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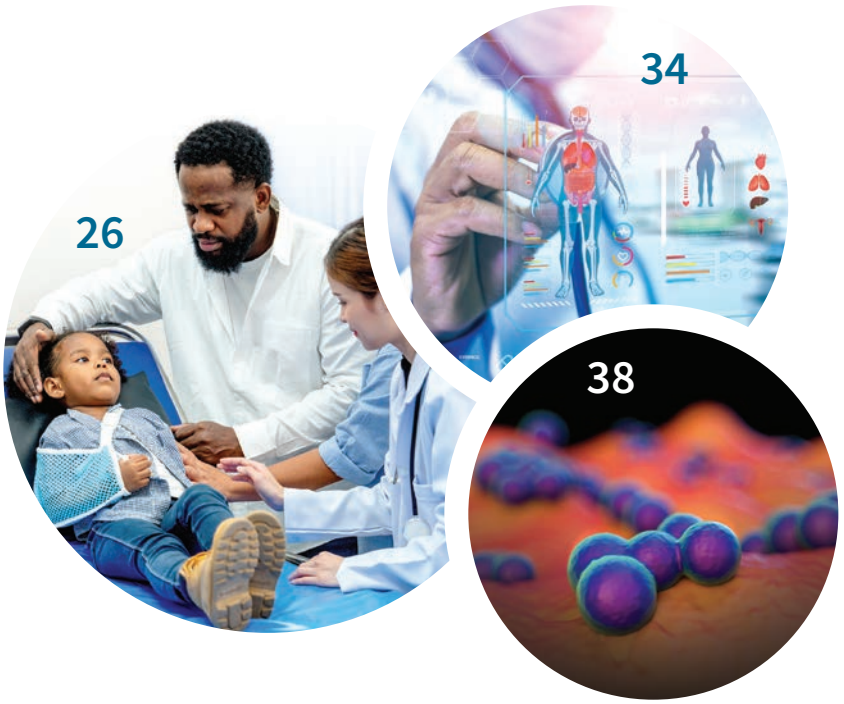

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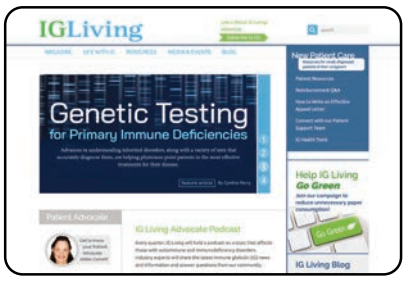

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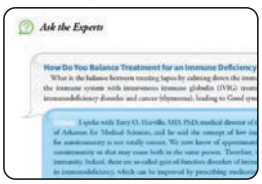

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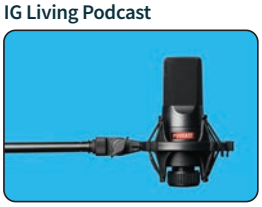

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Preparedness Builds Healthcare Resilience

PREPAREDNESS ISN'T about fear — it's about resilience. From pandemics that strain health systems to emergency rooms to serve pediatric populations and the very real possibility of adverse drug effects, today's healthcare landscape demands that providers think a step ahead. Rather than reacting in moments of crisis, it's essential to implement proactive planning and essential safeguards.

The COVID-19 pandemic exposed major gaps in international and national preparedness, equity and coordination. In response, as we explain in our article "WHO and CDC: Preparing for the Next Pandemic" (p.22), the World Health Organization adopted a new Pandemic Agreement in May 2025 aimed at strengthening prevention, preparedness and response through global cooperation, equity and shared responsibility, including new mechanisms for pathogen sharing and coordinated, sustainable financing. At the same time, the U.S. Centers for Disease Control and Prevention is updating its pandemic guidance by modernizing data and analytics, expanding laboratory capacity, improving domestic and global surveillance, strengthening vaccine infrastructure through a Vaccines for Adults program, and leveraging tools such as wastewater surveillance. Together, these efforts are intended to correct weaknesses revealed during COVID-19 and better position the world to respond more effectively and equitably to the next pandemic.

There is growing concern over hospital emergency department (ED) pediatric readiness, with EDs falling short of optimal preparedness. As pediatric-specific hospitals and inpatient services decline, many community and rural EDs — despite seeing fewer pediatric patients — remain critical points of care and must be equipped to stabilize and treat seriously ill or injured children. As we highlight in our article "Maximizing Pediatric Readiness in Emergency Departments" (p.22), children require specialized training, right-sized equipment and ongoing competency development, supported by national pediatric readiness standards and tools such as the National Pediatric Readiness Project. Evidence demonstrates that higher pediatric readiness is strongly associated with improved survival, especially for traumatic injuries, and that investments in staffing, training, equipment, and the appointment of a pediatric care coordinator are highly cost-effective.

Boxed warnings are FDA's strongest safety alerts designed to highlight rare but serious risks associated with certain medications. All IG products carry a boxed warning for thrombosis, and intravenous IG (IVIG) also carries a warning for renal dysfunction and acute renal failure. In our article "Unboxing Boxed Warnings and Risk Assessments for IG Products" (p.26), we outline why these risks occur, how they have been identified through post-marketing surveillance and the steps clinicians can take to mitigate them. While these adverse events are uncommon, adherence to established standards, ongoing monitoring and individualized therapy planning by coordinated healthcare teams are essential to ensure IG therapy remains both safe and effective.

As always, we hope you enjoy the additional articles in this issue of *BioSupply Trends Quarterly*, and find them both relevant and helpful to your practice.

Helping Healthcare Care,

Patrick M. Schmidt
Publisher

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Our mission is to serve as the industry's leading resource for timely, newsworthy and critical information impacting the biopharmaceuticals marketplace, while providing readers with useful tips, trends, perspectives and leading indicators on the topics pertinent to their business.

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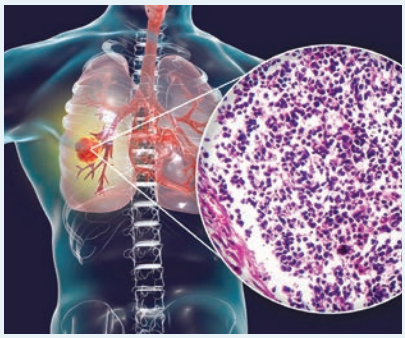
$2.7 Million Grant Awarded for NSCLC Research

Trethera Corp. has been awarded a new $2.7 million Small Business Innovation Research (SBIR) grant from the National Institutes of Health (NIH). The award evaluates the combination of Trethera's lead drug candidate, TRE-515, with KRAS inhibitor therapies to treat non-small cell lung cancer (NSCLC). Lung cancer is responsible for more deaths annually than breast, prostate and colorectal cancer combined — with NSCLC causing 80 percent of lung cancer deaths. The grant will fund testing TRE-515 with standard of care KRAS inhibitors (KRASi) in NSCLC mouse models to inform future clinical trials.



TRE-515 inhibits deoxycytidine kinase (dCK), the key enzyme for the nucleoside salvage pathway that becomes activated and essential for abnormal cell growth in autoimmune diseases and cancer. Consistent with observations that dCK activity is relatively minimal in the regulated cell division of healthy cells, inhibiting dCK with TRE-515 has demonstrated favorable safety in addition to clinical benefit in ongoing first-in-human trials.

"We are excited to receive this grant award, which underscores the strong mechanistic rationale for pairing a first-in-class dCK inhibitor with KRAS-targeted therapies," said UCLA Assistant Professor Evan Abt, PhD, and grant co-investigator. "KRAS inhibitor resistance remains a major challenge, and our data suggest that blocking the nucleoside salvage pathway directly disrupts a key metabolic escape route used by lung cancer cells." ❖

Trethera Receives $2.7 Million NIH Grant, Validating the Potential of First-in-Class TRE-515 to Overcome KRAS Inhibitor Resistance in Lung Cancer. Trethora Corp. press release, Dec. 16, 2025. Accessed at firstwordpharma.com/story/6746326.

$1.6 Million Grant Awarded for Hepatitis B Vaccine Research

The Centers for Disease Control and Prevention (CDC) has awarded an unsolicited $1.6 million grant for vaccine research to Danish researchers whose studies have been challenged by mainstream scientists but championed by anti-vaccine activists, including Health and Human Services (HHS) Secretary Robert F. Kennedy Jr.

According to a notice in the Federal Register, CDC is paying the University of Southern Denmark to conduct a single-blind clinical trial of the hepatitis B vaccine in newborns in Guinea-Bissau, a small country in West Africa with exceptionally high rates of maternal and infant mortality, where nearly one in five people are infected with the hepatitis B virus. Although the federal announcement did not include the names of the researchers, the Danish university's Bandim Health Project, which has conducted vaccine research in the developing African country for decades, has acknowledged being awarded the CDC grant. The Bandim project leaders have claimed to find "non-specific effects" from vaccines — some good and some bad — that they say should change how vaccine safety studies are conducted.

The new study was awarded without any competition from any other scientists, giving it "the appearance of blatant cronyism," said Angela Rasmussen, PhD, a virologist and professor at the University of Saskatchewan.

In June, Kennedy used a single study by the Bandim group to justify canceling more than $1 billion in funding for childhood vaccinations in developing countries. The observational study found an increased risk of death in children who received a combined vaccine for diphtheria, tetanus and pertussis that hasn't been used in the United States in three decades.

Scientists say people shouldn't put too much faith in that study, which is an outlier and conflicts with hundreds of studies showing vaccines are safe and save lives. Instead, they say, researchers and policymakers normally consider the totality of scientific evidence on vaccines, rather than a single study, which may be flawed. ❖

Szabo, L. CDC Awards $1.6 Million for Hepatitis B Vaccine Study by Controversial Danish Researchers. CIDRAP, Dec. 18, 2025. Accessed at www.cidrap.umn.edu/childhood-vaccines/cdc-awards-16-million-hepatitis-b-vaccine-study-controversial-danish-researchers.

Researchers Awarded $900,000 Grant to Develop Drug to Fight Cancer

Wei Gao, PhD, assistant professor of pharmacology at the University of Houston College of Pharmacy, has received a $900,000 grant from the Cancer Prevention and Research Institute of Texas to develop a stronger and more targeted anti-tumor therapy for pancreatic and lung cancer.

Pancreatic and lung cancers are among the deadliest cancers, partly because they create an environment that shields tumors from the immune system. One key player in this immune suppression is the regulatory B cell (Breg) — a type of immune cell that helps tumors grow by blocking the body's natural defenses. Some newer treatments, called STING agonists, are meant to activate the immune system but have limited success because they unintentionally increase Bregs, don't reach tumors effectively and can cause serious side effects.

"To address these challenges, our team developed Nano-273, a dual-function nanodrug packaged in a tiny albumin-based particle. Nano-273 both activates STING and blocks PI3Kγ — a pathway that drives Breg expansion, while albumin nanoparticles help deliver the drug directly to immune cells, reducing unwanted side effects," said Dr. Gao. "This approach reduces harmful Bregs while boosting immune cells that attack cancer, leading to stronger and more targeted anti-tumor responses."

In early studies, Nano-273 showed strong tumor-shrinking effects in pancreatic and lung cancer models, especially when combined with chemotherapy or immunotherapy. It also extended survival and showed low toxicity.

To move these promising results closer to clinical use, Dr. Gao's team will carry out several critical preclinical steps:

- Improve the production of Nano-273, ensuring it is consistently made with high quality for future clinical trials.
- Test how well Nano-273 works when combined with standard treatments like chemotherapy and immune checkpoint inhibitors in pancreatic and lung cancer models.
- Conduct safety studies. ❖

Fickman, L. UH Pharmacy Researcher Receives $900,000 CPRIT Grant to Develop Nanodrug That Boosts Immune System to Fight Cancer. University of Houston news release, Jan. 6, 2026. Accessed at www.uh.edu/news-events/stories/2025/january/01062026-wei-gao-cprit-nanodrug-immune-system.php.

HHS Invests $100 Million for Great American Recovery

The U.S. Health and Human Services (HHS) has developed a comprehensive plan to strengthen prevention, expand treatment and carry out the the Great American Recovery. The centerpiece of the plan is a $100 million investment to solve long-standing homelessness issues, fight opioid addiction and improve public safety by expanding treatment that emphasizes recovery and self-sufficiency.

The Safety Through Recovery, Engagement, and Evidence-based Treatment and Supports — or STREETS — initiative will fund targeted outreach, psychiatric care, medical stabilization and crisis intervention, while connecting Americans experiencing homelessness and addiction to stable housing with a clear focus on long-term recovery and independence. ❖

WTAS: Secretary Kennedy Announces $100 Million Investment in Great American Recovery. U.S. Department of Health and Human Services pres release, Feb. 3, 2026. Accessed at www.hhs.gov/press-room/wtas-secretary-kennedy-announces-100-million-investment-great-american-recovery.html.

Sustainability: Balancing Spend with Revenue to Support Outcomes

By Bonnie Kirschenbaum, MS, FASHP, FCSHP

AFFORDABILITY AND cost-containment pressures are top of mind in all healthcare systems, coupled with uncertainty as to which rapidly proposed/announced changes in pricing models, among others, will be implemented. Areas such as pharmacy with a high spend for the products they supply to patients must be proactive, taking every opportunity to increase revenue from payable services, as well as guaranteeing complete and clean claims submissions.

Sustainability inherently means being on high alert for every opportunity while maintaining balanced spend/revenue. The focus on health cost growth and affordability can't be ignored. Following are many of the changes impacting 2026, as well as what overlooked opportunities there are in remote patient monitoring.

Evolving ASP Methodology and Abrupt 2026 Resource Changes

Average sales price (ASP) is a market-based price that reflects the weighted average of all manufacturer sales prices. It includes all rebates and discounts privately negotiated between manufacturers and purchasers (with the exception of Medicaid and certain federal discounts and rebates). It isn't the price providers pay and doesn't take into consideration any contract terms or distributor markups.

The implementation date for ASP methodology applied to products on or after Jan. 1, 2005. The Centers for Medicare and Medicaid (CMS) required manufacturers to report their ASP data, for calendar quarters beginning on or after Jan. 1, 2004, for drugs or biological products payable under Medicare Part B and described in the Act with a Medicaid drug rebate agreement.

Subsequently, the rules were amended to add a new section that requires manufacturers without a Medicaid drug rebate agreement to report ASP information to CMS, for calendar quarters that began Jan. 1, 2022, for drugs or biological products payable under Medicare Part B and described in specific sections, including items, services, supplies and products payable under Part B as a drug or biological.

Manufacturers continue reporting this information to CMS for calendar quarters using the ASP Data Collection System, and CMS publishes quarterly ASP pricing files. These pricing files have been published in three formats, each with a different use: Medicare Part B Payment Limit Files, NDC-HCPCS Crosswalk Files and Not Otherwise Classified (NOC) Medicare Part B Payment Limit File. Additionally CMS publishes extensive listings of all products (not limited to drugs). Addendums A and B also reflect the status indicator (SI) assigned to each HCPCS code, as well as price. However, in 2026, there will be changes:[1]

ASP pricing tables. CMS hasn't released a January 2026 NOC Medicare Part B Payment Limit File. It does state that it evaluates drugs quarterly to determine if they should be published in the payment limit files. It also clarifies that it "may not publish an ASP-based payment limit or crosswalk for all drugs that are reported by manufacturers." The absence or presence of a HCPCS, NDC code and/or payment limit in the ASP pricing files does not indicate whether Medicare covers a particular product. Even if a product does not appear on a quarter's ASP pricing files, the local Medicare Administrative Contractor (MAC) may process the Part B claim after determining the payment limit, provided the claim is reasonable and necessary and meets all necessary requirements for payment.

ASP reporting changes: bona fide service fee certification and ASP reasonable assumptions. As of Jan. 1, 2026, manufacturers of drugs payable under Medicare Part B are required, as part of the submission of ASP data, to submit reasonable assumptions, including fair market value documentation for current, new and renewed contracts, and certification from the recipient of a bona fide service fee that the fee is not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. Refer to the 2026 Physician Fee Schedule Final Rule (90 FR 49532 through 49542) for details on both the rationale and the possible implications to ASP itself.

Addendum B. Although the calendar year 2026 outpatient prospective payment system (OPPS) rule set refers to Addendum B for details, CMS has opted not to publish it on its website. The last one available is dated October 2025.[2]

Advancing Chronic Care with the Effective, Scalable Solutions (ACCESS) Model

The ACCESS payment model created by the CMS Innovation Center (CMMI) reimburses providers for using telehealth, wearables and other digital health technologies for traditional Medicare benefi-

ciaries with chronic conditions who have improved outcomes. Providers receive recurring payments for managing patients' conditions with full payment tied to achieving measurable health outcomes. Focus is on clinical improvement of a condition based on each patient's starting point.

Prior Authorization: Two Approaches

CMMI has introduced a six-year model focused on prior authorization titled Wasteful and Inappropriate Service Reduction (WISeR). It's unique in that it is the only CMMI model in which voluntary participants will be those who are considered technology innovators. This is defined as technology vendors with demonstrated experience using AI and automation tools to manage the prior authorization processes and assess coverage determinations on behalf of payers for providers and suppliers for Traditional Medicare (excludes Medicare Advantage). Additionally, participation is limited to those operating in Arizona, New Jersey, Ohio, Oklahoma, Texas and Washington states.

The model requires healthcare providers either to submit a prior authorization request for the selected services or to opt for a retrospective review. The tech vendors then will apply their technology to assess coverage determinations and will receive a percentage of the savings associated with what has been averted as wasteful, inappropriate care. Initial selected services are those considered to be susceptible to fraud, waste and abuse and include skin and tissue substitutes, electrical nerve stimulator implants and knee arthroscopy.

The model design focuses on the timeliness of response and the clarity of the explanation of the determination, both of which are considered to be lacking in current prior authorization processes, as well as clinical quality outcomes from the use of alternative services.[3]

CMS Advancing Interoperability and Improving Prior Authorization Processes Final Rule

This rule (CMS-0057-F), which impacts both healthcare providers and payers, focuses on improving the electronic exchange of healthcare data, as well as streamlining prior authorization processes. To encourage providers to adopt electronic prior authorization processes, it adds a new measure for Merit-based Incentive Payment System (MIPS)-eligible clinicians under the promoting interoperability performance category of MIPS, as well as for eligible hospitals and critical access hospitals, under the Medicare Promoting Interoperability Program. Impacted payers must implement certain operational provisions, generally beginning Jan. 1, 2026. To improve the prior authorization processes, payers are required to send prior authorization decisions within 72 hours for expedited (i.e., urgent) requests and seven calendar days for standard (i.e., non-urgent) requests. They also must provide a specific reason for denied prior authorization decisions, regardless of the method used to send the prior authorization request using portal, fax, email, mail or phone. However, this provision does not apply to prior authorization decisions for drugs at this point in time.[4]

Remote Patient Monitoring

Medicare will reimburse for remote patient monitoring for eligible patients with chronic or acute conditions who require monitoring and can collect their own health data using an Internet-connected medical device that meets FDA's definition and digitally uploads data to the provider's site. This applies to the treatment and management of blood pressure, weight and glucose levels.

Three components are required by Medicare for reimbursement:

1) Education about how to use the device and transmit the health data to ensure patients use the device appropriately to collect accurate data.

2) An Internet-connected device, including the collection and transmission of at least 16 readings every 30 days, to get the appropriate health information. Examples of these devices include connected blood pressure cuffs, weight scales and pulse oximeters.

3) A review of the health data and its use to manage the patient's condition.[5,6] ❖

References

1. Centers for Medicare and Medicaid Services. Bona Fide Service Fee Certification and Average Sales Price Reasonable Assumptions Frequently Asked Questions. Accessed at www.cms.gov/files/document/frequently-asked-questions-faqs-bfsf-certification-asp-reasonable-assumptions.pdf.
2. Centers for Medicare and Medicaid Services. Quarterly Addenda Updates. Accessed at www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/quarterly-addenda-updates.
3. Centers for Medicare and Medicaid Services. WISeR (Wasteful and Inappropriate Service Reduction) Model. Accessed at www.cms.gov/priorities/innovation/innovation-models/wiser.
4. Centers for Medicare and Medicaid Services. CMS Finalizes Rule to Expand Access to Health Information and Improve the Prior Authorization Process. Accessed at www.cms.gov/newsroom/press-releases/cms-finalizes-rule-expand-access-health-information-and-improve-prior-authorization-process.
5. Centers for Medicare and Medicaid Services. Remote Patient Monitoring. Accessed at www.cms.gov/medicare/coverage/telehealth/remote-patient-monitoring.
6. Centers for Medicare and Medicaid Services. Telehealth & Remote Monitoring. Accesed at www.cms.gov/files/document/mln901705-telehealth-remote-monitoring.pdf.

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Ensuring Healthcare Worker Safety During Emerging Outbreaks

By Lee Warren

WHEN AN EMERGING infectious outbreak occurs, it places large demands on healthcare systems, as well as exposing healthcare workers. Early failures to recognize, isolate and control outbreaks can amplify transmission within healthcare settings.

Historical data underscores the occupational risks healthcare workers face during emerging outbreaks. During influenza outbreaks, studies indicate up to 22 percent of healthcare workers, particularly those who are unvaccinated, may become infected in a given season.[2] Measles can linger in the air for up to two hours after a patient exits a space,[2] leaving both clinical and nonclinical staff at risk. Additionally, novel influenza strains, SARS-CoV-2 variants, Candida auris and multidrug-resistant tuberculosis reinforce the need for sustained preparedness.

Effective protection requires coordinated action across clinical, infection prevention, occupational health and leadership teams. The following strategies outline key measures to support healthcare worker safety.

Prioritize Early Recognition and Isolation

Early recognition is one critical way to protect healthcare workers during emerging outbreaks. Many high-risk pathogens initially present with nonspecific symptoms (such as fever, cough, malaise, GI upset), requiring early recognition of infectious risk during patient evaluation. Risk factors include recent travel, workplace exposure or contact with a known outbreak.

Early recognition of nonspecific symptoms combined with red flags, such as recent travel or some sort of exposure, can help healthcare providers take quick action, such as early isolation, source control, cohorting strategies and standard precautions, while diagnostic testing is underway. Immediate identification allows infection control measures to be implemented before transmission occurs within clinical settings.

