SHIELDING AGAINST RESPIRATORY DISEASES WITH VACCINES

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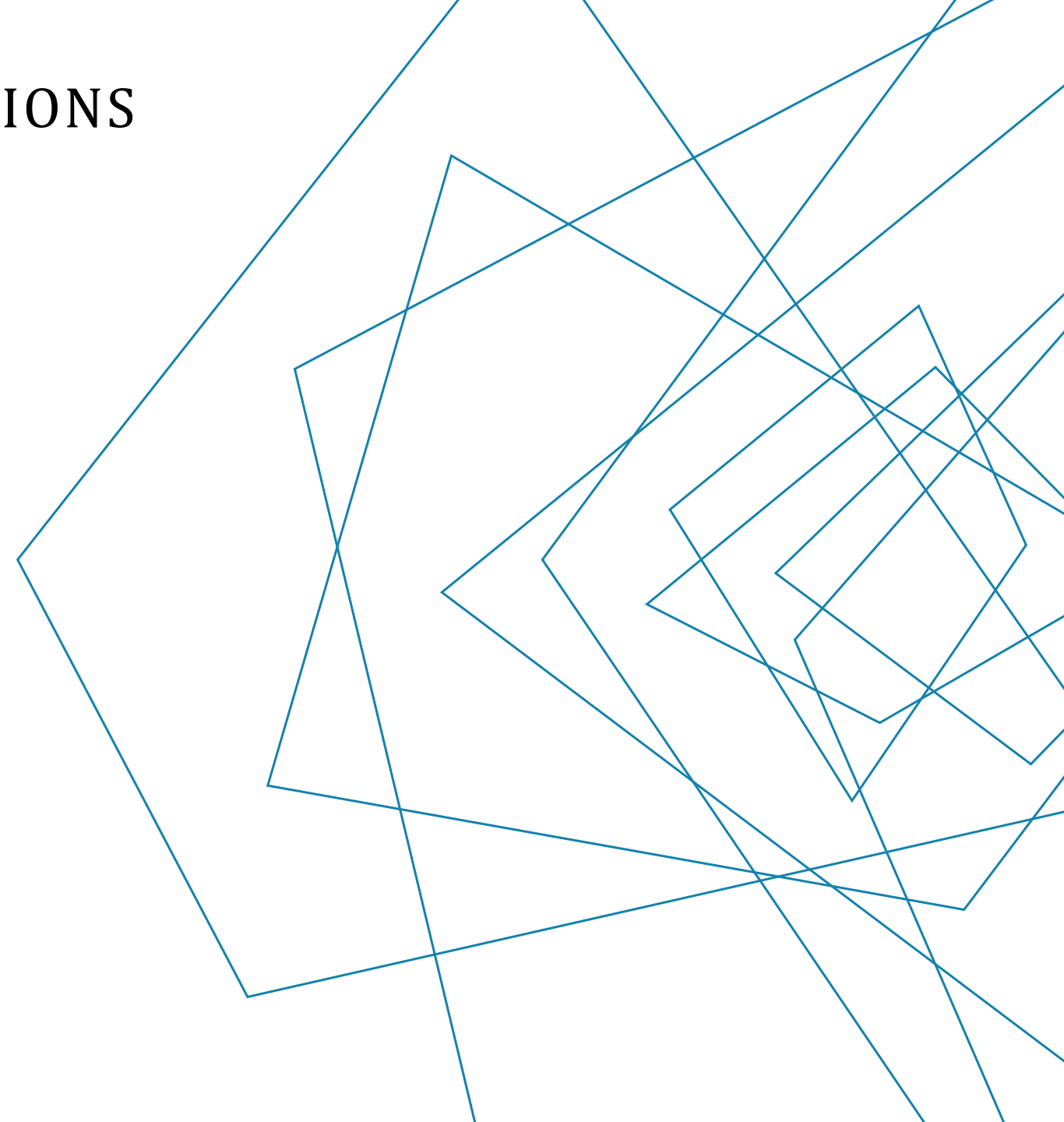
RESPIRATORY TRACT INFECTIONS

PNEUMONIA

INFLUENZA

RSV

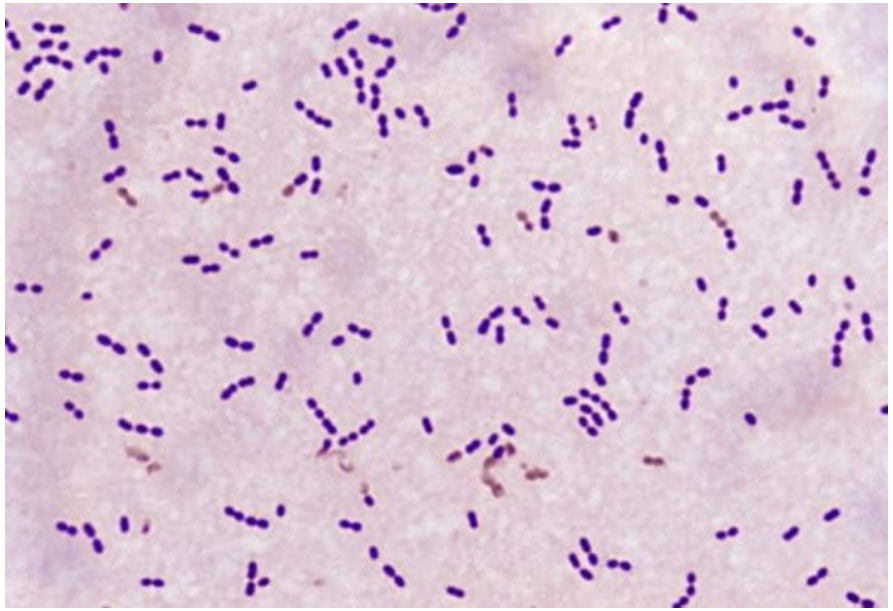
COVID-19



OBJECTIVES

ABOUT THE DISEASE	Introduction and Disease Burden
NEED FOR VACCINES	Indications and High Risk Populations
AVAILABLE VACCINES	Current formulations, schedules, adverse effects and vaccination rates
RECENT UPDATES	New guidelines, anticipated practices

PNEUMOCOCCAL VACCINATIONS



STREPTOCOCCUS PNEUMONIAE

- Historically important organism
- First discovered in 1880
- Basis for discovery of humoral immunity against organisms

↓

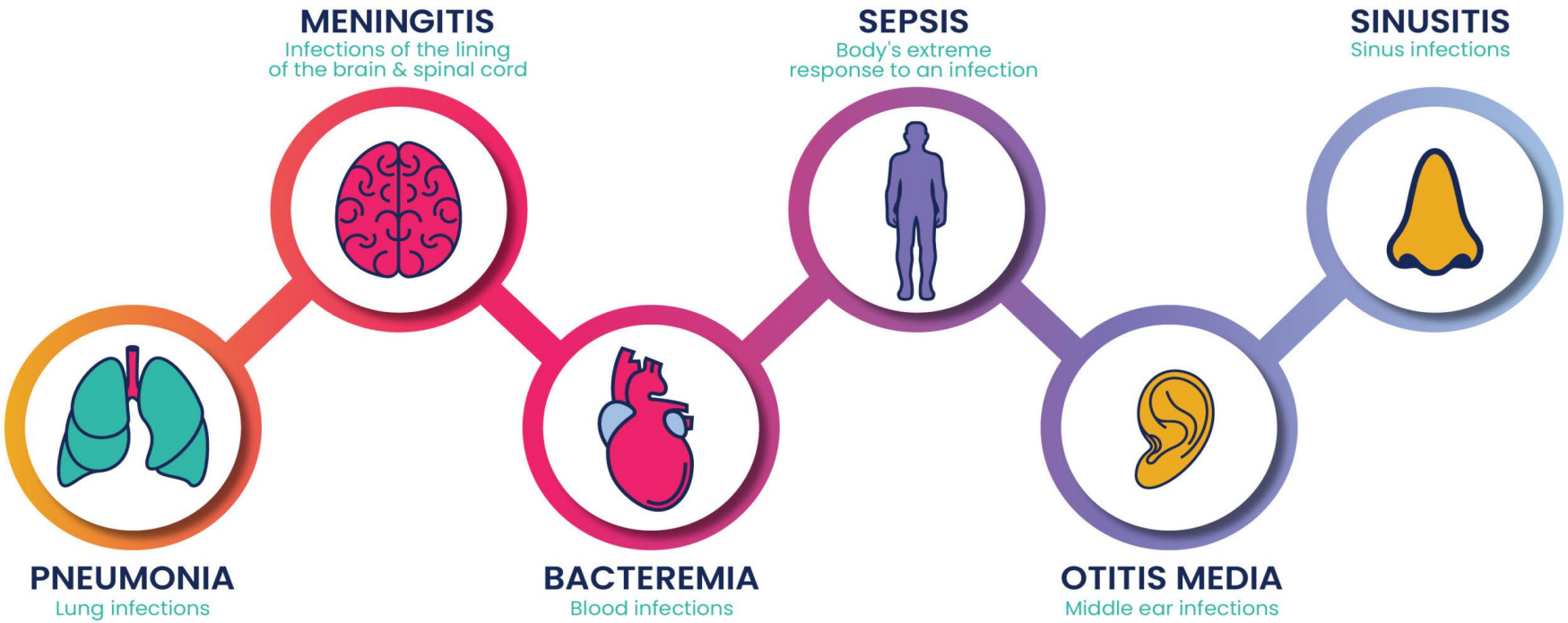
Discovery of protective antibodies against capsular polysaccharides

↓

Basis for many bacterial vaccines

- Spread : Direct contact, droplets, asymptomatic carriers
- Asymptomatic carriers : Up to 30-40 % children, 5-10 % of adults

PNEUMOCOCCAL INFECTIONS



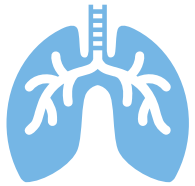
- Invasive pneumococcal disease : Isolation of *S. pneumoniae* from blood or other normally sterile sites.

- Supportive: Identification of *S. pneumoniae* from a normally sterile body site by a CIDT without isolation of the bacteria.

- Confirmatory: Isolation of *S. pneumoniae* from a normally sterile body site.

DISEASE BURDEN

- **Pneumococcal pneumonia > 150,000 hospitalizations** each year in the United States.
- Mortality > about **5-7 percent**, or 1 in 20 of those infected.
- **Pneumococcal meningitis and bacteremia** has higher mortality > approximately **3,250 people** in the United States in 2019.
- Pneumococcal meningitis kills about 1 in 6 older patients and bloodstream infections kill about 1 in 8 adults.



Reportable diseases	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	Total
Leprosy	0	0	0	0	0	0	0	0	0	**0**	**0**
Listeriosis	1	0	0	0	0	0	2	1	0	**2**	**6**
Lyme disease	4	4	4	2	5	11	12	7	10	**8**	**67**
Malaria	2	5	7	5	4	4	8	9	6	**2**	**52**
Measles	0	0	0	8	2	0	0	0	0	**0**	**10**
Meningococcal disease	3	0	4	2	1	1	0	0	0	**0**	**11**
Mumps	0	0	0	0	0	2	0	0	12	**0**	**14**
Pertussis	37	71	67	109	16	15	9	163	147	**34**	**668**
Q fever	1	2	4	5	5	4	5	12	11	**8**	**57**
Rabies, animal	40	60	28	21	29	27	22	15	16	**10**	**268**
Salmonellosis	162	170	183	164	230	305	226	227	166	**179**	**2012**
Shiga toxin-producing *E. coli*	41	48	42	41	62	84	91	204	136	**97**	**846**
Shigellosis	6	11	190	616	285	28	29	26	9	**12**	**1212**
Spotted fever rickettsiosis	1	1	7	3	2	6	13	14	10	**7**	**64**
Methicillin-resistant *Staph aureus* (MRSA), invasive	91	89	94	124	159	144	115	173	156	**169**	**1314**
Strep. pneumoniae, invasive	42	97	99	88	110	129	135	106	101	**71**	**978**
Syphilis (primary, secondary, and early non-primary non-secondary)	0	21	49	76	48	41	52	50	56	**101**	**494**
Syphilis, congenital	0	0	0	3	0	2	3	1	3	**4**	**16**
Toxic shock syndrome	0	0	0	0	3	1	0	1	0	**0**	**5**
Tularemia	8	5	7	5	25	14	13	9	17	**10**	**113**
Tuberculosis	15	19	9	8	17	12	14	12	16	**16**	**138**
Typhoid fever	0	0	3	0	1	2	0	0	0	**0**	**6**
West Nile fever	2	141	92	45	29	117	46	122	11	**9**	**614**
West Nile neuroinvasive	0	62	57	12	11	35	27	47	0	**11**	**262**
Vibriosis	NR	NR	NR	NR	NR	5	12	9	3	**3**	**32**

*NR – not reportable

South Dakota specific data on Reportable Diseases between 2011 – 2020

*Incidence : cases per 100,000 population

Table 73 Reportable Diseases by Gender, Race and Age, South Dakota, 2020 (Calendar years)

	Campylobacteriosis	Chlamydia	CRE	Cryptosporidiosis	Giardiasis	Gonorrhea	Hepatitis B, chronic	Hepatitis C, chronic	HIV and AIDS	MRSA, invasive	Pertussis**	Salmonellosis	Shiga Toxin-Producing *E. coli*	Shigellosis	*Strep. pneumo*, invasive	Syphilis (P, S, E non-P non-S)	Tuberculosis	Tularemia	Varicella (Chicken pox)	West Nile disease
Total	**324**	**4007**	**29**	**76**	**66**	**2399**	**53**	**723**	**40**	**169**	**34**	**179**	**97**	**12**	**71**	**101**	**16**	**10**	**18**	**20**
Incidence*	36.3	448.9	3.2	8.5	7.4	268.7	5.9	81.0	4.5	18.9	3.8	20.1	10.9	1.	8.0	11.3	1.8	1.1	2.0	2.2
Gender																				
Female	124	2763	18	26	32	1269	20	317	9	72	18	102	48	5	36	40	6	5	7	3
Male	200	1244	11	50	34	1130	33	406	31	97	16	77	49	7	35	61	10	5	11	17
Race																				
White	268	1835	24	68	53	656	20	280	18	104	29	139	87	9	40	35	2	1	8	18
Am.Indian	29	1525	5	5	11	1357	3	337	10	64	2	21	4	2	22	54	7	8	7	2
Black	3	281	0	0	0	255	16	12	9	0	0	1	3	0	4	9	3	0	0	0
Asian	1	36	0	0	0	12	6	1	1	0	0	3	0	0	3	0	4	0	0	0
Other	4	93	0	0	1	36	4	29	1	0	0	3	0	1	1	3	0	0	0	0
Unknown	19	237	0	3	1	83	4	64	1	1	3	12	3	0	1	0	0	1	3	0
Age group																				
<1 yr	5	2	0	0	2	1	0	0	0	2	7	6	2	0	4	0	0	0	3	0
1-4 yrs	41	0	0	8	4	1	0	0	0	3	6	14	24	0	2	0	0	1	7	0
5-14 yrs	34	34	0	15	7	15	0	0	0	1	9	18	7	2	1	0	0	2	7	1
15-24 yrs	49	2498	1	13	8	890	4	72	6	6	5	19	19	1	5	15	1	0	1	3
25-39 yrs	70	1303	0	22	20	1228	25	305	21	19	2	29	20	5	4	65	9	0	0	2
40-64 yrs	83	167	8	13	17	259	20	278	13	70	1	49	14	3	30	21	4	4	0	7
≥65 yrs	42	0	20	5	8	3	4	68	0	68	0	44	11	1	25	0	2	3	0	7

ADULTS AT INCREASED RISK/INDICATIONS

- **Adults 65 years or older** are at increased risk for pneumococcal disease.

