Developing research capacity for implementation science: St. John's Experience

WHF-EL 2016

Dr. Denis Xavier MD, MSc (Clin Epi & Biostats)

Vice-Dean (PG)

Professor and Head, Dept. of Pharmacology,

St. John's Medical College

Head, Division of Clinical Research &Training,

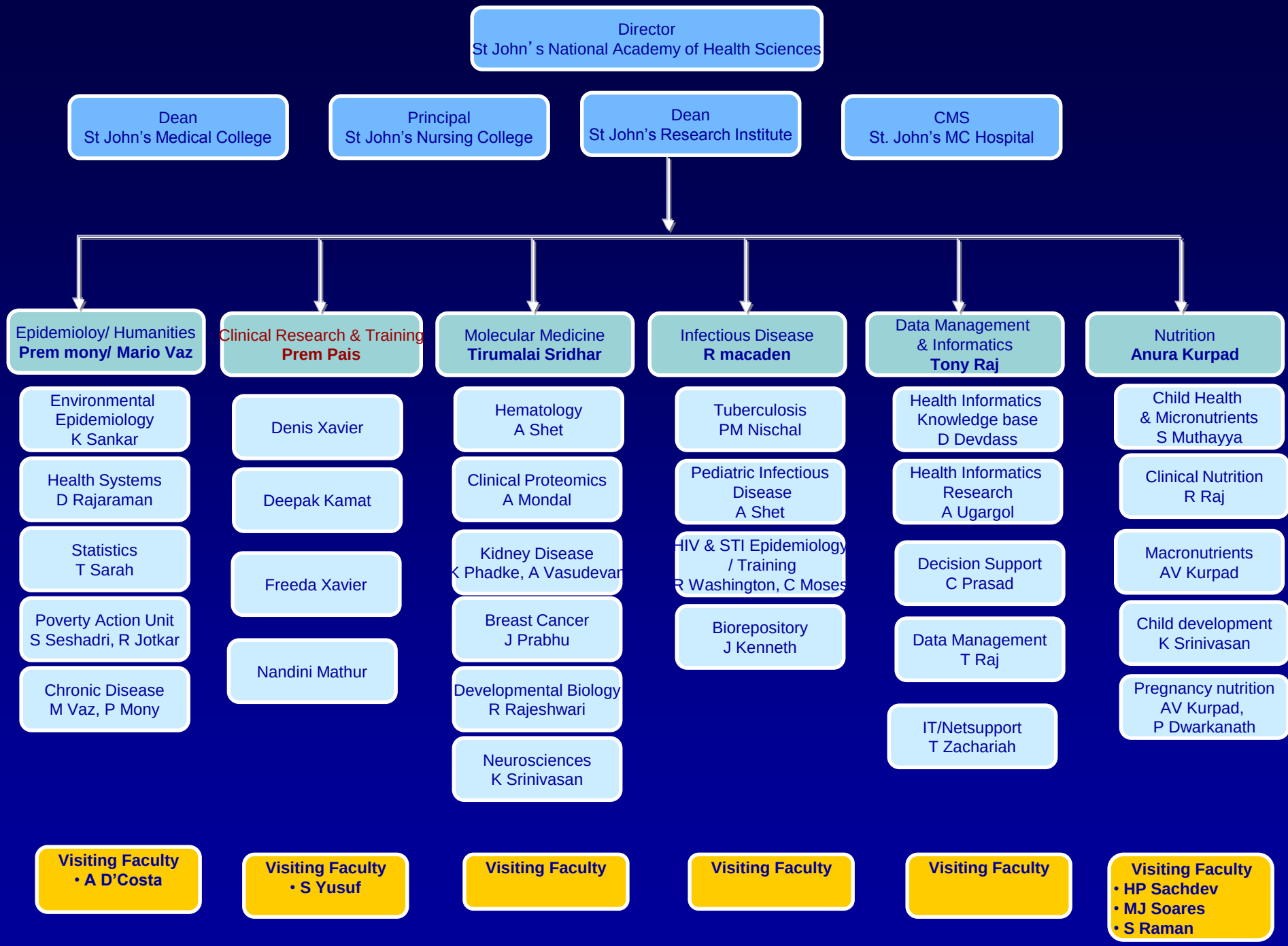
St. John's Research Institute

Outline

- Introduction to St. John’s
- Our research questions
- Studies completed
- Research training
- Our contributions

History of St John's

- 1963 – St John's Medical College
- 1975 – St John's Hospital
- 1989 – St John's College of Nursing
- 2004 - St John's Research Institute


Director
St John's National Academy of Health Sciences
Dean
St John's Medical College
Principal
St John's Nursing College
Dean
St John's Research Institute
CMS
St. John's MC Hospital
Epidemioloy/ Humanities
Prem mony/ Mario Vaz
Environmental Epidemiology
K Sankar
Health Systems
D Rajaraman
Statistics
T Sarah
Poverty Action Unit
S Seshadri, R Jotkar
Chronic Disease
M Vaz, P Mony
Visiting Faculty
• A D'Costa
Clinical Research & Training
Prem Pais
Denis Xavier
Deepak Kamat
Freeda Xavier
Nandini Mathur
Visiting Faculty
• S Yusuf
Molecular Medicine
Tirumalai Sridhar
Hematology
A Shet
Clinical Proteomics
A Mondal
Kidney Disease
K Phadke, A Vasudevan
Breast Cancer
J Prabhu
Developmental Biology
R Rajeshwari
Neurosciences
K Srinivasan
Visiting Faculty
Infectious Disease
R macaden
Tuberculosis
PM Nischal
Pediatric Infectious Disease
A Shet
HIV & STI Epidemiology / Training
R Washington, C Moses
Biorepository
J Kenneth
Visiting Faculty
Data Management & Informatics
Tony Raj
Health Informatics Knowledge base
D Devdass
Health Informatics Research
A Ugargol
Decision Support
C Prasad
Data Management
T Raj
IT/Netsupport
T Zachariah
Visiting Faculty
Nutrition
Anura Kurpad
Child Health & Micronutrients
S Muthayya
Clinical Nutrition
R Raj
Macronutrients
AV Kurpad
Child development
K Srinivasan
Pregnancy nutrition
AV Kurpad,
P Dwarkanath
Visiting Faculty
• HP Sachdev
• MJ Soares
• S Raman

Division of
Clinical Research & Training

Our Staff

- Medical 6
  - Prem Pais, Denis Xavier, Deepak Kamath
  - Padmini Devi, Atiya Faruqui, Mangala Rao
- Technical Staff 18
  - Freeda Xavier, Nandini Mathur, Preeti Girish, Nisha George, Usha KT, Deepthi KB, Remya, Susan Thomas, Sangeeta Roy, Hemalata, Kuldeep Sharma, Swamy GM, Sherin G, Sangeeta Domingo, Nidhi, jinsy, Sangeetha P
- Support Staff : 3
  - Rajan C, Jagadish, Radha

A brief history

- Early 1990's
  - Dr. Prem Pais – CERTC
  - Collaborations with Dr. Salim Yusuf, Canada
  - SY: Donation $500,000 to St. John's research
  - First report of risk factors for heart attack in Indians – Lancet 1996
- Late 1990's
  - ICMR task force study → INTERHEART
  - Denis Xavier – Joined in 1997
- 1999 – CREATE studies
  - First large academic network CVD in India

Evolution of our Research Questions

- In all regions of India:

1. What is the burden of heart disease & strokes?
2. What is causing them?
3. How are they treated and their outcomes?
4. How can we treat them better?
5. How can we change health systems to prevent and better treat them?
6. How to reach best systems to our people?

