Federal Health & Medicine

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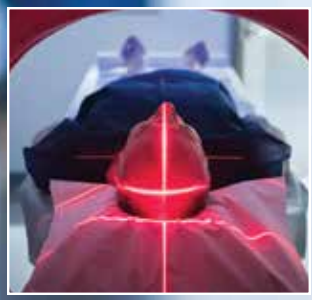

DEACTIVATION AND DISPOSAL: CRITICAL TOOLS IN PREVENTING PRESCRIPTION OPIOID ABUSE

More than half of all veterans receiving care through the Veterans Health Administration are affected by chronic pain.[1]

For members of our military community suffering visible and invisible wounds of war, pain management often involves prescription medications including opioids and other painkillers. These are critical tools in helping our brave heroes, but they carry real risk of addiction, misuse and potentially fatal overdose.

Nearly one in four active-duty service members and retirees had at least one opioid prescription in 2017.[2]

Of particular concern are the enormous quantities of opioids that are leftover, unneeded and unused:

- It's estimated that up to 70% of opioids prescribed for surgical use were leftover and unused.[3]
- Studies show that more than 60% of people with leftover prescription opioids kept their pills for future use rather than disposing of them – with one in five reporting they had shared their medication with another person.[4]
- More than half of those individuals currently misusing prescription opioids, received or took the drug from a friend or relative, meaning they never had a prescription themselves.[5]

If we are to protect our service members, veterans, and their loved ones from the dangers of prescription opioid misuse and put this crisis behind us, **effective deactivation and disposal of these dangerous, leftover drugs is a must.**

Take-back programs and kiosks provide an important route for disposal of leftover drugs, but rural Americans or those of limited mobility – including many veterans – deserve other options.

There's a need for at-home alternatives that deactivate these drugs – rendering them non-retrievable for all practical purposes - and then allows them to be safely disposed of in the normal trash.

The Deterra® Drug Deactivation System is an independently tested, safe and environmentally sound solution to permanently deactivate, destroy and dispose of unneeded pills, patches, liquids, creams and films right at home.

Visit DeterraSystem.com to learn how you can equip service members and veterans with Deterra to safely dispose of their leftover opioids and other medications at home.

Call 612.568.1128 or email Sales@DeterraSystem.com to speak with a representative.

[1]https://www.psychologytoday.com/us/blog/invisible-wounds/201701/va-says-68000-vets-addicted-opioid-painkillers
[2]https://www.militarytimes.com/pay-benefits/2018/12/04/one-in-four-troops-have-an-opioid-prescription-in-a-given-year/
[3]https://jamanetwork.com/journals/jamasurgery/article-abstract/2644905
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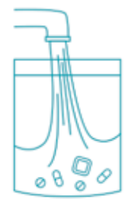
DETERRA® drug deactivation system

THE DETERRA DRUG DEACTIVATION SYSTEM HELPS STOP PRESCRIPTION DRUG MISUSE BEFORE IT STARTS.

Deterra® can rid any home or healthcare facility of dangerous, leftover drugs in minutes,[6] ensuring that unused prescription opioids and other drugs are **gone – for good**.

Deterra's process is powered by proprietary MAT$_{12}$® Molecular Adsorption Technology which deactivates medications using activated carbon - rendering them inert, unavailable for misuse, non-retrievable for all practical purposes and safe for the environment, in three easy steps.

1 Tear open pouch – do not remove inner pod(s). Place unused medications inside.



2 Fill pouch halfway with warm water and wait 30 seconds for air to release. Some foaming may occur.

3 Seal pouch tightly, gently shake and dispose of in normal trash.

VISIT DETERRASYSTEM.COM TO EXPLORE THE SCIENCE.

Deterra deactivates many dosage forms including pills, patches, liquids, creams and films, and is available in a variety of sizes that can destroy from 15 to over 25,000 pills.[7]

Call 612.568.1128 or email Sales@DeterraSystem.com to get a customized quote for a disposal solution that meets your needs.

[6] The deactivation process starts quickly but takes time to complete.
[7] Deterra deactivates many dosage forms including pills, patches, liquids, creams and films.

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Secretary Azar Statement on Confirmation of Stephen Hahn as FDA Commissioner December 12, 2019

The United States Senate voted, 72-18, to confirm Dr. Stephen Hahn as Commissioner of Food and Drugs. Health and Human Services Secretary Alex Azar issued the following statement:

"I congratulate Dr. Hahn and thank the Senate for prioritizing his nomination. President Trump has chosen a superbly qualified leader for FDA, and Dr. Hahn garnered strong bipartisan support. Having a confirmed FDA Commissioner of Dr. Hahn's caliber will be a major boost to the already rapid pace of the President's aggressive public health agenda.

Dr. Hahn brings an impressive set of scientific and leadership qualifications to the job, and I look forward to seeing the FDA and its people thrive under his leadership. I am also grateful to Admiral Brett Giroir and Dr. Ned Sharpless for their dedicated work as Acting Commissioners and for their enduring commitment to public health."

hhs.gov

HHS Secretary Alex Azar (left) administered the oath of office. Photo courtesy of the US Department of Health and Human Services

Dr. Stephen M. Hahn

Dr. Stephen M. Hahn is a dedicated clinician, having trained in both medical oncology and radiation oncology. In his previous leadership roles, he has always carefully balanced executive management with clinical time to continue to serve oncology patients, his true passion. He specializes in treating both lung cancer and sarcoma.

Throughout his oncology career, Dr. Hahn maintained a keen interest in research, authoring more than 220 peer-reviewed original research articles. His research focuses on the molecular causes of the tumor microenvironment, particularly the study of chemical signals that go awry (known as aberrant signal transduction pathways), and the evaluation of proton therapy as a means of improving the effectiveness of radiation therapy. His experience in medical product development and clinical trials spans drugs, biologics, medical devices, and diagnostics.

Prior to joining the FDA, Dr. Hahn served as the chief medical executive (CME) at The University of Texas MD Anderson Cancer Center, a facility that cares for more than 140,000 patients a year. He has proven executive leadership that spans research, development, clinical trials, patient care, health system management and education. In his role as CME, he was responsible for day-to-day management of the institution, including business, clinical and faculty matters. Under his purview was one of the largest clinical trial groups in the country. Dr. Hahn joined MD Anderson in 2015 as Division Head, Department Chair and Professor of Radiation Oncology. Before joining MD Anderson, he served as chair of the Radiation Oncology department at the University of Pennsylvania's Perelman School of Medicine from 2005 to 2014.

Dr. Hahn earned the rank of Commander in the U.S. Public Health Service Commissioned Corps while at the National Institute of Health's National Cancer Institute, where he also completed a fellowship in medical oncology and a residency in radiation oncology. He also a completed residency in internal medicine at University of California, San Francisco. He graduated from the Lewis Katz School of Medicine at Temple University in Pennsylvania and received his bachelor's in biology from Rice University in Texas.

Although it was not known by its present name until 1930, the Food and Drug Administration is the oldest comprehensive consumer protection agency in the U.S. federal government.

Since 1848 the federal government has used chemical analysis to monitor the safety of agricultural products, beginning with the Drug Importation Act passed by Congress that required U.S. Customs Service inspection to stop entry of adulterated drugs from overseas.

1862 President Lincoln appoints a chemist, Charles M. Wetherill, to serve in the new Department of Agriculture. This was the beginning of the Bureau of Chemistry, the predecessor of the Food and Drug Administration.

1883 Dr. Harvey W. Wiley becomes chief chemist, expanding the Bureau of Chemistry's food adulteration studies. Campaigning for a federal law, Dr. Wiley is called the "Crusading Chemist" and "Father of the Pure Food and Drugs Act."

1898 Association of Official Agricultural Chemists (now AOAC International) establishes a Committee on Food Standards headed by Dr. Wiley. States begin incorporating these standards into their food statutes.

1902 The Biologics Control Act is passed to ensure purity and safety of serums, vaccines, and similar products used to prevent or treat diseases in humans. Congress appropriates $5,000 to the Bureau of Chemistry to study chemical preservatives and colors and their effects on digestion and health. Dr. Wiley's studies draw widespread attention to the problem of food adulteration. Public support for passage of a federal food and drug law grows.

1906 The original Food and Drugs Act and he Meat Inspection Act are passed by Congress and signed by President Theodore Roosevelt, prohibiting interstate commerce in misbranded and adulterated foods, drinks and drugs.

1912 Congress enacts the Sherley Amendment to prohibit labeling medicines with false therapeutic claims intended to defraud the purchaser.

1914 The Harrison Narcotic Act requires prescriptions for products exceeding the allowable limit of narcotics and mandates increased record-keeping for physicians and pharmacists who dispense narcotics.

1940 FDA transferred from the Department of Agriculture to the Federal Security Agency, with Walter G. Campbell appointed as the first Commissioner of Food and Drugs.

1941 Insulin Amendment requires FDA to test and certify purity and potency of this lifesaving drug for diabetes.

1944 Public Health Service Act is passed, covering a broad spectrum of health concerns, including regulation of biological products and control of communicable diseases.

1950 The Delaney Committee starts congressional investigation of the safety of chemicals in foods and cosmetics, laying the foundation for the 1954 Miller Pesticide Amendment, the 1958 Food Additives Amendment, and the 1960 Color Additive Amendment. The Delaney proviso prohibits the approval of any food additive shown to induce cancer in humans or animals.

1954 Miller Pesticide Amendment spells out procedures for setting safety limits for pesticide residues on raw agricultural commodities.

1965 Drug Abuse Control Amendments are enacted to deal with problems caused by abuse of depressants, stimulants and hallucinogens.

1970 Environmental Protection Agency established; takes over FDA program for setting pesticide tolerances. Low-acid food processing regulations issued, after botulism outbreaks from canned foods, to ensure that low-acid packaged foods have adequate heat treatment and are not hazardous. Consumer Product Safety Commission created by Congress; takes over programs pioneered by FDA under 1927 Caustic Poison Act, 1960 Federal Hazardous Substances Labeling Act, 1966 Child Protection Act, and PHS accident prevention activities for safety of toys, home appliances, etc.

1980 Infant Formula Act establishes special FDA controls to ensure necessary nutritional content and safety.

1983 Orphan Drug Act passed, enabling FDA to promote research and marketing of drugs needed for treating rare diseases.

1988 Food and Drug Admin Act officially establishes FDA as an agency of the Department of Health and Human Services.

1990 Nutrition Labeling and Education Act requires all packaged foods to bear nutrition labeling and all health claims for foods to be consistent with terms defined by the Secretary of Health and Human Services.

1994 Dietary Supplement Health and Education Act establishes specific labeling requirements.

2002 Public Health Security and Bioterrorism Preparedness and Response Act is designed to improve the country's ability to prevent and respond to public health emergencies.

2004 Project BioShield Act authorizes FDA to expedite its review procedures to enable rapid distribution of treatments as countermeasures to chemical, biological, and nuclear agents that may be used in a terrorist attack against the U. S., among other provisions.

2013 Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA). Establishes and reauthorizes certain programs under the Public Health Service Act and the Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response.

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Surgeon General Releases First Report Focused on Smoking Cessation in 30 Years

Three decades after the first Surgeon General's report on smoking cessation, today, the Surgeon General is releasing a new report that reviews and updates evidence on the importance of quitting smoking. The report finds that more than two-thirds of U.S. adult cigarette smokers report interest in quitting cigarette smoking; and the majority of adult cigarette smokers in the United States have tried to quit during the past year.

In addition to discussing the immediate and long-term health and economic benefits of smoking cessation at the individual and societal levels, this report presents updated findings on nicotine addiction and genetic factors that may impact smoking behaviors. Finally, the report discusses the wide variety of clinical and population-based interventions that have been scientifically shown to effectively increase smoking cessation.

"We know more about the science of quitting than ever before. As a nation, we can and must do more to ensure that evidence-based cessation treatments are reaching the people that need them," said Surgeon General Vice Adm. Jerome M. Adams. "Today, I'm calling on healthcare professionals, health systems, employers, insurers, public health professionals, and policy makers to take action to put an end to the staggering—and completely preventable — human and financial tolls that smoking takes on our country."

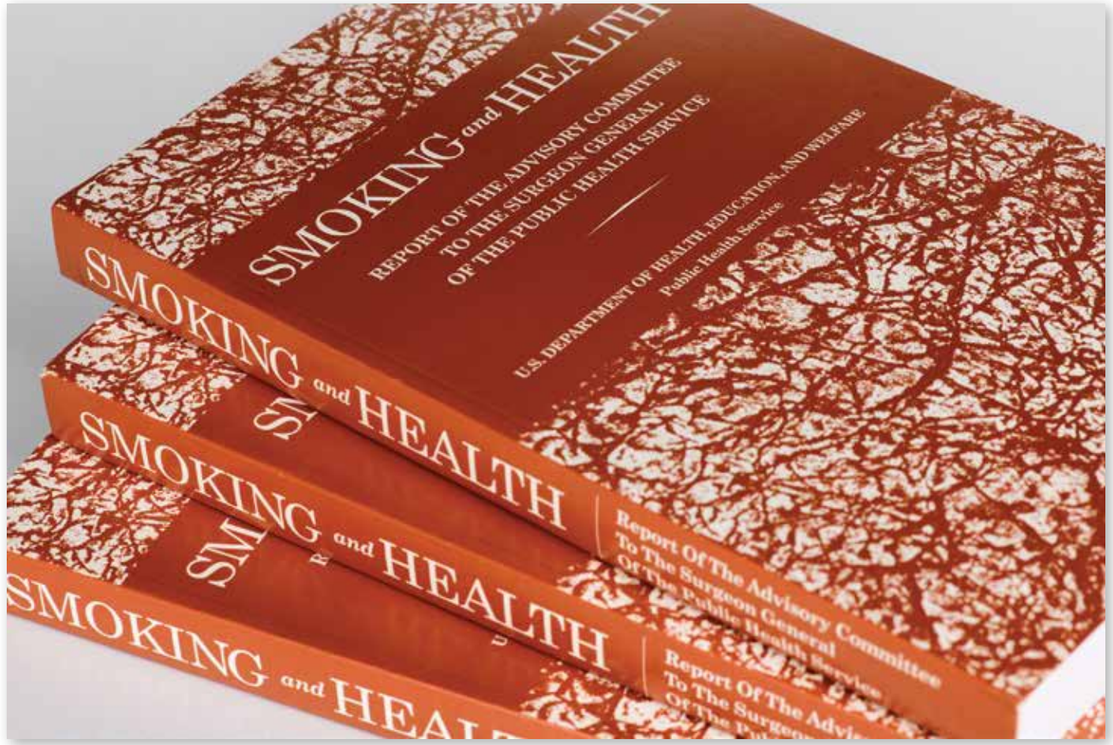
"The steady decline in the number of Americans who smoke cigarettes is one of the great public health victories of recent decades, and this success has continued under President Trump," said HHS Secretary Alex Azar. "Americans who quit cigarettes can add as much as a decade to their life expectancy. Unfortunately, millions of Americans still smoke cigarettes. But the good news is that, as the Surgeon General's report shows, we know more than ever before about effective ways to help Americans quit. Working together, we can make tobacco-related disease and death a thing of the past."

Though cigarette smoking among American adults is at an all-time low (14%), it remains the leading cause of preventable disease, disability, and death in the United States. Approximately 34 million American adults currently smoke cigarettes.

This report expands on the findings from the 1990 report on the same topic, as well as past Surgeon General's reports on tobacco, reaching the following major conclusions:

VADM Jerome M. Adams, MD, MPH, 20th Surgeon General of the United States

- Smoking cessation benefits persons at any age.
- Smoking cessation reduces the risk of premature death and can add as much as a decade to life expectancy.
- Smoking places a substantial financial burden on smokers, healthcare systems, and society. Smoking cessation reduces this burden.
- More than 3 out of 5 U.S. adults who have ever smoked cigarettes have quit; however, less than one-third use FDA-approved cessation medications or behavioral counseling.
- Disparities in key indicators of smoking cessation exist



1964 first report of the Surgeon General's Advisory Committee on Smoking and Health by Luther L. Terry, MD. Photo courtesy of CDC

among subgroups within the U.S. population — including quit attempts, receiving advice to quit from a health professional, and using cessation therapies.

- Smoking cessation reduces the risk of many negative health effects, including reproductive health outcomes, cardiovascular diseases, chronic obstructive pulmonary disease (or COPD), and numerous cancers.
- Cessation medications approved by the FDA and behavioral counseling increase the likelihood of successfully quitting smoking, particularly when used in combination.
- Insurance coverage for smoking cessation treatment that is comprehensive, barrier-free, and widely promoted increases the use of these treatment services, leads to higher rates of successful quitting, and is cost-effective.
- E-cigarettes, a continually changing and diverse group of products, are used in a variety of ways. Therefore, it is difficult to make generalizations about efficacy for cessation based on clinical trials involving a particular e-cigarette. There is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation.
- Smoking cessation can be increased by raising the price of cigarettes, adopting comprehensive smoke-free policies, implementing mass media campaigns, requiring pictorial health warnings, and maintaining comprehensive statewide tobacco control programs.

This Surgeon General's report on smoking cessation, the 34th report on smoking and health since 1964, was compiled using a longstanding, peer-reviewed, and comprehensive process to safeguard the scientific rigor and practical relevance of Surgeon General's reports on tobacco. The evidence reviewed and summarized in this report can serve as a catalyst for efforts to further reduce the health and economic burden of tobacco product use in the United States.

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Public Health Centers Awarded Additional $107 Million to Support Health Center Quality Improvement

U.S. Department of Health and Human Services (HHS) announced nearly $107 million in Quality Improvement Awards to 1,273 health centers across nearly all U.S. states, territories and the District of Columbia. Funded by the Health Resources and Services Administration (HRSA), health centers will use these awards to improve the quality, efficiency, and value of the health care they provide.

"President Trump's vision for healthcare aims to deliver Americans better value from the care they receive and, ultimately, better health. Community health centers have consistently delivered these kinds of results, including high-quality primary care at a significantly lower cost than their peers and above-average results in controlling chronic conditions," said HHS Secretary Alex Azar. "This week's awards recognize especially high-achieving health centers. America's health centers are essential to producing results on our actionable public health challenges, like HIV/AIDS and the opioid crisis, as well as to building a healthcare system that delivers better value and puts the patient at the center."

By providing patients access to high quality, value-based care, health centers are uniquely positioned to meet the nation's most pressing health care needs, as well as emerging health priorities. HRSA-funded health centers are the first line of care in combatting the nation's opioid crisis. In 2018, health centers screened nearly 1.1 million people for substance use disorder and ultimately provided medication-assisted treatment to nearly 95,000 patients nationwide.

HRSA-funded health centers are also playing an important role in the White House Initiative Ending the HIV Epidemic by serving as a key point of entry for the detection, diagnosis, prevention, and treatment of HIV. In 2018 alone, health centers provided over 2.4 million HIV tests to more than 2 million patients. Nationwide, health centers provide care to 1 in 6 patients diagnosed with HIV.

HRSA's Quality Improvement Awards recognize the work that health centers do to address health priorities by designating health centers that ranked in the top 1-2% in one or more key areas — behavioral health, diabetes prevention and management, and heart health — as National Quality Leaders. The top 30% of health centers that achieve the best overall clinical performance receive designation as Health Center Quality Leaders.

From left, Maria Gomez, CEO of Mary's Center in Washington, D.C., received a $200,000 Quality Improvement grant from HHS Deputy Secretary Eric Hargan and HRSA Administrator Dr. George Sigounas. The agency issued $125 million in awards to 1,352 grantees during Health Center Week.

These awards also recognize health center achievements in other areas, including improving cost-efficient care delivery while also increasing quality of care, reducing health disparities, increasing both the number of patients served and patients' ability to access comprehensive services, advancing the use of health information technology, and delivering patient-centered care.

"HRSA-funded health centers continue to lead the U.S. healthcare system in providing quality, value-based care to their communities" said HRSA Acting Administrator Tom Engels. "Today we are recognizing nearly all HRSA-funded health centers for their continued improvements on clinical quality measures and supporting them to continue as quality leaders nationwide in the years to come."

For more than 50 years, health centers have delivered affordable, accessible, quality, and cost-effective primary health care services to patients. Today, nearly 1,400 health centers operate approximately 12,000 service delivery sites that provide care to more than 28 million patients nationwide.

hhs.gov

HHS Awards $20 million to 27 Organizations to Increase the Rural Workforce through the Creation of New Rural Residency Programs

The U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA) awarded approximately $20 million in Rural Residency Planning and Development Program (RRPD) grants. Recipients across 21 states will receive up to $750,000 over a three-year period to develop new rural residency programs while achieving accreditation through the Accreditation Council for Graduate Medical Education.

"Promoting the health of rural America is one of the Trump Administration's healthcare priorities," said HHS Secretary Alex Azar. "Supporting the training of healthcare providers in rural areas through grants like these is a key way to help expand rural access to care, and is part of an overall effort to support rural healthcare in sustainable, innovative, and flexible ways."

The RRPD program, administered by HRSA's Federal Office of Rural Health Policy (FORHP) and Bureau of Health Workforce (BHW), is part of a multi-year initiative by HRSA to expand the physician workforce in rural areas by developing new, sustainable residency programs in family medicine, internal medicine, and psychiatry. The recipients of the awards include rural hospitals, community health centers, health centers operated by the Indian Health Service, Indian tribes or tribal organizations, and schools of medicine.

"The health challenges in rural America are clear: rural communities face a greater risk of poor health outcomes than their urban counterparts," said HRSA Administrator George Sigounas, MS, PhD. "Programs like the Rural Residency Planning and Development grants take aim at one of the most persistent disparities: access to high quality healthcare providers. HRSA is committed to increasing the number of providers serving rural communities and improving health in rural America."

Rural residency programs often face challenges in securing sustainable financing and faculty support. The RRPD grant award funding will help recipients address these challenges.

"Training residents in rural areas is one strategy shown to successfully encourage graduates to practice in rural settings," said HRSA Associate Administrator for FORHP Tom Morris. "The rural residency grants set up these 27 future residency programs for success."

"We know that clinicians who train in rural settings are more likely to continue to practice there after they complete their residencies," said HRSA Associate Administrator for BHW Dr. Luis Padilla. "Rural communities are more likely to have a shortage of health professionals. The rural residency grants are one more way HRSA is helping to expand the health workforce and increase access to quality healthcare for these communities."

hhs.gov

Photo courtesy of the Utah Office of Primary Care and Rural Health

HHS Awards More than $50 Million to Establish New Health Center Sites

The U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), awarded more than $50 million to fund 77 health centers across 23 states, Puerto Rico, and the Commonwealth of the Northern Mariana Islands. This funding provides operational support for new organizations to become HRSA Health Center Program grantees and for existing health centers to establish new service delivery sites.

"HHS aims to help provide all Americans with access to quality healthcare and, ultimately, improve their health. Community health centers play a vital role in that mission, and in the Trump Administration's vision for healthcare," said HHS Secretary Alex Azar. "Opening new community health centers and creating additional sites of care is a vital way to help expand access to care and improve the health of the nation's underserved communities, both rural and urban."

HRSA's Health Center Program New Access Points funding expands access to quality health care services for vulnerable populations. The investments support the creation of service delivery sites to strengthen comprehensive primary health care services in areas where geographic, economic, or cultural barriers limit access to affordable health care.

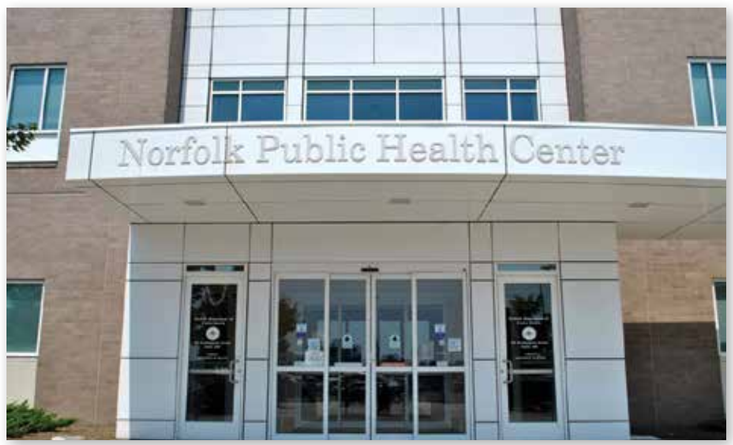
"This new funding will increase access to health care for more than 400,000 new patients," said HRSA Acting Administrator Tom Engels. "HRSA's Health Center Program provides resources and services to health centers nationwide to improve access to quality health care for all, regardless of their ability to pay."

Funding supports both construction of new facilities and improvements to existing health centers

Nearly 1,400 health centers located in every U.S. state, the District of Columbia, Puerto Rico, the Virgin Islands, and the Pacific Basin operate approximately 12,000 sites to provide accessible, affordable, quality health care services to more than 28 million people.

For more information on these awards, visit https://bphc.hrsa.gov/program-opportunities/funding-opportunities/new-access-points/awards

hhs.gov



State of the Opioid Abuse and Overdose Crisis in America

According to the CDC's National Vital Statistics System, more than 130 people in the United States die after overdosing on opioids each day.

The misuse of and addiction to opioids, including prescription pain relievers, heroin, and synthetic opioids such as fentanyl is a serious national crisis that affects public health as well as social and economic welfare. The Centers for Disease Control and Prevention estimates that the total "economic burden" of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.

Opioid overdose rates began to increase. In 2017, more than 47,000 Americans died as a result of an opioid overdose, including prescription opioids, heroin, and illicitly manufactured fentanyl, a powerful synthetic opioid. That same year, an estimated 1.7 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers, and 652,000 suffered from a heroin use disorder.

National Institute on Drug Abuse Statistics Show that roughly 21 to 29 percent of patients prescribed opioids for chronic pain misuse them, and that between 8 and 12 percent develop an opioid use disorder. An estimated 4 to 6 percent who misuse prescription opioids transition to heroin, and about 80 percent of people who use heroin first misused prescription opioids.

Opioid overdoses increased 30 percent from July 2016 through September 2017 in 52 areas in 45 states. The Midwestern region saw opioid overdoses increase 70 percent from July 2016 through September 2017, and overdoses in large cities increase by 54 percent in 16 states.

This issue has become a public health crisis with devastating consequences including increases in opioid misuse and related overdoses, as well as the rising incidence of neonatal abstinence syndrome due to opioid use and misuse during pregnancy. The increase in injection drug use has also contributed to the spread of infectious diseases including HIV and hepatitis C. As seen throughout the history of medicine, science can be an important part of the solution in resolving such a public health crisis.

In response to the opioid crisis, the U.S. Department of Health and Human Services (HHS) is focusing its efforts on five major priorities:

1. improving access to treatment and recovery services
2. promoting use of overdose-reversing drugs

Photo by city of Mesa Arizona

3. strengthening our understanding of the epidemic through better public health surveillance
4. providing support for cutting-edge research on pain and addiction
5. advancing better practices for pain management

The National Institutes of Health (NIH), a component of HHS, is the nation's leading medical research agency helping solve the opioid crisis via discovering new and better ways to prevent opioid misuse, treat opioid use disorders, and manage pain. In the summer of 2017, NIH met with pharmaceutical companies and academic research centers to discuss safe, effective, non-addictive strategies to manage chronic pain along with new, innovative medications and technologies to treat opioid use disorders, and improved overdose prevention and reversal interventions to save lives and support recovery.

In April 2018 at the National Rx Drug Abuse and Heroin Summit, NIH Director Francis S. Collins, MD, PhD, announced the launch of the HEAL (Helping to End Addiction Long-term) Initiative, an aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis.

drugabuse.gov

HHS Releases Additional $487 million to States, Territories to Expand Access to Effective Opioid Treatment; 2019 SOR Grants Will Total $1.4 billion

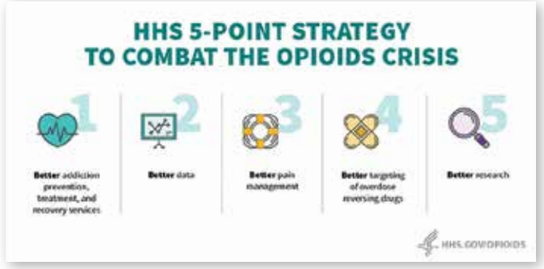
Today, the U.S. Department of Health and Human Services (HHS) released an additional $487 million to supplement first-year funding through its State Opioid Response (SOR) grant program. The awards to states and territories are part of HHS's Five-Point Opioid Strategy and the Trump administration's tireless drive to combat the opioid crisis.

Together with the $933 million in second-year, continuation awards to be provided under this program later this year, the total amount of SOR grants to states and territories this year will total more than $1.4 billion. This funding will expand access to treatment that works, especially to medication-assisted treatment (MAT) with appropriate social supports.

"One year ago this week, President Trump launched his national opioid initiative, which called for expanding access to compassionate, evidence-based treatment, including MAT. This week's funding awards to states were possible because of legislation Congress passed and President Trump signed since then," said HHS Secretary Alex Azar. "Our strategy is beginning to produce results, thanks to so many Americans working on the ground, in their own communities, to turn the tide on this crisis."

The State Opioid Response grants administered by HHS's Substance Abuse and Mental Health Services Administration (SAMHSA) aim to address the opioid crisis by increasing access to MAT using the three Food and Drug Administration (FDA) approved medications for the treatment of opioid use disorder, reducing unmet treatment need, and reducing opioid overdose-related deaths through the provision of prevention, treatment and recovery activities for opioid use disorder.

"Strategies such as employing psychosocial supports, community recovery services and MAT using medicines approved by



Dr. Elinore F. McCance-Katz, Assistant Secretary for Mental Health and Substance Use

the FDA constitute the gold standard of treatment for opioid use disorders," said Dr. Elinore F. McCance-Katz, Assistant Secretary for Mental Health and Substance Use.

Last summer, SAMHSA announced the first year of SOR funding. States and territories received funding based on a formula, with a 15 percent set-aside for the 10 states with the highest mortality rates related to drug overdose deaths.

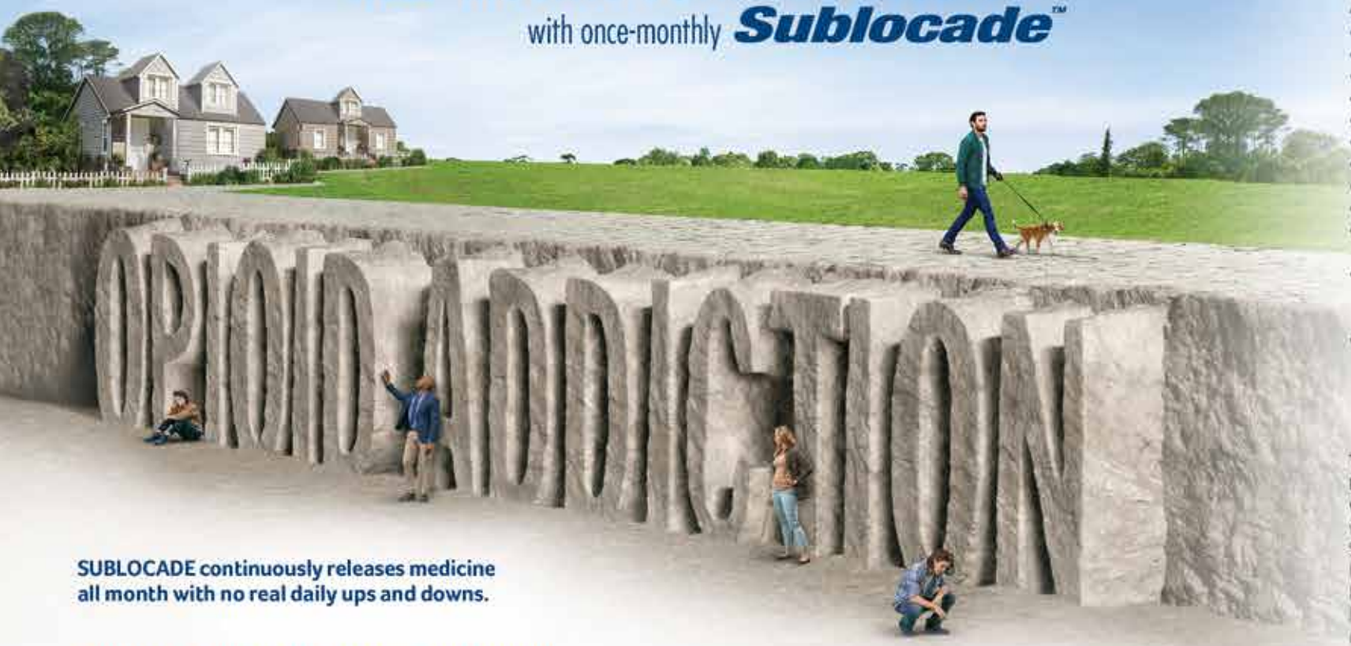
Other funding, including $50 million for tribal communities under the Tribal Opioid Response exit disclaimer icon (TOR) grant program, has been awarded separately. These programs are built from the foundations laid in the $1 billion provided to states and territories through SAMHSA's Opioid State Targeted Response (STR) program. SAMHSA has complemented the work of the STR program with a national center of excellence that provides technical assistance and training to leverage local subject matter experts at the community level to sharpen treatment access and delivery.

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.

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

Individuals depicted are for illustrative purposes only.
- 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 Ⓒ

100mg·300mg

The NIAAA Alcohol Treatment Navigator

By George F. Koob, PhD, Director of the National Institute on Alcohol Abuse and Alcoholism (NIAAA)

George F. Koob, PhD, Director of the National Institute on Alcohol Abuse and Alcoholism (NIAAA)

In any given year, more than 15 million adults in the US meet the diagnostic criteria for alcohol use disorder (AUD), but less than 10% of them receive treatment. Meanwhile, many of those in treatment may not receive the care that best fits their needs.

What accounts for this alcohol "treatment gap"

Often, finding quality AUD care can be complicated, and many people aren't aware of the full range of available treatment options. It can also be difficult to tell if a provider is offering good quality treatment, what we call "evidence based care" that is, treatment that is grounded in clinical and health services research that demonstrates positive treatment outcomes.

During my tenure as Director of NIAAA, I've received numerous calls from colleagues and the general public asking for advice on finding "good" alcohol treatment providers in or near their communities for their family and friends.

Those calls inspired us to develop the Navigator which makes this complicated process easier by telling people what they need to know, and what they need to do, to recognize and choose quality care. This landmark resource is comprehensive, yet easy to use, guiding the user through a step-by-step process to find highly-qualified treatment professionals. It helps them better understand their options, empowering families to help their loved ones, and giving health professionals a resource to share with clients who need a referral.

The Navigator helps create informed consumers by explaining AUD and the various treatment options available, along with tips on how to recognize five signs of quality care and steps to find quality treatment, including 10 questions to ask a potential provider. It also features several online directories of providers, with instructions on how to use them most effectively.

For more than two years, we worked to develop the Navigator by drawing on decades of scientific research on clinical interventions and health services delivery, and getting input from patients, families, treatment providers and researchers. I am grateful to everyone who contributed to this effort.

We believe that the NIAAA Alcohol Treatment Navigator will be a game-changer for people looking for quality treatment for AUD. We hope you will visit the site and go through it, then share it widely. And we plan to refine and update the Navigator regularly, so please give us your feedback. It is available at AlcoholTreatment.niaaa.nih.gov

niaaa.nih.gov

In 2005, an estimated 22 million Americans struggled with a drug or alcohol problem. Almost 95 percent of people with substance use problems are considered unaware of their problem. Of those who recognize their problem, 273,000 have made an unsuccessful effort to obtain treatment. These estimates highlight the importance of increasing prevention efforts and improving access to treatment for substance abuse and co-occurring disorders. — Healthy People 2020

HHS Awards $16 Million to Help Primary Care Practices Address Patients' Unhealthy Alcohol Use

The U.S. Department of Health and Human Services, through the Agency for Healthcare Research and Quality (AHRQ), announced a $16 million initiative to help primary care practices increase efforts to address patients' unhealthy alcohol use.

Excessive alcohol use, which affects almost a third of adults, is the nation's third leading cause of preventable death. It is a major risk factor for many health, social, and economic problems, and has an estimated annual economic burden of over $250 billion.

"President Trump has promised Americans a healthcare system that's patient-centric, and treats you like a person, not a number. That means caring for Americans' full range of health needs, including substance use challenges such as unhealthy alcohol use," said HHS Secretary Alex Azar. "Primary care providers have emerged as an important pathway for connecting patients to treatment for substance use challenges, and HHS is pleased to support, through AHRQ, the testing of innovative approaches toward this end."

Six grantees will work with more than 700 primary care practices over three years to implement and evaluate strategies to increase the use of evidence-based interventions such as screening for unhealthy alcohol use; brief interventions for adult patients who drink too much; and medication-assisted therapy for patients with an alcohol use disorder.

"In keeping with HHS Secretary Azar's commitment to confronting the challenges of substance misuse and addiction, we recognize that many Americans struggle with unhealthy alcohol use, and primary care clinicians are critical to helping patients understand and address this challenge," said AHRQ Director Gopal Khanna, MBA. "These grants will help primary care practices apply proven interventions to tackle this preventable problem."

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Dr. Debara Tucci Named New Director of the National Institute on Deafness and Other Communication Disorders

Debara L. Tucci, MD, MS, MBA

National Institutes of Health Director Francis S. Collins, MD, PhD, has selected Debara L. Tucci, MD, MS, MBA, to lead the National Institute on Deafness and Other Communication Disorders (NIDCD) as its new director. Dr. Tucci currently is professor of surgery and director of the cochlear implant program in the Division of Head and Neck Surgery & Communication Sciences at Duke University, Durham, North Carolina.

