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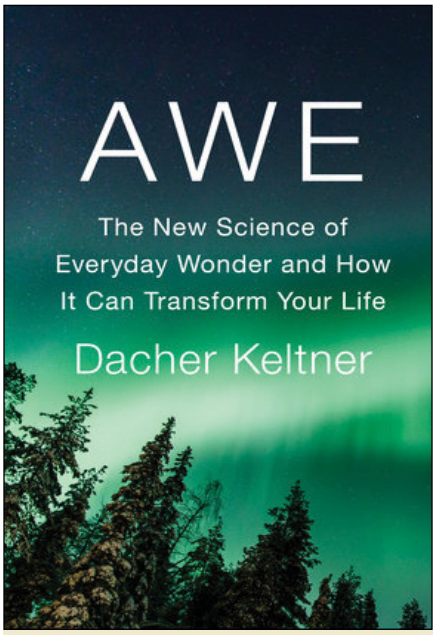
FROM THE EDITOR'S DESK

What Awe Might Do for Our Community

Corey D. Fogleman, MD, FAAFP
Editor in Chief

We are again pleased to present several compelling articles in this issue. One particularly inspiring contribution is "Exploring Vaccine-Preventable Pediatric Illnesses and Vaccine Hesitancy" by Drs. Moodley, Hintze, Bramley, Fenimore, and Martin. My own conversations with patients regarding immunizations have taken on added weight during the past few years, and I appreciate the suggestions regarding how to negotiate often-fraught encounters.

As health care stewards, we clinicians have a commitment to both the health of individuals and the community of citizens at large. Thus, the conversation regarding immunizations, for example, is not only about personal choice, but also the impact of the intervention on the broader population. In a way, we are all public health clinicians and practice in such a way to keep our community safe. What remains in the back of our minds is that to help create so-called "herd immunity," we must immunize as many patients as possible, as early as possible, to protect as many for as long as we can.



New York, Penguin Press, 2023,
336 p, 28.00 hardcover

If one goal is to have people consider others as well as themselves, how can we promote this sense of sharing and unity in our patients? For answers, I recently reread Dacher Keltner's inspiring *Awe: The New Science of Everyday Wonder and How It Can Transform Your Life.* In it, he discusses the role awe — amazement, or as he characterizes it, that which invokes "Whoa!" — plays in our lives, the benefits of opening ourselves to awe, and the role it plays in knitting our communities and society together. We may experience awe in the everyday and mundane, certainly in nature, art, and music, but perhaps most reliably, awe can be found in human courage, in triumph over either suffering or death.

Derived from the Middle English word "ege" and the Old Norse "agi," awe might have at one time implied something similar to fear, dread, or terror. And indeed, witnessing something awesome can still yield cold chills and goosebumps, whose physiological purpose may be to suggest we huddle together.

Wonder — for example, reflecting on what we find to be awesome — may be as healthy as exercise, getting enough sleep, and avoiding toxins. It appears that individuals who experience awe are more likely to be social, to share with their community an investment in overcoming threat. Keltner details that awe can also engender more creativity, more apt communication, more cohesion and solution-oriented action.

If awe and wonder could be prescribed, they might outsell sertraline. That's because those who experience wonder regularly are able to quiet parts of their brain that tend toward self-criticism, that are overstimulated by trauma. They are less prone to exacerbations of anxiety and depression. Even more, people who experience awe and reflect upon it regularly are more likely to expand their circle of caring, to feel empathy toward others. Individuals who witness awe are more likely to express gratitude and be moved to kindness and generosity, and to model their behavior on fellow citizens who are courageous, kind, and generous.

Who among us wouldn't benefit from more awe and wonder in our lives? William James suggested that wonder is one of the most important opportunities for bringing us into contact with the divine, and Ralph Waldo Emerson in his Harvard Divinity address of 1838 implored listeners to set aside dogma and go in search of the benevolent lifeforce that unifies us all;

in that search, he suggests, we are likely to experience wonder and distill our experiences into joy.

Let's preserve what it is that brings community together and create more opportunities to reinforce our shared connections.

We can all support the Stormers baseball season, because spectating is indeed a way to form community, and we can also foster programs that allow shared awe and wonder. One such movement is the Walk with a Doc program (walkwithadoc.org).

Walk with a Doc is as simple as it sounds: a health professional leads a group of community members in a walk of 30-60 minutes from once a week to once a month. Informal conversations on health topics may be covered, but even more important, participants enjoy spending time together outdoors — sharing a common route, an opportunity to take in a beautiful sunset, the changing leaves and expanse of sky. Perhaps they may also find what Emerson said would distill into joy.

To my knowledge there is not yet a Walk with a Doc program in Lancaster, but they can be found in Harrisburg, Lebanon, Reading, and Philadelphia. We have many accessible trails here in our community that would further support this awe-inspiring opportunity.

Going in search of shared awe with a program like Walk with a Doc seems like a great way to build community, and individuals who have joined in the past not only experience increased physical activity but have demonstrated more social connectedness and a better knowledge of health care-related issues. This seems like a great way to inspire trust and have a positive impact on the lifestyle of our patients and friends. It could be ... awesome!

JLGH Spring 2025 Recap

Q&A for Extended Learning

The Spring issue of The Journal of Lancaster General Hospital *offered articles on transcarotid artery revascularization, opioid-induced constipation, caring for older adults, and other practice recommendations. Review the questions and answers below to see how much you remember from the issue. Need a refresher? All issues of* JLGH *are available at JLGH.org.*

Q
A

Are there safe and effective alternatives to carotid endarterectomy to treat stenosis?
The ROADSTER 3 trial demonstrated that transcarotid artery revascularization (TCAR), in standard-risk patients, is safe and effective at treating stenosis without incurring increased risk of stroke. Clinicians should review the study's data to aid in shared decision-making discussions with patients being offered the procedure.

Q
A

In the context of caring for older patients, we must sometimes assess capacity to ensure we are acting in their best interest. What is capacity and how can it be assessed?
Capacity is the ability to comprehend relevant information about illness and make decisions that align with personal values and preferences. One option to help evaluate a patient's capacity in the inpatient setting is to use the University of Toronto's Aid to Capacity Evaluation (ACE).

Q
A

What are the three peripherally acting *mu*-opioid receptor antagonists approved for use in treating opioid-induced constipation, and when can they be used?
Methylnaltrexone, naloxegol, and naldemedine can be used after patients have been on opioids for a minimum of four weeks.

Q
A

What assessments should clinicians use in the initial workup for older adults with suspected kidney disease?
Glomerular filtration rate, electrolytes, and the albumin-to-creatinine ratio. Additionally, tools such as the Kidney Failure Index can help determine the need for further nephrology consultation.

Q
A

What are some causes of acquired methemoglobinemia?
Although methemoglobinemia is rare, use of dapsone, exposure to nitric oxide or nitrates in food or well water, use of isobutyl nitrates, and exposure to topical anesthetics such as benzocaine and lidocaine are all potential causes of this life-threatening condition.

The Transition to Adult Medical Care for Pediatric Patients with Complex Medical Conditions

Understanding the Barriers and Unique Needs

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The transition from pediatric to adult care for patients with chronic and complex medical issues is essential and yet fraught with gaps, both in terms of medical needs and community needs. While the topic has gained interest in the last 20 years, published literature has focused specifically on the pediatric population with chronic and complex needs rather than on methods of transition. Studies typically focus on one disease and/or population, which can make data or conclusions regarding this transition hard to generalize to all complex pediatric patients.

Transition remains a novel concept to many practitioners, and there are as yet no systematic or accepted transition methodology used and understood by pediatric and adult health care providers.[1] This article seeks to summarize the current literature and our initiatives at LGHP Roseville Pediatrics.

"Transition" is very different from a "transfer" of care.[2] While a transfer simply refers to a suggestion or referral to an adult-care physician following medical emancipation from their pediatric-care provider, *transitioning* involves an educational process that should start early in adolescence and continue until after the care has been initiated with an adult-care provider.[2]

The American Academy of Pediatrics historically has defined this transition as "the deliberate, coordinated process of moving a patient from pediatric-oriented health care to adult-oriented health care with the goal of optimizing the young adult's ability to assume adult roles and function."[3] The goal of health care transition is the maximization of "lifelong functioning and potential through the provision of high-quality, developmentally appropriate health care services that continue uninterrupted as the individual moves from adolescence to adulthood."[3]

BARRIERS IN ACHIEVING A SMOOTH TRANSITION

Each pediatric patient with chronic disease is unique, and the transition process for children with disabilities can be challenging. A study examining patients with chronic conditions that had aged out of a pediatric special needs program demonstrated that 65% had had a poor transition experience as defined by occurrence of at least one of the following: loss of a consistent source of care, a missed or postponed appointment within the preceding six months, and/or loss of or a gap in insurance coverage.[4]

Pediatric-Specific Diseases

Lack of familiarity with pediatric-specific diseases, as well as a paucity of providers with the training to care for pediatric-specific diseases, challenges the medical transition of these patients. Adult physicians are not always up to date on the current treatments for the pediatric diseases with which their transitioned patients present, creating a potentially less-than-ideal situation for these patients.[1]

Adult-care providers have indicated feeling uneasy with the possibility that patients may be in the end stages of their disease and require a level of care outside of their scope. Concurrent psychosocial issues may also cause apprehension for physicians who are accepting these new patients.[5]

In a study of 112 eligible internists, participants ranked concerns associated with the care of transitioning complex patients (see Table 1 on page 37). The listed fears broke down into six main categories: psychosocial care, patient maturity level, dealing with family, being medically competent to treat the pediatric disease, orchestrating the transition with the pediatric team, and dealing with the health care system.[6]

When the relative frequency of each category was tallied, the fear of being incompetent to treat foreign childhood-specific diseases was at the top, along with the fear of waning family involvement in care, inability to understand and address the psychosocial needs of the patients, how to find a superspecialist, not having experience with adolescent medicine or needs, having to mediate end-of-life care with a patient they barely know, and mediating the expectations of the families, all while facing the financial burden of the extra time required for this unique care.

The conclusion of the paper was that internists require training that affords them increased understanding and familiarity with pediatric onset conditions.[6] Contrary to what some may assume, the article demonstrated that the adult-care physicians appreciate having family support. This suggests that the role of the family should not be phased out upon completion of the transition.

Lack of Communication

Even when there are willing internists to receive transitioning patients, a lack of communication and/or trust between pediatric- and adult-care providers can often be an additional challenge. Communication between pediatric- and adult-care providers was noted as a key factor in the success of a transition; adult-care doctors need to know specifics about their own patient's condition and the history of that condition.[7]

A related study revealed that adult-care physicians appreciate having those patients who are entering their practice arrive with a medical summary or accompanied by a phone conference with the patient's previous pediatrician.[8]

Conversely, a lack of communication between pediatric- and adult-care providers can cause a downstream ripple effect in which the parents and/or the patient are challenged to connect with an unprepared adult-care physician.[1]

Loss to Follow-Up

Loss to follow-up is often a consequence of a rocky transition experience. In one published study, adolescents and young adults with congenital heart disease were frequently lost to follow-up for a variety of reasons, including being uninformed or misinformed about the need for ongoing care.

Some felt that a lack of symptoms equated to being cured; many experienced insurance barriers.[2] In a study of 158 adult congenital heart disease patients, 63% had had at least a two-year lapse in care, the average lapse being closer to 10 years. Even more concerning is the fact that these patients later followed up when manifesting dangerous sequelae that could have been prevented.[9]

Young diabetic patients who opted out of care once they left their pediatric practice reengaged with the health care system when they experienced complications that could have been avoided.[10] Inadequate transition is a major factor in over-reliance on emergency health services.[11]

Medication Compliance

Medication compliance is also a critical issue. Enlisting parents during the adolescent years may improve compliance in studies, but if a transition plan does not enforce medication adherence, there are higher rates of non-adherence and serious medical complications.[12]

In a study of patients who had undergone organ transplant as children, medication adherence to tacrolimus dropped after they left pediatric care.[13] Responsibility and self-care is especially difficult for teenagers who must assume ownership of their own health care,[7] which speaks to the need for a transition process founded on education and personal care skills.

SPECIFIC MODELS AND REQUIREMENTS OF IDEAL TRANSITIONS

The variability in the disease processes and care needs of the medically complicated pediatric population makes creating a standardized transition process impossible, yet studies have validated specific tools and methods for successfully transitioning complex pediatric patients. Success requires attention be given not only to the patient but also to the families and caregivers, as well as pediatric- and adult-care providers.[14]

Focus on the Patient

Although physician focus is largely upon the specifics of diagnoses and management, ideal transition considers the many aspects of a patient's identity. The transition must include concern for psychosocial well-being, education, interests, social groups, and career pursuits, including a patient's goals for independence.

Good transitioning must include collaborations between specialists, primary providers, and medical care centers. It may be important to connect with the patient's school programs, social and employment entities, case management, and other service organizations. This may require knowledge of other professionals within the community and each patient's environmental and social circles.[14]

Intentional Programming

Ideal transition of a medically complex pediatric patient to adult care requires intentional programming to connect patients and families to resources for success in their adult life.

In a study of patients with cerebral palsy, patients needed help with medical decision-making, utilizing vocation-related resources, and overcoming other barriers.[15] Pediatricians often need to enlist care coordinators and social workers to connect patients with com-

munity programs, a practice that is widely considered efficacious,[16] but one that requires institutional recognition and financial support.

Identifying Goals

Identifying the many goals and hopes for the future, as well as the needed skills to achieve them, is a difficult yet vitally important task. It therefore makes sense to keep track of necessary skills.

Helping patients create a list of goals will elucidate what is needed. Non-medical goals can include vocation training, college education, or achieving a specific level of independence. Establishing goals early can help determine what education and resources patients may need.[17] Affixing a checklist of discussion points and skills to the medical record was found to be helpful in a study of primary care physicians involved in transitioning complex patients. This way, every medical professional who sees the patient will know where the patient is in the transition process.[7]

Medical Workbooks

Medical workbooks that the patient, physicians, parents, and other care team members fill out are another tool for transition. Workbooks can include worksheets that teach and help patients organize information about their disease and disease process, medications, health care plans, and what they understood from their appointments.

Workbooks also help patients plot progress that they have made and demonstrate to providers a record of their patients' progress. Finally, workbooks can double as a record of medical decisions and information that may be valuable to future providers.[7]

Transition Plan

Be it a checklist or other template, a written transition plan should be prepared by the time the patient is 14 years old.[2] Transition plans clarify what will help with education, independent living, and employment opportunities.

