BIOTHERAPEUTICS QUARTERLY

Diagnostic and Pharmaceutical News for You and Your Medical Practice

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VOL 55

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BIOTHERAPEUTICS QUARTERLY

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New DRUG APPROVALS

ZELSUVMI™ (berdazimer sodium) Topical Gel

Date of Approval: January 5, 2024
Company: Ligand Pharmaceuticals
Treatment for: Molluscum Contagiosum
Zelsuvmi (berdazimer sodium) is a nitric oxide-releasing agent indicated for the topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older.

WAINUA® (eplontersen) Injection

Date of Approval: December 21, 2023
Company: Ionis Pharmaceuticals and AstraZeneca
Treatment for: Hereditary Transthyretin-Mediated Amyloid Polyneuropathy (ATTRv-PN)
Wainua (eplontersen) is a transthyretin-directed antisense oligonucleotide indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

FILSUVEZ™ (birch triterpenes) Topical Gel - formerly Oleogel-S10

Date of Approval: December 19, 2023
Company: Chiesi Global Rare Diseases
Treatment for: Epidermolysis Bullosa
Filsuvez (birch triterpenes) is a topical birch bark extract indicated for the treatment of wounds associated with dystrophic epidermolysis bullosa and junctional epidermolysis bullosa in adult and pediatric patients 6 months of age and older.

iDOSE®TR (travoprost) Intracameral Implant

Date of Approval: December 13, 2023
Company: Glaukos Corporation
Treatment for: Glaucoma, Open Angle, Glaucoma/Intraocular Hypertension
iDose TR (travoprost intracameral implant) is a long-duration prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT).

CASGEVY™ (exagamglogene autotemcel) Suspension for Intravenous Infusion

Date of Approval: December 8, 2023
Company: Pharmaceuticals and CRISPR Therapeutics
Treatment for: Sickle Cell Disease, Beta Thalassemia
Casgevy (exagamglogene autotemcel) is a CRISPR/Cas9 genome-edited cell therapy for the treatment of sickle cell disease and transfusion-dependent beta-thalassemia.

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#R3099P-450, Strips

(570-0327).....50/box

Controls

#R5H01-1, Level 1

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#R5H01-2, Level 2

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#R5H01-3, Level 3

(125-4036).....ea

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Turning Discovery Into Health

January 9, 2024

Anti-diabetes drugs may reduce the risk of colorectal cancer

At a Glance

- People with diabetes who took drugs called GLP-1 receptor agonists had a lower risk of colorectal cancer compared with those prescribed other diabetes drugs.
- More research is needed to understand how GLP-1 receptor agonists may reduce the risk of colorectal cancer.

People with obesity are at increased risk for many chronic health problems. These include type 2 diabetes and heart disease. Obesity also increases the risk of many common cancers, including colorectal cancer.

Doctors often prescribe medications for people with type 2 diabetes. These include metformin, insulin, and other drugs that help manage blood glucose (blood sugar) levels to reduce long-term complications of diabetes.

Drugs called GLP-1 receptor agonists may have benefits beyond diabetes control and weight loss. *Myskin / Shutterstock*

Over the last two decades, a class of antidiabetic drugs called GLP-1 receptor agonists (GLP-1RAs) has become available for use by people with type 2 diabetes. These drugs—which include Ozempic, Trulicity, Wegovy, and Zepbound—not only help control blood glucose but can also promote weight loss. They reduce appetite both by their impact on the brain and by slowing movement of food through the digestive tract.

Researchers have wondered if these drugs could reduce the risk of other diseases in people with type 2 diabetes. In a new study, funded in part by NIH, a research team led by Drs. Rong Xu and Nathan Berger from Case Western Reserve University and the Case Comprehensive Cancer Center looked at this question for colorectal cancer.

The researchers examined the medical records of more than 1.2 million people with type 2 diabetes who were prescribed antidiabetic medications between 2005 and 2019. The team identified newly diagnosed colorectal cancer cases over a follow-up period of up to 15 years. They then compared the risk of developing colorectal cancer among people who were taking seven different types of antidiabetic drugs.

To compare the drugs, the team matched people between groups by known risk factors for colorectal cancer, other pre-existing medical conditions, age, sex, race, and socioeconomic status. Thousands of such matches were made between each of the drugs. The results were published on December 7, 2023, in *JAMA Oncology*.

The team found that, overall, people with type 2 diabetes who took GLP-1RAs had a lower risk of developing colorectal cancer than those taking the other medications. Those taking GLP-1RAs had a 44% lower risk of developing colorectal cancer than those who took insulin. They had a 25% lower risk than those who took metformin.

This reduced risk was seen whether or not people had obesity or overweight. Among people with excess weight, GLP-1RA users had an even stronger reduction in colorectal cancer risk. This group had a 50% lower risk of developing colorectal cancer than those who took insulin, and a 42% lower risk than those who took metformin.

A smaller but significant reduction in colorectal cancer risk was also seen with the use of GLP-1RAs compared to other antidiabetic drugs for people with obesity or overweight.

"[This] research is critically important for reducing incidence of colorectal cancer in patients with diabetes, with or without overweight and obesity," Berger says.

These findings suggest that GLP-1RAs could be protective against colorectal cancer in people who have type 2 diabetes, regardless of weight. More research is needed to confirm these observations, to determine whether GLP-1RAs can reduce the risk of other types of cancer associated with obesity, and to understand their mechanisms of action.

—by Sharon Reynolds

Related Links

- Intermittent Fasting for Weight Loss in People with Type 2 Diabetes
- Popular Diabetes Drugs Compared in Large Trial
- How Fructose May Contribute to Obesity and Cancer
- Diabetes Control Worsened Over the Past Decade
- The Structures of Receptors Involved in Blood Sugar Control
- Diabetes Increasing in Youths
- Obesity and Cancer
- Colorectal Cancer
- Diabetes

References: GLP-1 receptor agonists and colorectal cancer risk in drug-naive patients with type 2 diabetes, with and without overweight/obesity. Wang L, Wang W, Kaelber DC, Xu R, Berger NA. *JAMA Oncol*. 2023 Dec 7:e235573. doi: 10.1001/jamaoncol.2023.5573. Online ahead of print. PMID: 38060218.

Funding: NIH's National Cancer Institute (NCI), Office of the Director (OD), National Institute on Aging (NIA), and National Institute on Alcohol Abuse and Alcoholism (NIAAA); American Cancer Society; Landon Foundation.

Source: https://www.nih.gov/news-events/nih-research-matters/anti-diabetes-drugs-may-reduce-risk-colorectal-cancer

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1 Brown, H. *Improving the Diagnosis of Vulvovaginitis.* Population Health Management. Vol. 23, suppl 1, 2020

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PREVENTING CHRONIC DISEASE
PUBLIC HEALTH RESEARCH, PRACTICE, AND POLICY
Volume 21, E05 JANUARY 2024

ORIGINAL RESEARCH

The Effect of Disability and Social Determinants of Health on Breast and Cervical Cancer Screenings During the COVID-19 Pandemic

LaShae D. Rolle, MPH[1]; Maurice J. Chery, MD[1]; Michaela Larson, MPH[1]; Melissa Lopez-Pentecost, PhD[2]; Carmen J. Calfa, MD[2]; Matthew P. Schlumbrecht, MD[2,3]; Tracy E. Crane, PhD[1,2]

Accessible Version: www.cdc.gov/pcd/issues/2024/23_0234.htm

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PEER REVIEWED

Summary

What is already known on this topic?

Prior research investigated the effect of disability status and social determinants of health on cancer screenings. Few studies have considered the implications of these factors on breast and cervical cancer screening during health crises such as the COVID-19 pandemic.

What is added by this report?

We compared cancer screening rates among women before (2018) and amid (2020) the COVID-19 pandemic. Women with disabilities and lower income, and women lacking health insurance coverage had reduced odds of being up to date on mammograms and Pap tests, before as well as amid the COVID-19 pandemic.

What are the implications for public health practice?

The findings highlight the critical need for health policies and interventions tailored for people who have disabilities and are socially marginalized, especially during times of health crises, when disparities, including disparities in access to essential preventive screenings, are exacerbated.

Abstract

Introduction

The objective of this study was to examine the effect of disability status and social determinants of health (SDOH) on adherence to breast and cervical cancer screening recommendations during the COVID-19 pandemic.

Methods

We conducted a secondary analysis of the 2018 and 2020 Behavioral Risk Factor Surveillance System (BRFSS) data sets. We defined adherence to screenings according to the US Preventive Services Task Force guidelines for breast and cervical cancer screening. The analysis included respondents assigned female at birth, aged 50 to 74 years (breast cancer screening) or aged 21 to 65 years (cervical cancer screening). We performed logistic regression to evaluate breast and cervical cancer screening adherence, by disability status and SDOH (health insurance coverage, marital status, and urban residency), independently and simultaneously.

Results

Our analysis included 27,526 BRFSS respondents in 2018 and 2020. In 2018, women with disabilities had lower adjusted odds than women without disabilities of being up to date with mammograms (adjusted odds ratio [AOR] = 0.76, 95% CI, 0.63–0.93) and Pap (Papanicolaou) tests (AOR = 0.73; 95% CI, 0.59–0.89). In 2020, among women with disabilities, the adjusted odds of mammogram and Pap test adherence decreased (AOR = 0.69; 95% CI, 0.54–0.89; AOR = 0.59; 95% CI, 0.47–0.75, respectively). In 2018, the adjusted odds of mammogram adherence among rural residents with and without disabilities were 0.83 (95% CI, 0.70–0.98), which decreased to 0.76 (95% CI, 0.62–0.93) in 2020.

Conclusion

The findings of this study highlight the effect of disability status and SDOH on breast and cervical cancer screening rates during the COVID-19 pandemic. Public health strategies that acknowledge and address these disparities are crucial in preparing for future public health crises.

Introduction

Breast cancer is the most prevalent type of cancer among women in the US; an estimated 287,850 cases and 43,250 deaths attributed to breast cancer occur annually (1). Additionally, nearly 13,000 new cases of cervical cancer and 4,000 cervical cancer deaths occur annually (2). Adherence to cervical cancer screening recommendations can substantially mitigate the incidence and death associated with the disease. Similarly, biennial breast cancer screenings can decrease breast cancer mortality by up to 40% (3–5). However, disparities in breast and cervical cancer screening rates and access to health care services persist according to race, ethnicity, and social determinant of health (SDOH), and these disparities were exacerbated during the COVID-19 pandemic (6–9). In 2020, the pandemic led to a reduction or halt in breast and cervical cancer screening services in many parts of the US (7,8,10), and the precise implications arising from these reductions in cancer screening as a result of this global event are inconclusive.

Approximately 61 million adults in the US live with a disability (11). A disability is a condition that impairs normal body function or cognition, restricts activity, and limits participation in societal roles (11). The nature and effect of disabilities, which can be congenital, developmental, injury-related, or associated with other health conditions, are diverse and can affect areas such as vision, movement, thinking, communication, and social relationships (11). Cancer screening uptake among people with disabilities is lower than among people without disabilities (12). Disability status and SDOH can substantially affect breast and cervical cancer screening rates. People with disabilities, particularly those with low socioeconomic status, have lower rates of breast and cervical cancer screening (13). Addressing disparities in cancer screening uptake among people with disabilities and varying socioeconomic circumstances calls for a multilevel, comprehensive approach that goes beyond individual interventions to address the broader SDOH. Interventions, such as tailored education programs, can enhance awareness and understanding of the importance of regular screenings (14). The objective of this study was to fill gaps in knowledge by investigating disparities in adherence to breast and cervical cancer screening among women with disabilities; exploring the effect of SDOH, including health insurance coverage, income, marital status, employment, education, and urban residency, during the COVID-19 pandemic; and assessing the degree of need for tailored interventions to improve access and use of screening services and address health equity.

Methods

We conducted a secondary analysis of data from the 2018 and 2020 Behavioral Risk Factor Surveillance System (BRFSS). BRFSS is an annual, nationwide cross-sectional survey that collects data on risk behaviors, chronic health conditions, and use of preventive services by US residents. In 2018, BRFSS had an overall landline response rate of 53.3% and a cell phone response rate of 43.4% (15), resulting in 437,436 records collected for 2018. In 2020, BRFSS had an overall response rate of 47.9% (16), collecting 401,958 records for the year. The inclusion criteria for our study were based on US Preventive Services Task Force (USPSTF) recommendations for breast cancer screening updated in 2016 (17) and recommendations for cervical cancer screening updated in 2018 (18). For breast cancer screening, our analysis included respondents aged 50 to 74 years assigned female at birth (hereinafter, women); we considered respondents who received a mammogram in the previous 2 years to be up to date with screening. For cervical cancer screening, our analysis included respondents aged 21 to 65 years assigned female at birth (hereinafter, women); we considered respondents who received a Papanicolaou (Pap) test in the previous 3 years to be up to date with screening. We used the weighted calculated variables procedures outlined by BRFSS and applied weight, cluster, and strata variables to obtain population-based estimates and odds ratios (ORs) representative of the general population of US women (19).

