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WHITE PAPER

US Vaccines Trends and Strategies for Manufacturers.

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ABSTRACT

Since 2020, there has been considerable change and upheaval in the US vaccine landscape, both as a result of the COVID-19 pandemic and other factors including emerging technologies and shifting ACIP priorities. Manufacturers aiming to commercialize novel vaccines will need to contend with this evolved landscape and have a full appreciation for current and future success factors.

In this work, we detail our observations on how the US vaccine landscape has evolved as well as our hypotheses regarding near-term future evolution. We also provide commentary on implications for novel vaccine launches and suggest strategic imperatives for maximizing success potential based on the authors' collective vaccine advisory experience over the past 25 years.

Introduction

The vaccines landscape in the US has experienced considerable change since the start of the COVID-19 pandemic. Some of these changes were clearly related to COVID-19 itself, while for others the causes are more opaque and varied. Changes have and will continue to impact a variety of stakeholders in the complex vaccination ecosystem, from regulators and governmental bodies to providers to consumers. In this white paper, we detail future vaccination trends in the US as well as potential implications for manufacturers seeking to launch new vaccines in the US. The trends we have identified are:

1. Increasing consumer engagement in vaccination and waning brand-level awareness
2. Increasing consumer vaccine hesitancy and declining overall vaccination rates
3. Shift in sites of adult vaccinations
4. Greater scrutiny on vaccine cost and cost-effectiveness
5. Increasingly crowded adult schedule on top of already-crowded pediatric schedule driving to combination products
6. Continued focus on convenient vaccine presentations

Key Trends in the US Vaccine Landscape

1. Increasing Consumer Engagement in Vaccination but Waning Brand Level Awareness

Consumers are increasingly engaged in choice not only to be vaccinated but with which vaccine.

The overwhelming impact the COVID-19 pandemic had on the daily lives of ordinary Americans dramatically increased the attention paid in the media to vaccination. As COVID-19 vaccines became increasingly available from December 2020 through the spring of 2021, the proportion of consumers wanting to receive the vaccine as soon as possible rose from roughly a third to nearly half[1]. By February 2022, a majority of adults had completed the primary COVID-19 vaccine primary series, with 95% of adults above the age of 50 receiving at least one dose[2].

Consumers are also more aware of vaccine technology, with the mRNA platforms used by Pfizer and Moderna for their COVID-19 vaccines garnering substantial public interest. As a result, providers and those responsible for vaccine purchasing have had to consider consumer preference in decision making (for instance, in the 2024-2025 respiratory season, large retail pharmacies have been allowing consumers to choose which COVID-19 vaccine they receive when booking appointments).

However, to-date, consumer preference has been largely restricted to COVID-19 vaccines. It remains to be seen to what extent consumer brand-level preference can be driven in markets with less mainstream media attention, like RSV or pneumococcal. This is likely

to be particularly challenging given that it is in the best interest of retail pharmacies and health systems for consumers to not have a preference, instead allowing them to stock whichever is most advantageous for their organization (considering economics, presentation and logistics, etc.), and as a result, these organizations are unlikely to be strong partners to manufacturers in informing consumers about specific brands.

2. Increasing Consumer Vaccine Hesitancy and Declining Overall Vaccination Rates

Consumer vaccine hesitancy has increased and rates of routine annual immunizations declined for both adults and children.

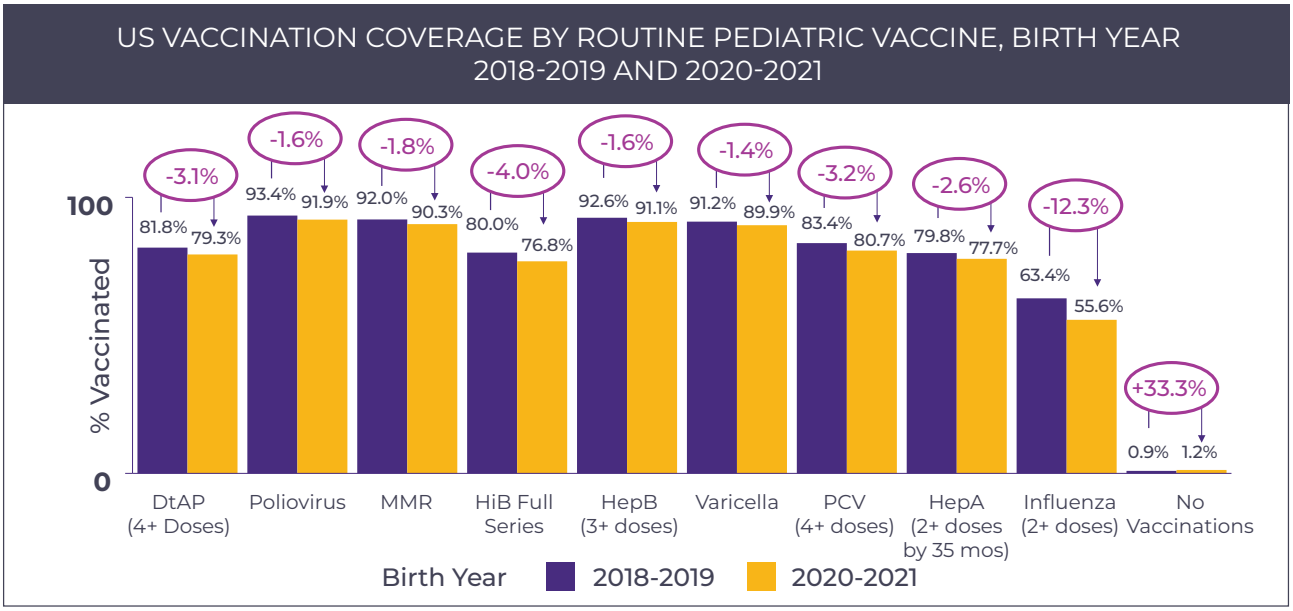
New vaccine technologies have also, however, been associated with higher consumer skepticism, with one study showing that, on average, consumers require a 19% higher vaccine efficacy to adopt a vaccine with a new technology[3]. With increasing vaccine awareness has come rampant misinformation and misunderstanding, for example:

- In January 2021, prior to the widespread rollout of COVID-19 vaccines to the general adult population, a third of those who had not yet been vaccinated had heard one of three tested inaccurate claims about vaccination (e.g., that the vaccines include live virus, cause infertility, or are not covered by insurance) and either believed the claim or weren't sure if it was true[1].
- Demonstrably false claims about linkages between childhood MMR vaccination and autism spectrum disorder also continue to persist[4].

As a result, overall vaccine hesitancy has increased, contributing at least in part to declines in vaccination rates for routinely recommended vaccines.

- **Vaccination rates of routinely recommended childhood vaccines are down:** The 2022 National Immunization Survey found that vaccination rates of almost all recommended childhood vaccines were lower for those born in 2020 and 2021 vs those born in 2018 and 2019 (Figure 1), attributable in part to parental vaccine hesitancy[5]. Pandemic disruption leading to missed well child visits are also a contributing cause of declining childhood vaccination rates, and it remains unclear to what extent rates will recover.

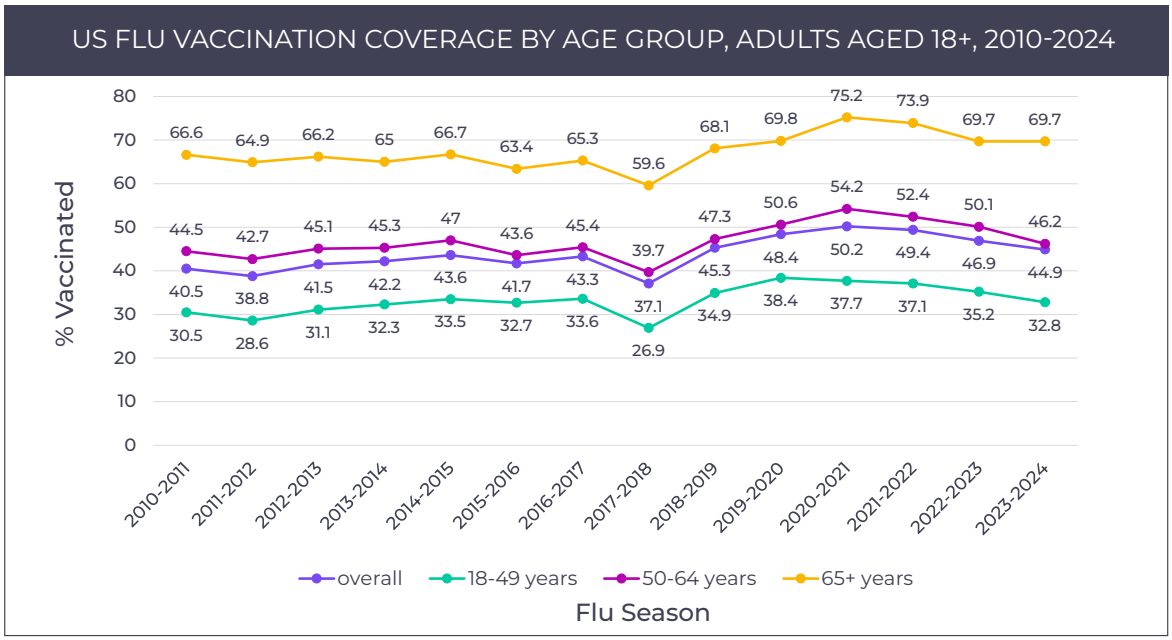
Fig. 1



Source:
Centers for Disease Control and Prevention. (2023). Decline in vaccination coverage by age 24 months and vaccination inequities among children born in 2020 and 2021 — National Immunization Survey-Child, United States, 2021–2023. Morbidity and Mortality Weekly Report, 73(38), 1040-1047. https://www.cdc.gov/mmwr/volumes/73/wr/mm7338a3.htm#T1_down

- **Adult influenza vaccination rates have steadily declined:** Influenza vaccine rates in adults aged 18+ in the 2023-2024 season were only 44.9%, with coverage steadily declining since the 2020-2021 season[6] (Figure 2), to rates lower than the pre-pandemic 2018-2019 influenza season across for adults under the age of 65.

Fig. 2



Source:
Centers for Disease Control and Prevention. (2024, October 2). Flu vaccination coverage, United States, 2023–24 influenza season. FluVaxView. https://www.cdc.gov/mmwr/volumes/73/wr/mm7338a3.htm

The impacts on overall public health are magnified in children due to declining herd immunity. For instance, there have been spikes in measles cases to 1,274 in 2019 and 264 cases already in 2024 (as of October), in contrast to 1997-2010, where annual cases were consistently below 200, widely attributed to decreasing vaccination rates in children[7].