By listing these desires, adolescents learn the importance of continued care for their condition; increased responsibility in their care management may improve compliance.[2] The importance of a known and documented plan was demonstrated in a study of 4,000 adolescents with chronic health conditions; fewer than 20% of surveyed patients had developed any semblance of a plan with their pediatric doctors.[18]

Table 1. Top Concerns of Adult-Care Providers When Transitioning Patients to Their Care
(study categories in parentheses)

1. Internists may not have the training in congenital and childhood chronic illnesses to prepare them for management. (Medical Competency)
2. It is difficult to care for patients with cerebral palsy or mental retardation if the family does not stay involved. (Family Involvement)
3. It can be difficult to meet psychosocial needs of young adults, especially those living with chronic illness. (Psychological Needs)
4. Some patients may need a superspecialist to manage complex problems (e.g., complex congenital heart disease). (Medical Competency)
5. Internists often lack training in adolescent medicine, adolescent development, and adolescent behavior. (Medical Competency)
6. It is often difficult to face disability and end-of-life issues at an early age and early in the doctor-patient relationship. (Medical Competency, Psychological Issues)
7. Managed care/financial considerations limit the time an internist is able to spend with transitioning young patients. (System Issues)
8. The families of transitioning patients have high expectations of the amount of time/attention needed for proper care. (Family Involvement)

Adapted from Peter et al.[6]

Transition Coordinator

A transition coordinator can be an important part of a successful transition. This is a person who serves as a primary contact for the patient and family. As such, this individual needs to have time dedicated to this type of care. It follows that this individual must be a health care professional trained as an educator and an expert in the disease of the patient.[2] Institutional support in the form of dedicated time and commensurate salary for such coordinators will help prepare complex patients for success.

Support

Transition programs benefit tremendously from the support of a larger medical institution, because these processes require advanced planning and additional time. These programs further require paid personnel, office space, supplies, and time. The support of a larger institution therefore becomes necessary in many cases.[2]

COMPLEX CARE CLINIC AT ROSEVILLE PEDIATRICS

The Complex Care Clinic at Roseville Pediatrics was created four years ago with the aim of providing comprehensive primary care and care coordination to close gaps that would otherwise thwart health outcomes. The time required to coordinate subspecialty appointments, transportation, medical equipment, insurance coverage, home nursing services, and medical literacy requires decreased personnel.

In our clinic, a nurse care coordinator partners with the primary physician for management of the logistics and big picture in addition to the diagnoses. Our current program services almost 100 patients, and one of the biggest challenges we and our patients face is the transition from pediatric to adult care.

Our patients negotiate all the challenges described in this article, including gaps in insurance coverage as well as lack of access to medical subspecialty care, specific financial programs, home nursing agency coverage, and finding medical equipment. In addition, some encounter legal battles over medical decision-making.

As our current cohort of patients ages into adult care, our initiatives include creating workbooks to help parents coordinate and organize the myriad forms and lists they need to ensure fluid transitions regarding care needs. We are also developing a phone application — or "app" — to help patients organize care needs. The workbook and app will be used in coordination with attendance at a transition care clinic — separate from and in addition to other clinic visits — which we ask patients to start attending as early as age 12 years. We plan to use prospective surveys of this first cohort to examine and improve the effect of our interventions.

While developing this program, we have discovered that, in addition to the physician and nurse team who can lead medical coordination, we also need a social worker who can bring a unique skill set and knowledge of community services and how to access those services. We plan to continue building this comprehensive care model and anticipate that this transition care initiative could be expanded to help other medically complex patients who need assistance across the Lancaster General Health system.

REFERENCES

1. Levine L, Levine M. Health care transition in thalassemia: pediatric to adult-oriented care. *Ann N Y Acad Sci.* 2010;1202:244-247.
2. Kovacs AH, Verstappen A. The whole adult congenital heart disease patient. *Prog Cardiovasc Dis.* 2011;53(4):247-253.
3. American Academy of Pediatrics; American Academy of Family Physicians; American College of Physicians-American Society of Internal Medicine. A consensus statement on health care transitions for young adults with special health care needs. *Pediatrics.* 2002;110(6 Pt 2):1304-1306; and subsequent updates.
4. Strickland BB, Singh GK, Kogan MD, Mann MY, van Dyck PC, Newacheck PW. Access to the medical home: new findings from the 2005-2006 National Survey of Children with Special Health Care Needs. *Pediatrics.* 2009;123(6):e996-1004.
5. Mennito SH, Clark JK. Transition medicine: a review of current theory and practice. *South Med Journal.* 2010;103(4):339-342.
6. Peter NG, Forke CM, Ginsburg KR, Schwarz DF. Transition from pediatric to adult care: internists' perspectives. *Pediatrics.* 2009;123(2):417-423.
7. Fair CD, Sullivan K, Gatto A. Best practices in transitioning youth with HIV: perspectives of pediatric and adult infectious disease care providers. *Psychol Health Med.* 2010;15(5):515-527.
8. LoCasale-Crouch J, Johnson B. Transition from pediatric to adult medical care. *Adv Chronic Kidney Dis.* 2005;12(4):412-417.
9. Yeung E, Kay J, Roosevelt GE, et al. Lapse of care as a predictor for morbidity in adults with congenital heart disease. *Int J Cardiol.* 2008;125(1):62-65.
10. de Beaufort C, Jarosz-Chobot P, Frank M, de Bart J, Deja G. Transition from pediatric to adult diabetes care: smooth or slippery? *Pediatr Diabetes.* 2010;11(1):24-27.
11. Solanke F, Colver A, McConachie H. Are the health needs of young people with cerebral palsy met during transition from child to adult health care? *Child Care Health Dev.* 2018;44(3):355-363.
12. Fredericks EM, Dore-Stites D, Well A, et al. Assessment of transition readiness skills and adherence in pediatric liver transplant recipients. *Pediatr Transplant.* 2010;14(8):944-953.
13. Annunziato RA, Emre S, Shneider B, Barton C, Dugan CA, Shemesh E. Adherence and medical outcomes in pediatric liver transplant recipients who transition to adult services. *Pediatr Transplant.* 2007;11(6):608-614.
14. Treadwell M, Telfair J, Gibson RW, Johnson S, Osunkwo I. Transition from pediatric to adult care in sickle cell disease: establishing evidence-based practice and directions for research. *Am J Hematol.* 2011;86(1):116-120.
15. Berens J, Wozow C, Peacock C. Transition to adult care. *Phys Med Rehabil Clin N Am.* 2020;31(1):159-170.
16. Colver A, Pearse R, Watson RM, et al. How well do services for young people with long term conditions deliver features proposed to improve transition? *BMC Health Serv Res.* 2018;18(1):337.
17. Lotstein DS, Kuo AA, Strickland B, Tait F. The transition to adult health care for youth with special health care needs: do racial and ethnic disparities exist? *Pediatrics.* 2010;126 Suppl 3:S129-S136.
18. Scal P, Ireland M. Addressing transition to health care for adolescents with special health care needs. *Pediatrics.* 2005;115(6):1607-1612.

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Exploring Vaccine-Preventable Pediatric Illnesses and Vaccine Hesitancy

Review from LG Health's Second Annual Pediatric Conference


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Practice guidelines summarized in this article were presented at Penn Medicine Lancaster General Health's Second Annual Pediatric Conference by four infectious disease specialists: Sarah Long, MD; Jessica Ericson, MD, MPH; Lori Handy, MD, MSCE; and Nitin Patel, MD. The event, held in November 2024, was organized by Pia Fenimore, MD; Harry Bramley, DO; and Lyndsay Tawney, Lancaster General Health Foundation. Full conference recordings are available as CME Enduring Materials online.

Vaccines can be a challenging topic for clinicians and parents. Some clinicians look forward to intellectual debates during well-child visits, helping parents better understand the risks and the benefits of vaccines; others might dread these time-intensive discussions. Most of us fall somewhere in between.

This article outlines three vaccine-preventable pediatric illnesses — polio, respiratory syncytial virus (RSV), and Bordetella pertussis — and debunks some vaccine-related myths, before concluding with time-saving strategies for clinicians navigating vaccine hesitancy. Vaccine-preventable illnesses have not disappeared, and we must be ever-vigilant to educate our patients regarding even routine vaccines.

To begin, let's consider the two broad ways to conceptualize the benefits of vaccinations: for the individual and for the population.

INDIVIDUAL IMMUNITY

To state that the purpose of vaccines is to prevent infection may be misleading. Rather, flu and RSV vaccines induce antibodies that offer basic protection against infection; they are most effective at reducing the risk of hospitalization and preventing progressive life-threatening infections.[1,2] For example, a child vaccinated against RSV is less likely to need bilevel positive airway pressure (BiPAP) in the hospital and less likely to die from RSV-related complications.

Studies show that vaccinated infants develop fewer complications from infection compared to their unvaccinated peers.[3-6]

Studies suggest that vaccine-induced immunity is initially strong but may decrease over time. That is, there is a decrease in antibody levels or immune memory. Either can occur when vaccination rates or exposure to vaccines decrease in a community. This is why routine recommended vaccines include booster doses, which help the body maintain antibody levels. This offers protection from transmittable illnesses mutating with time.[7]

Vaccination campaigns help to mitigate the effects of waning immunity,[8] which are more pronounced in those with compromised immune systems, like newborn infants.[9] This is worth highlighting at the well-child visit when parents seem hesitant about vaccines.

POPULATION IMMUNITY

Vaccines also contribute to population immunity, previously called herd immunity.[10] This public health concept suggests that a community is protected from an infection when 95% of its members have antibodies to that infection. Immunity comes from either a prior infection or the antibodies arising from the body's response to a vaccine. When 95% of a community is immune, there is enough protection to prevent an infection outbreak.

Immunized individuals effectively create a barrier to prevent further disease transmission. In essence, routine infant vaccinations protect more than just the individual infant — they protect the community, including those who cannot receive vaccines such as immune-suppressed infants with autoimmune disorders (e.g., thyroid disorders) or malignancies.[11-15] These infants are usually not able to receive live or attenuated vaccines, although they can safely receive immunizations against RSV and pertussis.[12-15]

Waning population immunity describes the progressive and gradual decline of immunity within a population, particularly following vaccination or infection. Vaccination campaigns help to mitigate this herd immunity as well. However, if vaccines are not given, then population immunity decreases and individuals become more susceptible to infections, leading to potential disease outbreaks. Community members may spread disease like RSV or pertussis without knowing they are doing so. Inadequately vaccinated populations have increased risk of weakened response and run the risk of reinfection.[16-17]

Consider measles as an example. After decades of eradication, researchers are now suspicious of measles returning to America based on several large-scale outbreaks and more than 1,200 confirmed cases across the country.[18,19] In March 2025, Pennsylvania's Montgomery County reported measles in an unvaccinated child,[20] and in April a case was diagnosed in Ephrata, here in Lancaster County.

Measles case numbers recently surpassed those recorded in prior years largely due to decreased vaccination rates.[21] In Lancaster County in the 2023-2024 school year, 88% of seventh graders had received all required measles, mumps, and rubella (MMR) vaccines. Compare this to Philadelphia County where almost all children (97%) of the same age cohort had received all recommended MMR vaccinations. Interestingly, vaccination rates among the Amish population have been declining since 2014 when they were 52% to 2022 when they were down to 30%.[22]

PREVENTABLE PEDIATRIC ILLNESSES

Polio

Mass vaccine campaigns gained appeal during the polio epidemic. The polio virus paralyzed approximately 500,000 children worldwide each year during the 1940s and 1950s. For comparison, the entire state of Montana was home to 558,000 people in 1940. Imagine polio paralyzing nearly the entire state of Montana year after year. Due to scarce treatment options, many children died.

Vaccine campaigns heralded Dr. Albert Sabin's oral polio vaccine, which was soon replaced by Dr. Jonas Salk's intramuscular polio vaccine. It took more than 50 years to eliminate polio from developing countries. This was possible thanks to funding from global organizations such as Rotary International and the Gates Foundation. Sadly, anecdotal evidence today shows that polio infections still lead to varying degrees of paralysis in hard-to-reach parts of the world.[23]

Respiratory Syncytial Virus

Like polio, RSV can affect countless infants each season. RSV causes pernicious flu-like symptoms and inflammation of the small lung bronchioles, leading to bronchiolitis. Studies show that almost 2 in 50 infants aged 1 month or younger are hospitalized with RSV each year.[24,25] For comparison, the average daycare in Pennsylvania might have 25 infants.

Hospitalizations for infants who require breathing treatments contribute to significant newborn morbidity and mortality. Unfortunately, RSV-related hospitalization rates are even higher for premature infants, and for infants born between December and March. Thus, the RSV vaccine is crucial: receiving the vaccine decreases the risk of hospitalization.[24]

Infants can acquire RSV immunization in two ways. Pregnant individuals can receive RSV vaccines so that maternal antibodies offer protection in the newborn period. The vaccine can be given safely between 32 and 36 weeks estimated gestational age (EGA) to optimize newborn protection during the initial eight months of life. If the infant is born more than 14 days after the birthing person received the RSV vaccine, the infant is protected via passive immunization. Alternately, if the opportunity for immunity through maternal antibodies has been missed, infants can safely receive a

monoclonal antibody vaccine (nirsevimab, brand name Beyfortus®) at birth through 8 months of age.[26]

Pertussis

In addition to the RSV vaccine, pregnant individuals are also encouraged to receive tetanus, diphtheria, and pertussis (Tdap) vaccines to protect newborns against Bordetella pertussis. This bacterial infection causes whooping cough — a characteristic high-pitched cough progressing to intense coughing fits that can lead to apnea, emesis, and even broken ribs. Infants younger than age 2 months are at risk of developing pulmonary hypertension, which can lead to death. The whole-cell pertussis vaccine was rolled out in 1914 and replaced by the better-tolerated acellular vaccine in the 1990s.

Pregnant women should receive the inactive Tdap vaccine in the third trimester; newborns usually receive pertussis immunity from their mothers. Vaccine-induced maternal antibodies in pregnancy protect infants during the first three months of life. Unfortunately, studies show that fewer than 60% of pregnant women agree to receiving this vaccine.[27-29] Without the vaccine, pregnant women cannot confer immunity to unborn infants, placing the newborn babies at risk for pertussis infections. From a public health perspective, this contributes to waning population immunity.

VACCINE HESITANCY

Misinformation about unsubstantiated vaccine side effects can confuse parents and clinicians. This may lead parents to make choices without understanding the true benefits and risks of vaccines.

While all vaccines can cause mild fevers, muscle pain, or self-limiting rash, these can be explained by the body's immune response. This response creates antibodies that will protect an infant from severe infections and/or hospitalizations in the future. Side effects beyond these well-tolerated reactions have been described elsewhere. The following paragraphs aim to debunk misnomers surrounding vaccine side effects.

From the time of its inception, vaccination with the oral polio vaccine has been associated with reports of vaccine-derived paralysis as a rare side effect.[30] This is described by infectious disease specialist Paul Offit, MD, in his hallmark book, *The Cutter Incident.* Out of 220,000 people receiving the vaccine, there were 70,000 reports of muscle weakness, 164 cases of paralysis, and 10 deaths.[31] This was because Cutter Laboratories failed to properly inactivate the live virus in the oral polio vaccine. It appeared that the live vaccine, in turn, was supposedly associated with paralytic poliomyelitis for 1 in 2.4 million vaccine doses.

