Umbiflow
Improving Primary-Level Ante-Natal Care Whilst Reducing Secondary-Level Patient Load

4th Biennial Conference

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What is Umbiflow?

- A low cost, Doppler ultrasound system used to assess blood flow in the umbilical cord
- Targeted at ante-natal clinics for use by nursing sisters / midwives
- Changes the paradigm of ultrasound being used only by specialists at the secondary level
- Tests the proposal: can you shift secondary level diagnostic tests to the primary level and achieve improvements in health care quality & efficiency?
Infant Mortality Rates are a good indicator of a country’s Maternal & Child Health status

(infant deaths before age 1 per 1000 live births)

http://www.indexmundi.com/facts/indicators/SP.DYN.IMRT.IN
4. Reduce by two thirds, between 1990 and 2015, the under-five mortality rate

5. Reduce by three quarters, between 1990 and 2015, the maternal mortality ratio
   Achieve universal access to reproductive healthcare
Progress towards Millennium Development Goals 4 and 5 on maternal and child mortality: an updated systematic analysis
The Lancet Volume 378, Issue 9797 2011 1139 - 1165
http://dx.doi.org/10.1016/S0140-6736(11)61337-8
DOH Key Outcome (1 of the 12 Outcomes of Government):
- A Long & Healthy Life For All South Africans

Four Outputs:
1. Improve the life expectancy of all South Africans
2. Decreasing maternal & child mortality
3. Dealing with the scourge of HIV & AIDS & TB
4. Improving the efficiency and effectiveness of the healthcare system

Umbiflow, the subject of this presentation, is a technological intervention in Doppler Ultrasound for **Ante-Natal Health Care** that targets:
- Millennium Development Goal 4 – Reducing child mortality
- Millennium Development Goal 5 – Achieve universal access to reproductive health
- DOH Outputs 2 & 4.
Ante-Natal Care in the Primary Health Care Sector

- Monthly maternal visits to a PHC / Ante-Natal Clinic: track maternal & foetal health
- Accepted practice is to track foetal growth: Symphysis Fundal Measurement (SF)

- Works at a level of aggregation:
  - Irrespective of sickness condition: foetal growth will be restricted
- SF is effective at identifying “Small for Gestational Age” (SGA) foetuses (<10th %)
Ante-Natal Care: 3rd Trimester Referral Process

- Clinic-Based Care
  - SGA
    - No
    - Yes
      - Refer

Primary Level: CLINIC

- Doppler Ultrasound
  - Assess Blood Flow
    - Caution
    - Healthy
    - At Risk
      - Possible Urgent Intervention

2 Weekly

9 Out of 10 Cases

Secondary Level: HOSPITAL

Jane Doe

RI = 0.67
PI = 1.01
S/D = 3.05
FHR = 142
Umbiflow's Value Proposition:

- Position umbilical blood flow assessment at clinics
- Immediate assessment of healthy versus sick SGA
- Greatly reduce referral rate & patient load upwards
- Reduced maternal stress / transport / time off work
- Reduced perinatal mortality rate potential

These benefits align with our national priorities:

- Improved maternal access to ante-natal care
- Reduced child mortality rates
- Improved efficiency & effectiveness of the healthcare system
Umbilical Blood Flow Measurement – Clinical Need

- First reported use in 1977

- By 1996: American Journal of Obstetrics & Gynaecology reported:
  - “There is now compelling evidence that women with high-risk pregnancies, including pre-eclampsia and suspected intrauterine growth retardation should have access to Doppler ultrasonographic study of umbilical artery waveforms”

- When Umbiflow development started, available equipment:
  - Used only at secondary level of health care
  - Used only by specialist staff
  - Cost typically R250k each: out of reach of primary health clinics.
Umbiflow : The Challenge

• **Key design challenges**:
  - Low cost
  - Easy to use by non-specialist medical staff

• **The solution**:
  - Plug & Play USB Doppler Ultrasound Probe
  - PC based software (moving later to Tablet PCs and Smart Phones).
Umbiflow: Hardware Design
Umbiflow: Clinical Progress

• Clinical tests successfully completed to validate Umbiflow’s accuracy:

  • “Comparison between a newly developed PC-based Doppler umbilical artery waveform analyser and a commercial unit” (South African Medical Journal, Vol. 95, No. 1, 01/2005)
    “… comparing Umbiflow to a gold standard, mean difference of RI values ‘very small’ <0.024”

    “… concurs with Alfirevic & Neilson’s meta-analysis finding that demonstrated that the odds for perinatal death are reduced by 38% with the use of Doppler studies in the high-risk pregnancy population”
Umbiflow: Remaining Tasks

- Quality Systems
  - ISO 13485
  - ISO 9001
  - CE Mark

- Finalise System Design / Industrialisation
  - Hardware
  - Software

- Facilities
  - Acoustic Test
  - Assembly

- Operational Effectiveness Study
  - Ethics Process
  - Study: w/o Umbi
  - Study: with Umbi

- Commercialisation
Umbiflow: Summary

- Umbiflow is a PC-Based Doppler-Ultrasound system for Umbilical Blood Flow Measurement, targeted at Ante-Natal care at the Primary Level
- Empowers nurses & midwives to provide an improved quality of health care at the Primary Level
- Achieves improved access to ante-natal care for pregnant women outside the major urban areas
- Greatly reduces referral rates to the Secondary Level (by factor ~ 5-10)
  - e.g. ~2,000 less patients per annum at a secondary level hospital such as Tygerberg in Cape Town (in just one department)
  - Cost savings at the more expensive Secondary Level
- Assist with reduced perinatal mortality rates.
Umbiflow : Thanks!

- Thanks to a very special CSIR team who are making this happen:

  Absent when picture taken: Kiri Nicolaides, Peet de Wet, Liesl Baben, Louise Nortman, Hein Swart, Dawid Oosthuizen

- As well as our partners & advisors:
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  - WC DOH: Dr Stefan Gebhardt
  - Kalafong: Dr Petro Mulder
  - SUN / Tygerberg: Professor Gerhard Theron
  - UP: Prof. Bob Pattinson
  - EC: Prof. Justus Hofmeyr

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Thank you

SA Deputy Minister of Health, 
Dr Gwen Ramokgopa

*At the Umbiflow stand, 
mHealth Summit, 
Washington DC, 
Dec. 2011.*

www.umbiflow.com