Multilevel Pharmacy Intervention for Patients with Chronic Cardiovascular Diseases

National Institute on Aging

(R01 AG19105)

National Heart, Lung, and Blood Institute
(R01 HL69399)

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Overview of the study

- Aims
- Study design
- Conceptual model
- Intervention materials

Aims

Design a multi-leveled, pharmacy-based program to improve medication adherence by using tailored strategies such as written and verbal patient education from a pharmacist and special medication packaging.

Aims

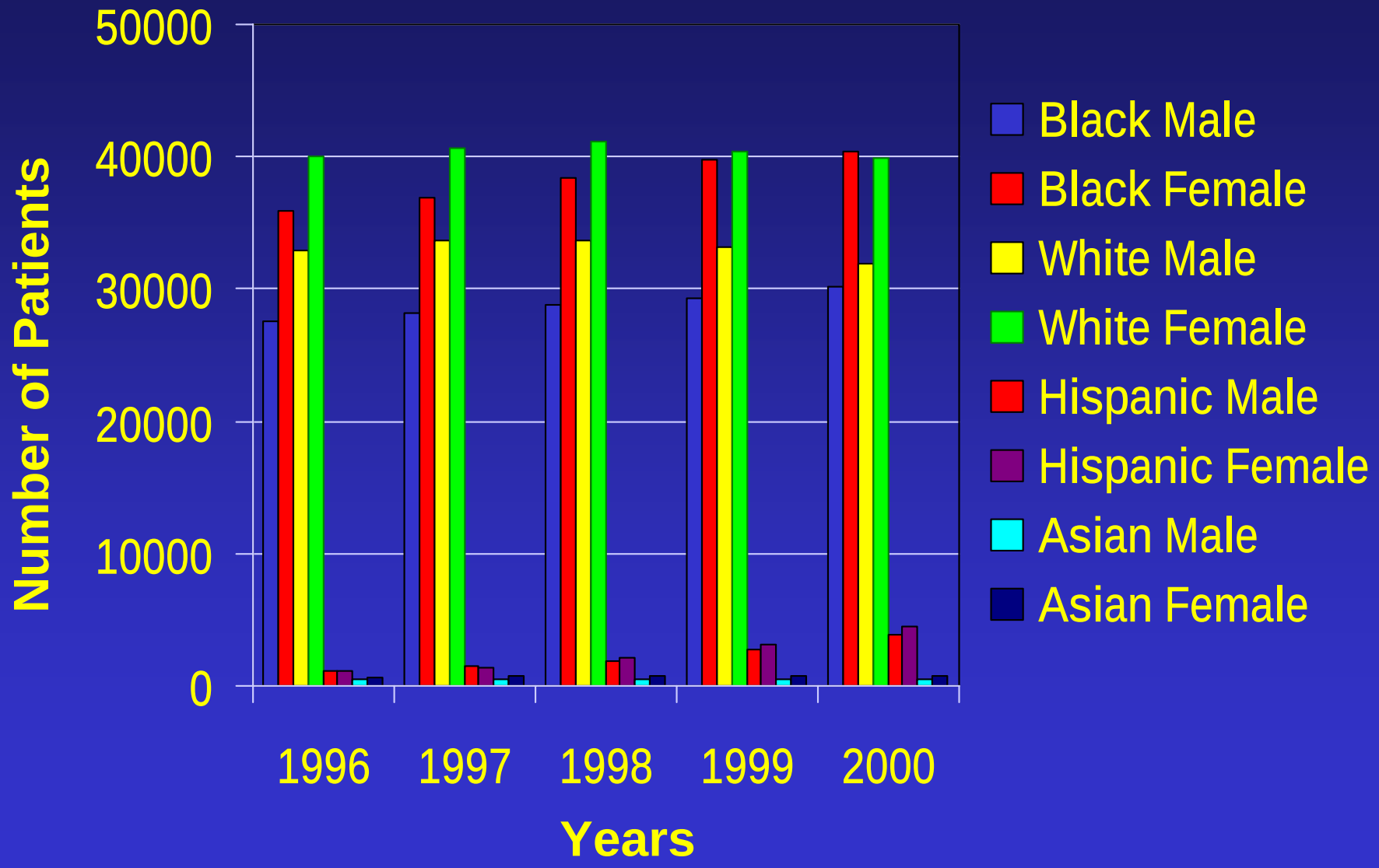
Conduct randomized controlled trials in which patients with heart failure or hypertension are randomly assigned to usual care or to intervention by a specially trained and equipped pharmacist.

Aims

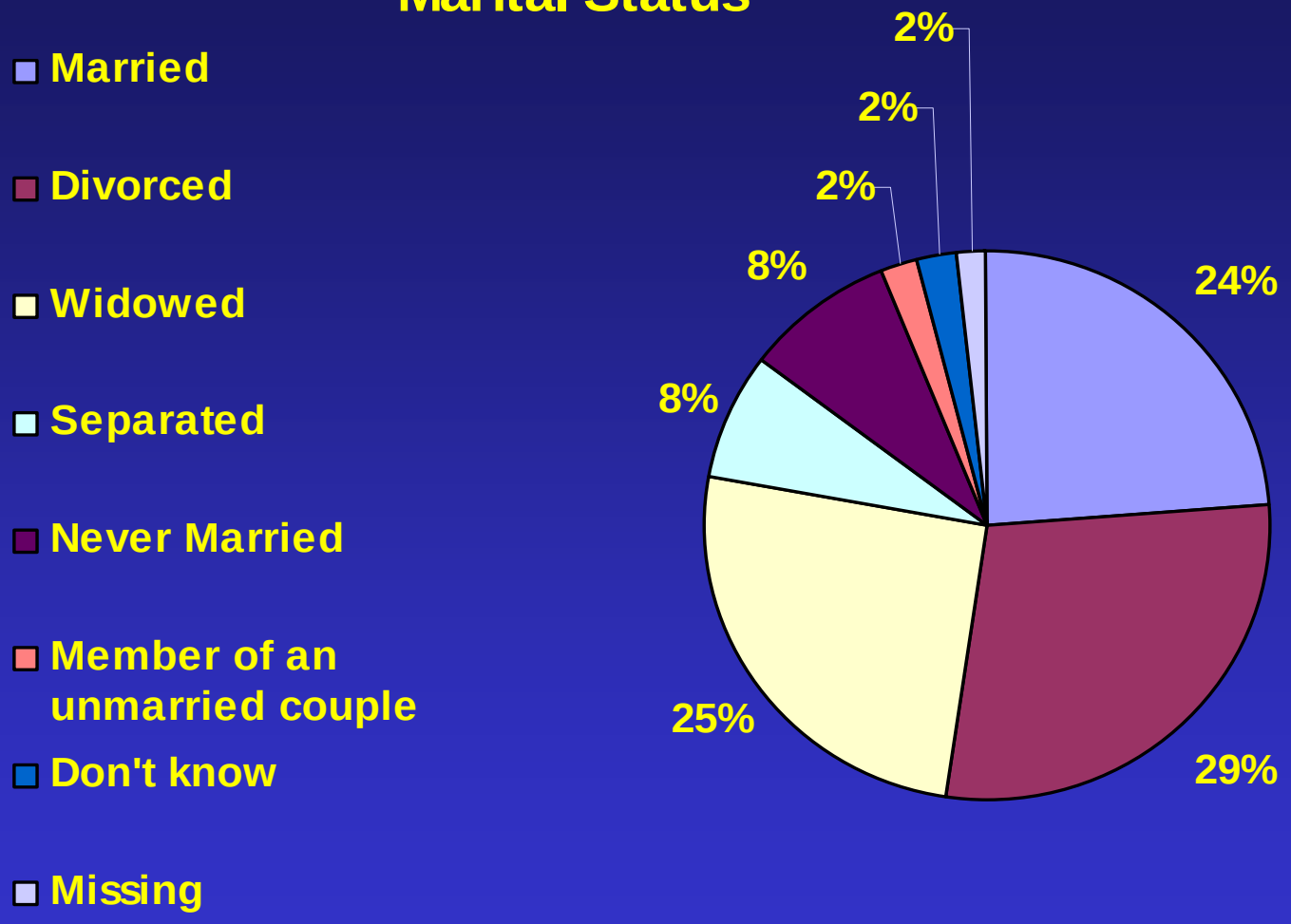
Determine cost-effectiveness of the intervention.

