

Health Research Designs: Beyond T-3

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Overview

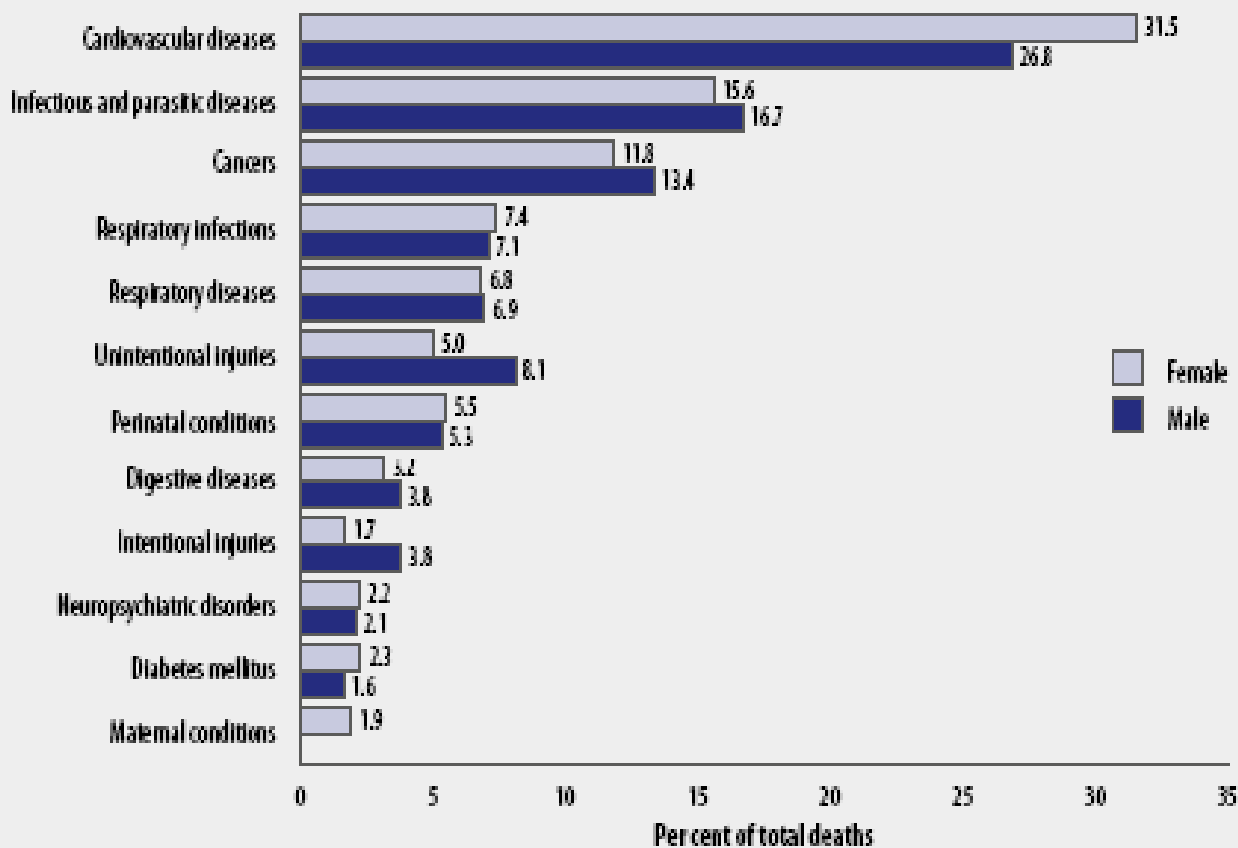
- ❖ Why we do it? Health needs and costs of care
- ❖ What is chronic diseases (NTCD)?
- ❖ Steps to close the research gap: the different sides of translational research
- ❖ Changing research paradigm – Innovative designs
- ❖ The need for integrating medicine, public health, and prevention research
- ❖ Community based participatory research

WHY DO WE NEED
RESEARCH?

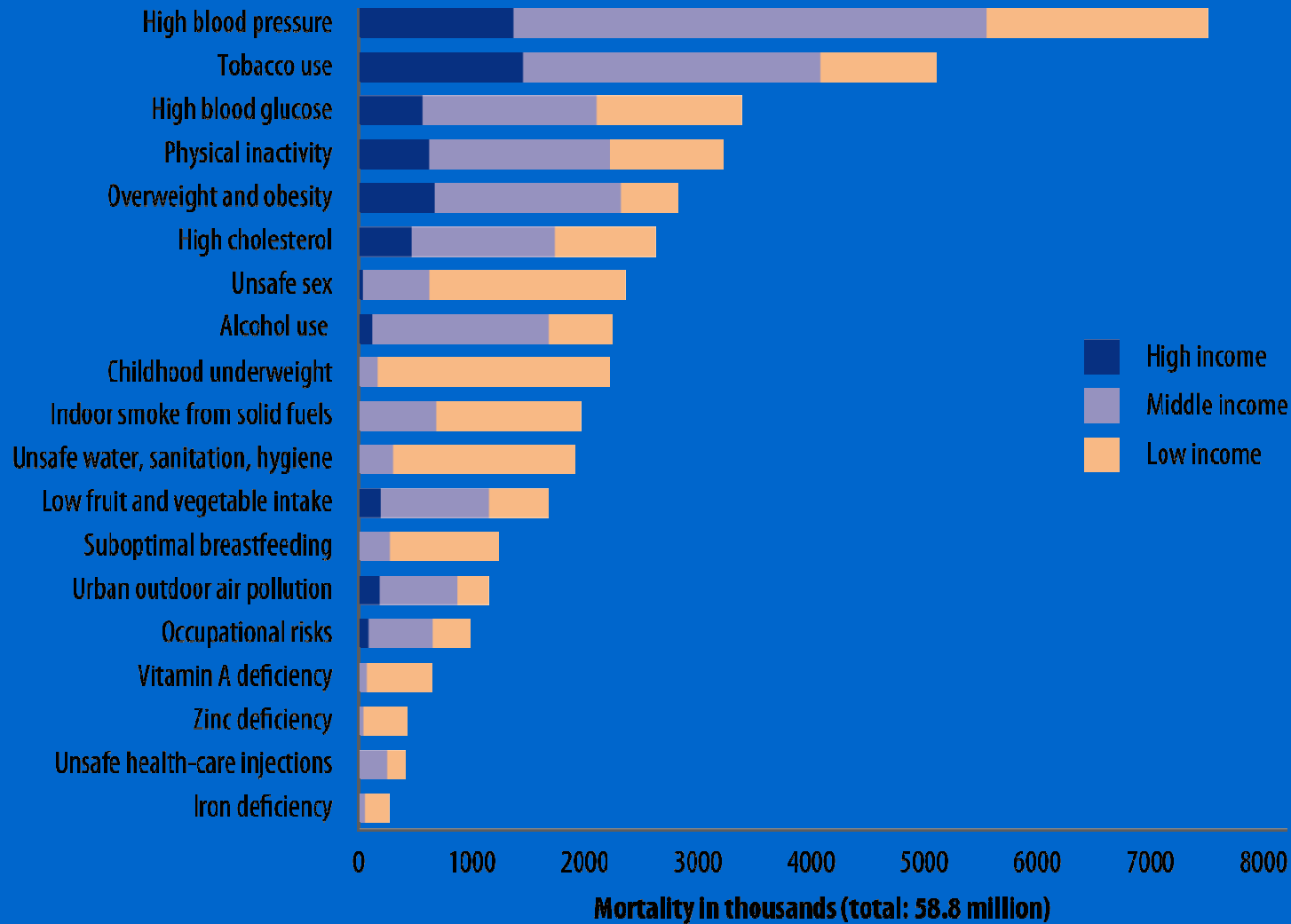
THE HEALTH NEED

Distribution of deaths by leading cause in the world

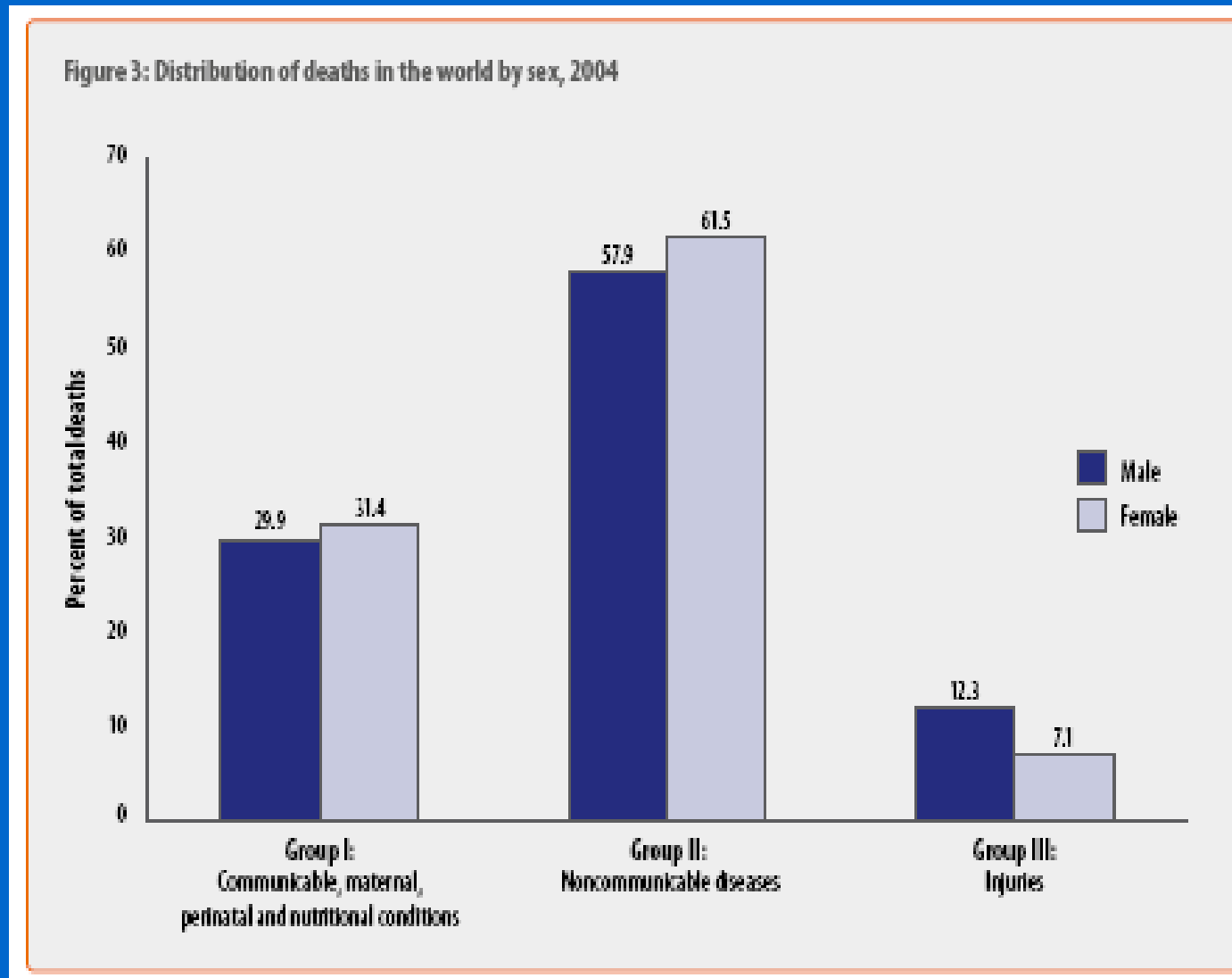
Figure 4: Distribution of deaths by leading cause groups, males and females, world, 2004



Deaths attributed to 19 leading factors, by country income level, 2004



Distribution of Deaths in the World by Sex



Urban Growth in Developing Countries

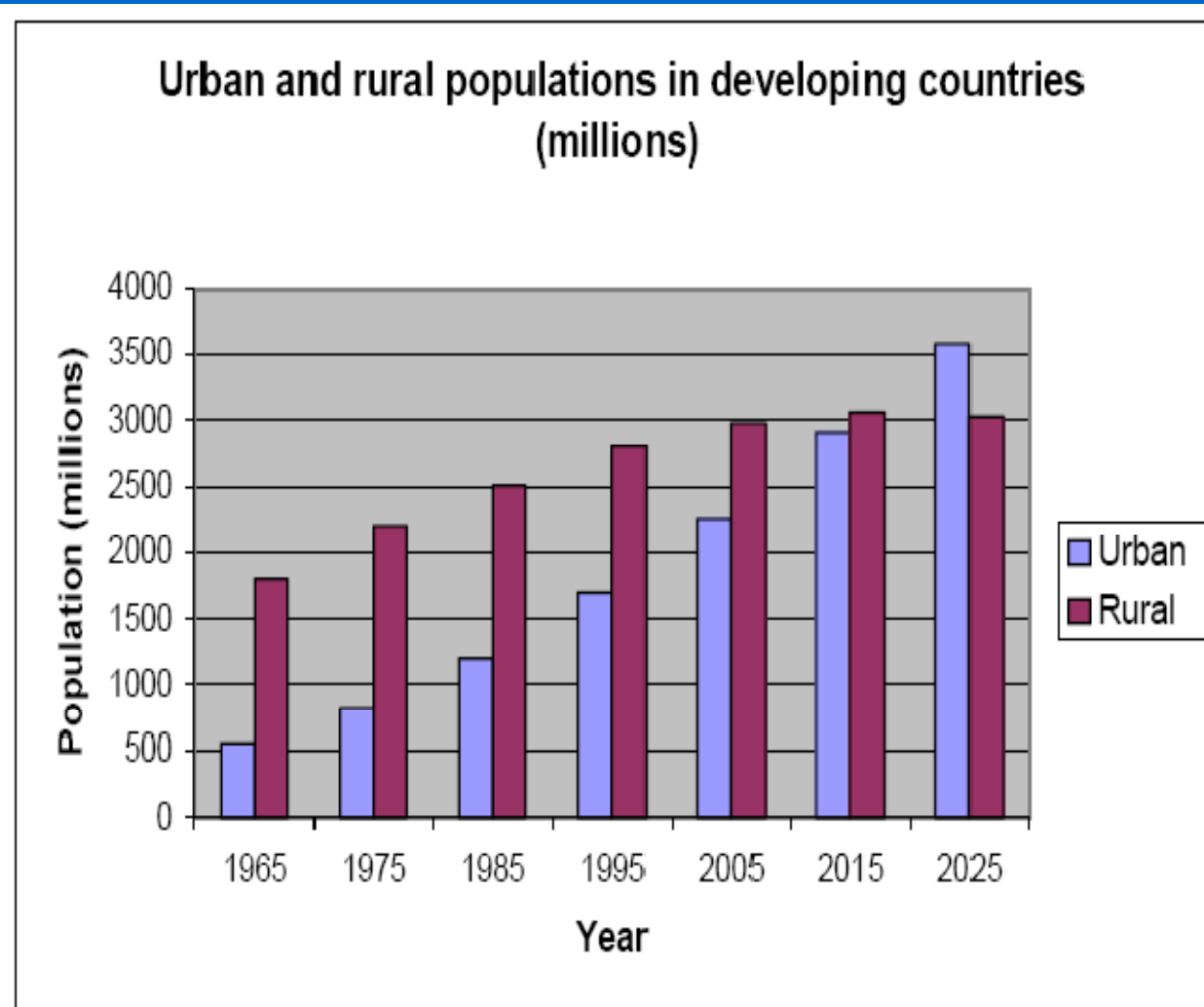
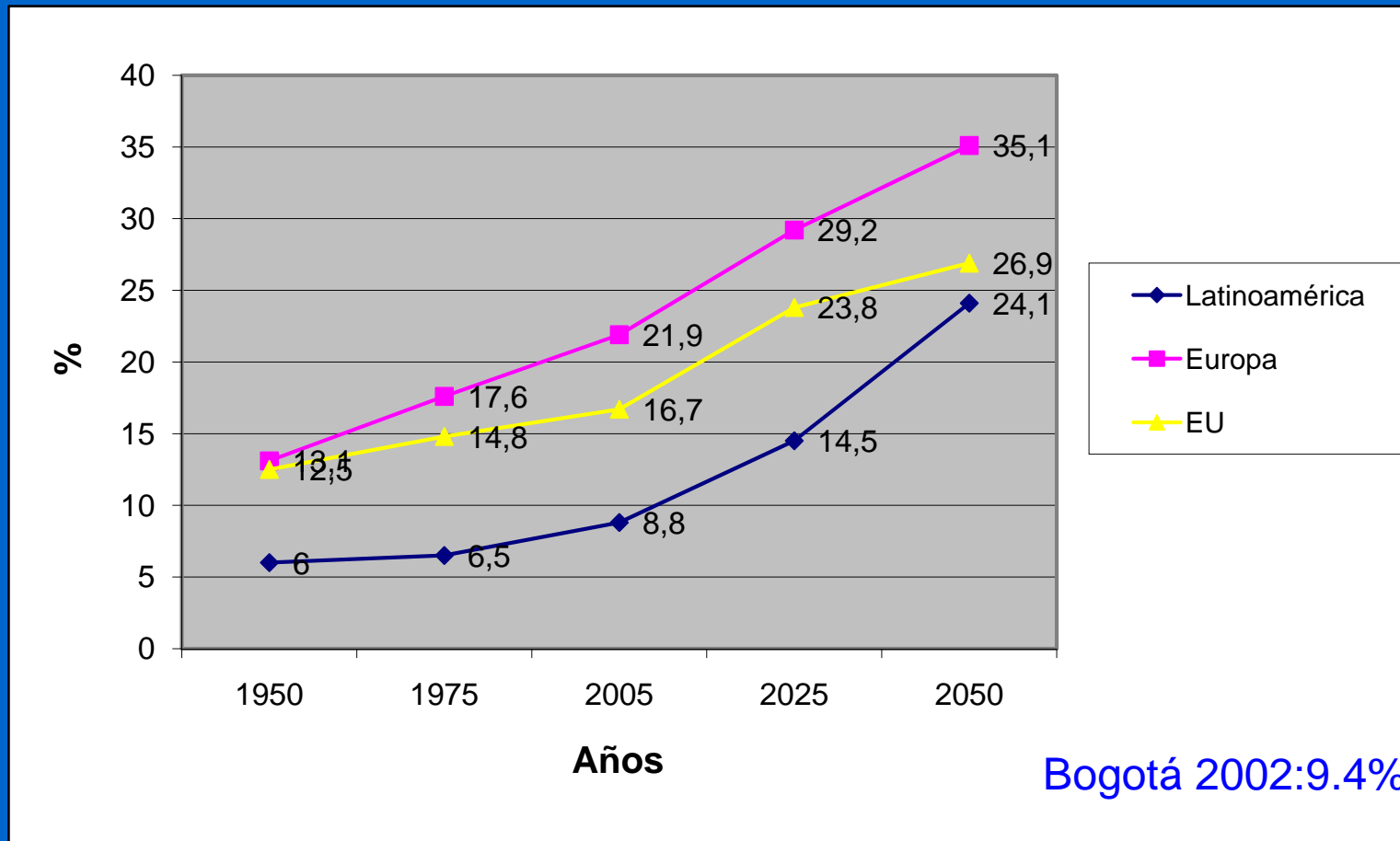


Fig. 1 The urban population in developing countries will soon surpass the rural population.

