

# Translational research in Health Disparities

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# Sources of Funding

- **RC1 NCMHD/NIH** “ Improving Adherence to Post PCIS Antiplatelet Therapy in Minority Populations ”.
- **Robert Wood Johnson** “ Using a Point of Care Automated Medication Delivery System to Improve Medication Adherence and Outcomes among Minorities with Diabetes ”.
- **James and Esther King Biomedical Research Program** “ Improving Adherence to Cholesterol Lowering Medications among Minority Populations in Florida: A Randomized Trial ”.

# Objectives

- Describe the impact that translational research can have in health disparities reduction.
- Describe the challenges encountered for conducting translational research in health disparities.
- Present novel strategies to overcome these challenges and to produce real world knowledge that can help investigators identify sustainable solutions for health disparities.

# Disparity Definitions

- **Healthy People 2010/** disparities in health: *unequal burden in disease morbidity* and mortality rates experienced by ethnic/racial groups as compared to the dominant group
- **HRSA:** population-specific differences in the presence of disease, health outcomes, or access to health care
- **OMH:** gaps between the health status of minorities and non-minorities in the United States

# Health disparities in the US

- Defined in the US as “health differences between specific groups”.
- Euro/WHO: “Differences in health which are not only unnecessary and avoidable but are considered unfair and unjust”.

# Why are disparities important?

- Social Justice
- Mortality
  - 800,000 excess deaths due to disparities
- Economy
  - Eliminating health disparities for minorities would have reduced direct medical care expenditures by \$229.4 billion for the years 2003-2006
  - Eliminating health inequalities for minorities would have reduced indirect costs associated with illness and premature death by more than one trillion dollars between 2003 and 2006

# Life expectancy at birth by race and ethnicity

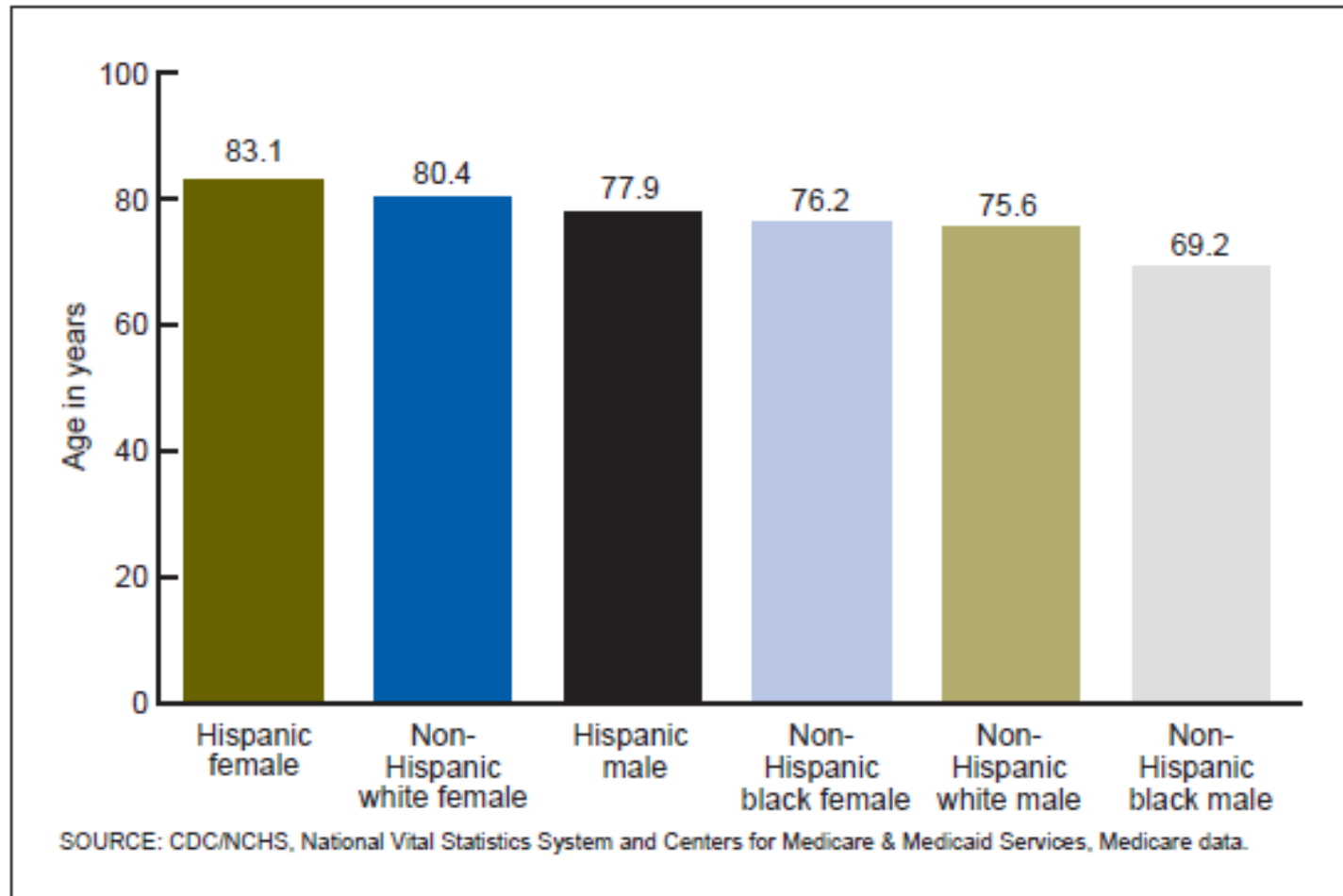
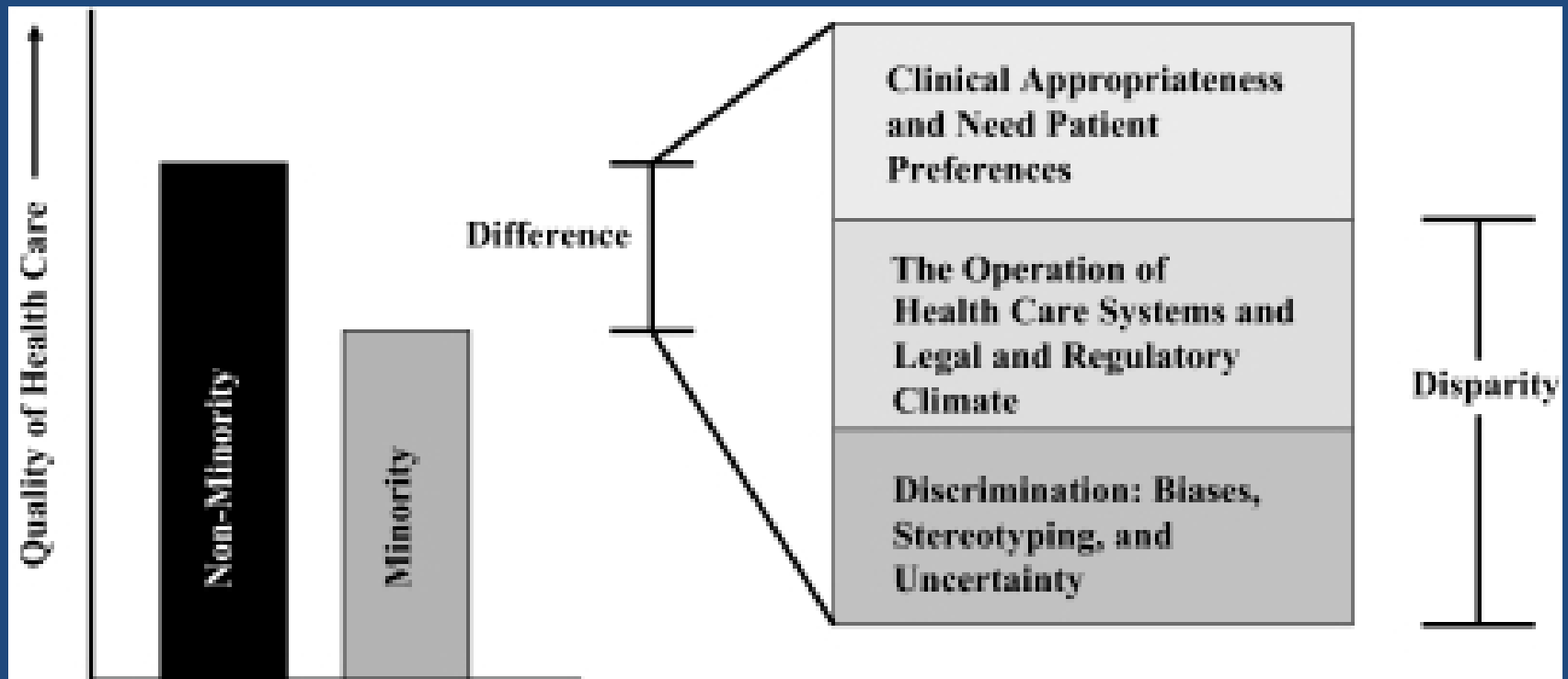