Dependent variables

The BRFSS-calculated variables MAM5023 (women aged 50–74 years who had a mammogram in the previous 2 years) and _RFPAP35 (women aged 21–65 years who had a Pap test in the previous 3 years) were the main dependent variables.

Independent variables

Per the guidelines from the Centers for Disease Control and Prevention's "A Data Users' Guide to the Disability Questions," we combined the variables deaf; blind; difficulty concentrating, remembering, or making decisions; difficulty walking or climbing stairs; difficulty dressing or bathing; and difficulty doing errands alone due to a physical, mental, or emotional condition to create the binary (yes/no) variable disability (20). We included race and ethnicity to investigate the intersection of race and ethnicity and screening in the sample. We included the variables health insurance coverage, annual household income, marital status, employment, educational attainment, and urban or rural residence in the multivariate regression models. These variables represent key SDOH, in alignment with the Healthy People 2030 SDOH domains: economic stability (income), education access and quality

(educational attainment), health care access and quality (health insurance coverage), neighborhood and built environment (urban or rural residence), and social and community context (marital status).

Statistical analyses

We first conducted descriptive analyses to characterize the sample of women, categorizing them as either up to date or not on mammograms and Pap tests, by disability status and SDOH. We generated bivariate and multivariable logistic regression models to examine the association between disability status and SDOH (independently and simultaneously) and the odds of being up to date on mammograms and Pap tests. We evaluated SDOH through measures of health insurance coverage, annual household income, marital status, employment, educational attainment, and urban or rural residence. We assessed the odds of women with disabilities being up to date on mammograms and Pap tests, taking into account the influence of SDOH by using a domain statement. All tests were 2-sided, with an α of $< .05$. We used SAS version 9.4 (SAS Institute, Inc) for all statistical analyses.

Results

Of the 27,526 respondents in both years, a substantial majority were current with mammograms and Pap tests in both 2018 and 2020. In 2018, 78.4% (n = 13,138) were up to date on mammograms, and 78.4% (n = 13,067) were up to date on Pap tests. In 2020, 77.8% (n = 8,388) were up to date on mammograms and 77.4% (n = 8,235) on Pap tests. In 2018, 24.6% (4,099 of 16,669) of respondents reported having a disability; in 2020, 22.6% (n = 2,456 of 10,857) of respondents reported having a disability. Among women with disabilities, 72.1% (n = 2,991) were up to date on mammograms in 2018, and 69.6% (n = 1,744) were up to date in 2020. Pap test uptake among women with disabilities was 69.4% (n = 2,915) in 2018 and 66.1% (n = 1,639) in 2020 (Table 1).

In 2018 and 2020, more than 95% of women with health insurance coverage were current with both mammograms and Pap tests. In contrast, among women without health insurance coverage, 3.9% (2018) and 3.4% (2020) were up to date on mammograms and 4.3% (2018) and 4.1% (2020) were up to date on Pap tests. In 2018, by annual household income, women with incomes of $75,000 or more had the highest rates of being up to date on both mammograms (47.7%) and Pap tests (48.0%). Similarly, in 2020, this income bracket had the highest rates (48.6% for mammograms and 49.3% for Pap tests). Married women had consistently higher rates of being up to date on both tests in both years (2018: 69.6% for mammograms, 70.0% for Pap tests; 2020: 70.0% for mammograms, 70.2% for Pap tests). College graduates had the highest rates of being up to date on both mammograms (2018: 35.6%, 2020: 37.6%) and Pap tests (2018: 36.6%, 2020: 38.3%). Additionally, urban residents had higher rates than their rural counterparts in both years for mammograms (2018: 82.8%, 2020: 83.3%) and Pap tests (2018: 83.5%, 2020: 83.3%).

Adjusted model: independent comparison of mammogram and Pap test screening rates based on SDOH and disability status before (2018) vs during COVID-19 (2020)

In 2018, women with disabilities had lower odds than women without disabilities of being up to date on mammograms (AOR = 0.76; 95% CI, 0.63–0.93) and Pap tests (AOR = 0.73; 95% CI, 0.59–0.89). In 2020, these odds decreased to 0.69 (95% CI, 0.54–0.89) for mammograms and 0.59 (95% CI, 0.47–0.75) for Pap tests (Figure 1 and Figure 2). Women without health insurance coverage in 2018 had odds of 0.27 (95% CI, 0.20–0.37) for mammograms and 0.37 (95% CI, 0.27–0.52) for Pap tests, compared with women with health insurance coverage. In 2020, these odds changed to 0.26 (95% CI, 0.18–0.35) for mammogram and 0.42 (95% CI, 0.30–0.58) for Pap tests. In 2018, women with an annual household income of less than $25,000, compared with women with an annual household income of $75,000 or more, had an adjusted odds of 0.54 (95% CI, 0.40–0.73) for mammograms and 0.59 (95% CI, 0.43–0.82) for Pap tests. In 2020, these odds were 0.59 (95% CI, 0.43–0.82) for mammograms and 0.50 (95% CI, 0.36–0.69) for Pap tests. In 2018, married women, compared with women who were not married, had an adjusted odds of 1.12 (95% CI, 0.93–1.36) for mammograms and 1.21 (95% CI, 0.99–1.49) for Pap tests. In 2020, these odds changed to 1.25 (95% CI, 1.01–1.56) for mammograms and 1.18 (95% CI, 0.96–1.45) for Pap tests. Among rural residents, compared with urban residents, the adjusted odds in 2018 were 0.83 (95% CI, 0.70–0.98) for mammograms and 0.76 (95% CI, 0.62–0.93) for Pap tests. In 2020, these odds were 0.76 (95% CI, 0.62–0.93) for mammograms and 0.78 (95% CI, 0.64–0.95) for Pap tests. In 2018, women with some high school education, compared with women who were college graduates, had an adjusted odds of 1.47 (95% CI, 1.00–2.17) for mammograms and 1.61 (95% CI, 1.03–2.53) for Pap tests. These odds changed in 2020 to 1.61 (95% CI, 1.03–2.53) for mammograms and 1.11 (95% CI, 0.68–1.82) for Pap tests. Additionally, in 2018, unemployed women had significantly lower odds than employed women (AOR = 0.78; 95% CI, 0.65–0.95) of being up to date on Pap tests; in 2020, the AOR for Pap tests became nonsignificant (AOR = 1.08; 95% CI, 0.87–1.34).

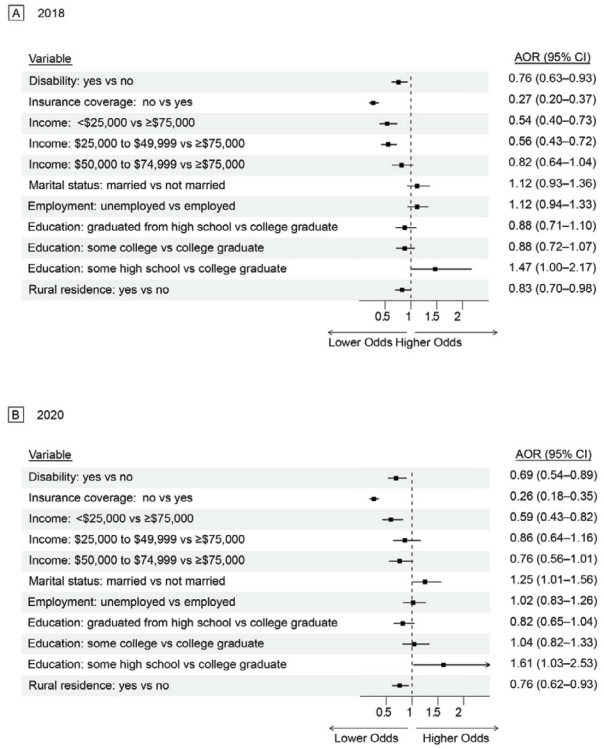

Figure 1. Adjusted odds of being up to date on mammogram screening in A) 2018 and B) 2020 by social determinants of health among all women eligible for screening, Behavioral Risk Factor Surveillance System, 2018 and 2020.

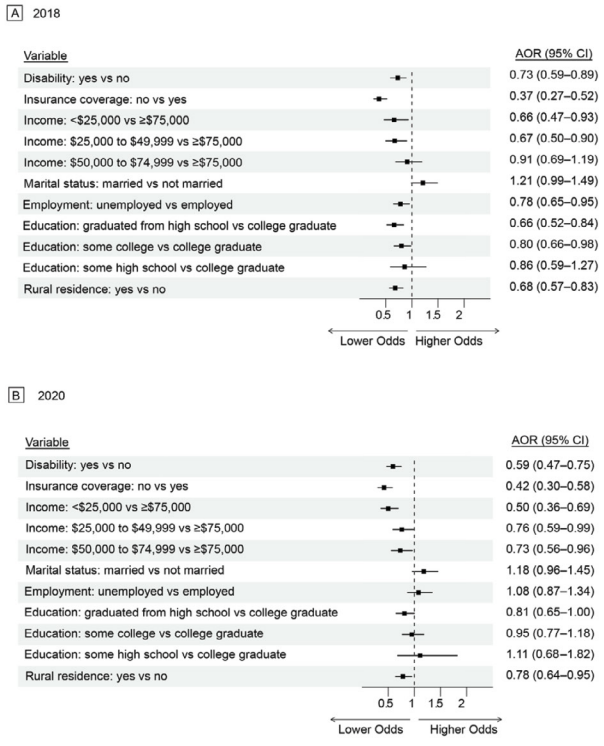

Figure 2. Adjusted odds of being up to date on Pap test screening in A) 2018 and B) 2020 by social determinants of health among all women eligible for screening, Behavioral Risk Factor Surveillance System, 2018 and 2020.

Adjusted model: analysis of SDOH and race and ethnicity among women with disabilities

In 2018, among women with disabilities, the likelihood of being up to date with mammograms was higher among Hispanic (AOR = 2.42; 95% CI, 1.37–4.26) and non-Hispanic Black women (AOR = 2.20; 95% CI, 1.27–3.83) than non-Hispanic White women (Table 2). Income disparities were evident: women with an annual household income of $25,000 to $49,999 had lower odds than women with an annual household income of $75,000 or more of being up to date with mammograms (AOR = 0.47; 95% CI, 0.29–0.74). Compared with non-Hispanic White women with disabilities, Hispanic (AOR = 2.08; 95% CI, 1.16–3.74) and non-Hispanic Black (AOR = 2.04; 95% CI, 1.08–3.87) women with disabilities were more likely to have Pap tests. Women with an annual household income of less than $25,000 had lower odds than women with an annual household income of $75,000 or more of

being up to date with Pap tests (AOR = 0.54; 95% CI, 0.31–0.93). In 2020, non-Hispanic Black women had higher odds for mammograms (AOR = 2.70; 95% CI, 1.40–5.21) and Pap tests (AOR = 2.15; 95% CI, 1.19–3.87) than they did in 2018.

Discussion

Building on existing evidence of how disability status and SDOH influence preventive screening behaviors, our study offers a novel perspective by examining these factors during the COVID-19 pandemic. By analyzing SDOH and disability separately, we aimed to shed light on the unique influence of each on access to preventive care and health outcomes. The pandemic likely heightened or introduced new barriers to use of health care services. Our adjusted models underscored the intricate relationships and complexities of disability status and SDOH in influencing preventive screening behaviors for breast and cervical cancer during the pandemic.

In 2018, SDOH shaped the screening behaviors of women with disabilities. Those earning below $50,000 had lower odds, compared with those earning $75,000 or more, of receiving a Pap test or mammogram, and married women had higher odds than unmarried women of receiving a mammogram. Regardless of the screening type, health insurance access was critical, and its absence hampered rates of receipt.

During the COVID-19 pandemic in 2020, we found shifts in screening dynamics among racial and ethnic minority groups. Racial differences in rates of receipt for mammograms were more pronounced in 2020 than in 2018: the odds of being up to date with screening among non-Hispanic Black women, compared with non-Hispanic White women, were higher in 2020 than in 2018. Although screening rates might be increasing among racial and ethnic minority groups, addressing the broader disparities in breast and cervical cancer outcomes requires a comprehensive approach that encompasses early detection, equitable access to high-quality care, culturally sensitive health care delivery, and ongoing support throughout the cancer care journey. Meanwhile, disparities in being up to date with screening persisted from 2018 to 2020, but with attenuated intensity. The central role of health insurance coverage also persisted, with lack of insurance consistently associated with reduced odds of screening uptake.

