Family Doctor

A Journal of the New York State Academy of Family Physicians

New York State Academy of Family Physicians

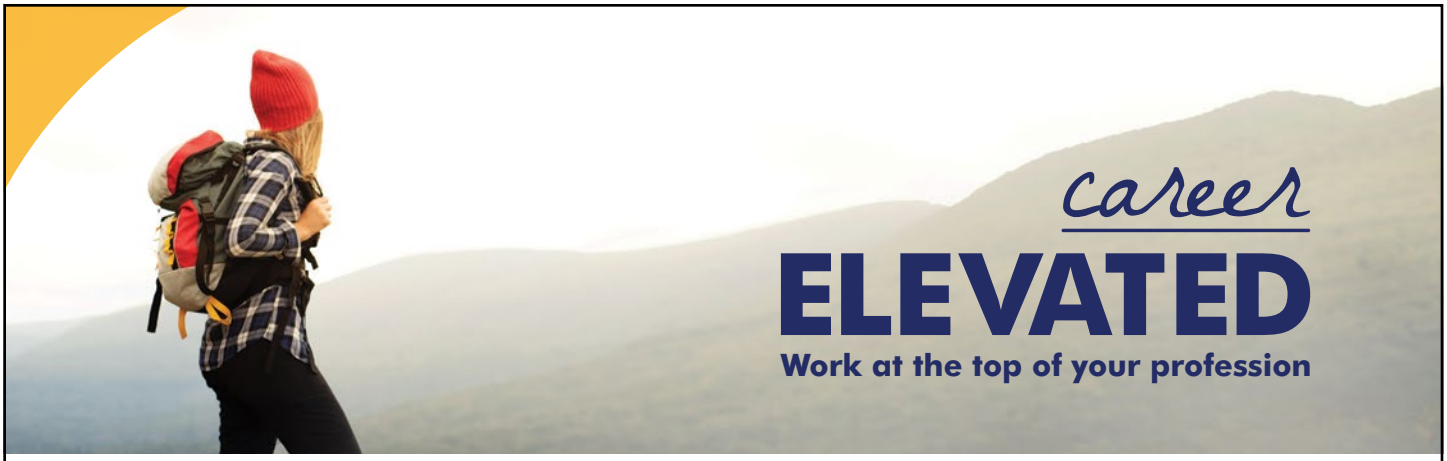
Fall 2022

Volume eleven, Number two

Focus:

Vaccination and Immunization

FEATURE ARTICLES:



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Antoinetta M. Backus, CPRP, Recruitment Manager
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16% DAILY VALUE

VITAMIN D

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15% DAILY VALUE

PHOSPHORUS

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15% DAILY VALUE

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NIACIN

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15% DAILY VALUE

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ZINC

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10% DAILY VALUE

IODINE

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*Source: USDA FoodData Central. FDA's Daily Value (DV) for potassium of 4700 mg is based on a 2005 DRI recommendation. In 2019, NASEM updated the DRI to 3400 mg. Based on the 2019 DRI, a serving of milk provides 10% of the DRI. FDA rule-making is needed to update this value for the purpose of food labeling.

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New York State Academy of Family Physicians
16 Sage Estate, Suite 202
Albany, New York 12204
www.nysafp.org
Phone: 518-489-8945
Fax: 518-888-7648

Letters to the Editor, comments or articles can be submitted by mail, fax or email to journaleditor@nysafp.org

Editor: Penny Ruhm, MS

Articles

Departments

Index of Advertisers

COVID-19 Vaccine *PEARLS* for Special Populations

Maternity Care

- Pregnant and recently pregnant people are at an increased risk for severe illness from COVID-19.
- Pregnant people with COVID-19 are at increased risk of preterm birth and might be at increased risk of other adverse pregnancy outcomes.
- Safety of mRNA COVID-19 vaccines in pregnancy is well documented. These vaccines do not increase risks for miscarriage or other adverse outcomes.
- COVID-19 vaccination is recommended for people who are breastfeeding.
- Reports have shown that breastfeeding people who have received mRNA COVID-19 vaccines have antibodies in their breast milk, which could help protect their babies.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html

https://www.acog.org/covid-19/covid-19-vaccines-and-pregnancy-conversation-guide-for-clinicians

COVID-19 Vaccines While Pregnant or Breastfeeding

Immunocompromised

- Immunocompromised individuals are especially vulnerable to COVID-19, and may not experience the same robust antibody response to vaccines as those with completely intact immune systems.
- The CDC and FDA advise a 3rd dose of mRNA vaccine for immunocompromised individuals.
- Fully vaccinated immunocompromised people made up a large proportion of hospitalized "breakthrough cases," suggesting immunocompromised people are more likely to transmit the virus to household contacts.

https://www.cdc.gov/hiv/basics/covid-19.html#:~:text=Yes.,included%20in%20vaccine%20clinical%20trials.

COVID-19 Vaccines for Moderately to Severely Immunocompromised People

Effectiveness of a Third Dose… Immunocompromised Adults

HIV

- COVID-19 vaccines are safe for people with HIV. People with HIV can safely continue antiretroviral (HIV treatment) while receiving these vaccines.
- PrEP medications (preexposure prophylaxis to prevent HIV infection) do not interact with COVID-19 vaccines. People taking PrEP can safely receive COVID-19 vaccines.

https://www.cdc.gov/hiv/basics/covid-19.html#:~:text=Yes.,included%20in%20vaccine%20clinical%20trials.

What to Know About HIV and COVID-19

Children's' Health

- AAP recommends Pfizer BioNTech COVID-19 vaccination for all children and adolescents 5-18 years of age who do not have contradictions.
- Moderna vaccine is still being considered for approval by the FDA for 12-18 year olds, but needs further study by the FDA due to potential myocarditis risk.
- AAP supports coadministration of routine childhood and adolescent immunizations with COVID-19 vaccines (or vaccination in the days before or after).
- The Pfizer COVID-19 vaccine offers well documented safety and effectiveness at prevention COVID-19 infections in general, and specifically hospitalization.
- In clinical trials, incidence of major adverse events was extremely rare for both children and adolescents.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html?s_cid=11370:cdc%20covid%20vaccine%20children:sem.ga:p:RG:GM:gen:PTN:FY21

https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/covid-19-vaccine-for-children/

COVID-19 Vaccines for Children and Teens

Chronic Medical Conditions

- Patients with underlying medical conditions ranging from hypertension to asthma to autoimmune conditions are at higher risk for severe COVID-19.
- COVID-19 vaccines are generally recommended for all patients based on age criteria, with no specific contraindications for underlying medical conditions.

COVID-19 Vaccines for People with Underlying Conditions

Upcoming Events

2022

October 11
Nassau/Suffolk County Resident Meet-and-Greet

November 6
Fall Cluster Board Meeting
(Commissions meet prior)
Albany Renaissance

2023

January 13-15
Winter Weekend
Virtual

February 26
Winter Cluster
Renaissance Hotel
Albany

February 27
Advocacy Day
Albany

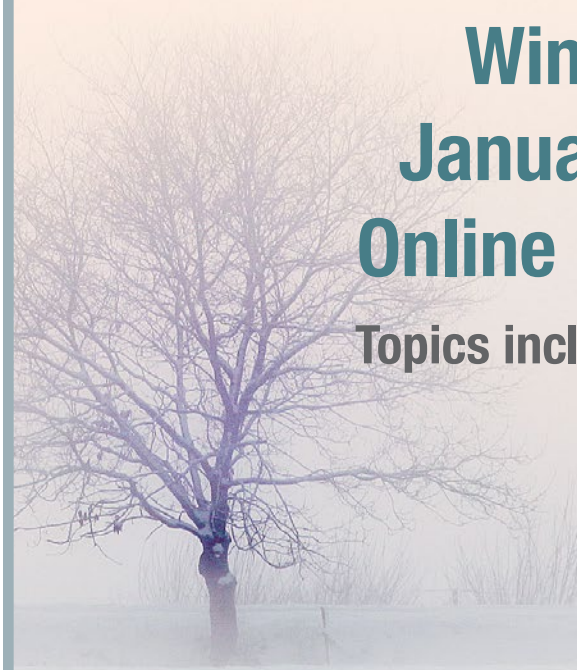
May 20-21
Congress of Delegates
Albany

August 5-6
Summer Cluster
Edith Macy Center
Briarcliff Manor

For updates or registration information for these events go to www.nysafp.org

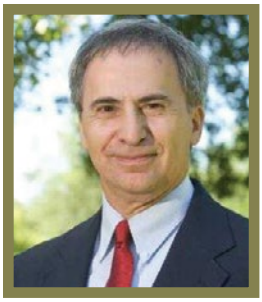
Save the Date!

Winter Weekend
January 13-15, 2023
Online CME conference



Topics include:

- Medical Cannabis
- Addiction Medicine
- Chronic Pain Disorders
- Anxiety & Panic Disorder
- Vitamin D
- Hypertension
- PrEp for HIV



From the Executive Vice President

By Vito Grasso, MPA, CAE

It wasn't long ago when vaccine safety and value were well-established foundational concepts of public health. The history and success of vaccines in preventing disease and the personal and societal trauma associated with pandemics and epidemics was generally known and recognized.

The anti-vaccine movement and the fear and uncertainty of COVID have fueled the proliferation of anti-vaccine sentiment and eroded public confidence in vaccines and trust in the science that produces vaccines and medical treatments. Fears about COVID and doubts about the safety and effectiveness of rapidly developed and launched COVID vaccines have reinforced the anti-vaccine movement. The movement has also been politicized as science doubters and those resistant to government "overreach" have capitalized on understandable concerns regarding the safety and effectiveness of COVID vaccines to advance these agendas by stoking fear, confusion and doubt.

The effort to restore public confidence in science is now confronted with the challenge of recovering critical ground lost during the pandemic. The entire public health infrastructure has been severely strained by the response to COVID. As we reinvest in that infrastructure, we are also challenged to restore confidence in primary care as the front line in our defense against future pandemics and other public health emergencies.

In New York, the Academy has long been a part of the public health community and our members have been among the most trusted sources of current and objective information about health care, prevention and treatment. We have been associated with and have been leaders in various coalitions to foster public awareness and to facilitate dissemination of evidence-based information.

Early in the COVID experience, we formed a multi-stakeholder coalition and initiated a public-facing campaign to provide objective information about COVID and about vaccines generally. The campaign is called Let's Get Immunized New York (LGINY) and a website was launched by the same name on December 8, 2020. The coalition has grown to 45 organizations including medical societies, labor unions, business organizations, patient advocacy groups, academic institutions, pharmaceutical companies and health care professional associations.

LGINY has provided current information vetted through state and national experts. The campaign has encouraged people to get all recommended vaccines and has supported policies to increase awareness of the public health benefits of vaccination. Additionally, LGINY has addressed disparities in access to vaccination especially in medically underserved areas and communities with low immunization rates.

Our commitment to public health and our expertise in addressing critical primary care issues has been well recognized. The NYS Department of Health reached out to us to assist practices that participate in the Vaccines for Children Program in addressing consumer questions and concerns about vaccine safety and effectiveness. Through this project, we developed and implemented an academic detailing program to engage practices in conversations about how best to discuss patient concerns. Our Vaccine Policy Committee was instrumental in developing the protocol for the project and facilitating the discussions.

Our staff and representatives of our Vaccine Policy Committee have participated in regular briefings on COVID by the NYS Health Department. These briefings have included discussion regarding issues associated with public information and vaccine distribution and administration. We have contributed to those discussions and have kept our members informed as developments have occurred.

COVID remains an area of focus for us as we begin to incorporate the entire experience of the pandemic into our ongoing advocacy, education and public information activities. We are working with other public health stakeholders to achieve increased investment in public health and primary care. LGINY continues to operate and remains a source of objective information on vaccines.

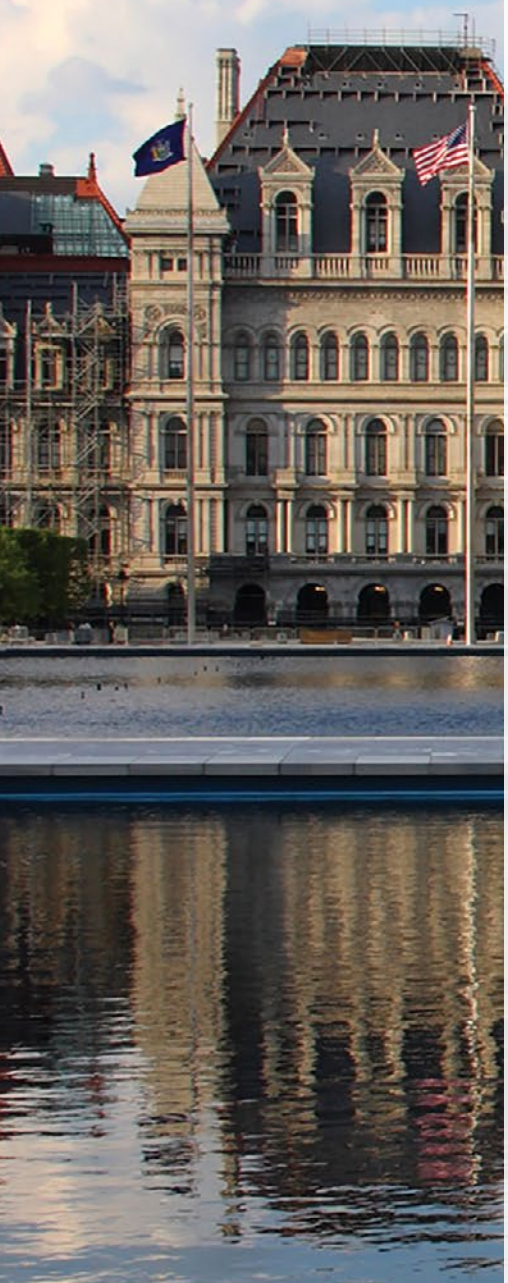
Throughout the pandemic, we have relied on our members to inform and direct our activities. Our Vaccine Policy Committee has been especially important in this and has been a major force in shaping our response to COVID and in maintaining our commitment to promoting confidence in vaccines and immunization generally.

There are, of course, concerns about what may be next in public health. Another pandemic? Natural disasters? Something else? Whatever may occur, we can take some comfort in the knowledge that our response to COVID demonstrates both the will and ability to remain a relevant and reliable source of information and action for our members and the communities you serve.

As we reinvest in that infrastructure, we are also challenged to restore confidence in primary care as the front line in our defense against future pandemics and other public health emergencies.

Albany Report

By Reid, McNally & Savage



Let's Get Immunized NY Coming Up on Two-Year Anniversary

With the New York State Academy of Family Physician's fall 2022 journal focused on vaccinations, we wanted to provide an update on NYSAFP's successful endeavor to create a new campaign to promote vaccines across New York State.

By the late spring and early summer of 2020 as COVID-19 was spreading throughout our state and country like wildfire, it became more and more apparent that New York State should have a diverse, dedicated, statewide coalition focused on vaccine education and promotion to serve as a trusted resource for New Yorkers. There was so much chaos, uncertainty and ever-changing information surrounding the virus and the efforts already underway to create one or more vaccines to try stopping the virus in its tracks.

Given its longstanding work and leadership in vaccine education and advocacy efforts, NYSAFP received a grant through its Foundation for the purpose of creating a campaign, ***Let's Get Immunized NY***, to strengthen public health communication, education and policy related to immunizations in New York State, and to encourage New Yorkers to get all recommended vaccines. The topline goals set out for the campaign were to increase awareness of the public health benefits of vaccination, serve as a consistent and trusted resource about vaccines, and address health disparities with vaccine access, especially in medically underserved areas and communities with low immunization rates.

Our firm helped NYSAFP create the campaign and provides organizational and staff support for *Let's Get Immunized NY*. We spent the fall of 2020 working with the Academy to create a campaign steering committee and broad, diverse coalition comprised of organizations focused on health care, public health, racial and social equity, lower and higher education, business, and other areas. The complete list of campaign partners follows on page 9.

In December of 2020, *Let's Get Immunized NY* was officially launched and in its first year was very active in a range of educational, vaccine promotion and public relations activities throughout NYS with NYSAFP at the lead. This included co-hosting a Town Hall about COVID-19 vaccines with Bronx-based State Senate Health Chair Gustavo Rivera. The campaign also sponsored a radio advertisement encouraging COVID-19 vaccination in upstate areas of NY with lower vaccination rates. The campaign has also helped to amplify voices and messaging that support and promote immunization through blog posts, opinion pieces, and other earned media. The campaign website and social media accounts Facebook, Twitter, and Instagram were also launched to serve as a hub of information and resources to help New Yorkers make informed choices about their health and immunization. It has also served as a resource to many of the campaign partners helping to provide information, join in webinars, and assist with organizational efforts to promote immunization.

As *Let's Get Immunized NY* embarked on its second year, the campaign added a vaccine policy and advocacy focus releasing an advocacy platform in 2022 to support policies that protect and improve access to immunization and that increase awareness of the public health benefits of vaccination. The campaign set forth the following priorities:

Campaign Advocacy Priorities

1. Support improvements to vaccine access and investment in public health infrastructure including the PREPARE Act which calls for a $216.5 million for local health departments to carry out key public health programming, including vaccinations.
2. Request additional state resources dedicated to a sustained public relations campaign around general vaccine promotion and education focused on the importance of vaccination for all New Yorkers and combatting disinformation efforts.

3. Support improvements to vaccine recordkeeping including policies that allow for greater interoperability between the state and city vaccine registries, and state legislation to require reporting of all vaccinations given to individuals 19 years of age or older to the state or city registry, moving from an "opt-in" to an "opt-out" of such reporting in New York (S75a, Hoylman/A279a, Gottfried).
4. Oppose measures to weaken New York's strong vaccination policies that ensure the protection and safety of our communities.

NYSAFP and other campaign partners worked throughout the 2022 session to pursue these budget and legislative priorities. We succeeded in securing funding in the final state budget as part of the NYS County Health Officials PREPARE Act initiative to restore public health infrastructure funding. In May, *Let's Get Immunized NY* held a virtual lobby day with over a dozen partners joining with NYSAFP to meet with key lawmakers, committee chairs, and staff to legislative leaders to continue to raise awareness about the campaign and urge their support for our priorities.

Regarding NYSAFP's leading vaccine policy priority, we were able to leverage the support of many *Let's Get Immunized NY* partners to join in advocacy efforts supporting the adult vaccine reporting bill (S75a/A279a) discussed above. This was a priority for the campaign lobby day in May, and NYSAFP was able to get 16 organizations to co-sign a joint letter of support urging its advancement, and partners helped us promote the bill in the media and through other activities. This was in addition to the strong NYSAFP-specific advocacy this year during NYSAFP's own lobby day. Several other legislative meetings were held with Academy leaders including immediate past-President Dr. James Mumford, President Dr. Andrew Symons, Vaccine Subcommittee Chair Dr. Phil Kaplan, EVP Vito Grasso and our firm, as well as strong grassroots support from our members.

Because of these efforts, we succeeded this year in having the bill move to the Assembly floor for the first time after being introduced a few years ago. Unfortunately, the Senate was unwilling to advance any "controversial vaccine bills" given anti-vaccine opposition this year so we were unable to see advancement on the Senate side. We will continue to press for the passage of this bill in the next session that begins in 2023 when the environment may be more conducive since it will not be an election year for legislators. With the strong foundation that has been laid supporting the bill by NYSAFP and working more broadly with the *Let's Get Immunized NY* campaign, we are optimistic that can make this law a reality to strengthen vaccine reporting and infrastructure in New York State.

To learn more about *Let's Get Immunized NY* and its educational, advocacy efforts and vaccine resources, please visit: www.letsgetimmunizedny.org

Partners

Hot Topics

From time to time, an article is submitted which does not coincide with the theme of a particular issue but is determined to be a timely benefit for our members. We welcome additional submissions to our Hot Topics section. – P. Ruhm, Editor

G6PD Deficiency:
What is a Family Physician to do?
Making Sense of the G6PD Mandate and its Implementation

By Tianrae Chu, MD and Sarah Hudson, MD

Introduction

On June 22nd, 2022, the NYS Legislature passed and the Governor signed into law HL Public Health (PBH) CHAPTER 45, ARTICLE 25, TITLE 1 § 2500-a.[1] This mandate includes three parts: glucose-6-phosphate dehydrogenase (G6PD) quantitative/diagnostic testing in two relevant clinical disease states, and targeted G6PD screening for infants with certain risks based on family of origin (see Figure 1). New York joins Pennsylvania and Washington D.C. as the only places in the United States where such a clinical mandate has become law.[2] In this article, we will review the pathophysiology and epidemiology of glucose-6-phosphate dehydrogenase deficiency (G6PDD). We will outline the key elements of an effective screening program, and comment on important reasons to advocate for applying scientific rigor to testing programs and to advocate against specific mandates on clinical practice. Finally, we will discuss some challenges in interpreting G6PD test results and review some of the challenges with implementation of the screening portion of this mandate in routine newborn care.

