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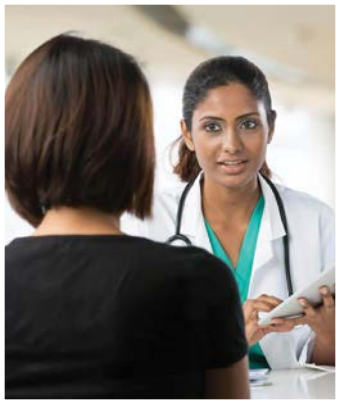

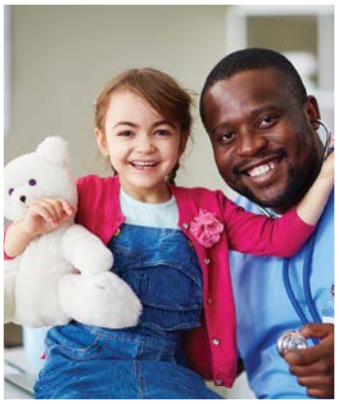
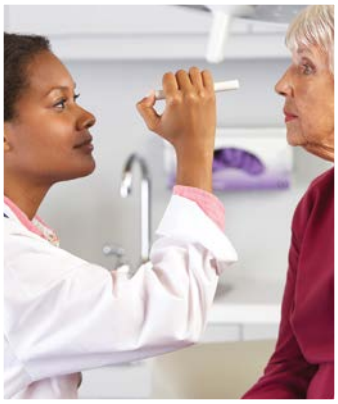

Brenda Fitzgerald, MD, New CDC Director and ATSDR Administrator

Brenda Fitzgerald, MD

Brenda Fitzgerald, MD, is now the 17th Director of the Centers for Disease Control and Prevention (CDC) and Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR).

Dr. Fitzgerald has been the commissioner of the Georgia Department of Public Health (DPH) and state health officer for the past six years. She replaces Dr. Anne Schuchat, who has been the acting CDC director and acting ATSDR administrator since January 20. Dr. Schuchat is returning to her role as CDC's principal deputy director.

Dr. Fitzgerald, a board-certified obstetrician-gynecologist, has practiced medicine for three decades. As Georgia DPH Commissioner, she oversaw various state public health programs and directed the state's 18 public health districts and 159 county health departments. Prior to that, Dr. Fitzgerald held numerous leadership positions. She served on the board and as president of the Georgia OB-GYN Society and she worked as a health care policy advisor with House Speaker Newt Gingrich and Senator Paul Coverdell. She has served as a Senior Fellow and Chairman of the Board for the Georgia Public Policy Foundation.

Dr. Fitzgerald holds a Bachelor of Science degree in Microbiology from Georgia State University and a Doctor of Medicine degree from Emory University School of Medicine. She completed postgraduate training at the Emory-Grady Hospitals in Atlanta and held an assistant clinical professorship at Emory Medical Center. As a Major in the U.S. Air Force, Dr. Fitzgerald served at the Wurtsmith Air Force Strategic Air Command (SAC) Base in Michigan and at the Andrews Air Force Base in Washington, D.C.

cdc.gov

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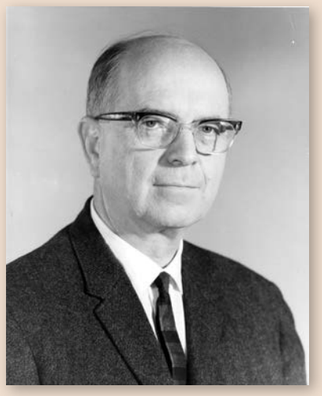
The 70th Anniversary of the CDC 1947-2017

In 1947, CDC made a token payment of $10 to Emory University for 15 acres of land on Clifton Road in Atlanta where CDC headquarters is located today. Field stations and laboratories were expanded and diversified, and employee training became an immediate task. The new institution would expand to include all communicable diseases, and would be the servant of the states, providing practical help whenever called.

Malaria Control in War Areas (MCWA), the predecessor to CDC, was established in 1942 to control malaria around military training bases in the United States. After World War II ended, Dr. Joseph W. Mountin of the U. S. Public Health Service's Bureau of State Services envisioned an agency that could support state and local health units in investigating and controlling communicable disease outbreaks, and in maintaining the nation's health through local measures. Building upon the work of the MCWA, the Communicable Disease Center (CDC) initially focused on fighting malaria, typhus and

This photograph depicted the portrait of the Centers for Disease Control's founder, Dr. Joseph W. Mountin (1891-1952), who established the organization in 1946, as a descendant of the post-World War II agency, Malaria Control in War Areas, MCWA. Dr. Mountin's credentials included a position as Assistant Surgeon General, and Chief of the Bureau of State Services of the Public Health Service. For 35 years, Dr. Mountin served as a Public Health Service officer, and was often referred to as the father of many of the public health service programs still active today.

other infectious diseases. The agency was located in Atlanta, Georgia because the South was the area of the country with the most malaria transmission as well as the headquarters of MCWA. In the next 60 years, minor changes were made to the name (The National Communicable Disease Center, Center for Disease Control, Centers for Disease Control, Centers for Disease Control and Prevention), but the initials, CDC, have remained the same.



Dr. Alexander Duncan Langmuir

Medical epidemiologists were scarce, and it was not until 1949 that Dr. Alexander Langmuir arrived to head the epidemiology branch. He saw CDC as "the promised land," full of possibilities. Within months, he launched the first-ever disease surveillance program, which confirmed his suspicion that malaria, on which CDC spent the largest portion of its budget, had long since disappeared. Subsequently, disease surveillance became the cornerstone on which CDC's mission of service to the states was built and, in time, changed the practice of public health.

Through the years, CDC's work has expanded to include all infectious diseases, noncommunicable diseases, injury and environmental health, health statistics, and occupational health. Reporting today to the Department of Health and Human Services and working in collaboration with public health partners, CDC tirelessly leads the fight against known, new, and emerging diseases around the world. At the same time, CDC leads prevention efforts to reduce the burden of preventable and chronic diseases.

MCWA was established to control malaria around military training bases in the southern United States and its territories, where malaria was still a problem. Many of the military bases were established in areas where mosquitoes that transmit were abundant. MCWA was created to prevent reintroduction of malaria into the civilian population by mosquitoes that would have fed on malaria-infected soldiers, in training or returning from endemic areas. During these activities, MCWA also trained state and local health department officials in malaria control techniques and strategies.

Today, CDC is known as the nation's premiere health promotion, prevention, and preparedness agencies.

CDC is globally recognized for conducting research and investigations and for its action-oriented approach. CDC applies research and findings to improve people's daily lives and responds to health emergencies — something that distinguishes CDC from its peer agencies.

CDC works with states and other partners to provide a system of health surveillance to monitor and prevent disease outbreaks (including bioterrorism), implement disease prevention strategies, and maintain national health statistics. CDC also guards against international disease transmission, with personnel stationed in more than 50 countries.

CDC is now focusing on becoming a more efficient and impactful agency by focusing on five strategic areas: supporting state and local health departments, improving global health, implementing measures to decrease leading causes of death, strengthening surveillance and epidemiology, and reforming health policies.

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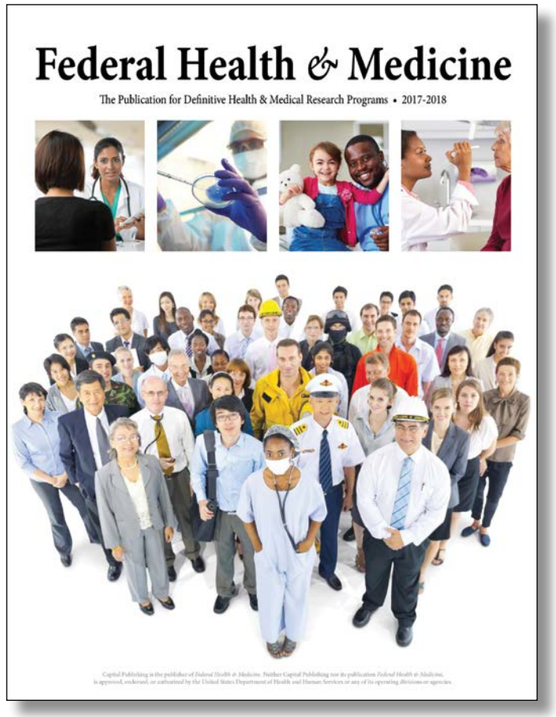

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Health Promotion Methods for Smoking Prevention and Cessation

A Comprehensive Review of Effectiveness and the Way Forward

By Mahaveer Golechha

Abstract

Tobacco smoking is one of the greatest causes of mortality in the world, responsible for over 5 million deaths per annum. The prevalence of smoking is over 1 billion people, with the majority coming from low or middle income countries. Yet, the incidence of smoking varies vastly between many countries. Some countries have been able to decline the smoking and tobacco related morbidity and mortality through the introduction of health promotion initiatives and effective policies in order to combat tobacco usage. However, on the other hand, in some countries, the incidence of smoking is increasing still further. With the growing body of evidence of detriment of tobacco to health, many control policies have been implemented as health promotion actions. Such methods include taxation of smoking, mass advertising campaigns in the media, peer education programs, community mobilization, motivational interviewing, health warnings on tobacco products, marketing restrictions, and banning smoking in public places.

However, the review of the effectiveness of various health promotion methods used for smoking prevention and cessation is lacking. Therefore, the aim of this review is to identify and critically review the effectiveness of health promotion methods used for smoking prevention and cessation. All available studies and reports published were considered. Searches were conducted using PubMed, MEDLINE, Ovid, Karger, ProQuest, Sage Journals, Science Direct, Springer, Taylor and Francis, EMBASE, CINAHL, and Cochrane and Wiley Online Library. Various relevant search terms and keywords were used. After considering the inclusion and exclusion criteria, we selected 23 articles for the present review.

INTRODUCTION

Smoking is a serious public health challenge across the world. It has assumed the dimension of an epidemic resulting in enormous disability, disease, and death.[1] The tobacco use attributed to more than 5 million preventable deaths every year globally.[2] Further, at the present rate, the number of such deaths is expected to double by 2020. The tobacco use not only detrimental to personal health but also results in severe societal costs such as reduced productivity and health care burden, poverty of the families, and environmental damage. Ample body of evidence available to infer causal relationship between smoking and vascular diseases such as coronary heart disease, subclinical atherosclerosis and stroke, respiratory diseases such as pneumonia and chronic obstructive pulmonary disease, and cancer at ten sites.[3]

Despite the serious health risks, a considerable number of people across the world continue to smoke. It is well recognized that overall mortality rates for cigarette smokers are 60–80% higher than for nonsmokers.[4] The degree of devastation brought to bear upon the individual and society outstrips the returns generated by tobacco production and consumption in terms of revenue and employment. As awareness of the dangers posed by tobacco spread, countries across the globe resolved to forge a campaign strategy and frame a battle plan to overcome the tobacco threat.

Health promotion is pivotal in the drive to reduce the growing burden of chronic disease worldwide due to tobacco and particularly smoking. Comprehensive and active awareness of the population through the health promotion strategies are the primary tools for smoking prevention and cessation. Public education is an integral part of the efforts to both prevent the initiation of smoking use and encourage smoking cessation. Increased health promotion efforts about the detrimental health effects from smoking use may result in higher levels of knowledge about the harms of smoking and this in turn could increase quit intentions and subsequent quitting among users. By increasing their knowledge about smoking cessation methods, health professionals can support and encourage the large majority of smokers who want to quit.

Several health promotion methods are being used for smoking prevention and cessation. Evaluation of some of the health promotion intervention studies has shown a positive impact on the reduction in smoking prevalence. However, studies showing the effectiveness of various methods are lacking. Therefore, the present review was carried out to comprehensively evaluate the effectiveness of important health promotion methods used for smoking prevention and cessation.

METHODS

To obtain all related studies, we searched in PubMed, MEDLINE, Ovid, Karger, ProQuest, Sage Journals, Science Direct, Springer, Taylor and Francis, EMBASE, CINAHL, and Cochrane and Wiley Online Library. The search terms were "smoking cessation," "smoking prevention," "health promotion methods for smoking cessation," "health promotion methods for smoking prevention," "Cochrane" and smoking cessation/prevention."

Inclusion and exclusion criteria

We included all available population-based studies including local, subnational studies and national studies, which were related to single health promotion method used for smoking cessation and prevention. We excluded studies which involved multiple health promotion methods for smoking cessation and prevention.

Data extraction

Data were collected according to a standard protocol by the author and reviewed by an independent reviewer. The disagreement was resolved by discussion between them. In cases could not reach a consensus, a third reviewer was consulted. The extracted information from the literature included the name of the first author, the year of publication, the study region, type of study (local study or survey), type of health promotion method used, total sample size, age and sex groups, urban/rural areas, and the effectiveness of the health promotion method. After considering inclusion and exclusion criteria, we selected 23 articles.

Peer education

Peer education "involves sharing of information in small groups or one to one by a peer matched either demographically or through risky behavior to the target population."[5] The theoretical basis of peer education method can primarily be derived from behavioral theories relating to health, theory of participatory education, Information, Motivation, Behavioral skills, and Resources model and developmental theory.

Effectiveness

A Stop Smoking in Schools Trial (ASSIST) program assessed the effectiveness of a peer-led intervention that aimed to prevent smoking uptake in secondary schools. The study has shown that the ASSIST training program was effective in the achievement of a sustained reduction in uptake of regular smoking in adolescents for 2 years after its delivery. Furthermore, it was well received by both students and school staff.[6] Further, the multilevel modeling showed a 22% reduction (odds ratio: 0.78 [95% confidence interval (CI): 0.64–0.96]) in the odds of being a regular smoker in an intervention school compared with a control school, with the 95% of CIs not including a null effect.[6] Pooled results from 10 randomized controlled trials (RCTs) that used experimental smoking as the main outcome also found that peer education interventions could be marginally effective in preventing smoking uptake.[7]

Resnicow et al., reported that the programs based on peer training model produced a net change of 6% in the smoking habit relative to the 3% change brought about by other models (harm minimization, and life skills training) among the South African high school students.[8] Prince compared a six-session peer-led smoking intervention program for high school youth to the same program led by the adults. Self-efficacy was measured post- and follow-up.[9] The significant reduction in a number of cigarettes smoked was found in both peer- and adult-led groups when compared to the control group. Furthermore, there was a continuous reduction in smoking both treatment groups at the 1-month follow-up measure.

Although the peer education has proven efficacy one must consider relevant factors before its implementation. These include selection, training, supervision, type of intervention, and the relationship between peer educators and peer educated. It is important to have the right environment and motivated peer educators for successful implementation.

Theatre in health promotion

For health promotion, the theater is an effective platform to create awareness and disseminate messages related to good health. The theater provides an interesting strategy as the audience is whole heartedly involved and encouraging the actor. The actor, who is integral to the dramatic narrative, explores the chosen topic as a relationship between facts and fiction.[10] The theater method premised upon the drama theories and social cognitive theory, which recognizes the human behavior as an interaction between the individual aspects, behavior, and the context.[11]

Thrush et al., in their study divided 24 primary schools into 3 groups, a theater in education intervention group, a school smoking policy intervention group and a control group. The results showed that there was a weak positive effect on the boys but none of the girls in the intervention group.[12] The theater production 2 Smart 2 Smoke and accompanying activities showed a significant impact on psychosocial risk factors for smoking among students in grades 1–3 and grades 4–6. The percentage of students who told that they would "never smoke a cigarette" increased by 10% following play intervention.[13]

While theater could possibly be a vehicle for long-term change, it still remains to be seen if the positive results can be elicited for those concentrating on promotion of nonsmoking habit. It is important that the content is assessed on a professional level, and the intervention be made as scientific as possible.

Media advocacy

Media advocacy is to frame an issue well and advocate that issue using the media as a platform. Information is disseminated through the media with a view to alter public mind or change their views.[14] Media advocacy needs to be based on the solid principles of planning. Media advocacy planning used "GOTME" approach: Goal, objective, target, message, and evaluation.[14]

Effectiveness

Media advocacy was used in many health promotion interventions and it is particularly concerned with significant environmental and policy change. The Project Tobacco Reduction Using Effective Strategies and Teamwork involved

the media advocacy and the retailer were rewarded with positive newspaper coverage for compiling the underage laws for selling tobacco products, whereas those who did not were "named and shamed."[15] The impact of the project was significant on smoking prevention. Niederdeppe et al., assessed the impact of media advocacy activities on news coverage, policy changes, and reductions in youth smoking implemented by the Florida Tobacco Control Program. They demonstrated a significant decrease in volume of program-related news coverage after the onset of media advocacy initiatives, but the ratio of coverage about students working against tobacco relative to other topics increased. Because of news coverage, there was a passage of tobacco product placement ordinances in Florida counties, but these ordinances did not significantly reduce the prevalence of smoking among the youth.[16]

Media advocacy can be looked at as a tool in the broader policy implementation. It can help provide a platform to raise policy related issues. Further studies to see its effectiveness needs to be done. The use of media as an advocacy tool must be conceived and developed only in the context of other approaches such as community organizing, coalition building, and policy advocacy.

Community mobilization

Community mobilization is aimed at inducing a change of normal social norms from the utility of various intricate interventions to help raise awareness of community participants. It is brought about by teamwork, educational entertainment and the participation of other members, and groups and associations to help inspire revolutionize a change. Community mobilization is based on 3 key concepts: Social capital, empowerment, and social change.[17]

Effectiveness

A systematic review by Secker-Walker et al., of community interventions to reduce the prevalence of smoking shows the effectiveness of community-based health promotion initiatives. A favorable outcome was suggested as a significant change in smoking behavior, being either lower prevalence, reduced cigarette consumption per capita or an increase in smoking cessation rate. Of the studies, 23 (62%) suggested at least one favorable outcome with relation to smoking change, whilst 14 studies (38%), showed no marked difference. Where the community was the unit of assignment and analysis, 5 of the 8 studies (62.5%) reported a positive change in smoking behavior. In the remaining studies, where the individual was the unit of analysis, hence with a reduced significance level, 18 out of 29 studies (62%) showed at least one favorable outcome with relation to smoking behavioral outcome. This systematic review concluded that community health promotion methods were more effective than other methods of smoking prevention.[18]

Community mobilization methods are essential in the field of health promotion. Empowering communities to bring about change in their own social domains is not only more sustainable but however, is also extremely effective.

Social marketing

Kotler and Zaltman coined the term "social marketing" using it in an article evaluating the application of commercial marketing principles.[19] The social marketing is the systematic application of principles and techniques of marketing to create, communicate, and deliver value in order to influence a target audience to achieve specific behavioral goals, for social good.[20] It is best described as a behavioral approach that helps to create a long-term sustainable impact upon the choices of people. Social marketing draws on and incorporates the use of behavioral theory.

Effectiveness

Despite many challenges, the evidence for the effectiveness of social marketing interventions does exist and is growing. The project 16 incorporates social marketing method for reducing both illegal sales of tobacco and youth tobacco use showed a significant effect on lowering the smoking prevalence.[21] In a review by Gordon et al., 18 out of 21 studies examined short-term impact (up to 1-year) of social marketing intervention on smoking prevention. Thirteen studies demonstrated the significant positive effects.[22] The Sunderland project was based on social marketing strategy for increasing the uptake of smoking cessation services and quit rate among pregnant women in Sunderland. The intervention primarily includes the design and pretesting of new marketing/information material and consumer friendly cessation support. There was a significant impact of project and there was a 10-fold increase in the smoking quitting or setting a date for quitting smoking among pregnant women as compared to neighboring primary-care trusts which did not apply similar social marketing approach.[23]

A meta-analysis of the efficacy of SMS text message interventions for smoking cessation showed that smoking quit rates for the text messaging intervention group were 35% higher compared to the control group quits rates. Results also suggest that SMS text messaging may be a promising way to improve smoking cessation outcomes.[24]

The social marketing interventions should always be adapted according to local needs and contexts. There is a need for integrating specific vertical and horizontal interventions with social marketing to make it more sustainable and effective.

Motivational interviewing

Motivational interviewing (MI) defined as a client-centered, directive approach to stimulate the positive behavior change and resolve ambivalence.[25] The important guiding principles of MI are expressing empathy, supporting self-efficacy, developing discrepancy and rolling with resistance. It primarily derived from social psychology, cognitive dissonance, self-efficacy, and empathic processes. Various forms of MI are Motivational Enhancement Therapy, Brief MI (BMI), and telephone consultation.

Effectiveness

MI has been used successfully for smoking cessation. Glasgow et al., demonstrated the effectiveness of a BMI-based intervention given by clinical staff versus advice to quit smoking among 1154 women attending planned-parenthood clinics. There were a higher 7-day abstinence rates in the MI intervention group at 6 weeks (10.2% vs. 6.9%). The MI intervention group showed a significant reduction in a number of cigarettes smoked at both 6 weeks and 6 months.[26] The relatively brief training of staffs for MI and low rate of completion for follow-up telephone calls were a limitation of this study. Valanis et al., found a significant impact of MI intervention for women attending prenatal clinics on self-reported quitting rates both during pregnancy and 6–12 months after delivery.[27]

In another study, 536 smokers from 21 clinical practices were randomized to receive either MI or brief advice to quit smoking from their general practitioner showed a significant effect on smoking cessation.[28] Meta-analysis of MI versus brief advice or usual care yielded a modest but significant increase in quitting. Subgroup analyzes demonstrated that the MI intervention was more effective when administered by primary-care physicians and by counselors, and when it was conducted in longer sessions (more than 20 min per session).[29]

Recently conducted systematic review of RCTs in which MI used for smoking cessation showed that MI versus brief advice or usual care yielded a modest but significant increase in quitting (risk ratio: 1.26; 95% CI: 1.16–1.36; 28 studies; n = 16,803).[30]

MI appears to have broad application to behavioral medicine. Although the initial outcome studies have produced mixed results, MI appears to have potential efficacy. Further research studies required to address the numerous questions regarding how MI works in different conditions and individuals and which health professionals are best able to deliver MI with fidelity.

Mass media campaigns

Mass media campaigns are widely used to expose the population to messages through television, radio, and newspapers. Such campaigns can produce positive or negative changes in health-related behavior in populations and is a useful method for raising an issue and encouraging debate.[31] The mass media campaign approach based on the theories of the social influences or social learning theory.

Effectiveness

It has been suggested that the mass media is particularly appropriate for delivering antismoking messages to young people because they are more exposed to the media. In the interventional review of studies for assessing smoking behavior by Brinn et al., investigated the effect of a mass media prevention effort directed at young people <25 years using a parallel group RCT or controlled clinical trial design.[31] Three studies were associated with a reduction in smoking outcomes. One study found a statistically significant decrease in smoking uptake by girls (with net increase of 8.6% in Intervention County vs. 12.4% in the control) and a nonsignificant trend in boys at 3-year follow-up (6.8–10.5%). In an another study, impact compared between school based programs with mass media and school based intervention alone, showed a significant effect of combined intervention as compared to school alone. The results reported in all seven studies tended to be based on outcome data relating to a sub-sample of participants rather than on the basis of allocation to groups. Evaluation of effectiveness on the basis of data provided by those participants available at follow-up is likely to be biased.[32]

Bala et al., assessed the effectiveness of mass media interventions in reducing smoking among the adults through systematic review has shown that the comprehensive tobacco control programs which include the mass media campaigns can be effective in changing smoking behavior in adults. The intensity and duration of campaigns may influence effectiveness.[33]

Mass media campaigns should be included as a key component of approaches to improve population health behavior. Careful planning and testing with target audiences is crucial. Emphasis should be placed on the involvement of small groups of representative samples at whom the campaign is directed. Such groups can also be involved in message development.

Setting based approach

The emergence of the settings approach has been attributed to the Ottawa Charter's assertion that, "health is created and lived by people within the settings of their everyday life; where they learn, work, play, and love."[34] Settings for health are defined as "the place for social context in which the people engage in daily activities in which environmental organizational and personal factors interact to affect health and wellbeing."[35] A settings approach is built upon the principles of health promotion, in a holistic manner, and as a process of enabling people to increase control over, and to improve their health.

Effectiveness

The workplace has potential as a setting through which the large groups of people can be reached to encourage the smoking cessation. Cahill et al., conducted an interventional review of 51 studies covering 53 interventions. They found 37 studies of workplace interventions aimed at individual workers, covering group therapy, individual counseling, self-help materials, nicotine replacement therapy, and social support. Group programs, individual counseling, and nicotine replacement therapy increased cessation rates in comparison to no treatment or minimal intervention controls. Self-help materials were less effective. They also found 16 studies testing interventions applied to the workplace as a whole and found the settings based approach is more effective than other interventions.[36] But overall, there was a lack of evidence that comprehensive programs reduced the prevalence of smoking. Incentive schemes increased the attempts to stop smoking though there was less evidence

that they increased the rate of actual quitting. They failed to detect an effect of comprehensive programs in reducing the prevalence of smoking.

The better understanding of health promoting setting among various actors, politicians, and well as workers is essential for the efficient implementation of setting based health promotion methods. There is a need to understand the implementation process and the importance of carrying out systematic evaluations for sustainable, healthy settings.

CONCLUSIONS

Health promotional interventions for prevention and cessation of smoking are thought to involve a three-tiered approach. Reaching the mass public by social marketing and mass media interventions, reaching the individual by MI, peer education, whilst approaching the community via community mobilization and changing the environment by media advocacy and setting based intervention seems to be an extremely effective method of inducing smoking prevention and cessation. These methods incorporate the principles of inducing change at an individual level, a change in social norms in the community and socio-political efforts to promote the health of the population. It would be more effective to implement the interventions focusing on social attitudinal and environmental changes before trying to focus on individual behavioral change, which is difficult to bring about. Foundation for multiple interventions can only be developed with innovative approaches to work with the population at different levels. In the past years, we have learned how to engage the population and various stakeholders for developing effective and sustainable partnership for health promotion. Population capacity to address change and readiness are the key factors influences effective health promotion efforts for smoking prevention and cessation.

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New Study Gives Hope to Better Cessation Treatment

By Claire Tousley

Researchers at the University of Wisconsin Center for Tobacco Research and Intervention have found a potential culprit that may be responsible responsible for how heavily a person can be addicted to nicotine and how hard it could be for them to quit.

Depending on the variation of a gene a person has, the gene will tell the liver to make different amounts of FM03, an enzyme that breaks down nicotine. This means people might react to nicotine in totally different ways. Different variations of a gene tells the brain how soon a person needs a smoke after they wake up, which is one of the key ways to evaluating a person's level of nicotine addiction.

If a person makes more of this FM03 enzyme, nicotine is broken down more quickly, causing them to feel the urge to light up as soon as they wake up. Different types of this enzyme also affect how well a person does on nicotine replacement therapy.

Tobacco cessation counseling offered by physicians as well as non-physician clinicians is effective. Increasing the length of a counseling session and the number of sessions increases abstinence rates.

What does this mean? Physicians could test patients that are interested in quitting and see what their genes have to say about how nicotine affects them specifically. Could scientists figure out how to "turn off" the gene that makes the body produce more FMO3 enzyme, making smoking less tempting? Only time will tell, but this could lead to many more exciting discoveries.

tobaccofreeboonecounty.com

Celebrate Living Tobacco-Free in Tennessee

The Tennessee Department of Health joined partners in the Statewide Tobacco-Free Coalition in celebrating Tennessee Quit Week Feb. 13-17, 2017. The "It's Quittin' Time in Tennessee" theme was chosen to celebrate Tennesseans who have quit using tobacco products and inspire more people to join them.

TDH Commissioner John Dreyzehner, MD, MPH joined former U.S. Senator Bill Frist, MD, founder and chairman of NashvilleHealth and Governor's Foundation for Health and Wellness CEO Richard Johnson at the Tennessee State Capitol to celebrate Tennessee Quit Week and discuss opportunities for citizens, government, business and non-profit leaders to partner in reducing tobacco use in Tennessee.

"The impacts of tobacco use in Tennessee go beyond the damage done to the health, quality of life and incomes of those who choose to smoke," said Dreyzehner. "Tobacco use costs our state billions of dollars each year in lost productivity and health care costs, serious and preventable consequences that hurt the prosperity of our state and those who live and work here. We want to increase our partnerships across the public and private sectors to educate people on the harms of tobacco use and how we can work together to help people improve their health and their lives by beating nicotine addiction."

Tennessee Quit Week raises awareness of the free resources available to help Tennesseans quit smoking and/or using other tobacco products. These proven, effective services can double a tobacco user's chances of quitting.

Tennesseans who smoke and are ready to quit can call the Tennessee Tobacco QuitLine, use a web-based program or attend in-person counseling services and may receive free FDA-approved nicotine replacement therapy. These services are provided at no charge to participants.

Along with counseling, teamwork with health professionals is a proven way to help smokers quit for good. People who work with health care professionals to quit smoking are ultimately more successful in quitting tobacco use and report higher satisfaction with overall health care received compared to untreated tobacco users, according to the U.S. Public Health Service. Smokers who quit can add up to 10 years to their life expectancy.

The Impact of Tobacco Use in Tennessee:

- Tobacco use claims at least 30 Tennessee lives every day.
- If current smoking rates continue, 125,000 Tennessee children alive today who are younger than 18 years of age will die prematurely as a result of smoking.
- In 2009, $2.67 billion in annual health care costs in Tennessee were directly caused by smoking.

The TDH Statewide Tobacco-Free Coalition consists of key stakeholders and community partners from around the state whose purpose is to identify strengths, gaps and opportunities for tobacco control in Tennessee. Learn more about Tennessee Quit Week and resources available to help reduce tobacco use at www.tn.gov/health/topic/FHW-tobacco.

tn.gov

STDs at Record High, Indicating Urgent Need for Prevention

Latest U.S. data reveal threat to multiple populations

More than two million cases of chlamydia, gonorrhea and syphilis were reported in the United States in 2016, the highest number ever, according to the annual Sexually Transmitted Disease Surveillance Report released today by the Centers for Disease Control and Prevention (CDC).

The majority of these new diagnoses (1.6 million) were cases of chlamydia. There were also 470,000 gonorrhea cases and almost 28,000 cases of primary and secondary syphilis – the most infectious stages of the disease. While all three of these STDs can be cured with antibiotics, if left undiagnosed and untreated, they can have serious health consequences, including infertility, life-threatening ectopic pregnancy, stillbirth in infants, and increased risk for HIV transmission.

"Increases in STDs are a clear warning of a growing threat," said Jonathan Mermin, MD, MPH, director of CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. "STDs are a persistent enemy, growing in number, and outpacing our ability to respond."

Epidemic accelerating in multiple populations — impact growing in women, infants, and gay and bisexual men

While young women continue to bear the greatest burden of chlamydia (nearly half of all diagnosed infections), surges in syphilis and gonorrhea are increasingly affecting new populations.

Syphilis rates increased by nearly 18 percent overall from 2015 to 2016. The majority of these cases occur among men – especially gay, bisexual and other men who have sex with men (MSM). However, there was a 36 percent increase in rates of syphilis among women and a 28 percent increase in syphilis among newborns (congenital syphilis) during this period.

More than 600 cases of congenital syphilis were reported in 2016, which has resulted in more than 40 deaths and severe health complications among newborns. The disease is preventable through routine screening and timely treatment for syphilis among pregnant women.

Gail Bolan, MD, Director, Division of STD Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

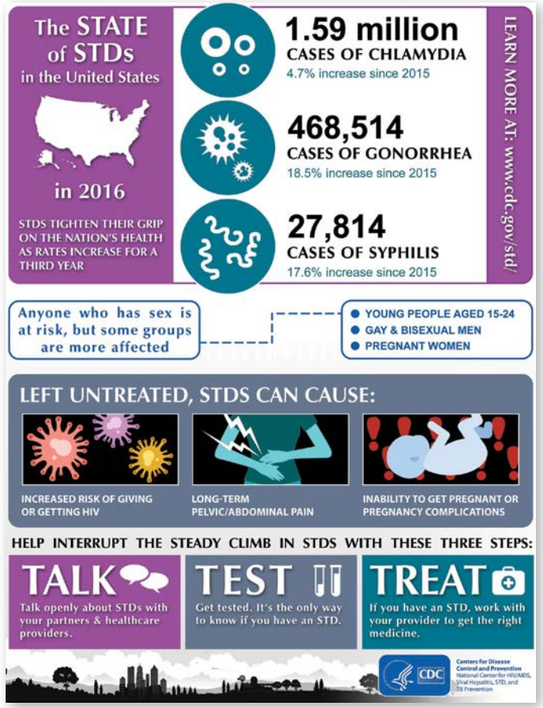
"Every baby born with syphilis represents a tragic systems failure," said Gail Bolan, director of CDC's Division of STD Prevention. "All it takes is a simple STD test and antibiotic treatment to prevent this enormous heartache and help assure a healthy start for the next generation of Americans."

While gonorrhea increased among men and women in 2016, the steepest increases were seen among men (22 percent). Research suggests that a large share of new gonorrhea cases are occurring among MSM. These trends are particularly alarming in light of the growing threat of drug resistance to the last remaining recommended gonorrhea treatment.

MSM also bear a great syphilis burden. MSM make up a majority of syphilis cases, and half of MSM diagnosed with syphilis were also living with HIV — pointing to the need to integrate STD and HIV prevention and care services.

Essential to confront most urgent threats, upgrade prevention infrastructure

CDC uses STD surveillance data and other tools to detect and respond to these evolving threats and new challenges, directing resources where they can have the greatest impact. Targeted efforts include:



The Council of State and Territorial Epidemiologists (CSTE) approved the Update to Public Health Reporting and National Notification for Syphilis. This new position statement for syphilis (17-ID-11) includes revisions to the surveillance case definition for syphilis. These changes will take effect January 1, 2018. By ensuring that cases of syphilis are reported in accordance with this revised surveillance case definition, we can obtain the most accurate surveillance for this disease and its clinical manifestations, and we can better address syphilitic infection and transmission.

- Strengthening the congenital syphilis response with focused efforts to improve diagnosis and treatment of pregnant women and ensure prompt treatment of newborns at birth in the ten states hardest hit by congenital syphilis.
- Helping state and local health departments rapidly test for drug-resistant gonorrhea and quickly find and treat affected individuals, as part of the federal government's Combating Antibiotic Resistant Bacteria (CARB) Action Plan.
- Assisting state health departments and health clinics integrate

Pregnant Women should be tested for syphilis and receive immediate treatment if positive to prevent the infection from spreading to their unborn baby, which can lead to premature or stillborn delivery. An infected baby may be born without signs or symptoms of disease. However, if not treated immediately, the baby may develop serious problems within a few weeks. Untreated babies can have health problems such as cataracts, deafness, seizures, or death.

STD prevention into care for people living with HIV.

Maintaining and strengthening core prevention infrastructure is also 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

Only About One-Third of Americans Use Condoms

They aren't the best method of birth control, but they do help prevent STDs, health experts say

Condoms can help prevent pregnancy and the spread of sexually transmitted diseases (STDs), but only about a third of Americans use them, a new federal report shows.

"The use of condoms is a public health issue," said report author Casey Copen, a statistician at the U.S. Centers for Disease Control and Prevention's National Center for Health Statistics. "STDs can lead to long-term consequences, such as infertility," she said. "Condoms, when used consistently and correctly, reduce the risk of HIV and STDs."

About 20 million new cases of STDs are diagnosed each year in the United States, the CDC said. These infections include human papillomavirus (HPV), gonorrhea, chlamydia, syphilis, hepatitis and HIV.

The choice of whether to use a condom or not is influenced by a number of factors. These include: a woman's desire to get pregnant, one's experience using other methods of contraception, and the relationship of the partners, Copen said.

"People who say they are dating casually use more condoms than people who say they are co-habitating or engaged," she said. Most people who use condoms say they use them to prevent pregnancy and avoid getting an STD, Copen said.

One expert said there are other, better choices of birth control. "We have much better methods of birth control than a condom. If people don't want to have a baby, they should be using a more effective method," said Dr. Jill Rabin.

"Sex can be wonderful, but I don't know any climax that's worth the heartache of an unwanted pregnancy," said Rabin. She is co-chief of the division of ambulatory care in the Women's Health Programs-PCAP Services at Northwell Health in New Hyde Park, N.Y.

But condoms do have a role in preventing STDs, Rabin said. Often people don't know they have an STD until it's too late and they are infertile or sick, she said.

"We know that condoms can protect against many STDs," Rabin said. "So why would you deliberately place yourself in a position to get hepatitis B or C or HIV? "I understand human nature, but take responsibility and think ahead," Rabin said.

For the Aug. 10 report, Copen collected data on condom use among men and women aged 15 to 44 from the 2011-2015 U.S. National Survey of Family Growth. The findings were compared with surveys from 2002 and from 2006 to 2010.

The researchers interviewed 11,300 women and more than 9,300 men about condom use between September 2011 and September 2015. During that time, about 24 percent of women and 34 percent of men used a condom during their last sexual intercourse. That's an increase for men since 2002, when about 30 percent reported using a condom, Copen said.

Among those who used condoms, nearly 60 percent of women and 56 percent of men said condoms were the only means of contraception used in the past year.

Another 25 percent of women and 33 percent of men used condoms plus hormonal methods such as birth control pills or implants. Fifteen percent of women and 10.5 percent of men used condoms plus nonhormonal contraception.

Copen also found that during past month intercourse, 18 percent of women and nearly 24 percent of men used a condom every time. Nearly 7 percent of women who used a condom in the past month said the condom broke or fell off during intercourse or withdrawal. Nearly 26 percent said they used a condom only part of the time during intercourse, Copen said.

Dr. Dennis Fortenberry is a professor of pediatrics at Indiana University School of Medicine. "Although the overall proportions of condom use are relatively small, there are several positive aspects of the data," he said.

First, the overall proportion of condom use has been stable during recent years, without large changes in use across the U.S. population, said Fortenberry, a board member of the American Sexual Health Association. "In addition, condom use is quite high among younger, sexually active populations, where STDs and pregnancy are important and where access to other means of prevention may be limited," he said.

The relatively high frequency of condoms that break or fall off suggests the need for continued public health education and training, he said.

"Although condoms will never solve all of the STD and pregnancy prevention needs of a diverse population, they remain an accessible and low-cost technology necessary for comprehensive public health prevention approaches," he added.

medlineplus.gov

HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis

Acting Health and Human Services (HHS) Secretary Eric D. Hargan issued the following statement upon declaring a nationwide public health emergency regarding the opioid crisis, as requested by President Donald Trump on Thursday:

"Today's declaration, coupled with the President's direction that executive agencies use all appropriate emergency authorities and other relevant authorities, is another powerful action the Trump Administration is taking in response to America's deadly opioid crisis.

"President Trump has made this national crisis a top priority since he took office in January, and we are proud to be leading in this effort at HHS. His call to action today brings a new level of urgency to the comprehensive strategy HHS unveiled under President Trump, which empowers the real heroes of this fight: the communities on the frontlines of the epidemic."

As a result of the consequences ofthe opioid crisis affecting our Nation, on this date and after consultation with public health officials as necessary, I, Eric D. Hargan, Acting Secretary of Health andHuman Services, pursuant to the authority vested in me under section 319 ofthe Public Health Service Act, do hereby determine that a public health emergency exists nationwide.

Background:

- Each day, according to the Centers for Disease Control and Prevention, more than 140 Americans die from drug overdoses, 91 specifically due to opioids.
- 52,404 Americans died from drug overdoses in 2015, and preliminary numbers indicate at least 64,000 died in 2016.
- Declaring a nationwide public health emergency will enable HHS to accelerate temporary appointments of specialized

personnel to address the emergency (pending any funding needed); work with DEA to expand access for certain groups of patients to telemedicine for treating addiction; and provide new flexibilities within HIV/AIDS programs.

- Under President Trump, in April 2017, HHS unveiled a new five-point Opioid Strategy, with the five following priorities:
  - Improve access to prevention, treatment, and recovery support services
  - Target the availability and distribution of overdose-reversing drugs
  - Strengthen public health data reporting and collection
  - Support cutting-edge research on addiction and pain
  - Advance the practice of pain management
- In Fiscal Year 2017, HHS invested almost $900 million in opioid-specific funding, including to support state and local governments and civil society groups — to support treatment and recovery services, target availability of overdose-reversing drugs, train first responders, and more.
- HHS has supported the efforts of the President's Commission on Combating Drug Addiction and the Opioid Crisis, and the department looks forward to reviewing the upcoming final report.

hhs.gov

HHS Announces over $70 million in Grants to Address the Opioid Crisis

Health and Human Services Secretary today announced the availability of over $70 million over multiple years to help communities and healthcare providers prevent opioid overdose deaths and provide treatment for opioid use disorder, of which $28 million will be dedicated for medication-assisted treatment (MAT).

"Putting an end to the opioid crisis ravaging our country is a top priority for President Trump and all of us at the Department of Health and Human Services," said HHS Secretary. "We are committed to bringing everything the federal government has to bear on this health crisis. Building partnerships and providing resources to state and local governments as well as non-government organizations are absolutely critical to this effort. The purpose of these grants is to empower the heroes in this fight—the men and women on the forefront of supporting prevention, treatment, and recovery initiatives in their communities."

Opioid overdoses claimed more than 33,000 lives in 2015, but preventive actions, treatment for addiction, and proper response to overdoses can help. Money from two grant funding opportunities, recently authorized by the Comprehensive Addiction and Recovery Act (CARA), will expand access to lifesaving overdose reversal medications and train healthcare providers to refer patients to appropriate follow-up drug treatment; funds from a third grant funding opportunity will provide for medication-assisted treatment of opioid use disorders.

The announcement followed a separate award of $485 million in grants in April 2017 — provided by the 21st Century Cures Act — to all 50 states, the District of Columbia, four U.S. territories, and the free associated states of Palau and Micronesia for opioid abuse prevention, treatment, and recovery. Administered through the Substance Abuse and Mental Health Services Administration (SAMHSA), these funds will be made available through the following three grants:

- **Medication-Assisted Treatment and Prescription Drugs Opioid Addiction:** Up to $28 million to 5 grantees to increase access of medication-assisted treatment for opioid use disorder. Medication-assisted treatment combines behavioral therapy and FDA-approved medication.
- **First Responders:** Up to $41.7 million over 4 years available to approximately 30 grantees to train and provide resources for first responders and members of other key community sectors on carrying and administering an FDA approved product for emergency treatment of known or suspected opioid overdose.
- **Improving Access to Overdose Treatment:** Up to $1 million over 5 years to one grantee to expand availability to overdose reversal medications in healthcare settings and to establish protocols to connect patients who have experienced a drug overdose with appropriate treatment.

"The grants we announce today clearly demonstrate our efforts to meet the opioid crisis with every tool at our disposal," said SAMHSA Acting Deputy Assistant Secretary Kana Enomoto. "The evidence-based training, medication, and behavioral therapies provided here will save lives and help people with addictions start a path toward reaching their potential."

Additionally, on May 4, SAMHSA released two other Comprehensive Addiction and Recovery Act-related funding opportunities. These funding opportunities will be open through July 3, 2017:

- **State Pilot Grant Program for Treatment for Pregnant and Postpartum Women:** Up to $3.3 million to support a range of family-based services for pregnant and postpartum women with substance use disorder.
- **Building Communities of Recovery:** Up to $2.6 million to mobilize resources within and outside of the recovery community to increase the prevalence and quality of long-term recovery support from substance abuse and addiction.

The Trump Administration and Health and Human Services Secretary have identified the opioid crisis as one of the top priorities for improving the health of the American people. HHS has outlined five specific strategies to combat the ongoing opioid crisis: strengthening public health surveillance, advancing the practice of pain management, improving access to treatment and recovery services, targeting availability and distribution of overdose-reversing drugs, and supporting cutting-edge research. With the completion of the fiscal year 2017 spending package passed by Congress, HHS moved quickly to announce these funding opportunities which are critical to improving access to treatment and recovery services as well as targeting availability and distribution of overdose-reversing drugs.

hhs.gov

HHS Announces the Availability of $195 Million to Expand Substance Abuse and Mental Health Services at Health Centers Nationwide

The Department of Health and Human Services (HHS) announced the availability of $195 million in a new funding opportunity for community health centers to expand access to mental health and substance abuse services focusing on the treatment, prevention and awareness of opioid abuse in all U.S. states, territories and the District of Columbia. The awards are expected to be made in September of this year.

Health centers that receive an award will use the funds to increase the number of personnel dedicated to mental health and substance abuse services and to leverage health information technology and training to support the expansion of mental health and substance abuse services and their integration into primary care.

This funding will address two of Health and Human Services' highest priorities: to better address serious mental illness and to fight the opioid epidemic.

The Trump Administration and Secretary Price have identified the opioid crisis as one of the top priorities for improving the health of the American people. HHS has outlined five specific strategies to combat the ongoing opioid crisis: improving access to treatment and recovery services; targeting availability and distribution of overdose-reversing drugs; strengthening timely public health data and reporting; supporting cutting-edge research; and advancing the practice of pain management.

"Addressing serious mental illness across our nation and combating the opioid epidemic are two of the Department's top priorities," said the HHS Secretary. "Integration is key to solving these challenges. This funding will help our nation's health centers provide that integration for mental health services and opioid addiction treatment."

"Providing behavioral health care in a primary medical care

setting reduces costs and leads to improved patient outcomes," said Dr. George Sigounas, Administrator of the Health Resources and Services Administration (HRSA). "This is especially true when it comes to substance abuse, including opioid addiction."

HRSA's Health Center Program provides funding to community-based health care providers in underserved areas. Nearly 1,400 community health centers operate at more than 10,400 sites, providing care to over 24 million people across the nation, in every state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin.

Today, health centers employ nearly 190,000 people. With this new funding opportunity, health centers will be able to increase personnel to help expand access to mental health services and substance abuse services.

Applications for the Access Increases for Mental Health and Substance Abuse Services (AIMS) award are due July 26, 2017.

Additionally, the Federal Office of Rural Health Policy (FORHP) is making $3 million available to expand opioid-related healthcare services in rural communities. The grants will support up to 12 grantees for three years. Applications for the FORHP program are due July 21, 2017.

The Trump Administration and Secretary Price have identified the opioid crisis as one of the top priorities for improving the health of the American people. HHS has outlined five specific strategies to combat the ongoing opioid crisis: improving access to treatment and recovery services; targeting availability and distribution of overdose-reversing drugs; strengthening timely public health data and reporting; supporting cutting-edge research; and advancing the practice of pain management.

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HRSA Awards $200 Million to Health Centers Nationwide to Tackle Mental Health and Fight the Opioid Overdose Crisis

The Health Resources and Services Administration (HRSA) awarded more than $200 million to 1,178 health centers and 13 rural health organizations in every U.S. state, the District of Columbia, Puerto Rico, the Virgin Islands, and the Pacific Basin to increase access to substance abuse and mental health services.

"No corner of our country, from rural areas to urban centers, has escaped the scourge of the opioid crisis," said HHS Secretary Tom Price, MD. "The Trump Administration is taking strong, decisive action to respond to the crisis caused by the opioid epidemic. These grants from HRSA go directly to local organizations, which are best situated to address substance abuse and mental health issues in their own communities."

Approximately $200 million will support 1,178 health centers to support expansion and integration of mental health services and substance abuse services. These services focus on the treatment, prevention, and awareness of opioid abuse in the primary care setting by increasing personnel, leveraging health information technology, and providing training.

The expanded funding is part of the Department of Health and Human Services' five-point strategy to fight the opioid epidemic by:

- Improving access to treatment and recovery services.
- Targeting use of overdose-reversing drugs.
- Strengthening our understanding of the epidemic through better public health surveillance.
- Providing support for cutting-edge research on pain and addiction.
- Advancing better practices for pain management.

"Nationally, about half of all care for common mental health conditions happens in the primary care settings," said HRSA Administrator George Sigounas, MS, PhD. "In health centers, where people are often most comfortable, staff with varied expertise have a unique opportunity to provide mental health and substance abuse services to patients who wouldn't otherwise seek or have access to treatment."

Rural states are more likely to have higher rates of overdose

death, particularly from prescription opioid overdose. To address their unique needs, 496 of the health centers that receive The Access Increases in Mental Health and Substance Abuse Services (AIMS) awards are located in rural communities.

An additional nearly $3.3 million supports 13 rural health organizations to increase access to treatment and recovery services for opioid abuse under the Rural Health Opioid Program (RHOP) and the Substance Abuse Treatment Telehealth Network Grant Program (SAT-TNGP). The organizations will use these awards to advance evidence-based, opioid use disorder interventions to overcome challenges in rural communities, such as longer emergency response times and lack of access to substance abuse treatment providers.

The new RHOP provides approximately $2.5 million for 10 rural health organizations in Arizona, Arkansas, Indiana, Kentucky, Maine, Maryland, Montana, Ohio, and Virginia to help community members struggling with opioid abuse find locally available treatment options and support services through partnerships with local health care providers and other community-based groups.

The SAT–TNGP provides approximately $670,000 for three organizations to use evidence-based, telehealth programs and networks to improve access to substance abuse treatment in rural, frontier and underserved communities.

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NIAAA Alcohol Treatment Navigator Points the Way to Quality Treatment

A new online resource is now available to help people recognize and find high quality care for alcohol use disorder, which affects more than 15 million adults in the United States. The Alcohol Treatment Navigator, designed by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), part of the National Institutes of Health, is a comprehensive, yet easy-to-use tool to help individuals and their loved ones navigate the often-complicated process of choosing treatment for alcohol problems. With many treatment options available, the navigator makes the search easier by telling them what they need to know - and what they need to do — to find appropriate, quality care.

"We developed this tool to help address the alcohol 'treatment gap,'" said NIAAA Director George F. Koob, PhD. "In any given year, less than 10 percent of individuals diagnosed with alcohol use disorder receive treatment, and many of them do not receive the type of care that best fits their needs. A big reason for that, we believe, is that people with alcohol use disorder often don't know where to turn for help. The Alcohol Treatment Navigator offers a comprehensive strategy to help people search for professionally-led, evidence-based alcohol treatment, which should improve their chances for success."

The release of the Alcohol Treatment Navigator culminates a nearly two-year development effort grounded in a review of decades of scientific research on clinical interventions and health services, and with input from people seeking alcohol treatment, treatment providers, and researchers.

"Good alcohol treatment can be very hard to find," said Lori Ducharme, PhD, NIAAA's program director for Health Services Research and lead developer of the navigator. "Knowing where to look for treatment is difficult, mainly because treatment takes many forms which often are not well integrated into general health care. That makes it hard for people to find the kind of care that they need, when they need it. The navigator is designed to take the mystery and frustration out of that search by guiding them through a step-by-step process to find a qualified treatment provider."