No scientific studies could corroborate this.[32] Still, worried parents became hesitant to allow their children to receive the vaccine. It was this kind of hesitancy that resulted in one of the last polio epidemics in the United States, which occurred in part here in Lancaster County in 1979. Thankfully, swift efforts to make vaccinations available among those who were most vulnerable helped stop the spread.[33]

The oral polio vaccine was replaced by Dr. Jonas Salk's inactivated intramuscular polio vaccine, which has resulted in few to no side effects since its rollout in the early 2000s. While the intramuscular vaccine does not counteract the polio virus within the gut biome in the same way that the oral vaccine did, the overall benefits it offers and its benign side-effect profile make it the vaccine of choice today.

Post-marketing studies for the RSV vaccine suggested that the vaccine might increase the risk of contracting Guillain-Barré syndrome.[34] This syndrome causes ascending bilateral paralysis that can eventually suppress breathing support. Therefore, early detection and treatment are crucial. Further clinical trials, however, have not substantiated an association between RSV vaccines and Guillain-Barré syndrome, while many clinical studies have demonstrated an increased incidence of pneumonia among infants infected with RSV.

Regarding the risks of receiving the RSV vaccine, recent publications yield conflicting conclusions. In one trial, those who received the RSV vaccine were 1.9% more likely to deliver early.[35] This risk appeared higher in those from low- to middle-income countries; notably, the timing of vaccine administration in this study — the vaccine was given as early as 24 weeks EGA — was inconsistent with how it is given in the United States, where patients receive the RSV vaccine between 32 and 36 weeks EGA.

Another observational study conducted on U.S. women showed preterm birth was less likely among individuals receiving RSV immunization.[36] Since late preterm babies have a higher risk of hospitalization due to RSV infection, it is not recommended that clinicians withhold RSV immunization due to concerns for preterm labor.

Before the RSV vaccine, approximately 500 children died from the infection every year in the United States.[37] Since the vaccine became available, the rates of severe infection and hospitalization have decreased dramatically.[38] The Centers for Disease Control and Prevention continues to recommend RSV vaccine be given to pregnant persons who are between 32 0/7 and 36 6/7 weeks EGA during RSV season in most of the continental United States where RSV season is predictable.

Regarding pertussis vaccine, parents and clinicians may worry that immunization may lead to fever-induced seizures,[39,40] but that has never been demonstrated.[41] In fact, the study that led to this initial suggestion described seizures that occurred due to untreated fevers; "vaccine-related" seizures were thus unrelated to the vaccine.

Febrile seizures are uncommon and must be distinguished from vaccine-induced fevers. Febrile seizures are caused by the rate-of-rise of body temperature, not a statically elevated body temperature. It follows that treating a fever does not do much to prevent a febrile seizure, since the rate of rise in body temperature has already occurred. In most cases, febrile seizures occur in the setting of infections to which the immune system mounts its natural response and do not occur as the result of vaccination. In fact, vaccines decrease illness severity and therefore decrease the risk of a viral illness progressing to febrile seizures.

Still, some infants may experience temperature elevation after receiving vaccines. These vaccine-induced fevers are typically low grade in nature and can be attributed to the body's immune response as antibodies are generated and stored to fight future infections. It is this immune response that will protect the infant when exposed to infections within the community. This is how vaccines decrease illness severity and ultimately prevent infant hospitalizations. Yet, fevers can be concerning for many parents, and clinicians should discuss this vaccine reaction during the well-child visit.

A STRATEGY FOR CLINICIANS

One remaining challenge is how to appropriately convey the role vaccines are intended to play. Clinicians can guide vaccine discussions to ensure that families understand the risks, benefits, and challenges of vaccine-preventable conditions while helping to manage social media myths. One discussion guide is the 3A approach: *avoid fear tactics, ask permission,* and *adapt language.*

Avoid fear tactics when counseling parents during a well-child visit. During discussions with parents, clinicians should provide objective knowledge about vaccine risks and benefits. Consider dividing the conversation into three core areas: knowledge, behavioral changes, and access. Discussing the plethora of recommended childhood vaccines with a vaccine-hesitant parent is a daunting task. Fear-based tactics are to be avoided at all costs. Moreover, clinicians should avoid overwhelming parents with excess information.

Ask for permission to debunk myths in the office. In 2020, researchers found that 4 in 10 parents were hesitant about certain vaccines (especially the SARS-CoV-2 vaccine) for their children.[42] Hesitancy decreased when clinicians offered parents detailed, scientific evidence regarding vaccine safety and effectiveness.

Vaccine hesitancy is complex. It involves a combination of factors: misinformation, misunderstanding, fear, personal beliefs, and cultural values. Addressing vaccine hesitancy requires demonstrating respect, showing empathy, and offering evidence-based information.

Clear communication is crucial to combat misinformation. Clinicians should validate — rather than dismiss — concerns. Also, acknowledge that other parents have similar worries.

Normalizing concerns about vaccines may comfort parents. Clinicians can build rapport by offering flexible after-hours vaccine workshops during the busy back-to-school season, as well as offering personalized attention to address each family's concerns and values.

Adapt language and key phrases to use with every family. This can help clinicians offer neutral reactions to vaccine acceptance or hesitancy. Clinicians may convey presumptive phrases such as, "We will return in a minute with the vaccines." Studies show that using this kind of language makes it 17.5 times more likely for vaccines to be given to an infant.[43]

Clinicians can also try using conversational language: "What are you thinking about vaccines for your child?" Statements such as "Most infants who come to this clinic receive this vaccine" can be helpful for a parent or guardian to hear. Key phrases with positive connotations such as "Giving the vaccine is a great thing to do for your child" tend to result in more favorable outcomes than using phrasing with negative connota-

tions. Changing clinician behavior is perhaps one of the best ways to engage hesitant parents.

Below we share an example case where clinician and parent interact during a well-child visit. We outline a few ways that a clinician might mold the 3A approach to reflect personal style and then use this framework to address a hesitant parent.

CONCLUSION

Most clinicians recognize that vaccine hesitancy is a growing global challenge that may have disastrous public health consequences. This article is offered to share information from LG Health's Second Annual Pediatric Conference, shed light on vaccine-preventable pediatric illnesses, and debunk some of the myths that may fuel vaccine hesitancy.

Parental hesitancy regarding the use of pediatric vaccinations underscores the ongoing importance of primary care, where clinicians can take advantage of the confidence they can instill while building proactive, long-term patient relationships. Discussing vaccines can strengthen the sanctity of the parent-clinician relationship. Conversational strategies like the 3A approach encourage us to avoid fear tactics, ask permission, and adapt language; in this way clinicians can negotiate emotional discussions about vaccines. Ultimately, parents and clinicians can bond over a shared goal: a healthy, happy child.

Case Example

Clinician: Today your child is here for a well-child visit. I noticed we haven't yet discussed the measles, mumps, rubella — the MMR — vaccine.

Dad: Honestly, I'm just not sure about it. I've heard a lot of things, especially about autism. I don't want to risk it.

Clinician: I understand your concern. There's a lot of misinformation out there, especially about vaccines and a possible link to autism. If you're open to it, I can explain some of the facts and clear up the myths. Would that be alright?

Dad: Well, I'm not sure. But I am listening.

Clinician: Thank you for being open to a discussion. First, let me reassure you that extensive research has been done with the MMR vaccine. Because of this, we know that there is no credible scientific evidence linking this vaccine, or any vaccine, to autism. The study that started this rumor was thoroughly discredited and retracted long ago. Since then, many studies have been done. No studies have found a connection between the MMR vaccine and autism.

Dad: Really? I had no idea the studies were retracted.

Clinician: The MMR vaccine is safe and effective. It protects infants from diseases like measles that can be life-threatening. Measles is highly contagious and can cause severe complications like pneumonia and brain swelling. In fact, there was a measles case reported here in Lancaster County just two months ago.

Dad: I had no idea this was so serious. I just thought measles caused a cold.

Clinician: Well, I am not trying to scare you. Hopefully, I'm sharing what you have already seen on the news. The reality is that I want the same thing you want — for your baby to grow up healthy. I understand that, as a parent, you want to make the best decision for your child. The beauty of the MMR vaccine is that it is incredibly effective at preventing measles, which will protect your infant and those around your child. By vaccinating, you are not only protecting your baby, but also your family and your community. Giving the vaccine is an important thing to do for your baby.

Dad: Well … are there any side effects?

Clinician: Like any vaccine, there can be mild side effects. Most parents notice low-grade fevers or rash within the first 7-12 days. Serious side effects are rare. The overall benefit — protecting your baby from potentially severe diseases — outweighs potential side effects. And those mild side effects are much more manageable than what your child could face if they needed to be admitted to the hospital because of a measles infection.

Dad: It still feels like there is so much to worry about.

Clinician: I hear you. It is important to understand what these vaccines are for and how they can help your child. Many parents in my clinic ask the same questions you have, and I encourage these discussions so we can learn together.

Dad: Oh, it's not just me? That makes me feel better. This makes more sense. I did not realize the risks of measles. I guess I was just influenced by things people around me said.

Clinician: I am here to support you in making the best choice for your baby's health. I think it is great that you are asking these questions. I hope this helped.

Dad: I really appreciate you taking the time to explain all of this.

Clinician: I am happy to help. If you feel ready, we can go ahead with the MMR vaccine today. It is safe, effective, and will help ensure your child is protected against some serious illnesses.

Dad: Yes, let's do it. After hearing this, I feel more comfortable with vaccines in general.

Clinician: Great, I will let your nurse know. If you have any questions down the road, please reach out. We are here to make sure your baby is healthy and safe.

Clinician icon by Wilson Joseph, Dad icon by Jamil Akhtar — from Noun Project (CC BY 3.0).

REFERENCES

1. Hardelid P, Verfuerden M, McMenamin J, Gilbert R. Risk factors for admission to hospital with laboratory-confirmed influenza in young children: birth cohort study. *Eur Respir J.* 2017;50(3):1700489.
2. Raymond SL, Rincon JC, Wynn JL, Moldawer LL, Larson SD. Impact of early-life exposures to infections, antibiotics, and vaccines on perinatal and long-term health and disease. *Front Immunol.* 2017;8:729.
3. Chong C, Yung C, Gan C, et al. The burden and clinical manifestation of hospitalized influenza among different pediatric age-groups in the tropics. *Influenza Other Respir Viruses.* 2020;14(1):46-54.
4. Regan AK, Moore HC, Binks MJ, et al. Maternal pertussis vaccination, infant immunization, and risk of pertussis. *Pediatrics.* 2023;152(5):e2023062664.
5. Schaltz-Buchholzer F, Biering-Sørensen S, Lund N, et al. Early BCG vaccination, hospitalizations, and hospital deaths: analysis of a secondary outcome in 3 randomized trials from Guinea-Bissau. *J Infect Dis.* 2019;219(4):624-632.
6. Shane AL, Sánchez PJ, Stoll BJ. Neonatal sepsis. *Lancet.* 2017;390(10104):1770-1780.
7. Klein SL, McKinnon KP, McKinnon M, et al. Vaccine-induced immunity and waning immunity. *JAMA.* 2021;326(10):1007-1009.
8. Global Routine Immunization Strategies and Practices (GRISP). World Health Organization. May 29, 2016. Accessed May 1, 2025. https://www.who.int/publications/i/item/global-routine-immunization-strategies-and-practices-(grisp)
9. Friedman J, Decato C, Goldberg D, et al. Effects of waning immunity in older populations. *Lancet.* 2021;398(10295):1466-1474.
10. Jones D, Helmreich S. A history of herd immunity. *Lancet.* 2020;96(10254):810-811.
11. Banik GL, Shindo ML, Kraimer KL, et al. Prevalence and risk factors for multifocality in pediatric thyroid cancer. *JAMA Otolaryngol Head Neck Surg.* 2021;147(12):1100-1106.
12. Segni M. Disorders of the thyroid gland in infancy, childhood and adolescence. In: Feingold KR, Anawalt B, Blackman MR, et al., eds. *Endotext.* South Dartmouth (MA): MDText.com, Inc; 2000.
13. Siegel DA, King JB, Lupo PJ, et al. Counts, incidence rates, and trends of pediatric cancer in the United States, 2003-2019. *J Natl Cancer Inst.* 2023;115(11):1337-1354.
14. Sultan I, Alfaar AS, Sultan Y, Salman Z, Qaddoumi I. Trends in childhood cancer: incidence and survival analysis over 45 years of SEER data. *PLoS One.* 2025;20(1):e0314592.
15. Zhang L, Muscat JE, Chinchilli VM, Behura CG. Trends in cancer

