

RetroDUR

Newsletter

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Wishing everyone a safe and healthy holiday season!

Distinguishing COVID-19 from Influenza and the Common Cold

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Introduction

- COVID-19 cases are on the rise and peak cold and influenza season is rapidly approaching (typically between December and February).
- COVID-19, influenza and the common cold are all contagious respiratory illnesses but are caused by different viruses.
- There is a significant overlap between symptoms of COVID-19, influenza, and the common cold (see chart p. 2). Cold symptoms tend to be milder than those caused by COVID-19 and/or influenza.

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The best way to prevent influenza is with a vaccine; however, there are currently no available vaccines for COVID-19 or the common cold.



Symptom Checker

Symptom	COVID-19	Influenza	Cold
Loss of smell/taste	Common	Rare	Rare
Fever	Common	Common	Rare
Cough	Common*	Common*	Mild
Shortness of breath	Sometimes	No	No
Muscle pain	Sometimes	Common	Common
Sore throat	Sometimes	Sometimes	Common
Runny or stuffy nose	Rare	Sometimes	Common
Headache	Sometimes	Common	Rare
Fatigue	Sometimes	Common	Sometimes
Sneezing	No	No	Common
Nausea/vomiting	Sometimes	Sometimes	No
Diarrhea	Rare	Sometimes ^y	No

*Usually dry cough, ^yfor children

Sources: Centers for Disease Control and Prevention, World Health Organization

Prevent Infection/Slow Transmission

- The following techniques may help to prevent infection and to slow the transmission of respiratory illnesses like COVID-19, influenza, and the common cold:
 - Wash hands regularly with soap and water or clean them with alcohol-based hand rub.
 - Cover your mouth and nose when coughing or sneezing.
 - Stay home if unwell.
 - Avoid touching your face.

The following specifically apply to COVID-19:

- Cover your mouth and nose with a mask when in public settings or around others.

- Maintain at least six feet distance between you and people coughing or sneezing.
- Practice physical distancing by avoiding unnecessary travel and staying away from large groups of people.

The following specifically applies to influenza:

- Obtain yearly influenza vaccine

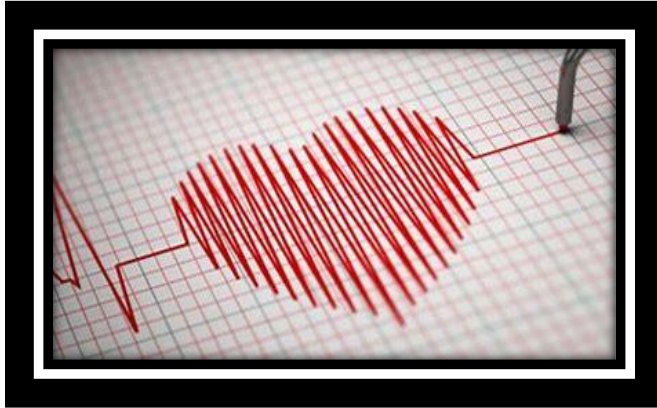
Summary

- There are several symptoms that vary between COVID-19, influenza, and the common cold but one major difference is that people who experience COVID-19 often report a change or loss of smell and taste.
- Regardless of the illness -- COVID-19, influenza, or the common cold -- washing hands frequently and covering the mouth and nose when coughing or sneezing can prevent infection and/or slow transmission.

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Beneficial Effects of SGLT2 Inhibitors in Heart Failure with or without Type 2 Diabetes Mellitus

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The reductions in hospitalizations and mortality benefit of SGLT2 inhibitors in patients with Heart Failure with reduced Ejection Fraction (HFrEF) who also have Type 2 Diabetes Mellitus (T2DM) is likely to be a class effect.¹ Both the American Diabetes Association's *2020 Standards of Care* and the American College of Cardiology's *2020 Expert Consensus Decision Pathway on Novel Therapies for Cardiovascular Risk Reduction in Patients With Type 2 Diabetes: A Report of the American College of Cardiology Solution Set Oversight Committee* recommend the use of SGLT2 Inhibitors in patients who have both T2DM and HFrEF.^{2,3} The American College of Cardiology is recommending SGLT2 Inhibitors as first-line in patients with HFrEF and T2DM whereas the American Diabetic Association is recommending SGLT2 inhibitors after metformin.

Additionally, In May 2020 the FDA approved the SGLT2 Inhibitor dapagliflozin (Farxiga), for patients who have HFrEF, with or without T2DM.⁴ This approval for HFrEF represents the addition of another class of medications in the heart failure arsenal. However, there has been no specific recommendation when to add it to existing therapy leaving it to clinical judgment.