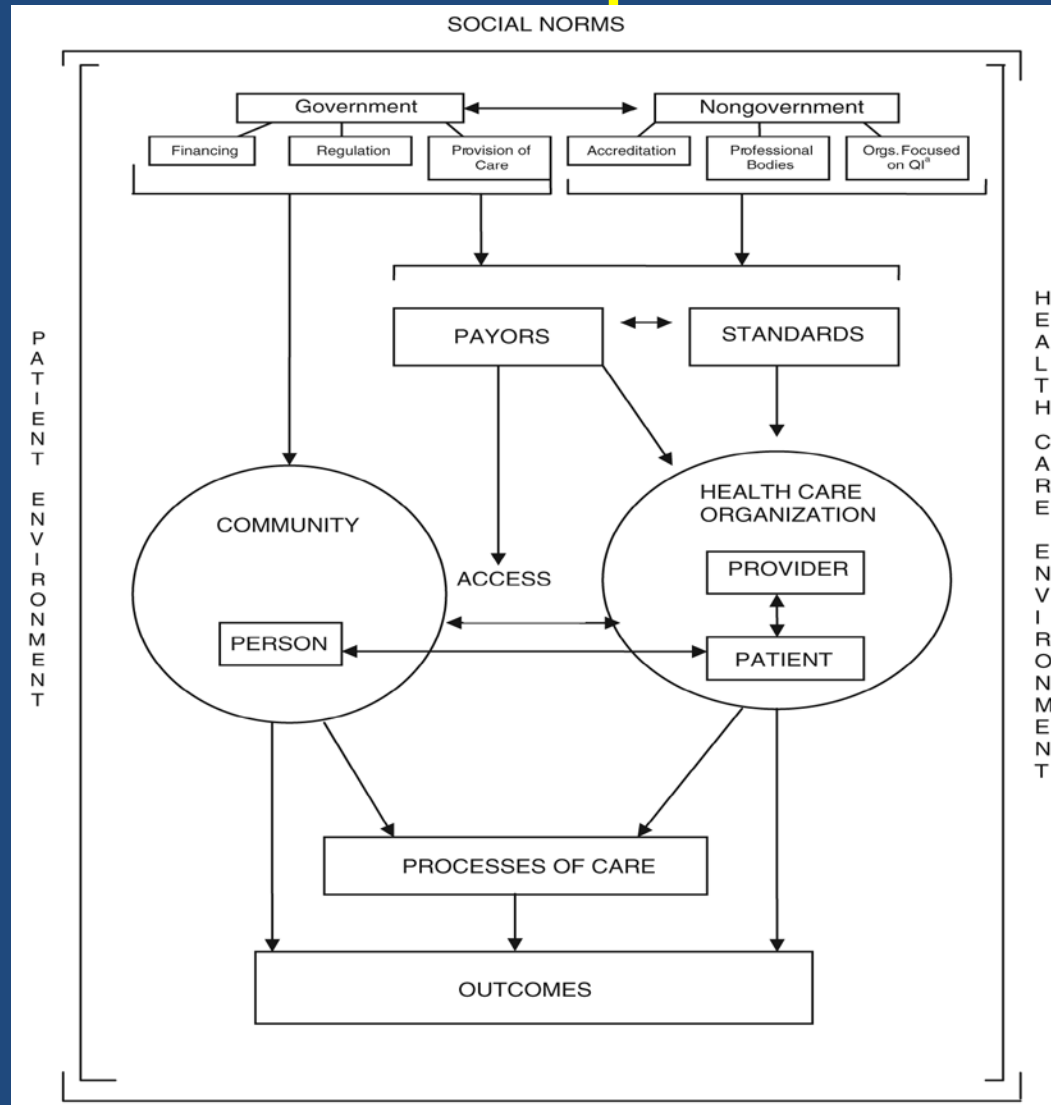
Figure 6. Life expectancy at birth, by Hispanic origin, race, and sex: United States, 2006

