IN THIS ISSUE
Sickle Cell Disease: Is a Widely Available Cure in Sight?
Beyond Pain Relief: Total Knee Replacement Surgery
Cold, Flu, or Allergy? Spot the Signs

COVER STORY
Actor Jim Parsons of “The Big Bang Theory” shares experience with NIH’s Clinical Center, also known as America’s

HOUSE OF HOPE
Behind the Lens: Patients Come First at the NIH Clinical Center

THE DISCOVERY CHANNEL DOCUMENTARY series, “First in Human,” which first aired in August 2017, represents a shining moment for NIH, the Clinical Center, and the biomedical research community.

It provides a personal and realistic look at the challenges of carrying out cutting-edge, experimental medicine—all of which couldn’t take place without the brave patients whom we have the honor of serving.

Between September 2015 and June 2016, Discovery film crews followed patients, their families, doctors and researchers, and other care staff at the Clinical Center’s hospital and labs. It was a massive undertaking, with Discovery capturing more than 1,000 hours of footage.

While the cameras have left the building, the dedication and hard work continues every day at the Clinical Center, also known as the “House of Hope,” to advance scientific discovery and provide the very best in care to our patients.

Our patients are always our first and most important priority.

Whether these men, women, and children who come through our doors arrive as a last resort or as a healthy volunteer, they are helping contribute to the future health of the U.S. and the world.

MAJOR GENERAL JAMES K. GILMAN, M.D.
CEO, NIH Clinical Center
Welcome to NIH MedlinePlus magazine’s new look!
We’ve added new sections and a new design to give you even more of the NIH MedlinePlus magazine content you like to read. Stay tuned for more updates.

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FEATURES
08 The Next Frontier in Antibiotic Resistance Battling drug-resistant diseases at NIH
14 America’s House of Hope Actor Jim Parsons shares documentary experience with NIH’s Clinical Center
20 The Future of Total Knee Replacement Surgery NIH researchers look beyond pain relief
24 Fighting Sickle Cell Disease Is a widely available cure in sight?

DEPARTMENTS
04 To Your Health News, notes, & tips from NIH
28 From the Lab Latest research updates from NIH
30 On the Web Find it all in one place!
31 Contact Us NIH is here to help

NIH Clinical Center staff featured in “First in Human” with Jim Parsons (center).

PHOTO TOP AND COVER COURTESY OF DISCOVERY
Achoo! Cold, Flu, or Something Else?

Allergies are a little different. Airborne allergies are caused by your immune system's reaction to an allergen, like pollen from trees, dust mites in the home, or pet dander. Allergy symptoms caused by pollens can last up to six weeks during pollen seasons in the spring, summer, or fall. Allergy symptoms caused by dust mites or pet dander can be present throughout the year. Allergies can also cause nose itching and watery, itchy eyes, which you don’t get with colds or the flu.

Complications from the cold or flu can also lead to pneumonia. Pneumonia is a serious infection in one or both of the lungs. It’s caused by bacteria or a virus and requires quick treatment.

To treat colds or the flu, get plenty of rest and drink lots of fluids. If you have the flu, pain relievers can help reduce fever or aches. Allergies can be treated with nasal steroid sprays, antihistamines, or allergy shots.

If you think you have pneumonia, your symptoms are severe, or you are not improving, contact your health care provider.

**Common Cold**
- Symptoms last up to two weeks.
- Include stuffy and runny nose, sore throat, and cough.
- Treated with rest, fluids, and over-the-counter medicines to ease symptoms.

**Seasonal Flu**
- Symptoms usually last one to two weeks.
- Include high fever (100–102 °F, or higher in kids), headache, aches and pains, weakness, exhaustion, cough, and chest discomfort.
- Treated with rest, fluids, OTC medicines, and prescription antiviral drugs.
**Gum Disease**

**BY THE NUMBERS** Gum (or periodontal) disease is one of the leading threats to dental health. It’s typically caused by poor brushing and flossing habits that allow plaque—a sticky film of bacteria—to build up on teeth and harden.

In its early stage, the gums can become red, swollen, and may bleed easily. That’s called gingivitis. In its more serious form, called periodontitis, the gums pull away from the teeth and form spaces (called “pockets”) that become infected. This can cause loss of the bone that holds teeth in place, and eventually tooth loss.

To help prevent or control gum disease, it is important to brush daily and floss regularly. Also, make sure to see your dentist for routine checkups.

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**Almost half of all adults** aged 30 years and older have some form of gum disease.

**Gum disease increases with age.**

**70.1% of adults 65 years and older** have periodontal disease.

**Periodontal disease is more common in men than women.**

**56.4% vs 38.4%**

**Smoking can put you at risk for gum problems.**

In fact, **64.2% of current smokers** have gum disease.

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**Airborne Allergy**

- Lasts as long as allergens are present. Examples of allergens include pollen, dust mites, and pet dander. Pollens are present during certain seasons and for short duration, while indoor allergens may be present all year.
- Symptoms include stuffy and runny nose, nose itching, and itchy and watery eyes.
- Treated with nasal steroids, antihistamines, decongestants, and in some patients, allergy shots.

**Pneumonia**

- Symptoms include high fever, chills, cough that doesn’t improve or gets worse, shortness of breath, and chest pain when you breathe or cough.
- Signs include feeling suddenly worse after a cold or the flu.
- Treated with antibiotics or antiviral medicines depending on the type of pneumonia you have.

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**SOURCES:** MedlinePlus; NIH News in Health; National Institute of Allergy and Infectious Diseases
NIH Teams with Public Libraries for ‘All of Us’ Research Program

RESEARCH NIH is coming to a library near you.

The National Library of Medicine (NLM) has teamed up with NIH’s All of Us Research Program to gather health data from across the U.S.

All of Us aims to securely gather diverse health data from about 1 million people living in the U.S. Their ultimate goal is to advance precision medicine, which is a bigger goal of both NIH and the U.S. Department of Health and Human Services. That means including people from communities that have been traditionally underrepresented in research.

To help reach that goal and make sure all people have a chance to participate, All of Us is partnering with NLM’s National Network of Libraries. Thanks to the partnership, people who may not have access to the internet or want to learn more about the program can visit their local library.