Figure 1, NY Public Health Law[1]

Section 2500-A; Test for phenylketonuria and other disease and conditions

(j) Glucose-6-phosphate dehydrogenase deficiency using a quantitative enzymatic test or other diagnostic test in cases where:

- the newborn infant presents with hemolytic anemia, hemolytic jaundice, or early-onset increasing neonatal jaundice, that is, jaundice (bilirubin level greater than fortieth percentile for age in hours) persisting beyond the day of birth through the week after birth
- the newborn infant has been admitted to the hospital for jaundice following birth
- the biological parent of the newborn infant indicates a family, racial, or ethnic risk of glucose-6-phosphate dehydrogenase deficiency, including having significant African,Asian, Mediterranean, or Middle Eastern ancestry.

G6PDD Pathophysiology

Glucose-6-phosphate dehydrogenase is an enzyme that catalyzes the reduction of NADP to NADPH in the pentose phosphate pathway. In erythrocytes, this supply of NADPH helps protect cells from hemolysis due to oxidative stress. Compared to the general population, enzyme deficient newborns are at twice the risk of developing neonatal jaundice from hyperbilirubinemia.[3] If untreated during infancy, affected newborns are at great risk of developing kernicterus which may lead to irreversible brain damage. G6PDD has also been identified as a risk factor for developing neonatal sepsis.[4] Affected individuals of all ages are prone to hemolytic anemia as a result of infection or exposure to oxidative drugs (e.g. dapsone, primaquine, nitrofurantoin) or certain foods (e.g. fava beans). Presenting symptoms of a hemolytic anemia episode may include fatigue, pallor, jaundice, shortness of breath, abdominal pain, and back pain. The onset of symptoms can be within hours to several days after exposure to the offending trigger; most episodes are self-resolving with supportive therapies.[5] Rarely, affected children may have a form of chronic hemolytic anemia that occurs without a triggering event.

Epidemiology & Genetics

The inheritance pattern of G6PDD is X-linked, and its prevalence is highest in Africa, the Mediterranean, Middle East, and Southeast Asia. In these areas, the prevalence ranges from 5-30%.[6] The World Health Organization has recommended that universal screening be done for any inherited disorder when its prevalence exceeds 3%,[7] a topic we will discuss in greater detail below. Prevalence in the United States can be extrapolated from data from the US Department of Defense (DoD), as the DoD requires G6PDD testing for all service members. In the cohort of all members from the period May 2004 to September 2018 (n=2,311,223), the prevalence of G6PDD was 11.2% of Non-Hispanic Black males and 4.7% of Non-Hispanic Black females. The overall prevalence was 2.2%, with prevalence being higher amongst males (2.3%) than females (1.5%).[8]

Review of the Mandate

The NYS G6PDD mandate, as put into law, includes both conditions which are considered *diagnostic testing* and conditions which are considered *screening*. Subsequent communication from both the legislature and the NYS Department of Health refer to both conditions as "testing" despite their differences. As a reminder: diagnostic testing is performed to identify the presence of disease in clinical situations where the disease is suspected, whereas screening is performed to identify the presence of disease prior to the onset of symptoms. The first two lines of the mandate require practitioners to perform quantitative testing for G6PD levels under specific clinical conditions in which G6PDD may be suspected, including hemolytic anemia, hemolytic jaundice, early-onset increasing jaundice, and hospital readmission for jaundice. Presumably, this is already standard of care and part of routine clinical practice for those admitting newborns; certainly, that has been the response in our medical community. However, some aspects of this seem arbitrarily set (for example, what criteria were used to decide that persistent bilirubin levels higher than the *fortieth* percentile warranted diagnostic testing?)

What is the rationale for the state consequently mandating our clinical care? Should we anticipate state mandates that we test for diabetes in all individuals admitted to the hospital with a metabolic acidosis, or that we perform blood cultures on all newborns with persistent hypothermia?

The third component of the mandate outlines screening requirements based on specific hereditary backgrounds with a higher prevalence, a type of screening known as *high-risk* or *targeted* screening. This contrasts with *universal* screening which is carried out across an entire population regardless of risk factors, as is done with New York's Newborn Screening Program (NSP). The NSP currently screens for 52 diseases and despite the new mandate, G6PDD was not added to this program.

As outlined in Figure 2, the evaluation of a screening test should consider the degree to which screening can improve health outcomes as well as the benefits vs. the harms of screening. A fundamental question is whether identifying G6PDD is useful in preventing kernicterus. Although there is evidence that newborn screening programs in combination with increased parental education has been associated with a decrease in incidence of severe hyperbilirubinemia and kernicterus in several countries in Asia, the Middle East, and Greece,[7] studies in the United States are lacking. Furthermore, there would need to be data to show that G6PDD screening provides greater benefit in preventing adverse outcomes than our existing practices of hyperbilirubinemia screening, discharge, and follow-up. The consequences of overdiagnosis are not insignificant. These include increased stress/anxiety for parents and increased costs incurred with testing; it is unclear who shoulders the burden of all the increased testing this mandate may incur.

Figure 2: What Makes an Effective Screening Program?

1. The condition being screened for has serious/irreversible consequences if not treated early (e.g. congenital hypothyroidism) or is life threatening (e.g. colorectal cancer).
2. Early treatment is more effective than treatment after the development of symptoms.
3. Prevalence of the preclinical phase of disease is high in the screened population (this relates to the cost effective use of testing, and the positive predictive value), or the cost/consequence of untreated disease justifies the use of screening for low prevalence conditions (e.g. PKU).
4. Suitable screening methods are available, with low risk/side effects of the screen.
5. Appropriate follow up and treatment is available.

Adapted from NY DOH, https://www.health.ny.gov/diseases/chronic/discreen.htm

It is outside the scope of this article to fully evaluate the appropriateness of screening for G6PDD, either in targeted or universal populations. However, while the impact of G6PDD on individuals and families is apparent, it is not clear that there was any evaluation of this with scientific rigor prior to implementation of this mandate. It is also not apparent what benefit there is to the quality of newborn care by mandating diagnostic testing under clinical conditions where this type of testing is already considered the standard of care. We advocate that family physicians and family medicine organizations should insist that lawmakers partner with the medical community on this kind of evaluation prior to creating additional demands on our clinical care.

Practical Implementation of Mandate

Given that this mandate has already been passed into law, how does a family physician incorporate it into clinical practice? One concern that has arisen in our medical community is the complexity of determining a patient's "familial, racial, or ethnic risk" for G6PDD. Consider, for example, individuals of mixed ancestry or individuals without much knowledge of their familial lineage. Until more reliable markers of genetic ancestry become practical and widely available, the use of race/ethnicity in the identification and stratification of disease is necessary, both to comply with the state mandate and as we aim to reduce health inequities.[9] Data gathered in the Pilot USA Kernicterus Registry from 1992 to 2004 unsurprisingly indicate that African American neonates compromised the majority (73%) of infants with kernicterus found to be G6PD deficient, which is consistent with the prevalence patterns of G6PDD in the United States.[7] As we continue to pursue many avenues to prevent inequities in healthcare, we must address G6PDD as well.

We recommend asking all parents to self-identify their ethnicity/background as a way to mitigate risk of bias. Other steps we recommend include attempting to minimize infant discomfort when possible by ordering screening for high risk infants to be done at 24 hours of life alongside the NSP, confirming that pending tests are communicated to the newborn's PCP, and ensuring that the G6PD quantitative order has been added to the appropriate order sets for newborn admissions/re-admissions in your hospital system.

Interpreting Results

Finally, we will discuss challenges inherent to G6PDD testing and share our local practices. There are three primary methods of G6PDD testing: qualitative, quantitative, and gene sequencing. The gold standard is gene sequencing, but barriers to this form of testing include cost and processing time. Quantitative testing is the next best test; results are reported as enzyme activity level in U/gm of hemoglobin.

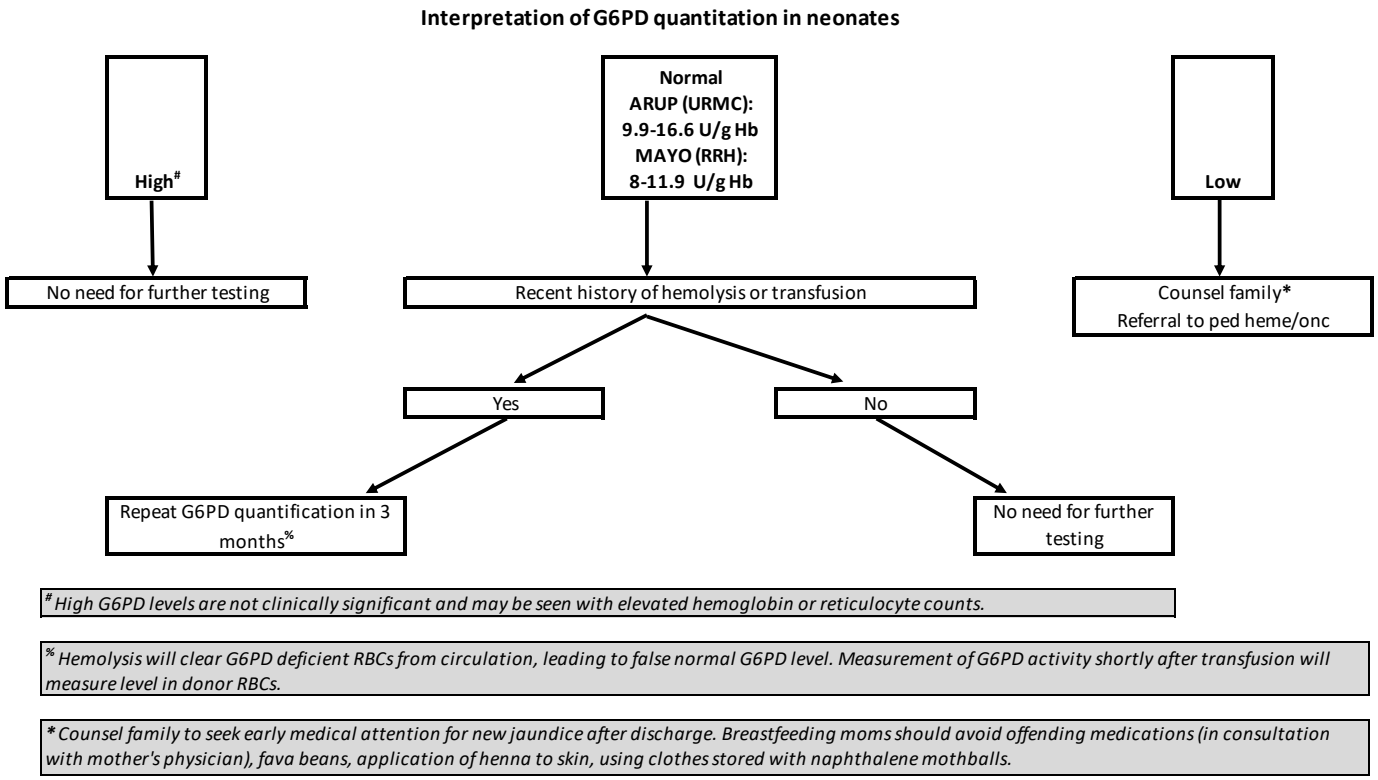
Interpretation of quantitative tests of enzyme level must consider differences due to inheritance pattern as well as the clinical history. Males are either enzyme deficient-hemizygotes or normal; while females can be normal homozygotes, deficient-homozygotes, or heterozygotes with varying degree of X-linked inactivation. As a result, due to greater variation in enzyme activity, the test can be more difficult to interpret in females. Interpretation can be further complicated by the clinical history. For example, during hemolysis, enzyme levels may be falsely normal due to the clearance of enzyme-deficient RBCs. Additionally, in the setting of recent blood transfusion, enzyme levels may be falsely normal due to the measurement of normal enzyme in donor RBCs. Notably, it is normal for neonates to have higher G6PD enzyme levels than the general population.

Our practice in Rochester (Figure 3) has been that if a neonate has a high G6PD enzyme level on the quantitative screening test, it can be reasonably concluded that they are not G6PD deficient. If they have a low enzyme level, they most likely have G6PDD and should be appropriately counselled or referred to appropriate specialist care. If they have a normal enzyme level in the setting of acute hemolysis or transfusion, the result is considered indeterminate and repeat G6PD quantification should be repeated in roughly 3 months. Female neonates with normal enzyme levels may be G6PDD carriers, and thus repeat

continued on page 12

continued from page 11

Figure 3: G6PD Interpretation and follow-up algorithm



Borrowed with permission from AHP Network (https://ahpnetwork.com/newborn-screening-update-g6pd-deficiency/)

evaluation should also be considered. Our practice is supported by a 2005 study of G6PD activity in African American male newborns as well as a 2012 study of high-risk male and female newborns from Mediterranean regions. Both studies examined the use of quantitative enzyme measurement as a screening tool in populations with a high prevalence of G6PDD.[10,11]

Endnotes

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Additional Resources

NYS Provider Fact Sheet https://www.wadsworth.org/sites/default/files/WebDoc/361298874/G6PD%20Provider%20Fact%20Sheet%207.1.pdf

List of conditions in NYS Newborn Screening Program https://www.wadsworth.org/programs/newborn/screening/screened-disorders

Annual data from NYS Newborn Screening Program https://www.wadsworth.org/newborn-screenings-annual-report-2014

Tianrae Chu, MD *is a second-year resident at the University of Rochester Family Medicine Residency Program. He received his medical degree from the Geisel School of Medicine at Dartmouth. His residency continuity practice is at Brown Square Health Center.*

Sarah Hudson, MD *is an Assistant Professor in the Department of Family Medicine at the University of Rochester. She is the Assistant Program Director for the Brown Square FQHC Site, and is part of the URMC Family Medicine maternity care faculty.*

Recent Updates on the ACIP Vaccine Recommendations

By Jamie Loehr, MD, FAAFP

The Advisory Committee on Immunization Practices (ACIP) reviews data and makes recommendations to the Director of the CDC on the use of vaccines in the United States. These recommendations are usually approved by the CDC Director, and then the recommendation and clinical considerations about the appropriate use of the vaccine are printed in the MMWR. In urgent situations, such as the recent pandemic, the process from recommendation to publication can occur in just a few days but usually takes several months.

Over the past year, ACIP has made several vaccine recommendations that affect family physicians. These recommendations include offering hepatitis B vaccine to adults and the zoster vaccine to immuno-compromised patients, stating a preference for high-dose or adjuvanted influenza vaccines for patients over age 65, and changing the pneumococcal vaccine recommendation entirely. This article will review these and other recommendations in more detail.

Before we move on, there is a small caveat about insurance coverage of these recommendations. Under the Affordable Care Act, beginning one year after approval by the Director of the CDC, the majority of insurances in the United States are required to cover the immunization as recommended, without any cost to the patient. Exceptions to this rule include Medicare, which is allowed to make its own decisions regarding which vaccines are covered, and certain grandfathered insurance plans, which are becoming more rare as time passes. While some insurances may cover the immunization immediately, others may take several months before implementing the recommendation. Practices should take that into consideration to avoid billing difficulties before administering vaccines under the new recommendations.

Covid-19 Vaccines

The majority of the ACIP recommendations over the last year have been related to the Covid-19 pandemic. The clinical considerations for these vaccines frequently change and have been updated on a weekly or monthly basis as new information becomes available, with subsequent updating of the recommendations. The link to the current clinical considerations for the use of the Covid-19 vaccine is https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

However, the following is a high- level overview of the current Covid-19 vaccine recommendations as of July 2022:

The Covid-19 vaccine is recommended for everyone older than six months of age. In practice, this will usually include a primary series of two doses of an mRNA vaccine 3-8 weeks apart. There is some evidence that a longer spacing interval will improve the immune response and decrease the risk for vaccine associated myocarditis and/or pericarditis.

There are several vaccines approved for use in the United States:

- Pfizer and Moderna are mRNA vaccines approved for all recommended ages.
- Janssen is only approved for over 18 years and is no longer a recommended first line vaccine due to a small risk of TTS (thrombosis with thrombocytopenia syndrome). However, if a person in unable or unwilling to receive an alternate vaccine, the Jansen vaccine is acceptable as the risk of TTS is less than the risk from the Covid disease itself.
- The Novavax vaccine was approved in July of 2022 – more information to come.

Immunocompromised patients have a less robust response to the mRNA vaccines so additional doses are recommended. There is a list of immunocompromising conditions and treatments from the clinical considerations link above.

One and sometimes two booster doses are recommended for everyone over age 5. Please note that the Moderna vaccine was only recently approved for pediatric use and does not have a recommendation for a booster under age 18.

Covid-19 vaccines may be administered with other vaccines without any regard to timing or spacing between the vaccines.

Covid-19 vaccines are strongly recommended for women who are pregnant because of the small but increased risk of serious illness, preterm delivery, stillbirth, and maternal death from a covid-19 infection and the lack of any significant risks from the vaccine.

Moving on from covid-19, ACIP made many other recommendations over the last year. The following list is in descending order for the number of people affected by the recommendation.

Hepatitis B Vaccines for Adults

On November 2, 2021, ACIP recommended that hepatitis B vaccine should routinely be given to all adults through age 59 years who have not previously received the vaccine. It also recommended that all people over the age 60 years with any risk factor be given the vaccine. Any adult over age 60 years with no risk factors may be vaccinated after a discussion with a health care provider about the minimal benefits of the vaccine and low rates of hepatitis B in the elderly. The MMWR and clinical considerations about this recommendation were published on April 1, 2022.

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Hepatitis B vaccination has been recommended for adults at higher risk for the disease for many years. However, there is still a large burden of disease in the United States. The rationale for a universal recommendation is that it will prevent more cases than the current risk-based protocol.

Pneumococcal Vaccines for Adults

On October 20, 2021, in light of two newly approved conjugate pneumococcal vaccines PCV15 and PCV20, ACIP voted to update the pneumococcal vaccine recommendation. The actual details are a bit complicated and I refer practitioners to the MMWR and clinical considerations published on January 28, 2022 for specific questions. This link to pneumococcal vaccine timing for adults is particularly helpful:

https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

However, the short version is that persons aged 65 years or older and younger adults with given risk factors or certain medical conditions should receive either PCV20 or PCV15. If PCV15 is used, it should be followed by a dose of PPSV23. There is no stated preference for either option.

If a patient has already started a pneumococcal series with PCV13, then they should finish that series using the previous recommendations.

In addition, on June 22, 2022, ACIP approved the following recommendation: "PCV15 may be used as an option to PCV13 for children aged <19 years according to currently recommended PCV13 dosing and schedules."

Unfortunately, these recommendations leave practitioners in a bit of a quandary as to which vaccines to order, especially if they also provide pediatric care. PCV15 has just recently been approved for use in children but PCV20 has not and might not have such approval for over a year. So while PCV20 is simpler in adults, requiring just one dose, practices would still need PCV13 or PCV15 for children.

Influenza Vaccines for Adults 65 Years and Older

On June 22, 2022, ACIP voted in favor of the following resolution:

"ACIP recommends that adults aged >65 years preferentially receive one of the following higher dose or adjuvanted influenza vaccines: quadrivalent high-dose inactivated influenza vaccine (HD-IIV4), quadrivalent recombinant influenza vaccine (RIV4), or quadrivalent adjuvanted inactivated influenza vaccine (aIIV4). No preference is expressed for any one of these three vaccines. If none of these three vaccines is available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine should be used."

There is a good deal of evidence that each of the three vaccines listed above was better for persons >= 65 years than standard dose influenza vaccine in one or several influenza seasons. However, none of the three vaccines was consistently better than standard dose influenza vaccine and there is not good evidence that one is consistently better than the other two vaccines. For that reason, the preferential recommendation is for any one of the three vaccines for the elderly.

Zoster Vaccine for Immunocompromised Adults Ages 19-49

Most family physicians are aware of the recommendation that all adults >=50 years should receive two doses of the recombinant herpes zoster vaccine two to six months apart, regardless of a history of herpes zoster infection or the prior receipt of the live herpes zoster vaccine. This new recommendation extends that opportunity to include adults age 19 years or older who are or will be immunodeficient or immunosuppressed due to disease or therapy.

