Federal Health & Medicine

The Publication for Definitive Health & Medical Research Programs • 2021

Please keep this edition available to share in your facility with confidence.

Each publication is protected 24/7 with the new antimicrobial treated coating that contains an EPA registered antimicrobial agent. Independent laboratory testing demonstrated a 99.99% reduction in microbes after 24 hours. For more details about this process, please visit biomasterusa.com

Get your free subscription at federalhealthmedicine.com/subscribe

Dr. Anthony S. Fauci Remarks at the World Health Organization Executive Board Meeting

"Director-General Dr. Tedros, distinguished representatives, friends and colleagues:

It is an honor for me to be here, representing the United States of America, on behalf of the newly inaugurated Biden-Harris administration, and as the Chief Medical Adviser to President Biden.

I also am here to represent the scientists, public health officials and frontline healthcare workers, and community health workers who have worked so heroically this past year to fight COVID-19, developing medical countermeasures at truly phenomenal speed, adapting policy responses as we learn more about the virus, and courageously treating the millions of people who have been stricken by this historic scourge.

One year ago, to the day, the United States confirmed its first case of SARS-COV-2, in the State of Washington. Today, in my country and around the world, we have surpassed 90 million cases, a devastating number that continues to grow.

I join my fellow representatives in thanking the World Health Organization for its role in leading the global public health response to this pandemic. Under trying circumstances, this organization has rallied the scientific and research and development community to accelerate vaccines, therapies and diagnostics; conducted regular, streamed press briefings that authoritatively track global developments; provided millions of vital supplies from lab reagents to protective gear to health care workers in dozens of countries; and relentlessly worked with nations in their fight against COVID-19.

Photo courtesy of the U.S. Mission in Geneva

I also know first-hand the work of WHO with whom I have engaged in a collaborative manner touching all aspects of global health over the past 4 decades.

As such, I am honored to announce that the United States will remain a member of the World Health Organization. Yesterday, President Biden signed letters retracting the previous Administration's announcement to withdraw from the organization, and those letters have been transmitted to the Secretary-General of the United Nations and to you Dr. Tedros, my dear friend.

In addition to retracting the notification of withdrawal and retaining membership in the WHO, the United States will cease the drawdown of U.S. staff seconded to the WHO and will resume regular engagement of U.S. government personnel with the WHO both directly and through our WHO Collaborating Centers.

The United States also intends to fulfill its financial obligations to the organization. The United States sees technical collaboration at all levels as a fundamental part of our relationship with WHO, one that we value deeply and will look to strengthen going forward.

As a WHO member state, the United States will work constructively with partners to strengthen and importantly reform the WHO, to help lead the collective effort to strengthen the international COVID-19 response and address its secondary impacts on people, communities, and health systems around the world.

hhs.gov

CDC Welcomes New Director

Statement from Rochelle P. Walensky, MD, MPH, Director, Centers for Disease Control and Prevention

It is truly a privilege to join the world's premier public health agency. For 75 years, CDC has carried out a mission to protect America's safety, health, and security at home and abroad.

I am proud to join this agency, and I recognize the seriousness of the moment. The toll that the COVID-19 pandemic has had on America is truly heartbreaking — for the loss of our loved ones and our beloved ways of life. At Massachusetts General Hospital, I saw firsthand the many difficulties this pandemic brings to our frontline workers and first responders, hospitals and public health systems, communities, and loved ones.

Better, healthier days lie ahead. But to get there, COVID-19 testing, surveillance, and vaccination must accelerate rapidly. We must also confront the longstanding public health challenges of social and racial injustice and inequity that have demanded action for far too long. And we must make up for potentially lost ground in areas like suicide, substance use disorder and overdose, chronic diseases, and global health initiatives.

America and the world are counting on CDC's science and leadership. Just as it has since the beginning of the pandemic, CDC will continue to focus on what is known — and what more can be learned — about the virus to guide America. As part of that promise, CDC's Principal Deputy Director Anne Schuchat will begin leading a comprehensive review of all existing guidance related to COVID-19. Wherever needed, this guidance will be updated so that people can make decisions and take action based upon the best available evidence.

I am so proud to join CDC. Our 24/7 mission is truly more critical than ever.

Rochelle P. Walensky, MD, MPH, is the 19th Director of the Centers for Disease Control and Prevention and the ninth Administrator of the Agency for Toxic Substances and Disease Registry. She is an influential scholar whose pioneering research has helped advance the national and global response to HIV/AIDS. Dr. Walensky is also a well-respected expert on the value of testing and treatment of deadly viruses.

Dr. Walensky served as Chief of the Division of Infectious Diseases at Massachusetts General Hospital from 2017-2020 and Professor of Medicine at Harvard Medical School from

*Rochelle P. Walensky, MD, MPH. P*hoto courtesy of the CDC

2012-2020. She served on the frontline of the COVID-19 pandemic and conducted research on vaccine delivery and strategies to reach underserved communities.

Dr. Walensky is recognized internationally for her work to improve HIV screening and care in South Africa and nationally recognized for motivating health policy and informing clinical trial design and evaluation in a variety of settings.

She is a past Chair of the Office of AIDS Research Advisory Council at the National Institutes of Health, Chair-elect of the HIV Medical Association, and previously served as an advisor to both the World Health Organization and the Joint United Nations Programme on HIV/AIDS.

Originally from Maryland, Dr. Walensky received her Bachelor of Arts from Washington University in St. Louis, her Doctor of Medicine from the Johns Hopkins School of Medicine, and her Masters in Public Health from the Harvard School of Public Health.

hhs.gov

Table of Contents

Table of Contents

CAPITAL PUBLISHING

Published by Capital Publishing, Inc.

Telephone: (813) 286-8444 • Facsimile: (813) 286-8883

capitalpublishing.com • federalhealthmedicine.com

Corporate Address: 507 East Jefferson Street • Brooksville, FL 34601

Mailing Address: 7341 Spring Hill Drive, Unit 3138 • Spring Hill, FL 34606

Publisher & Editor: Thomas S. Adams III

Assistant to the Publisher: Ashley Adams

Designer: Debi Marsh • **Printing:** Associated Printing Productions, Inc.

Advertising Executives: Sonja Homer, Steve Blakemore, John Phillips

Federal Health & Medicine publication is provided at no charge to medical professional subscribers within the United States for the purpose of improving education and public health awareness. To sign up for your free subscription please visit: **federalhealthmedicine.com/subscribe**

HHS Office of the Assistant Secretary for Health Presents Award to Dr. Kwaku Ohene-Frempong

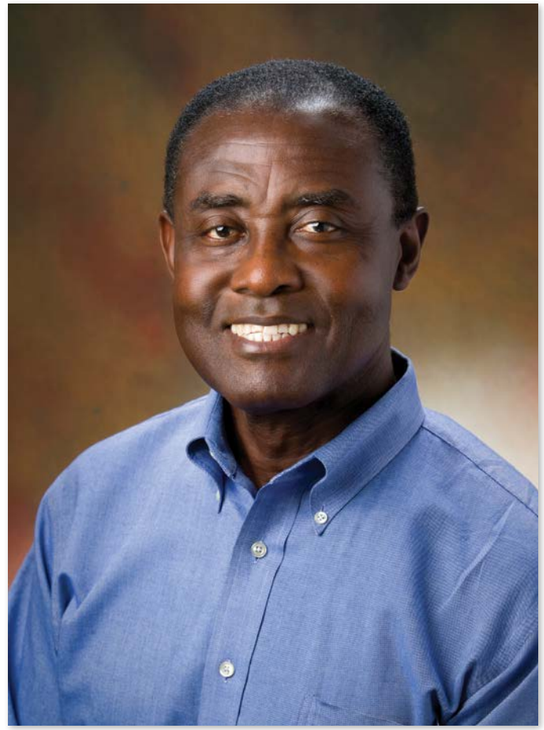
Assistant Secretary for Health, ADM Brett P. Giroir, MD, presented the Assistant Secretary of Health (ASH) Exceptional Service Medal to Dr. Kwaku Ohene-Frempong recognizing him for his outstanding contributions on behalf of the millions of people worldwide suffering from sickle cell disease (SCD). The civilian medal is awarded for exceptional achievement to the cause of public health and medicine, and is the highest civilian award from the Public Health Service, which includes all health divisions of the Department of Health and Human Services. Dr. Ohene-Frempong is the first civilian recipient of the ASH Exceptional Service Medal.

Dr. Ohene-Frempong is Professor Emeritus of Pediatrics at the Perelman School of Medicine at the University of Pennsylvania, and is an inspirational force for the Global Coalition on Sickle Cell Disease. He continues to work tirelessly towards the Coalition's goal of preventing the deaths of 9 million children with sickle cell disease by the year 2050. His experience as a clinician in Ghana serves a model for how to incorporate management of sickle cell disease in primary healthcare; and his mentorship and dedication to the disease have impacted thousands of children in Ghana and around the world.

"I am honored and humbled to present Dr. Ohene-Frempong with the Assistant Secretary for Health Exceptional Service Medal" said ADM Brett P. Giroir, MD. "Dr. Ohene-Frempong deserves this award many times over. I want this award to bring light to his singular accomplishments as a physician, scientist, and humanitarian, but also to the cause of people living with sickle cell disease around the world. His diligent advocacy, clinical expertise and visionary leadership serve as an inspiration for the Global Coalition and the sickle cell community"

Throughout his 40 year career, Dr. Ohene-Frempong served on many professional organizations, boards, and committees dedicated to finding a cure for SCD. His leadership was instrumental in the development of newborn screening for sickle cell disease in Ghana and in Africa. He is a founding member of the Global Sickle Cell Disease Network, and has conducted important research including the first multi-center clinical trial of hydroxyurea therapy in children with sickle cell disease in the United States.

Dr. Ohene-Frempong's contributions to public health and program development in Africa are numerous and ongoing. Recently Dr. Ohene-Frempong has been involved in the establishment of 12 new sickle cell disease treatment centers in regional hospitals in Ghana and is the President of the Sickle Cell Foundation of Ghana.



Kwaku Ohene-Frempong, MD (Photo courtesy of the University of Pennsylvania). The ASH ESM is awarded at the sole discretion of an ASH who serves in uniform to a member of any uniformed service for the highest level of contribution to initiatives of the ASH. As the award is bestowed at the discretion of an ASH who serves in uniform, there is no nomination procedure.

hhs.gov

My First Year as HHS Assistant Secretary for Health

By Adm. Brett P. Giroir, MD, Assistant Secretary for Health

One year ago I was sworn in as the 16th assistant secretary for health. It is an honor to serve as the ASH, and thanks to the dedicated professionals I work with on a daily basis, it has been an incredible year.

The Office of the Assistant Secretary for Health is leading America to healthier lives in small ways and large, every single day. A recent example is our historic initiative to end the HIV epidemic in America, which was announced in the president's State of the Union address. The plan focuses on the hardest hit communities — offering more diagnostic, prevention and treatment resources, and, over the next 10 years, expects to decrease new HIV infections by 90 percent.

We have worked diligently with multiple external partners to initiate — and achieve — many public health milestones, including the Physical Activity Guidelines for Americans; the revised Common Rule; the cross-agency task force on Sickle Cell Disease; the first Tick-Borne Disease Working Group Report; the Pain Management Interagency Best Practices Task Force Draft Report Healthy People 2030 planning; the National Youth Sports Strategy; improved mental and physical health for women veterans; empowering minority communities; and beginning the first federal inter-agency plan to combat sexually transmitted infections. We also have been enabling the international community to benefit from our work through new collaborations with the U.S. Department of Health and Human Services' Office of Global Affairs and partnerships with the World Health Organization.

I expect OASH to oversee many more impactful initiatives during 2019.

Adm. Brett P. Giroir, MD, Assistant Secretary for Health

With an eye toward that goal, we have recruited world-class leaders and staff, including an exceptional principal deputy assistant secretary for health, Rear Adm. Sylvia Trent-Adams, and talented new office directors for minority health, women's health, HIV/AIDS and infectious disease policy, and population affairs.

Secretary Alex Azar, First Lady Melania Trump, and Assistant Secretary for Health Adm. Brett Giroir honored the work of Dr. Loretta Finnegan at the HHS National Convening on Neonatal Abstinence Syndrome in October. Photo courtesy of the US Department of Health & Human Services

In addition to my role as ASH, I serve as the secretary's senior advisor on opioid policy, making OASH's efforts to prevent and treat substance use disorders even more impactful. We have led HHS efforts to develop a comprehensive strategy, advance evidence based-interventions, support novel research, develop new guidelines and highlight voiceless victims through efforts such as the HHS National Convening on Neonatal Abstinence Syndrome, which was attended by both HHS Secretary Alex Azar and First Lady Melania Trump.

Finally, I have the incredible privilege of leading the U.S. Public Health Service Commissioned Corps with Surgeon General Jerome Adams, whom I consider one of the most effective surgeons general in our nation's history. The Commissioned Corps serves in hundreds of locations, both domestic and global, to deliver compassionate care to those in need, to pioneer science and to advance public health policies. We deploy whenever and wherever needed, most recently to provide health screenings and primary care on the U.S. southern border. Our legacy is storied, but to improve our ability to impact public health in the future, we are in the process of modernizing our service to enhance our capabilities, responsiveness and focus.

In these and all future efforts as assistant secretary for health, I am working to ensure that our primary focus is leading America to healthier lives, especially for those who are most vulnerable, including those who have suffered historic disparities.

hhs.gov

HHS Releases Healthy People 2030 with National Disease Prevention and Health Promotion Objectives for the Next Decade

The U.S. Department of Health and Human Services released Healthy People 2030, the nation's 10-year plan for addressing our most critical public health priorities and challenges. Since 1980, HHS's Office of Disease Prevention and Health Promotion has set measurable objectives and targets to improve the health and well-being of the nation.

This decade, Healthy People 2030 features 355 core — or measurable — objectives with 10-year targets, new objectives related to opioid use disorder and youth e-cigarette use, and resources for adapting Healthy People 2030 to emerging public health threats like COVID-19. For the first time, Healthy People 2030 also sets 10-year targets for objectives related to social determinants of health.

"Healthy People was the first national effort to lay out a set of data-driven priorities for health improvement," said HHS Secretary Alex Azar. "Healthy People 2030 adopts a more focused set of objectives and more rigorous data standards to help the federal government and all of our partners deliver results on these important goals over the next decade."

Healthy People has led the nation with its focus on social determinants of health, and continues to prioritize economic stability, education access and quality, health care access and quality, neighborhood and built environment, and social and community context as factors that influence health. Healthy People 2030 also continues to prioritize health disparities, health equity, and health literacy.

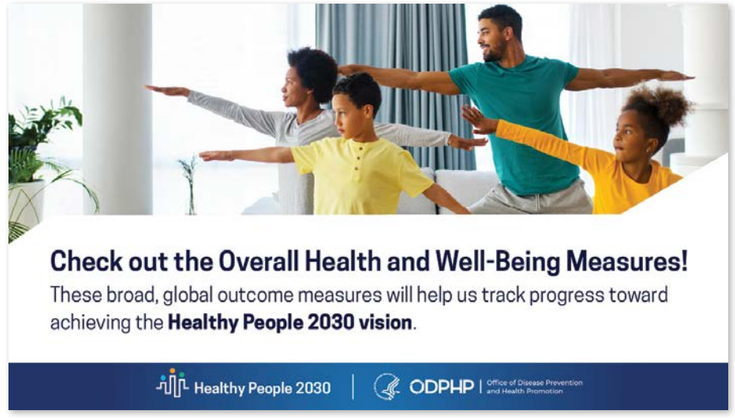
"Now more than ever, we need programs like Healthy People that set a shared vision for a healthier nation, where all people can achieve their full potential for health and well-being across the lifespan," said ADM Brett P. Giroir, MD, Assistant Secretary for Health. "COVID-19 has brought the importance of public health to the forefront of our national dialogue. Achieving Healthy People 2030's vision would help the United States become more resilient to public health threats like COVID-19."

Healthy People 2030 emphasizes collaboration, with objectives and targets that span multiple sectors. A federal advisory committee of 13 external thought leaders and a workgroup of subject matter experts from more than 20 federal agencies contributed to Healthy People 2030, along with public comments received throughout the development process.

The HHS Office of Disease Prevention and Health Promotion leads Healthy People in partnership with the National Center for Health Statistics at the Centers for Disease Control and Prevention, which oversees data in support of the initiative.

HHS Secretary Alex M. Azar II, ADM Brett P. Giroir, MD, Assistant Secretary for Health, and U.S. Surgeon General Jerome M. Adams, MD, MPH, and others from HHS and CDC launched Healthy People 2030 during a webcast on August 18 at 1 pm (EDT) at https://www.hhs.gov/live

hhs.gov



Specializing Care for Individuals of Size

By Tom Adams, Dr. Tony Hilton, and Jill Earwood

Higher risk populations of bariatric patients ranging from a weight between 300 to 1,000 pounds have greater limitations of mobility that can be very challenging for their caregivers. The Department of Veterans Affairs is committed to providing the highest level of care for patients with specialized needs such as these, by continuing development of technologies and procedures that perpetually improve patient outcomes.

Leading development in this field is a highly specialized team at The Veterans Health Administration headed by Dr. Tony Hilton DrPH, MSN, FNP, CRRN, Safe Patient Handling and Mobility National Program Manager, Occupational Safety and Health in VA Central Office, Washington DC, and Jill Earwood MSN-HCQ, RN, CSPHP, VHA Office of Nursing Service Liaison for Safe Patient Handling & Mobility, Western NC VA Healthcare System Safe Patient Handling & Mobility Coordinator/Nursing Quality Manager.

What struck me most in our conversation was their true passion to honor their patients by combining compassionate care with the most advanced technologies. The result of their work has produced a foundation of results that continues to advance both inside and out of the VA system.

"We have a number of technologies available that should be considered and a plan of always continuing to find even better ways to advance, where the technology and resources are sometimes very limited", said Dr. Hilton, "It's because of these high risk complications that we feel this is an important area the VA should really look at and always find ways do things better."

An overview of how their process begins with each encounter with patients and includes highly educated guidance available to caregivers beyond the VA is described by Jill Earwood. "We begin the process in the VA by assessing and screening our

SimLearn Excellence in Veterans Healthcare Team. Photo courtesy of the Department of Veterans Affairs

continued on page 12

continued from page 10

SPHM simulation training at the VA's Orlando SIMLearn Center.
Photo courtesy of the Department of Veterans Affairs

patients, from their clinic appointments to their admission and throughout their continued care, and that screening allows us to choose the technology the facility has to complete high risk tasks required to mobilize these patients. "We provide several resources for our staff, including an application they can download on smart phones or access via the web [https://mobile.va.gov/app/safe-patient-handling] that anyone can access. This application uses algorithms to help guide the care and equipment selection for mobilizing regular size individuals as well as individuals of size. We also have available guidebooks for both safe patient handling in general and bariatric specific care. These guidebooks are available on the Tampa VA Research and Education Foundation's website (tampavaref.org/safe-patient-handling/implementation-tools.htm) and we also have links for those for all of our staff to be able to access and are loaded on the mobile app as well for anyone to access."

In addition to making these resources available to all caregivers inside and out of the VA community, Dr. Hilton describes how the VA is partnering with other caregivers in their community for input towards continued improvements and education. "These resources are available to everyone with the knowledge that we are always improving the technology as updated as we learn," stated Dr. Hilton, "We partner with professionals in our community and other community efforts because we want to make sure our Veterans are taken care of outside the VA and getting the same level of care we expect them to receive in a VA setting."

Ms. Earwood expanded on how specialized training would help achieve this level of care by saying, "Specific to training for direct care providers throughout the VA, we do have requirements regarding the Safe Patient Handling and Mobility (SPHM) technology for equipment, and that all staff who are going to care for those individuals of size are to be trained for it. This training is done upon the new employee orientation and follows through with extensive hands on training to achieve clinical competencies for the use of this technology. It is critical the training be done in advance by learning in a simulation lab, which is the safest environment conducive to learning as opposed to with a patient initially, which is why this is our goal and focus. We use case studies as a great way to start the initial encounter and walk the staff members through what it will look like in the outpatient setting and across all settings in the healthcare system like imaging, dental, vision, pathology, the perioperative environment or any other location like acute care, ICU, long term care, or short stay, rehab, and hospice units.

Our national program office offers training at our VA simulation center in Orlando Florida, where we take the individuals who attend through these case studies so they can practice using the right technology in that large simulation environment. Every two years we rotate where we bring the subject matter experts from the facilities called SPHM Facility Coordinators then each alternate year we bring therapy partners of occupational and physical therapists to the center to be trained on using that technology, not just for staff and patient protection but also for therapy side because the technology can certainly help with individuals of size in terms of therapy, and then the stakeholders take that information back to both the VISN and the healthcare system to replicate the training as closely as possible because usually there's innovations that we want to share and spread, and then at the local level resources are provided so that direct care staff can access instructions, video clips, skills checklist, etc. in a formal way of checking off for competency with the high risk tasks and record that in the system that the healthcare service uses for maintaining competency records."

How can expectations of anticipated equipment and technology that are needed for patients of size by a facility be better achieved as a form of readiness from these methods to meet such specialized needs?

Earwood explains, "We have some creative healthcare systems, one in particular has identified their spaces and locations for care throughout their system. They have identified the weight capacities of rooms and such using a calculator and database where the nursing supervisor of the day enters the patient's information in the calculator with other specifics about the patient and then they are sent to a page that identifies all the patient rooms appropriate for that size patient, where the equipment is throughout the facility that will accommodate that particular patient and gives them a bird's eye view of what they should plan and do. We have another healthcare system example where each room has a specific weight thresholds limit, once a patient meets a threshold they are placed in an appropriate room, and this has become a part of most healthcare systems now. Another example is one facility that, rather than choosing to maintain a fleet of specialty beds for individuals of size, rents the beds so they always have the most advanced technology available and certainty the beds will be functional at all times, they are not just sitting and waiting to be used. So the healthcare systems do have designated spaces and are aware of what those are and what their capacity levels are. As far as the percentage of bariatric beds and the facilities anticipating the use of those, we track patients nationally each year and Dr. Hilton pulls that data on where those patients are being seen, and categories for different weights that correlates definitively with geographic locations where we know bariatric populations are common anyway, not just in the VA. We see patterns where different VISNs have larger percentages than others as we see in the population of area as well. We share this information with healthcare systems and VISNs, so they can look and verify the accuracy of the data, and more importantly identify who these patients are by name and what they anticipate their needs are so they can prepare their healthcare systems to have enough designated rooms and spaces to meet their needs. For most healthcare systems in VA, one to two patient rooms or bed spaces per unit are designated as bariatric. This means wider doors and ceiling lifts accommodating more than 500 pounds, specialized bathrooms, toilets, showers, etc. that meet the needs of the patient's size. Of course this number may be different depending on the local needs of the systems, but it is usually about one to two patients rooms per unit for 24 hour space."

A Department of Veterans Affairs employee is simulating a patient of size being cared for using a special sling (purple device) and ceiling lift (not shown). The sling and lift are being used to hold up the simulated abdominal pannus (apron-like excess of skin) during a training session at the Orlando SIMLearn Center at a Conference in January 2020.
Photo courtesy of the Department of Veterans Affairs

Dr. Hilton added, "The needs of patients of size can change as their weight changes. Once that happens, we have to look at what the patient's functional ability is, if they can actually get up and move around and walk, to provide them independent care to a certain extent, and that also helps us to know what kind of room, space and technology they are going to need. The patients are screened for those very special conditions, if they are coming in for a specific procedure that is taken into account, and then once those spaces have been identified then that is where the patient will go. But before that happens, we have construction guidelines specifically written and published for these spaces that are being put together, so its not something you have to do a makeshift with but rather something you plan for in advance to build your spaces to accommodate them. There is a lot of thought that goes into those spaces. You plan door sizes up to 60 inches wide and you look at the circumference of where the technology is being located in those spaces. You cannot use the same space for a regular patient as you do versus a bariatric patient. Those guidelines and standards are printed and available out there to anyone, and the VA has actually led in defining what those standards are and we are really happy to be able to continue to learn about how we can make it better each day."

The VA's partnerships include a highly valued one with the Department of Defense. Dr. Hilton expanded on this by saying, "We are really excited about partnering with the DoD, and we will continue to doing this because there is a transfer of care across our organization and the VA is really strong on making sure that we are making this transition as smooth as possible, even when there are family members involved we want to make sure those family members stay intact, that our Veterans and their families are safe, so we are very happy that we can talk with the DoD and share what we are doing with patient handling and we want to continue to partner with the DoD."

For more information on how you can access these VA resources and share in community partnerships, please contact https://www.publichealth.va.gov/employeehealth/patient-handling/index.asp

Safe Patient Handling and Mobility (SPHM) and Bariatric Guidebooks are available via the SPHM VHA APP and also through the Tampa VA Research and Education Foundation's website:

SPHM VHA APP
https://mobile.va.gov/app/safe-patient-handling

Tampa VA Research and Education Foundation
http://www.tampavaref.org/safe-patient-handling/implementation-tools.htm

Additional Resources:

Injured Nurses by National Public Radio
http://www.npr.org/series/385540559/injured-nurses

HHS Awards $1.3 Billion to Health Centers in Historic U.S. Response to COVID-19

The U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), awarded more than $1.3 billion to 1,387 health centers as part of a historic U.S. response to the Coronavirus Disease 2019 (COVID-19) pandemic. HRSA-funded health centers may use the awards to help communities across the country detect coronavirus; prevent, diagnose, and treat COVID-19; and maintain or increase health capacity and staffing levels to address this public health emergency.

On March 27, 2020 the President signed the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, into law. This unprecedented legislation will help secure the resources needed to keep Americans safe from the coronavirus. HRSA is making these vital health center

investments available immediately, as they are a key element of the nation's public health response to the COVID-19 pandemic.

"This new funding secured by President Trump will help our community health centers continue the work they're doing on the ground against the coronavirus," said HHS Secretary Alex Azar. "HRSA-funded health centers are already playing a critical role by delivering essential services, serving as community testing and screening sites, and alleviating burdens on our nation's emergency rooms and hospitals. HHS will continue bringing every resource we have to support heroic healthcare workers across the diverse settings health centers serve, from our cities to our rural towns."

The funding supports health centers' ability to detect, prevent, diagnose, and treat COVID-19. The awards will also help maintain or increase health center capacity and staff.

"HRSA-funded health centers are part of the backbone of our nation's health care system, serving 1 in 12 people nationwide," said HRSA Administrator Tom Engels. "Increasingly, people are turning to health centers for the first line of defense in combating emergency public health priorities like the novel coronavirus. Health centers will put these resources to immediate use to respond to emerging and evolving local needs and continue to deliver high quality primary health care services to their patients."

HRSA funds nearly 1,400 health centers that operate in nearly 13,000 locations nationwide. Health centers deliver care to the nation's most vulnerable individuals and families, including people experiencing homelessness, agricultural workers, residents of public housing, and our nation's veterans. Led by patient-majority boards, these health centers provide affordable, accessible, and quality primary health care to over 28 million people a year, regardless of their ability to pay.

hhs.gov

HHS Releases $1.5 Billion to States, Tribes to Combat Opioid Crisis

The U.S. Department of Health and Human Services' Substance Abuse and Mental Health Services Administration (SAMHSA) is distributing the first-year funds of its two-year State Opioid Response (SOR) and Tribal Opioid Response (TOR) grant programs.

The two programs ultimately will award nearly $3 billion over two years to help states and tribes provide community-level resources for people in need of prevention, treatment and recovery support services.

"This continues to provide historic levels of support for treating Americans with substance use disorders, because the COVID-19 pandemic hasn't put a pause on our country's opioid crisis," said HHS Secretary Alex Azar. "We're committed to a science-based approach for fighting the opioid crisis, focusing these State and Tribal Opioid Response grants on providing the gold standard for treatment: medication-assisted treatment with appropriate psychosocial services and community supports."

Through SOR, states across the country are funded to develop tailored approaches to prevention, treatment, and recovery from opioid use disorders and/or stimulant use disorders.

The program provides access to lifesaving, evidence-based medication to treat opioid use disorders, along with psychosocial services and community supports. The TOR program enables the development of these same comprehensive approaches among tribal communities.

The grant programs are part of the administration's tireless commitment to combating the nation's opioid crisis and the U.S. Department of Health and Human Services' Five-Point Opioid Strategy. Both programs have included a new flexibility to allow for stimulant misuse to also be addressed.

"Programs such as these are instrumental because they facilitate greater access to evidence-based treatment," said Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, MD, PhD. "Now, more than ever, this access to treatment for those with substance use disorders is especially critical."

Through these existing funding streams, states and tribes have been able to develop and utilize integral systems of comprehensive care to address their jurisdictions' individual needs. This new round of funding will be instrumental in continuing and expanding upon these efforts. The funding formulas for both programs can be found in their respective funding announcements' Appendices K.

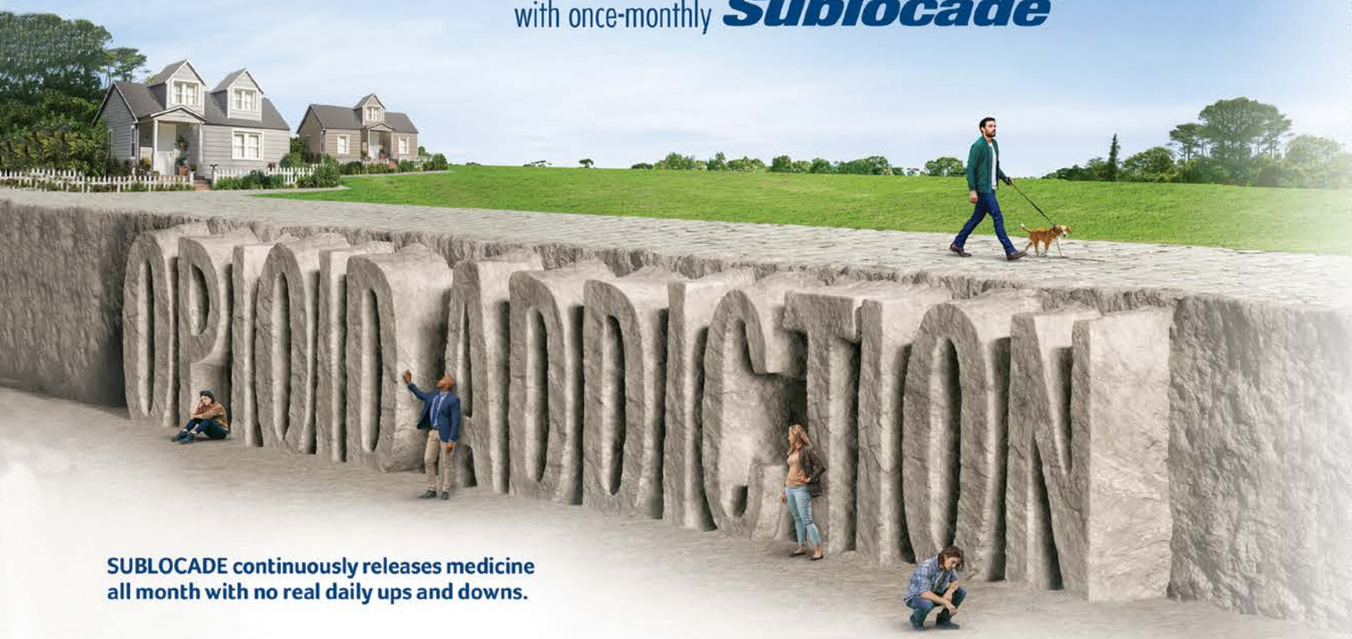
Patients looking for treatment resources can call SAMHSA's National Helpline at 800-662-HELP (4357) or can visit http://findtreatment.gov

hhs.gov

SUBLOCADE® (buprenorphine extended-release) injection, for subcutaneous use (CIII) is a prescription medicine used to treat adults with moderate to severe addiction (dependence) to opioid drugs (prescription or illegal) who have received an oral transmucosal (used under the tongue or inside the cheek) buprenorphine-containing medicine at a dose that controls withdrawal symptoms for at least 7 days. SUBLOCADE is part of a complete treatment plan that should include counseling.

KEEP MOVING TOWARDS RECOVERY

with once-monthly **Sublocade®**



SUBLOCADE continuously releases medicine all month with no real daily ups and downs.

Individuals depicted are for illustrative purposes only.

SUMMARY OF IMPORTANT SAFETY INFORMATION

What is the most important information I should know about SUBLOCADE?

Because of the serious risk of potential harm or death from self-injecting SUBLOCADE into a vein (intravenously), it is only available through a restricted program called the SUBLOCADE REMS Program.

- **SUBLOCADE is not available in retail pharmacies.**
- **Your SUBLOCADE injection will only be given to you by a certified healthcare provider.**

In an emergency, you or your family should tell the emergency medical staff that you are physically dependent on an opioid and are being treated with SUBLOCADE.

Buprenorphine, the medicine in SUBLOCADE, can cause serious and life-threatening problems, especially if you take or use certain other medicines or drugs. Call your healthcare provider right away or get emergency help if you:

- feel faint or dizzy
- have mental changes such as confusion
- have slower breathing than you normally have
- have severe sleepiness
- have blurred vision
- have problems with coordination
- have slurred speech
- cannot think well or clearly
- have a high body temperature
- have slowed reflexes
- feel agitated
- have stiff muscles
- have trouble walking

These can be signs of an overdose or other serious problems.

Death or serious harm can happen if you take anxiety medicines or benzodiazepines, sleeping pills, tranquilizers, muscle relaxants, or sedatives, antidepressants, or antihistamines, or drink alcohol during treatment with SUBLOCADE. Tell your healthcare provider if you are taking any of these medicines and if you drink alcohol.

SUBLOCADE is a controlled substance (CIII) because it contains buprenorphine that can be a target for people who abuse prescription medicines or street drugs.

Death has been reported in those who are not opioid dependent who received buprenorphine sublingually.

Do not use SUBLOCADE if you are allergic to buprenorphine or any ingredient in the prefilled syringe (ATRIGEL® Delivery System, a biodegradable 50:50 poly(DL-lactide-co-glycolide) polymer and a biocompatible solvent, *N*-methyl-2-pyrrolidone (NMP)).

SUBLOCADE may not be right for you. Before starting SUBLOCADE, tell your healthcare provider about all of your medical conditions, including:

- trouble breathing or lung problems
- an enlarged prostate gland (men)
- a head injury or brain problem
- problems urinating
- a curve in your spine that affects your breathing (scoliosis)
- liver problems
- gallbladder problems
- adrenal gland problems
- Addison's disease
- low thyroid hormone levels (hypothyroidism)
- a history of alcoholism
- mental problems such as hallucinations (seeing or hearing things that are not there).
- are pregnant or plan to become pregnant. If you receive SUBLOCADE while pregnant, your baby may have symptoms of opioid withdrawal at birth.
- are breastfeeding or plan to breastfeed. SUBLOCADE can pass into your breast milk and may harm your baby. Talk with your healthcare provider about the best way to feed your baby during treatment with SUBLOCADE. Watch your baby for increased drowsiness and breathing problems.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. SUBLOCADE may affect the way other medicines work and other medicines may affect how SUBLOCADE works. Some medicines may cause serious or life-threatening medical problems when taken with SUBLOCADE. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine.

