IHCA INCAL

Regulatory Roundup

Weekly Webinar for Long-Term Care Professionals

IHCA.org/regulatory-roundup

PRESENTERS

Lori Davenport
Indiana Health Care Association

Team Members from
Indiana Department of Health

September 21, 2023

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Today's Agenda

- CMS Staffing Rule Call to Action – Nick Goodwin, IHCA Director of Government Affairs
- ATP Equipment LTC, Vaccination – COVID-19, Flu and RSV Trends – Dr. Shireesha Vuppalanchi, MD, Medical Director
- CHIRP – Question and Answer from last week – Lori Davenport, IHCA Director of Regulatory Clinical Affairs
- Q&A

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Upcoming Education Offerings

- Sept. 26, Webinar – Meaningful Meetings, details HERE
- Sept. 28, Webinar – The Only Constant is Change: Preparing for October 1, 2023, details HERE
- Sept. 28-29, In-person – Assisted Living Symposium, details HERE
- Oct. 17, In-person and Virtual option – IDOH Health Care Leadership Conference, details HERE
- Oct. 24, Webinar – Steering Survey Success, details HERE

Indiana Department of Health

ATP EQUIPMENT IN LTC VACCINATION COVID-19, FLU, RSV TRENDS

SHIREESHA VUPPALANCHI, M.D.
MEDICAL DIRECTOR

09/21/2023

OUR MISSION:

To promote, protect, and improve the health and safety of all Hoosiers.

OUR VISION:

Every Hoosier reaches optimal health regardless of where they live, learn, work, or play.

ATP equipment

Background

- Healthcare associated infections (HAIs) are a major public health issue
- Proper environmental cleaning and disinfection in healthcare settings is crucial for reducing the risk of HAIs
- Adenosine triphosphate (ATP) is the energy molecule found in all living cells and can be measured as a useful marker for bioburden
- Evaluating cleaning practices with an ATP luminometer can help identify gaps of cleaning and disinfection processes
- Food industry has been using ATP machines for 30 years
- Acute care hospitals and other setting also use this equipment

ATP luminometer

A handheld device can be used to detect the amount of ATP present on surfaces

- Readings are given in relative light units (RLU)
  - Lower RLUs: low contamination (properly cleaned)
  - Higher RLUs : higher contamination (not clean)
- Pass/fail: Different RLU settings can be set up based on the surface being checked

ATP equipment for use by LTC

- Indiana Department of Health (IDOH) is purchasing ATP luminometers and swabs for long-term care facilities using funds provided by the Centers for Disease Control and Prevention.
- The long-term care (LTC) facilities that would like to receive the ATP equipment must fill out the survey by Oct. 15. ATP Equipment Request Survey (in.gov)
- The ATP equipment (device and swabs) will be delivered directly to the facility.

Information needed to complete the survey

- Full name of the facility
- Exact shipping address
- Contact person's name, phone number, and email address
- Number of beds in the facility
- Number of ATP equipment requested
  - It is recommended to request for one unit if the facility has fewer than 100 skilled nursing beds and two units if more 100 skilled nursing beds.
  - Facilities with high infection control needs such as MDRO unit/ vent unit/ high MDRO infections may request for two units even if they have fewer than 100 beds.
- Each facility must complete survey only once. If more than one survey is received, only the latest submission will be used in final planning.

Usage, Storage and Training

- Use the swabs to evaluate the cleanliness after environmental cleaning
- Store the swabs at appropriate temperatures per the manufacturer guidance
- Once the packet of swabs is open, finish using the swabs within the time frames recommended by the manufacturer
- Follow the instructions provided by the manufacturer for use of ATP equipment
- Further education on how and where to use the ATP equipment will be provided at a later date by the manufacturer and/or IDOH's HAI-AR (Healthcare-Associated Infections- Antibiotic Resistance) team as needed.

Additional information

- Manufacturer will provide warranty information
- We are asking them to ship swabs periodically to save fridge space and not to run into expiration dates
- If desired, facilities will have option to order additional swabs, additional equipment at their expense

Vaccination

Indiana Department of Health

Pneumonia vaccination

- Pneumococcal conjugate vaccine (PCV): PCV 7, 13, 15, 20
- Pneumococcal polysaccharide vaccine (PPSV): PPSV or PPSV23

Pneumococcal Vaccine Timing for Adults

Make sure your patients are up to date with pneumococcal vaccination.

