Thank you for joining

The presentation will begin shortly

Rise to Immunize® Monthly Webinar

Adapting to Shifting Immunization Recommendations

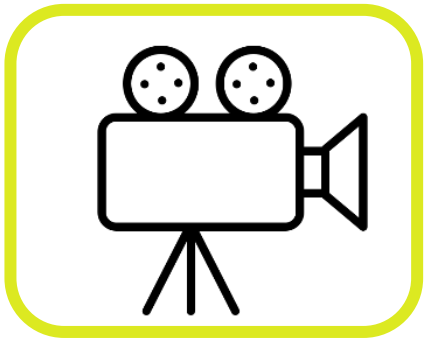
Alix Schnibben, PharmD, BCACP, CTTS, *Northeast Georgia Physician Group*

February 20, 2025

Today's Webinar

- **Campaign Updates**
  - AC25
  - RIZE Meet & Greet Breakfast
  - Resource of the Month
  - Campaign Measure Changes
  - Maternal RSV Webinar
- **Adapting to Shifting Immunization Recommendations**
  - Alix Schnibben, PharmD, BCACP, CTTS, *Northeast Georgia Physician Group*
- **Q&A Session**

Webinar Reminders



Today's webinar recording will be available the **week of 2/24**

- Will be sent via email
- Will be available on website

(RiseToImmunize.org → "Resources" → "Webinars")

Ask questions during the webinar using the **Q&A feature**

- Questions will be answered at the end of the presentation

AMGA 2025 Annual Conference Is Reimagined

What's New at AC25

Two Concurrent Learning Tracks
Health Systems or Independent Groups

Deep Dives
Focused Sessions on Critical Healthcare Topics

The Hub
A Bustling Exhibit Hall With Booths, Tech Demos, and Networking Spaces

Learn More and Register Today at amga.org/AC25

AMGA™

AMGA 2025 ANNUAL CONFERENCE
MARCH 26–29 | GAYLORD TEXAN | GRAPEVINE, TX

Thank you to AMGA's 2025 Annual Conference Platinum Sponsor sanofi

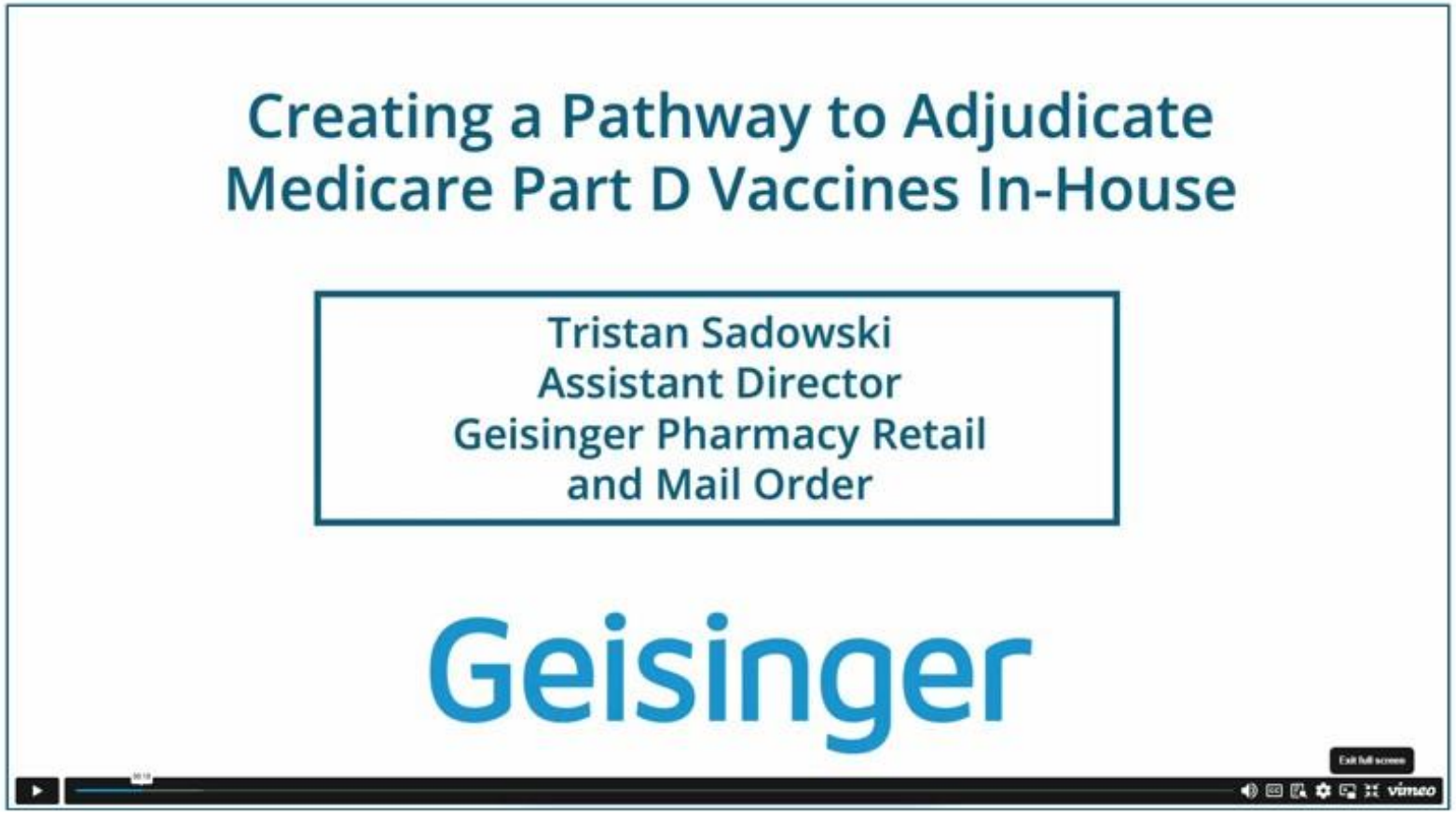
RIZE Meet & Greet Breakfast

Saturday, **March 29**

7-8:15 am CT

Free RIZE notebooks available!

Resource of the Month



RiseToImmunize.org/RIZEVideos

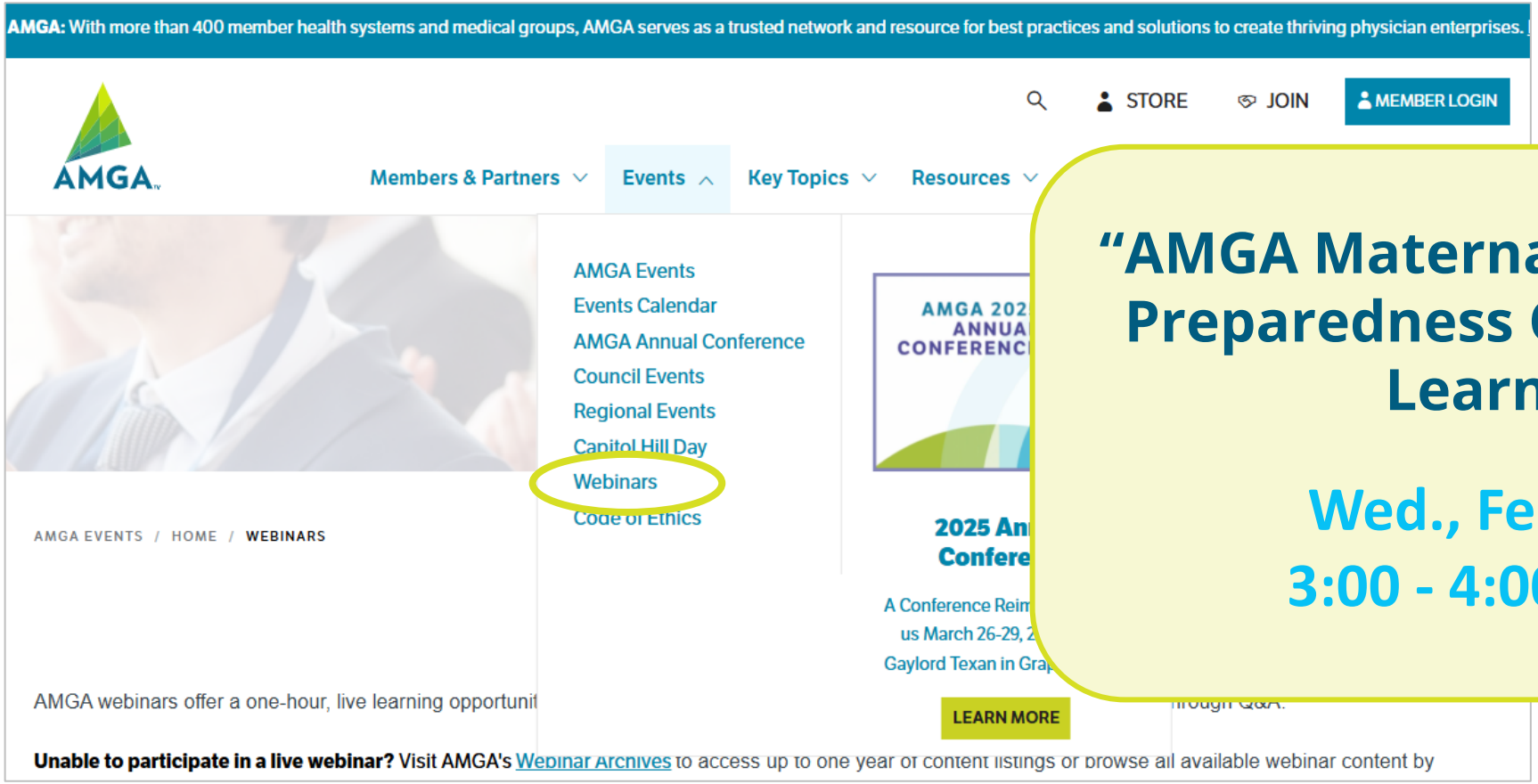
Campaign Measure Changes

Pneumococcal: Change the age group to **50+**

Bundle: Change the age group to **50+**

Starting Q3 2025

AMGA Webinar



"AMGA Maternal RSV Vaccine Preparedness QuIC Lessons Learned"

Wed., Feb. 26th
3:00 - 4:00 PM ET

Today's Speaker

Alix Schnibben, PharmD, BCACP, CTTS, Director, Quality and Ambulatory Pharmacy Services, *Northeast Georgia Physician Group*

Adapting to Shifting Immunization Recommendations

Alix Schnibben, PharmD, BCACP, CTTS
Director, Ambulatory Pharmacy Services & Clinical Quality
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Northeast Georgia PHYSICIANS GROUP

Objectives

Review operational strategy for immunizations

Discuss education tools for clinical support staff

Review key stakeholders for immunizations

Northeast Georgia Health System

- 5 hospitals
- NGPG with 650+ providers
- 1400+ medical staff
- 860+ total beds
- 100+ primary care and specialty offices
- 9 urgent care locations
- 8 rehabilitation locations
- 3 long-term care centers

Background

Work Groups

- Review relevant published and unpublished data and develop recommendation options for presentation to the ACIP
- Goal is to increase the effectiveness of ACIP.

