[High Priority] - H0619 :   [COVID-19] Home-Use SpO2: Considerations before Prescribing or Using Consumer-Grade Pulse Oximeters in the Home Care Environment [ECRI Exclusive Hazard Report]
Medical Device Hazard Report

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UMDNS Terms:

- Oximeters, Pulse [17148]
- Monitors, Physiologic, Pulse Oximetry, Personal [22855]

Geographic Regions: Worldwide

Suggested Distribution: Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Nursing, Pulmonology/Respiratory Therapy, Risk Management/Continuous Quality Improvement, Home Care, Physical Therapy/Rehabilitation, Staff Education, EMS/Transport

Problem:

1. Consumers and non-COVID patients are showing interest in getting home-use SpO_2 devices (consumer-grade pulse oximeters) for monitoring oxygen levels at home.

2. During the COVID-19 patient surge, some hospitals are experiencing a shortage of hospital beds and resources to host patients.

3. Because of this limitation of resources, facilities may be considering home-use SpO_2 for non-COVID patients.

4. However, without proper training on the use of these devices, patients may have:

   1. Misleading results

   2. False sense of security

ECRI Recommendations:

1. Consider whether the patient truly needs a home pulse oximeter device.

   1. Professional medical organizations such as the American Lung Association and the American Thoracic Association are advising otherwise healthy patients to not buy a pulse oximeter [1].

   2. Physicians normally prescribe pulse oximeters for patients with chronic lung disease, such as emphysema or pulmonary hypertension, who receive supplemental oxygen at home. Such patients need to regularly monitor their oxygen levels so that they know when to increase the flow rate of their supplemental oxygen.

2. If you are prescribing the use of a home SpO_2 device:

   1. Give appropriate directions to patients on when they should be using the device to monitor blood oxygen levels.

      1. Patients should be instructed to contact their physician if SpO_2 readings get below a certain threshold defined by the facility or the care team.

   2. To get the best readings, train the patients on the use of these devices to ensure that:

      1. The sensor is both properly placed and securely attached. Motion or poor perfusion can negatively affect SpO_2 and pulse rate readings [2.1].

      2. There is good blood circulation to the hand and finger wearing the device. The best reading is achieved when the hand is warm, relaxed, and held below the level of the heart.

      3. The device offers a signal quality indicator (e.g., plethysmography waveform, perfusion index indicator).

   3. Educate patients on the limitations of this technology.

      1. The pulse oximeter reading may be less accurate if a person is wearing nail polish, artificial nails, has cold hands, or has poor blood circulation.

      2. Certain pulse oximeters may also be less accurate with dark pigmented skin or with very low oxygen saturation levels.

   4. Assign an in-house champion to address any questions patients may have while using this device during home use.

For facilities or patients considering purchasing home-use/consumer-grade pulse oximeters:

1. Consider the following purchasing recommendations when selecting a consumer-grade pulse oximeter [2.2]:

   1. Instructions for use: Review the instructions for use and the vendor's recommendations for cleaning and disinfection. Ensure that you are confident in using the device and have information on the features and intended use of the device.

   2. Operating requirements: Review the labeling and the instructions for use to learn whether the device requires specific components, such as power sources, outlets, telephonic connection, and access to the Internet to ensure that it is operational.

   3. Accessories: Review which accessories are needed to obtain optimal functionality from these devices. Accessories include batteries, smartphones if the device needs to be connected to an app, cables, and sensors.

   4. The pulse oximeter complies with ISO 80601-261:2011 or equivalent standard.

5. Whether data from the pulse oximeter can be sent to a remote monitoring platform (this may be helpful if your facility is planning to monitor the data remotely).

6. Device usability: The device can be used independently in the home environment with appropriate instructions for use available. If possible, evaluate the usability of the device you are interested in using.

   1. Is the text large enough for you to read?

   2. Are the displays readable across a range of lighting conditions?

   3. Are the buttons, keypad, or touchscreen display easy to use?

   4. Are the instructions for use available in the patient's preferred language?

   5. Will the patient be physically comfortable while using the device (e.g., applying sensors, connecting cables to the devices)?

   6. Is it easy to reset/reboot the device if needed?

   7. Is it easy to identify factors in your home environment that could limit or impede use of the device?

7. Purchasing sources: Ensure that you are buying from a reliable source; for example, if you buy a device online, check the customer reviews. Also, check the seller's return policy and customer support statement before you place an order.

8. Problem reporting and customer support: Ensure that the vendor offers responsive customer support for reporting problems with the device and obtaining troubleshooting assistance.

9. Alarm notifications: Review whether the device will provide alarms that notify you of any abnormal change in the monitored or tracked parameters. Ensure that you are familiar with the various alarm messages and have access to information helpful in interpreting them.

Background:

1. Pulse oximetry is a way to measure how much oxygen your blood is carrying. By using a small device called a pulse oximeter, your blood oxygen level can be checked without needing to be stuck with a needle by measuring light-absorbance changes resulting from arterial blood flow pulsations.

2. Pulse oximeters noninvasively measure blood oxygen saturation (SpO_2) of arterial hemoglobin. This is generally expressed as a percentage (e.g., 70% to 100%) of how much oxygen your blood is carrying compared to the maximum it is capable of carrying. Their use allows continuous and instantaneous monitoring of oxygenation and pulse rate, can provide early detection of hypoxia before other signs such as cyanosis are observed, and may reduce the frequency of arterial puncture and laboratory blood gas analysis.

3. Most people do not need a pulse oximeter. Some people are prescribed a pulse oximeter if they have or could have periods of low oxygen.

   1. If the patient has a lung disease, their blood oxygen level may be lower than normal and may be in need of supplemental oxygen.

References & Source Documents:
https://www.thoracic.org/patients/patient-resources/resources/pulse-oximetry.pdf
ECRI Resources:

1. Guidance: Pulse Oximetry: Choosing the Right Sensor and Applying It Correctly

2. Guidance: The Growing Use of Consumer-Grade Medical Devices: Advice for Physicians and Their Patients

Comments:

- This alert is a living document and may be updated when ECRI receives additional information.

Source(s):

- 2020 Jun 3. ECRI researched report