Researchers will use data from the All of Us program to learn more about how individual differences can affect health and disease. Factors include lifestyle, environment, and biological makeup.

“All of the things that make the All of Us effort unique are not only our size, but also the diversity of participants, health conditions, and data types we aim to include, from surveys and electronic health records to biosamples, physical measurements, and wearable data,” said All of Us Director Eric Dishman.

The three-year partnership between All of Us and NLM aims to accelerate research and improve health.

Some other goals include:

- Giving public library staff tools to improve health literacy
- Highlighting public libraries as a technology resource for the All of Us program, particularly in underserved communities
- Establishing an online platform for education and training about All of Us and precision medicine

“The collaboration presents a perfect opportunity to help the public understand how health research impacts all of us,” said Patricia Flatley Brennan, R.N., Ph.D., director of NLM.

WHAT IS PRECISION MEDICINE?
Disease treatment and prevention that takes into account individual differences in genes, environment, and lifestyle for each person

SOURCES: All of Us Research Program: joinallofus.org; National Library of Medicine
What’s funny about being sick?
Most of the time, nothing.
But some people are finding a way to share their experiences through comics.
Graphic medicine helps patients and their loved ones, caregivers, and health professionals tell stories about health and medicine through comics.
Pictures and words combine to present health information in a powerful way.

Would you like to learn more?
The National Library of Medicine’s new banner exhibition called “Graphic Medicine: Ill-Conceived and Well Drawn!” shows how comics convey health information and messages with humor and emotion.
Check out information online, visit the National Library of Medicine in Bethesda, Maryland, and find out when a traveling banner exhibition may be at a library near you on the National Library of Medicine’s website.

SOURCE: www.nlm.nih.gov/graphicmedicine
For the past 70 years, antimicrobial drugs, such as antibiotics, have successfully treated patients with infections. But over time, many infectious organisms have adapted to the drugs that kill them, making them less effective. Overusing or misusing these drugs can make resistance develop even faster. Each year in the U.S. at least 2 million people become infected with bacteria that are resistant to antibiotics. At least 23,000 people die annually as a direct result of these infections. Many more people die from complications of antibiotic-resistant infections.

To address this growing problem, the National Institute of Allergy and Infectious Diseases (NIAID) is working to speed the development of faster ways to detect resistance and ultimately to find new treatments that are effective against these drug-resistant bacteria.
Each year in the U.S., at least 2 million people become infected with bacteria that are resistant to antibiotics.

-Centers for Disease Control and Prevention
Drug-Resistant Bacteria: On the Edge of a Crisis

Anthony S. Fauci, M.D., has been the director of the National Institute of Allergy and Infectious Diseases (NIAID) since 1984. He helped pioneer the field of human immunoregulation, or the control of specific immune responses and interactions. He has also advised five presidents and the U.S. Department of Health and Human Services on HIV/AIDS and many other health issues. He spoke to NIH MedlinePlus magazine to discuss NIAID’s drug-resistant bacteria research program.

Why are certain bacteria becoming more resistant to drugs?

There is a multi-part answer to that question. One of the most important reasons is that bacteria generally mutate—all microbes mutate—naturally and spontaneously. However, you can do things that pressure them to mutate even more and develop resistance to drugs.

One of the major factors in certain bacteria becoming resistant to drugs today is the overuse of antibiotics, particularly the inappropriate use of antibiotics. This includes using antibiotics when you do not really have to—either when you have a viral infection that you think is bacterial and treat it with an antibiotic, or you treat someone with the wrong antibiotic that is not particularly suited to the bacteria in question.

In other words, if you are given antibiotics, you will kill all the sensitive bacteria. Most of the ones that will survive will be the resistant ones.

You and other experts in the field have said that we are on the edge of a national, even global crisis of drug-resistant bacteria. Why is that?

The more we see this growing problem of antimicrobial resistance throughout the world, the more we will begin to see bacteria that are relatively untreatable or very, very difficult to treat. And if those bacteria become very widespread, that could lead to a serious crisis.

What might such a situation look like to most people?

A typical, real-life example would be someone gets a surgical procedure like a hip or knee replacement, or goes to the hospital for abdominal surgery. Then they get an infection that happens to come from another hospital patient who has resistant bacteria. What should be a routine procedure could lead to an infection that you struggle to treat, and you end up with a high degree of morbidity or even mortality. The routine surgical case becomes a medical emergency.

What kinds of antimicrobial-resistant bacteria are common in the U.S.?

We still have the problem of methicillin-resistant Staphylococcus aureus (MRSA), which is disturbing. Another one that is also disturbing is called Carbapenem-resistant Enterobacteriaceae, or CRE. That is a growing problem. We see that in hospital patients who are immunosuppressed as a result of, for example, transplants or drugs that suppress their cancer or their inflammatory disease. Another bacteria that causes infections when
antibiotics are overused is Clostridium difficile (C. Difficile), which we see a lot of in nursing homes and hospital settings.

Those three are big ones—MRSA, CRE, and C. Difficile. And, depending on the population in question, globally we are seeing more and more resistance to gonorrhea, a sexually transmitted disease.

"If you are given antibiotics, you will kill all the sensitive bacteria. Most of the ones that will survive will be the resistant ones."

—Anthony S. Fauci, M.D.

How is NIAID approaching research to help solve the challenges associated with antimicrobial resistance?

Our research spans a wide range of activities, starting with understanding the molecular basis of how bacterial resistance evolves.

The second thing we are doing is a molecular analysis of microbes to determine what the targets are for resistance and for new antibiotics. Another is to develop new, unique ways of combating bacteria, such as understanding how microbes survive in different environments and exploiting that to fight them.

We also spend a lot of time working with the pharmaceutical companies on concept development towards the ultimate development of new antibiotics. While new antibiotics will ultimately be made by pharmaceutical companies, NIH and NIAID have a basic, fundamental role in the clinical and applied research and development of these new antibiotics.

The National Institute of Allergy and Infectious Diseases (NIAID) invests in basic research to understand the biology of microbes, their behavior, and how drug resistance develops. Understanding how microbes cause disease (the process called pathogenesis) is also crucial for finding new ways to combat them.

NIAID laboratories are at the forefront of basic, translational, and clinical research on antimicrobial resistance. Focusing on emerging public health threats, such as drug-resistant Staphylococcus aureus, tuberculosis, and malaria, NIAID researchers seek to understand the fundamental causes of resistance.