Impacts on individual health in those unvaccinated can also be profound. For example, in the COVID-19 Omicron wave, approximately 40% of those that required invasive mechanical ventilation or died in the hospital were unvaccinated[8]. More recently, as of October 2024 RSV vaccines have been associated with a reduction in ICU admissions of ~3,700 and ~5,600 hospitalizations 320 and 790 deaths and per 1M persons vaccinated ages 60-74 and ages 75+, respectively[9].

Collectively, this suggests that considering strategies to support public willingness to be vaccinated in additional to driving provider demand and strength of recommendation will be increasingly important for future vaccine launches.

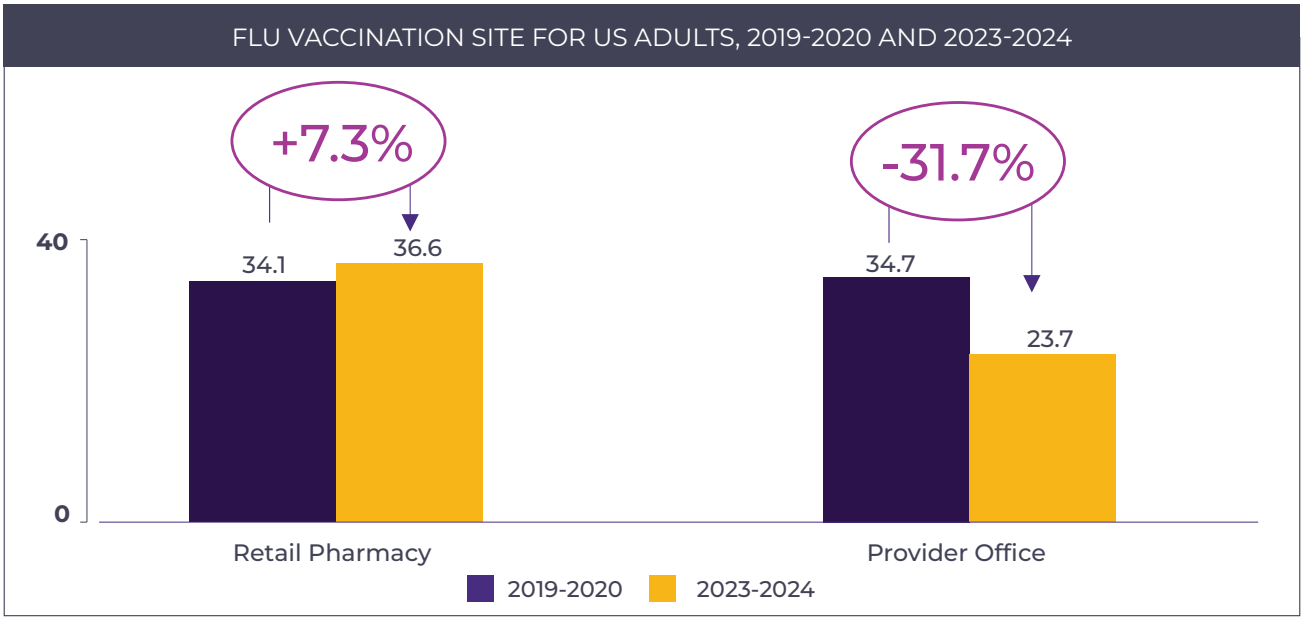
3. Shift in Sites of Adult Vaccinations

Site of adult vaccinations is evolving, with increasing importance of retail pharmacies.

For adults, retail pharmacies are increasingly likely to be a site of vaccination, with more adult flu vaccines administered in retail pharmacies than in provider offices in the 2023-2024 season (Figure 3)[10]. Retail pharmacies are continuing to gain increased strength in both:

- Influencing consumer choice to be vaccinated (e.g., through in store loudspeaker and print advertisements, pharmacist reminders, etc.) and for which vaccine preventable diseases vaccination should be prioritized
- For a given vaccine preventable disease, deciding which vaccine is administered through their purchasing and stocking decision-making

Fig. 3



Source:
Centers for Disease Control and Prevention. (2023, October 10). 2023–2024 flu vaccination coverage update. https://www.cdc.gov/flu/whats-new/2023-2024-flu-coverage-update.html

On average, retail pharmacies have greater geographical reach and serve more consumers than health systems (with many having nationwide influence), meaning decision-making power is increasingly concentrated. This creates potential for large swings in demand for a certain vaccine depending on vaccine brand stocking approaches taken by the largest retailers. Being prepared to partner with the large retail pharmacies is critical for manufacturers preparing to launch novel adult vaccines.