We found that mammogram and Pap test screening rates among women with disabilities declined by 2.5 percentage points (from 72.1% to 69.6% for mammograms) and 3.3 percentage points (from 69.4% to 66.1% for Pap tests), respectively, from 2018 to 2020, indicating an exacerbation of disparities based on disability during COVID-19. The finding that women with disabilities had lower odds than the general population of being up to date on breast and cervical cancer screenings before and during the pandemic corroborates previous findings that highlighted challenges in accessing health care services among people with disabilities (13). Similar patterns of health care underutilization have been reported among people with disabilities across a range of preventive services and medical examinations (21,22). This underutilization may be attributed to various factors, such as physical accessibility, communication barriers, and lack of health care provider expertise in managing patients with disabilities; these factors warrant further research (23). Research on disability and health behaviors underscores the effect of these factors on the engagement of people with disabilities in preventive behaviors (24,25). During the COVID-19 pandemic, these factors were most likely intensified.

Interventions need to be tailored to the unique needs and challenges of people with disabilities, encompassing strategies such as individualized communication, physical adjustments, and specialized health care provider training (23). The design of interventions aimed at promoting mammograms and Pap tests among this group must prioritize the accessibility and adaptability of health care facilities and services, especially during a public health crisis.

We examined the relationship between economic factors and mammograms and Pap tests. Women with higher income and health insurance coverage had higher odds of being up to date with screening. Our findings resonate with recent studies indicating financial constraints and lack of health insurance as barriers to mammogram screening (26). Expanding access to affordable health insurance and reducing out-of-pocket costs for preventive services should be prioritized.

Studies by Wong et al and Friedman demonstrated that people with disabilities were more financially affected by the pandemic than their counterparts without disabilities. These financial challenges, including job loss and reductions in income, amplified the existing barriers to preventive health care services. More than half of people with disabilities surveyed reported difficulties in paying for usual household expenses during the pandemic (27). Many people relied on credit cards, loans, or borrowing from friends and family to meet their needs (27). Increased financial hardship among people with disabilities, particularly women, could extend to preventive health services such as mammograms and Pap tests (27,28). Women with disabilities, low income, or lost income may forgo these services, potentially leading to late-stage diagnosis and poorer health outcomes. Our findings, in alignment with previous literature, emphasize the necessity to address the economic barriers influencing health-seeking behaviors and the need for inclusive health care strategies during public health emergencies.

Our research provides a nuanced understanding of how marital status and educational attainment influenced screenings during the pandemic. The observed association between marital status and

adherence to mammograms and Pap tests highlights the crucial role of SDOH in health behaviors. Although we did not find a significant association between educational attainment and odds of being up to date on mammograms or Pap tests in our adjusted model, higher educational attainment has been shown to positively affect health-seeking behaviors in other studies (29). The discrepancy between our findings and previous findings may suggest that the influence of education may interact with other factors in complex ways, requiring further research. Nevertheless, considering the broader evidence linking educational attainment to health-seeking behaviors, public health initiatives should focus on strategies that can appeal to people with lower education levels or people who lack social support. These interventions could be implemented through community-based interventions or partnerships with educational institutions.

Our research uniquely evaluated health care accessibility and use in the context of rural and urban disparities. We found a significant association between urban residency and adherence to mammogram and Pap test screening: the odds of being up to date with mammograms and Pap tests were lower among rural residents than urban residents. Differences in health care access between urban and rural areas may contribute to disparities in adherence to mammograms and Pap test screening (30). Innovative solutions, such as mobile mammography units and telemedicine consultations, can improve access to screening services in rural and underserved areas (31). Novel approaches, such as mail-in self-sampling for cervical cancer screening, can help address accessibility and acceptability issues in this population (32). An evaluation of health care accessibility and use among disabled people during the COVID-19 pandemic is of paramount importance.

Limitations

Our study has several limitations. First is the cross-sectional design of the data set. Although our approach allowed us to generate a snapshot of data at 2 points in time, it inherently precluded the ability to infer causality. Second, our reliance on the BRFSS data set, which uses self-reported data, might have introduced recall bias, response bias, or social desirability bias. Although the BRFSS data set is a robust and widely used resource in public health research, the potential discrepancies in self-reported data versus actual behaviors or status cannot be ignored. Third, we did not test whether changes in being up to date on screening from 2018 to 2020 were significant. Future studies using a longitudinal design and validated self-reported data with objective measures may provide more precise findings and elucidate the causal relationships between disability status, SDOH, and cancer screenings during health crises such as the COVID-19 pandemic.

Conclusion

Our study reaffirms the significance of SDOH in mammogram and Pap test screening behaviors. The effect of disability status, income, health insurance coverage, marital status, educational attainment, and urban or rural residence on screening adherence for breast and cervical cancer during the COVID-19 pandemic has magnified pre-existing health care challenges and disparities. Considering the unique circumstances brought about by the pandemic, it is crucial to design interventions that address the barriers imposed by sociodemographic factors. By enhancing accessibility, affordability, and awareness of screenings, especially among populations who lack access to health care, we could mitigate the detrimental effects of a health care crisis like the pandemic on breast and cervical cancer screening rates. A tailored approach could contribute to reducing disparities and improving breast cancer outcomes.

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Tables

Table 1. Sample Characteristics by Mammogram and Pap Test Uptake in 2018 (n = 16,669) and 2020 (n = 10,857), BRFSS

Variable	Up to date on mammogram, no. (%[a])				Up to date on Pap test, no. (%[a])			
	2018		2020		2018		2020	
	Yes	No	Yes	No	Yes	No	Yes	No
Overall	13,138 (78.4)	3,531 (21.6)	8,388 (77.8)	2,469 (22.2)	13,067 (78.4)	3,602 (21.6)	8,235 (77.4)	2,622 (22.6)
Disability								
Yes	2,991 (72.1)	1,108 (27.9)	1,744 (69.6)	712 (30.4)	2,915 (69.4)	1,184 (30.6)	1,639 (66.1)	817 (33.9)
No	10,147 (80.7)	2,423 (19.3)	6,644 (80.4)	1,757 (19.6)	10,152 (81.5)	2,418 (18.5)	6,596 (81.0)	1,805 (19.0)
Health insurance coverage								
Yes	12,715 (96.1)	3,101 (85.6)	8,131 (96.6)	2,150 (85.9)	12,595 (95.7)	3,221 (87.1)	7,939 (95.9)	2,342 (88.3)
No	423 (3.9)	430 (14.4)	257 (3.4)	319 (14.1)	472 (4.3)	381 (12.9)	296 (4.1)	280 (11.7)
Annual household income, $								
<25000	2,271 (17.9)	1,008 (29.1)	1,316 (15.8)	656 (28.6)	2,224 (17.2)	1,055 (31.4)	1,254 (15.1)	718 (30.6)
25,000–49,999	2,575 (16.9)	891 (24.3)	1,656 (19.7)	604 (20.8)	2,537 (17.1)	929 (23.5)	1,595 (19.5)	665 (21.5)
50,000–74,999	2,422 (17.5)	576 (15.3)	1,489 (15.9)	433 (16.4)	2,400 (17.6)	598 (14.8)	1,468 (16.0)	454 (15.9)
>75,000	5,870 (47.7)	1,056 (31.3)	3,927 (48.6)	776 (34.2)	5,906 (48.0)	1,020 (30.2)	3,918 (49.3)	785 (32.0)
Marital status								
Married	8,185 (69.6)	1,888 (60.9)	5,396 (70.0)	1,381 (60.5)	8,213 (70.0)	1,860 (59.8)	5,373 (70.2)	1,404 (59.8)
Not married	4,953 (30.4)	1,643 (39.1)	2,992 (30.0)	1,088 (39.5)	4,854 (30.0)	1,742 (40.2)	2,862 (29.8)	1,218 (40.2)
Employment								
Employed	8,002 (58.6)	1,997 (54.3)	5,051 (57.5)	1,352 (51.2)	8,099 (60.5)	1,900 (47.4)	5,022 (57.8)	1,381 (50.2)
Unemployed	5,136 (41.4)	1,534 (45.7)	3,337 (42.5)	1,117 (48.8)	4,968 (39.5)	1,702 (52.6)	3,213 (42.2)	1,241 (49.8)
Education								
Some high school	403 (6.4)	163 (7.0)	209 (7.0)	91 (6.4)	375 (5.8)	191 (9.0)	196 (6.5)	104 (8.3)
Graduated from high school	2,900 (26.3)	964 (32.0)	1,763 (23.9)	706 (32.8)	2,852 (25.3)	1,012 (35.2)	1,708 (24.0)	761 (32.2)
Some college	3,493 (31.7)	1,052 (34.3)	2,296 (31.4)	693 (30.6)	3,478 (32.2)	1,067 (32.3)	2,219 (31.2)	770 (31.5)
College graduate	6,342 (35.6)	1,352 (26.7)	4,120 (37.6)	979 (30.2)	6,362 (36.6)	1,332 (23.4)	4,112 (38.3)	987 (28.0)
Rural residence								
No	8,718 (82.8)	2,150 (77.5)	5,523 (83.3)	1,438 (76.1)	8,735 (83.5)	2,133 (74.8)	5,406 (83.3)	1,555 (76.3)
Yes	4,420 (17.2)	1,381 (22.5)	2,865 (16.7)	1,031 (23.9)	4,332 (16.5)	1,469 (25.2)	2,829 (16.7)	1,067 (23.7)

Abbreviations: BRFSS, Behavioral Risk Factor Surveillance System; Pap, Papanicolaou.
[a] Percentages were calculated as column percentages, except for the category for disability, which were calculated as row percentages. All percentages were weighted by using the BRFSS dataset methodology, accounting for the complex survey design of BRFSS, which includes stratification (_ststr), clustering (_psu), and weight (_llcpwt) variables.

Table 2. Adjusted Odds[a] of Being Up to Date on Mammogram and Pap Test by SDOH and Race and Ethnicity Among Women With Disabilities, Behavioral Risk Factor Surveillance System, 2018 and 2020

Variable	Mammogram, AOR (95% CI)		Pap test, AOR (95% CI)	
	2018	2020	2018	2020
Race and ethnicity				
Hispanic	2.42 (1.37–4.26)	1.43 (0.51–4.01)	2.08 (1.16–3.74)	2.25 (0.74–6.83)
Non-Hispanic Black	2.20 (1.27–3.83)	2.70 (1.40–5.21)	2.04 (1.08–3.87)	2.15 (1.19–3.87)
Non-Hispanic White	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Health insurance coverage				
No	0.24 (0.15–0.37)	0.27 (0.14–0.52)	0.34 (0.21–0.55)	0.49 (0.26–0.94)
Yes	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Annual household income, $				
<25,000	0.64 (0.38–1.05)	0.67 (0.36–1.24)	0.54 (0.31–0.93)	0.63 (0.34–1.17)
25,000–49,999	0.47 (0.29–0.74)	0.93 (0.49–1.77)	0.53 (0.33–0.83)	0.83 (0.46–1.52)
50,000–74,999	0.88 (0.50–1.54)	1.23 (0.62–2.40)	0.74 (0.41–1.35)	0.90 (0.43–1.88)
>75,000	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Marital status				
Married	1.39 (1.01–1.91)	1.48 (0.96–2.29)	1.32 (0.91–1.92)	1.30 (0.86–1.98)
Not married	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Employment				
Unemployed	1.04 (0.74–1.45)	1.33 (0.90–1.98)	0.82 (0.59–1.14)	1.14 (0.78–1.68)
Employed	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Educational attainment				
Graduated from high school	0.83 (0.59–1.17)	0.78 (0.45–1.36)	0.74 (0.50–1.09)	0.75 (0.44–1.26)
Some college	0.85 (0.61–1.20)	1.26 (0.75–2.10)	0.86 (0.61–1.20)	0.88 (0.53–1.45)
Some high school	0.93 (0.56–1.55)	2.09 (0.99–4.42)	0.72 (0.45–1.16)	1.10 (0.54–2.24)
College graduate	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Residence				
Rural	0.86 (0.64–1.14)	1.10 (0.72–1.68)	0.82 (0.62–1.10)	0.89 (0.60–1.31)
Urban	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]

Abbreviation: AOR, adjusted odds ratio; Pap, Papanicolaou; SDOH, social determinants of health.
[a] Adjusted for race, annual household income, marital status, employment status, health insurance coverage, education level, and rural/urban residence, taking into account the complex survey design factors such as weighting, stratification, and clustering.