Another factor, notes Dr. Ducharme, are popular stereotypes about alcohol treatment. Many people think their only treatment options are either a mutual help group or a long-term residential rehab facility. While those options certainly can be helpful for some people, they are not a good fit for everyone.

"In fact, a theme of the navigator is that different people need different options," said Dr. Ducharme. "We need to help people understand the whole range of treatment options that are available, how to find one that meets their unique needs and preferences, and that treatments with the strongest chances for success are those that are informed by the results of rigorous scientific research on alcohol use disorder."

Overall, the Alcohol Treatment Navigator is an easy-to-use and comprehensive resource that can inform the search for quality treatment. It includes:

- An overview of alcohol use disorder
- A description of different kinds of professionally-led treatment options
- Step-by-step instructions for searching several existing online directories of treatment providers, including information from the Substance Abuse and Mental Health Services Behavioral Health Treatment Locator
- Ten questions to ask a provider, and 5 signs of quality to listen for
- A downloadable Toolkit to help organize and simplify the search process

As its name implies, the navigator is designed to help point the way to evidence-based alcohol treatment options delivered by skilled health professionals, and to help people choose the best options for their specific situations.

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CPG

Expanding Hearing Healthcare

Addressing an urgent public health need

Mild-to-moderate hearing loss affects more than 60 percent of 70-year-olds, and more than 80 percent of 80-year-olds have hearing loss, according to NIH's National Institute on Deafness and Other Communication Disorders (NIDCD).

Hearing health care affordability and accessibility is an urgent public health problem. Nearly 37.5 million adults in the U.S. report hearing loss in one or both ears. This number is rising as the number of senior citizens increases.

"Hearing loss is a hidden disability that usually occurs gradually over time, so it's often hard to know how much hearing loss you have or how much you're missing," says Debara Tucci, MD, of Duke University.

An NIDCD-funded researcher, Dr. Tucci specializes in ear surgery and health care for people with hearing disorders. She says that if hearing loss is not treated, it can result in serious health, social, and financial problems.

"People with hearing loss have a higher risk of falls, depression, and hospitalization. They also have more difficulties accessing health care," Dr. Tucci says. Hearing loss has also been associated with a higher risk of social withdrawal and dementia in older adults.

Of the millions of adults who could benefit from hearing aids, only 25 percent has actually used one, according to NIDCD.

Social stigma

There are many reasons why people with hearing loss don't use hearing aids. One reason is that there is a stigma associated with them.

Photo Courtesy of the Food and Drug Administration (FDA)

"People often see hearing aids as a sign of being old, so they avoid getting the help they need," Dr. Tucci says. Before seeking medical treatment, most hearing aid users have lived with hearing loss for more than 10 years, and their hearing has become worse over time.

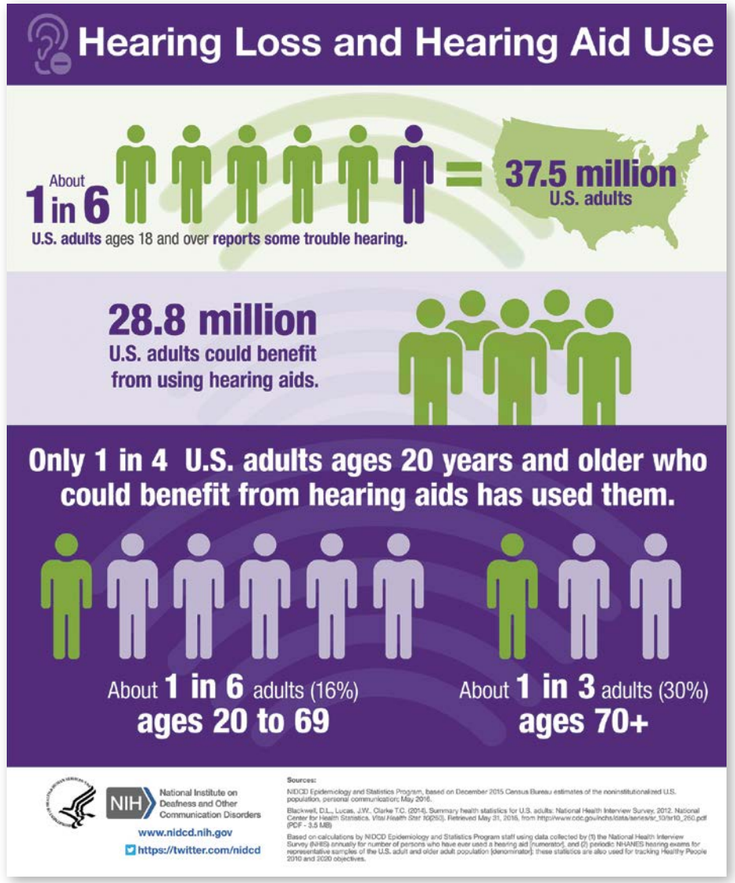
Hearing aids, provider visits, and other hearing care treatment can also be very expensive. Medicare and Medicaid offer limited to no coverage for hearing aids, which can cost up to $3,000 per aid.

Researchers have been exploring why many people don't get the help they need and whether there are ways to ensure that more adults with mild-to-moderate hearing loss get hearing health care.

"The NIDCD has a long history of research and discovery in hearing health," says NIDCD Director James F. Battey, Jr., MD, PhD. "We support studies not only on how we hear, but also on technologies to help people hear better and on delivery models to get hearing loss interventions into the hands of the people who need them."

One study recently found that participants who selected pre-programmed hearing aids using an over-the-counter delivery model reported a similar level of benefit as participants who purchased the same hearing aids through an audiologist following best practices.

The audiology services included fitting the hearing aids and counseling the consumers on how to use them. The study is the first randomized, double-blind, controlled clinical trial to compare the effectiveness of two service-delivery models of hearing aids.



Larry Humes, PhD, professor of speech and hearing sciences at the University of Indiana, is the lead researcher on the study. "I'm excited about the research results," Dr. Humes says. "I'd like more hearing aids to be available to consumers."

On August 18, 2017, a new law was established that will provide more options for some adults with hearing loss. The law gives the Food and Drug Administration (FDA) three years to create standards for safety, effectiveness, and labeling of over-the-counter hearing aids. This new law was a provision in the FDA Reauthorization Act of 2017.

Over-the-counter hearing aids would be FDA-approved for adults with perceived mild-to-moderate hearing loss. Consumers would not need to see licensed hearing professional to purchase certain hearing aids.

Advocates of the law expect the cost of the hearing aids will be much lower than hearing aids sold through current service delivery models.

FDA is developing language to help consumers determine if they are a good candidate for these devices, or if they have symptoms that suggest that they should see a health care professional.

"Over the counter is a good option for people who think they have hearing loss," says Dr. Humes. "It's an affordable way for people to try out the hearing aids at low cost. As their hearing needs become more complex, they may then go to a professional to get more assistance."

"People think they can just use a hearing aid and they will have 20-20 hearing, like they do with eyeglasses," says Dr. Humes. "The problem with older adults and hearing loss is a little more complex."

It takes weeks or months to get used to the louder sound from hearing aids. And treating a hearing problem involves adjustments for the inner ear and the brain.

"The convenience of over-the-counter hearing aids is good, but older people must not have expectations that they will hear like a 20-year-old again as soon as they put on their hearing aids," Dr. Humes says.

Photo Courtesy of the CDC

Adults with perceived mild- to-moderate hearing loss are encouraged to check out low-cost hearing care options when they become available.

And, if you are over 65, a visit with an audiologist should be within reach.

"I encourage everyone over age 65 to see their primary care doctor and get a referral to an audiologist for a hearing test, which is covered by Medicare," advises Dr. Tucci. "This is the best way to determine if you have hearing loss and to prevent other health issues related to hearing loss."

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Hearing Loss Can Challenge Relationships

It can trigger feelings of frustration, guilt and isolation — for patients and those who love them

By Mary Elizabeth Dallas

People with hearing loss face daunting challenges, but so do those who love them, researchers report.

Problems with hearing can be socially isolating for everyone involved, the British researchers explained.

"This is research which reviews the existing evidence we have on the impact of hearing loss on those diagnosed with the condition, as well as those around them," said study leader Venessa Vas, who's with the National Institute of Health Research Nottingham Biomedical Research Center.

Vas and her colleagues analyzed more than 70 existing studies investigating the problems faced by people with hearing loss. The studies also examined the issues faced by people who are close to someone with hearing impairments.

"Hearing loss is a chronic condition that affects the whole family," Vas said in a University of Nottingham news release. "Yet, to our knowledge, our work represents the first attempt to piece together a picture of the effect of hearing loss from the perspectives of people with hearing loss and their partners."

Some of the most common issues faced by people with hearing loss, as well as those closest to them, include:

- **Phone calls.** People with trouble hearing often can't hear the phone ring or hear a person talking on the other end. On the flip side, those around them report feeling frustrated by having to constantly answer the phone or alert someone when it's ringing.
- **Volume control.** People with hearing loss often raise the volume on the radio and TV, which may be problematic for those nearby.
- **Social isolation.** People with hearing loss often have trouble talking in crowds or noisy environments, which leaves them feeling left out or isolated from others. Meanwhile, their friends and loved ones may enjoy socializing, but be forced to attend events alone.
- **Guilt and frustration.** Hearing loss can make communication much more difficult and draining. This can put added strain on relationships, particularly when a partner feels guilty about not understanding the problems people with hearing loss face.

U.S. Fire Administration installs smoke alarms with flashing lights or vibrating signals for people with hearing loss

"Evidence from video-recorded audiology appointments shows that family members have a strong interest in being involved and sharing their experiences of the patient's hearing loss," Vas said. "However, they are typically discounted by the audiologist."

The researchers concluded that by listening to patients' loved ones and friends during office visits, doctors can get a more accurate picture of the hearing loss challenges they face and develop better treatment plans to help them manage these difficulties.

The findings were published recently in the journal *Trends in Hearing.*

SOURCE: University of Nottingham

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High Blood Pressure Linked to Racial Segregation in Neighborhoods

Living in racially segregated neighborhoods is associated with a rise in the blood pressure of black adults, while moving away from segregated areas is associated with a decrease — and significant enough to lead to reductions in heart attacks and strokes, a National Institutes of Health-funded study has found.

The findings, reported in the May issue of JAMA Internal Medicine, offer further evidence that policies to reduce residential racial segregation may have meaningful health benefits, especially for African-Americans, who suffer the highest rates of hypertension of any group in the United States.

Residential segregation, the separation of groups into different neighborhoods by race, has long been identified as a major cause of health disparities between blacks and whites. This is the first study to explore whether increases or decreases in residential segregation specifically affect blood pressure.

"Our study suggests that the stress and the inadequate access to health-promoting resources associated with segregation may play a role in these increases in blood pressure," said David Goff, MD, director of the Division of Cardiovascular Diseases of the National Heart, Lung, and Blood Institute (NHLBI), part of NIH. "While stress raises blood pressure, access to health-promoting resources, such as full service grocery stores, recreation centers, and health care clinics, is critical to keeping blood pressure at healthier levels."

Partly funded by NHLBI, the researchers examined blood pressure readings for 2280 blacks who participated in the Coronary Artery Risk Development in Young Adults (CARDIA) study. The project focused on adults aged 18-30, who were initially screened in 1985 and 1986 and then re-examined several times over the next 25 years.

Neighborhood segregation was categorized as high, medium or low based on a scale that compares the percentage of black residents in a neighborhood to the surrounding area.

The study found that when their neighborhoods were more segregated, the participants experienced small but statistically significant increases in systolic blood pressure. The opposite was also true. Reductions in segregation correlated with a notable decrease in blood pressure.

The most significant improvements were experienced by those who initially lived in a highly segregated neighborhood and moved to a less segregated one. Their systolic blood pressure (top number) dropped 3 to 5 mm Hg.

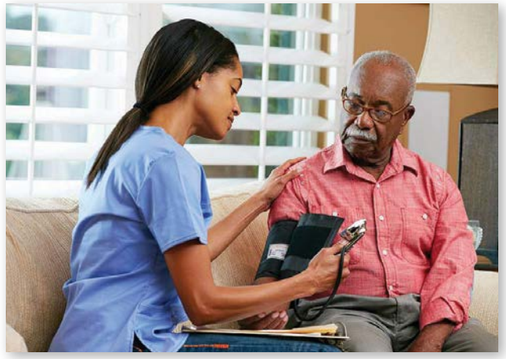
"This is a powerful effect," said lead author Kiarri Kershaw, an assistant professor of preventive medicine at Northwestern University Feinberg School of Medicine.

"In terms of impact, just 1 mm Hg of reduction of the systolic blood pressure at the population level could result in meaningful reductions in heart attacks, strokes and heart failure."

These links persisted even after researchers took into account the participants' marital status, body mass index, smoking history, physical activity levels, and the socio-economic status of their communities.

"Longitudinal, long-term studies like CARDIA make this research possible and are critical to our ability to shine a light on the root causes of chronic diseases, such as heart disease," Goff said. "Only by understanding these root causes can we effectively promote health and health equity at the societal level."

Kershaw and coauthors concluded that improved access to resources for those living in segregated neighborhoods, as well as opportunities for residents in those areas to move to places with better access to resources, could help reduce persistent racial health disparities.



A healthcare worker checks a man's blood pressure.

nih.gov

CPG

After Heart Attack, Just 1 in 3 Go for Rehab

Recommended outpatient treatment reduces risk of recurrence

By Margaret Farley Steele

Only one in three heart attack survivors in the United States goes for outpatient cardiac rehabilitation, government health officials report.

Despite guidelines that recommend rehab for reducing the risk of future heart attacks, it's greatly underused, according to statistics released Thursday by the U.S. Centers for Disease Control and Prevention.

Each year, about 790,000 U.S. adults have heart attacks, of which 210,000 are repeat heart attacks, the CDC report said.

Exercise counseling, healthy heart lifestyle advice and stress-reduction tips — which are part of cardiac rehab — help reduce those odds of recurrence. There's another advantage as well: extended medical supervision after discharge, the researchers said.

The report was led by Dr. Jing Fang, of the CDC's division for heart disease and stroke prevention. Fang's team analyzed health survey data from 20 states and the District of Columbia in 2013. It also looked at survey results from four states in 2015.

In 2013, 34 percent of roughly 9,000 heart attack survivors entered cardiac rehab after leaving the hospital. Among the four states studied in 2015, that number was only slightly higher -- about 36 percent, the researchers reported.

Looking at who did and did not go for cardiac rehab, researchers found women, blacks, Hispanics, younger adults and less-educated patients were more likely to skip the recommended post-discharge treatment.

Lack of insurance was also linked to lower odds for cardiac rehabilitation.

State-by-state differences were also significant. In Hawaii, just one in five heart

attack patients entered cardiac rehab in 2013 compared to 60 percent of heart patients in Minnesota, the findings showed.

These "suboptimal" rates put thousands of people at risk of another heart attack, the researchers stressed.

Heart experts agreed.

"Recent data has shown that enrollment in cardiac rehab has been associated with improved outcomes and even decreased mortality in patients with significant cardiac events, especially those who have suffered a heart attack," said Dr. Rachel Bond. She is associate director of women's heart health at Lenox Hill Hospital in New York City.

"Despite that, this paper highlights a problem that is widespread in our field," Bond noted.

"Interestingly, this paper was able to show certain factors and groups that are even more underutilizing cardiac rehab," she added. "This included minorities, younger patients, low socioeconomic income patients, patients with less co-morbid conditions and females."

Bond suggested that "we may have the biggest impact at targeting these groups, as they stand to benefit as much, if not more, than any patient who has suffered a heart attack."

How to do that?

The CDC researchers suggested that lowering out-of-pocket costs and standardizing referrals might help boost rates. Also, access to affordable cardiac rehab programs should become a priority, especially in areas with the lowest rehabilitation rates.

"Health-system interventions to promote cardiac rehab referral and use, supported by access to affordable rehab programs within the community, should be prioritized to improve outcomes and prevent recurrent events," Fang and colleagues wrote in the report.

Another heart expert said there is no downside to cardiac rehab.

Recent data has shown that enrollment in cardiac rehab has been associated with improved outcomes and even decreased mortality in patients with significant cardiac events, especially those who have suffered a heart attack.

— Dr. Rachel Bond, Lenox Hill Hospital

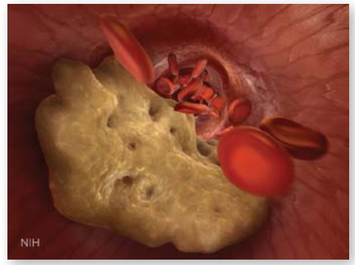


Illustration of artery partially blocked by a cholesterol plaque

"Cardiac rehabilitation has been shown to increase life expectancy and reduce the emotional and physical challenges heart attack survivors often experience," said Dr. Benjamin Hirsh. He directs preventive cardiology at Northwell Health's Sandra Atlas Bass Heart Hospital, in Manhasset, N.Y.

The analysis was published in the Aug. 25 issue of the CDC's Morbidity and Mortality Weekly Report.

SOURCES: Rachel Bond, MD, associate director, women's heart health, Lenox Hill Hospital, New York City; Benjamin Hirsh, M.D., director, preventive cardiology, Northwell Health's Sandra Atlas Bass Heart Hospital, Manhasset, N.Y.; U.S. Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report

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Preventable Deaths from Heart Disease & Stroke

Improving care can save more lives

Nearly 1 in 3 deaths in the US each year is caused by heart disease and stroke. At least 200,000 of these deaths could have been prevented through changes in health habits, such as stopping smoking, more physical activity, and less salt in the diet; community changes to create healthier living spaces, such as safe places to exercise and smoke-free areas; and managing high blood pressure, high cholesterol, and diabetes.

More people will have access to health care coverage and preventive care through the Affordable Care Act. Health care providers should talk with their patients about healthy habits at every visit and follow patients' progress.

Health care systems and providers can also:

- Use electronic health records to identify and support patients who need help quitting smoking or who have high blood pressure or high cholesterol.
- Refer patients to community resources, such as smoking quitlines and blood pressure selfmanagement programs.
- Track patient progress on the ABCS of heart health—Aspirin when appropriate, Blood pressure control, Cholesterol management, and Smoking cessation.

*Preventable (avoidable) deaths are defined as those from ischemic heart disease, stroke, chronic rheumatic heart disease, and hypertensive disease in people under age 75, although changes in health habits and the health care system can reduce death among all ages. Many deaths from heart disease and stroke can be prevented.

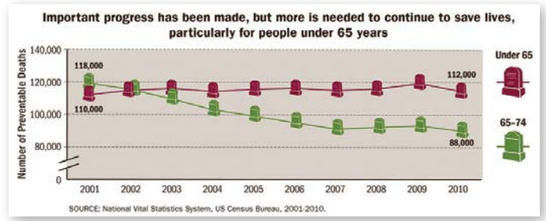
What do we know about preventable deaths from heart disease and stroke?

Your chances of dying from heart disease and stroke depend on many things.

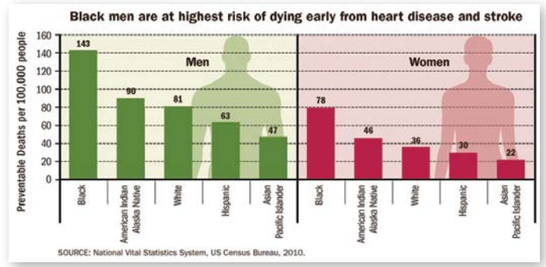
Age: While the number of preventable deaths has declined in people ages 65-74, it has remained virtually unchanged in people under 65.

Important progress has been made, but more is needed to continue to save lives, particularly for people under 65 years

Race/ethnicity: Blacks are nearly twice as likely as whites to die early from heart disease and stroke.



National Vital Statistics System, US Census Bureau, 2001-2010



National Vital Statistics System, US Census Bureau, 2010

Sex: Men have the highest risk of death across all races and ethnic groups. Black men are most at risk. Black men are at highest risk of dying early from heart disease and stroke.

Health departments and community organizations can:

- Work with health care systems to monitor national quality indicators, including "controlling high blood pressure," and carry out quality improvements, such as clinical innovations including team-based care.
- Encourage health systems to use health information technology to identify patients who have high blood pressure. Establish follow-up systems to monitor those patients.
- Promote smoking quitlines, tobacco-free areas, safe walking areas, and access to healthy food.
- Partner with hospitals to address health care issues in the community and perform a community health needs assessment to ensure interventions reach those most in need.

cdc.gov

State Heart Disease and Stroke Prevention Programs Take Action

State Health Departments work to prevent and control high blood cholesterol and reduce the burden of heart disease and stroke by promoting activities that can be implemented in health care, work sites, communities, and schools. For example, a state program might:

- Promote policy development, training, and system changes (e.g., electronic medical records, automated prescription systems, and paper or electronic reminders) to assist health care practitioners to adhere to treatment protocols consistent with national guidelines for preventing and controlling high blood cholesterol.
- Partner with organizations to assure that detection and follow–up services are available for controlling high cholesterol in various settings, including health care, work site, and community.
- Promote the use of clinical care teams that include health educators to assure consistent screening, detection, risk–factor education, medication monitoring, and follow–up to prevent and control high blood cholesterol.
- Educate the public using simple and frequent messages that high blood cholesterol is a major modifiable risk factor for heart disease and stroke, and that having one's blood cholesterol checked is an important first step in identifying and controlling high blood cholesterol and reducing the risk of heart disease and stroke.
- Collaborate on professional medical education, self–care workshops, policy interventions, and incentives to improve detection and control of high blood cholesterol.
- Encourage health care insurance coverage for blood cholesterol screening, treatment, and control, as well as rehabilitation services for heart attack and stroke survivors.
- Partner with other agencies to establish organizational policies and environmental interventions that support healthy lifestyles including access to screening, low–cost healthy food choices, smoke–free facilities, stress management options, and places for physical activity.

ATP* III Classification of LDL, HDL, Total Cholesterol and Triglycerides (milligrams/deciliter [mg/dL])†

LDL (Bad) Cholesterol	
Less than 100	Optimal
100–129	Near optimal/above optimal
130–159	Borderline high
160–189	High
190 and above	Very high
HDL (Good) Cholesterol	
Less than 40	Low
60 and above	High (Protective against heart disease)
Total Cholesterol	
Less than 200	Desirable
200–239	Borderline high
240 and above	High
Triglycerides	
Less than 150	Desirable
150–199	Borderline high
200–499	High
500 and above	Very high
*ATP = Adult Treatment Panel	

† Note: From the Third Report of the National Cholesterol Education Program (NCEP) on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), by the National Heart, Lung, and Blood Institute of the National Institutes of Health, May 2001, pg. 3.

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Severe Psoriasis Linked to Higher Risk of Earlier Death

But experts say there may be ways to reduce those odds

People with severe cases of the skin disease psoriasis appeared to have almost double the risk of dying during a four-year study than people without the condition, research suggests.

But the increased death rate was only seen in those with psoriasis affecting more than 10 percent of their body surface area. For those with less-severe disease, the risk of dying early was actually less than it was for people who didn't have the skin condition.

Dr. Robert Kirsner, chair of dermatology at the University of Miami Miller School of Medicine, said that over the last decade or so, doctors have learned that people with psoriasis tend to be less healthy.

"They are overweight, have diabetes mellitus, smoke, drink and have high cholesterol," he said.

"These factors — as well as the presence of psoriasis itself — increases their risk for vascular disease and other poor medical outcomes. As a result, they more often have heart attacks and strokes and more often die," Kirsner said. He wasn't involved in the current research, but did review the findings.

Kirsner and study author Dr. Megan Noe suggested that people with severe psoriasis talk with their doctor about treating their psoriasis and controlling risk factors that may contribute to a higher risk of early death, such as smoking, high cholesterol and diabetes.

It's also important to note that it's not clear from this study alone whether severe psoriasis actually causes a higher death rate, or if there's just an association between those factors.

The study included nearly 8,800 adults with psoriasis and almost 88,000 without the condition. The study participants were followed for about four years on average.

The study volunteers all lived in the United Kingdom. About half of the participants were women. Their average age was about 45. Those with psoriasis were more likely to smoke and to drink alcohol.

After the researchers adjusted their statistics so they wouldn't be thrown off by factors such as smoking and diabetes, they found that those with the highest level of psoriasis -- affecting more than 10 percent of their body surface -- were nearly two times more likely to die over the period of the study.

About 12 percent of the psoriasis patients fell into the severe category, the researchers said.

When it comes to death rates, severe psoriasis is riskier than smoking and but less risky than diabetes, said Noe.

She teaches clinical dermatology at the University of Pennsylvania.

People with less-severe psoriasis were slightly less likely to die than the general population. And, that held true even when the researchers took other risk factors into account, such as age, smoking status and weight.

There are theories, but not firm evidence, about why there's a link between extreme psoriasis and higher death rates, Kirsner said.

One theory is that psoriasis creates more inflammation — swelling — in the body, which hurts the arteries and veins.

It's also possible that people with psoriasis already have body-wide inflammation that isn't caused by the skin condition.

Maria Morasso, PhD, Chief of the NIAMS Laboratory of Skin Biology, discusses NIAMS research with representatives from the National Psoriasis Foundation during a visit to NIAMS

Another possibility is that the social stigma of psoriasis could contribute to mental conditions, such as depression, by making it harder for patients to do certain things, including finding a job, Noe suggested.

Should patients with extreme psoriasis be very worried about their condition? Kirsner said that in terms of a higher risk of premature death, "we know that worse psoriasis and having psoriasis longer are important, but the individual risk for any given patient is not clear."

The researchers didn't estimate average life span in this study.

Patients with psoriasis, especially severe psoriasis, should work with their doctors to treat the condition, reduce their cholesterol, stop smoking, lower their weight, control their blood sugar, exercise and take aspirin, Kirsner said.

The National Psoriasis Foundation recommends talking with your doctor about the risks and benefits of medications, such as aspirin, before taking them.

Noe said, "We have lots of very successful treatments, and the newer biologic medications work for most people."

However, Kirsner added, while "treatments likely matter, whether any treatment will help reduce risk is not clearly known."

The study was published Aug. 29 in the Journal of Investigative Dermatology.

SOURCES: Megan Noe, MD, MPH, clinical instructor, department of dermatology, University of Pennsylvania; Robert Kirsner, MD, PhD, chairman and professor, department of dermatology and cutaneous surgery, and professor, department of public health sciences and director, University of Miami Hospital Wound Center, University of Miami Miller School of Medicine

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Scientists Identify Single-gene Mutations That Lead to Atopic Dermatitis

NIH-supported research suggests potential treatment strategy

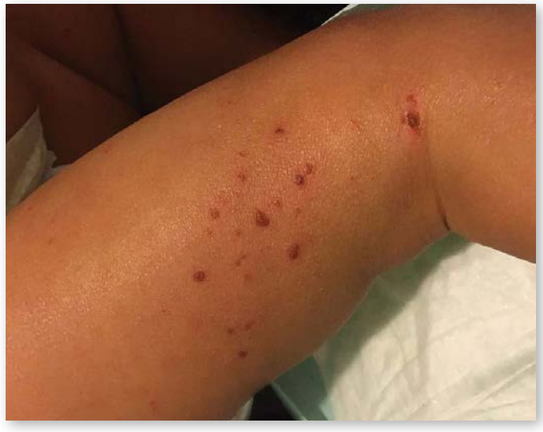
By Joshua Milner, MD, chief of the Genetics and Pathogenesis of Allergy Section in NIAID's Laboratory of Allergic Diseases

Researchers have identified mutations in a gene called CARD11 that lead to atopic dermatitis, or eczema, an allergic skin disease. Scientists from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, and other institutions discovered the mutations in four unrelated families with severe atopic dermatitis and studied the resulting cell-signaling defects that contribute to allergic disease.

Their findings, reported in Nature Genetics, also suggest that some of these defects potentially could be corrected by supplementation with the amino acid glutamine.

The scientists analyzed the genetic sequences of patients with severe atopic dermatitis and identified eight individuals from four families with mutations in the CARD11 gene, which provides instructions for production of a cell-signaling protein of the same name.

While some people with these mutations had other health issues, such as infections, others did not, implying that mutations in CARD11 could cause atopic dermatitis without leading to other medical issues often found in severe immune system syndromes.



Eczema, or atopic dermatitis, is an inflammatory skin condition that affects an estimated 30 percent of the U.S. population, mostly children and adolescents. Photo credit: NIAID

The Laboratory of Allergic Diseases (LAD) Staff, August 2017

The scientists next set out to understand how the newly discovered CARD11 mutations contribute to atopic dermatitis.

Each of the four families had a distinct mutation that affected a different region of the CARD11 protein, but all the mutations had similar effects on T-cell signaling.

With cell culture and other laboratory experiments, the researchers determined that the mutations led to defective activation of two cell-signaling pathways, one of which typically is activated in part by glutamine.

Growing cultured T cells from patients with CARD11 mutations with excess glutamine boosted mTORC1 activation, a key part of one of the affected pathways, suggesting the potential to partially correct the cell-signaling defects that may contribute to atopic dermatitis.

The scientists now are planning a study to assess the effect of supplemental glutamine and leucine, another amino acid that activates mTORC1, in people with atopic dermatitis with and without CARD11 mutations.

nih.gov

Putting Policy to Work on the Ground

By Rachel Kaul, Senior Policy Analyst, Office of the Assistant Secretary for Preparedness and Response (ASPR)

Rachel Kaul

I haven't always been in policy — or in crisis counseling. And I haven't always worked for the government.

But after working in sales and management for a weight loss company, my life took a dramatic turn. In 1995, I was diagnosed with cervical/uterine cancer. The difficulty of navigating the U.S. healthcare system on my own inspired me to make a change, and I went to the University of Michigan to get my master's in social work intending to work in women's oncology.

However, while getting my master's, I found my true calling in trauma work, joining ride-alongs and fly-alongs with first responders, and working in the ER. I have seen many people through the worst moments of their lives.

On 9-11, I was driving to the D.C. area to visit my parents when the Red Cross contacted me to help survivors at the Pentagon. I volunteered as a disaster mental health responder. I provided support on site to responders recovering the dead and also to survivors of the attack who had returned to work in the building. A month later, the Red Cross sent me to ground zero in New York. At the respite center there, I helped responders to cope and to carry on.

I developed disaster mental health training programs and plans for the state of Maryland and, later, for the federal Substance Abuse and Mental Health Services Administration. Two weeks into my job at SAMHSA, Hurricane Katrina hit New Orleans, and off I went, this time working on federal crisis counseling grant programs for survivors on the Gulf Coast and also for those displaced all across the nation.

Office of Public Health Preparedness and Response Board of Scientific Counselors 2017

I have since joined ASPR's Division for At-Risk Individuals, Behavioral Health and Community Resilience. We coordinate federal and local behavioral health partners in disaster response. This means that when public health emergencies and disasters happen, we find where the needs are and quickly mobilize resources to meet them.

At ASPR, it's about "giving it away." Whatever knowledge or tools you have that can help, you get it out there. When I was thinking about doing policy work, a mentor said: "If you can do both policy and clinical work, you should do it." And I agreed. If you are called to do something, do it.

ASPR's programs help save lives. We translate policy into practice. Disasters are not going away. Weather events, manmade events — they will continue to show up on our doorsteps. We're ready when they do.

This work is about humanity, compassion and meaning. Sometimes the 30,000-foot work, the policy work, may not feel as personal and critical as being on the ground, but it makes all that other work possible.

I'm Rachel Kaul. I'm a social worker and a change agent. And I Am HHS.

Rachel Kaul works in the Office of the Assistant Secretary for Preparedness and Response, and is one of more than 79,000 individuals who make HHS run every day.

hhs.gov

HHS Medical Reserve Corps Volunteers Aiding Local Response to Hurricane Harvey

Amid the devastation wrought by Hurricane Harvey along the Texas coastline, more than 1,000 local members of the U.S. Department of Health and Human Services' Medical Reserve Corps (MRC) Program have been volunteering to meet the overwhelming community needs in the storm's wake.

"While Medical Reserve Corps volunteers are vital to supporting their local communities' public health every day, their efforts during disasters are essential," said HHS' Assistant Secretary for Preparedness and Response (ASPR) Dr. Robert Kadlec. "These volunteers live in the communities where they are serving and have been personally impacted by the storm, which makes their readiness and willingness to respond to their neighbors' needs especially admirable."

Medical professionals who serve as members of their local MRCs also are providing medical services at shelters, as well as psychological first aid and other mental health services for patients and family members.

Veterinary volunteers with the MRC assisted with animal rescues and provided emergency care in Texas, and are caring for displaced pets at an animal shelter in Oklahoma where animals from storm-impacted areas have been transported after local resources were strained.

MRC volunteers also are supporting local Hurricane Harvey response efforts in 16 Texas counties, managing administrative functions at 28 shelters and three evacuation centers; providing information and resources to storm victims at call centers, and helping to manage and distribute donations, including cleaning supplies, personal care items, diapers and other items.

Approximately 20 MRC units active in local responses to Hurricane Harvey come from the following Texas counties: Bell, Bexar, Brazoria, Brazos, Dallas, Denton, Fort Bend, Galveston, Nolan, and Tarrant. In Louisiana, MRC volunteers from Orleans and Calcasieu Parishes have contributed to the disaster response. In Oklahoma, MRC volunteers from Tulsa and Oklahoma Counties are participating in the response.

The MRC is a national network of volunteers, organized locally to improve the health and safety of their communities. The MRC network comprises nearly 1,000 community-based units and almost 200,000 volunteers located throughout the United States and its territories.

MRC volunteers include medical and public health professionals, as well as other community members without healthcare backgrounds. MRC units engage these volunteers to strengthen public health, improve emergency response capabilities, and build community resiliency.

In addition to the support being provided by MRC volunteers, HHS has more than 1,100 personnel from the National Disaster Medical System and U.S. Public Health Service Commissioned Corps on the ground providing care to people affected by Hurricane Harvey. These personnel have so far provided care to more than 1,000 people affected by the storm.

hhs.gov

Keeping Americans Safe Through Hurricane Irma

By Steven Wagner, Acting Assistant Secretary, Administration for Children and Families

Before Hurricane Irma struck the islands east of Florida, the Office of Refugee Resettlement at HHS' Administration for Children and Families started repatriation efforts to ensure Americans were safely transported back to American soil and out of harm's way.

From Saturday evening September 9 through September 15, over 2,600 evacuees were moved from St. Maarten to Puerto Rico. A substantial portion of these individuals will eventually return back to the continental U.S.

This was done in collaboration with the Department of State and Department of Defense, and through the U.S. Repatriation Program. The program was established in 1935 to provide temporary assistance to U.S. citizens who are returning to the US because of a crisis. Once they arrive, the Office of Refugee Resettlement steps in to provide medical care, shelter, food and other necessary services.

This help is in the form of service loans from both the Department of State and Department of Health and Human Services — once the citizens are back on American soil they are expected to repay the government for the help.

The program can be initiated for small or large groups of people. On 9/11, an American citizen on dialysis was helped by HHS and the government of Puerto Rico with urgent travel to return to North Carolina in time for a scheduled kidney transplant procedure.

ACF employees, in conjunction with the Department of State and Department of Defense, will continue to work tirelessly to safeguard the lives of those American citizens in need of assistance.

acf.hhs.gov

A New York Air National Guardsman helps evacuees get comfortable inside a HC-130 Hercules aircraft as it takes off from St. Maarten to San Juan, Puerto Rico, Sept. 10, 2017, during relief efforts following the aftermath of Hurricane Irma. Air Force photo by Staff Sgt. Erin Mill

Tetanus Prevention after a Disaster

In most settings, a disaster does not increase the risk for tetanus. However, the risk of tetanus among disaster survivors and emergency responders can best be minimized by following standard immunization recommendations and providing proper wound care.

Key points to remember

- Patients without a clear history of at least three tetanus vaccinations who have a wound that is anything other than clean and minor NEED tetanus immune globulin (TIG) not
- Passive vaccination with tetanus immune globulin (Hypertet) is useful in treating wounded people who have not been actively vaccinated and those whose wounds are highly contaminated, as well as those with tetanus.
- Tetanus in the United States is most commonly reported in older people who are less likely to be adequately vaccinated than younger persons. From 2001-2008, about half of
- 233 cases reported were among people 50 years or older and about a third were among people 65 years or older. Incidence among Hispanics was nearly twice that among non-Hispanics.
- Older women are especially susceptible; a majority of those 55 years or older do not have protective levels of tetanus antibody.
- Diabetics are at increased risk. Reported tetanus is about 3 times more common and fatalities are about 4 times more common in diabetics.
- Non-acute wounds (e.g., chronic ulcers, gangrene, abscesses/cellulitis) account for about 1 out of 6 cases of reported tetanus; 1 out of 12 reported cases had no reported injury or lesion.

According to the most recent CDC surveillance data, an analysis of sufficiently complete case reports of patients with acute wounds who sought medical care reveals that 96% did not receive postexposure prophylaxis as is recommended.

Age (years)	Vaccination history	Clean, minor wounds	All other wounds
0 through 6	Unknown or not up-to-date on DTaP series based on age	DTaP	DTaP TIG
	Up-to-date on DTaP series based on age	No indication	No indication
	Unknown or incomplete DTaP series	Tdap and recommend catch-up vaccination	Tdap and recommend catch-up vaccination TIG
7 through 10	Completed DTaP series AND <5 years since last dose	No indication	No indication
	Completed DTaP series AND ≥5 years since last dose	No indication	Td, but Tdap preferred if child is 10 years of age
	Unknown or <3 doses of tetanus toxoid containing vaccine	Tdap and recommend catch-up vaccination	Tdap and recommend catch-up vaccination TIG
11 years and older	3 or more doses of tetanus toxoid containing vaccine AND <5 years since last dose	No indication	No indication
	3 or more doses of tetanus toxoid containing vaccine AND 5-10 years since last dose	No indication	Tdap preferred (if not yet received) or Td
	3 or more doses of tetanus toxoid containing vaccine AND >10 years since last dose	Tdap preferred (if not yet received) or Td	Tdap preferred (if not yet received) or Td

*(*if pregnant, see footnote)*

"Patients without a clear history of at least three tetanus vaccinations who have a wound that is anything other than clean and minor NEED tetanus immune globulin (TIG) not just a tetanus toxoid containing vaccine"

Routine vaccination

Primary series of diphtheria, tetanus, acellular pertussis (DTaP) in infancy and childhood. Recommended schedule is 2, 4, 6 months, 15 through 18 months, and 4 through 6 years.

Booster shot of tetanus, diphtheria, acellular pertussis (Tdap) — single dose — in adolescents aged 11 through 18 years who have completed the recommended childhood DTaP vaccination series and adults aged 19 and older. Adolescents should preferably receive Tdap at 11 or 12 years old. After receipt of Tdap, then a booster shot of tetanus, diphtheria (Td) is recommended every 10 years.

**Pregnant Women:* As part of standard wound management care to prevent tetanus, a tetanus toxoid — containing vaccine might be recommended for wound management in a pregnant woman if 5 years or more have elapsed since the previous Td booster. If a Td booster is recommended for a pregnant woman, health-care providers should administer Tdap.

cdc.gov

During winter months, frostbite can also be a tetanus prone wound. Proper treatment begins with checking the patient's immunization history or lack therof, especially so in immigrants/visitors/refugees, older patients, immunocompromised patients, etc.

The need for active immunization, with or without passive immunization, depends on the condition of the wound and the patient's immunization history -MMWR 2006;55[RR-17]

People make their way down partially flooded roads in Galveston, Texas. (© Brendan Smialowski/AFP/Getty Images)

Volunteer rescue workers help an elderly woman from her home, which was inundated by flooding in Port Arthur, Texas. © Joe Raedle/Getty Images

Persons with wounds that are neither clean nor minor, and who have had fewer than 3 prior doses of tetanus toxoid or have an unknown history of prior doses should receive TIG as well as Td or Tdap. This is because early doses of toxoid may not induce immunity, but only prime the immune system. The TIG provides temporary immunity by directly providing antitoxin. This ensures that protective levels of antitoxin are achieved even if an immune response has not yet occurred. -CDC/Epidemiology and Prevention of Vaccine-Preventable Diseases The Pink Book Course Textbook - 13th Edition (2015) - Chapter 21

Important Safety Information

HyperTET® S/D (tetanus immune globulin [human]) is indicated for prophylaxis against tetanus following injury in patients whose immunization is incomplete or uncertain.

HyperTET S/D should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations.

In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, HyperTET S/D should be given only if the expected benefits outweigh the risks.

Slight soreness at the site of injection and slight temperature elevation may be noted at times. Sensitization to repeated injections of human immunoglobulin is extremely rare. In the course of routine injections of large numbers of persons with immunoglobulin, there have been a few isolated occurrences of angioneurotic edema, nephrotic syndrome, and anaphylactic shock after injection. Administration of live virus vaccines (eg, MMR) should be deferred for approximately 3 months after tetanus immune globulin (human) administration.

HyperTET S/D is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses and theoretically, the Creutzfeldt-Jakob disease (CJD) agent that can cause disease. There is also the possibility that unknown infectious agents may be present in such products.

Please see a brief summary of Prescribing Information for HyperTET® S/D (tetanus immune globulin [human]) on the adjacent page or visit www.HyperTET.com for full Prescribing Information.

Hyper**TET**® S/D

Tetanus Immune Globulin (Human) Solvent/Detergent Treated 250 Units

BRIEF SUMMARY
CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

Tetanus Immune Globulin (Human) — Hyper**TET**® S/D is indicated for prophylaxis against tetanus following injury in patients whose immunization is incomplete or uncertain (see below). It is also indicated, although evidence of effectiveness is limited, in the regimen of treatment of active cases of tetanus.

A thorough attempt must be made to determine whether a patient has completed primary vaccination. Patients with unknown or uncertain previous vaccination histories should be considered to have had no previous tetanus toxoid doses. Persons who had military service since 1941 can be considered to have received at least one dose, and although most of them may have completed a primary series of tetanus toxoid, this cannot be assumed for each individual. Patients who have not completed a primary series may require tetanus toxoid and passive immunization at the time of wound cleaning and debridement.

The following table is a summary guide to tetanus prophylaxis in wound management:

Guide to Tetanus Prophylaxis in Wound Management

History of Tetanus Immunization (Doses)	Clean, Minor Wounds		All Other Wounds*	
	Td†	TIG‡	Td	TIG
Uncertain or less than 3	Yes	No	Yes	Yes
3 or more§	No‖	No	No¶	No

* Such as, but not limited to, wounds contaminated with dirt, feces, soil, and saliva; puncture wounds; avulsions; and wounds resulting from missiles, crushing, burns and frostbite.
† Adult type tetanus and diphtheria toxoids. If the patient is less than 7 years old, DT or DTP is preferred to tetanus toxoid alone. For persons ≥7 years of age, Td is preferred to tetanus toxoid alone.
‡ Tetanus Immune Globulin (Human).
§ If only three doses of fluid tetanus toxoid have been received, a fourth dose of toxoid, preferably an adsorbed toxoid, should be given.
‖ Yes if more than 10 years since the last dose.
¶ Yes if more than 5 years since the last dose. (More frequent boosters are not needed and can accentuate side effects).

CONTRAINDICATIONS

None known.

WARNINGS

HyperTET** S/D is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, and, theoretically, the Creutzfeldt-Jakob Disease (CJD) agent that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products. Individuals who receive infusions of blood or plasma products may develop signs and/or symptoms of some viral infections, particularly hepatitis C. ALL infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Grifols Therapeutics Inc. [1-800-520-2807].**

The physician should discuss the risks and benefits of this product with the patient, before prescribing or administering it to the patient.

Hyper**TET** S/D should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations.

In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, Hyper**TET** S/D should be given only if the expected benefits outweigh the risks.

PRECAUTIONS

General

HyperTET** S/D should not be given intravenously.** Intravenous injection of immunoglobulin intended for intramuscular use can, on occasion, cause a precipitous fall in blood pressure, and a picture not unlike anaphylaxis. Injections should only be made **intramuscularly** and care should be taken to draw back on the plunger of the syringe before injection in order to be certain that the needle is not in a blood vessel. Intramuscular injections are preferably administered in the deltoid muscle of the upper arm or lateral thigh muscle. The gluteal region should not be used as an injection site because of the risk of injury to the sciatic nerve.

Chemoprophylaxis against tetanus is neither practical nor useful in managing wounds. Wound cleaning, debridement when indicated, and proper immunization are important. The need for tetanus toxoid (active immunization), with or without TIG (passive immunization), depends on both the condition of the wound and the patient's vaccination history. Rarely has tetanus occurred among persons with documentation of having received a primary series of toxoid injections. See table under INDICATIONS AND USAGE.

Skin tests should not be done. The intradermal injection of concentrated IgG solutions often causes a localized area of inflammation which can be misinterpreted as a positive allergic reaction. In actuality, this does not represent an allergy; rather, it is localized tissue irritation. Misinterpretation of the results of such tests can lead the physician to withhold needed human antitoxin from a patient who is not actually allergic to this material. True allergic responses to human IgG given in the prescribed intramuscular manner are rare.

Although systemic reactions to human immunoglobulin preparations are rare, epinephrine should be available for treatment of acute anaphylactic reactions.

Drug Interactions

Antibodies in immunoglobulin preparations may interfere with the response to live viral vaccines such as measles, mumps, polio, and rubella. Therefore, use of such vaccines should be deferred until approximately 3 months after Hyper**TET** S/D administration.

No interactions with other products are known.

Pregnancy Category C

Animal reproduction studies have not been conducted with Hyper**TET** S/D. It is also not known whether Hyper**TET** S/D can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Hyper**TET** S/D should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

ADVERSE REACTIONS

Slight soreness at the site of injection and slight temperature elevation may be noted at times. Sensitization to repeated injections of human immunoglobulin is extremely rare.

In the course of routine injections of large numbers of persons with immunoglobulin there have been a few isolated occurrences of angioneurotic edema, nephrotic syndrome, and anaphylactic shock after injection.

GRIFOLS

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Research Triangle Park, NC 27709 USA
U.S. License No. 1871

08941121-BS

Acting Secretary Hargan Declares Public Health Emergency in California Due to Wildfires

Following President Trump's major disaster declaration for California, Health and Human Services Acting Secretary Eric D. Hargan declared a public health emergency in California due to the wildfires devastating the state. The declaration allowed the secretary to issue a waiver under section 1135 of the Social Security Act for the state to enable the Centers for Medicare & Medicaid Services to take action that gives beneficiaries and their health care providers and suppliers greater flexibility in meeting critical health needs.

"Wildfires burning across more than 200,000 acres and 10 Northern California counties threaten the lives of tens of thousands of people," said Acting Secretary Hargan. "[This] public health declaration will ensure that those who rely upon Medicare, Medicaid and Children's Health Insurance Program coverage will receive uninterrupted care during this disaster. HHS stands ready to assist California's medical response to the wildfires should it be needed."

HHS deployed four regional emergency coordinators (RECs) for the area to coordinate with state and local emergency response officials. RECs serve as HHS' primary representatives throughout the country at the regional level and build relationships with federal, state, local, tribal and territorial officials and healthcare representatives to plan for effective federal emergency responses and facilitate coordinated response activities with local officials.

A firefighter wipes his face as he searches for survivors at an apartment complex in Rockport, Texas.
© Jabin Botsford/The Washington Post via Getty Images

Photo Courtesy of Air Force Lt. Col. Frank Wilde

Two Regional Incident Support Team pharmacists were deployed to the region to provide technical support if the state requests the activation of the Federal Emergency Management Agency's ambulance contract to support the transport of a large number of patients.

hhs.gov

About Half of Americans Get Health Care in ER

By Robert Preidt

When Americans need medical care, almost one in two people choose the emergency room, a new study reveals.

"I was stunned by the results. This really helps us better understand health care in this country," said Dr. David Marcozzi. He is an associate professor in the University of Maryland's department of emergency medicine.

"This research underscores the fact that emergency departments are critical to our nation's health care delivery system," Marcozzi said in a university news release.

"Patients seek care in emergency departments for many reasons. The data might suggest that emergency care provides the type of care that individuals actually want or need, 24 hours a day," he added.

The analysis of data from several national sources showed that there were more than 3.5 billion emergency department visits, outpatient visits, and hospital admissions during the 1996 to 2010 study period.

U.S. emergency department visits increased by nearly 44 percent over the 14-year period, the findings showed. Outpatient cases accounted for nearly 38 percent of visits, and inpatient care accounted for almost 15 percent of visits.

In 2010, there were nearly 130 million emergency department visits, compared with almost 101 million outpatient visits and nearly 39 million inpatient visits, according to the report.

Black Americans were much more likely to seek emergency department care than other racial/ethnic groups. In 2010, black people used the emergency department almost 54 percent of the time.

The rate was even higher for black people in cities, at 59 percent, the researchers said.

The study also found that Medicare and Medicaid patients were more likely to use the emergency department.
Certain areas of the country also appeared to have a fondness for the emergency room. Rates of emergency department use were much higher in the South and West — 54 percent and 56 percent, respectively — than in the Northeast (39 percent).

The findings suggest that increasing use of emergency departments by vulnerable groups may be due to inequality in access to health care, the study authors noted in the news release.

The study was published online recently in the *International Journal of Health Services.*

SOURCE: University of Maryland

Patients seek care in emergency departments for many reasons. The data might suggest that emergency care provides the type of care that individuals actually want or need, 24 hours a day.

medlineplus.gov

Simulation Training Saves Veteran

By Gerald Sonnenberg

The nation's Veterans spend their military careers training and preparing for those rare times when that training may be needed to defend our nation. That same dedication to service and training holds true for VA medical professionals who prepare for those times when their skills are needed to help save a life.

Dr. John Hoy, Orlando VA Medical Center (OVAMC) associate chief of staff of radiology is a believer in using simulation and mock codes regularly to train his staff and make sure his radiology team is prepared for a medical emergency.

"Although it requires discipline to perform routine simulations, the regret of negative outcomes is much more difficult to deal with," said Hoy. That disciplined training came in handy in 2016 at the OVAMC.

Orlando VA Medical Center at Lake Nona

John Browning, an Air Force Veteran who served in civil engineering during the Vietnam War era, is a patient at the facility. He was connected to an electrocardiogram (EKG) having just completed a nuclear medicine stress test in the radiology department.

"I remember watching the EKG when everything froze in my vision, and I couldn't hear anything," said the 65-year-old Browning, who suffered from diabetes, hypertension and dyslipidemia,

Simulation training assists Orlando team in helping save Veterans

which is an elevation of plasma cholesterol, triglycerides, or both.