Clinical research projects related to antibacterial resistance focus on a variety of approaches, including evaluating the safety and effectiveness of new antimicrobial therapeutics, and developing novel prevention strategies.
Leading Antimicrobial Drug-Resistant Diseases

The National Institute of Allergy and Infectious Diseases (NIAID) is supporting research on several organisms that have developed resistance to antimicrobial drug treatment. The institute manages a research portfolio of grants aimed at the problem of antimicrobial resistance and hospital-acquired infections.

Here is a list of some of the leading antimicrobial drug-resistant organisms NIAID is researching.

Mycobacterium tuberculosis
The bacterium that causes tuberculosis (TB)
TB is an often severe airborne disease caused by a bacterial infection. TB typically affects the lungs, but it also may affect many other organs of the body. It is usually treated with a regimen of several drugs taken for six months to two years, depending on the type of infection. In most cases, TB is treatable. However, some bacteria are becoming resistant to the two most potent TB drugs. This is known as multi-drug-resistant TB (MDR TB).

C. difficile (Clostridium difficile)
C. difficile is a pathogen infecting the colon of patients following antibiotic treatment. The communities of microbes that normally live in the gut usually prevent C. difficile colonization and suppress C. difficile-associated disease. Antibiotic treatment can alter the microbiota that allows C. difficile, a bacterium that is naturally resistant to many common antibiotics, to grow and cause inflammation in the colon. C. difficile is a major health care-associated infection in the U.S., causing mild to severe diarrhea. Around half a million people are infected each year, resulting in approximately 15,000 deaths.

VRE (Vancomycin-resistant Enterococci)
Enterococci are bacteria that are commonly found colonizing the human digestive tract and female genital tract. VRE infections tend to occur in people who are in hospitals or other health care facilities. They also often occur in people who are susceptible to infection due to other medical problems or the presence of certain catheters or other devices. Health care providers commonly use the antibiotic vancomycin to treat Enterococcal infections, but VRE are resistant to the drug.

MRSA (Methicillin-resistant Staphylococcus aureus)
During the past four decades, methicillin-resistant Staphylococcus aureus, or MRSA, has evolved from a controllable nuisance into a serious public health concern. MRSA is one of the most common hospital-acquired infections. Increasingly, however, strains are circulating in the community and can cause severe infections.

Neisseria gonorrhoeae
The bacterium that causes gonorrhea
Gonorrhea is a sexually transmitted infection and the second most commonly reported infection in the U.S. It can cause severe reproductive complications if left untreated, and it disproportionately affects sexual, racial, and ethnic minorities. Gonorrhea control relies on prompt identification and treatment of infected persons and their sex partners. Because some drugs are becoming less effective in treating gonorrhea, the CDC recently updated its treatment guidelines to slow the emergence of drug resistance. Gonorrhea is a global problem. Action in the U.S. alone is unlikely to prevent resistance from developing, but rapid detection and effective treatment of patients and their partners might slow the spread of resistance.

CRE (Carbapenem-resistant Enterobacteriaceae)
CRE is a family of highly resistant bacteria that includes Klebsiella species and Escherichia coli (E. coli). CRE primarily affect patients in hospitals and those who have compromised immune systems. The bacteria can enter the body through medical devices like ventilators or catheters. Some CRE infections are resistant to most available antibiotics and can be life-threatening.
Battling C. Difficile: Don’t Delay

Marty Katz’s quick action got his infection under control

When Marty Katz returned from a vacation to Puerto Vallarta, Mexico, in April 2017, he didn’t feel well. He had diarrhea and felt fatigued. Initially, he assumed it was food poisoning or something else related to his trip. But it turned out to be something much more serious.

“At one point, I could hardly get out of the bed to go to the bathroom. It was extremely debilitating.”

- Marty Katz

Although Marty didn’t know much about C. difficile before contracting it last year, he is no stranger to microorganisms. “My background is in microbiology. I worked for the Food and Drug Administration as a biologist for 35 years and before that, I worked as a research biologist for the U.S. Navy,” he said.

Marty’s message to others who think they may have C. difficile is to see your provider as soon as possible. “If you start developing constant diarrhea that’s black, get yourself to a provider immediately,” Marty said. “You need to get it diagnosed as quickly as you can.”

With C. difficile out of the way, Marty and Judi can focus on wedding planning and preparing for newlywed life in two cities: Philadelphia in the warmer months and Hilton Head in the cooler ones.

Find Out More

- MedlinePlus
  Antibiotic Resistance: medlineplus.gov/antibioticresistance.html

- National Institute of Allergy and Infectious Diseases: Antibiotic Resistance: www.niaid.nih.gov/research/antimicrobial-resistance

- Centers for Disease Control and Prevention: www.cdc.gov/drugresistance/index.html

Your lower colon and rectum using a flexible tube, Marty’s gastroenterologist confirmed that he had contracted Clostridium difficile (C. difficile).

Marty was prescribed two antibiotics for an upper respiratory infection before his trip to Mexico. This combination, Marty’s gastroenterologist determined, had facilitated the C. difficile. He immediately took Marty off the two antibiotics he was on. He then prescribed another targeted antibiotic to cure the C. difficile and a probiotic to prevent further complications.

“It took about seven to 10 days to get it under control,” Marty said. “My gastroenterologist warned me that it can come back, so I’ve been staying on probiotics ever since and so far, I’ve been fine.”

While many C. difficile patients go to the hospital to improve, Marty was able to go home where his fiancee, Judi, took care of him 24/7. Judi flew down from Philadelphia, where she was living at the time, to stay with Marty in his Hilton Head, South Carolina, home.

“We came back from Mexico on a Tuesday, and by that Saturday, Judi came down to South Carolina because of how sick I was,” Marty said. In addition to looking after Marty, Judi kept everything as clean as possible to prevent transmission since C. difficile is highly contagious.

When Marty didn’t know much about C. difficile before contracting it last year, he is no stranger to microorganisms. “My background is in microbiology. I worked for the Food and Drug Administration as a biologist for 35 years and before that, I worked as a research biologist for

PHOTO: COURTESY OF MARTY KATZ

Marty Katz battled a C-diff infection in April 2017.
TV Star
Jim Parsons
Shines Light on NIH Research

‘First in Human,’ a three-part documentary series from the Discovery Channel, follows four patients at NIH’s Clinical Center, also known as the House of Hope.

