Mobile Health for Cardiovascular Disease risk screening and management tool in resource-constrained environments

SMARTh ealth

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"Although a large proportion of CVDs is preventable, they continue to rise mainly because preventive measures are inadequate." - WHO
CVD in India

• Tackling the transition from Communicable to Chronic Disease.

<table>
<thead>
<tr>
<th>Population distribution</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Urban areas</strong></td>
<td>24%</td>
</tr>
<tr>
<td><strong>Rural areas</strong></td>
<td>76%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Area</th>
<th>Doctor : Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rural India</td>
<td>1:20,000</td>
</tr>
<tr>
<td>Urban India</td>
<td>1:2000</td>
</tr>
<tr>
<td><strong>WHO</strong></td>
<td>1:250</td>
</tr>
</tbody>
</table>

• Is Western style-care that is physician-centric sustainable here?

Need more innovative solutions!
mHealth Review

- Commonly documented use of mHealth
  - 1-way text-message and phone reminders to encourage follow-up appointments, healthy behaviors, and data gathering.

- Few studies demonstrating an impact on clinical outcomes in LMIC.

- Key challenge
  - From pilot to national, scalable programs

- Need Innovative mHealth applications
  - Job aids
  - Clinical Decision Support Systems (CDSS)
  - for Data submission.

Objectives

• Develop and validate a Clinical Decision Support System (CDSS) for CVD risk assessment and management

• Enhance capacity of community health workers (ASHAs) and Primary Health Center (PHC) physicians

• Evaluate preliminary acceptability and feasibility of the tool before large-scale deployment
CVD risk prediction

Developed a model to mimic World Health Organization/International Society of Hypertension’s CVD risk charts – tailored for Indian subcontinent

• Age
• Blood Pressure
• Blood Glucose (Diabetes)
• Smoking Status
• Cholesterol (if known)
• Medical history
CVD risk prediction

65-year-old male with SBP of 144 mmHg, total cholesterol of 4.7 mmol/l who is a current smoker. The individual does not have diabetes.

\[
\mu = \beta_0 + \beta_1 \times \text{age} + \beta_2 \times (\text{smoking status}) + \beta_3 \times \text{SBP} + \beta_4 \times \text{TC}
\]

\[
\mu = -0.5874 + 0 \times (65) + 0.8628 \times (1) + (-1.0957) \times (1) + 0 \times (4.7)
\]

\[
\mu = -8.203
\]

The 10-year risk score is then computed as follows:

\[
h(\mu) = \frac{1}{1+e^{-(-8.203)}}
\]

\[
h(\mu) = .3057 \text{ or } 30.57\% \text{ 10-year CVD risk}
\]
2-stage Validation Process

Stage 1 - Code validation

**CDSS**

1. Recommendations and Referral advice *(ASHAs)*

1. Management Support *(Doctors)*

- Physician coded CDSS (SPSS statistical package)
- 1000 patient dataset
- Non-physician coded CDSS (Android app)
2-stage Validation Process

Stage 2 – Independent Physician Validation

Manual review of Guidelines

100 patient dataset

Manual validation

Output from CDSS (Android app)
Employing User Centered Design

Difficult to evolve the optimum model without engaging the customers or end-users. And with limited capabilities, they cannot drive the design.
CDSS Design

Patient Summary

- Age: 46
- Gender: Male
- Smoking status: Non-Smoker
- Blood Pressure: 141.0/81.0
- Diabetes: Present

Absolute Risk

<10% risk

Absolute risk may be underestimated. Please interpret with caution.

Risk Projection

Save and Upload

Change the button/sliders to desired values to see CVD Risk change.

- Vary Diabetes status: Diabetic
- Vary Smoking Status: Non-Smoker
- Vary Systolic BP:
- Vary Total Cholesterol:
- Vary Age:
CDSS Design

Eliciting the right response

HealthTracker-India

Patient ID: 93191
Consent Number:
Given name:
Surname:
Contact Number:
Address:
Village:
Gender: Male, Female

Birthday: [Date] OR Age:

Event Calendar:
- 1947: India Independence day.
- 1948: Assasination of Mahatma Gandhi
- 1948: Liberation of Hyderabad from Nizam’s Rule
- 1950: India’s Republic day.
- 1956: Formation of Andhra Pradesh state
1. ASHA screens patients in her village using the CVD risk application on the android tablet.
2. Point of care decision support provided to the ASHA and advice given to patient.