Source: UN Habitat, 2002

Demographic Transition. Percentage of the population 60 yrs and older



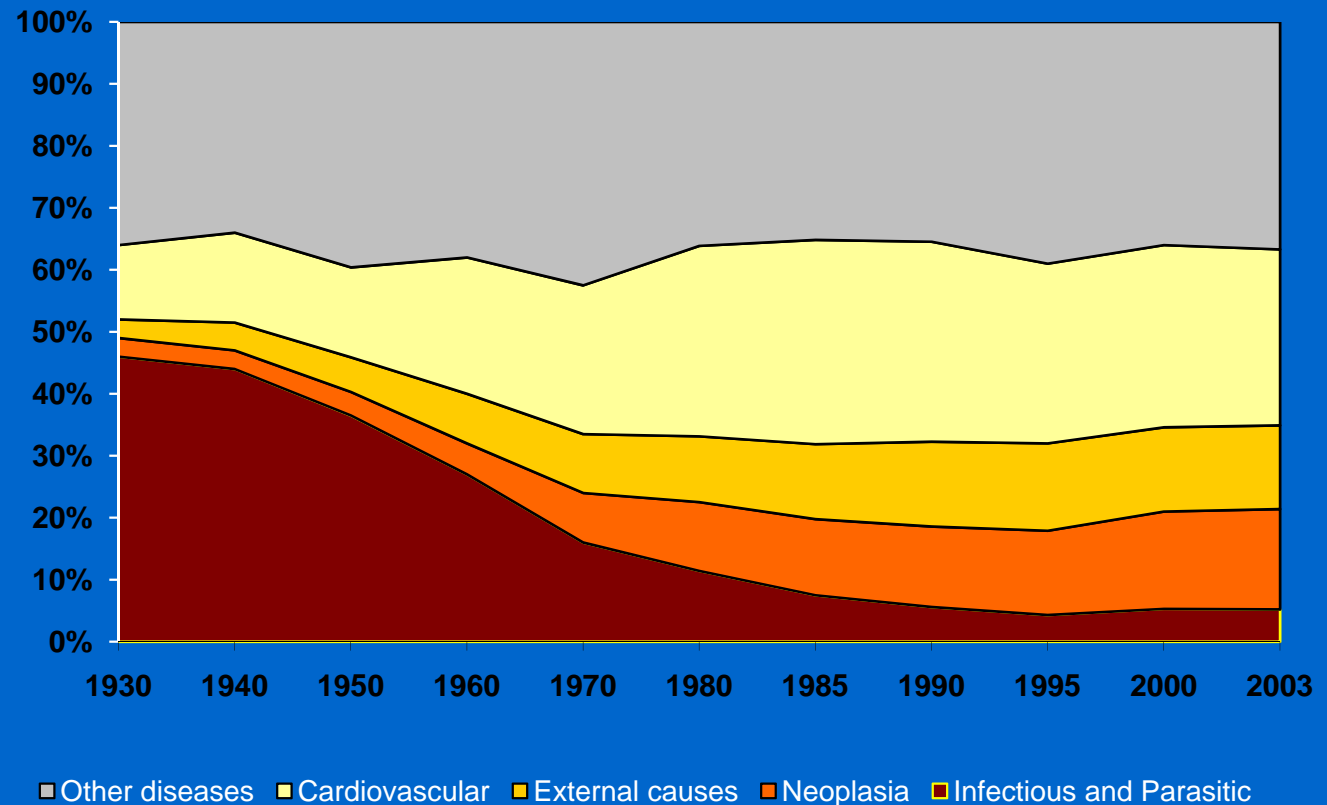
United Nations. World Economic and Social Survey 2007. Development in an Ageing World.

<http://www.un.org/esa/policy/wess/wess2007files/wess2007.pdf>. Fecha de acceso: 8/09/2008

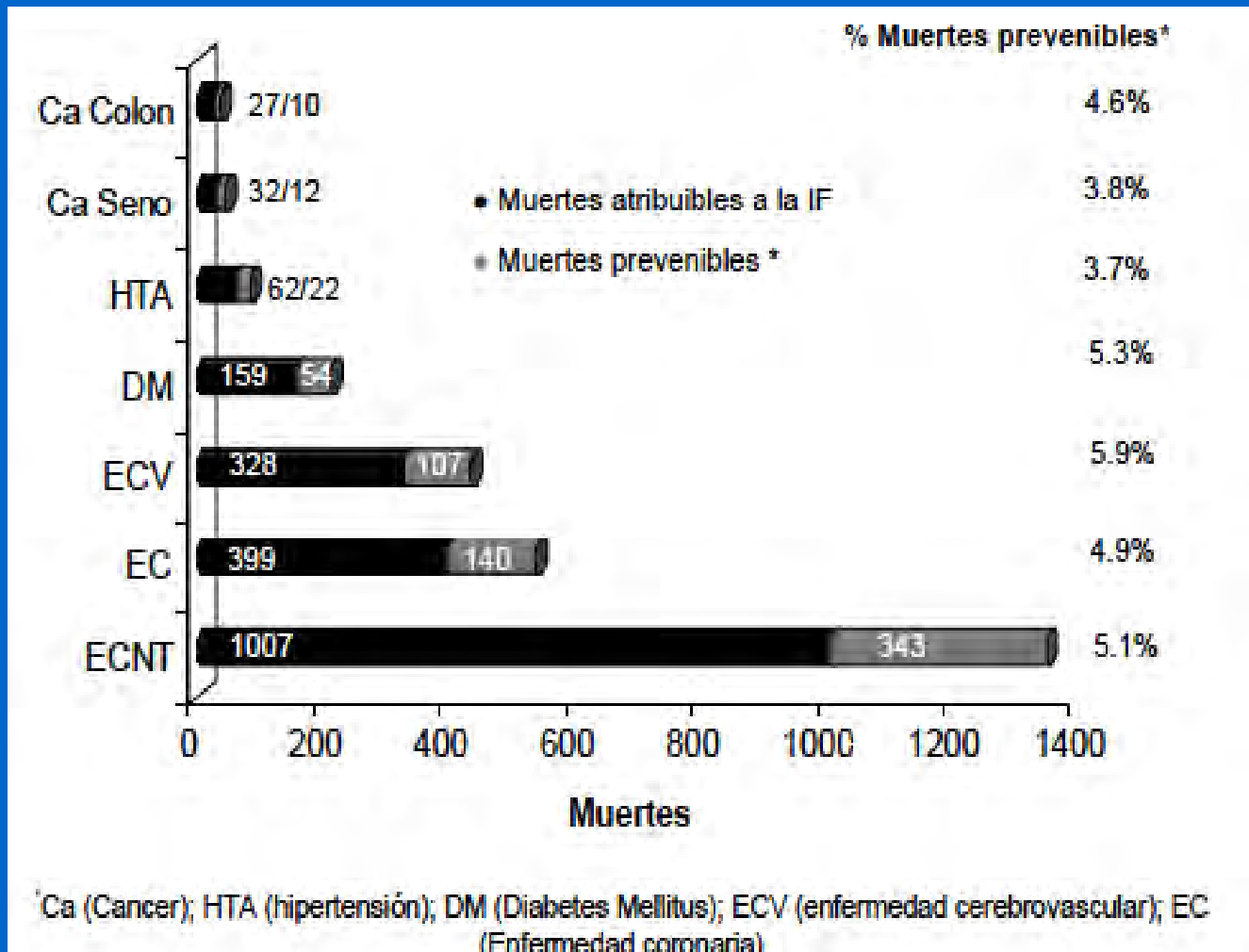
Epidemiologic Transition in Brasil

Mortality (%)

- Infectious and Parasitic diseases:
46% in 1930
5% in 2003
- Cardiovascular diseases:
12% in 1930
31% in 2003



Burden of Mortality Associated to Physical Inactivity in Bogota, Colombia



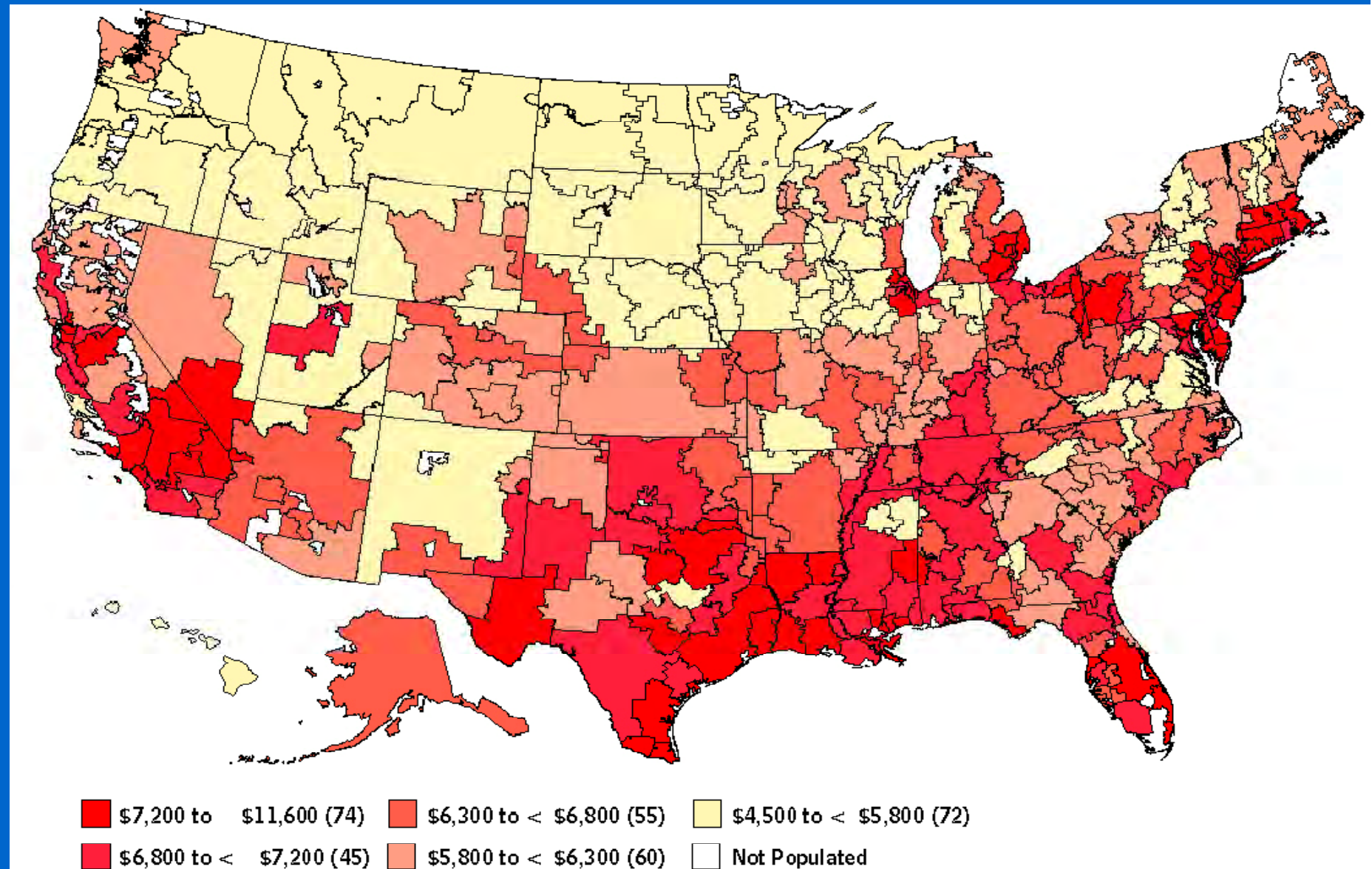
How might we address
physical activity and obesity in
Latin America?

**RATIONALE FOR RESEARCH
THAT INTEGRATES THE
CONTINUUM OF CARE**

CONGRESS OF THE UNITED STATES-CONGRESSIONAL BUDGET OFFICE: A PAPER (CBO)

- In 30 years, federal spending on Medicare and Medicaid has roughly tripled as a share of gross domestic product (GDP) - from about 1.3 percent in 1975 to about 4 percent in 2007.
- **Under current policies such spending will reach about 12 percent of GDP by 2050:**
- **If costs per enrollee grows over the next four decades about 2.5 percentage points faster than per capita GDP—then federal spending on those programs would reach about 17 percent of the economy.**
- If, instead, costs per enrollee did not exceed the growth of GDP, those federal costs would reach about 6 percent of GDP in 2050 solely because of demographic changes
- Same in Brazil, Europe, BRICS and everywhere by now

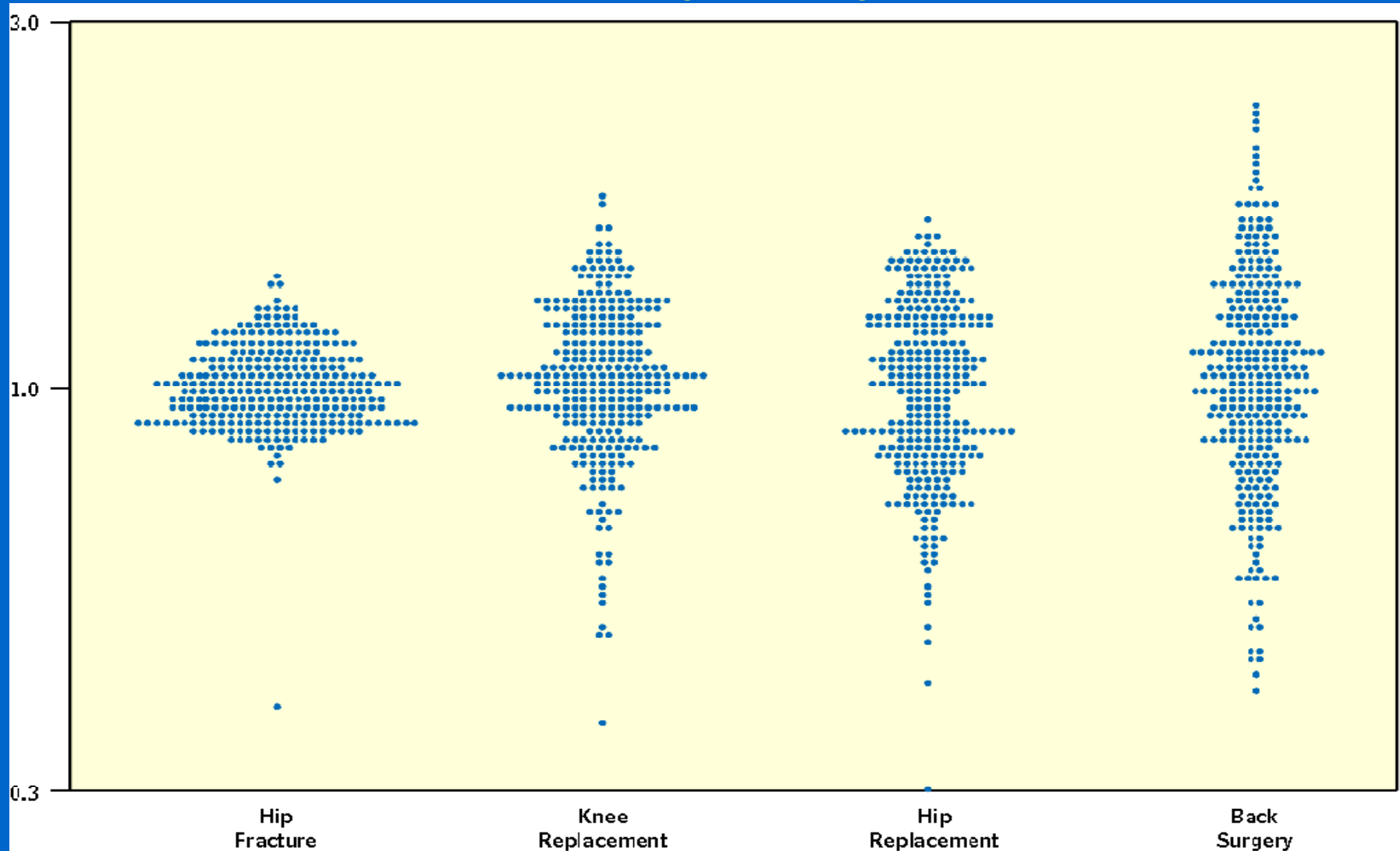
Medicare Spending per Capita in the United States, by Hospital Referral Region, 2003



Source: The Dartmouth Atlas of Health Care.

Note: Numbers in parentheses refer to the number of hospital referral regions with per capita spending in each interval.

Rates of Four Orthopedic Procedures Among Medicare Enrollees, 2002 and 2003 (Standardized discharge ratio, log scale)



Source: Dartmouth Atlas Project, The Dartmouth Atlas of Health Care.

Notes: In the figure, each point represents a hospital referral region; the country was divided into about 300 such regions on the basis of where Medicare enrollees typically receive their hospital care. The points indicate how the rate at which the procedure is performed (per 1,000 Medicare enrollees) in each referral region compares with the national average rate (which has been normalized to 1.0). Differences in procedure rates were adjusted to account for differences among regions in the age, sex, and race of enrollees and for measures of illness rates.

Is it all because of poor research?

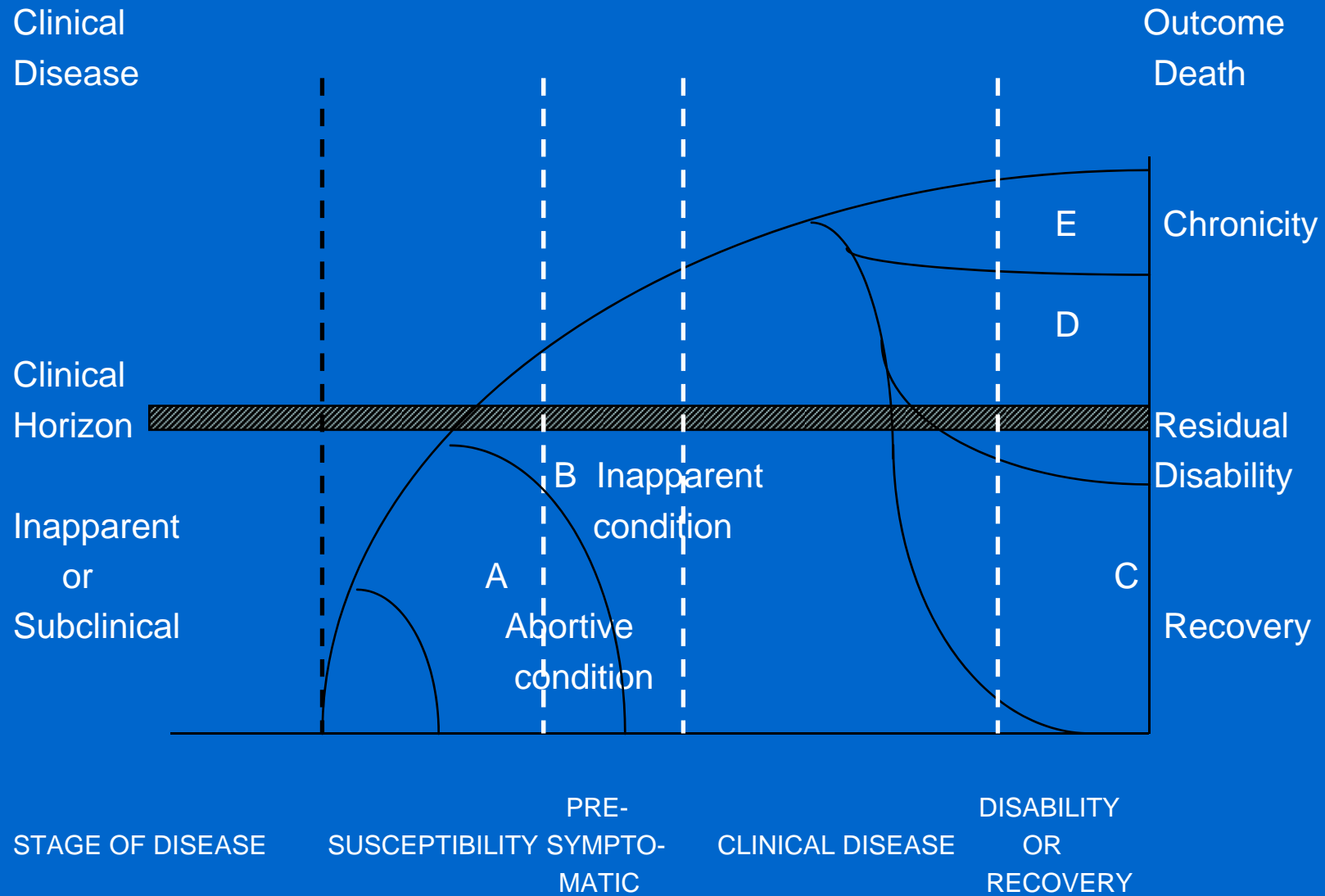
**CLEARLY NOT BUT THE
PURPOSE OF HEALTH
RESEARCH IS TO IMPROVE
HEALTH**

So what is a chronic disease?