"Dr. Tucci's rich experience melds basic and clinical research in communication disorders with an impressive clinical and surgical practice in otology and neurotology," said Dr. Collins. "This experience, combined with her leadership roles for numerous scientific and professional organizations, as well as serving previously as an advisor at NIH, makes her ideally suited to lead the NIDCD into the future."

In her new role, Dr. Tucci will oversee NIDCD's annual budget of approximately $459 million (fiscal year 2018) and lead the institute's research and training programs in hearing, balance, taste, smell, voice, speech and language. Discoveries in these areas can have a dramatic impact on the lives of the tens of millions of people with deafness and other communication disorders.

Dr. Tucci has been on the faculty of the Duke University Medical Center since 1993, where she co-founded the Duke Hearing Center. She has received continuous NIH funding since beginning her academic career. Her primary research interests focus on addressing barriers to hearing health care for older adults, starting with the primary care setting, and establishing a network of academic and community-based research sites to conduct clinical research in hearing and balance disorders. Dr. Tucci also leads NIDCD grants to train and mentor the next generation of clinician investigators in otolaryngology and communication sciences. While at the NIH, she will continue her work to address hearing loss as a global public health problem in her role as co-chair of the Lancet Commission on Global Hearing Loss.

Dr. Tucci is the recipient of the Distinguished Service Award from the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). She has served on its Research Advisory Board, Board of Directors, Executive Committee and numerous subcommittees. She has served as president of the Association for Research in Otolaryngology, the American Otological Society and the American Neurotology Society, and is active in numerous other professional societies.

"I want to extend my appreciation and gratitude to Judith Cooper, PhD, for her commitment and leadership in serving as the NIDCD acting director after the retirement of long-time director James F. Battey, Jr., MD, PhD, last May," said Dr. Collins. "She has agreed to continue to serve in a leadership role as the NIDCD deputy director."

nih.gov

NIH Director Francis Collins, MD, PhD, administered the oath of office to the new NIDCD director, Debara L. Tucci, MD, MS, MBA, on September 4, 2019. They were joined by members of Dr. Tucci's family. L-R: Nathan VanLandingham (son), Julia VanLandingham (daughter), Dr. Collins, Barbara Tucci (mother), Dr. Tucci, Kevan VanLandingham (husband), Michael Tucci (brother), and Amy Tucci (sister-in-law). Photo courtesy of the National Institute on Deafness and Other Communication Disorders

HHS OCR Secures Voluntary Resolution with CHRISTUS Trinity Mother Frances Health System to Strengthen its Provision of Auxiliary Aids and Services to Individuals Who Are Deaf or Hard of Hearing

The U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR), has entered into a Voluntary Resolution Agreement (VRA) with CHRISTUS Trinity Mother Frances Health System (CHRISTUS TMF) resolving a compliance review concerning the rights of patients who are deaf or hard of hearing, to ensure that they receive effective communication.

Through this agreement, CHRISTUS TMF affirms that it will comply with its obligations under Section 504 of the Rehabilitation Act of 1973 (Section 504) and Section 1557 of the Affordable Care Act (Section 1557) to provide appropriate auxiliary aids and services to persons who are deaf or hard of hearing.

CHRISTUS TMF is a faith-based, not-for-profit organization that includes six hospitals and over thirty clinics and outpatient centers in Texas. CHRISTUS TMF receives federal financial assistance through its participation in the Medicare and Medicaid programs and is subject to the requirements of Section 504 and Section 1557.

OCR initiated the compliance review after it received a complaint, on behalf of a CHRISTUS TMF patient, that a CHRISTUS TMF clinic and hospital failed to provide adequate or timely interpreter services despite multiple requests. OCR subsequently received information from additional patients alleging deficiencies in CHRISTUS TMF's provision of auxiliary aids and services to individuals who are deaf or hard of hearing. These allegations led OCR to conduct a broad review of CHRISTUS TMF's policies and procedures regarding its obligations under Section 504 and Section 1557.

Photo courtesy of the Teacher Retirement System of Texas

As a result of OCR's investigation and review, CHRISTUS TMF and OCR have agreed that CHRISTUS TMF will take steps to strengthen the provision of auxiliary aids and services, including:

- Performing communication assessments at patient intake and reassessing communication effectiveness regularly;
- Improving and upgrading its review, assessment, and provision of qualified interpreters, including in-person and by video remote interpreting;
- Providing annual staff training on effective communication;
- Submitting reports to OCR regarding CHRISTUS TMF's ongoing compliance activities, on which OCR will provide CHRISTUS TMF with substantive technical assistance and feedback; and
- Conducting outreach to local disability groups on the available auxiliary aids and services that CHRISTUS TMF provides to individuals who are deaf or hard of hearing.

Director Roger Severino, Director of OCR said, "Good healthcare starts with effective communication and this agreement helps eliminate unnecessary barriers to equal treatment for persons who are deaf of hard of hearing."

Roger Severino, Director, Office for Civil Rights (OCR)

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Moderate or Severe Sleep Apnea Doubles Risk of Hard-to-Treat Hypertension in African-Americans

Treatment of sleep disorder might help improve blood pressure control in this high-risk group

African-Americans with moderate or severe sleep apnea are twice as likely to have hard-to-control high blood pressure when their sleep apnea goes untreated, according to a new study funded mainly by the National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health. The findings, which researchers say may partially explain why African-Americans suffer hypertension at rates higher than any other group, point to screening and treatment of sleep apnea as another important strategy for keeping uncontrolled high blood pressure at bay.

A common disorder that blocks the upper airways and causes people to stop breathing during sleep, sleep apnea already has been linked to an increased risk of high blood pressure in whites, but the association in blacks has been largely understudied. This new research demonstrates this link in a large population of African-Americans. The results are scheduled to be published Dec. 10 in Circulation, a journal of the American Heart Association.

"This is an example of how NHLBI funded research is making important advances to our basic understanding of cardiovascular risk and sleep health," said Michael Twery, PhD, director of the National Center on Sleep Disorders Research at NHLBI. "This report underscores the need for studies to determine whether screening groups at high risk for sleep apnea, such as African-Americans, would facilitate early medical intervention and reduce the risk or severity of heart disease."

"This study identifies a risk factor for hard-to-control hypertension that until now has gone underrecognized in African-Americans," said study leader Dayna Johnson, PhD, an assistant professor in the Department of Epidemiology at Rollins School of Public Health at Emory University in Atlanta. Johnson added that the disproportionately high rate of uncontrolled hypertension among African-Americans makes the study results even more consequential. A recent NIH-funded study showed that about 75 percent of African-American men and women are likely to develop high blood pressure by age 55, compared to 55 percent of white men and 40 percent of white women of the same age.

Johnson noted that the current findings could provide more of an impetus for African-Americans with the condition to get evaluated for sleep apnea, which also appears to affect them more than it does whites. An estimated 1 in 4 African-Americans in the United States have moderate or severe sleep apnea, but most have not been diagnosed or treated by a doctor, according to a 2018 study led by Johnson when she worked at Brigham and Women's Hospital in Boston.

Susan Redline, MD, MPH, Associate Clinical Director, Professor, Harvard Medical School, Cardiovascular Medicine, Sleep Medicine

"Earlier studies indicate that untreated sleep apnea can cause blood pressure to surge during sleep and remain high during the day when a patient is awake."

In the new study, the researchers followed 664 African-Americans with hypertension who were participants in the Jackson Heart Study, the largest investigation of causes of cardiovascular disease in African-Americans. The researchers tested the participants for obstructive sleep apnea (the most common kind) with a special device used overnight in the home.

Researchers classified sleep apnea as unaffected, mild, moderate, or severe based on the number of times a person either partially or completely stopped breathing during sleep. The tests revealed that more than a quarter of the participants had moderate or severe sleep apnea and that the condition had gone undiagnosed in almost all of them — i.e., 94 percent of the cases. The remaining participants had either no sleep apnea, or a milder form of it.

The researchers also took blood pressure measurements and found that 48 percent of the participants had "uncontrolled" high blood pressure, meaning they had the condition even though they took one or two antihypertensive medications. About 14 percent had "resistant" hypertension, meaning they had the condition while on three or more antihypertensive medications. "Resistant" hypertension is more severe than "uncontrolled" and carries a higher risk for heart disease and death, the researchers said.

The researchers then compared measures of sleep apnea to categories of blood pressure control. Study participants with moderate or severe sleep apnea were twice as likely to have resistant hypertension when compared to participants without sleep apnea. Those with severe sleep apnea were 3.5 times as likely to have resistant hypertension compared to participants without sleep apnea. Somewhat unexpectedly, the researchers found no association between milder forms of sleep apnea and uncontrolled or resistant hypertension.

The results suggest that African-Americans with more severe forms of sleep apnea are at higher risk of having hard-to-treat hypertension, the researchers said. The current study did not explore what proportion of resistant hypertension is attributable to sleep apnea.

The study did not examine the mechanisms by which sleep apnea increases blood pressure. But Susan Redline, MD, senior physician at Brigham and Women's Hospital and the study's senior author, said that earlier studies indicate that untreated sleep apnea can cause blood pressure to surge during sleep and remain high during the day when a patient is awake.

Her earlier research showed that treatment of sleep apnea with continuous positive air pressure (CPAP) lowers blood pressure, especially during the night. CPAP and other breathing devices deliver slight air pressure through a mask and are highly effective for treatment of sleep apnea.

The study was supported by grants from the NHLBI (R01HL110068, 3R01HL110068-03S2; T32HL007901-18, and K01HL138211). Additional NHLBI support included the following: KL2TR001874, R01HL117323, and 5R35HL135818. Other NIH support included funding from the National Institute of General Medical Sciences (U54GM115428) through the University of Mississippi Medical Center.

The Jackson Heart Study is supported and conducted in collaboration with Jackson State University (HHSN268201300049C and HHSN268201300050C), Tougaloo College (HHSN268201300048C), and the University of Mississippi Medical Center (HHSN268201300046C and HHSN268201300047C) contracts NHLBI and the National Institute for Minority Health and Health Disparities.

The study was also supported by additional institutions outside of NIH, including the American Heart Association.

nhlbi.nih.gov

Photo courtesy of the National Heart, Lung, and Blood Institute

NIH Researchers Available to Discuss Latest Findings from Landmark Study of Hispanic/Latino Health

Hispanics in the United States suffer from high prevalence of cardiometabolic disorders such as heart disease, stroke, and obesity, according to the Centers for Disease Control and Prevention.

These chronic conditions are a top research priority for the National Heart, Lung, and Blood Institute (NHLBI), and Hispanic Heritage Month, from September 15 to October 15, offers a timely opportunity to highlight the most significant research findings.

Experts at the NHLBI, part of the National Institutes of Health, are available to discuss recent findings from the Hispanic Community Health Study/Study of Latinos (HCHS/SOL), the largest epidemiological study of diverse Hispanics/Latinos in the United States.

This landmark study enrolled 16,415 Hispanic/Latino adults living in San Diego, Chicago, Miami, and the Bronx, NY, who self-identified as being of Central American, Cuban, Dominican, Mexican, Puerto Rican, or South American origin.

These studies also underscore that this segment of the U.S. population is diverse not only in ancestry, heritage, culture, and economic status, but also in the prevalence of certain diseases, risk factors, and lifestyle habits across the different groups.

NHLBI researchers are available for interviews on the findings and implications of the following studies of the HCHS/SOL study cohort:

Diet, DASH, and metabolic disorders

Federal health experts say all Americans could benefit from following more closely the Dietary Guidelines, and a recent study found that Hispanics as a whole are no exception.

While the study found that individuals with Mexican, Dominican, and Central American heritage appear to follow a better-quality diet, it concluded that Latinos as a group could benefit from significantly reducing their consumption of sodium and eating more good fats such as nuts and fish. In fact, another study found that Hispanics consume too much sodium and too little potassium, problems researchers say warrant targeted interventions in this population.

Scientists also assessed the association between the Dietary Approaches to Stop Hypertension (DASH) diet — recommended for lowering blood pressure and preventing cardiovascular disease — and the prevalence of metabolic syndrome, or risk factors for increased cardiovascular disease and diabetes.

The research observed different associations with DASH by heritage, such as lower overall prevalence of metabolic syndrome in populations from Central and South America, and lower diastolic blood pressure in those from Mexico, Central and South America.

Physical activity, sedentarism, and obesity

Hispanics are not clocking in enough hours of physical activity, and the problem starts at an early age. A study found that despite some differences based on heritage, Latino youth average 25 minutes per day of moderate physical activity — less than half of what federal guidelines recommend — while they spend on average ten hours per day being sedentary. Previous research of Hispanic youth found that little physical activity and high amounts of sedentary behavior are linked to increased cardiometabolic risk. Among Hispanic adults, a study also found that physical activity was associated with better physical health-related quality of life.

Photo courtesy of the Office of Minority Health

Photo courtesy of the National Heart, Lung, and Blood Institute

Sleep and cardiometabolic health

Mounting evidence links sleep to overall health. The contribution of sleep deficiency to health disparities is an increasing concern of researchers and healthcare providers. Sueño, a HCHS/SOL ancillary study, provides important sleep-related evidence for the U.S. Hispanic population. This study found that shorter sleep duration was linked to a higher prevalence of obesity, and daytime napping was even more strongly associated with greater adiposity.

Another finding from the Sueño study showed that the timing and regularity of sleep-wake schedules — not just sleep duration — was strongly associated with the prevalence of hypertension, a key risk factor for cardiometabolic diseases.

"A study found that despite some differences based on heritage, Latino youth average 25 minutes per day of moderate physical activity — less than half of what federal guidelines recommend — while they spend on average ten hours per day being sedentary."

nhlbi.nih.gov

Excellence in Hypertension Control in a Rural Setting

Members of rural populations, which make up 15% of the United States, are at greater risk of dying from heart disease. High blood pressure, smoking, and obesity are more common among rural residents. But two rural family practices have been able to overcome these challenges and achieve blood pressure readings below 140/90 for more than 80% of their patients. These two practices' strategies of educating patients and leveraging technology can be used anywhere.

High Plains Community Health Center

Established in 1995 and centered in Lamar, Colorado, High Plains is a family practice surrounded by farms and ranches. High Plains' six clinics serve about 9,300 patients per year. Its most remote clinic, 30 miles away from Lamar in Holly, achieved a hypertension control rate of 83%. By forming partnerships in their community they have helped facilitate healthy lifestyle changes, and their partnership with the Big Timbers Community Alliance helped develop more outdoor recreational options around town, including an 8.9-mile walking path and a skate park.

Astoria's Pacific Family Medicine

Established in 2001 on the coast of Oregon, this single clinic serves 3,500 patients that started with an exceptional control rate, and with added support from the Oregon Rural Practice-based Research Network (ORPRN), the practice achieved blood pressure control for an impressive 89% of patients last year.

These results were achieved by investing in patient education. Both High Plains and PFM realized how important it was for patients to understand a chronic condition such as high blood pressure and what was needed to manage it. Both practices make patient education a priority.

"With more education, patients do come to understand about the risks," said Susanna Storeng, MPAS, PA-C, a physician assistant at High Plains. "If we can take the time to educate our patients on what hypertension is, why it happens, and what the poor outcomes from it are, then it does definitely help."

High Plains health coaches are trained in motivational interviewing, a counseling method that helps people make healthy lifestyle changes by having them commit to specific, reasonable goals they can achieve in a realistic time frame.

At ORPRN's recommendation, PFM trained its medical assistants (MAs) to talk with patients about blood pressure, answer common questions, and set patients up with home blood pressure monitors if necessary. By getting the discussion started with the MAs during the check-in process, physicians have more time to discuss the details of diagnosis and treatment.

Members of rural populations are at greater risk of dying from heart disease. High blood pressure, smoking, and obesity are more common among rural residents.

Leveraging electronic health records

Coordinating team-based care can be tricky, and patients can easily fall through the cracks unless a structure prevents it. That's why both High Plains and PFM rely on electronic health record (EHR) systems to keep tabs on patients.

For example, PFM programmed its EHRs to alert the provider when a patient qualifies for a different screening or is due for a visit. PFM can also run complex reports to find patients with hypertension and other chronic conditions who may be overdue for a follow-up visit. "We leverage our EHRs and other capabilities to protect patients," said Janet Mossman, FACMPE, clinic manager for PFM.

At High Plains, care teams use the EHR system to communicate. For example, team members can set up "flags" in EHRs to notify other team members, such as alerting a health coach to call a patient for a home blood pressure measurement. The health coach can then set a flag for the primary care provider to review the measurement at the patient's next visit.

Both practices emphasize that strong patient relationships are key.

PFM focuses on its culture of communication and mutual responsibility. All new patients sign a "contract" agreeing to meet certain milestones. For example, people who have chronic diseases agree to make at least three visits a year. Patients who miss appointments are contacted personally by Mossman for a frank discussion about their condition and care.

"We have an amazing relationship with our patients," Mossman said. "They know it's a two-way street. We're very communicative about the fact that patients need to be equally engaged in their care. That's the culture we share with them from the first visit onwards."

Storeng says High Plains benefits from the small-town atmosphere. The clinic makes sure patients always see the same team members. High Plains also performs quarterly patient satisfaction surveys.

"We are a small community, and that really makes family medicine very important," Storeng said. "We understand the patient's culture and values, and this helps the patient to know that they are cared for."

Although rural practices may face unique challenges, any practice can implement these solutions for improving hypertension control rates. High Plains and PFM recommend the following strategies:

- Educate patients so that they understand why certain medicines and steps are needed to manage their condition.
- Embrace technology such as EHRs to increase efficiency among the care team and to provide a safety net for patients.
- Hire qualified staff so that your practice has the support it needs to reach its benchmarks.
- Have passion and compassion for your patients.

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CPG

Native American Women and Heart Health

A New Vision for Research and Outreach

Brandie Taylor is watching her teenage son, Hunter Banegas, grow into a man. She is proud of his talent and his embrace of Kumeyaay Bird Singing, which is performed at traditional gatherings of their tribe, the Iipay Nation of Santa Ysabel, near San Diego, Calif.

But 13 years ago, a future filled with song — a future with Hunter — seemed doubtful. When Taylor was eight months pregnant with Hunter, she was hospitalized for sleeplessness, coughing, and fatigue. These symptoms were at first attributed to a complicated pregnancy, but they turned out to be warning signs of heart failure. Taylor was rushed into intensive care, where Hunter was delivered by emergency C-section. Hunter was born healthy, but it took years of treatment — including a heart transplant in 2008 — for Taylor "to start feeling good again."

Hers is not an uncommon story. Heart disease, the leading cause of death for all American women, takes a disproportionately heavy toll on Native American women. American Indian and Alaska Native women die from it at a rate 20-30 percent higher than non-Native women, and Native Hawaiian women at a rate 100 percent higher.

Taylor, who is now the chairwoman of her tribe, shared her story last year at a forum sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and WomenHeart: The National Coalition for Women with Heart Disease, with guidance from the Indian Health Service (IHS). As a WomenHeart Champion, Taylor is part of a nationwide network of trained community educators sharing information and experiences with women heart patients. This time, her story reached a new audience.

Brandie Taylor at the convening with her son, Hunter Banegas, who opened the event in song. Photo courtesy of WomenHeart

The Kā-HOLO Project, based at the University of Hawaii, is examining hula dancing as an approach to high blood pressure management in Native Hawaiian women and men. A pilot clinical trial found that a three-month hula program helped people with hypertension lower their blood pressure. A larger trial is now underway. Photo courtesy of Nicasello Photography

Health education is central to the NHLBI's Strong Heart Study. Here a health care worker meets with a participant in Eagle Butte, S. Dak. Celebrating its 30th year, the Strong Heart Study is the largest and longest-running study of cardiovascular health in American Indians. Photo courtesy of Missouri Breaks Industries Research

The Convening on Native American Women's Heart Health, in December 2018, took place at the Smithsonian Institution's National Museum of the American Indian, where Taylor and her son joined more than 40 other people — including Native American health experts and educators — to explore how to better prevent heart disease among Native American women and enhance support for those living with the disease.

The day included presentations on prevalence and outcomes of heart disease in Native American women, panel discussions on evidence-based approaches to prevention and education, and small breakout sessions to discuss lessons learned and potential new approaches. A host of themes emerged that might help inform public health policy, community heart health programs, and medical and research protocols to ultimately reduce the high burden of heart disease Native American women.

The values and resources a community cherishes — its culture, its elders — can be as important to emerging heart programs as that community's health data. That's why many Native American communities are returning to traditional wisdom and practices in developing interventions that improve heart health. A research project investigating the cardiac benefits of traditional Native Hawaiian hula dancing was crafted with that idea in mind.

The personal stories of Native American women living with heart disease can be a rich resource for those trying to shape effective prevention and treatment programs. Health workers and researchers must listen to these real-life stories, even deputize as "ambassadors" the women who tell them. In turn, these women can help reach others in the community and educate policymakers, too.

Linda Poolaw, a Kiowa member and Delaware tribal leader, served as a tribal liaison and recruiter for the Strong Heart Study for 22 years and has heart disease herself. Photo courtesy of WomenHeart

Women are stewards of their own health and also play important roles in the health of their families and communities. Reaching out to those who are at-risk — directly and also indirectly through their personal relationships and service providers — can be highly effective. Likewise, enlisting help from women who hold traditional leadership roles, as they can help guide and implement heart health programs that work. This approach allows many voices to carry the same messages and spreads the responsibility to protect women's health across the community.

Many Native American communities consider pregnancy a sacred time for passing traditional wisdom to the expectant parents. And because women may be more likely to make healthy lifestyle changes — more for their children than for themselves — this can be an ideal time to encourage women to improve their heart health. For expectant mothers, heart disease raises the risk not only of early disability and death, but of passing on risk factors to their children, including obesity and type 2 diabetes.

Compared with other U.S. demographic groups, Native Americans have high rates of ACE, such as neglect, abuse, or parental incarceration. Because ACE has been linked to heart disease, addressing it at community and individual levels should be an early part of any intervention aimed at improving cardiovascular health in Native American women and girls. Some ACE trauma has its roots in historical abuses, and acknowledging this history is important to the success of health initiatives.

Young people in Native American communities may see older family members struggle with heart disease in their 40s or even earlier. This can give them a sense of fatalism about their future health and well-being. Poverty and other ACEs may also lead young Native Americans to focus more on short-term survival than on long-term health. Interventions designed with and tailored to young women and girls can help shift their attitudes and behaviors toward wellness over the short and long term.

Convening attendees gather at the Smithsonian Institution's National Museum of the American Indian Photo courtesy of WomenHeart

Efforts to address the disproportionate burden of heart disease in Native American women cannot succeed without providers, educators, and researchers who understand the culture and life experiences of these women. The NHLBI supports programs that provide training and development to Native American health scholars across the career spectrum, including the Programs to Increase Diversity Among Individuals Engaged in Health-Related Research (PRIDE) initiative and the Native American Summer Research Internship program.

Community tradition, history, and culture should be considered part of an evidence base that also includes clinical trial or observational study data. There is value in considering new kinds of evidence and outcomes measures (e.g., "How did that food make you feel?" in addition to "How many calories were in that food?"). Identifying ways of merging Native American traditional knowledge and other sources of knowledge, rather than viewing them as incompatible, has value, as well.

Sovereignty over clinical, genetic, and other biomedical data from research and public health surveillance is a top priority for Native American communities. It should be coupled with support from researchers and federal health agencies to analyze, interpret, and translate the data into clear, actionable terms for community leaders. Data ownership and translation can empower leaders to optimize health programs necessary for the women and men in their communities to thrive.

During her recovery from her 2008 transplant surgery, Brandie Taylor connected with a local WomenHeart support group, where she met women whose experiences closely reflected her own. "That's what really saved me," she says.

At the Convening, a different kind of relationship-building took place. Participants came together from diverse professions — including healthcare and health-related research, education, and policy. They shared their unique stories — from the perspective of clinician, scientist, educator, and patient. Collectively, more than one dozen indigenous tribes and cultures were represented. This rare gathering was a step toward a new collaborative vision toward heart disease research, intervention, and support programs geared to the unique challenges, needs, and strengths of Native American women. Participants were encouraged to take ideas that resonated with them back to their organizations and communities. Together, we will continue to work toward a heart-healthy future for Native American women.

nhlbi.nih.gov

Researchers Find Cause of New Autoinflammatory Disease

By Prabarna Ganguly, PhD

Members of three families came to NIH's Clinical Center with symptoms similar to those caused by an autoinflammatory disease, but with no known cause. The seven patients ranged from 10 to 82 years old. Their symptoms included fevers, swollen lymph nodes, severe abdominal pain, gastrointestinal problems, headaches and, in some cases, abnormally enlarged spleen and liver. Although their condition isn't life-threatening, they can have persistent fever and swollen lymph nodes from childhood to old age, as well as other symptoms that can lead to lifelong pain and disability.

A team of researchers led by Dr. Daniel Kastner of NIH's National Human Genome Research Institute (NHGRI) and Dr. John Silke at the Walter and Eliza Hall Institute in Australia carried out a study looking for the cause of the syndrome. After ruling out infections and cancer, they sought answers by genomic sequencing. The study, which was funded by several NIH components, was published on January 2, 2020, in Nature.

The team discovered only one gene — RIPK1 — that was consistently different in all patients. Each of the three families had its own unique mutation affecting the very same DNA letter in the RIPK1 gene. Each affected person had one mutant and one normal copy of the gene, while unaffected family members had two normal copies.

The protein encoded by the RIPK1 gene is involved in inflammation and programmed cell death — the process by which old cells die so they can be replaced by new ones. Each of the patients' mutations occur at the location where RIPK1 can be cleaved to prevent it from initiating inflammation and cell death.

Identification of a previously unknown autoinflammatory disease — and the mechanism that causes it — could lead to new treatments for this and other inflammatory conditions. Photo courtesy of NIH and Weekend Images Inc.

Thus, Kastner's team named the disease cleavage-resistant RIPK1-induced autoinflammatory, or CRIA, syndrome.

Mouse embryos with two mutant copies of RIPK1 did not survive in the uterus due to excessive cell death signals. However, mice with one mutant copy and one normal copy, like the CRIA patients, were mostly normal but had heightened inflammatory responses.

The team tested therapies known to reduce inflammation in seven patients with CRIA syndrome. While drugs such as etanercept and anakinra, which are used to treat autoinflammatory and chronic diseases such as rheumatoid arthritis, had little effect, one drug called tocilizumab did. Tocilizumab is a drug that suppresses a specific signaling molecule in the immune system. It reduced the severity and frequency of CRIA syndrome symptoms in five out of the seven patients — in some cases with life-changing effects.

"This discovery underscores the tremendous power of combining astute clinical observation, state-of-the-art DNA sequencing, and the sharing of sequence data in large publicly-accessible databases," Kastner says.

Researchers are now trying to understand the molecular mechanism that enables tocilizumab to treat CRIA syndrome. Specific inhibitors of RIPK1, which are under development, may also hold promise in both CRIA syndrome and other seemingly intractable inflammatory conditions.

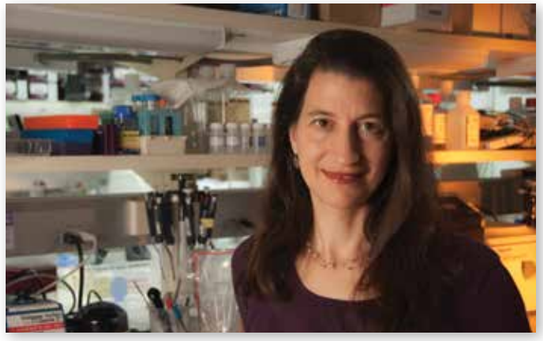
nih.gov

Researchers Unearth Community of Viruses on Skin of People with Rare Disease

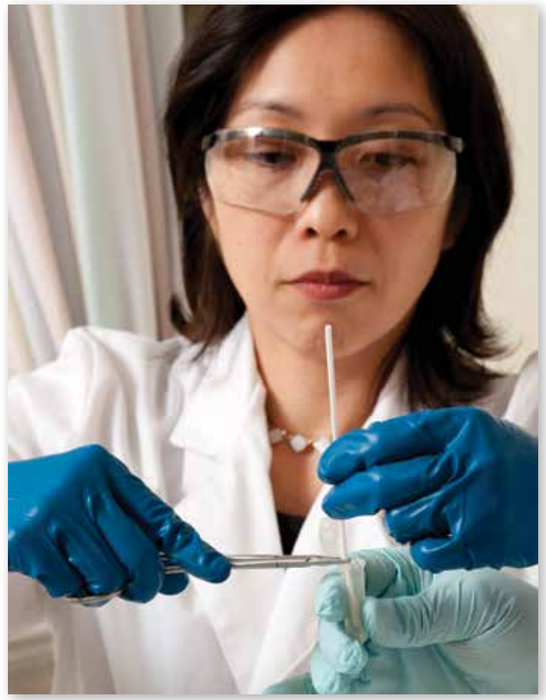
NIH researchers studied microbial populations in skin samples from 27 adults and children with a rare immune disorder, DOCK8 deficiency. People with this primary immunodeficiency disease often have severe infections, are susceptible to cancer and have skin problems that can include difficult-to-treat warts, molluscum and eczema. The findings appear in Nature Medicine.

While most healthy people have skin microbial communities composed mainly of bacteria, the scientists found that these patients had microbial populations rich in viruses. Using sophisticated sequencing tools, the researchers uncovered and catalogued hundreds of novel viral genomes.

- The most common viruses detected in participants' skin samples were human papillomaviruses (HPVs), even when there were no clinically apparent skin lesions, such as warts. The team identified many novel HPVs.
- Despite finding many viruses on the skin, they weren't abundant in microbial communities in other parts of the body, such as the mouth and gut. This highlights the importance of studying different parts of the body because not all areas show the same type of host-microbial differences.
- The findings raise questions about whether viruses may or may not contribute to some of the cancers that these patients develop.
- The study provides a unique perspective on the degree to which a person's altered immunity may shape their microbiome, and how, in return, their microbial community may interact to drive disease.



Dr. Julie Segre. Photo courtesy of the National Human Genome Research Institute



Dr. Heidi Kong. Photo courtesy of the National Cancer Institute

"The contribution of viruses to the human microbiome has been underappreciated. This study adds important evidence for the need to better understand these relationships", said Heidi Kong, MD, MHSc, study author, Head and Investigator, Cutaneous Microbiome and Inflammation Section, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).

"Studying people with this rare primary immune deficiency opens the door to study the larger group of patients who are undergoing transplant and are immunosuppressed, some of whom develop squamous cell carcinoma", said Julie Segre, PhD, study author, Chief and Senior Investigator, Translational and Functional Genomics Branch, National Human Genome Research Institute (NHGRI).

niams.nih.gov

What's New on the Horizon for Scleroderma?

NIH-supported experts review stem cell transplantations, anti-fibrosis drugs, and more

There may not be a cure yet, but many scleroderma experts are optimistic about ongoing research into new treatments.

We asked John Varga, MD, professor of medicine and director of the Northwestern University Scleroderma Program, and Carol Feghali-Bostwick, PhD, a scleroderma patient herself and a professor of medicine at the Medical University of South Carolina, to discuss potential new advancements. Both researchers work with NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases.

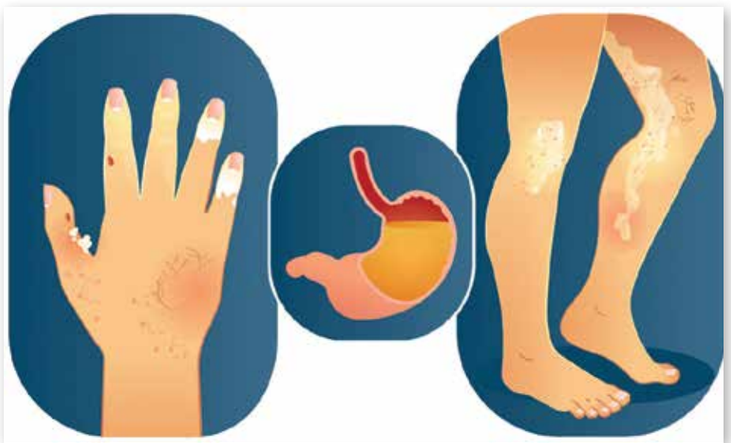
"Stem cell transplants could be a promising treatment for those with very severe scleroderma." – John Varga, MD

Carol Feghali-Bostwick, PhD and John Varga, MD work with NIH on scleroderma research.

Anti-fibrosis drugs

There are major lung studies looking at drugs that can halt the development of thick scarring tissue, called fibrosis, that can occur in systemic scleroderma, as well as other lung diseases like asthma and chronic obstructive pulmonary disease, Dr. Feghali-Bostwick says.

"My team and I also have used NIH funding to identify an essential peptide — a small piece of protein — that seems to be able to stop and possibly reverse the formation of fibrosis in mouse and human tissue. We are now researching how this peptide works, with hopes of testing it in a clinical trial," she adds.



More drugs for rare diseases

Many immunomodulatory drugs, which can regulate the immune system, are in clinical trials. And a number of recent studies have found that drugs that block an inflammation-causing protein in lupus and similar diseases may also work for scleroderma.

Stem cell transplants

There is a lot of interest in a recent NIH-funded study that found that stem cell transplants for people with severe scleroderma could have long-term, beneficial results, says Dr. Varga. In the study, chemotherapy and radiation were used to wipe out the person's immune system, and then the person's own stem cells were used to rebuild a new system. But Dr. Varga and others warn that a stem cell transplant is not appropriate for every patient and can involve dangerous side effects. "But it could be a promising treatment for those with very severe scleroderma," he says.

medlineplus.gov

'Don't Give up Hope'

Bob Saget's unlikely path to scleroderma advocacy

Photo courtesy of Bob Saget

Television actor and comedian Bob Saget has been making Americans laugh for decades.

The "Full House," "America's Funniest Home Videos," and "Fuller House" star has also won praise for his longtime advocacy on behalf of people battling scleroderma, a chronic autoimmune disease. He recently spoke with NIH MedlinePlus magazine about his advocacy and commitment to finding a cure for the disease.

How did you first get involved as an advocate for those with scleroderma?

It's an unusual story. One day I got a call from someone I did not know asking me to host a comedy fundraiser for a disease I knew very little about. The call was from Sharon Monskey, a wonderful and amazing woman, a former ice skater who had scleroderma and founded the Scleroderma Research Foundation (SRF).

I said yes and hosted the event, which starred Ellen DeGeneres, Rosie O'Donnell, and others. Little did I know that just a few years later, my sister would be diagnosed with the disease.

I have been on the board of directors of the SRF for over a decade now and hosted their events for 25 years.

Your sister fought a long battle with scleroderma. Can you share her story with us?

My sister, Gay Saget, was a school teacher near Philadelphia. She was 44 when she was diagnosed with systemic scleroderma. She got treatment, but it was just treating her symptoms with drugs like prednisone and cortisone. She had to move to Los Angeles to live with my parents because she needed so much help. She passed away just two years later.

The good news is that since then we have made some remarkable progress. There are new drugs specifically for scleroderma that are helping people. But we have a long way to go to get to even more effective treatments and eventually a cure.

What message do you have for those living with the condition and their loved ones?

I speak with and meet a lot of people with the condition. My word to them is don't give up hope because we are making incredible progress.

I also advise them to get educated about the condition and to find a real expert in scleroderma to care for them. That is key. And if they can, try to get help from a center of excellence to get the best treatment.

It is incredibly painful to have a loved one experience a condition like this. It is a very painful disease. My family is still having post-traumatic stress disorder. I don't know how my parents endured. But I would tell loved ones: Don't give up hope. Stand by them and get them help. And get them help as early as possible.

Why is research like that supported by NIH so important? There is no improved treatment and there is no cure without the research. Research is the key that opens the door for the cure. You cannot eradicate the disease or diminish the disease without understanding it. We have some of the greatest minds in science working on this. And when you unlock the gate on scleroderma, it will impact a lot of other conditions.

medlineplus.gov

Transforming Containers into Modern Medical Clinics

By Avery Waite

Capable of serving as primary care clinics, surgical centers, and even mobile pharmacies, the pods are far more robust than pop-up clinics often present in hot zones.

Dr. Sharmila Anandasabapathy works with a team at Baylor College of Medicine in Texas to harness the power of technology to solve medical problems in remote places around the globe that have scarce resources. The Emergency Smart Pod is a great example of this approach.

"I had this idea for developing amobile, expandable, low-cost shipping container for performing medical procedures like endoscopy," says Anandasabapathy. "When the Ebola outbreak occurred in 2014, we took that concept and adapted it for a clinic that would be suitable for handling high-level infectious agents."

As Anandasabapathy and her team further refined the portable clinic idea, they were selected as one of 14 winners of USAID's Fighting Ebola Grand Challenge, which aimed to provide health care workers on the front lines with better tools to battle the epidemic. "The greatest thing about science is that the work is no longer done in isolation. The support of USAID gave us the chance to collect information from those in the field. As an example, we learned that the equipment we originally planned to use was too heavy to transport on roads in West Africa, which helped us in thinking through a new direction for using lighter materials," says Anandasabapathy.

Over the past three years, the Baylor College of Medicine team has developed and tested the Emergency Smart Pod, a rapidly deployable treatment center that can serve as an isolation unit for patient care during infectious disease outbreaks, such as the 2014 Ebola epidemic in West Africa.

