

M E M O R A N D U M

November 17, 2021

TO: Government Operations Committee
Health & Human Services Committee

FROM: Christine Wellons, Legislative Attorney

SUBJECT: Expedited Bill 34-21, Personnel and Human Resources – COVID-19 Vaccination Required

PURPOSE: Committee worksession – recommendation expected

Expected Attendees

Dr. Stoddard, Assistant Chief Administrative Officer
Mr. Attila, Director, Human Resources
Ms. Kinch, Chief, Division of Labor Relations and Public Safety, Office of the County Attorney
Ms. Harling, Chief Labor Relations Officer

Expedited Bill 34-21, Personnel and Human Resources – COVID-19 Vaccination Required, sponsored by Lead Sponsors Councilmembers Riemer and Jawando with Co-Sponsor Council Vice-President Albornoz, was introduced on September 28, 2021. A public hearing was held on October 19, 2021.

Expedited Bill 34-21 would require all County employees to be vaccinated against COVID-19 as a condition of employment. Accommodations to the requirement would be available for medical reasons.

Procedurally, an employee who fails to provide proof of vaccination (or to apply for a medical accommodation), within 7 days of notification from the County, would be placed on unpaid leave. The employee placed on leave would have 7 leave days in which to provide proof to the County that the employee has received at least one dose of a COVID-19 vaccine. The employee would have to provide proof of full vaccination within 40 days of having been placed on unpaid leave. Ultimately, an employee who fails to fulfill the vaccination requirement (or to secure a medical accommodation) after having been placed on leave would be subject to dismissal from County employment.

The requirements and implementation of Expedited Bill 34-21 would be expressly exempt from collective bargaining and provisions of the Code related to collective bargaining.

SUMMARY OF THE PUBLIC HEARING

At the public hearing on October 19, 12 speakers testified regarding Expedited Bill 34-21. Dr. Stoddard, on behalf of the County Executive, stated that the bill might result in staff shortages.

Specifically, Mr. Stoddard stated that according to a risk assessment, a 3-5% reduction in public safety staff would result in a reduction in County services to the public.

Mr. Buttle and Mr. Holland testified, on behalf of the firefighters' and police unions respectively, in strong opposition to the bill. They objected to the lack of collective bargaining under the bill and stated that the bill was an example of government overreach. They further testified that the bill would result in attrition and, thus, a reduction in County services. In addition, Mr. Buttle noted that the bill should contain a religious exemption.

Several employees and former employees also testified in opposition to the bill, noting concerns about personal freedom to decline "experimental" medical treatments. Two individuals testified that employees should be given the option to learn about "plant-based lifestyles" instead of receiving the vaccine.

The Council also has received dozens of letters from residents and employees, both pro and con, regarding Expedited Bill 34-21.

ISSUES FOR THE COMMITTEES' CONSIDERATION

1. Approaches of Other Jurisdictions and Employers

Council Staff (C. Camacho and N. Rodríguez-Hernández) have conducted extensive jurisdictional research regarding vaccination requirements for employees – both locally and around the country. See ©83.

Notably, several other public local employers require employee vaccinations. These employers provide accommodations based upon religious and medical grounds, and they also provide for progressive discipline of employees who fail to comply with vaccination requirements.

The staff analysis also reveals that, of the local/state jurisdictions reviewed that have implemented an employee vaccine mandate, approximately a third of the jurisdictions have reported employee compliance rates above 89%. Another third of employers had compliance rates below 89%, in large part due to it reflecting an in-progress compliance rate (future mandate deadline). The remaining third of jurisdictions have unknown compliance rates due to unavailable in-progress or final compliance information. A majority of healthcare institutions experienced termination/resignation rates of less than 2% of employees. See ©97. Mr. Camacho and Ms. Rodríguez-Hernández are available to answer questions about this research.

2. Potential Impacts on Employee Attrition and County Services

Assistant Chief Administrative Officer Stoddard expressed during public testimony that a reduction in the County workforce of 3-5% would result in a reduction in important County services to residents, including public safety and emergency response services. The Committees might wish to ask the Executive staff to elaborate upon their concerns about potential reductions in services.

In particular, the Committee might wish to ask Executive staff: (1) which agencies would be most affected; (2) which services would be reduced and by how much; and (3) are there

modifications to Bill 34-21 that would mitigate any impacts of public services? Would an explicit religious accommodation reduce anticipated resignations/terminations under the bill?

3. Religious Accommodations

Several Councilmembers, including Councilmembers Friedson, Riemer, and Jawando, have requested amendments to Bill 34-21 that would explicitly provide for religious accommodations to the vaccination requirements of the bill.

Under Title VII the Civil Rights Act of 1964, employers must provide employees with religious accommodations in certain contexts. Specifically, in response to an employee request, the employer must provide a reasonable accommodation to the employee when the employee's sincerely held religious beliefs, practices, or observances conflict with work requirements – unless the accommodation would create an undue hardship to the employer. This is a case-by-case process between the employer and employee, and the nature of the accommodation might look somewhat different for different employees depending upon job duties. See [What You Should Know: Workplace Religious Accommodation | U.S. Equal Employment Opportunity Commission \(eeoc.gov\)](https://www.eeoc.gov/what-you-should-know/workplace-religious-accommodation).

The following amendment would expressly provide for religious accommodations under the bill:

Add a new subsection to read as follows:

Religious accommodation.

- (1) An employee may apply for an accommodation to the requirements of this section based upon a sincerely held religious belief of the employee.**
- (2) The Director of Human Resources, or the Director's designee, must approve an application for an accommodation if the accommodation is required under Title VII of the federal Civil Rights Act of 1964 or other applicable law.**
- (3) Within 7 days after the denial of an application for an accommodation under paragraph (1), the employee must provide to the County proof that the employee has received at least one dose of a COVID-19 vaccine. Within 40 days after the denial of the application, the employee must provide to the County proof that the employee is fully vaccinated.**

4. Booster Shots

Bill 34-21, as originally drafted, does not address the issue of booster shots. To address the issue of boosters, Councilmember Riemer plans to support the following amendment:

Amend lines 11-12 to read as follows:

Fully vaccinated means having received, at least 2 weeks previously, all doses of a COVID-19 vaccine, except any vaccine booster.

Add a new subsection to read as follows:

Vaccine boosters.

- (1) If the Health Officer determines that requiring employees to receive a COVID-19 vaccine booster is in the best interests of the public health, the Executive must notify employees that the booster is required.
- (2) Within 14 days after a notification to employees under paragraph (1), an employee who is eligible to receive a COVID-19 vaccine booster must receive the booster.
- (3) Within 7 days after receiving a COVID-19 vaccine booster, the employee must:
 - (A) provide to the County proof that the employee received the booster;
 - or
 - (B) apply for an accommodation under this Section.
- (4) An employee who fails to comply with paragraphs (1) and (2) must be placed on leave without pay.
- (5) Within 7 days after being placed on leave without pay under paragraph (2), an employee must:
 - (A) provide to the County proof that the employee has received the COVID-19 vaccine booster; or
 - (B) apply for an accommodation under this Section.
- (6) An employee who fails to comply with paragraph (3) must be dismissed from County employment.

Decision point: whether to adopt the amendment described above regarding vaccine boosters.

5. Employee Discipline

As indicated by Council staff research (©84), the policies of Montgomery College and Montgomery County Public Schools (MCPS) include progressive discipline – up to and including termination of employment – for employees who do not comply with vaccination requirements.

Throughout the nation, employers have taken varying approaches to employee discipline in response to noncompliance. Some policies result in leaves of absence, followed by dismissal, for noncompliant employees, whereas others provide for progressive discipline. See ©86. Some jurisdictions have also created incentives and rewards for employees that do comply with the mandate.

If the Committees wish to require progressive discipline consistent with County personnel regulations – as opposed to requiring unpaid leave followed by dismissal – the following amendments could be adopted. These amendments are supported by Councilmember Friedson.

Amend lines 34-36 as follows:

(5) An employee who fails to comply with paragraphs (3) or (4) of this subsection, or with paragraph (3) of subsection (d), must be [[dismissed from County employment]] subject to progressive discipline, up to and including dismissal, under this Chapter and County personnel regulations.

Decision point: whether to adopt the amendment described above regarding progressive discipline.

6. County Contractual Employees / Volunteer Firefighters / Volunteers

As originally drafted, Bill 34-21 would apply to any “individual employed by the County, regardless of the individual’s merit system status or representation by an employee organization.” The bill does not address the issue of contractual employees or volunteers.

A number of employers – including the National Institutes of Health and many institutions of higher education – require the vaccination of contractual staff and volunteers. *See, e.g., [Update-on-COVID-19-Vaccine-Requirements-for-NIH-Staff](#); [COVID-19 vaccination requirement for on-site volunteers | Return to on-site work \(uw.edu\)](#); [Volunteer and Contractor COVID-19 Vaccine Requirement | Northern Illinois University \(niu.edu\)](#).*

MCPS also requires the vaccination of its volunteers. *See <https://news.montgomeryschoolsmd.org/staff-bulletin/school-volunteers-must-upload-proof-of-vaccination-complete-attestation/>*

If the Committees wish to include contractual employees – which is supported by Councilmember Friedson – the following amendment could be adopted:

Amend lines 8-10 to read as follows:

Employee means an individual employed by the County, regardless of the individual's merit system status or representation by an employee organization.
Employee includes a contractual employee.

The Committees also might wish to apply the bill's requirements to volunteer firefighters, and to volunteers in general. The following amendment regarding volunteers is supported by Councilmember Riemer.

Amend lines 8-10 to read as follows:

Employee means an individual employed by the County, regardless of the individual's merit system status or representation by an employee organization.
Employee includes:

- (1) a contractual employee; and
- (2) a local fire and rescue department volunteer.

Add a new subsection to read as follows.

Volunteers. As a condition of volunteering for the County, an individual must provide to the County proof that:

- (1) the individual is fully vaccinated; and
- (2) if eligible to receive a COVID-19 vaccine booster, the individual has received the booster.

Decision point: whether to adopt any of the amendments described above regarding contractual employees and volunteers.

Next Step: Recommendation by the GO/HHS Committees on whether to enact Expedited Bill 34-21.

This packet contains:

Expedited Bill 34-21
LRR
Economic Impact Statement
Racial Equity and Social Justice Impact Statement
Public Testimony
Charles Green
Cornelia Hart
John Hansman

Circle #

© 1
© 5
© 6
© 10
© 13
© 14
© 15

Commission on Health	© 16
Rob Deppa	© 17
Andrew Sharp	© 18
Lindsay Haley	© 20
Cathy Roberts	© 23
Adama Benjoure	© 24
Donna Okeiff	© 25
Earl Stoddard	© 26
Karen Lovejoy	© 28
Nathan Street	© 30
Thomas Wayne	© 31
Yelena Gakh	© 32
Jo Saint-George	© 34
Constantine Tseronis	© 79
Joseph Corbett	© 80
Lee Holland	© 81
Memorandum to Council President from Council Staff	© 83

\\Mcg-C058\DEPT\Central_Staff\LAW\BILLS\2134 Employee Vaccination Requirement\GO-HHS Memo.Docx

Expedited Bill No. 34-21
Concerning: Personnel and Human
Resources – COVID-19 Vaccination
Required
Revised: 09/24/2021 Draft No. 3
Introduced: September 28, 2021
Expires: March 28, 2023
Enacted: _____
Executive: _____
Effective: _____
Sunset Date: _____
Ch. _____, Laws of Mont. Co. _____

COUNTY COUNCIL FOR MONTGOMERY COUNTY, MARYLAND

Lead Sponsors: Councilmembers Riemer and Jawando
Co-Sponsor: Council Vice-President Alborno

AN EXPEDITED ACT to:

- (1) require the vaccination of County employees against COVID-19;
- (2) permit medical accommodations to the COVID-19 vaccination requirements;
- (3) exempt the COVID-19 vaccination requirements from collective bargaining; and
- (4) generally amend the County personnel and human resources law.

By amending

Montgomery County Code
Chapter 33, Personnel and Human Resources
Section 33-22

Boldface	<i>Heading or defined term.</i>
<u>Underlining</u>	<i>Added to existing law by original bill.</i>
[Single boldface brackets]	<i>Deleted from existing law by original bill.</i>
<u>Double underlining</u>	<i>Added by amendment.</i>
[[Double boldface brackets]]	<i>Deleted from existing law or the bill by amendment.</i>
* * *	<i>Existing law unaffected by bill.</i>

The County Council for Montgomery County, Maryland approves the following Act:

Sec 1. Section 33-22 is amended as follows:

33-22. [Reserved.] COVID-19 Vaccination Required.

(a) Definitions. For purposes of this section, the following words have the meanings indicated.

COVID-19 Vaccine means a vaccine authorized or approved by the federal Food and Drug Administration to prevent or reduce the transmission of SARS-CoV-2.

Employee means an individual employed by the County, regardless of the individual's merit system status or representation by an employee organization.

Fully vaccinated means having received all doses of a COVID-19 vaccine.

(b) Vaccination Required. As a condition of employment by the County, an
employee must:

(1) be fully vaccinated and provide to the County proof of vaccination
under subsection (c); or

(2) receive an accommodation under subsection (d).

(c) Procedures; remedies for noncompliance.

(1) Within 7 days after notification by the County to an employee of
the requirements of this section, the employee must:

(A) provide to the County proof that the employee is fully vaccinated; or

(B) apply for an accommodation under subsection (d).

(2) An employee who fails to comply with paragraph (1) must be
placed on unpaid leave.

(3) Within 7 days after being placed on unpaid leave under paragraph (2), an employee must:

(A) provide to the County proof that the employee has received at least one dose of a COVID-19 vaccine; or

(B) apply for an accommodation under subsection (d).

(4) An employee under subparagraph (3)(A) must provide to the County, within 40 days of being placed on unpaid leave, proof that the employee is fully vaccinated.

(5) An employee who fails to comply with paragraphs (3) or (4) of this subsection, or with paragraph (3) of subsection (d), must be dismissed from County employment.

(d) Health-based accommodation.

(1) An employee may apply for an accommodation to the requirements of this section based on the health of the employee.

(2) The Director of Human Resources, or the Director's designee, must approve an application for an accommodation if the accommodation is required for the health of the employee, as documented by a licensed physician.

(3) Within 7 days after the denial of an application for an accommodation under paragraph (1), the employee must provide to the County proof that the employee has received at least one dose of a COVID-19 vaccine. Within 40 days after the denial of the application, the employee must provide to the County proof that the employee is fully vaccinated.

(e) Exemption from Collective Bargaining. The requirements and implementation of this section:

(1) are not subject to collective bargaining; and

(2) are exempt from Sections 33-80, 33-107, and 33-152.

Sec. 2. Expedited Effective Date; Transition. The Council declares that this legislation is necessary for the immediate protection of the public interest. This Act takes effect on the date that it becomes law.

LEGISLATIVE REQUEST REPORT

Bill 34-21

*Expedited Bill 34-21, Personnel and Human Resources –
COVID-19 Vaccination Required*

DESCRIPTION:	Expedited Bill 34-21 would: <ul style="list-style-type: none">• require the vaccination of County employees against COVID-19;• permit medical accommodations to the COVID-19 vaccination requirements;• exempt the COVID-19 vaccination requirements from collective bargaining; and• generally amend the County personnel and human resources law.
PROBLEM:	Protect employees and residents against the global COVID-19 pandemic
GOALS AND OBJECTIVES:	Maximize number of County employees who are vaccinated against COVID-19
COORDINATION:	DHHS; Human Resources
FISCAL IMPACT:	OMB
ECONOMIC IMPACT:	Office of Legislative Oversight (OLO)
EVALUATION:	To be done.
EXPERIENCE ELSEWHERE:	To be researched.
SOURCE OF INFORMATION:	Christine Wellons, Legislative Attorney
APPLICATION WITHIN MUNICIPALITIES:	Applies to all County employees
PENALTIES:	Discipline up to and including dismissal from employment

Economic Impact Statement

Office of Legislative Oversight

Expedited Bill 34-21

Personnel and Human Resources – COVID-19 Vaccination Required

SUMMARY

The Office of Legislative Oversight (OLO) anticipates that enacting Expedited Bill 34-21 would have an insignificant impact on economic conditions in the County. However, OLO believes it is worth noting that because the County to date has achieved the highest rate of adult (age 18+) residents fully vaccinated against COVID-19 compared to surrounding jurisdictions, County residents may be more likely to replace employees residing in other jurisdictions who would be terminated from County employment for refusing to comply with the COVID-19 vaccination requirement. Increasing the share of County employees based within the County would reduce capital outflow in the form of employee compensation spent outside the County.

BACKGROUND

If enacted, Expedited Bill 34-21 would require all County employees to be vaccinated against COVID-19. The Bill would also permit medical accommodations to the COVID-19 vaccination requirements and exempt the vaccination requirements from collective bargaining.¹

METHODOLOGIES, ASSUMPTIONS, AND UNCERTAINTIES

OLO believes that enacting Expedited Bill 34-21 may have an *indirect* impact on economic conditions in the County by reducing capital outflow in the form of County employee spending in other jurisdictions. To date, the County has achieved the highest rate of adult (age 18+) residents fully vaccinated against COVID-19 compared to surrounding jurisdictions. See **Table 1**. County residents therefore may be more likely to replace individuals residing in other jurisdictions who would be terminated from County employment for refusing to comply with the COVID-19 vaccination requirement. This outcome would be beneficial for County economic conditions for two reasons. First, given the strong relationship between proximity to home and transaction location,² County employees who reside locally are more likely to patronize County-based businesses. Second, locally-based employees contribute to the stimulating effects of County government expenditure by paying local taxes.

¹ Montgomery County Code, Expedited Bill 34-21, Personnel and Human Resources – COVID-19 Vaccination Required, Introduced on September 28, 2021.

² Agarwal, Jensen, and Monte, “Consumer Mobility and the Local Structure of Consumption Industries.”

Economic Impact Statement

Office of Legislative Oversight

Table 1. Vaccination Rates Among Adults (Age 18+) by Jurisdiction

Jurisdiction	Pct. Fully Vaccinated
Montgomery	91%
Howard	88%
Fairfax	81%
Frederick	80%
Arlington	78%
Loudon	76%
Prince George's	74%
District of Columbia	68%
Alexandria	64%

Source: Nytimes.com, "[See How Vaccinations Are Going in Your County and State](#)," *New York Times*, accessed on October 16, 2021.

OLO does not expect however that enacting Expedited Bill 34-21 would result in a positive economic impact of significant magnitude. The reason being that it is doubtful the number of County residents who would replace non-resident employees terminated for refusing to comply with the vaccination requirement would be sufficiently large for the Bill to significantly reduce capital outflow from the County.

The claims made in subsequent sections are based on the potential for enacting Expedited Bill 34-21 to have a positive, albeit marginal, impact on local economic conditions.

VARIABLES

The primary variable that would affect the economic impacts of enacting Expedited Bill 34-21 is the following:

- Total employee salaries of County residents who would replace non-resident employees terminated for refusing to comply with the COVID-19 vaccination requirement.

Economic Impact Statement

Office of Legislative Oversight

IMPACTS

WORKFORCE ▪ TAXATION POLICY ▪ PROPERTY VALUES ▪ INCOMES ▪ OPERATING COSTS ▪ PRIVATE SECTOR CAPITAL INVESTMENT ▪ ECONOMIC DEVELOPMENT ▪ COMPETITIVENESS

Businesses, Non-Profits, Other Private Organizations

OLO anticipates that enacting Expedited Bill 34-21 would have insignificant impacts on private organizations in the County in terms of the Council's priority indicators.³ However, OLO notes that some businesses would benefit from the potential increase in the share of County employees who reside locally given their higher likelihood to patronize locally-based businesses.⁴

Residents

As previously discussed, OLO anticipates that enacting Expedited Bill 34-21 may have indirect economic impacts on a small number of County residents. County residents who may replace non-residents terminated from County employment may experience a net increase in household income. It is also worth noting that any household with a member who would otherwise refuse to take the COVID-19 vaccination without the requirement may experience fewer economic disruptions associated with contracting the disease.

DISCUSSION ITEMS

Not applicable.

³ Montgomery County Code, Sec. 2-81B, Economic Impact Statements.

⁴ Agarwal, Jensen, and Monte, "Consumer Mobility and the Local Structure of Consumption Industries."

Economic Impact Statement

Office of Legislative Oversight

WORKS CITED

Agarwal, Sumit, J. Bradford Jensen, and Ferdinando Monte. "[Consumer Mobility and the Local Structure of Consumption Industries](#)." National Bureau of Economic Research, 2017.

Montgomery County Council. [Expedited Bill 34-21, Personnel and Human Resources – COVID-19 Vaccination Required](#), Introduced on September 28, 2021.

Montgomery County Code. [Sec. 2-81B, Economic Impact Statements](#).

Nytimes.com. "[See How Vaccinations Are Going in Your County and State](#)." *New York Times*. Accessed on October 16, 2021.

CAVEATS

Two caveats to the economic analysis performed here should be noted. First, predicting the economic impacts of legislation is a challenging analytical endeavor due to data limitations, the multitude of causes of economic outcomes, economic shocks, uncertainty, and other factors. Second, the analysis performed here is intended to *inform* the legislative process, not determine whether the Council should enact legislation. Thus, any conclusion made in this statement does not represent OLO's endorsement of, or objection to, the Bill under consideration

CONTRIBUTIONS

Stephen Roblin (OLO) prepared this report.

Racial Equity and Social Justice (RESJ) Impact Statement

Office of Legislative Oversight

EXPEDITED PERSONNEL AND HUMAN RESOURCES — COVID-19 BILL 34-21: VACCINATION REQUIRED

SUMMARY

The Office of Legislative Oversight (OLO) anticipates that Expedited Bill 34-21 will favorably impact racial equity and social justice in the County by narrowing public health disparities by race and ethnicity.

PURPOSE OF RESJ STATEMENT

The purpose of RESJ impact statements is to evaluate the anticipated impact of legislation on racial equity and social justice in the County. Racial equity and social justice refer to a **process** that focuses on centering the needs, power, and leadership of communities of color and low-income communities with a **goal** of eliminating racial and social inequities.¹ Achieving racial equity and social justice usually requires seeing, thinking, and working differently to address the racial and social harms that have caused racial and social inequities.²

PURPOSE OF EXPEDITED BILL 34-21

The purpose of Expedited Bill 34-21 is to limit the spread of the coronavirus by requiring all Montgomery County Government employees to be immunized against it. If enacted, the Bill will require all County employees to be vaccinated against COVID-19 in order to maintain their employment except for exempted employees who meet certain medical qualifications. More specifically, employees who fail to provide proof of receiving at least one dose of the vaccination within seven days of notification would be placed on unpaid leave, and possibly face termination within 40 days of being placed on leave. Expedited Bill 34-21 was introduced to the County Council on September 28, 2021.

COVID-19, COUNTY SERVICES, AND RACIAL EQUITY

The COVID-19 public health and economic collapse of 2020 has disproportionately impacted BIPOC (Black, Indigenous, and People of Color) communities across America. According to an analysis of data from the National Center for Health Statistics, between 2018 and 2020, the life expectancy for Blacks was reduced by 3.25 years and for the Latinx population by 3.88 years compared to being reduced by 1.87 years for the White population as a result of the COVID-19 pandemic.³ Additional research reveals that BIPOC, especially the Black and Latinx populations, were less likely to be vaccinated against COVID-19 but are most likely to have occupations that exposes them to the virus.⁴

The workplace environment has been identified by the Center for Disease Control and Prevention (CDC) as one of the social determinates of health⁵ that increases BIPOC risks for COVID-19.⁶ According to the CDC, Black and Latinx people are more likely to work in frontline industries (i.e., jobs that require public exposure and/or in-person social interaction); which makes them more susceptible to experiencing the harsh consequences of the COVID-19 pandemic, such as work layoffs or loss of income and health insurance, along with contracting the coronavirus.⁷ These workplace environments can also trigger outbreaks that could negatively impact the public health of residents and possibly overwhelm hospitals in Montgomery County. The CDC identifies workplace vaccination programs as an effective strategy to help protect workers and the public they serve from the harmful impacts of COVID-19.

RESJ Impact Statement

Expedited Bill 34-21

According to the Montgomery County Dashboard on October 14th, 98 % of County residents aged 18 and over had received at least one dose of a COVID-19 vaccination compared to almost 80% percent of County employees.⁸ Of note, 7,523 County employees are at least partially vaccinated while 648 employees indicated not being vaccinated and 1,261 employees had not reported their status. It is currently unknown how many County employees are exempt from needing the vaccine due to meeting the medical qualifications.

Whereas about 21 % of County employees had not reported being vaccinated and could potentially face termination as a consequence of Expedited Bill 34-21, if actual rates and numbers of County employees potentially impacted by this bill varies by department. As noted in Table 1, compliance with the bill could impact up to:

- 493 Fire and Rescue Service employees (36.3% of department employees)
- 373 Police employees (19.8% of department employees)
- 299 Transportation employees (24.0% of department employees)
- 252 Health and Human Services employees (14.3% of department employees)
- 167 Corrections and Rehabilitation employees (34.0% of department employees)
- 111 General Service employees (28.0% of department employees)
- 104 Alcohol Beverage Services employees (25.0% of department employees)

Table 1: Montgomery County Employee COVID-19 Vaccination Status, October 14, 2021

Departments	Number of Employees	Not Vaccinated	Status Not Reported	No Vaccination or Report
Fire and Rescue Services	1,359	70	423	493
Police	1,881	117	256	373
Transportation	1,244	183	116	299
Health and Human Services	1,764	91	161	252
Correction and Rehabilitation	491	54	113	167
General Services	396	38	73	111
Alcohol Beverage Services	415	46	58	104
All Other Departments	1,929	140	61	201

Source: Montgomery County Dashboard MCG Employee Vaccination Information

ANTICIPATED RESJ IMPACTS

OLO anticipates a favorable public health impact of Expedited Bill 34-21 on racial equity and social justice. The COVID-19 pandemic has disproportionately harmed BIPOC residents, especially those who are Black and Latinx. Mandating that County employees receive the COVID-19 vaccination under the Bill could enhance the public health outcomes for Black and Latinx residents in the short- and long-term by reducing rates of infection, hospitalization and death. Reducing the public health effects of the pandemic could also mitigate the disproportionately negative economic effects of the pandemic on communities of color and low-income residents.

OLO also anticipates that Expedited Bill 34-21 could potentially undermine County services that exacerbate racial and social inequities. For example, given the greater utilization of public transportation, health and human services among BIPOC and low-income residents, a decline in these County services resulting from employee terminations could

RESJ Impact Statement

Expedited Bill 34-21

adversely impact racial and social inequities. The racial equity and social justice implications of reduced Fire and Rescue, Police, Corrections and Rehabilitation, General Services, and Alcohol and Beverage Services, however, remain unknown.

While acknowledging that that Bill may challenge the County's ability to deliver key public services in the short-term if current employees do not comply with the vaccination mandate, OLO finds that the public health benefits of the bill exceed the potential public service costs on racial equity and social justice. As such, OLO finds that Expedited Bill 34-21 will advance racial equity and social justice in Montgomery County.

RECOMMENDED AMENDMENTS

The County's Racial Equity and Social Justice Act requires OLO to consider whether recommended amendments to bills aimed at narrowing racial and social inequities are warranted in developing RESJ impact statements.⁹ OLO finds that Expedited Bill 34-21 should narrow public health related racial and ethnic inequities by increasing the County's COVID-19 vaccination rate and does not offer any further recommendations.

CAVEATS

Two caveats to this racial equity and social justice impact statement should be noted. First, predicting the impact of legislation on racial equity and social justice is a challenging, analytical endeavor due to data limitations, uncertainty, and other factors. Second, this RESJ impact statement is intended to inform the legislative process rather than determine whether the Council should enact legislation. Thus, any conclusion made in this statement does not represent OLO's endorsement of, or objection to, the bill under consideration.

CONTRIBUTIONS

OLO staffers Dr. Theo Holt, Performance Management and Data Analyst, and Dr. Elaine Bonner-Tompkins, Senior Legislative Analyst, drafted this racial equity and social justice impact statement.

¹ See the Government Alliance for Race and Equity's "Advancing Racial Equity and Transforming Government" for understanding government's role in creating inequities https://racialequityalliance.org/wp-content/uploads/2015/02/GARE-Resource_Guide.pdf

² Adopted from racial equity definition provided by Racial Equity Tools. <https://www.racialequitytools.org/glossary>

³ Stephen Woolf, Ryan Masters, and Laudan Aron, "Effect of the Covid-19 pandemic in 2020 on life expectancy across populations in the USA and other high income countries: simulations of provisional mortality data, BMJ 2021; 373:n1343 (May 2021) <https://www.bmj.com/content/373/bmj.n1343>

⁴ COVID-19 Vaccine Equity for Racial and Ethnic Minority Groups, COVID-19, September 9, 2021, National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases, Center for Disease Control and Prevention (CDC). <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/vaccine-equity.html>

⁵ As defined by the CDC, social determinates of health are conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of-life-risks and outcomes.

⁶ Ibid

⁷ Ibid

⁸ Montgomery County Dashboard MCG Employee Vaccination Information.

<https://www.montgomerycountymd.gov/covid19/data/case-counts.html - mcg-vaccinations>

⁹ Montgomery County Council, Bill 27-19, Administration – Human Rights - Office of Racial Equity and Social Justice – Racial Equity and Social Justice Advisory Committee - Established

I am addressing the council for the purpose of stating my opinion on Bill 34-21. I am outraged and more than disappointed that there are members of the Council that are ready and willing to throw away the careers and futures of employees simply over a medical choice.

I understand that the Council, sitting as the Board of Health may enact regulations. While I disagree with elected officials acting in any medical capacity, I recognize this is an accepted practice.

What is happening with 34-21 is going far beyond established practices. The council is circumventing established and functioning collective bargaining between labor and the County in order to force their agenda through, without a legal process. The Council is literally going to force Montgomery County employees to either leave their careers or abandon their ability to make a personal health choice. Should an employee who has a substance abuse disorder be terminated? What about obesity? Both of those conditions cause thousands of deaths and are preventable.

I do sympathize with the position that public safety is part of the Councils obligation to the citizens. I also recognize that personal health decisions should be made through conference between the patient and their Doctor.

Please remember that we are discussing Montgomery County Governments most valuable asset, our people. Please do not ratify Bill 34-21.

Respectfully, Charles Greene.

September 27, 2021

Re: Expedited Bill 34-21

To all members of the Montgomery County Council:

Ladies and Gentlemen:

This bill (Expedited Bill 34-21) mandating the Covid vaccine as a condition of employment for all County employees is a clear violation of civil rights, and will adversely impact the lives of many good people who have served this county with years of service.

Many people object to the vaccines currency available, whether because of concerns about lack of research and available data on their effectiveness and safety, or because of questions about their morality.

It is clear evidence of the tone-deafness of the council, and of so many in authority right now, that there is no accommodation for religious exemptions in this bill. Why? Is this (as well as the disregard of the deeply held reservations of minority people) evidence of bigotry on your part? Are you all so privileged and isolated from the lives of real people that you feel entitled to impose your medical dictatorship on the peasants? Shame on you all if you dare to pass this bill.

Sincerely,
Mrs. C. Hart
Silver Spring

9-29-21

Councilmembers,

I am a retired County employee. If I were still working, I would strongly support a requirement that my colleagues be vaccinated, just as I was. I would be safer working with others who were vaccinated. The public with whom we interact would be safer. And the public would further benefit by fewer work days lost by employees because of avoidable covid infections.

