Role of task shifting and DSS in management of CV risk factors: Examples from multiple settings in India.

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Professor, Department of Epidemiology, London School of Hygiene and Tropical Medicine, London, UK
Why do we need to think of alternate strategies for hypertension control
We Know

….. Control of blood pressure is no longer disputed & is supported by most impressive evidence base medicine in past and even today
We Know: Lower BP = better outcomes

Importance of Lowering BP
Meta-Regression Analysis


Maroon circles indicate actively controlled trials. Blue circles indicate placebo-controlled studies or trials with an untreated control group.

Negative values indicate tighter BP control for control treatment vs reference.
We Know: At population level small reductions result in major gains

BP Reductions as Small as 2 mm Hg Reduce the Risk of CV Events by Up to 10%

- Meta-analysis of 61 prospective, observational studies
- 1 million adults
- 12.7 million person-years

For an individual with HT it is important to get the BP to as low as possible and tolerable level. At the minimum less than 140/90

Reality: Poor compliance to treatment

Vrijens et al. BMJ 2008;336:1114-7

Compliance with BP Medicines in the UK
What is task Shifting

- Allocation of tasks in health system delivery to the least costly health worker capable of doing that task reliably

McPake and Mensah. Lancet 2008; 372: 870-871

Task shifting: Contextual Issues

- Task shifting vs Task sharing
- Specialists vs non specialists/primary care physicians (PCP)
- Physicians vs non physician health care providers /workers (NPHW: nurses/pharmacists/frontline health workers)
- Trial/Demonstration to Scale up

Why task shifting/task sharing

- High patient load
- Emphasis on curative care over prevention
- Positive experience of task shifting from HIV and other diseases
Task Shifting: Potential Paths in Hypertension Control

• Down shifting and strengthening long term management of hypertension to Primary care physicians: PHFI training programs
• Care- Coordinators /physician assistants to improve quality of care at all levels of health care: CARRS-T
• CHW to improve screening, adherence and provide lifestyle advice in patients with hypertension at community level: SIMCARD, DISHA study
• Innovative use of Traditional healers/yoga instructors in Chronic Disease management
• Integrating ICT/e/m- health with task shifting: Anchala study, m- power, CARRS-T, SIMCARD, m- Wellcare trial;
<table>
<thead>
<tr>
<th>Challenges</th>
<th>Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Compromised Quality of Care (perceived or real)</td>
<td>• Generate evidence through trials</td>
</tr>
<tr>
<td>• Resistance from health professional groups</td>
<td>• Early engagement/partnerships/horizontal approaches</td>
</tr>
<tr>
<td>• Struggle for legitimacy (new cadres of NPHWs)</td>
<td>• Clear Career paths (e.g., allied health services cadre in India)</td>
</tr>
<tr>
<td>• Lack of Prescription rights</td>
<td>• Regulation</td>
</tr>
<tr>
<td>• Need for ongoing supervision/Continuous training</td>
<td>• Use of ICT and remote continuous training</td>
</tr>
<tr>
<td>• Issues with incentives</td>
<td>• Rationalization of pay-scales</td>
</tr>
<tr>
<td>• Scaling up</td>
<td>• Sustainable financial and cost models</td>
</tr>
</tbody>
</table>
Why mHealth technologies

• Consumers: improved convenience, more active engagement in self-care, and greater personalization.

• Clinicians: Reduced demands on time and refocus on the art of medicine.

• Potential to change every aspect of the health care environment and to do so while delivering better outcomes and substantially lowering costs

Need: Real-world clinical trial evidence to provide a roadmap for implementation

Steinbuhl, Muse, Topol, JAMA, Oct 2013
A gallery of disruptive technologies

Estimated potential economic impact of technologies across sized applications in 2025, $ trillion, annual

1. Mobile Internet
2. Automation of knowledge work
3. Internet of Things
4. Cloud
5. Advanced robotics
6. Autonomous and near-autonomous vehicles
7. Next-generation genomics
8. Energy storage
9. 3-D printing
10. Advanced materials
11. Advanced oil and gas exploration and recovery
12. Renewable energy

SOURCE: McKinsey Global Institute
From asking a research question to scaling up: an example

Can we demonstrate the efficacy of frontline health workers enabled with IT or smart phones in reducing outcomes for patients with hypertension and diabetes?
IT support systems in HT management: What is the evidence?

