December 30, 2021

LTC COVID-19 Update

Presented by:

Zach Cattell, President

Lori Davenport, Director of Regulatory & Clinical Affairs

Indiana Department of Health Team

Indiana Department of Health

IHCA INCAL

INDIANA HEALTH CARE ASSOCIATION

INDIANA CENTER FOR ASSISTED LIVING

Today's Topics

- Antiviral Treatments
- Staffing Strategies
- Quarantine and isolation duration for general public
- Current Trends
- Q&A

***The Proficient Infection Preventionist**, a webinar series in 2022, pre-purchase now and save $$, details HERE*

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COVID-19 UPDATE

SHIREESHA VUPPALANCHI, MD

MEDICAL DIRECTOR FOR LONG-TERM CARE

12/30/2021

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.

Omicron

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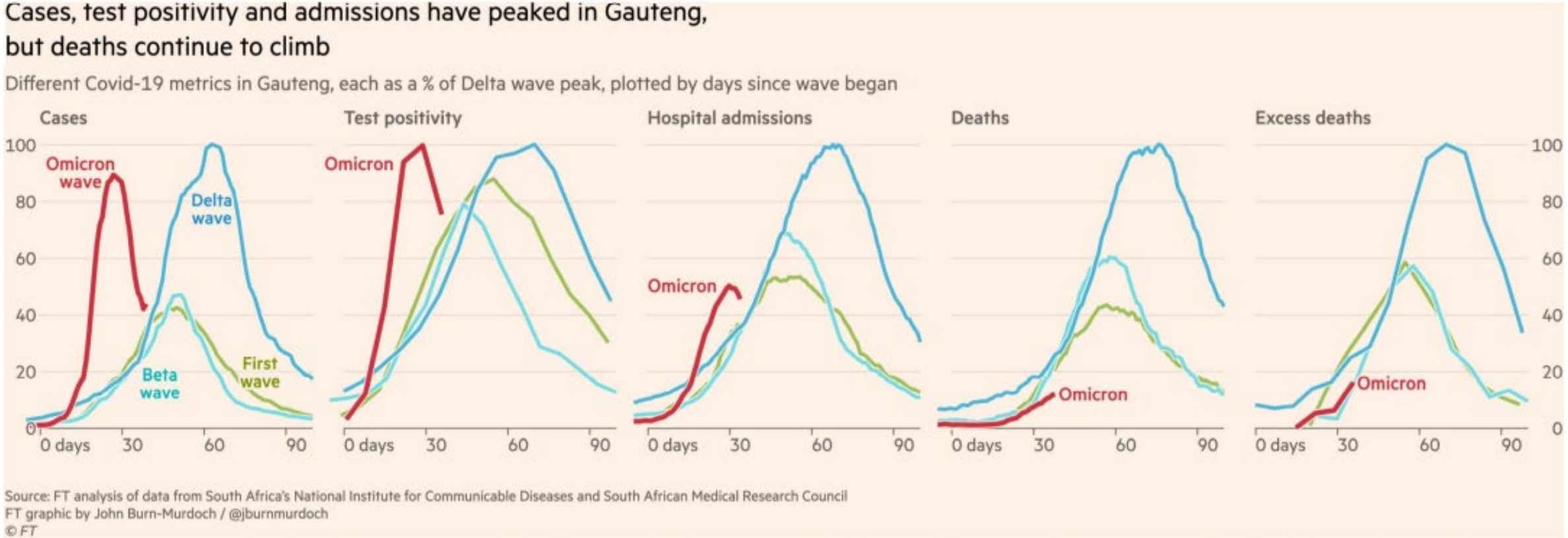
South Africa Omicron Trends



Though cases and test positivity peaked in the Gauteng region near Delta levels, hospital admissions peaked lower, and deaths are expected to peak lower as well.

South Africa has a young population and significant infection coverage from previous waves, likely influencing these trends.

