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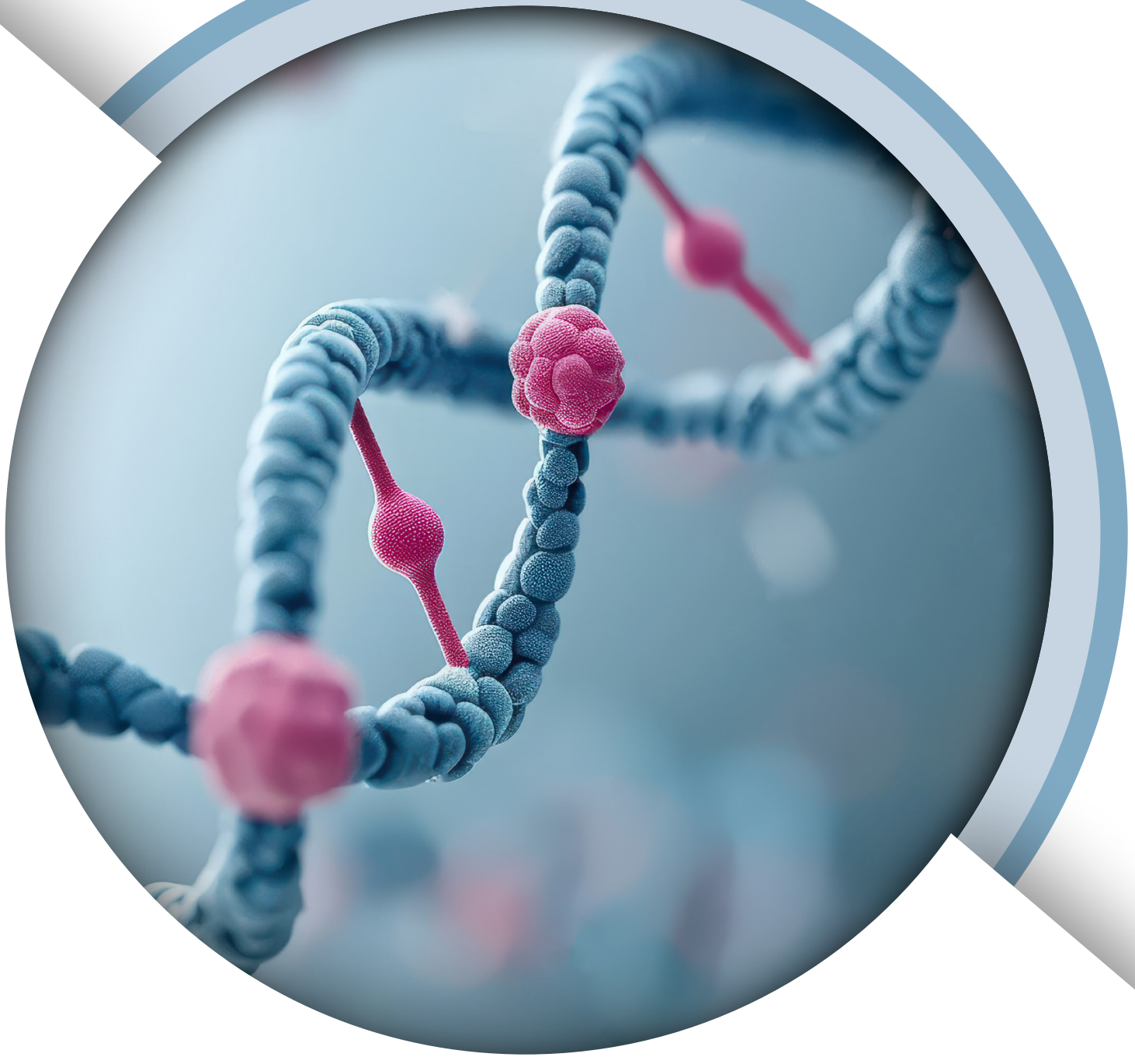

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Diagnostic and Pharmaceutical News for You and Your Medical Practice

BIOTHERAPEUTICS QUARTERLY

Diagnostic and Pharmaceutical News for You and Your Medical Practice

2025/Spring/Volume 59

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New DRUG APPROVALS

PENMENVY (meningococcal groups A, B, C, W, and Y vaccine) Lyophilized Powder for Injection
Date of Approval: February 14, 2025
Company: GlaxoSmithKline
Treatment for: Meningococcal Disease Prophylaxis
Penmenvy (meningococcal groups A, B, C, W, and Y vaccine) is a vaccine indicated for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroups A, B, C, W, and Y in individuals 10 through 25 years of age.

VIMKUNYA (chikungunya vaccine, recombinant) Injection
Date of Approval: February 14, 2025
Company: Bavarian Nordic A/S
Treatment for: Chikungunya Disease Prevention
Vimkunya (chikungunya vaccine, recombinant) is a vaccine used for the prevention of disease caused by chikungunya virus.

OSPOMYV (denosumab-dssb) Injection
Date of Approval: February 13, 2025
Company: Samsung Bioepis Co., Ltd.
Treatment for: Osteoporosis
Ospomyv (denosumab-dssb) is a RANK ligand (RANKL) inhibitor biosimilar to Prolia used in the treatment of osteoporosis.

DATROWAY (datopotamab deruxtecan-dlnk) Lyophilized Powder for Injection
Date of Approval: January 17, 2025
Company: AstraZeneca and Daiichi Sankyo
Treatment for: Breast Cancer
Datroway (datopotamab deruxtecan-dlnk) is a TROP2-directed antibody and topoisomerase inhibitor conjugate used for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer.

OPDIVO QVANTIG (nivolumab and hyaluronidase-nvhy) Subcutaneous Injection
Date of Approval: December 27, 2024
Company: Bristol-Myers Squibb Company
Treatment for: Renal Cell Carcinoma, Melanoma, Non-Small Cell Lung Cancer, Head and Neck Cancer, Urothelial Carcinoma, Colorectal Cancer, Hepatocellular Carcinoma, Esophageal Carcinoma, Gastric Cancer Opdivo Qvantig (nivolumab and hyaluronidase-nvhy) is a programmed death receptor-1 (PD-1)-blocking antibody and hyaluronidase combination for use in the treatment of renal cell carcinoma, melanoma, non-small cell lung cancer, squamous cell carcinoma of the head and neck, urothelial carcinoma, colorectal cancer, hepatocellular carcinoma, esophageal cancer, gastric cancer, gastroesophageal.

National Institutes of Health
Turning Discovery Into Health

January 14, 2025

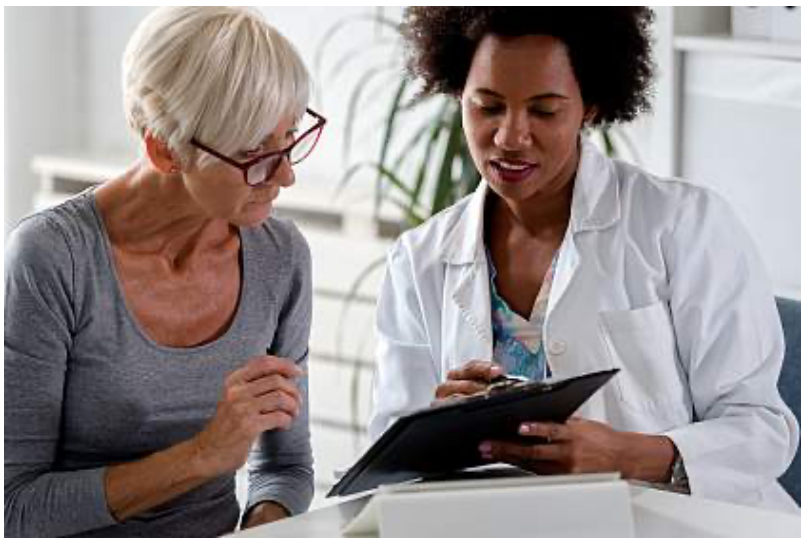
Prevention and screening drive drop in cancer deaths

At a Glance

- Most deaths avoided from common cancers between 1975 and 2020 could be traced to prevention and screening efforts.
- Improved treatments, however, accounted for most of the reduction in deaths from breast cancer.
- Understanding which strategies have been most effective in reducing cancer deaths can help guide their future use nationwide.

Over the last five decades, the number of deaths from many cancer types has dropped substantially in the U.S. A range of factors have played a role in this decrease. These include better treatments, prevention efforts such as smoking cessation, and nationwide screening campaigns to catch cancers—or precancerous growths—early.

It hasn't been clear how much each of these factors has contributed to the overall drop in deaths observed since 1975. Understanding the largest contributors could help focus further research and promotion of the most effective strategies.



The success of prevention and screening approaches differs between cancer types. *Lordn / Shutterstock*

A research team led by Drs. Katrina Goddard and Philip Castle from NIH set out to better understand the contributions of prevention, screening, and treatment to the observed drop in cancer mortality. They used models developed by the Cancer Intervention and Surveillance Modeling Network (CISNET) through 2020.

The models examined deaths from five of the most common types of cancer: breast, cervical, colorectal, lung, and prostate cancer. They projected how cancer mortality rates changed under four different scenarios. These scenarios were: no advances in prevention, screening, or treatment; prevention and screening only; treatment advances only; and advances in prevention, screening, and treatment. Results were published on December 5, 2024, in *JAMA Oncology*.

The researchers estimated that, between 1975 and 2020, almost 6 million deaths from these cancers were averted through a combination of prevention, screening, and improved treatments. Together, prevention and screening averted about 4.75 million, or 80%, of the deaths.

The contributions of prevention and screening differed between cancer types. For example, 98% of lung cancer deaths were averted by efforts to help people stop smoking. Nearly all deaths averted from cervical cancer were by screening and the removal of pre-cancerous growths. In contrast, only 25% of breast cancer deaths averted were due to regular mammography. Rather, improved treatments were responsible for most of these averted deaths.

“Although many people may believe that treatment advances are the major driver of reductions in mortality from these five cancers combined, the surprise here is how much prevention and screening contribute to reductions in mortality,” Goddard says. “Eight out of 10 deaths from these five cancers that were averted over the past 45 years were due to advances in prevention and screening.”

“The impact of these interventions cannot be understated because they not only saved lives, but they also kept healthy people healthy,” Castle notes. He adds, “The success of these interventions also emphasizes the need for continued research to discover ways to prevent and screen for other cancers.”

More recent prevention and screening strategies, such as lung cancer screening and HPV vaccination to prevent cervical and other HPV-related cancers, were not in wide use during the study period and could further reduce cancer death rates.

The study did not address the potential harms of interventions, such as false-positive results and overdiagnosis during screening. It also didn’t measure other outcomes, such as quality of life. Further work will be needed to fine-tune and personalize screening recommendations.

Related Links

- Urine Test Identifies High-Risk Prostate Cancers
- Sigmoidoscopies Decrease Colon Cancer Deaths
- CT Screening Significantly Reduces Lung Cancer Mortality
- Advances in Breast Cancer: Screening and Treatment Get Personal
- Lowering Your Cancer Risk: Healthy Living for Cancer Prevention
- Better Check Your Bowels: Screening for Colon and Rectal Cancer
- Cancer Screening

References: Estimation of cancer deaths averted from prevention, screening, and treatment efforts, 1975-2020. Goddard KAB, Feuer EJ, Mandelblatt JS, Meza R, Holford TR, Jeon J, Lansdorp-Vogelaar I, Gulati R, Stout NK, Howlader N, Knudsen AB, Miller D, Caswell-Jin JL, Schechter CB, Etzioni R, Trentham-Dietz A, Kurian AW, Plevritis SK, Hampton JM, Stein S, Sun LP, Umar A, Castle PE. *JAMA Oncol*. 2024 Dec 5:e245381. doi: 10.1001/jamaoncol.2024.5381. Online ahead of print. PMID: 39636625.

Funding: NIH’s National Cancer Institute (NCI).

Source: https://www.nih.gov/news-events/nih-research-matters/prevention-screening-drive-drop-cancer-deaths

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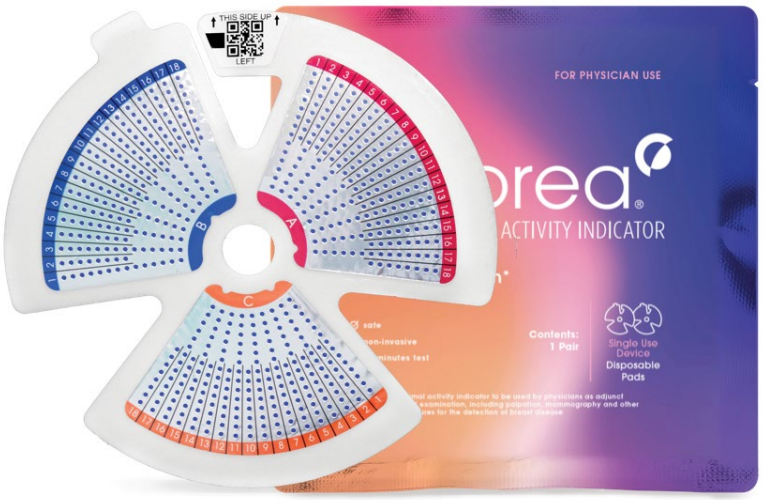

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National Institutes of Health
Turning Discovery Into Health

December 10, 2024

Chromosome abnormalities found in healthy breast tissue

At a Glance

- Researchers found that normal human breast tissue harbors rare cells with chromosome abnormalities previously linked to invasive cancers.
- Future studies will be needed to assess the significance of these abnormal cells for breast cancer risk.