Difference in SBP (mm of Hg) between the DSS (both computerised and non-computerised) versus control groups

mhealth in HT: Development of DSS

Development
- Stakeholder and situational analysis
- Algorithmic approach based on guidelines
- Knowledge base development
- Feb - April 2011

Beta Testing
- End user testing
- User interface fine tuning
- Feedback sessions
- May – June 2011

Validation
- Real versus virtual comparison
- DSS output compared to independent experts
- Risk, staging of BP, drug management, lifestyle support and follow up advice compared
- July – Sep 2011

Qualitative Research
Feasibility
Demonstration

Receiver Operator Curve for comparing the DSS and independent experts on drug management.

Area under ROC curve = 0.8482
mhealth in HT: cRCT among physicians (16 PHCs; AP)

Mean blood pressure in randomised groups by month and differences vs. baseline

Unpublished data – not for quoting

CBS: Chart based support; DSS: Decision Support System

*Covariates included: age, gender, height, waist, body mass index, alcohol intake, pickle and papad (salty food) intake, portions of vegetable/fruit consumed per day and baseline differences in blood pressure
Can these results be extended to Community Health Workers?

To design a **sustainable** evidence-based, decision support-enabled, health care **delivery model** for the management of HT and DM at PHCs of Himachal Pradesh

Funded by Medtronic foundation

Unpublished data: Please do not quote
Physician certified co-morbid conditions

- PVD
- Myocardial Infarction
- COPD/Asthma
- Renal/Liver Failure (Creatinine>3mg)
- Heart Block
- Diabetic

Diastolic Blood Pressure Reading2 (mm of Hg)
100

Height in cms:
165

Weight in kgs:
80

Body Mass Index (BMI) [kg/m^2]:
29.4

18. FBS (Fasting Blood Sugar)

19. PP (Post Prandial)

20. OHA (Oral Hypoglycemic Agent)
OHA = 0

21. Insulin
No

Unpublished data: Please do not quote
Screenshot of DS-EHR management plan

<table>
<thead>
<tr>
<th>Date</th>
<th>HbA1c</th>
<th>FBG</th>
<th>PPBG</th>
</tr>
</thead>
<tbody>
<tr>
<td>23/Apr/2013</td>
<td>7.5</td>
<td>157.0</td>
<td>146.0</td>
</tr>
<tr>
<td>09/Jul/2011</td>
<td>9.5</td>
<td>90.0</td>
<td>125.0</td>
</tr>
<tr>
<td>27/May/2011</td>
<td>9.3</td>
<td>134.0</td>
<td>180.0</td>
</tr>
</tbody>
</table>

Likely poor control
Review SMBG, titrate insulin accordingly
Weekly phone calls to check SMBG and titrate insulin based on FBG until goal is reached (target:

Reason for rejecting the DS-EHR prompt
- pt has stopped insulin, FBG, PPBG-ok, A1c high, advised diet control

BP prompt
Continue with existing regimen

LDLc prompt
Increase treatment by 1 increment (Atorvastatin 10 mg, Simvastatin 20 mg, Rosuvastatin 10 mg)
Follow-up at 3-monthly visit: check lipid profile and LFTs

Physicians review of DS-EHR prompts & agreement as Yes/No
Screening of eligible patients at 5 CHCs (12 Months: March 2013- Feb 2014)

82,698 clinic attendees

17,590 eligible (>30 years)

5,968 HT or DM
New HT or DM (50.4%)

Unpublished data: Please do not quote
Changes in BP and FBS at 3 and 6 months Follow up

Unpublished data: Do not Quote
CHW to improve screening, adherence and provide lifestyle advice in patients with hypertension at community level
SIMCARD : AIMS