Chronic diseases defined

- Aka, chronic illnesses, noncommunicable diseases
- Properties
 - Often characterized by
 - uncertain etiology
 - multiple risk factors
 - a long latency (induction) period
 - a prolonged course of illness
 - Non-contagious origin
 - functional impairment or disability, and incurability

Schematic Representation of the Natural History of Chronic Disease



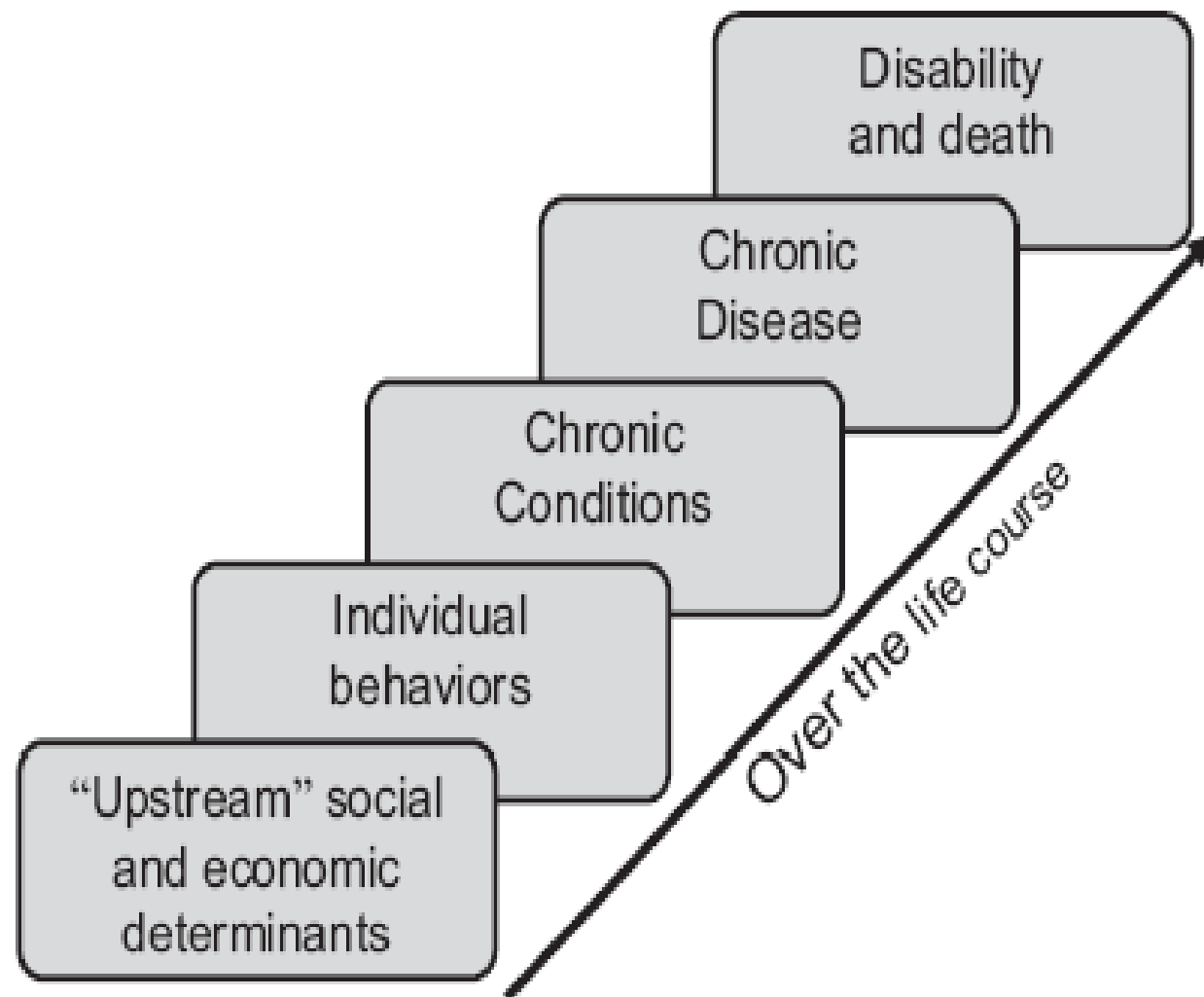


Figure 1.1. The Chronic Disease Continuum.

Causes

- Psychosocial factors
- Peer pressure
- Industry marketing and promotion
- Cost of the product
- Minors' access
- Clean indoor air policies
- Social norms
- Biologic susceptibility to develop nicotine dependence

Tobacco Use

High risk populations

- Adolescents
- People with low incomes
- People with less education
- Racial and ethnic minorities

Consequences

- Lung cancer
- Other cancers (see table)
- Heart disease
- Stroke
- Atherosclerosis
- Aortic aneurysm
- Pneumonia, influenza
- Bronchitis, emphysema
- Perinatal conditions from maternal smoking during pregnancy
- Sudden infant death syndrome
- Burn deaths
- Second-hand smoke deaths
- Nicotine dependence

	Cardiovascular Disease	Cancer	Chronic Lung Disease	Diabetes
Tobacco use	+	+	+	
Alcohol use	+	+		
High cholesterol	+			
High blood pressure	+			
Diet	+	+		+
Physical inactivity	+	+		+
Obesity	+	+		+
Stress	?	?		
Environmental tobacco smoke	?	+	+	
Occupation	?	+	+	
Pollution		+	+	
Low socioeconomic status	+	+	+	+

SO WE ARE SPEAKING OF COMPLEX
MODELS OF DISEASE CAUSATION

**SUCH MODELS REQUIRE
COMPLEX INTERVENTIONS
AND ALL TYPE OF DESIGNS**

DO WE HAVE THEM?

Current Research Output

- ***Gnanalingham MG et al (2006)***. From the 27030 articles evaluated, there were 2283 (8.4%) RCTs, 166 (0.6%) meta-analyses, and 4153 (15.4%) other clinical trials.
- ***Stelfox HT et al (2008)***. Searched MEDLINE and the Cochrane Central Register of Controlled Trials for reports of RCTs of interventions in the prevention and care of injuries published between January 1, 1966 and January 1, 2006.
- The rate of publication of injury-related RCTs increased from 1.2 to 5.3 articles per 100 RCTs published in MEDLINE ($p < 0.001$) during the study period.

WILL THIS BE SUFFICIENT?

Example: Canadian Cancer Society RFP for a Review to Answer 4 Questions

- Are group counseling programs for smoking cessation effective?
- If so, what is the optimal content of the sessions?
- What is the optimal number and frequency of the sessions?
- What are the characteristics of the most effective facilitators?

Manske SR, Miller S, Moyer C, Phaneuf MR, Cameron RC. Best practice in group-based smoking cessation: Results of a literature review. *AJHP* 18:409-23, 2004.

University of Waterloo Study*

- A comprehensive literature review of over 40 years of published and unpublished studies
- Deficiencies in purpose, design and reporting for most studies
- Researchers could answer only the first question after 40 years of research

*Manske SR, Miller S, Moyer C, Phaneuf MR, Cameron RC. Best practice in group-based smoking cessation: Results of a literature review. *AJHP* 18:409-23, 2004.

So we need Translational Research and Medicine

- Insufficient translation of scientific knowledge into patient care and disease prevention
- Insufficient diffusion of evidence-based treatment and prevention practices
- But a missing component of evidence-based practice is outcome- and system-based research: not enough “experiments” or much of “wrong experiment”
- Traditional separation between treatment of individuals and disease prevention in populations.

Steps to Close the Gap

- Practitioners need to implement the lessons of research by translating them into practice.
- Recognize that research and practice are separate disciplines that must develop unique answers.
- Researchers' and practitioners' complementary perspectives and skills must be used together to produce scientific knowledge that informs health policy and practice.

Van De Ven A, Johnson P. Knowledge for theory and practice. *Academy of Management Review*. 2006;31(4).

Steps to Close the Gap

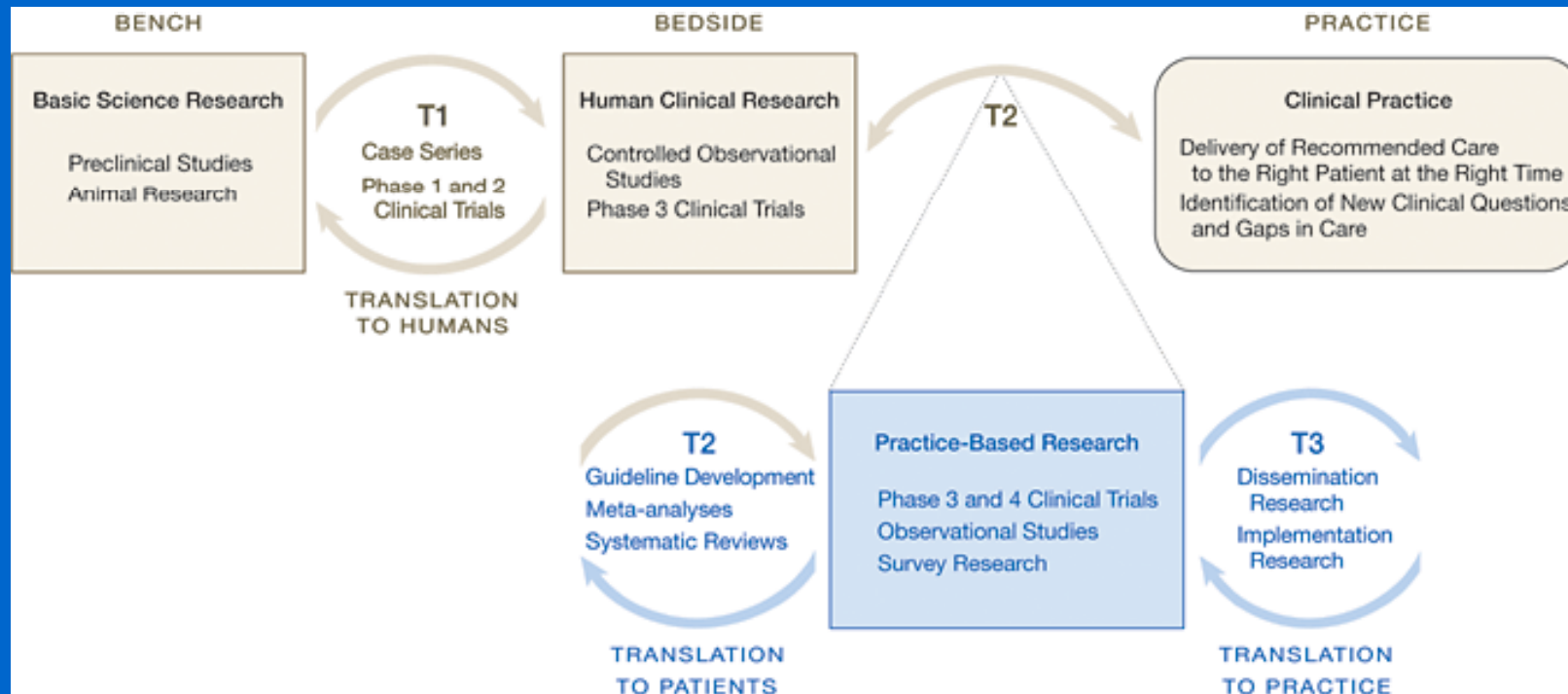
- Non-traditional view of research evidence
- *Patient- and population (community)-centric health systems,
- System-based modeling and research
- Bridging the gap between medicine and public health in science and practice

*Simoes EJ, Sumaya C. Protecting and Enhancing Health: Community Engagement, Collaborations and Incentives for Prevention. J Prim Prev. 2010;31(1-2):21-29. © 2010

Bench to Bedside

- Basic science knowledge to produce new drugs, device, or treatment options for patients
- Interface between basic sciences and clinical medicine
- Production of new treatment that can be used clinically or brought to commercial market

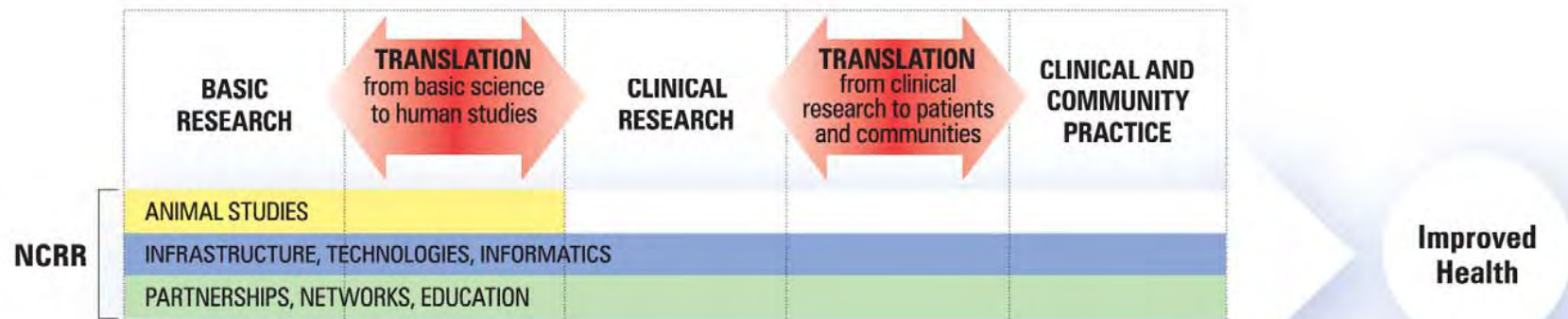
"Blue Highways" on the NIH Roadmap



Westfall, J. M. et al. JAMA 2007;297:403-406.

NCCR Strategic Plan 2009–2013

Translating Research from Basic Discovery to Improved Patient Care



T 1- Bench-bedside: basic sciences research to clinical

T 2 - Bench-bedside: clinical research to patients

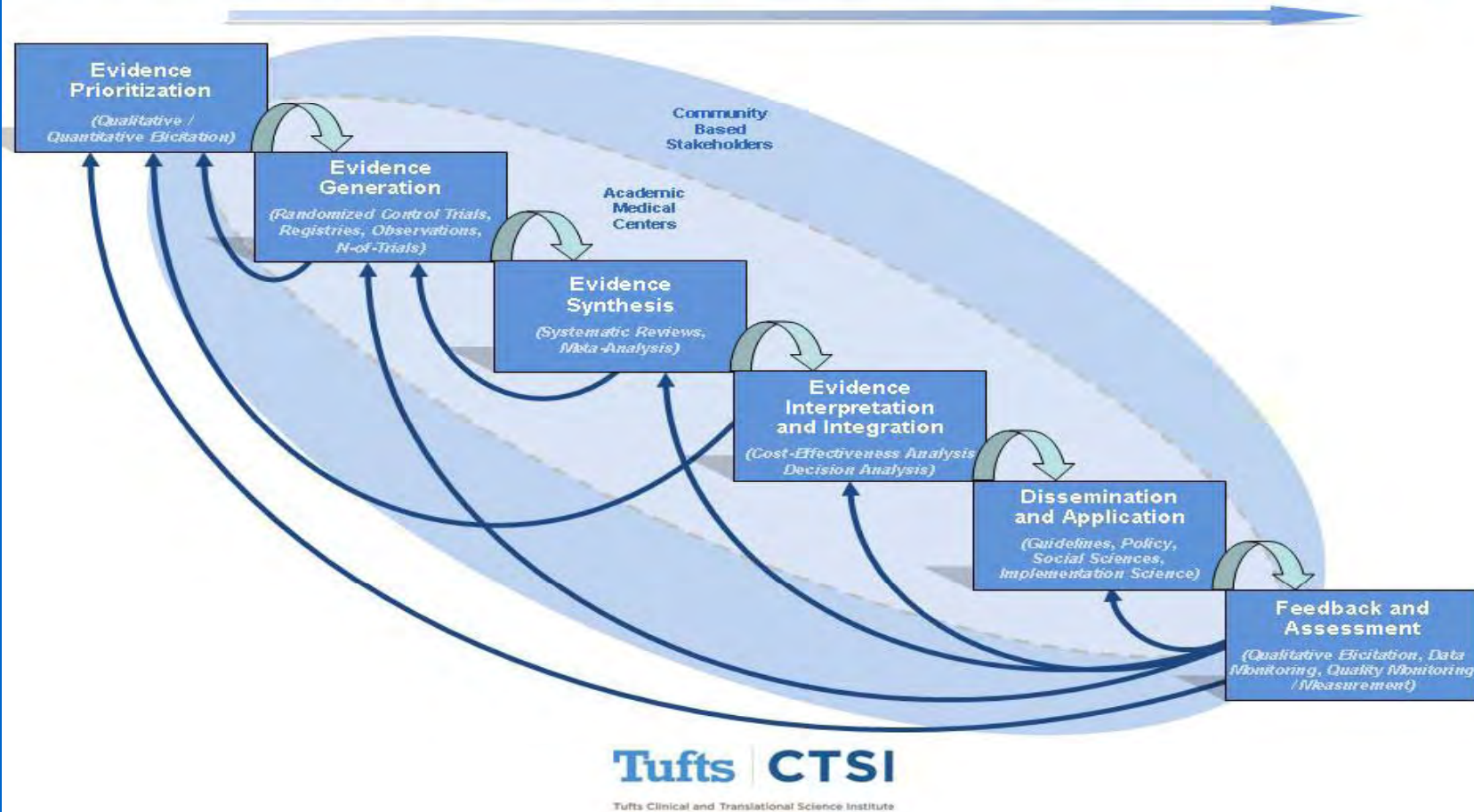
T-3 Bench-bedside: practice-based outcome research to practice

T-4 Bench-bedside: practice-based system research to systems

Need Comparative Effectiveness

- Traditional clinical research typically examines the effectiveness of one method, product, or service at a time.
- CER compares two or more different methods for preventing, diagnosing, and treating health conditions
- Such research is performed using methods such as practical clinical trials, analyses of claims records, computer modeling, and systematic reviews of existing literature.
- aim to improve health outcomes by developing and disseminating evidence based information to patients, providers, and health care decision-makers about the effectiveness of treatments relative to other options

Translational Spectrum of Comparative Effectiveness Research at Tufts CTSI



Both TR and CE seek to determine which options are most effective for which patients.