Dr. Steven Lee, section chief of nuclear medicine, was covering the service and supervising the stress testing team for the day.

"He (Browning) reached 90 percent maximum predicted heart rate without significant symptoms and was recovering, sitting upright in a chair," said Lee. "Without any verbal or visual warnings, he suddenly became unresponsive to verbal or physical simulation."

A quick glance at the monitoring EKG demonstrated an arrhythmia, likely (pulseless) ventricular tachycardia or ventricular fibrillation. Nurse Elizabeth Maddux activated a code blue. Lee and Physician's Assistant Jose Rios then placed Browning on to a bed, checked for a pulse and began chest compressions when no pulse was detected.

Numerous radiology staff members responded to the code call. The AED was turned on, and Rios placed the chest pads on Browning.

"Chest compressions were stopped to analyze the rhythm, and a shock was advised by the AED," said Lee. "Chest compressions resumed as the AED charged. Once it was charged, compressions stopped, and a shock was delivered."

"Mr. Browning was very fortunate to be in a hospital, monitored by an EKG, and have a code cart with an AED next to him when he experienced a lethal arrhythmia," added Lee.

Browning had been down for a couple of minutes when his pulse returned, and he became alert. "I remember asking if I passed the test," said Browning, somewhat chuckling. "'No,' someone said to me, 'You don't pass if your heart stops.'" He was later transferred to a hospital, and it was determined Browning needed a procedure to place a stent in his heart.

He also had an automatic implantable cardioverter-defibrillator (AICD) device inserted to monitor his heartbeat. This device can deliver an electrical impulse or shock to the heart when it senses a life-threatening change in the heart's rhythm. Like a pacemaker, the AICD is small enough to be implanted.

Browning has since recovered, and his recovery is at least due in part to having a medical team prepared for this type of emergency.

Hoy said, "Incorporation of formal standardized simulation training in medicine is essential. The practice and incorporation of simulation training is like anything else; it is dependent on discipline, commitment and creation of positive habits. When these positive habits are

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created, positive actions become second nature."

His belief in simulation partially comes from his training at Massachusetts General Hospital. But he says the core foundation in simulation training comes from the football field.

"Football has been performing simulations for over 100 years, simulating plays hundreds of times prior to game day. After game day, films are reviewed and areas of improvement are identified. The following week you are back on the practice field simulating these plays again, with corrective actions," said Hoy.

Like a team returning to the field, Browning recently returned to pay a visit to the OVAMC radiology department to thank them for their help that fateful day. He took the time to pose for a photograph surrounded by the team, and in the very room, where he was revived. Doctors told Browning it is extremely rare for someone's heart to stop while on an EKG, and is comparable to the chances of being struck by lightning.

"It was amazing it happened the way it did," said Browning. "They said it could have happened anytime or anywhere. They said I couldn't have been in a better place."

Hoy added, "This was a well-coordinated effort with seamless delivery of care. The simulation training was unequivocally instrumental in saving the Veteran's life. Many fields such as the airline industry are miles ahead of medicine with regards to simulation training integration, so the new VHA SimLEARN National Simulation Center will have a tremendously, positive impact on patient care and outcomes for our Veterans like John Browning. They deserve the best."

The Employee Education System partners with peer VHA program offices to design, develop, implement, evaluate and accredit quality education and training programs to improve outcomes in Veteran clinical care, health care operations and administration. EES training and education programs provide core accredited content needed by staff to maintain licensure and certification; EES also develops specialized learning content to equip VHA's health care providers with the most current knowledge and skills to address the challenging needs unique to a Veteran patient population.

va.gov

CPG

Assistive Technology Course Helps Staff Make a Difference in Veterans' Lives

By Gerald Sonnenberg

Approximately 120 VHA staff participated in a "hands on" assistive technology course June 20-22 at the VHA SimLEARN National Simulation Center. It was sponsored by the Rehabilitation and Prosthetics Services Program Office of the VHA Physical Medicine and Rehabilitation (PM&R) Service.

The course exposed staff, such as physical therapists, occupational therapists, speech pathologists, recreation therapists, prosthetics staff, vocation rehabilitation counselors and others, to a wide variety of assistive equipment and technology.

It demonstrated how technology can help Veteran patients living with varying physical disabilities, like missing limbs, traumatic brain injury, PTSD or paralysis, to be more active and reach their highest level of potential.

Similar courses were conducted the past two years at Tampa, Florida and Long Beach, California; with this event at SimLEARN being the largest so far, according to Bill Wenninger, a rehabilitation planning specialist at PM&R based at the Milwaukee VA Medical Center (VAMC). He is the primary planner and coordinator of the event.

"The main mission (of the event)," said Wenninger, "is to make staff aware of the technology and help them understand the different scopes of technology available in certain areas like wheeled mobility or augmentative communication.

It also helps them understand the prescription parameters for those devices, and to be able to network with others in case they have questions about the technology.

The prescription parameters are dependent on the disability of the individual and the equipment being prescribed. It gives them an idea of what they can do for their patients when they get back to their facilities."

In preparation for the course, a monthly assistive technology virtual training event gave attendees an overview of the equipment and assessments and recommendations before seeing them up close and handling the devices.

The breakout sessions addressed a variety of technologies in the areas of adaptive sports and recreation, drivers training (for VA staff), telehealth, augmentative communication, sensory (vision and hearing) devices, electronic cognitive

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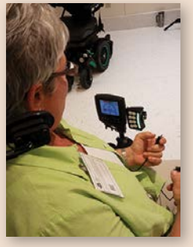

Leslie Mangiapani, director of occupational therapy working in prosthetics at the Northern Indiana Health Care System in Marion, Indiana, tests a specially modified wheel chair during the Assistive Technology training course.
VA photo by Gerald Sonnenberg

devices, adaptive computer access, electronic aids to daily living and wheeled mobility and seating.

"This course is almost completely hands-on giving attendees the opportunity to understand how the equipment functions," said Mona Wright, an Employee Education System staff member and project manager for the training. "Additionally, because the assistive technology experts are presenting, this gives attendees a chance to ask questions and discover device functions that they may not otherwise know.

One attendee commented that being exposed to devices outside their focus area was beneficial when working with Veterans. They could suggest devices to complement their treatment focus and engage a multidisciplinary approach."

Leslie Mangiapani is director of occupational therapy working in prosthetics at the Northern Indiana Health Care System in Marion, Indiana, and was one of the attendees. She had the opportunity to test some of the equipment, including a sophisticated wheelchair during the Wheeled Mobility breakout session.

"This (chair) is designed for Veterans who may have ALS (Amyotrophic Lateral Sclerosis), spinal cord injuries or other issues limiting their movement," said Mangiapani.

A VA employee for more than nine years, Mangiapani enjoys what she does for Veterans. "As therapists, we do much more than showing Veterans how to use equipment; we help change their environments. I love doing what I do, and it is amazing the difference I can help make in their lives."

One of the more popular breakout sessions was demonstrated by staff from the James A. Haley VAMC Adaptive Sports Program in Tampa, Florida. They addressed something that many people may not realize is available; adaptive technology to participate in sports.

Staff demonstrated a variety of equipment that can help Veterans become more active, such as an attachment for a Veteran with a missing hand to be able to grip the handlebar of a bicycle so they can ride again, or a specially molded grip so they can rock climb.

Sports ranged from bowling, to target shooting, archery, and several other activities, and the equipment is often designed in house and specifically for a single Veteran.

VA staff attend training regarding operating and transporting Veterans in specially designed vans.
VA photo by Gerald Sonnenberg

"That's part of the point of this is to make people aware and knowledgeable, as well as see the variety of technology available," explained Wenninger.

"It's important to have them (staff) think about how to apply it to different patients they would come across; to talk about the technology, and how they would follow up with the technology to adjust it as the disability changes, or as the person gets more efficient with the product they have. It's not a luxury item we're trying to get to people. It really makes a difference in their independence and their overall function. I value the opportunity to provide this type of education to a wide variety of disciplines."

simlearn.va.gov

CPG

This grip designed for a Veteran by the James A. Haley VAMC Adaptive Sports Program in Tampa, Florida, helps the Veteran continue his love of rock climbing.
VA photo by Gerald Sonnenberg

Native Americans Walk to the Four Corners to Fight Diabetes

American Indians left their western tribal communities on foot to gather at the Four Corners Monument in an effort to raise awareness of health disparities.

By Judy Sarasohn, HHS (Public Affairs)

Hundreds of American Indians left their western tribal communities early in the morning on Friday, May 5th, on a journey that would take them to Four Corners. They walked as many as 20 miles to meet up at the Four Corners Monument to promote their people's health and well-being.

The walkers represented the Navajo, the Ute, the Zuni and other Tribes, and walked in from New Mexico, Arizona, Utah and Colorado to gather where those states share a common boundary — the only place in the United States where four states meet.

This was the 21st annual Walking Together for Healthier Nations event, cosponsored by Navajo Area Indian Health Service (IHS) facilities — the Shiprock Service Unit, Four Corners Regional Health Center, and the Northern Navajo Medical Center — as well as the Ute Mountain Ute, Southern Ute and White Mesa tribal communities.

The purpose of the annual walk is to raise awareness of the health disparities and challenges that Native people face, particularly with diabetes. Rita King, a Ute Mountain Ute member and coordinator for the Sleeping Ute Diabetes Prevention program at the IHS facility in Towaoc, Colorado, said 11 percent of her Tribe suffers from either type 1 or type 2 diabetes.

The Tribe, she said, promotes exercise, good nutrition and other preventive actions including community activities like the Walking Together event to fight diabetes. "Walking is free. It's good to get out, meet old friends, make new ones," King said.

According to the Centers for Disease Control and Prevention and IHS, Native Americans have a greater chance of diabetes and kidney failure resulting from diabetes than any other U.S. racial or ethnic group. But the CDC also reported recently that kidney failure among Native Americans dropped by 54 percent between 1996 and 2013, the fastest rate for any racial or ethnic group in the U.S.

Courtesy of the Indian Health Service (IHS)

This hard-fought progress in reducing kidney failure has happened since the IHS began using population health and team-based approaches to diabetes and kidney care, according to the CDC and IHS.

"If we can start now educating the young people, we can beat this diabetes," added Kenny Frost, a Southern Ute from Ignacio, Colorado, who carried a staff of eagle feathers representing all the Tribes. He said traditional blessings for the gathering at Four Corners.

That they could tie in health awareness with their cultural and traditional ways was important. "Walking with the Tribes into the park and going around the monument was great," Frost said, noting that the Utes were welcomed into the monument area by a group of Navajo veterans. "When we do something like this, it's a part of history."

Kenny James, a Navajo from Shiprock, New Mexico, said walking is an important and enjoyable way to stay healthy. "I do a lot of hiking. I like to participate with a group." He's 62 and said he did all 19 miles of his group's route. A veteran of the Marines and state and reservation law enforcement, James said this was his second year on Walking Together. He wore the wrong shoes last year and suffered from blisters; this year he wore light hiking shoes and had no problems.

Roberta Diswood, a recreation specialist with Shiprock Health Promotion at Northern Navajo Medical Center, agreed that the walk promotes good health and well-being. She coordinated a group of about 100 Navajo and some non-Native people who made the 21-mile journey from northwest New Mexico to Four Corners.

Harold Cuthair, 56, chairman of the Ute Mountain Ute Tribe, also participated in the walk and said he encourages tribal leaders, staff and the community to participate in healthy activities. "Health is a priority in our lives and [important] today, tomorrow and in the future. … [O]ne thing my heart, soul and mind tell me is anything is possible. I walked all the way!"

Participating in healthy activities doesn't end with the great walk, stressed Eli Bigthumb, a Navajo and a recreation specialist for the Crownpoint Service Unit who coordinated a group of 88 Navajo walkers for a related event on May 3rd. Ten walked the entire 27-mile route from Pueblo Pintado to Torreon, New Mexico. Bigthumb said, "This is a kickoff point for our spring and summer season."

hhs.gov

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Rates of New Diagnosed Cases of Type 1 and Type 2 Diabetes on the Rise Among Children, Teens

Fastest rise seen among racial/ethnic minority groups

Rates of new diagnosed cases of type 1 and type 2 diabetes are increasing among youth in the United States, according to a report, Incidence Trends of Type 1 and Type 2 Diabetes among Youths, 2002-2012, published today in the New England Journal of Medicine.

In the United States, 29.1 million people are living with diagnosed or undiagnosed diabetes, and about 208,000 people younger than 20 years are living with diagnosed diabetes.

This study is the first ever to estimate trends in new diagnosed cases of type 1 and type 2 diabetes in youth (those under the age of 20), from the five major racial/ethnic groups in the U.S.: non-Hispanic whites, non-Hispanic blacks, Hispanics, Asian Americans/Pacific Islanders, and Native Americans.

However, the Native American youth who participated in the SEARCH study are not representative of all Native American youth in the United States. Thus, these rates cannot be generalized to all Native American youth nationwide.

The SEARCH for Diabetes in Youth study, funded by the CDC and the NIH, found that from 2002 to 2012, incidence, or the rate of new diagnosed cases of type 1 diabetes in youth increased by about 1.8 percent each year.

During the same period, the rate of new diagnosed cases of type 2 diabetes increased even more quickly, at 4.8 percent. The study included 11,244 youth ages 0-19 with type 1 diabetes and 2,846 youth ages 10-19 with type 2.

"Because of the early age of onset and longer diabetes duration, youth are at risk for developing diabetes related complications at a younger age. This profoundly lessens their quality of life, shortens their life expectancy, and increases health care costs," said Giuseppina Imperatore, MD, PhD, Epidemiologist in CDC's Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion.

The study results reflect the nation's first and only ongoing assessment of trends in type 1 and type 2 diabetes among youth and help identify how the epidemic is changing over time in Americans under the age of 20 years.

- Across all racial/ethnic groups, the rate of new diagnosed cases of type 1 diabetes increased more annually from 2003-2012 in males (2.2 percent) than in females (1.4 percent) ages 0-19.
- Among youth ages 0-19, the rate of new diagnosed cases of type 1 diabetes increased most sharply in Hispanic youth, a 4.2 percent annual increase. In non-Hispanic blacks, the rate of new diagnosed cases of type 1 diabetes increased by 2.2 percent and in non-Hispanic whites by 1.2 percent per year.
- Among youth ages 10-19, the rate of new diagnosed cases of type 2 diabetes rose most sharply in Native Americans (8.9 percent), Asian Americans/Pacific Islanders (8.5 percent) and non-Hispanic blacks (6.3 percent). Note: The rates for Native Americans cannot be generalized to all Native American youth nationwide.
- Among youth ages 10-19, the rate of new diagnosed cases of type 2 diabetes increased 3.1 percent among Hispanics. The smallest increase was seen in whites (0.6 percent).
- The rate of new diagnosed cases of type 2 diabetes rose much more sharply in females (6.2 percent) than in males (3.7 percent) ages 10-19.

"These findings lead to many more questions," said Barbara Linder, MD, PhD, senior advisor for childhood diabetes research at the NIDDK. "The differences among racial and ethnic groups and between genders raise many questions. We need to understand why the increase in rates of diabetes development varies so greatly and is so concentrated in specific racial and ethnic groups." Current NIH-funded studies include:

- Type 1 Diabetes TrialNet screens thousands of relatives of people with type 1 diabetes annually and conducts prevention studies with those at highest risk for the disease.
- The Environmental Determinants of Diabetes in the Young (TEDDY) study seeks to uncover factors that may increase development of type 1 diabetes.
- For youth with type 2 diabetes, the ongoing Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY) study is examining methods to treat the disease and prevent complications.

nih.gov

Youth with Type 2 Diabetes Develop Complications More Often Than Type 1 Peers

NIH, CDC funded study finds many in both groups quickly develop kidney, nerve, eye diseases

Teens and young adults with type 2 diabetes develop kidney, nerve, and eye diseases — as well as some risk factors for heart disease — more often than their peers with type 1 diabetes in the years shortly after diagnosis. The results are the latest findings of the SEARCH for Diabetes in Youth study, published Feb. 28 in the Journal of the American Medical Association.

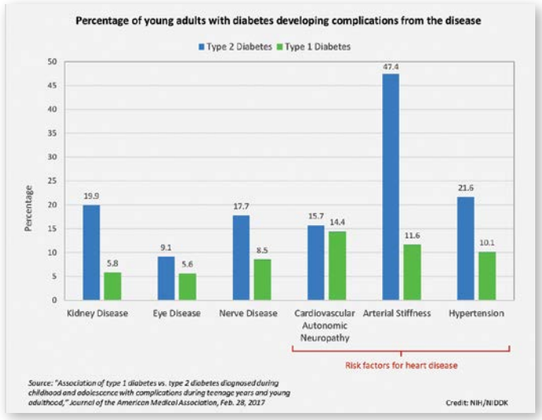
Funded by the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), SEARCH researchers examined how quickly and often youth developed signs of kidney, nerve and eye diseases, among the most common complications of diabetes. They also measured several risk factors for heart disease. Participants had diabetes an average of under eight years at the end of the study.

The study is the largest of its kind in the U.S. Key findings are:

- For youth with type 2 diabetes, nearly 20 percent developed a sign of kidney disease by the end of the study, compared to about 6 percent of youth with type 1 diabetes.
- For youth with type 2, about 18 percent developed nerve disease, versus about 9 percent with type 1.
- For youth with type 2, about 9 percent developed eye disease, compared to about 6 percent of youth with type 1.
- Measures for two risk factors for heart disease (hypertension and arterial stiffness) were greater for youth with type 2 but close to equal for a third risk factor (cardiovascular autonomic neuropathy).

Though youth with type 2 diabetes showed signs of complications more often in nearly every measure than their peers with type 1, many youth in both groups developed complications.

"There's often the assumption that young people don't develop complications from diabetes, but that's just not true. We saw that young people with diabetes are developing signs of major complications in the prime of their lives," said Dr. Barbara Linder, a study author and senior advisor for childhood diabetes research within the NIH's National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). "Particularly for youth with type 2, this research demonstrates the clear need to learn how to reduce or delay the debilitating complications of diabetes, itself a huge challenge for young people to manage."



Percentage of young adults with diabetes developing complications from the disease.

SEARCH examined 1,746 youth with type 1 diabetes (averaging about 18 years old) and 272 with type 2 diabetes (average age about 22) between 2002-2015. All were diagnosed before age 20. The researchers looked at factors including glucose control, body mass index, waist-to-height ratio and blood pressure, but no factor could explain why people with type 2 developed more complications than counterparts with type 1. By about age 21, about 1/3 of participants with type 1 diabetes and about 3/4 of participants with type 2 had at least one complication from diabetes or were at high risk for a complication.

"This study highlights the need for early monitoring for development of complications among young people with diabetes," said Dr. Sharon Saydah, senior scientist at CDC and an author on the paper. "If young people can delay onset of these complications from diabetes by even a few years, that can ease their burden and lengthen their lives."

Type 1 diabetes typically develops in young people. In type 1, the body does not make insulin, a hormone needed to live. In type 2 diabetes, the body does not make enough insulin or does not use insulin well. In the past, type 2 diabetes was extremely rare in youth, but occurrences have risen alongside the obesity epidemic.

nih.gov

Fracture Risk Higher for Seniors with Diabetes

Bone weaknesses seen in those with blood sugar disease

By Robert Preidt

Seniors with type 2 diabetes may be at increased risk for fractures. And researchers think they know why.

"Fracture in older adults with type 2 diabetes is a highly important public health problem and will only increase with the aging of the population and growing epidemic of diabetes," said study author Dr. Elizabeth Samelson.

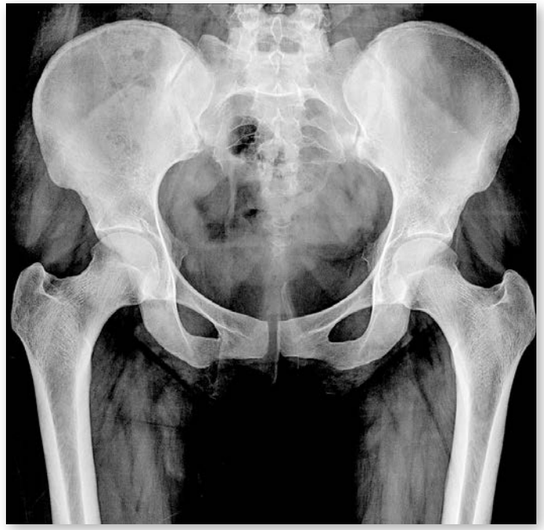
Samelson and her colleagues used special medical scans to assess more than 1,000 people over a three-year study period.

The investigators found that older adults with type 2 diabetes had bone weakness that cannot be measured by standard bone density testing.

"Our findings identify skeletal deficits that may contribute to excess fracture risk in older adults with diabetes and may ultimately lead to new approaches to improve prevention and treatment," said Samelson, of Hebrew SeniorLife's Institute for Aging Research in Boston.

Fractures among seniors with osteoporosis — the age-related bone-thinning disease — are a major concern.

Such fractures can lead to decreased quality of life, disability and even death, as well as significant health care costs, she said in an institute news release.



Even those with normal or higher bone density than their peers appeared to have a higher fracture risk if they had type 2 diabetes, the researchers said.

Specifically, these people had a 40 percent to 50 percent increased risk of hip fracture, the findings showed.

This is considered the most serious type of osteoporosis-related fracture.

The study authors said that better understanding of the various factors that influence bone strength and fractures will aid prevention efforts.

The report was published Sept. 20 in the Journal of Bone and Mineral Research.

SOURCE: Hebrew SeniorLife's Institute for Aging Research

medlineplus.gov

Campylobacter, Salmonella Led Bacterial Foodborne Illnesses in 2016

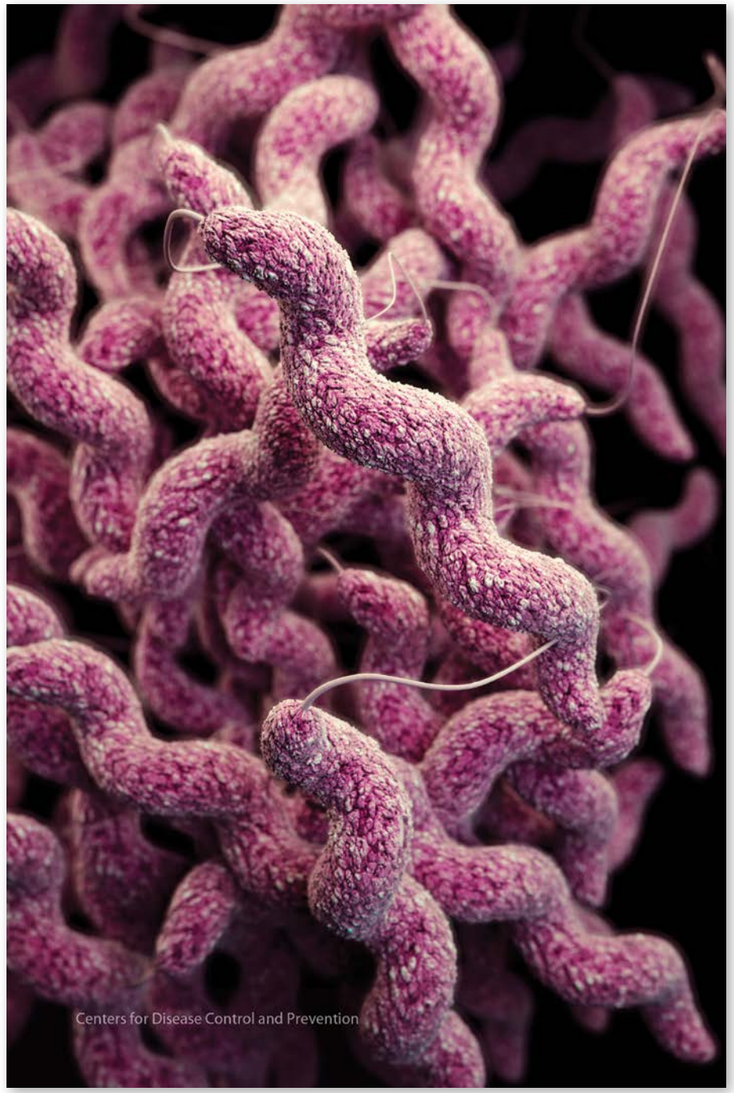
Data from rapid diagnostic tests included in total infections for the first time

Campylobacter and Salmonella caused the most reported bacterial foodborne illnesses in 2016, according to preliminary data published today in CDC's Morbidity and Mortality Weekly Report. CDC's Foodborne Diseases Active Surveillance Network (FoodNet) report provides the most up-to-date information about foodborne illnesses in the United States.

FoodNet collects data on 15 percent of the U.S. population. FoodNet sites alone reported 24,029 foodborne infections, 5,512 hospitalizations, and 98 deaths in 2016. The numbers of reported illnesses by germ are: Campylobacter (8,547), Salmonella (8,172), Shigella (2,913), Shiga toxin-producing E. coli (1,845), Cryptosporidium (1,816), Yersinia (302), Vibrio (252), Listeria (127) and Cyclospora (55). This is the first time the report also includes in the total number of infections those foodborne bacterial infections diagnosed only by rapid diagnostic tests in FoodNet sites. Previously, the report counted foodborne bacterial infections confirmed only by traditional culture-based methods in the total numbers.

Salmonella Typhimurium infections, often linked to beef and poultry, decreased 18 percent in 2016 compared with the average for 2013-2015. The continuing decreases in Salmonella Typhimurium may be due to regulatory action to reduce Salmonella contamination in poultry and vaccination of chicken flocks by producers. Reported Yersinia, Cryptosporidium, and Shiga toxin-producing E.coli infections increased.

These increases are likely due to newly available rapid tests that make infections easier to diagnose, rather than to a true increase in illness.



Campylobacter bacteria

Salmonella bacteria

Escherichia coli bacteria

"This report provides important information about which foodborne germs are making people sick in the United States," said Robert Tauxe, MD, MPH, director of CDC's Division of Foodborne, Waterborne, and Environmental Diseases. "It also points out changes in the ways clinicians are testing for foodborne illness and gaps in information as a result."

Rapid tests speed treatment but miss important information

The new data reflect the increasing popularity of rapid tests known as culture-independent diagnostic tests, or CIDTs. These faster tests can have immediate benefits for treatment, but do not collect information needed to determine if an infection is antibiotic-resistant or if it is linked to an outbreak. Positive results on rapid tests can be followed up by culture-based tests to get detailed data, but often are not, according to the report.

"We need foodborne-illness trend data to monitor progress toward making our food supply safer," Tauxe said. "It's important that laboratories continue to do follow-up cultures on CIDT-positive patients so public health officials can get the information needed to protect people from foodborne illness."

Foodborne illness remains a substantial public health concern in the United States. Previous analyses have indicated that the number of infections far exceeds those diagnosed; CIDTs might be making those infections more visible. However, the shift to CIDTs poses challenges to monitoring foodborne illness trends because changes in the number of new infections could reflect changes in testing practices rather than a true increase in infections.

For this reason, comparisons of the 2016 data with data from previous years may not accurately reflect trends. Estimated infections this year and in years past are accurate, but cannot be directly compared because the total now includes results from diagnostic tests. FoodNet is developing new tools that will allow it to continue to track the needed progress toward reducing foodborne illness.

Improving food safety

FoodNet provides the information needed for effective food-safety policies and prevention efforts. CDC works closely with other federal, state, and local partners and with the food industry to improve food safety in the United States.

"We are making progress in detecting and responding more quickly to foodborne illness, but our priority remains preventing illnesses from happening in the first place," said Susan Mayne, PhD, FACE, director of FDA's Center for Food Safety and Applied Nutrition.

Susan Mayne, PhD, FACE, director of FDA's Center for Food Safety and Applied Nutrition

"The final rules we are implementing under the FDA Food Safety Modernization Act focus on prevention, and we will continue to work closely with other government agencies at the local, state and federal levels, as well as our tribal and territorial partners, to support industry compliance with the new requirements."

In 2016, USDA's Food Safety and Inspection Service (FSIS) finalized new performance standards for reducing harmful bacteria in chicken parts and ground poultry. FSIS expects these actions could prevent as many as 50,000 illnesses each year caused by Salmonella and Campylobacter in chicken and turkey products.

"Our new performance standard for chicken parts is a perfect example of the type of proactive, prevention-based food policies that we're focused on at FSIS — policies that are based on science, that are supported by strong data, and that will truly improve public health," said Al Almanza, FSIS Administrator.

cdc.gov

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Climate Change and Waterbourne and Foodbourne Diseases

Heavy rains can wash contaminants into drinking, recreational, and irrigation waters, potentially leading to human illnesses. Harmful contaminants include human and animal waste, industrial chemicals, oil and fuel, and pesticides and fertilizers.

Heavy rains can also result in overflows of combined sewer systems, which are designed to treat both stormwater and wastewater at the same time. During heavy rains, there may not be enough capacity in the system, leading to the discharge of untreated or partially treated wastewater. Flooding can make all of these problems even worse.

Researchers Connect Brain Blood Vessel Lesions to Intestinal Bacteria

NIH-funded pre-clinical study links gut microbes and the immune system to a genetic disorder that can cause stroke and seizures.

A study in mice and humans suggests that bacteria in the gut can influence the structure of the brain's blood vessels, and may be responsible for producing malformations that can lead to stroke or epilepsy. The research, published in Nature, adds to an emerging picture that connects intestinal microbes and disorders of the nervous system.

The study was funded by the National Institute of Neurological Disorders and Stroke (NINDS), a part of the National Institutes of Health.

Cerebral cavernous malformations (CCMs) are clusters of dilated, thin-walled blood vessels that can lead to seizures or stroke when blood leaks into the surrounding brain tissue. A team of scientists at the University of Pennsylvania investigated the mechanisms that cause CCM lesions to form in genetically engineered mice and discovered an unexpected link to bacteria in the gut. When bacteria were eliminated the number of lesions was greatly diminished.

"This study is exciting because it shows that changes within the body can affect the progression of a disorder caused by a genetic mutation," said Jim I. Koenig, PhD, program director at NINDS.

The researchers were studying a well-established mouse model that forms a significant number of CCMs following the injection of a drug to induce gene deletion. However, when the animals were relocated to a new facility, the frequency of lesion formation decreased to almost zero.

"It was a complete mystery. Suddenly, our normally reliable mouse model was no longer forming the lesions that we expected," said Mark L. Kahn, MD, professor of medicine at the University of Pennsylvania, and senior author of the study. "What's interesting is that this variability in lesion formation is also seen in humans, where patients with the same genetic mutation often have dramatically different disease courses."

While investigating the cause of this sudden variability, Alan Tang, a graduate student in Dr. Kahn's lab, noticed that the few mice that continued to form lesions had developed bacterial abscesses in their abdomens — infections that most likely arose due to the abdominal drug injections. The abscesses contained Gram-negative bacteria, and when similar bacterial infections were deliberately induced in the CCM model animals, about half of them developed significant CCMs.

"The mice that formed CCMs also had abscesses in their spleens, which meant that the bacteria had entered the bloodstream from the initial abscess site," said Tang. "This suggested a connection between the spread of a specific type of bacteria through the bloodstream and the formation of these blood vascular lesions in the brain."

The question remained as to how bacteria in the blood could influence blood vessel behavior in the brain. Gram-negative bacteria produce molecules called lipopolysaccharides (LPS) that are potent activators of innate immune signaling. When the mice received injections of LPS alone, they formed numerous large CCMs, similar to those produced by bacterial infection. Conversely, when the LPS receptor, TLR4, was genetically removed from these mice they no longer formed CCM lesions.

The researchers also found that, in humans, genetic mutations causing an increase in TLR4 expression were associated with a greater risk of forming CCMs.

"We knew that lesion formation could be driven by Gram-negative bacteria in the body through LPS signaling," said Kahn. "Our next question was whether we could prevent lesions by changing the bacteria in the body."

The researchers explored changes to the body's bacteria (microbiome) in two ways. First, newborn CCM mice were raised in either normal housing or under germ-free conditions. Second, these mice were given a course of antibiotics to "reset" their microbiome. In both the germ-free conditions and following the course of antibiotics, the number of lesions was significantly reduced, indicating that both the quantity and quality of the gut microbiome could affect CCM formation.

Finally, a drug that specifically blocks TLR4 also produced a significant decrease in lesion formation. This drug has been tested in clinical trials for the treatment of sepsis, and these findings suggest a therapeutic potential for the drug in the treatment of CCMs, although considerable research remains to be done.

nih.gov

Stomach Bacteria Crank Up Stem Cell Renewal, May Be Link to Gastric Cancer

By Todd Dubnicoff

The Centers for Disease Control and Prevention estimate that two-thirds of the world's population is infected with H. pylori, a type of bacteria that thrives in the harsh acidic conditions of the stomach.

Data accumulated over the past few decades shows strong evidence that H. pylori infection increases the risk of stomach cancers.

The underlying mechanisms of this link have remained unclear. But research suggests that the bacteria cause stem cells located in the stomach lining to divide more frequently leading to an increased potential for cancerous growth.

Tumors need to make an initial foothold in a tissue in order to grow and spread. But the cells of our stomach lining are replaced every four days. So, how would H. pylori bacterial infection have time to induce a cancer?

The research team — a collaboration between scientists at the Max Planck Institute in Berlin and Stanford University — asked that question and found that the bacteria are also able to penetrate down into the stomach glands and infect stem cells whose job it is to continually replenish the stomach lining.

Further analysis in mice revealed that two groups of stem cells exist in the stomach glands – one slowly dividing and one rapidly dividing population. Both stem cell populations respond similarly to an important signaling protein, called Wnt, that sustains stem cell renewal.

But the team also discovered a second key stem cell signaling protein called R-spondin that is released by connective tissue underneath the stomach glands.

H. pylori infection of these cells causes an increase in R-spondin which shuts down the slowly dividing stem cell population but cranks up the cell division of the rapidly dividing stem cells.

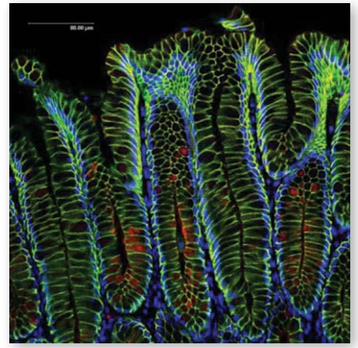
First author, Dr. Michal Sigal, summed up in a press release how these results may point to stem cells as the link between bacterial infection and increased risk of stomach cancer.

Vitamin C is known to have a number of health benefits, from preventing scurvy to limiting the buildup of fatty plaque in your arteries. Now a new study says we might soon be able to add another benefit: it may be able to block the progression of leukemia and other blood cancers.

Researchers at the NYU School of Medicine focused their work on an enzyme called TET2. This is found in hematopoietic stem cells (HSCs), the kind of stem cell typically found in bone marrow. The absence of TET2 is known to keep these HSCs in a pre-leukemic state; in effect priming the body to develop leukemia.

The researchers showed that high doses of vitamin C can prevent, or even reverse that, by increasing the activity level of TET2.

In the study, in the journal Cell, they showed how they developed mice that could have their levels of TET2 increased or decreased. They then transplanted bone marrow with low levels of TET2 from those mice into healthy, normal mice. The healthy mice started to develop leukemia-like symptoms.



Stomach glands. Credit: MPI for Infection Biology

However, when the researchers used high doses of vitamin C to restore the activity levels of TET2, they were able to halt the progression of the leukemia.

Now this doesn't mean you should run out and get as much vitamin C as you can to help protect you against leukemia. In an article in The Scientist, Benjamin Neel, senior author of the study, says while vitamin C does have health benefits, consuming large doses won't do you much good.

However, Neel says these findings do give scientists a new tool to help them target cells before they become leukemic.

cirm.ca.gov

National Vaccine Advisory Committee (NVAC) Standards for Adult Immunization Practice

Nancy Messonnier, MD (CAPT, USPHS), Director for the National Center for Immunization and Respiratory Diseases (NCIRD)

These updated Standards call on ALL healthcare professionals — whether they provide vaccinations or not — to take steps to help ensure that their adult patients are fully immunized.

ASSESS immunization status of all your patients at every clinical encounter.

- Stay informed. Get the latest CDC recommendations for immunization of adults.
- Implement protocols and policies. Ensure that patients' vaccine needs are routinely reviewed and patients get reminders about vaccines they need.

Strongly **RECOMMEND** vaccines that patients need.

- Share tailored reasons why vaccination is right for the patient.
- Highlight positive experiences with vaccination.
- Address patient questions and concerns.
- Remind patients that vaccines protect them and their loved ones against a number of common and serious diseases.
- Explain the potential costs of getting sick.

ADMINISTER needed vaccines or **REFER** your patients to a vaccination provider.

- Offer the vaccines you stock.
- Refer patients to providers in the area that offer vaccines that you don't stock.

DOCUMENT vaccines received by your patients.

- Participate in your state's immunization registry. Help your office, your patients, and your patients' other providers know which vaccines your patients have had.
- Follow up. Confirm that patients received recommended vaccines that you referred them to get from other immunization providers.

ACIP Vaccine Recommendations and Guidelines can be found at: www.cdc.gov/vaccines/hcp/acip-recs/index.html

Since beginning her public health career in 1995 as an Epidemic Intelligence Service Officer in the National Center for Infectious Diseases (NCID), Dr. Messonnier has held a number of leadership posts across CDC and within NCIRD.

She brings strong management and leadership skills, commitment to staff mentoring and development, and a passion for immunization and infectious disease prevention.

Dr. Messonnier has played critical roles in several successful public health initiatives including the vaccination of millions of people living in the African Meningitis Belt with MenAfriVac; serving on anthrax response teams during the 2001 intentional anthrax release; leading the evaluation of an anthrax vaccine and post-exposure antibiotic; overseeing a family of studies exploring resurgence of pertussis; championing for prevention and control of bacterial meningitis in the U.S; and providing vital leadership to CDC's cross-cutting laboratory, global health, and surveillance initiatives.

She has written more than 140 articles and chapters and received numerous awards.

Dr. Messonnier received her BA from the University of Pennsylvania and MD from the University of Chicago School of Medicine. She completed internal medicine residency training at the University of Pennsylvania.

cdc.gov

Recommended Vaccines for Healthcare Workers

Healthcare workers (HCWs) are at risk for exposure to serious, and sometimes deadly, diseases. If you work directly with patients or handle material that could spread infection, you should get appropriate vaccines to reduce the chance that you will get or spread vaccine-preventable diseases. Protect yourself, your patients, and your family members. Make sure you are up-to-date with recommended vaccines.

Healthcare workers include physicians, nurses, emergency medical personnel, dental professionals and students, medical and nursing students, laboratory technicians, pharmacists, hospital volunteers, and administrative staff.

Vaccines Recommendations:

Hepatitis B

If you don't have documented evidence of a complete hepB vaccine series, or if you don't have an up-to-date blood test that shows you are immune to hepatitis B (i.e., no serologic evidence of immunity or prior vaccination) then you should:

- Get the 3-dose series (dose #1 now, #2 in 1 month, #3 approximately 5 months after #2).
- Get anti-HBs serologic tested 1–2 months after dose #3.

Flu (Influenza)

Get 1 dose of influenza vaccine annually.

MMR (Measles, Mumps, & Rubella)

If you were born in 1957 or later and have not had the MMR vaccine, or if you don't have an up-to-date blood test that shows you are immune to measles or mumps (i.e., no serologic evidence of immunity or prior vaccination), get 2 doses of MMR (1 dose now and the 2nd dose at least 28 days later).

If you were born in 1957 or later and have not had the MMR vaccine, or if you don't have an up-to-date blood test that shows you are immune to rubella, only 1 dose of MMR is recommended. However, you may end up receiving 2 doses, because the rubella component is in the combination vaccine with measles and mumps. For HCWs born before 1957, see the MMR ACIP vaccine recommendations.

Varicella (Chickenpox)

If you have not had chickenpox (varicella), if you haven't had varicella vaccine, or if you don't have an up-to-date blood test that shows you are immune to varicella (i.e., no serologic evidence of immunity or prior vaccination) get 2 doses of varicella vaccine, 4 weeks apart.

Tdap (Tetanus, Diphtheria, Pertussis

- Get a one-time dose of Tdap as soon as possible if you have not received Tdap previously (regardless of when previous dose of Td was received).
- Get Td boosters every 10 years thereafter.
- Pregnant HCWs need to get a dose of Tdap during each pregnancy.

Meningococcal

Those who are routinely exposed to isolates of N. meningitidis should get one dose.

cdc.gov

Hand Hygiene Back to Basics in Infection Prevention

By Katherine Ellingson, PhD

Katherine Ellingson, PhD

Hand hygiene is a simple practice that has been at the core of infection prevention for over 150 years. Yet getting healthcare personnel to follow recommended hand hygiene practices in today's complex and demanding healthcare environment continues to be a monumental challenge. Even in the developed world, adherence is estimated to be less than 50%, meaning healthcare personnel practice hand hygiene fewer than half of the times that they should.

In the past year, the visibility of novel strategies to improve hand hygiene in healthcare has increased — from technologies that can monitor and report hand hygiene performance in real time, to smartphone applications that streamline hand hygiene data collection by human observers, to financial incentive schemes that pay or fine healthcare personnel based on hand hygiene performance.

We at CDC are very interested and engaged in understanding how these strategies work, what their strengths and limitations are, and how feasible and affordable their implementation is. Creative or high-tech solutions must work in parallel with the fundamental building blocks of hand hygiene improvement: education, grassroots promotion, and leadership.

Each year the World Health Organization (WHO) hosts a call to action to improve hand hygiene in healthcare settings across the world. To date more than 12,500 facilities have joined the "SAVE LIVES: Clean Your Hands campaign", including nearly 2,500 U.S. healthcare facilities. This campaign is centers around the WHO's multimodal hand hygiene improvement strategy, which includes as key elements: 1) system change, 2) training and education, 3) evaluation and feedback, 4) reminders in the workplace, and 5) institutional safety climate.

In support of this important global effort, we would like to highlight some important grass roots perspectives. In Part 2 of this blog, we will hear about efforts in the state of South Carolina, which has adopted WHO's campaign strategy in a state-wide effort to improve hand hygiene. In Part 3 of this blog series, we will hear from Victoria Nahum, Executive Director of the Safe Care Campaign, who reminds us of the patient perspective and the valuable role that patients and family can play in patient safety.

We must do all we can to protect patients and ensure that patients within our healthcare facilities are receiving safe care. We hope that some of the information provided in the next several blog posts will provide creative solutions for how to enhance hand hygiene compliance across healthcare settings. In the meantime, tell us what has worked in your facility.

Kate Ellingson is an epidemiologist at the Centers for Disease Control and Prevention (CDC) in the Division of Healthcare Quality Promotion (DHQP). She began her CDC career in 2006 in the Epidemic Intelligence Service, where she spent two years with DHQP investigating the transmission of infectious pathogens in healthcare settings and evaluating prevention initiatives designed to reduce such infections. She has worked on several projects specific to Methicillin-Resistant Staphylococcus aureus (MRSA), including an evaluation of an initiative to reduce MRSA transmission in VA hospitals, an assessment of antimicrobial resistance on the US-Mexico border, and a policy analysis of a state mandate for public reporting of hospital-associated MRSA infections.

Dr. Ellingson has worked internationally in Kenya and Uganda to build infection control capacity and reduce amplification of outbreaks in East African hospitals. She has also led domestic investigations into quality of care for dialysis patients and for transfusion and transplant recipients. Her current position emphasizes quantitative statistical analysis and the translation of CDC-guidelines into feasible practices.

cdc.gov

What Can You Do as a Healthcare Professional to Prevent HAIs?

The Centers for Disease Control and Prevention (CDC)'s healthcare-associated infection (HAI) prevalence survey provides an updated national estimate of the overall problem of HAIs in U.S. hospitals. Based on a large sample of U.S. acute care hospitals, the survey found that on any given day, about 1 in 25 hospital patients has at least one HAI. There were an estimated 722,000 HAIs in U.S acute care hospitals in 2011. About 75,000 hospital patients with HAIs died during their hospitalizations. More than half of all HAIs occurred outside of the intensive care unit. HAIs result in an estimated $30 billion in excess healthcare costs nationally each year.

Hand Hygiene

Proper hand hygiene in Healthcare Settings provides healthcare workers and patients with a variety of resources including guidelines for providers, patient empowerment materials, the latest technological advances in hand hygiene adherence measurement, frequently asked questions and links to promotional and educational tools published by the World Health Organization (WHO), universities and health departments.

- 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.

Recently ODH joined the One & Only Campaign, a public safety campaign led by the CDC Foundation and the Safe Injection Practices Coalition (SIPC). The Campaign offers a wide array of evidenced-based information about safe injection practices on its website where you can also watch videos and download safety presentations and printable materials like the Healthcare Provider Toolkit.

Personal Protective Equipment

Guidance for the Selection and Use of Personal Protective Equipment in Healthcare Settings

CDC has developed this staff development presentation for use by infection control and occupational health personnel to train healthcare workers on how to select and use personal protective equipment (PPE).

Use Antibiotics Wisely

Studies indicate that 30-50% of antibiotics prescribed in hospitals are unnecessary or inappropriate. There is no doubt that overprescribing 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. Get Smart for Healthcare is a CDC campaign focused on improving prescribing practices in inpatient healthcare facilities.

Stay Current

Visit the Agency for Health Research and Quality (AHRQ). This agency provides free continuing education events in the areas of comparative effectiveness, quality and patient safety and prevention/care management as well as through conferences. Select continuing education opportunities are described here:

- AHRQ PSNet—A national web-based resource featuring the latest news and essential resources on patient safety
- 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

Educate Your Patients

Encourage your patients to become more involved with their healthcare by asking questions and keeping the conversation open. Informed patients are safe patients. Patients and families who engage with healthcare providers ask good questions and help reduce the risk of errors and hospital admissions.

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Report Outbreaks

Outbreaks of HAIs are reportable per Ohio Administrative Code 3701-3-02. The Ohio Department of Health (ODH) Bureau of Infectious Diseases' Outbreak Response and Bioterrorism Investigation Team (ORBIT) assists local health departments (LHDs) in Ohio with the investigation of all infectious disease outbreaks, including healthcare-associated outbreaks. For assistance, please call your LHD.

Acute Care

The Compendium of Strategies to Prevent Health Care-Associated Infections in Acute Care Hospitals synthesizes best evidence for the prevention of surgical site infections, central line-associated bloodstream infections, catheter-associated urinary tract infections, ventilator-associated pneumonia, Clostridium difficile and methicillin-resistant Staphylococcus aureus (MRSA). It also highlights basic HAI prevention strategies and advanced approaches for outbreak management and other special circumstances. Included are recommendations for performance and accountability measures to apply to individuals and groups working to implement infection prevention practices.

Ambulatory/Outpatient

The Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care is a summary guide of infection prevention recommendations for outpatient (ambulatory care) settings. The recommendations included in this document are not new but rather reflect existing evidence-based guidelines produced by the CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). This summary guide is based primarily upon elements of Standard Precautions and represents the minimum infection prevention expectations for safe care in ambulatory care settings.

The Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care distills existing infection prevention guidance from the CDC and HICPAC.

Dialysis

Patients who undergo dialysis treatment have an increased risk for getting a healthcare-associated infection (HAI). Hemodialysis patients are at a high risk for infection because the process of hemodialysis requires frequent use of catheters or insertion of needles to access the bloodstream. Also, hemodialysis patients have weakened immune systems, which increase their risk for infection, and they require frequent hospitalizations and surgery where they might acquire an infection.

Long Term Care

Prevention of Norovirus: In a long term care (LTC) facility, patients with suspected norovirus may be placed in private rooms or share rooms with other patients with the same infection. Additional prevention measures in LTC facilities can decrease the chance of coming in contact with noroviruses:

- Follow hand-hygiene guidelines, and wash hands with soap and water after contact with patients with norovirus infection
- Use gowns and gloves when in contact with patients who are symptomatic with norovirus
- Routinely clean and disinfect high touch patient surfaces and equipment with an Environmental Protection Agency-approved product with a label claim for norovirus
- Remove and wash contaminated clothing or linens
- Exclude from work healthcare workers who have symptoms consistent with norovirus

Dentistry

Although the principles of infection control remain unchanged, new technologies, materials, equipment and data require continuous evaluation of current infection control practices. The unique nature of many dental procedures, instruments and patient care settings also require specific strategies directed to preventing pathogen transmission among dental healthcare personnel and their patients.

Rehabilitation and Corrections

Often health, mental health and substance abuse problems are more apparent in jails and prisons than in the community. Incarcerated men and women may be diagnosed with health, mental health and substance abuse problems after receiving care from a correctional healthcare provider. The CDC has created correctional health resources.

The Federal Bureau of Prisons' (BOP) Clinical Practice Guidelines (CPGs) are available to the public. Infectious disease topics include: hepatitis A, B and C, human immunodeficiency virus (HIV), sexually transmitted diseases (STDs), MRSA, lice, scabies and tuberculosis (TB). Proper medical practice necessitates that all cases be evaluated on an individual basis and that treatment decisions be patient-specific.

HAIs lead to 99,000 deaths annually. There are more than 75,000 bloodstream infections a year among hospital patients, and as many as 25 percent of infected patients die. Nurses are on the frontline of preventing these infections, and by implementing certain evidence-based recommendations these infections can be dramatically reduced.

Urinary tract infections (UTIs) account for about 40 percent of all HAIs. More than 80 of those infections are associated with catheters. Nursing staff can be instrumental in preventing urinary catheter-related infections.

Ventilator associated pneumonia (VAP) is the leading cause of death among HAIs. Reducing mortality due to VAP requires an organized process that guarantees early recognition of pneumonia and consistent application of the best evidence-based practices.

In the United States, about 15 million central vascular catheter (CVC) days occur in intensive care units (ICUs) each year.

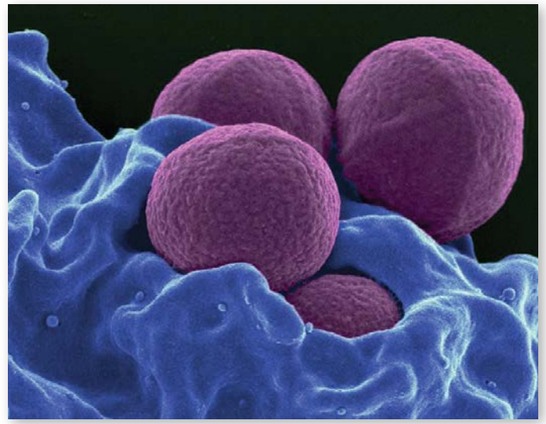
cdc.gov

Common Antimicrobials Help Patients Recover from MRSA Abscesses

NIAID-funded trial counters current thinking about treatment effectiveness

By Dennis Dixon, PhD. chief of the Bacteriology and Mycology Branch of NIAID's Division of Microbiology and Infectious Diseases

Methicillin-resistant Staphylococcus aureus (MRSA) bacteria are resistant to multiple antibiotics and commonly cause skin infections that can lead to more serious or life-threatening infection in other parts of the body. In new findings published in The New England Journal of Medicine, researchers found that two common, inexpensive antimicrobials can help patients heal from MRSA skin abscesses.