To develop, Pilot-test and Evaluate the feasibility and effectiveness of a

*Simplified*, but *guideline-based* cardiovascular disease management program delivered by the *community health workers (CHWs)* in resource-constrained settings in Tibet, China and Haryana, India
Methods: Subjects

Inclusion criteria

• Age ≥ 40
• Resident in the selected village

Exclusion criteria

• Bed-ridden
• Life-threatening disease
• Unable to stay >8 months in a year
• CVD related complications that can’t be managed

Screening
**CVD high-risk**

Meeting any one of the following conditions:

- History of diabetes
- History of stroke
- History of coronary heart disease
- Both SBP ≥ 160mmHg at two different time points in the same day during the survey
Method – intervention

Electronic Decision Support System (EDSS)

Salt Reduction
Smoking Cessation

BP lowering agent
Aspirin

2 Lifestyle Modifications
2 Drug Prescriptions
Outcomes

Primary outcome:
- Net difference in the proportion of anti-hypertensive medication use between the intervention and control groups.

Secondary outcomes:
- Binary outcome of aspirin use;
- The difference in pre-and-post SBP;
- Difference in smoking status and knowledge on salt.

Outcome evaluation:
- Baseline and post-intervention follow-up survey
- Identical instruments for both surveys implemented in standardized ways
Results: Recruitment and analysis

52 villages (China: 30, India: 32)

- 5 villages were excluded

47 villages were recruited. 2,086 high-risks were identified (China: 1,036, India: 1,050) as high-risk.

- Intervention Group: 1,095 high-risks from 23 villages (China: 557, India: 538)
- Control Group: 991 high-risks from 24 villages (China: 479, India: 512)
- 866 high-risks from 24 villages (China: 431, India: 435)

IIT: 1,095 were analyzed.

IIT: 991 were analyzed.
## Results: Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristics (Mean, SD or %)</th>
<th>India</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>59.9, 11.8</td>
</tr>
<tr>
<td>Control</td>
<td>61.5, 12.1</td>
</tr>
<tr>
<td>Female (%)</td>
<td>58.6</td>
</tr>
<tr>
<td></td>
<td>63.1</td>
</tr>
<tr>
<td>Illiterate (%)</td>
<td>56.4</td>
</tr>
<tr>
<td></td>
<td>60.3</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>24.1, 4.7</td>
</tr>
<tr>
<td></td>
<td>24.5, 4.8</td>
</tr>
<tr>
<td>Current smoker (%)</td>
<td>35.9</td>
</tr>
<tr>
<td></td>
<td>38.7</td>
</tr>
<tr>
<td>Coronary heart disease (%)</td>
<td>28.4</td>
</tr>
<tr>
<td></td>
<td>12.1</td>
</tr>
<tr>
<td>Stroke (%)</td>
<td>14.1</td>
</tr>
<tr>
<td></td>
<td>10.4</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>24.3</td>
</tr>
<tr>
<td></td>
<td>17.2</td>
</tr>
</tbody>
</table>
Results: Primary outcome

Total

- Intervention (n=1,095) 32.3%
- Control (n=991) 8.8%

Net: 22.1%
P<0.001

China

- Intervention (n=557) 22.4%
- Control (n=479) 1.7%

Net: 20.8%
P<0.001

India

- Intervention (n=538) 42.6%
- Control (n=512) 16.0%

Net: 24.4%
P<0.001
## Results: Secondary Outcomes

<table>
<thead>
<tr>
<th>India</th>
<th>Aspirin (%)</th>
<th>SBP (mmHg)</th>
<th>Current smoker (%)</th>
<th>Awareness of high salt harm (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>5.0</td>
<td>156.2, 27.4</td>
<td>35.9</td>
<td>29.1</td>
</tr>
<tr>
<td>Post</td>
<td>13.8</td>
<td>146.6, 25.3</td>
<td>36.5</td>
<td>31.1</td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>3.7</td>
<td>158.5, 26.5</td>
<td>38.7</td>
<td>21.4</td>
</tr>
<tr>
<td>Post</td>
<td>3.7</td>
<td>149.5, 25.7</td>
<td>37.2</td>
<td>36.7</td>
</tr>
<tr>
<td><strong>Net</strong></td>
<td>8.8</td>
<td>-0.5</td>
<td>2.1</td>
<td>-13.3</td>
</tr>
<tr>
<td><strong>P value</strong></td>
<td>&lt;0.001</td>
<td>0.71</td>
<td>0.22</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Summary

