Ontario Health
Quality

N95 Equivalents as an Alternative to N95 Respirators in a Health Care Setting: Supplemental Information

Key Messages

This supplemental information was generated to support decision-making and to provide information on N95 equivalents from other countries during the novel coronavirus disease (COVID-19) pandemic.

We examined the recommendations from national and international health authorities and organizations and completed a targeted search of published literature. We found the following:

- No research studies were identified that compared the equivalence of N95 respirators from international jurisdictions to those used in health care settings in Canada and the United States (National Institute for Occupational Safety and Health [NIOSH] certified). The US Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for importing non-NIOSH–approved N95 respirators from Australia, Brazil, Europe, Japan, Korea, and Mexico, which have similar standards to NIOSH. The FDA also issued a new EUA for non-NIOSH–approved N95 respirators made in China, which makes KN95 respirators eligible for authorization if certain criteria are met, including evidence demonstrating that the respirator is authentic.

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Background and Context

On April 7, Ontario Health (Quality) received a request from the Ontario Health Secretariat for information around N95 equivalents from other countries during the COVID-19 pandemic. In response to that request, this supplementary information provides a summary of the evidence from Ontario Health's rapid evidence summary (March 31) and from a targeted search for published scientific literature and guidance.

Guidance and Peer-Reviewed Studies

Filtering facepiece respirators (FFR) are subject to various regulatory standards around the world (3M, 2020[1]). These standards specify certain required physical properties and performance characteristics in order for respirators to claim compliance with the particular standard. During pandemic or emergency situations, health authorities often reference these standards when making respirator recommendations, stating, for example, that certain populations should use an "N95, FFP2, or equivalent" respirator (3M, 2020[2]).

The U.S. National Institute for Occupational Safety and Health (NIOSH) evaluates, tests and certifies N95 respirators (Health Canada, 2020[3]). The masks must pass minimum performance requirements, such as filter efficiency and breathing resistance. All N95 respirators certified by NIOSH must have an approval number stamped on the mask, represented as TC-84A-####n (Health Canada, 2020[4]).

Research Studies

No peer-reviewed, published studies were identified that compared the equivalence of N95 respirators from international jurisdictions to those used in health care settings in Canada/US (NIOSH certified).

Guidance

Health Canada

Health Canada, the regulator for medical devices in Canada, lists N95 respirators (or particulate filtering face-piece respirators) as Class I medical devices and are manufactured by companies that hold a Medical Device Establishment Licence (MDEL) (Health Canada, 2020[5]).

Health Canada accepts the NIOSH certification as an appropriate quality standard for N95 masks used by health care providers (Health Canada, 2020[6]). Equivalent alternate standards are also acceptable (although Health Canada does not specify these standards on the website). Health Canada is fast-tracking the MDEL application process for companies that want to manufacture, import or distribute Class I masks. The goal is to complete the process within 24 hours from the time Health Canada receives a completed application (Health Canada, 2020[7]).

United States

On March 28, 2020, the US Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for importing non-NIOSH-approved N95 respirators (US FDA, 2020[8]). Under this EUA, among other criteria, the FDA accepts marketing authorization from Australia, Brazil, Europe, Japan, Korea and

Mexico who have similar standards to NIOSH. On April 3, 2020, in response to continued respirator shortages, the FDA issued a new EUA for non-NIOSH-approved N95 respirators made in China, which makes KN95 respirators eligible for authorization if certain criteria are met, including evidence demonstrating that the respirator is authentic (US FDA, 2020[9,10]).

The US FDA also issued guidance (US FDA, 2020[11]) to provide a policy to help expand the availability of general use face masks for the general public and respirators for health care professionals during this pandemic. The guidance applies to KN95 respirators as well. It explains that for the duration of the pandemic, when FDA-cleared or NIOSH-approved N95 respirators are not available, the FDA generally would not object to the importation and use of respirators without an EUA, including KN95 respirators, if they are on the Centers for Disease Control and Prevention (CDC) list of respirator alternatives during the COVID-19 pandemic (Tables 1 and 2) (Centers for Disease Control and Prevention, 2020[12]). Although not required, if a KN95 respirator does not have an EUA, importers may want to take appropriate steps to verify authenticity of these products.

Table 1: Respirators Approved Under Standards Used in Other Countries That Are Similar to NIOSH-Approved N95 Filtering Facepiece Respirators (Centers for Disease Control and Prevention, 2020[13])

Country	Performance Standard	Acceptable Product Classification	May Be Used in Lieu of NIOSH-Certified Products Classified as
Australia	AS/NZS 1716:2012	P2	N95
		P3	N99 or lower
Brazil	ABNT/NBR 13698:2011	PFF2	N95
		PFF3	N99 or lower
People's Republic of China	GB 2626-2006 GB 2626-2019	KN/KP95	N95
		KN/KP100	N95
Europe	EN 149-2001	P2	N95
		P3	N99 or lower
Japan	JMHLW-2000	DS/DL2	N95
		DS/DL3	N99 or lower
Korea	KMOEL-2017-64	Special 1st	N95
Mexico	NOM-116-2009	N95	N95
		R95	R95 or lower
		P95	P95 or lower
		N99	N99 or lower
		R99	R99 or lower
		P99	P99 or lower
		N100	N100 or lower
		R100	R100 or lower
		P100	P100 or lower

Table 2: Respirator-Cartridge Units Approved Under Standards Used in Other Countries That Are Similar to NIOSH-Approved Elastomeric Half-Facepiece Respirators (Centers for Disease Control and Prevention, 2020[14])

Country	Performance Standard	Acceptable Product Classification	May Be Used in Lieu of NIOSH-Certified Products Classified as
Australia	AS/NZS 1716:2012	P2	N95
		P3	N99 or lower
Brazil	ABNT/NBR 13694:1996; ABNT/NBR 13697:1996	P2	N95
		P3	N99 or lower
People's Republic of China	GB 2626-2006; GB 2626-2019	KN/KP95	N95
		KN/KP100	N95
Europe	EN140-1999; EN 143-2000	P2	N95
		P3	N99 or lower
Japan	JMHLW-2000	RS/RL2	N95
		RS/RL3	N99 or lower
Korea	KMOEL-2014-46	Special 1st	N95
Mexico	NOM-116-2009	N95	N95
		R95	R95 or lower
		P95	P95 or lower
		N99	N99 or lower
		R99	R99 or lower
		P99	P99 or lower
		N100	N100 or lower
		R100	R100 or lower
		P100	P100 or lower

Recalls of International Respirators

There have been recent recalls of imported respirators in various countries including the Netherlands, Spain and Turkey (NOS, 2020[15]).

In the Netherlands, KN95 respirators were imported (with Chinese KN95 quality certificate) and distributed to hospitals. The respirators were initially rejected due to poor fit. Additionally, Dutch hospitals quantitatively tested the imported KN95 respirators on their own initiative and determined the masks were of substandard filtration quality (Inspector General for Healthcare and Youth, 2020[16]). The 600,000 KN95 respirators were subsequently recalled by the Dutch Ministry of Health, Welfare and Sport (Inspector General for Healthcare and Youth, 2020[17]).

When NIOSH becomes aware of counterfeit respirators or those misrepresenting NIOSH approval on the market, the Centers for Disease Control and Prevention posts them on their website to alert users, purchasers, and manufacturers (Centers for Disease Control and Prevention, 2020[18]).

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