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https://www.ft.com/content/0ee745ce-ac55-46a9-9766-0b419821a79d

Testing

Early data suggests that antigen tests do detect the omicron variant but may have reduced sensitivity (12/28/21)

Follow up test with PCR if antigen negative in suspected COVID-19 individual

Tests Expected to Fail to Detect the SARS-CoV-2 Omicron Variant (As of 12/27/2021)

Due to the inability of these tests to detect the SARS-CoV-2 omicron variant, the FDA recommends that these tests should not be used until this issue of these tests' inability to detect the omicron variant is resolved.

Meridian Bioscience, Inc. Revogene SARS-CoV-2

Applied DNA Science Linea COVID-19 Assay Kit

SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests | FDA

Anti-virals

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Paxlovid (nirmatrelvir-ritonavir)

- Twice daily for five days
- Start within five days of symptom onset
- Adults and Age 12 or more at least 40 KG or more
- Mild to moderate COVID, at high risk for progression
- Confirmed Covid positive

NOT FOR

- Hospitalized
- Pre-exposure or post-exposure
- Longer than five consecutive days

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https://www.fda.gov/media/155049/download

Molnupiravir

- Adults (>18)
- Twice daily for five days
- Start within five days of symptom onset
- Mild to moderate COVID, at high risk for progression
- Confirmed Covid positive
- Other alternative COVID-19 treatment options authorized are not accessible (Sotrovimab, Paxlovid, Remdesivir)

Not for

(1) For use in patients less than 18 years of age
(2) For initiation of treatment in patients requiring hospitalization due to COVID-19.
(3) Benefit of treatment with molnupiravir has not been observed in subjects when treatment was initiated after hospitalization due to COVID-19.
(4) For use for longer than 5 consecutive days.
(5) For pre-exposure or post-exposure prophylaxis for prevention of COVID-19

https://www.fda.gov/media/155053/download

Molnupiravir

Not recommended for use during pregnancy.

- Molnupiravir is only authorized to be prescribed to a pregnant individual
  - after the prescribing healthcare provider has determined that the benefits of being treated with molnupiravir would outweigh the risks
  - after the prescribing health care provider has communicated the known and potential benefits and the potential risks
- **Females** of childbearing potential are advised to use a **reliable method of birth control** correctly and consistently during treatment with molnupiravir and **for four days after the final dose**.
- **Males** of reproductive potential who are sexually active with females of childbearing potential are advised to use a reliable method of birth control correctly and consistently during treatment with molnupiravir and **for at least three months** after the final dose.
- Questions and concerns about reliable birth control methods that are appropriate for use during treatment with molnupiravir, as well as how molnupiravir may affect sperm cells, should be directed at one's healthcare provider.
- Lactation: Breastfeeding is not recommended during treatment and for 4 days after the last dose of molnupiravir. A lactating individual may consider interrupting breastfeeding and may consider pumping and discarding breast milk during treatment and for 4 days after the last dose of molnupiravir.

https://www.fda.gov/media/155053/download

Map, Method, distribution

Map is in development.

Working with Probari to help LTC in finding medications.

Very low supplies of anti-virals

Other Therapeutics

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Preventive and Therapeutic options

No illness	Exposed	Mild to moderate	Hospitalized/ ICU
Vaccines			
Monoclonal antibodies for pre-exposure prophylaxis (LAAB)= EvuSheld	~~mAb for PEP =Bamlanivimab and etesevimab~~ - ~~Casirivimab and imdevimab~~	Sotrovimab Paxlovid Molnupiravir IV Remdesivir ~~Bamlanivimab and etesevimab~~ - ~~Casirivimab and Imdevimab~~	Steroids, Remdesevir, Baricitinib, Tocilizumab Resp support

Monoclonal Antibody COVID-19 Infusion | Guidance Portal (hhs.gov)

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AstraZeneca Evusheld

- On December 8th, the U.S. Food and Drug Administration (FDA) issued an EUA for AstraZeneca's Evusheld COVID-19 monoclonal antibody product.
- Evusheld is a combination product that includes two recombinant human monoclonal antibodies (tixagevimab and cilgavimab) targeting the spike protein of SARS-CoV-2; these monoclonal antibodies are administered as two separate consecutive intramuscular (IM) injections.
- This long-acting monoclonal antibody therapy can be used for pre-exposure prophylaxis (PrEP) in
  - Persons 12 years of age or older, who weigh at least 40 kg, and who are either
    - 1) moderately to severely immunocompromised (see FDA Fact Sheet below for medical conditions or treatments that might result in moderate to severe immunosuppression), or
    - 2) not recommended to receive COVID-19 vaccination due to a history of a vaccine contraindication.
- This product is NOT for treatment of people infected with SARS-CoV-2 and NOT for post-exposure prophylaxis (PEP).