Wishard Hospital					
	1996	1997	1998	1999	2000
Number of Patients	146,770	152,676	157,124	160,401	162,885
Age					
Mean	31	32	32	33	33
S.D.	21	21	21	21	21
Minimum	0	0	0	0	0
Maximum	100	101	100	101	102

Wishard Health Services

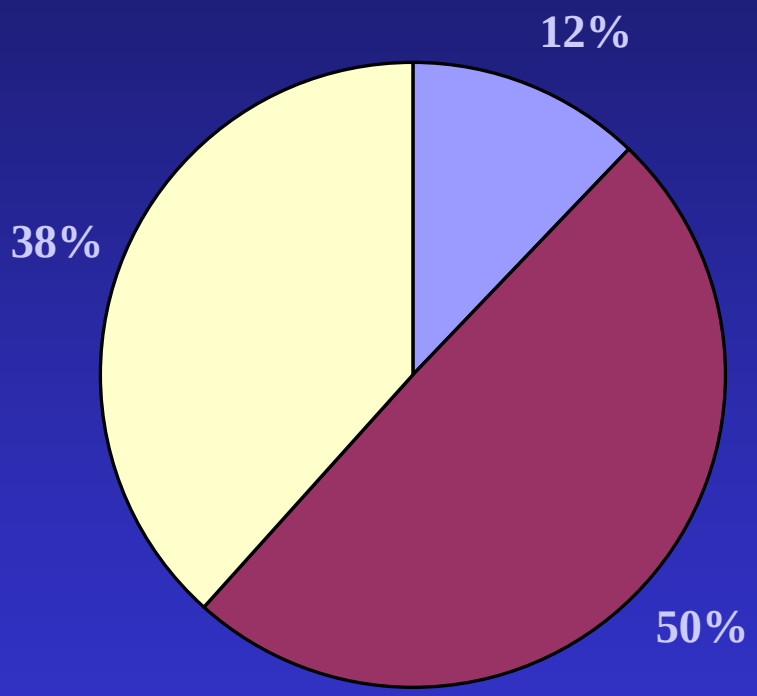


Marital Status

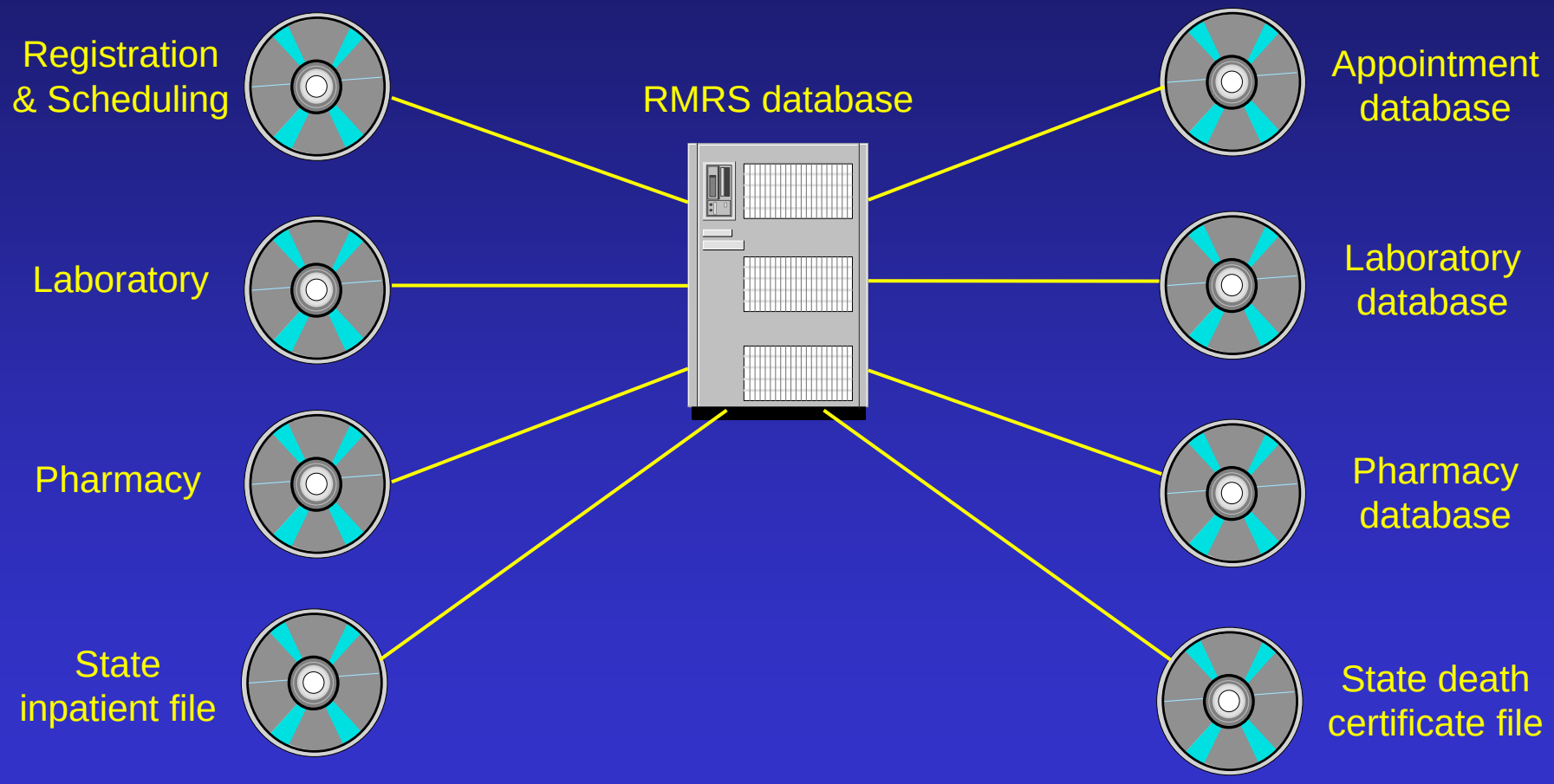


Relative Income

- Comfortable
- Just enough to make ends meet
- Do NOT have enough to make ends meet



Regenstrief Medical Record System (RMRS)



ARBs Bisoprolol Digoxin Irbesartan

Lanoxin

Toprol XL Carvedilol Heart Pill

Diuretics Captopril Losartan Bumex®

Valsartan

Vasotec β adrenergic antagonists

Metoprolol Trandolapril Lisinopril Tenormin

Bumetanide Demadex Furosemide

Angiotensin converting enzyme (ACE) inhibitors Lasix

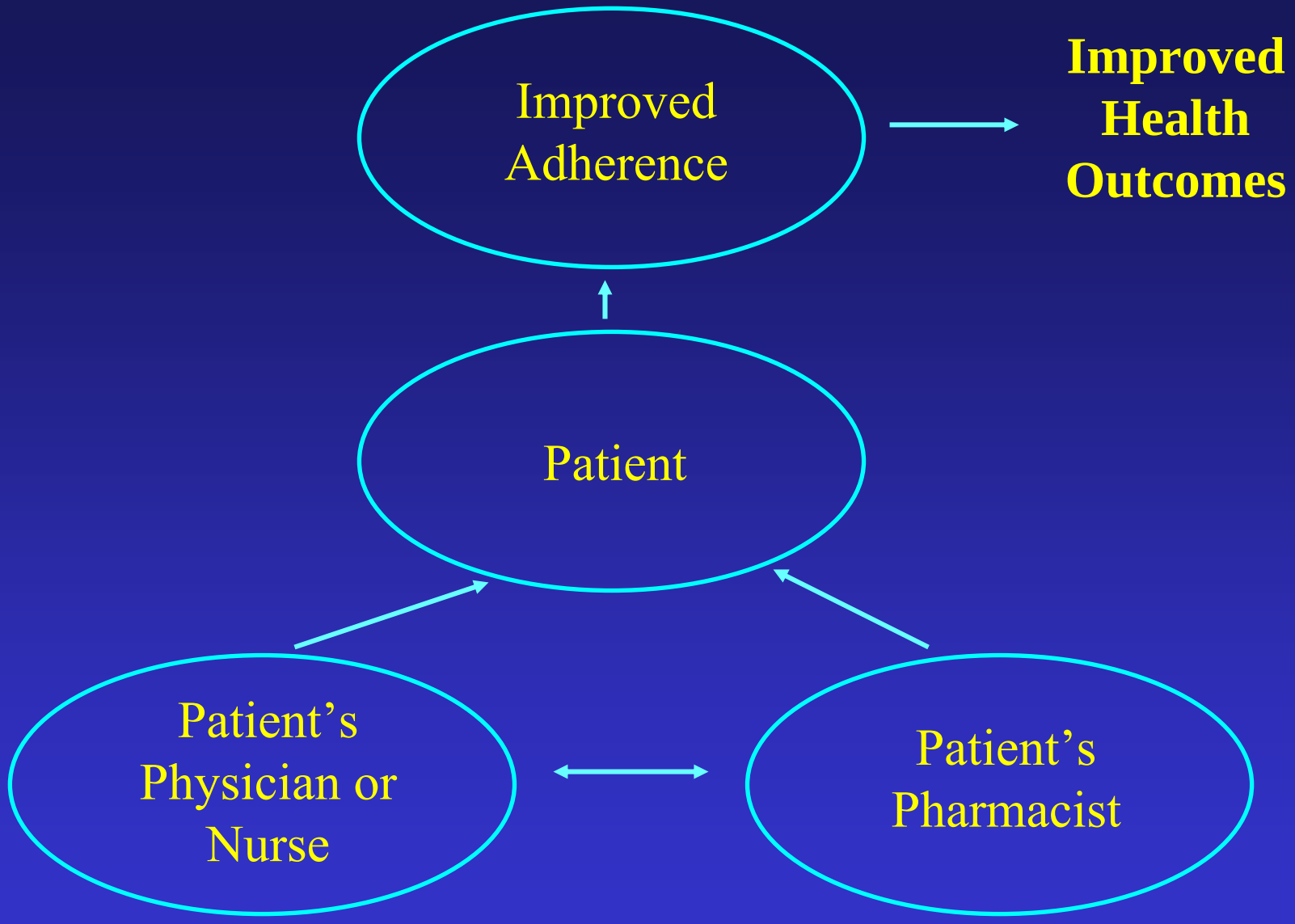
Moexepril Enalapril Coreg Ramipril Propranolol