Dr. Sharmila Anandasabapathy and her team designed the Emergency Smart Pod, a rapidly deployable patient care unit.
Photo courtesy of Lindsey Kingston Lampp, Baylor College of Medicine

The Emergency Smart Pod now serves as an isolation unit for infectious patients at ELWA Hospital in Monrovia, Liberia. Photo courtesy of USAID

Each pod can be shipped directly to its destination by boat, truck, or air, and assembled in less than five minutes with a team of four people. In addition, multiple pods can fit together like Legos to create larger medical clinics.

"The pod is designed to provide a lower-cost, 'off-grid' solution to areas that lack medical capacity or need augmentation of existing capacity," says Anandasabapathy.

The Baylor team has been adapting the Smart Pod for use in different community settings. Capable of serving as primary care clinics, surgical centers, and even mobile pharmacies, the pods are far more robust than the pop-up clinics often present in hot zones during an infectious disease outbreak.

In September 2017, the Emergency Smart Pod was shipped to Monrovia, Liberia, where it was used to prepare Ebola survivors for cataract surgeries at ELWA Hospital. The pod now functions as an isolation unit for infectious patients.

Looking toward the future, the Baylor team even has an eye toward Smart Pod uses beyond Earth — they have been working with NASA on the Mars habitat program.

state.gov

Treatment Guidelines Improve Survival of People with Severe Head Injury

NIH-funded study shows protocol may help people with severe traumatic brain injury

A large study of more than 21,000 people finds that training emergency medical services (EMS) agencies to implement prehospital guidelines for traumatic brain injury (TBI) may help improve survival in patients with severe head trauma. The findings were published in JAMA Surgery, and the study was supported by the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health.

"This demonstrates the significance of conducting studies in real-world settings and brings a strong evidence base to the guidelines," said Patrick Bellgowan, PhD, program director at NINDS. "It suggests we can systematically increase the chances of saving lives of thousands of people who suffer severe traumatic brain injuries."

Based on scores of observational studies, guidelines for prehospital management of TBI that were developed in 2000, and updated in 2007, focused on preventing low oxygen, low blood pressure, and hyperventilation in people with head injury. Collectively, the studies suggested that controlling those factors before patients arrived at the hospital could improve survival, but actual adherence to the guidelines had not been examined.

The Excellence in Prehospital Injury Care (EPIC) Study, led by Daniel Spaite, MD, professor of emergency medicine at the University of Arizona in Tucson, trained EMS agencies across Arizona in the TBI guidelines and compared patient outcomes before and after the guideline implementation. All patients in the study experienced head injury with loss of consciousness. This public health initiative was a collaboration between the university and the Arizona Department of Health Services. The EPIC study is the first time that the guidelines were assessed in real-world conditions.

Photo courtesy of the National Institue of Neurological Disorders and Stroke

The results showed that implementing the guidelines did not affect overall survival of the entire group, which included patients who had moderate, severe, and critical injuries. However, further analysis revealed that the guidelines helped double the survival rate of people with severe TBI and triple the survival rate in severe TBI patients who had to have a breathing tube inserted by EMS personnel. The guidelines were also associated with an overall increase in survival to hospital admission.

"We found a therapeutic sweet spot and showed that the guidelines had an enormous impact on people with severe TBI. The guidelines did not make a difference in the moderate TBI group because those individuals would most likely have survived anyway and, unfortunately, the extent of injuries sustained in many critical patients was too extreme to overcome," said Dr. Spaite.

Bentley Bobrow, MD, professor of emergency medicine at the University of Arizona and co-principal investigator for the study said, "It was exciting to see such dramatic outcomes resulting from a simple two-hour training session with EMS personnel."

Although the guidelines provide specific recommendations for oxygen levels and blood pressure, researchers will examine whether those ranges should be revised. More research is needed to determine the best strategies for airway management and breathing support to optimize ventilation. Additional studies will investigate the best methods for national and global adoption of the TBI guidelines.

References: Association of Statewide Implementation of the Prehospital Traumatic Brain Injury Treatment Guidelines With Patient Survival Following Traumatic Brain Injury: The Excellence in Prehospital Injury Care (EPIC) Study.

nih.gov

Making a Difference to Reduce Kidney Failure from Diabetes in Native Americans

Team-based and population approaches can be a model for other groups

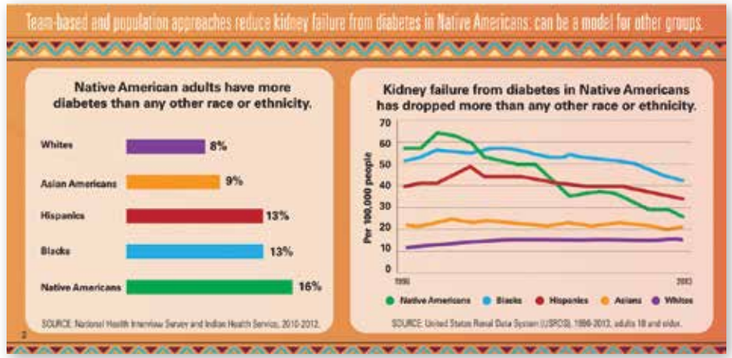
Recent health surveys from the Indian Health Service show Native American adults have more diabetes than any other race or ethnicity, (Source: IHS 2010-2012).

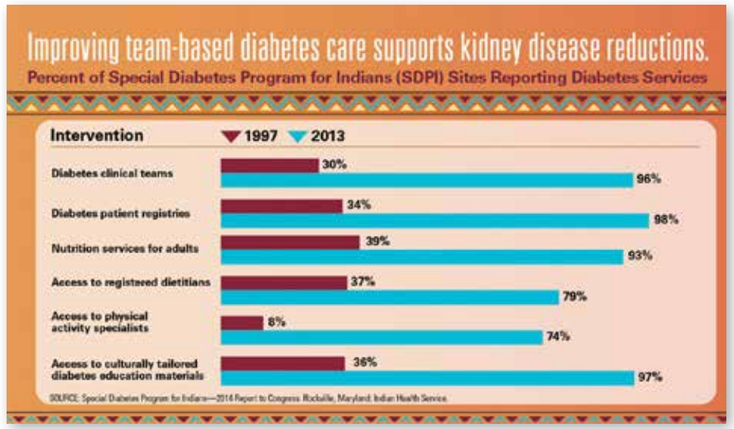
In response to the diabetes epidemic among American Indians and Alaska Natives, Congress established the SDPI grant programs in 1997. This $150 million annual grant program, coordinated by IHS Division of Diabetes with guidance from the Tribal Leaders Diabetes Committee, provides funds for diabetes treatment and prevention to IHS, Tribal, and Urban Indian health programs across the United States.

This intervention has been attributed to a reduction of kidney failure from diabetes in Native Americans, having dropped more than any other race or ethnicity.

Comparing kidney failure from diabetes in Native Americans to other groups from 1996 to 2013, in 1996 Native Americans had more kidney failure than blacks, Hispanics, Asians and whites.

By 2013 however, Native Americans were third in kidney failure from diabetes despite having the most diabetes.





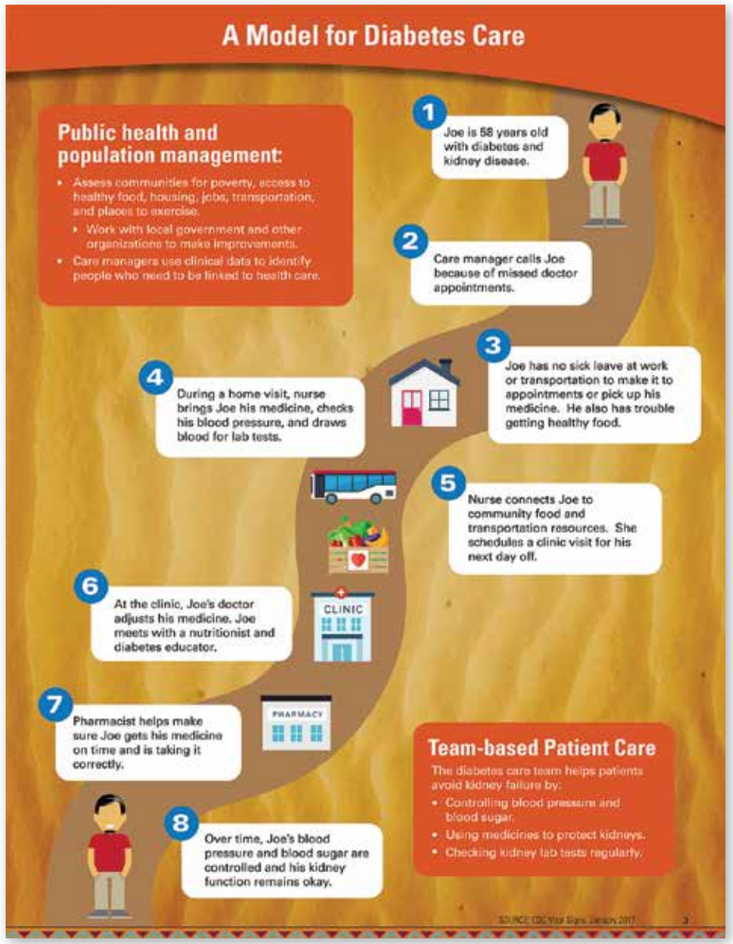
Per 100,000 people:

General population	(1996)	(2013)	(% change)
American Indians/Alaska Natives	(57.3)	(26.5)	(-54)
Asians	(23.1)	(22.2)	(-4)
Blacks	(52.2)	(42.7)	(-18)
Whites	(12.1)	(15.5)	(+28)
Hispanics	(40.1)	(34.2)	(-15)

Source: United States Renal Data System (USRDS), 1996-2013, adults 18 and older.

The 2014 report to Congress from Indian Health Service's Special Diabetes Program for Indians (SDPI) demonstrated tremendous improvements to key attributes in both Diabetes prevention and treatments.

Current efforts such as the IHS Diabetes in Indian Country Conference are continuing to make improvements, such as the with the 2019 conference held in Oklahoma City which provided continuing education opportunities and collaboration on issues related to improving outcomes for people with diabetes and those at risk for developing diabetes.



This points can be used in all populations effectively and have been made available for all Public Health providers to use in their local communities.

Public health and population management include:

- Assess communities for poverty, access to healthy food, housing, jobs, transportation, and places to exercise.
- Work with local government and other organizations to make improvements.
- Care managers use clinical data to identify people who need to be linked to health care.

The diabetes care team helps patients avoid kidney failure by:

- Controlling blood pressure and blood sugar.
- Using medicines to protect kidneys.
- Checking kidney lab tests regularly.

CDC.gov

State Public Health Actions to Prevent and Control Diabetes, Heart Disease, Obesity and Associated Risk Factors, and Promote School Health

Barbara Z. Park, RDH, MPH; Letitia Cantrell, PhD; Holly Hunt, MA; Rosanne P. Farris, PhD; Patricia Schumacher, MS, RD; Ursula E. Bauer, PhD

Chronic diseases, including heart disease, cancer, stroke, diabetes, and related risk factors, are among the leading causes of death and disability in the United States. In 2010, 7 of the top 10 causes of death were chronic diseases, which account for 86% of US health care costs. Furthermore, half of all adults have one or more chronic health conditions, and one-fourth of adults have 2 or more.

For 25 years, the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) of the Centers for Disease Control and Prevention (CDC) has provided scientific leadership and technical expertise to state health and education departments to assist them in developing, implementing, and sustaining chronic disease prevention and health promotion programs.

To facilitate greater progress in reducing the prevalence and incidence of multiple chronic diseases and their associated risk factors, NCCDPHP began funding programs to implement coordinated activities aligned with the 4 domains of public health action:

1) epidemiology and surveillance,

2) environmental approaches,

3) health care system interventions, and

4) community programs linked to clinical services.

Together, the 4 domains provide a framework for addressing chronic conditions (eg, diabetes, hypertension) and their risk factors (eg, obesity) across multiple settings and sectors, and they allow CDC to support complementary strategies to prevent and manage the underlying risk factors for chronic diseases and to assist health care providers and individuals in self-managing multiple chronic conditions.

By investing resources to implement key evidence-based strategies, NCCDPHP has sought to address multiple risk factors, conditions, and diseases simultaneously; improve program efficiency; increase program impact; and, ultimately, improve the health of communities.

To guide implementation of this new approach, the staff members of NCCDPHP programs reviewed evidence-based approaches and funding priorities across several chronic disease programs, developed a logic model of strategies and activities, and solicited partner feedback.

This approach resulted in the creation of the program, State Public Health Actions to Prevent and Control Diabetes, Heart Disease, Obesity and Associated Risk Factors, and Promote School Health (State Public Health Actions), for state health departments.

Partnering with state health departments began in July 2013, and by June 2018, NCCDPHP will have partnered with 50 state health departments and the District of Columbia to address chronic diseases and other risk factors through the 4 domains.

This approach leverages data to inform action, supports healthy choices and behaviors, strengthens delivery of clinical preventive services, and helps Americans better manage their health.

Figure 1

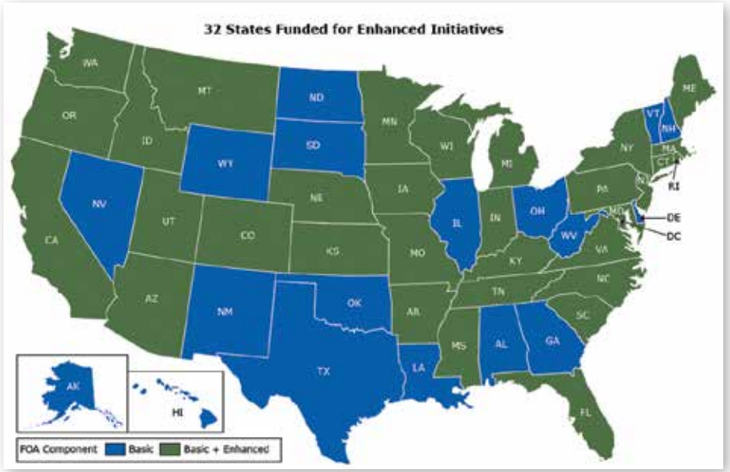
The 4 domains provide focus for State Public Health Actions to address chronic disease at the individual level by promoting health care interventions and at the population level by developing policies and creating environments that promote health. We anticipate that this coordinated approach will lead to the following outcomes:

- Increased consumption of a healthy diet.
- Increased physical activity across the life span.
- Improved medication adherence for adults with high blood pressure or diabetes.
- Increased self-monitoring of high blood pressure tied to clinical support.
- Increased access to and participation in diabetes self-management programs and type 2 diabetes prevention programs.
- Increased breastfeeding.

If successful, this approach also could lead to long-term improvement in the prevention and control of hypertension, diabetes, and obesity (Figure 1).

Strategies and Activities Within State Public Health Actions

- Promote the adoption of food service guidelines and nutrition standards, including dietary sodium.
- Promote the adoption of physical education and physical activity in schools.
- Promote adoption of physical activity in early care and education and worksites.
- Promote reporting of blood pressure and hemoglobin A1C control measures; as able, initiate activities that promote clinical innovations, team-based care, and self-monitoring of blood pressure to improve blood pressure control.
- Promote awareness of high blood pressure among patients.
- Promote awareness of prediabetes among people at high risk for type 2 diabetes.



- Promote participation in diabetes self-management education programs.
- Environmental approaches to promote health and support healthful behaviors
  - Promote access to healthy food and beverages.
  - Promote food service guidelines and nutrition standards where foods and beverages are available. Guidelines and standards should address sodium.
  - Promote supportive nutrition environments in schools.
  - Promote physical activity access and outreach.
  - Promote physical activity in early care and education.
  - Promote quality physical education and physical activity in grades kindergarten through 12 in schools.
  - Promote access to breastfeeding-friendly environments.
- Health system interventions to improve the delivery and use of clinical and other preventive services
  - Develop quality improvement processes in health systems.
  - Promote the use of team-based care in health systems.
- Community clinical linkages to support cardiovascular disease and diabetes prevention and control efforts
  - Promote the use of diabetes self-management education programs in community settings.
  - Promote the use of CDC-recognized lifestyle change programs in community settings for primary prevention of type 2 diabetes.
  - Promote the use of non-medical doctor health care providers in the community to support self-management of high blood pressure and diabetes.
  - Promote the use of chronic disease self-management programs in community settings.
  - Develop policies, processes, and protocols in schools to meet the management care needs of students with chronic conditions.

cdc.gov

Celebrating 70 Years of The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Established in 1947 as the Experimental Biology and Medicine Institute, subsequently incorporated in 1950 by President Harry S. Truman into the National Institute of Arthritis and Metabolic Diseases, the name of the institute was changed in 1972 to National Institute of Arthritis, Metabolism, and Digestive Diseases, and then changed again in 1981 to the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, and in 1986 to its present name following the creation of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).

Today the NIDDK is approximately the fifth-largest of the 27 NIH institutes, and continues its mission to conduct and support medical research and research training and to disseminate science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases, to improve people's health and quality of life.

Many significant accomplishments have been achieved over the past 70 years by NIDDK supported research, including the original metabolic chamber developed by Drs. G. Donald Whedon and Russell M. Wilder in 1957, and several Nobel Prize winning grantees such as the 2019 awards to Dr. Gregg L. Semenza in Physiology Medicine with NIH grantee Dr. William G. Kaelin Jr. for their discoveries of how cells sense and adapt to oxygen availability.

President Harry S. Truman at the laying of the cornerstone for the NIH Clinical Center

President Harry S. Truman signed the Omnibus Medical Research Act into law, establishing the National Institute of Arthritis and Metabolic Diseases (NIAMD) in the U.S. Public Health Service. The new Institute incorporated the laboratories of the Experimental Biology and Medicine Institute and expanded to include clinical investigation in rheumatic diseases, diabetes, and a number of metabolic, endocrine, and gastrointestinal diseases. Photo courtesy of the US National Archives.

Leading this organization since 2007 is Dr. Griffin P. Rodgers who provides scientific leadership and manages a staff of more than 630 employees and a budget of nearly $2.25 billion. Dr. Rodgers received his undergraduate, graduate, and medical degrees from Brown University in Providence, R.I. He completed his residency and chief residency in internal medicine at Barnes Hospital and the Washington University School of Medicine in St. Louis. His fellowship training in hematology was in a joint program of the NIH with George Washington University and the Washington Veterans Administration Medical Center. In addition to his medical and research training, he earned an MBA, with a focus on the business of medicine/science, from Johns Hopkins University in 2005.

During a keynote address at the 2019 Johns Hopkins Henrietta Lacks Memorial Lecture, Dr. Rogers spoke of how more than 50 years ago, NIDDK funded research on insulin pumps that hopefully could one day measure and deliver insulin for people with type 1 diabetes and how that successful pump was developed then being about the size of a large backpack and now about the size of your palm, and how they are being designed to operate wirelessly with a continuous glucose monitor using a computer algorithm — a device called the artificial pancreas.

"For people with type 1 diabetes who require insulin 24/7 and need daily insulin injections, these new devices are revolutionizing the way we deliver medical care. Thus, medical advancements that once seemed impossible are becoming reality and have a significant impact on public health", he said. "Long-term vision, creativity, and sustained dedication are necessary to advance a research mission. As we see with the insulin pump and developing the artificial pancreas system discovery leading to a new treatment or cure often emerges from incremental insights gained over many years and across multiple disciplines."

In an address to Americans regarding diabetes and minority health during National Diabetes Month, Dr. Rodgers emphasized how "of the more than 30 million people in the United States living with diabetes, each one is the most important member of their diabetes care team. But there's no one-size-fits-all approach to diabetes care, and treatment plans need to consider each person's values, goals, needs, and preferences. Developing realistic goals – such as taking breaks for short walks during the day if you are too tired to be active in the evening– can help you manage your diabetes in a way that works for you.

At NIH, we are learning more about the importance of taking each person's needs into account through research taking a "precision medicine" approach where a person's genes, environment, lifestyle and other factors all help determine the best treatment for that person." explained Dr. Rodgers.

nih.gov

NIDDK Director Dr. Griffin P. Rogers giving the keynote address at the 2019 Johns Hopkins Henrietta Lacks Memorial Lecture. Credit: Joshua Franzos, Johns Hopkins ICTR. Photo courtesy of NIDDK.

NIH Strategic Research Plan Addresses Growing Tickborne Diseases Threat

The incidence of reported cases of tickborne diseases in the United States has significantly increased in recent years. It is expected to continue to grow as tick species expand their geographical reach and new tick-transmitted pathogens emerge, raising the potential for serious human illness and death. A new strategic research plan from the National Institutes of Health aims to build on — and accelerate — new and existing research initiatives to improve scientific understanding of ticks and the pathogens they may transmit and to develop the necessary tools and strategies to better diagnose, prevent and treat tickborne diseases.

According to the U.S. Centers for Disease Control and Prevention, 59,349 cases of tickborne disease were reported in 2017 compared to 48,610 cases in 2016. Lyme disease accounted for the bulk (82%) of the cases. Recent CDC estimates suggest that Lyme disease is underreported and that the true incidence is likely 10 times higher. At least 20 different disease-causing bacteria, viruses and parasites are known to be transmitted from ticks to people. Depending on the disease, patients can experience symptoms that range from mild infections that resolve on their own to serious illness, extended disability, or death.

Many tickborne diseases have been discovered only recently. For example, in 2009, scientists reported a red-meat allergy, known as "alpha gal syndrome." Growing evidence suggests that this reaction may be associated with the bite of a tick, but further research is needed to understand this connection. Newly identified tick-transmitted pathogens continue to be reported, raising concerns about missed diagnoses, inadequate treatment, and knowledge gaps related to tickborne diseases.

The new NIH Strategic Plan for Tickborne Disease Research focuses on five scientific priorities for advancing research and development over the next five years. First, the plan calls for improving fundamental knowledge of tickborne diseases, including the biology of tickborne pathogens; how they are transmitted to humans, evade the immune system, and spread within the body. This area also includes determining the cause of persistent symptoms in some people infected with tickborne diseases, such as Lyme disease, and furthering the understanding of how tick-derived factors contribute to the establishment and severity of disease.

Second, the plan calls for improving detection and diagnosis of tickborne diseases by developing rapid diagnostic tests that can detect a pathogen both early and late in infection and distinguish between active and past infections. Third, NIH will support the development of diagnostics capable of predicting treatment success and identifying human biomarkers of infection and persistent symptoms.

The new plan also prioritizes the acceleration of research designed to prevent tickborne disease infection, including vaccines, and immune-based treatments, as well as strategies to reduce the transmission of tickborne pathogens to animal populations that serve as hosts.

This image shows how the design of the mouth makes ticks generally difficult to remove once they've attached for a blood meal. Photo courtesy of NIAID

Fourth, the plan focuses on research to develop new treatments for tickborne diseases and techniques to reduce disease complications. Fifth, the plan prioritizes the development of tools and resources to advance tickborne disease research by improving scientists' access to biological samples, tickborne disease genetic data, and supporting preclinical development of promising products.

NIH intends to expand collaborations across its institutes and centers to promote a multidisciplinary approach to tickborne disease research, answer complex biological questions and encourage the application of state-of-the-art technologies used successfully in a range of scientific disciplines.

The new NIH strategic plan builds on the activities of the Department of Health and Human Services Tick-Borne Diseases Working Group, which issued a 2018 report to Congress outlining research recommendations. NIH sought input from the research and medical communities, patient advocacy groups, pharmaceutical industry, and the general public in developing this strategic plan.

nih.gov

Non-Toxic Lice Treatments

By Tillia Griffin

One day your kids come home from school with dreaded, unwelcome new friends, head lice. For many years, we have dealt with lice by using a variety of pharmacological products containing Permethrin or Pediculicides, which kill live lice and their eggs (1). But due to changes in lice populations and a general push towards greener, non-toxic products, many people are in search of alternative treatments.

Researchers studied head lice populations in 30 states throughout the country and found that lice in many places (including Oregon and Washington) have developed genetic mutations that make them resistant to the most commonly used pharmaceutical treatments, like Permethrin and Pediculicides (2). The overuse of a pest control element can lead to natural selection within the species and an eventual gene mutation to help ensure their survival. Luckily, age-old home remedies and progressive scientific thinking have provided plenty of alternative methods for tackling this itchy issue.

An image taken through a microscope shows a head louse up close and personal. Photo Credit: Vincent S. Smith, Natural History Museum, London

Although it sounds harsh, many of these alternative solutions focus on "suffocating" the lice in order to get rid of them. Some people swear by the use of olive oil, mayonnaise or petroleum jelly to drench the scalp, thereby suffocating the lice, however, keeping olive oil or mayonnaise on the head of a squirming child for 8 hours can be difficult. Instead, Dale Pearlman, a dermatologist who teaches at Stanford University, suggests covering the head with Cetaphil Gentle Skin Cleanser, blow-drying until completely dry and leaving it for 8 hours before shampooing. This process repeated several times may be successful in getting rid of the lice (3).

There are also plenty of ways to cleanse the household during and after a lice episode that are non-toxic and safe. Lice and their eggs are killed by exposure to heat greater than 128 degrees Fahrenheit for more than 5 minutes, so clothing, pillowcases, sheets, and towels can be washed and dried on high settings in your washer. Combs and brushes can be soaked in hot water and furniture and floors can be vacuumed in order to remove any hair follicles with eggs attached to them. Lice and their eggs cannot survive more than 2 days without being attached to a person's scalp. (1)

In addition there are also new technologies being developed by the scientific field, including a device called the "LouseBuster" developed by the University of Utah and the National Science Foundation. This hairdryer-like device is particularly effective because it kills louse eggs, which chemical treatments have never done very well," said Dale Clayton, a University of Utah biologist who led the research and co-invented the machine. "It also kills hatched lice well enough to eliminate entire infestations."

Reporting shows that each year between 6 to 12 million Americans are infested with head lice, making children miss 12 to 24 million school days.

The machine blows warm air through a flexible hose, which has a rake-like hand piece on the end. It kills lice and nits by drying them out, not by heating them. It works in one 30-minute treatment. Comparatively, chemical treatments require multiple applications 1 to 2 weeks apart.

"This research has dramatically improved our understanding of these parasites and how to deal with them," said Juan Carlos Morales, a program director in the National Science Foundation's Division of Environmental Biology. "The LouseBuster is an example of the important benefits to society that result from basic biological research."

Overall, the best way to deal with head lice is to prevent them in the first place. We all know sharing is caring, but consider teaching kids not to share hats, coats, scarves or hair items, and ask where your child's things will be stored at school or camps, making sure their items like hats and coats will not be touching other kids'. Also, check the school's policy on dealing with lice to find out if lice information

Biologist Dale Clayton demonstrates the LouseBuster. Photo Credit: Sarah Bush, University of Utah

and outbreaks will be shared among parents and whether or not kids have to stay home if they have lice. You can also inspect your child's hair and scalp, looking for tiny red bumps (lice bites) and white or yellow looking grains of sand (eggs), that may be signs of lice.

Lice are an itchy nuisance, but they don't carry diseases and they aren't indicative of being dirty or disregarding hygiene, they're just another part of the human experience. So, remember; when it comes to hair, don't share.

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Bariatric Surgery for Teens with Severe Obesity Study: Teen-LABS

The NIDDK funded the Teen-LABS (Longitudinal Assessment of Bariatric Surgery) study to look at the short- and long-term risks and benefits of bariatric (weight-loss) surgery in teens, including gastric band, gastric sleeve, and gastric bypass.

Teen-LABS is the first large-scale study of this procedure in teens who have severe obesity (a much greater-than-normal amount of body fat) and serious weight-related health problems, such as prediabetes, type 2 diabetes, cardiovascular disease (heart and blood vessel disease), sleep apnea (breathing problems during sleep), nonalcoholic fatty liver disease (NASH), or other conditions.

For teens with severe obesity, lifestyle changes such as following a healthy eating plan for weight loss and being more active are important, but if not enough weight is lost to improve health, then additional treatments such as weight-loss surgery may be considered.

Weight-loss surgery is being used more often as a treatment for teens who have severe obesity, but more research is needed in this area better understand how effective it is with teens and whether there are risks associated with the surgery.

Results

Researchers found major improvements in weight, heart health, prediabetes, type 2 diabetes, high blood pressure, high blood cholesterol, and abnormal kidney function 3 years after weight-loss surgery in teens who were in the study.

Five years after weight-loss surgery, researchers compared results for teens who were in the study and had gastric bypass surgery to adults who had the same procedure in the LABS (Longitudinal Assessment of Bariatric Surgery) study.

Adults in the LABS study reported having obesity when they were teens but did not have surgery until they were adults. Researchers found that earlier gastric bypass surgery may have greater benefits compared to waiting until later in life.

- Teens lost 26 percent of their bodyweight and adults lost 29 percent of their bodyweight.
- Teens with type 2 diabetes before surgery were more likely than adults to have better blood glucose (blood sugar) control without the use of diabetes medications. After surgery no teens needed diabetes medications compared to 88 percent of teens before surgery. After surgery 26 percent of adults needed diabetes medications compared to 79 percent of adults before surgery.
- Teens were more likely than adults to no longer have high blood pressure or take blood pressure medications. After surgery 11 percent of teens needed blood pressure medications compared to 57 percent of teens before surgery. After surgery 33 percent of adults needed blood pressure medications compared to 68 percent of adults before surgery.

Researchers also identified some risks from surgery. Five years after surgery teens were more likely than adults to need additional abdominal surgery, most commonly gallbladder removal. Teens were also more likely to have low iron and vitamin D levels, possibly because teens may be less likely to take enough vitamin D and mineral supplements after surgery. There was a similar death rate for teens and adults.

Study Size, Participant Demographics, Study Design, and Follow-up

About 240 teens, ages 13 to 19, were enrolled in Teen-LABS between 2006 and 2012. 161 teens in the study had bariatric surgery at five medical centers:

- Cincinnati Children's Hospital Medical Center, Ohio
- Texas Children's Hospital, Texas
- Children's Hospital of Alabama, Alabama
- University of Pittsburgh Medical Center, Pennsylvania
- Nationwide Children's Hospital, Ohio

Before joining the study, all of the teens made the decision to have weight-loss surgery. While the study did not provide their surgeries, all surgeries took place at one of the Teen-LABS' clinical locations specialized in the surgical evaluation and management of young people with severe obesity. Their health was then evaluated as part of the study before and after surgery. The surgeries were performed between 2007 and 2012.

Research findings on the longer-term health outcomes of weight-loss surgery will guide treatment decisions to improve the health of teens with severe obesity.

niddk.nih.gov

Hand Hygiene in Healthcare Settings

May 5 is World Hand Hygiene Day and the Clean Hands Count campaign aims to improve healthcare provider adherence to CDC hand hygiene recommendations, address the myths and misperceptions about hand hygiene, and empower patients to play a role in their care by asking or reminding healthcare providers to clean their hands.

What can you do as a Healthcare Professional to Prevent HAIs?

- Wash your hands
- Educate your patients
- Wear Personal Protective Equipment as appropriate
- Use antibiotics wisely
- Follow Safe Injection Practices
- Report Outbreaks

Clean your hands before and after every patient contact to protect yourself as well as your patients from infections. As a healthcare provider, you might need to clean your hands as many as 100 times per 12-hour shift, depending on the number of patients and intensity of care you administer.

Keep the conversation going. Talk with you patients and explain how and why caregivers clean their hands before, after, and sometimes during patient care. Let your patients know it's ok to ask about hand hygiene and how they and their visitors can protect themselves by cleaning their own hands often.

Explain the facts about Alcohol-based hand sanitizers. Alcohol-based hand sanitizers are the preferred hand hygiene method in healthcare settings because they kill most of the bad germs that can make you and your patients sick. Overall

Photo courtesy of the Betsy Lehman Center for Patient Safety

continued on page 48

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they are more effective, and cause less drying of the skin than using soap and water, and alcohol-based hand sanitizers also do not create antibiotic-resistant superbugs.

Understand the exceptions where alcohol-based hand sanitizers are not effective by themselves, such as in killing the common healthcare-associated infection know as C. difficile that causes severe diarrhea. Patients with C. difficile should wash their hands with soap and water, and their healthcare providers must always wear gloves when caring for them.

Key points of these recommendations when cleaning hands with soap and water are:

- Avoid using hot water to prevent drying of skin. Wet hands first with water, then apply the amount of product recommended by the manufacturer.
- Rub hands together vigorously for at least 15 seconds to ensure coverage of all surfaces of hands and fingers.
- Rinse with water and use disposable towels to dry hands, and also to turn off the faucet.

Other entities have recommended that cleaning your hands with soap and water should take around 20 seconds, but regardless of the time needed, the focus should remain on cleaning your hands at the right times to reduce contamination between caregiver and patient.

Use Antibiotics Wisely

Studies indicate that 30-50% of antibiotics prescribed in hospitals are unnecessary or inappropriate. There is no doubt that over prescribing and inappropriate prescribing are contributing to the growing challenges posed by Clostridium difficile and antibiotic-resistant bacteria. Studies demonstrate that improving prescribing practices in hospitals can not only help reduce rates of Clostridium difficile infection and antibiotic resistance, but can also improve individual patient outcomes, all while reducing healthcare costs.

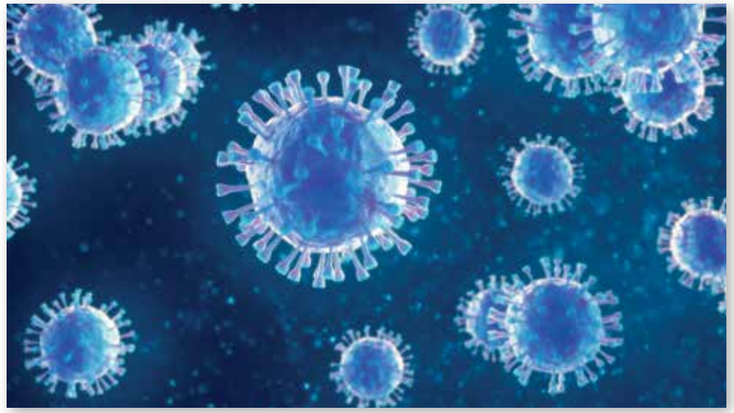


Photo courtesy of the California Department of Public Health

Injection safety

It is a provider's responsibility to keep patients, providers and the community safe and to minimize the risk of spreading infections when preparing and administering every injection. Remember that needles and syringes are single-use devices. They should not be used for more than one patient or re-used to draw up additional medication. 1 Needle + 1 Syringe + 1 Time = 0 Infections.

- Single-dose vials or IV bags should not be administered to multiple patients.
- Multi-dose vials' use should be limited and dedicated to a single patient whenever possible.

The One & Only Campaign, a public safety campaign led by the CDC Foundation and the Safe Injection Practices Coalition (SIPC), offers a wide array of evidenced-based information about safe injection practices on its website "oneandonlycampaign.org" where videos and safety presentations along with printable materials are available including the Healthcare Provider Toolkit.

Report outbreaks to your local health department to aid in the fight to contain and minimize infection transmissions, and continue receiving education in the areas of comparative effectiveness, quality and patient safety and prevention/care management. Several resources available include:

AHRQ PSNet — A national web-based resource featuring the latest news and essential resources on patient safety available at "psnet.ahrq.gov"

TeamSTEPPS™ — Eligible for Continuing Medical Education (CME) or Continuing Education Units (CEU) if health care professionals attend the 2 1/2-day training session at one of the 5 National Implementation of TeamSTEPPS™ training centers available at "teamstepps.ahrq.gov/trainingEligibility.htm"

Infection Prevention and Control Training for Healthcare Professionals — a new online interactive infection control training program for healthcare professionals designed to address the first line of defense against healthcare-associated infections (HAIs) and the spread of germs in healthcare settings, available at cdc.gov.

And the "Let's Talk Patient Safety: Reducing HAI Transmission Risk," program to help healthcare professionals identify infection risks and prevent the spread of HAIs. This training provides free continuing education for healthcare professionals, including nurses, physician assistants, medical assistants, health educators, and other clinicians, which can be completed anywhere. It has two modules and takes approximately 30 minutes to complete the entire training, and is available at cdc.gov.

cdc.gov

Healthcare-Associated Infections (HAI) for Healthcare Providers

Preventing and reducing healthcare-associated infections (HAI) is a top priority for the U.S. Department of Health and Human Services (HHS). The HHS Steering Committee for HAI was established in July 2008, to develop the HHS Action Plan to Prevent Healthcare-Associated Infections, which provides a roadmap for HAI prevention in acute care hospitals. The HHS Action Plan includes recommendations for surveillance, research, communication and metrics for measuring progress towards national goals.

The second State HAI Plan to respond and prevent healthcare-associated infections (HAI) was published in 2017. The HAI Program and other stakeholders use the plan to identify current progress, guide future initiatives, and identify areas for improvement. The plan can be used as a resource for healthcare facilities and consumers to understand current and planned future HAI prevention and response activities.

The HAI Plan focuses on three primary calls to action:

- RESPOND to threats of infectious disease transmission
- ANALYZE data to target prevention activities
- PREVENT future HAIs, infection control breaches, high threat infectious diseases (e.g. Ebola) and antimicrobial resistance

The Centers for Disease Control and Prevention (CDC) and the Healthcare Infection Control Practices Advisory Committee (HICPAC) have published numerous infection prevention guidelines for use in healthcare facilities. The HICPAC is a federal advisory committee made up of 14 external infection control and public health experts who provide guidance to the CDC regarding the practice of healthcare infection prevention and control, strategies for surveillance, and prevention and control of HAI in United States healthcare facilities.

cdc.gov

Photo courtesy of the California Department of Public Health

Get Ahead of Sepsis: Knowing the Risks, Spotting the Signs, and Acting Fast

By CAPT Stephen "Miles" Rudd, MD, Division of Patient Safety and Clinical Risk Management, Office of Quality

September 13 is World Sepsis Day. On this day, health systems are urged to develop a concerted effort on sepsis prevention, diagnosis and management. Agencies across the US Department of Health and Human Services, including the IHS, are collaborating closely on public awareness and best practices in order to save lives.