The doses of certain medicines may need to be changed if used during treatment with SUBLOCADE. Do not take any medicine during treatment with SUBLOCADE until you have talked with your healthcare provider. Your healthcare provider will tell you if it is safe to take other medicines during treatment with SUBLOCADE.

You should not take anxiety medicines or benzodiazepines (such as Valium® or Xanax®), sleeping pills, tranquilizers, muscle relaxants, or sedatives (such as Ambien®), antidepressants, or antihistamines that are not prescribed to you during treatment with SUBLOCADE, as this can lead to slowed breathing, drowsiness, delayed reaction time, loss of consciousness or even death. If a healthcare provider is considering prescribing such a medicine for you, remind the healthcare provider that you are being treated with SUBLOCADE.

You may have detectable levels of SUBLOCADE in your body for a long period after stopping treatment with SUBLOCADE.

What should I avoid while being treated with SUBLOCADE?

- **Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how this medicine affects you.** Buprenorphine can cause drowsiness and slow reaction times. This may happen more often in the first few days after your injection and when your dose is changed.
- **Do not drink alcohol** during treatment with SUBLOCADE, as this can lead to slowed breathing, drowsiness, slow reaction time, loss of consciousness or even death.

What are the possible side effects of SUBLOCADE?

SUBLOCADE can cause serious side effects, including:

See "What is the most important information I need to know about SUBLOCADE?"

- **Physical dependence and withdrawal.** Your body can develop a physical need for SUBLOCADE (dependence). If you stop receiving SUBLOCADE, you could have opioid withdrawal symptoms such as: shaking, goose bumps, muscle aches, sweating more than normal, feeling hot or cold more than normal, runny nose and watery eyes, or diarrhea or vomiting. These symptoms may start weeks to months after your last dose of SUBLOCADE.
- **Liver problems.** Call your healthcare provider right away if you notice any of these signs of liver problems: your skin or the white part of your eyes turns yellow (jaundice), urine turns dark, bowel movements (stools) turn light in color, decreased appetite, or stomach (abdomen) pain or nausea. Your healthcare provider may do tests before and during treatment with SUBLOCADE to check your liver.
- **Allergic reaction.** Call your healthcare provider or get emergency help right away if you get: rash, hives, itching, swelling of your face, wheezing or dizziness, or a decrease in consciousness.
- **Decrease in blood pressure.** You may feel dizzy when you get up from sitting or lying down.
- **The most common side effects of SUBLOCADE include:** constipation, headache, nausea, injection site itching, vomiting, increase in liver enzymes, tiredness, or injection site pain.
- Long-term (chronic) use of opioids, including SUBLOCADE, may cause fertility problems in males and females. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects. Call your healthcare provider for medical advice about side effects.

This is only a summary of important information about SUBLOCADE and does not replace talking to your healthcare provider about your condition and your treatment. Talk to your healthcare provider if you have questions about SUBLOCADE. Share this important information with members of your household.

To report pregnancy or side effects associated with taking SUBLOCADE, please call 1-877-782-6966. You are encouraged to report negative side effects of drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

To learn more about SUBLOCADE, go to SUBLOCADE.com. For REMS information visit www.sublocadeREMS.com.

Visit sublocade.com and ask your healthcare provider if SUBLOCADE is right for you.

ONCE-MONTHLY

Sublocade®

(buprenorphine extended-release) injection for subcutaneous use (C-III)

100mg·300mg

SUBLOCADE is manufactured for Indivior Inc., North Chesterfield, VA 23235 by AMRI, Burlington, MA 01803. P-BAG-US-00701 EXPIRY APRIL 2022

HHS Invests Nearly $115 Million to Combat the Opioid Crisis in Rural Communities

The U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA) awarded approximately $25 million to 80 award recipients across 36 states and two territories as part of the Rural Communities Opioid Response Program (RCORP). RCORP is a multi-year HRSA initiative to reduce morbidity and mortality of substance use disorder (SUD) and opioid use disorder (OUD) in high-risk rural communities. This builds upon HRSA's RCORP awards made this August, reflecting a total fiscal year 2020 investment of nearly $115 million.

"This provides historic levels of support for Americans with substance use disorders, especially those in rural areas, because the COVID-19 pandemic hasn't put a pause on our country's opioid crisis," said HHS Secretary Alex Azar. "These grants are part of the Rural Action Plan that HHS launched in response to President's Executive Order on rural health, which lays out a path forward to transform and improve rural healthcare in tangible ways."

"RCORP-Planning will continue to help rural communities build the coalitions needed to fight opioid use disorder, and RCORP-NAS will provide needed funding to rural residents grappling with the opioid epidemic to help many people reach recovery."

HRSA's Federal Office of Rural Health Policy (FORHP) awarded nearly $15 million to 30 award recipients through the Rural Communities Opioid Response Program-Neonatal Abstinence Syndrome (RCORP-NAS). Each recipient will receive up to $500,000 over three-years to reduce the incidence and impact of neonatal abstinence syndrome in rural communities by improving systems of care, family supports, and social determinants of health.

In addition, through the Rural Communities Opioid Response Program-Planning (RCORP-Planning), $10 million is being awarded to 50 award recipients to strengthen and expand the capacity of rural communities to provide SUD/OUD prevention, treatment, and recovery services to high-risk populations. Award recipients will use the funds to build partnerships and develop comprehensive plans to address SUD/OUD workforce and service delivery challenges in their communities.

"We are excited to celebrate these awards during National Recovery Month," said HRSA Administrator Tom Engels. "RCORP-Planning will continue to help rural communities build the coalitions needed to fight opioid use disorder, and RCORP-NAS will provide needed funding to rural residents grappling with the opioid epidemic to help many people reach recovery."

Through the RCORP initiative, the funding will help rural communities address barriers to care and additional strains that COVID-19 has placed on both rural individuals with SUD and on rural organizations providing prevention, treatment, and recovery services.

hhs.gov

Alcohol-related Deaths Increasing in the United States

An analysis of U.S. death certificate data by researchers at the National Institute on Alcohol Abuse and Alcoholism (NIAAA), part of the National Institutes of Health, found that nearly 1 million people died from alcohol-related causes between 1999 and 2017. The number of death certificates mentioning alcohol more than doubled from 35,914 in 1999 to 72,558 in 2017, the year in which alcohol played a role in 2.6% of all deaths in the United States. The increase in alcohol-related deaths is consistent with reports of increases in alcohol consumption and alcohol-involved emergency department visits and hospitalizations during the same period. The new findings are reported online in the journal *Alcoholism: Clinical and Experimental Research*.

"Alcohol is not a benign substance and there are many ways it can contribute to mortality," said NIAAA Director Dr. George F. Koob. "The current findings suggest that alcohol-related deaths involving injuries, overdoses, and chronic diseases are increasing across a wide swath of the population. The report is a wakeup call to the growing threat alcohol poses to public health."

In the new study, Aaron White, PhD, senior scientific advisor to the NIAAA director, and colleagues analyzed data from all U.S. death certificates filed from 1999 to 2017. A death was identified as alcohol-related if an alcohol-induced cause was listed as the underlying cause or as a contributing cause of death. The researchers found that, in 2017, nearly half of alcohol-related deaths resulted from liver disease (31%; 22,245) or overdoses on alcohol alone or with other drugs (18%; 12,954). People aged 45-74 had the highest rates of deaths related to alcohol, but the biggest increases over time were among people age 25-34.

High rates among middle-aged adults are consistent with recent reports of increases in "deaths of despair," generally defined as deaths related to overdoses, alcohol-associated liver cirrhosis, and suicides, primarily among non-Hispanic whites. However, the authors report that, by the end of the study period, alcohol-related deaths were increasing among people in almost all age and racial and ethnic group.

As with increases in alcohol consumption and related medical emergencies, rates of death involving alcohol increased more for women (85%) than men (35%) over the study period, further narrowing once large differences in alcohol use and harms between males and females. The findings come at a time of growing evidence that even one drink per day of alcohol can contribute to an increase in the risk of breast cancer for women. Women also appear to be at a greater risk than men for alcohol-related cardiovascular diseases, liver disease, alcohol use disorder, and other consequences.

"Alcohol is a growing women's health issue," said Dr. Koob. "The rapid increase in deaths involving alcohol among women is troubling and parallels the increases in alcohol consumption among women over the past few decades."

The authors note that previous studies have shown that the role of alcohol in deaths is vastly underreported. Since the present study examined death certificates only, the actual number of alcohol-related deaths in 2017 may far exceed the 72,558 determined by the authors.

"Taken together," said Dr. Koob, "the findings of this study and others suggests that alcohol-related harms are increasing at multiple levels — from ED visits and hospitalizations to deaths. We know that the contribution of alcohol often fails to make it onto death certificates. Better surveillance of alcohol involvement in mortality is essential in order to better understand and address the impact of alcohol on public health."

About the National Institute on Alcohol Abuse and Alcoholism (NIAAA): The National Institute on Alcohol Abuse and Alcoholism (NIAAA), part of the National Institutes of Health, is the primary U.S. agency for conducting and supporting research on the causes, consequences, diagnosis, prevention, and treatment of alcohol use disorder. NIAAA also disseminates research findings to general, professional, and academic audiences. Additional alcohol research information and publications are available at www.niaaa.nih.gov

nih.gov

Hearing Health Care is a Global Priority

Statement for World Hearing Day on March 3 from NIDCD Director Dr. Debara Tucci

Approximately 466 million children and adults worldwide have disabling hearing loss, according to the World Health Organization (WHO). Unaddressed hearing loss costs an estimated US$750 billion annually worldwide and potentially interferes greatly with an individual's physical, behavioral, and social functioning.

Deafness and hearing loss affect people of all ages and in all segments of the population, including millions who live in countries with sparse resources and strategies to address ear and hearing problems.

The good news is that experts and organizations around the world are turning their attention toward making hearing health care a global priority. As part of World Hearing Day, I'd like to share with you some of these important international efforts, including several in which the National Institute on Deafness and Other Communication Disorders (NIDCD), part of the National Institutes of Health, participates.

Every year on March 3, WHO, the health agency of the United Nations, engages organizations in World Hearing Day public awareness activities. This year's theme, "Hearing for life: Don't let hearing loss limit you," highlights the importance of hearing loss prevention and timely and effective interventions for those who are deaf or hard-of-hearing.

The NIDCD is dedicated to supporting research and initiatives to prevent, detect, and treat hearing loss in the United States and beyond. We collaborate with other agencies and with researchers to encourage more effective and accessible hearing health services for babies, children, and adults. We also offer evidence-based information for the public on hearing screening and hearing loss (see our fact sheets on Your Baby's Hearing Screening, Noise-Induced Hearing Loss, and Age-Related Hearing Loss).

A major catalyst for the increased interest in global hearing health care was the World Health Assembly (WHA) resolution on the prevention of deafness and hearing loss, issued in May 2017. The WHA is the governing body of WHO. To facilitate implementation of the resolution, WHO established the World Hearing Forum, a global network of stakeholders, in 2018. The NIDCD is one of 138 agencies and organizations that comprise the forum.

The WHA resolution calls for WHO to publish the first World Report on Hearing. This report will highlight evidence-based best practices and priorities for ear and hearing health care, and will reflect a variety of cultural contexts and approaches. The report is scheduled for release this May.

Finally, a complementary initiative, the Lancet Commission on Hearing Loss, has been underway for a year now. As one of the co-chairs of this important effort, I am confident that the commission's work will extend the drive to reduce the immense burden of hearing loss worldwide. We will do so by seeking innovative solutions focused on prevention, policy, technology, and protection, and on how these themes interact.

These efforts provide a collective voice

NIDCD Director Dr. Debara Tucci

from experts — across disciplines and in dozens of countries — to paint a robust global picture of the state of the science and clinical practice in ear and hearing health care. The forthcoming results and recommendations will help guide efforts to improve communication for millions of people around the world through advancements in practice, research, and policy at local, national, and international levels. As the director of the lead U.S. agency promoting the nation's hearing health care, I am proud that the NIDCD is a part of this important movement.

nih.gov

CPG

Study Charts Developmental Map of Inner Ear Sound Sensor in Mice

Data offers valuable resource for developing stem cell-based therapies for hearing loss

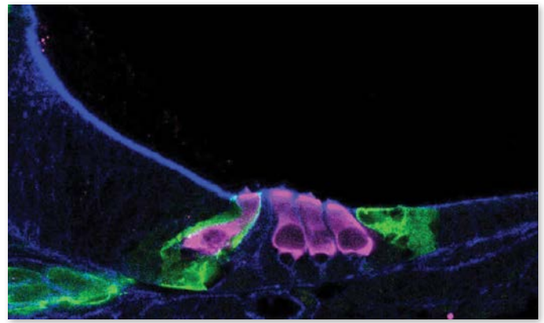
A team of researchers has generated a developmental map of a key sound-sensing structure in the mouse inner ear. Scientists at the National Institute on Deafness and Other Communication Disorders (NIDCD), part of the National Institutes of Health, and their collaborators analyzed data from 30,000 cells from mouse cochlea, the snail-shaped structure of the inner ear. The results provide insights into the genetic programs that drive the formation of cells important for detecting sounds. The study also sheds light specifically on the underlying cause of hearing loss linked to Ehlers-Danlos syndrome and Loeys-Dietz syndrome.

The study data is shared on a unique platform open to any researcher, creating an unprecedented resource that could catalyze future research on hearing loss. Led by Matthew W. Kelley, PhD, chief of the Section on Developmental Neuroscience at the NIDCD, the study appeared online in Nature Communications(link is external). The research team includes investigators at the University of Maryland School of Medicine, Baltimore; Decibel Therapeutics, Boston; and King's College London.

"Unlike many other types of cells in the body, the sensory cells that enable us to hear do not have the capacity to regenerate when they become damaged or diseased," said NIDCD Director Debara L. Tucci, MD, who is also an otolaryngology-head and neck surgeon. "By clarifying our understanding of how these cells are formed in the developing inner ear, this work is an important asset for scientists working on stem cell-based therapeutics that may treat or reverse some forms of inner ear hearing loss."

In mammals, the primary transducers of sound are hair cells, which are spread across a thin ribbon of tissue (the organ of Corti) that runs the length of the coiled cochlea. There are two kinds of hair cells, inner hair cells and outer hair cells, and they are structurally and functionally sustained by several types of supporting cells. During development, a pool of nearly identical progenitor cells gives rise to these different cell types, but the factors that guide the transformation of progenitors into hair cells are not fully understood.

To learn more about how the cochlea forms, Kelley's team took advantage of a method called single-cell RNA sequencing. This powerful technique enables researchers to analyze the gene activity patterns of single cells. Scientists can learn a lot about a



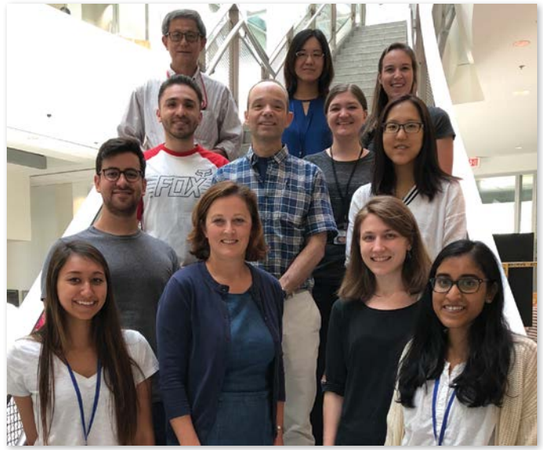
Single-cell RNA sequencing helped scientists map how sensory hair cells (pink) develop in a newborn mouse cochlea. Photo credit Helen Maunsell, NIDCD/NIH

cell from its pattern of active genes because genes encode proteins, which define a cell's function. Cells' gene activity patterns change during development or in response to the environment.

"There are only a few thousand hair cells in the cochlea, and they are arrayed close together in a complex mosaic, an arrangement that makes the cells hard to isolate and characterize," said Kelley. "Single-cell RNA sequencing has provided us with a valuable tool to track individual cells' behaviors as they take their places in the intricate structure of the developing cochlea."

Building on their earlier work on 301 cells, Kelley's team set out to examine the gene activity profiles of 30,000 cells from mouse cochleae collected at four time points, beginning with the 14th day of embryonic development and ending with the seventh postnatal day. Collectively, the data represents a vast catalog of information that researchers can use to explore cochlear development and to study the genes that underlie inherited forms of hearing impairment.

Kelley's team focused on one such gene, Tgfbr1, which has been linked to two conditions associated with hearing loss, Ehlers-Danlos syndrome and Loeys-Dietz syndrome. The data showed that Tgfbr1 is active in outer hair cell precursors as early as the 14th day of embryonic development, suggesting that the gene is important for initiating the formation of these cells.



Dr. Matthew W. Kelley, chief of the Laboratory of Cochlear Development, National Institute on Deafness and Other Communication Disorders (center), surrounded by Laboratory of Cochlear Development staff; Front row L-R: Tara Balasubramanian, Elizabeth Driver, Helen Maunsell, Likhitha Kolla. Second row L-R: Joey Mays, Matt Kelley, Kelly Kim. Third row L-R: Alejandro Anaya, Tessa Sanders. Back row L-R: Weise Change, Beatrice Mao, Madison Mehlferber. Photo courtesy of NIDCD.

To explore Tgfbr1's role, the researchers blocked the Tgfbr1 protein's activity in cochleae from 14.5-day-old mouse embryos. When they examined the cochleae five days later, they saw fewer outer hair cells compared to the embryonic mouse cochleae that had not been treated with the Tgfbr1 blocker. This finding suggests that hearing loss in people with Tgfbr1 mutations could stem from impaired outer hair cell formation during development.

The study revealed additional insights into the early stages of cochlear development. The developmental pathways of inner and outer hair cells diverge early on; researchers observed distinct gene activity patterns at the earliest time point in the study, the 14th day of embryonic development. This suggests that the precursors from which these cells derive are not as uniform as previously believed. Additional research on cells collected at earlier stages is needed to characterize the initial steps in the formation of hair cells.

The results provide insights into the genetic programs that drive the formation of cells important for detecting sounds. The study also sheds light specifically on the underlying cause of hearing loss linked to Ehlers-Danlos syndrome and Loeys-Dietz syndrome.

In the future, scientists may be able to use the data to steer stem cells toward the hair cell lineage, helping to produce the specialized cells they need to test cell replacement approaches for reversing some forms of hearing loss. The study's results also represent a valuable resource for research on the hearing mechanism and how it goes awry in congenital forms of hearing loss.

The authors have made their data available through the gEAR portal(gene Expression Analysis Resource), a web-based platform for sharing, visualizing, and analyzing large multiomic datasets. The portal is maintained by Ronna Hertzano, MD, PhD, and her team in the Department of Otorhinolaryngology and the Institute for Genome Sciences (IGS) at the University of Maryland School of Medicine.

"Single-cell RNA sequencing data are highly complex and typically require significant skill to access," said Hertzano. "By disseminating this study data via the gEAR, we are creating an 'encyclopedia' of the genes expressed in the developing inner ear, transforming the knowledge base of our field and making this robust information open and understandable to biologists and other researchers."

This press release describes a basic research finding. Basic research increases our understanding of human behavior and biology, which is foundational to advancing new and better ways to prevent, diagnose, and treat disease. Science is an unpredictable and incremental process; each research advance builds on past discoveries, often in unexpected ways. Most clinical advances would not be possible without the knowledge gained through basic research.

This research was supported by the NIDCD Division of Intramural Research (ZIADC000039) as well as (ZICDC000086) to the Genomics and Computational Biology Core, which is led by Robert Morell, PhD, and by King's College London. The gEAR portal is primarily supported by the Hearing Restoration Project of Hearing Health Foundation, New York City, with additional funding from the NIDCD (R01DC013817) and from NIH's National Institute of Mental Health (R24MH114815). Computational resources of the NIH HPC Biowulf cluster were used in this study.

nih.gov

Using Artificial Intelligence to Catch Irregular Heartbeats

By Dr. Francis Collins, Director of the National Institutes of Health

Thanks to advances in wearable health technologies, it's now possible for people to monitor their heart rhythms at home for days, weeks, or even months via wireless electrocardiogram (EKG) patches. In fact, my Apple Watch makes it possible to record a real-time EKG whenever I want. (I'm glad to say I am in normal sinus rhythm.)

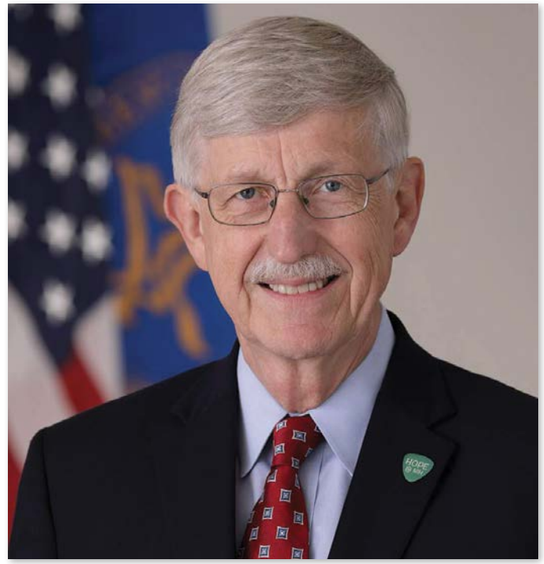
For true medical benefit, however, the challenge lies in analyzing the vast amounts of data — often hundreds of hours worth per person — to distinguish reliably between harmless rhythm irregularities and potentially life-threatening problems. Now, NIH-funded researchers have found that artificial intelligence (AI) can help.

A powerful computer "studied" more than 90,000 EKG recordings, from which it "learned" to recognize patterns, form rules, and apply them accurately to future EKG readings. The computer became so "smart" that it could classify 10 different types of irregular heart rhythms, including atrial fibrillation (AFib). In fact, after just seven months of training, the computer-devised algorithm was as good — and in some cases even better than — cardiology experts at making the correct diagnostic call.

EKG tests measure electrical impulses in the heart, which signal the heart muscle to contract and pump blood to the rest of the body. The precise, wave-like features of the electrical impulses allow doctors to determine whether a person's heart is beating normally.

The Zio patch is a 2-by-5-inch adhesive patch, worn much like a bandage, on the upper left side of the chest. It's water resistant and can be kept on around the clock while a person sleeps, exercises, or takes a shower. The wireless patch continuously monitors heart rhythms, storing EKG data for later analysis.

For example, in people with AFib, the heart's upper chambers (the atria) contract rapidly and unpredictably, causing the ventricles (the main heart muscle) to contract irregularly rather than in a steady rhythm. This is an important arrhythmia to



Dr. Francis Collins, Director of the National Institutes of Health

detect, even if it may only be present occasionally over many days of monitoring. That's not always easy to do with current methods.

Here's where the team, led by computer scientists Awni Hannun and Andrew Ng, Stanford University, Palo Alto, CA, saw an AI opportunity. As published in Nature Medicine, the Stanford team started by assembling a large EKG dataset from more than 53,000 people[1]. The data included various forms of arrhythmia and normal heart rhythms from people who had worn the FDA-approved Zio patch for about two weeks.

The Zio patch is a 2-by-5-inch adhesive patch, worn much like a bandage, on the upper left side of the chest. It's water resistant and can be kept on around the clock while a person sleeps, exercises, or takes a shower. The wireless patch continuously monitors heart rhythms, storing EKG data for later analysis.

The Stanford researchers looked to machine learning to process

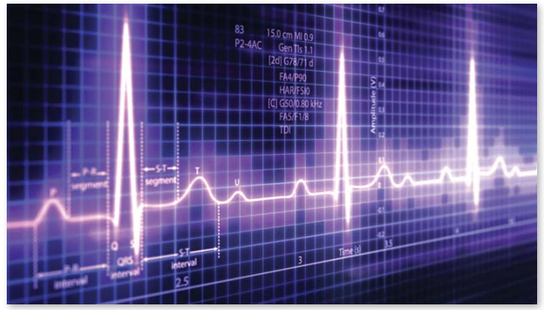


Photo courtesy of the National Institutes of Health and gettyimages/ enot-poloskun

all the EKG data. In machine learning, computers rely on large datasets of examples in order to learn how to perform a given task. The accuracy improves as the machine "sees" more data.

But the team's real interest was in utilizing a special class of machine learning called deep neural networks, or deep learning. Deep learning is inspired by how our own brain's neural networks process information, learning to focus on some details but not others.

In deep learning, computers look for patterns in data. As they begin to "see" complex relationships, some connections in the network are strengthened while others are weakened. The network is typically composed of multiple information-processing layers, which operate on the data and compute increasingly complex and abstract representations.

Those data reach the final output layer, which acts as a classifier, assigning each bit of data to a particular category or, in the case of the EKG readings, a diagnosis. In this way, computers can learn to analyze and sort highly complex data using both more obvious and hidden features.

Woman wearing a Zio patch
Photo Credit: National Institutes of Health adapted from JAMA Network Summary Vide

Ultimately, the computer in the new study could differentiate between EKG readings representing 10 different arrhythmias as well as a normal heart rhythm. It could also tell the difference between irregular heart rhythms and background "noise" caused by interference of one kind or another, such as a jostled or disconnected Zio patch.

For validation, the computer attempted to assign a diagnosis to the EKG readings of 328 additional patients. Independently, several expert cardiologists also read those EKGs and reached a consensus diagnosis for each patient. In almost all cases, the computer's diagnosis agreed with the consensus of the cardiologists. The computer also made its calls much faster.

Next, the researchers compared the computer's diagnoses to those of six individual cardiologists who weren't part of the original consensus committee. And, the results show that the computer actually outperformed these experienced cardiologists!

The findings suggest that artificial intelligence can be used to improve the accuracy and efficiency of EKG readings. In fact, Hannun reports that iRhythm Technologies, maker of the Zio patch, has already incorporated the algorithm into the interpretation now being used to analyze data from real patients.

As impressive as this is, we are surely just at the beginning of AI applications to health and health care. In recognition of the opportunities ahead, NIH has recently launched a working group on AI to explore ways to make the best use of existing data, and harness the potential of artificial intelligence and machine learning to advance biomedical research and the practice of medicine.

Meanwhile, more and more impressive NIH-supported research featuring AI is being published. In my next blog, I'll highlight a recent paper that uses AI to make a real difference for cervical cancer, particularly in low resource settings.

Reference:

1. Cardiologist-level arrhythmia detection and classification in ambulatory electro-cardiograms using a deep neural network. Hannun AY, Rajpurkar P, Haghpanahi M, Tison GH, Bourn C, Turakhia MP, Ng AY. Nat Med. 2019 Jan;25(1):65-69.

nih.gov

CPG

Surgeon General Releases Call to Action on Hypertension Control High Blood Pressure Control IS Possible

Surgeon General VADM Jerome M. Adams, MD, MPH, issued a Call to Action urging Americans to recognize and address hypertension control as a national, public health priority. The Surgeon General's Call to Action to Control Hypertension provides strategies for those on the frontlines of health care and public health to address this costly, dangerous and far too common chronic health condition.

Hypertension is often known as a "silent killer," as it frequently has no signs or symptoms. If left uncontrolled, hypertension can increase a person's risk for heart disease, stroke, heart failure, kidney disease, pregnancy complications, and cognitive decline or dementia later in life. However, hypertension is a preventable risk factor for heart disease and stroke. Hypertension is all too common, as nearly 1 in 2 adults have hypertension, yet only about 1 in 4 have it under control. Hypertension care and treatment are also costly, resulting in an estimated $131 billion to $198 billion in medical costs each year.

Currently, there are limited data and information about the impact of underlying medical conditions — including hypertension — on the risk for severe illness from COVID-19. While our understanding of COVID-19 is still improving and evolving, we know that people with hypertension may be at an increased risk for severe illness from COVID-19.

We know what works to improve hypertension control: continue to take hypertension medications as directed; continue to practice safe social distancing when being physically active; continue healthy eating; and stay connected to a medical care team. Most importantly, if you are feeling any signs or symptoms of a heart attack or stroke, do not delay medical attention.

"Hypertension is a costly, preventable health condition that disproportionately impacts Black Americans and feeds so many other burdensome conditions, like kidney disease and maternal mortality and morbidity, which we've prioritized, " said HHS Secretary Alex Azar. "The Surgeon General's call to action on hypertension gives us all solid strategies to fight this 'silent killer' and represents exactly the kind of thinking we need: a healthcare system focused on patients being empowered to control their health and outcomes."

Some subsets of the U.S. population have higher rates of hypertension and lower rates of controlled blood pressure. For example, more than half of Black men and women have hypertension, and only about 20% have it under control. African Americans have higher rates of hypertension than any other racial or ethnic groups. Black men and women also develop hypertension at younger ages and have more severe outcomes than whites.

Hypertension rates (based on blood pressure ≥130/80 mm Hg) for non-Hispanic Black adults is 54%; non-Hispanic white adults is 46%, non-Hispanic Asian adults is 39%, and Hispanic adults is 36%. The Surgeon General's Call to Action identifies factors that negatively affect hypertension control in minority populations, including persistent health disparities and inequalities in the distribution of social, economic, and environmental conditions necessary for better health.

"The Surgeon General's Call to Action to Control Hypertension provides a roadmap for helping people, communities, health professionals and others improve the heart health of our nation by working together to eliminate differences in access to quality healthcare and addressing social factors that influence overall health," stated Surgeon General Adams. "Communities can ensure that the places where people live, learn, work, play and pray support hypertension control by promoting access to and availability of physical activity opportunities, healthy food options, and links between clinical services and community programs."

The Surgeon General's Call to Action summarizes recent data on hypertension control for all populations, identifies the 10 most

effective strategies for achieving control, and provides recommendations to individuals and organizations that can improve rates of hypertension prevention and control. Among the strategies identified are:

- Increase awareness of health risks;
- Recognize economic burden;
- Eliminate disparities in access to care and health outcomes;
- Promote physical activity opportunities;
- Promote opportunities to access healthy foods and good nutrition;
- Connect to lifestyle change resources;
- Use standardized treatment approaches;
- Promote team-based care;
- Empower and equip patients; and
- Recognize and reward clinicians.

Everyone can improve hypertension control by taking action in our communities and in our healthcare system. As community partners, we all can take deliberate steps to address the social determinants of health necessary to help people in our communities better manage and improve their blood pressure and overall health.

hhs.gov

Timeline of hypertension

Study	Year	Primary question/issues	Conclusion of the study/impact
VA-1st	1967	Is severe hypertension (dias) 115–129 treatable	Yes, less stroke/CHF
VA-2nd	1970	Same question for moderate BP (90–115)	Treated group less stroke/CHF
HDFP	1979	Goal-oriented BP therapy better than usual therapy?	Yes. Targeting BP goal of dias 90 reduced CVA by 36% more
MRFIT	1982	Lowering BP and lipid and stopping smoking may reduce CHD mortality	No difference in CHD mortality 17.9 vs. 19.3% (per 1000)
MRC	1985	Hypertension treatment in younger patients (35–64) is beneficial also?	Yes. Total CV events 286 in treated group vs. 352 in control ($p<0.05$)
EWHPE	1986	Hypertension treatment in exclusively older people (60) beneficial?	Yes. Mortality reduction 26% decrease in CV mortality 43%
SHEP	1991	Is treatment of systolic hypertension beneficial	Treating isolated systolic hypertension over 160 prevented stroke (ARR 3%), MI, and all CVD
TOMHS	1993	Outcome of 5 different classes BP meds vs. placebo	BP lowering similar among all classes CV events and death reduced (ARR 2.2%)
DASH	1997	Does Mediterranean diet with or without salt restriction lowers BP?	Compared to western diet it lowers bp and salt restriction adds to the effect
MRC	1997	Salt reduction in older people Lowers BP?	Reducing salt intake to 2 g Na lowered BP 7.2/3.2 mmHg
HOT	1998	Lowering Dias BP to 85 or 80 beneficial compared to standard 90 goal	No significant benefit in whole study but small benefit in diabetic
UKPDS	1998	Multiple studies 2 involved BP Tight BP control and agents (captopril vs. atenolol)	Group target <150/85 had 32, 44, and 34% less death, stroke, and retinopathy, respectively. No difference in ACEI group vs. BB
AASK	2002	To reduce progression of CKD BP goal mean 92 better than 105 ACEI, BB, or CCB better as drug?	No difference in mean BP goal of 92 vs. 105. ACEI use protected progression of CKD better than CCB
ALLHAT	2002	Compared to old thiazide (CTDN) new class of BP drugs CCB, ACEI, or AB has better outcome? AB gr closed for high incidence of CHF	No difference in MI, mortality, or CKD progression among 3 classes. CTDN vs. CCB for CHF RR 1.38. CTDN vs. ACEI for stroke and CHF RR 1.15 and 1.19
ANBP2	2003	ACEI vs. thiazide (HCTZ) for CV outcomes in Australian	In this study unlike ALLHAT, ACE was better all CV events RR was 0.88
ASCOT	2005	CCB and ACE inhibitor compared to BB and thiazide for BP control	CCB and ace inhibitor combination group showed better CV outcomes
CAFÉ	2006	Why Betablocker for BP does not prevent stroke	Betablocker lowers peripheral BP but not central (aortic) BP
HYVET	2008	Should we treat elderly (>80) hypertensive (sys > 160)	Yes. Treated group had 30% less stroke & 64% less CHF, 21% less death
AC-SH	2008	Combination of ACEI + CCB better than ACEI + thiazide (HCTZ)	ACEI + CCB group had 2.2% ARR of composite CV events and death
ACCRD	2010	In diabetics Goal BP sys < 120 better than 140?	No significant difference in mortality, total CV events, or renal protection
SPRINT	2015	Same as ACCORD but in non-diabetic	27% improved all-cause mortality and 25% improvement in primary CV outcomes

Source: U.S. National Library of Medicine

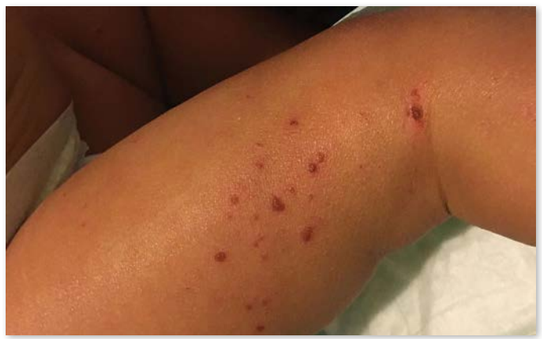
NIH-Supported Scientists Demonstrate How Genetic Variations Cause Eczema

Finding could lead to genetic tests that identify infants at risk for the disease.

New research supported by the National Institutes of Health delineates how two relatively common variations in a gene called KIF3A are responsible for an impaired skin barrier that allows increased water loss from the skin, promoting the development of atopic dermatitis, commonly known as eczema. This finding could lead to genetic tests that empower parents and physicians to take steps to potentially protect vulnerable infants from developing atopic dermatitis and additional allergic diseases.