Zestril Angiotensin receptor antagonists

Telmisartan Water pill Inderal Torsemide

Fosinopril ACE Quinapril Spironolactone

Mavik Cozaar Aldactone Candesartan Innovade


Improved Adherence
Improved Health Outcomes
Patient
Patient's Physician or Nurse
Patient's Pharmacist

Improve Drug Use for Elderly Patients

CHF
(I IV)

(Baseline Echo)

Inclusion: phone, care at WHS, > 50 years of age

Exclusion: unable to interview, participated in focus groups or pre-testing

R

Usual Care
(N=244)

Intervention
(N=122)

Follow-up: 9 mo active/3 mo post

Primary Dependent Variable: HRQL

Secondary Dependent Variables:
body weight, ADEs, patient satisfaction with healthcare and pharmacy, direct health care costs

Covariates: Age, gender, race, social support, income, barriers to compliance, cognitive function, concentrations of neurohormones, diuretic status, medication adherence

Patient-level

MEMS containers
Medication Education
Patient pamphlets
Reminders
Icon labeled containers

Physician-level

MEMS plots
Daily weight graph
Refill adherence plots
Reported compliance
Compliance summary from RPh
Provides advice to RPh
Designs strategy with RPh

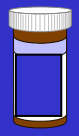
Pharmacist-level

Body weight graph
MEMS plots
Refill adherence
Reported compliance
Prepares bottle labels
Prepares MEMS packaging
Writes compliance summary
Communicates to MD compliance summary

DIURETIC
PEE YELLOW

DIGOXIN
PURPLE HEART

ACE INHIBITOR
BLOOD RED



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Conceptual Model

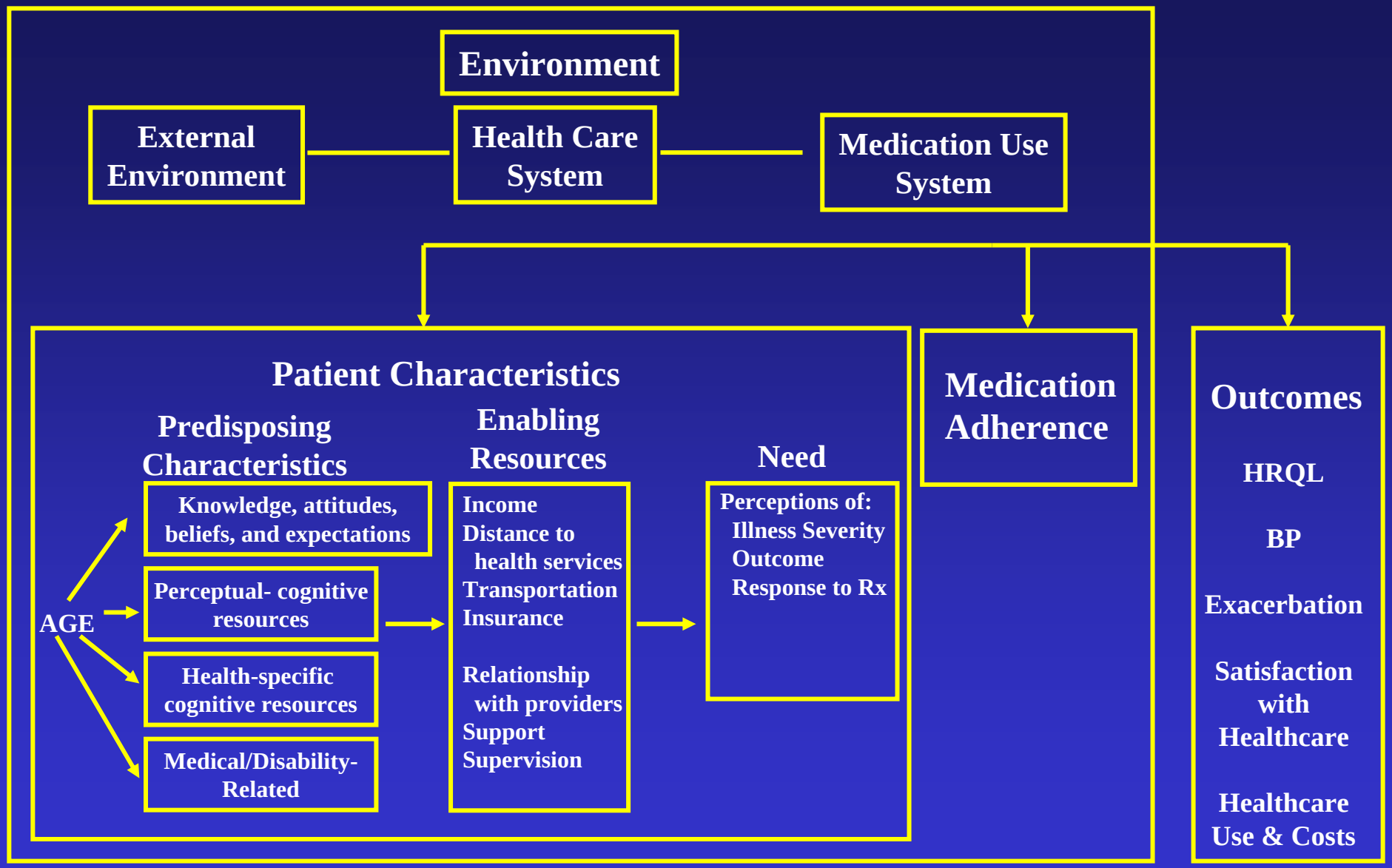
- Focuses on the relationships among:
  - Patient characteristics
  - Environmental factors
  - Medication adherence
- In predicting:
  - Outcomes

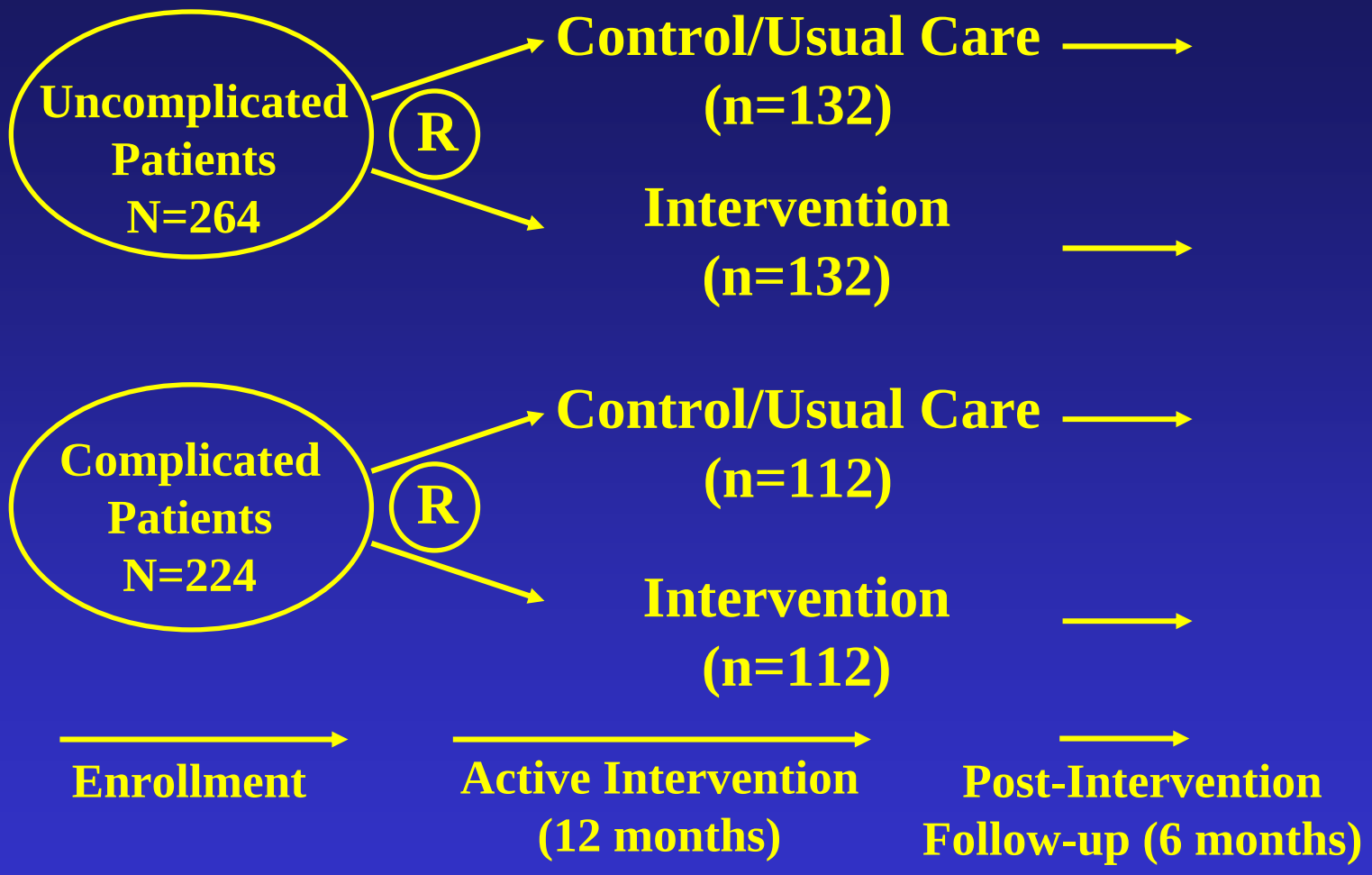
Conceptual Model

- No one model fit our study plan
- So, we integrated two existing models:
  - Behavioral healthcare utilization model [1]
    - Medication adherence is a self-care healthcare utilization process affected by many social and behavioral factors
  - Medication adherence model by Parks and Jones [2]
    - Specific to older adults' medication taking