Standard Precautions

Once a potential infectious risk is identified and isolation begins, the next step is a consistent application of baseline infection control practices that are designed to protect both healthcare workers and patients. According to the Centers for Disease Control and Prevention (CDC), standard precautions are the basic practices that apply to all patient care, regardless of the patient's suspected or confirmed infectious state, and apply to all settings where care is delivered.[3] These precautions are designed to reduce the risk of transmission of bloodborne and other pathogens from both recognized and unrecognized sources of infection.

Practically speaking, this would include many clinical practices. Hand hygiene before and after patient contact is a great first step. Use of personal protective equipment (PPE), such as gloves, gowns, masks or eye protection, is always important. Additionally, respiratory hygiene and cough etiquette, safe injection practices, proper cleaning and disinfection of equipment and the environment and safe handling of blood, body fluids, secretions, excretions (except sweat), non-intact skin and mucous membranes will all help ensure healthcare worker safety.

Transmission-Based Precautions

The next level of precautions is transmission-based and is used in addition to standard precautions when patients are known or suspected to have infections that spread in specific ways. CDC groups these precautions into three categories: contact, droplet and airborne, based on how an infection is transmitted.[4] During emerging outbreaks, quickly identifying which type of precaution is needed and putting it in place early helps reduce the risk of healthcare worker exposure.

Following these precautions means using the appropriate PPE, placing patients in the correct care setting and following recommended infection control practices consistently. CDC advises applying transmission-based precautions for patients with suspected infectious risk and updating those precautions as diagnostic information evolves.[3] Clear communication, staff training and support from infection prevention teams help ensure these measures are applied correctly and consistently.

Ongoing Fit Testing and PPE Training

Proper use of PPE depends on the correct fit and technique. Fit testing

ensures N95 respirators (not surgical masks) and other tight-fitting respirators provide the level of protection they are designed to deliver, particularly during airborne or aerosol-generating exposures. Changes in facial structure, weight or the type of respirator used can affect the fit over time, making periodic retesting essential. Without proper fit, even consistent respirator use may fail to protect healthcare workers during high-risk encounters.

This makes ongoing PPE training equally important, especially during emerging outbreaks when staff may need to use unfamiliar equipment or escalate precautions rapidly. Regular education on donning and doffing, coupled with hands-on practice, reduces self-contamination and errors during high-stress clinical situations.

Current Vaccinations and Prophylaxis

Vaccination remains effective for protecting healthcare workers during emerging outbreaks. Up-to-date immunization against vaccine-preventable diseases such as influenza and measles reduces the risk of occupational infection and limits secondary transmission within healthcare settings. Maintaining high vaccination coverage among healthcare workers also helps preserve staffing capacity during outbreaks. Absenteeism due to illness or exposure can significantly strain clinical operations.

In addition to routine immunizations, outbreak-specific prophylaxis may be indicated based on exposure risk or evolving public health guidance. This can include post-exposure prophylaxis, targeted vaccination campaigns or antiviral use for certain pathogens. Clear protocols for rapid access to prophylaxis, timely communication of eligibility criteria and coordination with occupational health services ensure healthcare workers receive appropriate protection as recommendations change.

Advocate for Environmental Controls

Environmental controls play a critical role in reducing healthcare worker exposure during emerging outbreaks, particularly for airborne and droplet-transmitted pathogens. Adequate ventilation, use of airborne infection isolation rooms and proper airflow management help limit the concentration and spread of infectious particles in clinical spaces. When environmental controls are insufficient or inconsistently applied, reliance on PPE alone may not fully mitigate risk, especially during prolonged or repeated exposures.

Healthcare staff can support safer environments by identifying gaps in ventilation, isolation capacity or environmental cleaning, and communicating concerns through established institutional channels. Collaboration with infection prevention, facilities management and occupational health teams ensures engineering controls are prioritized alongside clinical measures. Proactive advocacy for these safeguards strengthens outbreak preparedness and provides an additional layer of protection for both staff and patients.

Address Fatigue and Workforce Sustainability

Staff fatigue and burnout significantly increase the risk of infection control lapses during emerging outbreaks. Extended shifts, staffing shortages and sustained high-acuity care can impair judgment, reduce adherence to precautions and increase the likelihood of errors during tasks such as PPE donning and doffing. Protecting healthcare workers requires recognizing fatigue as a safety issue, not merely an individual endurance challenge.

Sustainable workforce strategies are essential to maintaining safe care during prolonged outbreak response. Adequate staffing, protected rest periods and access to mental health support help preserve vigilance and performance over time. Clear communication and leadership support reduce burnout and improve compliance with infection prevention practices, ultimately protecting both healthcare workers and the patients they serve.

Safeguarding Those on the Front Lines

During emerging outbreaks, protecting staff requires more than reactive measures; it depends on early recognition, consistent application of infection prevention principles and sustained clinical support. Ensuring healthcare worker safety is not only an ethical obligation but a cornerstone of effective outbreak response. By prioritizing prevention, preparedness and sustainability, healthcare organizations can better safeguard those on the front lines while delivering high-quality care throughout emerging infectious threats. ❖

References

1. JĘdrzejek, MJ, and Mastalerz-Migas, A. Seasonal Influenza Vaccination of Healthcare Workers: A Narrative Review. *International Journal of Occupational Medicine and Environmental Health*, 2022 Mar 1;35(2):127–139. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC10464734.
2. Occupational Safety and Health Administrattion. Hazard Recognition. Accessed at www.osha.gov/measles/hazards.
3. Centers for Disease Control and Prevention. CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings, April 12, 2024. Accessed at www.cdc.gov/infection-control/hcp/core-practices/index.html.
4. Centers for Disease Control and Prevention. Transmission-Based Precautions, April 3, 2024. Accessed www.cdc.gov/infection-control/hcp/basics/transmission-based-precautions.html.

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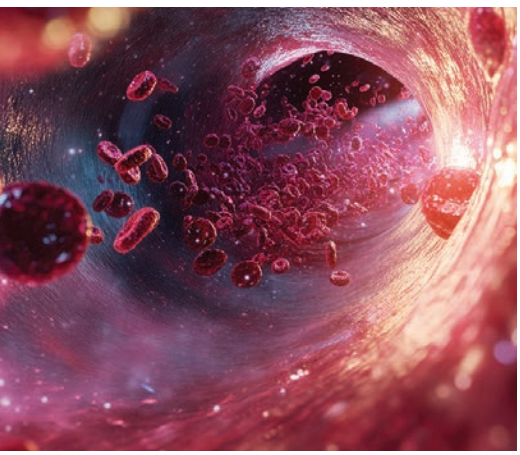
Medicines

FDA Grants Breakthrough Designation for Wayrilz to Treat Autoimmune Hemolytic Anemia



The U.S. Food and Drug Administration (FDA) has granted designation breakthrough therapy to Wayrilz (rilzabrutinib), a novel oral, reversible Bruton's tyrosine kinase (BTK) inhibitor, for the treatment of patients with warm autoimmune hemolytic anemia (wAIHA), a rare autoimmune disorder marked by the destruction of red blood cells.

The designation is based on clinical data from the ongoing LUMINA 2 Phase IIb study (NCT05002777) assessing the efficacy and safety of rilzabrutinib for patients with wAIHA. In addition, the new LUMINA 3 Phase III study (NCT07086976) is assessing rilzabrutinib compared with placebo in patients with wAIHA. There is currently no approved treatment that specifically targets the underlying cause of this rare autoimmune condition, which can lead to anemia, fatigue and serious organ damage.

"These recognitions highlight the critical unmet need that persists for people living with wAIHA," said Karin Knobe, global head of development, rare diseases, at Sanofi. "Furthermore, receiving such designations reinforces our commitment to advancing innovative medicines for rare diseases that currently have limited or no approved treatment options." ❖

Sanofi's Rilzabrutinib Designated Breakthrough Therapy in the US and Orphan Drug in Japan for the Treatment of Warm Autoimmune Hemolytic Anemia. Sanofi press release, Feb. 9, 2026. Accessed at finance.yahoo.com/news/press-release-sanofi-rilzabrutinib-designated-060000640.html.

Research

Vaccine Against SARS Virus Family Enters Human Clinical Trials

A vaccine candidate called GBP511 that builds upon a self-assembling nanoparticle technology, developed by researchers at the UW Medicine and its Institute for Protein Design, has begun human clinical testing in Australia. The vaccine is intended to broadly protect against COVID-19 and related coronaviruses, including some that haven't yet jumped from animals to people.

The international Phase I/II trial, which began enrollment in January 2026, will evaluate safety and immune responses in approximately 368 healthy adults in Perth, Western Australia. The study will include comparisons with Comirnaty, an mRNA COVID vaccine currently in clinical use, with results expected by 2028.

The vaccine's core is a computer-designed protein particle — a precise molecular assembly that does not exist in nature. To turn it into a vaccine, scientists at UW Medicine attached four immune-system cues from different coronaviruses: two from SARS-CoV-2, one from SARS-CoV-1 and one from a bat coronavirus, BtKY72.

"GBP511 is the first vaccine to reach human testing that is intended to protect against multiple strains of the virus that causes COVID-19, as well as related coronaviruses, with the potential to spark dangerous outbreaks," said Neil King, PhD, associate professor of biochemistry at UW Medicine and co-inventor of the nanoparticle platform underlying the vaccine. The clinical trial is an important step toward vaccines that guard against a family of viruses, not just individual types or strains.

In preclinical studies, GBP511 protected animals from related viruses they weren't directly immunized against. ❖

First Vaccine Against SARS Virus Family Enters Human Trials. UW Medicine newsroom, Feb. 3, 2026. Accessed at newsroom.uw.edu/blog/first-vaccine-against-sars-virus-family-enters-human-trials.

Research

Study Shows Nasal Spray Protects Against Any Flu Strain

According to preliminary human trials, an antibody nasal spray shows promise for protecting against flu, and it may be useful for combating future flu pandemics because it seems to neutralize any kind of influenza virus, including those that are transferred from non-human animals.

Initially developed by Johnson & Johnson, the antibody (called CR9114) can neutralize any flu strain by recognizing and binding to a part of the virus that always stays the same, regardless of how other parts of it are changing. However, when it was initially injected into animals' bloodstreams, it failed to provide robust protection against flu because only a small proportion reached the nose, the main point of entry for influenza viruses. But, in 2022, when Leyden Labs licensed CR9114 and developed a formulation that could be sprayed up the nose, the company has shown spraying CR9114 up the noses of mice and macaques stops them from getting sick when they are exposed to various strains of influenza A and B, including one collected from a bad flu season in 1933.

Preliminary tests were also conducted in 143 people aged 18 to 55 and found that administering the spray twice a day maintained steady levels of the antibody inside participants' noses and didn't cause any major side effects. Samples of their nasal mucus collected afterward also neutralized a range of influenza strains, including a bird flu strain that crossed into people in China in 2013.

According to the researchers, the next step will be to directly expose people who have used the spray to a range of influenza viruses to confirm it actually stops them from getting sick. ❖

Klein, A. Nasal Spray Could Prevent Infections from Any Flu Strain. New Scientist, Feb. 4, 2026. Accessed at www.newscientist.com/article/2514199-nasal-spray-could-prevent-infections-from-any-flu-strain.

Research

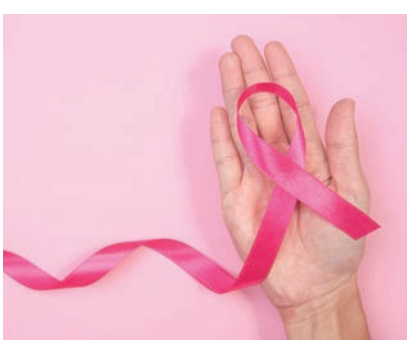
Breast Cancer Vaccine Study Shows Positive Results

A clinical trial funded by the U.S. Department of Defense that evaluated an alpha-lactalbumin (aLA) vaccine demonstrated an immune response in 74 percent of patients who presently have or are at high risk for triple-negative breast cancer (TNBC). The trial evaluated 35 patients across three cohorts:

Phase Ia, which evaluated patients who finished standard-of-care treatment for early-phase TNBC in the past three years and had no remaining tumors but remained at high risk of recurrence;

Phase Ib, which evaluated patients who did not have cancer but carried genetic mutations for breast cancer risk and opted for a preventive bilateral mastectomy (study of this cohort is ongoing to evaluate toxicity in the breast tissue); and

Phase Ic, which evaluated patients with early-stage TNBC who received surgery and chemotherapy followed by immunotherapy pembrolizumab but had residual disease that increased their risk of recurrence.



Patients enrolled in the study received a total of three aLA vaccinations, administered once every two weeks. They had blood draws at days 14, 28 and 56 after the first vaccination to gauge cellular response using enzyme-linked immunosorbent spot (ELISpot) and antibody response using enzyme-linked immunosorbent (ELISA) assays. Researchers also examined the breast tissue of patients in the Phase Ib cohort to check for inflammatory or occult lactational foci changes.

Resulted showed DL1 (10 mcg) is the maximum tolerated dose, which produced an immune response in most patients. Of the patients who received this dose, all experienced grade 1 toxicity, which were injection site reactions. Study co-author G. Thomas Budd, MD, noted that the research team set a low bar for an acceptable level of side effects since adverse events need to be low for vaccines that may be used as a preventive strategy.

Based on the results of the Phase I trial, the new study sponsor, Anixa Biosciences Inc., plans to open the Phase II study late in 2026. ❖

Breast Cancer Vaccine Moves One Step Forward. Cleveland Clinic, Jan. 28, 2026. Accessed at consultqd.clevelandclinic.org/breast-cancer-vaccine-moves-one-step-forward.

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8 Critical Steps

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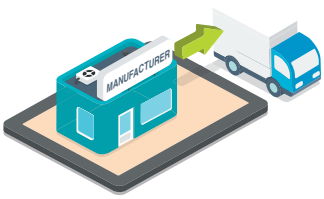

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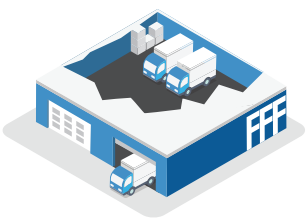

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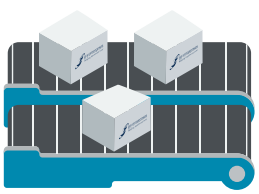

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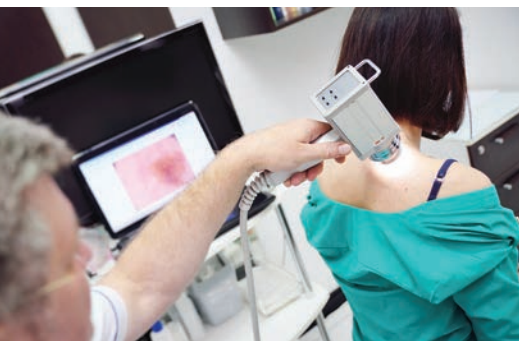
Research

Scientists Develop Inhalabale Nanotherapy to Fight Melanoma Resistant to Checkpoint Inhibitors



Researchers at Columbia Engineering have developed an inhalable nanotherapy called BEAT (Bispecific Exosome Activator of T Cells) that can activate the immune system against cancers resistant to current checkpoint inhibitor therapies. BEAT uses tiny bubbles, called exosomes, to directly deliver therapeutic proteins to the lungs — the most common non-skin metastasis site in melanoma.

"Unlike existing antibody drugs that block a single immune checkpoint, BEAT uses engineered exosomes — the body's own nanosized vesicles — to simultaneously block two pathways that suppress immune attack," said Ke Cheng, PhD, Alan L. Kaganov professor of biomedical engineering at Columbia Engineering. "The tandem exosome engineering method opens a new way to deliver multiple therapeutic proteins locally — a platform that could apply to autoimmune, infectious or fibrotic diseases where multi-target modulation is needed."

Dr. Cheng and his colleagues created an exosome system that co-displays two therapeutic proteins to treat lung metastases. One protein blocks the PD-1/PD-L1 immune checkpoint pathway, a process that has been shown to boost the immune response against melanoma cells and shrink tumors. The other protein blocks the Wnt/β-catenin signaling pathway that drives immune exclusion in tumors, a phenomenon in which immune cells are unable to infiltrate tumor tissues.

Results demonstrated that, compared to a systemically delivered approach with antibodies targeting the same pathways, inhaled BEAT showed better retention in the lungs and dramatically suppressed tumor growth to a larger extent. "By co-displaying them on a single exosome, BEAT can 'reprogram' the tumor microenvironment and recruit cancer-killing T cells directly to the tumor site," said Dr. Cheng. "In mouse models of metastatic melanoma resistant to checkpoint inhibitors, inhaled BEAT completely reversed immune resistance, outperforming dual antibodies and showing minimal side effects."

The novel approach allows for simultaneous targeting of the immunosuppressive tumor microenvironment — a common source of resistance to checkpoint inhibitor therapy — with one protein and immune checkpoints with the other. In addition, administering the proteins locally rather than systemically serves to limit damage to healthy tissue.

Next, Dr. Cheng and his colleagues aim to validate BEAT in larger animal models and across different cancer types. They also plan to conduct formal toxicology and pharmacokinetic studies to prepare for early-phase clinical trials. "While the approach is still preclinical, its safety profile in mice — no detectable liver, kidney or autoimmune toxicity — is promising," he said. "Translational work with biotech partners could enable first-in-human testing within several years if these safety findings hold." ❖

Kim, M. Inhalable Therapy Aims for One-Two Punch Against Advanced Melanoma. Columbia Engineering, Jan. 5, 2026. Accessed at www.engineering.columbia.edu/about/news/inhalable-therapy-aims-one-two-punch-against-advanced-melanoma.

Medicines

FDA Fast Tracks Gamgertamig for ITP

The U.S. Food and Drug Administration (FDA) has granted fast track designation to gamgertamig (OM336) for the treatment of immune thrombocytopenia (ITP) and cold and warm autoimmune hemolytic anemia (AIHA). Gamgertamig is a BCMAxCD3 bispecific T-cell engager antibody being developed by Ouro Medicines as an "immune reset" therapeutic. The drug aims to deliver durable disease control while avoiding prolonged, nonspecific immunosuppression by directing T cell-dependent cytotoxicity toward BCMA-expressing cells implicated in pathogenic autoantibody production.

Gamgertamig is being assessed in an open-label, multinational basket study (NCT07083960) enrolling adults with active ITP, relapsed/refractory AIHA or both in the United States and Australia. The study is assessing the safety, tolerability and pharmacokinetics following subcutaneous administration, with a primary endpoint at week 12. Dosing has been completed in the first cohort, and enrollment is ongoing in subsequent cohorts. ❖

Garlapow, M. FDA Fast Track Accelerates Gamgertamig for ITP. Hematology Advisor, Jan. 29, 2026. Accessed at www.hematologyadvisor.com/news/gamgertamig-immune-thrombocytopenia-itp-fda-fast-track-treatment.

Medicines

Novartis' Ianalumab Granted FDA Breakthrough Therapy Designation for Sjögren's Disease

The U.S. Food and Drug Administration (FDA) has granted breakthrough therapy designation to ianalumab for Sjögren's disease. Ianalumab is a fully human monoclonal antibody with a novel dual mechanism of action that depletes B cells and inhibits their activation and survival via BAFF-R blockade.

"This breakthrough therapy designation recognizes the potential for ianalumab to substantially improve the standard of care for people with Sjögren's disease, who currently don't have effective treatment options for this debilitating disease," said Angelika Jahreis, MD, PhD, global head of development, immunology, at Novartis. "We look forward to working

with the agency through the regulatory review process with the hope of making ianalumab available to appropriate patients as quickly as possible."

The designation is supported by positive data from multiple studies, including replicate Phase III trials NEPTUNUS-1 and NEPTUNUS-2, which delivered a clinically meaningful benefit, showing improvement in disease activity and reductions in patient burden. Ianalumab demonstrated a favorable safety profile with an overall incidence of adverse events and serious adverse events comparable to placebo in both studies.

Novartis plans to submit ianalumab for regulatory approval globally starting in early 2026. If approved, ianalumab would become the first targeted treatment for patients with Sjögren's disease. ❖

U.S. FDA Grants Breakthrough Therapy Designation to Novartis' Ianalumab for Sjögren's Disease. Pharmabiz, Jan. 19, 2026. Accessed at www.pharmabiz.com/NewsDetails.aspx?aid=183640&sid=2.

Research

Human Trials Begin for Fentanyl Vaccine to Prevent Overdoses

A vaccine that blocks the effects of fentanyl, including overdoses, is scheduled for Phase I human trials in the Netherlands in early 2026 to assess its safety. In previous rat studies, the vaccine blocked fentanyl from entering the rodents' brain and also blocked the drug from depressing respiration and causing overdose.

Opioids work by binding to opioid receptors in the brain and spinal cord, triggering changes in nerve cell signaling that prevent pain and can create a euphoric high. But these opioid receptors are also found in the part of the brain that controls breathing, which can be fatal. The vaccine, which is licensed by startup ARMR sciences, works in the circulatory system before the drug can reach the brain. However, to keep fentanyl from reaching the brain, the immune system must first recognize the drug. But since immune cells don't naturally react to fentanyl's presence, ARMR's researchers chose a deactivated diphtheria toxin called CRM197, a compound already used in vaccines on the market. To boost the immune response, they added dmLT, a compound distilled from toxins produced by the Escherichia coli bacterium. They attached these two components to a synthetic piece of the fentanyl molecule that cannot cause a high or pain relief. When the immune system meets this combination, it builds antibodies that react to bind to the opioid, keeping it from crossing the blood-brain barrier and then clearing it from the body.

Forty people will be enrolled in the initial human trials and will focus on detecting any safety issues with the vaccines, such as unwanted or dangerous side effects. Researchers will also draw blood samples from participants to make sure the vaccine is spurring the creation of anti-fentanyl antibodies. If these trials are successful, Phase II trials will test the vaccine's efficacy. The Phase II trials will also be dosed with safe levels of fentanyl used for pain relief in medical procedures under close supervision to check that the vaccine works in the presence of the drug.

This would be the first treatment that does not work on the opioid receptor. ❖

Pappas, S. A Fentanyl Vaccine Enters Human Trials in 2026 — Here's How It Works. Live Science, Dec. 29, 2025. Accesssed at www.livescience.com/health/a-fentanyl-vaccine-enters-human-trials-in-2026-heres-how-it-works.