Sepsis is the body's extreme response to an infection. It is life-threatening, and without timely treatment, sepsis often rapidly leads to tissue damage, organ failure, and death. The risk is higher in people with weakened immune systems; infants and children; adults 65 and older and people with chronic illnesses such as diabetes or liver disease.

Each year in the United States, sepsis takes more lives than opioids, breast cancer, and prostate cancer combined -- about 270,000 deaths a year. It is the leading cause of death in US hospitals. American Indians and Alaskan Natives are at least 1.5 times more likely to die from sepsis than the US average.

Sepsis can be prevented by preventing infections

Sepsis can't always be prevented, but the risk drops when you take steps to prevent or treat infections as quickly as possible. You can do this by staying current with vaccinations, cleaning and covering open wounds, good hand washing, taking antibiotics appropriately and seeking medical help when you suspect you have an infection.

There is no simple test or cure for sepsis. Healthcare professionals often have a hard time recognizing this condition. The key to saving lives is TIME. As many as 80% of sepsis deaths could be prevented with rapid diagnosis and treatment.

When it comes to treatment of sepsis, remember IT'S ABOUT TIME™. Watch for:

- **T** Temperature — higher or lower than normal
- **I** Infection — may have signs or symptoms of infection
- **M** Mental Decline — confused, sleepy, difficult to rouse
- **E** Extremely Ill — "I feel like I might die," severe pain or discomfort

Capt. Stephen "Miles" Rudd, MD, FAAFP, is a family physician who has served within the Commissioned Corps of the US Public Health Service through assignment to the Indian Health Service since 1994. He also represents IHS on the US Department of Health and Human Services Value-Based Transformation Initiative on the sepsis team.

Watch for a combination of these symptoms. If you suspect that you or a loved one may have sepsis, see a medical professional immediately or call 911 and say "I am concerned about sepsis".

I urge everyone to recognize the symptoms and to share and educate others about the risks. Anyone can get an infection and almost any infection can lead to sepsis.

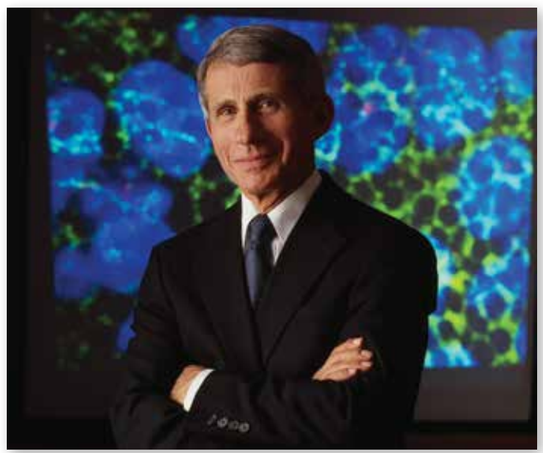
ihs.gov

NIH Bolsters Funding for HIV Implementation Research in High-Burden U.S. Areas

The National Institutes of Health has awarded approximately $11.3 million to 23 institutions across the United States to collaborate with community partners to develop locally relevant plans for diagnosing, treating and preventing HIV in areas with high rates of new HIV cases.

The awards will help enhance the implementation science knowledge base needed for the proposed Ending the HIV Epidemic: A Plan for America. The plan aims to leverage the powerful data and tools now available to reduce new HIV diagnoses in the United States by 75 percent in five years and by 90 percent by 2030. President Donald J. Trump announced this bold new initiative during the State of the Union Address in February. If funds are appropriated by Congress, the 10-year initiative will begin in fiscal year 2020. The awards announced today are one-year awards to support pilot and formative studies to prepare for more extensive implementation science research proposals expected in 2020.

"With existing, powerful HIV treatment and prevention tools, we can end the epidemic in the United States," said Anthony S. Fauci, MD, director of the National Institute of Allergy and Infectious Diseases (NIAID) at NIH. "The new initiative is a practical, achievable implementation plan. By working directly with health departments and other community organizations, researchers can find the best ways to use the highly effective methods at our disposal to diagnose, prevent and treat HIV in the United States."



Anthony S. Fauci, MD, director of the National Institute of Allergy and Infectious Diseases

The one-year supplemental awards were made to 17 institutions that participate in the NIH-funded Centers for AIDS Research (CFAR) program. The nationwide network of CFARs supports multidisciplinary NIH-funded research aimed at reducing the burden of HIV domestically and globally. Awards also were made to six AIDS Research Centers (ARCs), an interdisciplinary mental health research program funded by the NIH National Institute of Mental Health (NIMH).

As part of the new effort, CFARs and ARCs will build on existing relationships with local health authorities, community-based groups and other U.S. Department of Health and Human Services (HHS) agencies involved in the Ending the HIV Epidemic initiative, including the Centers for Disease Control and Prevention and the Health Resources and Services Administration. With these partners, researchers will work to identify and evaluate strategies to diagnose new cases of HIV, help connect people living with HIV or at risk of HIV acquisition with medical care and HIV prevention services, and ensure they continue to receive care to treat or prevent HIV. With much of the needed research infrastructure already in place, the new effort is expected to yield critical findings with modest funding.

The new initiative will focus on implementing proven HIV treatment and prevention tools. These include daily antiretroviral therapy that suppresses HIV to undetectable levels, which benefits people living with HIV and prevents sexual transmission of the virus to others (Undetectable=Untransmittable, or U=U); pre-exposure prophylaxis (PrEP), a single pill that can reduce the risk of acquiring HIV by more than 95 percent when taken daily; and emergency post-exposure prophylaxis (PEP), which can prevent HIV infection if begun within three days of exposure and taken for an additional 28 days. Implementation strategies that demonstrate success in these initial research locations will be shared as best practices to inform efforts in other jurisdictions.

Most new HIV cases in the United States are concentrated in certain geographic areas. More than 50 percent of new HIV diagnoses in 2016 and 2017 occurred in 48 counties; Washington, D.C.; and San Juan, Puerto Rico. Additionally, seven states have a disproportionate occurrence of HIV in rural areas.

The 65 supplemental awards announced today will fund research in 36 of the 48 counties and five of the seven states with a high rural burden, as well as in Washington, DC, and Puerto Rico. Within these geographic areas, the new research will investigate how to best deliver evidence-based interventions and services for populations that face a disproportionate risk of HIV, including Black and Latinx women and men, transgender women and youth aged 13-24 years.

Researchers will collaborate closely with local health officials and community groups to design and test implementation techniques that take local issues into account. The Ending the HIV Epidemic initiative will foster active partnerships with city, county and state public health departments; local and regional clinics and health care facilities; clinicians; providers of medication-assisted treatment for opioid use disorder; and community- and faith-based organizations. This community engagement is critical to developing the type of creative, local interventions that meet a community's unique needs. Researchers and their community partners will examine local policies to identify structural and social barriers that hinder HIV prevention and treatment efforts and investigate methods to overcome these challenges.

"The rubber meets the road in communities," said Dianne M. Rausch, PhD, director of the NIMH Division of AIDS Research. "Our partnerships with community and local health professionals are critical. All parties must gain value from this research to ultimately find success in ending the HIV epidemic in the United States."

A full list of awards can be found online. The CFARs are co-funded and managed by 13 Institutes and Centers and the Office of AIDS Research at NIH. The new supplements will be funded by the Minority HIV/AIDS Fund from the HHS Office of the Assistant Secretary, and by NIH.

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CPG

Trump Administration Awards $1 Million in Ryan White HIV/AIDS Program Grants to Counties

Awards strengthen efforts to End the HIV Epidemic in the United States, supporting a comprehensive system of HIV primary medical care, medication, and essential support services to more than half a million people with HIV in the U.S.

The Trump Administration, through the Health Resources and Services Administration (HRSA), awarded approximately $1 million in Ryan White HIV/AIDS Program grants to 10 metropolitan areas that are Part A jurisdictions to provide technical assistance to enhance efforts to end the HIV epidemic. This funding through HRSA's HIV/AIDS Bureau supports a comprehensive system of HIV primary medical care, medication, and essential support services to more than half a million people with HIV.

"Today, on National HIV Testing Day, we are proud to be taking initial steps to support the implementation of President Trump's strategy to end the HIV epidemic in America by 2030," said HHS Secretary Alex Azar on June 27, 2019. "The Ryan White HIV/AIDS Program has a long track record of success in providing HIV treatment, and the President's plan to end the HIV epidemic involves building on that success."

"HRSA's Ryan White HIV/AIDS Program Part A plays a critical role in the United States' public heath response to ending the HIV epidemic," said HRSA Administrator George Sigounas, MS, PhD. "These grants will help ensure proactive programming so the most vulnerable people living with HIV/AIDS in the U.S. have access to life-saving care and treatment to improve health outcomes and reduce HIV transmission."

Under Part A of the Ryan White HIV/AIDS Program, 52 metropolitan areas provide core medical and support services to people with HIV. The program provides grant funding to eligible metropolitan areas (EMA) and transitional grant areas (TGA) with the highest number of people with HIV and AIDS and experiencing increases in HIV and AIDS cases and emerging care needs.

Funding under the *Building Capacity for HIV Elimination in Ryan White HIV/AIDS Program Part A Jurisdiction* project will provide technical assistance to strengthen efforts to end the HIV epidemic through improvements along the HIV care continuum. Based on the awarded jurisdictions' needs, activities under this initiative will include: community engagement, enhancing core medical and support services, infrastructure support, and information dissemination efforts. Eight of the grant recipients are also among the 48 priority counties identified as part of the U.S. Department of Health and Human Services' Ending the HIV Epidemic: A Plan for America initiative.

"As we recognize National HIV Testing Day today, we understand there is an unprecedented opportunity to end the HIV epidemic in America," said HRSA's HIV/AIDS Bureau Associate Administrator Laura Cheever, MD, ScM. "The Ryan White HIV/AIDS Program has a track record of success. In 2017, approximately 86 percent of program clients who received HIV medical care were virally suppressed, significantly higher than the national average of 60 percent among all those with diagnosed HIV."

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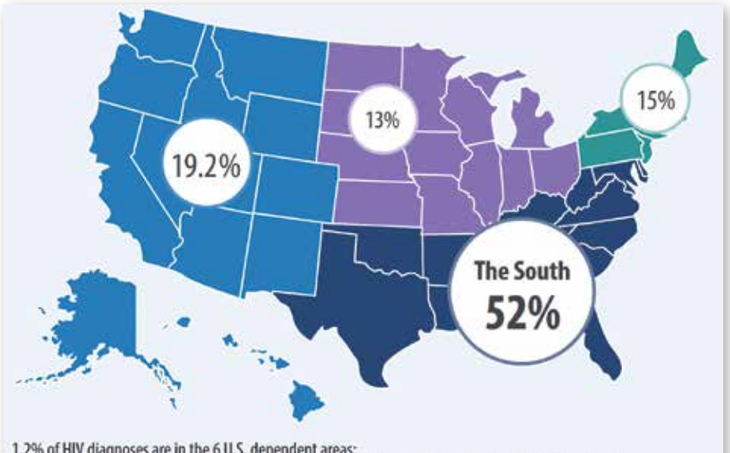
HHS Awards $2.27 Billion in Grants to Help Americans Access HIV/AIDS Care, Support Services, and Medication



The U.S. Department of Health and Human Services announced today approximately $2.27 billion in Ryan White HIV/AIDS Program grants were awarded to cities, counties, states, and local community-based organizations in fiscal year (FY) 2019. This funding through the Health Resources and Services Administration (HRSA) supports 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 played a major role in the in the improved outcomes we see for Americans with HIV," said HHS Secretary Alex Azar. "Thanks to expanded access to treatment and medical advances, HIV/AIDS has gone from being a likely death sentence to a condition that allows a nearly normal lifespan if properly treated.

Ryan White HIV/AIDS Program clients, despite often very challenging circumstances, have a viral suppression rate that far exceeds the national average. The successes of the Ryan White HIV/AIDS Program are in part thanks to how the program cares for the needs of the whole person, including non-health factors.

With President Trump's new initiative to end the HIV epidemic in America by 2030, we will build on the successes of the Ryan White HIV/AIDS Program to connect Americans, especially in the communities most at risk, to the treatment and prevention services they need."

"For nearly three decades, HRSA's Ryan White HIV/AIDS Program has played a critical role in the United States' response to ending the HIV epidemic," said HRSA Acting 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 quality and medical outcomes."

HRSA oversees the Ryan White HIV/AIDS Program, which provides 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 people with diagnosed HIV infection in the United States.

In 2017, approximately 86 percent of Ryan White HIV/AIDS Program clients who received HIV medical care were virally suppressed, up from 69 percent in 2010. The Ryan White HIV/AIDS Program will play a leading role in continuing to diagnose, treat, prevent, and respond to HIV as part of the Administration's Ending the HIV Epidemic: A Plan for America initiative.

HRSA's Ryan White HIV/AIDS Program is critical to improving health outcomes and reducing HIV transmission by improving access to HIV treatment and antiretroviral medication.

People with HIV who take HIV medication daily as prescribed and who reach and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to a partner without HIV.

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Indian Health Service Highlights Initiative to Eliminate Hepatitis C and HIV/AIDS in Indian Country

During National Native HIV/AIDS Awareness Day of 2019 the Indian Health Service announced it is highlighting the Eliminating Hepatitis C and HIV/AIDS in Indian Country Initiative, in line with the president's fiscal year 2020 budget proposal that includes $25 million in new investments to expand partnerships between IHS and Native communities to end the HIV epidemic in Indian Country.

The plan and proposed budget would provide treatment and case management services to prevent hepatitis C infection and enhance HIV testing and linkages to care in support of the administration's Ending HIV Epidemic: A Plan for America

"During National Native HIV/AIDS Awareness Day, we are excited to highlight the Eliminating Hepatitis C and HIV/AIDS in Indian Country Initiative, part of the president's Ending the HIV Epidemic: A Plan for America," IHS Principal Deputy Director Rear Adm. Michael Weahkee said. "This new initiative specifically directs additional funds to Indian Country and provides significant support to the ongoing HIV prevention and treatment provided by IHS and our tribal and urban Indian organization partners. This is a historic turning point in ending HIV in Indian Country."

Since the late 1980s, enormous progress has been made in the fight against HIV, but there is still work to be done. National interventions have reduced the number of new HIV diagnoses in 2017 to approximately 40,000 per year — the lowest level ever, but not everyone is benefiting equally from these advances. New diagnoses are highly concentrated among men having sex with men; minorities, including American Indians and Alaska Natives ; and those who live in the southern United States.

The president's plan focuses on three major areas of action, one being increasing investments in geographic hotspots. Many of the counties and states identified in the plan are in locations with federal, tribal and urban health sites. American Indians and Alaska Natives are ranked fourth in the nation for the estimated rate of new HIV diagnoses when compared with all other races and ethnicities.

Stigma in Native communities can also be a debilitating barrier preventing someone living with HIV or at risk for HIV from receiving the healthcare services they need and deserve. IHS continues to address barriers for people living on Indian

Rear Adm. Michael D. Weahkee, an enrolled member of the Zuni Tribe, is principal deputy director of the Indian Health Service (IHS) agency.

reservations and in other rural communities that limit opportunities for education and HIV testing.

In 2018, IHS received a competitive $3.5 million award from the Secretary's Minority AIDS Initiative Fund to address communities that are disproportionately affected by HIV. The funds are designed to respond to the National HIV/AIDS Strategy goal of reducing HIV-related disparities and health inequities. These funds are distributed to federal, tribal, and urban Indian health programs around the U.S. supporting local, state, regional, and national HIV education, prevention, and treatment programs.

IHS has applied for $3.5 million in continuing funds in 2019 and an additional $3.5 million from the new FY19 Ending the HIV Epidemic: A Plan for America funding opportunity under the Secretary's Minority AIDS Initiative Fund.

National Native HIV/AIDS Awareness Day serves as an opportunity to increase awareness of the impact of HIV/AIDS on American Indians, Alaska Natives, and Native Hawaiians. It also welcomes the opportunity for Native people and others to create a greater awareness of the risks of HIV/AIDS to their communities, to remember those who have passed, and to acknowledge those who are effected and affected by HIV/AIDS.

The IHS provides a comprehensive health service delivery system for approximately 2.6 million American Indians and Alaska Natives. Our mission is to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level.

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IHS and Cherokee Nation Launch New HIV Pilot Project

On National HIV Testing Day 2019, the Indian Health Service (IHS) and Cherokee Nation Health Service announced the launch of a new HIV pilot project to ensure the future success of Ending the HIV Epidemic: A Plan for America.

The pilot project will provide an opportunity to begin implementing and evaluating some key foundational activities that will help accelerate progress toward ending the HIV epidemic in Indian Country.

"These foundational efforts will set the IHS and our tribal partners on a path for rapid progress in reducing new HIV infections," Principal Deputy Director RADM Michael D. Weahkee said. "The pilot project will also reveal important insight into the HIV prevention and treatment activities that should be implemented early — and those that should be strengthened over time."

Findings will be shared with other communities to accelerate and support their efforts to implement the most effective prevention strategies locally — and to move the initiative forward should Ending the HIV Epidemic resources be funded in 2020.

"We have proven to be a successful partner in developing cutting-edge pilot programs that can drastically decrease health disparities, not just for Cherokees but for all of Indian Country," said Cherokee Nation Principal Chief Bill John Baker. "Improved health care over multiple generations is our top priority, and if we can collaborate with our federal partners at IHS to raise awareness, increase education, and actively work to prevent new cases of HIV, then we will be creating a healthier future for northeast Oklahoma."

Principal Chief Bill John Baker

The Ending the HIV Epidemic plan focuses efforts on 48 counties, Washington, DC, San Juan, Puerto Rico, along with seven states, with a high proportion of HIV diagnoses in rural areas. The Cherokee Nation is located in Oklahoma, the state with the highest American Indian population among those seven states.

This pilot is part of efforts by the HHS Office of the Assistant Secretary for Health to jumpstart key activities in select communities using Fiscal Year 2019 resources from the Minority HIV/AIDS Fund.

The Cherokee Nation was chosen for this pilot project because of their proven track record in Hepatitis C prevention and treatment, which screened 50 percent of health services patients. Among the 3.2 percent testing positive, the cure rate is over 90 percent. The Ending the HIV Epidemic plan will use a similar model. Current statistics show that 35 percent of Cherokee Nation patients utilizing the tribe's health centers have been screened for HIV, with less than one percent testing positive. Ninety percent of those patients diagnosed with HIV are receiving care, and 90 percent of those are virally suppressed. The pilot project will help increase the number of patients screened.

Along with the National Institutes of Health, Centers for Disease Control and Prevention (CDC), Substance Abuse and Mental Health Services Administration, and the Health Resources and Services Administration, IHS is a key partner in this HHS effort. The CDC is also working to launch additional pilot projects in select communities.

National HIV Testing Day is observed annually on June 27 to encourage people to get tested for HIV, know their status, and get into treatment right away if they have HIV. This year's theme, "Doing It My Way," highlights how and why people make testing part of their lives in a way that is comfortable for them.

The IHS provides a comprehensive health service delivery system for approximately 2.6 million American Indians and Alaska Natives. Our mission is to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level.

The Cherokee Nation is the federally recognized government of the Cherokee people and has inherent sovereign status recognized by treaty and law. The seat of tribal government is the W.W. Keeler Complex near Tahlequah, Oklahoma, the capital of the Cherokee Nation. With more than 370,000 citizens, 11,000 employees, and a variety of tribal enterprises ranging from aerospace and defense contracts to entertainment venues, Cherokee Nation is one of the largest employers in northeastern Oklahoma and the largest tribal nation in the United States.

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Center of Excellence at Phoenix Indian Medical Center Achieving Excellence in HIV and HCV Care

By Rick Haverkate, IHS National HIV & Hepatitis C Program Coordinator

Many of the health facilities of the Indian Health Service are in rural locations. Among the exceptions is the Phoenix Indian Medical Center. Clinical providers at this hospital in Phoenix, Arizona, see over 140,000 American Indian and Alaska Native patients each year, including patients referred for specialty services from rural locations. Among PIMC's specialty services is a Center of Excellence focused on advancing and coordinating treatment of HIV, hepatitis C, diabetes, and cancer.

The HIV clinic at PIMC is the largest in all of IHS, with over 300 patients. It is supported by a medical officer, clinical pharmacist, and registered nurse medical case managers. The HIV team receives clinical support and cross-coverage from the hepatitis C team that is supported by a nurse practitioner, pharmacist, and clinical care coordinator. The Center of Excellence receives some financial support from IHS headquarters via the Secretary's Minority AIDS Initiative Fund, which greatly assists with the HIV Cascade of Care.

The cascade is a model of care for people living with HIV that takes them from their initial diagnosis to medical treatment that helps them achieve a very low level of HIV in the body — known as viral suppression. The PIMC program provides direct access to an expert HIV pharmacist during all clinic hours. The clinic also provides adherence counseling, case management, and care navigation services that are commonly available in HIV care. All of these services are conveniently located in one clinic. Traditional medical services are also available at the Center of Excellence in a medical home model. Preventive services, chronic disease management, and behavioral health are all part of the medical home model and available during routine clinic visits at PIMC.

Rick Haverkate, National HIV/AIDS Program Director, Indian Health Service

The Phoenix Indian Medical Center which sees over 140,000 American Indian and Alaska Native patients each year.

The program is working hard and showing results. In 2017, PIMC's HIV Cascade of Care demonstrated 93 percent adherence to care and 92 percent viral suppression for their patients. The PIMC HIV Center of Excellence's work has a significant positive impact on American Indian and Alaska patients statewide. American Indian and Alaska Native people who are living with HIV in Arizona have the best viral suppression rates of all racial groups in the state!

The Center of Excellence credits relationships with its patients as a key factor in these successful results. PIMC strives to be known as a facility where quality HIV services are accessible, confidential, and culturally competent.

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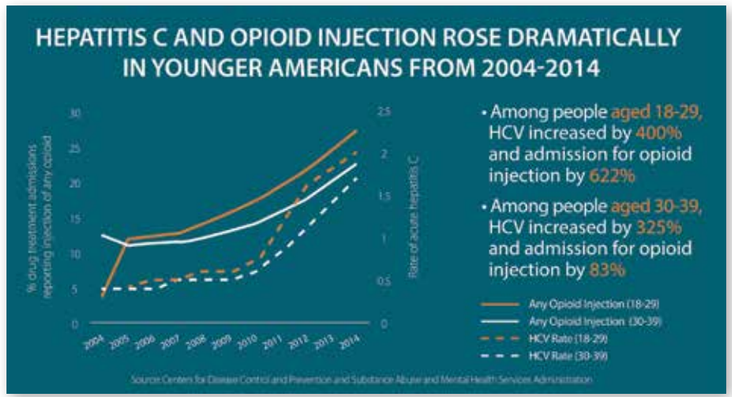
Indian Health Service Highlights Hepatitis Awareness Month

By Matthew Hudson MD, MPH, Preventive Medicine Fellow,
Johns Hopkins School of Bloomberg School of Public Health

The Indian Health Service is committed to eliminating hepatitis C in Indian Country, and we are successfully overcoming the obstacles in the way of achieving this goal. Hepatitis C is a serious liver disease that results from infection with the Hepatitis C virus, or HCV.

We know that at least 30,000 American Indian and Alaska Native individuals have been diagnosed with hepatitis C, which can lead to chronic liver disease, cirrhosis, and liver cancer. Tens of thousands of American Indian and Alaska Native people may have HCV and not even know their status.



Fortunately, the overwhelming majority of the men and women with chronic hepatitis C can now be cured — often in as little as two months with new generations of pills that have few, if any, side effects. Even if past medications have failed, the latest treatments have a very high likelihood of working. But there's a catch — we have to screen patients for HCV and get them into treatment.

In November 2018, the IHS National Pharmacy and Therapeutics Committee added three different HCV treatments to the agency's National Core Formulary, meaning that these medications can now be accessed at all IHS facilities. IHS and tribal clinicians have used in-person training and video conferencing support to gain the expertise needed to start HCV treatment protocols in areas of the country where liver specialists are not available.

This support comes from federal, tribal, and external experts such as specialists at the University of New Mexico's Project ECHO and the University of California-San Francisco's Clinical Consultation Center. Since January 2017, clinicians from 64 IHS, tribal, and urban Indian healthcare facilities (representing all 12 IHS areas) have received training through ECHO, and 37 facilities have initiated treatment for their patients. "As a result, over 500 American Indian and Alaska Native patients have received recommendations on Indian Country tele-ECHO clinics," writes Northwest Portland Area Indian Health Board ECHO Clinical Director David Stephens.

IHS clinics have been working to help patients overcome additional barriers to successful treatment such as substance use disorders. "Many of our patients with substance use disorder had a difficult time making scheduled appointments, or following-up for lab tests or liver imaging, and were hard to contact after they left the clinic," writes Dr. Justin Iwasaki, the special projects director at the Lummi Tribal Health Center.

Keeping this in mind, Dr. Iwasaki and his colleagues redesigned the healthcare delivery model of Lummi's HCV treatment program to expedite treatment. "Using a Single Visit Ready to Treat Model, which incorporates bundled lab ordering and on-site imaging, we were able to meet the needs of our patients by providing nearly all of the HCV diagnosis and staging elements of HCV treatment in one visit," Iwasaki writes. The results have been outstanding—in a little over 2 1/2 years the Lummi Tribal Health Center has treated over 100 patients under this model.

The IHS is committed to stopping the spread of HCV in American Indian and Alaska Native communities. I urge you to get the message out to your friends, family, and get tested for HCV yourself, it can save your life.

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NIH Statement on World Tuberculosis Day, March 24, 2019

Statement of Alan Embry, PhD, Richard Hafner, MD, and Anthony S. Fauci, MD
National Institute of Allergy and Infectious Diseases, National Institutes of Health

Tuberculosis (TB) is the world's leading infectious cause of death. In the 137 years since Dr. Robert Koch's discovery of Mycobacterium tuberculosis (Mtb), the bacterium that causes TB, as many as one billion people worldwide have died of TB disease. This year's World TB Day theme is "It's Time" to end tuberculosis once and for all. We at the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH, are committed to accelerating the cutting-edge research necessary to ending this ancient disease.

Mtb is transmitted through the air and primarily affects the lungs. According to the World Health Organization (WHO), an estimated 2 billion people are latently infected with TB, meaning they carry the infection in an inactive form but do not experience TB symptoms, such as cough, fever, weight loss and night sweats. A person with latent TB infection cannot transmit the bacteria to others. The U.S. Centers for Disease Control and Prevention (CDC) estimates that as many as 13 million people in the United States have latent TB infection. Overall, people with latent TB infection have a 5 to 15 percent lifetime risk of developing active TB disease. However, individuals with compromised immune systems, such as those with HIV, people receiving immunosuppressive therapy, diabetics, smokers and the malnourished are at increased risk of developing active TB disease. In 2017, an estimated 10 million new cases of active TB disease occurred worldwide, including 558,000 new cases of multi-drug resistant TB, and 1.6 million deaths, according to the WHO.

The huge burden of TB has, deservedly, made it a priority for global health leaders in recent years. At a September 2018 United Nations General Assembly High-Level Meeting on Ending TB, national leaders presented two goals to achieve by 2022: prevent at least 30 million people from developing active TB disease and treat 40 million people who are sick with the disease. In connection with that meeting, NIAID released its Strategic Plan for Tuberculosis Research, which builds on the institute's existing TB research portfolio and details NIAID's priorities for further understanding of TB and developing and applying cutting-edge tools to fight the disease. Specifically, the plan prioritizes expanding fundamental knowledge of TB using modern technologies, such as imaging and systems biology methods, to better understand how TB remains latent in some individuals but progresses to active disease in others, as well as the host and microbial factors that affect TB disease, transmission, and epidemiology. The Lancet Commission on TB, which includes 37 commissioners from 13 countries, echoed these priorities in its March 20 report (link is external) calling for increased global investment in TB research, scale up of existing interventions and reaching high-risk groups, and increased accountability among government leaders for TB outcomes.

Photo courtesy of the Ohio Department of Health

In keeping with its strategic plan, NIAID also is working to find improved TB diagnostics; specifically, rapid, accurate inexpensive point-of-care tests. NIAID research played a key role in the development of the WHO-endorsed GeneXpert MTB/rifampicin resistance test currently used worldwide, and the institute continues to pursue other next-generation diagnostics. Additionally, NIAID supports a large-scale Mtb genome sequencing project at the Broad Institute in Cambridge, Massachusetts, to better understand genetic diversity and patterns of drug resistance, which will contribute to the development of new diagnostics and more rapid drug susceptibility tests for multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB).

Treating TB involves antibiotics that must be taken for six months or longer, often with toxic side effects. With MDR-TB, the drug regimens can require even longer periods (up to 20 months) and are costly and prone to failure. XDR-TB is even more difficult to treat, and effective treatment regimens may not exist for some patients. NIAID supports two-thirds of the current experimental TB treatments currently in clinical studies around the world. The focus is to identify both improved, shorter-duration treatment regimens and make better use of existing TB drugs for both treatment and prevention. For example, an NIAID-supported clinical trial comparing a 9-month regimen of isoniazid to a one-month regimen of rifapentine and isoniazid (link is external) for preventing active TB in HIV-infected patients demonstrated the shorter regimen worked just as well as the longer regimen. For treatment of active disease, the WHO approved in 2018 a shorter, all-oral treatment regimen for MDR-TB. Additionally, last year NIAID-funded researchers discovered through a refined analysis of TB strains collected from volunteers before TB treatment that they could accurately predict whether those volunteers would be likely to relapse after standard treatment was completed. This finding could help to improve TB treatment success rates and decrease the development of drug-resistant TB.

Finding a broadly effective, preventive TB vaccine remains a key focus of NIAID-sponsored research. The current Bacillus Calmette-Guerin (or BCG) vaccine, developed in 1921, protects children and infants from disseminated TB disease and death, but this protection does not extend to adults. Further, the vaccine must be kept refrigerated to remain effective. NIAID is conducting and supporting research involving multiple vaccine candidates. For example, a temperature-stable experimental TB vaccine called ID93 entered Phase 1 human clinical trials in January through NIAID's support. A freeze-dried vaccine like ID93, if proven to be safe and effective, would be cheaper and easier to distribute in developing countries where a refrigerated supply chain is not guaranteed. NIAID has also contributed significant preclinical data to H56, a TB vaccine candidate that may help the immune system target a protein produced during latent TB infection, helping to prevent the infection from becoming active. In other encouraging developments, GlaxoSmithKline's M72/AS01E candidate TB vaccine reduced the incidence of pulmonary TB disease in HIV-negative adults with latent TB infection in Phase 2b clinical trials.

Significant progress had been made in the fight against TB, with a 2 percent annual decline in TB incidence worldwide and roughly 54 million lives saved through TB diagnosis and treatment between 2000 and 2017, according to the WHO. However, the challenges the disease presents are daunting and the rate of improvement not fast enough. It will require an intensified research effort, investment and collaboration with global partners to build on the progress to date and make TB a historical footnote. On this World TB Day, we stand with our global health partners in our firm resolve to end TB.

Anthony S. Fauci, MD, is Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health in Bethesda, Maryland. Richard Hafner, MD, is chief of the TB Clinical Research Branch in NIAID's Division of AIDS. Alan Embry, PhD, is chief of the Respiratory Diseases Branch in NIAID's Division of Microbiology and Infectious Diseases.

niaid.nih.gov

Trends in Human Rabies Deaths and Exposures, United States, 1938–2018

By Emily G. Pieracci, Veterinary Epidemiologist at the Centers for Disease Control and Prevention (CDC)

Each year, rabies causes approximately 59,000 deaths worldwide, including approximately two deaths in the United States. Before 1960, dogs were a common reservoir of rabies in the United States; however, increasingly, species of wildlife (e.g., bats, raccoons) are the main reservoirs. This report characterizes human rabies deaths, summarizes trends in rabies mortality, and highlights current rabies risks in the United States.

Rabies trends in the United States during 1938–2018 were analyzed using national rabies surveillance data. Data from the Healthcare Cost and Utilization Project for 2006–2014 were used to estimate the number of postexposure prophylaxis (PEP) visits per 100,000 persons during 2017–2018. The Centers for Medicare & Medicaid Services' average sales price data were used to estimate PEP costs.

From 1960 to 2018, a total of 125 human rabies cases were reported in the United States; 36 (28%) were attributed to dog bites during international travel. Among the 89 infections acquired in the United States, 62 (70%) were attributed to bats. In 2018, approximately 55,000 persons sought PEP after contact with a potentially rabid animal.

In the United States, wildlife rabies, especially in bats, continues to pose a risk to humans. Travelers also might be exposed to canine rabies in countries where the disease is still present; increased awareness of rabies while traveling abroad is needed. Vaccinating pets, avoiding contact with wildlife, and seeking medical care if one is bitten or scratched by an animal are the most effective ways to prevent rabies. Understanding the need for timely administration of PEP to prevent death is critical.

Rabies virus, a Lyssavirus that infects mammals, is transmitted through saliva, most commonly from the bite or scratch of an infected animal. In the United States, several variants, or strains, of rabies virus circulate in animal reservoirs, including raccoons, skunks, foxes, and bats (1). Rabies virus infection, regardless of the variant or animal reservoir, is fatal in over 99% of cases, making it one of the world's most deadly diseases. There is no treatment once signs or symptoms of the disease begin, and the disease is fatal in humans and animals within 1–2 weeks of symptom onset. Prompt administration of postexposure prophylaxis (PEP), consisting of rabies vaccine and immune globulin, immediately after exposure effectively prevents disease (1,2).

The elimination of canine rabies virus variant (CRVV) from the United States is one of the most important public health successes of the 20th century. However, globally, approximately 59,000 persons still die from rabies every year; 98% of these cases are caused by CRVV (3). At the beginning of the 20th century, CRVV was enzootic in the United States, but beginning in 1947, animal vaccination and leash control laws led to improved rabies control nationwide. Canine rabies and associated human rabies cases fell sharply (4). By the late 1960s, fewer than 500 rabid dogs and three human rabies cases were reported annually (5).

FIGURE 1. Rabies cases in humans and domestic animals — United States, 1938–2018

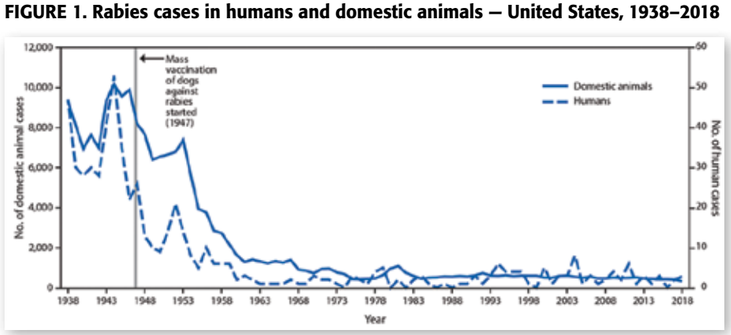
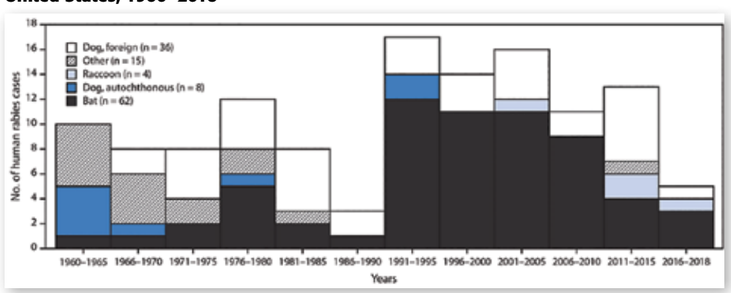


FIGURE 2. Rabies virus variants* associated with human rabies cases (N = 125)† — United States, 1960–2018



Although domestic animal exposures account for a large portion of human PEP usage, bat rabies virus variants are responsible for most human rabies deaths in the United States (1). This apparent paradox might be due to several factors, including lack of awareness of the risk of acquiring rabies from bats, or difficulty identifying bat bites and scratches (10). This analysis highlights current rabies risks in the United States, and assesses the cost and public health impact of rabies control efforts.

U.S. National Rabies Surveillance data maintained by CDC's Poxvirus and Rabies Branch were analyzed to assess trends in human and animal rabies in the United States during the past 81 years (1938–2018) (1). Initial risk assessment and treatment for exposure to a rabid animal commonly occurs in the emergency department because of the need for wound treatment and rabies immune globulin, typically only available in emergency departments (11).

The Agency for Healthcare Research and Quality's Healthcare Cost and Utilization Project's (HCUP; https://www.hcup-us.ahrq.gov/) 2006–2014 data, which include longitudinal U.S. hospital care data, were used to estimate the rate of PEP visits (number per 100,000 persons) for 2017–2018 based on the U.S. population. HCUP patient data from emergency departments with an International Classification of Diseases, Ninth Revision diagnosis code of V04.5 (need for rabies prophylaxis) were evaluated (https://hcupnet.ahrq.gove). In addition, 2017 national sales data for rabies immune globulin were provided by an independent consultant (Marketing Research Bureau, Inc., unpublished data, 2019).