AREAS OF OUR WORK

- Observational studies
  - Cross-sectional Cohort, Case Control, Registries
- Clinical Trials
- Guidelines Development
- Health Policy & Advocacy
- Training
  - Health Professionals
  - Research Support Staff

CREATE Registry

Treatment and outcomes of acute coronary syndromes in India (CREATE): a prospective analysis of registry data

Denis Xavier, Prem Pais, P J Devereaux, Changchun Xie, D Prabhakaran, K Srinath Reddy, Rajeev Gupta, Prashant Joshi, Prafulla Kerkar, S Thanikachalam, K K Haridas, T M Jaison, Sudhir Naik, A K Maity, Salim Yusuf; on behalf of the CREATE registry investigators*

Lancet 2008; 371: 1435–42

See Comment page 1394

*Investigators listed at end of paper

Summary

Background India has the highest burden of acute coronary syndromes in the world, yet little is known about the treatments and outcomes of these diseases. We aimed to document the characteristics, treatments, and outcomes of patients with acute coronary syndromes who were admitted to hospitals in India.

Interpretation Patients in India who have acute coronary syndromes have a higher rate of STEMI than do patients in developed countries. Since most of these patients were poor, less likely to get evidence-based treatments, and had greater 30-day mortality, reduction of delays in access to hospital and provision of affordable treatments could reduce morbidity and mortality.

Funding Division of Clinical Trials, St John's Research Institute, Bangalore, India; Population Health Research Institute (PHRI), McMaster University, Canada; Sanofi-Aventis India.

Coronary artery disease in India: challenges and opportunities

Although cardiovascular disease is the leading cause of death worldwide, its epidemic shows remarkable geographic variation. While the mortality associated with

the registry data from developed countries. The use of lipid-lowering treatments, β blockers, and angiotensin-converting-enzyme inhibitors was low, and few patients

Kim Eagle
Division of Cardiology, University of Michigan Medical Center, Ann Arbor, MI 48109, USA
keagle@umich.edu

coronary syndrome. Widespread use of these drugs in the hospital and discharge from hospital has been the major driver of improved outcomes in acute coronary syndrome in developed countries,[9] and initiatives to enhance quality through consistent delivery of these therapies can achieve remarkable improvements in survival.[10]

On average, these strategies are not expensive. Most of the decline in coronary mortality in the USA is believed to be secondary to improving risk-factor profiles, and effective primary and secondary treatments of acute

This registry is a major milestone, since it provides the first comprehensive view of the epidemic of acute coronary syndrome in India and helps to identify opportunities for improvement in care. As the Indian economy grows, there is a possibility for further increase in cardiovascular disease before we see a decline similar to that being witnessed in developed countries. Major

A problem well defined is half solved. Xavier and colleagues need to be commended for defining the challenges pertinent to the treatment of acute coronary syndrome in India. The next obvious step is to define and implement improved measures for primary prevention and more evidence-based treatment of acute coronary syndrome.

CSI CARDIAC PREVENT 2015

NATIONAL CONFERENCE ON HEART DISEASE PREVENTION

Preventive Council, Cardiological Society of India

25TH – 27TH SEP 2015
TAJ PALACE
SARDAR PATEL MARG, DIPLOMATIC ENCLAVE
NEW DELHI - 110 021, INDIA.

ON THE THEME

Innovative Approaches in CVD Prevention

- Smart phones EMPOWERedwith Decision Support System (DSS) in prevention
- PREPARingfor primary prevention
- SPREADingthe message of secondary prevention
- Innovations in prevention of diabetes

Session on 25 September 2.50 PM

REGISTER HERE

SJRI: DCRT studies (Nov 2015)

Designed / coordinated since 1999

- CVD Obs epidemiology [~30,000]
  - ICMR-National C-C in AMI [2,600]
  - INTERHEART [950] [Lancet-04-07]
  - CREATE ACS Registry [~20,500] [Lancet-08]
  - INTERSTROKE [4,000] [LANCET 2010]
- Large Clinical Trials
  (170+ institutions, 60 cities >25,000)
  - CREATE, 8,060, [JAMA-04, AHJ-04]
  - POISE, 777 [Lancet-08]
  - PRoFESS, 1,620,[NEJM-08]
  - OASIS 5, 544[NEJM-06]
  - OASIS 6, 1,450 [JAMA-07]
  - CURRENT, 2300+ [Lancet-10]
  - VITATOPS, 1450+ [Lancet-N-10]
  - RELY, 650 [NEJM - 09]
  - POLYCAP, 2053 **[ACC' 09,**Lancet' 09**]**
  - AVVEROES, 200 [NEJM 2011]
  - ARISTOTLE, 650 [NEJM 2011]
  - OASIS-8, 500 [JAMA 2010]
  - APPRAISE – 500 [NEJM 2011]
  - RIVAL – 500 [Lancet-11]
  - HOPE-3, 2,822 [Can J Card 2015]
  - MARS – 400 [Blood Pressure 2011]
  - ASPIRE, 400 [NEJM -2014]
  - RECREATE, 250 [Diab Care 2011]
  - RELY AF Registry, 2,450 [completed]
  - TIPS-K [Circl Res 2012]
  - FRIENDS-BLR-1,450 [completed]
  - POISE-2 – 1,000 [NEJM]
  - NHLBI- UH projects
    - INSPIRE – 11,001
    - SPREAD - 806
    - PREPARE – 8,615
  - TIPS-3 (Wellcome)- 2,000
  - VISION - 2,000
  - MACE – 2,000
  - SPECTRUM – 1,350
  - ODYSSEY – 650
  - DECLARE – 500
  - SPIRE – 600
  - MANAGE – 300
  - PROGRESS – 3,000
- Studies to initiate
  - DIAMOND – 10,000
  - INFORM – 5,000
  - FRIENDS INDIA- 2,000
  - ENHANCE - 200
  - COMPASSION – 1,000
  - CKD - 850

DCRT SUMMARY

- Studies:
  - Completed: 26; Subjects: ~55,000
  - Ongoing: 9; Subjects: ~30,000
  - To initiate: 8; Subjects: ~20,000
- Publications
  - Total: ~80
    - Lancet- 10
    - NEJM- 9
    - JAMA- 5
    - Am H J - 6
    - Lancet Neurol/DE- 3
    - Circulation- 2