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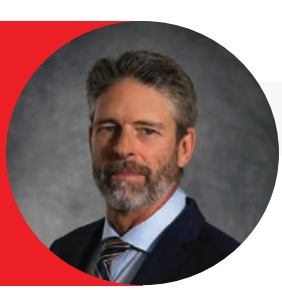

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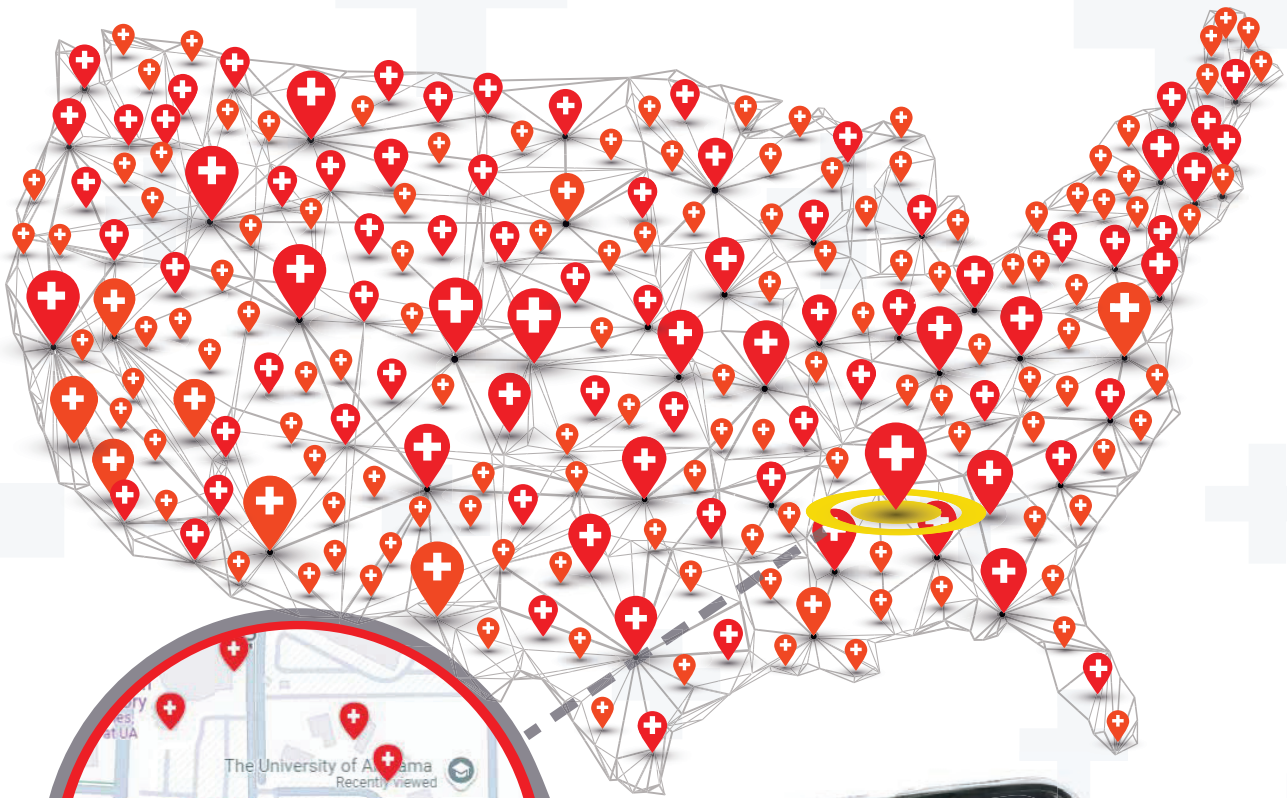

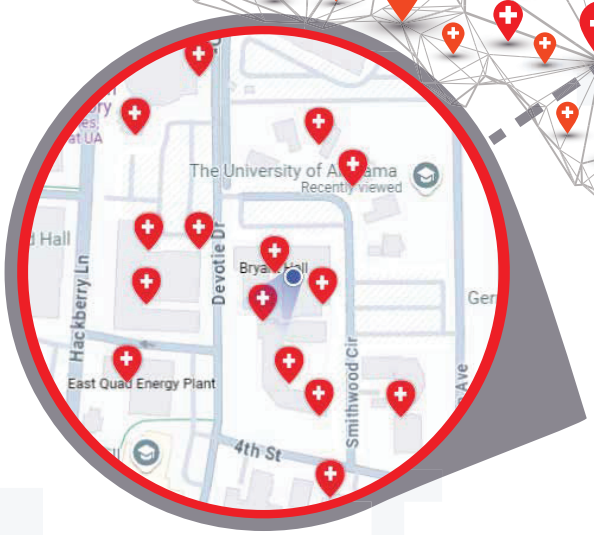

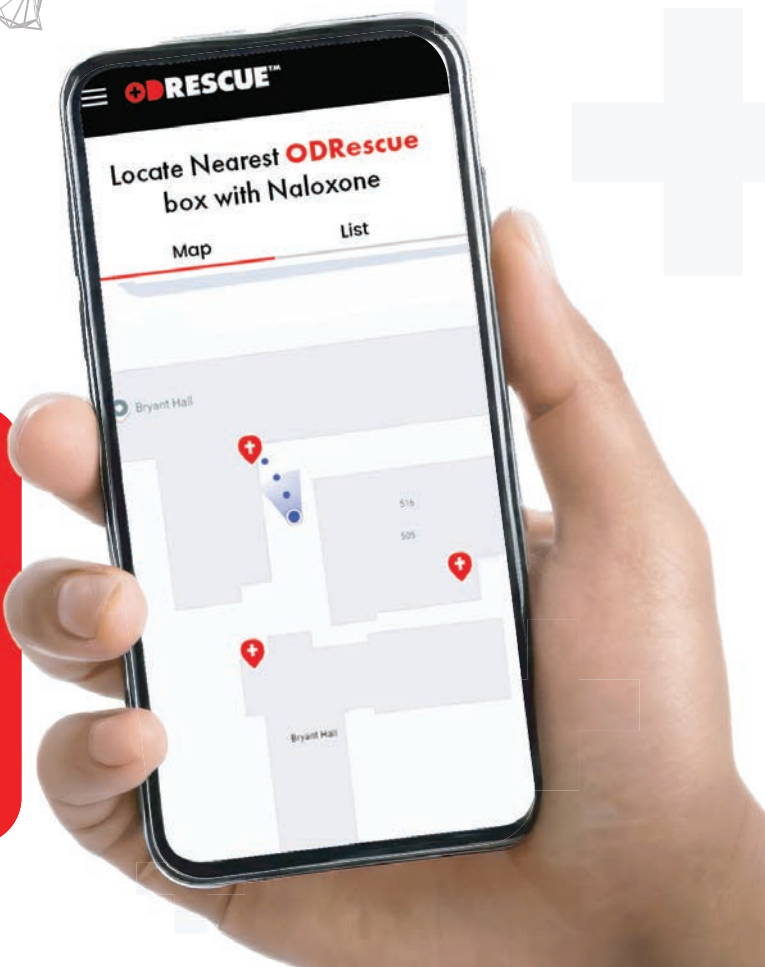

Naloxone Locator Map

A FREE, interactive map pinpoints where naloxone is located, helping individuals, organizations, and agencies quickly connect communities with life-saving medication.

WHO and CDC: *Preparing for the Next Pandemic*

The World Health Organization's and Centers for Disease Control and Prevention's new guidance are expected to strengthen prevention, preparedness, surveillance and response capacities for diseases that have pandemic potential.

By Diane L.M. Cook

PANDEMICS ARE devastating public health emergencies that claim millions of lives, disrupt societies and devastate economies. These global outbreaks of diseases occur between every 10 and 50 years, making them hard to predict and hard to prepare for.

The last pandemic, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), or COVID-19, was declared by the World Health Organization (WHO) in March 2020 and was officially declared over in May 2023. While WHO's 2009 Pandemic Influenza Preparedness and Response: A WHO Guidance Document[1] provided some guidance for the COVID-19 pandemic, it was obvious as the COVID-19 pandemic unfolded how unprepared the Member States were for this novel respiratory pandemic. After it ended, there were many lessons learned.

Therefore, while this latest pandemic was still fresh in the minds of the public, the healthcare industry and government agencies, WHO adopted a new Pandemic Agreement on May 20, 2025.[2] This new agreement is expected to address prevention, preparedness and response capacities to ensure communities, governments and sectors are better prepared and protected and to prevent and respond more equitably to future pandemics. According to WHO, this "Pandemic Agreement represents a global commitment to a more robust international health architecture, one that is grounded in equity, cooperation

and shared responsibility."[3] It addresses many lessons learned from the COVID-19 pandemic, which includes identifying gaps, and it includes two new annexes: a Pathogen Access and Benefit Sharing (PABS) system and a Coordinating Financial Mechanism (CFM).

The Centers for Disease Control and Prevention (CDC) is also addressing new guidance for responding to the next pandemic, including data and analytics, laboratory capacity, domestic and global preparedness and response, and a Vaccines for Adults (VFA) program.

WHO's New Pandemic Agreement

According to WHO, "At the heart of the [new Pandemic] [A]greement is the need to ensure equity in access to the tools needed to prevent and prepare for pandemics (including technologies like vaccines, personal protective equipment, information and expertise) and access to healthcare for all people."[4]

The agreement addresses gaps, weaknesses and inequities in key areas that were witnessed during the COVID-19 pandemic, including:[5]

- prevention, preparedness and response arrangements;
- coordinated funding for pandemic prevention, preparedness and response; and
- mechanisms to increase equitable access to pandemic-related health products, including vaccines, therapeutics and diagnostics.

The agreement represents a global commitment by Member States to work together, as an international community of sovereign nations, to prevent, prepare for and equitably respond to pandemics so that individuals, communities and countries do not witness a repeat of what happened during the COVID-19 pandemic.

It also establishes principles, priorities and targets for pandemic prevention, preparedness and response, with the aim to:

- build resilience to pandemics;
- support prevention, detection and responses to outbreaks with pandemic potential;
- ensure equitable access to pandemic countermeasures; and
- support global coordination through a stronger and more accountable WHO.

"Equity is a key driver, principle and outcome within the new agreement," says WHO. "The agreement promotes political commitment at the highest level, through ensuring an all-of-government and whole-of-society approach within countries, and sustained and sufficient political and financial investment within and among countries."[6]

"The PABS system aims to enable safe, transparent and accountable access and benefit-sharing for pathogen materials and sequence information, as well as equitable, rapid and timely sharing of vaccines, therapeutics, diagnostics and other resulting benefits."[7]

Under article 12 of the new Pandemic Agreement, the PABS system will provide that, "… each participating manufacturer shall make available to [WHO], pursuant to legally binding contracts signed with [WHO], rapid access targeting 20 percent of their real-time production of safe, quality and effective vaccines, therapeutics and diagnostics for the pathogen causing the pandemic emergency, provided that a minimum threshold of 10 percent of their real-time production is made available to [WHO] as a donation, and the remaining percentage, with flexibility based on the nature and capacity of each participating manufacturer, is reserved at affordable prices to [WHO]."

While this latest pandemic was still fresh in the minds of the public, the healthcare industry and government agencies, WHO adopted a new Pandemic Agreement on May 20, 2025.

PABS and CFM

The Intergovernmental Working Group (IGWG), a subdivision of the World Health Assembly established by WHO's Member States, was directed to develop two key components of the new Pandemic Agreement: the PABS system and the CFM.

PABS system. IGWG will draft an annex PABS system, which will be designed to ensure the transparent and equitable sharing of pathogen samples and genetic sequence data. The PABS system will be submitted to the 79th World Health Assembly in 2026 for its consideration. According to WHO,

The PABS system also includes that "… the distribution of these vaccines, therapeutics and diagnostics shall be on the basis of public health risk and need, with particular attention to the needs of developing countries and the Global Supply Chain and Logistics Network …."

The PABS system will also include additional benefit sharing provisions, including options for capacity-building and technical assistance; research and development cooperation; rapid access

to available vaccines, therapeutics and diagnostics; nonexclusive licenses to manufacturers in developing countries; and the transfer of relevant knowledge, skills and technical expertise.[8]

CFM. IGWG will also develop a proposal for the terms of reference for the CFM. The CFM aims to improve the coherence, efficiency and transparency of global pandemic preparedness and response funding. According to WHO, "The [CFM] is to promote sustainable, predictable, inclusive and transparent financing for implementation of both the [new Pandemic] Agreement and the International Health Regulations (2005)."

The CFM will "… enhance, facilitate and work to remove barriers and ensure equitable, timely, rapid, safe and affordable access to pandemic-related health products for countries in need during public health emergencies of international concern, including pandemic emergencies, and for prevention of such emergencies."[9]

Under Article 18, Sustainable Financing in the new Pandemic Agreement, sustainable and predictable financing will be strengthened, to the extent feasible, in an inclusive and transparent manner for the implementation of the WHO Pandemic Agreement.

The CFM will be "… established to promote sustainable financing for the implementation of the WHO Pandemic Agreement, to support strengthening and expanding capacities for pandemic prevention, preparedness and response, and contribute to the prompt availability of surge financing response necessary as of day zero, particularly in developing country parties."

The CFM will "identify all sources of financing that are available to serve the purposes of supporting the implementation of the WHO Pandemic Agreement, and maintain a dashboard of such sources and related information and the funds allocated to countries from these sources," as well as "leverage voluntary monetary contributions for organizations and other entities supporting pandemic prevention, preparedness and response, free from conflicts of interest, from relevant stakeholders, in particular those active in sectors that benefit from international work to strengthen pandemic prevention, preparedness and response."[10]

According to WHO, "[The CFM] will be considered by the Conference of the Parties (COP) to the WHO Pandemic Agreement, which is expected following the ratification of the Agreement by national legislatures in at least 60 countries. The COP will define the CFM's operational modalities within one year of the agreement entering into force."

Based on lessons learned from the COVID-19 pandemic, the Centers for Disease Control and Prevention (CDC) is already preparing for the next pandemic.

CDC's Pandemic Guidance Changes

Based on lessons learned from the COVID-19 pandemic, the Centers for Disease Control and Prevention (CDC) is already preparing for the next pandemic. In its congressional testimony in November 2024, CDC outlined several items that will support public health's core capabilities.

World-class data and analytics. CDC has made investments in modernizing public health and healthcare data and is moving toward a more secure, interoperable health data infrastructure. "We continue to identify novel data sources and strengthen mission-critical data sources such as electronic case reporting, syndromic surveillance, electronic laboratory reporting, vital statistics and hospitalization data," says the agency. "These data are used to detect, understand and respond to the full spectrum of health conditions."

In October 2024, CDC launched the One CDC Data Platform (1CDP) to leverage data across the entire agency as one team. "The goal of the 1CDP is to improve programmatic, scientific and response work using proven technology, common tools and shared data assets that enable programs and public health experts to act on data to improve health and help save lives," says CDC.

The 1CDP platform sets a foundation for CDC data throughout the agency and builds on CDC's Response Ready Enterprise Data Integration platform (RREDI). According to CDC, "RREDI pulls data from state, local, tribal and territorial partners and other sources into one common operating picture and enables HHS [U.S. Department of Health and Human Services], other response leaders and public health partners to analyze, visualize and share that data in real-time during a public health response."

CDC also says it needs to continue to innovate and expand its analytical abilities: "We are doing this by generating forecasts and scenario models in our

Center for Forecasting and Outbreak Analytics to extract as much information as possible from the available data. These forecasts and models deliver actionable analyses to guide decision-makers at all levels of government."

State-of-the-art laboratory capacity. CDC's scientists are working in laboratories across the United States and in countries around the world, building capacity for the prevention and control of diseases domestically and abroad, as laboratories are often the first to detect, identify and respond to health threats. "Modern, high-performing laboratories will prepare the CDC to detect emerging threats and react quickly in emergencies," says the agency.

CDC will work closely with state and local public health entities, as well as clinical laboratory companies, which is critical to providing timely and actionable data to protect public health, particularly at the onset of emergency responses and testing surges. CDC has also implemented extensive quality control measures internally and expanded partnerships to support development and distribution of tests. This means companies will be developing new tests for public health response alongside CDC, an arrangement "… intended to help move testing to clinical laboratory companies, where most people get tested, with the ability to scale up quickly and early rather than during an emergency."

Domestic and global preparedness and response. CDC is improving how it collects and shares key disease data by bringing together multiple data sources, such as emergency department visits, test positivity, wastewater surveillance, hospitalizations, deaths and vaccine uptake, into its Respiratory Illness Data Channel (RIDC). According to CDC, "… we will be collecting and analyzing vaccine effectiveness data which informs our vaccination guidance, decisions on vaccine production and vaccine purchases."

Vaccines for Adults (VFA) program. Currently, there is no central system in the United States that supports streamlined and efficient access to vaccines for adults. With funding from Congress, CDC will create a VFA program that will a) support routine vaccination for uninsured adults in the United States and b) create a warm base for future vaccine administration in the event of another widespread threat: "Having a VFA program already in place will prevent CDC from having to build infrastructure from scratch when a new threat emerges. With a VFA program, public health entities will be able to more efficiently administer future vaccines, whether as routine, outbreak or pandemic-related immunizations."

Data authority. CDC plans to improve public health data capabilities at all government levels: "As of October 2024, more than 45,800 healthcare facilities across all 50 states are delivering automated, real-time, electronic case reports — up from only 187 before the COVID-19 pandemic. And more than 80 percent of hospital emergency departments now provide syndromic surveillance data to the CDC."

However, it says "86 percent of providers still use some form of manual reporting to share information with health departments, and only approximately 20 percent of providers use electronic case reporting. Updating CDC's policy levers will support CDC and the nation in having better real-time situational awareness for the next potential threat."

Wastewater surveillance. CDC is leveraging wastewater surveillance to support all public health entities to rapidly detect infectious diseases that are spreading in their communities. CDC also uses wastewater data as part of its Traveler-Based Genomic Surveillance program, a public-private partnership that anonymously monitors for infectious disease threats in international travelers at nine sentinel airports.[11]

Better Prepared for the Next Pandemic

Neither WHO nor CDC know when the next pandemic will occur, or what the disease will be, but WHO expects its new Pandemic Agreement should provide the critical components that were missing from the 2009 Pandemic Guidance Document. And, both WHO and CDC anticipate the world will fare much better during the next pandemic than it did during the COVID-19 pandemic. ❖

References

1. World Health Organization. Pandemic Influenza Preparedness and Response: A WHO Guidance Document, 2009. Accessed at iris.who.int/server/api/core/bitstreams/e41f13ed-9ca8-4689-b183-58bfc8944603/content.
2. World Health Organization. Pandemic Agreement, May 20, 2025. Accessed at apps.who.int/gb/ebwha/pdf_files/WHA78/A78_R1-en.pdf.
3. World Health Organization. World Leaders Recognized for Championing the WHO Pandemic Agreement, July 11, 2025. Accessed at www.who.int/news/item/11-07-2025-world-leaders-recognized-for-championing-the-who-pandemic-agreement.
4. World Health Organization. Pandemic Prevention, Preparedness and Response Agreement: Why Did WHO's Member States Decide to Create an Agreement for Pandemic Preparedness and Response? June 27, 2025. Accessed at www.who.int/news-room/questions-and-answers/item/pandemic-prevention--preparedness-and-response-accord.
5. World Health Organization, Pandemic Prevention, Preparedness and Response Agreement: What Is the Role of the WHO Secretariat in the Pandemic Agreement Process? June 27, 2025. Accessed at www.who.int/news-room/questions-and-answers/item/pandemic-prevention--preparedness-and-response-accord.
6. World Health Organization, Pandemic Prevention, Preparedness and Response Agreement, When Will the Pandemic Agreement Process Be Concluded and the Treaty Open for Signature? June 27, 2025. Accessed at www.who.int/news-room/questions-and-answers/item/pandemic-prevention--preparedness-and-response-accord..
7. World Health Organization. Member States Advance Vital Work in Support of WHO Pandemic Agreement, Sept. 25, 2025. Accessed at www.who.int/news/item/25-09-2025-member-states-advance-vital-work-in-support-of-who-pandemic-agreement.
8. World Health Organization. WHO Pandemic Agreement, pages 20 to 23, May 20, 2025. Accessed at apps.who.int/gb/ebwha/pdf_files/WHA78/A78_R1-en.pdf.
9. Pan American Health Organization. Member States Approve WHO Pandemic Agreement in World Health Assembly Committee, Paving Way for Its Formal Adoption, page 27, May 19, 2025. Accessed at www.paho.org/en/news/19-5-2025-member-states-approve-who-pandemic-agreement-world-health-assembly-committee-paving.
10. World Health Organization. WHO Pandemic Agreement, pages 27 and 28, May 20, 2025. Accessed at apps.who.int/gb/ebwha/pdf_files/WHA78/A78_R1-en.pdf.
11. Centers for Disease Control and Prevention. Preparing for the Next Pandemic: Lessons Learned and the Path Forward, CDC Congressional Testimony, Nov. 14, 2024. Accessed at www.cdc.gov/washington/testimony/2024/t20241114.htm#print.

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Maximizing Pediatric Readiness in Emergency Departments

Pediatric readiness is associated with improved survival. But to be ready, EDs must ensure the right equipment and specialized staffing are available.

By Amy Scanlin, MS

HOSPITAL EMERGENCY room (ER) pediatric readiness has received media attention in recent years, most recently with the release in 2024 of a Stanford University-led study that found 75 percent of hospital emergency departments (EDs) are below the top quartile of pediatric readiness. Fortunately, the study also showed that cost-effective improvements could save thousands of lives annually. The data, collected from nearly 750 hospitals in 11 states, representing a variety of community sizes, urban and rural, public and private, concluded that improvements to staffing, training, equipment or some combination could better maximize emergency room pediatric readiness.[1]

Efforts to improve ER pediatric readiness, defined as the ability to care for acutely ill and injured children, has been on the upswing, says Teale Ryan, PhD, RN, in Salina, Kan. And although pediatric-specific hospitals have the highest level of expertise, despite how the Stanford study results sound, she says pediatric care in regional EDs, big picture, should not be described as inadequate.

