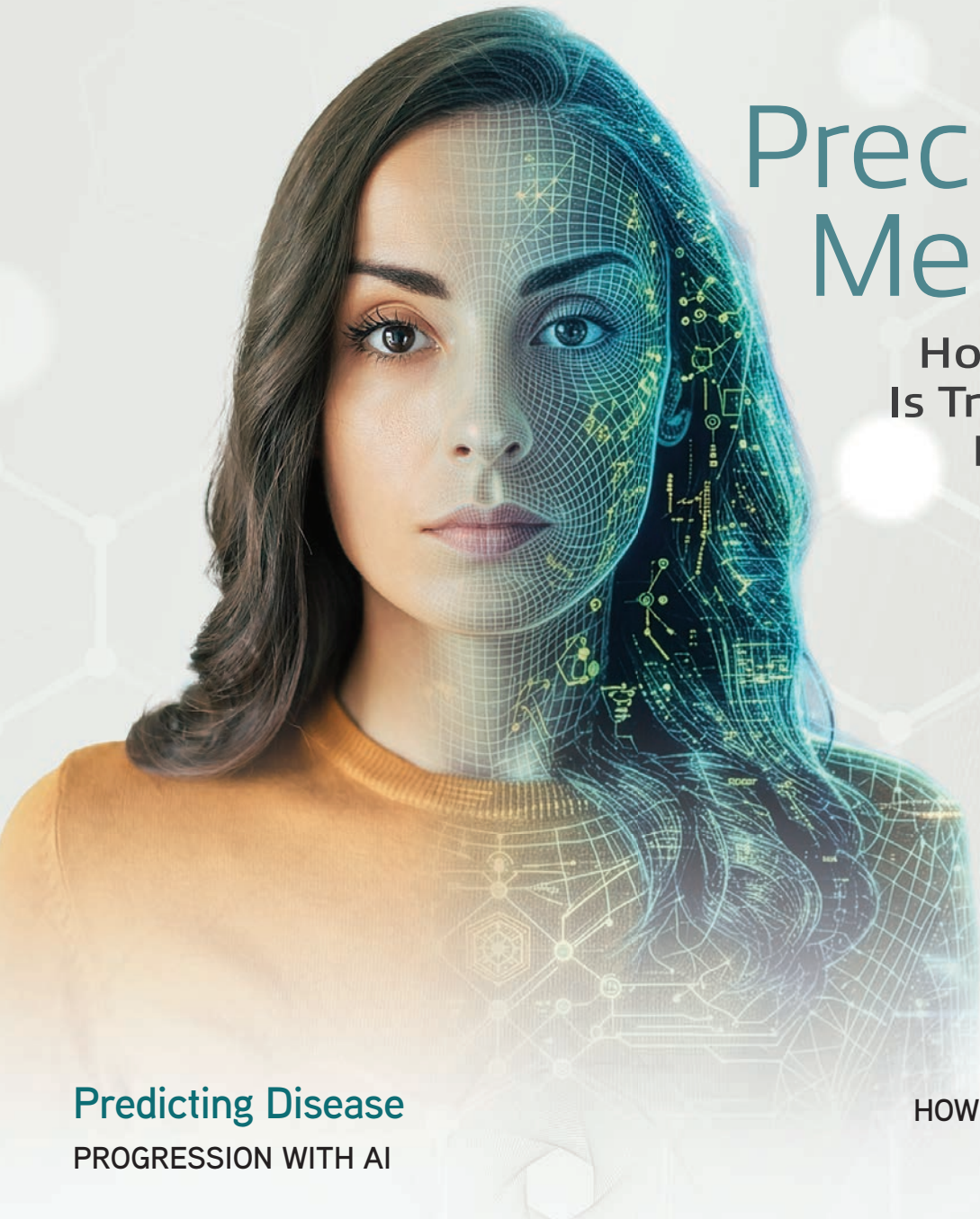




Precision Medicine

How AI
Is Transforming
Healthcare

Predicting Disease
PROGRESSION WITH AI

USING AI IN
Drug Discovery

HOW AI IS PERSONALIZING
Treatment Plans

MYTHS AND FACTS ABOUT
Childhood Vaccines

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About BioSupply Trends Quarterly

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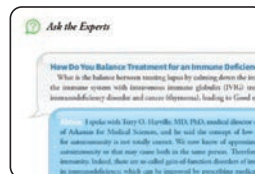
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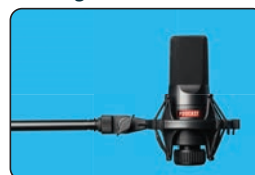
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AI Connects Data, Discovery and Precision Care

AS HEALTHCARE continues to evolve toward more proactive, personalized care, artificial intelligence (AI) is becoming an increasingly powerful tool. From predicting how diseases may progress and accelerating drug discovery to combining genomic sequencing with

AI-assisted analytics, these advances are helping clinicians and researchers move beyond traditional, one-size-fits-all approaches. Together, these innovations point toward a future of functional precision medicine (FPM) — where data-driven insights support earlier intervention, more targeted therapies and individually tailored treatment plans.

As these advances demonstrate, AI is moving healthcare beyond simply identifying disease toward anticipating how disease may develop and helping clinicians intervene earlier. In our article “Using AI to Predict Disease Progression” (p.18), we show how by integrating genetic, clinical, imaging and other patient data, predictive AI models are opening new possibilities for earlier detection, disease staging and more personalized treatment strategies across autoimmune and other complex conditions. Yet, realizing this potential will require more than increasingly sophisticated algorithms; it will depend on high-quality data, rigorous validation, thoughtful regulation and continued physician oversight.

That same predictive power of disease progression is now extending upstream, into the process of discovering and developing the therapies used to treat those diseases. By analyzing complex biological data, predicting protein structures and molecular interactions, and identifying promising drug candidates, AI is helping researchers accelerate a process traditionally measured in years and billions of dollars. Our article “AI in Drug Discovery and Development” (p.22) explores how AI is reshaping drug discovery — from understanding disease biology and designing novel therapies to advancing candidates into clinical trials — while also examining the scientific, regulatory and ethical challenges that must be addressed along the way.

The evolution of AI in disease prediction and drug development points toward an even more individualized approach to cancer care — one that combines what we know about a tumor with how that specific tumor actually responds to treatment. FPM brings together genomic and molecular insights, patient-derived living cells, advanced drug-response testing and AI-assisted analytics to help oncologists move beyond population-based treatment decisions. By directly measuring a patient's tumor response to available therapies and integrating those findings with genomic data, FPM has the potential to identify more effective treatment options, reduce reliance on trial and error, and accelerate clinical decision-making. We explore how emerging FPM platforms are putting this convergence of biology, technology and AI into practice and shaping a more personalized future for oncology in our article “Genomic Sequencing + AI-Assisted Analytics = Functional Precision Medicine” (p.28).

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

biosupplytrends
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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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HHS Awards \$102 Million to Expand Health Center Program

The U.S. Department of Health and Human Services (HHS) is providing \$102 million in New Access Points awards to significantly expand the reach of the Health Center Program. The awards represent the first major expansion of the Health Center Program, supporting 158 new and existing health centers to establish 415 new sites and expand access to comprehensive primary care for nearly one million people nationwide.

New Access Points funding is the primary pathway for organizations to become Health Resources and Services Administration (HRSA)-funded health

centers while also supporting existing health centers to expand into new medically underserved communities. HRSA-funded health centers provide comprehensive primary care to more than 32 million people at more than 16,000 service sites nationwide, serving one in eight children, one in five rural residents and one in 15 adults age 65 and older. Health centers play a critical role in preventing and managing chronic disease while delivering integrated primary care, behavioral health, oral health and other essential services in communities across America.

“Strong primary care prevents disease and gives Americans greater control over their health,” said HHS Secretary Robert F. Kennedy, Jr. “This \$102 million investment will bring high-quality care to nearly one million more Americans, expand prevention and nutrition services and help communities tackle chronic disease at its roots. We are giving more Americans the tools to live healthier lives and Make America Healthy Again.” ❖

HHS Announces Historic Investment to Expand Health Center Program, Bringing Primary Care to Nearly 1 Million More Americans. U.S. Department of Health and Human Services press release, Aug. 13, 2026. Accessed at www.hhs.gov/press-room/hhs-invests-102-million-expand-health-centers-primary-care.html.

NIH Launches \$4 Million Study of Autoimmune Disease Causes

The National Institutes of Health has given a University of Houston (UH) pioneer in autoimmune research, Chandra Mohan, \$4 million to launch a 10-year study to examine what causes the body to attack itself and identify biological pathways that could become targets for new treatments.

The focus of the study will be on systemic autoimmune rheumatic diseases such as lupus, rheumatoid arthritis, Sjögren's syndrome and systemic sclerosis. The hope is to identify the earliest biological triggers of autoimmune disease, as well as identify early biological changes in autoimmune

diseases, years before the disease develops, potentially opening the door to new prevention strategies and treatments. ❖

Fickman, L. Ten-Year Study Aims to Uncover Earliest Biological Triggers of Lupus, Rheumatoid Arthritis and Related Auto Immune Diseases. University of Houston, July 6, 2026. Accessed at www.uh.edu/news-events/stories/2026/july/07062026-mohan-autoimmune-longitudinal-triggers.php.

NIH Awards Cash Prizes to 15 Teams for Ideas That Integrate Diet and Nutrition in Autoimmune Disease Research

The National Institutes of Health (NIH) has chosen 15 scientific teams from across the nation as cash prize winners for their submissions to a national crowdsourcing challenge designed to generate innovative ideas that integrate diet and nutrition into autoimmune disease research. Winning submissions investigated the effectiveness of dietary interventions; microbiome, immune system and multi-omic approaches; personalized and data-driven predictive nutrition; and community and patient-center research frameworks.

The challenge, known as the Nutrition

for Our Immune System Health (NOURISH): Autoimmunity Challenge and led by NIH's Office of Autoimmune Disease Research, yielded highly competitive submissions, resulting in 15 prize awards totaling \$10,000 to each team. The winners showed thoughtful planning and designs that, with further development, could result in innovative solutions to benefit Americans affected by autoimmune diseases. Each winning entry contributed innovative, scientifically rigorous and patient-centered ideas to advance the science of autoimmune disease research and care in one of four

thematic areas: 1) effectiveness of dietary interventions in autoimmune disease; 2) microbiome, immune and multi-omics mechanisms; 3) personalized, data-driven and predictive nutrition; and 4) community voice, landscape assessment and patient-centered frameworks.

A full list of winning submissions and honorable mentions can be viewed at orwh.od.nih.gov/in-the-spotlight/winners-of-nutrition-for-our-immune-system-health-nourish-autoimmunity-challenge. ❖

NIH Awards Top Scientific Teams for Innovations Linking Nutrition and Autoimmune Disease. National Institutes of Health press release, March 30, 2026. Accessed at www.nih.gov/news-events/news-releases/nih-awards-top-scientific-teams-innovations-linking-nutrition-autoimmune-disease.



NIH Awards \$1.7 Million Grant for Lupus Research

The National Institutes of Health (NIH) has awarded a \$1.7 million grant to a University of Oklahoma researcher to continue investigating a protein that may help explain why lupus develops and how it might be treated more precisely.

Carol Webb, PhD, a professor at the University of Oklahoma College of Medicine, has spent her career studying the protein ARID3a. Her research has shown that people with lupus have higher numbers of B cells (a type of immune cell) containing ARID3a than healthy individuals, and patients with more of these cells tend to have more active and severe disease. In mouse research models, increasing ARID3a in B cells caused the animals to produce harmful antibodies that attacked their own tissues, similar to what is observed in lupus. In contrast, Dr. Webb's team found that in healthy people, these young B cells do not contain ARID3a.

But, in people with lupus, some of these young B cells do contain the protein. This finding suggests ARID3a may allow harmful cells to slip past the body's natural protections.

With the new NIH funding, the researchers will focus on three main goals: identifying the genes directly controlled by ARID3a, understanding how the protein helps B cells break normal safety rules, and testing whether blocking ARID3a in mice can reduce lupus symptoms. If the studies are successful, ARID3a could become both a warning sign of disease activity and a possible target for new treatments. Instead of suppressing the entire immune system, which is how many current lupus drugs work, future therapies might more precisely target the pathways that cause harm.

"Lupus is a complicated disease in which the immune system turns against



the body and can damage organs such as the kidneys and brain, making it especially challenging to study and treat," said Dr. Webb. "We believe these B cells may eventually help us detect disease earlier and guide the development of more effective, targeted therapies." ♦

Wilkerson, A. New NIH Grant Advances Lupus Protein Research. University of Oklahoma news release, March 3, 2026. Accessed at ou.edu/news/articles/2026/march/new-nih-grant-advances-lupus-protein-research.

Stanford Researchers Awarded \$18 Million to Develop a Universal Vaccine

The Advanced Research and Invention Agency (ARIA) has awarded a team at Stanford's Institute for Immunity, Transplantation and Infection a four-and-a-half year, approximately \$18 million grant to develop a universal vaccine platform that could protect against viruses such as influenza and COVID-19, as well as bacteria that cause pneumonia and allergens ranging from pollen to dust mites.

ARIA, a research and development funding agency based in the United Kingdom, made the award through its Sustained Viral Resilience program. The goal of the program is to create a new class of medicines, called sustained

innate immunoprophylactics, which provide enduring protection through the innate immune system — one of the two arms of the immune system that has been historically overlooked in vaccine development.

The award supports a collaboration between Stanford University and Imperial College London aimed at advancing a next-generation vaccine platform toward human testing. The researchers will use the award to translate their intranasal universal vaccine platform — recently described in a *Science* paper in which the team demonstrated broad protection against diverse respiratory pathogens in preclinical studies — toward human

studies, with the goal of assessing the vaccine's capacity to induce safe and broadly protective immunity against diverse respiratory pathogens and allergens.

"We are looking to leverage the innate immune system, an incredibly broad system of defense, to create a new and transformative vaccine paradigm," said Bali Pulendran, PhD, director of the Institute for Immunity, Transplantation and Infection, the vaccine project's principal investigator and the Violetta L. Horton Professor II. ♦

Hadhazy, A. Stanford Medicine Team Awarded \$18 Million to Develop a Universal Vaccine. Stanford Medicine News Center, June 25, 2026. Accessed at med.stanford.edu/news/all-news/2026/06/universal-vaccine-award.html.

CMS Updated Payment Rules for 2027

By Bonnie Kirschenbaum, MS, FASHP, FCSHP

FINANCIAL STABILITY remains critical with a laser focus on preparing for fiscal year (FY) 2027 (Oct. 1, 2026) inpatient settings with calendar year (CY) 2027 following for all other sites of care. Geopolitical instability has impacted Medicaid, Medicare and the Affordable Care Act (ACA) negatively. Medicaid reduced volume and reimbursement rates, and increased uncompensated care, including millions with asthma. Medicare reduced reimbursement rates, and ACA reduced volume with increased uncompensated care. Pharmacy departments must understand they're not immune to these implications and be acutely aware of financial environments. This article summarizes a few 2027 rules and how your practice can prepare for the upcoming changes.

The outpatient prospective payment system (OPPS), ambulatory surgical center (ASC) and physician fee schedule (PFS) are the predominant fee schedules for services in outpatient arenas. Your system most likely is involved in a myriad of different sites of care, each with a Centers for Medicare and Medicaid Services (CMS) rule set governing conditions of participation and payment for goods and services. With similar time frames, private sector payers often follow the CMS lead on priorities being stressed. Paying attention to these proposed rules will provide insight into your strategic planning moving forward into a year reeling under budget cuts passed by Congress.

Key areas under OPPS/ASC payments are facility payments for incident-to-administered drugs and facility quality systems. PFS covers payment for professional services and quality systems,

telehealth/digital health, physician administered drugs and the Inflation Reduction Act (IRA). Rule scope is broad, covering healthcare in all outpatient settings, including ASCs and physician office practices. Shifting between various sites of care best meets patient needs and achieves critical savings when costs are rapidly spiraling to new heights. Several other pieces of legislation under debate will significantly impact your practice from revenue streams, operations and clinical services standpoints. Prevailing themes reflect a deeper dive into prior authorizations, pharmacy benefit managers (PBMs), transparency and site-of-care changes, and significant changes to the 340B program. Financial survival strategies depend on working in sync with finance/revenue cycle teams to determine strategies for negotiating with commercial payers.

Critical access hospitals; hospitals located in Maryland paid under Maryland's All-Payer or Total Cost of Care Model; hospitals located outside the 50 states, the District of Columbia and Puerto Rico; Indian Health Service hospitals; and rural emergency hospitals are excluded.

Preparing For What's Coming

Although there are many changes taking place, you can take steps now to prevent issues that might appear later in the process.

Electronic prior authorization (PA) improvements: Take action now to start submitting PA requests electronically in 2027. Start testing and don't delay involvement in streamlining and improving PA systems. This involves participating in Fast Healthcare Interoperability Resources

application programming interface (API) testing with your electronic health record (EHR) vendor and payer partners. EHR vendors implementing standardized electronic PA transactions will be ready Jan. 1, 2027, when certain health plans regulated by CMS must implement and maintain these APIs: Patient Access API, Provider Directory API, Provider Access API, Payer-to-Payer API and Prior Authorization API. Gaps need to be identified and workflows validated, all of which may entail changes to your EHR system. Functionality with technical readiness is crucial; think of all the PAs and sites of care affected!^{1,2}

Site of care: Whichever site is chosen — inpatient, outpatient or infusion center chemotherapy — there must be sufficient documentation to defend the choice and status. Subsequent claims, as well as actual payment, depend on enough complete, accurate, codeable data to tell the patient's story.

Action step: The pharmacy bears the responsibility for the continuous diagnostics and mitigation (CDM) build and subsequent link to periodic data matching in the computerized provider order entry within EHR with correct Healthcare Common Procedure Coding System (HCPCS) codes. Review your most expensive and most frequently used drugs, all status indicator "G" drugs and all new technology add-on payment (NTAP) drugs.

Miscellaneous codes: Sort your CDM by HCPCS code. Focus on codes C9399, J3490 and J3590. How many of these actually have specific assigned HCPCS codes? Fix these immediately to avoid payment denial.



Multiple drugs to a single code: Focus on any HCPCS codes with multiple drugs assigned to them. Delete unnecessary ones.

National drug codes (NDC): Is the correct and current NDC assigned to the HCPCS code? If a different brand or generic from a different company is purchased, how quickly does the info get corrected in the CDM? Who does this?

The billing unit crosswalk: Doses of medication the patient receives must be converted into CMS-assigned billing units. Usually, this is automatic based on a commercial crosswalk or one built by your facility. Decimal place errors are the most frequent culprits resulting in underpayment or overpayment. The dose the patient got was correct, but the claim represented the dose incorrectly and paid for it incorrectly. A two decimal place error equals 1/100th of the payment with the claim showing the patient got 1/100th of the dose ordered. This is what is sent to the data pool used for AI creation.

Drug administration fees: These are payable in all sites except inpatient for all separately payable status indicator “G” and “K” drugs and for all “N” drugs paid for in bundled/package codes, not separately. Status indicator “N” drugs must be included on the claim for payment of lucrative drug administration fees. Their cost isn’t part of the cost of the bundle if revenue cycle fails to submit them.

Key FY 2027 Payment Rules and Models

Hospital inpatient prospective payment system final rule: This rule increases payments by 2.4 percent if your facility participates in the Hospital Inpatient Quality Reporting program and has meaningful users of EHRs. Disproportionate share hospitals providing uncompensated care will see reductions in payment. The expansion

of the Comprehensive Care for Joint Replacement model has been delayed until 2028.³

NTAP drugs: Most NTAPs are medical technology breakthroughs followed by drugs and antibiotics eligible for additional payment if found to be new, disproportionately costly to the existing Medicare Severity Diagnosis-Related Group (MS-DRG), a substantial clinical improvement or follow alternative pathways for certain technologies with different criteria. For 2027, 41 technologies continue and 13 are discontinued having ended the two-to-three-year “newness” window and are now absorbed into standard MS-DRGs. Only three new ones were added. CMS didn’t consider any applications with qualified infectious disease product designation or the limited population for antibacterial and antifungal drugs pathways.⁴

NTAP action step: Ensure the revenue cycle team understands how to bill separately for NTAPs, including the requirements for payment such that they’re met and documented. Since there are very few separately payable inpatient items, you wouldn’t want these to be missed!

CY proposed outpatient settings and ASCs: Detailed tables are no longer in the published rules, but updates are provided as needed at CMS.gov. The CY 2027 CMS outpatient focus is on strengthening care quality, cutting drug costs and slashing out-of-pocket expenses.

“Medicare beneficiaries deserve a program that pays for the right care, in the right setting, at the right time,” said Mehmet Oz, MD, CMS administrator. “This proposed rule focuses squarely on patient affordability by strengthening our utilization management tools, aligning drug payments with actual acquisition costs, and removing site-of-care disparities that have unnecessarily driven up costs

for millions of seniors. We are committed to ensuring that Medicare resources are directed toward clinically appropriate, affordable high-value care for every patient we serve.”⁵

Several other pieces of legislation being debated will significantly impact your pharmacy practice from revenue streams, operations and clinical services standpoints. Prevailing themes reflect a deeper dive into PAs, PBMs, transparency and site-of-care changes, as well as the 340B program. ❖

References

- Centers for Medicare and Medicaid Services. Electronic Prior Authorization, updated Aug. 8, 2026. Accessed at www.cms.gov/priorities/electronic-prior-authorization/overview.
- Centers for Medicare and Medicaid Services. 2026 CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule (CMS-0062-P), updated May 12, 2026. Accessed at www.cms.gov/priorities/burden-reduction/overview/interoperability/policies-regulations/cms-interoperability-standards-prior-authorization-drugs-proposed-rule-cms-0062-p.
- Centers for Medicare and Medicaid Services. Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2027 Rates; Requirements for Quality Programs; and Other Policy Changes. *Federal Register*, April 14, 2026. Accessed at public-inspection.federalregister.gov/2026-07203.pdf.
- Centers for Medicare and Medicaid Services. Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2027 Rates; Requirements for Quality Programs; Other Policy Changes; and Adoption of Updated Versions of Certain Health Information Technology Standards. *Federal Register*, Aug. 4, 2026. Accessed at www.federalregister.gov/documents/2026/08/04/2026-15833/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-ippss-and.
- CMS Acts to Strengthen Care Quality, Cut Drug Costs, and Slash Out-of-Pocket Expenses for Medicare Beneficiaries. Centers for Medicare and Medicaid Services press release, July 2, 2026. Accessed at www.cms.gov/newsroom/press-releases/cms-acts-strengthen-care-quality-cut-drug-costs-slash-out-pocket-expenses-medicare-beneficiaries.

