Memo

To: EMS Providers & Agencies using Check & Inject

From: Dr. Walters, Medical Director – MD 1

Date: 11/29/2018

Re: Check & Inject Recall from Bound Tree

Agencies/Providers using the Check and Inject "Epi-Safe" syringe-

You have received a recall from Curaplex (Bound Tree) regarding the recall of the syringe.

The recall is based not on any defect in the contents of the kit, but the fact that the "Epi-Safe" Syringe and the directions provided in the kit for its use, instruct the administration of a 0.15 mg dose of epinephrine to children under 30 kg (66 lbs) that are experiencing anaphylaxis. This is the SAME dose provided by a pediatric epi-auto injector (epi-pen jr). The FDA approved dosage of 1:1,000 epinephrine for children is 0.01 mg/kg, so the administration of 0.15 mg is an "overdose" according to the FDA for patients less than 15 kg and is considered an "off-label" indication. This is why the syringe has been recalled.

Again, protocol indicates that for adults you give 0.3, for children less than 30 kg (66 lbs) you give 0.15 mg. This has been the protocol dose for as long as I can remember, and has been done as an "off label" indication for decades. In fact, consensus guidelines indicate that 0.15 mg auto injectors are acceptable in patients less than 15 kg and much of our pediatric dosing is done off-label. It is also highly unlikely that an IM dose of 0.15 mg in a child in anaphylaxis would cause harm. I cannot find any literature to indicate it has. Lastly, computation and administration of more precise weight-based doses of epinephrine for children under 15 kg is not within the scope of practice nor is there a protocol dose provided for the EMT. Thus again, the benefit/risk ratio favors benefit for a less than 15 kg child receiving more than 0.01 mg/kg but less than 0.15 mg total dose.

Thus although the SYRINGE has not been approved by the FDA, the DOSE is standard and has not changed. Ultimately the decision to continue to use the syringe or not is up to your medical director.

If I am your agency Medical Director, I offer no concern with continuing to use the existing Epi-Safe syringe as it is more likely to allow the provider to administer a correct dose than an incorrect one.

If I am not your Medical Director, contact your doc to determine next steps.

In either case, it is likely that the "Epi-Safe" syringe will become increasingly unavailable. Thus it will be critical to train personnel on how to draw up 0.15 or 0.3 mg in a 1 ml graduated syringe – which admittedly increases potential dosing errors for the reasons the Epi-Safe syringe was designed. It is unknown if Bound Tree will be seeking FDA approval for the off-label, but practice standard, dose of 0.15 in children less than 30 kg.

Any questions please do not hesitate to contact me.

Brian M. Walters DO

Brian M. Walters, DO
Medical Director
Cattaraugus County Office of Emergency Services

** Information contained in this memo is intended for EMS Agencies that receive medical direction from Dr. Walters. These agencies/providers must follow the directives outlined above in addition to any agency, WREMAC or State guidelines/policies that are applicable.*

Agencies who utilize a different medical director should follow directives provided by their Medical Director in addition to any agency, WREMAC, and/or State guidelines/polices that are applicable.