However, as hospitals trend away from pediatric-specific facilities, and EDs toward level 4 care that offers minimal pediatrics beyond EDs (level 4 hospitals have seen an increase of 137 percent in

the past 20 years), concern for pediatric readiness may be warranted. In fact, pediatric inpatient services are also declining, according to a study conducted at the Oregon Health and Science University and the University of the Utah School of Medicine that looked at ERs across all 50 states and Washington, D.C.[2] Some cite lower reimbursement rates for pediatric services as a possible cause for the reduction. Others warn pediatric capabilities may worsen under proposed federal funding changes.[3]

Regardless, pediatric readiness is associated with improved survival across the age spectrum, particularly related to traumatic injuries, with younger children deriving the greater benefit, possibly because of their need for specialized personnel and right-sized equipment.[4]

Despite 30 million pediatric ER visits in the U.S., half of ER doctors see fewer than 15 pediatric patients per day.[5] "Even small EDs who see few children need to have equipment and supplies to care for a critically ill or injured child, as they may be the closest ED in an emergency and would need to stabilize the child to the best of their abilities before transferring out to a children's hospital," says Theresa A. Walls, MD, MPH, an attending physician in the Emergency Department at Children's Hospital of Philadelphia (CHOP). "While only 5 to 10 percent of emergency medical services runs are for children, pediatric patients typically make up 20 to 25 percent of all ED visits to community EDs. They are doing a decent job. They want to take good care of kids."

Children Are Not Small Adults

Being fully prepared for so few pediatric patients might seem daunting, particularly in a world of cost-reduction strategies. However, addressing the unique needs of children means preparing for the unexpected, providing right-sized equipment and hiring staff who are credentialed and trained to ensure appropriate care for all body sizes.

Better equipment, better staffing and better training for treating pediatric ER patients saves critical time, improves recovery and health outcomes, and reduces the risk of disability and death by nearly half.

Nursing schools often teach to a nurse generalist position, says Dr. Ryan, although some include specific coursework in pediatrics. Generalist training enables nurses to apply learned concepts across the lifespan, but it also means some skills must be acquired at pediatric-specific in-services, continuing education and on-the-job annual training. She cites HALO competencies (high acuity, low occurrence) as critical skills to maintain even though they are less frequently used. As an example, ER nurses will always receive training in pediatric life support, but they might be tempted, in a time-constrained environment, to overlook training to respond to the less common pediatric stroke.

Medical staff need to be ready to assess and care for all pediatric emergencies. For example, use of the Broselow Tape system to measure a patient's height with color-coded tape will reasonably estimate the patient's weight if a true weight cannot be obtained. From this measurement, appropriately sized equipment and pre-calculated medication dosing can be determined in an easy-to-use color-coded system. "Though children are not small adults, the inventories in a pediatric Broselow crash cart are similar," says Dr. Ryan. "If a child measures in the blue section of the tape, the provider knows to open the blue drawer. If the same child needs to be sedated, the blue drawer contains the dose that should be used."

National standards for 24-hour hospital-based ERs were developed in 2009, updated in 2018 and reaffirmed in 2024 in a joint policy statement by the American Academy of Pediatrics, American College of Emergency Physicians and the Emergency Nurses Association. Covering critical domains of pediatric readiness, the National Pediatric Readiness Project provides a checklist and toolkit based on the joint policy statement that articulates the necessary components of administration and care coordination; policy development; competencies and evaluations; quality and performance improvement plans; procedures and protocols; and all-hazard preparedness that addresses unique needs of pediatric patients. The toolkit is being updated in 2026.[6]

Training Today to Be Ready Tomorrow

According to Dr. Walls, one of the most impactful pediatric readiness improvements a hospital ED can make is the appointment of a pediatric emergency care coordinator who is dedicated to pediatric patient care, inclusive of training and equipment, and ensuring

pediatric patients are represented in quality improvement plans. "Getting the right equipment is fairly easy and inexpensive, but equally important is making sure all ED staff know where the equipment is and how to use it," she explains. Dr. Walls encourages hospital EDs to reach out to their local or regional children's hospital for help and/or contact their state Emergency Medical Services for Children program manager. There are also a wealth of resources available at the Emergency Innovation and Implementation Collaborative.

Dr. Walls participates in CHOP's Outreach Center for Expertise in Pediatric Emergency Readiness and Training (ExPERT), working with hospitals, EDs, outpatient clinics, EMS departments and schools in the greater Philadelphia area on improving pediatric emergency care. The ExPERT team enables coordinated efforts at skill improvement through simulations that are as realistic as possible. "This allows the nurses, doctors, respiratory techs, pharmacy, all who would care for sick kids, to simulate what to do, to know what equipment they have and what to do in an emergency," she explains. The training is meant to augment annual training, not replace it. "The size of the hospital might influence what sort of case we do, but even experienced clinicians who see many sick children appreciate the chance to practice skills and ensure their ED is ready."

Since 2023, CHOP's ExPERT program has conducted nearly 100 simulation sessions with 39 different organizations (hospital, prehospital, outpatient and community) in the greater Philadelphia area. But, says Dr. Walls, any medical facility can gain instant insight into their own pediatric readiness through the National Pediatric Readiness Project online assessment found at pedsready.org. "This will allow an ED to take the survey and get an immediate score with a gap report to help address the areas most in need of improvement," she adds. "The site also allows you to print a PDF of the survey to research your answers before submitting online." In one example, a rural hospital was able to raise its ER pediatric readiness score by 25 points in two years.[7]

Cost of Care

Better equipment, better staffing and better training for treating pediatric ER patients saves critical time, improves recovery and health outcomes, and reduces the risk of disability and death (which is rare even in less-than-prepared ERs) by nearly half.[1]

While it may seem like the cost of upgrading ER policies, procedures and staffing capabilities to maximize outcomes of pediatric patients might be prohibitive for smaller rural hospitals in particular, both the Stanford study and the Oregon and Utah studies confirm just the opposite.

The Stanford study, which was comprised of data from 7.9 million pediatric ER visits to the nearly 750 ERs, found patients who received treatment for acute or traumatic injuries in ERs that ranked below the readiness threshold fared worse. The study authors estimated a gain of 76,800 years of life expectancy and 69,100 quality-adjusted life years for pediatric patients receiving treatment in well-prepared hospital ERs, and the impact could be greater in situations of disaster, mass casualty and pandemics.[2]

The cost of these improvements? Approximately $9,300 per quality-adjusted life year gained or $244,000 per life saved. The study authors found that even improvements costing less than $50,000 per gained quality-adjusted life year were highly cost effective and advantageous. According to the Oregon and Utah university studies, adopting a universal standard of high pediatric readiness could save more than 2,100 pediatric lives, at an annual cost of around $12 or less per child.[2]

"The cost of equipment is minimal compared to other hospital spending," adds Dr. Walls, so it should not be a limiting factor in improving pediatric readiness. Improving readiness takes knowledge of what gaps need to be filled, as well as a commitment of the time, personnel and training resources necessary to connect the dots and ensure pediatric readiness is a priority.

Worth the Effort and Cost

Maximizing pediatric readiness takes a concerted effort across multiple domains. The structure of comprehensive and timely care can mean the difference between a child's complete recovery or years of illness, disability and even death. If there is one change hospital ERs can make it is the assignment of a pediatric care coordinator to assess the current level of readiness and lead the way for continual improvements. These youngest patients need specialized care, and investment in them is worth the cost. ❖

References

1. Weyant, C, Lin, A, Newgard, D, et al. Cost-Effectiveness and Health Impact of Increasing Emergency Department Pediatric Readiness in the US. *Health Affairs*, Volume 43, No. 10, October 2024. Accessed at www.healthaffairs.org/doi/10.1377/hlthaff.2023.01489.
2. Newgard, CD, Lin, A, Goldhaber-Fiebert, JD, et al. State and National Estimates of the Cost of Emergency Department Pediatric Readiness and Lives Saved. *Journal of the American Medical Association Open Network*, Nov. 1 2024. Accessed at jamanetwork.com/journals/jamanetworkopen/fullarticle/2825748.
3. Agarwal, M. As Pediatric Capabilities Shrink, Family Strain Grows. AAP Journals blog, Dec. 10, 2025. Accessed at publications.aap.org/journal-blogs/blog/33951/As-Pediatric-Capabilities-Shrink-Family-Strain?searchresult=1.
4. Newgard, CD, Lin, A, Olson, LM, et al. Evaluation of Emergency Department Pediatric Readiness and Outcomes Among US Trauma Centers. *Journal of the American Medical Association Pediatrics*, June 7, 2021. Accessed at jamanetwork.com/journals/jamapediatrics/fullarticle/2780353.
5. Remick, K, Gausche-Hill, M, Joseph, MM, American Academy of Pediatrics Committee on Pediatric Emergency Medicine and Section on Surgery, American College of Emergency Physicians Pediatric Emergency Medicine Committee and Emergency Nurses Association Pediatric Committee. Pediatric Readiness in the Emergency Department. *Pediatrics*, 2018;142(5):e20182459. Accessed at www.annemergmed.com/article/S0196-0644(18)31167-3/fulltext.
6. National Pediatric Readiness Project Checklist and Toolkit. Accessed at emscimprovement.center/domains/pediatric-readiness-project/readiness-toolkit.
7. Blog: Ensuring Disaster Preparedness in Pediatric Health Care. Children's Hospital Association, Oct. 10, 2025. Accessed at www.childrenshospitals.org/news/cha-blog/2025/10/ensuring-disaster-preparedness-in-pediatric-health-care.

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Unboxing Boxed Warnings and Risk Assessment for IG Products

Adverse drug reactions with IG products are infrequent; however, FDA mandates boxed warnings to highlight potential risks, and clinicians are urged to perform comprehensive patient-specific risk evaluations.

By Amy Ehlers, BS, PharmD, CSP, IgCP

BOXED WARNINGS (formerly known as black box warnings) are the highest safety related warning assigned by the U.S. Food and Drug Administration (FDA). These warnings are used to communicate potential rare but dangerous side effects or important instructions for safe use of the drug. As the name implies, a boxed warning will appear in bold font with a heading in all capital letters surrounded by a black border. This boxed warning must appear in the drug's prescribing information, the drug's manufacturer website and any promotional items.

A boxed warning is typically assigned to the entire class of drugs since the risk is associated with a specific action of the medication causing an undesired effect. Boxed warnings may be assigned before or after the drug comes to market and may be modified at any time. The intent of a boxed warning is not to preclude the use of the drug or class of drugs, but to make clinicians and patients aware of the potential severe side effects and ensure the benefits outweigh the risk.

More than 400 drugs contain a boxed warning. Examples include selective serotonin reuptake inhibitor antidepressants, fluroquinolone antibiotics, isotretinoin and immune globulin (IG) products. All IG products contain a boxed warning for thrombosis and those IG products administered intravenously (IVIG) also contain a boxed warning for renal dysfunction and acute renal failure (ARF).

The Use of IG Product Boxed Warnings

IVIG, subcutaneous IG (SCIG) and facilitated SCIG (fSCIG) infusions can cause arterial and/or venous blood clots that may result in myocardial infarction, cerebrovascular accidents, transient ischemia attack, deep vein thrombosis, pulmonary embolism and retinal vein occlusion. These thromboembolic events (TEs) may occur during or after an IG infusion. Patients with thrombosis risk factors appear to be at a higher risk, but TEs have been reported in the absence of known risk factors.

Why do TEs occur with IG products? After IG administration, heightened plasma viscosity and platelet aggregation may be seen. This may promote platelet, erythrocyte and leukocyte aggregation, induce arterial vasospasm or encourage release of vasoconstrictive cytokines. In addition, IG products contain contaminants, such as Factor XIa (FXIa), antiphospholipid antibodies and pre-kallikrein activator (PKA), all of which may induce clot formation, increasing the risk of thrombosis.

The boxed warning on IG products for thrombosis was added in 2013. Since 1986, there had been reports of TEs, and the number of events stayed consistent with the number of IG grams sold from 1986-2010. In 2009, an IG product had an increase of TEs reported, and it was determined FXIa had not been effectively removed. In 2010 and 2011, two additional IG products (one IVIG and one SCIG) had increased FXIa and PKA levels. After analysis of health database and post-marketing reports of serious TEs, FDA mandated the addition of a boxed warning on all IG products for thrombosis and the associated risk factors: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity and cardiovascular risk factors. This was in addition to requiring IG manufacturers to implement changes during the purification process to minimize or remove FXIa.

Mitigating Thrombosis Risk

To minimize thrombosis risk in patients receiving IVIG, adequate hydration in patients is important the day before, day(s) of infusion and the day after. While oral hydration is preferred and appropriate in most cases, IV hydration may be used. If using IV hydration, providers should consider possible compatibility issues with the IG, the increase in the required infusion time and other co-morbid conditions such as congestive heart failure, kidney dysfunction

or liver disease. Antithrombotic therapy may be considered, although there are no guidelines officially endorsing this recommendation.

In patients at risk for hyperviscosity due to factors such as hypergammaglobulinemia, cryoglobulinemia, markedly increased triglycerides and paraproteinemia, blood viscosity should be assessed.

IG should be administered at the minimum dose necessary and infused at the slowest rate practicable. Large doses of IVIG may need to be split and infused over more than one day.

Patients should also be monitored for signs and symptoms of thrombosis. Myocardial infarction and pulmonary embolism symptoms include chest pain, shortness of breath or pain while breathing. Cerebral vascular accident and transient ischemic attack symptoms include confusion, slurred speech, weakness on one side, facial drooping and loss of consciousness. Deep vein thrombosis symptoms include swelling, intense pain or tenderness (often in the calf) and warm, red discolored skin.

IG and Serious Adverse Drug Reactions

In addition to boxed warnings, IG products also have several serious adverse drug reactions (ADRs) that should be considered when developing an IG therapy regimen. These include anaphylaxis, aseptic meningitis syndrome (AMS) and hemolysis/hemolytic anemia.

- **Anaphylaxis**. This is a rare but potentially life-threatening ADR that may, within minutes, cause rapid and severe hypotension, extreme respiratory distress and cardiopulmonary arrest that must be addressed immediately. If this occurs, the IG infusion should be stopped, emergency medical services should be contacted and epinephrine should be administered. Organization-specific policies may include other interventions that include IV fluids, antihistamines, bronchodilators or steroid administration.

The cause of anaphylaxis is thought to be due to a response to impurities in the IG such as IgG fragments, IgG aggregates and PKA. This reaction can occur in any patient, but those with IgA deficiency and IgA autoantibodies may be more susceptible. True IgE-mediated anaphylaxis with release of mediators from tissue mast cells and peripheral blood basophils is exceptionally rare. Ensuring an anaphylaxis kit is available for all IG infusions is recommended in the IgNS *Immunoglobulin Therapy Standards of Practice Edition 3.2*.

If a patient experiences an anaphylactic reaction, the decision to continue IG therapy should be reassessed by the healthcare team and the patient. In individuals with IgA deficiency, transitioning to SCIG or to an IVIG product with the lowest available IgA content is recommended. For patients without IgA deficiency, switching to SCIG or to an alternate IVIG product may be appropriate, provided premedications are used and therapy is administered under close monitoring in a controlled clinical setting.

- **AMS.** This occurs when the brain and spinal cord become inflamed, but the cerebrospinal fluid is negative for any bacterial, viral or fungal infection. Symptoms include a severe headache (rated 8+/10), nausea, vomiting, photophobia, neck stiffness and fever. These appear within hours of the infusion but may be seen for up to 48 hours post infusion. While the exact cause of AMS by IG is not known, IgG does cross the blood brain barrier, which may cause an inflammatory reaction or osmotic shift. Hypersensitivity to the various stabilizers and contaminants may also contribute to AMS. Risk factors of AMS are large doses of IG, rapid infusion rates, dehydration and those patients with a history of migraine headaches.

Possible interventions may include changing the brand of IG used or considering the use of SCIG or fSCIG in patients in whom AMS occurred with IVIG. Decreasing the maximum infusion rate, increasing the number of infusion days, possibly nonconsecutive, and adequate hydration are also important considerations. In patients who have migraine treatment prescribed, ensure the medicine if scheduled or available if needed.

- **Hemolysis.** This occurs when red blood cells break down faster than the body can replace them, which can lead to hemolytic anemia. Mild hemolysis may cause no symptoms or only slight tiredness, but more severe hemolytic anemia can become life-threatening. Symptoms such as dark colored urine, jaundice, increased heart rate or enlargement of the liver or spleen may appear several days to weeks after an IG infusion.

The exact cause of hemolysis from IG therapy is not fully understood, but it is believed to be related mainly to anti-A and anti-B antibodies that are not fully removed during the manufacturing process. Other possible contributors include the way IG may increase red blood cell removal by the body or activity from other types of antibodies. Hemolysis is more common in people with non O blood types because they naturally have both anti-A and anti-B antibodies.

Patients receiving high doses of IG (more than 2 g/kg) are at higher risk. When large doses are needed, spreading the total amount over several days — sometimes on nonconsecutive days — can help reduce this risk.

While all forms of IG carry the boxed warning for thrombosis, the risk with SCIG and fSCIG is considered to be less than with IVIG. This is because the IG is administered into the subcutaneous tissue and is slowly absorbed over 24 to 72 hours. SCIG traditionally has smaller doses administered more frequently and with a slower infusion time per dose. This may make SCIG or fSCIG a better IG option for patients at higher risk for thrombotic events.

While all forms of IG carry the boxed warning for thrombosis, the risk with SCIG and fSCIG is considered to be less than with IVIG.

Mitigating Renal Dysfunction Risk

IVIG products also contain a boxed warning for renal dysfunction and ARF. Acute renal dysfunction includes increased serum creatinine, oliguria, ARF and osmotic nephrosis. This is usually seen within seven days of the IVIG infusion. These significant renal issues were mostly associated with IG products using sucrose as the stabilizer. It is important to note that the last sucrose-containing product was voluntarily discontinued by the manufacturer in 2018.

Risk factors for renal dysfunction and ARF include advanced age, preexisting renal disease or renal insufficiency, diabetes, obesity, hypovolemia, volume depletion, sepsis, paraproteinemia and concurrent use of nephrotoxic drugs.

To minimize renal issues, providers should obtain baseline kidney function labs such as serum creatinine and BUN, and then monitor as appropriate. Because renal issues may not present until days or weeks after the IVIG infusion, patients should be educated on the signs and symptoms of renal dysfunction/ARF. These include decreased urine output, dark or tea-colored urine, sudden weight gain due to fluid retention and shortness of breath.

The same recommendations seen with minimizing thrombosis risk are also important. IG should be administered at the minimum dose necessary and infused at the slowest rate practicable. Large doses of IVIG may need to be split and infused over more than one day. Also, because SCIG and fSCIG products do not contain the boxed warning for renal dysfunction and ARF, these products may be more suitable for patients at high risk.

The Necessity of Risk Assessment

The IgNS *Immunoglobulin Therapy Standards of Practice Edition 3.2* recommends a complete and thorough risk assessment, to include screening for box warnings, upon start of care and annually at a minimum thereafter. In addition, a risk assessment should be completed if there is a significant change in the patient's clinical status or clinical event.

This risk assessment should include a review of the patient's history and physical, laboratory reports, diagnostic tests, recent hospitalizations, current and past medication history, and other relevant health information. Prescribers or pharmacists should also review the potential risk factors for adverse drug reactions in patients with comorbidities such as diabetes, IgA deficiency status, blood type, current infection/sepsis, history of thromboembolic events or cardiac, renal or liver dysfunction.

Based on the outcome of this risk assessment, prescribers or pharmacists should make any necessary adjustments to the drug therapy regimen. The more risk factors a patient has, the more conservative they may need to be. Adjustments to IG therapy may include lowering the maximum infusion rate, lowering the dose per day, lowering the IG concentration (5% versus 10%), more frequent monitoring of renal function and monitoring of serum viscosity. The specific IG brand may need to be considered due to the varying individual product differences, or it may be necessary to consider changing the route of administration from IVIG to SCIG or fSCIG.

Ensuring Safe, Effective Therapy

While IG products carry boxed warnings, these events are uncommon. Patients and their healthcare team should collaborate to determine an optimal therapeutic plan that minimizes risk factors and potential adverse effects while supporting the best possible clinical outcomes. Clinicians — including prescribers, nurses and pharmacists — should work together to develop an individualized treatment approach that incorporates all relevant clinical data, evaluates the appropriate IG product and route of administration, and outlines a comprehensive monitoring strategy. Such coordination helps ensure safe, effective therapy and supports the achievement of the most favorable patient outcomes. ❖

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Health Optimization: Is Longevity Medicine the Future of Wellness?

Data-driven healthcare decisions are shifting healthcare from reactive management to proactive prevention.

By Rachel Maier, MS

"WE MIGHT BE the first generation that doesn't die."[1] It's a bold statement, one that entrepreneur and originator of the Don't Die protocol Bryan Johnson built a health and wellness empire upon. His goal is simple: Stay alive, and share his strategy with the world.

For centuries, people have sought the fabled Fountain of Youth. Could it be that this generation has finally found it in the form of longevity medicine? For Johnson, it's a legitimate possibility: Thanks to the intersection of drug discovery, cellular reprogramming, biomarker tracking, regenerative medicine and artificial intelligence, he believes death is optional.[2]

Johnson's single-minded pursuit of not dying is an extreme example of the growing interest in health optimization — a proactive, personalized approach to health management that aims to help people reach their own personal optimal level of well-being, both physically and mentally. The idea is to get ahead of age-related health problems — to stop disease before it starts, and to set the body up for its absolute best possible health through protocols and practices that support wellness across the lifespan. Increasingly, this is called longevity medicine, and the goal isn't just to live longer: It's also to live better.

Is Aging Optional?

However drastic the methods, Johnson mirrors longevity medicine's goal of taking the long view of one's health. He utilizes the very same wellness habits healthcare providers emphasize all the time: prioritizing sleep, managing stress, eating nutrient-dense foods and exercising regularly. He also utilizes biomarkers, gene therapy, alternative therapies such as red light therapy, undergoes experimental procedures such as plasma exchange therapy, embraces gene therapy — anything that optimizes his health.

Does he live well? In his mind, yes. His body is healthy and strong ("quantitatively the healthiest person alive," he says), but he foregoes simple pleasures of enjoying a celebratory slice of birthday cake.[4] Johnson's efforts are clearly an extreme example of putting the theory of health optimization into practice, yet they do echo the questions longevity medicine researchers are asking: What are the processes behind aging?

What can we do to slow those processes down? Does delaying physiological aging decrease diseases associated with old age such as cancer, dementia and heart disease? Is it possible to prevent death?