1. Phillips KA, Morrison KR, Andersen R, Aday LA. Understanding the context of healthcare utilization: assessing environmental and provider-related variables in the behavioral model of utilization. HSR. 1998;33:571-96.

2. Park DC, Jones TR. Medication adherence and aging. In *Handbook of Human Factors and the Older Adult*. Arthur Fisk and Wendy Rogers, eds. Academic Press. 1997.


Environment
External Environment
Health Care System
Medication Use System
Patient Characteristics
Predisposing Characteristics
Enabling Resources
Need
AGE
Knowledge, attitudes, beliefs, and expectations
Perceptual- cognitive resources
Health-specific cognitive resources
Medical/Disability-Related
Income
Distance to health services
Transportation
Insurance
Relationship with providers
Support
Supervision
Perceptions of:
Illness Severity
Outcome
Response to Rx
Medication Adherence
Outcomes
HRQL
BP
Exacerbation
Satisfaction with Healthcare
Healthcare Use & Costs


Uncomplicated Patients N=264
R
Control/Usual Care (n=132)
Intervention (n=132)
Complicated Patients N=224
R
Control/Usual Care (n=112)
Intervention (n=112)
Enrollment
Active Intervention (12 months)
Post-Intervention Follow-up (6 months)

Hypotheses

- **Primary**
- **In the intervention group:**
  - Medication adherence will be greater, which will, in turn, improve health outcomes

Hypotheses

- **Secondary**
- **In the intervention group**
  - Lower blood pressure
  - Fewer exacerbations (urgent and emergent visits to the emergency department and all cause hospital admissions will be fewer)
  - Patient satisfaction with healthcare will be greater
  - Health care costs will be less.

Intervention Components

- Patient Education
- Therapeutic Monitoring
- Communication with Providers

Intervention Components

Patient Education: To provide verbal and written education to improve patient understanding of their medications and encourage medication adherence.

1) Verbal Patient Education
2) Written Icon-based Materials
    - Icon-based patient pamphlets
    - Icon-labeled mediation containers

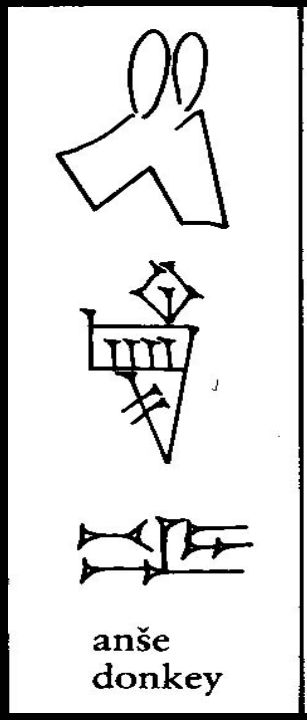
Medication Adherence

- Medication Event Monitoring System (MEMS)
- Refill compliance
  - Medication possession ratio using the RMRS
- Patient report

Icon-labeled materials

Icon-Based Medication Instructions

- **Based on four principles from Dan Morrow's research:**
  - **Content**
  - **Language**
  - **Organization**
  - **Presentation**
- **Basic Principle: Emphasize older adult's strengths and help overcome the weaknesses**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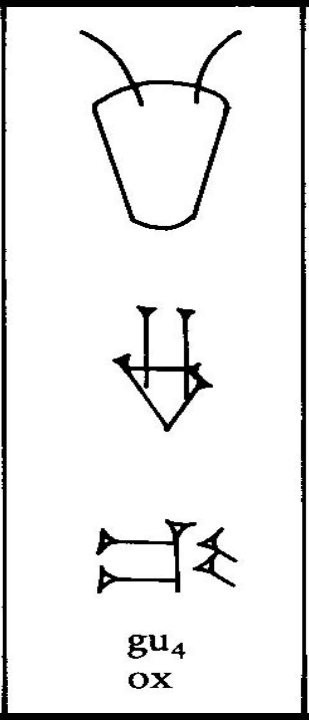
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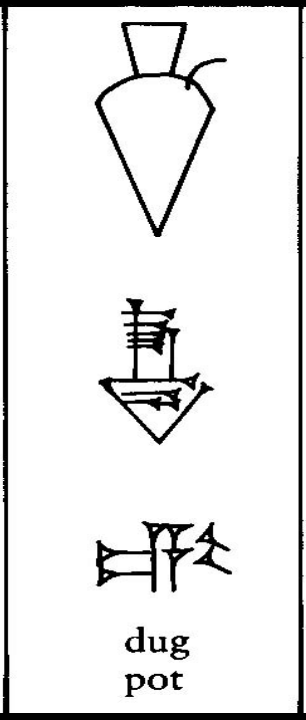
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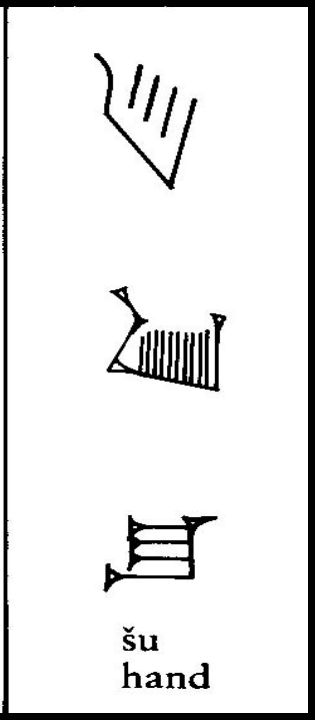
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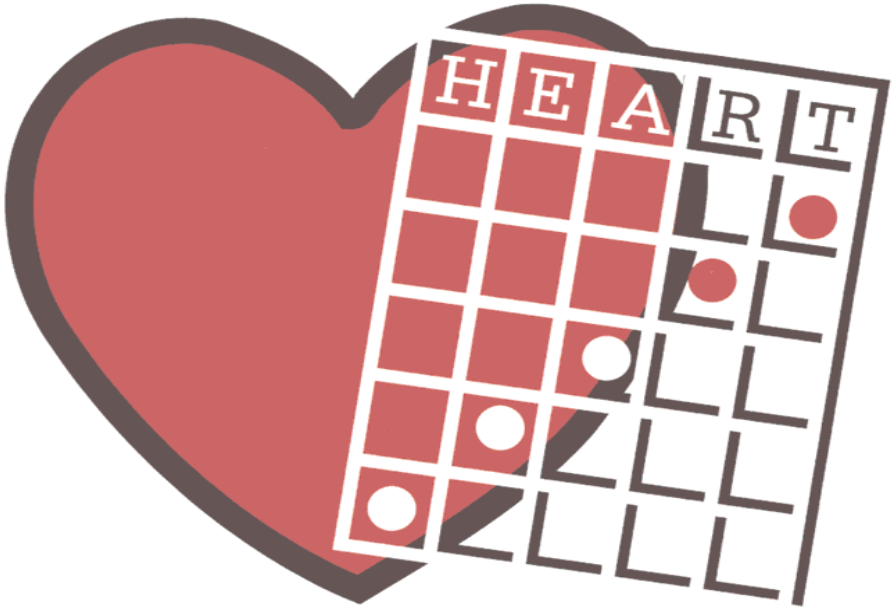
The Seven Sins of Memory

How the Mind Forgets and Remembers

DANIEL L. SCHACTER

RULES TO PLAY BY



RULES TO LIVE BY

AN IMPORTANT MESSAGE TO HEART PATIENTS, LIKE YOU...

YOUR DOCTOR IS ON YOUR TEAM. BE A TEAM-PLAYER. BE A WINNER.

In games — and in health
there are some rules
you just have to follow.

Like the rules
for making your heart better.

Cheating on those rules
will make you sick.

It can even take
you out of the game.

Don't jeopardize your heart.
Don't hurt your chances
to feel better.

Take your pills
according to directions.

You'll be a big winner.
You'll feel better.
You'll live longer.