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

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines
† Consider minimum interval (8 weeks) for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak (CSF) leak
§ For adults with an immunocompromising condition, cochlear implant, or CSF leak, the minimum interval for PPSV23 is ≥8 weeks since last PCV13 dose and ≥5 years since last PPSV23 dose; for others, the minimum interval for PPSV23 is ≥1 year since last PCV13 dose and ≥5 years since last PPSV23 dose

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.

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Pneumococcal Vaccine Timing for Adults greater than or equal to 65 years (cdc.gov)

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

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines
† Adults with chronic medical conditions were previously not recommended to receive PCV13

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[Pneumococcal Vaccine Timing for Adults greater than or equal to 65 years (cdc.gov)]

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	

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines
† The minimum interval for PPSV23 is ≥8 weeks since last PCV13 dose and ≥5 years since last PPSV23 dose
§ Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease)
¶ Includes diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy

Pneumococcal Vaccine Timing for Adults greater than or equal to 65 years (cdc.gov)

Adults 19–64 years old with a cochlear implant or cerebrospinal fluid leak
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 Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
PCV13 and 1 dose of PPSV23	≥5 years → PCV20	**No vaccines** recommended at this time. Review pneumococcal vaccine recommendations again when your patient turns 65 years old.

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines

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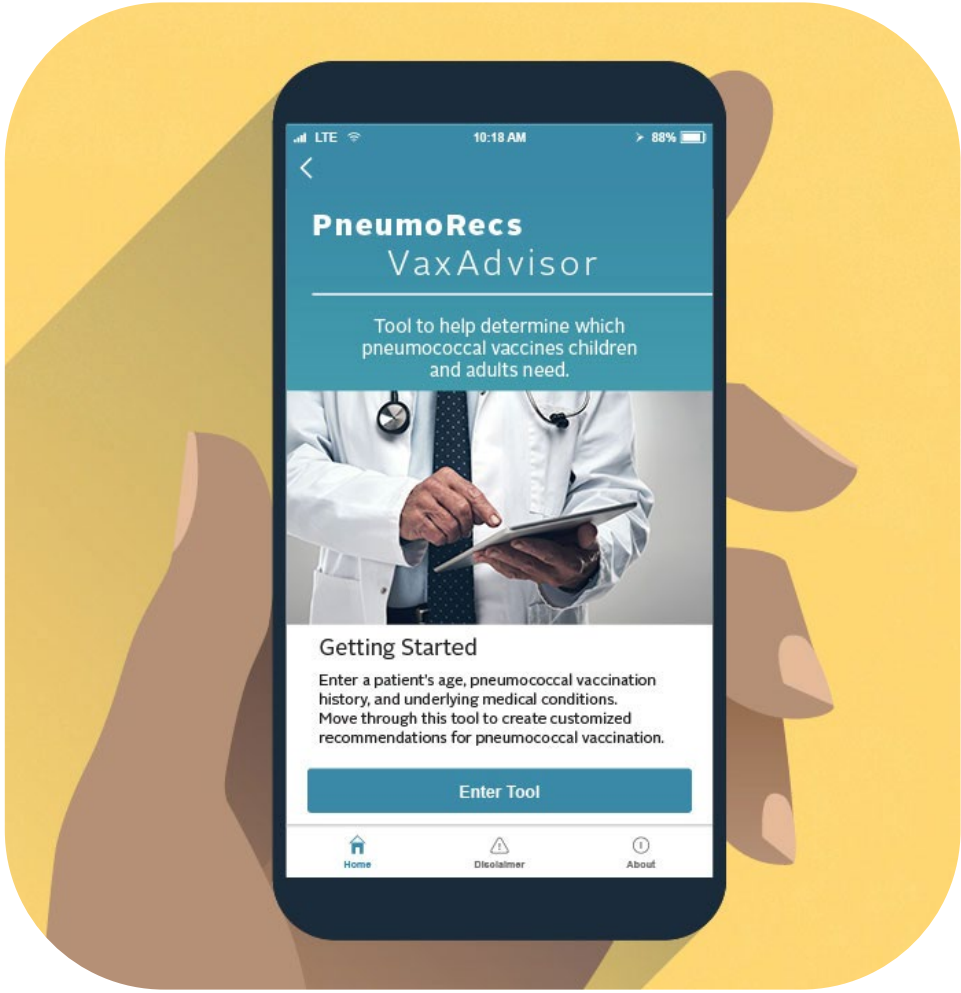
Pneumococcal Vaccine Timing for Adults greater than or equal to 65 years (cdc.gov)