Atopic dermatitis is an inflammatory skin condition that affects up to 20% of children in developed countries. This chronic disease is characterized by dry, thickened and intensely itchy skin, particularly in skin folds. People with eczema are more susceptible to bacterial, viral and fungal skin infections and frequently develop additional allergic diseases such as asthma.

KIF3A is a gene that codes for a protein involved in generating signals from the outside to the inside of a cell, part of a complex sensory apparatus. Previously, scientists had identified an association between two genetic variations in KIF3A and asthma in children who also had eczema. In the new study, the researchers found that these variations, or single nucleotide polymorphisms (SNPs), changed parts of the KIF3A gene to a form that can regulate, through a process called methylation, the rate at which a gene is transcribed into the blueprint for protein production. The investigators confirmed that skin and nasal-lining cells from people with the KIF3A SNP variants had more methylation and contained fewer blueprints for the KIF3A protein than cells in which KIF3A lacked the SNPs. In addition, the researchers demonstrated that people with the SNP-created regulating sites had higher levels of water loss from the skin.



Limb of a young child who is experiencing the dry, itchy skin associated with eczema, also called atopic dermatitis. Photo courtesy of the NIAID

To determine whether lower levels of KIF3A caused atopic dermatitis, the scientists studied mice lacking the mouse version of KIF3A in skin cells. They found that these mice also had increased water loss from the skin due to a dysfunctional skin barrier and were more likely to develop features of atopic dermatitis. The investigators concluded that the presence of either or both of the two SNPs in human KIF3A leads to lower production of the KIF3A protein, promoting dysfunction of the barrier that normally keeps skin well hydrated, thereby increasing the likelihood that a person will develop atopic dermatitis.

Now that investigators have established that these KIF3A SNPs increase the risk for atopic dermatitis, infants could potentially be screened for them. Therapies directed specifically at water loss from the skin, such as intensive topical moisturization regimens, could be evaluated for their ability to prevent atopic dermatitis in children with the SNPs. Preventing atopic dermatitis in early childhood could in turn prevent a cascade of additional allergic diseases later in life, such as asthma, food allergy and allergic rhinitis — a cascade known as the atopic march.

This research was co-funded by the National Institute of Allergy and Infectious Diseases and the National Center for Advancing Translational Sciences, both part of NIH. The study was led by Gurjit K. Khurana Hershey, MD, PhD, professor of pediatrics and director of the Division of Asthma Research at Cincinnati Children's Hospital Medical Center, which is part of the NIAID-supported Asthma and Allergic Diseases Cooperative Research Centers.

References:

ML Stevens et al. Disease-associated KIF3A variants alter gene methylation and expression impacting skin barrier and atopic dermatitis risk. Nature Communications DOI: 10.1038/s41467-020-17895-x (2020).

Lisa Wheatley, MD, MPH, Chief of the Food Allergy, Atopic Dermatitis, and Allergic Mechanisms Section in the NIAID Division of Allergy, Immunology and Transplantation.

nih.gov

Probiotic Skin Therapy Improves Eczema in Children, NIH Study Suggests

An experimental treatment for eczema that aims to modify the skin microbiome safely reduced disease severity and increased quality of life for children as young as 3 years of age, a National Institutes of Health study has found. These improvements persisted for up to eight months after treatment stopped, researchers report Sept. 9 in Science Translational Medicine.

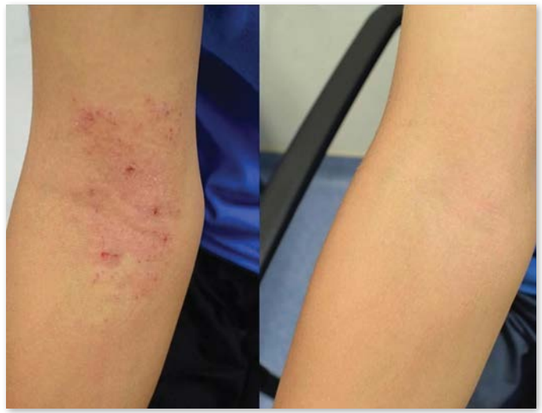
Atopic dermatitis, commonly called eczema, is a chronic inflammatory skin disease characterized by dry, itchy skin and rashes. The disease is most common in children and is linked to an increased risk of developing asthma, hay fever and food allergy. While available treatments can help manage eczema symptoms, current options can be costly, and many require multiple daily applications.

The experimental therapy contains strains of live Roseomonas mucosa — a bacterium naturally present on the skin — originally isolated from healthy volunteers and grown under carefully controlled laboratory conditions. For four months, clinical trial participants or their caregivers periodically applied this probiotic therapy to areas of skin affected by eczema.

"A child suffering from eczema, which can be itchy, painful and distracting for the child, also is very difficult for the entire family," said Anthony S. Fauci, MD, director of NIH's National Institute of Allergy and Infectious Diseases (NIAID), which led the study. "These early-stage findings suggest that R. mucosa therapy may help relieve some children of both the burden of eczema symptoms and the need for daily treatment."

Numerous genetic and environmental factors contribute to eczema, and scientists are learning more about the role that the skin's microbiome plays in this condition. In 2016, NIAID researchers reported that R. mucosa strains isolated from healthy human skin improved outcomes in cell culture and mouse models of eczema.

To build on these preclinical findings, NIAID launched a Phase 1/2 clinical trial at the NIH Clinical Center in Bethesda, Maryland, to assess the safety and potential benefit of R. mucosa therapy in people with eczema. Interim results reported in 2018 for 10 adults and five children aged 9 to 14 years indicated that the treatment was safe and associated with reduced eczema severity. Since then, the trial has enrolled an additional 15 children, for a total of 20 children with mild to severe eczema ranging in age from 3 to 16 years.



Inner elbow of a child with eczema before Roseomonas mucosa therapy (left) and after four months of treatment (right). Photo courtesy of the NIAID

Twice weekly for three months and every other day for an additional month, children or their caregivers sprayed a solution of sugar water containing live R. mucosa onto areas of skin with eczema. For the first 15 children enrolled in the study, the dose of live R. mucosa was gradually increased each month. The last five children to enroll received the same dose throughout the four-month treatment period. Regardless of dosing strategy, no serious adverse events were attributed to the therapy.

"Most children in the study experienced substantial improvements in their skin and overall wellbeing following R. mucosa therapy. Encouragingly, the therapeutic bacteria stayed on the skin and continued to provide benefit after therapy stopped," said NIAID's Ian Myles, MD, principal investigator of the trial. "These results support a larger study to further assess the safety and effectiveness of this experimental treatment by comparing it with a placebo."

For more information, see ClinicalTrials.gov using identifier NCT03018275.

nih.gov

Study Links Metabolic Syndrome to Higher Cardiovascular Risk in Patients with Psoriasis

Psoriasis has long been known to increase the risk of cardiovascular disease, which includes heart attack and stroke. Now, researchers have identified a key culprit: the presence of metabolic syndrome (MetSyn), a condition that includes obesity, diabetes, high cholesterol, and hypertension, and is highly prevalent among psoriasis patients.

The findings, which could lead to new ways to help prevent cardiovascular disease among people with psoriasis, appear online today in the Journal of the American Association of Dermatology (JAAD). The study was funded by the National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health.

"Metabolic syndrome, so common among our psoriasis patients, drives up coronary artery disease in this population by increasing the plaque buildup that clogs the heart's arteries," said Nehal N. Mehta, MD, MSCE, preventive cardiologist and head of the NHLBI's Lab of Inflammation and Cardiometabolic Diseases. "Our study shows that, of the MetSyn components, hypertension and obesity contribute the most to coronary plaque buildup, and hence can be good targets for intervention."

Partly because it worsens vascular and systemic inflammation, psoriasis, a common skin disease affecting 2-3% of adults, not only increases but speeds up atherosclerosis, the plaque buildup that clogs arteries and can lead to heart attack and stroke. Metabolic syndrome affects about 25% of adults and is on the rise, and its prevalence is even greater among patients with psoriasis.

To reach their conclusions, Mehta and his team conducted an observational study of the NIH Psoriasis, Atherosclerosis, and Cardiometabolic Initiative cohort, which included 260 patients with psoriasis, 80 of whom met the criteria for metabolic syndrome. All participants underwent CT scanning to take pictures of their coronary arteries using a technique called cardiac computed tomography angiography (CTA).

The study found that systemic inflammation, insulin resistance, and blood cholesterol were significantly higher in the participants who had both psoriasis and metabolic syndrome. And those with MetSyn had higher coronary artery plaque buildup, assessed by CTA, which is a high-risk factor for heart attacks.

"Even after adjusting for individual MetSyn factors, blood pressure and obesity assessed by waist circumference were the most significant links to coronary plaque buildup," Mehta explained.

Obesity is the most salient aspect of MetSyn, and excess visceral fat tissue, technically known as visceral adipose tissue (VAT), plays a large role in it, the researchers concluded after the amount of VAT measured by CT scans was associated to MetSyn factors such as waist circumference, blood pressure, triglycerides, high cholesterol.

VAT is a known predictor of cardiovascular disease in the general population, as well as a predictor of increased plaque buildup in psoriasis patients. However, due to the needed imaging technology, measuring VAT is not currently feasible in a doctor's office.

This new study, Mehta said, demonstrates a critical link between excessive VAT and metabolic syndrome in psoriasis patients. It suggests that identifying metabolic syndrome, especially waist circumference, can significantly help in estimating VAT and assessing cardiovascular disease risk in clinical settings for patients with psoriasis.

Nehal N. Mehta, MD, MSCE, FAHA, Senior Investigator, Section of Inflammation and Cardiometabolic Diseases at NHLBI.

It also showed for the first time, he said, the impact of metabolic syndrome on early vascular disease in psoriasis patients, measured through the plaque buildup.

"In psoriasis patients, traditional risk factors of cardiovascular disease, such as age, do not relate strongly to cardiovascular risk as in the general population," Mehta said. However, he added, the findings in the study show the importance of evaluating for the presence of the metabolic syndrome as a heretofore unexplored risk factor.

Because this was an observational study, the researchers cannot establish cause-effect links, Mehta noted. But the new research provides strong evidence that psoriasis patients with metabolic syndrome have high levels of disease-producing plaque.

nih.gov

HHS Awards $79 Million to Support Health Center Response to Emergencies

The U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), awarded over $79 million in construction and other capital support for 165 HRSA-funded health centers impacted by recent hurricanes, typhoons, wildfires, earthquakes, and floods.

"HRSA-funded health centers play a vital role on the front lines in their communities every day, and even more so during a crisis," said HHS Secretary Alex Azar. "This funding is the latest in the Administration's efforts to support Americans affected by the past several years of hurricanes, wildfires, typhoons, and earthquakes, and builds on other HHS investments to strengthen health centers' readiness to serve their communities after disasters."

HRSA's Capital Assistance for Disaster Response and Recovery Efforts (CADRE) funding will help ensure access to health care services for communities impacted by disasters and increase health center capacity to respond to and recover from future emergencies. CADRE funding was made available by the Additional Supplemental Appropriations for Disaster Relief Act in 2019.

"HRSA funded health centers are uniquely positioned to deliver needed services during an emergency," said HRSA Administrator Tom Engels. "This funding will ensure affected health centers have the resources they need to maintain operations during a crisis, while continuing to provide quality care to our nation's most vulnerable populations."

For 55 years, HRSA-funded health centers have delivered affordable, accessible, quality, and value-based primary health care to millions of people regardless of their ability to pay. HRSA funds nearly 1,400 health centers operating almost 13,000 sites, providing care to nearly 30 million people across the nation, in every state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin.

hhs.gov

Ready Reserve Corps Re-Established as Part of the United States Public Health Service

The Administration recognized and thanked the U.S. Public Health Service (USPHS) Commissioned Corps at its Headquarters, as the USPHS continues to deploy more than two-thirds of its force to support the fight against the COVID-19 public health emergency. Commissioned Corps leadership discussed the future of USPHS with the establishment of a trained and deployable Ready Reserve Corps to provide surge capacity to deploy clinical care and health professionals for both domestic and global response efforts.

"Creating a Ready Reserve for the U.S. Public Health Service Commissioned Corps will improve our capability to respond to the ongoing COVID-19 crisis and future public health emergencies," said HHS Secretary Alex Azar. "One of HHS's paramount responsibilities is to protect Americans from public health threats like infectious diseases, Congress and the Administration have come together to give us a new capability for accomplishing that mission with the Ready Reserve. The men and women of the Commissioned Corps have effectively protected Americans' health for more than a century, and having a reserve element will prepare them for another century of lifesaving service."

During the Coronavirus Aid, Relief, and Economic Security (CARES) Act provides the authority to re-establish the Ready Reserve Corps. Like other uniformed services, the Ready Reserve Corps will provide trained and ready personnel available on short notice to fill critical public health needs. "Through the COVID-19 pandemic we have been reminded having a Reserve Corps is critical to our emergency response capabilities and will augment our capacity to strategically address public health needs across the nation," said the head of the service ADM Brett P. Giroir, MD, assistant secretary for health. "The Ready Reserve will also provide opportunities for public health professionals who can commit to part-time active duty positions to serve their country."

USPHS Commissioned Corps' deployments have increased more than 44% over the past six years in support of critical national health security missions such as COVID-19 and the Ebola response. More than 4,500 of the 6,100 Public Health Service officers have deployed during the COVID-19 pandemic in support of our worldwide efforts, including deploying to the Diamond Princess cruise ship in Japan and repatriating Americans to our military bases.

Commissioned Corps officers have assisted community-based testing sites with testing and providing infection control and clinical care to long-term care facilities, hospitals, and field hospitals in hard-hit communities across 28 states, four territories, and numerous Tribes.

"The USPHS Commissioned Corps are America's Health Responders, and they've been on the front lines of our whole-of-America response to the COVID-19 pandemic since day one," said Surgeon General VADM Jerome M. Adams, MD, MPH. "USPHS' unique and historic service will be augmented by a long-needed Ready Reserve Corps and this activation will ensure a robust response to the public health needs of the future."

The CARES Act gave the U.S. Department of Health and Human Service statutory authority to re-establish the reserve component and provide compensation and benefits. The USPHS Commissioned Corps

will commission its first officers into the Ready Reserve Corps beginning in Spring 2021. Trained and ready personnel will fill critical public health needs and will:

- Support the USPHS Commissioned Corps' capacity to respond to regional, national, and global health emergencies and improve access to health services;
- Preserve clinical care positions by maintaining a surge capacity of health professionals available for deployment without jeopardizing the service of clinicians in hard to fill roles;
- Offer an opportunity to serve for mission-driven clinical and public health professionals who cannot commit to a full-time active duty position in the USPHS Commissioned Corps; and
- Enable access to highly specialized skill sets that would be impractical in full-time active duty positions.

The USPHS Commissioned Corps will accept Ready Reserve Corps applications online beginning in Fall 2020. The Corps is looking for service-driven individuals who desire to work in public health programs and clinical settings. For more information, visit www.USPHS.gov

About the U.S. Public Health Service Commissioned Corps

The U.S. Public Health Service Commissioned Corps is a team of more than 6,100 full-time health professional officers from 11 professional categories dedicated to promoting and advancing public health and disease prevention programs. As one of America's eight uniformed services, the USPHS Commissioned Corps fills essential public health leadership, clinical and service roles within Federal agencies and programs, including the Indian Health Service, U.S. Food and Drug Administration, National Institutes of Health, the Centers for Disease Control and Prevention, Bureau of Prisons, Department of Defense and Department of Homeland Security. The USPHS Commissioned Corps is part of the U.S. Department of Health and Human Services and is overseen by the Assistant Secretary for Health and U.S. Surgeon General.

hhs.gov

Commissioned Corps of the U.S. Public Health Service History

For more than 200 years, men and women have served on the front lines of our nation's public health. Originally created to protect the health of sailors and immigrants in the late 1700s, the USPHS Commissioned Corps' role in healthcare delivery, research, regulation, and disaster relief became critical over time. Thanks to our legacy of service across multiple agencies and around the globe, we are now the largest public health program in the world.

1798 — President John Adams signs into law the Act for the Relief of Sick and Disabled Seamen, which triggers the creation of marine hospitals along major American waterways.

1801 — The network expands as more marine hospitals are established in major port cities from Boston to New Orleans.

1870 — The Marine Hospital Service centralizes hospital administration under the leadership of the supervising surgeon, known today as the Surgeon General.

1871 — The first "Surgeon General", John Maynard Woodworth, adopts a military model for his medical staff, assigning a cadre of mobile, uniformed physicians to various marine hospitals.

1878 — The Marine Hospital Service plays a pivotal role in thwarting the spread of global epidemic diseases like smallpox and yellow fever in the United States.

1889 — Congress establishes the U.S. Public Health Service Commissioned Corps with the Marine Hospital Service, organizing officers along military lines with titles and pay corresponding to Army and Navy grades.

1902 — Congress broadens the reach of the USPHS Commissioned Corps. In addition to their disease prevention duties, officers are now authorized to research human diseases, sanitation, water supplies, and sewage disposal.

1944 — The U.S. Public Health Service Act of 1944 broadens the USPHS Commissioned Corps' scope and paves the way for nurses, scientists, dieticians, physical therapists and sanitarians to join. By 1945, the USPHS Commissioned Corps quadruples its numbers from 625 to nearly 3,000.

1964 — Surgeon General Dr. Luther Terry releases a landmark report on smoking-related lung cancer and bronchitis, the first report detailing the connection between tobacco and chronic disease.

1986 — Surgeon General Dr. C. Everett Koop writes "Understanding AIDS," a USPHS Commissioned Corps brochure that is sent to all 107 million households in the U.S., the largest public health mailing ever at the time.

2005 — More than 2,400 officers provide disaster relief to the Gulf Region amidst Hurricanes Katrina, Rita, and Wilma.

2008 — The Department of Defense and the Department of Health and Human Services establishes the DoD-USPHS Commissioned Corps for Psychological Health, enabling USPHS Commissioned Corps officers to provide behavioral health services to military members and their families.

usphs.gov

Emergency Triage, Treatment and Transport Model Announcement

By Alex M. Azar II, Healthcare and Emergency Medicine Stakeholders

Remarks from Washington, D.C. speech on February 15, 2019

Thank you, Chief Dean, for welcoming us here today, and thank you everyone for coming to join us at what has to be the most interesting place we've ever rolled out a CMS payment model.

I'd like to begin by thanking Administrator Verma for the key role she's played in the thinking we've done across HHS about the transformation of our health system into one that pays for value.

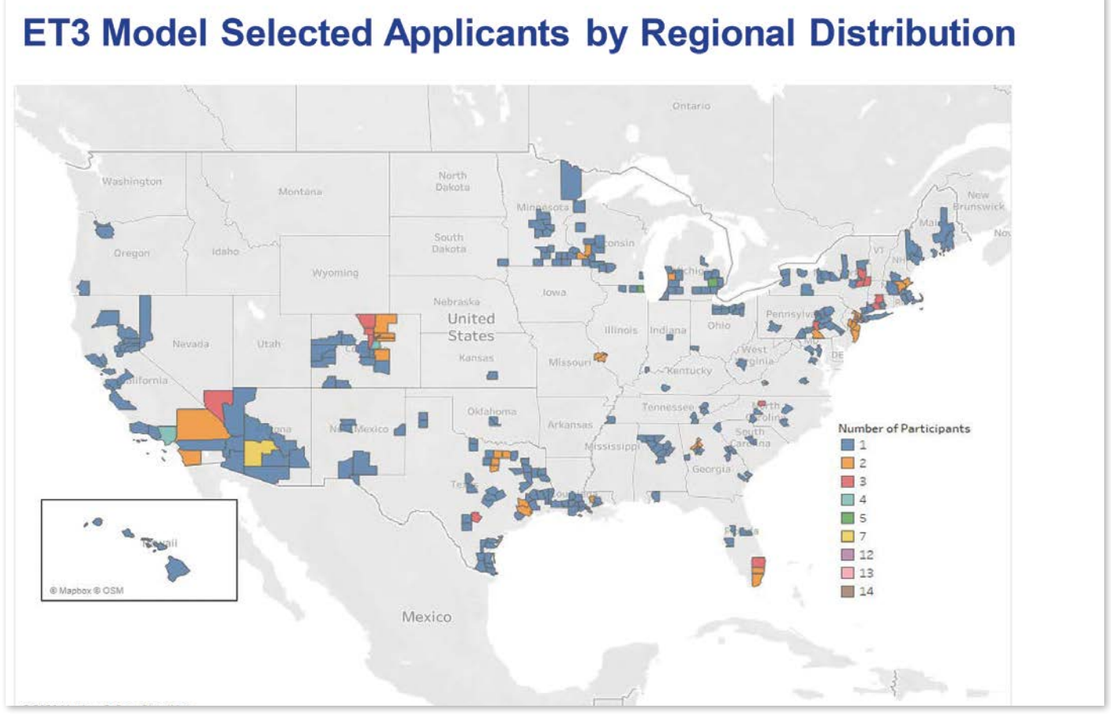
I'm also grateful to Adam Boehler, my senior advisor for value-based transformation, for the work he's done to turn our leadership vision into reality, including with today's announcement.

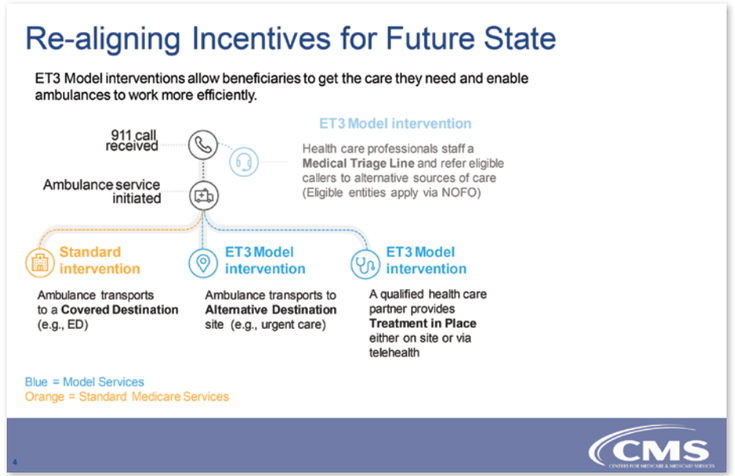
Today is an exciting day to celebrate one piece of our vision that will now become reality: rethinking how our system provides emergency care and transport.

It's appropriate that this is one of the first major value-based models we've rolled out, because getting an emergency medical service is one of the most stressful experiences any of us could have in healthcare.

We've identified a part of that system that is in obvious need of improvement.

Medicare only pays first responders if they bring you to the hospital or a few other alternative sites — which you may not need, which may be really expensive, and which may not be the best place for you to get care.





There is an important, basic healthcare lesson here: You get what you pay for. When you essentially only pay for people to get taken to the hospital, people get taken to the hospital!

That's why Adam's team at the Center for Medicare and Medicaid Innovation has created the Emergency Triage, Treat and Transport payment model, or ET3.

ET3 will create a new set of incentives for emergency transport and care, ensuring patients get convenient, appropriate treatment in whatever setting makes sense for them.

ET3 is an exciting opportunity for our country's great first responders to expand the care they provide. We're grateful for the work they do today, and we appreciate how excited they are about this model. Together, this effort is going to save lives and improve the quality of care. But I also want everyone to look at the bigger picture, beyond emergency services. ET3 is a signal to everyone involved in American healthcare that we want to rethink how and where patients are treated.

A value-based healthcare system will deliver each patient the right care, at the right price, in the right setting, from the right provider. In many cases, that may look a lot different from what a patient typically receives today.

ET3 shows that we can radically rethink the incentives around care delivery even in one of the trickiest parts of our system. So I want everyone to stay tuned, and work with us, regarding other areas where we can reimagine care delivery to lower costs and save lives.

hhs.gov

Secretary Alex Azar Statement on National EMS Week

May 17–23, 2020, marks the 46th annual celebration of National EMS Week, recognizing Emergency Medical Services personnel, such as emergency medical technicians and paramedics.

"In life-threatening emergencies, we all depend on the bravery, skill, and professionalism that define America's Emergency Medical Services. Since the beginning of the COVID-19 pandemic, we have been especially grateful for EMS personnel, who define what it means to be on the frontlines of our response.

Emergency medical technicians and paramedics have stepped up to the challenge, serving Americans in need and often putting their own lives at risk to help preserve the health of others. These courageous men and women are trained to provide vital medical services in a broad range of settings, and they do so every day in our neighborhoods, our homes, and our streets, from dense cities to small rural towns.

"HHS has recognized the high-value care provided by EMS and other medical first responders through the introduction of the Emergency Triage, Treat, and Transport (ET3) payment model, which will pay participating first responders for a broader range of emergency services, in settings that make sense for the patient. Throughout the COVID-19 pandemic, continue to provide these frontline heroes with the flexibility, equipment, and support they need to do their lifesaving work."

hhs.gov

NIH Funds First Nationwide Network to Study Rare Forms of Diabetes

A nationwide study funded by the National Institutes of Health will seek to discover the cause of several unusual forms of diabetes. For years, doctors and researchers have been stymied by cases of diabetes that differ from known types. Through research efforts at 20 U.S. research institutions, the study aims to discover new forms of diabetes, understand what makes them different, and identify their causes.

The Rare and Atypical Diabetes Network, or RADIANT, plans to screen about 2,000 people with unknown or atypical forms of diabetes that do not fit the common features of type 1 and type 2 diabetes.

A person with atypical diabetes may be diagnosed and treated for type 1 or type 2 diabetes, but not have a history or signs consistent with their diagnosis. For example, they may be diagnosed and treated for type 2 diabetes but may not have any of the typical risk factors for this diagnosis, such as being overweight, having a family history of diabetes, or being diagnosed as an adult. Alternately, a person with atypical diabetes may respond differently than expected to the standard diabetes treatments.

"It's extremely frustrating for people with atypical diabetes when their diabetes seems so different and difficult to manage," said the study's project scientist, Dr. Christine Lee of NIH's National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). "Through RADIANT, we want to help patients and the broader healthcare community by finding and studying new types of diabetes to shed light on how and why diabetes can vary so greatly."

RADIANT researchers will build a comprehensive resource of genetic, clinical, and descriptive data on previously unidentified forms of diabetes for the scientific and healthcare communities.

The study's researchers will collect detailed health information using questionnaires, physical exams, genetic sequencing, blood samples, and other tests. People found to have unknown forms of diabetes may receive additional testing. Some participant family members may also be invited to take part in the study.

"With help from participants and their families, we aim to develop a comprehensive description of the genetic and clinical characteristics of these rare forms of diabetes," said study chair,

Photo courtesy of NIH

Dr. Jeffrey Krischer, director of the Health Informatics Institute at the University of South Florida (USF), Tampa. "This information could help to establish new diagnostic criteria for diabetes, find new markers for screening, or identify drug targets for new therapies that could ultimately bring precision medicine to diabetes."

USF is the study's coordinating center, and the lead centers include Baylor College of Medicine in Houston and the University of Chicago. The Broad Institute in Cambridge, Massachusetts, and Baylor serve as the genomic sequencing centers for the project. University of Florida, Gainesville, provides the study's laboratory services.

"The RADIANT study will further clarify diabetes as a disease that has many different forms, and for which diagnosis and management for some of those forms remain a challenge," said NIDDK Director Dr. Griffin P. Rodgers. "The discoveries of the study should provide critical understanding of the spectrum of diabetes and improve lives of people with rare forms of diabetes and everyone who cares for them."

The study opened recruitment on September 30, 2020 for people with atypical diabetes or a form of diabetes that seems different from known types of diabetes. Visit www.atypicaldiabetesnetwork.org for more information on the study and how to join.

nih.gov

Artificial Pancreas Effectively Controls Type 1 Diabetes in Children Age 6 and Up

A clinical trial at four pediatric diabetes centers in the United States has found that a new artificial pancreas system — which automatically monitors and regulates blood glucose levels — is safe and effective at managing blood glucose levels in children as young as age six with type 1 diabetes. The trial was funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of the National Institutes of Health. Results from the trial were published August 26 in the New England Journal of Medicine.

"Fewer than 1 in 5 children with type 1 diabetes are able to successfully keep their blood glucose in a healthy range with current treatment, which may have serious consequences on their long-term health and quality of life," said Guillermo Arreaza-Rubín, MD, director of NIDDK's Diabetes Technology Program and project scientist for the study. "Earlier research showed that the system tested in this study was safe and effective for people ages 14 and older. This trial now shows us this system works in a real-world setting with younger children."

The artificial pancreas, also known as closed-loop control, is an "all-in-one" diabetes management system that tracks blood glucose levels using a continuous glucose monitor (CGM) and automatically delivers the insulin when needed using an insulin pump. The system replaces reliance on testing by fingerstick or CGM with delivery of insulin by multiple daily injections or a pump controlled by the patient or caregiver.

The study enrolled 101 children between ages 6 and 13 and assigned them to either the experimental group, which used the new artificial pancreas system or to the control group which used a standard CGM and separate insulin pump. Check-ins and data collection were conducted every other week for four months.

Study participants were instructed to continue about their daily lives so that the researchers could best understand how the system works in the typical routines of the children.

The study found that youth using the artificial pancreas system had 7% improvement in keeping blood glucose in range during the daytime, and a 26% improvement in nighttime control compared to the control group. Nighttime control is of particular importance for people with type 1 diabetes, as severe, unchecked hypoglycemia can lead to seizure, coma or even death. The overall time-in-range goal for the artificial pancreas reflected a nearly 11% improvement, which translated to 2.6 more hours per day in range.

A study participant reviews his information on his artificial pancreas device. Photo courtesy of the University of Colorado

"The improvement in blood glucose control in this study was impressive, especially during the overnight hours, letting parents and caregivers sleep better at night knowing their kids are safer," said protocol chair R. Paul Wadwa, MD, professor of pediatrics at the Barbara Davis Center for Childhood Diabetes at the University of Colorado, Aurora (CU). "Artificial pancreas technology can mean fewer times children and their families have to stop everything to take care of their diabetes. Instead, kids can focus on being kids."

Sixteen adverse events, all classified as minor, occurred in the artificial pancreas group during the study, with most due to problems with the insulin pump equipment. Three events occurred in the control group. No cases of severe hypoglycemia or diabetic ketoacidosis occurred during the study.

"For decades, NIDDK has funded research and technology development to create a user-friendly automated device that could ease the constant burden of type 1 diabetes, from the finger sticks and insulin injections, to the insulin dose calculations and constant monitoring while improving diabetes control outcomes and preventing both short- and long-term complications of the disease," said Arreaza-Rubín. "The artificial pancreas is a culmination of these years of effort, and it's exciting to see how this technology may benefit children with type 1 diabetes and their families, and hopefully benefit everyone with diabetes in the future."

The artificial pancreas technology used in this study, the Control-IQ system, has an insulin pump that is programmed with advanced control algorithms based on a mathematical model using the person's glucose monitoring information to automatically adjust the insulin dose. This technology was derived from a system originally developed at the University of Virginia (UVA), Charlottesville, with funding support from NIDDK.

This four-month study was part of a series of trials conducted in the International Diabetes Closed-Loop (iDCL) Study. In addition to CU and UVA, study sites included Stanford University School of Medicine, Palo Alto, California; and Yale University School of Medicine, New Haven, Connecticut. Jaeb Center for Health Research served as the data coordinating center.

Based on data from the iDCL trials, Tandem Diabetes Care has received clearance from the U.S. Food and Drug Administration for use of the Control-IQ system in children as young as age 6 years.

"As we continue to search for a cure for type 1 diabetes, making artificial pancreas technology that is safe and effective, such as the technology used in this study, available to children with type 1 diabetes is a major step in improving the quality of life and disease management in these youth," said NIDDK Director Dr. Griffin P. Rodgers.

nih.gov

CPG

Until recently, the common type of diabetes in children and teens was type 1, called juvenile diabetes. Now younger people are also getting type 2 diabetes, becoming more common in children and teens. Children have a higher risk of type 2 diabetes if they are overweight or have obesity, have a family history of diabetes, or are not active. Children who are African American, Hispanic, Native American/Alaska Native, Asian American, or Pacific Islander also have a higher risk. To lower the risk of type 2 diabetes in children it is recommended to encourage:

- Maintaining a healthy weight
- Being physically active
- Eating smaller portions of healthy foods
- Limiting time with the TV, computer, and video

While the vast majority of American Indian and Alaska Native (AI/AN) patients with diabetes have type 2, type 1 diabetes and its variants do occur in AI/AN patients, particularly those of mixed heritage. Type 1 diabetes must be considered in patients of any age or weight who present with a new onset of diabetes and an unclear clinical picture. This is especially true in children, even if they are overweight.

Although no test can distinguish definitively between type 1 and type 2 diabetes, several laboratory studies may be helpful when the diagnosis is not clinically clear. Providers should consider obtaining consultation if they are unfamiliar with the use of these tests or how to make a diagnosis in a complex patient.

First-ever Research Network Tackles Diabetic Foot Complications

Funded by the National Institutes of Health, six U.S. research institutions are launching the first-ever multicenter network to study diabetic foot ulcers, a common and burdensome complication of diabetes and the leading cause of lower limb amputations in the United States.

The Diabetic Foot Consortium (DFC) aims to lay the foundation for a clinical trial network to test how to improve diabetic wound healing and prevent amputations among the 27 million American adults with diabetes. The DFC is supported by the NIH's National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

"People with diabetic foot ulcers have to manage careful at-home foot care over a long time to avoid infection until the wound heals," said Dr. Teresa Jones, NIDDK's project scientist for the consortium. "This consortium will address a major research gap in finding ways to effectively treat diabetic foot ulcers and to prevent the risk of complicated infections and potential amputation."

The first studies will focus on finding biological clues, called biomarkers, in people with diabetic foot ulcers that can guide treatment and predict how the ulcer will heal and the likelihood of an ulcer returning. For example, the first study of the DFC, led by the Indiana University School of Medicine, will test whether body fluid leaking through the skin on a newly healed ulcer can predict how likely an ulcer might return.

A second study, led by the University of Miami, will test whether the presence of or a change in specific cellular proteins in tissue samples from an ulcer can predict the likelihood of healing in the next 12 weeks.

Up to 34% of people with diabetes will develop a foot ulcer in their lifetime, and half of foot ulcers become infected. Each year, about 100,000 Americans with diabetes will lose part of their lower limb because a foot ulcer becomes infected or does not heal.

Each clinical research site in the DFC will recruit up to 70 participants per study who are undergoing foot ulcer treatment or follow-up care. Each biomarker will be tested in its own study within the larger network. Researchers will collect various measurements, biological samples, and other data over two years. In addition, the DFC will build a roadmap and framework that will provide an opportunity for researchers to follow up interesting leads or pursue new studies.

"Many complicating factors of diabetes interrupt the healing process, making diabetic foot ulcers extremely difficult to treat. Those factors also make studying effective treatments challenging," said DFC Study Chair Dr. Geoffrey Gurtner, professor of surgery at Stanford University. "This group of studies represents a remarkable opportunity to learn if these biomarkers can predict healing or recurrence in a large group of patients and if they can be tools to improve how foot ulcers are treated and healed."