Early Estimates of Updated 2023–2024 (Monovalent XBB.1.5) COVID-19 Vaccine Effectiveness Against Symptomatic SARS-CoV-2 Infection Attributable to Co-Circulating Omicron Variants Among Immunocompetent Adults — Increasing Community Access to Testing Program, United States, September 2023–January 2024

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Abstract

On September 12, 2023, CDC's Advisory Committee on Immunization Practices recommended updated 2023–2024 (updated) COVID-19 vaccination with a monovalent XBB.1.5–derived vaccine for all persons aged ≥6 months to prevent COVID-19, including severe disease. During fall 2023, XBB lineages co-circulated with JN.1, an Omicron BA.2.86 lineage that emerged in September 2023. These variants have amino acid substitutions that might increase escape from neutralizing antibodies. XBB lineages predominated through December 2023, when JN.1 became predominant in the United States. Reduction or failure of spike gene (*S*-gene) amplification (i.e., *S*-gene target failure [SGTF]) in real-time reverse transcription–polymerase chain reaction testing is a time-dependent, proxy indicator of JN.1 infection. Data from the Increasing Community Access to Testing SARS-CoV-2 pharmacy testing program were analyzed to estimate updated COVID-19 vaccine effectiveness (VE) (i.e., receipt versus no receipt of updated vaccination) against symptomatic SARS-CoV-2 infection, including by SGTF result. Among 9,222 total eligible tests, overall VE among adults aged ≥18 years was 54% (95% CI = 46%–60%) at a median of 52 days after vaccination. Among 2,199 tests performed at a laboratory with SGTF testing, VE 60–119 days after vaccination was 49% (95% CI = 19%–68%) among tests exhibiting SGTF and 60% (95% CI = 35%–75%) among tests without SGTF. Updated COVID-19 vaccines provide protection against symptomatic infection, including against currently circulating lineages. CDC will continue monitoring VE, including for expected waning and against severe disease. All persons aged ≥6 months should receive an updated COVID-19 vaccine dose.

Introduction

On September 12, 2023, CDC's Advisory Committee on Immunization Practices recommended that all persons aged ≥6 months receive the updated 2023–2024 (updated) monovalent COVID-19 vaccine (*1*). Most persons aged ≥5 years are recommended to receive 1 updated dose. These vaccines contain a component from the SARS-CoV-2 Omicron XBB.1.5 lineage and unlike previous COVID-19 vaccines, do not contain the ancestral SARS-CoV-2 strain. During the period of analysis, XBB lineages predominated early, many with evolutionarily advantageous amino acid changes in the spike gene (*S*-gene). In September 2023, the divergent JN.1 lineage was detected in the United States. JN.1 has more than 30 mutations in the spike protein compared with XBB.1.5, including a change (L455S) similar to one found in circulating XBB lineages (L455F).* JN.1 accounted for 69% (range = 65%–73%) of SARS-CoV-2 infections nationally by the 2-week period ending January 6, 2024.† Results of spike gene (*S*-gene) amplification in real-time reverse transcription–polymerase chain reaction (RT-PCR) can be used to distinguish certain SARS-CoV-2 lineages over time (*2*). Detection of *S*-gene target presence (SGTP) by a widely used commercial test was noted in most lineages that circulated in 2023, including XBB lineages,§ whereas *S*-gene target failure (SGTF), resulting from a mutation in the *S*-gene, is detected in JN.1 and other BA.2.86 lineages.¶ Vaccine effectiveness (VE) of receipt of updated COVID-19 vaccine in preventing symptomatic SARS-CoV-2 infection was assessed in adults aged ≥18 years, by time since dose and by SGTF and SGTP as a proxy for likely JN.1 versus other lineages. Whereas the goal of the U.S. COVID-19 vaccination program is to prevent severe disease, VE against symptomatic infection can provide useful insights into protection early after introduction of updated vaccines and during the emergence of new lineages, such as JN.1.

*https://www.cdc.gov/respiratory-viruses/whats-new/SARS-CoV-2-variant-JN.1.html
†https://covid.cdc.gov/covid-data-tracker/#variant-proportions
§XBB sublineages representing >1% of all sequenced variants include HV.1, JD.1.1, HK.3, JG.3, and EG.5 (last updated January 9, 2024).
¶SGTF lineages are defined by the presence of a deletion at positions 69–70 in the spike protein.

Methods

Overall Assessment of VE

Increasing Community Access to Testing (ICATT) is a CDC program that provides access to no-cost SARS-CoV-2 testing at pharmacies nationwide to persons who are uninsured,** prioritizing socially vulnerable areas.†† ICATT VE methods have been described§§ (*3*). Tests conducted at participating CVS Pharmacy and Walgreen Co. (Walgreens) locations during September 21, 2023–January 14, 2024, among adults who reported ≥1 symptom of COVID-19 were included in the test-negative design study. For the full analysis, case-patients were persons who received a positive nucleic acid amplification test (NAAT) result; control patients were those who received a negative NAAT result. Tests among persons fulfilling any of the following criteria were excluded from analyses: 1) self-reported immunocompromising condition¶¶; 2) reported receipt of Novavax as the most recent dose and reported receipt of <2 total COVID-19 vaccine doses***; 3) reported receipt of a Janssen (Johnson & Johnson) COVID-19 vaccine dose after May 12, 2023†††; 4) receipt of the most recent dose <7 days before the date of testing or during September 1–12, 2023; 5) receipt of a COVID-19 vaccine <2 months before date of testing for those who did not receive an updated COVID-19 vaccine dose; or 6) registration for testing with a version of the questionnaire that only reported month and year of the most recent vaccine dose rather than calendar date. In addition, tests from persons reporting receipt of a positive SARS-CoV-2 test result during the preceding 90 days§§§ were excluded. Type of most recent vaccine dose (original monovalent, bivalent, or updated monovalent) was determined by the reported date of receipt of the dose.¶¶¶

VE against symptomatic disease was calculated by comparing odds of receipt versus nonreceipt of the updated COVID-19 vaccine among case- and control patients. Secondary analyses examined alternative reference groups, including 1) receipt of a bivalent dose and 2) being either unvaccinated or having received only original COVID-19 vaccines. Odds ratios (ORs) were estimated using multivariable logistic regression****; VE was calculated separately based on SGTF or SGTP status as (1 – OR) x 100%.

Analysis of VE by SGTF and Time Since Vaccination

A subanalysis of VE by SGTF status and time since last dose included RT-PCR tests performed by one pharmacy chain during October 27, 2023–January 12, 2024, and analyzed at a commercial laboratory that used the TaqPath COVID-19 Combo Kit (Thermo Fisher Scientific). Quantitative results were reported as cycle threshold (Ct) values for each of three SARS-CoV-2 gene targets (*S, N*, and *ORF1ab*). Only specimens with Ct values available for both *N* and *ORF1ab* were

** ICATT vendors also report data for tests administered to people with medical insurance. Tests for persons with and without health insurance are included in this analysis.

†† The Social Vulnerability Index (SVI) is a composite measure that uses U.S. Census Bureau data on 16 social factors to rank social vulnerability by U.S. Census Bureau tract. The scale is from 0 to 1; higher SVIs represent more vulnerable communities. Tests with missing SVI data (<1% of total) were excluded from all analyses. https://www.atsdr.cdc.gov/placeandhealth/svi/data_documentation_download.html

§§ At test registration, adults report information on COVID-19 vaccination history, current COVID-19–like illness symptoms, history of previous positive SARS-CoV-2 test results, and underlying medical conditions. At Walgreens, comprising 95% of tests meeting inclusion criteria, test registrants who reported receiving COVID-19 vaccines were asked to report the total number of doses received and for the most recent dose, the manufacturer and the date of receipt as part of test registration. At CVS Pharmacy, comprising 5% of tests meeting inclusion criteria, test registrants' vaccination status was ascertained from a visit with a nurse practitioner or physician associate.

¶¶ Test registration forms asked persons to report whether they had an immunocompromising condition and provided the following examples: immunocompromising medications, solid organ or blood stem cell transplant, HIV, or other immunocompromising conditions.

*** Persons aged ≥12 years without immunocompromise and receiving updated Novavax COVID-19 vaccination are recommended to receive 2 updated COVID-19 vaccine doses if previously unvaccinated and 1 updated dose if previously vaccinated with any COVID-19 vaccine. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html

††† On May 12, 2023, CDC removed guidance for use of Janssen COVID-19 vaccine because the vaccine was no longer available in the United States. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html

§§§ Tests from persons reporting a positive SARS-CoV-2 test result during the preceding 90 days were excluded to avoid analyzing multiple tests for the same illness episode or reinfections within a relatively short time frame. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html

¶¶¶ Persons were assumed to have received only original monovalent COVID-19 vaccine doses if they reported receiving their last dose before September 2, 2022, or if they reported receiving 1 or 2 total doses before April 18, 2023; persons were assumed to have received a bivalent dose and no updated monovalent dose if they reported receiving >2 total doses with their last dose during September 2, 2022–April 18, 2023, or reported receiving any number of doses with their last dose during April 19–September 12, 2023; persons reporting receipt of a dose after September 12, 2023, were assumed to have received an updated monovalent dose because these were the only authorized COVID-19 doses in the United States during that period. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html

**** Multivariable logistic regression models were controlled for age (as a continuous variable), gender, race and ethnicity, SVI of the testing location (<0.5 versus ≥0.5), pharmacy contractor, underlying conditions (presence versus absence), U.S. Department of Health and Human Services region of testing location, and date of testing. The following underlying conditions were included on the test registration questionnaire: heart conditions, high blood pressure, overweight or obesity, diabetes, current or former smoker, kidney failure or end stage renal disease, cirrhosis of the liver, and chronic lung disease (such as chronic obstructive pulmonary disease, moderate to severe asthma, cystic fibrosis, or pulmonary embolism).

included in the SGTF subanalysis. SARS-CoV-2–positive specimens with either null or reduced amplification of the *S*-gene (Ct for *S*-gene >4 cycles from the average of *N* and *ORF1ab* Ct values) were considered to have SGTF (*2*,*4*), an indication of a particular deletion in the SARS-CoV-2 spike protein, which currently indicates an infection with BA.2.86, JN.1, and their sublineages. SARS-CoV-2–positive specimens without SGTF were considered to exhibit SGTP, which likely indicates infection with previously dominant XBB.1.5 lineages (Supplementary Figure; https://stacks.cdc.gov/view/cdc/145936).

For the SGTF and SGTP subanalysis, overall VE (regardless of time since dose) and VE during the 7–59 days after an updated dose were not calculated because the emergence of JN.1 parallels time since dose; statistical power for SGTF (likely JN.1) during the 7–59 days was therefore limited. Analyses were conducted using R software (version 4.1.2; R Foundation). This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.[††††]

Results

Overall VE

Among 9,222 NAAT results for persons with COVID-19–like illness symptoms eligible for the full analysis, 3,295 (36%) were positive for SARS-CoV-2 (Table 1). Among 1,125 persons who had received updated COVID-19 vaccine ≥7 days earlier, more control patients (844; 14%) reported having received the vaccine than did case-patients (281; 9%). Among those who received updated vaccine, the median interval since the last dose was 60 days (IQR = 32–79 days) for case-patients and 51 days (IQR = 28–73) for control patients. Among the 8,097 persons who reported that they had not received an updated vaccine dose, 2,435 (30%) were unvaccinated. Among the remaining 5,662 (70%) who were vaccinated but had not received an updated vaccine dose, the median interval since the last dose was 378 days (IQR = 321–413 days) for case-patients and 363 days (IQR = 254–402 days) for control patients. In the full analysis, VE for persons aged 18–49 years was 57% (95% CI = 48%–65%) and for persons aged ≥50 years was 46% (95% CI = 31%–58%) (Table 2). Overall VE was 58% (95% CI = 48%–65%) among those who received testing 7–59 days after receipt of updated vaccine and 49% (95% CI = 36%–58%) among those who received testing 60–119 days after receipt of updated vaccine.

VE by SGTF Status

In the subanalysis, 679 tests with *S*-gene target results from eligible persons were available, including 258 (38%) exhibiting SGTF (likely JN.1 lineages) and 421 (62%) with SGTP (likely non-JN.1 lineages) (Table 3). Because of recent emergence of JN.1 in the United States, VE was imprecise for tests with SGTF during the 7–59 days after receipt of updated vaccine. VE during the 60–119 days since receipt of updated vaccine was 49% (95% CI = 19%–68%) for tests with SGTF (median interval since dose = 80 days) and 60% (95% CI = 35%–75%) for tests with SGTP (median interval since dose = 73 days).

Secondary VE Analyses

Secondary analyses showed similar VE estimates for receipt of updated vaccine compared with those who previously received only original monovalent doses and those who received original monovalent and bivalent doses. (Supplementary Table; https://stacks.cdc.gov/view/cdc/145937).

Discussion

This report provides early estimates of effectiveness of updated monovalent XBB.1.5 COVID-19 vaccines against symptomatic SARS-CoV-2 infection and the first estimates of VE against symptomatic infection with the JN.1 lineage. These preliminary estimates from pharmacy testing conducted during September 2023–January 2024 showed updated monovalent COVID-19 vaccine provided protection for JN.1 and other circulating lineages.

