Cardiovascular research needs to achieve “25 x 25” in India

D Prabhakaran DM, FRCP, FNASc

Executive Director, Centre for Chronic Disease Control, New Delhi

Director, CoE-CARRS, Public Health Foundation of India

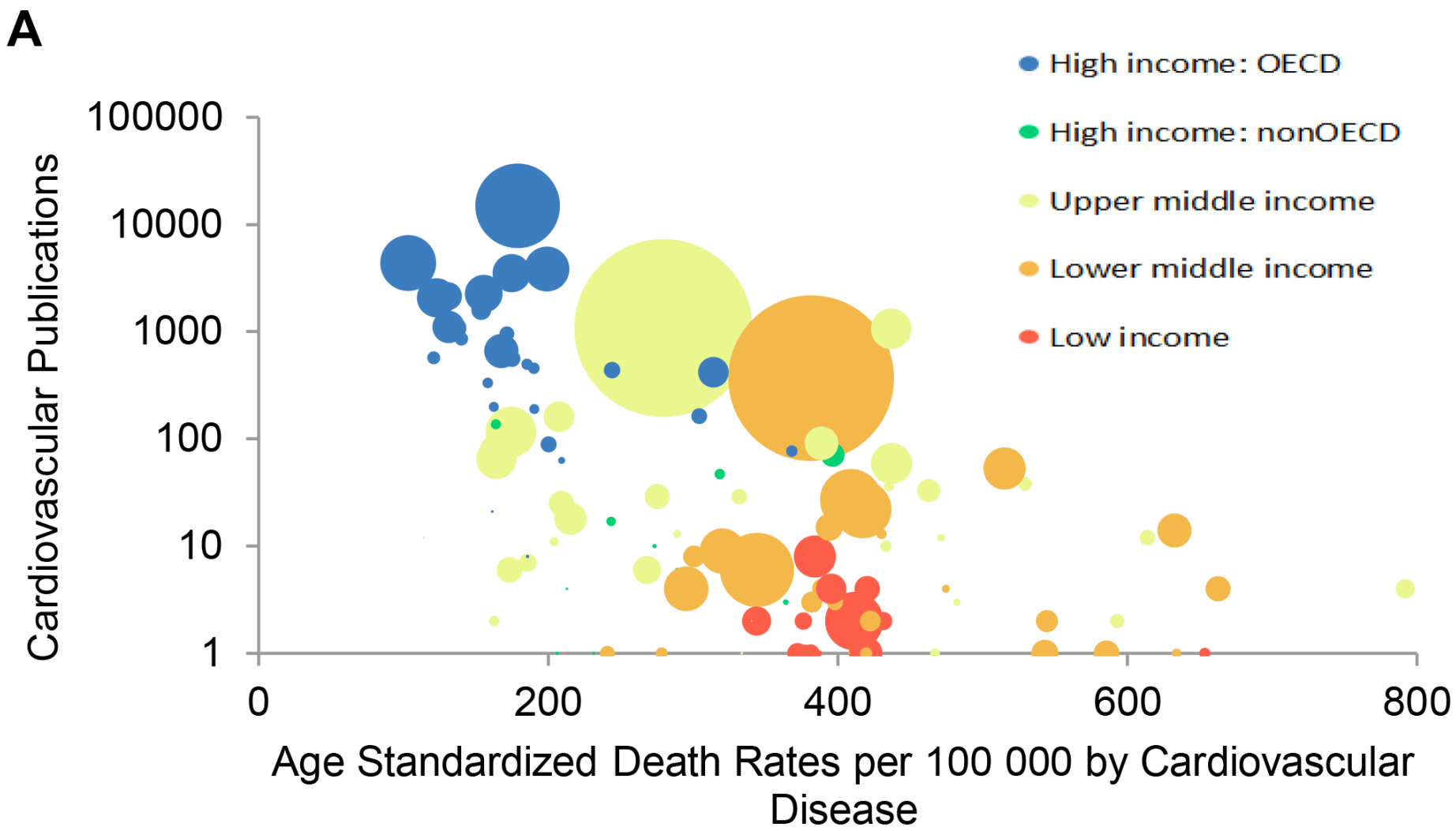
Adjunct Professor, Emory University

Honorary Professor, London School of Hygeine and Tropical Medicine

Outline

- General Comments
- Past Studies : What have we learnt ?
- Current landscape
- What more do we need to do ?

The 80:20 gap : Prabhakaran P et al 2007; JACC



Huffman et al. PlosOne 2013

Research in India: The past landscape

Community Studies

- Prevalence : Multiple Cross sectional surveys
- Incidence studies : few
- Birth cohorts : few
- Demonstration projects
- Migration studies
- Cohort studies: PURE

Hospital based/clinical Studies

- Registries
- Clinical trials
- Economic impact

Highlights of Research

- Understanding the dynamics of CVD & risk factors in Indians
- Role of life course approach in CVD
- Economic impact of CVD in 4 developing countries including India
- Translational research on low cost approaches (task shifting, technology, traditional methods) for CVD risk reduction at worksites and communities