Epithelial cells, which line many body surfaces, can transform into several types of cancer. These transformed cancer cells often have an abnormal number of chromosomes, either more or less than the standard 23 pairs of chromosomes. This condition, called aneuploidy, is a hallmark of cancer, and it is commonly seen in breast cancer.

A few studies in recent years have used advanced genetic sequencing techniques to detect small numbers of aneuploid cells in normal body tissues, including the brain, colon, liver, lymphocytes, and sperm. But the significance of these rare aneuploid cells in healthy tissues is not well understood.

Abnormal cells were found in normal breast tissue, challenging previous notions of what constitutes a cancerous cell. *Gregory Miller / Adobe Stock*

A research team led by Dr. Nicholas Navin of the University of Texas MD Anderson Cancer Center set out to learn about the prevalence and potential impact of aneuploid epithelial cells in normal breast tissue. They analyzed breast epithelial cells from 49 women who were undergoing breast reduction surgery. All of the women were healthy and had no signs of breast cancer. Their ages ranged from 18 to 63.

The researchers used a combination of advanced sequencing techniques to assess chromosome additions and deletions in more than 83,000 breast epithelial cells from these women. They then compared their findings to previously gathered data from women who had invasive breast cancer. Study results appeared in *Nature* on November 20, 2024.

The researchers found that all of the 49 healthy women harbored rare aneuploid epithelial cells in their breast tissue. A median of about 3% of the tested cells in each woman were aneuploid. The number of aneuploid epithelial cells in each woman tended to increase with age. Most of these abnormal cells (median more than 80%) had undergone significant chromosomal changes, many of which are seen in invasive breast cancers.

The findings suggest that most healthy women have low levels of aneuploid cells in their breast tissues. Additional studies are needed to determine if increased levels of these rare cells raise the risk for future breast cancer. In addition, the researchers note that their findings might also be applicable to other organs and tissues that contain epithelial cells.

“We’ve always been taught that normal cells have 23 pairs of chromosomes. But that appears to be inaccurate because every healthy woman that we analyzed in our study had irregularities, bringing up the very provocative question about when cancer actually occurs,” Navin says. “This has pretty big implications not just for the field of breast cancer, but potentially for multiple cancer types.”

—by Vicki Contie

Related Links

- Gene Variants and Breast Cancer Risk in Black Women
- Technique May Improve Detection of Breast Tumors
- Test Predicts Whether Chemotherapy Will Help Early-Stage Breast Cancer Patients
- Breast Cancer Tumor Test to Tailor Treatments
- Advances in Breast Cancer: Screening and Treatment Get Personal
- The Cancer Genome Atlas Program (TCGA)

References: Normal breast tissues harbour rare populations of aneuploid epithelial cells. Lin Y, Wang J, Wang K, Bai S, Thennavan A, Wei R, Yan Y, Li J, Elgamal H, Sei E, Casasent A, Rao M, Tang C, Multani AS, Ma J, Montalvan J, Nagi C, Winocour S, Lim B, Thompson A, Navin N. *Nature*. 2024 Nov 20. doi: 10.1038/s41586-024-08129-x. Online ahead of print. PMID: 39567687.

Funding: NIH’s National Cancer Institute (NCI); Cancer Prevention and Research Institute of Texas Single Cell Genomics Center; Vivian Smith Foundation.

Source: https://www.nih.gov/news-events/nih-research-matters/chromosome-abnormalities-found-healthy-breast-tissue

PREVENTING CHRONIC DISEASE
PUBLIC HEALTH RESEARCH, PRACTICE, AND POLICY
Volume 21, E102 DECEMBER 2024

GIS SNAPSHOTS

Mapping Geographic Access to Illinois Birthing Hospitals, 2016–2023

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Accessible Version: www.cdc.gov/pcd/issues/2024/24_0332.htm

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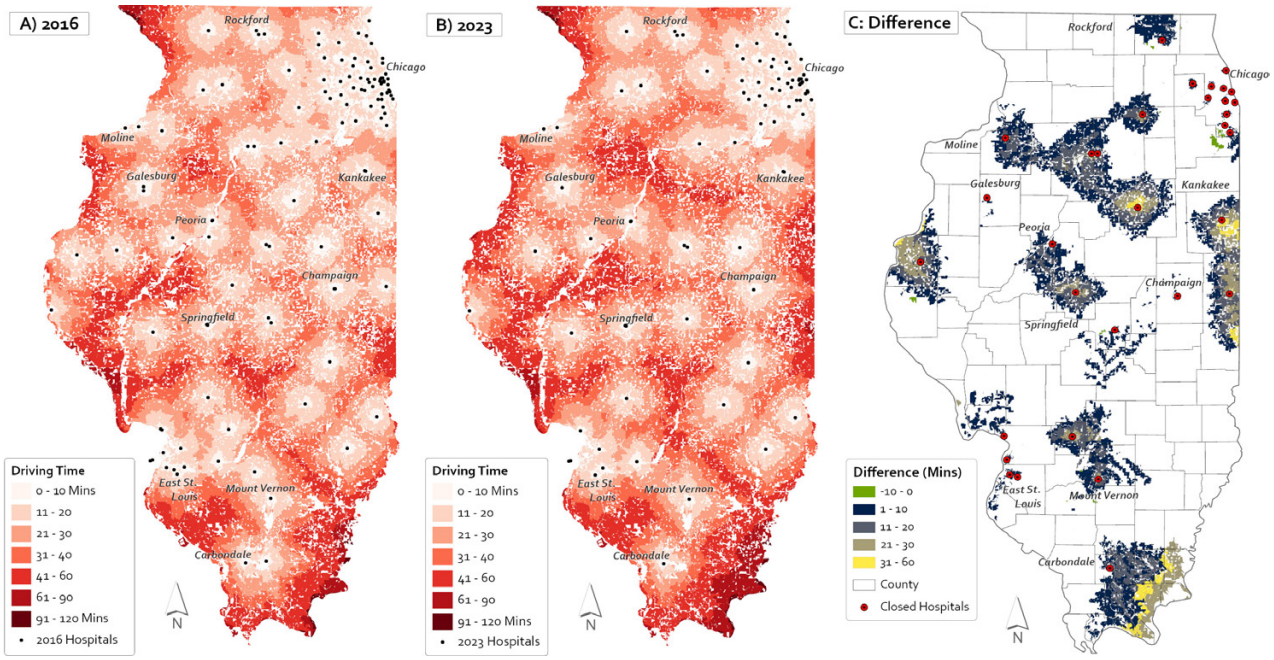

Three maps depict driving time from Illinois census blocks to the nearest birthing hospital in 2016 (Map A) and 2023 (Map B). Driving time to the nearest birthing center increased near hospital closures, particularly in the east and southeast, near Kankakee and Carbondale (Map C). Source: Illinois Department of Public Health, US. Census Bureau.

Purpose

Timely access to quality obstetric care is a critical component in promoting maternal health and positive birth outcomes (1). Access to risk-appropriate care, or care in facilities equipped with necessary personnel and services, is critical for optimizing obstetric and neonatal outcomes (2). The closure of hospital-based obstetric services, which include specialized resources and a specialized health care workforce, has been associated with an increase in out-of-hospital and preterm births, particularly in rural areas (3–5). Additionally, longer travel distances may delay or disrupt receipt of prenatal care, impede specialized care for patients with high-risk conditions, and adversely affect birth outcomes (6).

The objectives of our study were to assess the spatial and temporal changes in geographic access to Illinois birthing hospitals from 2016 to 2023 for women of reproductive age (15 y to 49 y) residing in Illinois. Additionally, we illustrate the use of novel methods to estimate geographic access, by using isochrones (areas that represent equal travel time from a central location) to calculate driving time and census blocks, the smallest US Census spatial unit, to estimate access to birthing hospitals for women of reproductive age. This approach captures drive time estimates for all populated census blocks in Illinois, in contrast to census tract or county-level centroid analyses, which may obscure travel times for populations not residing near the geographic or population center of these larger spatial units.

Data and Methods

We obtained Illinois birthing hospital addresses and closures from 2016, the first year of data collection, to 2023 from the Illinois Department of Public Health. We used ESRI ArcGIS (Esri) to geocode the locations of these hospitals and used an isochrone-based approach to calculate drive times to the hospitals in 10-minute increments from 0 to 40 minutes, followed by increments of 40 to 60 minutes, 60 to 90 minutes, and 90 to 120 minutes.

Drive-time isochrones represent the area accessible within a specified driving time to or from a particular point of interest, such as a hospital. Compared with the straight-line distance measures often used in birthing hospital access literature (7,8), drive-time isochrones provide a more accurate estimate of geographic access by accounting for travel routes, speed limits, and traffic patterns. This method considers the real-world complexities of travel, such as road network layouts and obstacles, resulting in a more realistic measure of how long it takes to reach a specific location, such as a hospital. Accuracy is crucial when assessing geographic access to health care services because travel time may affect health outcomes (9).

We obtained US Census block polygons and demographic information (age, sex, rural or urban place of residence) from the Integrated Public Use Microdata Series National Historical Geographic Information System (10). The US Census uses census blocks, the smallest geographic sampling unit, to tabulate decennial data that are then aggregated into larger spatial units such as census tracts and counties. In Illinois, census blocks average 0.16 square miles with an average population of 35 people. In comparison, census tracts average 17.3 square miles with 3,929 people, and counties average 552.4 square miles with 126,107 people.

To assess geographic access to Illinois birthing hospitals for women of reproductive age, we converted census block polygons to geographic centroids and joined them with isochrone polygons to determine the drive-time increment for each block. We visualized the spatiotemporal patterns of geographic access to birthing hospitals in maps for 2016 (Map A) and 2023 (Map B) and the driving time difference between these years (Map C). Additionally, we tabulated a summary of the proportion of women residing within 10, 30, 60, 90, and 120 minutes of a birthing hospital in 2016 and 2023 and the change over time, stratified by rural or urban residence. To generate an estimate of the birthing population that may be affected by birthing hospital closures, we assumed that the population of women of reproductive age remained static from 2016 through 2023.

Highlights

From 2016 to 2023, the number of birthing hospitals in Illinois decreased from 118 to 86, affecting geographic accessibility for women of reproductive age residing in Illinois (Map C). Women mostly resided in urban census blocks (89.4%, n = 2,635,775) compared with rural census blocks (10.6%, n = 313,273). In 2016, 76.5% (n = 239,654) of women in rural census blocks lived within 30 minutes of a birthing hospital, compared with 99.1% (n = 2,612,053) of women in urban census blocks. By 2023, these percentages decreased to 65.4% (n = 204,881) for rural women and 98.0% (n = 2,583,060) for urban women.

These findings highlight a decline in geographic access to birthing hospitals in Illinois from 2016 to 2023, especially for women of reproductive age in rural areas, where 11.1% (n = 34,773) of women were no longer within a 30-minute drive, compared with 1.1% (n = 28,993) in urban areas. Although most women of reproductive age live in urban areas, rural women experienced a greater decline in geographic access from 2016 to 2023, leading to longer travel times and potentially delaying essential obstetric care, which may exacerbate rural–urban maternal health disparities.

Action

The maps from our analysis depict the increase in driving time to the nearest birthing hospital resulting from birthing hospital closures, particularly in east and southeast Illinois, resulting in decreased geographic access in rural areas. Equitable access is essential for achieving positive and equitable maternal and infant health outcomes. Access to timely care may play a role in the disparities that exist in maternal health outcomes by rurality (11). Strategies could address gaps in access to high-quality obstetric health care in rural areas. The National Rural Health Association recommends strategies such as obstetric training and simulations for rural health care providers in hospital emergency departments, telemedicine consultation with regional perinatal centers, improved equipment and consultation resources for emergency medical services, and support of a doula workforce in rural communities to reduce pregnancy complications (12). The American College of Obstetricians and Gynecologists describes the importance of regionalized perinatal centers for providing rural hospitals with ready access to consultation, referral, and outreach education, and in establishing interhospital agreements for the timely transport of pregnant patients (13).

Acknowledgments

This work was supported by the Illinois Department of Public Health and the Division of Reproductive Health in the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). The authors declare no potential conflicts of interest with respect to the research, authorship, or publication of this article. No copyrighted materials were used in this article. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.

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Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years or Older — United States, 2025

A. Patricia Wodi, MD[1]; Anindita N. Issa, MD[1]; Charlotte A. Moser, MS[2]; Sybil Cineas, MD[3]

At its October 2024 meeting, the Advisory Committee on Immunization Practices* (ACIP) approved the Recommended Immunization Schedule for Adults Ages 19 Years or Older, United States, 2025. The schedule supports health care providers, as well as public health and other professionals, by providing a consolidated summary of current ACIP recommendations for adult vaccination. The 2025 schedule includes several updates to the cover page, tables, notes, and appendix.† The addendum remains part of the schedule and will be used to summarize new or updated ACIP recommendations that occur before the next annual schedule update. Health care providers are strongly encouraged to use all parts of the schedule (the cover page, tables, notes, appendix, and addendum) together when making recommendations for individual patients. The 2025 adult immunization schedule can be found on the CDC website (https://www.cdc.gov/vaccines/hcp/imz-schedules/index.html).

Consistent with previous years' schedules, the 2025 adult immunization schedule is recommended by ACIP (https://www.cdc.gov/acip/index.html) and approved by CDC (https://www.cdc.gov), the American College of Physicians (https://www.acponline.org), the American Academy of Family Physicians (https://www.aafp.org), the American College of Obstetricians and Gynecologists (https://www.acog.org), the American College of Nurse-Midwives (https://www.midwife.org), the American Academy of Physician Associates (https://www.aapa.org), the American Pharmacists Association (https://www.pharmacist.com), and the Society for Healthcare Epidemiology of America (https://shea-online.org).

