain practitioners, to rates for an urgent care center to tracking, testing and funding for a virus that no longer exists. Each of these things should be considered separately with thoughtful debate, not thrown together in a bill that is too far reaching.

Regards,
Melissa Burns

TESTIMONY OF MICHAEL RYAN VS MD SENATE BILLS 0839

Uploaded by: Michael Ryan

Position: UNF

TESTIMONY OF MICHAEL RYAN VS. MD SENATE BILLS 0839 & 0840

Requiring a vaccine passport to engage in normal life activities is a horrible idea and a violation of many personal freedoms. Whether you are in favor of vaccinations or not, people should not be required to have a foreign substance injected into their body to live normal lives. If the vaccines are very effective, then those vaccinated have nothing to fear from the unvaccinated.

Forcing or coercing someone in any way to take a vaccine or any medication violates the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. The first of its ten points begins as follows:

"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, overreaching, 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 code of ethics must be upheld in any civilized country. The COVID-19 vaccines were not tested for long-term effects and thus were and are experimental. Each person should choose whether to take the vaccine or not. Future vaccines may have similar experimental natures or may be carefully tested. Regardless, each person must have the right to accept or refuse the vaccine without any coercion, or penalty.

People decline COVID-19 vaccines for medical reasons or sincerely held ethical, moral, or religious beliefs. The valued and valuable ethical and legal traditions of the United States and Maryland are clear that it not acceptable to discriminate on the basis of medical condition/disability or on the basis of religion/religious belief.

Doctor/medical practitioner-patient confidentiality is legally protected and essential for a myriad of reasons, and the privacy & protection of medical records is also important. The COVID-19 passports and other COVID requirements erode or remove these legal protections.

COVID passports set the groundwork for a two-tiered society, in which persons who have received vaccinations may live normal lives (including work, schooling, right to assembly, and access to various services) and persons who have not received vaccinations are denied those rights. Do we want to live in such a society? Recall history, our worst moments and our greatest achievements! Does it not always go badly when one group is dehumanized and denied rights based on a physical or religious characteristic? Are we not proudest of those movements which restore those rights?

: Everyone has the right to bodily integrity, which includes the right to decline medical interventions. There is some serious philosophical inconsistency among the legislation under consideration this session. Bills to expand access to abortion and to enshrine abortion in Maryland law are under debate, underpinned by a 'my body, my choice' argument. Persons who wish to decline COVID vaccines are not being offered the same respect for 'my body, my choice'! You can't have it both ways!

03022022-Unfavorable-OPPOSE-SB840-red.pdf
Uploaded by: Michelle Bailey
Position: UNF

I am writing to OPPOSE SB840, COVID-19 Response Act of 2022.

If you are intending to enforce Covid-19 vaccine passports and/or vaccine mandates in the State of Maryland, as per SB 839 and SB 840 for which hearings are scheduled tomorrow, I would presume that your reason for doing so would be to prevent the spread of the disease, and to keep Marylanders safe. If so, please consider the following:

The Covid-19 vaccines are using a novel technology and are still in their experimental phase, using undisclosed ingredients for which we do not yet know the long-term consequences, which are used only under Emergency Use Authorization (EUA), and for which vaccine manufacturers are completely exempt from any liability. To justify vaccinating, let alone coercing vaccination with such a product through vaccine passports and vaccine mandates, I challenge you to prove that (1) data shows that these vaccines are absolutely necessary in order to protect Maryland residents; (2) data shows that these vaccines are highly effective to protect against and prevent the spread of Covid-19; and (3) data shows that these vaccines are safe.

The data clearly supports three compelling and urgent reasons why passing this regulation, paving the way for vaccine passports, will put Maryland residents at unnecessary and unimaginably high risk:

The Covid-19 vaccines are:

1. **UNNECESSARY** due to the *high survivability* of Covid-19; due to *natural immunity* being far stronger and long-lasting than vaccine-induced immunity; and because – for those who do get seriously ill – there is *safe and efficient outpatient treatment* of Covid-19 that saves lives.

   Supporting data:

   - The median Infection Fatality Rate (or IFR – **the risk of dying from Covid-19, if infected**, is 0.0013% in 0 - 19-year-olds; 0.0088% in 20 - 29-year-olds; 0.021% in 30 - 39-year-olds; 0.042% in 40 - 49-year-olds; 0.14% in 50 - 59-year-olds; 0.65% in 60 - 69-year-olds; and 2.9% in over-70-year-olds.

     See Axfors, Cathrine and John P. A. Ioannidis: "Infection fatality rate of COVID-19 in community-dwelling populations with emphasis on the elderly: An overview" (This pre-print article is providing updated findings from Stanford Professor John Ioannidis May 2021 article "Reconciling estimates of global spread and infection fatality rates of COVID-19: An overview of systematic evaluations" European Journal of Clinical Investigation, 2021-05, Vol.51 (5))

- There is mounting evidence that natural immunity against COVID-19 not only exists, but is robust and long-lasting.
  See 146 Research Studies Affirm Naturally Acquired Immunity to Covid-19: Documented, Linked, and Quoted

- For an overview of the effectiveness and amplitude of early treatments for Covid-19, see COVID-19 Early Treatment: Real-Time Analysis of 1,316 Studies

2. **NOT EFFECTIVE** in protecting against and preventing the spread of Covid-19

Supporting data:

- A recent large study published in the journal *Science* showed that by the end of September 2021 the effectiveness of all three Covid-19 vaccines had fallen dramatically (Moderna: 58%, Pfizer: 45%; Johnson & Johnson: 13%) and even more recent data suggests that with the Omicron variant the effectiveness has fallen even further.
  See Cohn, Barbara et al., "SARS-CoV-2 Vaccine Protection and Deaths Among US Veterans During 2021" *Science*, November 4, 2021.

