

Rhode Island Life Science Hub awards \$98,780 in first round of small grants

PROVIDENCE – The Rhode Island Life Science Hub (Hub) has announced its first round of small grants to advance the state's life sciences sector. The \$98,780 in funding will support a range of projects, including hands-on learning experiences for students, advancing research collaborations with local institutions, sponsoring life science and venture capital investor events and bolstering federal advocacy efforts.

Established by the Hub board earlier this year, the Small Grant Fund provides grants of up to \$10,000 to educational and academic organizations, non-profits and trade associations. The funding is designed to support existing stakeholders and activities, while fueling new projects that grow Rhode Island's life sciences community.

Recipients of the first round of funding in the medical and research areas include:

- **The Office of Research at Rhode Island Hospital (Lifespan)** will receive \$10,000 to support the AI/HI and Immunoinformatic Workshop in Providence. The event will bring together academic leaders, local biotech and global experts to foster collaboration and promote Rhode Island as a prime location for innovation and growth in the biotech sector.
- **The College of Pharmacy at the University of Rhode Island** will receive \$10,000 to advance innovative cancer immunotherapy research. The research addresses a critical global health challenge and strengthens the state's research capabilities while fostering collaboration within the scientific community.
- **The Center for Spine Tumor and Chordoma Research at Brown/Lifespan** will receive \$9,970 to support the development of an innovative gel medicine that manages post-surgical pain associated with Chordoma, a rare, highly morbid cancer along the spinal axis, thus minimizing reliance on opioids.
- **New England Medical Innovation Center (NEMIC) & the Clinical Research Center at Lifespan** will receive \$10,000 to streamline and expand the capabilities of Lifespan's Clinical Research Center (CRC). The funding will enhance the efficiency and capacity of clinical validations, trials and studies, addressing the high demand in New England and positioning Rhode Island as a hub for clinical research.
- **New England Medical Innovation Center (NEMIC)** will receive \$5,000 to host a Q4 2024 Pitch Event, showcasing numerous startups specializing in the medical device and health technology sectors. The event will foster connections between industry professionals, investors, academia and entrepreneurs, highlighting the state as a center of excellence in health technology and life sciences.
- **The Department of Chemistry at the University of Rhode Island** will receive \$10,000 to support a new research program to develop novel therapeutic agents for treating cancers. This initiative will integrate cutting-edge chemistry, chemical

biology and life sciences, while providing resources and opportunities for training the next generation of scientists in Rhode Island's biomedical sector.

- **The Neuropsychology Program at Rhode Island Hospital (Lifespan)** will receive \$7,500 to develop further and validate a digital health tool, the Rhode Island Preclinical Alzheimer's Composite, for early detection of Alzheimer's disease and related dementias.
- **Brown Technology Innovations** will receive \$10,000 to host their second annual Innovation@Brown Showcase during Rhode Island Startup Week. The event celebrates local innovation in and around Brown University featuring panel discussions and a showcase of over 20 Brown and Hospital affiliated ventures.

A total of \$151,220 remains in the Rhode Island Life Science Hub's Small Grant Fund. The Hub will continue to accept applications for the Small Grant Fund on a rolling basis, and award grants, subject to the availability of funds when applications are completed, viewed, and approved by the interim president and treasurer. Grant guidelines and application information can be found at <https://tinyurl.com/RILSHSmallGrants>. ❖

Help your Patients Keep their Medicaid Coverage

Medicaid members will need to renew their eligibility with the State of Rhode Island to keep their health insurance.

You can help now by reminding your Medicaid patients to update their account information with their current address and phone number. Medicaid members can update their information by:

- Logging into their HealthSource RI account: <https://healthyrhode.ri.gov/>
- Calling HealthSource RI at 1-855-840-4774 (TTY 711)

Thank you from all of us at Neighborhood for your commitment and partnership in ensuring Rhode Island families keep their health care coverage!



Neighborhood members can scan the QR code to update their address through our new e-form or visit www.nhpri.org



Neighborhood Health Plan
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www.nhpri.org 1-800-459-6019 (TTY 711)

Rhode Island Voices seeks panelists to share their voice on the health and well-being of Rhode Island's diverse communities

PROVIDENCE – Blue Cross & Blue Shield of Rhode Island (BCBSRI) and the Brown University School of Public Health have jointly launched Rhode Island Voices, a project of the RI Life Index that will take an even deeper dive into learning about the lived experiences of Rhode Islanders and what they have to say about the health and well-being of their communities.

While the RI Life Index will continue to be updated every year based on an annual phone survey, this new component, Rhode Island Voices, will enlist a panel of Rhode Islanders to participate in web-based questionnaires throughout the year. These surveys will delve into such topics as food access, affordable housing, education, job opportunities and other social determinants of health.

Recruitment of a Rhode Island Voices panel of up to 1,000 Rhode Islanders has already begun, with online surveys planned for the remainder of the year. Results of the first surveys will be available in early fall.

“Now in its 6th year, the RI Life Index has proven to be a valuable and enlightening barometer to better understand – and act upon – the social factors that Rhode Islanders tell us are the most critical to their well-being,” said **CAROLYN BELISLE**, BCBSRI vice president of corporate social responsibility. “We hope that Rhode Island Voices will build upon

that success by further enhancing how Rhode Islanders can lend their voices to these important issues and help shape the future of public health in their communities.”

“The RI Life Index is unique across our country because of its breadth, covering the entire state year after year,” said **MELISSA CLARK, PhD**, director of the Survey Research Center and professor of health services, policy and practice at the Brown University School of Public Health. “The addition of the Rhode Island Voices panel now allows us to go deeper into the issues facing residents of our state and help researchers, policymakers and community organizations craft solutions to these seemingly intractable challenges.”

A panel survey is a longitudinal project that measures the perceptions and experiences of individuals over time. Because panel surveys benefit from individuals who agree to participate in multiple questionnaires, topics can be asked of the group in more depth compared to a one-time survey. In addition, by collecting data at multiple points in time, patterns of change can be observed on specific topics among the same individuals.

Individuals may register to volunteer as panelists. The surveys will be confidential, take about 5 to 10 minutes to complete, and occur every few months. In recognition of their contribution,

volunteers will receive up to \$25 per year.

As part of the effort, organizers are seeking community-based organizations to partner in the ongoing effort to recruit individuals for Rhode Island Voices.

Survey methodology for Rhode Island Voices is being overseen Dr. Clark and **MICHELLE ROGERS, PhD**, associate director of the Survey Research Center and assistant professor of behavioral and social sciences. They also direct the survey for the RI Life Index.