Methicillin-Resistant Staphylococcus aureus (MRSA).NIAID

The findings suggest that current treatment options for MRSA still have a role, even as scientists continue to search for new antimicrobial products. The research was funded by the National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health.

The study was conducted at hospitals across the United States and involved 796 children and adults with small, uncomplicated skin abscesses. All patients had their abscesses opened and drained as part of standard MRSA treatment.

The patients were then sorted into three groups, each of which received a different, ten-day oral treatment regimen. One group received clindamycin, a second group received trimethoprim-sulfamethoxazole (TMP-SMX), and the third group received placebo.

The group treated with clindamycin had an 81.7 percent cure rate, and the group that received TMP-SMX had an 84.6 percent cure rate. The placebo group had a 62.9 percent cure rate. According to the researchers, the findings contradict a commonly held belief that antimicrobial treatment is little better than doing nothing for MRSA skin infections.

It corroborates the findings of another NIAID-funded study demonstrating that TMP-SMX treatment resulted in better clinical outcomes than placebo for MRSA skin abscesses, and also upholds other findings that both clindamycin and TMP-SMX are equally beneficial in treating MRSA skin infections.

The researchers note, however, that the side effects of clindamycin and TMP-SMX (including nausea, diarrhea, and possible new Clostridium difficile infections) can be severe. In addition, some strains of Staphylococcus are resistant to clindamycin. The authors recommend that healthcare providers weigh the risks, but not dismiss these antimicrobials out of hand as viable treatment options for MRSA skin abscesses.

Additional funding for the study was provided in part by NIH's National Center for Advancing Translational Sciences.

nih.gov

HRSA Awards $2.36 Billion in Grants to Help Americans Access HIV/AIDS Care and Medications

The Health Resources and Services Administration (HRSA) announced today approximately $2.36 billion in Ryan White HIV/AIDS Program grants awarded to cities, counties, states, and local community-based organizations in fiscal year (FY) 2017. This funding supports a comprehensive system of HIV primary medical care, medication, and essential support services to more than half a million people living with HIV in the United States.

"The Ryan White HIV/AIDS Program plays a critical role in the United States' public health response to HIV," said HRSA Administrator George Sigounas, MS, Ph.D. "These grants will ensure that the most vulnerable Americans living with HIV/AIDS will have access to the necessary care and treatment needed to improve their health quality and medical outcomes."

HRSA oversees the Ryan White HIV/AIDS Program, which is a patient-centered system that provides care and treatment services to low income people living with HIV to improve health outcomes and reduce HIV transmission among hard to reach populations. The program serves more than 50 percent of people living with diagnosed HIV infection in the United States.

"The Ryan White HIV/AIDS Program is vital to improving clinical and public health outcomes by extending life expectancy of people living with HIV and reducing HIV transmission," said Laura Cheever, MD, ScM, Associate Administrator, HIV/AIDS Bureau. "In 2015, more than 83 percent of program clients who received HIV medical care were virally suppressed, up from 69 percent in 2010."

Under Part A of the Ryan White HIV/AIDS Program, approximately $629.7 million was awarded to 52 metropolitan areas to provide core medical and support services for people living with HIV/AIDS. These grants were awarded to 24 eligible metropolitan areas and 28 transitional grant areas with the highest number of people living with HIV and AIDS and experiencing increases in HIV and AIDS cases and emerging care needs.

Under Part B of the Ryan White HIV/AIDS Program, approximately $1.4 billion was awarded to 59 states and territories for core medical and support services and for the AIDS Drug Assistance Program (ADAP). Additionally, 16 states received Emerging Community grants based on the number of AIDS cases over the most recent five-year period. Thirty-one states and territories were also awarded approximately $10.9 million in Part B Minority AIDS Initiative grants.

Under Part C Early Intervention Services (EIS) of the Ryan White HIV/AIDS Program, approximately $181.7 million was awarded across the country to 344 local, community-based organizations to provide core medical and support services to people living with HIV. Additionally, 28 organizations were awarded approximately $3.8 million in Part C Capacity Development grants.

Under Part D of the Ryan White HIV/AIDS Program, approximately $70.6 million was awarded to 116 local community-based organizations across the country to provide family-centered comprehensive HIV care and treatment for women, infants, children, and youth.

Under Part F of the Ryan White HIV/AIDS Program, approximately $67.8 million was awarded to support clinical training, oral health services, quality improvement, and the development of innovative models of care through several different programs. Approximately $8.7 million was awarded to 56 recipients through the HIV/AIDS Dental Reimbursement Program and approximately $3.2 million was awarded to 11 recipients through the Community-Based Dental Partnership Program.

Also under Part F, the AIDS Education and Training Centers Program (AETC) awarded approximately $30.9 million through 16 grants, cooperative agreements and contracts to support education and training of health care professionals, which includes a network of eight regional and two national centers.

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

Grant awards in FY 2017 also support states, cities, counties, and communities to achieve the national goals to end the HIV epidemic. These include efforts to reduce new HIV infections, increase access to HIV care and improve health outcomes for people living with HIV infection, and reduce HIV-related disparities and health inequities.

hrsa.gov

Charting the Course to End HIV Transmission in the United States

By Sylvia Trent-Adams, PhD, RN, FAAN, Rear Admiral, U.S. Public Health Service, and Deputy Surgeon General

Sylvia Trent-Adams, PhD, RN, FAAN

I've devoted a substantial part of my career to our national response to HIV and AIDS, and I am grateful that in my current role I am able to continue to contribute to this important work that engages and concerns so many of us in public health.

My work in HIV has included experience as a researcher, clinician, and administrator, including two years serving as HRSA's Deputy Associate Administrator for the HIV/AIDS Bureau where I assisted in managing the Ryan White HIV/AIDS Program. Over the course of my career, I have witnessed tremendous progress in HIV prevention, care, and treatment. But our work isn't done.

So I was pleased to author a column about how far we've come and what remains to be done in our response to HIV. The column in Public Health Reports was published online earlier this fall ahead of the release of the November/December issue this month. Public Health Reports is the official journal of the Office of the U.S. Surgeon General and the U.S. Public Health Service.

In the column, I reflect on my experience as well as the improvements in HIV prevention, care, and treatment over the years that have put us within reach of achieving an end to HIV in the United States.

More work remains to be done before we achieve that life-saving goal. So, I also look to the future in the column. We now have potent medications (antiretroviral treatment or ART) that protect the health of people living with HIV and, as a result, reduce the number of HIV-related deaths. We also now have strong scientific evidence of the prevention effectiveness of ART: when ART results in viral suppression, it prevents sexual transmission of HIV.

The collective wisdom we've gained from our evolving response since the 1980s, and the systems of care that we've built to help prevent, diagnose, and treat HIV infection, give us the knowledge, skills, tools, and infrastructure that are needed to chart a course to the end of HIV infections in the United States.

My column concludes by discussing the multifaceted approach we must pursue together in order to achieve that goal, so that the United States will become a place where new HIV infections are rare, and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity, or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination.

I invite you to read the column, "Charting the Course to End HIV Transmission in the United States," and join me in reflecting on our progress and renewing our commitment to ending HIV. Each of us has a role to play and, working together, we can achieve this important public health goal.

hiv.gov

Partnerships for Care Project Leverages Existing Resources to Increase Efficiency and Effectiveness of HIV Care in HRSA-funded Health Centers

By Selena Gonzales, MPH, ORISE Fellow, Office of HIV/AIDS and Infectious Disease Policy,
U.S. Department of Health and Human Services

In its first two years, Partnerships for Care (P4C) has advanced primary care capacity for HIV diagnosis, treatment, and care among Health Resources and Services Administration (HRSA) funded health centers (health centers) and this has already resulted in important gains.

With funding from both the Secretary's Minority AIDS Initiative Fund (SMAIF) and HRSA, P4C provided 3 years of funding to 22 health centers in four (4) jurisdictions (New York, Maryland, Florida, and Massachusetts) to build capacity and strengthen partnerships between the health centers and state health departments. Through these partnerships, P4C is leveraging the existing primary care infrastructure in health centers to:

- develop and establish new protocols and procedures for integrating routine HIV testing, treatment, and care into primary care;
- enhance the use of data systems for public health follow-up and re-engagement in care;
- build the capacity of the health care workforce; and
- improve HIV outcomes along the continuum of care for disproportionately impacted racial and ethnic minorities.

The SMAIF and HRSA investments enable health centers and state health departments to expand and improve HIV prevention and care services within communities most impacted by HIV. P4C is generating lessons learned for integrating HIV services into primary care to reduce HIV transmission and improve HIV outcomes for patients living with HIV so they can live long and healthy lives, ultimately saving health care dollars.

Since the start of P4C in 2015, important progress has been made. By the end of the project's second year, the 22 health centers were able to expand their HIV services to:

- Provide HIV testing to 77,347 patients
- Integrate HIV services into primary care and serve 7,427 HIV-positive persons by the second year; 83% of these persons were prescribed antiretroviral therapy.
- Show an improving trend in viral suppression rates for patients living with HIV; 76% of these patients were virally suppressed.

Additionally, health centers participating in P4C have worked with their state health departments to re-engage 857 HIV-positive people in HIV care. These achievements were possible because of P4C investments by SMAIF, HRSA, and the Centers for Disease Control and Prevention (CDC) that fostered new collaborations between participating health centers and state health departments. These unique working relationships have allowed health center patients who have been lost to follow-up to be found (within and across states), contacted, and re-engaged in care, preventing costly illnesses and reducing transmission risk.

The P4C-funded health centers have also implemented routine HIV testing among all patients, including those who may not have been considered to be at risk for HIV. This has resulted in the identification of 259 patients with new diagnoses at the 22 health centers, 86% of whom were linked to HIV care within 90 days.

In addition, each health center now has one or more HIV care team members who can provide basic HIV care and treatment directly to patients, and changes to electronic health records have improved delivery, follow-up, and coordination of HIV services. Planned changes will further improve quality of care and service delivery for health center patients living with HIV.

The federal investments for P4C will have important public health impacts, particularly in translating and disseminating key lessons learned through the development of a toolkit that will be available to HRSA-funded health centers and state health departments across the nation.

hiv.gov

NIDA Announces Recipients of 2017 Avant-Garde Awards for HIV/AIDS Research

NIH awards highlight novel approaches to HIV prevention and treatment.

The National Institute on Drug Abuse (NIDA), part of the National Institutes of Health, today announced that three scientists have been selected to receive the 2017 Avant-Garde Award for HIV/AIDS Research. The winning proposals focus on a variety of novel approaches, including: improving HIV prevention through effective gene therapies; enhancing innate (natural) immunity against HIV and other related viruses; and developing new small-molecule drugs to treat HIV-1 infection. The three scientists will each receive $500,000 per year for five years to support their research, subject to the availability of funds. NIDA's tenth annual Avant-Garde Award competition is intended to stimulate high-impact research that may lead to groundbreaking opportunities for the prevention and treatment of HIV/AIDS in drug users.

"With nearly 37 million people living with HIV worldwide, it is essential that researchers continue to develop effective prevention and treatment strategies for those suffering from this devastating disease, including people with substance use disorders," said NIDA Director Nora D. Volkow, MD. "These scientists are pioneering exciting new approaches aimed at preventing and treating new cases of HIV and helping people at risk live longer, healthier lives."

Awardees

Michael Farzan, PhD, The Scripps Research Institute

Project: A safety switch for an effective HIV-1 vaccineDr. Farzan plans to use preclinical models to explore safe and effective gene therapies for the long-term prevention of HIV infection in high-risk populations, such as injection drug users. He will use an adeno-associated virus to deliver broadly neutralizing antibodies (bNAbs) or eCD4-Ig, proteins that prevent HIV-1 from infecting cells. His group will also explore safety switch mechanisms to control bNAbs and eCD4-Ig, thereby increasing safety during long-term exposure to these molecules.

Eric M. Poeschla, PhD, University of Colorado Denver

Project: Novel Approaches to Innate Immunity Against HIV-1 and Other Co-infection VirusesDr. Poeschla will use animal and human cells to explore the use of viral RNA-dependent RNA polymerase (RdRP) to enhance broad-spectrum (innate) immunity against various viruses, including HIV-1. Evidence suggests that this stable innate immune system activation does not trigger autoimmunity or inflammatory pathways.

"These scientists are pioneering exciting new approaches aimed at preventing and treating new cases of HIV and helping people at risk live longer, healthier lives."

This approach may also protect against viruses that infect people with addiction.

Peter S. Kim, PhD, Stanford University

Project: Making the HIV-1 gp41 pocket amenable to small-molecule drug discoveryDr. Kim's group proposes a strategy that alters the HIV-1 gp41 region, thereby increasing structural rigidity in this region. This will enhance testing of new therapeutics that target the gp41 pocket to prevent HIV infection. Because the pocket is structurally similar across different HIV-1 strains, these therapeutics could treat patients, including people with substance use disorders, who are at higher risk of developing resistance to one or more classes of anti-HIV drugs.

The Avant-Garde Awards are modeled after the NIH Pioneer Awards and are granted to scientists of exceptional creativity who propose high-impact research that could open new avenues for prevention and treatment of HIV/AIDS among people with substance use disorders.

nih.gov

More Than a Name Change: AIDS.gov Becomes HIV.gov

The U.S. Department of Health and Human Services today officially changed the name of AIDS.gov, the federal government's leading source for information about HIV, to HIV.gov. The announcement coincides with the 36th anniversary of the Centers for Disease Control and Prevention's first report of the initial cases of what would become known as AIDS. The name change reflects major scientific advances that have transformed an almost universally fatal disease to a condition that, if diagnosed and treated early and continuously, can be controlled and prevented from progressing to AIDS. In fact, there are more people living with HIV in the United States now than people living with AIDS.

"Much progress has been made in HIV/AIDS research since the disease was first recognized in 1981. Today, lifesaving antiretroviral therapies allow those living with HIV to enjoy longer, healthier lives — an outcome that once seemed unattainable," said Anthony S. Fauci, MD, director, National Institute of Allergy and Infectious Diseases. "The website AIDS.gov has been a valuable resource for those seeking information about HIV/AIDS, and its name change to HIV.gov appropriately reflects our evolution in transforming the pandemic, even as work remains to bring about an end to HIV."

"Today, lifesaving antiretroviral therapies allow those living with HIV to enjoy longer, healthier lives — an outcome that once seemed unattainable,"

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

In 2016, more than 8 million people used the AIDS.gov website and its social media channels to find information about HIV or to find HIV-related programs and services, including HIV testing, medical care and treatment. The name change also embraces the way most people now search online for information about the disease. "HIV" is a much more common Internet search term than "AIDS."

"The shift to HIV.gov is proactive and inclusive, and it sends a strong, supportive message to the 1.1 million people across America who are living with HIV," said Jonathan Mermin, MD, MPH, director of CDC's National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention. "The number of annual HIV infections in the U.S. fell 18 percent between 2008 and 2014, but progress has not been the same for all communities. HIV.gov will deliver current science, accurate information and links to effective resources for the people who need them most."

"We've made important progress in the fight against HIV and AIDS in the United States. These improvements are the hard-won result of decades of work on the part of advocates, healthcare providers, researchers, the federal government — and many others — but our work is not done," said Richard Wolitski, PhD, director of the HHS Office of HIV/AIDS and Infectious Disease Policy. "The newly named website will bring people helpful, timely information to support our collective efforts to sustain and advance our progress in this fight."

hhs.gov

New Hepatitis C Infections Nearly Tripled over Five Years

Deadly virus concentrated among baby boomers and increasing rapidly among new generations of Americans

Over just five years, the number of new hepatitis C virus infections reported to CDC has nearly tripled, reaching a 15-year high, according to new preliminary surveillance data released today by the Centers for Disease Control and Prevention (CDC).

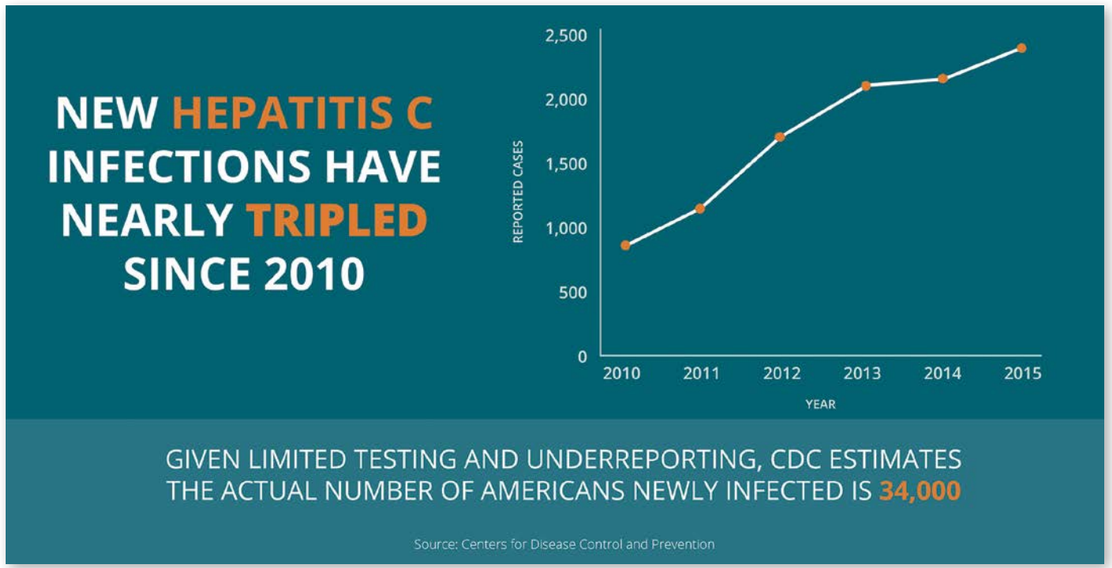
Because hepatitis C has few symptoms, nearly half of people living with the virus don't know they are infected and the vast majority of new infections go undiagnosed. Further, limited surveillance resources have led to underreporting, meaning the annual number of hepatitis C virus cases reported to CDC (850 cases in 2010 and 2,436 cases in 2015) does not reflect the true scale of the epidemic. CDC estimates about 34,000 new hepatitis C infections actually occurred in the U.S. in 2015.

Hepatitis C kills more Americans exit disclaimer icon than any other infectious disease reported to CDC. The data released today indicate that nearly 20,000 Americans died from hepatitis C-related causes in 2015, and the majority of deaths were people age 55 and older.

"By testing, curing, and preventing hepatitis C, we can protect generations of Americans from needless suffering and death," said Jonathan Mermin, MD, director of CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. "We must reach the hardest-hit communities with a range of prevention and treatment services that can diagnose people with hepatitis C and link them to treatment. This wide range of services can also prevent the misuse of prescription drugs and ultimately stop drug use — which can also prevent others from getting hepatitis C in the first place."

Hepatitis C spreading rapidly in new generations, but boomers bear biggest burden

New hepatitis C virus infections are increasing most rapidly among young people, with the highest overall number of new infections among 20- to 29-year-olds. This is primarily a result of increasing injection drug use associated with America's growing opioid epidemic.



However, the majority (three-quarters) of the 3.5 million Americans already living with hepatitis C are baby boomers born from 1945 to 1965. Baby boomers are six times more likely to be infected with hepatitis C than those in other age groups and are at much greater risk for death from the virus.

While surveillance data do not accurately capture hepatitis C infection rates among infants, other recent CDC studies indicate that hepatitis C virus infections are growing among women of childbearing age — putting the youngest generation of Americans at risk. Hepatitis C treatment not only cures the vast majority of people living with the virus, but also prevents transmission to their partners and children.

Urgent need for expanded testing, treatment, and prevention

Comprehensive approaches are needed to combat the dual epidemics of opioid addiction and injection-related infectious diseases. The U.S. Department of Health and Human Services (HHS) has brought five specific strategies to fight against the opioid epidemic that will save lives and reduce the impact of injection-related infectious diseases.

These are: improving access to treatment and recovery services; promoting use of overdose-reversing drugs; strengthening our understanding of the opioid epidemic through better public health surveillance; providing support for cutting-edge research on pain and addiction; and advancing better practices for pain management. Comprehensive syringe service programs (SSPs) are one of many tools that communities can use to prevent hepatitis and other injection-related infectious diseases. These programs also help link people to treatment to stop drug use, testing for infectious diseases that can be spread to others, and other medical care.

> *"CDC studies indicate that hepatitis C virus infections are growing among women of childbearing age"*

Two recent CDC analyses provide data to support communities in expanding access to SSPs, should they decide to implement this tool, where it is consistent with local laws. One study exit disclaimer icon indicates that 80 percent of young people with hepatitis C live more than 10 miles from an SSP. Another study, published in today's issue of CDC's Morbidity and Mortality Weekly Report, examines the range of state laws that can influence access to both SSPs and curative treatment for hepatitis C. The study finds that only three states have laws that support full access to both comprehensive SSPs and hepatitis C-related treatment and preventive services for people who inject drugs.

While new medicines can now cure hepatitis C virus infections in as little as two to three months, many people in need of treatment are still not able to get it. HHS recently released the

John Ward, MD, Director, Division of Viral Hepatitis

National Viral Hepatitis Action Plan, 2017-2020 that sets goals for improving prevention, care, and treatment of viral hepatitis and puts the nation on a course toward eliminating new hepatitis infections. The importance of this effort was underscored recently by the National Academies of Sciences, Engineering and Medicine, which in a recent report concluded that eliminating hepatitis C as a public health threat in the United States is feasible if the right steps are taken.

"Stopping hepatitis C will eliminate an enormous disease and economic burden for all Americans," said John Ward, MD, director of CDC's Division of Viral Hepatitis. "We have a cure for this disease and the tools to prevent new infections. Now we need a substantial, focused, and concerted national effort to implement the National Viral Hepatitis Action Plan and make effective prevention tools and curative treatment available to Americans in need."

For more information from CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and Tuberculosis Prevention, visit www.cdc.gov/nchhstp/newsroom.

hhs.gov

Antidepressant May Enhance Drug Delivery to the Brain

NIH rat study suggests amitriptyline temporarily inhibits the blood-brain barrier, allowing drugs to enter the brain

New research from the National Institutes of Health found that pairing the antidepressant amitriptyline with drugs designed to treat central nervous system diseases, enhances drug delivery to the brain by inhibiting the blood-brain barrier in rats. The blood-brain barrier serves as a natural, protective boundary, preventing most drugs from entering the brain. The research, performed in rats, appeared online April 27 in the *Journal of Cerebral Blood Flow and Metabolism.*

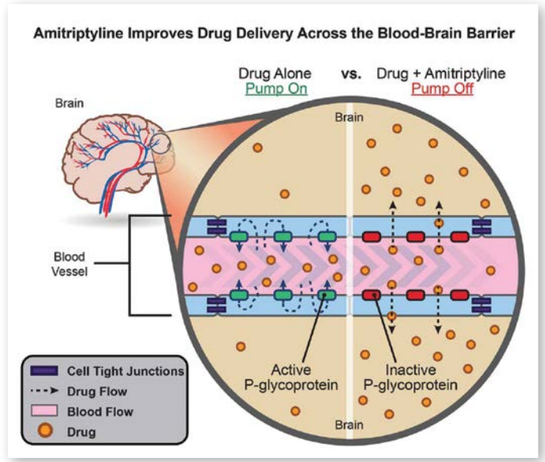
Although researchers caution that more studies are needed to determine whether people will benefit from the discovery, the new finding has the potential to revolutionize treatment for a whole host of brain-centered conditions, including epilepsy, stroke,human amyotrophic lateral sclerosis (ALS), depression, and others. The results are so promising that a provisional patent application has been filed for methods of co-administration of amitriptyline with central nervous system drugs.

According to Ronald Cannon, PhD, staff scientist at NIH's National Institute of Environmental Health Sciences (NIEHS), the biggest obstacle to efficiently delivering drugs to the brain is a protein pump called P-glycoprotein. Located along the inner lining of brain blood vessels, P-glycoprotein directs toxins and pharmaceuticals back into the body's circulation before they pass into the brain.

To get an idea of how P-glycoprotein works, Cannon said to think of the protein as a hotel doorman, standing in front of a revolving door at a lobby entrance. A person who is not authorized to enter would get turned away, being ushered back around the revolving door and out into the street.

"For example, as good as vegetables are for us to eat, they have molecules that could be toxic if they slipped into the brain," Cannon said. "They don't get in, because of P-glycoprotein, but this same protector also keeps out helpful therapeutics."

Cannon and his NIEHS colleagues initially found that amitriptyline significantly reduced P-glycoprotein's pump activity in brain capillaries from wild-type rats. Later, they saw amitriptyline had the same effect in brain capillaries from genetically modified rats designed to mimic human ALS. In both rat models, amitriptyline turned off P-glycoprotein within 10–15 minutes. When amitriptyline was removed, P-glycoprotein pump activity returned to full-strength.



Normally, P-glycoprotein prevents most medicines from entering the brain by pumping them back into the blood stream (left). The addition of amitriptyline temporarily turns off P-glycoprotein pumps, allowing drug molecules to cross the blood-brain barrier (right). NIEHS

NIEHS postbaccalaureate fellow David Banks is lead author on the paper and described amitriptyline's action on P-glycoprotein as rapid and reversible. It's these advantages that make the therapy so appealing.

"Most inventions developed at the bench don't make it to the clinic, but I'm hopeful that our findings will translate into better treatment options for doctors and their patients," Banks said.

Cannon anticipates that administering amitriptyline along with a lower dose of an opioid could relieve pain and reduce the negative side effects, such as constipation and addiction, usually seen with higher doses of prescribed opioids.

"As our nation faces increases in Alzheimer's disease, autism, and opioid abuse, we're hopeful that this discovery will help address these serious health challenges," said NIEHS Director Linda Birnbaum, PhD.

nih.gov

“Residual Echo” of Ancient Humans in Scans May Hold Clues to Mental Disorders

Researchers from the National Institute of Mental Health (NIMH) have produced the first direct evidence that parts of our brains implicated in mental disorders may be shaped by a “residual echo” from our ancient past. The more a person’s genome carries genetic vestiges of Neanderthals, the more certain parts of his or her brain and skull resemble those of humans’ evolutionary cousins that went extinct 40,000 years ago,, says NIMH’s Karen Berman, MD. NIMH is part of the National Institutes of Health.

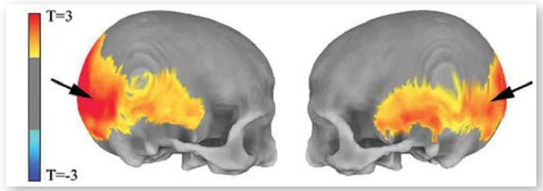
In particular, the parts of our brains that enable us to use tools and visualize and locate objects owe some of their lineage to Neanderthal-derived gene variants that are part of our genomes and affect the shape of those structures — to the extent that an individual harbors the ancient variants. But this may involve trade-offs with our social brain. The evidence from MRI scans suggests that such Neanderthal-derived genetic variation may affect the way our brains work today — and may hold clues to understanding deficits seen in schizophrenia and autism-related disorders, say the researchers.

Dr. Berman, Michael Gregory, MD, of the NIMH Section on Integrative Neuroimaging, and colleagues, report on their magnetic resonance imaging (MRI) study published online, July 24, 2017 in the journal Scientific Reports.

During their primordial migration out of Africa, ancestors of present-day humans are thought to have interbred with Neanderthals, whose brain characteristics can be inferred from their fossilized skulls. For example, these indicate that Neanderthals had more prominent visual systems than modern humans.

“It’s been proposed that Neanderthals depended on visual-spatial abilities and toolmaking, for survival, more so than on the social affiliation and group activities that typify the success of modern humans — and that Neanderthal brains evolved to preferentially support these visuospatial functions,” Berman explained. “Now we have direct neuroimaging evidence that such trade-offs may still be operative in our brains.”

Might some of us, more than others, harbor Neanderthal-derived gene variants that may bias our brains toward trading sociability for visuospatial prowess — or vice versa? The new study adds support to this possibility by showing how these gene variants influence the structure of brain regions underlying those abilities.



MRI data shows (left) areas of the skull preferentially affected by the amount of Neanderthal-derived DNA and (right) areas of the brain’s visual system in which Neanderthal gene variants influenced cortex folding (red) and gray matter volume (yellow). Michael Gregory, MD, NIMH Section on Integrative Neuroimaging

To test this possibility, Gregory and Berman measured the impact of Neanderthal variants on MRI measures of brain structure in a sample of 221 participants of European ancestry, drawn from the NIMH Genetic Study of Schizophrenia.

The new MRI evidence points to a a gene variant shared by modern-day humans and Neanderthals that is likely involved in development of the brain’s visual system. Similarly, Neanderthal variants impacting development of a particular suspect brain area may help to inform cognitive disability seen in certain brain disorders, say the researchers.

For example, in 2012, Berman and colleagues reported on how genetic variation shapes the structure and function of a brain area called the Insula in the autism-related disorder Williams Syndrome. People with this rare genetic disorder are overly sociable and visuo-spatially impaired — conspicuously opposite to the hypothesized Neanderthal propensities and more typical cases on the autism spectrum. Mice in which a gene affected by Williams syndrome is experimentally deleted show increased separation anxiety. And just last week, researchers showed that the same genetic variability also appears to explain why dogs are friendlier than wolves.

Reference:

Gregory MD, Kippenhan JS, Eisenberg DP, Kohn PD, Dickenson D, Mattay VS, Chen Q, Weinberger DR, Saad ZS, Berman KF. Neanderthal-derived genetic variation shapes modern human cranium and brain. Scientific Reports, July 24, 2017, DOI:10.1038/s41598-017-06587-0

nih.gov

Higher Death Rate among Youth with First Episode Psychosis

NIH-funded study highlights need for increased early intervention programs

A new study shows that young people experiencing first episode psychosis have a much higher death rate than previously thought. Researchers analyzed data on approximately 5,000 individuals aged 16-30 with commercial health insurance who had received a new psychosis diagnosis, and followed them for the next 12 months. They found that the group had a mortality rate at least 24 times greater than the same age group in the general population, in the 12 months after the initial psychosis diagnosis. This study, funded by the National Institute of Mental Health (NIMH), part of the National Institutes of Health, underscores that young people experiencing psychosis warrant intensive and proactive treatments, services and supports.

The research, led by Michael Schoenbaum, PhD, Senior Advisor for Mental Health Services, Epidemiology, and Economics at NIMH, was published online today by Schizophrenia Bulletin.

The research team used insurance claims data to identify young people aged 16-30 who had been diagnosed with a first episode of psychosis in 2008-2009. They used data from the Social Security Administration to identify deaths in this population within 12 months of the initial psychosis diagnosis. Data on cause or manner of death were not available for this research.

“These findings show the importance of tracking mortality in individuals with mental illness.”

— Michael Schoenbaum, PhD, Senior Advisor for Mental Health Services, Epidemiology, and Economics, NIMH

Data showed that young people with a new psychosis diagnosis had surprisingly low rates of medical oversight and only modest involvement with psychosocial treatment providers.

The 12-month mortality rate for these young people — from any cause — was at least 24 times higher than their peers in the general population. In the general United States population, only individuals over age 70 come close to a similar 12-month mortality rate.

“These findings show the importance of tracking mortality in individuals with mental illness,” said Schoenbaum. “Health systems do this in other areas of medicine, such as cancer and cardiology, but not for mental illness. Of course, we also need to learn how these young people are losing their lives.”

In addition to mortality, the study examined the health care individuals received in the 12 months after the initial psychosis diagnosis. Those data showed that young people with a new psychosis diagnosis had surprisingly low rates of medical oversight and only modest involvement with psychosocial treatment providers. Overall, 61 percent of them did not receive any antipsychotic medications, and 41 percent did not receive any psychotherapy. Those who died within 12 months of diagnosis received even less outpatient treatment and relied more heavily on hospital and emergency care.

“Other studies have shown that early coordinated treatment for psychosis produces the best results. However, we know that the typical duration of untreated psychosis in the United States is around 17 months,” said Robert Heinssen, PhD, director of the Division of Intervention Services at NIMH and co-author on the paper. “This study reinforces federal and state support for funding evidence-based psychosis treatment programs across the country, and the need for communities to invest in more treatment programs.”

“Grants from the Substance Abuse and Mental Health Services Administration promote many of these programs in communities throughout the U.S.,” said Acting Deputy Assistant Secretary Kana Enomoto, head of the Substance Abuse and Mental Health Services Administration (SAMHSA).

“The future of this research will show us what is happening with young people in this population, and help us tailor interventions to address their risks,” added Schoenbaum. “In the meantime, this study is a wake-up call telling us that young people experiencing psychosis need intensive, integrated clinical and psychosocial supports.”

Reference

Schoenbaum, M., Sutherland, J., Chappel, A., Azrin, S., Goldstein, A., Rupp, A., Heinssen, R. Twelve-Month Health Care Use and Mortality in Commercially Insured Young People with Incident Psychosis in the United States.

nih.gov

Kidney Failure Declining Among U.S. Diabetics

By Margaret Farley Steele

While diabetes cases continue to rise in the United States, one potential outcome — kidney failure — has decreased by one-third, health officials report.

The rate of kidney failure requiring dialysis or transplantation among people with diabetes fell 33 percent from 2000 to 2014, a new report from the U.S. Centers for Disease Control and Prevention shows. This continued a trend begun in the 1990s.

"Continued awareness of risk factors for kidney failure and interventions to improve diabetes care might sustain and improve these trends," wrote researchers led by Nilka Rios Burrows. She's an epidemiologist in the CDC's division of diabetes translation.

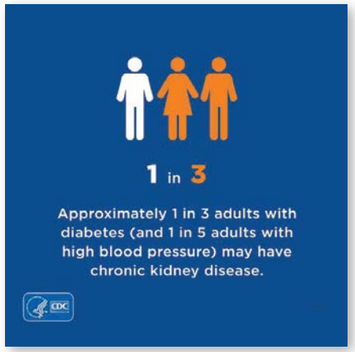
The survey data reflects all 50 states, the District of Columbia and Puerto Rico.

It's likely that people with diabetes have better control of blood pressure and blood sugar, two risk factors for kidney failure, the researchers suggested. For example, treatment with so-called ACE inhibitors or angiotensin-receptor blockers can slow the decline in kidney function while lowering blood pressure, they noted.

Dr. Maria DeVita, a nephrologist at Lenox Hill Hospital in New York City, agreed.

"We can conclude that the measures that physicians take to delay progression is working to some degree," she said.

However, "we have to be cautious about the data as some of it was from



self-reporting," DeVita added. "In addition, there has been a significant increase in those patients undergoing preemptive kidney transplant, thus not technically reaching [end-stage kidney failure] and therefore not being captured on federal forms."

According to the report, about 1 in 3 adults with diabetes has kidney damage or reduced kidney function. But most are unaware of it.

The researchers said earlier screening for kidney disease in people with diabetes is important. And better treatment can prevent complications, they noted.

More than 9 percent of Americans are estimated to have diabetes, according to recent CDC figures. The overwhelming majority have type 2, which is linked to overeating and a sedentary lifestyle.

Preventing type 2 diabetes is one way to lower the odds of chronic kidney disease, the CDC says.

Lifestyle changes, including healthy eating and weight management, can help in that regard.

Despite improving numbers with regard to kidney failure, doctors and patients with diabetes should not become complacent, experts said.

"Diabetic kidney disease remains a major health concern and certainly more work needs to be done," DeVita said.

The study findings appear in the CDC's Nov. 3 Mortality and Morbidity Weekly Report.

SOURCE: U.S. Centers for Disease Control and Prevention, Nov. 3, 2017, Mortality and Morbidity Weekly Report

cdc.gov

This World Kidney Day, Pledge to Maintain a Healthy Weight

NIH statement from Dr. Griffin P. Rodgers, Director, National Institute of Diabetes and Digestive and Kidney Diseases

NIDDK Director Dr. Griffin P. Rodgers

This World Kidney Day, improve your kidney health by making a commitment to reach or maintain a healthy weight. Extra weight increases the risk of developing diabetes and high blood pressure, the two most common causes of chronic kidney disease (CKD). People affected by obesity have an 83 percent higher risk of developing CKD compared to those who have a healthy weight.

More than 20 million people — approximately 1 in 10 American adults — have kidney disease. More than 1 in 3 U.S. adults, and about 1 in 5 teens, are affected by obesity. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of the National Institutes of Health, is working to improve those odds.

Today and every day, the NIDDK joins organizations around the world in promoting healthy habits to prevent obesity and its harmful consequences, including kidney disease. On World Kidney Day on March 9, consider taking these steps to embrace a healthy lifestyle:

- Work with a health care provider to create a realistic weight-control plan.
- Use the NIH Body Weight Planner to help achieve and stay at a healthy weight.
- Choose foods that are heart healthy, such as fresh fruits, fresh or frozen vegetables, whole grains, and low-fat or fat-free dairy products. Cut back on salt and added sugars. Replace soda and other sweet drinks with water or juice that doesn't contain added sugar.
- Be physically active for 30 minutes or more on most days.
- Reduce screen time and spend less time sitting still.
- Aim for 7 to 8 hours of sleep each night.
- Join family, friends, or coworkers in encouraging each other to stick to healthy routines.

Reaching and maintaining a healthy weight can be a difficult goal, but the rewards pay off — for kidney health and beyond. A recent NIDDK-funded study called the Teen Longitudinal Assessment of Bariatric Surgery, or Teen-LABS, showed that a significant number of severely obese teens who had bariatric weight-loss surgery also had evidence of early kidney disease. However, this research found that three years after having bariatric surgery, 86 percent of teens with kidney damage had improved kidney function. As this study looked at a small number of teens, further research is needed to determine the long-term effects of bariatric surgery on health and well-being.

nih.gov

Kidney Disease May Boost Odds of Infection

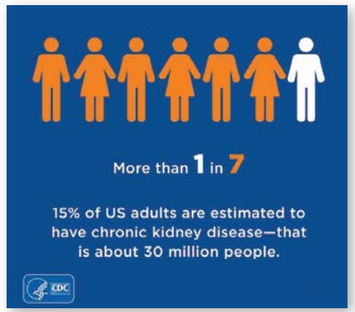
Patients become more vulnerable as organ function declines, study says

By Randy Dotinga

As kidney function declines, infection risk rises, a new study shows. Infections facing people with advanced kidney disease include lower respiratory tract disease, urinary tract infections and blood poisoning, researchers said. The findings were published Aug. 17 in the *Clinical Journal of the American Society of Nephrology*.

"Given the fact that chronic kidney disease remains underdiagnosed and unrecognized in most societies, our findings may help patients and clinicians become more aware of chronic kidney disease and its complications," said co-lead author Juan Jesus Carrero, of the Karolinska Institute in Sweden.

"This in turn may be useful to identify patients at increased risk of infection and



inform discussions about prevention strategies, such as vaccination and health service planning," Carrero said in a journal news release.

The researchers tracked 12 months of data from 1.1 million Swedes who took part in a study examining measures of kidney function.

The researchers found that infection rates grew almost sixfold in people with stage 4 or higher chronic kidney disease, compared to people with normal kidney function. Several types of infection — lower respiratory tract infections, urinary tract infections and sepsis — made up a larger proportion of infections as kidney function worsened.

The study focused on infections that people develop in the community, not hospitals and other health care settings.

SOURCE: *Clinical Journal of the American Society of Nephrology*

medlineplus.gov

Dialysis Patients Often End Up Back in the Hospital

But the readmission is usually for a different problem, study finds

By Robert Preidt

Nearly one-quarter of kidney dialysis patients admitted to the hospital are readmitted within 30 days after discharge, a new study finds.

In many cases, the readmissions are for a different problem than the one that led to the first hospitalization, according to the report. For the study, researchers reviewed data from nearly 391,000 initial hospitalizations of dialysis patients in the United States in 2013. Within 30 days after leaving the hospital, 22 percent of the patients had unplanned readmissions. Only 20 percent of those readmissions were for the same diagnosis as the first admission, the findings showed.

Just 2 percent of all patients accounted for 20 percent of all readmissions. Women and younger people were more likely to be readmitted, the researchers found. In addition, people who were depressed, had liver disease, heart failure or who abused drugs were more likely to end up back in the hospital.

"To reduce readmissions in dialysis patients, perhaps a good starting place would be to institute interventions targeted at high utilizers and create a validated risk score incorporating likely risk factors," study co-lead author Dr. Girish Nadkarni, of Icahn School of Medicine at Mount Sinai in New York City, said in a news release from the American Society of Nephrology.

The study was published online Sept. 28 in the Clinical Journal of the American Society of Nephrology.

SOURCE: American Society of Nephrology

medlineplus.gov

After a Stroke, I Transformed Myself

By Deborah Cotter, Independent Living Program Specialist, Independent Living Administration, Administration for Community Living (ACL)

I grew up in Maine as the quiet type. I came to Washington to work on Capitol Hill for then-Sen. George Mitchell of Maine. But as a seemingly healthy 24-year-old in 1992, I had a stroke due to a birth defect, which, among other things, partially paralyzed my left side. It was not the life I had envisioned.

Despite physical therapy, getting "back to normal" was impossible, and so I hit the restart button. I had to find a new normal. Part of that was to put others at ease with my disability.

Rather than searching for the holy grail, a cure for my paralysis, I realized that I had to transform. I became more outgoing — because people are always going to ask you what is wrong with you. I find that if I put others at ease with my disability it's easier to get what I need. I went to work for a variety of nonprofits, and later government programs, that support people with disabilities. I finally emerged as more self-directed, the CEO of my own life.

A major turning point in my life came in 2014, when I performed in a talent show for the Combined Federal Campaign, the federal government's workplace charitable giving campaign. My standup comedy routine poked fun at my own condition, in a way the audience could understand. People loved it! And I got the comedy bug. Now I take comedy classes, and perform at open mic nights.

I live on my own now and I'm proud to empower others to do the same.

I started with the Independent Living Program in 2009 when it was at the Department of Education and I stayed with the newly created Independent Living Administration (ILA) when the Workforce Innovation and Opportunity Act transferred the program in 2014 to the Administration for Community Living (ACL) at the Department of Health and Human Services. I now manage grants at ILA.

I administer 87 Independent Living grants in eight states. These grants to state and local governments and nonprofit organizations help provide information, tools, resources and supports to help people with disabilities live fully integrated in their communities and to promote equal opportunities, self-determination and respect. The Independent Living programs are critical to helping people avoid or leave, costly institutions, which often are paid for by Medicaid.

The programs also empower people with disabilities to be actively in charge of their lives. They help people find their new normal and live their lives without being dependent on anyone except themselves.

I recently suffered from gallstones and ended up having my gallbladder removed at Sibley Hospital, whose staff participated in a training program on person-centered planning led by the D.C. No Wrong Door System. These programs are funded and supported by ACL to help service providers improve their processes to ensure that people receiving care or services are in the driver's seat for decisions. With their person-centered system, I could be my own advocate and know everything that was going on with my procedure.

This was a very welcome contrast to my experience when I had my stroke in 1992. Then I was left out of the loop, and the doctors ignored me or only talked to my parents. This time I was at the center of everything and knew what to expect. I could have done without the pain, but I was pleased to have the opportunity to see how ACL funding works in practice through Sibley's programs.

Administration for Community Living grantees make an invaluable contribution to society, helping people with disabilities make their own choices and live independently in their communities with the people they choose. I am proud to be a part of this mission.

I'm Deb Cotter and I am HHS.

Deb Cotter is an Independent Living Program Specialist at ACL. She is one of more than 79,000 people who make HHS run every day.

hhs.gov

ACL Administration for Community Living

Migraine in the Spotlight NIH STEP Forum Explores Headaches

By Belle Waring

Millions of Americans suffer from migraines and NIH wants to help. A panel of experts recently convened in Lister Hill auditorium for a STEP forum on the science and management of headaches.

"Right now, today, on average," said the University of California, San Francisco's Dr. Peter Goadsby, "around 1.1 million Americans have a migraine and are out there just trying to get on with life."

Migraine, the most common kind of headache, strikes up to 18 percent of women and 7 percent of men, as well as 8 percent of children/adolescents. "However," Goadsby continued, "today we will spend one-tenth of one penny on each American [who gets] migraine each day…making headache research perhaps a little under-resourced."

The forum focused on headaches that are primary (without any underlying disorder) rather than secondary (produced by something else). The vast majority of people get headaches at least occasionally, said epidemiologist Dr. Ann Scher of the Uniformed Services University of the Health Sciences. "The most common types of primary headaches are tension-type headache, migraine and chronic daily headache," said Scher.

Tension-type headache, by definition, is less disabling than migraine headache. As for chronic daily headache, "it's prevalent in about 3 to 4 percent of adults, 2 percent of children/adolescents and is about twice as common in women as men."

Migraine typically affects only one side of the head, although not always. It is more than a headache and may include nausea and vomiting as well as weakness and sensitivity to light and sound. It may also be preceded by an aura: transient neurological symptoms that are usually visual, such as seeing stars or spots or partial loss of vision. Less common aura symptoms include transient numbness, motor or speech problems. About one-third of migraine sufferers experience an aura at least occasionally. Migraine attacks, which can be episodic or chronic, can last up to 72 hours.

"Migraine is the most common neurological disorder in both women and men," Scher said.

There are almost 30 million migraine sufferers in the U.S., but up to 50 percent of migraineurs (folks who get migraines) do not consult physicians. Yet the 1997 Global Burden of Disease Study ranked severe migraine in the same class as active psychosis and quadriplegia (paralysis of the arms and legs).

Another study showed $1 billion per year in direct costs (physician visits, etc.) and $13 billion in indirect costs, as in missed work and "presentee-ism," when you come to work but can't perform well.

Dr. Elizabeth Loder of Harvard Medical School and Brigham and Women's/Faulkner Hospitals reviewed differential diagnosis. Doctors diagnose migraine by a physical examination, patterns of symptoms and a thorough patient history to distinguish it from other headaches, whether tension, cluster or "primary stabbing headache." She said that "as clinicians, we have very poor treatment therapies for most of these people; it's an area of significant unmet need." Migraine is often refractory — stubbornly resistant — to treatment.

"Current treatments work well for people who have occasional headaches," she said, "but the treatments we have for people with daily or almost daily headache problems are limited and for many people are not especially effective."

Goadsby, who heads UCSF's headache group, returned to discuss migraine pathophysiology (changes in normal function). "While it's common to have a first degree relative with migraine," he said, "the genetics [have] yet to be worked out… "Migraine is a dreadful phenomenon," he said, "and one of the greatest unmet needs is prevention."

Dr. Stephen Silberstein, director of Thomas Jefferson University's Headache Center, spoke of integrated therapies: medications, both prescription and over the counter, as well as quiet, rest, cold compresses and behavioral interventions such as stress management. He suggested a "headache calendar" to help patients identify and remove triggers such as hormonal factors, stress and certain foods.

There is no cure for migraines.

"Depakote — we're talking about the best drug we have — is barely able to break the 50 percent barrier," he said.

"Migraine may be progressive [going from bad to worse] within an individual attack and within the disorder." There is nothing to be gained by delaying treatment. "If you see a patient with migraine, treat early," he advised.

nih.gov

TROKENDI XR® (topiramate) extended-release capsules for oral use

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

For full prescribing information see Package Insert

Rx Only

CONTRAINDICATIONS

TROKENDI XR is contraindicated in patients:

- With recent alcohol use (i.e., within 6 hours prior to and 6 hours after TROKENDI XR use)
- With metabolic acidosis who are taking concomitant metformin

WARNINGS AND PRECAUTIONS

Acute Myopia and Secondary Angle Closure Glaucoma

A syndrome consisting of acute myopia associated with secondary angle closure glaucoma has been reported in patients receiving topiramate. Symptoms include acute onset of decreased visual acuity and/or ocular pain. Opthalmologic findings can include myopia, anterior chamber shallowing, ocular hyperemia (redness) and increased intraocular pressure. Mydriasis may or may not be present. This syndrome may be associated with supraciliary effusion resulting in anterior displacement of the lens and iris, with secondary angle closure glaucoma. Symptoms typically occur within 1 month of initiating topiramate therapy. In contrast to primary narrow angle glaucoma, which is rare under 40 years of age, secondary angle closure glaucoma associated with topiramate has been reported in pediatric patients as well as adults. The primary treatment to reverse symptoms is discontinuation of TROKENDI XR as rapidly as possible, according to the judgment of the treating physician. Other measures, in conjunction with discontinuation of TROKENDI XR, may be helpful.

Elevated intraocular pressure of any etiology, if left untreated, can lead to serious sequelae including permanent vision loss.

Visual Field Defects

Visual field defects (independent of elevated intraocular pressure) have been reported in clinical trials and in postmarketing experience in patients receiving topiramate. In clinical trials, most of these events were reversible after topiramate discontinuation. If visual problems occur at any time during treatment with TROKENDI XR, consideration should be given to discontinuing the drug.

Oligohydrosis and Hyperthermia

Oligohydrosis (decreased sweating), resulting in hospitalization in some cases, has been reported in association with topiramate use. Decreased sweating and an elevation in body temperature above normal characterized these cases. Some of the cases were reported after exposure to elevated environmental temperatures.

The majority of the reports have been in pediatric patients. Patients, especially pediatric patients, treated with TROKENDI XR should be monitored closely for evidence of decreased sweating and increased body temperature, especially in hot weather. Caution should be used when TROKENDI XR is prescribed with other drugs that predispose patients to heat-related disorders; these drugs include, but are not limited to, other carbonic anhydrase inhibitors and drugs with anticholinergic activity.

Metabolic Acidosis

Hyperchloremic, non-anion gap, metabolic acidosis (i.e., decreased serum bicarbonate below the normal reference range in the absence of chronic respiratory alkalosis) is associated with topiramate, and can be expected with treatment with TROKENDI XR. This metabolic acidosis is caused by renal bicarbonate loss due to the inhibitory effect of topiramate on carbonic anhydrase. Such electrolyte imbalance has been observed with the use of topiramate in placebo-controlled clinical trials and in the post-marketing period. Generally, topiramate-induced metabolic acidosis occurs early in treatment although cases can occur at any time during treatment. Bicarbonate decrements are usually mild to moderate (average decrease of 4 mEq/L at daily doses of 400 mg in adults and at approximately 6 mg/kg/day in pediatric patients); rarely, patients can experience severe decrements to values below 10 mEq/L. Conditions or therapies that predispose patients to acidosis (such as renal disease, severe respiratory disorders, status epilepticus, diarrhea, ketogenic diet or specific drugs) may be additive to the bicarbonate lowering effects of topiramate.