Meeting Cadence

- February, June and October
- Ad hoc meetings as needed

Vaccine Schedules

- Regular cadence

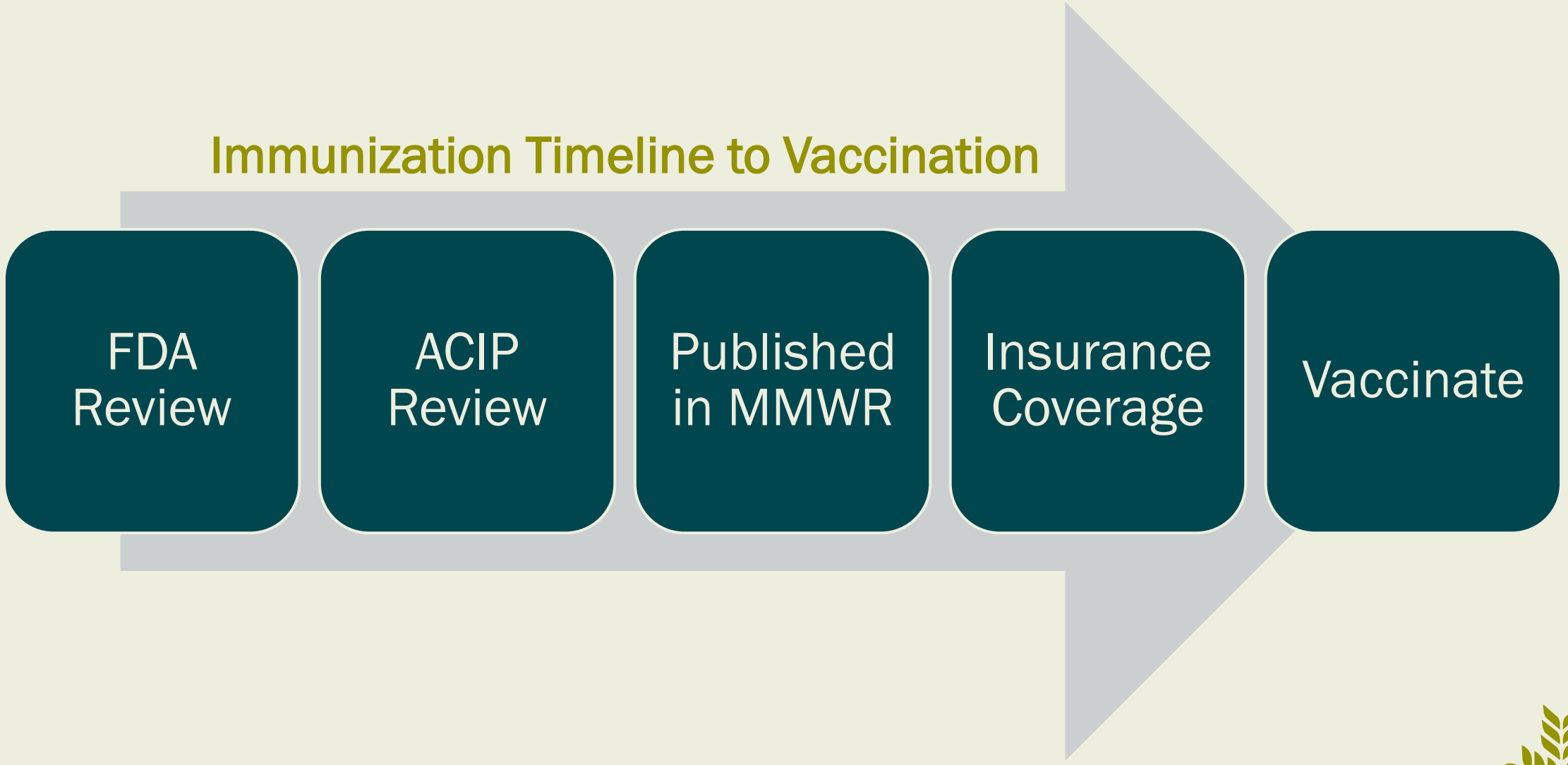
- The Advisory Committee on Immunization Practices (ACIP) comprises medical and public health experts who develop recommendations on the use of vaccines in the civilian population of the United States.
- ACIP's recommendations stand as public health guidance for safe use of vaccines and related biological products.

Background

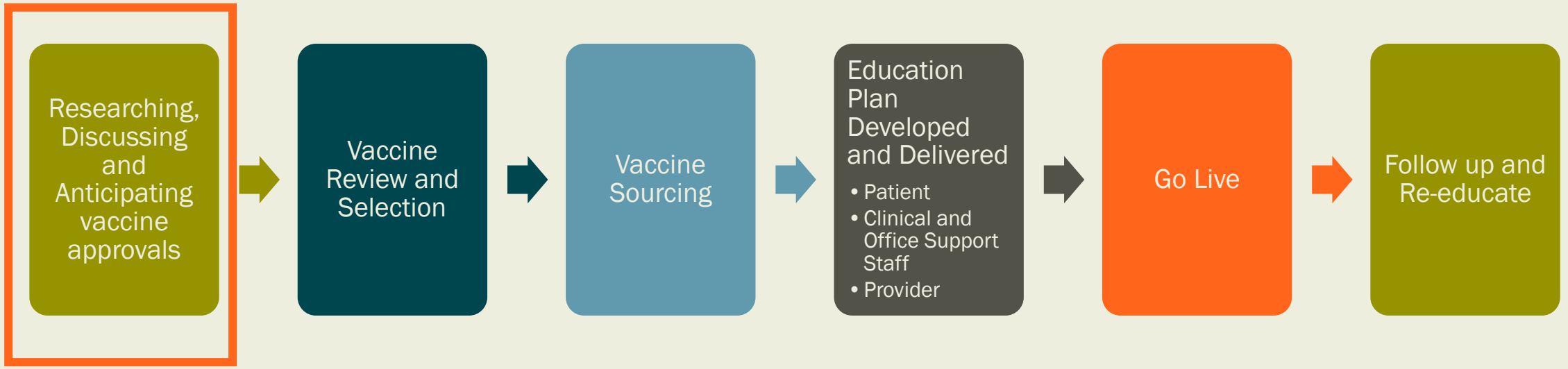
- Evidence to Recommendations (EtR) Framework

EtR Domain	Question
Public Health Problem	• Is the problem of public health importance?
Benefits and Harms	• How substantial are the desirable anticipated effects? • How substantial are the undesirable anticipated effects? • Do the desirable effects outweigh the undesirable effects? • What is the overall certainty of this evidence for the critical outcomes?
Values	• Does the target population feel the desirable effects are large relative to the undesirable effects? • Is there important variability in how patients value the outcomes?
Acceptability	• Is the intervention acceptable to key stakeholders?
Feasibility	• Is the intervention acceptable to key stakeholders?
Resource Use	• Is the intervention a reasonable and efficient allocation of resources?
Equity	• What would be the impact of the intervention on health equity?

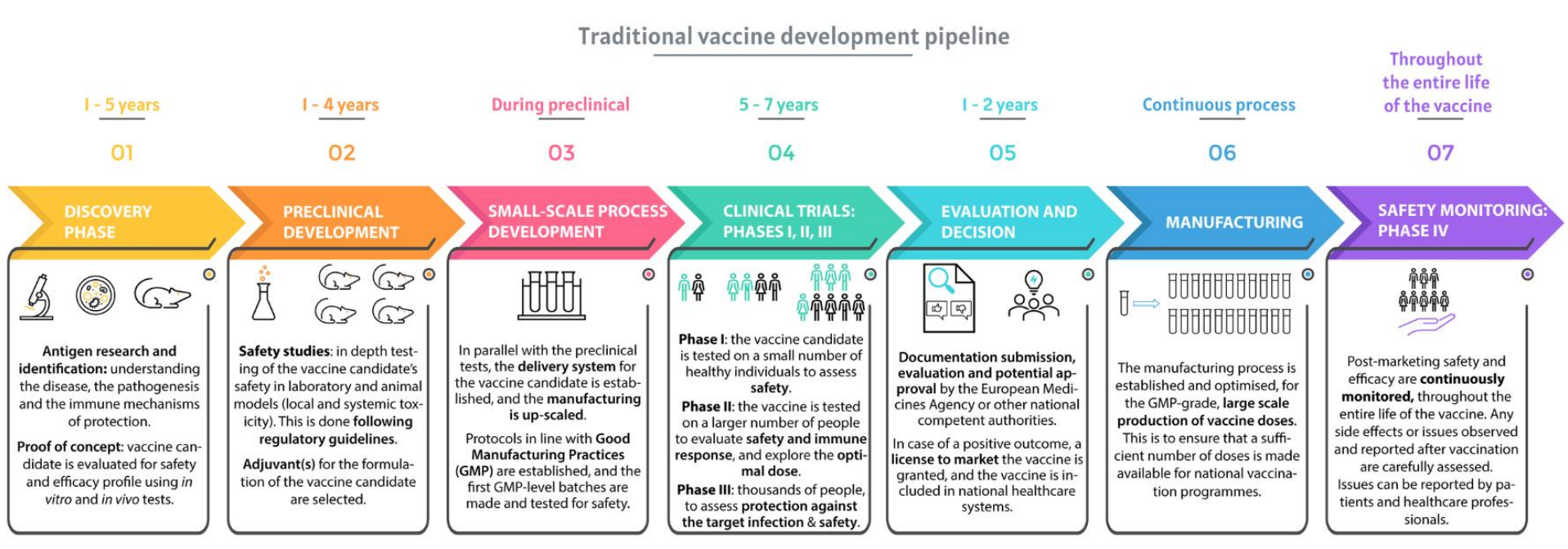
Background


Immunization Timeline to Vaccination
FDA Review
ACIP Review
Published in MMWR
Insurance Coverage
Vaccinate

Operationalizing Immunizations



On the Horizon



https://www.bactivax.eu/blog/the-process-of-designing-and-testing-a-vaccine

Researching, Discussing and Anticipating vaccine approvals

Research

- Vaccine Research & Development
- Review all vaccines available for each indication
- Cost and Coverage

Discuss

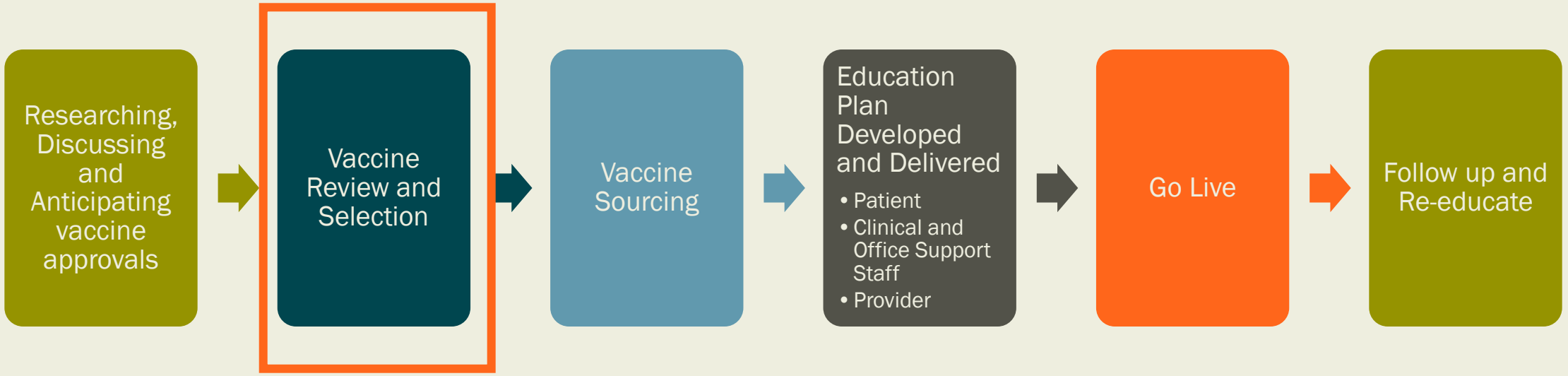
- Medical Science Liaison interactions
  - Pipeline vs Seeking Approval
- Providers conversations
  - Safe vs efficacy