ACIP's recommendations for use of each vaccine are developed after in-depth reviews of vaccine-related data including disease epidemiology and societal impacts, vaccine efficacy and effectiveness, vaccine safety, quality of evidence, feasibility of program implementation, impact on health equity, and economic analyses of immunization policy (*1*,*2*). For each vaccine in the schedule, clinical trials are conducted in the context of standard-of-care related to the routine adult immunization schedule (*3*). Routinely recommended vaccines are monitored by CDC and the Food and Drug Administration (FDA) for safety through ongoing and cumulative efforts including multiple surveillance systems, safety studies, and review of the literature (https://www.cdc.gov/vaccine-safety-systems/about/cdc-monitoring-program.html). Recommendations for specific vaccines that occur between annual schedule updates§ are summarized in the addendum section; however, health care providers should refer to detailed ACIP recommendations for use of each vaccine (https://www.cdc.gov/acip-recs/hcp/vaccine-specific/index.html). ACIP vaccine recommendations do not establish mandates.

The use of vaccine trade names in this report and in the adult immunization schedule is for identification purposes only and does not imply endorsement of a specific product by ACIP or CDC.

Changes in the 2025 Adult Immunization Schedule

Compared with the 2024 adult schedule, vaccine-specific changes in the 2025 immunization schedule for adults include new and updated recommendations for COVID-19 vaccines (*4*), influenza vaccines (*5*), meningococcal serogroup B vaccines (*6*), pneumococcal conjugate vaccines (PCV) (*7*,*8*), and respiratory syncytial virus vaccines (RSV) (*9*). In all sections of the schedule, recommended influenza vaccines have been changed from the quadrivalent to trivalent formulation to be consistent with the vaccine products approved by FDA for the 2024–25 influenza season. In addition, inactivated polio vaccine was added to the Tables. Other changes include clarification in the Notes sections for hepatitis B vaccine (HepB); mpox vaccine (Mpox); and tetanus and diphtheria toxoids, and acellular pertussis vaccine (Tdap).

* Recommendations for routine use of vaccines in adults are developed by ACIP, a federal advisory committee chartered to provide expert external advice and guidance to the CDC director on use of vaccines and related agents for the control of vaccine-preventable diseases in the civilian population of the United States. Recommendations for routine use of vaccines in adults are harmonized to the greatest extent possible with recommendations made by the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists. ACIP recommendations become official agency guidelines once the recommendations have been adopted by the CDC director. Additional information about ACIP is available at https://www.cdc.gov/acip/index.html.

† Past immunization schedules are available at https://www.cdc.gov/vaccines/hcp/imz-schedules/resources.html.

§ CDC encourages organizations to use syndication as a more reliable method for displaying the most current and accurate immunization schedules on an organization's website, rather than copying these schedules to their websites. Use of content syndication requires a one-time step that ensures an organization's website displays current schedules as soon as they are published or revised; instructions for the syndication code are available on CDC's website (https://www.cdc.gov/vaccines/hcp/imz-schedules/syndicate-resources.html). CDC also offers technical assistance for implementing this form of content syndication (requests can be emailed to ncirdwebteam@cdc.gov).

Cover Page

- Trivalent adjuvanted inactivated influenza vaccine (aIIV3), trivalent cell culture–based inactivated influenza vaccine, trivalent high-dose inactivated influenza vaccine (HD-IIV3), newly licensed 21-valent pneumococcal conjugate vaccine (PCV21), and the newly licensed mRNA respiratory syncytial virus vaccine (mResvia) were added to the table listing abbreviations and trade names of the vaccines.

Table 1 (Age-Based Immunization Schedule)

- The legend definition for the gray box was revised to harmonize with Table 2 and the child and adolescent immunization schedule. The text states, "No Guidance/ Not Applicable."
- **COVID-19 row:** The text overlay was revised to reflect updated vaccination recommendations. The text overlay for adults aged 19–64 years now states, "1 or more doses of updated 2024–2025 vaccine (See Notes)," and that for those aged ≥65 years states, "2 or more doses of updated 2024–2025 vaccine (See Notes)."
- **Influenza row:** This row was revised to reflect the preferential recommendation for use of HD-IIV3, aIIV3, and trivalent recombinant influenza vaccine in persons aged ≥65 years. In addition, a purple row and overlaying text is used to reflect the recommendation adding HD-IIV3 and aIIV3 to the vaccines that may be administered to solid organ transplant recipients aged 19–64 years who are receiving immunosuppressive medications.
- **IPV row:** This row is a new addition to the table. The color of this row is yellow, indicating that vaccination is routinely recommended for all adults who are incompletely vaccinated. The text overlay states, "Complete 3-dose series if incompletely vaccinated. Self-report of previous doses acceptable (See Notes)."
- **Mpox row:** The text overlay "2 doses" was added.
- **Pneumococcal row:** PCV21 was added to the list of recommended pneumococcal conjugate vaccines. For adults aged ≥50 years, the row is yellow, indicating that pneumococcal vaccination is universally recommended for adults in this age group if they have never received a dose of PCV (PCV15, PCV20, or PCV21) or if their previous pneumococcal vaccination history is unknown. For adults aged 19–49 years, the row is purple, indicating that pneumococcal vaccination is recommended for adults in this age group if they have medical conditions or other risk factors that increase their risk for pneumococcal disease.
- **RSV row:** This row was revised to reflect current RSV recommendations for adults aged ≥60 years. For adults aged ≥75 years, the row is yellow, indicating that vaccination is universally recommended for adults in this age group if they have not been previously vaccinated. For adults aged 60–74 years, the row is purple, indicating that vaccination is recommended for this age group if they have a risk factor or other indication that increases their risk for severe RSV disease.

Table 2 (Immunization Schedule by Medical Indication)

- **COVID-19 row:** In the column for immunocompromised persons (excluding those with HIV infection) and in the column for those with HIV infection and CD4+ T-lymphocyte count <15% or <200/mm^3, the row color was changed to brown to reflect that additional doses are recommended.
- **Influenza (inactivated, recombinant) row:** A text overlay "Solid organ transplant (See Notes)" was added under the immunocompromised (excluding HIV) column to reflect updated vaccination recommendations for this subgroup.
- **IPV row:** This row is a new addition to the table; it includes an orange bar for the pregnancy column, indicating that vaccination might be indicated if benefit of protection outweighs the risk for an adverse reaction. For other columns, the row is yellow, indicating that vaccination is routinely recommended for all adults who are incompletely vaccinated. The text overlay states, "Complete 3-dose series if incompletely vaccinated. Self-report of previous doses acceptable (See Notes)."
- **RSV row:** This row was revised to reflect current RSV recommendations. Except for the pregnancy column, all other columns are purple indicating vaccination is recommended for some adults who have these conditions. The text overlay "See Notes" is added to medical conditions known to increase risk for severe RSV disease.

Vaccine Notes

The notes for each vaccine are presented in alphabetical order. Edits have been made throughout the Notes section to harmonize language, to the greatest extent possible, with that in the child and adolescent immunization schedule.

- **COVID-19:** The "Routine vaccination" and "Special situations" sections were revised to reflect recommendations for use of 2024–2025 COVID-19 vaccine in adults. The "Routine vaccination" section describes recommendations for the general population, and the "Special situations" section describes recommendations for persons who are

moderately or severely immunocompromised. In each section, the recommendations are outlined by previous COVID-19 vaccination history, and in the "Routine vaccination" section, they are also outlined by age group. Hyperlinks to the interim clinical considerations for use of COVID-19 vaccines as well as Emergency Use Authorization indications for COVID-19 vaccines are included.

- **HepB:** In the "Special situations" section, dosing recommendations for immunocompromised persons aged ≥20 years were added. The guidance on vaccines that are not recommended for use during pregnancy was revised to remove Heplisav-B.
- **Influenza:** The "Routine vaccination" section was updated with new recommendations adding aIIV3 and HD-IIV3 as vaccine options that can be administered to solid organ transplant recipients aged 19–64 years who are receiving immunosuppressive medications.
- **Meningococcal:** The "Special situations" section for MenACWY was revised to clarify that booster doses are recommended after completion of the primary series. In the MenB notes, both the "Routine vaccination" and "Special situations" sections were revised to include the new Bexsero vaccination schedule. For healthy persons aged 16–23 years, a series of 2 doses separated by 6 months is recommended based on shared clinical decision-making. Adults at increased risk for serogroup B meningococcal disease are recommended to receive a 3-dose series at 0-, 1–2-, and 6-month intervals. In addition, the information for MenB use during pregnancy was revised to clarify that the recommendation to delay vaccination until after pregnancy is based on a lack of safety data in pregnant persons.
- **Mpox:** Language for vaccinating health care personnel was revised to clarify that vaccination to protect against occupational risk in health care settings is not routinely recommended.
- **Pneumococcal:** PCV21 was added to all sections of the notes as an option when vaccination is indicated. The "Routine vaccination" section now reflects the new recommendation for universal vaccination for adults aged ≥50 years, and the "Special situations" section outlines the risk-based recommendation for adults aged 19–49 years. In addition, information was added for use of pneumococcal vaccines during pregnancy, and recommendations for situations when PPSV23 is unavailable.
- **RSV:** The "Routine vaccination" section now outlines recommendations for universal vaccination for pregnant persons and adults aged ≥75 years. The "Special situations" section includes risk-based recommendations for adults aged 60–74 years and the list of medical and other conditions that increase the risk for severe RSV disease. Language was added to clarify that persons can self-attest to the presence of a risk factor.
- **Tdap:** The "Routine vaccination" section was revised to describe the recommendations according to previous vaccination history.

Appendix (Contraindications and Precautions)

- **Hepatitis B row:** In the "Contraindicated and Not Recommended" column, the language about vaccines not recommended for use during pregnancy was revised to remove Heplisav-B. The corresponding footnote with hyperlink to the pregnancy registries was also revised to remove information for the Heplisav-B registry, which is no longer active.
- **Pneumococcal row:** PCV21 was added.
- **Zoster row:** The "Precautions" column was revised to clarify that vaccination should be delayed during a current episode of herpes zoster.

Additional Information

The Recommended Adult Immunization Schedule, United States, 2025, is available at https://www.cdc.gov/vaccines/hcp/imz-schedules/adult-age.html. The full ACIP recommendations for each vaccine are also available at https://www.cdc.gov/acip-recs/hcp/vaccine-specific/index.html. All vaccines identified in Tables 1 and 2 (except Zoster vaccine) also appear in the Recommended Immunization Schedule for Children and Adolescents, United States, 2025 (https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html). For vaccines that appear in both the adult immunization schedule and the child and adolescent immunization schedule, the language in both schedules has been harmonized to the greatest extent possible.

Acknowledgments

Rosters of current and past members of the Advisory Committee on Immunization Practices are available at https://www.cdc.gov/acip/membership/index.html.

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Expanded Recommendations for Use of Pneumococcal Conjugate Vaccines Among Adults Aged ≥50 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, 2024

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Abstract

Before October 2024, the Advisory Committee on Immunization Practices (ACIP) recommended use of a pneumococcal conjugate vaccine (PCV) for all adults aged ≥65 years, as well as for those aged 19–64 years with risk conditions for pneumococcal disease who have not received a PCV or whose vaccination history is unknown. Options included either 20-valent PCV (PCV20; Prevnar20; Wyeth Pharmaceuticals) or 21-valent PCV (PCV21; CAPVAXIVE; Merck Sharp & Dohme) alone or 15-valent PCV (PCV15; VAXNEUVANCE; Merck Sharp & Dohme) in series with 23-valent pneumococcal polysaccharide vaccine (PPSV23; Pneumovax23; Merck Sharp & Dohme). There are additional recommendations for use of PCV20 or PCV21 for adults who started their pneumococcal vaccination series with 13-valent PCV (PCV13; Prevnar13; Wyeth Pharmaceuticals). The ACIP Pneumococcal Vaccines Work Group employed the Evidence to Recommendations framework to guide its deliberations on expanding the age-based PCV recommendation to include adults aged 50–64 years. On October 23, 2024, ACIP recommended a single dose of PCV for all PCV-naïve adults aged ≥50 years. Recommendations for PCVs among adults aged 19–49 years with risk conditions and PCV13-vaccinated adults have not changed from previous recommendations. This report summarizes evidence considered for these recommendations and provides updated clinical guidance for use of PCV.

Introduction

Streptococcus pneumoniae (pneumococcus) is a common bacterial cause of respiratory tract infections, bacteremia, and meningitis. Widespread use of pneumococcal conjugate vaccine (PCV) in children reduced the incidence of pneumococcal disease, both among children through direct effects and among older children and adults who have not received PCV through indirect effects (i.e., reduction in disease incidence in the population because of decreased transmission of pneumococcus from children) (*1*,*2*). However, persons with underlying conditions or factors that increase their risk for pneumococcal disease (risk conditions)* and older adults experience higher pneumococcal disease rates. In addition, racial disparities in pneumococcal disease incidence persist, including higher rates among non-Hispanic Black or African American (Black) and non-Hispanic American Indian or Alaska Native (AI/AN) adults (*3*).

* Alcoholism; cerebrospinal fluid leak; chronic heart, liver, or lung disease; chronic renal failure; cigarette smoking; cochlear implant; congenital or acquired asplenia; diabetes mellitus; generalized malignancy; HIV; Hodgkin disease; immunodeficiency; iatrogenic immunosuppression; leukemia, lymphoma, or multiple myeloma; nephrotic syndrome; solid organ transplant; or sickle cell disease or other hemoglobinopathies.