The RI Life Index, including the Rhode Island Voices panel, is guided by the expert recommendations and support of the RI Life Index Coalition, whose member organizations are dedicated to improving the health and well-being of Rhode Islanders.

Coalition members include AARP Rhode Island; BCBSRI; Brown University School of Public Health; Community Provider Network of Rhode Island; The Economic Progress Institute; Housing-Works RI; Latino Policy Institute; Life-span Community Health Institute; Medical Legal Partnership Boston; Rhode Island Community Food Bank; the Rhode Island Department of Health; Rhode Island Foundation; Rhode Island Kids Count; and United Way of Rhode Island.

For more information on Rhode Island Voices or to volunteer for the panel, please visit rilifeindex.org/rivoices. ❖

RIDOH issues reminder about health risks of open wounds and coastal waters following fatal case of vibriosis

PROVIDENCE – The Rhode Island Department of Health (RIDOH) is sharing a press release issued on Thursday. Vibriosis is an immediately reportable disease. Please call 401-222-2577 Monday–Friday from 8:30 am–4:30 pm or 401-276-8046 to report cases by phone upon recognition or suspicion of disease. Laboratory confirmation is not necessary prior to report being filed. Healthcare professionals are encouraged to review the CDC’s clinical overview of vibrio: <https://www.cdc.gov/vibrio/about/>.

For healthcare professionals’ awareness, the text of the press release follows:

The Rhode Island Department of Health (RIDOH) reminds residents to be aware of the potential dangers of Vibrio bacteria if they have an open wound and enter salt water or brackish water, which is a mixture of salt water and fresh water. Open wounds include recent cuts and scrapes, recent surgery sites, and recent piercings and tattoos.

The exposure of open wounds to salt water or brackish water can lead to dangerous infections from bacteria, such as Vibrio. Vibrio are different types of bacteria that normally live in warm seawater or brackish water. They can be found in higher concentrations in warmer months, from May to October.

RIDOH is issuing this reminder after identifying a fatal case of vibriosis (which is an infection with Vibrio) in a Rhode Island resident this month, caused by the bacteria Vibrio vulnificus. Infections with Vibrio vulnificus are very rare, and they are much more serious for people with existing, underlying health issues. In severe cases, wounds infected with Vibrio vulnificus can lead to sepsis and can be life-threatening.

“While Vibrio is rare, it is important for anyone at risk to take precautions while spending time in or around brackish water or salt water when the weather is warm,” said Director of Health **JERRY LARKIN, MD**. “Stay out of the water and take precautions if you have a break in the skin or open wound, particularly if you are at higher risk for serious illness.”

In addition to infections resulting from wound exposures, people can also become infected with Vibrio after consuming raw or undercooked seafood. Cases can range from mild to severe and rarely result in death. Vibriosis can cause symptoms including vomiting, watery and bloody diarrhea, fever, and headache.

Before this case, Rhode Island’s last reported cases of Vibrio vulnificus occurred in 2017. Vibrio vulnificus bacteria thrive in warmer waters, and the geographic range is expanding with rising sea temperatures. As coastal water temperatures increase, Vibrio vulnificus infections are expected to become more common.

Last summer, the CDC issued a press release describing an increase in severe Vibrio vulnificus cases in the Eastern United States. Cases were identified in North Carolina, New York, and Connecticut in 2023. Vibrio vulnificus can be relatively common in marine environments, including salt water and brackish water.

Anyone can get vibriosis, but individuals with certain medical conditions or who are taking certain medications are at an increased risk of infection and complications. They include:

- Having liver disease, cancer, diabetes, HIV or thalassemia;
- Receiving immune-suppressing therapy for the treatment of disease;
- Taking medication to decrease stomach acid levels;
- Having undergone recent stomach surgery.

RIDOH recommends the following to keep yourself safe from Vibrio:

- If you have an open wound or cut, avoid salt and brackish water. If you get a cut while you are in the water, leave the water immediately.
- If your open wounds and cuts could come in contact with salt water, brackish water, or raw or undercooked seafood, cover them completely with a waterproof bandage.
- Wash open wounds and cuts thoroughly with soap and clean, running water after they come in contact with salt water, brackish water, or drippings from raw or undercooked seafood.
- If you are immunocompromised, cook raw oysters and other shellfish before eating.
- Always wash your hands with soap and water after handling raw shellfish.
- Seek medical attention right away for infected wounds.
- If you have signs and symptoms of infection, be sure to tell your healthcare professional, if:
- You have an open wound that might have come in contact with coastal water (including salt or brackish water), or raw or undercooked seafood or its drippings.
- You recently ate raw or undercooked seafood, especially oysters.

For more information on Vibrio, visit CDC’s website. For Rhode Island enteric disease data from 2018–2022, including vibriosis, please see RIDOH’s enteric disease data dashboard. ❖

CDC data show improvements in youth mental health but need for safer and more supportive schools

ATLANTA, GA – New CDC data released August 6 highlight improvements in mental health among some United States teens, including decreases in the percentage of students feeling persistently sad or hopeless. However, the report also highlights concerning increases in the percentage of teens reporting experiences of school-based violence and absenteeism due to safety concerns.

The report provides a detailed analysis of the health behaviors and experiences of high school students across the nation, comparing 2021 and 2023 Youth Risk Behavior Survey data. The 2021 data are drawn from a year when schooling was still substantially disrupted due to COVID. The report also provides 10-year data trends by sex, race and ethnicity, and sexual and gender identity. As students head back to school, these data are critical to highlighting the challenges faced by millions of young people so that communities can better address their health and safety.

“One of our main priorities at CDC is improving Americans’ mental health,” said **DEBRA HOURY, MD, MPH**, CDC’s chief medical officer and deputy director for program and science. “The data released today show improvements to a number of metrics that measure young people’s mental well-being – progress we can build on. However, this work is far from complete. Every child should feel safe and supported, and CDC will continue its work to turn this data into action until we reach that goal.”

Key improvements to youth mental health from 2021 to 2023 include:

- Decreases in the percentage of students overall who experienced persistent feelings of sadness or hopelessness (from 42% to 40%).
- Decreases in the percentage of female students who experienced persistent feelings of sadness or hopelessness



(from 57% to 53%) and who seriously considered attempting suicide (30% to 27%).

- Decreases in the percentage of Hispanic students who felt persistently sad or hopeless (from 46% to 42%), who experienced poor mental health (30% to 26%), who seriously considered attempting suicide (22% to 18%) and who made a suicide plan (19% to 16%).
- Decreases in the percentage of Black students who attempted suicide (from 14% to 10%) and who were injured in a suicide attempt (4% to 2%).