Evusheld Continued

- The PROVENT Phase 3 clinical trial found that tixagevimab/cilgavimab recipients experienced a 77% reduction in incidence of COVID-19 compared placebo and showed effect for 6 months postadministration (re-dosing can be considered every 6 months).
- Tixagevimab/cilgavimab is not a substitute for vaccination and any age-eligible person who is immunocompromised should still be vaccinated against COVID-19; tixagevimab/cilgavimab can be administered at least 2 weeks after vaccination.
- **Less effective against Omicron**

Sotrovimab

- Early in vitro data suggests sotrovimab retains activity against the Omicron variant.
  - Federal partners are actively preparing approximately 55,000 doses of sotrovimab for immediate allocation
  - Product arrived last week
- Please note that the federal government's current supply of sotrovimab is extremely limited, and additional doses of the product will not be available until the week of January 3rd.
- **Continue to use the bam/ete and REGEN-COV monoclonal antibody products while reserving sotrovimab for treatment of eligible outpatients at highest risk who are either:**
  - diagnosed with a test that may identify a potential case of the Omicron variant (e.g., by S gene Target Failure in the ThermoFisher TaqPath assay); or
  - are present in local settings where the reported prevalence of Omicron is greater than 20%.
- **Until local prevalence of Omicron is greater than 20%, jurisdictions are encouraged to direct sotrovimab to sites that can provide IV treatment (within 48 hours of collection of a patient sample) to highest risk, eligible individuals diagnosed with a test that may identify a potential case of the Omicron variant.**

Remdesivir to prevent progression to severe illness

- As effective as monoclonals
- IV-administered in three sequential doses (one per day)
- Plentiful supply but infected person must visit infusion center for three sequential visits

- Randomized, double-blind, placebo-controlled trial involving non-hospitalized patients with Covid-19 who had symptom onset within the previous 7 days and who had at least one risk factor for disease progression
- 200 mg on day 1 and 100 mg on days 2 and 3
- 279 patients in the remdesivir group and 283 in the placebo group.
- Covid-19–related hospitalization or death from any cause occurred in 2 patients (0.7%) in the remdesivir group and in 15 (5.3%) in the placebo group
- A total of 4 of 246 patients (1.6%) in the remdesivir group and 21 of 252 (8.3%) in the placebo group had a Covid-19–related medically attended visit by day 28
- No patients had died by day 28. Adverse events occurred in 42.3% of the patients in the remdesivir group and in 46.3% of those in the placebo group

Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients | NEJM

COVID-19 Treatment

Merck - Molnupiravir *Antiviral pills* *(4 capsules 2x/day for 5 days)*	*Treatment of mild to moderate COVID in **18+** at high risk of severe COVID and for whom alternative COVID treatment options are not accessible or clinically appropriate* *Works best within 5 days of symptom onset* *Reduces the risk of severe disease by 30%*	*First 4,880 courses allocated to CVS and Walmart pharmacies* *Requires prescription*
Pfizer - Paxlovid *Antiviral pills* *(3 tablets 2x/day for 5 days)*	*Treatment of mild to moderate COVID in **12+** at high risk of severe COVID* *Works best within 5 days of symptom onset* *Reduces the risk of hospitalization and death by 89%*	*First 1,060 courses allocated to hospitals* *Requires prescription*
AstraZeneca - Evusheld *Monoclonal antibody* *(2 consecutive IM injections)*	*Pre-exposure prevention (prophylaxis) of COVID in individuals **12+** if the individual has either:* *1) Compromised immune system due to medical condition or immunosuppressant meds; or* *2) History of adverse reactions to a component of vaccine meaning vaccination is not recommended* *Treatment is for individuals not currently infected and who have not been recently exposed*	*First 984 courses allocated to transplant centers and soon to cancer centers*