As a County citizen and taxpayer, the second two of those benefits still apply.

What is the objection? From union leaders who want to bargain for more benefits for employees already well treated? From libertarians who believe in their right to infect others?

Please do the right and necessary thing, and set an example for other employers.

John Hansman

Rockville



Montgomery County Commission on Health

**Testimony in Support of Expedited Bill 34-21
Personnel and Human Resources - COVID-19 Vaccination Required
Tuesday, October 19, 2021**

To: Members of the Montgomery County Council
From: The Montgomery County Commission on Health

The Montgomery County Commission on Health (COH) strongly supports the passage of Bill 34-21, introduced to require County employees be vaccinated against the coronavirus, with no option to have frequent testing as an alternative except in the event of a medical accommodation.

Public health officials have long advocated for vaccination as their best tool against the pandemic, and more governments and private employers are issuing mandates requiring their employees to get vaccinated.¹ The Montgomery County Public School system has wisely decided to require its entire staff to be vaccinated, even those not directly working with students.²

There is no controversy regarding the efficacy and safety of vaccinations, which has been proven since late 2020.^{3,4} We know that an unvaccinated person is 11 times more likely to die of Covid than someone who is vaccinated.⁵

County leadership has rightly touted the high level of vaccination of our residents, among whom the vaccination rate is 90%.⁶ Yet only 75% of County employees are known to have been vaccinated.⁷ Roughly a third of the County's 10,000 employees, including first responders have at some point missed work because of contracting the virus or being exposed to it. Sadly, five county employees have died, and about 140 are currently quarantined, having tested positive or awaiting test results.⁸

County residents and employees deserve to live and work in the safest possible environment, and it is incumbent on County leadership to do everything possible to protect County employees, and its residents, from a lethal and highly communicable disease. The COH asks that you support Bill 34-21 to ensure that we continue to protect the County residents and help save lives.

¹ The Washington Post. https://www.washingtonpost.com/local/montgomery-county-covid-vaccines-employees/2021/08/25/5a32bc28-05c8-11ec-8c3f-3526f81b233b_story.html

² Montgomery County Public Schools <https://news.montgomeryschoolsmd.org/staff-bulletin/covid-19-vaccinations-required-for-all-mcps-employees/>

³ The New England Journal of Medicine. <https://www.nejm.org/doi/full/10.1056/nejmoa2035389>

⁴ Centers for Disease Control and Prevention. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>

⁵ The BMJ. <https://www.bmj.com/content/374/bmj.n2282>

⁶ Montgomery County Government https://www2.montgomerycountymd.gov/mcgportalapps/Press_Detail.aspx?Item_ID=36644

⁷ Montgomery County Government. <https://www.montgomerycountymd.gov/covid19/data/case-counts.html#mcg-vaccinations>

⁸ The Washington Post. <https://www.washingtonpost.com/opinions/2021/10/04/montgomery-county-maryland-covid-vaccine-mandate/>

To the Members of the Montgomery County Council:

I strongly urge the Council to take the necessary action immediately to require all county employees (with the exception of certain limited medical accommodations) to be vaccinated against COVID-19 as soon as possible; to exempt the COVID-19 vaccination requirements from collective bargaining; and to amend the county personnel and human resources law as necessary.

County employees are public servants; their jobs are to execute public services. They are paid, not by some employer, business, or organization, but by the people of the County. Their jobs are not driven by profit or opinion, but by the need for services to all the people of the County.

People who chose not to be vaccinated endanger their own lives, but far more importantly, they endanger the lives of everyone else. There is no valid excuse for refusing to be vaccinated, except in some unusual cases for extenuating medical conditions. It is beyond comprehension that consideration be given to allowing public servants to choose not to be vaccinated. There are plenty of other requirements for holding a public job and being vaccinated against this deadly disease must be a requirement.

The Council is asked to weigh facts and make tough decisions; the facts in this case clearly support vaccination, so it should not be a tough decision. There are no facts to support people's willful refusal to be vaccinated and there are overwhelming facts in favor of vaccination. It is not rational for our County's public servants not to be required to get vaccinated as soon as possible. County employees hold their jobs to provide public services; to be vaccinated serves the public good, and there certainly is no public service to be gained from not being vaccinated. County employees must not be allowed to put their own misguided actions against the public good.

Roy W. Deppa, P.E.

Dear Council Members,

In my Opinion, No One Should Be Forced to Participate In An Ongoing Experiment Or Be Threatened With Job Loss.

Everyone Has Rights Under Informed Consent Laws (45 CFR 46) & Anti-Discrimination Laws (Title VII of the 1964 Civil Rights Act), and if vaccines are offered to public employee it needs to be offered on volunteer basis or employer needs to sign informed consent.

Who is liable if employee gets injured and unable to work for any length of time? How long will it take an employee to receive injury compensation, so his family isn't left out in the cold while he recovers?

As an employee of Montgomery County I would be open to vaccinate only if Montgomery county government employer signs informed consent that in case of an employee vaccine injury, the employer is liable for any expenses related to the vaccine injury.

Most of Montgomery County employees have been working front facing non- stop since the pandemic begun, unvaccinated and without proper protection. Services have never ceased, and health risks have never been greater then during this pandemic. First responders and others who take caution to vaccinate need to be given an alternative such as weekly testing instead of forced vaccination as there are reservations regarding the experimental covid vaccine.

Those who chose not to vaccinate made a difficult decision that needs to be respected, that decision is not based on lunacy as some may think. If after reading my narrative you still think, an employee must vaccinate please consider addressing the following concerns and provide your informed consent to each of the following:

- 1. Employers are required to disclose any and all potential conflicts of interest (COI) including public and personal investments in the pharmaceutical companies manufacturing COVID vaccines, as well as COIs via private contracts with the local, state, and federal government. Can you please provide the full list of any and all financial conflicts of interest? Has the business received any money from local, state, or federal governments, agencies or pharmaceutical companies that incentivize the administration of COVID vaccinations?***
- 2. Who is liable if I get injured and am unable to work for any length of time? How long will it take me to receive injury compensation, so my family isn't left out in the cold while I recover?***
- 3. Will my consent to get inoculated terminate any aspect of my employee benefits I may be entitled to during my years of service to this company or government entity, if I'm injured or killed by these vaccines still in clinical trial?***
- 4. Can you please provide the full breakdown of post-inoculation death and injury reports in the federal Vaccine Adverse Events Reporting System (VAERS) and any other surveillance systems? How many people have died? How many people have been permanently disabled? How many people have experienced life threatening events? How many people have been hospitalized? How many people have needed urgent or emergent care? How many babies have been miscarried?***

5. *What is the potential gain of benefit vs risk of injury in my age demographic if I elect to get inoculated? What are the specific benefits if I get inoculated? What are the specific risks? Is there a risk of death or permanent disability if I receive the COVID vaccine? What are the other current warnings for each experimental vaccine?*
6. *If I'm injured, how do I ensure a healthcare professional reports my injury to VAERS?*
7. *What long-term data (36+ months) is available on how many people have developed autoimmunity, infertility or similar debilitating conditions after getting inoculated?*
8. *What are all of the ingredients in the experimental COVID vaccines? Which of them are carcinogenic, mutagenic, or teratogenic? Which of them have been classified as toxins, poisons, or dangerous for human consumption by the US EPA and/or International Agency for Research on Cancer (IARC)?*
9. *Will this shot protect me against all variants?*
10. *Can I still get COVID and transmit the infection even if I'm fully vaccinated?*
11. *I've already recovered, and the scientific literature shows that I have 'long-term, robust and durable' immunity against SARS-CoV-2 virus. Why am I required to be vaccinated against something I already have immunity against? Am I eligible to prove my immunity using EUA approved antibody and/or T-cell tests?*
12. *There are many peer-reviewed scientific papers supporting the use of Monoclonal Antibodies, Ivermectin, Vitamin D, C, A, Zinc and Hydroxychloroquine. What treatment options exist should I elect to use my civil right to refuse this inoculation?*

Andrew Sharp

Council members,

I wanted to appear before you during the hearing but there were no positions left. My statements are regarding the proposed Vaccine Mandate Bill and I've included very important facts and numbers on the impact that passing this bill will have on our county. You have the best interests of the county, of course, so I expect you'll find these comments to be worthwhile.

In regards to the proposed mandate, Hans Reimer was quoted in Bethesda magazine on October 7 as referring to about 23% of the county workforce as "a bunch of Trump-loving deplorable anti-vaxers who are making this pandemic last longer and hurt more people than it should." Is this how little the county council values it's first responders and workforce? Not only are these crass comments by Mr. Reimer highly inappropriate, they are also inaccurate. If you speak to any employee who is against the mandate, I can assure you that you will not find even one of them who cites "loving Trump" or being an "anti-vaxer" as the reason for their opposition. His comments are beneath the dignity of an elected official in Montgomery County, they are slanderous, display malice toward these county employees and they are unnecessary. They do nothing to further the debate.

First Responders and other front-line county employees assumed all of the risk throughout the pandemic to ensure that the critical functions of government and public safety were not interrupted. In the beginning of the pandemic, this was done without PPE and without a vaccine available. In spite of that, no call went unanswered no matter how much risk was involved. First Responders, at this point last year, were considered heroes. Many components of our local government continue working from home while First Responders continue to answer emergency calls without interruption, only now, from Mr. Reimer's comments, many of those same employees are portrayed as the worst villains, accused of endangering the public and "hurting more people" than should be, as Mr. Reimer so callously stated. These employees are doing the exact same job as before. Mr Reimer should publicly apologize for and retract those comments and if he won't, he should be censured by the rest of the council. His negativity and public statements are not in the best interests of our county. Apologizing or censuring him serves our county and county employees and shows good will.

Regarding the above referenced bill, the Racial Justice and Social Equity Act of 2019 requires the council to provide an equity impact statement with any bill under consideration by the council. As of yet there is no such statement attached to Bill 34-21. The county council is will likely find that the demographics of those officers opposing the mandate are far from the "Trump-loving deplorable anti-vaxers" that Mr. Reimer believes they are. You will find a substantial number of minority officers included in those numbers of employees. The police department has made significant inroads into hiring minority officers and this bill threatens those gains in ways you are not anticipating. Those employees who leave or are forced out will be highly sought after in this region, as will the others. The negative impact on the county will take years to recover, if recovery is possible at all. This is not in the best interests of our county.

Mr. Elrich and the unions have been working on an agreement that seems to be reasonable, provided that appropriate safeguards are in place for employee privacy, accurate and appropriate metrics for ending testing and solid policies that detail how the testing is done and what happens based on the results obtained. Mr. Elrich was assuming his proper role as head of the executive branch, addressing issues in the branch of government that he directs. Consider reversing those circumstances - if Mr. Elrich came to the county council and told them he was going to fire certain employees in the legislative branch for not doing something he demanded, there would be an uproar from the council that he was overstepping his Section 216 chartered authority and rightly so. Allowing Mr. Elrich and the unions to continue to work on agreements that are reasonable is in the best interests of our county and its employees.

The county assumes that 77% of its employees are legally vaccinated, according to the definition provided in Bill 34-21. This is not an accurate number. The 77% reflects employees who have received at least one shot, not those who are fully vaccinated. The 77% vaccinated number will be smaller when adjusted for those employees. The 77% vaccinated number will also be dramatically reduced when boosters are required to maintain the legally vaccinated status. One should not assume that employees who are legally vaccinated now will also consent to boosters to maintain that status. Many will not consent to boosters and it will further exacerbate staffing levels, starting this whole process over again with another large group of employees.

If the mandate becomes law, Montgomery County will be the only major jurisdiction in Maryland except Baltimore City that either doesn't have a mandate or doesn't offer a testing option for its employees. Recently, the Baltimore City FOP president instructed their officers to provide zero information as to their vaccine status. This will render their mandate moot. Baltimore cannot afford to suspend its entire police department and will not have any real mechanism for enforcement. Fortunately here in Montgomery County, the FOP president and county executive are working together to find a solution. They are collaborating - the council should, in the best interests of the county, allow them to continue to collaborate. Let's keep the best interests of the county on the forefront of the agenda.

For the last year or two and before, police agencies across the nation have had little success recruiting and hiring police officers. Many of those young officers recently hired are now leaving within a few years of hire for better pay and better working conditions than here in the county, or leaving the profession altogether. The Washington DC region has mirrored nationwide difficulties in hiring and retaining officers and Montgomery County is no different. With one of the lowest pay rates in the region, a very difficult political environment biased against police officers and a steadily rising violent crime rate, it should come as no surprise that many of the best police officer applicants are looking elsewhere for careers. It also shouldn't be a surprise that attrition rates for retirements and resignations in the department are accelerating like never before. There are many opportunities in this region, both local and federal. Bill 34-21 is the best recruiting tool for competitor agencies in the region who stand to reap the benefits of highly trained, college educated police officers with good levels of experience leaving the department for agencies that either have no mandate at all or at best only require a testing process. This

includes unvaccinated and vaccinated officers alike, because those left behind will not want to work in an environment that has become significantly less safe due to staffing shortages and the loss of experienced officers. I can't imagine that handing competitor agencies such an easy recruiting tool is in the best interests of our county. Our officers will leave quickly - and MCPD will be unable to fill their roles, leaving an undue burden on the remaining officers.

Furthermore, Title VII of the Civil Rights Act of 1964 is crystal clear that both medical and religious exemptions are required in any mandate. The Maryland Declaration of Rights also requires these exemptions. Bill 34-21 curiously omits these civil rights in its text. Montgomery County has a highly educated workforce. This is a testament to the hiring practices that have occurred here for years. The council should assume that these same employees are well aware of their civil rights and will exercise all available options in defending them.

I know members of the council might believe that many of these officers, firefighters, corrections officers and professional staff are bluffing. If Bill 34-21 becomes law, there might be a small percentage of these employees who will decide to go ahead and get vaccinated to avoid having to leave county employment. Those employees will remain in county employment, more bitter than ever that their employer made them make the Faustian Choice of trading their moral beliefs for keeping their jobs. Those who are terminated will face financial ruin, foreclosure on their homes and other personal property and reputational harm. All of this going into the holiday season. I ask you, is that the type of employer you want to be known to be? Is this in the best interest of the county?

I believe that many who support this mandate do not yet fully understand the nature of the opposition to the mandate. Even the vast majority of those who are fully vaccinated do not support a mandate, because it leaves those employees saying to themselves "ok, they didn't come for me this time, but it's only a matter of time before they do so for something else."

There are alternatives to a mandate and those alternatives are under negotiation. The essential purpose of collective bargaining is workforce harmony between the employer and the employee. Bill 34-21 threatens to permanently alter that relationship. This is not in the best interests of Montgomery County. I love this county and hope to continue to live here happily. Please put the best interests of our county on the forefront of the council's agenda. Oppose Bill 34-21, allow Mr. Elrich to continue to work with local unions on alternatives to vaccine mandates, and please consider ALL those who live in the county - even residents like me, who are fully vaccinated by choice, but are 100% opposed to a mandate.

Thank you for your time in reading this.

Sincerely,

Lindsay Haley

Dear Montgomery County Councilmembers,

As you consider mandating vaccines for all Montgomery County employees, please consider this study, dated September 30, 2021, *“Increases in Covid-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the U.S.”* The lead author is from Harvard Center for Population and Development Studies, Cambridge, MA USA. The article indicates that data show a trend toward higher numbers of Covid cases in more vaccinated populations rather than the other way around which would be expected.

The authors final paragraph reads “In summary (bold and italic mine), even as **efforts should be made to encourage populations to get vaccinated it should be done so with *humility and respect. Stigmatizing populations can do more harm than good.***”

Here is the link to the study as published at the National Library of Medicine of The National Institutes of Health.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8481107/>

As I see it, voting to mandate vaccines is NOT following the science and is a political rather than public health response to Covid-19.

Sincerely,

Cathy Roberts

Adama Benjoure Testimony

On June 7th I received my first pfizer shot. I got it because I was looking for work and my husband said that I would not be able to get a job without it. After receiving the shot I went home and felt a little off but by the second day I started having shooting pains down my right arm and leg. It felt like the area where I had received the shot was on fire. I was in so much pain I could hardly walk and could not use my right arm to get things done. It is going on six months since the first shot and the pain has not gone away. The only way I am able to function is to take Tylenol which is a problem because I was told that this can damage my liver over time. With the help of the Tylenol I try to push through the pain so that I can function. I have a husband and two children and I do not know if my life will ever be the same. I will not take the second shot and I will not have my children vaccinated. How do I get my life back? I have since spook with others who have similar stories and are struggling with large medical bills and or difficulty working because of their vaccine injuries. What compensations are you prepared to provide the increasing number of victims from this forced policy? I have no money for medical care. What will happen to me.

I believe that all Montgomery County employees MUST be vaccinated against COVID 19 to retain their jobs. It is very important to ensure the health of the public.

Donna O'Keiff

Good Afternoon Council President Hucker, Council Vice President Alborno, and members of the County Council,

My name is Earl Stoddard, Assistant Chief Administrative Officer and I am here to provide testimony on behalf of County Executive Marc Elrich on Expedited Bill 34-21 which would impose a COVID-19 vaccine mandate on county employees and mandates disciplinary remedies, including termination, for those that do not comply.

County Executive is proud of the enormous effort undertaken by County employees during the COVID-19 pandemic and the great sacrifices they made to maintain the delivery of critical services to our residents. Mr. Elrich knows the Council shares this sentiment and appreciates the intent of Bill 34-21 but is deeply concerned the bill as written will create critical challenges to the delivery of essential services.

The County Executive supports vaccine mandates. We have seen across the country that they result in significantly higher vaccine uptake in places where they are implemented. The County Executive's principal concern is with the collateral impacts from staff loss associated with those personnel who may retire, transfer, resign, or – as would be mandated by law - be terminated, particularly within the public safety agencies. The Council is aware that recruitment and retention in the Police Department, Fire & Rescue Services, and Corrections have been challenges for several years now. In combination with the difficult working environment of the last 20 months has left those departments understaffed and have no choice but to use service protection mechanisms like overtime, forced holds, and leave restrictions.

On September 27, the County Executive directed frontline public safety agencies to conduct risk assessments about the range of impacts caused by potential noncompliance with a vaccine mandate. Those reviews were provided to the Council ahead of this hearing. The key takeaway is that even if a mandate results in 95% or greater compliance (as I suspect it would), most of our public safety programs cannot sustain a 3-5% reduction in staffing without reducing services. It takes time to recruit and train replacement staff, so those impacts would inherently be long-lasting. The County Executive strongly believes that any personnel reduction reduces public safety coverage puts our residents at unnecessary risk and must be avoided.

Pursuant to the Board of Health's Regulation 19-975 requiring the implementation of a Vaccine or Testing plan, Executive Branch staff are continuing to implement the Vaccine or Testing plan. Testing programs are being stood up across county agencies while we work concurrently to get additional employees to report their vaccination status. The County Executive strongly believes that testing, even for those that are vaccinated, is an important addition to protecting our workforce and residents. This effort will expand with acquisition of additional rapid tests made available through ongoing State and Federal efforts, as well as County procurement.

The County Executive asks that the Council be cognizant of the collateral impacts described in risk assessments and mitigate negative impacts to essential services. There are many sectors where personnel losses result in inconvenience or longer wait times; but our public safety agencies provide services that sustain life and protect property.

All of us want vaccinated county workers. All of us also want to maintain the timely services that protect lives. Right now, Expedited Bill 34-21 does not adequately address the preservation of services and should not be enacted without amendment to address protection of public safety service delivery.

Lovejoy Testimony With References

The United States' Covid outcomes rank among the worst around the world. This is because local and state governments have followed federal guidelines, apparently doing no independent research. We accepted the narrative that there was no treatment for the virus. Our only hope was to wait for a vaccine, suppressing the voices of our best and brightest doctors. These doctors have provided us with successful early at-home treatment protocols that they say could have ended our pandemic in 2020! Last year, they were trying to educate us. Now they are plainly saying people have not been dying from covid but medical malfeasance, that is, no treatment or wrong treatment.

Though media suggest otherwise, manufacturers state the vaccines do not keep people from getting, transmitting, or dying from covid. Israel is touting one of the largest vaccination rates, yet 65 percent of covid hospitalizations are from fully vaccinated. In the states and elsewhere vaccinated people are dying from covid. Hospitals in the US are reporting that 45 percent of covid hospitalizations are from fully vaccinated. In an August study done in a medical facility, fully vaccinated personnel were locked in a ward, no one else came in or out. They gave each other covid and when nose swabs were taken their viral loads were 250 times higher than unvaccinated. The vaccinated were super-spreaders.

Vaccination is not working but we're doing more of it. What is the definition of insanity? Instead of listening to our doctors and scientists we have allowed the pharmaceutical companies to push a very expensive vaccine agenda. Compare that to treatments costing pennies, that are saving lives, and ended the pandemic in other countries last year. I am here to ask you to stop the insanity. Instead of mandating vaccines that don't work and have unprecedented death and injury, a fact which I must add has been swept under the rug, let's invest in early treatment protocols. Stop blaming the unvaxxed. Invite doctors with proven answers to give a public forum to educate our citizens. I will volunteer to do the leg work – under your supervision of course – to make this happen. I will be sending documentation.

Real science requires a steady flow of dialog and information which, during the pandemic, has not happened. Name calling like 'anti-vaxxer' or 'Republican dissident' is propaganda. I am vaccinated and a registered Democrat. So what do you want to call me? Stop the name calling and let's look at the facts. Bring in the doctors to discuss their successful early treatment protocols.

Below are references:

Below is a very small sampling of information. I would be happy to send more.

Dr. Pierre Kory – US Senate hearing – cure for COVID-19

<https://www.c-span.org/video/?c4930160/user-clip-dr-pierre-kory-senate-hearing-ivermectin-100-cure-covid-19>

Article by leading US doctor:

<https://childrenshealthdefense.org/defender/vaccinated-healthcare-workers-threat-unvaccinated-patients-co-workers/>

The Lancet paper (preprint) on the hospital lock down study:

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733

A European Journal of Epidemiology paper detailing the vaccine failures is here:

<https://link.springer.com/article/10.1007/s10654-021-00808-7>

The FLCCC Alliance home page is here. An organization of top US doctors formed specifically to fight COVID-19. Unlike Fauci, NIH, and other agencies these doctors have no financial interest in the vaccines and have risked their own careers to speak out.

<https://covid19criticalcare.com/>

Protocols:

<https://covid19criticalcare.com/covid-19-protocols/>

Dear County Council,

My name is Nathan Street I'm an Equipment Operator III at D.O.T. I've been employed here for 18 years. The vaccine should not be mandated. The vaccine is ineffective at reducing transmission and injury. Natural Immunity has been proven to be more effective than the vaccine even according to Pfizer scientists. Many nations have reduced their Covid related deaths by using an outpatient early treatment protocol that uses supplements to boost the immune system coupled with Ivermectin and steroid inhalants. Doctors and nurses have gotten together to spread this information.

<https://covid19criticalcare.com/about/>

Please take the time to look through this valuable information.

Take a look at the people's story.

A news channel asked "Have you lost an unvaccinated loved one due to Covid?"

The responses tell a different story than the media's one-sided reporting.

<https://www.facebook.com/wxyzdetroit/photos/after-the-vaccines-were-available-to-everyone-did-you-lose-an-unvaccinated-loved/10158207966696135/>

Mandating this ineffective vaccine that has caused thousands of deaths and numerous side effects would be a very poor decision. Israel was the first nation to have over 80% of its population vaccinated. They currently have some of the highest Covid cases. Please don't allow politics to overrule common sense.

Nathan Street

Expedited Bill 34-21,

Please respect the human rights of individuals freedom of choice and privacy. DO NOT MANDATE A VACCINE! This can jeopardize the health and safety of those who had covid before. Studies show your antibodies are way more stronger and effective against the virus.

Thomas Wayne

OBJECTION TO EXPEDITED BILL 34-21

Dear MoCo Council Members,

I strongly object to Expedited Bill 34-21, Personnel and Human Resources – COVID-19 Vaccination Required.

Here are the facts that cannot be ignored now and will not be ignored in the future - when all actions will be evaluated correspondingly.

1. According to VAERS data through September 17, 2021 (VAERS is COVID Vaccine Adverse Event Reports created by CDC): **726,963** reports of
15,386 deaths; **66,642** hospitalizations;
82,854 urgent care; **114,127** doctors office visits;
6,378 anaphylaxis (severe, potentially life-threatening allergic reaction);
8,626 Bell's (an unexplained episode of facial muscle weakness or paralysis); **2,122** miscarriages.

2. According to Compliant Management System (CMS) of FDA which reflects data from Medicare (over 65 y.o.) and Medicaid (poorest population) there were over 45 K deaths after vaccination within 3 days period.

You should all remember that you will be responsible for all deaths and debilitating severe adverse effects caused by this vaccine, which has never passed through the regular FDA trials.

3. mRNA COVID-19 vaccines are not efficient with their efficacy going below 50% within first 3-4 months which is unacceptable by FDA standards.

4. mRNA COVID-19 vaccines do not prevent from spreading disease. On the contrary, they assist spreading COVID-19, as they suppress COVID symptoms. Thus, vaccinated people who are sick with COVID and do not realize that they are sick, become superspreaders.

5. There are latest data on correlation between the extent of vaccination and the rate of COVID-19 spread. Scientists have found that countries with highest vaccination, such as Israel and Singapore have the highest number of COVID patients in hospitals.

This means that you, as Councilmembers, are about to force MoCo employees to get vaccination with untested and damaging preparation of a new type, which is not only inefficient, but which will lead to increased rate of COVID cases in MoCo, similar to what is observed in Israel and Singapore.

It is unclear, as to what medical authority or knowledge you have in the fields of virology, immunology and infectious diseases for such an act.

6. You, as a governing body of Montgomery County, are creating discrimination of a new type, i.e. discrimination on the basis of the vaccination status. Constitutions of the United States and of Maryland prohibit discrimination of any type, so your action is unconstitutional.

7. The councilmember at large, Mr. Hans Riemer, who is one of the authors of the proposed bill, has direct financial interest in the bill. Mr. Hans Riemer is married to Vice President, Federal Government Relations at Pfizer. This is a clear conflict of interests and a violation of work ethics, which lead to corruption of a government official.

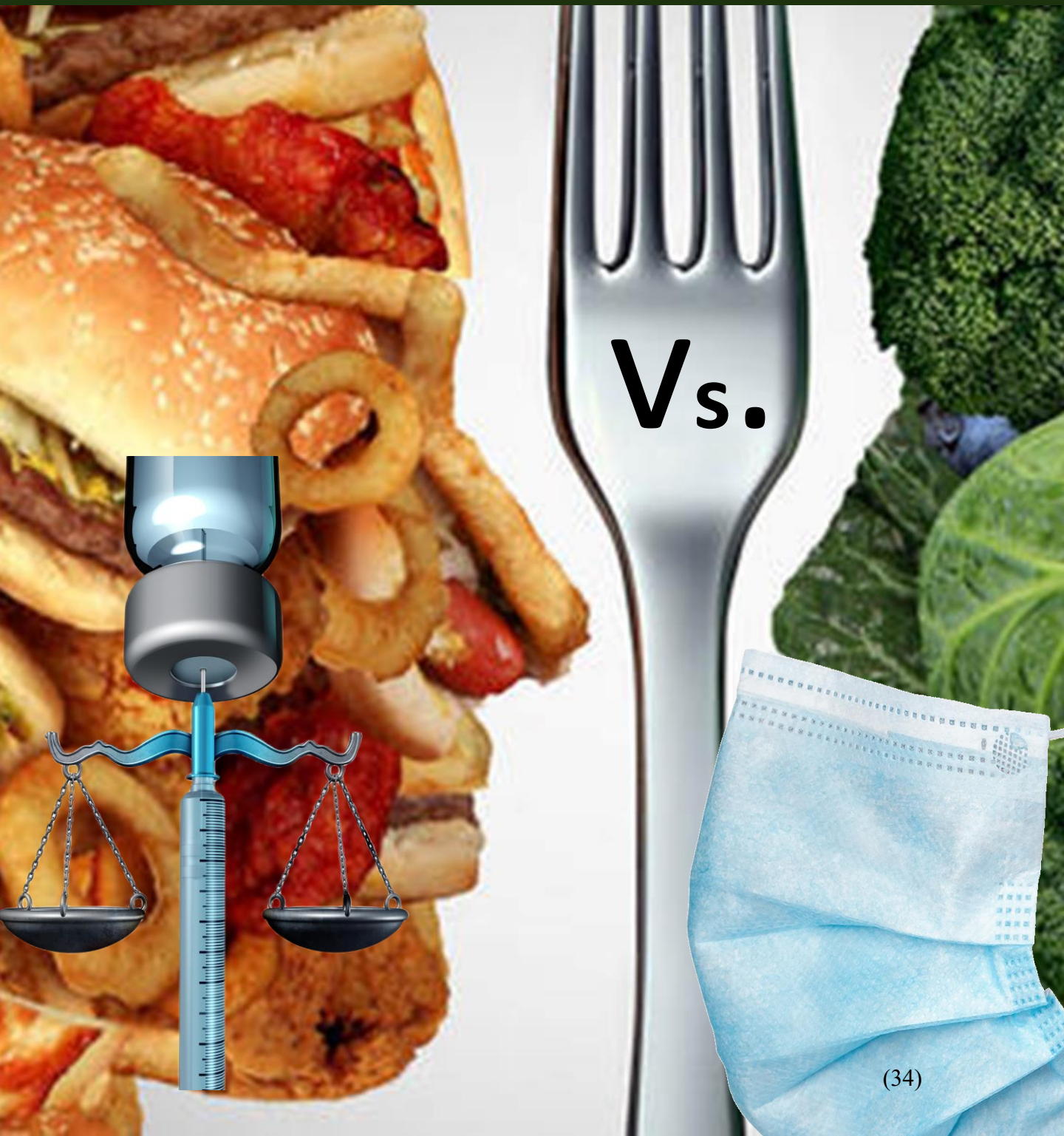
Letters regarding this issue have been submitted to MoCo Inspector General.

I believe that all these facts indicate that the pending bill is unacceptable, and that there will be potential consequences for parties involved, if the bill will be accepted.

Sincerely,

Yelena G. Gakh, Ph.D. /Yelena Gakh/

The Plant-Based Mandate Option - Bill #34-21



**SUPPORT WITH
PROPOSED FRIENDLY AMENDMENTS
PLANT-BASED MANDATE OPTION
Expedited Bill 34-21 COVID-19 Vaccination Required
October 18, 2021**

Council President: Tom Hucker
Council Vice President: Gabe Albornoz
Montgomery County Council
Stella B. Werner Council Office Building
100 Maryland Avenue
Rockville, MD 20850

President, Vice President and entire Montgomery County Council (Council), thank you for the opportunity to share our support of Expedited Bill 34-21 with “friendly amendments” (Amendments) that our medical advisory council are confident will help to achieve the Council’s expressed interest in reducing severe Covid, and even its spread, in employees.