- Adults of **all ages** are also at increased risk for pneumococcal disease if they have :

- Diabetes
- Chronic heart, lung, kidney, or liver disease
- Chronic lung illnesses such as chronic obstructive lung disease, asthma.
- Smoking, alcoholism.
- Immunosuppressive conditions such as HIV infection, cancer, solid organ transplant, or use of medications.
- Nephrotic syndrome
- Sickle cell disease, a damaged spleen, or no spleen
- Cochlear implant
- CSF leak

- ✓ Increased risk of acquiring disease, increased morbidity and mortality from disease process
- ✓ Chronic co-morbidities increase risk of CAP/IPD and vice versa
- ✓ Increased healthcare costs and economic burden : 17 billion USD/year

INDICATIONS FOR PNEUMOCOCCAL VACCINATION IN ADULTS

- ➢ People with age greater than or equal to 65 years
- ➢ People aged between 19-64 years with certain risk factors or medical conditions
- ➢ All children < 2 years of age
- ➢ Older children with certain risk factors

PNEUMOCOCCAL VACCINES

TYPES

Pneumococcal Polysaccharide Vaccines

PPSV23 (Pneumovax23®)

Pneumococcal Conjugate Vaccines

- PCV13 (Prevnar 13®)
- PCV15 (Vaxneuvance®)
- PCV20 (Prevnar 20®)

History

1977

First PPSV14 licensed for use

1983

PPSV23 introduced. Not effective in children < 2 years

2000

PCV7 introduced, first conjugate vaccine.

2010

PCV13 licensed

2021

PCV15 and PCV20 licensed

Pneumococcal Polysaccharide Vaccine

Trade Name	PPSV23 (Pneumovax23®)
History	Introduced in 1983, after PPSV14
Type	Non-live, subunit and purified
Content	Contains purified capsular polysaccharides of 23 different serotypes.
MOA	Polysaccharide subunits are highly immunogenic > producing Ab.
Route and Dose	0.5 mL. Route : Intramuscular or subcutaneous
Efficacy	65% against diseases caused by the 23 serotypes
Limitations	B-cell mediated immunity independent of T cell help. Cannot be used < 2 years. Does not reduce pneumococcal carriage. Immunity wanes over time (~5y)

Pneumococcal conjugate vaccines

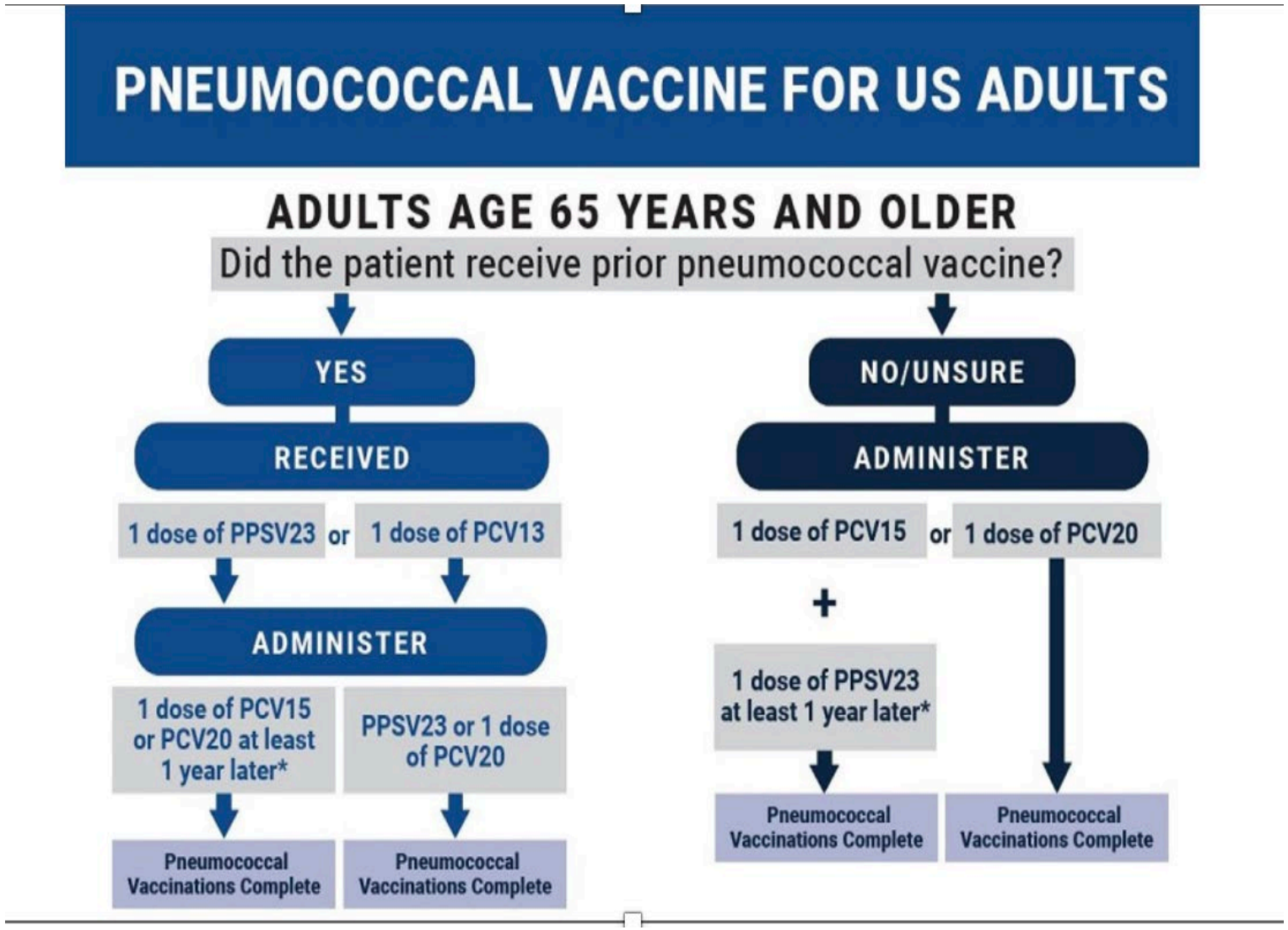
- History : First introduced in 2000 - PCV7 (97% reduction in vaccine-type IPD in children)
- PCV13 replaced PCV7 in 2010. Approved for adults in 2011.
- MOA : Capsular polysaccharide **conjugated** to non-toxic diphtheria protein.
- Elicits T-cell dependent response and memory B cells > long-term immunization.
- Enhanced immunogenicity when conjugated administered before unconjugated.
- Type : Non-live, subunit and engineered
- Route and dose : Intramuscular, 0.5 mL. Series of 4 doses in infants.
- Efficacy : PCV13 with 45% for PP, 75% for IPD. 15/20 : likely higher.

Vaccine	4	6B	9V	14	18C	19F	23F	1	3	5	6A	7F	19A	22F	33F	8	10A	11A	12F	15B	2	9N	17F	20
PCV7[a]	■	■	■	■	■	■	■																	
PCV13[b]	■	■	■	■	■	■	■	■	■	■	■	■	■											
PCV15[c]	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■									
PCV20[d]	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■				
PPSV23[e]	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■

Pneumococcal vaccination and serotype coverage

Kobayashi M, et al. *MMWR* 2022;71:109-117.

VACCINATION SCHEDULES IN ADULTS



To remember :

- Choose **valencies ≥15**
- Inclusion of a **conjugate vaccine**
- Remember PPSV23 immunity wanes over time.
- Re-establish immunity

Note : Can administer PPSV23 **8 weeks later** for immunocompromised patients, CSF leak or cochlear implant

CDC RECOMMENDATIONS FOR PNEUMOCOCCAL VACCINATIONS

Adults ≥65 years old
Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B
None*	PCV20	PCV15 → ≥1 year† → PPSV23
PPSV23 only at any age	≥1 year → PCV20	≥1 year → PCV15
PCV13 only at any age	≥1 year → PCV20	≥1 year† → PPSV23
PCV13 at any age & **PPSV23** at <65 yrs	≥5 years → PCV20	≥5 years§ → PPSV23

Shared clinical decision-making for those who already completed the series with PCV13 and PPSV23

Prior vaccines	Shared clinical decision-making option
Complete series: PCV13 at any age & **PPSV23** at ≥65 yrs	≥5 years → PCV20 Together, with the patient, vaccine providers **may choose** to administer PCV20 to adults ≥65 years old who have already received PCV13 (but not PCV15 or PCV20) at any age and PPSV23 at or after the age of 65 years old.

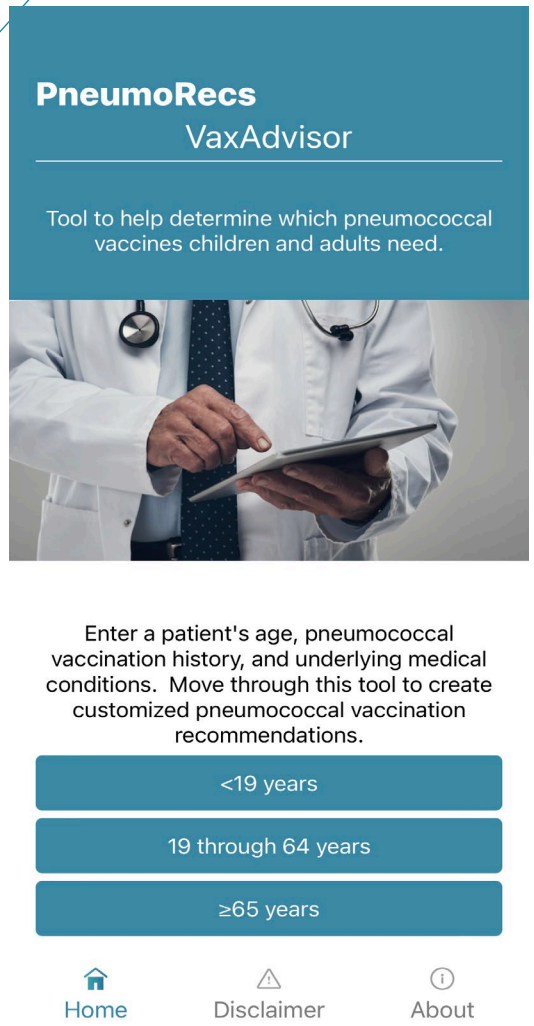
Adults 19–64 years old with chronic health conditions
Complete pneumococcal vaccine schedules

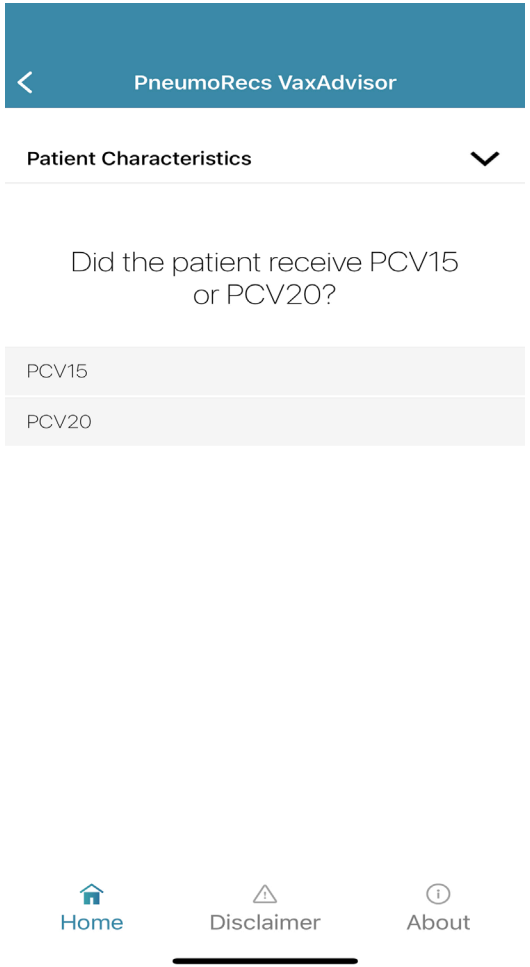
Prior vaccines	Option A	Option B
None*	PCV20	PCV15 → ≥1 year → PPSV23
PPSV23 only	≥1 year → PCV20	≥1 year → PCV15
PCV13† only	≥1 year → PCV20	≥1 year → PPSV23 Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
PCV13† and PPSV23	**No vaccines** are recommended at this time. Review pneumococcal vaccine recommendations again when your patient turns 65 years old.	
Chronic health conditions	▪ Alcoholism ▪ Chronic heart disease, including congestive heart failure and cardiomyopathies ▪ Chronic liver disease	▪ Chronic lung disease, including chronic obstructive pulmonary disease, emphysema, and asthma ▪ Cigarette smoking ▪ Diabetes mellitus