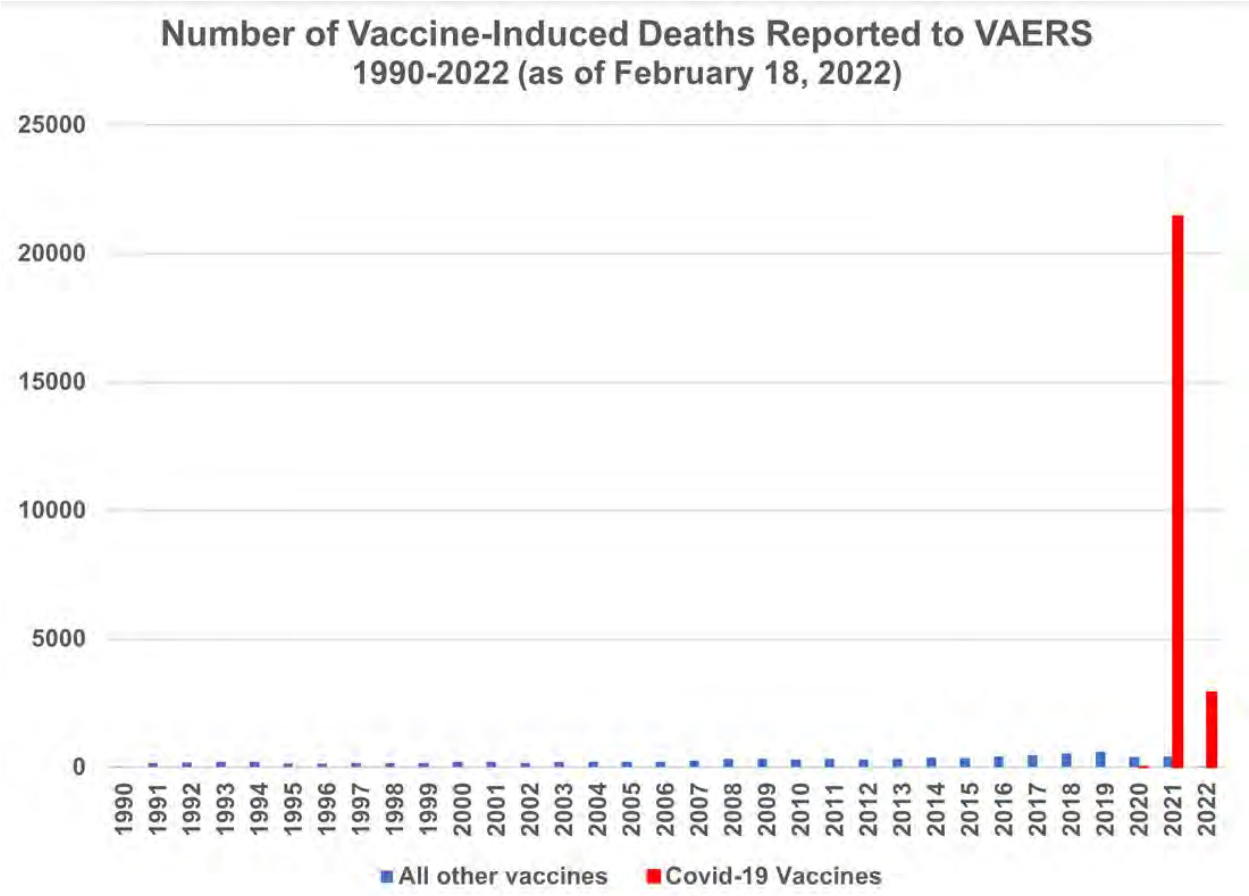
- The argument that the Covid-19 vaccines, when they work, protect against serious illness and death are also being disproven as we speak, for example as 83% of COVID-19 deaths between mid-October and mid-November of 2021 were among vaccinated individuals in Scotland
  See page 55 in Public Health Scotland COVID-19 Statistical Report (Published December 1, 2021)

- Recent UK government data as well as a recent German study find that Covid-19 vaccine boosters neither prevent infection nor transmission, and also continue to lead to severe illness and death among triple-vaccinated.

  See COVID-19 vaccine surveillance report - Week 45 (Published by the UK Health Security Agency on November 11, 2021) and Kuhlmann, C. et al., "Breakthrough Infections with SARS-CoV-2 Omicron Variant Despite Booster Dose of mRNA Vaccine" (Published December 10, 2021)

3. **NOT SAFE**, as unconscionable numbers of reports of serious side-effects have been submitted into the U.S. Government-run Vaccine Adverse Event Reporting System (VAERS), including 24,402 of which resulted in death, 133,057 of which resulted in hospitalization, 44.512 of which resulted in permanent disability, 12,511 of which resulted in heart attacks, and 34,448 of which resulted in myocarditis/pericarditis, all following Covid-19 vaccination. To put things in perspective, here is a graph that shows the total number of deaths reported into

VAERS since 1990, when this system was created to serve as a safeguard in order to stop new vaccines that prove to be unsafe. Note that all blue bars represent all of the the 196 vaccines that have been put through the system since 1990, except the three Covid-19 vaccines which are depicted in red:



Source: United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 01/07/2022, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on March 1, 2022 9:24 PM

The graph above speaks for itself. Add to the picture the fact that scientific analyses from Harvard University and Columbia University have concluded that the reporting rate to VAERS is somewhere between 1% and 5% of true cases. Multiply the COVID-19 vaccine deaths by those proportions, and **a stunning 480,040 to 2,400,200 Americans have died from the Covid-19 vaccines**, with at least as many being permanently disabled.

Recent reports from life insurance companies around the U.S. confirm that there is a stunning increase in death claims in 2021 compared to 2020, by as much as 40% among people ages 18-64 (as in this reported case of Indiana-based life insurance company OneAmerica).

Supporting Data:

- Vaccine Adverse Event Reporting System (VAERS)
- The weekly updated summaries and charts from OPEN VAERS provide an easier way to browse through key data

If you pass this proposed legislation effectively coercing Maryland residents to take this vaccine despite being aware of the severe risks and deficiencies outlined above, you are NOT acting in the best interest of the citizens of Maryland, but are knowingly putting them at risk. For this, we will hold you liable.

I have expressed no matter of mere “concern” or any other non-substantive matter, but solely matters of substance, of fact, and law. I accept and appreciate your oath of office.

Sincerely,

Michelle Bailey and Anna Olsson (Silver Spring)

SB840 UNFAV.pdf
Uploaded by: Michelle Borowy
Position: UNF

SB840

UNFAV

Michelle Borowy

A pharmacy is not doctor's office and pharmacists (and their assistants) are not doctors. They should not have the authority to ORDER and vaccinate our children even more so without parental or guardian informed consent.

This bill was originally intended to expire by the end of 2022 and it should expire. It was an emergency use bill intended for a pandemic which has passed. The authorizations given in the original bill should expire as intended.

The bill is a mishmash of all kinds of unrelated things from listing the qualifications for certain practitioners to rates for an urgent care center to tracking, testing and funding for a virus that no longer exists. Each of these things should be considered separately with thoughtful debate, not thrown together in a bill that is too far reaching

I oppose any vaccine passport as our medical information should be private and not used to divide and segregate the population based on vaccination status.

mandate.pdf
Uploaded by: Paul Hartley
Position: UNF

Forcing or coercing someone in any way to take a vaccine or any medication violates the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. The first of its ten points begins as follows:

"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, overreaching, 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 code of ethics must be upheld in any civilized country.

The COVID-19 vaccines were not tested for long-term effects and thus were and are experimental. Each person should choose whether to take the vaccine or not. Future vaccines may have similar experimental natures or may be carefully tested. Regardless, each person must have the right to accept or refuse the vaccine without any coercion, or penalty.

SB0840 oppose.pdf
Uploaded by: Peggy Williams
Position: UNF

SB840 OPPOSE

Dear Committee Members:

Please withdraw this bill. The state of emergency is over. Therefore I oppose any emergency use tests and vaccinations being forced on the people. A bill where pharmacists are able to vaccinate minor children without well-defined parental consent parameters is not acceptable. There are also too many unrelated topics discussed in this legislation. I am not comfortable with such a sweeping, far-reaching bill being on the table. Thank you.

Peggy Williams
Severna Park
D33

Covid testimony Peter D'Orazio .pdf
Uploaded by: Peter DOrazio
Position: UNF

Hello Distinguished Members of the Maryland Senate,

I am writing today as a Maryland citizen and registered pharmacist in opposition of SB839 and SB840.

I hope by now the Senate realizes that vaccination for Sars-Cov-2 does not significantly prevent infection or transmission of the virus. My own Montgomery County, MD is one of the most vaccinated in the country, yet during the height of Omicron we experienced 5000 positive tests in one day; approximately one in every 200 citizens. However, at no time did our hospitals become overrun or even rise above the 'Low" occupancy threshold of 80%, which would be a normal rate during a non-covid year. Current occupancy is 64.7%, a level at which is extremely low and rarely seen.

Therefore, I am opposed to vaccination mandates and passports as they are ineffective in preventing disease, as proven in NY, DC, and most of Europe. Now that the CDC is finally focusing on morbidity and mortality as opposed to "cases", we need to follow suit and end all exorbitant and wasteful state funded testing, tracing, vaccination, and electronic passports. What purpose does a passport serve if a vaccinated, yet infected individual can walk into an establishment while a healthy, unvaccinated individual is prevented from entry?