VE against symptomatic infection provides helpful information about the range of protection provided by updated vaccines and against emerging lineages. An important strength of ICATT SARS-CoV-2 testing data is the ability to distinguish JN.1 from XBB lineages, allowing for comparison of VE during the same period after vaccination. Monitoring the potential impact on VE of JN.1 is critical because of the spike mutations in JN.1 (as compared with XBB lineages), which might be associated with increased immune escape[§§§§] (*5*). Recent laboratory data show that the updated vaccines elicit neutralizing antibodies against emerging XBB lineages and JN.1 (*6*). Although point estimates during the 60–119 days after vaccination were lower for SGTF than SGTP results in this analysis, CIs overlapped, indicating no statistically significant difference. These data provide reassurance that updated vaccines are providing protection against JN.1 and XBB lineages.

These early estimates include the period only through 119 days since vaccination, a relatively brief postvaccination

[††††] 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

[§§§§] JN.1 is a sublineage of BA.2.86, defined by the spike substitution L455S. Changes at this amino acid position have conferred immune escape advantages to other lineages and might be associated with increased immune escape.

TABLE 1. Characteristics of patients with SARS-CoV-2 tests conducted at national pharmacy testing locations (N = 9,222) — Increasing Community Access to Testing program, United States, September 2023–January 2024

Characteristic	Full analysis (all eligible NAATs), no. (column %)			Subanalysis (eligible TaqPath COVID-19 Combo Kit tests only),* no. (column %)			
	Total no. of tests	SARS-CoV-2–negative (control patients) n = 5,927	SARS-CoV-2–positive (case-patients) n = 3,295	Total no. of tests	SARS-CoV-2–negative (control patients) n = 1,520	SGT presence (likely non-JN.1) n = 421	SGT failure (likely JN.1) n = 258
All tests (row %)	**9,222 (100)**	**5,927 (64)**	**3,295 (36)**	**2,199 (100)**	**1,520 (69)**	**421 (19)**	**258 (12)**
Age group, yrs							
18–49	**7,155 (78)**	4,673 (79)	2,482 (75)	**1,694 (77)**	1,187 (78)	306 (73)	201 (78)
50–64	**1,547 (17)**	916 (15)	631 (19)	**363 (17)**	238 (16)	88 (21)	37 (14)
≥65	**520 (6)**	338 (6)	182 (6)	**142 (6)**	95 (6)	27 (6)	20 (8)
Gender							
Female	**5,581 (61)**	3,656 (62)	1,925 (58)	**1,341 (61)**	966 (64)	233 (55)	142 (55)
Male	**3,586 (39)**	2,228 (38)	1,358 (41)	**836 (38)**	535 (35)	187 (44)	116 (45)
Other	**55 (1)**	43 (1)	12 (0.4)	**22 (1)**	21 (1)	1 (0.2)	0 (—)
Race and ethnicity†							
Black or African American	**1,465 (16)**	1,002 (17)	463 (14)	**273 (12)**	223 (15)	27 (6)	23 (9)
White	**3,578 (39)**	2,277 (38)	1,301 (39)	**1,003 (46)**	622 (41)	245 (58)	136 (53)
Hispanic or Latino	**2,662 (29)**	1,717 (29)	945 (29)	**512 (23)**	400 (26)	68 (16)	44 (17)
Other	**815 (9)**	487 (8)	328 (10)	**226 (10)**	147 (10)	52 (12)	27 (10)
Unknown	**702 (8)**	444 (7)	258 (8)	**185 (8)**	128 (8)	29 (7)	28 (11)
HHS testing site region§							
1	**316 (3)**	201 (3)	115 (3)	**143 (7)**	96 (6)	24 (6)	23 (9)
2	**999 (11)**	463 (8)	536 (16)	**368 (17)**	151 (10)	126 (30)	91 (35)
3	**519 (6)**	351 (6)	168 (5)	**135 (6)**	86 (6)	35 (8)	14 (5)
4	**1,775 (19)**	1,260 (21)	515 (16)	**413 (19)**	399 (22)	39 (9)	35 (14)
5	**1,286 (14)**	823 (14)	463 (14)	**298 (14)**	213 (14)	59 (14)	26 (10)
6	**2,048 (22)**	1,403 (24)	645 (20)	**358 (16)**	327 (22)	20 (5)	11 (4)
7	**225 (2)**	141 (2)	84 (3)	**29 (1)**	25 (2)	3 (1)	1 (0.4)
8	**207 (2)**	136 (2)	71 (2)	**36 (2)**	27 (2)	6 (1)	3 (1)
9	**1,593 (17)**	971 (16)	622 (19)	**396 (18)**	236 (16)	107 (25)	53 (21)
10	**254 (3)**	178 (3)	76 (2)	**23 (1)**	20 (1)	2 (0.5)	1 (.04)
SVI, mean (SD)¶	**0.6 (0.3)**	0.6 (0.3)	0.6 (0.3)	**0.5 (0.3)**	0.5 (0.3)	0.5 (0.3)	0.5 (0.3)
Self-reported history of SARS-CoV-2–positive test result							
None	**3,699 (40)**	2,267 (38)	1,432 (43)	**807 (37)**	545 (36)	169 (40)	93 (36)
Positive >90 days before current test	**5,523 (60)**	3,660 (62)	1,863 (57)	**1,392 (63)**	975 (64)	252 (60)	165 (64)
SARS-CoV-2 test type							
Rapid NAAT**	**5,338 (58)**	3,438 (58)	1,900 (58)	**NA**	NA	NA	NA
Laboratory-based NAAT††	**3,884 (42)**	2,489 (42)	1,395 (42)	**2,199 (100)**	1,582 (100)	421 (100)	258 (100)
At least one self-reported chronic underlying condition							
No	**5,966 (65)**	3,844 (65)	2,122 (64)	**1,389 (63)**	955 (63)	280 (67)	154 (60)
Yes	**3,256 (35)**	2,083 (35)	1,173 (36)	**810 (37)**	565 (37)	141 (33)	104 (40)

See table footnotes on the next page.

period, with no substantial waning. Because consistent patterns of waning VE were observed after original monovalent and bivalent COVID-19 vaccination, waning of VE is expected with more time since updated vaccination, especially against less severe outcomes such as symptomatic infection. Additional analyses conducted at longer intervals since authorization of updated vaccines are needed for continued monitoring of expected waning and to determine how well vaccines are working to prevent severe disease.

Limitations

The findings in this report are subject to at least five limitations. First, vaccination status, previous infection history, and underlying medical conditions were self-reported and might be subject to recall bias. Self-reported frequency of previous infections >90 days before testing differed by vaccination status and SGTF status, but statistical power was not adequate for stratification of results. Further, previous infection is likely underreported (*7*). Previous infection provides some protection against repeat infection (*8*) and U.S. adults have a high

TABLE 1. (*Continued*) Characteristics of patients with SARS-CoV-2 tests conducted at national pharmacy testing locations (N = 9,222) — Increasing Community Access to Testing program, United States, September 2023–January 2024

Characteristic	Full analysis (all eligible NAATs), no. (column %)			Subanalysis (eligible TaqPath COVID-19 Combo Kit tests only),* no. (column %)			
	Total no. of tests	SARS-CoV-2–negative (control patients) n = 5,927	SARS-CoV-2–positive (case-patients) n = 3,295	Total no. of tests	SARS-CoV-2–negative (control patients) n = 1,520	SGT presence (likely non-JN.1) n = 421	SGT failure (likely JN.1) n = 258
Self-reported most recent COVID-19 vaccine dose received before test date§§,¶¶							
Unvaccinated	**2,435 (26)**	1,705 (29)	730 (22)	**430 (20)**	333 (22)	68 (16)	29 (11)
Original monovalent	**4,493 (49)**	2,669 (45)	1,824 (55)	**1,140 (52)**	749 (49)	245 (58)	146 (57)
Bivalent	**1,169 (13)**	709 (12)	460 (14)	**402 (18)**	264 (17)	85 (20)	53 (21)
Updated dose, ≥7 days earlier	**1,125 (12)**	844 (14)	281 (9)	**227 (10)**	174 (11)	23 (5)	30 (12)
Updated dose, 7–59 days earlier	**634 (7)**	494 (8)	140 (4)	**NA**	NA	NA	NA
Updated dose, 60–119 days earlier	**491 (5)**	350 (6)	141 (4)	**227 (10)**	174 (11)	23 (5)	30 (12)
Updated dose product manufacturer¶¶							
Moderna	**472 (5)**	356 (6)	116 (4)	**91 (4)**	72 (5)	7 (2)	12 (5)
Novavax	**49 (1)**	43 (1)	6 (0.2)	**5 (0.2)**	4 (0.3)	0 (—)	1 (0.4)
Pfizer-BioNTech	**604 (7)**	445 (8)	159 (5)	**131 (6)**	98 (6)	16 (4)	17 (7)
None	**8,097 (88)**	5,083 (86)	3,014 (91)	**1,972 (90)**	1,346 (89)	398 (95)	228 (88)
Self-reported total no. of COVID-19 vaccine doses							
0 (unvaccinated)	**2,435 (26)**	1,705 (29)	730 (22)	**430 (20)**	333 (22)	68 (16)	29 (11)
1	**780 (8)**	461 (8)	319 (10)	**186 (8)**	116 (8)	39 (9)	31 (12)
2	**2,655 (29)**	1,618 (27)	1,037 (31)	**605 (28)**	415 (27)	116 (28)	74 (29)
3	**1,843 (20)**	1,090 (18)	753 (23)	**552 (25)**	354 (23)	132 (31)	66 (26)
4	**878 (10)**	581 (10)	297 (9)	**271 (12)**	180 (12)	52 (12)	39 (15)
5	**438 (5)**	339 (6)	99 (3)	**102 (5)**	83 (5)	8 (2)	11 (4)
≥6	**193 (2)**	133 (2)	60 (2)	**53 (2)**	39 (3)	6 (1)	8 (3)

Abbreviations: HHS = U.S. Department of Health and Human Services; ICATT = Increasing Community Access to Testing program; NA = not applicable; NAAT = nucleic acid amplification test; SGT = spike gene target; SVI = Social Vulnerability Index.

* Tests included in the subanalysis represent a subset of those included in the full analysis.

† Persons of Hispanic or Latino (Hispanic) origin might be of any race but are categorized as Hispanic; all racial groups are non-Hispanic.

§ Regions are defined by HHS and include only states and territories with ICATT sites. U.S. Virgin Islands (Region 2) and American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, and Palau (Region 9) were not included because they did not have pharmacies participating in ICATT. https://www.hhs.gov/about/agencies/iea/regional-offices/index.html.

¶ SVI is a composite measure that uses U.S. Census Bureau data on 16 social factors to rank social vulnerability by U.S. Census Bureau tract. The scale is from 0 to 1; higher SVIs represent more vulnerable communities. Tests with missing SVI data (<1% of total) were excluded from all analyses. https://www.atsdr.cdc.gov/placeandhealth/svi/data_documentation_download.html

** Rapid NAAT was performed on-site on self-collected nasal swabs using ID Now (Abbott Diagnostics Scarborough, Inc.), Xpert Xpress (Cepheid), and Accula (Thermo Fisher Scientific).

†† Laboratory-based NAAT was performed on self-collected nasal swabs at contracted laboratories using a variety of testing platforms.

