



# Non-adherence? Should we call the psychiatrist or clinical pharmacist?

David Blackburn

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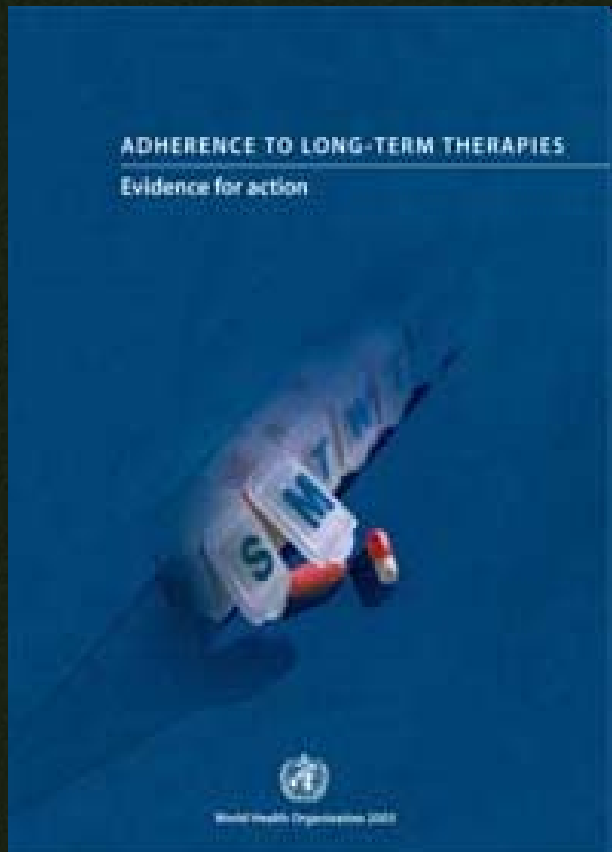


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# Plan...

- **To get you as confused as I am**

# Defining Adherence



**“The extent to which a person’s behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider”**

**-WHO 2003**

# What is adherence? - *really*

**“...the extent to which a person takes medications, follows a diet, and/or executes lifestyle changes that are known to benefit their health.”**

***Blackburn Subcommittee (BS)***

# The problem of adherence..

- Staggering for most diseases – most countries
- Approx 50% of individuals take medications regularly
- Causes 33% - 69% of all drug related hospital admissions
- Cost is \$100 billion per year in USA alone
  - *AKA - America's other drug problem*
- Single biggest barrier to effective outpatient treatment

Examples...

# Relationship Between Adherence to Evidence-Based Pharmacotherapy and Long-term Mortality After Acute Myocardial Infarction

Jeppe N. Rasmussen, MD

Alice Chong, BSc

David A. Alter, MD, PhD, FRCPC

**C**LINICAL TRIALS HAVE DEMONSTRATED that selected pharmacotherapies reduce cardiovascular mortality.<sup>1,2</sup> However, their projected survival impact in the real world is less known, in part because of variations in drug adherence.<sup>3,4</sup> Although it is known that adherence to evidence-based pharmacotherapy predicts better survival,<sup>5-11</sup> no population outcome study has attempted to differentiate whether these associations are attributable to the drug's biological responsiveness (herein termed *drug effect*) or to the adoption of healthier lifestyles that often accompany adher-

**Context** The extent to which drug adherence may affect survival remains unclear, in part because mortality differences may be attributable to "healthy adherer" behavioral attributes more so than to pharmacological benefits.

**Objective** To explore the relationship between drug adherence and mortality in survivors of acute myocardial infarction (AMI).

**Design, Setting, and Participants** Population-based, observational, longitudinal study of 31 455 elderly AMI survivors between 1999 and 2003 in Ontario. All patients filled a prescription for statins,  $\beta$ -blockers, or calcium channel blockers, with the latter drug considered a control given the absence of clinical trial-proven survival benefits.

