## AU InforMed

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#### **Key Inforbits**

- Population Risks for Disease
- National Immunization Awareness Month 2025
- Recommended Immunizations for Adults
- COVID-19 2025-2026 Vaccine Controversy



Image from: https://www.aarc.org/news/an23-august-is-national-immunization-awareness-month/

#### Fun FACTS!

#### As of April 12, 2025:

- An estimated ~27.57 million doses of the 2024-2025 COVID-19 vaccine were administered in retail pharmacies
- An estimated ~3.21 million doses of the 2024-2025 COVID-19 vaccine were administered in physicians' medical offices

That's an estimated overall documented total of ~30.78 million COVID-19 vaccines given!

#### Table 1: Seven Populations Who Benefit from Immunizations<sup>2,3,4,5</sup>

#### Infants and Young Children

- Immature immune systems can cause high vulnerability to infections.
- Common diseases that can cause severe disease and hospitalization in this age group are pertussis (whooping cough), measles, and Haemophilus influenzae (Hib).
- Vaccines protect them during this critical age when they are least able to fight infection.

#### Older Adults (> 65 years old)

- Immune function declines with age, and those older than 65 are at increased risk for severe disease
- Common infections that can cause severe complications are pneumonia, RSV, influenzae, shingles, and COVID-19.
- Vaccines reduce the risk of developing complications that can lead to hospitalization and long-term disability.

#### **Pregnant Women**

- Pregnancy naturally suppresses the immune system, so they are at increased risk of severe disease, like COVID-19 and influenzae
- Pregnant women can provide protection to their unborn child through recommended vaccinations. like the flu vaccine and Tdap vaccine.

#### **People with Chronic Health Conditions**

- Conditions such as asthma, heart disease, weakened immune system, chronic kidney disease, and others increase the risk of disease severity
  - Vaccines can reduce the risk of severity and complications and decrease vulnerability to infection

#### **Healthcare Workers**

- Constant exposure to ill patients and bodily fluids makes them more likely to become infected and increase spread
- Vaccines not only protect healthcare workers, but also for their patients who may also be at increased risk for infection

#### **People Living in Close Quarters**

- People such as college students, military personnel, and people living in group homes have an increased risk of infection since close contact can cause faster spread of diseases like meningitis, COVID-19, and influenzae.
- Vaccinations prevent outbreaks in close quarter situations

#### **Travelers**

- Diseases such as yellow fever. typhoid, and polio are not commonly contracted within the US, so it is important for travelers to receive these vaccines to protect them from infection and to prevent the reintroduction of diseases once returned home
- Other vaccines, like COVID-19 and flu vaccines, are also encouraged if the traveler intends to travel via public transportation in order to prevent infection due to the close quarter of these vehicles.

Bottom Line: No matter your age or health status, vaccines are a safe and powerful tool to prevent serious disease and spread to others



#### **National Immunization Awareness Month**

Each year, August is recognized as the National Immunization Awareness month. It is an annual observance that highlights the importance of vaccinations for protecting people of all ages. The goal of this observance is to become informed on the benefits of vaccines, address any misperceptions, and bring awareness to the importance of staying up to date with your vaccination status. During this month, organizations and healthcare officials encourage others to consult with healthcare providers to ensure the public is doing their best to stop the spread. Ask your doctor or pharmacist about your vaccine status today!



Image from: https://schaeffer.usc.edu/research/covid-vaccine-lives-saved-study/

## Recommended Routine Immunizations

#### Influenzae<sup>6</sup>

- Inactivated influenza vaccine (IIV4), recombinant influenza vaccine (RIV4), or live attenuated intranasal vaccine (LAIV4, ages 19-49 if healthy and non-pregnant)
- Adults <u>></u> 65 years should receive 1 dose

#### COVID-198,10

- Updated 2024-2025 monovalent mRNA vaccine (Pfizer-BioNTech or Moderna) or Novavax protein subunit
- 1 annual dose of most recent formulation, regardless of prior series