The HBCU College of Plant-Based Lifestyle Medicine (HBCUCPLM) is a new Maryland 501c3 born out of the pandemic in August 2020, whose mission is to educate and train medical professionals of color and HBCU health science students and grads in the practice of prescribing whole plant-based “Food as Medicine” and lifestyle interventions known as THE TEN LAWS of Plant-based Lifestyle Medicine (THE TEN LAWS). THE TEN LAWS is the evidence based therapeutic use of whole food plant-based nutrition and lifestyle interventions for the prevention, treatment, and reversal of chronic degenerative diseases and to reduce the severity of communicable diseases in communities of color. There are over 100 peer reviewed studies on the benefits of a plant-based diet and lifestyle interventions in treating and even reversing chronic diseases and optimizing immunity in persons of all ages, ethnicities and genders.¹

While Bill 34-21 focuses on mandating employee vaccination as the single medical intervention capable of reducing severe Covid and its spread, the mandate fails to address what the Centers for Disease Control (CDC) has determined are key “risk factors” (pre-existing chronic disease), which have been identified as the underlying causes for severe Covid outcomes and death.²

PRO MANDATE ALTERNATIVE – ALL SHOULD BE ACCOUNTABLE FOR REDUCING SEVERE COVID

Consequently, the proposed friendly amendments are aimed at reducing the primary risk factors, particularly for those who choose to remain unvaccinated based on “sincerely held religious beliefs”. At the same time, the Amendments seek to provide an “alternative mandate” that offers a **form of exemption** to religious objectors to the vaccine (which Judge David Hurd of the U.S. District Court for the Northern District of New York citizens have constitutional right to seek³) that also requires the unvaccinated to take personal action for reducing severe Covid and its spread by participating in THE TEN LAWS of Plant-Based Lifestyle Medicine. Several scientific studies have demonstrated that a plant-based diet can reduce severe Covid by 73%, which will be discussed later in the memorandum of support.

¹ See Plant-based Research Database - <https://plantbasedresearch.org/>

² See CDC Report - *Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Providers*, Updated Oct. 14, 2021 - <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html>

³ See Memorandum & Order for Injunction from Judge Hurd in Dr.’s A-Z v. NY Gov. Hochul - <https://eadn-wc01-1479010.nxedge.io/cdn/wp-content/uploads/2021/09/Dr.-A-v.-Hochul-Order-GRANTING-PI-10-12-21.pdf>

RELIGIOUS EXEMPTION NOT NEEDED – ALTERNATIVE MANDATE REDUCES MARGINALIZING SINCERE RELIGIOUS OBJECTORS

While the HBCUCPLM supports everyone’s right to seek religious exemptions, we are concerned that those who obtain religious exemptions who are not already on a plant-based diet will do nothing (in addition to masking or testing) to reduce the risks of severe Covid in the workplace by remaining unvaccinated without addressing their own pre-existing risk factors for contracting severe Covid and dying. On the other hand, we are also concerned that many in the very small religious communities who do practice a plant-based lifestyle, Hindus, Buddhist, Seventh-Day Adventist and some Muslims may get terminated despite the fact that their employment does not pose a safety risk to the County because the scientific evidence establishes that those who practice a plant-based diet have a 73% reduce chance of getting severe covid or even contracting the disease. (The studies will be discussed later in the memorandum.)

Because religious exemptions pursuant to Title VII does allow employers to reject religious exemption and accommodations based on a claim that any accommodation could place a “de minimis amount” of undue burden on the workplace, it is our position that religious exemptions, including medical exemptions can be a breeding ground for workplace discrimination that will not meet the objectives of the Council, which is to reduce severe Covid in the workplace.

To avoid the unnecessary process of the County having to try to evaluate whether an unvaccinated employee should or should not receive a religious exemption or medical exemption, the HBCUCPLM proposes the following amendments as the best solution to meet the Council’s true objectives without the risk of the County treating religious groups or medical conditions differently and harming employees and the County.

PROPOSED FRIENDLY AMENDMENT

The HBCUCPLM proposes the following friendly amendments to Bill 34-21, wherein the vaccine mandate should eliminate the medical exemption and add the mandate that unvaccinated employees who elect not to take the vaccine regardless of the reason – whether religious or medical, are required to complete a plant-based lifestyle medicine training course so that they will change their diet, which is a primary determinate of Covid severity and death. The specific amendment language is as follows: (See Draft Amendment redlines attached as **Exhibit A**):

1. Add to section 33-22(b)(3) the following:
 - a. “Or alternatively complete THE TEN LAWS of Plant-Based Lifestyle Medicine 28-day online training course;
2. Add to Section 33022(c)(1)(A) the following:
 - a. attend the first online THE TEN LAWS of Plant-Based Lifestyle Medicine course and report weekly attendance;
3. Add to Section 33022(c)(1)(b) – B. All employees enrolled in the online THE TEN LAWS of Plant-based Lifestyle Medicine are required to:
 - a. test once a week for Covid-19 utilizing free testing services by the County.
 - b. provide electronic proof of course attendance
 - c. within thirty (30) days from completing the course until the need for the Covid vaccine mandate is declared ended by the County Executive, submit monthly grocery receipts to the Human Resource Department to show compliance with the plant-based dietary plans learned in the course; and
 - d. at the option of the employee, disclose any positive changes in medical condition due to participating in the training by submitting a video, photo or written narrative.
4. Add a new Section that states: The Director of Department of Health and Human Services shall approve all instructors that will provide THE TEN LAWS of Plant-Based Lifestyle Medicine training.

- (C) “All instructors, at minimum, shall have practiced a whole food plant-based lifestyle for at least three (3) years and are either a licensed physician in any state, a PhD in Nutrition, Dietetics, Naturopath, Preventative Health, or Naturopath, a registered nurse or certified plant-based lifestyle medicine coach.”
5. Eliminate the medical exemption. If the Plant-Based Mandate option is added to the bill, there is not need for a medical exemption. Having the medical exemption without a religious exemption leaves the bill subject to constitutional challenge as in the New York case decided last week.

COMPELING INTEREST FOR THE AMENDMENT

According to the CDC, Covid-19 vaccines are effective at helping to protect against severe disease and death caused by the Covid-19 virus and variants. Nowhere on the CDC website regarding the benefits of the vaccine does it say that those who are vaccinated cannot “cause” the spread of the virus that causes Covid-19.⁴ Most important it states plainly on the OSHA website⁵, (which is the organization directed by President Biden to create workplace safety standards for private and public employers), the following:

“However, preliminary evidence suggests that fully vaccinated people who do become infected with the Delta variant can be infectious and can spread the virus to others.”

According to Dr. Christina Parks, PhD, a molecular biology scientist, (experienced in mRNA vaccine research), experts have always been aware that vaccines, in general, do not STOP the spread of viruses. At hearing before the Michigan legislators, Dr. Parks testified on August 19, 2021, stating that neither the Covid vaccines, nor any other vaccine, are designed to “prevent” transmission of a virus. Dr. Parks explained that vaccines are merely created to reduce symptoms.⁶ This testimony is consistent with the statements on the websites for the CDC and OSHA regarding the new Covid vaccine’s ability to reduce severity.

Based on the forgoing evidence, there is technically no difference between vaccinated and unvaccinated employees in the workplace as it relates to stopping the spread of Covid-19, which is why the CDC updated its website to require vaccinated to people to continue to wear masks, particularly indoors.

Moreover, the death of General Colin L. Powell, former U.S. Secretary of State and Chairman of the Joint Chiefs of Staff, also establishes that the Covid vaccines do not stop the spread and possibly may not reduce the severity of Covid. According to the CNN, report, Secretary Power died due to complications from Covid 19,” according to the Powell family post on Facebook, noting he was fully vaccinated.

PLANT-BASED LIFESTYLE MEDICINE MUST BE ADDED TO THE ARSENAL AGAINST COVID

Based on these undisputed facts, the County has a compelling interest in mandating THE TEN LAWS of Plant-Based Lifestyle Medicine as an additional intervention to mitigate against severe Covid and death in the County’s population.

In a very recent review in the British Journal of Nutrition it was reported that people with optimal levels of micronutrients may be more resilient to COVID-19.⁷ Micronutrients are vitamins and minerals that

⁴ See CDC Website – Key Things To Know about the Covid Vaccines - <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/keythingstoknow.html>

⁵ See OSHA website - Protecting Workers: Guidance on Mitigating and Preventing the Spread of COVID-19 in the Workplace <https://www.osha.gov/coronavirus/safework>

⁶ See Testimony of Dr. Christina Parks, PhD – Michigan State Legislature Hearing -Aug. 19, 2021.

⁷ See Nutritional status of micronutrients as a possible and modifiable risk factor for COVID-19: a UK perspective - British Journal of Nutrition (2021), 125, 678–684 - <https://www.cambridge.org/core/services/aop-cambridge-core/content/view/35B4C4BC5B0FBD132370128EC03FE309/S000711452000330Xa.pdf/div-class-title-nutritional-status-of-micronutrients-as-a-possible-and-modifiable-risk-factor-for-covid-19-a-uk-perspective-div.pdf>

people obtain from their diet. Human bodies also produce [vitamin D](#) in response to exposure to sunlight. Plant foods contain many vitamins and minerals essential for a healthy immune system, such as [zinc](#), [selenium](#), and vitamins A, C, and E. Selenium is a trace mineral that benefits immune system health and cognitive function. According to the CDC however,⁸ only one in 10 adults in the United States eat enough fruits or vegetables.

Furthermore, according to a recent study of a few thousand healthcare workers published June 7, 2021, in BMJ Nutrition Prevention & Health,⁹ it was established that those medical workers who ate a 100% plant-based diet had a **73% reduction in Covid severity**. The study also showed that those who eat a “pescatarian diet” which is a predominantly plant-based diet, with some consumption of only fish, has an approximate 51% reduction in Covid-19 severity. That same study also showed that those who were on a predominantly animal flesh diet had an approx. 45% increase in Covid-19 severity.

In a second study performed by Massachusetts General Hospital just published September 8, 2021, it was stated that a healthy plant-based diet was also linked to a lower risk of “getting” Covid-19 and a lower risk of severe symptoms. Lastly, a third study of approximately 600,000 individuals was published in June 24, 2021, also concluded that a plant-based diet was associated with lower risk and severity of Covid-19.¹⁰

While more and more studies are being done and have been done on the macronutrients in plants and their effectiveness in preventing severe Covid, legislators have a compelling interest for insuring these no risk Interventions are implemented in conjunction with the other interventions including masks and testing.

TESTING ALONG WITH ALTERNATIVE PREVENTATIVE STRATEGIES ARE EFFECTIVE AT STOPPING THE SPREAD OF COVID-19 AND REDUCES COVID SEVERITY

While the proposed alternative mandate relieves the unvaccinated from taking the covid vaccine if employees choose the option, the option does not or should not relieve ALL employees from periodic testing and mask wearing. According to the Safer Federal Workforce Task Force report of April 7, 2021, it states that screen testing is useful to detect and stop transmission of Covid, which the report states as follows:

Screening Testing of asymptomatic persons without known or suspected exposure to SARS-CoV-2
Viral testing of asymptomatic workers without known or suspected exposure to SARS-CoV-2 (screening testing) may be useful to detect SARS-CoV-2 early and stop transmission quickly, particularly in areas with community COVID-19 indicators in the moderate to high categorizations (Table 2, Table 3). Persons with asymptomatic or presymptomatic SARS-CoV-2 infection are significant contributors to SARS-CoV-2 transmission. Screening testing should be used as an addition to, not as a replacement for, other prevention strategies.

While the report indicates that the screening should be used as an addition to other prevention strategies, the other preventative strategy is the plant-based mandate option, wherein the goal is to convert the unvaccinated to a 100% whole food plant-based diet to eliminate the risks of Covid.

In summary, weekly testing is an effective method for early detection of Covid that reduces the spread of the virus along with the preventative strategy of a plant-based diet and THE TEN LAWS which the medical evidenced contained in the above medical literature establishes are effective “preventative strategies” that should be added to the bill.

⁸ See CDC - <https://www.cdc.gov/nccdphp/dnpao/division-information/media-tools/adults-fruits-vegetables.html>

⁹ See Plant-based diets, pescatarian diets and COVID-19 severity: a population-based case-control study in six countries – BMJ Journal Jun 2021 - <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8219480/>

¹⁰ See Diet may affect risk and severity of COVID-19 - September 8, 2021, <https://www.sciencedaily.com/releases/2021/09/210908180530.htm>

WHAT ARE THE TENS LAW OF PLANT-BASED LIFESTYLE MEDICINE?

THE TEN LAWS is an acronym our organization has developed to describe the wholistic approach that we follow to promote health by promoting the lifestyle laws of nature, which when followed collectively on a daily basis, the scientific literature reveals are effective at preventing, reducing and reversing common degenerative disease. The law are as follows: T = **law of Trust** in natural laws as revealed either by an intelligent creator or revealed according to one's faith or belief system – daily everyone exercises trusts in something in order to function in this world and that trust or belief impacts health positively – violation of the law of trust results in poor emotional states depression and fear that impact health negatively according to the scientific literature, H = The **law of Hygiene**, which requires each person to wash themselves and keep a clean environment to maintain health – violation of this law result in sickness and disease, E= The **law of Exercise** – which requires all person to engage in daily physical movement to maintain proper blood flow – violation of this law results in obesity and other diseases that result in premature death, T = **law of Temperance**, this natural law informs each person that he or she should refrain from ingesting harmful toxic substances, like smoking, alcohol, illicit drugs other illicit behaviors, which such substances are ingested one natural system is harmed, E = **law of Excellent Air** – no one can live without air, and poor air quality can be harmful to one's health and contribute to sickness and disease, N = **law of natural whole food plant-based food** – no person can go more than 50 days without food and when someone is starving they need food that is nutrient dense to survive and only living plant-based food provide all the micro and macronutrients that body needs, L = **Law of rest**, scientific studies shows that lost rest reduces life expectancy and contributes to mental health problems, A = **law of an attitude of gratitude**, studies have shown that a grateful heart works like a medicine to the mind and contributes to preventing mental health diseases, W= **law of Water** – a person can only go two weeks without water before they die – water is essential to all health, and S = **Law of Sunshine** – nothing can live or survive on the earth without sunshine, including humans – daily we must obtain sunshine to maintain adequate amounts of sunshine for the body to make Vit D an essential vitamin needed for proper respiratory function and more.

The course will provide attendees with live physician discussions regard the scientific research, medical journal articles and clinical studies that support the effectiveness of following THE TEN LAWS along with practical implementation tools, schedules, meal plans and groups discussions about real cases involving success stories.

In addition, attendees are educated about the importance of following each one of the lifestyle laws on a daily basis based on the anatomy and physiology of their body. Attendees do not just focus on “food”, attendees are taught to manage all aspect of wellness from a wholistic approach focusing on mind, body and spirit as they define their spiritual life.

The proposed instructors who will teach this course may call their course by a different name, but the subject matter will be the same. Below are proposed medical professionals that can provide the online course along with links to their websites that provide details regarding how the courses are structured to optimize the learning experience to result in lasting behavior modifications that can reduce severe Covid and other chronic diseases.

CAN THE TEN LAWS OF PLANT-BASED LIFESTYLE MEDICINE AFFECT THE HEALTH STATUS OF THE UNVACCINATED IN THE SHORT-TERM? YES!!!!

While many believe it takes years before bad food can affect your health, compromise your immune system, and result in deadly chronic disease and death. A recent study demonstrated in the block buster documentary “The Game Changers” shows that every meal a person eats has a positive or negative impact on their blood flow and overall health within hours. This evidence further supports the need for the unvaccinated to participate in THE TEN LAWS of plant-based lifestyle medicine to receive immediate benefits from a lifestyle change.

[CLICK HERE TO WATCH THE
3 MIN VIDEO TO SEE THE IMPACT OF A
PLANT-BASED MEAL v. AN ANIMAL BASED MEAL](https://www.hbcuplantbasedlifestyle.com/Evidence%20of%20Impact%20of%20Animal%20Food%20On%20Blood-%20Game%20Changers%20Clip%20-%20BILI%2034-21.mp4)

<https://www.hbcuplantbasedlifestyle.com/Evidence%20of%20Impact%20of%20Animal%20Food%20On%20Blood-%20Game%20Changers%20Clip%20-%20BILI%2034-21.mp4>

14216 DUNWOOD VALLEY DR., BOWIE MD 20721
www.HBCUPlantBasedLifestyle.com - Phone: 602-326-8663

IMPLEMENTATION & COST SAVINGS

The HBCUCPLM is happy to announce that our advisory board members have the tools to provide THE TEN LAWS of plant-based lifestyle medicine ready for the County to implement. Below are two of our advisory board members and their programs which are currently available for the County's employees to commence once the bill is passed with the friendly amendments.

DR. BATER MONTGOMERY

Dr. Baxter Montgomery, one of our HBCUCPLM board members, is a board-certified Cardiologist and Electro physicist and has for over 15 years practiced plant-based lifestyle medicine at the Montgomery Heart & Wellness Clinic where he serves as the Medical Director. Dr. Montgomery particularly serves communities of color and has completed medical research studies published in acclaimed journals on the benefits of a plant-based diet. (See Dr. Montgomery's three (3) clinical studies attached as **Exhibit A** along with his CV and he will be starting another study this November) Dr. Montgomery provides online plant-based lifestyle medicine group trainings, as well as one on one care, that reverse heart disease (still the number # killer over Covid), diabetes, lowers blood pressure and helps patients get off of medications. To learn more about Dr. Montgomery – [click here to watch a quick overview](#) of how Dr. Montgomery has used plant-based interventions on patients in critical care in the ICU.¹¹ Dr. Montgomery offers his 30 day version of THE TEN LAWS online plant-based lifestyle courses offered weekly in the evenings at the total cost of \$599, which includes a year access and support which County employees can enrolled at any time.

Finally, Dr. Montgomery has treated more than several dozen patients who have tested positive for Covid during this past year, and he has not lost one patient to sever Covid or death. In the event any of the unvaccinated employees do test positive for Covid, Dr. Montgomery has a very aggressive protocol that he uses to help patients that test positive. However, by having the County's employees enroll in his online course as soon as possible, they can start the detox to improve their immune system so that they have better protections as they continue to work. [Click here to view](#) the course that best fits the Counties unvaccinated employee needs.¹²

DR. RUBY LATHON

Another HBCUPLM board member that is available to implement the mandate is Ruby Lathon, PhD. She is a board-certified holistic nutritionist with an inspiring powerful story of how she recovered from thyroid cancer through natural treatments focused on a whole food, plant-based diet. Dr. Lathon was featured in the hit documentary, [What the Health](#). Dr. Lathon lives in Montgomery County, has an office in D.C. and the only plant-based African American nutritionist in the entire state that exclusively practice plant-based lifestyle medicine nutrition education. To help individuals with the learning curve of changing to a plant-based diet, Dr. Lathon provides weekly in-person and virtual group cooking classes. However, during the beginning of the Covid pandemic, Dr. Lathon also launched an affordable whole food Plant-Based meal delivery service called [Ruby Reds Vegan](#). See Dr. Lathon's CV attached as Exhibit B.

With these two awesome plant-based lifestyle medicine practitioners ready to work with the County to implement the proposed plant-base mandated option, we hope that the Council will strongly consider all of the upsides of this very friendly amendment.

It is important to note that, there are less than 25 board certified plant-based lifestyle medicine physicians of color in the entire United States out of over 55,000 physicians of color. These two medical professionals represent the very tiny community of practitioners of color that live and practice this form of medicine.

¹¹ See Dr. Baxter Montgomery – The Plant-Based Doctor - <https://www.youtube.com/watch?v=KMidCUcDdJc&t=158s>

¹² See Dr. Montgomery Weekly Plant-Based Food Rx Healthy Lifestyle Series - <https://www.online.montgomeryheart.com/lifestyle>

It is the mission of the HBCCLPLUM to create a pipeline of future plant-based physicians of color in the state of Maryland and particularly in Montgomery County by focusing on training efforts on the states four HBCUs.

Therefore, one of our additional goals is to develop a Center of Plant-Based Lifestyle Medicine and Business Innovation in Montgomery County patterned after the clinical facility operated by Dr. Baxter Montgomery. However, we seek to add with the clinic an incubator/accelerator space for continued research and plant-based business development so that we can create a farm, to medical professional to table supply chain solution that also increases the availability of fresh whole plant-based foods in Maryland's "food deserts".

POTENTIAL IMPLEMENTATION COST TO COUNTY

Please note that if County were to pay for the course for all its unvaccinated employees as an employee benefit, Dr. Montgomery would provide a special rate for the County so that the impact is not drastic unexpected budgetary expense to the County. However, it is our understanding that Montgomery County received Federal Cares/Covid County Relief Funding which allows for expenditures for Covid mitigation education. If those funds are available, the proposed plant-based mandate option would have a ZEOR fiscal impact on the Counties budget.

POTENTIAL COST TO THE EMPLOYEE WITH UPSIDE BENEFITS

Alternatively, if the County is not in the position to fund employee's participation in the program, the County could still mandate the plant-based option and have the unvaccinated employees pay for the course on their own, thereby saving THE County from experiencing an unexpected budget item. This implementation option is most closely akin to what happened in the Supreme Court [Jacobson v. Massachusetts 1905](#) vaccine mandate case. In that case, the Supreme Court upheld a fine levied against Mr. Jacobson failing to get vaccinated under the state's mandatory vaccination program. In this case, however, the cost of the program could be charged to the employee without infringing on any constitutional rights of the employees. Because the plant-based mandate option is truly narrowly tailored to the Government interest of reducing severe Covid based on substantive medical research that shows that such a course is truly beneficial to the reduction of Covid severity, the County should prevail in any court challenge. The course is not a "fine" per se, but rather a "safety" program that benefits the entire health of the employee directly. As mentioned before, it may be a small price that employees will pay rather than have the threat of loosing a job or going against their sincerely held religious beliefs.

LONG TERM COST SAVINGS TO THE COUNTY

Lastly, if the County does decide to pass the plant-based mandate option and pay the cost of the course, the County will realize a huge long term cost savings on the healthcare cost for the unvaccinated. According to the Maryland Diabetes Association, the state of Maryland spends approximately [\\$7 Billion on diabetes](#) care for its residents. If any of the unvaccinated employees required to take the training do suffer from diabetes, the County could save thousands if not millions of dollars if any of unvaccinated employees comply with the program and their diabetes is reversed and they are able to get off of their insulin or whatever medication they may be on. According to the Maryland Diabetes Association, insulin for 1 year for 1 employee is between \$8,000 and \$12,000 per year. If just 45 unvaccinated employees are on insulin are required to take the plant-based lifestyle medicine course and they are able to get off their medication, the cost of the entire online training for all 800 employees would be paid for and year after year the County will save millions.

CONCLUSION

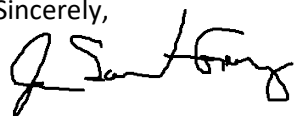
The HBCUCPLM respectfully requests that the Council accept the proposed friendly amendments and pass Bill 34-21 with the Plant-Based Mandate Option. This proposal is a WIN/WIN for the County on multiple levels and for the unvaccinated employees who want to keep their jobs and would value the opportunity to take such a valuable course, this bill amendment could save their lives and improve their overall health.

To pass the bill without a religious exemption and only with a medical exemption which does nothing to address the underlying causes of severe Covid and Covid related deaths, will only open the door for litigation and tons of money spent on lawyers rather than on employees that deserve the opportunity to “choose” an option that can truly have a positive impact on the reduction of severe Covid in their lives.

If the Council would like to receive more information about the programs, please contact Jo Saint-George, Chair of the HBCUCPLM at cell #602-326-8663 or by email at exec@HBCUPlantbasedlifestyle.com

Thank you for your attention to this proposal and your vote.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jo Saint-George', written in a cursive style.

Jo Saint-George (I am a resident of Gaithersburg, Maryland)
Chair

w/Attachments

Supported by:

Dr. Baxter Montgomery

Dr. Ruby Lathon

Dr. Theodor Watkins

Dr. John St. Rose

FRIENDLY AMENDMENT

Proposed by the HBCU College of

Plant-Based Lifestyle Medicine

Expedited Bill No. 34-21
Concerning: Personnel and Human
Resources - COVID-19 Vaccination
Required
Revised: 09/24/2021 Draft No. 3
Introduced: _____
Expires: _____
Enacted: _____
Executive: _____
Effective: _____
Sunset Date: _____
Ch. _____, Laws of Mont. Co. _____

COUNTY COUNCIL FOR MONTGOMERY COUNTY,

Lead Sponsors: Councilmembers Riemer and

AN EXPEDITED ACT to:

- (1) require the vaccination of County employees against COVID-19; or alternatively
(2) require THE TEN LAWS of Plant-Based Lifestyle Medicine 28-day mandatory online
training option
(3) permit medical accommodations to the COVID-19 vaccination requirements;
(4) exempt the COVID-19 vaccination requirements from collective bargaining; and

By amending

Montgomery County Code
Chapter 33, Personnel and Human
Resources

Boldface	<i>Heading or defined term.</i>
<u>Underlining</u>	<i>Added to existing law by original bill.</i>
[Single boldface brackets]	<i>Deleted from existing law by original</i>
bill. <u>Double underlining</u>	<i>Added by amendment.</i>
[[Double boldface brackets]]	<i>Deleted from existing law or the bill by amendment.</i>
* * *	<i>Existing law unaffected by bill.</i>

The County Council for Montgomery County, Maryland approves the following

1 **Sec 1. Section 33-22 is amended as follows:**

2 **33-22. [Reserved.] COVID-19 Vaccination**

3 (a) Definitions. For purposes of this section, the following words have the

4 meanings indicated.

5 COVID-19 Vaccine means a vaccine authorized or approved by

6 the federal Food and Drug Administration to prevent or reduce

7 the transmission of SARS-CoV-2.

8 Employee means an individual employed by the County, regardless of

9 the individual's merit system status or representation by an

10 employee organization.

11 Fully vaccinated means having received all doses of a COVID-19

12 vaccine.

13 (b) Vaccination Required. As a condition of employment by the County,

14 an

15 (1) be fully vaccinated and provide to the County proof of

16 vaccination

17 (2) under subsection (c); or complete the 28-day THE TEN LAWS

18 of Plant-based Lifestyle Medicine online course

18 (c) Procedures; remedies for

19 (1) Within 7 days after notification by the County to an employee of

20 the requirements of this section, the employee must:

21 (A) provide to the County proof that the employee is fully

22 vaccinated; or attend the first online THE TEN LAWS of

23 Plant-based Lifestyle Medicine Course and complete the course

24 (B) apply for an accommodation under subsection (d)

25 (2) An employee who fails to comply with paragraph (1) must

be

22 See rest of
23 additional
24 language
 on last page.

(3) Within 7 days after being placed on unpaid leave under paragraph

(A) provide to the County proof that the employee has received

(B) at least one dose of a COVID-19 vaccine; or

(4) An employee under subparagraph (3)(A) must provide to the

County, within 40 days of being placed on unpaid leave, proof that the employee is fully vaccinated.

(5) An employee who fails to comply with paragraphs (3) or (4) of this subsection, or with paragraph (3) of subsection (d),

(d) Health-based

(1) An employee may apply for an accommodation to the requirements of this section based on the health of the

(2) employee. The Director of Human Resources, or the Director's designee, must approve an application for an accommodation if the accommodation is required for the health of the employee, as documented by a licensed

(3) physician.

Within 7 days after the denial of an application for an accommodation under paragraph (1), the employee must provide to the County proof that the employee has received at least one dose of a COVID-19 vaccine. Within 40 days after the denial of the application, the employee must provide to the County proof

(e) Exemption from Collective Bargaining. The requirements and implementation of this section:

Formatted: Indent: Left: 0"

(c)(1)(B) [Continued]

B. All employees enrolled in the online THE TEN LAWS of Plant-based Lifestyle Medicine are required to:

- i) test once a week for Covid-19 using free services provided by the County;
- ii) provide electronic proof of course attendance
- iii) within thirty (30) from completing the course, submit monthly grocery receipts to the Human Resources Department to show compliance with the plant-based dietary plans learned in the course; and
- iii) at the option of the employee, disclose any positive medical condition changes as a result of participating in the training by submitting a video, photos or written narrative.

C. The Director of Department of Health and Human Services shall approve all instructors that will provide THE TEN LAWS of Plant-Based Lifestyle Medicine training, which minimum requirements shall be that the instructor lives the whole food plant-based lifestyle and is either a licensed physician in any state, a PhD in Nutrition, Dietetics, Naturopath, Preventative health, or Naturopath MD, a registered nurse or certified plant-based lifestyle medicine coach.

Formatted: Indent: Left: 1", First line: 0.5"

BAXTER DELWORTH MONTGOMERY, MD

The Plant-Based Physician
[Montgomery Heart & Wellness](#)
[Video Bio](#)

EXPERIENCE:

Clinical Assistant Professor
The University of Texas Health Science Center
Department of Medicine
Division of Cardiology/Clinical Cardiac Electrophysiology

President and CEO
Houston Associates of Cardiovascular Medicine, PA.
(1997-Present)

Executive Director
The Johnsie and Aubary Montgomery Institute of Medical Education and
Research (a 501(c) 3 nonprofit organization)

BIRTHPLACE:

Houston, Texas
United States of America

OFFICE ADDRESS:

10480 South Main Street
Houston, Texas 77025
(713) 599-1144 phone
(713) 599-1199 fax
bmontgomery@drbaxtermontgomery.com

UNDERGRADUATE EDUCATION:

William Marsh Rice University
Houston, Texas
Bachelor's Degree in Biochemistry (1986)

GRADUATE EDUCATION:

The University of Texas Medical Branch at Galveston
Galveston, Texas
Doctor of Medicine

RESIDENCY:

Baylor College of Medicine
Houston, Texas
Internal Medicine

FELLOWSHIP:

The University of Texas Health Science Center at Houston
Houston, Texas
Cardiovascular Diseases
Clinical Cardiac Electrophysiology

CERTIFICATION: Diplomate of the American Board of Internal Medicine, Cardiovascular Diseases

 Diplomate of the American Board of Internal Medicine, Clinical Cardiac Electrophysiology

LICENSURE: Texas State Board of Medical Examiners (Since 1999)
 Permit Number H9549

HOSPITAL APPOINTMENTS:

 Attending Physician
 Memorial Hermann Hospital - The Texas Medical Center
 Houston, Texas

 Attending Physician
 The Heart and vascular Institute
 Memorial Hermann Hospital - The Texas Medical Center
 Houston, Texas

 Consulting Physician
 Select Specialty Hospital - Heights
 Houston, Texas

TEACHING RESPONSIBILITIES:

 Teaching Faculty for Cardiology Fellows and Clinical Advanced Nurse Practitioners
 The Heart and Vascular Institute
 Memorial Hermann Hospital - The Texas Medical Center
 1997 - Present

 Cardiovascular Disease Lecturer
 GlaxoSmithKline, Inc.
 2000 - Present

 Cardiovascular Disease Lecturer
 Novartis, Inc.
 2006 - Present

 Cardiovascular Disease Lecturer
 Boston Scientific, Inc.
 2006 - Present

 Co-Director and Lecturing Faculty
 Cardiology Concepts for Non-Cardiologists
 (An Annual Houston Area Educational Symposium)

JAM Institute, Inc.

2006 - 2008

Steering Committee Member and Lecturing Faculty

Close the Gap

Boston Scientific, Inc.

2006 - Present

RESEARCH:

CLINICAL STUDIES:

ALLHAT: Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial. ALLHAT was a blinded, randomized trial that investigated the relative efficacy of different classes of antihypertensive agents in reducing stroke, illness and death from cardiovascular diseases. A subgroup of patients with hyperlipidemia was randomized comparing Pravastatin compared to usual care.

A Houston Site - Principal Investigator (1998)

INVEST: The International Verapamil SR/Trandolapril Study.

INVEST was a randomized controlled clinical trial comparing a calcium antagonist treatment strategy (Isoptin® SR) with a non calcium antagonist treatment strategy for the control of hypertension in a primary care coronary artery disease patient population.