Our tax dollars must be spent on recovery from the heavy-handed restrictions that caused so much damage. Our schools need therapists to treat the anxious and depressed students who are so scared of a 10-day quarantine with no academic support. Many will not remove their masks to eat lunch s they fear being traced and quarantined, despite being vaccinated and already having covid.

In a recent Board of Education meeting, I listened to MCPS members state that they cannot afford to pay licensed therapists their current rate and directed their team to investigate hiring student therapists in training. This is appalling, especially since MCPS led country in virtual days of learning. Let's use our state surplus to heal our kids and support businesses that were unjustly affected. Please end the idea of vaccine passports, quarantining healthy people, etc. now and in the future. Vaccinations have been available for a long time and those hesitant accept their risk. Please return to normal now.

Even though I am no longer a retail pharmacist, I am opposed to expanding vaccination privileges for pharmacists to administer all vaccines to 3-year-olds and up. Pharmacists are already too busy to comply with mandatory counseling regulations, much less keep up with the constant interruption of vaccination. Interruption is a primary cause of dispensing errors. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6499714/. However, we all know retail chains will jump on this financial windfall and ask even more of their pharmacists and technicians, who are quitting now in record numbers. https://www.nbcbayarea.com/news/national-international/im-so-burned-out-pharmacy-staffs-struggling-to-keep-up-with-ever-rising-demands/2765456/. Please do not aggravate an already dangerous situation by adding this burden to our pharmacists.

In conclusion, please let our state end the fixation on Covid mitigation and let our citizens return to pre-pandemic life. Remove all mask and vaccination mandates in workplaces, schools (UMD especially) and anywhere else, as well as required quarantining. The time is now.

Sincerely,

Peter D'Orazio

Peter D'Orazio, RPh.

senate testimony 0840.pdf
Uploaded by: Rochelle Kane
Position: UNF

Vote **UNFAVORABLE** for **SB0840**
Rochelle Kane 47 S Church St Westminster, MD

Unconstitutional Tyrannical Overreach

Senators of Maryland,

Given the information concerning the origin, statistical danger, and political narrative surrounding the covid 19 “phenomenon” I feel that this bill in consort with other covid legislation sets into motion very dangerous precedents including but not limited to unnecessary government overreach and intervention into the private lives of Maryland citizens, unlawful tracking of citizens, and a potential for unlawful and egregious discrimination based on private medical information.

I oppose bill SB0840 for several reasons

1. Forcing a human being to take a vaccine violates the Nuremberg Code of 1947. A person should have the legal capacity to give consent, power of free choice, and to act without intervention of force, fraud, deceit, government overreach or any other ulterior form of coercion.
2. Vaccines have not been tested for long term effects and are experimental. Statistically these vaccines have saved 1 in 20,000 people, but have killed 5 people per 20,000. They are killing more people than they help.
3. This bill provides for extreme medical and religious discrimination flying in the face of valued ethical and legal traditions of the state of Maryland as well as the United States of America, in that it is unacceptable to discriminate on the basis if medical or religious belief.
4. Future implications: covid passports set the ground work for a two tiered society wherein vaccinated people can live normal lives and unvaccinated are denied rights. Our most noble movements in history have been those which restore rights not take them away as this bill would.
5. Potential for the misuse of the MYIR mobile app is widely acknowledged as dangerous to our liberties by expanding illegal and unjust overreaching surveillance of American citizens. It would open the door to a communist style credit system.

I highly oppose the bill SB0840 for these reasons. YOU SENATORS took an oath to uphold the Constitution Of the United States of America and this bill infringes on our GOD GIVEN RIGHTS and is highly Unconstitutional. You are accountable to not only the people of America, but to GOD! This bill must be killed!!!!

SB840_Unfav_Cusack.pdf
Uploaded by: Sarah Cusack
Position: UNF

SB840: COVID-19 Response Act of 2022
UNFAV
Citizen

Dear Members of the Senate Finance and Budget and Taxation Committees,

I oppose SB840. I am opposed to the concept of a digital health passport for any pharmaceutical product, but am most upset that language regarding pharmacists vaccinating children was hidden in this much larger bill. This has always been its own bill because it has enormous consequences for the safety of young children and for all patrons of pharmacies in our state. This bill has been sponsored every year in Maryland since 2015. It is a bill to make money for CVS and other chain pharmacies.

I reached out to a friend who has been a Pharmacist for 15 years and asked her what she thought of this bill. She said, "Sarah… Some Pharmacists do not like children."

Her comment ripped through me. I am a Pediatric Physical Therapist and I know that Pediatrics is a difficult specialty that takes a special person and skill set.

Pharmacists, who are smart enough to have gone through Medical or Nursing School, chose a profession that does not require them to do direct patient care. They certainly did not choose to do specialized direct patient care with pediatrics. Vaccinating a 3-year-old child is nothing like vaccinating an adult who sits patiently for a shot that they want to receive. Pharmacists are not pediatric specialists, and 3-year-olds will run, cry, and scream, especially if a provider does not know how to work with them.

According to the CDC's Recommended Child Immunization Schedule, children between ages 4-6 are recommended to get vaccinations for Measles, Mumps, Rubella, Chicken Pox, Diphtheria, Tetanus, Pertussis, Polio, and Influenza. Now Covid 19 will be added to that long list. If the child is found to be appropriate, these can all be given in a single visit. Often 2 nurses assist a parent to hold a young child down to receive these shots. My friend, who works in a Wal Mart Pharmacy said she has two chairs with pull down tables to vaccinate people in. This is completely inappropriate. Young children are going to be half-dressed and screaming in the middle of Wal Mart, Target, and CVS.

This is not fair to Pharmacists who are busy filling prescriptions and will have to stop every time a child gets in line for some shots.

When children are vaccinated at the Pediatrician, they receive a full physical examination and assessment for vaccine readiness and appropriateness. The CDC recommended "schedule" is ONLY A RECOMMENDATION. It is not a checklist. Pharmacists do not have this level of expertise.

Please, I ask that the Committee give this bill an UNFAVORABLE report.

Sarah Cusack, MPT
Ashton, MD 20861
District 14

SB840_UNFAV.pdf
Uploaded by: Shawna Sherrell
Position: UNF

SB840
UNFAV
Shawna Sherrell

Dear Senate Finance Committee,

I'm writing as a Maryland resident who is opposed to this proposed bill: "COVID 19 Response Act of 2022" - SB840.

A statewide digital vaccine passport does nothing to make Maryland citizens safer. The vaccine does not prevent transmission or spread of the virus. A vaccine passport will make it much easier to legally segregate others and discriminate against populations who medically cannot receive this vaccine as well as provide economic barriers for small businesses. It's a waste of time and resources when many localities are consistently dropping any mandates they may have had in place.

As a parent, I would not choose to have a pharmacist who has very little training in adverse reactions or a patient's family medical history to vaccinate a child. Pediatricians are in a highly specialized field for a reason - they are trained to assess children for vaccine readiness and other childhood concerns. Pharmacists are not trained in the same way. The last two years, pharmacies have been overloaded and overwhelmed, making mistakes more likely.

Please oppose this bill.

Sincerely,

Shawna Sherrell

13b - SB 840 – FIN - PHARM - LOO.docx.pdf
Uploaded by: State of Maryland (MD)
Position: UNF

Maryland

Board of Pharmacy

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

Jennifer L. Hardesty, Board President – Deena Speights-Napata, Executive Director

March 2, 2022

The Honorable Delores G. Kelley
Chair, Senate Finance Committee
3 West Miller Senate Office Building
Annapolis, MD 21401

RE: SB 840 – COVID-19 Response Act of 2022 - Letter of Opposition

Dear Chair Kelley and Committee Members:

The Maryland Board of Pharmacy (the Board) is submitting this Letter of Opposition for Senate Bill (SB) 840 – COVID-19 Response Act of 2022. SB 840 will amend certain provisions of the Health Occupations Article for Pharmacists and Pharmacies.