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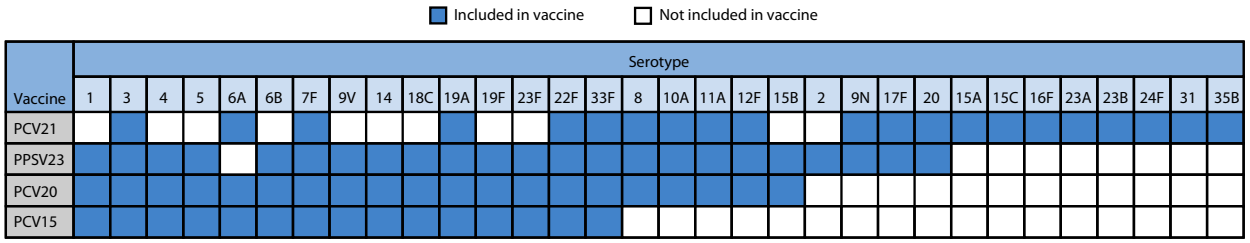
Before its October meeting, the Advisory Committee on Immunization Practices (ACIP) recommended receipt of a single dose of PCV for all adults aged ≥65 years and those aged 19–64 years with a risk condition who have not received PCV or whose vaccination history is unknown. Options included either 20-valent PCV (PCV20; Prevnar20; Wyeth Pharmaceuticals) (*4*) or 21-valent PCV (PCV21; CAPVAXIVE; Merck Sharp & Dohme) (*5*) alone, or 15-valent PCV (PCV15; VAXNEUVANCE; Merck Sharp & Dohme) (*6*) followed by 23-valent pneumococcal polysaccharide vaccine (PPSV23; Pneumovax23, Merck Sharp & Dohme) (*7*). Additional recommendations are applicable for use of PCV20 or PCV21 for adults who commenced their pneumococcal vaccination series with 13-valent PCV (PCV13; Prevnar13, Wyeth Pharmaceuticals) (*8,9*).

In June 2024, ACIP recommended PCV21 as an option for adults who are recommended to receive PCV and proposed a review of available evidence to determine whether data supported lowering the age-based recommendation to ≥50 years for all recommended PCVs (*8*). The approval of PCV21, which was specifically developed to target pneumococcal serotypes that commonly cause disease in adults (Figure), was seen as a unique opportunity to reduce pneumococcal disease incidence and health disparities among U.S. adults. This report summarizes the evidence considered by ACIP regarding the expansion of the age-based recommendation to include adults

FIGURE. Serotypes*,† included in pneumococcal vaccines currently recommended for adults — United States, 2024



Abbreviations: PCV = pneumococcal conjugate vaccine; PCV15 = 15-valent PCV; PCV20 = 20-valent PCV; PCV21 = 21-valent PCV; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

* PCV21 is approved for the prevention of invasive pneumococcal disease caused by serotype 15B based upon prespecified criteria for the proportion of participants with fourfold or more rise in opsonophagocytic activity responses. https://www.fda.gov/media/179426/download?attachment

† PCV21 contains serotype 20A.

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aged 50–64 years, highlighting considerations of pneumococcal disease incidence and mortality, health disparities, and resource use.

Methods

During July–October 2024, the ACIP Pneumococcal Vaccines Work Group considered PCV use among PCV-naïve adults aged 50–64 years within the Evidence to Recommendations (EtR) framework.† Published and unpublished data on pneumococcal disease incidence and mortality, pneumococcal vaccination coverage, and economic models of age-based PCV use at age ≥50 years were reviewed; and findings were summarized by race and ethnicity whenever available (*3,10*). Previous Grading of Recommendations, Assessment, Development and Evaluation (GRADE) reviews for PCV15, PCV20, and PCV21 (*8,11,12*) were supplemented by an updated search of MEDLINE, (using PubMed) and ClinicalTrials.gov to identify additional literature on safety and immunogenicity. Postlicensure safety data on PCV20 from the Vaccine Adverse Event Reporting System (VAERS) and an analysis using Centers for Medicare & Medicaid Services (CMS) data were reviewed.

Rationale and Evidence

Pneumococcal Disease Incidence in Adults Aged ≥19 Years

Pneumococcal pneumonia, accounting for 12%–13% of all hospitalized pneumonia cases, has been estimated to result in approximately 225,000 U.S. adult hospitalizations annually (*13–15*). Among adults aged 50–64 years with invasive pneumococcal disease (IPD) and those hospitalized with pneumococcal pneumonia, approximately 90% had one or more risk condition (*3,14*). Before the COVID-19 pandemic, approximately 30,000 IPD§ cases occurred annually among U.S. adults (*16*). In 2022, adults aged 50–64 years experienced IPD incidence and mortality rates of 13.2 and 1.8 per 100,000 population, respectively. These rates were higher than those in all other age groups except adults aged ≥65 years, whose incidence and mortality rates were 17.2 and 2.7 per 100,000 population, respectively (*1*). According to CDC's Active Bacterial Core surveillance (ABCs) data, during 2018–2022 (before PCV20 was widely used and before PCV21 approval among adults), 56% and 83%¶ of IPD cases were due to pneumococcal serotypes contained in PCV20 and PCV21 in adults aged 50–64 years, respectively (*17*).

Racial Disparities in Pneumococcal Disease Incidence and Vaccination Coverage

An estimated 32%–54% of adults aged 50–64 years had at least one risk condition that qualifies for risk-based pneumococcal vaccination.** However, 2022 Behavioral Risk Factor Surveillance System data showed that only 37% of adults aged 50–64 years with a risk-based vaccination recommendation received a pneumococcal vaccine, compared with 70% of adults aged ≥65 years with an age-based recommendation; racial disparities in vaccination rates were apparent†† (*3*). ABCs data showed that IPD rates among Black adults peaked at a younger age (55–59 years) compared with rates among non-Black adults whose IPD rates increased with increasing age (*3*). Although PCV13 use among U.S. children has reduced disparities in PCV13-type IPD incidence in adults, likely because of indirect effects; remaining racial disparities are driven by non-PCV13 serotypes, with non-PCV13 serotype IPD rates among AI/AN and Black adults (25 and 10 per 100,000 population, respectively) exceeding the population average of six per 100,000 (*3*).

PCV Immunogenicity and Safety from Clinical Trials

An updated literature search identified six PCV15 trials (*18–23*), three PCV20 trials (*24–26*), and seven PCV21 trials (*27–32*) that included immunogenicity and safety data for adults aged ≥50 years. Summary of evidence from the updated literature search remained essentially unchanged from previous summaries (*3,8,11,12*). Compared with PCV13, PCV15 met noninferiority criteria for all shared PCV13 serotypes, and immune responses for non-PCV13 serotypes 22F and 33F were statistically significantly higher. PCV20 met noninferiority criteria for all PCV13 serotypes compared with PCV13 and for six of seven non-PCV13 serotypes (not met for serotype 8) compared with PPSV23 (*24–26*). Compared with PCV20, PCV21 met noninferiority criteria for 10 of 10

† https://www.cdc.gov/acip/evidence-to-recommendations/adults-50-64-without-pneumococcal-vaccine-etr.html

§ Defined as a pneumococcal infection in a normally sterile site (e.g., blood, cerebrospinal fluid, bone, or joint space).

¶ PCV21 received indication for protection against IPD serotype 15B based on immunogenicity data. The percentage increases to 85% if serotype 15B is included as part of PCV21 serotype.

** At least one of the following conditions, according to the 2020 National Health Interview Survey: chronic heart disease, chronic lung disease, chronic liver disease, diabetes, smoking, alcoholism, weakened immune system due to prescriptions, weakened immune system due to health condition, solid cancer (not including nonmelanoma skin cancer or unknown type of skin cancer), and blood cancer. The percentages were 32% for non-Hispanic Asian (Asian) adults; 43% for Hispanic or Latino (Hispanic) adults; 50% for non-Hispanic White (White) adults; and 54% for Black adults.

†† According to 2022 Behavioral Risk Factor Surveillance System data, coverage with any pneumococcal vaccine among adults aged 50–64 years with risk-based recommendation by race and ethnicity was 27.9% (Hispanic), 39.3% (White), 38.2% (Black), 36.5% (Asian), and 35.1% (AI/AN); coverage among adults aged ≥65 years by race and ethnicity was 55.1% (Hispanic), 72.7% (White), 63.1% (Black), 64.1% (Asian), and 62.1% (AI/AN).

shared serotypes, and immune responses for 10 of 11 unique serotypes were statistically significantly higher (not met for serotype 15C). No vaccine-related serious adverse events (SAEs) were reported after PCV15 or PCV20 administration; two vaccine-related SAEs had been previously reported after PCV21 administration (*8*).

PCV20 Postlicensure Safety Data

Analysis of reports to VAERS after PCV20 administration in adults aged ≥19 years during October 2021–August 2024 showed a signal for Guillain-Barré syndrome (GBS); however, the overall reporting rate remained low (0.7 cases per million doses distributed) (*3*). Primary analysis of CMS data through May 2024 showed a statistically significant signal for GBS[§§] after PCV20 administration in Medicare beneficiaries aged ≥65 years. However, the signal was not statistically significant when applying an alternative GBS definition in sensitivity analysis or adjusted for the positive predictive value of diagnostic codes compared with confirmation by chart review (*3*).

Economic Analysis

Two economic models (Tulane-CDC and Merck) assessed the cost-effectiveness of PCV20 and PCV21 use among PCV-naïve adults aged 50–64 years (*10*). A third model (Pfizer) assessed the cost-effectiveness of PCV20 use only (*10*). All three models used quality-adjusted life-year (QALY) as the primary health outcome. The Tulane-CDC model estimated costs of $131,023–$214,430 per QALY gained for PCV21 and $251,037–$546,811 for PCV20. The Merck model estimated $251,048–$425,455 per QALY gained for PCV21 and $548,114–$879,117 for PCV20. The Pfizer model estimated $56,376–$133,524 per QALY gained for PCV20. Cost-effectiveness estimates were most sensitive to assumptions about indirect effects from pediatric vaccination and duration of protection from vaccination. Limitations of the models included uncertainties about duration of protection from vaccination, magnitude of indirect effects from pediatric vaccination, and impact of future supplementary pneumococcal vaccine doses for adults.

Recommendations for Use of PCV

ACIP recommended PCV for all PCV-naïve adults aged ≥50 years. Recommendations for PCVs for adults aged 19–49 years with a risk condition and for adults who have previously received PCV13 remain unchanged (Table) (*8*). The recommendation was supported by several factors, including the potential to improve vaccination coverage and reduce pneumococcal disease incidence and mortality in adults aged 50–64 years, particularly among demographic groups experiencing higher disease rates. Ease of implementing consistent age-based recommendations for all PCVs was also considered. Uncertainties regarding key assumptions guiding the economic models and higher cost per QALY estimates for PCV20 compared with PCV21 were acknowledged.

Summary

What is already known about this topic?

Before October 2024, a single dose of 15-valent, 20-valent, or 21-valent pneumococcal conjugate vaccine (PCV), was recommended for adults aged 19–64 years with risk conditions for pneumococcal disease and for all adults aged ≥65 years.

What is added by this report?

On October 23, 2024, the Advisory Committee on Immunization Practices recommended a single dose of PCV for all adults aged ≥50 years who are PCV-naïve or who have unknown vaccination history. The risk-based recommendation for adults aged 19–49 years is unchanged.

What are the implications for public health practice?

The updated, expanded age-based recommendation is expected to improve pneumococcal disease prevention in adults aged 50–64 years, particularly among demographic groups experiencing higher disease rates.

Selection of PCV in Populations with High Proportions of Serotype 4 Pneumococcal Disease

In many U.S. settings, PCV21 is expected to cover more circulating pneumococcal strains than do other recommended PCVs. In certain populations in which ≥30% of pneumococcal disease[¶¶] is due to serotype 4, pneumococcal vaccines that include serotype 4 (PCV20 alone or PCV15 and PPSV23 in series) (Figure) are expected to provide broader serotype coverage against locally circulating strains than does PCV21 (Box).

PPSV23 Use in PCV13-Experienced Adults Who Have Not Completed the Recommended Vaccination Series

Among adults aged ≥19 years who have started their pneumococcal vaccination series with PCV13 but have not received all recommended doses, PPSV23 is no longer recommended as an option to complete the series. Either PCV20 or

[§§] These cases were based on claims without chart confirmation. Therefore, in addition to the GBS definition used for the primary analysis (*International Classification of Diseases, Tenth Revision, Clinical Modification* [ICD-10-CM] code: G61.0), an alternative definition based on literature search (ICD-10-CM codes: G61.0, G61.81, G61.1, G61.8, and G61.9) was used for sensitivity analysis.