Anticipate

- ACIP meeting attendance
- Gathering Key Stakeholders
  - Providers Representation
  - Pharmacy*
  - Operations
  - PR
  - Clinical Care Director
  - Purchasing department
- Contracting

*Primary Owner of the Process

Operationalizing Immunizations



Vaccine Review and Selection

Financial Stewardship

- Contracts
- Transact Rx
- Coverage

Patient Safety

- Pediatrics vs Adults
- Storage
- Preparation and Administration

Complexity

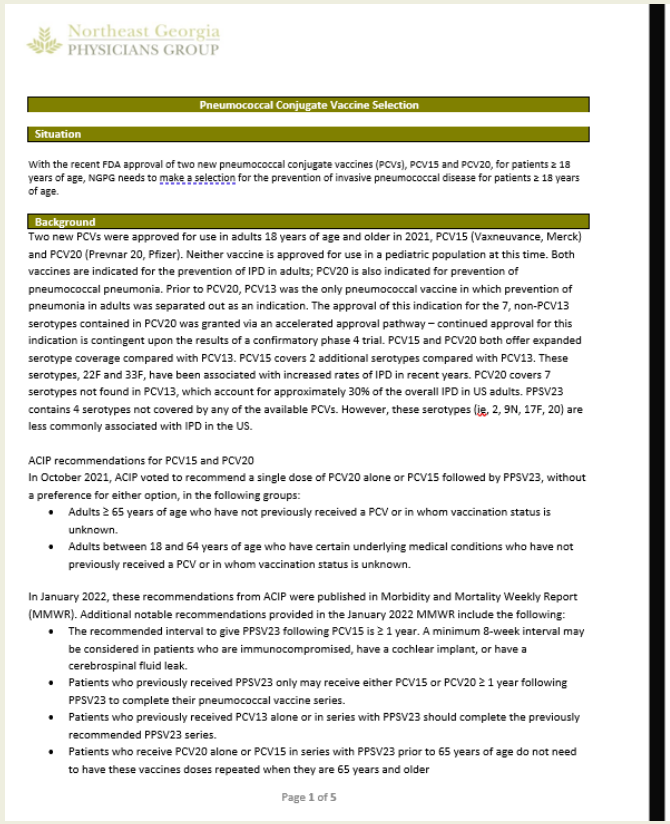
- Vaccine Technology
- Vaccine Hesitancy

Clinical Review

- Safety
- Efficacy
- Review All Available Options

Vaccine Review and Selection

- Situation, Background, Assessment, Recommendation methodology used to present to Key Stakeholders



Northeast Georgia PHYSICIANS GROUP

Pneumococcal Conjugate Vaccine Selection

Situation

With the recent FDA approval of two new pneumococcal conjugate vaccines (PCVs), PCV15 and PCV20, for patients ≥ 18 years of age, NGPG needs to make a selection for the prevention of invasive pneumococcal disease for patients ≥ 18 years of age.

Background

Two new PCVs were approved for use in adults 18 years of age and older in 2021, PCV15 (Vaxneuvance, Merck) and PCV20 (Prevnar 20, Pfizer). Neither vaccine is approved for use in a pediatric population at this time. Both vaccines are indicated for the prevention of IPD in adults; PCV20 is also indicated for prevention of pneumococcal pneumonia. Prior to PCV20, PCV13 was the only pneumococcal vaccine in which prevention of pneumonia in adults was separated out as an indication. The approval of this indication for the 7, non-PCV13 serotypes contained in PCV20 was granted via an accelerated approval pathway – continued approval for this indication is contingent upon the results of a confirmatory phase 4 trial. PCV15 and PCV20 both offer expanded serotype coverage compared with PCV13. PCV15 covers 2 additional serotypes compared with PCV13. These serotypes, 22F and 33F, have been associated with increased rates of IPD in recent years. PCV20 covers 7 serotypes not found in PCV13, which account for approximately 30% of the overall IPD in US adults. PPSV23 contains 4 serotypes not covered by any of the available PCVs. However, these serotypes (ie, 2, 9N, 17F, 20) are less commonly associated with IPD in the US.

ACIP recommendations for PCV15 and PCV20
In October 2021, ACIP voted to recommend a single dose of PCV20 alone or PCV15 followed by PPSV23, without a preference for either option, in the following groups:

- Adults ≥ 65 years of age who have not previously received a PCV or in whom vaccination status is unknown.
- Adults between 18 and 64 years of age who have certain underlying medical conditions who have not previously received a PCV or in whom vaccination status is unknown.

In January 2022, these recommendations from ACIP were published in Morbidity and Mortality Weekly Report (MMWR). Additional notable recommendations provided in the January 2022 MMWR include the following:

- The recommended interval to give PPSV23 following PCV15 is ≥ 1 year. A minimum 8-week interval may be considered in patients who are immunocompromised, have a cochlear implant, or have a cerebrospinal fluid leak.
- Patients who previously received PPSV23 only may receive either PCV15 or PCV20 ≥ 1 year following PPSV23 to complete their pneumococcal vaccine series.
- Patients who previously received PCV13 alone or in series with PPSV23 should complete the previously recommended PPSV23 series.
- Patients who receive PCV20 alone or PCV15 in series with PPSV23 prior to 65 years of age do not need to have these vaccines doses repeated when they are 65 years and older

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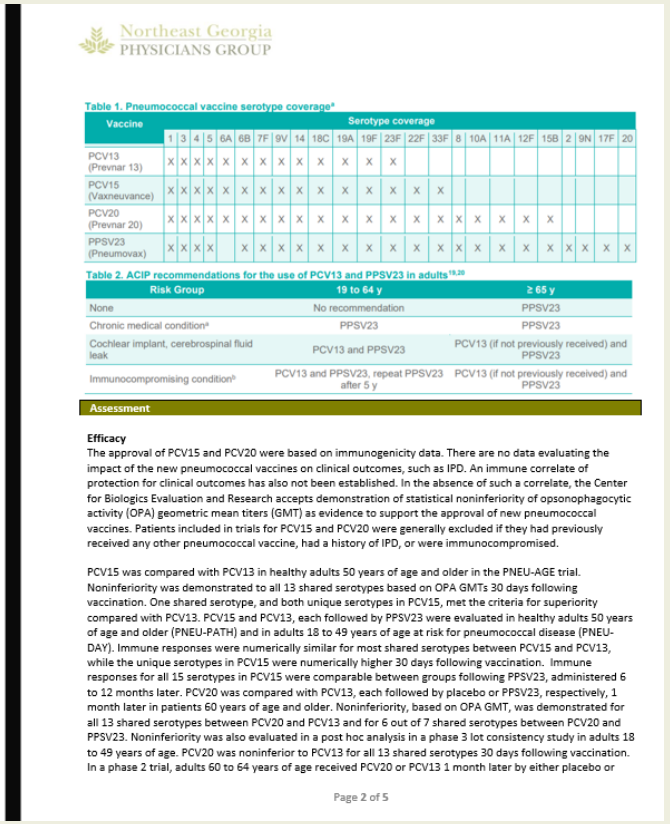

Northeast Georgia PHYSICIANS GROUP

Table 1. Pneumococcal vaccine serotype coverage[a]

Vaccine	Serotype coverage																					
	1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F	22F	33F	8	10A	11A	12F	15B	2	9N	17F	20
PCV13 (Prevnar 13)	X	X	X	X	X	X	X	X	X	X	X	X	X											
PCV15 (Vaxneuvance)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X									
PCV20 (Prevnar 20)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X				
PPSV23 (Pneumovax)	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Table 2. ACIP recommendations for the use of PCV13 and PPSV23 in adults[18,20]

Risk Group	19 to 64 y	≥ 65 y
None	No recommendation	PPSV23
Chronic medical condition[a]	PPSV23	PPSV23
Cochlear implant, cerebrospinal fluid leak	PCV13 and PPSV23	PCV13 (if not previously received) and PPSV23
Immunocompromising condition[b]	PCV13 and PPSV23, repeat PPSV23 after 5 y	PCV13 (if not previously received) and PPSV23

Assessment

Efficacy
The approval of PCV15 and PCV20 were based on immunogenicity data. There are no data evaluating the impact of the new pneumococcal vaccines on clinical outcomes, such as IPD. An immune correlate of protection for clinical outcomes has also not been established. In the absence of such a correlate, the Center for Biologics Evaluation and Research accepts demonstration of statistical noninferiority of opsonophagocytic activity (OPA) geometric mean titers (GMT) as evidence to support the approval of new pneumococcal vaccines. Patients included in trials for PCV15 and PCV20 were generally excluded if they had previously received any other pneumococcal vaccine, had a history of IPD, or were immunocompromised.

PCV15 was compared with PCV13 in healthy adults 50 years of age and older in the PNEU-AGE trial. Noninferiority was demonstrated to all 13 shared serotypes based on OPA GMTs 30 days following vaccination. One shared serotype, and both unique serotypes in PCV15, met the criteria for superiority compared with PCV13. PCV15 and PCV13, each followed by PPSV23 were evaluated in healthy adults 50 years of age and older (PNEU-PATH) and in adults 18 to 49 years of age at risk for pneumococcal disease (PNEU-DAY). Immune responses were numerically similar for most shared serotypes between PCV15 and PCV13, while the unique serotypes in PCV15 were numerically higher 30 days following vaccination. Immune responses for all 15 serotypes in PCV15 were comparable between groups following PPSV23, administered 6 to 12 months later. PCV20 was compared with PCV13, each followed by placebo or PPSV23, respectively, 1 month later in patients 60 years of age and older. Noninferiority, based on OPA GMT, was demonstrated for all 13 shared serotypes between PCV20 and PCV13 and for 6 out of 7 shared serotypes between PCV20 and PPSV23. Noninferiority was also evaluated in a post hoc analysis in a phase 3 lot consistency study in adults 18 to 49 years of age. PCV20 was noninferior to PCV13 for all 13 shared serotypes 30 days following vaccination. In a phase 2 trial, adults 60 to 64 years of age received PCV20 or PCV13 1 month later by either placebo or

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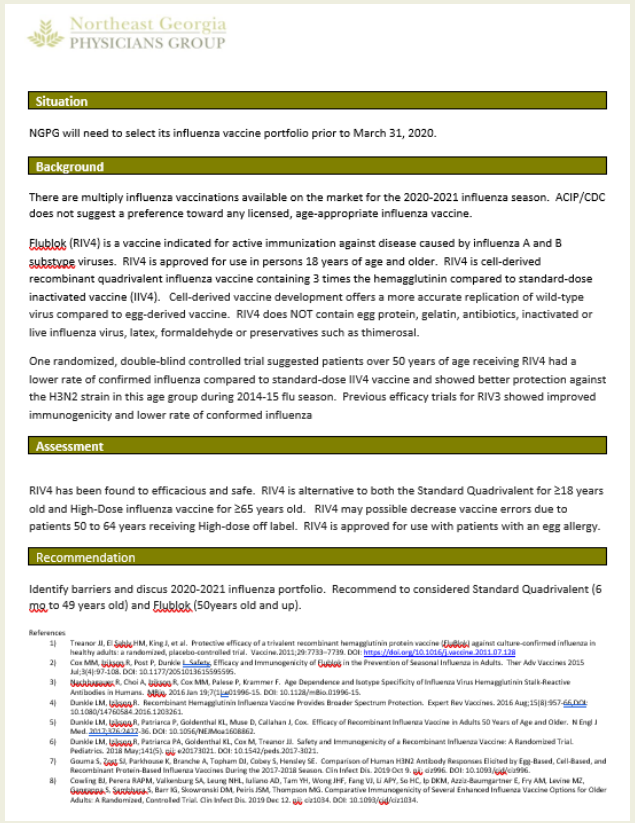


Northeast Georgia PHYSICIANS GROUP

Situation

NGPG will need to select its influenza vaccine portfolio prior to March 31, 2020.