The 2019 Centers for Medicare & Medicaid Services average sales price data were analyzed to estimate the cost of PEP (12,13). The average sales price data lists rabies immune globulin at $312 per 150-IU dose (a 165-pound [75-kg] adult needs 10 doses and a 95-pound [45-kg] child needs 6 doses) and rabies vaccine at $290 per dose (4 total doses needed). The average PEP cost and range were determined using the 2019 average sales price data and previously published data from 2004, adjusted for inflation (13,14).

The cost and frequency of U.S. public health system rabies responses were derived from previously published literature and opinions of subject matter experts (13,15,16). An economic analysis conducted by CDC provided estimates of the number of imported dogs from countries at high risk for rabies and the public health cost associated with importation events (15).

During 1938–2018, 588 cases of human rabies were reported in the United States. The elimination of CRVV in the United States through canine rabies vaccination has resulted in a tenfold decrease in human rabies cases reported from 1938 through 2018. During 1960–2018, among 125 reported human rabies cases, 89 were U.S.-acquired, including six organ transplantation cases. Among all U.S.-acquired cases, 62 (70%) were caused by bat rabies virus variants. Since 1960, 36 (28%) U.S. residents have died of rabies acquired from dogs while traveling abroad.

During 2017–2018, an average of 55,000 (range = 45,453–66,000) persons were treated for potential rabies exposure each year. The cost for rabies PEP averages $3,800 (range = $1,200–$6,500), not including costs for hospital treatment or wound care. This results in annual estimated PEP costs of $209 million (range = $66 million–$358 million).

Since 2003, the U.S. public health system has responded to approximately two human rabies deaths, 175 mass bat exposure

continued on page 79

Indicated for post-exposure prophylaxis (PEP) of rabies infection

KEDRAB. RELIABLE COVERAGE FOR EVERY RABIES EXPOSURE

Ready-to-use human rabies immune globulin (HRIG) solution[1]

- **Dependability in the 150 IU/mL potency you know and trust[2]**
- **May be stored at room temperature not exceeding 25°C (77°F) for up to one month. Use within one month; do not return to refrigeration[1]**
- **No need for dilution with dextrose[1]**
  - **May help reduce the potential for errors caused by the need to prepare an admixture[3]**

2-mL vial/300 IU
NDC 76125-150-02

10-mL vial/1500 IU
NDC 76125-150-10

INDICATIONS AND USAGE

KEDRAB® (Rabies Immune Globulin [Human]) is a human rabies immunoglobulin (HRIG) indicated for passive, transient post-exposure prophylaxis (PEP) of rabies infection, when given immediately after contact with a rabid or possibly rabid animal. KEDRAB should be administered concurrently with a full course of rabies vaccine.

- Additional doses of KEDRAB should not be administered once vaccine treatment has been initiated, since this may interfere with the immune response to the rabies vaccine.
- KEDRAB should not be administered to patients with a history of a complete pre-exposure or post-exposure vaccination regimen and confirmed adequate rabies antibody titer.

IMPORTANT SAFETY INFORMATION

- Patients who can document previous complete rabies pre-exposure prophylaxis or complete post-exposure prophylaxis should only receive a booster rabies vaccine without KEDRAB, because KEDRAB may interfere with the anamnestic response to the vaccine (ACIP).

KEDRAB® Rabies Immune Globulin (Human)

Visit KEDRAB.com or call 1-855-353-7466 to order KEDRAB today.

IMPORTANT SAFETY INFORMATION (CONTINUED)

- KEDRAB should not be injected into a blood vessel because of the risk of severe allergic or hypersensitivity reactions, including anaphylactic shock. KEDRAB can induce a fall in blood pressure associated with an anaphylactic reaction, even in patients who tolerated previous treatment with human immunoglobulin. KEDRAB should be discontinued immediately if there is an allergic or anaphylactic type reaction. In case of shock, standard medical treatment should be implemented. Epinephrine should be available.
- Patients with a history of prior systemic allergic reactions following administration of human immune globulin preparations should be monitored for hypersensitivity. KEDRAB contains a small quantity of IgA. Patients who are deficient in IgA have the potential to develop IgA antibodies and may have anaphylactic reactions following administration of blood components containing IgA. The healthcare provider should assess the risks of this reaction against the benefits of administering KEDRAB.
- Patients at increased risk of thrombosis or thrombotic complications should be monitored for at least 24 hours after KEDRAB administration.
- Hemolysis may occur in patients receiving immune globulin products, particularly those who are determined to be at increased risk. Clinical symptoms and signs of hemolysis include fever, chills and dark urine. If any of these occur, appropriate laboratory testing should be performed and medical therapy administered as indicated.
- KEDRAB administration may interfere with the development of an immune response to live attenuated virus vaccines. After KEDRAB administration, immunization with measles vaccine should be avoided within 4 months; other live attenuated virus vaccines avoided within 3 months.
- A transient rise of the various passively transferred antibodies in the patient's blood may result in misleading positive results of serologic tests after KEDRAB administration. Passive transmission of antibodies to erythrocyte antigens may interfere with serologic tests for red cell antibodies such as the antiglobulin test (Coombs' test).
- KEDRAB is derived from human plasma; therefore, the potential exists that KEDRAB administration may transmit infectious agents such as viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. There is also the possibility that unknown infectious agents may be present in KEDRAB.
- In clinical trials, the most common adverse reactions in subjects treated with KEDRAB were injection site pain (33%), headache (15%), muscle pain (9%), and upper respiratory tract infection (9%).

Please see Brief Summary of Prescribing Information on the next page.

KEDRAB Dose Calculator

Access the online calculator: 1. Scan the QR code with the camera on your phone. 2. Open the link to access or visit **KEDRABDoseCalculator.com**.

References: 1. KEDRAB [package insert]. Fort Lee, NJ: Kedrion Biopharma Inc.; 2017. **2.** Scott D. Scientific basis for approval of human rabies immune globulin in combination with rabies vaccine. Presented at: Developing Rabies Monoclonal Antibody Products as a Component of Rabies Post-Exposure Prophylaxis; July 17, 2017; Silver Spring, MD. **3.** Billsten-Leber M, Carrillo CJD, Cassano AT, Moline K, Robertson JJ. ASHP Guidelines on Preventing Medication Errors in Hospitals. *Am J Health Syst Pharm*. 2018; 75:1493-1517. doi: 10.2146/ajhp170811.

KEDRION BIOPHARMA

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events (events where >10 persons are exposed to a potentially rabid bat), and one rabid dog importation every year (Table). CDC estimates that 1.06 million dogs enter the United States every year, including 107,000 (10%) that are imported from countries where CRVV is enzootic, thereby posing a potential risk for reintroduction of CRVV into the United States. Since 2015, three canine rabies cases have been imported in rescue dogs adopted from countries with a high risk for rabies. Canine rabies importation events are estimated to cost $213,833 (range = $171,066–$256,599) per event in public health response and health care costs to prevent the spread of the disease to humans and their pets. Total estimated costs associated with rabies public health emergency response activities are $7.6 million per year (range = $2.6 million–$12.9 million) (Table).

Discussion and Conclusions

Bats are currently the leading cause of human rabies deaths in the United States. Unlike rabies management programs targeting raccoon, fox, and coyote populations, bat vaccination is not yet logistically feasible, nor are any rabies vaccines currently approved for use in bats. Despite the rabies exposure risk, the vast majority of bats submitted for testing (94%) do not have rabies (1). Thus, widespread killing of bats is not recommended to prevent rabies. However, increased awareness of the risk for rabies from bats and knowledge of when to seek medical attention for PEP are needed. In addition to bat rabies cases, international travel-related rabies cases occur because of a lack of awareness about the ongoing global risk of rabies in dogs.

Efforts to control rabies in wildlife and maintain canine rabies elimination in the United States require ongoing, high-quality rabies surveillance and timely response capabilities. Rabies continues to be a priority zoonotic disease for One Health collaboration (17), requiring multi-agency cooperation to ensure continued success of the U.S. rabies control program. Currently, U.S. public health laboratories and United States Department of Agriculture Wildlife Services test approximately 100,000 animals per year, and approximately 5,000 are rabies-positive (1). Although CRVV has been eliminated from the United States, dogs might still acquire rabies from wildlife.

Whereas canine rabies vaccination is required throughout the United States, animal registration and rabies vaccination laws vary by county, making it difficult to estimate the current rabies vaccination coverage rates among dogs in the United States. In addition, recent antivaccination sentiments have been documented in owners reluctant to vaccinate their dogs against diseases (18). Failure to vaccinate dogs against rabies could constitute a considerable public health threat to both humans and animals. Thus, maintaining current rabies vaccination rates of at least 70% in dogs is critical not only to protect pets, but to protect pet owners as well (19).

The findings in this report are subject to three limitations. First, although rabies is a notifiable disease for both humans and animals, data on PEP use among persons seeking care for a potential exposure are limited and rely on emergency department data, some of which may be incomplete. Second, previously published data and current average sales price data from the Centers for Medicare & Medicaid were used to estimate costs for this analysis, but the actual amount hospitals bill for PEP varies considerably, making it difficult to assess the true cost of PEP (10). Finally, rabies prevention and control costs have a high degree of variability. For example, costs for public health emergency responses can vary considerably between states depending on the number and type of animals and humans involved.

As the human urban environment encroaches into wildlife settings, human rabies exposures continue to occur. However, the relatively few human rabies deaths that occur in the United States are a testament to the robust response capabilities of the nation's public health system, as well as the success of wildlife and pet vaccination programs and the availability of effective PEP. Although human rabies is now a rare disease in the United States, it remains one with extremely high consequences.

Recommendations

A critical component of rabies prevention in the United States is to avoid contact with wildlife, especially bats. Contact with a bat includes bites and scratches, which are often small and can be overlooked. Contact might also occur unknowingly if a bat is present in a room with a young child or mentally impaired person, including a child or person under the influence of medication, drugs, or alcohol or a person who is asleep. In those cases where unrecognized contact might have occurred, persons should assume they have a potential exposure to rabies if the bat is not available for testing and urgently seek care from their medical provider. If the bat can be safely collected and tested, this can inform the need for PEP.

CDC Travelers' Health provides vaccination recommendations for international travelers (https://www.cdc.gov/travel). Although the risk of travel-associated rabies infection is generally low, travelers should know the risk, avoid contact with animals, have a plan to get care if they are scratched or bitten, and have travel health insurance to pay for treatment should they need it. Travelers at higher risk (i.e., those who might be working with animals abroad or come into close contact with animals while traveling) should additionally consider preexposure prophylaxis vaccination and be aware that PEP is still recommended after a potential exposure, even among vaccinated persons (2).

Human rabies is 99% fatal. However, it is 100% preventable through vaccinating pets against rabies, avoiding contact with wildlife and unknown animals, and seeking medical care as soon as possible after being bitten or scratched by an animal.

Acknowledgments

State and Local Health Departments; Animal Control Officers; the USDA Wildlife Services program; Kristina Angelo, Laurie Barker, Harrell Chesson, Joo Heesoo, Ronald Henry, Seonghye Jeon, Brian Maskery, Jennifer McQuiston, Martin Meltzer, Megan O'Sullivan, Agam Rao.

cdc.gov

Rabies: One of the World's Oldest and Deadliest Threats to Military Soldiers

By Tom Adams, Publisher

I had the great pleasure of speaking with Peter Costa recently, founding co-organizer of the annual observance that's become known as "World Rabies Day", and discussing the very serious threat that Rabies, one of the world's oldest recorded diseases, still poses to U.S. Military personnel serving both domestically and abroad.

Peter Costa has worked with the Veterinary Medical Corps, helping educate military personnel in Afghanistan and other nations about this disease and raise awareness to bring improvements in prevention measures and medical response following an exposure.

"Soldiers were positioned on base perimeters to monitor for feral animal activity, because of the higher risks of infection to animals in those countries and the higher risks for them to transmit the Rabies infection to humans. Instruction was given on ways to prevent animal to human contact whenever possible, but unfortunately exposures still happen as was the case several years ago when a solder died after coming back from deployment overseas."

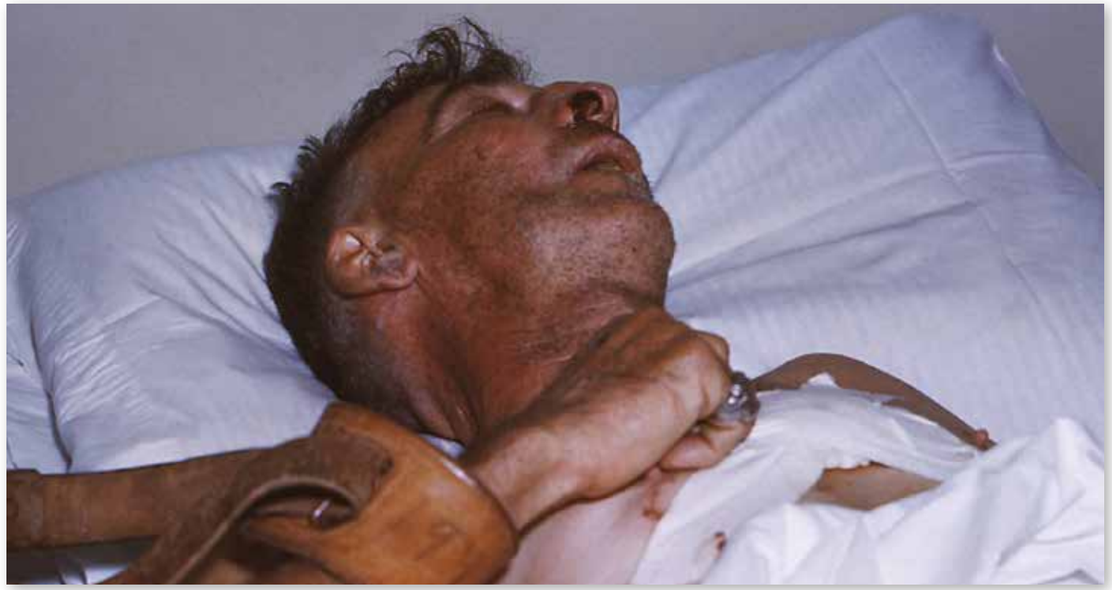
Rabies continues to be one of the world's most deadly diseases. "Despite all of the emerging infectious diseases that our hospitals are up against, and including our U.S. Military, which is going into countries that are higher-risk for Rabies infection as well as a variety of other serious health issues, Rabies continues to be the deadliest disease. Of all the infectious diseases we hear about on the news such as Ebola, Zika, MERS, SARS, and recently a rise in Yellow Fever, Rabies continues to have the highest case fatality rate of any disease and kills 99.9 percent of those who become infected."

Military health experts agree that education should begin at the pre-deployment stage, during the initial preparation of readiness. Whether or not soldiers will ever be exposed is secondary, the fact remains that if they do get exposed, their chance of survival depends on receiving prompt and proper medical care from qualified and educated health care providers.

Kedrion Biopharma, the company for which Peter Costa now works, presented a poster at last year's International Rabies in the Americas (RITA) Conference to highlight their human rabies immune globulin (HRIG), which can be stored at room

temperature for up to one month. HRIG, and the rabies vaccine series along with thorough washing of wounds provides 100% protection as long as the exposure is treated in a timely manner. [CPI]

Cold-chain storage of rabies biologics has long been a topic of concern for treating rabies exposures in locations where proper refrigeration cannot be guaranteed and is often discussed at the annual RITA Conference by the world's leading rabies researchers and scientists. Notably, Kedrion Biopharma's HRIG product is the only HRIG with 30-day room temperature stability, which helps reduce waste through loss prevention. The extended temperature stability may also be beneficial for use in remote areas, non-acute settings and field-based medical applications such as wilderness medicine and armed forces operations.



Hospitalized human rabies victim restrained while bedridden. (Photo credit: CDC)

Peter Costa stated that, "During my time working with the Veterinary Medical Corps, we promoted specific posters developed by the U.S. Army Public Health Command showing the basic educational points needed most for rabies prevention. The Military has so many possible areas that can be connected to the disease and this also includes a veterinary component for vaccinating and protecting working animals, guard dogs and recovery animals that are coming back into the United States".

Costa's current education to U.S. medical providers also includes information about a recent change to the HRIG market landscape, where a new formulation was introduced by Grifols. This formulation is a different concentration than what has been the industry standard for nearly 50 years and may cause confusion among medical providers.

"This concentration change brings with it operational, clinical, and medication safety considerations, which all medical personnel must be made aware of in order to make informed treatment decisions. We have been working extensively over the past few months to describe what changes have occurred and how it impacts hospitals and practice guidelines/protocols for rabies post-exposure prophylaxis."

Peter Costa is a public health educator and epidemiologist by training. He received a master's degree in public health and went on to become a master certified health education specialist. He has been recognized for his contributions to veterinary public health and human health with an honorary diploma from the American Veterinary Epidemiological Society. In 2006, the U.S. CDC conducted a national search looking for a public health educator to help spearhead their global rabies education campaign. They had done a national search through the state health departments, where at the time Costa was working at the North Carolina Division of Public Health and their State Public Health Veterinarian mentioned it to him.

Signs and Symptoms: The early symptoms of rabies include malaise, alternating periods of irritability and anxiety, headache, fever, and sometimes, itching or pain at the site of the bite. The disease progresses to depression, agitation, throat spasm followed by excessive salivation (foaming at the mouth) and hydrophobia. In the later stages of the disease rabies leads to; numbness or paralysis, spasms of the throat muscles, seizures, mental confusion, coma, and death. Death usually occurs within 2 weeks of onset of symptoms. The incubation period is related to the distance between the bite site and the brain, wound severity and amount of virus. The symptoms usually start 2 to 8 weeks after exposure to a rabid animal. Rarely, it can take as few as 5 days or more than a year for symptoms to appear. (Photo credit: Hawaii State Public Health)

U.S. Army Capt. Brian Smith takes down information about a puppy belonging to a Liberian man before the animal is inoculated with a rabies vaccine, March 24, 2008. Smith is a veterinarian assigned to the 64th Medical Battalion, attached to Africa Partnership Station. Photo credit: The Department of Defense

Costa applied for the position and was selected to help a non-profit group called the Global Alliance for Rabies Control launch a new program that is now known across the globe as World Rabies Day. This annual event is recognized by the United Nations and during 2007-2012 Costa directed all of the global awareness, education and communication efforts around Rabies prevention in over 150 countries. He dealt with religious issues, cultural barriers, and understanding why certain people are dying from rabies in different areas, and how to work with the Ministries of Health and Agriculture to help prevent the disease.

He helped to clear up misunderstandings and myths about Rabies and conceptualized novel programs like the Rabies Educator Certificate to encourage more individuals to pursue specializing in rabies education.

Costa continues to stay active in the rabies prevention community and currently serves on the International Steering Committee for Rabies in the Americas, and works with the Public Library of Science (PLOS) Neglected Tropical Diseases journal to review and edit publications on Rabies.

And while he now devotes much of his time to Kedrion Biopharma, the company that markets KEDRAB (Rabies Immune Globulin [Human]), he remains active in helping to fill the public health gap that still exists in preventing rabies — despite the long history of the disease.

U.S. Army Pvt. Valerie McCants, assigned to the 64th Medical Battalion, prepares one of 150 doses of rabies vaccine administered to pets in Monrovia, Liberia. Photo credit: The Department of Defense

IHS and AAP Release Clinical Recommendations to Improve Care of American Indian, Alaska Native Women and Infants Impacted By Prenatal Opioid Exposure

The Indian Health Service and the American Academy of Pediatrics Committee on Native American Child Health released clinical recommendations on neonatal opioid withdrawal syndrome, or NOWS, for IHS, tribal, and urban Indian organization health care facilities. These recommendations provide standards of care surrounding screening, diagnosing, and treatment of pregnant mothers and infants affected by prenatal opioid exposure.

"Infants born withdrawing from opioids represent one of the most heartbreaking aspects of our country's addiction crisis, which has hit American Indian and Alaska Native communities especially hard," said HHS Secretary Alex Azar. "The new clinical recommendations will help elevate the quality of care offered to mothers and infants affected by the opioid crisis, and this cooperative project reflects the priority that the Trump Administration has put on addressing substance abuse and increasing the quality of care provided through the Indian Health Service."

"At IHS, we recognize that preserving the infant-mother relationship is of the utmost importance," said IHS Chief Medical Officer Rear Adm. Michael Toedt, MD. "These recommendations further establish the need for ongoing monitoring and clinical management of opioid-exposed infants to improve health outcomes as part of our comprehensive strategy to address the opioid epidemic."

The recommendations will serve as a resource to improve identification, care, and outcomes of infants at risk for NOWS. The recommendations were developed based on critical feedback the IHS received on the importance of prenatal opioid exposure in opioid listening sessions and tribal consultations throughout the past year.

Photo courtesy of the Arizona Department of Health Services

"American Indian and Alaska Native women face significant barriers in obtaining appropriate care for substance use disorders while pregnant, which may delay early intervention efforts that are best for the newborn's health," said Shaquita Bell, MD, FAAP, chair of the AAP Committee on Native American Child Health. "AAP is proud to partner with IHS to support efforts to prevent neonatal opioid withdrawal syndrome, to provide the most appropriate and effective treatments for infants and keep them connected with their families and communities."

The recommendations are also a companion guide to clinical recommendations to improve care of American Indian and Alaska Native pregnant women and women of childbearing age with opioid use disorder, which were announced by IHS and the American College of Obstetricians and Gynecologists in March 2019.

Maintaining relationships and forging new partnerships with tribes and tribal health organizations in rural and urban Indian communities are essential to addressing the opioid epidemic and caring for American Indian and Alaska Native mothers, infants, and families affected by NOWS. The IHS engages with communities and partners with tribes to promote evidence-based programs and policies to support recovery, as well as prevention efforts. The IHS is committed to developing strategies to implement these new recommendations that include sharing best practices in comprehensive care approaches, collaborating with community service providers, and sharing training and patient education resources.

NOWS occurs in 55-94 percent of infants prenatally exposed to opioids and varies in severity from mild to, in rare cases, life-threatening. Management of NOWS begins with identifying women at risk for opioid withdrawal to improve outcomes for both mothers and newborns and help to keep the family unit together.

Health and Human Services Secretary Alex Azar has identified ending the crisis of opioid addiction and overdose in America as one of the department's top priorities and an area of focus as an impactable health challenge. In 2017, the Department declared a public health emergency and announced a 5-Point Strategy to Combat the Opioid Crisis.

The IHS National Committee on Heroin, Opioids and Pain Efforts, or HOPE Committee, was established to promote appropriate and effective pain management, reduce overdose deaths from heroin and prescription opioid misuse, and improve access to culturally appropriate treatment.

hhs.gov

Four IHS Hospitals Complete Baby-Friendly Re-designation

By Tina Tah, IHS Senior Nurse Consultant

The Indian Health Service launched the Baby-Friendly Hospital Initiative in 2011. Four of the 10 IHS hospitals that have been designated as Baby-Friendly have recently achieved re-designation, indicating their ongoing commitment to promoting a healthy start for babies.

Baby-Friendly hospitals focus on increasing breastfeeding initiation and duration using quality improvement processes to improve breastfeeding rates through new maternity care and infant feeding practices. Exclusive breastfeeding protects against obesity and type II diabetes , conditions to which American Indians and Alaska Natives are particularly prone.

At the IHS we are proud to be a part of this global effort to provide better support for breastfeeding mothers in maternity wards. The initiative was introduced in 1991 by the World Health Organization and the United Nations Children's Fund at a time when worldwide breastfeeding rates had fallen to alarmingly low levels, and commercial interests had seeped into maternity care practices.

The Baby-Friendly Hospital Initiative was created to reverse that trend by changing some standard practices in the maternity ward, the setting which is most influential in a mother's decision to initiate breastfeeding and helping her establish lactation and achieve ongoing breastfeeding success.

IHS Baby-Friendly hospitals encourage the broad-scale implementation of the Ten Steps to Successful Breastfeeding and the International Code of Marketing of Breast-milk Substitutes. These guidelines were developed by a team of global experts and consist of evidence-based practices that have been shown to increase breastfeeding initiation and duration. U.S. facilities that achieve these high standards of care are designated as "Baby-Friendly" by Baby-Friendly USA, the authority for the BFHI in this country.

Achieving Baby-Friendly designation is an important part of the journey, but it is not the endpoint. Routine data collection, monitoring of practices and quality improvement activities are vital to ensuring that the Baby-Friendly standards are maintained. Facilities are responsible for ongoing adherence to the most current Guidelines and Evaluation Criteria.

Photo courtesy of the Indian Health Service

IHS facilities that are designated as Baby-Friendly are required to be surveyed and re-designated every five years. The process to become re-designated can take up to two years.

IHS congratulates the four facilities that have completed re-designation:

- Claremore Indian Hospital
- Phoenix Indian Medical Center
- Quentin N. Burdick Memorial Health Care Facility
- Zuni Comprehensive Community Health Center

The Baby-Friendly Hospital Initiative has become the standard for obstetrical care in the Indian Health Service. The Indian Health Service credits patient satisfaction, promotion of mother-baby bonding, successful breastfeeding, and outstanding patient care as key factors in these successful results.

ihs.gov

Advancing American Kidney Health

A bold new initiative to improve the lives of Americans suffering from kidney disease

The Department of Health and Human Services is expanding options for American patients with kidney disease and reducing healthcare costs as this new initiative provides specific solutions to deliver on three goals: fewer patients developing kidney failure, fewer Americans receiving dialysis in dialysis centers, and more kidneys available for transplant.

As directed by the Executive Order, the U.S. Department of Health and Human Services (HHS) announced today that the Centers for Medicare & Medicaid Services (CMS), through its Center for Medicare and Medicaid Innovation (CMMI), released a proposed required payment model and four optional payment models to adjust payment incentives to encourage preventative kidney care, home dialysis, and kidney transplants. The Department's Assistant Secretary for Planning and Evaluation (ASPE) also released a paper entitled *Advancing American Kidney Health*, which lays out a number of areas for action, including measures called for in the executive order, for various components of HHS to improve kidney care.

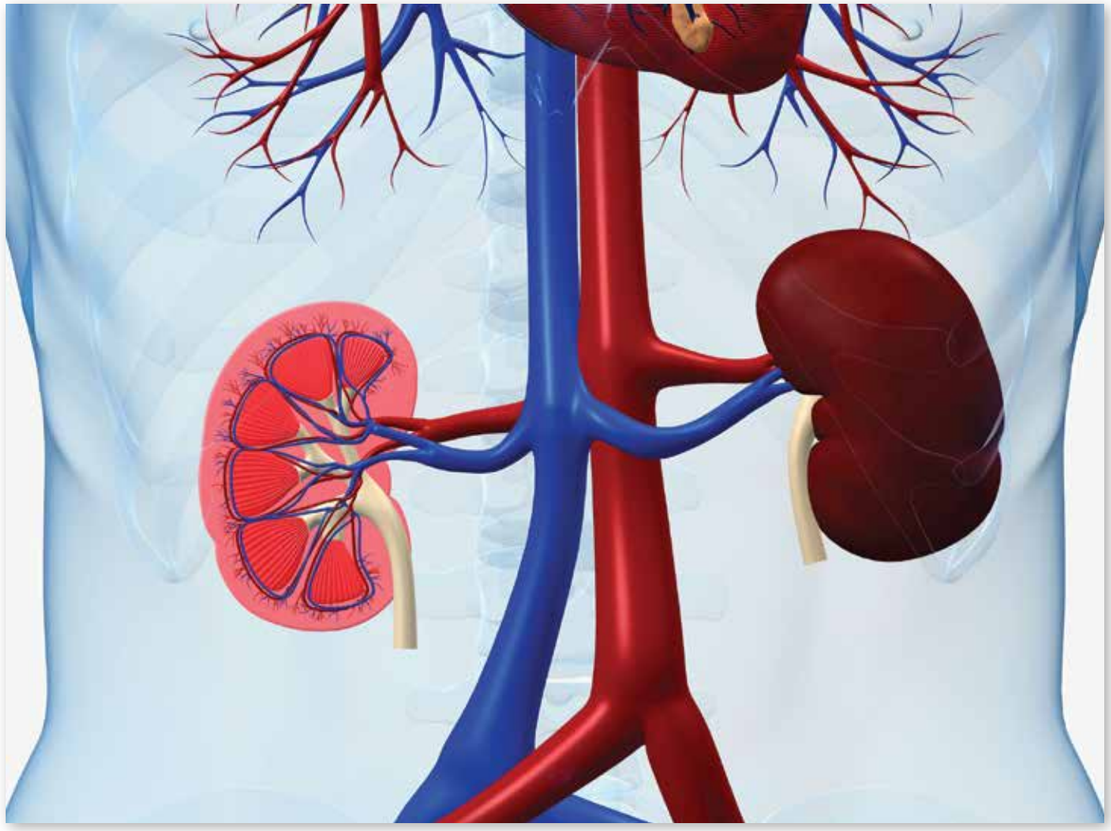


Photo courtesy of NIH

"President Trump is tackling the toughest issues in American healthcare, and few areas need reform more than the way we treat kidney disease," said HHS Secretary Alex Azar. "Decades of paying for sickness and procedures in kidney care, rather than paying for health and outcomes, has produced less-than-satisfactory outcomes at tremendous cost. Through new payment models and many other actions under this initiative, the Trump Administration will transform this situation and deliver Americans better kidney health, more kidney treatment options, and more transplants."

Across America, 37 million patients suffer from chronic kidney disease and more than 726,000 have end-stage renal disease (ESRD). There are nearly 100,000 Americans waiting on the list to receive a kidney transplant, and kidney disease ranks as the ninth leading cause of death in America.

Approximately twenty percent of dollars in traditional Medicare, $114 billion a year, are spent on Americans with kidney disease. Yet of the more than 100,000 American who begin dialysis to treat end-stage renal disease each year, one in five will die within a year. HHS has laid out three goals for improving kidney health:

1. Reducing the number of Americans developing end-stage renal disease by 25 percent by 2030
2. Having 80 percent of new ESRD patients in 2025 either receiving dialysis at home or receiving a transplant
3. Doubling the number of kidneys available for transplant by 2030

HHS is taking a number of immediate actions toward these goals. To reduce the development of end-stage renal disease, CMMI released a set of four optional payment models, expected to enroll more than 200,000 Medicare patients in arrangements that give providers new incentives for preventing kidney disease and managing kidney patients' health in a more comprehensive and person-centered way.

To provide more options for people with kidney failure, CMMI also announced a required payment model, known as ESRD Treatment Choices, which will enroll all dialysis providers in approximately half of the country and provide new incentives to encourage dialysis in the home.

To enhance patient access to transplantable organs, all five new payment models will give providers new incentives to help eligible patients receive transplants.

The President's Executive Order also calls for HHS to:

- Launch a public awareness campaign to increase knowledge of chronic kidney disease, which 40 percent of American patients do not know they have
- Reform the organ procurement and management system in the United States to significantly increase the supply of transplantable kidneys
- Expand support for living donors through compensation for costs such as lost wages and child care expenses
- Encourage development of wearable or implantable artificial kidneys, through cooperation between developers and the Food and Drug Administration (FDA) and support for KidneyX, a public-private partnership between HHS and the American Society of Nephrology

As laid out in the ASPE paper, Advancing American Kidney Health, HHS will also, among other measures:

As laid out in the ASPE paper, *Advancing American Kidney Health*, HHS will also, among other measures:

- Improve Centers for Disease Control and Prevention (CDC) work on tracking and detecting chronic kidney disease throughout the population and supporting state and local efforts to develop a public health response for people with key risk factors
- Expand work to study and implement evidence-based approaches to preventing kidney disease through CDC and the National Institutes of Health
- Support work on portable dialysis options through the Assistant Secretary for Preparedness and Response to ensure individuals who need dialysis have ready access to treatment in the aftermath of disaster situations
- Inform development of new kidney disease treatments that align with patient preferences, including alternatives to dialysis, through patient surveys being developed by the FDA
- Examine ways to improve CMS's ESRD payment policies
- Continue research work through NIH to advance precision medicine for kidney disease
- Launch additional prize competitions through KidneyX to support the development of new tools for preventing, managing, and treating kidney disease
- Work further toward reducing disparities in performance among Organ Procurement Organizations (OPOs) and transplant centers with the goal of increasing recovery of kidneys by OPOs and utilization of kidneys by transplant centers.

hhs.gov

HHS and the American Society of Nephrology Launch $1.5 Million Phase 2 of Prize Competition to Redesign Dialysis

KidneyX seeks breakthrough solutions to transform kidney care

Redesigning Dialysis is part of a series of KidneyX prize competitions to catalyze the development of innovative solutions that can prevent, diagnose, and treat kidney diseases. Phase two seeks prototype solutions, or components of solutions, that can replicate normal kidney functions or improve dialysis access. Participants may compete in the second phase even if they did not submit a solution in the first phase. Prototypes should address at least one of the following areas: blood filtration, electrolyte homeostasis, volume regulation, toxin removal and secretion, filtrate drainage and connectivity, and dialysis access.

KidneyX patient family partnership meeting

The competition calls on researchers, innovators, patients, and investors with expertise in nephrology, biotechnology, bioengineering, and medical devices to submit solutions exit disclaimer icon by 5:00 p.m. ET on January 31, 2020. Up to three winners will each be awarded $500,000. Participants can find more information, including the submission requirements, judging criteria, and eligibility, in the prize announcement.

"Dialysis treatment has not changed substantially since it was first introduced over 60 years ago," said HHS Chief Technology Officer Ed Simcox. "The pace of innovation in kidney care is unacceptable. Through KidneyX, we are creating a clear path for disruptive innovation in a $114 billion market."

An estimated 850 million people worldwide exit disclaimer icon are living with kidney diseases, including more than one in seven American adults. For people with kidney failure, the only treatment option other than a transplant is dialysis, which takes a serious toll. Dialysis patients typically spend 12 hours a week attached to a machine and their five-year life expectancy is worse than that of most cancer patients. The treatment is also extremely costly, with Medicare alone spending more than $35 billion annually for beneficiaries with kidney failure.

"We were thrilled to see the enthusiastic response to Redesign Dialysis Phase 1 from innovators across a spectrum of disciplines," said KidneyX Steering Committee Chair Dr. John Sedor. "We're building a strong community dedicated to developing breakthrough solutions that will change outcomes and transform patients' lives."

Redesign Dialysis Phase 1 invited participants to submit proposals on approaches that could enable the design of new artificial kidney devices, extending life and improving quality of life. This first phase received 165 submissions that ranged from innovations in vascular access and fluid filtration to innovations in hemodialysis and biosensors. The 15 Phase 1 winners each received $75,000.

"We know that building an artificial kidney will be a highly collaborative process, and Redesign Dialysis is driving critical advancements in this space," HHS KidneyX Program Director Dr. Sandeep Patel said. "KidneyX is facilitating collaboration across the National Institutes of Health, Food and Drug Administration, and Centers for Medicare & Medicaid Services to create a funding, regulatory, and payment landscape that can support accelerated innovation and investment."

The KidneyX Artificial Kidney Prize is expected to launch in April 2020 and run for up to four years. It is designed to build on the goals of Redesign Dialysis and further advance the development of an artificial kidney that can replace enough physiological kidney function to sustain life and improve patient quality of life. HHS is seeking input on the Artificial Kidney Prize; responses to the RFI are due on or before December 13, 2019.

hhs.gov

Dr. John Ngai Named Director of NIH BRAIN Initiative

John J. Ngai, PhD, Photo courtesy of Brittany Hosea-Small, UC Berkeley

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. Dr. Ngai is expected to join NIH in March.

"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 understanding 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."

nih.gov

Lou Gehrig's ALS "Disease in a Dish" Creates Opportunities for Advanced Motor Neuron and Therapeutic Drug Screening

By Justin Ichida, PhD, University of Southern California

Some cases of amyotrophic lateral sclerosis (ALS), also called Lou Gehrig's disease, are thought to be the result of genetic mutations in a specific region of DNA, such as the C9ORF72 gene region. There are only 4 FDA-approved drugs on the market to manage ALS, with each only providing modest effect. There is no cure for ALS and no proven treatments, leaving few options for ALS patients.

Drug screening using patient-derived cells is an emerging area in biomedicine and an early step in drug development. Dr. Ichida and colleagues were one of the first to perform this type of screening in ALS at a large scale. With support from a Fiscal Year 2014 ALSRP Therapeutic Development Award, Dr. Ichida developed a stem cell technology that successfully converts the blood cells of ALS patients into a model of C9ORF72 ALS motor neurons. Dr. Ichida has shown that these patient-derived motor neurons die faster than normal motor neurons and that they demonstrate the "disease in a dish." In addition, the team developed a high throughput screening technique incorporating image analysis software that allows for automated detection of the rate of neurodegeneration in the cells following treatment. In collaboration with Icagen, Inc. and DRVision Technologies LLC, Dr. Ichida's team is using this technique to screen the effects of roughly 40,000 different small molecule compounds as well as combinations of drugs that that synergize to generate a greater neuroprotective effect. Several drugs already FDA-approved have shown promise slowing the degeneration of C9ORF72 motor neurons.

Dr. Ichida has presented the results of his team's work thus far at several prominent meetings including to audiences composed of both ALS and other neurodegenerative disease patients, as well as fellow neurologists. The project results were also published in Nature Medicine in March 2018. The team is currently working to develop the analysis software further, to complete screening on the 40,000 compounds with Icagen, Inc., and to verify top therapeutic candidates by re-testing them in additional ALS cell cultures for their effect on neuroprotection. Dr. Ichida's ALS cell lines and screening platform are available to the ALS community and his hope is that this will increase the throughput of experiments in the field and enable others, including pharma, biotech, and academia to perform large-scale screens. If we are successful in identifying targets or drugs that effectively slow ALS disease progression, says Dr. Ichida, we anticipate that the use of stem cell technology will start to factor more into health care policy in the future.