Need Comparative Effectiveness

- Classic RCT design (Superiority Trial):
 - Formulate null hypothesis of no difference between 2 or more treatment groups
 - Identify a clinically relevant difference in primary endpoint
 - Power trial to accumulate patients and data to test hypothesis
 - Test the hypothesis
 - Reject the null to demonstrate difference between treatment groups

Need Comparative Effectiveness

- Non-inferiority and Equivalence Trials:
 - A non-inferiority trial is one-sided in nature and seeks to determine whether a new intervention is no worse than a reference intervention within a specified non-inferiority interval ($-\Delta$ to 0) for the primary outcome
 - An equivalence trial seeks to identify whether two interventions have a similar effect within a pre-specified interval ($-\Delta$ to $+\Delta$)
 - With no-placebo group, the two interventions may in fact have similar effect, but that effect may be no different from placebo

Need Comparative Effectiveness

- Uses of non-inferiority and equivalence trials:
 - When an unrelated control group may be considered unethical
 - Dose escalating and varying exposure studies
 - Evaluation of different (inhaler versus a patch) delivery system
 - Studying safety: Cox-II trials

Need Patient Centered

- Helping clinicians and patients change behavior and make informed decisions
- Using reminders and point-of-care decision tools
- Improving access; reorganizing and coordinating systems of care
- Ensuring that new treatments reach the patients for whom they are intended and are implemented correctly

Need Population Centered-System

- New research knowledge reaches population for which intended and implemented correctly
- Risk factors are identified and prevention or treatment strategy devised
- Effective strategies are successfully diffused and adopted
- Effective strategies are effectively implemented
- Effective, adoptable and implementable strategies are sustained (practice-based research)

Need RE-AIM framework for evaluating complex interventions

- **Reach**
 - –The absolute number, proportion, and representativeness of individuals who are willing to participate
- **•Efficacy/Effectiveness**
 - –The impact of an intervention on important outcomes, including potential negative effects, quality of life, and economic outcomes.
- **•Adoption**
 - –The absolute number, proportion, and representativeness of settings and intervention agents (people who deliver the program) who are willing to initiate a program.
- **•Implementation**
 - –Setting level: users' fidelity to various elements of intervention's protocol, including consistency of delivery as intended and the time and cost of the intervention.
 - –Individual level: clients' use of the intervention strategies.
- **•Maintenance**
 - –Setting level: the extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies.
 - –Individual level: the long-term effects of a program on outcomes after 6 or more months after the most recent intervention contact.
- ***Glasgow R et al. 2001***

What do we still need?

- “Feds” translational research is still a forward looking model, traditional science, not comprehensive enough and though patient-centric does not fully incorporate systems and community
- A broad definition of research needed that takes scientific discoveries and translates them into practical applications by asking:
 - What discoveries?
 - What research?
 - What practices?

Expanding the research model

Complex intervention trials

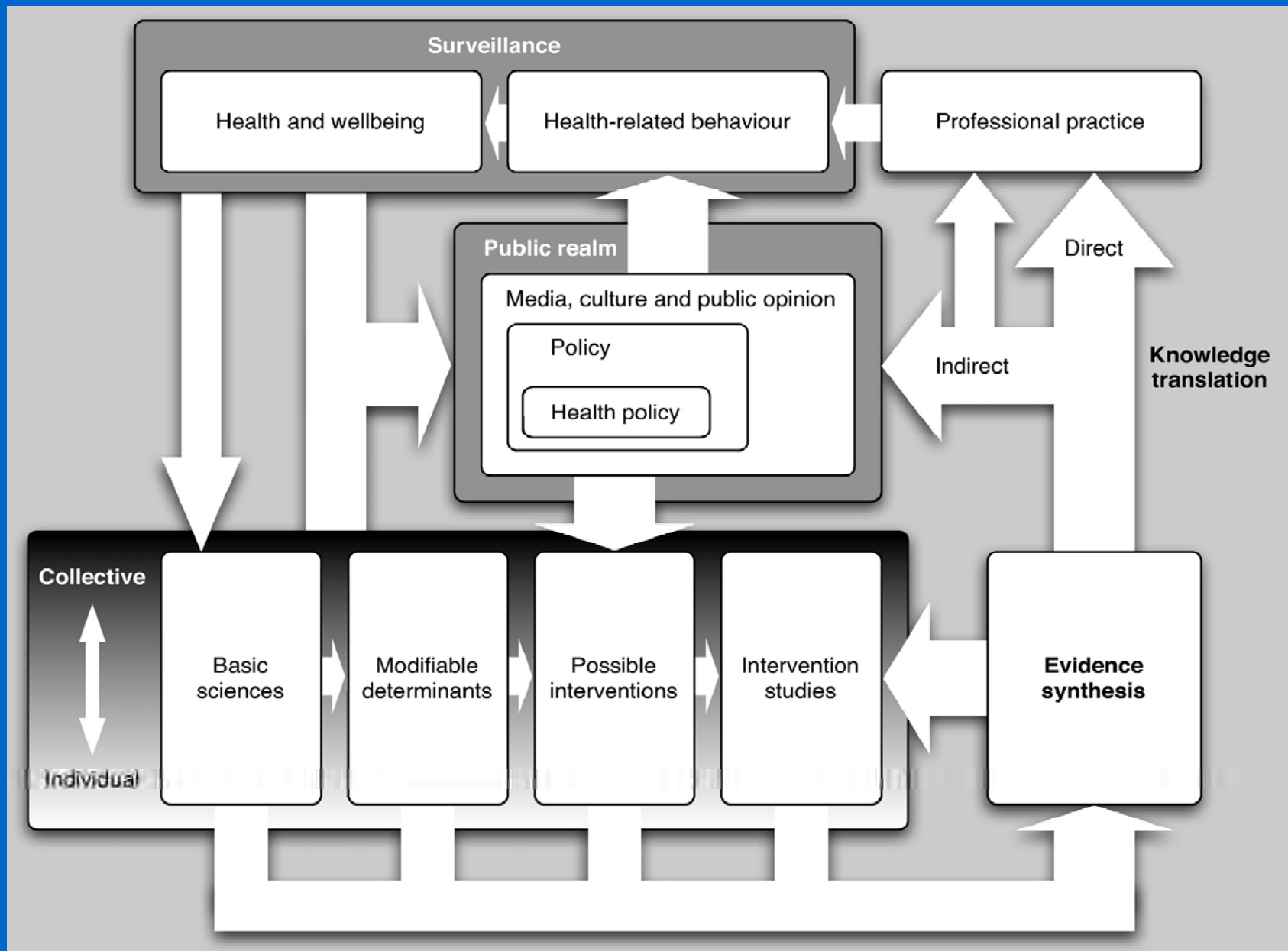
- Complex interventions include several components, often at different levels e.g. individual, group, setting, system, societal-levels.
- The evaluation of complex interventions is difficult –particularly when they are conducted under ‘real world’ conditions
- A phased approach to the development and evaluation of complex interventions is important
- Evaluation of complex interventions requires use of different study designs and approaches to measurement

Interventions for a Comprehensive Framework for Health in Missouri

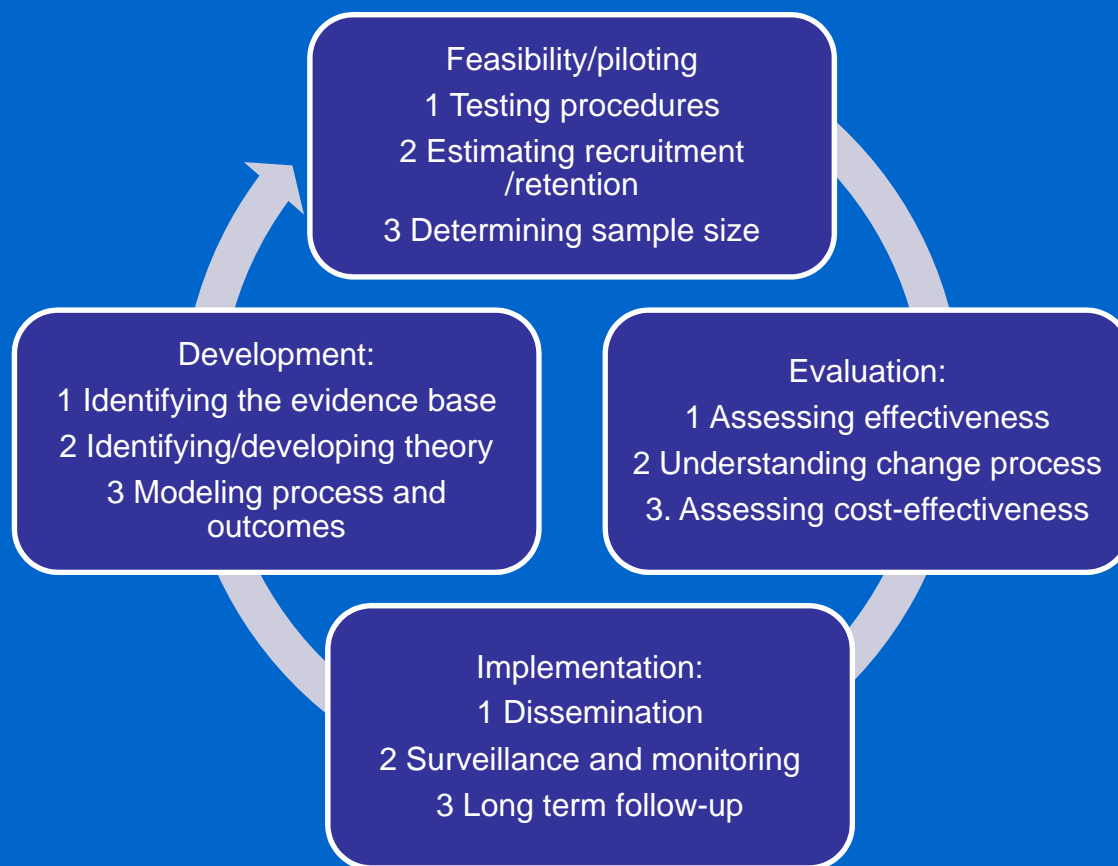
Interventions Priority Diseases/ Conditions	Policy Environmental Change	Behavior Change Risk Factor Detection and Control					PRIMARY CARE: Emergency Care/ Case Management/ Rehabilitation/End-of-Life Care			
	Community Coalitions and Partnerships	Multi-Media Awareness Campaign	Health Promotion Initiatives	School Health Initiative	Home Visiting by Nurses	Work Site Education	Provider Education	Counseling by Providers	Preventive Services Screening	Curative Rehabilitation Services
Chronic Disease/Condition										
COPD						■		■	■	■
Diabetes	■	■	■	■			■			
Stroke	■	■	■	■		■	■	■	■	■
Heart disease							■			
Lung cancer	■	■	■	■		■	■	■	■	■
Asthma	■	■	■	■			■			
Arthritis										
Prostate Cancer										
Mental Health Disease/Conditions										
Substance-related conditions										
Suicide attempts								■	■	■
Senility										
Alcohol-related conditions	■	■	■	■			■	■	■	■
Injuries								■		■
Motor vehicle injuries										
Assaults	■	■	■	■	■					
Fall injuries										
Infant Health Conditions	■	■	■	■	■		■	■	■	■
Infectious Diseases										
Pneumonia & Influenza	■	■	■	■				■	■	■

Translational framework for public health research

Ogilvie. *BMC Public Health* 2009, **9**:116 doi:10.1186/1471-2458-9-116



Key elements of the development and evaluation process



All Evaluation Research Designs

Post	--	X		O
Pre-post	O	X		O
Pre-post w/C	O	X		O
(post only)	--	--		O
Pre-post w/C	O	X		O
	O	--		O
Pre-post w/C	O	X		O
& post only C	O	--		O
	--	X		O
Pre-post w/C	O	X		O
& post only	O		--	O
P & C	--	X		O
(Solomon)	--	--		O

Prevention Research Designs– forward looking but still traditional

- ❖ Define health problem by assessing patient and community needs with patient and community
- ❖ Gain understanding of the problem and educate/train each other about factors
- ❖ Decide on most promising interventions
- ❖ Pilot test interventions

Prevention Research Designs– forward looking but still traditional

- ❖ If promising, test intervention efficacy
- ❖ If efficacious, test intervention effectiveness
- ❖ If effective, test intervention translatability
- ❖ If translatable, test intervention dissemination
- ❖ Replication? Adoptability? REAIM? Evaluation?

Forward looking often means traditional designs- Remember:

The “Gold Standard” - Randomized Controlled Trial (RCT):

- **random selection of subjects / participants**
- **random assignment to experimental conditions**
- **a “no treatment” or “placebo” control group**
- **The origins of the RCT are in experimental and clinical medicine where physicians evaluate the efficacy of a particular drug or treatment**
- **Often described interchangeably as “evidence-based”**

Ted Scharf, Ph.D., Research Psychologist, National Institute for Occupational Safety and Health, CDC, Cincinnati, Ohio

RCTs are criticized

- for not being practical or generalizable
- ethical concerns about denying the control group an intervention that they *believe* will be helpful.
- RCTs were not developed for the purpose of determining individual treatment

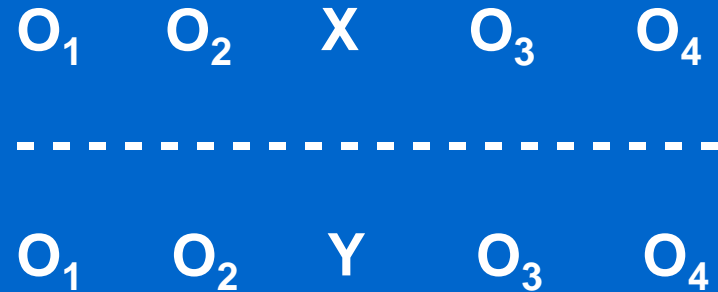
Example:

Experimentally trained researchers tend to focus on the requirements of internal validity (e.g. requiring a “true” experiment) to the exclusion of concerns related to external validity.

Inappropriate use of a Randomized Controlled Trial (RCT):

- CDC study regarding the prevention of transmission of HIV from birth mother to baby, in Côte d'Ivoire and Thailand, using:
 - reduced dosage of AZT, compared to a . . .
 - placebo control group, rather than to the U.S. standard of care
- *New England Journal of Medicine*, v.337, no.12, September 18, 1997 e.g.:
 - Angell, M. The ethics of clinical research in the third world. pp. 847-849.
 - Lurie, P., and Wolfe, S.M. Unethical trials of interventions to reduce perinatal transmission of the human immunodeficiency virus in developing countries. pp.853-856.

In Cook and Campbell notation, the CDC research design:



CDC design:

X = experimental, reduced AZT protocol

Y = placebo

participants:

HIV positive, pregnant women

A “comparison” group instead of a “control” group:

O₁ O₂ X O₃ O₄

O₁ O₂ Y O₃ O₄

O₁ O₂ Z O₃ O₄

Comparison groups design:

X = experimental, reduced AZT protocol

Y = U.S. standard AZT treatment

Z = AZT protocol, midway between X & Y

Another Model: change traditional research paradigm?

- From Experimental to observational – going backward on Ho
- From externally valid to internally valid- going backward in levels of validity
- Natural Experiments
- Pragmatic trials
- Comparative Effectiveness
- Patient, service, system, community

From Experimental to Observational Trials (backward)

- Efficacy (RCT) trials=hypothesis generating
- Effectiveness RCTs still hypothesis generating but closer to confirmatory evidence in a continuous process
- Under hypothetico-deductive logic, RCTs are considered “exploratory” and observations, “confirmatory”.

From externally to internally valid (backward level of validity)

- Top-down approach assumes linear progression from efficacy to dissemination
- with all deductive methods, the benefit that the conclusions follow deductively in the ideal case comes with narrowness of scope
- Complex causal chains of interventions make RCT results subject to effect modification in different populations

Are RCTs the Gold Standard? Nancy Cartwright .BioSocieties (2007), 2, 11–20

Victoria CG et al. Evidence-Based Public Health: Moving Beyond Randomized Trials. American Journal of Public Health | March 2004, Vol 94, No. 3

Bottom Up (Non-Linear) Approach

- Start with practice-based observational research or evaluation (patient, system or community based)
- Followed by practice-based quasi-experiment
- Close the evidence-based loop with RCT, if needed

Plausibility Research Designs

- Plausibility statements are derived from evaluations using observational designs with a comparison group.
- Adequacy statements result from demonstrations that trends in process indicators, impact indicators, or both show substantial progress, suggesting that the intervention is having an important effect.
- Complement probability statements or hold on their own

Community-Based Participatory Research

“Community-based participatory research is a **collaborative approach** to research that **equitably involves all partners** in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community with the aim of combining knowledge and action for social change to improve community (health)...”

Community Advisory Board



Benefits of Participatory Research in Practice-Based Evidence

- Results are relevant to interests, circumstances, and needs of those who would apply them
- Results are more immediately actionable in local situations for people and/or practitioners

Benefits of Participatory Research in Practice-Based Evidence

- Generalizable findings are more credible to other practitioners, policymakers, and communities because they were generated in partnership with people like themselves
- Helps to reframe issues from health behavior of individuals to encompass system and structural issues

Faridi Z, Grunbaum JA, Gray BS, Franks A, Simoes E. Community-based participatory research: necessary next steps. *Prev Chronic Dis.* 2007 Jul;4(3):A70. Epub 2007 Jun 15

EXAMPLE OF BACKWARD
APPROACH IN RESEARCH AND
MODIFICATION OF TRADITIONAL
RESEARCH PARADIGM:

CASE STUDY OF HEALTH
PROMOTION

RECIFE - BRAZIL

Rationale for Research on PA Interventions

- Prevention efforts in many developing countries are increasingly targeting risk factors, such as sedentary lifestyles
- Physical inactivity prevalence
 - 87% (0 days of 30-min LTPA) in NE and SE Brazil (Monteiro 2003)
 - 41% (<150 weekly min mod-vig PA) in Pelotas, Brazil (Hallal 2003)
 - 14.7 % of adults met LTPA recommendations, 15.6% of the population is completely sedentary (Malta 2009)

Rationale for Research on PA Interventions

- Although many promising PA interventions are being carried out in Latin America, the types and effectiveness of most interventions have not been systematically examined (2006)
- Methods used in the US (by CDC) have applicability in Latin America
 - The Community Guide
 - Observational methods

Challenges for Evaluation of ACP –Strategy Used

- Ongoing PA interventions - No baseline
- Intervention widespread in metro area with no natural comparison at time of first research
- Diversity of PA interventions
- Physical Activity measures- no standards
- But:
 - Evidence of acceptability and political support

Proposed Evaluations Strategy

- **Mixed strategy (6 studies in 2006-2008):**
 - Formative – historical, logic model, **ACP image penetration**, access & acceptance
 - **Prevalence CA-CO study**- ACP past & present measured - outcome in the present
 - **Short cohort with direct observation** estimate of PA & park usage
- **Followed by more rigorous design if indication of effect (2011):**
 - Natural experimental design

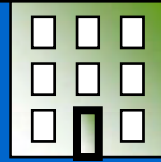
Program: “Academia da Cidade”

It is characterized as a policy of health promotion in physical activity and leisure that has as objective to contribute for the promotion of the collective health, potentiating re-qualified public spaces for leisure, units and equipment of the municipal network of health, with actions regarding practice of physical activities as leisure and improvement of physical fitness, that contemplate a better life quality to the population.