incidence and mortality in US adolescents and young adults, 2016-2021. *Cancers (Basel).* 2024;16(18):3153.
16. Roltgen K, Hutter S, Dold C, et al. Waning immunity in COVID-19 and other vaccines. *Nat Rev Immunol.* 2020;20(12):753-762.
17. Tregoning JS, Kinnear E, Linch DC, et al. The immune response to vaccination and waning immunity. *Nat Rev Immunol.* 2021;21(11):657-671.
18. Feemster KA, Szipszky C. Resurgence of measles in the United States: how did we get here? *Curr Opin Pediatr.* 2020;32(1):139-144.
19. Kujawski SA, Ru B, Afanador NL, Conway JH, Baumgartner R, Pawaskar M. Prediction of measles cases in US counties: a machine learning approach. *Vaccine.* 2024;42(26):126289.
20. One Case of Measles Reported in Montgomery County. Montgomery County | PA. March 2, 2025. Accessed March 4, 2025. https://www.montgomerycountypa.gov/CivicAlerts.aspx?AID=4649
21. Paules CI, Marston HD, Fauci AS. Measles in 2019 — going backward. *N Engl J Med.* 2019;380(23):2185-2187.
22. Miller K, Yost B, Thompson S, Voight SL. Community health needs assessment of plain populations in Lancaster County, Pennsylvania. *Plain Anabaptist Journal of Anabaptist and Mennonite Studies.* 2025;8(1):1-17.
23. Poliomyelitis. World Health Organization. Updated April 2, 2025. Accessed April 30, 2025. https://www.who.int/news-room/fact-sheets/detail/poliomyelitis
24. Buchan SA, Chung H, To T, et al. Estimating the incidence of first RSV hospitalization in children born in Ontario, Canada. *J Pediatric Infect Dis Soc.* 2023;12(7):421-430.
25. Hall CB, Weinberg GA, Blumkin AK, et al. Respiratory syncytial virus-associated hospitalizations among children less than 24 months of age. *Pediatrics.* 2013;132(2):341.
26. Gantenberg JR, van Aalst R, Bhuma MR, et al. Risk analysis of respiratory syncytial virus among infants in the United States by birth month. *J Pediatric Infect Dis Soc.* 2024;13(6):317-327.
27. Egan RC, Chaiken SR, Derrah K, et al. Universal tetanus-diphtheria-pertussis vaccination during pregnancy: a cost-effectiveness analysis. *Obstet Gynecol.* 2023;141(4):837-844.
28. Law AW, Judy J, Atwell JE, Willis S, Shea KM. Maternal Tdap and influenza vaccination uptake 2017-2021 in the United States: implications for maternal RSV vaccine uptake in the future. *Vaccine.* 2023;41(51):7632-7640.
29. Razzaghi H, Kahn KE, Calhoun K, et al. Influenza, Tdap, and COVID-19 vaccination coverage and hesitancy among pregnant women — United States, April 2023. *MMWR Morb Mortal Wkly Rep.* 2023;72(39):1065-1071.
30. Horaud F. Albert B. Sabin and the development of oral polio vaccine. *Biologicals.* 1993;21(4):311-316.
31. Carapetis JR. The Cutter incident: how America's first polio vaccine led to the growing vaccine crisis. *BMJ.* 2006;332(7543):733.
32. Polio: The Disease & Vaccines. Children's Hospital of Philadelphia. Updated January 2, 2024. Accessed February 7, 2025. https://www.chop.edu/vaccine-education-center/vaccine-details/polio-vaccine
33. Hendrix, E. Poliomyelitis in Lancaster County with emphasis on the iron lung. *JLGH.* 2015;10(2):55-60.
34. FDA Requires Guillain-Barré Syndrome (GBS) Warning in the Prescribing Information for RSV Vaccines Abrysvo and Arexvy. Food and Drug Administration. Updated January 7, 2025. Accessed February 7, 2025. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-requires-guillain-barre-syndrome-gbs-warning-prescribing-information-rsv-vaccines-abrysvo-and
35. Dieussaert I, Kim JH, Luik S, et al. RSV prefusion F protein-based maternal vaccine — preterm birth and other outcomes. *N Engl J Med.* 2024;390(11):1009-1021.
36. Harris E. Prenatal RSV vaccine not tied to higher risk of preterm births. *JAMA.* 2024;332(8):610-611.
37. Blanco JCG, Boukhvalova MS, Shirey KA, Prince GA, Vogel SN. New insights for development of a safe and protective RSV vaccine. *Hum Vaccin.* 2010;6(6):482-492.
38. Blondeau JM. So we now have RSV vaccines. What's our next steps? *Expert Rev Respir Med.* 2024;18(1-2):17-22.
39. Plotkin SA. The pertussis problem. *Clin Infect Dis.* 2014;58(6):830-833.
40. Liu H, Zhang G, Liu Y, et al. TPX2 siRNA regulates growth and invasion of esophageal cancer cells. *Biomed Pharmacother.* 2014;68(7):833-839.
41. Cherry JD. The 112-year odyssey of pertussis and pertussis vaccines — mistakes made and implications for the future. *J Pediatric Infect Dis Soc.* 2019;8(4):334-341.
42. Szilagyi PG, Shah MD, Delgado JR, et al. Parents' intentions and perceptions about COVID-19 vaccination for their children: results from a national survey. *Pediatrics.* 2021;148(4):e2021052335.
43. Opel DJ, Heritage J, Taylor JA, et al. The architecture of provider-parent vaccine discussions at health supervision visits. *Pediatrics.* 2013;132(6):1037-1046.

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Kopp

Amish Home Remedies and the Research Surrounding Them — Part 2

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This two-part report examines the composition and efficacy of "folk" remedies used by the Amish of Lancaster County. While not a complete list of the plants used, the report seeks to educate medical practitioners regarding Amish practices to help guide patient interviews and prescription recommendations.

Part 1, published in the Spring 2025 issue of this journal, included an introduction to illustrate the need to better understand the supplements and alternative treatments patients consume. Please see that introduction for further reference.[1]

METHOD

In this qualitative project, 22 members of the Amish community of Lancaster County were interviewed and the ingredients of these "natural remedies" were examined. Interviews took place from February 2022 to July 2024. Steps were taken to preserve interviewee anonymity.

The interviewer began by asking what common ailments and treatments families encounter and use. Ingredients were cataloged and the literature was consulted to determine which supported indications, contraindications, and adverse effects might concern the medical community.

Families were not included if they did not have their home church located in Lancaster County. This process ensured more consistent information was gathered, as the uses and ingredients of "home remedies" reported by the Lancaster Amish community can vary from those remedies used by others in other locations. This review is in no way comprehensive. Attempts have been made to describe the pertinent ingredients, along with adverse effects, method of action, contraindications, and indications for use.

DISCUSSION

Indian Snakeroot

Indian snakeroot, Devil's pepper, or serpentine root (*Rauwolfia serpentina*) is not native to Pennsylvania. Although it has several biologically active alkaloids, Amish respondents reported that it is used to treat high blood pressure; it may also improve blood circulation after a stroke.

This plant was studied as a treatment for hypertension as early as 1949. Alkaloids in the bark of this root probably act by depleting both catecholamine and serotonin stores, and preventing their reuptake.[2] However, this root has many active substances and associated side effects, so its reliability has been inconsistent. No correlation with cancer was found in a study in 2001.[3]

A 2015 study demonstrated that hypertension could indeed be treated appropriately with Indian snakeroot with relatively few side effects.[4] Yet Indian snakeroot has been shown to cause nasal congestion, sedation, gastrointestinal upset, angina-like symptoms, bradycardia, and extrapyramidal-like symptoms. These effects are dose dependent.[2]

Guidelines for its use have not been established in the United States. While Indian snakeroot may decrease blood pressure, it should be discontinued if side effects occur or hypertension is not properly controlled.

Fenugreek

Fenugreek (*Trigonella foenum-graecum*, see Fig. 1) has been used for various purposes for hundreds of years.[5] The Amish of Lancaster County use this plant mainly to treat individuals who have had strokes, suffer from dementia or age-related memory loss, or to prevent decline in memory. It is unclear if it has any demonstrable effect for any of these.

The pharmacologically active substances in this plant include saponins, steroidal compounds, alkaloids, flavonoids, phenolic acids, and styrylic acids.[6] These may act as antioxidant, anti-inflammatory, antimicrobial, antidiabetic, antihyperlipidemic, antitumor, and anti-obesity compounds.[4]

This study was found to be exempt by the ATSU-Kirksville IRB according to 45CFR46.104 (d)(2)(i). IRB Number: #JK20220314-001.

Additionally, the dosing of this substance has been extensively studied. Its suggested oral dose range of 3.16 g/60 kg to 48.64 g/60 kg is broad to allow for whether the seeds have been "debitterized," meaning there is great potential for dosing errors.[7]

Fenugreek may be toxic when it is used at a higher dose than prescribed. Fenugreek has been shown to decrease fertility and have abortifacient properties. In addition, allergy to any of the other legumes should be considered a contraindication to use.[5] Fenugreek can lower blood sugar, and due to its antidiabetic properties, patients should be monitored for hypoglycemia. Finally, it should be used with caution when patients are on medications such as warfarin or antiplatelet agents.[8]

Fig. 1. Fenugreek *(Trigonella foenum-graecum).*

Citicoline

Citicoline is a naturally occurring phospholipid frequently used by the Amish for memory, general brain health, and traumatic brain injury. This phospholipid may increase neurotransmitters, especially phosphatidylcholine, by interacting with the synthesis of certain cellular membrane phospholipids.[9] Interestingly, citicoline may have positive effects on numerous disease processes such as Alzheimer's disease, stroke, glaucoma, and amblyopia. It may modulate diseases by reducing infarct volume and generalized brain edema.[10] However, it has not been shown to be useful in patients who have traumatic brain injury.[11]

The safety profile of citicoline is considered to be very good, as few patients experience side effects. Drug interactions may be a concern, as citicoline has been shown to interact with several antipsychotic medications via an unknown mechanism of action.[12]

Water Hyssop

Water hyssop (*Bacopa monnieri*) is used by the Amish for general brain health. It may be included in many teas and supplements, and consumed regularly. Typically, it is not used as treatment after a brain injury or after onset of cognitive decline.

B. monnieri is thought to contain active compounds that inhibit acetylcholinesterase and activate choline acetyltransferase; these may result in decreased β-amyloid production, increased monoamine production, and promotion of cerebral blood flow.[13] Additionally, it may act as an antioxidant, hepatoprotective, analgesic, anti-inflammatory, antimicrobial, antiulcerogenic, anti-anxiolytic, antineoplastic, neuroprotective, and immunostimulatory agent.[14] Although *B. monnieri* contains nicotine, it may protect against nicotine-induced lipid peroxidation and mutagenicity in mice.[15]

In aggregate, *B. monnieri* is thought to reduce memory loss when individuals are learning new information.[11] The mechanism of action for side effects is not well understood, but a study with rats showed that it is very safe (LD50 was 2,400 mg/kg after oral ingestion and 500 mg/kg during intravenous administration).[16] Rare side effects include reduced gastric motility.[12]

Additionally, a study using mice showed that *B. monnieri* decreases the expression of CYP3A in the liver and intestine which may affect the bioavailability of certain medications; a careful medication review is indicated.[17] There are no long-term studies about its effect on human ingestion, thus caution is advised.

Fucoidan

Fucoidan is a long-chain sulfated polysaccharide found in several seaweed species, one of which is Devil's apron (*Laminaria japonica,* see Fig. 2 on page 48). It is used primarily within the community to treat headaches and in patients who have had concussions; it may prevent seizures and further brain injury. While the literature demonstrates some utility as an analgesic agent, there are limited studies showing fucoidan acting as an anticonvulsant.

Instead, fucoidan may suppress the toxicity of anticancer medications and reduce fatigue during chemotherapy.[18] It may activate caspase-8 in tumor cells but

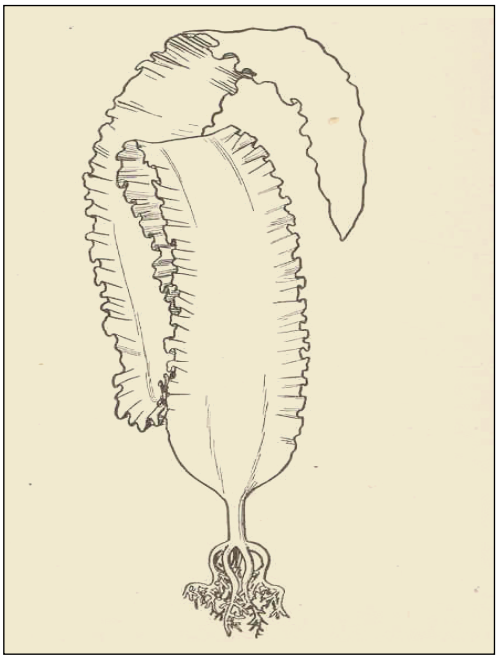

Fig. 2. Fucoidan (*Laminaria japonica).*

not in healthy cells, making it a powerful pro-apoptotic agent. Moreover, fucoidan targets neuraminidase and cellular epidermal growth factor receptor, which is a pathway utilized in treating upper respiratory infection.[19] Again, it does not appear to be widely used for these purposes in the Lancaster Amish community.

Fucoidan is generally safe. However, patients should be discouraged from taking fucoidan to treat symptoms of concussion, as it has been shown to have anti-coagulant activity that varies based on the molecular weight of the polysaccharide.[20] Further, the structure of the compounds varies based on when they are harvested from specific species.[21]

It is difficult to prepare this herbal to yield exact dosing without understanding the species variability, so it should not be recommended. Patients should be cautious if they don't understand the exact composition of their supplement.

Oregano

Oregano (*Origanum vulgare,* see Fig. 3) has been documented for its use in medicine for more than a millennium. It is mentioned in Greek medical texts of Hippocrates as well as the Chinese book of herbs, *Shen-nung Pen-ts'ao Ching.* In Aristophane's *The Frogs,* a comedy about Dionysus, the herb is used to bestow courage upon the protagonist so he may travel to the underworld.

Though historically used for a variety of ailments, today the Amish of Lancaster County nebulize it when treating asthma. Additionally, the oil is ingested orally for head colds and to treat dyspepsia. Like many of the other substances discussed, oregano has been shown to exert both antimicrobial and antioxidant effects.[22] However, the Amish community that was interviewed unanimously agreed that nebulized oregano works better than albuterol for acute symptoms associated with asthma.

Oregano inhibits the expression and secretion of IL-1-beta, IL-6, and TNF-alpha in RAW264.7 cells, which may cumulatively decrease inflammation.[23] Moreover, it may decrease alveolar macrophage activity and the symptoms of asthma. More studies must be conducted since the dosing when oregano is nebulized varies; there have been no studies on long-term effects of use on developing lungs. There is as yet insufficient information available to recommend this as a treatment option.

Fig. 3. Oregano (*Origanum vulgare).*

Hyperbaric Oxygen Therapy

Hyperbaric oxygen therapy (HBOT) chambers are currently being used by the Amish of Lancaster County. One member of the community may purchase a chamber and allow others to use it for various pathologies, including treating the effects of Lyme disease, flu, and even chronic pain exacerbated by heavy labor.

Research is evolving on the indications for HBOT. Animal studies suggest it may reduce chronic pain; it may work for this purpose in humans as well.[24] Further, HBOT has more frequently been used in the treatment of atypical wound healing.[25] Exposing the

tissues to higher levels of oxygen may promote neovascularization and encourage limb salvage.

The safety profile of HBOT is relatively favorable. The most common side effect is middle ear barotrauma, but more serious adverse effects such as myopia, dyspnea, and inspiratory pain can occur.[26] The majority of these adverse effects are reversible with cessation of therapy.

CONCLUSION

Often, patients will pursue what practitioners of Western medicine characterize as "alternative" therapies. To serve communities, indications for use and risks, as well as drug interactions for these "alternative" therapies, must be considered. Practitioners should try to understand these therapies and be prepared to offer recommendations based on the best available evidence.

Further study regarding what community members are using is warranted. If we can cite the latest evidence to establish standards regarding how and when to use herbal remedies, we may more appropriately advise patients regarding herbal remedies.

Occasionally during the interviews cited here, individuals described past encounters with physicians who prescribed medication without adequately explaining the risks and benefits. These conversations may have been better received if clinicians had presented a clear understanding of the evidence regarding commonly used herbals and supplements.

With knowledge comes understanding and an opportunity to build rapport. Further study of Amish home remedies is warranted to appropriately care for our patients and community and to continue building therapeutic alliances.