Violence and safety concerns

Despite these positive signs, there are increases in the percentage of students reporting violence and safety concerns at school or on the way to school:

- Increases in the percentage of students who were threatened or injured with a weapon at school (7% to 9%).
- Increases in the percentage of students who were bullied at school (15% to 19%).

- Increases in the percentage of students who missed school because of safety concerns either at school or on the way to school (9% to 13%).

Health disparities

The report also underscores significant health disparities, particularly among female and LGBTQ+ high school students, who report higher rates of violence, poor mental health and suicidal thoughts and behaviors than their peers. In 2023, nearly three in 10 LGBTQ+ students were bullied at school, and two in 10 attempted suicide.

“These data show that we’ve made some progress in tackling these issues in recent years, which proves that they are not insurmountable. However, there’s still much work ahead,” said CDC Division of Adolescent and School Health Director

KATHLEEN ETHIER, PhD. “Considering the vital role schools play in promoting health and well-being, it is critical to address school-based violence and safety concerns.”

CDC’s What Works in Schools program helps promote adolescent health and well-being by supporting school districts to teach quality health education, connect young people to needed health services and make school environments safer and more supportive. This program positively impacts many behaviors and experiences presented in today’s report.

CDC has collected and analyzed data on youth health and well-being for more than three decades. Data are analyzed from the Youth Risk Behavior Survey, which monitors adolescent health behaviors and experiences over time. It identifies emerging issues and helps us understand health-related topics affecting youth, including mental health. Overall, it gives the best picture of what is going on at the national, state, and local level. ❖

US response to the Clade I Mpox outbreak in Africa

ATLANTA, GA – On August 14, 2024, the World Health Organization (WHO) declared a Public Health Emergency of International Concern about the upsurge of mpox cases in the Democratic Republic of the Congo (DRC) and a growing number of countries in Africa. This announcement followed the Africa Centres for Disease Control and Prevention's (Africa CDC) declaration of a Public Health Emergency of Continental Security on August 13. The significant increase of clade I mpox cases, in both endemic countries (those that have previously had mpox outbreaks) and non-endemic countries (those that have historically not reported mpox outbreaks), threatens the health security of the region, as well as countries outside Africa. In addition, clade I mpox has a newer sub-clade referred to as clade Ib. Both clade Ia and clade Ib are circulating in DRC and have been detected in neighboring countries and in Sweden and Thailand (one case each associated with travel to Africa with known clade I cases).

In 2022, the world experienced a global outbreak of clade IIb mpox, which led to more than 95,000 cases across 115 non-endemic countries and continues to occur in the United States. The Biden-Harris Administration responded by ensuring the JYNNEOS mpox vaccine was available to at-risk populations in the U.S.

In February, as the clade I mpox outbreak grew in DRC, the Biden-Harris Administration established an incident response structure across federal departments and agencies to ensure a coordinated response and to take a proactive approach to U.S. domestic preparedness for potential clade I mpox cases. Clade I mpox causes a higher number of severe infections and has a higher mortality rate than clade IIb mpox. Because evidence for clade I mpox clinical outcomes is based primarily on data from endemic countries without widespread supportive care, particularly DRC, it is not yet known how clade I mpox would impact Americans; we do expect it would cause lower morbidity and mortality in the United States.

United States preparedness for clade I mpox

The Biden-Harris Administration has been closely monitoring the spread of mpox, specifically clade I mpox, and has been working since December 2023 to prepare domestically. The risk to most Americans from clade I mpox circulating in Central and Eastern Africa and the travel associated cases outside of Africa is very low, and there are no known cases in the United States at this time. The United States is well prepared to rapidly detect, contain, and manage clade I cases should they occur domestically.

The United States continues to increase our capacity to detect cases of clade I and clade IIb mpox through existing surveillance systems, including wastewater testing, and through expanding the robust diagnostic testing capacity built during the ongoing clade IIb outbreak to ensure coverage for clade I. The ability to expedite such diagnostic testing – in particular for those with recent travel to DRC or neighboring countries – also supports rapid detection. In addition to reaffirming the importance of mpox vaccination for those who are eligible, we are working to prevent the spread of both clades of mpox by providing and

disseminating recommendations for clinicians, health departments, diagnostic laboratories, and the public.

From August 2022 to August 2024, the Administration for Strategic Preparedness and Response (ASPR), part of the Department of Health and Human Services (HHS), distributed more than one million vials of the JYNNEOS vaccine across the United States to mitigate the spread and severity of the clade II mpox outbreak. In addition to the preventive vaccine, partners across the U.S. government are working to better understand the effectiveness of existing treatments for mpox and have treatment options available in the event that clade I mpox is reported in the United States. The United States will continue to provide information to the public on transmission, prevention, and treatment of mpox. Those who have already had clade IIb mpox or who are fully vaccinated against it are expected to be protected against clade I mpox.

CDC has issued an updated Health Alert Network advisory for clinicians and public health departments and partners, as well as an updated Travel Health Notice, recommending travelers to DRC and neighboring countries to practice enhanced precautions. Through the State Department, our embassies are working to keep U.S. citizens abroad informed of these updates. At this time, CDC and WHO do not discourage travel to DRC or elsewhere due to the mpox outbreaks.

In addition to scaling up surveillance, testing, and treatment of cases, vaccination will be a critical element of the response to this outbreak. Successful vaccination campaigns will require health workers to provide vaccinations, financial support to roll out vaccine and vaccination supplies, and regulatory approval for use of vaccines in affected countries. To support this effort, USAID is donating 50,000 doses of the FDA-approved JYNNEOS vaccine to DRC, as well as financial support for rollout of the vaccine doses. The United States is working with other countries that have vaccine stockpiles, WHO, and international partners to encourage additional donations that support vaccine efforts and address challenges with vaccine delivery. This includes evaluating vaccine demand, supporting country engagement on regulatory pathways, planning vaccine implementation, and providing technical assistance to deliver the vaccines.

The United States is working with bilateral, multilateral, and private sector partners to develop and implement a coordinated response – including encouraging collaboration between WHO and Africa CDC on their response plans. The United States, through the State Department, will continue working through the U.S.-Africa CDC Joint Action Plan adopted in November 2023 to increase African Union Member States' capacity to prevent, detect, and respond to health emergencies.

The Biden-Harris Administration will continue its whole-of-government response to this growing outbreak, building on lessons learned from the 2022 mpox response. To learn more about mpox, signs and symptoms, treatments, and prevention, please visit the CDC website [here](#). ❖

FDA approves first nasal spray for treatment of anaphylaxis

SILVER SPRING, MD – On Aug. 9th, the U.S. Food and Drug Administration approved neffy (epinephrine nasal spray) for the emergency treatment of allergic reactions (Type I), including those that are life-threatening (anaphylaxis), in adult and pediatric patients who weigh at least 30 kilograms (about 66 pounds).