# Differences, Disparities and Discrimination: Populations with Equal Access to Health Care

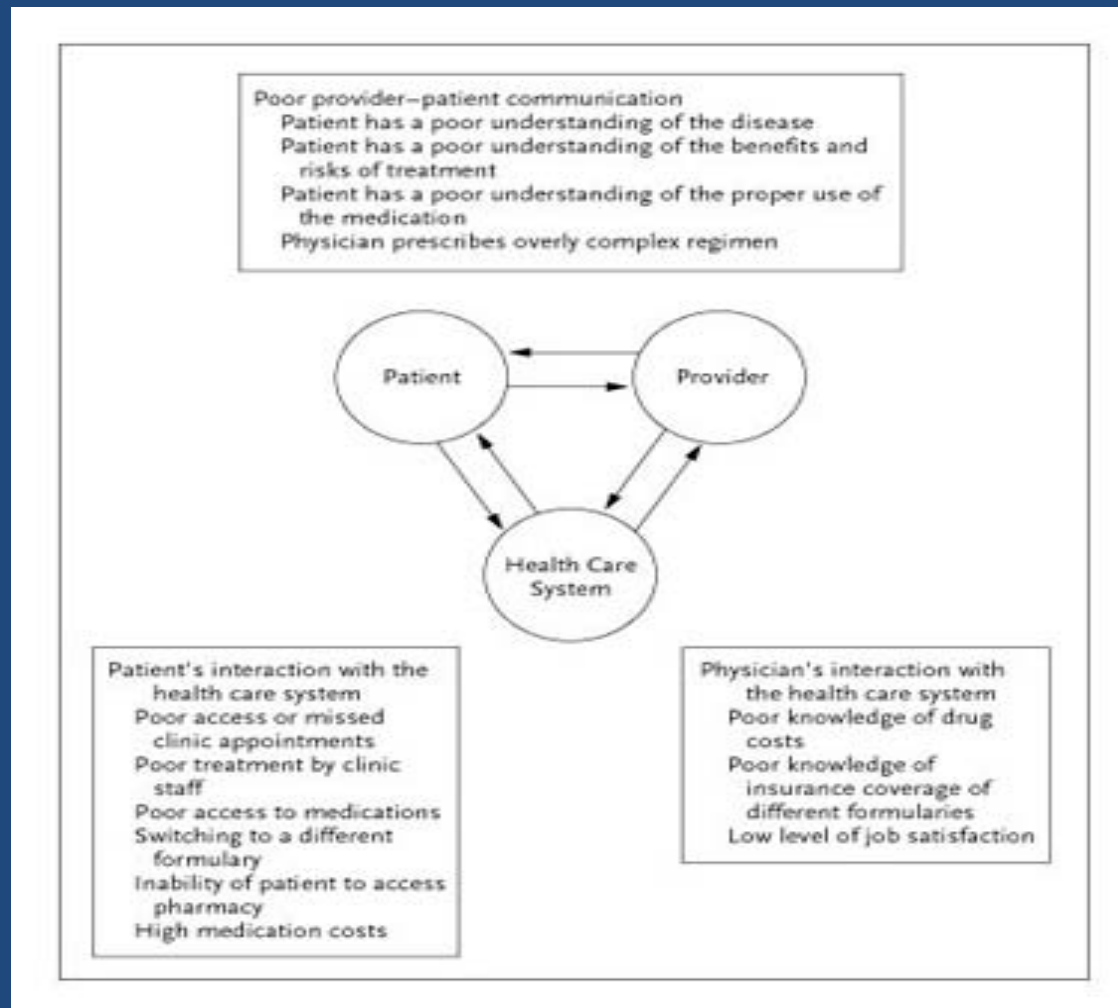




# RWJ: Conceptual Model of Health Disparities



# Barriers to Medication Adherence



# Impact of Translational Research

- Apply biologic/laboratory/experimental data for minority populations in real practice.
- Translation from conceptual model to a sustainable cost-effective intervention.
- Key to inform the Affordable Care Act health reform initiatives:
  - Accountable Care organizations
  - Meaningful use
  - Health Homes

# NIH Mandate

- Since 1993, the National Institute of Health (NIH) has required that racial and ethnic minority groups be adequately represented in all NIH (2009) sponsored research.
- Increasing the participation of racial and ethnic minorities in clinical trials is recognized as a key strategy for the reduction of health disparities.

Freedman et al. 1995; Institute of Medicine 1999; Corbie-Smith, Moody-Ayers, and Thrasher 2004)

# Institute of Medicine Health Disparities Report

- Representation of minorities in clinical trials continues to be suboptimal in many areas of biomedical research.

IOM Health disparities report 2007

# Barriers for translational research on health disparities

- Recruitment of minorities into clinical trials  
Identification, access, trust, language, fear of harm
- Lack of Race/ethnicity data
- Lack of longitudinal data on minority populations, tend to get sporadic care
- Difficulty in providing access to preventive care or continuity care for uninsured/non legal immigrants

Swanson and Ward 1995; Hall 1999; Heiat, Gross, and Krumholz 2002; Sateren et al. 2002; Swanson and Bailar 2002; Sullivan et al. 2007; Ford et al. 2008; CorbieSmith et al. 2003; HussainGambles, Atkin, and Leese 2004; Williams and Corbie-Smith 2006 ,Lauderdale and Goldberg 1996; Arday et al. 2000; National Research Council 2004)

# Approaches

- Community based recruitment
- Recruitment from safety net hospitals
- Use of national surveys
- Use of registry data if race/ethnicity present
- Use of vital statistics/state data

# Usual Limitations

- Sample size
- External validity
- Sustainability
- Investigators career needs
- Cross-sectional data
- Geographically limited
- Lack of diversity within the minority group (similar SES, education, country of origin, etc)



# New Approaches

- Use of health benefits data to identify and recruit minority populations into trials and follow their longitudinal data.
- Use of data collected in electronic medical records from community based clinics.
- Mandate/Incentivize collection of REAL data  
(Race/Ethnicity/Ancestry/Language of preference) in all health systems and registries.

# New Approaches

- Utilization of mixed methods to try to elucidate biological determinants from social, cultural, educational determinants.
- Development of interventions that collect data while testing the effect of real world interventions on the patients and their context (clinic, community, family, payers) to fine tune other hypotheses and evaluate sustainability.

# Identification of Minorities

- The Medicare Race Code (MRC) has a sensitivity of 97 percent for white persons and 95 percent for black persons, but less than 40 percent for Hispanic Medicare beneficiaries. (Arday et al. 2000)
- The addition of the Spanish Surname list to the MRC increases sensitivity to identify elderly Hispanics to 97% for males and 95% for females. (Wei et al 2006)
- The use of geocoding and of census based surname lists have shown 70-97% sensitivity and specificity. (Fremont et al. 2005; Fiscella and Fremont 2006; Elliott et al. 2008)

# Identification of Minorities

- Geographic racial segregation remains widespread and thus geocoding continues to be very accurate for the identification of black subjects. (Fremont et al. 2005; Glaeser and Vigdor 2001)
- A bayesian approach showed an improved sensitivity over the additive approach. (Fremont et al 2008)
- These approaches viewed as tools to be used for population based observational studies and not to identify an individual subject. (Fremont et al 2008)

# A new algorithm to identify an individual minority subject

- Used data from a health benefits company (Humana) to develop algorithm and later pilot it.
- Humana has 3.5 million members enrolled.
- We identified all subjects older than 18 years who received a coronary stent (ICD-9 codes 36.06, 36.07) during September and October of 2009.
- We excluded subjects who died or dis-enrolled from the health plan, those living in states where neither of the two Humana study nurses held a nursing license, and self insured employer groups for whom Humana only provides administrative services.

