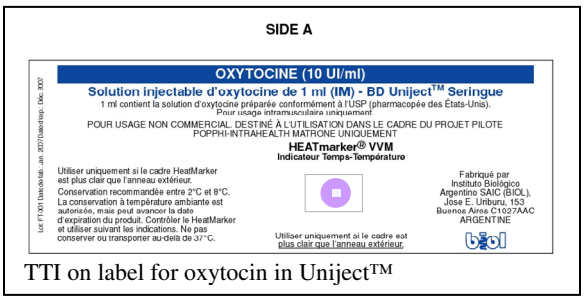
Newsflash: Oxytocin can take the heat…
More storage flexibility with a TTI



TTI on label for oxytocin in Uniject™

PATH's HealthTech program recently presented data showing that the time temperature exposure indicators (TTIs) used with almost all vaccines purchased by the United Nations Children's Fund (UNICEF) may also be used with oxytocin.

TTIs (which have been called Vaccine Vial Monitors [VVMs] when used with vaccines) are small colored stickers placed on drug or vaccine vials in which one area of color becomes darker in relation to its cumulative exposure to heat. Immunization workers are trained to only use vaccines in which the area of color change remains lighter than a surrounding reference shade of color. The rate of color change can be adjusted by the TTI producer to fit differing stability profiles of the drug or vaccine. For vaccines, the World Health Organization (WHO) has categorized the stability of various vaccines into four general stability groups; the TTI producer then developed four TTI versions with individual color change rates calibrated to each stability group. Use of TTIs with vaccines has allowed WHO to change its policy to now allow more flexibility to move vaccines in and out of the cold chain depending on the needs of the immunization program. More than 1.5 billion TTI's have been used on UNICEF-procured vaccines over the past 10 years.

As part of a project to make oxytocin available in the Uniject™ prefilled injection device, the HealthTech program has been collaborating with BIOL, a pharmaceutical producer in Argentina. BIOL has been conducting detailed stability studies of oxytocin in Uniject™ and recently shared the data with the HealthTech team. In a very pleasant surprise, the HealthTech team noticed a match between the oxytocin in Uniject™ stability profile (the different lengths of time the oxytocin remained fully potent at different storage temperatures) and the existing TTI developed for the most stable group of vaccines. With a donation of TTI's from the producer, TempTime Inc., PATH, and BIOL have incorporated TTIs with a recently-produced lot of oxytocin in Uniject™ that will be used in an evaluation program in Mali.

Use of TTIs with oxytocin in either Uniject™ or standard ampoules could improve programs' ability to flexibly transport and store the product at varying temperatures while at the same time ensuring that only fully potent doses are used. For example, if cold-chain capacity was a problem at one level of a system, the oxytocin with TTIs could be stored in an air-conditioned room for a period of time. If midwives and other trained health workers wanted to make outreach visits, they could even keep oxytocin with TTIs at ambient room temperatures and use the product as long as the TTI confirmed acceptable cumulative heat exposure.

Steve Brooke, Team Leader for Uniject™ applications within HealthTech, presented the concept of using TTIs with oxytocin, as well as the stability data, at the POPPHI Postpartum Hemorrhage Working Group meeting held March 26, 2007. Please see http://www.pphprevention.org/news.php to view his presentation. Meeting attendees expressed encouraging support for this new approach.

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