“Today’s approval provides the first epinephrine product for the treatment of anaphylaxis that is not administered by injection. Anaphylaxis is life-threatening and some people, particularly children, may delay or avoid treatment due to fear of injections,” said **KELLY STONE, MD, PhD**, Associate Director of the Division of Pulmonology, Allergy and Critical Care in the FDA’s Center for Drug Evaluation and Research. “The availability of epinephrine nasal spray may reduce barriers to rapid treatment of anaphylaxis. As a result, neffy provides an important treatment option and addresses an unmet need.”

Allergic reactions happen when a person’s immune system reacts abnormally to a substance that normally does not cause symptoms. Anaphylaxis is a severe, life-threatening allergic reaction that typically involves multiple parts of the body and is considered a medical emergency. Common allergens that can induce anaphylaxis include certain foods,

medications and insect stings. Symptoms usually occur within minutes of exposure and include, but are not limited to, hives, swelling, itching, vomiting, difficulty breathing and loss of consciousness. Epinephrine is the only life-saving treatment for anaphylaxis and has previously only been available for patients as an injection.

Neffy’s approval is based on four studies in 175 healthy adults, without anaphylaxis, that measured the epinephrine concentrations in the blood following administration of neffy or approved epinephrine injection products. Results from these studies showed comparable epinephrine blood concentrations between neffy and approved epinephrine injection products. Neffy also demonstrated similar increases in blood pressure and heart rate as epinephrine injection products, two critical effects of epinephrine in the treatment of anaphylaxis. A study of neffy in children weighing more than 66 pounds showed that epinephrine concentrations in children were similar to adults who received neffy.

Neffy is a single dose nasal spray administered into one nostril. As with epinephrine injection products, a second dose (using a new nasal spray to administer neffy in the same nostril) may be given if there is no improvement in symptoms

or symptoms worsen. Patients may need to seek emergency medical assistance for close monitoring of the anaphylactic episode and in the event further treatment is required.

Neffy comes with a warning that certain nasal conditions, such as nasal polyps or a history of nasal surgery, may affect absorption of neffy, and patients with these conditions should consult with a health care professional to consider use of an injectable epinephrine product. Neffy also comes with warnings and precautions about use of epinephrine by people with certain coexisting conditions and allergic reactions associated with sulfite.

The most common side effects of neffy include throat irritation, tingling nose (intranasal paresthesia), headache, nasal discomfort, feeling jittery, tingling sensation (paresthesia), fatigue, tremor, runny nose (rhinorrhea), itchiness inside the nose (nasal pruritus), sneezing, abdominal pain, gum (gingival) pain, numbness in the mouth (hypoesthesia oral), nasal congestion, dizziness, nausea and vomiting.

The FDA granted neffy Fast Track designation for this application.

The FDA granted the approval of neffy to ARS Pharmaceuticals. ❖

FDA authorizes updated mRNA COVID-19 vaccines

SILVER SPRING, MD – On Aug. 22nd, the U.S. Food and Drug Administration approved and granted emergency use authorization (EUA) for updated mRNA COVID-19 vaccines (2024–2025 formula) to include a monovalent (single) component that corresponds to the Omicron variant KP.2 strain of SARS-CoV-2. The mRNA COVID-19 vaccines have been updated with this formula to more closely target currently circulating variants and provide better protection against serious consequences of COVID-19, including hospitalization and death. Today’s actions relate to updated mRNA COVID-19 vaccines manufactured by ModernaTX Inc. and Pfizer Inc.

In early June, the FDA advised manufacturers of licensed and authorized COVID-19 vaccines that the COVID-19

vaccines (2024–2025 formula) should be monovalent JN.1 vaccines. Based on the further evolution of SARS-CoV-2 and a rise in cases of COVID-19, the agency subsequently determined and advised manufacturers that the preferred JN.1-lineage for the COVID-19 vaccines (2024–2025 formula) is the KP.2 strain, if feasible.

“Vaccination continues to be the cornerstone of COVID-19 prevention,” said **PETER MARKS, MD, PhD**, director of the FDA’s Center for Biologics Evaluation and Research. “These updated vaccines meet the agency’s rigorous, scientific standards for safety, effectiveness, and manufacturing quality. Given waning immunity of the population from previous exposure to the virus and from prior vaccination, we strongly encourage those who are eligible to consider receiving

an updated COVID-19 vaccine to provide better protection against currently circulating variants.”

The updated mRNA COVID-19 vaccines include Comirnaty and Spikevax, both of which are approved for individuals 12 years of age and older, and the Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine, both of which are authorized for emergency use for individuals 6 months through 11 years of age.

What You Need to Know

- Unvaccinated individuals 6 months through 4 years of age are eligible to receive three doses of the updated, authorized Pfizer-BioNTech COVID-19 Vaccine or two doses of the updated, authorized Moderna COVID-19 Vaccine.

- Individuals 6 months through 4 years of age who have previously been vaccinated against COVID-19 are eligible to receive one or two doses of the updated, authorized Moderna or Pfizer-BioNTech COVID-19 vaccines (timing and number of doses to administer depends on the previous COVID-19 vaccine received).
- Individuals 5 years through 11 years of age regardless of previous vaccination are eligible to receive a single dose of the updated, authorized Moderna or Pfizer-BioNTech COVID-19 vaccines; if previously vaccinated, the dose is administered at least 2 months after the last dose of any COVID-19 vaccine.
- Individuals 12 years of age and older are eligible to receive a single dose of the updated, approved Comirnaty or the updated, approved Spikevax; if previously vaccinated, the dose is administered at least 2 months since the last dose of any COVID-19 vaccine.
- Additional doses are authorized for certain immunocompromised individuals ages 6 months through 11 years of age as described in the Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine fact sheets.

Individuals who receive an updated mRNA COVID-19 vaccine may experience similar side effects as those reported by individuals who previously received mRNA COVID-19 vaccines and as described in the respective prescribing information or fact sheets. The updated vaccines are expected to provide protection against COVID-19 caused by the currently circulating variants. Barring the emergence of a markedly more infectious variant of SARS-CoV-2, the FDA anticipates that the composition of COVID-19 vaccines will need to be assessed annually, as occurs for seasonal influenza vaccines.

For today's approvals and authorizations of the mRNA COVID-19 vaccines, the FDA assessed manufacturing and

nonclinical data to support the change to include the 2024-2025 formula in the mRNA COVID-19 vaccines. The updated mRNA vaccines are manufactured using a similar process as previous formulas of these vaccines. The mRNA COVID-19 vaccines have been administered to hundreds of millions of people in the U.S., and the benefits of these vaccines continue to outweigh their risks.