Johnson's critics oppose his strategy, explaining that at best, Johnson is encouraging people to embrace habits that are linked to a longer, healthier life, but at worst, he's propagating false hope of immortality.

"Death is not optional; it's written into our genes," explained Pinchas Cohen, MD, dean of the Leonard Davis School of Gerontology at the University of Southern California, in an article published in *Time Magazine*.[3] Dr. Cohen is a renowned expert on the biology of aging and says "there is absolutely no evidence that [living forever] is possible, and there's absolutely no technology right now that even suggests that we're heading that way."[3]

Aging isn't optional either. According to Scott F. Gilbert, PhD, emeritus professor of biology (emeritus) and author of *Developmental Biology*, "Aging is the time-related deterioration of the physiological functions necessary for survival and fertility."[5] According to Dr. Gilbert, although we don't fully understand the mechanism behind aging — is it continuous development, cellular senescence, mitochondrial dysfunction, genetic instability or something else? — it is nevertheless a certainty of the human experience. While getting older isn't optional, experts increasingly agree that aging well is.

The Burden of Chronic Disease

While not the key to everlasting life, longevity medicine does aim to help people age well. Its goal is to help people live longer, healthier lives by changing the practice of medicine. Instead of addressing a disease after it arises, longevity medicine aims to prevent the disease altogether.

While the characteristics of aging such as gray hair and wrinkles eventually affect everyone, the diseases of aging are a different story. Predisposition, genetics and epigenetics, lifestyle choices, family history, etc., all play a part in determining who develops disease, and when. Increasingly, understanding these data points informs individuals about interventions that can help them evade disease. The best strategies we have for prolonging life are proactive, preventive measures and early disease detection, which together can create highly personalized approaches meant to extend healthy lifespan.[6]

According to the Centers for Disease Control and Prevention (CDC), the life expectancy for males in 2023 was 75.8 years; the life expectancy for females was 81.1 years, with an average of 78.4 years for both sexes in the United States.[7] Among the top 10 leading causes of death in the U.S. are chronic diseases such as heart disease, cancer, lower respiratory diseases, Alzheimer's disease, diabetes, kidney disease and chronic liver disease. And, one in four Americans has at least one chronic condition, and more than half have two or more.[8] Risky behaviors such as smoking, poor nutrition, lack of exercise, excessive alcohol and insufficient sleep not only contribute but directly cause the majority of these diseases; family history plays a role as well. Chronic disease is taking a substantial social and economic toll; these conditions drive the nation's $4.9 trillion in annual healthcare costs.[8] Experts agree that the world is set to face an unsustainable burden of chronic disease if a new medical and wellness paradigm isn't adopted soon.[6]

Proactive, not Reactive — and Deeply Personal

Longevity medicine may be the answer.

Conventional medicine is reactive: It follows a model of maintenance and management by relying on routine checkups and screenings to catch diseases and leaning on symptom management during the treatment of those diseases. However, the model is impersonal, designed for large demographic groups that share the same general risk factors (e.g., mammograms are recommended for women beginning at age 40). Screenings do not necessarily consider an individual's unique biological makeup or genetic markers, and data collection is limited. Baseline information is tracked, and diseases are treated when they arise. Routine screenings are a helpful start, but they are fragmented and only show a snapshot of what's happening in the body at the time of the test.

Instead of addressing a disease after it arises, longevity medicine aims to prevent the disease altogether.

Longevity medicine is proactive: It seeks to avoid disease in the first place. The familiar foundation of regular checkups, recommended health screenings, vaccines and risk avoidance measures are augmented by advanced diagnostics — frequent, patient-specific screenings look at biomarkers to reveal an individual's internal aging processes,

which can be used to determine interventions that will improve the quality and duration of a person's life. Specialized tests look at genetic markers, oxidative stress, metabolic health, inflammatory mediators, cellular aging, hormone levels and more.[9] These biomarkers are regularly collected and track subtle shifts over time. The continuous monitoring gathers data points that can reveal underlying patterns and provide actionable insights such as genetic predispositions, nutritional deficiencies, visceral fat and inflammatory markers. Consistently measuring the function of various systems gives clinicians deeper insight into how the organs are working and what they might need to function more effectively.

This approach is deeply personal. Not only are tests conducted based on individualized recommendations, not broad ones (e.g., a test reveals a young woman carries a gene for the same type of breast cancer that took her mother's life), but lifestyle factors and individual health profiles as well.[10] And, because longevity medicine tracks subtle shifts in a patient's body that may point to what could become larger, long-term problems, catching issues early helps providers and patients work together to develop a personalized plan to address the issues that particular patient may face before those issues become significant.

Driven by Data

In longevity medicine, data and agency go hand in hand. Patients want personal health data, and they increasingly expect personal data. In fact, a recent survey conducted by the National Institutes of Health All of Us Program showed 58 percent of adults surveyed would like to use some sort of wearable fitness tracker to track their health.[10] And, patients increasingly want to be involved in their health decisions, too. According to the Personalized Care Institute, a 2022 survey showed that 44.6 percent of patients would like to be more involved than they currently are.[12] They want to be proactive with their healthcare — and their future. Longevity medicine gives patients the information they need to understand their bodies better, and empowers them to make decisions that are best for them. The data collected helps inform lifestyle choices, direct healthcare decisions and improve quality of life.

- *Advanced laboratory testing:* Blood panels check for chronic disease indicators, metabolic dysfunction and inflammatory biomarkers.
- *Functional and physical testing:* Cardiorespiratory fitness, strength and mobility are tested to assess functional age.
- *Imaging*: Whole-body magnetic resonance imaging (MRI), 3T MRIs, computer tomography (CT) scans, coronary CT angiograms and more provide detailed imaging that detects age-related diseases in their earliest stages.
- *High-resolution molecular profiling (multi-omics)*: Analysis of genomics, epigenetics, transcriptomics, proteomics and metabolomics assess molecular aging. Not only do these tests make it possible to identify an individual's susceptibility to disease, but they also point to the therapeutic interventions that may be most successful and the epigenetic markers that can help predict life expectancy.[9,12]
- *Continuous data collection*: The explosion of wearable health trackers use data to provide insight and encourage behavior change as well. What's more, wearables give unprecedented access to real-time health data. According to Harvard Medical, "The newest crop of wearable devices is optimized to capture a variety of distinct patient health indicators that can provide a clear snapshot of a person's health status during everyday activities in a more detailed way than in-person measurements typically can provide."[13] Devices such as smartwatches and smart rings gather data points in real-life settings in real time. They track activity levels, measure sleep quality and quantity, assess heart rate and other vital signs, which together paint a more realistic, holistic picture of patient health than can be done in a single healthcare visit.[13]
- *Artificial intelligence (AI)*: A team of experts from the Aging Research and Drug Discovery Meeting say AI is central to longevity medicine. "AI-driven biomarker discovery is increasingly recognized as a cornerstone for advancing personalized medicine and improving healthcare outcomes."[14] AI is being used in aging research, biomarker identification, drug discovery and even longevity science itself. "Machine learning algorithms, deep learning methods and big data analytics have facilitated the discovery of novel biomarkers of aging crucial for disease diagnosis, prognosis and predicting treatment outcomes."[14] AI-powered predictive analytics analyze patient health history, lifestyle and known risk factors, along with data gathered from wearable devices, to identify potential health issues before they become serious problems.[15]

Together, all of this information gives providers insight into a particular patient's unique health, enabling the healthcare team to give personalized recommendations for supporting health going forward.

Longevity Medicine for All?

Longevity medicine isn't the norm — yet. Barriers to access remain, but there's a growing consumer interest in and demand for preventive, proactive healthcare, and experts foresee a future in which the healthcare model is proactive and preventive, optimizing every individual's health. In fact, Saeju Jeong,

co-founder and executive chairman of Noom, a digital health and wellness company, described the consumer-led trend toward preventive medicine as a prelude to a deeper reimagining of healthcare delivery, one that is led by patients. "We need a healthcare system that acts before a crisis, not after it. A system that uses diagnostics to direct attention, uses medication to unlock agency and uses daily habits to make gains durable," Jeong says.[16]

According to Jeong, the emerging system will be:[16]

- Predictive: Tests identify health issues before they escalate.
- Personalized: Practitioners tailor healthcare plans to each individual patient.
- Longitudinal: Continuous monitoring supports health all year, not just once a year.
- Patient-led: Information empowers patients, giving them more agency.

Toward a Data-Heavy, Patient-Led Future

Although Johnson's dream of immortality isn't the end goal of longevity medicine, the data-driven optimization of patient health — and thus a far better quality of life — sure is. The days of reactive healthcare — addressing health issues once they arise — are numbered. While aging itself is certain, aging *well* is increasingly optional. ❖

References

1. Johnson, B. Don't Die: Blueprint Protocol. Accessed at protocol.bryanjohnson.com.
2. Arrazati, DG. The Anti-Aging Debate Everyone's Talking About: Inside Bryan Johnson's Jubilee Showdown. NAD+ Aging Science, Jan. 19, 2026. Accessed at www.nad.com/news/the-anti-aging-debate-everyones-talking-about-inside-bryan-johnsons-jubilee-showdown.
3. Alter, C. The Man Who Thinks He Can Live Forever. *Time Magazine*, Sept. 20, 2023. Accessed at time.com/6315607/bryan-johnsons-quest-for-immortality.
4. Johnson, B. Don't Die. Accessed at dontdie.com/#blueprint.
5. Gilbert, SF. *Developmental Biology*, 6th ed. Sunderland, MA: Sinauer Associates, 2000. Accessed at www.ncbi.nlm.nih.gov/books/NBK10041.
6. Martinovic, A, Mantovani, M, Trpchevka, N, et al. Climbing the Longevity Pyramid: Overview of Evidence-Driven Healthcare Prevention Strategies for Human Longevity. *Frontiers in Aging*, 2024 Nov. 26, 5:1495029. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC11628525.
7. Centers for Disease Control and Prevention. Mortality in the United States, 2023, December 2024. Accessed at www.cdc.gov/nchs/products/databriefs/db521.htm.
8. Centers for Disease Control and Prevention. About Chronic Diseases, March 4, 2025. Accessed at www.cdc.gov/chronic-disease/about/index.html.
9. Jinfiniti. Longevity Testing Guide: 15 Biomarkers for Healthy Aging, April 25, 2025. Accessed at www.jinfiniti.com/longevity-testing-guide-biomarkers/?srsltid=AfmBOoq_PviQveDLg4kXJCrlSdlDmtjl-sO8jzxFyKdezXH3ghywPkOL.
10. Wearable Fitness Tracker Use in Federally Qualified Health Center Patients: Strategies to Improve the Health of All of Us Using Digital Health Devices. *npj Digital Medicine*, 2022, 5:53. Accessed at www.nature.com/articles/s41746-022-00593-x.
11. Personalized Care Institute. New Data Shows Patients Want More Involvement in Healthcare Decisions. Accessed at www.personalisedcareinstitute.org.uk/2022/09/06/new-data-shows-patients-want-more-involvement-in-healthcare-decisions.
12. Babu, M, and Snyder, M. Multi-Omics Profiling for Health. *Molecular & Cellular Proteomics*, 2023 Jun;22(6):100561. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC10220275.
13. Ellis, LD. Exploring the Promise of Wearable Devices to Further Medical Research. Harvard Medical School Professional, Corporate and Continuing Education, May 19, 2023. Accessed at learn.hms.harvard.edu/insights/all-insights/exploring-promise-wearable-devices-further-medical-research.
14. Lyu, YX, Fu, Q, Wilczok, D, et al. Longevity Biotechnology: Bridging AI, Biomarkers, Geroscience and Clinical Applications for Healthy Longevity. *Aging*, 2024 Oct. 16;16(20):12955-12976. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC11552646.
15. AI in Healthcare: Enhancing Patient Care and Diagnosis. Park University, Dec. 2, 2024. Accessed at www.park.edu/blog/ai-in-healthcare-enhancing-patient-care-and-diagnosis.
16. Preventive Medicine Can Usher in a New Era of Longevity. Here's How. World Economic Forum, Jan. 14, 2026. Accessed at www.weforum.org/stories/2026/01/preventive-medicine-longevity.

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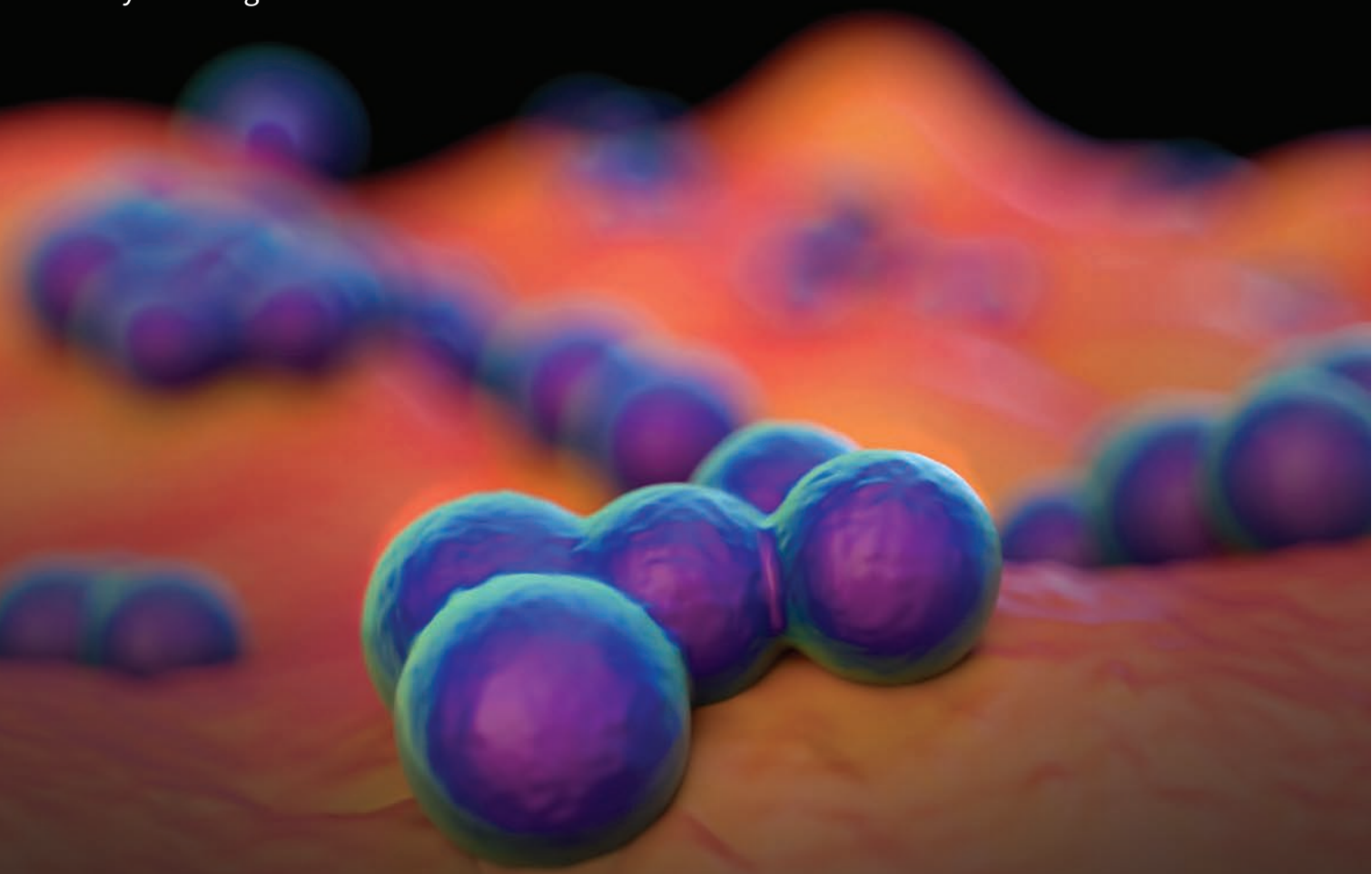
Update on MRSA and MSSA

Staphylococcus continues to be a challenging disease for the medical industry, particularly those that are resistant strains. Here, we discuss the types of Staphylococcus infections, who is most at risk and how it is diagnosed and treated.

By Jim Trageser



A STAPHYLOCOCCUS infection is one of the more common conditions a physician will treat. It can also be among the most challenging. While there are more than 30 different types of Staphylococcus bacteria identified, one species — Staphylococcus aureus — is responsible for most staph infections in humans. In fact, about 30 percent of all people have Staphylococcus aureus on their skin or in their nasal passages, where it simply lives without harming the host most of the time.[1]

While most Staphylococcus aureus infections will manifest as mild skin infections easily treated with standard antibiotics, when it gets into the bloodstream, it can be life-threatening — with sepsis, endocarditis or osteomyelitis common complications. There are more than 100,000 of these cases each year in the United States alone, with about one-fifth proving fatal.[2] Anther potential lethal Staphylococcus aureus complication is toxic shock syndrome.[3]

Staphylococcus aureus can also cause food poisoning and pneumonia. Food poisoning, which is the body's reaction to toxins produced by the Staphylococcus bacteria, is only rarely serious,[4] while Staphylococcal pneumonia is much less common although quite dangerous even with prompt treatment.[5]

Staphylococcus aureus is easily spread through physical contact — primarily skin to skin, although the bacteria can

also survive on other items, such as furniture, clothing, door knobs, etc., long enough to be passed on.[6] Its ability to form biofilms also makes it notoriously difficult to fully remove from invasive medical devices, including endoscopes, invasive ventilators and implants.[7]

Then there is this: Staphylococcus aureus has developed the ability to bypass much of the human body's intricate immune system. These bacteria secrete enzymes that attack the body's defenses.[8]

If all that isn't enough of a challenge for the medical community, it is also one of the most rapidly adaptable types of bacteria, with strains arising that can resist most drugs introduced to combat it to date. As one researcher wrote, "Staphylococcus aureus is notorious for its ability to become resistant to antibiotics."[9]

Suddenly, that mild skin infection isn't quite as easy to treat, and the more serious infections are degrees more dangerous. These resistant strains have not only proven to be the bane of healthcare facilities where they have thrived despite all efforts at controlling them, but they have now spread into the community causing physicians new challenges in trying to treat an infection that does not respond to readily available treatments.

What Is MRSA?

Staphylococcus was first described in 1880 by Scottish physician Alexander Ogston, who noticed clusters of bacteria while using his microscope to examine samples taken from surgical wounds that had become infected.[10] Four years later, German doctor Friedrich Julius Rosenbach divided Staphylococcus into two variants based on the color of their colonies: Staphylococcus aureus for the yellow-colored bacteria, and Staphylococcus albus for the white (later renamed Staphylococcus epidermidis due to its common habitat in the skin).[11]

The only treatment for a Staphylococcus aureus infection in the 19th century was a topical application of carbolic acid, which meant wounds had to be open to treat the infection. The development of penicillin treatments during World War II proved highly effective vs. Staphylococcus aureus — until, just two years after penicillin was first used to fight the disease, resistant strains of Staphylococcus aureus were detected.[10] Other antibiotics were developed to counter this, but in 1961 the first strains that could survive the penicillin derivative methicillin were noted — a mere year after its introduction.[9]

Today, "MRSA" is used as shorthand to denote not only "methicillin-resistant Staphylococcus aureus" but Staphylococcus aureus that is resistant to a variety of antibiotics. And all strains of Staphylococcus aureus are now classified as either MRSA, which is resistant, or MSSA, methicillin-susceptible Staphylococcus aureus, which responds to antibiotic treatment.

Treating patients with a MRSA infection is challenging, as the specific strain may not respond to first-line antibiotics. And in a troubling development, new strains of Staphylococcus aureus have arisen that are resistant to vancomycin, an antibiotic of last resort in treating stubborn cases of MRSA. Vancomycin-intermediate Staphylococcus aureus (VISA) and vancomycin-resistant Staphylococcus aureus (VRSA) were first reported in 2002, and fortunately remain extremely rare.[12] They also are still susceptible to some even newer antiobiotics — for now.

After its discovery in 1961, MRSA was primarily a healthcare setting-acquired condition (HA-MRSA). However, beginning in the 1990s, MRSA spread beyond clinics and hospitals, and now, community-associated MRSA (CA-MRSA) is likely responsible for a majority of total MRSA infections, although Staphylococcus aureus remains the second-leading cause of healthcare-associated infections (HAIs), accounting for some 11 percent of all HAIs, according to the Centers for Disease Control and Prevention (CDC).[13] (The government now divides HA-MRSA into two distinct types: healthcare-associated community-onset [HACO-MRSA] and hospital-onset [HO-MRSA][14].)

A Minnesota Department of Health fact sheet defines CA-MRSA as those that occur in patients with a positive MRSA culture test who have not had any of the following events within the previous year:[15]

- Hospitalization or surgery
- Residence in a long-term care facility
- Permanent catheter or other percutaneous device
- Dialysis
- A positive MRSA culture within 48 hours of hospital admission

That same fact sheet points out some differences between CA-MRSA and HA-MRSA:

- CA-MRSA patients are younger on average.
- HA-MRSA infections are more resistant to treatment.
- There are genetic differences between the two strains.

How Prevalent Is MRSA?

While as noted above roughly 30 percent of all people carry Staphylococcus aureus, CDC estimates only 2 percent of the population carries MRSA on their skin or in their nasal passages, which would make it roughly 6.5 percent of all people carrying Staphylococcus aureus.[16] As with nonresistant Staphylococcus aureus, most of these will never develop an active infection.

A recent study from Japan found that from 2014 to 2019, HA-MRSA decreased

from 50.2 percent to 19 percent of documented MRSA cases, while CA-MRSA increased from 44.7 percent to 76.4 percent of all MRSA cases in the Kyoto and Shiga regions.[17] A 2016 study from California showed a similar pattern of CA-MRSA cases becoming more common while HA-MRSA decreased, likely due to increased emphasis on fighting HAIs.[18]

The overall number of people diagnosed with MRSA was declining before the COVID-19 panic, when it shot up. CDC estimates that as of last year, MRSA caused more than 70,000 severe infections, with some 9,000 of them proving fatal.[19]

How Does Resistance Develop?

In complex organisms, species more or less die with the genome they're born with (outside random mutations in individual cells) — meaning species only gain native resistance to disease vertically, from surviving members passing their resistant genes to their offspring.