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Six Strategies for Improving Patient Flow

By Rachel Maier, MS

WHETHER ATTENDING a scheduled appointment or seeking emergency care in a hospital, visiting a healthcare provider is a multi-step process, and patients move through several touchpoints for a single encounter. Inefficiencies at any touchpoint create bottlenecks, increasing wait times and decreasing patient satisfaction. A well-structured patient journey can make or break your medical facility's efficiency and the patient experience.

What Is Patient Flow?

Patient flow refers to patients' movement through various stages of care in a healthcare facility. From scheduling an appointment to checking out after seeing a doctor, the patient journey involves many steps.

Why Patient Flow Matters

Improving patient flow improves patient safety and quality of care, increases revenue and enhances patient satisfaction. According to Eugene Litvak, PhD, an expert in the field of patient flow, when facilities prioritize patient flow, it would "accelerate progress toward reliable, safe, efficient care."¹ When patients move through departments efficiently, they get diagnosed and treated faster, which is especially important in emergency departments and hospital settings. Resources such as staff and medical equipment are optimized, lowering operating costs and limiting waste. Smooth transitions from one touchpoint to another create a positive experience for patients.

Improving patient flow involves creating an environment that quickly, efficiently and effectively meets the

demand for patient care by moving them through the care pathway. Optimizing patient flow also involves coordinating care and prioritizing patient safety for improving health outcomes. The best patient flow ensures patients receive timely, appropriate care; providers, staff and resources are allocated efficiently; and bottlenecks are minimized.

Implement and Optimize SEO

Once your information is online, patients need to find it. That's where SEO comes in. SEO stands for "search engine optimization," and it helps your practice appear higher in a list of Internet search results. According to Net One Click, a marketing agency specializing in small and mid-sized medical practices, most patients begin their healthcare search on Google, and the top three map results get the most clicks.³

When you implement SEO, you give search engines the information they need to find your practice, and when done correctly, it ranks higher in search results, meaning it will (ideally) be within the first several business listings. SEO involves developing a well-structured website and clear, descriptive page titles with relevant content, including keywords, helping search engines understand who you are, what you offer and how you can help patients. It not only sends more traffic to your website, but also establishes your practice as a trusted leader in your field.

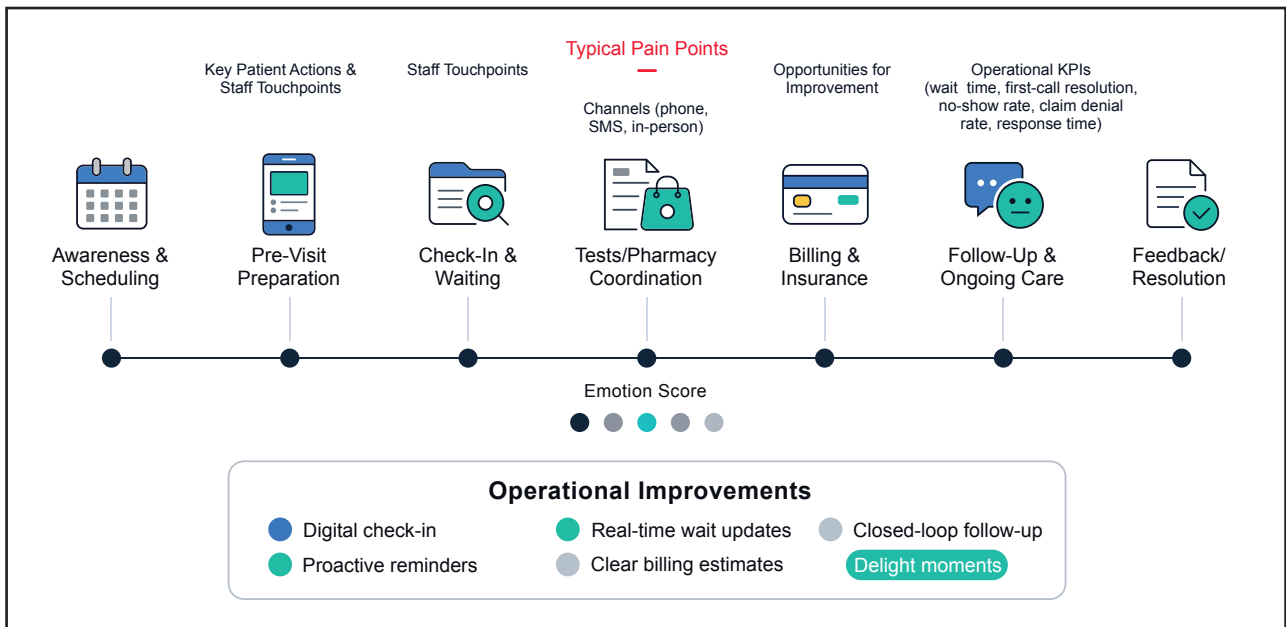
You can implement SEO yourself, but you may opt to hire an expert to help. Many marketing firms specialize in SEO for medical practices; their expertise may be worth the expense, especially as AI reshapes how people find answers online.

Six Strategies for Improving Patient Flow

1) *Assess the situation.* The first step toward better patient flow is to evaluate current patient flow, assess throughput and look for bottlenecks:

- Map the layout of your facility. Think about it from the patients' perspective. Is its layout logical and easy to navigate, or does it leave patients guessing or lost? The layout should be logical and flow from one touchpoint to another.
- Follow the patient journey. Choose a sample of random patient visits on a variety of days and times. Log the timestamps for every step. How long does each touchpoint take? Do you ever retrace your steps? Do you observe any redundancies? Are staff members actively involved with patients?
- Collect data. Use analytics to pinpoint problem areas.
- Find bottlenecks. Look for places where patients wait the longest. These are the places to prioritize.
- Analyze schedules. Compare bottlenecks between patient arrivals and provider schedules to find the reason for the delay.
- Ask for feedback. Ask staff and patients for their perspective. Identify nonclinical tasks that contribute to slower patient transitions.

2) *Streamline workflows.* Next, create an ideal patient journey and standardize the clinical workflow for every step so every department follows the same patient flow process. Consider every touchpoint, including scheduling, check-in, registration, intake, workup, testing, exams, clinical discussions and check-out. Then, match each step with an actionable solution. For example, if you discover that



filling out forms stalls the patient journey, consider implementing an online check-in for patients to complete before arriving for their appointment. If you find exam rooms sit empty, implement a flag system or digital clinical dashboard to track exam room status.

3) *Leverage technology.* There are myriad technological tools designed to make administrative tasks easier and more efficient. From simple digital check-ins to comprehensive, AI-powered smart hospital platforms, there's a solution to unify fragmented systems and coordinate patient-centered care. Explore digital check-in software, digital queue management, smart scheduling algorithms, real-time tracking systems, inpatient tracking dashboards, digital wayfinding apps, AI-powered predictive volume forecasting and automated secure messaging (to name a few). Technology saves time, allowing providers and support staff to focus on the patient rather than paperwork.

4) *Restructure schedules.* In the clinical setting, a well-structured appointment schedule is crucial for optimal patient flow. The first rule of thumb? Avoid overbooking. Find out how many patients

a provider can realistically see in an hour, and stick to that number. Also important: Develop criteria for various types of appointments (new patient, new concern, follow-up, annual wellness visit, same day/sick visit, urgent care/walk-in, etc.), and align appointment lengths with them. Limit the number of staff authorized to overwrite schedules. Stagger patient arrival times so patients don't all arrive at the same time, which can cause long lines and longer waits. Stagger lunch breaks for providers and medical staff.

5) *Improve communication.* Patients interact with many departments during a given visit. A provider may order imaging or tests, prescribe medicines or refer patients to another provider. Utilize a centralized database to make collaboration seamless and efficient. Further, make it easy for patients to communicate with the facility and provider. Utilize a patient portal to connect patients with providers and information in their electronic medical record such as test results, clinical notes, after-visit summaries and upcoming appointments.

6) *Train your staff.* Offer regular, ongoing training to your staff. Reinforce the importance of time management,

communicate updated workflows and emphasize the goal of patient safety and satisfaction. Hold your own training sessions, or encourage staff to attend seminars on effective communication, office organization and time management.

Better Flow, Better Outcomes

A smooth, efficient office is the goal, and the more you know about how your facility currently operates, the better equipped you will be to implement changes. Efficient patient flow shows patients their time is valuable. It prioritizes their care while also maximizing your time and resources. Well-managed care systems do more than make workflows easier and more efficient; they ensure patients receive the care they need when they need it. ♦

References

1. What Is Patient Flow? NEJM Catalyst, Jan. 1, 2018. Accessed at catalyst.nejm.org/doi/full/10.1056/CAT.18.0289.
2. Why Is Patient Flow Critical in Healthcare? Airsta, Aug. 22, 2025. Accessed at www.airstaflow.com/blog/what-is-patient-flow-in-healthcare.
3. Shuman, JT. The Four S's of Clinic Flow Optimization. Cataract & Retraction Surgery Today, May 12, 2023. Accessed at crstoday.com/topics/practice-management/the-four-ss-of-clinic-flow-optimization/45017.

RACHEL MAIER, MS, is a contributing writer for *BioSupply Trends Quarterly*.



Medicines

FDA Approves First Freeze-Dried Plasma Product

The U.S. Food and Drug Administration (FDA) has licensed Ezplaz Freeze Dried Plasma (FDP), the first freeze-dried plasma product licensed for use in the U.S. Ezplaz is intended for transfusion in adult patients who need plasma and for whom other plasma products are not available.

Ezplaz is a freeze-dried (lyophilized) plasma product derived from a single unit of fresh frozen plasma collected from FDA-licensed blood establishments. It is available in Group AB and Group A with low-titer anti-B blood types, chosen to mitigate risk of giving to patients in emergencies before their blood type is determined.

Unlike conventional plasma products that must be stored frozen and thawed before use, Ezplaz can be stored at room temperature, is stable after exposure to temperature fluctuations and is rapidly reconstituted. It is packaged in a plastic bag rather than a glass bottle, reducing the risk of breakage during handling and transport. FDA expects these features will make the use of Ezplaz compatible with austere environments, potentially including combat zones, remote areas and disaster response settings.

Each Ezplaz kit is a complete, self-contained package containing one unit of freeze-dried plasma sealed in an outer foil pouch, one 250 mL bag of sterile water for

injection, one sterile fluid transfer set and one sterile blood transfusion set.

“Patients experiencing life-threatening bleeding in combat zones, disasters, rural settings or other austere environments may now have faster access to plasma when conventional frozen plasma is unavailable,” said Karim Mikhail, BPharm, MS, acting director of the Center for Biologics Evaluation and Research. “This milestone action addresses an important unmet medical need — particularly for our military personnel and others who may be far from traditional hospital infrastructure.” ♦

FDA Licenses First-Ever Freeze-Dried Plasma Product in the U.S. U.S. Food and Drug Administration press release, July 29, 2026. Accessed at www.fda.gov/news-events/press-announcements/fda-licenses-first-ever-freeze-dried-plasma-product-us.

Medicines

FDA Approves Lisraya to Treat Dermatomyositis



The U.S. Food and Drug Administration (FDA) has approved Lisraya (brepocitinib) tablets to treat dermatomyositis in adults.

Approval is based on a Phase III randomized, double-blind, multicenter, placebo-controlled study (NCT05437263) that included 241 adults with dermatomyositis. Participants were randomized to receive Lisraya (brepocitinib) 30 mg once daily, brepocitinib 15 mg once daily or placebo

for a 52-week treatment period. The study measured total improvement score (TIS) at week 52, a standardized scoring tool that tracks changes across six areas (muscle strength, physical function, skin and other disease activity, muscle enzymes and both physician and patient assessments of overall health) to assess how much a patient's dermatomyositis has improved.

Participants treated with Lisraya 30 mg had a higher average TIS score (indicating greater clinical response and disease control) at week 52 compared to those who received a placebo. They also showed improvements in physical function and skin disease activity and were more likely to reduce corticosteroid use by week 48.

Some of the most common adverse reactions to Lisraya were upper respiratory tract infection, headache, fatigue, urinary tract infection and nausea. Discontinuation due to adverse reactions occurred in six percent of participants treated with Lisraya 30 mg, compared

with 11 percent of those given a placebo. Lisraya carries a boxed warning for serious infections, increased all-cause mortality (a higher risk of death from any cause), malignancies (cancers), major adverse cardiovascular events (serious heart and blood vessel problems) and thrombosis (blood clots).

“For too long, patients with dermatomyositis have faced a significant unmet need for effective treatments, often relying on therapies meant for other diseases,” said Nikolay Nikolov, MD, director of the Office of Immunology and Inflammation in the FDA's Center for Drug Evaluation and Research. “Today's approval is a meaningful step forward, giving patients and their healthcare providers an approved oral therapy proven to help manage this rare and debilitating disease.” ♦

FDA Approves First Oral Drug Indicated to Treat Dermatomyositis in Adults. U.S. Food and Drug Administration press release, Aug. 27, 2026. Accessed at www.fda.gov/news-events/press-announcements/fda-approves-first-oral-drug-indicated-treat-dermatomyositis-adults.



Medicines

New COVID Vaccines Approved by FDA

Updated COVID-19 vaccines from Moderna, Novavax-Sanofi and Pfizer-BioNTech have been approved by the U.S. Food and Drug Administration (FDA). All four vaccines are designed to prevent severe disease caused by the dominant strain, the JN.1 lineage XFG subvariant.

Approval is for adults 65 and older, as well as younger people with one or more chronic conditions that put them at higher risk for severe disease. And, each vaccine approval is slightly different:

- Pfizer's mRNA vaccine, Comirnaty XFG, is approved for adults 65 years and older, and people ages 5 years and older with an underlying condition. Pfizer has already begun distributing vaccines, and they should arrive in pharmacies soon.

- Moderna's mRNA vaccine, Spikevax, is approved for people age 65 and older, and those 6 months and older with an underlying condition.

- Moderna's new, lower-dose vaccine, mNEXSPIKE, is approved for people age 65 and older, as well as people 12 years and older with an underlying condition.

- Sanofi also has received FDA approval for its COVID-19 vaccine, Nuvaxovid, originally licensed by Novavax, which does not use mRNA technology. Nuvaxovid is approved for adults ages 65 years and older, and people ages 12 years and older who are at high risk for severe COVID-19.

AHIP, an organization that includes most health insurers, has said its members will cover the total cost of vaccines



recommended by a Centers for Disease Control and Prevention committee at least until the end of 2027. ❖

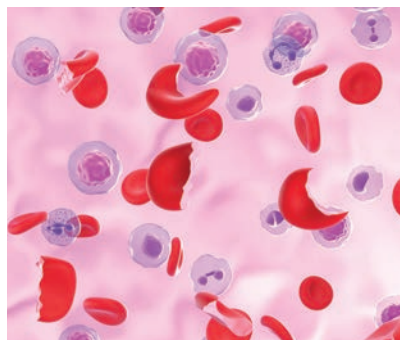
Szabo, L. FDA Approves New COVID Vaccines. University of Minnesota Center for Infectious Disease Research and Policy, Aug. 28, 2026. Accessed at www.cidrap.umn.edu/covid-19/fda-approves-new-covid-vaccines.

Medicines

FDA Approves IMAAVY to Treat Warm Autoimmune Hemolytic Anemia

The U.S. Food and Drug Administration (FDA) has approved IMAAVY (nipocalimab-aahu) to treat warm autoimmune hemolytic anemia (wAIHA), a rare, life-threatening autoantibody disease, in adults and pediatric patients 12 years of age and older currently or previously treated with corticosteroids. The approval, which follows FDA priority review, marks the first time a therapy was proven safe and effective specifically for the treatment of wAIHA.

Approval was based on the Phase II/III ENERGY study, which met its primary endpoint, a stringent endpoint definition that reflects meaningful increases in Hgb levels over time. The randomized, placebo-controlled trial demonstrated approximately three times as many patients receiving the approved dose of IMAAVY and achieved durable Hgb levels versus placebo by 24 weeks. Overall, patients in this treatment group showed a mean increase in Hgb of



1g/dL at week one. In addition, IMAAVY was associated with a 3.5-point higher mean FACIT-Fatigue score versus placebo at week 24, with higher scores defined as less fatigue. IMAAVY also demonstrated a safety profile consistent with the established safety profile of IMAAVY in generalized myasthenia gravis (gMG). The most common adverse reactions in patients with wAIHA treated with IMAAVY were peripheral edema, diarrhea and fever.

“Today’s announcement marks the second approval for IMAAVY and is an extraordinary milestone for people living with warm autoimmune hemolytic anemia, an underserved community that has waited far too long for an FDA-approved treatment,” said David M. Lee, MD, PhD, global immunology therapeutic area head at Johnson & Johnson. “As the first therapy approved for wAIHA, IMAAVY has the potential to redefine the management of wAIHA, particularly for those with uncontrolled disease. This milestone reinforces our motivation to continue pursuing advanced therapies for people living with allo- and autoantibody diseases like wAIHA.” ❖

FDA Approves IMAAVY® (nipocalimab-aahu) as First-Ever Treatment for Warm Autoimmune Hemolytic Anemia (wAIHA), Representing a Landmark Advancement for Patients. Johnson & Johnson press release, Aug. 25, 2026. Accessed at www.jnj.com/media-center/press-releases/fda-approves-imaavy-nipocalimab-aahu-as-first-ever-treatment-for-warm-autoimmune-hemolytic-anemia-waiha-representing-a-landmark-advancement-for-patients.



Research

Cancer Vaccine Plus KEYTRUDA Study Shows Positive Results in Treating Melanoma

A Phase III INTerpath-001 trial evaluating adjuvant treatment with intismeran autogene (intismeran; V940 or mRNA-4157), a novel investigational mRNA-based individualized neoantigen therapy (INT) being jointly developed by Merck and Moderna, in combination with KEYTRUDA (pembrolizumab), Merck's anti-PD-1 therapy, showed positive results in treating patients with completely resected stage IIB-IV melanoma. Specifically, the trial met its primary endpoint of recurrence-free survival (RFS) and a key secondary endpoint of distant metastasis-free survival (DMFS). This represents the first positive Phase III readout for an INT and for an mRNA-based cancer

therapy, as well as the first Phase III study to demonstrate a clinically meaningful improvement over KEYTRUDA alone, a standard-of-care immunotherapy, in the adjuvant setting for patients with resected melanoma. In addition, the safety profiles of intismeran and KEYTRUDA in this trial were consistent with those observed in previously reported studies for the combination, with no new safety signals observed.

"By intervening earlier in the course of disease, when many cancers are considered most treatable, the goal of adjuvant therapy given after surgery is to increase the possibility of cure for more patients," said Dean Y. Li, MD, PhD, president

of Merck Research Laboratories. "These first Phase III findings for intismeran in combination with KEYTRUDA as adjuvant therapy reinforce the promise of a more personalized approach to cancer treatment. We believe individualized neoantigen therapies have the potential to redefine how patients with completely resected stage IIB-IV melanoma are treated. Together with Moderna, we look forward to presenting data from INTerpath-001 at an international medical meeting and sharing with regulatory authorities." ♦

Trial of Intismeran Autogene Plus KEYTRUDA® Met Endpoints of Recurrence-Free Survival (RFS) and Distant Metastasis-Free Survival (DMFS) in Patients with Completely Resected Stage IIB-IV Melanoma. Moderna news release, Aug. 19, 2026. Accessed at news.modernatx.com/merck-and-moderna-announce-phase-3-interpath-001-trial-of-intismeran-plus-keytruda-met-endpoints-of-rfs-and-dmfs-in-melanoma.

Diagnostics

FDA Approves Elecsys pTau217 to Identify Alzheimer's in Individuals 55 Years and Older



The U.S. Food and Drug Administration (FDA) has cleared the Elecsys Phospho-Tau (217P) Plasma (pTau217) blood test, providing clinicians across primary and specialty care with a single blood-based option to aid in identifying amyloid pathology associated with

Alzheimer's disease in individuals 55 years and older with signs, symptoms or complaints of cognitive decline. Developed in collaboration with Eli Lilly and Company, Elecsys pTau217 is the first and only FDA-cleared, single-biomarker blood test that supports both rule-in and rule-out assessment of amyloid pathology using the same validated clinical cutoffs across primary and specialty care settings.

The assay provides positive, intermediate and negative result categories to support assessment of the likelihood of amyloid pathology. Results are interpreted in conjunction with clinical information and other relevant findings as part of the Alzheimer's disease diagnostic pathway.

According to a Roche news release, Elecsys pTau217 may help healthcare providers and health systems:

- Support clinical decision-making across primary and specialty care settings through a single-biomarker blood test that provides positive, intermediate or negative amyloid pathology results to aid clinical assessment of amyloid pathology.
- Help identify appropriate next steps by distinguishing patients with a high or low likelihood of amyloid pathology and those who should be considered for further testing.
- Support a more efficient diagnostic pathway by providing a minimally invasive blood-based option that may help clinicians determine when additional evaluation, including PET imaging or CSF testing, is appropriate. ♦

Folk, Z. Roche Receives FDA Clearance for Elecsys® pTau217, Advancing Alzheimer's Disease Assessment Across Primary and Specialty Care. Roche news release, Aug. 24, 2026. Accessed at diagnostics.roche.com/us/en/news-listing/2026/fda-elecsys-ptau217-alzheimers-blood-test.html.

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Using AI to Predict Disease Progression

Artificial intelligence shows great promise in diagnosing diseases, but human oversight is still critical for its ongoing use.

By Amy Scanlin, MS

WHILE ARTIFICIAL intelligence (AI) has been used to support many aspects of healthcare for a number of years, its reliability in clinical decision support (CDS) has grown in the past five to 10. AI can democratize healthcare, providing rural and urban, low-income and affluent areas with the potential to access the same information regardless of location.