Background

There are multiply influenza vaccinations available on the market for the 2020-2021 influenza season. ACIP/CDC does not suggest a preference toward any licensed, age-appropriate influenza vaccine.

Flublok (RIV4) is a vaccine indicated for active immunization against disease caused by influenza A and B substype viruses. RIV4 is approved for use in persons 18 years of age and older. RIV4 is cell-derived recombinant quadrivalent influenza vaccine containing 3 times the hemagglutinin compared to standard-dose inactivated vaccine (IIV4). Cell-derived vaccine development offers a more accurate replication of wild-type virus compared to egg-derived vaccine. RIV4 does NOT contain egg protein, gelatin, antibiotics, inactivated or live influenza virus, latex, formaldehyde or preservatives such as thimerosal.

One randomized, double-blind controlled trial suggested patients over 50 years of age receiving RIV4 had a lower rate of confirmed influenza compared to standard-dose IIV4 vaccine and showed better protection against the H3N2 strain in this age group during 2014-15 flu season. Previous efficacy trials for RIV3 showed improved immunogenicity and lower rate of conformed influenza

Assessment

RIV4 has been found to efficacious and safe. RIV4 is alternative to both the Standard Quadrivalent for ≥18 years old and High-Dose influenza vaccine for ≥65 years old. RIV4 may possible decrease vaccine errors due to patients 50 to 64 years receiving High-dose off label. RIV4 is approved for use with patients with an egg allergy.

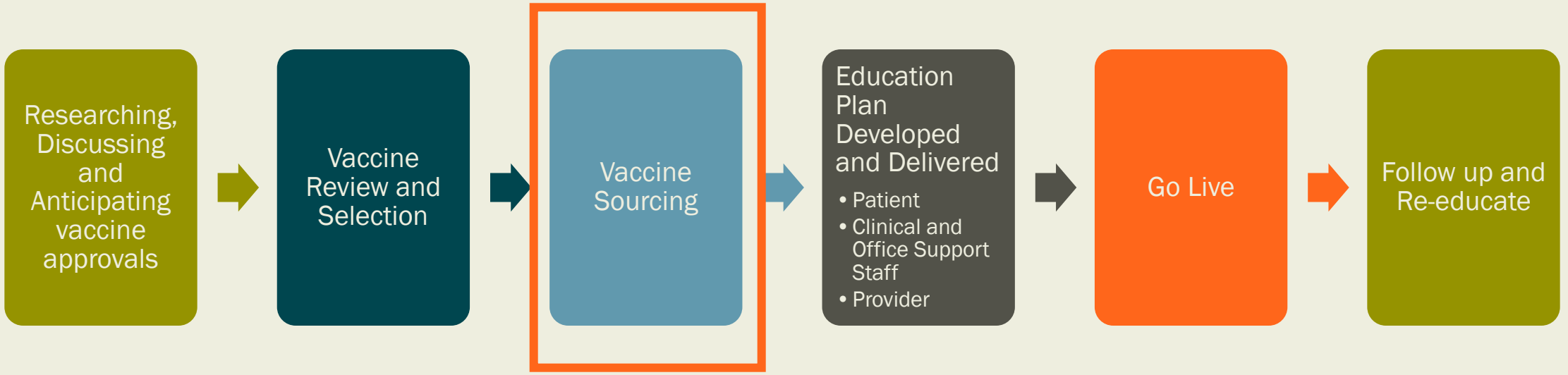
Recommendation

Identify barriers and discus 2020-2021 influenza portfolio. Recommend to considered Standard Quadrivalent (6 mo to 49 years old) and Flublok (50years old and up).

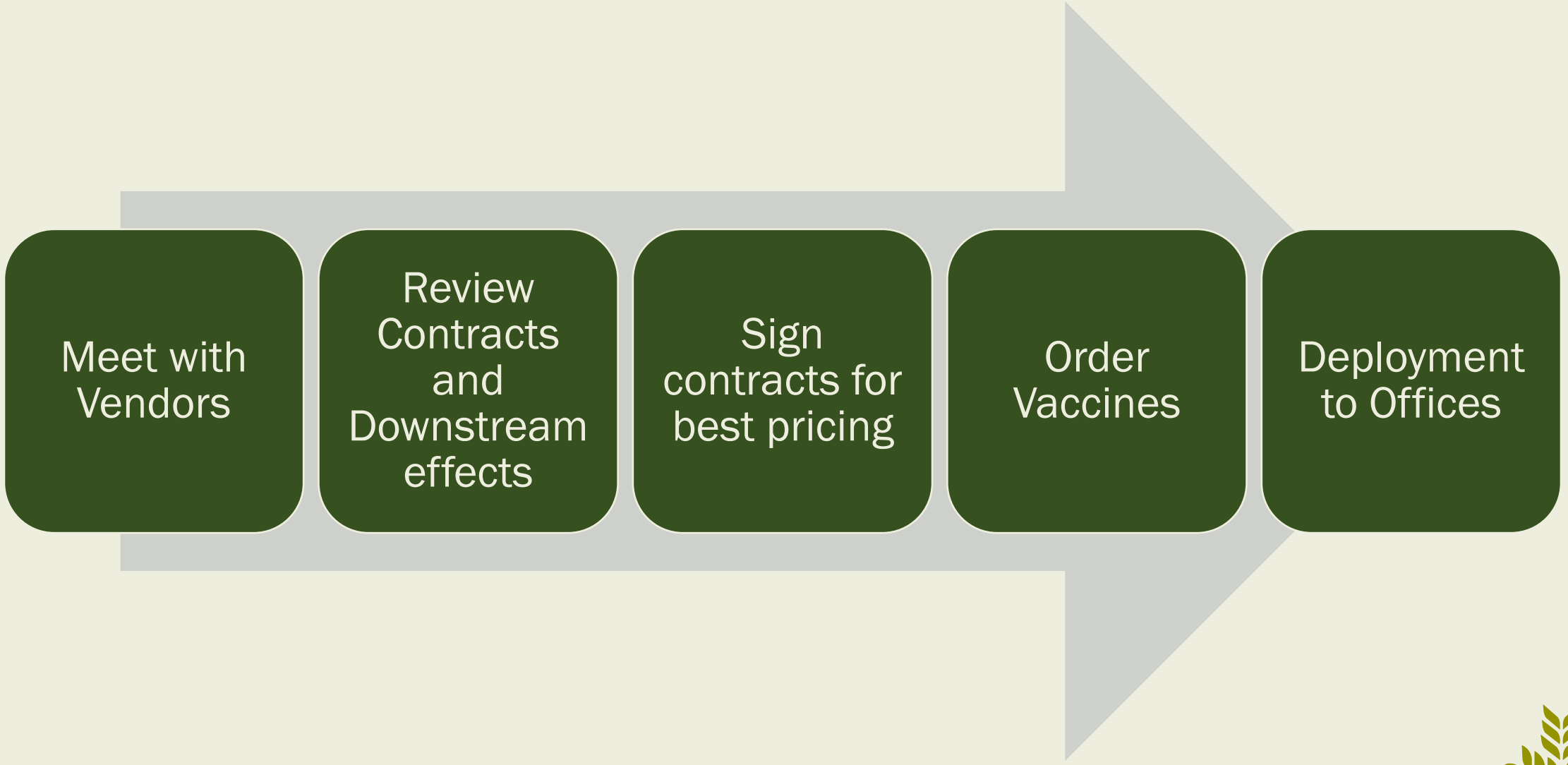
References

1) Treanor JJ, El Sahly HM, King J, et al. Protective efficacy of a trivalent recombinant hemagglutinin protein vaccine (FluBlok) against culture-confirmed influenza in healthy adults: a randomized, placebo-controlled trial. Vaccine.2011;29:7733–7739. DOI: https://doi.org/10.1016/j.vaccine.2011.07.128
2) Cox MMJ, Izikson R, Post P, Dunkle L. Safety, Efficacy and Immunogenicity of Flublok in the Prevention of Seasonal Influenza in Adults. Ther Adv Vaccines 2015 Jul;3(4):97-108. DOI: 10.1177/2051013615595595.
3) Nachbagauer R, Choi A, Izikson R, Cox MMJ, Palese P, Krammer F. Age Dependence and Isotype Specificity of Influenza Virus Hemagglutinin Stalk-Reactive Antibodies in Humans. MBio. 2016 Jan 19;7(1):e01996-15. DOI: 10.1128/mBio.01996-15.
4) Dunkle LM, Izikson R. Recombinant Hemagglutinin Influenza Vaccine Provides Broader Spectrum Protection. Expert Rev Vaccines. 2016 Aug;15(8):957-66.DOI: 10.1080/14760584.2016.1203261.
5) Dunkle LM, Izikson R, Patriarca P, Goldenthal KL, Muse D, Callahan J, Cox. Efficacy of Recombinant Influenza Vaccine in Adults 50 Years of Age and Older. N Engl J Med. 2017;376:2427-36. DOI: 10.1056/NEJMoa1608862.
6) Dunkle LM, Izikson R, Patriarca PA, Goldenthal KL, Cox M, Treanor JJ. Safety and Immunogenicity of a Recombinant Influenza Vaccine: A Randomized Trial. Pediatrics. 2018 May;141(5). pii: e20173021. DOI: 10.1542/peds.2017-3021.
7) Gouma S, Zost SJ, Parkhouse K, Branche A, Topham DJ, Cobey S, Hensley SE. Comparison of Human H3N2 Antibody Responses Elicited by Egg-Based, Cell-Based, and Recombinant Protein-Based Influenza Vaccines During the 2017-2018 Season. Clin Infect Dis. 2019 Oct 9. pii: ciz996. DOI: 10.1093/cid/ciz996.
8) Cowling BJ, Perera RAPM, Valkenburg SA, Leung NHL, Iuliano AD, Tam YH, Wong JHF, Fang VJ, Li APY, So HC, Ip DKM, Azziz-Baumgartner E, Fry AM, Levine MZ, Gentleman S, Sandboe S, Barr IG, Skowronski DM, Peiris JSM, Thompson MG. Comparative Immunogenicity of Several Enhanced Influenza Vaccine Options for Older Adults: A Randomized, Controlled Trial. Clin Infect Dis. 2019 Dec 12. pii: ciz1034. DOI: 10.1093/cid/ciz1034.