That's just how it is.

PLAY TO WIN. WIN FOR LIFE.

MED/pharmacy #9944 Ph: 317-987-6543

2929 E. 38TH ST.
INDIANAPOLIS, IN
46220-0000

www.med.com

IF YOU HAVE ANY QUESTIONS ABOUT YOUR MEDICATION, PLEASE CONTACT YOUR PHARMACIST:
JOHN MILLER, RPh.

PATIENT PRESCRIPTION INFORMATION

JONES, MIKE W
2255 OAKLAWN DR
INDPLS,IN 46224-0000
Ph: 317-956-8432

01-29-2001
DR. JACKSON, ANN C
Refills: 0

COREG 50MG TABLET TEV

TAKE 1 TABLET BY MOUTH 2 TIMES A DAY

CARVEDILOL (BETA BLOCKER) - ORAL

WARNING: If you have angina or have had heart problems, do not suddenly stop using this medication without first consulting your doctor. If your doctor decides you should no longer use this medication, you must stop this medication gradually according to your doctor's instructions.

USES: This medication is used for chest pain (angina), high blood pressure and irregular heartbeats.

HOW TO TAKE THIS MEDICATION: Take this medication exactly as prescribed. Try to take it at the same time(s) each day. Do not suddenly stop taking this medication without consulting your doctor. Some conditions may become worse when the drug is suddenly stopped.

SIDE EFFECTS: You may experience dizziness, lightheadedness, drowsiness, and blurred vision as your body adjusts to the medication. Use caution engaging in activities requiring alertness. Because beta-blockers reduce blood circulation to the extremities, your hands and feet may be more susceptible to the cold. Dress warm. Inform your doctor if you develop: easy bruising or bleeding, swollen hands or feet, confusion, depression, a sore throat. In the unlikely event you have an allergic reaction to this drug, seek medical attention immediately. Symptoms of an allergic reaction include; rash, itching, swelling, dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS: Before taking this drug, tell your doctor if you have a history of: heart disease, kidney disease, liver disease, asthma, bronchitis, emphysema, any other lung disease, diabetes, overactive thyroid gland, any drug allergies. Before having surgery, tell the doctor or dentist in charge that you are taking a beta-blocker. This drug should be used only if it is clearly needed during pregnancy. Discuss the risks and benefits with your doctor. This drug is excreted into breast milk and though no problems have been noted, the possibility for adverse effects to the infant exists. Consult your doctor before breast feeding.

DRUG INTERACTIONS: Tell your doctor of all prescriptions and nonprescription drugs you may use, especially of: diuretics, cold preparations and nasal decongestants, reserpine, other heart or high blood pressure medications. Do not start or stop any medications without doctor or pharmacist approval.

OVERDOSE: If overdose is suspected, contact your local poison control center or emergency room immediately. Symptoms of overdose may include unusually fast or slow heartbeat, dizziness, slow or shallow breathing, seizures, unconsciousness, weakness, or fatigue.

NOTES: Your doctor may want you to take your pulse each day while taking this medication. Learn how to monitor your pulse.

MISSED DOSE: If you miss a dose, take as soon as remembered but not if it is within 4 hours of next dose (8 hours for penbutolol, atenolol, nadolol). If it is, skip the missed dose and resume your usual dosing schedule. Do not "double-up" the dose to catch up.

STORAGE: Store at room temperature between 59 and 86 degrees F (15-30 degrees C) away from moisture and sunlight. Do not store in the bathroom.

ACE Inhibitors

(Pronounced: ACE in-HIB-it-ors)

RULES TO PLAY BY
RULES TO LIVE BY

IDENTIFYING YOUR MEDICATION

- The ACE Inhibitor label is red.
- ACE Inhibitors are used to manage blood pressure and chronic heart failure.
- The types of ACE Inhibitors are Fosinopril (Monopril®), Benazepril (Lotensin®), Enalapril (Vasotec®), Lisinopril (Prinivil®,Zestril®), Quinapril (Accupril®), Ramipril (Altace®), Moexipril (Univasc®), and Trandolapril (Mavik®).

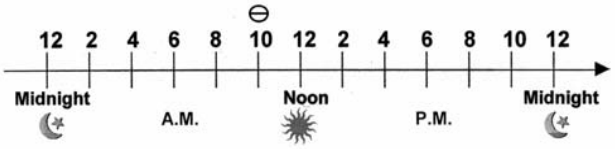
DIRECTIONS

The pills in the bottle with the red label are used to decrease the blood pressure and severity of chronic heart failure, and should be taken continuously. Ask your pharmacist if you can take this medication with food.

If you forget to take your ACE Inhibitor on time, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed and go back to your regular schedule. DO NOT DOUBLE-DOSE.

TAKE 1 TABLET AT 10:00 A.M.

⊖ = 1 tablet



SIDE EFFECTS

Some patients experience dizziness, headache, low blood pressure, nausea, vomiting, diarrhea, fatigue, bad rash or swelling, difficulty breathing, fever or a cough. Contact your doctor if these symptoms become bothersome to you.

NOTES

- Before taking these medications, make sure your doctor and pharmacist know about all other prescription and over-the-counter medications that you take.

REMINDER:

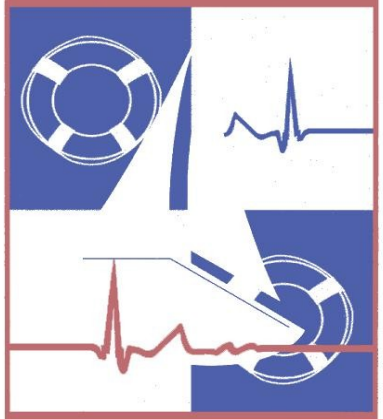
WINNING TAKES WORK. YOU HAVE TO CONCENTRATE.

GETTING BETTER TAKES WORK. YOU HAVE TO FOCUS ON YOUR GOAL: A BETTER TOMORROW.

PLAY TO WIN. WIN FOR LIFE.

Example of Icon-Based Labeling

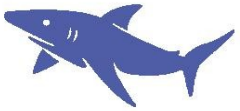
Stay the Course



For Smooth Sailing Ahead

Your medication is a lifeline to better health. Don't let go. **Hold on.** Even **when the waters** get rough.

Lifesaving information to help you steer clear of harmful effects from your Hypertension.



Treating your Hypertension Requires Sailing Around Complications & Risks.

Hypertension is high blood pressure. It can be difficult to treat. Sometimes it takes 2 or more medications to decrease your blood pressure to safe levels.

Hypertension has few symptoms. If you are feeling fine now, why rock the boat. There are hidden dangers in not taking your pills as directed by your doctor. These dangers include stroke, heart attack, or kidney damage. These dangers not only affect you, but they also affect others. For example, your family worries about you when you are sick.

Your doctor may have prescribed pills. There are many types of pills available to treat hypertension. Some people experience side effects. Mild side effects often go away. So, stay on course. If you have severe side effects, call your doctor or pharmacist right away.

Your doctor may have also suggested reducing the amount of salt and fat in your diet. Your doctor also might ask you to exercise more often. This is important advice for you to follow.

This package contains information to help you and your family understand why it is so important to stay on course with your treatment. You can do it.

Diuretics

(pronounced: Di-yu-ret 'ik)

Identifying your Medication

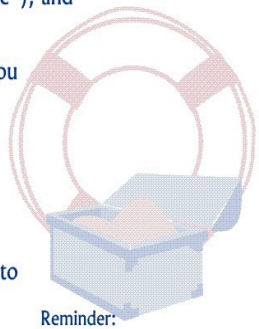
The Diuretic label is yellow.
These pills get rid of extra water in your body. They are often called water pills.
Common Diuretics are hydrochlorothiazide, spironolactone (Aldactone®), triamterene/hydrochlorothiazide (Maxide®), and metolazone (Zaroxolyn®).

Directions

The pills in the bottle with the yellow label will make you have to go the bathroom more often than usual. So, when possible, take them in the morning — so you won't have to get up during the night. You can take the pills with or without food. Either way is O.K.

Take the last dose of your medicine no later than 6 p.m. so that you don't wake up during the night to go to the bathroom.

If you forget to take your diuretic on time, take it as soon as you remember. Talk to your doctor or pharmacist about how to get back on schedule.



Reminder: Your pills are your lifesaver. When taken correctly, they allow you more time to spend with the people you love and treasure.

Hypertension can lead to a stroke or heart attack. Take your pills to avoid these dangers.

Side Effects

You may be making more trips to the bathroom to urinate. This can be annoying, but, try to remember that it means your pills are working.

Some patients experience dizziness from low blood pressure, have headaches, or get diarrhea. Call your doctor if these symptoms become really bothersome.

Notes

Before taking these pills, make sure your doctor and pharmacist know about all other prescriptions and over-the-counter medications you take.

Beta Blockers

(pronounced: Bay-ta Blockers)

Identifying your Medication

The Beta Blocker label is blue.
This type of pill controls electrical impulses in the heart.
Common Beta Blockers are atenolol (Tenormin®), carvedilol (Coreg®), metoprolol (Lopressor®) and Toprol XL®.