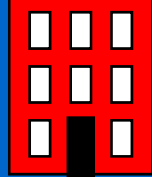
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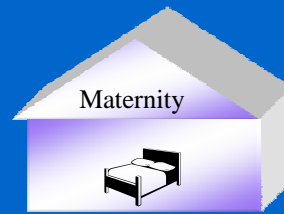
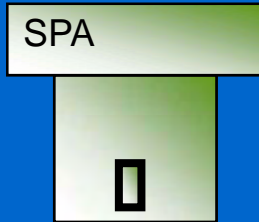
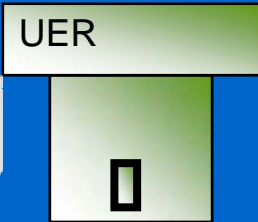
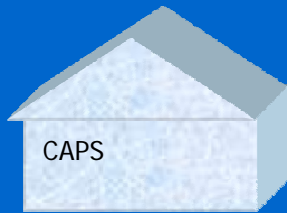
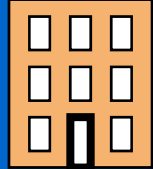
Clinics Hospital



General Hospital



Specialized Hospital



ADVANCED ACTIONS



USF



USF



USF



USF



USF



USF










ACADEMIA DA CIDADE



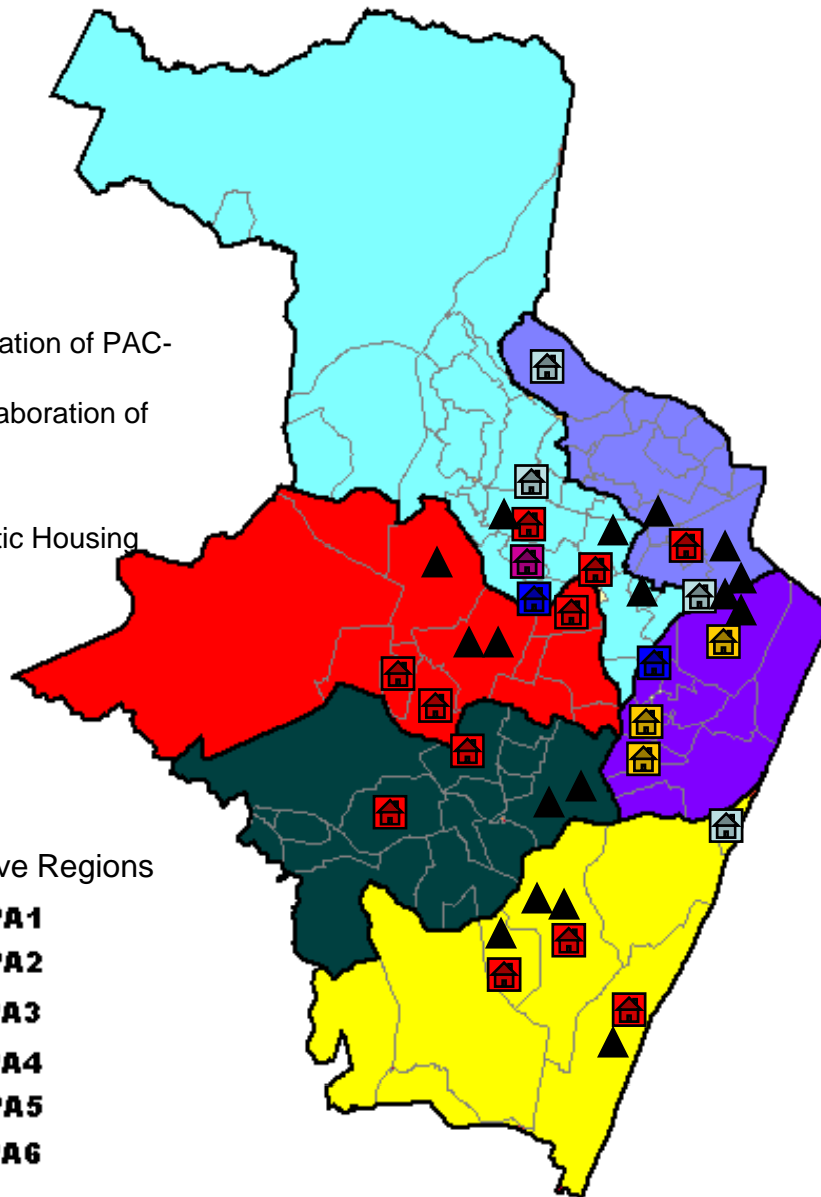
Map distribution of Basic Attention Health Promoters Units (Academia da Cidade Poles), Recife, 2006

Legend:

-  Implanted Pole (11)
-  (To inaugurate 4)
-  In process for inauguration of PAC-Itinerante (2)
-  Poles in process of elaboration of the projet (3)
-  Special Pole (1)
-  CAPS and Therapeutic Housing (17)
- 

Politic-administrative Regions

-  RPA1
-  RPA2
-  RPA3
-  RPA4
-  RPA5
-  RPA6

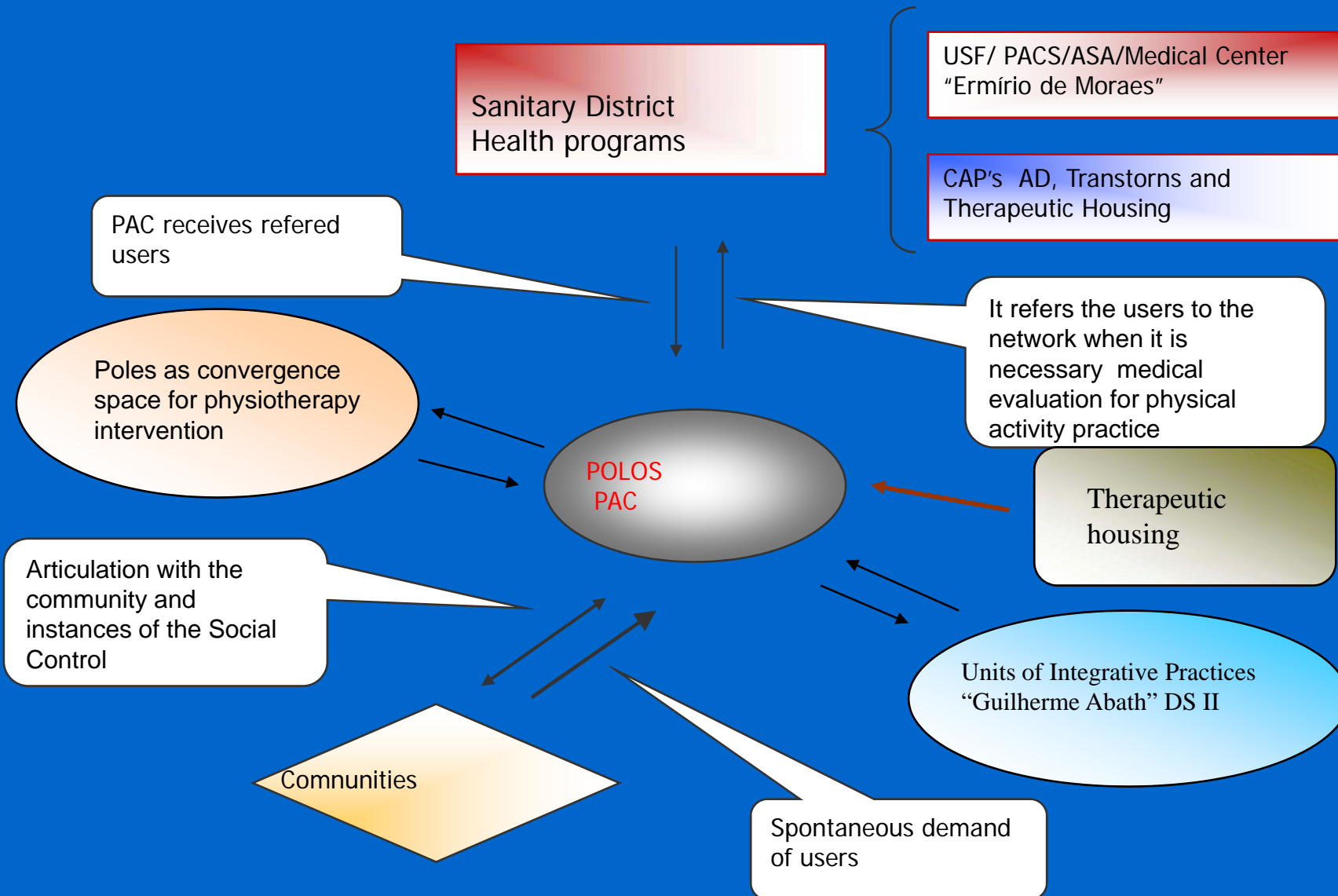


Program “Academia da Cidade”

- Activities in 11 public spaces (polos) and Medical Center “Ermírio de Moraes” (2006):
 - Physical evaluation
 - Nutritional evaluation and orientation
 - Exercise prescription
 - Orientation for walking/running
 - Gymnastic and dance classes
 - Stretching
 - Lectures
 - Holiday celebrations

By 2010, close to 30 polos do PAC

■ “— ‡○ fft> †>“Rfft ○>fffi■□SM



Effect of Academia da Cidade Program on Leisure-Time Physical Activity in Recife, Brazil, 2007 – Survey Based Evaluation

Eduardo J. Simoes, Pedro C. Hallal, Mike Pratt, Luiz Ramos, Marcia Munk, Wilson Damasceno, Deborah C. Malta e Ross Brownson For the GUIA Team

¹ Centers for Disease Control and Prevention, ² Universidade de Pelotas, ³ Universidade Federal de Sao Paulo, ⁴ Ministerio da Saude do Brazil, ⁵ Secretaria de Saude do Recife, ⁵ Saint Louis University School of Public Health

Simoes et al. Effects of a Community-Based, Professionally Supervised Intervention on Physical Activity Levels Among Residents of Recife, Brazil. Am. J Pub. Health, January 2009, 99 (1):68-75



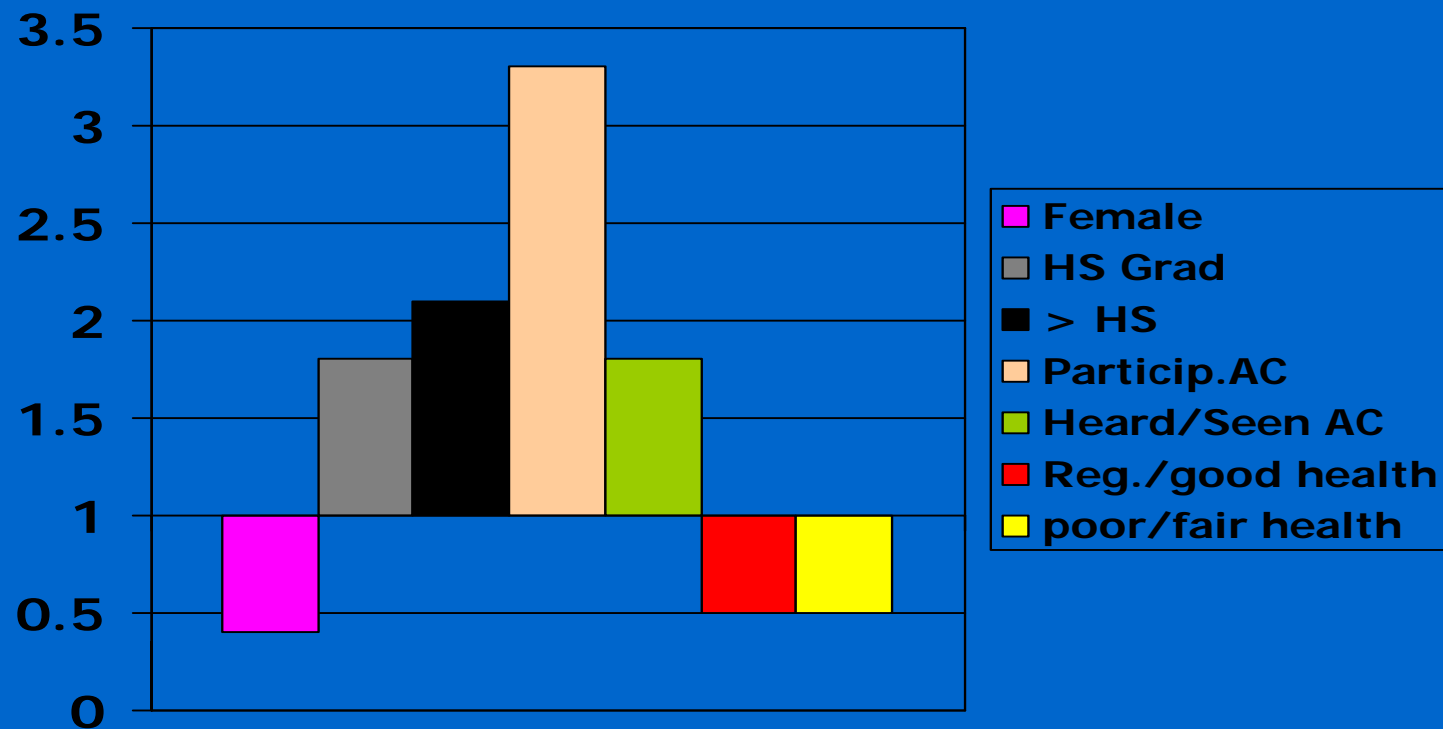
Survey-Based Evaluation- Material and Methods

- RPAS 2007 - a telephone survey-stratified cluster probability sample-2 strata - 24 clusters - oversampling of strata w/ACP site
- self-reported questionnaire administered to adults (ages 16 and older).
- 3, 632 eligible -2046 interviews completed
- Crude response rate of 56% and adjusted response rate of 64.5%
- Data weights-compensate for unequal selection probabilities due to – stratification, clustering, oversampling, # residents/# phone in household

Recommended levels of LTPA

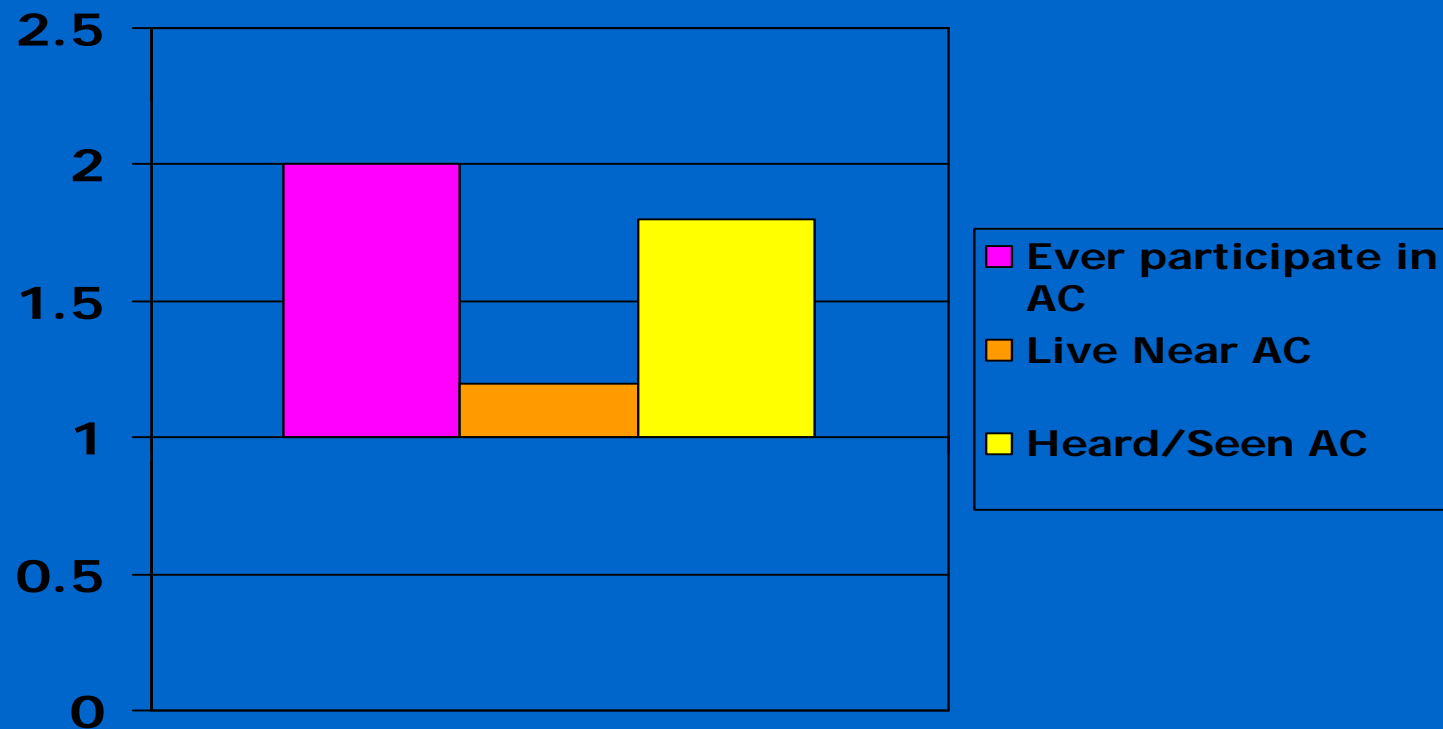
- Sensitivity Analysis:
 - IPAQ
 - VIGITEL (similar)
 - Mets/minute distribution- cut off 70-75%
- Main exposure:
 - Ever heard about/ever seen ACP activity (y/n)
 - Living near ACP site (y/n)
 - ACP participant: former, current, never - ever

Predictors of Moderate-High Leisure-time Physical Activity



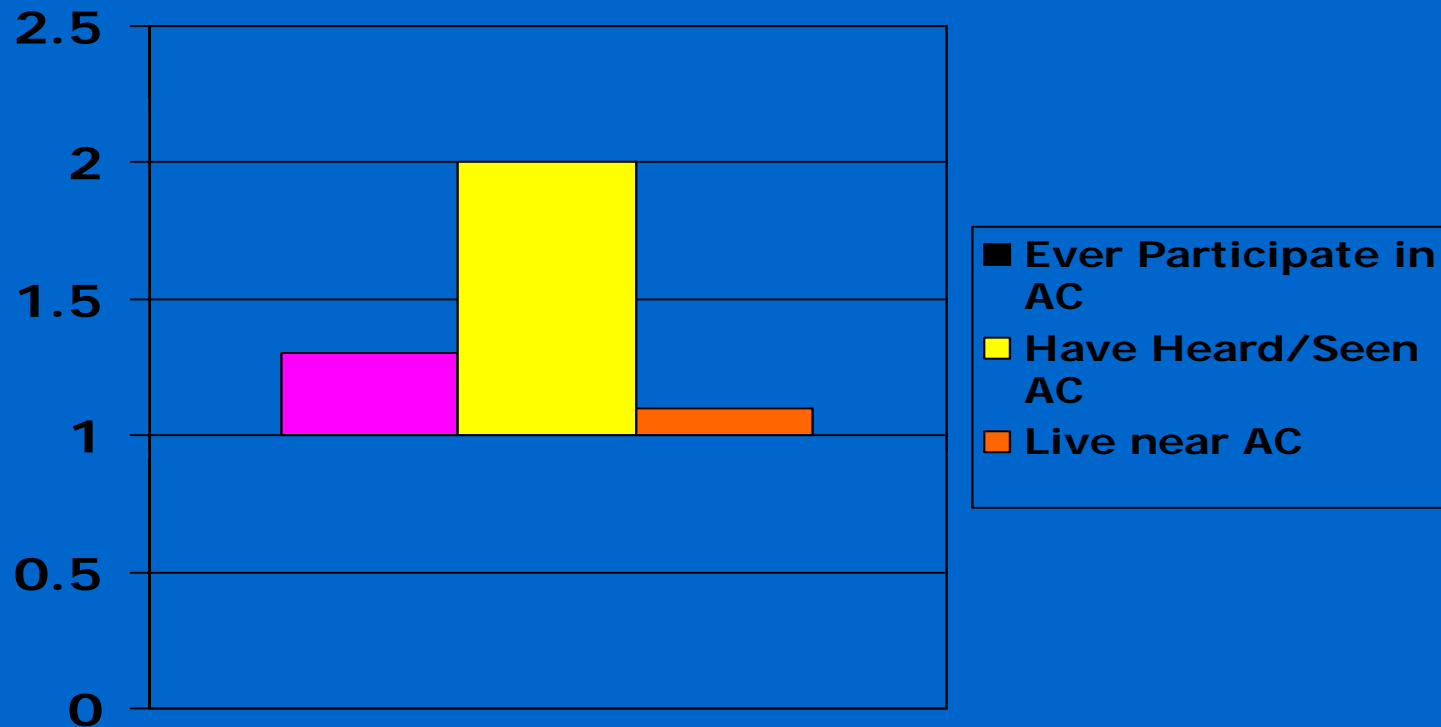
- ORs adjusted for all covariates in the model.
- Only statistically significant findings are presented.