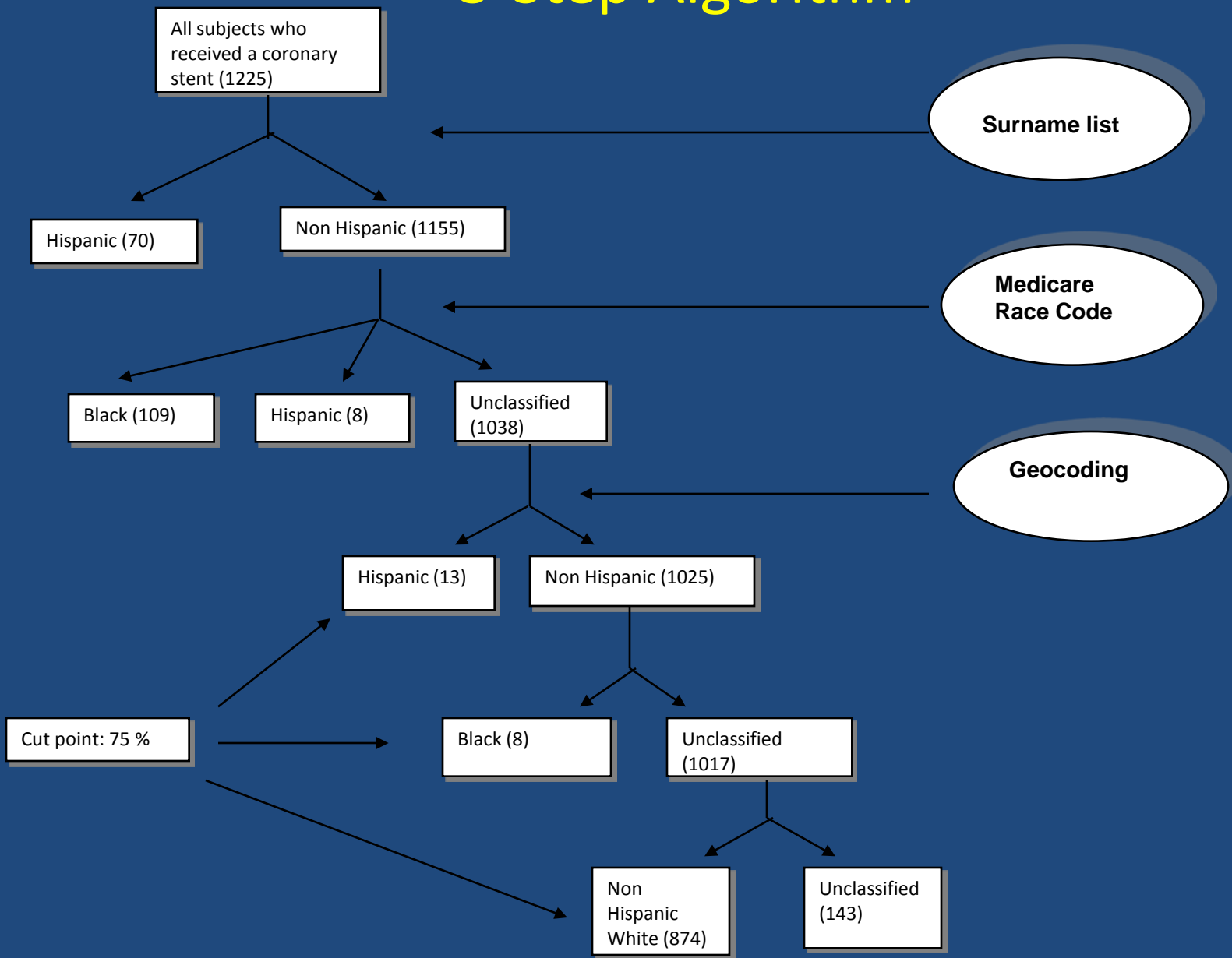
# Assignment of Race/Ethnicity

- We assigned a likely race/ethnicity according to a 3- step sequential algorithm:
  - 1) The 1990 Census Spanish Surname list
  - 2) The Medicare race code and
  - 3) Geocoding techniques to identify subjects that live in neighborhoods where 75% are of a particular race/ethnicity.
- For geocoding we used the full address of each subject.

# Gold Standard

- We ascertained race/ethnicity information by self report.
- Two bilingual (Spanish/English) Humana nurses made up to ten attempts to reach each subject during a one week period.
- For verification of race and ethnicity subjects were asked "Are you of Hispanic or Latino origin?" and "Do you consider yourself Black or African American, White or other race?"

# 3-Step Algorithm





# Baseline Characteristics

Characteristic	
Number	94/164
Age (yr)	70.6 8.9
Female, %	46
Likely Black, %	72
Likely Hispanic, %	28
Drug eluting stents, %	76
Medicare, %	96

# Accuracy of the Algorithm

Population	Number	PPV (95% CI)
Entire population	94	93% (85-97)
Blacks	60	98% (91-100)
Hispanics	27	89% (71-98)

# Challenge grant: Improving adherence to post PCIS antiplatelet medications

- Using the algorithm we recruited 452 minority subjects in a period of 10 months
- The PPV was 92.3%
- Design : RCT to evaluate the comparative effectiveness of Motivational interviewing and a mailed educational DVD at improving medication adherence to antiplatelet medications post stent placement.
- 384 completed the final survey.

# Outcomes

- **Primary Outcome:**
  - Medication Possession ratio
- **Secondary Outcomes:**
- Self reported adherence
  - New stent/re-stenting
  - Myocardial Infarction
  - All cause mortality

# Medication possession ratio

- Medication Possession Ratio (MPR)  
Defined as the sum of the days' supply of medication during each 12 month period divided by the number of days between the date of the first prescription and the last day of follow up

$$MPR = \frac{\sum \text{Days' supply of medication}}{\sum \text{days between 1st and the last day of the analyses period}}$$

# Study Arms: Motivational Interviewing

- “A patient-centered counseling style for eliciting behavior change by helping patients to explore and resolve ambivalence”
- Two Humana nurses trained in MI made 4-7 phone calls over a period of 9 months to subjects in that study arm to discuss their medication taking behaviors and promote desire/readiness for change from within the subject.