The mechanism of action of SGLT2 inhibitors is via inhibition of reabsorption of glucose from the nephron.^{4,5,6} Most adverse effects of SGLT2 Inhibitors are directly related to the increased glucose in the urine and include an increase in genital mycotic infections and urinary tract infections. Rare cases of necrotizing fasciitis of the perineum (Fournier's gangrene) have been reported. Hypoglycemia is a concern especially if added to patients receiving insulin or insulin-releasing agents like the sulfonylureas. There have been reports of patients developing diabetic ketoacidosis even in the absence of hyperglycemia (euglycemic diabetic ketoacidosis). In patients with very poor renal function the prescribing information indicate they should not be used.^{4,5,6} Since SGLT2 inhibitors work via the kidneys, they are less effective in lowering hemoglobin A1c in patients with very poor renal function. There are concerns regarding canagliflozin and amputations; however, the FDA removed the *Black Box Warning* about amputation risk due to lower risk than previously assumed but notes the risk of amputations is still increased canagliflozin and the warning is now described in the *Warnings and Precautions* section of the prescribing information.⁷

The following medications are SGLT2 Inhibitors on the 2020 WV Medicaid Preferred Drug List:

- Dapagliflozin (Farxiga)
- Empagliflozin (Jardiance)
- Canagliflozin (Invokana)

What about Type 1 Diabetes Mellitus? FDA expert panels have reviewed SGLT2 inhibitors for possible use in Type 1 Diabetes Mellitus and found the data lacking. The FDA this year has rejected both dapagliflozin and sotagliflozin for an indication in Type 1 Diabetes Mellitus. This was not a unanimous decision and with the same data the European Commission approved both for Type 1 Diabetes Mellitus.⁸

On the horizon – An agent which inhibit SGLT1 in addition to inhibiting SGLT2. SGLT1 is of primary importance in the small intestines though SGLT1 transportation also occurs in the proximal tubules of the nephron as well. Inhibition of SGLT1 in the gut would be expected to benefit diabetic patients regardless of renal function.⁹ Recently, first-in-class sotagliflozin (Zynquista), which is still investigational, completed two phase 3 trials, SOLOIST-WHF and SCORED, and demonstrated at least similar efficacy as SGLT2 Inhibitors. Importantly, sotagliflozin reduced hemoglobin A1c by 0.6% in patients with poor renal function who had an eGFR between 25-29 mL/minute per 1.73m².¹⁰

Concluding, if appropriate for your patient who has been identified as having both HFrEF and Type2DM, consider SGLT2 Inhibitor therapy and monitor for adverse effects.

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What is the Consensus on Adverse Drug Events Associated with Long-Term Use of Proton-Pump Inhibitors?

By: Craig Kimble, PharmD, MBA, MS, BCACP

Proton-pump inhibitors (PPIs) are sold over the counter (OTC) with the indication for self-treatment of frequent heartburn for up to 14 days and are one of the best-selling OTC drug classes in the US¹. PPIs are also commonly prescribed for a variety of gastrointestinal complaints in both inpatient and outpatient settings. Overall, these products are affordable and extremely effective in providing relief in many different clinical situations. In this article, we will look at possible risk with long-term use and when it might be appropriate to consider de-prescribing these agents.

In the US, there are currently six FDA-approved PPIs available on the market with a variety of indications and dosing. Available agents include omeprazole (Prilosec®)², esomeprazole (Nexium®)³, pantoprazole (Protonix®)⁴, lansoprazole (Prevacid®)⁵, dexlansoprazole (Dexilant®)⁶, and rabeprazole (Aciphex®)⁷. FDA approved indications vary by product but include duodenal ulcer treatment and maintenance, H pylori eradication

(as part of triple therapy), erosive esophagitis treatment and maintenance, GERD, gastric ulcer, NSAID-associated gastric ulcer, heartburn, and other pathological hypersecretory conditions.²⁻⁷

As a result of the many FDA approved indications, overall low price, formulary acceptance, efficacy, and years of experience with these products, in general clinicians feel that PPIs are tolerable and safe. As a result of this prescriber and patient comfort level, they are one of the most prescribed classes of medication in the country.⁸ However, with this prescribing comfort level, there are some potential risks and associated FDA warnings with these drugs that should be considered especially when looking at long-term use.