Emmy and Golden Globe award-winning actor Jim Parsons has millions of fans worldwide. He stars in the hit TV show “The Big Bang Theory” and memorable movies like “Hidden Figures.” Parsons recently produced and narrated “First in Human,” a Discovery Channel documentary series that followed four patients at the NIH Clinical Center. He discussed his experiences visiting NIH and learning directly from NIH researchers and their patients with NIH MedlinePlus magazine.

Did you know about the NIH Clinical Center and its work before starting on “First in Human”?

I had no clue, no. I didn’t even know what “NIH” stood for, to be honest.

What did you take away from working with the NIH doctors and nurses and the patients they served?

Oh, my goodness. Everyone who works at NIH on these trials has an ability to combine devotion to their work and passion and care of individual patients that borders on the profound. I suppose it’s what everyone would hope to find in any health professional but I can’t imagine one always does—this super-intelligent workhorse who is also so human and compassionate.

What was interesting to me about the patients was how individual and unique each seemed, while at the same time, they all had a certain aura of hope about them that was strikingly similar.

They were different from each other in so many ways—be it age, ethnicity, disease—and yet you sense about each of them this bright quality, a “looking toward the future.”

“I felt so happy to know I was a small part of helping truly life-changing work like this go on.”

- Jim Parsons

What would you say to someone who might consider participating in a clinical trial?

Obviously it’s a very personal and individual decision for each person and their family. That being said, I talked to one patient who described to me how her personal doctor had actively discouraged her participation in the trials the NIH offered.
Her doctor’s reasoning was that she would be setting herself up as, essentially, a guinea pig for these researchers to experiment on. I understand the worry expressed because, as the name “trials” implies, it is, indeed, an experiment and, therefore, a process with guaranteed risk and no guaranteed reward.

In answer to this, though, I would reiterate what I said before about the doctors and nurses who are actually on the floors of the research facility at the NIH. They were universally caring, empathetic, and always erring on the side of not going through with a treatment or course of action if they felt it was too risky.

I would hope that more doctors could learn more about what they are really like. It’s probably difficult for many to manage, but visiting the NIH Clinical Center itself would be eye-opening in this regard. It was for me.

**What message do you have for Americans about the investment we make in medical research through NIH?**

As taxpayers whose money helps fund the work at NIH and the trials they conduct, we should be extremely proud. That’s how I felt when I visited NIH and when I watched the documentary we had made. I felt so happy to know I was a small part of helping truly life-changing work like this go on, if I also felt a little foolish for not knowing it was going on earlier in my life.

**VIEWING ‘FIRST IN HUMAN’**

“First in Human” premiered on the Discovery Channel last August. You can watch clips for free on Discovery’s website as well as full episodes with a cable subscription.
From Bench to Bedside: Researchers of NIH’s Clinical Center

Documentary highlights key sickle cell and cancer trials

NIH’s Clinical Center is divided into two parts. One side is a hospital for patients. The other side includes offices and labs where researchers like John Tisdale, M.D., and Steven Rosenberg, M.D., Ph.D. work.

Dr. Tisdale and Dr. Rosenberg are senior investigators at NIH. Their title is fitting as they are not simply doctors or researchers. Their teams bridge the gap between the two.

Using a mix of science, patient care, and medical detective work, they answer some of medicine’s most difficult questions.

“The Clinical Center is a unique place. Investigators focus on diseases from the bench all the way to the bedside. We can take risks on harder-to-accomplish therapies and bring them to the clinic all under one roof,” Dr. Tisdale said. “That’s really an extraordinary opportunity for those of us who are trying to make a difference in a disease.”

Strides in sickle cell research

There are more than 1,600 clinical research studies taking place at the Clinical Center today.

One of the four studies featured in “First in Human” was led by Dr. Tisdale, who has worked at NIH since 1994.

He helps lead the Clinical Center’s sickle cell disease research. NIH has a history of making important advances in sickle cell research.

NIH investigators, including National Institute of Diabetes and Digestive and Kidney Diseases Director Dr. Griffin P. Rodgers, M.D., had earlier developed the first effective, FDA-approved therapy for sickle cell anemia.

“First in Human” follows Dr. Tisdale and his team in their groundbreaking work using stem cell transplants to stop the rare blood disease in its tracks.

The transplants help patients with sickle cell disease produce normal red blood cells and stop producing sickle cells by altering bone marrow.

One of their patients with sickle cell disease, Deidra Williams, came to the Clinical Center with no other options. Her excruciating pain, which most sickle cell patients have to deal with constantly, was making normal things hard to do.

But thanks to Dr. Tisdale’s team and the first in human trial, she had a successful stem cell transplant from her sister and now lives free of the disease.

For more than a year, Discovery’s documentary crew filmed Dr. Tisdale’s team as they met with Deidra and worked in the lab. Although it took a little adjustment, the film crew and research team quickly found a routine.

“It felt awkward at first but Discovery was so professional and the producers and film crew almost became members of our team,” he added. “We really got to know each other and that made it so much easier.”

“We can take risks on harder-to-accomplish therapies and bring them to the clinic all under one roof.”

- John Tisdale, M.D.

Cancer breakthroughs

Dr. Steven Rosenberg is a pioneer in the field of cancer research. For decades he has investigated the immune system’s role in cancer treatment. This immunotherapy work has been critical to advancing care.
Some of his team’s latest immunotherapy research was featured in “First in Human.” It focuses on using lymphocytes, a white blood cell in the immune system, to attack cancer that has spread.

In the documentary, researchers led by Dr. Rosenberg and Stephanie Goff, M.D. explore removing lymphocytes found in cancerous tumors, altering them to help them fight off cancer, and putting them back into patients.

The research has already shown promise for skin and breast cancer.

Since joining NIH in 1974, Dr. Rosenberg has worked on numerous first in human trials that have led to major treatment breakthroughs.

One message he has to patients considering a first in human trial is to keep in mind that there are years—and often decades—of research and testing that come before it.

“Studies with patients are based extensively on studies in the laboratory. Before anything ever gets to humans, there’s a lot of research that takes place,” said Dr. Rosenberg. “Most people don’t realize how much preparation goes into that first patient.”