• Effectively changed CHWs and patients' behaviors in increasing uptake of evidence-based medicine (anti-hypertensive medication and aspirin)
• No significant changes in lifestyle factors
• Reduced systolic blood pressure by 2.1 mmHg

Simplified evidence-based culturally-appropriate interventions using the high-risk approach could improve quality of primary care and have the potential to reduce disease burden in resource-constrained settings.
Acknowledgement

China site:
Z Liu, D Dunzhu, X Zhao, H Chen, K Cho
R Li, C Li, X Li, J Ji, E Delong, E Peterson
Y Wu, L Yan

India site:
V Ajay, S Hameed, D Jindal
I Rawal, M Ali, R Amachand
A Krishnan, N Tandon, D Prabhakaran
CHW to improve screening, adherence and provide lifestyle advice in patients with hypertension at community level
Innovations in Health Promotion: Can we use frontline health workers?

• Diet and lifestyle interventionS for Hypertension Risk reduction through Anganwadi Workers and Accredited Social Health Activists

Acknowledgement: ICMR

‘Tell Me and I Will Forget; Show Me and I May Remember; Involve Me and I Will Understand.’

Confucius, 551 - 479 BC
DISHA Trial: some facts

- Cluster randomized trial in 9 states in India;
- Baseline survey → Intervention → Endline survey
- 120 clusters and 36,000 participants; Baseline survey completed in 5 states (18,000 individuals)
- Intervention using IEC tools at the individual, family and community level for control of hypertension, diabetes and dyslipidemia through promoting balanced diet, reduction of salt, tobacco and alcohol consumption, and increasing physical activity
- **18 months intervention by multiple methods including household visits**
- **Control Cluster: USUAL intervention through IEC tools.**
## Intervention Tools: Individual Level

<table>
<thead>
<tr>
<th>Tools to be Used</th>
<th>Description and Purpose of Tool</th>
</tr>
</thead>
<tbody>
<tr>
<td>Booklet</td>
<td>An information guide that provides information and education (increasing awareness) on NCD, Hypertension, Risk factors and Key Messages.</td>
</tr>
<tr>
<td>18-month Calendar</td>
<td>Contains health information on NCD and importance of leading healthy lifestyle. It also has a monitoring sheet for noting the oil and salt consumption.</td>
</tr>
<tr>
<td>Oil Dispenser</td>
<td>A calibrated container used for storing and quantifying oil used by families in cooking.</td>
</tr>
<tr>
<td>Salt Spoon</td>
<td>A calibrated spoon used for quantifying the usage of salt by families.</td>
</tr>
</tbody>
</table>

## Intervention Tools: Mass Level

Visual cues and high frequency of encountering messages (by display of posters in common public places).
Integrating chronic Disease care and demonstration for scale up
mWellcare Trial

An integrated mHealth system for prevention and care of chronic conditions

- To develop and evaluate a mHealth system aimed to improve the treatment and care of patients with chronic diseases
- Integrates a range of risk factors including conventional CV risk factors, depression and alcoholism
- To produce a business plan for scalability and sustainability in partnership with potential users
- Cluster randomized control trail of 24 PHCS involving 3600 participants from Haryana and Karnataka
- Outcomes: 10-year CVD risk, systolic blood pressure, HbA1c levels
An Exemplar of Comprehensive Approach
UDAY Summary

- **AIM:** To implement and evaluate multi-component, multi-level, interventions to prevent, detect, reduce the risk of diabetes and hypertension and to improve management
- **Location:** Vizag (South India) and Sonipat (North India)
- **Population:** Adults aged ≥30 years; urban and rural sub-sites; population ~1,00,000 people, yielding a total population of 4,00,000
## Key Innovations

