MEDICAL CONTROL POLICY STATEMENT/ADVISORY

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Mucosal Atomization Device Shortage and Recall

ALL SVMCA PROVIDERS, AGENCIES, AND PHARMACIES:

There is currently a recall of select Mucosal Atomization Devices (MAD®) manufactured by LMA. The recalled devices may not adequately atomize intra-nasal medications into sufficiently small droplets thus causing a decline in therapeutic effect for the patient.

After checking with our pharmacies, we have found that there are many of these recalled MAD® adapters in our drug boxes, BLS Kits, and MFR Kits. Right now, production of replacement devices has not started and non-recalled adapters are in limited supply. We anticipate shortages will continue until possibly the first of the year. With this in mind, we need to EMS providers and pharmacies follow the practices listed below:

- Intra-nasal administration of any medication by ALS providers should only be done if another route for administration is not feasible or possible. We need to preserve non-recalled devices for the MFR and BLS personnel who have no other route to administer medication (naloxone).
- Pharmacies should replace recalled MAD®s whenever possible. However, if there are not any non-recalled adapters left in your stock; replace with recalled devices.
- EMS providers are allowed to use a recalled device on a patient if needed. However, keep in mind that there is a possibility that the medication may not be as therapeutically effective as expected. For the opioid overdose patient; remember the best treatment for hypoxia is a BVM.

Eric Snidersich, BS EMT-P
EMS Manager, SVMCA

Attachments:
1. MDHHS BETP Letter – November 4, 2016

Michigan Department of Health & Human Services

MDHHS

Michigan Department of Health & Human Services

RICK SNYDER, GOVERNOR | NICK LYON, DIRECTOR

To: Life Support Agencies, Medical Control Authorities, Hospitals

From: Bureau of EMS, Trauma, and Preparedness

RE: Limited Availability of Naloxone Atomization Device

There is a national supply chain problem in the Mucosal Atomization Devices (MAD®). These devices are the primary device required for intranasal syringe administration of naloxone (Narcan). First, there is a recall of specific lots of the devices based on a potential to ineffectively atomize the medication (see attachment). This could result in a clinically significant under dosing of the medication resulting in ineffective reversal of the opiate overdose (i.e., failure to restore effective respirations). Second, the manufacturer has suspended production of new devices until the atomization problem can be resolved. At this time, we have been advised that manufacturing will not resume for another 4-5 weeks. When delivery of devices will occur remains unknown. We are unaware of an effective substitute device to permit intranasal syringe administration of naloxone.

Considering the current opiate crisis, this problem with the device supply chain may have an important impact on EMS operations. Therefore, the Bureau offers the following recommendations:

1. All responders should constantly be reminded that effective bag-valve-mask ventilation continues to be the preferred initial treatment for opiate overdoses and can be used by BLS responders until ALS arrival.
2. Hospitals should immediately suspend non-EMS use of MAD® devices for non-EMS purposes (e.g., ENT, pediatric sedation/analgesia)
3. Life support agencies, MCAs, and hospitals, should immediately assess inventories of MAD® devices to identify lots that may be subject to the recall.
4. To the extent possible, life support units should have recalled devices replaced with non-recalled devices.
5. Return of recalled MAD® devices should be deferred until the supply chain is reestablished.
6. At this time, it is felt that if a non-recalled MAD® device is not readily available, intranasal administration of naloxone through a recalled MAD® device maybe preferable to no administration at all, provided effective ventilatory support is provided.
7. To conserve MAD devices for MFR and BLS agencies, ALS and Limited ALS units and personnel should avoid administering all intranasal medications unless no other option (IM, IV, IO) is available.
8. Redistribution of MAD® devices from ALS and L-ALS units to MFR and BLS units may be considered, if needed.
9. Consistent with the Naloxone Administration Procedure, MFR and BLS agencies should be reminded to not administer intranasal naloxone when ALS or L-ALS units are likely to arrive within 5 minutes, assuring effective ventilatory support is provided.
10. Preference for non-recalled MAD® devices should be given to MFR and BLS units likely to experience delayed or no access to ALS or L-ALS
11. Naloxone should NOT be delivered by syringe without the use of a MAD® device.
12. Each MCA should coordinate activities between life support agencies and hospitals.

If you have any questions or concerns, please contact Kathy Wahl.

Kathy Wahl

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