[¶¶] The 30% threshold was guided by economic models that showed that once the percentage of cases of pneumococcal disease caused by serotype 4 exceeds 30%, PCV21 use might result in higher cost and, in some cases, worse health outcomes compared with PCV20 use. https://www.cdc.gov/acip/downloads/slides-2024-06-26-28/02-Pneumococcal-Stoecker-508.pdf

TABLE. Clinical guidance for implementing pneumococcal vaccine recommendations for adults aged ≥19 years — United States, October 2024

Risk or age group	Vaccine received previously	Options for vaccination
Adults aged ≥50 years	None or PCV7 only at any age	A single dose of PCV21, PCV20, or PCV15. If PCV15 is administered, a single dose of PPSV23* should be administered ≥1 year after the PCV15 dose. A minimum interval of 8 weeks can be considered if PCV15 is used in adults with an immunocompromising condition,† cochlear implant, or CSF leak.
	PPSV23 only	A single dose of PCV21, PCV20, or PCV15 ≥1 year after the last PPSV23 dose.
	PCV13 only	A single dose of PCV21 or PCV20 ≥1 year after the PCV13 dose.
	PCV13 at any age and PPSV23 at age <65 years	A single dose of PCV21 or PCV20 ≥5 years after the last pneumococcal vaccine dose.
	PCV13 at any age and PPSV23 at age ≥65 years	Shared clinical decision-making is recommended regarding administration of either a single dose of PCV21 or PCV20 for any adult aged ≥65 years who has completed the recommended vaccination series with both PCV13 and PPSV23 (i.e., PPSV23 administered at age ≥65 years) but PCV21, PCV20, or PCV15 not yet received. If a decision to administer PCV21 or PCV20 is made, a single dose is recommended ≥5 years after the last pneumococcal vaccine dose.
Adults aged 19–49 years with an immunocompromising condition,† a CSF leak, or a cochlear implant	None or PCV7 only at any age	A single dose of PCV21, PCV20, or PCV15. If PCV15 is used, administer a single dose of PPSV23* ≥8 weeks after the PCV15 dose.
	PPSV23 only	A single dose of PCV21, PCV20, or PCV15 ≥1 year after the last PPSV23 dose.
	PCV13 only	A single dose of PCV21 or PCV20 administered ≥1 year after the PCV13 dose.
	PCV13 and 1 dose of PPSV23	A single dose of PCV21 or PCV20 ≥5 years after the last pneumococcal vaccine dose. The pneumococcal vaccination series is complete, and it need not be followed by additional pneumococcal vaccine doses.
	PCV13 and 2 doses of PPSV23	The pneumococcal vaccination recommendations should be reviewed again when the person turns age 50 years. Alternatively, a single dose of either PCV21 or PCV20 should be administered ≥5 years after the last pneumococcal vaccine dose. If PCV21 or PCV20 is used, the series is complete, and it need not be followed by additional pneumococcal vaccine doses.
Adults aged 19–49 years with chronic medical conditions§	None or PCV7 only at any age	A single dose of PCV21, PCV20, or PCV15. If PCV15 is administered, a single dose of PPSV23* should be administered ≥1 year after the PCV15 dose.
	PPSV23 only	A single dose of PCV21, PCV20, or PCV15 ≥1 year after the last PPSV23 dose.
	PCV13 only	A single dose of PCV21 or PCV20 ≥1 year after the PCV13 dose.
	PCV13 and 1 dose of PPSV23	The pneumococcal vaccination recommendations should be reviewed again when the person reaches age 50 years.

Abbreviations: CSF = cerebrospinal fluid; PCV = pneumococcal conjugate vaccine; PCV7 = 7-valent PCV; PCV13 = 13-valent PCV; PCV15 = 15-valent PCV; PCV20 = 20-valent PCV; PCV21 = 21-valent PCV; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

* For adults who have received PCV15 but have not completed their recommended pneumococcal vaccine series with PPSV23, 1 dose of PCV21 or PCV20 may be used if PPSV23 is not available.

† Chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, HIV infection, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplant, congenital or acquired asplenia, or sickle cell disease or other hemoglobinopathies.

§ Alcoholism; chronic heart disease, including congestive heart failure and cardiomyopathies; chronic liver disease; chronic lung disease, including chronic obstructive pulmonary disease, emphysema, and asthma; cigarette smoking; or diabetes mellitus.

PCV21 is recommended to complete the series as previously recommended. (Table).

Coadministration with Other Vaccines

In accordance with CDC's General Best Practice Guidelines for Immunization, routine administration of a pneumococcal vaccine with other age-appropriate doses of vaccines at the same visit is recommended for adults who have no specific contraindications to vaccination at the time of the health care visit (*33*).

Contraindications and Precautions

Vaccination providers should consult the vaccine package insert for precautions, warnings, and contraindications (*4–7*). Vaccination with PCV or PPSV23 is contraindicated in persons known to have had a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine. Because PCVs are conjugated to CRM197, a nontoxic genetically altered diphtheria toxin, these vaccines are also contraindicated in persons known to have had a severe allergic reaction to any diphtheria toxoid–containing vaccine (*4–7*).

Reporting of Vaccine Adverse Events

Adverse events occurring after administration of any vaccine should be reported to VAERS. Instructions for reporting to VAERS are available at https://vaers.hhs.gov/reportevent.html or by calling 800-822-7967.

BOX. Clinical guidance on selection of pneumococcal conjugate vaccine in communities with high percentages of serotype 4 pneumococcal disease — United States, 2024

- PCV21 contains eight pneumococcal serotypes that are not included in previously recommended pneumococcal vaccines (i.e., PCV15, PCV20, and PPSV23). However, PCV21 does not contain certain pneumococcal serotypes that are contained in previously recommended pneumococcal vaccines, one of which is pneumococcal serotype 4.
- In certain adult populations in the western United States, high percentages (i.e., ≥30%) of IPD caused by serotype 4 have occurred. The available IPD serotype data from CDC's Active Bacterial Core surveillance, as well as similar surveillance from Alaska and Navajo Nation, indicate that this serotype is particularly prevalent in Alaska, Colorado, Navajo Nation, New Mexico, and Oregon. Serotype 4 IPD occurs across age groups; however, cases are frequently observed among adults aged <65 years who have underlying conditions such as alcoholism, chronic lung disease, cigarette smoking, homelessness, and injection drug use. In such populations in these geographic areas, other recommended pneumococcal vaccines (e.g., PCV20 alone or both PCV15 and PPSV23) are expected to provide broader serotype coverage against locally circulating strains compared with PCV21.
- The percentages of serotype 4 IPD cases in other areas of the western United States without IPD surveillance are currently unknown. IPD surveillance from other geographic areas in the United States (e.g., midwestern, eastern, and southern regions) has not detected significant percentages of serotype 4.
- This clinical guidance will be reviewed and updated as pneumococcal disease epidemiology evolves.

Abbreviations: IPD = invasive pneumococcal disease; PCV = pneumococcal conjugate vaccine; PCV13 = 13-valent PCV; PCV15 = 15-valent PCV; PCV20 = 20-valent PCV; PCV21 = 21-valent PCV; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

Future Research and Monitoring Priorities

CDC and ACIP will continue to assess safety and public health impact of pneumococcal vaccines among adults. This includes monitoring the duration of vaccine-conferred immunity from PCV to determine the need for a booster to ensure that older adults continue to be protected under the updated vaccine recommendation and to measure any indirect effects on incidence in adults from routine childhood vaccination.

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ACIP Pneumococcal Vaccines Work Group

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Vaccine Administration Record for Adults

Before administering any vaccines, give the patient copies of all pertinent Vaccine Information Statements (VISs) and make sure they understand the risks and benefits of the vaccine(s). Always provide or update the patient's personal record card.

Patient name _____

Birthdate _____ Chart number _____

PRACTICE NAME AND ADDRESS

Vaccine	Type of Vaccine[1]	Date Vaccine Given (mo/day/yr)	Funding Source (F,S,P)[2]	Site[3]	Vaccine		Vaccine Information Statement (VIS)		Vaccinator[5] (signature or initials and title)
					Lot #	Mfr.	Date on VIS[4]	Date given[4]	
Tetanus, Diphtheria, Pertussis (e.g., Tdap, Td) Give IM.[3]									
Hepatitis A[6] (e.g., HepA, HepA-HepB) Give IM.[3]									
Hepatitis B[6] (e.g., HepB, HepA-HepB) Give IM.[3]									
Human papillomavirus (HPV) Give IM.[3]									
Measles, Mumps, Rubella (MMR) Give MMRII Subcut or IM; give Priorix Subcut.[3]									
Varicella (VAR) Give Subcut or IM.[3]									
Meningococcal ACWY[6] (e.g., MenACWY, MenABCWY) Give IM.[3]									
Meningococcal B[6] (e.g., MenB-4C, MenB-FHbp, MenABCWY) Give IM.[3]									

CONTINUED ON THE BACK ▶

Abbreviation	Trade Name and Manufacturer
Tdap	Adacel (Sanofi); Boostrix (GSK)
Td	Tenivac (Sanofi); Tdvax (MA Biological Labs)
HepA	Havrix (GSK); Vaqta (Merck)
HepB (see note #1)	Engerix-B (GSK); Recombivax HB (Merck); Heplisav-B (Dynavax)
HepA-HepB	Twinrix (GSK)
HPV	Gardasil 9 (Merck)
MMR	MMR II (Merck); Priorix (GSK)
VAR	Varivax (Merck)
MenACWY	MenQuadfi (Sanofi); Menveo (GSK)
MenB-4C (see note #1)	Bexsero (GSK)
MenB-FHbp (see note #1)	Trumenba (Pfizer)
MenABCWY (see note #1)	Penbraya (Pfizer)

How to Complete this Record

1. For hepatitis B and meningococcal B vaccines (MenB or MenABCWY), record the trade name (see table at left); for all other vaccines, record the standard abbreviation (e.g., Tdap).
2. Record the funding source of the vaccine given as either F (federal), S (state), or P (private).
3. Record the route by which the vaccine was given as either intramuscular (IM), subcutaneous (Subcut), or intranasal (NAS), and also the site where it was administered as either RA (right arm), LA (left arm), RT (right thigh), or LT (left thigh).
4. Record the publication date of each VIS as well as the date the VIS is given to the patient.
5. To meet the space constraints of this form and federal requirements for documentation, a healthcare setting should keep a reference list of vaccinators that includes their initials and titles.
6. For combination vaccines, fill in a row for each antigen in the combination.

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FOR PROFESSIONALS www.immunize.org / **FOR THE PUBLIC** www.vaccineinformation.org

www.immunize.org/catg.d/p2023.pdf

Item #P2023 (1/24/2025)

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Vaccine Administration Record for Adults (continued)

Patient name _____

Birthdate _____ Chart number _____

PRACTICE NAME AND ADDRESS

Before administering any vaccines, give the patient copies of all pertinent Vaccine Information Statements (VISs) and make sure they understand the risks and benefits of the vaccine(s). Always provide or update the patient's personal record card.

Vaccine	Type of Vaccine[1]	Date Vaccine Given (mo/day/yr)	Funding Source (F,S,P)[2]	Site[3]	Vaccine		Vaccine Information Statement (VIS)		Vaccinator[5] (signature or initials and title)
					Lot #	Mfr.	Date on VIS[4]	Date given[4]	
Poliovirus (IPV) Give IM or Subcut.[3]									
Pneumococcal conjugate (e.g., PCV15, PCV20, PCV21) Give IM.[3]									
Pneumococcal polysaccharide (e.g., PPSV23) Give IM or Subcut.[3]									
Influenza (IIV, ccIIV, RIV, LAIV) Give IIV, ccIIV, and RIV IM.[3] Give LAIV NAS.[3]									
Zoster (shingles) Give RZV IM.[3]									
COVID-19 (e.g., 1vCOV-mRNA; 1vCOV-aPS) Give IM.[3]									
Hib Give IM.[3]									
RSV Give IM.[3]									
Mpox Give Subcut.[3]									
Other:									
Other:									

Abbreviation	Trade Name and Manufacturer
IPV	Ipol (Sanofi)
PCV15, PCV20, PCV21	PCV15: Vaxneuvance (Merck); PCV20: Prevnar 20 (Pfizer); PCV21: Capvaxive (Merck)
PPSV23	Pneumovax 23 (Merck)
aIIV (adjuvanted inactivated influenza vaccine [IIV])	Fluad (GSK)
ccIIV (cell culture-based IIV)	Flucelvax (Seqirus)
HD-IIV (high-dose IIV)	Fluzone High-Dose (Sanofi)
LAIV (live attenuated influenza vaccine]	FluMist (AstraZeneca)
RIV (recombinant influenza vaccine)	Flublok (Sanofi)
SD-IIV (standard dose IIV)	Fluarix, FluLaval (GSK); Afluria (Seqirus); Fluzone (Sanofi)
Mpox	Jynneos (Bavaria Nordic)
RZV (recombinant zoster vaccine)	Shingrix (GSK)
1vCOV-mRNA (see note #1)	Comirnaty (Pfizer-BioNTech); Spikevax (Moderna)
1vCOV-aPS (see note #1)	Novavax (Novavax)
Hib	ActHIB (Sanofi); Hiberix (GSK); PedvaxHib (Merck)
RSV (respiratory syncytial virus vaccine) (see note #1)	Arexvy (GSK); Abrysvo (Pfizer), mResvia (Moderna)

How to Complete this Record

1. For RSV and COVID-19 vaccines, record the trade name (see table at left); for all other vaccines, record the standard abbreviation (e.g., Tdap) or the trade name for each vaccine (see table at left).
2. Record the funding source of the vaccine given as either F (federal), S (state), or P (private).
3. Record the route by which the vaccine was given as either intramuscular (IM), subcutaneous (Subcut), or intranasal (NAS), and also the site where it was administered as either RA (right arm), LA (left arm), RT (right thigh), or LT (left thigh).
4. Record the publication date of each VIS as well as the date the VIS is given to the patient.
5. To meet the space constraints of this form and federal requirements for documentation, a healthcare setting should keep a reference list of vaccinators that includes their initials and titles.

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PREVENTING CHRONIC DISEASE
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ORIGINAL RESEARCH

Trends in Gestational Weight Gain and Prepregnancy Obesity in South Carolina, 2015–2021

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PEER REVIEWED

Summary

What is already known on this topic?

The prevalence of prepregnancy obesity, inadequate weight gain, and excessive weight gain is high among pregnant women and varies by race and ethnicity. However, whether the COVID-19 pandemic (eg, food shortages, isolation due to lockdown measures) had a significant long-term effect on weight gain in this population is unclear.

What is added by this report?

The COVID-19 pandemic did not alter trends of gestational weight gain. It did, however, have a small effect on trends in prepregnancy obesity, with differential effects across racial and ethnic groups.