There are also some travel vaccine recommendations that are new or have changed in the last year. These affect fewer people but are still relevant to family physicians when counseling travelers to certain parts of the world.

Tick-borne Encephalitis Vaccine

The ticks that carry the virus that causes tick-borne encephalitis (TBE) are endemic in parts of Europe and much of northern and eastern Asia. The risk of exposure is related to the amount of time spent outdoors in endemic areas. The TBE vaccine has been used in parts of Europe for more than 20 years.

On February 23, 2022, ACIP voted to recommend use of this vaccine for laboratory workers with a potential for exposure to TBE virus. More relevant for family physicians, ACIP also voted to recommend this vaccine for persons who will have extensive exposure to ticks based on their planned outdoor activities and itinerary in a TBE-endemic area. Family physicians should query travelers about their planned activities and itinerary, the time of year of travel (highest risk is April through November), and the traveler's personal perception and tolerance of risk.

The vaccine series involves three doses over 6-12 months for persons aged 12 months and older. There is an optional booster dose three years later if there is ongoing exposure.

Cholera Vaccine

Family physicians may have been aware that cholera vaccines have been recommended for adults traveling to an area with active cholera transmission. On February 23, 2022, ACIP voted to extend its existing recommendation to include children and adolescents age two through 17 years.

The cholera vaccine for children is complicated and practitioners must follow the specific instructions in the package insert. The vaccine must be reconstituted in a buffer solution, might require sweeteners to make it more palatable, and be taken in the office by the recipient at the vaccination visit. In addition, the vaccine cannot be given within 14 days of antibiotics and must be given at least 10 days before starting chloroquine for malaria prophylaxis.

Rabies Vaccine

ACIP now recommends a 2-dose (days 0 and 7) intramuscular rabies vaccination series in immunocompetent adults for whom rabies vaccine pre-exposure prophylaxis (PrEP) is indicated. This new two-dose recommendation replaces the previous three-dose recommendation and is consistent with recommendations from the World Health Organization. The MMWR was published on May 6, 2022 and has extensive details about how to categorize individuals according to their potential risk of exposure and likelihood that an exposure would be recognized.

Both travel and rabies vaccines are covered in greater depth elsewhere in this issue.

Finally, there are a few other vaccine updates that family physicians might want to be aware of.

Orthopox Vaccine (Which Includes Monkeypox)

On November 2, 2021, ACIP recommended Jynneos vaccine as an alternative to ACAM 2000 for protection against orthopox viruses in people at increased risk. Details of the recommendations can be found in the MMWR published on June 3, 2022.

Since then, more than 20,000 cases of monkeypox have been diagnosed in the United States. The CDC is working with states to provide Jynneos vaccine for either pre-exposure prophylaxis or post-exposure prophylaxis for monkeypox. Family physicians should work with their local health department to provide vaccines to exposed patients. The optimal time for receiving the vaccine to prevent outbreak of the disease is within four days of exposure. The recommended dosing schedule for Jynneos is two doses administered 28 days apart.

New Brand of MMR Vaccine

On June 22, 2022, ACIP recommended that a new brand of MMR vaccine (Priorix, GSK) be endorsed for use as an option to prevent measles, mumps, and rubella following current schedules and including any off-label uses. In short, this means that Priorix from GSK may be used interchangeably with MMR from Merck. Please note however that Priorix is not a substitute for MMRV (Proquad, Merck) which is a combination of MMR and varicella vaccines.

Meningitis ACWY

Practices should have been informed that Sanofi is phasing out production of Menactra in favor of its alternative meningitis ACWY vaccine Menquadfi. This will be relevant for young children because Menactra was approved down to age 9 months, while Menquadfi is only approved for persons aged 2 years and older. Fortunately, Menveo is approved down to age 2 months.

At the other end of the age spectrum, Menquadfi has no upper age limit and can be given to adults over age 55. In contrast, both Menveo and Menactra were only FDA approved up to age 55. However, ACIP recommended an off label use for either of those vaccines when needed for persons older than 55 years.

HPV Vaccine

There was a presentation to ACIP in June 2022 with data that suggested that one dose of HPV vaccine provides a high level of durable protection comparable to that of two doses. The Strategic Advisory Group of Experts (SAGE) of the World Health Organization (WHO) is recommending that resource poor countries can consider one dose sufficient for protection in order to stretch their supply of vaccine even farther. There was no discussion about considering a one-dose HPV vaccination schedule in the US at this time.

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https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

Jamie Loehr, MD, FAAFP *has practiced family medicine in Rochester and Ithaca, NY for the past 32 years. He received his medical degree from Baylor College of Medicine and did his residency in Rochester, founding Cayuga Family Medicine in 2000. Dr. Loehr became especially interested in vaccines while discussing the topic with vaccine hesitant families in Ithaca. He authored "The Vaccine Answer Book: 200 Essential Answers to Help You Make the Right Decisions for Your Child" and did a vaccine fellowship with the AAFP. He served as the AAFP liaison to the ACIP from 2011-2015, has been a member of the ACIP influenza work group from 2011-present and is currently a voting member on the ACIP.*

The State Of Vaccination: NY Strategies

VIEW ONE

ADVOCATING FOR UNIVERSAL ADULT NYSIIS – OPTIMISM IN DEFEAT

By Philip Kaplan, MD, FAAFP

NYS Public Health Law §2168 required that any vaccine given to a child under age 19 after July 1, 2008, must be reported to a registry, either NYSIIS (NYS Immunization Information System) or CIR (City Immunization Registry). Within two weeks of such immunization, all prior immunization records known to the immunizer must be uploaded to the registry. We uttered a collective groan under the burden of the upload, but most family physicians and pediatricians complied. In the ensuing fourteen years, we have come to appreciate the patient and public health benefits of the registries. Child records must be included, and adult records may be included with permission of the adult vaccine recipient. The benefits of vaccine registries seem obvious:

- Vaccine records can no longer be lost. We no longer have to depend on the baby book in the attic.
- New patients, ER visits, school admissions, travelers, hospitalizations, popup vaccine clinics, pharmacies – any of these venues either administer or require a record of vaccines.
- Registries allow instant access for recall or mitigation of a "bad batch."
- Public health efforts can focus on areas of vaccine access inequity or vaccine declination.
- Louisiana had a vaccine registry in place when hurricane Katrina drowned many kids 'office vaccine records.
- Individual physicians can assess their vaccination prowess by running practice level reports[1] that are not available in most EMRs.

Two amendments to §2168 approached our goal of a universal registry:

1. The required adult permission had consisted of a specified NYS issued form. This was amended to require only verbal permission; the content of such permission was not specified in the amendment.
2. Pharmacists must report. This requirement was sometimes ignored, and apparently not enforced. The law has a loophole – pharmacists must report with adult permission, but they are not required to ask permission.

We now have a cohort of young adults who were children in 2008, and whose vaccine records in NYSIIS or CIR will become inactive in the absence of a universal adult registry. Very few adults carry a durable copy of their vaccine records. Adults are immunized in many different venues resulting in excess doses. The pneumococcal vaccine recommendations for adults recently became more complex – two alternative schedules. And, the adult being sutured in the ER has no recollection of his last toxoid. The traveler or adult entering a health profession requires a durable vaccine record.

VIEW TWO

MANAGING VACCINE HESITANT/RESISTANT PATIENTS

By Erica Chito Childs, PhD; Vito Grasso, MPA, CAE; Mark Josefski, MD; Phil Kaplan, MD; Jamie Loehr, MD; Kelly Madden, MS; Robert Morrow, MD; and Robert Ostrander, MD

INTRODUCTION

Vaccine hesitancy and vaccine resistance have been increasingly common challenges for primary care clinicians in providing necessary care, and more relevantly, an impediment to the control of the COVID pandemic in general in NY State. Many of us in primary care also struggle with the resistance of some parents to required routine vaccination in general. This challenge occurs in many strata of our practices. Hesitancy and resistance have already become an important public health problem in communities across the State, whether we are looking at the spread of COVID or measles or polio or monkey pox. Individual hesitancy has been exacerbated by an organized campaign against vaccination generally. That effort has been reinforced by concerns with the rapid development and deployment of vaccines to prevent COVID. So how do we help our providers help their patients and communities accept the benefits--and risks--of vaccination? An implementation strategy could address both the challenges and benefits of a vaccination campaign.

To address issues of vaccine hesitancy and resistance by parents, the NYSAFP team conducted outreach to primary care medical practices in New York State that participate in the Vaccines for Children Program. Outreach to practices focused on an implementation framework with different tools and techniques, including focus groups, academic detailing sessions, NYSIIS training sessions and an assessment tool. Twenty-one practices participated in these sessions, which included both health care professionals and administrative staff. The focus groups were conducted by a qualitative researcher to collect and discuss information regarding practices' experiences with vaccine resistant patients or parents, and to identify common themes and experiences. The academic detailing sessions were implemented by one of our family medicine health professionals. These academic detailers discussed the issues with vaccine resistance and hesitancy faced by other practices, listened to their particular experiences and challenges, and offered strategies of what works and what does not work with patients. A pre- and post-assessment was administered, as well.

Academic detailing is a technique initially used by the pharmaceutical industry and entails brief visits to medical offices to engage those medical providers in problem solving, using a planned focus to help create drivers for implementation of behavioral change. In this project, that change was to explore ways of reducing both vaccination resistance and missed opportunities in practice. Detailing is an educational process that focuses on the issues and ideas of the learners, and helps learners develop strategies for both change and the

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We passed a COD (NYSAFP Congress of Delegates) resolution advocating universal adult registry submission in 2017.[2] Physicians who care for only adult patients were slow to warm to the idea of a universal (euphemism for mandated) registry. Without a mandated registry, the individual vaccine record is incomplete. The MSSNY (Medical Society State of NY) committee on legislative advocacy had other priorities, but the MSSNY infectious disease committee was more receptive. The breakthrough came at a county medical society meeting when I was sitting next to an internist who was also a MSSNY counselor, and medical director of the local HIE (health information exchange). He noted that most internists send all data including vaccine data to the HIE. If the law for a universal adult registry could allow reporting to the HIE to constitute compliance, internists could effortlessly comply. The current state law does not allow HIEs to report. The MSSNY infectious disease committee brought a resolution to the MSSNY House of Delegates, and the resolution became MSSNY policy. A bill appeared in both houses of the state legislature which had the elements of universal adult registry and reporting to the HIE constituting compliance. This bill did not advance in the first year.

Then came a pandemic. Executive order 202.82 issued by Governor Cuomo in December 2020, reflected the Federal mandate that all covid vaccines be reported to an IIS (Immunization Information System). The order stated that covid vaccines and flu vaccines must be reported within 48 hours, and all adult vaccines may be reported without adult permission. While this order has expired, two outcomes persist:

1. Any adult who received a covid vaccine in NYS now has a registry record in NYSIIS or CIR.
2. Hospitals and physicians who did not immunize children were required to become proficient at submitting registry data to be eligible to receive vaccine from the Federal government, distributed by the state.

Marcy Savage, our retained lobbyist who has served our Academy over twenty years, found that there are 62 state and city registries in the USA. Only five require adult permission. The rest either require no permission or allow "opt out" for the individual patient. Two of the five remaining "opt in" registries are NYSIIS and CIR.

It became clear that there were vocal advocates opposing this pair of bills, so the bills were amended to allow individual patients to opt out. A registry that allows individuals but not vaccinators to opt out still has an intact record for the great majority of patients.

We tried to reassure at each lobbying visit that registry data could be used only for the benefit of the patient or for public health efforts, as stated in §2168. The CIR issued guidance in December 2021 alerting physicians that they could not use CIR data to screen applicant nurses. Employers may ask these nurses for proof of immunization, but they may not access the CIR if they are not the physician of record and they may not use CIR as an enforcement tool.

Armed with all the above information, the Academy mounted a concerted advocacy effort. After our standard lobby day activities, Marcy arranged a series of virtual visits to key legislators and staff. She and Vito Grasso, EVP, and President Dr. James Mumford, despite competing distractions during his presidency, supported me in these visits over several weeks.

But we lost. Two reasons:

1. A vocal antivaccine minority was still feeling the sting of the 2019 amendment to school public health law §2164 which removed the religious exemption for school vaccine mandates.
2. This was a year when assembly members and senators were running for reelection.

I am grateful to Marcy, Vito, President Mumford, NYSAFP and its COD and advocacy process. And I am optimistic we will eventually see this effort become state law and am reminded of the effort surrounding the HIV law. I was a member of our local volunteer fire department. Federal law, the Ryan White Act, allowed the fire department physician access to the infection information of a source individual transported to a hospital, who may have exposed a first responder. State law pre-empted this in the case of HIV. If a source individual died or was unconscious, there was no way to obtain permission to test that patient for HIV. I brought a resolution to COD in 2002 and we lobbied for a solution for the next eight years. In 2010, the law was changed. Senator Tom Duane, Chair of the Senate Health Committee with a special interest in and knowledge of this problem, found the key: the law was amended to allow me as the treating physician of the exposed first responder to order an HIV test on the deceased or unconscious source individual, anonymously, for the benefit of the first responder. Eight years, but eventual success, both from serendipity (Senator Duane ascending to chair the senate health committee or the internist sitting near me at a county medical society), and because such a law is good public policy and good medicine.

Successful advocacy requires patience, collaboration and compromise. We have a process for determining our policy, commissions and a board for enacting that policy, a committed lobbing firm to show us the way, and an agenda as altruistic as our profession. It is a privilege to be a member of this club.

Endnotes

1. How am I Doing with Vaccination, Philip Kaplan, MD, Family Doctor summer 2020, p 41-42
2. Resolution 16'-16, NYSAFP COD June 2016

Philip Kaplan, MD, FAAFP *is a family physician at Fairgrounds Family Physicians in Manlius, NY. He is Chair of NYSAFP's Advocacy Subcommittee on Vaccine Policy and is a past president of the Academy. He can be reached at philzoffice@gmail.com.*

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implementation of change. It allows for 'tailoring on the go,' by addressing issues as those issues arise, and is significantly different from a more structured lecture.

In general, we have found a dichotomy exists between 'antivaxxers,' who reject all vaccination and patients who are hesitant to accept vaccines, who have a less formal, less systematic rejection of all vaccines. Hesitancy resolution requires an understanding of a person's particular issues, which then can be addressed. Antivaxxers are also not monolithic in their understanding of vaccines, but have become convinced that vaccines are a threat, whose risks far outweigh their benefits. Some others simply do not wish to be told what to do.

IMPLEMENTATION

The academic detailing format has proved very effective in facilitating candid conversation and exchange of information and ideas, using a process that focuses on the issues and ideas of the learners, and helps learners develop strategies for both change and the implementation of change. Clinicians actively participated in the discussion and offered insights informed by their experiences with patients. The informal format also supported comparison of experiences across the full spectrum of vaccines used in practices as well as by geographic location. Sessions took 30 minutes to an hour, depending upon the number of participants of the group

We identified a number of challenges that practices were facing with vaccine hesitancy and resistance. Given the pandemic, some participants noted that their practices have been overwhelmed by COVID, COVID related questions and anxiety, and COVID vaccine issues. Calls about COVID vaccine were primarily from patients who wanted the vaccine. Those who declined the vaccine, or expressed hesitancy cited a few reasons, including distrust in the government, the perception that the vaccine was rushed, and the dangers of side effects. Some practices reported additional concerns voiced by patients of color and about the safety of the vaccine for pregnant patients. Additionally, some providers expressed frustration dealing with resistant patients, especially those who know people who have contracted COVID but still do not see the benefit of being vaccinated, or patients who were vaccinated but are afraid to have their children vaccinated. There was speculation that this last category of hesitant parents would be assuaged by approval of COVID vaccine for children when that approval does occur.

During the detailing sessions, strategies for dealing with resistant and hesitant patients were introduced and discussed. Some strategies were introduced by team facilitators while others emerged from participants during the discussion. These included how to talk to our patients regarding the decision about getting the vaccines. Such conversations should involve non-judgmental listening and reliance upon the documented trust that people have with their family physician and other health professionals. Being supportive and non-judgmental is far more likely to be helpful for people to change behaviors and accept treatments than being confrontational and argumentative.

Additionally, the academic detailers led conversations about how to respond to the common reasons for hesitancy, by using personal but up-to-date understanding of safety, efficacy, and necessity, as well as discussion about harm versus benefit. For example, providing information about the regulatory process for vaccinations, citing trusted sources and explaining that the COVID vaccine went through the normal approval process, but that process was only compressed into a shorter period of time because of the urgent need presented by the pandemic.

While much of the detailing sessions focused on COVID, since this was a current and overwhelming focal point for practices, challenges encountered with vaccine hesitancy and resistance with other vaccinations were covered. Practices reported that fewer patients have inquired about the flu vaccine this year, and that in previous years, many parents would permit vaccination of their children for everything except flu. Also, adaptations required by COVID volume required practices to suspend internal quality practices including monitoring compliance with vaccination schedules, and a decline in wellness visits has reduced the frequency of discussions with hesitant or resistant patients. With childhood vaccinations, most practices mentioned that parents often rejected letting their child get multiple vaccinations, opting instead for a slower schedule. Additionally, resistance to HPV vaccinations was discussed. One successful framework identified by participants was the success of school based medical services in getting students vaccinated. This was likely due at least partly to the convenience of being able to administer vaccinations in school. This has also been true with the flu vaccine and could be the case with COVID when made available for students.

Any effort at self-improvement must begin with self-assessment. Most EMRs, including those used by all the offices we have visited thus far, have EMRs that lack the capacity to produce practice level assessment of vaccination rates. Each physician could generate immunization records only for individual patients. Those practices were introduced to the process of generating AFIX reports for their practice, using a PowerPoint presentation of screenshots. We led them through entering the HPN, adding NYSIIS to their account, entering NYSIIS, finding the AFIX report section, and generating a report for the fixed cohorts, childhood and adolescent. Practices were asked to generate a practice assessment report and forward it to us to demonstrate we had effectively instructed them. They were also instructed to generate missing immunization patient lists for internal use to guide them in outreach.

PRE AND POST DETAILING ASSESSMENTS

Practices were asked to complete surveys measuring awareness of and response to vaccination levels within the practice. Surveys were emailed to practices as they agreed to participate. The survey also asked about patient concerns regarding vaccines and patient resistance. It was very difficult to get practices to respond to the pre and post detailing assessment surveys. It was apparent that practices were busy with patient volume and were reluctant to take the time required to answer questions about patient compliance with recommended schedules or patient questions. Responses improved after we allowed estimates and switched to SurveyMonkey to accommodate easier response.

Even when estimates were allowed it was apparent most practices were unaware of the compliance levels for adults or children in the practice. This improved only slightly after detailing, probably because there was insufficient time to permit implementation of lessons learned from the detailing experience. Practices all had thousands of patients and many months of experience would be necessary to accommodate a high enough volume of patient encounters to actually measure the effectiveness of applying lessons learned from the detailing in addressing patient concerns. During the detailing sessions, participants regularly commented on their value.

Most practices did not report regular self-assessment of the practice's compliance levels either before or after detailing. Even among practices which did do some self-assessment, none used the

AFIX program embedded in the New York State Immunization Information System. During detailing discussions, few practices seemed to know what AFIX was or how to use it and most reported they had not used it. Post detailing assessments occurred too soon after detailing to permit widespread application of AFIX or other self-assessment resources. It would be worthwhile to survey practices enrolled in NYSIIS to ascertain how many use AFIX, to conduct training in how to use the program and then to survey practices which participate in the training over a 12-month period to determine whether use of AFIX can improve compliance.

All practices reported some level of resistance both before and after detailing. Practice confidence in the ability to manage conversations regarding vaccines was high before the detailing sessions and remained high thereafter. During detailing discussions, participants identified a variety of questions, concerns and biases raised by patients. Although there was a level of frustration in dealing with some patient concerns, especially those emanating from political bias, everyone felt capable of applying relevant and current information and experience in addressing patient concerns. Detailing discussions did surface some ideas and approaches which some participants had not considered. This was especially true regarding the value of self-assessment and the availability of tools to facilitate monitoring of levels of compliance with recommended vaccination schedules.

CONCLUSION

Our training focused on the needs of professionals as they struggled with the concerns of their patients, who can at times become confrontational. We counseled patience, listening, and clarity of purpose – lowering the heat when changing patient behavior in the face of urgent needs of the public. The harder you push, the harder the pushback.

