Heat Stable Carbetocin for prevention of PPH

The case to include on the NURHT List

Dr Hans Vemer
Concept Foundation
Approved Product

- HSC is a new formulation of the existing carbetocin molecule
- Carbetocin first approved in 1997
- Carbetocin registered in 70 countries
- Heat-stable carbetocin (HSC) is registered in 27+ countries
- Carbetocin (including new formulation) used in over 8 million women
WHO Trial

- WHO trial to demonstrate efficacy in PPH prevention following vaginal delivery (IM)
- 30,000 patients to be recruited - 11,582 already completed.
- Will be completed within 12 months
Stability

• Product has data on heat stability as follows:
  • 30 degrees – 48 months (4 years)
  • 40 degrees – 6 months
  • 50 degrees – 9 weeks
• Product is ICH Zone IVA and B stable – hot and humid climates.
• Does not require any cold chain or storage.
Unique partnership

- Product is currently available for high price in rich countries
- Will be made available in LMICs in a public-private partnership with
  - WHO
  - Merck for Mothers
  - Ferring
  - Concept Foundation
Potential application in LMICs

• Heat stable
  • Appropriate for settings where sustained cold storage is not feasible

• Single dose
  • Appropriate for settings where intensive monitoring of woman after birth is difficult

• Quality assured
  • Only quality assured product to be made available

• Most appropriate for births attended by Qualified Birth Attendants, by injection
New? Underused?

NEW
• Existing product – new formulation, new indication – specifically adapted to LMICs

UNDERUSED
• Safe, tested, approved, registered and available BUT ONLY in higher income countries
• Not available in LMICs because of restricted indication, higher price and current manufacturing arrangements

Need listing on NURHT now to expedite availability in LMICs.