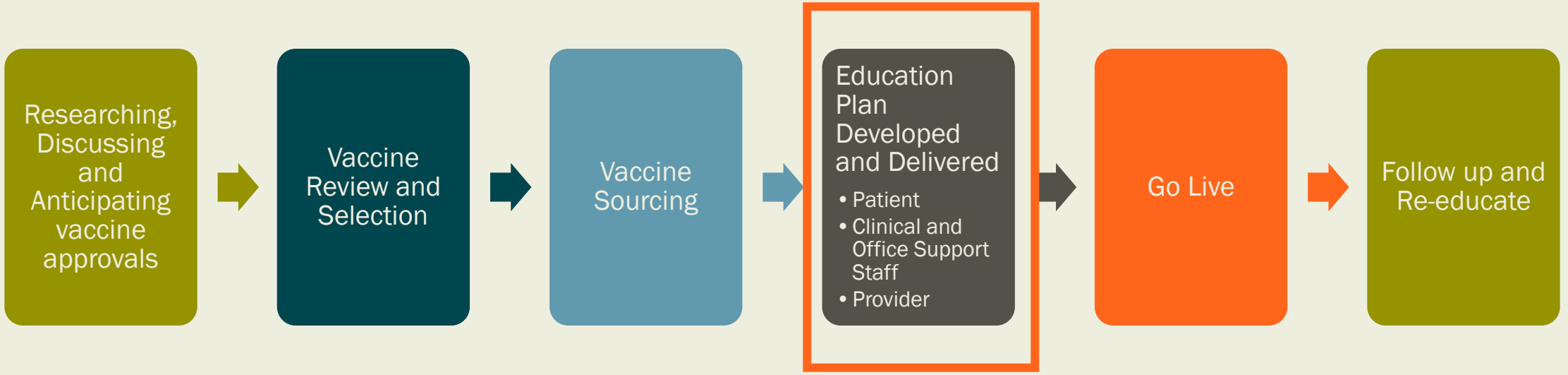
Operationalizing Immunizations



Vaccine Sourcing



Operationalizing Immunizations



Provider Communication

Newsletters

Update to Pneumococcal Conjugate Vaccine

The Advisory Committee on Immunization Practices (ACIP) met on October 19 and 20, 2023. During this meeting, ACIP clarified vaccination of persons who had previously received PCV13 and may be eligible for PCV20.

Population	Pneumococcal vaccine history	Vaccine(s) recommended to complete pneumococcal series
Adults with an Immunocompromising condition, cochlear implant, or cerebrospinal fluid leak	PCV13 and one or more PPSV23 doses (before age 65), but have not completed all previously recommended doses of PPSV23	**Option A:** PCV20 at least 5 years after the most recent pneumococcal vaccine dose **Option B:** PPSV23 as previously recommended
≥65 yo	PCV13 and PPSV23	PCV20 may be given ≥5 years after most recent pneumococcal dose (shared clinical decision making)
≥19 yo previously recommended to receive PCV13 followed by PPSV23, but who have received only PCV13	PCV13 only	**Option A:** PCV20 ≥1 year after PCV13 **Option B:** PPSV23 as previously recommended

Respiratory Vaccines Season

As temperatures cool, the risks of respiratory illnesses rise. This year, there are more vaccine optio prevent serious illness from flu, COVID-19, pneumonia, and RSV. All four vaccines, in general, are s recommended for their respective populations. After last winter's flu, COVID-19, and RSV tripledem public health and the stability of the U.S. health care system, doctors are urging virtually everyone t vaccinated against the flu and COVID and for people to talk to their health care providers about wh available RSV vaccine is right for them.

Vaccine Type	ACIP Recommendation	Whe
Influenza	ACIP recommends that all persons aged ≥6 months who do not have contraindications, receive a licensed and age-appropriate seasonal influenza vaccine. ACIP recommends that adults aged ≥65 years preferentially receive any 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).	Ideall during for most patients. However, vaccination should continue after October and throughout the season as long as influenza viruses are circulating, and an unexpired vaccine is available.
COVID-19	ACIP recommends 2023–2024 (monovalent, XBB containing) COVID-19 vaccines as authorized under EUA or approved by BLA in persons ≥6 months of age.	≥8 weeks after last dose
RSV	Pfizer RSV vaccine, Abrysvo, for pregnant persons at 32–36 weeks' gestation to prevent RSV-associated LRTI in infants aged <6 months.	September–January in most of the United States
	Nirsevimab for infants aged <8 months born during or entering their first RSV season and for infants and children aged 8–19 months who are at increased risk of severe RSV disease entering their second RSV season.	October through the end of March
	Persons aged ≥75 years or 60-74 years old with certain chronic conditions may receive a single dose of RSV vaccine, using shared clinical decision-making. Sufficient evidence does not exist currently to determine the need for revaccination.	Before the onset of the RSV season
Pneumonia	PCV15 or PCV20 to infants as a series of 4 doses, one dose at each of these ages: 2 months, 4 months, 6 months, and 12 through 15 months.	As determined by the patient's vaccine history
	PCV15 followed by 1 doses of PPSV23 or PCV20 for individuals aged 2 to 64 years with certain risk conditions (https://www.cdc.gov/vaccines/vpd/pneumo/hcp/recommendations.html)	
	Pneumococcal conjugate vaccine (PCV15 or PCV20) for all adults 65 years or older who have never received any pneumococcal conjugate vaccine or whose previous vaccination history is unknown: if PCV15 is used, this should be followed by a dose of PPSV23 one year later.	

Formulary Review

Respiratory Syncytial Virus vaccines (RSV): Options for Infant RSV Prevention

	Maternal RSV Vaccine: Use ONLY Pfizer RSVPreF vaccine (trade name Abrysvo™)	Infant RSV Monoclonal Antibody*
Recommendation	RSVPreF vaccine (trade name Abrysvo™) is recommended for people during weeks 32 through 36 of pregnancy, using seasonal administration, to prevent severe RSV disease in infants. In clinical trials, there was a small increase in the number of preterm birth events in vaccinated pregnant people after vaccination. It is not clear if this is a true safety problem related to RSV vaccine or if this occurred for reasons unrelated to vaccination.	RSV monoclonal antibody (generic name nirsevimab, trade name Beyfortus™) is recommended for the following: • Infants less than 8 months of age born during or entering their first RSV season if: ○ Mother did not receive maternal RSV vaccine or it is unknown if mother received RSV vaccine OR ○ Infant was born less than 14 days after maternal RSV vaccination† In rare circumstances, nirsevimab may be considered for infants born to mothers vaccinated 14 or more days before birth when the health care provider believes the potential incremental benefit is warranted. These situations include, but are not limited to: ○ Infants born to mothers who might not have mounted an adequate immune response to vaccination (e.g., people with immunocompromising conditions) ○ Infants born to mothers who have conditions associated with reduced transplacental antibody transfer (e.g., people living with HIV infection) ○ Infants who might have experienced loss of maternal antibodies, such as those who have undergone cardiopulmonary bypass of extracorporeal membrane oxygenation (ECMO) ○ Infants with substantial increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, intensive care admission with the requirement for oxygen at hospital discharge) • Some infants and children aged 8 through 19 months who are at increased risk of severe RSV disease entering their second RSV season. ○ American Indian/Alaska Native children ○ Children with chronic lung disease of prematurity who require medical support during the six months before the start of their second RSV season ○ Children with severe immunocompromise ○ Children with severe cystic fibrosis
Description	RSVPreF vaccine Trade name: Abrysvo™	Generic name nirsevimab Trade name: Beyfortus™

*Note: A different monoclonal antibody, palivizumab, is used in children under 24 months of age with certain conditions that place them at high risk for severe RSV disease. Please see AAP guideline for palivizumab. AAP has published considerations on the use of nirsevimab and palivizumab: https://publications.aap.org/aapnews/resources/23370. Children who have received nirsevimab should not receive palivizumab during the same RSV season.
†From time of maternal vaccination, at least 14 days are needed for the development and transplacental transfer of maternal antibodies to protect the infant.
‡Children 8–19 months who are at increased risk of severe RSV disease (American Indian and Alaska Native children; children who are severely immunocompromised; children with cystic fibrosis with severe disease; and children with chronic lung disease of prematurity who require medical support during the six months before the start of their second RSV season) should receive nirsevimab 200 mg dose administered as two IM injections (2 x 100 mg light blue plunger rod) shortly before the start of their second RSV season.
§One dose for each RSV season except for children undergoing cardiac surgery with cardiopulmonary bypass where an additional dose is recommended as soon as the child is stable after surgery. See label (fda.gov).

Respiratory Syncytial Virus vaccines (RSV): Options for Infant RSV Prevention

	Mother – Active immunity Infant – Passive immunity	Passive immunity
Immunity		
Duration of Protection	Approximately 3 to 6 months for infant	Approximately 5 months or more
How Supplied	A kit that includes a vial of lyophilized antigen component, a prefilled syringe containing sterile water diluent, and a vial adapter. The lyophilized antigen component is reconstituted with the sterile water diluent to form a single dose.	Single dose pre-filled syringe with a purple (for 50 mg dosage) or light blue (for 100 mg dosage) plunger rod. No reconstitution needed.
Recommended Dosage	0.5 mL Currently recommended for administration as a single dose. It is not yet known whether additional doses might be needed in later pregnancies.	**Age less than 8 months** • Less than 5 kg: 50 mg (0.5mL) • 5 kg and greater: 100 mg (1mL) **Age 8 through 19 months‡** • 200 mg (administered as two IM injections)
Number of Doses	One	One§
How Administered	IM injection	IM injection
Coadministration	Can be administered without regard to timing of other routine immunizations, including simultaneous administration	Can be administered without regard to timing of other routine immunizations, including simultaneous administration
Gestation or Age for immunization	32 through 36 weeks	• Less than age 8 months depending on mother's RSV vaccination status • Ages 8 through 19 months if at increased risk for severe RSV disease ‡
When to Administer (Seasonality)	Beginning of September through end of January in most of the continental United States. In jurisdictions with RSV seasonality that differs from most of the continental United States, including Alaska, southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands, healthcare providers should follow state, local, or territorial guidance on timing of maternal RSV vaccination.	Beginning of October through end of March in most of the continental United States. In jurisdictions with RSV seasonality that differs from most of the continental United States, including Alaska, southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands, healthcare providers should follow state, local, or territorial guidance on timing of nirsevimab administration.
Contraindications (Product Should Not Be Administered)	History of severe allergic reaction (e.g., anaphylaxis) to any component of the maternal RSV vaccine	History of severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of nirsevimab
Precautions (Administration Should Typically Be Deferred)	The presence of a moderate or severe acute illness, with or without a fever.	The presence of a moderate or severe acute illness, with or without a fever.
Cost	$295 per dose	$445 per dose 1st season/$890 per dose 2nd season

*Note: A different monoclonal antibody, palivizumab, is used in children under 24 months of age with certain conditions that place them at high risk for severe RSV disease. Please see AAP guideline for palivizumab. AAP has published considerations on the use of nirsevimab and palivizumab: https://publications.aap.org/aapnews/resources/23370. Children who have received nirsevimab should not receive palivizumab during the same RSV season.
†From time of maternal vaccination, at least 14 days are needed for the development and transplacental transfer of maternal antibodies to protect the infant.
‡Children 8–19 months who are at increased risk of severe RSV disease (American Indian and Alaska Native children; children who are severely immunocompromised; children with cystic fibrosis with severe disease; and children with chronic lung disease of prematurity who require medical support during the six months before the start of their second RSV season) should receive nirsevimab 200 mg dose administered as two IM injections (2 x 100 mg light blue plunger rod) shortly before the start of their second RSV season.
§One dose for each RSV season except for children undergoing cardiac surgery with cardiopulmonary bypass where an additional dose is recommended as soon as the child is stable after surgery. See label (fda.gov).