Using the implementation framework outlined above, the health care professionals and administrative staff were able to describe the spectrum of resistance, ranging from patients who are hesitant but can be moved with conversation and information, to a group of patients who are anti-vaccine, and will only budge if it is required by law. For those patients who are hesitant for specific reasons, they can be persuaded that it is safe through a non-judgmental conversation with a respectful health care professional who listens and provides personal narratives beyond simple statistics and medical documentation. Through the academic detailing and assessment tool, it is clear that having discussions about vaccine hesitancy and resistance, along with strategies for handling these challenges, helps health care professionals and other staff to address this issue. While much of the focus was on the COVID vaccine, moving forward we can also use this implementation framework for childhood vaccines, and bring in additional expertise, such as an epidemiologist.

This project was funded through a contract with the New York State Department of Health. In addition to funding, the Department helped in identifying practices which participate in the VFC program. Staff of the Department also provided perspective and expertise in characterizing the scope of hesitancy and resistance experienced across the state and shared information regarding development of COVID vaccine distribution plans. We are grateful to the Department for their support and assistance.

The Project Implementation Team: *Erica Chito Childs, PhD; Vito Grasso, MPA, CAE; Mark Josefski, MD; Phil Kaplan, MD; Jamie Loehr, MD; Kelly Madden, MS; Robert Morrow, MD; and Robert Ostrander, MD*

IN THE SPOTLIGHT

What does the Future of Family Medicine look like? Reflections from the 2022 AAFP National Conference

By Evani Patel

The AAFP held its National Conference in Kansas City on July 28-30th, bringing together more than 3,000 medical students, residents, and practitioners with a common goal: exploring the vast field of family medicine. As the first in-person conference in over two years, many current third or fourth year medical student attendees had likely never been to an AAFP event of similar magnitude during the span of their medical school careers. The national conference was truly a celebration of unity. Throughout the weekend, there were many common themes, which resonated across the sessions I attended.

One of these was celebrating the resiliency of family medicine, and reflecting on how the COVID19 pandemic highlighted unique opportunities for current physicians and students to become community champions. I learned that empowering future and current family doctors to find comfort with ambiguity was one such way. The impact and uncertainty the pandemic brought to the delivery of medical education, day-to-day logistics of family practices, and the future of human interaction was unprecedented. Speaking with other students who became attuned to the new model of hybrid and online education, and doctors who had to use telemedicine as their primary mode of practice exemplified this. Besides increasing the number of hours one had to work-from-home, some doctors and healthcare team members throughout the US were also called back to the hospitals to address increasing issues of short-staffing and medical emergencies. Community health centres and urgent care centres, were hit hard at the pandemic's peak. Sharing emotions and experiences with attendees made me realize just how much this pandemic has truly tested our limits as part of the healthcare workforce. It also demonstrated how privileged we are, as advocates and members of family medicine, to fulfil our duties as community leaders during a period of drastic change, and to be able to serve as the first point of contact for patients at their weakest and most vulnerable. Joining together in Kansas City following two years of online-conferences was an extremely surreal experience emphasizing a strong message of continued resilience.

One of my favorite parts of the conference was being given the opportunity to channel my inner advocate. Family medicine is a specialty that is impacted by policy every day at all levels – the individual patient, the clinic, the community, and even through research. Specific AAFP sessions outlined the impact that being active advocates has on building structural competency within the healthcare system, and helps to achieve many goals within family medicine. These goals include improving healthcare coverage and access, strengthening the primary care workforce, reducing administrative burden, and one that has become more central over the

Congratulations to New York's own Dr. Tochi Iroku-Malize on her appointment as AAFP President!

past few years – addressing population health. These sessions identified previous examples of how students and residents have actively contributed to these goals, citing position papers and community engagement that played a role in passing the Elizabeth Whitefield End-of-Life Options Act in 2021, as well as the HB 40 Private Detention Moratorium Act. The continued demand for activism within family medicine was further emphasized when I spoke with program directors who promoted new educational tracks in their residency programs dedicated to community leadership and advocacy. As a medical student, these conversations are encouraging. They focus on empowerment as we embark on our brand new careers, while helping us recognize the power in our position as patients' voices.

The AAFP National Conference continuously reflects on the many challenges and accomplishments that family medicine has faced over the years. Through discussions of the importance of advocacy, and engaging in conversations with other students and residents actively involved with policy efforts, I was able to realize that family medicine goes far beyond its manifest function of treatment and cure. Family medicine also serves as a voice for those without one, and emphasizes that positive, sustainable changes stem from addressing the system we operate within. With the COVID19 pandemic raging across communities at its peak, there was also a shared sentiment of "the fear of the unknown," and bringing together attendees for the first in-person conference this year made us realize how much we yearned for this sense of community and belonging.

As a medical student from New York studying in Ireland, I recognize the privilege in developing a rounded understanding of health systems within both the US, and Ireland. My background in global health initially led me to pursue education abroad, and after experiencing the impact of COVID19 in both countries, I was compelled to connect with a community rooted in passions for global health issues and primary care. The AAFP conference allowed me to do exactly this. Looking through poster presentations of projects that were conducted online, and speaking transparently about how work-life merged its way into home-life, truly highlighted the resiliency that we have all had to build along the way. There is no doubt that these conferences will continue to bring together those who believe in the principles of family medicine, and also allow for students like me to consciously reflect on the many reasons why working as a primary care provider is such a gratifying and humbling job.

Evani Patel *is a member of the class of 2023 in the School of Medicine, Royal College of Surgeons in Ireland.*

My Experience with Vaccines

By Kristin Mack, DO

When I was a senior at Vanderbilt, a beloved professor of mine assigned his class of scientists a paper on any subject that had caused a dramatic impact on the health of humans in the last 100 years. Having spent most of my last three years writing laboratory results and bulleted lists of objective data, I was overwhelmed not just by having to write full paragraphs, but because the subject was so broad. So, I sought out my professor during his office hours. He responded immediately to my concerns, saying, "It's simple. There can be no argument that vaccines have had the single greatest impact on human health in this century. You should write about vaccines."

I didn't write about vaccines. None of my classmates wrote about vaccines either even though my professor had suggested to every one of us that vaccines was really the best subject matter to address his assignment. We all had the same reasons not to write about vaccines. Vaccines were boring.

The next fall, I went on to graduate school in Cincinnati to study microbiology and immunology while working in a molecular genetics laboratory. In hindsight, based on my work in these disciplines from 2003-2007, my skill set was being honed perfectly for vaccine research. But, I did not study vaccines. At this point, the only vaccine that was not boring to me was the research underway on a potential HIV vaccine. Though the sentiment of this potential vaccine being exciting was always underscored by the casual remark from scientists that in their personal opinion the research was very unlikely to ever be successful.

In graduate school though, I did have the opportunity to learn from an amazing immunology professor who required that our class understand our way through the most minute details of vaccines within the human body. I found everything he said interesting, and as a result, vaccines were too, but they were all essentially "set" and I was a young researcher ready to forge new paths. Aside from the embarrassingly error prone system for "picking" new strains of influenza from which to protect the population and the aforementioned HIV vaccine that everyone thought would never come to bear, there wasn't much potential for a project with the ambition level I was seeking.

I did, however, continue to be interested in joining the EIS (Epidemiological Intelligence Service) out of the CDC, whose researchers were dispatched to areas of the world where epidemics were occurring and tasked with stopping them. In fact, I had been interested in this type of work since my middle school science classes and my dad giving me Robin Cook books to read. And, I had done a spring break externship at the CDC my senior year in college to explore the possibility of this type of work. Instead of joining the EIS though, I went to medical school. My graduate studies had allowed me to research the prevention of an infection in immunocompromised people, and I had glimpses into hospitals and real patients, and I realized that I wanted to be one on one with people empowering good health.

Ultimately, I went to medical school at a school that focused on the training of rural family medicine doctors. My perspective up until this point was on the microscopic and molecular level, and now my thoughts were quickly being panned out to the broadest scope I could imagine – help every facet of health for an individual – and hopefully even a community.

I loved medical school and had no reservations to staying up to date on my vaccines. I felt like a soldier fighting against all the infectious diseases that I had loved to study. I was re-immunized against MMR immediately after my first son was born because I was found to be seronegative during my pregnancy. But, I was finding at this moment in time, that vaccines were

not boring at all. In fact, they were being made controversial. It was incredibly tough in my mind to reconcile the claims from popular media and celebrities about vaccines, and the detailed knowledge my favorite professors had given me. At first, I turned my back on the controversy because it was not based in science, but soon learned that this was not the smart approach. I was training to be a doctor, and doctore from Latin means to teach. So, it was my responsibility to teach my patients about vaccines. I could not use the language of science that my professors had. I would have to translate the science to language for parents and individuals that were not scientists. In some of the communities where I would work, this meant language for those who did not have high school science backgrounds. For years, I worked to inform families and individuals of the importance of vaccines, and over time, finally convinced myself of what my college professor told me years ago, "there can be no argument that vaccines have had the single greatest impact on human health in this century."

My vaccine conversations with patients honed my communication skills, which I eventually put to use in advocacy. As a member of the NYSAFP Public Health Commission, I had the opportunity to participate in the work to eliminate the religious exemptions to mandated vaccines for schools. Honestly, this shift from individual based medical care to population level care was a huge leap for me – bigger even than my leap from molecular level thinking to medical care for the individual. I struggled with arguments of personal choices. All day in my practice, I educated and empowered people to make their own health decisions, even when they were not the best ones. I championed advocacy to fight the broken system that put obstacles between my patients and their healthcare tools. But, I did not judge my patients if they were their own barrier, I continued to work with them. Sometimes as I advocated for vaccine mandates and the removal of religious exemptions, I felt like I was helping the system to be above the people. This contrary feeling left me uneasy, but because I was trained and confident on the positive impact of vaccines through my years of experience, I marched on. Public health thought processes were harder skills for me to learn than any other science skill set, but the value of public health topics was not to be underestimated. I was happy to have built a voice based on science and the ultimate goal to empower all individuals within communities to have the ability to be healthy and avoid catastrophic disease.

Then, COVID-19.

March 14, 2020 was the Saturday that I went to my health center to outfit it with walkie-talkies, protective shields, telemedicine options, and PPE instead of spending the weekend with my son and nephew whose birthday parties were cancelled at the last minute. And, my life looked a lot like what was on the news every night until nine months later when a vaccine became available. When there was specific information on the mRNA vaccines, I stayed up every night studying the data, using the skills I had been taught – lives were on the line. And there was no trial period.

On December 14, 2020, I watched Sandra Lindsey get her vaccine on livestream from my phone, then called everyone together in the health center and adjacent nursing home to show them too. I had tears in my eyes. I literally felt a weight come off my chest. I saw our staff in full PPE watch Sandra – and watch me watch Sandra. And I saw doubt in some of their eyes. And my relief, though pleasant, was not complete.

I realized that for the foreseeable future, I would be calling on all my past science knowledge and communication skills combined with my public health training to communicate information on this specific vaccine to a lot of humans who were in survival mode and scared. The newspaper covered our team getting our vaccinations, so there was no question about our recommendations to vaccinate. We also openly shared stories about our own childrens' vaccinations to minimize anxiety. We moved forward with "face mask to face mask" talks, went into the cafeterias at the nursing facility while people were working, and had "non-huddle huddles" to review it from every direction and perspective I could have ever imagined. Some of these conversations have nearly broken me. We had moments of sincere bonding and realizations of a shared humanity that transcended the noise of our modern cultural misadventures. And, still we lost some we should not have had to lose.

I am only one of hundreds of thousands of doctors in the US that exist daily in this pandemic. Trying to describe personal and global health impact on a scale we have extraordinary difficulty wrapping our minds around, is exhausting. We, as humans, are a species under attack. While our biology is reacting, we are also animals with large brains, and thus are trying to make sense of something that is tragic and lacks meaning in the ways we are accustomed to experiencing. So, we look to blame, shame, invalidate, and discount. But, even our best thoughts that satisfy us and make us comfortable with the situation do not protect us from the virus. The virus is not malevolent, but it is dangerous. As the virus is doing, we could be listening to our biology – adapt and survive. But, still we look for intent and context. There are appropriate moments for us to scrutinize data and to tout facts. There are moments we need to use less of our amazing brainpower, and just survive. And then, there are moments, that we need to just share experience and find some release. Below are snippets of painful and wonderful conversations:

"He was going to have the vaccine. I mean it, he told me he had decided to get it, but then he got sick. Now, he's gone. He was 50." (In Memoriam)

Me: "What questions can I answer for you about the vaccine and Covid-19?" Patient: "Are you working for Biden?"

"I'll take two! Why would anyone not get this as soon as possible?"

"Do I have to get it?"

"I have to get it for my job."

"I cannot be around them. I don't even care to understand. I lost my son. And they won't get the vaccine. They were his friends, and they still don't see. I am so angry all the time." (In Memoriam)

"I've fought cancer, and I've never been this sick and hurt this much. Is it ever going to stop? I wish the vaccine had been around before I got this. I've made sure everyone I know is getting it."

"If I get it, I know I'll die, but isn't the vaccine killing people too?"

"You know the Chinese did this on purpose, right?"

"I think they are all idiots."
(Referring to people who decline/refuse vaccination)

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"I think you are all idiots."
(Referring to people who get vaccinated)

(40 minutes into drawing cells, explaining vaccines with back and forth questions with a highly educated person asking for the scientific details)... "I'm done here. I have to go." (Doesn't get the vaccine that day, office schedule is 30 minutes behind)

(40 minutes into plain language back and forth questions) Me: "Would you like me to draw a picture of where the vaccine goes in the cell since you seem worried about DNA? (Accepted and done). Patient: That was awesome. Can you do that again? I want to film it, is that ok? I want to show my friends. Why does no one else just say this?" (Repeated the drawing and talk while being filmed, he got the vaccine that day)

(20 minutes into conversation, but her tone has shifted to less interested) Me: "You seem to have a different understanding about some of the science behind it, are there other things that bother you too?" Patient: "Yes, everyone I hear on TV says it's bad and even the doctors on the news say it is dangerous." (More conversation) Patient: "I just don't know." Me: "It really comes down to who you trust." (Doesn't get the vaccine, continues to come for acute and routine care visits)

"I thought this was going to be a lot harder, but I trust you, I want to get the vaccine."

"I thought we were all vaccinated. But, Dad got it from my brother-in-law who didn't get his vaccine. Now, they are both positive, but Dad's in the hospital, and my sister doesn't talk about it. I can't even look at them."

"It's just too fast. I don't trust it."

"She wants to get it now, but I want you to know that if my mom is hurt by this vaccine, I'm going to sue you for everything you're worth."

"This is so exciting! It feels like a concert! We are waiting in line out in the cold; everybody is happy. There is good energy here." (At our very fist larger scale evening vaccine event)

"I hate needles, but I know if I get COVID there a lot more things to be afraid of, just give it to me fast." "Nope. I hate needles."

"You should be ashamed of yourselves, putting that into that child is dangerous."

"My generation understands vaccines. (Showing small pox vaccination scar) I don't understand what has changed."

"Will you give it to me?" Yes.

"Will you sit with me for a while when I get it?" Of course.

"Will you be here when I get it?" Absolutely. I'm your doctor.

Kristin Mack, DO *holds a Bachelor of Science in molecular and cellular biology from Vanderbilt University, along with a Master of Science in Immunology and Microbiology from University of Cincinnati. She began her career in research before attending medical school at West Virginia School of Osteopathic Medicine and completing her residency at Ellis Medicine in Albany. Dr. Mack brings extensive experience in family medicine, women's health, rural and community-based care, telehealth, home visits, palliative care and treatment for opiate use disorder. She is a member of the NYSAFP Board of Directors and past Chair of the Public Health Commission.*

Rabies Pre and Post Exposure Prophylaxis

By William Klepack, MD

This article will focus on rabies, a disease which has been aggressively and well controlled due to public health measures. Rabies prevention is a year-round problem that has seasonal fluctuation. I will review the essential components of prophylaxis, the levels of exposure risk, important considerations for those with immunocompromising conditions, and considerations for those who have had prior treatment or whose therapy is interrupted.

Family physicians who deliver primary care are very familiar with most vaccinations that are routine in the United States. They have less opportunity to become familiar with the role public health plays in controlling many diseases and preventing community spread. That role often involves conducting a case investigation to determine if treatment is warranted, and rabies exposures present a somewhat complex case investigation. For family physicians, being generally familiar with this process is helpful in understanding your patient's situation and knowing when to contact public health should your patient be at risk.

Many patients and not a few physicians think of rabies treatment as arduous, unpleasant, and involving many, many injections. That has not been the case for several decades. Treatment is well tolerated, expeditiously delivered, and lifesaving. Rabies (just to reinforce the point) is a nearly 100% fatal disease which has no specific treatment.

Requirement to Report

Public Health Law and State Sanitary Code stipulate that physicians are mandated to report all potential rabies exposures to their local health department (LHD). At the county level the LHD is your point of first contact for information and services and in most cases take responsibility for evaluating the case and ensure appropriate steps are taken including (when indicated) rabies post-exposure prophylaxis (RPEP). This service is of great benefit to you. There is no need for the family physician to bear the burden of determining whether RPEP is warranted for a disease that has a very high fatality rate.

Pre-Exposure Prophylaxis (PrEP)

Some individuals by virtue of their occupation or avocation should receive vaccination prophylactically. These are enumerated in Table 1 at the end of the article. When in doubt your LHD can make the determination. Vaccination is urged for these individuals since they may have unrecognized exposures to rabies (e.g., laboratory personnel working with the virus, and veterinarians).

Their subsequent treatment if a *recognized* exposure occurs is dependent on having had a timely satisfactory post vaccination serological test. See Figure 1 below. The RPEP regimen required is quite different compared to those who have not had PrEP.

Figure 1

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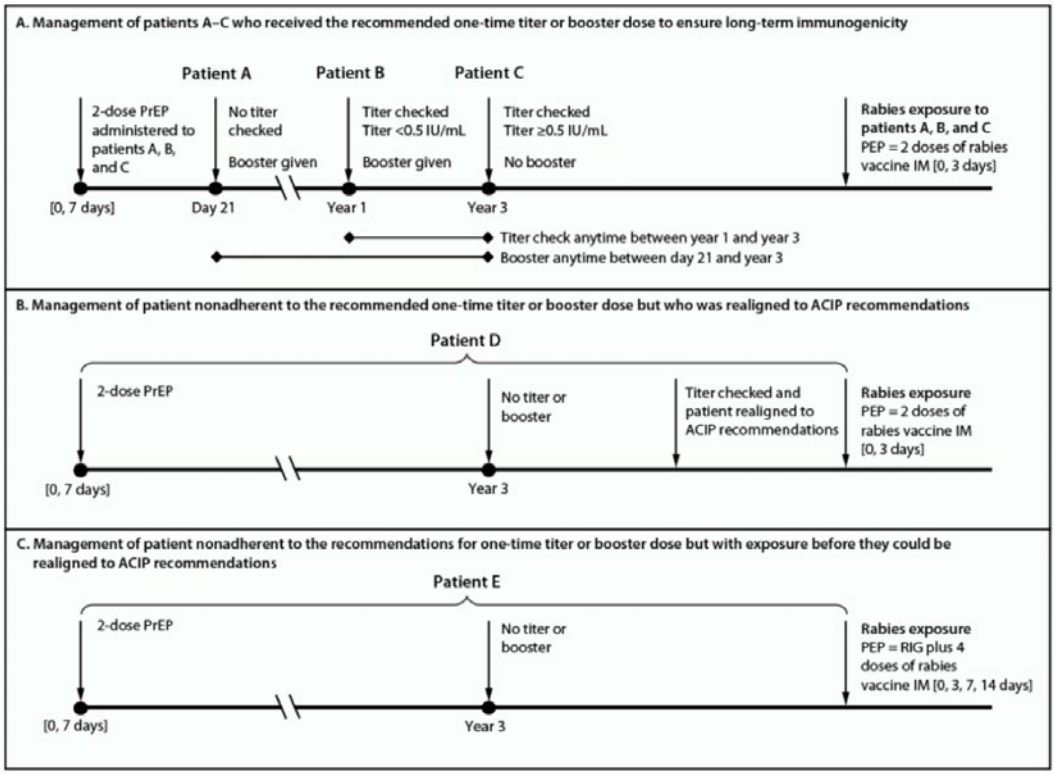
FIGURE. Management of long-term immunogenicity* for hypothetical patients (A–E)†,§,¶ who received the Advisory Committee on Immunization Practices recommended 2-dose rabies preexposure prophylaxis schedule** and have sustained risk for recognized exposures (risk category 3) — Advisory Committee on Immunization Practices, United States, 2022



http://dx.doi.org/10.15585/mmwr.mm7118a2external

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PrEP is administered by some county LHDs, clinics specializing in occupational issues, some colleges/universities, and other settings where stocking the vaccine is practical, and the volume justifies it.