**Working for patients**

Though first in human trials involve risk, they also hold great promise. They are often a patient’s last treatment option.

That is something NIH staff like Dr. Rosenberg and Dr. Tisdale think about all the time.

“NIH is often referred to as the National Institutes of Hope. These patients have exhausted all other treatments that might be effective and are quite advanced in their disease. They come to NIH with hope that there’s something new that might be of value to them,” Dr. Rosenberg said.

“And, as this documentary has demonstrated, very often these first in human patients can be treated with something quite new that can have dramatic results and dramatic improvements,” he added.

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**Clinical Trials and You**

When you volunteer to take part in clinical research, you help doctors and researchers learn more about disease and improve health care for people in the future.

- Clinical trials are important research studies that explore whether a drug, surgery, or medical device is safe and effective for humans.
- They can also look at other aspects of care, such as improving the quality of life for people with chronic illnesses.
- The studies follow strict scientific standards that protect patients and help produce reliable study results.
- NIH Clinical Center Studies and ClinicalTrials.gov are good resources to find studies.

To learn more about participating and hear from past participants, visit the NIH Research Clinical Trials and You website.

**Source:** clinicalcenter.nih.gov/recruit/index.html
The NIH Clinical Center is the largest clinical research hospital in the country. Located in Bethesda, Maryland, the center supports NIH doctors and researchers testing groundbreaking clinical therapies on patients, often for the first time.

Now you can step behind hospital doors and learn about these courageous patients, their caregivers, and the dedicated NIH staff treating them.

“First in Human,” a documentary series from the Discovery Channel, follows four patients at the Clinical Center also known as the “House of Hope.” Two of the patients have cancer and two have rare, inherited diseases.

The three-part documentary, released in 2017, is named for the “first in human” trials, or trials in which new, innovative medical therapies are tested on patients for the first time.

Many NIH Clinical Center patients have rare diseases or diseases that don’t respond to other available treatments. For these patients, the Clinical Center is often their last hope.

A history of healing

For more than 60 years, the NIH Clinical Center has been at the forefront of developing treatments for deadly and damaging diseases.

The center has seen many medical firsts. These include chemotherapy first used to treat cancerous tumors, gene therapy undergoing its first human tests, and the first antiviral drug for HIV/AIDS meeting with early success.

There are many more Clinical Center advances on the horizon. But clinical trial participation is key to helping doctors find answers.

Helping future generations

“With the attention now being drawn to the value of clinical research by ‘First in Human’ and other outreach efforts, I hope we can begin to build momentum to encourage more Americans to take part in clinical trials,” said NIH Director Francis Collins, M.D., Ph.D.

“Not only do clinical trials offer sick people who have no other options a chance to receive experimental treatments that may extend or save their lives, such work is essential for advancing scientific knowledge in ways that will benefit the health of future generations,” Dr. Collins added.
Deidra Flowers-Williams realized in elementary school that she couldn’t do the same things as other kids her age. She was diagnosed with sickle cell disease before she was 6 months old.

“I was always sick and always needed to go to the hospital,” she said. “It was a frustrating existence at times because my mind and spirit didn’t match my body.”

Sickle cell disease is caused by a genetic problem that makes your blood produce abnormal blood cells, called sickle cells. It can lead to anemia, which can leave you feeling tired and weak.

The disease also causes severe pain and organ damage that make normal things, like working or even moving around, hard to do.

Deidra, now 39, struggled with the side effects of sickle cell disease all her life. Since the disease didn’t have a cure, all she could do was minimize the side effects and try to feel comfortable.

She regularly went to the hospital and took medication to cope with the nonstop pain. But that changed in 2016.

“I was declining in health rapidly and there was nothing my doctors could do but keep me comfortable,” Deidra said. My quality of life was poor. I was extremely depressed.”

Her last hope was a first in human trial with the NIH Clinical Center.

“When I found out about the trial, I wasn’t sure what the outcome was going to be. I didn’t want to get my hopes up but I couldn’t let the opportunity pass me by. If volunteering for this trial made me better, then great, that’s what I wanted. I am a mother of two and I want to be here for my children.”

The trial, led by John Tisdale, M.D., and his team, happened to be part of the Discovery documentary “First in Human.” She knew being part of the trial and documentary could not help just her, but also other patients suffering from the disease.

“I wanted to do something to bring a spotlight to sickle cell disease,” said Deidra. “Even in 2017 with all the technology we have, there are many individuals and health care providers who don’t understand the true damage it causes.”

Working with Dr. Tisdale and his team, Deidra received a stem cell transplant from her sister.

She is now free of sickle cell disease and free of the pain that prevented her from doing everyday activities like walking or playing with her kids.

Deidra says NIH and the trial were the hope that she had been waiting for her entire life.

“As a chronically ill person for 39 years, I have had my experience with doctors and hospital admissions. I can truly say that I felt the researchers and staff at NIH cared about people,” Deidra said. “I didn’t feel like a science project. I felt like a human being and I was around other human beings who wanted to help save my life.”

- Deidra Flowers-Williams

For more information on sickle cell disease research at NIH, read the other feature in this issue on page 24.
With total knee replacement surgery, researchers are looking beyond simply reducing pain. The hope is to return patients to the same high level of activity they had before surgery—like participating in sports or even running marathons.

"People would like to go back and be long distance runners or high performing athletes,” said orthopedic surgeon Joshua J. Jacobs, M.D. NIH’s National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) supports Dr. Jacobs' research.

The surgery involves replacing weight-bearing surfaces of the knee joint. Patients who commonly have this surgery have arthritis in their knees. Arthritis affects an estimated 54.4 million adults in the U.S. It causes joint inflammation, pain, swelling, and stiffness.

"Where the technology is now, the total knee replacement operations are effective for reducing pain and improving function. But we have a ways to go before we can assure our patients that this surgery can allow the extreme levels of activity that one can do on a healthy joint,” said Dr. Jacobs, who works at Chicago’s Rush University Medical Center.

Improving knee implants

An important step forward would be to make knee implants last longer. Current replacement joint surfaces can wear away after 15 to 20 years. Providers often delay surgery because of an implant’s limited lifespan.