§§ Persons were assumed to have received only original monovalent COVID-19 vaccine doses if they reported receiving their last dose before September 2, 2022, or if they reported receiving 1 or 2 total doses before April 18, 2023; persons were assumed to have received a bivalent dose and no updated dose if they reported receiving >2 total doses with their last dose during September 2, 2022–April 18, 2023, or receiving any number of doses with their last dose during April 19–September 12, 2023; persons reporting receipt of a dose after September 12, 2023, were assumed to have received an updated dose because these were the only authorized COVID-19 doses in the United States. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html

¶¶ "Updated" refers to 2023–2024 monovalent COVID-19 vaccine.

prevalence of infection-induced SARS-CoV-2 immunity.¶¶¶¶ Thus, VE in this analysis reflects the current situation among U.S. adults and can be interpreted as the incremental benefit of receipt of updated COVID-19 vaccine beyond existing vaccination-induced, infection-induced, or hybrid immunity. Second, test registration questionnaires did not ask registrants about the number of updated vaccine doses received; therefore, the analysis might have included some persons who received >1 updated dose. Third, these estimates are derived from a population choosing to be tested for SARS-CoV-2 and are potentially subject to selection biases related to these factors. In addition, updated vaccination coverage to date has been low (approximately 22% as of January 13, 2024*****) among persons aged ≥18 years and varies by age, which could bias results if persons being vaccinated earlier are systematically different from those vaccinated later. Thus, residual confounding might be present and could affect these early estimates. Fourth, this

¶¶¶¶ https://covid.cdc.gov/covid-data-tracker/#nationwide-blood-donor-seroprevalence-2022

***** https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adult-coverage-vaccination.html

TABLE 2. Effectiveness of updated 2023–2024 monovalent COVID-19 vaccine against symptomatic SARS-CoV-2 infection among adults aged ≥18 years, by interval since last dose and age group — Increasing Community Access to Testing program, United States, September 2023–January 2024

Age group, yrs/COVID-19 vaccination dosage pattern	Total no. of tests	SARS-CoV-2–positive test results, no. (row %)	Median days (IQR) since last dose among vaccinated	VE* (95% CI)
≥18				
No updated dose (Ref)	**8,097**	3,014 (37)	670 (422–843)	Ref
Received updated dose	**1,125**	281 (25)	52 (29–75)	54 (46–60)
7–59 days earlier	**634**	140 (22)	32 (19–46)	58 (48–65)
60–119 days earlier	**491**	141 (29)	79 (68–90)	49 (36–58)
18–49				
No updated dose (Ref)	**6,475**	2,332 (36)	681 (429–852)	Ref
Received updated dose	**681**	150 (22)	53 (30–74)	57 (48–65)
7–59 days earlier	**381**	69 (18)	32 (19–46)	64 (53–73)
60–119 days earlier	**300**	81 (27)	77 (67–89)	48 (31–60)
≥50				
No updated dose (Ref)	**1,623**	682 (42)	583 (398–787)	Ref
Received updated dose	**444**	131 (30)	50 (29–77)	46 (31–58)
7–59 days earlier	**253**	71 (28)	32 (21–45)	45 (26–60)
60–119 days earlier	**191**	60 (31)	81 (70–91)	47 (24–62)

Abbreviations: Ref = referent group; VE = vaccine effectiveness.
* VE = (1 − adjusted odds ratio) x 100. Odds ratios were calculated using multivariable logistic regression, adjusting for age (as a continuous variable), gender, race and ethnicity, Social Vulnerability Index of the testing location (<0.5 versus ≥0.5), pharmacy contractor, underlying conditions (presence versus absence), U.S. Department of Health and Human Services region of testing location, and date of testing. Previous analyses from this platform included local SARS-CoV-2 incidence in regression models; however, this variable is no longer available since the end of the public health emergency declaration in May 2023.

TABLE 3. Effectiveness of updated 2023–2024 monovalent COVID-19 vaccine against symptomatic SARS-CoV-2 infection among adults aged ≥18 years with samples tested at a commercial laboratory with spike gene target testing available, by interval since last dose and spike gene target status (N = 2,199) — Increasing Community Access to Testing program, United States, October 2023–January 2024

		SARS-CoV-2–negative test results		SARS-CoV-2–positive test results (n = 679)					
				SGT presence (likely non-JN.1)			SGT failure (likely JN.1)		
COVID-19 vaccination dosage pattern	Total no. of tests N = 2,199	No. (row %) n = 1,520	Median (IQR) days since last dose among vaccinated	No. (row %) n = 421	Median (IQR) days since last dose among vaccinated	VE* (95% CI)	No. (row %) n = 258	Median (IQR) days since last dose among vaccinated	VE* (95% CI)
No updated dose (Ref)	**1,972**	1,346 (68)	637 (398–805)	398 (20)	672 (402–800)	Ref	228 (12)	674 (412–816)	Ref
Updated dose, 60–119 days earlier†	**227**	174 (77)	80 (69–90)	23 (10)	73 (68–82)	60 (35–75)	30 (13)	80 (69–90)	49 (19–68)

Abbreviations: Ref = referent group; SGT = spike gene target; VE = vaccine effectiveness.
* VE = (1 − adjusted odds ratio) x 100. Odds ratios were calculated using multivariable logistic regression, adjusting for age (as a continuous variable), gender, race and ethnicity, Social Vulnerability Index of the testing location (<0.5 versus ≥0.5), pharmacy contractor, underlying conditions (presence versus absence), U.S. Department of Health and Human Services region of testing location, and date of testing. Previous analyses from this platform included local SARS-CoV-2 incidence in regression models; however, this variable is no longer available since the end of the public health emergency declaration in May 2023.
† Overall VE, regardless of time since dose, and VE during the 7–59 days since vaccination were not calculated for the subanalysis based on SGT presence or SGT failure. Because of the timing of JN.1 spread in the United States, JN.1 VE estimates would be inherently weighted as longer time since dose and non-JN.1 VE estimates as shorter time since dose, biasing overall estimates of VE by lineage. Similarly, because of the timing of JN.1 spread, statistical power for VE for JN.1 lineages during the 7–59 days after receipt of vaccination was limited.

analysis used a subset of data with SGTF status as a proxy for infection with a JN.1 lineage. Although SGTF identifies other BA.2.86 lineage viruses, JN.1 represents the majority of these and was the primary lineage increasing in proportion during the analytic period. Finally, this analysis did not control for time since receipt of the most recent dose before the updated dose; however, because of waning effectiveness of previous doses, particularly against symptomatic infection†††† (*9*), this limitation likely had a minimal effect on results.

†††† https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/05-COVID-Link-Gelles-508.pdf

Implications for Public Health Practice

Updated monovalent COVID-19 vaccines provided 54% (95% CI = 46–60%) protection against symptomatic SARS-CoV-2 infection in persons recently vaccinated compared with those who did not receive an updated vaccine dose. Vaccination provided protection for infections caused by JN.1 and infections caused by XBB-related lineages. Waning of effectiveness is expected with additional elapsed time since vaccination, especially against less severe disease. CDC will continue to monitor trends in VE. All persons aged ≥6 months should stay up to date with COVID-19 vaccination, including receiving a dose of updated vaccine.

Summary

What is already known about this topic?

In September 2023, CDC's Advisory Committee on Immunization Practices recommended updated 2023–2024 (monovalent XBB.1.5) COVID-19 vaccination for all persons aged ≥6 months to prevent COVID-19, including severe disease. Many variants co-circulated during fall 2023; the JN.1 lineage became predominant in January 2024. Few estimates of updated 2023–2024 vaccine effectiveness (VE) are available.

What is added by this report?

Receipt of updated COVID-19 vaccine provided approximately 54% increased protection against symptomatic SARS-CoV-2 infection compared with no receipt of updated vaccine. Vaccination provides protection against JN.1 and other circulating lineages.

What are the implications for public health practice?

All persons aged ≥6 months should receive updated 2023–2024 COVID-19 vaccine. CDC will continue monitoring COVID-19 VE, including against severe disease and for expected waning.

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Selection of Antibiotics as Prophylaxis for Close Contacts of Patients with Meningococcal Disease in Areas with Ciprofloxacin Resistance — United States, 2024

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Abstract

Meningococcal disease, caused by the bacterium *Neisseria meningitidis*, is a rare but life-threatening illness that requires prompt antibiotic treatment for patients and antibiotic prophylaxis for their close contacts. Historically, *N. meningitidis* isolates in the United States have been largely susceptible to the antibiotics recommended for prophylaxis, including ciprofloxacin. Since 2019, however, the number of meningococcal disease cases caused by ciprofloxacin-resistant strains has increased. Antibiotic prophylaxis with ciprofloxacin in areas with ciprofloxacin resistance might result in prophylaxis failure. Health departments should preferentially consider using antibiotics other than ciprofloxacin as prophylaxis for close contacts when both of the following criteria have been met in a local catchment area during a rolling 12-month period: 1) the reporting of two or more invasive meningococcal disease cases caused by ciprofloxacin-resistant strains, and 2) ≥20% of all reported invasive meningococcal disease cases are caused by ciprofloxacin-resistant strains. Other than ciprofloxacin, alternative recommended antibiotic options include rifampin, ceftriaxone, or azithromycin. Ongoing monitoring for antibiotic resistance of meningococcal isolates through surveillance and health care providers' reporting of prophylaxis failures will guide future updates to prophylaxis considerations and recommendations.

Introduction

Neisseria meningitidis causes invasive meningococcal disease, a severe and life-threatening illness. Close contacts of patients with invasive meningococcal disease are at increased risk for acquiring the disease, and antibiotic prophylaxis is recommended for these persons. First-line options for prophylaxis are rifampin, ciprofloxacin, and ceftriaxone; azithromycin can also be used in areas with ciprofloxacin-resistant strains (*1*). Historically, antibiotic resistance in *N. meningitidis* has been uncommon in the United States (*2*). However, in 2020, CDC identified 11 ciprofloxacin- and penicillin-resistant *N. meningitidis* serogroup Y (NmY) isolates from cases occurring in 2019 and 2020 (*3,4*).

More recent data show that 29 cases caused by ciprofloxacin-resistant strains were reported during 2019–2021: 24 NmY (also resistant to penicillin), four NmB, and one nongroupable strain. No direct epidemiologic linkages among cases were identified. The median patient age was 24 years (range = 2 months–88 years) and 20 (69%) cases occurred among Hispanic or Latino persons; one case (3%) was fatal.

Although no instances of prophylaxis failure associated with ciprofloxacin resistance in the United States have been reported to date, use of ciprofloxacin as prophylaxis in areas with ciprofloxacin resistance might increase the likelihood of failure. Based on emerging evidence, CDC is providing updated guidance for health departments to aid in making decisions about when and where recommended antibiotic options other than ciprofloxacin should be preferentially considered for use as prophylaxis for close contacts of patients with invasive meningococcal disease.

Methods

CDC considered four main criteria in developing the guidance for preferentially considering options other than ciprofloxacin for meningococcal disease prophylaxis. These include 1) a threshold for action (i.e., the number and percentage of cases caused by ciprofloxacin-resistant strains in a specified area and period, after which alternatives to ciprofloxacin should be preferentially considered), 2) the alternative antibiotics that should be used, 3) the duration of the guidance, and 4) the catchment area (i.e., the area in which cases are counted for determining the threshold and that will follow the changes in prophylaxis prescribing practices).

During October 2022–April 2023, these four criteria, as well as five contextual considerations (acceptability to public health partners, feasibility in implementation, effect on health equity, potential indirect outcomes, and anticipated opposition), were evaluated using an iterative process. CDC began by soliciting feedback on the criteria and contextual considerations from governmental and nongovernmental subject matter experts, including experts from within the agency, jurisdictional health departments, and academic institutions, to gain information on the need for updated guidance and to discuss the practical considerations that could affect guidance implementation. CDC experts developed draft implementation guidance, after which additional feedback was solicited from state and local public health professionals who would potentially implement this guidance. This feedback was considered by CDC when formulating the final guidance.

Rationale and Evidence

Invasive Meningococcal Disease Cases and Resistance Patterns

An annual average of 1.25 cases of invasive meningococcal disease caused by ciprofloxacin-resistant strains were reported in the United States during 2011–2018; however, the number of such cases has increased sharply since 2019. An annual average of 9.7 cases of invasive meningococcal disease caused by ciprofloxacin-resistant strains were reported in 2019, 2020, and 2021, despite an overall 75% decline in disease incidence from 0.24 cases per 100,000 population (2011) to 0.06 (2021) (Figure 1). Recent cases were predominantly caused by ciprofloxacin- and penicillin-resistant NmY strains and were distributed across the United States, but clusters were identified in some geographic areas (Figure 2).

Considerations in Determining Resistance Thresholds

Resistance thresholds for recommending changing antibiotics are inconsistent across pathogens and contexts (*5*). CDC experts agreed that, because of the severity of invasive meningococcal disease and high mortality risk in potential instances of prophylaxis failure, the threshold should be low. In determining the threshold for action, both a specific number of resistant cases (e.g., one or two) and a percentage (e.g., 20%) of all cases were needed to allow sufficient flexibility for jurisdictions with high invasive meningococcal disease incidence to act while ensuring areas with low incidence were not changing recommendations based on a single, potentially sporadic, resistant case.