Rabies Post-Exposure Prophylaxis (RPEP)

The RPEP regimen varies depending on factors outlined below in Table 2. However, an absolute requirement is that human rabies immune globulin (HRIG) must be given at the initiation of RPEP unless the person has received prior vaccination either as PrEP or having previously had RPEP. HRIG must be given at the same time as the first dose of vaccine.

Should you become aware that your patient started RPEP, be sure to verify that they did receive HRIG. The most common mistakes made in emergency rooms and urgent care settings in rendering RPEP care are: HRIG was omitted; failing to infiltrate the wound with some or all the HRIG; the HRIG dose was inadequate,; or using the buttock for the site of vaccine injection. These mistakes occur despite frequent teaching of personnel and provision of written guidelines. Should you become aware that there might be a problem contact your LHD and they will investigate.

Table 2

RPEP Regimens Based on Prior Status:

RPEP for exposed persons *never* previously vaccinated for rabies:

For all persons who have never been previously vaccinated for rabies, RPEP includes:

- Wound management
- Administration of Human Rabies Immune Globulin (HRIG)
- Administration of four doses of rabies vaccine on days 0, 3, 7, and 14
- Administration of a fifth dose of rabies vaccine on day 28 for persons with *immunosuppression*

RPEP for exposed persons previously vaccinated for rabies*:

- Wound management, *plus*
- Two doses of rabies vaccine given on day 0 and day 3

*Previously vaccinated persons are those individuals who have received either:

A complete rabies pre-exposure or post-exposure prophylaxis regimen in accordance with ACIP recommendations using a modern, cell culture-derived rabies vaccine or

Rabies vaccination following another protocol or with another vaccine with a subsequent documented rabies virus neutralizing antibody titer.

Wound Management

All RPEP should begin with immediate, thorough wound cleansing with soap and water and irrigation of the wound with a virucidal agent such as povidone-iodine solution. Following immediate wound management, contact your LHD by phone to get instructions as to where to send the patient for day 0 treatment. This will include administering at least some HRIG into the site(s) where the wound(s) are or (if healed) occurred.

Treatment failures have been documented in other countries when HRIG was not administered at the site of the actual wound(s).

Rabies Vaccine Administration Considerations:

Although you will likely not be called upon to give the vaccine you should know the following to ensure your patient has been treated properly. Immediately notify your LHD if:

- A dose of vaccine has erroneously been given in the gluteal area (which may result in lower neutralizing antibody titers).
- Rabies vaccine was given in the same muscle as HRIG which may inactivate the vaccine. (It is acceptable to give HRIG in the same limb as vaccine as long as they are administered in different muscles (e.g. HRIG in a bite wound on the hand, vaccine in the deltoid muscle of the same arm).

Exposure Type and Indications for RPEP

Human exposures to rabies can generally be categorized as bite, open wound, mucous membrane (eyes, nose, mouth), or other types of exposure. Bites are obvious. For the next two routes of exposure, these are the considerations:

Type of potentially infectious material must be:

- saliva
- cerebrospinal fluid
- spinal cord
- brain tissue

If an open wound it must be broken skin or a rash that weeps or bled within the past 24 hours).

Regarding the "other exposure" category - This category accounts for the greatest number of RPEP treatments delivered. It encompasses "any interaction with a rabid or potentially rabid animal where a bite, open wound, or mucous membrane exposure cannot be definitively ruled out." The vast majority of potential exposures are situations where a bat is found in a room with a sleeping person, unattended child, intoxicated or mentally compromised person. Most cases of clinical rabies in the U.S. have genetically been traced to a bat having been in a house. For more information on this see below.

Factors in Assessing Rabies Risk Exposure

- Is the animal a high-suspect for rabies? (rabies vector species include but are not limited to bat, raccoon, fox, skunk)
- Was their behavior abnormal for the species or were there changes in the behavior of a known animal? (e.g., stumbling, seizures, tremors, reduced or heightened excitability)
- Were there clinical signs compatible with rabies?

- Was it an unprovoked attack versus provoked attack?

Always err on the side of caution, and leave it to your LHD to determine whether an exposure is significant.

Role of Observation and Testing

Not all animals are suspect for rabies. Non-mammals are a large category which pose low risk.

The following are situations that **don't** warrant RPEP:

- Exposure situations of any type involving *wild/free- roaming* rabbits or small rodents (e.g., squirrels, chipmunks, rats, mice).
- Exposure situations of any type involving pet rabbits or small pet rodents (e.g., rats, mice) **housed exclusively indoors**. (Outdoor exposures of these animals could expose them to rabies – your LHD should make the determination.
- Contact with only blood, urine, feces (e.g., guano), milk, or spray (e.g., from a skunk) of a rabid or potentially rabid animal.
- Secondary exposure scenarios (i.e., contact with an animal, surface, or object that has had contact with a rabid or potentially rabid animal) if they do not meet the definition of an open wound or mucous membrane exposure.

All other animals should be captured, euthanized and tested. Doing so can obviate many people from having to receive HRIG. Bats account for the greatest number of exposures and capturing them would have the greatest impact. (For a video regarding how to "catch the bat" see references on page 28.)

Exposures by Volume and Unusual Exposures

In New York State during 2020, rabies virus infection was diagnosed in 347 animals including but not limited to 159 raccoons, 71 bats, 28 skunks, 31 cats, 34 foxes, 4 horses, 4 woodchucks, 4 deer, 3 bobcat, 3 cattle, 2 fishers, 2 dogs, and 1 ferret.

Cats remain one of the highest submitted animals for rabies testing. Cats are the most common *domestic* animal diagnosed with rabies in NY and are the 4th most common animal species in New York diagnosed with rabies overall. For both cats and dogs rabies infection is highly correlated with not being vaccinated or not being up to date.

It is safe to say that fewer than 1 bat in 10 or more exposure scenarios is captured for testing. Thus, a great number of people receive RPEP but wouldn't have had to if they had captured the bat. But, the risk of dying from rabies is too great to not treat.

Over the years I have seen rare cases of a rabid beaver, a rabid donkey in a petting zoo, and a wide range of domestic pets that fell ill with rabies. So, one must investigate these potential exposures carefully and conservatively. Your LHD is trained to do this.

Immunosuppressed Patients

Immunosuppression (either due to illness, medication, or therapy for an illness or condition) is a clinical diagnosis determined by the patient's physician. You may be called upon to make this determination.

Those who are immunosuppressed should receive a 5th dose of rabies vaccine on day 28. In addition, these patients should have their response to treatment assessed with serum antibody titers 1–2 weeks after finishing the postexposure treatment course (your LHD will likely arrange this to be done and reviewed and interpreted by them automatically). In general, it is better for you to err on the side of calling someone immunosuppressed than not given that this is a highly fatal disease.

Information on specific conditions that may cause immunosuppression can be found in the Advisory Committee on Immunization Practices (ACIP) General Recommendations on Immunization, available at: www.cdc.gov/vaccines/pubs/acip-list.htm.

When the Regimen is Interrupted

For a PrEP schedule interrupted – see Figure 1

For RPEP schedule variations:

- If a patient gets off schedule, your LHD will determine the course to take. Notify the LHD of non-compliant patients or those who have not been in touch with their LHD.
- Under no circumstances should the series be re-started.
- HRIG should not be administered more than once, except in certain circumstances determined by your LHD.

Initiation of Treatment

In general, RPEP should only be delayed when a suspect animal's rabies status can be determined with confinement/observation, or when laboratory test results will be available in a timely manner.

Exposure in Distant Past

For incidents involving bite, mucous membrane, open wound, or other exposures from an animal known to be rabid or is a high suspect for rabies but is not available for testing, RPEP should be initiated regardless of the length of time since the exposure occurred.

International Travel with or without RPEP

If a patient began RPEP in another country and needs to continue here and has not been in touch with the LHD, immediately consult your LHD to continue therapy.

Discontinuation of RPEP

If RPEP is started and the animal's rabies status is ultimately determined to be negative by laboratory testing or confinement/

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observation, RPEP is discontinued. Those who receive partial RPEP (2 or more doses of vaccine) should be advised to have a serum antibody titer drawn 1–2 months after the last vaccine dose in order to allow use of the shortened treatment course in the event of a future rabies exposure (if the titer is adequate). Two doses of vaccine constitute PrEP, however, to be valid for the future a serum antibody titer is also required. See Figure 1.

Risks of HRIG and Vaccine

Although low, the risk of PrEP or RPEP is not zero. In very special circumstances which mostly concern remote exposures, your LHD may counsel a patient about not being treated. These, however, are the exception. No life-threatening reactions from treatment have been reported to date. Decisions on the necessity for RPEP in lower-risk exposures should include consideration of the risk of treatment versus that of disease. The LHD is responsible for this discussion.

The Economics of Rabies Prevention

The estimated public health expenditures on rabies disease diagnostics, prevention, and control in the US is $245 to $510 million annually. This estimate includes:

- The vaccination of companion animals (dogs and cats)
- National rabies diagnostic testing
- Biologics for rabies postexposure prophylaxis (RPEP) and pre-exposure prophylaxis (PrEP).

However, the total expenditures for rabies accounting for associated healthcare costs, animal control measures, and time lost from work is much greater.

Is Cost a Barrier to Care?

Since urgent care centers, hospitals and health departments typically bill insurances for the care rendered, cost is **not** a barrier to care. **In NYS, any costs assumed by a citizen who is uninsured or having to pay deductibles or co-pays is borne by the taxpayer as a guarantee that no one will die of rabies due to economics.** Please remember to reassure your patients.

About 55,000 Americans get RPEP each year. Although the cost per treatment varies (typically from about $1,200 to $6,500), a course of rabies immune globulin and four doses of vaccine given over a two-week period average about $3,800, not including costs for hospital treatment or wound care. Typically, Day 0 treatment involves urgent care or hospital charges. Day 3 through day 14 (or 28) vaccinations are usually delivered by LHDs.

The cost per human life saved from rabies ranges from approximately $10,000 to $100 million, depending on the nature of the exposure and the probability of rabies in a region.

Conclusions

Family physicians are not called upon to deliver PrEP or RPEP to their patients. Being knowledgeable about the topic can help you identify patients who need LHD help, understand your patients' therapy, and answer their questions. PrEP and RPEP, education, and vaccination of animals have prevented all but a very few cases of rabies annually. You can help reduce rabies risk by advising your patients via your webpage, posters in the office and in conversation to:

- Bat proof their homes,
- Report all possible exposures to rabies,
- Capture bats for testing,
- Avoid contact with wild or unfamiliar animals,
- Vaccinate their animals, and
- If they are exposed to a potentially rabid animal to get sufficient information to enable the LHD to find, identify, and put the animal under observation.

Additionally, you can help ensure your patients received proper care by inquiring whether HRIG was part of day 0 treatment.

All potential exposure scenarios covered and not covered in this article should be discussed with your LHD. Together we can prevent rabies disease.

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New York State Guidelines

https://www.health.ny.gov/diseases/communicable/zoonoses/rabies/docs/nys_rabies_treatment_guidelines.pdf

Video on catching a bat: https://www.health.ny.gov/diseases/communicable/zoonoses/rabies/ The upper left corner has a box with video downloads.

How to capture a bat:
https://www.cdc.gov/rabies/animals/bats/index.html#capture

Batproofing with picture of a bat bite:
https://www.cdc.gov/rabies/pdf/BATS_Final_508.pdf

Printable rabies prevention bookmark:
https://www.health.ny.gov/publications/3011.pdf

Rabies information for children:
https://www.cdc.gov/rabiesandkids/

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Table 1 Rabies preexposure prophylaxis recommendations – United States, 2022

Risk category	Nature of exposure	Typical population*	Relevant disease biogeography‡	Recommendations	
				Primary PrEP§ immunogenicity	Long-term immunogenicity¶
1. Elevated risk for unrecognized** and recognized†† exposures including unusual or high-risk exposures	Exposure, often in high concentrations, might be recognized or unrecognized, might be unusual (e.g., aerosolized virus)	Persons working with live rabies virus in research or vaccine production facilities or performing testing for rabies in diagnostic laboratories	Laboratory	IM rabies vaccine on days 0 and 7	Check titers every 6 months; booster if titer <0.5 IU/mL§§
2. Elevated risk for unrecognized** and recognized†† exposures	Exposure typically recognized but could be unrecognized; unusual exposures unlikely	Persons who frequently 1) handle bats, 2) have contact with bats, 3) enter high-density bat environments, or 4) perform animal necropsies (e.g., biologists who frequently enter bat roosts or who collect suspected rabies samples)	All geographic regions where any rabies reservoir is present, both domestic and international	IM rabies vaccine on days 0 and 7	Check titers every 2 years; booster if titer <0.5 IU/mL§§
3. Elevated risk for recognized†† exposures, sustained risk¶¶	Exposure nearly always recognized; risk for recognized exposures higher than that for the general population and duration exceeds 3 years after the primary vaccination	Persons who interact with animals that could be rabid***; occupational or recreational activities that typically involve contact with animals include 1) veterinarians, technicians, animal control officers, and their students or trainees; 2) persons who handle wildlife reservoir species (e.g., wildlife biologists, rehabilitators, and trappers); and 3) spelunkers	All domestic and international geographic regions where any rabies reservoir is present	IM rabies vaccine on days 0 and 7	1) One-time titer check during years 1–3 after 2-dose primary series; booster if titer <0.5 IU/mL,§§ or 2) booster no sooner than day 21 and no later than year 3 after 2-dose primary series†††
		Selected travelers. PrEP considerations include whether the travelers 1) will be performing occupational or recreational activities that increase risk for exposure to potentially rabid animals (particularly dogs) and 2) might have difficulty getting prompt access to safe PEP (*e.g.*, rural part of a country or far from closest PEP clinic)	International geographic regions with rabies virus reservoirs, particularly where rabies virus is endemic in dog populations		
4. Elevated risk for recognized†† exposures, risk not sustained¶¶	Exposure nearly always recognized; risk for exposure higher than for general population but expected to be time-limited (≤3 years from the 2-dose primary PrEP vaccination series)	Same as for risk category 3 (above), but risk duration ≤3 years (e.g., short-term volunteer providing hands-on animal care or infrequent traveler with no expected high-risk travel >3 years after PrEP administration)	Same as for risk category 3 (above)	IM rabies vaccine on days 0 and 7	None
5. Low risk for exposure	Exposure uncommon	Typical person living in the United States	Not applicable	None	None

http://dx.doi.org/10.15585/mmwr.mm7118a2external
*Abbreviations have been omitted due to space constraints. Contact penny@nysafp.org for complete list.

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NYS annual reports on Rabies https://www.wadsworth.org/programs/id/rabies/reports

The Economics of Prevention https://www.cdc.gov/rabies/location/usa/cost.html

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William Klepack, MD *is Medical Director of the Tompkins County Health Department and a retired private practice family physician. Send questions or comments to wklepack@tompkins-co.org*

Recognizing Occult Immunosuppression in Primary Care

By Andrew J. Jacobs, MD and Ani A. Bodoutchian, MD, MBA, FAAFP, CPE

Introduction

There is a correlation between the rise in iatrogenic immunosuppression to the increased use of biologic agents for rheumatologic and dermatologic conditions, as well as the widespread use of systemic corticosteroids in urgent care practice.[1] Centers for Disease Control and Prevention (CDC) vaccination guidelines include iatrogenic immunosuppression as an indication for supplementary vaccination.[2] Immunocompromised patients are particularly susceptible to encapsulated gram positive bacteria. Given the currently available vaccines in the United States, protection for the immunocompromised patient centers around pneumococcal and varicella vaccination, and the recent, and rapidly evolving evidence supports supplemental vaccination against SARS-CoV-2. Systemic fragmentation of medical care and current reimbursement models disincentivize provision of recommended vaccinations for immunocompromised patients. Furthermore, vaccine resistance among both patients and some physicians has obstructed the risk-stratification and vaccination of immunocompromised patients. As is often the case for primary and secondary prevention, it falls to the family physician to navigate these challenges.

The Problem

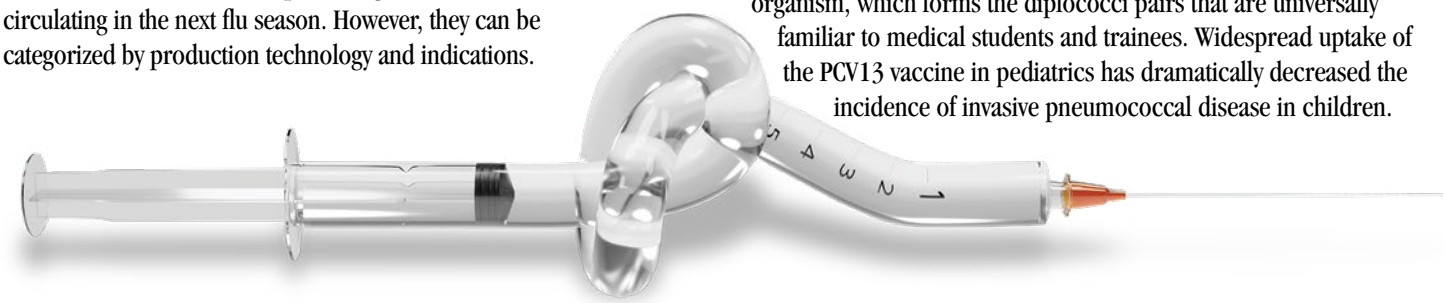
The development and use of immunosuppressive agents is one of the great achievements of modern medicine, and they are utilized, at least to some extent, by nearly every medical specialty.[3] There is an increasing use of biologic agents in the treatment of a number of rheumatologic conditions[4], as well as the increasing use of corticosteroids.[5,6]

Iatrogenic immunosuppression is an indication for deviance from the standard adult CDC vaccine recommendations. Numerous barriers exist to the implementation of these recommendations in the outpatient practice setting.

Influenza

Influenza is perhaps the most common vaccine-preventable disease encountered by the family physician. Often dismissed as a simple annoyance by the healthy adult or by parents, influenza causes 12,000-52,000 annual deaths in the United States.[7,8]

The precise number, composition, and brand-names of influenza vaccines available in the United States varies from year-to-year due to the CDC's unenviable task of predicting which strains will be circulating in the next flu season. However, they can be categorized by production technology and indications.



Influenza Inactivated (IIV4)

This is the *classic flu shot* envisioned by most patients and clinicians. These are traditional vaccines, with influenza virus painstakingly cultured in either chicken eggs or mammalian cell lines, before being purified and inactivated. These vaccines are indicated for adults of any age and can be used in patients aged 65 and older if high dose vaccines are unavailable. Of note, vaccines produced using mammalian cells (current brand name Flucelvax Quadrivalent) are devoid of egg proteins and may safely be administered to patients with reported egg protein allergy.

Influenza Recombinant (RIV4)

These vaccines are produced using contemporary recombinant protein technologies and therefore lack egg protein. Like IIV4, they are indicated for adults of any age. Interestingly, due to their design, they contain three times the quantity of antigens as IIV4 vaccines.[9] Although there are currently no evidence-based recommendations for a preference for RIV4 in immunosuppressed patients under 65 years of age, logically this may be the preferred vaccine if available, however further research is needed. See Figure 1.

Influenza Live Attenuated (LAIV4)

Indicated in patients ages 2-49, this vaccine technology permits administration in an intranasal spray. It use may be a reasonable option for healthy young patients to increase vaccine acceptance. However, because it is a live vaccine, it is contraindicated in immunosuppressed patients.[9]

High Dose Influenza Vaccine and Adjuvanted Influenza Vaccine

These are egg-derived inactivated vaccines, similar to IIV4, that are approved for use in patients aged 65 and above. They promote increased immunogenicity by either increasing the quantity of antigen delivered (Fluzone High-Dose Quadrivalent) or by including a proprietary compound, which increases the immunogenicity of the administered viral antigens (Fluad Quadrivalent).[10] Currently, these vaccines are not approved for use in iatrogenically immunosuppressed patients under the age of 65. This is an area in need of further research.