However, Staphylococcus aureus possess the ability to engage in horizontal gene transfer where bacterial cells acquire and deploy DNA from other organisms. This allows for a gene that confers resistance to a particular drug to be spread throughout a population rather quickly. The methods of horizontal gene transfer include:[20]

- Transduction: bacteriophages (viruses that infect bacteria) that carry DNA from one to another
- Transformation: free DNA molecules are absorbed through a cell's outer membrane
- Conjugation: two bacteria temporarily connect and exchange DNA

Researchers believe that transduction is the most likely path for sharing genes between members of Staphylococcus aureus.[21]

So not only do resistant bacteria survive exposure to an antibiotic and share that with their descendants, but they can actually spread their resistance to their neighbors that weren't previously resistant.

With penicillin, strains of Staphylococcus aureus that possessed the blaZ gene were able to create an enzyme that counteracted the antibiotic properties of penicillin. Later, some strains had the mecA gene that changed their cellular membrane to remove the protein that methicillin would bind to in order to destroy the bacteria.[22]

Who Is Most at Risk from MRSA?

The risk factors of contracting MRSA vary significantly between CA-MRSA and HA-MRSA.

Of course, patients with a compromised immune system are most at risk, regardless of strain or setting.

For HA-MRSA, anyone who is hospitalized is at greater risk of contracting a resistant staph infection, as are those admitted to a long-term care facility. But the elderly are at heightened risk — as is anyone with invasive medical devices, including intravenous lines, urinary catheters or mechanical ventilators. Mechanical implants, including artificial joints, also increase one's risk.

Risk factors for CA-MRSA include injecting illegal drugs, working around farm animals, playing contact sports or having a chronic skin condition.[6]

MRSA Symptoms and Progression

Symptoms of a Staphylococcus aureus infection will depend on where the infection is manifesting. They range from pimples or boils on the skin, to shivering, confusion or shortness of breath for a blood infection. Infected surgical sites are not uncommon, with redness and swelling, and infections of medical implants may include internal pain in addition to fever and swelling.

The symptoms do not vary depending on whether the infection is caused by a MRSA or MSSA variant. If untreated, or if treatment is unsuccessful, systemic staph infections can progress rapidly and quickly become life-threatening. Once in the bloodstream, the bacteria can infect organs such as the heart valves or bones, or it can lead to sepsis.

MRSA Diagnosis and Treatment

Because treatment will vary between resistant and susceptible strains, it is crucial that culture samples be tested to confirm both Staphylococcus aureus infection, as well as whether it is resistant.[23] In cases of severe infection, a polymerase chain reaction test may be called for since results can be available in just a few hours, allowing for treatment to begin quickly.

MSSA will be treated by draining and cleaning an infected skin lesion. Mild skin infections may be treated by topical ointments containing an antibiotic, while more serious infections will typically call for oral or intravenous application. Antibiotics should be employed only if that is not successful. Antibiotics typically prescribed for MSSA are dicloxacillin, erythromycin, nafcillin and clindamycin.[24]

If a blood culture tests positive, other symptoms may call for additional tests such as imaging to look for oseomyelitis or renal or splenal infarct. If there is risk of endocarditis, an echocardiogram may be called for.[25] The above antibiotics are still likely to be called for, but will most certainly be given intravenously.

MRSA treatment will follow the same path as MSSA, but with a different set of antibiotics — possibly a

"cocktail" of antibiotics to overwhelm the bacteria's defenses. The antibiotics could include vancomycin, rifampin, trimethoprim/sulfamethoxazole (TMP/SMX), ceftaroline linezolid, daptomycin, doxycycline and/or delafloxacin.

When the infection is in the bloodstream, hospitalization will generally be required, with careful observation of the patient to catch any worsening of symptoms.[26]

For the new, even more resistant VISA (vancomycin-immediate Staphylococcus aureus) and VRSA (vancomycin-resistant Staphylococcus aureus) variants, there is no set recommended treatment due to the very small number of people who have contracted these infections. Instead, a physician will consider the many antibiotics that are effective in treating MRSA. Ceftaroline has shown promise, as have televancin, quinupristin/dalfopristin and other combinations of available antibiotics, which are discussed in a paper from the University of Nebraska Medical Center.[27]

There is also evidence that intravenous immune globulin is an effective antibody therapy for CA-MRSA necrotizing pneumonia, particularly when used in conjunction with antibiotics.[28]

MRSA Prevention

While there is ongoing research into a vaccine for Staphylococcus aureus, at present the best preventive measures are hygienic: washing hands after touching someone else; avoiding sharing personal items such as razors, towels or needles; keeping wounds clean and properly dressed; and showering immediately after contact sports.

Healthcare facilities can do their part by following local, state and national protocols on disinfection and sterilization, as well as following infection control measures with patients with easily communicable diseases.

Ongoing Research

On the U.S. Food and Drug Administration's clinicaltrials.gov website, there are hundreds of recent and ongoing experiments into detecting, treating and, hopefully, preventing MSSA, MRSA and VRSA.

One manufacturer is testing a device to detect Staphylococcus aureus in the nose, which could greatly speed up diagnosis.[29]

A German team is studying a new compound, HY-133, as a nasal spray to see if it can prevent Staphylococcus aureus from colonizing the nasal passage of uninfected patients in hospitals.[30]

And an American study is looking at a new phage, AP-SA02, used in conjunction with existing best available therapies to treat Staphylococcus aureus in the bloodstream.[31]

Looking Ahead

While Staphylococcus aureus is a uniquely challenging disease-causing bacteria due to its ability to evade new treatments, as well as the body's own defenses, researchers continue to try to outpace the pathogen's ability to adapt. However, for the foreseeable future, resistant strains of Staphylococcus aureus will continue to challenge physicians to effectively respond to their patients' infections — particularly those that are resistant. ❖

References

1. Centers for Disease Control and Prevention. Staphylococcus Aureus: Staphylococcus Aureus Basics, April 15, 2024. Accessed at www.cdc.gov/staphylococcus-aureus/about/index.html.
2. Centers for Disease Control and Prevention. Vital Signs: Staph Infections Can Kill, March 22, 2019. Accessed at www.cdc.gov/vitalsigns/staph/index.html.
3. Otto, M. Staphylococcus Aureus Toxins. *Current Opinion in Microbiology*, February 2014. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC3942668.
4. Centers for Disease Control and Prevention. Staphylococcal Food Poisoning: About Staph Food Poisoning, April 16, 2024. Accessed at www.cdc.gov/staph-food-poisoning/about/index.html.
5. Clark, S, and Hicks, M. Staphylococcal Pneumonia. *StatPearls*, Aug. 8, 2023. Accessed at www.ncbi.nlm.nih.gov/books/NBK559152.
6. Mayo Clinic. Staph Infections. Accessed at www.mayoclinic.org/diseases-conditions/staph-infections/symptoms-causes/syc-20356221.
7. Koo, H, Allan, R, Howlin, R, et al. Targeting Microbial Biofilms: Current and Prospective Therapeutic Strategies. *Nature Reviews Microbiology*, December 2017. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC5685531.
8. Pietrocola, G, Nobile, G, Rindi, S, and Speziale, P. Staphylococcus Aureus Manipulates Innate Immunity Through Own and Host-Expressed Proteases. *Frontiers in Cellular and Infection Microbiology*, May 5, 2017. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC5418230.
9. Chambers, H, and DeLeo, F. Waves of Resistance: Staphylococcus Aureus in the Antibiotic Era. *Nature Reviews Microbiology*, September 2009. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC2871281.
10. Myles, I, and Datta, S. Staphylococcus Aureus: An Introduction. *Seminars in Immunopathology*, March 2012. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC3324845.
11. Cheung, G, and Otto, M. Staphylococcus Epidermidis — Key to Understanding Biofilms, Commensalism, and More. *Journal of Bacteriology*, Aug. 25, 2025. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC12445090.
12. Centers for Disease Control and Prevention. Staphylococcus Aureus Resistant to Vancomycin — United States, 2002. *Morbidity and Mortality Weekly Report*, July 5, 2002. Accessed at www.cdc.gov/mmwr/preview/mmwrhtml/mm5126a1.htm.
13. Centers for Disease Control and Prevention. HAI Pathogens and Antimicrobial Resistance Report, 2018-2021. Accessed at www.cdc.gov/nhsn/hai-report/data-tables-adult/table-3.html.
14. Dall, C. COVID-19 Fueled Increase in Hospital-Onset MRSA, Study Finds. Center for Infectious Disease Research and Policy, May 12, 2025. Accessed at www.cidrap.umn.edu/antimicrobial-stewardship/covid-19-fueled-increase-hospital-onset-mrsa-study-finds.
15. Minnesota Department of Health. Community-Associated Methicillin-Resistant Staphylococcus Aureus (CA-MRSA): Fact Sheet for Healthcare Providers. Accessed at www.health.state.mn.us/diseases/staph/mrsa/mrsahealthcare.html.
16. Centers for Disease Control and Prevention. Clinical Overview of Methicillin-Resistant Staphylococcus Aureus (MRSA) in Healthcare Settings, June 27, 2025. Accessed at www.cdc.gov/mrsa/hcp/clinical-overview/index.html.
17. Kishita, M, Motsumura, Y, Yamamoto, M, et al. Increase in the Frequency of Community-Acquired Methicillin-Resistant Staphylococcus Aureus Clones Among Inpatients of Acute Care Hospitals in the Kyoto and Shiga Regions, Japan. *Journal of Infection and Chemotherapy*, May 2023. Accessed at www.sciencedirect.com/science/article/abs/pii/S1341321X23000211.
18. Sutton, J, and Steiner, C. Hospital-, Health Care-, and Community-Acquired MRSA: Estimates from California Hospitals, 2013. *Healthcare Cost and Utilization Project (HCUP) Statistical Briefs*, October 2016. Accessed at www.ncbi.nlm.nih.gov/books/NBK396238.
19. Centers for Disease Control and Prevention. Infection Control Guidance: Preventing Methicillin-Resistant Staphylococcus Aureus (MRSA) in Healthcare Facilities. Accessed at www.cdc.gov/mrsa/hcp/infection-control/index.html.
20. Stated Clearly. Quick Definition: What Is Horizontal Gene Transfer? Accessed at www.statedclearly.com/videos/quick-definition-what-is-horizontal-gene-transfer.
21. McCarthy, A, Witney, A, and Lindsay, J. Staphylococcus Aureus Temperate Bacteriophage: Carriage and Horizontal Gene Transfer is Lineage Associated. *Frontiers in Cellular and Infection Microbiology*, Feb. 7, 2012. Accessed at www.frontiersin.org/journals/cellular-and-infection-microbiology/articles/10.3389/fcimb.2012.00006/full.
22. Vestergaard, M, Frees, D, and Ingmer, H. Antibiotic Resistance and the MRSA Problem. *Microbiology Spectrum*, March 22, 2019. Accessed at journals.asm.org/doi/10.1128/microbiolspec.gpp3-0057-2018.
23. Penn Medicine. Methicillin-Resistant Staphylococcus Aureus (MRSA). Accessed at www.pennmedicine.org/conditions/methicillin-resistant-staphylococcus-aureus-mrsa.
24. Curtis, L. MSSA: Causes, Symptoms, and Treatments Explained. Health, Jan. 31, 2026. Accessed at www.health.com/mssa-7644007.
25. Abraham, L, and Bamberger, D. Staphylococcus Aureus Bacteremia: Contemporary Management. *Missouri Medicine*, July-August 2020. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC7431060.
26. Cleveland Clinic. MRSA (Methicillin-Resistant Staphylococcus Aureus). Accessed at my.clevelandclinic.org/health/diseases/11633-methicillin-resistant-staphylococcus-aureus-mrsa.
27. Van Roy, Z. #PharmtoExamTable: Vancomycin-Resistant Staphylococcus Aureus- Emergence and Treatment. University of Nebraska Medical Center, Nov. 3, 2022. Accessed at blog.unmc.edu/infectious-disease/2022/11/03/pharmtoexamtable-vancomycin-resistant-staphylococcus-aureus-emergence-and-treatment.
28. Shopsin, B, Kaveri, S, and Bayry, J. Tackling Difficult Staphylococcus Aureus Infections: Antibodies Show the Way. *Cell Host & Microbe*, Nov. 9, 2016. Accessed at www.sciencedirect.com/science/article/pii/S1931312816304449.
29. ClinicalTrials.gov. Evaluation of a Diagnostic Device for Detection of Nasal Staphylococcus Aureus. Accessed at clinicaltrials.gov/study/NCT00406549.
30. ClinicalTrials.gov. First-in-Man Single-Dose and Multiple Dose Study to Evaluate the Safety, Tolerability and Efficacy ofHY-133 (HY-133). Accessed at clinicaltrials.gov/study/NCT06290557.
31. ClinicalTrials.gov. Study Evaluating Safety, Tolerability, and Efficacy of Intravenous AP-SA02 in Subjects with S. Aureus Bacteremia (diSArm). Accessed at clinicaltrials.gov/study/NCT05184764.

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Myths & Facts: Sepsis

Many people are unaware of sepsis and its causes, and others are confused by the many circulating misconceptions. Therefore, it's imperative to educate the public about the facts surrounding this life-threatening illness that often results in death.

By Ronale Tucker Rhodes, MS

SEPSIS HAS continued to challenge the medical profession throughout history. It is a serious life-threatening medical condition triggered by the body's response to infection and dates back some 5,000 years ago. The oldest written mention of sepsis occurred in 3,000 B.C. in a surgery treatise that referred to "48 cases of traumatic wounds, fractures and dislocations in different parts of the body," as well as fever. Sepsis was also cited by physician and philosopher Hippocrates circa 400 B.C. as "dangerous biological decay believed to occur in the colon and release various substances which caused 'auto-intoxication.'"[1]

In 129-199 A.D., Roman pharmacologist Claudius Galenus, known as "Galen," "theorized about sepsis, wound healing and pus which lasted for 1,500 years." The Romans believed sepsis was caused by "invisible creatures that gave off fumes," rather than considering person-to-person contact of infectious disease.[1]

It took until the late 19th and early 20th centuries for sepsis to be better understood. The first consensus as to how sepsis should be defined was developed at a conference in the early 1900s, but it was modified in 2001 to distinguish between an infection, sepsis, severe sepsis and septic shock. Modern guidelines for severe sepsis and septic shock developed in 2003 were modified in 2012. Those included some of the same principles outlined in 1964, including cardiac resuscitation, identifying the pathogen to start targeted treatment and support for the respiratory system. Today, there are newer management techniques.[2]

Sepsis is one of the most frequent causes of death worldwide. Unfortunately, the collection of reliable data is challenging. However, published data in 2020 show there were 48.9 million cases and 11 million sepsis-related deaths worldwide, representing 20 percent of all global deaths, almost half (20 million) of which occurred in children under 5 years of age. Sepsis occurs in an estimated 15 out of every 1,000 hospitalized patients as a complication of receiving healthcare. It can affect any individual worldwide, but significant regional disparities in incidence and mortality exist with the highest rates in lower-middle-income countries.[3] In the U.S., at least 1.7 million adults develop sepsis each year, and at least 350,000 adults who develop sepsis die during hospitalization or are discharged to hospice.

While most sepsis cases start before a patient goes to the hospital, one in three who dies in a hospital had sepsis

during their hospital stay. In addition, most people who develop sepsis have at least one existing medical condition such as chronic lung disease or a weakened immune system. And, nearly a quarter to a third of people with sepsis had a healthcare visit in the week before they were hospitalized.[4] On average, the hospital-wide cost of sepsis is estimated to be more than $32,000 per patient in high-income countries.[3]

Unfortunately, many myths surround sepsis that can delay diagnosis and treatment both at the patient and clinical level. And, with sepsis causing more deaths than prostate cancer, breast cancer and AIDS combined,[5] it is more important than ever to separate myth from fact.

Separating Myth from Fact

Myth: Sepsis is just a bad infection.

Fact: According to the Sepsis Alliance, sepsis isn't actually an infection, but rather the body's overreaction to an infection, causing the body to injure its own tissues and organs.[6] Although the words "sepsis" and "infection" are often used interchangeably, the word "sepsis" always indicates the presence of an infection, but the word "infection" does not indicate sepsis. Sepsis is actually the most severe form of infection with some degree of organ dysfunction present, with the patient presenting as hypotensive, oliguric and/or obtunded.[7]

Myth: Sepsis is always obvious.

Fact: Sepsis is not always obvious because its symptoms are very similar to other illnesses. As such, sepsis can often be overlooked. And symptoms can occur anywhere on a person's body. Common symptoms of sepsis include:[8]

- Reduced energy or weakness
- Low blood pressure
- Fever or hypothermia (extremely low body temperature)
- Shortness of breath or hyperventilation (rapid breathing)
- Extreme discomfort or pain
- Urinary issues such as reduced or increased urge to urinate
- Chills or shaking
- Sweaty skin
- Confusion and agitation

The Sepsis Alliance suggests using the word TIME to remember the most common sepsis symptoms:[9]

T: Is the person's temperature higher or lower than normal?

I: Did the person have any signs of an infection, and does he or she now?

M: Is there any change in the person's mental status such as confusion or excessive sleepiness?

E: Is the person experiencing any extreme pain or illness, even a feeling of "I feel I might die"?

Myth: Sepsis is only developed by coming into contact with bacteria.

Fact: Bacterial infections do cause most cases of sepsis, but they are not the only cause. Sepsis can also be caused by viral or fungal infections. According to the University of Chicago, the most common sites of infection include:[10]

- Lungs (i.e., pneumonia)
- Skin (i.e., burns, wounds, cellulitis)
- Bloodstream
- Brain or spinal cord
- Gastrointestinal system (i.e., appendicitis, peritonitis, gall bladder or liver infections)
- Digestive system
- Kidneys, bladder or other parts of the urinary system
- Catheter sites

Myth: Only old people or people with preexisting conditions get sepsis.

Fact: Sepsis can affect anyone, even those in good health. People who are at high risk of sepsis include those who:[11]

- Are over age 65
- Are pregnant
- Have certain medical conditions such as diabetes, obesity, cancer and kidney disease
- Have a weakened immune system
- Are in the hospital for other medical reasons
- Have severe injuries such as large burns or wounds
- Have catheters, IVs or breathing tubes
- Newborns and infants

Myth: Sepsis only happens in hospitals.

Fact: While sepsis often develops in hospitalized patients, it can begin anywhere. In fact, 87 percent of cases start in the community rather than the hospital, according to the Centers for Disease Control and Prevention.[6]

Sepsis is a life-threatening illness and continues to be a challenge for the healthcare profession.

Community-acquired sepsis is typically diagnosed within the first 48 to 72 hours of hospitalization. According to a report from The Medical Algorithms Company titled "The Many Faces of Sepsis (5): Progression from a Community Acquired Infection," while there are a wide range of community infections associated with sepsis, some common causes include:[12]

- Pneumonia
- Urinary tract infection
- Cholecystitis
- Soft tissue infection
- Intra-abdominal infections such as bacterial enteritis or diverticulitis

Myth: Persons being treated with

antibiotics can't get sepsis.

Fact: While antibiotics treat many bacterial infections, sepsis can still develop if an infection worsens or when the cause is viral or fungal.

According to the Sepsis Alliance, viral infections are usually treated by managing the symptoms using over-the-counter pain relievers to ease pain and reduce fever, rest for fatigue, etc., until the virus is gone. Some medications may speed healing if they are taken early enough after exposure to the virus, including medications for influenza and shingles (herpes zoster).[13]

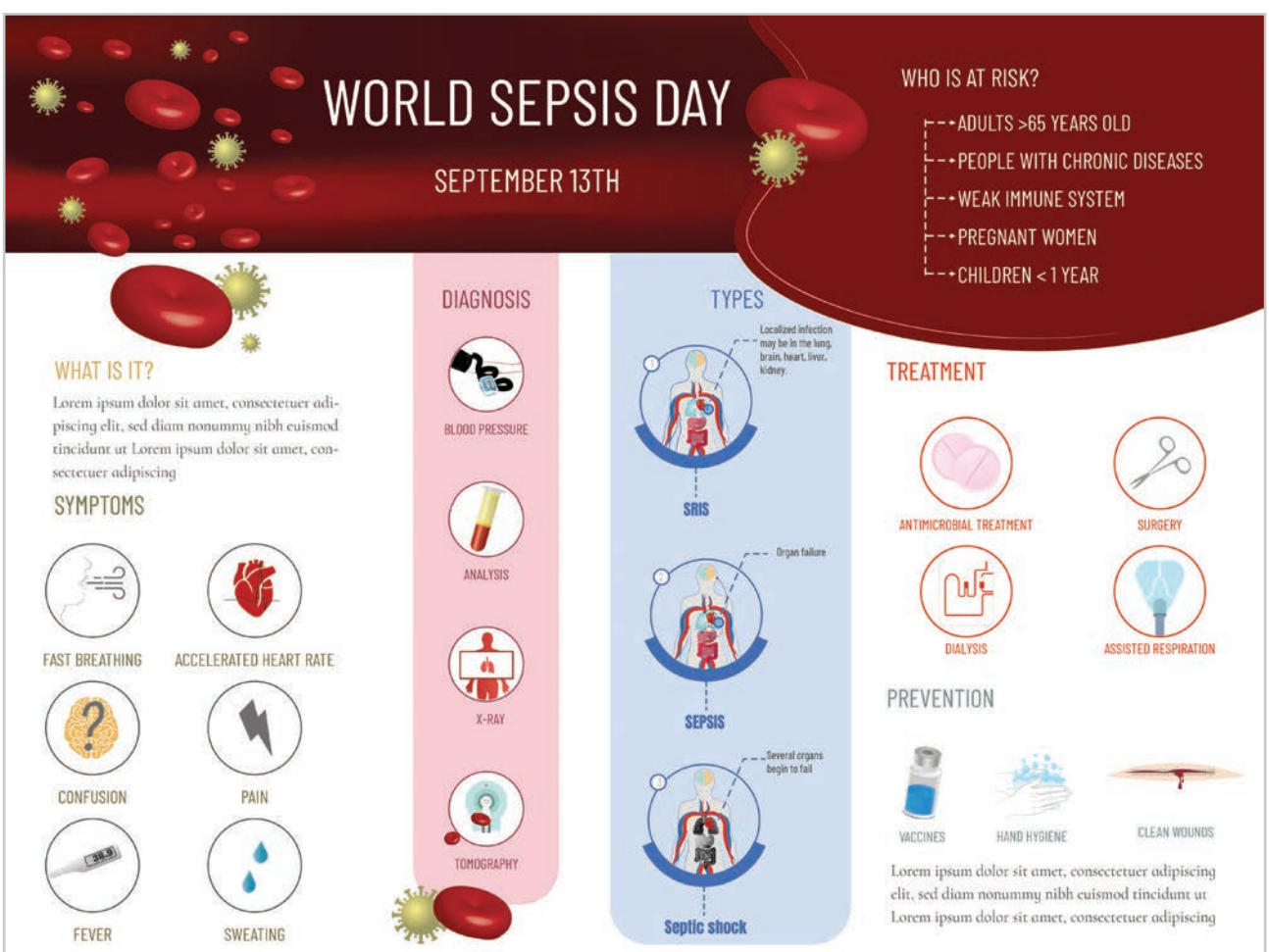
Also according to the Sepsis Alliance, fungal infections are treated with antifungal medications, such as creams, ointments, suppositories or pills, specific to the particular fungus that caused the infection. However, antibiotics are not used for fungal infections because they are not effective.[14]

Myth: Sepsis is contagious.