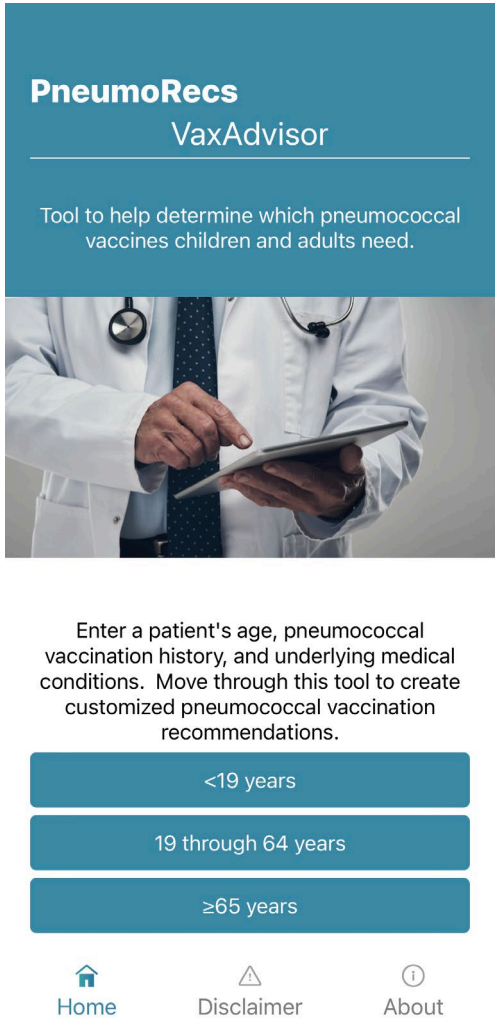
Adults 19–64 years old with specified immunocompromising conditions
Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B
None*	PCV20	PCV15 → ≥8 weeks → PPSV23
PPSV23 only	≥1 year → PCV20	≥1 year → PCV15
PCV13 only	≥1 year → PCV20	≥8 weeks → PPSV23 → ≥5 years → PPSV23 Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
PCV13 and 1 dose of PPSV23	≥5 years → PCV20	≥5 years† → PPSV23 Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
PCV13 and 2 doses of PPSV23	≥5 years → PCV20	**No vaccines** recommended at this time. Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
Immunocompromising conditions	▪ Chronic renal failure ▪ Congenital or acquired asplenia ▪ Congenital or acquired immunodeficiency§ ▪ Generalized malignancy ▪ HIV infection ▪ Hodgkin disease ▪ Iatrogenic immunosuppression¶ ▪ Leukemia ▪ Lymphoma ▪ Multiple myeloma ▪ Nephrotic syndrome ▪ Sickle cell disease/other hemoglobinopathies ▪ Solid organ transplant	

USER-FRIENDLY…







PneumoRecs VaxAdvisor App

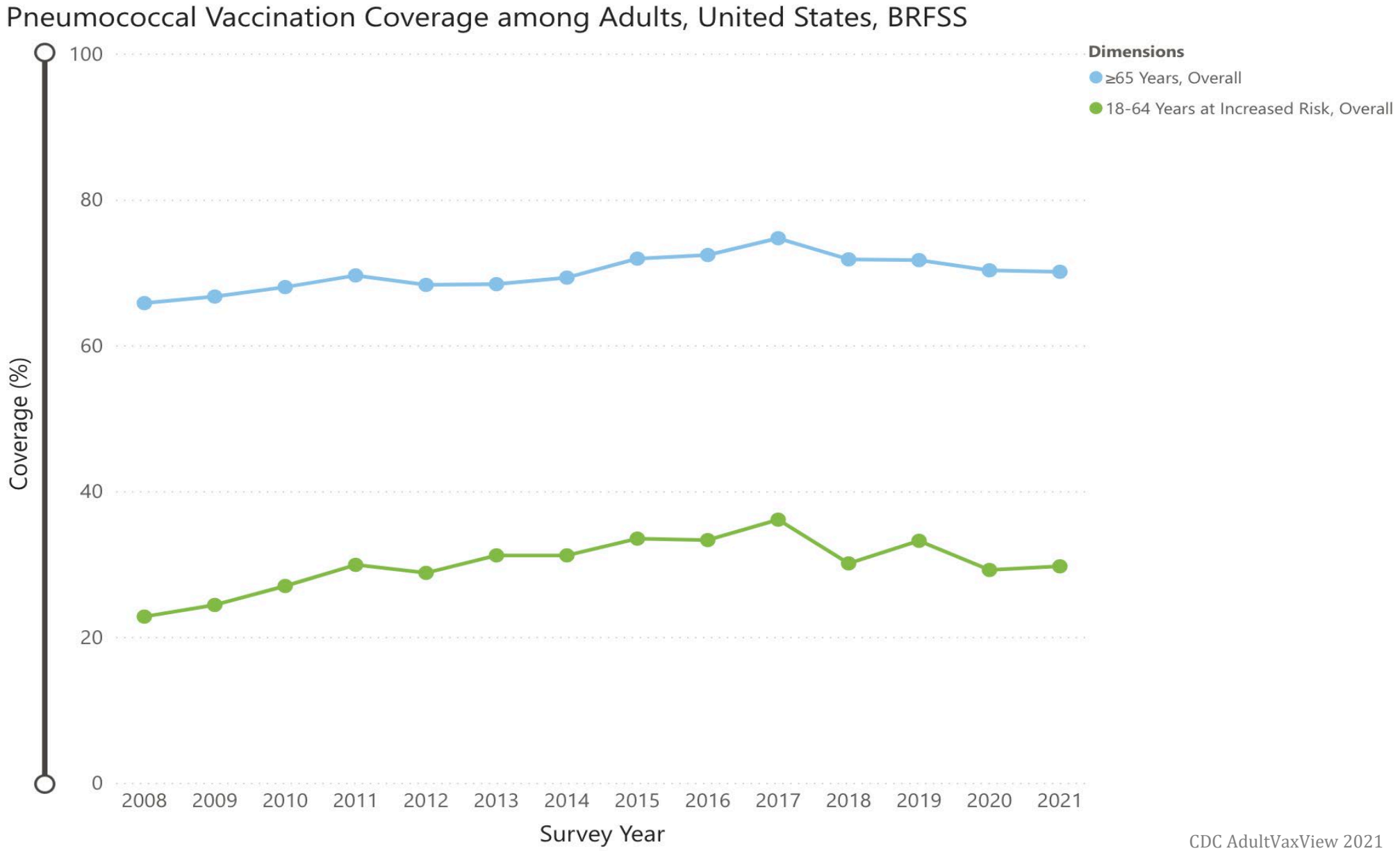
ADVERSE EFFECTS

- Local reactions : Soreness, swelling of site
- Drowsiness
- Fever, chills
- Decreased appetite
- Generalized muscle/joint pain
- Headache
- Rarely, anaphylactic reactions

CONTRAINDICATIONS

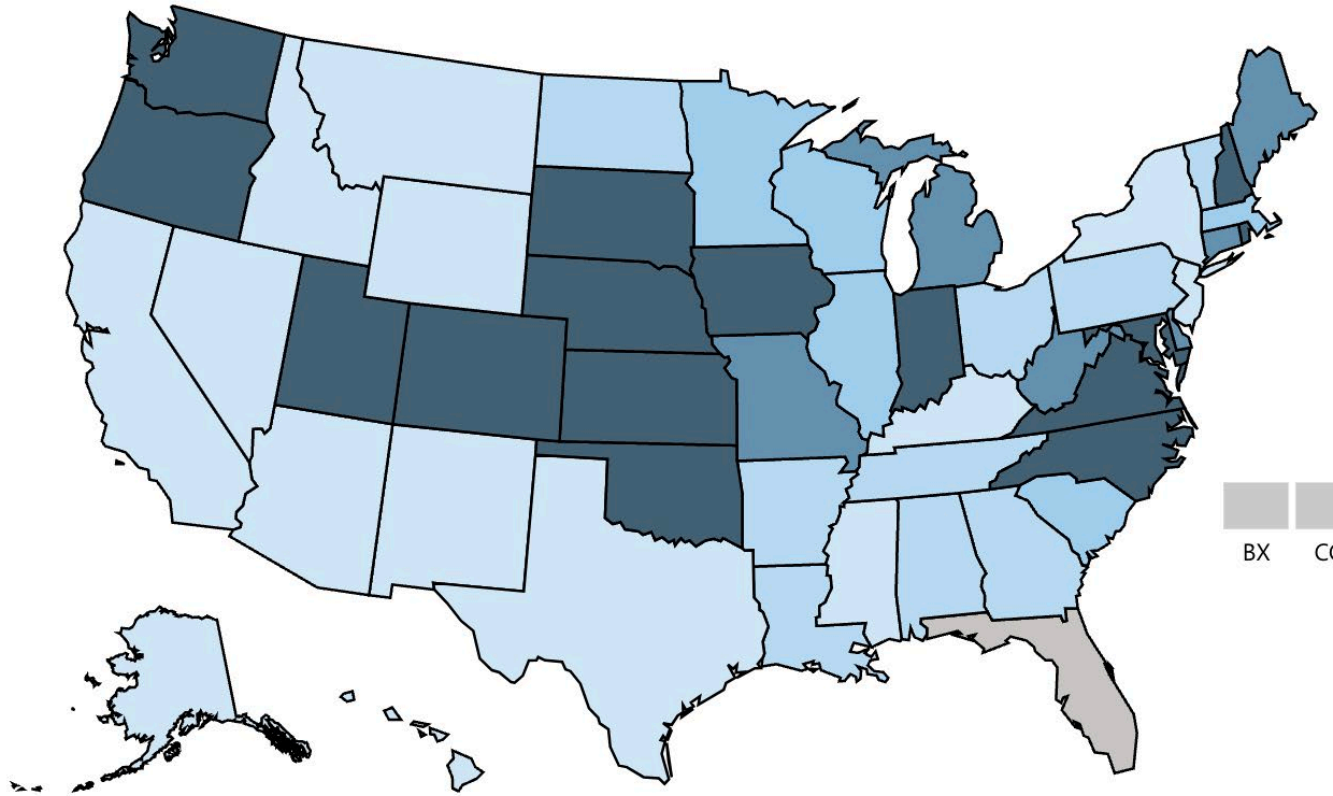
- Previous allergic reaction to vaccine, diphtheria toxoid or component of vaccines

Pneumococcal Vaccination Rates in the US



CDC AdultVaxView 2021

Pneumococcal Vaccination Coverage among Adults Age ≥65 Years, 2021, BRFSS



Cities/Counties

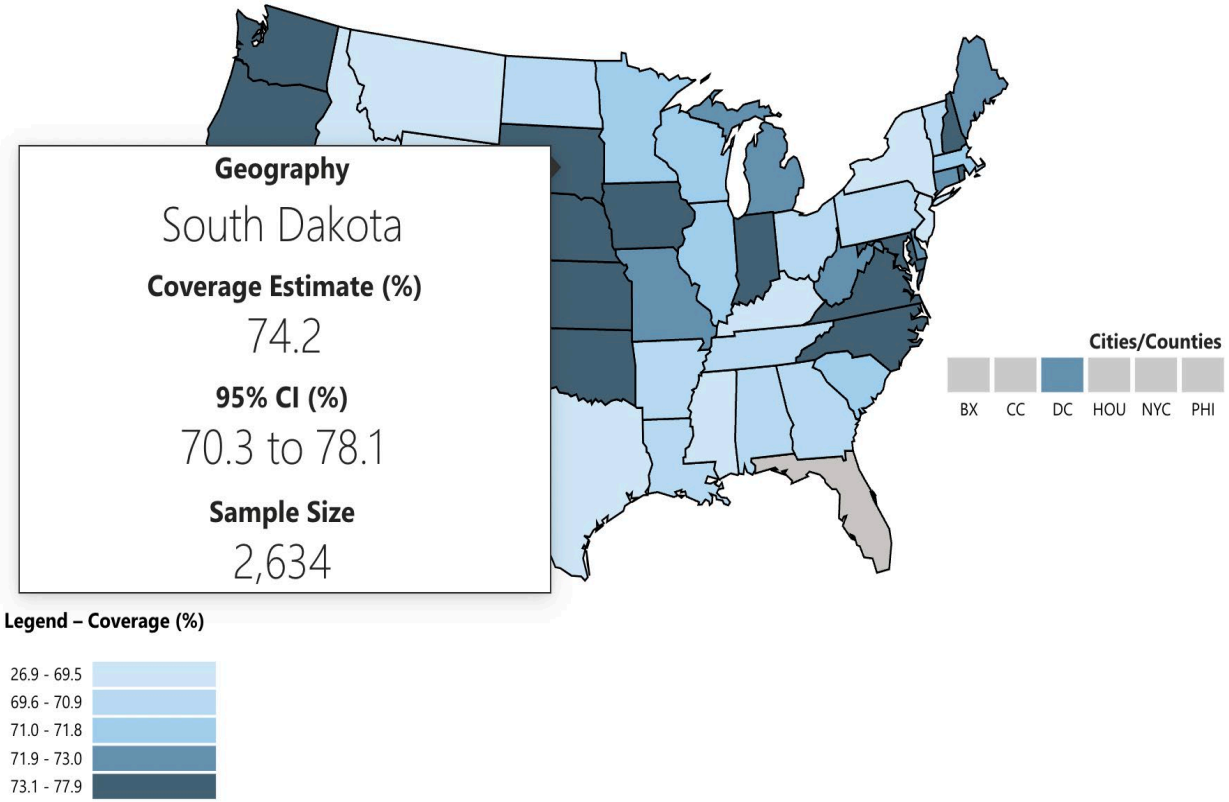
BX CC DC HOU NYC PHI

Legend – Coverage (%)