4. Greater Scrutiny on Vaccine Cost and Cost-Effectiveness

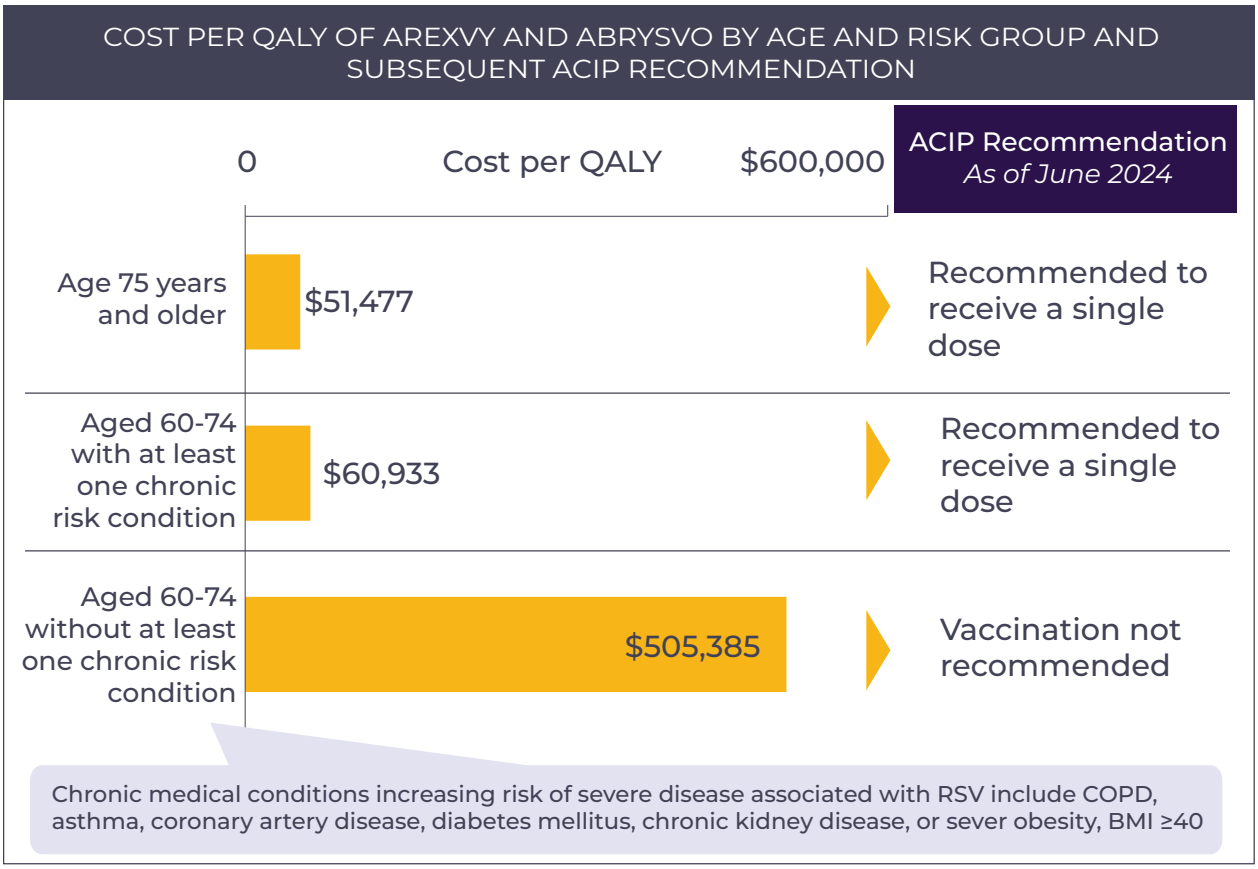
Cost-effectiveness and per-dose cost of vaccines have played a more prominent role in influencing recent ACIP recommendations.

As part of its Evidence to Recommendations framework, the CDC's Advisory Committee on Immunization Practices (ACIP) considers cost-effectiveness, asking "Is the intervention a reasonable and efficient allocation of resources?"[11] Attention to this element of the framework has been increasing, with potential to help drive favorable decisions but also risk less favorable ones for manufacturers:

- **Zoster:** Shingrix was found to have a cost per quality-adjusted life year (QALY) saved of $31,000 for older adults, which in all scenarios modeled was more cost-effective than the existing vaccine, Zostavax. This helped support a recommendation for all adults 50 and older to be vaccinated with Shingrix regardless of prior Zostavax receipt (in addition to other factors like highly compelling efficacy), which was a rare instance of a preferential ACIP recommendation for one vaccine over others also approved.[12]

- **Respiratory Syncytial Virus (RSV):** Arexvy and Abrysvo were found to have widely varying costs per QALY saved depending on age and risk factors (Figure 4). While many factors were considered in the recommendations, the high cost per QALY saved certainly played a role in the decision, with the notably less cost-effective group, adults ages 60-74 without certain risk conditions previously included in the 2023-2024 season recommendation under shared clinical decision-making, not being recommended for vaccination for the 2024-2025 season.[13]

Fig. 4



Source:
Centers for Disease Control and Prevention. (2023, June 21). ACIP evidence to recommendations for use of protein subunit RSV vaccines in older adults. https://www.cdc.gov/acip/evidence-to-recommendations/protein-subunit-rsv-vaccines-older-adults-etr.html

Attention on vaccine price and cost-effectiveness may be increasing, particularly in vaccine classes with poor cost-effectiveness ratios today.

Historically, ACIP has not had a specific threshold for what cost per QALY saved is considered cost-effective, unlike other National Immunization Technical Advisory Groups across the world. As a result, there have been widely disparate levels of cost-effectiveness accepted in recommendations across different vaccine preventable diseases, with some like influenza and COVID being cost saving (i.e., cost per QALY saved less than $0) with others costing hundreds of thousands of dollars per QALY saved.