On an ongoing basis, the FDA will review any additional COVID-19 vaccine applications submitted to the agency and take appropriate regulatory action.

The approval of Comirnaty (COVID-19 Vaccine, mRNA) (2024–2025 formula) was granted to BioNTech Manufacturing GmbH. The EUA amendment for the Pfizer-BioNTech COVID-19 Vaccine (2024–2025 Formula) was issued to Pfizer Inc.

The approval of Spikevax (COVID-19 Vaccine, mRNA) (2024–2025 formula) was granted to ModernaTX Inc. and the EUA amendment for the Moderna COVID-19 Vaccine (2024–2025 formula) was issued to ModernaTX Inc. ❖

Groundbreaking held on new DCYF Female Adolescent Facility

PROVIDENCE – In mid-August, **Governor DAN MCKEE** was joined by members of his cabinet and legislative leaders for a groundbreaking ceremony for a new Department of Children Youth & Families (DCYF) female adolescent residential campus on state-owned land off Main Street in Exeter. The 16-bed facility will provide a new Rhode Island-based option to address the behavioral health needs of female youth ages 13 to 18. Construction is scheduled for completion by late Spring 2026.

Funded with a three-year, \$45 million capital projects appropriation, the new facility will include two eight-bedroom suites, activity rooms, classrooms, a media center, visitor space and staff offices. Recreational spaces will include a fitness center, gym, multi-use outdoor courts and a sports field.

“As chairwoman of the House Oversight Committee, I’ve listened to the heartbreaking testimony of family members of children who desperately need the treatment provided in a facility like the one that will be built here,” said Representative **PATRICIA A. SERPA**. “For girls especially, our state needs to move swiftly to create more facilities like this one, and ensure that they are safe and offer high-quality programs that are well-staffed with caring professionals, and that the children in them are getting the services they need, close to home.”

“Today is a long time coming and Rhode Island will finally have a proper facility to help and support our state’s most vulnerable young women. Over the years, I have heard heartbreaking stories and intense frustration about Rhode Island not having the ability to care for the girls in our state who needed the most

support. Starting today, the young women who will receive the aid they need and deserve in this facility, will know they are no longer forgotten,” said Representative **JULIE A. CASIMIRO**.

“Across the Secretariat, we are focused on building a more robust continuum of care to ensure that Rhode Islanders receive the mental healthcare they require in settings that best meet their individual needs,” said EOHHS Secretary **RICHARD CHAREST**. “Construction of this residential facility will allow more Rhode Island girls to receive the residential treatment they need here in their home state. I greatly appreciate Governor McKee, the General Assembly, DCYF Director Deckert and our partners at the Rhode Island Family Court and the Office of the Child Advocate for their leadership and advocacy.”

“Addressing the behavioral health needs of our female adolescents is not just a mission; it’s a commitment to their futures. We are dedicated to ensuring that these young women receive the care they deserve right here in our state. Through our collaboration with EOHHS, the RI Family Court, and the Office of the Child Advocate, we are making significant strides toward establishing a new residential treatment facility in Rhode Island. This initiative is crucial for providing our youth with the support they need, fostering their well-being, and helping them thrive in a nurturing environment,” said Director **ASHLEY DECKERT**.

The architect for the project is DBVW Architects. Peregrine Group LLC is the project manager and Gilbane Building Company is the general contractor. ❖

Health Care Legislative Package signed into law

PROVIDENCE – Governor **DAN MCKEE** recently ceremonially signed seven bills into law as part of a health care package aimed at improving outcomes, increasing access, and protecting patients across Rhode Island.

“This comprehensive legislative package speaks to the commitment Rhode Island is making to improve health outcomes, strengthen our health care workforce, and protect patients,” said Governor McKee. “I thank all legislative sponsors for their dedication to making the lives of Rhode Islanders easier and healthier.”

“Strengthening our health care system has never been more urgent, and action is essential to ensure that quality care is accessible and affordable for all Rhode Islanders,” said Senator **JOSHUA MILLER** (D-Dist. 28, Cranston, Providence). “As Chairman of the Senate Committee on Health & Human Services, I am grateful to the Senate’s leadership, our partners in government, the many staff members and stakeholders who support and inform our work, and my Senate colleagues for their efforts to advance this important initiative.”

“In my work as a primary care nurse practitioner, it has become increasingly clear the many ways in which our state’s health care system is struggling,” said Senator **PAMELA J. LAURIA** (D-Dist. 32, Barrington, Bristol, East Providence). “Through the legislation being celebrated today, we are taking critical steps to increase provider availability and care quality, contain costs, and protect consumers. As a health care professional, a legislator, and a Rhode Islander, I deeply appreciate everyone’s support and hard work to improve care in our state.”

The legislative package includes:

Prohibiting medical debt reporting to credit bureaus (7103A [zk8ngbyab.cc.rs6.net]/2709A [zk8ngbyab.cc.rs6.net]): Sponsored by Senator **MELISSA MURRAY** (D-Dist. 24, Woonsocket, North Smithfield) and Representative **MARY ANN SHALLCROSS SMITH** (D-Dist. 46, Lincoln, Pawtucket), this bill prohibits hospitals and other medical providers from reporting an individual’s medical debt to consumer reporting agencies/credit bureaus. The legislation also puts in place rules for communicating with consumers, false and misleading representation by debt collectors, and a prohibition against collections during insurance appeals.

Increasing access to mental health support (7350A [zk8ngbyab.cc.rs6.net]/2184A [zk8ngbyab.cc.rs6.net]): Sponsored by Senator **ALANA DIMARIO** (D-Dist. 36, Narragansett, North Kingstown, New Shoreham) and Representative **JUSTINE CALDWELL** (D-Dist. 30, East Greenwich, West Greenwich), this bill makes Rhode Island a founding state in the Interstate Social Work Licensure Compact which will help increase access to mental health support for Rhode Island residents and increase employment options for social workers.

Increasing access to professional counseling (7141 [zk8ngbyab.cc.rs6.net]/2183 [zk8ngbyab.cc.rs6.net]): Sponsored by Senator **MATTHEW LAMOUNTAIN** (D-Dist. 31, Warwick, Cranston)

and Representative **KATHY FOGARTY** (D-Dist. 35, South Kingstown), this bill allows Rhode Island to participate in an Interstate Counseling Compact with the goal of improving public access to professional counseling services by providing for the mutual recognition of other member state licenses. This act would further provide for the uniformity of professional counseling license requirements throughout the United States to promote public safety and public health benefits and eliminate the necessity to maintain licenses to practice in multiple states.