Risk factors for acute myocardial infarction in Indians: a case-control study

Lancet 1996; **348:** 358–63

Prem Pais, J Pogue, H Gerstein, E Zachariah, D Savitha, S Jayprakash, P R Nayak, Salim Yusuf

Summary

Background South Asians who have settled overseas and those in urban India have an increased risk of ischaemic

beedis (a local form of tobacco), with individuals who currently smoked 10 or more per day having an OR of 6·7 ($p<0·001$). History of hypertension and of overt diabetes mellitus were also independent risk factors (OR 2·69

Effects of Reviparin, a Low-Molecular-Weight Heparin, on Mortality, Reinfarction, and Strokes in Patients With Acute Myocardial Infarction Presenting With ST-Segment Elevation

The CREATE Trial Group Investigators*

APPROXIMATELY 15.5 MILLION cardiovascular deaths occur every year.[1] Of these, about half are likely to be due to

Context Although reperfusion therapy, aspirin, β-blockers, and angiotensin-converting enzyme inhibitors reduce mortality when used early in patients with acute myocardial infarction (MI), mortality and morbidity remain high. No antithrombotic or newer antiplatelet drug has been shown to reduce mortality in acute MI.

Objective To evaluate the effects of reviparin, a low-molecular-weight heparin, when initiated early and given for 7 days in addition to usual therapy on the primary com-

Journal of Human Hypertension (2012), 1–7

www.nature.com/jhh

REVIEW

Prevalence, risk factors and awareness of hypertension in India: a systematic review

P Devi[1,2], M Rao[1,2], A Sigamani[1,2], A Faruqui[1,2], M Jose[1], R Gupta[3], P Kerkar[4], RK Jain[5], R Joshi[6,14], N Chidambaram[7], DS Rao[8], S Thanikachalam[9], SS Iyengar[10], K Verghese[11], V Mohan[12], P Pais[2,13] and D Xavier[1,2]

Indians have high rates of cardiovascular disease. Hypertension (HTN) is an important modifiable risk factor. There are no comprehensive reviews or a nationally representative study of the burden, treatments and outcomes of HTN in India. A systematic

Systematic Review

Prevalence, treatments and outcomes of coronary artery disease in Indians: A systematic review

Mangala Rao [a,b], Denis Xavier [c,d,*], Padmini Devi [a,b], Alben Sigamani [a,b], Atiya Faruqui [a,b], Rajeev Gupta [e], Prafulla Kerkar [f], Rajendra Kumar Jain [g], Rajnish Joshi [h], N. Chidambaram [i], Daya Sagar Rao [j], S. Thanikachalam [k], S.S. Iyengar [l], Kiron Verghese [m], V. Mohan [n], Prem Pais [b]

[a] Department of Pharmacology, St. John's Medical College, Bangalore, India

[b] Division of Clinical Research and Training, St. John's Research Institute, Bangalore, India

Blood Pressure, 2011; Early Online, 1–8

ORIGINAL ARTICLE

Effect of fixed dose combinations of metoprolol and amlodipine in essential hypertension: MARS – A randomized controlled trial

PADMINI DEVI[1,2], DENIS XAVIER[1,2], ALBEN SIGAMANI[1,2], SUDHANSHU PANDEY[3], TINKU THOMAS[4], SREENIVAS MURTHY[5], KAMAL SHARMA[6], BALRAJ BOSCO[7], KETAN MEHTA[8], SINDHU JOSHI[9], RAJEEV GUPTA[10], GIRIJA SINGH[11], JAGADISH HIREMATH[12], CHADHA DS[13], ASHOKAN NAMBIAR[14] & PREM PAIS[2,11]

[1]*Department of Pharmacology, St John's Medical College, Bangalore, India,* [2]*Division of Clinical Trials, St John's Research Institute, Bangalore, India,* [3]*AstraZeneca, Bangalore, India,* [4]*Epidemiology and Biostatistics Unit, St John's*

Rationale and design of a randomized controlled trial evaluating community health worker–based interventions for the secondary prevention of acute coronary syndromes in India (SPREAD)

Deepak Y. Kamath, MD,[a] Denis Xavier, MD, MSc,[a] Rajeev Gupta, MD, PhD,[b] P. J. Devereaux, MD, PhD,[c] Alben Sigamani, MD,[a] Tanvir Hussain, MD,[d] Sowmya Umesh, DNB,[e] Freeda Xavier, MSc,[a] Preeti Girish, MSc,[a] Nisha George, MSc,[a] Tinku Thomas, PhD,[f] N. Chidambaram, MD,[g] Rajnish Joshi, MD,[h] Prem Pais, MD,[a] and Salim Yusuf, DPhil, FRCPC[i]
Bengaluru, Rajasthan, India; Ontario, Canada; Baltimore, MD; Tamil Nadu, and Bhopal, India

Background There is a need to evaluate and implement cost-effective strategies to improve adherence to treatments in coronary heart disease. There are no studies from low- to middle income countries (LMICs) evaluating trained community health worker (CHW)–based interventions for the secondary prevention of coronary heart disease.

Effects of a polypill (Polycap) on risk factors in middle-aged individuals without cardiovascular disease (TIPS): a phase II, double-blind, randomised trial

*The Indian Polycap Study (TIPS)**

Summary

Background The combination of three blood-pressure-lowering drugs at low doses, with a statin, aspirin, and folic acid (the polypill), could reduce cardiovascular events by more than 80% in healthy individuals. We examined the

Published Online
March 30, 2009

VIEWPOINT

www.nature.com/clinicalpractice/cardio

Focus on the polypill

The need to test the theories behind the Polypill: rationale behind the Indian Polycap Study

Denis Xavier,* Prem Pais, Alben Sigamani, Janice Pogue, Rizwan Afzal and Salim Yusuf, on behalf of The Indian Polycap Study (TIPS) Investigators

D Xavier is Professor and Head of Department,

Antihypertensive, lipid-lowering and antiplatelet drugs are proven to reduce cardiovascular disease (CVD) events when used in primary and secondary

randomized, controlled trials that evaluated the effect of using folic acid to lower homocysteine levels showed no improvement in treated

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

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The Polypill in the Prevention of Cardiovascular Diseases

Key Concepts, Current Status, Challenges, and Future Directions

Eva Lonn, MD, MSc; Jackie Bosch, MSc; Koon K. Teo, MD, PhD; Prem Pais, MD;
Denis Xavier, MD; Salim Yusuf, MBBS, DPhil

Circulation
Cardiovascular Quality and Outcomes

American Heart Association®

Comparison of Risk Factor Reduction and Tolerability of a Full-Dose Polypill (With Potassium) Versus Low-Dose Polypill (Polycap) in Individuals at High Risk of Cardiovascular Diseases: The Second Indian Polycap Study (TIPS-2) Investigators

