EpiPen malfunctions may delay medication delivery

On March 24, 2020, the FDA released a warning to patients and health care providers that Epipen (epinephrine) auto-injectors, 0.3mg, 0.15mg and approved generics, may malfunction causing delayed or inadequate injection. There are several causes for the auto-injector to malfunction; including, premature activation from using a sideways force to remove the blue safety release, inadvertent activation from a raised blue safety release, difficulty removing the device from container, and user errors. A letter from the manufacturer, Pfizer/Mylan, provides further details about the possible malfunctions. To prepare the auto-injector for use the device should be held in one hand while the other hand is used to remove the safety release by pulling straight up. If the device's blue safety release is slightly raised the device can malfunction and prematurely activate. A malformation of the device carrier tube can make it difficult for users to remove the device from the carrier delaying emergency treatment. In addition, the manufacturer's letter lists specific examples of user errors that could occur; forgetting to remove blue safety release, not getting the needle end of the device in contact with or applying enough pressure on the patients outer thigh to administer a dose, and not holding the device in place for a minimum of three seconds after administration. Health care professionals and patients should check devices for possible defects and contact the manufacturer if an issue is detected. The FDA released an update on April 09, 2020 that no recalls were being made, and patients should use Epipens they may have.

Epipen auto-injectors are used to treat anaphylaxis, a life threating reaction that can have a rapid onset. Epinephrine is the first line choice for treating anaphylaxis and should be administered promptly when anaphylaxis is identified (throat tightening, difficulty breathing) in either a community or hospital setting, and more than one dose of epinephrine may be needed. Following administration of epinephrine in a community setting medical assistance should be called. Diagnosis of anaphylaxis involves a detailed history of the incident (activities around incident, potential triggers, exposure to new substance, symptoms, treatment). Diagnosis criteria includes rapid onset of symptoms involving skin-mucosal tissue, respiratory compromise, reduced blood pressure or symptoms of end-organ dysfunction, or persistent gastrointestinal distress following exposure to a likely allergen. Triggers can be confirmed by performing a graded challenge test. Once anaphylaxis has been diagnosed patients should obtain and carry an epinephrine auto-injector with them at all times.

References:

- Brooks, M. Epipens may malfunction, delaying life-saving med, FDA warns. Emedicine. https://www.medscape.com/viewarticle/927515. Accessed June 17, 2020
- Drug Safety and Availability. FDA alerts patients and health care professionals of EpiPen auto-injector errors related to device malfunctions and user administration. FDA. https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-patients-and-health-care-professionals-epipen-auto-injector-errors-related-device. Accessed June 17, 2020
- Mustafa, S. Anaphylaxis. Emedicine. https://emedicine.medscape.com/article/135065-overview#a. Accessed June 17, 2020
- Simons FE, Ebisawa M, Sanchez-Borges M, et al. 2015 update of the evidence base: World Allergy Organization anaphylaxis guidelines. *World Allergy Organ J.* 2015;8(1):32. Published 2015 Oct 28. doi:10.1186/s40413-015-0080-1

- Simons FE, Ardusso LR, Bilò MB, et al. World allergy organization guidelines for the assessment and management of anaphylaxis. *World Allergy Organ J*. 2011;4(2):13-37. doi:10.1097/WOX.0b013e318211496c

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