

Alberta Health Services - Addressing Procedure Mask Concerns

Purpose: This document addresses concerns raised by AHS staff and physicians about new procedure masks, provides information about safety and fit, and how to report safety concerns.

Overarching:

- AHS staff and physicians have raised concerns about some of the new surgical/procedure masks they are using — concerns about fit, concerns about odour, concerns about its effectiveness in protecting them from COVID-19.
- AHS is taking these concerns very seriously and has acted on them immediately.
 - AHS has worked with the suppliers to have the nose pieces adjusted and is increasing the length of the mask (from nose to chin) for a better fit. These changes will be in place for next shipment to AHS.
 - Until then, we suggest the following strategies:
 - Compressing the entire edge of the mask containing the nose piece in a 'W' shape will help the fit across the nose. (we will be posting pictures and videos to demonstrate this technique)
 - if you are providing direct patient care and you are experiencing mask fit issues, we would suggest that you add a faceshield to offer extra protection.
 - Note that for patients suspected or known to have COVID-19, face shield/goggles, mask, gown and gloves should always be used.
 - We have already taken steps to reduce odour from the masks that occurs as a result of the masks being shrink packed right after manufacture.
 - The manufacturer will package these differently to allow for air movement in the masks, instead of a shrink pack.
 - Again, these changes will come through on the next shipment. Until then, masks will be unpacked from the plastic before sending to our sites to allow the masks time to breathe.
- We are working very closely with the manufacturer on the issues that you have brought forward. We are extremely pleased with their responsiveness and are confident that we can resolve the issues that have been identified
- Please be assured that all of our PPE meets the required safety standards. All products are tested prior to being ordered and then are inspected again before they are supplied to our sites.
- The procedural masks that are raising concerns were tested on March 17, before being shipped to Alberta.
 - They were tested by a well-recognized laboratory in China that does most of the standards testing.
 - The testing was done for EU Standards EN14683 Type II and Type II R. which is consistent with an ASTM Level 1 and 2. The results showed that the masks meet expected standards.

- AHS also re-examines all the products upon arrival to ensure that there are no defects.
- Despite the controls we have in place, we know that quality concerns have been raised; these are being addressed.
- We have created a quality control group to field test any new models or products brought into AHS; this will include front line employees and union representatives. This will be increasingly important as we continue to expand the number of suppliers from whom we receive supply. We must explore new suppliers in order to meet the demand for PPE in Alberta, including the new requirement for continuous masking within AHS.
- It's important to note that none of our masks from our standard suppliers have been shipped out of province.
- It is also important to emphasize that these are extraordinary times with massive global demand for PPE supplies; it is in this context of intense competition that AHS continues to source products to protect our front line staff and physicians.

ABOUT SAFETY AND FIT, and the role of staff in testing products:

- The mask products concerning staff - like all PPE products procured by AHS - are certified, and meet the regulatory requirements.
- But, fit is also a very important part of safety. Sometimes, an adjustment period is needed. At other times, however, challenges persist past the initial adjustment phase and more needs to be done.
- Impaired fit can impact the effectiveness of any PPE, and this is of great concern to us.
- We need to know about those concerns, ideally, before these products are in heavy use.
- This is why we are working to establish a "PPE Quality Group" that builds on our existing PPE Taskforce Clinical Support Advisory Group. We see the function of this Quality group being to clinically "field test" incoming products prior to sending them into circulation – this will allow us to understand unique considerations for new models of product.

About reporting safety concerns:

- We need to hear from the frontline. There are two routes right now to report quality concerns such as ear loops breaking or the nose piece not fitting properly, resulting in sliding or fogging of eye protection, odours, and the other concerns that people have identified with the VANCH masks.
- But this is also important for ANY concern that people have with PPE product quality.
- Staff who note any product concerns with personal protective equipment are encouraged to report through the existing [Medical Device Incident or Problem](#) reporting process (ahs.ca/covidppe), or to email ppe@ahs.ca.

About the CPSM Team's work:

- Our CPSM teams have worked proactively, since the end of December, to not only identify existing supply chains that could meet the anticipated surge in demand for PPE here in Alberta, but also new suppliers of products that we know – and already are seeing – will be harder to procure, but essential to our COVID response.
- We continue to work with both short and long-term suppliers. None of the masks from long-term suppliers have been shipped out of the province.
- Alberta Health Services is confident we have sufficient supplies to distribute to our frontline healthcare workers and physicians, as well as our partners.
- In most categories we have more than 30 to 60 days' worth of supplies, and we monitor our supply status every day.
- We will continue to ensure frontline workers have the PPE they need.