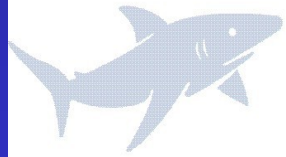
Directions

Pills in the bottle with the blue label must be taken regularly — at the same time each day. Ask your doctor or pharmacist if you can take your beta- blocker with food.

If you happen to miss a dose, DON'T DOUBLE-UP. Just wait until the next dose should be taken and begin taking the medication at the dose prescribed by your doctor.

Your body will adjust to your medication and you can sail into better health.

Complications from untreated hypertension include heart attacks.



Side Effects

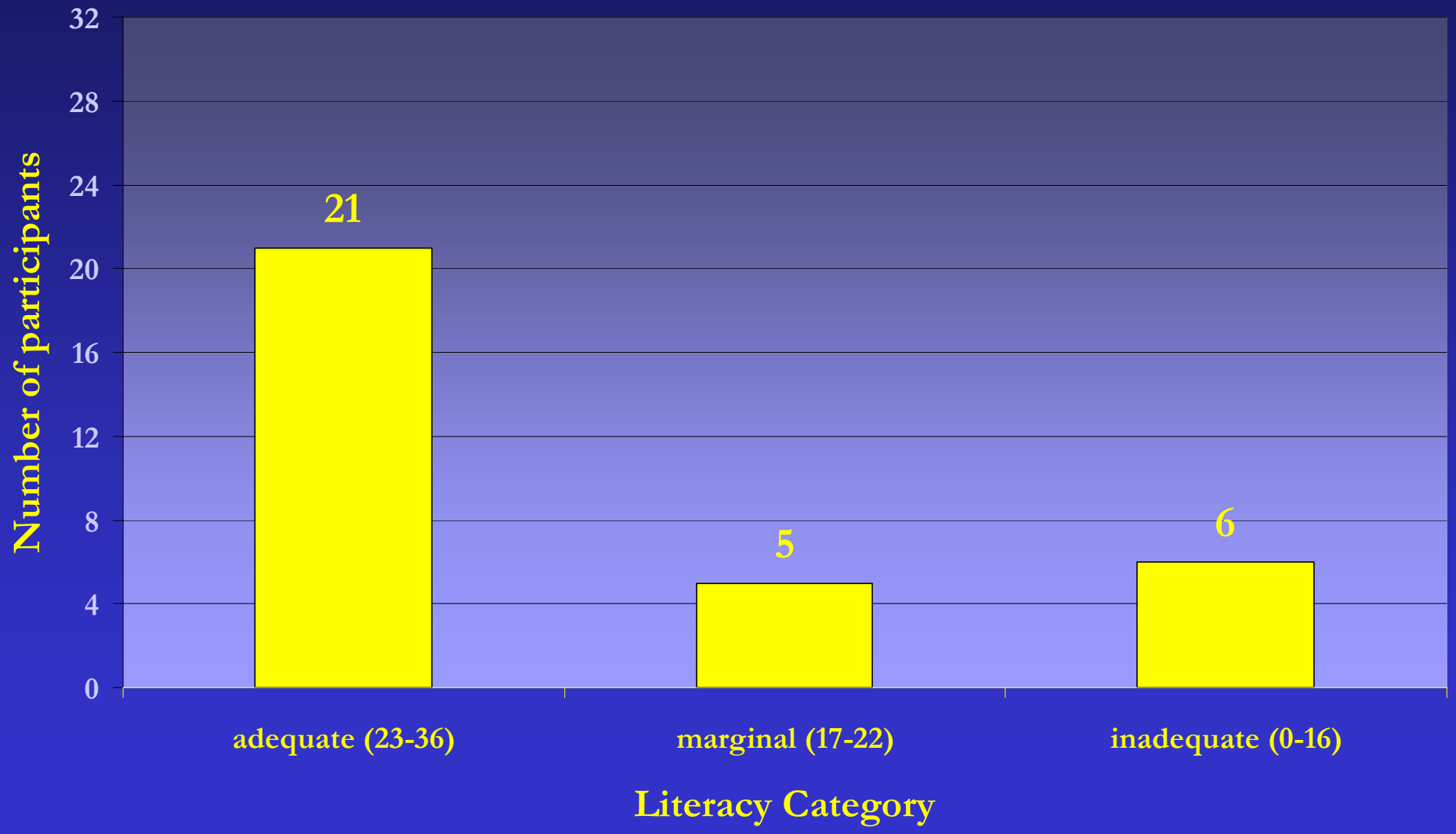
Some patients experience dizziness from low blood pressure, tiredness and weakness. Contact your doctor if these symptoms become bothersome to you.

Notes

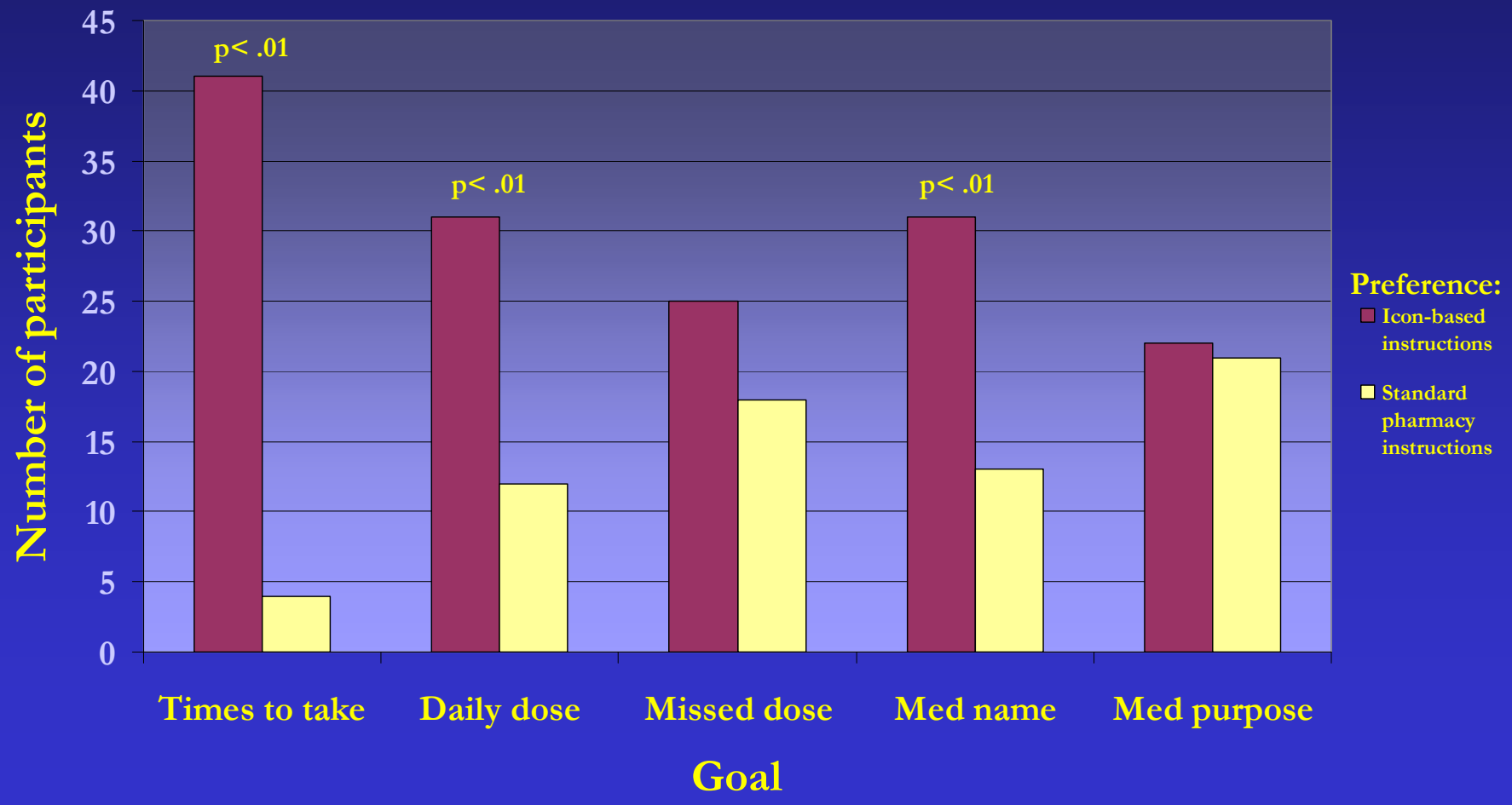
Before taking these pills, make sure your doctor and pharmacist know about all other prescription and over-the-counter medications you take. DON'T stop taking these medications without talking to your doctor.