Predictors of Moderate-High Leisure-time Physical Activity



- Odds Ratios adjusted for all covariates in the model.
- Only heard about AC/seen AC activity remained statistically significant, participation in AC became of borderline significance ($p=0.054$) but direction of associations is retained.

Predictors of Moderate Leisure-time Walking



- Odds Ratios adjusted for all covariates in the model.
- Only heard about AC/seen AC activity remained statistically significant

Conclusion- Study 1

- Among adults (ages 16 or older) in Recife (2007):
 - 19.4% reach WHO recommended levels of PA in leisure-time
 - 28.7% reach WHO recommended levels of PA through transport
 - Men are significantly more active than women in LTPA and TPA
 - 65% have heard about or seen ACP activity
 - Compared to non-participants of ACP:
 - ACP participants in the past are twice more likely to reach recommended levels of LTPA
 - ACP participants at present time are eleven times more likely to reach recommended levels of LTPA
 - ever participants of ACP are three times more likely to reach recommended levels of LTPA
 - Compared to those who never heard about or seen ACP activity, those who did were twice more likely to reach recommended levels of LTPA

GUIA

SOPARC in Recife



Parra et al. Assessing physical activity in public parks in Brazil using systematic observation. Published in the Am. J Pub. Health (2009)



Ministério
da Saúde



Why SOPARC in Recife?

- To establish comparisons between sites with and without Academia da Cidade pólos over a short period of time while indirectly adjusting for different socio economic status and factors influencing PA, represented by different social-economical districts of the city, and considering its proximity to the beach.
- To gather objective information on park use such as type of Physical Activity and percentage of age groups of the users.

Why SOPARC in Recife?

- The Academia da Cidade Activities are usually located in various public spaces, usually parks, plazas or squares. Therefore it is important for project GUIA to estimate the percentage of users, main type of activity, activity level, gender and age group.

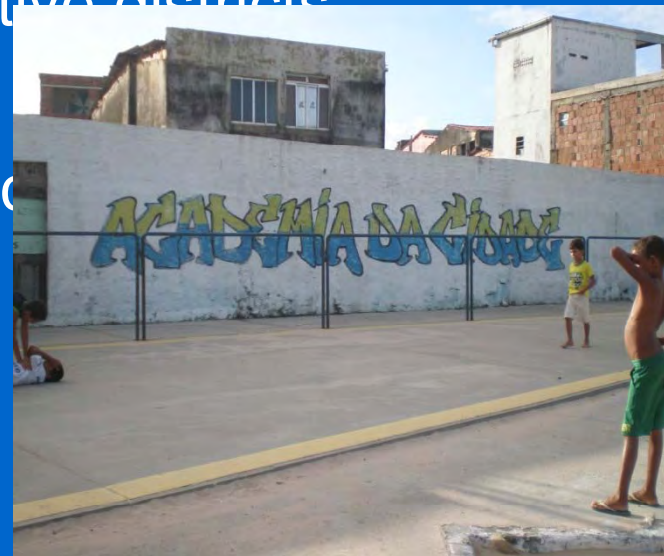
Introduction to SOPARC

- System for observing play and recreation in communities
- An objective tool, created by Thom McKenzie, used to look at “open” environments
- Used to obtain information about park and community space use through measurement of:
 - physical activity
 - age
 - gender
- Looks at characteristics of activity areas
- Provides a time-sample of use



SOPARC in Recife

- Conducted training of Academia da Cidade (ADC) staff
- Mapped 10 areas representing different socio-economic status (SES) and ADC presence, as well as most of the administrative districts
- SOPARC is well-suited for Recife
 - Size of parks/squares
 - Use of area
 - Well-defined boundaries



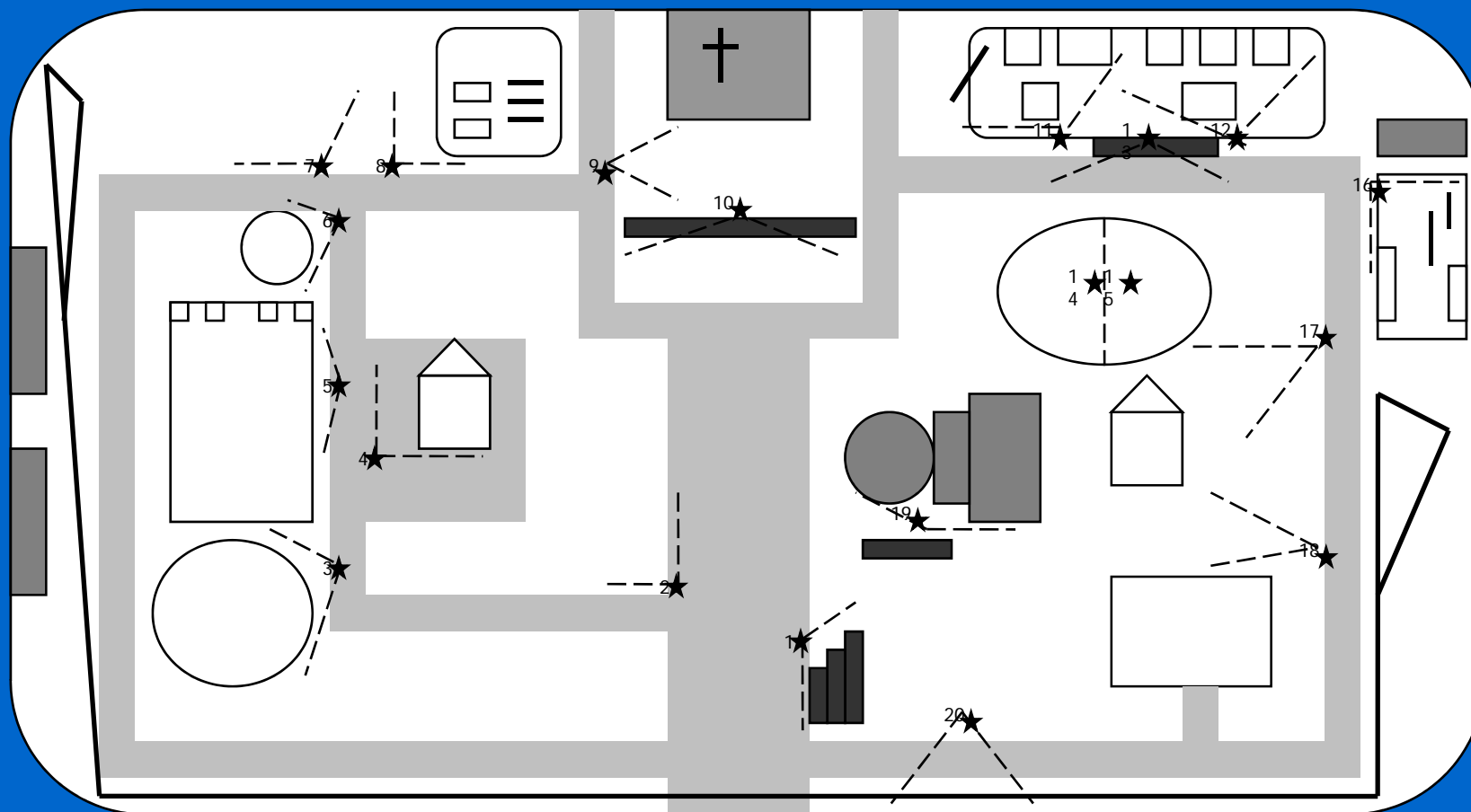
Mapping Areas

SES	Control (no ADC)	Intervention (ADC present)
Square		
High	Casa Forte	Jaqueira
Middle	Treze de Maio	Hipodromo
Low	Ypiranga	Sitio da Trinidade
Beach		
High	Boa Viagem	Boa Viagem
Middle	Piedade (Jaboatao)	
Low		Brasilia Teimosa

Basic Information

- Total parks observed: 10
- Total target areas observed: 128 mean 12.8
- Total of observation periods: 5589
- Times of observation: 6:30 am, 9:30 am, 2:30 pm, 5:30 pm
- Observers: 9
- Coordinators: 2

Jaqueira



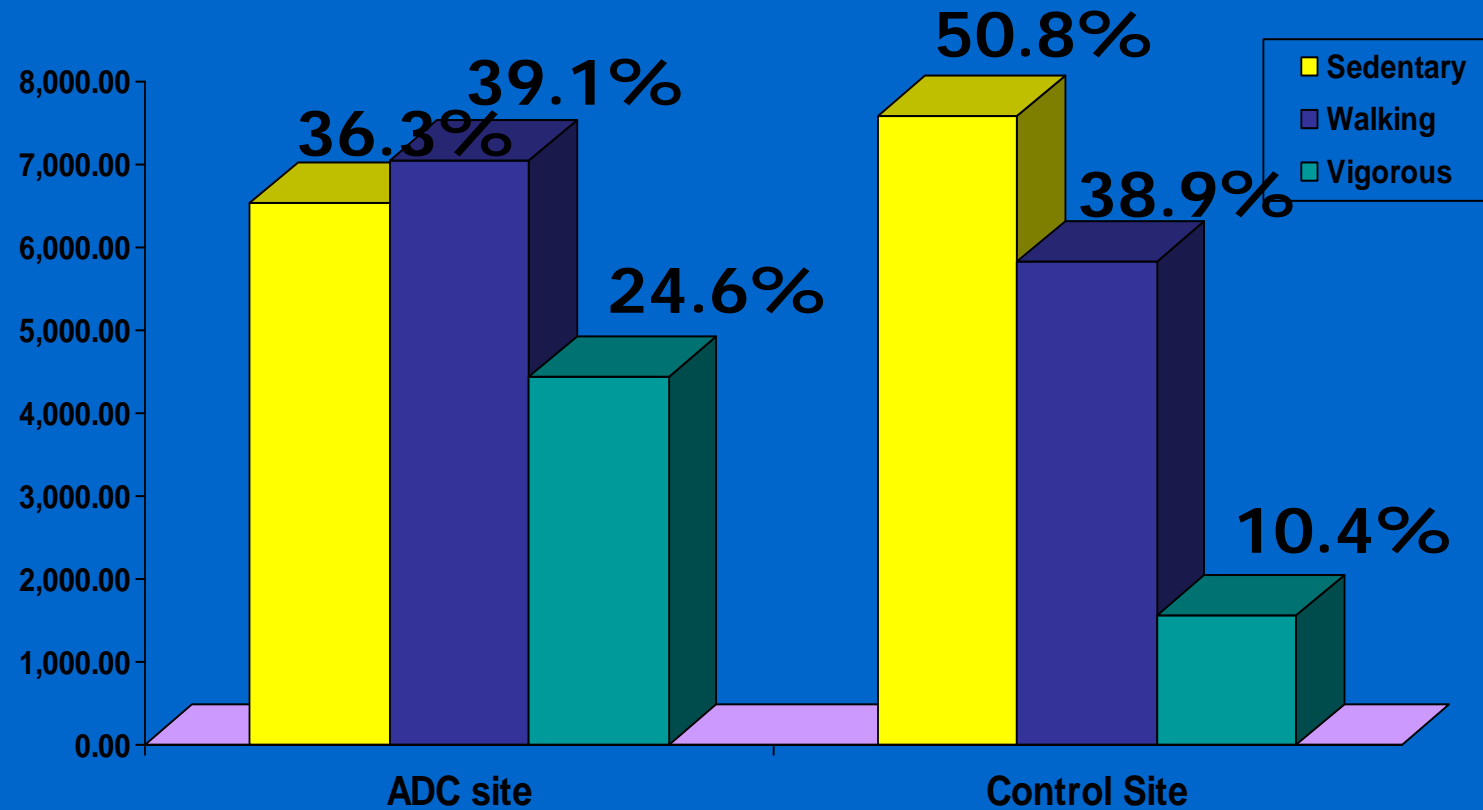
Target Area



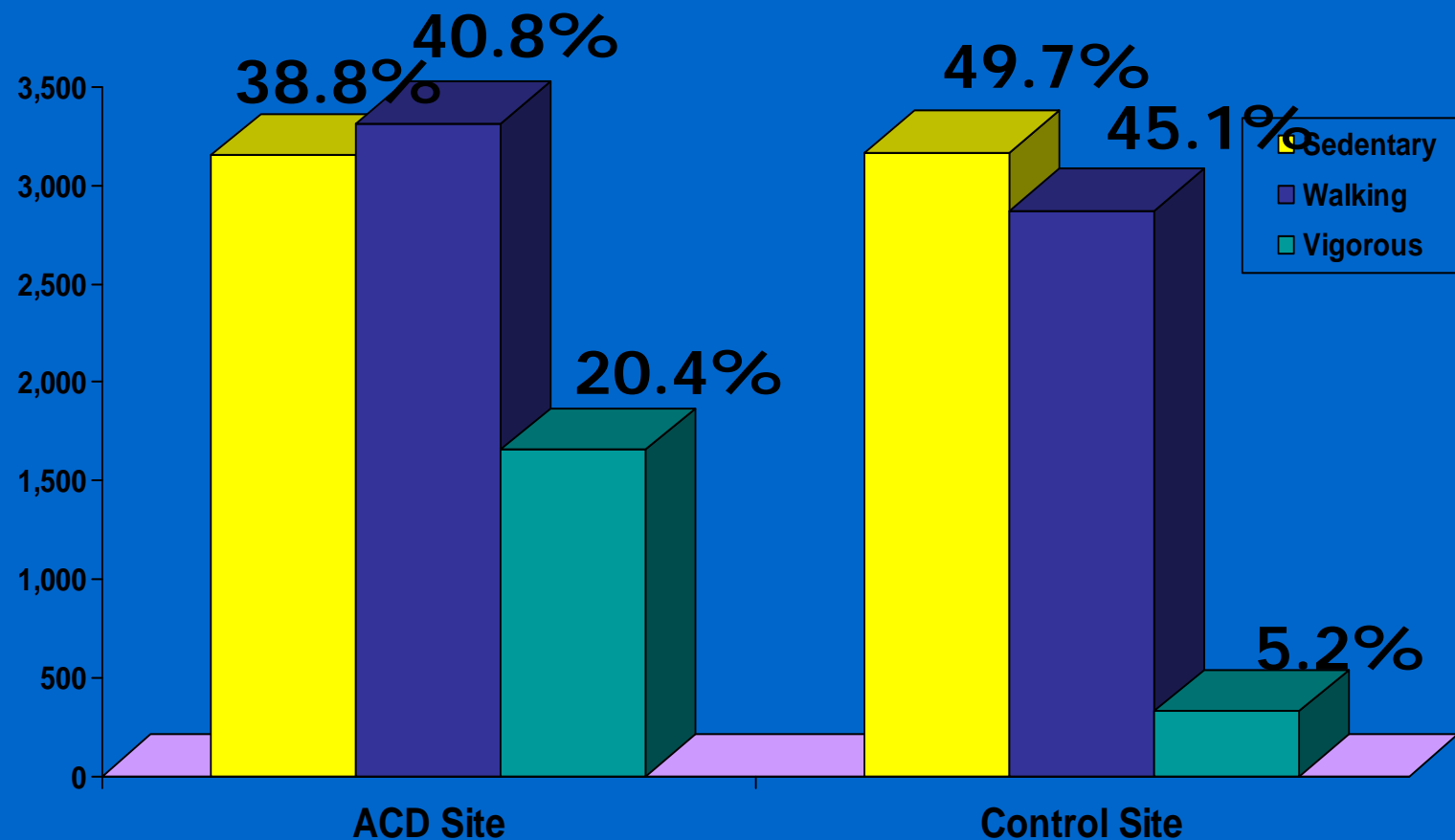
Research Phase Results

- Number of Observations: 5,589
- Over a period of 28 days
- Number of people observed: 32,974
average 3, 297.4 per park (range 935 - 9885)

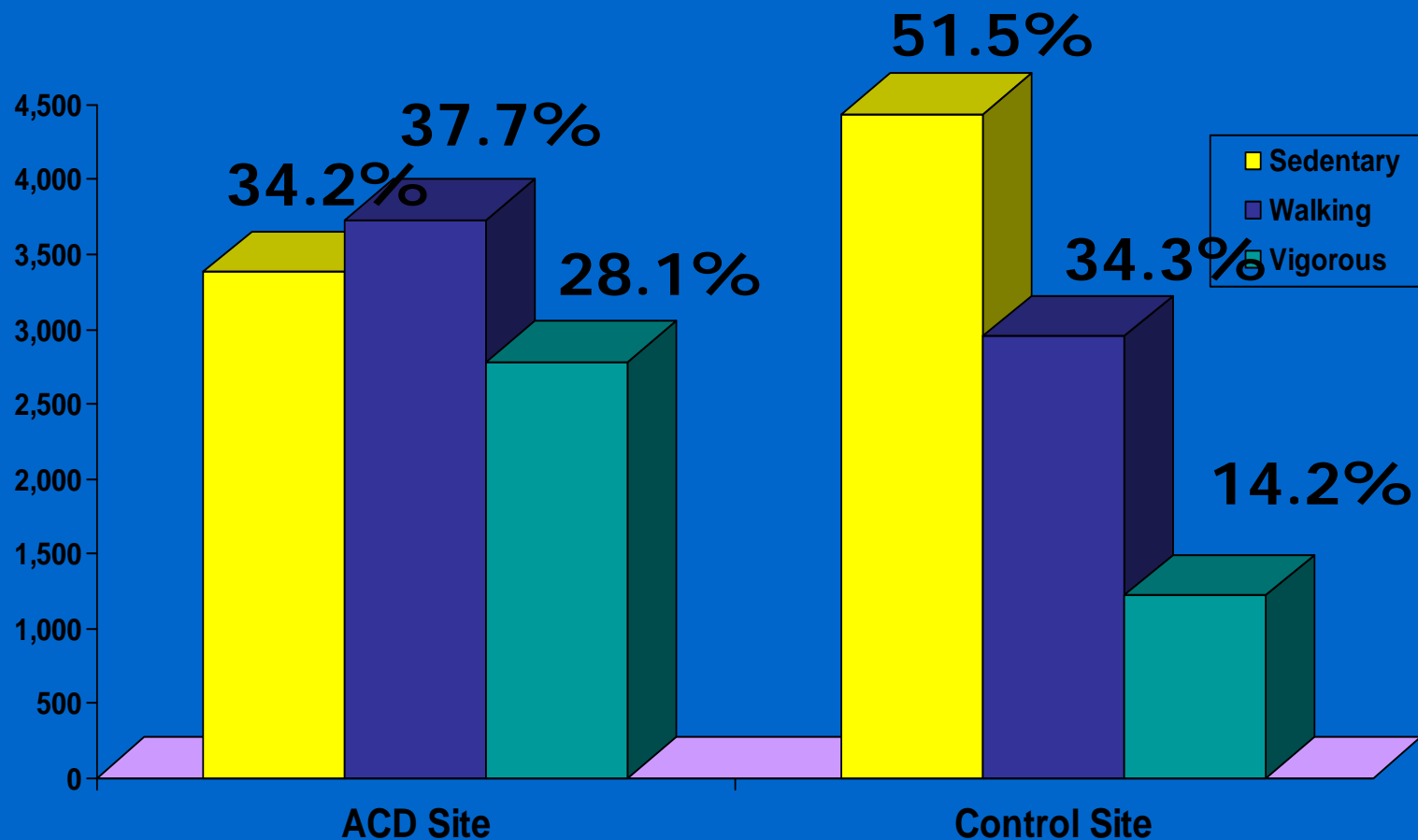
Total PA by PAC site



Total PA Females by PAC site



Total PA Males by PAC site



Conclusion-Study 2

- In Recife (2007) :
 - There are significantly more users in parks with ACP sites compared to non-site parks.
 - LTPA is significantly more frequent among users of parks with ACP sites than users of other parks
 - Moderate and vigorous LTPA are significantly more frequent among users of parks with ACP sites than among users of other parks