Increasing access to audiology and speech-language pathology services (8219 [zk8ngbyab.cc.rs6.net]/2173 [zk8ngbyab.cc.rs6.net]): Sponsored by Senate President Pro Tempore **HANNA GALLO** (D-Dist. 27, Cranston, West Warwick) and Representative **ARTHUR HANDY** (D-Dist. 18, Cranston), this bill allows Rhode Island to join the Audiology and Speech-Language Pathology Interstate Compact and creates a commission to administer the provisions in the compact between the states.

Increasing access to occupational therapy (7945A [zk8ngbyab.cc.rs6.net] [zk8ngbyab.cc.rs6.net]/2623A [zk8ngbyab.cc.rs6.net]): Sponsored by Senator **JOSHUA MILLER** (D-Dist. 28, Cranston, Providence) and Representative **JOSEPH MCNAMARA** (D-Dist. 19, Cranston, Warwick), this bill allows Rhode Island to join the Occupational Therapy Licensure Compact, which has been adopted by 27 states. Joining this compact enables licensed occupational therapists and occupational therapy assistants to practice in all member states, removing the need for practitioners to get an individual license in each state where they want to practice.

Enhancing the health care workforce (7826 [zk8ngbyab.cc.rs6.net]/2083 [zk8ngbyab.cc.rs6.net]) Sponsored by Senate Majority Whip **VALARIE LAWSON** (D-Dist. 14, East Providence) and Representative **STEPHEN CASEY** (D-Dist. 50, Woonsocket), this bill allows a nurse to be exempt from certain licensing requirements before taking and receiving results of the National Council Licensure Examination (NCLEX).

Protecting patients (2086 [zk8ngbyab.cc.rs6.net]/7365 [zk8ngbyab.cc.rs6.net]): Sponsored by Senator **LINDA UJIFUSA** (D-Dist. 11, Portsmouth, Bristol) and Representative **CALDWELL**, this bill protects patients by ending a practice called “white bagging” where insurers require patients to get their prescriptions from insurer-affiliated pharmacies that are often mail order-only. With this bill, patients now have the right to select a pharmacy of their choice.

“We know that when people are healthy, they have the potential to live happier and fuller lives,” said Rhode Island Executive Office of Health and Human Services Secretary **RICHARD CHAREST**. “This bill package will ensure we bolster our health workforce, expand services, and, overall, make healthcare in Rhode Island more accessible to those who need it. I’m grateful to the General Assembly and the Governor for making the health of our residents a top priority and delivering legislation that reflects that.” ❖

RI delegation delivers \$3.28M to bolster public safety and training for local firefighters

WASHINGTON, DC – In an effort to ensure Rhode Island firefighters have the equipment and training they need to safely and effectively protect and serve their communities, U.S. Senators **JACK REED** and **SHELDON WHITEHOUSE** and Congressmen **SETH MAGAZINER** and **GABE AMO** recently announced \$3,277,138 in federal grants for fire departments in Warwick, Pawtucket, and Burrillville and the Rhode Island Fire Academy.

The federal funds are being awarded through the U.S. Department of Homeland Security's Federal Emergency Management Agency (FEMA) Assistance to Firefighters Grant (AFG) program. These federal grants are designed to enhance local fire departments' abilities to comply with response, equipment, and operational standards established by the National Fire Protection Association (NFPA).

The following communities will receive AFG grants to enhance the safety of firefighters through training and the acquisition of needed equipment:

- **Warwick Fire Department** will receive \$1 million to strengthen training for paramedics and firefighters and to purchase new self-contained breathing apparatus (SCBA) units. Warwick's current SCBA units are no longer NFPA compliant and are in need of replacement.
- **Pawtucket Fire Department** will receive \$1 million to upgrade the licenses of 16 department members from AEMT-Cardiacs to Paramedics and to purchase new cardiac monitors. Last year, Pawtucket responded to over 14,000 emergency medical (EMS) calls and assisted in more than 800 mutual aid EMS requests, making up approximately 79 percent of all emergency responses by the department.
- **Oakland-Mapleville Fire Department** in Burrillville will receive \$928,571 to acquire a new pumper vehicle that will replace the department's outdated and obsolete 47-year-old engine that is no longer in compliance with NFPA standards.
- **Rhode Island Fire Academy** will receive \$348,566 to purchase new equipment that will strengthen the safety of firefighters and help improve training, including two new fire pump simulators and various safety equipment that will allow students at the Academy to master basic operations and functions in a controlled environment.

Over the last two years, Rhode Island fire departments and other first responders across the state have been awarded over \$30 million in federal funding through FEMA's AFG and Staffing For Adequate Fire and Emergency Response (SAFER) grant funding. Congress appropriated \$648 million for the AFG and SAFER programs in the fiscal year 2024 appropriations law.

Last month, the Rhode Island congressional delegation announced \$1.1 million in federal AFG grants for firefighters in East Greenwich, Middletown, Lincoln, Providence, Smithfield, and Central Coventry. ❖

NIH researchers find increases in preteen suicide rate since 2008

BETHESDA, MD – Researchers at the National Institutes of Health (NIH) found that rates of preteen suicide (ages 8–12) have been increasing by approximately 8% annually since 2008. These increases were most pronounced among female preteens, American Indian/Alaska Native or Asian/Pacific Islander preteens, and Hispanic preteens. While the overall number of preteen suicides is small compared to teen and adult populations, the researchers say the findings from this analysis underscore the need for age-appropriate and culturally responsive prevention efforts that include suicide risk screening and lethal means safety counseling. The findings also highlight the need to better understand, identify, and help preteens who may be at risk for suicide.

The researchers also found:

- Female preteens had a disproportionate increase in suicide rate compared to male preteens.
- Black preteens had the highest overall suicide rate.
- Hispanic preteens had the greatest percent increase in suicide rate.
- Hanging and suffocation were the most common suicide methods, but firearms were the most rapidly increasing suicide method.

Using 2001–2022 data from the Centers for Disease Control and Prevention's [Web-based Injury Statistics Query and Reporting System](#) for U.S. youth (ages 8–12), the researchers examined suicide deaths overall and by sex, race, ethnicity, suicide method, metropolitan or non-metropolitan area, and geographic region.

The study was conducted in collaboration with lead researcher Donna A. Ruch and colleagues from The Ohio State University College of Medicine and Nationwide Children's Hospital, Columbus, and researchers at the Washington University School of Medicine, St. Louis.