Literacy Categories from S-TOFHLA

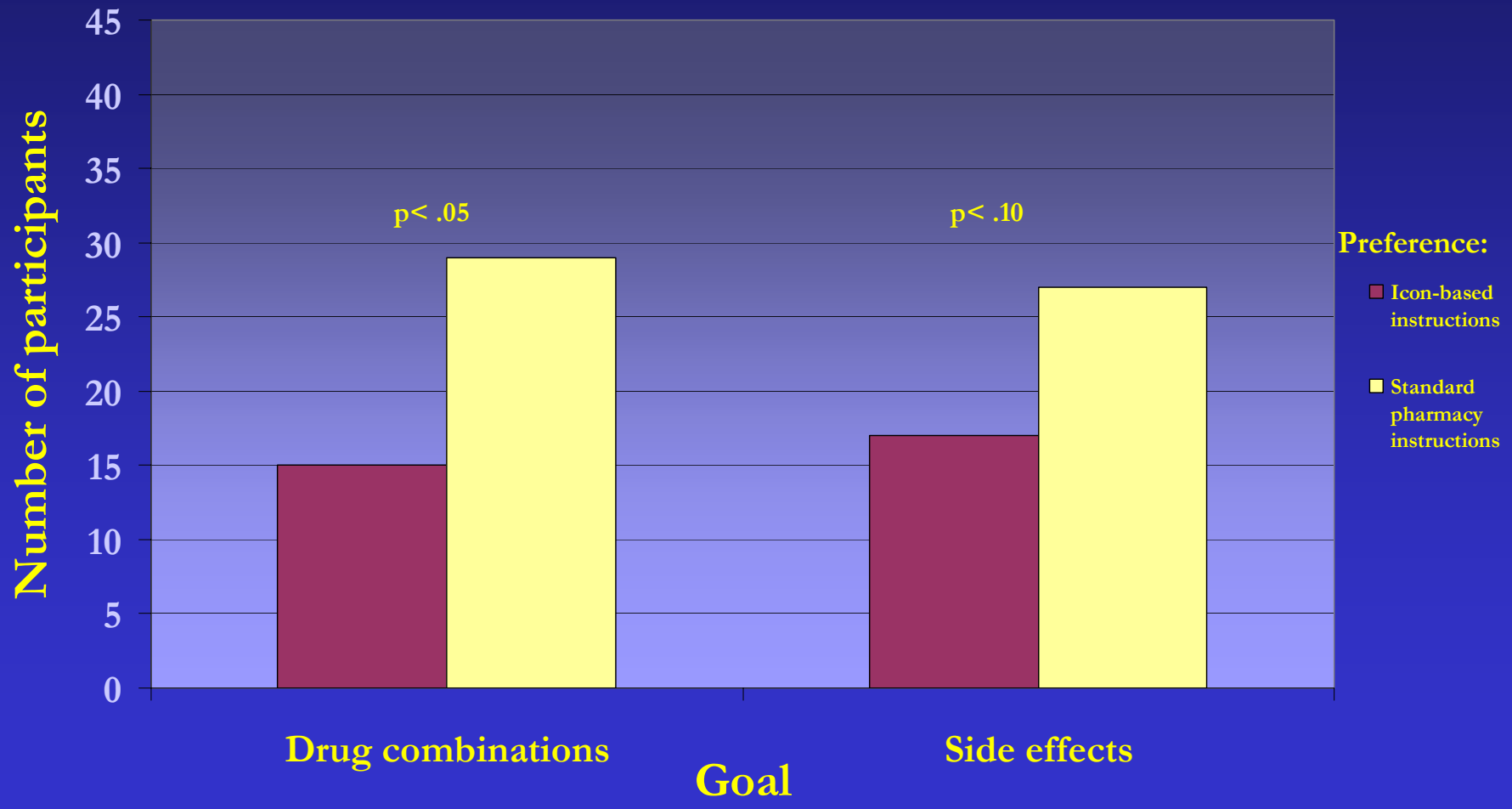
range of scores = 6 to 36 *average score = 26.34*