REFERENCES

1. Kopp J, Fritz L. Amish home remedies and the research surrounding them — part 1. *JLGH.* 2025;20(1):11-15. https://www.jlgh.org/Past-Issues/Volume-20-Issue-1/Kopp_remedies_part1.aspx
2. Indian Snakeroot. NatMed, Therapeutic Research Center. Updated January 16, 2025. Accessed March 28, 2025. https://naturalmedicines.therapeuticresearch.com/databases/food,-herbs-supplements.aspx?letter=I
3. Weiss RF. *Weiss's Herbal Medicine.* Theime; 2001: 153-158.
4. Lobay D. Rauwolfia in the treatment of hypertension. *Integr Med (Encinitas).* 2015;14(3):40-46.
5. Petropoulos GA, ed. *Fenugreek – The Genus Trigonella.* Taylor and Francis; 2002.
6. Nagulapalli Venkata KC, Swaroop A, Bagchi D, Bishayee A. A small plant with big benefits: fenugreek (Trigonella foenum-graecum Linn.) for disease prevention and health promotion. *Mol Nutr Food Res.* 2017;61(6):10.1002/mnfr.201600950.
7. Ouzir M, El-Bairi K, Amzazi S. Toxicological properties of fenugreek (Trigonella foenum-graecum). *Food Chem Toxicol.* 2016;96:145-154.
8. Lambert JP, Cormier A. Potential interaction between warfarin and boldo-fenugreek. *Pharmacotherapy.* 2001;21(4):509-512.
9. Grieb P. Neuroprotective properties of citicoline: facts, doubts and unresolved issues. *CNS Drugs.* 2014;28(3):185-193.
10. Gutiérrez-Fernández M, Rodríguez-Frutos B, Fuentes B, et al. CDP-choline treatment induces brain plasticity markers expression in experimental animal stroke. *Neurochem Int.* 2012;60(3):310-317.
11. Zafonte RD, Bagiella E, Ansel BM, et al. Effect of citicoline on functional and cognitive status among patients with traumatic brain injury: Citicoline Brain Injury Treatment Trial (COBRIT). *JAMA.* 2012;308(19):1993-2000.
12. Talih F, Ajaltouni J. Probable nootropicinduced psychiatric adverse effects: a series of four cases. *Innov Clin Neurosci.* 2015;12(11-12):21-25.
13. Roodenrys S, Booth D, Bulzomi S, Phipps A, Micallef C, Smoker J. Chronic effects of Brahmi (Bacopa monnieri) on human memory. *Neuropsychopharmacology.* 2002;27(2):279-281.
14. Aguiar S, Borowski T. Neuropharmacological review of the nootropic herb Bacopa monnieri. *Rejuvenation Res.* 2013;16(4):313-326.
15. Vijayan V, Helen A. Protective activity of Bacopa monniera Linn. on nicotine-induced toxicity in mice. *Phytotherapy Res.* 2007;21(4):378-381.
16. Allan J, Damodaran A, Deshmukh NS, Goudar KS, Amit A. Safety evaluation of a standardized phytochemical composition extracted from Bacopa monnieri in Sprague-Dawley rats. *Food Chem Toxicol.* 2007;45(10):1928-1937.
17. Singh R, Panduri J, Kumar D, et al. Evaluation of memory enhancing clinically available standardized extract of Bacopa monniera on P-glycoprotein and cytochrome P450 3A in Sprague-Dawley rats. *PLoS One.* 2013;8(8):e72517.
18. Ikeguchi M, Yamamoto M, Arai Y, et al. Fucoidan reduces the toxicities of chemotherapy for patients with unresectable advanced or recurrent colorectal cancer. *Oncol Lett.* 2011;2(2):319-322.
19. Wang W, Wu J, Zhang X, et al. Inhibition of influenza A virus infection by fucoidan targeting viral neuraminidase and cellular EGFR pathway. *Sci Rep.* 2017;7:40760.
20. Wang J, Zhang QB, Zhang ZS, Song HF, Li PC. Potential antioxidant and anticoagulant capacity of low molecular weight fucoidan fractions extracted from Laminaria japonica. *Int J Biol Macromol.* 2010;46(1):6-12.
21. Luthuli S, Wu S, Cheng Y, Zheng X, Wu M, Tong H. Therapeutic effects of fucoidan: a review on recent studies. *Mar Drugs.* 2019;17(9):487.
22. Rostro-Alanis MJ, Báez-González J, Torres-Alvarez C, Parra-Saldívar R, Rodriguez-Rodriguez J, Castillo S. Chemical composition and biological activities of oregano essential oil and its fractions obtained by vacuum distillation. *Molecules.* 2019;24(10):1904.
23. Cheng C, Zou Y, Peng J. Oregano essential oil attenuates RAW264.7 cells from lipopolysaccharide-induced inflammatory response through regulating NADPH oxidase activation-driven oxidative stress. *Molecules.* 2018;23(8):1857.
24. Sutherland AM, Clarke HA, Katz J, Katznelson R. Hyperbaric oxygen therapy: a new treatment for chronic pain? *Pain Pract.* 2016;16(5):620-628.
25. Benedict Mitnick CD, Johnson-Arbor K. Atypical wounds; hyperbaric oxygen therapy. *Clin Podiatr Med Surg.* 2019;36(3):525-533.
26. Camporesi EM. Side effects of hyperbaric oxygen therapy. *Undersea Hyperb Med.* 2014;41(3):253-257.

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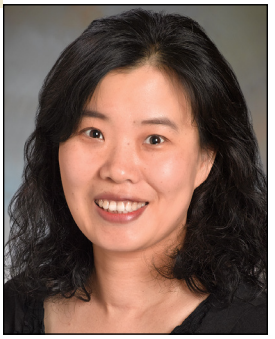
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Safety Considerations When Prescribing GLP-1 RAs

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Stories about celebrities using glucagon-like peptide-1 receptor agonists (GLP-1 RAs) for weight loss have put them in the spotlight but have not emphasized the need for in-depth conversation about anti-obesity and antidiabetic medication in high-risk individuals.

The U.S. Food and Drug Administration (FDA) approved semaglutide in 2017 as Ozempic® to treat type 2 diabetes and then as Wegovy® in 2021 to treat obesity. This GLP-1 receptor agonist works in the gut, brain, and pancreas to exert its metabolic effects. Tirzepatide, which is a dual GLP-1 receptor agonist/glucose-dependent insulinotropic polypeptide (GIP), was FDA approved as Mounjaro® for diabetes in 2022 and Zepbound® for obesity in 2023. Both medications have gained popularity.

A survey from May 2024 suggested that as many as one in eight U.S. adults have tried a GLP-1 receptor agonist or GLP-1 RA/GIP, and more than 15 million people are currently using these medications.[1]

This class of medications is effective in reducing body weight, as well as lowering blood sugar levels and benefitting the cardiovascular system.[2] However, clinicians need to discuss related risks with patients when prescribing.

Discussed in this article are safety concerns related to these medications. For simplicity, these medications are jointly referred to here as GLP-1 receptor agonists.

DRUG SIDE EFFECTS

The most common side effects of GLP-1 receptor agonist use are gastrointestinal symptoms, such as nausea, vomiting, heart burn, diarrhea, constipation, and stomach pain associated with bloating from gas. Starting with the lowest dose and titrating slowly can mitigate these risks.

Fatigue, dizziness, depression, hypoglycemia, and gall bladder disease have also been reported, and the risk of developing pancreatitis is increased. In addition, prescribing GLP-1 receptor agonists warrants telling patients that medullary thyroid tumor risk is increased based on results of rodent studies.

NUTRITIONAL CONCERNS

GLP-1 receptor agonists reduce appetite, which helps with weight loss. The following should be emphasized.

- *Adequate hydration.* Encourage pure water intake (at least 64 ounces per day). Patients often reduce both food and water intake when using these medications, and thus dehydration may result. Acute kidney injury from dehydration has been reported. Good water intake also helps prevent constipation. Monitoring kidney function is also recommended.
- *Adequate protein intake.* The goal is to lose body fat but preserve muscle. In general, when an individual loses one pound of body weight, about 25% is due to muscle loss. To help retain muscle mass, adequate protein intake is essential, thus 1.0-1.2 g/kg protein per day using adjusted body weight, which is ideal body weight plus 25% of remaining weight; for chronic kidney disease with glomerular filtration rate less than 30, a protein intake of 0.8g/kg per day is recommended, best divided into multiple servings throughout the day.
- *Regular exercise.* It is appropriate to recommend resistance exercise be performed at least 20 minutes twice weekly and cardiovascular exercise be performed at least 150 minutes per week.
- *Balanced diet including a variety of foods.* Eating less should not mean eating fewer kinds of food. Human beings are omnivores who need variety. A rule-of-thumb is that half of intake should be vegetables and fruit, which will also provide needed fiber.
- *Screening for mineral and vitamin deficiencies.* Patients with inadequate nutritional intake run the risk of anemia and vitamin D or B_{12} deficiencies, based on clinical scenarios.

DOSING OF OTHER MEDICATIONS

GLP-1 receptor agonists can help patients lose 10% to 20% of body weight, and this may decrease patients' other prescription drug dosage requirements. It is not uncommon to find that blood pressure and diabetes parameters improve with weight loss, which can increase the risk for postural hypotension and hypoglycemia. Therefore, antihypertension and diabetic regimens may need to be reduced.

Psychiatry medications, such as Adderall®, may cause over-stimulation if the dose is not reduced after weight loss, and thyroid hormone requirements may need to be re-assessed due to possible change in absorption. Therefore, patients need continued holistic clinical evaluations when using GLP-1 receptor agonists.

SPECIAL CONSIDERATIONS FOR GERIATRIC PATIENTS

Geriatric patients can be more prone to developing drug side effects and at greater risk for developing more severe effects, including dehydration and malnutrition with GLP-1 receptor agonists.[3] This warrants individual assessment to balance medication benefits and risks.

COMPOUND DRUG SAFETY

GLP-1 receptor agonists are expensive medications. Some insurances do not cover anti-obesity medications at all. Pharmaceutical companies have begun to offer their FDA-approved GLP-1 receptor agonist products directly to consumers at considerable savings, about half the cost of obtaining them at the local pharmacy. This service is available to consumers on certified pharmaceutical websites.

While GLP-1 receptor agonists are only available by prescription, pharmaceutical companies will facilitate online prescriber availability. The cost is around $500 per month, which is comparable to prices on GoodRx®. Therefore, many consumers choose online non-FDA-approved compounded versions for about half the price of the consumer-direct FDA-approved medicines.

The FDA recently eliminated the shortage allowance for compounded GLP-1 receptor agonists, but compounding pharmacies now make their own brands of GLP-1 receptor agonists by adjusting dosage or adding cyanocobalamin (vitamin B_{12}). However, there must be a valid prescription from a licensed medical provider and a pharmacy with a pharmacist who are both FDA registered and credentialed to compound. Patients must be advised to steer clear of using products that come from an unidentified licensed prescriber who may not have access to their medical records, and also not to buy if they cannot identify the FDA-registered compounding pharmacy where the product is produced.

It is very important to reconcile the medication list each time patients encounter the medical establishment and ask about additional medications and supplements that may have been obtained elsewhere.

Counterfeit semaglutide has been reported in the United States. The FDA issued this statement:

> [We] recognize the substantial consumer interest in using compounded semaglutide products for weight loss. However, compounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, effectiveness, or quality. Therefore, compounded drugs should only be used to meet a patient's needs if the patient's medical needs cannot be met by an available FDA-approved drug.[4]

Jasmine Gonzalvo, PharmD, a clinical professor in the College of Pharmacy and director of the Center for Health, Equity and Innovation at Purdue University, noted:

> [R]isks can likely be minimized if patients get their prescriptions filled at state-licensed compounding pharmacies that are able to obtain the base form of semaglutide from FDA-registered facilities, ensure sterility during the compounding process, and avoid the addition of other ingredients with unknown potential for interactions.[5]

UNWANTED CHANGES IN APPEARANCE

Weight loss can result in sagging facial skin ("Ozempic face") and body skin, along with a more aged look after significant weight loss. While this may not always be prevented, focusing not on rapid weight loss but rather on adequate nutritional goals, especially proteins, plant-based antioxidants, and good hydration, is important.

Generally, one pound per week is a reasonable rate of weight loss. Sometimes, weight loss can be more rapid at first but decelerates over time. Clinicians should ensure patients have reasonable expectations about physical appearance.

DISSATISFACTION WITH RESULTS

Every patient who is treated with GLP-1 receptor agonists responds uniquely, yet they need to understand that 10% to 20% weight loss from these medications may occur over the course of treatment. A 300-pound person who settles out at 240-270 pounds may be happier with the results if they have been counselled regarding these expectations ahead of time. Some do respond more, while others respond less.

It is worth reminding patients that health benefits may begin with merely 5% to 10% weight loss. Focusing on health goals rather than scale goals may help patients understand expectations.

RISK OF OPTIC NERVE STROKE AND BLINDNESS

According to a new study by Mass General Brigham researchers, patients taking semaglutide face a greater risk of optic nerve stroke, which can cause blindness.[6] Further evidence review is warranted. There are also some post-marketing concerns about retinopathy, especially with diabetes, so patients should continue to get their annual eye exams.[7]

WEIGHT REGAIN WITH ABRUPT CESSATION

Obesity is a chronic relapsing disease, so regaining weight is common regardless of the means by which excess weight is lost. GLP-1 receptor agonists are meant for long-term use. Data confirms significant weight regain after these medications are stopped. STEP extension trials are currently underway, and the published STEP 1 trial extension concluded:

> [O]ne year after withdrawal of once weekly subcutaneous semaglutide 2.4 mg and lifestyle intervention, participants regained two-thirds of the prior weight loss, with similar changes in cardiometabolic variables. Findings confirm the chronicity of obesity and suggest ongoing treatment is required to maintain improvement in weight and health.[8]

It is very important to explain to patients prior to starting a GLP-1 receptor agonist that this is a long-term investment, possibly lifelong, so that they understand the need for ongoing surveillance, and the long-term financial investment as well.

CONCLUSION

In summary, GLP-1 receptor agonists are very effective in treating diabetes and obesity, but use of these medications comes with potential risks. Upfront discussions and ongoing communication will help patients remain clear about the opportunities this class of medications may offer.

REFERENCES

1. Montero A, Sparks G, Presiado M, Hamel L. KFF health tracking poll May 2024: the public's use and views of GLP-1 drugs. KFF. May 10, 2024. Accessed March 31, 2025. https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-may-2024-the-publics-use-and-views-of-glp-1-drugs/
2. Patterson ML, Harrsch F. A review of novel pharmacotherapeutic agents for the management of type 2 diabetes mellitus. *JLGH.* 2024;19(2):42-47.
3. Onoviran OF, Li D, Toombs Smith S, Raji MA. Effects of glucagon-like peptide 1 receptor agonists on comorbidities in older patients with diabetes mellitus. *Ther Adv Chronic Dis.* 2019;10:2040622319862691.
4. FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products. Food and Drug Administration. Updated July 26, 2024. Accessed April 30, 2025. https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded
5. Collins S. Semaglutide shortage gives rise to unauthorized products. *Pharmacy Today.* 2023;29(8):34.
6. Katz BJ, Lee MS, Lincoff NS, et al. Ophthalmic complications associated with the antidiabetic drugs semaglutide and tirzepatide. *JAMA Ophthalmol.* 2025;143(3):215-220.
7. Hathaway JT, Shah MP, Hathaway DB, et al. Risk of nonarteritic anterior ischemic optic neuropathy in patients prescribed semaglutide. *JAMA Ophthalmol.* 2024;142(8):732-739.
8. Wilding JPH, Batterham RL. Weight regain and cardiometabolic effects after withdrawal of semaglutide: the STEP 1 trial extension. *Diabetes Obes Metab.* 2022;24(8):1553-1564.