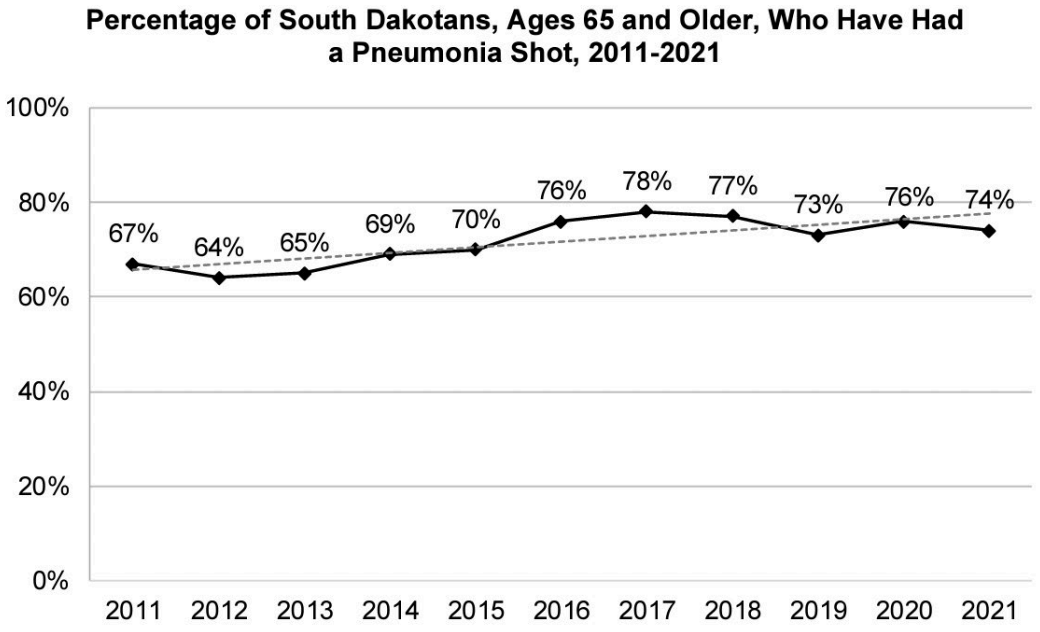
26.9 - 69.5
69.6 - 70.9
71.0 - 71.8
71.9 - 73.0
73.1 - 77.9

South Dakota specific Vaccination Rates

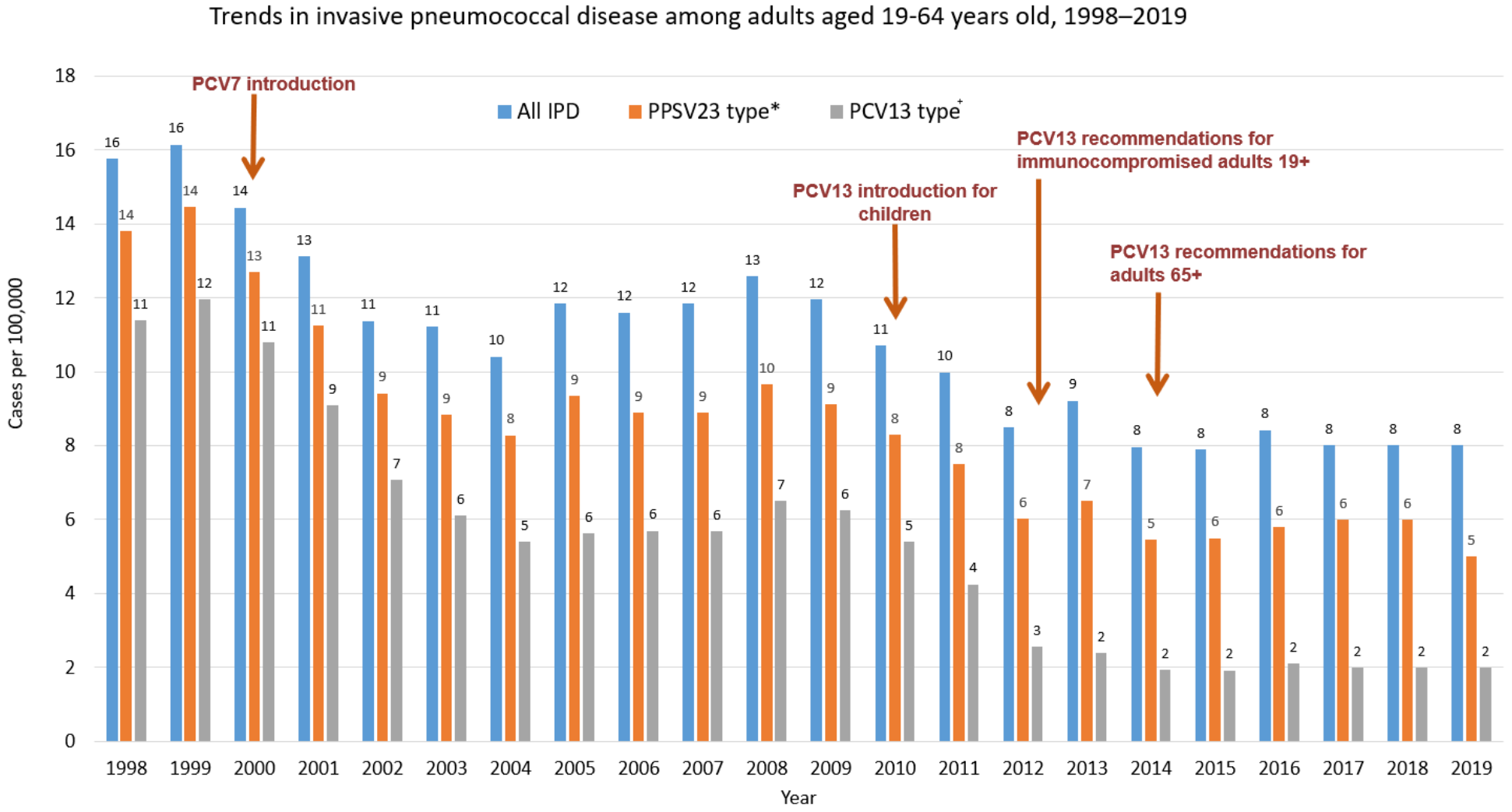
Pneumococcal Vaccination Coverage among Adults Age ≥65 Years, 2021, BRFSS



CDC AdultVaxView 2021



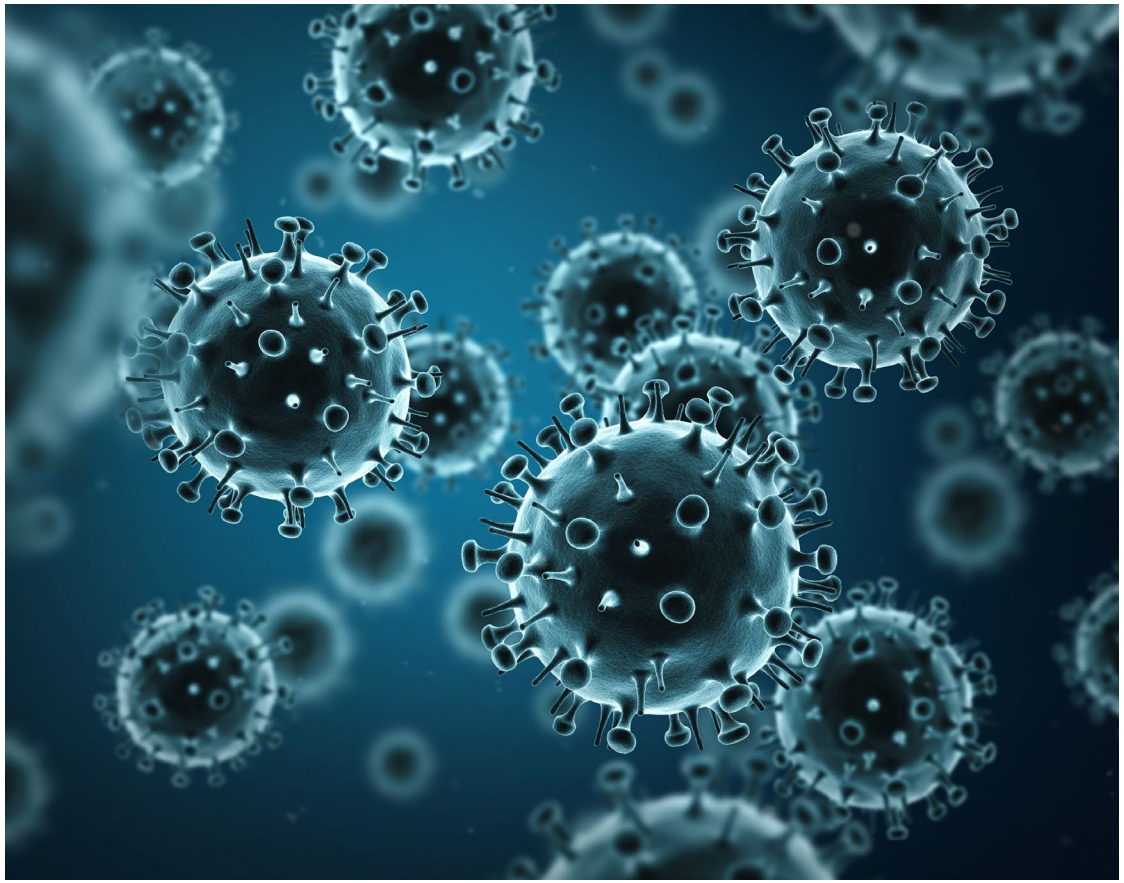
DECLINE IN TRENDS AFTER VACCINATION



*PPSV23 serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, and 33F
+PCV13 serotype: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F

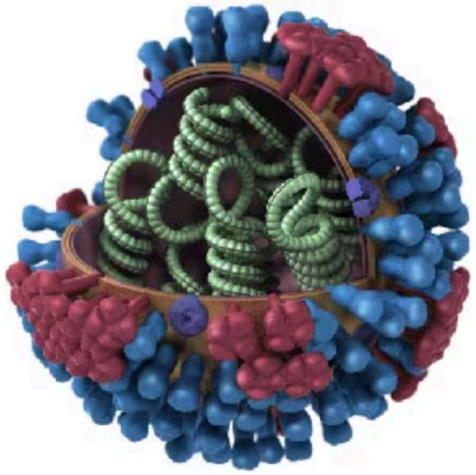
CDC.gov, 2020.

INFLUENZA (FLU) VACCINATIONS



Influenza Virus

- Important Types A and B : Seasonal flu epidemics during winter in the US



INFLUENZA A

- Divided based on hemagglutinin and neuraminidase proteins
- 18 H subtypes and 11 N subtypes
- Routine subtypes include A(H1N1) and A(H3N2).
- Can cause global pandemics
- Antigenic drift : minor HA and NA gene mutations > antigenically drifted strains > seasonal epidemics > necessity for **annual vaccine updates**
- Antigenic shift : major HA and NA mutations > antigenically and genetically different **novel influenza A virus** > spontaneous infections and pandemics

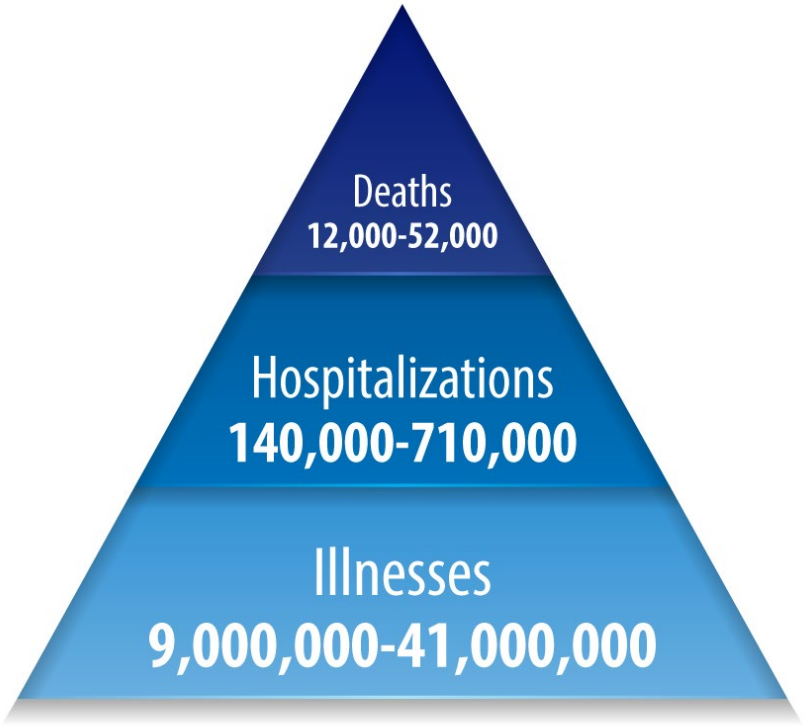
INFLUENZA B

- Classified into two lineages: B/Yamagata and B/Victoria.
- Slow to change > decreased epidemics (dominant in one every 7 seasons)
- B/Yamagata likely extinct by now.