Set of 9 voluntary global NCD targets for 2025

Premature mortality from NCDs 25% reduction

Harmful use of alcohol 10% reduction

Essential NCD medicines and technologies 80% coverage

Physical inactivity 10% reduction

Drug therapy and counseling 50% coverage

Salt /Sodium reduction by 30%

Diabetes/ obesity 0% increase

Tobacco use 30% reduction

Raised blood pressure 25% reduction

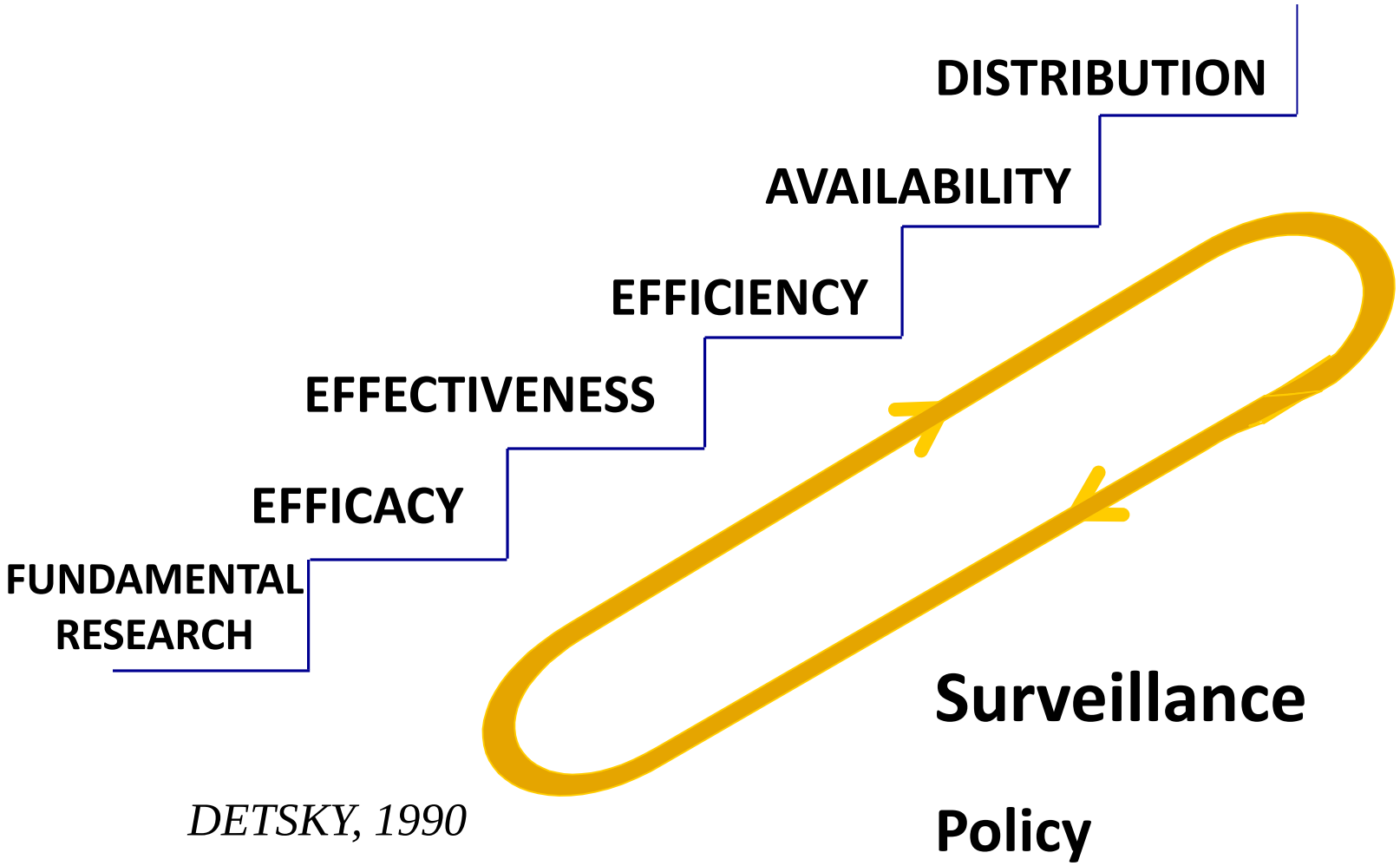
Mortality and Morbidity

Risk Factors for NCDs

National Systems Response

World Health Organization

Research: What should India do to achieve 25x25 goals



DETSKY, 1990

Epi Research : Salt intake in India

- The last robust data from INTERSALT study in 1985 : From Delhi and Ladhak
- What is the current intake : Most studies suggest average of 15-18 gms
- Recent 24 hours urinary Na excretion from Delhi suggests total mean salt (NACL) intake: 9.7g, Median intake: 8.3g.
- Can we obtain this on a nationwide level?

Surveillance

Efficacy and Effectiveness research

Do we know enough about improving compliance in primary and secondary prevention?

What are the innovations in improving secondary prevention ?

Efficiency : the role of registries and Quality improvement programs

- Powerful data particularly for outcomes research
- CREATE Registry : SPREAD study
- Kerala ACS registry : ACS QUIK
- RHD registries
- CHF registries

Improving access : an example

heartMAP: A scalable, cost-effective, mobile health program to improve adherence to anticoagulation medications among low-literacy patients with advanced heart disease.

- **Scalable program**
- **Low cost mobile health program**
- **Strategically combines machine learning and behavioural economics**

- **An educational tool**
- **A POC diagnostic device**
- **Creation of a virtual clinic through an interactive IT tool**