Streptococcus Pneumoniae

Streptococcus pneumoniae is a familiar foe to the family physician. First isolated by Louis Pasteur in 1881, it is a gram-positive anaerobic organism, which forms the diplococci pairs that are universally familiar to medical students and trainees. Widespread uptake of the PCV13 vaccine in pediatrics has dramatically decreased the incidence of invasive pneumococcal disease in children.

These bacteria remain a danger to our adult patients and in particular those who are immunocompromised.

Pneumococcal vaccination is indicated in adults 65 years of age and older, and immunosuppressed adults 19-64 years of age. There exists a substantial challenge in selecting the most appropriate vaccine.

There are two groups of pneumococcal vaccines available in the United States:

- PPSV23 is a polysaccharide vaccine and contains purified capsular polysaccharides which are moderately immunogenic.[11]
- PCV13, PCV15 and PCV20 are conjugate vaccines, meaning that capsular polysaccharides are bonded to a highly immunogenic diphtheria toxoid. This increases the immunogenicity of the vaccine.

For immunosuppressed adults ages 19-64, who have never received a pneumococcal conjugate vaccine, or those with unknown vaccination history, both PCV15 and PCV20 are indicated.[12] While PCV20 is a single-dose series, PCV15 must be followed up by a dose of PPSV23. The standard minimum dosing interval between PCV15 and PPSV23 is one year. Iatrogenic immunosuppression, however, is an indication for a reduced interval of eight weeks. This is in recognition of a higher risk of invasive pneumococcal disease in this patient population.[12]

With the introduction of childhood PCV13 vaccination in 2010, the family physician encounters young iatrogenically immunosuppressed adults who have completed a series of PCV13. The use of PCV15 or PCV20 have not been adequately studied in this group. Accordingly, it is recommended that these patients only receive a dose of PPSV23.

In summary, for the adult immunocompromised patient who has never received a pneumococcal conjugate vaccine, PCV20 is likely the best option as it is a single dose. If PCV20 is unavailable, PCV15 followed by PPSV23 at least 8 weeks later would be the alternative regimen.

Zoster

Cutaneous herpes zoster eruptions are rarely life threatening, but exquisitely painful to many patients. This often results in clinic visits, missed days of work, and the further administration of immunosuppressive systemic corticosteroids. Computed tomography scans and coronary angiograms may be performed for undifferentiated abdominal or chest pain prior to the observance of the dermatomal rash.

Immunocompromised patients under the age of 50 are thought to have a risk of shingles equal to, or possibly greater than, immunocompetent patients over the age of 50.[13] Prior to the FDA's approval for the use of the recombinant 2-dose RZV vaccine in immunosuppressed and immunocompromised patients in 2021, there was no option for vaccinating this group. The previously available live attenuated vaccine (Zostavax) was contraindicated in immunocompromised patients.[14]

COVID-19

The recommendations for SARS-CoV-2 are continually evolving, and likely to change between the time this manuscript is written and its publication. Of note is the plethora of conditions that have been associated with increased morbidity and mortality from COVID-19. This has resulted in fairly liberal criteria for supplemental vaccination such as with a second booster mRNA vaccine. In this current digital age of vaccine misinformation and political divide, it is often more challenging to convince patients to get vaccinated, rather than identifying an indication for it.

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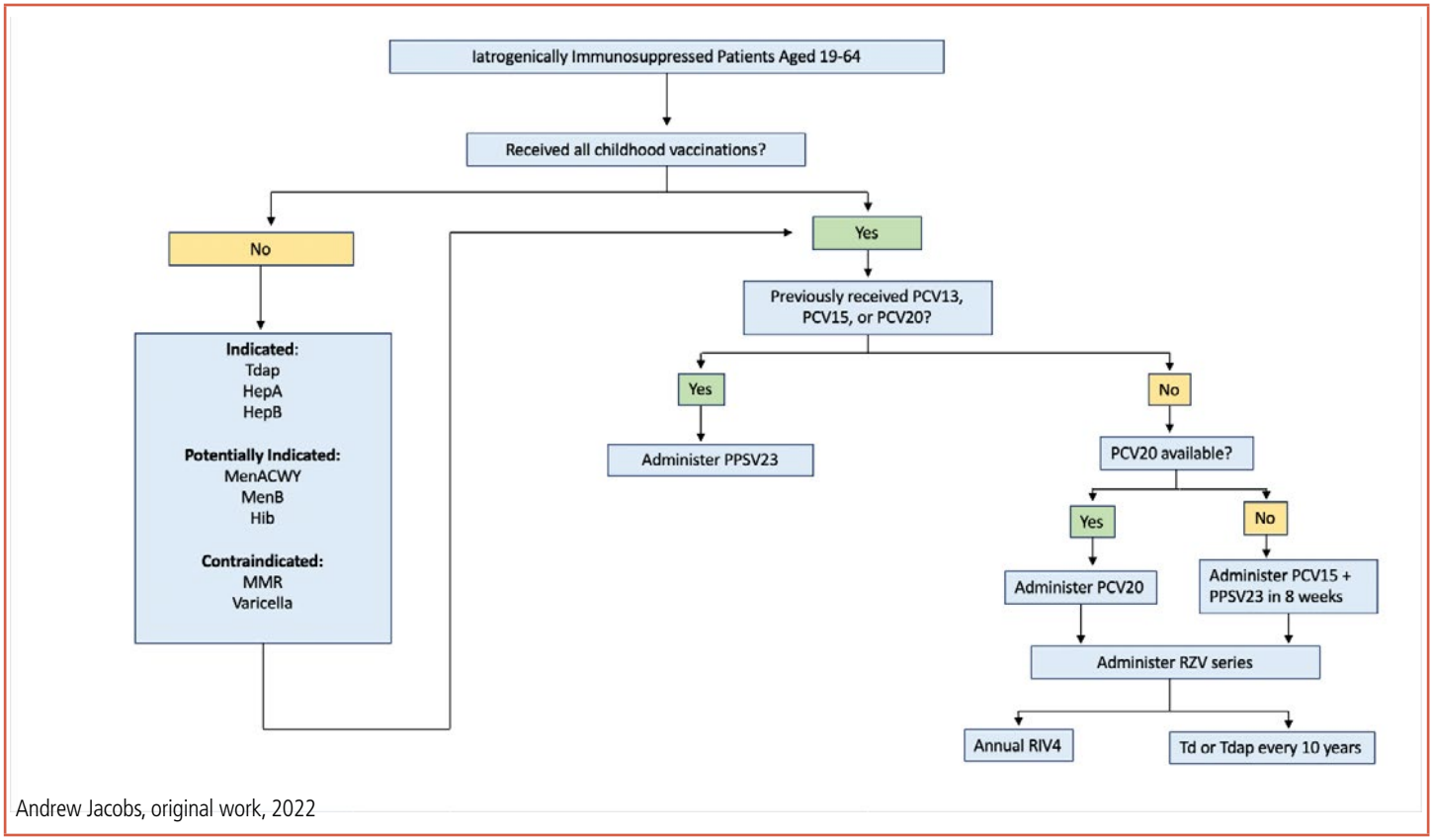
Figure 1. Suggested simplified vaccination algorithm for iatrogenically immunosuppressed adults aged 19-64.



Andrew Jacobs, original work, 2022

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Conclusion

The development and use of immunosuppressive agents is one of the great achievements of modern medicine. Immunosuppressant medications are utilized, at least to some extent, by nearly every medical specialty. Classic cases of immunosuppression will be obvious in the case of solid organ transplant recipients, chemotherapy patients, and chronic alcohol abusers. However, the increasing use of biologic agents and corticosteroids means that patients will present for both routine and acute care with more subtle iatrogenic immunosuppression.

The Food and Drug Administration (FDA), CDC, and Advisory Committee on Immunization Practices (ACIP) all recognize iatrogenically immunosuppressed patients as being at higher risk for vaccine-preventable illnesses than the general population and have issued approval and guidance for supplementary vaccinations in this population. Complicating this is a patchwork of public and private reimbursement schemes, which do not universally incentivize, or even fully compensate, physicians to provide these vaccinations. On the micro level, it is the individual family physician's challenge to identify patients with iatrogenic immunosuppression, and to recommend appropriate supplementary vaccinations. On the macro level, it is a challenge for the public health agencies and professional medical societies to advocate for a preventive medicine paradigm in which all public and private health insurers are mandated to fully reimburse for all indicated vaccinations.

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Andrew J. Jacobs, MD *is a board certified family physician. He graduated from Hofstra-Northwell School of Medicine. He completed residency training at Southside Hospital-Northwell, and currently practices urgent care medicine at CityMD on Long Island. He has numerous publications and presentations at regional, national, and international conferences. His research interests include public health, epidemiology, and quality improvement.*

Ani Bodoutchian, MD, MBA, FAAFP, CPE *is board certified in family medicine. She graduated from the Universidad Autonoma de Guadalajara School of Medicine in Mexico, completed residency at South Shore University Hospital, Northwell Health and has been serving the Suffolk County community for the past 21 years. Dr. Bodoutchian has served on numerous committees and was elected president of the medical staff/board while at South Shore University Hospital. Dr. Bodoutchian is currently Clinical Associate Professor at Stony Brook Medicine, Associate Professor of Family Medicine Stony Brook School of Nursing and has been involved in teaching medical students, residents, fellows, and nurse practitioner students for over two decades. She has numerous publications as well as multiple presentations locally, regionally, nationally, and internationally. She is active in numerous medical organizations and currently serves NYSAFP as Board Secretary, Chair of the Membership Commission, Delegate to MSSNY, and as an editor of* Family Doctor.

The First Vaccine:
A Practical Discovery by Village Doctors

By Thomas C. Rosenthal, MD

In Leviticus, the Bible describes garments spreading disease. The mummy of Egyptian pharaoh Ramses V (died: 1156 BC) bears the scars of smallpox. In AD 108, a smallpox epidemic marked the decline of the Roman Empire. Smallpox terrified communities because of fatality rates ranging from 20% for healthy adults to 80% for infants. Even survivors were left with disfiguring scaring.[1] Ancient and modern religions all attributed plagues, epidemics and fevers to a curse by an angry spirit.

For centuries, to say that something was contagious was to say that it acted like smallpox. It would take the scientific enlightenment of the nineteenth century before anyone could imagine that anything as small, or smaller than bacteria could cause these devastating scourges. Yet, blankets used by smallpox victims were known to carry some vital element that spread the disease, and isolation was the only known way to limit its spread. Some argued the vital element was a chemical; others thought it might be one of the Leeuwenhoek animalcules he described in 1673, and traditionalists stuck with the idea that a bad air miasma transmitted smallpox. No smallpox animalcule could be identified under the microscope, so if smallpox was spread by bacteria (today's word for animalcule), it had to be very, very tiny. In 1728, the word virus came into use to describe a contagious element so much smaller than bacteria that it passed through filters. Fortunately, it did not take a complete understanding of these vital elements for the discovery of vaccination.

Smallpox began with high fever, intense headache, and muscle pain. On the third day pustules erupted on the forehead and scalp, soon spreading over the body, including the mouth, nose and throat. The pain was intense, the putrid odor stifling, and delirium was common. Ten to fourteen days of suffering brought death or recovery. Smallpox spread through upstate New York in 1837 killing as many as thirty percent of its victims, including thousands of Native Americans.[2]

Dating back to the Egyptian pharaohs, survivors of smallpox were recruited to nurse the sick and ill because they had lifetime protection from smallpox. History has lost the origin of the idea that a mild and survivable case of smallpox might induce this lifetime protection. As early as 430 BC, medicine men in Africa, India, and China accomplished this magic using a small drop of smallpox pus on scarified skin. In 1670, traders introduced inoculation (aka variolation, variola being Latin for pustule) to the Ottoman Empire. In 1714, the Royal Society of London received a letter from Lady Mary Wortley Montague, wife of the British ambassador to the Ottoman court that described the Istanbul technique. At her urging, Dr. Charles Maitland was granted a royal license to perform a trial of variolation on a group of orphans and Newgate prisoners. All participants survived the procedure and, when exposed to smallpox, they showed no signs of disease. More widespread use of variolation followed and it became clear that, while most recipients spent ten days feeling quite ill, 2% to 3% died. There were also occasions when recently inoculated patients spread smallpox to their family or friends. None-the-less, variolation was ten times safer than the natural disease.[3]

Inoculation reached America in 1721 when a slave belonging to Boston's Reverend Cotton Mather demonstrated a scar on his arm from an inoculation he received as a child in Africa. After testing the technique on several family members, Mather joined with Dr. Zabdiel Boylston to convince many of his parishioners to be inoculated. Later that year a ship from the West Indies brought an epidemic of smallpox to Boston. The fatality rate among Mather's inoculated parishioners was 2% while the uninoculated experienced a 14% mortality.[4] Later, George Washington would credit American's ultimate victory to his 1777 order that all colonial soldiers be smallpox inoculated.[1]

In 1757 England, an 8-year-old boy was inoculated with smallpox as the disease waxed and waned throughout the British Empire. The boy's name was Edward Jenner. At age 13 he was apprenticed to a village surgeon who, along with many other village doctors, had observed that dairymaids with a history of the milder cowpox disease seemed protected from smallpox. Moreover, a number of village physicians were substituting the pus from cowpox

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pustules for inoculations. On May 4, 1796, Edward Jenner, now forty-seven and a well-regarded naturalist, happened upon Sarah Nelms, a young dairymaid with fresh cowpox lesions on her hands and arms. Recalling his earlier experience, Jenner used matter from Nelm's lesions to inoculate James Phipps, an 8-year-old boy. James experienced a mild fever and discomfort in the axillae for about 10 days. Two months later Jenner exposed the boy to smallpox. No disease developed.[1]

Over the next two years, Jenner carefully documented several cowpox inoculations and in 1798 he published the first edition of a pamphlet entitled *An Inquiry into the Causes and Effects of the Variolae Vaccinae*. A second edition in 1802 added details from twenty-three cowpox inoculations and several cases of natural inoculation occurring among those exposed to the pustules on cattle.[5] In the pamphlet Jenner acknowledged village doctors for being the technique's pioneers. Hoping to differentiate this safer technique from the more dangerous inoculation, he called it 'vaccination' based on vacca, the Latin word for cow.[1] Though vaccination was not original to Jenner, he was the first to carefully document cases and offer an explanation of the science, as he understood it. Jenner spent the next several years relentlessly promoting his technique and, in the process, changed the way medicine was practiced worldwide.[1]

In 1800, Jenner sent some cowpox material to Benjamin Waterhouse, a professor of physic at Harvard University. Dr. Waterhouse vaccinated his 5-year-old son and six servants. None contracted smallpox when purposely exposed some months later. Initially hoping to become wealthy, Waterhouse sought to franchise the distribution of cowpox, but soon he was bypassed by physicians who ordered their own cowpox from the more generous Jenner. Waterhouse did manage to convince America's new president, Thomas Jefferson, to try vaccination among his slaves. Jefferson was so impressed that he appointed Waterhouse to establish a National Vaccine Institute to implement a vaccination program throughout the United States. Within a decade the Medical Society of the State of New York and its county chapters advocated for universal vaccination and by 1840, England banned the older inoculation technique.[1]

Throughout the first quarter of the nineteenth century, vaccination became very common, though some worried it was the 'devil's work' to interfere with God's plan.[6] Vaccination rates jumped every time news of another outbreak made the headlines of local newspapers as the efforts of New York's physicians to vaccinate every patient made the 1837 epidemic New York's last major outbreak.

In the 1890s, a second vaccination was recommended to assure lifelong immunity. The virus, so much smaller than Leuwenhoek's animalcules, was seen under the electron microscope in the 1930s. As late as the 1950s smallpox caused catastrophic epidemics in sixty-three countries. Finally, the World Health Organization began a global campaign of mandatory vaccination in 1967, and by 1977 smallpox was eradicated. In 1980, two centuries after Jenner's experiments documented observations made by village doctors, the World Health Assembly recommended that vaccination was unnecessary.[7] Today only two world laboratories maintain frozen vials of the smallpox virus.

It took a team, Jenner and village doctors, to discover safe vaccination. What is the next disease family doctors, teamed with today's specialists, will eliminate from the villages and cities we serve today?

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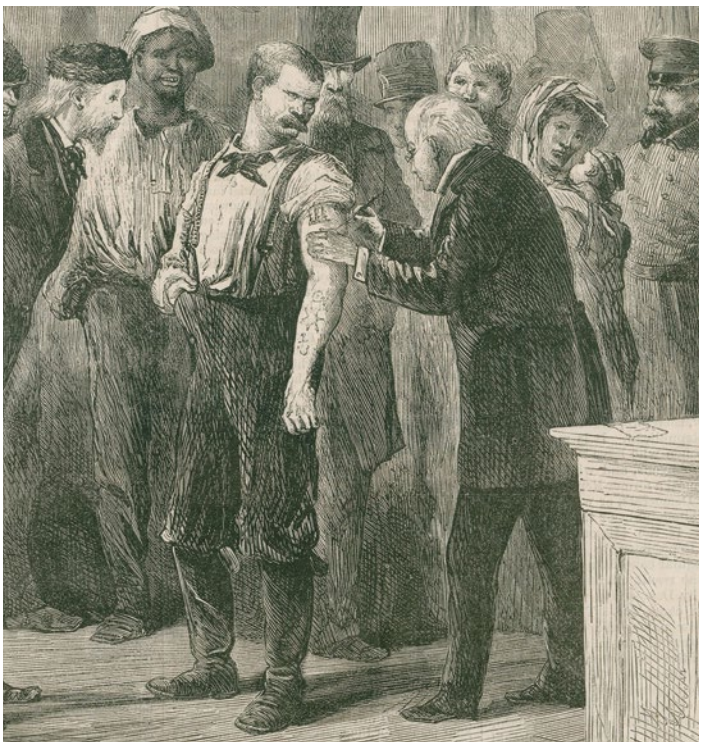
***Thomas Rosenthal, MD** is the author of* Bloodletting and Germs: A Doctor in Nineteenth Century Rural New York *(Amazon rated 5/5). He is professor and chair emeritus of Family Medicine at the University at Buffalo.*



Vaccine Vignettes:
Information and Insights to Enhance Your Practice

By Donna I. Meltzer, MD and Farah Haq, MD, MPH

Vaccinations are vital to public health and many vaccines are available with new ones always in development. Vaccine schedules are also complicated, and guidelines frequently change. Healthcare professionals who administer vaccines are responsible for counseling patients and their families in addition to ensuring the safe and appropriate delivery of vaccines.

The Centers for Disease Control and Prevention (CDC) officially sets the vaccines schedules for children, adolescents and adults based on recommendations from the Advisory Committee on Immunization Practices (ACIP), which solicits input from the American Academy of Family Physicians (AAFP) and the American Academy of Pediatrics (AAP). Family physicians care for patients of all ages and provide preventive care while tending to acute and chronic illnesses. On top of having to remember which vaccine and dose, age group and when to administer, one must tailor recommendations based on pregnancy, breastfeeding or immunocompromised states. There are some lesser-known immunization nuances and practices that might help us deliver safer, more efficient and patient centered healthcare. This article will highlight some of the complex scenarios that family physicians may encounter in daily office practice.

CASE 1: A 22-year-old male who is new to your practice presents to the office for a physical exam prior to entry into medical school. He is overall quite healthy and is up to date on all his vaccines. He has documentation from his previous family physician of two varicella and two MMR vaccines that were administered at appropriate ages and intervals. Should you order titers to document that he has sufficient immunity to measles, mumps, rubella, or varicella prior to engaging in patient contact?

No, per the Advisory Committee on Immunization Practices (ACIP), serologic testing for immunity to MMR or varicella is not required for healthcare personnel who have adequate presumptive evidence of immunity.[1]

In general, appropriate evidence of immunity to measles includes laboratory evidence of immunity (positive titer), laboratory confirmation of measles (a verbal history is not considered as acceptable evidence), two doses of measles-containing vaccine and birth before 1957.[2,3] Healthcare workers who have two documented doses of MMR are considered immune regardless of the results of subsequent serologic tests for measles, mumps or rubella.

Similarly, the ACIP considers an individual to have immunity to varicella if there is written documentation of two doses of varicella that were administered at appropriate ages and intervals; a healthcare provider's diagnosis of varicella infection; verification of a history of varicella or a history of varicella zoster; laboratory evidence of either confirmation of disease or immunity; or birth in the United States (US) before 1980. However, US birth before 1980 is not considered acceptable evidence of immunity for varicella in healthcare personnel.