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https://www.coronavirus.in.gov/covid-19-treatment-information/

COVID-19 Treatment

Treatment and Form	Usage	Distribution
Gilead Veklury - Remdesivir *Antiviral drug* *(IV infusion)*	*Treatment of COVID in patients **12+*** *Studies indicate a 3-day course of Remdesivir in high-risk COVID patients early in illness cuts hospitalization rates and death by 87%*	*Providers can directly order through typical supply chains*
GlaxoSmithKline - Sotrovimab *Monoclonal antibody* *(IV infusion)*	*Treatment of mild to moderate COVID in individuals **12+** at high risk of severe COVID* *Not authorized for use in hospitalized patients or individuals requiring oxygen for COVID treatment*	*IDOH allocates to hospitals / infusion clinics* *Supply remains limited*
Eli Lilly - Bamlanivimab and Etesevimab *Monoclonal antibody* *(IV infusion)*	***Not effective against Omicron*** *Treatment of mild to moderate COVID in **all individuals** at risk of severe COVID* *Authorized for both treatment and post-exposure prevention*	*IDOH allocates to hospitals / infusion clinics* *HHS to stop shipping week of 1/3*
Regeneron - REGEN-COV *Monoclonal antibody* *(IV infusion)*	***Not effective against Omicron*** *Treatment of mild to moderate COVID in individuals **12+*** *Authorized for both treatment and post-exposure prevention*	*IDOH allocates to hospitals / infusion clinics* *HHS to stop shipping 1/3*

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https://www.coronavirus.in.gov/covid-19-treatment-information/

Staffing strategies

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New concepts

High-risk exposure is defined as a contact longer than 15 minutes cumulative in 24 hours with any individual with confirmed COVID-19 infection in **ANY** of the following situations.

- HCP did not use a respirator mask during the contact period
- **HCP used a face mask, but the COVID -19 contact individual didn't wear a cloth mask or face mask (new)**
- HCP did not use eye protection and COVID-19 contact individual didn't wear a cloth mask or face mask
- HCP did not use any of the recommended PPE (gown, gloves, eye protection, and respirator) during an aerosol-generating procedure of a COVID-19 contact individual

Symptom onset day or test positive day in asymptomatic is day 0. Count duration of isolation starting from the next day after symptom onset or the test date if asymptomatic. If symptoms start after a positive test while asymptomatic, count the next day after the onset of symptoms as day 1 of isolation. (New)

Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2 | CDC

COVID-19 Quarantine and Isolation | CDC 12-9-21

HCP with high-risk exposure

After high-risk exposure	Received Booster according to CDC guidance	Unvaccinated or not taken a booster or COVID-19 infection in the last 90 days
Conventional	No restriction from work Viral test at 2 days. If negative, repeat the test at 5-7 days after exposure	10 days isolation Or Return after 7 days if no symptoms and negative viral test
Contingency	Same as conventional, but skip testing	No work restriction but test on days 1, 2, 3, 5-7
Crisis	Same as conventional, but skip testing	No work restrictions, test as possible

Monitor for symptoms
Follow infection control principles
Mask at all times for 14 days while in the facility while in presence of any person
Test if symptoms
Isolate if symptoms or if positive test

Strategies to Mitigate Healthcare Personnel Staffing Shortages | CDC 12-23-21
Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2 | CDC 12-23-21

HCP with COVID-19-Conventional staffing

<table>
<tr><th colspan="3">Not moderately to severely immunocompromised HCW with COVID-19</th></tr>
<tr><th>Asymptomatic</th><th>Mild to moderate illness</th><th>Severe to Critical illness</th></tr>
<tr><td rowspan="2">Return to work after 10 days (or
7 days if negative viral test within 48 hours of work)</td><td rowspan="2">Return to work after 10 days (or 7 days with negative viral test within 48 hours of work),
AND
Fever free for 24 hours without fever-reducing medication
AND
Symptoms have improved</td><td>20 days after the start of symptoms
AND
Fever free for 24 hours without fever-reducing medication
AND
Symptoms have improved

