MINNESOTA
OFFICE OF OMBUDSMAN
FOR MENTAL HEALTH AND
DEVELOPMENTAL DISABILITIES

"Giving Voice to Those Seldom Heard"

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June 2022

Dear Colleague:

Extending best wishes to you and the clients with whom you work. This office continues to recommend the following source of up-to-date information about COVID-19:

> **Minnesota Department of Health Coronavirus Disease 2019 (COVID-19) Homepage**
> (https://www.health.state.mn.us/diseases/coronavirus/index.html)

The Medical Review Subcommittee (MRS) continues to review reports of individual deaths and reviews 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 Summer Alerts for 2022 (https://mn.gov/omhdd/documents/medical-alerts.jsp):

Summer Alert **Heat Stroke Alert** **Insect Sting Alert** **Water Safety Alert**

For continued updates from the (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 the OMHDD website.

Please Use the Webforms for Reporting Deaths and Serious Injuries

In 2020 the 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)
>
> **Serious Injury webform** (https://omhddcms.i-sight.com/portal/serious-injury)
>
> **Reporting Death or Serious Injury – Downloadable Forms** (https://mn.gov/omhdd/reporting-death-or-serious-injury/download-forms.jsp)

The OMHDD appreciates the use of the death report and the serious injury webforms.

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 example: the client's first and last names,

the client's date of birth, the date of death, if known, and the contact information for the reporter including the reporter title (case manager, social worker, program director, mental health practitioner, etc.) and the Reporter Facility/Agency Name (when applicable).

Reports of deaths and serious injuries can 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.

FDA Drug Alerts and Statements

Since the 2021 Winter Alert, the Food and Drug Administration (FDA) has released Drug Alerts and Statements for many medications, some of which are prescribed for clients of the OMHDD. These medications include the following:

> **FDA warns about risks of dental problems associated with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and pain** (https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-risks-dental-problems-associated-buprenorphine-medicines-dissolved-mouth-treat)
>
> **[1/12/2022]** The U.S. Food and Drug Administration is warning patients and prescribers about the potential for dental problems associated with buprenorphine medicines dissolved in the mouth to treat opioid use disorder (OUD) and pain. Dental problems (including tooth decay, cavities, dental abscesses/infection, tooth erosion, and, in some cases, total tooth loss), have been reported even in patients with no history of dental issues.
>
> Buprenorphine is an opioid that works by changing the way the brain and nervous system respond to pain. Buprenorphine was approved in 2002 as a tablet to be administered under the tongue to treat OUD. In 2015, buprenorphine was approved as a film to be placed inside the cheek to treat pain. The buprenorphine medicines that are associated with dental problems are tablets and films dissolved under the tongue or placed against the inside of the cheek. These medicines are available as single-ingredient products and also in combination with naloxone. There are also buprenorphine products for pain and OUD delivered by other routes such as a skin patch and injection, but FDA has not identified a concern for dental health related to these other forms…

Please refer to the complete FDA alert for more details.

> **Pulse Oximeter Accuracy and Limitations: FDA Safety Communication**
> (https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication)

Update June 21, 2022: The FDA continues to evaluate all available information pertaining to factors that may affect pulse oximeter accuracy and performance. Because of ongoing concerns that these products may be less accurate in individuals with darker skin pigmentations, the FDA is planning to convene a public meeting of the Medical Devices Advisory Committee later this year to discuss the available evidence about the accuracy of pulse oximeters, recommendations for patients and health care providers, the amount and type of data that should be provided by manufacturers to assess pulse oximeter accuracy, and to guide other regulatory actions as needed. Further details concerning the agenda, timing, and location of the Advisory Committee meeting will be announced in the coming weeks.

The FDA recommendations provided below have not changed. The FDA will continue to keep the public informed as significant new information or recommendations become available.

Date Issued: February 19, 2021

The Coronavirus Disease 2019 (COVID-19) pandemic has caused an increase in the use of pulse oximeters, and a recent report (Sjoding et al.) suggests that the devices may be less accurate in people with dark skin pigmentation. The U.S. Food and Drug Administration (FDA) is informing patients and health care providers that although pulse oximetry is useful for estimating blood oxygen levels, pulse oximeters have limitations and a risk of inaccuracy under certain circumstances that should be considered. Patients with conditions such as COVID-19 who monitor their condition at home should pay attention to all signs and symptoms of their condition and communicate any concerns to their health care provider.

Recommendations for Patients and Caregivers

How to take a reading:

Follow your health care provider's recommendations about when and how often to check your oxygen levels.