The study appears in the journal *JAMA Network Open*: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2821658?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=073024 ❖

A \$1.2M NIH grant will bring a state-of-the-art mass spectrometer to Brown

PROVIDENCE [BROWN UNIVERSITY] – A new mass spectrometer is coming to Rhode Island to advance research in cancer biology, aging, neurodegenerative diseases, immunology, infectious diseases and other fields.

With a \$1.2 million grant from the National Institutes of Health, Brown University will acquire an Orbitrap Ascend Tribrid mass spectrometer — a state-of-the-art analytical tool that scientists can use to sequence and quantify proteins as they study cell biology underlying diseases.

The technologically advanced, highly sensitive instrument will enable single-cell protein analysis at a rapid speed, said **ARTHUR SALOMON, PhD**, a Brown professor of molecular biology, cell biology and biochemistry.

“This single-cell analysis capability doesn’t currently exist at Brown, and it’s essential for understanding the biology of disease,” he said, noting that analyses that currently require up to four hours will take about 30 minutes with the new technology, which will also offer unprecedented sensitivity and accuracy.

Salomon is the faculty director of Brown’s Proteomics Core Facility and is the principal investigator for the federal grant. Proteomics is the study of the structure and function of proteins, and the facility provides proteomics instruments and expertise to researchers from Brown and others in the Rhode Island scientific community.

The acquisition of the mass spectrometer will enhance the facility’s capabilities and enable cutting-edge research in major disease areas, Salomon explained. For example, in support of the Legorreta Cancer Center at Brown, the instrument will benefit cancer biology research, where the ability to detect and quantify specific proteins and their modifications is critical for understanding disease mechanisms and developing new therapies. It will also assist with research at the Center on the Biology of Aging and the Carney Institute for Brain Science, where identifying disease-related biomarkers from samples is essential. In immunology and infectious disease research, Salomon said the system will enable the identification and quantification of immune system proteins and parasite- or pathogen-derived molecules, aiding in the development of vaccines and therapies.

Housed in the Proteomics Core Facility in Brown’s Department of Molecular Biology, Cell Biology and Biochemistry at 70 Ship Street in Providence, the mass spectrometer will be available for use by researchers across campus as well as Brown’s affiliated hospitals and other universities in the state.

Proteomics Core Facility Manager **NICHOLAS DASILVA** said that as the most capable shared mass spectrometer in the state, the tool will support the facility in its mission to provide well-maintained, state-of-the-art instrumentation and fundamental proteomics expertise to the Brown and Rhode Island scientific communities.

“This new grant brings rapid, highly sensitive and robust proteomic analysis capabilities to researchers in Rhode Island,” DaSilva said. “The PCF provides both consultative and bespoke proteomic services to principal investigators and research staff,” and the mass spectrometer opens new possibilities for research in fields as varied as evolutionary biology to metabolic syndrome.

Salomon estimates that in addition to future research endeavors, the new instrument will be used immediately by at least 17 researchers working on existing projects funded by the National Institutes of Health and the National Science Foundation.

Due to the time it takes to custom-build the mass spectrometer, ship it from Germany, assemble it and establish workflows, the system will likely be available for use within the next four to six months. The new mass spectrometer will use technologies developed by a national network of proteomic cores that will provide Rhode Island researchers with a highly sophisticated tool for protein analysis, Salomon said.

“This builds up critically important research infrastructure for Rhode Island,” Salomon said. “We will have a world-class facility for performing life science research.”

The work is supported by the National Institutes of Health under Award No. 1S10OD036295-01. ❖



The Orbitrap Ascend Tribrid mass spectrometer is a state-of-the-art analytical tool that scientists can use to sequence and quantify proteins as they study cell biology underlying diseases.

[Brown University]

NIH-funded study finds long COVID affects adolescents differently than younger children

BETHESDA, MD – Scientists investigating long COVID in youth found similar but distinguishable patterns between school-age children (ages 6–11 years) and adolescents (ages 12–17 years) and identified their most common symptoms. The study, supported by the National Institutes of Health (NIH) and published in *JAMA*, comes from research conducted through the NIH's Researching COVID to Enhance Recovery (RECOVER) a wide-reaching effort to understand, diagnose, treat, and prevent long COVID.

Children and adolescents were found to experience prolonged symptoms after SARS-CoV-2 infection in almost every organ system with most having symptoms affecting more than one system.

“Most research characterizing long COVID symptoms is focused on adults, which can lead to the misperception that long COVID in children is rare or that their symptoms are like those of adults,” said **DAVID GOFF, MD, PhD**, division director for the Division of Cardiovascular Sciences at the NIH's National Heart, Lung, and Blood Institute. “Because the symptoms can vary from child to child or present in different patterns, without a proper characterization of symptoms across the life span, it's difficult to know how to optimize care for affected children and adolescents.”

The observational study included 3,860 children and adolescents with a SARS-CoV-2 infection history at more than 60 sites across the United States between March 2022 and December 2023. A comparison group of 1,516 children and adolescents with no history of a SARS-CoV-2 infection were also included to disentangle whether prolonged symptoms of those who had experienced COVID-19 were related to SARS-CoV-2 itself or more broadly related to the effects of the pandemic.

Caregivers completed a comprehensive symptom survey that asked about 75 prolonged symptoms in all major body systems that occurred at least 90 days after an initial SARS-CoV-2 infection and lasted for at least a month. They also completed a survey asking for their perception of the child's overall health, physical health, and quality of life. The researchers then employed a commonly used statistical technique to identify which symptoms were best at differentiating participants who did and did not have history of SARS-CoV-2 infection. They identified combinations of symptoms distinct for each age group that together generated a long COVID research index, which indicates the likely condition of long COVID.

Researchers identified 18 prolonged symptoms that were more common in school-age children, including headache (57%), followed by trouble with memory or focusing (44%), trouble sleeping (44%), and stomach pain (43%). Other common symptoms in school-age children not included in the research index included body, muscle, and joint pain; daytime tiredness/sleepiness or low energy; and feeling anxious.

In adolescents, 17 symptoms were more common, including daytime tiredness/sleepiness or low energy (80%); body, muscle, or joint pain (60%); headaches (55%); and trouble with memory or focusing (47%). Feeling anxious and trouble sleeping were other commonly reported symptoms that were not included in the research index.

“The symptoms that make up the research index are not the only symptoms a child may have and they're not the most severe, but they are most predictive in determining who may have long COVID,” said **RACHEL GROSS, MD**, associate professor in the departments of pediatrics and population health at New York University Grossman School of Medicine and lead author on the study.

Symptoms' overlap

Fourteen symptoms overlapped between the age groups. Comparing previous research on long COVID in adults, the new study found that adults and adolescents had a greater overlap in symptoms, such as loss of or change in smell or taste. Researchers found less overlap between adults and school-age children, underscoring the importance of age-based long COVID research.