Participating centers are University of Michigan at Ann Arbor; University of California, San Francisco; Stanford University, Palo Alto, California; University of Miami Miller School of Medicine; University of Pittsburgh; and Indiana University, Indianapolis. The University of Michigan also serves as the data coordinating center for the study. Biomarker analysis will be conducted by the Indiana University and the University of Miami.

"For people with diabetes, foot ulcers can be devastating and lead to even more devastating amputation. They affect quality of life and cost the United States up to $13 billion a year in care," said NIDDK Director Dr. Griffin P. Rodgers. "Finding biological clues from these ulcers to help tailor treatment to the individual will provide much-needed relief and could prevent future diabetic foot injuries."

For more information about the Diabetic Foot Consortium, please visit diabeticfootconsortium.org

The Diabetic Foot Consortium is funded through NIH grants DK119085, DK119083, DK119094, DK119099, DK119100, DK119102, and DK122927.

The NIDDK, a component of the NIH, conducts and supports research on diabetes and other endocrine and metabolic diseases; digestive diseases, nutrition and obesity; and kidney, urologic and hematologic diseases. Spanning the full spectrum of medicine and afflicting people of all ages and ethnic groups, these diseases encompass some of the most common, severe and disabling conditions affecting Americans. For more information about the NIDDK and its programs, see https://www.niddk.nih.gov

nih.gov

HHS Announces Nearly $1 Billion in CARES Act Grants to Support Older Adults and People with Disabilities in the Community During the COVID-19 Emergency

The Department of Health and Human Services (HHS) is announcing $955 million in grants from the Administration for Community Living (ACL) to help meet the needs of older adults and people with disabilities as communities implement measures to prevent the spread of COVID-19. The grants will fund home-delivered meals; care services in the home; respite care and other support to families and caregivers; information about and referral to supports; and more.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into on March 27, 2020. The CARES Act provides supplemental funding for programs authorized by the Older Americans Act of 1965 and the Rehabilitation Act of 1973, as amended by the Workforce Innovation and Opportunity Act of 2014.

Through these programs, a network of community-based organizations, such as Area Agencies on Aging, Centers for Independent Living, senior centers, faith-based organizations, and other non-profits provide a vast array of resources and services to help older adults and people with disabilities stay healthy and live independently in their communities across the United States.

The need for these services has increased as community measures to slow transmission of COVID-19 have closed locations where many people typically receive services and made it difficult for families to assist loved ones who live alone. In addition, the adaptations necessary to provide these services in the current environment have increased costs to service providers.

"This nearly $1 billion in new funds will help communities support older adults and people of all ages with disabilities in staying healthy, safe, and independent during the COVID-19 pandemic," said HHS Secretary Alex Azar. "The new funding is a historic boost to programs that support community living for all people, representing an increase of over 40 percent in this year's funding for ACL's programs. The aging and disability networks supported by these programs are delivering meals, ensuring safe transitions home following hospitalizations, and providing other essential services to older Americans and Americans with disabilities during this challenging time, and HHS will continue supporting these partners and the Americans they serve throughout this crisis."

The CARES Act funding includes:

- $200 million for Home and Community Based Services (HCBS), which will help greater numbers of older adults shelter in place to minimize their exposure to COVID-19. These include personal care assistance; help with household chores and grocery shopping; transportation to essential services (such as grocery stores, banks, or doctors) when necessary; and case management.
- $480 million for home-delivered meals for older adults. With this funding, states can also expand "drive-through" or "grab-and-go" meals for older adults who typically would participate in meal programs at community centers and other locations that have been closed due to social distancing measures.
- $85 million for Centers for Independent Living to provide direct and immediate support and services to individuals with disabilities who are experiencing disruptions to their independent, community-based living due to the COVID-19 pandemic. Services will ensure individuals with disabilities have the supports they need to safely stay in their homes or return home after a hospitalization or institutionalization during (and directly after) COVID-19.
- $20 million for nutrition and related services for Native American Programs to help tribes and tribal organizations provide meals and supportive services directly to Native American elders.
- $100 million for the National Family Caregiver Support Program to expand a range of services that help family and informal caregivers provide support for their loved ones at home. These include counseling, respite care, training, and connecting people to information.

- $20 million to support State Long-term Care Ombudsman programs in providing consumer advocacy services for residents of long-term care facilities across the country. Restrictions on visitation have significantly increased demand for ombudsman services, as families seek assistance in ensuring the well-being of their loved ones. Ombudsman programs will seek to expand their virtual presence to residents and their families, and continue to promote the health, safety welfare, and rights of residents in the context of COVID-19. This funding will give Ombudsman programs the flexibility to hire additional staff and purchase additional technology, associated hardware, and personal protective equipment once in-person visits resume.
- $50 million for Aging and Disability Resource Centers (ADRCs), which will fund programs that both connect people at greatest risk to COVID-19 to services needed to practice social distancing and seek to mitigate issues created by it, such as social isolation. ADRCs across the country are reporting unprecedented demand for assistance with applications for services, care coordination, services that support people in returning home following hospitalization, and the like.

"Area Agencies on Aging, Centers for Independent Living, and other community-based organizations are working hard to expand capacity to meet the needs of older adults and people with disabilities during this extraordinary time," said ACL Administrator Lance Robertson.

"These additional funds will allow for an incredible response at the state and local level to meet the needs of people who are facing some of the greatest risks during the COVID-19 emergency."

The majority of these additional funds ($905 million) are being awarded today to states, territories, and tribes for subsequent allocation to local service providers. Grant amounts are determined based on the formulas defined under the program authorizing statutes. The remaining $50 million will be awarded by the close of April.

Older adults who need assistance can contact the Eldercare Locator to find services available in their community. The Eldercare Locator can be reached at 1-800-677-1116 or https://eldercare.acl.gov

People with disabilities can locate their local Center for Independent Living at https://www.ilru.org/projects/cil-net/cil-center-and-association-directory

About the Administration for Community Living

The Administration for Community Living (ACL) was created around the fundamental principle that older adults and people of all ages with disabilities should be able to live where they choose, with the people they choose, and with the ability to participate fully in their communities.

By funding services and supports provided by networks of community-based organizations, and with investments in research, education, and innovation, ACL helps make this principle a reality for millions of Americans.

hhs.gov

HHS Seeks Public Input on Leveraging Novel Technologies for Chronic Disease Management for Aging Underserved Populations

RFI aims to identify technological advances like artificial intelligence with the greatest potential to improve health outcomes for aging Americans

In an effort to improve access to emerging technologies and healthcare services, the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Health (OASH), in partnership with federal agencies, has issued a Request for Information (RFI) to better inform the direction of Federal efforts. OASH and partners also seek to identify opportunities to strengthen the U.S. healthcare system through public-private partnerships for data sharing, comprehensive analytics, and other potential mechanisms.

"Identifying how technologies can be used at home and in communities will help our aging populations access care, monitor and maintain healthy activities, and enable as much independent living as possible, especially in underserved areas of our nation," said Assistant Secretary for Health Admiral Brett P. Giroir, MD.

This graphic is very low quality

Assistant Secretary for Health Admiral Brett P. Giroir, MD
Photo courtesy of Dietary Guidelines for Americans

The COVID-19 pandemic's further exacerbation of inequities in healthcare delivery introduces the opportunity to identify and develop new technological approaches to chronic disease management. Such advances have potential to improve health outcomes in the aging population, particularly for those in underserved areas (e.g., low income, Medicaid-eligible, rural, etc.) by empowering patients and facilitating integrated healthcare delivery.

OASH — in partnership with the Administration for Community Living; Agency for Healthcare Research and Quality; Federal Communications Commission; National Institutes of Health; U.S. Department of Agriculture; and the White House Office of Science and Technology Policy — invites feedback from a broad range of relevant stakeholders.

Feedback from health systems, community-based organizations, academic institutions, non-federal government agencies, innovators, entrepreneurs, and non-profit organizations will help OASH and partners develop a comprehensive landscape of how potential technologies (e.g. artificial intelligence, biosensors, apps, remote monitoring, etc.) can be leveraged to improve health for aging populations in underserved areas.

hhs.gov

Largest Study of Sepsis Cases among Medicare Beneficiaries Finds Significant Burden

U.S. hospitals saw a 40 percent increase in the rate of Medicare beneficiaries hospitalized with sepsis over the past seven years, and in just 2018 had an estimated cost to Medicare of more than $41.5 billion according to an unprecedented study by researchers from the U.S. Department of Health and Human Services.

Sepsis is a life-threatening condition caused by the body's extreme response to an infection. The research team analyzed data from all Medicare beneficiaries from 2012 through 2018. The study included more than 9.5 million inpatient hospital admissions, making this the largest sepsis study based on contemporary Medicare data to be published in the United States. Research team members included the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Medicare & Medicaid Services (CMS), and collaborators from Acumen LLC of Burlingame, California. The study appears in the journal Critical Care Medicine

HHS Assistant Secretary for Preparedness and Response Dr. Robert Kadlec

Photo courtesy of the Public Health and Medical Emergency Support for a Nation Prepared

Researchers determined that the increase in sepsis was not due to the growing number of American seniors enrolling in Medicare. From 2012 through 2018, the U.S. saw a 22 percent increase in the Medicare enrollment rates but a 40 percent increase in the rate of sepsis-related hospital admissions among beneficiaries.

"Sepsis is a lethal and costly health threat affecting Americans' lives and our economy, yet many Americans may have never heard of it," said HHS Assistant Secretary for Preparedness and Response Dr. Robert Kadlec. "Any infection can lead to sepsis, including infections caused by influenza or emerging diseases like coronaviruses, which makes sepsis a significant concern in public health emergencies."

"This groundbreaking study sheds new light on the sepsis-related challenges faced by patients, providers, and taxpayers alike," said CMS Administrator Seema Verma. "It demonstrates the urgent need for an approach to address a problem that is threatening the health and lives of Medicare beneficiaries. To that end, CMS continues to clear away regulatory obstacles and financial disincentives that have long inhibited the development of life-saving antibiotics capable of treating sepsis patients. Patients suffering from sepsis deserve to see America's full innovative potential mobilized to address this devastating condition."

Most patients with sepsis arrived at the hospital with the condition, rather than developing sepsis in the hospital, a possible indicator of success for CMS efforts to reduce hospital-based cases of sepsis. However, two-thirds of these sepsis patients had a medical encounter in the week prior to hospitalization. This finding represents an opportunity for improved education and awareness among patients and healthcare providers, as well as the need for diagnostics to detect sepsis early.

The analysis explored the impact of sepsis severity on health outcomes for Medicare beneficiaries. Despite declining mortality overall, 10 percent of patients with non-severe forms of sepsis died while in the hospital or within a week of discharge, and 60 percent with non-severe forms of sepsis died within three years.

Outcomes were worse among patients with the most severe form of sepsis known as septic shock. Forty percent of these patients died while in the hospital or within a week of being discharged, and 75 percent died within three years. The risk of sepsis was even greater for patients who had other chronic health conditions and the risk of death in the hospital and within three years was greater among these patients if they developed sepsis.

The study also identified the high costs of treating sepsis. Although the inpatient costs of care per stay among Medicare beneficiaries decreased between 2012 and 2018, the increase in the number of patients with sepsis led to an estimated overall increase in Medicare spending from $27.7 billion in 2012 to more than $41.5 billion in 2018 for inpatient hospital admissions and subsequent skilled nursing facility care.

The research team also projected future costs by modeling the increasing number of cases and estimates for all payer costs outside the Medicare population, and concluded that overall costs rose 12-14 percent every two years. Based on that estimate, inpatient hospital and skilled nursing care for sepsis care in 2019 may exceed $62 billion.

"We were astonished by the study's results," said Rick Bright, PhD, a study author, HHS deputy assistant secretary for preparedness and response (ASPR) and director of the Biomedical Advanced Research and Development Authority (BARDA) at ASPR. "To save lives in public health emergencies, we must solve sepsis. The findings of this study have implications not only for patient care, particularly after patients are discharged, but also for investments by industry, non-government organizations and government agencies. Solving sepsis requires working together. Because of the health security implications, we are taking a holistic approach to this national threat."

BARDA currently is partnering with industry and academia to develop and encourage adoption of new technologies to detect sepsis earlier as well as to predict and identify the severity of the infections. BARDA also is collaborating with other government agencies and non-government organizations on improved awareness, education, and training for healthcare providers.

CMS has implemented an inpatient bundled sepsis measure in its Inpatient Hospital Quality Reporting Program. This measure is a series of steps to detect and treat sepsis earlier in its course. CMS data have shown that since implementation, organizations that follow all the steps have significantly lower mortality rates for patients diagnosed with severe sepsis and septic shock. The agency is also tackling sepsis in post-acute care settings and is developing a measure for early detection and treatment of healthcare-associated infections, including sepsis in post-acute care settings.

To foster innovation in treating infections that lead to sepsis, CMS is removing barriers to developing new antimicrobial therapies to treat drug-resistant infections. In 2019, CMS finalized an expanded pathway for certain new antibiotics to more quickly receive additional Medicare payments and to increase payments for them. The agency also updated its payments to hospitals to provide them with appropriate resources to treat sick patients with drug-resistant infections. This step helps people who need these medications get access to them.

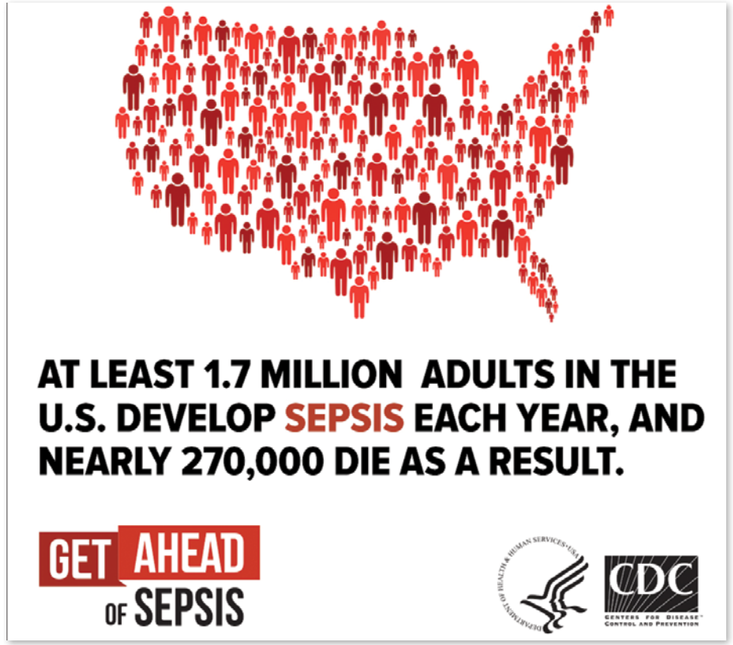


Photo courtesy of the CDC

In addition, to broaden the understanding of the epidemiology of sepsis, CDC continues to assess the adult sepsis burden and identify factors that put people at higher risk for sepsis and has begun a similar effort to assess sepsis burden in children.

CDC has also developed tools for tracking sepsis in individual hospitals to help healthcare facilities assess adult sepsis incidence within their facilities and measure their prevention progress. By working with partners, including the CDC Prevention Epicenters, CDC has invested in innovative ways to improve sepsis early detection and treatment. CDC's national educational campaign, Get Ahead of Sepsis for patients, healthcare professionals, and the general public emphasizes the importance of early recognition, timely treatment, reassessment of antibiotic needs, and prevention of infections.

The study analyzed claims made on behalf of traditional Medicare beneficiaries as well as from Medicare Advantage plans to explore the burden of sepsis in highly impacted populations including older Americans, those with end-stage renal disease, and those who depend on both Medicare and Medicaid.

The publication includes detailed methods that could enable similar analyses of data from patients covered by private insurance, Veterans Affairs, Department of Defense healthcare facilities, and state Medicaid programs that could lead to an even more accurate understanding of how sepsis affects Americans.

hhs.gov

HHS Awards $2.24 Billion in Grants to Help Americans Access HIV/AIDS Care, Support Services, and Medication

The U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), today announced approximately $2.24 billion in Ryan White HIV/AIDS Program grants were awarded to cities, counties, states, and local community-based organizations in fiscal year (FY) 2020. This funding supports a comprehensive system of HIV primary medical care, medication and essential support services vital to improving the health quality of more than half a million people with HIV in the United States.

This announcement builds on HRSA's Ryan White HIV/AIDS Program FY 2020 Coronavirus Aid, Relief and Economic Security (CARES) Act awards made in April and the Ending the HIV Epidemic: A Plan for America initiative awards made in February, reflecting a total FY 2020 investment of approximately $2.39 billion.

"HRSA's Ryan White HIV/AIDS Program plays a pivotal role in improving health outcomes for Americans with HIV and has helped lay the groundwork for our initiative to end the HIV epidemic by 2030," said HHS Secretary Alex Azar. "More than $2 billion in grants through the Ryan White HIV/AIDS Program in 2020 are helping to continue the program's incredible track record of viral suppression that saves lives, keeps communities healthy, and slows the spread of the virus."

For three decades, the Ryan White HIV/AIDS Program has provided care and treatment services to low-income people with HIV who are among the hardest to reach populations. The program serves approximately 50 percent of all people with diagnosed HIV in the United States. In 2018, approximately 87.1 percent of Ryan White HIV/AIDS Program clients who received HIV medical care were virally suppressed, up from 69.5 percent in 2010.

"HRSA's Ryan White HIV/AIDS Program has played a critical role in the Ending the HIV Epidemic: A Plan for America (EHE) initiative, which aims to reduce new HIV infections in the United States by 90 percent by 2030," said HRSA Administrator Tom Engels. "These grants will help ensure that Americans with HIV/AIDS have access to life-saving care and treatment needed to improve their health outcomes and to reduce HIV transmission."

Under Part A of the Ryan White HIV/AIDS Program, approximately $626.9 million was awarded to 52 metropolitan areas to provide core medical and support services for people with HIV. These grants were awarded to 24 eligible metropolitan areas and 28 transitional grant areas with the highest number of people with HIV and AIDS and also experiencing increases in HIV and AIDS cases and emerging care needs. For a list of the FY 2020 Ryan White HIV/AIDS Program Part A award recipients, visit https://hab.hrsa.gov/about-ryan-white-hivaids-program/part-a-grants-emerging-metro-transitional-areas/fy2020-awards

Under Part B of the Ryan White HIV/AIDS Program, approximately $1.3 billion was awarded to 59 states and territories to improve the quality, availability and organization of HIV health care and support services and for the AIDS Drug Assistance Program (ADAP). Additionally, 16 states received Emerging Community grants based on the number of AIDS cases over the most recent five-year period. In addition, 31 states and territories were also awarded approximately $10.3 million in Part B Minority AIDS Initiative grants. For a list of the FY 2020 Ryan White HIV/AIDS Program Part B award recipients, visit https://hab.hrsa.gov/about-ryan-white-hivaids-program/part-b-grants-states-territories/fy2020-awards

Under Part C Early Intervention Services (EIS) of the Ryan White HIV/AIDS Program, approximately $179.8 million was awarded across the country to 347 local, community-based organizations to provide core medical and support services to people with HIV.

Thomas J. Engels, Administrator, Health Resources and Services Administration, U.S. Department of Health and Human Services

Additionally, 58 organizations were awarded approximately $7.9 million in Part C Capacity Development grants.

For a list of the FY 2020 Ryan White HIV/AIDS Program Part C EIS award recipients, visit https://hab.hrsa.gov/about-ryan-white-hivaids-program/part-c-early-intervention-services-and-capacity-development-program-grants/fy2020-eis-awards

For a list of the FY 2020 Ryan White HIV/AIDS Program Part C Capacity Development award recipients, visit https://hab.hrsa.gov/about-ryan-white-hivaids-program/part-c-early-intervention-services-and-capacity-development-program-grants/fy2020-capacity-awards

Under Part D of the Ryan White HIV/AIDS Program, approximately $69.8 million was awarded to 115 local community-based organizations across the country to provide family-centered comprehensive HIV care and treatment for women, infants, children, and youth with HIV. For a list of the FY 2020 Ryan White HIV/AIDS Program Part D award recipients, visit https://hab.hrsa.gov/about-ryan-white-hivaids-program/part-d-services-women-infants-children-and-youth/fy2020-awards

Under Part F of the Ryan White HIV/AIDS Program, approximately $68.1 million was awarded to support clinical training, oral health services, quality improvement, and the development of innovative models of care through several different programs. Approximately $9.1 million was awarded to 49 recipients through the Dental Reimbursement Program, and approximately $3.5 million was awarded to 12 recipients through the Community-Based Dental Partnership Program.

For a list of the FY 2020 Ryan White HIV/AIDS Program Part F Dental Reimbursement Program award recipients and Community-Based Dental Partnership Program award recipients, visit https://hab.hrsa.gov/about-ryan-white-hivaids-program/part-f-dental-programs/fy2020-awards

Also under Part F, the AIDS Education and Training Centers (AETC) Program awarded approximately $30.5 million through 14 grants and cooperative agreements to support education and training of health care professionals, which includes a network of eight regional and two national centers.

For a list of the FY 2020 Ryan White HIV/AIDS Program AETC award recipients, visit https://hab.hrsa.gov/about-ryan-white-hivaids-program/part-f-aids-education-and-training-centers-aetc-program/fy2020-awards

In addition, $25 million was awarded through the Ryan White HIV/AIDS Program Special Projects of National Significance (SPNS) Program under Part F, which includes $11.2 million in funding for new initiatives. SPNS supports the development of innovative models of care, informing evidence-based interventions for populations with HIV who are significantly difficult to engage, retain in care, and reach and sustain viral suppression with antiretroviral therapy.

For a list of current SPNS initiatives, visit here. For a list of the FY 2020 Ryan White HIV/AIDS Program SPNS award recipients, visit https://hab.hrsa.gov/about-ryan-white-hivaids-program/part-f-special-projects-national-significance-spns-program/fy2020-awards

hhs.gov

Unveiling the Newest Prevention Resources from the Let's Stop HIV Together (Together) Campaign

Statement by Demetre Daskalakis, MD, MPH, Director, Division of HIV/AIDS Prevention, CDC

As one of my first acts as the new director of CDC's Division of HIV/AIDS Prevention (DHAP), I am thrilled to have the honor of unveiling the newest prevention resources from the Let's Stop HIV Together (Together) campaign. These materials represent an important expansion of the campaign's prevention resources and are designed for all who can benefit from HIV prevention information. The new materials are built around a status neutral theme: Whatever your HIV status, there are options to prevent HIV. Know your options and choose what's best for you.

Despite COVID-19, HIV doesn't stop, neither do you, and neither do we. In that spirit, the new materials were developed through our first ever virtual production. Our campaign participants from across the country represent highly diverse populations, including Black and Latino gay men, heterosexual cisgender Black and Latina women, and transgender people. These participants did a phenomenal job in becoming their own at-home production crews and the result is a new and vibrant suite of materials created in English and Spanish. Digital and print materials include PSAs, posters, web banners, palm cards, brochures, GIFs, memes, social media videos, and a webisode. I hope you'll take a look at them on the Together prevention and campaign materials search page. https://www.cdc.gov/stophivtogether/index.html

Photo courtesy of the CDC

Demetre Daskalakis, MD, MPH
Photo courtesy of the CDC

The new resources highlight a range of HIV topics, including condoms, medicines that prevent HIV such as pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP), treatment and its role in prevention, and overall sexual health. Additionally, we are continuously adding new resources and materials across the Together portfolio, addressing HIV testing, treatment, and stigma. All materials are downloadable, free to order, and available now. Videos can be accessed on the English and Spanish Together websites and on our YouTube channel. Also note that our campaign materials are available for co-branding, so feel free to contact us about that.

CDC partners will support the launch of these new HIV prevention resources through a number of social media activities, including reaction videos, watch parties, and sharing social media posts from our new HIV Prevention Social Media Toolkit. https://www.cdc.gov/stophivtogether/partnerships/social-media-toolkit.html

For more information on these fun and meaningful events, and to keep up to date on the campaign, I invite you to follow these handles:

@StartTalkingHIV Instagram
@StartTalkingHIV Facebook
@stophivtogether Instagram

We are grateful for your expertise and willingness to work with DHAP to stop HIV together. Please feel free to reach out if you have questions or suggestions by emailing us at stophivtogether@cdc.gov

Best,
Demetre Daskalakis, MD, MPH
Director, Division of HIV/AIDS Prevention, CDC

hiv.gov

New HRSA HIV/AIDS Bureau Funding Opportunities Support Innovative Health Interventions and Data Capacity Building

The Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau has released three new Notices of Funding Opportunity (NOFO) through the Ryan White HIV/AIDS Program (RWHAP). All of these NOFOs are part of the RWHAP's Part F Special Projects of National Significance (SPNS) Program and support the Ending the HIV Epidemic initiative.

Innovative Interventions to Improve Health Outcomes among People with HIV

Two of these NOFO announcements are for an initiative that will use an implementation science framework to support the scale-up of effective and innovative intervention strategies to improve health outcomes for people with HIV in four areas:

- Improving HIV health outcomes for people with substance use disorder;
- Improving HIV health outcomes for lesbian, gay, bisexual, transgender, or queer (LGBTQ+) youth;
- Improving HIV health outcomes for people who are or have been incarcerated; and
- Improving HIV health outcomes by using telehealth services.

The first NOFO (HRSA-21-076), entitled "Using Innovative Intervention Strategies to Improve Health Outcomes among People with HIV — Coordinating Center," will fund an organization to act as a coordinating center for technical assistance (CCTA). The CCTA will solicit and subaward up to 20 RWHAP-funded recipients/subrecipients to serve as implementation sites. Each site will pilot one intervention strategy in one of the focus areas. During the pilot, the coordinating center will provide technical assistance and develop highly accessible and engaging replication tools and materials to describe the piloted intervention strategies.

For more information visit the NOFO for the coordinating center and the NOFO for the evaluation center. Applications for both opportunities are due March 8, 2021.

Building Capacity to Improve Collecting and Reporting Viral Suppression Data for the Medicaid Health Care Quality Measure

Photo courtesy of hiv.gov

In addition, HRSA's HIV/AIDS Bureau also released a NOFO (HRSA-21-083) entitled "Building Capacity to Improve Collecting and Reporting Viral Suppression Data to the Medicaid Adult Core Set." This four-year initiative seeks to develop strategies to build capacity among HIV surveillance and Medicaid programs for reporting high-quality HIV viral suppression data to comply with reporting of the HIV Viral Load Suppression (HVL-AD) measure in the Core Set of Adult Health Care Quality Measures for Medicaid (Medicaid Adult Core Set). This work is a continuation of a collaboration among HRSA, CMS, and CDC to better coordinate data among Medicaid, Medicare, and the RWHAP to improve engagement and retention in care and patient outcomes. HRSA will award one (1) System Coordination Provider (SCP) to select, fund, and work with up to 10 RWHAP Part B state health departments and their associated HIV surveillance and Medicaid programs. The SCP also will work with RWHAP Part B states and HRSA staff to disseminate and promote the replication of findings and lessons learned from the project. Through the SPNS program, HRSA will provide funding in the form of a cooperative agreement. Approximately $4,000,000 will be available annually to fund one SCP recipient. The application due date is February 16, 2021.

All application material is currently available on Grants.gov

hiv.gov

Celebrating 30 Years of the Ryan White CARE Act

August 18, 2020 marked the 30th anniversary of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. This landmark legislation created the largest federal program focused exclusively on providing care and treatment to people with HIV, called the Ryan White HIV/AIDS Program.

Administered by the U.S. Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA), the Ryan White HIV/AIDS Program funds grants to cities, states, counties, and local community-based organizations across the country. For 30 years the Ryan White HIV/AIDS Program has bolstered a comprehensive system of HIV primary medical care, medication and essential support services to more than half a million people with HIV in the United States.

"The Ryan White HIV/AIDS Program has been a cornerstone of the public health response to HIV in the United States for the last three decades," said HHS Secretary Alex Azar. "What was once a deadly disease is now a manageable chronic condition, and we see that in the success of the Ryan White HIV/AIDS Program, with the vast majority of its clients reaching viral suppression. In large part due to the Ryan White HIV/AIDS Program, we now have the tools we need to end the HIV epidemic in the United States."

"The Ryan White HIV/AIDS Program is a key part of the Administration's Ending the HIV Epidemic: A Plan for America, a 10-year initiative that aims to reduce new HIV infections in the United States by 90 percent by 2030," said HRSA Administrator Tom Engels. "During the COVID-19 pandemic, the program remains committed to providing lifesaving services to the nation's most vulnerable populations, including people with HIV."

Graphic courtesy of the Health Resources & Services Administration

Ryan White (left) with classmates at Hamilton Heights High School.
Photo courtesy of The Indiana History Blog and Britannica.com

The Ryan White HIV/AIDS Program provides care and treatment services to low-income people with HIV — who are among the hardest to reach populations. The program serves approximately half of all Americans diagnosed with HIV in the United States. In 2018, approximately 87.1 percent of Ryan White HIV/AIDS Program clients who received HIV medical care were virally suppressed, up from 69.5 percent in 2010.

Early in the HIV epidemic, HRSA and the Ryan White HIV/AIDS Program led on the frontlines in addressing the critical needs of people with HIV to reduce stigma and train providers to deliver culturally-appropriate HIV care and treatment. HRSA remains committed to addressing health disparities in underserved communities and to ensuring access to and retention in quality, integrated care, and treatment services for all people with HIV.

The program was named for a courageous young man diagnosed with AIDS in 1984. Ryan White fought AIDS-related discrimination in his Indiana community while fighting for his right to attend school and by doing so educated the nation about his disease. Ryan White died only months before Congress passed the legislation in 1990.

The Ryan White CARE Act has been reauthorized four times and has accommodated new and emerging needs of people with HIV as well as addressed disparities in access to care to improve HIV-related health outcomes.

hhs.gov

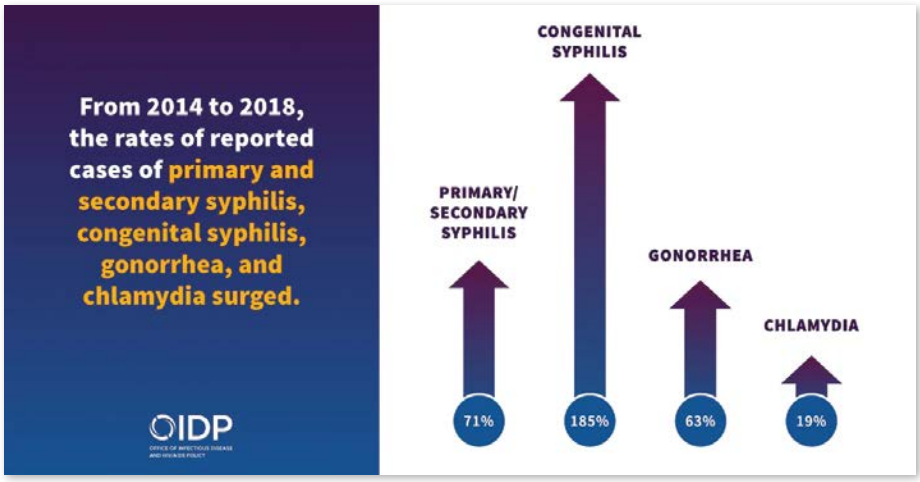
HHS Releases First National Strategic Plan to Address Sexually Transmitted Infections

The U.S. Department of Health and Human Services (HHS) has released the first-ever national plan to address the public health crisis caused by alarming increases in rates of sexually transmitted infections (STIs) in the United States over the past six years. The STI National Strategic Plan 2021-2025 (STI Plan) sets national goals, objectives, and strategies to respond to the STI epidemic. The plan will serve as a roadmap to help federal and non-federal stakeholders at all levels and in all sectors reverse the sharp upward trends in STI rates.

"The consequences of the STI epidemic are steep. When left untreated, STIs can lead to long-term, irreversible health outcomes affecting the quality of life for millions of Americans and costing the health care system billions of dollars annually," said Admiral Brett P. Giroir, MD, Assistant Secretary for Health. "The STI Plan provides an actionable roadmap to develop and implement programs at the national, state and local levels to help our nation stem and reverse the growing STI epidemic in the U.S."

Increases in STIs have been dramatic. From 2014–2018, the most recent available data, the rates of reported cases of primary and secondary syphilis, congenital syphilis, gonorrhea, and chlamydia rose 71%, 185%, 63%, and 19%, respectively. Human papillomavirus (HPV), the most common STI, accounts for 14 million new infections each year.

The impact of the STI epidemic does not fall equally across all populations and regions. Adolescents and young adults, men who have sex with men, and pregnant women are disproportionately impacted by STIs. Social determinants of health contribute to a substantial unequal burden of STIs in Black, American Indian/Alaska Native and Hispanic communities. In addition, people living in the Southern and Western regions of the U.S. are disproportionately affected.



This inaugural STI Plan lays out a clear vision for preventing those consequences:

The United States will be a place where sexually transmitted infections are prevented and where every person has high-quality STI prevention, care, and treatment while living free from stigma and discrimination.

This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance.

The STI Plan's five goals to guide planning efforts are:

- Prevent new STIs;
- Improve the health of people by reducing adverse outcomes of STIs;
- Accelerate progress in STI research, technology, and innovation;
- Reduce STI-related health disparities and health inequities; and
- Achieve integrated, coordinated efforts that address the STI epidemic.

Each goal has a set of objectives and strategies to help guide federal partners and other stakeholders toward achieving them. The objectives and strategies are evidence- and science-based, flexible, integrated, and promote innovative approaches.

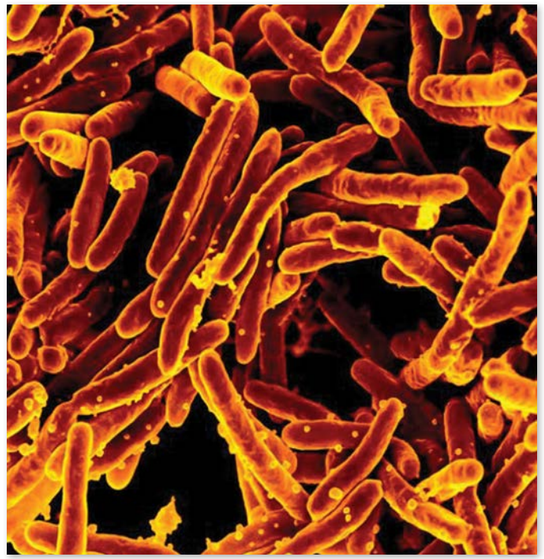
hhs.gov

Recent Advances in Addressing Tuberculosis Give Hope for Future

NIH officials describe "banner year"

In September 2018 the National Institute of Allergy and Infectious Diseases (NIAID) issued its Strategic Plan for Tuberculosis Research, which outlined research priorities to reduce and ultimately end the burden of tuberculosis (TB). TB is a bacterial disease that has claimed the lives of more than a billion people in the past two centuries. Now, a new "Perspective" in *The Journal of Infectious Diseases* by NIAID Director Anthony S. Fauci, MD, and other Institute officials summarizes recent progress in improved TB diagnostics, therapeutic regimens and prevention approaches that made 2019 a "banner year" for TB research.