The PneumoRecs VaxAdvisor mobile app

Users simply:

- Enter a patient's age.
- Note if the patient has specific underlying medical conditions.
- Answer questions about the patient's pneumococcal vaccination history.

Then the app provides patient-specific guidance consistent with the immunization schedule recommended by the U.S. Advisory Committee on Immunization Practices (ACIP).



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PneumoRecs VaxAdvisor: Vaccine Provider App | CDC

COVID-19 Vaccines

- LTC facilities should procure the updated COVID-19 vaccine through their pharmacy partnerships and offer it to all the eligible residents
- Vaccination remains the best protection against COVID-19-related hospitalization and death. Vaccination also reduces the chance of suffering the effects of Long COVID, which can develop during or following acute infection and last for an extended duration.

COVID-19 Vaccines

- Recommendations for use of the 2023–2024 formulations of Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine:
  - Everyone ages 5 years and older is recommended to receive 1 dose of updated (2023–2024 Formula) mRNA COVID-19 vaccine
- The CDC's recommendation is that anyone who has not received a COVID-19 vaccine in the past 2 months get an updated COVID-19 vaccine.
- Bivalent mRNA COVID-19 vaccines are no longer recommended in the United States

Clinical Guidance for COVID-19 Vaccination | CDC

Ages 12 years and older

COVID-19 vaccination history prior to updated (2023–2024 Formula) mRNA vaccine*	Updated (2023–2024 Formula) mRNA vaccine	Number of updated (2023–2024 Formula) mRNA doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors§	Interval between doses
Unvaccinated	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	—
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	—
1 or more doses any mRNA	Moderna OR	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 8 weeks after last dose
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 8 weeks after last dose
1 or more doses Novavax or Janssen, including in combination with any mRNA vaccine dose(s)	Moderna OR	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 8 weeks after last dose
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 8 weeks after last dose

Moderately or severely immunocompromised

People who are moderately or severely immunocompromised:

- Initial vaccination: should receive a 3-dose series of updated (2023–2024 Formula) Moderna or updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 vaccine
- Received previous mRNA doses: need 1 or 2 doses of updated (2023–2024 Formula) Moderna or updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 vaccine, depending on the number of prior doses
- Received 3 or more mRNA doses: 1 updated (2023–2024 Formula) mRNA COVID-19 vaccine doses at least 8 weeks after the last dose
    - They have the option to receive another additional dose at least after two months. Any further doses are at clinician's discretion may be given at least two months after the last dose.

Clinical Guidance for COVID-19 Vaccination | CDC

Ages 12 years and older*

COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine†	Updated (2023–2024 Formula) mRNA vaccine	Number of updated (2023–2024 Formula) mRNA doses indicated‡	Dosage (mL/ug)	Vaccine vial cap and label colors§	Interval between doses
Unvaccinated	Moderna	3	0.5 mL/50 ug	Dark blue cap; blue label	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
	Pfizer-BioNTech	3	0.3 mL/30 ug	Gray cap; gray label	Dose 1 and Dose 2: 3 weeks Dose 2 and Dose 3: At least 4 weeks
1 dose any Moderna	Moderna	2	0.5 mL/50 ug	Dark blue cap; blue label	Dose 1: 4 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
2 doses any Moderna	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 4 weeks after last dose

COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine[†]	Updated (2023–2024 Formula) mRNA vaccine	Number of updated (2023–2024 Formula) mRNA doses indicated[‡]	Dosage (mL/ug)	Vaccine vial cap and label colors[§]	Interval between doses
1 dose any Pfizer-BioNTech	Pfizer-BioNTech	2	0.3 mL/30 ug	Gray cap; gray label	Dose 1: 3 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
2 doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 4 weeks after last dose
3 or more doses any mRNA vaccine	Moderna OR	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 8 weeks after last dose
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 8 weeks after last dose

COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine[†]	Updated (2023–2024 Formula) mRNA vaccine	Number of updated (2023–2024 Formula) mRNA doses indicated[‡]	Dosage (mL/ug)	Vaccine vial cap and label colors[§]	Interval between doses
1 or more doses of Novavax or Janssen, including in combination with any mRNA vaccine dose(s)	Moderna OR	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 8 weeks after last dose
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 8 weeks after last dose

Novavax COVID-19 Vaccine

Novavax COVID-19 Vaccine is currently authorized to provide:

- A 2-dose primary series to people ages 12 years and older. The primary series doses are separated by 3–8 weeks. An 8-week interval between the first and second primary series doses might be optimal for some people ages 12–64 years, especially for males ages 12–39 years, as it might reduce the small risk of myocarditis and pericarditis associated with this vaccine.
- A booster dose in limited situations to people ages 18 years and older who previously completed primary vaccination using any FDA-approved or FDA-authorized COVID-19 vaccine; have not received any previous booster dose(s); and are unable (i.e., mRNA vaccine contraindicated or vaccine not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose. The Novavax booster dose is administered at least 6 months after completion of any primary series.

Novavax's updated vaccine is still under review by the FDA

CHIRP access

- Most LTC now have read only access to CHIRP, the immunization registry. If you would like to change your access, please email David McCormick, DMcCormick@health.in.gov
- Adult reporting will be voluntary once the vaccine is commercialized unless the vaccination is done through a pharmacy or pharmacy partnership.
- Any vaccine that is administered by a pharmacy or through a pharmacy partnership must be entered into the registry.

Influenza vaccination

- Routine annual influenza vaccination of all persons aged ≥6 months who do not have contraindications continues to be recommended.
- 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).
- If none of these three vaccines is available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine should be administered

Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023–24 Influenza Season | MMWR (cdc.gov)

Persons with a History of Egg Allergy

- ACIP recommends that all persons aged ≥6 months with egg allergy should receive influenza vaccine. Any influenza vaccine (egg based or nonegg based) that is otherwise appropriate for the recipient's age and health status can be used (https://www.cdc.gov/vaccines/acip/recs/grade/influenza-egg-allergy.html; https://www.cdc.gov/vaccines/acip/recs/grade/influenza-egg-allergy-etr.html).
- It is no longer recommended that persons who have had an allergic reaction to egg involving symptoms other than urticaria should be vaccinated in an inpatient or outpatient medical setting supervised by a health care provider who is able to recognize and manage severe allergic reactions if an egg-based vaccine is used.
- Egg allergy alone necessitates no additional safety measures for influenza vaccination beyond those recommended for any recipient of any vaccine, regardless of severity of previous reaction to egg. All vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of acute hypersensitivity reactions are available.

Summary

What is already known about this topic?

Effectiveness of seasonal influenza vaccine varies by season and circulating virus type.

What is added by this report?

The 2023 Southern Hemisphere seasonal influenza vaccine reduced the risk for influenza-associated hospitalizations by 52%. Circulating influenza viruses were genetically similar to those targeted by the 2023–24 Northern Hemisphere influenza vaccine formulation. This vaccine might offer similar protection if these viruses predominate during the coming Northern Hemisphere influenza season.

What are the implications for public health practice?

Vaccination remains one of the most effective ways to protect against influenza-associated complications. In anticipation of Northern Hemisphere influenza virus circulation, CDC recommends that health authorities encourage U.S. health care providers to administer seasonal influenza vaccine to all eligible persons aged ≥6 months.