Salim Yusuf, Prem Pais, Alben Sigamani, Denis Xavier, Rizwan Afzal, Peggy Gao and Koon K. Teo

Circ Cardiovasc Qual Outcomes. 2012;5:463-471; originally published online July 10, 2012;
doi: 10.1161/CIRCOUTCOMES.111.963637

EUROPEAN SOCIETY OF CARDIOLOGY®

European Heart Journal
doi:10.1093/eurheartj/eht407

REVIEW

Controversies in cardiovascular medicine

Combination pharmacotherapy to prevent cardiovascular disease: present status and challenges

Working Group on the Summit on Combination Therapy for CVD†

Journal of Human Hypertension (2012), 1–7

www.nature.com/jhh

REVIEW

Prevalence, risk factors and awareness of hypertension in India: a systematic review

P Devi[1,2], M Rao[1,2], A Sigamani[1,2], A Faruqui[1,2], M Jose[1], R Gupta[3], P Kerkar[4], RK Jain[5], R Joshi[6,14], N Chidambaram[7], DS Rao[8], S Thanikachalam[9], SS Iyengar[10], K Verghese[11], V Mohan[12], P Pais[2,13] and D Xavier[1,2]

Indians have high rates of cardiovascular disease. Hypertension (HTN) is an important modifiable risk factor. There are no comprehensive reviews or a nationally representative study of the burden, treatments and outcomes of HTN in India. A systematic

Risk factors for ischaemic and intracerebral haemorrhagic stroke in 22 countries (the INTERSTROKE study): a case-control study

*Martin J O'Donnell, Denis Xavier, Lisheng Liu, Hongye Zhang, Siu Lim Chin, Purnima Rao-Melacini, Sumathy Rangarajan, Shofiqul Islam, Prem Pais, Matthew J McQueen, Charles Mondo, Albertino Damasceno, Patricio Lopez-Jaramillo, Graeme J Hankey, Antonio L Dans, Khalid Yusoff, Thomas Truelsen, Hans-Christoph Diener, Ralph L Sacco, Danuta Ryglewicz, Anna Czlonkowska, Christian Weimar, Xingyu Wang, Salim Yusuf, on behalf of the INTERSTROKE investigators**

Background The contribution of various risk factors to the burden of stroke worldwide is unknown, particularly in countries of low and middle income. We aimed to establish the association of known and emerging risk factors with

Published Online
June 18, 2010
DOI:10.1016/S0140-

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 SEPTEMBER 17, 2009 VOL. 361 NO. 12

Dabigatran versus Warfarin in Patients with Atrial Fibrillation

Stuart J. Connolly, M.D., Michael D. Ezekowitz, M.B., Ch.B., D.Phil., Salim Yusuf, F.R.C.P.C., D.Phil., John Eikelboom, M.D., Jonas Oldgren, M.D., Ph.D., Amit Parekh, M.D., Janice Pogue, M.Sc., Paul A. Reilly, Ph.D., Ellison Themeles, B.A., Jeanne Varrone, M.D., Susan Wang, Ph.D., Marco Alings, M.D., Ph.D., Denis Xavier, M.D., Jun Zhu, M.D., Rafael Diaz, M.D., Basil S. Lewis, M.D., Harald Darius, M.D., Hans-Christoph Diener, M.D., Ph.D., Campbell D. Joyner, M.D., Lars Wallentin, M.D., Ph.D., and the RE-LY Steering Committee and Investigators*