SB 840 will remove the administration of an influenza vaccination from the list of tasks that cannot be delegated by a pharmacist to a pharmacy technician. SB 840 will also change the definition of "direct supervision" to remove the requirement that a pharmacist be onsite at the pharmacy, and allow a pharmacist to supervise a pharmacy technician via "technological means." Furthermore, SB 840 will change the requirements to refill an unauthorized prescription, will authorize vaccine orders from a pharmacist, delete the vaccine-specific written protocol requirement, and eliminate the Board's entire vaccine registration program. Lastly, SB 840 will allow a pharmacist to delegate the administration of a vaccine to a pharmacy technician that has completed certain requirements.

Below, the Board has identified several issues of concern and offered suggestions to amend or modify SB 840:

1. SB 840 will expand the tasks that a pharmacist may delegate to a pharmacy technician to include administration of a FDA-approved, ACIP-recommended vaccine. As pharmacy interns and pharmacy technicians have been successfully administering COVID-19 vaccines, as well as FDA-approved, ACIP-recommended vaccines pursuant to PREP Act authorizations, the Board supports the expansion of duties that a pharmacist may delegate to a pharmacy technician. The Board is supportive of SB 840's requirement that a pharmacy technician complete an ACIP-approved practical training program of at least six hours that includes hands-on injection techniques, and the recognition and treatment of emergency reactions to vaccines. The Board would like to suggest that SB 840 be **amended** to include a mandatory requirement that a pharmacy intern or pharmacy technician obtain ***a current certificate in basic cardiopulmonary resuscitation*** (CPR)

4201 Patterson Avenue, Baltimore, Maryland 21215 · Main 410-764-4755 · Fax 410-358-6207
· Toll Free 800-542-4964 · Maryland Relay Service 1-800-735-2258
Web Site: health.maryland.gov/pharmacy

through in-person classroom instruction prior to receiving authorization to administer a vaccine.

2. SB 840 will eliminate the current definition of "direct supervision" in favor of a much lighter standard that requires a "pharmacist who is readily and immediately available at all times the delegated tasks are being performed; is aware of the delegated tasks being performed; and provides personal assistance, direction, and approval throughout the time the delegated tasks are being performed." Additionally, SB 840 clarifies that "direct supervision" includes supervision by "technological means." In practice, this will mean a pharmacy stocked with inventory consisting of regulated pharmaceutical drugs and devices, including controlled dangerous substances, could operate without supervision by the responsible licensed pharmacist. Such a wholesale change to the current definition of "direct supervision" is not supported by the Board. A licensed pharmacist charged with responsibility for every medication dispensed, every vaccine administered, every patient counseled, and all other pharmaceutical services provided in a pharmacy. It is the Board's position that such clinical services should only be offered with the responsible healthcare practitioner, i.e., the pharmacist, onsite. Furthermore, an absence of the responsible supervising pharmacist may lead to an increase in pharmacy technician diversion of controlled dangerous substances, such as Oxycontin, Percocet, and Suboxone, which are highly addictive and have significant street value. The Board's current disciplinary docket is replete with examples of pharmacy technicians who have been disciplined by the Board for diverting controlled dangerous substances; these are cases in which a pharmacist was present on the premises. The Board's enforcement actions will undoubtedly increase, and public health and safety may be at unnecessary risk should pharmacies operate without onsite supervision of a pharmacist. Removing the responsible supervising licensed pharmacist from the pharmacy establishment, particularly without any increase in requirements for security, drug auditing, or drug reporting, may create a tempting environment for unsupervised pharmacy technicians who will have ready access to a pharmacy's entire store of inventory. During a time when the opioid epidemic in Maryland is escalating, it is not advisable to allow a pharmacy to operate without the onsite supervision of a responsible licensed pharmacist. The Board is amenable to a **revision** to the "direct supervision" definition that will make an exception for the supervision of ***non-drug handling tasks*** such as prescription data entry, which will permit a pharmacy technician to work remotely at home or other location outside the pharmacy.

3. SB 840 will make substantial changes to the laws and regulations that govern a pharmacist's ability to refill a prescription that has not been authorized by a patient's health care provider. Currently, a pharmacist may only provide a "14-day supply" of an unauthorized refill to a patient that will experience a "life" altering impact, but for receiving the prescription. SB 840 proposes allowing a pharmacist to provide a "30-day supply" (extended to a "90-day supply" during a state of emergency declared at the federal or state level) of an unauthorized refill to a patient that will experience any negative impact to their "well-being," but for receiving the prescription. The Board is supportive of providing pharmaceutical services to patients during temporary emergency situations; however, the Board is concerned the term "well-being" may be open to many interpretations and create unnecessary friction when a pharmacist uses their clinical

judgment to deny or approve a refill. The Board would like to suggest that SB 840 be **amended** to **define "well-being."**

4. SB 840 will eliminate the Board's existing vaccine registration program and enforcement efforts. Currently, the Board requires a Maryland-licensed pharmacist to register with the Board prior to administering any vaccine. The Board does not collect a fee to register a pharmacist and the process serves as an initial check to ensure that the individual has completed the required CDC training in vaccinations and obtained an in-person CPR certification. Additionally, the Board requires a pharmacist to renew their registration biennially with proof of a current CPR certificate and four continuing education credits related to vaccinations. Since SB 840 is expanding the authority of a pharmacist to include ordering vaccinations in addition to administering vaccinations, including childhood immunizations, it is the Board's position that it is not responsible to allow such an expansion while simultaneously removing all vetting and monitoring of vaccinating pharmacists by the Board. The Board would like to suggest that SB 840 be **amended** to **restore the Board's registration program**.

5. SB 840 will authorize a pharmacist to order and administer an FDA-approved, ACIP-recommended vaccine to an individual who is at least three years old without a prescription and without performing a preliminary check in ImmuNet to review a patient's immunization record to ensure that the individual has not previously received the vaccine. While the Board is supportive of the expanded scope of practice, it has severe concerns with the blanket authorization to order and administer a vaccine to individuals, especially children, without a mandatory review of a patient's immunization record in ImmuNet to ensure that the individual has not already received the vaccine. Previously, a pharmacist could only vaccinate children ages 11-17 with a prescription from the child's healthcare provider; thus, the assumption was that the child's healthcare provider was knowledgeable about the child's immunization history when issuing the prescription. By eliminating the prescription requirement, it is integral to the safe delivery of healthcare that a pharmacist check ImmuNet prior to ordering and administering a vaccination, particularly to a child. The Board would like to suggest that SB 840 be **amended** to include that a pharmacist **must check ImmuNet prior to ordering and administering a vaccine**.

6. SB 840 will remove the Board's requirement that a pharmacist develop or adopt a protocol prior to administering a vaccine. Currently, a pharmacist is required to develop or adopt a vaccine-specific written protocol prior to administering any vaccine. The criteria for an appropriate protocol was developed by the Board in consultation with the Maryland Department of Health, the Board of Nursing, and the Board of Physicians. It is the Board's position that these regulations are necessary for awareness, education, and patient safety. The Board would like to suggest that SB 840 be **amended** to restore the Board's regulations regarding a **vaccine-specific written protocol**.