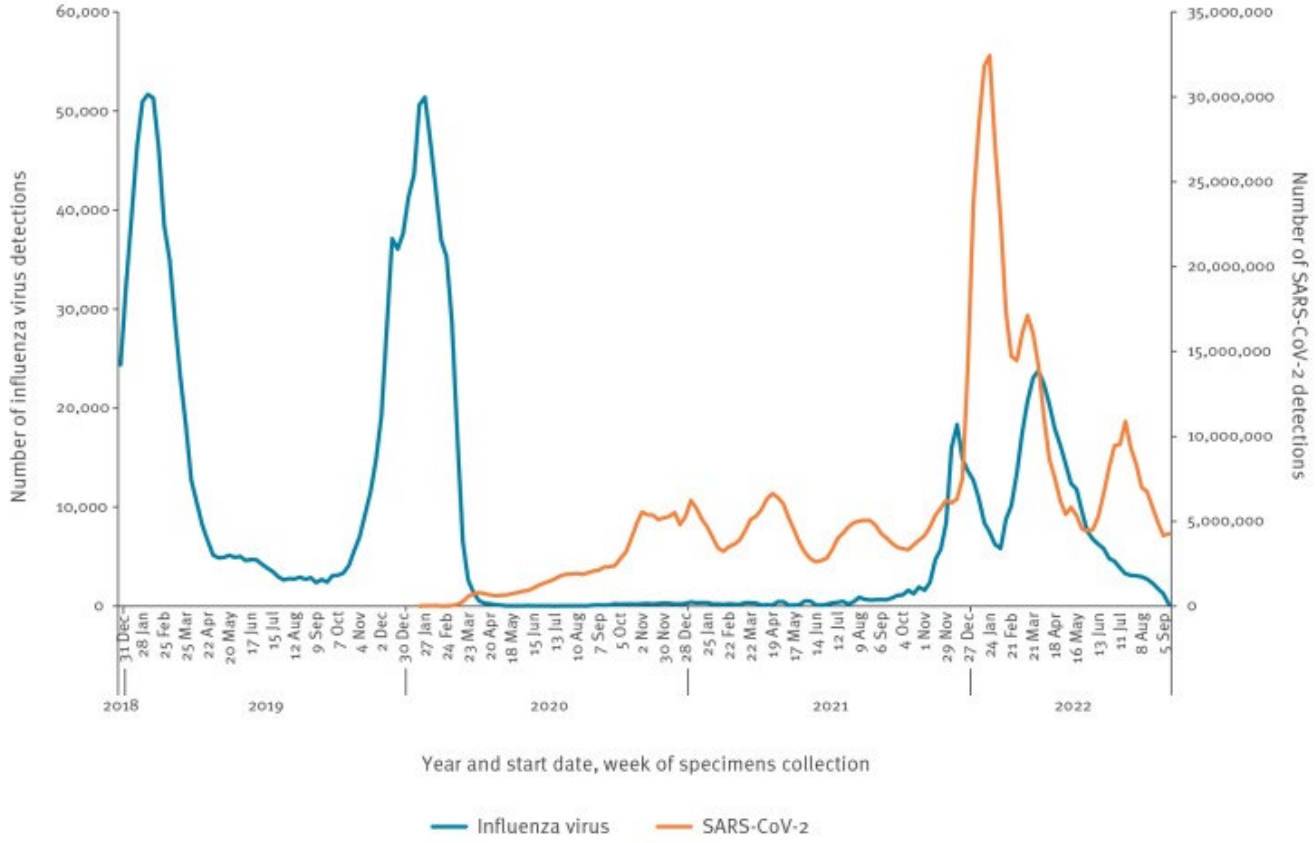
DISEASE BURDEN

Season	Symptomatic Illnesses	Medical Visits	Hospitalizations	Deaths
2018-2019	29,000,000	17,000,000	380,000	28,000
2019-2020	36,000,000	16,000,000	390,000	25,000
2021-2022	9,000,000	4,000,000	100,000	5,000

CDC NCIRD 2022



Range of burden in US between 2010-2020



INDIVIDUALS AT HIGHER RISK FOR COMPLICATIONS

- Adults ≥ 65 years
- Children < 2 years (highest hospitalization and death rates among infants < 6 months old)
- Obese patients with BMI ≥ 40
- Chronic lung, heart, kidney and liver diseases
- History of stroke
- Endocrine disorders
- Neurologic and neurodevelopment conditions, metabolic disorders
- Hematologic conditions
- Patients < 19y on long-term aspirin or salicylate-containing drugs
- Immunosuppressive medications/immunocompromised state
- Pregnancy and up to 2 weeks postpartum
- Nursing home and long term care facility residents
- Certain racial and ethnic minorities

VACCINE COMPOSITION

- Vaccine composition updated every year due to antigenic drift, based on global surveillance
- Quadrivalent vaccine > Two Influenza A and two influenza B antigens

- **Updated Composition** :

- Egg-based vaccines
  - an A/Victoria/**4897/2022** (H1N1)pdm09-like virus; **(Updated)**
  - an A/Darwin/9/2021 (H3N2)-like virus;
  - a B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and
  - a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.
- Cell- or recombinant-based vaccines
  - an A/Wisconsin/**67/2022** (H1N1)pdm09-like virus; **(Updated)**
  - an A/Darwin/6/2021 (H3N2)-like virus;
  - a B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and
  - a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

  Projected supply of **156.2 million to 170 million doses** of influenza vaccines for the 2023-2024 season.

INFLUENZA VACCINE FORMULATIONS

➢ Inactivated influenza vaccines (Intramuscular)

1. Egg based

Vaccine	Content	Ages approved
Standard dose, parenterally administered	15 mcg of each HA per virus	All adults
Standard dose, 'needle free'	15 mcg of each HA	18-64 years
Standard dose, adjuvanted	15 mcg of each HA	≥ 65 years
High dose	60 mcg of each HA	≥ 65 years

2. Cell culture based, standard dose

- Produced in cultured mammalian cells. Approved ≥ 6 months

➢ Recombinant HA influenza vaccine (IM)

- For > 18 years
- Only HA antigens

➢ Live attenuated influenza vaccine

- Nasal spray
- Egg based
- Non pregnant individuals 2– 49 years
- Multiple contraindications

AVAILABLE INFLUENZA VACCINES

Quadrivalent IIVs – Egg based – Standard dose	Quadrivalent IIV – Egg based - High dose	Adjuvanted quadrivalent IIV – egg based – MF59 adjuvant	Quadrivalent IIV – Cell-culture based – standard dose	Quadrivalent RIV – Recombinant HA	Quadrivalent LAIV – Egg based
○ Afluria ○ Fluarix ○ FluLaval ○ Fluzone	Fluzone High-Dose	Fluad	Flucelvax	Flublok	FluMist

Indications : Routine annual vaccination recommended for **all individuals aged ≥ 6 months** without contraindications

Timing : September and October. Should be offered throughout the season. July and August only in special situations > Children of any age requiring only 1 dose, third trimester of pregnancy etc.

Special Populations

- **Pregnancy** : Any age-appropriate IIV4 or RIV4 during influenza season, in any trimester. LAIV4 is contraindicated, except in postpartum.
- **Children** aged 6 months through 8 years : Based on previous history of ≥ 2 doses of trivalent of quadrivalent vaccine before July 1, 2023

- Received : 1 dose of 2023-24 vaccine
- Not received : 2 doses of updated vaccine ≥ 4 weeks apart

- **Adults aged ≥ 65 years** : Any one of the higher dose or adjuvanted influenza vaccines
- **Chronic medical conditions** : Avoid LAIV4
- **Immunocompromised people** : Age-appropriate IIV4 or RIV4. Avoid LAIV4. Timing related to interventions.
- **Caregivers/contacts** : Receiving LAIV4 > avoid contact for 7 days
- **Egg allergy** : Any appropriate vaccine. No additional safety measures. Only history of allergic reaction is a contraindication.

Contraindications and Precautions

Contraindications

- Previous severe allergic reaction to any influenza vaccine : avoid all egg-based IIV4s and LAIV4
- Previous severe allergic reaction to respective vaccine or components of vaccine
- LAIV4 : Pregnancy, immunocompromised status (close contacts), children with asthma/wheezing, CSF leak, cochlear implant, receipt of antiviral medications. Caution in asthmatic adults, chronic diseases.

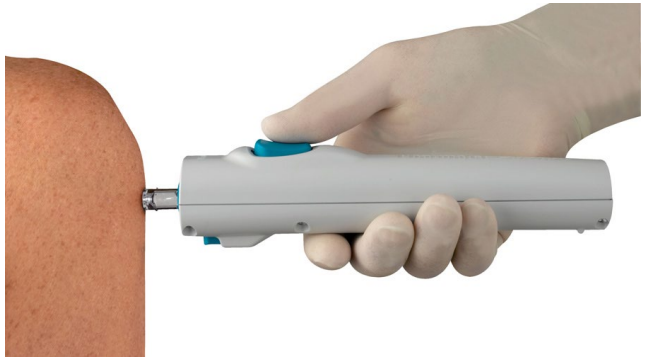
Precautions

- Moderate or severe acute illness with or without fever
- History of GBS within 6 weeks of receipt of flu vaccine
- History of severe allergic reaction to any previous influenza vaccine

Vaccine (of any valency) associated with previous severe allergic reaction (e.g., anaphylaxis)	Available 2023–24 influenza vaccines		
	Egg-based IIV4s and LAIV4	ccIIV4	RIV4
Any egg-based IIV or LAIV	Contraindication*	Precaution†	Precaution†
Any ccIIV	Contraindication*	Contraindication*	Precaution†
Any RIV	Contraindication*	Precaution†	Contraindication*
Unknown influenza vaccine	Allergist consultation recommended		

https://www.cdc.gov/flu/professionals/acip/summary/summary-recommendations.htm

Adverse Reactions



- Local site reactions
- Shoulder bursitis : Deltoid muscle injections
- Guillain-Barre syndrome : Inconsistent, variable results. Minimal risk if present.
- Allergic reaction : Rare, even in people with egg allergy
- Higher frequency of adverse reactions : High-dose vaccines, needle-free vaccines
- Live attenuated vaccine : Rhinorrhea, congestion, headache, sore throat. Very few cases of anaphylaxis (7), GBS (2), Bell's palsy (1), asthma exacerbation (8) amongst 2.5 million people.

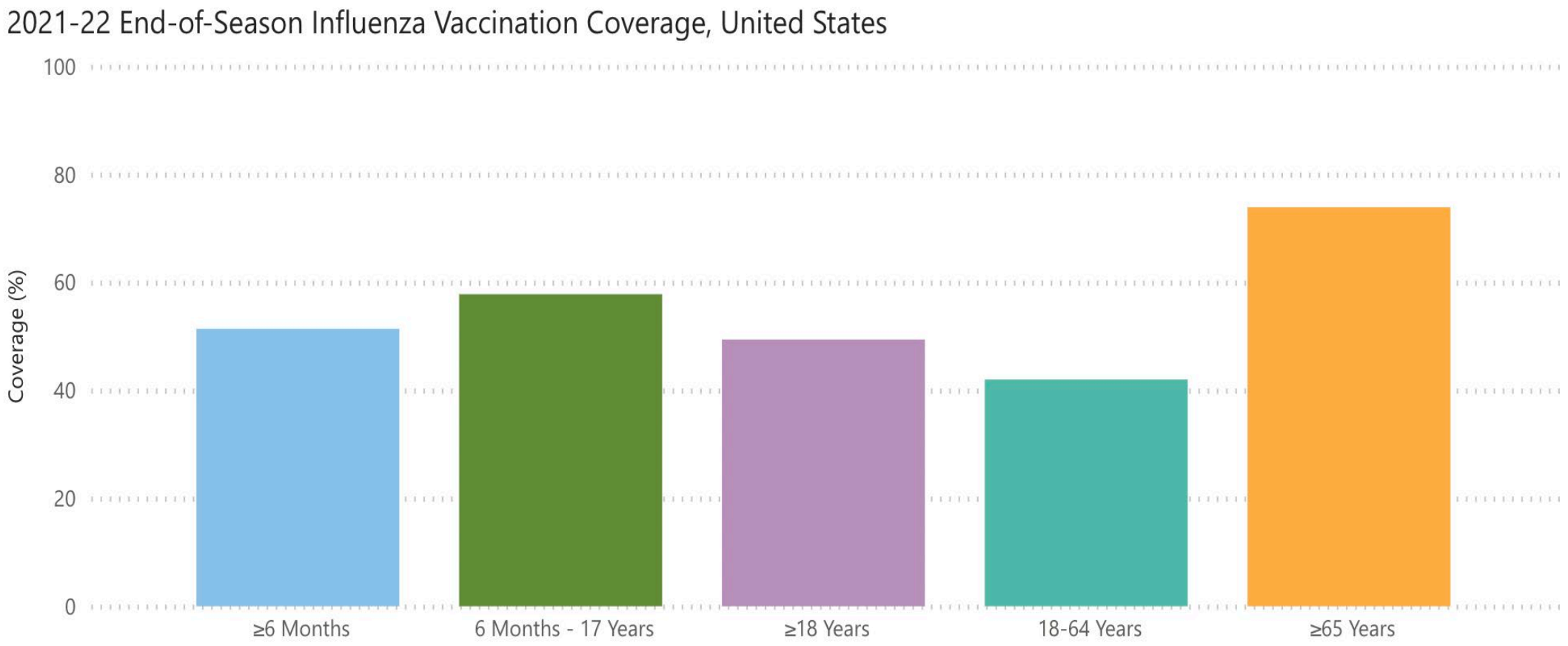
Benefits and Efficacy

- Significant decrease in the burden of illnesses and hospitalizations

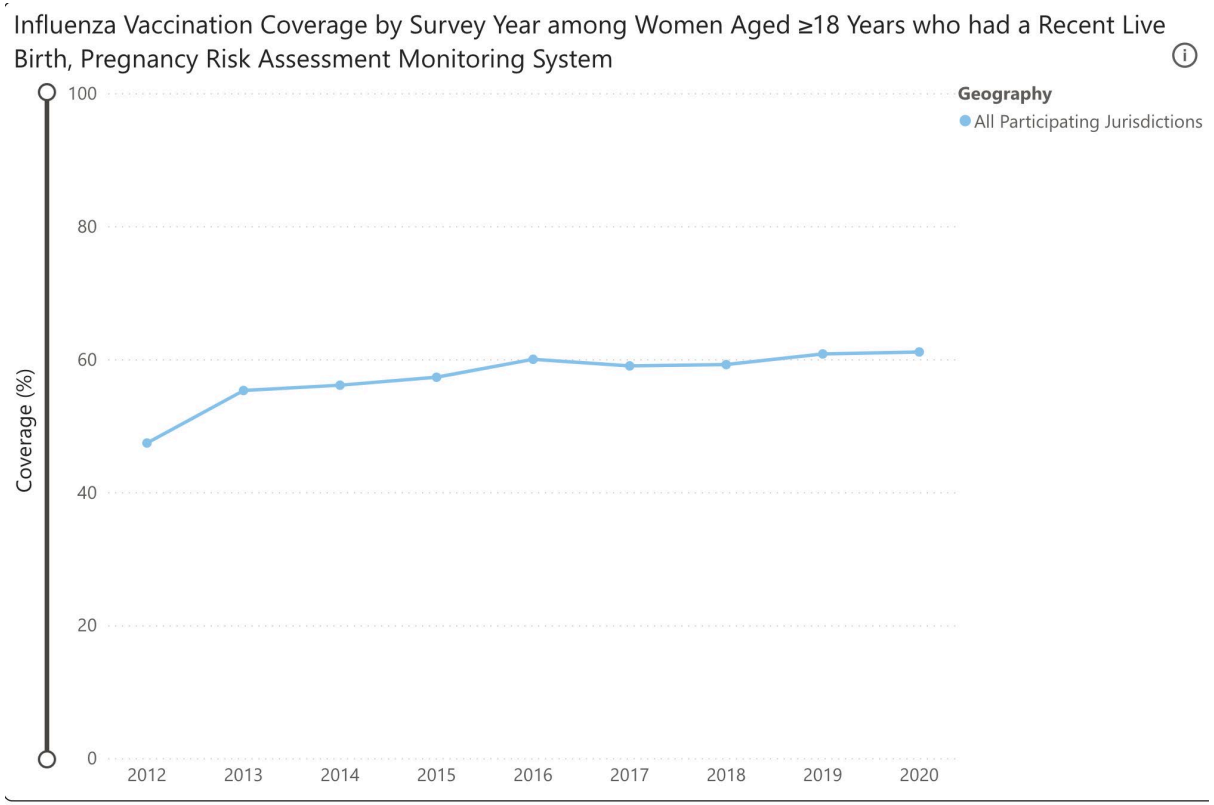
Averted Symptomatic Illnesses (2021-22)	Medical Visits Averted	Hospitalizations Averted	Deaths Averted
1,800,000	1,000,000	22,000	1,000