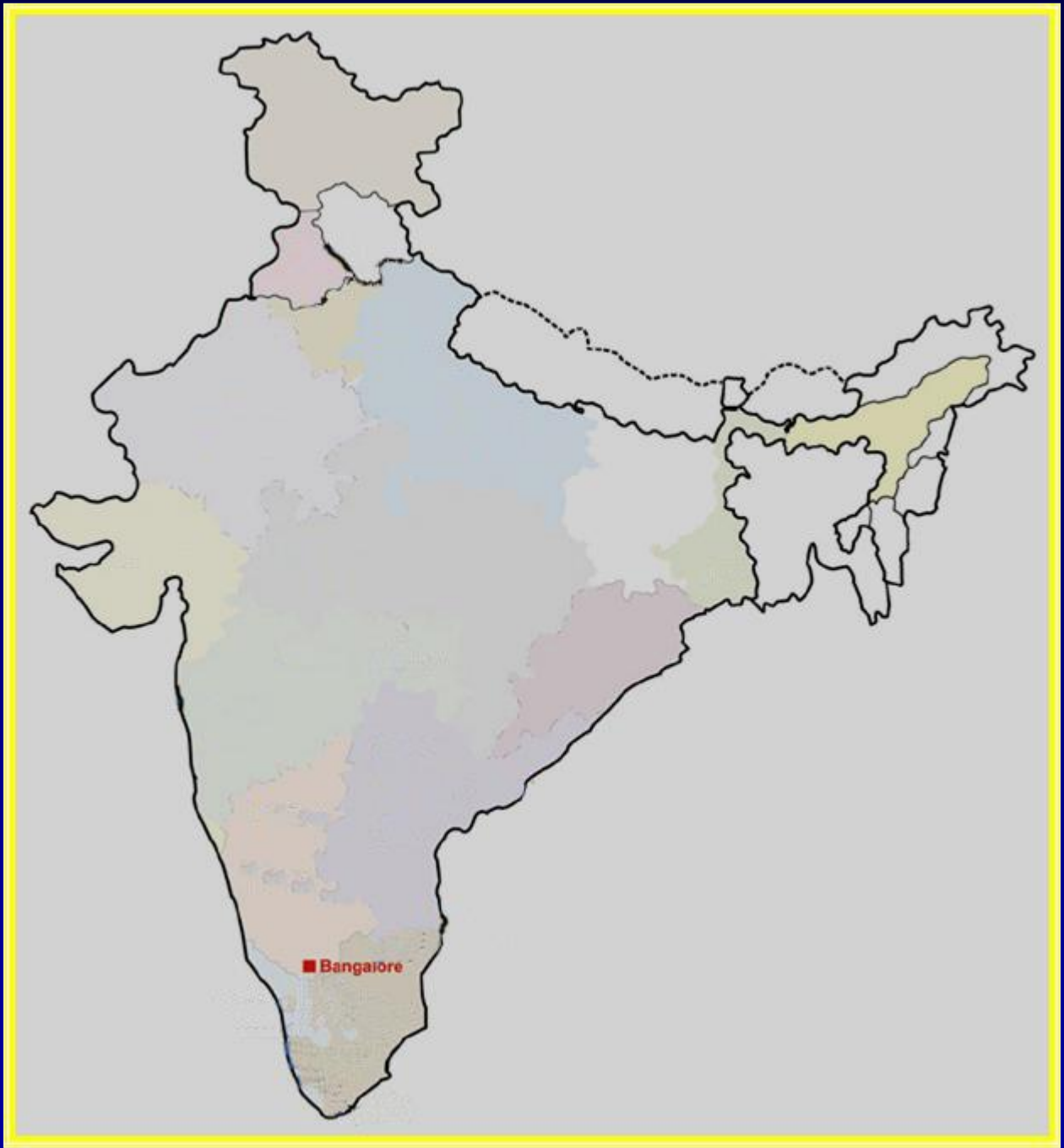
The NEW ENGLAND JOURNAL of MEDICINE

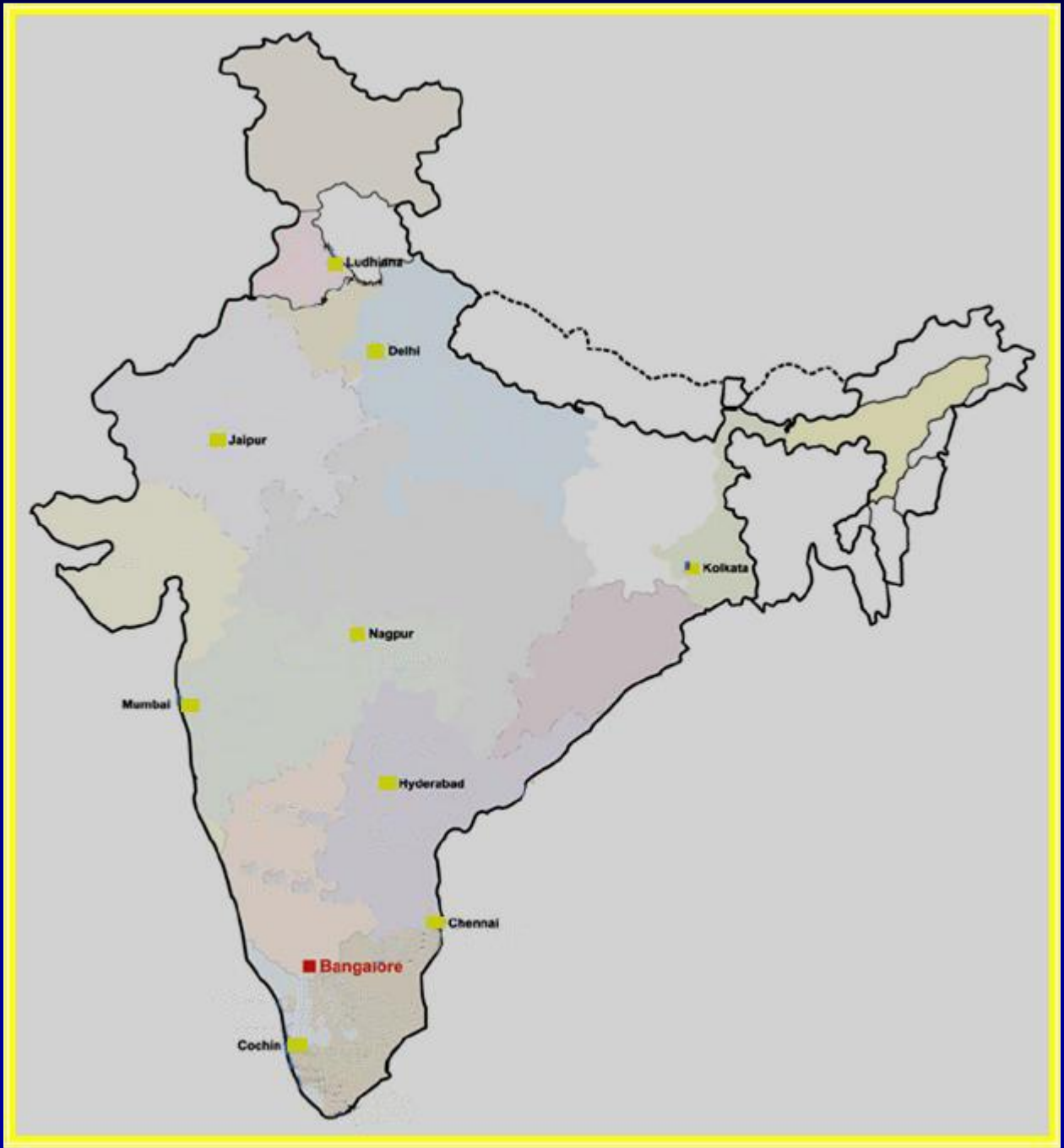
ORIGINAL ARTICLE

Low-Dose Aspirin for Preventing Recurrent Venous Thromboembolism

Timothy A. Brighton, M.B., B.S., John W. Eikelboom, M.B., B.S., Kristy Mann, M.Biostat., Rebecca Mister, M.Sc., Alexander Gallus, M.B., B.S., Paul Ockelford, M.B., Harry Gibbs, M.B., Wendy Hague, Ph.D., Denis Xavier, M.Sc., Rafael Diaz, M.D., Adrienne Kirby, M.Sc., and John Simes, M.D., for the ASPIRE Investigators*