Existing guidance states that rifampin (4 oral doses in 48 hours), ciprofloxacin (single oral dose), or ceftriaxone (single injection) are first-line antibiotics for meningococcal prophylaxis; a single oral dose of azithromycin has also been used in areas with ciprofloxacin-resistant strains (*1*). A published systematic review and meta-analysis determining effectiveness, adverse events, and development of drug resistance for different meningococcal prophylaxis regimens was used as supporting evidence for determining when to favor the use of recommended prophylaxis options other than ciprofloxacin (*6*). Six studies presented data on rifampin compared with placebo and found that rifampin was effective at eradicating *N. meningitidis* 1 week after prophylaxis (meta-analysis pooled risk ratio [RR] = 0.17; 95% CI = 0.13–0.24) (*6*). No trials evaluated ceftriaxone or azithromycin against placebo, but two studies comparing rifampin with ceftriaxone found no statistically significant difference in eradication (RR = 3.71; 95% CI = 0.73–18.86) (*6*), and one study comparing azithromycin to rifampin reported no statistically significant difference in eradication (RR = 0.30; 95% CI = 0.30–5.54) (*6,7*). Across nine studies examining side effects and adverse events for at least one of the alternative antibiotics, reported adverse events were mild and included nausea, diarrhea, abdominal pain, headaches, dizziness, and skin rashes. Compared with rifampin, one study found a higher adverse event rate with ceftriaxone (RR = 1.39; 95% CI = 1.10–1.75); however, this difference was primarily driven by reports of pain at the injection site. Six studies reported on the antibiotic susceptibility of

FIGURE 1. Meningococcal disease incidence and number of invasive meningococcal disease cases caused by ciprofloxacin-resistant or ciprofloxacin- and penicillin-resistant strains of *Neisseria meningitidis* — United States, 2011–2021

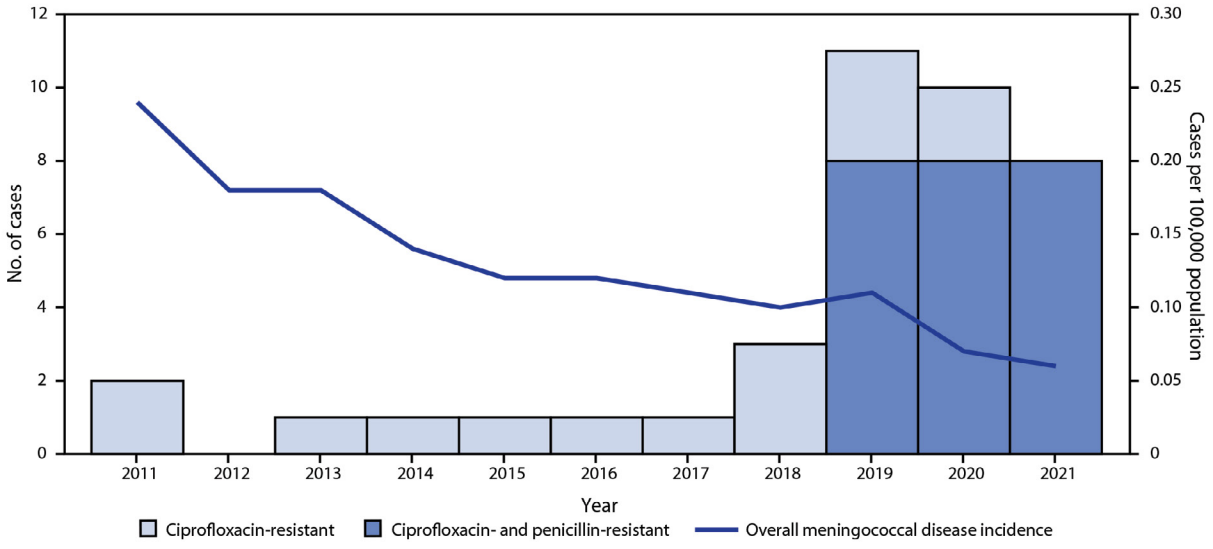
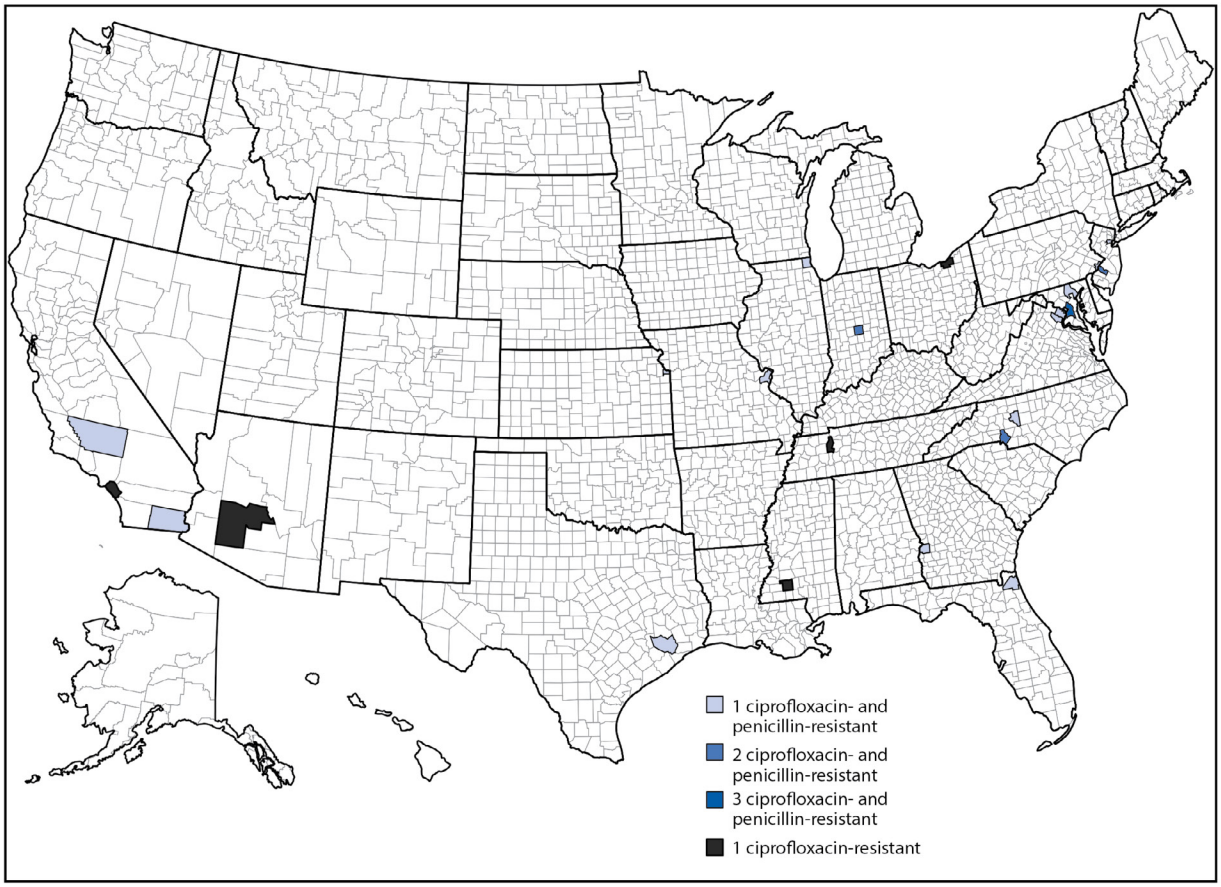


FIGURE 2. Number of invasive meningococcal disease cases caused by ciprofloxacin-resistant or ciprofloxacin- and penicillin-resistant *Neisseria meningitidis* strains, by county — United States, 2019–2021



persistent isolates to at least one of the alternative antibiotics; development of resistance following prophylaxis was detected only for rifampin (*6*). Resistance to rifampin has also been reported in mass chemoprophylaxis settings, but because there is a fitness cost to the mutations associated with resistance, resistant strains have not become widespread (*8*); occasional rifampin prophylaxis failures have also been reported (*9*). CDC experts reviewed the literature since 2013 for updated data on the effectiveness of alternative prophylaxis regimens; no new data were identified.

The CDC expert group also considered adherence, acceptability, contraindications, and dosing regimens for the alternative antibiotics and noted that despite limited evidence of effectiveness, azithromycin would likely be the logistically simplest replacement for ciprofloxacin among the existing recommended prophylaxis options. In determining the duration of guidance, feasibility and communication challenges were considered, recognizing that frequent changes in recommended prophylaxis antibiotics within a local area might cause confusion among providers and public health staff members and might lead to lack of adherence. Flexibility in guidance criteria to allow for unique jurisdictional and cross-jurisdictional considerations during implementation, particularly when defining a catchment area, was emphasized in feedback discussions.

Presentation of Guidance

Implementation Guidance for Health Departments

Based on the currently recommended prophylaxis options (*1*), the 2013 systematic review (*6*), and expert feedback using the stated criteria and contextual considerations, the implementation guidance for health departments includes the circumstances under which ciprofloxacin prophylaxis should be discontinued and alternative antibiotic prophylaxis options

Summary

What is already known about this topic?

Meningococcal disease cases caused by ciprofloxacin-resistant strains of *Neisseria meningitidis* have increased in the United States. Use of ciprofloxacin for antibiotic prophylaxis in areas with ciprofloxacin resistance might result in prophylaxis failure.

What is added by this report?

CDC provides implementation guidance for health departments for the preferential use of other recommended prophylaxis options (i.e., rifampin, ceftriaxone, or azithromycin) in place of ciprofloxacin when two or more ciprofloxacin-resistant meningococcal disease cases that account for ≥20% of all cases are reported in a local catchment area during a 12-month period.

What are the implications for public health practice?

Monitoring for prophylaxis failures and antimicrobial resistance among meningococcal isolates is essential to support the need for additional updates to recommendations.

should be preferentially considered, alternative prophylaxis regimens, and the extent and duration of implementation of the updated guidance (Box).

Health departments have flexibility in guidance implementation. Updated prophylaxis guidance can be implemented at a lower threshold or extended across a broader area, such as across a metropolitan statistical area or health department catchment area. Other health department considerations in determining guidance implementation include local epidemiology; feasibility (e.g., logistical simplicity of having a particular geographic area follow uniform guidance); epidemiologic linkages among patients; travel history, including college and other students' travel to or from school*; and patterns in population movement, including movement across jurisdictional borders.

Benefits and Harms

The primary anticipated public health benefit of this guidance is a reduced likelihood of ciprofloxacin prophylaxis failure. However, potential prophylaxis failures with alternative antibiotics might occur, and the potential for reduced adherence or slower administration of less convenient alternative prophylaxis options remains.

Discussion

CDC's implementation guidance for choosing antibiotics for invasive meningococcal disease prophylaxis is based on observed increases in the number of cases of invasive meningococcal disease caused by ciprofloxacin-resistant strains since 2019 and concerns about potential prophylaxis failures in areas with ciprofloxacin resistance. These data, combined with evidence that alternative recommended prophylaxis options are effective and are associated with minimal adverse events, support preferentially considering the use of antibiotics other than ciprofloxacin in areas reaching a minimum threshold for action.

Antimicrobial susceptibility testing for *N. meningitidis* is typically conducted at CDC rather than locally and is not routinely conducted in support of patient care. Therefore, results to guide prophylaxis options for close contacts of individual cases are often not available. However, if antimicrobial susceptibility testing results demonstrating resistance in an index patient are promptly available by local testing, adjustments in prophylaxis can also be made, regardless of whether a local area has reached the recommended threshold.

Effective guidance implementation will depend on rapid communication of antimicrobial susceptibility testing results between CDC and jurisdictions to guide local threshold calculations, strong cross-jurisdictional communication regarding catchment area borders, availability of alternative antibiotics, and monitoring for potential prophylaxis failures. A need remains to generate more data on azithromycin's effectiveness

BOX. Implementation guidance for health departments for preferentially considering antibiotics other than ciprofloxacin for invasive meningococcal disease prophylaxis

Discontinue use of ciprofloxacin as prophylaxis for close contacts when both of the following threshold criteria have been met in the catchment area* during a rolling 12-month period:

- Two or more invasive meningococcal disease cases caused by ciprofloxacin-resistant strains have been reported, and
- Cases caused by ciprofloxacin-resistant strains account for ≥20% of all reported invasive meningococcal disease cases.

Prescribe rifampin, ceftriaxone, or azithromycin instead of ciprofloxacin as prophylaxis when the threshold criteria have been reached.†

Implement updated prophylaxis guidance in all counties within the catchment area.

Maintain updated prophylaxis guidance until a full 24 months have passed without any invasive meningococcal disease cases caused by ciprofloxacin-resistant strains having been reported in the catchment area.

* The catchment area should be a single contiguous area that contains all counties reporting ciprofloxacin-resistant cases. Jurisdictions should include surrounding counties, if warranted, based on population mixing patterns.
† https://www.cdc.gov/vaccines/pubs/surv-manual/chpt08-mening.html

* https://learn.cste.org/images/dH42Qhmof6nEbdvwIIL6F4zvNjU1NzA0MjAxMTUy/Course_Content/Case_based_Surveillance_for_Syphilis/CSTE_Revised_Guidelines_for_Determining_Residency_for_Disease_Reporting_Purposes.pdf

because it is likely the most convenient and readily available alternative antibiotic for meningococcal prophylaxis.

CDC staff members are available to provide technical assistance if questions about guidance implementation arise. To support monitoring and evaluation of guidance implementation, health departments are requested to notify CDC about any changes made to prophylaxis guidance at meningnet@cdc.gov. CDC will continue to monitor for prophylaxis failures and antimicrobial resistance among meningococcal isolates to determine whether adjustments are needed and will update the guidance as new data become available.

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Comparing side effects after prostate cancer treatment

At a Glance

- Men with cancer confined to the prostate experienced different long-term side effects depending on the type of treatment received.
- Understanding the pros and cons of different treatments may help men and their health care teams make more informed treatment decisions.

Although prostate cancer is the most common cancer in men in the United States, it comes with a relatively good prognosis. Most men with prostate cancer will still be alive 15 years after their diagnosis.