Therapeutics trials described by the NIAID authors include BRIEF TB/A5279, a Phase 3 clinical study demonstrating that a one-month course of two antibiotic drugs worked as well as a nine-month regimen of a single drug to prevent TB disease among adults and adolescents with HIV at risk of developing active TB. In June 2019, NIAID and the Eunice Kennedy Shriver National Institute of Child Health and Human Development, also part of NIH, launched the Phase 3 PHOENIx MDR-TB trial in 12 countries. PHOENIx MDR-TB (Protecting Households on Exposure to Newly Diagnosed Index Multidrug-Resistant Tuberculosis Patients) will compare two oral regimens for preventing active TB in adults, teens and children who are at high risk of infection because they live with adults who have multidrug-resistant TB. "Results from this innovative study will inform new TB prevention guidelines to avert the pain, disability and death associated with MDR-TB," Dr. Fauci and his coauthors write.



Scanning electron micrograph of Mycobacterium tuberculosis bacteria, which cause TB. Photo courtesy of the NIAID

Advances in TB vaccine development in 2019 included exciting preclinical and clinical results from several studies, the Perspective authors write. A study in macaques, in which the Bacille Calmette-Guerin (BCG) vaccine — the world's only licensed TB vaccine — was administered intravenously (IV) instead of by the standard intradermal route resulted in a dramatic increase in efficacy.

The findings support further investigation of IV BCG administration in future human clinical trials. The authors described results of a Phase 2b trial of a candidate TB vaccine M72/AS01 (developed by GlaxoSmithKline) as "groundbreaking." The trial enrolled 3,575 volunteers in three countries and demonstrated 50% efficacy in preventing development of active pulmonary TB compared with placebo.

The challenge in 2020 and beyond is to build on the momentum generated by these recent accomplishments, the authors note. Still urgently needed are rapid, inexpensive and accurate point-of-care diagnostics; new and more effective drugs; and new and improved vaccines that prevent transition from latent infection to active TB disease or that prevent infection altogether.

Achieving the end of TB within a generation is possible only through concerted, collective and collaborative efforts that involve government, academia, industry and civil society at all levels, the authors conclude.

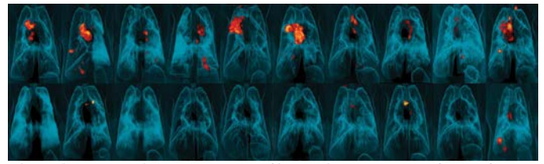
Reference:

RW Eisinger et al. 2019: A banner year for tuberculosis research. *The Journal of Infectious Diseases* DOI: 10.1093/infdis/jiaa051 (2020).

nih.gov

Temperature-stable Experimental Tuberculosis Vaccine Enters Clinical Testing

Vaccinations have begun in a Phase 1 human clinical trial testing a freeze-dried, temperature-stable formulation of an experimental tuberculosis (TB) vaccine called ID93. The powder formulations are mixed with sterile water for administering with a needle and syringe. Investigators are examining if a powder formulation combining ID93 and the adjuvant GLA-SE in a single vial, reconstituted with sterile water, is as effective at inducing an immune response in participants as the previously tested two-vial combination of powdered ID93 and liquid GLA-SE.



Three-dimensional PET-CT scans of lungs showing areas of TB infection and tissue inflammation (red and orange) in macaques challenged with Mtb after vaccination with either ID BCG (top row) or IV BCG (bottom). University of Pittsburgh School of Medicine

"Tuberculosis remains the leading infectious cause of death worldwide, and a highly effective vaccine would be a crucial tool in ending this pandemic," said NIAID Director Anthony S. Fauci, MD. "A vaccine that did not require a cold chain could be much more easily distributed to communities in need."

"To our knowledge, the freeze-dried formulation of ID93 + GLA-SE represents the first time a thermostable vaccine candidate containing a modern immune-boosting substance has reached clinical testing," said Christopher Fox, PhD, vice president of Formulations at IDRI and principal investigator of the NIAID contract. "Implementing technologies designed for low-resource settings early in product development could help accelerate vaccine rollout in hard-to-reach areas."

nih.gov

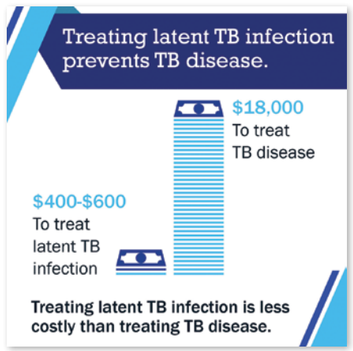
CDC and the National Tuberculosis Controllers Association Release New Guidelines for Treatment of Latent TB Infection

By Philip LoBue, MD, FACP, FCCP, Director, Division of Tuberculosis Elimination, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention

Dear Colleague:

Treatment of latent tuberculosis (TB) infection is essential to controlling and eliminating TB in the United States because it substantially reduces the risk that latent TB infection will progress to TB disease. Up to 13 million people in the United States have latent TB infection. Without treatment, they are at risk for developing TB disease in the future; however, treatment greatly reduces this risk.

The U.S. Centers for Disease Control and Prevention (CDC) and the National Tuberculosis Controllers Association (NTCA) published *"Guidelines for the Treatment of Latent Tuberculosis Infection"* in CDC's Morbidity and Mortality Weekly Report Recommendations and Reports. This is the first comprehensive update to U.S. latent TB infection treatment guidelines since 2000. CDC and NTCA preferentially recommend short-course, rifamycin-based, 3- or 4-month latent TB infection treatment regimens over 6- or 9-month isoniazid monotherapy.



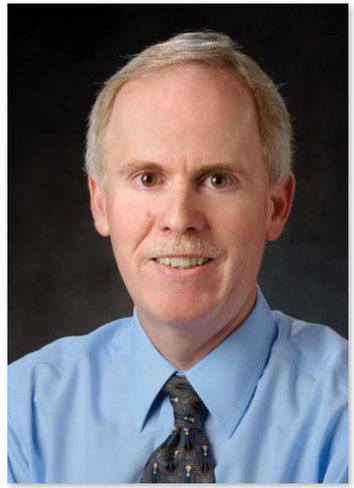
To treat latent TB infection, CDC and NTCA preferentially recommend:

- Three months of once-weekly isoniazid plus rifapentine (3HP). 3HP is strongly recommended for adults and children older than 2 years, including HIV-positive persons.
- Four months of daily rifampin (4R). 4R is strongly recommended for HIV-negative adults and children of all ages.
- Three months of daily isoniazid plus rifampin (3HR) is conditionally recommended for adults and children of all ages and for HIV-positive persons.

If short-course treatment is not a feasible or available option (e.g., due to drug interactions with rifamycins), CDC and NTCA recommend six or nine months of daily isoniazid (6H/9H) as alternative, effective latent TB infection treatment regimens.

More than 80% of people who develop TB disease in the United States each year get sick from longstanding, untreated latent TB infection. Short-course latent TB infection treatment regimens are effective, safe, have a lower risk of hepatotoxicity, and have higher completion rates than longer 6 to 9 months of isoniazid monotherapy. The availability of short-course regimens can also enable providers to treat larger numbers of people who are at risk for TB disease.

Our public health system and private providers play a crucial role in expanding the testing and treatment of latent TB infection. Clinicians can work with patients to determine the best latent TB infection



Philip LoBue, MD

treatment regimen, prescribe shorter regimens, and provide support and resources to help patients complete latent TB infection treatment successfully.

We encourage clinicians, pharmacists, and public health professionals to review the new guidelines for the treatment of latent TB infection. Clinicians can contact state and local TB control offices for additional information on diagnosing and treating latent TB infection.

Additionally, CDC has resources and tools for latent TB infection for health care providers, public health professionals, and patients available at https://www.cdc.gov/tb/publications/ltbi/ltbiresources.htm

cdc.gov

HHS Awards Nearly $360 Million To Programs Supporting Maternal and Child Health

The U.S. Department of Health and Human Services (HHS) announced approximately $341 million in funding to 55 states, territories and nonprofit organizations through the Maternal, Infant and Early Childhood Home Visiting (MIECHV) Program and approximately $16 million in funding to the State Maternal Health Innovation (State MHI) Program to improve maternal health outcomes.

Maternal, Infant, and Early Childhood Home Visiting Program

These funds support communities to provide voluntary, evidence-based home visiting services to pregnant women and parents with young children up to kindergarten entry.

"We know that home visiting programs are an effective way to improve moms' and kids' health and well-being, and they continue to play a critical role addressing needs during the pandemic," said HHS Secretary Alex Azar. "In addition to tackling the pressing challenge of maternal and child health, these awards support exactly the kind of person-centered program that we believe can help foster long-term health and independence."

In FY 2019, the MIECHV Program served approximately 154,000 parents and children in all 50 states, the District of Columbia, and five territories, and provided over one million home visits. The Program also reached many of the most underserved families in FY 2019.

Almost three-fourths of families participating in the Program had household incomes at or below 100 percent of the Federal Poverty Level, two-thirds of adult participants had a high school education or less, and 76 percent of adults and children relied on Medicaid or the Children's Health Insurance Program.

"The MIECHV Program aims to improve the well-being of both parents and children across the life course, leading to healthier and stronger families and communities," said HRSA Administrator Tom Engels. "In these voluntary programs, trained professionals meet regularly with expectant parents or families with young children in their homes, fostering strong, positive relationships with families who want and need support."

Administered by HRSA, in partnership with the Administration for Children and Families, the MIECHV Program supports pregnant women and families in at-risk communities as they raise children who are physically, socially and emotionally healthy and ready to succeed. This year marks the 10th anniversary of the MIECHV program, which has provided more than 6 million home visits, and empowered parents and families with the tools they need to thrive since 2010.

State Maternal Health Innovation Program

The State MHI Program is comprised of nine cooperative agreements aimed at addressing the high rates of maternal mortality and morbidity in the United States and improving maternal health outcomes. This is the second year of five total years of funding to help strengthen states' capacity to address disparities in maternal health, convene a state level maternal health task force, develop each state's strategic plan and implement innovative approaches, such as expanding telehealth services to improve access to care.

For more information on HRSA's Home Visiting Program, visit http://mchb.hrsa.gov/programs/homevisiting

hhs.gov

HHS Issues Challenges to Find Best Practices in Maternal Health

The U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health announced two challenges to improve maternal health. The first challenge will address care for women with hypertension who are pregnant and/or postpartum, while the second challenge will address breastfeeding initiation and continuation disparities among breastfeeding mothers. The partnership will bridge data gaps in maternal health outcomes across the country.

HHS Hypertension Innovator Award Competition: Innovative Methods of Blood Pressure Monitoring and Follow-up in Women during Pregnancy and/or Postpartum

The $3.3 million dollar competition will identify pre-existing programs that care for women with hypertension who are pregnant and/or postpartum. The competition looks for programs that provide effective monitoring and follow-up to improve rates of hypertension control.

"I issued a Surgeon General's Call to Action to Control Hypertension urging Americans to recognize and address hypertension control as a national, public health priority," said Surgeon General VADM Jerome M. Adams, MD, MPH "We've seen how costly and dangerous uncontrolled hypertension can be for all Americans, but the impact is extremely critical for women who are pregnant and/or postpartum. We must ensure that women with and at risk for hypertension receive optimal care, including support for self-monitoring, in order to control high blood pressure before, during, and after pregnancy. Achieving control of hypertension will help women live

Dorothy Fink, MD, Deputy Assistant Secretary for Women's Health, U.S. Department of Health and Human Services

longer, healthier lives."

In the United States, high blood pressure affects in one in every 12 to 17 pregnancies among women ages 20 to 44. In addition, high blood pressure is a major risk factor for heart disease and stroke, which were responsible for one in three pregnancy-related deaths from 2011 – 2015.

"Women's hearts work harder than normal during pregnancy. Having hypertension adds stress to the body and significantly increases the risk of pregnancy complications," said Deputy Assistant Secretary for Women's Health and Director of the Office on Women's Health, Dorothy Fink, MD. "The hypertension challenge will align with the Surgeon General's recent Hypertension Call to Action and help us identify existing programs that show promise for women during pregnancy and after giving birth."

HHS Reducing Disparities in Breastfeeding Innovation Challenge

The $800,000 competition will identify effective, pre-existing programs that increase breastfeeding initiation and continuation rates and decrease disparities among breastfeeding mothers in the United States. This competition seeks programs that target gaps in breastfeeding education, instruction, and/or support for breastfeeding mothers.

"Although the conversation on breastfeeding has traditionally focused on the nutritional benefits for the baby, more studies show that breastfeeding also has health benefits for new moms," said Deputy Assistant Secretary for Women's Health and Director of the Office on Women's Health, Dorothy Fink, MD. "Breastfeeding can lower the risk of hypertension along with the risks of diabetes, breast cancer, and ovarian cancer. We want more mothers to understand this connection and have the necessary tools to successfully start and continue breastfeeding their babies."

The American Academy of Pediatrics recommends that babies are breastfed exclusively for about 6 months, and then continue to be breastfeed and introduced complementary foods until one year of age or longer. According to CDC, only one in four infants is exclusively breastfed until they are 6 months old. Recent data shows African American mothers have lower breastfeeding rates and black infants are 15% less likely to have ever been breastfed compared with other racial/ethnic groups.

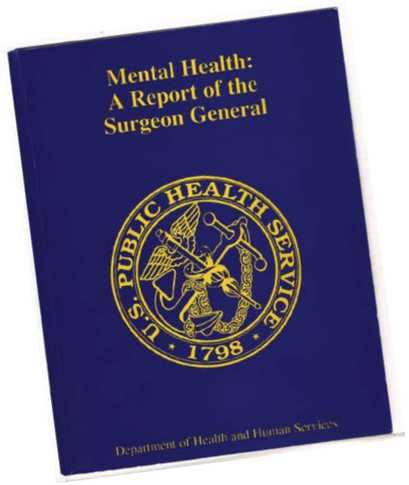
hhs.gov

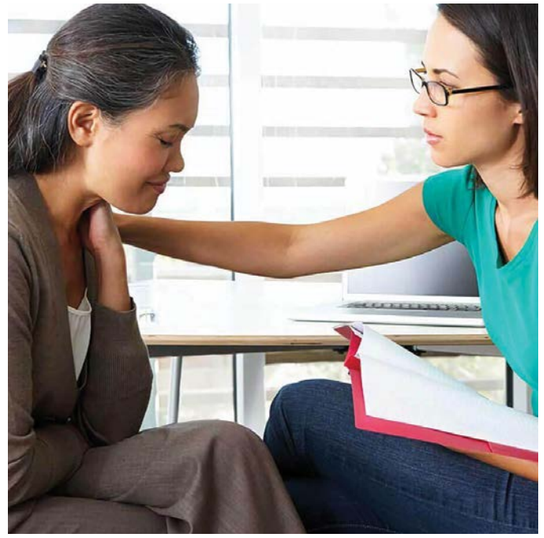
Improvements in Mental Health Care for Women

The first Surgeon General's report on mental health was released in 1999. Since then, awareness of the societal burden of mental illness, and the need for equitable treatment of it alongside physical health concerns, has increased. HHS, with leadership from SAMHSA and CMS, implements mental health parity laws to ensure that insurers cannot discriminate against those with mental illness by covering mental health treatments at a lower level than physical health concerns.

Mental health research, including research funded by the National Institute of Mental Health and other parts of NIH, has highlighted gender differences in mental health and the greater burden women face from several types of mental illness. Major depressive disorder affects women twice as often as men, and 1 in 5 women develop a major depressive disorder in her lifetime. Women also have higher rates of other mental health issues, such as anxiety, PTSD, and eating disorders.

One mental health treatment advance occurred in 1987 when the FDA first approved a new class of drugs called selective serotonin reuptake inhibitors (SSRIs). SSRIs were a breakthrough in depression treatment because they tend to have fewer side effects and are easier to take. After SSRIs were introduced, antidepressant prescriptions greatly increased, with the majority of them being for SSRIs and other newer antidepressant medications.





In 2009, OWH coordinated the Women's Mental Health Initiative and published the report Action Steps for Improving Women's Mental Health. Along with the release of the Federal Mental Health Action Agenda in 2009, led by SAMHSA, the federal government took steps forward in recognizing mental illness in women and removing barriers to treatment and care.

Also, every other year, SAMHSA releases its Mental Health, United States report on the state of mental health services.

Today the 2010 Affordable Care Act provides one of the largest expansions of mental health and substance use disorder coverage in a generation, requiring Health Insurance Marketplace plans to cover these services. These new protections build on the Mental Health Parity and Addiction Equity Act to expand mental health benefits and parity protections to 62 million Americans.

womenshealth.gov

HHS Announces MENTAL Health Innovation Challenge

Challenge seeks online tool to help socially isolated Americans connect and engage

The Administration for Community Living (ACL) and the Office of the Assistant Secretary for Health launched the MENTAL Health Challenge to combat the social isolation and loneliness that older adults, people with disabilities and veterans often experience. A total of $750,000 in prizes will be awarded for development of an easy-to-use online system that offers recommendations for programs, activities and resources that can help users connect to others and engage in the community, based on their individual needs, interests and abilities.

The winning system will be announced and demonstrated in January 2021 at CES, an annual trade show produced by the Consumer Technology Association. It ultimately will become the centerpiece of a national public awareness campaign.

Social disconnection has enormous health consequences. Social isolation has been found to be as harmful to a person's health as smoking 15 cigarettes a day, and people who are socially isolated or lonely face higher risk of hospitalization; depression, anxiety and suicide; heart failure and stroke; dementia; and even premature death. Not surprisingly, a recent analysis found that Medicare spends an additional $6.7 billion every year on enrollees who are socially isolated.

"We need a multipronged public health approach to change the way we address social isolation, especially among our most at-risk populations," said U.S. Surgeon General, VADM Jerome M. Adams, MD, MPH. "This approach must include the development of innovative solutions to combat the harmful physical and mental health effects of social isolation and the role technology has in promoting better connections for all."

For a variety of reasons, older adults, people with disabilities, and veterans are more likely to be socially isolated and to report feeling lonely. Nearly a quarter of Americans who are 65 or older have few social relationships or infrequent social contact with others, and more than 40 percent of people 60 and older report feeling lonely.

In one small study, people with disabilities were more than three times more likely to report feelings of loneliness than people without disabilities. Veterans report higher rates of loneliness than civilians, particularly if they have functional limitations or have experienced traumatic events, and loneliness has been cited as the top risk factor for suicidal ideation in veterans.

The number of older adults is projected to almost double by the year 2060, the population of people with disabilities also is growing, and 22 veterans die by suicide every day. There is a clear and critical need to help all three connect with others and engage in their communities. This is particularly true when normal social interaction is limited due to a crisis like the COVID-19 pandemic.

"For many older adults and people with disabilities, increased social isolation and loneliness is one unfortunate consequence of physical distancing to slow the spread of COVID-19," said Lance Robertson, ACL Administrator and HHS Assistant Secretary for Aging. "We need to have a wider range of tools and resources to help people remain connected and engaged, and an easy-to-use way for people to find and access them."

Lance Robertson, ACL Administrator and HHS Assistant Secretary for Aging

Supporting partners for the Mobilizing and Empowering the Nation and Technology to Address Loneliness & social isolation (MENTAL) Health Innovation Challenge include the Federal Communications Commission (FCC) and the Department of Veterans Affairs. The Challenge was coordinated by the White House Office of Science and Technology Policy.

"Staying connected to family, friends, and colleagues is important, especially during the pandemic," said FCC Chairman Ajit Pai. "The FCC has a long history of helping ensure that those at risk for isolation, like older Americans and people with disabilities, can access the communications technologies that can keep them connected, healthy, and safe. We look forward to joining HHS and others in this important effort to enable technology to help vulnerable Americans."

"For many older adults and people with disabilities, increased social isolation and loneliness is one unfortunate consequence of physical distancing to slow the spread of COVID-19," said Lance Robertson, ACL Administrator and HHS Assistant Secretary for Aging.

"Technology can provide unique solutions to combat social isolation. The Trump Administration is committed to leveraging the Nation's entrepreneurial spirit to address the pandemic, and we know America's innovators will rise to this challenge," said U.S. Chief Technology Officer Michael Kratsios.

More information about the MENTAL Health Innovation Challenge, including deadlines and evaluation criteria, can be found at ACL.gov/challenge and at https://www.challenge.gov/challenge/MENTAL-health-social-isolation-challenge

About the partners for MENTAL Health Innovation Challenge:

The Administration for Community Living (ACL) was created around the fundamental principle that older adults and people of all ages with disabilities should be able to live where they choose, with the people they choose, and with the ability to participate fully in their communities.

By funding services and supports provided by networks of community-based organizations, and with investments in research, education, and innovation, ACL helps make this principle a reality for millions of Americans.

The Office of the Assistant Secretary for Health oversees the Department's key public health offices and programs, a number of Presidential and Secretarial advisory committees, 10 regional health offices across the nation, the Office of the Surgeon General, and the U.S. Public Health Service Commissioned Corps.

In 1976, Congress established the White House Office of Science and Technology Policy to provide the President and others within the Executive Office of the President with advice on the scientific, engineering, and technological aspects of the economy, national security, homeland security, health, foreign relations, the environment, and the technological recovery and use of resources, among other topics.

The mission of the U.S. Department of Veterans Affairs (VA) is to fulfill President Lincoln's promise "To care for him who shall have borne the battle, and for his widow, and his orphan" by serving and honoring the men and women who are America's veterans.

Within the VA, the Veterans Health Administration is the largest integrated health care network in the United States, with 1,255 health care facilities serving nine million enrolled veterans each year.

The Federal Communications Commission regulates interstate and international communications by radio, television, wire, satellite, and cable in all 50 states, the District of Columbia and U.S. territories. An independent U.S. government agency overseen by Congress, the Commission is the federal agency responsible for implementing and enforcing America's communications law and regulations.

hhs.gov

HHS Marks One-Year Anniversary of Advancing American Kidney Health Initiative

"We have brought more change to American kidney policy in the last year than we saw in the past several decades. America's kidney patients were forgotten for far too long — but no more. HHS has launched models to improve kidney payments, proposed new ways to increase transplants and support organ donors, changed guidelines to expand the supply of organs, and launched a historic public awareness campaign to promote kidney health. Because of the hard work of the HHS team and kidney patients and advocates, American kidney care will change and improve dramatically in the years to come."

Since the signing of the executive order, HHS has taken numerous actions to advance American kidney health, including the following:

- The Centers for Medicare & Medicaid Services launched the Kidney Care Choices payment model, a voluntary model to provide new incentives for delaying the need for dialysis in patients with chronic kidney disease, which is expected to enroll more than 200,000 Medicare beneficiaries.
- CMS proposed the ESRD Treatment Choices model, a mandatory model that aims to increase rates of home dialysis and transplants, and is currently considering comments on it.
- CMS proposed a rule to change the way organ procurement organizations (OPOs) are held accountable for their performance, estimating that the number of annual transplants would increase from about 32,000 to 37,000 by 2026, for a total of almost 15,000 additional transplants in that time.
- CMS finalized a change to increase the new technology add-on payment in Medicare and expand the eligibility for it, with the goal of supporting new technologies, including for kidney care.
- The Health Resources and Services Administration (HRSA) issued a proposed rule to remove financial barriers to living organ donation by expanding support for living donors.
- HRSA issued a request for information to begin exploring more effective ways in which modern IT systems may be able to manage allocating organs and handling patient and donor data on a national scale.
- HHS announced new guidelines for the donation of organs such as kidneys from patients with HIV, hepatitis B, and hepatitis C, using scientific advances to allow donations that previously would not have been possible.

- HHS launched a nationwide kidney risk awareness campaign with the National Kidney Foundation (NKF) and the American Society of Nephrology (ASN).
- KidneyX, a public private partnership between HHS and ASN, made awards in the first-ever Patient Innovator Challenge. The KidneyX Summit 2020 on July 22 will award $3 million in prizes to six winners of the Phase 2 Redesign Dialysis Prize. KidneyX also issued a request for information to help shape a moonshot Artificial Kidney Prize, soon to be announced.
- HHS's Office of the Assistant Secretary for Preparedness and Response deployed a new form of portable dialysis machines in March 2020 to New York City to help patients suffering kidney injury from COVID-19.
- The FDA awarded a contract to the Kidney Health Initiative, a public-private partnership between FDA and ASN, for a three-year project that will measure patient preferences and risk tolerance for novel treatments for kidney failure, allowing the FDA to better incorporate patient input into the development and review of new technologies.
- The NIH-funded Kidney Precision Medicine Project (KPMP) has been conducting research that will help improve identification of populations at risk and those in early stages of kidney disease. Since the summer of 2019, KPMP has collected renal biopsies from over 30 patients, and recent KPMP publications have demonstrated the utility of kidney tissue in optimizing research tools and defining discrete, disease state-specific cell types based on molecular profiles.

hhs.gov

KidneyX Artificial Kidney Prize Offers $10 Million to Accelerate Artificial Kidney Development

The U.S. Department of Health and Human Services (HHS) and the American Society of Nephrology (ASN) launched the KidneyX Artificial Kidney Prize on October 30, 2020 to accelerate the development of artificial kidneys toward human clinical trials. This multiphase competition is KidneyX's first fully dedicated effort toward artificial kidney advancement, with initial phases offering up to $10 million in prizes. Phase 1 seeks solutions that enable and advance the functionality, effectiveness, and/or reliability of artificial kidneys.

The goal of the Artificial Kidney Prize is to accelerate the development of continuous kidney replacement therapies that provide transformational treatment options beyond current dialysis methods, as outlined in the Technology Roadmap for Innovative Approaches To Renal Replacement Therapy.

Entrants are encouraged to address one or more priority topic areas; however, the competition remains open to solutions that advance artificial kidneys in other ways.

"The KidneyX Artificial Kidney Prize aims to radically improve kidney care by bringing together innovators across expertise areas, including nephrology, bioengineering, materials science, regenerative medicine, and medical devices," said HHS Secretary Alex Azar. "Transformative innovation-like steps toward an artificial kidney are key to delivering on the goals of the President's Advancing American Kidney Health initiative and helping the millions of Americans suffering from kidney disease who have been neglected for far too long."

Innovation in kidney care is urgently needed: More than 850 million people worldwide live with kidney disease, including 37 million Americans. Current treatment methods have not changed significantly in more than 60 years and cost more than $100 billion per year in the U.S. alone. Thirteen people die each day waiting for a kidney transplant, and those on dialysis face a 40% mortality rate within the first three years of treatment, which is a worse outcome than most cancers.

"KidneyX is growing an innovator community with the expertise and vision to create a paradigm shift in kidney care — the public-private partnership is on track to foster catalytic change to improve kidney health and, most importantly, achieve the outcomes important to patients, their caregivers, and those that love them," said John Sedor, MD, FASN, Chair, KidneyX Steering Committee. "The Artificial Kidney Prize is committed to supporting multidisciplinary teams in bringing forward solutions that increase survival and restore quality of life for people with kidney failure."

"Our Administration is implementing a comprehensive plan to prevent and treat Chronic Kidney Disease, which impacts tens of millions of Americans," said Assistant Secretary for Health, ADM Brett P. Giroir. "The Artificial Kidney Prize is an outstanding step to provide novel life-saving treatments to those who would otherwise require dialysis or traditional transplantation. And this prize is just the beginning of the bold plans we have to improve the lives of those with, or at risk for, chronic kidney disease."

The Artificial Kidney Prize is open to U.S. and international entrants, subject to eligibility requirements. Phase 1 calls for component or integrated prototype solutions with demonstrated performance, including proof of concept data, and detailed development plans. Phase 1 submissions are due by 4:59 p.m. ET on March 24, 2021. The judging panel will recommend up to eight winners, and up to $4 million in Phase 1 prizes will be distributed at the discretion of HHS and ASN.

Phase 2 of the Artificial Kidney Prize will be open to eligible entrants from Phase 1, as well as new eligible entrants who did not enter the first phase. The second phase of the competition will focus on initial integration of prototype solutions into an artificial kidney, or advancement of already integrated prototype solutions. Phase 2 will award up to $6 million in prizes and is expected to launch in October 2021.

Learn more about the Artificial Kidney Prize at akp.kidneyx.org

hhs.gov

Pursuing Precision Medicine for Chronic Kidney Disease

By Dr. Francis Collins

Every day, our kidneys filter more than 30 gallons of blood to allow excretion of molecules that can harm us if they build up as waste. But, for more than 20 million Americans and a growing number of people around the world, this important function is compromised by chronic kidney disease (CKD)[1]. Some CKD patients are at high risk of progressing to actual kidney failure, treatable only by dialysis or kidney transplants, while others remain generally healthy with stable kidney function for many years with minimal treatment.

The dilemma is that, even when CKD is diagnosed early, there's been no good way to predict which individuals are at high risk for rapid progression. Those individuals would potentially benefit from more intensive measures to slow or prevent kidney failure, such as drug regimens that tightly control blood pressure and/or blood glucose. So, I'm pleased to report that NIH-funded researchers have made some progress toward developing more precise strategies for identifying individuals at high risk for kidney failure. International research team has identified a protein, easily detectable in urine, which appears to serve as an early warning sign of CKD progression.

A wide range of conditions, from diabetes to hypertension to the autoimmune disease lupus, can contribute to the gradual loss of kidney function seen in people with CKD. But research suggests that once kidney damage reaches a critical threshold, it veers off to follow a common downhill course, driven by shared cell signaling pathways and almost independent of the conditions causing it. If there was an easy, reliable way to determine when a CKD patient's kidneys are approaching this threshold, it could open the door to better strategies for protecting them from kidney failure. Researchers looked for patterns of gene activity that corresponded with the patients' estimated glomerular filtration rates, an indicator of renal function frequently calculated as part of a routine blood workup. Their first pass produced a list of 72 genes that displayed varying levels of activity that corresponded to differences in the patients' estimated glomerular filtration rates. Importantly, the activity of many of those genes is also increased in cell signaling pathways thought to drive CKD progression. The researchers then zeroed in on the gene that codes for epidermal growth factor (EGF), a protein that, within the kidney, seems to be produced specifically in tubules, which are key components of the waste filtration system. Because EGF appears to enhance tubular repair after injury, researchers had a hunch that it might serve as a positive biomarker of tubular function that could be combined with existing tests of glomerular filtration to detect progression of CKD at an earlier stage.

In groups of CKD patients from the United States and China, the researchers went on to find that the amount of EGF in the urine provides an accurate measure of the protein's activity in the kidney, making it a promising candidate for a simple urine test. In fact, CKD patients with low levels of EGF in their urine were four times more likely than those with higher EGF levels to have their kidney function worsen within a few years.

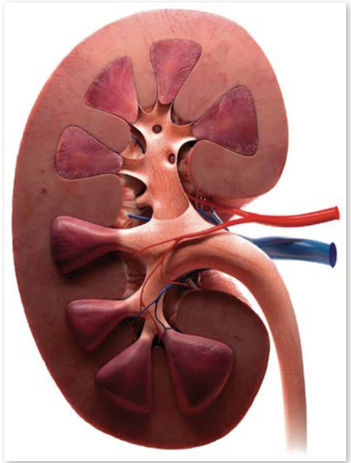


Photo courtesy of the National Center for Biotechnology Information, U.S. National Library of Medicine

References:

1. National Chronic Kidney Disease Fact Sheet, 2014. Centers for Disease Control and Prevention.
2. Tissue transcriptome-driven identification of epidermal growth factor as a chronic kidney disease biomarker. Ju W, Nair V, Smith S, Zhu L, Shedden K, Song PX, Mariani LH, Eichinger FH, Berthier CC, Randolph A, Lai JY, Zhou Y, Hawkins JJ, Bitzer M, Sampson MG, Thier M, Solier C, Duran-Pacheco GC, Duchateau-Nguyen G, Essioux L, Schott B, Formentini I, Magnone MC, Bobadilla M, Cohen CD, Bagnasco SM, Barisoni L, Lv J, Zhang H, Wang HY, Brosius FC, Gadegbeku CA, Kretzler M; ERCB, C-PROBE, NEPTUNE, and PKU-IgAN Consortium. Sci Transl Med. 2015 Dec 2;7(316):316ra193.

nih.gov

New NIH BRAIN Initiative Awards Move Toward Solving Brain Disorders

Researchers using recently developed tools to gain new insights into brain function.

The National Institutes of Health will fund more than 175 grants, totaling nearly $500 million, through the NIH's Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, part of a large effort among federal and non-federal partners to use knowledge about how the brain works to develop more effective therapies for neurological disorders.

"Recent discoveries and new technologies supported by the BRAIN Initiative provide a solid foundation for the next phase of the program, which will focus on large transformative projects and lay the foundation for novel interventions for human brain disorders," said John Ngai, PhD, director of the NIH BRAIN Initiative. "We are moving closer to a complete list of all of the components in the brain and learning how those parts work together. That knowledge will enable us to develop better treatments for neurologic and neuropsychiatric diseases."

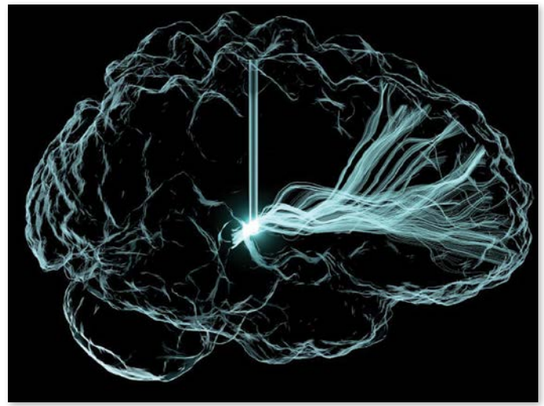
The researchers represent a variety of scientific disciplines from chemistry to engineering to psychology and more.

The new awards include efforts to use deep brain stimulation to enhance sleep in people with Parkinson's disease; explore the neural circuits behind pain; employ ultrasound technology to precisely deliver drugs to the brain; and help people with acute spinal cord injury recover movements and bladder control.

Scientists are also making significant advances in human brain imaging by developing a new type of MRI scanner to watch the brain in action as someone moves; generating ultra-high resolution images of brain chemistry using new PET technology; and using ultrasound to noninvasively map brain electrical activity.

Some grants support integrated research on neuroethical implications of BRAIN-funded neuroscience projects, including issues concerning certain types of neurosurgery and ethical challenges of using mobile neuroimaging technology in field studies.

Meanwhile, others will take a unique approach to studying the brain by developing a range of innovative model systems, beyond traditional fruit flies and rodents. For example, they will study the circuits behind the way an octopus sees and makes decisions; how moths detect harmful stimuli; and the brain connections bats use to navigate in the dark. These studies will provide insights into ways that brain circuitry can affect human behavior.