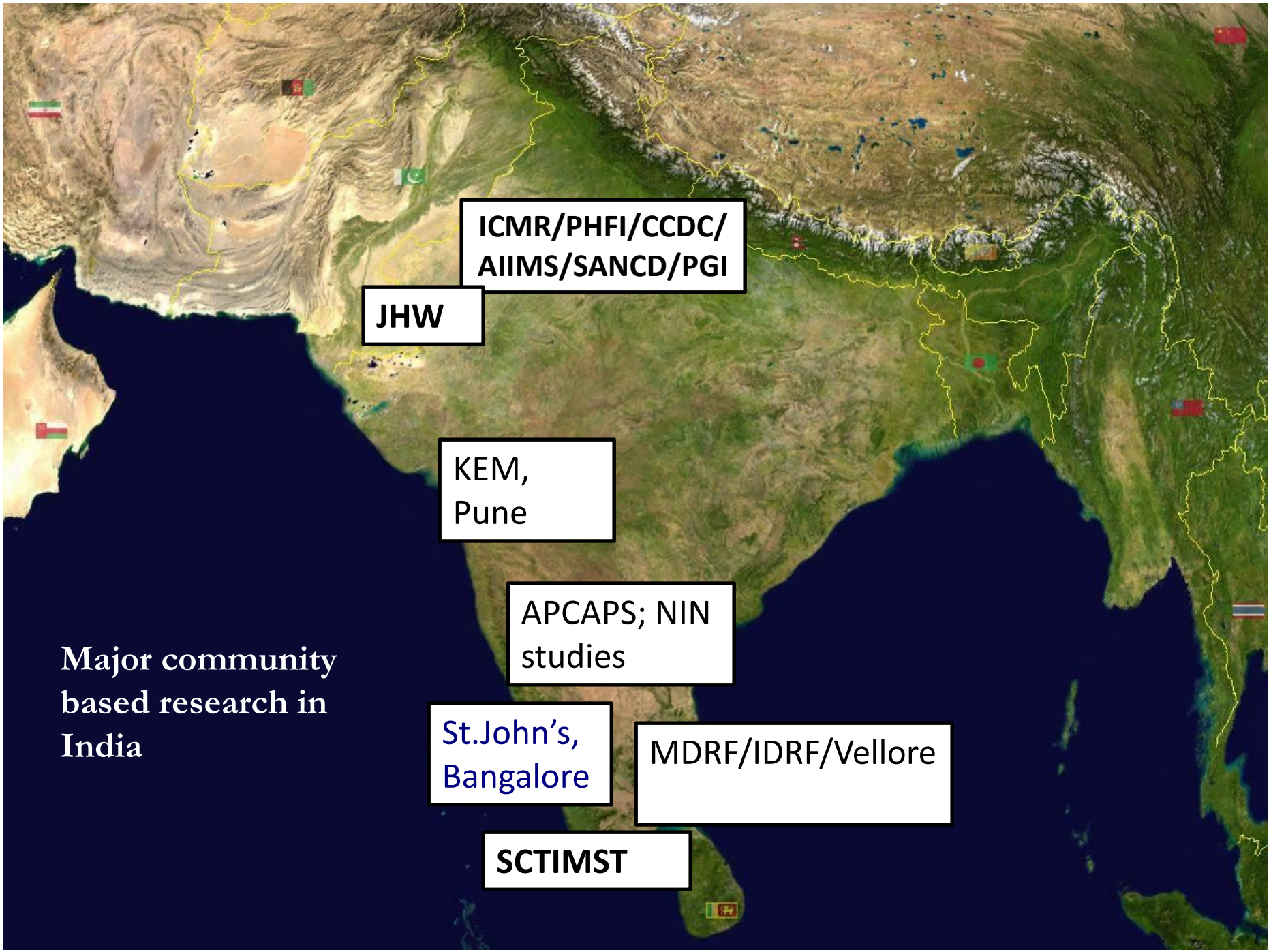
Personal Communication:
Dhruv Kazi; Stanford University

CVD Research in India

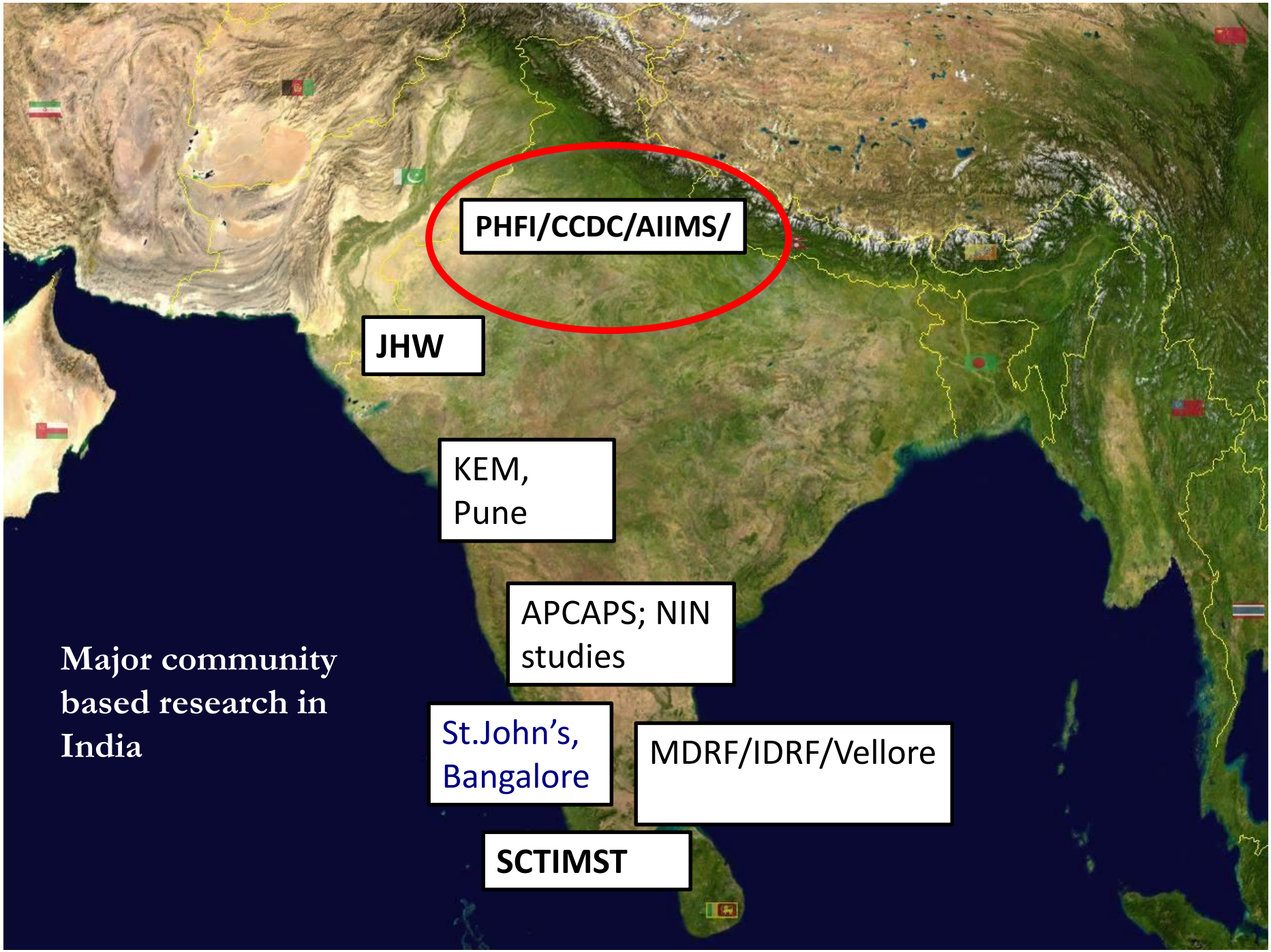
Domain	Adult	Gender	Children	Special Gps	Regional
CVD/RF Epi	Yes	Yes	Yes	Yes	Yes
Mortality					
Incidence					
Nutrition					
Physical Activity					
Complications/rehabilitation					
Access/quality of care					
Cost/Cost-effectiveness					
Environmental data					

	Available		Partial		Nil/few

Where is the research happening in India



Major community based research in India



Major community based research in India

What can help achieve 25-25 goals

- Surveillance
- Secondary prevention
- **Health system improvements**
- Health Promotion
- Comprehensive approaches
- Increasing Human resource capacity

How do we establish a model surveillance system in India?

