Stability of oxytocin along the supply chain

Objectives and Background

The objective of this study is to determine if temperature variations during the shipment of oxytocin ampoules from the manufacturer to the health care providers, following the routine supply chain, affects the potency of the oxytocin’s active ingredient.

Postpartum haemorrhage (PPH) is the leading cause of maternal mortality in low-income countries. The use of uterotonics plays a central role in the prevention and treatment of PPH and oxytocin is the first drug of choice. Despite oxytocin being a well-known and extensively studied peptide hormone, there is limited information on its stability at tropical temperatures, mainly at extreme climate conditions. Depending upon the manufacturer, oxytocin products should be stored at either controlled room temperature (25°C or less) or in refrigerated storage (2°- 8°C) in order to ensure quality and comply with the labelled storage conditions. WHO recommends that oxytocin should be kept refrigerated as much as possible, however, oxytocin at the point of care is still largely delivered outside the cold chain. Several studies looked at the quality of oxytocin at the point of sale and found that in many places the active pharmaceutical ingredient was below the specifications. The possible causes identified were the quality of manufacturing and inappropriate conditions during transport or storage at the health facility but, no rigorous research has been done to be able to confirm this. We therefore propose to evaluate how temperature variations during the supply chain and storage might affect the potency of the active ingredient of oxytocin products at health care provider level.

The results of this study indicate that the activity of oxytocin was not affected by temperature excursions which occurred along the supply chain. The quality of the oxytocin from the manufacturer as well as from the service level was within the required specifications.


Geographic location

Ghana

Main deliverables

Field stability data of oxytocin ampoules.

Partners

WHO and Merck for Mothers

Sources of funding

Merck for Mothers

Date Issued

January 2018