A Houston Site - Principal Investigator (2000)

INVEST SUB-STUDY: This study was a sub-study of the INVEST patient population designed to evaluate the impact of genetic differences on pharmacokinetics.

A Houston Site - Principal Investigator (2000)

The Safety and Efficacy of PNU-182716 Versus Rosiglitazone: This was a one-year, randomized, double blind, parallel group, and active comparator study.

A Houston Site - Principal Investigator (2000)

FACTOR: Fenofibrate and Cerivastatin Trial Optimizing Response.

FACTOR was a multicenter, randomized, double blind, placebo controlled, parallel group, study of the safety and efficacy of Cerivastatin in combination with Fenofibrate compared to Cerivastatin alone, Fenofibrate alone and placebo in a population of Type 2 Diabetic Men and Women.

Grant Sponsor - Bayer 2001

A Houston Site - Principal Investigator

ADHERE: ADHERE was a national registry of patients admitted to hospitals with acute decompensated congestive heart failure.

A Houston Site - Principal Investigator (2001)

STELID TM AND STELIX TM LEADS STUDY: This study was a

safety and efficacy study of steroid-eluting cardiac pacing leads.

Grant Sponsor - Ella Medical 2002

ARRHYTHMIA PATHWAY STUDY: This was a patient registry study designed to assess the efficacy of a clinical algorithm for identifying and assessing patients at risk of sudden cardiac arrest.

Grant Sponsor - Medtronic, Inc. 2002

A Houston Site - Principal Investigator

RAPIDO CATHETER STUDY: This study was to evaluate the efficacy of a left ventricular defibrillator-pacemaker lead delivery system.

Grant Sponsor - Guidant, Inc. 2003

A Houston Site - Principal Investigator

PROTOS HEART RATE DISTRIBUTION STUDY: This was a clinical study designed to compare the heart rate distribution in patients undergoing pacemaker implants requiring heart rate response therapy. This study compared the heart rate distribution of accelerometer rate response therapy to the BIOTRONIK Closed Loop System therapy.

Grant Sponsor - Biotronik, Inc. 2003

A Houston Site - Principal Investigator

CSPP100A2404 - A 54 week, randomized, double-blind, parallel-group, multicenter study evaluating the long-term gastrointestinal (GI) safety and tolerability of Aliskiren (300 mg) compared to Ramipril (10 mg) in patients with essential hypertension.

Sponsored by Novartis, since April 4, 2008.

A Houston Site - Principal Investigator

CSPP100AUS03 - An 8 week Prospective, Multicenter, Randomized, Double-Blind, Active Control, Parallel Group Study to Evaluate the Efficacy and Safety of Aliskiren HCTZ versus Amlodipine in African American Patients with Stage 2 Hypertension.

Sponsored by Novartis, since August 2008.

A Houston Site - Principal Investigator

CSPP100A2409- An 8 week randomized, double-blind, parallel-group, multicenter, active-controlled dose escalation study to evaluate the

efficacy and safety of Aliskiren HCTZ (300/25 MG) compared to Amlodipine (10 mg) in patients with stage 2 systolic hypertension and diabetes mellitus.

Sponsored by Novartis, since December 2008.

A Houston Site - Principal Investigator

SPAIOOAUSOI - An 8 week randomized, double-blinded, parallel-group, multicenter, active-controlled dose escalation study to evaluate the efficacy and safety of Aliskiren Administered in Combination with Amlodipine (150/5 mg, 300/10 mg) versus Amlodipine alone (5 mg, 10 mg) in African American patient with Stage 2 Hypertension.

Sponsored by Novartis, since February 2009.

CLAF237B22OI- A multicenter, randomized, double-blind study to evaluate the efficacy and long-term safety of vildagliptin modified release (MR) as monotherapy in patients with type 2 diabetes.

Sponsored by Novartis, since February 2009.

A Houston Site - Principal Investigator

CLAF237B2224 - A multi-center, randomized, double-blind study to evaluate the efficacy and long-term safety of vildagliptin modified release (MR) as add-on therapy to metformin in patients with type 2 diabetes.

Sponsored by Novartis, since February 2009.

A Houston Site - Principal Investigator

Galaxy study: An aftermarket registry of one of the Biotronik implantable cardioverter defibrillators ICD leads (2009 to present)

A Houston Site - Principal Investigator

Paradigm study: A multicenter, randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of LCZ696 compared to enalapril on morbidity and mortality in patients with chronic heart failure and reduced ejection fraction. 2009 -2014

A Houston Site - Principal Investigator

BASIC RESEARCH:

In Rapid Separation of Mitochondria from Extra- mitochondrial Space Applied to Rat Heart Mitochondria. An abstract presented at an NIH sponsored student research poster session, Univ. of Texas Medical Branch, Galveston, TX, June 17, 1987.

Regulation of the Adenine Nucleotide Pool-Size of Heart Mitochondria by the ADP/ATP Translocase. Abstract and poster presented at the Galveston-Houston Conference for Cardiovascular

Research, Univ. of Texas, Medical Branch, Galveston, TX, February 26, 1988.

The Adenine Nucleotide Pool-Size of Heart Mitochondria is Regulated by the ADP/ATP Translocase. Abstract presented at the 29th Annual National Student Research Forum, University of Texas Medical Branch, Galveston Texas, April 6-8, 1988.

Increased Frequency of the Deletion Allele of the ACE Gene in African-Americans Compared to Caucasians. This study evaluated the prevalence of the deletion allele of the ACE gene in a population of African Americans compared to Caucasians. The findings were presented at the annual meeting of the American College of Cardiology in March of 1996.

Determination of the effect of Calcium infusion on CGRP mRNA Production. A pilot study investigating a possible mechanism by which calcium supplementation may increase CGRP (Calcitonin gene-related peptide, a potent peripheral vasodilator) content in afferent neurons of Sprague Dawley rats, 1990.

PUBLICATIONS:

Montgomery, B, D, MD. A Review of Microanatomy for Medical Students, 1987, chapter 1-8.

Baxter D. Montgomery, MD, Elizabeth A. Putnam, Ph.D., John Reveille, MD, Dianna M. Milewicz. MD, Ph.D.: Increased Frequency of the Deletion Allele of the ACE Gene in African-Americans Compared to Caucasians. (Abstract) J. American College of Cardiology March, 1996

Doyle, N.M., Monga, M., **Montgomery, B.**, Dougherty, A.H.: Arrhythmogenic right ventricular cardiomyopathy with implantable cardioverter defibrillator placement in pregnancy. J Mat Fetal Neo Med 18:141-4, 2005

Baxter D. Montgomery, MD Co-Author of Dreams of the nation Book: "Improving Health" with focus on strengthening the food and health connection and replacing unnatural foods from our diet and replacing them with natural foods as a way of reversing illness. 2009

Montgomery, Baxter D: The Food Prescription for Better Health, Houston: Delworth Publishing, 2011

Montgomery,B.D, MD, Effects of the Montgomery Food Prescription on Clinical Biomarkers of Cardiovascular Disease. Plant-based diet can improve clinical biomarkers associated with cardiovascular disease. This study was submitted to the 10th annual Texas A&M University System Pathways Student Research Symposium 2012.

Baxter D. Montgomery, MD Co-Author of the book Rethink Food: About the need for revolutionary change in how to address chronic illness with optimal nutrition.2014

CLINICAL PRESENTATIONS:

Clinical Concepts for Non Cardiologist, Director and Faculty. An educational symposium held for primary care and other non-cardiology specialists in the Houston area. October 2006

Patients at Risk for Sudden Cardiac Arrest Dinner Symposium at the Houston Forum June, 2007

Clinical Concepts for Non Cardiologist, Director and Faculty. An educational symposium held for primary care and other non-cardiology specialists in the Houston area. October 2007

Clinical Concepts for Non Cardiologist, Director and Faculty. An educational symposium held for primary care and other non-cardiology specialists in the Houston area. October 2008

Houston Town Hall Meeting, Director and Faculty. Health summit on the benefits of a healthy nutritional lifestyle for the management of chronic illnesses held for both health care professional and the general public in the Houston area. 2009

Houston Town Hall Meeting, Director and Faculty. Health summit on the benefits of a healthy nutritional lifestyle for the management of chronic illnesses held for both health care professional and the general public in the Houston area. 2010

Houston Health Summit (Town Hall Meeting), Director and Faculty. Health summit on the benefits of a healthy nutritional lifestyle for the management of chronic illnesses held for both health care professional and the general public in the Houston area. 2011

Houston Health Summit (Town Hall Meeting), Director and Faculty.
Health summit on the benefits of a healthy nutritional lifestyle for the management of chronic illnesses held for both health care professional and the general public in the Houston area. 2012

Houston Health Summit (Town Hall Meeting), Director and Faculty.
Health summit on the benefits of a healthy nutritional lifestyle for the management of chronic illnesses held for both health care professional and the general public in the Houston area. 2013

PROFESSIONAL APPOINTMENTS:

Clinical Assistant Professor of Medicine, University of Texas Health Science Center - Houston 1996 - Present

Steering Committee Member, Boston Scientific Close the Gap Initiative
2005 - Present

Scientific/Medical Board of Advisors, Nutritional Excellence, Inc. 2007 - Present

Medical Board of Directors, Twelve Oaks Medical Center Independent Physician's Association 2005 - Present

Medical Executive Committee (Twelve Oaks Hospital), Member at Large
2002 - 2006

Patient Safety Committee (Twelve Oaks Hospital), Chairman 2002 - 2004

Physician Peer Review Committee (Twelve Oaks Hospital) 2002 - 2005

Medical Director, SCCI (Specialized Complex Care) Hospital, 2003 - 2005

Physician Relation Council Advisory Board, Unicare, 2002 - 2004

Aldine Education Foundation: The mission of the Aldine Education Foundation is to provide community-based support to the Aldine Independent School District in pursuit of excellence in teaching, innovation in the classroom and superior learning opportunities for all students.

CLINICAL INTERESTS:

Nutritional Lifestyle Interventions for the Management of Chronic Illnesses
Cardiac Pacing and Electrophysiology

Diastolic and Systolic Heart Failure
Hypertensive Heart Disease
Cardiovascular Exercise Physiology
Basic Echocardiography
Nuclear Cardiology
Diagnostic Cardiac Catheterization
Cardiovascular Wellness and Nutrition

PROFESSIONAL ASSOCIATIONS:

American College of Cardiology (Elected as Fellow of the College in January, 1999)
American Heart Association
Heart Rhythm Society (North American Society of Pacing and Electrophysiology, NASPE)
American College of Physicians
Harris County Medical Society
Houston Medical Forum

HONORS AND AWARDS:

Benjamin Spock Award for Compassion in
Medicine - 2010

America's Top Physicians - 2007

Cumulative evaluation of "Superior" performance by senior house staff and faculty during first year of residency (Baylor College of Medicine), 1990

Outstanding Young Men of America, 1988

Kempner Award (University of TX Medical Branch) 1986-87 and 1987-88

Academic Scholarship (University of TX Medical Branch) 1986-87

Who's Who Among American Colleges and Universities (Rice University) 1986

Franz Brotzen Outstanding Senior Award (Rice University) 1986

Jones College Service Award (Rice University) 1986 and 1985

100 Black Men of Metropolitan Houston (Awarded in 2012) for the dedication to the improvement of the community.

Physicians Committee for Responsible Medicine- Member of Advisory Board- Current.

ACTIVITIES:

Gardening
Scouting
Physical Conditioning

DR. RUBY D. LATHON

Email: Ruby@RubyLathon.com

99 Blair Alley SW Suite W962; Washington, DC 20024

Mobile (202) 709-7829

SUMMARY: Dr. Ruby Lathon is a certified holistic nutritionist and inspires with a powerful story of recovering from thyroid cancer through alternative treatment focused on a whole food, plant-based diet. Dr. Lathon worked as a researcher and an award-winning engineer, and now teaches others how to re-engineer their health and live disease free. In the technical arena Dr. Lathon is a highly skilled professional with a wide range of experience in strategic planning and management for resolving long-standing problems and creating solutions that improve operational efficiency. Dr. Lathon has a rich mix of technical analysis, program management, business development, and business management.

EDUCATION

Holistic Nutrition Certification, 8/2013
Washington Institute of Natural Medicine, Wash DC

Holistic Nutritionist, Holistic Nutrition Practitioner
American Naturopathic & Holistic Association

Ph.D., Industrial & Systems Engineering, 8/2000
University of Alabama in Huntsville
Dissertation: *The Use of Clustering Analysis & Feature Extraction for the Reduction of Very Large Data Sets*

Major: Operations Research
Minor: Engineering Management, Statistics

M.S., Industrial & Systems Engineering, 5/95
University of Alabama in Huntsville
Thesis: *An Intelligent Strategy Discriminator for an Automated Guided Vehicle System*

Major: Operations Research
Minor: Artificial Intelligence, Statistics

B.S., Computer Science, Cum Laude, 5/92
Oakwood University, Huntsville, AL

EXPERIENCE

5/2010 - Present

DIRECTOR/HOLISTIC NUTRITIONIST, Roadmap to Holistic Health, LLC, Washington DC

Roadmap to Holistic Health, LLC was founded in 2010, and is headquartered in Washington, D.C. Through the leadership of Dr. Ruby Lathon, Ph.D., Roadmap to Holistic Health specializes in health and wellness consultations, whole foods nutrition education, cooking instruction, seminars, and workshops. It works with individuals and groups to deliver scalable and customized nutrition programs. Dr. Lathon is a sought-after speaker in the health and wellness industry. Dr. Lathon's personal experiences uniquely qualify Roadmap to Holistic Health as an expert in a lifestyle-centered, holistic approach to overall health and wellness. www.RubyLathon.com

10/10 – 6/2016

STRATEGIC PLANNING OFFICER, Government of the District of Columbia, Department of Human Services, Washington, DC.

Implement strategies to redesign the DC public assistance program, including the development of community, and inter and intra-agency relationships. Oversee, plan, and coordinate various aspects of research, design, and program implementation. Provide strategic analysis including analyzing and evaluating the public assistance employment program. Survey and analyze program performance, such as organizational structures; process flow and work systems. Perform independent research and analysis of other state and local public benefits assistance programs to ensure use of best practice standards and innovations in the agency's public assistance program. Collaborate with local and national officials to develop strategies to improve the quality and effectiveness of services. Review and assist in the preparation of legislation that affects agency programs.

- 12/08 – 10/10 **NUTRITION POLICY MANAGER, Physicians Committee for Responsible Medicine, Wash, DC.**
Developed and managed child nutrition public policy initiatives with a focus on implementing campaigns to promote healthful diets and effect change at state and federal levels. Designed and implemented campaigns to advocate healthful diets to the federal government, non-government organizations, nonprofit health organizations, educational institutions, and the general public through writing, speaking, advertising campaigns, and media outreach. Analyzed legislation and regulations and developed strategic partnerships to further organizational goals. Developed a successful national grassroots campaign. Prepared public education materials and lobbied Members of Congress and state legislators to formulate legislation on critical child nutrition issues. Promoted organization and its mission in professional settings.
- 5/03 – 12/09 **VICE PRESIDENT, EMT Inc. (Engineering, Management & Technology), Albuquerque, NM.**
Lead efforts in business and technology development and established and operated division offices in Albuquerque, NM. Assisted in development of policies, procedures, and standards and in the development of the long and short-term organizational goals and strategic plans. Responsible for marketing, planning, and management of technical research initiatives. Lead successful development of flagship logistics support software product, OptSim®, including conceptual design, development, testing and marketing. **Major Achievements:** Highly instrumental in significantly increasing company revenue (>30%) through the cultivation of strategic partnerships, developed all marketing/sales materials, provided increased organizational structure, built and managed the Systems Engineering Division from the ground up.
- 11/98 – 5/03 **SENIOR MEMBER TECHNICAL STAFF, Sandia National Laboratories, Albuquerque NM.**
Emerging Threats Division, Systems Reliability Department. Project Manager for the Support Enterprise Model Program, a program designed to facilitate instantaneous “situation awareness” of the entire operating, support, and logistics environment for the Joint Strike Fighter and other large, complex systems. Served as Laboratory Project Manager of the Demand Activated Manufacturing Architecture Project that was part of the American Textile Partnership (AMTEX). This project represented a nationwide effort focused on increasing the competitiveness of the fiber, textile, apparel and retail industries. Responsibilities included project management and planning, development of collaboration guidelines, coordinating tasks among four national labs, two commercial software vendors, and four major textile sectors, from the project planning phase through pilot implementation. Other responsibilities include overseeing the development and implementation of a large-scale textile supply chain simulation tool. **Other Projects:** Project/Technical Lead for the Lockheed Martin P-3C Orion Performance Based Logistics Program; Task Lead for research/development of Information Assurance Toolkit for the DARPA Information Assurance Science & Engineering Tools Program; Spare parts optimization, modeling and simulation, and algorithm development for multi-echelon supply and support systems.
- 8/94 – 10/98 **RESEARCH FELLOW, NASA Marshall Space Flight Center, Huntsville AL.**
Astrionics Laboratory, Software Simulation Division. Major Project: Worked in cooperation with Lockheed Martin to develop a prototype Automated Diagnostic System for the main propulsion system of the Reusable Launch Vehicle modeled in Gensym’s G2 development system. Responsible for development and implementation of the neural network model for the solenoid valve signature traces as well as development of the test conductor control modules for automated test and checkout.
- 8/92-8/94 **GRADUATE RESEARCH FELLOW, Intelligent Systems Laboratory, Univ. of AL, Huntsville.**
Assisted in various research projects in the areas of simulation modeling and expert system design and development. Modeling platforms included AutoMod by AutoSimulations, LISPS and CLIPS. Responsibilities included knowledge acquisition, literary research, and software development. Major Project: Chrysler Huntsville Electronics Division, Automated Guided Vehicle simulation development and analysis.
- TEACHING EXPERIENCE**
- 5/2006 **SEMINAR INSTRUCTOR, Huntsville AL Elementary School Leadership Teams, “Developing Culture Through Vision, Mission & Values”, May 2006.**
- 5/98- 7/98 **INSTRUCTOR, Oakwood University, Huntsville, AL; LEAP Adult Degree Continuing Education Program. Course: Statistics & Business Research Methods.**
- 8/94-8/96 **SUBSTITUTE TEACHER, Huntsville City Schools, Huntsville AL. Took on responsibilities of absent teachers ranging from kindergarten through 10th grade, throughout the Huntsville City School System.**
- 3/91-5/92

1/91-3/91	<p>COMPUTER LAB ASSISTANT, Business & Information Systems, Oakwood University, Huntsville AL. Tutored and assisted students with computer programs, monitored students in progress, responsible for daily lab operations. Utilized knowledge of programming languages and analytical and problem solving skills.</p> <p>TEACHING ASSISTANT, Business & Information Systems, Oakwood University, Huntsville AL. Numerous responsibilities including grading test papers and class work, electronically documenting grades and general clerical duties. Utilized knowledge of programming languages and general computer skills.</p>
HONORS & AWARDS	<ul style="list-style-type: none"> • 2007 Girl Scouts of Chaparral Council, Inc. Hall of Fame: Women in Science, Technology, & Engineering • Technologist of the Year Award, National Society of Engineers, March 2002 • Technology All-Star in Government and Defense Award, Career Communications Group (CCG), July 2001 • NASA Graduate Student Researchers Fellowship, 1994-1998; National Science Foundation Assistantship, 1992-1994; Who's Who Among American Colleges & Universities, 1997; General Conference of SDA Regional Scholarship, 1996,1997; ASRS/AGVS User's Association Student Scholarship, 1995,1996; Scholastic Achievement Award (UAH), 1995; ITT Hartford Insurance Student Scholarship, 1991; Scholastic Achievement Scholarship Oakwood University, 1988-1990; National Deans List & Honor Roll.
ASSOCIATIONS & COMMUNITY INVOLVEMENT	<ul style="list-style-type: none"> • Board Chair, Vice President - Endorphin Power Company (Substance Abuse Recovery Center) (2005-2007) • Del Norte Rotary Club, Paul Harris Fellow, International Committee Matching Grants Chair (2005 – 2009) • President, Strategic Action Forum, Albuquerque Think Tank on Public Policy (2006 – 2009) • Vice President, National Society of Engineers Alumni Extension-ABQ (99-2001); Coordinated quarterly Professional Development Workshops, tutored students for regional/national competitions and SAT/ACT exams, coordinated a variety of community outreach programs and fundraising events. • Graduate Studies Representative - University Judicial Board, University of Alabama, Huntsville • Youth Motivation Task Force Consultant, Oakwood University • Licensed Foster Parent (2000) • Vice President, UAH Graduate Student Association, 96-98 • Youth Mentor, CO-ARMM (Coalition for At-Risk Males) Youth Mentor Program, 91 – 97
PROFESSIONAL DEVELOPMENT	<ul style="list-style-type: none"> • Selected for participation in the 2007 Leadership Albuquerque Class. Leadership Albuquerque is the Greater Albuquerque Chamber of Commerce Leadership program developed to enhance the skills of veteran leaders and prepare aspiring leaders to “make a difference” in the economic health and quality of life of the community by teaching how they can take a leadership role in the voluntary (nonprofit) and public (government) sectors. • Selected by Sandia National Lab's (SNL) Vice President for the Employee Development, Growth, & Education (<i>EDGE</i>) Program, October 2000. Program's goal is to create next generation leaders by targeting and focusing attention on high-performing managers and staff. • Selected for SNL's first Business Development Scholarship Program, February 2001. • On-going Training: <i>Social Styles Training Course</i>: Developing communication skills, managing diversity, developing and motivating others, May 2001. • Developed, coordinated, and obtained funding for the First Annual Spring Symposium focusing on academic excellence and advancement at the University of Alabama in Huntsville, April 1998. Presented workshop on “Making Professional & Dynamic Presentations”.
SELECTED CONFERENCE PAPERS	<p>“Optimization Strategies for Complex Supply Chains”, R. Lathon, Proceedings of the IIE Annual Conference, Orlando FL, May 2006; Proceedings of Simulation Solutions Annual Conference, Atlanta, GA, March 2005 – Invited (Committee Chair).</p> <p>”Achieving the Objectives of Performance Based Logistics Modeling”, R. Lathon, Proceedings of the 2004 Simulation Solutions Annual Conference, Orlando FL, March 2004 (Committee Chair).</p> <p>“Supply Chain Optimization via Modeling and Simulation”, R. Lathon, Proceedings of the 2002 Defense Manufacturing Conference, Dallas, TX, December 2002.</p> <p>“The Use of Clustering Analysis and Feature Extraction for the Reduction of Very Large Data Sets, Analyzed Via a RBF Neural Network”, R. Lathon, American Institute of Aeronautics and Astronautics (AIAA) Journal, (98-5182), November 1998.</p>

“An Application of G2 & Neuron-Line to An Automated Propulsion Diagnostic System”, R. Lathon, J. Patterson, Proceedings of the Gensym Users Society Worldwide Conference, Paris, France, April 1997. Also in the Proceedings of the NASA University Research Center Technical Conference, Huntsville, AL, Feb 1998.

“Theories-in-use Versus Espoused Theories”, C. Bell-Roundtree, R. Lathon, J. Westbrook, D. Utley, Proceedings of the 17th Annual American Society of Engineering Management (ASEM) Conference, University of Texas at Dallas, October 1996.

“Negotiation Among Scheduling Agents to Achieve Global Productions Goals”, R. Lathon, A. Claassen, D. Rochowiak, L. Interrante, in Proceedings of the 1994 IEEE International Conference on Systems, Man and Cybernetics, San Antonio, TX, October 1994.

“Intelligent, Dynamic Scheduling of AGV’s: Simulation, OR, and AI,” L. Interrante, L. Shields, R. Lathon, N. Romero, Proceedings of the CICHME Colloquium, April 1994.

“Design of an Intelligent Manufacturing Scheduling System”, L. Interrante, A. Claassen, R. Lathon, Proceedings of the 3rd IERC, January 1994.

SECURITY CLEARANCE: Held DOE Top Secret Clearance (Q) – 2/1999 through 9/2007; Reinvestigation -2005.



A defined, plant-based diet as a potential therapeutic approach in the treatment of heart failure: A clinical case series

Rami S. Najjar^a, Baxter D. Montgomery^{b,c,*}

^a Department of Nutrition, Georgia State University, Atlanta, Georgia

^b Houston Cardiac Association, Houston, Texas, United States

^c University of Texas Health Science Center, Houston, Texas, United States

ARTICLE INFO

Keywords:

Diet
Vegan
Cardiovascular diseases
Nutrition therapy
Complementary therapies

ABSTRACT

Background: Individuals diagnosed with congestive heart failure (CHF) have a 50% five-year mortality rate and approximately 650,000 new cases of CHF are diagnosed annually. Plant-based diets are known to improve plasma lipid concentrations, reduce blood pressure, and as part of a lifestyle intervention, lead to the regression of atherosclerotic lesions. However, a paucity of data exists with regards to plant-based diets in the treatment of CHF.

Methods: Three patients diagnosed with CHF opted to undergo a dietary intervention consisting of a defined plant-based diet as an adjunct to standard medical treatment for CHF. Cardiac magnetic resonance imaging was performed. Patients' consumed the defined plant-based diet for an average of 79 days.

Results: Follow-up cardiac magnetic resonance images revealed a 92% increase in ejection fraction [mean \pm standard deviation for all data] ($22.0 \pm 6.9\%$ vs $42.2 \pm 18.4\%$), 21% reduction in left ventricular mass (214 ± 90 g vs 170 ± 102 g), 62% increase in stroke volume (55.8 ± 24.3 cc vs 90.3 ± 30.6 cc) and a 17% increase in cardiac output (3.6 ± 1.2 L/min vs 4.2 ± 1.6 L/min). In patient 1, 90–95% ostial stenosis of the left anterior descending artery nearly completely regressed following the dietary intervention. All patients subjectively reported significant clinical improvements, including less angina, shortness of breath and fatigue.

Conclusion: As an adjunct treatment, a defined plant-based diet may contribute to the reversal of cardiac morphological and functional abnormalities in the setting of CHF.

1. Introduction

Congestive heart failure (CHF) independently increases the risk of mortality by 50% within the first five years of diagnosis.¹ Cardiac remodeling due to increased left ventricular pressure, increased reactive oxygen species (ROS), decreased antioxidant enzymatic activity, and decreased nitric oxide (NO), may also contribute to structural remodeling of the myocardium, promoting the development of CHF.²

Plant-based diets have emerged as effective therapeutic interventions to treat and even reverse coronary atherosclerosis.^{3,4} Both interventional and observational evidence suggests that plant-based diets may decrease the incidence and severity of CHF.⁵ These positive effects may be due to decreased saturated fat and dietary cholesterol intakes, which may reduce serum cholesterol,^{6,7} as well as increased phytonutrient consumption, such as antioxidants, which can reduce oxidative stress and inflammation. Indeed, previous investigations utilizing plant-based diets have demonstrated reduced inflammation, body weight and

blood pressure.^{8,9}

Current pharmacological therapies to treat CHF rely on modifying hemodynamics to reduce cardiac work as well as modifying cardiac signaling via neurohormonal means.¹⁰ While these drugs prolong survival and decrease hospitalizations, these therapies have not definitely been shown to improve cardiac function and morphology. Despite compelling evidence suggesting that plant-based diets may be beneficial in the treatment of CHF, it has yet to be demonstrated in the clinical setting.⁵ Presented are a case series of 3 patients with CHF and reduced ejection fraction (EF) who underwent a defined, plant-based dietary intervention to treat CHF without surgical interventions.

2. Methods

2.1. Patient presentations

A 46-year-old female (Patient 1) presented with complaints of mild

* Corresponding author at: Houston Cardiac Association, Houston, Texas, United States.

E-mail addresses: rnajjar1@student.gsu.edu (R.S. Najjar), bjsam05@hotmail.com (B.D. Montgomery).

<https://doi.org/10.1016/j.ctim.2019.06.010>

Received 7 May 2019; Received in revised form 31 May 2019; Accepted 14 June 2019

Available online 29 June 2019

0965-2299/ © 2019 Elsevier Ltd. All rights reserved.

Table 1
Baseline characteristics.

Patient	Patient 1	Patient 2	Patient 3
Gender	Female	Male	Male
Ethnicity	African American	African American	African American
Age (y)	46	58	70
Smoking status	No	Quit 1–5 y	Quit > 20 y
Alcohol consumption	Occasional	No	Occasional
Diet	Regular	Regular	Regular
Exercise	No	No	No
BMI (kg/m ²)	37.9	30.1	33.7
SBP (mmHg)	149	174	128
DBP (mmHg)	85	94	84
HR (beats/min)	74	69	57
Medical history	None	Hypertension Type II diabetes Kidney disease	Hypertension Hypercholesterolemia Cardiac arrhythmia
Medications	None	furosemide 40 mg, 1 tablet 2x/day Tribenzor [olmesartan medoxomil, amlodipine & hydrochlorothiazide] 5 mg-25 mg-40 mg, 1 tablet 1x/day One-A-Day Men 50 Plus, 1 tablet 1x/day	amiodarone 200 mg, 1 tablet 1x/day furosemide 20 mg, 4 tablets 2x/day metoprolol tartrate 50 mg, 0.5 tablets 2x/day potassium chloride 8 mEq, 4 tablets 1x/day simvastatin 80 mg, 0.5 tablets 1x/day finasteride 5 mg, 1 tablet 1x/day isosorbide dinitrate 40 mg, 1 tablet 3x/day lisinopril 20 mg, 1 tablet 2x/day ferrous sulfate 325 mg, 1 tablet 2x/day

Abbreviations: BMIbody mass index; SBPsystolic blood pressure; DBPdiastolic blood pressure; HRheart rate.

Table 2
Clinical and pharmacological changes.

	Baseline	Final
BMI (kg/m ²)		
Patient 1	37.9	34.2
Patient 2	30.1	26.1
Patient 3	33.7	32
SBP (mmHg)		
Patient 1	149	123
Patient 2	174	158
Patient 3	128	124
DBP (mmHg)		
Patient 1	85	82
Patient 2	94	92
Patient 3	84	73
HR (beats/min)		
Patient 1	74	61
Patient 2	69	50
Patient 3	57	64
Ejection Fraction (%)		
Patient 1	24.9	50
Patient 2	27.1	55.6
Patient 3	14.2	21.2
LV Mass (g)		
Patient 1	117.4	94
Patient 2	295.18	286
Patient 3	231	130
Stroke Volume (cc)		
Patient 1	46.6	100
Patient 2	83.5	115
Patient 3	37.5	56.1
Cardiac output (L/min)		
Patient 1	4.7	4.6
Patient 2	4	5.6
Patient 3	2.2	2.4
Perscription medications (n)		
Patient 1	0	6
Patient 2	2	2
Patient 3	8	9

Abbreviations: BMI, body mass index; SBP, systolic blood pressure.

chest pain, fatigue, night palpitations and shortness of breath induced by physical activity. She was not taking any medications at the time of her office visit and had no previous medical diagnoses as indicated in [Table 1](#) detailing baseline patient characteristics. A baseline physical examination revealed a normal heart rate, normal first and second heart sounds and normal cardiac amplitude. The heart rhythm was regular and no murmurs, gallops or rubs were identified. An electrocardiogram (EKG) revealed nonspecific ST and T wave abnormalities. Based on the presented symptoms and abnormal EKG findings, cardiac magnetic resonance imaging (MRI) and a coronary angiogram were ordered. Findings from the cardiac MRI revealed a left ventricular (LV) mass of 117 g and an EF of 22.1% ([Table 2](#)). The coronary angiogram revealed a 90%–95% ostial left anterior descending coronary artery (LAD) stenosis with diffuse left main disease. The left main coronary artery was notably small compared to the LAD and circumflex arteries. This finding was consistent with the likelihood of diffuse atherosclerosis in the left main coronary artery.

