

"Giving Voice to Those Seldom Heard"

December 17, 2021

Dear Colleague:

Extending best wishes to you and the clients with whom you work. The past nearly two years during the COVID-19 pandemic have been challenging and likely will remain so. This office recommends the following sources of up-to-date information about COVID-19:

[The Minnesota Department of Health's Coronavirus Disease 2019 \(COVID-19\) Homepage](https://www.health.state.mn.us/diseases/coronavirus/index.html)

(<https://www.health.state.mn.us/diseases/coronavirus/index.html>)

[MDH - Community Settings: COVID-19](https://www.health.state.mn.us/diseases/coronavirus/communities.html)

(<https://www.health.state.mn.us/diseases/coronavirus/communities.html>)

[Minnesota's COVID-19 Response - Stay Safe MN](https://mn.gov/covid19/) (<https://mn.gov/covid19/>)

[CDC – Centers for Disease Control and Prevention - Coronavirus \(COVID-19\)](https://www.cdc.gov/coronavirus/2019-ncov/index.html)

(<https://www.cdc.gov/coronavirus/2019-ncov/index.html>)

The Medical Review Subcommittee (MRS) continues to review reports of individual deaths and accumulated data on all deaths and serious injuries reported to the Office of Ombudsman for Mental Health and Developmental Disabilities (OMHDD). Periodically, the MRS develops Medical Alerts based upon those reviews.

Announcing the [Winter Alerts for 2022](https://mn.gov/omhdd/documents/medical-alerts.jsp) (<https://mn.gov/omhdd/documents/medical-alerts.jsp>)

Winter Alert

Frostbite Alert

Hypothermia Alert

NWS Wind Chill Chart

For continued updates from (OMHDD), you can [Subscribe to the OMHDD Medical Alerts E-Mail List Service](#). When you subscribe to this service, you will be notified by e-mail when new Medical Alerts are posted to OMHDD website.

New Method for Reporting Deaths and Serious Injuries

In early 2020, OMHDD made webform reporting available for the routine reporting of deaths and serious injuries. Webform reporting is the preferred method of reporting deaths and serious injuries, but the paper forms remain available on the OMHDD website for use when preferred by reporters.

[Death Review webform](https://omhddcms.i-sight.com/portal/death-review) (<https://omhddcms.i-sight.com/portal/death-review>)

[Serious Injury webform](https://omhddcms.i-sight.com/portal/serious-injury) (<https://omhddcms.i-sight.com/portal/serious-injury>)

[Reporting Death or Serious Injury – Download Forms / Minnesota.gov \(mn.gov\)](https://mn.gov/omhdd/reporting-death-or-serious-injury/download-forms.jsp)

(<https://mn.gov/omhdd/reporting-death-or-serious-injury/download-forms.jsp>)

While webform reporting has been going well so far, the office has received Serious Injury reports on the Death Report webform and Death Reports on the Serious Injury webform. If you report a death on the Serious Injury webform, the data you reported must be manually transferred to a death report form, and the number assigned to the report you have made will no longer apply.

In addition, while the office recognizes that you may not have all the information requested on the forms, please provide the information to which you do have access; for examples, the client's first and last names, the client's date of birth, the date of death (when applicable/known), the contact information for the reporter including the reporter title (case manager, social worker, program director, mental health practitioner, etc.), and the Reporter's Facility/Agency Name.

Please Note: Both the Death Report and Serious Injury Report forms will timeout after 15 minutes of inactivity. Although the form can be printed after submission, it cannot be "saved" for later completion.

New – Both online Death Reports and online Serious Injury Reports now permit the secure upload of up to ten attachments.

Reports of deaths and serious injuries can still be faxed to the OMHDD at the following number:

Fax: 651-797-1950 Please note the fax number. (The old back-up fax number is no longer available.)

Thank you for continuing to report Serious Injuries and Deaths to the OMHDD and for your continuing cooperation with the review process. Please call Voice: 651-757-1800 or Toll Free: 1-800-657-3506 with any questions.

MedWatch Safety Alerts are now called Drug Safety Communications by the FDA

Since the 2021 Summer Alert, the FDA has released **Drug Safety Communications** for many medications, some of which are prescribed for and used by clients of the OMHDD. Some of the most recent Drug Safety Communications follow:

[11-2-2021 FDA Drug Safety Communication - FDA warns that getting alcohol-based hand sanitizer in the eyes can cause serious injury. Immediately and thoroughly rinse eyes with gently running water if this occurs](https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-getting-alcohol-based-hand-sanitizer-eyes-can-cause-serious-injury) (<https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-getting-alcohol-based-hand-sanitizer-eyes-can-cause-serious-injury>)

What safety concern is FDA announcing? The U.S. Food and Drug Administration (FDA) is warning that getting alcohol-based hand sanitizer in the eyes from splashing or touching the eyes after use of hand sanitizer can result in serious injury, including severe irritation and damage to the surface of the eye. Eye exposure to hand sanitizer has been reported in all age groups; however, it has occurred most often in children. Such eye injuries have become much more

frequent, likely due to the marked increase in the use of alcohol-based hand sanitizer during the COVID-19 pandemic...