Fact: Sepsis can't be spread to other people. However, the viral or fungal infections that lead to sepsis are contagious and can spread from person to person. As mentioned previously, bacterial infections cause most cases of sepsis, but sepsis can also be a result of other infections, including fungal and viral infections.

Myth: There is no way to prevent or lessen the effects of sepsis.

Fact: The only way to prevent sepsis is to prevent infections. Vaccinations are one way to significantly reduce the risk of infections caused by certain illnesses. According to the End Sepsis website, the most important vaccines for reducing the risk of getting sepsis include pneumococcal vaccines since pneumonia is a leading cause of sepsis; influenza vaccines since the flu can lead to complications such as pneumonia, which can progress to sepsis; meningococcal vaccines; the measles, mumps and rubella vaccine;



and other vaccines, such as those for Haemophilus influenzae type b (Hib), varicella (chickenpox) and COVID-19 vaccines, which also contribute to reducing the risk of infections that could lead to sepsis.[15]

In addition, a new promising medicine, Tyzavan (vancomycin injection), is an FDA-approved, ready-to-infuse, room-temperature stable formulation of vancomycin used to treat serious bacterial infections. It was launched by Hikma Pharmaceuticals in late 2025, and is indicated for septicemia, endocarditis and other serious infections in patients 1 month and older.[16]

Myth: Sepsis cannot be overcome.

Fact: Sepsis is curable if it's treated on time. There are three stages of sepsis:[8]

- Sepsis: when an infection enters the bloodstream and causes inflammation
- Severe sepsis: when sepsis begins affecting organ function
- Septic shock: when sepsis causes a drop in blood pressure and complications such as organ dysfunction, heart failure or respiratory failure, stroke or even death

Myth: If sepsis is suspected, treatment should begin only after testing.

Fact: Because sepsis is a serious and life-threatening illness, it's critical that people are treated in a timely manner, and that means getting treatment as soon as sepsis is suspected rather than waiting for a diagnosis of sepsis. Sepsis is known as the "silent killer" for good reason, because it's often hard to detect.

According to the Sepsis Alliance, treatment may include broad-spectrum intravenous antibiotics, which are the first-line medications that work against several of the more common bacteria; IV fluids to help keep blood pressure from dropping dangerously low, causing shock; and oxygen, either by mechanical ventilator, mask or nasal cannula, to ensure the body has enough oxygen in its system.[17] Some patients may require an operation or procedure to control the infection.

Dispelling the Myths Now

Sepsis is a life-threatening illness and continues to be a challenge for the healthcare profession. Many people are simply unaware of it and its cause, and others are confused by its many circulating misconceptions. As such, it's imperative to educate the public about the facts surrounding this illness that often results in death.

In 2024, the Sepsis Alliance conducted its annual awareness survey and found that 69 percent of U.S. adults are aware of the term "sepsis," up significantly from 63 percent in 2023 and in contrast to its first survey in 2007 when only 16 percent were aware of the term "sepsis." Since its founding in 2007, the Sepsis Alliance has "implemented awareness-raising campaigns, prioritizing Spanish-language materials and outreach to underserved communities in the last several years." However, according to the alliance, the survey revealed striking misconceptions about infections and sepsis that showed most people (77 percent) do not believe or do not know that influenza can progress to sepsis, or haven't heard the term "sepsis." In addition, 82 percent do not believe or do not know that vaccines can prevent someone from getting sepsis.

While the alliance's website explains that this progress is encouraging, it adds that "there is a need for additional education and action." According to the site, a national sepsis action plan could save thousands of lives from sepsis each year, citing one example from the Centers for Disease Control and Prevention's 2012-2018 TIPS education campaign featuring "real people from many different backgrounds living with serious long-term health effects from smoking and secondhand smoke exposure" that is estimated to have helped one million people successfully quit smoking. A National Sepsis Action Plan, supported by government agencies, media and multiple partners, it says, would provide accessible education and resources in an effort to increase knowledge and awareness of sepsis.

More information on how healthcare providers can help educate and spread awareness about the seriousness of sepsis can be found on the alliance's website at www.sepsis.org/news/sepsis-awareness-reaches-69-while-misconceptions-about-sepsis-and-infections-exist.[18] ❖

References

1. Webb, J. Sepsis Biomarkers: Tracing the Evolution, A Historical Perspective. Epi Medicine. Accessed at epidisease.com/en/2023/10/01/tracing-the-evolution-of-sepsis-biomarkers-a-historical-perspective.
2. Ryding, S. Sepsis History. News Medical Life Sciences, updated Sept. 11, 2018. Accessed at www.news-medical.net/health/Sepsis-History.aspx.
3. World Health Organization. Sepsis. Accessed at www.who.int/news-room/fact-sheets/detail/sepsis.
4. Centers for Disease Control and Prevention. About Sepsis. Accessed at www.cdc.gov/sepsis/about/index.html.
5. Thomas, P. Myths and Facts Surrounding Sepsis. University of Florida Health, Sept. 26, 2019. Accessed at ufhealth.org/stories/2019/myths-and-facts-surrounding-sepsis.
6. Jones, A. Myth vs. Fact: Debunking Common Misunderstandings About Sepsis. Moffitt Cancer Center, Sept. 9, 2025. Accessed at www.moffitt.org/endeavor/archive/myth-vs.-fact-debunking-common-misunderstandings-about-sepsis.
7. Vincent, JL. Sepsis and Infection: Two Words That Should Not Be Confused. *Frontiers in Medicine*, 2023 Mar 9;10:1156732. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC10033658,
8. Top 5 Myths Busted About Sepsis. Dr. Lal Pathlabs, Dec. 5, 2024. Accessed at www.lalpathlabs.com/blog/myths-about-sepsis.
9. Sepsis Alliance. What Is Sepsis? What It Is and What It Isn't, Dec. 14, 2018. Accessed at www.sepsis.org/news/what-is-sepsis-what-it-is-and-what-it-isnt.
10. University of Chicago Medicine. Sepsis. Accessed at www.uchicagomedicine.org/conditions-services/sepsis.
11. Cleveland Clinic. Sepsis, updated, Jan. 19, 2023. Accessed at my.clevelandclinic.org/health/diseases/12361-sepsis.
12. The Medical Algorithms Company. The Many Faces of Sepsis (5): Progression From a Community Acquired Infection. Accessed at blog.medicalalgorithms.com/community-acquired-infection.
13. Sepsis Alliance. Sepsis and Viral Infections: Treatment. Accessed at www.sepsis.org/sepsisand/viral-infections..
14. Sepsis Alliance. Sepsis and Fungal Infections: Treatment. Accessed at www.sepsis.org/sepsisand/fungal-infections.
15. End Sepsis. Sepsis and Vaccines. Accessed at www.endsepsis.org/what-is-sepsis/sepsis-and-vaccines.
16. Hikma Receives FDA Approval for TYZAVAN™ (Vancomycin Injection, USP) in the U.S. Hikma press release, July 2, 2025. Accessed at www.hikma.com/news/hikma-receives-fda-approval-for-tyzavan-vancomycin-injection-usp-in-the-us.
17. Sepsis Alliance. Treatment. Accessed at www.sepsis.org/sepsis-basics/treatment.
18. Sepsis Awareness Reaches 69%, While Misconceptions About Sepsis and Infections Exist. Sepsis Alliance, Sept. 13, 2024. Accessed at www.sepsis.org/news/sepsis-awareness-reaches-69-while-misconceptions-about-sepsis-and-infections-exist.

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Sepsis: *A Patient's Perspective*

By Trudie Mitschang

KIMORA BRANCH never imagined a routine illness could nearly cost her life. As a college student living in a dorm, she came down with strep throat and pneumonia — conditions she had experienced before. This time, however, the symptoms were far more severe and alarming. "It would take me half an hour just to push myself out of bed to go to the bathroom," Kimora recalled. "My ribs ached from coughing so violently. I couldn't sleep more than 30 minutes at a stretch without waking up drenched in sweat or shivering uncontrollably."

Her fatigue was overwhelming, and even basic tasks became monumental challenges. Chores she normally handled without thinking, like carrying groceries or drinks, became nearly impossible. On one occasion, when she ran out of beverages in her dorm, she ordered two smoothies — knowing she wouldn't be able to carry anything heavier upstairs. By the time she returned, she nearly lost consciousness. "I had to practically crawl back to my room," she said.

Initially, Kimora sought care at her university's Student Health Center. She was prescribed a short course of antibiotics and sent home. But her symptoms only worsened. Concerned, her mother, a former nurse, urged her to get additional treatment, warning that the prescribed medication might not be sufficient. Attempts to speak directly with a doctor initially met with resistance. "I truly felt at my lowest," Kimora said. "I kept telling them I was getting worse, not better. I didn't feel like anyone was really listening."

Eventually, she sought care at a hospital emergency room. There, the attending physician delivered a sobering warning: "I don't want to scare you, but you could die." Within hours, Kimora was admitted and diagnosed with sepsis.

Sepsis is a life-threatening condition in which the body responds improperly to an infection. According to the Mayo Clinic, this abnormal response triggers widespread inflammation, which can lead to organ failure and, in severe cases, death. When sepsis progresses to septic shock, blood pressure drops dramatically, making the condition even more dangerous. "Sepsis is basically your body going haywire because of an infection — overreacting or sometimes underreacting," Kimora explained. "It's scary because it can happen from practically any infection."

Despite the severity of her illness, she admitted she didn't understand the danger at the time. "I didn't even know what sepsis was until I was in the hospital," she said.

Even after her discharge, Kimora's struggles continued. She was later diagnosed with post-sepsis syndrome, a condition characterized by lingering complications such as chronic fatigue, persistent pain, cognitive challenges and emotional strain. "The reason I went to the hospital was sepsis, and I almost lost my life," she said. "A year later, I was still dealing with the aftermath. It's been a long road, and in many ways, my battle with this infection isn't over yet."

Motivated by her experience, Kimora turned survival into advocacy. She founded SHINE, the nation's first collegiate sepsis awareness club at the University of Alabama. The organization's mission is to educate students and the wider community about the signs, risks and long-term impacts of sepsis. Through SHINE, she partners with campus groups to deliver educational presentations, host awareness events and support fundraising initiatives for the Sepsis Alliance. The club also leverages social media to reach beyond the campus community. "We get a lot of 'What even is sepsis?' moments," Kimora said. "If someone Googles it after seeing our page, that's already a step toward saving lives."

Her advocacy work has even taken her to Capitol Hill, where she met families who lost loved ones to sepsis, including the father of a 4-year-old girl who died within hours of diagnosis. "Over 300,000 people die from sepsis every year," Kimora noted. "They can't speak for themselves. I'm fortunate to have survived and to use my voice for those who can't."

Looking ahead, she hopes to expand SHINE nationwide. "My long-term goal is to have a chapter in every state," she said. "It's an ambitious mission, but it's absolutely necessary."

At the heart of her advocacy is a simple belief: Education can save lives. "Just knowing what sepsis is and talking about it can make all the difference," Kimora said. "I believe five minutes of education can stick with someone forever — and those five minutes could be the difference between life and death."

Through her journey from patient to advocate, Kimora embodies resilience and purpose. Her story is a stark reminder of how quickly common illnesses can become life-threatening — and how awareness and action can make a profound difference. ❖

REFERENCE: 1. TYZAVAN® (VANCOMYCIN INJECTION, USP). [PACKAGE INSERT]. HIKMA PHARMACEUTICALS USA INC.

Important Safety Information for TYZAVAN™ (vancomycin injection, USP):

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Sepsis: *A Physician's Perspective*

MATTHEW DETTMER, MD, serves as a staff physician in the Critical Care Medicine and Emergency Medicine departments and as co-medical director of the Sepsis Emergency Response Team at the Cleveland Clinic main campus.

BSTQ: How is sepsis typically defined for diagnosis?

Dr. Dettmer: There are a couple of different ways clinicians define sepsis. Over the last 25 years, especially since the early 2000s, there have been important studies that taught us not only how to define sepsis, but also which interventions help prevent deaths from sepsis. In parallel, the U.S. government became increasingly aware of the risk sepsis poses to patients and worked to standardize care nationally.

As a result, there are now multiple definitions in use. One is the international consensus definition released in 2016, known as Sepsis-3. Another uses SIRS criteria — Systemic Inflammatory Response Syndrome — which informs many regulatory and reporting efforts. These definitions exist for different purposes, which is why clinicians may refer to more than one framework when diagnosing sepsis.

BSTQ: Which patient populations are at higher risk of developing sepsis and/or having worse outcomes?

Dr. Dettmer: Patients with underlying conditions are at higher risk. For example, patients with cancer who are receiving chemotherapy often have suppressed immune systems. If they develop an infection that progresses to sepsis, their outcomes can be worse compared to patients without those underlying conditions.

Another risk factor depends on where sepsis develops and where patients receive their initial care. Most sepsis cases in the U.S. develop in the community, and those patients come to the emergency department for treatment. That's often referred to as community-onset sepsis or present-on-admission sepsis. In contrast, some patients develop sepsis after they are already hospitalized for another condition, such as heart failure or cancer. This is called hospital-onset sepsis, and while that group is smaller, it carries a higher mortality rate. That makes it a particularly important population for us to understand and target with focused interventions.

BSTQ: Why do patients who develop sepsis in the hospital have a higher mortality rate?

Dr. Dettmer: Even though hospital-onset sepsis represents a smaller proportion of total cases, the higher mortality makes it an especially important group to study. We need to better understand what contributes to those worse outcomes and whether different strategies are needed for that population compared to community-onset sepsis.

BSTQ: Tell us about the Sepsis Emergency Response Team (SERT).

Dr. Dettmer: SERT's focus is to identify and manage patients who show early signs of sepsis on the regular nursing floors at our main campus. In a hospital of our size, there are large populations of patients receiving care in different settings: the emergency department, the nursing floors and the intensive care unit. Each environment is different, so it's important to have dedicated workflows that ensure evidence-based sepsis care is delivered effectively in each setting. We primarily use an electronic screening mechanism to identify patients at risk. Our physician assistants and nurse practitioners then evaluate those patients, work with the primary care teams and determine whether symptoms are due to sepsis or another condition. If it is sepsis, we help ensure timely, evidence-based interventions are put into place to improve outcomes.

BSTQ: What is currently being done to improve sepsis identification and care?

Dr. Dettmer: One of the ongoing challenges in sepsis care is balancing sensitivity and specificity — identifying patients early without overwhelming clinicians with alerts that aren't meaningful. A lot of our current work focuses on improving how we identify patients who truly need intervention. We have teams dedicated to analyzing data, and we are increasingly deploying new technologies, including artificial intelligence, to help screen patients. Rather than relying on single abnormal numbers, these tools help us understand the full context of a patient's condition and alert providers more intelligently.

BSTQ: Any closing thoughts on sepsis care?

Dr. Dettmer: The struggle against sepsis continues. There are still opportunities to improve outcomes, particularly in specific high-risk populations. Remaining vigilant, innovative and thoughtful about how we approach this disease process is essential as we continue that work. ❖

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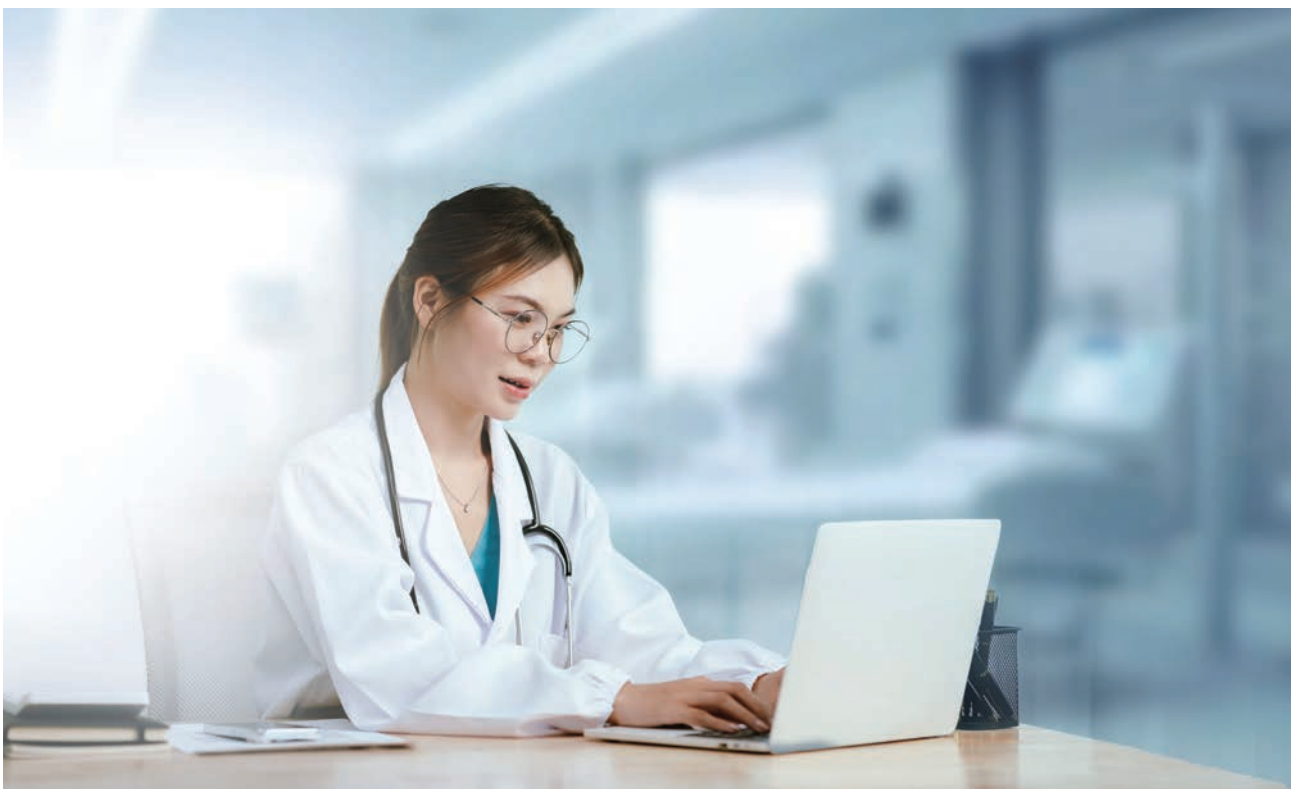
VAERS: The Role of Healthcare Professionals in Vaccine Safety Monitoring

By Brian Gaul, PharmD



VACCINES SAVE lives, but they come with risks. For children born from 1994 to 2023, vaccines prevented 508 million illnesses and 32 million hospitalizations, and saved 1.1 million lives in the United States.[1] Unfortunately, vaccines also cause undesired effects and must be monitored.

Surveillance of vaccine-related adverse events does not end when the U.S. Food and Drug Administration (FDA) approves them for use in the general population. Healthcare professionals play a key role in monitoring ongoing safety signals through the Vaccine Adverse Event Reporting System (VAERS). VAERS allows healthcare providers, patients and parents/caregivers to report adverse health events that occur during or after vaccination. It is a tool for the Centers for Disease Control and Prevention (CDC) and FDA to monitor vaccine safety.[2]

By definition, "vaccine adverse events" occur near the time of the vaccine but may or may not be caused by it. These events are also termed "adverse events following immunization," abbreviated AEFI.[2] The Council for International Organizations of Medical Sciences (CIOMS) defines an AEFI as "… any untoward medical occurrence which follows vaccination and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory findings, symptoms or disease."[3] Product quality defects, vaccination errors and anxiety reactions are also classified as AEFIs. When a causal link is discovered between a vaccine and an adverse event, it is termed a "vaccine adverse effect" or "vaccine adverse reaction."[2]

Reports to VAERS are voluntary and "spontaneous," meaning there is no active effort by the agencies to search for, identify or collect information on vaccine adverse events.[2] CDC and FDA analyze data from VAERS reports and use it to

make decisions on vaccine regulations and regulatory actions.

How Is Vaccine Safety Determined Before Approval?

Researchers identify and characterize the most common adverse events in pre-licensure clinical trials. However, these trials have their limitations, including the following:[2]

- They may miss rare adverse events; these may not occur until larger numbers of people have received the vaccine in the post-marketing setting.
- Vaccine clinical trials often are short — typically a few years. This may not be long enough to detect adverse effects that occur over more extended periods.
- Only healthy individuals receive vaccines in clinical trials, limiting the data available on their effect on groups such as individuals with chronic disease or pregnant women.

VAERS was established to provide robust post-marketing surveillance of vaccines to overcome these deficiencies.

What Is VAERS?

VAERS provides a national early warning system to identify potential problems with vaccines given in the U.S. It involves passive, voluntary reporting.

VAERS was created in 1990 to fulfill a requirement of the National Childhood Vaccine Injury Act of 1986.[2] The main objectives of VAERS include the following:[4]

- Detect new, unusual or rare events.
- Monitor reporting trends that might indicate actual increases in adverse events.
- Identify potential risk factors for adverse events.
- Assess the state of newly licensed vaccines and new recommendations for existing ones.
- Detect and address reporting clusters (groups of reports connected by time or geography, as well as by product-batch-lot specific reporting).
- Discover persistent safe use problems and administration errors.
- Provide a national health safety monitoring system for response to public health emergencies (such as pandemics).