Justin Ichida, PhD, University of Southern California. Photo courtesy of the DoD Congressionally Directed Medical Research Programs

What research is being done?

The mission of the National Institute of Neurological Disorders and Stroke (NINDS) is to seek fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease. The NINDS is a component of the National Institutes of Health (NIH), the leading supporter of biomedical research in the world.

The goals of NINDS research on ALS are to understand the cellular mechanisms involved in the development and progression of the disease, investigate the influence of genetics and other potential risk factors, identify biomarkers, and develop new and more effective treatments.

Cellular defects

Scientists are seeking to understand the mechanisms that selectively trigger motor neurons to degenerate in ALS, and to find effective approaches to halt the processes leading to cell death. Using both animal models and cell culture systems, scientists are trying to determine how and why ALS-causing gene mutations lead to the destruction of neurons. These animal models include fruit flies, zebrafish, and rodents.

Initially, genetically modified animal models focused on mutations in the SOD1 gene but more recently, models have been developed for defects in the C9ORF72, TARDP, FUS, PFN1, TUBA4A, and UBQLN2 genes. Research in these models suggests that,

depending on the gene mutation, motor neuron death is caused by a variety of cellular defects, including in the processing of RNA molecules and recycling of proteins, and structural impairments of motor neurons. Increasing evidence also suggests that various types of glial support cells and inflammation cells of the nervous system may play an important role in the disease.

Stem Cells

In addition to animal models, scientists are also using innovative stem cells models to study ALS. Scientists have developed ways to take skin or blood cells from individuals with ALS and turn them into stem cells, which are capable of becoming any cell type in the body, including motor neurons and other cell types that may be involved in the disease. NINDS is supporting research on the development of stem cell lines for a number of neurodegenerative diseases, including ALS.

Familial versus sporadic ALS

Overall, the work in familial ALS is already leading to a greater understanding of the more common sporadic form of the disease. Because familial ALS and sporadic ALS show many of the same signs and symptoms, some researchers believe that some familial ALS genes may also be involved in sporadic ALS.

Clinical research studies supported by NINDS are looking into how ALS symptoms change over time in people with C9ORF72 mutations. Other NINDS-supported research studies are working to identify additional genes that may cause or put a person at risk for either familial or sporadic ALS.

Additionally, researchers are looking at the potential role of epigenetics in the development of ALS. Epigenetic changes can switch genes on and off, and thus can profoundly affect the human condition in both health and disease. These changes can occur in response to multiple factors, including external or environmental conditions and events. Although this research is still at a very exploratory stage, scientists hope that understanding epigenetics can offer new information about how ALS develops.

Biomarkers

Biomarkers are biological measures that help to identify the presence or rate of progression of a disease or the effectiveness of a therapeutic intervention. Since ALS is difficult to diagnose, biomarkers could potentially help clinicians diagnose ALS earlier and faster.

Additionally, biomarkers are needed to help predict and accurately measure disease progression and enhance clinical studies aimed at developing more effective treatments. Biomarkers can be molecules derived from a bodily fluid (such as those in the blood and cerebrospinal fluid), an image of the brain or spinal cord, or a measure of the ability of a nerve or muscle to process electrical signals. The NINDS is supporting research on the development biomarkers for ALS.

New treatment options

Potential therapies for ALS are being investigated in a range of disease models. This work involves tests of drug-like compounds, gene therapy approaches, antibodies, and cell-based therapies. For example, NINDS-supported scientists are currently investigating whether lowering levels of the SOD1 enzyme in the brain and spinal cord of individuals with SOD1 gene mutations would slow the rate of disease progression.

Other NINDS scientists are studying the use of glial-restricted progenitor cells (which have the ability to develop into other support cells) to slow disease progression and improve respiratory function. Additionally, a number of exploratory treatments are being tested in people with ALS. Investigators are optimistic that these and other basic, translational, and clinical research studies will eventually lead to new and more effective treatments for ALS.

More information about ALS research supported by NINDS and other NIH Institutes and Centers can be found using NIH RePORTER, a searchable database of current and past research projects supported by NIH and other federal agencies. RePORTER also includes links to publications and resources from these projects.

cdmrp.army.mil

Smartphone Apps Show Promise for Assessing Multiple Sclerosis Symptoms

By Brandon Levy

The three-quarters of Americans who own a smartphone use them not just for communicating but also keeping a calendar, playing games, scouring the Internet for funny cat memes, and — soon — maybe even evaluating their neurological health. A new study conducted by IRP and University of Maryland researchers has confirmed the potential of smartphone apps for gauging symptoms of the neurological disease multiple sclerosis.[1]

Multiple sclerosis, or MS, is caused by the loss of the fatty coating that helps neurons transmit electrical signals. The disease, for which there is no cure and limited treatment, can cause a wide array of symptoms, including numbness, motor weakness, coordination difficulties, and vision loss.

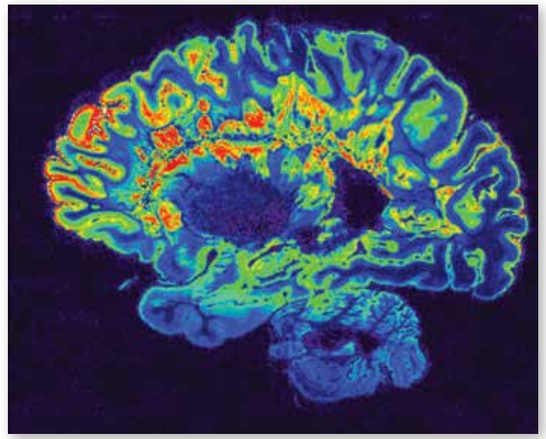
According to IRP investigator Bibiana Bielekova, MD, the new study's senior author, the assessments commonly used in clinical trials for MS therapies are not very sensitive. In fact, she says, in a trial that tracks the progression of MS symptoms for just one or two years, those measures might only detect worsening symptoms in around 10 percent of patients. This makes it extremely difficult to determine the effectiveness of a new medication without running extremely long or large studies.

"It's unsustainable — these clinical trials are very expensive and we are running out of patients" says Dr. Bielekova. "We need to be able to measure disability progression in the smallest possible number of patients in the shortest possible time frame because that way we can screen drugs much more efficiently."

Dr. Bielekova's IRP team focuses on remedying this problem by creating easier and more sensitive neurological assessments. For example, her group has created an iPad program called NEUREX[2] that allows time-crunched doctors to quickly determine a patient's scores on several measures of MS-related disability.

Dr. Bielekova's new study was born out of an attempt to further decrease the time and effort needed to gauge MS symptoms. She teamed up with Atif Memon, PhD, a professor at the University of Maryland, College Park, who was teaching a class on app development for the Android operating system used on many smartphones. With guidance from Dr. Bielekova and her IRP colleagues, Dr. Memon's students developed a range of smartphone apps that could assess patients' motor and cognitive abilities in similar ways to traditional tests like the 9-Hole Peg Test (9HPT), which measures the time it takes a patient to place nine pegs in nine holes and then remove them.

"You don't need to have nurses administering these tests in the clinic," Dr. Bielekova explains. "You can simply have patients doing them with their phones."



This MRI scan shows the brain of a patient with multiple sclerosis (MS). A new IRP study suggests that smartphone apps might provide an easier, cheaper, and faster way to measure MS symptoms. Photo courtesy of NIH

After further polishing the students' programs, Dr. Bielekova's group put two of them to the test: a finger-tapping app that had participants simply tap the screen as many times as possible in ten seconds and a balloon-popping app in which players used their fingers to pop balloons that appeared in randomly generated locations on the screen. These tests differentiated MS patients from healthy volunteers nearly as well as the 9HPT and were easier to do, as four patients were unable to complete the 9HPT but all patients could do the app-based assessments. In addition, each patient's scores on the app-based tests were similar to their performance on the 9HPT. Moreover, compared to performance on the 9HPT, scores on the app-based tests more closely corresponded to scores on neurological exams done using the NEUREX software, suggesting that the smartphone apps

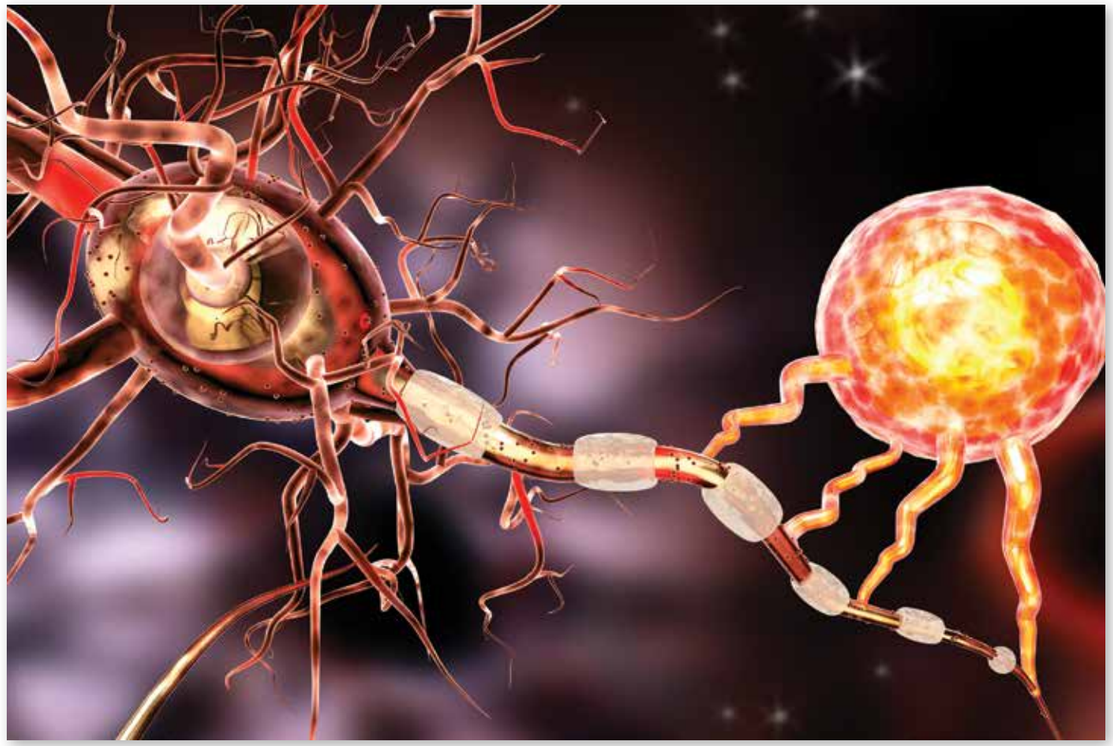


Illustration of an oligodendrocyte, right, creating a myelin coating around a nerve cell extension. Damage to myelin can affect communication between nerve cells. Ralwel/iStock/Thinkstock photo courtesy of NIH

were not just easier and faster gauges of MS symptoms than an in-person test done in a hospital setting but they might also provide a better means of assessing symptoms than traditional functional assessments.

The app-based tests also had the added benefit of allowing the researchers to collect other types of data related to patients' symptoms. For example, since the finger-tapping test required only motor skills while the balloon-popping test required motor, visual, and cognitive abilities, comparing scores on the two tests allowed the researchers to more specifically measure visual and cognitive impairments. Similarly, the amount of time that patients' fingers remained in contact with the screen during the finger-tapping test showed promise as a means of identifying patients with coordination problems caused by damage to a part of the brain called the cerebellum.

Dr. Bielekova's team is currently finalizing a study of six other apps that originated in Dr. Memon's class. After additional refinement, she aims to combine her team's NEUREX iPad software with the smartphone apps to create an improved assessment for evaluating MS patients.

"Obviously these apps will not replace doctors, but I really believe that they can fill an important gap," Dr. Bielekova says. "They will provide reliable data to the clinicians about how the patient is doing, and they will also empower patients by providing them with feedback about whether their disease is progressing."

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nih.gov

Four Million Reasons To Celebrate! National Nurse's Week

By Cmdr. Angela Fallon, Deputy Director, Office of Clinical and Preventive Services

Nurses Week recognizes the contributions of nurses in the health care setting and beyond. At IHS, our mission is to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level. IHS nurses play a vital role in fulfilling that mission.

IHS nurses can be found working throughout the United States from remote village clinics, rural critical access hospitals, and large urban hospitals and health centers, in all different nursing specialties from general staff nursing to advanced practice nursing.

More than 2,380 nurses comprise the largest healthcare provider group in the Indian Health Service and form the foundation of high quality health care. Nationwide, there are four million registered nurses provide daily lifesaving care.

In addition to clinical nurses, the IHS Public Health Nurse Program supports population-focused services to promote healthier communities through community based direct nursing services, community development, and health promotion and disease prevention activities.

Public health nurses are licensed, professional nursing staff available to improve care transitions by providing patients with tools and support that promote knowledge and self-management of their condition as they transition from the hospital to home. Their expertise in communicable disease assessment, outreach, investigation, and, surveillance helps to manage and prevent the spread of communicable diseases.

35th graduating class of the Indian School of Practical Nursing, Albuquerque, New Mexico (National Archives). Photo courtesy of the Indian Health Service

IHS nurses have a proud and rich history. In 1924, Elinor Gregg established the first nursing division at the Indian Office, forerunner of the nursing program in the IHS. In the early 1970's, the IHS was among the first healthcare programs to hire advanced practice nurses such as nurse-midwives and nurse practitioners.

In 1927, Susie Walking Bear Yellowtail (Apsáalooke/Lakota) became one of the first Native Americans to become a registered nurse. Susie dedicated her life to improving the health of Native Americans and became an outspoken leader for changes to improve healthcare for Native Americans. She was one of the original organizers to develop the Native American Nurses Association.

Now is a great time to become part of the IHS nursing team. Nursing in the IHS is a very rewarding career filled with opportunity and the chance to experience other cultures and beliefs.

Information on current nursing opportunities can be found on the IHS Job Opportunities website: www.ihs.gov/nursing/jobops/

ihg.gov

HHS Awards $319 Million to Support Health Workforce Providers Caring for the Underserved

The U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), announced $319 million in scholarship and loan repayment awards for clinicians and students through the National Health Service Corps (NHSC).

With these providers entering NHSC service, there are now more than 13,000 medical, dental and behavioral health care clinicians providing quality care to more than 13.7 million Americans in rural, urban and tribal communities. There are also almost 1,480 students and medical residents preparing to serve in the Corps.

"President Trump has prioritized improving healthcare for Americans in rural communities, which includes building a strong, sustainable rural healthcare workforce," said HHS Secretary Alex Azar. "These loan repayment awards and scholarships make it possible for dedicated clinicians to care for the patients who need them most, including Americans with opioid use disorder and other substance abuse challenges."

This year's awards significantly expand the NHSC's efforts to combat the opioid epidemic in areas of greatest need. The investment includes $80 million that will support almost 1,250 clinicians providing substance use disorder treatment in underserved communities, including at more than 2,000 rural sites. These providers commit to three-year loan repayment contracts, ensuring sustained impact and continuity of care for these communities.

Photo courtesy of the Department of Veterans Affairs

"The NHSC story of service, commitment, and community is a powerful one. These awards not only get more NHSC providers into the communities that need them the most, but also help to keep those physicians working there long term," said HRSA Acting Administrator Tom Engels.

The NHSC is a critical component of the federal government's health care safety net programs. More than 60% of NHSC participants work in federally funded community health centers, which provide a lifeline to quality health care in high-need communities throughout the nation.

HHS awards support the following programs:

National Health Service Corps Loan Repayment Program ($156.7 million) provides 4,012 new and 2,385 continuation awards to fully trained, licensed primary care clinicians in exchange for providing primary health care services in an area of greatest need.

National Health Service Corps Substance Use Disorder Workforce Loan Repayment Program ($66.0 million) provides 1,074 new awards to recruit and retain health professionals in underserved areas to expand access to substance use disorder treatment and prevent overdose deaths.

National Health Service Corps Rural Community Loan Repayment Program ($14.1 million) provides 174 new awards to health care providers working to combat the opioid epidemic in the nation's rural communities.

National Health Service Corps Scholarship Program ($47.6 million) provides 200 new and 11 continuation awards to students pursuing primary care training leading to a degree in medicine, dentistry, or a degree as a nurse-midwife, physician assistant, or nurse practitioner in exchange for providing primary health care services in areas of greatest need.

National Health Service Corps Students to Service Loan Repayment Program ($15.2 million) provides 127 new awards. This program provides loan repayment assistance to medical and dental students in their last year of school in return for their choosing primary care as a practice focus and working in rural and urban areas of greatest need.

National Health Service Corps State Loan Repayment Program ($19.0 million) provides cost-sharing grants to 41 states and two territories that operate their own loan repayment programs, funding 1,957 new and continuation awards.

hhs.gov

A Surgeon's View of Prostate Cancer

By Robert Reiter, MD, MBA, Professor of Urology and Molecular Biology, Director of the Prostate Cancer Treatment and Research Program, and Director of Urologic Research at the David Geffen School of Medicine at the University of California, Los Angeles (UCLA)

Looking back, I thought I wanted to be an academic clinician-scientist and thought I needed the intellectual stimulation of an academic setting, but I was not sure what kind of research I wanted to do or even if I wanted to do research. I had done three years of clinical training at Baylor, so I stepped out and explored something different. I had two fantastic years at NCI.

I trained at NCI on the recommendation of our chair at Baylor, who had also spent time there. I was looking to explore research and find what I wanted to do. In the clinical service, we were doing immunotherapy and taking care of patients with an inherited form of kidney cancer, Von Hippel-Lindau (VHL) disease. The lab was trying to clone the VHL gene at the time, and I worked on number of projects, including one of my own to look at mutations in the p53 gene in kidney cancer.

Personally, I found the link between what I was doing clinically and what we were doing in the lab rewarding; and that is what got me interested in an academic medicine career. It set me on a course that I continue today.

Markers of Success

My research remains highly translational; it is about taking insights from the clinic into the lab, whether from the operating room or patient management. Today, I spend about 60 percent of my time doing surgery and taking care of patients, and about 40 percent of my time on running the laboratory and administrative work. Our lab has been focused on identifying new therapeutic and imaging targets in cancer. We have developed a series of different antibodies against prostate cancers, aimed both at therapies and at imaging for surgery or disease monitoring.

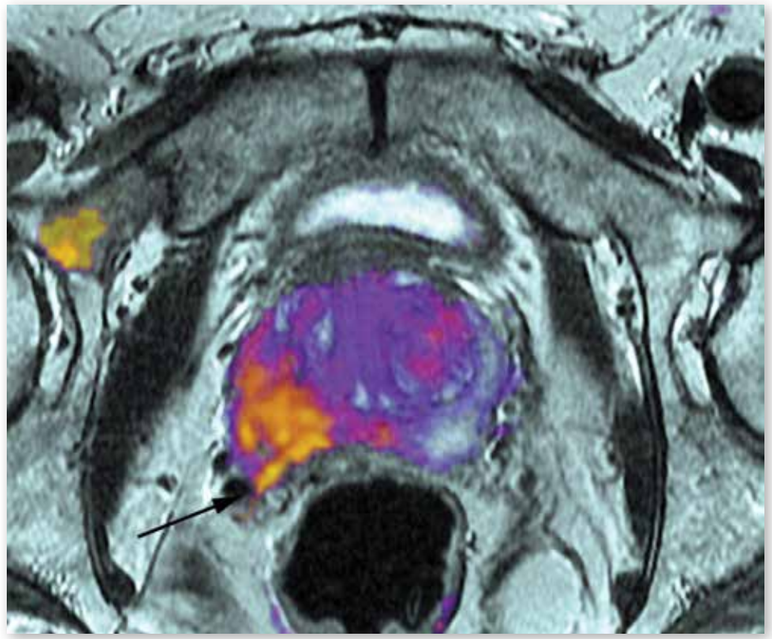
We have a definite interest in cancer stem cells. In the late 1990s, we first identified prostate stem cell antigen (PSCA) as a cell-surface marker overexpressed in prostate cancer. Early on, I wrote a number of papers with the hypothesis that prostate cancers

> *Prostate cancer can be successfully eradicated through surgery, but a major correlate or predictor of failure is the presence of cancer at the margins of a tumor that is excised.*

Robert Reiter, MD

arise from stem cells in the basal cell layers, and, interestingly, the field has evolved to suggest that this is actually true! We are still interested in understanding the evolution of differentiated cell types from these stem cells, in particular, the evolution into neuroendocrine tumors.

In 2010, we published a paper in *Nature Medicine* in which we showed that N-cadherin, a mesenchymal cadherin associated with epithelial-to-mesenchymal transition (EMT), was reproducibly upregulated in several models of castration-resistant cancer. We showed that the ectopic expression of N-cadherin is sufficient for converting androgen-dependent prostate cancer into invasive, metastatic, and castration-resistant prostate cancer in animal models, and that these effects can be inhibited by



RSI-MRI image shows high grade cancer extending from prostate (purple) into the right seminal vesicle (orange) and a bony metastasis in the right hip (upper left, orange). Photo courtesy of David Karow, University of California, San Diego

N-cadherin-specific antibodies. We are now trying to understand the role N-cadherin plays in the transdifferentiation process.

Surgical Strikes

Prostate cancer can be successfully eradicated through surgery, but a major correlate or predictor of failure is the presence of cancer at the margins of a tumor that is excised. Surrounding the prostate are nerve bundles that control the bladder, urethra, etc…, making surgery particularly challenging. You are always trying to split hairs: preserving normal function while getting cancer out. It is almost impossible to do that perfectly. If we could see the edges of the cancer, we could do a better job of excising it.

In order to address this problem, we are engineering antibodies to PCSA that are conjugated to different fluorophores that could help us visualize the cancer cells in the operating theater. In addition, we have developed different animal models that can replicate the kinds of problems we see in the operating room in order to test our antibodies.

Over the years, my closest collaborator has been Anna Wu, PhD, Professor of Molecular and Medical Pharmacology at UCLA. She has a background in radioimmunotherapy. I have clinical insight into the problems that can be addressed through antibody targeting; she has expertise in antibody engineering and radiobiology. My lab does the target identification and animal modeling; her lab reengineers the antibodies.

We have taken several antibodies into clinical trials and even started a few companies. My first commercial experience was with an antibody company spun out of my department; it licensed one of the antibodies that was developed in our laboratory. Then I went to business school, and eventually started a company in 2007 to develop a prostate imaging agent and an imaging agent to track the immune system during immunotherapy. The company is venture backed and currently testing agents in the clinic. We have also started a virtual company to commercialize some of our newer antibodies. The whole purpose of my research is to try and make a difference for patients, and, in my opinion, start-up companies are vital channels for translation into the clinic and a way to maintain some control over the translational process once it leaves academia.

Surgeons and Science

If you look at the evolution of different fields across medicine, success has depended on discoveries that emanate from those fields. Urology has seen these successes many times, whether in the treatment of kidney stone diseases or the management of prostate cancer by castration (for which Charles Huggins, MD, was awarded the Nobel Prize in Medicine).

Surgical fields have not been as adept at recruiting, fostering, or training clinician-scientists. I was just at a molecular biology course sponsored by the American Association for Cancer Research this summer and 90 percent of the students were medical oncologists. Research is a more established career path in medical oncology, so it is not surprising that most of the major advances in cancer treatment and biology (with notable exceptions) are coming from medical oncology or basic science, and less so from urology and even surgery. Add to that the economics of our time, which result in residency programs dropping their research year requirement, and research experiences like I had at CCR are fewer and farther between. I hope this trend reverses because the future of these fields depends on not just clinical practice but on research conducted by those practitioners.

cancer.gov

Muscogee (Creek) Nation Celebrates Breast Cancer Awareness Month

"I got this feeling inside my bones, It goes electric, wavy when I turn it on, all through my city, all through my home, we're flying up, no ceiling, when we're in our zone". The lyrics to Justin Timberlake's hit song, 'Can't stop the feeling,' blared through the speakers at the 17th annual Muscogee (Creek) Nation Department of Health Pink Party.

Accompanying the song was a dance video involving Muscogee (Creek) employees and youth throughout the jurisdiction.

Employees, citizens and above all, survivors of cancer filled the event center for this year's celebration.

MCN Secretary of Health Shawn Terry welcomed everyone to the party and recognized the many survivors that participated.

"It is such a celebration in who we get to honor," he said. "More and more people want to become a part of this [Pink Party] and get more knowledge and awareness on breast cancer."

Terry said Native American women have some of the highest rates in getting breast cancer and the event has helped with recognizing the women and men that have faced this type of cancer.

"We have done such an amazing job in honoring the survivors," Terry said. "When someone is diagnosed with cancer, it's not only affecting that person. It affects their family."

MCN Principal Chief James Floyd spoke to the audience about the importance of having the Pink Party and why it is necessary for the awareness of breast cancer.

"It tells me the people here at the Pink Party are interested in learning how to recognize breast cancer and the steps they should do if they have a concern," Floyd said.

Survivors discuss experiences dealing with disease. Photo courtesy of Muscogee (Creek) Nation

According to breastcancer.org, about 1 in 8 U.S. women, roughly 12 percent, will develop invasive breast cancer over the course of her lifetime.

This year, an estimated 268,600 new cases of invasive breast cancer are expected to be diagnosed in women in the U.S., along with 62,930 new cases of non-invasive (in situ) breast cancer.

Doctors representing the Saint Francis Oncology and Breast Cancer Group in Tulsa, Okla., were keynote speakers for the Pink Party. They spoke to the audience on how they team up to help patients who are combating breast cancer.

"No two cancer cases are the same," Oncologist Dr. Fuad Hassany said. "Each breast cancer is different."

Muscogee (Creek) citizen and butterfly whisperer, Virginia Williams was there and served as moderator for a panel of survivors who spoke about their breast cancer experiences.

"One of the things that bothered me when I found out I had breast cancer was not being in control," breast cancer survivor Sandra Lambert said. "I wanted it gone (breast cancer). It was a process and I like things to happen quickly. Having to depend on others was hard for me."

Floyd had one last thing to say to the survivors at the Pink Party.

"I want to thank you for being here today at the Pink Party," he said. "You are beacons in your family and the communities. You represent strength and we need that."

mcn-nsn.gov

NIH Supported Breast Cancer Clinical Detection Trial Tests Mammography Diagnostic Imaging Tools

A new trial may be the answer for finding breast cancer in women who don't have symptoms.

The trial will test two types of imaging tools — 2-D and 3-D mammography.

2-D mammography takes pictures from two sides of the breast to create a flat image. 3-D mammography takes images from different angles around the breast and builds it into 3-D-like image.

The study is now open for enrollment. It's led by the ECOG-ACRIN Cancer Research Group in collaboration with the National Cancer Institute (NCI).

Researchers are looking for healthy women ages 45 to 74 who are already planning to get routine mammograms.

Participants will help researchers learn how to best scan patients for breast cancer. It will also help women make more informed decisions about the screening tests in the future.

Photo courtesy of U.S. National Library of Medicine

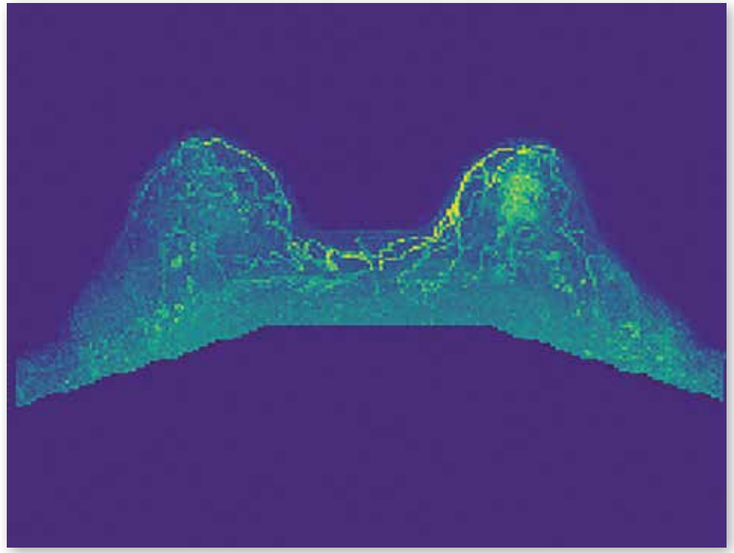


Photo courtesy of Pacific Northwest National Laboratory

"Nearly 50 million screening mammograms occur each year in the U.S., yet it has been decades since a large-scale randomized trial of mammography has been done," said Worta McCaskill-Stevens, MD.

Dr. McCaskill-Stevens is the director of NCI's Community Oncology Research Program, which supports the trial.

"The evolution of mammography technology provides us with an opportunity to fill in the gaps in our knowledge about two available breast cancer screening tests," she added.

medlineplus.gov

Older Biologic Age Linked to Elevated Breast Cancer Risk

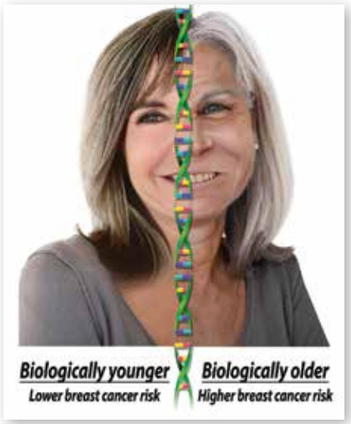
NIH scientists use epigenetics to help predict disease development

Biologic age, a DNA-based estimate of a person's age, is associated with future development of breast cancer, according to scientists at the National Institutes of Health. Biologic age was determined by measuring DNA methylation, a chemical modification to DNA that is part of the normal aging process. The study showed for every five years a woman's biologic age was older than her chronologic or actual age, known as age acceleration, she had a 15 percent increase in her chance of developing breast cancer. The study was published online Feb. 22 in the Journal of the National Cancer Institute.

Scientists from the National Institute of Environmental Health Sciences (NIEHS), part of NIH, speculate that biologic age may be tied to environmental exposures. If so, it may be a useful indicator of disease risk. They used three different measures, called epigenetic clocks, to estimate biologic age. These clocks measure methylation found at specific locations in DNA. Researchers use these clocks to estimate biologic age, which can then be compared to chronologic age.

The researchers used DNA from blood samples provided by women enrolled in the NIEHS-led Sister Study, a group of more than 50,000 women in the U.S. and Puerto Rico. The study was specifically designed to identify environmental and genetic risk factors for breast cancer. The research team measured methylation in a subset of 2,764 women, all of whom were cancer-free at the time of blood collection.

"We found that if your biologic age is older than your chronologic age, your breast cancer risk is increased. The converse was also true. If your biologic age is younger than your chronologic age, you may have decreased risk of developing breast cancer," said corresponding author Jack Taylor, MD, PhD, head of the NIEHS Molecular and Genetic Epidemiology Group. "However, we don't yet know how exposures and lifestyle factors may affect biologic age or whether this process can be reversed."



If a woman's biologic age is older than her chronologic age, she has an increased risk of developing breast cancer. Photo courtesy of NIEHS

Lead author Jacob Kresovich, PhD, a postdoctoral fellow in the Taylor group, had read studies that used epigenetic clocks to predict age-related mortality. Since age is the leading risk factor for breast cancer, he hypothesized that age acceleration may be associated with higher breast cancer risk.

"If you look at a group of people who are all the same age, some may be perfectly healthy while others are not," Kresovich said. "That variability in health may be better captured by biologic age than chronologic age."

Kresovich suggests that using DNA methylation to measure biologic age may help scientists better understand who is at risk for developing cancer and other age-related diseases.

This research is an example of epigenetics, a field that studies how biochemical processes turn individual genes on or off, without affecting the DNA sequence.

The Taylor group plans to continue using epigenetic data, along with information on genetics, environment, and lifestyle to better understand how these factors interact and contribute to disease risks.

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 of fundamental basic research.

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National Eye Institute Takes on Low Vision and Driving

Tim Goetz drives about 200,000 miles each year. Remarkably, Goetz is legally blind. Research funded by the National Eye Institute (NEI) is helping Goetz and others like him get or stay behind the wheel while keeping roads safe for everyone.

Goetz has 20/200 vision due to ocular albinism and drives using miniature telescopes mounted on regular glasses. Ocutech bioptic telescopes, as they are called, were developed with NEI funding by optometrist Henry Greene from Durham, North Carolina. Prior to obtaining his Ocutech glasses, Goetz got around on foot or bicycle. With the telescopes, he obtained a restricted driver's license and now works as an engineer for a large agricultural company, making site visits across the country. Goetz can drive safely in most places — even in urban areas during rush hour.

Ensuring that people with visual impairment can safely operate a motor vehicle is no simple matter. If fact, states' vision standards for drivers vary. NEI is funding the development of strategies and devices to help visually impaired drivers meet driving standards, along with research to help states better assess driving performance.

Driving performance studies

Studies of on-the-road driving performance have helped researchers examine the relationship between common eye conditions and collision risk. NEI-funded scientist Cynthia Owsley, PhD, University of Alabama at Birmingham, conducted a battery of vision tests on 2000 drivers, ages 70 and older, and tallied the group's collisions over the next three years.

Owsley discovered that loss of visual field, including peripheral (side) vision, was associated with more car crashes. "It looks like the lower left part of the visual field is most important, at least for drivers in the U.S. where the oncoming traffic is to the left," explained Owsley. A major cause of visual field loss is glaucoma — a condition that damages the optic nerve, which carries signals from the eye to the brain.

Driving simulators enable researchers to safely evaluate driving. Photo credit, Alex Bowers

Slowed visual processing speed — a measure of how long it takes to identify objects — affects about a third of older adults and also is associated with more car crashes, Owsley said. Causes may include eye disease, neurological conditions, stroke, cognitive impairment, side effects of medication, and other circumstances that often accompany aging.

Cataracts — clouding of the eye's lens — also affect driving. In a study of older drivers with cataract, those who underwent surgery to remove their cataracts had a 50-percent lower risk of collision, according to Owsley's research. "There was a protective benefit to having had cataract surgery," Owsley said.

Naturalistic driving studies

To conduct naturalistic driving studies, researchers install cameras in study participants' cars and sensors that record vehicle kinematics (e.g., acceleration and speed), providing data on near crashes, excessive speed, sudden stops, and so on. Owsley is conducting a naturalistic driving study involving about 200 older drivers (70 years or older) with a wide range of visual capabilities. The participants undergo vision screening tests and then their driving is video-monitored for six months.

Anjali Bhorade, MD, of Washington University in St. Louis, is leading a naturalistic driving study of people with glaucoma. Results from a pilot project suggest that about 50 percent of drivers with glaucoma are able to drive safely. "Our goal is to identify compensatory strategies to help develop a training program to increase driving safety," Bhorade said.

Driving simulation studies

Driving simulation studies enable researchers to safely study potentially dangerous driving situations by taking them off the road. To study how drivers respond to road hazards, a research team led by Eli Peli, OD, at the Schepens Eye Research Institute at Harvard Medical School, devised a pedestrian detection task using a driving simulator. In the simulation, virtual pedestrians run or walk in front of the vehicle. The researchers then measure how long drivers take to react.

Alex Bowers, PhD, also of Schepens Eye Research Institute, is studying how people with hemianopia — loss of half of the visual field — detect and respond to potential road hazards. "There is an underlying assumption that if someone has visual field loss they will automatically learn to compensate for that by moving their head and eyes," said Bowers.

But that's not what she found in the driving simulator. "When we tested 12 drivers with similar hemianopias, some scanned the environment very well and detected as many pedestrians on the blind side as the seeing side. Others hardly scanned at all." Bowers' findings suggest that drivers with hemianopia should be allowed to demonstrate their fitness to drive.

Peripheral prism glasses provide an early warning system for drivers with peripheral vision loss. Photo credit, Alex Bowers

Interventions

Clinical rehabilitation

When Robert Sullivan had a stroke six years ago he lost the top left part of his field of vision. His neurologist said that he would never drive or ride a bike again, but Sullivan was extremely motivated to maintain his independence. And so, he made up his own rehabilitation program, teaching himself to scan his environment. "I had to work it out over time and get the confidence to get back in the car," he said. But rehabilitation guidelines or protocols would have been helpful.

Many people with low vision give up driving because they aren't sure how to proceed alone, he said. A few rehabilitation clinics teach scanning strategies, but studies have yet to test whether they improve driver safety or performance.

Computer-based cognitive training software can help drivers improve visual processing speed and regain confidence behind the wheel. The most rigorously evaluated program is speed of processing training, a technique that uses repeated practice to train the visual/neural system to capture visual stimuli at increasingly brief durations of exposure (ranging from 16 to 500 milliseconds, akin to what we think of as a single glance), explained Virginia Wadley Bradley, PhD, also of the University of Alabama. The technique was successfully used as part of the Advanced Cognitive Training for Independent and Vital Elderly (ACTIVE) Trial. Currently, the commercially available cognitive training system contains a speed of processing module. With funding from the National Institute on Aging, Bradley is conducting a clinical trial of the module in people with mild cognitive impairment. The trial will measure on-road driving performance.

"There is some evidence in the literature that speed of processing training reduces the collision rate," Owsley said. "However, many more studies are needed before I could definitively say that it could make you a safer driver."

Until better standards and regulations are established, one way to increase safety of visually disabled drivers is the use of driving assessment clinics, Owsley suggested. These clinics employ certified driving rehabilitation specialists, who are often trained occupational therapists.

