Health problem addressed

The transmission of HIV from mother to child during the birth process can be largely prevented by administering antiretroviral drugs to the infant within 24 hours of birth. In countries like Tanzania 50% of mothers deliver at home without access to drugs. Existing drug delivery methods are not robust and can be indiscreet for HIV positive mothers.

Product description

A foilized polyethylene pouch that can extend the life of ARVs such that mothers can be given the pouch in the second trimester to later squeeze the drug into the baby’s mouth immediately after delivery at home, if unable to deliver at a health facility. Pouches are provided as a bridge until the mother can reach a health facility and receive ARVs for the child.

Product functionality

Local pharmacist fills and seals each pouch with pre-dosed antiretroviral medication, according to local protocols. The medication in the pouch is stable for 12 months following sealing. When a mother gives birth, she tears open the pouch and squeezes the medication into the baby’s mouth, much like using a ketchup packet.

Developer’s claims of product benefits

Normally, it is not possible to provide oral suspensions of ARV months before delivery because the drug loses potency once placed in a syringe. Storage is not possible for more than 2 months outside the original packaging, so many rural mothers are left without access to medications if they do not reach a hospital. The pouch maintains the life of oral suspension medications for 12 months, allowing for distribution to mothers in resource poor settings. It is anticipated that the pouch will increase the number of children receiving ARVs to 90% whether or not the mother delivers in a hospital. Filling and sealing the pouch can be done in a resource poor setting. The small size (1 week the size of a deck of cards) and home use makes the pouch discreet to help address the problem of stigma associated with HIV.

Operating steps

Using the pouch does not require any particular infrastructure, since it can be stored and torn open under most conditions. Filling and sealing the pouch requires an electric heat sealer, and should be performed on a clean workbench using aseptic technique. Filling and sealing may be done once at a central location.

Development stage

The impact of medication handling (oxygen, light, filling and sealing pouches) was examined and not shown to affect nevirapine (NVP) concentration, levels of preservatives, or introduce contaminants. Nurse interviews showed 100% confidence in patient use at home. Clinical trials are about to begin.

Future work and challenges

Currently the pouch is undergoing feasibility studies regarding distribution to HIV+ mothers who are likely to deliver at home. Future clinical trials will need to be completed before full scale distribution can begin.

User and environment

User: Self-use/patient, pharmacist
Training: Mothers are trained by the pharmacist to tear open the pouch. Distributors train the pharmacist.
Maintenance: None

Environment of use

Settings: Rural settings, at home
Requirements: Filling and sealing the pouch requires an electric heat sealer, and should be performed on a clean workbench using aseptic technique.

Product specifications

Dimensions (mm): 80 x 35 x 0.1
Weight (kg): 0.00057
Consumables: pouch, syringe, syringe tip, tissue paper
Life time: 12 months

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