Despite the name, total knee replacement doesn't replace all of the knee joint. Doctors put in an artificial joint (implant or prosthesis), composed of different human-made parts.

Replacement joints are made of a mix of metal, ceramic, or plastic. They are designed so that certain materials, like metal, always border with others, like plastic. This creates smoother movement and less implant wear-and-tear.

Even though implant materials have improved since knee replacement surgery first started more than 50 years ago, Dr. Jacobs and his colleagues strive for more improvements.

They are exploring new types of material combinations. Dr. Jacobs is researching how implant surfaces or materials release different kinds of debris from a patient’s natural bone or tissue. Materials with less impact on the body could make for better implants.

“That interaction actually is quite important. In many cases, it determines the outcomes of the joint reconstructions and will dictate how long the implant will function well in a particular patient,” said Dr. Jacobs.

Common Causes of Knee Pain

**Osteoarthritis** usually happens gradually over time due to overuse or injury to the joint, excess weight, and other factors. The cartilage, or cushion between joints, breaks down causing pain, stiffness, and swelling.

**Rheumatoid arthritis** is an autoimmune form of arthritis that causes pain, swelling, stiffness, and loss of function in your joints. It can affect other parts of the body, as well.
“In the research community we want to figure out a way to make better and better implants that are both longer lasting and allow the functions that our patients seek,” Dr. Jacobs said.

Treatment doesn’t end at surgery

Implant success also relies on patient work after surgery. Recovery and continued physical activity are key to lasting knee replacement success.

In a clinical trial, supported by NIAMS, Elena Losina, Ph.D., and her team looked at how physical activity can improve total knee replacement outcomes.

“Many researchers noticed that people who had complained about a lot of pain prior to surgery are very grateful that the pain is gone,” Dr. Losina, of Brigham and Women’s Hospital in Boston, explained. “But what other researchers noticed was that while the pain is gone, people were not getting more physically active.”

Her clinical study used one-on-one coaching and reward money to get 200 patients to become more active after surgery. To measure progress, patients wore activity trackers and reported key information in real time.

The study helped patients understand how physical activity contributes to long-term recovery. The money offered immediate encouragement to get active.

“We found that joint intervention, which includes both coaching using motivational interviewing and financial incentives, substantially improves the number of steps that total knee replacement recipients did daily and the total minutes of physical activity,” Dr. Losina said.

For patients who are advised by a physician that they may need total knee replacement surgery, Dr. Jacobs says the first step is talking to an orthopedic surgeon or specialist.

“You need to be evaluated by a health care professional who can zero in on the diagnosis of where you are with your pain,” he said.

SOURCES: NIH’s National Institute of Arthritis and Musculoskeletal and Skin Diseases; American Academy of Orthopaedic Surgery; Centers for Disease Control and Prevention

Joint Replacement Surgery: What you Need to Know

- Joint replacement surgery removes damaged or diseased parts of a joint. It replaces them with new, human-made parts.

- Joints may need to be replaced when they are damaged from:
  - Arthritis (inflammation of joints that causes pain and stiffness)
  - Years of use
  - Disease

- The goals of joint replacement surgery are to relieve pain, help the joint work better, and improve walking and other movements.

- Your provider will likely first suggest other treatments to reduce pain and help you move better, such as:
  - An exercise program
  - Walking aids like a cane or walker
  - Physical therapy
  - Medications

- Complications after joint replacement surgery include infection, blood clots, and joint failure.

- Wearing away of the joint surface may become a problem after 15 to 20 years.

SOURCE: National Institute of Arthritis and Musculoskeletal and Skin Diseases
Melanie Modlin, 62, had total knee replacement last June. Her number one question after surgery was, “When am I going to feel normal again?” The answer came slowly.

For Melanie, feeling normal involved more than just becoming pain-free. She focused on rebuilding her range of motion and her strength. “With knee surgery and replacement, it’s important to get moving right away or else scar tissue can settle around that new joint,” says Melanie. “If that happens, you can lose range of motion very quickly.”

Exercise was key to getting better. Melanie did all the exercises her doctor and physical therapists recommended. A positive mental attitude helped, too, she says.

During her recovery, Melanie focused on “little victories.” The first little victory was standing from a chair without using her arms. Another was walking with a cane instead of crutches. Later victories included walking without a cane and finally going up and down the stairs.

After four months, she felt much better. After six months, she felt fantastic. “But I know it’s different for everyone,” Melanie says.

The first time Melanie dislocated her kneecap, she was in eighth grade. As an adult, she experienced that same feeling a few more times. When she was 49 years old, she learned that she had osteoarthritis in her knee. Osteoarthritis causes pain, swelling, and reduced motion. She could manage the pain on her own until one day in 2015.

On her way to work, carrying a heavy briefcase and purse, Melanie felt her right knee give way on the stairs near the parking lot. She couldn’t get up. Luckily, she could call for help at NIH’s National Library of Medicine, where she works.

Melanie had torn the cartilage in her knee and would need total knee replacement surgery, her doctor said. Knowing that joint replacements last about 15 to 20 years, Melanie did everything she could to manage pain and keep active until her surgery. She did physical therapy, used crutches when necessary, and got regular cortisone shots.

But in the spring of 2017, she couldn’t wait any longer. Her knee joint was bone-on-bone, meaning the cartilage had worn away, and she was in terrible pain. She needed surgery.

More than eight months after surgery, Melanie says she feels fortunate. In addition to celebrating “little victories” along the way to recovery, she also found what she calls “great gifts.”

“I always thought of myself as a patient person, but now I’m even more patient,” she said. “And I’m not as afraid to ask for help. People have been kind and generous. A friend stayed with me after my surgery and coworkers helped by bringing me lunch and visiting me.”

One step and one victory at a time—plus the gifts of patience and gratitude—continue to help Melanie live a better life after surgery.
In the U.S., the life expectancy of a person with sickle cell disease is now about 40 to 60 years. In 1973, the average lifespan was only 14 years.
Is a Widely Available Cure for Sickle Cell Disease on the Horizon?

When the pain from sickle cell disease became too much, Kirti Dasu often went to the nearest hospital emergency room. Those days are gone. Today the 29-year-old Syracuse University student is pain-free thanks to a revolutionary but experimental gene transfer procedure at NIH.