The Board is opposed to SB 840 and recommends an unfavorable report, unless the proposed amendments are incorporated.

I hope this information is useful. If you would like to discuss this further, please do not hesitate to contact me at deena.speights-napata@maryland.gov / (410) 764-4753.

Sincerely,

Deena Speights-Napata, MA
Executive Director

Jennifer L. Hardesty,
PharmD, FASCP
President

The opinion of the Board expressed in this document does not necessarily reflect that of the Department of Health or the Administration.

13c - SB 840 - FIN - MBON - LOO.docx.pdf
Uploaded by: State of Maryland (MD)
Position: UNF

Maryland

Board of Nursing

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

March 2, 2022

The Honorable Delores G. Kelley
Chair, Senate Finance Committee
3 East Miller Senate Office Building
Annapolis, MD 21401-1991

RE: SB 840 – COVID 19 Response Act of 2022 – Letter of Opposition

Dear Chair Kelley and Committee Members:

The Maryland Board of Nursing (the Board) respectfully submits this letter of opposition for Senate Bill (SB) 840 – COVID 19 Response Act of 2022. This bill establishes and alters certain requirements related to the COVID-19 pandemic; establishes that certain urgent care centers are not subject to the rate-setting jurisdiction of the Health Services Cost Review Commission; requires the State Board of Nursing to establish an apprentice geriatric nursing assistant program; and alters the authority of pharmacists to refill prescriptions, administer certain vaccinations, and delegate certain functions to pharmacy technicians.

The Board sincerely appreciates the Maryland General Assembly's diligence in addressing the nursing workforce shortage by focusing on efforts in recruitment and retention of frontline staff. The Board additionally supports the intent of establishing an avenue for geriatric nursing assistant certification for individuals working as temporary nursing assistants. The Board has great concerns, however, with implementing an apprentice geriatric nursing assistant program.

SB 840 will create two (2) pathways to certification as a geriatric nursing assistant. The first will require temporary nursing assistants who worked during the public health emergency to complete a training program in accordance with federal requirements and successfully pass the state competency exam. The second will require temporary nursing assistants to complete an apprenticeship, certain hours of training, and pass the state exam. The second category will permanently institute a separate and distinct apprentice geriatric nursing assistant designation. The Board finds this designation unnecessary and cumbersome.

The Centers for Medicare and Medicaid Services (CMS) issued a blanket waiver to suspend the nurse aide training and certification requirements in 42 CFR §483.35(d) in response to staffing shortages in nursing homes and other long-term healthcare facilities. The CMS Emergency Regulatory 1135 Waiver permits nurse aides (also known as temporary nursing assistants (TNA) in the state of Maryland) to work for longer than four (4) months without having completed a state approved Nurse Aide Training and Competency Evaluation Program[1]. Nurse aides are only

[1] Centers for Medicare and Medicaid Services. COVID Declaration Blanket Waivers for Health Providers.

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permitted to work if the facility can ensure that the aide demonstrates competency in the skills and techniques needed to care for residents. The termination of the federal public health emergency, however, would subsequently lead to the termination of the waiver and the role of a temporary nursing assistant. As such, nurse aides will have four (4) months from the end of the waiver to successfully complete federal and state required training and certification.

The Board is concerned that once the CMS waivers terminate, the nursing assistant apprenticeship pathway will be under the strict purview of federal regulations that govern the practice of geriatric nursing assistants. The long-term healthcare field will be mandated to follow those requirements as to not jeopardize facility reimbursements. The Board, as a regulatory agency, will need to ensure individuals are competent to practice within this particular healthcare setting.

Federal regulations at 42 CFR §483.152 (a) and (b) require individuals to attend and successfully complete at least seventy-five (75) hours of training in certain areas that are critical for performing their role as a nursing assistant, such as infection control, residents' rights, and basic nursing skills.[2] The State of Maryland requires individuals to attend and successfully complete a minimum of one-hundred (100) hours of instruction with similar curriculum to the federal requirements.[3] It is imperative that geriatric nursing assistants meet both federal and state requirements so they are properly equipped to perform tasks in the long-term care setting.

Alternatively, House Bill 1208 – Health Occupations – Health Care Workforce Expansion will allow the Board to collaborate and survey the needs of long-term healthcare facilities, and implement a comprehensive transition for temporary nursing assistants.

For the reasons discussed above, the Board of Nursing respectfully submits this letter of opposition for SB 840.

I hope this information is useful. For more information, please contact Iman Farid, Health Policy Analyst, at (410) 585 – 1536 (iman.farid@maryland.gov) or Rhonda Scott, Deputy Director, at (410) 585 – 1953 (rhonda.scott2@maryland.gov).

Sincerely,

Gary N. Hicks
Board President

The opinion of the Board expressed in this document does not necessarily reflect that of the Department of Health or the Administration.

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[2] Centers for Medicare and Medicaid Services. § 483.152 Requirements for Approval of a Nurse Aide Training.
[3] Subtitle 39 Board of Nursing – Certified Nursing Assistants. COMAR 10.39.02.07 – Training Program

SB0840 (1).pdf
Uploaded by: Stephanie Gorecki
Position: UNF

The original bill, an emergency use bill to address COVID-19 concerns was intended to expire at the end of 2022. The authorizations in the original bill should not be extended, especially in light of the most recent research and of statements from the CDC that the vaccine does not prevent transmission of the virus. Vaccine mandates and vaccine “passport” requirements are being phased out across the country and internationally. Public funding should not be used to promote outdated and invasive approaches that serve only to encroach on personal medical privacy and have proven of little or no benefit to public health.

SB840 UNFAV.pdf
Uploaded by: Stephanie Quaerna
Position: UNF

SB840

UNFAV

Stephanie Quaerna

6546 Blackhead Road

Baltimore, MD 21220

3/2/2022

As a citizen of MD, I strongly oppose this bill and the implications it has for infringing upon our individual liberties, parental rights, and privacy.

Thank you!

Testimony.pdf
Uploaded by: Stephen Lawrence
Position: UNF

Forcing or coercing someone in any way to take a vaccine or any medication violates the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. The first of its ten points begins as follows:

"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, overreaching, 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 code of ethics must be upheld in any civilized country.

The COVID-19 vaccines were not tested for long-term effects and thus were and are experimental. Each person should choose whether to take the vaccine or not. Future vaccines may have similar experimental natures or may be carefully tested. Regardless, each person must have the right to accept or refuse the vaccine without any coercion, or penalty.

V/R,

SB839 -SB 840 second reason.pdf
Uploaded by: Sue Pappas
Position: UNF

Why we oppose this bill:

1. We oppose any vaccine passport as our medical information should be private and not used to divide and segregate the population into vaxed and unvaxed.
2. Vaccine passports have been withdrawn globally
3. Pharmacies are not doctor's offices and pharmacists (and their assistants) are not doctors. They should not have the authority to ORDER and vaccinate our children even more so without parental or guardian informed consent.
4. This bill was originally intended to expire by the end of 2022, and it should expire. It was an emergency use bill intended for a pandemic which has passed. The authorizations given in the original bill should expire as intended.
5. The bill is a mishmash of all kinds of unrelated things from listing the qualifications for certain practitioners to rates for an urgent care center to tracking, testing, and funding for a virus that no longer exists. Each of these things should be considered separately with thoughtful debate, not thrown together in a bill that is too far reaching.

testimony for bills SB0839 and SB0840.pdf
Uploaded by: Susan Murphy
Position: UNF

From Susan Murphy

I was informed that the legislature is considering bills that would facilitate the use of vaccine passports. What a terrible idea to discriminate against individuals who choose not to be vaccinated! Those vaccinated are protected from the disease so why deprive others of their freedom to choose. Many are doing this for religious reasons and should be admired for risking their health and perhaps their life for their religious beliefs. What is freedom of religion worth if one is punished for exercising it? We need to respect our fellow citizens and allow them to make their own choice.