Attention on cost has been most stark for meningococcal vaccines. While the per-dose cost of these vaccines is not notably higher than other vaccines and the consequences of meningococcal disease can be severe, the low incidence rates in the vaccine eligible population result in very high cost per QALY saved of vaccination. In the most recent October 2024 ACIP meeting, ACIP chair of the meningococcal working group, Dr. Jamie

Loehr stated:

> *"We're talking ICERs in the millions of dollars, and I really want to emphasize that…in private communication with other ACIP-like organizations, they will not consider ICERs above $100-150k/QALY. I really want us to be aware that we are contemplating spending a lot of money for very few cases. I recognize that [meningitis] is a dramatic, devastating disease for those who get it, but I also want to think about fiscal prudence…this is all based on the price of the manufacturer and I would suggest that the manufacturers heed these concerns that these prices are getting too expensive for me as an ACIP member to contemplate."* [14]

However, other members subsequently noted that:

- Cost-effectiveness models are imperfect and are heavily reliant on uncertain assumptions.
- Although it infects relatively few individuals, the morbidity and mortality risk associated with meningitis is very high. As a result, they emphasized that there were a variety of points of view on the committee regarding the importance of cost in informing recommendation decision-making.

However, meningococcal vaccines are not the only space in which vaccine cost-effectiveness has been heavily scrutinized. Recently, ACIP has taken a seemingly stronger stance on vaccine cost-effectiveness. They have pushed manufacturers for price guarantees, as with RSV in June 202315. They have also provided pointed commentary about the cost of vaccines, for example in June 2024: "[the] Work Group felt that if RSV vaccine list prices were substantially reduced, then RSV vaccination may be a cost-effective intervention for a broader adult population" with the implication that the risk-based recommendation for RSV vaccines established was heavily driven by vaccine cost[16].

While views on the importance of cost-effectiveness are likely to continue to vary across ACIP members and will be difficult to predict given the regular turnover of members, it is increasingly important for manufacturers to be aware of the potential implications of price on cost-effectiveness and subsequent recommendations from even very early stages of vaccine development. This is particularly so in vaccine spaces already considered expensive, like RSV or meningococcal.

5. Increasingly Crowded Adult Schedule on Top of Already-Crowded Pediatric Schedule Driving to Combination Products

Combination vaccines are poised to transform the vaccination landscape.

The US pediatric vaccine schedule has had a high level of complexity with many different vaccines for many years. However, the crowdedness of the adult vaccine space has increased in recent years and will likely continue due to:

- Recent addition of COVID, with annual recommendations for all adults (or more frequent, depending on risk status)
- Approval of RSV vaccines for adults 60+ as well as adults with certain risk conditions and pregnant women
- Expansion of pneumococcal and Hep B age-based recommendations to additional adult age groups

- Expected future vaccines for additional diseases, e.g., C. difficile, hMPV/PIV, norovirus, etc.

To address declining vaccination rates as well as the increasing crowdedness of the vaccination schedule (Figure 5), many manufacturers are developing combination vaccines. Combinations may have several advantages:

- **Increase overall vaccination rates**: By reducing the number of vaccinations required and the associated number of visits and/or needle-based injections a consumer must receive, adherence rates for individual vaccines may improve.
- **Improve ease of vaccination for administering organizations**: Combining two vaccines into one will likely reduce the vaccine storage footprint required. Depending on the presentation, it may also reduce the logistics associated with dual vaccine administration (e.g., preparing two syringes), saving staff time and reducing the likelihood of administration errors.
- **Enhance manufacturer competitiveness**: ACIP and purchasing organizations are likely to recognize the advantages combination vaccines may offer, and as a result reward manufacturers with favorable recommendations and stocking behavior. Having a combination vaccine in the portfolio may also help a manufacturer boost purchasing of other non-combination vaccines through contracting.