The choice of treatment for prostate cancer may be influenced by the side effects of the different treatments. *Ground Picture / Shutterstock*

Currently, men with prostate cancer that hasn't spread outside the gland have several treatment choices. Because most men with prostate cancer are expected to live a long time, weighing the long-term side effects of different treatments is important. Side effects can include bladder and bowel problems, and difficulty with sexual functioning.

Men with prostate cancer at low risk of spreading may undergo surgery to remove the whole prostate or radiation therapy. Some may instead choose active surveillance: observing the cancer over time with imaging and tissue biopsies, and only starting treatment if it grows. Men with cancer at higher risk of spreading may have surgery, or radiation plus therapy to suppress hormones that fuel prostate cancer growth.

Studies have shown that how long men live is similar regardless of the chosen treatment. Whether the long-term side effects differ substantially between these treatments hasn't been clear.

A research team led by Drs. Bashir Al Hussein Al Awamlh and Daniel Barocas from Vanderbilt University Medical Center decided to look more closely at this issue. They recruited almost 2,500 men, 80 years old or younger, from diverse racial backgrounds and geographic areas across the country for a new study, funded in part by NIH. All the men were treated for prostate cancer between 2011-2012 and followed for side effects for 10 years after treatment. The results were published on January 23, 2024, in *JAMA*.

As seen previously, survival rates were similar between men in the two groups, regardless of treatment received. Overall, 0.4% of men with low-risk cancer and 5% of men with high-risk cancer died of their disease over the following 10 years.

Participants reported similar levels of overall physical and mental health regardless of treatment choice. But the researchers did observe differences in some specific side effects between treatments. Men with low-risk cancer who underwent surgery were more likely to report problems with sexual functioning up to 5

years after treatment than men who had radiation or who initially chose surveillance. However, the differences between groups was no longer significant by the 10-year mark.

Among men with low-risk cancer, 14% who had surgery had trouble with leaking urine 10 years after treatment, compared with 4% of those who had radiation therapy and 10% of those who initially chose active surveillance. But 8% of men who had radiation reported serious bowel problems after 10 years compared with 3% of those who had surgery.

For men with high-risk cancer, no differences in sexual functioning were seen between surgery or radiation therapy plus hormone therapy at any time point. About a quarter of those who had surgery reported urinary leakage after 10 years, compared with 11% who had radiation therapy. Seven percent of men who had radiation plus hormone therapy reported serious bowel problems, compared with 2% to 5% of men who had surgery.

"Many men with localized prostate cancer survive for 15 years or more, with minimal differences in survival among various treatment strategies," says Al Hussein Al Awamlh. "Given this long-time horizon and similar survival rates, the choice of treatment for patients may be influenced by the adverse effects of the treatments."

—by Sharon Reynolds

Related Links

- New Insight into Regenerating Prostate Tissue
- Combining Tests More Accurately Diagnoses Prostate Cancer
- Biomarker Signatures of Prostate Cancer
- Genomic Diversity of Metastases Among Men with Prostate Cancer
- Combination Therapy for Metastatic Prostate Cancer
- Prostate Predicaments: When Bladder Problems Are Pressing
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Funding: NIH's National Cancer Institute (NCI) and National Center for Advancing Translational Sciences (NCATS); Agency for Healthcare Research and Quality.

Source: https://www.nih.gov/news-events/nih-research-matters/comparing-side-effects-after-prostate-cancer-treatment

How to Administer Multiple Intramuscular Vaccines to Adults During One Visit

It is not unusual for adults to need more than one vaccination at an office visit. When that occurs, CDC recommends giving all needed vaccines at the same visit to reduce missed opportunities.

These vaccines commonly administered to adults* are administered via the intramuscular route:

COVID-19	Influenza
Hepatitis A	Pneumococcal
Hepatitis B	Respiratory Syncytial Virus (RSV)
Human papillomavirus (HPV)	Tdap and Td
	Zoster

Determine vaccines to be administered.

- Review each patient's vaccine history and determine needed vaccines (see CDC's recommended schedule of immunizations for adults at www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf).

Determine which vaccines to give in separate limbs.

- Administer vaccines more likely to cause a local reaction in separate limbs, if possible. Vaccines that cause injection site pain in at least half of recipients include COVID-19, zoster, HepA, HPV, pneumococcal (PCV, PPSV), and tetanus-containing vaccines (Tdap, Td).†
- If administration in separate limbs is not feasible or desired, administration in the same limb, separated by at least 1" (inch), is appropriate.

Select the injection site(s) for intramuscular injections.

- Determine which vaccine(s) will be administered in each limb (see options in diagrams at right). You can administer 1, 2, or 3 injections per deltoid, spaced at least 1" apart.
- *Deltoid muscle:* Locate the central and thickest portion of the deltoid muscle – above the level of the armpit and approximately 2" below the acromion process (see diagram at right).
- *Anterolateral thigh muscle:* Locate the outer portion of the middle third of the thigh (see diagram at right).

Prepare to administer IM injections.

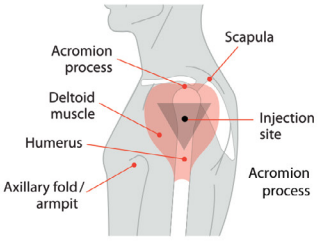
- Choose the needle gauge and length needed for the patient's age and weight (see "Administering Vaccines to Adults: Dose, Route, Site, and Needle Size" at www.immunize.org/catg.d/p3084.pdf).
- Draw up each vaccine using a separate, new needle and syringe.
- Label each vaccine syringe and clearly indicate on the label or tray the planned injection site (e.g., right arm [RA], left arm [LA], right thigh [RT], left thigh [LT]).
- Administer injection at a 90° angle (see "How to Administer Intramuscular and Subcutaneous Vaccine Injections to Adults" at www.immunize.org/catg.d/p2020a.pdf). If more than one injection is given in a single limb (arm or leg), separate the injections by a minimum of 1".

* Additional vaccines may be indicated for an adult due to missed childhood vaccinations, medical conditions, exposure risk, travel plans, or occupational risk.
† According to clinical trial data provided in prescribing information.

The diagrams below illustrate options for administering one, two, or three vaccinations in a single arm, spaced at least 1" apart. Additional injections can also be administered in the opposite arm.

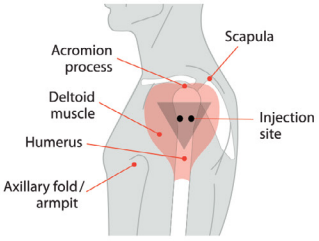
Use anatomical landmarks to determine the injection site in the deltoid muscle (a large, rounded, triangular shape). Find the acromion process, which is the bony point at the end of the shoulder. Then, locate the injection site which will be approximately 2" below the bone and above the axillary fold/armpit.

Single IM injection in deltoid



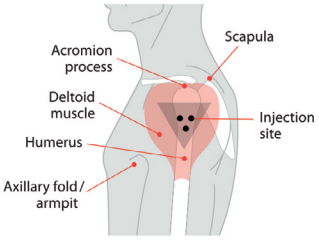
Two IM injections in deltoid

Space injections at least 1" apart.

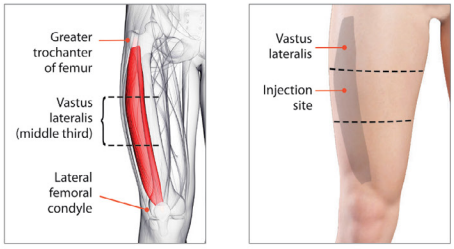


Three IM injections in deltoid

Space injections at least 1" apart.



An IM injection may also be administered in the anterolateral thigh muscle as shown below.



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www.immunize.org/catg.d/p2030.pdf
Item #P2030 (12/4/2023)

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HORIBA
Medical

New Moderate Complexity Drugs of Abuse for the Yumizen C1200

Increasing your laboratory's efficiency and walkaway time, enabling you to work on other laboratory tasks, by using our automated and efficient clinical chemistry and drugs of abuse screening analyzer.

The Yumizen C1200 is an ideal platform for laboratories performing drugs of abuse screening due to its:

- **Throughput** → 1200 test/hour with ISE
- **Compact Design** → Requires minimal floorspace
- **Micro-volume Technology** → Uses less reagent

By combining general and specialty chemistry assays with drugs of abuse screening on a single platform, HORIBA offers an exceptional tool to monitor patient health.

Moderate Complexity Drugs of Abuse Assays for the Yumizen C1200

Amphetamine/Methamphetamine	Ecstasy	Methadone Metabolite	**Adulterants:**
Barbiturate	Ethyl Alcohol	Opiate	Creatinine
Benzodiazepine	Fentanyl	Oxycodone	General Oxidant
Buprenorphine	Heroin Metabolite (6-AM)	Phencyclidine (PCP)	pH
Cannabinoid (THC)	Hydrocodone	Propoxyphene	Specific Gravity
Cocaine Metabolite	Methadone		

Features & Benefits

- Excellent correlation with LCMS
- Offers full test menu including DAU screening and chemistry assays
- High throughput system with a compact footprint
- HORIBA Service & Support team maximizes analyzer uptime
- Decreases cost per test with micro-volume technology

Sensitivity and Specificity Rates for Fentanyl II Assay Method Comparison

		LCMS	
		Positive	Negative
Yumizen C1200	Positive	57	1[1]
	Negative	1	50

[1] Sample contained both fentanyl and norfentanyl. Yumizen C1200 Fentanyl II Assay detects both analytes. LCMS result reflects only the detection of fentanyl

HORIBA and Henry Schein have programs available to help you bring drugs of abuse screening into your lab with the Yumizen C1200.

For more information, contact your local Henry Schein representative

Explore the future

Addressing Vaccination Anxiety in Adolescents and Adults

Strategies for Healthcare Professionals

Anxiety about injections is common among adolescents and adults, and can contribute to dreading, delaying, or even refusing vaccination. However, anxiety and pain are subjective feelings: what you do and say can help an anxious patient gain confidence and more readily accept vaccinations in the future.

Below are strategies that can improve the vaccination experience for adolescents and adults. Consider what is practical. Simply acknowledging the patient's feelings and letting them know you care can help.

Before the Visit

Pre-registration may minimize time in the waiting room where anxiety can mount.

Establish expectations. If possible, let patients know they will be offered any needed vaccinations and that you'll work with them to make the experience comfortable.

Set up the vaccination room/area so it's comfortable and private. Keep needles out of sight until necessary.

Consider topical analgesia (e.g., 5% lidocaine cream, spray, or patch). This may help with pain but needs to be applied to the vaccination site 30 to 60 minutes ahead of time. With guidance, some patients may accomplish this before arriving.[1]

During the Visit

Screen for vaccination-related anxiety. Immunize.org's screening checklists for contraindications to vaccines now ask about anxiety.[2]

Invite patients to ask questions about the vaccination process so they feel prepared.

Watch your words! Use words that help the patient cope during vaccination. Using fear-provoking words (e.g., "shot," "sting") or false reassurances ("It won't hurt a bit") can increase distress and pain.

Ask each patient what helps them feel comfortable. Make suggestions, if needed. Slow deep breaths can be calming. A lot of people like to be distracted (some don't) and they can be encouraged to chat or use their mobile devices. Posters can serve as distractions, too. Offer pain management options, if feasible (see below).

KEY IDEA: **Asking patients how they prefer to manage their anxiety is essential.**

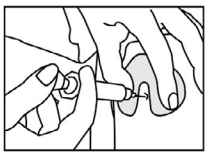
Non-pharmacological Pain Management Options (to minimize pain signals from the skin)

Cooling the injection site with a vapocoolant spray immediately before injection.

Using injection techniques that diminish the pain experience: Don't aspirate before intramuscular injections. Inject quickly. If giving multiple injections, give the most painful vaccine last.

Placing a vibrating case with optional ice pack (e.g., Buzzy by Pain Care Labs) proximal to the injection site (closer to the trunk).

Placing a plastic device with several short, blunt contact points (e.g., ShotBlocker by Bionix, pictured right) on the patient's skin before injection. These are non-prescription, inexpensive and can be cleaned and reused.



After the Visit

Use of pain-reducing medicines (e.g., ibuprofen or acetaminophen) before vaccination is not recommended because it might diminish the immune system's response to vaccination. They may be used to treat pain or fever after vaccination.

For more information, see Immunize.org's resources on Addressing Vaccination Anxiety, available at www.immunize.org/handouts.

1. *Guide to Topical Anesthetics and Numbing Cream* from the Meg Foundation at www.megfoundationforpain.org/2022/7/22/topical-anesthetics-infographic/
2. Screening Checklists about Vaccine Contraindications and Precautions from Immunize.org at www.immunize.org/clinic/screening-contraindications.asp
3. *Improving the Vaccination Experience: What Health-Care Providers Say* from AboutKidsHealth (Canada) at assets.aboutkidshealth.ca/AKHassets/CARD_HCP_WhatYouCanSay.pdf?hub=cardcommvac#card

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