Pharmacy Team Support including journal club

Provider Communication

Provider Meeting Presentations

Electronic Education

Priorix: MMR Vaccine

Coding Tip Sheet

CPT Code (Vaccine): 90707

CPT Codes (Administration):

Immunization administration through 18 years of age with counseling by physician or other qualified healthcare professional	90460	Immunization administration via any route, first vaccine/toxoid component
	+90461	Immunization administration via any route, each additional vaccine/toxoid component *(List separately in addition to code for primary procedure)*
Immunization administration of any vaccine for a patient through 18 years of age that is not accompanied by counseling, or for administration of vaccines to patients over 18 years of age	90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections), one vaccine (single or combination vaccine/toxoid)
	+90472	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections), each additional vaccine (single or combination vaccine/toxoid) *(List separately in addition to code for primary procedure)*

ICD 10: Z23

NDC (outer carton): 58160-0824-15

Charge Amount: $119.00

Dose: 0.5mL

Who: 12 months of age and older

Indications: PRIORIX is a vaccine indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age and older.

Medicare Part D Vaccine Eligible—utilize Transact Rx!

Town Halls

Hepatitis B Serologic Testing vs Vaccination

Hepatitis B Serologic Testing Recommendations	
USPSTF	
2020 Recommendations: • Pregnant women: The USPSTF recommends screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit. • Adolescents and adults at increased risk for infection: The USPSTF recommends screening for hepatitis B virus (HBV) infection in adolescents and adults at increased risk for infection. o Those at increased risk for infection: ▪ Persons born in countries with a prevalence of hepatitis B surface antigen (HBsAg) of 2% or greater ▪ Persons born in the US with parents from regions with higher prevalence are also at increased risk of HBV infection during birth or early childhood, particularly if they do not receive appropriate passive and active immunoprophylaxis (and antiviral therapy for pregnant women with a high viral load) and adolescents and adults born in the US who did not receive the HBV vaccine as infants and whose parents were born in regions with an HBsAg prevalence of 8% or greater (regardless of their biological mother's HBsAg status). ▪ Persons from such risk groups include persons who have injected drugs in the past or currently; men who have sex with men; persons with HIV; and sex partners, needle-sharing contacts, and household contacts of persons known to be HBsAg positive. • Screening test: Screening for hepatitis B should be performed with HBsAg tests approved by the US Food and Drug Administration, followed by a confirmatory test for initially reactive results. • Screening interval: For patients with negative HBsAg results who have not received the HBV vaccine series, periodic screening may be useful for those who report continued risk for acquiring HBV transmission, such as persons who continue to inject drugs and men who have sex with men. Clinical judgment should be used to determine screening frequency. The USPSTF found no evidence to determine optimal screening intervals.	
CDC	
General Recommendations	2023 Recommendations: • Adults: CDC recommends screening all adults aged 18 years and older for hepatitis B at least once in their lifetime using a triple panel test. To ensure increased access to testing, anyone who requests HBV testing should receive it regardless of disclosure of risk. Many people might be reluctant to disclose stigmatizing risks. • Infants: CDC recommends testing infants born to HBsAg positive people for HbsAg and anti-HBs seromarkers. • Pregnant people: CDC recommends HBV screening for hepatitis B surface antigen (HbsAg) for all pregnant people during each pregnancy, preferably in the first trimester, regardless of vaccination status or history of testing. Pregnant people with a history of appropriately timed triple panel screening without subsequent risk for exposure to HBV (i.e., no new HBV exposures since triple panel screening) only need HbsAg screening. • People at increased risked: CDC recommends testing susceptible people periodically, regardless of age with ongoing risk for exposures, while risk for exposures persists. Including: o People with a history of sexually transmitted infections or multiple sex partners o People with hepatitis C infection or a history of hepatitis C virus infection o People incarcerated or formerly incarcerated in a jail, prison, or other detention setting o Infants born to HbsAg-positive people o People born in regions with HBV infection prevalence of ≥2% o US born people not vaccinated as infants whose parents were born in geographic regions with HbsAg prevalence of >8% o People who inject drugs or have a history of injection drug use o People with HIV infection o Men who have sex with men

Provider Communication

Letters to Providers

Know Do Say

Quality Initiatives/Measures

Northeast Georgia PHYSICIANS GROUP

To: NGPG Providers
From: Alix Schnibben, PharmD, BCACP, CTTS
Director, Clinical Quality and Ambulatory Pharmacy Services
Re: Prevnar 20™ (Pneumococcal 20-valent Conjugate Vaccine) Formulary Information

Dear NGPG Providers:

I am pleased to share that Northeast Georgia Physicians Group has placed Prevnar 20™ (Pneumococcal 20-valent Conjugate Vaccine) on formulary. Approved by the US Food and Drug Administration (FDA) on June 8, 2021, Prevnar 20 is indicated for the prevention of invasive pneumococcal disease and pneumococcal pneumonia in adults. The indication for the prevention of pneumonia caused by *S. pneumoniae* serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA) assay. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.[1]

Prevnar 20 delivers the most serotypes in a pneumococcal conjugate vaccine by adding 7 serotypes to Prevnar 13 (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM_{197} Protein]).[1-3] Prevnar 13 and Prevnar 20 are the only conjugate vaccines that are FDA-approved for the prevention of pneumococcal pneumonia.[1-3*]

On October 20, 2021, the CDC's Advisory Committee on Immunization Practices (ACIP) voted to revise its adult pneumococcal vaccination recommendations.

ACIP adult pneumococcal vaccination recommendations

Aged 65 years or older	Vaccination recommendations
Adults who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown	Prevnar 20 OR PCV15 followed by PPSV23
Aged 19 to 64 years old	**Vaccination recommendations**
Adults with certain underlying medical conditions or other risk factors* who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown	Prevnar 20 OR PCV15 followed by PPSV23

*Alcoholism, chronic heart/liver/lung disease, cigarette smoking, diabetes mellitus, chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease or other hemoglobinopathies, CSF leak, or cochlear implant.

CDC = Centers for Disease Control and Prevention; CSF = cerebrospinal fluid; PCV15 = pneumococcal 15-valent conjugate vaccine; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

As a healthcare provider, you play a vital role in educating your adult patients. The Centers for Disease Control and Prevention recommends that all healthcare providers assess immunization status of all patients at every visit and recommend vaccines that patients need. Your recommendation can help make a difference.[5]

Vaccines: Vaccine Updates ACIP October 2024 vote

Things to Know, Do and Say

KNOW	• **COVID 2024-2025 Formulation** ○ On October 23, 2024, CDC Director Mandy Cohen endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) recommendation for **people 65 years and older and those who are moderately or severely immunocompromised to receive a second dose of 2024-2025 COVID-19 vaccine six months after their first dose.** ▪ ACIP recommends a second dose of 2024-2025 COVID-19 for adults ages 65 years and older ▪ ACIP recommends a second dose of 2024-2025 COVID-19 vaccine for people ages 6 months-64 years who are moderately or severely immunocompromised ○ These updated recommendations also allow for flexibility for additional doses (i.e., three or more) for those who are moderately or severely immunocompromised, in consultation with their healthcare provider (a strategy known as shared clinical decision making). ▪ ACIP recommends additional doses (i.e., 3 or more doses) of 2024-2025 COVID-19 vaccine for people ages 6 months and older who are moderately or severely immunocompromised under shared clinical decision making ○ If previously unvaccinated and receiving Novavax, 2 doses are recommended as initial vaccination series followed by a third dose of any age-appropriate 2024-2025 COVID-19 vaccine 6 months (minimum interval 2 months) after second dose. ○ If previously unvaccinated or receiving initial vaccination series, at least 2 doses of 2024–2025 vaccine are recommended, and depending on vaccination history more may be needed. This additional 2024–2025 vaccine dose is recommended 6 months (minimum interval 2 months) after completion of initial vaccination series. • **Pneumococcal** ○ On October 23, 2024, CDC Advisory Committee on Immunization Practices' (ACIP) recommendation for lowering the age for pneumococcal vaccination from 65 to **50 years old.** ▪ ACIP recommends a pneumococcal conjugate vaccine (PCV) for all PCV-naive adults aged ≥50 years ○ Lowering the age for pneumococcal vaccination gives more adults the opportunity to protect themselves from pneumococcal disease at the age when risk of infection substantially increases. Pneumococcal bacteria can cause serious illnesses, including pneumonia, meningitis, and bloodstream infections, and older adults are at increased risk for pneumococcal disease. ○ Adults 50 years or older should talk with a healthcare provider to make sure they're up to date with pneumococcal vaccination. Now is a great time to get vaccinated against pneumococcal disease in preparation for the winter respiratory season. ○ Currently, ACIP has made no preferential vote for PCV15, PCV20, or PCV21. NGPG will continue to use PCV20 at this time as it is still recommended by ACIP for pediatrics and adults. • **Meningococcal** ○ ACIP recommends MenB-4C (Bexsero®) be administered as **a 2-dose series at 0 and 6 months** when given to healthy adolescents and young adults aged 16–23 years based on shared clinical decision-making for the prevention of serogroup B meningococcal disease ○ ACIP recommends MenB-4C (Bexsero®) be administered as a **3-dose series at 0, 1–2, and 6 months when given to persons aged ≥10 years at increased risk for serogroup B meningococcal disease** (i.e., persons with anatomic or functional asplenia, complement component deficiencies, or complement inhibitor use; microbiologists routinely exposed to *N. meningitidis* isolates; and persons at increased risk during an outbreak) It will take several weeks for Epic to update health maintenance to reflect these votes.
Do	• Inform, offer, and vaccinate patients who are eligible for updated recommendations for 2024-2025 COVID 19 formulation and pneumococcal.
Say	• Providers are responsible for the shared decision-making conversation. • NGPG will continue to follow FDA/CDC/ACIP for guidance.