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Helping Parents Navigate the Screen-Time Dilemma

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Clinicians have recently added a new platitude to their repertoire of routine counseling: *Spend less time on devices.* Even clinicians who are not currently using DAX Copilot, Duo Mobile, and Haiku may sense the irony in this "do as I say, not as I do" advice. For those of us who care for youth, we may add an additional twist as we speak with parents: *Make your kid spend less time on devices.* We might as well be advising them to kick a hornet's nest with bare feet.

Fortunately, there is a growing body of literature on the topic. Not only is there evidence of the adverse effects of screen time on developing minds, but research suggests effective methods for parents and clinicians to help manage our children's electronics use.

It is worth noting that not all screen time is the same. Moderate use — typically up to one hour per day — of high-quality, age-appropriate educational content may benefit children between the ages of 2 and 5 years; this may be particularly true when it is co-viewed with parents. Conversely, lower quality, inappropriate, or "background" screen time, such as having the television on while playing, may negatively affect children's learning, attention, and emotional regulation.[1]

What qualifies as "high-quality content" may be different in each family, and defining this will also necessitate that parents actively moderate what their child is watching or playing. However, several organizations offer helpful online resources for both parents and clinicians (see table on page 54).

Parents may consider diverting time spent on devices toward other activities, particularly those involving both parent and child. The activity itself need not be particularly exciting or demanding — going for a walk, helping with dinner, or even just talking about their favorite characters. The key ingredient of a positive experience is affirming engagement and interaction between parent and child; this may benefit children's healthy development more than almost anything else a clinician can offer.

As children get older, the challenges also evolve, and as teens gain independence, parents may find their family members at an impasse regarding device usage. A recent editorial in *World Psychiatry* provides some suggestions, intended as "directly actionable advice, rather than general principles on healthy usage patterns."[2] While behavioral change is seldom easy, these suggestions are realistic, evidence based, and practical.

Recommendations for Adolescents

- *Out of sight, out of mind.* Devices should be put away for an hour before bedtime. Ideally, this means outside of the bedroom. Having the charging station outside of the bedroom will make for a much more restful night of sleep. Mealtimes should similarly be tech-free.
- *Use device features to control usage.* By using "Do Not Disturb" mode and the "Notifications" setting, unnecessary and distracting alerts can be disabled some of or all the time. Access to specific apps can also be limited by total daily time or by time of day. This may be particularly helpful with video or social media apps.
- *Replace rather than restrict.* Spending less time on devices means having more time for other activities, such as family activities, exercise, or sleep. Furthermore, even with device in hand, less time on passive activities, such as "the infinite scroll," can mean more time for active online engagement, socialization, and enrichment.

Recommendations for Parents

- *Agree on a plan.* The family should come up with a written plan, made with input from all sides, which should be reviewed regularly and updated accordingly. As with all behavioral plans, positive reinforcement of desired behaviors is more effective than deterrence, although potential consequences for non-adherence with a plan

should be discussed and agreed upon from the beginning.

- *Become an example.* Having device-free times and places, such as family meals and family activities, will help parents just as much as they help kids. Children pay attention to what their parents say as well as to what they do. Attempting to change a child's behavior in a way that does not reflect the parents' behavior is unlikely to succeed. Thus, parents may appreciate being reminded to be good role models.
- *Communicate often and openly.* As noted above, any family plan for reducing screen time will only succeed with buy-in from everyone in the family, so it must be borne of open discussion. The internet can be a dangerous place for a young person, with bad actors shaming and isolating a youngster from their supports. For example, an adolescent entangled in a toxic or abusive community may anticipate punishment if they are "caught" by parents. Parents must strive to be supportive, remain calm, and strike a non-judgmental tone.

Parents and clinicians may feel that any free time young people spend on devices is time wasted. Young people may feel that adults in their lives come across as naïve and out of touch regarding electronics and the larger digital landscape. The truth, as so often is the case, is probably somewhere in between.

Those of us in positions of authority can take an active role in moderating the time spent with devices and the content consumed by the young people in our care. At the same time, we should be open to understanding each child's position and experience, which — as every next generation of parents soon realizes — is starkly different from any that preceded it.

At some point conflicts may manifest regarding a child's natural desire for independence and natural need to prioritize peer relationships. Thus, we must continue to balance each child's shifting priorities with our own responsibilities to see them through their healthy development.

REFERENCES

1. Council on Communications and Media. Media and young minds. *Pediatrics.* 2016;138(5):e20162591.
2. Firth J, Solmi M, Löchner J, et al. Promoting healthy digital device usage: recommendations for youth and parents. *World Psychiatry.* 2025; 24(1):1-2.

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Helpful Online Resources to Guide Parents

Common Sense Media: Age-Based Media Reviews for Families
A nonprofit organization "dedicated to improving the lives of kids and families by providing the trustworthy information, education, and independent voice they need to thrive."
commonsensemedia.org

Fairplay
A nonprofit organization "committed to helping children thrive in an increasingly commercialized, screen-obsessed culture … dedicated to ending marketing to children."
fairplayforkids.org

American Academy of Pediatrics Center of Excellence on Social Media and Youth Mental Health
"A centralized, trusted source for evidence-based education and technical assistance to support the mental health of children and adolescents as they navigate social media."
aap.org/en/patient-care/media-and-children/center-of-excellence-on-social-media-and-youth-mental-health

NARRATIVE MEDICINE

Clinician Turned Patient: Lessons from the Heart

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When I entered my 26th year, I did not imagine that I would soon undergo open heart surgery. Yet, in November 2018, my doctor and I discovered a myxoma in my left atrium. The events leading up to, and those subsequent to, this terrifying diagnosis were trying yet ultimately eye opening. Unbeknownst to me at the time, I would meet some remarkable individuals during this journey. These individuals have taught me valuable lessons in patient care that I have tried to incorporate into my own practice.

At the time of diagnosis, I was relatively new to practice, having finished my pharmacy residency in the summer of 2017. In March 2018, I opened a new anticoagulation clinic within the Penn Medicine Lancaster General Health system, caring for about 80 patients from a family medicine outpatient practice. As a new practitioner, I was still developing relationships with my team — providers, staff, fellow pharmacists — and my patients.

ATTENTIVENESS

The solitary symptom that prompted my adventure was a periodic, non-painful "pang," or tapping, in my chest. The episodes would last only a few seconds. I underwent a myriad of lab testing over the next few weeks. By the time my primary care provider (PCP), Dr. Maria Calderon, and I discussed these results, my symptoms had become less frequent. She nevertheless ordered an echocardiogram, which revealed the tumor and led to surgery.

Later, Family Medicine and Cardiology colleagues reflected on my PCP's diligence, admitting that if in her position, they might have refrained from ordering the echocardiogram given my improved symptoms. That comment was eye opening to me. Without my PCP knowing me well, sharing the clinical decision with me, and exhausting all options, I may have unknowingly continued with this benign but nevertheless disconcerting heart abnormality.

During my admission, I battled post-operative nausea, although it improved day by day. One morning, I was taken via wheelchair to have an x-ray. The ride there and back with all its turns left me on the verge of vomiting. When I returned to the floor, my nurses, Tim and Clinton, took one look at my usually cheery face, now a miserable sheet of white, and followed me into my room. All I could muster to say was, "I feel sick," and Tim was off in a flash for ondansetron, an anti-emetic.

During my admission, many staff members encouraged me to ambulate as much as possible. Several times per day, I walked around the unit. Each time, I would go a little farther, and eventually I was able to complete several laps. I was so pleased with myself at every new distance, feeling victory in recovery. I didn't share this with Tim and Clinton. Still, they celebrated with me at *every* milestone — an approving nod, a smile, a brief "great job." Their validation and support encouraged me even more.

Since this experience, I have found myself paying more attention to and acting on subtleties such as nonverbal communication and changes in tone or demeanor. For example, if I sense hesitation with a proposed medical plan, I share my observation with the patient and get their thoughts on the matter. With a simple question, I have been able to identify and remove more barriers to care and engage in greater shared clinical decision-making than if I had relied on the patient speaking up on their own.

Similarly, I have come to applaud my patients' achievements more often than I had previously. Really, who am I to say what is a "little" or "big" accomplishment when it comes to their health? Now, I celebrate it all with them, and I have experienced a better connection with my patients for it.

CREATIVITY

During my admission, I had an IV line that needed to be flushed with saline every few hours. When the lines were being flushed, I experienced a smell of rotten sea water, which exacerbated my nausea. I shared this with Tim, and though sympathetic, he didn't know how to prevent this reaction. That evening, however, he shared an idea with me — I was to eat a spoonful of applesauce while he flushed the line to mask what I otherwise perceived to be odorous. It worked! I smelled and tasted lightly salted applesauce and, better still, did not experience nausea. From that point forward, I ate applesauce each time my nursing staff flushed my line.

While in cardiac rehab, there was a prescribed maximum heart rate permitted during exercises. This was calculated based on my resting heart rate, which had been measured during my initial visit. Yet, at that time, I was treated with metoprolol, a medicine that slowed my heart rate and was soon thereafter discontinued. In truth, I have been a very healthy, active individual all my life, and my physical ability quickly surpassed the level of exercise permitted. As a patient, this was a significant hindrance and annoyance.

At one point, I was ordered a Carnation Ambulatory Monitor (CAM) to watch my heart rate for a week. The cardiac rehab nurse, Lisa, had an idea. While I was wearing the CAM, she would remove the heart rate limit to allow a "real world" test of my heart rate and cardiac response while working out. She obtained approval from my cardiologist, and we did just that. I felt wonderful, challenged, and healthy.

While many patient encounters and treatment plans are straightforward, not all situations fit "the norm." After returning to practice, I have tried to pause in atypical situations and consider creative alternatives.

THE "WHY"

As a clinician, the rationale for medical decisions have become common knowledge through my own repeated use and exposure. It can be easy to fall into the rut of simply advising the patient and not explaining *why* I have given specific advice.

During my journey, I came to realize how important explanations of reasoning can be when trying to motivate a patient. For example, on post-op day one, I was still too weak and in too much pain to move on my own. The nursing staff had to turn me from one side to the next every few hours to encourage blood circulation and reduce the risk of bed sores. Because I had been taught the reason for this tortuous experience, I did not complain or resist.

I was also instructed to perform spirometry every two hours while admitted and regularly upon my return home after surgery to help regain breathing capacity and reduce the risk of developing pneumonia. Upon being told the latter, I was determined not to miss a single spirometry. Without that explanation, I would have likely been less diligent in my practice, opting to rest or nap.

Further, I was told to cough, whenever I felt the urge, using the "heart pillow" (see Fig. 1). Coughing would help to clear out the lungs and prevent pneumonia, while hugging the pillow applied pressure to the incision site to prevent tearing. Coughing was excruciating with chest tubes, lines, and freshly closed wounds. The pillow's pressure to the surgical sites only added further discomfort. Still, knowing the "why" kept me determined to not suppress that tickle in my throat.

Fig. 1. The author's "heart pillow," given to her and other heart surgery patients at the time of her procedure to aid in recovery efforts. *Photo courtesy of the author.*

EMPATHY

Empathy is another essential component to good patient care. It was not until I was on the receiving end of such provider empathy that I fully realized its significance and impact.

As I waited in the exam room for my first meeting with cardiothoracic surgeon Dr. Mark Epler, I was terrified. I had a *tumor inside my heart!* While my cardiologist had said myxomas are typically benign, the remote possibility of the tumor being cancerous plagued me. Enter Dr. Epler. He sat down and looked me directly in the eye. His first words were, "You do not have cancer. I repeat, you do *not* have cancer." I felt his words pierce the dark shroud that had descended over my mind and life, allowing rays of light and hope to filter back into my thoughts.

While preparing for hospital discharge, the nurse practitioner, Ashley, was given the task of removing my two cardiac pacer wires. The first came out very easily; the second did not. I asked if she could tug harder. She replied that she should not, as she feared she could incise the heart tissue and send me back to the operating room.

Yet, I did not want this metallic keepsake, so I asked if she would gently try again. She agreed to try, although she didn't seem hopeful it would release. To my delight, the wire gave with her soft tug. Thanks to her empathy and consideration, the only souvenirs I live with are a few faded scars.

SUMMARY

From lectures and literature, we learn the facts and data. We learn that metoprolol can cause fatigue and tramadol can cause central nervous system depression. The diagnostic process can take time and extensive testing.

When we hear about the experiences from our patients, we add anecdotal information to our body of knowledge. We hear how tired that dose increase of metoprolol made one patient. We listen to another describe a lack of mental clarity while taking tramadol. We see the tears brimming in a third patient's eyes in fear of what the test results may reveal. However, it brings another level of understanding to each of us when we become patients.

While I was prescribed the lowest dose of metoprolol, this resulted in fatigue and lack of motivation so that I felt as if I had pulled an all-nighter without coffee. Tramadol clouded my mind such that I could not focus to even read a novel; I could engage in nothing more than mindless movie marathons.

I sobbed in my car after learning my symptoms were due to a mass inside my heart, but I had not yet met with the cardiologist to learn the diagnosis. Like many, I feared that "mass" meant "cancer." All that diagnosis suggests — including chemotherapy, surgery, chronic pain, and more — flashed before my eyes.

This formative personal experience has been one I've revisited often, and the lessons I have taken have enabled me to form stronger relationships with my patients, based on close attention to detail, careful communication, and above all, empathy.

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PHOTO QUIZ FROM URGENT CARE

Ingestion of Dental Implant

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CASE HISTORY

A 55-year-old male presents with a complaint of left-sided flank pain that started four days prior but is worsening on the day of presentation. He accidentally swallowed a dental implant and its filling pin two weeks prior while eating dinner. He tried vomiting the dental implant back up not long after swallowing it without success. He has been checking his stools but has not noticed any foreign bodies so far.

He describes the flank pain as a dull throbbing ache without radiation. He denies any vomiting, abdominal pain, constipation, diarrhea, hematochezia, or melena.

Upon physical exam, his abdomen is flat, soft, and nontender without rigidity or guarding. His bowel sounds are normal, and he has no costovertebral angle (CVA) tenderness.

QUESTIONS

1. Which imaging modalities can be used to identify this foreign body?
2. What is the next step after identifying the foreign body on imaging?
3. Is this an emergent or non-emergent situation?
4. What complications can occur if this foreign body does not pass through?