A 58-year-old male (Patient 2) complained of chest pain, shortness of breath, low energy levels and edema of the lower extremities. Patient 2 reported taking furosemide (40 mg), tribenzor [olmesartan medoxomil, amlodipine & hydrochlorothiazide] (5 mg–25 mg–40 mg) and a multivitamin ([Table 1](#)). He had been previously diagnosed with hypertension, diabetes, and kidney disease. At the time of his office visit, his heart rate was normal with no abnormal sounds. An echocardiogram was performed which indicated an estimated EF of 20–25%, mild to moderate LV hypertrophy, severe LV dilation, left and right atrial enlargement and mild pulmonary and tricuspid valve regurgitation. A cardiac MRI was ordered which revealed an EF of 27.1%, and an LV mass of 295 g.

Lastly, a 70-year-old male (Patient 3) presented with complaints of shortness of breath at rest, dyspnea with minimal physical exertion, orthopnea, profuse diaphoresis, fatigue and chest pain at rest and with exertion. Patient 3 had been previously diagnosed with hypertension, hypercholesterolemia and cardiac arrhythmia. He had been prescribed 8 different medications ([Table 1](#)) to manage these conditions. His EKG showed sinus bradycardia with occasional premature ventricular complexes. The QRS duration on EKG was mildly increased. His echocardiogram estimated his EF to be 20–25% in addition to LV

enlargement, mild-moderate LV hypertrophy, restrictive diastolic dysfunction, moderate left atrial enlargement, thickened aortic and mitral valves as well as mild to moderate mitral and tricuspid valve regurgitation. A cardiac MRI also revealed an LV mass of 231 g and an EF of 14.2%.

2.2. Intervention

Each patient was prescribed a defined, plant-based dietary intervention (DPBD) within levels 0-4b in The Food Classification System described elsewhere.⁶ The composition of the DPBD consisted of raw fruits, vegetables, avocado, seeds, with small amounts of raw oats and buckwheat. Patients were advised to eliminate the consumption of all animal products, cooked foods, free oils, soda, alcohol, and coffee.

Patient 1 was prescribed nebivolol 5 mg (1 tablet once per day), valsartan 160 mg (1 tablet once per day), ranolazine 500 mg (1 tablet twice per day), rosuvastatin 10 mg (1 tablet once per day), clopidogrel bisulfate 75 mg (1 tablet once per day) and diazepam 5 mg (1 tablet twice per day). Patient 2 was prescribed nebivolol 5 mg (1 tablet once per day) in place of furosemide. Patient 3 was prescribed spironolactone 25 mg (tablet once per day) and remained on his current medications.

3. Results

The DPBD was followed for 53, 88 and 95 days by Patient 1, Patient 2 and Patient 3, respectively. Each patient was mostly compliant with the nutritional intervention without adverse reactions. Overall, morphological and functional parameters of the heart improved for all 3 patients (Fig. 1). Patient 1 reported having more energy and less chest discomfort within 2 weeks of the intervention, and greater exercise tolerance within 4 weeks with full compliance. Her body mass index, blood pressure and heart rate (Table 2) dramatically improved. Her EF improved by 100%, cardiac stroke volume improved by 115%, LV mass

decreased by 20% and her cardiac output was relatively unchanged. Cardiac MRI footage for Patient 1 demonstrated a clear visual improvement in LV function (Supplementary video file 1).

Additionally, stenosis of the ostial LAD coronary artery nearly completely regressed after initiating the DPBD (Fig. 2). Patient 2 reported feeling better within 4 weeks of the DPBD. He was mostly compliant and did not require any significant medication changes during his course of treatment. He experienced complete resolution of his symptoms within 5 weeks, including resolution of angina and shortness of breath. His EF improved by 105%, LV mass regressed by 3%, stroke volume improved by 38%, and cardiac output improved by 40%.

Patient 3 experienced a more complex clinical course. He was admitted to the hospital with decompensated heart failure 4 days after his initial evaluation in our clinic prior to starting the dietary intervention. He started the nutritional intervention during this hospitalization. He had decreased shortness of breath and chest discomfort and continued to have subjective improvements until 6 weeks after initiation of his dietary treatment; he suffered a clinical stroke with resolution of his symptoms in 48 h and a subsequent transient ischemic attack 2 days later. His follow-up cardiac MRI was performed during this hospitalization. In addition to having sustained improvement in his heart failure symptoms, he was found to have a 50% improvement in EF, a 44% regression in LV mass, a 19% improvement in cardiac stroke volume, and a 9% improvement in his cardiac output.

4. Discussion

This dietary intervention has previously been shown to significantly reduce blood pressure, heart rate and systemic inflammation.^{8,9} These hemodynamic and biochemical changes suggest a possible mechanism by which the DPBD improves cardiac function. There was a significant reduction in LV mass observed in each subject, including a 101 g regression seen in Patient 3. This large reduction in LV mass could be due

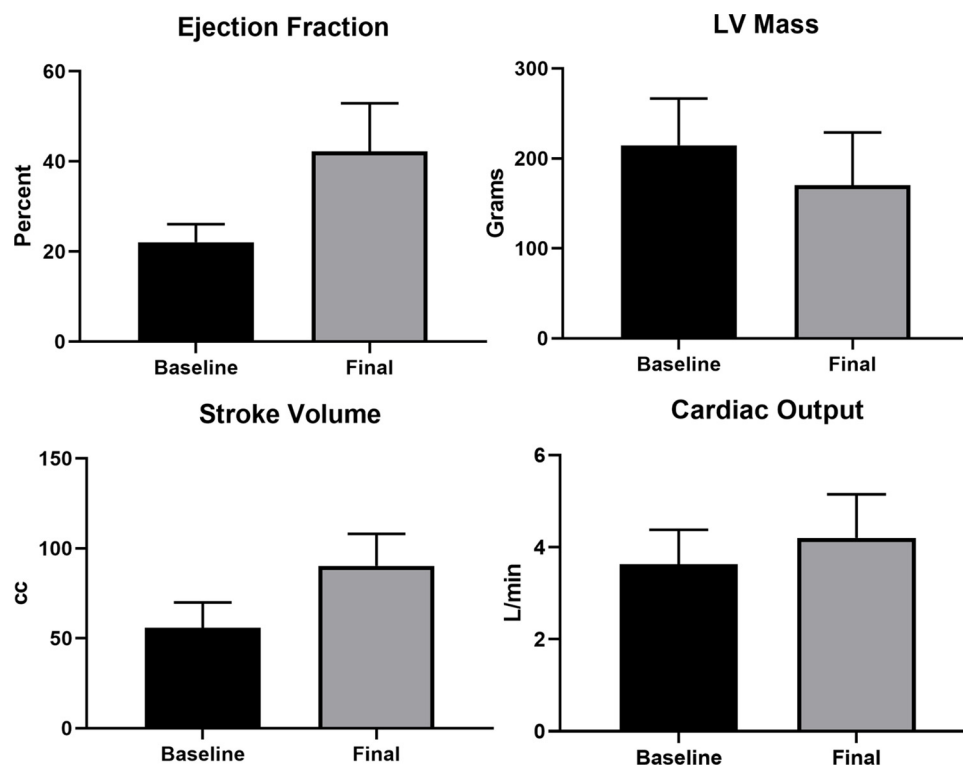


Fig. 1. Cardiac function and morphological changes of all patients.

Legend: Mean cardiac function and morphology of all 3 patients at baseline and final as determined by cardiac magnetic resonance imaging. Error bars are standard error of the mean.

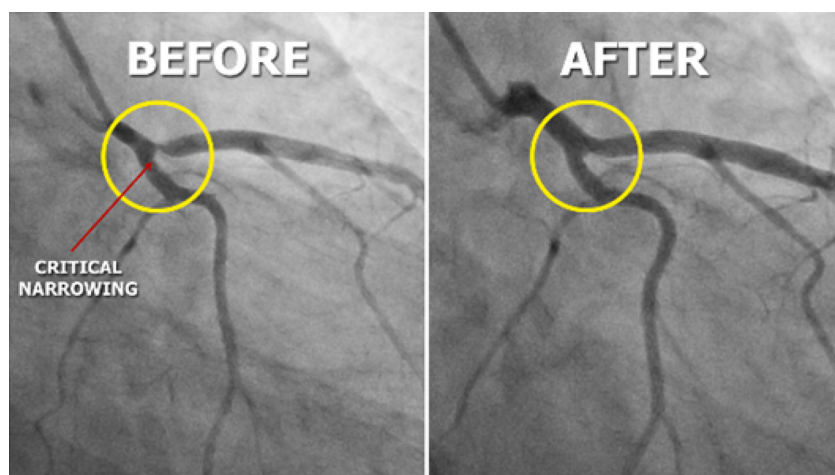


Fig. 2. Coronary angiogram changes for Patient 1. Legend: Baseline coronary angiogram (left) showing diffusely small left main coronary artery with a 90–95% ostial stenosis of the left anterior descending artery. Follow up angiogram (right) showing increased luminal size of left main coronary artery with a near-total regression of ostial left anterior descending artery lesion.

to a reduction in intramyocardial edema, possibly due to reduced leukocyte infiltration causing a decrease in reactive oxygen and nitrogen species which may have ameliorated the degradation of the extracellular matrix and decreased collagen deposition.¹¹

In general, the consumption of animal based foods are associated with increased oxidative stress and inflammation in humans, while plant-based foods have an inverse association.¹² These positive redox effects associated with consuming plants could result in the higher bioavailability of nitric oxide, resulting in vasodilation and a reduction in blood pressure likely due to reduced systemic vascular resistance (SVR).¹³ With a reduction in SVR, stroke volume would increase, improving cardiac output and possibly reducing heart rate. None of these clinical improvements would be expected to occur with the standard medical treatments for CHF. Multicenter drug trials have not definitely shown improvements in EF, nor have these investigations demonstrated changes in physiological function of the heart to the extent that was examined here.^{10,14} Hence, the DPBD resulted in both stabilization and partial reversal of advanced cardiovascular disease across a broad age spectrum of patients with differing clinical courses. Indeed, previous investigations have demonstrated that a plant-based diet can reverse coronary atherosclerosis, however, a paucity of data exists with regards to plant-based diets in the treatment of CHF.^{3,4}

5. Conclusion

In the standard treatment of CHF, such dramatic and rapid improvements in heart morphology and function would be deemed highly improbable. However, the findings in this case series demonstrate that a plant-based diet as an adjunct to standard medical therapies may reverse certain pathophysiologic processes in heart failure. This intervention provides an outline for a potential novel therapy for heart failure with reduced ejection fraction. A larger case series or a prospective clinical trial utilizing this plant-based dietary intervention is needed to confirm these findings.

Funding

Johnsie and Aubary Montgomery Institute of Medical Education and

Research (Houston, TX) and Boston Scientific (Marlborough, MA).

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.ctim.2019.06.010>.

References

1. Lubitz SA, Benjamin EJ, Ellinor PT. Atrial fibrillation in congestive heart failure. *Heart Fail Clin.* 2010;6(2):187–200.
2. Tsutsui H, Kinugawa S, Matsushima S. Oxidative stress and heart failure. *Am J Physiol Heart Circ Physiol.* 2011;301:2181–2190.
3. Ornish D, Brown SE, Scherwitz LW, et al. Can lifestyle changes reverse coronary heart disease? The lifestyle heart trial. *Lancet Lond Engl.* 1990;336:129–133.
4. Esselstyn Jr CB, Gendy G, Doyle J, Golubic M, Roizen MF. A way to reverse CAD? *J Fam Pract.* 2014;63:356–364.
5. Kerley CP. A review of plant-based diets to prevent and treat heart failure. *Card Fail Rev.* 2018;4(1):54–61.
6. Rizzo NS, Jaceldo-Siegl K, Sabate J, Fraser GE. Nutrient profiles of vegetarian and nonvegetarian dietary patterns. *J Acad Nutr Diet.* 2013;113(12):1610–1619.
7. Velagaleti RS, Massaro J, Vasan RS, Robins SJ, Kannel WB, Levy D. Relations of lipid concentrations to heart failure incidence: The Framingham Heart Study. *Circulation.* 2009;120(23):2345–2351.
8. Najjar RS, Moore CE, Montgomery BD. A defined, plant-based diet utilized in an outpatient cardiovascular clinic effectively treats hypercholesterolemia and hypertension and reduces medications. *Clin Cardiol.* 2018;41:307–313.
9. Najjar RS, Moore CE, Montgomery BD. Consumption of a defined, plant-based diet reduces lipoprotein(a), inflammation, and other atherogenic lipoproteins and particles within 4 weeks. *Clin Cardiol.* 2018;41:1062–1068.
10. Pinilla-Vera M, Hahn VS, Kass DA. Leveraging signaling pathways to treat heart failure with reduced ejection fraction. *Circ Res.* 2019;124(11):1618–1632.
11. Givertz MM, Colucci WS. New targets for heart-failure therapy: Endothelin, inflammatory cytokines, and oxidative stress. *Lancet.* 1998;352:134–8.
12. Romeu M, Aranda N, Giral M, Ribot B, Nogues MR, Arijia V. Diet, iron biomarkers and oxidative stress in a representative sample of Mediterranean population. *Nutr J.* 2013;12:102.
13. Wink DA, Miranda KM, Espey MG, et al. Mechanisms of the antioxidant effects of nitric oxide. *Antioxid Redox Signal.* 2001;3:203–213.
14. McMurray JJ, Packer M, Desai AS, et al. Angiotensin-neprilysin inhibition versus enalapril in heart failure. *N Engl J Med.* 2014;371:993–1004.



A defined, plant-based diet utilized in an outpatient cardiovascular clinic effectively treats hypercholesterolemia and hypertension and reduces medications

Rami S. Najjar¹  | Carolyn E. Moore¹ | Baxter D. Montgomery^{2,3}

¹Department of Nutrition and Food Sciences, Texas Woman's University, Houston, Texas

²University of Texas Health Science Center, Houston, Texas

³Montgomery Heart & Wellness, Houston, Texas

Correspondence

Rami S. Najjar, MS, 10480 Main Street, Houston, TX 77025
Email: rnajjar@twu.edu

Funding information

Johnsie and Aubary Montgomery Institute of Medical Education and Research; This study was funded by the Johnsie and Aubary Montgomery Institute of Medical Education and Research. The authors were not influenced by this funding source in any way, including in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript. This study took place at Montgomery Heart & Wellness in Houston, Texas.

Background: Cardiovascular disease (CVD) is a major economic burden in the United States. CVD risk factors, particularly hypertension and hypercholesterolemia, are typically treated with drug therapy. Five-year efficacy of such drugs to prevent CVD is estimated to be 5%. Plant-based diets have emerged as effective mitigators of these risk factors.

Hypothesis: The implementation of a defined, plant-based diet for 4 weeks in an outpatient clinical setting may mitigate CVD risk factors and reduce patient drug burden.

Methods: Participants consumed a plant-based diet consisting of foods prepared in a defined method in accordance with a food-classification system. Participants consumed raw fruits, vegetables, seeds, and avocado. All animal products were excluded from the diet. Participant anthropometric and hemodynamic data were obtained weekly for 4 weeks. Laboratory biomarkers were collected at baseline and at 4 weeks. Medication needs were assessed weekly. Data were analyzed using paired-samples *t* tests and 1-way repeated-measures ANOVA.

Results: Significant reductions were observed for systolic (−16.6 mmHg) and diastolic (−9.1 mmHg) blood pressure ($P < 0.0005$), serum lipids ($P \leq 0.008$), and total medication usage ($P < 0.0005$). Other CVD risk factors, including weight ($P < 0.0005$), waist circumference ($P < 0.0005$), heart rate ($P = 0.018$), insulin ($P < 0.0005$), glycated hemoglobin ($P = 0.002$), and high-sensitivity C-reactive protein ($P = 0.001$) were also reduced.

Conclusion: A defined, plant-based diet can be used as an effective therapeutic strategy in the clinical setting to mitigate cardiovascular risk factors and reduce patient drug burden.

KEYWORDS

Biomarkers, General Clinical Cardiology/Adult, Hypertension, Preventive Cardiology, Vegetarian Diet

1 | INTRODUCTION

Cardiovascular disease (CVD) is a major economic burden to the United States. Currently, 17% of all healthcare expenditures go toward CVD care.¹ Projections are expected to rise, as 40.5% of the US population may have some form of CVD by 2030, leading to a near tripling in medical care costs, from \$273 billion to \$818 billion. CVD has been the leading cause of death in the United States since 1950.² The standard of clinical care in the primary prevention of CVD is to reduce CVD risk factors, particularly through lipid-lowering and antihypertensive drug therapy.³ It has been estimated that nearly

40% of the population has high serum low-density lipoprotein cholesterol (LDL-C).⁴ In addition, approximately one-third of individuals age 40 to 59 years are estimated to be hypertensive.⁵ Of those with hypertension (HTN), 76% are on medications to reduce blood pressure, but only 52% achieve blood-pressure control. The highest drug prices in the world are found within the United States. On average, per capita spending on prescription drugs in the United States is \$858, compared with an average of \$400 in 19 other industrialized countries.⁶

Patients' opinion of the efficacy of drug therapy in CVD prevention is often inflated multifold.^{7,8} It has been estimated that high-risk

patients have a < 5% chance of benefiting from cardioprotective drugs within the next 5 years. Moreover, most patients wish to take drugs at a benefit threshold of $\geq 20\%$ over 5 years.⁹ Thus, if patients were aware of the actual benefit of cardioprotective drugs, many patients may not be willing to take such medications.

Based on growing evidence,^{10–15} it has been recommended that physicians encourage patients to consume plant-based diets.¹⁶ The aim of this investigation was to evaluate the effectiveness of a defined, plant-based diet as an adjunct to or replacement of prescription drugs in the treatment of hypercholesterolemia and HTN in an outpatient clinical setting.

2 | METHODS

2.1 | Study population

All subjects were registered new patients of a cardiovascular center. The study intervention was carried out in an outpatient clinical setting. All participants provided written informed consent after the study protocol and procedure had been fully explained. The study was approved by the Texas Woman's University Institutional Review Board.

Baseline characteristics of the patients are shown in Table 1. All participants were age 32 to 69 years with HTN, elevated LDL-C, and excess body weight. HTN was defined as systolic blood pressure (SBP) ≥ 140 mmHg or diastolic blood pressure (DBP) ≥ 90 mmHg. Elevated LDL-C was considered to be a serum LDL-C concentration ≥ 100 mg/dL, and excess body weight was defined as a body mass index ≥ 25 kg/m².

Exclusion criteria included current tobacco use, current drug abuse, excessive alcohol use (defined as >2 glasses of wine or alcohol equivalent per day for men or >1 glass of wine or alcohol equivalent for women), a current cancer diagnosis, an ongoing clinically defined infection, a mental disability that would prevent the participant from following the study protocol, an estimated glomerular filtration rate < 60 mg/dL, current pregnancy or lactation, a hospitalization within the past 6 months, and previous exposure to the nutrition program.

2.2 | Screening

Eligibility was determined through initial screening of participants who expressed interest in participating in the intervention. Demographics, lifestyle habits, anthropometrics, and hemodynamics were used to determine the eligibility of participation for each subject. A trained medical assistant measured blood pressure, heart rate, and body weight. Medical history and lifestyle habits were obtained by the medical assistant and/or nurse practitioner. Fasting blood was collected by a licensed phlebotomist. The clinical care of all patients was overseen by a board-certified cardiologist.

2.3 | Weekly visits

After subjects were screened for study inclusion, follow-up appointments were arranged for study enrollment. Participants were instructed to attend 4 follow-up weekly office visits in addition to a baseline assessment. Baseline weight, blood pressure, heart rate,

TABLE 1 Baseline patient demographics and clinical diagnoses

	Participants, n = 31
Mean age, y	53.4 (32–69)
Sex	
M	10 (33)
F	21 (67)
Race/ethnicity	
African American	25 (80)
Hispanic	3 (10)
White	3 (10)
BMI, kg/m ²	37.5 \pm 8.3
25–29.9 (overweight)	6 (19)
30–34.9 (obese class 1)	6 (19)
35–39.9 (obese class 2)	10 (33)
≥ 40	9 (29)
Current diagnoses	
CAD	10 (33)
T2DM	8 (27)
Arthritis	7 (23)
Prediabetes	5 (17)
Medications, n	
BP medications, total	49
ACEI	5
ARB	11
Central antiadrenergic	1
Cardioselective (β 1)-blocker	6
Noncardioselective (β 1)-blocker	2
CCB	9
Potassium-sparing diuretic	1
Thiazide diuretic	14
Other prescription drugs, total	33
Biguanide	2
Sulfonylurea	3
Dipeptidylpeptidase-4 inhibitor	1
Insulin	2
NSAID	1
Biologic immune suppressant	1
Statin	2
Bronchodilator/steroid inhaler	5
Thyroid drugs	3
Xanthine oxidase inhibitor	2
PPI	1
Antiplatelet	1
Antianginal	2
Digitalis glycoside	1
Vasodilator	1
Other	5
Total medications	82

Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; BMI, body mass index; BP, blood pressure; CAD, coronary artery disease; CCB, calcium channel blocker; F, female; M, male; NSAID, nonsteroidal anti-inflammatory drug; PPI, proton pump inhibitor; SD, standard deviation; T2DM, type 2 diabetes mellitus. Unless otherwise noted, data are presented as n (%) or mean \pm SD (range).

waist circumference, medications, and biochemical indicators were documented. A baseline 24-hour dietary recall was conducted by a trained nutritionist with the utilization of food models to verify portion sizes of foods and beverages consumed. Nutrient intake was analyzed by the Nutrition Data System for Research software, version 2016 (University of Minnesota, Minneapolis).

Follow-up visits (weeks 1–4) consisted of obtaining weight, blood pressure, heart rate, and waist circumference. Medications were assessed and adjusted as needed by the medical doctor or nurse practitioner during the follow-up visits. The final visit (week 4) consisted of a second 24-hour dietary recall and a second collection of fasting blood to assess biochemical measures.

2.4 | Medications

Medications were documented following the conclusion of each office visit. All medications listed at baseline were chronic stable medications (>3 months), except for medications changed during the baseline office visit as outlined in the protocol below. All other medication changes were documented in the medication tracking of this study. No lipid-lowering medications were added at the onset or during the study. The medication needs-assessment protocol is as follows:

- Baseline: All nonessential medications and supplements were discontinued. Additionally, diuretics were discontinued in patients who were clinically euvoletic. Insulin, sulfonylureas, and other potential glucose-lowering medications were either removed or the dosage was decreased in patients whose glucose levels were

routinely below 250 mg/dL. All baseline medications are indicated in Table 1.

- Week 1 follow-up: If a patient's blood pressure was low and the patient had symptoms of dizziness or fatigue associated with low blood pressure, then blood pressure medications were decreased by 25% to 50%. Other medications were reviewed with consideration of removal based on patient needs (eg, hypoglycemics).
- Week 2 follow-up: The patients' clinical response to the diet was reevaluated and medication adjustments were made according to their clinical response. Medications primarily prescribed for symptom management were assessed (eg, sleep, allergies, mood disorders, pain) and discontinued if necessary.
- Weeks 3 and 4 follow-up: Based on the patients' clinical response to the dietary intervention, changes were made to the medications as needed for the remainder of the intervention.

2.5 | Dietary protocol

Participants were instructed to follow a defined plant-based dietary intervention for 4 weeks. A food classification system using a scale of 0 to 10 was devised to create a simple, reproducible way of prescribing a nutritional regimen to patients in the clinical setting (Table 2). Participants were instructed to consume foods within this food classification system. Food levels 0 through 4B were permitted, whereas all other food levels were excluded. Briefly, food levels 0 through 4B exclude all animal products, with the exception of honey. Cooked foods, free oils, soda, alcohol, and coffee were also excluded. Emphasized were raw fruits and vegetables, with avocado and raw seeds

TABLE 2 The food classification system

Food Level	Description
0	Liquids including water, tea, unpasteurized fruit and vegetable juices, and blended fruit and vegetable smoothies. These foods would be consumed raw, except for tea, which can be steeped in hot water.
1	Raw fruits and vegetables with a low glycemic index (<56)
2	Raw fruits and vegetables with a medium to low GI (56–70)
3	Raw fruits and vegetables with a high GI (>70)
4A	Plant foods that are raw with a high fat content (≥20% of caloric content from fat), such as raw seeds and avocados
4B	Plant foods that are dehydrated to temperatures ≤160°F
4C	Plant foods that are dried, dehydrated, or warmed (dry-heat cooking) at 160°F–175°F, or steamed or boiled for a short duration (steaming, <4 min; boiling, <10 min). Includes lightly steamed, soaked, sprouted, dehydrated, or warmed fruits, vegetables, legumes or beans, and grains. Heated foods with >20% of calories from fat are excluded.
5	Foods that are warmed, dried, or dehydrated at 175°F to 200°F, and steamed or boiled for a medium duration (steaming, 4–10 min; boiling, 10–45 min). Typical foods include greens, beans and legumes, and starches, including grains, bean or mixed-vegetable soups, and other fruit and vegetables boiled for up to 45 min or oven-warmed (at 155°F–200°F). Heated foods with >20% of calories from fat are excluded.
6	Foods that are baked, warmed, dried, or dehydrated at >200°F, or steamed or boiled for a long duration (steaming, >10 min; boiling, >45 min). Heated foods with >20% of calories from fat are excluded.
7	Fish with low mercury content lightly steamed or poached for ≤8 min. Processed plant foods with preservatives or additives, free oils, and heated foods with >20% calories from fat are included.
8	Same as level 7, except also includes wild-game meats, low-mercury fish lightly steamed or poached for >8 min, and plant-based foods that are grilled or heavily processed. May also include carbohydrates with white flour or white rice, or natural foods that have been stripped of their natural components.
9	Animal-based foods that include domestically raised animals (excluding beef and pork) and plant-based foods that are sautéed, stir-fried, medium-fried or deep-fried in oil. Other animal-based foods include all other types of fish. May also include foods containing dairy products.
10	All other types of animal-based foods, and plant-based foods prepared in any way. May include processed foods of any kind.

Abbreviations: F, Fahrenheit; GI, glycemic index. Food classification levels 0 through 4B were permitted for consumption during the dietary intervention; levels >4B were excluded from the intervention. Sodium consumption was low, although the food provided to patients contained small amounts of sea salt.

provided as condiments. All meals and snacks were provided at no cost to the participants for the full duration of the 4-week intervention. Vitamin, herbal, and mineral supplements were to be discontinued unless otherwise clinically indicated. Participants were not advised to alter their exercise habits, nor were exercise habits monitored.

Participants were free to consume foods outside of what was provided, as long as the foods fell within food levels 0 through 4B. No caloric targets were prescribed, nor were any macronutrient restrictions advocated; participants were free to consume food ad libitum. Participants were also instructed to track dietary adherence with a daily adherence-assessment tool. Participants indicated in writing each day whether they were “100% on the diet” or “ate anything off of the diet.” The number “1” was assigned to an adherent day, and “0” was assigned to a nonadherent day. Scores after 4 weeks could therefore range from 0 to 28 points for each participant. Evaluation of the adherence-assessment tool was conducted during each weekly follow-up visit by a trained nutritionist.

2.6 | Biochemical measures

After a 12-hour fast during the baseline and final office visits, the following serum biomarkers were obtained: total cholesterol, LDL-C, high-density lipoprotein cholesterol, triglycerides, insulin, glucose, glycated hemoglobin (HbA_{1c}), and high-sensitivity C-reactive protein (hs-CRP). These specific biomarkers of interest were analyzed by either True Health Diagnostics (Frisco, TX) or Singulex (Alameda, CA), depending on the subject's insurance. The same company that analyzed the baseline laboratory tests for a participant was used for the follow-up testing to ensure assay consistency.

Serum lipids were measured by enzymatic colorimetric assay, and insulin was measured by a no-competitive sandwich-type enzyme-linked immunosorbent assay with electrochemical detection for both True Health Diagnostics and Singulex. Glucose was measured by an enzymatic reference method with hexokinase using colorimetric detection, and hs-CRP was measured by a particle-enhanced immunoturbidometric assay for both Singulex and True Health Diagnostics. HbA_{1c} was measured by a turbidometric inhibition immunoassay for Singulex. Boronate affinity chromatography was used by True Health Diagnostics for HbA_{1c}.

2.7 | Statistical analysis

Paired-samples *t* tests were used for the analysis of biochemical and nutrient intake means. A one-way repeated-measures ANOVA was used to analyze the means for anthropometric, hemodynamic, and medication data. Significance was set at a *P* value of < 0.05. SPSS version 24 (IBM Corp., Armonk, NY) was used for data analysis.

3 | RESULTS

3.1 | Demographics

During screening, a total of 65 patients showed interest in participating in the study; however, 30 patients did not meet inclusion

criteria or were excluded. Two individuals were unable to participate due to scheduling conflicts. Although 33 participants initially enrolled into the study, 2 participants were either lost to contact (*n* = 1) or no longer wished to follow the dietary protocol (*n* = 1). One participant refused to complete the final 24-hour dietary recall during week 4 due to time availability. Thus, a total of 31 participants provided clinical data and 30 participants provided nutrient intake data.

Based on clinical diagnoses and medical history, 33% of participants had coronary artery disease and 44% were either prediabetic (HbA_{1c} 5.7%–6.4%) or had diabetes mellitus (HbA_{1c} ≥ 6.5%; Table 1). The average body mass index was 37.5 kg/m² ± 8.3 kg/m², and approximately 81% of the participants were obese.

3.2 | Nutrient intake

Nutrient intake of participants on the defined, plant-based diet significantly changed after 4 weeks (Table 3). Significant reductions in energy intake, saturated fat as a percent of energy, dietary cholesterol, protein as a percent of energy, total fat, monounsaturated and polyunsaturated fat as a percent of energy, trans fat, vitamin D, vitamin B12, calcium, zinc, and sodium were observed after 4 weeks. Carbohydrate intake as a percent of energy, vitamin A, vitamin C, folate, dietary fiber, magnesium, and potassium intake increased significantly after 4 weeks. Patients anecdotally reported overall satisfaction with the food provided during the clinical follow-ups, and no significant symptoms of increased hunger were reported.

3.3 | Clinical variables

Anthropometric and hemodynamic characteristics, as well as medications, changed significantly (*P* ≤ 0.018) from baseline to 4 weeks (Table 4). Adherence was well maintained over the 4-week period. Overall, participants were noncompliant for 3.6 out of 28 days. There were no significant differences between subjects with 100% adherence and lower-adherent subjects. Participants lost on average a total of 6.7 kg (14.7 lbs.) after 4 weeks on the defined plant-based diet (Table 4). SBP and DBP decreased by 16.6 mmHg and 9.1 mmHg, respectively. The reduction in blood pressure was accompanied with a decreased use of blood pressure medications (decreased 33% by week 4). Additionally, those taking hypoglycemic drugs, including insulin, reduced medication usage by 87%. Overall, total medication usage decreased 40% by week 4.

3.4 | Biomarkers

All biochemical changes were significant (*P* ≤ 0.037) at 4 weeks compared with baseline, with the exception of the total cholesterol to high-density lipoprotein cholesterol ratio (*P* = 0.068) and glucose (*P* = 0.25; Table 5). Although fasting glucose was not significantly reduced, HbA_{1c} was significantly reduced (*P* = 0.002).