Programa Academia da
Cidade
Recife, PE
Quali-quantitative Evaluation

Hallal et al. In press: Cadernos de Saude
Publica

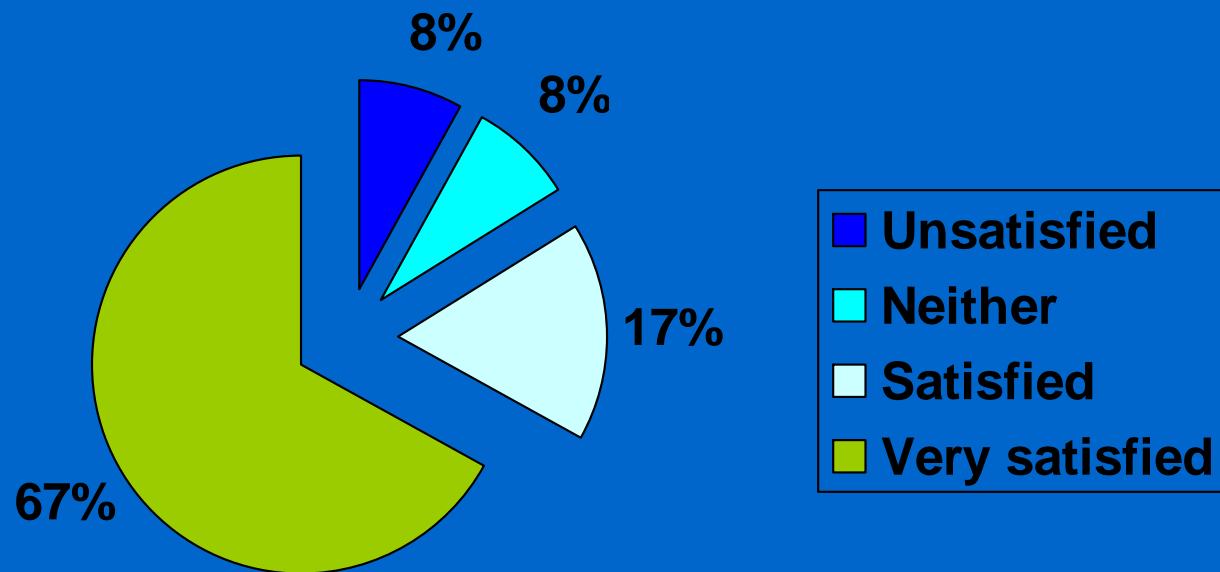
Metodology

- Managers-staff
 - In-depth interview (original sample)
- Professionals / fellows-interns
 - Closed questionnaire and in-depth interview (sub-sample)
- ACP participants
 - Closed questionnaire and in-depth interview (sub-sample)
- Non-members of ACP
 - Closed questionnaire and in-depth interview (sub-sample)

Metodology

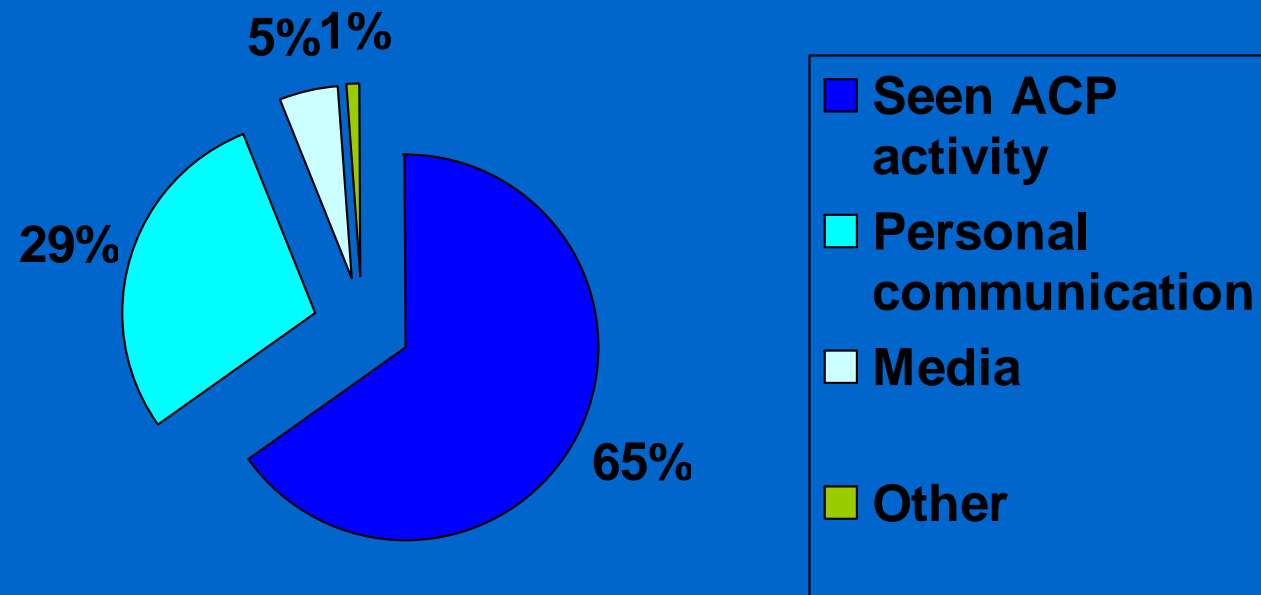
- Selected Site (representative)
 - Jaqueira
 - Sítio da Trindade
 - Avenida do Forte
 - Lagoa do Araçá
- Study subjects
 - 100 participants and 100 non-participants, selected from 4 ACP sites
 - 100 professional & fellow & other ACP staff

Results (professionals)



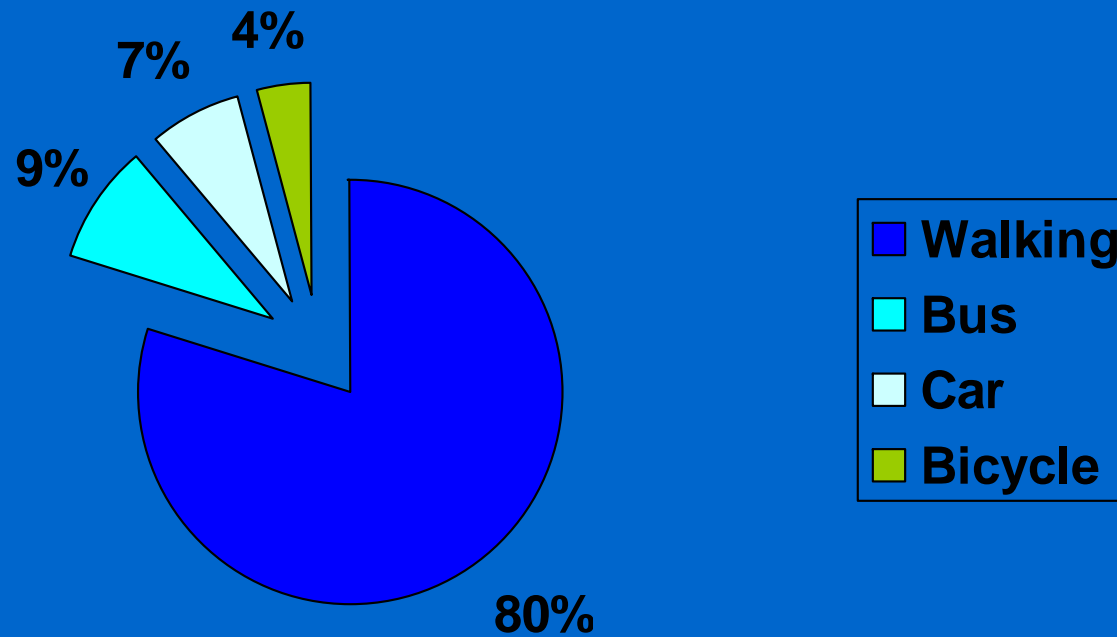
Professional Satisfaction

Resultados (usuários)



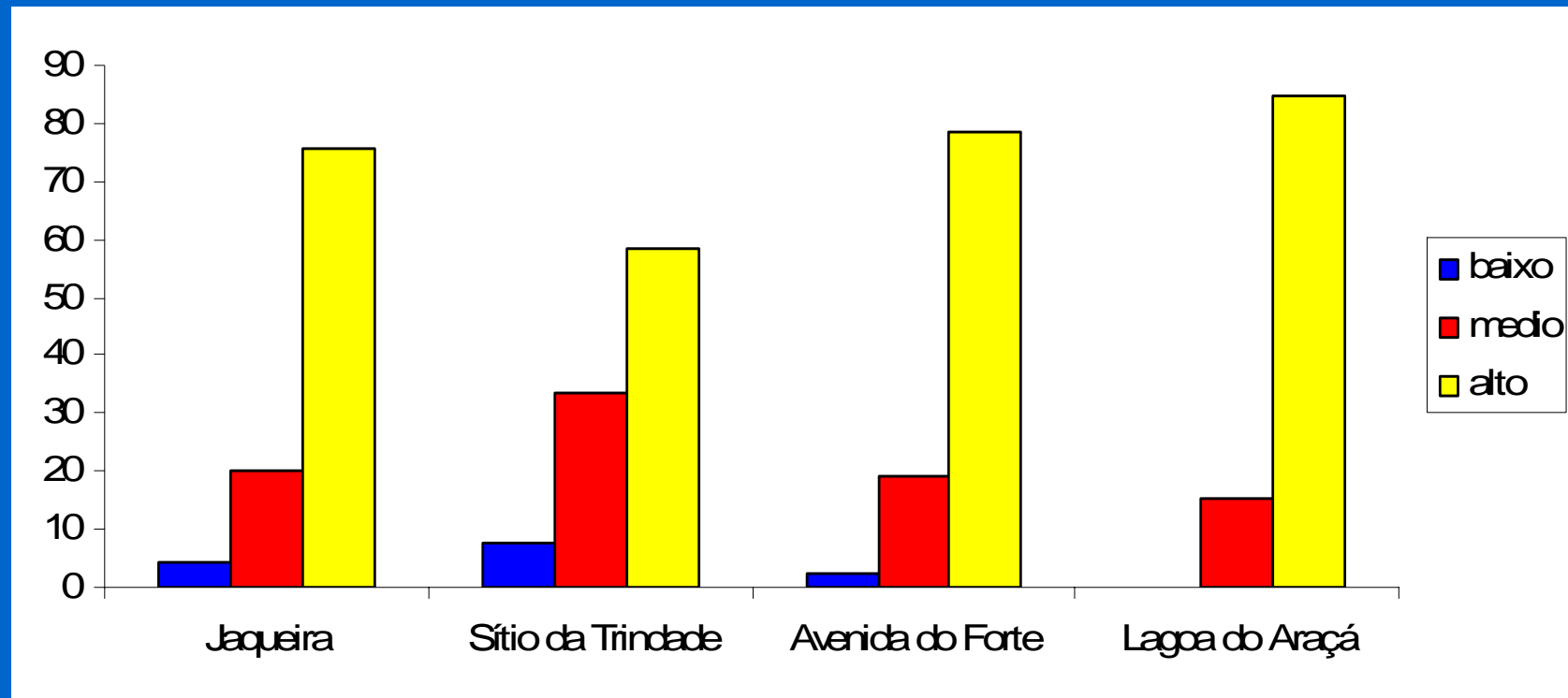
Learning about ACP

Results (participants)



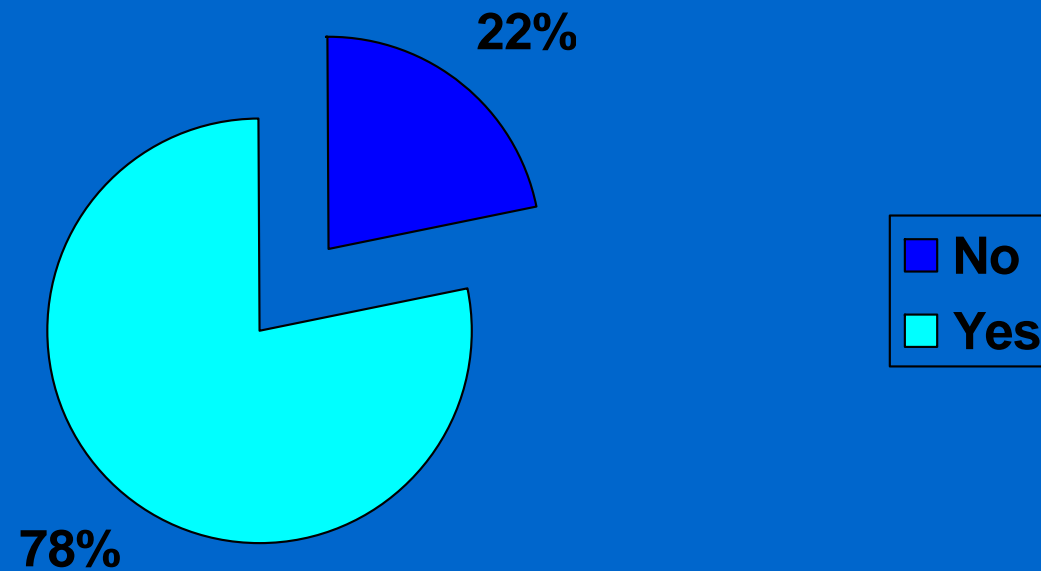
Accessing ACP site - transport

Results (participants)



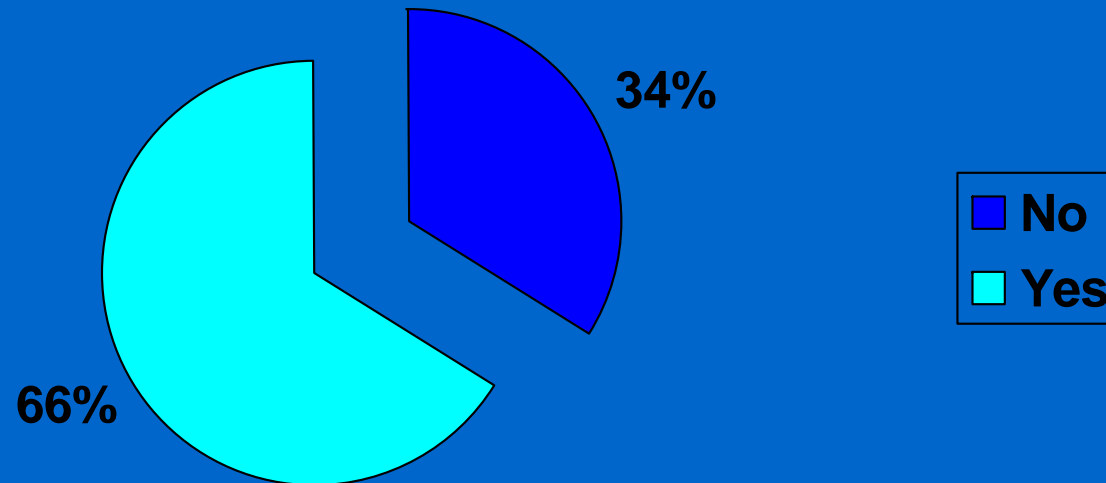
Levels of Satisfaction with ACP

Results (non-participants)



Heard about ACP

Results (Non-participants)



Intends to join ACP in the future

Conclusions – Study 3

- Penetration of the AC image and acceptability are very high:
 - 78% have heard about AC activity (62% in survey have heard about/seen activity)
 - 66% of non-participants of AC are thinking about joining the program (45% in survey)
- Very high levels of satisfaction with AC among participants (60-80%) and staff (67%)
- AC sites easily accessible to participants with 80 % routinely walking to site

Conclusions - Overall

- Penetration of the AC program image is very high
- Acceptability of ACP is very high
- Accessibility to ACP is very high
- There is sufficient evidence that ACP is effective and has had an impact on raising levels of LTPA in Recife (two different methodologies-same phenomenon)

Overall Recommendations

- Continue offering of ACP in Recife
- Expanding ACP in Brazil may be feasible
 - if necessary adapt to environmental, organizational and cultural differences and perform rigorous evaluation
 - Use similar survey and environmental measures over time (every two-four years) to monitor ACP growth and impact
 - If opportune, implement ***Natural Experiment***

Evaluating the Expansion of a Natural Experiment: PACID - a Population Wide Physical Activity Intervention

Eduardo J Simões (University of Missouri, School of Medicine)

Pedro C. Hallal (Federal University of Pelotas)

Rodrigo Reis (Catholic University of Curitiba)

Summary of four earlier studies

- ACP exposure associated with higher population levels of physical activity
 - Frequent members (active and past) more active than population (Parra et al)
 - Population more active than non-ACP (Parra et al)
- ACP members had better self-perception than non-members (Parra et al)
- ACP professionals were more satisfied with their professional activity (Hallal et al)

Evidence-based support for ACP

ACP Expansion: PE (PACID)

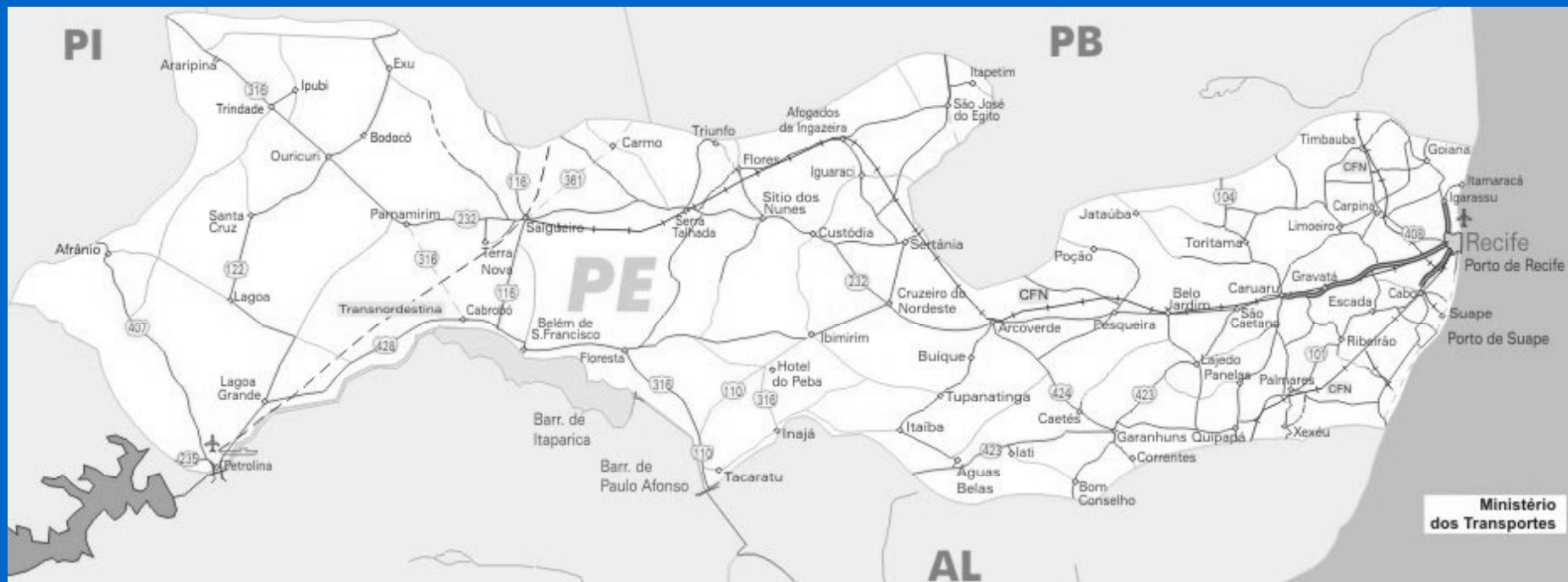


ACP Expansion in PE

- ACP is being expanded to all cities in Pernambuco state
 - PACID (also US other cities in Brasil)
 - Secretariat of the Cities
- Offer opportunity to augment evidence-based recommendations from a practice-based perspective
- IMIP-Recife conducted an “Evaluability Study” under guidance of EJ Simoes (GUIA)
 - Critical information on future expansion
 - Logistic elements for feasibility of implementing an impact evaluation

Goal

- Evaluate PACID impact on the Pernambuco State, first in the capital (Recife), then all 185 cities in the state



Objectives

- Evaluate PACID impact on population levels of leisure time physical activity in the state of Pernambuco, Brasil
- Evaluate sustainability and cost-effectiveness of the program using a logic model to identify inputs, processes and outputs that contribute to impact
- Build a community participatory approach that empowers community and enhance governance of municipalities receiving PACID resources
- Disseminate results of this evaluation project

Intervention Theoretical Model

- The Socio-Ecological Model for Latino Health Promotion, developed by San Diego University for the coming edition of the Annual Review of Public Health⁴⁷
 - depicts the role and interaction of various theoretically-driven health behavior change approaches to achieve health and environmental change in Latino communities.