# Study Arms: DVD

- Based on role play theory, this DVD the patient-physician relationship of two subjects (one Black and one Hispanic) and their cardiologist (Dr. Juan Zambrano).
- They communicate in their own words how they achieved behavior change after the stent placement, how they seek information from their doctor, the importance of being engaged in their health care etc.

# Challenge Grant: Baseline Characteristics

Characteristic	Black (n=251)	Hispanic (n=201)	P-value
Age (yr)	69.1±8.7	70.0±8.9	0.28
Male, %	52	65	<0.01
Income < 30K, %	80	75	0.25
Education greater than middle school, %	20	25	0.18
Current smoker, %	14	10	0.23



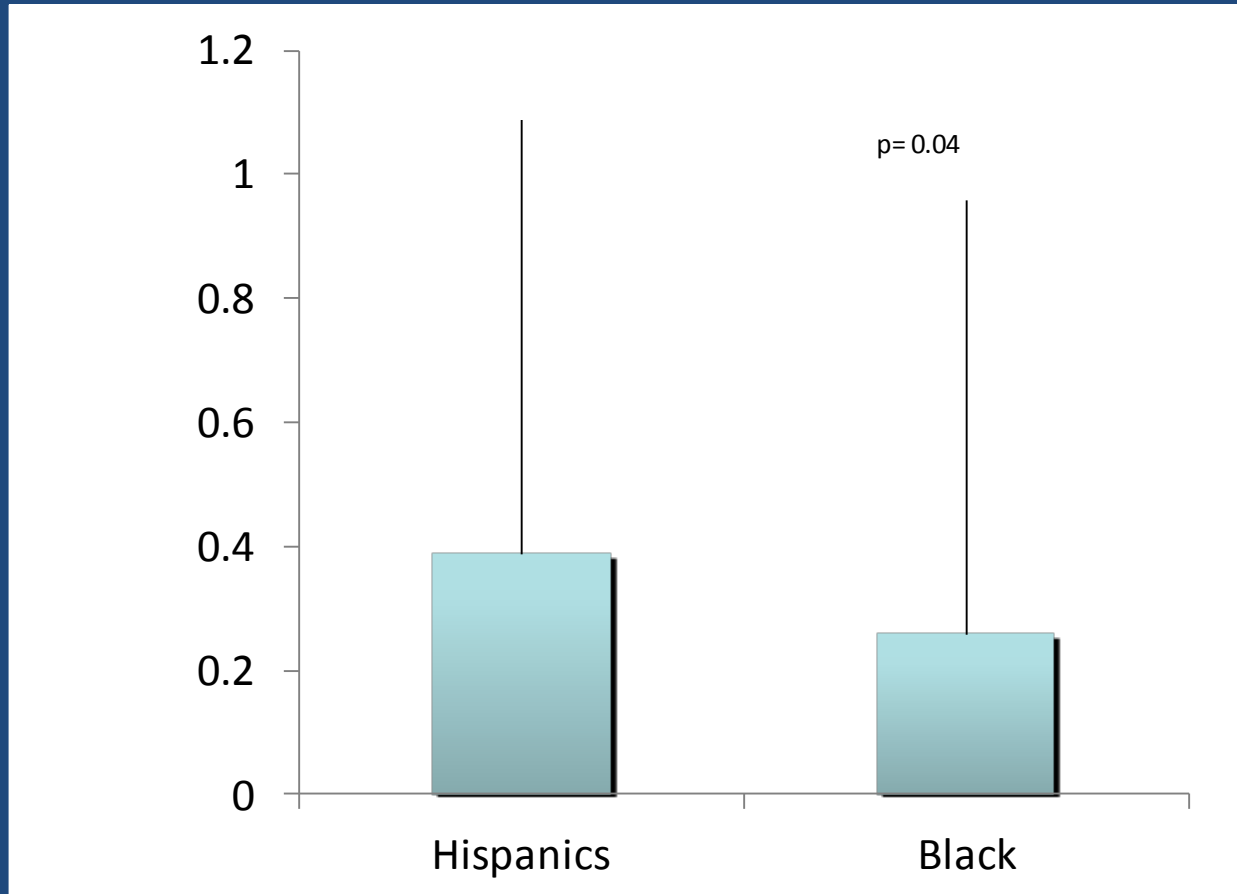
# Predictors of self reported adherence at baseline

Correlates	Odds ratio (95% CI)
Lack of access to care	2.5 (1.0-5.9)
Health literacy (problems learning)	2.5 (1.4-4.0)
Age	0.9 (0.95-1.0)
Female gender	1.4 (0.8-2.7)
Black race	1.4 (0.8-2.6)
Income < 30 K	0.8 (0.3-1.6)
Education level	1.0 (0.5-2.1)

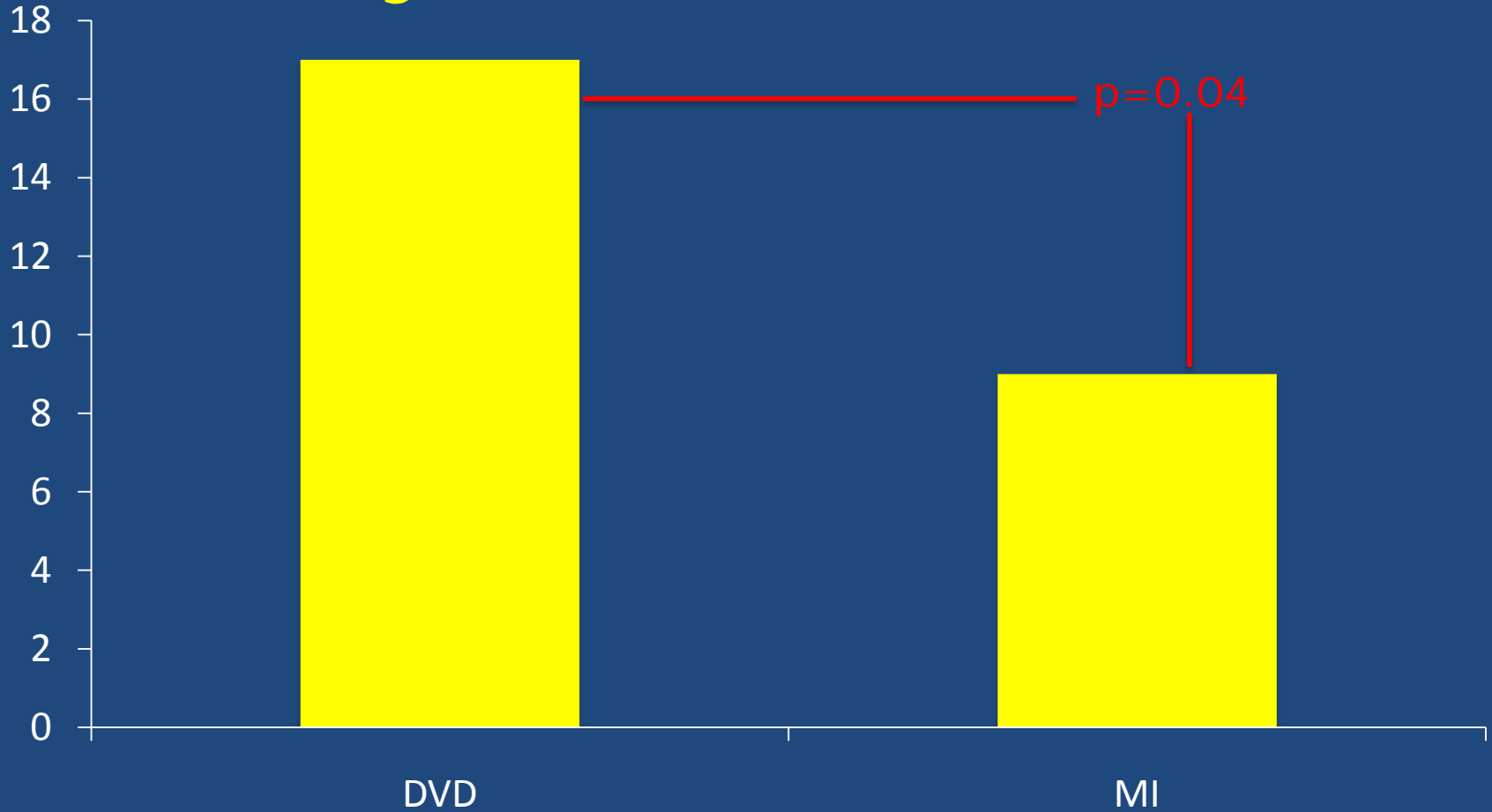
## Differences in use of clopidogrel in 452 minorities at baseline