Medication-related Goals with Majority Preference for Icon-based Instructions

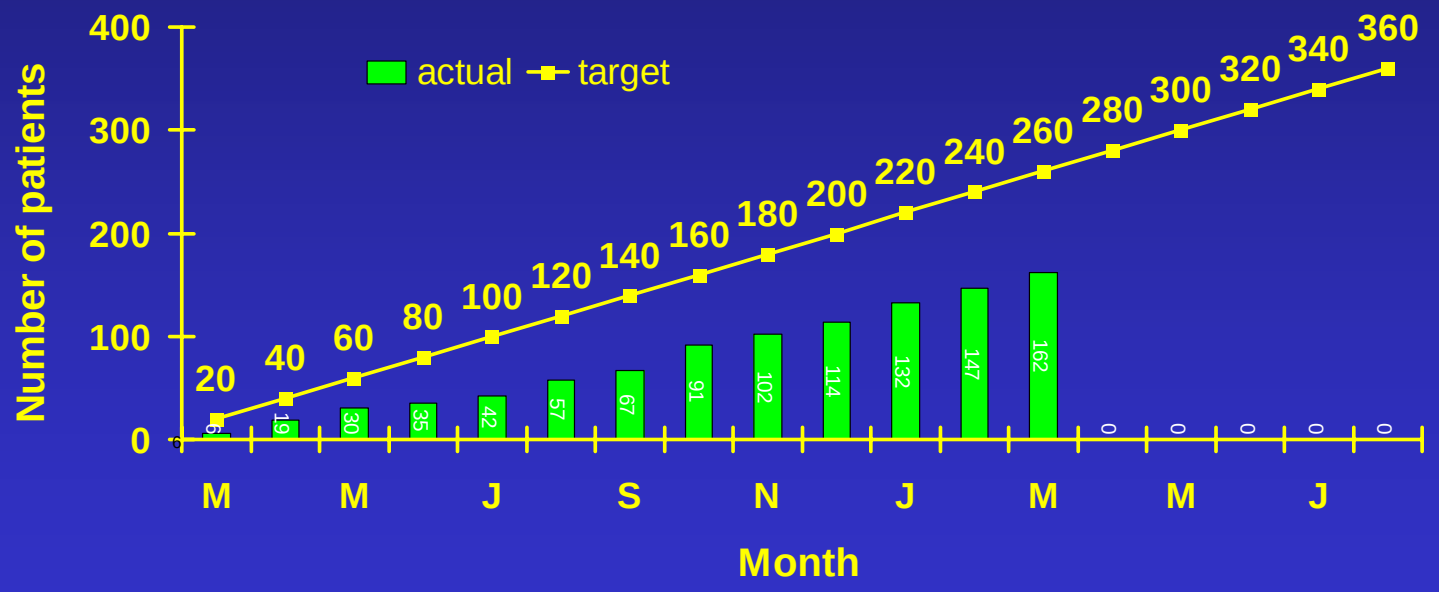


Medication-related Goals with Majority Preference for Standard Instructions

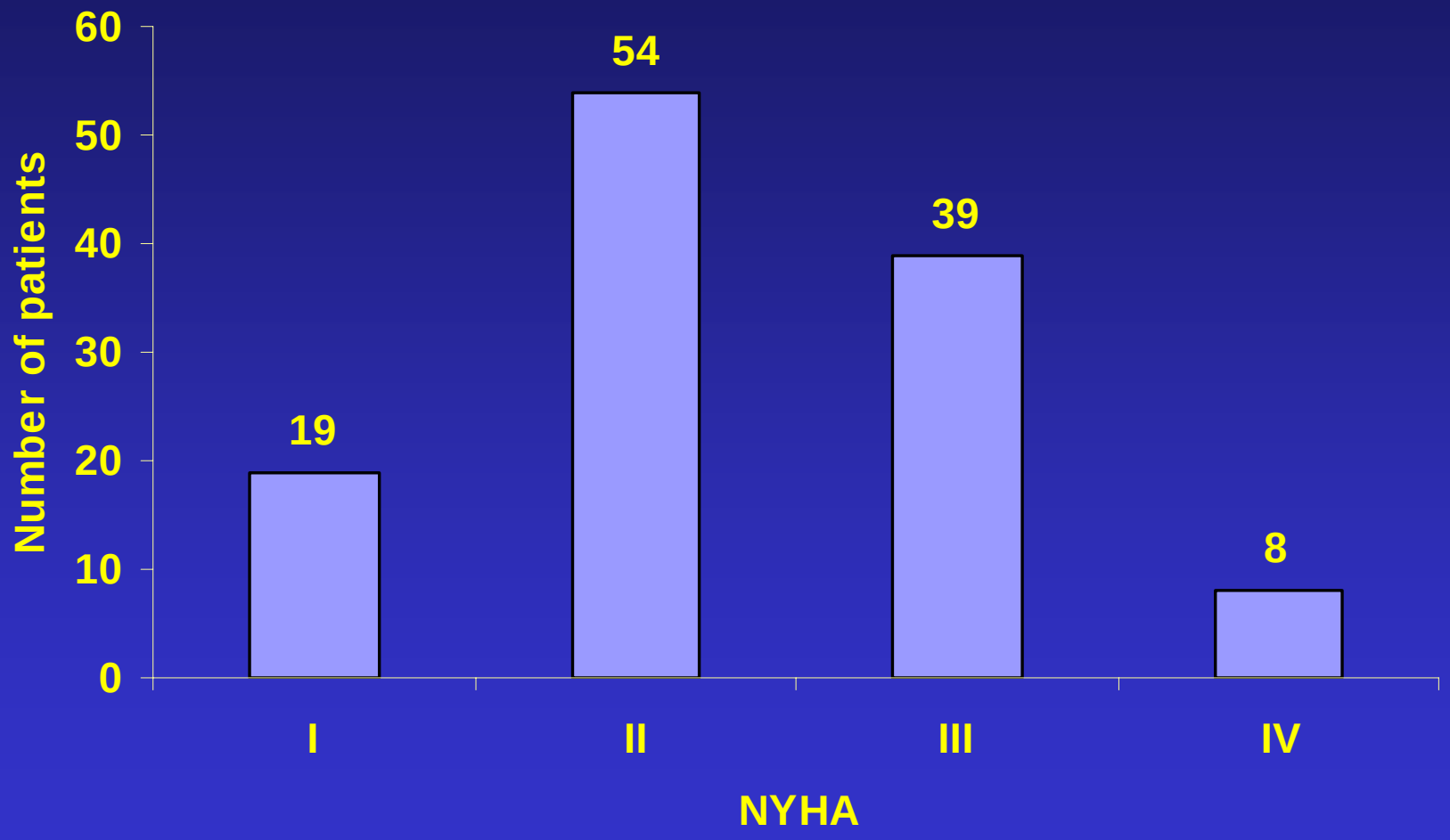


CHF ENROLLMENT

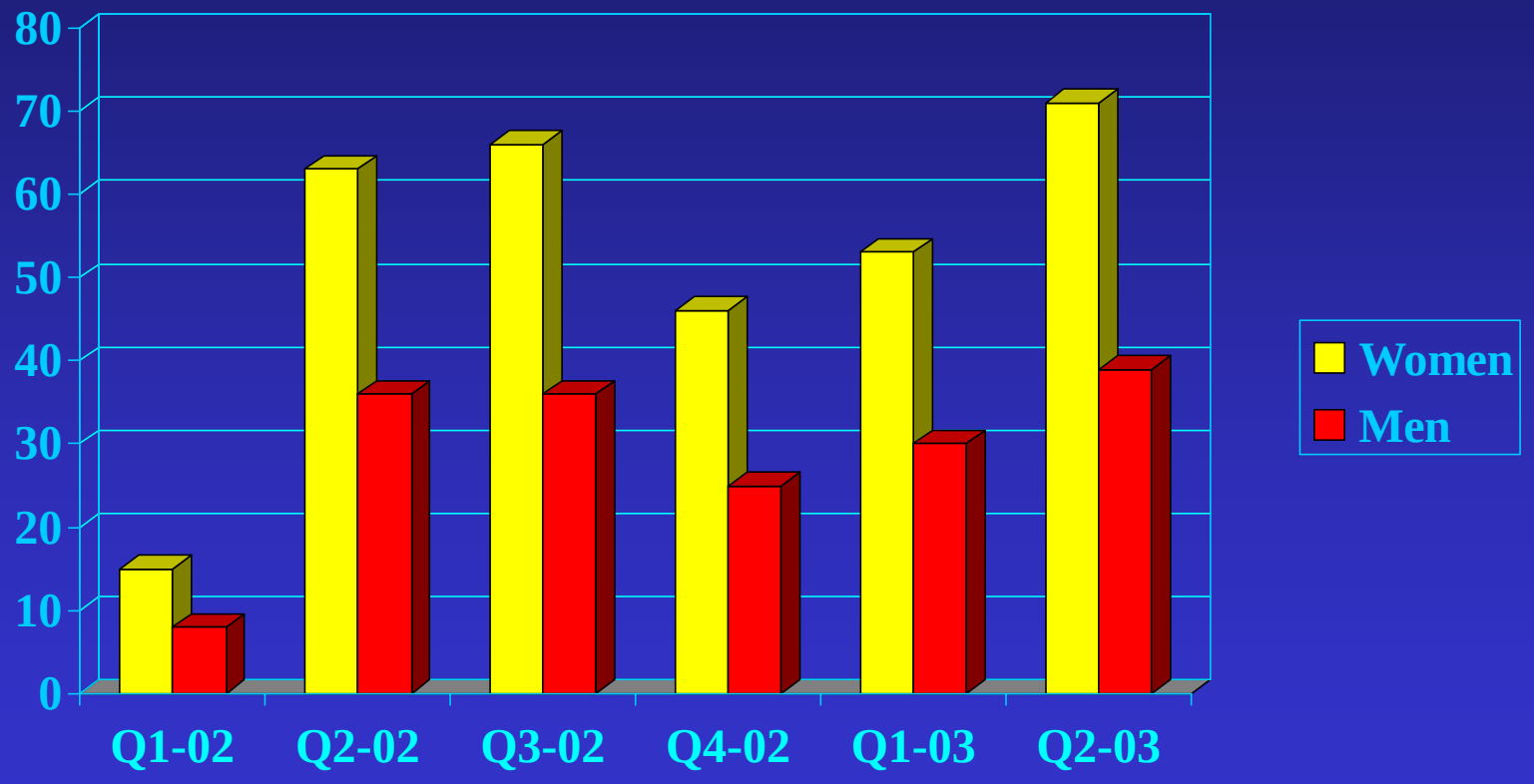
Baselines Completed=127/366
Control=84/243
Intervention=431/123

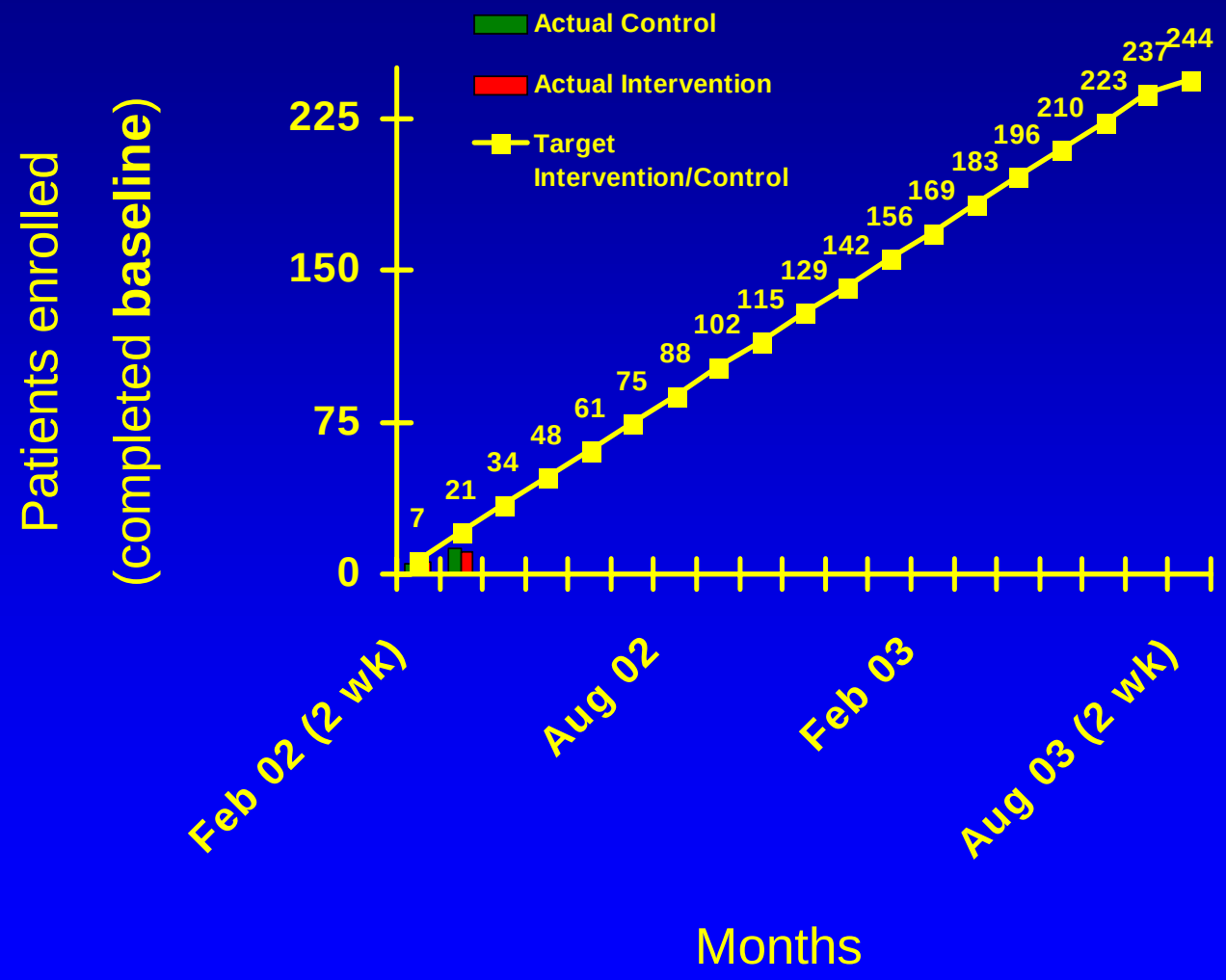


NYHA Classification



HTN Recruitment milestones



HYPERTENSION ENROLLMENT

Control vs. Intervention