PIERS on the Move: Pre-eclampsia integrated estimate of risk assessment on a mobile phone

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Background

- Pre-eclampsia is the second leading cause of maternal death globally (70-80,000 deaths estimated each year)
- A further 500,000 infants die as a consequence of pre-eclampsia
- Over 99% of these maternal and infant deaths occur in low and middle income countries as a result of delays in diagnosis, triage, transportation and treatment
PIERS on the Move

• PIERS on the Move (POM) is a mobile health application developed for use by health workers in community and primary health care

• POM tool is based on a decision algorithm that incorporates:
  – 1) miniPIERS (Pre-eclampsia Integrated Estimate of RiSk):
    • demographics (gestational age at presentation),
    • clinical signs (blood pressure and dipstick proteinuria)
    • symptoms (chest pain or dyspnoea, headache or visual disturbances, vaginal bleeding with abdominal pain)
  – 2) mobile phone based pulse oximeter (Phone Oximeter)
    • smartphone application, which obtains real-time data from a connected pulse oximeter (measures blood oxygen saturation)

• Decision points in the algorithm are used to provide recommendations of care for women found to be hypertensive during pregnancy
**Example Decision Tree**

Ms. Jones – Decision Tree

- Eligible for assessment (Box 1)
  - Yes: Admit to Hospital
    - Eclampsia?
      - Yes: Treat with MgSO₄ according to local protocol
      - No: Eclampsia or Other adverse maternal events? (Box 2)
        - Yes: Admit to Hospital for care relating to adverse event based on local protocols
        - No: Diagnosis criteria for new hypertensive disorder not met - Continue antenatal care according to local protocols
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    - Yes: Admit to Hospital for care relating to adverse event based on local protocols
    - No: Diagnosis criteria for new hypertensive disorder not met - Continue antenatal care according to local protocols

Eclampsia?
- Yes
  - sBP > 160 mmHg?
    - Yes: Treat with antihypertensive according to local protocol
    - No: Post delivery?
      - Yes: Post delivery?
        - Yes: Proceed with local protocols for delivery
        - No: Reassess within 24hrs*
      - No: In Labour?
        - Yes: Delivery when stabilized
        - No: Post delivery?
          - Yes: Proceed with local protocols for delivery
          - No: Reassess within 24hrs*
  - No: minIPiERS probability > 25%
    - Yes: Expectant Management (Reassess in 72 hrs*)
    - No: Pulse Oximetry <= 93% ?
      - Yes: Expectant Management (Reassess in 72 hrs*)
      - No: Other adverse maternal events? (Box 2)
        - Yes: Admit to Hospital for care relating to adverse event based on local protocols
        - No: Diagnosis criteria for new hypertensive disorder not met - Continue antenatal care according to local protocols

Post delivery?
- Yes
  - GA < viability OR GA > 36+0
    - Yes: Treat with antihypertensive according to local protocol
    - No: GA > viability & GA <= 34+0
      - Yes: Treat with corticosteroids according to local protocol
      - No: Expectant Management (Reassess in 24 hrs*)
  - No: In Labour?
    - Yes: Delivery when stabilized
    - No: Post delivery?
      - Yes: Proceed with local protocols for delivery
      - No: Reassess within 24hrs*

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**Box 1: Eligibility criteria for assessment**
- Hypertension OR
- Proteinuria AND
- Severe signs or symptoms (frontal headache, RUQ pain, visual changes, vaginal bleeding + abdominal pain)

**Box 2: Maternal Events to consider**
- Any component of the PIERS combined adverse maternal outcome (mortality or any one of: hepatic failure, dysfunction, hematoma, or rupture; one or more seizures of eclampsia; Glasgow coma score < 13; stroke; reversible ischemic neurological deficit; posterior reversible encephalopathy syndrome; cortical blindness or retinal detachment; need for positive inotrope support; infusion of a third parenteral antihypertensive; myocardial ischemia or infarction; acute renal insufficiency; dialysis; pulmonary oedema; severe breathing difficulty; requirement of ≥ 50% FiO2 for more than one hour; intubation (other than solely for Caesarean section); transfusion of any blood product; PPH; and placental abruption)

* Values still to be finalised
Usability Study Objectives

• To usability test a mobile health application for use by community healthcare workers to aid with pre-eclampsia adverse outcome risk assessment
  – determine design inconsistencies and usability problem areas within the user interface and content areas
Usability Study Methods

• Group 1: advanced midwifery students at Tygerberg Hospital (Cape Town)

• Group 2: maternal nursing staff at Frere Maternity Hospital (East London)
Usability Study Methods

• All subjects asked to complete a series of 16 tasks simulating a patient evaluation
• Time taken for each task and overall time was recorded
• Subject’s were asked to “think aloud”
  – Gather info on thoughts/comments, etc
• Complete post-study usability questionnaire
Usability Study Results