Keeping a count

CARRS SURVEILLANCE STUDY

Features:

- Largest Cohort modeled surveillance study in South Asia
- ***17000 individuals from randomly chosen representative communities of Delhi, Chennai and Karachi ; to be expanded to 32000***
- 20+ years, both genders, stratified for residence and location
- Several demographic, behavioral, anthropometric and blood measurements.
- Huge research platform for young researchers
- Policy implications

Baseline survey and two follow ups in all locations completed

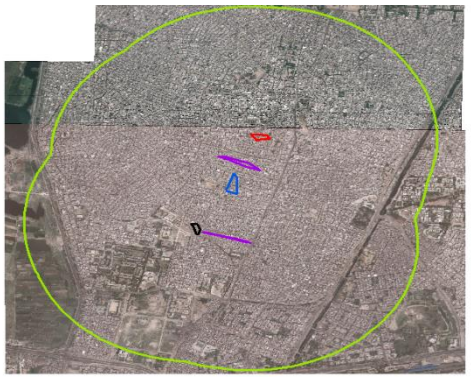
Research platform for young researchers, potential for several publications

CARRS Rural Counterpart: Solan Surveillance Study (SSS)

- Largest rural cohort in India enrolling 40,000 (recruited 25000 individuals as of 28th Feb 2014) participants for cardio-metabolic health morbidity, mortality and related health indicators
- Full blood collection in 8000 subjects
- Led by Centre for Chronic Disease Control, All India Institute of Medical Sciences – 2 collaborating institutions of PHFI – with the support of the Govt. of Himachal Pradesh

CMD and Built Environment : CARRS- GIS

Relate CMD and risk factors with Built Environment factors (Green spaces, Hospitals, Traffic density, Pollution parameters etc) in South Asia.



Overall study plan

Subject data from CARRS
-CMD
-Risk factors
-Health information
-Address for geo-coding
-Demographics

Household location + Neighbourhood landmarks

Geographic Information System (GIS) analysis of CARRS data overlaid on satellite data

Statistical Analysis
-Association of CMD with built environment factors

Spatial methods

- Distance calculations,
- Spatial aggregation,
- Clustering,
- Spatial smoothing and interpolation,
- Spatial regression.

Safraj S

Secondary Prevention

- Low hanging fruit for improving outcomes
- Large scope for improvement
- Role of Polypill (CAD/Stroke/CHF)
- Example of some innovations

CARRS
Translation Trial
Center for cArdiometabolic Risk Reduction in South Asia

CARRS Translation Trial

An open label randomized controlled translation trial to evaluate implementation of low-cost, and sustainable delivery improvement strategies for CVD risk reduction in 1120 diabetes patients in 10 centres in India and Pakistan.

1) Care coordinator (CC) :

- **Coordinate patient care with clinical team**
- **Promote guideline adherence by clinic providers**
- **Facilitate patient follow-up, referrals, and self-care adherence**
- **Advocate for patients**

2) Electronic Health Records-Decision Support Software :

- **Store/track pt. data – web-based**
- **Management prompts**
- **SMS/email reminders - clinical team and patients**