AND</td></tr>
<tr><td>May consider Test-based strategy as used in moderate to severely immunocompromised (see below)</td></tr>
</table>

Conventional-Immunocompromised HCP with COVID-19

Moderate to severely immunocompromised HCP with COVID-19 (Consider a consultation with an infectious disease specialist)	
Asymptomatic	**Symptomatic**
Return to work after 10-20 days of isolation **AND** Two negative virals tests collected at least 24 hours apart	Return to work after 10-20 days of isolation **AND** Fever free for 24 hours without fever-reducing medication **AND** Improving symptoms **AND** Two negative virals tests collected at least 24 hours apart

HCP with COVID- Contingency and Crisis

Positive COVID infection	ALL HCP regardless of vaccination status, booster status or previous infection
Conventional	Depends on the severity of illness and immune status of the HCP (see the above tables)
Contingency	Return to work after 5 days with or without negative viral test, if asymptomatic or mild symptoms that are improving and fever free for 24 hours without fever-reducing medication *Follow infection control principles* *Mask at all times for 14 days while in the facility while in presence of any person*
Crisis	No work restrictions, with prioritization consideration (asymptomatic or mildly symptomatic)- Try to staff in the following sequential priority: **nonresident care, red zone, yellow zone, as a last resort in green zone** *Follow infection control principles* *Mask at all times for 14 days while in the facility while in presence of any person*

Boosters

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Almost there!

If completed offering boosters and not attested already, please do so ASAP!

Make sure you have ongoing plans to administer boosters for new residents and those that become eligible each month.

Encourage previously eligible residents that declined boosters, to take the booster at the next opportunity

Guidance for general public

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General Public guidance

Revised CDC quarantine and isolation guidance for the general public is not for the family of healthcare personnel. **This does not apply to HCP (as return to work criteria) or LTC residents**.

Current Trends

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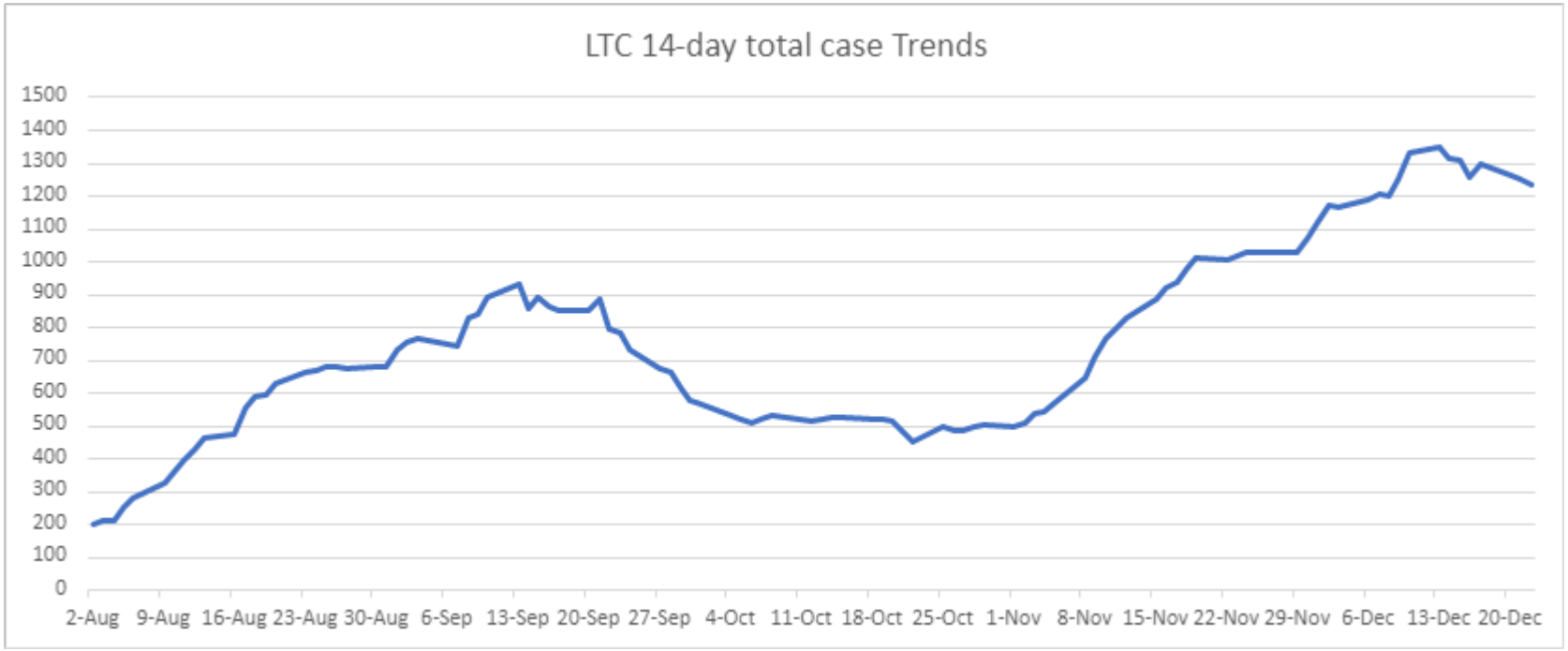
LTC 14 day total cases