The distribution of high-interest clinical variable changes during the intervention are displayed in Supporting Information, Figure, in the online version of this article.

TABLE 3 Nutrient intake^b

	Baseline	Final	Change, % ^a	P Value ^c
Energy, Kcal	2053 ± 873	1369 ± 488	-33 (-683 ± 808)	<0.0005
Fat, % of energy	36.4 ± 10.4	19.0 ± 8.9	-48 (-17.3 ± 12.8)	<0.0005
Saturated fat, % of energy	11.6 ± 4.5	3.8 ± 2.7	-67 (-7.7 ± 5.5)	<0.0005
Monounsaturated fat, % of energy	13.2 ± 4.8	7.0 ± 3.9	-47 (-6.2 ± 5.4)	<0.0005
Polyunsaturated fat, % of energy	8.4 ± 5.6	5.4 ± 2.7	-36 (-3.0 ± 3.5)	<0.0005
Omega-6, g	18.5 ± 11.1	6.0 ± 4.7	-67 (-12.4 ± 10.6)	<0.0005
Omega-3, g	2.11 ± 1.60	2.14 ± 1.95	1 (0.03 ± 2.16)	0.92
Omega-6/omega-3 ^d	9.8 ± 3.7	4.3 ± 3.0	-56 (-5.5 ± 3.8)	<0.0005
Trans fat, g	2.25 ± 1.97	0.04 ± 0.09	-99 (-2.21 ± 2.00)	<0.0005
Cholesterol, mg	295.4 ± 211.7	12.2 ± 56.2	-96 (-283.2 ± 214.8)	<0.0005
Carbohydrate, % of energy	46.3 ± 14.0	72.6 ± 11.3	57 (26.3 ± 17.0)	<0.0005
Protein, % of energy	16.5 ± 6.4	7.5 ± 2.1	-54% (-9.0 ± 6.1)	<0.0005
Total fiber, g	20.4 ± 11.9	51.0 ± 17.7	150 (30.6 ± 17.8)	<0.0005
Total vitamin A activity, IU	8265 ± 9258	33387 ± 19052	303 (25 121 ± 21 876)	<0.0005
Vitamin D, IU	159.1 ± 154.3	12.3 ± 30.4	-92 (-146.8 ± 161.8)	<0.0005
Vitamin E, mg	9.9 ± 6.3	10.5 ± 5.6	6 (0.6 ± 6.4)	0.60
Vitamin C, mg	87.7 ± 108.8	412.7 ± 164.7	370 (325.0 ± 197.3)	<0.0005
Vitamin B12, µg	4.0 ± 1.9	0.3 ± 0.8	-92 (-3.6 ± 2.3)	<0.0005
Folate, µg	298 ± 229	741 ± 298	115 (343 ± 329)	<0.0005
Iron, mg	15.4 ± 7.2	15.3 ± 6.9	-1 (-0.1 ± 9.9)	0.97
Calcium, mg	796 ± 438	566 ± 279	-29 (-229 ± 527)	0.024
Sodium, mg	3730 ± 1783	839 ± 778	-76 (-2891 ± 1776)	<0.0005
Magnesium, mg	288.1 ± 119.9	488.1 ± 186.0	69 (200.0 ± 178.0)	<0.0005
Zinc, mg	12.2 ± 5.9	7.8 ± 3.4	-76 (-4.4 ± 7.0)	0.002
Potassium, mg	2668 ± 1190	5078 ± 1758	90 (2410 ± 1764)	<0.0005

Data are presented as mean ± standard deviation unless otherwise indicated.

^a Data are presented as percent change (mean ± standard deviation).

^b Data are for subjects who completed 24-hour recalls at both baseline and 4 weeks and do not include dietary supplements (n = 30).

^c Paired samples *t* tests for within-group comparisons of changes from baseline to final values.

^d Values indicate a ratio.

TABLE 4 Change of anthropometrics, hemodynamics, medications, and adherence over 4 weeks

	Baseline	Week 1	Week 2	Week 3	Week 4	P Value ^a
Weight, kg, mean ± SE	108.1 ± 5.1	105.4 ± 4.8 ^b	103.9 ± 4.8 ^b	102.6 ± 4.7 ^b	101.4 ± 4.7 ^b	<0.0005
BMI, kg/m ²	37.5 ± 1.4	36.5 ± 1.4 ^b	36.0 ± 1.4 ^b	35.6 ± 1.4 ^b	35.2 ± 1.4 ^b	<0.0005
WC, cm	111.9 ± 2.5	109.2 ± 2.5 ^b	107.6 ± 2.5 ^b	106.3 ± 2.5 ^c	105.3 ± 2.5 ^b	<0.0005
SBP, mm Hg	146.6 ± 2.8	131.9 ± 2.8 ^b	127.0 ± 2.4	129.5 ± 1.9	130.0 ± 2.3	<0.0005
DBP, mm Hg	91.2 ± 1.3	81.5 ± 1.4 ^b	79.0 ± 1.3	82.1 ± 1.2	82.1 ± 1.2	<0.0005
BP medications	1.6 ± 1.1	1.6 ± 1.0	1.4 ± 1.0 ^d	1.1 ± 1.0 ^d	1.0 ± 0.1	<0.0005
Heart rate, bpm	69.8 ± 1.8	71.8 ± 1.9	68.4 ± 1.7	68.1 ± 1.7	66.2 ± 1.2	0.018
Other prescription drugs	1.0 ± 1.4	1.0 ± 1.4	0.9 ± 1.5	0.6 ± 0.9	0.5 ± 0.9	0.008
Total medications	2.6 ± 2.0	2.7 ± 2.0	2.3 ± 2.0 ^d	1.8 ± 1.6	1.6 ± 1.3	<0.0005
Adherence, d/wk ^e	—	6.32 ± 0.19	6.03 ± 0.25	6.06 ± 0.27	5.96 ± 0.27	0.531

Abbreviations: ANOVA, analysis of variance; BMI, body mass index; BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure; SE, standard error; WC, waist circumference.

^a Repeated-measures 1-way ANOVA with a Greenhouse–Geisser correction due to violation of Mauchly's test of sphericity (*P* > 0.05).

^b *P* ≤ 0.001 compared with previous week.

^c *P* ≤ 0.01 compared with previous week.

^d *P* ≤ 0.05 compared with previous week (all pairwise comparisons were determined by post hoc analysis with a Bonferroni adjustment).

^e Measured by weekly adherence-assessment tool. Values represent the number of days on average that adherence was 100% out of 1 week (7 days).

4 | DISCUSSION

Four weeks of a defined, plant-based dietary intervention resulted in clinically significant reductions in SBP, DBP, blood pressure medication usage, total medication usage, and serum lipids. Statistically significant reductions were also observed for other CVD risk factors, including body weight, heart rate, waist circumference, insulin, HbA_{1c}, and hs-CRP. This intervention demonstrated that a plant-based diet can be used effectively in the clinical setting with profound results. Additionally, subjects were able to transition from a standard American diet to the plant-based diet outlined in this intervention with good adherence. Physician advice can significantly impact the dietary choices of patients,¹⁷ as demonstrated in this trial.

Although weight was reduced, this likely did not contribute fully to the reduction in blood pressure. A recent Cochrane review of randomized trials lasting ≥ 24 weeks examined the effects of weight loss on blood pressure and concluded that a 4-kg reduction in weight resulted in a 4.5-mmHg and 3-mmHg reduction in SBP and DBP, respectively.¹⁸ Results from this review would underestimate expected outcomes of this trial. In comparison, participants in the present study lost 6.7 kg and reduced SBP and DBP by 16.6 mmHg and 9.1 mmHg, respectively. These findings are striking considering that blood pressure medications were reduced by 33% by week 4 and blood pressure nearly normalized. Participants' blood pressure was better even when discontinuing medications, which may indicate superiority of the dietary intervention over drug therapy. The reduction in blood pressure by this nutritional intervention was due to a variety of contributing factors, which may include a reduction in hs-CRP (-2.4 ± 3.7 mg/L)¹⁹ and increased consumption of nitrates,²⁰ potassium,²¹ and magnesium.²² Increased dietary fiber,²³ phytosterols,²⁴ and polyphenols²⁵ also likely contributed to reduced serum lipids in addition to the exclusion of animal-based foods.²⁶

It is interesting to note that fasting blood glucose was not significantly reduced ($P = 0.25$), yet HbA_{1c} was significantly reduced ($P = 0.002$). It is likely that reduced postprandial glucose fluctuations accounted for this decrease in HbA_{1c}, although this was not directly

tested. It has been previously demonstrated that HbA_{1c} $< 7\%$ is mostly influenced by postprandial glucose.²⁷ The average HbA_{1c} of this sample was 5.9%; therefore, postprandial blood glucose would likely play a more significant role.

Other similar plant-based dietary trials have also demonstrated reduced CVD risk factors. In a 4-week randomized trial comparing a low-fat, plant-based diet to an American Heart Association diet, Macknin et al²⁸ reported significant reductions in weight (3.64 ± 3.41 kg), SBP (7.96 ± 12.28 mmHg), and LDL-C (27.00 ± 26.72 mg/dL) compared with baseline in adults on the plant-based diet. Bloomer et al²⁹ conducted a trial in which subjects consumed a plant-based diet for 3 weeks. Despite normal baseline clinical indicators, large reductions were observed in LDL-C (22.3 mg/dL), SBP (8.8 mmHg), and DBP (5.2 mmHg).

Jenkins et al³⁰ fed 3 weight-maintaining diets for 2 weeks that were low in saturated fat to participants with elevated LDL-C (~ 115 mg/dL at baseline). The dietary groups included a conventional low-fat diet, a vegetarian diet high in complex carbohydrates, and a raw vegan diet similar to that of the present study. Significant differences in changes of serum LDL-C were observed between these dietary groups. The conventional low-fat diet reduced LDL-C by 8 mg/dL, the starch-based vegetarian diet reduced LDL-C by 27 mg/dL, and the raw vegan diet reduced LDL-C by 38 mg/dL ($P < 0.001$). Thus, a raw plant-based diet may result in greater reductions in serum lipids than one that includes cooked complex carbohydrates.

4.1 | Study strengths and limitations

Several strengths of the present study should be noted. First, the utilization of the food classification system allows for reproducibility in other clinical practices and trials, as the food selection type, preparation, and degree of processing is detailed. Second, the utilization of a prescribed nutrition program in an outpatient cardiovascular clinic allows for the close assessment of the patient's clinical response to the diet. This was facilitated by weekly office visits that allowed for medication weaning as needed. In addition, the provision of food to participants helped facilitate adherence to the dietary protocol. Although there were no statistical differences between high- and low-adherent subjects, a lack of statistical power may be present due to a reduced sample size when groups were divided based on adherence. Additionally, strict adherence standards may also have required a larger sample size for statistical significance to be apparent between groups. A single bite or drink of any food outside of the prescribed diet counted against adherence for the day, even if the remainder of the day represented complete dietary compliance. Lastly, the range of reported dependent variables represents meaningful clinical indicators often evaluated in cardiology practices across the United States. These clinical indicators are most commonly used in the assessment of CVD risk. Thus, this study has real-world applicability in the clinical setting.

Limitations of the current study include the small sample size, lack of a control group, and short duration of follow-up. Although the sample size was small, the large effect sizes indicate that the sample size was more than sufficient for adequate power of the primary endpoints. Further research is needed to determine whether medications,

TABLE 5 Change in biochemical variables after 4 weeks

	Baseline	Final	Change	P Value ^a
TC, mg/dL	216.6 \pm 34.2	182.7 \pm 29.9	-33.8 \pm 25.9	<0.0005
LDL-C, mg/dL	143.0 \pm 28.9	118.4 \pm 26.4	-24.6 \pm 21.3	<0.0005
HDL-C, mg/dL	54.8 \pm 9.4	49.5 \pm 10.6	-5.2 \pm 6.2	<0.0005
TC/HDL ^b	4.04 \pm 0.88	3.81 \pm 0.88	-0.22 \pm 0.64	0.068
TG, mg/dL	124.1 \pm 58.1	104.5 \pm 53.6	-19.6 \pm 38.4	0.008
Insulin, uIU/mL	14.6 \pm 7.6	10.3 \pm 7.6	-4.2 \pm 5.1	<0.0005
Glucose, mg/dL	90.1 \pm 12.0	87.1 \pm 4.7	-2.9 \pm 14.0	0.25
HbA _{1c} , %	5.9 \pm 0.5	5.7 \pm 0.3	-0.2 \pm 0.3	0.002
hs-CRP, mg/L	7.8 \pm 6.4	5.3 \pm 4.7	-2.4 \pm 3.7	0.001

Abbreviations: HbA_{1c}, glycated hemoglobin; HDL-C, high-density lipoprotein cholesterol; hs-CRP, high-sensitivity C-reactive protein; LDL-C, low-density lipoprotein cholesterol; SD, standard deviation; TC, total cholesterol; TG, triglycerides. Data are presented as mean \pm SD; n = 31.

^a Paired-samples t tests for within-group comparisons of changes from baseline to final values.

^b Values indicate a ratio.

serum lipids, and blood pressure would continue to decrease if the diet were consumed for an extended period of time. In addition, extended trials are needed to assess long-term adherence to the diet. Lastly, inclusion of periodic postprandial glucose testing during the intervention may help establish a potential relationship between postprandial glucose fluctuations and reduced HbA_{1c}.

5 | CONCLUSION

A defined plant-based diet can be used as an effective therapeutic approach in the clinical setting in the treatment of HTN, hypercholesterolemia, and other cardiovascular risk factors while simultaneously reducing overall medication usage. Patients may find this therapeutic approach preferable to conventional and costly drug therapy. Further replication trials are needed with larger sample sizes, control groups, and other dietary comparison groups.

ACKNOWLEDGMENTS

The authors thank Garden Kitchen in Houston for providing the food used in this study.

Conflicts of interest

The authors declare no potential conflicts of interest.

ORCID

Rami S. Najjar  <http://orcid.org/0000-0001-5348-3008>

REFERENCES

- Heidenreich PA, Trogdon JG, Khavjou OA, et al. Forecasting the future of cardiovascular disease in the United States: a policy statement from the American Heart Association. *Circulation*. 2011;123:933–944.
- Heron M, Anderson RN. Changes in the leading cause of death: recent patterns in heart disease and cancer mortality. *NCHS Data Brief*. 2016;254:1–8.
- Institute of Medicine Committee on a National Surveillance System for Cardiovascular and Select Chronic Diseases. Cardiovascular disease. In: *A Nationwide Framework for Surveillance of Cardiovascular and Chronic Lung Diseases*. Washington, DC: National Academies Press; 2011:19–32.
- Muntner P, Levitan EB, Brown TM, et al. Trends in the prevalence, awareness, treatment and control of high low density lipoprotein-cholesterol among United States adults from 1999–2000 through 2009–2010. *Am J Cardiol*. 2013;112:664–670.
- Nwankwo T, Yoon SS, Burt V, et al. Hypertension among adults in the United States: National Health and Nutrition Examination Survey, 2011–2012. *NCHS Data Brief*. 2013;133:1–8.
- Kesselheim AS, Avorn J, Sarpatwari A. The high cost of prescription drugs in the United States: origins and prospects for reform. *JAMA*. 2016;316:858–871.
- Leaman H, Jackson PR. What benefit do patients expect from adding second and third antihypertensive drugs? *Br J Clin Pharmacol*. 2002; 53:93–99.
- Lytsy P, Westerling R. Patient expectations on lipid-lowering drugs. *Patient Educ Couns*. 2007;67:143–150.
- Trewby PN, Reddy AV, Trewby CS, et al. Are preventive drugs preventive enough? A study of patients' expectation of benefit from preventive drugs. *Clin Med (Lond)*. 2002;2:527–533.
- Berkow SE, Barnard N. Vegetarian diets and weight status. *Nutr Rev*. 2006;64:175–188.

- Yokoyama Y, Nishimura K, Barnard ND, et al. Vegetarian diets and blood pressure: a meta-analysis. *JAMA Intern Med*. 2014;174:577–587.
- Le LT, Sabaté J. Beyond meatless, the health effects of vegan diets: findings from the Adventist cohorts. *Nutrients*. 2014;6:2131–2147.
- Fraser G, Katuli S, Anousheh R, et al. Vegetarian diets and cardiovascular risk factors in black members of the Adventist Health Study-2. *Public Health Nutr*. 2015;18:537–545.
- Tonstad S, Butler T, Yan R, et al. Type of vegetarian diet, body weight, and prevalence of type 2 diabetes. *Diabetes Care*. 2009;32:791–796.
- Dinu M, Abbate R, Gensini GF, et al. Vegetarian, vegan diets and multiple health outcomes: a systematic review with meta-analysis of observational studies. *Crit Rev Food Sci Nutr*. 2017;57:3640–3649.
- Tuso PJ, Ismail MH, Ha BP, et al. Nutritional update for physicians: plant-based diets. *Perm J*. 2013;17:61–66.
- Kreuter MW, Chheda SG, Bull FC. How does physician advice influence patient behavior? Evidence for a priming effect. *Arch Fam Med*. 2000;9:426–433.
- Semlitsch T, Jeitler K, Berghold A, et al. Long-term effects of weight-reducing diets in people with hypertension. *Cochrane Database Syst Rev*. 2016;3:CD008274.
- Hage FG. C-reactive protein and hypertension. *J Hum Hypertens*. 2014;28:410–415.
- Kapil V, Khambata RS, Robertson A, et al. Dietary nitrate provides sustained blood pressure lowering in hypertensive patients: a randomized, phase 2, double-blind, placebo-controlled study. *Hypertension*. 2015;65:320–327.
- Gröber U, Schmidt J, Kisters K. Magnesium in prevention and therapy. *Nutrients*. 2015;7:8199–8226.
- Haddy FJ, Vanhoutte PM, Feletou M. Role of potassium in regulating blood flow and blood pressure. *Am J Physiol Regul Integr Comp Physiol*. 2005;290:R546–R552.
- Bazzano LA. Effects of soluble dietary fiber on low-density lipoprotein cholesterol and coronary heart disease risk. *Curr Atheroscler Rep*. 2008;10:473–477.
- Ras RT, Geleijnse JM, Trautwein EA. LDL-cholesterol-lowering effect of plant sterols and stanols across different dose ranges: a meta-analysis of randomised controlled studies. *Br J Nutr*. 2014;112:214–219.
- Nagasako-Akazome Y, Kanda T, Ohtake Y, et al. Apple polyphenols influence cholesterol metabolism in healthy subjects with relatively high body mass index. *J Oleo Sci*. 2007;56:417–428.
- Clarke R, Frost C, Collins R, et al. Dietary lipids and blood cholesterol: quantitative meta-analysis of metabolic ward studies. *BMJ*. 1997;314:112–117.
- Monnier L, Colette C. Contributions of fasting and postprandial glucose to hemoglobin A1c. *Endocr Pract*. 2006;12(suppl 1):42–46.
- Macknin M, Kong T, Weier A, et al. Plant-based, no-added-fat or American Heart Association diets: impact on cardiovascular risk in obese children with hypercholesterolemia and their parents. *J Pediatr*. 2015;166:953–959.e1–3.
- Bloomer RJ, Kabir MM, Canale RE, et al. Effect of a 21-day Daniel Fast on metabolic and cardiovascular disease risk factors in men and women. *Lipids Health Dis*. 2010;9:94.
- Jenkins DJ, Kendall CW, Popovich DG, et al. Effect of a very-high-fiber vegetable, fruit, and nut diet on serum lipids and colonic function. *Metabolism*. 2001;50:494–503.

SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

How to cite this article: Najjar RS, Moore CE, Montgomery BD. A defined, plant-based diet utilized in an outpatient cardiovascular clinic effectively treats hypercholesterolemia and hypertension and reduces medications. *Clin Cardiol*. 2018;41:307–313. <https://doi.org/10.1002/clc.22863>

CLINICAL INVESTIGATIONS

Consumption of a defined, plant-based diet reduces lipoprotein(a), inflammation, and other atherogenic lipoproteins and particles within 4 weeks

Rami S. Najjar¹  | Carolyn E. Moore² | Baxter D. Montgomery^{3,4}

¹Department of Nutrition, Georgia State University, Atlanta, Georgia

²Department of Nutrition and Food Science, Texas Woman's University, Houston, Texas

³University of Texas Health Science Center, Houston, Texas

⁴Montgomery Heart & Wellness, Houston, Texas

Correspondence

Rami S. Najjar, MS, Department of Nutrition, Georgia State University, Atlanta, Georgia.
Email: rnajjar@twu.edu

Funding information

Johnsie and Aubary Montgomery Institute of Medical Education and Research

Background: Lipoprotein(a) [Lp(a)] is a highly atherogenic lipoprotein and is minimally effected by lifestyle changes. While some drugs can reduce Lp(a), diet has not consistently shown definitive reduction of this biomarker. The effect of consuming a plant-based diet on serum Lp(a) concentrations have not been previously evaluated.

Hypothesis: Consumption of a defined, plant-based for 4 weeks reduces Lp(a).

Methods: Secondary analysis of a previous trial was conducted, in which overweight and obese individuals ($n = 31$) with low-density lipoprotein cholesterol concentrations >100 mg/dL consumed a defined, plant-based diet for 4 weeks. Baseline and 4-week labs were collected. Data were analyzed using a paired samples t -test.

Results: Significant reductions were observed for serum Lp(a) (-32.0 ± 52.3 nmol/L, $P = 0.003$), apolipoprotein B (-13.2 ± 18.3 mg/dL, $P < 0.0005$), low-density lipoprotein (LDL) particles (-304.8 ± 363.0 nmol/L, $P < 0.0005$) and small-dense LDL cholesterol (-10.0 ± 9.2 mg/dL, $P < 0.0005$). Additionally, serum interleukin-6 (IL-6), total white blood cells, lipoprotein-associated phospholipase A2 (Lp-PLA2), high-sensitivity c-reactive protein (hs-CRP), and fibrinogen were significantly reduced ($P \leq 0.004$).

Conclusions: A defined, plant-based diet has a favorable impact on Lp(a), inflammatory indicators, and other atherogenic lipoproteins and particles. Lp(a) concentration was previously thought to be only minimally altered by dietary interventions. In this protocol however, a defined plant-based diet was shown to substantially reduce this biomarker. Further investigation is required to elucidate the specific mechanisms that contribute to the reductions in Lp(a) concentrations, which may include alterations in gene expression.

KEYWORDS

general clinical cardiology/adult, lipoproteins, preventive cardiology, vegetarian diet

1 | INTRODUCTION

Lipoprotein(a) [Lp(a)] is an atherogenic lipoprotein structurally similar to low-density lipoprotein cholesterol (LDL-C), although synthesis occurs through independent pathways. Key differences include the linkage of apolipoprotein B100 (Apo-B) to apolipoprotein(a) on the LDL surface.^{1,2} It has been estimated that expression of the genomic region encoding apolipoprotein(a) (LPA gene) accounts for approximately 90% of plasma Lp(a) concentrations.³ Elevated Lp(a) is independently associated with cardiovascular disease,⁴ and the LPA gene

was observed to have the strongest genetic link to cardiovascular disease.⁵ Individuals with Lp(a) plasma concentrations >20 mg/dL have twice the risk of developing cardiovascular disease and approximately 25% of the population may have this plasma concentration.⁶ The mode of action by which Lp(a) exerts its atherogenic effect is likely similar to that of LDL-C, by deposition in the sub-endothelial space and uptake by macrophages mediated via the VLDL receptor.⁷ Lp(a) is particularly atherogenic due to its unique property of being a carrier of oxidized phospholipids, in addition to its higher binding affinity to negatively charged endothelial proteoglycans.⁸ Lp(a) can facilitate

endothelial dysfunction when concentrations are elevated likely due to this effect.⁹

While PCSK9 inhibitors, high dose atorvastatin, ezetimibe and niacin have resulted in significant reductions in Lp(a),^{10–12} lifestyle interventions have not reliably demonstrated reduced Lp(a) to a clinically significant degree. Interestingly, even high saturated fat and high cholesterol diets known to induce hypercholesterolemia have had little influence on plasma Lp(a) concentrations.¹³ Despite the lack of evidence in the literature indicating a relationship between diet and Lp(a) concentrations, a defined, plant-based has not been previously evaluated with respect to its potential effect to reduce Lp(a). Previous investigations have found that a very-high fiber diet comprised of vegetables, fruits and nuts can reduce LDL-C by 33% and Apo-B by 26%,¹⁴ although Lp(a) was not measured. Since such a diet can result in dramatic reductions in LDL-C and Apo-B, secondary analysis of a previously published investigation¹⁵ employing a similar plant-based diet were analyzed to evaluate if Lp(a) could be significantly reduced after 4 weeks among other inflammatory indicators and atherogenic lipoproteins and particles.

2 | METHODS

2.1 | Study population

Participants were subjects of a previous study in which written informed consent was obtained to draw blood for analysis.¹⁵ Laboratory reports for each subject included biomarkers used for clinical purposes, and selected biomarkers are included in the present investigation. The study protocol was approved by the Texas Woman's University Institutional Review Board, Houston.

The study protocol has been previously described.¹⁵ Briefly, all participants were registered new patients of a cardiovascular center and were hypertensive (systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg), had elevated LDL-C (≥ 100 mg/dL) and excess body weight (body mass index ≥ 25 kg/m²) at baseline. Exclusionary criteria included current tobacco use, current drug abuse, excessive alcohol use (>2 glasses of wine or equivalent for men or >1 glass of wine or equivalent for woman), a current cancer diagnosis, an ongoing clinically defined infection, a mental disability that would prevent a participant from following the study protocol, an estimated glomerular filtration rate < 60 mg/dL, current pregnancy or lactation, a hospitalization within the past 6 months, and previous exposure to the nutrition program.

2.2 | Intervention

Participants were instructed to consume a defined, plant-based diet for 4 weeks ad-libitum which included the consumption of foods within a food classification system.¹⁵ These foods fell within food levels 0 to 4b of the food classification system (Table S1, Supporting information). Briefly, excluded were animal products, cooked foods, free oils, soda, alcohol, and coffee. Allowed for consumption were raw fruits, vegetables, seeds, and avocado. Small amounts of raw buckwheat and oats were also permitted. Vitamin, herbal, and mineral

supplements were to be discontinued unless otherwise clinically indicated. All meals and snacks were provided to subjects, although they were free to consume food on their own within food levels 0 to 4b. In addition, subjects were not advised to alter their exercise habits. Adherence was measured daily as previously described¹⁵ with an adherence assessment tool. Participants indicated in writing each day whether they were adherent. Dietary recalls (24-hour) were conducted by a trained nutritionist at baseline and at 4 weeks. Nutrient intake was analyzed by the Nutrition Data System for Research software (University of Minnesota, version 2016). No lipid lowering medications were altered throughout the intervention.

2.3 | Measures

After a 12-hour fast, the following plasma biomarkers were obtained at baseline and after 4-weeks: total cholesterol (Total-C), LDL-C, high-density lipoprotein cholesterol (HDL-C), triglycerides, LDL particles (LDL-P), small-dense low-density lipoprotein cholesterol (sdLDL-C), Apo-B, high-density lipoprotein 2 cholesterol (HDL2-C), apolipoprotein A-1 (Apo A-1), and Lp(a). Additionally, high-sensitivity c-reactive protein (hs-CRP), endothelin, interleukin-6 (IL-6), tumor necrosis factor alpha (TNF- α), lipoprotein-associated phospholipase A2 (Lp-PLA2), myeloperoxidase, fibrinogen, troponin-I, N-terminal pro b-type natriuretic peptide (NT-proBNP), total white blood cell count (WBC), neutrophil count, lymphocyte count, monocyte count, eosinophil count, and basophil count were documented. These specific biomarkers of interest were analyzed by either True Health Diagnostics (Frisco, Texas) or Singulex (Alameda, California) depending on the subject's health insurance. The same company that analyzed the baseline labs for a participant was used for the follow-up labs to ensure consistency.

2.4 | Data analysis

Paired samples t-tests were used for the analysis of biochemical measures at baseline and 4-weeks, and significance was confirmed with non-parametric tests. Significance was determined to be a *P* value less than 0.05. SPSS (version 24) was used for data analysis.

3 | RESULTS

Baseline demographics are indicated in Table 1. Subjects represent a sample that was 81% obese with multiple clinical diagnoses. Two-thirds of subjects were women and 80% were African American.

Adherence to the dietary intervention was approximately 87% over the course of the 4 weeks as measured by the daily adherence assessment tool. Food group consumption is indicated in Table 2 at baseline and 4-weeks. Notably, total fruit consumption increased from 1.3 ± 2.0 servings to 11.8 ± 10.4 servings (808% increase, $P < 0.0005$) and total vegetable consumption increased 2.7 ± 2.0 servings to 16.0 ± 9.2 servings (493% increase, $P < 0.0005$). Additionally, total animal product consumption decreased from 7.9 ± 4.7 servings to 0.4 ± 1.4 servings (95% decrease, $P = 0.001$). The consumption of avocados, dark-green vegetables, deep-yellow vegetables, tomatoes,

TABLE 1 Baseline characteristics and clinical diagnoses

	Participants ^a
<i>n</i>	31
Age (years)	53.4 (32-69)
Sex	
Male	10 (33%)
Female	21 (67%)
Race, ethnicity	
African American	25 (80%)
Hispanic	3 (10%)
White	3 (10%)
Mean BMI (kg/m ²)	37.5 ± 8.3
Overweight (25-29.9 kg/m ²)	6 (19%)
Obesity class 1 (30-34.9 kg/m ²)	6 (19%)
Obesity class 2 (35-39.9 kg/m ²)	10 (33%)
Obesity class 3 (≥40 kg/m ²)	9 (29%)
Current diagnoses	
Coronary artery disease	10 (33%)
Type II diabetes mellitus	8 (27%)
Arthritic condition	7 (23%)
Pre-diabetes	5 (17%)

Abbreviation: BMI, body mass index.

^a Data are mean (range) unless otherwise indicated.

and other vegetables also significantly increased ($P \leq 0.006$). A decreased consumption of white potatoes, fried potatoes, total grains, refined grains, whole grains, added oils, added animal fat, red meat, white meat, eggs, and dairy were also observed ($P \leq 0.027$). The consumption of sweets (5% decrease, $P = 0.90$) and the consumption of nuts/seeds (17% increase, $P = 0.736$) did not significantly change between baseline and 4-weeks.

Body weight, BMI, total cholesterol, LDL-C, HDL-C, and triglycerides (Table 3) were significantly reduced after 4-weeks of the dietary intervention ($P \leq 0.008$). Lp(a) was also significantly reduced (-32.0 ± 52.3 nmol/L, $P = 0.003$). In addition, LDL-P, sdLDL-C, Apo-B, HDL2-C, and Apo A-1 were significantly reduced ($P \leq 0.03$). Of the atherogenic lipoproteins, sdLDL-C had the greatest relative reduction of approximately 30% (Figure 1). Lp(a) reduced 16% which was proportional to the decrease in Total-C, triglycerides and LDL-P.

Of the inflammatory indicators, hs-CRP, IL-6, Lp-PLA2, and fibrinogen significantly decreased ($P \leq 0.004$) (Table 4). The WBC, neutrophil, lymphocyte, monocyte, eosinophil and basophil count also significantly decreased ($P \leq 0.033$). Interestingly, no statistically significant changes were observed for endothelin-1, TNF- α , myeloperoxidase, troponin-I, or NT-proBNP ($P \geq 0.056$) between baseline and 4-weeks.