KNOWLEDGE TO ACTION
phfi
PUBLIC HEALTH FOUNDATION OF INDIA

QIP

Trichur ACS study

↓

Kerala ACS Registry

↓

ACS QUIK

Kerala ACS Registry

European Heart Journal Advance Access published September 7, 2012

European Heart Journal
doi:10.1093/eurheartj/ehs219

CLINICAL RESEARCH

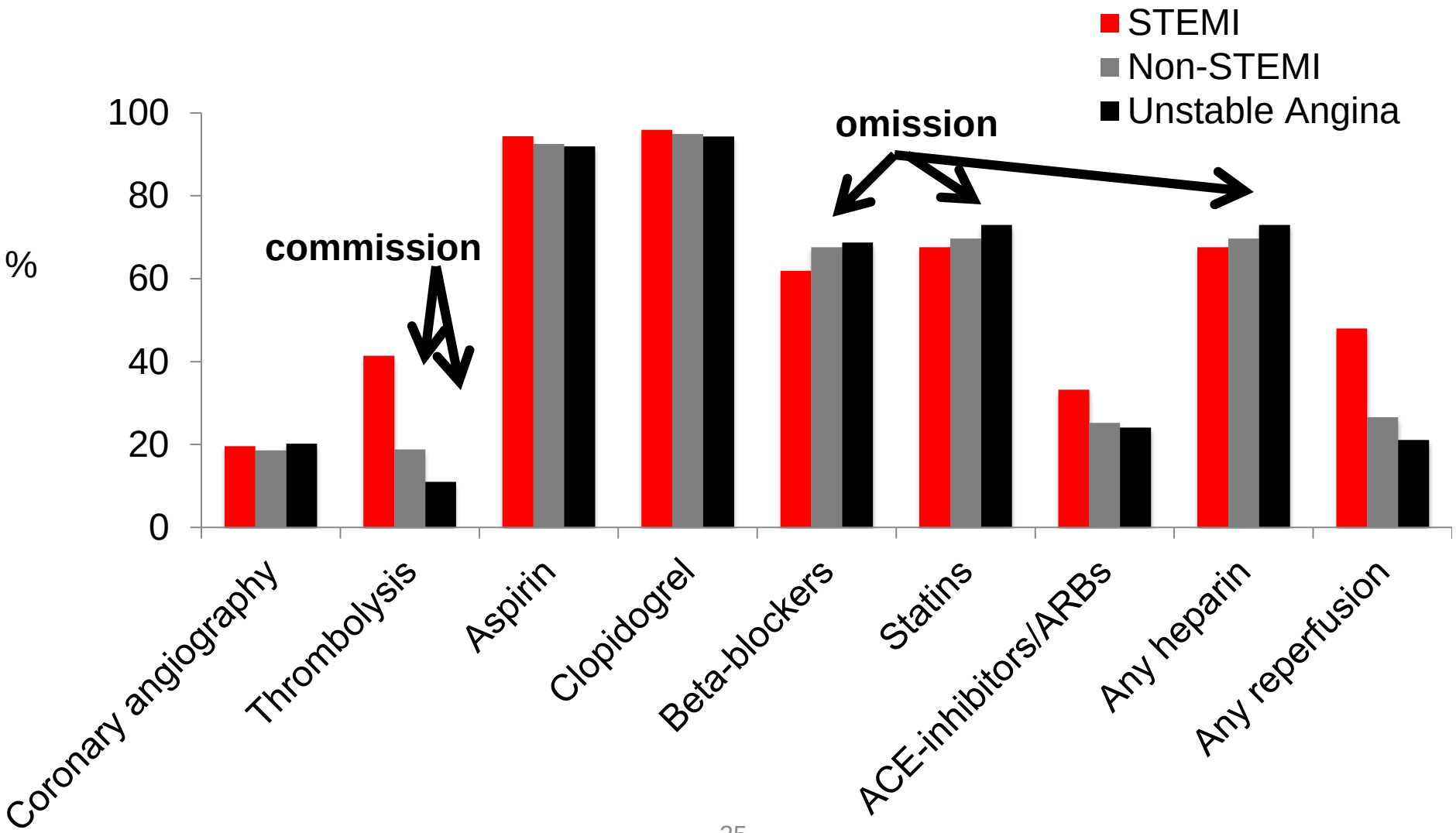
Presentation, management, and outcomes of 25 748 acute coronary syndrome admissions in Kerala, India: results from the Kerala ACS Registry

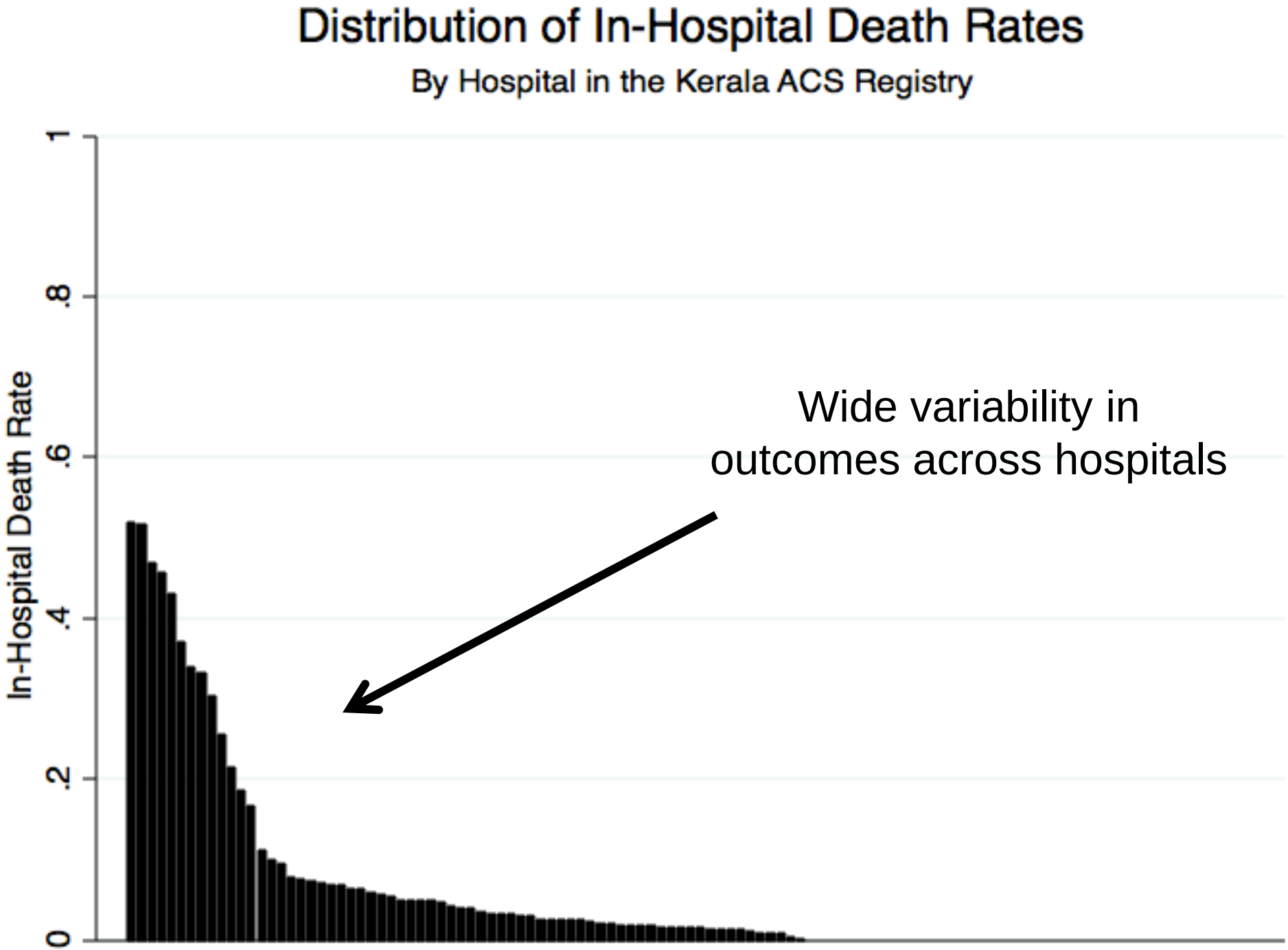
Padinhare Purayil Mohanan[1]*, Rony Mathew[2], Sadasivan Harikrishnan[3], Mangalath Narayanan Krishnan[4], Geevar Zachariah[5], Jhony Joseph[6], Koshy Eapen[7], Mathew Abraham[8], Jaideep Menon[9], Manoj Thomas[10], Sonny Jacob[11], Mark D. Huffman[12], and Dorairaj Prabhakaran[13,14], on behalf of the Kerala ACS Registry Investigators