AI models train on peer-reviewed literature and high-quality research to help with decision-making support. They transcribe conversations by listening during patient appointments; assist with

scheduling, billing and prescription reminders; and now, more than ever, support disease diagnosis and targeted treatment plans, learning and perfecting its knowledge from a multitude of data points. In this new era of medicine, exciting opportunities abound as AI continues to integrate into practice settings.

The possibilities of AI are particularly dramatic in the area of autoimmune disease research where accuracy of disease diagnosis and now disease progression are coming into the fold. From rheumatoid arthritis (RA) and

lupus to Alzheimer's disease and diabetes, AI's analysis and decision-making support for conditions with known and suspected malfunctions of the immune system are indisputable.

But, despite the incredible potential of AI, some warn of inconsistencies and sometimes inaccurate results produced by machine learning. The ability to adapt to multimodal learning is not always accurate. Reliability, flexibility and contextualization in the face of incomplete and ambiguous information stunts machine learning, making for a stark reminder that overreliance on AI

without human intervention could be risky if not downright dangerous.

Even so, doctors and patients continue to demand faster and more accurate diagnoses and disease treatments using AI as an incredibly powerful tool. Continually learning and advancing, this CDS tool will forever stay in the physician's toolbox as it advances healthcare beyond diagnoses and treatments and into disease progression prediction.

Improving Autoimmune Disease Progression Prediction

Researchers across the U.S. are conducting AI studies to improve disease progression for autoimmune diseases. Results show AI's abilities in the broader ecosystem of health research and implementation of more effective therapies.

A team of researchers at Penn State College of Medicine conducted a study to pioneer the use of AI in determining who is most at risk for advanced autoimmune disease progression. Through analysis of electronic health records (EHRs) and large genetic studies, a newly created genetic prediction score (GPS) was found to be up to 1,000 percent more accurate than 20 other commonly used methods of disease prediction scoring.

In this study, the researchers used transfer learning to develop its GPS, testing both in patients with RA and lupus. They found AI was able to detect antibodies of those with RA five years before symptoms began. This ability to foretell preclinical disease enables the initiation of suitable and personalized treatments, thus extending patients' health span and potentially slowing disease progression.

With transfer learning, the system initially trained on smaller and simpler data subsets (for example, distinguishing between a cat and a dog) before it moved

on and fine-tuned its skills to learn a different but related set of data (such as malignant and benign tumor cells). Given the smaller subset of patients who have or will develop autoimmune disease (eight percent of the American population, according to the National Institutes of Health, most of whom are women), the real benefit of this transfer learning was its ability to create a reliable forecasting model given a smaller sample size.

In this case, the GPS trained on genome-wide association studies and EHR-based biobanks containing information about genetic variants, lab tests and more to identify genetic differences in those with autoimmune diseases. By determining which patients were in the preclinical stage of autoimmune disease, the machine could create a prediction score for those who would be most at risk of progressing to the disease stage.¹

The possibilities of AI are particularly dramatic in the area of autoimmune disease research where accuracy of disease diagnosis and now disease progression are coming into the fold.

In another study, researchers at Boston University built an AI model that predicts the presence of amyloid beta and tau proteins using memory score tests and brain scans in combination with age, health history and genetic information to predict a likelihood of developing Alzheimer's disease. This model not only predicted Alzheimer's, but also identified the area in the brain that would be affected and could detect disease progression from mild cognitive impairment to Alzheimer's within a six-year window. Better staging and subtyping of Alzheimer's enables the

development of personalized treatment plans that could potentially slow the disease progression. The model also scored well when tested on participants who were not part of the training regimen, accurately predicting high amyloid or tau levels as an indicator of cognitive decline.²

Type 2 diabetes mellitus, with suspected ties to the immune system, is also benefiting from AI research, with some models achieving up to 90 percent accuracy in predicting diabetes onset before clinical symptoms appear. Another notable highlight was a more accurate diagnosis of diabetic retinopathy using retinal images and clinical data. By using new AI-powered diagnostic technologies that read data from metal oxide semiconductor sensors, breath analysis and real-time retinal screening, patients may one day no longer need invasive blood draws or glucose tolerance

tests. The modeling also hinted at the possibility of expansion into prediction for diabetic retinopathy, peripheral neuropathy and others. When these technologies are ready for prime-time U.S. Food and Drug Administration (FDA) review, they may well offer a comprehensive approach that integrates EHRs, noninvasive monitoring and a better ability to manage disease outcomes.³

One of the most promising areas of AI use in prediction medicine is the creation of treatment plans and forecasting of individual response to personalized

therapies. For example, in the case of type 1 and type 2 diabetes, AI is enabling earlier diagnoses and better optimization of disease management to help to prevent or delay complications and adverse outcomes. Researchers in one study applied logistic regression analysis to two datasets, one for Pima Indians (type 1) and another for rural African Americans (type 2), with accurate disease prediction of 78 percent and 93 percent, respectively. Patients identified to be at risk were encouraged to adopt healthier behaviors supported by data-driven tools used in predictive modeling for lifestyle adjustments.⁴

The Challenges of AI Decision-Making

While AI is well-known for passing medical exams and text modality challenges, multi-modality inputs and even the data itself can sometimes challenge AI decision-making. For example, inconsistencies in the quality of EHRs may significantly limit machine learning accuracy that may cause fragmented or incomplete data quality. Without human oversight to verify results, health disparities and inequitable treatments may perpetuate.

Stress tests reveal some limitations in multimodal AI robustness and performance. While high scores on medical benchmarks may suggest clinical competence, when input prompts are altered or reordered, such as removing or adding an image, the system can become confused and generate incorrect responses, but they do so with a high confidence of accuracy. More worrisome to some is AI's sometimes flawed reasoning for determining its response, hinting to competency gaps in multimodal systems capabilities.⁵

The adoption and integration of multi-disease diagnostic AI models into clinical workflows faces both operational

and integration obstacles. Effective implementation of AI relies on the ability to pivot to new data collection methods, new analyses based on AI inputs and the capacity to interpret AI's decision-making and reasoning.

Further, it is imperative that AI tools perform accurately and consistently across a variety of patient populations, infrastructure differences and varying robustness of EHR data so AI modeling does not exacerbate healthcare inequities or bias.

Patchwork Regulatory Environment

The regulatory framework around the use of AI in healthcare is patchy at best. For instance, in the U.S., FDA regulates algorithm-based CDS when it meets the definition of a medical device. But, state laws and executive orders, including those focused on privacy, make the situation more complex. Additionally, the World Health Organization (WHO) in 2023 created a set of expectations for using AI in health that focused on transparency, documentation, risk management, validation, data quality, data privacy and protection, and collaboration. The European Union, also in 2023, created the EU AI Act, "a binding worldwide regulation" for the use of AI in the EU. Both WHO and EU frameworks allow for monitoring of CDS solutions throughout a product lifecycle, ensuring achievements in quality and ethics.⁶

Ironically, the benefit of AI's evolutionary learning is also one of its biggest liabilities from a regulatory perspective. As AI trains on ever-evolving historical data, incoming data that facilitates new learning is subject to privacy laws that make it more difficult to acquire and use the data. FDA has been looking into the potential of synthetic data, generated through computer

simulations, to supplement real-world datasets to protect data privacy. Federated learning, a decentralized AI approach, offers another option. Instead of each system collecting and storing large datasets, in federated learning, AI would train across datasets that remain at their original source locations and would, in theory, provide better patient privacy.³

Also, differing AI applications require unique regulatory frameworks, yet across the board, regulatory agencies are demanding that AI be explainable, transparent, traceable and accountable.

Ensuring Accurate and Reliable Prediction

AI's powerful support of healthcare continues to grow and evolve, creating more robust opportunities to understand disease and design meaningful projection models that forge new treatment outcomes. While there are certainly risks with the use of AI, as with any newer technology, thoughtful design and regulatory and human oversight will help to ensure machine learning supports accurate and reliable disease progression prediction now and into the future. ♦

References

1. Yu, C. Predicting the Progression of Autoimmune Disease with AI. The Pennsylvania State University News, Jan. 7, 2025. Accessed at www.psu.edu/news/research/story/predicting-progression-autoimmune-disease-ai.
2. Jasodanand, VH, Kowshik, SS, Puducheri, S, et al. AI-Driven Fusion of Multimodal Data for Alzheimer's Disease Biomarker Assessment. *Nature Communications*, Aug. 11, 2025. Accessed at www.nature.com/articles/s41467-025-62590-4.
3. Zhou, J, Park, S, Dong, S, et al. Artificial Intelligence-Driven Transformative Applications in Disease Diagnosis Technology. *Medical Review*, April 11, 2025. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC12558038.
4. Alshorman, J, Mehran, MJ, Bahrami, Y, et al. Artificial Intelligence in Immunotherapy: Revolutionizing Diagnostic and Therapeutic Applications in Cancer and Autoimmune Diseases. *Clinical and Experimental Medicine*, March 6, 2026. Accessed at link.springer.com/article/10.1007/s10238-026-02107-5?fromPaywallRec=true.
5. Gu, Y, Fu, J, Liu, X, et al. The Illusion of Readiness in Health AI. Johns Hopkins University, Dec.11, 2025. Accessed at cdhai.carey.jhu.edu/wp-content/uploads/sites/5/2026/02/HASTC-Paper-4.pdf.
6. Lin, AL, Parrish, AB, Cary, M, et al. Algorithm-Based Clinical Decision Support: Evolving Regulatory Landscape and Best Practices for Local Oversight. *Annual Review of Biomedical Data Science*, 2025 Aug.8. Accessed at www.annualreviews.org/content/journals/10.1146/annurev-biodatasci-103123-094601.

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AI in Drug Discovery and Development

Each stage of drug development takes time, but artificial intelligence is helping to shorten the timeline with improved odds of success.

By Lee Warren

DEVELOPING A new drug generally takes 10 to 15 years and carries a 90 percent failure rate with a hefty price tag of \$1 billion to \$2 billion.¹ Artificial intelligence (AI) is changing that. By shortening these timelines, reducing costs and improving the odds of success, AI is beginning to reshape every stage of drug discovery and development. It is not replacing scientists, but it is helping them to make better decisions faster.

Many aspects of drug development have been painstakingly slow because they depend on unraveling complex biological systems. Disorders such as cancer, autoimmune disorders and neurodegenerative conditions involve thousands of interacting genes, proteins and biochemical pathways that are difficult for even the most experienced researchers

to fully understand in a timely manner.

But, AI has the ability to recognize patterns within enormous datasets, an ability nearly impossible for humans. It can also identify previously overlooked relationships between genes and diseases, offer a prediction of how drug candidates may interact with target proteins and estimate whether a compound is likely to succeed or fail.

That's why, while still in its early stages, AI may become one of the most influential technologies in modern drug development. Let's examine each stage of development, explore some recent advances and assess the limitations.

The Catalyst

One of the fundamental problems scientists have faced in biomedical research

is determining the three-dimensional structure of proteins. A protein's shape largely determines its function. When researchers know the shape of a protein involved in a disease, they are often better able to design drugs that bind to it more effectively. Historically, solving these structures has been one of the slowest and most technically challenging tasks in biomedical research.

For decades, researchers have relied on experimental techniques, such as X-ray crystallography, cryo-electron microscopy and nuclear magnetic resonance spectroscopy, to determine protein structures. While these methods produce accurate results, they are costly and time-consuming. And some proteins are so difficult to analyze that researchers cannot determine their structures at all.

All this started to change in 2018 when Google DeepMind, Google's AI research laboratory, first introduced the promise of an AI-driven protein structure prediction with a model called AlphaFold. It demonstrated that deep learning could predict protein structures with unprecedented accuracy, setting the stage for its successor.

Two years later, Google DeepMind introduced AlphaFold2 — an AI model that could predict protein structures from amino acid sequences with near-experimental accuracy, and it could do so in minutes or hours. The work earned Demis Hassabis, PhD, a British artificial intelligence (AI) researcher and entrepreneur and John Jumper, PsyD, an American chemist and computer scientist, a share of the 2024 Nobel Prize in chemistry for developing AlphaFold, while David Baker, a biochemist, shared the prize for computational protein design.²

Their work was a game-changer. Instead of solving one protein structure at a time, researchers could use the model to predict the structures of virtually all known proteins — currently more than 200 million — and it made those predictions available through a database to scientists around the world.

Andrei Lupas, PhD, a molecular biologist at what was then known as the Max Planck Institute for Developmental Biology (now the Max Planck Institute for Biology Tübingen), had spent more than 10 years trying to determine the structure of a protein his laboratory was studying before AlphaFold2 successfully predicted it.³ “This will change medicine,” Lupas said at the time. “It will change research. It will change bioengineering. It will change everything.”⁴

Since then, AlphaFold3 was released in 2024, taking the process a step further. AlphaFold2 focused on predicting the three-dimensional structure of proteins. Building on AlphaFold2, AlphaFold3 expanded

beyond predicting what a protein looks like to predicting how it interacts with other molecules. That distinction is important because drug discovery depends not only on understanding a protein's structure but also on understanding how it interacts with other biologically important molecules.

For instance, could a potential drug bind to its intended target? How tightly? Might it also interact with DNA, RNA or other proteins? Instead of simply revealing a protein's structure, AlphaFold3 helps researchers understand the molecular interactions that influence how future medicines may work.

From Prediction to Creation

AlphaFold's success sparked an explosion of AI innovation. Competitors such as Boltz-1, Chai-1 and Meta's ESMFold have expanded the field, offering researchers additional options for predicting protein structures, although they differ in design, speed and capabilities. Yet predicting protein structures was only the beginning.

Their work was a game-changer. Instead of solving one protein structure at a time, researchers could use the model to predict the structures of virtually all known proteins.

Researchers soon began asking whether AI could help design the next generation of medicines. Rather than simply analyzing existing data, these new AI systems can propose novel molecules, predict their properties and help researchers identify the most promising candidates for further development. Some of these AI-designed therapies are already reaching patients through clinical trials.

Patients with idiopathic pulmonary

fibrosis (IPF) — a progressive and often fatal lung disease with limited treatment options — have reason for cautious optimism, thanks to Insilico Medicine's AI platform. It identified a novel biological target, designed a new molecule (INS018_055) and advanced it into clinical trials in approximately 30 months,⁵ which is much faster than the traditional timeline. Phase IIa clinical trials were encouraging, and they progressed into larger clinical studies. The results suggest the drug may slow disease progression.

Seventy-one IPF patients in China, between July 2023 and June 2024, were randomly assigned to receive the drug Rentosertib (formerly INS018_055/ISM001-055) 30 mg once daily, 30 mg twice daily or a placebo for 12 weeks. Investigators reported Rentosertib was safe and generally well-tolerated across all dosage groups. The 60 mg once-daily group showed the strongest improvement in lung function with the mean forced vital capacity increasing by approximately 98 mL over the 12-week period. However,

the placebo group experienced a mean decline of approximately 20 mL.⁶

That same study reported favorable changes in several serum biomarkers associated with pulmonary fibrosis, which suggests the drug affected the biological pathways it was designed to target. Larger trials are needed to confirm these findings.

In July 2026, Insilico announced the drug had entered Phase III clinical

testing.⁷ The Phase IIa results, coupled with the advancement to Phase III, represent one of the first demonstrations that an AI-generated drug candidate can progress from AI-assisted discovery to encouraging clinical outcomes. That doesn't prove AI has led to a cure for IPF, and Rentosertib may not ultimately receive regulatory approval. But, the fact that AI played a central role in generating a drug candidate capable of advancing this far is encouraging.

is the use of AI to design complex therapeutic modalities, including antibodies, engineered proteins and RNA-based therapies.¹¹ These are often more difficult to design than traditional small-molecule drugs because of their size and structure. Researchers hope AI will help identify and optimize these therapies more quickly, which would potentially open new treatments for diseases that have proven resistant to conventional drugs.

were trained, but their accuracy may decline when applied to new patient populations, different patient populations, laboratory settings or diseases with limited available data. When accuracy drops for any of these reasons, the model is said to have poor generalizability. Ensuring AI models perform reliably across diverse populations remains an active area of research.

As such, AI predictions still require laboratory validation. While AI models can predict protein structures, drug-target interactions, toxicity and binding affinity, every prediction still needs to be confirmed experimentally. In short, AI generates hypotheses, rather than proof.

AI can model many interactions, but biology is incredibly complex. Living systems involve immune responses, metabolism, off-target effects and disease heterogeneity. Promising compounds can still fail because living systems are more complex than computer models can fully capture.

AI also has a “black box” problem, meaning there is often little transparency in how complex models arrive at their outputs. Even when deep-learning systems produce highly accurate results, they may not explain how or why they reached those conclusions. That lack of interpretability makes researchers and regulators cautious, particularly because FDA reviewers generally expect evidence that can be independently evaluated.

Finally, regulatory and ethical challenges remain. Standards for transparency, reproducibility and validation continue to evolve, and U.S. Food and Drug Administration guidance for AI-assisted drug development is still being refined.

A Scientific Enhancement

Despite these challenges, AI is transforming drug discovery in ways that would have seemed impossible

Some of these AI-designed therapies are already reaching patients through clinical trials.

The Next Generation and Beyond

Besides IPF, AI-driven platforms are being used to accelerate multiple stages of early drug discovery across a growing range of therapeutic areas.

Isomorphic Labs is using AI to design therapies for cancer and immunological and inflammatory disorders in collaboration with Novartis, Eli Lilly and Johnson & Johnson.⁸

Recursion Pharmaceuticals is using its AI-powered Recursion OS to identify drug targets and design new therapies for oncology and rare diseases. The company's Phase II investigational therapy REC-4881 for familial adenomatous polyposis emerged from therapeutic insights generated by Recursion OS.⁹

Xaira Therapeutics, which launched in 2024, is being more secretive with its AI-first platform, only revealing they are aiming at “really hard targets and large molecule therapeutics,” with immunology being one area of interest.¹⁰

While all of this is going on, researchers are exploring ways to push the technology even further. One of the most promising areas of research

Scientists are also investigating how AI can make drug discovery more personalized. For example, rather than developing a single therapy for all patients with a disease, future AI platforms may be able to analyze genomic, proteomic and clinical data to identify treatments best suited for specific populations or individuals with unique genetic mutations.¹²

Other researchers are focusing their efforts on AI-assisted drug repurposing that evaluates existing medications for new therapeutic uses.¹³ This sort of use of AI technology is at the early stages of development, but it does illustrate how AI's role may expand well beyond today's drug discovery process.

AI Limitations

Even as AI continues to advance, it remains a tool with significant limitations. AI is only as good as the data on which it's trained. Incomplete or biased datasets, poor-quality experimental data and underrepresentation of certain diseases or populations can all reduce the accuracy and reliability of AI models.

AI models often perform well when tested using the datasets on which they

a decade ago. It's helping researchers solve complex problems more quickly and efficiently than ever before. The early successes of AlphaFold and AI-generated drug candidates entering clinical trials demonstrate these are not just theoretical concepts but rather practical tools that are influencing modern medicine.

At the same time, AI is not a substitute for careful scientific investigation. Computer models cannot replace laboratory experiments, clinical trials or the expertise of biologists, chemists, physicians and regulatory scientists. Every prediction generated by an algorithm must still be validated through rigorous testing to ensure new therapies are both safe and effective. As AI systems continue to evolve, improvements in data quality, model transparency and regulatory oversight will be essential in realizing their full potential.

Perhaps AI's greatest contribution is not replacing the scientific method but enhancing it. By uncovering patterns that might otherwise remain hidden, speeding up the process and helping researchers prioritize the most promising drug candidates, AI allows scientists to focus their expertise where it matters most.

While many challenges remain, AI is poised to become an indispensable partner in the search for tomorrow's medicines. ❖

References

1. Sun, D, Gao, W, Hu, H, and Zhou, S. Why 90% of Clinical Drug Development Fails and How to Improve It? *Acta Pharmaceutica Sinica B*, 2022 July;12(7):3049-3062. Accessed at www.sciencedirect.com/science/article/pii/S2211383522000521.
2. The Nobel Prize in Chemistry 2024. The Royal Swedish Academy of Sciences press release, Oct. 9, 2024. Accessed at www.nobelprize.org/prizes/chemistry/2024/press-release.
3. Howes, L. DeepMind AI Predicts Protein Structures. *Chemical & Engineering News*, Dec. 1, 2020. Accessed at cen.acs.org/physical-chemistry/protein-folding/DeepMind-AI-predicts-protein-structures/98/web/2020/12.
4. Advisory Board. 'This Will Change Medicine': How DeepMind Is Answering One of Biology's Biggest Questions, Dec. 3, 2020. Accessed at www.advisory.com/daily-briefing/2020/12/03/alphafold.
5. Ren, F, Aliper, A, Chen, J, et al. A Small-Molecule TNiK Inhibitor

Targets Fibrosis in Preclinical and Clinical Models. *Nature Biotechnology*, March 8, 2024. Accessed at www.nature.com/articles/s41587-024-02143-0.

6. Xu, Z, Ren, F, Wang, P, et al. A Generative AI-Discovered TNiK Inhibitor for Idiopathic Pulmonary Fibrosis: A Randomized Phase 2a Trial. *Nature Medicine*, June 3, 2025. Accessed at www.nature.com/articles/s41591-025-03743-2?utm.
7. Insilico Initiates Phase III Clinical Trial for Rentosertib, Its AI-Empowered TNiK Inhibitor for Idiopathic Pulmonary Fibrosis. Insilico press release, July 7, 2026. Accessed at insilico.com/news/xmjsn4091-insilico-initiates-phase-iii-clinical-tr.
8. Isomorphic Labs. Partnerships. Accessed at www.isomorphiclabs.com/partnerships.
9. Recursion to Report First Quarter 2026 Business Updates and Financial Results on May 6. Recursion news release, April 29, 2026. Accessed at ir.recursion.com/news-releases/news-release-details/recursion-report-first-quarter-2026-business-updates-and.
10. Armstrong, A. Secretive AI Drug Hunter Xaira Dips Toe Into Dealmaking with Hunt For Partners. *BioSpace*, July 8, 2026. Accessed at www.biospace.com/business/secretive-ai-drug-hunter-xaira-dips-toe-into-dealmaking-with-hunt-for-partners.
11. Tang, J, Gong, D, Li, H, Li, S. Artificial Intelligence in Biologic Drug Discovery: A Review of Methodological Evolution and Therapeutic Applications. *Acta Pharmaceutica Sinica B*, 2026 Feb;16(7): 3996-4023. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC13366306.
12. Liu, Y, Zhu, K, Peng, W, and Mao, X. Multi-Omics and Artificial Intelligence For Precision Drug Discovery and Potential Clinical Applications. *Signal Transduction and Targeted Therapy*, June 3, 2026. Accessed at www.nature.com/articles/s41392-026-02631-6.
13. Tanoli, Z, Fernández-Torres, A, Özcan, UO, et al. Computational Drug Repurposing: Approaches, Evaluation of In Silico Resources and Case Studies. *Nature Reviews Drug Discovery*, March 18, 2025. Accessed at www.nature.com/articles/s41573-025-01164-x.