• N = 37 subjects total (all female, 31-50 yrs)
• Improvements made to the app based on results of Group 1, thereby improving:
  – Total time for task completion by 20% by making modifications to:
    • Layout, form redesign
    • Changes to data input methods (scroll wheel vs number pad for data entry)
• Overall usability questionnaire results were positive
Clinical Study Objectives

• To recalibrate and extend the miniPIERS model to include SpO₂ measured by pulse oximetry
• To pilot test the feasibility and acceptability of use of the POM in a clinical setting
Clinical Study Methods

- Prospective data collection using POM app
- Inpatient women at Tygerberg Hospital with hypertension
- Evaluated approximately every 4 days during hospital stay
- Recommendations for care generated by the decision algorithm were blinded to the caregivers and woman
Clinical Study Results

• Between November 2012 – December 2013 202 women were recruited and enrolled in the study
• 8 of these women went on to have adverse maternal outcomes
• Combined the POM cohort with 617 cases from Aga Khan University (Pakistan) Hospitals and a further 33 from Tygerberg collected during the original miniPIERS study (111 outcomes total)
## Demographics of cohort

<table>
<thead>
<tr>
<th>Site</th>
<th>n</th>
<th>Maternal outcomes (n(%))</th>
<th>$\text{SpO}_2$ (mean $\pm$sd)</th>
<th>Systolic blood pressure (mean $\pm$sd)</th>
<th>Gestational age in weeks (mean $\pm$sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tygerberg Hospital</td>
<td>235</td>
<td>28 (11.9%)</td>
<td>97.2 ($\pm$1.7)</td>
<td>153 ($\pm$22)</td>
<td>33.7 ($\pm$4.9)</td>
</tr>
<tr>
<td>AKU</td>
<td>617</td>
<td>91 (14.7%)</td>
<td>96.7 ($\pm$2.1)</td>
<td>156 ($\pm$23)</td>
<td>36.6 ($\pm$3.1)</td>
</tr>
<tr>
<td>Total</td>
<td>852</td>
<td>119 (14.0%)</td>
<td>96.9 ($\pm$2.0)</td>
<td>155 ($\pm$23)</td>
<td>35.8 ($\pm$3.9)</td>
</tr>
</tbody>
</table>
Adverse outcome rate by strata of SpO$_2$ (n=852)
*denominator used is number of women in cohort with SpO$_2$ in the given range

<table>
<thead>
<tr>
<th>SpO2 level</th>
<th>Women in the cohort [n(%)]</th>
<th>Women with adverse outcomes [n(%)*]</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 93%</td>
<td>38 (4.5%)</td>
<td>25 (65.8%)</td>
</tr>
<tr>
<td>94-95%</td>
<td>153 (18.0%)</td>
<td>34 (22.2%)</td>
</tr>
<tr>
<td>96-97%</td>
<td>271 (31.8%)</td>
<td>37 (13.7%)</td>
</tr>
<tr>
<td>&gt;97%</td>
<td>390 (45.8%)</td>
<td>23 (5.9%)</td>
</tr>
</tbody>
</table>
ROC curve for Original miniPIERS model (AUC 0.781 [0.729, 0.832]) and extended model (AUC 0.798 [0.752, 0.846])
• Erika reported that the tool was easy to use and learn
• One complication encountered was achieving adequate signal quality when measuring the $\text{SpO}_2$
Time taken in seconds to complete an evaluation presented chronologically with smooth trend line. Average time 5 min 57 sec (ranging from 0.6 min – 96 min)
Conclusions

• Decreasing SpO$_2$ is strongly associated with occurrence of adverse maternal outcomes

• Small improvement in ability to correctly classify high-risk women when model includes SpO$_2$

• Use of the POM tool appears to be feasible in a clinical setting base on this pilot work

• Improvement to the model is not significant overall but does exist for identification of high-risk
Next Steps: Clinical Validation Study

• Ongoing large scale clustered randomized controlled trial: Community Level Interventions for Pre-eclampsia (CLIP)
• Plan to test the CLIP POM solution with at least 21,000 women over 2 years

<table>
<thead>
<tr>
<th>SOUTH ASIA</th>
<th>AFRICA</th>
</tr>
</thead>
<tbody>
<tr>
<td>India (control for SpO2)</td>
<td>Pakistan</td>
</tr>
<tr>
<td>CLIP Local standard of care</td>
<td>CLIP + SpO2 Local standard of care</td>
</tr>
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<td>CLIP + SpO2 Local standard of care</td>
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</table>
Sensor Processing (local or central)

Signal Processing
- Signal Quality
- Respiratory Rate Trends
- HRV
- PPV
- Apnea

Authentication/Identification

Decision Support Engine

Data Storage

Interface for Input
- Thresholds, Demographics
- Survey tool confirmation
- Initiation, Authentication

Interface for Output
- Visual display
- Audio display
- Tactile display

Cellular Internet
- Backup/sync
- Real-time monitoring
- Location services
- SMS messages

PIERS Phone Oximeter

Cloud

Encryption