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HSA Health Sciences Authority

MEDICAL DEVICE Alert

Risk of Allergies and Medical Complications associated with the Use of Powdered Gloves

Medical gloves are ubiquitous and indispensable for use at healthcare institutions. They serve as a protective barrier during medical procedures between the healthcare provider and the patient. Medical gloves can be made of different polymers, including latex, nitrile rubber, PVC and neoprene. They are supplied in powdered and non-powdered forms, where powdered medical gloves are coated with lubricating dry powders that make donning easier and prevent multiple gloves from sticking together. The glove powder contains dry lubricants, typically either corn starch or silicone. However, significant risks to users and patients, such as allergic reactions, have been posed by powdered gloves.[1]

Safety issues with glove powder in healthcare settings

Glove powder from natural rubber latex (NRL) gloves can adhere to latex antigens (proteins), which may be aerosolised and dispersed into the surroundings. This leads to an overall increased aeroallergen levels within the immediate healthcare facility environment. These dispersed powder particles with latex allergens increase allergy risks and can aggravate hypersensitivity, sensitisation responses and allergic reactions when they come in contact with the skin or are inhaled. Potential hypersensitivity reactions include allergic rhinitis, urticaria, asthma and in extreme cases, fatal anaphylactic reactions.[2] Studies have demonstrated a significant reduction in adverse skin reactions in healthcare workers who switched to powder-free latex gloves, with sensitisation rates declining 16-fold.[3, 4]

In addition to allergy concerns, glove powder can be deposited in the surgical site during surgeries. Such powder deposits may induce inflammatory responses as well as cause other complications such as granulomas, peritoneal/tissue adhesions, infections, and delayed wound healing.[5]

International situation

Globally, several regulatory and advisory bodies have highlighted the need to switch to powder-free medical gloves. Powdered medical gloves are not permitted to be used for medical purposes in the United States of America.[6] In the United Kingdom, national guidelines from the Royal College of Physicians recommend the use of powder-free latex gloves in the healthcare setting.[7] The Japanese Ministry of Health, Labour and Welfare has issued a mandate for powdered medical gloves to be phased out from use in Japan by the year 2018.[8]

Local situation and HSA's advisory

The Workplace Safety and Health Guidelines (Healthcare) for Singapore actively recommends control measures to reduce exposure to NRL, such as elimination/substitution of powdered NRL gloves.[9] In view of the risk of allergies and potential medical complications related to the use of powdered gloves, and the increase in the usage of powder-free gloves in healthcare practices globally, HSA, in consultation with its Medical Device Advisory Committee, strongly encourages the use of powder-free gloves in healthcare settings.

References

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3. *Occupational and Environmental Medicine 2006; 63: 121-5*
4. *J Occup Environ Med. 2011; 53: 934-40*
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7. *http://www.hse.gov.uk/healthservices/latex/index.htm*
8. *https://www.pmda.go.jp/files/000216103.pdf*
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Adverse Event Reporting Made Easier for Healthcare Professionals

The Health Sciences Authority (HSA) conducts regulatory assessments of medical devices (MDs) to ensure that they comply with stipulated regulatory standards of safety, quality and performance. However, many medical device adverse events (MD AEs) are not detected until there is extensive post-marketing user experience. A robust spontaneous AE reporting system is a critical safety net to identify safety signals early to minimise patient harm. Healthcare professionals (HCPs), as end-users of MDs, are best positioned to recognise problems that may result from the use of MDs in clinical practice and real-life healthcare settings.

To facilitate reporting of MD AEs by HCPs to HSA, a simpler method has been implemented effective 14 August 2017. HSA urges HCPs to write in and report serious AEs that they have encountered and where possible, to return the affected devices involved in an AE to the local supplier or manufacturer to facilitate device investigation.

New simplified method to MD AE reporting

Previously, HCPs can report MD AEs to HSA by filling up the HSA AE reporting form available on HSA's website, and email or fax the completed form to HSA. In order to simplify the reporting process, HCPs now have the option to send an **email** to HSA with basic information about the AE and associated MD (refer below), without needing to attach a completed HSA AE reporting form. The AE reporting form has also been streamlined with fewer mandatory information, for HCPs who prefer to use the form to report AEs to HSA.

1) Ways to submit an MD AE report to HSA

- Email basic information of MD AEs to HSA at HSA_Medical_Device@hsa.gov.sg
- Email or fax completed MD AE reporting form available at:
- Phone: (65) 6866 1048 Fax: (65) 6478 9028

2) Basic Information needed for HSA's review

- Device information:
  - *Device name, model number, serial number, batch/ lot number and manufacturer, expiry/manufacture date. (Alternatively, photo of the device label with the above information clearly visible can be sent.)*
  - *Name of local supplier*
- Description of the event:
  - *Event details e.g., sequence of the event that led to the AE, patient outcome, and remedial actions taken*
- Particulars of reporting person
  - *Name, designation, place of practice and contact details*

When to report an event and the importance of reporting MD AE to HSA

The confirmation of the causality of the AE is not a prerequisite for reporting (refer below for guidance on when to report an MD AE to HSA). As long as a HCP suspects that a medical device may be related to a serious adverse event, an AE report may be submitted. All AE reports received by HSA are reviewed to detect potential MD-related safety signals, with focus on AEs that are serious and unexpected. Therefore, receiving sufficient first-hand reports directly from HCPs will provide substantial aggregated safety data and allow HSA to analyse the data for event trending. This will facilitate the detection of new risks or hazards arising from the device design or device use, and safety signals that may be unique to our local demographics.

3) When to report an MD AE?

Report an MD AE to HSA if:

- An adverse event has occurred, **and**
- A medical device is associated with the adverse event, **and**
- Adverse event led to one of the following outcomes:
  - *a serious threat to public health;*
  - *death of a patient, user or other person;*
  - *serious deterioration in the state of health of a patient, user or other person;*
  - *no death or serious injury occurred but the event might lead to death or serious injury of a patient, user or other person if the event recurs.*

Following the review of AE reports, HSA can initiate various risk mitigating measures. These include the issuance of a "*Dear Healthcare Professional Letter*" to warn users/HCPs of the safety issue. HSA would also be able to alert other manufacturers of related MDs that similar AEs may occur with the use of their devices. Other potential regulatory actions that can be instituted include inspections of the dealer's facilities/records and working with the manufacturer to recall the MD from the market.

The sooner HSA is made aware of a problem, the earlier actions can be taken to protect patients and MD users. HCPs are key partners in our vigilance efforts for MDs as early detection of potential issues with the device originates from the astute HCP who highlights the case for further assessment. HSA seeks to develop a strong working partnership with HCPs in our endeavour to safeguard public health.

Please send your enquiries, comments and suggestions to:

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