ANSWERS

1. This type of foreign body can be seen both on X-ray and computed tomography (CT). Generally, posteroanterior/lateral chest X-rays and abdominal X-rays (see Fig. 1) are utilized to determine the location of a foreign body.
2. The next step after identifying where the foreign body is on imaging is often a surgical consult. Usually, the foreign body passes asymptomatically, but it is prudent to collaborate with the surgical team to determine if and when surgical management is necessary versus when conservative management can be utilized.
3. Whether the situation is emergent or non-emergent depends on a few factors: length of time since ingestion, whether there is movement through the intestines, and the presence of pain or other symptoms. If the patient is asymptomatic and weekly X-rays demonstrate the foreign body is moving through the intestine appropriately, this may not be an emergency — that is, the foreign body is likely to pass without complications or intervention. If the patient presents with an ingested foreign body that is causing symptoms of pain, vomiting, obstruction, bleeding, etc., or if the foreign body has not passed through after two to three weeks, emergency interventions may be warranted.
4. Intestinal perforation, bleeding, sepsis, compression necrosis, or obstruction are the most likely complications of an ingested foreign body, especially if the object is larger than 5 cm in diameter or if the object has a sharp edge.

DISCUSSION

Ingestion of a foreign body can occur in adults, such as in this patient who swallowed a dental object while eating. It may also occur during dental implantation or due to impairment as a result of alcoholism. Predisposition may be due to strictures, malignancy, or esophageal rings.[1] Clinicians should consider that ingestion of a foreign body may be due to secondary objectives such as to avoid incarceration or as a suicidal attempt.[2]

The most ingested foreign bodies in adults are fish bones, other bones, and dental devices.[1] Fortunately, most foreign bodies, especially dental implants, can be seen on X-ray, which allows for outpatient evaluation and management. However, objects such as thin bones, plastic, glass, and wood may not be readily seen.[3]

CT scan is also utilized for clearer evaluation of the location of the foreign body as well as assessing for complications.[3] As long as the patient is asymptomatic, weekly X-rays can be performed in the outpatient

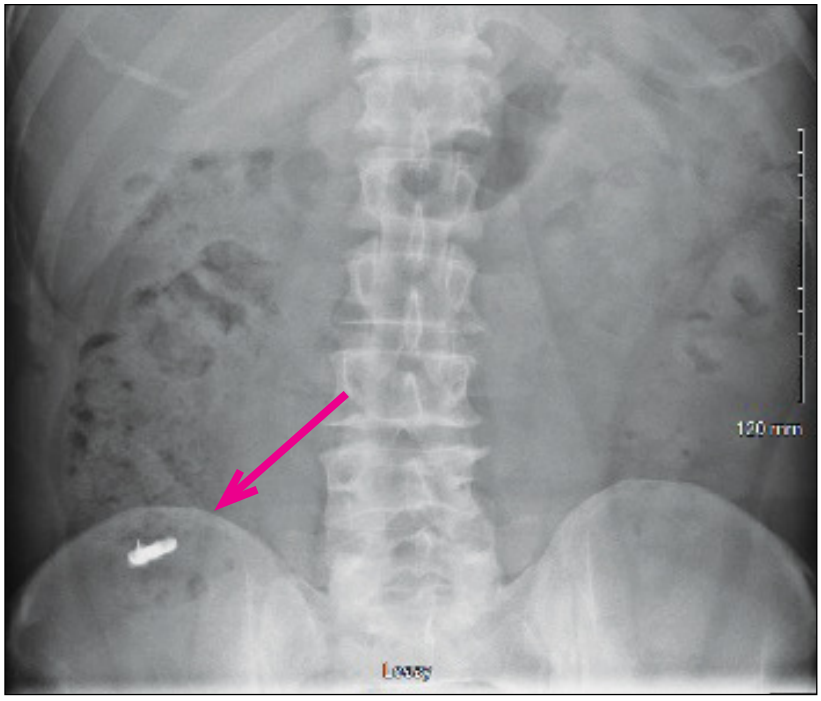

Fig. 1. Anteroposterior abdominal X-ray of 2.2-cm metallic foreign body overlying the right lower quadrant, likely in proximal ascending colon.

setting to evaluate the progress of the foreign body through the intestinal tract.[4]

Ingested foreign bodies can cause serious complications, however perforation and sepsis are rare. The risk of injury does increase with objects that are greater than 5 cm in length or with sharp, pointed shapes. Therefore, characteristics of the foreign body should also be considered along with symptoms.[4]

What is most important is early diagnosis for successful management; this reduces the risk and severity of complications. Ingested foreign bodies can often be excreted within a few days to a few weeks without intervention.[5]

The most common places for a foreign body to get stuck are in the lower esophageal sphincter as well as in the ileocecal region, appendix, sigmoid colon, or rectum. Objects larger than 5 cm in diameter should be removed emergently, regardless of length of time or whether the patient is symptomatic or asymptomatic, as it will not be able to pass the pylorus or the ileocecal valve and will cause obstruction.[2] Other emergent concerns include abdominal pain, bloody stools, dysphagia, vomiting, sore throat, cyanosis, and coughing.[6]

Removal often requires endoscopy, colonoscopy, or enteroscopy.[3] Treatment should not be delayed if signs of complications are present. In this case, the patient was treated with outpatient elective colonoscopy since the dental implant had not moved from the cecum after three weeks from ingestion.

The implant was successfully removed via colonoscopy without complications. Follow-up one month later showed that the patient was doing well and not having any residual symptoms or complications from either the foreign body or removal.

REFERENCES

1. Ambe P, Weber SA, Schauer M, Knoefel WT. Swallowed foreign bodies in adults. *Dtsch Arztebl Int.* 2012;109(50):869-875.
2. Negrete JR, Carrillo MD, Molina GA, Ayala O AV, Flores D, Castillo D. Do not open wide; accidentally swallowed dental mold causing bowel obstruction. A case report. *J Surg Case Rep.* 2022;2022(9);rjac384.
3. Fung BM, Sweetser S, Wong Kee Song LM, Tabibian JH. Foreign object ingestion and esophageal food impaction: an update and review on endoscopic management. *World J Gastrointest Endosc.* 2019;11(3):174-192.
4. Kigozi KC, Agirembabazi N, Kanyike AM, etc. Retention of a swallowed dental tool in the small bowel: unusual lodgment and prolonged conservative management. *Case Rep Dent.* 2024;2024:5586308.
5. Jain A, Baliga SD. Accidental implant screwdriver ingestion: a rare complication during implant placement. *J Dent (Tehran).* 2014;11(6):711-714.
6. Shin Y, Hong S, Kim R, Jee YJ. Strategies for dental aspiration and ingestion accidents that can lead to serious complications: a report of three cases and a review of articles. *J Korean Assoc Oral Maxillofac Surg.* 2022;48(5):318-325.

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SPOTLIGHT ON CLINICAL RESEARCH

The Role of the IRB and How to Submit Studies for Review

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Editor's note: This is the 23rd in a series of articles from the Penn Medicine Lancaster General Health Research Institute that describes ongoing research studies. Members of the LG Health staff who are conducting research and wish to have their studies described here are encouraged to contact the JLGH editorial offices.

Submitting a research study to an Institutional Review Board (IRB) can be a daunting process whether you are a first-time researcher or a seasoned investigator. For many, determining what to do, when to do it, and who to reach out to with questions can cause frustrating delays in getting a research study started. This spotlight is meant to demystify the role of the IRB and outline how to submit studies for IRB review.

The Lancaster General Hospital (LGH) IRB officially merged with the University of Pennsylvania's IRB on July 1, 2024. This merger provides expanded access to Penn's resources and expertise, but LGH researchers may now need to navigate a larger, centralized system. References to the IRB in this spotlight refer to the University of Pennsylvania (Penn) IRB.

What is the IRB?

An Institutional Review Board is a group that has been formally designated to review and monitor research involving human subjects. It is tasked with reviewing, monitoring, and approving research studies. At its core, the IRB ensures that the rights, safety, and welfare of research participants are protected. The IRB has authority to:

- Approve a study.
- Require modifications to secure approval.
- Disapprove research that does not meet ethical or regulatory standards.

The IRB may also determine whether a proposal constitutes human subjects research.

The IRB has multiple boards that review research studies across the University of Pennsylvania and the University of Pennsylvania Health System. Studies are assigned to boards based on specialty, disease state, or availability of reviewers.

Must I always submit my project to the IRB?

Any research study involving human subjects requires review by the IRB. The study must receive IRB approval before it can begin.

The Penn IRB follows the Department of Health & Human Services (HHS) Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) definitions of *research* and *human subjects* to determine whether a project constitutes human subjects research. According to the HHS, *research* is defined as "a systematic investigation, including research development, and testing and evaluation, designed to develop or contribute to generalizable knowledge." A *human subject* is "a living individual about whom an investigator conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; OR
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Please note, researchers cannot make their own determination regarding whether research with existing private data or specimens is human subjects research. If you are unsure whether your study constitutes human research, you can:

1. *Contact the IRB* via telephone (215-573-2540) or email (PROVOST-IRB@pobox.upenn.edu). They also host office hours that anyone can join. To find upcoming IRB office hours, visit zcal.co/pennirb/officehrs.
2. *Submit a "Human Subjects Research Determination" form.* This form can be found on the Penn IRB website and can be submitted via email or via the Penn IRB system.

If the project may be quality or performance improvement, you can review the Quality/Performance Improvement (QI/PI) Guidance on the IRB website.

Visit Penn IRB online at **irb.upenn.edu**

How do I know what level of review to select in the IRB application?

Research studies require review by a convened meeting of the IRB unless the research falls into an Exempt or Expedited review category (see Table 1). Final review category and submission requirements will be determined by the IRB.

Table 1. IRB Review Categories

Exempt	Research involves *no more than minimal risk* to participants. Research procedures must fit within at least one exemption category. The Penn IRB system has eight exempt categories to choose from.
Expedited	Research involves *no more than minimal risk* and doesn't meet criteria for exempt status. The Penn IRB system has seven expedited categories to choose from.
Full Board Review	Research does *not meet exempt or expedited status;* it must be reviewed at a monthly meeting of the full IRB.

NOTE: If you select Exempt or Expedited for a study that actually requires full board review, the IRB reviewer will send the submission back to you with additional questions to answer within the application. If you are unsure which option to select, you should select "full board review." Your study will be routed by an IRB analyst for the appropriate level of review.

What should I include in the IRB application?

The application will walk you through what information is required by the IRB for the study being submitted. However, it's important to have all study documents finalized before submitting to the IRB. Study documents most commonly include:

- *Protocol:* A detailed plan of the study that includes the objective, methodology, data collection processes, analysis plans, etc.
- *Informed consent form:* A document outlining the details of the research study including the purpose, procedures, risks, benefits, and alternatives to participation (if informed consent is being obtained).
- *Investigators' brochure or drug inserts* (if the study involves a drug): Documents detailing the drug's characteristics.
- *Recruitment materials:* Flyers, brochures, posters, and other documents used for participant recruitment.
- *Data collection tool(s):* Blank versions of case report forms, questionnaires, or surveys.
- *Regulatory documents:* Approval letters, such as Investigation New Drug (IND), Investigational Device Exemption (IDE), FDA correspondence, or letters of support from departments participating in the study.

NOTE: All participant-facing materials (documents that study participants will see) must be submitted to the IRB for review and approval.

The Penn IRB strongly recommends including a cover letter with all submissions (initial or subsequent). The cover letter should provide additional information that may help the reviewer complete their review of the study and explain anything not covered in the application. It should also provide a documents list that outlines all the documents submitted with the application.

How long will it take for the study to be reviewed by the IRB?

The turnaround time depends on the type of study and type of submission being reviewed. See Table 2 for goals Penn IRB staff members set for turnaround times for review categories.

Table 2. Goals for IRB Staff Processing

Submission Type	Reviewed Within	Letter Posted
For studies that are Exempt or Expedited		
Initial Review	10 business days	Within 2 business days of Director or IRB Chair approval
Response	2 business days	
Modifications	3 business days	
For studies that require Convened (Full Board) Review		
Initial and Modification Reviews	Within ~30 days from time of submission	Within 3 business days of the meeting date
Continuing Reviews	On the day of or prior to expiration	On the day of expiration (if expiring the day of the meeting) or within 3 business days of the meeting date

What happens after submission?

A determination letter for the submission will be provided once it is reviewed by the IRB. You will receive an email when the determination letter is available. If the determination letter indicates that the study is approved, study activities may begin. If you are an LG Health researcher and would like support submitting to/interacting with the Penn IRB office or other regulatory requirements for research, please contact Heather Madara at the email address below.

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TOP TIPS FROM FAMILY PRACTICE

Diabetes Care, Stroke Risk, Migraine Guidelines

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UPDATED DIABETES STANDARDS OF CARE

The American Diabetes Association (ADA) has offered new guidance on broader use of continuous glucose monitoring (CGM), use of glucagon-like peptide-1 receptor agonists (GLP-1 RAs) beyond weight loss, management of metabolic dysfunction-associated fatty liver disease, plus a strong endorsement for drinking water. Among the newly published standards:

- Clinicians should consider use of CGM devices in adults with type 2 diabetes (T2D) who don't use insulin. Medicare and many other payers currently only cover CGM for people who use insulin or are otherwise at risk for hypoglycemia. However, some CGMs are now available over-the-counter.
- In the event of medication shortage, the ADA advises substituting a different GLP-1 RA if possible.
- Recommendations were revised to explicitly advise on choice of pharmacotherapy for individuals with T2D, based on new data about patients with established or high risk for atherosclerotic cardiovascular disease, heart failure with preserved ejection fraction, and chronic kidney disease.
- The ADA adopted new nomenclature: nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH) are now metabolic dysfunction-associated fatty liver disease (MAFLD) and metabolic dysfunction-associated steatohepatitis (MASH). Resmetirom is a thyroid hormone receptor-beta agonist that shows promise in reducing progression to fibrosis.
- The ADA, in collaboration with the Obesity Society, advises that patients continue weight therapy beyond achieving weight-loss goals. Discontinuing weight-loss therapies is associated with weight regain and increased cardiovascular risk.
- Antibody-based screening for presymptomatic type 1 diabetes (T1D) should be considered in family members with T1D and others who may be at risk. Individuals with these autoantibodies should be provided with or referred for counseling and prevention. Specialized centers may provide further evaluation and/or access to clinical trials and approved therapies.
- People with diabetes should be screened for adjustment disorder, depression, anxiety, hypoglycemia, and disordered eating behaviors. People using insulin or sulfonylureas may be afraid of hypoglycemia, but feeling overwhelmed about the disorder, sometimes called "diabetes distress," can happen to anyone with diabetes. Caregivers and family members should be screened as well. The Centers for Disease Control and Prevention provides some guidance about how to help individuals cope.[1]

← Scan to access "10 Tips for Coping with Diabetes Distress" from the CDC

- In the nutrition section, an important new recommendation strongly advises drinking water instead of nutritive or nonnutritive-sweetened beverages. Nonnutritive sweeteners are preferred over other sweeteners, in moderation and for a brief duration, but water is always best.