Adverse Events Associated with Long-Term PPI use:

PPIs in general have proven to be effective treatment options with limited adverse drug events. The concern with PPIs centers mainly with adverse events that occur with long-term use of these agents (See table 1). Long-term use of these products has been associated with a number of potential adverse drug events including hypomagnesemia⁹⁻¹¹, vitamin B12 deficiency^{12,13}, increased clostridium infections¹⁴⁻¹⁶, increased risk for community acquired pneumonia¹⁷⁻¹⁸, increased risk of bone fractures¹⁹⁻²¹, drug-drug interactions^{22,23}, dementia^{24,25}, and increased cardiovascular risk^{26,27}. The level of evidence varies by ADE type but some have generated FDA warnings.



Table 1: Adverse Events Associated with Long-Term PPI Use

Adverse Event	Mechanism	Comments
Hypomagnesemia ⁹⁻¹¹	↑ gastric pH alters Mg transport and absorption	FDA warning long-term PPI use may lower serum Mg levels. ¹¹ Supplementation alone may not correct. If severe: muscle weakness, tetany, seizures, cardiac arrhythmias, and hypotension.
Vitamin B ₁₂ deficiency ^{12,13}	↑ gastric pH alters absorption, potential for microbial overgrowth that utilizes cobalamin.	Elderly may be prone to see this with prolonged use Serious medical implications if left undiagnosed
Clostridium difficile infection ¹⁴⁻¹⁶	Alteration in gut microbiome leading to subsequent increase in bacterial colonization	FDA public safety alert associated with PPI use. ¹⁶
Community-acquired pneumonia (CAP) ^{17,18}	Alteration in gut microbiome leading to subsequent increase in bacterial colonization	Risk of CAP may be 1.5-fold higher in patients on PPI.
Bone fracture ¹⁹⁻²¹	Reduction in calcium absorption due to increased gastric pH.	FDA issued alert regarding potential increased risk of fractures associated with PPI use of > 1 year. ²¹ Osteoporosis associated with morbidity, mortality, and high cost of care. Increased risk of hip fracture, spine fracture or fracture at any site in as short as 1 year.
Myocardial infarction ²⁶⁻²⁷	Unknown, believed to be related to the impairment of endothelial nitric oxide synthase	Not definitive. Further studies needed
Clopidogrel interaction and increased cardiovascular risk ²²⁻²³	Severe drug interaction	FDA issued statement warning against the combination of clopidogrel and PPI due to severe drug interaction, diminished antiplatelet effect ²³
Dementia ²⁴⁻²⁵	↑ Production and degradation of amyloid and binding to tau. Decreased availability of other nutrients.	Not definitive Further studies needed

Long-Term Use of PPIs - Conflicting Information

In a large, multi-year, randomized trial studying the safety of the proton pump inhibitor pantoprazole versus placebo, researchers found no evidence to support claims that PPIs cause serious health issues such as pneumonia, chronic kidney disease, diabetes and dementia. They did note an increase in enteric infections. The trial lasted approximately 3 years and was limited to one PPI (pantoprazole). It should be noted that we do not know if ADEs are a class effect and only one PPI was studied.²⁸

De-prescribing or De-escalating PPIs:

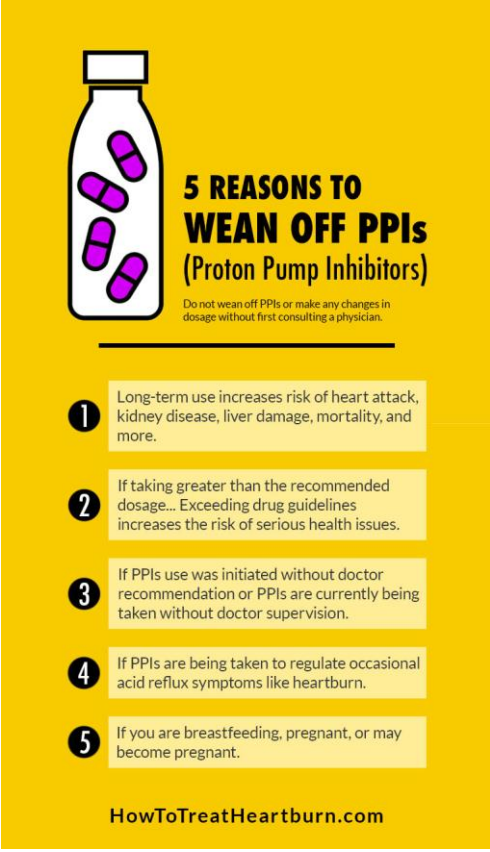
Even with conflicting data, with the FDA identifying the risks of long-term use, many clinicians have considered de-prescribing in some cases. De-prescribing is a concept that has been used to get patients off drugs when no longer required or when concern about long-term use arises. It really is a practice we should look at for many drugs not just PPIs. Some guidelines for reducing the use of PPIs was published in Canada in the Canadian Family Physician in 2017. Strategies included reducing the dose, stopping, or using “on-demand” dosing when appropriate.²⁹⁻³¹