Peripheral prism glasses

Peripheral prism glasses (Peli prisms), developed by Peli with NEI funding, help people with hemianopia compensate for blind spots. Prisms are placed on eyeglasses above and below the usual line of sight and shift peripheral light from the blind side to the seeing side. "They work like an early warning system,"

> *Slowed visual processing speed — a measure of how long it takes to identify objects — affects about a third of older adults and also is associated with more car crashes.* — Cynthia Owsley, PhD

Bioptic telescopes enable drivers with low vision to read faraway signs. Photo credit, Alex Bowers

Bowers said. Bowers tested use of the prism glasses in a driving simulator and found they helped some drivers better detect hazards.

Bioptic telescopes

Bioptic telescopes like Goetz's magnify distant objects. Typically, a telescope is mounted on just one lens. Users briefly glance through the telescopes to make out road signs and other fine details.

Using a driving simulator, Bowers, in collaboration with engineer Gang Luo, PhD, also of Schepens, found that use of a bioptic telescope reduces the ability to detect driving hazards when the alternate eye was closed, underscoring the importance of maintaining good field of vision while driving.

Luo has developed an in-car surveillance system and data analysis software to conduct naturalistic driving studies of bioptic drivers,. "The results will give us insight into how people use telescopes in their everyday driving, what they use them for, and generally how well they drive," said Bowers.

Public policy and driving regulations

Vision standards for driving were established when there was little evidence to support them, and regulations still vary from state to state. "The current driving regulations are not good, but we lack sufficient evidence to say what they should be," Bowers explained. With help from NEI, future screening tests will more accurately and reliably identify safe drivers.

Computer-based cognitive training software can help drivers improve visual processing speed and regain confidence behind the wheel.

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Neuroscientists Discover Brain Pressure Controls Eye Pressure, Revealing New Avenues for Glaucoma Treatment

Researchers at the University of South Florida have discovered a novel feedback pathway from the brain to the eye that modulates eye pressure — a significant advancement in the effort to diagnose and treat glaucoma. Glaucoma is associated with increased pressure in the eye due to a reduce ability of the eye to maintain proper fluid drainage. The heightened pressure applies mechanical strain to the optic nerve as the nerve exits the eye, resulting in vision loss and potential blindness.

It has long been hypothesized that brain pressure might also play a role in glaucoma because the amount of strain on the optic nerve depends not just on eye pressure, but the difference in pressure between the eye and brain. The groundbreaking study published in the *Journal of Physiology* shows, for the first time, that eye and brain pressure are physiologically connected. The neuroscientists came to this conclusion by altering brain pressure in animal models and noting changes in the fluid drainage properties of the eye that could be blocked by chemicals that eliminate feedback signals from the brain. Interestingly, the eye's ability to clear fluid changed in a manner that restored a healthy pressure difference across the optic nerve.

"The drainage control system may service to protect the optic nerve from swings in eye or brain pressure," said Chris Passaglia, PhD, professor in the USF Department of Medical Engineering. "Its discovery offers a new target for glaucoma treatment, wherein the modulatory mechanisms of the system might be exploited to help lower eye pressure and impede disease progression in glaucoma patients."

Photo courtesy of he Poarch Creek Indians

The groundbreaking study published in the Journal of Physiology shows, for the first time, that eye and brain pressure are physiologically connected.

Glaucoma is the leading cause of blindness in people over the age of 60. Since symptoms often don't arise until the condition has advanced, ophthalmologists check the eye pressures of patients during routine exams by administering an "air puff test." However, Passaglia says there are more complex aspects of the disease that make diagnosis a challenge. Some patients exhibit symptoms of glaucoma yet have normal eye pressure. While others with high eye pressure, don't always show signs of the condition.

Researchers are now trying to pinpoint the location of the brain cells that are sending signals to the eye and find which nerve fibers in the eye are being mediated by the brain. This will help physicians better diagnose glaucoma and have a greater understanding of what's causing it to develop.

This study was funded by the National Eye Institute, part of the National Institutes of Health.

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Potential Way to Halt Blinding Macular Degeneration Identified

Researchers have successfully treated age-related macular degeneration (AMD) in mice after finding an unexpected link between the two main forms of the blinding eye disease, the leading cause of vision loss in people 60 and older.

Researcher Brad Gelfand, PhD, of the University of Virginia School of Medicine and the UVA School of Engineering, cautions that his team is far from being able to use the approach in patients with AMD, but he is excited about the potential it holds. "It's not as if this is the final answer to the problem, but it's certainly a big step along the way, hopefully," he said.

'Equal Parts Excitement and Disbelief'

The new discovery links the "dry" and "wet" forms of macular degeneration in a surprising way. Gelfand has focused primarily on the more common, and currently untreatable, dry form. But after making a discovery about dry AMD, he went on to determine that the finding held true for wet AMD as well. "It was almost chance – we were like, 'Why don't we just go ahead and look for wet?' When we first saw the results, I was very surprised," he said. "Initially, it was equal parts excitement and disbelief."

Gelfand, of UVA's Center for Advanced Vision Science, found that the absence of a particular enzyme could drive both forms of AMD. The enzyme, called Dicer, is lost with age, and that loss leads to an overgrowth of blood vessels in the retina and other damage, he and his team determined.

The discovery was so unexpected he wanted to confirm. "We weren't really satisfied with just one system," he said. "We actually got a different model that had originated from a totally different lab, in Japan, and found the same exact thing. Then we went back to some of our old models where we had gotten rid of Dicer and found the same exact thing."

An Enzyme to Stop Macular Degeneration

Gelfand was able to restore the enzyme in mice by adapting a form of gene therapy already used to treat other eye diseases in people. His work suggests that a similar approach could treat both forms of AMD, but much more testing will need to be done to determine a potential treatment's safety and effectiveness. If successful, though, it would be the first treatment for dry AMD and could significantly improve treatment for wet AMD.

AMD causes the loss of cell function in the macula, the area of the retina required for seeing details in one's central area of vision. AMD is a leading cause of vision loss and blindness among people age 65 and older. Photo courtesy of the National Eye Institute

"As it stands, patients with [wet] AMD have to undergo frequent injections into their eye, which can be painful and comes with some risks. They have to come to the eye doctor once a month or every other month. A lot of these people can't drive. So it's a huge burden," he said. "The idea behind using gene therapy like the one we propose is that one treatment would last for a very long time. It's a sustained therapy. So we can improve their vision and reduce the number of doctor's visits they have to make."

Developing a Dicer-based treatment will likely take several years if all goes well. For now, though, Gelfand's discovery has shed important light on the poorly understood relationship between the two forms of AMD. "It certainly solidifies the idea that wet and dry AMD share a lot of mechanisms," he said. "It's something that researchers today are still trying to grapple with – why might one person have wet AMD and one person have dry. Sometimes it's the case that the same person has wet in one eye and the other eye has dry. Sometimes the same eye has both. This adds another important piece of evidence that the underlying mechanisms of these two processes are really tightly linked."

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IHS Introduces Recommendations for Management of Acute Dental Pain

By Cmdr. Brandy Larson, DDS, Dental Director, Cass Lake IHS Hospital Dental Clinic

The Indian Health Service released new clinical guidelines to assist dentists with selecting the safest pain control options. The Recommendations for Management of Acute Dental Pain will limit opioid prescribing to patients who cannot safely use alternative pain medication.

Led by the Division of Oral Health, in collaboration with the IHS National Committee on Heroin, Opioids and Pain Efforts, the guidelines were developed by an inter-professional workgroup consisting of both dentists and pharmacists. The guidelines aim to reinforce evidence-based acute pain management strategies, including optimizing non-steroidal anti-inflammatory drugs, acetaminophen, and topical/local pain strategies to avoid or reduce opioid use. The guidelines also include a decision tree for pre- and post-operative pain management, as well as recommended dosing of systemic analgesics based on anticipated operative pain.

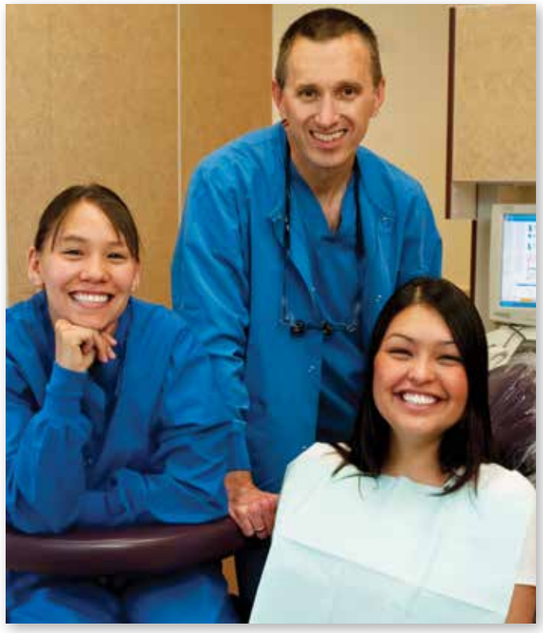

Photo courstey of Indian Health Service

Approximately 18.5 million opioid prescriptions are written annually by dentists in the United States, accounting for 12% of prescribed immediate release opioids. Despite this volume, there is evidence showing that nearly half of all opioids prescribed by dentists post-operatively go unused, which can result in non-medical use or diversion of the unused medications.

Additionally, opioids prescribed after wisdom teeth removal are frequently the first opioid experience for patients under the age of 25. Opioid use at this age can alter brain development and increase the risk of developing substance use disorders. Reducing unused opioids and opioid exposure in the adolescent and young adult populations are two critical strategies to combat the opioid epidemic.

The new clinical guidelines include recommendations to address strategies for both the general population and more medically complex populations.

Medically complex patients include those:

- with allergy and drug intolerances
- who are pregnant
- with substance use disorders
- with gastrointestinal conditions
- with kidney and liver impairment
- with respiratory impairment
- taking blood thinners
- being treated with benzodiazepines, medication commonly used to treat conditions such as anxiety, nervousness and panic disorders
- being treated for chronic pain
- utilizing medication-assisted treatment for substance abuse

The guidelines are available on the HOPE Committee's Pain Management website: https://www.ihs.gov/painmanagement/treatmentplanning/dentalpain/

ihs.gov

Recognizing the CDC Dental Public Health Residency Program

The aim of the CDC Dental Public Health Residency Program is to produce skilled specialists in dental public health who can work collaboratively with their public health and dental colleagues in an array of health settings to achieve improved oral health for populations. Such positions could be located within:

- health agencies,
- voluntary organizations,
- research settings,
- health care delivery,
- or health care reimbursement systems

The Residency Program provides opportunities to gain experience and skills across all ten designated competency areas outlined by the American Board of Dental Public Health, as a foundation for future examination and certification by the Board, and for a career as a specialist in dental public health. The program offers guided practice in collaborating with public health and dental stakeholders to achieve improved oral health for populations. The Resident will develop skills in the methods of scientific inquiry and research, emphasizing oral health epidemiology and population-based efforts to prevent oral diseases and promote oral health. The program culminates in a certificate of completion that meets educational requirements established by the American Board of Dental Public Health for specialty certification.

This formal training program for dentists is located in Atlanta, Georgia. Each year, up to two qualified dentists are admitted into CDC's Residency Program. The program usually starts in July of each year and extends over 12 months (full-time) or 24 months (part-time).

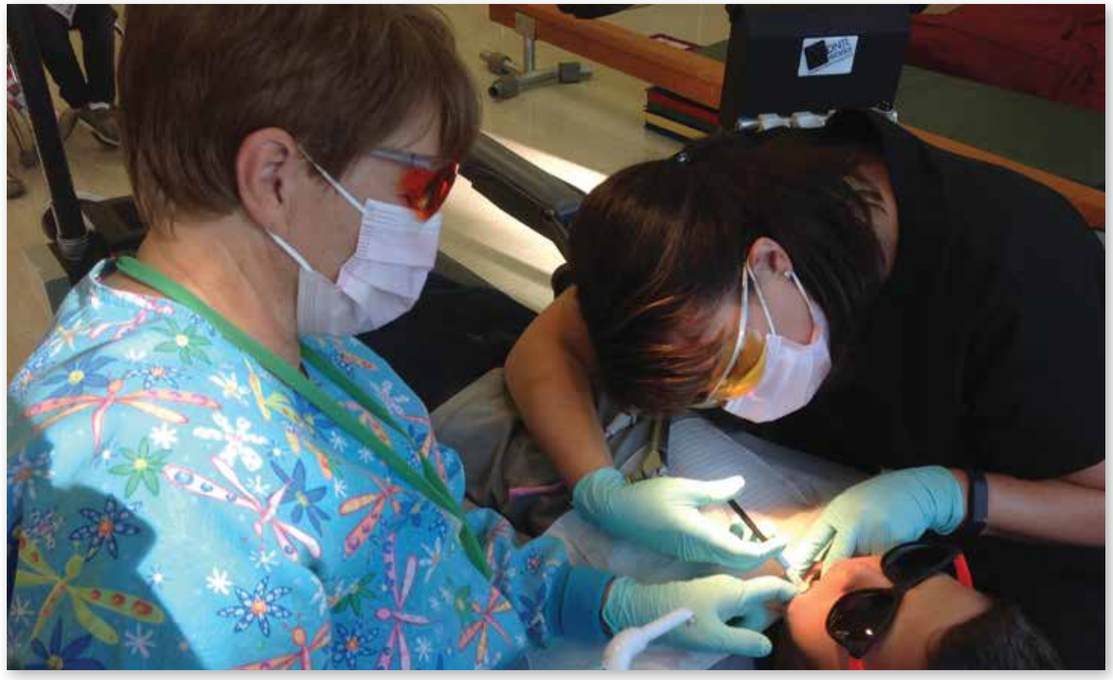

Photo courtesy of the Wisconsin Vilas County Public Health

Admission Requirements

1. Applicants must have completed the following: A dental degree (DDS or DMD) from a U.S. dental school accredited by the Commission on Dental Accreditation or a Canadian school accredited by the Commission on Dental Accreditation of Canada.

   a. Applicants who are graduates of a school of dentistry outside the U.S. or Canada must be deemed to have equivalent education. For more details, please see the International Dentists section on the How to Apply page.

2. A Master of Public Health (MPH) or comparable degree from an institution accredited by an agency recognized by the U.S. Department of Education.

   a. Courses for the MPH or comparable degree would include biostatistics, epidemiology, health care policy and management, environmental health, and behavioral sciences.

   b. If the applicant's public health training was completed in an institution outside the U.S., satisfactory completion of two or more years (full-time equivalent) of advanced education in an area related to the practice of dental public health is required. The same content areas described above apply to course work completed by public health graduates from outside the U.S.

Photo courtesy of Georgia Department of Public Health

The Residency Training Plan

Instruction within the program follows an individualized training plan focused on competency objectives developed by the American Board of Dental Public Health.

Each Resident develops a training plan based on prior education and experience. The plan addresses competencies to be developed or refined during the training program, activities designed to achieve these improved skills, and methods or criteria for evaluating progress. Both a supervised field experience and an applied research project must be included in the plan. While the plan accommodates individual differences and considers current issues, it emphasizes applying fundamental public health principles to prevent dental disease and promote oral health.

The Residency Program provides opportunities to gain experience and skills across all ten designated competency areas and for a career as a specialist in dental public health.

Financial Considerations

No tuition or fees are required. Stipends for Residents are provided through CDC's Regular Fellowship Program. This program is designed to encourage training for research and advancing science related to health. In 2018, program stipends ranged from $45,000 to $65,000, depending on the Resident's prior professional experience.

Although Residents in CDC's Regular Fellowship Program are not federal employees, they can access a wide array of training resources and experiences. Interested employees of other federal agencies, including commissioned officers in the United States Public Health Service, can discuss their circumstances with the Residency Director.

Residency Resources

CDC's Dental Public Health Residency Program is sponsored by the Division of Oral Health, within the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). NCCDPHP offers an abundance of learning opportunities and has programs addressing the prevention and control of cancer, diabetes, heart disease, and tobacco use, as well as programs focused on reproductive health, school health, aging, obesity prevention, and nutrition and physical activity. In addition, Residents will have access to the larger CDC community of programs and residents as well as other institutions and partner organizations to explore potential collaboration opportunities.

CDC employs professionals who can contribute their expertise during the residency (e.g., dentists, statisticians, economists, epidemiologists, social and behavioral scientists, physicians, and specialists in health policy, health communication, and evaluation). Residents also have access to CDC resources including excellent library facilities, computer services, training courses, and frequent seminars and guest lectures on public health topics.

For more information, please contact the Division of Oral Health, DPH Residency Director at E-mail: DPHResidency@cdc.gov

cdc.gov

NIH Awards Funding for Early Autism Screening

Funded projects will help develop and validate screening tools used to detect autism in the first year of life.

Although there's no cure for ASD, most experts agree that early intervention can improve a child's quality of life in later years. However, many studies show a significant time lag between a parent's first reported concerns about a child's behavior and an eventual diagnosis of ASD.

The National Institutes of Health (NIH) has awarded more than four million dollars in FY 2019 to support seven research projects aimed at developing and validating screening tools to detect signs of autism spectrum disorder in the first year of life. Approximately 19 million dollars is projected to be awarded to these projects by NIH over the duration of the funded projects.

"Early detection and treatment of children with autism spectrum disorder are two of the most important factors for optimizing children's outcomes," said Dr. Joshua Gordon, director of the National Institute of Mental Health (NIMH). "It is critical that we develop screening tools that can pick up on early emerging signs of autism risk so that doctors can be vigilant in tracking children's development and ensure they get intervention services as early as possible."

It is estimated that autism spectrum disorder (ASD) — a developmental disorder that affects social communication and behavior — affects 1 in 59 children in the United States. Reliably detecting autism in young children is difficult, and the average age of diagnosis for ASD hovers around four years of age. Delays in diagnosis can have profound and long-lasting effects on children, since early intervention has been demonstrated to improve cognitive and behavioral outcomes for young children with ASD.

Because early treatment is so critical for children with ASD, efforts have been made to try to reduce the age of diagnosis by universally screening all children for signs of autism. Children who are found to be at high risk for developing autism can then be connected with intervention services as soon as possible. Although well-validated instruments exist to screen toddlers for ASD between 18 and 24 months of age, there is evidence that many infants at risk for ASD show differences in the way social attention and early forms of communication develop over the first year of life.

The seven projects — supported jointly by the NIH's NIMH, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Institute of Neurological Disorders and Stroke, and the National Institute on Deafness and Other Communication Disorders — seek to translate findings related to early-emerging signs of autism into practical ASD screening tools that can be implemented in the general population and in community settings.

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Photo courtesy of the National Institutes of Health

Pediatrics and Public Health: Working Together to Prepare for Emergencies

Children represent a considerable portion of our population and they are among our nation's most vulnerable citizens. When a public health emergency or disaster strikes, children are often the most severely affected. Such as the 2009 Swine flu (H1N1 influenza) pandemic, the Ebola outbreak in 2014, the presence of lead in drinking water in Flint, Michigan, and the emergence of the Zika virus in 2016. All of these emergencies had an effect on the health and well-being of children, and they highlight the unique physical, emotional and social needs of children that require special consideration when preparing for an emergency.

Photo courtesy of CDC

The Centers for Disease Control and Prevention (CDC) makes the needs of children a priority at every level of planning for an emergency. One critical way to achieve this is to have pediatricians and local and state public health professionals collaborate on planning for an emergency so as to ensure that children's needs are met.

iStock photo courtesy of the National Institutes of Health

CDC's Children's Preparedness Unit (CPU) and Office of Public Health Preparedness and Response, in collaboration with the American Academy of Pediatrics (AAP), recently held CDC's first ever public health and pediatric virtual tabletop exercise. A tabletop exercise uses a made-up public health emergency scenario that helps professionals gain experience by "role playing" through an emergency response. In the case of this pediatric tabletop exercise, public health officials and pediatricians from AAP chapters in Iowa, Kansas, Missouri, and Nebraska worked through a smallpox outbreak scenario affecting children. Using web-based technology to connect participants, the exercise was facilitated from CDC headquarters in Atlanta, Georgia, and teams from each state participated remotely. Throughout the exercise, the teams evaluated how their state's emergency plans and procedures worked during the scenario, how the teams responded, and what changes were needed to ensure the safety and health of children.

"This exercise represented an important opportunity for the public health and pediatric communities to share their unique perspectives and experiences," says Dr. Georgina Peacock, CPU's founder and the Director of the Division of Human Development and Disability at CDC. "By working together to respond to a simulated but realistic emergency, participants were able to see firsthand how working together across diverse areas of expertise can save children's lives."

CDC hopes to help more states carry out similar virtual preparedness exercises so they can better protect children during emergencies. In addition, CDC plans to develop a user-friendly exercise toolkit specifically for the needs of children. This toolkit will be available as a virtual package to rural communities and other jurisdictions to expand preparedness planning opportunities in these communities.

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Breathing Easier Meeting Addresses Implementation, Tracking of the COPD National Action Plan

National Heart, Lung, and Blood Institute

It is the fourth leading cause of death in the United States, affecting nearly 16 million people, but for many Americans, chronic obstructive pulmonary disease, or COPD, still remains a mystery. That's why in 2017, at the request of Congress, the NHLBI led a year-long, multi-team effort to figure out what it would take to relieve the burden of this debilitating lung disease.

The result was the COPD National Action Plan, a comprehensive roadmap designed to change the very trajectory of a disease that not only can make it difficult for a person to breathe, but also to perform the most basic tasks of daily life. The plan promotes a coordinated national approach to tackling the problem, and it sets goals aimed at raising awareness about the disease, empowering patients and their caregivers, advancing research, and improving current prevention and treatments with an eye toward a cure.

Now, two years later, some of the key players involved in both developing and implementing that plan are taking stock and asking the simple question: How's it going?

The short answer: not so badly. Promising signs of progress are showing up everywhere — from new education toolkits for patients, providers, and caregivers to high-tech mobile apps for patients — but lots more work has yet to be done.

That was the word at an NHLBI-hosted town-hall style meeting, held November 13 on the NIH's main campus in Bethesda, Maryland. About 50 people — federal and state partners, researchers, patients, their caregivers, advocates, and industry representatives — gathered in a room at the Natcher Conference Center to share how they have begun addressing the plan's goals and objectives and, importantly, how they might collectively track their progress. Another 200 people tuned in to the conference via the NIH Videocast.

These kinds of periodic check-ins are critical, said James Kiley, PhD, director of the NHLBI Division of Lung Diseases . "It's one thing to put the plan together, but we don't want it to just sit on the shelf, in a library, or, worse yet, a doorstop in somebody's office," Kiley said. "What we really want to do is to see how we can peel elements of this plan out and make it work."

Kiley expressed optimism that success is within reach, but he

acknowledged the challenges are formidable, requiring the coordinated resources of the broader public health community. Consider: In addition to the 16 million diagnosed with the disease nationwide, millions of others have it and do not know it, in part because of persistent barriers to earlier diagnosis and treatment. And while the disease is most prevalent among smokers, studies now show that it is on the rise in nonsmoker — indeed, a quarter of cases occur in people who never smoked, possibly because of environmental pollutants and second-hand smoke.

Unfortunately, early symptoms of COPD — such as shortness of breath — lead many people to think of them as just normal signs of aging, so those who have the disease lose significant lung function before ever seeing a provider. It's one reason COPD-related health care costs are projected to increase to nearly $50 billion by 2020.

At the meeting, participants shared various resources and ideas, some still being refined, that are helping to address some of the issues around diagnosis and prevention.

Paul Moore, DPh, senior health policy advisor in the Federal Office of Rural Health Policy (FORHP) housed in the Health Resources and Services Administration (HRSA), said his office is trying to address the unique challenges of COPD in rural areas, for example. According to estimates from the Centers for Disease Control and Prevention, adults in rural areas have significantly higher rates of the disease than their urban counterparts, and rural areas see more COPD-related Medicare hospitalizations and deaths. "COPD is bad no matter where you live, but the outcomes are worse for those in rural areas," Moore said.

Panelists attend the COPD National Action Plan "Tracking Our Progress" meeting on November 13, 2019. At the podium is James Kiley, PhD, director of the NHLBI Division of Lung Diseases.

To help, Moore said HRSA funded development of the Rural Chronic Obstructive Pulmonary Disease Toolkit, that positions in one place, promising, evidence-based models to guide rural-based organizations looking to implement COPD programs. The office also helped in the development of A Rural Hospital Guide to Improving Chronic Obstructive Pulmonary Disease, which Moore described as a "step-by-step cookbook" that shows how to use best practices to manage the care of rural residents with COPD.

Other new resources for improving care and treatment capitalize on the booming trend in mobile health technology. Jamie Sullivan, vice president of public affairs at the COPD Foundation, noted that her organization has developed a downloadable app — called the COPD Pocket Consultant Guide — that helps both patients and healthcare providers.

The app features several videos, including one that demonstrates helpful exercises and another that shows how to use the various inhalers currently available to patients. It also provides preliminary screening tests for depression and anxiety (a frequent comorbidity in COPD), a pulmonary referral checklist, and links to COPD Foundation resources.

To help the patients' caregiver — unpaid family members or friends who help care for those with COPD — the Respiratory Health Association (RHA) Midwest developed The COPD Caregiver's Toolkit. Joel Africk, RHA's president and CEO, noted that 70% of COPD patients lean on informal caregivers who need support themselves.

"Despite the value of these caregivers, we've learned that the caregivers are struggling," Africk said. "They're unprepared for the range of challenges of caring for someone with COPD." He noted that many of these unpaid caregivers show more signs of anxiety and depression than the patients for whom they are caring. "We consider that a call for help."

His organization's toolkit offers advice on how caregivers can take better care of themselves and their loved ones, with tools to keep them organized: pages that can be used to write down information such as medications and doctor appointments, along with folders for relevant medical documents. Caregivers who have tested the toolkit have offered positive feedback, Africk said.

For its part, NHLBI continues to build and refine its own COPD resources

In addition to the 16 million diagnosed with the disease nationwide, millions of others have it and do not know it, in part because of persistent barriers to earlier diagnosis and treatment.

through the "Learn More Breathe Better" program, a national health education program that provides educational resources on lung health and research to a variety of audiences, including people with COPD and health professionals who treat them.

Meanwhile, NHLBI-funded researchers are using genetic and genomics tools, developmental science, imaging technologies, as well as animal models and clinical data to better understand COPD, and target improved treatments and, possibly, a cure. They are even looking toward the use of precision medicine in the treatment of COPD.

While these kinds of efforts all contribute to helping fulfill the goals of the COPD National Action Plan, participants at the meeting agreed that the plan won't have "legs" until progress gets measured and shared among all the COPD stakeholders.

To that end, Kiley said, the community will develop a practical tracking system for use by the COPD community in tracking and monitoring progress toward implementing the goals of the National Action Plan. NHLBI hopes to launch the tracking system in the Spring of 2020.

"The successful implementation of the COPD National Action Plan depends on the entire COPD community," Kiley said. "Stakeholders can use the plan to drive change, collaborate, and support programs and activities that help relieve the burden of disease."

nhlbi.nih.gov

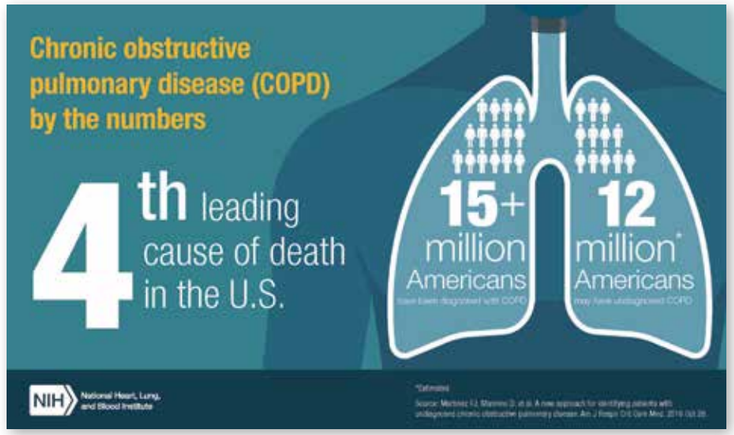
Study Funded by NIH Supports Optimal Threshold for Diagnosing COPD

A new study provides evidence to support a simple measurement for diagnosing clinically significant airflow obstruction, the key characteristic of chronic obstructive pulmonary disease (COPD), the fourth leading cause of death in the United States. The study found that a 70% ratio of two indicators of lung function proved as or more accurate than other thresholds for predicting COPD-related hospitalizations and deaths.

The study was funded by the National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health, and its findings were published online today in the Journal of the American Medical Association. Approximately 16 million Americans have COPD, and it is estimated that millions more have the disease and do not know it.

The research, which draws on a wide range of multi-ethnic studies, validates current guidelines from major respiratory societies and contributes to identify a fixed threshold of disease severity. This approach has led to great strides in early detection and treatment of other conditions such as hypertension and diabetes.

"Diagnosis of airflow obstruction remains a major hurdle to improving care for patients with COPD," said James Kiley, PhD, director of the NHLBI Division of Lung Diseases. "This validation of a fixed threshold confirms the usefulness of a simple approach for assessment of the disease. As we celebrate the 50th anniversary of the Division of Lung Diseases, this rigorous analysis of populations-based, multiethnic studies is yet another example of research we fund that improves clinical practice, public health, and patient care."



To monitor lung function and gauge the severity of a lung disease, doctors use spirometry, a test that measures several indicators. Those include the ratio of forced expiratory volume in one second (FEV1) — that is, the amount of air exhaled forcefully in one second — over forced vital capacity (FVC) — or the full amount of air that can be forcefully exhaled in a complete breath. The two values are usually proportional; and lower ratios are seen in individuals with obstructive lung diseases, such as asthma or COPD.

The researchers aimed to determine how accurate various thresholds were in predicting COPD-related hospitalizations and mortality. For that, the NHLBI Pooled Cohorts Study analyzed data from four U.S. population-based studies that collected spirometry results and followed up participants for COPD-related clinical events. The study included 24,207 adult participants, of which 54% were women, 69% white, and 24% black.

"The selection of a threshold for defining airflow obstruction has major implications for patient care and public health, as the prevalence of the condition could vary by more than a third depending on the metric used," said study author Elizabeth C. Oelsner, MD, MPH, the Herbert Irving Assistant Professor of Medicine at Columbia University, New York City. "Defining 'normal' lung function is very challenging in diverse and changing populations, and certain approaches might interpret low levels of lung function as normal in women, non-whites, or the elderly. We were able to show that a simple fixed threshold worked well in our study's very diverse sample, which improves the generalizability of our results."

The researchers said establishing a diagnostic threshold that is easy to use not only is critical to improving the adoption of spirometry in primary care; it may also result in earlier detection and treatment for patients.

nhlbi.nih.gov

New Clues on Tissue Damage Identified in Rheumatoid Arthritis and Lupus

Research supported by the Accelerating Medicines Partnership (AMP) on Rheumatoid Arthritis and Systemic Lupus Erythematosus (RA/SLE) provides new insights into tissue damage for these autoimmune conditions. Findings include the identification of novel molecular signatures related to immune system signaling in kidney cells that may reflect their active role in disease process; molecular targets, including specific white blood cells, for potential treatment in lupus nephritis; and specific types of fibroblasts and white blood cells that are involved in rheumatoid arthritis. These discoveries set the stage for uncovering potential drug target candidates that could advance to experimental treatments. Results of the studies were published today (June 18, 2019) in three papers in Nature Immunology.

"AMP is laying the foundation for precision medicine in rheumatoid arthritis and lupus," said NIH Director Dr. Francis S. Collins, MD, PhD. "The public and private sector working together has sparked new hope for those living with these and other autoimmune diseases, and we anticipate that these early results are only the beginning of what is serving as a new model to transform medical care."

A primary goal of the AMP RA/SLE program, which is led by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), is to study tissues where the disease is active in patients, whereas most previous work studied mouse models or only blood samples from humans. AMP researchers looked at all the cell types in either biopsy samples from kidneys of people with SLE or the synovial tissues of joints from people with RA. The program seeks to quickly find the most promising treatment targets so less time is lost chasing unsuccessful leads.

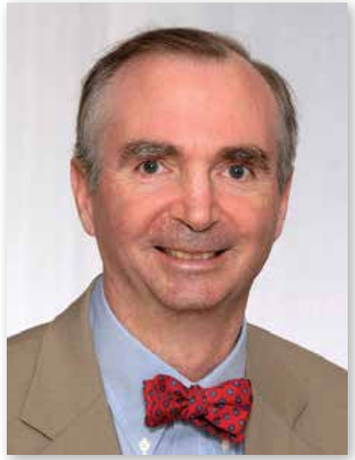
Highlights from the papers:

Profiling kidney and skin cells in lupus nephritis. Lupus nephritis is a potentially fatal kidney disease that occurs in about 50% of people with lupus. There can be a wide variety of changes in the kidneys, making the disease hard to diagnose and treat. AMP investigators led by co-senior investigator Jill Buyon, MD, at New York University analyzed a large number of individual cells from kidney and skin samples from people with lupus in order to understand more about the complex mechanisms involved in tissue damage. Researchers discovered molecular signatures, related to immune system signaling and scar-forming gene activity, in kidney cells that may reflect their active role in disease process. This finding was unexpected since inflammatory cells were thought to be the primary cause of tissue damage. Single cell analysis of skin revealed similar changes, suggesting that in the future it may be possible to monitor a person's disease progress and treatment responses from skin samples instead of more invasive kidney biopsies.

Understanding the role of immune cells in lupus nephritis. AMP investigators led by Betty Diamond, MD, at The Feinstein Institute for Medical Research, Manhasset, New York, analyzed kidney, blood and urine samples from people with and without lupus nephritis to learn more about how immune cells cause progressive damage in the kidneys. The scientists uncovered subsets of white blood cells that are active in the disease process and identified molecules that may be potential therapeutic targets. Single cell analysis of immune cells in urine yielded similar results. These findings suggest it may be possible to track immune cell status in the kidneys easily through urine analysis.

> *"The public and private sector working together has sparked new hope for those living with these diseases, and we anticipate that these early results are only the beginning of what is serving as a new model to transform medical care."*

Defining inflammatory cell states in rheumatoid arthritis joint tissue. The autoimmune disease rheumatoid arthritis is characterized by chronic inflammation of the synovium — a thin tissue that lines joints. AMP investigators led by Soumya Raychaudhuri, MD, PhD, at Brigham and Women's Hospital, Boston, used single cell profiling technologies to analyze synovial biopsies. They identified subsets of cells — including fibroblasts, which are involved in producing cellular scaffolding, specific white blood cells and others — that appear more often in people with rheumatoid arthritis. Researchers will need to determine whether the identified cell subsets are involved in tissue inflammation, and whether targeting these cells could potentially provide a therapeutic benefit. The white blood cells identified may also play a role in other immune diseases.



Dr. Robert Carter, acting director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases. Photo courtesy of NIAMS

"These AMP rheumatoid arthritis and lupus findings offer insights into intriguing immune system targets that are worthy of more investigation," said Robert Carter, MD, acting director of NIAMS. "We look forward to bringing the most promising of these findings forward to clinical trials, potentially leading to much-needed new treatment options for those living with rheumatoid arthritis, lupus and other immune system disorders."

To date, the program has made major advances in creating standardized ways to collect kidney and synovial tissue for research in the United States. This standardization has allowed scientists to use state-of-the-art technologies to analyze individual immune cells and other cells from affected tissues. By studying genes, proteins and biological pathways at such high resolution, scientists hoped to uncover novel insights into the mechanisms behind RA and lupus nephritis, a serious complication of lupus.

A primary goal of the program is to study tissues where the disease is active in patients, whereas most previous work studied mouse models or only blood samples from humans.

Launched in 2014, AMP is a public-private collaboration between the National Institutes of Health, the U.S. Food and Drug Administration and multiple biopharmaceutical and life science companies and not-for-profit organizations. The current AMP funding commitments for all projects are over $350 million, including in-kind contributions. The Foundation for the NIH (FNIH) manages contributions from AMP private-sector partners, and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and the National Institute of Allergy and Infectious Diseases collaborated to oversee AMP RA/SLE, which was recently extended for an additional year.

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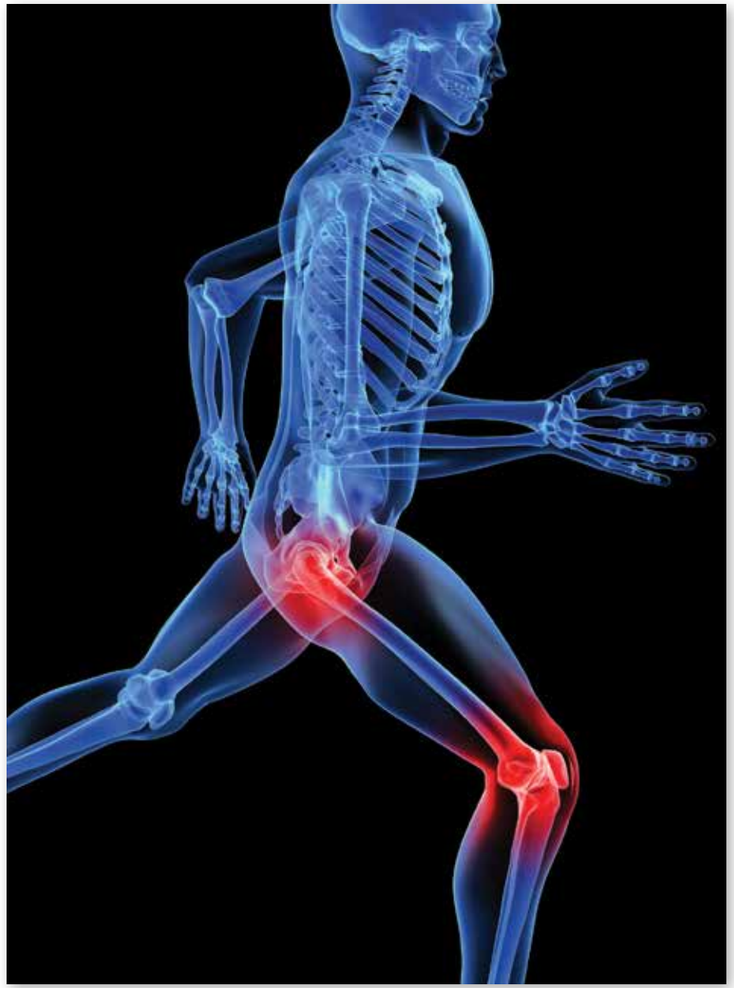

Molecular differences between knee and hip joints with rheumatoid arthritis may inform more personal treatment strategies. Photo courtesy of Sebastian Kaulitzki/Hemera/Thinkstock

NIAMS Celebrates Lupus Research Progress at Fourth Annual D.C. Lupus Consortium Meeting

By Samuel Bara

On May 17, 2019, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) lupus clinical research team gathered for the upcoming 25th anniversary of the natural history of systemic lupus erythematosus (SLE) protocol at the annual D.C. Lupus Consortium (DCLC) meeting. "We are here to celebrate and recognize the patients, providers, researchers and advocates who have supported lupus research at the Clinical Center over the last 25 years," said Robert Carter, MD, acting director of NIAMS, during his welcoming address to over 175 guests in attendance.