Be aware that multiple factors can affect the accuracy of a pulse oximeter reading, such as poor circulation, skin pigmentation, skin thickness, skin temperature, current tobacco use, and use of fingernail polish. To get the best reading from a pulse oximeter:

Follow the manufacturer's instructions for use.

When placing the oximeter on your finger, make sure your hand is warm, relaxed, and held below the level of the heart. Remove any fingernail polish on that finger.

Sit still and do not move the part of your body where the pulse oximeter is located.

Wait a few seconds until the reading stops changing and displays one steady number.

Write down your oxygen levels with the date and time of the reading so you can easily track changes and report these to your health care provider.

How to interpret a reading:

When taking pulse oximeter measurements, pay attention to whether the oxygen level is lower than earlier measurements, or is decreasing over time. Changes or trends in measurements may be more meaningful than one single measurement. Over the counter products that you can buy at the store or online are not intended for medical purposes.

Do not rely only on a pulse oximeter to assess your health condition or oxygen level.

If monitoring oxygen levels at home, pay attention to other signs or symptoms of low oxygen levels, such as:

Bluish coloring in the face, lips, or nails;

Shortness of breath, difficulty breathing, or a cough that gets worse;

Restlessness and discomfort;

Chest pain or tightness; and

Fast or racing pulse rate.

Be aware that some patients with low oxygen levels may not show any or all of these symptoms. Only a health care provider can diagnose a medical condition such as hypoxia (low oxygen levels).

When to contact your health care provider:

If you are concerned about the pulse oximeter reading, or if your symptoms are serious or getting worse, contact a health care provider.

If you think you may have COVID-19, contact your health care provider or local health department about getting a diagnostic test for COVID-19. Pulse oximeters cannot be used to diagnose or rule out COVID-19.

For more consumer information on pulse oximeters, see Pulse Oximeters and Oxygen Concentrators: What to Know About At-Home Oxygen Therapy…

Please refer to the complete FDA Safety Communication for more details.

Baxter Healthcare Corporation Recalls Volara System For Risk Of Respiratory Distress In Ventilated Patients During Home Use (https://www.fda.gov/medical-devices/medical-device-recalls/baxter-healthcare-corporation-recalls-volara-system-risk-respiratory-distress-ventilated-patients?utm_medium=email&utm_source=govdelivery)

Content Current as of: 06/23/2022

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- Product Name: Volara system with in-line ventilator adaptor (OPTIMUS Handset 2) or Volara patient circuit kit (OPTIMUS OLE AC Patient Circuit Kit)
- Product Model Numbers: PVLIHCBA, M08594, M08594A
- Devices Recalled in the U.S.: 268
- Dates distributed: May 28, 2020, to April 19, 2022
- Date Initiated by Firm: April 26, 2022

Device Use

The Volara system is intended to help people clear mucus out of their airways, expand the lungs, and to treat or prevent a partial collapsed lung (pulmonary atelectasis). The system's in-line ventilator adaptor component makes it possible for it to be used together with a ventilator (in-line) in home-care settings.

Reason for Recall

Baxter Healthcare Corporation, and its subsidiary company Hillrom, are recalling the Volara system because the in-line ventilator adaptor may prevent home-use patients from getting enough oxygen from their ventilators. The risks to affected patients include:

- Choking on mucus or other airway secretions
- An infection in the lungs (pneumonia) that prevents oxygen from getting to the blood (respiratory failure)
- Brain injury caused by lack of oxygen to the brain (hypoxia)
- Death

The risk of serious injury or death is more significant in home-care settings if the caregivers are not trained properly, the device is not connected properly, or if the caregiver is not prepared to address any issues that may arise caused by use of this device.

There has been one complaint and one injury, as well as two deaths, associated with the use of this device…

Please refer to the complete FDA Medical Device Recall for more details.

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.

Please be aware of the Medical Review Subcommittee's Medical Alerts that may apply to your clients. The OMHDD continues to receive reports of the deaths of clients who had been given pain reducing medications for fevers of unknown origin and clients whose pulse oximeter reading were

under 90%. In these cases, neither the client's physician, nor other health care provider was notified, nor was 911 called until after the client stopped breathing.

Use of over-the-counter medications and possible delay of treatment [PDF] (https://mn.gov/omhdd/assets/OTC-and-Delay-of-Tx-2013_tcm23-27625.pdf)

Breathing Alert – think pink, not blue! [PDF] (https://mn.gov/omhdd/assets/breathing-alert-2013_tcm23-27664.pdf)

Medical Alert - Pulse Oximetry [PDF] (https://mn.gov/omhdd/assets/PulseOximetry2016_tcm23-264999.pdf)

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