- Amongst hospitalizations, 26% lower risk of intensive care unit (ICU) admissions and a 31% lower risk of death from flu (2021)
- Reduced medical visits by 40-60% when vaccine viruses are similar
- Vaccination reduced children's risk of severe life-threatening influenza by 75% (2022)
- Beneficial in pregnant patients and patients with chronic diseases
- Efficacy depends on patient characteristics and "match" between vaccine and viruses

VACCINATION RATES

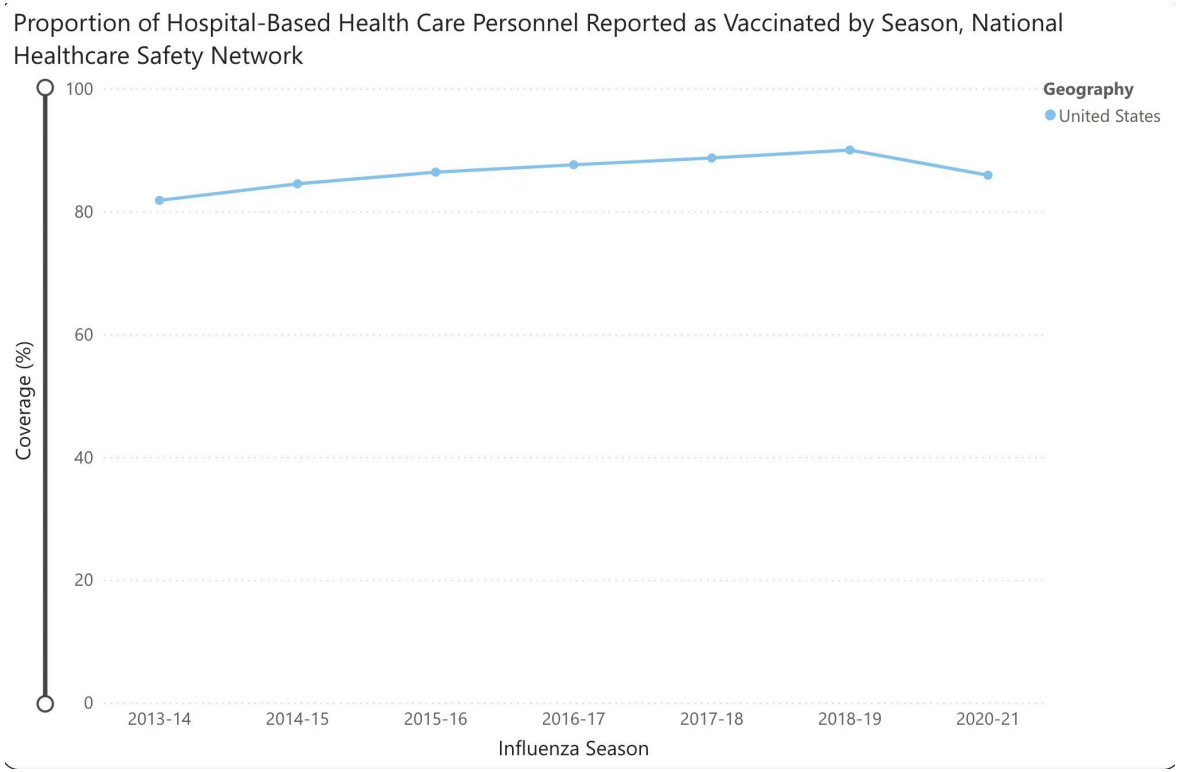


Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases (NCIRD)



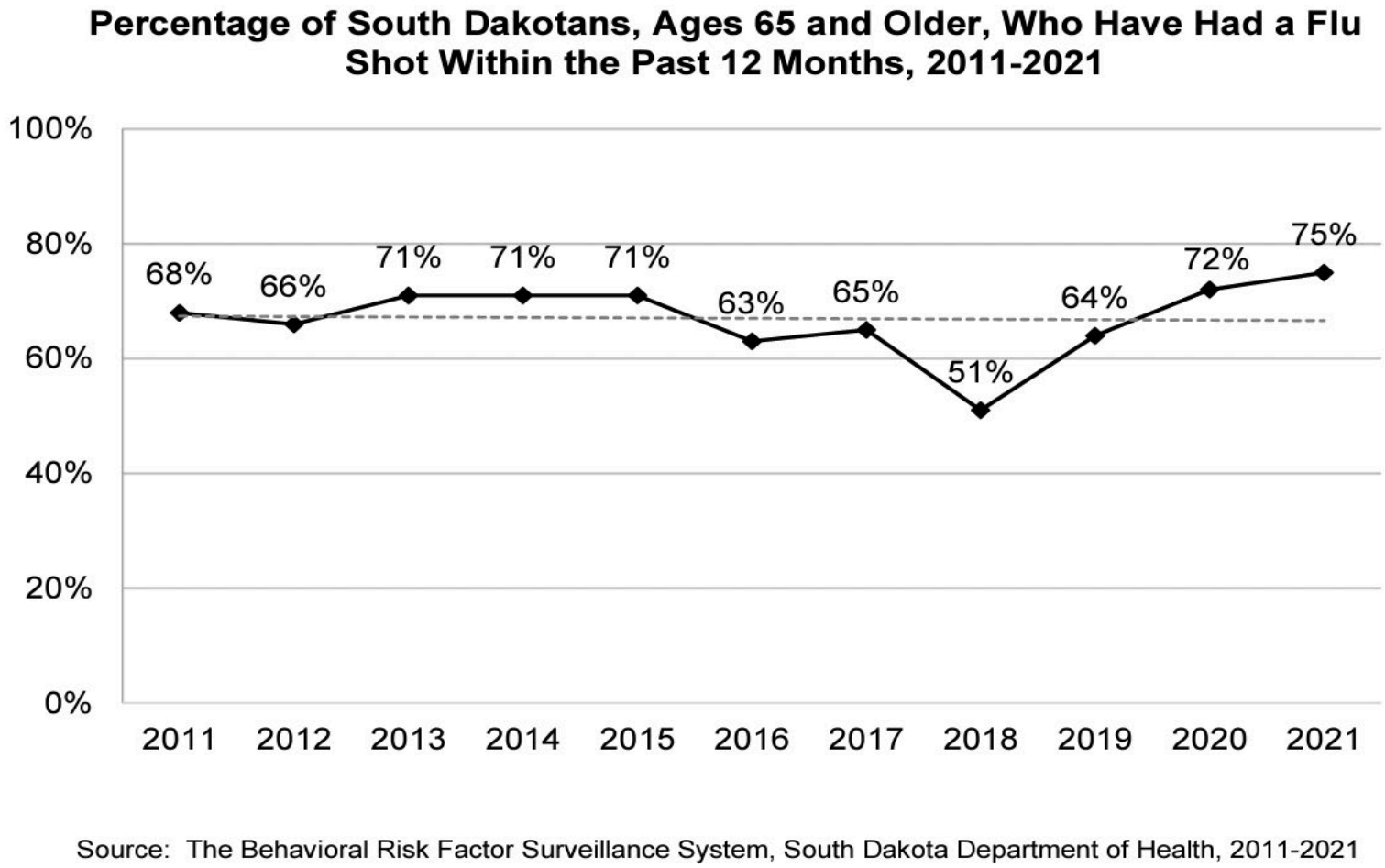
Pregnant population

Health Care Personnel



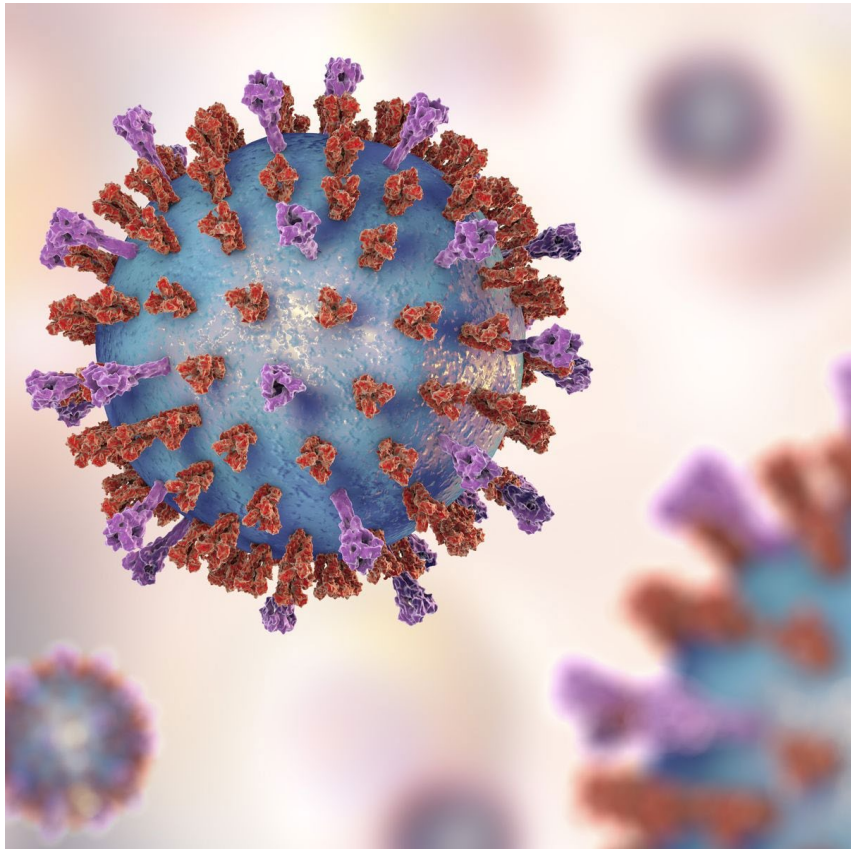
Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases (NCIRD)

South Dakota specific..



Nationwide median : 69%

RESPIRATORY SYNCYTIAL VIRUS



RSV

- Type A and Type B. Simultaneous. Type A more severe. Strains vary every season.
- RSV causes annual outbreaks of ARTI all age groups
- Most common cause of hospitalization in infants, most common cause of LRTIs
- All children are infected by 2 years, also reinfected
- RSV season starts in fall, peaks during winter. Variable by region.
- Disruption of typical season > off-season outbreaks

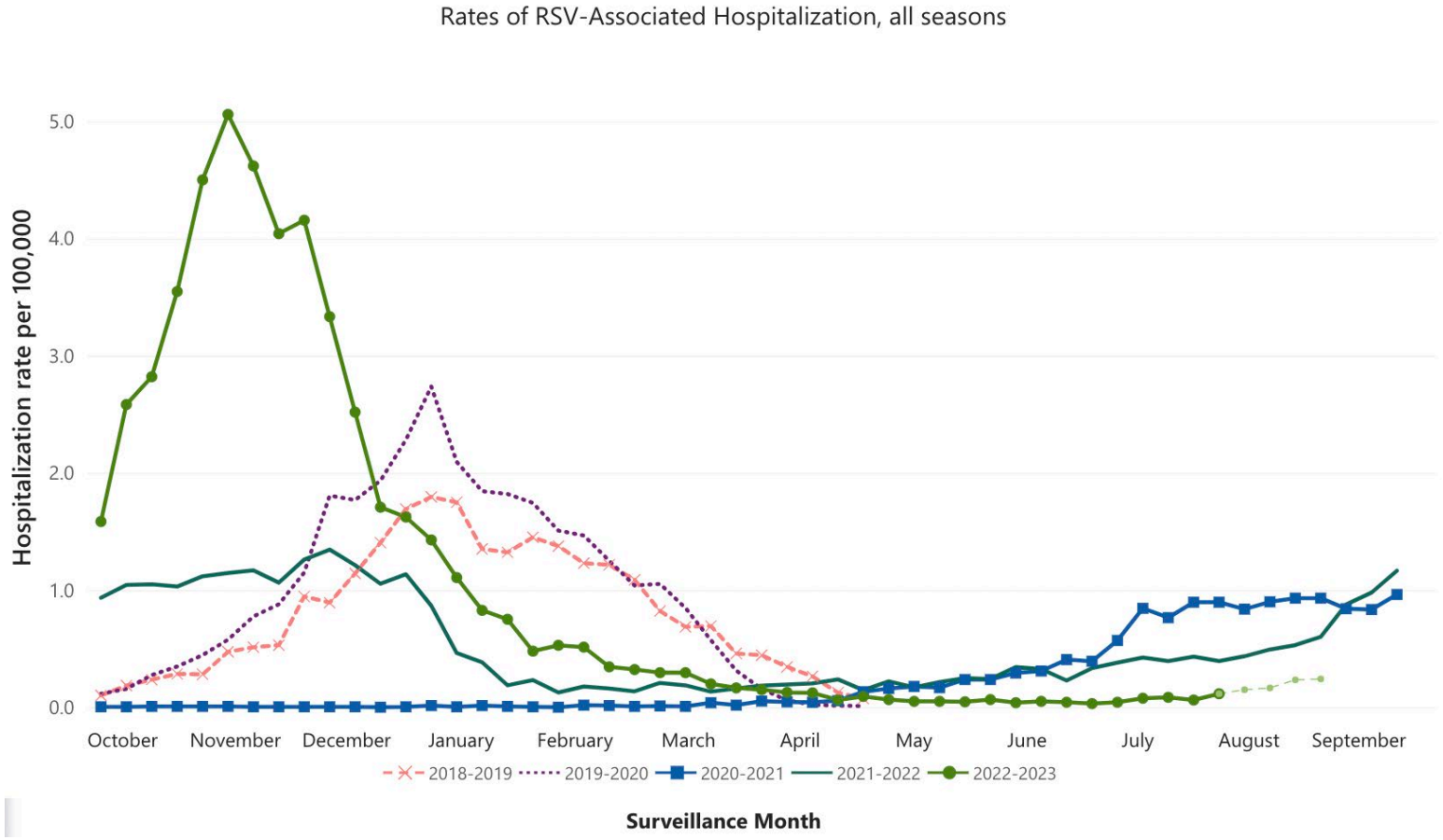
Disease burden (per year) :

Children/Infants	Adults
• 2.1 million outpatient visits among children < 5 years old • 58,000 – 80,000 hospitalizations among children < 5 years old • 100 – 300 deaths in children < 5 years old	• 60,000 – 160,000 hospitalizations among adults 65 years and older • 6,000– 10,000 deaths among adults 65 years and older

CDC 2023

2022-23 season..