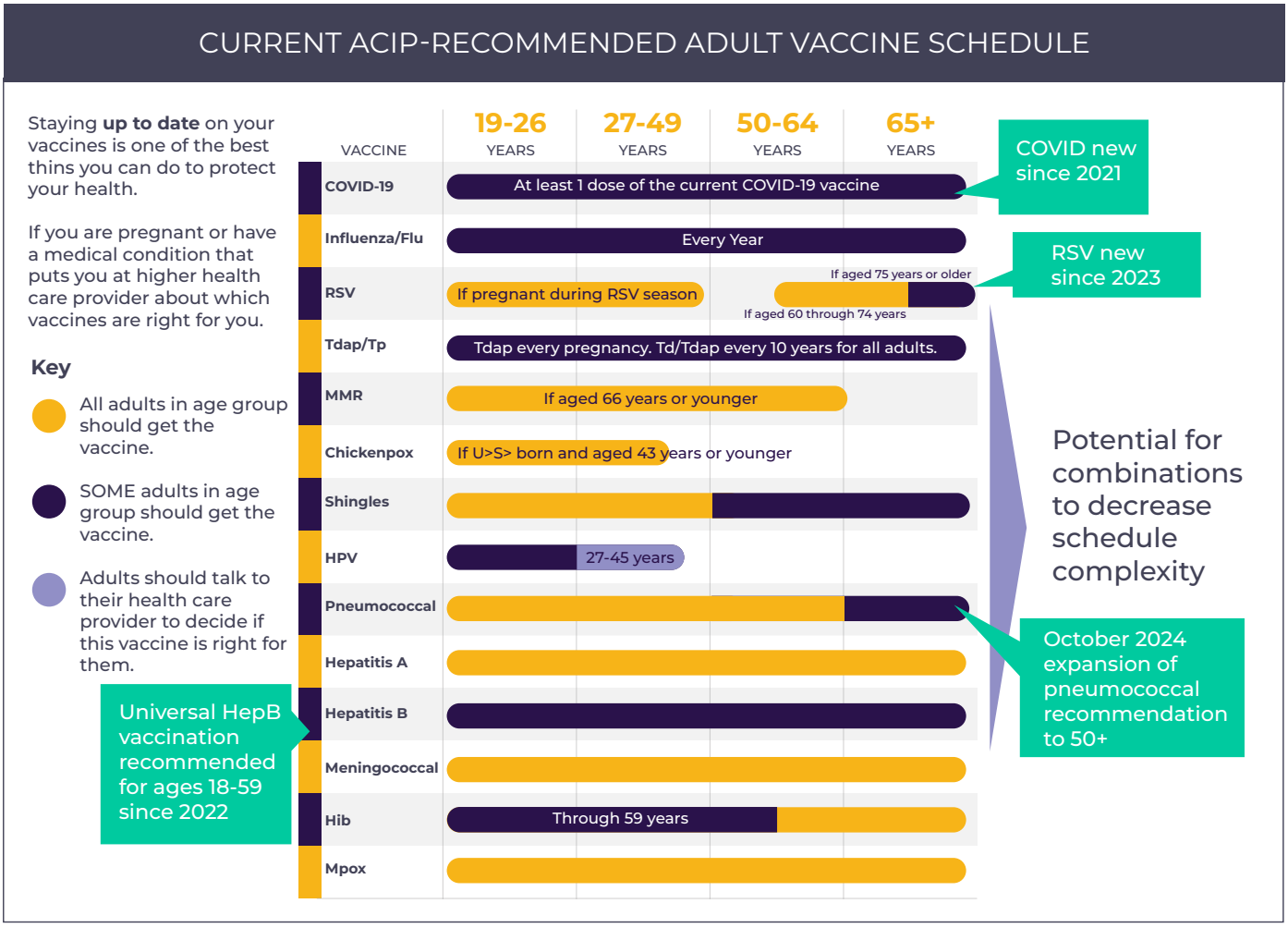


Fig. 5

Source:
Centers for Disease Control and Prevention. (n.d.). Adult immunization schedule (easy-to-read). Retrieved November 18, 2024, from https://www.cdc.gov/vaccines/imz-schedules/downloads/adults-schedule-easy-read.pdf

Many manufacturers have already recognized these advantages and are developing combination vaccines, with particular focus on respiratory combinations (Figure 6). Of these, Pfizer / BioNTech's and Moderna's COVID + influenza combinations leveraging their mRNA platforms are the most advanced, but there are numerous others in clinical stage development targeting both a variety of different disease combinations and leveraging a variety of technologies.

RESPIRATORY COMBINATION VACCINES IN CLINICAL DEVELOPMENT BY ANTIGEN TYPE

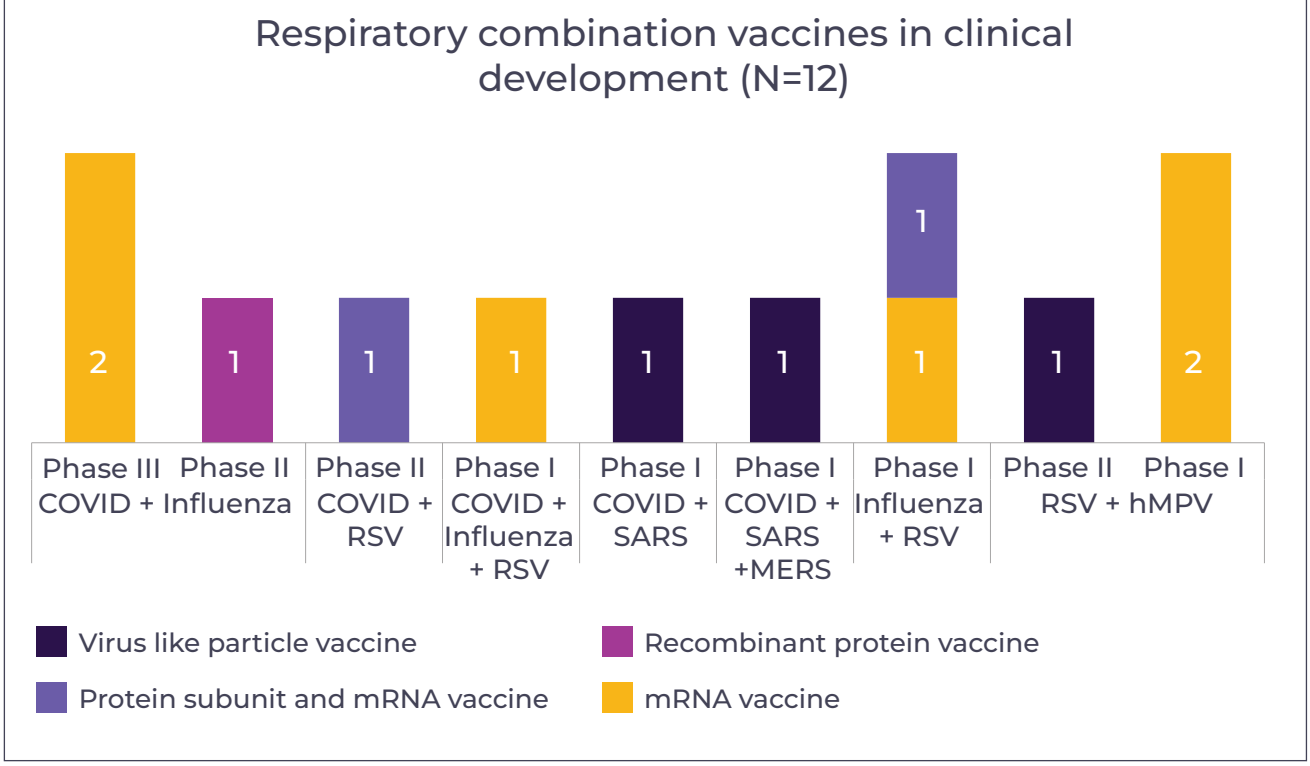


Fig. 6 **Source:**
Biomedtracker. (n.d.). Biomedtracker. https://www.biomedtracker.com/

Developmental / technological hurdles with combination vaccines will need to be overcome.