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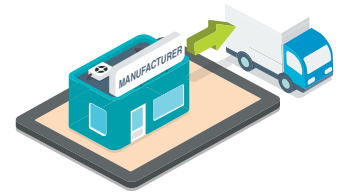
* name has been changed

8 Critical Steps

1

PURCHASING

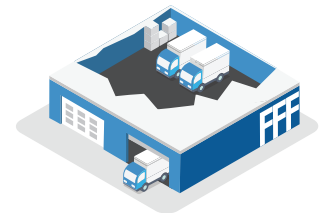
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2

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3

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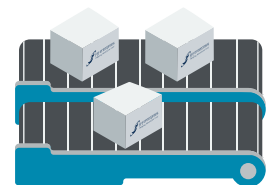
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4

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5

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Our delivery guidelines are in compliance with the State Board of Pharmacy requirements. Products we deliver must only be transported to facilities with a state-issued license, and only to the address on the license. We make no exceptions. And we will not ship to customers known to have a distributor's license.



6

METHOD OF DELIVERY

We monitor for extreme weather conditions, and when the need arises, we ship overnight to maintain product efficacy. We also track patient need during life-threatening storms to make sure products are delivered when and where patients need them most.



7

VERIFICATION

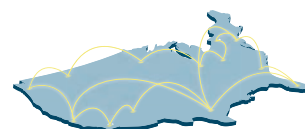
In compliance with U.S. Drug Supply Chain Security Act (DSCSA) requirements, every product shipped from FFF is accompanied by a packing slip that includes information regarding the manufacturer and presentation, as well as the three T's: Transaction Information, Transaction History, and Transaction Statement.



8

TRACKING

To meet DSCSA requirements, FFF provides product traceability information on all packing slips. In addition, Lot-Track® electronically captures and permanently stores each product lot number, matched to customer information, for every vial of drug we supply.



Genomic Sequencing + AI-Assisted Analytics = Functional Precision Medicine

Evolving technology in functional precision medicine artificial intelligence platforms is transforming how individual treatment plans are developed for patients with advanced cancer.



By Diane L.M. Cook

THE AMERICAN Cancer Society (ACS) expected more than two million new cancer cases to be diagnosed and more than 618,000 people to die from cancer in 2025 in the U.S. However, while ACS said progress is being made to reduce the number of people being diagnosed with cancer due to decreases in smoking, advances in treatment and early detection for some cancers,¹ cancer diagnoses and treatments remain two of healthcare's most complex challenges.

Historically, cancer has been treated with standardized protocols driven by population-level data or trial-and-error approaches. More recently, evolving artificial intelligence (AI)-driven functional precision medicine (FPM) platforms combine patient-derived tumor biology with advancements in proprietary cell enrichment processes, automation, robotics and AI. FPM platforms enable oncologists to rapidly test how an individual patient's cancer responds to hundreds of U.S. Food and Drug Administration (FDA)-approved

drugs and combinations, delivering ranked treatment options within days.²

What is FPM?

FPM is an advanced medical approach that takes a patient's living cells — most commonly from a tumor — and tests them directly against hundreds of different drugs or drug combinations in a laboratory. Instead of relying solely on DNA sequencing to find genetic matches, it measures which treatments actually kill the cells.

While traditional precision medicine uses DNA or genomic sequencing to identify specific mutations, it can only guide treatments for a fraction of patients whose tumors have a known, targetable mutation. FPM provides immediately actionable, personalized data by directly perturbing a patient's viable cells and physically measuring the response. This method bypasses the limitations of genetics by revealing how the unique biology of an individual's disease behaves in real time.³

What Are the Benefits of Functional Precision Medicine?

FPM provides additional treatment avenues for patients who have exhausted standard-of-care options or who lack actionable genetic mutations. It also reveals which drugs a tumor responds to and which ones it resists, preventing the prescription of ineffective drugs and reducing unnecessary toxicity.

According to an article from *Trends in Molecular Medicine*, "Growing evidence has ... shifted the mindset in oncology, considering cancer as a highly individualized disease that requires a tailored therapeutic strategy, based on both molecular and functional data, thereby emphasizing the value of FPM approaches."⁴

By using FPM AI platforms, doctors can now accelerate the discovery of novel targets, predict the effectiveness of treatments, identify potentially lifesaving clinical trials and diagnose multiple diseases earlier.

Many oncology companies have developed FPM AI platforms to identify types of cancers and how those cancers are expected to progress, as well as to identify the best course of treatment specifically tailored to each patient's cancer. Following are summaries of First Ascent Biomedical, Tempus and Strata Oncology's FPM AI platforms.

First Ascent Biomedical

First Ascent Biomedical is a precision oncology company that provides oncologists and patients with data, based on each patient's biology, to enable them to design an evidence-based, personalized treatment plan for patients who have failed the standard-of-care regimens.

The company's FPM platform, called xDRIVE (Ex Vivo Drug Response Identification & Validation Engine), is an AI-powered clinical decision support for oncologists treating refractory or treatment-resistant cancers. xDRIVE combines three core components: functional drug validation, genomic sequencing and AI cancer weakness mapping.

First Ascent's proprietary live-cell approach is the first and only platform capable of testing up to 150-plus FDA-approved therapies and combinations in parallel on both liquid and solid cancers that delivers precise, patient-specific evidence on how an individual's cancer responds in approximately 10 days or less.⁵

xDRIVE begins with a fresh tumor or blood sample containing viable cancer cells. Those living cancer cells are tested ex vivo against a broad panel of FDA-approved therapies and combinations to observe how the patient's cancer actually responds.

First Ascent then integrates those functional drug-response results with genomic DNA/RNA data and individualized machine learning (ML)-guided analysis to identify the tumor's vulnerabilities and prioritize treatment options for the treating physician.

For physicians, the key distinction of xDRIVE is that it does not rely on genomics predictions. Genomic testing can identify mutations, molecular markers and potential targets, but it does not always indicate whether a patient's living cancer cells will respond to a specific drug or combination of drugs.

xDRIVE bridges that gap by adding a

functional layer through direct testing of the patient's own viable cancer cells. The resulting data is intended to support, not replace, the oncologist's clinical judgment.

First Ascent's current FPM AI platform is focused on cancer treatment decision support, rather than broad disease diagnosis. Its potential to change care lies in shifting oncology from a largely population-based model toward a more individualized model based on the biology of each patient's living cancer cells.

Jim Foote, co-founder and CEO of First Ascent Biomedical, said, "In conventional oncology, treatment selection is often guided by tumor type, stage, population-based standard protocols and, increasingly, genomic markers. These tools are essential, but they can still leave physicians with difficult questions, particularly in relapsed, refractory, rare or aggressive cancers. A genomic test may show no actionable mutation, or it may identify a possible target without proving that the cancer will respond to a specific therapy. First Ascent's premise is that physicians need both molecular information and functional evidence: not only 'What mutations does this cancer have?' but also 'Which drugs actually affect this patient's cancer cells?'

"This is where individualized ML becomes important. The xDRIVE platform generates and integrates multiple layers of information, including live-cell drug response, genomic sequencing, cancer characteristics and treatment sensitivity patterns. ML is used to synthesize the data and highlight treatment vulnerabilities that may not be obvious from genomics or standard pathology alone. First Ascent believes this can help physicians move away from trial-and-error treatment selection and toward faster, evidence-based prioritization of therapies for individual patients, because all of the data used to train the ML model

is specific to each patient.

“For health systems, this approach could have implications beyond the individual case. If validated at a larger scale, FPM could help reduce time spent on ineffective therapy, limit avoidable toxicity, identify rational drug combinations and make better use of FDA-approved drugs. For patients with advanced disease, time matters. A platform that can return actionable treatment information within roughly 10 days may help physicians make decisions while the patient is still clinically eligible for therapy.

“The goal is not to replace today’s standard of care, but to strengthen it with evidence specific to the individual patient.”

“The goal [of FPM] is not to replace today’s standard of care, but to strengthen it with evidence specific to the individual patient.”

A recent example of a cancer patient who has benefited from First Ascent’s xDrive platform is Logan Jenner, a child treated through the FPM approach developed with investigators at Florida International University and Nicklaus Children’s Hospital.

“Logan was diagnosed with acute myeloid leukemia at age 3. He received chemotherapy and a bone marrow transplant but his cancer returned 14 months later,” said Foote. “He was enrolled in the clinical trial, and the functional testing results identified a drug combination that appeared likely to work for his cancer. The results also helped indicate that idarubicin, a drug associated with cardiac toxicity at very high doses, could be withheld without reducing the expected efficacy of the regimen. Thirty-three days after starting treatment guided

by the results, Logan reached remission; five years later, he remained cancer-free and without any heart problems.”

Strata Oncology, Inc.

Strata Oncology is a next-generation precision oncology company that combines molecular profiling tests, biomarker algorithms, — such as the Immunotherapy Response Score (IRS) and Antibody-Drug Conjugates (ADCs) biomarkers — real-world data, and a large-scale clinical trial platform to identify and deliver optimal treatments

targets and tumor types. Independent evaluation showed improved response rates, progression-free survival and overall survival for biomarker-high patients.

The company’s Strata PATH (Precision Indications for Approved Therapies) is a 700-patient pan tumor clinical trial that evaluates the safety and efficacy of multiple FDA-approved therapies in new, biomarker-guided populations. The trial matches patients with specific therapies based on advanced DNA and RNA analysis.⁶

“Identifying patients who will successfully respond to immunotherapy treatment is key to providing the best possible therapy for patients with cancer,” said Dan Rhodes, PhD, co-founder and CEO of Strata Oncology, Inc. “Using a single small tissue sample, our integrated platform provides treatment selection guidance across therapeutic modalities.”⁷

Tempus

Tempus is a healthcare technology company advancing FPM in oncology through the application of AI. With one of the world’s largest libraries of multimodal data and an operating system to make that data accessible and useful, Tempus provides AI-enabled precision medicine solutions to physicians to deliver personalized patient care and in parallel facilitates discovery, development and delivery of optimal therapeutics. The goal is for each patient to benefit from the treatment of others who came before them by providing physicians with tools that learn as the company gathers more data.

The Tempus xH platform is a comprehensive whole-genome sequencing (WGS) assay and analytical tool designed to uncover actionable oncologic targets. By utilizing a next-generation sequencing (NGS) approach, it consolidates multiple tests into a single, cost-effective assay to streamline workflows in clinical settings

for patients who have advanced cancer.

Launched in 2023, the Strata Select platform is a first-of-its-kind pan solid tumor molecular profiling test integrating DNA and quantitative RNA sequencing. The platform features the IRS, a proprietary, pan-solid tumor predictive biomarker for anti-PD-1/PD-L1 checkpoint inhibitor monotherapy benefit that has been validated in multiple publications. IRS has been shown to have utility beyond standard biomarkers used to guide anti-PD-1/PD-L1 therapy, including tumor mutation burden, microsatellite instability and PD-L1 immunohistochemistry.

Strata Select also provides comprehensive genomic profiling results, along with supplemental information, including quantitative RNA gene express-based results that provide insights that can be informative for other classes of therapy such as ADCs.

ADC Biomarker, Strata’s proprietary multi-factorial biomarker, can predict response to ADCs across multiple

and drug development pipelines. xH is expected to be commercially available for clinical ordering in late 2026.

The company recently announced the upcoming clinical availability of the xH test, first announced in January 2025 for research use, a next-generation sequencing test that uses a WGS approach for the detection of actionable oncologic targets in peripheral blood and bone marrow samples from patients with hematologic malignancies. Specifically, this test was developed for use in acute myeloid leukemia, myelodysplastic syndromes (MDS), myeloproliferative neoplasms (MPN) and overlap syndromes (MDS/MPN). It is optimized for myeloid neoplasms and is designed to support disease understanding, biomarker discovery and therapeutic research.

The performance of Tempus' xH test was established in an analytical validation study using 235 unique specimens, including whole blood, bone marrow and cell lines. Assay performance was evaluated by comparison with established orthogonal methods to assess analytical accuracy and precision across multiple variant classes.

The analytical validation demonstrated high accuracy across all major alteration types and achieved a positive percent agreement (PPA) of 97.29 percent for single nucleotide variants (SNVs) and insertions and deletions (indels) against the Tempus xT (DNA; 648 gene) assay, 92.86 percent PPA for structural variants (SVs) against the Tempus xR (RNA; whole transcriptome sequencing [WTS]) assay and confirmation Sanger sequencing, and 93.43 percent PPA for CNAs against an oligo-SNP chromosomal microarray.

In addition to high accuracy, the xH assay demonstrated excellent precision, ensuring reliable and reproducible results. The assay achieved a positive predictive value (PPV) of 98.97 percent for SNVs and indels, and 100 percent for SVs. These results indicate a low false-positive rate

and support high confidence in the assay's reported genomic findings.

Data presented at the 2026 American Society of Clinical Oncology Annual meeting demonstrate the assay's clinical utility in resolving historical diagnostic blind spots. In a blinded study of an MDS cohort, xH achieved greater than 99 percent sensitivity and uncovered 40 percent more clinically relevant genomic findings, surfacing critical actionable genomic variations that were completely missed by traditional standard-of-care techniques.⁸

"When we introduced xH, our goal was to create a standardized WGS platform that could transform care in hematologic oncology," said Tom Schonherr, CEO of Diagnostics at Tempus. "We've realized that vision by replacing multiple time-consuming diagnostic tests with a single, high-throughput whole-genome workflow that helps clinicians make faster, smarter decisions. At the same time, xH provides biopharma partners with a comprehensive multiomic foundation to improve clinical trial design, accelerate biomarker discovery and support the development of next-generation targeted therapies."⁹

Looking Forward

The Society for Functional Precision Medicine, whose vision is to make FPM a rigorous, clinically actionable and measurable part of how precision medicine is used to treat cancer, believes the next decade will require marrying tumor profiling with systematic, scalable functional testing directly on patient-derived tissue and models to guide therapy, accelerate discovery and benefit patients.¹⁰

An article in *Trends in Molecular Medicine* stated, "We envision the integration of AI into FPM programs as the cornerstone of the future of personalized cancer care, enabling the personalization of monotherapy and combination therapy regimens tailored to

the unique characteristics of each cancer patient across all ages and cancer types."⁴

In an article published in the journal *Cancer Cell* titled "Functional Precision Oncology: Testing Tumors with Drugs to Identify Vulnerabilities and Novel Combinations," the authors write, "We predict that the next five years will see an increasing marriage of these two approaches [genomics and FPM] in clinical trials whose completion will be necessary for the establishment of functional precision medicine as a standard tool in clinical oncology. This union will be necessary for the rational selection of active combination regimens that will ultimately be necessary for precision medicine in oncology to provide its greatest benefit to patients."¹¹

"The biggest breakthrough in cancer care is unlikely to be a single drug or algorithm," added Foote. "It will be the engineered intersection of biology, technology, AI and therapeutics working synergistically around each individual patient."¹² ♦

References

1. American Cancer Society. Cancer Facts & Figures 2025. Accessed at www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2025/2025-cancer-facts-and-figures-acsc.pdf.
2. Foote, J. How AI-Driven Functional Precision Medicine Unlocks Personalized Cancer Therapy. *HealthCare Business News*, March 16, 2026. Accessed at www.dotmed.com/news/story/66082.
3. Society for Functional Precision Medicine. SPM Is Working to Bring Functional Precision Medicine from Promise to Clinical Care. Accessed at www.sfpml.io.
4. Acanda de la Rocha, AM, Berlow, N, and Azzam, D. Functional Precision Medicine: The Future of Cancer Care. *Trends in Molecular Medicine*, 2025 May;31(5): 404-408. Accessed at [www.cell.com/trends/molecular-medicine/fulltext/S1471-4914\(24\)00282-X](http://www.cell.com/trends/molecular-medicine/fulltext/S1471-4914(24)00282-X).
5. First Ascent Biomedical. Accessed at www.firstascentbiomedical.com.
6. Strata Oncology. Accessed at www.strataoncology.com.
7. Strata Oncology Recognized as "Diagnostics Innovation of the Year" by Bioech Breakthrough Awards. Strata Oncology press release, Nov. 8, 2023. Accessed at strataoncology.com/publications/110823/.
8. Tempus. Accessed at www.tempus.com.
9. Tempus Announces the Upcoming Clinical Availability of Its First Whole-Genome Sequencing Assay, xH. Tempus press release, June 1, 2026. Accessed at www.businesswire.com/news/home/20260601323021/en/Tempus-Announces-the-Upcoming-Clinical-Availability-of-Its-First-Whole-Genome-Sequencing-Assay-xH.
10. About SPM. Society for Functional Precision Medicine. Accessed at www.sfpml.io/about.
11. Letai, A, Bhola, P, and Welm, AL. Functional Precision Oncology: Testing Tumors with Drugs to Identify Vulnerabilities and Novel Combinations. *Cancer Cell*, 2021 Dec;40(1):26-35. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC8752507.
12. Foote, J. From Consensus Oncology to Individualized Biology: How AI-Enabled Functional Precision Medicine Could Rewrite Cancer Care. *Medical Design Briefs*, Feb. 1, 2026. Accessed at www.medicaldesignbriefs.com/component/content/article/54543-from-consensus-oncology-to-individualized-biology.

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Empathy:

Are Future Physicians Learning the Crucial Piece of Clinical Practice?

Research suggests empathy softens during clinical training, but new curricula are testing whether that decline is inevitable.

By Trudie Mitschang

A FIRST-YEAR medical student walks into her first patient interview carrying more compassion than she may ever have again in her career. What sounds like a cynical joke is actually very close to reality, based on a growing body of research. Decades of studies using validated instruments like the Jefferson Scale of Empathy (JSE) have tracked a familiar arc: high empathy at matriculation, followed by a measurable dip once students hit the wards.^{1,2} Nearly everyone agrees empathy in healthcare matters. The harder question for medical educators, hospital administrators and practicing physicians alike is whether medical training is structured in a way that keeps empathy intact.

What the Data Show

The empathy-decline narrative traces back to Mohammadreza Hojat and colleagues at Thomas Jefferson University, who developed the JSE because no tool existed to measure empathy in a clinical, rather than general, context. Their prospective study of 125 medical students found a statistically measurable decline in empathy scores between the beginning and end of the third year, the point at which students move from classroom learning into direct patient care.¹ A 2011 systematic review of studies involving medical students and residents concluded this erosion undermines the pursuit of professionalism and may threaten the quality of healthcare. It also flagged the

third and fourth years, when clinical exposure intensifies, as the period of steepest decline.

More recent data complicate that picture. A 2024 cross-sectional study of nearly 900 students across all five years at Leicester Medical School in the United Kingdom found a small but statistically significant drop in empathy scores as students moved from preclinical to clinical training, with male students scoring consistently lower than female students.³

A University of Chicago research team pushed the question further by separating empathy into its cognitive and affective components. Self-reported cognitive empathy scores did decline in line with

prior studies, but the picture grew more nuanced once affective empathy, the capacity to actually feel what a patient feels, was measured using different methods.⁴ Medical students, in other words, may not be losing their capacity to care so much as learning, sometimes for self-protective reasons, to regulate how much of that caring they let show.

Taken together, the research supports a more precise conclusion than the blanket claim that medical school kills empathy. Empathy does appear to soften somewhat as students enter clinical training. The drop is generally small in magnitude, and the timing, right when students begin sitting across from real, suffering patients, is the detail that should worry educators most, regardless of how one interprets the exact numbers.

Empathy and Patient Outcomes

Ask researchers why empathy dips during training and the same list of culprits recurs: chronic sleep deprivation, unrelenting time pressure, a curriculum still organized around biomedical facts rather than human narratives, weak or absent role modeling and the informal, often cynical lessons students absorb by watching how attending physicians actually behave, as opposed to what they are told in lectures.³ Add the emotional toll of encountering death, suffering and system dysfunction for the first time, often without adequate support, and a decline in outward empathic expression starts to look less like moral failure and more like an adaptive, if costly, coping response.

Physician and author Abraham Verghese, MD, MACP, who built the Stanford 25 program to keep bedside physical examination alive in an age of scans and algorithms, has argued the problem is not that medical schools fail to teach empathy, but that training

actively erodes what students already bring with them. “What we need in medical schools is not to teach empathy, as much as to preserve it,” Dr. Verghese said. “The process of learning huge volumes of information about disease, of learning a specialized language, can ironically make one lose sight of the patient one came to serve; empathy can be replaced by cynicism.”⁵ Dr. Verghese also described how modern training takes lovely people and converts them into bottom-line, somewhat cynical, disease-oriented people, in part because students are taught a clinical vocabulary that strips the humanity out of a patient’s story.

The implications of empathy-free patient interactions extend beyond good bedside manner. A widely cited 2011 study of 891 diabetic patients treated by 29 family physicians found that patients of high-empathy physicians, as measured by the JSE, were significantly more likely to have good control of hemoglobin A1c (56 percent versus 40 percent) and LDL cholesterol (59 percent versus 44 percent) than patients of low-empathy physicians.⁶ In addition, a review of empathy’s effectiveness in general practice similarly concluded that empathy correlates with better patient satisfaction and adherence, lower patient anxiety and distress, and improved diagnostic and clinical outcomes.⁷

Physician empathy has also been linked to fewer malpractice claims, greater patient safety and lower rates of physician burnout, a two-way relationship in which burned-out clinicians express less empathy and low-empathy environments contribute to burnout in turn.⁸ Helen Riess, MD, a psychiatrist at Massachusetts General Hospital and Harvard Medical School who has spent much of her career studying the neuroscience of empathy, put it bluntly in a recent interview: Physicians who train in relational skills also become “more resilient” over time,

because connecting authentically with patients feeds back into a clinician’s own sense of purpose rather than draining it.⁹

Can Empathy Be Taught, or Just Protected?