RSV vaccine

- Single dose for adults 60 years of age and older using shared clinical decision-making
- Two vaccines are available: RSVPreF3 (Arexvy, GSK) and RSVpreF (Abrysvo, Pfizer).
- Optimally, vaccination should occur before the onset of the fall and winter RSV season. However, typical RSV seasonality was disrupted by the COVID-19 pandemic and has not returned to pre-pandemic patterns. For the 2023–24 RSV season, providers should offer RSV vaccination as early as vaccine supply becomes available.
- Currently, the RSV vaccine series consists of a single dose. Studies are ongoing to determine whether older adults might benefit from receiving additional RSV vaccines in the future. So far, RSV vaccines appear to provide some protection for at least two RSV seasons.

TABLE 3-4. Guidelines for spacing of live and non-live antigens

Antigen combination	Recommended minimum interval between doses
Two or more non-live[a],[b],[c]	May be administered simultaneously or at any interval between doses
Non-live and live[d]	May be administered simultaneously or at any interval between doses
Two or more live injectable[d]	28 days minimum interval, if not administered simultaneously

COVID-19, RSV, Flu Trends

Indiana Department of Health

Data Update for the United States

Hospitalizations

Hospital Admissions

18,871

(August 27 to September 2, 2023)

Trend in Hospital Admissions

+8.7% in most recent week

Aug 4, 2023 Sep 2, 2023

Deaths

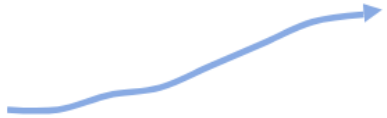
% Due to COVID-19

2.3%

(September 3 to September 9, 2023)

Trend in % COVID-19 Deaths

+4.5% in most recent week



Jul 22, 2023 Sep 9, 2023

Vaccinations

Total Updated (Bivalent) Vaccine Doses Distributed

153,471,660

(through September 13, 2023)