<table>
<thead>
<tr>
<th>Best Practices</th>
<th>Approach</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention, early detection and referral</td>
<td>Health promotion, screening</td>
<td>400,000 population</td>
</tr>
<tr>
<td>Capacity building, task shifting of healthcare providers</td>
<td>CME, short trainings, distance learning, QIP</td>
<td>Providers</td>
</tr>
<tr>
<td>Early diagnosis and prevention of complications</td>
<td>Registry</td>
<td>10,000 patients</td>
</tr>
<tr>
<td>m-Health system</td>
<td>Electronic data system + DSS</td>
<td>400,000 population</td>
</tr>
<tr>
<td>Electronic data capture</td>
<td>Tablet based surveys,</td>
<td>13,000</td>
</tr>
<tr>
<td>Spatial and built environment assessment</td>
<td>GIS mapping</td>
<td>All study areas</td>
</tr>
<tr>
<td>Improved access by social marketing initiatives</td>
<td>Quality of service</td>
<td>300 pharmacists</td>
</tr>
<tr>
<td>Culturally tailored patient education and networks for enabling self care</td>
<td>Utilizing health workers</td>
<td>Patients</td>
</tr>
</tbody>
</table>
**Integrated m-Health System**

**In the Community**
- Screening by health workers;
- Referral of high risk and those with DM and HT to health care facility;
- Use of tablet based DSS

**At the Health Facility**
- Screening by nurses, & physicians of patients who come directly.
- Evaluation of those referred by health workers
- Use of tablet based physician DSS

**Assignment of unique ID and generation of electronic record**

**Transmission to central database**

**Health workers
nurses, physicians**
Screening Program

Public education on diabetes and hypertension through social marketing campaigns

Screening of ≥30 year olds by trained health workers using diabetes risk score and glucometers (Unique ID assigned)

Low risk
Provide health education materials + lifestyle advice

High risk
Refer to healthcare system

Program trained healthcare providers

Patient education and engagement in patient networks by health workers in the health facility/community + Guideline based management + Follow-up, adherence tracking using m-Health tools
e-Screening

Screening Application

Login

User name

Password

Login

Work Offline

Settings

Remember me

Exit
SECTION 1: DEMOGRAPHIC, LIFESTYLE and FAMILY INFORMATION

01) 3501407142159
02) 14/07/2014
03) 21:59
04) Participant Name
05) Father’s name
06) Spouse’s name
07) Address
08) Phone number/Mobile number
09) Age
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant Name</td>
<td>Nikhil</td>
</tr>
<tr>
<td>Age</td>
<td>38</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
</tr>
<tr>
<td>Risk Status</td>
<td>High Risk</td>
</tr>
<tr>
<td>TOTAL SCORE</td>
<td>21</td>
</tr>
</tbody>
</table>
Electronic Data Capture
First of all, I would like to collect details about you, where you live at present, and how we can contact you.

01) 1107131520
02) 1
03) 111547797

04) 11071315201
05) 1
06) 15Hr:22Min

07) Participant Name
08) Head Name
09) Fathers/Spouse’s Name

10) Address/Details
11) Telephone Number
12) Place of Birth
Surveys with Tablets
Surveys in Progress
UDAY DSS: Components

- Evidence-based management algorithms to assist physicians/healthcare providers in: screening, diagnosis and formulation of a management plan for individual patients

- Helps extend and expand the scope of chronic care interventions beyond the traditional clinical settings, improve self-management skills of patients and outcomes
Impact Indicators

Increase over baseline in levels of:

- awareness and knowledge about diabetes and hypertension in the general population
- those aware, diagnosed, treated and controlled to targets
- the use of guideline based management by providers leading to improved outcomes
- access to care, adherence to treatment, conformity to IPHS recommendations
“If you want something you have never had, You must be willing to do something you have never done”

*Thomas Jefferson*