The most encouraging development in this field is found in a growing body of evidence that empathy is trainable. Dr. Riess developed a neuroscience-grounded curriculum built around the acronym E.M.P.A.T.H.Y. (eye contact, muscles of facial expression, posture, affect, tone of voice, hearing the whole person and your response), and tested it in a randomized controlled trial of resident physicians. Patients rated physicians in the trained group as significantly more empathic than those in the control group, and the trained residents also scored better on tests of reading subtle facial emotion.¹⁰

“Most people believed that you had a fixed amount of empathy, and you either had it or you didn’t,” Dr. Riess said of the assumption her research set out to challenge.¹¹ Her broader argument is that empathy is closer to a skill than a personality trait, one that can atrophy under stress and can also be deliberately rebuilt.

A second, increasingly common intervention is narrative medicine, a field founded by Rita Charon, MD, PhD, at Columbia University, which trains clinicians in close reading, reflective writing and attentive listening to patients’ stories. “The effective practice of medicine requires narrative competence,” Dr. Charon said. “That is, the ability to acknowledge, absorb, interpret and act on the stories and plights of others.”¹² Residency programs have begun building narrative medicine sessions directly into required didactic time, on the theory that giving trainees structured space to process difficult clinical experiences, rather than simply pushing through them, protects both empathy and professional identity

during a uniquely formative and stressful period.¹³

Programs combining these approaches, communication skills training, reflective writing, humanities coursework and protected time for processing difficult encounters, are proliferating across U.S. medical schools and residencies, though implementation remains uneven and is often squeezed out by the demands of an already saturated curriculum.

Embedding Empathy into the Curriculum

The response to the empathy problem is no longer confined to a single elective or a communication skills seminar bolted onto the first year. At Leicester Medical School, the Stoneygate Centre for Empathic Healthcare, launched in 2023, has taken the unusual step of building its curriculum with patients themselves at the table. Working alongside educators and students in a series of co-production workshops, the center designed a five-year program that threads empathy training through every stage of learning rather than isolating it to a single course.¹⁴ Students conduct structured home visits with patients early in training, receive workplace-based empathy assessments built on real patient feedback and revisit communication skills repeatedly as they progress through clinical rotations. The center now trains faculty from other institutions through a three-day course, betting the model can travel beyond Leicester.

That instinct, toward sustained exposure rather than a single intervention, shows up elsewhere, too. At the University of Navarra in Spain, an obligatory medical identity journey program introduced in 2013 runs through the fourth, fifth and sixth years of the medical curriculum, pairing humanities-based workshops and case discussion with personal written

reflections tied to each clinical rotation. A longitudinal study tracking one class across all six years found a significant increase in self-reported empathy between the end of year three and the end of year six, the exact window the program covers, a reversal of the pattern researchers usually find, suggesting that spaced, repeated reflection may do more than any single course.¹⁵ It's worth noting the same research group's earlier work found standardized patients rated trained students as more empathic, even when the students' own self-reported scores didn't move, a reminder that empathy measures don't always agree with each other.

Teaching methods themselves are also shifting. An examination of empathy training across medicine, nursing and allied health increasingly favors structured role play with real-time feedback over lecture-based instruction, reinforcing something Dr. Riess' work has long argued: Empathy behaves less like a fact to memorize and more like a clinical skill to drill.¹²

What This Means for the Profession

The full arc of medical training, from the first year of medical school through residency and into independent practice, is where empathy is formed, tested and, the evidence increasingly suggests, at real risk of quiet erosion. That decline is modest, structural rather than a failure of character, and consequential enough for patient satisfaction and very possibly for clinical outcomes, that it deserves more than passing concern.

Dr. Verghese's framing is the more useful one for educators to adopt: The goal isn't to instill empathy students lack, but to protect what most already bring on day one. Curriculum reform, protected reflective time, communication skills training and

narrative medicine programs all point to the same conclusion: Empathy is a clinical competency like any other, one that must be taught, assessed and defended throughout training rather than assumed to survive on its own. Whether medical education is doing that well enough remains an open question, and one the profession can no longer treat as optional. ♦

References

1. Hojat, M, Mangione, S, Nasca, TJ, et al. An Empirical Study of Decline in Empathy in Medical School. *Medical Education*, 2004 Sep;38(9):934-941. Accessed at pubmed.ncbi.nlm.nih.gov/15327674.
2. Neumann, M, Edelhäuser, F, Tauschel, D, et al. Empathy Decline and Its Reasons: A Systematic Review of Studies with Medical Students and Residents. *Academic Medicine: Journal of the Association of American Medical Colleges*, 2011 Aug;86(8):996-1009. Accessed at pubmed.ncbi.nlm.nih.gov/21670661.
3. Keshkar, L, Ward, A, Winter, R, et al. Does Empathy Decline in the Clinical Phase of Medical Education? A Study of Students at Leicester Medical School. *PEC Innovation*, 2024 Jul;5. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC11705371.
4. Cormier, T. Study Challenges Perception That Empathy Erodes During Medical School. University of Chicago News, Sept. 8, 2017. Accessed at news.uchicago.edu/story/study-challenges-perception-empathy-erodes-during-medical-school.
5. Cohen, S. The Human Whisperer. *Stanford Magazine*, January/February 2009. Accessed at stanfordmag.org/contents/the-human-whisperer.
6. Hojat, M, Louis, DZ, Markham, FW, et al. Physicians' Empathy and Clinical Outcomes for Diabetic Patients. *Academic Medicine: Journal of the Association of American Medical Colleges*, 2011 Mar;86(3):359-364. Accessed at pubmed.ncbi.nlm.nih.gov/21248604.
7. Derksen, F, Bensing, J, and Lagro-Janssen, A. Effectiveness of Empathy in General Practice: A Systematic Review. *The British Journal of General Practice: The Journal of the Royal College of General Practitioners*, 2012 Dec;63(666):e76-e84. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC3529296.
8. Wilkinson, H, Whittington, R, Perry, L, and Eames, C. Examining the Relationship Between Burnout and Empathy in Healthcare Professionals: A Systematic Review. *Burnout Research*, 2017 Sep;6:18-29. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC5534210.
9. Cleveland Clinic. The Neuroscience of Empathy. Studies in Empathy podcast. Accessed at my.clevelandclinic.org/podcasts/studies-in-empathy/the-neuroscience-of-empathy.
10. Riess, H, Kelley, JM, Bailey, RW, et al. Empathy Training For Resident Physicians: A Randomized Controlled Trial of a Neuroscience-Informed Curriculum. *Journal of General Internal Medicine*, 2012 May;27(10):1280-1286. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC3445669.
11. Center for Compassionate Leadership. Closing the Compassion Gap — Dr. Helen Riess on the Role of Empathy and Compassion in Healthcare. Accessed at www.centerforcompassionateleadership.org/blog/closing-the-compassion-gap-dr-helen-riess-on-the-role-of-empathy-and-compassion-in-healthcare.
12. Downey, R. Narrative Medicine Develops Empathy Among Physicians. KevinMD, Aug. 31, 2022. Accessed at kevinmd.com/2022/08/narrative-medicine-develops-empathy-among-physicians.html.
13. Silver, M, and Hussain, F. A Resident Narrative Medicine Curriculum to Promote Professional Identity Development: Story-Based Sessions Grounded in Narrative Learning Theory. *MedEdPORTAL*, Oct. 22, 2024. Accessed at www.mededportal.org/doi/10.15766/mep_2374-8265.11446.
14. Bennett-Weston, A, Harrell, C, Ward, A, et al. Co-Producing an Empathy-Focused Medical Curriculum with Patients, Educators and Students. *The Clinical Teacher*, 2025 May;22(3). Accessed at asmedpublications.onlinelibrary.wiley.com/doi/10.1111/tct.70100.
15. Díez, N, Rodríguez-Díez MC, Arbea, L, et al. Increase in Self-Reported Empathy During Medical School Training: A Longitudinal Study. *PLoS One*, 2025 Sep;20(9). Accessed at journals.plos.org/plosone/article/file?type=printable&id=10.1371/journal.pone.0332343.

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Myths & Facts: Childhood Vaccines

As vaccine hesitancy continues to rise, it is imperative that healthcare providers clearly communicate the facts about childhood vaccines and reinforce that immunization remains one of the greatest public health achievements of modern times.

By Ronale Tucker Rhodes, MS



FOR DECADES, childhood vaccines have been one of the greatest achievements in public health, dramatically reducing the burden of once-common diseases such as polio, measles, diphtheria and meningitis. Indeed, routine immunizations have saved millions of lives and prevented countless hospitalizations and long-term disabilities. Their efficacy and safety are built on decades of rigorous scientific research, extensive clinical testing and continuous safety monitoring.

Over the years, several organizations joined forces to develop a single vaccine schedule for children. It all began in 1964 when the American Academy of Pediatrics (AAP), the government and other organizations agreed a unified policy would be the best for U.S. children to save even more lives. These groups formed an independent group of experts known as the Advisory Committee on Immunization Practices (ACIP) in charge of reviewing the latest research and advising the American public on immunizations for children and adults. This resulted in the creation of a single vaccine schedule in 1955. Today, this recommended schedule has vaccines against more than 20 different diseases.¹

According to the National Conference of State Legislatures (NCSL), all 50 states now have legislation requiring specified vaccines for students, and all 50 states, as well as Washington, D.C., are required to follow the vaccine schedule set forth by the Centers for Disease Control and Prevention (CDC). Yet, many states provide exemptions from childhood vaccines, which vary from state to state. For instance, all school immunization laws grant exemptions to children for medical reasons.² Only four states do not allow any type of non-medical exemption.³ And, 44 states and Washington, D.C., grant exemptions for people who have religious objections to immunizations.²

Despite the overwhelming body of evidence of the safety of vaccines, the childhood vaccination schedule has become increasingly politicized in recent years. And, on March 26 of this year, CDC released a report that stated U.S. child vaccination coverage by age 2 was declining. The report also found that coverage varied by race and ethnicity, poverty status, urbanicity and jurisdiction.⁴ What's more, according to a news report from the University of Michigan's Center for Infectious Disease Research and Policy (CIDRAP), "a new Axios/Ipsos American Health Index poll shows Americans are losing confidence in the federal government to make recommendations about childhood vaccines. From June 2025 to March 2026, public trust in federal childhood vaccine recommendations dropped 11 points, from 71 percent to 60 percent, with only eight percent of those polled saying they trust CDC more than AAP." The report goes on to say, one in three respondents (35 percent) have more confidence in

guidelines from AAP than in those from CDC. And, about one-quarter (23 percent) express equal confidence in both sources, while 16 percent are not confident in either source.⁵

Unfortunately, public debate, misinformation and declining trust in health institutions have led some parents to question vaccines' safety, effectiveness and necessity — despite having protected generations of children. Therefore, understanding the science behind childhood immunization — and separating evidence from misconception — has never been more important for protecting the health of children and communities alike.

Separating Myth from Fact

Myth: Children don't need to be vaccinated because infection rates are already so low in the U.S.

Fact: Yes, the rates of infection are low. But, this is due to herd immunity, which occurs when a large portion of a community is immunized against a contagious disease, reducing the chance of a disease outbreak.

Estimated Illnesses and Hospitalizations Prevented by Childhood Vaccines in Children Born 1994-2023¹⁸

Disease	Illnesses Prevented	Hospitalizations Prevented
Diphtheria	7,528,000	7,528,000
Tetanus	5,000	5,000
Pertussis	80,738,000	3,646,000
Haemophilus influenza type b	536,000	495,000
Polio	1,847,000	786,000
Measles	104,984,000	13,172,000
Mumps	63,355,000	2,020,000
Rubella	54,225,000	199,000
Congenital rubella syndrome	17,000	26,000
Hepatitis B	6,061,000	940,000
Varicella	106,270,000	272,000
Hepatitis A	4,048,000	78,000
Pneumococcus-related diseases	47,804,000	1,969,000
Rotavirus	30,265,000	819,000
Total	507,683,000	31,955,000

As long as a large majority of people are immunized in any population, even the unimmunized minority will be protected. For instance, infants, pregnant women and immunocompromised people cannot receive vaccines, so they depend on herd immunity.^{6,7}

people with HBV globally are unaware they have it.

HBV is very stable in the environment, capable of remaining infectious for weeks and even months on surfaces, and it requires only a very tiny dose to cause infections. The most common cause of

Importantly, while babies are administered more vaccines than ever before, small children are actually exposed to fewer immunologic components overall than children in past decades due to the efficiency of today's vaccines.⁷

Myth: It's better to acquire natural immunity to a disease than to get vaccinated.

Fact: The benefits of vaccines far outweigh natural immunity simply due to the complications that are likely to arise from infections. According to the Yale School of Public Health, the complications from 10,000 children getting measles infections include 2,000 hospitalizations, 10 cases of brain swelling, 10 to 30 child deaths, 1,000 ear infections with potential permanent hearing loss and 500 cases of pneumonia. On the other hand, complications from 10,000 children getting the MMR vaccine include three fever-related seizures, between zero and one cases of abnormal blood clotting and 0.035 allergic reactions.¹⁰ Even chickenpox or the flu can lead to pneumonia, brain inflammation and death.¹¹

Myth: Vaccines contain harmful ingredients.

Fact: Any substance can be harmful in significantly high doses. But, vaccines contain ingredients at a dose that is even lower than the dose all individuals are naturally exposed to in the environment.

Most of the concern about the ingredients in vaccines centered on thimerosal, mercury, formaldehyde and aluminum.

Thimerosal, which is a mercury-containing compound, is a preservative that was removed from childhood vaccines in the U.S. starting in 1999 as a precautionary measure. However, it *was* used recently in multidose vials of influenza vaccines, but the influenza vials containing thimerosal were discontinued as of 2025. Today, there are no U.S. vaccines that contain thimerosal or mercury.⁶

Unfortunately, public debate, misinformation and declining trust in health institutions have led some parents to question vaccines' safety, effectiveness and necessity — despite having protected generations of children.

If too many people decide not to vaccinate themselves or their children, this opens up opportunities for viruses and bacteria to establish themselves and spread.⁷ We saw this happen most recently with measles. From January 2025 through early March 2026, there were 3,564 confirmed cases of measles in 46 states, mostly among children and teenagers due to declining vaccination rates. This is the largest number of cases in an outbreak since 2000, when the disease was declared eliminated in the U.S.⁸ While another contributing cause of the measles outbreak is international travel, CDC emphasizes that the majority of cases are among people who were not vaccinated against measles.⁹

Myth: Babies don't need the hepatitis B (HBV) vaccine if they aren't at high risk.

Fact: If the HBV vaccine is given only to people who believe they are high-risk, many cases will be missed because it can take decades from the time a person contracts HBV before symptoms become apparent. For instance, even if a parent has had only one partner for over a decade, it's still possible the parent has the hepatitis B virus since the majority of

chronic HBV infection is mother-to-baby transmission at birth, which can lead to liver cancer, liver failure and death. Ninety-five percent of babies who contract hepatitis B disease near birth develop the chronic form. The safest bet: getting the HBV vaccine, which induces protective immune responses in 80 to 100 percent of people.¹⁰

Myth: Children receive too many vaccines, too soon, which can weaken their immune systems.

Fact: While many parents worry the number of vaccines administered will weaken their child's immune system, that's not true. Infant immune systems are very strong due to the number of antibodies present in their blood, which theoretically would give babies the ability to respond to approximately 10,000 vaccines at one time. If all scheduled vaccines were administered at once, it would only use up slightly more than 0.1 percent of a baby's immune capacity. Also, the immune system could never truly be overwhelmed because its cells are constantly being replenished. Compared to the countless bacteria and viruses babies are exposed to every day, immunizations are negligible.

Formaldehyde is present in some vaccines as an inactivating agent and is also used to detoxify bacterial toxins in some vaccines. However, it is also found in carpets, upholstery, cosmetics, paint and felt-tip markers, as well as in health products such as antihistamines, cough drops and mouthwash.⁶ What's more, all people have formaldehyde detectable in their blood as part of normal metabolism, and that level is approximately 10-fold higher than what any vaccine contains. Indeed, the quantity in vaccines is at least 600-fold lower than that necessary to induce toxicity in experimental animals.¹²

Aluminum is added to vaccines to boost and build a stronger immunity to the vaccine. But, not all vaccines contain aluminum, and again, those that do typically contain aluminum in amounts that are much less than what the average person consumes in a day from food, drinking water and medicines.⁶ Recently, the largest study ever was conducted on aluminum in vaccines. That study analyzed data on more than 1.2 million Danish children, examining whether cumulative aluminum exposure from vaccines was associated with 50 different conditions, including autism, ADHD, asthma and autoimmune disorders. The researchers found no association between aluminum exposure from vaccines and an increased risk for any of these conditions.¹²

Myth: Vaccines make people sick.

Fact: Vaccines help children *avoid* illness. Most vaccines are inactivated (killed) vaccines, so it is literally impossible to contract the disease from the vaccine.⁶ However, some kids do develop flu-like symptoms following vaccines, but these symptoms happen as children's immune systems ramp up to produce antibodies focused on warding off disease.¹¹ If individuals are vaccinated with live vaccines, it may lead to a mild

case of the disease. For example, the chickenpox vaccine can cause a child to develop a mild rash, which isn't harmful, and can actually show the vaccine is working. An exception was the live oral polio vaccine, which could very rarely mutate and actually cause a case of polio. However, the oral polio vaccine is no longer administered in the U.S.⁶

Myth: Vaccines cause autism and sudden infant death syndrome (SIDS).

Fact: While diagnoses for autism and SIDS are usually made during the same time frame that childhood vaccines are administered, science has not yet determined the cause of them. The widespread fear that vaccines increase risk of autism stemmed from a 1997 study published in the journal *The Lancet* by Andrew Wakefield, a British surgeon, that suggested the measles, mumps, rubella (MMR) vaccine was increasing autism in British children. However, that study was completely discredited due to serious procedural errors, undisclosed financial conflicts of interest and ethical violations. And, after the article was retracted from the journal, Wakefield lost his medical license. Since the hypothesis was taken so seriously, other major studies were conducted, none of which found a link between any vaccine and the likelihood of developing autism.⁷

performed a meta-analysis to summarize the evidence from case-control and cohort studies that assessed the relationship between vaccine administration and the subsequent development of autism. Two reviewers extracted data on study characteristics, methods and outcomes, and disagreement was resolved by consensus with another author. In that meta-analysis, five cohort studies involving 1,256,407 children, and five case-control studies involving 9,920 children, the cohort data revealed no relationship between vaccination and autism or ASD, nor was there a relationship between autism and MMR, thimerosal or mercury (Hg). Similarly the case-control data found no evidence for increased risk of developing autism or ASD following MMR, Hg or thimerosal exposure when grouped by condition or exposure type.¹³

More recently, a World Health Organization (WHO) global expert committee on vaccine safety found, based on available evidence, no causal link exists between vaccines and ASD. The Nov. 27, 2025, analysis "focused first on the relationship between thimerosal-containing vaccines and ASD, and the association between vaccines in general and ASD. Evidence based on 31 primary research studies, published between

The benefits of vaccines far outweigh natural immunity simply due to the complications that are likely to arise from infections.

In 2014, based on the increasing prevalence of vaccine-preventable diseases due to the fear of a "link" between vaccinations and autism or autism spectrum disorder (ASD), researchers

January 2010 and August 2025, including data from multiple countries, strongly supports the positive safety profile of vaccines used during childhood and pregnancy, and confirms the absence of

a causal link with ASD. The committee also assessed the review of potential health risks associated with vaccines with aluminum adjuvants, drawing on studies conducted from 1999 through March 2023. In addition, it reviewed a recent large cohort study analyzing nationwide registry data of children born in Denmark between 1997 and 2018. In summary, the available high-quality evidence shows no association between the trace amounts of aluminum used in some vaccines and ASD, supporting the ongoing use of vaccines with aluminum adjuvants.”¹⁴

There is also no evidence to support a link between vaccines and SIDS, the sudden and unexpected death of an apparently healthy baby younger than 12 months. In the last two decades, scientific understanding of SIDS has improved because medical experts realized a proportion of sudden deaths were caused by suffocation versus an unknown cause, which resulted in the term SIDS expanding to sudden unexpected infant death syndrome, or SUID. And, according to AAP, “numerous large-scale studies and research reviews, conducted over many years, have confirmed that vaccines do not cause SIDS.” In fact, the association says, the “incidence of SIDS is

abnormality in the anatomy such as a brain stem abnormality that prevents a baby from being able to wake up.”¹⁵

Myth: Vaccines haven’t been properly tested.

Fact: Vaccines are held to the highest scientific standards since they are administered to healthy people. According to AAP, all recommended childhood vaccines have undergone extensive research, including clinical trials that are tested on tens of thousands of study participants, and use placebos or comparison groups to ensure they are safe and effective. And, once approved, vaccines continue to be monitored for safety.¹⁶

Unfortunately, the myth that vaccines aren’t properly tested is perpetuated by a statement from U.S. Health and Human Services (HHS) Secretary Robert F. Kennedy, Jr. that was published in *The New York Times* on May 1, 2025. In that statement, Kennedy announced plans to require all new vaccines to be tested against placebos, which a spokesman for HHS called “a radical departure” from existing standards. However, most new vaccines are already tested either against placebos or, in some cases, against vaccines for other diseases.

I, Phase II and Phase III studies. Testing vaccines against comparison products in Phase III studies has been the norm with vaccines licensed in the U.S., and around the world, for the last 75 years.” There are several valid options when choosing a placebo, says Dr. Gräbenstein: a saline (or salt) solution or a liquid that differs from the vaccine only in the antigenic content (the part that evokes a specific immune response). For example, he says, a candidate vaccine containing an adjuvant, a component that helps increase a protective immune response, may be compared to a solution that contains only the adjuvant. This option may be chosen if the adjuvant is known to cause injection-site side effects such as a sore arm.