Manifestations of Metabolic Acidosis

Some manifestations of acute or chronic metabolic acidosis may include hyperventilation, nonspecific symptoms such as fatigue and anorexia, or more severe sequelae including cardiac arrhythmias or stupor. Chronic, untreated metabolic acidosis may increase the risk for nephrolithiasis or nephrocalcinosis, and may also result in osteomalacia (referred to as rickets in pediatric patients) and/or osteoporosis with an increased risk for fractures. Chronic metabolic acidosis in pediatric patients may also reduce growth rates.

A reduction in growth rate may eventually decrease the maximal height achieved. The effect of topiramate on growth and bone-related sequelae has not been systematically investigated in long-term, placebo-controlled trials. Long-term, open-label treatment of infants/toddlers, with intractable partial epilepsy, for up to 1 year, showed reductions from baseline in Z SCORES for length, weight, and head circumference compared to age and sex-matched normative data, although these patients with epilepsy are likely to have different growth rates than normal infants. Reductions in Z SCORES for length and weight were correlated to the degree of acidosis. Topiramate treatment that causes metabolic acidosis during pregnancy can possibly produce adverse effects on the fetus and might also cause metabolic acidosis in the neonate from possible transfer of topiramate to the fetus.

Migraine

Adult Patients

The incidence of persistent decreases in serum bicarbonate in placebo-controlled trials with immediate-release topiramate in adults for the prophylaxis of migraine was 44% for 200 mg per day, 39% for 100 mg per day, 23% for 50 mg per day, and 7% for placebo. The incidence of a markedly abnormally low serum bicarbonate (i.e., absolute value less than 17mEq/L, and greater than 5mEq/L decrease from pretreatment) in these trials was 11% for 200 mg per day, 9% for 100 mg per day, 2% for 50 mg per day, and less than 1% for placebo.

Adolescent Patients

In pooled, double-blind migraine prophylaxis studies in adolescent patients (12 to 17 years of age), the incidence of persistent decreases in serum bicarbonate was 77% for 200 mg/day, 27% for 100 mg/day, 30% for 50 mg/day, and 9% for placebo. The incidence of markedly low serum bicarbonate (i.e., absolute value <17 mEq/L and >5 mEq/L decrease from pretreatment) was 6% for 100 mg/day, 2% for 50 mg/day, and 2% for placebo. This bicarbonate criterion was not met by any patients in the 200 mg/day group, which had a low number of subjects (n=13).

Risk Mitigation Strategies

Measurement of baseline and periodic serum bicarbonate during topiramate treatment is recommended. If metabolic acidosis develops and persists, consideration should be given to reducing the dose or discontinuing topiramate (using dose tapering). If the decision is made to continue patients on topiramate in the face of persistent acidosis, alkali treatment should be considered.

Interaction with Alcohol

In vitro data show that, in the presence of alcohol, the pattern of topiramate release from TROKENDI XR capsules is significantly altered. As a result, plasma levels of topiramate with TROKENDI XR may be markedly higher soon after dosing and subtherapeutic later in the day. Therefore, alcohol use should be completely avoided within 6 hours prior to and 6 hours after TROKENDI XR administration.

Suicidal Behavior and Ideation

Antiepileptic drugs (AEDs) increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED, including TROKENDI XR for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

Pooled analyses of 199 placebo-controlled clinical trials (mono- and adjunctive therapy) of 11 different AEDs showed that patients randomized to one of the AEDs had approximately twice the risk (adjusted Relative Risk 1.8, 95% CI:1.2, 2.7) of suicidal thinking or behavior compared to patients randomized to placebo. In these trials, which had a median treatment duration of 12 weeks, the estimated incidence rate of suicidal behavior or ideation among 27,863 AED-treated patients was 0.43%, compared to 0.24% among 16,029 placebo-treated patients, representing an increase of approximately one case of suicidal thinking or behavior for every 530 patients treated. There were four suicides in drug-treated patients in the trials and none in placebo-treated patients, but the number is too small to allow any conclusion about drug effect on suicide.

The increased risk of suicidal thoughts or behavior with AEDs was observed as early as one week after starting drug treatment with AEDs and persisted for the duration of treatment assessed. Because most trials included in the analysis did not extend beyond 24 weeks, the risk of suicidal thoughts or behavior beyond 24 weeks could not be assessed.

The risk of suicidal thoughts or behavior was generally consistent among drugs in the data analyzed. The finding of increased risk with AEDs of varying mechanisms of action and across a range of indications suggests that the risk applies to all AEDs used for any indication. The risk did not vary substantially by age (5 to 100 years) in the clinical trials analyzed.

Table 1 shows absolute and relative risk by indication for all evaluated AEDs.

Table 1: Risk by Indication for Antiepileptic Drugs in the Pooled Analysis

Indication	Placebo Patients with Events per 1,000 Patients	Drug Patients with Events per 1,000 Patients	Relative Risk: Incidence of Events in Drug Patients/ Incidence in Placebo Patients	Risk Difference: Additional Drug Patients with Events per 1,000 Patients
Epilepsy	1.0	3.4	3.5	2.4
Psychiatric	5.7	8.5	1.5	2.9
Other	1.0	1.8	1.9	0.9
Total	2.4	4.3	1.8	1.9

The relative risk for suicidal thoughts or behavior was higher in clinical trials for epilepsy than in clinical trials for psychiatric or other conditions, but the absolute risk differences were similar for the epilepsy and psychiatric indications.

Anyone considering prescribing TROKENDI XR or any other AED must balance the risk of suicidal thoughts or behavior with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Should suicidal thoughts and behavior emerge during treatment, the prescriber needs to consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

Patients, their caregivers, and families should be informed that AEDs increase the risk of suicidal thoughts and behavior and should be advised of the need to be alert for the emergence or worsening of the signs and symptoms of depression, any unusual changes in mood or behavior or the emergence of suicidal thoughts, behavior or thoughts about self-harm. Behaviors of concern should be reported immediately to healthcare providers.

Cognitive/Neuropsychiatric Adverse Reactions

Adverse reactions most often associated with the use of topiramate, and therefore expected to be associated with the use of TROKENDI XR, were related to the central nervous system and were observed in both the epilepsy and migraine populations. In adults, the most frequent of these can be classified into three general categories: 1) Cognitive-related dysfunction (e.g., confusion, psychomotor slowing, difficulty with concentration/attention, difficulty with memory, speech or language problems, particularly word-finding difficulties), 2) Psychiatric/behavioral disturbances (e.g., depression or mood problems), and 3) Somnolence or fatigue.

Adult Patients

Cognitive Related Dysfunction

The majority of cognitive-related adverse reactions were mild to moderate in severity, and they frequently occurred in isolation. Rapid titration rate and higher initial dose were associated with higher incidences of these reactions. Many of these reactions contributed to withdrawal from treatment.

In the 6-month migraine prophylaxis controlled trials of immediate release topiramate using a slower titration regimen (25 mg per day weekly increments), the proportion of patients who experienced one or more cognitive-related adverse reactions was 19% for topiramate 50 mg per day, 22% for 100 mg per day (the recommended dose), 28% for 200 mg per day and 10% for placebo. These dose-related adverse reactions typically began in the titration phase and often persisted into the maintenance phase, but infrequently began in the maintenance phase. Some patients experienced a recurrence of one or more of these cognitive adverse reactions and this recurrence was typically in the titration phase. A relatively small proportion of topiramate-treated patients experienced more than one concurrent cognitive adverse reaction. The most common cognitive adverse reactions occurring together included difficulty with memory along with difficulty with concentration/attention, difficulty with memory along with language problems, and difficulty with concentration/attention along with language problems. Rarely, topiramate-treated patients experienced three concurrent cognitive reactions.

Psychiatric/Behavioral Disturbances

Psychiatric/behavioral disturbances (depression or mood) were dose-related for migraine populations treated with topiramate.

Somnolence/Fatigue

For the migraine population, somnolence and fatigue were dose-related and more common in the titration phase.

Pediatric Patients

Migraine

The incidence of cognitive adverse reactions was increased in topiramate-treated patients (7%) versus placebo (4%) in pooled, double-blind placebo-controlled studies in which adolescent patients (12 to 17 years) were randomized to placebo or one of several fixed daily doses of immediate release topiramate (50 mg, 100 mg, 200 mg).

The incidence of cognitive adverse reactions was also increased in a placebo-controlled study of pediatric patients (6 to 16 years) treated with 2 to 3 mg/kg/day of immediate-release topiramate (10%) versus placebo treatment (2%). TROKENDI XR® is not approved for prophylaxis of migraine in pediatric patients under 12 years of age.

The risk for cognitive adverse reactions was dose-dependent, and was particularly evident at the 200 mg dose. This risk for cognitive adverse reactions was also greater in younger patients (6 to 11 years) than in older patients (12 to 17 years). The most common cognitive adverse reaction in these trials was difficulty with concentration/attention. Cognitive adverse reactions most commonly developed in the titration period and sometimes persisted into the maintenance period. These adverse reactions typically occurred in isolation as single type of cognitive adverse reaction. Cognitive adverse reactions that led to study discontinuation occurred in one patient (difficulty with concentration/attention and language problems). The Cambridge Neuropsychological Test Automated Battery (CANTAB) was administered to adolescents (12 to 17 years) to assess the effects of topiramate on cognitive function at baseline at the end of the study. Mean change from baseline in certain CANTAB tests suggests that topiramate treatment may result in psychomotor slowing and decreased verbal fluency.

Fetal Toxicity

Topiramate can cause fetal harm when administered to a pregnant woman. Data from pregnancy registries indicate that infants exposed to topiramate *in utero* have an increased risk for cleft lip and/or cleft palate (oral clefts) and for being small for gestational age. In multiple species, oral administration of topiramate to pregnant animals at clinically relevant doses resulted in structural malformations, including craniofacial defects, and reduced body weights in offspring.

Consider the benefits and risks of TROKENDI XR when administering the drug in women of childbearing potential, particularly when TROKENDI XR is considered for a condition not usually associated with permanent injury or death. TROKENDI XR should be used during pregnancy only if the potential benefit outweighs the potential risk. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be informed of the potential hazard to a fetus.

Withdrawal of Antiepileptic Drugs

In patients with or without a history of seizures or epilepsy, antiepileptic drugs including TROKENDI XR should be gradually withdrawn to minimize the potential for seizures or increased seizure frequency. In situations where rapid withdrawal of TROKENDI XR is medically required, appropriate monitoring is recommended.

Hyperammonemia and Encephalopathy

Hyperammonemia/Encephalopathy Without Concomitant Valproic Acid (VPA)

Topiramate treatment has produced hyperammonemia (in some instances dose-related) in a clinical investigational program in adolescent patients (12 to 17 years) who were treated with topiramate for migraine prophylaxis. The incidence of hyperammonemia (above the upper limit of normal reference) at any time in the trial was 9% for placebo, 14% for 50 mg, and 26% for 100 mg topiramate daily. In some patients, hyperammonemia was observed at the end of the trial at the final visit. The incidence of markedly increased hyperammonemia (at least 50% or higher above upper limit of normal) at any time in the trial in adolescent patients was also increased at 100 mg/day (9%) compared to 50 mg topiramate (0%) or placebo (3%). During this trial, markedly increased ammonia levels returned to normal in all but one patient (in whom the ammonia level fell to high instead of markedly abnormal).

Clinical symptoms of hyperammonemic encephalopathy often include acute alterations in level of consciousness and/or cognitive function with lethargy or vomiting.

Hyperammonemia with and without encephalopathy has also been observed in postmarketing reports in patients who were taking topiramate without concomitant valproic acid (VPA).

Hyperammonemia/Encephalopathy With Concomitant Valproic Acid (VPA)

Concomitant administration of topiramate and VPA has been associated with hyperammonemia with or without encephalopathy in patients who have tolerated either drug alone based upon postmarketing reports. Although hyperammonemia may be asymptomatic, clinical symptoms of hyperammonemic encephalopathy often include acute alterations in level of consciousness and/or cognitive function with lethargy or vomiting. In most cases, symptoms and signs abated with discontinuation of either drug. This adverse reaction is not due to a pharmacokinetic interaction.

Although TROKENDI XR is not indicated for use in infants/toddlers (1 month to 24 months), topiramate with concomitant VPA clearly produced a dose-related increase in the incidence of hyperammonemia (above the upper limit of normal, 0% for placebo, 12% for 5 mg/kg/day, 7% for 15 mg/kg/day, 17% for 25 mg/kg/day) in an investigational program using topiramate. Markedly increased, dose-related hyperammonemia (0% for placebo and 5 mg/kg/day, 7% for 15 mg/kg/day, and 8% for 25 mg/kg/day) also occurred in these infants/toddlers. Dose-related hyperammonemia was similarly observed in a long-term, extension trial utilizing topiramate in these very young, pediatric patients.

Hyperammonemia with and without encephalopathy has also been observed in postmarketing reports in patients taking topiramate with valproic acid (VPA).

The hyperammonemia associated with topiramate treatment appears to be more common when used concomitantly with VPA.

Monitoring for Hyperammonemia

Patients with inborn errors of metabolism or reduced hepatic mitochondrial activity may be at an increased risk for hyperammonemia with or without encephalopathy. Although not studied, topiramate or TROKENDI XR treatment or an interaction of concomitant topiramate-based product and valproic acid treatment may exacerbate existing defects or unmask deficiencies in susceptible persons.

In patients who develop unexplained lethargy, vomiting, or changes in mental status associated with any topiramate treatment, hyperammonemic encephalopathy should be considered and an ammonia level should be measured.

Kidney Stones

Kidney stones have been reported in pediatric patients taking topiramate for migraine prophylaxis. For the double-blind migraine prophylaxis studies, one adverse event (renal calculus) occurred in a topiramate-treated subject in the age 12 to 17 years group. The overall experience with open-label, long-term, topiramate treatment for migraine prophylaxis is limited in pediatric patients.

TROKENDI XR would be expected to have the same effect as topiramate on the formation of kidney stones. An explanation for the association of topiramate and kidney stones may lay in the fact that topiramate is a carbonic anhydrase inhibitor. Carbonic anhydrase inhibitors (e.g., zonisamide, acetazolamide or dichlorphenamide) can promote stone formation by reducing urinary citrate excretion and by increasing urinary pH. The concomitant use of TROKENDI XR with any other drug producing metabolic acidosis, or potentially in patients on a ketogenic diet may create a physiological environment that increases the risk of kidney stone formation, and should therefore be avoided.

Increased fluid intake increases the urinary output, lowering the concentration of substances involved in stone formation. Hydration is recommended to reduce new stone formation.

Hypothermia with Concomitant Valproic Acid Use

Hypothermia, defined as an unintentional drop in body core temperature to less than 35°C (95°F) has been reported in association with topiramate use with concomitant VPA both in the presence and in the absence of hyperammonemia. This adverse reaction in patients using concomitant topiramate and valproate can occur after starting topiramate treatment or after increasing the daily dose of topiramate. Consideration should be given to stopping topiramate or valproate in patients who develop hypothermia, which may be manifested by a variety of clinical abnormalities including lethargy, confusion, coma, and significant alterations in other major organ systems such as the cardiovascular and respiratory systems. Clinical management and assessment should include examination of blood ammonia levels.

Paresthesia

Paresthesia (usually tingling of the extremities), an effect associated with the use of other carbonic anhydrase inhibitors, appears to be a common effect of topiramate. Paresthesia was more frequently reported in the monotherapy epilepsy and migraine prophylaxis trials conducted with topiramate than in the adjunctive therapy epilepsy trials conducted with the same product. In the majority of instances, paresthesia did not lead to treatment discontinuation.

Interaction with Other CNS Depressants

Topiramate is a CNS depressant. Concomitant administration of topiramate with other CNS depressant drugs can result in significant CNS depression. Patients should be watched carefully when TROKENDI XR is co-administered with other CNS depressant drugs.

ADVERSE REACTIONS

TROKENDI XR has not been studied in a randomized, placebo-controlled Phase III clinical study. However, it is expected that TROKENDI XR would produce a similar adverse reaction profile as immediate-release topiramate.

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Increased Risk for Bleeding

Topiramate treatment is associated with an increased risk for bleeding. In a pooled analysis of placebo-controlled studies of approved and unapproved indications, bleeding was more frequently reported as an adverse event for topiramate than for placebo (4.5% versus 3.0% in adult patients, and 4.4% versus 2.3% in pediatric patients). In this analysis, the incidence of serious bleeding events for topiramate and placebo was 0.3% versus 0.2% for adult patients, and 0.4% versus 0% for pediatric patients.

Adverse bleeding reactions reported with topiramate ranged from mild epistaxis, ecchymosis, and increased menstrual bleeding to life-threatening hemorrhages. In patients with serious bleeding events, conditions that increased the risk for bleeding were often present, or patients were often taking drugs that cause thrombocytopenia (other antiepileptic drugs) or affect platelet function or coagulation (e.g., aspirin, nonsteroidal anti-inflammatory drugs, selective serotonin reuptake inhibitors, or warfarin or other anticoagulants).

Clinical Trial Experience in Migraine

Adult Patients

In the four multicenter, randomized, double-blind, placebo-controlled, parallel group migraine prophylaxis clinical trials (which included 35 adolescent patients age 12 to 15 years) conducted with immediate-release topiramate, most of the adverse reactions were mild or moderate in severity. Most adverse reactions occurred more frequently during the titration period than during the maintenance period.

The most common (≥5% more frequent than placebo) adverse reactions associated with the use of the 100 mg topiramate dose in controlled, migraine clinical trials of predominantly adults were paresthesia, anorexia, weight decrease, taste perversion, diarrhea, difficulty with memory, hypoesthesia, and nausea.

Table 2 includes those adverse reactions reported for patients in the placebo-controlled trials where the incidence in any immediate-release topiramate group was at least 2% and was greater than that for placebo patients.

Table 2: Incidence (%) of Adverse Reactions in Placebo-Controlled, Migraine Trials Where Incidence Was ≥ 2% in Any Immediate-Release Topiramate Group and Greater than the Rate in Placebo Patients**

Body System	Placebo	Topiramate dosage (mg/day)		
Adverse Reaction		50	100	200
	(N=445) %	(N=235) %	(N=386) %	(N=514) %
Body as a Whole–General Disorders				
Fatigue	11	14	15	19
Injury	7	9	6	6
Asthenia	1	Less than 1	2	2
Fever	1	1	1	2
Influenza-like symptoms	Less than 1	Less than 1	Less than 1	2
Allergy	Less than 1	2	Less than 1	Less than 1
Central & Peripheral Nervous System Disorders				
Paresthesia	6	35	51	49
Dizziness	10	8	9	12
Hypoaesthesia	2	6	7	8
Language problems	2	7	6	7
Involuntary muscle contractions	1	2	2	4
Ataxia	Less than 1	1	2	1
Speech disorders/Related speech problems	Less than 1	1	Less than 1	2
Gastro-Intestinal System Disorders				
Nausea	8	9	13	14
Diarrhea	4	9	11	11
Abdominal pain	5	6	6	7
Dyspepsia	3	4	5	3
Dry mouth	2	2	3	5
Vomiting	2	1	2	3
Gastroenteritis	1	3	3	2

(continued on next page)

TROKENDI XR® (topiramate) extended-release capsules for oral use

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

(continued from previous page)

Body System	Placebo	Topiramate Dosage (mg/day)		
Adverse Reaction		50	100	200
	(N=445) %	(N=235) %	(N=386) %	(N=514) %
Hearing and Vestibular Disorders				
Tinnitus	1	Less than 1	1	2
Metabolic and Nutritional Disorders				
Weight decrease	1	6	9	11
Thirst	Less than 1	2	2	1
Musculoskeletal System Disorders				
Arthralgia	2	7	3	1
Neoplasms				
Neoplasm	Less than 1	2	Less than 1	Less than 1
Psychiatric Disorders				
Anorexia	6	9	15	14
Somnolence	5	8	7	10
Difficulty with memory	2	7	7	11
Difficulty with concentration/ attention	2	3	6	10
Insomnia	5	6	7	6
Anxiety	3	4	5	6
Mood Problems	2	3	6	5
Depression	4	3	4	6
Nervousness	2	4	4	4
Confusion	2	2	3	4
Psychomotor slowing	1	3	2	4
Libido decreased	1	1	1	2
Aggravated depression	1	1	2	2
Agitation	1	2	2	1
Cognitive problems	1	Less than 1	2	2
Reproductive Disorders, Female				
Menstrual disorder	2	3	2	2
Reproductive Disorders, Male				
Ejaculation premature	0	3	0	0
Resistance Mechanism Disorders				
Viral Infection	3	4	4	3
Otitis media	Less than 1	2	1	1
Respiratory System Disorders				
Upper respiratory tract infection	12	13	14	12
Sinusitis	6	10	6	8
Pharyngitis	4	5	6	2
Coughing	2	2	4	3
Bronchitis	2	3	3	3
Dyspnea	2	1	3	2
Rhinitis	1	1	2	2
Skin and Appendages Disorders				
Pruritis	2	4	2	2
Special Sense Other, Disorders				
Taste perversion	1	15	8	12
Taste loss	Less than 1	1	1	2
Urinary System Disorders				
Urinary tract infection	2	4	2	4
Renal calculus	0	0	1	2
Vision Disorders				
Vision abnormal	Less than 1	1	2	3
Blurred vision	2	4	2	4
Conjunctivitis	1	1	2	1

[a] Includes 35 adolescent patients age 12 to 15 years

[b] Values represent the percentage of patients reporting a given reaction. Patients may have reported more than one adverse reaction during the study and can be included in more than one adverse reaction category.

[c] Blurred vision was the most common term considered as vision abnormal. Blurred vision was an included term that accounted for more than 50% of reactions coded as vision abnormal, a preferred term

Of the 1135 patients exposed to immediate-release topiramate in the placebo-controlled studies, 25% discontinued due to adverse reactions, compared to 10% of the 445 placebo patients. The adverse reactions associated with discontinuing therapy in patients in these studies included paresthesia (7%), fatigue (4%), nausea (4%), difficulty with concentration/attention (3%), insomnia (3%), anorexia (2%) and dizziness (2%).

Patients treated in these studies experienced mean percent reductions in body weight that were dose-dependent. This change was not seen in the placebo group. Mean changes of 0%, -2%, -3%, and -4% were seen for the placebo group, immediate-release topiramate 50 mg, 100 mg, and 200 mg groups, respectively.

Table 3 shows adverse reactions that were dose-dependent. Several central nervous system adverse reactions, including some that represented cognitive dysfunction, were dose-related. The most common dose-related adverse reactions (treatment difference ≥5% for the 100 mg dose) were: paresthesia, nausea, anorexia, difficulty with memory, diarrhea, weight decrease, and hypoesthesia.

Table 3: Incidence (%) of Dose-Related Adverse Reactions From Placebo-Controlled, Migraine Trials[a]

Body System	Placebo	Topiramate Dosage (mg/day)		
Adverse Reaction		50	100	200
	(N=445) %	(N=235) %	(N=386) %	(N=514) %
Paresthesia	6	35	51	49
Fatigue	11	14	15	19
Nausea	8	9	13	14
Anorexia	6	9	15	14
Dizziness	10	8	9	12
Weight decrease	1	6	9	11
Difficulty with memory	2	7	7	11
Diarrhea	4	9	11	11
Difficulty with concentration/ attention	2	3	6	10
Somnolence	5	8	7	10
Hypoaesthesia	2	6	7	8
Anxiety	3	4	5	6
Depression	4	3	4	6
Mood problems	2	3	6	5
Dry mouth	2	2	3	5
Confusion	2	2	3	4
Involuntary muscle contractions	1	2	2	4
Abnormal vision	Less than 1	1	2	3
Renal calculus	0	0	1	2

[a] Includes 35 adolescent patients age 12 to <16 years

[b] The incidence of adverse reactions in the 200 mg per day group was greater than or equal to 2% than the incidence in both the placebo group and the 50 mg per day group

Adolescents 12 to 17 Years of Age

In five randomized, double-blind, placebo-controlled, parallel group migraine prophylaxis clinical trials, most of the adverse reactions with immediate-release topiramate were mild or moderate in severity. Most adverse reactions occurred more frequently during the titration period than during the maintenance period. Among adverse reactions with onset during titration, approximately half persisted into the maintenance period.

In four, fixed-dose, double-blind migraine prophylaxis clinical trials in immediate-release topiramate treated adolescent patients, the most commonly observed adverse reactions associated with the use of 100 mg of immediate-release topiramate that were seen at an incidence higher (>5%) than in the placebo group were: paresthesia, upper respiratory tract infection, anorexia, and abdominal pain (see Table 4). Table 4 shows adverse reactions from the adolescent pivotal trial demonstrating the efficacy of immediate-release topiramate in which there were 103 adolescent patients who were treated with placebo or 50 mg or 100 mg of immediate-release topiramate, and three predominantly adult trials in which there were 49 adolescent patients (12 to 17 years) who were treated with placebo or 50 mg, 100 mg or 200 mg of immediate-release topiramate. Table 4 also shows adverse reactions in adolescents in the controlled migraine trials when the incidence in an immediate-release topiramate dose group was at least 5% or higher than the incidence of placebo. Many adverse reactions shown in Table 4 indicated a dose-dependent relationship.

Table 4: Incidence (%) of Adverse Reactions in at Least 5% or Greater than the Placebo Incidence of Adolescents (12–17 Years) in any Immediate-Release Topiramate Group in Pooled Double-Blind Migraine Prophylaxis Studies[ab]

Body System	Placebo	Immediate-Release Topiramate Dosage (mg/day)		
Adverse Reaction		50	100	200
	(N=45) %	(N=46) %	(N=48) %	(N=13) %
Body as a Whole – General Disorders				
Allergy	0	0	4	8
Fatigue	7	7	8	15
Fever	2	4	6	0
Leg pain	0	2	2	8
Central & Peripheral Nervous System Disorders				
Dizziness	4	4	6	0
Headache	2	2	4	8
Language problems	2	0	0	15
Muscle contractions involuntary	0	0	0	8
Paresthesia	7	20	19	38
Endocrine Disorders				
Hyperthyroidism	0	0	0	8
Gastrointestinal System Disorders				
Abdominal pain	9	7	15	15
Diarrhea	0	2	2	8
Nausea	4	4	8	0
Metabolic and Nutritional Disorders				
Edema pharynx	0	0	0	8
Weight decrease	2	7	4	31
Platelet, Bleeding & Clotting Disorders				
Epistaxis	0	2	2	8
Psychiatric Disorders				
Anorexia	4	9	10	15
Anxiety	0	0	0	8
Difficulty with concentration/ attention	0	0	2	15
Difficulty with memory	2	0	0	8
Insomnia	2	9	2	0
Mood problems	4	2	2	8
Psychomotor slowing	0	2	0	8
Somnolence	2	2	6	15
Resistance Mechanism Disorders				
Infection viral	4	4	8	15
Otitis media	0	0	0	8
Respiratory System Disorders				
Coughing	0	7	2	0
Laryngitis	0	0	0	8
Rhinitis	2	7	6	8
Sinusitis	2	9	4	15
Upper respiratory tract infection	11	26	23	23
Skin and Appendages Disorders				
Rash erythematous	0	0	0	8
Special Senses Other, Disorders				
Taste perversion	2	2	6	8
Vision Disorders				
Conjunctivitis	4	7	4	0

[a] 35 adolescent patients aged 12 to <16 years were also included in adverse reaction assessment for adults

[b] Incidence is based on the number of subjects experiencing at least 1 adverse event, not the number of events.

In the double-blind placebo-controlled studies, adverse reactions led to discontinuation of treatment in 8% of placebo patients compared with 6% of immediate-release topiramate-treated patients. Adverse reactions associated with discontinuing therapy that occurred in more than one immediate-release topiramate-treated patient were fatigue (1%), headache (1%), and somnolence (1%).

Laboratory Abnormalities

Topiramate decreases serum bicarbonate.

Topiramate treatment with or without concomitant valproic acid VPA can cause hyperammonemia with or without encephalopathy.

Immediate-release topiramate treatment was associated with changes in several clinical laboratory analytes in randomized, double-blind, placebo-controlled studies. Similar effects should be anticipated with use of TROKENDI XR.

Migraine

In pooled double-blind studies in pediatric patients (6 to 17 years), an increased risk for certain abnormalities (value outside normal reference range) in selected clinical laboratory analytes measured in blood has been observed during topiramate treatment of pediatric patients compared to placebo-treated patients. In some instances, abnormalities were also observed at the end of the trial at the final visit and the changes were considered markedly abnormal.

For patients 12 to 17 years, the following were noted to be abnormally increased more frequently with topiramate than with placebo: BUN, creatinine, uric acid, chloride, ammonia, total protein, and platelets. The following were abnormally decreased in some subjects: phosphorus, and bicarbonate.

For patients 6 to 11 years, the following were noted to be abnormally increased more frequently with topiramate than with placebo: alkaline phosphatase, creatinine and eosinophils. Analytes abnormally decreased were: total white count and neutrophils. There was no testing for serum bicarbonate, chloride, ammonia, or phosphorus in these younger patients.

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of topiramate. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The listing is alphabetized: bullous skin reactions (including erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis), hepatic failure (including fatalities), hepatitis, maculopathy, pancreatitis, and pemphigus.

DRUG INTERACTIONS

Alcohol

Alcohol use is contraindicated within 6 hours prior to and 6 hours after TROKENDI XR administration.

Oral Contraceptives

Exposure to ethinyl estradiol was statistically significantly decreased when topiramate (at doses above 200 mg) was given as adjunctive therapy in patients taking valproic acid. However, norethindrone exposure was not significantly affected.

In another pharmacokinetic interaction study in healthy volunteers with a concomitantly administered combination oral contraceptive product containing 1 mg norethindrone (NET) plus 35 mcg ethinyl estradiol (EE), topiramate, given in the absence of other medications at doses of 50 to 200 mg per day, was not associated with statistically significant changes in mean exposure to either component of the oral contraceptive.

The possibility of decreased contraceptive efficacy and increased breakthrough bleeding should be considered in patients taking combination oral contraceptive products with TROKENDI XR®. Patients taking estrogen-containing contraceptives should be asked to report any change in their bleeding patterns. Contraceptive efficacy can be decreased even in the absence of breakthrough bleeding.

Antiepileptic Drugs

Concomitant administration of phenytoin or carbamazepine with topiramate decreased plasma concentrations of topiramate.

Concomitant administration of valproic acid and topiramate has been associated with hyperammonemia with and without encephalopathy. Concomitant administration of topiramate with valproic acid has also been associated with hypothermia (with and without hyperammonemia) in patients who have tolerated either drug alone. It may be prudent to examine blood ammonia levels in patients in whom the onset of hypothermia has been reported.

Numerous AEDs are substrates of the CYP enzyme system. *In vitro* studies indicate that topiramate does not inhibit enzyme activity for CYP1A2, CYP2A6, CYP2B6, CYP2C9, CYP2D6, CYP2E1, and CYP3A4/5 isozymes. *In vitro* studies indicate that immediate-release topiramate is a mild inhibitor of CYP2C19 and a mild inducer of CYP3A4. The same drug interactions can be expected with the use of TROKENDI XR.

CNS Depressants

Topiramate is a CNS depressant. Concomitant administration of topiramate with other CNS depressant drugs or alcohol can result in significant CNS depression.

Other Carbonic Anhydrase Inhibitors

Concomitant use of topiramate, a carbonic anhydrase inhibitor, with any other carbonic anhydrase inhibitor (e.g., zonisamide, acetazolamide or dichlorphenamide), may increase the severity of metabolic acidosis and may also increase the risk of kidney stone formation. Patient should be monitored for the appearance or worsening of metabolic acidosis when TROKENDI XR is given concomitantly with another carbonic anhydrase inhibitor.

Metformin

Topiramate treatment can frequently cause metabolic acidosis, a condition for which the use of metformin is contraindicated. The concomitant use of TROKENDI XR and metformin is contraindicated in patients with metabolic acidosis.

Lithium

In patients, there was an observed increase in systemic exposure of lithium following topiramate doses of up to 600 mg per day. Lithium levels should be monitored when co-administered with high-dose TROKENDI XR.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to topiramate during pregnancy. Patients should be encouraged to enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry if they become pregnant. This registry is collecting information about the safety of antiepileptic drugs during pregnancy. To enroll, patients can call the toll-free number 1-888-233-2334. Information about the North American Drug Pregnancy Registry can be found at http://www.aedpregnancyregistry.org/.

Risk Summary

Topiramate can cause fetal harm when administered to a pregnant woman. Data from pregnancy registries indicate that infants exposed to topiramate *in utero* have increased risk for cleft lip and/or cleft palate (oral clefts) and for being small for gestational age *[see Human Data]*.

In multiple animal species, topiramate demonstrated developmental toxicity, including teratogenicity, in the absence of maternal toxicity at clinically relevant doses *[see Animal Data]*.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Consider the benefits and risks of topiramate when prescribing this drug to women of childbearing potential, particularly when topiramate is considered for a condition not usually associated with permanent injury or death. Because of the risk of oral clefts to the fetus, which occur in the first trimester of pregnancy before many women know they are pregnant, all women of childbearing potential should be informed of the potential risk to the fetus from exposure to topiramate. Women who are planning a pregnancy should be counseled regarding the relative risks and benefits of topiramate use during pregnancy, and alternative therapeutic options should be considered for these patients.

Labor or Delivery

Although the effect of topiramate on labor and delivery in humans has not been established, the development of topiramate-induced metabolic acidosis in the mother and/or in the fetus might affect the fetus' ability to tolerate labor. Topiramate treatment can cause metabolic acidosis. The effect of topiramate-induced metabolic acidosis has not been studied in pregnancy; however, metabolic acidosis in pregnancy (due to other causes) can cause decreased fetal growth, decreased fetal oxygenation, and fetal death, and may affect the fetus' ability to tolerate labor. Pregnant patients should be monitored for metabolic acidosis and treated as in the nonpregnant state. Newborns of mothers treated with topiramate should be monitored for metabolic acidosis because of transfer of topiramate to the fetus and possible occurrence of transient metabolic acidosis following birth.

Data

Human Data

Data from the NAAED Pregnancy Registry indicate an increased risk of oral clefts in infants exposed to topiramate monotherapy during the first trimester of pregnancy. The prevalence of oral clefts was 1.2% compared to a prevalence of 0.39% - 0.46% in infants exposed to other AEDs, and a prevalence of 0.12% in infants of mothers without epilepsy or treatment with other AEDs. For comparison, the Centers for Disease Control and Prevention (CDC) reviewed available data on oral clefts in the United States and found a similar background rate of 0.17%. The relative risk of oral clefts in topiramate-exposed pregnancies in the NAAED Pregnancy Registry was 9.6 (95% Confidence Interval=[CI] 4.0-23.0) as compared to the risk in a background population of untreated women. The UK Epilepsy and Pregnancy Register reported a similarly increased prevalence of oral clefts of 3.2% among infants exposed to topiramate monotherapy. The observed rate of oral clefts was 16 times higher than the background rate in the UK, which is approximately 0.2%.

Data from the NAAED Pregnancy Registry and a population-based birth registry cohort indicate that exposure to topiramate *in utero* is associated with an increased risk of small for gestational age (SGA) newborns (birth weight <10th percentile). In the NAAED Pregnancy Registry, 18% of topiramate-exposed newborns were SGA compared to 7% of newborns exposed to a reference AED, and 5% of newborns of mothers without epilepsy and without AED exposure. In the Medical Birth Registry of Norway (MBRN), a population-based pregnancy registry, 25% of newborns in the topiramate monotherapy exposure group were SGA compared to 9% in the comparison group who were unexposed to AEDs. The long-term consequences of the SGA findings are not known.

Animal Data

When topiramate (20, 100, and 500 mg/kg/day) was administered orally to pregnant mice during the period of organogenesis, the incidence of fetal malformations (primarily craniofacial defects) was increased at all doses. Fetal body weights and skeletal ossification were reduced at the highest dose tested in conjunction with decreased maternal body weight gain. A no-effect dose for embryofetal developmental toxicity in mice was not identified. The lowest dose tested, which was associated with teratogenic effects, is less than the maximum recommended human dose (MRHD) for epilepsy (400 mg/day) or migraine (100 mg/day) on a body surface area (mg/m^2) basis.

In pregnant rats administered topiramate (20, 100, and 500 mg/kg/day or 0.2, 2.5, 30, and 400 mg/kg/day) orally during the period of organogenesis, the frequency of limb malformations (ectrodactyly, micromelia, and amelia) was increased in fetuses at 400 or 500 mg/kg/day. Embryotoxicity (reduced fetal body weights, increased incidences of structural variations) was observed at doses as low as 20 mg/kg/day. Clinical signs of maternal toxicity were seen at 400 mg/kg/day and above, and maternal body weight gain was reduced at doses of 100 mg/kg/day or greater. The no-effect dose for embryofetal developmental toxicity in rats is less than the MRHD for epilepsy or migraine on a mg/m^2 basis.

In pregnant rabbits administered topiramate (20, 60, and 180 mg/kg/day or 10, 35, and 120 mg/kg/day) orally during organogenesis, embryofetal mortality was increased at 35 mg/kg/day and teratogenic effects (primarily rib and vertebral malformations) were observed at 120 mg/kg/day. Evidence of maternal toxicity (decreased body weight gain, clinical signs, and/or mortality) was seen at 35 mg/kg/day and above. The no-effect dose (20 mg/kg/day) for embryofetal developmental toxicity in rabbits is equivalent to the MRHD for epilepsy and approximately 4 times the MRHD for migraine on a mg/m^2 basis.

When topiramate (0.2, 4, 20, and 100 mg/kg/day or 2, 20, and 200 mg/kg/day) was administered orally to female rats during the latter part of gestation and throughout lactation, offspring exhibited decreased viability and delayed physical development at 200 mg/kg/day and reductions in pre- and/or postweaning body weight gain at 2 mg/kg/day and above. Maternal toxicity (decreased body weight gain, clinical signs) was evident at 100 mg/kg/day or greater.

In a rat embryo/fetal development study which included postnatal assessment of offspring, oral administration of topiramate (0.2, 2.5, 30, and 400 mg/kg/day) to pregnant animals during the period of organogenesis resulted in delayed physical development at 400 mg/kg/day and persistent reductions in body weight gain at 30 mg/kg/day and higher in the offspring. The no-effect dose (0.2 mg/kg/day) for pre- and postnatal developmental toxicity is less than the MRHD for epilepsy or migraine on a mg/m^2 basis.

Lactation

Risk Summary

Topiramate is excreted in human milk *[see Data]*. The effects of topiramate exposure in breastfed infants are unknown.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TROKENDI XR and any potential adverse effects on the breastfed infant from TROKENDI XR or from the underlying maternal condition.

Data

Limited data from 5 women with epilepsy treated with topiramate during lactation showed drug levels in milk similar to those in maternal plasma.

Females and Males of Reproductive Potential

Contraception

Women of childbearing potential who are not planning a pregnancy should use effective contraception because of the risks to the fetus of oral clefts and of being small for gestational age.

Pediatric Use

Not Recommended for Pediatric Patients Younger than 6 Years of Age

Because the capsule must be swallowed whole, and may not be sprinkled on food, crushed, or chewed, TROKENDI XR is recommended only for children age 6 or older.

Topiramate produced a dose-related increased incidence of hyperammonemia.

Treatment with immediate-release topiramate for up to 1 year was associated with reductions in Z SCORES for length, weight, and head circumference.

In open-label, uncontrolled experience, increasing impairment of adaptive behavior was documented in behavioral testing over time in this population. There was a suggestion that this effect was dose-related. However, because of the absence of an appropriate control group, it is not known if this decrement in function was treatment related or reflects the patient's underlying disease (e.g., patients who received higher doses may have more severe underlying disease).

In this open-label, uncontrolled study, the mortality was 37 deaths/1000 patient years. It is not possible to know whether this mortality rate is related to immediate-release topiramate treatment, because the background mortality rate for a similar, significantly refractory, young pediatric population (1 month to 24 months) with partial epilepsy is not known.

Other Pediatric Studies

Topiramate treatment produced a dose-related increased shift in serum creatinine from normal at baseline to an increased value at the end of 4 months of treatment in adolescent patients (ages 12 years to 16 years) in a double-blind, placebo-controlled study.

Migraine Prophylaxis in Adolescents 12 to 17 Years

Safety and effectiveness of topiramate in the prophylaxis of migraine was studied in 5 double-blind, randomized, placebo-controlled, parallel-group trials in a total of 219 pediatric patients, at doses of 50 mg/day to 200 mg/day, or 2 to 3 mg/kg/day. These comprised a fixed dose study in 103 adolescents age 12 to 17 years, a flexible dose (2 to 3 mg/kg/day), placebo-controlled study in 157 pediatric patients age 6 to 16 years (including 67 adolescent patients age 12 to 16 years), and a total of 49 adolescents age 12 to 17 years in 3 studies of migraine prophylaxis primarily in adults. Open-label extension phases of 3 studies enabled evaluation of long-term safety for up to 6 months after the end of the double-blind phase.

(continued on next page)

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Immune Cells May Heal Bleeding Brain after Strokes

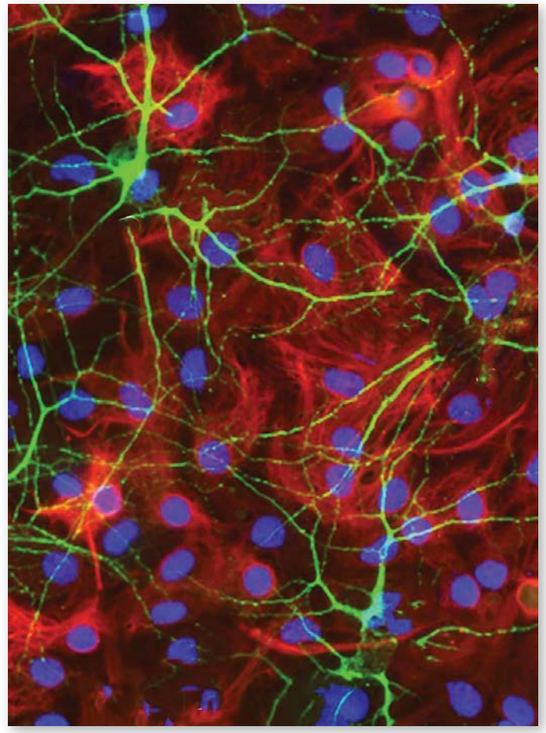
NIH-funded preclinical rodent study points to neutrophils for potential treatment options

Walter J. Koroshetz, MD, Director of the National Institute of Neurological Disorders and Stroke (NINDS)

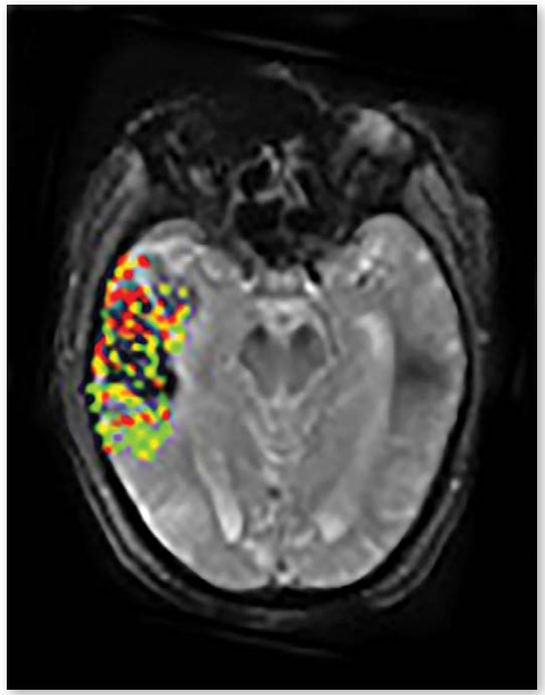
While immune cells called neutrophils are known to act as infantry in the body's war on germs, a National Institutes of Health-funded study suggests they can act as medics as well. By studying rodents, researchers showed that instead of attacking germs, some neutrophils may help heal the brain after an intracerebral hemorrhage, a form of stroke caused by ruptured blood vessels. The study suggests that two neutrophil-related proteins may play critical roles in protecting the brain from stroke-induced damage and could be used as treatments for intracerebral hemorrhage.

"Intracerebral hemorrhage is a damaging and often fatal form of stroke for which there are no effective medicines," said Jaroslaw Aronowski, MD, PhD, professor, department of neurology, at the University of Texas Health Science Center at Houston, and senior author of the study published in Nature Communications. "Our results are a hopeful first step towards developing a treatment for this devastating form of stroke."

Accounting for 10 to 15 percent of all strokes, intracerebral hemorrhages happen when blood vessels rupture and leak blood into the brain, often leading to death or long-term disability. Chronic high blood pressure is the leading risk factor for these types of strokes. The initial phase of damage appears to be caused by the pressure of blood leaking into the brain. Over time, further damage may be caused by the accumulation of toxic levels of blood products, infiltrating immune cells, and swelling.



Researchers studied how neutrophils may help protect the brain from damage caused by intracerebral hemorrhagic stroke.Aronowski lab, University of Texas Health Science Center, Houston



A revealing look at the stroke brain: This image combines pre- and post-treatment scans from the same patient. Analysis of the two scans revealed that the area and size of post-treatment bleeding corresponded to blood-brain barrier disruption (shown in green, yellow and red) prior to therapy. Dr. Leigh, NINDS.

Decades of research suggest that neutrophils are some of the earliest immune cells to respond to a hemorrhage, and that they may both harm and heal the brain. In this study, the researchers found that interleukin-27 (IL-27), a protein that controls the activity of immune cells, may shift the role of neutrophils from harming the brain to helping with recovery.

Injections of IL-27 after a hemorrhage helped mice recover. Days after the strokes, the treated mice had better mobility, including walking, limb stretching and navigating holes in a floor. In contrast, injections of an antibody that blocked natural IL-27 activity slowed recovery.

The brains of the mice treated with IL-27 also showed less damage. They had less swelling around the hemorrhages and lower levels of iron and the blood protein hemoglobin, both of which are toxic at high levels.

"This study shines a spotlight on the critical role the immune system may play in helping the brain heal after a hemorrhage or stroke and opens new avenues for stroke treatment strategies," said Jim Koenig, PhD, program director at the NIH's National Institute of Neurological Disorders and Stroke.

Neutrophils are born in bone marrow and carry chemicals in hundreds of densely filled packets called granules, which look like dark spots under a microscope.

Typically, when the body senses bacteria or an injury, neutrophils rush to the invasion site and release germ killing chemicals from the granules. This appears to happen minutes after a hemorrhagic stroke.

In this study, the researchers suggested that after a hemorrhagic stroke the brain secretes high levels of IL-27, which leads to a second wave of neutrophils arriving with granules filled with higher amounts of healing molecules. IL-27 levels were elevated in the brain and blood of the mice an hour after hemorrhages and stayed high for three days, peaking at 24 hours later. Further experiments suggested that brain cells called microglia produced the IL-27 in response to the presence of red blood cells.

Once released, IL-27 molecules appeared to travel to the bones of the mice, infiltrated the marrow, and changed the role newborn neutrophils played in response to a stroke.

When the researchers extracted newborn neutrophils from the bones of mice and treated them with IL-27, the chemical raised the activity of genes associated with healing, especially lactoferrin, while reducing the activity of genes associated with killing cells. Conversely, treating mice with an IL-27 neutralizing antibody after a hemorrhage lowered lactoferrin gene activity.

"Our results suggested that IL-27 links the brain to the bones," said Dr. Aronowski. "We can use these results as a source for ideas for developing potential treatments for hemorrhagic stroke."

Finally, the researchers showed the iron binding protein lactoferrin may protect the brain from intracerebral hemorrhagic strokes. Mice and rats injected with lactoferrin 30 minutes after hemorrhages recovered faster and had reduced brain damage as compared to animals given placebos.

In one set of experiments, the researchers found that giving mice lactoferrin 24 hours after a stroke was also effective.

"Lactoferrin appears to have a long treatment window," said Dr. Aronowski. "This means lactoferrin might one day be used to help patients recover from intracerebral hemorrhage."

Dr. Aronowski's team is taking the next steps towards testing lactoferrin treatment in patients.

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Waterlogged Brain Region Helps Scientists Gauge Damage Caused by Parkinson's Disease

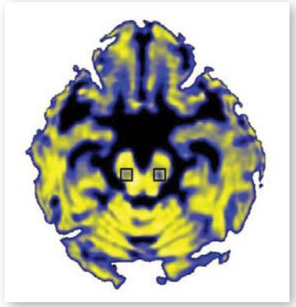
NIH-funded research could aid drug development for the condition

Scientists at the University of Florida have discovered a new method of observing the brain changes caused by Parkinson's disease, which destroys neurons important for movement. The development suggests that fluid changes in a specific brain area could provide a way to track that damage. The study, published in the journal Brain, was supported by the NIH's National Institute of Neurological Disorders and Stroke (NINDS).

"By finding a new way to detect and track how Parkinson's affects the brain, this study provides an important tool for assessing whether a drug might slow or stop those changes and keep symptoms from getting worse," said NINDS Program Director Daofen Chen, PhD.

The researchers, led by David Vaillancourt, PhD, a professor of applied physiology and kinesiology at the University of Florida in Gainesville, FL, used a form of MRI that differentiates between water contained in brain cells and "free" water outside of cells. Their analysis focused on the substantia nigra, a brain structure where Parkinson's disease kills neurons that use the chemical dopamine to communicate with other cells. The results showed that the amount of free water in that brain area stayed the same over the course of a year in healthy individuals but increased in early-stage Parkinson's patients during that period and increased further over the next three years. This confirms and expands on a prior study by the same group that measured free water over just one year. The new findings also revealed the increase in free water was linked to worsening symptoms.

"The amount of free water doesn't just change over one year – it keeps progressively increasing, which suggests that it's tracking the progressive degeneration of neurons," said Dr. Vaillancourt.



NIH-funded scientists have discovered that Parkinson's disease increases the amount of "free" water in a particular brain area.Image courtesy of David Vaillancourt, PhD, University of Florida.