[1]Department of Cardiology, Westfort Hi-Tech Hospital, Ltd, P.B. No. 930, Punkunnam, Thrissur 680 002

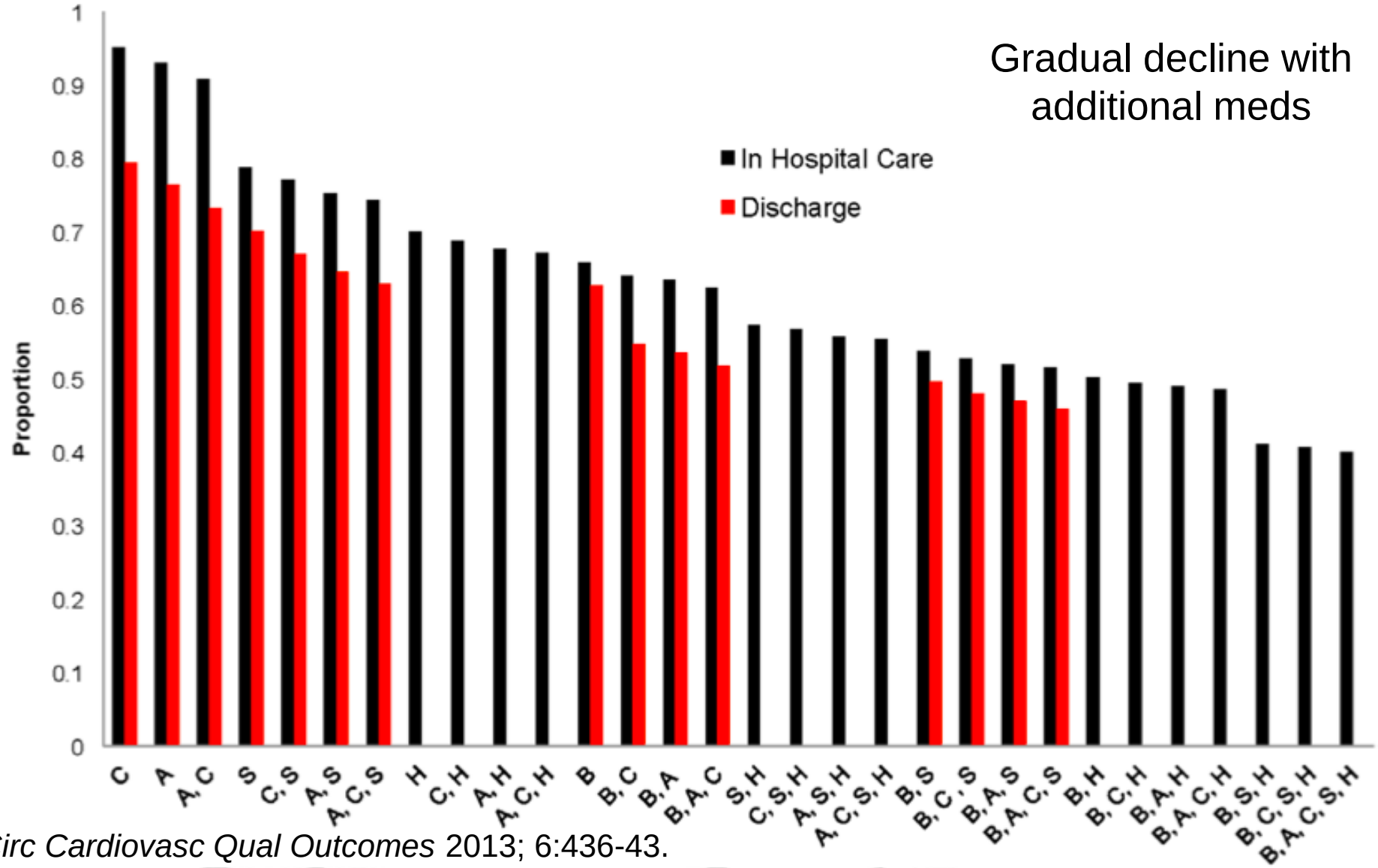
CARDIOLOGICAL SOCIETY OF INDIA
KERALA CHAPTER
Registered under the Societies Act XXI of 1860 (Reg. No. 659/2000)
Website : www.csikerala.org

In-hospital Diagnostics/Treatments




Distribution of In-Hospital Death Rates
By Hospital in the Kerala ACS Registry
In-Hospital Death Rate
0
.2
.4
.6
.8
1
Wide variability in
outcomes across hospitals

In-hospital vs. Discharge Optimal Medical Care



Circ Cardiovasc Qual Outcomes 2013; 6:436-43.

European Heart Journal Advance Access published October 10, 2012

European Heart Journal
doi:10.1093/eurheartj/ehs328

EDITORIAL

Channelling regional registries for optimization of cardiac care: lessons from around the world

Hitinder S. Gurm* and Kim A. Eagle

University of Michigan Cardiovascular Center, 2A394, 1500 E. Medical Center Drive, Ann Arbor, MI 48109-5853, USA

"This registry is a major milestone in both understanding the epidemiology of ACS in Kerala and identifying opportunities for improvement in care."

"The next obvious step is to define and implement improved measures for primary prevention and more evidence-based treatment of ACS."

ACS Quality Improvement in Kerala (ACS QUIK)

- We are leveraging the collaborative strength of the Kerala ACS Registry network to develop a quality improvement program for ACS patients in Kerala
  - First of its kind in India

- Northwestern University ,CSI-Kerala and Centre for Chronic Disease Control (CCDC) partnered to secure grant support from the National Heart, Lung, and Blood Institute to lead a quality improvement randomized clinical trial.