His abnormally shaped or “sickled” blood cells were replaced with normal ones derived from his own bone marrow.

Sickle cell disease is a group of inherited blood disorders. The disease creates abnormally shaped red blood cells that slow blood flow and prevent oxygen from reaching parts of the body. It can shorten lifespan, cause organ damage, and lead to debilitating pain.

In the U.S., the life expectancy of a person with the disease is now about 40 to 60 years. In 1973, the average lifespan was only 14 years.

Dasu has been part of an investigational NIH-sponsored clinical trial that holds great promise for curing the disease. Because of this and other sickle cell disease research like it, NIH Director Francis Collins, M.D., Ph.D. said in 2016 that a lasting cure could be only five years away.

“Genetic blood diseases are prime candidates for potentially therapeutic gene-editing approaches because a patient’s cells can be easily accessed, edited, and then replaced,” Dr. Collins wrote in a 2016 blog post. “Sickle cell disease is an obvious first choice, in part because the condition affects millions of people around the world—100,000 in the U.S. alone.”

“We can live free of this disease. We don’t need to live in pain anymore.”

- Kirti Dasu

For Dasu, the NIH-sponsored clinical trial transformed his life. He was diagnosed with sickle cell disease at four months of age in his native India. He even saw his younger brother die of the disease.

Dasu was able to access better medical care in the U.S. after moving here in 1999, which eventually led him to the clinical trial.

“The word miracle is very apt in my case,” he says. “My mom found a pamphlet about this trial sitting on the desk in my nurse’s office.”

On May 30, 2017, Dasu underwent an experimental gene therapy procedure at the NIH Clinical Center on the NIH campus in Bethesda, Maryland. His recovery has been amazing. He no longer suffers from intense pain and has more energy than ever before.

“I feel like I’ve been granted a new life. There is a significant difference in my energy levels now,” Dasu says. “We can live free of this disease. We don’t need to live in pain anymore.”

More research studies and clinical trials are still needed before everyone suffering from sickle cell disease can have relief like Dasu. He still requires careful monitoring and followup in the future to verify that the procedure is working.

He encourages others to take part in clinical trials to help speed better treatments for sickle cell disease and other conditions.

Dasu’s sickle cell disease experience has changed his life in more ways than one.

After graduating from college, he plans to pursue a medical career to help others like NIH researchers and doctors helped him.

SOURCES: National Heart, Lung, and Blood Institute; NIH Clinical Center
Sickle Cell Disease: What You Should Know

What is it?
Sickle cell disease is a group of red blood cell disorders passed by genes from parents to their children. People with the disease have abnormal hemoglobin, a protein in red blood cells that carries oxygen in the body. Sickle hemoglobin is not like normal hemoglobin. Sickle-shaped cells are not flexible and can stick to vessel walls. This causes a blockage that slows or stops the flow of blood. When this happens, oxygen can’t reach nearby tissues.

What are the symptoms?
The lack of tissue oxygen can cause attacks of sudden, severe pain, called “pain crises.” These attacks can occur without warning and a person often needs hospitalization for treatment. Most children with sickle cell disease are pain-free between pain crises, but adolescents and adults may suffer from ongoing pain.

The red cell sickling and poor oxygen delivery can also cause organ damage over time and anemia, a blood condition which makes you feel tired or weak.

Who does it affect?
Approximately 100,000 Americans have sickle cell disease. In the U.S. most of these people are of African ancestry or self-identify as black.

- About one in 13 African-American babies is born with sickle cell trait.
- About one in every 365 black children is born with sickle cell disease.

There are also many people with this disease who come from Hispanic, southern European, Middle Eastern, or Asian Indian backgrounds.

How is it diagnosed?
A blood test can show if you have the trait or anemia. Most states test newborn babies as part of their newborn screening programs.

SOURCES: National Heart, Lung, and Blood Institute; MedlinePlus

Learn how you can participate in NHLBI clinical trials related to sickle cell disease on NHLBI’s website: www.nhlbi.nih.gov/health-topics/sickle-cell-disease

Treating Sickle Cell Disease
Sickle cell disease is a lifelong illness. The only cure is a well-matched stem cell transplantation, but this procedure is not widely available to everyone. However, there are other effective treatments that can reduce symptoms and prolong life. Early diagnosis and regular medical care to prevent complications also contribute to improved well-being. Potential treatments include:

- **Stem Cell Transplantation:** Stem cells are a type of unspecialized cell that can change into a more specialized cell, such as a healthy red blood cell, under certain conditions. In stem cell transplantation, doctors replace a patient’s bone marrow with stem cells from a healthy, fully-matched donor (usually a sibling). It is a growing option for people with sickle cell disease.

- **Gene Therapy and Gene Editing:** The National Heart, Lung, and Blood Institute is leading a nationwide study to test the effects of an experimental gene therapy to treat sickle cell disease that involves removing a patient’s bone marrow and then adding copies of a correctly spelled gene for normal hemoglobin to generate normal red blood cells. Only a handful of patients have undergone the procedure in the U.S. They include three at the NIH Clinical Center in Bethesda, Maryland. Researchers are also exploring the feasibility of gene editing, an approach that aims to edit the blood-generating stem cells outside the body to correct the sickle cell mutation and then reinsert the corrected stem cells into the bone marrow.

- **Stimulating Fetal Hemoglobin Production:** NHLBI researchers are studying the genetic factors behind sickle cell disease. This includes fetal hemoglobin, which protects an infant from sickle cell disease for the first six months after birth.
When do sickle cell disease symptoms typically start?
Symptoms tend to start when a baby is 6 months to 1 year old.
The reason symptoms don’t show up at birth is that people with sickle cell disease are protected from it if they’re producing the kind of blood found in the mother’s womb. That blood is called fetal hemoglobin. It protects against sickle cell disease but gets turned off in the first six months after birth.

Can we determine who will get sickle cell disease?
In the U.S., every state does a newborn screening. That can identify not only those babies that have sickle cell disease, but babies that carry sickle cell trait (one gene has sickle cell and the other does not).
Someone with sickle cell trait who marries someone with that trait has a one-in-four chance of having a child with the disease.

What has the outlook been like for treatment up until recently?
Until recently, we’ve only had one way to correct the disease. This method transplants bone marrow from someone who is already a matched donor. The better the match, the better the outcome.
We’ve also had only one drug that would lessen some of the symptoms but not cure the disease.