TABLE 2 Number of food group servings at baseline and 4-weeks^a

Food group	Serving size	Baseline ^b	Final ^b	Change ^c	<i>P</i> ^d
Fruits, total	1/2 cup chopped, 1/4 cup dried or 1 medium piece	1.3 ± 2.0	11.8 ± 10.4	808% (10.5 ± 10.8)	<0.0005
Avocado	1/2 cup chopped	0.1 ± 0.2	0.9 ± 0.9	800% (0.8 ± 0.9)	<0.0005
Vegetables, Total	1/2 cup chopped or 1 cup raw leafy	2.7 ± 2.0	16.0 ± 9.2	493% (13.3 ± 9.2)	<0.0005
Dark-green vegetables	1/2 cup chopped or 1 cup raw leafy	0.7 ± 1	5.2 ± 3.8	643% (4.5 ± 4.0)	<0.0005
Deep-yellow vegetables	1/2 cup chopped	0.2 ± 0.4	1.2 ± 1.1	500% (1.0 ± 1.3)	<0.0005
Tomatoes	1/2 cup chopped	0.4 ± 0.5	1.7 ± 2.4	325% (1.3 ± 2.4)	0.006
Other vegetables	1/2 cup chopped	1.4 ± 1.2	7.9 ± 6.6	464% (6.5 ± 6.3)	<0.0005
White Potatoes ^e	1/2 cup chopped or 1 medium baked potato	0.3 ± 0.7	0.0 ± 0.0	-100% (-0.3 ± 0.7)	0.03
Fried potatoes	1/2 cup chopped or 70 g french fries	0.5 ± 0.9	0.1 ± 0.3	-80% (-0.4 ± 0.9)	0.027
Grains, Total	1 slice of bread or halfcup cooked cereal	5.7 ± 3.5	0.7 ± 0.9	-88% (-5.0 ± 3.6)	<0.0005
Refined grains	1 slice of bread or half cup cooked cereal	3.8 ± 2.7	0.2 ± 0.7	-95% (-3.6 ± 3.0)	<0.0005
Whole grains	1 slice of bread or half cup cooked cereal	1.9 ± 2.6	0.5 ± 0.7	-74% (-1.4 ± 2.7)	0.007
Sweets ^f	4 g of sugar, 1 tbsp honey or 2 tbsp syrup	1.8 ± 2.3	1.7 ± 1.5	-5% (-0.1 ± 2.7)	0.90
Nuts/seeds	1/2 oz	1.2 ± 3.0	1.4 ± 1.6	17% (0.2 ± 3.4)	0.736
Added oils	1 tsp	3.2 ± 3.5	0.1 ± 0.2	-97% (-3.1 ± 3.5)	<0.0005
Added animal fat	1 tsp	1.3 ± 2.3	0.0 ± 0.1	-100% (-1.3 ± 2.3)	0.005
Animal products, Total ^g	1 oz	7.9 ± 4.7	0.4 ± 1.4	-95% (-7.5 ± 5.3)	0.001
Red meat	1 oz	2.1 ± 2.9	0.1 ± 0.2	-95% (-2.0 ± 3.0)	<0.0005
White meat	1 oz	3.9 ± 3.7	0.2 ± 1.1	-95% (-3.7 ± 4.1)	<0.0005
Eggs	1 large egg	0.5 ± 0.7	0.0 ± 0.1	-100% (-0.5 ± 0.7)	0.002
Dairy	1 cup of milk/yogurt or 1.5 oz of cheese	1.5 ± 1.6	0.1 ± 0.3	-93% (-1.4 ± 1.7)	<0.0005

^a Data are for subjects who completed 24-h recalls at both baseline and 4-weeks ($n = 30$).^b Data are listed in serving size and are presented as mean ± SD.^c Data indicated as % change (mean ± SD).^d Paired samples *t*-tests for within-group comparisons of changes from baseline to final values.^e Excludes fried potatoes.^f Includes honey, candy, or other added sugars.^g Excludes added animal fat.

TABLE 3 Atherogenic lipoproteins and particles at baseline and 4-weeks

	Baseline ^a	Final ^a	Change ^b	P ^c
Weight (kg)	108.1 ± 28.6	101.4 ± 26.3	-6% (-6.6 ± 3.6)	<0.0005
BMI (kg/m ²)	37.5 ± 8.3	35.2 ± 7.8	-6% (-2.2 ± 1.1)	<0.0005
Total-C (mg/dL)	216.6 ± 34.2	182.7 ± 29.9	-16% (-33.8 ± 25.9)	<0.0005
LDL-C (mg/dL)	143.0 ± 28.9	118.4 ± 26.4	-17% (-24.6 ± 21.3)	<0.0005
HDL-C (mg/dL)	54.8 ± 9.4	49.5 ± 10.6	-9% (-5.2 ± 6.2)	<0.0005
Triglycerides (mg/dL)	124.1 ± 58.1	104.5 ± 53.6	-16% (-19.6 ± 38.4)	0.008
Lp(a) (nmol/L) ^d	200.7 ± 150.0	168.8 ± 126.7	-16% (-32.0 ± 52.3)	0.003
Apo-B (mg/dL)	115.2 ± 24.5	101.9 ± 17.7	-11% (-13.3 ± 18.3)	<0.0005
LDL-P (nmol/L) ^e	1891 ± 586	1586 ± 508	-16% (-305 ± 363)	<0.0005
sdLDL-C (mg/dL)	33.7 ± 11.5	23.7 ± 8.7	-30% (-10.0 ± 9.2)	<0.0005
HDL2-C (mg/dL)	17.4 ± 9.8	15.6 ± 9.9	-10% (-1.8 ± 4.5)	0.030
Apo A-1 (mg/dL)	189.7 ± 150.7	160.2 ± 126.5	-14% (-27.0 ± 19.6)	<0.0005

Abbreviations: Apo A-1, apolipoprotein A-1; Apo-B, apolipoprotein B100; BMI, body mass index; HDL-C, high-density lipoprotein cholesterol; HDL2-C, high-density lipoprotein-2 cholesterol; LDL-C, low-density lipoprotein cholesterol; LDL-P, low-density lipoprotein particles; Lp(a), lipoprotein(a); sdLDL-C, small-dense low-density lipoprotein cholesterol; total-C, total cholesterol.

^a Mean ± SD (n = 31 unless otherwise indicated).

^b Data indicated as % change (mean ± SD).

^c Paired samples t-tests for within-group comparisons of changes from baseline to final values.

^d n = 28 due to premature coagulation of sample (n = 1) and incompatible units (mg/dL) when merging laboratory results (n = 2).

^e n = 29 due to premature coagulation of samples.

4 | DISCUSSION

The consumption of a defined, plant-based diet resulted in a significant reduction in Lp(a) after 4 weeks; thus, the study hypothesis was accepted. The reduction in Lp(a) was profound and is one of the largest reductions due to lifestyle reported in the literature. The magnitude of change was comparable to other leading medical therapies, such as niacin (~20% reduction) and PCSK9 inhibitors (~25% reduction).¹² It is important to note that this dietary intervention rapidly reduced Lp(a) by 16% in only 4 weeks, whereas shorter duration

niacin and PCSK9 inhibitor drug trials typically lasted 8 to 12 weeks. It should also be noted that niacin may reduce inflammation, such as hs-CRP, by 15% after 3 months, although PCSK9 inhibitors do not.^{16,17} After 4 weeks, the dietary intervention reduced hs-CRP by 30.7%. In addition, IL-6, Lp-PLA2, fibrinogen, and white blood cells were significantly reduced, as were sdLDL-C, LDL-P, and Apo-B, all of which represent a systemic, cardio-protective effect.¹⁸⁻²⁴ Thus, the use of this single dietary approach in the clinical setting, vs multiple drug therapy, may be an appropriate tool in treating complex patients with a myriad of elevated CVD-related biomarkers.

Elevated Apo A1, HDL-C, and HDL2-C are associated with reduced cardiovascular disease risk.^{24,25} While these HDL fractions were significantly reduced in this trial, this is a common phenomenon observed when consuming plant-based diets. A systematic review and meta-analysis of plant-based observational and clinical trials found that while HDL-C was significantly reduced compared to those consuming non-vegetarian diets, LDL-C and total-C were also reduced.²⁶ Despite reductions in HDL-C, those who consumed plant-based diets had a 25% reduced incidence of ischemic CVD compared with non-vegetarian counterparts.²⁷

Lp(a) concentrations in the present study represent a high-risk population.²⁸ This may be explained by the higher proportion of African Americans in this sample, as African Americans may have higher Lp(a) concentrations compared with Caucasians.²⁹ An evaluation of 532 359 patients found that an Lp(a) concentration > 50 mg/dL was common among patients.³⁰ This range roughly corresponds to the mean nmol/L Lp(a) concentration observed in the present study.

4.1 | Effect of weight loss on plasma Lp(a) concentrations

An energy restricted diet was found to independently reduce serum Lp(a) in those with baseline concentrations >20 mg/dL, but not <20 mg/dL.³¹ Further studies have found that weight loss may not

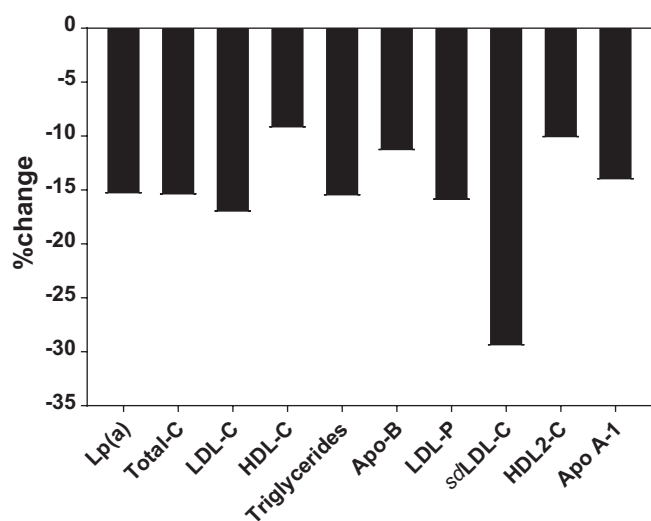


FIGURE 1 Percent change of atherogenic lipoproteins and particles from baseline to 4-weeks. All variable changes indicated are significant ($P < 0.05$). Lp(a), lipoprotein(a); Total-C, total cholesterol; LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; Apo-B, apolipoprotein B100; LDL-P, low-density lipoprotein particles; sdLDL-C, small-dense low-density lipoprotein cholesterol; HDL2-C, high-density lipoprotein-2 cholesterol; Apo A-1, apolipoprotein A-1

TABLE 4 Inflammatory and other cardiovascular indicators at baseline and 4-weeks

	Baseline ^a	Final ^a	Change ^b	P ^c
hs-CRP (mg/dL)	7.8 ± 6.4	5.4 ± 4.7	-30.7% (-2.4 ± 3.7)	0.001
Endothelin (pg/mL) ^d	2.2 ± 0.7	2.2 ± 0.8	0% (0.0 ± 0.7)	0.916
IL-6 (pg/mL) ^d	2.6 ± 1.4	2.0 ± 1.0	-23.1% (-0.6 ± 1.0)	0.001
TNF-α (pg/mL) ^d	2.0 ± 0.9	2.2 ± 0.9	10.0% (0.2 ± 0.6)	0.096
Lp-PLA ₂ (ng/mL) ^d	252.3 ± 136.3	210.7 ± 119.1	-16.4% (-41.6 ± 64.6)	0.001
Myeloperoxidase (pmol/L) ^e	124.1 ± 58.1	104.5 ± 53.6	-23.0% (-28.5 ± 66.1)	0.056
Fibrinogen (mg/dL) ^f	561.4 ± 112.2	530.1 ± 102.9	-5.6% (-31.3 ± 50.7)	0.004
NT-proBNP (pg/mL) ^d	65.2 ± 71.2	69.4 ± 75.9	6.2% (4.1 ± 23.2)	0.337
Total WBC (K/μL) ^d	6.3 ± 2.0	4.8 ± 1.3	-22.2% (-1.4 ± 1.1)	<0.0005
Neutrophils (K/μL) ^d	3.5 ± 1.4	2.5 ± 0.9	-28.6% (-1.0 ± 0.8)	<0.0005
Lymphocytes (K/μL) ^d	1.9 ± 0.7	1.6 ± 0.6	-15.8% (-0.3 ± 0.4)	<0.0005
Monocytes (K/μL) ^d	0.46 ± 0.12	0.38 ± 0.09	-15.2% (-0.07 ± 0.1)	<0.0005
Eosinophils (K/μL) ^d	0.18 ± 0.11	0.15 ± 0.11	-16.6% (-0.03 ± 0.07)	0.033
Basophils (K/μL) ^d	0.029 ± 0.016	0.024 ± 0.015	-17.2% (-0.005 ± 0.010)	0.016

Abbreviations: hs-CRP, high-sensitivity c-reactive protein; IL-6, interleukin-6; Lp-PLA₂, lipoprotein-associated phospholipase A2; NT-proBNP, N-terminal pro b-type natriuretic peptide; TNF-α, tumor necrosis factor-alpha; WBC, white blood cells.

^a Mean ± SD (n = 31 unless otherwise indicated).

^b Data indicated as % change (mean ± SD).

^c Paired samples t-tests for within-group comparisons of changes from baseline to final values.

^d n = 30 due to premature coagulation of samples.

^e n = 25 due to premature coagulation of samples.

^f n = 27 due to premature coagulation of samples.

independently reduce Lp(a) concentrations. A pooled analysis of cohorts found that as weight loss ensued, Lp(a) concentrations surprisingly increased.³² Baseline Lp(a) concentrations on average between the four cohorts analyzed were approximately 40 mg/dL, well above the >20 mg/dL threshold reported in the initial study.³¹ Other investigations examining the effect of weight loss on Lp(a) concentration have not demonstrated a relationship between these two variables.^{33,34} Interestingly, the emphasis on consuming plant-based foods, even with a calorie restricted diet, did not result in Lp(a) reductions compared with a calorie restricted red meat centered diet.³⁵ The plant-centered diet in this trial³⁵ still contained a significant number of calories derived from animal-based sources in addition to processed plant foods. Also, both diets contained similar quantities of dietary fiber, a measure of plant-food intake. Based on these weight loss trials, Lp(a) concentration is likely not influenced by weight reduction.

4.2 | Effect of diet on plasma Lp(a) concentrations

Other trials using diets emphasizing plant-based foods have not demonstrated similar results. A low-fat and low-saturated fat diet with an increased intake of fruits and vegetables interestingly increased Lp(a) concentrations.³⁶ Subjects consumed four to five servings of fruits or berries and five to six servings of vegetables daily for 5 weeks and all food was provided. It is important to note that subjects still consumed animal products throughout the intervention³⁶ which included dairy products and lean meats. The fiber content (40 g vs 51 g in the present study) was not as high as would be expected when consuming a higher quantity of plant-foods, and the number of fruits and vegetables did not meet the levels observed in the present study (11.8 servings of fruits and

16 servings of vegetables). Based on this data, it is probable that exclusively increasing fruit and vegetable intake is not sufficient to elicit reduced Lp(a) concentrations.

It has also been reported that a low-carbohydrate, high-fat diet (45% carbohydrate, 40% fat) may have a favorable impact on Lp(a) concentrations compared with a high-carbohydrate, low-fat diet (65% carbohydrate, 20% fat), although it is unclear as to what precisely was consumed on either of these diets.³⁷ In addition, the differences were small, as only a 2.17 mg/dL difference was observed between both groups, and baseline Lp(a) concentrations were <20 mg/dL. The Omni Heart Trial also found that replacing calories from carbohydrates and protein with unsaturated fats produced a smaller increase in Lp(a) comparatively, but both diets still elicited increased plasma Lp(a) compared with baseline. The differences between groups were also small at the end of the intervention (<4 mg/dL difference).³⁸

In individuals with low baseline Lp(a) concentrations (approximately 5.5 mg/dL), the consumption of copious saturated fat, cholesterol (derived from egg consumption) and polyunsaturated fat did not influence Lp(a) concentrations.¹³ Carbohydrate intake was low in this trial as well (39% to 46% carbohydrate as a percent of energy). While fat consumption does not appear to influence serum Lp(a) concentrations in the fasting state, a variety of fats may significantly increase postprandial, transient plasma Lp(a) concentrations over the course of 8 hours.³⁹ Investigators found that linoleic, oleic, palmitic, and stearic acid all resulted in significant transient increases in Lp(a) concentrations which closely tied to a proportional increase in triacylglycerol concentrations. While saturated fats, stearic acid and palmitic acid, appeared to have the greatest increase in serum Lp(a) compared with oleic acid and linoleic acid, this differing response did not reach statistical significance.

4.3 | Mechanisms contributing to reduced plasma Lp(a)

The observed reduction in Lp(a) in the present study may be due to decreased hepatic synthesis of apolipoprotein(a) and Apo-B. This may be in part due to decreased expression of the LPA gene. Since the LPA gene is almost exclusively expressed in the liver,⁴⁰ hepatic influences, including the production of *hs*-CRP and inflammatory cytokines, such as IL-6, may upregulate LPA gene expression.⁴¹ Indeed, those with inflammatory conditions may have increased Lp(a) concentrations compared with healthy controls.⁴²

Current data in our plant-based study supports this hypothesis, as reduced *hs*-CRP and IL-6 was observed. In contrast, previous studies utilizing plant-centered diets to reduce Lp(a) were unsuccessful, as animal products were still substantially consumed.^{35,36} Animal-based foods, including lean meat, can induce a postprandial inflammatory response, including increased *hs*-CRP and IL-6.⁴³ Pooled data of those consuming non-vegan, plant-based diets have shown reduced *hs*-CRP and IL-6,⁴⁴ although to a lesser extent compared with the present study (*hs*-CRP: -0.55 mg/dL vs -2.42 mg/dL, IL-6: -0.25 pg/mL vs -0.64 pg/mL). The elimination of animal products and processed foods completely on a defined, plant-based diet may be a more prudent dietary strategy to avoid potential fluctuations in inflammation. Thus, the fact that there were only minimally processed plant foods consumed during this dietary intervention may account for the observed reduction in serum Lp(a) concentrations that may be associated with reduced LPA gene expression. Further mechanistic research is needed to confirm this hypothesis.

4.4 | Strengths and limitations

The high dietary adherence and provision of all food to subjects supports the conclusion that the intervention likely fully accounted for the observed biochemical changes among the subjects. Furthermore, the study took place in an outpatient clinical setting with established patients providing a real-world example of a standard clinical practice. This study provides a model for the implementation of this intervention across other medical practices. In contrast, a limitation in the design of this study was the lack of a control group and the small sample size. A larger sample size and a control group would be needed to strengthen a causal relationship.

5 | CONCLUSION

A defined, plant-based diet has a favorable impact on Lp(a) and other atherogenic lipoproteins and particles. Lp(a) concentration was previously thought to be only minimally altered by lifestyle interventions. In this study, however, a defined plant-based diet resulted in a substantial reduction in Lp(a) in only 4 weeks. Further investigations are warranted to elucidate the specific mechanisms that contribute to reduced Lp(a) concentrations, which may include alterations in LPA gene expression mediated via hepatic inflammation.

ACKNOWLEDGMENTS

We would like to thank The Garden Kitchen (Houston, Texas) for providing the food to the subjects. This study was funded by the Johnnie and Aubrey Montgomery Institute of Medical Education and Research.

Conflict of interest

The authors declare no potential conflicts of interest.

ORCID

Rami S. Najjar  <http://orcid.org/0000-0001-5348-3008>

REFERENCES

1. Gaubatz JW, Chari MV, Nava ML, Guyton JR, Morrisett JD. Isolation and characterization of the two major apoproteins in human lipoprotein. *J Lipid Res.* 1987;28(1):69-79.
2. Frank S, Durovic S, Kostner GM. The assembly of lipoprotein Lp(a). *Eur J Clin Invest.* 1996;26:109-114.
3. Boerwinkle E, Leffert CC, Lin J, Lackner C, Chiesa G, Hobbs HH. Apolipoprotein(a) gene accounts for greater than 90% of the variation in plasma lipoprotein(a) concentrations. *J Clin Invest.* 1992;90(1):52-60. <https://doi.org/10.1172/JCI115855>.
4. Emerging Risk Factors Collaboration et al. Lipoprotein(a) concentration and the risk of coronary heart disease, stroke, and nonvascular mortality. *JAMA.* 2009;302:412-423. <https://doi.org/10.1001/jama.2009.1063>.
5. Clarke R, Peden JF, Hopewell JC, et al. Genetic variants associated with Lp(a) lipoprotein level and coronary disease. *N Engl J Med.* 2009;361:2518-2528. <https://doi.org/10.1056/NEJMoa0902604>.
6. Riches K, Porter KE. Lipoprotein(a): cellular effects and molecular mechanisms. *Cholesterol.* 2012;2012:923289.
7. Argraves KM, Kozarsky KF, Fallon JT, Harpel PC, Strickland DK. The atherogenic lipoprotein Lp(a) is internalized and degraded in a process mediated by the VLDL receptor. *J Clin Invest.* 1997;100(9):2170-2181. <https://doi.org/10.1172/JCI119753>.
8. Bergmark C, Dewan A, Orsoni A, et al. A novel function of lipoprotein [a] as a preferential carrier of oxidized phospholipids in human plasma. *J Lipid Res.* 2008;49:2230-2239.
9. Wu HD, Berglund L, Dimayuga C, et al. High lipoprotein(a) levels and small apolipoprotein(a) sizes are associated with endothelial dysfunction in a multiethnic cohort. *J Am Coll Cardiol.* 2004;43:1828-1833. <https://doi.org/10.1016/j.jacc.2003.08.066>.
10. Hernandez C, Francisco G, Ciudin A, et al. Effect of atorvastatin on lipoprotein (a) and interleukin-10: a randomized placebo-controlled trial. *Diabetes Metab.* 2011;37:124-130.
11. Nozue T, Michishita I, Mizuguchi I. Effects of ezetimibe on remnant-like particle cholesterol, lipoprotein (a), and oxidized low-density lipoprotein in patients with dyslipidemia. *J Atheroscler Thromb.* 2010;17(1):37-44.
12. van Capelleveen JC, van der Valk FM, Stroes ES. Current therapies for lowering lipoprotein (a). *J Lipid Res.* 2016;57:1612-1618.
13. Brown SA, Morrisett J, Patsch JR, Reeves R, Gotto AM Jr, Patsch W. Influence of short term dietary cholesterol and fat on human plasma Lp[a] and LDL levels. *J Lipid Res.* 1991;32:1281-1289.
14. Jenkins DJ, Kendall CW, Popovich DG, et al. Effect of a very-high-fiber vegetable, fruit, and nut diet on serum lipids and colonic function. *Metabolism.* 2001;50:494-503.
15. Najjar RS, Moore CE, Montgomery BD. A defined, plant-based diet utilized in an outpatient cardiovascular clinic effectively treats hypercholesterolemia and hypertension and reduces medications. *Clin Cardiol.* 2018;41:307-313. <https://doi.org/10.1002/clc.22863>.
16. Sahebkar A, Di Giosia P, Stamerra CA, et al. Effect of monoclonal antibodies to PCSK9 on high-sensitivity C-reactive protein levels: a meta-analysis of 16 randomized controlled treatment arms. *Br J Clin*

- Pharmacol.* 2016;81(6):1175-1190. <https://doi.org/10.1111/bcp.12905>.
17. Kuvlin JT, Dave DM, Sliney KA, et al. Effects of extended-release niacin on lipoprotein particle size, distribution, and inflammatory markers in patients with coronary artery disease. *Am J Cardiol.* 2006;98:743-745.
 18. Vittos O, Toana B, Vittos A, Moldoveanu E. Lipoprotein-associated phospholipase A2 (LpPLA2): a review of its role and significance as a cardiovascular biomarker. *Biomarkers.* 2012;17:289-302.
 19. Madjid M, Fatemi O. Components of the complete blood count as risk predictors for coronary heart disease: in-depth review and update. *Tex Heart Inst J.* 2013;40:17-29.
 20. Emerging Risk Factors Collaboration et al. C-reactive protein, fibrinogen, and cardiovascular disease prediction. *N Engl J Med.* 2012;367:1310-1320. <https://doi.org/10.1056/NEJMoa1107477>.
 21. Danesh J, Kaptoge S, Mann AG, et al. Long-term interleukin-6 levels and subsequent risk of coronary heart disease: two new prospective studies and a systematic review. *PLoS Med.* 2008;5:e78. <https://doi.org/10.1371/journal.pmed.0050078>.
 22. Cromwell WC, Otvos JD, Keyes MJ, et al. LDL particle number and risk of future cardiovascular disease in the Framingham offspring study—implications for LDL management. *J Clin Lipidol.* 2007;1:583-592.
 23. Austin MA, Breslow JL, Hennekens CH, Buring JE, Willett WC, Krauss RM. Low-density lipoprotein subclass patterns and risk of myocardial infarction. *JAMA.* 1988;260:1917-1921.
 24. Walldius G, Jungner I, Holme I, Aastveit AH, Kolar W, Steiner E. High apolipoprotein B, low apolipoprotein A-I, and improvement in the prediction of fatal myocardial infarction (AMORIS study): a prospective study. *Lancet.* 2001;358:2026-2033. [https://doi.org/10.1016/S0140-6736\(01\)07098-2](https://doi.org/10.1016/S0140-6736(01)07098-2).
 25. Williams PT, Feldman DE. Prospective study of coronary heart disease vs. HDL2, HDL3, and other lipoproteins in Gofman's Livermore cohort. *Atherosclerosis.* 2011;214(1):196-202. <https://doi.org/10.1016/j.atherosclerosis.2010.10.024>.
 26. Yokoyama Y, Levin SM, Barnard ND. Association between plant-based diets and plasma lipids: a systematic review and meta-analysis. *Nutr Rev.* 2017;75:683-698.
 27. Dinu M, Abbate R, Gensini GF, Casini A, Sofi F. Vegetarian, vegan diets and multiple health outcomes: a systematic review with meta-analysis of observational studies. *Crit Rev Food Sci Nutr.* 2017;57:3640-3649. <https://doi.org/10.1080/10408398.2016.1138447>.
 28. Nordestgaard BG, Chapman MJ, Ray K, et al. Lipoprotein(a) as a cardiovascular risk factor: current status. *Eur Heart J.* 2010;31:2844-2853. <https://doi.org/10.1093/eurheartj/ehq386>.
 29. Guyton JR, Dahlen GH, Patsch W, Kautz JA, Gotto AM. Relationship of plasma lipoprotein Lp(a) levels to race and to apolipoprotein B. *Arteriosclerosis.* 1985;5:265-272.
 30. Varvel S, McConnell JP, Tsimikas S. Prevalence of elevated Lp(a) mass levels and patient thresholds in 532 359 patients in the United States. *Arterioscler Thromb Vasc Biol.* 2016;36:2239-2245. <https://doi.org/10.1161/ATVBAHA.116.308011>.
 31. Kiortsis DN, Tzotzas T, Ciral P, et al. Changes in lipoprotein(a) levels and hormonal correlations during a weight reduction program. *Nutr Metab Cardiovasc Dis.* 2001;11:153-157.
 32. Berk KA, Yahya R, Verhoeven AJM, et al. Effect of diet-induced weight loss on lipoprotein(a) levels in obese individuals with and without type 2 diabetes. *Diabetologia.* 2017;60(6):989-997. <https://doi.org/10.1007/s00125-017-4246-y>.
 33. Corsetti JP, Sterry JA, Sparks JD, Sparks CE, Weintraub M. Effect of weight loss on serum lipoprotein(a) concentrations in an obese population. *Clin Chem.* 1991;37:1191-1195.
 34. Woodard GA, Peraza J, Bravo S, Toplosky L, Hernandez-Boussard T, Morton JM. One year improvements in cardiovascular risk factors: a comparative trial of laparoscopic roux-en-Y gastric bypass vs. adjustable gastric banding. *Obes Surg.* 2010;20:578-582. <https://doi.org/10.1007/s11695-010-0088-0>.
 35. Yamashita T, Sasahara T, Pomeroy SE, Collier G, Nestel PJ. Arterial compliance, blood pressure, plasma leptin, and plasma lipids in women are improved with weight reduction equally with a meat-based diet and a plant-based diet. *Metabolism.* 1998;47:1308-1314. [https://doi.org/10.1016/S0026-0495\(98\)90297-9](https://doi.org/10.1016/S0026-0495(98)90297-9).
 36. Silaste ML, Rantala M, Alfthan G, et al. Changes in dietary fat intake alter plasma levels of oxidized low-density lipoprotein and lipoprotein. *Arterioscler Thromb Vasc Biol.* 2004;24:498-503.
 37. Faghihnia N, Tsimikas S, Miller ER, Witztum JL, Krauss RM. Changes in lipoprotein(a), oxidized phospholipids, and LDL subclasses with a low-fat high-carbohydrate diet. *J Lipid Res.* 2010;51:3324-3330. <https://doi.org/10.1194/jlr.M005769>.
 38. Haring B, von Ballmoos MC, Appel LJ, Sacks FM. Healthy dietary interventions and lipoprotein (a) plasma levels: results from the Omni heart trial. *PLoS One.* 2014;9:e114859.
 39. Tholstrup T, Samman S. Postprandial lipoprotein(a) is affected differently by specific individual dietary fatty acids in healthy young men. *J Nutr.* 2004;134:2550-2555.
 40. McLean JW, Tomlinson JE, Kuang WJ, et al. cDNA sequence of human apolipoprotein(a) is homologous to plasminogen. *Nature.* 1987;330(6144):132-137. <https://doi.org/10.1038/330132a0>.
 41. Müller N, Schulte DM, Türk K, et al. IL-6 blockade by monoclonal antibodies inhibits apolipoprotein (a) expression and lipoprotein (a) synthesis in humans. *J Lipid Res.* 2015;56:1034-1042.
 42. Missala I, Kassner U, Steinhagen-Thiessen E. A systematic literature review of the association of lipoprotein(a) and autoimmune diseases and atherosclerosis. *Int J Rheumatol.* 2012;2012:480784-480710. <https://doi.org/10.1155/2012/480784>.
 43. Arya F, Egger S, Colquhoun D, Sullivan D, Pal S, Egger G. Differences in postprandial inflammatory responses to a 'modern' v. Traditional meat meal: a preliminary study. *Br J Nutr.* 2010;104(05):724-728. <https://doi.org/10.1017/S0007114510001042>.
 44. Eichelmann F, Schwingshackl L, Fedirko V, Aleksandrova K. Effect of plant-based diets on obesity-related inflammatory profiles: a systematic review and meta-analysis of intervention trials. *Obes Rev.* 2016;17(11):1067-1079. <https://doi.org/10.1111/obr.12439>.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

How to cite this article: Najjar RS, Moore CE, Montgomery BD. Consumption of a defined, plant-based diet reduces lipoprotein(a), inflammation, and other atherogenic lipoproteins and particles within 4 weeks. *Clin Cardiol.* 2018; 1-7. <https://doi.org/10.1002/clc.23027>

MOCO employees should not be put under a mandatory covid vaccine dictate. We need to keep our great county emergency, firefighters, & police personnel. If such a mandate is put in place, we will lose them to other counties. Medical decisions should only be made between employees and their doctors—certainly not politicians! There are other alternatives in dealing with covid such as testing, natural immunity (which is far greater than any of the Covid shots), and Ivermectin (which eradicated covid in southern India). On the morning news, they stated that MOCO is one of the most covid vaccinated counties in the country. Let's move on and also catch up with the rest of the counties in MD and get rid of the mask mandate.