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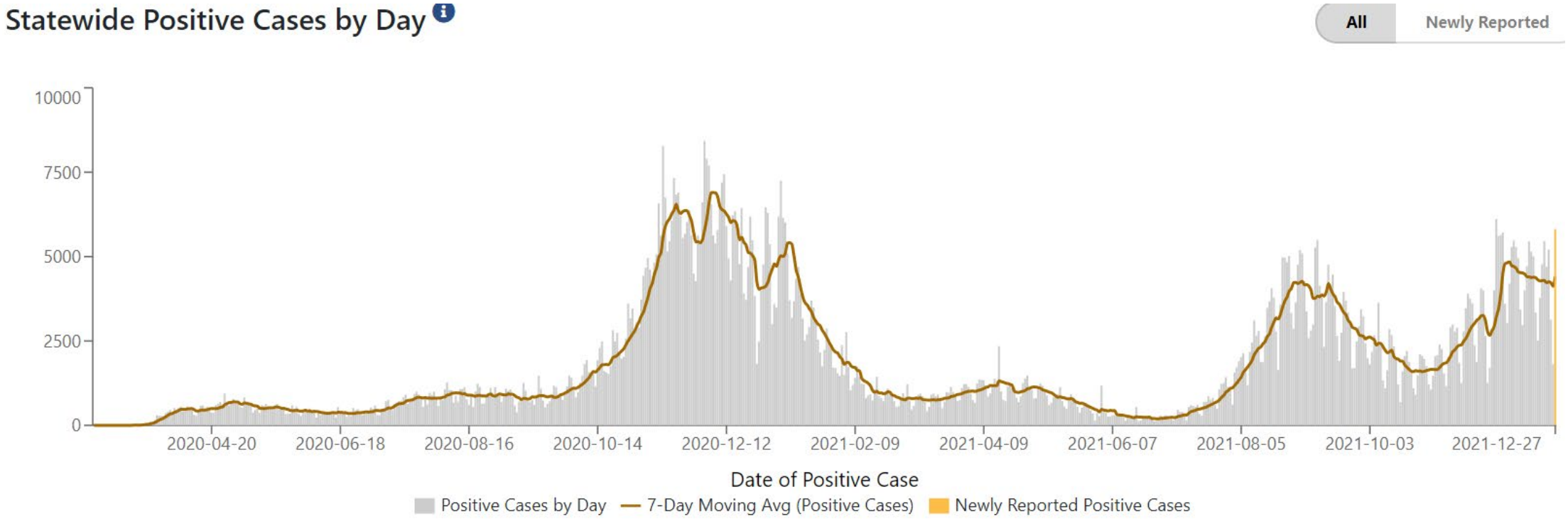
Statewide cases