<b>Characteristic</b>	<b>Black (n=251) %</b>	<b>Hispanic (n=201) %</b>	<b>P-value</b>
<b>Sometimes forgets to take clopidogrel</b>	12	19	0.06
<b>Lack of access to care</b>	9	9	0.80
<b>Adequate patient-physician communication</b>	93	95	0.45
<b>Health literacy (problems learning)</b>	42	38	0.40
<b>Health literacy (not confident filling forms)</b>	81	81	0.99

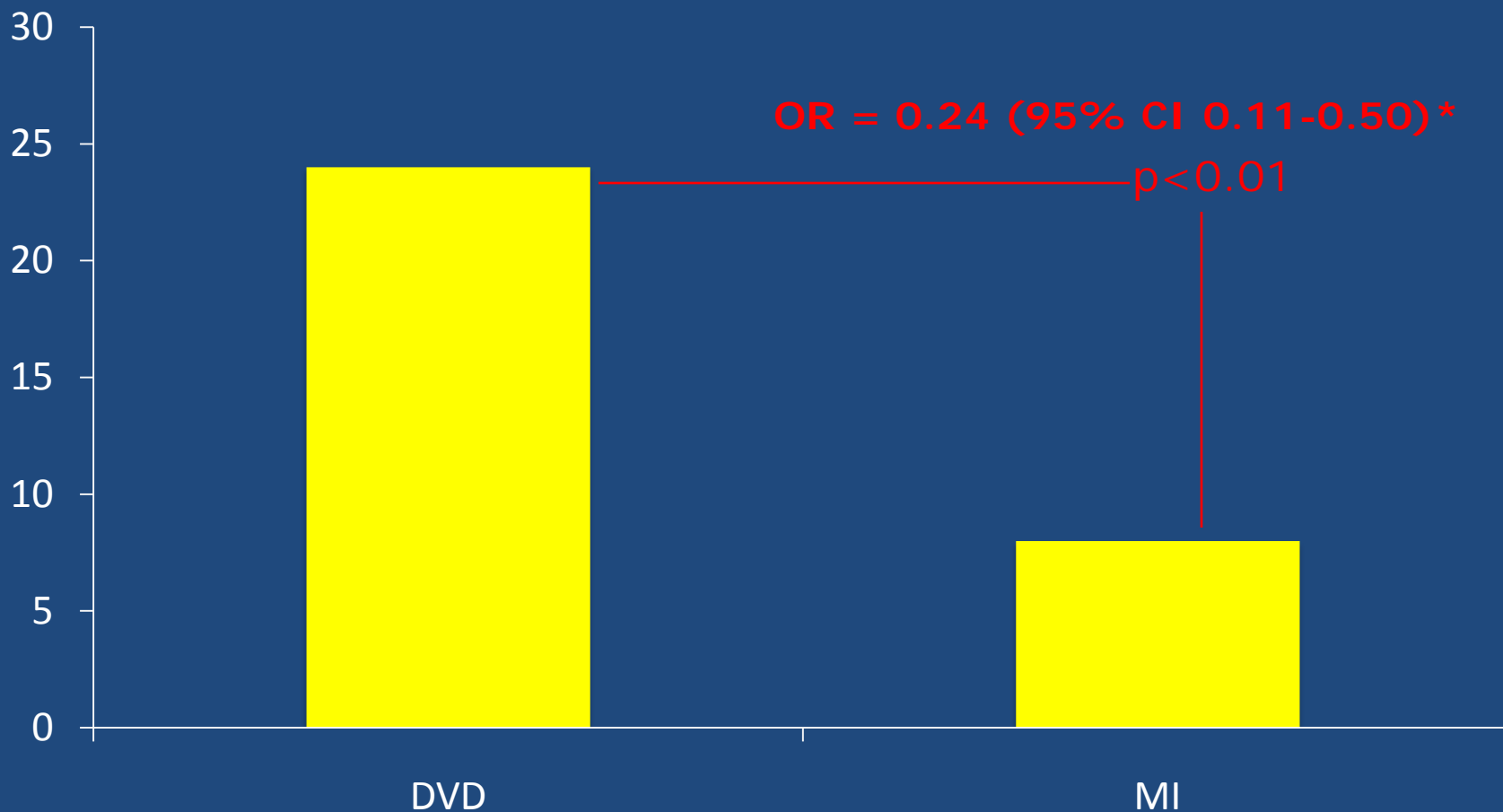
# Mean Morisky score by Ethnicity at baseline