A variety of challenges in developing combinations remain, including:

- **Antigen compatibility,** with each antigen triggering the hoped-for immune response while not being inhibited or overshadowed by others.
- **Adjuvant compatibility,** with including adjuvants that support the immune response to specific antigens but not reducing the efficacy of other antigens or causing undesired reactogenicity.
- **Stability,** with each component of the combination vaccine having similar storage requirements
- **Minimizing reactogenicity,** such that the vaccine is similarly tolerable to non-combination vaccines

These challenges have been overcome before, and if able to overcome in the respiratory space could signal a new era in adult vaccination similar to that witnessed upon the approval of the now-widespread DTaP vaccine used in children.

6. Increased Focus on Convenient Vaccine Presentations

At home self-administration of vaccines is newly possible and may becoming increasingly common.

To improve convenience for consumers, alternative vaccine administration sites may emerge with novel, more convenient vaccine presentations, in particular at home. In September 2024, FluMist, an influenza vaccine nasal spray developed by AstraZeneca and available for healthcare provider-administration since 2003, was approved by the FDA for self- or caregiver-administration at home for individuals ages 2 through 49 years[17]. Alternative routes of administration that can offer similar logistical and convenience advantages (or improve vaccine efficacy) and drive consumer demand may help differentiate new entrants in crowded vaccine spaces like influenza.

Needle-free vaccine administration is an active area of research

Indeed, novel delivery technologies that could enable self-administration is an active area of research by many companies across a variety of disease areas and administrative modalities. A few select examples beyond nasal sprays (like FluMist) include:

- **Oral:** Vaxart is currently developing oral tablet vaccines for COVID-19, influenza, norovirus, and HPV. The most advanced of these, for influenza, is currently in Phase 2 clinical trials and demonstrated in an early phase study superior reductions in clinical disease relative to a standard dose quadrivalent injected vaccine comparator (39% vs 27%, respectively) and a safety profile indistinguishable from placebo.[18]
- **Inhaled:** AuraVax is developing inhaled respiratory vaccines designed from the onset to be self-administered and stable at room temperature (currently in preclinical development).[19]
- **Patch:** Merck has partnered with Vaxxas to develop vaccines (with influenza as the lead candidate) using their HD-MAP micro-projection patch technology.[20] Self-administration potential and thermostability are key advantages Vaxxas expects over traditional vaccination approaches, along with potential for lower antigen amounts (particularly valuable in a pandemic environment where producing a large number of vaccines quickly is of paramount importance) and enhanced immunogenicity.

While providers can accommodate a range of presentations and storage requirements if needed, in competitive non-pandemic disease spaces convenient vaccine presentation is increasingly important.

For vaccines with transformational potential, providers have shown that they can and are willing to adapt and modify their storage and administration protocols.

Most notably, the "ultra-low temp" cold storage requirements for the mRNA COVID-19 vaccines were initially expected to be a barrier but US practices and pharmacies readily developed storage solutions that enabled widespread vaccination. The colder storage requirements for Pfizer's Comirnaty vs Moderna's Spikevax in their original presentations (-90°C to -60°C vs -50°C to -15°C, respectively[21,22]) did not pose a meaningful barrier to use of Comirnaty, which comprised nearly 60% of COVID-19 vaccine doses administered through April 2023[23]. Pfizer's reusable thermal shippers, which enabled the vaccine to be stored for multiple days if unopened or if resupplied with ice, were also critical to this effort.

However, more recently, as the COVID-19 vaccine market has matured, there has been an increasing focus on more favorable presentations. For instance, while both Comirnaty and Spikevax were initially supplied in multi-dose vials, both are now available in single-dose pre-filled syringes that can be stored at standard refrigerator temperatures for months[21,22]

Offering convenient presentations that consider both provider and consumer needs will likely be increasingly important, particularly for adult vaccinations in a non-pandemic context given increasing frequency of vaccination at retail pharmacies. These sites may be less accommodating of non-standard presentations and storage conditions for non-pandemic vaccines compared to health systems. While optimizing presentation and storage is important for all vaccines, it is most so for those in competitive markets with limited clinical differentiation.

Putnam's Recommendations for How to Successfully Navigate the Future US Vaccines Landscape

The rapidly evolving vaccines landscape in the US presents numerous challenges but also substantial opportunity for vaccines manufacturers. To successfully launch vaccines into this evolved landscape, we recommend:

1. Aim to be an early entrant into a new disease area.

Attractive characteristics of a new disease area likely include:

- Identified target population to vaccinate
- Sufficiently high numbers of infections in the US annually and sufficiently large ratio of severe disease risk (e.g., hospitalization, death) relative to the number of those infected (necessary to ensure both favorable cost-effectiveness and commercial opportunity size)
- Clear antigenic targets and technology

Leveraging any strategies possible to retain sole-source positioning following launch can lead to considerable commercial benefit, both directly associated with that vaccine as well as potential lifts to other vaccines in a manufacturer's portfolio as a result of contracting synergies.

