Introduction

- Obstetric shock as a consequence of Post-partum Haemorrhage is one of main causes of maternal mortality.
- Active Management of Third Stage Labor (AMSTL) has great impact in reducing maternal mortality.
- Non-pneumatic Anti-Shock Garment (NASG) is a health technology identified in WHO Medical devices and e-Health solutions Compendium of innovative health technologies for low-resource settings (2011).
- Health Technology Assessment is a tool for evidence based decision making on uptake of technology in public health system.
- This HTA on NASG is expected to measure the health impact of NASG.

Objectives

- PRIMARY OBJECTIVES:
  - To evaluate clinical effectiveness of NASG with systematic review of literature.
  - To conduct cost-effectiveness analysis on NASG.
  - To review regulatory and patent aspects associated with NASG.
  - To review social aspect associated with NASG.
  - To review safety aspects associated with NASG.

- SECONDARY OBJECTIVE:
  - To make recommendations based on results of HTA on uptake of NASG in Emergency Response Systems.

Introduction of NASG

- Non-pneumatic Anti-shock Garment is a medical device made up of Neoprene rubber.
- It has 9 articulated segments that are wrapped sequentially around the legs, pelvis and abdomen and fastened with Velcro.
- Courtesy: World Health Organization and Pathfinder International, India

Findings from Systematic Review of Literature

Sources for Literature Search – Cochrane database of systematic review, PUBMED and ScienceDirect and other publicly available information by organizations like WHO, UNICEF.

Methodological Quality Assessment – Critical Appraisal Skills Programme (CASP) tool for randomised trials was used for assessing quality of study.

Bias Identified in Study – Most of studies were published by same author. However, it did not affect outcome of review significantly.

Findings from Cost-Effectiveness Analysis

- Clinical Factor considered for analysis - Difference in Mortality
- Considering same device use without disposal in 40 patients, total number of NASGs required annually equals to 1006.

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Regulatory Status and Patent Status Review

- NASG is not formally regulated in India due to lack of Medical Device Regulatory Board.
- NASG is not FDA or CE certified which are international medical device regulatory standards.
- NASG is now off-patient and produced in several different locations.
- However, there is similar device filed as US patent 3933150 which is for general trauma and uses pressurized gas for increasing venous blood flow to victim’s heart. This was patented in 1974.

Social Aspects

- NASG is difficult to be applied along with “sari”, which is most common customary clothing for women in India.
- Cultural constraints and stigma associated with requirement for application of NASG may act as obstacle in successful acceptance of this health technology.

Safety Aspects

- NASG has no documented adverse events after its application and use.
- However, NASG must not be removed by lay person, but by the experienced clinician only.

Current Market Status

- International Manufacturer(s) – ZOEX Corporation (Portland, OR), Blue Fusion (Hong Kong) etc.
- Indian Manufacturer – VISCO – rubber product manufacturing company
- Indian distributor – PATH FINDER
- Price of NASG in International Market – USD 545, 120 $
- Price of NASG in Indian Market – INR 3000

Recommendations/Conclusion

- Given the outcomes of this HTA, NASG could be beneficially included in Emergency Maternal and Obstetric Care (EMOC) Management.

References