ACMT | American College of Medical Toxicology

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ACMT Supports the Use of Expired Naloxone When Unexpired Drug is Not Available

The position of the American College of Medical Toxicology (ACMT) is as follows:

The American College of Medical Toxicology (ACMT) supports the use of expired naloxone to reverse suspected opioid overdose in situations where unexpired drug is not available.

The opioid crisis remains a significant cause of morbidity and mortality, largely driven by fentanyl and fentanyl analogues. The timely administration of the antidote naloxone can reverse opioid overdose. Too often, deaths from overdose can occur before patients can reach hospital care. The distribution of naloxone to emergency responders and laypersons has saved lives [1],[2]. Because laypersons only occasionally administer the drug, many doses reach their expiration date without being used.

The U.S. Food and Drug Administration (FDA) requires naloxone, as with all approved medications, to be labeled with an expiration date. The expiration date is based on stability testing done by the drug manufacturer to ensure the quality, potency, and stability—along with a safety margin—of the medication for its anticipated shelf-life. The FDA has allowed for extension of expiration dates on medication during times of shortage if there is adequate stability data [3].

Despite the labeling requirements, there are data to suggest that many medications retain their potency well beyond the expiration date. For example, a study conducted by the FDA Shelf-Life Extension Program (SLEP), examined different products for the Department of Defense and was able to extend the shelf life of 88% of medications [4]. Medications stored in a controlled environment were stable for quite some time (even years) after the expiration date on the bottle. In fact, naloxone injection was included as one of the products studied and the mean expiration date could be extended by 77%.

Other studies have demonstrated the stability of naloxone in various environments. In one investigation, naloxone remained stable for at least 28 days even when exposed to temperature extremes [5]. A study of medications kept on alpine rescue helicopters under hot and cold conditions, found that naloxone maintained >90% of its labeled potency over a year [6]. An investigation that tested a batch of naloxone from emergency medical services (EMS) and law enforcement training supplies (kept for up to 30 years) found most samples contained >90% of the labeled naloxone concentration [7]. The potency of both the naloxone nasal spray and injection formulation has been studied post-expiration for up to 10 and 19 months and was

found to be >90% for both products [8]. Based on the available data, we can conclude that a vial of naloxone can contain a significant amount of active drug years after the labeled expiration date, even in the setting of real-world storage conditions.

In summary, opioid overdose is a life-threatening condition that requires timely treatment with naloxone. Available data has demonstrated that naloxone products retain a significant degree of potency beyond the labeled expiration date, even when stored under real-world conditions. (Degradation will depend on the specific formulation and storage conditions so we cannot specify a precise expiration time.) While it would be ideal to administer non-expired naloxone in the setting of opioid overdose, it is not always feasible or available. An expired naloxone vial may deliver less than the labeled amount of drug, but the risk of an untreated opioid overdose is far greater than any risk posed by the administration of expired naloxone. ACMT supports the use of expired naloxone to reverse suspected opioid overdose in situations where unexpired drug is not available.

Disclaimer

While individual practices may differ, this is the position of the American College of Medical Toxicology at the time written, after a review of the issue and pertinent literature.

References

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