High risk individuals are advised to visit the PHCs.
3. Data is uploaded securely to server hosting EMR (OpenMRS via Sana) and subsequently sent to the PHC doctor.
Blood Pressure meter  
Blood Glucose meter

Low-cost Android tablet

transmit/receive relevant data

Bluetooth

Villages

Patients

ASHA

Primary care Physician

1 1

1 N

Villages

1 N

3

Secure connection

data uploaded to server

4. Decision support is provided to PHC physician including the advice and treatment to be given to the patient.

Physician reviews this and approves follow up care plan.
Physician also independently evaluates the CVD risk tool in his clinic as a CDSS.
Pilot Study

<table>
<thead>
<tr>
<th>11 ASHAs</th>
<th>3 Physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=227</td>
<td>N=65</td>
</tr>
<tr>
<td>75 males and 152 females</td>
<td>41 males and 24 females</td>
</tr>
<tr>
<td>Mean age: 51 ± 13 years</td>
<td>Mean age: 55 ± 11 years</td>
</tr>
<tr>
<td>Explain the meaning of CVD risk</td>
<td>Explain the meaning of CVD risk</td>
</tr>
<tr>
<td>Lifestyle recommendations</td>
<td>Lifestyle recommendations</td>
</tr>
<tr>
<td>Referral</td>
<td>Medication</td>
</tr>
<tr>
<td>Screening</td>
<td>Targets</td>
</tr>
</tbody>
</table>
CVD risk profiles \( (N=227) \)

### CVD Risk Distribution - Male Patients \( (N=75) \)

- **<10% risk**
- **10-<20% risk**
- **20-<30% risk**
- **30-<40% risk**
- **>=40% risk**
- **CVD**
- **Clinically high risk (CHR)**
- **CVD and CHR**

### CVD Risk Distribution - Female Patients \( (N=152) \)

- **<10% risk**
- **10-<20% risk**
- **20-<30% risk**
- **30-<40% risk**
- **>=40% risk**
- **CVD**
- **Clinically high risk (CHR)**
- **CVD and CHR**
Referrals (N=227)

Referrals to a Physician

- Impaired Fasting Glucose
- Absolute Risk >=20%
- Clinically High Risk
- CVD
- Other factors

Not Recommended

Recommended
Recommendations (N=65)

- Obese
- Overweight
- Diabetes Screening - 3 years
- Diabetes Screening - 3-6 Months
- Diagnosed with diabetes
- Smoking cessation advice
Putting the tool in context…

**Median time taken for navigating through various steps of the CDSS**

<table>
<thead>
<tr>
<th>Step Description</th>
<th>Median Time (Minutes per Patient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median time taken for the <strong>entire CVD risk procedure</strong></td>
<td>12.07</td>
</tr>
<tr>
<td>Median time taken for <strong>Step 1</strong> of the CVD risk procedure</td>
<td>2.48</td>
</tr>
<tr>
<td>Median time taken for <strong>Step 2</strong> of the CVD risk procedure</td>
<td>0.59</td>
</tr>
<tr>
<td>Median time taken for <strong>Step 3</strong> of the CVD risk procedure</td>
<td>6.33</td>
</tr>
<tr>
<td>Median time taken for <strong>Step 4</strong> of the CVD risk procedure</td>
<td>1.49</td>
</tr>
<tr>
<td>Average time for <strong>Blood Pressure acquisition</strong></td>
<td>4.9 minutes per patient (for 1 measurement)</td>
</tr>
<tr>
<td>Average time for <strong>Blood glucose acquisition</strong></td>
<td>1.19 minutes per patient (for 1 reading)</td>
</tr>
</tbody>
</table>
Conclusion

• Designed and developed a comprehensive CVD risk screening and management tool
• Validated screening and management algorithm specific for Indian context
• Proper engagement of ASHAs, PHC physicians and communities
• Pilot tested the tool and found wide acceptability and utility.
• Understood barriers to large-scale deployment
• Need to demonstrate clinical impact
Main Study – RCT in India

- 54 villages trial in rural India
- 3 year stepped wedge cluster RCT study design

<table>
<thead>
<tr>
<th>Number</th>
<th>Time interval</th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>6 PHCs</td>
<td>Months 0-6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(18 villages)</td>
<td>CONTROL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 PHCs</td>
<td>Months 7-12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(18 villages)</td>
<td>INTERVENTION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 PHCs</td>
<td>Months 13-18</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(18 villages)</td>
<td>INTERVENTION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 PHCs</td>
<td>Months 19-24</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(18 villages)</td>
<td>INTERVENTION</td>
<td></td>
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Baseline | Time-intervals 1, 2, 3 | End of follow-up
Acknowledgements

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