Methods - Design

- During any time in July 2011 - July 2014, there will be municipalities in different stages of implementation of PACID:
 - Cities without physical changes (re-engineering of available spaces), professionals and LTPA classes (X1 or G1)
 - Cities with re-engineered spaces only (X2 or G2)
 - Cities with spaces and LTPA classes, professionals hired/contracted (X3 or G3)
 - Cities with spaces and LTPA classes, professionals hired/contracted, training of professionals (X4 or G4)
 - A combination of G1-G5 (or X1-X5) with early (1) and delayed start (2)

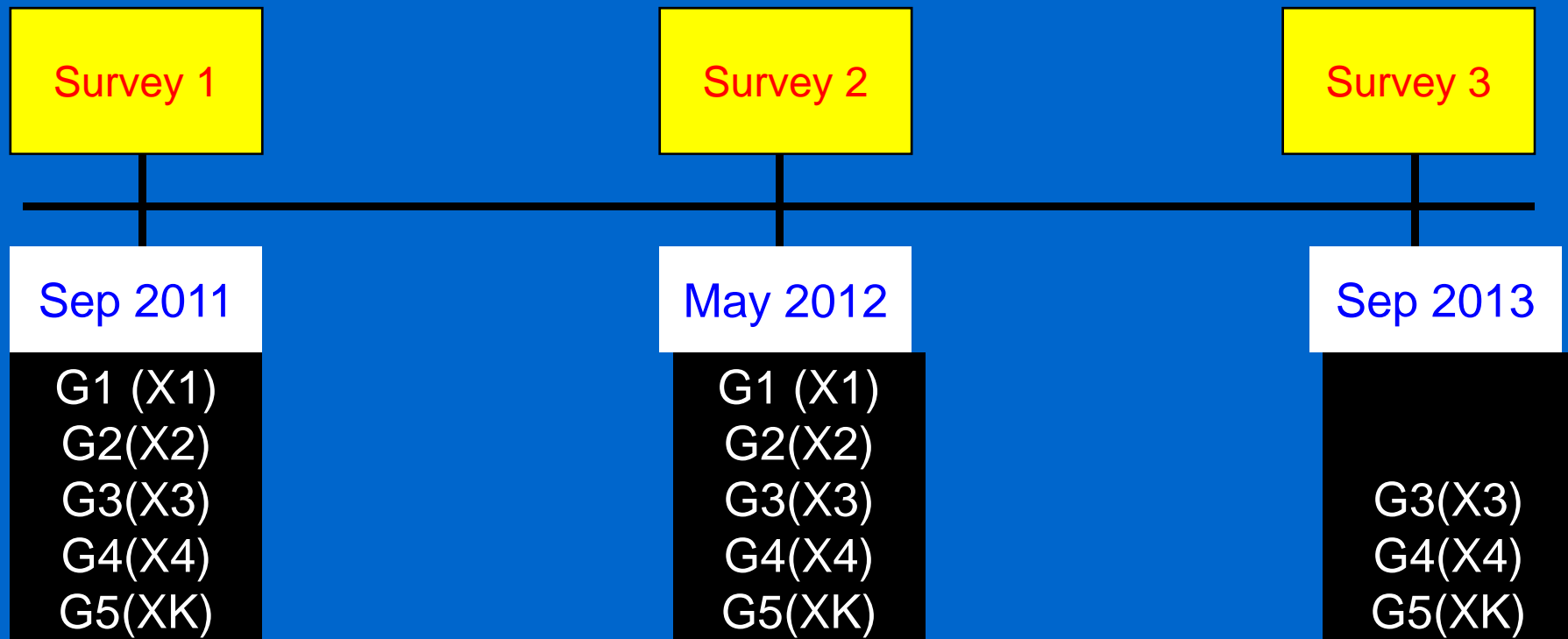
The success of the impact evaluation depends on the precise definitions and identifications of these groups

Methods - Design

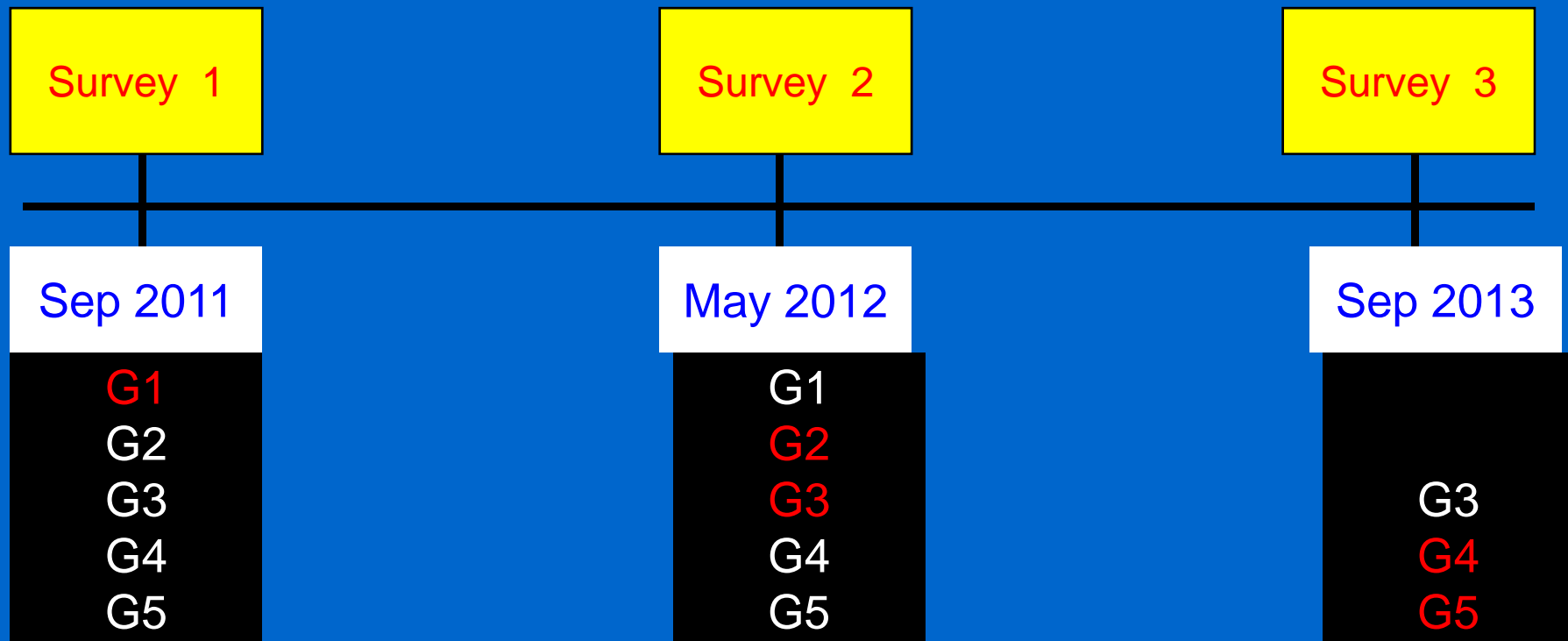
	T0		T1		T2		T3
N (1)	O ₁	X ₁	O _{1,2}	X _K	O _{1,2}	X _K	O _{1,2}
N (1)	O ₁	X ₂	O _{1,2}	X _K	O _{1,2}	X _K	O _{1,2}
N (1)	O ₁	X ₃	O _{1,2}	X _K	O _{1,2}	X _K	O _{1,2}
N (1)	O ₁	X ₄	O _{1,2}	X _K	O _{1,2}	X _K	O _{1,2}
N (2)	O ₁		O _{1,2}	X _K	O _{1,2}	X _K	O _{1,2}
N (2)	O ₁		O _{1,2}	X _K	O _{1,2}	X _K	O _{1,2}
N (2)	O ₁		O _{1,2}	X _K	O _{1,2}	X _K	O _{1,2}
N (2)	O ₁		O _{1,2}	X _K	O _{1,2}	X _K	O _{1,2}

Where N= Non-equivalent groups; (1) = *Immediate start*, (2) = *Delayed start*; O = observation; X₁=partial intervention-level 1; X₂=partial intervention-level2; X₃=partial intervention-level 3; X₄ = full intervention; X_K=any level of intervention (1-4). The timing of observations (measurements) indicated by column from left to right. The subscripts to observations (O₁ or O_{1,2}) indicate some measure or set of measures that were collected in *either* pretest (O₁) and posttest (O₂). Group intervention status need not to be known at time of sampling.

Many Comparisons



Many Comparisons



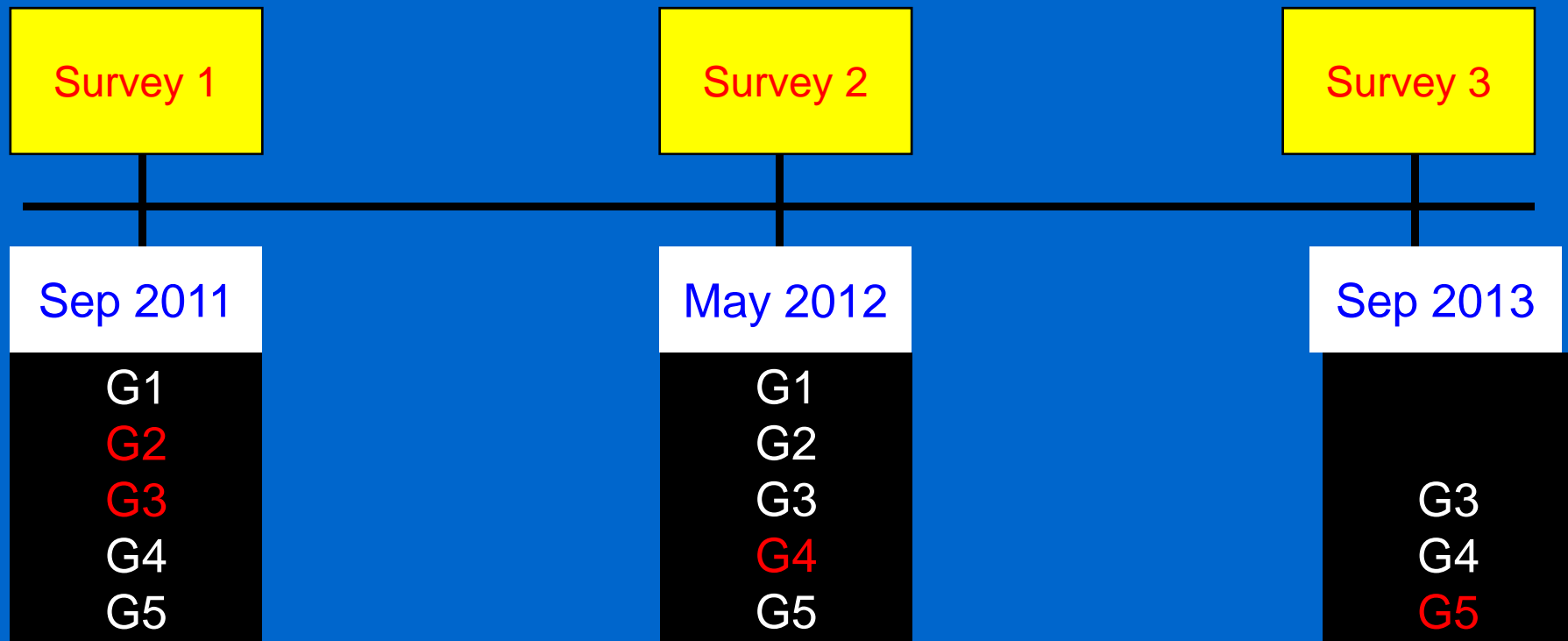
Many Comparisons



Many Comparisons



Many Comparisons



Biases

- Project allows for various comparisons between non-equivalent groups that mimics a RCT without the randomization
- Manner in which comparisons made (layers of intervention across groups with multiple baselines and follow-up intervals) allows for control or minimization of biases that commonly plague non-experimental designs (Design Strength):
 - Selection (specially loss to F-U)
 - History
 - Maturation
 - Contamination-bleeding
 - Confounding
 - Instrumentation; and
 - Statistical regression to the mean

Methods - Design

- Intervention Main Effect or Factorial Design?
 - Main effect - with only one intervention (PACID) in several layers compared to a control group
- Schedule for Data Collection
 - Natural history of intervention groups (city level) and sample of groups over time creates various designs in one study:
 - Two or more baselines
 - Additional follow-up intervals
 - Looked at as either a Posttest-only control group design or Pretest-Posttest Control Group Design

Methods –Design

- Cohort or Cross-sectional design?
 - Nested Cross-Sectional design – City with condition-intervention (PACID) is Group and individuals in a city are members – PACID affects entire population of members (Group =city)
- A priori matching or Stratification
 - Can be implemented with sampling units (SU) selected randomly from previously stratified Groups based on a factor that affect both Intervention status and outcome
 - Matching may be a possibility if # of groups (potential SU) is small

Methods – Sampling and Analysis Issues

- Units of assignment (sampling units=SU) = city (group): no-random allocation of condition/treatment (PACID) = Quasi-Experiment;
- Sample of intervention settings (SU): groups historically assigned to conditions/treatment
- Units of observation or analysis (UO): members within cities (members in the group)

Methods – Sampling and Analysis Issues

- Note that SU (X Groups 1 through 4) selected within one survey wave are independent (randomly sampled (rs) only once)
- Note that SU(X Groups 1 through 4) sampled in 2nd or 3rd survey wave are independent from each other in same wave and from SU in previous survey waves (rs only once – if large # of SUs to choose from)
 - However, it is possible that by chance same SU is re-sampled (repeated cohort design – correlation needs to be accommodated differently – more later)
- Also, because there are a limited # of groups randomization does not work well – selection bias likely (selection bias inevitable in quasi-experiment)- small DF
- But, members (unit of analysis) in each group are rs only once





Rua do Bom Jesus, no Recife Antigo, bairro de Sto. Antônio



A primeira Sinagoga das Américas, na rua do Bom Jesus



What else do we need? Policy Issues

- Outcomes research
- Health care management research
- System research
- Health informatics research
- Training and capacity building
- Public health-primary health care research

Prevention Research Centers

- Every country or region may need a Prevention Research Centers Network

A network of academic researchers, public health agencies, and community members that conducts applied research in disease prevention and control.

- Mission: The PRCs work as an interdependent network of community, academic, and public health partners to conduct prevention research and promote the wide use of practices proven to promote good health.

Medicine and Public Health Shared Mission and Complementary Approaches

Shared Mission

Improve health through education, research, and provision of evidence-based practice.

Public Health and Prevention Research

- **Public Health** is the science and practice of protecting and improving the health of communities and populations through education, research, policy and programs for preventing and treating diseases, and promoting health
- Prevention research is designed to provide a basis for the developing and diffusing effective policies, programs, and strategies to improve the health and well-being of communities and populations

Complementary Approaches

Medicine

Focus on the individual

Emphasis on treatment

Emphasis on clinical
research

Emphasis on researcher
driven investigations

Public Health

Focus on populations and
communities

Emphasis on prevention

Emphasis on prevention
research

Inclusion of participatory,
community-based research

Core Functions of Public Health

- Assess and monitor the health of the public to identify health priorities and disparities.
- Formulate policies to address identified local, state, and national health priorities and disparities.
- Assure that all populations have access to appropriate, evidence-based and cost-effective treatment and prevention services.

Primary Care and Public Health Exploring Integration to
Improve Population Health

at: <http://www.iom.edu/Reports/2012/Primary-Care-and-Public-Health.aspx>

PUBLIC RELEASE— MARCH 28, 2012

PAUL WALLACE, M.D. COMMITTEE CHAIR

LLOYD MICHENER, M.D.

MARY WELLIK, M.P.H., B.S.N.

INSTITUTE OF MEDICINE

Recommendation

- To create common research and learning networks to foster and support the integration of primary care and public health to improve population health, HRSA and CDC should:
 - support the evaluation of existing and the development of new local and regional models of primary care and public health integration, including by working with the CMS Innovation Center (CMMI) on joint evaluations of integration involving Medicare and Medicaid beneficiaries;
 - work with the Agency for Healthcare and Research Quality's (AHRQ's) Action Networks on the diffusion of best practices related to the integration of primary care and public health; and
 - convene stakeholders at the national and regional levels to share best practices in the integration of primary care and public health.

Principles for Successful Integration (IOM 2012)

- A shared goal of population health improvement;
- Community engagement in defining and addressing population health needs;
- Aligned leadership that
 - bridges disciplines, programs, and jurisdictions to reduce fragmentation and foster continuity,
 - clarifies roles and ensures accountability,
 - develops and supports appropriate incentives, and
 - has the capacity to manage change;
- Sustainability, key to which is the establishment of a shared infrastructure and building for enduring value and impact; and
- The sharing and collaborative use of data and analysis.

Case Studies of Integration

Durham, NC	San Francisco, CA	New York, NY
<p>Part of CCNC, a statewide network to coordinate and improve care</p> <p>Individual networks can tailor services to community needs</p> <p>A range of primary care, public health, and community participants</p> <p>Collaborative financing structure</p>	<p>Healthy SF is an intersectoral partnership to improve access to care</p> <p>Health Improvement Partnerships bring together a diverse group of community leaders to find innovative solutions to health issues</p>	<p>Promotes the use of electronic health records to improve the quality of primary care and generate public health data</p> <p>Engages with local communities to promote health education, access to care, and use of clinical preventive services</p>