The study identified separate research indexes for school-age children and adolescents along with overlapping, but distinguishable symptom patterns in each group. Of the 751 school-age children that had COVID-19, 20% met the long COVID research index threshold. Of the 3,109 adolescent children with a history of SARS-CoV-2 infection, 14% met the research index threshold, though researchers noted that these numbers should not be used as measures of incidence in the general population, since their study may have included more children with long COVID than the overall population.

Scientists note that the research index provides a framework for looking at common symptoms for research purposes – not necessarily as a guide for clinical care – and will likely be refined as researchers study more children with and without long COVID.

“Our next step is to study children ages 5 years and younger so we can better understand long COVID in the very young,” said Gross.

In compliance with NIH's Data Sharing and Management Policy, a dataset containing RECOVER Pediatric Observational Cohort Study data collected through June 15, 2024 – which includes data used for this publication – will be released on NHLBI BioData Catalyst® this fall.

Research reported in this press release was supported by NIH under award numbers OT2HL161841, OT2HL161847, and OT2HL156812. Additional support came from grant R01 HL162373.

(Study: Gross RS, Thaweethai T, Kleinman LC, et al. Characterizing Long COVID in Children and Adolescents: RECOVER Pediatric Study[link is external]. *Journal of the American Medical Association*. 2024. doi: 10.1001/jama.2024.12747)

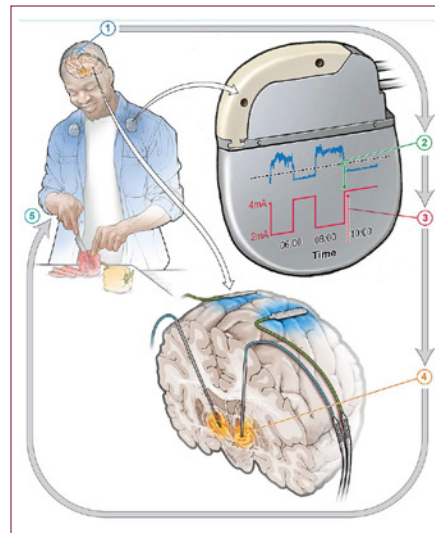
Self-adjusting brain pacemaker may help reduce Parkinson's disease symptoms

BETHESDA, MD – A small feasibility study funded by the National Institutes of Health (NIH) found that an implanted device regulated by the body's brain activity could provide continual and improved treatment for the symptoms of Parkinson's disease (PD) in certain people with the disorder. This type of treatment, called adaptive deep brain stimulation (aDBS), is an improvement on a technique that has been used for PD and other brain disorders for many years. The study found aDBS was markedly more effective at controlling PD symptoms compared to conventional DBS treatments.

"This study marks a big step forward towards developing a DBS system that adapts to what the individual patient needs at a given time," said **MEGAN FRANKOWSKI, PhD**, program director for NIH's *Brain Research Through Advancing Innovative Neurotechnologies*® Initiative, or The BRAIN Initiative®, which helped fund this project. "By helping to control residual symptoms while not exacerbating others, adaptive DBS has the potential to improve the quality of life for some people living with Parkinson's disease."

DBS involves implanting fine wires called electrodes into the brain at specific locations. These wires then deliver electrical signals that can help mitigate the symptoms of brain disorders such as PD. Conventional DBS provides a constant level of stimulation and can also lead to unwanted side effects, because the brain does not always need the same strength of treatment. Therefore, aDBS uses data taken directly from a person's brain and uses machine learning to adjust the level of stimulation in real time as the person's needs change over time.

Four people already receiving conventional DBS were first asked what they felt was their most bothersome symptom that had persisted despite treatment. In many instances this was either involuntary movements or difficulty in initiating movement. The participants were then set up to receive aDBS treatment alongside their existing DBS therapy. After training the aDBS algorithm for several months, the participants were sent home,



Implanted device responds to changes in brain biomarkers of Parkinson's symptoms by adjusting stimulation, allowing the treatment to be tailored to a patient's needs in real time. [NIH, Starr lab]

where the comparison test was performed by alternating between conventional and aDBS treatments. Changes occurred every two to seven days.

aDBS improved each participant's most bothersome symptom roughly 50% compared to conventional DBS. Notably, even though they were not told which type of treatment they were receiving at any one time, three of the four participants were often able to correctly guess when they were on aDBS due to noticeable symptom improvement.

This project is a continuation of several years of work led by **PHILIP STARR, MD, PhD**, and colleagues at the University of California, San Francisco. Previously, in 2018, they reported the development of an adaptive DBS system, referred to as a "closed loop" system, that adjusted based on feedback from the brain itself. Later, in 2021, they described their ability to record brain activity in people as they went about their daily lives.

Here, those two findings were combined to use brain activity recorded during normal life activities to drive the aDBS system. However, DBS treatment changed brain activity so much that the signal that had been expected to control

the aDBS system was no longer detectable. This required researchers to take a computational and data-driven approach to identify a different signal within the brains of people with PD who were receiving conventional DBS therapy.

Conventional treatment for Parkinson's disease often involves the drug levodopa, which is used to replace dopamine in the brain that has been lost because of the disorder. Because the amount of the drug in the brain fluctuates, peaking shortly after administration of the drug and gradually decreasing as it is metabolized by the body, aDBS could help smooth out the fluctuations by providing increased stimulation when drug levels are high and vice versa, making it an attractive option for patients requiring high doses of levodopa.

While these findings are promising, there remain significant challenges to overcome for this therapy to be more widely available. The initial setup of the device requires considerable input from highly trained clinicians. Researchers envision a future where most of the work would be managed by the device itself, greatly reducing the need for repeat visits to the clinic for fine tuning.

This type of automation is also necessary for other groups to test and eventually offer aDBS therapy in a clinical setting.

"One of the big issues facing DBS, even in approved indications like Parkinson's, is access, both for patients in terms of where they can get it and also the physicians who need special training to program these devices," said Frankowski. "If there were a way for a system to find the most optimal settings at the press of a button, that would really increase the availability of this treatment for more people."

This study was supported by NINDS and NIH's The BRAIN Initiative (NS10054, NS129627, NS080680, NS120037, NS131405, NS113637), Thiemann Foundation, and the TUYF Charitable Trust Fund. ❖

[Article: Oehr CR, Cerner S, Hammer LH, et al. "Chronic adaptive deep brain stimulation is superior to conventional stimulation in Parkinson's disease: a blinded randomized feasibility trial." *Nature Medicine* Aug. 19, 2024. DOI: 10.1038/s41591-024-03196-z]