Specific Aim #1

To develop, implement, and evaluate the impact of a quality improvement toolkit on 30-day major adverse cardiovascular event rates following ACS through a *cluster-randomized, stepped wedge* clinical trial.

Specific Aim #2

To evaluate patient-reported 30-day post-ACS health related quality of life using the *Seattle Angina Questionnaire.**

**Generous support from Dr. John Spertus, Paul Chan, and colleagues at the Mid-America Heart Institute (Kansas City).*

Descriptive Aim #3

To describe the individual- and household-level (or *microeconomic) impact* of ACS in the context of evolving health insurance schemes* in India.

**Rastriya Swathya Bima Yojna (RSBY)*

Exploratory Aim #4

To perform focus group discussions with clinicians to define optimal ACS in Kerala and elicit specific facilitators and barriers for development of toolkit components.

Quality Improvement Toolkit Goals

1. Identifying teams at each site prior to trial initiation

2. Target identified areas of improvement from prior research
   1. Inappropriate thrombolysis
   2. Sub-optimal use of inexpensive medications
   3. Minimize delays for decision making, particularly in STEMI patients

3. Adapt with innovative ideas
   1. Inpatient polypill (aspirin, clopidogrel, atorvastatin)?
   2. Bracelet method of risk stratification used by Berwanger?
   3. Other ideas generated through brainwriting?

4. Frequency of feedback: monthly vs. quarterly?

Conclusions

- **ACS QUIK aims to improve in-hospital quality of care in Kerala**
  - **Pre-hospital care**
  - **Post-hospital care**
  - **Other disease states (heart failure, stroke, e.g.)**
  - **Other Indian states**

- **We will collect new information on how ACS affects health related quality of life and individual-/household-level costs**

- **ACS QUIK has the potential to contribute to the larger shift of evaluating the effect of cardiovascular quality improvement interventions using a stronger study design.**

Using Traditional Approaches

Using traditional approaches

- **YogaCare Trial**

- **A clinical trial of yoga-based cardiac rehabilitation programme on cardiovascular health in India**
- **Mechanistic study in UK**
- **4000 patients from 16 hospitals in India**
- **Outcomes: Composite of death, MI & Stroke**

? Yoga Care for Stroke/difficult to treat diabetes

Health Promotion

Innovations in Health Promotion extension to the community

- Diet and lifestyle InterventionS for Hypertension Risk reduction through Anganwadi Workers and Accredited Social Health Activists

Acknowledgement: ICMR

DISHA: ICMR Multicentric Study for BP Management in Underserved Rural Populations

Cluster Randomised Controlled Trial

HP (2), Pondicherry, MP, Maharashtra, Rajasthan, AP, Orissa and Assam

12 AWCs/CEBs selected randomly from respective sites

6 intervention group

6 control group

300 adult participants from each intervention cluster
300*6=1800

300 adult participants from each control cluster
300*6=1800

Intervention Cluster: **INTENSE** intervention through IEC tools at the **individual**, **family** and **community** level. for control of hypertension, diabetes and dyslipidimia. The **GOAL** will be promotion of balanced diet, reduction of salt consumption, tobacco and alcohol consumption, and increasing physical activity. 18 months intervention.
Control Cluster: **USUAL** intervention through IEC tools.

Prabhakaran et al. DISHA Manual. 2012

Comprehensive approaches

- m Wellacre
- UDAY

A Comprehensive Diabetes Prevention and Management Program in India (an example of operational Research)

Project Summary

- UDAY aims to implement and evaluate multi-component, multi-level, interventions, with the overarching goal to prevent, detect, reduce the risk of diabetes and hypertension and to improve management of individuals with either of the conditions

- Location: Vizag (South India) and Sonipat (North India)

- Population: Adults aged ≥30 years in urban and rural sub-sites, each with a population of approximately 1,00,000 people, yielding a total population of 4,00,000

Objectives and Research Questions

- Principal Research Question: Will a multi-component, multi-level comprehensive intervention program improve the prevention, detection and management of diabetes and hypertension in the selected study sites?

Impact Indicators

Increase over baseline in levels of:

- the public's awareness and knowledge about diabetes and hypertension **General Population**
- those aware, diagnosed, treated and controlled to targets **Patients**
- the use of guideline based management by providers leading to improved outcomes **Providers**
- access to care, adherence to treatment, conformity to IPHS recommendations **Health System/Policy Makers**

Key Innovations

Best Practices	Approach	Target
Prevention, early detection and referral	Social marketing, health promotion, screening	400,000 population
Capacity building, task shifting of healthcare providers	CME, short trainings, distance learning, QIP	Providers
Early diagnosis and prevention of complications	Registry	10,000 patients
m-Health system	Electronic data system +DSS	400,000 population
Electronic data capture	Tablet based surveys	12000 (base and endline)
Improved access by social marketing initiatives	Quality of service	300 pharmacists
Culturally tailored patient education and patient networks for enabling self care	Utilizing health workers	Patients

Registry and Quality Improvement Program

- ~ 20 Hospitals in 2 study sites
- Register ~ 10000 people with diabetes
- Assess patient characteristics, treatments and outcomes
- Implement QIP for improving diabetes and hypertension detection and management
- QIP -
  - standard baseline risk assessment directed at detection of diabetes and hypertension
  - initiation of guideline based non-pharmacological and pharmacological therapy
  - measures of follow up and referral

Staff Training

Some learnings

- Extensive local stakeholder and community engagement required to drive implementation and acceptability of the project
  - Regular meetings with RWAs ,Sarpanches, key district health personnel
  - WDD events in both sites in partnership with district healthcare system and community participation
  - Recruitment from community
- Alignment with key local health system personnel and priorities
- High level of support and acceptance given the local epidemiological situation vis-à-vis disease burden and inadequate prevention and control
- Forging good working relationship with partner organizations

WDD Sonipat

- 175 people (health authorities, members of local organizations; Inner wheel, Senior citizens club, Rotary Club, Chemist Association, Bharat Vikas Parishad community, and media)
- Van based folk theatre show on diabetes, pledge to adopt healthy lifestyle, release of blue balloons , educational pamphlets