REGULAR FLOSSING REDUCES ISCHEMIC STROKE RISK

Regular dental flossing is linked to a lower risk of ischemic stroke and atrial fibrillation (AF), according to new research presented at the International Stroke Conference in February 2025.[2] The reduced risk is primarily the result of reduced systemic inflammation and is independent of oral care, such as regular brushing and visits to the dentist.

This was studied in 6,278 participants who had no history of stroke or AF (mean age of 62 years). Participants were categorized as flossers (n = 4,092) and nonflossers (n = 2,186). Notably, more women flossed than did not floss; more men were nonflossers than were flossers.

Flossers had fewer relevant cardiovascular risk factors. For example, 31.5% of flossers had hypertension and 11.7% had diabetes versus 36.3% and 16.1%, respectively, of the nonflossers. Flossers also had significantly higher high-density lipoprotein levels and significantly lower levels of periodontal and dental caries.[3]

Participants had regular follow-ups for 25 years. During that time, 434 strokes were identified. Of those, 146 were thrombotic, 102 were cardioembolic, and 95 were lacunar subtypes. The investigators found that flossing was associated with a decreased risk for ischemic stroke (adjusted hazard ratio [HR], 0.79; 95% CI, 0.64-0.97), cardioembolic stroke subtype (adjusted HR, 0.56; 95 CI, 0.36-0.86), and AF (adjusted HR, 0.88; 95% CI, 0.78-1.00).

The analysis suggested that the stroke risk reduction was primarily driven by fewer cardioembolic strokes which is possibly linked to a reduced rate of atrial fibrillation. Flossing did not seem to reduce the risk of thrombotic stroke (adjusted HR, 0.91; 95% CI, 0.63-1.32) or lacunar stroke (adjusted HR, 1.14; 95% CI, 0.54-1.88). There was a significant dose-effect between the frequency of flossing and the incidence of ischemic stroke.

NEW MIGRAINE GUIDELINES

The American College of Physicians (ACP) indicates there is no clinical advantage to choosing newer, expensive medications to prevent migraines. Rather, the ACP recommends that to prevent episodic migraines in nonpregnant adults, monotherapy be used.[4] This may constitute use of a beta-adrenergic blocker (metoprolol or propranolol), the antiseizure medication valproate, the serotonin and norepinephrine reuptake inhibitor venlafaxine, or the tricyclic antidepressant amitriptyline.

If patients do not respond to or tolerate these, ACP recommends a monotherapy with a calcitonin gene-related peptide (CGRP) antagonist (atogepant or rimegepant) or a CGRP monoclonal antibody (eptinezumab, erenumab, fremanezumab, or galcanezumab). If patients still do not respond to or tolerate treatment, the guidelines recommend monotherapy with the antiseizure medication topiramate.

The guidelines stress the importance of a patient's adherence to a pharmacologic treatment since improvement may occur gradually, with effects manifesting after the first few weeks of treatment.

Newer, more expensive medications, such as ubrogepant ($1,045/month) and dihydroergotamine mesylate nasal spray ($269/month) — the lowest available costs reported by GoodRx® — were not mentioned in the guidelines.

Migraine, characterized by recurrent episodes of moderate-to-severe intensity headache lasting 4 to 72 hours, is the second leading cause of global disability in adults and the top cause in females aged 15-49 years. Approximately 16% of people in the United States have migraine, and migraines account for about 4 million emergency department visits and more than 4.5 million office visits per year. The condition creates a substantial economic burden of over $78 billion annually in medical expenses.

ACP reports that their analysis did not demonstrate any clinical difference when comparing these treatments, therefore investigators looked at the economics of therapy. Initial recommended treatments — metoprolol ($123), propranolol ($393), valproate ($274), venlafaxine ($378), and amitriptyline ($67) — had substantially lower annual mean costs.

As a result, the ACP Clinical Guidelines Committee suggests that clinicians and patients try a β-blocker (metoprolol or propranolol), the antiseizure medication valproate, the serotonin-norepinephrine reuptake inhibitor venlafaxine, or the tricyclic antidepressant amitriptyline to prevent episodic migraine headache in nonpregnant adults before moving to a CGRP-mAb or a CGRP antagonist-gepant.

Choosing Wisely

Originally published in the Summer 2015 issue of JLGH *in conjunction with the American Board of Internal Medicine's now-complete Choosing Wisely campaign, this edited reprint is offered to remind physicians of the importance of talking with patients about what tests, treatments, and procedures are needed — and which ones are not.*

RECOMMENDATIONS FROM THE INFECTIOUS DISEASES SOCIETY OF AMERICA

❶ **Asymptomatic bacteriuria (ASB) should not be treated with antibiotics.** ASB, the asymptomatic presence of a significant number of bacteria in the urine, is a major contributor to antibiotic overuse. Antibiotics are appropriate for ASB in pregnant patients, patients undergoing prostate or other invasive urologic surgery, and kidney or pancreas transplant patients in the first year after receiving their transplant. Otherwise, antibiotics for ASB are not beneficial and do not improve morbidity or mortality. Not only is overtreatment of ASB costly, but it can lead to *C-difficile* infection and resistant pathogens.[5]

❷ **Stasis dermatitis of the lower extremities should not be treated with antibiotics.** Unfortunately, stasis dermatitis is sometimes misdiagnosed and antibiotics are used, but they do not improve healing rates for stasis dermatitis.[6] Proper treatment consists of leg elevation and compression.

❸ **In the absence of diarrhea, do not test for *Clostridium difficile*.** Only perform this test on unformed diarrheal stool, unless this organism is suspected to be causing ileus. If there is no diarrhea, the presence of *C-difficile* indicates a carrier state that should not be treated or tested for.

❹ **Do not give prophylactic antibiotics for mitral valve prolapse.** Prophylaxis is no longer recommended in patients with mitral valve prolapse for the prevention of infective endocarditis. The risk exceeds any potential benefit. Antibiotics increase resistant strains and perhaps the occurrence of *C-difficile*-associated colitis.[7]

GERIATRIC CARE PRIORITIES

Comprehensive geriatric assessment (CGA) is a way to consider the medical, psychosocial, cognitive, physical, and functional needs of older adults. A rapid assessment, known as the "Geriatric 5 Ms," can be practical and efficient for physicians to use in time-constrained settings.[8] The 5Ms are:

1. Mind. Numerous tests are available to assess cognitive function. A single test cannot validate a diagnosis, but it can indicate whether a patient deserves further evaluation. The Mini-Cog test is a quick screening tool for dementia that, when used correctly, has 76% sensitivity and 89% specificity. The test consists of having the patient repeat and remember three unrelated words, draw a clock, and remember the initial three words. It may be easily performed in less than five minutes; the Mini-Mental State Examination may take twice as long.

Depression and delirium can mimic dementia and should also be considered. Depression is common in older adults and may represent an exacerbation of a previously diagnosed mood disorder or a newly developed condition. The Patient Health Questionnaire-2 Screening Tool has nearly 100% sensitivity for detecting depression in noninstitutionalized older adults.

2. Mobility. The risk of falling contributes to the degree of mobility impairment. The STEADI (Stopping Elderly Accidents, Deaths, and Injuries) test helps assess fall risks in older adults using a three-question survey:

1. Have you fallen in the past year?
2. Do you feel unsteady when standing or walking?
3. Are you afraid of falling?

A single "yes" response indicates a positive test result and warrants further evaluation. Several functional tests are available, but two are particularly quick and easy to perform: the Timed Up and Go (TUG) Test and the 4-Step Balance Test. The TUG Test involves asking the patient to stand up from a chair, walk three meters, turn around, return to the chair, and sit down. A recorded time of more than 12 seconds is associated with an increased fall risk.

3. Medications. Various factors elevate the risk for adverse drug events from polypharmacy, including advanced age, female sex, cognitive impairment, multiple prescribers, low body weight, creatinine clearance <50 mL/min, frailty, limited medical knowledge, and concomitant use of nine or more medications.

Deprescribing plays a critical role in optimizing polypharmacy management. This involves reducing the dose of a medication, tapering it off, discontinuing it, or switching to a safer alternative when the risks outweigh the benefits. Family physicians should allocate time during visits to review and reconcile patients' medications.

4. What Matters Most. This step begins with a personalized patient assessment to align medical decisions with individual care preferences, goals, and meaningful health outcomes. Shared decision-making between the patient and the physician should guide diagnostic tests and treatment options, ensuring that indications, benefits, risks, and burdens are carefully considered.

Advance care planning is an essential component of this discussion, helping patients express their values and preferences for future medical care.

5. Multicomplexity. This encompasses both the care challenges posed by multiple chronic conditions (multimorbidity) and the broader biopsychosocial complexities affecting older adults. In this context, caregiving plays a fundamental role in supporting patients in daily activities. At this stage, the role of a clinician extends to supporting caregivers, offering guidance and assistance as they navigate the challenges of providing care for their loved ones.

REFERENCES

1. 10 Tips for Coping with Diabetes Distress. Centers for Disease Control and Prevention. May 15, 2024. Accessed April 28, 2025. https://www.cdc.gov/diabetes/articles/10-tips-coping-diabetes-distress.html
2. Williamson L. Flossing may reduce risk for stroke and irregular heart rhythm. American Heart Association. January 30, 2025. Accessed March 20, 2025. https://www.heart.org/en/news/2025/01/30/flossing-may-reduce-risk-for-stroke-and-irregular-heart-rhythm
3. Anderson P. Regular flossing tied to reduced ischemic stroke risk. Medscape. February 5, 2025. Accessed March 5, 2025. https://www.medscape.com/viewarticle/regular-flossing-tied-reduced-ischemic-stroke-risk-2025a10002t7
4. Qaseem A, Cooney TG, Etxeandia-Ikobaltzeta I, et al. Prevention of episodic migraine headache using pharmacologic treatments in outpatient settings: a clinical guideline from the American College of Physicians. *Ann Intern Med.* February 4, 2025. Accessed March 20, 2025. https://www.acpjournals.org/doi/10.7326/ANNALS-24-01052
5. Trautner BW, Kelly PA, Petersen N, et al. A hospital-site controlled intervention using audit and feedback to implement guidelines concerning inappropriate treatment of catheter-associated asymptomatic bacteriuria. *Implement Sci.* 2011;6:41.
6. Stevens DL, Bisno AL, Chambers HF, et al. Practice guidelines for the diagnosis and management of skin and soft tissue infections: 2014 update by the Infectious Diseases Society of America. *Clin Infect Dis.* 2014;59(2):147-159.
7. Gopalakrishnan PP, Shukla SK, Tak T. Infective endocarditis: rationale for revised guidelines for antibiotic prophylaxis. *Clin Med Res.* 2009;7(3):63-68.
8. Sohn BC, Tung EE, Takahashi PY, Verdoorn BP. Clinician's guide to geriatric assessment. *Mayo Clin Proc.* 2024;99(11):1773-1784.

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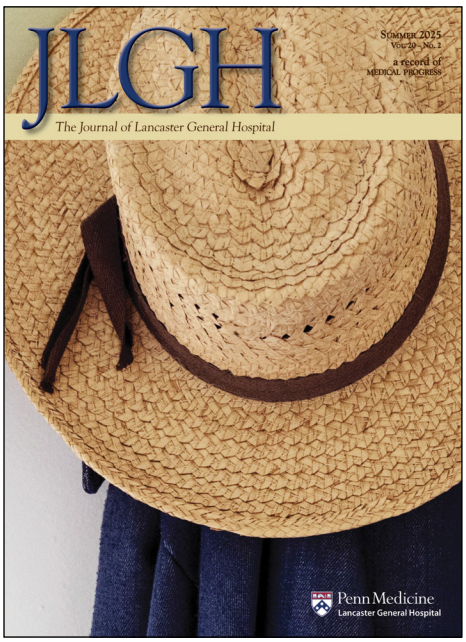

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See page 46 of this issue for part 2 of "Amish Home Remedies and the Research Surrounding Them."

INTERESTED IN WRITING FOR *JLGH*?

The following is a summary of the general guidelines for submitting an article to *The Journal of Lancaster General Hospital*. Details are located online at JLGH.org.

- Scientific manuscripts are typically between 2,500-4,500 words. Perspective articles are usually shorter, and photo quizzes average about 725 words plus illustrations.
- Medical articles should report research, introduce new diagnostic or therapeutic modalities, describe innovations in health care delivery, or review complex or controversial clinical issues in patient care.
- Reports of research involving human subjects must include a statement that the subjects gave informed consent to participate in the study and that the study has been approved by the Institutional Review Board (IRB).
- Patient confidentiality must be protected according to the U.S. Health Insurance Portability and Accountability Act (HIPAA).
- The Journal of Lancaster General Hospital *does not allow chatbot tools such as ChatGPT to be listed as authors.* JLGH *editors warn authors that the use of these tools poses a risk for plagiarism with inappropriate use of citations, and we require that use of such tools be disclosed.*

Please contact the managing editor, Maria M. Boyer, via email at Maria.Boyer@pennmedicine.upenn.edu to discuss submitting an article or for further information.

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Lancaster General Hospital

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EARN CME CREDIT

American Medical Association Category 2 activities consist of self-directed learning or courses that have not been through a formal approval process. According to the Pennsylvania State Board of Medicine, this includes "learning experiences that have improved the care [physicians] provide their patients." Reading authoritative medical literature – like medical journals – is one such activity.

For Pennsylvania physicians, more information and the Pennsylvania Board of Medicine CME Reporting Form are from the Pennsylvania Department of State. *For advanced practice providers,* more information is available from credentialing organizations.

Physicians can also log credit and advanced practice providers can access transcripts through their eeds accounts online.

← Scan to log in to your eeds account.

← Scan for additional information and links to individual reporting instructions and forms.

In-Person Only — Mandated Training for Act 31

Recognizing and Responding to Children at Risk: Suspected Child Abuse & Neglect Education for Hospital Staff
September 16, 6:00-8:00 p.m.

This in-person, live event will be presented by Mary Theresa Baker, MD, board certified in child abuse pediatrics, and Robin M. Boyer, MSW, director of intake services at Lancaster County Children & Youth. Space is limited.

Registration will open July 7. Registration deadline is September 9. License information is required for registration. Only individuals registered in eeds prior to the training are eligible for attendance/credit. Per the state-approved education provider, attendees must attend the full two hours to receive credit. Those who arrive late or depart early will not receive credit. LG Health is not a state-approved provider of this education and is not allowed to record the session.

Upcoming CME Offerings at LG Health

Department of Medicine Grand Rounds
June 4, August 6 — 12:00 noon-1:00 p.m.

Pediatric Grand Rounds
August 12, September 9 — 7:00-8:00 a.m.

The CME Department at LG Health offers a number of Enduring Materials online, including Department of Medicine Grand Rounds, Diversity, Equity & Inclusion Lecture Series, and more.

For the most up-to-date offerings and information, contact the LG Health Continuing Education Department.