Why are elected officials afraid of public opinion? Why give so little time for public comment? Why even consider laws that go against the constitution? Elected officials are supposed to serve the people not rule over them and treat them like children. These social changes should be widely discussed and discussed without censoring opposing opinions. Punishing people for making decisions for themselves and what is injected into their body is wrong. The bill uses the term voluntary but that is a clear deception because the whole purpose of the vaccine passports is to reduce the freedom of those who do not wish to be vaccinated.

testament.pdf
Uploaded by: Teresa Morales
Position: UNF

It is our personal right to control the substances that at put into our body. We should have full knowledge and fully consent. It is not reasonable or just to coerce anyone to take something into their body that they do not want. Our jobs are being taken away and our liberty to travel to certain places because we want the freedom our country promised us: life liberty and the pursuit of happiness. Do we really have life if we are forced to take something that could be detrimental to our health? Is it liberty if we are forced to take something that goes against our religious, moral and ethical or scientific beliefs? Please do not harass, intimidate or coerces me by fear, by taking away privileges, or any other abusive measure just because I have made a choice that I think is proper to me. Influenza vaccines have always been voluntary. All vaccines including the Covid vaccine, should be strictly voluntary. It is my life, liberty and pursuit of happiness that is at stake.
Thank you for listening!

Document (3).pdf
Uploaded by: Tricia Roberts
Position: UNF

SB840/HB1084

UNFAV

This Bill would violate my medical privacy and endanger children's medical care safety.

SB840 includes verbiage which would allow for pharmacists to administer any vaccines to children ages 3 and over. This is absurd and potentially dangerous. Pharmacists/techs receive only about 3 hours of vaccine training. How is this considered a safe practice for such young children? Just recently in November of 2021 a pharmacy in Virginia administered incorrect dosing to 112 children! This pharmacy KNEW that they did not have the correct dose for children ages 5-11, however, they decided they could make the unauthorized decision to administer doses meant for ages 12 and older at "smaller amounts." They knowingly and carelessly made the medical decision to purposely administer a wrong dosing. This is an extremely dangerous and slippery slope. Vaccines should ONLY be administered to children by licensed medical professionals, not pharmacists! A pharmacy error could have adverse effects or even lead to death. This should worry lawmakers, not encourage you to pave a pathway for even more egregious errors! A bill like this is harmful to children and families. You should be focused on protecting them, not setting them up for medical mistreatment.

I appreciate your time and urgently request that you oppose SB840.

Regards,

Tricia Roberts

SB0840_UNF.pdf
Uploaded by: vince mcavoy
Position: UNF

UNFAVORABLE on SB 840

This bill was originally passed last year as Emergency Use Authorization that was supposed to expire at the end of this year. This bill extends to 2024 emergency use authorizations that are no longer required! Furthermore it expands the authority and reach of administrators regarding testing, contact tracing and protocols in multiple settings to "control" COVID 19, a virus that no longer exists! The bill is allegedly to be able to reopen schools, colleges and workplaces which are already open. In fact, just this week the AELR did an about-face on masking. This issue is clearly over. The bill's advocates are advocating entrenched tyrannical control and – if you've been listening to the host of House bills aimed at denying this tyranny – you understand now that Marylanders will not tolerate this. You should remember that, to whatever extent you've embraced globalism, the citizenry has not. Do you want that confrontation? The people that testified spoke of freedom, American (NOT communist) values and their personal autonomy (which the United Nations enjoys promoting for world citizens....not so much for AMERICANS).

But there are even more egregious issue is reliance on "the really smart people" Gov. Hogan has referred to for the last 2 years guiding him on Maryland's medical tyranny. Odd thing is how the CDC, WHO, NIH, that stinking fraud Fauci and virtually every public health talking head was wrong. Dead wrong! And tens of thousands of elderly died at the hands of these misfits ignoring practical medical protocols and general commonsense.
The bill talks about incentivizing vaccine uptake of ANY CDC recommended vaccine now or in the future. Parents are not going to allow you to forcibly experimentally vaccinate their 3-year-olds against a virus which is long gone. You're barking up a wrong and dangerous tree. This kitchen-sink approach reeks of tyranny and it will be publicized if passed out of your committee. Are you going to allow everybody but the trashman & dog catcher to "vaccinate" with this poison? Are you watching young professional sports personalities fall dead on the ball-courts & on the soccer fields?
Draw up your rhetorical defenses in advance because parents, patriots and birthed-citizens of Maryland will not tolerate you giving in to the fear-mongering Rosapepe.

I urge you, for the sake of the reputation of the Senate and for the stake every one of the 6 million residents have invested in Maryland, to fail this bill in its entirety.

vince mcavoy

covid passport testimony.pdf
Uploaded by: warren feldman
Position: UNF

Position against Covid Vaccine Passport:

There is no valid reason for creating a Covid 19 Vaccine passport at this time. Every Marylander's Health information should be theirs and theirs alone (with the possible exception of their doctors) to know. By creating Vaccine Passports, Maryland is implying that others have the right to request information about my personal health. This violates the HIPPA laws and my civil rights. This passport would make it easier for them to think that they have the right to that information.

While this law currently makes it voluntary for a person to participate, that fact that the passport exists at all makes people think they have the right to know my personal medical information.

If a Maryland resident elects not to get the "vaccine", that is their right. No one has the right to tell another person what they should or should not inject, ingest, or otherwise consume. This passport will no doubt lead to further coercion of individuals who do not feel comfortable (for whatever reason) in taking the vaccine.

Forcing or coercing someone in any way to take a vaccine or any medication violates the Nuremberg Code established in 1947 after the terrible acts that took place by the Nazi regime. The first of its ten points begins as follows:

"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, overreaching, 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 code of ethics must be upheld in any civilized country.

The COVID-19 vaccines were not tested for long-term effects and thus were and are experimental. Each person should choose whether to take the vaccine or not. Future vaccines may have similar experimental natures or may be carefully tested. Regardless, each person must have the right to accept or refuse the vaccine without any coercion, or penalty.

In the free society that we as citizens of the United States have chosen to live in, we are entitled to do so without interference from the State or Federal Governments in our personal health decisions.

Sincerely

Warren G Feldman

13a - SB 840 - FIN - MDH - LOI .docx.pdf
Uploaded by: Maryland State of
Position: INFO

Maryland
DEPARTMENT OF HEALTH
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

March 2, 2022

The Honorable Delores G. Kelley
Chair, Senate Finance Committee
3 East Miller Senate Office Building
Annapolis, MD 21401-1991

RE: SB 840 – COVID-19 Response Act of 2022 – Letter of Information

Dear Chair Kelley and Committee Members:

The Maryland Department of Health (MDH) respectfully submits this letter of information for Senate Bill (SB) 840 – COVID-19 Response Act of 2022. SB 840 establishes and alters certain planning requirements related to COVID-19, requires Maryland Medicaid to provide coverage for COVID-19 tests to uninsured individuals after the end of the federal public health emergency, establishes Maryland MyIR Mobile as a voluntary vaccine passport technology, alters rate-setting policies for certain urgent care centers, requires the Maryland Board of Nursing to establish an apprentice geriatric nursing assistant program, and alters the authority of pharmacists.