Researchers are using new tools to gain insights into brain function.
Photo courtesy of Andrew Janson, University of Utah

The BRAIN Initiative started in 2013 as a large-scale effort to accelerate neuroscience research by providing researchers with tools to study and treat human brain disorders. The NIH BRAIN Initiative has focused on brain circuit structure and function as well as the development of technologies to manipulate connections. To date, more than 900 awards totaling approximately $1.8 billion have been supported by the NIH BRAIN Initiative, which is collaboratively managed by 10 institutes.

A number of BRAIN Initiative-supported research findings have been published over the past year including identification of neurons that help rats envision future scenarios; the discovery of specific cells activated by general anesthesia and that may be potential targets for chronic pain treatments; advances in imaging technology that can measure brain activity up to 3,000 times per second in animals; examining nonverbal behavior in people with severe depression who receive deep brain stimulation; watching as odor-sensing cells within the nose react to complex smells; finding brain cells that can initiate torpor, a state of inactivity similar to hibernation; and a new device that may allow real-time control of prosthetic limbs.

For more information, visit: https://braininitiative.nih.gov

nih.gov

Dr. John Ngai Named Director of NIH BRAIN Initiative

National Institutes of Health Director Francis S. Collins, MD, PhD, announced today the selection of John J. Ngai, PhD, as director of the NIH's Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative.

"The BRAIN Initiative aims to revolutionize our understanding of the brain and brain disorders," said Dr. Collins. "We welcome Dr. Ngai's leadership in steering this groundbreaking 21st century project."

The NIH BRAIN Initiative is a large-scale effort to accelerate neuroscience. Since it was launched in 2013, the initiative has funded hundreds of research projects that have led to several breakthroughs, including the creation of a self-tuning brain implant that could help treat Parkinson's disease patients, the development of a computer program that can mimic natural speech from people's brain signals and the construction of a brain cell inventory. BRAIN funded researchers have also shown the ability to make high-speed, high-resolution, 3D films of a nervous system in action.

"Recent technological and scientific advances are transforming our under-standing of the brain," said Dr. Ngai, who is currently the Coates Family Professor of Neuroscience at the University of California, Berkeley. "I am deeply inspired by these advances and look forward to my new role in enabling BRAIN Initiative investigators to unlock the secrets of the brain and lay new foundations for treating human brain disorders."

Dr. Ngai will oversee the long-term strategy and day-to-day operations of the initiative as it takes on the challenges of the next five year plan, just announced a few months ago. Congress has enthusiastically supported BRAIN through the appropriations process and the 21st Century Cures Act.

"Dr. Ngai's appointment marks a new chapter in the BRAIN Initiative," said Walter J. Koroshetz, MD, director of NIH's National Institute of Neurological Disorders and Stroke. "He will provide the initiative the clear vision the project needs to navigate through this critical period."

Dr. Ngai earned his bachelor's degree in chemistry and biology from Pomona College, Claremont, California, and PhD in biology from the California Institute of Technology (Caltech) in Pasadena. He was a postdoctoral researcher at Caltech and at the Columbia University College of Physicians and Surgeons before starting his faculty position at the University of California at Berkeley.

During more than 25 years as a Berkeley faculty member, Dr. Ngai has trained 20 undergraduate students, 24 graduate students and 15 postdoctoral fellows in addition to teaching well over 1,000 students in the classroom. His lab uses a wide array of tools and techniques to study the cells and molecules behind olfaction, or the sense of smell, including fundamental research on how the nervous system detects odors and turns them into neural signals sent to the brain. Dr. Ngai is also interested in unraveling the diversity of cell types in the brain and understanding how the nervous system repairs itself following injury or degeneration. His work has led to the publication of more than 70 scientific articles in some of the field's most prestigious journals and 10 U.S. and international patents. Dr. Ngai has received many awards including from the Sloan Foundation, Pew Charitable Trusts, and McKnight Endowment Fund for Neuroscience.

As a faculty member, Dr. Ngai has served as the director of Berkeley's Neuroscience Graduate Program and Helen Wills Neuroscience Institute. He has also provided extensive service on NIH study sections, councils and steering groups, including as previous co-chair of the NIH BRAIN Initiative Cell Census Consortium Steering Group.

"Dr. Ngai has the diverse skills and experience that are needed to build on the early successes of the BRAIN Initiative," said Joshua A. Gordon, MD, PhD, director of NIH's National Institute of Mental Health. "We are tremendously grateful that we were able to recruit him for such an important leadership position."

The NIH BRAIN Initiative® is managed by 10 institutes whose missions and current research portfolios complement the goals of the BRAIN Initiative: National Center for Complementary and Integrative Health, National Eye Institute, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute of Biomedical Imaging and Bioengineering, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute on Drug Abuse, National Institute on Deafness and Other Communication Disorders, National Institute of Mental Health, and National Institute of Neurological Disorders and Stroke.

nih.gov

NIH Selects Dr. Shannon Zenk Director of the National Institute of Nursing Research

National Institutes of Health Director Francis S. Collins, MD, PhD, has selected Shannon N. Zenk, PhD, MPH, RN, FAAN, as director of NIH's National Institute of Nursing Research (NINR). A registered nurse and leading nurse researcher, Dr. Zenk is currently Nursing Collegiate Professor in the Department of Population Health Nursing Science at the University of Illinois at Chicago (UIC) College of Nursing, and a fellow at the UIC Institute for Health Research and Policy. She is expected to begin her new role as the NINR director in early fall. NINR supports and conducts basic and clinical research that spans and integrates the behavioral and biological sciences and develops the scientific basis for clinical practice.

"Dr. Zenk's diverse and original research experience paired with her expertise as a nurse educator make her an ideal choice to lead NIH's efforts in nursing science," said Dr. Collins. "I am delighted to have her join the NIH leadership team in the fall. I also want to recognize Tara A. Schwetz, PhD, for her exemplary leadership in serving as the NINR acting director since January 2020, in addition to her role as NIH associate deputy director in the NIH Office of the Director."

As NINR director, Dr. Zenk will oversee NINR's annual budget of nearly $170 million, the large majority of which supports extramural research at institutions across the Nation. NINR science seeks to improve the lives of individuals and families living with illness and to develop personalized strategies to maximize health and well-being at all stages of life, and across diverse populations and settings. NINR's intramural program on the NIH campus conducts research to better understand and manage symptoms. Within both of those programs, NINR devotes significant resources to training and career development to foster the next generation of nurse scientists.

Dr. Zenk's own research focuses on social inequities and health with a goal of identifying effective, multi-level approaches to improve health and eliminate racial/ethnic and socioeconomic health disparities. Her research portfolio also includes NIH-supported work into urban food environments, community health solutions and veterans' health. Through pioneering research on the built environment and food deserts, Dr. Zenk and her colleagues helped bring national attention to the problem of inadequate access to healthful foods in low-income and Black neighborhoods.

Shannon N. Zenk, PhD, MPH, RN, FAAN

Dr. Zenk was elected as a fellow of the American Academy of Nursing in 2013 and was inducted into the International Nurse Researchers Hall of Fame in 2019. She has spent time as a visiting scholar in Rwanda and Australia. She earned her bachelor's in nursing, magna cum laude, from Illinois Wesleyan University, Bloomington; her master's degrees in public health nursing and community health sciences from UIC; and her doctorate in health behavior and health education from the University of Michigan, Ann Arbor.

nih.gov

Celebrating National Nurses Day

Statement by Patricia Flatley Brennan, RN, PhD, Director, US National Library of Medicine

On May 6 we celebrate National Nurses Day! I salute my nurse colleagues who work tirelessly to provide compassionate, expert health care to patients with a wide array of health challenges, and I affirm that NLM stands with you.

I hope you can take a moment to absorb the outpouring of gratitude from around the world for the work you've been doing on the frontlines (and behind the scenes) in response to the COVID-19 pandemic. I hope you'll extend those good thoughts to the other health professionals and support staff partners in your endeavors. I join my words and my heart to those expressions of thanks and pledge the resources of the National Library of Medicine in support.

Photo courtesy of State Representative Roland Lemar, East Haven Connecticut

While the Library can't manufacture more time, fabricate personal protective equipment, or stand beside the bed of a patient in need, we can help nurses find freely accessible literature, such as this informative article on palliative care for COVID-19 patients in nursing homes, through PubMed and our full-text literature database, PubMed Central.

And we know nurses are busy, so we're accelerating access to the literature by creating special search strategies like LitCovid, a curated literature hub for tracking up-to-date scientific information about the 2019 novel coronavirus. LitCovid provides centralized access to over 9,000 relevant articles in PubMed. Articles are categorized by research topic and geographic location for improved access and are updated daily to ensure relevancy. Read more about it in the recent piece by Chen et al. in Nature and download the data here.

We also know that clinicians don't have time to search widely for the information they need. So NLM is working with publishers and the White House Office of Science and Technology Policy to create the COVID-19 Open Research Dataset (CORD-19), a collection of more than 59,000 (and growing) journal articles, abstracts, and preprints on the SARS-CoV-2 virus. In partnership with the National Institute of Standards and Technology, the Allen Institute for Artificial Intelligence, Oregon Health & Science University, and the University of Texas Health Science Center at Houston, NLM is launching a community-wide challenge to devise new strategies to make it easier for clinicians and, ultimately, everyone to efficiently access the literature to get up-to-the-minute answers.

NLM's intramural researchers are engaged in building machine learning algorithms to assist in the rapid diagnosis of some of the clinical manifestations of COVID-19. An ensemble of machine learning algorithms has been trained to recognize bacterial and viral pneumonia opacifications (vague, fuzzy clouds of white in the darkness of a chest X-ray) from normal images and then further refine their own capability to differentiate COVID-19 from other viral pneumonias. This work, which has been ratified by three radiologists, can be quickly adapted for use in hospital and urgent care settings. And additional efforts are underway to provide predictive tracking and automated decision support for COVID-19 patients.

Through NLM's National Network of Libraries of Medicine, we're making sure that public libraries have access to the latest information about COVID-19. This supports nurses by providing community-level resources that raise awareness and inform the public about diagnosis and treatment. In a related effort, our New England Regional Medical Library recently offered a one-hour online class on strategies and resources to maintain sobriety during COVID-19 for individuals with substance use disorder and the people who support them, including nurses, who could earn continuing education credits.

Finally, NLM is working to make sure that the formal languages and terminologies used by nurses and others in the health care setting, such as LOINC, SNOMED CT, and RxNorm, include sufficient terms to correctly describe the COVID-19 patient experience and intervention. Through our Value Set Authority Center, a repository and authoring tool for public value sets (lists of codes and corresponding terms) that define clinical concepts to support effective and interoperable health information exchange, we've provided new COVID-19 value sets for use in quality monitoring and billing.

Compassion. Expertise. Trust.

I wonder if the creators of this tagline for National Nurses Day anticipated a world in such desperate need of compassion, expertise, and trust? How could they have envisioned the role that nurses would play in the patient journey through COVID-19? That a nurse would set up a video chat, so a new dad could be "present" at the birth of his child or a patient could say a final farewell? How could they have known that our nurse colleagues would need the support of all of us to face the daily professional challenges and personal risks of a global pandemic?

I am proud of the efforts of the NLM team to support nurses everywhere. We know we can't stand in your place, but we hope that our work makes your job a little easier.

nlmdirector.nlm.nih.gov

CPG

The Lady Who Became a Nurse

By Elizabeth Fee, Chief Historian in Office of the Associate Director for Library Operations at the National Library of Medicine, and Mary E. Garofalo, Research Nurse in the Laboratory of Host Defenses, National Institute of Allergy and Infectious Diseases, National Institutes of Health.

Florence Nightingale was born on May 12, 1820 of wealthy British parents who expected her to do all the things young ladies of her class did: to spend much of her time in the drawing room entertaining her sister or her friends; to take occasional rides in carriages, to visit others; to appear at parties and dinners; and to be occupied with embroidery, playing the piano, and painting — these activities were meant to be "charming" and not taken too seriously.

But Florence was different. She felt a higher calling; she wanted to work, to use her intellect, her skills, and her moral passion, to make a difference in the world. She was bored with the trivial lives that upper class women led; she had her destiny to fulfill. She told her parents that she wanted to be a nurse. They were horrified. "It was as if I had said I wanted to be a kitchen-maid," she wrote.

At last, after nine years of struggle, Florence's parents reluctantly allowed her to train as a nurse in Germany. On her return, she accepted a post as Superintendent of the "Establishment for Gentlewomen during Illness," on Harley Street in London. In 1853, her father gave her five hundred pounds a year, making her financially independent.

One year later, the Crimean War began. In 1854, under the authorization of Sidney Herbert, the Secretary of War, Florence Nightingale brought a team of 38 volunteer nurses to care for the British soldiers fighting in the Crimean War. Nightingale and her nurses arrived at the military hospital in Scutari and found soldiers wounded and dying amid horrifying sanitary conditions. Ten times more soldiers were dying of diseases such as typhus, typhoid, cholera, and dysentery than from battle wounds.

The hospital was dreadful: the soldiers were poorly cared for, medicines and other essentials were in short supply, hygiene was neglected, and infections were rampant. There was no clean linen; the clothes of the soldiers were swarming with bugs, lice, and fleas; the floors, walls, and ceilings were filthy; and rats were hiding under the beds. There were no towels, basins, or soap, and only 14 baths for approximately 2000 soldiers. The death count was the highest of all hospitals in the region. As Nightingale wrote in in a letter in 1855:

"I have seen the men come down through that long long dreadful winter (we received four thousand in seventeen days between Dec 17 /54 & Jan 3 /55) without other covering than a dirty blanket & a pair of old Regimental trousers when the stores were teeming with every kind of warm clothing, living skeletons devoured with vermin, ulcerated, hopeless & helpless & die without ever lifting up their heads 70–80 per diem on the Bosphorus alone up to the 13th Feby when we reached our maximum of mortality."

Nightingale's accomplishments in the Crimea were largely the result of her concern with sanitation and its relation to mortality, as well as her ability to lead, to organize, and to get things done. She fought with those military officers that she considered incompetent; they, in turn, considered her unfeminine and a nuisance. She worked endlessly to care for the soldiers themselves, making her rounds during the night after the medical officers had retired. She thus gained the name, "The Lady with the Lamp." Nightingale had to write sad letters about the fate of some of the wounded soldiers.

After the war, Nightingale returned to England, became an invalid and remained bed-ridden well into her sixties. From her bed, she produced over two hundred books, pamphlets, and reports, and over twelve thousand letters, mostly related to her work. When Nightingale got out of bed and reentered the world, she poured even more energy into her work. In the final years of her life, she reformed civilian hospitals, reorganized the War Office, founded the Nightingale School for the training of nurses, and brought public health and sanitation to India. After accomplishing an amazing amount, Nightingale died at the age of ninety in 1910.

National Library of Medicine

CPG

NIH Releases Strategic Plan to Accelerate Nutrition Research Over Next 10 Years

What if each of us had individualized dietary recommendations that helped us decide what, when, why, and how to eat to optimize our health and quality of life? This precision nutrition approach — developing targeted and effective diet interventions in a diverse population — is among the ambitious goals set out by the 2020-2030 Strategic Plan for National Institutes of Health Nutrition Research.

NIH, guided by its Nutrition Research Task Force (NRTF) and armed with the insights from the nutrition science community, practitioners, the public, and others, has created a bold vision to advance nutrition science discoveries over the next 10 years. With a focus on precision nutrition, the plan reflects the wide range of nutrition research supported across NIH – over $1.9 billion in fiscal year 2019. The strategic plan calls for a multidisciplinary approach through expanded collaboration across NIH Institutes and Centers to accelerate nutrition science and uncover the role of human nutrition in improving public health and reducing disease.

The strategic plan is organized around four strategic goals that answer key questions in nutrition research:

1. Spur Discovery and Innovation through Foundational Research: What do we eat and how does it affect us?
2. Investigate the Role of Dietary Patterns and Behaviors for Optimal Health: What and when should we eat?
3. Define the Role of Nutrition Across the Lifespan: How does what we eat promote health across our lifespan?
4. Reduce the Burden of Disease in Clinical Settings: How can we improve the use of food as medicine?

The plan has five cross-cutting areas relevant to all these strategic goals, including minority health and health disparities; health of women; rigor and reproducibility; data science, systems science, and artificial intelligence; and training the nutrition scientific workforce.

The strategic plan aligns with the National Nutrition Research Roadmap 2016-2021 created by the Interagency Committee on Human Nutrition Research, a trans-federal government committee charged with enhancing the coordination and communication among multiple federal agencies conducting nutrition research.

Dr. Catherine Woteki, USDA Chief Scientist and Under Secretary for Research, Education & Economics in Food and Nutrition Research and Science

As the plan is put into action, NIH will continue to seek input from the nutrition community and others. The task force will guide the plan's application through implementation working groups that will pursue opportunities to:

- advance the priorities identified in each of the strategic goals and cross-cutting research areas
- catalyze nutrition research at NIH-funded universities and institutions and in NIH labs

The task force will track the progress of the plan and post information on its website https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/nih-nutrition-research-task-force

nih.gov

Diet May Help Preserve Cognitive Function

According to a recent analysis of data from two major eye disease studies, adherence to the Mediterranean diet — high in vegetables, whole grains, fish, and olive oil — correlates with higher cognitive function. Dietary factors also seem to play a role in slowing cognitive decline. Researchers at the National Eye Institute (NEI), part of the National Institutes of Health, led the analysis of data from the Age-Related Eye Disease Study (AREDS) and AREDS2. They published their results today in Alzheimer's and Dementia: the Journal of the Alzheimer's Association.

"We do not always pay attention to our diets. We need to explore how nutrition affects the brain and the eye" said Emily Chew, MD, director of the NEI Division of Epidemiology and Clinical Applications and lead author of the studies.

The researchers examined the effects of nine components of the Mediterranean diet on cognition. The diet emphasizes consumption of whole fruits, vegetables, whole grains, nuts, legumes, fish, and olive oil, as well as reduced consumption of red meat and alcohol.

AREDS and AREDS2 assessed over years the effect of vitamins on age-related macular degeneration (AMD), which damages the light-sensitive retina. AREDS included about 4,000 participants with and without AMD, and AREDS2 included about 4,000 participants with AMD. The researchers assessed AREDS and AREDS2 participants for diet at the start of the studies. The AREDS study tested participants' cognitive function at five years, while AREDS2 tested cognitive function in participants at baseline and again two, four, and 10 years later. The researchers used standardized tests based on the Modified Mini-Mental State Examination to evaluate cognitive function as well as other tests. They assessed diet with a questionnaire that asked participants their average consumption of each Mediterranean diet component over the previous year.

Participants with the greatest adherence to the Mediterranean diet had the lowest risk of cognitive impairment. High fish and vegetable consumption appeared to have the greatest protective effect. At 10 years, AREDS2 participants with the highest fish consumption had the slowest rate of cognitive decline.

The numerical differences in cognitive function scores between participants with the highest versus lowest adherence to a Mediterranean diet were relatively small, meaning that individuals likely won't see a difference in daily function. But at a population level, the effects clearly show that cognition and neural health depend on diet.

The researchers also found that participants with the ApoE gene, which puts them at high risk for Alzheimer's disease, on average had lower cognitive function scores and greater decline than those without the gene. The benefits of close adherence to a Mediterranean diet were similar for people with and without the ApoE gene, meaning that the effects of diet on cognition are independent of genetic risk for Alzheimer's disease.

The AREDS and AREDS2 studies were supported by the NEI Intramural Research Program and contracts NOI-EY-0-2127 (AREDS), HHS-N-260-2005-00007-C (AREDS2), and N01-EY-5-0007 (AREDS2). Additional research funds were provided by the NIH Office of Dietary Supplements, the National Center for Complementary and Integrative Health, the National Institute on Aging, the National Heart, Lung, and Blood Institute, and the National Institute of Neurological Disorders and Stroke. The AREDS trial is registered at www.ClinicalTrials.gov as NCT00594672. AREDS2 is registered as NCT00345176. The studies took place at the NIH Clinical Center.

Reference

Keenan TD, Agron E, Mares J, Clemons TE, van Asten F, Swaroop A, and Chew E, for the AREDS and AREDS2 research groups. "Adherence to a Mediterranean diet and cognitive function in the Age-Related Eye Disease Studies 1 & 2." April 14, 2020. Alzheimer's and Dementia.

nih.gov

Annual Report to the Nation: Cancer Death Rates Continue to Decline

The Annual Report to the Nation on the Status of Cancer published in the journal Cancer finds that cancer death rates continued to decline from 2001 to 2017 in the United States for all cancer sites combined.

These decreases were seen in all major racial and ethnic groups and among men, women, adolescents, young adults, and children. Rates of new cancers (cancer incidence) for all cancers combined leveled off among men and increased slightly for women during 2012 to 2016.

In a companion paper to the report, researchers looked at progress toward Healthy People 2020 objectives for four common cancers: lung, prostate, female breast, and colorectal.

The annual report is a collaborative effort among the Centers for Disease Control and Prevention (CDC); the National Cancer Institute (NCI, part of the National Institutes of Health); the American Cancer Society (ACS); and the North American Association of Central Cancer Registries (NAACCR).

This year's report showed that overall cancer death rates decreased 1.5% on average per year from 2001 to 2017, decreasing more rapidly among men (by 1.8% per year) than among women (1.4% per year). The report found that overall cancer death rates decreased in every racial and ethnic group during 2013–2017.

"The United States continues to make significant progress in cancer prevention, early detection, and treatment," said CDC

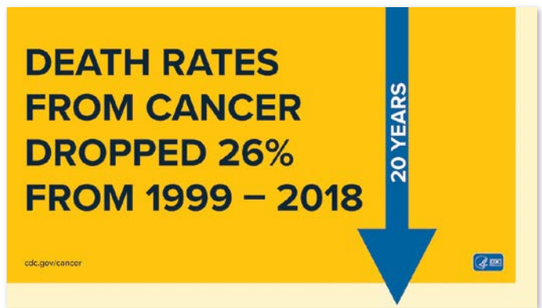


Photo courtesy of the CDC

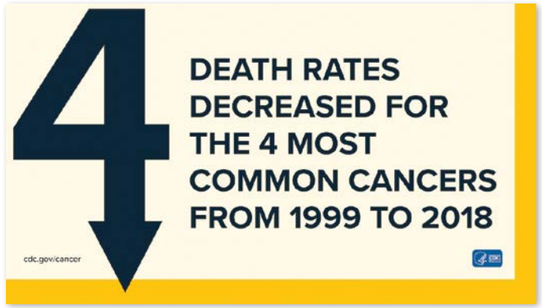


Photo courtesy of the CDC

Director Robert R. Redfield, MD. "While we are encouraged that overall cancer death rates have decreased, there is still much more we can do to prevent new cancers and support communities, families, and cancer survivors in this ongoing battle."

National Status of Cancer Report Findings

The data analyzed in the report combines cancer incidence data collected by CDC's National Program of Cancer Registries (NPCR) and NCI's Surveillance, Epidemiology, and End Results (SEER) Program, as well as mortality data from CDC's National Center for Health Statistics.

The report found that from 2013 to 2017:

- Among men, death rates decreased for 11 of the 19 most common cancers, were stable for four cancers (including prostate), and increased for four cancers (oral cavity and pharynx, soft tissue including heart, brain and other nervous system, and pancreas).
- Among women, death rates decreased for 14 of the 20 most common cancers, including the three most common cancers (lung and bronchus, breast, and colorectal), but increased for cancers of the uterus, liver, brain and other nervous system, soft tissue including heart, and pancreas. Rates were stable for oral cavity and pharynx cancer.
- Overall cancer death rates among children ages 0 to 14 years decreased an average of 1.4% per year. Among adolescents and young adults ages 15 to 39 years, overall cancer death rates decreased an average of 1.0% per year.
- Melanoma death rates decreased 6.1% per year among men and 6.3% per year among women.
- Lung cancer death rates decreased 4.8% per year among men and 3.7% per year among women. However, lung cancer continues to be the leading cause of cancer death, accounting for about one-fourth of all cancer deaths.

"The drops in mortality we're seeing are real, sustained, and a strong indication of what we can do when we work to prevent and treat cancer," said William G. Cance, MD, ACS Chief Medical and Scientific Officer. "But we can and must do more, particularly to ensure everyone in the United States has access to the resources that are all too often benefitting only the most fortunate."

Photo courtesy of the Office on Women's Health

For cancer incidence, notable findings include that from 2012 to 2016, incidence rates for all cancers combined were stable in men and increased slightly in women. In addition, rates of new cancers were stable among white men and decreased among black, Asian/Pacific Islander (API), American Indian/Alaska Native (AI/AN), and Hispanic men.

"Thanks to advances brought about by basic research, we are making remarkable progress against cancer," said NCI Director Norman E. "Ned" Sharpless, MD. "This report provides further evidence that cancer death rates continue to decline. But we must not be complacent. The cancer incidence data — especially the increase in cancer among women — is a clear reminder that there is more work ahead."

For the first time, the report provided rates and trends for the most common cancers among children (younger than 15 years) and among adolescents and young adults ages 15–39 years. Among children, overall cancer incidence rates increased an average of 0.8% per year during 2012 to 2016. The most common cancer types among children were leukemia, brain and other nervous system cancers, and lymphoma, with increasing incidence trends for each of these cancers during 2012 to 2016.

Among adolescents and young adults, overall cancer incidence rates increased an average of 0.9% per year from 2012 to 2016. The most common cancer among adolescents and young adults was female breast cancer; rates were highest among young black women.

"We look forward to improving surveillance of childhood cancers in the future by establishing specific databases for children to study these rare cancers. There are many unanswered questions in the realm of pediatric cancer and improving our tools to study them is essential to their ultimate prevention," said NAACCR Director Betsy Kohler.

Progress Toward Cancer-Reduction Targets

In a companion paper to the report, researchers measured progress toward the federal government's 10-year national objectives for improving Americans' health, an effort known as "Healthy People 2020." Specifically, researchers examined progress in four common cancers: lung, prostate, female breast, and colorectal.

Healthy People 2020 targets for reducing death rates were met for all cancers combined as well as for lung, prostate, female breast, and colorectal cancers overall — although not in all individual sociodemographic groups. Despite some progress over the past decade, the report shows the need to address disparities in cancer screening and in certain risk behaviors.

Healthy People 2020 targets were not met for adults to decrease cigarette smoking; to increase smoking cessation success; to reduce excessive alcohol use; or to reduce obesity prevalence — all behaviors linked to cancer risk.

Other findings on Healthy People 2020 targets include:

- From 2008 to 2015, breast cancer screening rates increased slightly among Hispanic women but dropped among other groups, particularly Asian women, women in rural areas, and women with public or no health insurance.
- The target for breast cancer screening of 81.1% was not met in any group except those with advanced educational degrees. Breast cancer screening rates were lowest among uninsured women.
- There was some improvement in colorectal cancer screening rates, which increased about 20% overall between 2008 and 2017 but did not reach the target of 70.5%, except among those with advanced educational degrees.
- Colorectal cancer screening increased by 35% or more in some groups, including AI/AN and Hispanic men and women, and men and women without health insurance.

nih.gov

NIH Scientists develop Blood Test to Help Improve Liver Cancer Screening

Scientists have developed a new test that can help identify people who are likely to develop hepatocellular carcinoma (HCC), the most common form of liver cancer. The approach uses a simple blood test to check for the patient's previous exposure to certain viruses.

A study of the new approach was led by researchers at the National Cancer Institute (NCI), part of the National Institutes of Health. The study also involved researchers from the National Institute of Diabetes and Digestive and Kidney Diseases and several academic centers. The findings were published June 10 in Cell.

"Together with existing screening tests, the new test could play an important role in screening people who are at risk for developing HCC. It could help doctors find and treat HCC early. The method is relatively simple and inexpensive, and it only requires a small blood sample," said the study's leader, Xin Wei Wang, PhD, co-leader of the NCI Center for Cancer Research (CCR) Liver Cancer Program.

Certain factors increase a person's chances of developing HCC, such as infection with hepatitis B or hepatitis C virus or cirrhosis of the liver. People who have risk factors are recommended to get screened for HCC every six months with an ultrasound with or without a blood test for alpha-fetoprotein.

But not everyone with risk factors for HCC will develop the disease. Although screening can lead to earlier detection, most patients are diagnosed when the cancer is advanced and often incurable. However, HCC that is caught early has a much better chance of being cured.

"We need a better way to identify people who have the highest risk for HCC and who should get screened more frequently," said Dr. Wang, who is also part of NCI's Translational Liver Cancer Consortium. Better early detection and surveillance approaches are particularly important because rates of HCC are rising in the United States.

"A main focus of the NCI CCR Liver Cancer Program is to develop new methods for early detection, diagnosis, and treatment, with the goal of improving outcomes for patients with HCC," said Tim Greten, MD, co-leader of the Liver Cancer Program and a collaborator of the study.

Many screening tests detect features of cancer cells. But those features can change over time, and not all cancer cells in a tumor have the same characteristics. The NCI team took a different approach: detecting features of the cancer's environment rather than cancer cells themselves.

More research is providing evidence that cancer development is influenced by interactions between viruses and the immune system. The team reasoned that certain interactions between viruses and the immune system may raise the risk of developing HCC. To explore that possibility, the scientists scanned people's blood for "footprints" left behind by past viral infections. Because these footprints are left in antibodies, proteins made by the immune system, they also reflect how the immune system reacted to the infection. The mixture of footprints each person has creates a unique pattern, which the researchers called a viral exposure signature.

The team checked for the footprints of more than 1,000 different viruses in blood samples from around 900 people, including 150 who had HCC. They identified a specific viral exposure signature that could accurately distinguish people with HCC from people with chronic liver disease and healthy volunteers. This signature contained footprints from 61 different viruses.

The researchers then tested the signature on blood samples from 173 people with chronic liver disease who were part of a 20-year study. During that time, 44 of the participants developed HCC. Using blood samples taken when the cancer was diagnosed, the signature correctly identified those who developed HCC (area under the curve, AUC=0.98). Importantly, the signature also worked when the researchers used blood samples taken at the beginning of the study, up to 10 years before diagnosis (AUC=0.91).

The signature appeared to be far more accurate than an alpha-fetoprotein test (AUC=0.91 vs. 0.62). An AUC of 0.5 indicates that a test is no better than chance in identifying disease, whereas an AUC of 1.0 represents a test with perfect accuracy.

The scientists are continuing to study their approach and plan to test it in clinical trials. They are collaborating with Katherine McGlynn, PhD, of NCI's Division of Cancer Epidemiology and Genetics to test the approach in a prospective surveillance study of people with risk factors for HCC.

It's possible that viral infections — even ones that don't cause cancer — may change the immune system in ways that influence the development of other cancers. For example, certain infections may lessen the immune system's ability to keep cancer cells in check. NCI scientists are testing the viral exposure signature in a study of prostate cancer, and others are considering applying the approach to a screening study for ovarian, esophageal, liver, and breast cancer in Africa.

nih.gov

CPG

Study of "Exceptional Responders" Yields Clues to Cancer and Potential Treatments

In a comprehensive analysis of patients with cancer who had exceptional responses to therapy, researchers have identified molecular changes in the patients' tumors that may explain some of the exceptional responses. The results demonstrate that genomic characterizations of cancer can uncover genetic alterations that may contribute to unexpected and long-lasting responses to treatment, according to the researchers.

The results appeared in Cancer Cell on Nov. 19. Researchers at the National Cancer Institute (NCI), part of the National Institutes of Health, conducted the study in collaboration with investigators from other institutions, including NCI-designated Cancer Centers.

"The majority of patients in this study had metastatic cancers that are typically difficult to treat, yet some of the patient responses lasted for many years," said Louis Staudt, MD, PhD, director of NCI's Center for Cancer Genomics, who co-led the study. "Researchers and the doctors who treat these patients have long been curious about the mechanisms underlying these rare responses to treatment. Using modern genomic tools, we can now start to solve these fascinating puzzles."

"As clinical researchers, we have a lot to learn from these patients, and they have a lot to teach us," said Percy Ivy, MD, of NCI's Division of Cancer Treatment and Diagnosis, who co-led the research. "The knowledge gained from studying exceptional responders can help inform how we take care of patients in the future and will help move us closer to the goal of precision oncology."

The retrospective study, which is now closed to accrual, included detailed medical histories and tumor samples from 111 patients with various types of cancer who had received standard treatments, such as chemotherapy. The patients had been identified by NCI's Exceptional Responders Initiative, a national project launched in 2014 to explore the feasibility of collecting and analyzing the data and biospecimens needed to better understand the biological basis of exceptional responses in cancer.

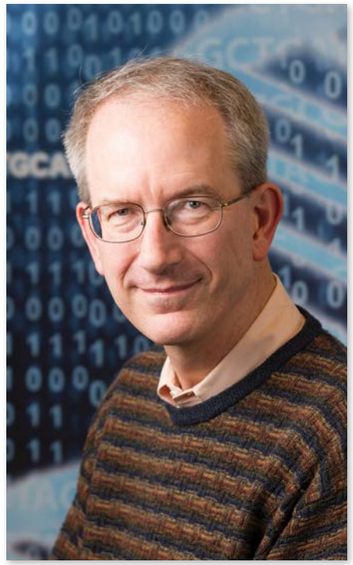
For 26 of the 111 (23.4%) patients, the researchers were able to identify molecular features that could potentially explain exceptional responses to treatment, such as the co-occurrence of multiple rare genetic changes in the tumor genome or the infiltration of the tumor with certain types of immune cells.

The study defined an exceptional responder as someone who had a partial or complete response to a treatment that would be effective in less than 10% of similar patients. The duration of an exceptional response is one that lasts at least three times longer than the median response time.

To analyze the tumor tissue (and normal tissue, when available) from patients in the study, the researchers used multiple genomic approaches — including analysis of DNA mutations, RNA expression levels, DNA copy number alterations, and DNA methylation — as well as analysis of the immune cells in the tumor microenvironment.

The mechanisms underlying exceptional responses in the study fit into several broad categories, including the body's ability to repair DNA damage and the immune system's response to tumors. Another category described rare combinations of genomic alterations that resulted in the death of tumor cells during treatment — a concept known as synthetic lethality.

For example, the researchers identified mutations in the BRCA1 or BRCA2 genes in two patients with cancers that rarely involve alterations in these genes, which help repair DNA. But in these patients, the researchers suggested, the mutations



Louis Staudt, MD, PhD is the Director of the NCI Center for Cancer Genomics and co-chief of the Lymphoid Malignancies Branch at the Center for Cancer Research, National Cancer Institute (NCI).

A genomic study has uncovered molecular changes in patient tumors that may give rise to dramatic and long-lasting responses to cancer therapy. Photo courtesy of the NHGRI

may have impaired the tumor's ability to fix damaged DNA, thereby increasing the effectiveness of treatments such as platinum-based chemotherapy that harm DNA.

"Our findings demonstrate the importance of testing patient tumors for alterations that may point to available treatments," Dr. Staudt said. "There is a need for a shift towards molecular diagnosis of cancer that provides information that cannot be gleaned from looking at tumors through a microscope."

The study also adds to the growing body of evidence highlighting the ability of the immune system to "kick in" and help eradicate tumors. In some patients in the study, increased levels of B lymphocytes, a type of immune cell, in tumors were associated with exceptional responses.