Furthermore, Dr. Gräbenstein adds, while there *are* vaccine studies performed without using a placebo in the control arm of the study, those studies are “still robust, randomized, double-blinded studies, but the comparison may be a previously tested product to ensure the study is ethical.” The comparison product can be an alternate vaccine, an earlier or existing version of the vaccine, or the same vaccine delayed in time (for instance, after initial safety testing, an Ebola vaccine trial used a time-delayed vaccination group for comparison, because the researchers considered it unethical to have a group that did not receive potential protection against such a dangerous pathogen).¹⁷

Myth: The recommended vaccine schedule differs from other countries, so it must be incorrect.

Fact: It has been argued, especially most recently, that the U.S. childhood vaccine schedule should be modified to mirror recommendations from other developed nations. However, according to the organization Partnership to Fight Infectious Diseases, that argument

Vaccines are held to the highest scientific standards since they are administered to healthy people.

the same in children who do and do not receive vaccines, further supporting the fact that SIDS is not caused by vaccines.” What’s more, it says, “studies have shown that not only do vaccines not cause SIDS, they also may decrease the risk by 50 percent.” Research actually shows “SIDS is caused by something physiological, an

According to an interview with John D. Gräbenstein, RPh, PhD, a pharmacist who has specialized in vaccines since 1983, with the Children’s Hospital of Philadelphia, “Before any vaccine can be widely used, we need to know if it is safe and if it provides any protective value (efficacy). This takes the form of Phase

“fundamentally misrepresents how vaccine schedules actually work — and why differences between countries exist in the first place.” This is because the U.S. operates under epidemiological and healthcare conditions vastly different from peer nations, especially in regard to disease burden, healthcare access and population demographics.

One major difference is that the U.S. healthcare system consists of a network of private insurance, Medicaid, Children’s Healthcare Insurance Program and safety-net programs that are distinctly different from the centralized, universal systems common in Europe. Also, comparisons to other countries lack context. For instance, critics of the U.S. childhood vaccination recommendation have recently compared ours to Denmark’s recommendation that calls for fewer doses of vaccines. But, as the Partnership to Fight Infectious Diseases points out, “a schedule developed for a small, wealthy nation with universal healthcare and low baseline disease prevalence reflects Denmark’s specific needs, not a universal standard.” And, it states even Denmark’s health authorities question the relevance of using their schedule as a model for other nations.

Moreover, comparing the U.S. recommendation to the United Kingdom, France, Germany, Israel, Japan and Scandinavian countries suggests the U.S. is not an outlier. They all vaccinate against approximately a dozen to 15 serious pathogens during childhood, but those countries base that on their own epidemiological realities. The U.S. schedule was calibrated over decades to American disease patterns and healthcare realities. “Public health decisions must be grounded in evidence and the realities of American healthcare delivery,” says the Partnership to Fight Infectious Diseases.¹⁸

Myth: Vaccines aren’t worth the risk.

Fact: Despite concerns, the U.S. has

been successfully vaccinating children for decades without any credible studies linking vaccines to long-term health conditions.

According to a report that assessed and quantified the health benefits and economic impact of routine U.S. childhood immunizations among both Vaccines for Children (VFC)-eligible and non-VFC-eligible children, “Among approximately 117 million children born during 1994 to 2023, routine childhood vaccinations will have prevented approximately 508 million lifetime cases of illness, 32 million hospitalizations and 1,129,000 deaths, at a net savings of \$540 billion in direct costs and \$2.7 trillion in societal costs.... Childhood immunizations continue to provide substantial health and economic benefits, while promoting health equity.”¹⁹

Dispelling the Myths Now

In 2019, WHO named vaccine hesitancy one of the top 10 threats to global health. In a study titled “Vaccine Safety: Myths and Misinformation,” published in *Frontiers in Microbiology*, the authors write that one of the main factors behind vaccine hesitancy is lack of confidence in vaccine safety. Many parents fear adjuvants, preservatives, inactivating agents and manufacturing residuals, they state. And, they believe vaccines are causing autism, diabetes, developmental delays, hyperactivity and attention-deficit disorders, among others.

Yet, vaccines are among the greatest public health achievements of modern times.²⁰ This is why healthcare workers, especially those in primary care, remain key influencers on vaccine decisions. It is important they communicate the facts and dispel the myths concerning childhood vaccines to parents so all children, even those who are unable to receive vaccines, are protected. ❖

References

1. Frenc, RW, Jr. How Vaccine Schedules Changed Over Time & Why. Accessed at www.healthychildren.org/English/safety-prevention/immunizations/Pages/History-of-Immunizations.aspx.
2. History of Vaccines: Vaccines for Children: The Development of the Immunization Schedule, updated April 22, 2022. Accessed at historyofvaccines.org/getting-vaccinated/vaccines-children/development-immunization-schedule.
3. National Conference of State Legislatures. State Non-Medical Exemptions From School Immunization Requirements, updated May 1, 2026. Accessed at www.ncsl.org/health/state-non-medical-exemptions-from-school-immunization-requirements.
4. CDC Immunization Report Finds Declines in 5 Childhood Vaccines by Age 2. American Hospital Association, March 27, 2026. Accessed at www.aha.org/news/headline/2026-03-27-cdc-immunization-report-finds-declines-5-childhood-vaccines-age-2.
5. Soucheray, S. Trust in Federal Government Drops When It Comes to Childhood Vaccines, Poll Suggests. University of Minnesota Center for Infectious Disease Research and Policy, March 18, 2026. Accessed at www.cidrap.umn.edu/childhood-vaccines/trust-federal-government-drops-when-it-comes-childhood-vaccines-poll-suggests.
6. American Academy of Allergy, Asthma and Immunology. Vaccines: The Myths and the Facts. Accessed at www.aaaai.org/tools-for-the-public/conditions-library/allergies/vaccine-myth-fact.
7. PublicHealth.org. Vaccine Myths Debunked. Accessed at www.publichealth.org/public-awareness/prenatal-care/vaccine-myths-debunked.
8. Shmerling, RH. Measles Is Making a Comeback: Can We Stop It? Harvard Health Publishing, March 9, 2026. Accessed at www.health.harvard.edu/blog/measles-is-making-a-comeback-can-we-stop-it-202503063091.
9. Centers for Disease Control and Prevention. Measles Cases and Outbreaks, updated July 24, 2026. Accessed at www.cdc.gov/measles/data-research/index.html.
10. Yale School of Public Health. Childhood Vaccinations. Accessed at ysph.yale.edu/research/information-sheets/childhood-vaccinations/#1-are-childhood-vaccines-safer-than-the-diseases-themselves?
11. One World Pediatrics. 5 Common Myths About Childhood Immunizations, Debunked, April 7, 2025. Accessed at www.oneworldpediatrics.com/post/5-common-myths-about-childhood-immunizations-debunked.
12. Scott, J. CIDRAP Op-Ed: Vaccine Myths That Won't Die and How to Counter Them — Part 1. University of Minnesota Center for Infectious Disease Research and Policy, Jan. 15, 2026. Accessed at www.cidrap.umn.edu/childhood-vaccines/cidrap-op-ed-vaccine-myths-wont-die-and-how-counter-them-part-1.
13. Taylor, LE, Swedfeger, AL, and Eslick, GD. Vaccines Are Not Associated with Autism: An Evidence-Based Meta-Analysis of Case-Control and Cohort Studies. *Vaccine*, 2014 Jun 17;32(29):3623-9. Accessed at pubmed.ncbi.nlm.nih.gov/24814559.
14. WHO Expert Group's New Analysis Reaffirms There Is No Link Between Vaccines and Autism. World Health Organization newsroom, Dec. 11, 2025. Accessed at www.who.int/news/item/11-12-2025-who-expert-group-s-new-analysis-reaffirms-there-is-no-link-between-vaccines-and-autism.
15. American Association of Pediatrics. Fact Checked: There Is No Link Between Vaccines and Sudden Infant Death. Accessed at www.aap.org/en/news-room/fact-checked/fact-checked-there-is-no-link-between-vaccines-and-sudden-infant-death/?srsltid=AfmBOorpVliZyBnliI3P31XMrPw6169ACL7x7_xn0HCE6MlycmQ0QoL644.
16. American Association of Pediatrics. Fact Checked: Childhood Vaccines Are Carefully Studied—Including with Placebos—to Ensure They're Safe and Effective. Accessed at www.aap.org/en/news-room/fact-checked/fact-checked-childhood-vaccines-are-carefully-studied-including-with-placebos-to-ensure-theyre-safe-and-effective.
17. Children's Hospital of Philadelphia. Technically Speaking: 75 Years of Placebo-Controlled Vaccine Testing in the U.S., June 17, 2025. Accessed at www.chop.edu/vaccine-update-healthcare-professionals/newsletter/75-years-placebo-controlled-vaccine-testing-us.
18. Why International Vaccine Schedule Comparisons Miss the Point. Partnership to Fight Infectious Diseases, July 8, 2026. Accessed at www.fightinfectiousdisease.org/post/why-international-vaccine-schedule-comparisons-miss-the-point.
19. 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. *Morbidity and Mortality Weekly Report*, Aug. 8, 202; 73(31):682–685. Accessed at www.cdc.gov/mmwr/volumes/73/wr/mm7331a2.htm.
20. Geoghegan, S, O'Callaghan, KP, and Offit, PA. Vaccine Safety: Myths and Misinformation. *Frontiers in Microbiology*, 2020 Mar 17;11:372. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC7090020.

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Update on ADHD

Attention deficit hyperactivity disorder can present in different ways, requiring a nuanced approach to diagnosis and treatment.

By Jim Trageser



ATTENTION DEFICIT hyperactivity disorder (ADHD) is among the most common mental health diagnosis in children and adolescents. The U.S. Centers for Disease Control and Prevention (CDC) reports that nearly 12 percent of American children have a current ADHD diagnosis.¹

While many will find their symptoms ease as they enter adulthood, some six percent of adults are also presently diagnosed with ADHD in the U.S.² (Interestingly, many of them were diagnosed only after they became adults.)

With diagnosis rates in children rising rapidly — an increase of 33 percent from 1997 to 2008 — there is a growing focus on ADHD within the medical and mental health professions. While some therapists argue the leap in diagnosis rates is due to ADHD being overdiagnosed — categorizing normal childhood behavior as a disorder — a significant number of others believe it is in fact underdiagnosed, depriving children of critical treatment that could markedly improve their quality of life.³

The specific term “attention deficit hyperactivity disorder” is a relatively recent formal diagnosis, only being added to the *Diagnostic and Statistical Manual of Mental Disorders (DSM)* revised third edition in

1987. The first inclusion of this disorder under any name in the DSM (the standard reference for mental health professionals) was in the second edition in 1968 as “hyperkinetic reaction of childhood.” That was updated to attention deficit disorder (ADD) in the third edition in 1980, and then, as mentioned, to ADHD in 1987.

Yet, the first description of the symptoms associated with ADHD was likely by Scottish physician Alexander Crichton, who in his 1798 three-volume overview of mental health included a chapter titled “On Attention and Its Diseases.”⁴ However, modern researchers and clinicians point out that the symptoms he described are also present in other conditions such as epilepsy and metabolic dysfunction.

Subsequent developments in describing and then diagnosing ADHD include:

- German physician Heinrich Hoffmann published a series of illustrated children’s books in 1844, including a story about “Fidgety Phil.” In this book, a young boy at the dinner table exhibits symptoms consistent with a modern diagnosis of ADHD.

- In 1902, British physician George Frederic Still gave a lecture at the Royal College of Physicians of London on behavior he described as a “lack of moral

control” that occurred “without general impairment of intellect and without physical disease.”

- Two German doctors in 1932 described what they called “hyperkinetic disease” in young children, in which they seemed incapable of sitting still for more than short periods of time.

- Five years later, U.S. physician Charles Bradley, in seeking to treat painful headaches in his patients following the use of pneumoencephalogram brain imaging, discovered that while benzedrine was ineffective in relieving their pain, it did ease symptoms of inattention in the classroom. This led to the eventual adoption of stimulants as a primary course of treating ADHD⁴ (alongside ongoing therapy to impart effective coping skills).

What is ADHD?

ADHD is classified as a neuro-developmental disorder. It is actually a bit of an umbrella term, taking in two distinct sets of symptoms that often coexist. These are classified into three subtypes of ADHD:⁵

- Predominantly inattentive (ADHD-I): Patients struggle to focus on the task at hand, may be forgetful and are often unorganized. This diagnosis is what replaced the earlier ADD.

- Predominantly hyperactive-impulsive (ADHD-H): Patients struggle to stay still, and may be moving or climbing when not socially appropriate to do so. This is usually accompanied by poor impulse control, including excessive talking.

- Combined ADHD (ADHD-C): Patients exhibit symptoms of both of the other types; this is the most common ADHD diagnosis.

In ADHD patients, symptoms will interfere with their ability to function successfully in school, work or social settings.

While it was originally thought children would outgrow ADHD,⁶ today it is believed that is true for only fewer than half of patients. The manifestation of symptoms changes in adulthood — primarily in the hyperactivity component. While in children the hyperactivity component often results in actual physical activity, in adults it is more likely to be experienced as a feeling of restlessness.⁷

Researchers have also shown that untreated ADHD increases the risks of developing depression or an anxiety disorder, and is tied to an increased likelihood of suicide. It is also tied to higher rates of drug abuse, criminal behavior and even medical complications such as sleep disorders. Less dramatically, but nearly as harmful, are lower educational outcomes, poorer professional performance and difficulty managing personal finances.⁸

What Causes ADHD?

The underlying cause of ADHD is not fully understood. Researchers believe it is a combination of genetic predisposition and exposure to environmental factors, including injury, nutrition and social interactions.⁸

Some schools of psychology view the condition as wholly psychological. Psychoanalytic theory (Freudian psychology) holds that ADHD is the

result of early parent-child interactions. Some psychoanalysts do acknowledge the biological component, but theorize that the negative early interactions affect the brain's own physical development.³

On the other hand, evolutionary psychology teaches that ADHD is an orphaned trait that formerly bestowed survival benefits in an earlier environment, but is maladaptive to modern life.³

However, research has discovered that patients with ADHD have measurable differences in the structure of their brain compared to non-ADHD patients.⁹ While it is not understood how exactly this leads to ADHD, or whether everyone with these structural differences will develop ADHD, it is widely accepted that there is a connection.

In addition, it is known that ADHD runs in families. Recent research indicates there is no single gene tied to ADHD, but instead many different genes each contributing a small variation.¹⁰

Of particular note are genes tied to the regulation of neurotransmitters.¹¹

And, one recent study found a strong correlation (more than 40 percent) between post-viral fatigue syndrome or myalgic encephalomyelitis/chronic fatigue syndrome and ADHD.¹²

Diagnosing ADHD

Since there is no single test for ADHD, arriving at a diagnosis consists of cataloging symptoms and measuring them against the DSM criteria, while also ruling out other potential causes.

A diagnosis of ADHD requires that:

- Symptoms are developmentally inappropriate for the patient's age
- Symptoms last longer than six months
- Symptoms manifest in at least two different settings
- Symptoms cause impairment in these settings
- Other possible causes of the symptoms

have been ruled out

For children (under age 17), six of nine symptoms for ADHD-I or ADHD-H must be confirmed, while only five are required for a diagnosis in an adult. (Having three from one list and three from the other does not meet the criteria.) In all patients, no matter the age at the time of initial consultation with a physician or therapist, at least some of the ADHD symptoms must have begun before age 12.

Conditions such as bipolar disorder, autism spectrum disorder, oppositional defiant disorder and certain learning disabilities can present similar symptoms and should be considered before a final diagnosis is made.¹³

A physical examination should also be performed to rule out any potential physiological causes of symptoms such as a sleep disorder, thyroid issues, seizure disorders, diabetes and others.¹⁴

For children or adolescents, physicians or therapists should reach out to the patients' teachers, coaches or other adults in their life to gain feedback about their behavior in these different settings.

The checklist of symptoms in the DSM-5 are broken up into ADHD-I and ADHD-H.

The nine criteria for ADHD-I are:¹⁵

- Does not pay attention to details or makes careless mistakes in schoolwork or with other activities
- Has difficulty sustaining attention on tasks at school or during play
- Does not seem to listen when spoken to directly
- Does not follow through on instructions or finish tasks
- Has difficulty organizing tasks and activities
- Avoids, dislikes or is reluctant to engage in tasks that require sustained mental effort over a long period of time
- Often loses things necessary for school tasks or activities

- Is easily distracted
 - Is forgetful in daily activities
- The nine ADHD-H criteria are:

- Often fidgets with hands or feet or squirms
- Often leaves seat in classroom or elsewhere
- Often runs about or climbs excessively where such activity is inappropriate
- Has difficulty playing quietly
- Often on the go, acting as if driven by a motor
- Often talks excessively
- Often blurts out answers before questions are completed
- Often has difficulty awaiting turn
- Often interrupts or intrudes on others

If patients meet six of nine criteria in both categories (five each for adults), then a combined ADHD diagnosis will be made.

Symptoms may present differently in adults than in children. ADHD-I may manifest by missing deadlines or forgetting meetings at work, or with difficulty paying attention during uninteresting meetings. ADHD-H may look like interrupting others, talking louder than appropriate or intruding on projects to which they're not assigned.¹⁶

And, in children, symptoms may manifest more subtly in girls than in boys — which is likely at least partially responsible for 16 times as many boys as girls being diagnosed with ADHD. Among those who are diagnosed, girls are more likely to have ADHD-I, while boys are statistically more likely to have ADHD-H. Even within the same subtype, the behavior is likely to differ. Where boys might become physically aggressive, girls may exhibit verbal aggression. And, because inattentiveness isn't as disruptive to a classroom setting, teachers may not think to talk to the parents about having the student tested.¹⁷

There is some evidence that cultural and sociological stereotypes may also

be subconsciously affecting diagnosis in different populations, with white males more likely to receive an ADHD diagnosis than females¹⁸ or non-white males, even when presenting with identical symptoms.¹⁹ In many cases, Black males are diagnosed with conduct disorder even though they meet the diagnostic criteria for ADHD.³ There is a stereotype of a typical ADHD patient being a white boy, and that may unknowingly shape a clinician's own expectations without any intent of bias.

In addition, with widespread access to ADHD criteria lists, parents of pediatric patients or adult patients themselves may have already self-diagnosed and have pressured a therapist for a formal diagnosis.¹⁴

Treating ADHD

ADHD in children is generally treated with a combination of behavior therapy and medications. The specifics will be based on the type of ADHD diagnosed, the age of the patient, the severity of the symptoms and any co-occurring medical or mental health conditions affecting the patient.

For patients younger than 6 years, CDC recommends training the parents in behavior management as the first course of action. This training helps parents create a stable routine and daily structure for the child, reducing the severity of symptoms. Research has shown parental training is just as effective as medication in young children, and the side effects of medication are often more pronounced in them.²⁰

Parent training is recommended through about age 12 years, at which point psychosocial therapy for the patient is advised, along with medication (if not already begun). Teens should meet with a therapist who will teach them about their condition and symptoms they're experiencing, and then identify a couple of behaviors to work together to improve.²¹

Adult patients are most commonly

referred for cognitive behavioral therapy (CBT). This focuses on teaching patients to be self-aware of their own behaviors, and allows them to intentionally change their actions to a desired behavior. There is also some research that shows a regular exercise program can help ease symptoms of ADHD.²² CBT has not proven effective in youth, however.

Medication can be prescribed for children who are at least 6 years old, and has proven to be effective in easing symptoms of a majority of patients. (Some medications can be prescribed as young as 4 years if symptoms are severe and therapy has proven ineffective.)

Two classes of medications are generally prescribed to treat ADHD, particularly in children: stimulants and non-stimulants.

The most widely prescribed ADHD drug is the stimulant methylphenidate (MPH), with the most popular brand name being Ritalin. This drug blocks the dopamine and norepinephrine reuptake transporters in the nervous system, which results in higher levels of those hormones that regulate how the brain works.²³ Long-term studies indicate MHP is effective not only in modifying behavior, but also in improving school learning outcomes, particularly in math.

Where Ritalin is a short-acting tablet (three to four hours), another MHP formula is sold under the brand name Concerta — which is an extended-release tablet that can last up to 12 hours. Ritalin can cause increased blood pressure and have negative interactions with blood pressure and other heart medications, making it less appropriate for many adult patients.

Another stimulant, dexamethylphenidate (brand name Focalin), comes in both short-acting and extended-release versions.

Several amphetamines are also approved by the U.S. Food and Drug Administration (FDA) for treating ADHD. These include

Adderall, lisdexamfetamine (Vyvanse) and dextroamphetamine (Dexedrine, Zenzedi, ProCentra). These work similarly to MHP, resulting in elevated levels of dopamine and norepinephrine.

Non-stimulants typically take longer to be effective than stimulants, but have different side effects. For patients who suffer sleep disruption or weight loss from stimulants, this second class may be more tolerable.

Two types of non-stimulants are prescribed to treat ADHD: selective norepinephrine reuptake inhibitors (NRIs) and alpha-2 adrenergic agonists.

NRIs — which include atomoxetine (Strattera) and viloxazine (Qelbree) — work somewhat similarly to MHP in that they block the brain from reabsorbing norepinephrine, resulting in elevated levels. Atomoxetine is associated with an increased risk of suicidal ideation, and carries a warning to that effect on its packaging.

Alpha-2 adrenergic agonists include brand names clonidine (Catapres, Kapvay, Onyda XR) and guanfacine (Intuniv). These drugs work by targeting specific receptors in the frontal cortex, which improves impulse control and attention.²⁴

Also, patients can have other conditions in addition to ADHD. As many as 70 percent of ADHD patients have co-existing psychiatric disorders, including anxiety and depression. These will also need to be treated in parallel with the ADHD.²³

Ongoing Research Into ADHD

As one of the most common disorders in children, ADHD understandably is the subject of numerous ongoing research studies. FDA's clinicaltrials.gov site lists just under 2,000 recent or current trials for ADHD. These range from the physiology of ADHD to the genetics thought to underlie it, to potential new drugs that may effectively treat it with fewer side

effects, as well as using existing FDA-approved drugs off-label to treat ADHD.