What are the implications for public health practice?

Prepregnancy obesity and gestational weight gain are public health issues that can lead to the development of adverse maternal and infant pregnancy outcomes, warranting effective public health interventions.

Abstract

Introduction

We examined trends in prepregnancy obesity and gestational weight gain, with a focus on racial and ethnic differences, before and during the COVID-19 pandemic in South Carolina.

Methods

Hospital and emergency department discharge codes were linked to birth certificates. Prepregnancy obesity was defined as a body mass index (kg/m^2) of 30 or higher. Gestational weight gain was defined as inadequate, adequate, or excessive based on the 2009 Institute of Medicine guidelines. A generalized linear model with a multinomial distribution and glogit link estimated the risk of inadequate weight gain and excessive weight gain with adequate weight gain as the reference group. The generalized linear model with a modified Poisson distribution and log link estimated prepregnancy obesity risk with nonobese as the reference group.

Results

Our study included 306,344 full-term, singleton live births among 239,597 mothers from 2015 through 2021. The prevalence of inadequate weight gain increased across all racial and ethnic groups prepandemic (relative risk [RR] = 1.02; 95% CI, 1.01–1.02) and attenuated during the pandemic (RR = 0.99; 95% CI, 0.96–1.01). The prevalence of excessive weight gain was high and remained stable across all races and ethnicities before and during the pandemic. The prevalence of prepregnancy obesity increased across all racial and ethnic groups prepandemic; the prevalence after the start of the pandemic increased only among women of "other" races and ethnicities (RR = 1.12; 95% CI, 1.05–1.19) while attenuating among Hispanic, non-Hispanic Black, and non-Hispanic White women.

Conclusion

The COVID-19 pandemic did not alter trends of gestational weight gain; however, it did have a small effect on trends in prepregnancy obesity, with differential effects across racial and ethnic groups. The prevalence of prepregnancy obesity, inadequate weight gain, and excessive weight gain remains high among pregnant women in South Carolina. Obesity and weight gain are risk factors for many adverse maternal and infant preg-

nancy outcomes. Their high prevalence indicates the importance of developing effective weight management programs for women of childbearing age and pregnant women.

Introduction

Over the past 40 years, obesity and weight gain have increased rapidly in the US, particularly among children, adolescents, and young adults. However, the literature is lacking assessment of how obesity and weight gain have changed over time among women of childbearing age. The Centers for Disease Control and Prevention's (CDC's) Pregnancy Risk Assessment Monitoring System and the National Vital Statistics System reported the prevalence of adequate weight gain during pregnancy as 32.1% during 2012 and 2013 (1). During the same period, the prevalence of inadequate weight gain during pregnancy was 20.4%, and the prevalence of excessive weight gain was 47.5%. Stratified by prepregnancy body mass index (BMI) (kg/m^2) category, underweight women (32.2%) were more likely to gain inadequate weight during pregnancy, whereas 61.6% of overweight and 55.8% of obese women were more likely to gain excessive weight than women of normal weight (1).

CDC's National Vital Statistics System reported that 27.2% of women were overweight before pregnancy and 30% had obesity in 2020. Among women who had obesity, 16.1% were classified as class I obese (BMI 30.0 to 34.9), 8.1% as class II obese (BMI 35.0 to 39.9), and 5.9% as class III obese (BMI ≥40.0) (2). Additionally, the prevalence of obesity was significantly higher among non-Hispanic Black women (40.3%) compared with non-Hispanic White (27.4%) and Hispanic women (33.6%) (2).

Prepregnancy obesity and gestational weight gain are associated with many adverse infant outcomes (low birthweight, preterm birth, large size for gestational age, admission to neonatal intensive care unit, macrosomia, childhood obesity, infant mortality) and poor maternal outcomes (cesarean delivery, gestational hypertension, preeclampsia) (3–7).

Although the association between prepregnancy obesity, gestational weight gain, and adverse maternal and infant outcomes has been established, few studies have focused on how the prevalence of these conditions has changed over time, especially during the COVID-19 pandemic. The pandemic has affected not only the health care system and subsequent health outcomes but also people's physical activity and eating behaviors because of social distancing measures (both self-imposed and mandated) and disruptions in the US food supply chain. Initial studies on the pandemic's effect on obesity and weight gain differ by whether the increase was significant (8–15). Our objective was to examine trends in prepregnancy obesity and gestational weight gain with a focus on racial and ethnic differences and associated sociodemographic and clinical factors before and during the COVID-19 pandemic in South Carolina, from January 2015 through December 2021.

Methods

Study design and population

Our sample population was South Carolina resident mothers who delivered live singleton births from January 2015 through December 2021. Because gestational weight gain is affected by preterm birth, we limited the population to full-term (37 weeks) deliveries. The South Carolina Department of Health and Environmental Control provided information from birth certificates. Data from birth certificates were linked to maternal inpatient hospital discharge records and emergency department (ED) visit records by the South Carolina Revenue and Fiscal Affairs office. Beginning in 2012, that office also provided data at least 3 years before each delivery on maternal inpatient discharges and ED visits to identify pre-existing health conditions. Database linkages were based on an algorithm created by the South Carolina Revenue and Fiscal Affairs office that used personal identifying information. The institutional review board of the Medical University of South Carolina approved our study as exempt research.

Variable definition

Maternal race and ethnicity were categorized as Hispanic, non-Hispanic Black, non-Hispanic White, or "other" race or ethnicity based on what was commonly reported on birth certificate and inpatient and ED visit records. However, a mother was classified as Hispanic if she identified as Hispanic 3 or more times in the dataset. The "other" race or ethnicity group included women who self-identified as Asian, American Indian/Alaska Native, Native Hawaiian/Other Pacific Islander or for whom race/ethnicity was missing. Birth certificates reported education (categorized as less than high school graduate, high school diploma or General Educational Development [GED], some college, or undergraduate or associate degree or more); residence (rural vs urban); receipt of Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) benefits during pregnancy; smoking during pregnancy or prepregnancy (smoker vs nonsmoker); and maternal prepregnancy weight and height. Women were classified as underweight (BMI 14.0–18.4), normal (BMI 18.5–24.9), overweight (BMI 25.0–29.9), or obese (BMI ≥30.0). For our analysis, the outcome of prepregnancy obesity was defined as obese versus nonobese. Firstborn was defined as the first live or stillborn birth from 2015 through 2021 of a mother without a history of a previous live birth or stillbirth on the birth certificate. Medicaid status was defined as being Medicaid eligible within 2 months of giving

birth based on the statewide Medicaid eligibility file. Gestational weight gain was categorized as adequate, inadequate, or excessive based on the mother's prepregnancy BMI, according to the 2009 Institute of Medicine guidelines (16). These guidelines state how much weight women with singleton pregnancies should gain during pregnancy based on the mother's prepregnancy weight status: underweight, 28 to 40 lb; normal weight, 25 to 35 lb; overweight, 15 to 25 lb; and obese, 11 to 20 lb.

Statistical analysis

We used the χ^2 test in preliminary statistical analyses to examine bivariate associations between sociodemographic, lifestyle, and clinical factors and outcomes of interest by maternal racial and ethnic group. A generalized linear model with a modified Poisson distribution and log link was used to estimate the risk of prepregnancy obesity, with nonobese as the reference group. A second generalized linear model with a multinomial distribution and glogit link was used to estimate the risk of inadequate or excessive weight gain with adequate weight gain as the reference group. Modified Poisson models were used to express estimates as risk ratios (RRs) because log–binomial models can have convergence issues as the model's complexity increases (17,18). Additionally, the point estimates of the modified Poisson model are proven to be unbiased when the link function is misspecified or the response rate is low (18). Generalized estimating equations with an exchangeable working correlation were used to account for mothers who had multiple pregnancies. To assess trends over time, a predetermined change point at the first quarter of 2020 (ie, March 2020), defining the start of the COVID-19 pandemic, was included in the models. No sensitivity analyses were conducted to assess robustness of results. Interaction terms were included to assess the association between racial and ethnic groups and trends over time. Covariates included in the models were identified a priori. For prepregnancy obesity, we ran an unadjusted model with the main effects of time before the change point, time after the change point, and race and ethnicity as well as interaction terms between time (before and after the change point) and race and ethnicity. For gestational weight gain, we ran an unadjusted model with the main effects of time before the change point, time after the change point and race and ethnicity. For both outcomes, models were adjusted for sociodemographic factors (age, education, rural residence, Medicaid, WIC receipt during pregnancy) and lifestyle and clinical factors (smoking during or prepregnancy, firstborn, prepregnancy BMI).

We then plotted the prevalence of each outcome from 2015 to 2021 by using the unadjusted models of each outcome for the specified period with 95% CIs. *P* values of.05, and corresponding 95% CIs were used to determine significance. Analyses were conducted in SAS (SAS Institute), and figures were created in R (R Foundation) software.

Results

Study population

Of 266,146 South Carolina mothers with at least 1 pregnancy from 2015 through 2021 (331,979 births), 671 (0.25%) were excluded because information on maternal age was inconsistent across multiple sources (defined as varying by more than ±2 years). We excluded 159 mothers (0.06%) who did not have a live birth during the study time frame, 881 (0.33%) who resided outside South Carolina, 64 (0.02%) who had a live birth of triplets or quadruplets during the study period, 6,417 (2.4%) who had a twin birth, and lastly, 18,357 (7.1%) who did not have a full-term (≥37 weeks) singleton birth. The final dataset consisted of 239,597 mothers with 1 or more live, full-term, singleton births (306,344 pregnancies) (Figure 1). Some sociodemographic, lifestyle, and clinical information was available for all mothers from linked inpatient hospital and ED visit data procedure and diagnostic code files.

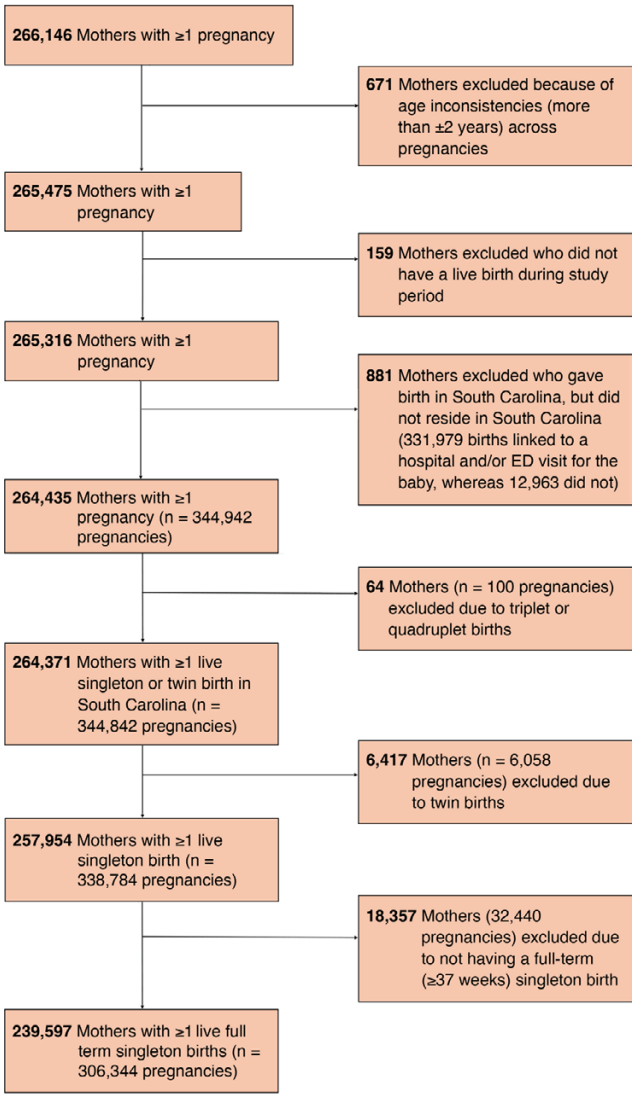

Figure 1. Flowchart of exclusion criteria for study sample, study of trends in gestational weight gain and prepregnancy obesity in South Carolina, 2015 through 2021.

Characteristics of the 306,344 pregnancies resulting in a live singleton birth varied by race and ethnicity (Table 1). From 2015 through 2021, 57.4% of pregnancies were among non-Hispanic White women, 30.2% were among non-Hispanic Black women, 7.6% were among Hispanic women, and 4.8% were among women of other racial or ethnic groups. Average (SD) age at delivery ranged from 29.1 (5.9) years among women of other races or ethnicities to 26.7 (5.7) years among non-Hispanic Black women. Among Hispanic women, approximately 42.9% had less than a high school education, compared with only 9.4% of non-Hispanic White women. Medicaid eligibility at delivery was 72.2% among non-Hispanic Black women, 70.4% among Hispanic women, 49.4% among women of other racial or ethnic groups, and 39.1% among non-Hispanic White women. WIC receipt during pregnancy was 61.8% among non-Hispanic Black women, 43.9% among Hispanic women, 31.5% among women of other racial or ethnic groups, and 27.5% among non-Hispanic White women. Maternal prepregnancy obesity ranged from 44.8% of pregnancies among non-Hispanic Black women to 22.2% of pregnancies among women of other racial or ethnic groups. Excessive weight gain during pregnancy ranged from 51.8% of pregnancies among non-Hispanic White women to 39.2% of pregnancies among Hispanic women.

Gestational weight gain by race and ethnicity

In the assessment of unadjusted trends in gestational weight gain before and after the start of the COVID-19 pandemic, the interactions between time and race and ethnicity were not significant (P = .30 and .47, respectively), indicating that trends over time were similar across all racial and ethnic groups.