De-prescribing or de-escalating PPIs was considered in adults who suffered from heartburn after completing a minimum of 4 weeks of treatment in which symptoms are relieved. De-escalation did not apply to patients with Barrett’s esophagus, severe esophagitis, or patients with a history of bleeding ulcers. For patients meeting the de-escalation guidelines, OTC antacids or H2 receptor antagonists (H2RA) may be used on a PRN basis in addition to nonpharmacologic approaches (avoiding meals 2-3 hours before bedtime, avoiding

dietary triggers, and addressing weight loss).³⁰

Detailed instructions for those who would like more information on de-prescribing and alternative options can be found in the Farrell et al. paper at: <https://pubmed.ncbi.nlm.nih.gov/28500192/>.

Because of PPIs popularity, low cost, OTC status, and general feeling of safety, when attempting a de-escalation or de-prescribing strategy, prescribers should involve patients in the decision to ensure success. Patients who are educated on the risks associated with long-term therapy and possible side effects associated with PPIs are more likely to understand the reasoning for de-prescribing and may experience better long-term outcomes and be more open to the process.



5 REASONS TO WEAN OFF PPIs (Proton Pump Inhibitors)

Do not wean off PPIs or make any changes in dosage without first consulting a physician.

- 1 Long-term use increases risk of heart attack, kidney disease, liver damage, mortality, and more.
- 2 If taking greater than the recommended dosage... Exceeding drug guidelines increases the risk of serious health issues.
- 3 If PPIs use was initiated without doctor recommendation or PPIs are currently being taken without doctor supervision.
- 4 If PPIs are being taken to regulate occasional acid reflux symptoms like heartburn.
- 5 If you are breastfeeding, pregnant, or may become pregnant.

HowToTreatHeartburn.com

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Antiviral Medications Recommended by the CDC this Flu Season

By: Sarah Plummer, Pharm.D

Many people with uncomplicated influenza use over-the-counter medicines, get rest, and take plenty of fluids to lessen their symptoms. Usually, uncomplicated influenza gets better with or without antiviral treatment but may cause substantial discomfort and limit activities while it lasts. Antiviral drugs available by prescription can reduce the time it takes for symptoms to improve, and some are also used in selected situations to reduce the chance of illness in people exposed to influenza virus. Currently, there are four FDA-approved antiviral medications recommended by the CDC to treat influenza.

- oseltamivir phosphate (available as a generic version or under the trade name Tamiflu®),
- zanamivir (trade name Relenza®)
- peramivir (trade name Rapivab®), and
- baloxavir marboxil (trade name Xofluza®)

Antiviral medications work best when started soon after flu illness begins. When treatment is started within two days of becoming sick with flu symptoms, antiviral drugs can lessen fever and flu symptoms and shorten the time you are sick by about one day. They may also lessen the risk of complications. This is especially important for people at high risk, as early treatment with an antiviral could mean having milder illness instead of a more severe illness that might require a hospital stay.

“Antiviral drugs are not a substitute for annual influenza vaccinations.”

Although there are prescription medications available to help treat the flu, the CDC recommends everyone over 6 months of age receive the influenza vaccine each year, as antiviral medications are not a substitute for getting a flu vaccine. Table 1 summarizes the key differences in the four FDA-approved antivirals, however complete prescribing information can be found below under the corresponding package insert link.



Table 1: FDA-Approved Antiviral Medications for Influenza

	Oseltamivir phosphate (Tamiflu®)	Zanamivir (Relenza®)	Peramivir (Rapivab®)	Baloxavir marboxil (Xofluza®)
FDA Approved	1999 (generic approved 2016)	1999	2014	2018
Age Approved	Treatment: 2 weeks and older Prevention: 3 months and older	Treatment: 7 years and older Prevention: 5 years and older	Treatment: 2 years and older	Treatment: 12 years and older Prevention: 12 years and older
Administration	Oral capsule Oral Suspension	Inhalation Disk	IV infusion	Oral tablet
Approved for Treatment of Influenza A & B	√	√	√	√
Approved for Prevention	√	√		√
Approved for Pregnant women	√	√		

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