Primary research is attempting to learn the specific causes of the condition. When that is more fully understood, more effective treatments can likely be developed.

In the meantime, as with many chronic medical conditions, a growing body of evidence suggests inflammation plays a role in ADHD.²⁵ One such recent study suggested anti-inflammatory drugs should be explored as a potential treatment for ADHD.²⁶

And, another recent study out of Washington University in St. Louis, Mo., found the stimulant drugs actually work by stimulating the brain's reward center, and by increasing wakefulness.²⁷ If true, this changes our understanding of how these drugs work, and suggests another approach to devising new drugs.

Transcranial direct current stimulation, in which very low-level electrical currents are delivered to the brain, was studied at Bradley Hospital in Rhode Island a few years ago. Previous research had found subjects who underwent this noninvasive procedure exhibited improved impulse control.²⁸

For the foreseeable future, however, physicians and therapists will continue to treat ADHD patients with an existing array of options that are safe and generally effective. ♦

References

- Centers for Disease Control and Prevention. Data on ADHD in Children, July 8, 2026. Accessed at www.cdc.gov/adhd/data/index.html.
- Staley, B., Robinson, L., Claussen, A., et al. Attention-Deficit/Hyperactivity Disorder Diagnosis, Treatment, and Telehealth Use in Adults — National Center for Health Statistics Rapid Surveys System, United States, October–November 2023. Centers for Disease Control and Prevention, Oct. 10, 2024. Accessed at www.cdc.gov/mmwr/volumes/73/wr/mm7340a1.htm.
- Staccio, B. ADHD: Is It Over-Pathologized and Over-Diagnosed? Understanding Potential Reasons for the Over-Diagnosis of ADHD and How Different Theoretical Lenses May Explain ADHD and Its Rising Prevalence Rates. *SUNY New Paltz Journal of Psychology*, May 15, 2025. Accessed at ojs.newpaltz.edu/index.php/SNPJP/article/view/22/21.
- Lange, K., Reichl, S., Lange, KM., Tucha, L., and Tucha, O. The History of Attention Deficit Hyperactivity Disorder. *ADHD Attention Deficit and Hyperactivity Disorders*, December 2010. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC300907.
- Kavanaugh, B. Understanding the Different Types of ADHD: What

Parents Should Know. *Brown Health*, Dec. 2, 2025. Accessed at www.brownhealth.org/be-well/understanding-different-types-adhd-what-parents-should-know.

- Gunnerson, T. A Brief History of ADHD. *WebMD*, Aug. 25, 2024. Accessed at www.webmd.com/add-adhd/adhd-history.
- Medline Plus. Attention Deficit Hyperactivity Disorder. Accessed at medlineplus.gov/attentiondeficithyperactivitydisorder.html.
- French, B., Daley, D., Groom, M., and Cassidy, S. Risks Associated with Undiagnosed ADHD and/or Autism: A Mixed-Method Systematic Review. *Journal of Attention Disorders*, June 21, 2023. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC10498662.
- Braaten, E. 5 Things Parents and Teachers Need to Know About ADHD. *Harvard Health Publishing*, Oct. 27, 2017. Accessed at www.health.harvard.edu/blog/5-things-parents-and-teachers-need-to-know-about-adhd-2017102712643.
- Faraone, S., and Larsson, H. Genetics of Attention Deficit Hyperactivity Disorder. *Molecular Psychiatry*, June 11, 2018. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC6477889.
- Sudre, G., Gildea, D., Shastri, G., et al. Mapping the Cortico-Striatal Transcriptome in Attention Deficit Hyperactivity Disorder. *Molecular Psychiatry*, Nov. 16, 2022. Accessed at www.nature.com/articles/s41380-022-01844-9.
- Harty, S. A Study of the Contribution of Common Virus in Activation of Attention-Deficit/Hyperactivity Disorder (ADHD). *International Journal of Advanced Multidisciplinary Research and Studies*, 2025. Accessed at www.multiresearchjournal.com/articles/list-2025.5.6/id-5273.
- Fitzgerald, A. Which Disorders Are Similar to ADHD, and When Should People Speak with a Doctor? *MedicalNewsToday*, Nov. 28, 2025. Accessed at www.medicalnewstoday.com/articles/disorders-similar-to-adhd.
- Sadek, J. Attention Deficit Hyperactivity Disorder Misdiagnosis: Why Medical Evaluation Should Be a Part of ADHD Assessment. *Brain Science*, Oct. 28, 2023. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC10669410.
- Merck Manual Professional Version. Attention-Deficit/Hyperactivity Disorder (ADHD). Accessed at www.merckmanuals.com/professional/pediatrics/learning-and-developmental-disorders/attention-deficit-hyperactivity-disorder-adhd.
- Attention Deficit Disorder Association. Adult ADHD Test. Accessed at add.org/adhd-types.
- Cleveland Clinic. How Are ADHD Symptoms Different in Boys and Girls? Jan. 10, 2024. Accessed at health.clevelandclinic.org/adhd-symptoms-boys-vs-girls.
- El-Houshy, S. ADHD in the Global West: How Gender Influences Diagnosis. *ETHEL*, April 23, 2026. Accessed at etheljournal.com/wp-content/uploads/2026/06/ADHD-in-the-Global-West-How-Gender-Influences-Diagnosis.pdf.
- Tam, LYC., Taechameekietichai, Y., and Allen, J.L. Individual Child Factors Affecting the Diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) in Children and Adolescents: A Systematic Review. *European Child & Adolescent Psychiatry*, Oct. 7, 2024. Accessed at link.springer.com/article/10.1007/s00787-024-02590-9.
- Centers for Disease Control and Prevention. Treatment of ADHD. Accessed at www.cdc.gov/adhd/treatment/index.html.
- Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD). Psychosocial Treatments. Accessed at chadd.org/for-parents/psychosocial-treatments.
- U.C. Davis MIND Institute. Evidence Based Treatment of ADHD. Accessed at health.ucdavis.edu/mind-institute/resources/understanding-adhd/adhd-treatment.
- Galvez-Contreras, A., Vargas-de la Cruz, I., Beltran-Navarro, B., et al. Therapeutic Approaches for ADHD by Developmental Stage and Clinical Presentation. *International Journal of Environmental Research and Public Health*, Oct. 8, 2022. Accessed at pmc.ncbi.nlm.nih.gov/articles/PMC9566361.
- Cleveland Clinic. ADHD Medication. Accessed at my.clevelandclinic.org/health/treatments/11766-adhd-medication.
- Fang, Z., Shen, G., Amin, N., et al. Effects of Neuroinflammation and Autophagy on the Structure of the Blood-Brain Barrier in ADHD Model. *Neuroscience*, Oct. 15, 2023. Accessed at www.sciencedirect.com/science/article/abs/pii/S030452223003846.
- Vázquez-González, D., Carreón-Trujillo, S., Alvarez-Arellano, L., et al. A Potential Role for Neuroinflammation in ADHD (chapter). *Neuroinflammation, Gut-Brain Axis and Immunity in Neuropsychiatric Disorders*, 2023, March;1411: 327-356. Accessed at link.springer.com/chapter/10.1007/978-981-19-7376-5_15.
- Ballard, S. Stimulant ADHD Medications Work Differently Than Thought. *WashU Medicine* news release, Dec. 24, 2025. Accessed at medicine.washu.edu/news/stimulant-adhd-medications-work-differently-than-thought.
- ClinicalTrials.gov. Modulation of Behavioral Inhibition in Attention Deficit Hyperactivity Disorder. Accessed at clinicaltrials.gov/study/NCT02290899.

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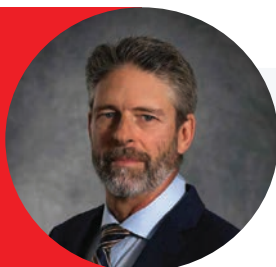
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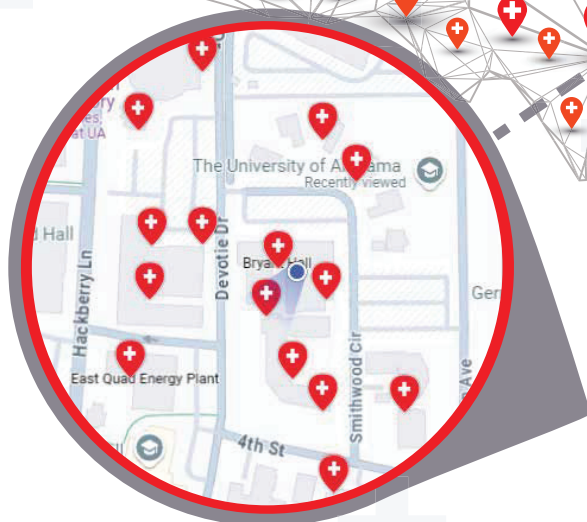
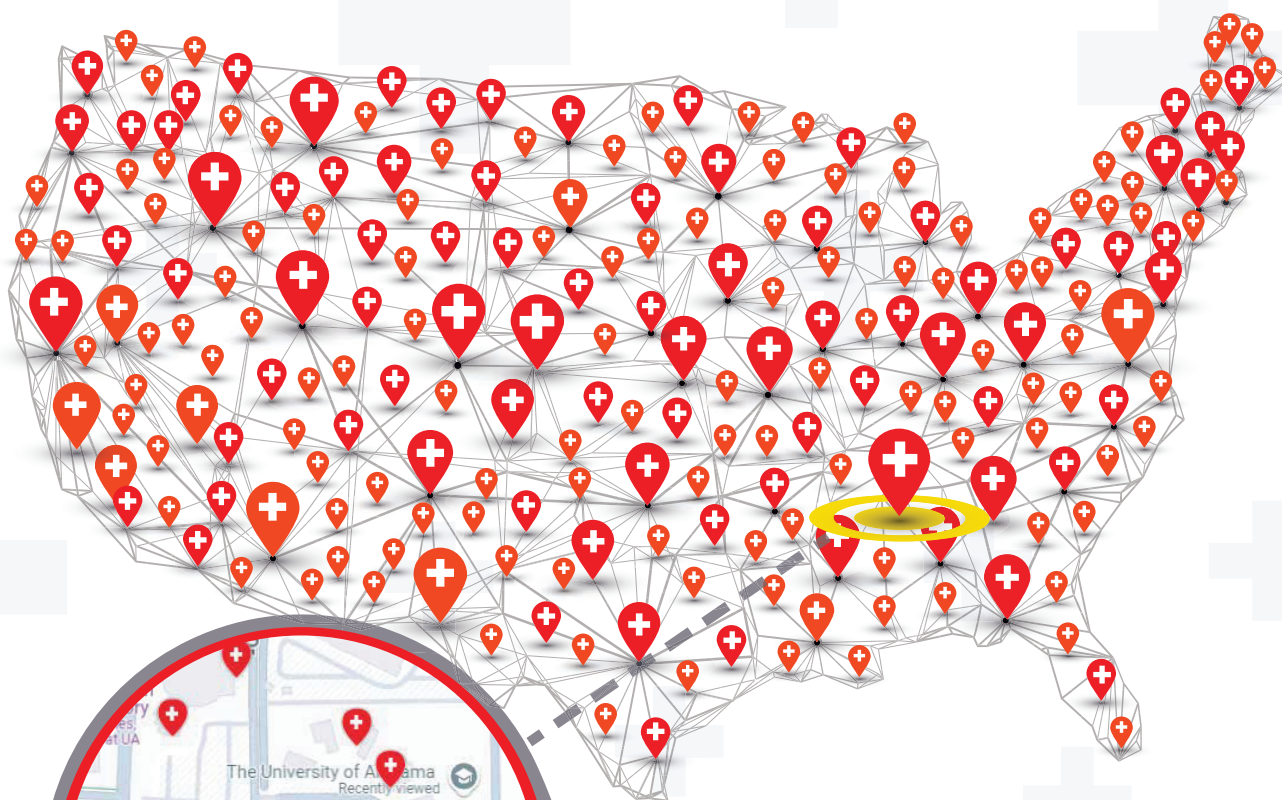
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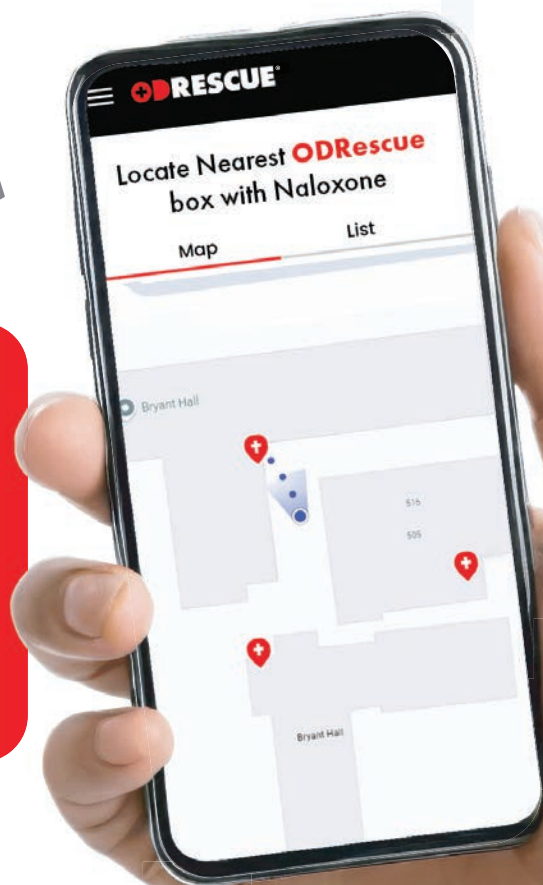
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**VANESSA WELCH-PEMBERTON**

belongs to a growing group of people who didn't learn they had attention-deficit/hyperactivity disorder (ADHD) until well into adulthood. The signs had been there since childhood, but because her symptoms were primarily inattentive rather than hyperactive, they didn't fit the picture most people associate with ADHD. Instead of receiving support, she was repeatedly told she simply needed to try harder.

That message shaped her for years. Vanessa became a perfectionist, pushing herself to meet expectations through sheer effort while constantly searching for new ways to learn, retain information and get things done. Eventually, that exhausting balancing act took a toll on her mental health. "I constantly sought new ways to learn, to retain information and to perform," she says. "My strenuous efforts to mask and cope with my symptoms inevitably led to anxiety and depression."

Her diagnosis finally came in adulthood, prompted by the overwhelming demands of becoming a new mother. It's a familiar story: Many adults with undiagnosed ADHD don't get answers until life presents challenges that their usual coping strategies can no longer manage. "It was like a warm breeze swept over me and my whole life suddenly made sense," she says. "Understanding my brain better, I

ADHD: A Patient's Perspective

By Trudie Mitschang

was able to give myself compassion and to begin, at last, to learn how to problem-solve more effectively."

Vanessa is quick to point out that ADHD looks different for everyone. For her, restlessness is a constant companion, even without full-blown hyperactivity. Sitting still for long periods creates an internal itch she finds difficult to ignore.

Money management is another challenge. Despite understanding the importance of budgeting and saving, impulsive spending can still get the better of her. Sensory input can also become overwhelming. Loud sounds, strong smells, bright lights and certain textures can quickly add up. Disneyland, she says, is a perfect example of a place that can overwhelm her senses all at once. When sensory overload hits — or when too many demands come at her simultaneously — her patience can wear thin quickly.

Then there's the flip side: hyperfocus. When something genuinely interests her, Vanessa can become completely absorbed, losing track of everything else on her agenda. "If I'm interrupted while engaged this deeply," she explains, "I get mad and frustrated and find it difficult to come back to the task, because by then, I'm engaged in something new."

Managing her ADHD, Vanessa says, has meant combining medication and behavioral, emotional and cognitive adjustments, along with increased self-awareness. "A lifetime of therapy has helped me learn skills to address and cope with anxiety and depression," she notes. "This has made a huge difference, because it has simplified my ADHD management."

Since beginning her treatment plan, Vanessa says the improvements have been noticeable. She multitasks less, feels less

on edge and doesn't experience the same wall of exhaustion by evening. Starting and completing tasks, managing her schedule and finances, and regulating her emotions have all become more manageable. She was also surprised to find that her physical health has improved; frequent stomach aches and headaches have eased. As she later learned, these physical symptoms are common issues for people living with ADHD.

Beyond medication and therapy, a daily practical habit has made a significant difference for Vanessa: Keeping a planner open on her desk where she can see it as soon as she sits down each morning encourages her to stay focused and grounded. That physical reminder, she notes, helps anchor her day.

Educating herself about ADHD has also been key. Learning more about her diagnosis has helped Vanessa understand and accept the symptoms that plagued her throughout her life, while giving her the language to explain them to the people closest to her. That understanding has strengthened her relationships, both because family and friends now know how to support her. It's also empowered Vanessa to take greater responsibility for managing her symptoms as they occur, rather than expecting others to compensate for them.

For Vanessa, an ADHD diagnosis wasn't the end of the story — it was the beginning of a journey toward understanding herself in a new way. After years of being told to try harder, she now has a framework for understanding herself and the ability to replace self-blame with compassion. "I struggle and I thrive," she says. "This may look different than it does for someone without a neurodevelopmental disorder or mental illness, but it's the same beautiful process of growth." ♦



LENARD A. ADLER, MD, is the director of the adult attention-deficit/hyperactivity disorder (ADHD) program in the department of psychiatry at New York University (NYU) Langone Health. He is also a professor in the departments of psychiatry and child and adolescent psychiatry at NYU Grossman School of Medicine. He is an active investigator, frequent lecturer and is the author of the popular book on adult ADHD titled *Scattered Minds*.

BSTQ: What are the key characteristics of ADHD?

Dr. Adler: ADHD shows up in three main forms, based on which symptoms dominate. The inattentive type struggles with distraction, organization and finishing tasks. These patients miss details, have trouble following instructions or conversations and often come across as careless. The hyperactive-impulsive type is different: constant fidgeting, excessive talking, restlessness and an inability to stay still. These patients tend to be impatient and impulsive, often interrupting others, speaking without thinking or acting before considering consequences, which can lead to more accidents and injuries. Some patients show a combined presentation, with symptoms from both categories.

BSTQ: How common is ADHD?

ADHD: A Physician's Perspective

Dr. Adler: It's quite widespread. ADHD shows up in roughly six to nine percent of children, and about 60 percent continue to have significant symptoms into adulthood. Globally, adult prevalence sits around four percent. In the U.S. alone, an estimated eight million adults live with ADHD, making it one of the more frequently diagnosed psychiatric conditions.

BSTQ: How is ADHD diagnosed?

Dr. Adler: In children, clinicians typically spot a pattern of behavioral and academic struggles tied to inattention or hyperactivity. Before landing on an ADHD diagnosis, other possibilities need to be ruled out. In children, that list includes learning disabilities, oppositional defiant disorder, mood disorders such as bipolar or depression, conduct disorder, anxiety and Tourette's syndrome, since all can mimic ADHD symptoms. For adults, symptoms need to trace back to childhood and have continued since then. Clinicians look at both recent symptoms, typically over the past six months, and a history stretching back to early life. Other clues that might prompt an ADHD evaluation include memory complaints, chronic forgetfulness, mood swings, low self-esteem and weak self-discipline.

BSTQ: What medications are used to treat adult ADHD?

Dr. Adler: Stimulant medications such as methylphenidate and dextro-amphetamine have been standard ADHD treatments for more than three decades. They're available in pill, patch and chewable forms, and dosing is usually split across two or three daily doses. While generally effective, these drugs require ongoing monitoring, and studies show many patients don't consistently stick with their medication regimen.

BSTQ: Are there effective alternative treatments?

Dr. Adler: Patients are often exposed to a wide range of unproven remedies, many accompanied by bold claims about their benefits. But, complementary and alternative approaches should be adopted only once solid evidence backs them up. Interest in researching these options for both children and adults with ADHD has grown, yet none has met the bar of rigorous, controlled clinical evidence to be considered a reliable alternative or complement to standard care. What's needed going forward is more double-blind, placebo-controlled research involving properly diagnosed ADHD patients.

BSTQ: What are the long-term effects of untreated ADHD?

Dr. Adler: A lot of adults with ADHD were never diagnosed as children, often because the relatively low demands and structured support of childhood masked how much their symptoms affected them. As adulthood brings heavier academic, career and social expectations, that impairment becomes much more apparent. The toll of untreated adult ADHD is steep, contributing to higher rates of academic failure, unemployment or underemployment, divorce and separation, substance abuse, smoking and car accidents. Many adults with ADHD end up performing well below their potential, weighed down by low self-esteem and a lack of motivation tied to their persistent symptoms. Earlier recognition and treatment would likely make a substantial difference in both their functioning and overall quality of life. ❖

TRUDIE MITSCHANG is a contributing writer for *BioSupply Trends Quarterly* magazine.



The Artificial Pancreas: A Developing Type 1 Diabetes Innovation

By Brian Gaul, PharmD



TYPE 1 diabetes (T1D) is a disease characterized by the loss of pancreatic cells that stimulate the production of endogenous insulin. An autoimmune attack destroys β cells, limiting insulin production and resulting in unstable blood glucose levels. When glucose levels are not properly controlled, various complications can occur, leading to morbidity and eventually mortality for

patients.

Innovative approaches to provide consistent regulation of blood glucose levels are being developed to improve outcomes for patients with T1D. One of the most recent breakthroughs has been the creation of artificial pancreas (AP) technology. AP devices try to mimic the function of the pancreas using available and investigational diabetes technology.¹

Physiological Blood Sugar Regulation

In healthy people, glucose levels are regulated by the release of two hormones, insulin and glucagon, into the bloodstream.² Insulin causes the uptake of glucose in the serum by certain tissues and suppresses the liver's output; glucagon stimulates the liver to produce glucose and release it into the circulation.

The system is regulated by communication between islet cells in the pancreas, specifically the α and β cells, among other physiologic actions.² β cells, which control the release of insulin, are the target of autoimmune attack in T1D. Glucagon release is controlled by α cells.

A third hormone, amylin, plays a role in glucose homeostasis during post-meal periods, promoting satiety (a feeling of fullness), slowing gastric emptying and suppressing glucagon secretion. Its action prevents glucose swings and excessive calorie intake.

What Is an AP?