Results and hypotheses developed during this retrospective analysis will need to be confirmed by larger studies, according to the researchers. But if confirmed, the findings could potentially provide leads for investigators trying to develop treatments that exploit the vulnerabilities of tumor cells like those found in some exceptional responders, they noted.

For example, in two patients treated with the DNA-damaging drug temozolomide, the researchers identified two DNA-repair pathways that needed to be simultaneously inactivated to achieve an exceptional response. This finding supports the development of drugs that block these DNA repair mechanisms, which might generally improve the responses of patients with cancer to temozolomide.

"This proof-of-concept study demonstrates that the analysis of the tumors of exceptional responders is not only possible but necessary to learn as much as we can from these patients," said Dr. Ivy. "We are immensely grateful to the many generous patients who participated in this study, even though they had nothing to gain personally from doing so, and to our many collaborators across the country, without whom this work would not have been possible."

Since the Exceptional Responders Initiative began, researchers have reviewed the medical histories of more than 500 patients who had been recommended to the initiative by a physician. Chemotherapy is among the most widely used treatments for cancer, and the vast majority of the patients considered for enrollment in the initiative had exceptional responses to chemotherapy agents.

For the majority of the patients in the analysis, multiple genomic approaches were needed to characterize the tumor samples. Focusing on DNA mutations alone would not have provided the clues the investigators needed to develop hypotheses about the biological underpinnings of the responses, the researchers said.

More research and additional analytical approaches are needed to describe the molecular underpinnings of the unsolved cases of unexceptional responders, they noted. To encourage participation in this effort by investigators around the world, the NCI team and their colleagues have made their molecular profiling results and clinical information publicly available in the NCI Genomic Data Commons.

nih.gov

NIH Selects Dr. Michael Chiang as Director of the National Eye Institute

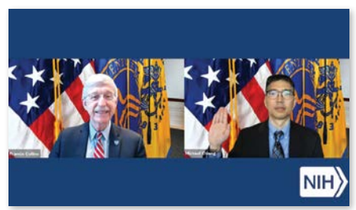
National Institutes of Health Director Francis S. Collins, MD, PhD, has chosen Michael F. Chiang, MD, as director of NIH's National Eye Institute (NEI). A practicing ophthalmologist, Dr. Chiang is currently the Knowles Professor of Ophthalmology & Medical Informatics and Clinical Epidemiology at Oregon Health & Science University (OHSU), Portland, and is associate director of the OHSU Casey Eye Institute. He is expected to begin his new role as the NEI director in late 2020. NEI conducts and supports research and training into blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight and the special health problems and requirements of the visually impaired.

"Dr. Chiang brings extensive experience as a clinician, researcher and educator to NIH. His work in biomedical informatics and telehealth research are particularly important for the future of vision research," said Dr. Collins. "I look forward to having him join the NIH leadership team later this year. I also want to recognize Santa J. Tumminia, PhD, for her dedicated leadership in serving as the acting director of NEI since October 2019."

As director, Dr. Chiang will oversee NEI's annual budget of nearly $824 million, the large majority of which supports vision research through approximately 1,600 research grants and training awards made to scientists at more than 250 medical centers, universities and other institutions across the country and around the world. NEI research leads to sight-saving treatments, reduces visual impairment and blindness and improves the quality of life for people of all ages. The institute also conducts laboratory and patient-oriented research at its own facilities on the NIH campus in Bethesda, Maryland.

Dr. Michael F. Chiang

Dr. Chiang's own research involves telemedicine and artificial intelligence for diagnosis of retinopathy of prematurity and other ophthalmic diseases, implementation and evaluation of electronic health record systems, modeling of clinical workflow and data analytics. He has been a principal investigator on multiple NIH grants since 2003, and he and his research group have published more than 200 peer-reviewed journal papers.



At a virtual ceremony on Nov. 16, 2020, Michael F. Chiang was sworn in as the new director of the National Eye Institute (NEI) by Director Francis S. Collins, MD, PhD.

Dr. Chiang's clinical practice focuses on pediatric ophthalmology and adult strabismus.

Dr. Chiang has mentored over 50 post-doctoral fellows, medical students and graduate students. He co-directs an OHSU-wide, NIH-funded vision science training program for pre-doctoral and post-doctoral students, and co-directs an NIH-funded, mentored clinician-scientist program in ophthalmology.

Dr. Chiang is past chair of the American Academy of Ophthalmology (AAO) Medical Information Technology Committee and has served as an at-large member of the AAO Board of Trustees. He is a member of the AAO IRIS (Intelligent Research in Sight) Registry Executive Committee and chair of the AAO IRIS Registry Data Analytics Committee. He serves as Associate Editor for the Journal of the American Medical Informatics Association and has served as an Associate Editor for the Journal of the American Association for Pediatric Ophthalmology & Strabismus. He serves on the editorial boards for the journals Ophthalmology, Asia-Pacific Journal of Ophthalmology and EyeNet.

Dr. Chiang earned his bachelor's in electrical engineering and biology from Stanford University, Stanford, California; his master's degree in biomedical informatics from Columbia University College of Physicians and Surgeons, New York City; and his MD and master's in medical science from Harvard Medical School and Harvard-MIT Division of Health Sciences and Technology, Boston.

nih.gov

NIH Launches International Study of AMD Progression

Natural history investigation will deploy latest advances to identify biomarkers, targets for early therapy.

February is National AMD Awareness Month and a new clinical study led by the National Eye Institute (NEI), part of the National Institutes of Health, will follow 500 people over five years to learn more about the natural history of early age-related macular degeneration (AMD). By using the latest technologies to visualize structures within the eye and measure their function, researchers hope to identify biomarkers of disease progression, well before it advances to late-stage disease and causes vision loss. AMD is the leading cause of vision impairment and blindness among people age 50 and older in the United States.

"The findings will contribute to our understanding of the underlying biology driving the transition from early to late-stage disease so that therapies can be developed to halt its progression," said the study's lead investigator, Emily Y. Chew, MD, deputy clinical director at NEI and director of the NEI Division of Epidemiology and Clinical Applications. "Treatments that halt the disease at its early stage would have an enormous public health impact."

People with early AMD typically do not have daylight vision loss. As it progresses, AMD causes cells to die in the retina, the light-sensitive tissue at the back of the eye. Much of the damage occurs in the macula, an area of the retina responsible for sharp, central vision.

Only about 10 to 20 percent of people with early AMD progress to late-stage disease within five years. It is difficult to predict who will progress because AMD is a complex, multifactorial disease influenced by a combination of age, family history, genetic and health behavioral factors. A diet rich in green leafy vegetables and fish, for example, may reduce the risk, while smoking cigarettes increases it.

"We want to better leverage advances in genetics, imaging and visual functioning tests so we can look at early stage disease with more granularity. There may be surrogate markers of an individual's risk of developing late-stage disease long before the disease progresses," Dr. Chew said.

The AMD Ryan Initiative Study (ARIS) will track the eye health of 200 people who have bilateral early AMD, defined by the presence of medium-size drusen, yellowish deposits that accumulate under the retina. In addition, ARIS will include 200 people with early, reticular pseudodrusen, a type of lesion that causes the retina to have a giraffe-like macular pattern. The composition and location of the reticular pseudodrusen differ from that of typical drusen. Some data suggest reticular pseudodrusen are associated with a higher than usual risk for progression to late disease, but more research is needed about this group. For comparison, the study will enroll 100 age-matched, drusen-free control participants.

All participants will undergo routine spectral domain optical coherence tomography (SD-OCT), a type of imaging that shows high-resolution, cross-sectional views of the retina. SD-OCT is sensitive enough to detect even small changes in the volume of drusen over time.

In addition, visual function will be measured by dark-adapted fundus perimetry, a test that measures the sensitivity of light perception in specific parts of the retina after a person's eyes have adapted to the dark. Another visual function test, dark adaption, is useful for evaluating night vision impairment. Dark-adaptation studies are relevant because AMD tends to first damage rod photoreceptors (the retinal cells that allow for vision under dim conditions) earlier than it does cone photoreceptors, which enable daylight vision.

Researchers at each of the 20 ARIS study sites will track drusen volume changes as well as other findings on SD-OCT to see if they correspond to functional changes in visual acuity and dark adaptation.

Ideally, the investigators would like to complement their studies by analyzing the participants' DNA to look for correlations between genes and AMD progression. In total, scientists have so far identified 52 independent genetic variants associated with AMD. Further research is needed to determine if and how these variants influence the development and progression of the disease.

The clinical study is funded by NEI, with study sites located throughout the United States, the United Kingdom, Australia, Germany and Italy.

The study is named after the late Stephen J. Ryan, MD, a widely recognized expert in retinal disease and president of the Doheny Eye Institute, an independent non-profit institution supporting ophthalmic research, training and clinical care. The Stephen J. Ryan Initiative for Macular Research is an interdisciplinary program at the Doheny Eye Institute that supports the ARIS investigation.

nih.gov

Cataract Surgery in Infancy Increases Glaucoma Risk

NIH-funded clinical trial shows risk is similar whether or not a cloudy lens is replaced with a lens implant. Study suggests lifelong monitoring is crucial to preventing glaucoma-related vision loss.

Children who undergo cataract surgery as infants have a 22% risk of glaucoma 10 years later, whether or not they receive an intraocular lens implant. The findings come from the National Eye Institute (NEI)-funded Infant Aphakic Treatment Study, which published 10-year follow-up results.

"These findings underscore the need for long-term glaucoma surveillance among infant cataract surgery patients. They also provide some measure of assurance that it is not necessary to place an intraocular lens at the time of cataract surgery," said Michael F. Chiang, MD, director of NEI.

Scott R. Lambert, MD, professor of ophthalmology at Stanford University

"The results challenge the notion that replacing the child's lens with an implanted one protects the child from developing glaucoma, a belief among some pediatric ophthalmology surgeons," said the trial's principal investigator, Scott R. Lambert, MD, professor of ophthalmology at Stanford University, Palo Alto, California.

At the time of cataract removal, the 114 study participants (ages 1-6 months) had been born with cataract in one eye. In the operating room, the infants were randomly assigned to receive an artificial lens implant or go without a lens, a condition called aphakia.

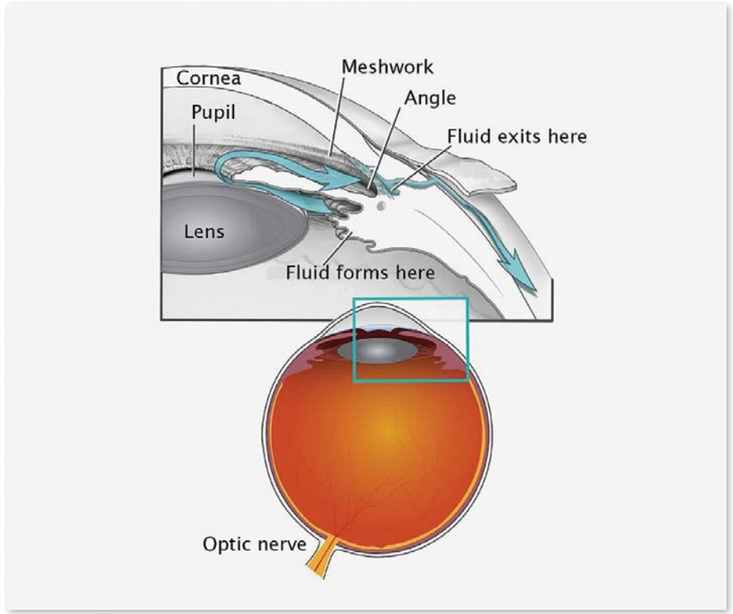
Annually, fewer than 2,500 children in the U.S. are born with cataract, a clouding of the eye's lens. Surgery is used to remove and replace the cloudy lens. To allow the child's eye to focus light properly following removal of the cataract, an intraocular lens implant may be placed at surgery, or the eye may be left aphakic, and a contact lens (or glasses, if both eyes have had a cataract removed) may be used to provide the needed correction.

"I tell patients' parents that implanting a lens in the infant's eye is like buying your child's wedding shoes when they're an infant. It is hard to predict what final power the intraocular lens should have, without knowing how that eye will grow over the years, so placing a lens at the time of cataract removal in an infant involves estimation, and may not turn out to be correct. Hence the eye may end up needing strong glasses or even replacement of the original lens implant.," said the lead author on the paper, Sharon F. Freedman, MD, a pediatric glaucoma specialist at Duke University, Durham, North Carolina.

Sharon Freedman, MD, Principal Investigator, Professor of Ophthalmology and Pediatrics Chief, Pediatrics and Strabismus Service, Duke University Ophthalmology

Children who undergo cataract removal have an increased risk of glaucoma, a sight-threatening condition that damages the optic nerve — the connection between the eye and brain. Scientists speculate that surgery to remove the cataract interferes with the maturation of how fluid flows out of the infant's eye leading to increased eye pressure and optic nerve damage in some of these eyes.

Among the 110 children who were available for re-examination at 10 years, 25 eyes (24%) had developed glaucoma, and 21 eyes (20%) were glaucoma suspects due to elevated eye pressure. However, visual acuity was similar among those



The meshwork and angle are structures that allow fluid to exit the eye, as shown. Scientists speculate that surgery to remove the cataract interferes with the maturation of this "drainage" system that removes fluid from the infant's eye, leading to increased eye pressure and damage to the child's eye. Photo courtesy of NEI

eyes that developed glaucoma compared to those eyes that had not. The researchers found no evidence of glaucoma-related eye damage, assessed by imaging of the optic nerve head to measure the retinal nerve fiber layer thickness.

The investigators attribute the absence of glaucoma-related eye damage to close patient monitoring, as any sign of glaucoma was aggressively treated.

While the lifetime glaucoma risk trajectory for patients who have cataract removal as infants remains unknown, this study found that the risk of glaucoma after cataract removal rose from 9% at 1 year, to 17% at 5 years, and to 22% at 10 years.

"Any child who has had a cataract removed needs to be seen by an eye care provider once a year at a minimum," said Freedman. "Any child diagnosed with glaucoma or above-normal intraocular pressure without signs of ocular damage — what we called glaucoma suspect — should be monitored every four to six months depending upon the stability of the condition and the health of the eye."

At 10 years, 40% of the followed children had developed the diagnosis of glaucoma or glaucoma suspect. A glaucoma suspect is an eye that has above normal eye pressure or another feature suspicious but not diagnostic of glaucoma.

The findings also confirm that the timing of cataract surgery is a balancing act: Whereas surgery at younger ages increases glaucoma risk, delaying surgery increases risk of amblyopia, a leading cause of visual impairment in children that results when cataract in one eye causes the brain to ignore signals from that eye and favor the other eye.

Future studies of glaucoma following cataract surgery in children will benefit from groundwork by the Infant Aphakic Treatment Study. Freedman said collaboration among the 12 study centers defined diagnostic standards for pediatric glaucoma and glaucoma suspect and criteria for glaucoma-related adverse events. "This cohort began the process leading to an international classification of childhood glaucoma in 2013 that is used around the world today," she said.

References

Freedman, SF; Beck, AD; Nizam, A; Vanderveen, DK; Plager, DA; Morrison, DG; Drews-Botsch, CD; Lambert, SR; The Infant Aphakia Treatment Study Group. "Glaucoma-related adverse events at 10 years in the Infant Aphakia Treatment Study: a randomized clinical trial". Published December 17, 2020, Journal of the American Medical Association Ophthalmology.

nih.gov

NIH Names Dr. Rena D'Souza as Director of the National Institute of Dental and Craniofacial Research

National Institutes of Health Director Francis S. Collins, MD, PhD, has selected Rena N. D'Souza, DDS, MS, PhD, as director of NIH's National Institute of Dental and Craniofacial Research (NIDCR). A licensed dentist, Dr. D'Souza is currently the assistant vice president for academic affairs and education for health sciences at the University of Utah, Salt Lake City. There she also serves as a professor of dentistry, the Ole and Marty Jensen Chair of the School of Dentistry and professor of neurobiology and anatomy, pathology and surgery in the School of Medicine and the Department of Biomedical Engineering. She is expected to begin her new role as the NIDCR director later this year.

"Dr. D'Souza is renowned for her research in craniofacial development, genetics, tooth development and regenerative dental medicine. She has worked as a proponent for NIH for decades, serving on critical advisory committees and as an expert consultant on multiple projects," said Dr. Collins. "I look forward to having her join the NIH leadership team later this year. I also want to thank NIH Principal Deputy Director Lawrence A. Tabak, DDS, PhD, for his valuable leadership as the acting director of NIDCR since January 1, 2020."

As NIDCR director, Dr. D'Souza will oversee the institute's annual budget of over $475 million, which supports basic, translational and clinical research in areas of oral cancer, orofacial pain, tooth decay, periodontal disease, salivary gland dysfunction, craniofacial development and disorders and the oral complications of systemic diseases. The institute funds approximately 770 grants, 6,500 researchers and 200 organizations. Additionally, NIDCR supports research training and career development programs for approximately 350 people at various stages of their careers, from high school students to independent scientists.

Dr. D'Souza has been a principal investigator on multiple NIH and other federal grants since 1987 and has published 140 peer-reviewed journal papers and book chapters. Her research focuses on developmental biology and genetics; matrix biology; biomaterials, tissue engineering and stem cells; and clinical research. Her group's discovery that a novel mutation in PAX9 was responsible for a severe form of human tooth agenesis opened a new field of research to discover genes and mutations as well as therapies for common human inherited disorders of the craniofacial complex.

Dr. D'Souza's career honors are significant. She was selected to be the inaugural dean of the University of Utah's School of Dentistry, which was established in 2012. She is currently the elected chair in Dentistry and Oral Health Sciences Section and elected as a fellow of the American Association for the Advancement of Science. She also is a former president of the American Association for Dental Research and the International Association for Dental Research, a fellow of the American College of Dentists and the recipient of the 2017 American Association for Dental Research Irwin D. Mandel Distinguished Mentoring Award. Dr. D'Souza served on the NIH Advisory Committee to the Director in 2013-14, and on NIH study sections. She is a devoted mentor and champion of diversity in the biomedical research workforce. Since 1985, she has served as a volunteer dentist for women in need and people struggling with homelessness in Salt Lake City, Dallas and Houston.

Rena N. D'Souza, DDS, MS, PhD.
Photo courtesy of the University of Utah

Dr. D'Souza received her bachelor's degree in dental surgery from the University of Bombay, India, after which she completed her general practice residency. She earned her DDS, PhD and master's degree in pathology/biomedical sciences from the University of Texas Health Science Center in Houston.

nih.gov

Fewer Hip Fractures May Be Associated with Reductions in Smoking, Heavy Drinking

A new study, which analyzed 40 years of Framingham Heart Study data, found an association between lowered rates of hip fractures and decreases in smoking and heavy drinking.The rates of hip fractures in the United States have been declining over the past few decades. Although some experts attribute this change primarily to improved treatments for bone health, a new National Institutes of Health-supported study suggests other factors. These results indicate that modifiable lifestyle factors, along with treatments, may be beneficial to bone health. The findings appear July 27, 2020 in *JAMA Internal Medicine*.

Timothy Bhattacharyya, MD, a researcher with the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), part of NIH, led the analysis to determine what may be causing the drop in hip fracture rates. The research team included scientists from NIH's National Cancer Institute, the Hinda and Arthur Marcus Institute for Aging Research, part of the Hebrew SeniorLife, Beth Israel Deaconess Medical Center, Boston, and Harvard Medical School, Boston.

The analysis included information from 4,918 men and 5,634 women who participated in the Framingham Study. These individuals were followed for a first hip fracture between Jan. 1, 1970, and Dec. 31, 2010. The rates for hip fractures, which were adjusted for age, dropped by 4.4% each year across the 40-year study period. The decrease was seen in both men and women.

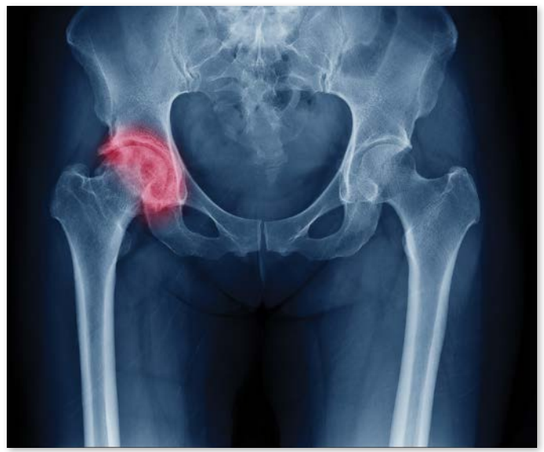


Photo courtesy of NIH

In this group, the rate of smoking decreased from 38% in the 1970s to 15% in the period from 2006 to 2010. During the same period, heavy drinking (defined as three or more drinks per day) fell from 7% to 4.5%. The rates of other risk factors for hip fracture, such as underweight and early menopause, did not change over the study period.

"This study points to the continued need for public health interventions to target modifiable lifestyle factors such as smoking and drinking, in addition to considering osteoporosis treatments in individuals at risk of hip fractures," said Bhattacharyya.

"As we learn more about lifestyle factors that impact bone health, we continue to conduct research aimed at understanding all the factors that contribute to reducing fractures, including both lifestyle and medications, so that we can all live longer lives without disability," Robert H. Carter, MD, acting director of NIAMS, added.

The Framingham Heart Study launched in 1948 to determine factors that contribute to cardiovascular disease. The National Heart, Lung, and Blood Institute, assumed responsibility for the project in 1949. Though many of the original participants have passed away, the study continues to examine another two generations of residents in and near Framingham, Massachusetts.

The study authors note that because the data was exclusively from white individuals, it is unclear whether other populations might show a similar correlation based on lifestyle factors. Another limiting factor was that Framingham participants had lower rates of obesity than the national average. Additionally, the study did not include measurements of bone mineral density, because such testing was not available until the 1990s.

nih.gov

HHS Congratulates NYSS Champions for Promoting Participation in Youth Sports

The U.S. Department of Health and Human Services (HHS) and the President's Council on Sports, Fitness and Nutrition (PCSFN) are pleased to recognize the National Youth Sports Strategy (NYSS) Champion organizations for their work promoting youth sports participation and supporting the NYSS. The NYSS is the first federal roadmap with actionable strategies to increase participation in youth sports, encourage regular physical activity, including active play, and promote good nutrition for all Americans. The NYSS aims to unite U.S. youth sports culture around a shared vision: that one day all youth will have the opportunity, motivation, and access to play sports — regardless of their race, ethnicity, sex, ability, or ZIP code. NYSS Champions represent organizations that are working toward achieving this vision.

"The National Youth Sports Strategy Champions are helping us advance toward the vision in youth sports: the day when all American youth have the opportunity, motivation, and access to play sports, whoever they are and wherever they live. Barriers to youth sports participation and the need for opportunities for physical exercise have only increased during the COVID-19 pandemic, and we look forward to continued work with the NYSS Champions to address these challenges," noted HHS Secretary Alex Azar.

Photo courtesy of the NIH Quarterly Wellness News

As a NYSS Champion, each organization has demonstrated its support of youth sports and commitment to the NYSS vision. NYSS Champions are recognized on health.gov as part of a growing network of organizations partnering with HHS to improve the youth sports landscape in America. Organizations will be formally announced today at the virtual PCSFN Annual Meeting.

"We know children who engage in regular physical activity experience important physical and mental health benefits, which are more important now during the COVID-19 pandemic than perhaps ever before," said ADM Brett Giroir, MD, assistant secretary for health at HHS. "I'm thrilled to acknowledge the work of the NYSS Champions who are furthering the mission of the NYSS and helping to foster a lifelong love of sports and physical activity for our Nation's youth."

NYSS Champions is led by the Office of Disease Prevention and Health Promotion (ODPHP) and the Executive Director of the PCSFN. The partnership opportunity is open to organizations that support the vision of the NYSS. More information on how to apply is available at https://health.gov/news/202006/announcing-opportunity-become-national-youth-sports-strategy-champion

The PCSFN is a Federal Advisory Committee supported by ODPHP and plays a vital role in keeping the Nation healthy. ODPHP and the Executive Director of the PCSFN accomplish this by setting national health goals and objectives and supporting programs, services, and education activities that improve the health of all Americans. ODPHP is part of the Office of the Assistant Secretary for Health within HHS. Visit ODPHP to learn more at https://health.gov/

hhs.gov

NIH Study Provides Genetic Insights into Osteosarcoma in Children

A study by researchers at the National Cancer Institute (NCI), part of the National Institutes of Health, offers new insight into genetic alterations associated with osteosarcoma, the most common cancerous bone tumor of children and adolescents. The researchers found that more people with osteosarcoma carry harmful, or likely harmful, variants in known cancer-susceptibility genes than people without osteosarcoma. This finding has implications for genetic testing of children with osteosarcoma, as well as their families.

The study was published March 19, 2020, in *JAMA Oncology*.

"With this study, we wanted to find out how many people with osteosarcoma may have been at high risk for it because of their genetics," said Lisa Mirabello, PhD, of NCI's Division of Cancer Epidemiology and Genetics (DCEG), who led the research. "We not only learned that at least a quarter of the people in the study with osteosarcoma had a variant in a gene known to predispose someone to cancer, we also uncovered variants that had never before been associated with this cancer."

In the study, the researchers looked for harmful (or likely harmful) variants in 238 known cancer-susceptibility genes in DNA samples from 1,244 people with osteosarcoma and compared the frequency of such variants with that in people in a cancer-free control group. They identified a harmful or likely harmful variant in a known cancer-susceptibility gene in 28% of the people with osteosarcoma. By contrast, only 12% of people in the cancer-free control group had such a variant.

When the authors looked at a subset of 166 genes that are known to be inherited in an autosomal dominant fashion—that is, where inheriting one alteration from one parent is sufficient to increase cancer risk — they saw harmful or likely harmful variants in about 18% of the patients but only 5% of controls. And another 25% of the patients had a rare variant of uncertain significance that was predicted to be harmful.

Patients who had harmful variants were younger at age of osteosarcoma diagnosis, on average, than patients who did not (15.3 years versus 16.9 years). In addition, the youngest children in the study (ages 0-10 years) had the highest prevalence of harmful variants.

If a child is found to have a gene variant associated with osteosarcoma, the authors say that genetic testing may be warranted for the child's family members, who may also carry the variant. Family members who have the variant could undergo screening for the cancers associated with that variant, potentially leading to earlier detection.

"The idea is, if you have a new patient with osteosarcoma, we found that a quarter of them have a [harmful] variant in a gene associated with increased risk of other cancers," said Sharon Savage, MD, senior author of the study, also of DCEG. "Genetic testing of the patient likely makes sense, because they could be at risk of other cancers, and they might have family members who carry the variant who might be at risk of other cancers."

Because osteosarcoma is a rare cancer, the researchers assembled case samples from 10 international research centers, making this the largest collection to date of a pediatric solid cancer evaluated for cancer-susceptibility gene variants.

The researchers found harmful or likely harmful variants in several cancer-susceptibility genes that hadn't been associated with osteosarcoma — or, indeed, pediatric cancers — before. Because the biological function for the variants newly found to be associated with osteosarcoma remain unknown, this could open new areas of research related to cancer susceptibility.

This study is part of a larger pediatric cancer susceptibility research program at NCI through which researchers are studying common and rare causes of osteosarcoma and other pediatric cancers. In earlier research, Dr. Mirabello found that TP53 gene variants, which are associated with the cancer predisposition disease Li-Fraumeni Syndrome, were more common than previously thought in children and adolescents with osteosarcoma. In the current study, TP53 gene variants had the highest frequency of the harmful or likely harmful cancer-susceptibility gene variants in children with osteosarcoma, another finding that Dr. Mirabello said warrants additional research.

nih.gov

Lung Development May Explain Why Some Non-Smokers Get COPD and Some Heavy Smokers Do Not

According to a new study, people with small airways relative to the size of their lungs may have a lower breathing capacity and, consequently, an increased risk for COPD — even if they don't smoke or have any other risk factors. The study, funded in part by the National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health, will publish in the June 9 issue of *JAMA*.

Chronic obstructive pulmonary disease (COPD), a debilitating lung condition, often develops as a result of smoking, but researchers have long puzzled over why nearly a third of cases occur in people who never smoked. Now they may finally have an answer — and it may be linked to how lungs develop in certain people.

"This work, stemming from the careful analysis of lung images of COPD patients, shows that an abnormal lung development may account for a large proportion of COPD risk among older adults," said James Kiley, PhD, director of NHLBI's Division of Lung Diseases. "More research is needed to understand what drives this occurrence and to devise possible interventions."

COPD, the fourth leading cause of death in the United States, causes airflow blockage and breathing-related problems that can severely limit a person's day-to-day activities. Smoking, asthma, or air pollution account for many COPD cases, but up to 30% of cases occur in people who never smoked, and only a minority of heavy smokers develop the disease, suggesting that there are other risk factors at play.

Previous research offered a clue about a possible cause, finding that about half of older adults with COPD appeared to have low lung function early in life. Benjamin Smith, MD, a pulmonary physician in the Department of Medicine at Columbia University Irving Medical Center, New York City, who was involved in the new study, explained the phenomenon.

When people breathe, they move air through their airways, beginning with the windpipe or trachea, which branches out to smaller airways called bronchi and bronchioles. As people grow, their airways are thought to develop in proportion to their lungs, but in some people, the airways grow smaller or larger than expected — a condition called dysanapsis — for reasons that are not clear.

To find out if small airways might be the culprit for COPD in people who did not smoke or have other risk factors, a team led by Smith looked at records for more than 6,500 older adults participating in three studies that included smokers and nonsmokers with and without COPD. Each study — the Multi-Ethnic Study of Atherosclerosis (MESA) Lung Study, the Subpopulations and Intermediate Outcome Measures in COPD Study (SPIROMICS), and the Canadian Cohort of Obstructive Lung Disease (CanCOLD) study — assessed dysanapsis using computed tomography (CT) scans of the lungs.

The MESA Lung study, based in six U.S. cities, included white, African American, Hispanic, and Chinese American people who were age 69 on average. The participants from the CanCOLD study were age 67 on average and came from nine Canadian cities. SPIROMICS, based at 12 U.S. medical centers, included people who were age 63 on average and reported 20 or more pack-years of smoking.

In the MESA Lung and CanCOLD studies, participants with smaller airways relative to lung size were much more likely to develop COPD compared with those with the larger airways relative to lung size. The association remained after considering standard COPD risk factors, including smoking, pollutants, and asthma.

The researchers then focused on participants from the CanCOLD study who never smoked and heavy smokers from the SPIROMICS study. Never smokers with COPD had much smaller airways relative to lung size, whereas the heavy smokers who did not have COPD had larger than normal airways.

"These results show that small airways relative to lung size are a very strong risk factor for COPD," said Smith, the lead study author. "This helps us to understand why 30% of COPD can occur in people who never smoked." With normal aging, lung function declines, so people who already have low lung function to begin with may develop COPD later in life, even if they don't smoke, he explained.

Smith added that the findings may also help explain why some lifelong heavy smokers do not develop COPD. People with larger airways relative to lung size may be able to withstand lung damage from smoking and still have enough breathing reserve to prevent them from developing COPD. Still, given the multiple health problems caused by tobacco, Smith emphasized that smokers should do their best to quit.

nih.gov

New Updates to Federal Guidelines Revamp Asthma Management

Updates to six key areas of asthma care focus on improving diagnosis, management and treatment.

The National Institutes of Health today announced 19 recommendations in six key areas of asthma diagnosis, management and treatment. The new guidance, published in the Journal of Allergy and Clinical Immunology, represents the first updates to federal comprehensive asthma management and treatment guidelines in more than a decade, and focuses on tailored treatment interventions for specific age groups based on disease severity using inhaled corticosteroids, long-acting antimuscarinic antagonists, immunotherapy, indoor allergen mitigation, fractional exhaled nitric oxide testing, and bronchial thermoplasty. The recommendations are based on systematic reviews conducted by the Agency for Healthcare Research and Quality and input from National Asthma Education Prevention Program (NAEPP) participant organizations, medical experts, and the public.

The National Heart, Lung, and Blood Institute (NHLBI), part of NIH, coordinates the NAEPP Coordinating Committee (NAEPPCC) and the 19-member expert panel working group which developed the 2020 Focused Updates to the Asthma Management Guidelines: A Report from The National Asthma Education and Prevention Program Expert Panel Working Group.

"NHLBI's goal is to ensure that care for all individuals living with asthma is optimal, equitable, and based on the best available evidence," said NHLBI Director Gary H. Gibbons, MD. "These updates to the guidelines are intended to support informed, shared decision making between patients and their providers, so that people living with this chronic condition can lead full and active lives."

Asthma affects the airways of the lungs, causing them to narrow and interfere with breathing. According to the Centers for Disease Control and Prevention, about 25 million people in the United States have the condition, including 5.5 million children. Without appropriate treatment, asthma can significantly limit activities and result in flare-ups that may lead to hospitalization or death.

"The last national guidance on asthma care was published 13 years ago, and since then we've made substantial progress in understanding how to treat asthma in children and adults," said Michelle M. Cloutier, MD, professor emerita, UCONN School of Medicine, and chair of the NAEPPCC Expert Panel Working Group. "In addition to asthma management varying by age group and disease severity, the preferences and values that individuals with asthma place on different therapies must be considered. The new guidelines reflect some of these new approaches."

The focused updates provide new guidance for six areas:

- Using inhaled corticosteroids when needed for recurrent wheezing or persistent asthma.
- Using long-acting antimuscarinic antagonists (LAMAs) with inhaled corticosteroids for long-term asthma management. A LAMA is a bronchodilator, a medicine that helps to keep airway muscles relaxed.
- Using allergy shots that contain very small amounts of allergen to treat some people with allergic asthma.
- Using one or more methods to reduce exposure to indoor asthma triggers.
- Using a fractional exhaled nitric oxide test to help manage asthma or help confirm a diagnosis in some patients when the diagnosis is unclear. This test involves breathing into a tube connected to a machine that measures the amount of nitric oxide, which can increase when there is airway inflammation.
- Using bronchial thermoplasty to treat selected adults with persistent asthma. During this procedure heat is used to reduce the muscle around the airways.

Several new features aim to help health care providers and clinicians engage successfully with their patients and families to put the recommendations into practice. For example, implementation guidance sections provide expanded summaries of the recommendations to quickly assist clinicians; indicate to whom the guidance applies; show how to use it in patient care and list issues to discuss with patients and families. The stepwise treatment tables for asthma management also have been updated.

Additional resources for health care providers, including the 2020 Focused Updates to the Asthma Management Guidelines clinician's and at-a-glance guides (with updated stepwise tables), fact sheets on the updated topic areas and FAQs, are available at www.nhlbi.nih.gov/asthmaguidelines. Along with these clinician resources, educational resources for patients and caregivers are also available through NHLBI's Learn More Breathe BetterSM program at www.nhlbi.nih.gov/BreatheBetter

nih.gov

NIH Selects Dr. Lindsey Criswell as Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases

National Institutes of Health Director Francis S. Collins, MD, PhD, has selected Lindsey A. Criswell, MD, MPH, DSc, as director of NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). A rheumatologist, Dr. Criswell is currently the vice chancellor of research at the University of California, San Francisco (UCSF). She is a professor of rheumatology in UCSF's Department of Medicine, as well as a professor of orofacial sciences in its School of Dentistry. She is expected to begin her new role as the NIAMS director in early 2021. She will succeed long-time director Stephen I. Katz, MD, PhD, who passed away suddenly in December 2018.