- Earlier, higher and more severe.
- Increased hospitalization rates amongst children, older children and older adults
- Hospitalization rate during the early winter for children 0 - 4 years rose to **61.5 per 100,000** in mid-November, from last year's peak of 13.3 per 100,000 people.



CDC 2023

Average hospitalization rate last season was 51.5 per 100,000 population

Populations at high risk

At risk for severe lower respiratory tract infections :

- Infants < 6 months of age, up to 12 months
- Premature infants < 35 weeks gestation
- Infants and children with chronic lung disease, congenital heart disease, HIV-exposed but uninfected infants.
- Children who have neuromuscular disorders (especially difficulty swallowing or clearing mucus secretions)
- Exposure to secondhand smoke
- Patients with Down syndrome
- Children <5 years with social vulnerability
- Any age group with persistent asthma
- Adults with cardiopulmonary disease
- Altitude > 2500m
- Institutionalized older adults, functional disability, advanced age
- Older adults with any chronic diseases

THE NEW RSV VACCINE

- **May 2023** : FDA approved first vaccine for prevention of RSV-associated LRTI in adults ≥ 60 years
- **June 21, 2023** : ACIP recommendations to consider a single dose in above population, using shared clinical decision-making.
- Prevention of substantial morbidity and mortality among older adults

Available Vaccines

- **RSVPreF3** (Arexvy, GSK) : 1-dose adjuvanted recombinant stabilized prefusion F protein vaccine
- **RSVpreF** (Abrysvo, Pfizer) : 1- dose recombinant stabilized preF vaccine

Vaccine Efficacy

Vaccine	Efficacy first season	Efficacy second season	Prevention of RSV-LRTD	Prevention of medically attended RSV-LRTD
GSK Vaccine	82.6%	56.1%	74.5%	77.5%
Pfizer Vaccine	88.9%	78.6%	84.4%	81%

Moderate to high efficacy in preventing symptomatic RSV-associated LRTD over two consecutive seasons among adults ≥ 60 years > Might prevent considerable morbidity

Vaccine Safety

- Acceptable safety profile
- Serious AE relative risk ~1, severe reactogenicity events GSK > Pfizer
- 6 cases of inflammatory neurologic events (such as GBS, ADEM)
- Few cases of atrial fibrillation reported
- Unsure of causality, pending post marketing surveillance
- **Shared decision making, individualized discussions**
- Adverse events to be reported to Vaccine Adverse Event Reporting System (VAERS)

RSV Vaccination Timing

- Seasonality disrupted
- As soon as vaccine is available
- Limited data on revaccination

Precautions and Contraindications

- Delayed with moderate or severe acute illness with or without fever
- Contraindicated with history of severe allergic reaction to any component of vaccine

Future Research and Monitoring

- Focused on adverse events, efficacy against RSV-hospitalizations
- Studies evaluating risk for adverse neurologic events and atrial fibrillation
- Studies evaluating revaccination strategies

Protection in Children : Monoclonal Antibody Products nirsevimab (Beyfortus) and palivizumab (Synagis)

COVID-19

SARS-COV-2

- The disease COVID-19 is caused by severe acute respiratory syndrome coronavirus 2
- Emerged at the end of 2019. Pandemic declared over May of 2023 by WHO
- Betacoronavirus in the same subgenus as the severe acute respiratory syndrome (SARS) virus
- Multiple variants in circulation. More recently > Omicron variants

Variants

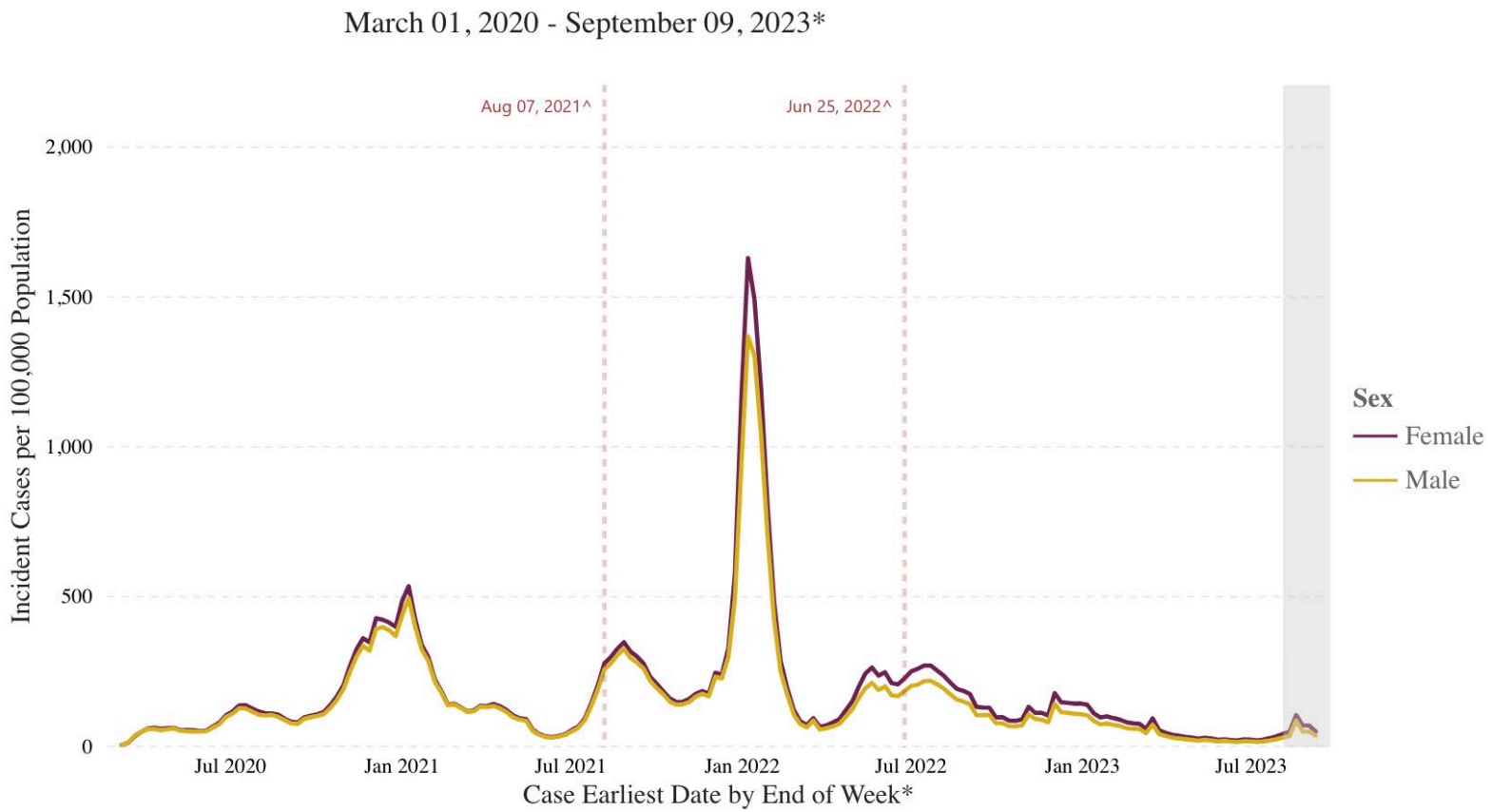
- A viral genome with one or more mutations
- Multiple variants have evolved : **Alpha**, Beta, Gamma, **Delta**, **Omicron**
- Omicron is the dominant variant now along with it sub-lineages
- No current Variants of Consequence or Variants of Concern
- Multiple Variants Being Monitored currently
- Variants of Interest : Variants containing the F456L spike mutations* - unnamed

DISEASE BURDEN

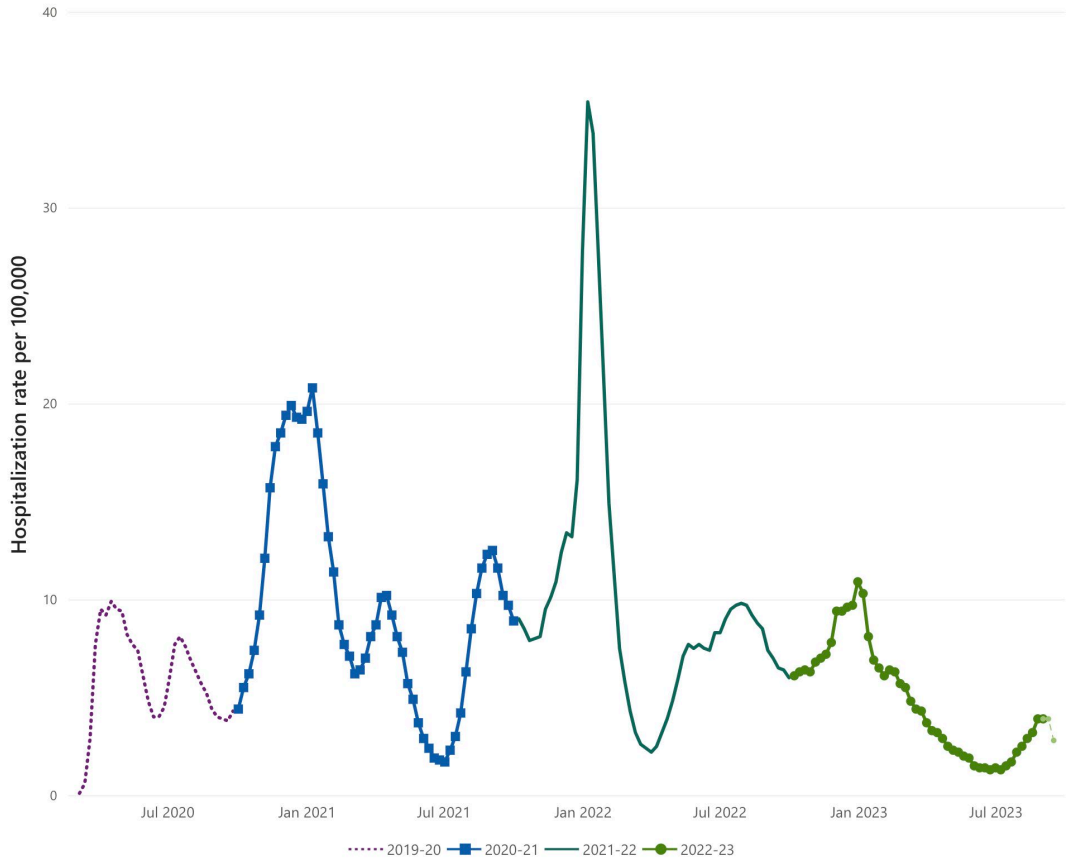
Region	Cumulative Cases	Cumulative Deaths
Global	770,778,396	6,958,499
United States	103,436,829	1,127,152

Underestimation > more than ten-fold cases (around 3 billion)

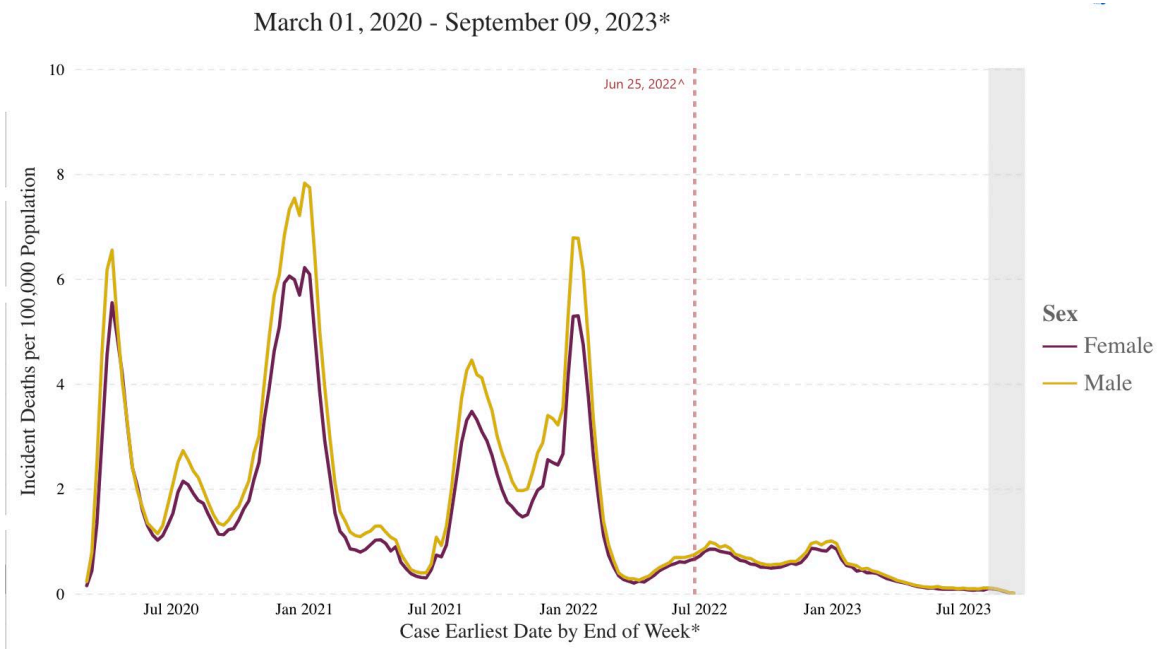
Case trends



CDC COVID Data Tracker



Hospitalization Trends



Mortality Trends

CDC COVID Data Tracker

Patients at risk of severe COVID-19

- Age > 65 years (Risk increases with age)
- Chronic systemic diseases
- Underlying pulmonary conditions
- Immunocompromised status
- Diabetes mellitus
- Obesity
- Pregnancy
- Smoking
- Substance Use Disorders
- Disabilities
- Mental health disorders
- Sickle cell disease
- Tuberculosis
- Systemic health and social equities

COVID-19 VACCINES

Vaccine Principle : Antigenic target is the surface spike protein. mRNA vaccines evolved to target mutations in variants.