Constantine Tseronis

I fully support the vaccine mandate for all Montgomery County employees and in particular for the police and all other public safety employees. It is ironic that any public safety employees and their unions oppose this mandate, I guess their definition of public safety does not include public health. If anything, those involved in public safety should be held to a higher standard of public health compliance given their mission and interaction with the public.

The arguments in the joint statement of the three unions opposed to the mandate are ridiculous. To essentially say that the council cannot enact public health measures to protect its citizens in a crisis but must negotiate through collective bargaining is totally absurd. And to attack the sponsors of this bill as hiding in their homes while their members serve the public is outrageous and disgusting. The mandate will protect their members, not the opposite. They are not serving the “public faithfully” when they will not comply with common sense public health measures.

County Executive Elrich says the mandate will run the risk of serious consequences meaning staff shortages. The opposite is true since this measure will both protect the health of the staff and as well the public. Nationally time and time again, when faced with a mandate, employees in both the public and the private sector have complied with the mandate with very minor exceptions. It’s unfortunate that for some only a mandate will get them to do the right thing.

The opposition to the mandate stems from either outright ignorance, an inability to analyze and comprehend scientific and medical information, or mindless regurgitation of the misinformation and political nonsense spewed out by FOX News and other right-wing media, as well as to the preposterous assertions of unions of what their rights are under collective bargaining agreements.

I also oppose any religious exemptions for the mandate. I am not aware of any religion that says “Thou shall not vaccinate.” Nevertheless, religious beliefs should not triumph over the need to protect the public health. People are not entitled to public service employment.

Regarding those who assert they have the individual liberty to determine whether to be vaccinated (despite the pandemic), I suggest you ask them, especially men, “do you support the absolute right of a women to get an abortion” to reveal their consistency or more likely hypocrisy on what individual liberty means.

I also suggest that those opposed to the mandate state their medical or scientific qualifications and the medical science supporting their position.

While the testimony of many on this bill may oppose the mandate, I believe the overwhelming majority of Montgomery County citizens support the mandate for all employees with no exception. I have not seen any polls on this matter specifically in Montgomery County but polls in other states and a national one on the Biden Covid Vaccine Mandate all show a large majority in support of vaccine mandates for employees. And Montgomery County is not Alabama!

Joseph P. Corbett

Olney



Fraternal Order of Police
Montgomery County Lodge 35

Phone 301.948.4286 Fax 301.590.0317

Testimony of Lee Holland, President of Fraternal Order of Police Lodge 35

OPPOSITION

Bill 34-21 – Mandating Vaccines for Montgomery County Employees

On behalf of the 1500 active and retired members of Fraternal Order of Police Lodge 35, we oppose Bill 34-21.

Our opposition isn't from being anti-vaccine, as publicly stated by some councilmembers. Instead, we oppose this bill for several reasons: the potential impact to county services; the (again) repeal of collective bargaining rights; the overstepping of the Council's authority into the powers of the Executive; and, the overstepping of the Executive's authority as the employer.

It is no secret that the county has been plagued with recruitment and retention challenges within our police department over the last year. For example, we have lost some 40 sworn officers since July 1, 2020, which does not include the 27 abolished positions during the last budget. In addition, over the last several months, we have seen a precipitous number of resignations, due in part to labor unrest and the political environment in which we find ourselves in our county and state. That dynamic presents additional challenges, given that approximately 25% of our police department is eligible to retire at this very moment. In all, the workforce density presents significant stability and readiness challenges that this county has never faced, and quite frankly, is not prepared to address.

Here is our challenge: Recent polling of Lodge 35's membership shows that approximately 300 officers are considering resigning, retiring, or allowing themselves to be terminated if Bill 34-21 passes. These numbers are real and scare me as a resident of this county. They should scare everyone.

These are staggering statistics, given how seriously our members take being vaccinated, and primarily see being vaccinated as an important public health issue.

As of today, at least 76% of our members have been voluntarily vaccinated against COVID-19. That is one of the highest vaccination rates for a major police department in the region, if not the entire nation. It's incredibly unfortunate that this vaccine has been so politicized – on both sides – and has caused a rift in our police department and in our society. Lodge 35 has encouraged our members to get vaccinated, and have worked to make vaccinations a priority. In fact, back in January, Lodge 35 partnered with the county to stand-up the mass vaccination site for all public safety employees, which was tremendously successful, and which I know saved lives. I'm extremely proud of that.

But there another side to this, which can not be overlooked. Controversial as it is, we also understand and respect the sanctity of each member to make their own health care choices. In fact, we, as their representative, must respect those choices. There are a number of reasons

that people choose not to get vaccinated – some have already had COVID-19, some have underlying medical conditions, some take religion exception, or have some other personal objection. Whatever the basis of their decision is, it is their own decision – and one that should and must be between them, their physician, their families, and their God -- not their employer.

This bill is a dangerous overreach of the Council's authority, and is an intrusion into the province's of the Executive branch. For these reasons, we strongly urge you to oppose Bill 34-21.

MEMORANDUM

November 12, 2021

TO: County Council

FROM: Carlos Camacho, Legislative Analyst
Nicole Rodríguez-Hernández, Legislative Analyst

SUBJECT: Jurisdictional Research on COVID-19 Vaccine Mandate for Employees

As requested by the Council President, Council staff will provide weekly updates on the impacts of COVID-19 vaccine mandates for jurisdictions across the nation, focusing on local government and local institutions. With many vaccine verification deadlines just recently passing and others occurring later this year, data is still being gathered on how the mandates will impact employee retirements, resignations, or terminations due to non-compliance. However, as jurisdictions reach their deadlines, staff will be able to provide additional context on workforce impacts. Council staff will continue to include information from the private and health sectors as well.

The Federal Government¹ announced a [new rule](#) mandating companies with more than 100 employees to require COVID-19 vaccination for their employees or undergo regular testing by January 4, 2022. On November 4, the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) issued an emergency temporary standard (ETS) to enforce the new mandate. The ETS impacts [county governments](#) located in states with OSHA-approved state plans, including Maryland. The County has already implemented a vaccination or weekly-testing requirement.

The table included on pages 2-14 summarizes available information on COVID-19 vaccine mandates for three County agencies² and 27 local and state governments across the nation. Information on the other sectors can be found after the table. Council staff reviewed preliminary data on the implementation and resulting impacts of vaccine mandates. Staff identified a few patterns that have emerged, specifically:

- Many vaccine mandates (at least 13 of the 30 reviewed) have been legally challenged, with some resulting in dismissal (meaning the mandate was upheld) but many still pending litigation;
- Several jurisdictions/institutions (9 out of 30) have extended their verification deadline; and/or provided monetary incentives to increase employee vaccination rates;
- Of the jurisdictions where data is available regarding medical and religious exemption requests, the percentage of employees filing for exemptions ranges from 3 to 12%. Final

¹ Vaccine rates among [U.S. service members](#) vary but hundreds of thousands remain unvaccinated despite compliance deadlines starting in November 2021. Those that remain unvaccinated will be unable to leave their home station. As of [Oct. 28](#), 12,000 Air Force personnel have rejected orders to get vaccinated and will not meet the Pentagon's vaccine deadline—96% of active-duty air force individuals are vaccinated.

² MCG Employee Vaccination Rate by Department: <https://montgomerycountymd.gov/covid19/data/case-counts.html#mcg-vaccinations>

determinations on exemption requests could have a substantial impact on compliance rates in some jurisdictions;

- 10 jurisdictions have shown positive impacts resulting from vaccine mandates, with compliance rates above 89%;
- Montgomery County Public Schools (MCPS), Montgomery College, and Maryland National Capital Park and Planning Commission have all implemented a vaccine mandate.

When reviewing data on vaccine mandates for the healthcare sector, it is important to note the unique impacts of the pandemic on healthcare employees and the subsequent significant staffing shortages, turnovers, and resignations. However, of the reviewed data, the percent of resignations/terminations related to vaccine mandates ranged from 0.2% to 9% (most rates are below 2%, with 9% being an outlier in the reviewed data). Council staff has prepared a graph depicting the known termination/resignation rates for the reviewed institutions (page 15).

Several large private companies have identified extremely high workforce vaccination rates and subsequently extremely low non-compliance/termination rates. The information on page 15 highlights several case studies.

Jurisdictions with Employee COVID-19 Vaccine Mandates Without a Testing Option³⁴

County/ Institution	Full Vaccination Verification Deadline	Exceptions Allowed (Y/N)	Consequences of Non-compliance	Impacts
Montgomery County Agencies				
MCPS	Fully vaccinated by 11/15 (postponed from 10/29)	Yes – medical and religious exemptions	Progressive discipline up to and including termination from MCPS.	- One employee filed a federal lawsuit challenging the mandate/lack of religious exemption. MCPS now allows religious exemption requests. The lawsuit is officially dismissed. - As of Oct. 1, 76% of employees provided proof of vaccination.
Montgomery College	Fully vaccinated by 11/8- employees; Students- 1/7/22	Yes – religious or medical exemptions	Failure to comply may result in progressive disciplinary action in accordance with applicable College policies and procedures.	- As of Oct. 28, 1,600 employees have verified their vaccination status and 45 employees have requested exemptions.

³ List of Counties based on NACo COVID-19 Vaccine Resource Hub - <https://www.naco.org/covid19/vaccine-distribution-plans>

⁴ Of 1,000 employees polled across sectors, [58%](#) of government workers were supportive of a vaccine mandate

				- The College will provide an update next week.
MNCPPC	All non-represented and Fraternal Order of Police employees must be fully vaccinated by 10/31/21. All new hires will be required to be fully vaccinated. An agreement is being reached for MCGEO employees.	Yes – religious or medical exemptions	Employees who fail to comply will receive unpaid leave, will be considered in violation of this policy, and will be subject to discipline, up to and including termination	- UFCW Local 1994 MCGEO has filed an unfair labor practice charge against MNCPPC over the implementation of a separation policy that separates unvaccinated workers from vaccinated colleagues. Almost 90 unvaccinated employees (17%) are now required to work at other worksites in the County. Most affected employees are maintenance staff who work outdoors. - MCGEO has been bargaining with MNCPPC over vaccine protocol for the past few weeks. Approximately, 85% of MCGEO employees are vaccinated.

For more examples of counties, cities, states, federal agencies, and companies who have implemented a COVID-19 vaccine mandate (with or without a weekly testing option), please visit the [NACo Mandate Tracker](#).

Other Cities/Counties/States ^{5,6}				
Allegheny County, PA	All executive branch county employees must show proof of vaccination by 12/1	Unknown.	Noncompliance consequence: termination.	The unions representing county police and corrections officers filed a lawsuit.
Ann Arbor, MI	City employees must be vaccinated by 11/19 (postponed from 11/1)	Yes—exemptions allowed	30 days of unpaid leave and maintained health benefits. Termination after 30 days of noncompliance.	79% of the city's workforce is vaccinated, 80% of the police force is vaccinated.
Athens-Clarke, GA	County employees must be vaccinated by 11/10	Yes—religious exemption	Employees who do not comply with the policy face discipline leading up to termination of employment.	The county is offering \$200 bonuses and 8 hours of paid time off as incentives.
Bucks County, PA	Receive at least one dose or request an exemption by 9/17. Must be fully vaccinated by 10/29	Yes – religious or medical exemptions	Termination of employment	91% of employees have complied with the mandate. No employees have been terminated for noncompliance. 211 medical or religious exemptions were issued. 21 employees have a pending vaccination status- half are on extended leave, the other half have “present circumstances” that do not require immediate vaccination/or an exemption.
Charleston, SC	Employees are required to be fully vaccinated by 10/24.		Unknown	- State legislators have filed almost a dozen bills against vaccine and mask mandates. - Nearly 80 firefighters, police officers, sheriff's deputies and paramedics filed four separate lawsuits against the mandates. A judge denied all of them.

⁵ Primary source: <https://www.naco.org/covid19/vaccine-distribution-plans>

⁶ [Baltimore County and City](#) have instituted vaccine or testing policies for their employees but have not made data available as to the percentage vaccinated. Baltimore Police is the only agency that has made data publicly available, showing that 64% of their employees are vaccinated.

City of Charleston, SC	All employees, volunteers, interns, and agency temps must be fully vaccinated no later than 11/22.	Yes—medical and other limited reasons exemptions	Unknown	<ul style="list-style-type: none"> - More than 40 city employees including dozens of first responders filed a lawsuit against the City. A judge denied the case. - Nearly 10 percent of city of Charleston employees requested an exemption from the new COVID-19 vaccine mandate by the Oct. 4 deadline.
City of North Charleston, SC	All employees, volunteers and interns must be fully vaccinated by 11/5	Yes--religious or medical exemptions	Unknown	<ul style="list-style-type: none"> - Employees filed a lawsuit but a judge denied the case. - As of Oct 7, 59% of city employees are fully vaccinated and 21% have received one shot of the COVID-19 vaccine. Out of 1,077 employees, 8% are "non-compliant" and 12% have asked for an exemption.
City of Rockville, MD	Employees must be fully vaccinated by 11/15	Yes – religious or medical exemptions	Employees who fail to comply will become ineligible to work and will be subject to disciplinary action up to and including termination.	Unknown
Contra Costa County, CA⁷	Fully vaccinated and provide proof of vaccination by 10/4 or have an approved exemption. Health care workers must be vaccinated or have an approved exemption by 9/30	Yes – religious or medical exemptions	Discipline up to and including termination of employment	607/617 exemptions were approved. The religious exemption only requires an employee to explain their feelings in writing. No employees have been fired for not being vaccinated.

Cook County, Ill	Policy effective 8/23. Must be fully vaccinated or submit for an exemption by 10/15	Yes – religious or medical exemptions	Unknown	<ul style="list-style-type: none"> - A judge effectively ruled that the city and the Chicago Police Department’s labor unions must bargain over the city’s COVID-19 vaccine mandate but also told the city it can’t require officers to get vaccinated by year’s end. - Data released by the City shows that 82% of the 87% of employees who have reported their status are fully vaccinated. 73% of CPD employees have reported their vaccine status, 80% of those saying they were vaccinated. - The sheriff’s office has decided to postpone the mandate deadline to give staff more time to get vaccinated. - As of Oct. 28, 28 firefighters and paramedics are on unpaid leave for not complying to vaccine rules.
Denver City/County, CO	Must receive their final dose by 9/15 in order to comply with policy to be fully vaccinated by 9/30	Yes – religious or medical exemptions	Each employer must decide how they will enforce this requirement . Disciplinary action is one of the consequences	<ul style="list-style-type: none"> - As of October 1, 10,704 full-time city workers (or 98.7%) had either been vaccinated or approved for a medical or religious exemption, representing more than a 35% increase in compliance over the last four weeks. - Nearly three dozen first responders have lost their jobs over the city’s vaccine mandate. Additionally, 27 sworn public safety personnel either resigned or retired in response to the vaccine mandate. The department has also issued 55 contemplation of discipline letters for noncompliance with the policy. - The Denver City Council will use \$5 million from the

				city's general fund to give \$400 bonuses to city employees who complied with Denver's COVID-19 vaccine mandate by the Sept. 30 deadline — including those who were granted religious or medical exemptions.
Honolulu, HI	All new and existing City and County employees must be vaccinated by 8/23.	Yes— medical or religious exemption.	Leave of absence and potential eventual termination.	<ul style="list-style-type: none"> - 90% of city workers received at least one dose of the vaccine. Only three of its 13,000 executive branch employees have been terminated for refusing to get vaccinated or comply with weekly testing. Five workers were fired for refusing the vaccine or for failing to fill out vaccine attestation forms. It employs about 10,000 workers. - 86% of Honolulu Police Dept. are vaccinated. No officers or firefighters have been terminated due to non-compliance yet. One officer was placed on leave of absence as they refused the vaccine/did not submit an exemption.
King County, WA	Must receive their final dose by 10/4 in order to comply with policy to be fully vaccinated by 10/18 (extended to 12/2)	Yes – religious or medical exemptions	Termination of employment for failing to meet legal job qualifications	<ul style="list-style-type: none"> - County reached an agreement with its unions over the vaccine mandate for county employees. The agreement extends the date of full vaccination to Dec. 2. - Approximately 450 employees face termination after failing to comply with the vaccination mandate, officials announced on Oct 19. The county-level order applied to more than 14,000 workers, and nearly 97% complied, including those who secured an exemption.

Leon County, FL	Must provide proof of vaccination by 10/1	Yes – religious or medical exemptions	Termination of employment	- The County terminated 14 employees who refused to comply with the vaccine mandate. The Florida Dept of Health fined Leon County \$3.5 million for requiring its 700 employees to be vaccinated. The County is now challenging the fine in court.
Los Angeles County, CA	<ul style="list-style-type: none"> - Policy in effect since 8/4, requiring proof of vaccination by 10/1 - LA City employees have until 12/8 to be fully vaccinated. 	Yes – religious or medical exemptions	Unknown	<ul style="list-style-type: none"> - As of 11/2, 78% of the county's 101,575 current employees are fully vaccinated. Nearly 10% have yet to submit their vaccination status. The sheriff's department has the lowest rate of compliance, with 52% of members fully vaccinated. Over 20% of the 16,070-person department has yet to register to submit a vaccination status - The L.A. County sheriff says he will not enforce the county's vaccine mandate in his agency. - Union representing the L.A. County Sheriff's Department has filed a legal action challenging the vaccine mandate. - Five L.A. County employees are suing alleging the vaccine mandate is unconstitutional - An estimated 3,000 employees of the Los Angeles Police Department are expected to request an exemption. - Nearly 600 Los Angeles County firefighters are suing over the county's vaccine mandate.

Los Angeles County Unified School District	<p>- Employees: Original deadline: 10/15 (two weeks post second dose) Extended deadline: 11/15</p> <p>- Students: Must receive first two doses by Oct. 31 to participate in extracurricular activities.</p> <p>- To return to school in January, the students 12+ must receive a first dose by Nov. 21 and a second dose no later than Dec. 19. Proof of vaccination is required by Jan 10.</p>	Yes — religious or medical exemptions	Original deadline: If the employee has not received their first shot, they would be suspended with pay and not allowed on campus. If they receive the first shot by Oct. 31, they could return to work while they await the second dose. If they refuse to be vaccinated, they will lose their jobs, but will be paid through October.	<p>- Employees: total - 75,000 employees</p> <p>- As of Sept. 27, ~10,000 people had not yet provided evidence of vaccination.</p> <p>- Unknown number of exemption requests.</p> <p>- The School District is already facing a 2,000 employee shortage.</p> <p>- Local 99 union (food service workers, custodians, bus drivers, etc.): 80% of 21,648 members have a record of vaccination.</p> <p>- About 70% of students participating in sports, band and drill had submitted documentation of at least one vaccine dose as of Oct 25. Of 21,295 students, 8,458 were at immediate risk on Oct. 20 of being cut from extracurricular activities. The district has also changed its vaccine mandate extracurricular policy, which no longer applies to middle schools and no longer applies to high school activities that are not sports related.</p> <p>- LA County School District is facing a lawsuit challenging its student vaccine mandate.</p>
Massachusetts State	Vaccination deadline 10/8.	Yes— religious or medical exemptions	Suspension to termination of employment.	<p>- The Governor reported that only a few hundred employees out of 44,000 are facing discipline for not complying with the vaccine policy. He pointed out that around 12,000 people who weren't vaccinated are now vaccinated. 95% of executive-branch employees, including 90% of State Police staff, are in compliance with the COVID vaccine mandate. Less than 4% of employees</p>

				have failed to submit vaccine status or exemption paperwork.
Milwaukee County, WI	Must provide proof of vaccination or submit an exemption by 10/1. Discipline due to non-compliance in effect 10/11	Yes – religious or medical exemptions	<ul style="list-style-type: none"> - Unpaid suspension for up to 10 days; - Consideration of non-compliance as a factor when making promotions decisions, hiring current employees into new positions, or temporary assignments to a higher classification; - Consideration of non-compliance as a factor in salary adjustments; - Ineligible for voluntary overtime or Risk Recognition Pay 	<ul style="list-style-type: none"> - 78% of employees have provided proof of COVID-19 vaccination or received an exemption. - 91% of Milwaukee City employees have complied with the vaccine mandate. - About 4,060 people work for the county, and a little more than 1,000 employees have not turned in vaccine documentation
Multnomah County, OR	Must be fully vaccinated by 10/18	Yes – medical, American With Disabilities Act (ADA), or religious exemptions. Law enforcement officers are also exempt	Termination of employment, which may be rescinded if an employee receives a vaccine.	<ul style="list-style-type: none"> - As of Oct. 13, 92% of employees have been vaccinated. 7% received approved religious/medical exemptions. 73 individuals (or 1.3%) have been notified they will be laid off or terminated without vaccination proof or submitted exemption request. Only 26 of the 73 individuals are full-time employees. Originally, 124 employees received separation notices on Oct. 1, after that 51 individuals received vaccines or an approved exception. - The City and County has stated that they cannot require sheriff's deputies or police officers to get the vaccine based on guidance from the Oregon Health Authority.

New York City, NY	<ul style="list-style-type: none"> - Most employees must have at least once dose by 10/29; mandate expands to remaining employees on 11/1 and 12/1. - Mandate is effective on 11/1 to the entire municipal workforce. Civilian employees of the Department of Correction (DOC) and uniformed members assigned to healthcare settings are also immediately subject to the mandate. Other uniformed members at DOC will be subject to mandate 12/1 	Unknown	<p>City employees will receive an extra \$500 in their paycheck for receiving their first shot at a City-run vaccination site. This benefit will end on 10/29, by which point City employees are required to have proof of at least one dose. Unvaccinated employees will be placed on unpaid leave until they show proof of vaccination.</p>	<ul style="list-style-type: none"> - Department of Education (DOE) and NYC Health and Hospitals (H+H) workers have been subject to vaccination mandates since late September; vaccination rates at DOE and H+H are 96% and 95%, respectively. 34 officers out of 35,000 were placed on unpaid leave on 11/1 when the deadline expired, in addition to 40 civilian NYPD staff out of roughly 17,000. In total, 85 percent of NYPD staff are vaccinated, he added. - Less than 1% of city employees are on leave-without-pay status on 11/11, out of 378,000 employees. Roughly 12,000 had applied for a religious or medical exemption. In total, more than 93% of city employees have been vaccinated and vaccination rates are up across many departments since the mandate went into effect. - The city has also agreed with nine unions over the vaccine mandate, including issues related to exemption requests and leave policies.
Orange County, FL	Must get their first dose of a two-dose regimen by 8/31 and must be fully vaccinated by 9/30, unless otherwise exempt (postponed to 10/31)	Yes - religious, disability-related, or other legally covered reasons. County will engage in impact bargaining with collective bargaining units	Unknown	<ul style="list-style-type: none"> - The Florida Dept of Health has threatened Orange County with fines for mandating the vaccine. - The Mayor stated that discipline for employee non-compliance would be capped at a letter of reprimand. - About 86% of the county's 7,250 employees have received at least one dose but more than 500 firefighter/paramedics are either not vaccinated or are yet to provide proof of vaccination. Firefighters are

				<p>eligible for a day off, plus \$250 for complying.</p> <ul style="list-style-type: none"> - Orange County Fire Rescue battalion chief was fired for refusing to discipline workers who hadn't gotten a COVID-19 vaccine in violation of a requirement for county employees. Almost four dozen Fire Rescue employees, including the Chief have sued the county over its vaccine mandate. 43 employees of Orange County Fire and Rescue have filed a lawsuit due to the vaccine mandate.
Richmond City, VA	Full vaccination -10/1	Yes – religious or medical exemptions	Employees will lose one day of pay in a period for not being vaccinated. Termination possible.	<ul style="list-style-type: none"> - Roughly 80% of Richmond Public Schools employees are fully vaccinated against COVID-19, and 99% of Richmond city employees were “in compliance” with vaccine policy as of Oct. 1. - Richmond School Board voted to halt disciplinary action against school employees who don't comply with the vaccine mandate.
San Diego City/County, CA	Must receive second dose, or first of J&J vaccine, by 10/19 to be fully vaccinated by 11/2 (extended to Dec 1)	Yes – religious or medical exemptions	<ul style="list-style-type: none"> - Vaccinations required as “a condition of continued employment,” but no specification as to how or when employees who decline would lose their jobs. - The City did reverse their claim that employees fired for noncompliance could not be rehired. These employees would be eligible for rehire after proof of vaccination. 	<ul style="list-style-type: none"> - San Diego Police - 65% of officers who responded to a survey said they would consider quitting over vaccine requirements. - Hundreds protested against San Diego City vaccine mandate for first responders who may be fired if they are not vaccinated by 12/1. About 22% of first responders have not been vaccinated. - As of late September, the vaccine mandate increased the vaccination rate from 65% to 69%. The City is still negotiating some of the terms for non-compliance with the unions.

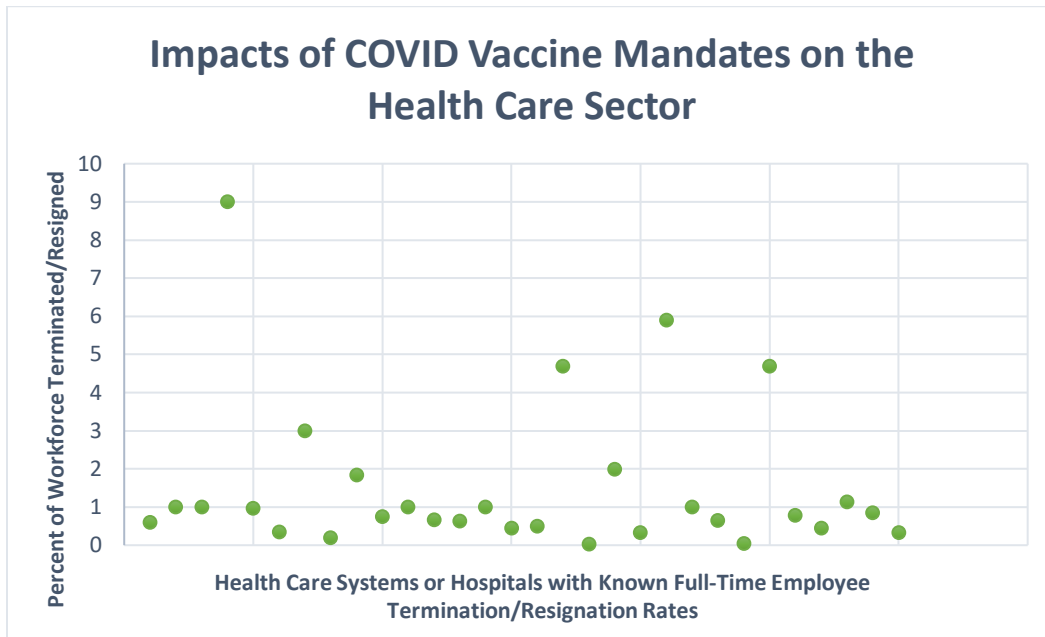
San Francisco County/City, CA	Must report vaccination status by 8/12. Employees working in high-risk or health care settings must receive final dose by 9/30 or have an approved exemption. Those who intermittently work in high-risk settings or are volunteers, interns, or fellows must be fully vaccinated ⁸ by 10/13. All other employees must be fully vaccinated by 11/1.	Yes – religious or medical exemptions	May result in a disciplinary action, or non-disciplinary separation from employment for failure to meet the minimum qualifications of the job	As of Nov. 3 , 97% of employees are vaccinated. Only 2.8% of employees (836) remain unvaccinated. 990 employees requested an exemption—875 exemptions were for religious reasons. HR only approved 22 exemptions (type unknown) so far. Impacts: several public transit lines were suspended due to 90 employees placed on suspension for noncompliance. 70 police officers were also put on leave for noncompliance.
St. Paul, Minnesota	All city employees must be fully vaccinated by 12/31 and provide proof of vaccination by 1/14/22	Yes – religious or medical exemptions	Employees who choose not to get vaccinated won't be allowed to work and may be subject to discipline	Unknown
Washington, DC	All employees, contractors, interns, and volunteers working in-person in a: - DC public school - Public charter school - Private school	Yes – religious or medical exemptions	- All adults who do not timely return a completed vaccination certification, exemption documentation, and/or COVID-19 test result for those with an exemption, shall be excluded from school or childcare facilities and shall not have contact with children (other than their own children) in an	- Impacts of school/childcare related mandate is unknown. - DC implemented a vaccine mandate that went into effect 9/30 for all DC health workers . As of September 30, nearly 2,500 health care workers had failed to comply with the mandate. Nearly 70% of those health care workers not yet vaccinated have

⁸ To be fully vaccinated, 14 days must have passed since an employee received the final dose of a two-shot vaccine or a dose of a one-shot vaccine

	<p>- Parochial school</p> <p>- Child care facility regulated by the Office of State Superintendent of Education (OSSE)</p> <p>Must be vaccinated by 11/1. Also, students aged 12 and older must be fully vaccinated in order to participate in school-based extracurricular athletics.</p>		<p>employment, volunteer, or athletic context until they have received a full course of vaccination or are granted an exemption. They may also be subject to adverse employment actions as specified by their employer.</p> <p>- Student-athletes shall not be permitted to train, compete, or otherwise participate with their school-based teams until they have been vaccinated.</p>	<p>requested religious exemptions. The largest number of exemption requests have come from the D.C. Fire and EMS. About 267 of the agency's 2,000 employees have sought an exemption, with the majority citing their religion. Firefighters whose requests are ultimately denied may face termination. Other health care workers might face having their medical licenses revoked. Those workers who appeal the decision will continue to be subjected to weekly testing. DC also implemented a vaccine mandate for government employees who work in agencies that report to the Mayor, however this mandate has a test-out option.</p>
Washington State	Most state employees and health care workers must be vaccinated by 10/18	Yes—religious or medical exemptions	Non-disciplinary dismissal	<p>- 95%, of approximately 60,000 employees, are verified as vaccinated or have received exemptions. 3% have left their job.</p> <p>- Washington State Patrol announced that 67 troopers, six sergeants, one captain, and 53 civilian employees separated themselves from employment.</p>

Healthcare Sector

A majority of reviewed healthcare institutions had mandate related termination/resignation rates below 2%. Predominantly, the institutions with the outlier high rates of termination/resignation were from hospitals with an extremely small workforce compared to those below 2%. Most of the small hospitals only lost a few workers.



Private Institutions

The National Association of Counties is collecting information on COVID-19 vaccine mandates for companies. Additional case studies can be found on their [website](#).

- At [United Airlines](#), 90% of staff have been vaccinated (of 67,000 employees) and “only a handful have resigned” due to the mandate. The company has begun to [lay off](#) 593 employees nationwide who have refused to become vaccinated against the COVID-19 virus. As of [Oct. 7](#), 99.5% of the employees are vaccinated. The deadline was October 25.
- Corporate campus Walmart staff had to be fully vaccinated by Oct. 4. Those who did not comply were placed on a leave of absence. As of Oct. 8, only a “very small percentage” were in noncompliance.
- Chief Executive Officer of [Raytheon Technologies](#) said that 3 percent of its 125,000-person workforce will likely refuse to get the vaccine before the Dec. 8 deadline. That’s roughly 3,500 people who will be at risk of losing their jobs.
- [Tyson Foods](#) says 96% of employees are vaccinated ahead of the Nov. 1 deadline. The number of vaccinated employees doubled since the mandate was announced.
- [3M corporate](#) is mandating employees are vaccinated by December 8 or face losing their jobs. A protest was held with approximately 150 employees.

- Washington Post will require Post employees to provide proof of vaccination for the return to office.
- [American Airlines and Southwest Airlines](#) announced they will comply with the mandate that employees be vaccinated by 12/8.