# Percentage of patients not taking antiplatelet agents by study arm at 12 months

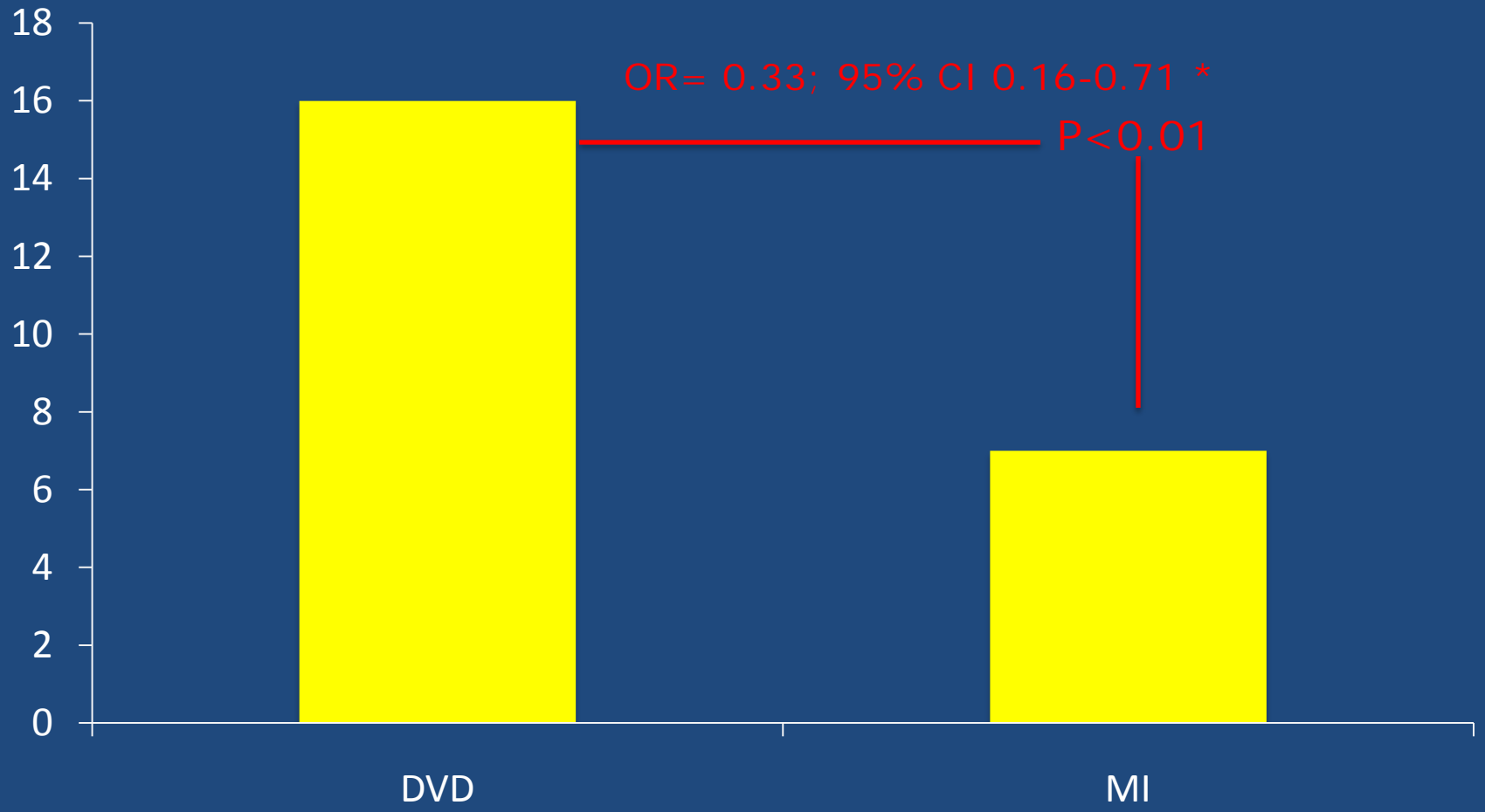


# Percentage of patients who forget to take antiplatelet agents by study arm at 12 months



\* Adjusted for baseline answer, age, gender, ethnicity

# Percentage of patients reporting being careless taking antiplatelet agents by study arm



\* Adjusted for baseline answer, age, gender, ethnicity

# Florida Biomedical Research Program

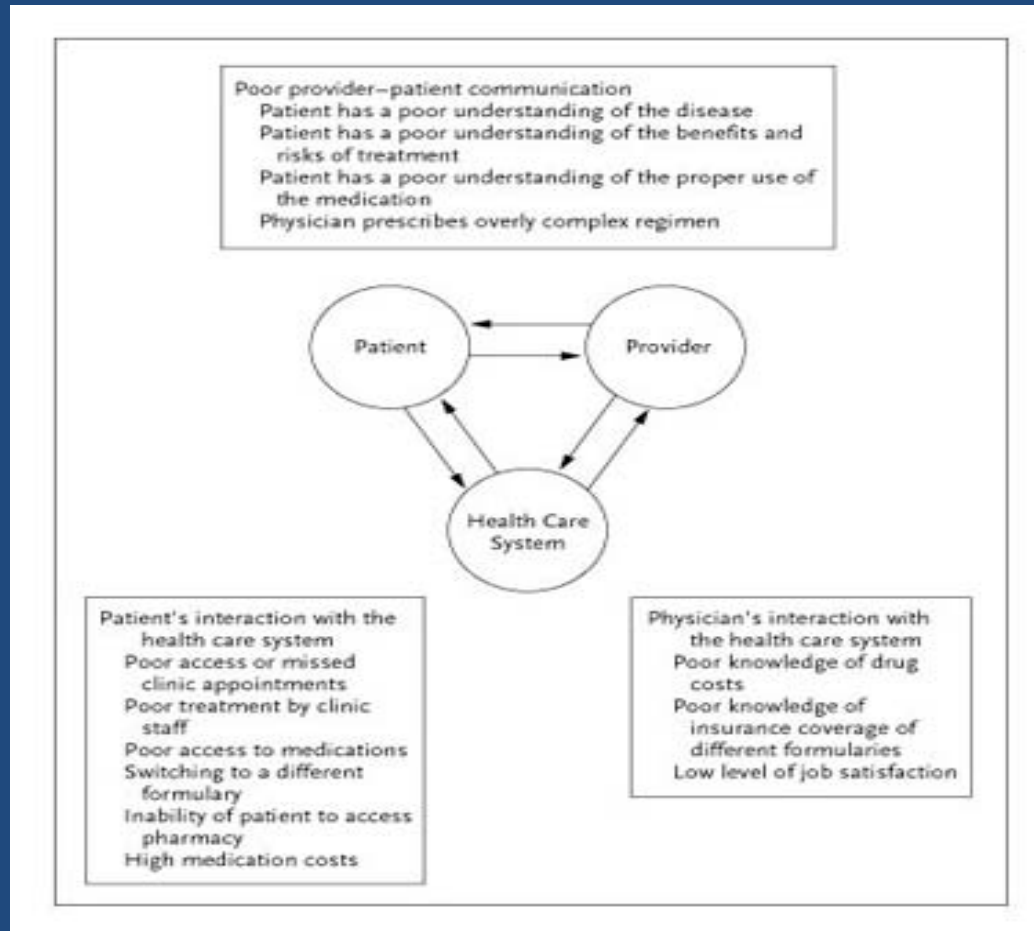
- Design : RCT to evaluate the efficacy of motivational interviewing at improving adherence to newly started statins when compared to usual care.
- Goal : 900 minority subjects
- Status: 150 subjects recruited in a period of 3 months.
- PPV of the algorithm: 92%