What should consumers and caregivers do? Do not use alcohol-based hand sanitizers in or near your eyes. After applying alcohol-based hand sanitizer to your hands, avoid touching your eyes because the alcohol in the hand sanitizer can cause severe irritation and damage to the surface of the eye. Adults should always supervise young children, particularly those younger than 6 years old, using alcohol-based hand sanitizers, especially around dispensers containing these hand sanitizers, which often are at children's eye level and can splash. Store alcohol-based hand sanitizers and all other OTC and prescription medicines up and away and out of children's reach and sight. If alcohol-based hand sanitizer does accidentally splash or get in your eyes, or those of a child, immediately and thoroughly rinse them under gently running water such as from a sink tap, water bottle, or emergency shower for at least 15 to 20 minutes. Do not delay rinsing your eyes, as immediate rinsing is the most important thing you can do to reduce the risk of serious eye injury. If symptoms such as redness, pain, irritation, visual impairment, blurred vision, or light sensitivity persist after rinsing, seek an urgent eye examination...

[09-01-2021 FDA Drug Safety Communication - FDA requires warnings about increased risk of serious heart-related events, cancer, blood clots, and death for JAK inhibitors that treat certain chronic inflammatory conditions. Approved uses also being limited to certain patients](https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-warnings-about-increased-risk-serious-heart-related-events-cancer-blood-clots-and-death)
(<https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-warnings-about-increased-risk-serious-heart-related-events-cancer-blood-clots-and-death>)

What safety concern is FDA announcing? Based on a completed U.S. Food and Drug Administration (FDA) review of a large randomized safety clinical trial, we [FDA] have concluded there is an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death with the arthritis and ulcerative colitis medicines Xeljanz and Xeljanz XR (tofacitinib). This trial compared Xeljanz with another type of medicine used to treat arthritis called tumor necrosis factor (TNF) blockers in patients with rheumatoid arthritis. The trial's final results also showed an increased risk of blood clots and death with the lower dose of Xeljanz. A prior DSC based upon earlier results from this trial, reported an increased risk of blood clots and death only seen at the higher dose. We [FDA] are requiring new and updated warnings for two other arthritis medicines in the same drug class as Xeljanz, called Janus kinase (JAK) inhibitors, Olumiant (baricitinib) and Rinvoq (upadacitinib). Olumiant and Rinvoq have not been studied in trials similar to the large safety clinical trial with Xeljanz, so the risks have not been adequately evaluated. However, since they share mechanisms of action with Xeljanz, FDA considers that these medicines may have similar risks as seen in the Xeljanz safety trial...

[06-16-2021 FDA Drug Safety Communication - FDA warns that vapors from alcohol-based hand sanitizers can have side effects. Apply hand sanitizer in a well-ventilated area](https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-vapors-alcohol-based-hand-sanitizers-can-have-side-effects)
(<https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-vapors-alcohol-based-hand-sanitizers-can-have-side-effects>)

What safety concern is FDA announcing? The U.S. Food and Drug Administration (FDA) is warning that symptoms such as headache, nausea, and dizziness can occur after applying alcohol-based hand sanitizers to the skin. These symptoms are likely to have occurred because of vapors from the hand sanitizer, potentially from exposure in enclosed spaces or places with poor air circulation. We [FDA] have received increasing reports of these side effects since the start of the COVID-19 pandemic. Most people experienced minor or minimal effects; however, some cases required treatment by a health care professional...

What are hand sanitizers and how can they help me? Hand sanitizers are over-the-counter (OTC) drug products that can help consumers reduce bacteria on their hands. However, the best way to prevent the spread of infections and decrease the risk of getting sick is by washing your hands with plain soap and water, advises the Centers for Disease Control and Prevention (CDC). Washing hands often with soap and water for at least 20 seconds is essential, especially after going to the restroom; before eating; and after coughing, sneezing, or blowing one's nose. If soap and water are not available, the CDC recommends consumers use an alcohol-based hand sanitizer that contains at least 60 percent alcohol. Hand sanitizers are left on the skin to dry. What should consumers do? Consumers should use hand sanitizers in a well-ventilated area. If you are using hand sanitizer in an enclosed area such as a car, open a window to improve ventilation until the hand sanitizer is dry and the vapors have cleared. Make sure your hands are completely dry and vapors have cleared before doing any activities involving heat, sparks, static electricity, or open flames. Read and follow the directions and warnings on the OTC Drug Facts label...

Additional FDA Drug Safety Communications are available at [FDA Drug Safety Communications](https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications) (<https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications>).

Medication Administration

When administering prescription and over-the-counter medications to your clients, please be aware of the potential side effects of the medications. Document any changes in the client's condition that the medications are intended to treat, as well as any side effects observed and/or reported by your clients, so the health care provider/prescriber can be informed.

This office continues to receive reports of the deaths of clients that appear to be related to the use of both over-the-counter acetaminophen and over-the-counter ibuprofen to relieve unexplained pain and/or to reduce unexplained fever. Please review the following Medical Alert originally released in December 2011 and reviewed in January 2013 -

Medical Alert: Use of over-the-counter medications and possible delay of treatment,

available at https://mn.gov/omhdd/assets/OTC-and-Delay-of-Tx-2013_tcm23-27625.pdf

During the COVID-19 pandemic, this office also has seen multiple cases where a client is found to have a positive test for COVID-19 but remains at the residence in "quarantine." Unfortunately, COVID-19 in some clients can rapidly cause serious problems with breathing/respiration leading to the death of the

client before medical aid can be sought. Please be certain that when clients remain home after a positive COVID-19 test, their attending residential staff are aware of how to care for the client, know whom to call for assistance (the facility's nurse, if there is one, OR the client's primary physician/clinic), and when to call 911.

Thank you for your interest in the Medical Alerts.

Please call me at 651-431-5202 or 1-800-657-3506 with any questions or concerns.

Sincerely,

Jo Zillhardt, RN-BC, PHN
Medical Review Coordinator