"Dr. Criswell has rich experience as a clinician, researcher and administrator. Her ability to oversee the research program of one of the country's top research-intensive medical schools, and her expertise in autoimmune diseases, including rheumatoid arthritis and lupus, make her well-positioned to direct NIAMS," said Dr. Collins. "I look forward to having her join the NIH leadership team early next year. I also want to thank Robert H. Carter, MD, for his exemplary work as the acting director of NIAMS since December 2018."

As NIAMS director, Dr. Criswell will oversee the institute's annual budget of nearly $625 million, which supports research into the causes, treatment and prevention of arthritis and musculoskeletal and skin diseases. The institute advances health through biomedical and behavioral research, research training and dissemination of information on research progress in these diseases.

Lindsey A. Criswell, MD, MPH, DSc, Director of NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

The NIAMS Division of Extramural Research supports scientific studies and research training and career development throughout the country through grants and contracts to research organizations in fields that include rheumatology, muscle biology, orthopaedics, bone and mineral metabolism and dermatology. NIAMS-supported research addresses some of the most common and disabling chronic diseases that affect almost every household in America.

Dr. Criswell has been a principal investigator on multiple NIH grants since 1994 and has published more than 200 peer-reviewed journal papers. Her research focuses on the genetics and epidemiology of human autoimmune disease, particularly rheumatoid arthritis and systemic lupus erythematosus. Using genome-wide association and other genetic studies, her research team contributed to the identification of more than 30 genes linked to these disorders.

Dr. Criswell's many honors include the Kenneth H. Fye, MD, endowed chair in rheumatology and the Jean S. Engleman Distinguished Professorship in Rheumatology at UCSF, and the Henry Kunkel Young Investigator Award from the American College of Rheumatology. She also received UCSF's 2014 Resident Clinical and Translational Research Mentor of the Year. During her career, she has mentored some four dozen students (high school through medical/graduate school), medical residents, postdoctoral fellows and junior faculty.

Dr. Criswell earned a bachelor's degree in genetics and a master's degree in public health from the University of California, Berkeley; a DSc in genetic epidemiology from the Netherlands Institute for Health Sciences, Rotterdam; and an MD from UCSF. In addition to completing a residency in internal medicine and a fellowship in rheumatology, she is certified as a first responder in wilderness medicine.

nih.gov

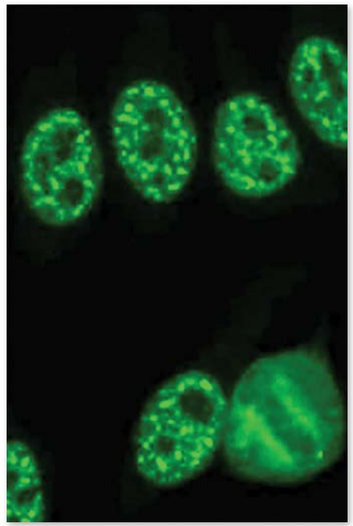
Autoimmunity May be Rising in the United States

Autoimmunity, a condition in which the body's immune system reacts with components of its own cells, appears to be increasing in the United States, according to scientists at the National Institutes of Health and their collaborators.

In a study published April 8 in Arthritis and Rheumatology, the researchers found that the prevalence of antinuclear antibodies (ANA), the most common biomarker of autoimmunity, was significantly increasing in the United States overall and particularly in certain groups. These groups include males, non-Hispanic whites, adults 50 years and older, and adolescents. The study is the first to evaluate ANA changes over time in a representative sampling of the U.S. population.

"The reasons for the increases in ANA are not clear, but they are concerning and may suggest a possible increase in future autoimmune disease," said corresponding and senior author Frederick Miller, MD, PhD, deputy chief of the Clinical Research Branch at the National Institute of Environmental Health Sciences (NIEHS), part of NIH. "These findings could help us understand more about the causes of these immune abnormalities and possibly learn what drives development of autoimmune diseases and how to prevent them."

The study included 14,211 participants, 12 years and older, in the U.S. National Health and Nutrition Examination Survey (NHANES). The scientists used immunofluorescence, a technique that uses fluorescent dye to visualize antibodies, to examine the frequencies of ANAs in subjects from three time periods. They found that ANA prevalence for 1988-1991 was 11.0%, while for 1999-2004 it was 11.5%, and for 2011-2012 it was 15.9%. These percentages corresponded to 22, 27, and 41 million affected individuals, respectively.



Immunofluorescent staining of human cells shows ANA as bright dots. Photo credit Edward Chan, PhD, University of Florida

Of the four demographic groups that displayed considerable ANA increases, findings in the adolescent group were the most worrisome to the research team. Young people, ages 12-19, had the largest ANA increases in the study, going from a two-fold to a three-fold increase over the three timeframes.

The researchers want to know why they are seeing these changes in autoimmunity in each of the groups, but especially in teenagers. Since people have not changed much genetically during the past 30 years, the scientists suggest that changes in lifestyle or the environment may be involved in ANA increases.

"These new findings may have important public health implications and will help us design studies to better understand why some people develop autoimmune diseases," said Christine Parks, PhD, co-author and staff scientist in the NIEHS Epidemiology Branch. She added that autoimmune diseases are a group of more than 100 chronic, debilitating conditions.

Determining whether autoimmune diseases, like lupus or myositis, are increasing in prevalence requires a clinical evaluation, which was not performed in this study. Nevertheless, ANA are commonly seen in patients with these conditions and similar autoimmune disorders. Co-author and NIEHS Scientific Director Darryl Zeldin, MD, said other studies have suggested there is an increase in autoimmune disease prevalence, but the findings are based on incomplete data. He and Miller hope that a national registry of autoimmune diseases will be established so that they can examine changes over time, define geographic hotspots, and eventually understand what is causing them.

"Hopefully, this important study will stimulate further research on the environmental factors related to the apparent increased prevalence of autoimmune diseases," Zeldin said.

nih.gov

Secretary Azar Statement on Final Rule to Increase Access to Lifesaving Organs

The Department of Health and Human Services, through the Centers for Medicare & Medicaid Services (CMS), is finalizing a rule that is designed to increase the supply of lifesaving organs available for transplant in the United States by requiring that the organizations responsible for organ procurement be transparent in their performance, highlighting the best and worst performers, and requiring them to compete on their ability to successfully facilitate transplants.

"There are few more transformative interventions for someone's health than an organ transplant, but thousands of Americans are deprived of this lifesaving opportunity every year by a broken system. By making overdue reforms to hold organ procurement organizations accountable, we're giving thousands of Americans waiting for organ transplants a chance at better, longer, and healthier lives.", said Secretary Azar.

hhs.gov

Dorry Segev, MD, PhD, a leader in the field of organ transplantation, pictured at right, is working on multiple NIH-funded studies on organ transplantation. Photo courtesy of the National Library of Medicine

HHS Announces New Organ Transplant Guidance

Update Improves Transplant Safety and Access to Lifesaving Organs

The U.S. Department of Health and Human Services and the U.S. Public Health Service (USPHS) published an updated solid organ transplant guideline to assess donors and monitor recipients for human immunodeficiency virus (HIV), hepatitis B virus, and hepatitis C virus infections. This guideline reflects advances in transplant technology and safety that can increase the number of organs available for transplants.

Currently, more than 110,000 patients in the United States are waiting for an organ transplant. "Under President Trump, HHS has made it a priority to expand access to lifesaving organ transplants," said HHS Secretary Alex Azar. "Updating our transplant guidelines to match the latest science will complement the other efforts made to expand the supply of donated organs and incentivize transplants, allowing more Americans to live longer, healthier lives."

"This guideline brings us one step closer to shortening the national transplant waiting list and saving more lives," said Admiral Brett P. Giroir, MD, assistant secretary for health. "It reflects the impressive advances in testing and treatment over the last seven years and provides actionable steps that will protect transplant patients from HIV and hepatitis B and C viruses."

Previously, organs available for transplant may have been declined because of concerns about the potential for HIV, hepatitis B virus, or hepatitis C virus infection, particularly when donors had risk factors for infection such as injecting drugs. Advances in highly accurate testing have made it easier for healthcare providers to quickly determine whether a potential organ donor has an infection. As a result, the risk for getting these infections because of a transplant is very low.

In the extremely rare case that a patient develops one of these infections as the result of an organ transplant, by following this new guidance, healthcare providers will be able to detect an infection early and immediately begin treatment. A cure for hepatitis C is available, and safe and effective treatments for HIV and hepatitis B allow patients with these infections to remain well despite the infection. This guideline also recommends that organ transplant recipients receive hepatitis B vaccination.

"This is an important step forward for individuals in need of solid organ transplants," said Centers for Disease Control and Prevention (CDC) Director Robert Redfield, MD. "Today's guideline is grounded in scientific evidence and advancements in testing technologies. These recommendations further expand the availability of life changing organs for those in need."

The COVID-19 pandemic impacted clinical operations and resources at many hospitals, transplant centers, and organ procurement organizations across the nation. Experts in the organ donation and transplantation community have carefully evaluated the risk of COVID-19 among organ transplant candidates and potential organ donors. Although there was a decrease in the number of organ transplants being performed in the United States because of the COVID-19 pandemic, the number is beginning to increase.

Several federal agencies provide oversight of organ donation, procurement, and transplantation. The CDC, in collaboration with USPHS partners, develops recommendations for organ donor testing and recipient monitoring intended to prevent and control the transmission of infectious diseases through organ transplantation. The Organ Procurement and Transplantation Network (OPTN), overseen by contract by the Health Resources and Services Administration (HRSA), develops policies for organ donation safety, donor selection and evaluation, organ procurement and transport, organ allocation, recipient informed consent and follow up monitoring for outcomes, safety and infections. OPTN is responsible for developing policies consistent with guidance of the CDC to test potential organ donors and following transplant recipients to prevent the spread of infectious disease. OPTN will conduct a systematic review of its existing policies to ensure they align with the new recommendations.

hhs.gov

HHS Launching Initiative to Track Physician Use and Burdens of Health IT ONC Awards Cooperative Agreement to American Board of Family Medicine

The U.S. Department of Health and Human Services (HHS) launched an initiative to measure health information technology (health IT) use among office-based physicians across the country.

The HHS' Office of the National Coordinator for Health Information Technology (ONC) awarded a cooperative agreement to the American Board of Family Medicine (ABFM) to measure the use and potential burdens experienced by office-based physicians. The results of the effort will provide ONC with national-level data on how office-based physicians use health IT, including key measures on interoperability and burden.

This effort builds on prior research that found, in 2017, approximately 80 percent of office-based physicians used a certified electronic health record (EHR), but only one in ten of those physicians reported that they were able to electronically send, receive, find, and integrate health data from EHRs outside of their networks. Under the three-year cooperative agreement, the American Board of Family Medicine will:

- Develop key measures related to health IT use and the interoperability of health information,
- Collect data from a nationally representative sample of office-based physicians to support national level progress,
- Collaborate with ONC on the analysis and interpretation of the survey results.

ONC expects the data will help identify disparities or unintended consequences due to the use of health IT and the impacts of federal health IT policies to guide future policy decisions.

The Office of the National Coordinator for Health Information Technology (ONC) is at the forefront of the administration's health IT efforts and is a resource to the entire health system to support the adoption of health information technology and the promotion of nationwide health information exchange to improve health care.

ONC is organizationally located within the Office of the Secretary for the U.S. Department of Health and Human Services (HHS).

ONC is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information.

The position of National Coordinator was created in 2004, through an Executive Order, and legislatively mandated in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009.

hhs.gov

Testing with Combined Biopsy Method Improves Prostate Cancer Diagnosis in NIH study

Improved diagnosis could reduce the risk of both overtreatment and undertreatment of the disease

A method of testing for prostate cancer developed at the National Cancer Institute (NCI) leads to more accurate diagnosis and prediction of the course of the disease, according to a large study. This method, which combines systematic biopsy, the current primary diagnostic approach, with MRI-targeted biopsy, is poised to greatly improve prostate cancer diagnosis, thereby reducing the risk of both overtreatment and undertreatment of the disease. NCI is part of the National Institutes of Health.

The findings were published March 5, 2020, in the *New England Journal of Medicine*. The study was conducted at the NIH Clinical Center in Bethesda, Maryland.

"Prostate cancer has been one of the only solid tumors diagnosed by performing systematic biopsies 'blind' to the cancer's location. For decades this has led to the overdiagnosis and subsequent unnecessary treatment of non-lethal cancers, as well as to missing aggressive high-grade cancers and their opportunity for cure," said Peter Pinto, MD, of the Urologic Oncology Branch in NCI's Center for Cancer Research and senior author of the study. "With the addition of MRI-targeted biopsy to systematic biopsy, we can now identify the most lethal cancers within the prostate earlier, providing patients the potential for better treatment before the cancers spread."

Prostate cancer can vary widely in severity and its potential to spread. Low-grade prostate cancer is associated with a very low risk of cancer-specific death and often doesn't require treatment, whereas high-grade cancers are much more likely to spread and are responsible for most prostate cancer deaths. This makes the correct assessment of the cancer grade very important for treatment decisions.

Unlike biopsies for most other types of cancer, which target abnormalities found by imaging, systematic biopsy uses a non-targeted method of taking systematically spaced samples across the prostate gland to find a cancer. Because this method can potentially miss areas of cancer, doctors may then overtreat a patient with low-grade disease, fearing there is high-grade disease they missed. Or, if an aggressive cancer is missed, a patient may be undertreated.

MRI-targeted biopsies, which merge previously taken MRI images of suspected cancer with real-time ultrasound technology, are better able to detect more high-grade cancers than systematic biopsies. The goal of this study was to determine whether it would be better to replace systematic biopsy with MRI-targeted biopsies or use both tests together.

In the study, 2,103 men who had MRI-visible lesions underwent both MRI-targeted and systematic biopsies. Of these men, 1,312 were diagnosed with cancer and 404 underwent prostatectomy, a full removal of the prostate. By comparing diagnoses from systematic biopsy alone to systematic biopsy plus MRI-targeted biopsy, the researchers found that adding MRI-targeted biopsy to systematic biopsy led to 208 more cancer diagnoses than systematic biopsy alone. The addition of MRI-targeted biopsy also led to 458 upgrades, or changes in diagnosis to a more aggressive cancer, based on analysis of the biopsy tissue by histopathology.

The researchers also determined that combined biopsy provided more accurate diagnosis than MRI-targeted biopsies alone. Among the men who underwent prostatectomy, the researchers found that systematic biopsy alone underdiagnosed about 40% and MRI-targeted biopsy alone underdiagnosed about 30% of the cancers, while combined biopsy underdiagnosed 14.4% of the cancers. In addition, while systematic biopsy underdiagnosed 16.8% and MRI-targeted biopsy underdiagnosed 8.7% of the most aggressive cancers, combined biopsy missed only 3.5% of the most aggressive cancers.

MRI-targeted biopsies were first developed more than 10 years ago by a team of NCI researchers led by Dr. Pinto; Bradford Wood, MD; Baris Turkbey, MD; and Peter Choyke, MD, all co-authors of the new study. The team, which included other researchers from NCI and other organizations, worked with Philips Healthcare to develop software that could overlay MRI images onto ultrasound images in real time, providing a view of lesions to be sampled that's not possible with systematic biopsy.

"Seeing this technology really make a difference in how we diagnose and treat prostate cancer is validation of the work we have done and continue to do at NIH," said Dr. Pinto. "But the change that matters most to us is how this impacts the patients we see every day, for whom we can now make more informed treatment decisions."

nih.gov

AI Dual-stain Approach Improved Accuracy, Efficiency of Cervical Cancer Screening in NIH Study

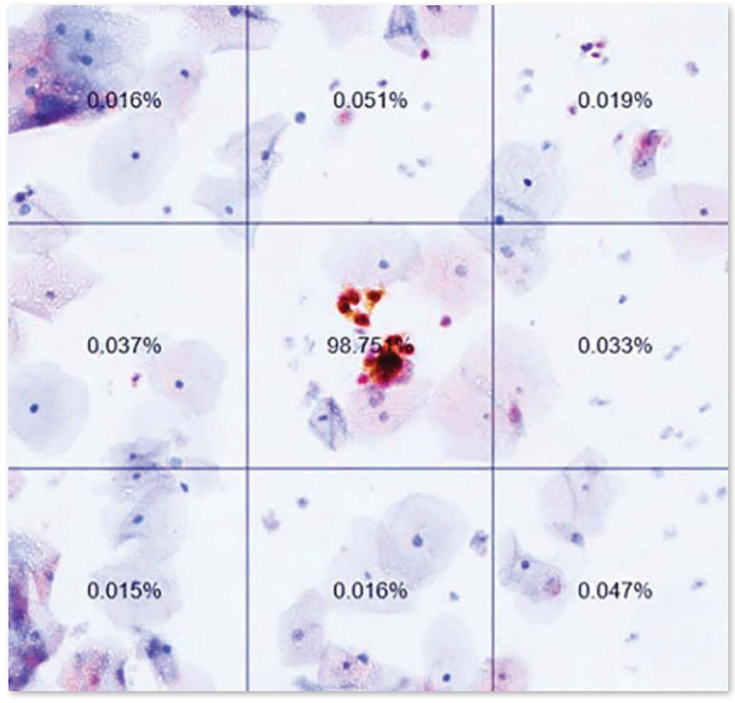
In a new study, a computer algorithm improved the accuracy and efficiency of cervical cancer screening compared with cytology (Pap test), the current standard for follow-up of women who test positive with primary human papillomavirus (HPV) screening. The new approach uses artificial intelligence (AI) to automate dual-stain evaluation and has clear implications for clinical care.

Findings from the study were published June 25, 2020, in the Journal of the National Cancer Institute. The algorithm was developed and the study conducted by investigators at the National Cancer Institute (NCI), part of the National Institutes of Health, in collaboration with researchers from several other institutions.

"We're excited to show we have a fully automated approach to cervical cancer screening as a follow-up to a positive HPV test that outperformed the standard method in our study," said Nicolas Wentzensen, MD, PhD, of NCI's Division of Cancer Epidemiology and Genetics, who led the study. "Based on our results, it could increase the efficiency of cervical cancer screening by finding more precancers and reducing false positives, which has the potential to eliminate a substantial number of unnecessary procedures among HPV-positive women."

In recent years, clinicians have hoped to take advantage of advances in digital imaging and machine learning to improve cervical cancer screening. Women who test negative for HPV are at low risk for cervical cancer for the following decade, and even most cervical HPV infections — which cause positive HPV tests — will not result in precancer. The challenge is to identify which women with positive HPV test results are most likely to have precancerous changes in their cervical cells and should, therefore, have a colposcopy to examine the cervix and take samples for biopsy, or who need immediate treatment.

Currently, women with positive HPV tests may have additional HPV tests or Pap cytology tests to assess the need for colposcopy, biopsy, or treatment. Pap cytology, in which specially trained laboratory professionals (cytotechnologists) analyze stained slides to look for abnormal cells, is used to find precancers before they progress to cancer. But these approaches are not ideal. For example, Pap cytology tests are time consuming, not very sensitive, and prone to false-positive findings.



A slide from an automated dual-stain cytology test. The percentages are AI-generated likelihoods of positive results. The image at center (labeled 98.75%) shows a positive result.
Photo credit Nicolas Wentzensen, MD, PhD

Photo courtesy of the Office on Women's Health

Dual-stain testing has emerged as a way to more accurately predict the chance that a woman with a positive HPV test has precancerous cervical changes. The test measures the presence of two proteins, p16 and Ki-67, in cervical samples. In two previous studies, Dr. Wentzensen and his colleagues found that women who had a negative result on a dual-stain test had a low risk of developing cervical precancer in the following five years and that fewer women test positive for dual-stain compared to Pap cytology. In March 2020, the manual dual-stain cytology test was approved by the U.S. Food and Drug Administration for women who have received a positive result on a primary HPV screening.

The manual dual-stain test has a subjective component, in that a cytotechnologist must look at the slide to determine the results. In the new study, the investigators wanted to see if a fully automated dual-stain test could match or exceed the performance of the manual approach. In collaboration with Niels Grabe, PhD, and Bernd Lahrmann, PhD, of the Steinbeis Transfer Center for Medical Systems Biology, which is associated with the University of Heidelberg, they developed a whole-slide imaging platform that, after being trained with deep learning, could determine if any cervical cells were stained for both p16 and Ki-67. They compared this method with both conventional Pap cytology and manual dual-stain testing in samples from a total of 4,253 people participating in one of three epidemiological studies of HPV-positive cervical and anal precancers at Kaiser Permanente Northern California and the University of Oklahoma.

The researchers found that the AI-based dual-stain test had a lower rate of positive tests than both Pap cytology and manual dual-stain, with better sensitivity (the ability to correctly identify precancers) and substantially higher specificity (the ability to correctly identify those without precancers) than Pap cytology. AI-based dual-stain reduced referral to colposcopy by about a third compared with Pap (approximately 42% vs. 60%). The testing method was also robust, showing comparable performance in anal cytology.

The new approach uses artificial intelligence (AI) to automate dual-stain evaluation and has clear implications for clinical care.

In short, the automated test surpassed the performance of the current standard, Pap cytology, reducing the number of false positive results and substantially reducing referral to unnecessary colposcopy procedures. The results also support further evaluation of the test as an option for anal cancer screening. The researchers note that their approach has clear clinical application, and through cloud-based implementation, it would be globally accessible. Other applications of the platform include assisted evaluation, second opinion, and quality control.

Because the manual dual-stain test has only recently received FDA approval for screening of women who have HPV-positive test results, its use is just getting started. Additional regulatory approval will be needed to allow for screening of HPV-positive women with a fully automated dual-stain test. The researchers say that their findings serve as an important example for introducing digital pathology and deep learning into clinical practice, and their approach has the potential to substantially improve cervical cancer screening, affecting millions of women testing HPV-positive each year.

nih.gov

NIH-funded Study Links Endometriosis to DNA Changes

DNA from uterine cells of women with endometriosis has different chemical modifications, compared to the DNA of women who do not have the condition, according to researchers funded by the National Institutes of Health. The changes involve DNA methylation — the binding of compounds known as methyl groups to DNA — which can alter gene activity. Moreover, the methylated DNA regions varied according to the stage, or severity, of endometriosis and responded differently to hormones involved in the menstrual cycle. Uterine responses to hormones influence pregnancy and other functions of uterine tissue.

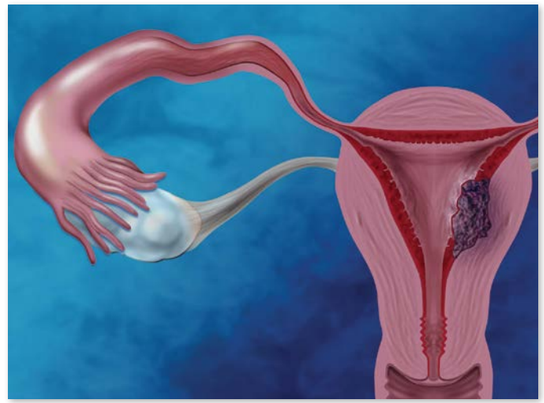


Photo courtesy of the National Cancer Institute

The study was conducted by Linda C. Giudice, MD, PhD, and colleagues at the University of California, San Francisco. It appears in PLOS Genetics. The study was funded by NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).

"The findings raise the possibility that differences in methylation patterns could one day be used to diagnose endometriosis and develop customized treatment plans for patients," said Stuart B. Moss, PhD, of NICHD's Fertility and Infertility Branch.

Endometriosis is a disease in which tissue similar to the lining of the uterus grows in other places in the body, such as on the ovaries, fallopian tubes or the bowels and bladder. It affects from 5 to 10% of women in the United States. Its main symptoms include pain, especially during menstrual periods, and infertility. Endometriosis is classified into four stages, ranging from minimal (stage I) to severe (stage IV). The only definitive way to diagnose endometriosis is with a surgical procedure called a laparoscopy(link is external).

The researchers analyzed a type of cell known as an endometrial stromal fibroblast, which regulates cells in the lining of the uterus. They compared methylation across DNA regions and differences in gene functioning in cells from women who did not have endometriosis or any other gynecological disorders to those of women with stage I endometriosis and of women with stage IV endometriosis. They also observed methylation patterns and gene functioning after the cells were exposed to estradiol (a form of estrogen) alone, progesterone alone, and to a combination of the two hormones to mimic changes in the levels of these hormones that occur during the menstrual cycle.

"The findings raise the possibility that differences in methylation patterns could one day be used to diagnose endometriosis and develop customized treatment plans for patients."

Stuart B. Moss, PhD

DNA methylation patterns and gene functioning differed among all groups of cells before exposure to the hormones, with exposure to each individual hormone, and to the combination of the two. The differences in methylation and gene functioning between stage I and stage IV endometrial cells could mean that the two may be distinct subtypes of endometriosis, rather than different degrees of the condition, Dr. Giudice added.

"The data indicate that the proper interactions of hormones and DNA methylation are critical in normal uterine function," said the study's lead author, Sahar Houshdaran, PhD, University of California, San Francisco. "The changes in these interactions that we've seen could play a role in the infertility that often accompanies endometriosis."

nih.gov

Boosting Energy Levels within Damaged Nerves May Help Them Heal

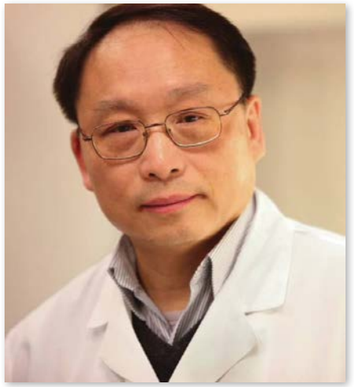
NIH-funded project in mice provides insights into why nerves fail to regrow following injury

When the spinal cord is injured, the damaged nerve fibers — called axons — are normally incapable of regrowth, leading to permanent loss of function. Considerable research has been done to find ways to promote the regeneration of axons following injury. Results of a study performed in mice and published in Cell Metabolism suggests that increasing energy supply within these injured spinal cord nerves could help promote axon regrowth and restore some motor functions. The study was a collaboration between the National Institutes of Health and the Indiana University School of Medicine in Indianapolis.

"We are the first to show that spinal cord injury results in an energy crisis that is intrinsically linked to the limited ability of damaged axons to regenerate," said Zu-Hang Sheng, PhD, senior principal investigator at the NIH's National Institute of Neurological Disorders and Stroke (NINDS) and a co-senior author of the study.

Like gasoline for a car engine, the cells of the body use a chemical compound called adenosine triphosphate (ATP) for fuel. Much of this ATP is made by cellular power plants called mitochondria. In spinal cord nerves, mitochondria can be found along the axons. When axons are injured, the nearby mitochondria are often damaged as well, impairing ATP production in injured nerves.

"Nerve repair requires a significant amount of energy," said Dr. Sheng. "Our hypothesis is that damage to mitochondria following injury severely limits the available ATP, and this energy crisis is what prevents the regrowth and repair of injured axons."



Zu-Hang Sheng, PhD, senior principal investigator at the NIH's National Institute of Neurological Disorders and Stroke. Photo courtesy of the Sheng Laboratory, National Institute of Neurological Disorders & Stroke, National Institutes of Health

Adding to the problem is the fact that, in adult nerves, mitochondria are anchored in place within axons. This forces damaged mitochondria to remain in place while making it difficult to replace them, thus accelerating a local energy crisis in injured axons.

The Sheng lab, one of the leading groups studying mitochondrial transport, previously created genetic mice that lack the protein — called Syntaphilin — that tethers mitochondria in axons. In these "knockout mice" the mitochondria are free to move throughout axons.

"We proposed that enhancing transport would help remove damaged mitochondria from injured axons and replenish undamaged ones to rescue the energy crisis" said Dr. Sheng.

To test whether this has an impact on spinal cord nerve regeneration, the Sheng lab collaborated with Xiao-Ming Xu, MD, PhD and colleagues from the Indiana University School of Medicine, who are experts in modeling multiple types of spinal cord injury.

"Spinal cord injury is devastating, affecting patients, their families, and our society," said Dr. Xu. "Although tremendous progress has been made in our scientific community, no effective treatments are available. There is definitely an urgent need for the development of new strategies for patients with spinal cord injury."

When the researchers looked in three injury models in the spinal cord and brain, they observed that Syntaphilin knockout mice had significantly more axon regrowth across the injury site compared to control animals. The newly grown axons also made appropriate connections beyond the injury site.

When the researchers looked at whether this regrowth led to functional recovery, they saw some promising improvement in fine motor tasks in mouse forelimbs and fingers. This suggested that increasing mitochondrial transport and thus the available energy to the injury site could be key to repairing damaged nerve fibers.

To test the energy crisis model further, mice were given creatine, a bioenergetic compound that enhances the formation of ATP. Both control and knockout mice that were fed creatine showed increased axon regrowth following injury compared to mice fed saline instead. More robust nerve regrowth was seen in the knockout mice that got the creatine.

"We were very encouraged by these results," said Dr. Sheng. "The regeneration that we see in our knockout mice is very significant, and these findings support our hypothesis that an energy deficiency is holding back the ability of both central and peripheral nervous systems to repair after injury."

Dr. Sheng also points out that these findings, while promising, are limited by the need to genetically manipulate mice. Mice that lack Syntaphilin show long-term effects on regeneration, while creatine alone produces only modest regeneration. Future research is required to develop therapeutic compounds that are more effective in entering the nervous system and increasing energy production for possible treatment of traumatic brain and spinal cord injury.

nih.gov

CPG

Utilizing Nerve Transfers to Improve Hand Function Following Cervical Spinal Cord Injury

By Wilson Z. Ray, MD, Washington University School of Medicine in St. Louis

Over 50% of SCIs occur in the cervical spine, resulting in loss of arm and/or hand function, making complete recovery exceedingly rare.[1] Upper extremity function is rated as one of the most desirable functions for persons with tetraplegia, ranking above bowel and bladder function, sexual function, standing, and pain control. Nerve transfer, a surgical method in which functionally redundant nerves are moved to a more critical area of motor function, has shown to be efficacious in the treatment of brachial plexus and peripheral nerve injuries.[2] Compared to the traditional nerve grafting methods used to treat brachial plexus/peripheral nerve injuries, nerve transfers lead to improved reinnervation of motor endplates[3] and limited-to-no functional deficit in the area of the donor nerve territory.[4] To date, there are no clinical guidelines on the utilization of nerve transfers to treat patients with SCIs This leaves researchers and clinicians in search of new and innovative techniques to improve quality of life for cervical SCI patients.

With support from a Spinal Cord Injury Research Program (SCIRP) Clinical Trial Award, Dr. Wilson Z. Ray and his team sought to establish and validate clinical guidelines on the use of nerve transfers to improve upper extremity function in patients with cervical SCI. To achieve this, cervical SCI patients with no hand function enrolled in Dr. Ray's trial and underwent nerve transfer surgery, followed by post-operative therapy. After successful surgery and completion of hand therapy, all 19 patients experienced improvements in hand and upper limb function. Notably, two patients with C4 SCIs experienced an increase in muscle power from 0 to 4 on the Medical Research Council (MRC) scale on the side that received nerve transfer. The MRC scale rates muscle power when subjected to normal resistance. A 0 is no muscle activation and no range of motion and 5 is full activation and full range of motion. Despite hand function not being completely restored for these patients, both cervical SCI participants experienced improvements in hand sensation, including light touch. One patient is now able to operate a wheelchair equipped with joystick and a mobile phone, increasing independence and providing a boost in quality of life. One of the most exciting aspects of this award is that many participants are continuing to experience improvement, even as far as 3 years post-surgery.

Dr. Wilson Z. Ray. Photo courtesy of Washington University School of Medicine in St. Louis

References:

1. Ackery A, Tator C, and Krassioukov A. 2004. A global perspective on spinal cord injury epidemiology. Journal of Neurotrauma 21:1355-1370. https://www.ncbi.nlm.nih.gov/pubmed/15672627
2. Dvali L and Mackinnon S. 2003. Nerve repair, grafting, and nerve transfers. Clin Plast Surg 30:203-221. PubMed PMID: 12737353. http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=12737353
3. Kobayashi J, Mackinnon SE, Watanabe O, et al. 1997. The effect of duration of muscle denervation on functional recovery in the rat model. Muscle Nerve 20:858-866. PubMed PMID: 9179158. http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=9179158
4. Mackinnon SE, Novak CB, Myckatyn TM, and Tung TH. 2005. Results of reinnervation of the biceps and brachialis muscles with a double fascicular transfer for elbow flexion. J Hand Surg Am 30:978-985. PubMed PMID: 16182054. https://www.ncbi.nlm.nih.gov/pubmed/?term=16182054

CDMRP

Negative Pressure Wound Therapy Does Not Cut Infection Risk in Obese Women after Cesarean Delivery

Negative pressure wound therapy (NPWT) does not appear to lower the risk of infection for obese women after cesarean delivery, suggests a study funded by the National Institutes of Health. The treatment involves placing a low-pressure pump over a closed surgical wound to create negative air pressure. Earlier studies had suggested that NPWT might reduce infection risk and promote healing after surgery. The study of more than 1,600 obese women found no significant difference in infection between women treated with NPWT and those receiving standard wound dressing.

The study was conducted by Methodius G. Tuuli, MD, of Indiana University School of Medicine and colleagues. It appears in the Journal of the American Medical Association and was funded by NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).

Researchers enriched the microbes of babies delivered by C-section to levels more typical of babies born vaginally. The health impacts remain to be studied. Photo courtesy of the NIH Studio-Annika/iStock/Thinkstock

Obese women are more likely to have cesarean delivery and more likely to develop an infection at the surgical site. In the current study, half of the women were assigned at random to receive NPWT; the other half received standard wound dressing.

In the negative pressure group, 29 women developed infection at the surgical site, compared to 27 in the standard dressing group, a difference that was not statistically significant. Rates of major adverse events, such as death, blood infection (sepsis) and need for hysterectomy after surgery, also did not differ significantly. However, women in the negative pressure group were more likely to have skin irritations, such as blistering, bleeding and redness.

Photo courtesy of the NIH

The study authors concluded that their findings do not support the routine use of NPWT for obese women who deliver by cesarean.

References:

Menachem Miodovnik, MD, project scientist in the NICHD Pregnancy and Perinatology Branch.

Tuuli MG, et al. Effect of prophylactic negative pressure wound therapy versus standard wound dressing on surgical-site infection in obese women after cesarean delivery. *Journal of the American Medical Association*. 2020.

nih.gov

Advertiser Directory

We are grateful to the companies advertising in this edition which support our efforts to provide free distribution to all our subscribers. Please investigate their innovative solutions for your practice with their featured advertisements contained within and also at www.federalhealthmedicine.com/