Family physicians often encounter patients who have appropriate documentation of vaccination of MMR or varicella and have titers drawn in a different setting indicating a nonimmune status to measles, mumps, rubella or varicella. The knee jerk response is to vaccinate with another MMR or varicella vaccine, but documented age-appropriate vaccination supersedes the results of subsequent serologic testing.[1] (One exception is the woman of childbearing age who should receive an additional dose of MMR if she has negative or equivocal serology for rubella.) If there is inadequate documentation of vaccination and the titer results for either MMR or varicella are nonimmune or equivocal, that individual should be immunized with two doses of MMR (separated by 28 days) or two doses of varicella. The recommendation to space out vaccines after administering a live vaccine is based on concern that the immune response might be impaired if another vaccine is given within the month.

Per the CDC, drawing titers after appropriate vaccination is not advised due to lack sensitive assays.[4] Commercially available laboratory testing for varicella antibodies is based on enzyme

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immunoassays (EIA) and can often detect antibodies that develop after a varicella viral infection but are generally not sensitive enough to detect vaccine induced antibodies. The assays that are more sensitive are not widely available and therefore the CDC does not recommend antibody titer testing after administration of varicella vaccines. In addition, studies have shown that 92%-99% of individuals develop antibodies after receipt of a second varicella vaccine. Similarly, the CDC does not recommend measles antibody testing after receipt of a MMR vaccine because commercial lab tests are often not sensitive enough to reliably detect vaccine-induced immunity. However, many healthcare organizations and health professional schools have requirements for serology and booster doses with negative titers that are not consistent with CDC regulations. It is unclear if these recommendations are due to lack of familiarity with CDC guidelines. The NYS Department of Health (DOH) follows the CDC guidelines.[5]

When a patient lacks documentation of appropriate vaccination against measles, mumps, or rubella, there is a tendency to check titers. The CDC does not recommend prevaccination antibody testing unless the medical facility considers it cost effective.[3,6] Healthcare personnel without evidence of immunity against varicella may get screening titers prior to vaccination. This might be a more cost-effective approach since 70-90% of adults who do not recall having varicella are found to have positive titers.

For clinicians who wonder about vaccine effectiveness, one dose of MMR is 93% effective for preventing measles, 78% for mumps and 97% for rubella.[3] Two doses of MMR offer on average 97% protection against measles and 88% for mumps. For rubella, the CDC considers a single dose of MMR vaccine as sufficient evidence of immunity.[1] Serologic and epidemiologic studies have demonstrated that while there is nearly lifelong protection against measles and rubella after appropriate vaccination, immunity to mumps may wane over time. In 2017, members of the ACIP unanimously approved the recommendation to consider a third dose of mumps virus containing vaccine (i.e., MMR or MMRV) when public health authorities consider individuals to be at an increased risk of acquiring disease during mumps outbreaks.[7]

CASE 2: A 54-year-old nurse presents to the office after sustaining a needle stick injury. She completed the 3-dose series of hepatitis B vaccination a decade earlier. How should you proceed?

A vaccinated health care worker who has written documentation of a complete hepatitis B series and post-vaccination hepatitis B surface antibodies (anti-HBs) >/= 10 mIU/mL) who subsequently sustains a needlestick injury does not need postexposure prophylaxis for hepatitis B virus (regardless of source patients hepatitis B surface antigen (HBsAg) status).[1,8] In this circumstance where there is documentation of a complete vaccine series and immunity, the source patient does not have to be tested for HBsAg. However, the health care worker with the needle stick injury should be tested for other blood borne pathogens such as hepatitis C and HIV.

When a health care worker has a written record of completing the hepatitis B series but lacks documentation of post-vaccination immunity (anti-HBs >/= 10mIU/ml), the source patient should undergo testing for HBsAg and the exposed worker should be tested for anti-HBs. If the antibody titer is less than 10 mIU/mL and the source patient is HBsAg-positive (or unknown status), the health care worker should receive one dose of hepatitis B immune globulin (HBIG) and begin revaccination against hepatitis B immediately, but at different anatomic injection sites. The health care worker should then complete the rest of the hepatitis B series. After completing the second vaccine series, it is recommended that the worker be checked for anti-HBs in 1-2 months. (See Table 1)

Healthy adults less than 40 years old who complete the traditional 3-dose hepatitis B series should anticipate seroprotection >90%.[8] Randomized controlled trials prompted the ACIP in 2018 to recommend a new yeast-derived vaccine with a novel adjuvant, HepB-CpG (Heplisav-B) as an option to prevent hepatitis B in individuals over 18 years.[9] Seroprotective antibodies (anti-HepBs) were higher with this new 2-dose series (administered over a month) than the traditional 3-dose series. Antibody responses to hepatitis B vaccination tend to decline with age and are only about 75% in individuals aged 60 years. Tobacco use, obesity, and chronic medical conditions might contribute to a less robust response to the hepatitis B vaccine. In April 2022, the CDC expanded hepatitis B vaccine recommendations to include universal vaccination of adults through 59 years without screening for risk factors and an option of vaccination for those 60 years and older without risk factors for hepatitis B.[10]

CASE 3: A 58-year-old patient who has rheumatoid arthritis is about to begin treatment for the disease that will make her immunocompromised. She is concerned about contracting shingles and asks you if she is a good candidate for the vaccine. You counsel her about the shingles vaccine, and she agrees to vaccination during that office visit. What is the earliest date that she can present for the second dose? What else should a clinician know about the shingles vaccine?

The second dose of recombinant zoster vaccine (RZV) (Shingrix) is normally administered 2-6 months after the first dose and the series does not need to be restarted if the second dose is given beyond this time frame. However, for individuals who are or will be immunosuppressed or immunodeficient, the second dose of the vaccine can be given 1-2 months after the initial dose.[11] If the second dose is given earlier than 4 weeks after the first dose, it does not count and a third dose of the vaccine should be administered at least 4 weeks after the second dose.

Initially, RZV was licensed in the US for adults 50 years of age or older. About one year ago, the ACIP recommended two doses of the vaccine for adults 19 years and older who are or will be immunosuppressed. Ideally, patients should be vaccinated prior to becoming immunosuppressed, but when that is not possible, vaccination should be timed when disease is stable and there is less immunosuppression.

Individuals who have had a history of shingles or received the live zoster vaccine (Zostavax) in years past are eligible to receive RZV. RZV is not for treatment of current zoster and should not be administered until zoster symptoms have lessened, and the acute stage is over. The live zoster vaccine is no longer available in the US.

Occasionally patients report never having a history of varicella or varicella vaccination and the question arises whether they are candidates for RZV. Technically, these individuals are not at risk for zoster, however 99% of Americans born in the US before 1980 have had varicella.[11] In the earlier publication, the ACIP did not recommend screening (either by history or laboratory testing) for varicella prior to giving RZV. Of note, children and adolescents who have received the live varicella vaccine are at a lower risk for zoster than those who have had varicella disease.

CASE 4: An 18-year-old who has always been home schooled presents for a physical exam prior to entering college. Although overall healthy, she has had sporadic preventive medical care and requires several catch up vaccines and screening for tuberculosis. She asks if you can administer the MMR and Tdap vaccines today and return next week for a varicella vaccine and PPD placement. As much as you would like to accommodate her request, you must suggest an alternate plan. Why?

Clinicians should recognize the importance of timing when ordering MMR vaccination and screening for tuberculosis. A measles (and possibly mumps, rubella and varicella) vaccine may transiently suppress the immune response and reactivity of the tuberculin skin test (TST) in a person with *Mycobacterium tuberculosis*. A TST can be placed on the same day as administering the MMR vaccine without interfering with reading the TST in 48 to 72 hours.[12] However, if a measles vaccine has been administered recently, the TST screening should be delayed for 28 days after vaccination to avoid concerns for theoretical transient suppression of TST reactivity. Data is not available for the potential TST suppression that may occur with other live attenuated vaccines such as varicella and yellow fever.

It may be tempting to troubleshoot this timing problem by ordering blood test alternatives such as the Interferon Gamma Release Assays (IGRAs) (i.e., QuantiFERON-TB Gold In-Tube test or T-Spot TB test) to screen for tuberculosis as it can be accomplished in a single office or laboratory visit. However, the same guidelines used for tuberculin skin testing and live vaccine administration apply to IGRAs.

A better scenario for this college bound student might be to administer the Tdap vaccines and place the PPD (or draw blood for IGRA) on the same visit and have the patient return for the MMR and varicella vaccines when the PPD is read in 2-3 days. The combination vaccine (MMRV) with MMR and varicella (ProQuad) is only licensed for use in children aged 12 months through 12 years so this would not be appropriate for our patient in this case. The minimal interval catch-up second dose of varicella vaccination is 4 weeks for those over 12 years of age. The minimal interval between the first and second dose of MMR is 4 weeks in all age groups. If an individual requires both MMR and varicella, the two live vaccines should be

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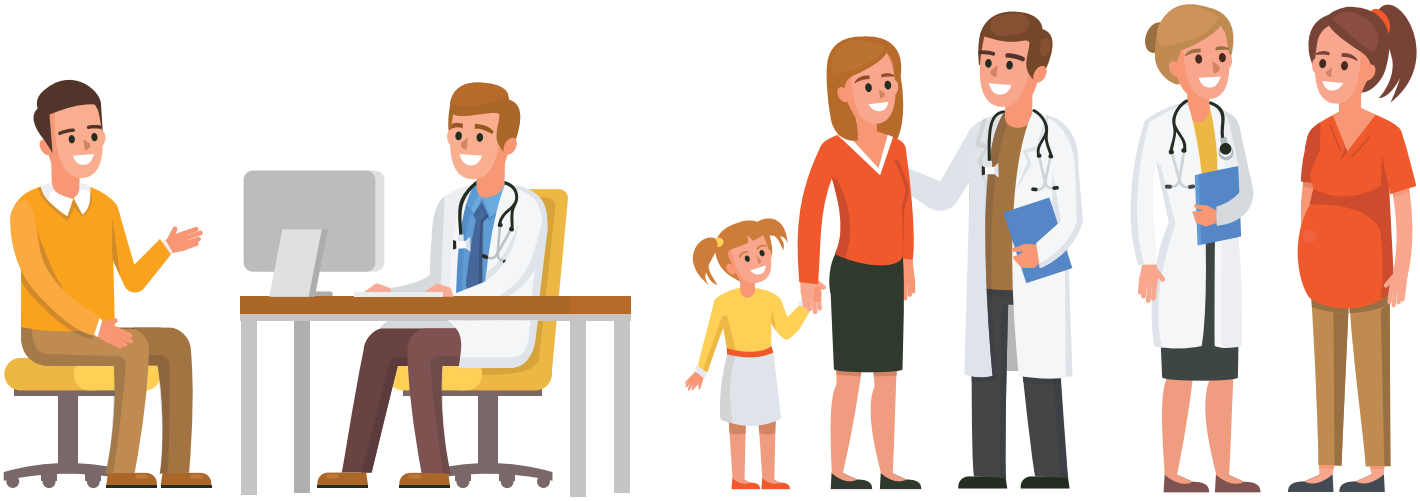

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administered on the same day. If not administered on the same day, one should wait 28 days before injecting a second live vaccine based on concern that the immune response is impaired when two live vaccines are given within four weeks of each other.

CASE 5: A mother of a two-year-old brings her son in for a well- child check. He attends day care and has had several ear infections and upper respiratory infections over the past several months. He is lagging behind in several vaccines and his mother wants to know how many vaccines he can receive in one visit.

Simultaneously administering all vaccines for which the child is eligible at the time of an office visit will increase the probability that he is fully vaccinated by the appropriate age. While the number of recommended vaccines has grown substantially over the years, the ACIP does not have a maximum number of vaccines that can be administered in the same setting. Routine childhood immunization schedules in the US currently include about ten vaccines directed against fourteen diseases in the first two years of life. Since many vaccines require additional doses to ensure immunity, a child may receive up to twenty-six separate vaccinations. (The SARS-CoV-2 (COVID-19) vaccines are not yet included in the CDC's Child/Adolescent Immunization 2022 Schedule, but dengue vaccine is for children 9-16 years old who live in endemic areas.) Combination vaccines licensed by the FDA have dramatically reduced the total number of injections, which makes it less distressing to clinicians, parents and child. Disadvantages to administering combination vaccines include potential adverse side effects, mix-ups or uncertainty about vaccine combinations and schedules.

One systemic review looking at issues related to multiple vaccine injections noted that healthcare personnel play a critical role in ensuring a child receives the recommended immunizations.[13] Younger or more recently trained providers were more apt to administer multiple vaccines in one setting. This review also demonstrated that clinicians tend to overestimate parental concerns which leads to delayed vaccinations. Family physicians are trained to take an open-ended approach with patients, but if this translates into not making a strong recommendation to immunize, parents may view vaccination as optional and defer them.

The AAFP, AAP and CDC do not support delayed or alternative vaccination schedules as postponing vaccination leaves children vulnerable to vaccine-preventable disease. Seroconversion rates and adverse reactions are similar for live and non-live vaccines that have been simultaneously administered compared to those that have been spaced out to separate visits. When giving multiple vaccines in one setting, injections should be separated by one inch to reduce the risk of overlapping localized skin reactions. Local reactions are more likely with DTaP and PCV so these vaccines should be administered in separate limbs but can be offered during the same office visit. Physicians who limit the numbers of vaccines that should be administered during an office visit are deviating from the standard evidence-based schedules recommended by authorities.

Additionally, a child may be vaccinated if suffering from a mild acute illness (i.e., common cold). Treatment with antibiotics is not necessarily a valid reason to defer vaccination if otherwise well and if less likely to return for another visit to immunize. Vaccination should be deferred if the child has a moderate or severe acute illness. Children who have been prescribed antibiotics for a moderate to severe illness should have immunization deferred until they recover from the illness.

CASE 6: A happily retired 70-year-old patient presents for a routine blood pressure check. He is up to date on all his health care maintenance and exercises regularly. He plans on wintering in the south and will be very busy with social engagements in September. The patient wants to know if he can get his annual influenza vaccine in August instead of waiting until October. How will you counsel him?

While delaying receipt of the influenza vaccine until later in the autumn or early winter seasons may lead to a higher levels of immunity during winter and early spring months, this should be balanced against possible risks, such as missed opportunities to receive the vaccine and difficulties a practice may encounter when trying to vaccinate a larger number of people within a shorter period of time.[14] Often, the ideal time to vaccinate individuals can also vary because the flu season fluctuates from year to year and some locations may have more than one outbreak within the year. Antibody levels tend to wane over time and might not afford adequate protection if the influenza vaccine is administered too early. Revaccination later in the season has not been recommended.

The NYS DOH tracks influenza activity in the state and publishes a weekly update (health.ny.gov/diseases/communicable/influenza/surveillance) during the flu season, which tends to run from October through May. The CDC has recommended that influenza vaccination be offered by the end of October. It takes about two weeks to build protective antibodies and protection should persist for at least six months. In the past year, there was a peak of influenza activity in NYS in mid-December and again in the months of April and May. Helpful information on influenza surveillance by county is also available on the DOH website.

So, our active senior citizen should be counselled to try to avoid early vaccination in July or August and ideally wait a month with a goal of being vaccinated against influenza before the end of October.

Vaccines serve an important function in preventing disease at the individual as well as population level. Family physicians play an essential role in promoting vaccine acceptance and administering the right vaccine dose at the right age and right time. It is challenging to stay abreast of all the vaccine innuendos and immunization schedules which are constantly undergoing evaluations, revisions and updates. Reviewing the new vaccine schedules released by the CDC annually and reading some of the footnotes is a good way to keep better informed and provide appropriate preventive care. The NYS DOH and CDC websites are outstanding resources for individuals seeking more information on vaccines and immunizations.

Endnotes

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Table 1: Management of Healthcare Worker after Hepatitis B Exposure

HCW	Source patient (HBsAg)	HCW Anti-HBs	Post-Exposure Prophylaxis	Post-Vaccine Serology Testing (1-2 months after final vaccine dose)
Vaccinated and Known Responder	+ or unknown	+ (no need to remeasure)	Not needed (already immune)	N/A
Vaccinated and Unknown Response	+ or unknown	–	HBIG x1 and revaccinate	Measure anti-HBs
	–	–	Revaccinate x 1 dose	Measure anti-HBs; if negative, complete vaccine series
	+, –, unknown	+	No post exposure prophylaxis	N/A
Vaccinated (two series) and Known Nonresponder	+ or unknown	– (No need to remeasure)	HBIG x2 (one month apart)	No
	–	– (No need to remeasure)	No post exposure prophylaxis	
Unvaccinated or Incomplete vaccine series	+ or unknown	– (No need to measure)	HBIG x1 and complete vaccine series	Check for Hep B infection (anti-HBc at baseline; 6 months later check HBsAg, anti-HBc) Defer post-vaccine anti-HBs until 6 months after HBIG
	–	– (No need to measure)	Complete vaccine series	Measure anti-HBs

Responder= anti-HBs >/= 10 mIU/mL Nonresponder= anti-HBs < 10mIU/mL

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Donna Meltzer, MD *is Clinical Associate Professor of Family Medicine and Associate Vice Chair of Patient Safety, Healthcare Quality and Compliance in the Department of Family, Population & Preventive Medicine at Stony Brook. She is a faculty member of the Renaissance School of Medicine and a former residency director.*

Farah Haq, MD, MPH *is Clinical Assistant Professor of Occupational Medicine in the Department of Family, Population & Preventive Medicine at Stony Brook and Director of the Adult and Travel Vaccine Clinic. She is a faculty member in the Renaissance School of Medicine.*

A Preventative Bucket List:
Pre-embarkation Vaccination

By Afeera Chaudhry, BS, Mayra Goreja, MS, Elizabeth Loomis, MD

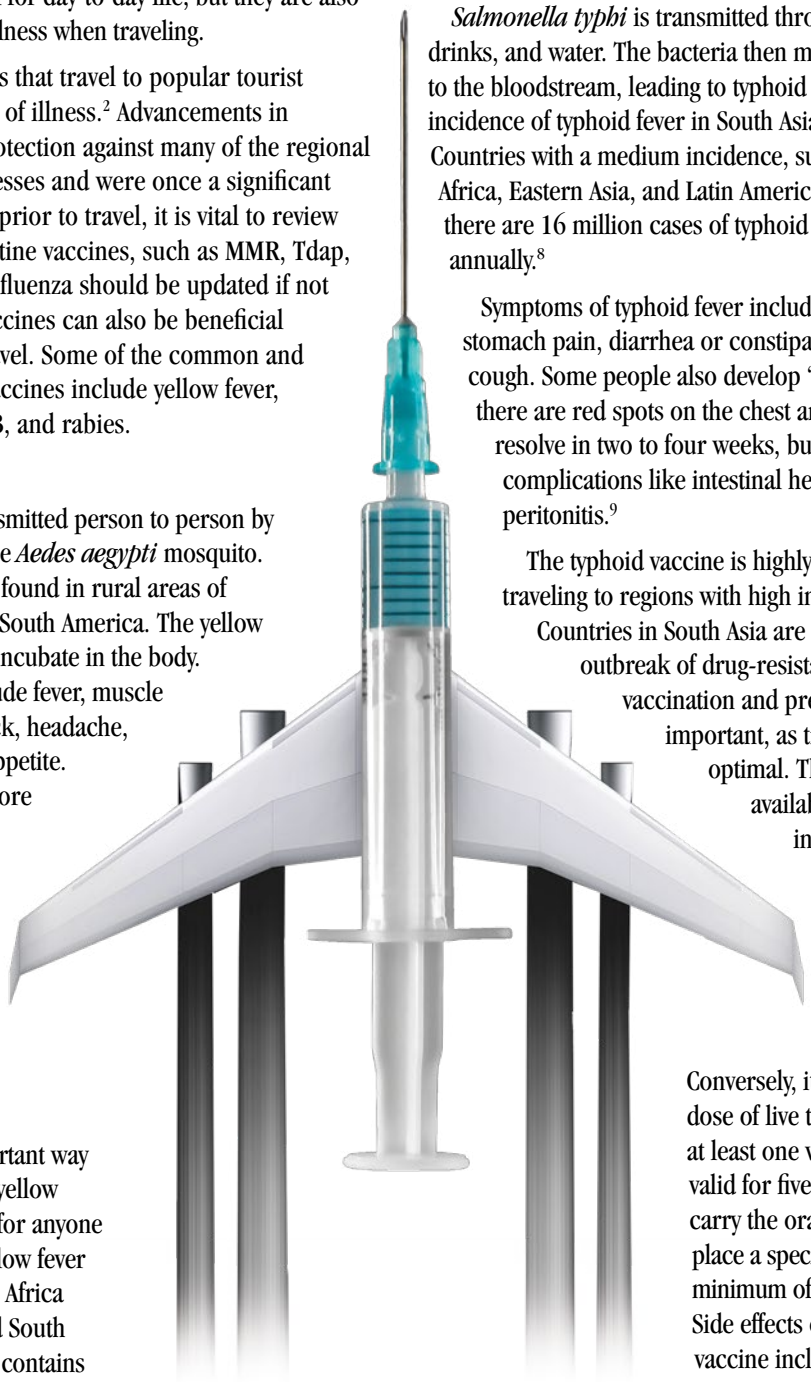
Introduction

Since the development of the first vaccine by Edward Jenner over 200 years ago, science has come a long way with vaccines against more than 50 preventable illnesses available today. It is estimated that vaccines prevent 6 million deaths annually and are credited as one of the major contributors to our increased life expectancy. Thanks to vaccines, widespread illnesses that were once a major threat to society now have minimal or no effect on the vaccinated population.[1] Vaccines are not only beneficial for day-to-day life, but they are also very important for preventing illness when traveling.