Total Hospitalizations

6,308,630

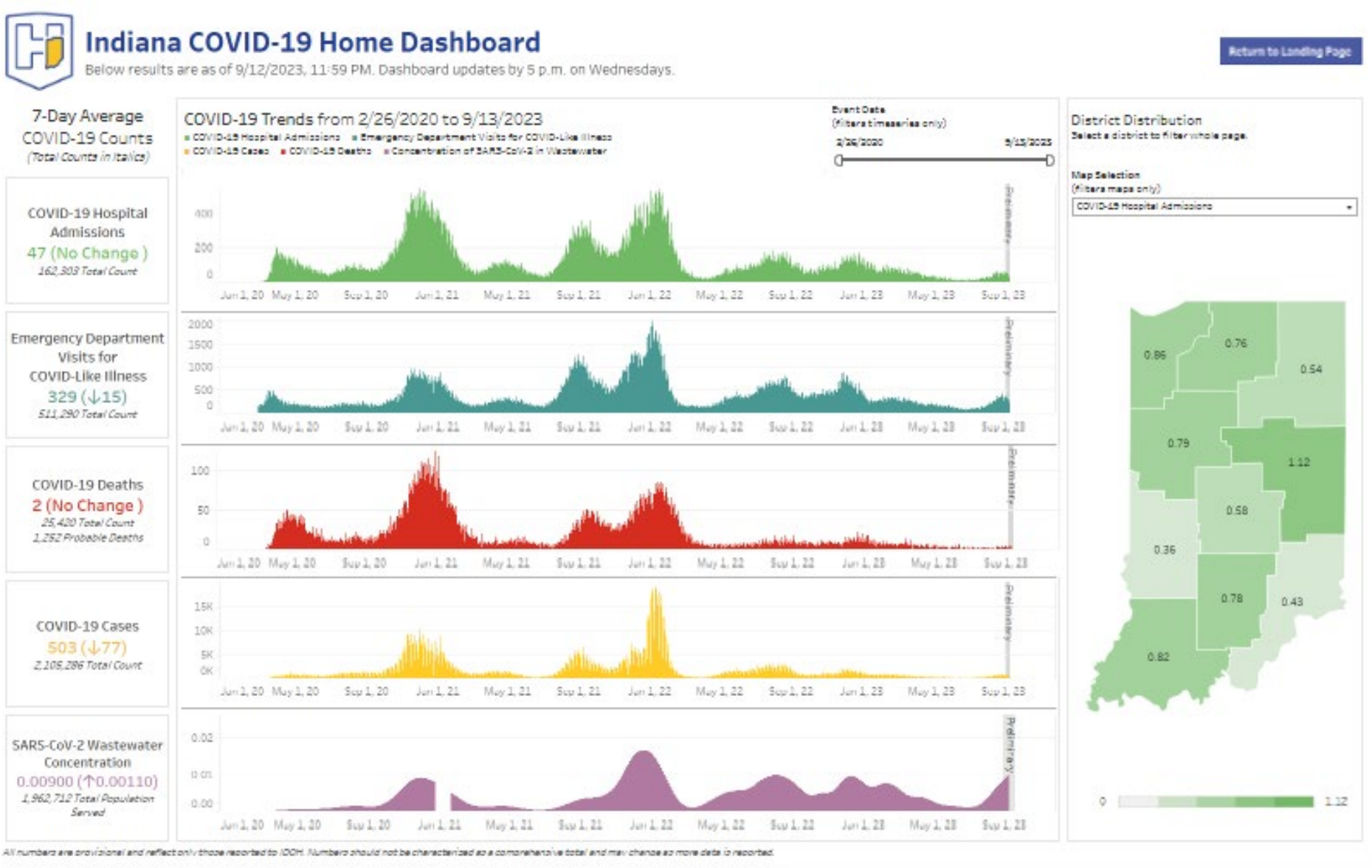
Total Deaths

1,141,782

CDC | Hospitalization data through: September 2, 2023; Death data through: September 9, 2023; Vaccination data through: September 13, 2023. Posted: September 14, 2023 4:08 PM ET

Indiana Department of Health

CDC COVID Data Tracker: Home



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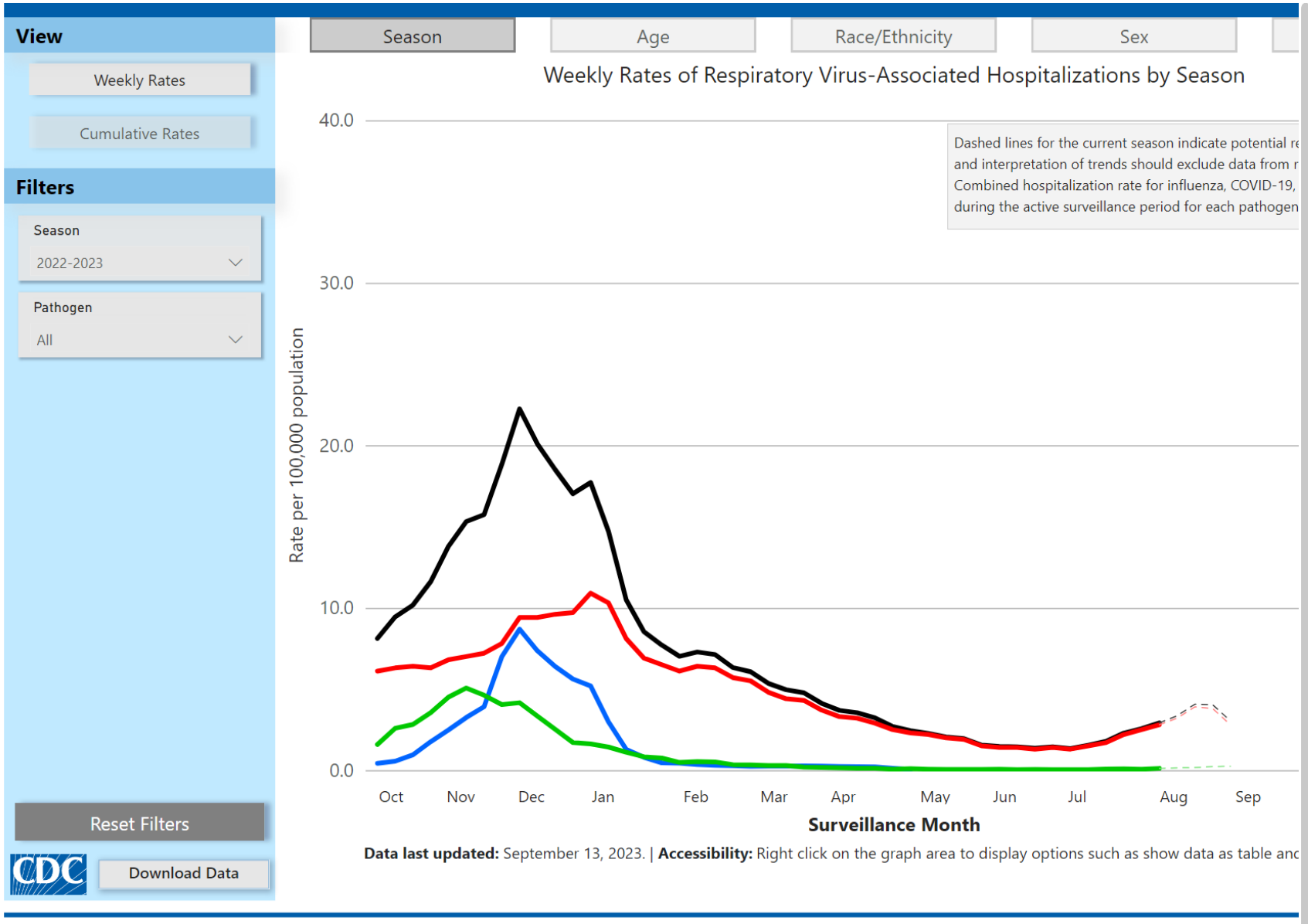
Coronavirus: Indiana COVID-19 Home Dashboard