The researchers used a scale to evaluate patient's movement problems, with Stage One on the scale being the least severe and Stage Five being the most advanced. Patients who moved up a stage on the scale during the four years of the study had a greater free water increase than patients who remained at the same stage, suggesting the change reflected Parkinson's-related damage to neurons.

Parkinson's disease destroys dopamine-producing cells in the substantia nigra, which connect to adjacent brain areas. Dr. Vaillancourt's study showed that a greater free water increase in the substantia nigra was associated with a decrease in dopamine neuron activity in one of these nearby regions, supporting the idea that free water changes are related to progression of the disease.

"That correlation is encouraging because it pins down the biological relevance of free water," Dr. Vaillancourt said.

The study's results suggest that the MRI-based free water measurement could be used in Parkinson's disease clinical trials. If a treatment slows or stops the increase in free water, it might be evidence that the drug is slowing the progressive loss of dopamine neurons.

The researchers used data from the Parkinson's Progression Markers Initiative (PPMI), a large study sponsored by the Michael J. Fox Foundation that has been collecting information on recently diagnosed Parkinson's patients from over 30 different U.S. and international sites. The fact that Dr. Vaillancourt's team found similar patterns in patients at every location boosted his confidence in the results because, like the PPMI, clinical trials must collect data from many sites using numerous different MRI machines.

"The PPMI data is real-world messy data, and when you find the effect in real-world messy data, it makes you think that it has legs," he said.

Dr. Vaillancourt speculated that his team's free water approach could make clinical trials less expensive by reducing the number of participants they would need to enroll. His team is currently running just such a study using free water to gauge the effect of a potential Parkinson's treatment. At the same time, the group is attempting to develop computer programs that will make free water analysis faster and easier. Future studies are needed to track changes in free water over longer time spans and in other brain regions and to determine what causes them.

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Immune System May Mount an Attack in Parkinson's Disease

NIH-funded study suggests role for specific immune cells in brain disease

By Barbara McMakin

A new study suggests that T cells, which help the body's immune system recognize friend from foe, may play an important role in Parkinson's disease (PD). The study, published in the journal Nature, was supported by the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health.

"This collaboration between neuroscientists and immunologists provides important new evidence for ways in which the immune system can play a role in PD, a link that can be used to further define this interaction," said Beth-Anne Sieber, PhD, a program director at NINDS.

A research team led by David Sulzer, PhD, professor of neurology at Columbia University in New York City and Alessandro Sette, DrBiolSci, professor of infectious diseases at the La Jolla Institute for Allergy and Immunology in California, examined the role of T cells in PD.

Drs. Sulzer and Sette, along with their colleagues, collected blood samples from 67 individuals with Parkinson's disease and 36 healthy controls. Immune cells were extracted from the samples and mixed with portions of the alpha-synuclein protein, which accumulates in the brains of people with PD and can result in cell death.

They found that T cells from people with PD responded to the presence of alpha-synuclein to a much greater degree than those gathered from the control group.

In particular, two regions of alpha-synuclein evoked reactions from T cells: a section that often contains mutations linked with PD, and a portion undergoing a chemical change that can lead to accumulation of the protein in the brain.

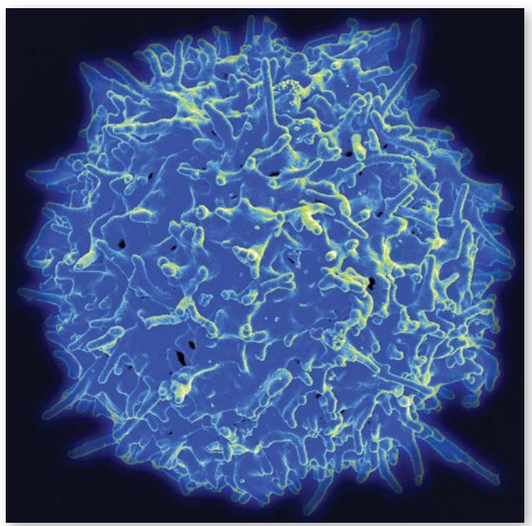
The researchers identified four genetic variations that were associated with T cell reactivity to alpha-synuclein. More than half of people with PD carried at least one of those variants, compared to 20 percent of controls.

"These findings expose a potential biomarker for PD that may someday help in diagnosing the disease or be used to evaluate how well treatments are working," said Dr. Sette.

According to the authors, the results suggest that PD may have characteristics of an autoimmune disease, in which the immune system incorrectly attacks the body's own cells.

"As we age, proteins throughout the body undergo various molecular modifications. If they become unrecognizable, the immune system may start going after them, thinking they may be dangerous invaders," said Dr. Sulzer.

PD is a neurodegenerative disorder in which dopamine-producing brain cells die off, resulting in tremors, muscle stiffness, loss of balance and slow movement. Additional symptoms may include emotional changes and disrupted sleep.



Immune system may wage a battle in brain disorders: An image of a T cell from a healthy person. NIAID

More research is needed to learn about the interactions between immune cells and alpha-synuclein. Improved understanding of those interactions may lead to information about disease progression as well as potential connections to other neurodegenerative disorders.

This study was funded by grants from NINDS (NS38377).

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Predicting Cognitive Deficits in People with Parkinson's Disease

NIH-funded tool may improve clinical trial design and aid in treatment development

By Carl P. Wonders, PhD

Parkinson's disease is commonly thought of as a movement disorder, but after years of living with the disease, approximately 25 percent of patients also experience deficits in cognition that impair function. A newly developed research tool may help predict a patient's risk for developing dementia and could enable clinical trials aimed at finding treatments to prevent the cognitive effects of the disease. The research was published in Lancet Neurology and was partially funded by the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health.

"This study includes both genetic and clinical assessments from multiple groups of patients, and it represents a significant step forward in our ability to effectively model one of the most troublesome non-motor aspects of Parkinson's disease," said Margaret Sutherland, PhD, program director at the NINDS.

For the study, a team of researchers led by Clemens Scherzer, MD, combined data from 3,200 people with Parkinson's disease, representing more than 25,000 individual clinical assessments and evaluated seven known clinical and genetic risk factors associated with developing dementia. From this information, they built a computer-based risk calculator that may predict the chance that an individual with Parkinson's will develop cognitive deficits. Dr. Scherzer is head of the Neurogenomics Lab and Parkinson Personalized Medicine Program at Harvard Medical School and a member of the Ann Romney Center for Neurologic Diseases at Brigham and Women's Hospital, Boston.

Currently available Parkinson's medications are only effective in improving motor deficits caused by the disease. However, the loss of cognitive abilities severely affects the individual's quality of life and independence. One barrier to developing treatments for the cognitive effects of Parkinson's disease is the considerable variability among patients. As a result, researchers must enroll several hundred patients when designing clinical trials to test treatments.

"By allowing clinical researchers to identify and select only patients at high-risk for developing dementia, this tool could help in the design of 'smarter' trials that require a manageable number of participating patients," said Dr. Scherzer.

Dr. Scherzer and team also noted that a patient's education appeared to have a powerful impact on the risk of memory loss. The more years of formal education patients in the study had, the greater was their protection against cognitive decline.

"This fits with the theory that education might provide your brain with a 'cognitive reserve,' which is the capacity to potentially compensate for some disease-related effects," said Dr. Scherzer. "I hope researchers will take a closer look at this. It would be amazing, if this simple observation could be turned into a useful therapeutic intervention."

Moving forward, Dr. Scherzer and his colleagues from the International Genetics of Parkinson's Disease Progression (IGPP) Consortium plan to further improve the cognitive risk score calculator. The team is scanning the genome of patients to hunt for new progression genes. Ultimately, it is their hope that the tool can be used in the clinic in addition to helping with clinical trial design. However, considerable research remains to be done before that will be possible.

One complication for the use of this calculator in the clinic is the lack of available treatments for Parkinson's-related cognitive deficits. Doctors face ethical issues concerning whether patients should be informed of their risk when there is little available to help them. It is hoped that by improving clinical trial design, the risk calculator can first aid in the discovery of new treatments and determine which patients would benefit most from the new treatments.

"Prediction is the first step," said Dr. Scherzer. "Prevention is the ultimate goal, preventing a dismal prognosis from ever happening."

This work was supported by the NINDS (NS082157, NS095736), the U.S. Department of Defense, M.E.M.O. Hoffman Foundation, and Brigham & Women's Hospital.

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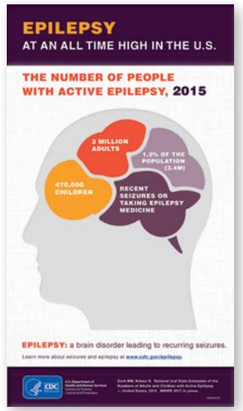
More Americans Have Epilepsy than Ever Before

First estimates available for every state show disorder is widespread.



The number of U.S. adults and children with epilepsy is increasing, with at least 3.4 million people living with the disorder, according to data released today in CDC's Morbidity and Mortality Weekly Report. It's the first time epilepsy estimates have been available for every state.

The data show the disorder is widespread. In 2015, about 3 million U.S. adults and 470,000 children had active epilepsy (under treatment or with recent seizures). The number of adults with active epilepsy rose from 2.3 million in 2010 to 3 million in 2015. The number of children with the condition increased from 450,000 in 2007 to 470,000 in 2015. These increases are likely due to population growth.

"Millions of Americans are impacted by epilepsy, and unfortunately, this study shows cases are on the rise," said CDC Director Brenda Fitzgerald, MD. "Proper diagnosis is key to finding an effective treatment — and at CDC we are committed to researching, testing, and sharing strategies that will improve the lives of people with epilepsy."

Epilepsy is a disorder of the brain that causes seizures. Different conditions can cause epilepsy, such as stroke, brain tumor, head injury, central nervous system infections, or genetic risks. Although epilepsy is widely recognized by the public, few people understand it, even among those who know someone with the disorder.

Key findings from analysis of epilepsy rates

The CDC study provides national and state-specific estimates of epilepsy prevalence based on the 2015 National Health Interview Survey, and the National Survey of Children's Health, and the 2014 Current Population Survey.

- Overall, 1.2 percent of the U.S. population (3.4 million people) reported active epilepsy in 2015.
- The number of cases of active epilepsy among adults ranged from 5,100 in Wyoming to 367,900 in California.
- The number of epilepsy cases among children ranged from 800 in Wyoming to 59,800 in California.
- Eleven states had more than an estimated 92,000 people with epilepsy.
- Data from 2010-2015 indicate increases in the number of persons with active epilepsy, probably because of population growth.

CDC researchers and others have previously reported that many adults with epilepsy face challenges including work limitations, difficulty finding transportation, and difficulty affording medical care. Students with epilepsy are more likely to fall behind in school and to need special education services. Children with epilepsy are more likely to live in low-income households.

"Epilepsy is common, complex to live with, and costly. It can lead to early death if not appropriately treated," said Rosemarie Kobau, MPH, head of CDC's Epilepsy Program. "Everyone should know how to recognize a seizure and how to give appropriate first aid."

CDC's Partnership efforts to address epilepsy

CDC's Epilepsy Program collects data to monitor epilepsy trends, mortality, costs, and impact on families. CDC also collaborates with partners such as the Epilepsy Foundation, the American Epilepsy Society, and other researchers to:

Keep children and adults with epilepsy safe in their communities by conducting seizure recognition and first aid training programs for school nurses, school staff, law enforcement, first responders, child care providers, and older adult caregivers.
Reach rural and underserved populations with proven epilepsy self-management programs that can reduce health care costs and improve quality of life.

cdc.gov

CPG

Epilepsy Can Follow Traumatic Brain Injury

Traumatic brain injury (TBI) can cause a seizure right after the injury happens or even months or years later. Researchers agree that the more severe the TBI, the greater the chance the person may develop epilepsy.[2]

Factors such as age and other medical conditions also influence the chance a person may develop epilepsy after a TBI. The terms post-traumatic epilepsy (PTE) and post-traumatic seizures (PTS) are both used to describe seizures that happen because of a TBI.[3] In 2013 there were over 280,000 hospitalizations for TBI in the US.[4]

A CDC-funded study found that among people aged 15 years and older, about 1 out of 10 developed epilepsy in the 3 years following a TBI that required hospitalization.[2]

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cdc.gov

CPG

Epilepsy and Seizures in Older Adults

Epilepsy is more likely to develop in older adults rather than younger adults because as people age, the risk of seizures and epilepsy rises.

Seizures are harder to recognize in older adults, and many go unnoticed. For example, memory problems, confusion, falls, dizziness, or sensory changes like numbness are often blamed on getting older, but these can actually be complex partial seizures which are the most common type in older adults.

With CDC funding, the Epilepsy Foundation developed Seniors & Seizures training. This training provides caregivers and staff of adult day care centers, senior centers, long-term care facilities, nursing homes, and other senior-serving organizations with strategies to better recognize and respond to seizures in older adults.

NAS Report: Promising But Inconclusive Evidence on Interventions to Prevent Cognitive Decline, Dementia

Suggests NIH, others carefully cue public about potential benefits of cognitive training, blood pressure management, exercise.

The public is enormously concerned about dementia and cognitive impairment, and a wide range of programs and products, such as diets, exercise regimens, games, and supplements, purport to keep these conditions at bay. It is difficult for individuals, health care providers and policy makers to ascertain what has been demonstrated to prevent or reduce risk. To help sort through the data and to understand the quality and weight of current evidence for possible interventions, the National Institute on Aging (NIA) at the National Institutes of Health, commissioned experts for an extensive scientific review and to provide recommendations for public health messaging and future research priorities. In response to that request, a National Academies of Sciences, Engineering and Medicine (NASEM) committee has concluded that current evidence does not support a mass public education campaign to encourage people to adopt specific interventions to prevent cognitive decline or dementia.

Importantly, the committee also cited "encouraging although inconclusive" evidence for three specific types of interventions — cognitive training, blood pressure control for people with hypertension, and increased physical activity. Based on that evidence, the committee recommended providing the public with accurate information about their potential positive impacts for some conditions while more definitive research on these and other approaches moves forward. The committee suggested that health care providers might include mention of the potential cognitive benefits of these interventions when promoting their adoption for the prevention or control of other diseases and conditions.

The full NASEM report, "Preventing Cognitive Decline and Dementia: A Way Forward," can be viewed at www.nationalacademies.org/dementia

The committee's recommendations are based in large part on an NIA-requested and supported systematic evidence review by the Agency for Healthcare Research and Quality's (AHRQ) Evidence-based Practice Center (EPC). The Minnesota EPC categorized hundreds of studies by strength and quality for the AHRQ part of the project.

"We're all urgently seeking ways to prevent dementia and cognitive decline with age," said NIA Director Richard J. Hodes, MD. "But we must consider the strength of evidence — or lack thereof — in making decisions about personal and public investments in prevention. I am grateful for the National Academies' and AHRQ's careful reviews, which recognize the progress research has made in beginning to answer such questions, while pointing the way for additional studies. This report will be very instructive for what we can tell the public now, as critical research continues."

The committee noted potential effects, as well as limitations of the evidence, for:

- Cognitive training — Interventions aimed at enhancing reasoning, memory, and speed of processing, to delay or slow age-related cognitive decline were found promising, based primarily on conclusions from the NIA-funded Advanced Cognitive Training for Independent and Vital Elderly (ACTIVE) trial and bolstered by additional data from prospective observational studies on the benefits of cognitively stimulating activities.

  The committee cautioned, however, that it could not draw conclusions about the relative effectiveness of different cognitive training approaches or techniques. It also noted that there was no evidence to support the notion that beneficial long-term cognitive effects suggested by the ACTIVE trial could be applied to computer based brain training applications being offered commercially, as the suite of cognitive interventions in the ACTIVE trial were substantially different.

  The committee found no evidence to suggest that cognitive training might prevent, delay or slow development of Mild Cognitive Impairment (MCI) or Alzheimer's, however.

- Blood pressure management for people with hypertension — Encouraging but inconclusive evidence suggests that blood pressure management, particularly in midlife, might prevent, delay or slow clinical Alzheimer's-type dementia, according to the committee. While clinical trials in this area do not offer strong support for blood pressure management against Alzheimer's, prospective population studies and what we have learned about the natural history and biology of the disease make it plausible, then, that blood pressure management for people with hypertension would also reduce their risk of dementia and cognitive decline, the report said. The committee pointed out the known cardiovascular benefits

from well-managed blood pressure, which would be experienced while Alzheimer's prevention is potentially addressed.

- Increased physical activity — Citing the many known health benefits of physical activity, the committee pointed to growing evidence that among these is the possible reduced risk of age-related cognitive decline. Here, too, the experts turned to what they called encouraging but inconclusive evidence, noting that clinical trials results in this area suggest effectiveness, taken together with observational studies and knowledge of neurobiological processes. There was not sufficient evidence to support increased physical activity as a preventive intervention for MCI or Alzheimer's disease, however. Further, the committee could not find sufficient evidence to help determine which specific types of physical activity might be particularly effective for preventing cognitive decline and dementia.

In communicating with the public, the committee said, the NIH, the Centers for Disease Control and Prevention and other organizations should present potential benefits of the three interventions as they apply to cognitive decline, MCI, and Alzheimer's dementia, while pointing out the limitations of the evidence. There are considerable challenges in presenting such nuanced messages, it added, as the public likely will not draw fine distinctions among the three conditions or about levels of evidence.

The committee expressed optimism for the future of research to provide answers that the public and providers are seeking. Substantial knowledge has been gained since the last comprehensive evidence review in 2010, and this complex and exciting area of discovery will continue to grow with investments in research. In addition to encouraging ongoing research in the three areas for which it found evidence most developed, the committee recommended as priority areas for further study: new anti-dementia treatments; treatments for diabetes and depression; dietary interventions; lipid-lowering treatments; sleep quality interventions; social engagement, and vitamin B12 plus folic acid supplementation.

For its evidence review, the AHRQ's EPC examined the scientific literature on 13 classes of interventions associated with preventing, slowing, or delaying the onset of clinical Alzheimer's-type dementia and MCI. The AHRQ report, issued in March 2017, found that most approaches showed no evidence of benefit to delay or prevent age-related cognitive decline, MCI, or Alzheimer's dementia. It concluded that, at present, there is not sufficient strength of evidence to justify large-scale investing in public health activities aimed at preventing dementia; some results may be viewed as potential added benefits to already identified public health interventions.

About the National Institute on Aging: The NIA leads the federal government effort conducting and supporting research on aging and the health and well-being of older people. It provides information on age-related cognitive change and neurodegenerative disease specifically at its Alzheimer's Disease Education and Referral (ADEAR) Center. For additional information about cognitive health and older adults, go to NIA's cognitive aging portal.

nih.gov

Midlife Cardiovascular Risk Factors May Increase Chances of Dementia

NIH funded study supports link between cognition and vascular health

A large, long-term study suggests that middle aged Americans who have vascular health risk factors, including diabetes, high blood pressure and smoking, have a greater chance of suffering from dementia later in life. The study, published in JAMA Neurology, was funded by the National Institutes of Health (NIH).

"With an aging population, dementia is becoming a greater health concern. This study supports the importance of controlling vascular risk factors like high blood pressure early in life in an effort to prevent dementia as we age," said Walter J. Koroshetz, MD, director of NIH's National Institute of Neurological Disorders and Stroke (NINDS), which partially funded the study and created the Mind Your Risks® public health campaign to make people more aware of the link between cardiovascular and brain health. "What's good for the heart is good for the brain," he added.

The study was led by Rebecca Gottesman, MD, PhD, professor of neurology at Johns Hopkins University in Baltimore. Her team analyzed the data of 15,744 people who participated in the Atherosclerosis Risk in Communities (ARIC) study, funded by the NIH's National Heart, Lung, and Blood Institute (NHLBI).

From 1987-1989, the participants, who were black or white and 45-64 years of age, underwent a battery of medical tests during their initial examinations at one of four centers in four different states. Over the next 25 years they were examined four more times. Cognitive tests of memory and thinking were administered during all but the first and third exams.

Her team found that 1,516 participants were diagnosed with dementia during an average of 23 follow-up years. Initially, when they analyzed the influence of factors recorded during the first exams, the researchers found that the chances of dementia increased most strongly with age followed by the presence of APOE4, a gene associated with Alzheimer's disease.

Whites with one copy of the APOE4 gene had a greater chance of dementia than blacks. Other factors included race and education: blacks had higher chance of dementia than whites; those who did not graduate from high school were also at higher risk.

In agreement with previous studies, an analysis of vascular risk factors showed that participants who had diabetes or high blood pressure, also called hypertension, had a higher chance of developing dementia. In fact, diabetes was almost as strong a predictor of dementia as the presence of the APOE4 gene.

Unlike other studies, the researchers discovered a link between dementia and prehypertension, a condition in which blood pressure levels are higher than normal but lower than hypertension. Also, race did not influence the association between dementia and the vascular risk factors they identified. Diabetes, hypertension and prehypertension increased the chances of dementia for white and black participants. Finally, smoking cigarettes exclusively increased the chances of dementia for whites but not blacks.

"Our results contribute to a growing body of evidence linking midlife vascular health to dementia," said Dr. Gottesman. "These are modifiable risk factors. Our hope is that by addressing these types of factors early, people can reduce the chances that they will suffer from dementia later in life."

Further analysis strengthened the idea that the vascular risk factors identified in this study were linked to dementia. For instance, in order to answer the question of whether having a stroke, which is also associated with the presence of vascular risk factors, may explain these findings, the team reanalyzed the data of participants who did not have a stroke and found similar results.

Diabetes, hypertension, prehypertension and smoking increased the risk of dementia for both stroke-free participants and those who had a stroke.

Recently, in a separate study partially funded by the NIH's National Institute on Aging, Dr. Gottesman's team analyzed brain scans from a subgroup of ARIC participants who did not have dementia when they entered the study. They found that the presence of one or more vascular risk factors during midlife was associated with higher levels of beta amyloid, a protein that often accumulates in the brains of Alzheimer's patients.

This relationship was not affected by the presence of the APOE4 gene and not seen for risk factors present in later life. The presence of vascular risk factors detected in participants older than 65 years of age during the final examination was not associated with greater levels of beta amyloid.

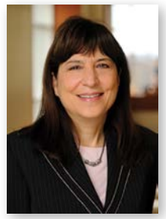
nih.gov

New Chair and New Members of Advisory Council on Alzheimer's Research, Care, and Services

Seven new members are to serve on the Advisory Council on Alzheimer's Research, Care, and Services. The council, established in 2011, convenes quarterly to advise the Secretary on federal programs that affect people with Alzheimer's disease and related dementias, and continue development and progress on the National Plan to Address Alzheimer's Disease by HHS, Veterans Affairs, the Department of Defense, and the National Science Foundation.

The new members will serve four-year terms and replace the members whose terms expire in September.

"We are pleased to welcome this group of experienced members, including a patient advocate living with dementia, to continue the important work of the advisory council in assisting HHS with further progress on treating and curing Alzheimer's disease and related dementias," said HHS Secretary. "We received over a hundred nominations for this round of new members, which clearly demonstrates the level of engagement and continued commitment towards making progress on this disease."



Dr. Laura N. Gitlin, ACARCS Chair of Council

Dr. Laura N. Gitlin, who joined the council in 2015, will be the next chair of the council, replacing Dr. Ronald Petersen. Dr. Gitlin is an applied research sociologist, is the Isabel Hampton Robb Distinguished Professor within the School of Nursing with joint appointments in the Department of Psychiatry and Division of Geriatric Medicine within the School of Medicine at Johns Hopkins University. Starting February 1, 2018, she will be the Distinguished Professor and Dean of the College of Nursing and Health Professions, Drexel University.

The new members are:

Cynthia Huling Hummel
(Patient Advocate – Person Living with Dementia)

Reverend Dr. Hummel was diagnosed with Alzheimer's disease in early 2016. She has participated in numerous presentations and speeches about her disease and is actively helping plan the upcoming National Research Summit on Care, Services and Supports for Persons with Dementia and Their Caregivers.

Debra Cherry (Patient Advocate)

Dr. Cherry is currently the Executive Vice President of Alzheimer's Greater Los Angeles. For more than 25 years, she has been an effective advocate for persons with dementia and their families. She has led numerous initiatives to develop and evaluate programs to improve quality of care for people living with dementia and advocated at the local, state, and national level to increase access to services. She has expertise across a number of areas as a provider in geriatric psychology, advocate, and leader of an association.

Katie Brandt (Caregiver)

Ms. Brandt is Director of Caregiver Support Services in the Frontotemporal dementia unit at Massachusetts General Hospital. She came as a member of the public to an advisory council meeting in July 2014, where she told her moving personal story of losing her young husband to frontotemporal dementia and caring for her father who was diagnosed with Alzheimer's disease at the same time.

Allan Levey (Healthcare Provider)

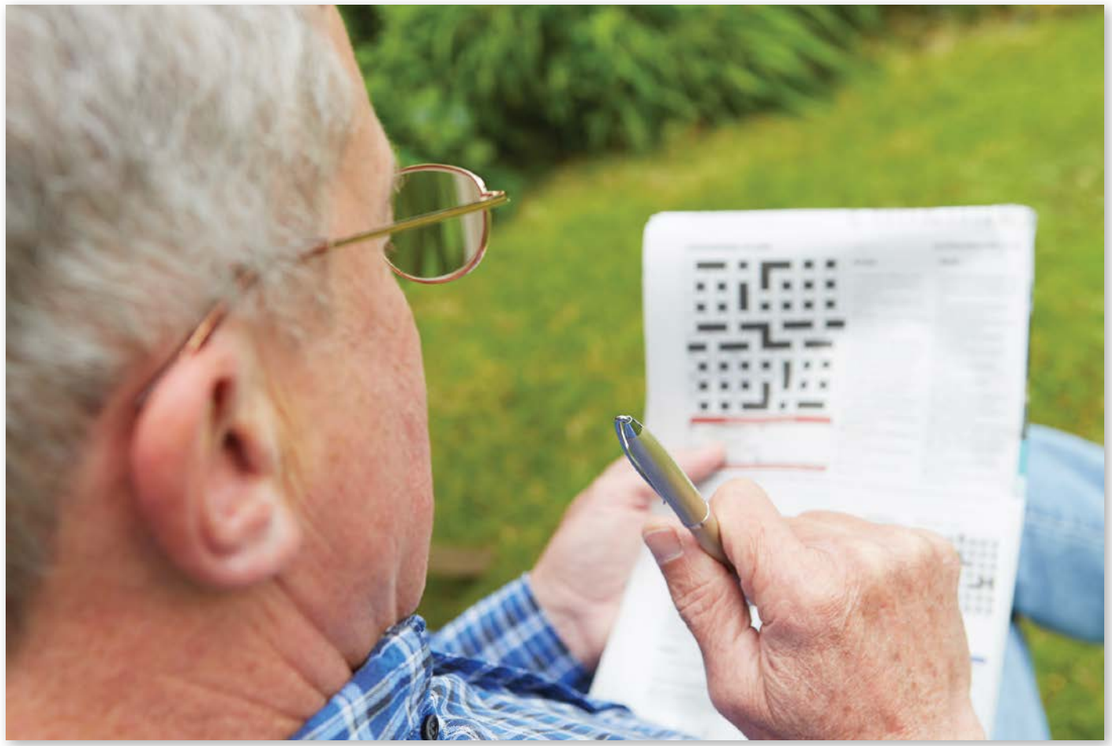
Dr. Levey is the Director of Emory University's Alzheimer's Disease Research Center and Chairman of the Department of Neurology. He is widely respected among providers and researchers in this field. Dr. Levey is a practicing neurologist in addition to his work on neurodegenerative research and will bring an important dually-informed perspective to the council.

Bradley Hyman (Researcher)

Dr. Hyman is a world renowned neurologist, neuropathologist and neuroscientist with extensive experience in basic and translational neurosciences of Alzheimer's disease and related dementias. Dr. Hyman has served at NACA, as chairman, and as an Alzheimer's Disease Research Center director. He is also involved in new criteria of Alzheimer's disease and related dementias and developed the standardized neuropathological criteria for Alzheimer's diagnosis.

Becky Kurtz (State or Local Health Department)

For more than 25 years, Ms. Kurtz has influenced aging policy at state and federal levels and led the provision of social and advocacy services for older adults and individuals with disabilities. Ms. Kurtz currently directs the Aging and Independence Services group within the Atlanta Regional Commission, widely regarded as one of the most innovative area agencies on aging (AAA) in the nation. Previously she led the Long-Term Ombudsman program both at the state and federal levels and provided legal services to low income elders. In each of these roles, Ms. Kurtz has served and advocated for individuals living with dementia, their families and caregivers.



"We are pleased to welcome this group of experienced members, including a patient advocate living with dementia, to continue the important work of the advisory council in assisting HHS with further progress on treating and curing Alzheimer's disease and related dementias," said HHS Secretary.

Robert Egge (Voluntary Health Association)

Mr. Egge is the Alzheimer's Association's Chief Public Policy Officer and Executive Vice President, Government Affairs, and leads the Association's Public Policy division based in Washington, DC. The division includes government affairs, policy development and grassroots advocacy teams working in pursuit of policies to better serve those affected by Alzheimer's disease and related disorders.

The full advisory council also includes federal members and meets quarterly to continue development and progress on the National Plan to Address Alzheimer's Disease by HHS, Veterans Affairs, the Department of Defense, and the National Science Foundation. Find the roster at: https://aspe.hhs.gov/advisory-council-alzheimers-research-care-and-services-members

Alzheimer's disease currently affects 5.3 million Americans and is expected to affect more than 20 million by 2050. The National Alzheimer's Project Act pledges to help people and families across the country whose lives are touched by Alzheimer's disease and related dementias. The Act continues to help strengthen dementia research, clinical care, and long-term care services and supports for affected individuals and their families.

hhs.gov

New Toolkit Helps Nurses Use Genomics in Patient Care

Nurses and other health professionals looking to integrate genomics into patient care now have access to an online toolkit with more than 100 resources, part of a new website launched by the National Human Genome Research Institute.

Developed with input from clinical educators and administrators, the Method for Introducing a New Competency Genomics (MINC) website provides resources for nursing leaders at all levels of genomics competency, ranging from basic knowledge about genomics to its practical impact on healthcare systems and policies.

The website addresses the need for healthcare professionals to stay abreast with the rapidly changing healthcare environment. Its resources can help practicing nurses care for patients undergoing genomic testing and treatments, build awareness in their communities, and understand how to prepare their workforce for emerging clinical applications.

"The MINC toolkit is a starting point for healthcare providers who want to promote genomic integration into practice to benefit their patients," said Laura Lyman Rodriguez, PhD, director of the Division of Policy, Communication and Education at NHGRI. "It was designed based on the efforts of Magnet hospital nurses whose experiences were used in the design and foundation for the toolkit."

The toolkit is structured in a question and answer format, allowing users to tailor their interventions based on the resources that will work best for them in their unique clinical setting. A key feature of the toolkit is "Champion Stories". These video testimonials from health administrators and educators describe how they overcame barriers as they developed the necessary genomics knowledge to offer personalized care to their patients.

MINC offers resources for providers with varying levels of experience, including:

- Assessing your Work Environment for Where to Begin
  http://genomicsintegration.net/what-needs-to-be-done.php
- How to Design an Action Plan for Your Organization
  http://genomicsintegration.net/data/GeneticsGenomicsEducationActionPlan.pdf
- Where to Find Help by Searching the Consultant Directory
  http://genomicsintegration.net/data/CONSULTATIONDIRECTORY.pdf
- Getting Started with Genomics Education/Action Plan Strategies
  http://genomicsintegration.net/data/GeneticsGenomicsEducationActionPlan.pdf
- Browse Resources to Select Interventions
  http://genomicsintegration.net/browse.php

nih.gov

Nurses Learn How to Get Patients to Say 'Yes' to Blood Thinners

Online training aims to make sure those hospitalized get treatment to prevent dangerous blood clots

By Robert Preidt

Online training for nurses increased hospital patients' use of medication that can prevent potentially deadly blood clots, a new study reveals.

Nurses sometimes won't give the blood thinning drugs if patients don't want them. So researchers developed the training to teach nurses how to respond when patients say they don't want to take blood thinners.

The study included more than 900 nurses at Johns Hopkins Hospital in Baltimore. After the online training, the number of patients who refused to take prescribed blood thinners dropped from 12.4 percent to 11.1 percent, the findings showed.

"We teach in hopes of improving patient care, but there's actually very little evidence that online professional education can have a measurable impact. Our results show that it does," study senior author Dr. Elliott Haut said in a Johns Hopkins news release.

Haut is vice chair of quality, safety and service in the department of surgery at Johns Hopkins University School of Medicine.

Each year, 350,000 to 600,000 people in the United States are affected by venous thromboembolism (VTE), a blood clot that forms in a vein (often in a limb). And more than 100,000 of those people die when a clot breaks off and travels to a lung. That's more deaths than from breast cancer, AIDS and motor vehicle collisions combined, the researchers noted.

According to study first author Brandyn Lau, an assistant professor of surgery, "While injectable blood-thinning drugs, such as heparin, can prevent VTE, upwards of 15 percent of prescribed doses are never administered to hospitalized patients, most often due to patient refusal."

The study was published Aug. 16 in the journal PLoS One.

SOURCE: Johns Hopkins University

medlineplus.gov

Dietary Supplement Information for Health Professionals

By Paul M. Coates, PhD, Director, Office of Dietary Supplements

Dr. Paul M. Coates, Director, Office of Dietary Supplements

The ODS website focuses on meeting the needs of consumers for several reasons. Surveys tell us that the majority of Americans take at least one dietary supplement each day. In fact, Americans spent more than $30 billion on dietary supplements each year for the past several years. And, of course, the Internet is a very common source of health information for most of us these days.

In Health Information you'll find fact sheets on the individual nutrients found in dietary supplements (such as vitamin B12, D, calcium, and zinc), one on multivitamins/minerals, and a fact sheet focusing on dietary supplements for weight loss. Many of the factsheets are available in three versions: the scientifically detailed and fully referenced health professional fact sheets and the consumer fact sheets written for consumers and busy health professionals — available in both English and Spanish. Y

ou'll also find links to other publications that have been developed by NIH and other government agencies to help consumers make informed decisions concerning dietary supplements.

Today there are at least 75,000 dietary supplement products available containing vitamins and minerals, herbs and botanicals, and other ingredients such as glucosamine, fish oils, and probiotics. Yet for many dietary supplements, there are questions about effectiveness and safety. ODS works in collaboration with other NIH institutes, centers, and other research institutions to answer such questions. I invite you to visit the Research & Funding section to learn about our research and other programs and activities.

We hope that the scientifically based information you find on this website will help you make your best decisions in your research, your practice, your business, or when making personal health decisions on dietary supplement use.

For Medical Professionals:

Easy access to up-to-date, evidence-based information from ODS and other sources that will help you discuss dietary supplements with your patients, clients, colleagues, and students.

"The Office of Dietary Supplements (ODS) at the National Institutes of Health (NIH) offers the Mary Frances Picciano Dietary Supplement Research Practicum, 2.5-day educational opportunity to provide fundamental knowledge of dietary supplements to faculty, students, and practitioners with a serious interest in this subject. This intensive practicum provides a thorough overview and grounding about issues, concepts, unknowns, and controversies about dietary supplements and supplement ingredients. It also emphasizes the importance of scientific investigations to evaluate the efficacy, safety, and value of these products for health promotion and disease prevention as well as how to carry out this type of research."

Dietary Supplement Fact Sheets: https://ods.od.nih.gov/factsheets/list-all
Evidence-based summaries for health professionals and consumers on vitamins, minerals, herbs, and other ingredients.

Dietary Supplements: What You Need to Know: https://ods.od.nih.gov/HealthInformation/DS_WhatYouNeedToKnow.aspx
Key points about dietary supplements, including their effectiveness, safety, and quality.

Dictionary of Dietary Supplement Terms: https://ods.od.nih.gov/HealthInformation/dictionary.aspx
The Dictionary features hundreds of terms related to dietary supplements

ods.od.nih.gov

Addressing Challenges in the Assessment of Botanical Dietary Supplement Safety

The safety of botanical dietary supplements, hereafter referred to as botanicals, is an important public health issue. According to the 2012 National Health Interview Survey, 17.7 percent of Americans reported having used nonvitamin, nonmineral dietary supplements (including botanicals) in the past 12 months (Clarke et al., 2015).

Botanicals pose several unique challenges to efficacy and safety evaluation because of their inherent complexity and potential for wide variability in nominally related products. The interrelated challenges associated with the evaluation of botanicals include: (1) developing methods and criteria for assessing phytoequivalence (i.e., similarity in chemical composition and biological activity) of botanicals, (2) identifying the active constituent(s) or patterns of biological response of botanicals, and (3) assessing absorption, distribution, metabolism, and elimination (ADME) of botanicals.

This workshop will engage experts from multiple disciplines to focus on practical approaches for addressing these challenges.

Multiple factors contribute to the variability in botanicals including complex and inconsistent source material, manufacturing processes, formulation, and storage. Botanicals in commerce often display a wide range in the concentration of known constituents.

Robust procedures for comparing constituent profiles across multiple botanicals are needed to determine how broadly safety or efficacy evaluations with a specific product can be applied

to related products. Topics for discussion at the workshop include definition of important chemical and biological activity features, statistical methods for comparing across complex mixtures, and how to define "similarity" across botanicals (i.e., how similar do botanicals have to be in order to apply safety data from a reference botanical to nominally-related botanicals).

Botanicals are often perceived to have significant health benefits with low risk of harm. Since botanicals are complex natural products, the particular constituent(s) responsible for biological activity, as related to efficacy or toxicity, is often unknown.

Participants at the workshop will discuss the relative merits of dedicating scientific attention to identifying the active constituent(s) in botanicals and identifying biological signatures that are predictive of adverse events (biomarkers of effect). Furthermore, presentations will address promising approaches (e.g., high throughput screening, computational tools) and accompanying challenges for using these approaches to advance our understanding of the risks associated with botanical use.

Botanicals are often perceived to have significant health benefits with low risk of harm.

Understanding the ADME of botanicals is critical to evaluating their safety. However, evaluating ADME in humans and animal models is complicated in the case of botanicals by the large number of constituents, the wide range of concentrations, potential interactions (botanical-botanical and botanical-drug interactions), as well as interindividual and animal-to-human differences in pharmacokinetics. The workshop will include discussion of knowledge gaps and available options for assessing ADME of botanicals to inform future safety evaluations.

Reference

Clarke, T.C., et al., Trends in the use of complementary health approaches among adults: United States, 2002–2012, in National health statistics reports. 2015, National Center for Health Statistics: Hyattsville, MD.

ntp.niehs.nih.gov

Norman Sharpless Sworn in as Director of the National Cancer Institute

Norman E. "Ned" Sharpless, MD took the oath of office late Tuesday, October 17, 2017, to become the 15th director of the National Cancer Institute (NCI), part of the National Institutes of Health. He succeeds Harold E. Varmus, MD, who stepped down as director in March 2015. Douglas R. Lowy, MD, has been NCI's acting director since April 2015.

"It is an honor to welcome Dr. Sharpless to the Department of Health and Human Services and the National Institutes of Health," said Acting Health and Human Services Secretary Eric D. Hargan. "We are grateful to Dr. Lowy for his service as acting director, and we look forward to Dr. Sharpless playing an integral role in this administration's aggressive efforts to advance cancer research and cures for cancer patients."

"Dr. Sharpless is an outstanding scientist, clinician, and administrator, and we are very fortunate to have him join the NIH leadership team," said NIH Director Francis S. Collins M.D., Ph.D. "I look forward to his insight, influence, and partnership at NCI, as cancer research is experiencing an unprecedented era of rapid progress."

Dr. Sharpless comes to NCI from the University of North Carolina School of Medicine, Chapel Hill, where he served as director of the NCI-Designated Lineberger Comprehensive Cancer Center and as the Wellcome Distinguished Professor in Cancer Research. As a practicing oncologist at the N.C. Cancer Hospital, the clinical arm of Lineberger, he specialized in the care of patients with hematologic cancers. He is the author of more than 150 original scientific papers, reviews, and book chapters, and is an inventor on 10 patents. His research has focused on the molecular biology of cancer and aging.

"Dr. Sharpless is an outstanding scientist, clinician, and administrator, and we are very fortunate to have him join the NIH leadership team,"

"I am honored and humbled to assume this role at NCI, the world's premier cancer research institution," Dr. Sharpless said. "This is an exciting moment for cancer research, as new discoveries and technological improvements are accelerating our progress against cancer, an ancient and unrelenting foe."

Norman E. "Ned" Sharpless, MD

After earning his undergraduate and medical degrees from the University of North Carolina at Chapel Hill, Dr. Sharpless completed his internal medicine residency at the Massachusetts General Hospital and a hematology/oncology fellowship at Dana-Farber/Partners Cancer Care, both of Harvard Medical School in Boston. He is a member of the American Society for Clinical Investigation and the Association of American Physicians. He cofounded two clinical-stage biotechnology companies: G1 Therapeutics and HealthSpan Diagnostics.

Dr. Lowy will resume his role as a deputy director at NCI, and will continue his work as chief of the Laboratory of Cellular Oncology in NCI's Center for Cancer Research.

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NCI-funded TMIST Study Compares 2-D and 3-D Mammography for Finding Breast Cancers

Study will help women make informed decisions about screening tests in the future

The Tomosynthesis Mammographic Imaging Screening Trial (TMIST), the first randomized trial to compare two types of digital mammography for breast cancer screening, is now open for enrollment. The study was developed by the ECOG-ACRIN Cancer Research Group (ECOG-ACRIN) and the National Cancer Institute (NCI), part of the National Institutes of Health. ECOG-ACRIN is leading the trial.

TMIST researchers are enrolling healthy women ages 45 to 74 who are already planning to get routine mammograms. By taking part in TMIST, the 165,000 planned participants will provide critical information that will help researchers learn how to most effectively screen women for breast cancer and help women make informed decisions about the screening tests in the future.

"Nearly 50 million screening mammograms occur each year in the United States, yet it has been decades since a large-scale randomized trial of mammography has been done," said Worta McCaskill-Stevens, M.D., director of the NCI Community Oncology Research Program (NCORP), the NCI program supporting 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."

TMIST is comparing two types of digital mammography approved by the Food and Drug Administration: tomosynthesis (known as three-dimensional, or 3-D) and conventional (two-dimensional, or 2-D). Although 3-D mammography, being the newer technology, is likely to detect more findings that require follow-up, it is also likely to lead to more procedures and treatments. It is not known if this newer mammography technology is reducing a woman's risk of developing a life-threatening (advanced) cancer compared with 2-D mammography. The TMIST trial aims to find out.

"We need to determine if 3-D mammography is better than 2-D at finding the sort of breast cancers that are most likely to spread and kill women," said ECOG-ACRIN study chair Etta D. Pisano, M.D., vice chair of research in the Department of Radiology at Beth Israel Deaconess Medical Center and professor in residence of radiology at Harvard Medical School, Boston. "If a newer screening technology does not reduce the numbers of advanced, life-threatening cancers, then are we really improving screening for breast cancer?"

TMIST researchers are collecting data on the results of every mammogram, whether the imaging shows no signs of cancer, findings suspicious of cancer, or a breast cancer. Any medical follow-ups, such as more imaging or biopsies, are also being reported. TMIST researchers intend to follow all participants for breast cancer status, treatment, and outcomes from the time of randomization until the end of the study (at least 2025).

Based on the findings of earlier studies, researchers know that the vast majority of women in the study will not develop breast cancer. If a woman does receive a diagnosis of any kind of breast cancer while in the trial, she will receive treatment just as she would if she was not part of TMIST, while continuing to be part of the trial.

In addition to data from mammograms, the trial is building a biorepository for future research on genetic markers for breast cancer by asking all participants to voluntarily submit blood samples and swabs of cells from inside the mouth (buccal cells). This data could, in the future, help women and their doctors decide the best ways to screen for breast cancer by evaluating their individual risk factors for developing the disease.

TMIST researchers are also analyzing tissue collected from women who have biopsies during the trial because of mammogram findings that require follow-up. This is to learn more about the biology of breast cancers detected through screening.

About 100 mammography clinics in the United States are planning to participate in the trial and are opening on a rolling basis over the next several months. Women are being told about the opportunity to enroll in the trial when they schedule a routine mammogram. Once enrolled, they will be assigned to either 2-D or 3-D mammography screening. Most women enrolled in the trial will be screened annually. Postmenopausal women with no high-risk factors will be screened every two years.

To ensure a diverse group of participants, sites are well represented both geographically and by the race/ethnicity of the women the sites serve. Several Canadian clinics are joining the trial, having already enrolled more than 3,000 women in a smaller lead-in study that is helping to inform TMIST.

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CPG

DNA Damage Caused by Cancer Treatment Reversed by ZATT Protein

By Scott Williams, PhD, deputy chief of the Genome Integrity and Structural Biology Laboratory at the National Institute of Environmental Health Sciences (NIEHS)

An international team led by scientists at the National Institutes of Health is the first to discover a new way that cells fix an important and dangerous type of DNA damage known as a DNA-protein crosslink (DPC). The researchers found that a protein named ZATT can eliminate DPCs with the help of another protein, TDP2. Since DPCs form when individuals receive some types of cancer treatments, understanding how TDP2 and ZATT work together to repair the damage may improve the health outcomes of cancer patients. The findings were published in the journal Science.

Researchers knew that TDP2 was important for removing DPCs, but they did not know how it was directed to where it needed to work, according to corresponding author Scott Williams, Ph.D., deputy chief of the Genome Integrity and Structural Biology Laboratory at the National Institute of Environmental Health Sciences (NIEHS), part of NIH. Williams and his team used a multi-pronged approach to identify ZATT as a new contributor to this process and determine how it guides TDP2 to DPCs so they can be repaired.

To visualize how these proteins choreograph DPC repair, one must first know how DPCs are created. Matthew Schellenberg, Ph.D., an NIEHS visiting fellow and lead author on the paper, said when DNA becomes tangled inside of cells, organisms use a protein called topoisomerase 2 (TOP2) to untangle it.

"Imagine your DNA is a giant ball of yarn," Schellenberg said. "TOP2 cuts and reties individual threads to disentangle the ball."

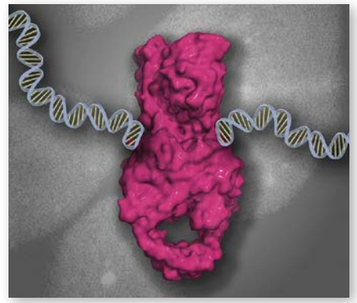

Illustration of a TOP2 DNA-protein cross-link (magenta) bound to DNA. Scott Williams

Schellenberg explained that TOP2 normally conceals its cut DNA ends within the core of the TOP2 protein that encircles DNA. Doing so ensures the protein can complete the second part of its job, which is rejoining DNA ends. However, chemotherapeutic drugs or environmental chemicals sometimes block the protein's DNA-retying ability, so that TOP2 remains stuck on DNA. This situation creates a stable TOP2-DPC complex, which leads to the accumulation of severed DNA that kills cells.

Williams likened TOP2-DPCs to ticking time bombs for cells. He said these molecular charges are armed by TOP2's interaction with environmental toxicants, chemical metabolites, tobacco exposures, or DNA damage caused by ultraviolet light.

He added that TOP2-DPCs are most potently formed by pharmaceutical drugs that humans exploit to eradicate cancer cells, making TOP2-DPCs double-edged swords. If they are not removed, they trigger cell death. While cancer drugs induce formation of TOP2-DPCs to treat cancer, TOP2-DPC lesions can also be the source of disease, as they can cause rearrangement of an organism's genome that leads to cancer. For this reason, Williams and his colleagues said it was necessary to learn how DPCs are located and broken down.

"In this study, we discovered a new molecular disarmament apparatus for these cell-killing bombs," Williams said. "ZATT is like a bomb sniffing dog, so when it locates its target, it sounds an alarm to mobilize the recruitment of TDP2, which cuts the red wire to disarm these threats."

Schellenberg said chemotherapeutic drugs, such as etoposide, are not the only pharmaceuticals that induce DPCs. Many of the antibiotics that are currently on the market use the same method to damage bacterial DNA. He said this work was part of a larger effort to figure out how researchers can exploit this key vulnerability to improve health.

"We've discovered how we defend against this potent means of cell killing," Schellenberg said. "It is our hope that this information will enable development of new drugs that target these defenses. By lowering the defenses, we may make drugs that kill cancer cells more effective."

Reference

Schellenberg MJ, Lieberman JA, Herrero-Ruiz A, Butler LR, Williams JG, Munoz-Cabello AM, Mueller GA, London RE, Cortes-Ledesma F, Williams RS. 2017. ZATT (ZNF451)-mediated resolution of topoisomerase 2 DNA-protein cross-links. Science 357(6358):1412-1416.

nih.gov

Social Interaction Affects Cancer Patients' Response to Treatment

Biological basis is unknown but may be related to stress response, NIH researchers say

How well cancer patients fared after chemotherapy was affected by their social interaction with other patients during treatment, according to a new study by researchers at the National Human Genome Research Institute (NHGRI), part of the National Institutes of Health, and the University of Oxford in the United Kingdom. Cancer patients were a little more likely to survive for five years or more after chemotherapy if they interacted during chemotherapy with other patients who also survived for five years or more. Patients were a little more likely to die in less than five years after chemotherapy when they interacted during chemotherapy with those who died in less than five years. The findings were published online July 12, 2017, in the journal Network Science.

"People model behavior based on what's around them," Jeff Lienert, lead author in NHGRI's Social and Behavioral Research Branch and a National Institutes of Health Oxford-Cambridge Scholars Program fellow. "For example, you will often eat more when you're dining with friends, even if you can't see what they're eating. When you're bicycling, you will often perform better when you're cycling with others, regardless of their performance."

Lienert set out to see if the impact of social interaction extended to cancer patients undergoing chemotherapy. Joining this research effort were Lienert's adviser, Felix Reed-Tsochas, PhD, at Oxford's CABDyN Complexity Centre at the Sai¨d Business School, Laura Koehly, PhD, chief of NHGRI's Social and Behavioral Research Branch, and Christopher Marcum, PhD, a staff scientist also in the Social and Behavioral Research Branch at NHGRI.

They based their findings on electronic medical records data from 2000 to 2009 from two major hospitals in the United Kingdom's National Health Service. The researchers examined the total time a patient spent with the same patients undergoing chemotherapy and their five-year survival rate. The five-year survival rate is the percentage of people who live at least five years after chemotherapy treatment is completed. For example, a five-year survival rate of 70 percent means that an estimated 70 out of 100 people are still alive five years after chemotherapy. They also reviewed a room schematic to confirm the assumption that patients were potentially positioned to interact.