AP is also known as a “closed-loop automated insulin delivery system.”³ It consists of three components, including the following:³

- a real-time continuous glucose monitor (CGM) inserted subcutaneously, which measures glucose concentrations every five minutes and wirelessly sends information to a control algorithm device (CAD) by a transmitter;
- the CAD, which may be a personal computer, tablet, smartphone or pump device. It hosts a dosing algorithm that



computes the correct amount of insulin to deliver, and adjusts the infusion rate based on predicted and current glucose levels; and

- a pump delivering insulin by a subcutaneous tube.

The small pump and infusion circuit are attached subcutaneously to the abdomen or buttocks. The needle must be replaced periodically, although newer systems have extended the period to as long as seven days.¹

Pumps come in two forms: tethered or patch types.¹ Tethered pumps are approximately the size of a mobile phone, deliver insulin through a tube and are worn under clothing. Patch pumps are directly attached to the body without a tube and work by remote control.

Current iterations of AP control only basal insulin delivery, with users required to input information on meals and exercise for calculation of bolus doses. Most require carbohydrate counting to determine mealtime insulin boluses. However, hybrid closed-loop pumps are under investigation that automatically adjust the basal insulin delivery based on CGM data.

AP units currently available on the

market deliver only insulin and are classified as single-hormone units. However, dual-hormone products that deliver a second hormone (such as glucagon) are being developed and show promise in improving clinical outcomes.¹

Artificial Pancreas vs. Standard Therapies

Outcome studies of AP use have shown the devices increase time in the desired therapeutic blood glucose range (TIR) and reduce the risk of hypo- and hyperglycemia. In one study, the AP group had a 12 percent higher TIR of 70 to 180 milligrams/deciliter (mg/dl) than the control group of children receiving standard care. The treatment effect was more pronounced (18 percent) from 10 p.m. to 6 a.m., suggesting its value during nighttime use when detection of hypoglycemia is challenging.⁴

Single-Hormone Systems

Single-hormone AP systems, which deliver only insulin, are easy to use and have a simple structure.¹ However, managing glucose levels can be challenging.

The rationale for using a single-hormone AP over a typical insulin pump

is to achieve tighter blood glucose control through real-time readings from the CGM. An early trial of their use showed the t:slim X2 pump improved outcomes. It increased TIR by 11 percent, reduced mean glucose levels by 13 mg/dl and reduced time in hypoglycemia by one percent over a sensor-augmented pump group. It also reduced HbA1c by 0.33 percent over six months of use compared to the control group.⁵

Challenges with the single-hormone systems include exercise-induced hypoglycemia, missed bolus doses and delayed insulin absorption. Mechanical problems with insulin delivery, delayed and variable absorption of insulin products in the subcutaneous tissue and variability in insulin action can also be issues.³

Dual Hormone Systems — Glucagon and Analogs

Dual-hormone AP systems, while still investigational, show promise in preventing rapid fluctuations in blood glucose levels.¹ They have the potential to achieve lower glucose levels, longer TIR and less hypoglycemia than insulin-only systems. They enable more stable glucose management; however, they are complex

Current FDA-Approved Artificial Pancreas Systems

System	Compatible pumps	Compatible CGM	Compatible insulin
Medtronic	Minimed 670G/770G/780G	Guardian 3/4	Rapid-acting: Novolog, Humalog, Fiasp, Lyumjev
CamAPS FX	Dana RS, Dana-I Ypsopump	Dexcom 6	Rapid- or ultra-rapid analogs: Novolog, Humalog, Fiasp, Lyumjev
Omnipod 5	Omnipod 5	Dexcom G6	Novolog, Humalog, Admelog
Control IQ	t:slim X2 pump	Dexcom G6; Dexcom G7; FreeStyle Plus sensor	Rapid-acting: Humalog, Novolog
iLet Bionic Pancreas	iLet ACE pump	Dexcom G6; Dexcom G7/G7 15 Day; Abbott FreeStyle Libre 3 Plus sensor	Rapid-acting: Novolog, Humalog, Fiasp, PumpCart
Tidepool Loop	ACE pumps validated for Tidepool Loop, including Tandem t:slim X2, Omnipod DASH	Dexcom G6; designed for use with compatible iCGM/ACE devices designated by Tidepool	Novolog or Humalog only

NOTE: Tidepool Loop is an app/algorithm, rather than a pump, but works as an artificial pancreas system.



systems that require advanced skills for operation and management.⁶

The rationale behind the use of glucagon and its analogs in dual-hormone systems is that the compound is rapidly absorbed, preventing hypoglycemia more effectively than stopping an insulin infusion.⁷ Rapid-acting insulins have a duration of three to five hours and remain detectable in the plasma for a period even after they are stopped.⁸ Glucagon is a

hormone AP systems. Deficiencies in amylin parallel those in insulin secretion and lead to poor postprandial blood glucose control and high variability.¹⁰

Studies indicate dual-hormone systems that deliver rapid-acting insulin and pramlintide improve glucose regulation compared with insulin-only systems. They increase TIR, reducing mean glucose levels and variability without increasing hypoglycemia.⁶

Innovative approaches to provide consistent regulation of blood glucose levels are being developed to improve outcomes for patients with T1D.

more effective choice in situations with patients experiencing rapidly dropping blood glucose levels, such as during aerobic exercise.⁹

The disadvantages of dual-hormone systems are that projected inflated costs and complexity of use may make them unsuitable for some users. The low stability of glucagon is also an issue, as cartridges must be replaced every eight to 24 hours. Analogs with longer stability windows, such as dasiglucagon, are in development; it is a ready-to-use aqueous solution that is stable in a prefilled cartridge for seven days. Other investigational options include biochaperone glucagon and nonaqueous soluble glucagon.³

Dual Hormone Systems — Amylin Analogs

Pramlintide, an analog of amylin, is also being investigated for use in dual-

One disadvantage of dual-hormone systems with insulin and pramlintide is that current hormones require distinct levels of acidity to be stable and effective. This difference requires two separate cassettes and cannulas.³ However, coformulations of insulin and pramlintide are in development that are stable at similar pH levels. Patients who receive pramlintide also may experience gastrointestinal symptoms, although most are not severe.³

Future Directions

Early research is being conducted on a triple-hormone pump (insulin, glucagon, pramlintide) that would completely mimic physiological pancreatic hormone production.³ It would require use of two cartridges, one with an insulin-pramlintide coformulation and one with glucagon or an analog. It would not require user input for meals or

carbohydrate counting.

Ultra-fast-acting insulins also are being developed for AP systems.³ They would better mimic the prandial insulin secretion pattern and prevent or control postprandial glucose swings. They help address insulin delivery delays in the presence of high glucose loads.

Reducing the Impact of Disease

AP therapy demonstrates the promise of improved glucose control, reduced hypoglycemic episodes and prevention of long-term complications for T1D patients. It highlights the continued research on T1D therapies to reduce the impact of this difficult disease. ❖

References

1. Kitagawa, H, Munekage, M, Seo, S, and Hanazaki, K. Artificial Pancreas: The Past and the Future. *Journal of Artificial Organs*, 2025;28(4):514-521. Accessed at [pmc.ncbi.nlm.nih.gov/articles/PMC12549763](https://pubmed.ncbi.nlm.nih.gov/articles/PMC12549763).
2. Röder, PV, Wu, B, Liu, Y, and Han, W. Pancreatic Regulation of Glucose Homeostasis. *Experimental and Molecular Medicine*, 2016;48(3):e219. Accessed at www.nature.com/articles/emmm20166.
3. Infante, M, Baidal, DA, Rickels, MR, et al. Dual-Hormone Artificial Pancreas for Management of Type 1 Diabetes: Recent Progress and Future Directions. *Artificial Organs*, 2021;45(9):968-986. Accessed at pubmed.ncbi.nlm.nih.gov/34263961.
4. Wadwa, RP, Reed, ZW, Buckingham, BA, et al. Trial of Hybrid Closed-Loop Control in Young Children with Type 1 Diabetes. *New England Journal of Medicine*, 2023;388(11):991-1001. Accessed at pubmed.ncbi.nlm.nih.gov/36920756.
5. Brown, SA, Kovatchev, BP, Raghinaru, D, et al. Six-Month Randomized, Multicenter Trial of Closed-Loop Control in Type 1 Diabetes. *New England Journal of Medicine*, 2019;381(18):1707-1717. Accessed at www.nejm.org/doi/full/10.1056/NEJMoa1907863.
6. Haidar, A, Tsoukas, MA, Bernier-Twardy, S, et al. A Novel Dual-Hormone Insulin-and-Pramlintide Artificial Pancreas for Type 1 Diabetes: A Randomized Controlled Crossover Trial. *Diabetes Care*, 2020;43(3):597-606. Accessed at pubmed.ncbi.nlm.nih.gov/31974099.
7. Haidar, A. Insulin-and-Glucagon Artificial Pancreas Versus Insulin-Alone Artificial Pancreas: A Short Review. *Diabetes Spectrum*, 2019;32(3):215-221. Accessed at [pmc.ncbi.nlm.nih.gov/articles/PMC6695257](https://pubmed.ncbi.nlm.nih.gov/articles/PMC6695257).
8. Morello, CM. Pharmacokinetics and Pharmacodynamics of Insulin Analogs in Special Populations with Type 2 Diabetes Mellitus. *International Journal of General Medicine*, 2011;4:827-835. Accessed at pubmed.ncbi.nlm.nih.gov/22267935.
9. Peters, TM, and Haidar, A. Dual-Hormone Artificial Pancreas: Benefits and Limitations Compared with Single-Hormone Systems. *Diabetic Medicine*, 2018;35(4):450-459. Accessed at pubmed.ncbi.nlm.nih.gov/29337384.
10. Kruger, DF, Gatcomb, PM, and Owen, SK. Clinical Implications of Amylin and Amylin Deficiency. *Diabetes Education*, 1999;25(3):389-397; quiz 398. Accessed at pubmed.ncbi.nlm.nih.gov/10531859.

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AI Innovations in Translation and Interpretation Services

By Rachel Maier, MS



IS YOUR medical facility equipped to interact with any patient, any time? You might say an emphatic “Yes,” thinking of the myriad medical staff and equipment you have on hand. But, what happens when a patient comes through your doors who does not speak a language you understand?

In medicine, communication is paramount. Providers must obtain a clear medical history, understand the patient complaint and communicate diagnoses and treatment plans. Patients, in turn, must communicate their complaint, convey medical history, understand the provider’s input and give informed consent. When these things aren’t happening, errors abound. Language barriers increase the risk of misdiagnosis and malpractice.

In the past, medical interactions relied on human translators, but innovations in translation and interpretation services build on human intelligence to make clear communication with patients not only accessible, but also more cost-effective and convenient. These services leverage artificial intelligence (AI) to prevent errors and ensure informed consent, provide equal access to medical care and, perhaps most importantly, conserve patient dignity and build trust. Here are three standout systems:

Care to Translate

Care to Translate is a digital medical translator app for healthcare professionals and patients that provides real-time medical translation for safer, faster care. The app can be downloaded on any smartphone, equipping providers to engage with patients or patients to

engage with providers. Built on a leading real-time translation engine with medical accuracy, the app features Live Translate in more than 130 languages and a phrase library with more than 3,500 medically verified phrases translated into 52 languages. Translations are verified by

native speakers with medical expertise, and cultural sensitivity is built in and tailored to diverse patient needs. It’s perfect for short conversations when there isn’t time to secure a human translator. For more information, visit www.caretotranslate.com.

Boostlingo

For Boostlingo, AI expands access and human interpreters protect trust. Built to support more languages, empower more encounters and equip more teams, Boostlingo is a smart language intelligence platform that brings language

access to routine medical interactions. Its comprehensive system uses AI for routine interpretation and leans on human interpreters for more complex situations. Boostlingo provides language access for more than 300 languages

from one secure platform that protects patient privacy, making on-demand and scheduled interpretation easy and reliable. For more information and to request a demo, visit www.boostlingo.com/industries/healthcare.

No Barrier

Designed for telehealth and in-person visits, No Barrier medical interpretation services bridge the gap between the 10,000 certified medical interpreters in the U.S. and the 25 million patients who need them. Instant, HIPAA-compliant medical interpretation covers more than 295 languages the moment a clinician needs it. Its fixed annual subscription

pricing model includes unlimited, secure encounters, with average cost savings of 50 percent. How it works: An AI medical interpreter instantly processes spoken language, translating conversations between patients and providers in real time. Additionally, No Barriers provides interpretation at every step of the patient’s journey; it supports diagnosis explanation, patient

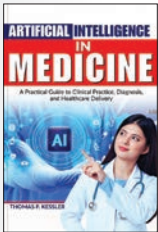
consent and care coordination, and it links to medical records to keep documentation consistent. For more information and to request a demo, visit www.nobarrier.ai.

RACHEL MAIER, MS, is a contributing writer for *BioSupply Trends Quarterly*.



ARTIFICIAL Intelligence In MEDICINE: A Practical Guide to Clinical Practice, Diagnosis, and Healthcare Delivery

Author: Thomas P. Kessler



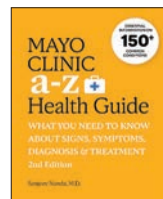
Written for clinicians, healthcare administrators, medical students and anyone working at the intersection of technology and patient care, this is a clear, no-hype guide to how artificial intelligence (AI) is transforming diagnosis, treatment planning and healthcare delivery — and what that means for the people doing the actual work of caring for patients. Readers will learn how AI-assisted diagnostic tools are changing radiology, pathology and early disease detection; where machine learning genuinely improves clinical decision-making — and where it still falls short; how predictive analytics is reshaping patient risk assessment and preventive care; what healthcare administrators need to know before adopting AI systems in hospitals and clinics; the ethical, legal and data-privacy questions every healthcare professional should be asking; and where the field is heading — and how to prepare for it instead of being caught off guard by it.

www.amazon.com/ARTIFICIAL-Intelligence-MEDICINE-practical-healthcare/dp/B0HDSYMK3N

Mayo Clinic A to Z Health Guide, 2nd Edition: What You Need to Know About Signs, Symptoms, Diagnosis and Treatment

Author: Sanjeev Nanda, MD

With topics ranging from hiccups to cancer, the full-color pages inside *Mayo Clinic A to Z Health Guide* feature medical illustrations that add clarity to complex medical concepts, and the user-friendly design helps readers easily find what they're looking for such as questions like, "What is it?" and "What's the cause?"; the latest knowledge of risk factors; symptom checker, with comprehensive lists of common signs and symptoms; what tests to expect, to help approach any healthcare visit feeling prepared; treatment, including updated medication options; and lifestyle tips for treatment and prevention in daily life.

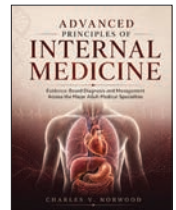


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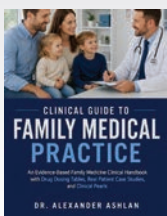
Advanced Principles of Internal Medicine: Evidence-Based Diagnosis and Management Across the Major Adult Medical Specialties

Author: Charles V. Norwood

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Clinical Guide to Family Medical Practice: An Evidence-Based Family Medicine Clinical Handbook with Drug Dosing Tables, Real Patient Case Studies, and Clinical Pearls

Author: Alexander Ashlan, MD

This handbook is designed to help healthcare providers navigate the realities of everyday clinical practice with clarity and confidence. Readers will discover evidence-based approaches to evaluating patients, making accurate diagnoses, recognizing red flags before they become emergencies, selecting appropriate investigations, initiating effective treatment and providing compassionate, patient-centered care across every stage of life. Sections include the core principles that define exceptional family medicine; practical diagnostic strategies that strengthen clinical reasoning; evidence-based management for common and complex medical conditions; emergency recognition and immediate intervention for life-threatening presentations; differential diagnosis frameworks that improve diagnostic accuracy; preventive care and health promotion strategies for long-term wellness; and more.

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Medicare Immune Globulin Reimbursement Rates

Rates are effective Oct. 1 through Dec. 30, 2026

	Product	Manufacturer	J Codes	ASP + 6% (before sequestration)	ASP + 4.3% (after sequestration)
IVIG	ALYGLO®	GC Biopharma	J1552	\$240.08	\$236.23
	ASCENIV™	ADMA Biologics	J1554	\$1016.91	\$1000.60
	BIVIGAM®	ADMA Biologics	J1556	\$161.58	\$158.99
	GAMMAGARD® SD	Takeda	J1566	\$165.51	\$162.86
	GAMMAPLEX®	BPL/Kedrion	J1557	\$124.60	\$122.60
	OCTAGAM®	Octapharma	J1568	\$94.27	\$92.75
	PANZYGA®	Octapharma/Pfizer	J1576	\$140.50	\$138.25
	PRIVIGEN®	CSL Behring	J1459	\$97.93	\$96.36
IVIG/SCIG	YIMMUGO®	Kedrion	J1553	\$43.33	\$42.63
	GAMMAGARD LIQUID®	Takeda	J1569	\$98.99	\$97.40
	GAMMAKED™	Kedrion	J1561	\$96.04	\$94.50
SCIG	GAMUNEX®-C	Grifols	J1561	\$96.04	\$94.50
	CUTAQUIG®	Octapharma	J1551	\$141.72	\$139.45
	CUVITRU®	Takeda	J1555	\$179.94	\$177.05
	HIZENTRA®	CSL Behring	J1559	\$147.86	\$145.49
	HYQVIA®	Takeda	J1575	\$192.93	\$189.84
	XEMBIFY®	Grifols	J1558	\$152.00	\$149.56

* 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
	ASCENIV™ LIQUID, 10%	ADMA Biologics	PI	5 g
	BIVIGAM® LIQUID, 10%	ADMA Biologics	PI	5 g, 10 g
	GAMMAGARD® S/D Lyophilized, 5% (Low IgA)	Takeda	PI, ITP, B-cell CLL, KD	5 g, 10 g
	GAMMAPLEX® Liquid, 5%	BPL/Kedrion	PI, ITP	5 g, 10 g, 20 g
	GAMMAPLEX® Liquid, 10%	BPL/Kedrion	PI, ITP	5 g, 10 g, 20 g
	OCTAGAM® Liquid, 5%	Octapharma	PI	1 g, 2.5 g, 5 g, 10 g, 25 g
	OCTAGAM® Liquid, 10%	Octapharma	ITP, DM	2 g, 5 g, 10 g, 20 g, 30 g
	PANZYGA® Liquid, 10%	Octapharma/Pfizer	PI, ITP, CIDP	1 g, 2.5 g, 5 g, 10 g, 20 g, 30 g
	PRIVIGEN® Liquid, 10%	CSL Behring	PI, ITP, CIDP	5 g, 10 g, 20 g, 40 g
IVIG/SCIG	YIMMUGO®, 10%	Kedrion	PI	5 g, 10 g, 20 g
	GAMMAGARD Liquid®, 10%	Takeda	IVIG: PI, MMN, CIDP SCIG: PI	1 g, 2.5 g, 5 g, 10 g, 20 g, 30 g
	GAMMAKED™ Liquid, 10%	Kedrion	IVIG: PI, ITP, CIDP SCIG: PI	1 g, 2.5 g, 5 g, 10 g, 20 g
	GAMUNEX®-C Liquid, 10%	Grifols	IVIG: PI, ITP, CIDP SCIG: PI	1 g, 2.5 g, 5 g, 10 g, 20 g, 40 g
SCIG	CUTAQUIG® Liquid, 16.5%	Octapharma	PI	1 g, 1.65 g, 2 g, 3.3 g, 4 g, 8 g
	CUVITRU® Liquid, 20%	Takeda	PI	1 g, 2 g, 4 g, 8 g, 10 g
	HIZENTRA® Liquid, 20%	CSL Behring	PI, CIDP	1 g PFS, 2 g PFS, 4 g PFS, 10 g PFS
	HYQVIA® Liquid, 10%	Takeda	PI, CIDP	2.5 g, 5 g, 10 g, 20 g, 30 g
	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) Trivalent	CSL Seqirus	0.5 mL PFS 10-bx	65 years+	90653
FLUARIX® (IIV4) Trivalent	GSK	0.5 mL PFS 10-bx	6 months+	90656
FLUBLOK® (ccIIV4) Trivalent	Sanofi	0.5 mL PFS 10-bx	9 years+	90673
FLUCELVAX® (ccIIV4) Trivalent	CSL Seqirus	0.5 mL PFS 10-bx	6 months+	90674
FLULAVAL® (IIV4) Trivalent	GSK	0.5 mL PFS 10-bx	6 months+	90656
FLUMIST® (LAIV4) Trivalent	AstraZeneca	0.2 mL PFS nasal spray 10-bx	2–49 years	90660
FLUZONE® (IIV4) Trivalent	Sanofi	0.5 mL PFS 10-bx	6 months+	90656
FLUZONE® (IIV4) Trivalent	Sanofi	5 mL MDV	6 months+	90658
FLUZONE® HIGH-DOSE (IIV4) Trivalent	Sanofi	0.5 mL PFS 10-bx	65 years+	90662
mFLUSIVA™ MRNA	Moderna US, Inc.	0.38 mL PFS 10-bx	50 years+	90616

ccIIV4 Cell culture-based trivalent inactivated injectable

IIV4 Egg-based trivalent inactivated injectable

LAIV4 Egg-based live attenuated trivalent nasal spray

mRNA Messenger ribonucleic acid

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	91320
mNEXSPIKE® (COVID-19 Vaccine, mRNA)	Moderna US, Inc.	0.2 mL PFS 10-bx	65 years+; 12–64 years with underlying condition	91321
NUVAXOVID™ (COVID-19 Vaccine, Adjuvanted)	Sanofi	0.5 mL PFS 10-bx	65 years+; 12–64 years with underlying condition	91304
PEMGARDA® (COVID-19 Vaccine, mRNA)	Invivyd, Inc.	500 mg/4 mL SDV 1-ctn	≥12 yrs	Q0224
SPIKEVAX® (COVID-19 Vaccine, mRNA)	Moderna US, Inc.	0.5 mL PFS 10-bx	12 years+	91322
SPIKEVAX® (COVID-19 Vaccine, mRNA)	Moderna US, Inc.	0.25 mL PFS 10-bx	6 months to 11 years	91321

Respiratory Syncytial 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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