Technical update on PPH Technologies:

High quality, affordable NASG; balloon Tamponade; and haemostatic Agents

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Drivers of affordability and quality initiatives

- High cost of the original NASG
- Additional costs incurred through logistics inefficiencies
- Quality issues

Photo credit: Suellen Miller
Process toward affordable, quality NASG

- Fingerprint mapping
- DMR (Device Master Record)
- Sourcing
- Quality plan
- Ordering
Process (finger print mapping)

Photo collage credit: A. Beddoe, PATH
Process (DMR)
Process (sourcing)

63 potential companies identified
53 responded to inquiries
35 qualified to receive RFQ
13 provided quotes

Signed NDA • To assure confidentiality
Reviewed RFQ and Drawings
Received Sample • Only sent to the most qualified vendors
Provided Quote

Qualified vendors generally worked with neoprene and/or medical garments
Process (Quality Plan)

- Ensures high quality of samples is carried out through production
- Development of the QP includes risk assessment, understanding supplier motives
- Qualified materials
- Final Inspection (3rd party) prior to shipment
Results

- Fully qualified large NASG manufacturer in China who can supply the garment at a price of US$54 (freight on board [FOB]).

- Technology transfer completed to a large NASG manufacturer in India who can supply the garment at a price of US$65 (FOB). Qualification of this manufacturer is still in progress.
Remaining challenges

• Vissco – Indian supplier
• Multiple Sizes
• Demand, minimum order quantities and lead times
• Cleaning logistics and protocol
Vissco

Photo credit: A. Beddoe

Photos courtesy: Vissco
Demand, minimum order, lead times

Market Dynamics

- % Adoption
- Annual Refreshment Purchases
- Sales and marketing efforts
- Annual New Purchases

Units

% Adoption

## NASG Sizes

<table>
<thead>
<tr>
<th></th>
<th>CURRENT</th>
<th>RECENT HISTORY</th>
<th>ANCIENT HISTORY</th>
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<tr>
<td>LARGE</td>
<td>standard geometry but with 4-5&quot; added to</td>
<td>standard geometry but with 4-5&quot;</td>
<td>standard geometry but with 4-5&quot;</td>
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<tr>
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<td>panels 5 and 6</td>
<td>added to panels 5/6</td>
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<tr>
<td>MEDIUM</td>
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<td>standard geometry</td>
<td>standard geometry</td>
</tr>
<tr>
<td>SMALL</td>
<td>small geometry designed for India</td>
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<td>N/A</td>
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</table>
Cleaning logistics and protocol
Other emerging PPH technologies

- Balloon tamponade
- Hemostatic agents
Hemostatic agents

- **Haemostatic agents:** have gained widespread use for pelvic surgery in last few years. Specifically, they are good for use in areas of difficult accessibility. (Shah, 2009)

- **Uterine Atony:** “FlowSeal delivered to the oozing area through single syringe, Hemostasis was achieved instantaneously – recommended as an adjunct to conventional methods” (Moriarity, 2007)

- **Challenges with mixing/packaging:** Further research needs to be conducted to improve product use. Current challenges include ease of mixing, form factor not specifically designed for uterine application, delivery method, pre-measured dose packaging.

- **Price negotiations**
Large NASG ordering details

Price: $53.76 USD FOB China

Lead time: 60 days

Minimum order: 1000 units

Manufacturer: Neil Pryde Performance Manufacturing, China

Orders placed to: Blue Fuzion Group Ltd- Hong Kong

http://www.bluefuziongroup.com/

Contact: julian.cosgrave@bfgroup.asia

Questions: contact Paul LaBarre, PATH; plabarre@path.org
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