RESP-NET

The Respiratory Virus Hospitalization Surveillance Network (RESP-NET) comprises three platforms that conduct population-based surveillance for laboratory-confirmed hospitalizations associated with COVID-19, Influenza, and Respiratory Syncytial Virus (RSV) among children and adults.

Surveillance is conducted through a network of acute care hospitals in select counties in 13 states. The surveillance platforms for COVID-19, Influenza, and RSV (known as COVID-NET, FluSurv-NET, and RSV-NET, respectively) cover more than 29 million people and include an estimated 8-10% of the U.S. population.

RESP-NET Interactive Dashboard | CDC



Indiana Department of Health

RESP-NET Interactive Dashboard | CDC

Respiratory Season

Assessment as of Thursday, Sept. 14:

CDC expects the upcoming fall and winter respiratory disease season will likely have a similar number of total hospitalizations compared to last year. As with last year, the number of hospitalizations is expected to be higher than that experienced prior to the COVID-19 pandemic, when severe disease was caused primarily by the influenza virus and the respiratory syncytial virus (RSV).

This outlook is based on expert judgment, historical data, and scenario modeling for COVID-19. We have low to moderate confidence in this assessment because of uncertainties in anticipating the timing of when diseases will peak and levels of disease.

Respiratory Disease Season Outlook (cdc.gov)

Questions?

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Question from last week

- Will reporting COVID-19 Vaccination into CHIRP still be required with moving into the Commercial market?
  - LTC providers currently have read only access.
  - When the vaccine moves to the commercial world, LTC providers will be able to administer it, so is the reporting changing or is CHIRP access able to change?

  ANSWER:

  Adult reporting will be voluntary once the vaccine is commercialized unless the vaccine is through a pharmacy or pharmacy partnership. Any vaccine that is administered by a pharmacy or through a pharmacy partnership must be entered into the registry.

  If access needs to be changed --- that can be done quickly.

  Call the CHIRP help desk.

Next 2 weeks

- No Regulatory Roundup meeting on September 28th – IHCA/INCAL Assisted Living Symposium on September 28th and September 29th
  - Register here: https://www.ihca.org/events/assisted-living-symposium/
- No Regulatory Roundup meeting on October 5th – AHCA Conference in Denver
  - Indiana has quite a few Quality Awards being acknowledged at the conference and had more than any other state!! Congratulations to all the recipients!!

- Next Regulatory Roundup meeting is October 12, 2023

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