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New Study Indicates Opioid Overdose Reversal Products Chemically Stable Well Past Expiration Date

Extended Shelf-Life Has Potential for Stockpiles and Communities

WASHINGTON, Nov. 6, 2018 — A widely used naloxone nasal spray (NNS) and naloxone injection (NIJ), otherwise known as Narcan® and Evzio®, which are administered to prevent opioid overdose deaths, were found to be chemically stable up for at least ten months and beyond one year of the expiration date, respectively. According to the National Institute on Drug Abuse, from 1996 to 2014, at least 26,500 opioid overdoses in the U.S. were reversed by laypersons using naloxone. The research, *Evaluation of Chemical Stability of Naloxone Products Beyond Their Labeled Expiration Dates*, was presented today at the 2018 American Association of Pharmaceutical Scientists (AAPS) PharmSci 360 Annual Meeting.

Researchers from the Marshall University School of Pharmacy and Appalachian College of Pharmacy evaluated the chemical stability of two different naloxone products, NNS-Narcan® and NIJ-Evzio®, past their labeled expiration dates, which currently have an 18-month to two-year shelf-life.

"Naloxone has a short half-life which may result in healthcare and community providers carrying or storing outdated product," said presenting author, Mohammad Faisal Hossain, B.Pharm., M.Pharm., Ph.D., instructor of pharmaceutical science at Appalachian College of Pharmacy. "What makes our research unique is that the products tested were unused expired doses from these local providers."

Both NNS and NIJ were kept at room temperature, simulating real-life storage, for six-19 months past the labeled expiration dates. Using USP adopted chromatographic methods, the researchers assessed the therapeutic content and degradation impurities of NNS and NIJ. The average potency of naloxone in NNS was 102.8 percent +/-2.55 and NIJ was 105.98 percent +/- 1.25, both within the acceptance limit of 90 – 100 percent.

The study's principal investigator Charles Babcock Pharm.D., CDE, BCACP, assistant professor at Marshall University School of Pharmacy noted, "The country is experiencing an opioid epidemic and given the continued increase in opioid overdoses our preliminary data suggests that extending the shelf life of these products should aid in avoiding the significant expense of replacing them every two years and also increase the availability of this life-saving medication in both stockpiles and communities."

The next stage of the research will be to conduct extensive longer-term (five years) stability studies such as microbiological stability, photo-stability, and chemical stability.

Hossain added, "Given the FDA Commissioner's recent statement, we hope that our research can be helpful as the agency discusses efforts to increase the availability of naloxone throughout the country."

Evaluation of Chemical Stability of Naloxone Products Beyond Their Labeled Expiration Dates will be presented Tuesday, Nov. 6, 12:30 p.m. – 1:30 p.m., Poster Forum 10 in the Walter E. Washington Convention Center.

Editor's Note: All media must provide press credentials to attend this meeting and register on-site at Walter E. Washington Convention Center, main registration. To schedule an interview with the researchers, or for any other press inquiries, please contact Stacey May at 703-459-7677 or mays@aaps.org or Hillarie Turner at hillarie@vaneperen.com. For the most up-to-date program information, please click here.

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