History

2020

FDA EUA for 2 mRNA vaccines – Pfizer-BioNTech and Moderna COVID-19

2021

FDA EUA for Janssen/Johnson & Johnson (viral vector vaccine). FDA approves Pfizer (Comirnaty) for age 16+ and EUA for 5 to 15 years

2022

FDA approves Moderna (Spikevax).
FDA approves Comirnaty ages 12 and older, EUA for ages 6 months – 12 years.
EUA of Moderna for ages 6 m to 11 y and
Novavax adjuvanted vaccine for ages 12 and older.

Benefits

- Reduced severity of disease, hospitalizations and mortality. Booster necessary to maintain effectiveness.
- Decreased risk of symptomatic infection. Not the case with Omicron (53% > 14%)
- Breakthrough infections – asymptomatic, shorter and less severe, low risk of 'long COVID'
- Reduced risk of transmissions

UPDATED COVID-19 VACCINE

- ✓ September 12, 2023 : the updated 2023-24 Pfizer-BioNTech and Moderna COVID-19 vaccines recommended for use by CDC (EUA by FDA)
- ✓ mRNA vaccines containing a monovalent (single) component that corresponds to the **Omicron variant XBB.1.5** of SARS-CoV-2.
- ✓ Novovax's updated vaccine under review by FDA for EUA

RECOMMENDATIONS

Population	Recommendations
Ages 5 and above	1 updated dose 2 months from previous dose
Moderate/severe immunocompromise	Multiple/Additional doses depending on vaccination status Unvaccinated : 3 updated doses 3 vaccine doses : 1 dose + additional dose
Children 6m – 4y (previously unvaccinated)	3 updated Pfizer doses 2 updated Moderna doses
Children previously vaccinated	Total of 3 Pfizer doses (including previous) Total of 2 Moderna doses
Unable or do not want Pfizer/Moderna	Novavax 2 doses + booster (>18y) > 12 years old

RISKS OF VACCINATION

Common adverse effects

- Local effects : Pain, redness, swelling and pruritus > mild-moderate
- Non severe systemic effects : Fatigue, headache, myalgia, fever, chills
- Younger > older adults
- Limit daily life activities in 10-20 % recipients

Serious effects (very rare)

- **Myocarditis and pericarditis :**

- Male adolescents and young adults (mRNA and recombinant vaccines).
- Mild disease, within first week, after second dose or booster.
- Possible increased risk following Janssen/Johnson & Johnson vaccine (discontinued)
- Vaccine Safety Datalink 2022 : 320 cases following 7 million doses (attention for younger males)
- Ages 5-39 years : Days 0-7 : 1/200000 (dose 1), 1/30000 (dose 2), 1/50000 (1st booster)
- Meta-analysis in 2022 : 7-fold increased risk in infection than with vaccination

Other adverse effects with vaccines outside of US

- Thrombosis with thrombocytopenia
- Guillain-Barre syndrome
- Related to Johnson & Johnson vaccine
- More thromboembolic/GBS complications secondary to actual infection

Reactions without established association

- Ischemic stroke : slightly higher incidence at ≥ 65 years after Pfizer BioNTech vaccine. Decreased with time. No associations in additional analyses.
- Possible anaphylaxis : Both mRNA vaccines. 4.5 events per million doses initially. History of prior reactions.
- No association with fertility problems
- Passive and active reporting systems are of importance in post-licensure phase

Contraindications

- History of severe allergic reaction to previous COVID-19 vaccine dose or component of vaccine or known allergy to component of vaccine

Precautions

- Non severe but immediate allergic reaction to a previous COVID-19 vaccine dose
- Allergic reactions to other COVID-19 vaccines > longer monitoring (cross-reactive hypersensitivity)
- Immediate allergic reaction to other non-COVID-19 vaccine or injectable therapy

EFFECTIVENESS

- Published in April 2023 :

  - Monovalent mRNA vaccination **76% effective** in preventing COVID-19 associated IMV and death <6 months after last dose. **56% at 1-2 years.**
  - Omicron Variant Period. February '22 – January '23. 19 US States

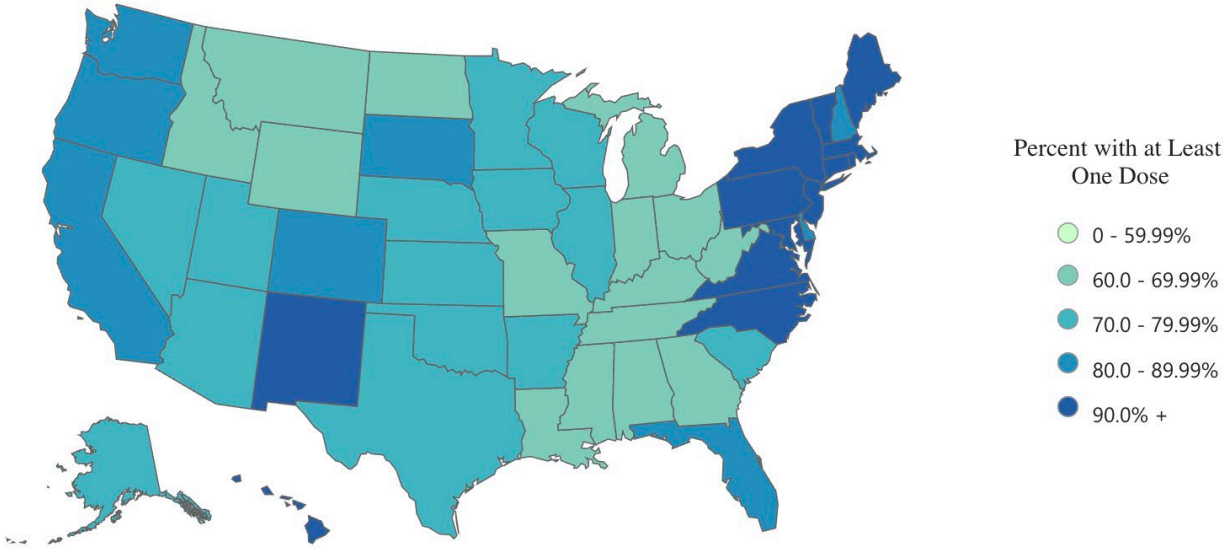
- Published in May 2023 :

  - Bivalent mRNA durability in preventing hospitalizations and critical illness (September 2022 – April 2023)
  - Vaccine effectiveness against hospitalizations **62 % at 7-59 days, 24% 120-179 days**
  - Efficacy sustained (69% and 50%) against critical outcomes including ICU admissions and death.

VACCINATION RATES

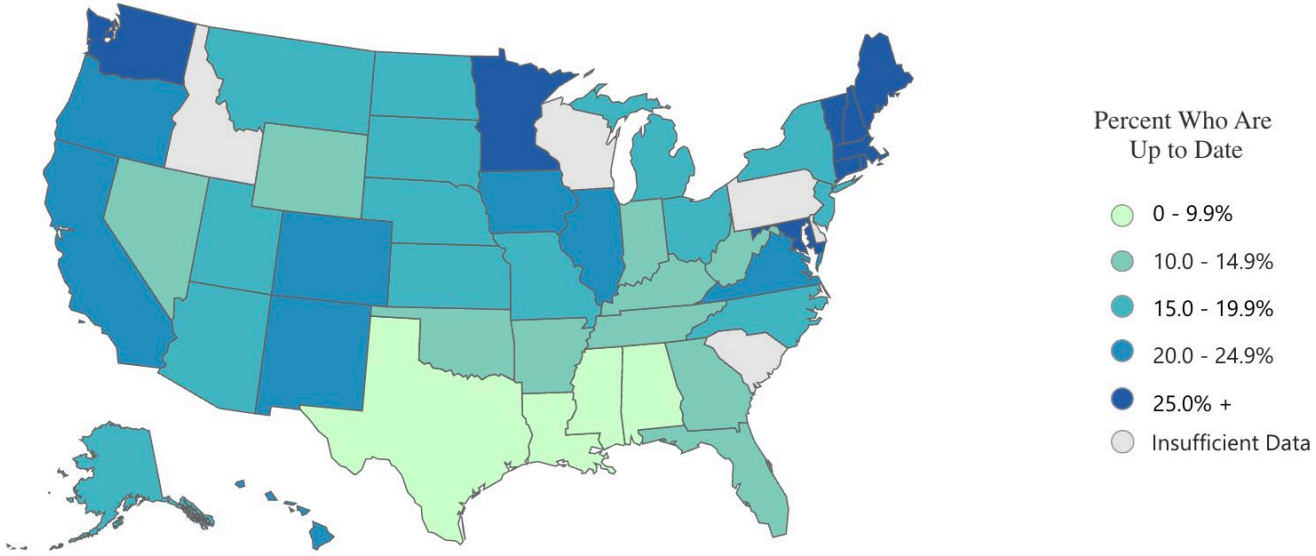
Percent of Population with at least of one dose of COVID-19 Vaccination up to August 2023

South Dakota 84.3 %



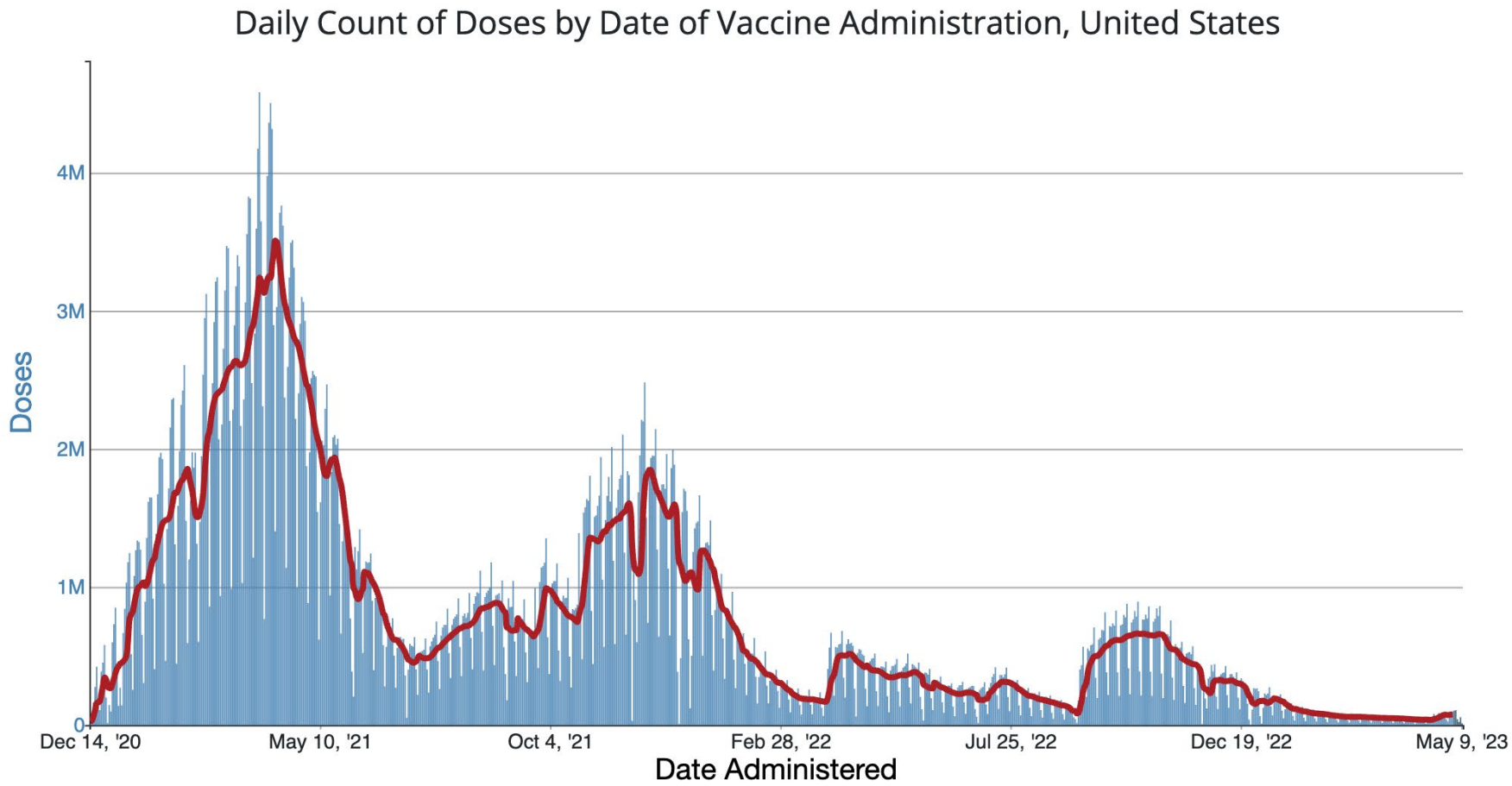
Percent up-to-date with COVID Vaccination

South Dakota 19.6 %



CDC Covid Data Tracker

Vaccination Trends



Centers for Disease Control and Prevention. COVID Data Tracker. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2023, September 21. https://covid.cdc.gov/covid-data-tracker

CONCLUSION..

- First fall/winter virus season where all three vaccines are available for viruses causing most hospitalizations > **COVID-19, RSV and Influenza**
- Important to address **vaccine hesitancy**
- Recognized as one of the top global threats in 2019 by WHO
- Misinformation, safety concerns and lack of awareness, lack of trust
- Risk factors : Younger age, rural populations, lack of insurance, other socioeconomic factors
- To be addressed by healthcare workers by identifying concerns, appropriate education and addressing misconceptions
- Significant benefits in terms of morbidity and mortality with high administration rates

THANK YOU !