"We had information on when patients checked in and out of the chemotherapy ward, a small intimate space where people could see and interact for a long period of time," Lienert said. "We used 'time spent getting chemotherapy in a room with others as a proxy for social connection."

When patients were around those during chemotherapy who died in less than five years following chemotherapy, they had a 72 percent chance of dying within five years following their chemotherapy. The best outcome was when patients interacted with someone who survived for five years or longer: they had a 68 percent chance of dying within five years. The researchers' model also predicted that if patients were isolated from other patients, they would have a 69.5 percent chance of dying within five years.

"A two percent difference in survival — between being isolated during treatment and being with other patients — might not sound like a lot, but it's pretty substantial," Lienert said. "If you saw 5,000 patients in nine years, that 2 percent improvement would affect 100 people."

"Mr. Lienert's research is the first to investigate, on a large scale, how social context in a treatment setting can play a significant role in disease outcomes," said Koehly. "As cancer care moves more towards targeted therapies based on genomic tumor assessments, NHGRI is interested in understanding how these social environmental factors might impact treatment efficacy."

The researchers didn't study why the difference occurred, but hypothesize that it may be related to stress response.

"When you're stressed, stress hormones such as adrenaline are released, resulting in a fight or flight response," Lienert said. "If you are then unable to fight or fly, such as in chemotherapy, these hormones can build up."

While the researchers also didn't investigate the impact of visitors on cancer patients undergoing therapy, the effect would likely be similar, he said.

"Positive social support during the exact moments of greatest stress is crucial," Lienert said. "If you have a friend with cancer, keeping him or her company during chemotherapy probably will help reduce their stress. The impact is likely to be as effective, and possibly more effective, than cancer patients interacting with other cancer patients."

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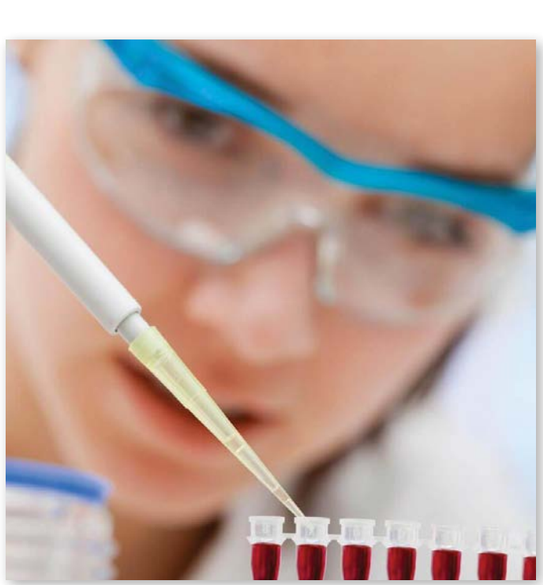
TCGA Study Identifies Genomic Features of Cervical Cancer

Investigators with The Cancer Genome Atlas (TCGA) Research Network have identified novel genomic and molecular characteristics of cervical cancer that will aid in the subclassification of the disease and may help target therapies that are most appropriate for each patient. The new study, a comprehensive analysis of the genomes of 178 primary cervical cancers, found that over 70 percent of the tumors had genomic alterations in either one or both of two important cell signaling pathways.

The researchers also found, unexpectedly, that a subset of tumors did not show evidence of human papillomavirus (HPV) infection. The study included authors from the National Cancer Institute (NCI) and the National Human Genome Research Institute (NHGRI), both parts of the National Institutes of Health, and appeared January 23, 2017, in Nature.



Cervical cancer accounts for more than 500,000 new cases of cancer and more than 250,000 deaths each year worldwide. "The vast majority of cases of cervical cancer are caused by persistent infection with oncogenic types of HPV. Effective preventive vaccines against the most oncogenic forms of HPV have been available for a number of years, with vaccination having the long-term potential to reduce the number of cases of cervical cancer," said NCI Acting Director Douglas Lowy, MD.
"However, most women who will develop cervical cancer in the next couple of decades are already beyond the recommended age for vaccination and will not be protected by the vaccine," noted Dr. Lowy. "Therefore, cervical cancer is still a disease in need of effective therapies, and this latest TCGA analysis could help advance efforts to find drugs that target important elements of cervical cancer genomes in addition to the HPV genes."

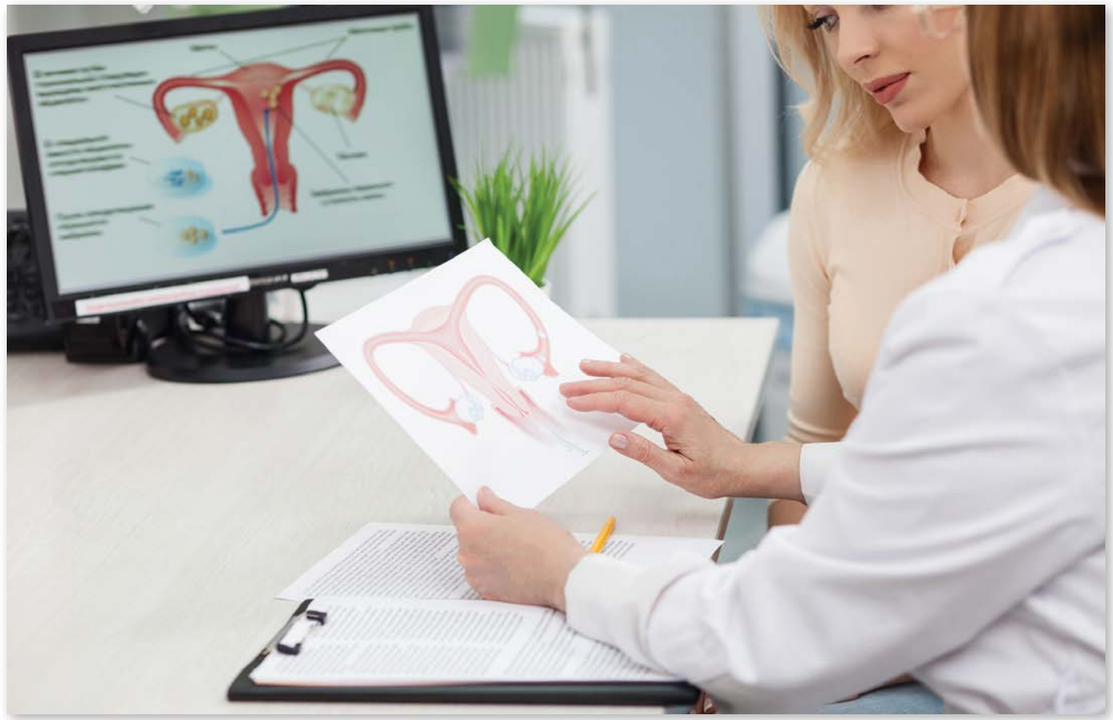
An aspect of the study that is of particular interest was the identification of a unique set of eight cervical cancers that showed molecular similarities to endometrial cancers. These endometrial-like cancers were mainly HPV-negative, and they all had high frequencies of mutations in the KRAS, ARID1A, and PTEN genes.

"The identification of HPV-negative endometrial-like tumors confirms that not all cervical cancers are related to HPV infection and that a small percentage of cervical tumors may be due to strictly genetic or other factors," noted Jean-Claude Zenklusen, Ph.D., director of NCI's TCGA program office. "This aspect of the research is one of the most intriguing findings to come out of the TCGA program, which has been looking at more than 30 tumor types over the past decade."

Because immunotherapies are becoming increasingly important for cancer therapy, the investigators examined genes that code for known immune targets to see if any were amplified, which may predict responsiveness to immunotherapy.

They found amplification of several such genes, specifically CD274 (which encodes the PD-L1 immune checkpoint protein) and PDCD1LG2 (which encodes the PD-L2 immune checkpoint protein). Several checkpoint inhibitors have been shown to be effective immunotherapeutic agents. In addition, the TCGA analysis identified several novel mutated genes in cervical cancer, including MED1, ERBB3, CASP8, HLA-A, and TGFBR2.

The researchers also identified several cases with gene fusions involving the gene BCAR4, which produces a long noncoding

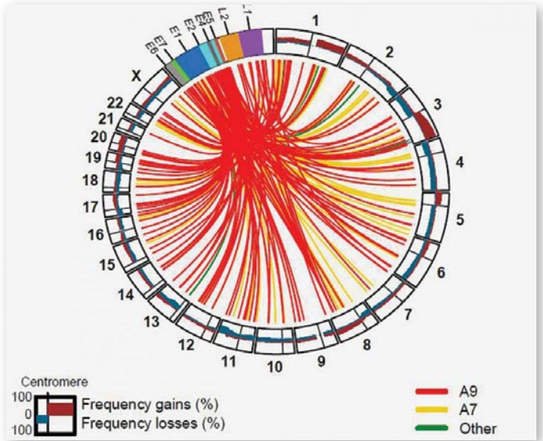


RNA that has been shown to induce responsiveness to lapatinib, an oral drug that inhibits a key pathway in breast cancer. Therefore, BCAR4 may be a potential therapeutic target for cervical cancers with this alteration.

When analyzing the biology behind the molecular alterations in these tumors, the researchers found that nearly three-quarters of cervical cancers had genomic alterations in either one or both of the PI3K/MAPK and TGF-beta signaling pathways, which may also provide targets for therapy. The authors noted that an important question raised by this study is whether HPV-positive and HPV-negative tumors will respond differently to targeted therapies.

NCI and NHGRI jointly manage the TCGA program. The TCGA Research Network has generated data and published analyses on a number of cancers, all of which can be found on the TCGA website, http://cancergenome.nih.gov. TCGA-generated data are freely available via the Genomic Data Commons at https://gdc.cancer.gov.

The TCGA Research Network consists of more than 150 researchers at dozens of institutions across the nation. A list of participants is available at http://cancergenome.nih.gov/abouttcga/overview. More details about The Cancer Genome Atlas, including Quick Facts, graphics, glossary, a brief guide to genomics and a media library of available images can be found at http://cancergenome.nih.gov



Circos plot showing cervical cancer chromosomes affected by HPV oncogenes. Cancer Genome Research Network

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National Eye Institute Awards Prize for 'Retina in a Dish' Competition

NEI 3-D Retina Organoid Challenge spurs next-generation models to study blinding diseases and test therapies

Erin Lavik, ScD

A proposal to create a living model of the human retina, the light-sensitive tissue at the back of the eye, won $90,000 in the National Eye Institute (NEI) 3-D Retina Organoid Challenge (3-D ROC). The NEI 3-D ROC is an initiative that seeks to design human retinas from stem cells. Erin Lavik, ScD, at the University of Maryland, Baltimore County, led the awarded team. The NEI is part of the National Institutes of Health.

An estimated 285 million people worldwide are visually impaired, including 39 million who are blind. For many, vision loss results from degenerative retinal diseases such as age-related macular degeneration, glaucoma, and diabetic retinopathy. Current research efforts to understand and cure retinal diseases are hampered by the lack of tissue models that replicate the complexity and functionality of the human retina.

In 2011, Japanese researchers demonstrated that embryonic mouse stem cells could be used in the lab to generate retinal tissue. The 3-D ROC participants were challenged to propose ideas to develop more sophisticated models. These so-called "retina organoids" can be used to study retina development and serve as disease models for drug screening.

The submitted 3-D ROC concepts were evaluated based on their innovativeness and feasibility. A review panel assessed how each proposal addressed scientific challenges, such as how to assemble distinct and anatomically correct layers of retinal tissue, assess retinal cell function, and use the prototypes to understand diseases or test therapies.

Combined, the 13 submissions involved more than 50 researchers with a range of expertise including stem cell biology, tissue imaging, and retinal vascularization. "The diversity of disciplines within each team is impressive and their concept proposals showcase the creativity that occurs when vision researchers collaborate with experts from other fields," said NEI Director Paul A. Sieving, MD, PhD.

NEI also awarded five teams with an honorable mention:

- Rebecca Carrier, PhD, Northeastern University, Boston
- David Gamm, MD, PhD, University of Wisconsin, Madison
- Wei Liu, PhD, Albert Einstein College of Medicine, Bronx, New York
- Daniel Pelaez, PhD, University of Miami, Florida
- Katja Schenke-Layland, PhD, Fraunhofer Institute for Interfacial Engineering and Biotechnology, Stuttgart, Germany

For more information about their ideas, read their abstracts at https://nei.nih.gov/ideation-winner

"We intend for these concepts to push the development of retinal organoids," Sieving added. "If developed, these next-generation human retina models would be invaluable resources for researchers in academia and industry."

NEI plans to launch a second phase of 3-D ROC this fall. NEI plans to award a combined total of $1 million to teams that demonstrate the functionality of a retina organoid prototype. Further details on the challenge will be provided in an official announcement.

Companies and non-profit organizations are interested in supporting the challenge participants by providing funding, expertise, and in-kind support such as discounts on reagents.

Descriptions of all submissions to the first phase of 3-D ROC are available at https://www.challenge.gov/challenge/nei-3-d-retina-organoid-challenge-3-d-roc

Full details of the 3-D Retina Organoid Challenge prize competition are available at https://nei.nih.gov/3DROC.

NEI leads the federal government's research on the visual system and eye diseases. NEI supports basic and clinical science programs to develop sight-saving treatments and address special needs of people with vision loss. For more information, visit https://www.nei.nih.gov.

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Stem Cell Secretions May Protect Against Glaucoma

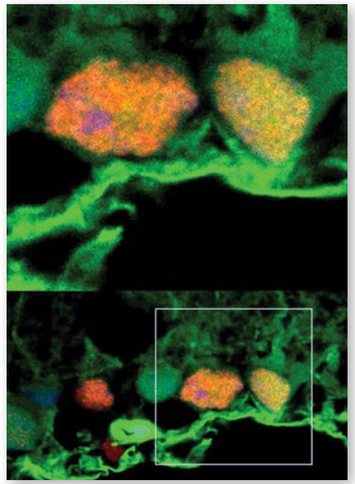
NEI scientists find that stem cell exosomes promote survival of retinal ganglion cells in rats

A new study in rats shows that stem cell secretions, called exosomes, appear to protect cells in the retina, the light-sensitive tissue in the back of the eye. The findings, published in Stem Cells Translational Medicine, point to potential therapies for glaucoma, a leading cause of blindness in the United States. The study was conducted by researchers at the National Eye Institute (NEI), part of the National Institutes of Health.

Exosomes are tiny membrane-enclosed packages that form inside of cells before getting expelled. Long thought of as part of a cellular disposal system, scientists have more recently discovered that exosomes are packed with proteins, lipids and gene-regulating RNA. Studies have shown that exosomes from one cell can be taken up by another by fusing with the target cell's membrane, spurring it to make new proteins. Exosomes also facilitate cell-to-cell interactions and play a signaling role, prompting research into their potential therapeutic effect.

In his study, Ben Mead, PhD, a post-doctoral fellow at NEI, investigated the role of stem cell exosomes on retinal ganglion cells, a type of retinal cell that forms the optic nerve that carries visual information from the eye to the brain. The death of retinal ganglion cells leads to vision loss in glaucoma and other optic neuropathies.

Stem cells have been the focus of therapeutic attempts to replace or repair tissues because of their ability to morph into any type of cell in the body. However, from a practical standpoint, using exosomes isolated from stem cells presents some key advantages over transplanting whole stem cells.



Microscopy shows exosomes (green) surrounding retinal ganglion cells (orange and yellow). Ben Mead, PhD

"Exosomes can be purified, stored and precisely dosed in ways that stem cells cannot," Mead said.

Another important advantage of exosomes is they lack the risks associated with transplanting live stem cells into the eye, which can potentially lead to complications such as immune rejection and unwanted cell growth.

In a rat glaucoma model, Mead studied the effects of exosomes isolated from bone marrow stem cells on retinal ganglion cells. Exosomes were injected weekly into the rats' vitreous, the fluid within the center of the eye. Prior to injection, the exosomes were fluorescently labelled allowing the researchers to track the delivery of the exosome cargo into the retinal ganglion cells. Exosome-treated rats lost about a third of their retinal ganglion cells following optic nerve injury, compared with a 90-percent loss among untreated rats. Stem cell exosome-treated retinal ganglion cells also maintained function, according to electroretinography, which measures electrical activity of retinal cells.

The researchers determined that the protective effects of exosomes are mediated by microRNA, molecules that interfere with or silence gene expression. Further research is needed to understand more about the specific contents of the exosomes, said Stanislav Tomarev, PhD, a principal investigator at NEI and the study's coauthor.

"We need to know which particular microRNA — there are more than 2000 different microRNA molecules — are delivered into the retinal ganglion cells and what proteins or signaling pathways are being targeted upon arrival," said Tomarev. "We also need to attempt to target exosomes to specific sets of neurons and other cell types or groups of cells."

Finally, the most optimal exosome approach needs to be identified, Tomarev added. It may be that the best approach would be to combine exosomes with additional therapies. From a treatment feasibility standpoint, a lot will depend on how frequently exosomes need to be administered to achieve a therapeutic effect.

This work was supported by the Intramural Research Programs of the National Eye Institute.

Reference

Mead, B. and Tomarev, S. (2017), Bone Marrow-Derived Mesenchymal Stem Cells-Derived Exosomes Promote Survival of Retinal Ganglion Cells Through miRNA-Dependent Mechanisms. STEM CELLS Translational Medicine

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Systemic Therapy Outperforms Intraocular Implant for Treating Uveitis

After seven years, NIH-funded clinical trial finds systemic therapy better preserves visual acuity and has fewer side effects.

Systemic therapy consisting of corticosteroids and immunosuppressants preserved vision of uveitis patients better — and had fewer adverse outcomes — than a long-lasting corticosteroid intraocular implant, according to a clinical trial funded by the National Eye Institute (NEI). After seven years, visual acuity on average remained stable among participants on systemic therapy but declined by an average of six letters (about one line on an eye chart) among participants who had the implant. NEI is part of the National Institutes of Health.

"This trial provides good evidence that for the average patient with uveitis, systemic therapy would be the first choice of treatment," said John Kempen, MD, PhD, of Massachusetts Eye and Ear/Harvard Medical School, Boston, chair of the writing committee for the report. "The visual outcome over the long run was better, on average, there were fewer adverse outcomes, and the cost is less." The findings were published today in the Journal of the American Medical Association.

Uveitis is an inflammatory disease of the eye and the fifth leading cause of vision loss in the United States. Concerns about potential adverse effects of systemic corticosteroid and immunosuppressive therapy drove the development of an intraocular implant to treat uveitis locally. The fluocinolone intraocular implant, developed by Bausch & Lomb, was approved by the U.S. Food and Drug Administration in 2005. Early data suggested the implant was effective at controlling inflammation but had local ocular side effects. The Multicenter Uveitis Steroid Treatment Trial (MUST) was undertaken to evaluate whether the implant treatment was an improvement over systemic therapy for management of uveitis.

Researchers recruited 255 uveitis patients at 23 sites (21 in the U.S., one in the U.K., and one in Australia) and randomly assigned them to receive the fluocinolone implant or systemic treatment with corticosteroids (prednisone) and immunosuppressants (such as methotrexate or mycophenolate mofetil). Systemic corticosteroids, which are FDA-approved for treatment of uveitis, reduce acute inflammation effectively but have potential systemic adverse effects when used at a high dose for a long time. The immunosuppressants, which are not FDA-approved for uveitis, inhibit pathological immune responses, thus reducing the amount of corticosteroids needed over the long-term, mitigating such side effects.

Through the first two years, the visual acuity remained about the same in the two groups (results published in 2011). At seven years, visual acuity on average remained stable in the systemic group but declined about six letters in the implant group. The researchers found that implant-treated eyes had reactivations of uveitis after about five years, which coincided with a decline in visual acuity. The loss of vision in the implant group appears to have been due to increased damage in the retina and choroid (a tissue rich in blood vessels lying underneath the retina).

"These results emphasize the importance of longer follow-up for studies of treatments for chronic diseases that are likely to require years of treatment," said Elizabeth Sugar, PhD, of Johns Hopkins University, Baltimore, chair of the statistical analysis committee for the MUST research group and lead statistician for the manuscript.

With respect to side effects, patients in the implant group were more likely to develop ocular side effects like cataracts, intraocular pressure elevation that required treatment with medicine and often surgery, and glaucoma. Patients receiving systemic therapy had increased risk of needing treatment with antibiotics, possibly due to immunosuppression, but otherwise did not have large increases in the risk of adverse effects typically associated with systemic corticosteroids such as high blood pressure or diabetes.

"We were able to avoid most of the systemic adverse outcomes that people worry about with systemic corticosteroid and immunosuppressive therapy by following expert panel guidelines. The result is meaningful not just in ophthalmology but in other disease areas, because many different fields use this strategy to treat the inflammatory diseases of many different organs," said Kempen.

"The results of this trial suggest that oral corticosteroids and immunosuppression may be a preferable initial choice for therapy of more severe uveitis," said Douglas A. Jabs, MD, of the Icahn School of Medicine at Mount Sinai, New York City, and chair of the MUST Research Group. "However, the implant may have a role in treating patients where systemic therapy fails to control inflammation or patients cannot tolerate the oral medications."

"MUST results provide guidance to clinicians and their patients in making informed decisions about uveitis treatment," said Sangeeta Bhargava, PhD, program director at the National Eye Institute.

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Caregiving Needs Double as End of Life Nears

Most rely on family members to provide that support, researchers say

Reliance on caregivers doubles as people near death, and half of those caregivers — typically unpaid family members — report having no time for themselves, a new study indicates.

The research used a nationally representative sample of about 2,400 older adults in the United States. The study authors found that caregivers provided nearly twice the number of hours of help each week to dying individuals than to those not at the end of life.

"We were certainly aware when dealing with end-of-life care that families are mostly involved, but we couldn't quantify that prior to this [research]," said study author Dr. Katherine Ornstein.

She's an assistant professor of geriatrics and palliative medicine at the Icahn School of Medicine at Mount Sinai in New York City.

More than 34 million Americans provided unpaid care to an adult aged 50 or older in the past 12 months, according to 2015 figures from the National Alliance for Caregiving and AARP. Most caregivers are female.

Ornstein and her team drew from two nationally representative surveys in which caregivers in the United States reported their experiences caring for dying adults over age 65. The researchers contrasted this data with that of other caregivers providing ongoing care.

Older adults were classified as being at the end of life if they died within 12 months of the surveys' completion.

The study found that dying adults had an average of 2.5 caregivers assisting them. Those near the end of life received 61 hours of help per week compared to 35 hours of help per week for older adults who weren't at the end of life.

More than one-third of the end-of-life caregivers reported physical difficulty related to their duties. Just over half reported having no time for themselves.

These figures were 21 percent and 40 percent, respectively, for other caregivers.

Nearly nine in 10 caregivers are unpaid, according to the study. For end-of-life caregivers who were spouses, nearly two-thirds reported receiving no help from family or friends.

"What we see now is, on average, there are 2.5 people helping someone at the end of life. You can imagine if they don't have that, it's much more difficult," Ornstein said. "When spouses are serving as caregivers, the majority are reporting doing it alone and have the [most challenging] consequences."

Barbara Coombs Lee is president of Compassion & Choices, a Washington, D.C.-based advocacy organization for patients' rights and end-of-life issues.

She pointed out that the caregivers surveyed in the new study didn't necessarily know ahead of time that the person they were caring for was at the end of life.

This lack of awareness may have increased caregivers' stress levels, she said.

"This told me the caregivers were probably struggling, not knowing this was an end-of-life situation. Our [organization's] research indicates that uncertainty about decision-making is an inherent and extremely powerful source of stress," Lee said.

"I would guess that many of these people didn't know they were dying ... so they pursued heroic, torturous, futile treatment," she added. "Often the default decision [to continue treatment] increases the caregiver burden."

Ornstein said she hopes greater awareness of the family burden of caregiving, especially at the end of life, comes from her research.

"We need to think about expanding access to palliative care services, which can help facilitate the delivery of supportive services to families earlier," she added. "And we can see how we need to provide more paid family leave so families can provide the support we're pretty much expecting them to provide."

Lee agreed with the need for expanded access to hospice and palliative care.

"One of the big barriers to access to hospice is [an] information gap," Lee said. "People don't understand that hospice is appropriate to them in their journey in their illness.

Palliative care utilization would go up if people had more candid conversations and were privy to information that physicians have but aren't sharing."

The study was published recently in the journal Health Affairs.

SOURCES: Katherine Ornstein, PhD, MPH, assistant professor, geriatrics and palliative medicine, Icahn School of Medicine at Mount Sinai, New York City; Barbara Coombs Lee, president, Compassion & Choices, Washington, D.C.

medlineplus.gov

Commissioners Proclaim Hospice and Palliative Care Month

On Tuesday, Nov. 15, the Charles County Board of Commissioners proclaimed November as National Hospice and Palliative Care Month.

Hospice and palliative care empowers people to live as fully as possible, surrounded and supported by family and loved ones, despite serious and life-limiting illness.

Patients and family caregivers receive the highest quality care delivered by an interdisciplinary team of skilled professionals including physicians, nurses, social workers, therapists, counselors, health aides, spiritual care providers, and others who make the wishes of each patient and family a priority.

Hospice professionals are an integral part of providing solutions to patients and loved ones, as nearly 1.6 million patients seek their services each year. Hospice of Charles County has supported Charles County residents with needed hospice and palliative care for more than 30 years.

Hospice of Charles County representatives with the Charles County Board of Commissioners

charlescountymd.gov

Federal Agencies Partner for Military and Veteran Pain Management Research

Joint HHS-DoD-VA initiative will award multiple grants totaling $81 million.

Through an interagency partnership, the U.S. Department of Health and Human Services, the U.S. Department of Defense (DoD), and the U.S. Department of Veterans Affairs (VA) announce a multi-component research project focusing on non-drug approaches for pain management addressing the needs of service members and veterans. Twelve research projects, totaling approximately $81 million over six years (pending available funds), will focus on developing, implementing, and testing cost-effective, large-scale, real-world research on non-drug approaches for pain management and related conditions in military and veteran health care delivery organizations. The National Institutes of Health will be the lead HHS agency in this partnership.

"Finding solutions for chronic pain is of critical importance, especially for military personnel and veterans who are disproportionately affected," said NIH Director Francis S. Collins, M.D., PhD. "Bringing the science to bear through these real-world research projects will accelerate our search for pain management strategies for all Americans, especially as we work to address the nation's opioid crisis."

These projects will provide important information about the feasibility, acceptability, safety, and effectiveness of nondrug approaches in treating pain. Types of approaches being studied include mindfulness/meditative interventions, movement interventions (e.g., structured exercise, tai chi, yoga), manual therapies (e.g., spinal manipulation, massage, acupuncture), psychological and behavioral interventions (e.g., cognitive behavioral therapy), integrative approaches that involve more than one intervention, and integrated models of multi-modal care.

The National Center for Complementary and Integrative Health (NCCIH), part of NIH, is contributing more than half of the total funding, and it is the lead for this multi-agency initiative called the NIH-DoD-VA Pain Management Collaboratory, which is modeled on the successful NIH Health Care Systems Research Collaboratory. This initiative also addresses the need to focus on "advancing better practices for pain management," which is outlined in HHS' 5-point strategy (link is external) to combat the opioid crisis.

"NCCIH has made pain research a priority — especially in military and veteran populations. We first partnered with the National Institute on Drug Abuse and the VA in 2014 and are delighted to expand the partnership to include the DoD and additional HHS/NIH components," said Dr. Josephine Briggs, director of NCCIH.

"We are so pleased to work alongside our federal partners to develop effective ways to treat pain in our service members and veterans that do not expose them to the risks of opioids," said Rachel Ramoni, DMD, ScD, chief research and development officer for the VA. "This work reflects the VA's commitment to reducing opioid overuse and expanding alternative pain management."

Studies report nearly 45 percent of soldiers and 50 percent of veterans experience pain on a regular basis, and there is significant overlap among chronic pain, post-traumatic stress disorder (PTSD), and persistent post-concussive symptoms. Data from the National Health Interview Survey shows that American veterans experience a higher prevalence of pain and more severe pain than nonveterans. Although opioids are often prescribed to treat chronic pain, research has not shown them to be very effective, and there are many issues with long-term use. Thus, there is a need for nondrug approaches to complement current strategies for pain management and to reduce the need for, and hazards of, excessive reliance on opioids.

"Pain is the most common medical condition requiring treatment for military personnel. Current drug treatments have limited efficacy and are often associated with severe adverse events, significant cognitive and physiological side effects, and pose a significant risk of abuse, misuse, addiction, tolerance, and diversion. The proposals funded under this interagency partnership will provide a significant step forward in pain management in our wounded service members. We are pleased to be working with our interagency partners in driving changes to clinical practice that will impact the military, our veterans, and the Nation as a whole," said Dr. George Ludwig, principal assistant for research and technology, U.S. Army Medical Research and Materiel Command (AMRMC).

Seven of the 12 projects have been awarded by HHS/NIH. The remaining five will be announced by the DoD and VA in the coming months.

nih.gov

Kids' Cases of High Blood Pressure May Rise Under New Guidelines

Simplified tables from American Academy of Pediatrics likely to raise detection rates

By Margaret Farley Steele

More U.S. kids and teens are likely to be diagnosed and treated for high blood pressure because of new guidelines released Monday from the American Academy of Pediatrics.

About 3.5 percent of children and teens have abnormally high blood pressure ("hypertension"), which often goes unnoticed and untreated, the academy said.

"If there is diagnosis of hypertension, there are many ways we can treat it," said Dr. David Kaelber, who helped develop the guidelines. "But because the symptoms are silent, the condition is often overlooked."

When high blood pressure isn't addressed, it can lead to heart and kidney problems years later, the academy added.

This is of special concern because incidence of childhood high blood pressure has risen in the United States since 1988, although recently it has plateaued, the guideline authors noted.

Under the new, simplified tables, children will have their blood pressure measured against normal-weight children, so ideal readings will likely be lower than in the past.

Obese or overweight kids — who were included under earlier guidelines —are more likely to have high blood pressure, possibly skewing recommended measurements.

As a result of this change, it's thought more children could be categorized as needing treatment. That's a good thing, Kaelber's team said.

Dr. Joseph Flynn, who co-chaired the guidelines subcommittee with Kaelber, explained that "by catching the condition early, we are able to work with the family to manage it, whether that's through lifestyle changes, medication or a combination of treatments."

Noting the link between obesity and high blood pressure, the academy pointed out that lifestyle changes — such as diet and exercise — are the first-line treatment for high blood pressure.

Doctors should prescribe blood pressure-lowering medications if those behavior changes don't reduce blood pressure, or if the child has another condition, such as kidney disease or diabetes, according to the guidelines.

But first, kids with an elevated blood pressure reading should have 24-hour monitoring at home, the academy said. This will rule out the possibility of "white coat effect" — anxiety in the doctor's office that raises blood pressure.

Also, to simplify classification for doctors, the academy recommends adults and teens use the same blood pressure tables.

"These guidelines offer a renewed opportunity for pediatricians to identify and address this important — and often unrecognized — chronic disease in our patients," Kaelber said. "The easy part was developing the new guidelines. Now we begin the harder work of implementing them to help children and adolescents."

SOURCE: American Academy of Pediatrics

medlineplus.gov

U.S. Explanation of Position on Ending Childhood Obesity: Implementation Plan

70th World Health Assembly, Agenda Item 15.5

Geneva, May 2017

The United States strongly supports efforts to end childhood obesity — a critical public health issue in our country, and many others. In fact, tackling childhood obesity in the United States is one of our top three clinical health priorities.

The United States believes that addressing childhood obesity requires identifying and pursuing comprehensive, cost-effective, evidence-based strategies. These strategies can include voluntary measures, best practices, or regulatory measures, appropriate to each national and local context, and consistent with Member States' domestic and international obligations, including trade obligations. Such strategies should also incorporate the use of public-private partnerships and other multi-sectoral collaborations.

The United States wishes to make clear that the Report of the Commission on Ending Childhood Obesity: implementation plan does not create legal rights or obligations under international law, and does not prejudice the sovereign rights of nations to determine their own policies, including on taxation.

In a federal system such as ours, decisions regarding many of the recommendations in the Implementation Plan rest with states and municipalities.

We believe that the prescriptive language used in this plan is inappropriate in light of the voluntary nature of the proposed interventions. In addition, we have concerns with some of the rights-related language in the plan. We also believe that the evidence underlying certain interventions is inadequate at this time to recommend them, and that recommendations for addressing childhood obesity should reflect the fact that all foods, including beverages, can be part of an overall diversified, balanced, and healthful diet.

Further, we expect that countries' implementation of any of the recommendations will be consistent with their international trade obligations.

The United States thanks the WHO Secretariat and Member States for the opportunity to discuss this important issue and we look forward to continuing to work together to make progress in this area.

geneva.usmission.gov

'Microbiomes' May Hold Key to Kids' Ear Infections

Germ communities in the middle ear differ greatly between affected and unaffected people, study shows

Recurrent ear infections are the bane of many children, and the parents who have to deal with their care.

Now, research suggests that naturally occurring, "helpful" bacterial colonies in the ear called "microbiomes" by scientists may help decide a person's vulnerability to these infections.

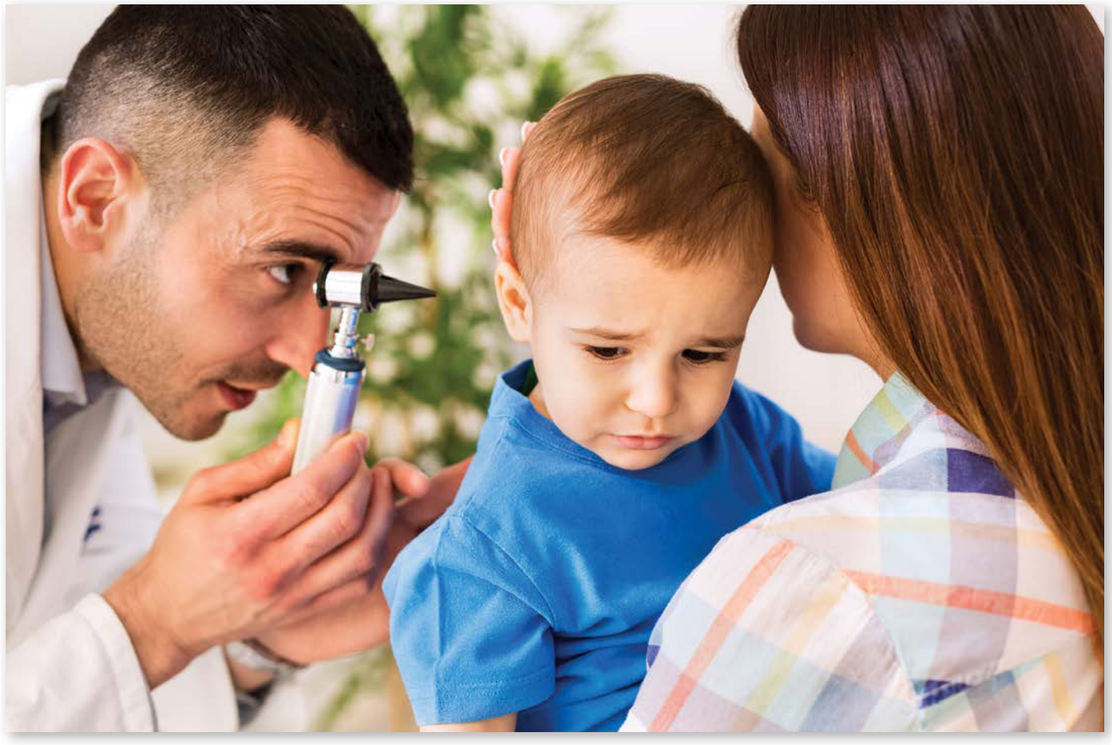
"The children and adults with normal middle ears differed significantly in terms of middle ear microbiomes," concluded a team of Japanese researchers led by Dr. Shujiro Minami of the National Institute of Sensory Organs in Tokyo.

One expert in the United States said the study is an important first step in learning more about ear infections.

"What this study tells us is that we have lots of bacteria living in our middle ears, regardless of whether or not we have chronic ear infections," said Dr. Sophia Jan, chief of pediatrics at Cohen Children's Medical Center in New Hyde Park, N.Y. "The study suggests that some kinds of bacteria don't seem to cause us problems when present in our middle ear."

However, "we still have a lot to learn before we can apply this research to the treatment or prevention of chronic ear infections," she added. "We don't know if the bacteria found in 'healthy' ears can be problematic, for example, if present in higher quantities."

Ear infections "are the most common reason parents bring their child to a doctor," according to the U.S. National Institute on



Deafness and Other Communication Disorders. These bacterial infections — called otitis media — typically start in the middle ear, and 5 out of 6 kids will develop at least one ear infection by the time they turn 3.

In the new study, Minami and colleagues wanted to see what role the ear's microbiome might play in these outbreaks. To do so, they took swab samples of the middle ears of 155 children and adults who were having ear surgery due to recurrent ear infections (88 cases) or some other condition.

Among patients with a history of ear infections, the researchers found significant differences in the makeup of microbial communities for people with active ("wet") or inactive ("dry") inflammation.

In fact, people whose ear infection was dormant "had similar middle ear microbiomes as the normal [no ear infection] middle ears group," the researchers said.

On the other hand, the researchers found that people with an active ear infection had bacterial communities that differed widely from those of people not suffering such outbreaks.

The bottom line, Minami's team said, is that "the human middle ear is inhabited by more diverse microbial communities than was previously thought. Alteration of the middle ear microbiome may contribute to the [cause] of chronic otitis media with active inflammation."

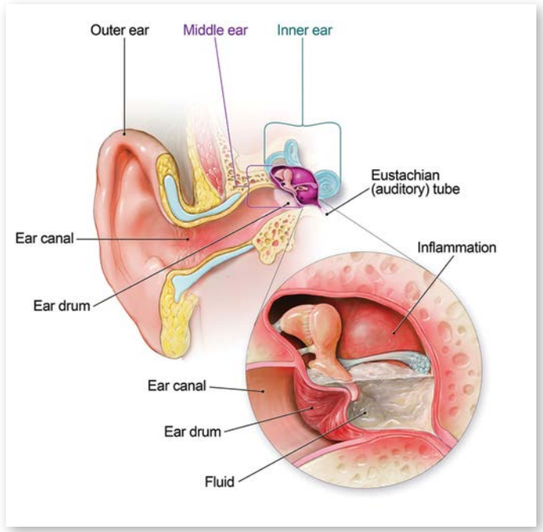
Dr. David Hiltzik is an otolaryngologist at Staten Island University Hospital in New York City. Reading over the study findings, he said that "as physicians, we continue to learn how the microbiomes in our bodies affect us."

But Hiltzik stressed that this work is in its infancy, and only further research will reveal "how these findings can assist us going forward in the treatment of ear infections."

For her part, Jan agreed that the study raises many new questions.

"Are specific bacteria causing wet, dry, or active inflammation? Or are different people genetically predisposed to be 'wet' with chronic ear infections, which then allows certain kinds of bacteria to grow in the middle ear?" she said. "Unfortunately, we still have a lot to learn."

The findings were presented earlier this week at the American Academy of Otolaryngology - Head and Neck Surgery annual meeting, in Chicago. Findings presented at medical meetings are typically considered preliminary until published in a peer-reviewed journal.



SOURCES: Sophia Jan, MD, director, general pediatrics, Cohen Children's Medical Center, New Hyde Park, N.Y.; David Hiltzik, M.D., otolaryngologist and director, head and neck surgery, Staten Island University Hospital, New York City; presentation, Sept 10, 2017, annual meeting, American Academy of Otolaryngology - Head and Neck Surgery, Chicago

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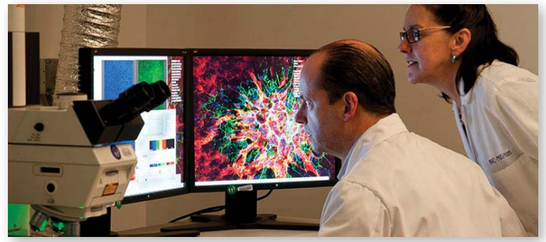
Neuroimaging Technique May Help Predict Autism among High-risk Infants

Brain patterns precede behavioral symptoms of autism, NIH-funded study suggest

Functional connectivity magnetic resonance imaging (fcMRI) may predict which high-risk, 6-month old infants will develop autism spectrum disorder by age 2 years, according to a study funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) and the National Institute of Mental Health (NIMH), two components of the National Institutes of Health. The study is published in the June 7, 2017, issue of Science Translational Medicine.



Autism affects roughly 1 out of every 68 children in the United States. Siblings of children diagnosed with autism are at higher risk of developing the disorder. Although early diagnosis and intervention can help improve outcomes for children with autism, there currently is no method to diagnose the disease before children show symptoms.

"Previous findings suggest that brain-related changes occur in autism before behavioral symptoms emerge," said Diana Bianchi, MD, NICHD Director. "If future studies confirm these results, detecting brain differences may enable physicians to diagnose and treat autism earlier than they do today."

In the current study, a research team led by NIH-funded investigators at the University of North Carolina at Chapel Hill and Washington University School of Medicine in St. Louis focused on the brain's functional connectivity — how regions of the brain work together during different tasks and during rest.

Using fcMRI, the researchers scanned 59 high-risk, 6-month-old infants while they slept naturally. The children were deemed high-risk because they have older siblings with autism. At age 2 years, 11 of the 59 infants in this group were diagnosed with autism.

The researchers used a computer-based technology called machine learning, which trains itself to look for differences that can separate the neuroimaging results into two groups — autism or non-autism — and predict future diagnoses. One analysis predicted each infant's future diagnosis by using the other 58 infants' data to train the computer program.

This method identified 82 percent of the infants who would go on to have autism (9 out of 11), and it correctly identified all of the infants who did not develop autism. In another analysis that tested how well the results could apply to other cases, the computer program predicted diagnoses for groups of 10 infants, at an accuracy rate of 93 percent.

"Although the findings are early-stage, the study suggests that in the future, neuroimaging may be a useful tool to diagnose autism or help health care providers evaluate a child's risk of developing the disorder," said Joshua Gordon, MD, PhD, NIMH Director.

Overall, the team found 974 functional connections in the brains of 6-month-olds that were associated with autism-related behaviors. The authors propose that a single neuroimaging scan may accurately predict autism among high-risk infants, but caution that the findings need to be replicated in a larger group.

About the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD): NICHD conducts and supports research in the United States and throughout the world on fetal, infant and child development; maternal, child and family health; reproductive biology and population issues; and medical rehabilitation

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nih.gov

NIH Awards Nearly $100 Million for Autism Centers of Excellence Program

The National Institutes of Health has awarded nine research grants totaling nearly $100 million over the next five years for the Autism Centers of Excellence (ACE), a program that supports large research projects aimed at understanding and developing interventions for autism spectrum disorder (ASD). The ACE program was created in 2007 from the consolidation of previous programs. Grants have been awarded every five years, and 2017 marks the third cycle of ACE grants.

ASD is a complex neurological and developmental disorder that begins early in life and affects how a person acts, learns and interacts with others.

"Autism spectrum disorder has myriad environmental, genetic, neurological and behavioral components," said Diana W. Bianchi, MD, director of NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), 1 of 5 institutes funding the ACE program. "These awards will allow us to understand how autism differs in girls versus boys, to develop earlier methods of screening, and to improve treatments based on specific symptoms."

In addition to NICHD, the NIH institutes that support ACE are the National Institute on Deafness and Other Communication Disorders, the National Institute of Environmental Health Sciences, the National Institute of Mental Health, and the National Institute of Neurological Disorders and Stroke.

The ACE awards seek to build on discoveries of the last 10 years by supporting innovative, multi-disciplinary research that promises to yield interventions and services for people with ASD. According to the Centers for Disease Control and Prevention, about 1 in 68 children has been diagnosed with the condition.

The awards will support research at individual centers or at research networks (which involve multiple institutions) dedicated to the study of ASD.

2017 Center Grants

University of California, Davis

Improving ASD treatments based on symptoms, features

David G. Amaral, PhD, and colleagues will continue their efforts to classify children into different subgroups, based on their symptoms, behavioral characteristics and genetic features and will attempt to develop behavioral and drug interventions appropriate for each subtype. The researchers have found that, by age 3, about 15 percent of boys with ASD have brains that are unusually large relative to the size of their bodies. These boys have a higher rate of regression, or loss of social and communications skills, and are more likely to have an intellectual disability. In contrast, at age 3, only 3 percent of girls with ASD had disproportionately large brains. The researchers plan to follow these children through childhood to determine if the structure of their brains differ from those of typically developing children.

University of California, Los Angeles

Tracing ASD symptoms to their origins

Susan Bookheimer, PhD, and colleagues will continue their efforts to look for clues into the nature of different subtypes of ASD by looking at areas of functioning often affected by the condition: sensorimotor processing, or how individuals process information from their senses; social motivation, the need to interact with others and be accepted by them; and social communication, the ability to use language and gestures for interactions with others. They will also test a medication to see if it can improve social functioning.

Yale University, New Haven, Connecticut

Examining development of functional brain connections

Katarzyna Chawarska, PhD, and colleagues will investigate brain connections in fetuses and newborns to identify early indicators of ASD. They will also determine if boys and girls with ASD differ in their brain circuity, with the aim of improving diagnosis and treatment. In addition, they will evaluate an intervention to improve social functioning in children at high risk for ASD.

Duke University, Durham, North Carolina

Understanding and potentially treating ASD-ADHD combination

An estimated 40 to 60 percent of people with ASD have attention deficit hyperactivity disorder (ADHD), which encompasses such symptoms as difficulty paying attention, problems controlling behavior and hyperactivity. Co-investigators Geraldine Dawson, PhD, and Scott Kollins, PhD, aim to learn how ADHD may influence the diagnosis and treatment of autism and plan to observe children who have ASD alone, ASD and ADHD, and ADHD alone and compare them to typically developing children. They will also test whether the stimulant medication used to treat ADHD will help children with both conditions.

Emory University, Atlanta

Studying social interaction to identify the early signs of ASD

Ami Klin, PhD, and colleagues will conduct studies on diagnosing autism early and developing the earliest possible interventions. The center will follow hundreds of infants from birth to 30 months, including those at high risk for ASD. They will study infant social interactions through measures of visual, vocal and brain development. Previously, the group showed that, when looking at videos of people speaking, infants who were later diagnosed with ASD had eye movements that differed from those of typically developing infants. More recently, the group found a genetic basis for those eye movements. When the children are 6 months of age, the researchers will test an intervention that will be easy for care givers to administer and tailored to each infant's individual characteristics.

"Autism spectrum disorder has myriad environmental, genetic, neurological and behavioral components," said Diana W. Bianchi, MD, director of NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), 1 of 5 institutes funding the ACE program.

"These awards will allow us to understand how autism differs in girls versus boys, to develop earlier methods of screening, and to improve treatments based on specific symptoms."

2017 Network Grants

George Washington University, Washington, D.C.

Investigating how ASD differs between boys and girls

Girls are diagnosed with ASD much less frequently than boys. Kevin Pelphrey, PhD, and network colleagues will follow children through adolescence and into adulthood to understand differences in ASD risk between boys and girls and in how they each respond to interventions. They will also collaborate with self-advocates with ASD to understand how well their findings reflect real-life experiences. Together, they aim to uncover information that will help males and females living with ASD better manage the transition to adulthood.

University of North Carolina, Chapel Hill

Tracking brain development, behavior as ASD progresses

Joseph Piven, MD, and network colleagues previously compiled detailed information on brain development and behavior for 300 children at high risk for ASD and 100 children at low risk. The researchers found that brain growth of infants later diagnosed with ASD differed from that of typically developing children. With the new award, the researchers will follow these children through ages 7 to 10 years to determine how their brains change as they grow and the potential effects of ASD on learning and social development. Based on what they learn, they aim to develop interventions tailored to school-age children with ASD.

Drexel University, Philadelphia

Evaluating autism screening for all toddlers. Should every toddler be screened for ASD?

Diana L. Robins, PhD, and network colleagues will conduct a randomized, controlled trial of 8,000 toddlers to determine if screening lowers the average age of ASD diagnosis, leads to earlier interventions and improves outcomes. Participating children from network clinics either will be evaluated at 18 months of age or be part of a group which will receive standard pediatric care. All children not screened at 18 months will be screened at 48 months and all children who are diagnosed with ASD will receive one year of behavioral therapy.

Florida State University, Tallahassee

Testing parent coaching, home intervention for toddlers

Amy Wetherby, PhD, and network colleagues will test a two-part intervention designed to empower parents of children with ASD. The researchers will offer parents Problem Solving Education, a six-session intervention to help them access the services their children need and to adapt to caring for a child with special needs. Parents will also receive training in Early Social Interaction, which teaches them to support their children's communication and social skills in everyday routines, activities and settings.

nih.gov

Newborn Screening Program Over 50 Years of Life Saving Results

Newborn screening programs across the United States currently screen more than 4 million infants per year. This public health program has saved countless lives through the early identification of infants who often appear healthy but who are at risk for disorders for which early interventions and treatments have the potential to save lives and improve the quality of life for children and their families.

The National Institute of Child Health and Human Development has led efforts on newborn screening since the Institute was founded in 1962.

One of the new Institute's earliest research successes was validation of the screening test for phenylketonuria (PKU), which was developed by Dr. Robert Guthrie in the late 1950s. The NICHD's mission has always included conducting, promoting, and funding research on ways to detect, treat, and even prevent diseases, including those that cause intellectual and developmental disabilities (IDDs) and other lifelong health problems.

NICHD research on newborn screening seeks to improve existing screening techniques and technologies or develop new ones, expand the number of conditions for which screening tests are available, and develop new treatments and disease-management strategies for conditions that can be detected through newborn screening but for which treatment is not yet available.

nichd.nih.gov

Robert Guthrie, MD, PhD

Start Skin Cancer Prevention Early, Health Experts Say

New proposal urges doctors to begin talking to parents when fair-skinned children are 6 months old

By Mary Elizabeth Dallas

How to keep from developing skin cancer should be something all doctors discuss with the parents of their young, fair-skinned patients, suggests the U.S. Preventive Services Task Force.

Those conversations should begin much earlier than previously recommended — starting when a child is just 6 months old, according to new recommendations from the task force.

"Providing behavioral counseling to children, their parents and young adults encourages sun-protective behaviors," said Karina Davidson, a U.S. Preventive Services Task Force (USPSTF) member.

"These actions — such as using sunscreen, wearing sun-protective clothing and avoiding indoor tanning — can help prevent skin cancer later in life," Davidson explained in a USPSTF news release.