Clinical and Front Office Education Plan

Newsletters

- Published in Pharmacy and Staff Newsletter about the vaccine added to formulary and what to expect

Pharmacy Team Support

- On-call pharmacy team to answer all questions about vaccine roll-out
- Support with tip sheets and at the elbow support

Electronic Education

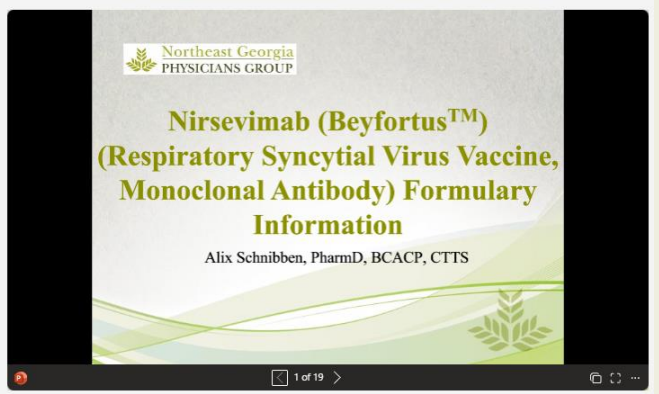
- Centralized repository of education on SharePoint
- Mandatory online education model

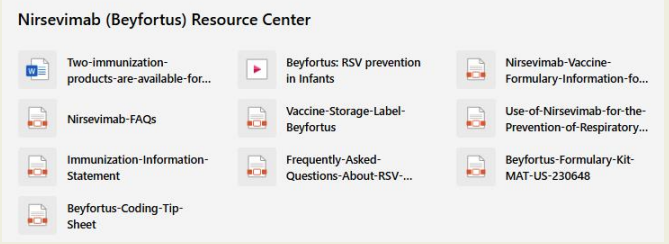
Town Halls

- Multiple town halls help to review new vaccine and what to expect and how to prepare
- Talking points for patients, Cost, Storage, etc. are reviewed
- Recorded and shared online

Vaccine Annual Competencies

- Mandatory vaccine annual education with competency check





Clinical and Front Office Education Plan

Educational Handouts

- Tip Sheets about the vaccine along with FAQ includes pricing
- VIS is stored within electronic health record

In-service with a Pharmacist

- Offices can request an on-site In-service and support for go-live

Pre-visit planning

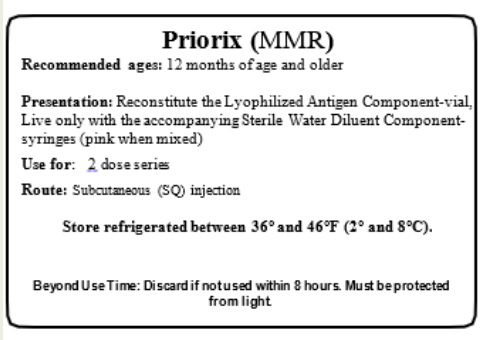
- Prior to appointment staff reviews the chart for appropriate vaccines (open care gaps)
- Checks state vaccine registry
- Review health maintenance

Vaccine Labels

- Implement new vaccine label in fridge
- Increases vaccine scan rate

Quality Initiatives/Measures

- Education about quality measures involving vaccine
- Strategy on how to succeed
- Data sharing



Priorix (MMR)

Recommended ages: 12 months of age and older

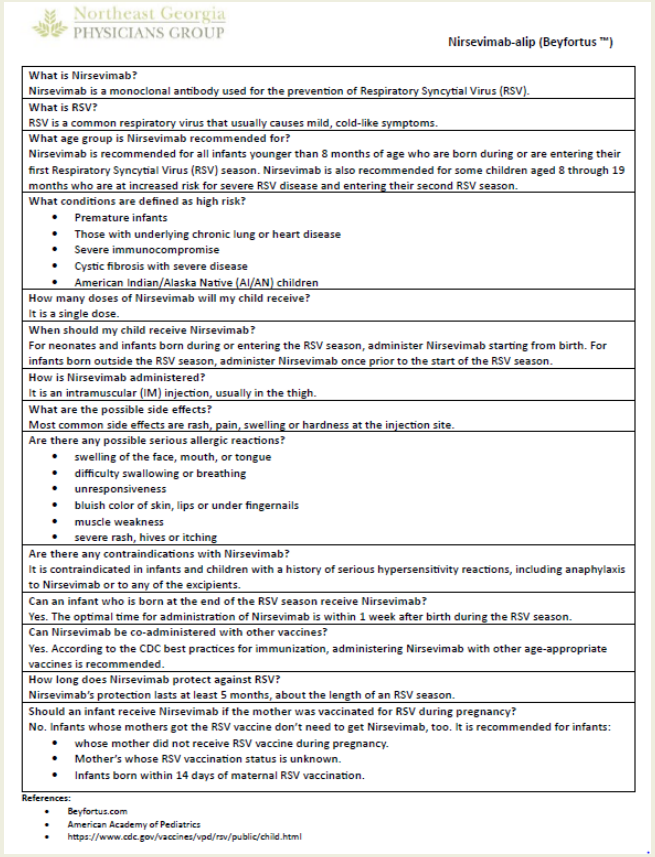
Presentation: Reconstitute the Lyophilized Antigen Component-vial, Live only with the accompanying Sterile Water Diluent Component-syringes (pink when mixed)

Use for: 2 dose series

Route: Subcutaneous (SQ) injection

Store refrigerated between 36° and 46°F (2° and 8°C).

Beyond Use Time: Discard if not used within 8 hours. Must be protected from light



Northeast Georgia PHYSICIANS GROUP

Nirsevimab-alip (Beyfortus ™)

What is Nirsevimab?
Nirsevimab is a monoclonal antibody used for the prevention of Respiratory Syncytial Virus (RSV).

What is RSV?
RSV is a common respiratory virus that usually causes mild, cold-like symptoms.

What age group is Nirsevimab recommended for?
Nirsevimab is recommended for all infants younger than 8 months of age who are born during or are entering their first Respiratory Syncytial Virus (RSV) season. Nirsevimab is also recommended for some children aged 8 through 19 months who are at increased risk for severe RSV disease and entering their second RSV season.

What conditions are defined as high risk?
- Premature infants
- Those with underlying chronic lung or heart disease
- Severe immunocompromise
- Cystic fibrosis with severe disease
- American Indian/Alaska Native (AI/AN) children

How many doses of Nirsevimab will my child receive?
It is a single dose.

When should my child receive Nirsevimab?
For neonates and infants born during or entering the RSV season, administer Nirsevimab starting from birth. For infants born outside the RSV season, administer Nirsevimab once prior to the start of the RSV season.

How is Nirsevimab administered?
It is an intramuscular (IM) injection, usually in the thigh.

What are the possible side effects?
Most common side effects are rash, pain, swelling or hardness at the injection site.

Are there any possible serious allergic reactions?
- swelling of the face, mouth, or tongue
- difficulty swallowing or breathing
- unresponsiveness
- bluish color of skin, lips or under fingernails
- muscle weakness
- severe rash, hives or itching

Are there any contraindications with Nirsevimab?
It is contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis to Nirsevimab or to any of the excipients.

Can an infant who is born at the end of the RSV season receive Nirsevimab?
Yes. The optimal time for administration of Nirsevimab is within 1 week after birth during the RSV season.

Can Nirsevimab be co-administered with other vaccines?
Yes. According to the CDC best practices for immunization, administering Nirsevimab with other age-appropriate vaccines is recommended.

How long does Nirsevimab protect against RSV?
Nirsevimab's protection lasts at least 5 months, about the length of an RSV season.

Should an infant receive Nirsevimab if the mother was vaccinated for RSV during pregnancy?
No. Infants whose mothers got the RSV vaccine don't need to get Nirsevimab, too. It is recommended for infants:
- whose mother did not receive RSV vaccine during pregnancy.
- Mother's whose RSV vaccination status is unknown.
- Infants born within 14 days of maternal RSV vaccination.

References:
- Beyfortus.com
- American Academy of Pediatrics
- https://www.cdc.gov/vaccines/vpd/rsv/public/child.html

Patient Communication

Televox

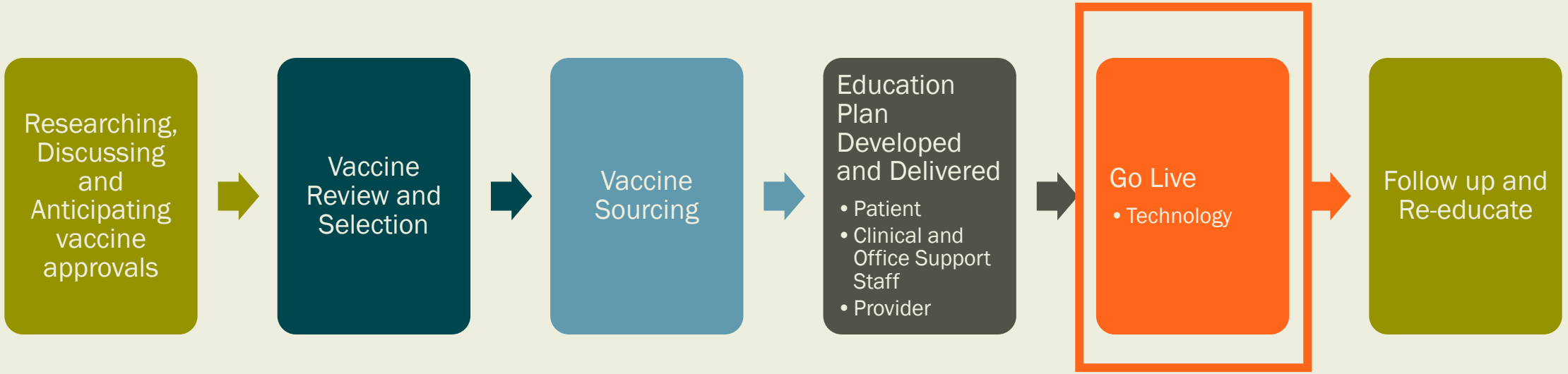
EHR direct messaging

Vaccine Information Sheets

Social Media Outreach

Shared-Decision Making

Operationalizing Immunizations



Technology

Transact Rx

Complete Claims and Payment Management Solution

The TransactRx Part D Vaccine Manager provides all the features necessary to manage the reimbursements for Medicare Part D covered vaccines.

