MedWatch - The FDA Safety Information and Adverse Event Reporting Program

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TOPIC: Wear Face Masks with No Metal During MRI Exams: FDA Safety Communication

AUDIENCE: Patient, Health Professional, Risk Manager

ISSUE: FDA is informing patients and health care providers that patients may be injured if they wear face masks (such as surgical or non-surgical masks and respirators) with metal parts and coatings during a Magnetic Resonance Imaging (MRI) exam. Metal parts, like nose pieces sometimes called nose clips or wires, nanoparticles (ultrafine particles), or antimicrobial coating that may contain metal (such as silver or copper), may become hot and burn the patient during an MRI.

The FDA recently received a report that a patient's face was burned from the metal in a face mask worn during an MRI. The FDA reminds patients and providers that patients should not wear any metal during an MRI.

BACKGROUND: Magnetic Resonance Imaging (MRI) uses strong magnets and radio waves (radiofrequency energy) to make pictures of the inside of the body. MRIs help health care providers diagnose a disease or injury, and monitor medical treatment.

Face masks (non-surgical masks), surgical masks, and certain respirators, such as N95 filtering facepiece respirators without exhalation valves, may help slow the spread of diseases that pass from person to person in respiratory droplets.

RECOMMENDATION:

Patients and Caregivers

- Do not wear a face mask containing metal parts, like a bendable nose piece or staples on the headband, nanoparticles, or antimicrobial coating that may contain metal, when having an MRI. You may not be able to tell whether your mask may have metal in it. Ask the person performing the MRI to confirm that the face mask you will wear does not contain metal parts.

- If you are burned by your face mask during an MRI, please report the event to the FDA. Your report, along with data from other sources, can provide information that helps improve patient safety.

Health Care Providers Who Perform MRI Exams

When it is appropriate for a patient to wear a face mask during an MRI exam, such as during the COVID-19 public health emergency, ensure the face mask contains no metal. Some face masks include flexible parts, nose pieces, headband staples, nanoparticles, or antimicrobial coating that may contain metal. If the absence of metal cannot be confirmed and it is determined to be appropriate for the patient to wear a face mask, an alternative face mask where the absence of metal can be confirmed should be used. Health care providers who perform MRI exams are encouraged to provide face masks without metal to patients who will undergo an MRI.

- Continue to screen all patients for MRI safety, including looking for metallic objects, prior to MRI examinations.

- If a patient experiences an adverse event, such as a burn, while wearing a face mask during an MRI, you are encouraged to report the event to the FDA. Your report, along with data from other sources, can provide information that helps improve patient safety.

Health professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online.

- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on form, or submit by fax to 1-800-FDA-0178.

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