### Tetanus, Diptheria, and Pertussis (Tdap)/Tetanus and Diptheria (Td)<sup>3,4</sup>

- Tdap (Boostrix®, Adacel®); Td (Tenivac®, generic)
- Adults: 1 dose Tdap if never received as an adult, then Td or Tdap booster every 10 years
- Pregnant adults: 1 dose Tdap during each pregnancy (27-36 weeks' gestation)

#### Shingles (Herpes Zoster)<sup>3,4</sup>

- Shingrix® (RZV, recombinant, adjuvanted)- 2 dose series (0 and 2-6 months) for:
  - o Áll adults > 50 years
  - Adults ≥ 19 years who are immunocompromised

#### Human Papillomavirus (HPV)3,4

- 9-valent HPV vaccine (Gardasil 9®)
- Adults ≤26 years: complete 2- or 3dose series if not already done.
- Adults 27–45 years: may receive based on shared clinical decisionmaking.

#### Pneumococcal<sup>7</sup>

- PCV20 (Prevnar 20®) OR PCV15 (Vaxneuvance®) followed by PPSV23 (Pneumovax 23®)
- Adults ≥50 years: 1 dose (≥1 year apart; ≥8 weeks if immunocompromised.)
- Adults 19–49 years with chronic conditions (e.g., diabetes, heart, lung, liver, CKD, alcoholism, smoking, immunocompromise): same as above.

#### Hepatitis B<sup>3,4</sup>

- Engerix-B® or Recombivax® (3-dose- 0, 1, 6 months); Heplisav-B® (2-dose- 0, and 1 month);
   Twinrix® [Hep A/B combo] (3-dose- 0, 1, and 6 months)
- Birth through adult: Engerix-B® or Recombivax®
- 18 years old only: Heplisav-B® or Twinrix®
- All adults 19–59 years: routine vaccination.
- Adults ≥60 years: recommended if risk factors, or on request.

## Respiratory Syncytial Virus (RSV)9

- Arexvy® (GSK, recombinant with adjuvant), Abrysvo® (Pfizer, bivalent prefusion F protein)
- Adults ≥60 years: 1 dose based on shared decision-making.
- Pregnant adults (32-36 gestation during RSV season): 1 dose Abrysvo® to protect infants in first 6 months of life.

Table 2: Recent CDC Updates to Vaccine Schedules<sup>3,4,6,8,9</sup>

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Vaccine	Update
COVID-19	<ul> <li>The FDA recently approved the updated 2024-25 COVID-19 vaccine for adults aged 65 and older based on age alone and for adults aged 19-64 with a risk factor such as heart disease, asthma, diabetes, and immunosuppression.</li> <li>There is controversy in the medical community and media today around these indications as it limits the populations that are available for the vaccine.</li> <li>The CDC recommendations have recently been released, but may not be sufficiently clear to guide plain and direct recommendations for certain age groups and disease populations, causing even more confusion and controversy.</li> </ul>
Pneumococcal	Routine vaccination now starts at age 50 (previously 65) for adults who are PCV-naïve or with unknown history and for adults aged 19-49 with certain chronic or immunocompromising conditions
Respiratory Syncytial Virus (RSV)	<ul> <li>The CDC recently added a new population recommended to receive the RSV vaccine, which is adults aged 50-74 at increased risk for severe RSV (e.g., chronic heart/lung disease, advanced CKD, and frailty)</li> <li>The recommendation for adults aged 75 years or older still stands</li> </ul>

## Controversy: 2025-2026 COVID-19 Vaccine11,12,13,14,16,17,18

- The FDA has recently approved updated 2025-2026 COVID-19 vaccines which narrows the indications to adults aged 65 years or older and for children and adults with "high-risk" conditions.
  - The conditions were not defined by the FDA, but the vaccine labels reference the CDC's list of "high-risk" conditions
    - Cancer, Cerebrovascular Disease, Chronic Liver disease, Chronic Lung disease, Cystic fibrosis, Diabetes, Heart Conditions, HIV, Overweight/Obesity
- The CDC has approved the following vaccines for the associated indications:

**Table 3: Indicated Populations for COVID-19 Vaccines** 

Vaccine	Approved for
Moderna (mRNA)	All adults 65+ Adults under 65 <u>with risk factors</u> Children 6 months+ <u>with risk factors</u>
Pfizer (mRNA)	All adults 65+ Adults under 65 <u>with risk factors</u> Children 5 months+ <u>with risk factors</u>
Novavax (protein-based)	All adults 65+ Adults and adolescents 12+ with risk factors

- Anyone who does not fall into one of these categories but would like to receive a COVID-19 vaccine may need to get a prescription from their physician.
  - CVS has restricted the vaccine's administration in some states.
    - Many states like Georgia, Florida, and Louisiana are requiring prescriptions, while others like Massachusetts and Nevada are preventing the COVID-19 vaccine from being administered at all.
  - Publix Pharmacy in the state of Alabama requires a prescription for individuals who do not fall into the approved categories.
- Even though FDA labeling is restricted, physicians are still able to vaccinate people outside of those groups, using clinical judgment and prescribing "offlabel".
  - Organizations are encouraging physicians to rely on evidence-based guidance from trusted specialty societies, use clinical judgment, and to make sure insurers and health systems align their policies with those evidence-based recommendations.
- The new FDA labels do not align with vaccine recommendations from major specialty societies such as the American Academy of Pediatrics (AAP)<sup>14</sup>, who

- strongly recommend COVID-19 shots for children ages 6 months to 2 years, and American College of Obstetricians and Gynecologists (ACOG)<sup>15</sup>, who state that COVID-19 vaccination is safe in pregnancy and can protect both the mother and infants after birth.
- Many associations are saying the FDA's decision to change the approved population is not guided by science, that it creates confusion for patients, and established barriers to access, especially as the respiratory virus season approaches<sup>16</sup>.
- The CDC's Advisory Committee on Immunization Practices (ACIP), including their newest five members, which sets formal national vaccine recommendations, have recently voted on recommendations for the coming season<sup>17,18</sup>. The committee unanimously voted to suggest that Americans under the age of 64 can get the shot "based on individual decision-making", meaning it is a personal choice. They also voted for states to not require a prescription for the vaccine, as it may create barriers for some patients and overwhelm physicians. The committee voted to make clear the risks of the COVID-19 vaccine, which will be an optional patient handout for states that list at least six risks for vaccination. The ultimate vote is that the public can still have access to this vaccine, ideally following a conversation with a health care provider discussing the risks and benefits, although that is not a requirement.
- These votes are not final as CDC director, Jim O'Neil, must approve them before they become an official CDC recommended immunization schedule.
- America's Health Insurance Plans, the group for private insurance companies, have stated that COVID-19 vaccines will be covered through the end of 2026, but there is no clear statement from other insurances, such as Medicaid<sup>17</sup>.
- The FDA's new limits on who can get the COVID-19 vaccine have caused much debate. Many medical experts feel the change doesn't match the best science and could make it harder for people to get protected, especially with different rules in each state. Because of this updated approval and CDC's lack of clear recommendation, the confusion is still ongoing. The lack of uniformity is causing pharmacies and states to act on their own to make decisions as to who will be giving and receiving the vaccine.

#### **Closing Remarks:**

Although populations at risk and routine recommendations have been established, information regarding vaccinations continues to change with ongoing updates. Recent changes have been seen with the pneumococcal vaccine having the routine age starting now at 50 and the RSV vaccine also including adults ages 50 to 74 with certain risk factors. More recently from the CDC, the COVID-19 vaccine has been updated for routine vaccination in adults who are at least 65 years old, while those younger than 65 received recommendations that were based more on individual decision-making. This new information has provided uncertainty and sparked controversy surrounding the COVID-19 vaccine.

The guidance on COVID-19 vaccines given by FDA, CDC, and other organizations are unclear and diverse. It is unknown if more recommendations will be made in the future; however, if controversy and disagreement continue, there will likely be a change to unify the guidance regarding COVID-19 vaccination nationwide.

As information changes regarding vaccinations, pharmacists maintain the responsibility to stay informed and to be updated with any new recommendations. Such awareness may be integral, as these updates may have a huge impact on patient outcomes in the future.

#### The last "dose" ...

# "Immunizations: A shot in the arm for humanity, not just for you." ~Anonymous

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