- **Check patient eligibility and determine the appropriate Part D Plan to bill**
- **The system displays the amount of co-payment the patient needs to make**
- **With one click the claim is submitted in real time to the Part D Plan**
- **Acceptance of the claim and amount to paid to provider is displayed in real time**
- **Check on the status of payments for outstanding claims**
- **Payments are made to providers twice a month via check or ACH**
- **Complete reporting is available to track and manage claims and payments**

- A web-based system used to help overcome the challenges with billing and reimbursement of vaccines covered by Medicare Part D
- All ACIP approved vaccines

Northeast Georgia PHYSICIANS GROUP

TransactRx Tip Sheet

Vaccines for Medicare Patients

Disclaimers:

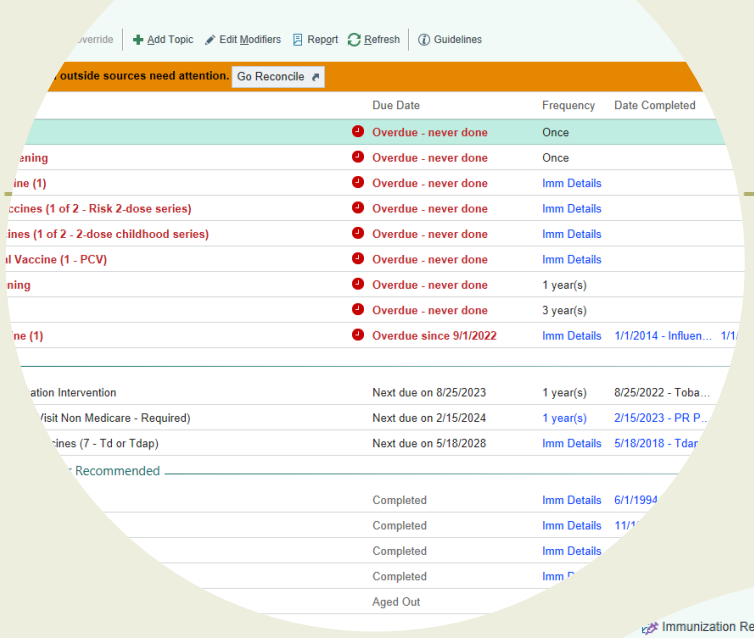
- TransactRx is the vendor to process vaccines for Medicare Part D or Medicare Advantage members. Do not use if the patient does not have Medicare pharmacy benefits.
- If no pharmacy benefit coverage returns for the patient, stop do not process the vaccine in TransactRx and discuss the patient alternative location to receive the vaccine or alternative pharmacy coverage such as Tricare or the VA.
- If the vaccine returns a cost, the patient must sign the TransactRx ABN if they would like to receive the vaccine in clinic as the patient will be charged the cost shown in TransactRx. A cost the vaccine generally means the patient must receive the vaccine at their preferred pharmacy in order not to be changed.
- Patient must sign and date all forms, then they are to be scanned as immediately as possible.

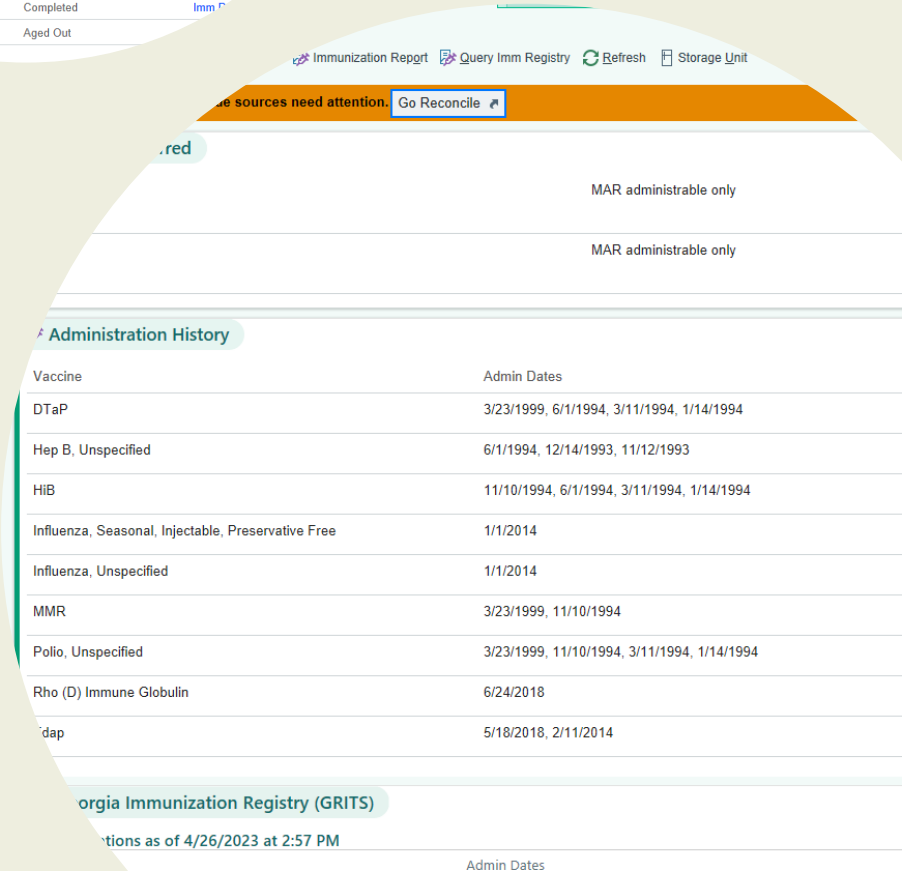
Process in TransactRx (Part D- Pharmacy coverage)	Vaccines that may be processed with TransactRx or Medical benefits	Medical Benefits (Part B)
HIB Hepatitis A HPV MMR Meningococcal ACWY Meningococcal B Polio RSV Tdap Varicella Zoster	Td Hepatitis B *Always complete medication Prior Auth on the vaccine in order receive instruction on which benefit to bill	Pneumococcal Influenza COVID 19

GRITS (Georgia Registry of Immunization Transactions and Services) is interfaced with our electronic medical record

Electronic Health Record

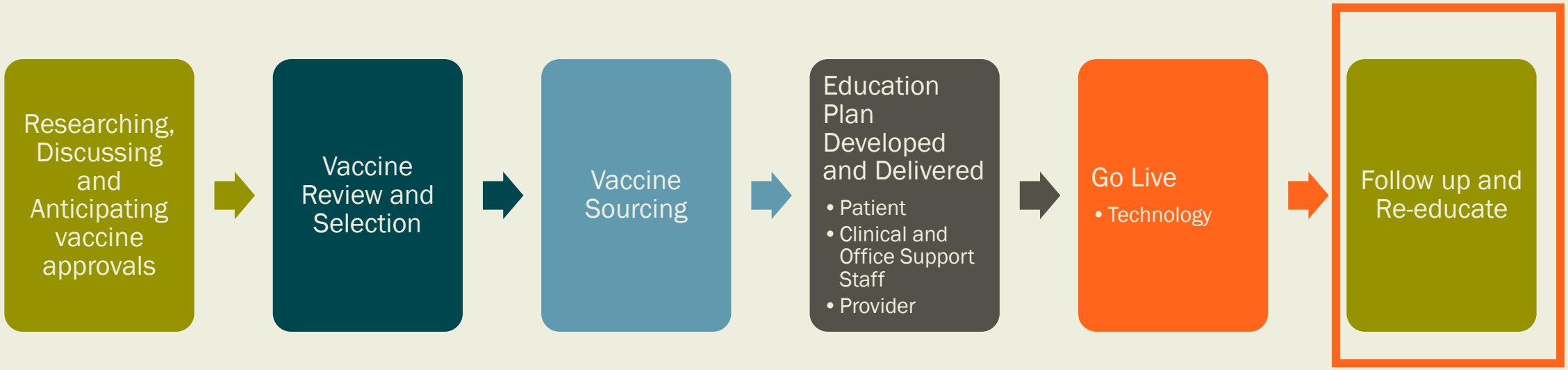
- Immunization documented directly in EHR
- Health Maintenance Overview
- Medication Scanning to increase safe vaccine practices
- Order Sets for providers to easily order vaccines (preventative and disease state specific)
  - Wellness Visits
  - COPD, DM, HTN, etc.



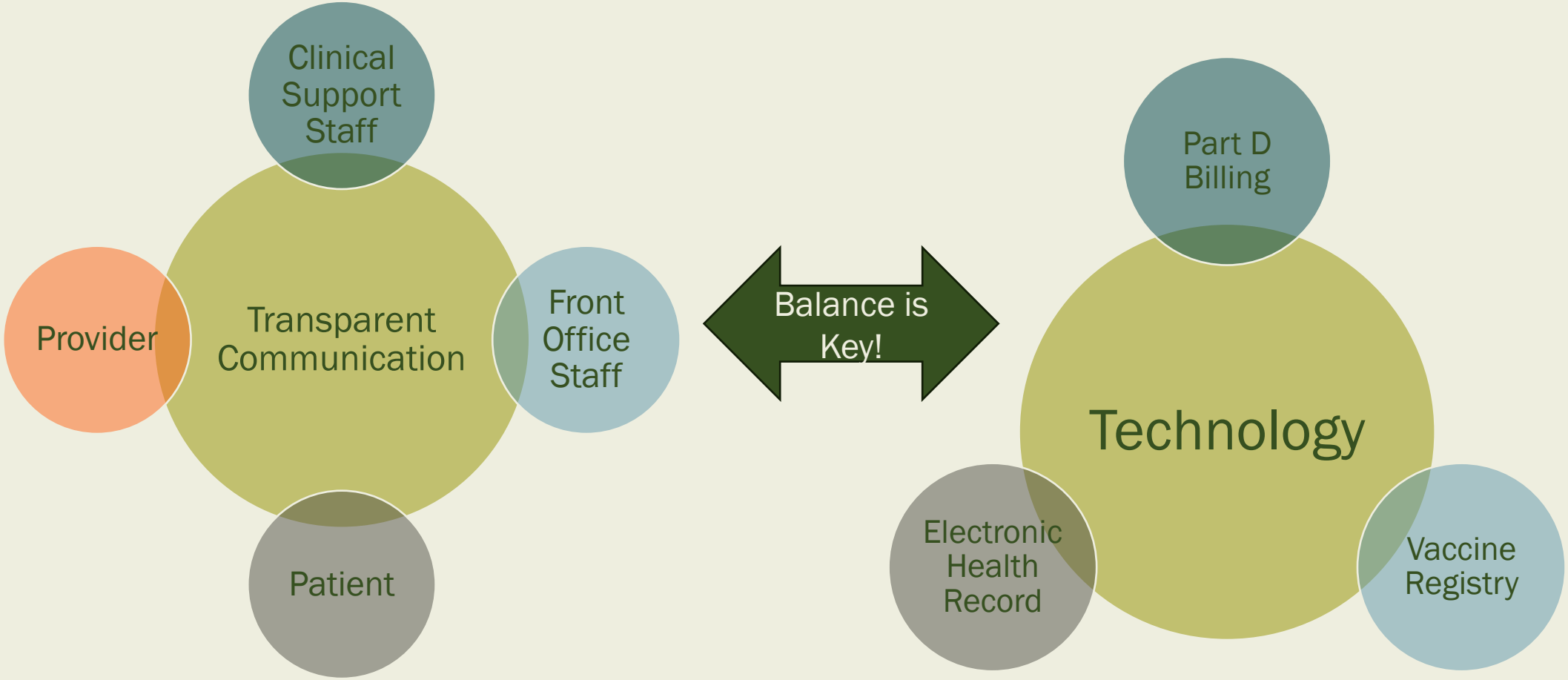


Go Live

Operationalizing Immunizations



Strategies for Success to Increase Adult Vaccinations



Questions

Adapting to Shifting Immunization Recommendations

Alix Schnibben, PharmD, BCACP, CTTS
Director, Ambulatory Pharmacy Services & Clinical Quality
alix.Schnibben@nghs.com

Northeast Georgia PHYSICIANS GROUP

Upcoming Webinar

Topic: Operationalizing the CDC's 2025 Adult Immunization Schedule

Date/ Time: Thursday, March 20 at 2pm ET

Presenters: L.J. Tan, PhD, MS, *Immunize.org*

Questions?

Submit your questions using the **Q&A feature** at the bottom of the screen