How did we build a large network


Bangalore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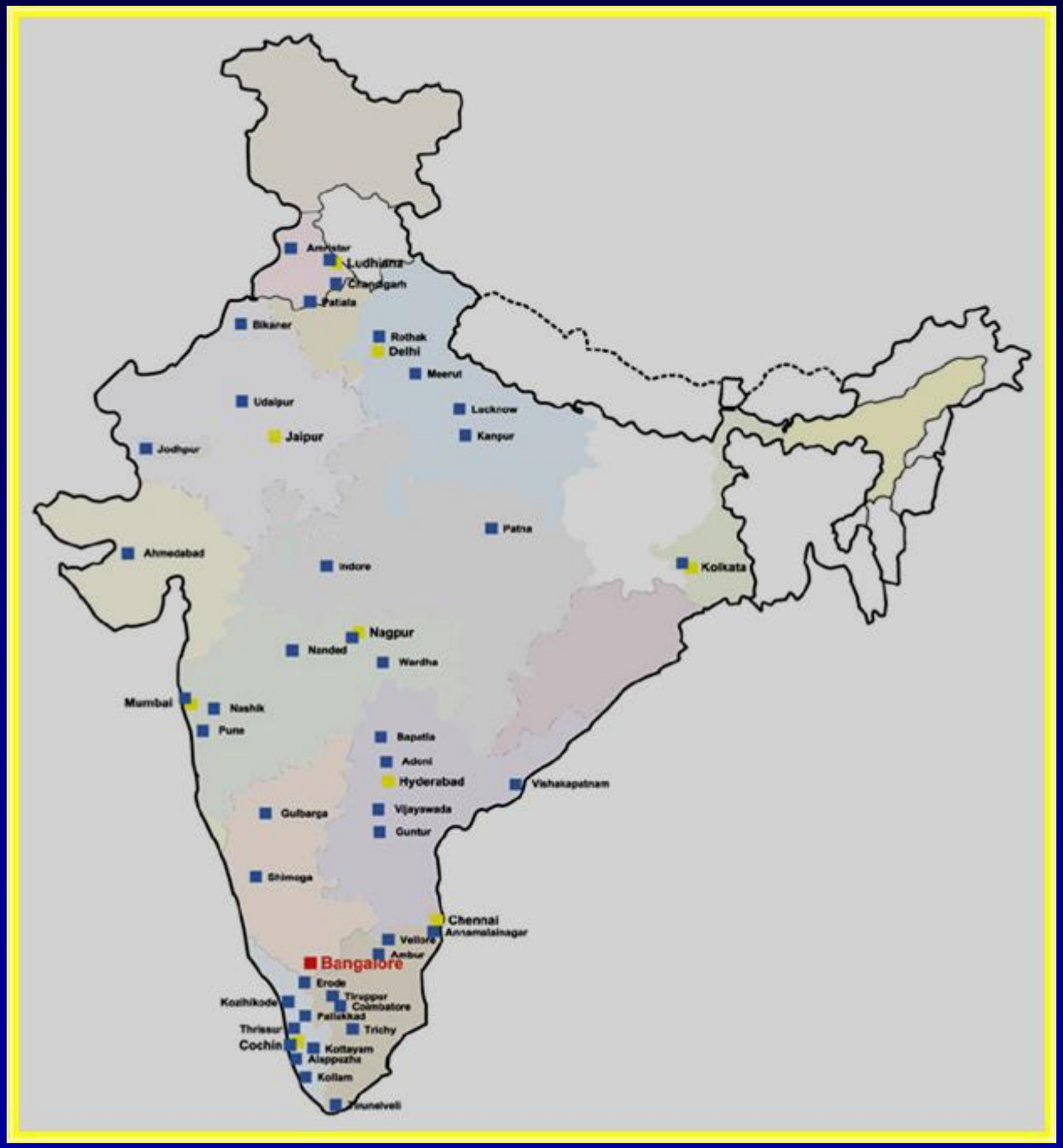
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Patna
Ahmedabad
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Hyderabad
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Vellore
Ambur
Bangalore
Erode
Tiruppur
Kozhikode
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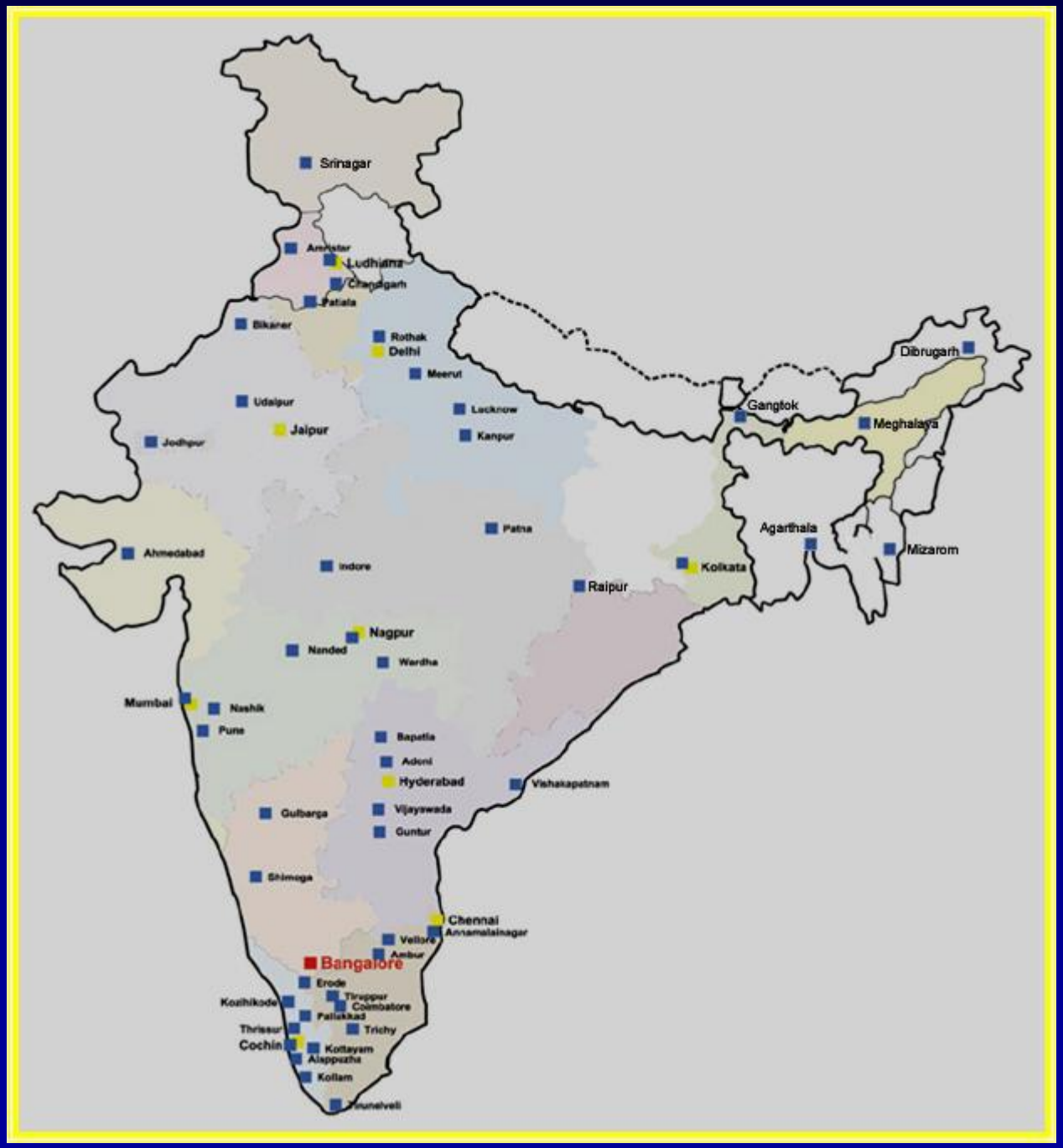
Alappuzha
Kollam
Tirunelveli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Nashik
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Hyderabad
Vishakapatnam
Gulbarga
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Chennai
Annamalainagar
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Ambur
Bangalore
Erode
Tiruppur
Kozhikode
Coimbatore
Palakkad
Thrissur
Trichy
Cochin
Kottayam
Alappuzha
Kollam
Tirunelveli

What we have done in 15 years

- Large network of clinical investigators
  - 180+ across the country.
- Team of trained & experienced coordinators and research assistants
  - Capacity to coordinate large multicentre global clinical trials
- Regulatory – DCGI, ICMR and HMSC, UK-MRC, NIH

What we have done in 15 years

- IP handling – Importation, storage, redistribution & accounting
- Data management
  - Develop Case Report Forms
  - Set up database
  - Handle data from over 100 sites
    - receive forms, enter data, generate queries, resolve queries, rolling database lock