The meeting highlighted the progress in lupus clinical research made by Institutes across the NIH, specifically celebrating the success of the lupus natural history protocol over the last quarter century. The event featured testimonials from research participants, updates on current lupus studies at NIAMS and discussions on future topics to explore.

Following Dr. Carter's introduction and overview of lupus research across the NIH, Sarfaraz Hasni, MD, director of the NIAMS lupus clinical research program, provided details on the history and current studies stemming from the natural history protocol. James Balow, MD, clinical director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), discussed the evolution and impact of lupus nephritis research at NIH. John O'Shea, MD, scientific director of the NIAMS intramural research program, and Mariana Kaplan, MD, senior investigator and chief, NIAMS systemic autoimmunity branch, delivered updates on lupus research and protocols.

The meeting also included presentations on the efforts to raise awareness for lupus through social media by Tiffany Peterson, Carly Harrison, Christele Felix and Elizabeth SantaCruz, of the online health community chat group, #LupusChat; the relationships between researchers and advocacy groups by Steve Gibson, president and CEO of the Lupus Foundation of America; and a discussion about the impact of NIH research on patients by DCLC member, Donald Thomas, MD. The audience heard from NIAMS lupus clinical research team members Laura Lewandowski, MD, Sarthak Gupta, MD and Jun Bie Chu, MSN, CRNP, on recent lupus research and the implementation of quality indicators for SLE patients at the NIH clinical center.

Additionally, NIAMS lupus clinical trials unit members, including Elaine Poncio, RN, Yenealem Temesgen-Oyelakin, RN, Isabel Ochoa and Michael Davis, MSN, CRNP, conducted brief interviews with Grace, Eddie, Silvana and Gina, participants in the lupus natural history protocol. The interviews focused on the patients' background of living with lupus and their experiences at NIH. The DCLC meeting concluded with a performance from the NIH's Affordable Rock 'n' Roll Act band.

niams.nih.gov

The lupus clinical research team from the second annual D.C. Lupus Consortium Meeting.
Photo courtesy of the National Institute of Arthritis and Musculoskeletal and Skin Diseases

Spotlight on Lupus: Interview with Dr. Lisa Sumner

By Tom Adams

American Indians and Alaska Natives (AI/AN) have high rates of Autoimmune Diseases and especially high rates of lupus. We are examining how the Indian Health Service (IHS) is working to improve outcomes in AI/AN affected by this disease.

In 2014, a medical team from the IHS published the study, "Prevalence and Incidence of Systemic Lupus Erythematosus", in a Population-Based Registry of American Indian and Alaska Native People, 2007-2009". This was the first population-based lupus registry of AI/AN and showed that AI/ANs have one of the highest rates of lupus among all ethnic groups in the United States.

We spoke to one of this study's authors, Dr. Lisa Sumner, a Rheumatologist working at the Phoenix Indian Medical Center. Dr. Sumner became interested in rheumatology when she was working as an Internist at the Hopi Health Care Center (HHCC) and noticed the high rate of autoimmune diseases among the patients she treated. Her agency, the Phoenix Area Indian Health Service (IHS), helped her arrange a fellowship in rheumatology at the University of Arizona and in 2003 they established the Phoenix Area Rheumatology Program. Today, the program includes 2 rheumatologists, a rheumatology NP, a rheumatology clinical pharmacist, and a certified nursing assistant.

Dr. Sumner has been with the IHS for 23 years now and spoke with us to share how IHS is working to improve outcomes in patients with Lupus. "I think one of the most important things we are doing is just being here to see patients. Rheumatologists are in short supply and

Dr. Lisa Sumner

we have two rheumatologists in our program. We are busy and have a large area to cover, but because we work closely with our primary care providers, we can see and manage a lot of patients. We maintain a very close collaboration with our IHS providers. They know when a patient should be referred to rheumatology, how to manage the patients between visits with us, and when to call us when something doesn't look right or their patient is having a problem.

I travel to remote clinic locations and I see some variation in diseases at different clinics and hospitals. Some locations have higher rates of specific autoimmune diseases than others. For example, at some locations we see more Ankylosing Spondylitis and at others we see more rheumatoid arthritis but overall we see Lupus scattered evenly. Lupus can be very mild but some of my sickest patients have lupus. I follow-up with patients having the most severe lupus on a very frequent basis, while others with much milder conditions or who are in good control may only need to be seen once a year. I see Lupus patients no matter what location I'm at." Dr. Sumner stated.

How do you test for lupus?

"Most patients come in with some sort of complaint such as a rash or joint pain. If we suspect Lupus then the main test we do is the antinuclear antibody (ANA) test. Unfortunately, that is still a very non-specific test, so some patients may test positive and still not have lupus. That can be very stressful of course to a patient that thinks he or she might have lupus so patient and provider Education is very important. We monitor patients with a positive ANA but they may never develop lupus.

On the other hand some patients with positive ANA do have lupus. They usually have other symptoms like rashes, arthritis, kidney or other organ diseases. Lupus is a systemic disease meaning it can involve pretty much any organ system. Because it is an autoimmune disease, meaning that the persons own immune system is causing the problem, it can often have puzzling symptoms. We as rheumatologists, have to figure out if the person's symptoms or positive lab tests suggest their lupus is active and how we need to treat it. Patients with lupus often have to be on medications that suppress the immune system so it is sometimes difficult to distinguish a flare of lupus from some other problem like an infection.

Testing is done both by our own laboratory teams at IHS as well as at outside facilities. Most of our specialty labs are sent out because of the nature of variance that can occur. For example, there's varying ways you can do an ANA test and some

Sage Honga, of the Hualapai tribewears a handmade dress and organic makeup traditionally used by the Hualapai people. Photo courtesy of shareamerica

of those test are more sensitive than others and others are more specific. It's really important to know what your lab is doing. The ANA is the probably the most important test in establishing a diagnosis of lupus and if your lab is doing a test that may not capture all positive ANA's, you may not recognize that a patient has lupus.

How has your experience with early intervention and testing been helpful?

I think it can be helpful if a patient is diagnosed w lupus early because that may allow us to prevent complications. By treating a patient w active lupus early, we may be able to get the disease controlled before the patient develops irreversible organ or joint damage.

I often prescribe Hydroxychloroquine (Plaquenil), when I see a patient that meets criteria for Lupus. This is very effective for people with mild symptoms and has been shown to prevent flares (usually in combination with other medications) in people with more active lupus. We work closely with our primary care physicians (PCP). The PCP's are truly the first step in early detection and may be who a lupus patients sees when they have a flare. If the PCP knows a patient has lupus and they come in feeling poorly, they usually run a basic lab test. If for example, the urine shows protein, blood or white blood cells, we might first think the patient has an infection, but if we also know the patient has lupus, we have the expertise to distinguish the two and initiate the correct treatment.

Patients with Lupus are living longer and fewer patients are actually dying of Lupus. This is good news, but it is important that we understand that patients with lupus are at higher risk for infection and often develop other diseases like heart attacks and strokes at an earlier age. Because patients with lupus are often treated with steroids, they are more likely to have osteoporosis. By having patients plugged into our system and following up with a

Old Horn-Purdy, from the Crow tribe is a retired Navy Chief Petty Officer. Photo by Marvin Lynchard, U.S. Department of Defense

PCP, we test for things like cholesterol or low bone density to ensure proper treatment, which in turn, helps our patients live longer and healthier lives.

Another thing we see in patients with Lupus are "overlap syndromes". Many patients with Lupus have more than one auto-immune condition so we may see features of RA, scleroderma, and Sjogrens Disease in combination with their Lupus symptoms. Some of the drugs we use to treat RA can actually make lupus symptoms worse or cause lupus. As a rheumatologist I am always on the lookout for overlap disease in my patients with Lupus because if I suspect an overlap I may have to change the way I manage the patient.

How do you treat lupus?

Again, Hydroxychloroquine is our first line drug because it has minimal side effects and is effective in controlling disease and reducing flares in patients with Lupus. Steroids such as prednisone are also highly effective at treating symptoms but because they are what we call "non-specific" in their action, they tend to have some unwanted side effects like weight gain, thinning of the bones, cataracts, and infections.

When possible, we try to minimize the use of steroids by using other medications such as Azathioprine, Mycophenolate, and Methotrexate to modulate the immune system, which in turn, allows us to minimize steroids. In addition there are a number of newer biologic medications that are highly effective at treating Lupus. These newer drugs can be very expensive. In our program, we have a pharmacist who works with insurance companies and the pharmaceutical program's "patient assistance programs" and our Pharmacy and Therapeutics Committee here at PIMC, to get drugs approved for our patients What I've seen is that IHS makes sure their patients get what they need, and I don't have to worry about my patients paying out of pocket or having to sell their house to get treatment."

Understanding Rheumatoid Arthritis at the Cellular Level

In rheumatoid arthritis (RA), immune cells mistakenly attack tissues lining the joints. This can lead to stiffness, swelling, pain, and disability.

More than a million people nationwide live with RA. Existing drugs can slow the progression of the disease in some people. But they don't work for everyone and can stop working in others over time.

The exact cause of RA isn't known. It involves complex interactions between immune cells and the cells in the joints responsible for normal tissue maintenance. A better understanding of these interactions could help scientists develop new drugs that work for more patients.

A large-scale collaboration among government, industry, and nonprofit organizations called the Accelerating Medicines Partnership (AMP) focuses on gene expression and signaling in tissues where disease is active, such as the joints of people with RA. AMP investigators led by Drs. Soumya Raychaudhuri and Michael Brenner at Brigham and Women's Hospital, Jennifer Anolik at the University of Rochester, and Laura Donlin at the Hospital for Special Surgery in New York examined synovium — the thin tissue that lines joints — to understand interactions at the single-cell level and find potential targets for treatment. They analyzed tissue collected by AMP investigators from 36 people with RA and 15 others with osteoarthritis for comparison.

The team used advanced laboratory techniques to examine gene expression patterns in single cells from groups of specific types of immune and joint cells. The work was funded by NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and others. Results were published in Nature Immunology on May 6, 2019.

The researchers identified 18 unique cell populations in the joints based on gene expression patterns. Some of the cell types were seen in large numbers in samples from people with RA. These included both certain immune cells and other cells like fibroblasts, which build connective tissue in the joints. The team was also able to trace which specific cell types produced several molecules that promote inflammation in RA. Future work will be needed to understand the roles of these cells in RA and other immune diseases.

Finding an effective medicine to treat rheumatoid arthritis can take time. Photo courtesy of NIH

Donlin's team focused on a type of immune cell called macrophages. In tissue samples grown in the lab, a subset of macrophages cued fibroblasts to destroy joint tissue through a growth factor called HB-EGF. Blocking the receptor for HB-EGF, known as EGFR, with an experimental anti-cancer drug shut down this destructive process. These findings were published in Science Translational Medicine on May 8, 2019.

The drug used in these experiments may be too toxic to use in people with RA. However, these results show that the disease could potentially be treated by methods other than suppressing the immune system, which is the basis for most current RA therapies. Other experiments using the tissues provided new insights into how drugs currently used to treat RA work at the cellular level.

"Our work…has identified previously unknown subsets of cells and provided new insights about how some of these cell types interact with each other to drive RA," Donlin says. "We hope that through a better understanding of the cell populations in individual patients we can provide a means by which we can treat them with precision medicine strategies at the earliest stages of disease."

nih.gov

$3M Awarded to Support Prevention and Screening of IPV and HIV

By Lt. Dantrell Simmons, DrPH, MA, Public Health Advisor, Office on Women's Health, U.S. Department of Health and Human Services

The association between violence against women and risk for HIV infection has been the focus of a growing number of studies. According to the Centers for Disease Control and Prevention, findings from these studies indicate that women who report a history of intimate partner violence (IPV) are also more likely to report factors known to increase the risk for HIV, including injection drug use, having a sexually transmitted infection, and exchanging money or drugs for sex.

Research findings also indicate that women who are living with HIV in the United States are significantly more likely to experience violence at the hands of their intimate partners than women in general. Overall, 25 percent of women report experiencing severe IPV (e.g., beating, burning, strangling), but 55 percent of women living with HIV report this level of abuse.[1,2]

To address this critical issue, the U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Health, Office on Women's Health (OWH) has awarded more than $3 million to community-level programs in Texas, Kentucky, and Louisiana through the Preventing HIV Infection in Women through Expanded Intimate Partner Violence Prevention, Screening, and Response Services initiative to reduce the negative health impacts of IPV and HIV.

Dorothy Fink, MD, Deputy Assistant Secretary for Women's Health and OWH Director said, "We are working to break this link between IPV and HIV by protecting women through violence-prevention efforts and providing services in communities where women are most at risk."

"HHS is proud to support these grants to bring us closer to integrating violence prevention and HIV prevention into health services," said Tammy Beckham, DVM, PhD, Director of the HHS Office of Infectious Disease and HIV/AIDS Policy. "That integration means we can offer women at risk for IPV both the medical care they need to prevent or treat HIV effectively and the social services that can help them avoid or end cycles of violence and abuse."

The four organizations receiving OWH funding are each located in one of the prioritized jurisdictions [PDF, 76KB] of the Ending the HIV Epidemic: A Plan for America (EHE) initiative, a plan to end the HIV epidemic in America by reducing new infections by 75 percent in five years and by 90 percent in 10 years. The organizations are:

Dr. Dorothy Fink, Deputy Assistant Secretary for Women's Health and Director of the Office on Women's Health in the Office of the Assistant Secretary for Health (OASH) at the U.S. Department of Health and Human Services.

University of Texas Southwestern Medical Center, Dallas, TX

University of North Texas Health Science Center, Fort Worth, TX

The Center for Women and Families, Inc., Louisville, KY

Institute of Women and Ethnic Studies, New Orleans, LA

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hiv.gov

HHS Awards $9 Million to Develop New Models to Improve Obstetrics Care in Rural Communities

U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), awarded nearly $9 million to launch the Rural Maternity and Obstetrics Management Strategies (RMOMS) program.

Recipients from three states, Missouri, New Mexico and Texas, will receive up to $600,000 in a planning year and up to $800,000 in three implementation years to pilot, test, and develop models that improve access to and continuity of maternal obstetrics care in rural communities.

"Strengthening rural and maternal health are important priorities for HHS and the Trump Administration. This program's investments will support both of these priorities by developing new and innovative networks to improve rural maternal care," said HHS Secretary Alex Azar. "By testing out approaches through pilot programs, we can lay the groundwork for making a real impact on these important health challenges."

The new program is unique because its network requirements detail the involvement of specific stakeholders, including rural hospitals, health centers, state Medicaid offices, and Healthy Start and home visiting programs, with the intention of developing sustainable strategies at a regional level.

The RMOMS program, administered by HRSA's Federal Office of Rural Health Policy (FORHP) and Maternal and Child Health Bureau (MCHB), is a part of a suite of maternal health investments made by HRSA to support local and state level efforts to improve maternal health nationwide.

The new program is unique because its network requirements detail the involvement of specific stakeholders, including rural hospitals, health centers, state Medicaid offices, and Healthy Start and home visiting programs, with the intention of developing sustainable strategies at a regional level.

Networks will develop strategies that focus on rural hospital obstetric service aggregation, developing a network approach to coordinating a continuum of care, leveraging telehealth and specialty care, and approaches to financial sustainability.

"We are eager to learn from our investments in these pilot programs," said HRSA Acting Administrator Tom Engels. "Our goal for the program is to identify new and sustainable strategies tailored to rural communities that will make a tremendous difference in the lives of mothers and children across America."

hhs.gov

Photo courtesy of Washington State Congressman Dan Newhouse

NIH Study Suggests Breastfeeding May Lower Risk of Early Menopause

Women who breastfed their infants exclusively for 7 to 12 months may have a significantly lower risk of early menopause than their peers who breastfed their infants for less than a month, according to an analysis funded by the National Institutes of Health. The study also suggests that pregnancy can reduce the risk of early menopause.

The study was conducted by Christine Langton, MSW, MPH, of the University of Massachusetts at Amherst, and colleagues. It appears in *JAMA Network Open*. Funding was provided by NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) and the National Cancer Institute.

"The study results provide the strongest evidence to date that exclusive breastfeeding may reduce the risk of early menopause," said Lisa Halvorson, MD, chief of the NICHD Gynecological Health and Disease Branch, which oversaw the research.

Previous studies have suggested that menopause before age 45 (early menopause) increases the risk of early death, cognitive decline, osteoporosis and cardiovascular disease. Smaller studies have found evidence linking pregnancy and breastfeeding with later menopause, but because of their size and other limitations, the results are inconclusive. Moreover, the earlier studies focused on timing of menopause and not on the risk of early menopause.

In the current study, researchers analyzed data from more than 100,000 women ages 25 to 42 years in the Nurses' Health Study II. Every two years, from 1989 to 2015, the participants responded to detailed questionnaires, providing health information and medical history, including pregnancy history. Compared to women who had never been pregnant or who had been pregnant for less than six months, women who had one full-term pregnancy had an 8% lower risk of early menopause. Those who had two pregnancies had a 16% lower risk, and those who had three pregnancies had a 22% lower risk.

Photo courtesy of the Office on Women's Health

Women who breastfed had an even smaller risk for early menopause. Those who breastfed for a total of 25 months or more during their premenopausal years had a 26% lower risk than women who breastfed for less than a month. Similarly, women who breastfed exclusively 7 to 12 months had a 28% lower risk of early menopause, compared to those who breastfed for less than a month.

The study did not determine why pregnancy and breastfeeding might lower the risk of early menopause. However, researchers theorize that because pregnancy and breastfeeding halt ovulation, the slowing of the egg loss may delay menopause.

Reference

Langton CR, et al. Association of Parity and Breastfeeding With Risk of Early Natural Menopause. *JAMA Network Open*. 2020.

nichd.nih.gov

Persistent Organic Pollutants in Maternal Blood Linked to Smaller Fetal Size, NIH Study Suggests

Pregnant women exposed to persistent organic pollutants, or POPs, had slightly smaller fetuses than women who haven't been exposed to these chemicals, according to an analysis of ultrasound scans by researchers at the National Institutes of Health and other institutions. The researchers also found that the women in their study had lower levels of POPs than women in the 2003-2004 U.S. Health and Nutrition Survey, the most recent comprehensive study of these compounds in U.S. pregnant women. The latest findings suggest that the chemicals, which are no longer produced in the United States but persist in the environment, may have lasting health effects even at low levels.

The study appears in *JAMA Pediatrics* and was conducted by Pauline Mendola, PhD, an investigator in the Epidemiology Branch at NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development, and colleagues.

Persistent organic pollutants are chemicals once used in agriculture, disease control, manufacturing, and industrial processes. They include the pesticide DDT and dioxin, a byproduct of herbicide production and paper bleaching. POPs are slow to break down, may persist in water and air, and may be passed through the food chain. Their health effects vary, but some compounds have been linked to reproductive disorders and a higher risk of birth defects.

Earlier studies of the potential effects of POP exposure during pregnancy have produced conflicting results. According to the authors, most of these studies looked at infant birth weight and length, measures that could suggest impaired fetal growth but could also indicate genetic factors that lead to smaller birth size and weight. Moreover, previous studies have investigated POPs as individual chemicals, but people typically are exposed to a mix of these compounds.

"The differences we found in fetal growth measures may be more sensitive indicators, compared to birth size, of the potential effects of these compounds," said Dr. Mendola. "Even at low levels, there is evidence of a possible effect on fetal growth."

In the current study, researchers analyzed records, stored blood samples, and a series of ultrasound scans taken from weeks 16-40 of 2,284 pregnant women enrolled in the NICHD Fetal Growth Study from 2009 to 2013. The blood samples were tested for the presence of 76 POPs soon after the women began the study. The POP levels in each woman's blood were listed as percentiles, with the highest levels set at 100 and the lowest at 1. The researchers then compared growth measurements of head circumference, abdominal circumference, and femur (thigh bone) length of the fetuses of women in the 75th percentile to those of women in the 25th percentile.

Photo courtesy of NIH

They found that, compared to fetuses in the 25th percentile of exposure to organochlorine pesticides, the fetuses of women with exposure in the 75th percentile had the most widespread growth reductions, with head circumference reduced by an average of 4.7 mm, abdominal circumference reduced by 3.5 mm, and femur length reduced by 0.6 mm. High levels of dioxin-like polychlorinated biphenyls were associated with an average head circumference reduction of 6.4 mm and an abdominal circumference reduction of 2.4 mm. High levels of polybrominated diphenyl ethers — flame-retardant chemicals used in furniture, electronics and other consumer products — were associated with an average abdominal circumference reduction of 2.4 mm and an average femur length reduction of 0.5 mm.

Reference

Ouidir, M, et al. Association of maternal exposure to persistent organic pollutants in early pregnancy with fetal growth. *JAMA Pediatrics*. 2019.

nichd.nih.gov

IHS Highlights New Data During STD Awareness Month

By Andria Apostolou, PhD, MPH, IHS National STD Program Lead, Division of Epidemiology & Disease Prevention

April is recognized as Sexually Transmitted Disease Awareness Month and brings attention to the nearly 20 million new STD cases that occur in the United States each year.

While STDs affect all racial and ethnic groups, American Indian and Alaska Native populations bear a disproportionate burden. The IHS National STD Program and the IHS Division of Epidemiology and Disease Prevention within the Office of Public Health Support recently released the Indian Health Surveillance Report — Sexually Transmitted Diseases 2015 . The report presents statistics and trends for STDs among American Indians and Alaska Natives in collaboration with the Centers for Disease Control and Prevention.

This surveillance report, summarizing 2011–2015 national and IHS Area-level data and trends for chlamydia, gonorrhea, and primary and secondary syphilis, serves as a valued resource for those working in Indian Country and others concerned with the public health implications of STDs for American Indians and Alaska Native populations.

The report shows the continuing trend of a nationwide increase in STDs and highlights national-level disparities indicating that American Indians and Alaska Natives had the second highest rates for chlamydia and gonorrhea and the fourth highest rates for syphilis among all racial and ethnic groups in 2015. Regional differences for each of the conditions were observed, with gonorrhea rates increasing nationally among American Indians and Alaska Natives. The report also highlights the higher STD burden among American Indians and Alaska Native youth and among American Indians and Alaska Native women, particularly women of reproductive age (15-44 years of age).

People who have an STD may be at an increased risk of getting HIV. The president's recently announced initiative, Ending the HIV Epidemic: A Plan for America , reinforces the imperative to work in partnership with various stakeholders to address screening of individuals at risk of HIV, to improve access to treatment for those with HIV, and to also strive for early recognition of risk factors for acquiring HIV, such as previous or recurrent STDs, to guide HIV prevention efforts.

The IHS National STD Program is committed to raising awareness of STDs as a high-priority health issue among American Indians and Alaska Natives and to supporting partnerships, collaborations, policies, and education that help reduce the impact of STDs in Indian Country. By visiting the IHS National STD program website , you can find an STD testing site near you. When you visit your healthcare provider, you should discuss sex as it relates to your health. Your provider calls this "taking a sexual history" and it helps them to understand what STD tests you may need. You can ask them questions, too! For example, you may want to know how to protect yourself from getting an STD, which STD tests you will be getting, or how often to get tested.

Lastly, the IHS National STD Program has recently launched a national workgroup on STDs. This new workgroup seeks to connect public health practitioners and clinical providers and provide a forum for discussing various perspectives regarding STDs in Indian Country. If you are a provider or public health practitioner working with American Indian and Alaska Native communities and are interested in joining the workgroup, please e-mail the National IHS STD Program lead Dr. Andria Apostolou.

ihs.gov

Courtesy of CDC

Increased Risk to Women with Bacterial Vaginosis

According to the CDC, having bacterial vaginosis (BV) can increase a woman's chance of getting an STD, and also cause pregnant women an increased chance of premature delivery and low birth weight for their baby. Prompt testing for accuracy and effective treatment is essentially important for pregnant women.

Maintaining and strengthening core prevention infrastructure is essential to mounting an effective national response to the STD epidemic.

CDC provides support to state and local health departments for disease surveillance, disease investigation, and health promotion.

CDC also issues and maintains testing and treatment guidelines for providers so individuals get the most effective care.

Turning back the rise in STDs will require renewed commitment from all players:

- State and local health departments should refocus efforts on STD investigation and clinical service infrastructure for rapid detection and treatment for people living in areas hardest hit by the STD epidemic.
- Providers should make STD screening and timely treatment a standard part of medical care, especially for pregnant women and MSM. They should also try to seamlessly integrate STD screening and treatment into prenatal care and HIV prevention and care services.
- Everyone should talk openly about STDs, get tested regularly, and reduce risk by using condoms or practicing mutual monogamy if sexually active.

"CDC uses its national-level intelligence to detect and respond to STD outbreaks while supporting the nation's on-the-ground workers who are spending each day protecting communities from STDs," Dr. Mermin stressed.

cdc.gov

Photo courtesy of CDC

Necrotizing Fasciitis: the Flesh-Eating Disease

Accurate diagnosis, rapid antibiotic treatment, and prompt surgery are important to stopping this infection that 1 in 3 people die from even with treatment.

Necrotizing fasciitis is suspected when the skin becomes red, warm, swollen, or very painful soon after an injury or surgery. Group A Strep bacteria is thought to be the most common cause, as well as bacteria such as Vibrio vulnificus that live in water.

The bacteria most commonly enter the body through a break in the skin, including:

- Cuts and scrapes
- Burns
- Insect bites
- Puncture wounds (including those due to intravenous or IV drug use)
- Surgical wounds

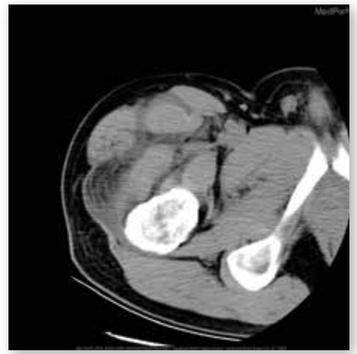
Symptoms Can Often Be Confusing and Develop Quickly

Early symptoms of necrotizing fasciitis can include:

- A red, warm, or swollen area of skin that spreads quickly
- Severe pain, including pain beyond the area of the skin that is red, warm, or swollen
- Fever

Later symptoms of necrotizing fasciitis can include:

- Ulcers, blisters, or black spots on the skin
- Changes in the color of the skin
- Pus or oozing from the infected area



Noncontrast CT scan of patient with necrotizing fasciitis showing extensive edema in the deep facia of several muscles. Photo courtesy of the NIH National Library of Medicine

- Dizziness
- Fatigue (tiredness)
- Diarrhea or nausea

Diagnosis Can Be Difficult and Acting Fast Is Key

There are many infections that look similar to necrotizing fasciitis in the early stages, which can make diagnosis difficult. In addition to looking at the injury or infection, doctors can diagnose necrotizing fasciitis by:

- Taking a tissue sample (biopsy)
- Looking at bloodwork for signs of infection and muscle damage
- Imaging (CT scan, MRI, ultrasound) of the damaged area

Antibiotics and surgery are typically the first lines of defense if a doctor suspects a patient has necrotizing fasciitis. Administering IV antibiotics as soon as possible is recommended, however, antibiotics sometimes cannot reach all of the infected areas because the bacteria have killed too much tissue and reduced blood flow. When this happens, the dead tissue must be surgically remove. It is not unusual for someone with necrotizing fasciitis to end up needing multiple surgeries, and in serious cases, the patient may need a blood transfusion.

Serious Complications Are Common

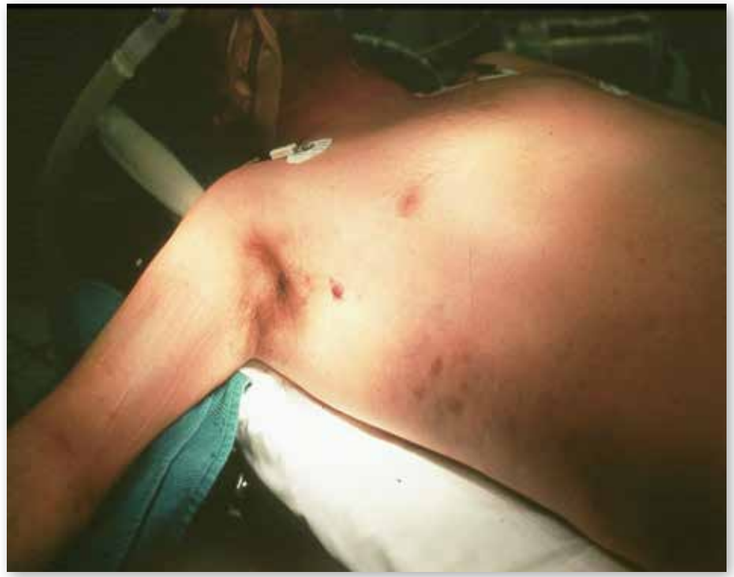
Necrotizing fasciitis can lead to sepsis, shock, and organ failure. It can also result in life-long complications from loss of limbs or severe scarring due to surgically removing infected tissue. Even with treatment, up to 1 in 3 people with necrotizing fasciitis die from the infection.

Six out of every 10 people who get both necrotizing fasciitis and streptococcal toxic shock syndrome at the same time die from their infections. Streptococcal toxic shock syndrome is another very serious illness caused by group A strep. It causes the body to go into shock and involves low blood pressure and multiple organ failure.

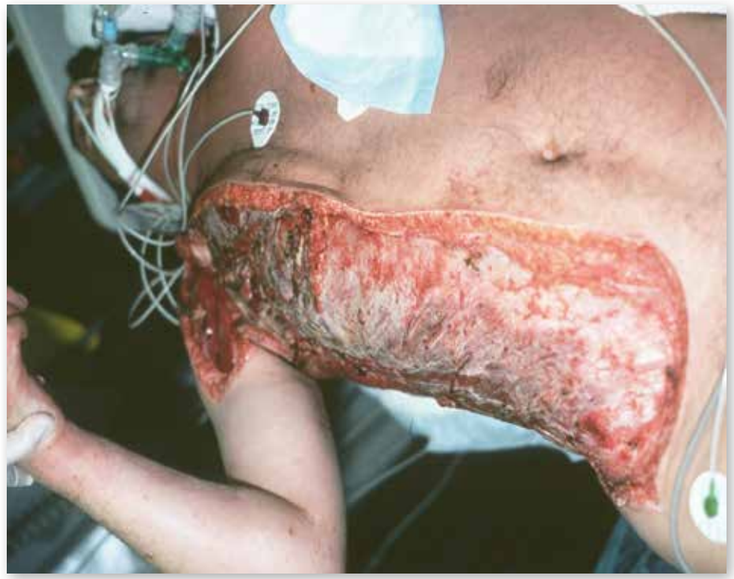
While Rare, Some People Are More Likely to Get Necrotizing Fasciitis

While anyone can get necrotizing fasciitis, it is rare. Most people who get this illness have other health problems that may lower their body's ability to fight infections. Some conditions that weaken the body's immune system include:

- Diabetes
- Kidney disease
- Scarring (cirrhosis) of the liver
- Cancer



Early infection state of necrotizing fasciitis.



Late infection state of necrotizing fasciitis.

Photos courtesy of National Institutes of Health Office of Science Education

Six out of every 10 people who get both necrotizing fasciitis and streptococcal toxic shock syndrome at the same time die from their infections.

Necrotizing fasciitis can also be a rare complication of chickenpox in young children.

Infection occur randomly so it is very rare for someone to spread the infection to other people. For this reason, preventive antibiotics to close contacts of someone with necrotizing fasciitis are not recommended.

Prevent sking infections begins with common sense and good wound care. Clean all minor cuts and injuries that break the skin (like blisters and scrapes) with soap and water. Clean and cover draining or open wounds with clean, dry bandages until they heal. Wash hands often with soap and water or use an alcohol-based hand rub if washing is not possible, and care for other fungal infections the patient may be experiencing like athlete's foot.

Open wound or skin infection should avoid water exposure such as got tubs, Swimming pools, or natural bodies of water (e.g., lakes, rivers, oceans). There are no vaccines to prevent group A strep infections, including necrotizing fasciitis.

CDC tracks necrotizing fasciitis caused by group A strep with a special system called Active Bacterial Core surveillance (ABCs). Since 2010, approximately 700 to 1200 cases occur each year in the United States. This is likely an underestimate. According to ABCs data, the number of annual group A strep necrotizing fasciitis infections reported to ABCs does not appear to be rising.

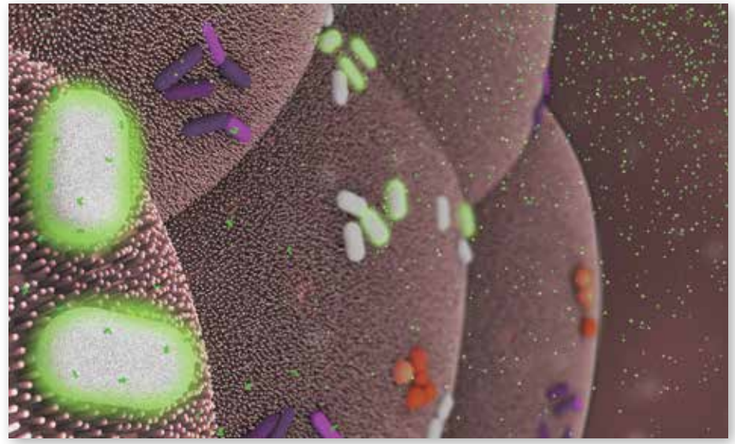
cdc.gov

Chronic Wound Microbiome Dynamics Influence Healing

Microbial infections have been associated with approximately 50% of impaired healing of chronic wounds, but there are many gaps in understanding this relationship. Technologies to dissect wound microbiomes, or microbial populations, have just become available; these new tools analyze microbiome composition directly, replacing unreliable culturing methods. Diabetic foot ulcers (DFUs) are common chronic wounds, affecting 15-25% of diabetes patients and can lead to amputation. Researchers conducted a longitudinal study of DFUs in a cohort of diabetes patients and identified characteristics of dynamic microbial populations for wounds that healed quickly and for wounds that persisted.

The study yielded four different microbial "community types" (CTs) with different percentages of microbial classes, such as predominantly staphylococcus, predominantly staph aureus, or highly diverse populations of more than 20 different microbes. The microbial populations of wounds that healed quickly were "unstable": over time, they changed from one CT to another CT more frequently. In wounds that took longer to heal, there were fewer transitions from one CT to another CT over the observation period. The researchers concluded that effective clinical control of chronic wounds disrupts bacterial colonization of the wound. These findings about microbiome dynamics may also be applicable to chronic wounds in a broad array of health conditions.

In a paper published in the journal *Cell Systems*, the MIT researchers used an innovative genome editing system called CRISPR-Cas (see Copy-Editing the Genome) to insert specially designed genetic circuits into the common human gut bacteria, Bacteroides thetaiotaomicron (B. theta).These engineered bacteria were then successfully introduced into the intestines of laboratory mice, where they were able to sense particular molecules delivered via drinking water and to respond to those molecules by turning certain genes in the circuit on or off.



Bacteroides thetaiotaomicron (white) living on mammalian cells in the gut (large pink cells coated in microvilli) and being activated by exogenously added compounds (small green dots) to express specific genes, such as those encoding light-generating luciferase proteins (glowing bacteria). Photo courtesy of Janet Iwasa, Broad Visualization Group, MIT Media Lab

In one experiment, led by Timothy Lu and Christopher Voigt, the team used their new toolbox to program B. theta to turn on a light-producing protein called luciferase when they sensed a compound called arabinogalactan. Within a day of the mice drinking water that contained arabinogalactan, luciferase activity increased about 75-fold in animals with engineered gut microbes. Similar activity was seen in the animals' microbe-laden feces, providing glowing evidence that the circuit was indeed working as intended!

The researchers tested more complex genetic circuits, too. For example, when the mice were fed a form of sugar called rhamnose, it activated an enzyme in engineered B. theta that permanently reverses the order of the DNA letters in a short section of the bacteria's genetic instruction book. The researchers were then able to detect whether mice had been exposed to that sugar through a simple DNA test.

The new toolkit makes it possible for scientists to manipulate the activity of any gene in B. theta on demand. While it has become clear in recent years that the microbiome is integral to our health and well-being, there is still much that scientists don't know about the precise roles of specific microbial species. These new tools can now be used to engineer the microbiome in ways that serve to answer those questions.

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