Currently, through Families First Coronavirus Response Act (FFCRA), Maryland provides coverage for COVID-19 tests for the uninsured.[1] Expenditures are subject to a 100 percent Federal Medical Assistance Percentage (FMAP). This coverage will continue until the end of the national Public Health Emergency (PHE). Once the national PHE ends, SB 840 will require MDH to create a new Medicaid eligibility group for the uninsured, authorized by FFCRA. Individuals eligible for this new group will receive a limited benefit package of services related to testing and diagnosis of COVID-19, not including vaccinations. MDH is unclear how much, if any, expenditures will be subject to the FMAP. The current reimbursement rates for COVID-19 tests received by Medicaid participants range from $35 to $416.

MDH recognizes that as an emergency bill, SB 840 will take effect immediately on passage. Large system changes to the eligibility system require advance notice and planning. Creation of a new coverage group typically requires a minimum of six (6) months to allow for development of business requirements, implementation of system programming changes, and testing prior to go-live. There are several system changes already in progress, including federally required system certification activities, as well as other enhancements including implementations of 12-months extended postpartum coverage and the expansion of the Employed Individuals with

[1] Families First Coronavirus Response Act (2020)
https://www.congress.gov/116/plaws/publ127/PLAW-116publ127.pdf

Disabilities (EID) Program. MDH anticipates it could not implement the new Uninsured Testing Group until calendar year 2023 without putting other activities at risk.

Additionally, SB 840 requires MDH to ensure that the Maryland MyIR immunization record service continues to be used for COVID-19 vaccinations. As a note, MyIR is not intended to serve as a vaccine passport; it is available to use as a voluntary vaccine record on a mobile device. The State does not have a contract with MyIR. MDH has worked with STChealth, a federal vendor, which owns and operates MyIR, as part of a U.S. Department of Health and Human Services (DHHS) pilot project to provide consumer access to immunization records, including for COVID-19 immunizations. Since DHHS is the administrator of this contract, MDH is not able to request services beyond what is provided to the pilot participants.

SB 840 also requires MDH to submit two updated reports on COVID-19 testing and vaccination efforts, as well as a new report on treating residents who have COVID-19. All three of these reports are due by June 1, 2022. This deadline does not allow ample time to coordinate with local health departments and the Maryland State Department of Education and meaningfully study, determine, and update and report on the criteria set forth in the bill.

MDH thanks the General Assembly for its ongoing support during the COVID-19 pandemic and looks forward to our continued partnership in our ongoing response efforts. If you have any questions, please contact Heather Shek, Director of Governmental Affairs, at heather.shek@maryland.gov or (443) 695-4218.

Sincerely,

Dennis R. Schrader
Secretary

OAG HEAU_INF_SB0840.pdf
Uploaded by: Patricia O'Connor
Position: INFO

BRIAN E. FROSH
Attorney General

ELIZABETH F. HARRIS
Chief Deputy Attorney General

CAROLYN QUATTROCKI
Deputy Attorney General

WILLIAM D. GRUHN
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OFFICE OF THE ATTORNEY GENERAL
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March 2, 2022

To: The Honorable Delores G. Kelley
Chair, Finance Committee

From: The Office of the Attorney General's Health Education and Advocacy Unit

Re: Senate Bill 840 (COVID-19 Response Act of 2022): Concern

The Office of the Attorney General's Health Education and Advocacy Unit (HEAU) acknowledges the many ways that the COVID-19 Response Act of 2022 strengthens protections against foreseeable COVID-19 surges in nursing homes, assisted living programs, higher education residential facilities and among the public generally through updates to the testing, contact tracing and vaccination plans effectuated by Chapters 29 and 31 of the 2021 special session, which are extended through December 31, 2023.

The HEAU is concerned, however, that the bill (1) does not extend the current insurance coverage mandate for COVID-19 testing beyond December 31, 2023;[1] (2) would make permanent lax training and oversight provisions for pharmacist orders and administrations of all FDA approved vaccinations for patients age 3 and older, that were enacted as temporary in 2021 with an express provision that permanent authority would *not* be considered without completion of 2 studies by the Maryland Department of Health (MDH) to determine the risks and benefits (neither study is completed) and MDH's recommendation; and (3) repeals the longstanding on-site pharmacist requirement for all pharmacies. We also seek more information about the provision that a "hospital-adjacent urgent care center" is not subject to the rate-setting jurisdiction of the Health Services Cost Review commission (HSCRC) and may set rates and receive reimbursement on an unregulated basis. We address each concern below.

[1] Md. Code Ann., Ins. § 15-856

(1) We believe the current insurance coverage mandate for COVID-19 testing should not be subject to a termination date because testing remains a key prevention tool and should be provided at no cost for the foreseeable future.

(2) The HEAU and other stakeholders expressed concerns about the temporary authority granted in 2021 to pharmacists to order and administer vaccinations to patients age 3 to 17, including delegation to pharmacy technicians.[2] Chapters 792 and 793 of 2021 authorize a pharmacist, from July 1, 2021, to June 30, 2023, to administer an FDA-approved vaccine to an individual age 3 to 17, if the vaccination is ordered and administered in accordance with ACIP immunization schedules. Stakeholders have been awaiting MDH's 2 mandated studies of the risks and benefits of this temporary authority as well as MDH's recommendation regarding permanent authority. The HEAU is deeply concerned about acting without the data, MDH's studies, and more public process regarding these important public health issues.

We are also concerned that the bill would hollow out essential protections in the temporary scheme. As the Fiscal Note explains at pages 11-12: "The bill also repeals the State Board of Pharmacy's authority to require a pharmacist to submit a registration form to the board that verifies that the pharmacist is qualified to provide vaccinations. Currently, the board requires a Maryland-licensed pharmacist to register prior to administering any vaccine. The process serves as an initial check to ensure that the individual has completed the required training and obtained an in-person CPR certification. Additionally, a pharmacist must renew his or her registration biennially with proof of a current CPR certificate and four vaccination-related continuing education credits. Repeal of the registration process removes the board's ability to confirm that a pharmacist meets specified requirements to administer vaccinations."

(3) The HEAU urges against a repeal of the requirement that a retail pharmacy have a pharmacist on-site during operations. Allowing a pharmacy to run without a pharmacist on-site seems contrary to the public's safety. We hope the committee can obtain information from the Board of Pharmacy regarding opioid diversion by pharmacy technicians--a chronic problem that has, as we understand it, spiked during the pandemic, contributing to the worsening opioid epidemic.[3] We submit that such concerns should be

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[2] https://mgaleg.maryland.gov/2021RS/chapters_noln/Ch_792_hb1040T.pdf https://mgaleg.maryland.gov/cmte_testimony/2021/hgo/1q0bgdWpPJQKCuK4ZxJDc8VrbBcZq8XPp.pdf (HEAU letter of opposition)

[3] https://www.dea.gov/press-releases/2019/11/21/chicago-pharmacy-technician-sentenced-five-years-prison-stealing-opioids (Two pharmacy techs "conspired to steal approximately 56,108 pills of hydrocodone and sell them outside the pharmacy") https://www.justice.gov/usao-edmi/pr/pharmacist-and-pharmacy-technician-charged-12-million-illegal-opioid-distribution (A pharmacist and a pharm technician stole "41,995 dosage units of opioid prescriptions during the course of the conspiracy. These controlled substances had a conservative street value in excess of $1,200,000.")

addressed with additional safeguards against opioid diversions such as daily inventories and multiple surveillance cameras; instead, this bill suggests removal of on-site oversight.