Achieving an early launch is particularly important in disease spaces where vaccines are expected to be one time, like shingles or pneumococcal, where there can be significant opportunity in the initial bolus and then declines as opportunity shifts to those that are newly aging into the recommended population and/or that newly develop risk conditions.

2. Identify and aggressively pursue opportunities to be preferentially recommended by ACIP in a category.

Preferential ACIP recommendations are exceptionally rare and extremely difficult to obtain, but when rendered provide a considerable market advantage to the manufacturer. For example, Zostavax was discontinued after Shingrix received a preferential recommendation for vaccination against shingles[24], while sales of Shingrix climbed to £3.4B in 2023 worldwide[25].

Critical to achieving a preferential recommendation in a competitive vaccine space is to provide a meaningful advantage over the other vaccine options with clear health benefits for those vaccinated (e.g., Shingrix's efficacy of >95% in comparison to <70% for Zostavax, along with ability to be used in higher risk populations specifically contraindicated for Zostavax's live attenuated formulation, longer duration of protection, and the resulting superior cost-effectiveness already noted).

3. Develop vaccines in existing spaces that offer meaningful convenience advantages for vaccinating organizations and/or consumers.

There may not be many remaining infectious diseases currently lacking available vaccines that fit the requirements of the first strategy, and achieving a preferential recommendation in accordance with the second strategy is exceedingly difficult. It may be relatively easier to develop vaccines that can offer other advantages to create differentiation in crowded markets as well as increase overall vaccination rates. These include (but are not limited to):

- Combination vaccines, to reduce vaccination schedule crowding and improve uptake rates
- More convenient logistics for administering organizations (e.g., superior storage and stability requirements, presentations that reduce preparation time and/or risk of vaccine administration errors)
- Consumer-friendly routes of administration (e.g., those not involving needles) that could potentially also enable at home self-administration, coupled with a robust direct-to-consumer marketing campaign

4. Fill portfolio gaps to optimize contracting position.

Historically, the vaccine market has been dominated by a small handful of manufacturers, which has resulted in portfolio-based contracting being widespread and many providers aligning their purchasing decisions around 1 or 2 primary manufacturers. Within this context, portfolio-based contracting has and will continue to be a key determinate of vaccine stocking and purchasing. A broad vaccine portfolio helps manufacturers deepen their relationships with providers and simplify their ordering, providing that manufacturer with an advantage in competitive vaccine spaces where they do not have either the sole available vaccine or a preferential recommendation.

Optimizing the portfolio also requires careful consideration of the customer. For example, a retail pharmacy would likely consider an adult-only vaccine portfolio to be sufficiently complete, while independent physician offices and health systems look to partner with manufacturers that also offer pediatric and adolescent vaccines.

Portfolio optimization can also be accomplished through partnerships. For example, to complement their influenza vaccine-dominated adult portfolio, Sanofi recently entered into a collaboration with Novavax for their COVID-19 vaccine[26]. However, such partnerships inevitably come with additional complexity for both the manufacturers and customers which can diminish their value relative to other "one stop shop" manufacturers.

Putnam's Experience in US Vaccines Strategy

Putnam brings unmatched expertise in vaccines, offering comprehensive support to vaccine manufacturers in areas like strategy, market access, pricing, and commercialization. Our experience spans over 30 years, supporting four of the top five global vaccine manufacturers across diverse populations and geographies.

Key Areas of Expertise

Vaccine Categories & Populations

- Supported over 30 vaccine-related disease areas, covering pediatric, adolescent, adult, elderly, and high-risk populations.
- Experience across major geographies, including both developed and developing markets: U.S., Europe, Asia-Pacific, South America, Middle East

Functional Expertise

- Value, Pricing, and Access: Designing optimized strategies to demonstrate, communicate, realize, and retain the value that vaccines provide to governments, private payers, health systems, and society.
- Commercial Strategy: Tailored market entry strategies considering competitive landscapes and market needs
- Medical Affairs: Custom scientific narratives and evidence plans to clearly and effectively communicate vaccine value.

Portfolio Strategy and Launch Excellence

- Extensive experience guiding clients in all phases of the vaccine life cycle from early-stage planning to market entry and competitive strategy.
- Expertise in transitioning legacy products to new-generation vaccines
- Execution of market-shaping initiatives to ensure launch success.

Innovative Methodologies

- Proprietary tools and databases for predictive modeling and market scenario planning.
- Thought leadership in emerging trends, including IRA-related impacts on vaccine pricing.
- Development of bespoke frameworks for strategic prioritization and scenario planning.
- Primary Research: Dozens of vaccines-related projects every year that include market research with key stakeholders (e.g., ACIP members, payers, purchasers, consumers) to inform strategic decisions.

Putnam's deep vaccine experience empowers manufacturers to confidently navigate the complexities of development, regulatory processes, and market access, ensuring successful product launches globally. Please contact us for more information.

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Putnam, an Inizio Advisory company, is a leading scientific and strategic consulting partner that helps the global life science community make confident decisions, build value, and bring life-changing innovations to clinicians and patients. For more than 30 years, our rigorous, bespoke approach and globally diverse team have delivered unrivaled depth across therapeutic areas, business functions, geographic markets, healthcare sectors, and technology platforms to maximize the human impact and commercial success of client innovations.