Each year, 64% of Americans that travel to popular tourist destinations report a symptom of illness.[2] Advancements in vaccinations have provided protection against many of the regional microbes that cause these illnesses and were once a significant obstacle for travel. Therefore, prior to travel, it is vital to review overall vaccination status. Routine vaccines, such as MMR, Tdap, poliovirus, SARS-CoV-2, and influenza should be updated if not completed.[3] Travel-specific vaccines can also be beneficial depending on the region of travel. Some of the common and most important of the travel vaccines include yellow fever, typhoid, hepatitis A, hepatitis B, and rabies.

Yellow Fever Vaccine

The yellow fever virus is transmitted person to person by mosquitoes, most commonly the *Aedes aegypti* mosquito. Outbreaks are most commonly found in rural areas of Africa, followed by Central and South America. The yellow fever virus takes 3 to 6 days to incubate in the body. Common initial symptoms include fever, muscle pain most prominent in the back, headache, nausea, vomiting, and loss of appetite. One in 7 people will develop more severe symptoms after a brief, initial remission. This can lead to the development of jaundice, dark urine, abdomen pain with vomiting, and bleeding from various places like the mouth, nose, eyes, and stomach.[4]



Vaccination is the most important way of preventing yellow fever. The yellow fever vaccine is recommended for anyone traveling to areas at risk for yellow fever virus, including 34 countries in Africa and 13 countries in Central and South America. The CDC yellow book contains more information on exactly for which countries the vaccine is recommended.[5] Most of these countries require proof of vaccination before issuing a visa. The yellow fever vaccine is a live attenuated vaccine, given as a single shot, which provides lifelong protection for most people; a booster is not needed. Reactions to the yellow fever virus are usually mild, including headaches, muscle aches, and a low-grade fever.[6]

Typhoid Vaccine

Salmonella typhi is transmitted through contaminated food, drinks, and water. The bacteria then multiply in the body and spread to the bloodstream, leading to typhoid fever.[7] There is a high incidence of typhoid fever in South Asia, followed by Southern Africa. Countries with a medium incidence, such as the remaining parts of Africa, Eastern Asia, and Latin America, also pose a risk. Each year, there are 16 million cases of typhoid fever, and 600,000 deaths annually.[8]

Symptoms of typhoid fever include a persistently high fever, stomach pain, diarrhea or constipation, loss of appetite, and cough. Some people also develop "rose spots," a rash in which there are red spots on the chest and abdomen. Symptoms usually resolve in two to four weeks, but some people may develop complications like intestinal hemorrhage, kidney failure, and peritonitis.[9]

The typhoid vaccine is highly recommended for anyone traveling to regions with high incidence of typhoid fever. Countries in South Asia are currently experiencing an outbreak of drug-resistant typhoid fever, which makes vaccination and preventative practices increasingly important, as treatment with antibiotics is not optimal. There are two types of vaccines available for prevention: an inactivated vaccine administered via a shot and a live oral vaccine. It is recommended that the inactivated typhoid vaccine is taken at least two weeks prior to travel, and it is valid for two years. Conversely, it is recommended that the last dose of live typhoid vaccine is administered at least one week prior to travel, and it is valid for five years. Most pharmacies do not carry the oral vaccine in stock and need to place a special order for it, which requires a minimum of one business day for shipping. Side effects of both the live and inactivated vaccine include injection site erythema,

fever, and headache while the live vaccine may have additional symptoms such as diarrhea, abdominal pain, and vomiting. Typhoid vaccines are unfortunately not 100% effective so practicing safe eating and drinking habits abroad help to prevent infection.[10]

Hepatitis A Vaccine

The hepatitis A virus (HAV) is transmitted from contaminated raw or inadequately cooked foods, such as fruits, vegetables, and seafood. Areas where HAV is highly endemic often have inadequate sanitation and limited clean water sources, serving as a reservoir for the virus; these areas include parts of Africa and Asia. Areas with intermediate endemicity of HAV, such as Central and South America, Eastern Europe, and parts of Asia, also pose a high risk for infection for travelers. High risk factors for HAV infection include users of injection drugs, men who have sex with men, individuals with chronic liver diseases, individuals with a blood clotting disorder, and individuals who are anticipating close contact with an international adoptee.[11]

Although it takes one to two weeks for symptoms to develop, people are infectious before the onset of clinical symptoms; it is at this time the concentration of virus is highest in the stool and blood. Infection manifestation can range from mild illness lasting 1-2 weeks to a disabling disease that lasts for several months. Symptoms include fever, malaise, nausea, and abdominal pain, which can be followed by jaundice days later. Severe hepatic and extrahepatic complications such as liver failure are more common in older individuals with underlying liver disease. Viral excretion and the risk of transmission diminish rapidly after liver dysfunction or symptoms appear.[12]

HAV is among the most common vaccine-preventable infections acquired during travel, as travelers of both developed and developing countries are at risk. Risk is highest for those visiting rural areas, hiking on backcountry roads, or consuming food in settings of poor sanitation. Individuals traveling to countries that have high or intermediate HAV endemicity should be vaccinated before traveling. The HAV vaccination, developed from an inactive virus, is a 2-dose series given 6-12 months apart; 95% of vaccinated people develop levels of anti-HAV appropriate for protection 1 month after the first dose is given. The vaccine should not be administered to travelers with a history of hypersensitivity to any vaccine component, including neomycin, but it is safe in pregnant women.[11]

Hepatitis B Vaccine

The Hepatitis B virus (HBV) is transmitted through contact with bodily fluids, such as blood, semen, breast milk, and urine. Exposure may occur through unhygienic medical or dental procedures, receiving blood products, use of intravenous drugs, tattooing or acupuncture (or any piercing of the skin), or unprotected sexual activity. Risk for HBV infection may be higher in countries where the prevalence of chronic HBV infection is greater than 2%, including the Western Pacific and African regions.[13]

Symptoms for HBV vary depending on the population acquiring the disease. Children under the age of 5 and immunosuppressed adults are generally asymptomatic if infected. Initial infection in children older than the age of 5 however, does manifest clinical symptoms; these symptoms include malaise, fever, fatigue, poor appetite, nausea, vomiting, abdominal pain, dark urine, light colored stool, joint pain, and jaundice. Some acute HBV infections will resolve themselves while others will develop into chronic infection. The risk of progression to chronic infection depends on the age of initial infection. People with chronic HBV infection will develop liver cirrhosis, hepatocellular carcinoma, or liver failure. People infected with HBV are susceptible to infection with Hepatitis D concomitantly; coinfection increases the risk of fulminant hepatitis that can rapidly progress to liver disease.[13]

The only treatment for HBV is supportive. Preventative practices are recommended for all international travelers, which includes prevention through vaccination. The HBV vaccine, a recombinant DNA vaccine, is administered as a three-dose series, with the second shot given one month after the first and the third shot given six months after the first. The vaccine is safe and available for all ages, including pregnant and breastfeeding women. Adverse reactions are minimal, including soreness at the injection site and fever.[14]

Rabies Vaccine

Rabies is a neurotropic virus transmitted through the saliva from the bite of a rabid mammal, with the most common hosts including dogs and bats. The virus travels through the peripheral nerves from the site of the animal bite to the central nervous system. Thus, the closer the bite is to the CNS, the shorter the incubation period is in the affected individual. Once the virus reaches the salivary glands, it can replicate and continue transmission. Canine rabies remains prominent in Africa, Asia, and parts of Central and South America. Bite by non-human primates is mainly common on the Indian subcontinent.[15]

Signs of illness begin after the asymptomatic incubation period, which varies due to the site of inoculation; this asymptomatic period can last from weeks to months. Pain and paresthesia at the site of exposure is the first clinical manifestation. Infection can rapidly progress, from a prodromal phase consisting of fever and vague symptoms, to encephalitis. Encephalitis manifests in patients as anxiety, paralysis, delirium, convulsions, and hydrophobia, where there are spasms of the swallowing muscle in response to the sight, sound, or perception of water. Clinical signs are rapidly followed by coma and death without intensive supportive care. Rabies is considered fatal and preventative measures, such as pre and postexposure prophylaxis, are the best and only proven way to optimize survival.[15]

The rate of rabies exposure in travelers is found between 16 to 200 per 100,000 travelers. Children are at a higher risk of contracting rabies due to their inquisitive nature and smaller stature. People traveling to endemic sites receive two pre-exposure immunizations before travel; partial immunization has not been proven to be beneficial. Pre-exposure vaccination does not eliminate the need for additional medical attention in the case of an animal bite.[15] See the article on page 25 of this issue for a complete description of rabies vaccination.

Conclusion

Vaccination occupies an important role in preventing illnesses while traveling. Although it is vital to ensure all vaccinations are up to date, it is important to take other steps to ensure safe travel as well. As prevention is the best treatment for many of these illnesses, risk prevention

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counseling is irreplaceable. Simple actions such as boiling water prior to consumption and avoiding certain uncooked foods, as well as abstaining from high-risk behaviors such as avoiding rabid animals, can save an individual from undesirable symptoms and illnesses.[15]

Special considerations for certain populations should be kept in mind when determining a vaccination schedule. These populations, which include the immunocompromised, people with chronic illnesses, and pregnant women, should be further counseled on the vaccines that are advised versus contraindicated for their conditions, and it is recommended that they consult their primary care physician. People with a history of hypersensitivity to vaccines should also speak to their doctor for alternatives.[16]

Each year, there are advances in the available vaccines. For example, there is a new malaria vaccine that is currently only available for children living in endemic areas. However, it would not be surprising if in the future it becomes available for children traveling to these areas as well.[17] While the information provided above is a guideline to be used to better decide the course of vaccination prior to travel, the *CDC Yellow Book Health Information for International Travel* has more information available, contains new vaccination updates, and will further prepare individuals for a happy and healthy vacation.[15]

Endnotes

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Afeera Chaudhry *is a 3rd year medical student at Lake Erie College of Osteopathic Medicine. She graduated from Fairleigh Dickinson University in Madison, NJ where she majored in biology and minored in chemistry. She is currently doing her clinical rotations at United Memorial Medical Center in Batavia, NY.*

Mayra Goreja *is an OMS3 at Lake Erie College of Medicine at Elmira, NY. She is currently completing her clinical years with the Rochester General Health System at United Memorial Medical Center in Batavia, NY. Mayra graduated with her master's degree from the department of biophysics at Case Western Reserve University and her undergraduate degree in neurobiology at Purdue University.*

Elizabeth Loomis, MD *is the Program Director for the Family Medicine Residency at United Memorial Medical Center/ Rochester Regional Health in Batavia, NY. She completed medical school at the University of Rochester and residency and fellowship at Lancaster General Health.*

COVID-19 Vaccine Schedule & Dosage Guide

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Pfizer-BioNTech
mRNA Vaccine

Immunization Schedule for Ages 6 Months to 4 Years

Primary Series: Monovalent

Dose 1		Dose 2		Dose 3
Dose: 0.2 mL	At least 3-8 weeks	Dose: 0.2 mL	At least 8 weeks	Dose: 0.2 mL

Pfizer Cap Key

- **Maroon Cap - MONOVALENT**
  - Ages 6 months to 4 years
  - 2.2 mL of diluent is required
  - Dose: 0.2 mL
- **Orange Cap - MONOVALENT**
  - Ages 5-11 years
  - 1.3 mL of diluent is required
  - Dose: 0.2 mL
- **Gray Cap - MONOVALENT**
  - Ages 12 years and older
  - No diluent is required
  - Dose: 0.3 mL
- **Gray Cap - BIVALENT**
  - Ages 12 years and older
  - No diluent is required
  - Dose: 0.3 mL

Immunization Schedule for Ages 5 Years and Older

Primary Series: Monovalent — **Booster**

Dose 1		Dose 2		Dose 3
Ages 5 - 11 Dose: 0.2 mL	At least 3-8 weeks	Ages 5 - 11 Dose: 0.2 mL	At least 5 months	***MONOVALENT*** Ages 5 - 11 Dose: 0.2 mL
Ages 12 & Up Dose: 0.3 mL	At least 3-8 weeks	Ages 12 & Up Dose: 0.3 mL	At least 8 weeks	***BIVALENT*** Ages 12 & Up Dose: 0.3 mL

Immunization Schedule for Those Who Are Moderately or Severely Immunocompromised

Primary Series: Monovalent — **Booster**

Dose 1		Dose 2		Dose 3		Dose 4
Ages 6 mos - 4 yrs Dose: 0.2 mL	At least 3 weeks	Ages 6 mos - 4 yrs Dose: 0.2 mL	At least 8 weeks	Ages 6 mos - 4 yrs Dose: 0.2 mL		*Booster dose for ages 6 months - 4 years not currently recommended*
Ages 5 - 11 Dose: 0.2 mL	At least 3 weeks	Ages 5 - 11 Dose: 0.2 mL	At least 8 weeks	Ages 5 - 11 Dose: 0.2 mL	At least 3 months	***MONOVALENT*** Ages 5 - 11 Dose: 0.2 mL
Ages 12 & Up Dose: 0.3 mL	At least 3 weeks	Ages 12 & Up Dose: 0.3 mL	At least 4 weeks	Ages 12 & Up Dose: 0.3 mL	At least 8 weeks	***BIVALENT*** Ages 12 & Up Dose: 0.3 mL

Moderna

mRNA Vaccine

Immunization Schedule for Ages 6 Months to 17 Years

Primary Series: Monovalent

Dose 1		Dose 2
Ages 6 mos to 5 yrs Dose: 0.25 mL	At least 4-8 weeks	**Ages 6 mos to 5 yrs** Dose: 0.25 mL
Ages 6 - 11 Dose: 0.5 mL	At least 4-8 weeks	**Ages 6 - 11** Dose: 0.5 mL
Ages 12 - 17 Dose: 0.5 mL	At least 4-8 weeks	**Ages 12 - 17** Dose: 0.5 mL

At least 8 weeks → **Ages 12 - 17** Pfizer-BioNTech bivalent vaccine should be used for the booster dose

Moderna Cap Key

- **Blue Cap with Magenta Label - MONOVALENT**
  - Ages 6 months to 5 years
  - Dose: 0.25 mL
- **Blue Cap with Purple Label - MONOVALENT**
  - Ages 6 - 11 years
  - Dose: 0.5 mL
- **Red Cap with Blue Label - MONOVALENT**
  - Ages 12 years and older
  - Dose: 0.5 mL
- **Blue Cap with Gray Label - BIVALENT**
  - Ages 18 and older
  - Dose: 0.5 mL

Immunization Schedule for Ages 18 Years and Older

Primary Series: Monovalent

Dose 1		Dose 2
Dose: 0.5 mL	At least 4-8 weeks	Dose: 0.5 mL

At least 8 weeks → **Booster**

Dose 3

BIVALENT Dose: 0.5 mL

Immunization Schedule for Those Who Are Moderately or Severely Immunocompromised

Primary Series: Monovalent

Dose 1		Dose 2		Dose 3
Ages 6 mos - 5 yrs Dose: 0.25 mL	At least 4 weeks	**Ages 6 mos - 5 yrs** Dose: 0.25 mL	At least 4 weeks	**Ages 6 mos - 5 yrs** Dose: 0.25 mL
Ages 6 - 11 Dose: 0.5 mL	At least 4 weeks	**Ages 6 - 11** Dose: 0.5 mL	At least 4 weeks	**Ages 6 - 11** Dose: 0.5 mL
Ages 12 - 17 Dose: 0.5 mL	At least 4 weeks	**Ages 12 - 17** Dose: 0.5 mL	At least 4 weeks	**Ages 12 - 17** Dose: 0.5 mL
Ages 18 & older Dose: 0.5 mL	At least 4 weeks	**Ages 18 & older** Dose: 0.5 mL	At least 4 weeks	**Ages 18 & older** Dose: 0.5 mL

Booster

Dose 4

Booster dose for ages 6 months - 11 years not currently recommended

At least 8 weeks →

- **Ages 12 - 17** Pfizer-BioNTech bivalent vaccine should be used for the booster dose
- ***BIVALENT*** **Ages 18 & older** Dose: 0.5 mL

Novavax

Protein Subunit Vaccine

Immunization Schedule for Ages 12 and Older

Novavax Cap Key

Royal Blue Cap - MONOVALENT
- Ages 12 & Up
- Dose: 0.5 mL

Primary Series: Monovalent

Dose 1

Dose: 0.5 mL

At least 3-8 weeks

Dose 2

Dose: 0.5 mL

Booster

At least 8 weeks

Dose 3

Ages 12 - 17
Pfizer-BioNTech bivalent vaccine should be used for the booster dose

Ages 18 & Up
Moderna or Pfizer-BioNTech bivalent vaccine should be used for the booster dose

Immunization Schedule for Those Over Age 12 Who Are Moderately or Severely Immunocompromised

Primary Series: Monovalent

Dose 1

Dose: 0.5 mL

At least 3 weeks

Dose 2

Dose: 0.5 mL

Booster

At least 8 weeks

Dose 3

Ages 12 - 17
Pfizer-BioNTech bivalent vaccine should be used for the booster dose

Ages 18 & Up
Moderna or Pfizer-BioNTech bivalent vaccine should be used for the booster dose

Guidance and Other Considerations per CDC's Interim COVID-19 Immunization Schedule for Persons 6 Months of Age and Older

- Administer the appropriate vaccine product based on the recipient's age and the product's age indications.
- Monovalent vaccine should be used for primary series doses. COVID-19 vaccine is a 2- or 3-dose primary series, depending on the recipient's age, immune state and the product used.
- For persons 12 years of age and older, administer a booster dose of bivalent vaccine after the primary series, regardless of the number of previous monovalent booster doses.
- COVID-19 vaccines may be administered on the same day as other vaccines, including influenza vaccine.
- The primary series should be completed with same product. If the vaccine product previously administered cannot be determined, is no longer available or contraindicated, any age-appropriate monovalent COVID-19 vaccine may be administered at least 28 days after the first dose to complete the primary series. Moderna or Pfizer-BioNTech bivalent COVID-19 vaccine can be administered for the booster dose, regardless of the primary series product.
- Persons with a recent SARS-CoV-2 infection may consider delaying a primary series or booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

Janssen (Johnson & Johnson)

Adenovirus Vector Vaccine

Janssen COVID-19 vaccine is authorized for use in certain limited situations due to safety considerations*

Janssen Cap Key

Blue Cap - MONOVALENT

- Ages 18 & Up
- Dose: 0.5 mL

Immunization Schedule for Ages 18 and Older

Primary Series: Monovalent

Dose 1

Dose: 0.5 mL

At least 2 months

Booster

Dose 2

Bivalent mRNA booster is recommended

Immunization Schedule for Those Over Age 18 Who Are Moderately or Severely Immunocompromised

Primary Series: Monovalent

Dose 1

Dose: 0.5 mL

At least 4 weeks

Dose 2

Additional dose of mRNA monovalent vaccine is recommended

At least 2 months

Booster

Dose 3

Bivalent mRNA booster is recommended

*COVID-19 vaccine recipients should be informed that Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines are recommended over Janssen COVID-19 Vaccine. The CDC recommends the Janssen/Johnson & Johnson COVID-19 vaccine should only be used in limited situations. For more information visit: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#considerations-Janssen

This COVID-19 Vaccine Schedule and Dosage Guide has been made available for informational and educational purposes only. Please always refer to the latest CDC Guidance for Vaccine Schedules which can be accessed here: https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-6months-older.pdf.

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New York State Academy of Family Physicians
16 Sage Estate, Suite 202
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