WDD Vizag Urban

- Walk on beach road flagged off by Vice Chancellor, Andhra University
- Pledge to adopt healthy lifestyle
- Educational pamphlets

What are the new methods that need to be incorporated in research to achieve 25/25 goals

- Qualitative research
- Adaptive designs; demonstration projects
- Advances in Statistical analysis (multi level modeling)
- Contextualization of research particularly incorporating social determinants
- Incorporating newer technologies (eg GIS)
- EWAS (cf GWAS)
- True partnerships vs “Collaboration”

Increasing and improving Human Resource capacity

Capacity building outcomes: A snap shot

CAPACITY BUILDING

Interdisciplinary research training: NCD epi and Prev. in India

Fogarty : FICRS (F)

ASCEND

SHARE

PH Leaders

Short courses : Nutrition; research methods; leadership; others

Training in clinical areas

Certificate Course in Evidence Based Diabetes Management (CCEBDM)

- **Objective:** To develop core skills and competencies in primary care physicians for the practice of evidence based diabetes management and establish networks between primary care physicians and existing specialized diabetes care centers in India.

- **Key Features:** 12 modular course, once a month contact session on designated Sunday, executive on-job training, 1:10-12 class ratio, latest and updated course curriculum taught by selected regional Faculty.

SYNOPSIS OF CCEBDM CYCLE – I, II, III

Cycle I launched on 8th Aug, 2010

- 18 States, 57 Cities,
- 100 Centers
- 15 National Expert,
- 128 Regional Faculty, 61 Observers
- 1208 Participants

Cycle II launched on 11th Dec, 2011

- 19 States, 65 Cities,
- 119 Centers
- 15 National Expert,
- 149 Regional Faculty, 84 Observers
- 1568 Participants

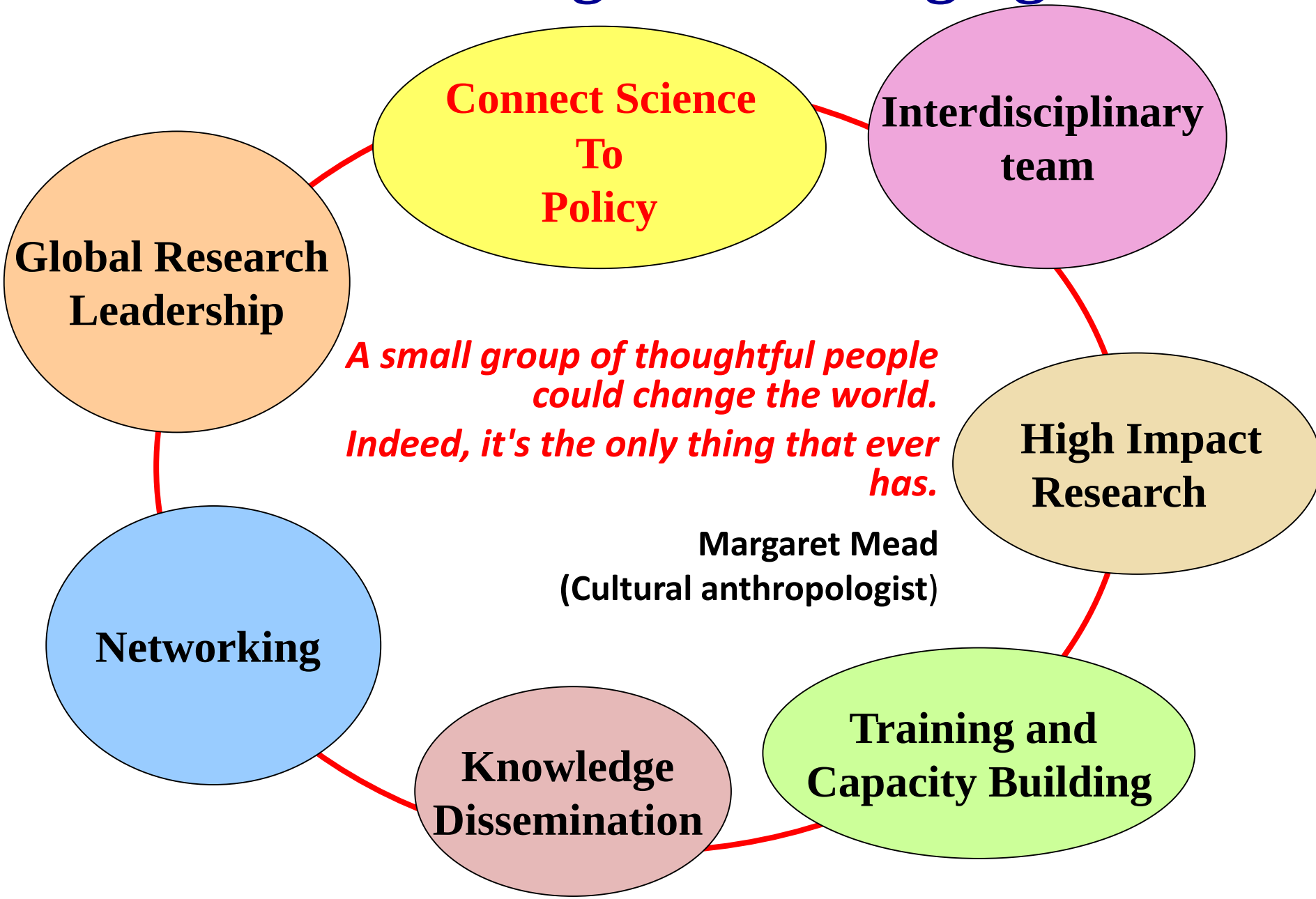
Cycle III launched on 24th Feb, 2013

- 19 States, 73 Cities,
- 134 Centers
- 15 National Expert,
- 164 Regional Faculty
- 2306 Participants

Others

Certificate Course in GDM (~ 2500)	Advanced Certificate Course in Prevention and Management of Diabetes & Cardiovascular Risk	Certificate Course in Hypertenison and Thyroid disorders

What are the strengths of emerging leaders ?



A small group of thoughtful people could change the world.

Indeed, it's the only thing that ever has.

Margaret Mead
(Cultural anthropologist)