She is vice dean at Columbia University Medical Center's departments of medicine, cardiology and psychiatry and director of the Center for Behavioral Cardiovascular Health, in New York City.

The task force recommends that doctors with fair-skinned patients aged 6 months to 24 years of age should talk with them, or their parents, about ways to protect skin from sun exposure to reduce the risk for skin cancer.

For patients older than 24, the task force suggests that doctors decide case-by-case whether counseling on skin cancer prevention would be appropriate.

Children and teens exposed to the sun's ultraviolet rays are at greater risk for skin cancer later in life, especially those with light skin and freckles who easily burn in the sun, the task force noted. People who've had sunburns in the past, used tanning beds or have had skin cancer also are at greater risk for the disease.

According to another task force member, Dr. John Epling, "Now, there is more evidence that counseling people to practice sun-protective behaviors can benefit some adults with fair skin." Epling is a professor of family and community medicine at the Virginia Tech Carilion School of Medicine in Roanoke.

At this point, the recommendation by the task force, an independent panel of national experts, is considered a draft. It expands on guidelines issued in 2012 that advised doctors to counsel fair-skinned patients aged 10 to 24 years on skin cancer protection.

Public comment on the draft will be accepted until Nov. 6, and a final, updated guideline will be issued after that.

Skin cancer is the most common form of cancer in the United States, according to the U.S. National Institutes of Health.

Children and teens exposed to the sun's ultraviolet rays are at greater risk for skin cancer later in life, especially those with light skin and freckles who easily burn in the sun, the task force noted. People who've had sunburns in the past, used tanning beds or have had skin cancer also are at greater risk for the disease.

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NIH Research Improves Health for People with Asthma

May is Asthma Awareness Month, and the National Institutes of Health is finding solutions to improve the health of the nearly 25 million people in the United States who currently have asthma. In recent decades, the prevalence of asthma has been increasing, resulting in millions of urgent medical visits and missed days of work and school each year.

Asthma is a chronic, and sometimes fatal, disease in which the airways become inflamed from a variety of triggers in the air, like indoor allergens from dust mites, mold, and cockroaches, and outdoor air pollution. Once the airways become swollen and inflamed, they become narrower, causing symptoms such as wheezing, coughing, chest tightness, and difficulty breathing.

Together, three institutes lead asthma research at NIH: the National Institute of Environmental Health Sciences (NIEHS), the National Heart, Lung, and Blood Institute (NHLBI), and the National Institute of Allergy and Infectious Diseases (NIAID). These three institutes support different aspects of asthma research but are united in a commitment to reduce the burden of this debilitating disease, as highlighted here through recent studies funded collaboratively by all three institutes.

For example, research funded by NIEHS, NHLBI, and NIAID has demonstrated the importance of healthy school environments. A study of students from inner-city schools, published in January 2017, linked airborne mouse allergens at schools to increased symptoms and decreased lung function in asthmatic children. This suggests there are steps

schools can take to improve air quality and potentially benefit children with asthma.

In fact, a preliminary study tested high-efficiency particulate air filters, commonly known as HEPA filters, in three urban elementary schools, which yielded two indoor air quality improvements: about a 40 percent reduction in fine dust particles, along with about a 55 percent reduction in traffic-related black carbon levels. Both pollutants can irritate the lungs of people with asthma.

NIH-supported researchers also are evaluating how much outdoor air pollution may come inside school buildings. One study found that levels of traffic-related black carbon were lower inside than outside, but when outdoor levels increased, so did the indoor levels. Fine dust particles inside schools came from both indoor and outdoor sources.

In addition to studying school environments, research funded by NIEHS, NHLBI, and NIAID has explored the complex role of the immune system in asthma. A study published in 2016 showed that children exposed to a wide range of bacteria and microbes, as found in dust on traditional Amish farms that use animals rather than machines, may be protected against asthma through the stimulation and shaping of non-specific, or innate, immune responses.

The study also took genetic factors into account by comparing genetically similar Amish and Hutterite children who live in communities with different agricultural practices. The researchers further strengthened the findings by reproducing the observed protective effect in mouse studies. The difference in triggering of the innate immune response may help explain why asthma remains rare among the Amish but affects nearly 1 in 10 U.S. children, who typically do not live in a rich microbial environment.

While bacteria and microbes can benefit the immune system, exposure to mold may make asthma worse. Scientists funded by NIEHS, NHLBI, and NIAID showed that children with high exposure to molds and fungi were more likely to have asthma at age 7. For children with allergies, the association was especially strong.

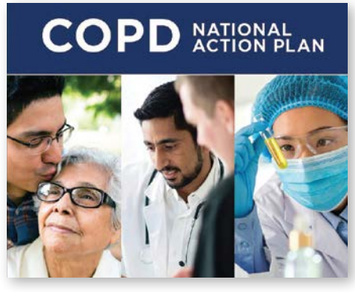
NIH-supported scientists continue to work to prevent and treat asthma. This month, we honor those children and adults who face the challenges of asthma every day, those who participate in clinical studies, and the researchers and health care professionals who help to address this condition.

nih.gov

COPD National Action Plan Aims to Reduce the Burden of the Third Leading Cause of Death

The National Heart, Lung, and Blood Institute (NHLBI), along with federal and non-federal partners, today released the first-ever COPD National Action Plan, a detailed, patient-centered roadmap for addressing one of the most urgent health concerns facing Americans. The plan was released at the American Thoracic Society International Conference meeting this week in Washington, D.C. NHLBI is part of the National Institutes of Health.

The third leading cause of death in the United States, chronic obstructive pulmonary disease, or COPD, affects 16 million Americans diagnosed with the disease and millions more who likely do not know they have it. The disease, which costs Americans more than $32 billion a year, can stifle a person's ability to breathe, lead to long-term disability, and significantly affect quality of life. This forward-looking plan — developed with the COPD community nationwide and at the request of Congress — offers a unified, coordinated approach to ending the COPD scourge by identifying the specific work doctors, educators, researchers, federal agencies, patients, advocates, and the biomedical industry can do to make a difference.

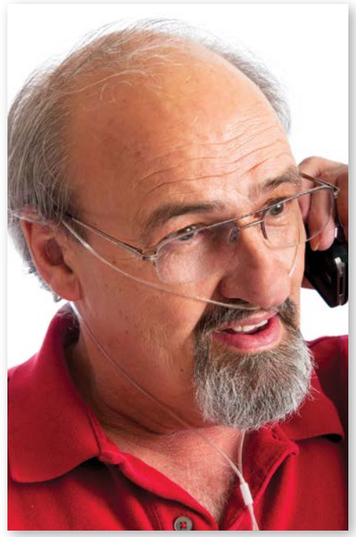


"This plan represents a new understanding of what it takes, at every level, to minimize the burden of COPD," said Gary H. Gibbons, MD, director of NHLBI. "Through thoughtful collaboration with federal agencies, patients, advocates, and researchers, we will help the millions who continue to endure this debilitating disease."

While COPD is not curable, it is often preventable and highly treatable, and early diagnosis can lead to improved outcomes. The newly-released action plan seeks to build on what the health and scientific communities already know by focusing on five goals:

- Empower patients, their families, and caregivers to recognize and reduce burden of COPD
- Equip health care professionals to provide comprehensive care to people with COPD
- Collect, analyze, report, and disseminate COPD data
- Increase and sustain COPD research
- Turn COPD recommendations into research, and public health care actions

To produce the plan, NHLBI announced and organized workshops and in early 2016 convened stakeholders of the COPD community, including patients and their families, health care providers, academics, and industry representatives, for a national COPD Town Hall. The comments shared at the COPD Town Hall directly informed the action plan, and engagement of the community remained integral to the plan, as its five goals were refined. In October 2016, NHLBI invited



the public to review and comment on the draft action plan, and used that feedback to finalize the plan.

"The enthusiasm of members from the COPD community in sharing its insights has been invaluable throughout this process," said James P. Kiley, PhD, director of NHLBI's Division of Lung Diseases. "The different perspectives brought by those who live these issues every day contributed to making this a clear, coordinated way forward for all stakeholders. We look forward to working together to improve the lives of those living with COPD."

The COPD National Action Plan provides a cohesive tool for health professionals and advocates to raise awareness about COPD and support activities that can change the trajectory of the disease.

nih.gov

Dr. James Ostell named Director of the National Center for Biotechnology Information

National Library of Medicine (NLM) Director Patricia Flatley Brennan, RN, PhD, has appointed James M. Ostell, PhD, as the director of the National Center for Biotechnology Information (NCBI), a division of NLM at the National Institutes of Health.

Dr. Ostell has been with NCBI since it was established by Congress in 1988, and has helped shape it into one of the most widely used biomedical resources in the world.

NCBI supports and maintains a series of biomedical databases, including PubMed, GenBank, BLAST, Entrez, RefSeq, dbSNP, PubMed Central and dbGaP.

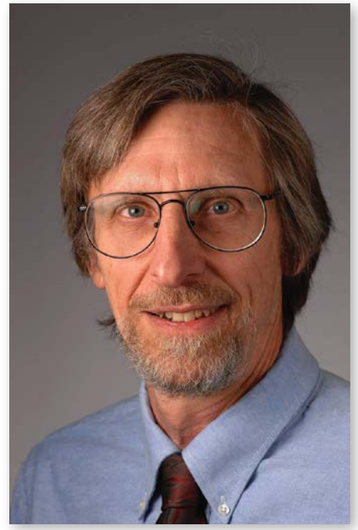
It also provides researchers with access to analysis and computing tools to better understand genes and their role in health and disease.

"We are fortunate to have Dr. Ostell as director of NCBI," said Dr. Brennan. "He brings a wealth of insight and experience, as well as vision, creativity, and a deep commitment to public service.

He holds the respect of the entire NCBI workforce, and has shepherded NCBI into a model organization that embraces discovery and excellence in technical development. His appointment will ensure the continued preeminence of NCBI and maintain its outstanding record of achievement."

Prior to his appointment as NCBI Director, Dr. Ostell served as chief of the NCBI Information Engineering Branch. In that role, he was responsible for designing, developing, building and deploying production resources at NCBI.

In 2007, Dr. Ostell was elected to the Institute of Medicine (now the National Academy of Medicine).



Dr. James Ostell, Director, NCBI

In 2011, he was named an NIH Distinguished Investigator, an honor reserved for NIH's most distinguished senior investigators at the highest level of career accomplishment.

Dr. Ostell earned a PhD in molecular biology from Harvard University, Cambridge, Massachusetts.

Before joining NCBI, he developed commercial molecular biology software.

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NIDCR Announces 2017 Sustaining Outstanding Achievement in Research Awards

Grants support ambitious, long-term research of meritorious mid-career investigators.

The National Institutes of Health announced that it has issued four awards totaling approximately $1 million each per year to support outstanding researchers in their pursuit of high-risk, high-reward projects with the possibility to profoundly enhance our understanding of dental, oral, and craniofacial diseases and conditions.

The support will go to scientists who are investigating skeletal tissue regeneration, craniofacial malformations, head and neck cancer, and links between viral infections and oral inflammation.

The Sustaining Outstanding Achievement in Research (SOAR) awards, issued by the NIH's National Institute of Dental and Craniofacial Research (NIDCR), provide up to eight years of grant support to allow mid-career investigators with outstanding records of productivity to have stable funding to pursue potentially transformative research programs.

"To ensure the long-term stability of the biomedical research enterprise, we must encourage successful, independent careers for early-stage investigators and retain them as they become more established," said NIDCR Director Martha Somerman, DDS, PhD. "The SOAR awards will enable these outstanding investigators to continue their career trajectories while pursuing dental, oral, and craniofacial research projects that have the potential to break new ground and ultimately improve human health."

NIDCR created the SOAR awards in 2015 to sustain exceptional scientists through a challenging early-established career phase, when many researchers are at risk for leaving the biomedical workforce due to a hypercompetitive funding environment. NIDCR issued the first round of SOAR awards in 2016, with support to two researchers, one focused on tooth regeneration and the other on human papilloma virus (for more about the initial grants, see Mid-Career Funding Helps Scientists Answer Big Questions)

"We are delighted that this round of funding will support diverse areas of dental, oral, and craniofacial science," said Lillian Shum, PhD, director of NIDCR's Division of Extramural Research. "Instead of focusing on several short-term projects, as is typical in academia, each investigator will be able to combine their separate but related areas of interest into one larger research program that could significantly advance the field."

The 2017 NIDCR SOAR investigators are:

Samantha Brugmann, PhD
Cincinnati Children's Hospital

Dr. Brugmann studies neural crest cells that give rise to the facial skeleton during development. Her work seeks to direct neural crest cells to develop into skeletal tissues that can be used to surgically repair craniofacial malformations.

Gage Crump, PhD,
University of Southern California, Los Angeles

Dr. Crump uses zebrafish models to unravel the developmental causes of congenital disorders of the head and face and to understand how stem cells build, maintain, and repair bones in the head. Ultimately, this knowledge could lead to regenerative medicine treatments for human craniofacial diseases.

Nisha D'Silva, PhD,
University of Michigan, Ann Arbor

Dr. D'Silva examines the molecular pathways that control the spread and recurrence of head and neck cancer. Her findings may ultimately enable clinicians to identify patients who will best respond to existing treatments, and might also lead to new treatment strategies.

Pinghui Feng, PhD
University of Southern California, Los Angeles

Dr. Feng's research explores the link between human herpesviruses (e.g. herpes simplex virus and Kaposi's sarcoma-associated herpesvirus) and chronic oral inflammation, which can cause gum disease. Understanding these molecular mechanisms may lead to therapies for oral and other inflammatory diseases.

NIDCR's SOAR awards reflect a broader trans-NIH effort to develop additional strategies to grow and retain talented scientists across critical career stages.

In August 2017 NIH launched the Next Generation Researchers Initiative, which places greater emphasis on current NIH funding mechanisms aimed at early and early-established investigators, such as NIDCR's SOAR program, the NIH Common Fund's New Innovator Awards, the National Institute of Arthritis and Musculoskeletal and Skin Diseases' Supplements to Advance Research (STAR) from Projects to Program, and the National Institute of General Medicine Sciences' Maximizing Investigators' Research Award (MIRA).

nih.gov

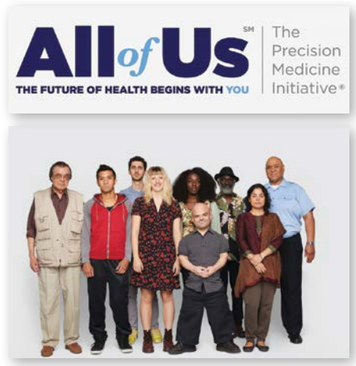
NIH's All of Us Research Program Expands National Network of Medical Centers

Awardees will help enroll participants in long-term precision medicine research effort

Three sets of health care provider organizations will add to a growing network of trusted leaders charged with implementing the National Institutes of Health's All of Us Research Program, an ambitious effort to advance research into precision medicine. Combined, the new awardees will receive $13.8 million to enroll interested individuals, gather participant health information and help retain participants in the program through ongoing engagement efforts. These awardees will extend the geographic coverage of the program and strengthen its reach within underserved communities, including lower-income, Hispanic and Latino, African American, American Indian and rural communities.

The All of Us Research Program is a bold effort to gather data over time from more than 1 million people living in the United States, with the ultimate goal of accelerating research and improving health. Researchers will use data from the program for studies on a variety of health conditions, to learn more about the impact of individual differences in lifestyle,

Eric Dishman, Director of the Precision Medicine Initiative (PMI) Cohort Program



environment and biological makeup. All of Us participants play an integral role in how we will approach improving health and treating disease in the future.

"We want this program to reflect the rich diversity of our country," said Eric Dishman, director of the All of Us Research Program at NIH. "Expanding our national network of health care provider organizations enhances our ability to reach communities traditionally underrepresented in medical research. Working with participants across the country, we hope to contribute to medical breakthroughs that may lead to more tailored disease prevention and treatment solutions in the future."

Awardees include:

Southern All of Us Network

University of Alabama at Birmingham (UAB); Cooper Green Mercy Hospital, Birmingham, Alabama; Huntsville Hospital, Alabama; Louisiana State University Health Sciences Center, New Orleans; Tulane Medical Center, New Orleans; Tuskegee University, Alabama; UAB Hospital, Birmingham, Alabama; UAB School of Medicine's Montgomery Internal Medicine and Selma Family Medicine programs, Birmingham, Alabama; University of Mississippi Medical Center, Jackson; University of South Alabama Health System, Mobile; and University Medical Center, Tuscaloosa, Alabama.

SouthEast Enrollment Center

University of Miami Miller School of Medicine, Florida; Emory University, Atlanta; Morehouse School of Medicine, Atlanta; and the OneFlorida Clinical Research Consortium led by the University of Florida in Gainesville.

All of Us, Wisconsin

Marshfield Clinic Research Institute; BloodCenter of Wisconsin, Milwaukee; Medical College of Wisconsin, Milwaukee; and the University of Wisconsin School of Medicine and Public Health in Madison.

The All of Us Research Program plans to continue building the network of health care provider organizations over time to engage a large participant community that reflects the geographic, ethnic, racial and socioeconomic diversity of the country. The network includes regional medical centers, community health centers and medical centers operated by the U.S. Department of Veterans Affairs.

The program is currently in beta testing. To learn more and to sign up for updates, please visit https://www.joinallofus.org

nih.gov

Awake for Aneurysm Brain Surgery, Better Results?

In new approach to the dangerous lesions, surgeons can get patient feedback during the procedure

"Awake" brain surgery may improve treatment of brain aneurysms, researchers say.

A brain aneurysm is a weak area in a blood vessel that supplies blood to the brain. It's commonly treated with a surgical technique known as "clipping" while the patient is under general anesthesia.

But a team of researchers at Saint Louis University in Missouri found that "awake brain surgery," using what's called conscious sedation, might improve results.

Testing the procedure on 30 aneurysm patients, study leader Dr. Saleem Abdulrauf and his team were able to communicate with the patients and test their brain function during surgery.

During the operation, surgeons open the skull and clip the artery below the aneurysm so blood can no longer enter it. This causes the blood vessel to shrink and prevents it from rupturing. A ruptured aneurysm can lead to serious disability or death, according to the U.S. National Institute of Neurological Disorders and Stroke.

While sedated but conscious, three of the 30 patients developed warning signs of blocked blood flow, such as blurred vision or the inability to make a fist.

When these warning signs developed, the doctors were able to reposition the clips and resolve potential issues within seconds, said Abdulrauf, chair of neurosurgery at the university.

"It happens instantly. It's amazing," he said.

The patients never felt pain, Abdulrauf said. They were deeply asleep as the surgical team removed a piece of their skull and exposed the affected part of their brain. The patients were only awake and alert while their aneurysm was being clipped and the brain itself has no pain receptors, he explained.

With standard surgery under general anesthesia, when one or more clips are placed there may be tiny vessels behind the aneurysm that could inadvertently get closed off, Abdulrauf said.

If these blocked arteries supply brain regions involved in critical function, such as speech, movement and vision, patients could wake up with permanent neurological deficits, he added.

Abdulrauf explained that brain wave monitoring that's done while patients are under general anesthesia isn't totally reliable. There is also no way to monitor patients' vision when they are asleep, he said.

Awake surgery may have other advantages, too. It eliminates some of the risks associated with general anesthesia and provides a viable option for patients with life-threatening brain aneurysms who are not candidates for general anesthesia, the researchers said.

This type of surgery is already used to treat seizures and some brain tumors. However, awake brain surgery isn't for everyone.

"It takes a special patient," said Dr. Mark Bain, a neurosurgeon at the Cleveland Clinic who wasn't involved in the study.

Also, larger studies are still needed to investigate the benefits of conscious sedation during aneurysm clipping, he said.

There are a couple of important reasons for this, said Bain. "When patients are under general anesthesia, they are being mechanically ventilated and their brain is more relaxed," he explained. Awake sedated patients may not breathe as well, causing the brain to swell. This can make it more difficult for surgeons to reach the aneurysm, he added.

Bain said brain aneurysm surgery is a very meticulous procedure involving tiny blood vessels. The possibility that a patient could move is a very big downside.

Meanwhile, there are effective nonsurgical treatments for brain aneurysms, such as coils and catheters, Bain pointed out. "We can get some type of protection with these less-invasive procedures," he said.

Most brain aneurysms do not cause symptoms until they either become very large or burst. Overall, about 30,000 people in the United States suffer a ruptured brain aneurysm each year.

Of these cases, about 40 percent are fatal within the first 24 hours and another 25 percent of patients die of complications within six months, according to the Institute of Neurological Disorders and Stroke.

The study findings were published in the August edition of the Journal of Neurosurgery.

SOURCES: Saleem Abdulrauf, M.D., chair, neurosurgery, Saint Louis University, Missouri; Mark Bain, M.D., neurosurgeon, Cleveland Clinic, Ohio; Journal of Neurosurgery

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Does Time of Neurosurgery Matter?

After-hours operations tied to more complications, study says

By Robert Preidt

Patients who have neurosurgery overnight are more likely to have complications than those whose operations occur during the day, a new study finds.

Risk of complications was 50 percent higher when surgeries began between 9 p.m. and 7 a.m., said University of Michigan researchers. They reviewed more than 15,800 neurosurgical procedures and their outcomes.

When accounting for the length of the surgery, the research team found the odds of a complication more than doubled.

Patients in the study underwent neurosurgery in the University of Michigan Health System between 2007 and 2014. There were 785 complications, including mild medication reactions, infections, heart attack and death.

Complications became more common after hours, but not necessarily more severe except in the case of emergency surgeries, the researchers said.

They noted that as it got later in the day, the percentage of elective cases fell while emergency cases increased. It's possible that complications become more likely because patients operated on overnight are sicker, according to the investigators.

Patients who have neurosurgery overnight are more likely to have complications than those whose operations occur during the day, a new study finds.

The study was published recently in the journal *Neurosurgery*.

"We need to continue to study this relationship [between after-hours surgery and increased risk of complications] as we aim to minimize surgery-related complications," said study lead author Dr. Aditya Pandey. He is an associate professor of neurological surgery at the university.

Pandey said the findings raise serious questions: Do health systems need to invest more to allow a greater proportion of surgeries during day hours? Should urgent cases be stabilized and operated on during the daytime?

"These are important questions that must be raised as we continue to solidify the relationship between surgical start time and surgical complications," Pandey said in a journal news release.

Previous research has found higher complication rates for off-hour surgeries in other health fields from orthopedics to heart care, the researchers said in background notes.

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Benham Badie, MD, director of the Department of Neurosurgery and the Brain Tumor program at City of Hope, performs a minimally invasive procedure to surgically remove a pituitary tumor.

Hernia Patients May Need Fewer Opioids After Surgery, Study Finds

After repair, smaller prescriptions led to fewer pills that could be diverted or abused

By Robert Preidt

Hernia surgery patients may require far fewer opioid painkillers than they're prescribed, new research suggests.

The study included 186 adult patients who had elective inguinal ("groin") hernia repair surgery under local anesthesia with intravenous sedation.

Each patient received a prescription for 10 tablets of the opioid painkiller Vicodin (hydrocodone/acetaminophen) to ease their post-surgery pain. But they were also encouraged to use non-opioid medications such as acetaminophen (Tylenol) or ibuprofen (Advil, Motrin) to manage their pain whenever possible.

The researchers found that 86 percent of the patients used less than half of their prescribed Vicodin. Almost two-thirds used no Vicodin at all, relying totally on non-opioid pain medications.

"The implication of our study is that, even though surgeons have been careful to limit the number of opioid tablets that we prescribe following operations, we may still be prescribing more medication than is actually needed by our patients," study senior author Dr. Peter Masiakos, from Massachusetts General Hospital, said in a hospital news release.

Masiakos said the findings need to be replicated at other practices and hospitals. But in the meantime, his hospital has initiated a change in how it prescribes these drugs.

"These results suggest that we should take a detailed look at our patient's experiences and our prescribing habits to really determine how much opioid medication we should provide our patients," Masiakos said.

Doctors work together to perform hernia surgery on a patient

He said that writing smaller prescriptions "should help reduce the number of extra opioid tablets that could be diverted or abused. Patients who experience more pain than expected or need more pain tablets than they are prescribed would alert us to the possibility of a postoperative problem that might need attention."

Data suggest that as many as 6 percent of patients who are prescribed opioids after surgery become addicted to the drugs. The risk may be even higher among patients who are prescribed longer-term, higher-dose opioid treatment.

One recent study found that patients were prescribed an average of 30 opioid tablets after hernia repair surgery and recommended reducing that to 15 tablets.

The study was published online recently in the journal Surgery.

SOURCE: Massachusetts General Hospital

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Is Successful Heart Surgery All in the Timing?

By Robert Preidt

New research shows that heart operations performed in the afternoon produced better outcomes than those done in the morning.

Because afternoon heart surgery syncs with the body's circadian clock (the internal body clock that controls when people sleep, eat and wake up), it reduces the risk of heart damage, the French researchers said.

"Currently, there are few other surgical options to reduce the risk of post-surgery heart damage, meaning new techniques to protect patients are needed," said study author Dr. David Montaigne, a professor at the University of Lille.

In one part of the study, his team tracked the medical records of nearly 600 people who had heart valve replacement surgery for 500 days, to identify any major cardiac events such as a heart attack, heart failure or death from heart disease. Half had surgery in the morning while the other half had it in the afternoon.

The risk of a major cardiac event was 50 percent lower among patients who had surgery in the afternoon than in those who had surgery in the morning. That would work out to one less major cardiac event per 11 patients who have afternoon surgery, the researchers said.

In another part of the study, the researchers monitored the health of 88 heart valve replacement surgery patients until they left the hospital. During the average follow-up of 12 days, patients who had afternoon surgery had less heart tissue damage than those who had morning surgery.

The researchers then tested 30 heart tissue samples from this group of patients and found that samples from afternoon surgery patients more quickly regained their ability to contract when put in conditions that replicated the heart refilling with blood.

Genetic analysis of the heart tissue samples also revealed that 287 genes linked to the circadian clock were more active in the samples from afternoon surgery patients than those from morning surgery patients.

That suggests that the heart is affected by the circadian clock, and that open heart surgery outcomes reflect the heart's poorer ability to repair in the morning, the researchers said.

At the Cleveland Clinic, Raisa Polacek, PA-C (left) assists during an open heart surgery, Cleveland, OH, 2015
Photo Courtesy of Cleveland Clinic

The findings were published Oct. 26 in The Lancet medical journal.

"Our study found that post-surgery heart damage is more common among people who have heart surgery in the morning, compared to the afternoon," Montaigne said in a journal news release.

"Our findings suggest this is because part of the biological mechanism behind the damage is affected by a person's circadian clock, and the underlying genes that control it. As a result, moving heart surgery to the afternoon may help to reduce a person's risk of heart damage after surgery," he added.

Montaigne and his colleagues also said it may be possible to develop drugs that can influence circadian clock-related genes to protect the heart during surgery.

SOURCE: The Lancet

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Common Treatment for Early Prostate Cancer May Carry Heart Risk

Hormone-suppressing regimen may raise odds for heart failure, but it brings benefits, too, researchers say

By Mary Elizabeth Dallas

Because testosterone can help prostate tumors grow, men with prostate cancer are often given hormone-suppressing treatment. But new research suggests that delivering the treatment in prostate cancer's early stages may, in turn, hike a man's odds for another illness — heart failure.

The treatment in question is known as androgen-deprivation therapy. The take-home message from the new study is that "patients with localized prostate cancer should be followed to minimize the health effects of androgen-deprivation therapy on the cardiovascular system," said study author Reina Haque. She's a researcher with the Kaiser Permanente Southern California Department of Research & Evaluation.

Haque's advice? "Patients should consider [heart-healthy] lifestyle changes, and physicians should actively monitor the patient's health for early signs of heart disease," she said in a Kaiser Permanente news release.

A prostate cancer expert who reviewed the study agreed. "This new data is important in deciding what treatment should be undertaken, if any, for early stage disease," said Dr. Elizabeth Kavaler, a urology specialist at Lenox Hill Hospital, in New York City.

Haque's research team noted that, in recent years, there's been an expansion in use of hormone-suppressing treatment for prostate cancer. The treatment was previously restricted to advanced prostate tumors, but now it's being given to a growing number of men with early stage prostate cancer that has not spread to other parts of the body.

However, the safety and effectiveness of androgen-deprivation therapy for these men hasn't been investigated, the study authors said.

In the new study, Haque and colleagues assessed outcomes for more than 7,600 men with early stage prostate cancer. The investigators tracked the men for up to 12 years, starting when they were diagnosed between 1998 and 2008. The researchers factored in certain heart risk factors — things such as overweight/obesity, history of smoking, diabetes, high blood pressure or if they required heart medications.

Initially, the men in the study were not undergoing any form of treatment but were being closely watched by their doctor to monitor the progression of their disease. But nearly 30 percent of the men did go on to receive androgen-deprivation therapy, the researchers said. Many of these men were younger than 60.

The study found the men with early stage prostate cancer who did not already have heart disease, but who received hormone-depleting treatments had an 81 percent higher risk for heart failure.

Meanwhile, those who already had heart disease when they received the anti-hormone treatment also had a greater risk for heart rhythm problems, including a 44 percent increased risk of an irregular heartbeat. These men were also three times more likely to develop "conduction disorder," which occurs when electrical impulses to the heart are interrupted.

One urologist experienced in the treatment of prostate cancer said that "there are two issues we need to look at to understand this report properly."

Dr. Nachum Katlowitz directs urology at Staten Island University Hospital in New York City. He said that, first of all, it's important to remember that "all treatments have risk. If androgen-deprivation therapy increases the risk of dying from cardiovascular disease, but decreases the risk of dying from prostate cancer, then we use it," he reasoned. "We watch for potential side effects. And sometimes, in select patients, the risk is greater than the benefit — so we do not [advise the therapy]."

Secondly, Katlowitz said, the findings come as little surprise, since physicians have long known that the suppression of testosterone can raise a man's odds for common heart disease risk factors.

"To summarize, yes, androgen-deprivation therapy has risk," he said, but so does the option of not providing the treatment in men with prostate cancer. "It is up to the doctor working with the patient to decide if the benefits are worth the risks and side effects," Katlowitz concluded.

Study author Haque agreed. "The findings allow men with localized prostate cancer to consider the positive and negative effects of androgen-deprivation therapy and discuss it with their physicians," she said. "If they move forward with the therapy, patients should work with their physicians to adjust their lifestyle to reduce the risk of cardiovascular disease."

The study was published Aug. 24 in the *British Journal of Cancer*.

SOURCES: Elizabeth Kavaler, MD, urology specialist, Lenox Hill Hospital, New York City; Nachum Katlowitz, MD, director of urology and male infertility, Staten Island University Hospital, New York City; Kaiser Permanente

medlineplus.gov

Couples with Obesity May Take Longer to Achieve Pregnancy, NIH Study Suggests

Couples in which both partners are obese may take from 55 to 59 percent longer to achieve pregnancy, compared to their normal weight counterparts, according to a study by researchers at the National Institutes of Health. The findings appear online in Human Reproduction.

"A lot of studies on fertility and body composition have focused on the female partner, but our findings underscore the importance of including both partners," said Rajeshwari Sundaram, PhD, a senior investigator in the Division of Intramural Population Health Research at NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development. "Our results also indicate that fertility specialists may want to consider couples' body compositions when counseling patients."

The couples in the study were part of the Longitudinal Investigation of Fertility and the Environment (LIFE) Study, which examined the relationship between fertility and exposure to environmental chemicals. The study enrolled 501 couples from Michigan and Texas from 2005 to 2009. The women ranged from 18 to 44 years of age, and the men were over 18 years old. Women kept journals to record their monthly menstrual cycles, intercourse and the results of home pregnancy tests. The couples were followed until pregnancy or for up to one year of trying to conceive.

Researchers also calculated body mass index (BMI) for each participant, categorizing couples with obesity into two subgroups: obese class I (with a BMI from 30 to 34.9) and the most obese group, obese class II (a BMI of 35 or greater).

The researchers compared the average time to achieve a pregnancy among couples in the non- obese group (84 men and 228 women) to that of the couples in the obese class II group (75 men and 69 women).

"Our results also indicate that fertility specialists may want to consider couples' body compositions when counseling patients."

— Rajeshwari Sundaram, PhD, Senior Investigator, Division of Intramural Population Health Research, NICHD

The researchers then calculated the probability that a couple would achieve pregnancy by using a statistical measure called the fecundability odds ratio (FOR). The measure estimates couples' probability of pregnancy each menstrual cycle while trying for pregnancy, relative to their BMIs.

The researchers found that the class II couples took much longer to achieve pregnancy than couples not struggling with obesity. Couples in the non-obese group had a FOR of 1. , Obese class II couples had a FOR of .45 — indicating that they took 55 percent longer to achieve pregnancy than their normal weight counterparts. When the researchers took into account other factors known to influence fertility — such as age, smoking status, physical activity level and cholesterol level &mdash ;the ratio for obese class II couples dropped to .41, or a 59 percent longer time to achieve pregnancy.

The study authors noted that previous studies have focused largely on just the female partner's BMI or self-reported height and weight. However, findings similar to the current study have been reported among couples undergoing assisted reproductive technologies. The current study focused on couples in the general population, not those undergoing treatment for infertility.

The authors concluded that couples' obesity may reduce fertility chances and that fertility specialists may want to take couples' weight status into account when counseling them about achieving pregnancy. In addition to the health benefits of a healthy weight for reducing risk of other diseases such as Type 2 diabetes, heart disease and cancer, taking steps to lose weight may help reduce the time needed to conceive.

nih.gov

Aspirin May Help Increase Pregnancy Chances in Women with High Inflammation, NIH Study Finds

By Lindsey A. Sjaarda, PhD, staff scientist in the NICHD Division of Intramural and Population Health Research

A daily low dose of aspirin may help a subgroup of women, those who have previously lost a pregnancy, to successfully conceive and carry a pregnancy to term, according to an analysis by researchers at the National Institutes of Health. The women who benefited from the aspirin treatment had high levels of C-reactive protein (CRP), a substance in the blood indicating system-wide inflammation, which aspirin is thought to counteract. The study appears in the Journal of Clinical Endocrinology and Metabolism.

Researchers at NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) analyzed data originally obtained from the Effects of Aspirin in Gestation and Reproduction (EAGeR) trial. The trial sought to determine if daily low-dose aspirin could prevent subsequent pregnancy loss among women who had one or two prior losses.

For the current study, researchers classified the women into 3 groups: low CRP (below .70 mg per liter of blood), mid CRP (from .70 to 1.95) and high CRP (at or above 1.95). Women within each group received either daily low-dose aspirin or a placebo. In their analysis, researchers found no significant differences in birth rates between those receiving aspirin and those receiving placebo in both the low CRP and mid CRP groups. For the high CRP group, those taking the placebo had the lowest rate of live birth at 44 percent, while those taking daily aspirin had a live-birth rate of 59 percent — a 35-percent increase. Aspirin also appeared to reduce CRP levels in the high CRP group when measured during weeks 8, 20, and 36 of pregnancy.

The authors concluded that more research is needed to confirm the findings and to examine the potential influence of inflammation in becoming pregnant and maintaining pregnancy.

Reference

Sjaarda LA, et al. Preconception low-dose aspirin restores diminished pregnancy and live birth rates in women with low grade inflammation: a secondary analysis of a randomized trial (link is external). Journal of Clinical Endocrinology and Metabolism

nih.gov

Women Falling Short on Birth Defect Prevention

New survey finds too few are taking folic acid before pregnancy

Only a third of women are taking a multivitamin containing folic acid — a nutrient known to prevent serious birth defects — before they know they're pregnant, a new survey has found.

The poll, conducted by the March of Dimes, also revealed significant racial disparities: Just 10 percent of black women and 27 percent of Hispanic women of childbearing age report taking multivitamins with folic acid before pregnancy.

"One of the things that's striking for us is how much more we need to make sure women understand the importance of being healthy before pregnancy," said Stacey Stewart, president of the March of Dimes Foundation.

"Half of all pregnancies are unexpected, which means women of childbearing age need to be doing all they can to be healthy in the event they do get pregnant," she said.

In the United States, more than 120,000 babies — about 3 percent of all births — will be born with birth defects this year, including about 3,000 babies born with neural tube defects, according to March of Dimes estimates.

Up to 70 percent of the neural tube defects, which affect the brain and spine, could be prevented if all women of childbearing age took daily multivitamins containing folic acid, the group said.

The survey on prenatal health measures, conducted online in August 2017 by The Harris Poll on behalf of the March of Dimes, polled a nationally representative sample of more than 1,000 U.S. women, 18 to 45 years of age. It also found that:

- 77 percent of women are concerned there may be changes to the U.S. health care system that may hamper access to prenatal care,
- 43 percent of women say that cost affects when and whether they seek prenatal care,
- nearly two-thirds of women identify folic acid as an important nutrient in birth defect prevention, and only 40 percent identify iron, calcium and vitamin D as other vitamins important for this purpose,
- 97 percent of women report taking prenatal vitamins or multivitamins during a pregnancy,
- 13 percent of women do not know that avoiding smoking or tobacco products reduces the risk for birth defects, and 12 percent are unaware that eliminating drinking and illegal drugs would do the same.

Stewart said that the number of women concerned about possible changes to the U.S. health care system, as well as costs, points to a serious regard for their access to proper care for themselves and their pregnancies.

"At the March of Dimes, we work very hard to make sure that members of Congress, especially over the last several months, understand how important it is to take into account the health of women and mothers, and the impact health care changes would have on pregnancies and newborn babies," she said.

"We have to make sure the most vulnerable in our country are safe and protected, and that certainly has to be true for babies," Stewart added.

Dr. Michael Pirics, an obstetrician-gynecologist at Houston Methodist Hospital in Texas, said he wasn't surprised by the new survey findings, noting that many women don't seek preconception care "either because they don't know that kind of thing is important or they're not getting regular gynecological checkups where it's addressed." He was not involved with the survey.

Pirics called the revelation of racial and ethnic disparities in multivitamin use among women of childbearing age "one snapshot of a larger problem" that he also found not surprising. All women in this age group should discuss taking folic acid-containing vitamins with their doctors well before conception, he said.

"But the idea of prevention is an overarching concern that should be more valued in our society," Pirics added. "We should be encouraging women to continue getting regular health visits, both for their own health and the health of their potential pregnancies in the future."

SOURCES: Stacey Stewart, president, March of Dimes Foundation, White Plains, N.Y.; Michael Pirics, MD, obstetrician-gynecologist, Houston Methodist Hospital, Texas; "Prenatal Health & Nutrition" survey

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New Study Shows Tdap Vaccination during Pregnancy Can Prevent Whooping Cough in Babies

Less than half of pregnant women in the United States take advantage of vaccination

A new CDC study published today in Clinical Infectious Diseases reported that vaccination with whooping cough vaccine, Tdap, during the third trimester of pregnancy prevented more than three out of four (78 percent) cases of whooping cough (also known as pertussis) in babies younger than two months. However, only 49 percent of pregnant women who delivered between fall 2015 and spring 2016 received the vaccine. CDC recommends women get Tdap during each pregnancy to provide critical short-term protection to babies when they are most at risk for this life-threatening illness.

The study used data from 2011 through 2014 on babies younger than two months from six states. It found that mothers whose babies had whooping cough were less likely to have received Tdap during pregnancy. The study reported that, in addition to being 78 percent effective at preventing whooping cough, Tdap vaccination during the third trimester was 90 percent effective at preventing serious cases of whooping cough that require hospitalization.

"Women have such a great opportunity to help protect their babies before they enter the world by getting Tdap vaccine while pregnant," said Nancy Messonnier, M.D., director of CDC's National Center for Immunization and Respiratory Diseases. "This study highlights how babies can benefit when their mothers get the vaccine and reinforces CDC's recommendation for women to get Tdap vaccine in the third trimester of each pregnancy."

Young babies at highest risk

Whooping cough is a serious disease that can cause uncontrollable, violent

coughing that often makes it hard to breathe. In this study, 65 percent of babies younger than two months who got whooping cough needed treatment in the hospital. Babies younger than one year are at the highest risk for severe complications or death. Typically, between five and 15 babies die from whooping cough each year in the United States. Most deaths are in those too young to be protected by getting their own whooping cough vaccines. Babies do not get vaccinated to start building their own protection against whooping cough until they are two months old.

Tdap vaccine history and recommendation

Before the introduction of whooping cough vaccines in the 1940s, more than 200,000 cases were reported per year in the United States. After vaccines became available, whooping cough cases declined dramatically to fewer than 10,000 cases reported by 1965. Beginning in the 1980s, whooping cough started making a comeback, though not to the levels seen before vaccines were available. Since 2010, there have been tens of thousands of whooping cough cases reported each year nationwide, with a peak of more than 48,000 cases reported in 2012. More than a third of all whooping cough hospitalizations and two thirds of all whooping cough deaths are in babies younger than two months. To date in 2017, more than 11,000 cases of whooping cough have been reported in the United States.

In 2012, CDC began recommending women get a whooping cough vaccine during each pregnancy. The American College of Obstetricians and Gynecologists and the American College of Nurse-Midwives, healthcare professionals who specialize in caring for pregnant women, support this recommendation, as do the American Academy of Pediatrics and the American Academy of Family Physicians.

CDC recommends that doctors and midwives administer Tdap at 27 through 36 weeks of pregnancy, preferably in the earlier part of that period. This timing leads to the most transfer of protective antibodies from mothers to their babies.

Previous research

Today's study adds to the growing body of research on Tdap vaccination during pregnancy that indicates it prevents whooping cough in babies who are too young to receive their own whooping cough vaccines. Three other studies from the United Kingdom and two from California also show much lower rates of whooping cough in babies whose mothers received Tdap during pregnancy. Another California study also found that babies with whooping cough whose mothers received Tdap during pregnancy were significantly less likely to need care in a hospital.

cdc.gov

Breast Cancer Screenings Still Best for Early Detection

Newer treatments, early diagnoses are improving outcomes for women with the disease, experts say

By Mary Elizabeth Dallas

Breast cancer is the second leading cause of cancer death among women in the United States, and routine screenings remain the most reliable way to detect the disease early, a breast cancer expert says.

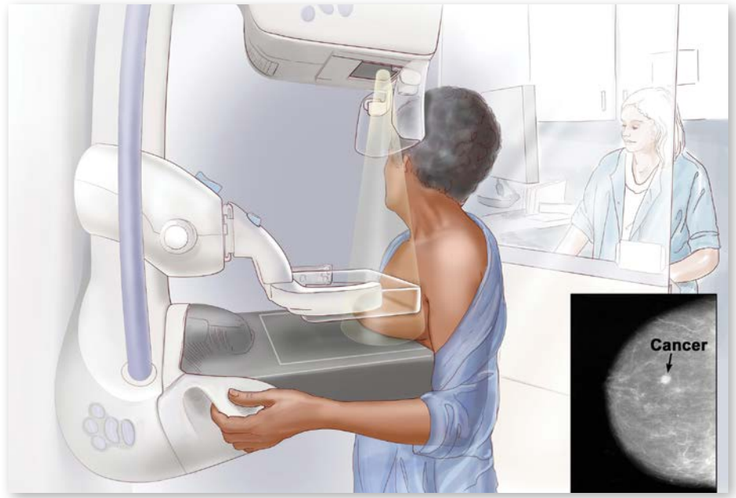
"Breast cancer can be treated more successfully if detected in its early phases, while it is small and has not yet spread," said Dr. Kathryn Evers, director of mammography at Fox Chase Cancer Center in Philadelphia. "With today's state-of-the-art treatment options and less extensive surgery, patients are experiencing better outcomes."

Older age is a leading risk factor for breast cancer. Most women are diagnosed after the age of 50. Having certain mutations in the BRCA1 and BRCA2 genes also predispose women to the disease. And there are some lifestyle-related risk factors that can be controlled, such as hormone therapy after menopause, obesity, alcohol intake and physical inactivity, Evers said.

"Having one risk factor or even several doesn't mean a woman will definitely develop breast cancer," she said in a Fox Chase news release. "Women need to become educated about the risk factors, especially those they can control, and then adjust their lifestyle accordingly."

Not all women with breast cancer experience the same warning signs of the disease. Symptoms of breast cancer may include:

- A lump in the breast or armpit.
- Swelling or thickening in part of the breast.
- Dimpling or irritation of the skin on the breast.



- Pain in the breast that doesn't go away.
- Redness or flaky skin on the breast or nipple.
- Unusual nipple discharge.
- A change in the size or shape of the breast.

In some cases, women never develop any of these symptoms, Evers noted.

"All women should know how their breasts look and feel so they can recognize any changes in them. This is an important part of breast health," she said. "But just being familiar with your breasts should never take the place of regular screenings and mammograms. These tests can help find breast cancer in its early stages, even before symptoms appear."

There are three tests often used to look for breast cancer, Evers said.

Mammogram: An X-ray of the breast used to examine breast changes. Its effectiveness depends on the size of a breast tumor and the density of breast tissue. Three-dimensional (3D) mammography involves X-ray machines that take pictures of thin slices of the breast from different angles, to build a 3D image.

Breast ultrasound: This test is often used along with mammography to screen high-risk women and those with dense breast tissue.

Breast MRI: This test may be used to screen high-risk women and more closely examine a suspicious area detected during a mammogram or an ultrasound. "I advise women to speak with their physician to determine what is right for them," Evers said.

SOURCE: Fox Chase Cancer Center

medlineplus.gov

Breast Cancer's Decline May Have Saved 322,000 Lives

But advances in care may not have helped black women as much as whites, report finds

By Mary Elizabeth Dallas

New research finds the number of American women who've lost their lives to breast cancer has fallen precipitously in the past 25 years, with more than 322,000 lives saved in that time.

Overall, advances in care have led to a 39 percent drop in breast cancer deaths of between 1989 and 2015, according to new research from the American Cancer Society (ACS).

One specialist who works with breast cancer patients daily was heartened by the news. "Early screening and better treatments are finally starting to pay off with better outcomes," said Dr. Stephanie Bernik, chief of surgical oncology at Lenox Hill Hospital in New York City.

However, the ACS was quick to point out that not every segment of Americans benefited equally. Despite some closure of the racial "gap" in breast cancer survival, black women are still more likely to die of the disease than their white peers, the study found.

Even though the rate of breast cancer diagnosis was slightly lower among black women than whites between 2010 and 2014, over about the same time period, black breast cancer patients were still 42 percent more likely to die of the disease than their white peers.

According to breast cancer specialist Dr. Cynara Coomer, that's probably due to a combination of factors. Black patients are more prone to be affected by aggressive, tough-to-treat breast tumors, she noted. But they also often lack access to the targeted treatments that can best fight these tumors.

So, when it comes to surviving breast cancer, "there remains a disparity between black women and white women across the country," said Coomer, who directs the Florina Rusi-Marke Comprehensive Breast Center at Staten Island University Hospital in New York City.

The vast majority of breast cancers are diagnosed among women aged 50 and older, the ACS found, and older women account for most deaths from the disease as well.

Still, race seemed to play a role here, as well. The median age of diagnosis for women overall in the United States is 62, but the disease tends to strike black women at a younger age, the report showed. The median age for breast cancer deaths is 68, but black patients died younger -- at 62, on average.

All of this means that, overall, breast cancer kills more black women than white women in the United States.

There was reason to hope, however, because this health disparity may be stabilizing in some parts of the country, the ACS said. For example, breast cancer death rates among black women ranged from 22 percent in Nevada to 66 percent in Louisiana, the report found.

But in seven states the researchers saw no significant difference in death rates between black and white patients -- showing that the racial gap can be closed.

While genetics and differences in overall health play a big role in the survival gap between blacks and whites, so do "social and structural factors," said Carol DeSantis, of the ACS's surveillance and health services research branch.

"Increasing access to health care to low-income populations" might shrink this racial gap even further across the country, she explained.

Coomer agreed, saying that black women with aggressive tumors, in particular, "would be better served with health care teams or centers that provide comprehensive breast treatment."

According to Bernik, progress is being made.

"The fact that we are finally seeing a close in the gap between our excellent outcomes between black and white women is also encouraging," she said, "especially since black women are more likely to be diagnosed with the more aggressive triple-negative breast cancers."

Excluding skin cancers, breast cancer is the second leading cause of cancer death among American women, trailing only lung cancer. It's estimated that 252,710 women will be diagnosed with breast cancer in 2017 and 40,610 will die from the disease.

The research was published Oct. 3 in *CA: A Cancer Journal for Clinicians and Breast Cancer Facts & Figures*.

SOURCE: Stephanie Bernik, MD, chief, surgical oncology, Lenox Hill Hospital, New York City; Cynara L. Coomer, MD, chief, breast surgery, and director, Florina Rusi-Marke Comprehensive Breast Center, Staten Island University Hospital, Staten Island, N.Y.; American Cancer Society

medlineplus.gov

Many High-Risk Women Skip MRI Breast Cancer Screenings

By Robert Preidt

Knowing they're at increased risk for breast cancer isn't enough to persuade many women to get MRI screenings — even if they're free.

Researchers studied more than 1,000 women in a U.S. military health system who had a 20 percent or greater lifetime risk of breast cancer due to genetics or personal or family history.

Between 2015 and 2016, they were offered free MRI cancer screening at the Madigan Army Medical Center in Tacoma, Wash. (Women with higher than average risk are advised to start annual MRIs and mammograms at age 30, according to the American Cancer Society.)

But only 23 percent of the women underwent MRI screening. That included 15 percent of those with a 20 to 24 percent lifetime risk of breast cancer, and only half of those with more than a 40 percent risk.

The study was to be presented Wednesday at an American College of Surgeons meeting in San Diego.

"The military health system is an equal access, no-cost system. This system allows us to study how well we are doing in terms of truly adhering to the current recommended guidelines for screening of breast cancer," said study lead author Dr. Vance Sohn. He's a surgical oncologist at the Madigan Army Medical Center.

Researchers studied more than 1,000 women in a U.S. military health system who had a 20 percent or greater lifetime risk of breast cancer due to genetics or personal or family history.

"In the interest of helping more women be screened earlier for breast cancer, we were intrigued about what this preliminary study identified — that 85 percent of women with a 20 to 24 percent lifetime risk still did not pursue high risk surveillance," he said said in a college news release.

"Ultimately, the question we are really trying to answer is why women at high risk for breast cancer are declining MRI screening. That issue is the next phase of this study," Sohn added.

Research presented at meetings is usually considered preliminary until published in a peer-reviewed medical journal.

SOURCE: American College of Surgeons

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