# Preliminary Results

- PPV of algorithm: 92%.
- 20% of called subjects within 3 months of receiving statin prescription were not taking medication.
- Common reasons cited were:
  - -Doctor only gave 1 month
  - -Fear of side effects
  - -Seeing in media outlets that cholesterol can be reduced without medications and that the statins can be detrimental.  
"Despierta America Effect"



# Barriers to Medication Adherence



# Innovative strategies: Point of care medication delivery system?

- Improve physician communication
- Improve access to medications
- Reduce the cost of medications
- Overcome health literacy issues



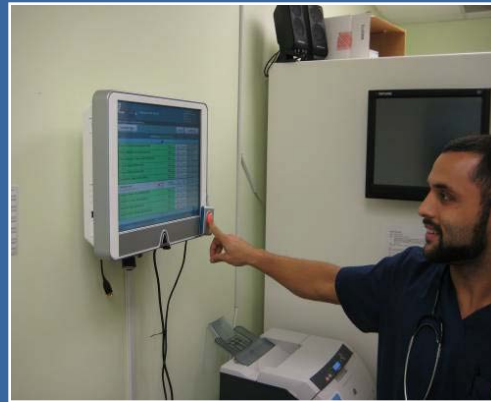
# How does it work?

## Step by step description

**1** Doctor prescribes medicine while attending patient



**2** Staff receives order and processes it



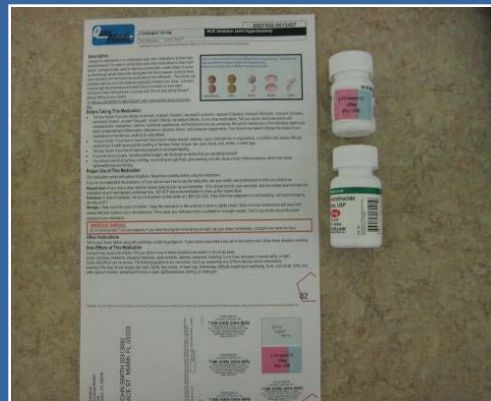
**3** Automated machine provides the medicine



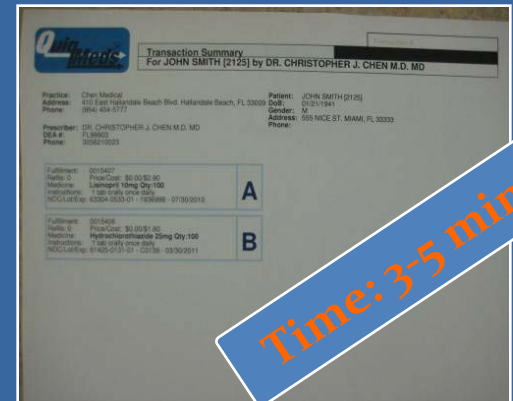
**4** Medicine is sealed- never touched by human hands



**5** Printed description and dosage



**6** Printed claim adjudication



**Time: 3-5 min**

# POCMDS

- Design: Pre-Post.
- Identify all diabetic subjects who were continuously enrolled for 12 months before and 12 months after the implementation of the POCMDS.
- Select all those on at least one of the following classes of medications before the implementation of POCMDS: oral diabetic medications, blood pressure medications, cholesterol lowering agents.

# Outcomes

- Self reported adherence
- Medication Possession Ratio (MPR)
- Hemoglobin A1C
- LDL
- Systolic Blood Pressure

# Baseline characteristics of diabetic minorities

Characteristic	White (n=125)	Black (n=678)	Hispanics (n=75)	p value
Age (yr)	74.1±8.4	73.1±7.5	73.0±7.5	0.25
Female, %	52	57	44	0.06
Hypertension, %	73	87	71	<0.01
Hypercholesterolemia, %	73	73	71	0.30
Coronary artery disease, %	20	14	12	0.16
Heart failure, %	36	30	33	0.30
Old Myocardial infarction, %	19	12	17	0.12

# Changes in Adherence to Statins

Race/ Ethnicity	Number	MPR before POCMDS	MPR after POCMDS	Diff (pre- post)	p-value
Black	238	0.40 (0.26)	0.84 (0.19)	0.43 (0.28)	<0.01
White	70	0.49 (0.28)	0.80 (0.22)	0.31 (0.24)	<0.01
p-value				<0.01	

# Pre-post clinical changes

<b>Race/Ethnicity</b>	<b>Number</b>	<b>HbA1c before POCMDS</b>	<b>HbA1c after POCMDS</b>	<b>p-value</b>
White	77	7.40±1.18	7.15±1.21	0.19
Black	472	7.51±1.47	7.25±1.41	<0.01
Hispanic	42	7.54±1.25	7.55±1.47	0.97
<b>Race/Ethnicity</b>	<b>Number</b>	<b>SBP before POCMDS</b>	<b>SBP after POCMDS</b>	<b>p-value</b>
White	125	132±16.4	130±29.4	0.48
Black	678	137±15.9	134±23.5	<0.01
Hispanic	75	133±22.4	133±22.2	0.74





The **NEW ENGLAND JOURNAL** of MEDICINE

Perspective  
APRIL 29, 2010

## Thinking Outside the Pillbox — Medication Adherence as a Priority for Health Care Reform

David M. Cutler, Ph.D., and Wendy Everett, Sc.D.

Poor adherence to treatment regimens has long been recognized as a substantial roadblock to achieving better outcomes for patients. Data show that as many as half of all patients do not adhere

faithfully to their prescription-medication regimens — and the result is more than \$100 billion spent each year on avoidable hospitalizations.<sup>1</sup> Nonadherence to

study showed that even among patients who have health plans with no cost sharing for medications, rates of nonadherence were nearly 40%.<sup>2</sup>

stantial investments of time by a skilled health care practitioner, as well as electronic data sharing among practitioners — neither of which is widely available in today's model of health care delivery.

There are also numerous factors that affect adherence at the individual level, including lifestyle, psychological issues, health liter-

# Conclusions

- The implementation of translational research projects to reduce health disparities requires thinking out of the box.
- Collaborations among stakeholders are key to access minority populations and to sustain interventions.
- Regulation of the collection of REAL data by all health systems will provide the best opportunity to make significant progress in the reduction of health disparities in the US.

Questions?