How does the new gene transfer technology work?
If you make a bone marrow transplant from another person, your body will attack that. But if the transplant is from your own modified bone marrow, it won’t attack it. This is gene transfer, which requires gene editing.
Sickle cell disease is caused by a single gene mutation. So, if we can reverse that mutation in the DNA using gene editing, we could change that one mutant gene back to normal and stop the disease.
There are now several gene editing tools in development.
Gene transferring is still experimental, but we’re hopeful that it will be available very soon. We’re cautiously optimistic.

“Gene transferring is still experimental, but we’re hopeful that it will be available very soon.”
-W. Keith Hoots, M.D.

Find Out More
► National Heart, Lung, and Blood Institute (NHLBI):
  Sickle Cell Disease
  www.nhlbi.nih.gov/health-topics/sickle-cell-disease
► MedlinePlus: Sickle Cell Anemia:
  medlineplus.gov/sicklecellanemia
► National Human Genome Research Institute (NHGRI):
  genome.gov/10001219/learning-about-sickle-cell-disease/
'Biggest Loser' Study: Exercise Key to Keeping Weight Off

LOSING WEIGHT IS NOT EASY but keeping it off can prove even harder. NIH researchers are studying ways to keep lost weight off in research that blends entertainment and science.

The researchers followed contestants from NBC’s televised weight loss competition, “The Biggest Loser.” The TV show encourages contestants to lose weight through a strict diet and exercise program.

After losing an average of 132 pounds during the show, many of the 14 former contestants the study followed gained back weight they had lost after six years. But the amount of weight they kept off varied. Half maintained an average weight loss of 25 percent of their starting weight. The other half returned to a weight very close to their starting weight.

The main difference between those who maintained significant weight loss and those who did not was their level of physical activity. Both groups had a lower calorie intake than before the show, but the half that maintained significant weight loss was substantially more active.

“Our findings are consistent with other studies in which participants who kept their weight off reported significantly more physical activity than those who regained their weight,” said lead researcher Kevin D. Hall, Ph.D.

Excess weight raises your risk of developing serious health problems. Healthy eating and regular physical activity help you lose weight.

To find out more about weight control, visit MedlinePlus.

SOURCE: NIH Research Matters
Testing Malaria-Resistant Mosquitoes

MALARIA IS A SERIOUS DISEASE that affects 200 million people every year and is found in tropical areas of the world. Malaria kills thousands of people (more than 400,000 in 2015), especially in developing countries. It spreads when an infected mosquito bites you.

Malaria drugs, insect-killing products called insecticides, and bed nets have reduced the number of malaria cases in some countries.

But new approaches are needed due to developing resistance to malaria drugs and resistance to insecticides in mosquitoes.

One approach involves changing the genes of some mosquitoes to make them resistant to malaria. Under experimental conditions in a lab, researchers mated malaria-resistant mosquitoes with regular mosquitoes. The researchers found that the malaria-resistant mosquitoes were able to mate and spread the malaria-resistant gene in the lab population.

The study started with equal numbers of wild and genetically modified mosquitoes. By the end of the study, 90 percent of the mosquitoes, on average, carried the resistance trait.

This research provides evidence that malaria-resistant mosquitoes may be able to compete with regular (wild) mosquitoes. This means they may be able to spread the malaria-resistance gene to natural populations. While the study had promising results, more research is needed to see whether the approach will prevent the spread of the disease.

SOURCES: NIH Research Matters; World Health Organization

Can Potassium Help Your Heart?

POTASSIUM IS A MINERAL in your body that helps your nerves and muscles work.

A recent study provides early evidence that increased potassium may help prevent hardening of the arteries, which contributes to serious heart-related conditions.

Hardening of the arteries causes plaques of fat, cholesterol, calcium, and other substances that reduce blood flow. This leads to serious conditions like high blood pressure, heart disease, and stroke.

The new research provides a deeper understanding of how dietary potassium prevents hardening of the arteries. Beans, spinach, bananas, yogurt, and potatoes are good sources of potassium.

For most people, natural foods rich in potassium are safe and part of a healthy diet. But extra potassium may not be right for everyone. Certain people need to watch their potassium intake, such as those with kidney issues or taking certain medicines.

This study is one step towards better understanding potassium’s beneficial effects in the body.

SOURCES: NIH Research Matters; NIH MedlinePlus
MedlinePlus Unveils New Cholesterol Pages

Speaking of cholesterol, MedlinePlus added three new topic pages to help you keep it in check. The new pages include “Cholesterol Levels: What You Need to Know,” “LDL: The ‘Bad’ Cholesterol,” and “HDL: The ‘Good’ Cholesterol.”

Learn about differences between good and bad cholesterol, what your cholesterol numbers mean (with a helpful chart), and what factors affect cholesterol.

All of the new topic pages are also in Spanish on MedlinePlus.

Animation Corner: Making Resistant Bacteria Irresistible

Is it possible to make learning about bacteria fun? We’re trying.

MedlinePlus released a new animation video on resistant bacteria to go along with the article on page 8.

The engaging animation helps answer questions like: Who are these bad bugs? What can you do to prevent infections? How is NIH research combating this global problem?

To find the video, search “antimicrobial resistance + medlineplus” in YouTube. It’s located in the NLM YouTube Channel under the MedlinePlus playlist.

NIH’s DASH Diet Tops Charts

U.S. News & World Report named the DASH eating plan the “best diet overall” for the eighth year in a row.

The diet, which was selected from a group of 40, was designed by NIH-sponsored researchers for treating high blood pressure. It can also help lower high cholesterol.

DASH stands for Dietary Approaches to Stop Hypertension. It emphasizes eating fruits, veggies, whole grains, lean protein, and fat-free or low-fat dairy products.

In addition to tying for first place in “best overall diet,” DASH ranked number one in the “healthy eating” and “heart disease prevention” categories.

The diet was created by researchers funded by the National Heart, Lung, and Blood Institute.
The National Institutes of Health (NIH)—the nation’s medical research agency—includes 27 Institutes and Centers and is a part of the U.S. Department of Health and Human Services. It is the primary federal agency for conducting and supporting basic, clinical, and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.

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