



Clarification on the Use of Imported KN95 Masks

Purpose

To clarify previously issued guidance on the use of imported KN95 masks.

Background

On April 13, 2020, the State of Missouri announced that it is recalling approximately 48,000 KN95 respirators that had been distributed to first responders during the first week of April. According to the announcement shared with Missouri's emergency response partners, testing by the Missouri Department of Health and Senior Services demonstrated that some of these respirators did not meet standards. They included respirators labeled "Huabai" and "Sanqi" as well as unmarked respirators that did not bear a brand name; however, the State of Missouri is recalling **all** previously distributed KN95 respirators.

Based on the recall of KN95 respirators in Missouri, the Illinois Department of Public Health (IDPH) issued guidance recommending that partner agencies who have received KN95 respirators ensure they are using authorized respirators from Appendix A of the U.S. Food and Drug Administration's (FDA) April 3 emergency use authorization (EUA) for imported respirators made in China. These respirators have been evaluated and found to meet the eligibility criteria outlined in the EUA. The KN95 respirators recalled in Missouri are not currently on the list of authorized respirators.

Recommendation

When supplies are available, IDPH recommends using NIOSH-approved N95s or similar respirators for aerosol generating procedures, such as intubations. When supplies of NIOSH-approved N95s are not available, authorized respirators listed on Appendix A may be used. When used in this manner, employees should still be fit tested to confirm a proper fit. A list of these respirators is available from: <https://www.fda.gov/media/136663/download>. This listing changes frequently so partner agencies should check it often.

IDPH recommends using KN95 respirators that are not included on Appendix A to FDA's EUA as acceptable crisis alternatives to medical procedure or cloth masks. KN95s may provide equal or greater protection under these circumstances. IDPH is not recalling previously distributed KN95 respirators.

IDPH and the Illinois Emergency Management Agency (IEMA) will evaluate future supplies of respirators that are shipped to Illinois to determine whether they are authorized under FDA's EUA or they should be used as alternatives to medical procedure or cloth masks.

Health Care Procedures that Require an N95 Respirator Mask

CDC recommends that all healthcare providers prioritize the use of an N95 respirator mask or equivalent for any patient procedures that are suspected or confirmed to have COVID-19 and undergoing aerosolizing procedures.

Aerosolizing procedures can include:

Endotracheal intubation
Manual ventilation
Nebulizer treatments
Noninvasive ventilation (bipap and cpap)
High flow nasal cannula
Open suctioning of the endotracheal tube
NP - Nasopharyngeal suctioning
Bronchoscopy procedures
Mechanical ventilation (opening of circuit)
HFOV- High Frequency Oscillatory Ventilation
IPV- Intrapulmonary Percussive Ventilator
Tracheostomy care
Cardiopulmonary resuscitation
Placement of nasogastric tube, oral gastric tube, transpyloric tube
Mist collar

Surgical or Procedural Facemasks

Procedures can include:

Protection from splashes or sprays not related to COVID-19
Surgical procedures
Direct patient care under droplet precautions
Healthcare staff use for source control