We also do not believe it is good policy to allow a pharmacy technician who has only trained for 6 hours to administer any FDA approved vaccine to patients age 3 and older, without the on-site presence of a pharmacist, and to expect the technician to know how to respond to life-threatening emergency reactions to vaccines.[4]

cc: Senator Rosapeppe, Sponsor

[4] The Fiscal Note states at page 11: "Under the bill, the requirement that a licensed pharmacist be physically available in the prescription area or in an area where pharmacy services are provided to supervise the practice of pharmacy and delegated pharmacy acts is repealed. The definition of direct supervision is altered to include supervision of a pharmacy technician through technological means. A pharmacist is authorized to delegate the administration of a vaccine to a pharmacy technician with specified training. The board advises that allowing a pharmacy to operate without the direct supervision of a licensed pharmacist physically available will lead to increased pharmacy concerns and complaints and result in the need to perform additional pharmacy inspections, conduct additional investigations, and potentially hold additional disciplinary hearings. To the extent this occurs, the board advises that it needs up to five additional staff, including one call center representative, two inspectors, two investigators, and one staff attorney. For illustrative purposes only, these additional personnel costs would increase board special fund expenditures by $392,224 on an annual basis."

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maryland
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cost review commission

March 2, 2022

The Honorable Delores G. Kelley
Chair, Senate Finance Committee
3 East, Miller Senate Office Building
Annapolis, MD 21401

RE: Senate Bill 840 – COVID-19 Response Act of 2022 – Letter of Information with Amendments

Dear Chair Kelley and Committee Members:

The Health Services Cost Review Commission (HSCRC)[1] submits this letter of information with amendment for Senate Bill 840 (SB 840) titled, "COVID-19 Response Act of 2022." HSCRC applauds the General Assembly's focus on COVID-19. HSCRC has been working closely with our colleagues in the Maryland Department of Health and other State Agencies during this crisis to support hospitals, improve infection control in long term care facilities, and support vaccine clinics in underserved communities throughout the State.

This letter focuses on changes to Maryland Code, Health General §19–211.1 on pages 10 to 11 of SB 840, which allow for the operation of a "Hospital-Adjacent Urgent Care Center" adjacent to a hospital facility. HSCRC supports the movement of appropriate services from high cost settings of care to lower cost settings of care. HSCRC also supports efforts to reduce emergency department (ED) overcrowding and ED wait times.[2] The HSCRC respectfully suggests a small change to the definition of "hospital-adjacent urgent care center" (see attached). This definition, as currently drafted, could be interpreted as de-regulating a broad set of hospital services. This change will clarify the scope of the urgent care provision to ensure that it does not inadvertently impact services outside of an urgent care center and aligns with the existing definition of urgent care center in COMAR 10.09.77.01. HSCRC has also attached an appendix describing current law on this issue and considerations for hospitals with adjacent urgent care centers

HSCRC is committed to working with hospitals and other providers throughout the State to continue to control health care costs, improve patient access to appropriate care, and improve healthcare quality and population health. HSCRC thanks the Committee for your consideration of the issues raised in this letter. If you have any questions or if we may provide you with any further information, please do not hesitate to contact me at megan.renfrew1@maryland.gov.

Sincerely,

Megan Renfrew
Associate Director of External Affairs

[1] The HSCRC is an independent state agency responsible for regulating the quality and cost of hospital services to ensure all Marylanders have access to high value healthcare.
[2] Extensive ED wait times have been a long-standing issue in Maryland. Maryland Institute for Emergency Medical Services Systems, Joint Chairmen's Report on Emergency Department Overcrowding, December 2017. Full report here: http://dlslibrary.state.md.us/publications/JCR/2017/2017_29a.pdf

HSCRC Proposed Amendments to Senate Bill 840
(First Reading File Bill)

On page 10, line 28, strike “”**ANY CENTER, SERVICE, OFFICE FACILITY, OR OTHER**” and insert “A NON-HOSPITAL ENTITY”

On page 10, line 31, strike “; and” and insert a semicolon

On page 11, line 2, strike the period at the end and insert a semicolon

On page 11, after line 2, insert **“(3)** IS DEDICATED TO THE DELIVERY OF UNSCHEDULED, WALK-IN CARE OUTSIDE OF A HOSPITAL EMERGENCY DEPARTMENT, A FREESTANDING CLINIC, OR A PHYSICIAN’S OFFICE; AND
(4) IS CLEARLY IDENTIFIED AS AN UNREGULATED URGENT CARE CENTER, SEPARATE FROM THE REGULATED HOSPITAL FACILITY.”

Appendix: Current Law and Considerations for Hospitals with Adjacent Urgent Care Centers

Current Law

Under current law and regulation, Maryland hospitals can operate an unregulated physician or urgent care center adjacent to a regulated hospital facility if it meets the proper requirements for signage and entrances to distinguish it from the regulated hospital facility. HSCRC allows hospitals that wish to provide unregulated services in buildings that are adjacent to HSCRC regulated space to apply to HSCRC for a determination as to whether the services are or will be subject to HSCRC rate regulation under COMAR 10.37.10.07 -1.[3] HSCRC provided such a determination to Sinai Hospital for an urgent care center on the Sinai's campus in 2016.

Considerations for Hospitals with Adjacent Urgent Care Centers

Although SB 840 does not require hospitals to place urgent care centers on hospital campuses, the following are considerations for hospitals with hospital-adjacent urgent care centers.

Diversion and EMTALA

The Federal Emergency Medical Treatment and Labor Act (EMTALA) requires hospitals to "provide an appropriate medical screening examination…to determine whether or not an emergency medical condition…exists" to "any individual…comes to the emergency department and a request is made on the individual's behalf for examination or treatment for a medical condition."[4] If a patient comes to a hospital's emergency department and requests to be seen, that hospital may run the risk of violating EMTALA requirements if the hospital directs that patient to an urgent care center before screening the patient and determining that the patient is stable.[5]

Financial Assistance, Medical Debt, and Uncompensated Care

Maryland law requires that hospitals provide financial assistance to lower-income patients, regardless of insurance status.[6] Settings that are not rate-regulated by the HSCRC are not required to provide financial assistance to low-income patients. If a lower-income patient went to an urgent care center instead of a hospital, that patient would not have access to the financial support that would have been available to that patient in the hospital.

Maryland law also has protections related to hospital medical debt.[7] For example, hospitals are required to offer payment plans to all patients and limit the actions that hospitals can take to collect medical debt to protect consumers. These protections do not apply to unregulated facilities, such as urgent care centers.

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[3] In making this determination, HSCRC considers factors such as the location of the entrances, parking, and registration, changing, and waiting areas, as well as whether there is any duplication of unregulated services within the hospital in order to avoid inappropriate patient steering.
[4] §1867.(a) of the Social Security Act
[5] EMTALA violations can result in potential termination of the hospital or physician's Medicare provider agreement (so that the hospital could not be paid by Medicare), hospital fines up to $104,826 per violation ($25,000 for a hospital with fewer than 100 beds), and the hospital may be sued for personal injury in civil court under a private cause of action. These penalties arise whether or not the patient was harmed by the EMTALA violation. https://www.acep.org/life-as-a-physician/ethics--legal/emtala/emtala-fact-sheet/
[6] Hospitals in Maryland are required to provide free care to patients with income at or below 200% of the federal poverty level (FPL) and provide reduced-cost care to patients with income between 200% and 300% of FPL. Reduced-cost care is also available to patients with income below 500% of FPL who have a substantial amount of medical debt. Health General §19-214.1
[7] Health General §19-214.2

Rates in HSCRC rate-regulated settings are the same for all payers and include some support for uncompensated care (including the required financial assistance provided to patients). Rates in unregulated settings, such as urgent care centers, differ by payer. Unregulated settings also do not receive support for uncompensated care in rates.