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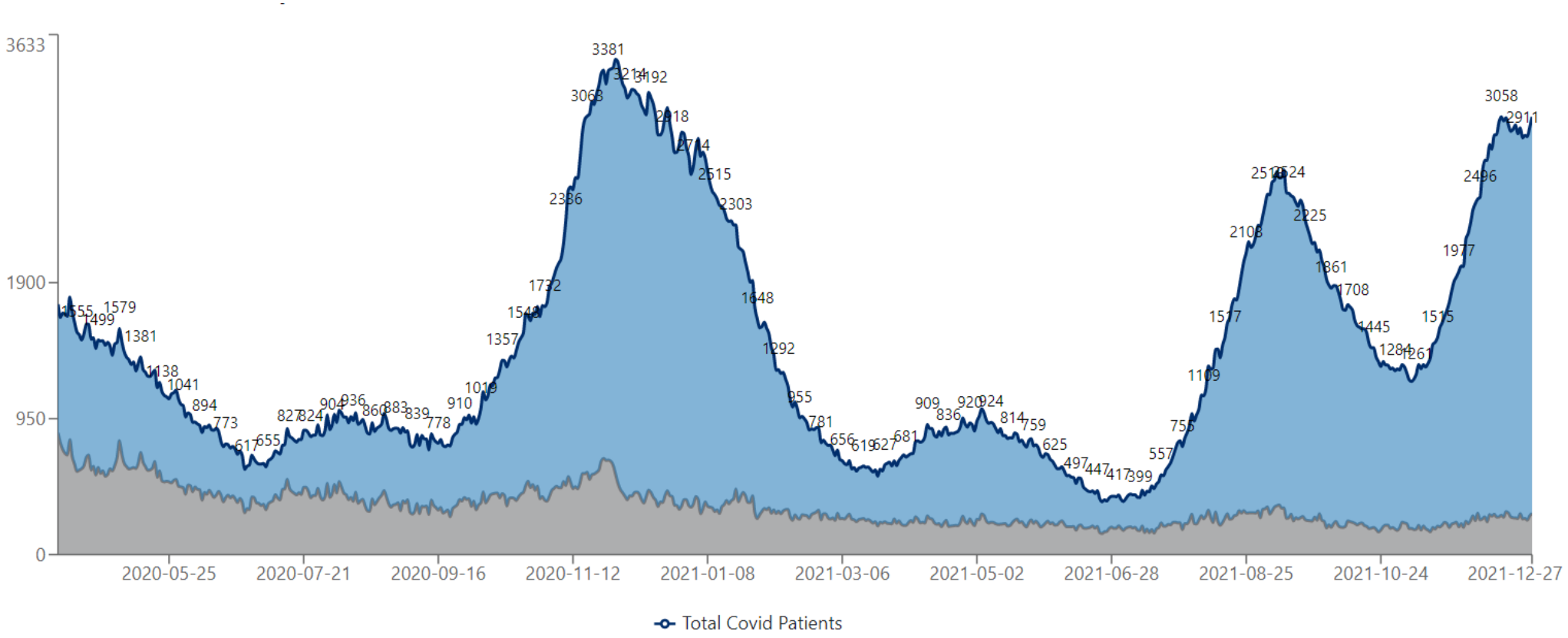
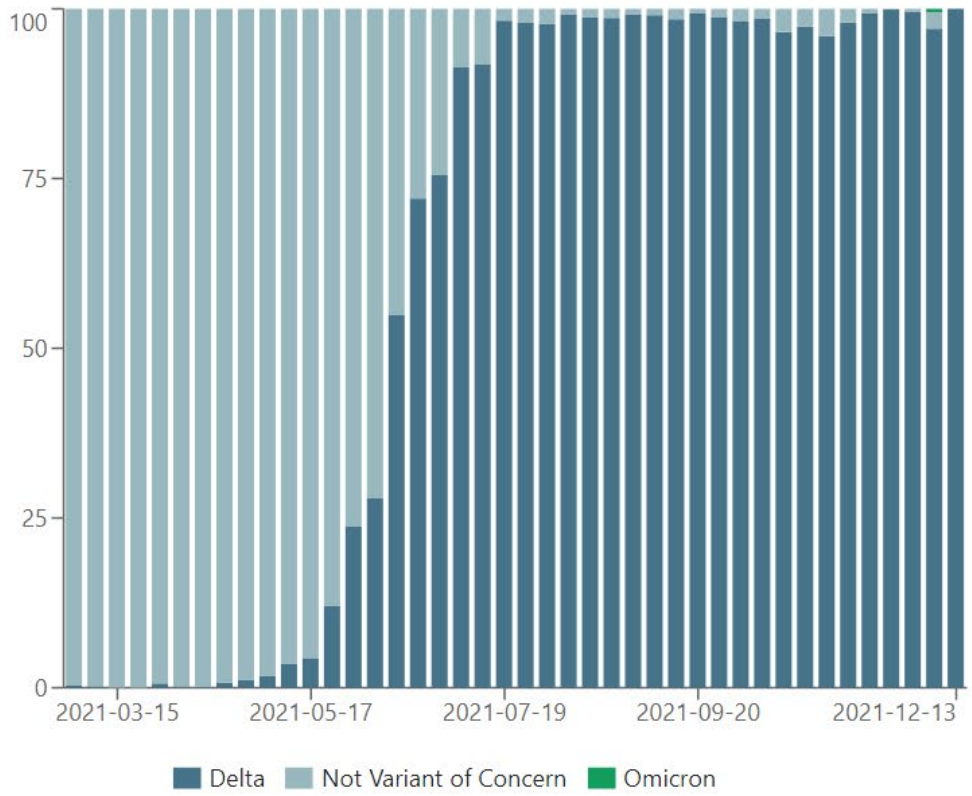
Hospitalizations