Inadequate weight gain. For non-Hispanic White women, the prevalence of inadequate weight gain in 2015, quarter 1 was 18.0%; in 2020, quarter 1, 19.1%; and in 2021, quarter 4, 19.1% (Figure 2, Panel A). Among non-Hispanic Black women, the prevalence in 2015, quarter 1 was 27.3%; in 2020, quarter 1, 29.0%; and in 2021, quarter 4, 29.0%. Among Hispanic women, the prevalence in 2015, quarter 1 was 27.5%; in 2020, quarter 1, 29.3%; and in 2021, quarter 4, 29.2%. The prevalence among women of other races or ethnicities in 2015, quarter 1 was 27.4%; in 2020, quarter 1, 29.1%; and in 2021, quarter 4, 29.1%.

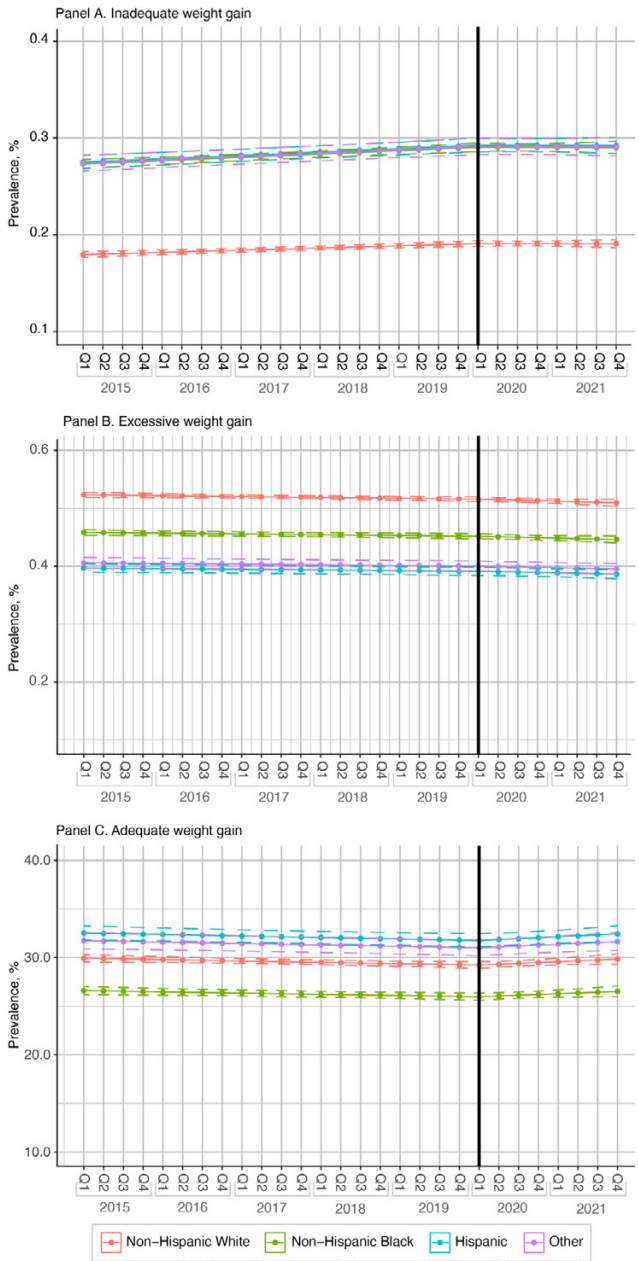

Figure 2. Prevalence of 3 categories of gestational weight gain among women with 1 or more full-term (≥37 weeks) singleton births in South Carolina, by race or ethnicity, from 2015 through 2021: inadequate weight gain (Panel A), excessive weight gain (Panel B), and adequate weight gain (Panel C). Thick black vertical line indicates the start of the COVID-19 pandemic. Dotted lines indicate 95% CIs. Other race or ethnicity includes women who self-identified as Asian, American Indian/Alaska Native, Native Hawaiian/Other Pacific Islander or those whose race/ethnicity was missing. Abbreviation: Q, quarter of year.

In the unadjusted model assessing the main effect for race and ethnicity (Table 2, Model 1), the RR for inadequate weight gain relative to adequate weight gain for a 1-year increase in calendar time was 1.02 (95% CI, 1.01–1.02) before the pandemic (ie, change point) and 0.99 (95% CI, 0.96–1.01) after the pandemic (ie, after the change point). Across all racial and ethnic groups, non-Hispanic Black (RR = 1.71, 95% CI, 1.67–1.75), Hispanic (RR = 1.41; 95% CI, 1.36–1.46), and women of other racial and ethnic groups (RR = 1.44; 95% CI, 1.37–1.51) were more likely to gain inadequate relative to adequate weight during each pregnancy compared with non-Hispanic White women.

In the fully adjusted model (Table 2, Model 2), the RR of inadequate weight gain relative to adequate weight gain for a 1-year increase in calendar time before the pandemic (ie, change point) was 1.02 (95% CI, 1.01–1.03) and 0.99 (95% CI, 0.97–1.02) after the start of the pandemic (ie, after the change point). Age, higher maternal education, Medicaid eligibility, rural residence, smoking during or prepregnancy, having a firstborn, and having obesity or being overweight prepregnancy were associated with inadequate weight gain during pregnancy.

Excessive weight gain. Among non-Hispanic White women, the prevalence of excessive weight gain for pregnancies in 2015, quarter 1, was 52.3%; in 2020, quarter 1, 51.6%; and in 2021, quarter 4, 50.9% (Figure 2, Panel B). Among non-Hispanic Black women, the prevalence in 2015, quarter 1 was 45.8%; in 2020, quarter 1, 45.2%; and in 2021, quarter 4, 44.6%. Among Hispanic women, the prevalence in 2015, quarter 1 was 39.7%; in 2020, quarter 1, 39.1%; and in 2021, quarter 4, 38.6%. Among women of other races or ethnicities, the prevalence in 2015, quarter 1 was 40.6%; in 2020, quarter 1, 40.0%; and in 2021, quarter 4, 39.5%.

In the unadjusted model assessing the main effect of race and ethnicity (Table 2, Model 1), the RR for excessive weight gain relative to adequate weight gain for a 1-year increase in calendar time was 1.00 (95% CI, 1.00–1.01) before the pandemic (ie, before the change point) and 0.98 (95% CI, 0.96–1.00) after the start of pandemic (ie, after the change point). Across racial and ethnic groups, non-Hispanic Black women (RR = 0.99, 95% CI, 0.97–1.01) had similar risk during each pregnancy of excessive weight gain, whereas Hispanic women (RR = 0.70; 95% CI, 0.67–0.72) and women of other racial and ethnic groups (RR = 0.73; 95% CI, 0.70–0.76) were less likely to gain excessive weight compared with non-Hispanic White women.

In the fully adjusted model (Table 2, Model 2), the risk of excessive weight gain relative to adequate weight gain for a 1-year increase in calendar time before the pandemic (ie, before the change point) was 1.00 (95% CI, 0.99–1.00) and 0.98 (95% CI, 0.96–1.00) after the start of the pandemic (ie, after the change point). Age, higher maternal education, WIC receipt during pregnancy, smoking during or prepregnancy, having a firstborn, and having obesity or being overweight before pregnancy were associated with increased likelihood of excessive weight gain during pregnancy.

Adequate weight gain. Across all groups, the prevalence of adequate weight gain decreased before the pandemic and rose after the pandemic (Figure 2, Panel C). The prevalence of adequate weight gain among non-Hispanic White women in 2015, quarter 1, was 30.0%; in 2020, quarter 1, 29.2%; and in 2021, quarter 4, 29.8%. Among non-Hispanic Black women, the prevalence in 2015, quarter 1 was 26.6%; in 2020, quarter 1, 26.0%; and in 2021, quarter 4, 26.5%. Among Hispanic women, the prevalence in 2015, quarter 1 was 32.5%; in 2020, quarter 1, 31.8%; and 2021, quarter 4, 32.4%. Among women of other races or ethnicities, the prevalence in 2015, quarter 1 was 31.8%; in 2020, quarter 1, 31.0%; and in 2021, quarter 4, 31.7%.

Obesity

The prevalence of prepregnancy obesity was 23.7% in 2015 quarter 1, 29.2% in 2020 quarter 1, and 29.4% in 2021 quarter 4 for non-Hispanic White women (Figure 3). For non-Hispanic Black women, the prevalence of prepregnancy obesity was 41.2% in 2015, quarter 1 and increased to 47.0% in 2020, quarter 1, then further increased to 48.0% in 2021, quarter 4. For Hispanic women, prepregnancy obesity increased from 25.2% to 31.4% between 2015, quarter 1 and 2020, quarter 1, and then decreased slightly to 31.0 % in 2021, quarter 1. Among women of other racial and ethnic groups, the prevalence of prepregnancy obesity in 2015, quarter 1 was 18.7% then increased to 23% in 2020, quarter 1 and further increased to 28.1% in 2021, quarter 4.

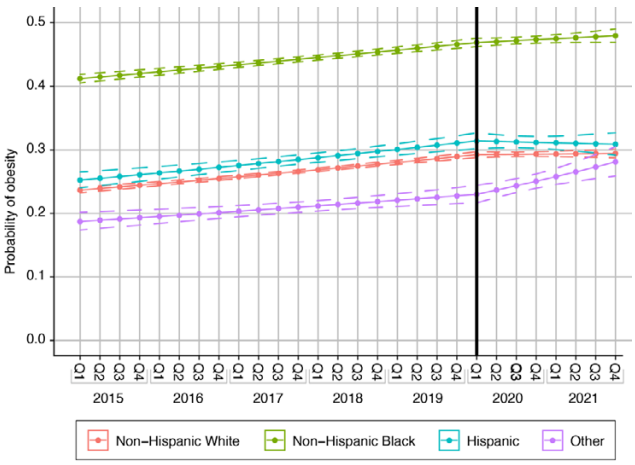

Figure 3. Prevalence of prepregnancy obesity among women with 1 or more full term (≥37 weeks) singleton births in South Carolina, by race and ethnicity, from 2015 through 2021. The change point was the start of the COVID-19 pandemic, quarter (Q) 1, the first quarter of 2020. Dotted lines indicate 95% CIs.

RRs of prepregnancy obesity, unadjusted and adjusted for sociodemographic and lifestyle and clinical factors, varied by racial and ethnic groups before and after the change point (start of the pandemic, 2020, quarter 1) (Table 3). Temporal trends differed by racial or ethnic group before (P =. 002) and after (P =. 03) the pandemic. In the model assessing the main effect of race and ethnicity (Table 3, Model 1), the RR of prepregnancy obesity among non-Hispanic White women for a 1-year increase in calendar time before the pandemic was 1.04 (95% CI, 1.04–1.05); among non-Hispanic Black women, 1.03 (95% CI, 1.02–1.03); among Hispanic women, 1.04 (95% CI, 1.03–1.06); and among women of other races or ethnicities, 1.04 (95% CI, 1.02–1.07). After the pandemic, the risk of prepregnancy obesity for a 1-year increase in calendar time attenuated among non-Hispanic White (RR = 1.01, 95% CI, 0.99–1.02), non-Hispanic Black (RR = 1.01, 95% CI: 1.00–1.03) and Hispanic women (RR = 0.99, 95% CI, 0.95–1.04). However, among women of other racial and ethnic groups, the risk of prepregnancy obesity for a 1-year increase in calendar time increased significantly after the pandemic (RR = 1.12, 95% CI, 1.05–1.19).

In the fully adjusted model (Table 3, Model 2), RRs of prepregnancy obesity for a 1-year increase in calendar time before and after the pandemic for racial and ethnic groups were similar to their unadjusted values after adjusting for sociodemographic, lifestyle and clinical factors. Age, higher maternal education, rural

residence, Medicaid eligibility at delivery, and WIC eligibility during pregnancy were significantly associated with an elevated risk of prepregnancy obesity.

Discussion

The objective of our study was to assess trends in gestational weight gain and prepregnancy obesity before and after March 2020 in South Carolina because we believed trends would be significantly affected by the COVID-19 pandemic in its early stage. Our principal findings showed the relative prevalence of prepregnancy obesity increased 3% to 4% per year across all racial and ethnic groups before the pandemic; however, the level stabilized after the pandemic for non-Hispanic White and Hispanic women, while increasing rapidly among non-Hispanic Black women and women of other racial and ethnic groups. The prevalence of inadequate weight gain increased 1% to 2% across all racial and ethnic groups before the pandemic and then stabilized afterwards. The prevalence of inadequate weight gain was significantly higher among non-Hispanic Black women, Hispanic women, and women of other racial and ethnic groups across the whole study period compared with non-Hispanic White women. In contrast, the prevalence of excessive weight gain was high across all racial and ethnic groups and remained stable before the pandemic, while decreasing slightly after the pandemic.

Literature on the COVID-19 pandemic's effect on body weight, prepregnancy BMI, and gestational weight gain among women of reproductive age (both teens and adults) remains sparse, although preliminary studies have begun to emerge. Two US studies reported a significant increase (0.06 kg and 0.46 kg) in gestational weight gain during the COVID-19 pandemic (19,20). Additionally, among women who were obese before pregnancy, gestational weight gain increased 0.17 kg during the pandemic (19). However, a Washington State study found a nonsignificant decrease in gestational weight gain (11.2 ±4.3 kg vs 10.6 ±5.4 kg) between women who delivered before and during the pandemic (21).