NIH-UH – Center of Excellence 2008-2014

- CVD prevention and capacity building in developing countries
- One of 11 Centers globally
- ~US$4.5 million
- 3 Knowledge Translation Studies
  - CVD Prevention and Stroke Registry
  - 185 researchers / support staff in India
- 6 training programs
  - ~200 trained


National Public Health Institute of Helsinki
McMaster Univ
Harvard Med
Johns Hopkins Univ
U.S.-Mexico Border
RAND
Whittier Institute
Univ Arizona
Univ Texas
Westat
Duke Univ
Emory Univ
Tulane Univ
Guatemala
Tunisia
China
India
Bangladesh
Kenya
Peru
Argentina
South Africa

Purpose of the program

- To combat non-communicable chronic cardiovascular and pulmonary diseases (CVPD), in developing countries, by
  - Conducting research on new or improved approaches, programs, and measures
    - to prevent or treat chronic CVPD.
  - Research training and
  - Enabling clinical research infrastructure development

Components of the ICRAG program

Identified three areas

1. Training
2. Infrastructure development
3. Research projects

Total numbers: Team + Research Subjects

- Training
  - Trainees: 350
  - Faculty + mentors: 62
- Three projects
  - Staff at 78 sites: 406
- Central staff: 51
- Total staff in the program: 869
- Total research subjects: 20,422

PREPARE

- Rural study; Aimed to test
  - Local community health workers (CHW) can reduce risk for heart disease
- 28 villages; 3 states (Kar, TN, Mah)
- Screened
  - 8,615 in 4,780 households
- Included
  - 2,348 households, 3,261 participants
- CHW interventions:
  - 6 house visits over one year

CHW home visits

Tobacco Show Cards

Salt container

Piggy bank

Poster

Risk reduction calendar

Pill pouches

Medicine adherence sticker

Physical activity sticker

Mobile pouch

Fruit key chains

PREPARE: results

- At baseline (3261 in 2,358 Houses)
  - Households with CV risk factors: 45%
  - Smokers: 22%, chew tobacco: 56%
  - HTN – 45%; diabetes 8%
- Follow up at one year: 2,756 (91%)
  - Blood pressure reduced 1.8mmHg (p=0.01)
  - Weight reduced (BMI: -0.33, p=0.05)
  - Small reduction tobacco use (9.7%, p: ns)

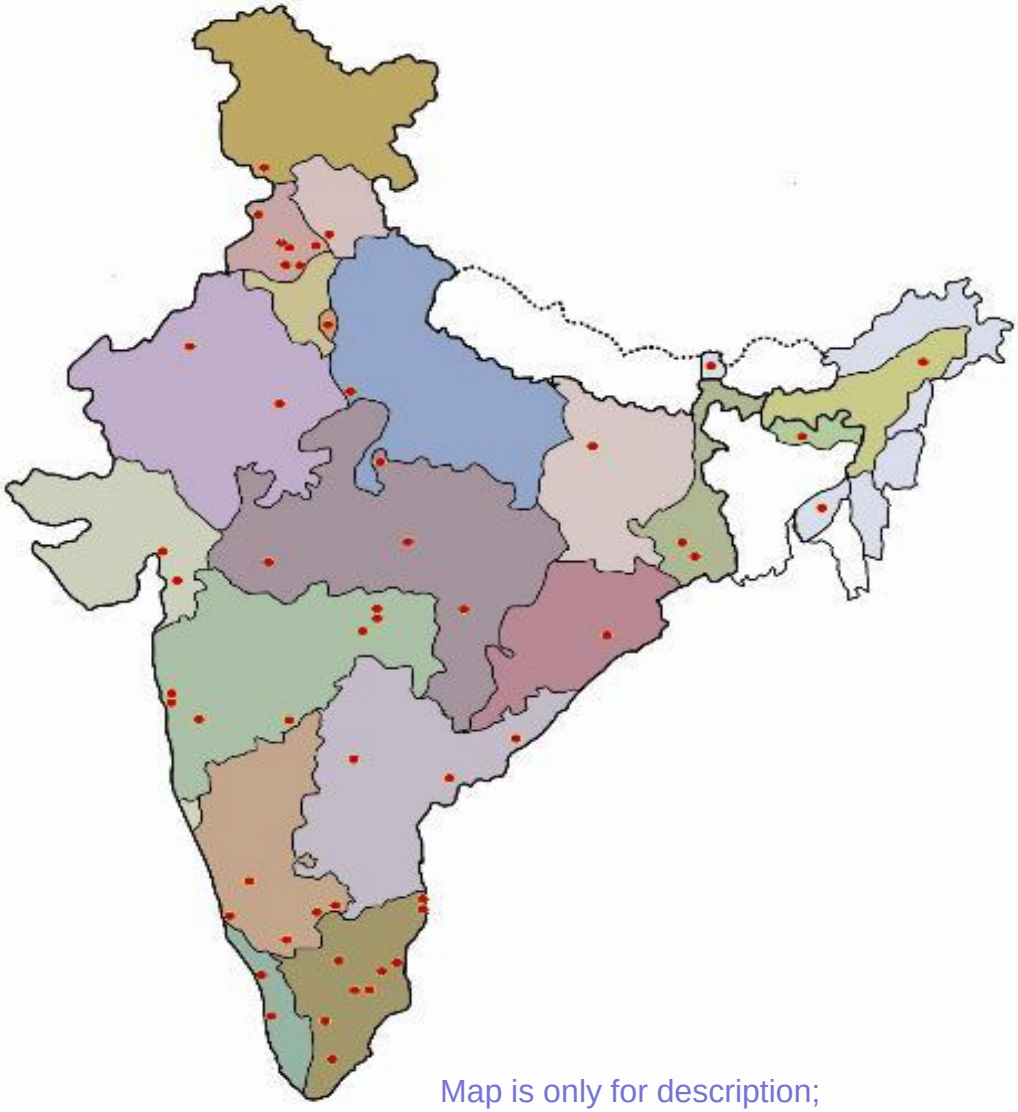
Treatments and outcomes of acute strokes in India:

INSPIRE - A Large hospital Registry

Need for study

- Stroke - leading cause of mortality and disability in India.
- Yet, there are no <u>representative</u> data in India on
  - Patient characteristics
  - Treatments and
  - Outcomes

INSPIRE- India sites



Map is only for description;
It is not to scale nor politically accurate

Region	Sites	Patients (%)
North	12	2147 (19.5%)
South	24	4375 (38.8%)
East	3	672 (6.1%)
Central	6	1653 (15.0%)
West	10	1137 (10.3%)
North East	6	1017 (9.2%)
Total	**61**	**11001**

Training in the Center of Excellence Program

Basic course 2009

Advanced Course 2010

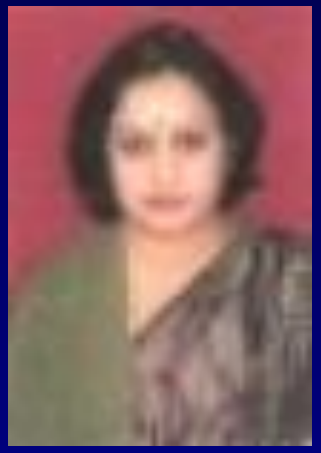
Basic course
2011

Advanced course
2012

Two year mentorship program

- Young medical faculty across India
- Internal and external mentor
- Design a project with mentors
- Funds up to INR500,000 (US$10,000)