Variants



Variant	% of Samples (in current month)	Change in % of Samples (from previous month)
Delta / B.1.617.2	99.4%	1.7%
Not Variant of Concern	0.5%	-1.8%
Omicron / B.1.1.529	0.1%	0.1%

Contact Information

Lori Davenport – IHCA/INCAL Clinical/Regulatory
- ldavenport@ihca.org
- 765-516-0148

Amy Kent – Assistant Commissioner, IDH
- amkent1@isdh.in.gov
- 317-233-7289

Jennifer Spivey – Infection Control, IDH
- JSpivey1@isdh.IN.gov
- 317-232-0639
- 317-471-7844 cell

Paul Krievins
- pkrievins@isdh.in.gov

Kelly White – Reporting, IDH
- kewhite@isdh.in.gov

David McCormick
- DMcCormick@isdh.IN.gov

Tammy Alley – Vaccine Questions, IDH
- talley@isdh.in.gov
- 317-223-7441

Randy Synder – Vaccine Questions, IDH
- rsnyder1@isdh.in.gov

Russell Evans
- russ@probarisystems.com

Zach Cattell – IHCA/INCAL President
- zcattell@ihca.org

Dr. Shireesha Vuppalanchi – Clinical, IDH
- svuppalanchi@isdh.in.gov

Brenda Buroker – Survey, IDH
- bburoker@isdh.in.gov
- 317-234-7340

Dr. Lindsey Weaver
- lweaver@isdh.in.gov

Jan Kulik
- jkulik@isdh.in.gov
- 317-233-7480

Peter Krombach
- pkrombach2@isdh.in.gov

Michelle Donner
- midonner@isdh.in.gov

Pam Pontones – CDC Guidance, IDH
- ppontones@isdh.IN.gov
- 317-233-8400

Kara Dawson – NHSN
- kdawson@qsource.org
- 317-628-1145 OR contact:
- Angeleta Hendrickson - ahendrickson@qsource.org
- Teresa Hostettler - thostettler@qsource.org

- Deeksha Kapoor – IHCA/INCAL Communications/PR
  - dkapoor@ihca.org

THANK YOU!