VAERS is best used as a safety monitoring system that helps generate theories on potential connections between vaccines and adverse reactions. Information must be interpreted carefully, as improper use could lead to incorrect conclusions about cause and effect.[2]

How Does VAERS Work?

VAERS reports can be submitted online (vaers.hhs.gov/esub/index.jsp) or by mail or FAX using a PDF form available on the website (See How to File a VAERS Report). Both forms collect information about the patient's background and medical history, the name of the vaccine, the facility where it was given, the date, the adverse event, the health outcomes and other relevant details. If a patient or caregiver makes a report to VAERS, the person receives an acknowledgment letter or email, along with a request for additional information if needed. Agency officials may ask healthcare providers to provide health records upon reporting a serious adverse event.

FDA regulatory definitions are used to classify the reports as "serious" or "nonserious."[2] Serious adverse events include the following: death following vaccination, life-threatening health events, hospitalization following vaccination, prolonged hospitalization if a vaccine was administered while the patient was already hospitalized, a congenital anomaly or birth defect, or long-term disability.[5]

Data from the reports is entered into an electronic database and sent to CDC and FDA for analysis. The agencies also remove information identifying the patients and the reporting source and make the data available to the public. It can be found online via the VAERS website (vaers.hhs.gov/data/datasets.html) and through CDC's searchable Wide-Ranging Online Data for Epidemiological Research (WONDER) tool (wonder.cdc.gov/vaers.html).

How to File a VAERS Report

1. Collect information about the vaccine: date, time and location of administration; healthcare facility location; name and type of vaccine adverse effect or issue; when the adverse event started; patient demographic information and medical history; any medical tests and laboratory results; health outcome; and any other relevant information. Also, be prepared to provide your contact information.
2. Fill out the form online at vaers.hhs.gov/esub/index.jsp or download and fill out the PDF form (vaers.hhs.gov/uploadFile/index.jsp) and upload, mail or FAX to:

   P.O. Box 1100
   Rockville, MD, 20849-1100
   Phone: (800) 822-7967
   FAX: (877) 721-0366

3. Provide follow-up information (such as medical records) if requested (may be uploaded to the VAERS website at vaers.hhs.gov/autoupload.html).

Reports From VAERS Played a Key Part in a Disagreement Over FDA's Role in Vaccine Management in December 2025.

A memo from Vinay Prasad, MD, MPH, head of the FDA's Center for Biologics and Research, proposed sweeping changes to the agency's vaccine approval process, claiming that COVID-19 vaccines had led to the death of "at least 10 children."[6]

- VAERS data was the source of the claim of 10 vaccine deaths. The children died from myocarditis, or inflammation of the heart muscle.
- In response, 12 former FDA commissioners drafted an unusual warning, which was published in the Dec. 3 issue of the *New England Journal of Medicine*. They stated that Dr. Prasad's policy changes and claims pose "a threat to evidence-based vaccine policy and public health security." They warned that if the changes take hold, the consequences could be fewer vaccines, slower vaccine updates and more disease outbreaks.[7]
- The report highlights the importance of properly interpreting VAERS data. While the patients received the COVID-19 vaccine and died of myocarditis, it is problematic to conclude causation from passive data.

How Is the Data Analyzed?

Physicians, epidemiologists and statisticians from CDC and FDA examine the data.[2] They examine the number of reports, the types of reports by severity, the most common adverse events, current versus historical data and reporting trends over time, among other assessments.

Experts at the agencies compare the reported rate in VAERS data to background adverse event rates reported in the medical literature. VAERS adverse event data is usually underreported; therefore, if the reported rate is close to the background rate, it may be a sign of an adverse effect.[2]

After evaluation, if either agency determines a safety signal warrants further investigation, epidemiological studies can be conducted to determine whether the link is causal.[4] These studies use data sources more robust than VAERS reports.

What Are VAERS' Strengths and Limitations?

Notable among VAERS' strengths are its scope, the speed of its safety signal detection and its transparency.[2]

VAERS is a national reporting mechanism. It rapidly identifies adverse effects and safety issues, enabling quick follow-up, data processing and analysis. The agencies make deidentified VAERS reports available to the public on the VAERS and WONDER websites, allowing transparency.

VAERS limitations include possible reporting bias, inconsistent quality and completeness of reports, and issues with determining causality.[2]

Under-reporting of adverse events is a problem in VAERS, especially for common and mild ones such as headache or fever. Reports may also be stimulated by increased media coverage or other public awareness efforts.[2]

The high volume of reports received, estimated at 30,000 annually, makes it challenging to collect follow-up information on all reports. Many are incomplete or low-quality.[2]

As mentioned earlier, VAERS reports cannot establish causality, except in rare cases or when the event is clearly related such as pain and redness at the injection site.

Common Misconceptions About VAERS

The public nature of VAERS data can fuel some misconceptions, including the following:[2]

- The belief that the close timing between an adverse event and a vaccine represents an indication of actual risk.
- The idea that VAERS reports of adverse events correlate with the actual incidence of risk.
- The notion that the rapid increase in the number of reports after the release of a new vaccine means the risk with the vaccine is high; an increase in reports is an expected effect.

The Importance of Healthcare Provider Reporting

The experience and intuition of healthcare professionals make them the first line of defense regarding vaccine issues. They are often the first to bring attention to problems to regulatory officials, and VAERS reporting provides them with an opportunity to impact national healthcare.[2] ❖

References

1. Zhou, F, Jatlaoui, TC, Leidner, AJ, et al. Health and Economic Benefits of Routine Childhood Immunizations in the Era of the Vaccines for Children Program — United States, 1994-2023. *The Morbidity and Mortality Weekly Report*, 2024;73(31):682-685. Accessed at www.cdc.gov/mmwr/volumes/73/wr/mm7331a2.htm.
2. Shimabukuro, TT, Nguyen, M, Martin, D, and DeStefano, F. Safety Monitoring in the Vaccine Adverse Event Reporting System (VAERS). *Vaccine*, 2015;33(36):4398-4405. Accessed at pubmed.ncbi.nlm.nih.gov/26209838.
3. CIOMS/WHO Working Group on Vaccine Pharmacovigilance, ed. Definition and Application of Terms for Vaccine Pharmacovigilance: Report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance. World Health Organization; 2012.
4. VAERS — About Us. Accessed at vaers.hhs.gov/about.html.
5. VAERS — FAQs. Accessed at vaers.hhs.gov/faq.html.
6. Gounder, C. Inside the FDA's Vaccine Uproar. KFF Health News, Dec. 19, 2025. Accessed at kffhealthnews.org/news/article/vaccine-uproar-fda-former-commissioners-vinay-prasad-memo-worldview.
7. Califf, RM, Von Eschenbach, AC, Friedman, MA, et al. A Threat to Evidence-Based Vaccine Policy and Public Health Security at the FDA. *New England Journal of Medicine*, 2026;394(1):4-6. Accessed at pubmed.ncbi.nlm.nih.gov/41337736.

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Choosing a Digital Health Platform that Supports Longevity Medicine

In today's healthcare environment, reactive medicine is giving way to proactive medicine. Addressing problems after they arise is no longer enough: Optimizing patient health is the name of the game. Understanding what's happening inside a patient's body on a cellular level allows providers to anticipate issues before they become significant problems. Gathering metabolic, inflammatory and hormonal biomarkers, along with genetic testing and advanced imaging, creates a comprehensive, holistic look at patients' overall wellness and enables providers to give better care. Identifying subtle shifts in health often leads to earlier diagnosis, which can lead to better outcomes and, ultimately, longer life. This is health optimization in action.

However, to optimize patient health, your practice must rely on more data than ever before. Are your systems equipped to manage it?

The right longevity medicine platform will help your office move from reactive to proactive preventive care; integrate remote monitoring and artificial intelligence (AI) to help you collect and interpret data; streamline clinical workflows; seamlessly integrate into electronic health records (EHRs); offer intuitive user interface; offer security and compliance; support a growing practice; and ultimately improve patient care.[1] Before choosing a platform, take time to work through these steps:

1) *Identify your practice needs*. Consider your practice size, model and services. Are you a large healthcare organization or a small private practice? Do you offer virtual visits or in-person only? Are there specific longevity services you offer such as genetic testing or hormone therapy? Look for platforms that meet your unique needs.

2) *Consider platform features*. Make a list of features important to your practice. Evaluate data aggregation and integration, patient tracking, patient plan management, AI support, patient engagement and communication tools, scalability and operations.

3) *Compare platforms*. Consult other practitioners to find out what platform they use and whether they like it. You can also search online for "longevity medicine platforms," and compare solutions side by side.

4) *Request a demo*. Once you have a short list of platforms, request a demonstration and ask questions.

Heads Up

HeadsUp is a longevity medicine platform powered by AI clinical intelligence that tracks patient data from bloodwork to biometrics, and gives you the tools to help patients optimize their lifespan.[2] The platform integrates fragmented health records and lab results, tracks biomarkers, motivates clients and helps optimize health span. It collects and tracks information related to general health and wellness, specialty metrics and medial information. End-to-end patient engagement tools, such as a patient portal, real time alerts and secure messaging tools, keep your patients connected. Apply an individualized, data-informed approach for addressing root causes of chronic conditions. The HeadsUp dashboard gives you a glimpse into biomarkers, lab results, medications and supplements, nutrition and more. And, it integrates into several of the most popular health app EHRs, medical devices and wearables. For more information, visit *headsuphealth.com/longevity-platform*.

HolistiCare.io

Built *by* practitioners *for* practitioners, HolistiCare turns patient health information into clinical action with a unified client management hub.[3] Data from lab results, genetic testing, wearable devices and patient questionnaires come together in one place that offers AI analysis, holistic plan builder, action plan generator and continuous patient engagement. HolistiCare is designed to interpret and analyze more than 800 biomarkers from blood, genetics, microbiome and lifestyle data using functional medicine principles so you can focus on patient relationships. With the power of AI, it generates personalized, comprehensive longevity plans unique to each patient's individual needs, saving you time and increasing patient satisfaction. Providers intervene at any time, and dictate workflows and next steps. For more information, visit *holisticare.io*.

References

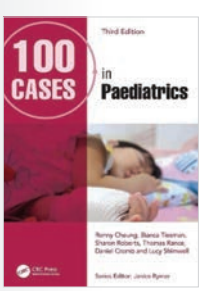
1. Actuvi. The 30 Best Digital Health Platforms for Practitioners: A Deep Dive. Accessed at www.actuvi.com/blog-hidden/the-30-best-digital-health-platforms-for-practitioners-a-deep-dive.
2. Heads Up. Longevity Medicine Platform Powered by AI Clinical Intelligence. Accessed at headsuphealth.com/longevity-platform.
3. HolistiCare.io. Holisticare Features: Empower Health with Intelligence. Accessed at holisticare.io/features.

100 Cases in Paediatrics

Authors: Ronny Cheung, Bianca Tiesman, Sharon Roberts, Thomas Rance, Daniel Cromb and Lucy Shimwell

100 Cases in Paediatrics presents 100 scenarios commonly seen in children by medical students and junior doctors in hospital and community settings. A succinct summary of the patient's history, examination and any initial investigations is followed by questions on the diagnosis and management of each case. The answer includes a detailed discussion on each topic, providing an essential revision aid, as well as a practical guide for students and resident doctors.

www.amazon.com/100-Cases-Paediatrics-Ronny-Cheung/dp/1041140134



Called to Care?: Health Care, Burnout, and the Search for Meaningful Work (Carework in a Changing World)

Author: Cindy L. Cain, PhD

Called to Care? argues that burnout can be mitigated by examining what is most meaningful about healthcare work. Using interviews and observation of a wide range of healthcare workers, Dr. Cain shows that workers who care for our most vulnerable adults find their work to be meaningful when they are able to connect to the work and make progress on something that matters — experiences consistent with better care for patients. And yet organizational practices, policy environments and cultural meanings get in the way of meaningful work, creating burnout. But, this book illustrates that workplaces can and should align meaningful work experiences with quality care for patients.

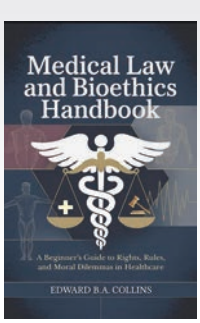
www.amazon.com/Called-Care-Meaningful-Carework-Changing/dp/1978839308

Communicating with Patients — Real Challenges. Real Solutions: Achieving Better Outcomes & Care Experience for Patients and Healthcare Professionals

Author: Yosuke Chikamoto, PhD

Drawing from years of work, Dr. Chikamoto brings together real clinical stories, behavioral science and cross-cultural insights. Through vivid vignettes and clear, relatable concepts, he reveals why communication so often breaks down — and how small shifts in approach can transform both patient care and clinician well-being. From navigating difficult conversations to rebuilding trust, motivating patients and using "the space between words" to support behavioral change, this book offers practical strategies that clinicians can apply immediately.

www.amazon.com/Communicating-Patients-Challenges-Solutions-Professionals/dp/B0G6LYTLXX



Medical Law and Bioethics Handbook: A Beginner's Guide to Rights, Rules, and Moral Dilemmas in Healthcare (Medical Handbook for Beginners)

Author: Edward B.A Collins

This book cuts through the legalese to provide a clear, practical map for navigating the ethical landscape of modern medicine — bridging the gap between the courtroom and the bedside, explaining not just what the rules are, but why they exist. The guide uses relatable analogies, real-life case studies and actionable advice. It is intended for medical students facing board exams, nurses charting complex cases or patient advocates seeking to understand rights.

www.amazon.com/Medical-Law-Bioethics-Handbook-Healthcare/dp/B0G662TP5X

Medicare Immune Globulin Reimbursement Rates

Rates are effective April 1, 2026, through June 30, 2026

	Product	Manufacturer	J Codes	ASP + 6% (before sequestration)	ASP + 4.3% (after sequestration)
IVIG	ALYGLO™	GC Biopharma	J1552	$246.50	$242.55
IVIG	ASCENIV™	ADMA Biologics	J1554	$1001.85	$985.78
IVIG	BIVIGAM®	ADMA Biologics	J1556	$158.88	$156.33
IVIG	GAMMAGARD® SD	Takeda	J1566	$160.80	$158.21
IVIG	GAMMAPLEX®	BPL/Kedrion	J1557	$129.30	$127.23
IVIG	OCTAGAM®	Octapharma	J1568	$94.07	$92.56
IVIG	PANZYGA®	Octapharma/Pfizer	J1576	$147.66	$145.29
IVIG	PRIVIGEN®	CSL Behring	J1459	$99.07	$97.48
IVIG	YIMMUGO®	Kedrion	J1553	$48.65	$47.87
IVIG/SCIG	GAMMAGARD LIQUID®	Takeda	J1569	$98.16	$96.59
IVIG/SCIG	GAMMAKED™	Kedrion	J1561	$99.45	$97.86
IVIG/SCIG	GAMUNEX®-C	Grifols	J1561	$99.45	$97.86
SCIG	CUTAQUIG®	Octapharma	J1551	$139.27	$137.04
SCIG	CUVITRU®	Takeda	J1555	$175.80	$172.99
SCIG	HIZENTRA®	CSL Behring	J1559	$145.15	$142.82
SCIG	HYQVIA®	Takeda	J1575	$188.04	$185.02
SCIG	XEMBIFY®	Grifols	J1558	$153.67	$151.21

* ASP-based Medicare payment rate not yet available; payment rate assigned by your Medicare Administrative Contractor.

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Immune Globulin Reference Table

	Product	Manufacturer	Indication	Size
IVIG	ALYGLO™	GC Biopharma	PI	5 g, 10 g, 20 g
IVIG	ASCENIV™ LIQUID, 10%	ADMA Biologics	PI	5 g
IVIG	BIVIGAM® LIQUID, 10%	ADMA Biologics	PI	5 g, 10 g
IVIG	GAMMAGARD® S/D Lyophilized, 5% (Low IgA)	Takeda	PI, ITP, B-cell CLL, KD	5 g, 10 g
IVIG	GAMMAPLEX® Liquid, 5%	BPL/Kedrion	PI, ITP	5 g, 10 g, 20 g
IVIG	GAMMAPLEX® Liquid, 10%	BPL/Kedrion	PI, ITP	5 g, 10 g, 20 g
IVIG	OCTAGAM® Liquid, 5%	Octapharma	PI	1 g, 2.5 g, 5 g, 10 g, 25 g
IVIG	OCTAGAM® Liquid, 10%	Octapharma	ITP, DM	2 g, 5 g, 10 g, 20 g, 30 g
IVIG	PANZYGA® Liquid, 10%	Octapharma/Pfizer	PI, ITP, CIDP	1 g, 2.5 g, 5 g, 10 g, 20 g, 30 g
IVIG	PRIVIGEN® Liquid, 10%	CSL Behring	PI, ITP, CIDP	5 g, 10 g, 20 g, 40 g
IVIG	YIMMUGO®, 10%	Kedrion	PI	5 g, 10 g, 20 g
IVIG/SCIG	GAMMAGARD Liquid®, 10%	Takeda	IVIG: PI, MMN, CIDP	1 g, 2.5 g, 5 g, 10 g, 20 g, 30 g
IVIG/SCIG			SCIG: PI	
IVIG/SCIG	GAMMAKED™ Liquid, 10%	Kedrion	IVIG: PI, ITP, CIDP	1 g, 2.5 g, 5 g, 10 g, 20 g
IVIG/SCIG			SCIG: PI	
IVIG/SCIG	GAMUNEX®-C Liquid, 10%	Grifols	IVIG: PI, ITP, CIDP	1 g, 2.5 g, 5 g, 10 g, 20 g, 40 g
IVIG/SCIG			SCIG: PI	
SCIG	CUTAQUIG® Liquid, 16.5%	Octapharma	PI	1 g, 1.65 g, 2 g, 3.3 g, 4 g, 8 g
SCIG	CUVITRU® Liquid, 20%	Takeda	PI	1 g, 2 g, 4 g, 8 g, 10 g
SCIG	HIZENTRA® Liquid, 20%	CSL Behring	PI, CIDP	1 g PFS, 2 g PFS, 4 g PFS, 10 g PFS
SCIG	HYQVIA® Liquid, 10%	Takeda	PI, CIDP	2.5 g, 5 g, 10 g, 20 g, 30 g
SCIG	XEMBIFY® Liquid, 20%	Grifols	PI	1 g, 2 g, 4 g, 10 g

CIDP Chronic inflammatory demyelinating polyneuropathy
CLL Chronic lymphocytic leukemia
DM Dermatomyositis
ITP Immune thrombocytopenic purpura
KD Kawasaki disease
MMN Multifocal motor neuropathy
PI Primary immune deficiency disease
PFS Prefilled syringes

2026-2027 Influenza Vaccines

Administration Codes: G0008 (Medicare plans)
Diagnosis Code: V04.81

Product	Manufacturer	Presentation	Age Group	Code
FLUAD® (IIV4)	CSL Seqirus	0.5 mL PFS 10-bx	65 years+	90674
FLUARIX® (IIV4)	GSK	0.5 mL PFS 10-bx	6 months+	90686
FLUBLOK® (ccIIV4)	Sanofi	0.5 mL PFS 10-bx	9 years+	90682
FLUCELVAX® (ccIIV4)	CSL Seqirus	0.5 mL PFS 10-bx	6 months+	90674
FLULAVAL® (IIV4)	GSK	0.5 mL PFS 10-bx	6 months+	90686
FLUMIST® (LAIV4)	AstraZeneca	0.2 mL PFS nasal spray 10-bx	2–49 years	90672
FLUZONE® (IIV4)	Sanofi	0.5 mL PFS 10-bx	6 months+	90686
FLUZONE® (IIV4)	Sanofi	5 mL MDV	6 months+	90685
FLUZONE® HIGH-DOSE (IIV4)	Sanofi	0.5 mL PFS 10-bx	65 years+	90662

ccIIV4 Cell culture-based trivalent inactivated injectable
IIV4 Egg-based trivalent inactivated injectable
LAIV4 Egg-based live attenuated trivalent nasal spray

* Providers should check with their respective payers to verify which code they are recognizing for Flucelvax Trivalent 5 mL MDV product reimbursement for this season.

2026-2027 COVID-19 Vaccines

Product	Manufacturer	Presentation	Age Group	Code
COMIRNATY® (COVID-19 Vaccine, mRNA)	Pfizer-BioNTech	0.3 mL PFS 10-bx	65 years+; 5–64 years with underlying condition	TBD
mNEXSPIKE® (COVID-19 Vaccine, mRNA)	Moderna US, Inc.	0.2 mL PFS 10-bx	65 years+; 12–64 years with underlying condition	TBD
NUVAXOVID™ (COVID-19 Vaccine, Adjuvanted)	Sanofi	0.5 mL PFS 10-bx	65 years+; 12–64 years with underlying condition	TBD
SPIKEVAX® (COVID-19 Vaccine, mRNA)	Moderna US, Inc.	0.5 mL PFS 10-bx	12 year+	TBD
SPIKEVAX® (COVID-19 Vaccine, mRNA)	Moderna US, Inc.	0.25 mL PFS 10-bx	6 months to 11 years	TBD

2026-2027 Respiratory Syncytical Virus (RSV) Products

Product	Manufacturer	Presentation	Age Group	Code
ABRYSVO™	Pfizer	0.5 mL PFS 1-bx	60 years+; 50–59 years at increased risk for LRTD caused by RSV; pregnant individuals 32–36 weeks gestation	90678
ABRYSVO™	Pfizer	0.5 mL PFS 10-bx		
AREXVY	GSK	0.5 mL SDV 10-bx	60 years+; 50–59 years at increased risk for LRTD caused by RSV	90679
BEYFORTUS®	Sanofi	0.5 mL PFS 5-bx	Neonates and infants born during or entering first RSV season; children up to 24 months who remain vulnerable to severe RSV through second RSV season	90380
BEYFORTUS®	Sanofi	1 mL PFS 5-bx		90381
ENFLONSIA™	Merck	0.7 mL PFS 10-bx	Neonates and infants born during or entering first RSV season	90382
mRESVIA®	Moderna US, Inc.	0.5 mL PFS 2-bx	60 years+; 18-59 years at increased risk for LRTD caused by RSV	90683
mRESVIA®	Moderna US, Inc.	0.5 mL PFS 10-bx		

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