Mentees: 2 year program
Batch -1






Mentees: 2 year program Batch -2








Summary of mentorship

- Two batches
  - 6 + 8 = 14
- 13 started and 12 completed the project
- Research areas
  - Community/ rural studies
    - CVD risk factors, CVD in elderly, diabetes, school children education in CVD, asthma,
  - Urban/ hospital studies
    - Diabetes prevention, pulmonary rehabilitation, birth cohort, CVD and AIDS

HRM-EBM course - 2013

Participants : 91, 32 institutions, 6 countries
18 Faculty: India + Devereaux, Guyatt, Sackett, Yusuf

Workshop on
Data Management and Biostatistics

March - 2014

Participants: 56 from 21 cities

UG medical students' research training

- Presently
  - No structured training for UG medical students in research
- Two Institutions
  - Mahatma Gandhi IMS, Sevagram:18+17=35
  - St. John's Medical College, Bangalore 5x10=50
- Structured training: 3/10 months
  - Research methods and biostatistics,
  - Ongoing mentorship with local faculty, and
  - Research projects –ICMR STS/SJ research grant (INR10,000*)

Summary of Training

- Total
  - Courses - 11
  - Participants – 1,100
  - Institutions - 120
  - Countries – 6
  - Faculty – from 7 institutions
- Topics
  - Research methods
    - Obs, RCT, SR/MA, Qualitative, Policy, Programs
  - Biostatistics, ethics/ regulatory,
  - Data & research management
  - Grants and publications

Our contribution...1

- Evidence from a developing country on risk factors and practice patterns for **Acute MI**
  - Indian Case control study and INTERHEART
  - CREATE Registry
- Evidence on risk factors and treatments for **Stroke**
  - INTERSTROKE (ongoing project – 5,000)
  - INSPIRE stroke registry – 11,001, 6 mo FU

Our contribution...2

- Global RCTs that have impacted clinical practice
  - CREATE Study – use of LMWH & GIK in Acute MI
  - OASIS 5 & 6 – use of fondaparinux in ACS
- Representation in unique RCTs
  - PRoFESS – largest secondary stroke prevention study
  - POISE 1 & 2; MANAGE –large RCTs in perioperative ischemia
  - TIPS -1, 2 & 3 –RCTs evaluating a “Polypill”

Our contribution...3

- Health systems research
  - IMPACT – A fib
  - PREAPRE – Primary prevention
  - SPREAD – Secondary prevention
  - PROGRESS – worksite interventions
- Training in clinical research & research management

Our contribution: Training 4

- International/ National
  - 2-Year mentorship program
  - HRM, then HRM-EBM courses
  - Data management and biostatistics
  - Research management
- At St. John's
  - UG students – 60+…
  - Faculty – mentorship 5 over 2 years each
  - Course for faculty – 136 from 34 depts

Collaborating agencies - Govt.

1. **Indian Council of Medical Research**
   - Task force study in Acute MI
   - Central clinical coordinating centre for MACE
   - Co - PI for biobank facility + INSERM
2. **World Health Organization**
   - Training of medical officers in detection of Non-communicable diseases
   - NCD guidelines for developing countries

Collaborating agencies - Govt

3. NHLBI-**UH** [USA]
   - Center of Excellence
4. UK – MRC/ WT/ DFID
   - PROGRESS

Collaborating agencies
Trusts, Acad, Pharma

5. Wellcome Trust
6. BMS/ Pfizer foundation
7. **Academic:** (10)
   - Canada: McMaster University
   - USA: Columbia, Duke University (USA)
   - Austr/ NZ: Green Lane, Royal Perth, Sydney, Monash (Mel)
   - Europe: Oxford-UK, Uppsala University (Sweden),
8. **Pharmaceutical Companies (13)**
   - Abbott, Aventis Pharma, AstraZeneca, BMS, Basilea Pharma, Boehringer Ingelheim, Cadila, Eli Lilly, GlaxoSmithKline, Novo Nordisk, Pfizer, sanofi

What we achieved in 15 years?

- Large network of clinical investigators
  - 190+ across the country.
- Team of trained & experienced coordinators and research assistants
  - Large multicentre global clinical trials
- Regulatory – DCGI, ICMR and HMSC, NIH
- IP handling – Import, store, distribution & accounting
- Data management
  - Set up database – 5
  - Handle data from over 100 sites
    - receive forms, enter data, generate queries, resolve queries, rolling database lock

Online resources

- Website for CVD prevention
- LMS for CVD prevention

St. John's

www.abhiyanwebsolutions.co.in/demo/

St. John's
National Academy of Health Sciences BANGALORE, INDIA

Know and Prevent Heart Disease

Home | About Heart | FAQs | Patient Blog | News | About Us | Contact Us | Search

Home

How healthy are you?

- BMI Calculator
- Heart Risk Calculator
- Calorie Meter

Patient Blog

Recent | Popular

- Which oil is best for cooking?
- What changes in my lifestyle can help me prevent a stroke?
- How do I recognise a heart attack?

Choose your food carefully, it's in your hands to stay healthy.

Read more

Heart disease is preventable

Importance of prevention

A heart attack may be the first symptom of heart disease. By this the person has had significant damage to the heart. Don't let yourself or anyone you love reach this point.When you lower blood pressure, you lower the risk of heart attack by 20 to 25 percent and the risk of stroke by 35 to 40 percent.

Read more

What is good for your heart

8 Microsoft Office... | Screenshots of AME... | St. John's - Google ... | 13:51

GRANTS - as PI/ Co-PI

Investigator initiated : 4 (~US$7.5Mil)

1.NIH/ Ovations UH Centre of Excellence US$4.1mil

2.UK-MRC/ Wellcome Trust/ DFID: PROGRESS:

GBP137,000

3.BMS/ Pfizer foundation IMPACT through Duke University,

US$275,000

4.Wellcome Trust: (TIPS-3) thro PHRI, CPL US$2.7 million

Grants – as collaborator
Apx US$20 mil

1. CIHR: HOPE-3 CD$5.8 mil
2. CIHR: POISE-2 CD$3.7 mil
3. CIHR foundation grant: CD$8.4 mil
4. PHRI/ HHS: MANAGE CAD$832,500
5. NHMRC: ASPIRE AU$1.92mil
6. NHMRC and NHF Australia : AU$2.71 mil
7. ICMR MACE INR25 L+

Summary

- Largest academic clinical and research center in India
- Research studies hospital and community based
  - in CVD → NCDs
- Obs → interventional → health systems
- Training Health research methods & research management
  - across India and other Asian/ African countries.