Though studies assessing the effect of the COVID-19 pandemic on prepregnancy weight and gestational weight gain among pregnant women are limited, several studies have been published on the effect of the pandemic on body weight, weight gain, and dietary and lifestyle behaviors among the overall adult population in the US and worldwide. In general, the pandemic appears to have had mixed effects on eating and lifestyle behaviors, because the prevalence of weight gain and mean increase in body weight and BMI varied between studies, with some people gaining weight and others losing weight. Most studies found that weight gain was due to physical inactivity, sedentary behaviors (eg, increased screen time), unhealthy eating habits (eg, increased consumption of highly processed food, increased number of meals, snacking, alcohol consumption), reduced sleep, emotional eating, stress, depression, and anxiety (8–15). People who were overweight and obese before the pandemic were more likely to gain weight during the pandemic (12–14).

Although the aforementioned studies showed that the pandemic affected body weight, weight gain, and eating and lifestyle behaviors, whether the effect is clinically significant and long-term remains in question. Furthermore, because most of these studies were cross-sectional (eg, self-reported online survey), they cannot be used to infer causality and they are vulnerable to bias, which can affect reliability and generalizability of their findings. Such bias includes selection bias (eg, some studies had mostly female or male participants), recall bias (eg, self-reported body weight, BMI, height), and reporting bias (eg, participants may not answer truthfully to questions asked on social and lifestyle behaviors).

Strengths and limitations

The main strengths of our study were that first, we were able to follow women over time by linked vital statistics and inpatient hospital discharge and ED visit encounter data. Second, though administrative data and birth certificates may have some reliability and validity issues, they provide information on all births at the population level and provide important population-based estimates.

Our study had limitations, including the use and reliability of administrative data and miscoding of BMI classification, gestational weight gain, and race and ethnicity. BMI was based on self-reported prepregnancy weight and height taken from medical records, which can lead to misclassification. Similarly, with gestational weight gain, misclassification could result from BMI misclassification and incorrect report of weight before pregnancy. Self-reported weight tends to be underestimated and individuals who are overweight or obese tend to be more likely to underestimate their weight (22). Pregnant women tend to underreport prepregnancy and delivery weight and overreport gestational weight gain; however, misclassification has been found not to bias the association between BMI, pregnancy weight, and pregnancy outcomes (23). Misclassification of race and ethnicity could have occurred because it was based on information found in administrative data and might not reflect self-reported race and ethnicity. Information was lacking on such factors as diet, physical activity, stress, and neighborhood characteristics, which may be related to obesity and gestational weight gain. Lastly, we excluded pregnant women who had preterm birth from the analysis because early delivery reduces overall gestational weight gain.

Conclusion

In South Carolina, the COVID-19 pandemic did not alter trends of gestational weight gain. The pandemic did, however, have a small effect on trends in prepregnancy obesity, with differential effects across racial and ethnic groups. Prepregnancy obesity and gestational weight gain are important public health issues that affect maternal and infant pregnancy outcomes and therefore warrant effective public health interventions. More studies are needed to fully understand the pandemic's effect on BMI, prepregnancy obesity, and gestational weight gain among women of childbearing age and pregnant women, with an emphasis on racial and ethnic differences. A better understanding of patterns and determinants of pregnancy outcomes after the pandemic can inform effective public health strategies in this population.

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Tables

Table 1. Characteristics of 306,344 Pregnancies Resulting in a Live Full-Term (≥37 Weeks) Singleton Birth, South Carolina, 2015–2021[a]

Characteristic	Racial and or ethnic group			
	Non-Hispanic White (n = 175,991)	Non-Hispanic Black (n = 92,402)	Hispanic (n = 23,423)	Other (n = 14,708)
Sociodemographic				
Age at delivery, mean (SD), y	28.4 (5.5)	26.7 (5.7)	28.2 (6.1)	29.1 (5.9)
Education, %[b]				
Less than high school education	9.4	13.3	42.9	17.0
High school diploma or GED	20.0	34.4	27.0	20.6
Some college	23.1	30.4	13.6	17.8
College or associates degree or more	47.5	22.0	16.5	44.6
Rural residence, %	29.9	36.0	28.1	23.3
Medicaid eligibility at delivery, %	39.1	72.2	70.4	49.4
WIC receipt during pregnancy, %[a]	27.5	61.8	43.9	31.5
Lifestyle and clinical factors				
Smoking during or prepregnancy, %[a]	14.8	8.5	2.0	4.7
Firstborn, %[b]	33.1	29.3	25.9	34.2
Prepregnancy BMI (kg/m^2), %[b]				
Underweight (<18.5)	3.6	2.8	2.0	4.6
Normal (18.5–24.9)	44.2	27.6	36.5	46.7
Overweight (25.0–29.9)	25.1	24.8	32.4	26.6
Obese (≥30.0)[b]	27.1	44.8	29.1	22.2
Gestational weight gain, %[b,c]				
Adequate	29.6	26.3	32.1	31.4
Inadequate	18.7	28.4	28.6	28.5
Excessive	51.8	45.3	39.2	40.2

Abbreviations: BMI, body mass index; GED, General Educational Development; WIC, Special Supplemental Nutrition Program for Women, Infants, and Children.
[a] Stratified by racial and ethnic group.
[b] Number of women with missing data values on outcomes and covariates: education, 844; smoking during or prepregnancy, 195; firstborn, 66; prepregnancy BMI, 3,696; WIC, 14; prepregnancy obesity, 3,696; gestational weight gain classification, 3,696.
[c] Adequate weight gain during pregnancy for women who were underweight was 50 to 62 lb; normal weight gain, 25 to 35 lb; overweight, 15 to 25 lb; and obese, 11 to 20 lbs. Inadequate weight gain was defined as gaining less than the recommended weight during pregnancy. Excessive weight gain was defined as gaining more than the recommended weight during pregnancy. In our study, 87,350 women gained adequate weight during pregnancy, 68,998 women gained inadequate weight, and 146,300 gained excessive weight.

Table 2. Trends in Inadequate and Excessive Weight Gain Among Live Full Term (≥37 Weeks) Singleton Births, Unadjusted and Adjusted for Sociodemographic and Lifestyle and Clinical Factors, South Carolina, 2015–2021

Characteristic	Inadequate, relative risk (95% CI)[a]		Excessive, relative risk (95% CI)[a]	
	Model 1[b]	Model 2[c]	Model 1[b]	Model 2[c]
Time before change point (per year)[d]	1.02 (1.01–1.02)[e]	1.02 (1.01–1.03)[e]	1.00 (1.00–1.01)	1.00 (0.99–1.00)
Time after change point (per year)[d]	0.99 (0.96–1.01)	0.99 (0.97–1.02)	0.98 (0.96–1.00)	0.98 (0.96–1.00)
Trend by sociodemographic characteristic				
Race or ethnicity				
Non-Hispanic White	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Non-Hispanic Black	1.71 (1.67–1.75)[e]	1.45 (1.42–1.49)[e]	0.99 (0.97–1.01)	0.85 (0.83–0.87)[e]
Hispanic	1.41 (1.36–1.46)[e]	1.17 (1.13–1.22)[e]	0.70 (0.67–0.72)[e]	0.67 (0.65–0.69)[e]
Other[f]	1.44 (1.37–1.51)[e]	1.42 (1.36–1.49)[e]	0.73 (0.70–0.76)[e]	0.76 (0.73–0.79)[e]
Age at delivery (per year)	—[g]	1.00 (0.995–0.996)[e]	—[g]	1.00 (0.994–0.998)[e]
Education				
Less than high school education	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
High school diploma or GED	—[g]	0.85 (0.82–0.88)[e]	—[g]	1.08 (1.05–1.12)[e]
Some college	—[g]	0.73 (0.70–0.76)[e]	—[g]	1.13 (1.10–1.17)[e]
College or associate degree or more	—[g]	0.62 (0.60–0.64)[e]	—[g]	1.08 (1.04–1.12)[e]
Rural residence (vs urban)	—[g]	1.07 (1.05–1.10)[e]	—[g]	1.01 (0.99–1.03)
Medicaid eligibility at delivery (yes vs no)	—[g]	1.11 (1.08–1.14)[e]	—[g]	1.01 (0.99–1.03)
WIC receipt during pregnancy (yes vs no)	—[g]	1.01 (0.99–1.04)	—[g]	1.05 (1.02–1.07)[e]
Trends by lifestyle and clinical factors				
Smoking during or prepregnancy (yes vs no)	—[g]	1.07 (1.03–1.10)[e]	—[g]	1.26 (1.22–1.30)[e]
Firstborn (yes vs no)	—[g]	0.91 (0.88–0.93)[e]	—[g]	1.31 (1.28–1.33)[e]
Prepregnancy BMI (kg/m^2)				
Underweight (<18.5)	—[g]	1.02 (0.97–1.07)	—[g]	0.55 (0.52–0.58)[e]
Normal (18.5–24.9)	—[g]	1 [Reference]	—[g]	1 [Reference]
Overweight (25.0–29.9)	—[g]	0.79 (0.77–0.81)[e]	—[g]	2.26 (2.21–2.32)[e]
Obese (≥30.0)	—[g]	1.28 (1.25–1.32)[e]	—[g]	2.11 (2.06–2.15)[e]

Abbreviations: BMI, body mass index; GED, General Education Development; WIC, Special Supplemental Nutrition Program for Women, Infants, and Children.
[a] Relative risks represent the risk of inadequate and excessive weight gain for a 1-year increase in calendar time.
[b] Model 1: relative risks for time before and after change point (first quarter of 2020) for the main effect for race and ethnicity. The change point is a predetermined point at the first quarter of 2020 (ie, March 2020) defining the start of the COVID-19 pandemic.
[c] Model 2: relative risks for time before and after change point (first quarter of 2020) adjusted for sociodemographic characteristics and lifestyle and clinical factors. The change point is a predetermined point at the first quarter of 2020 (ie, March 2020) defining the start of the COVID-19 pandemic.
[d] Interaction *P* value for time before change point and race or ethnicity was.30. Interaction *P* value for time after change point and race or ethnicity was .47 in Model 1. The change point is a predetermined point at the first quarter of 2020 (ie, March 2020) defining the start of the COVID-19 pandemic.
[e] Significant at *P* <. 05.
[f] Includes women who self-identified as Asian, American Indian/Alaska Native, Native Hawaiian/Other Pacific Islander, or those whose race/ethnicity was missing or unknown.
[g] Indicates no relative risks were estimated for sociodemographic characteristics and lifestyle and clinical factors.

Table 3. Trends in Prepregnancy Obesity Among Live, Full Term (≥37 Weeks) Singleton Births, Unadjusted and Adjusted for Sociodemographic and Lifestyle and Clinical Factors, South Carolina, 2015–2021

Characteristic	Prepregnancy obesity, relative risk (95% CI)[a]	
	Model 1[b]	Model 2[c]
Time before change point (per year)[d]		
Race or ethnicity		
Non-Hispanic White	1.04 (1.04–1.05)[e]	1.04 (1.04–1.05)[e]
Non-Hispanic Black	1.03 (1.02–1.03)[e]	1.03 (1.02–1.03)[e]
Hispanic	1.04 (1.03–1.06)[e]	1.06 (1.04–1.07)[e]
Other[f]	1.04 (1.02–1.07)[e]	1.05 (1.03–1.07)[e]
Time after change point (per year)[a]		
Race or ethnicity		
Non-Hispanic White	1.01 (0.99–1.02)	1.01 (0.99–1.02)
Non-Hispanic Black	1.01 (1.00–1.03)	1.01 (1.00–1.03)
Hispanic	0.99 (0.95–1.04)	1.00 (0.96–1.04)
Other[f]	1.12 (1.05–1.19)[e]	1.13 (1.06–1.20)[e]
Trend by sociodemographic characteristic		
Age at delivery (per year)	—[g]	1.02 (1.02–1.03)[e]
Education		
Less than high school education	—[g]	1 [Reference]
High school diploma or GED	—[g]	1.05 (1.03–1.07)[e]
Some college	—[g]	1.09 (1.07–1.11)[e]
College or associates degree or more	—[g]	0.84 (0.82–0.85)[e]
Rural residence (vs urban)	—[g]	1.11 (1.10–1.13)[e]
Medicaid eligibility at delivery (yes vs no)	—[g]	1.11 (1.09–1.12)[e]
WIC receipt during pregnancy (yes vs no)	—[g]	1.21 (1.19–1.22)[e]
Trends by lifestyle and clinical characteristic		
Smoking during or prepregnancy (yes vs no)	—[g]	0.94 (0.92–0.96)[e]
Firstborn (yes vs no)	—[g]	0.89 (0.88–0.90)[e]

Abbreviations: BMI, body mass index; GED, General Educational Development; WIC, Supplemental Nutrition Program for Women, Infants, and Children.
[a] Relative risks represent the risk of prepregnancy obesity for a 1-year increase in calendar time.
[b] Model 1: relative risks for the interaction of time before and after the change point (first quarter of 2020) and the main effect for race and ethnicity. The change point is a predetermined point at the first quarter of 2020 (ie, March 2020) defining the start of the COVID-19 pandemic.
[c] Model 2: relative risks for the interaction of time before and after the change point (first quarter of 2020) adjusted for sociodemographic characteristics and lifestyle and clinical factors. The change point is a predetermined point at the first quarter of 2020 (ie, March 2020) defining the start of the COVID-19 pandemic.
[d] Interaction *P* value for time before the change point and race or ethnicity was <.001. Interaction *P* value for time after change point and race and ethnicity was. 03 in Model 1. The change point is a predetermined point at the first quarter of 2020 (ie, March 2020) defining the start of the COVID-19 pandemic.
[e] Significant at *P* <.05.
[f] Includes women who self-identified as Asian, American Indian/Alaska Native, Native Hawaiian/Other Pacific Islander, or those whose race/ethnicity was missing.
[g] Indicates no relative risks were estimated for sociodemographic characteristics and lifestyle and clinical factors.

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