**Main Outcome Measures** Patient adherence was subdivided a priori into 3 categories—high (proportion of days covered,  $\geq 80\%$ ), intermediate (proportion of days covered, 40%-79%), and low (proportion of days covered,  $<40\%$ )—and compared with long-term mortality (median of 2.4 years of follow-up) using multivariable survival models (and propensity analyses) adjusted for sociodemographic factors, illness severity, comorbidities, and concomitant use of evidence-based therapies.

**Results** Among statin users, compared with their high-adherence counterparts, the risk of mortality was greatest for low adherers (deaths in 261/1071 (24%) vs 2310/14 345 (16%); adjusted hazard ratio, 1.25; 95% confidence interval, 1.09-1.42;  $P = .001$ ) and was intermediary for intermediate adherers (deaths in 472/2407 (20%); adjusted hazard ratio, 1.12; 95% confidence interval, 1.01-1.25;  $P = .03$ ). A similar but less pronounced dose-response-type adherence-mortality association was observed for  $\beta$ -block-

# Real world subjects

- Survivors of heart attacks in Ontario b/w 1999 & 2003
- Filled either
  - Statin, beta-blocker, or calcium channel blocker
- Adherence divided as
  - High 80%
  - Intermediate 40%-79%
  - Low  $\leq$  40%
- Followed for 2.4 years on average

# Death Rates

- **High adherence 16% (2,310 / 14,345)**
- **Low adherence 24% (261 / 1,071)**

## Hypertension

### Adherence to Antihypertensive Medications and Cardiovascular Morbidity Among Newly Diagnosed Hypertensive Patients

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**Background**—Nonadherence to antihypertensive treatment is a common problem in cardiovascular prevention and may influence prognosis. We explored predictors of adherence to antihypertensive treatment and the association of adherence with acute cardiovascular events.

**Methods and Results**—Using data obtained from 400 Italian primary care physicians providing information to the Health Search/Thales Database, we selected 18 806 newly diagnosed hypertensive patients  $\geq 35$  years of age during the years 2000 to 2001. Subjects included were newly treated for hypertension and initially free of cardiovascular diseases. Patient adherence was subdivided a priori into 3 categories—high (proportion of days covered,  $\geq 80\%$ ), intermediate (proportion of days covered, 40% to 79%), and low (proportion of days covered,  $\leq 40\%$ )—and compared with the long-term occurrence of acute cardiovascular events through the use of multivariable models adjusted for demographic factors, comorbidities, and concomitant drug use. At baseline (ie, 6 months after index diagnosis), 8.1%, 40.5%, and 51.4% of patients were classified as having high, intermediate, and low adherence levels, respectively. Multiple drug treatment (odds ratio, 1.62; 95% CI, 1.43 to 1.83), dyslipidemia (odds ratio, 1.52; 95% CI, 1.24 to 1.87), diabetes mellitus (odds ratio, 1.40; 95% CI, 1.15 to 1.71), obesity (odds ratio, 1.50; 95% CI, 1.26 to 1.78), and antihypertensive combination therapy (odds ratio, 1.29; 95% CI, 1.15 to 1.45) were significantly ( $P < 0.001$ ) associated with high adherence to antihypertensive treatment. Compared with their low-adherence counterparts, only high adherers reported a significantly decreased risk of acute cardiovascular events (hazard ratio, 0.62; 95% CI, 0.40 to 0.96;  $P = 0.032$ ).

**Conclusions**—The long-term reduction of acute cardiovascular events associated with high adherence to antihypertensive treatment underscores its importance in assessments of the beneficial effects of evidence-based therapies in the population. An effort focused on early antihypertensive treatment initiation and adherence is likely to provide major benefits. (*Circulation*. 2009;120:1598-1605.)

**Key Words:** antihypertensive agents ■ cardiovascular diseases ■ cohort studies ■ medication adherence ■ prevention

# Subjects

- **Newly diagnosed with HTN (Italy)**
- **Prescribed medication within 90 days**
- **No serious CV disorder**

# Adherence at 6 months

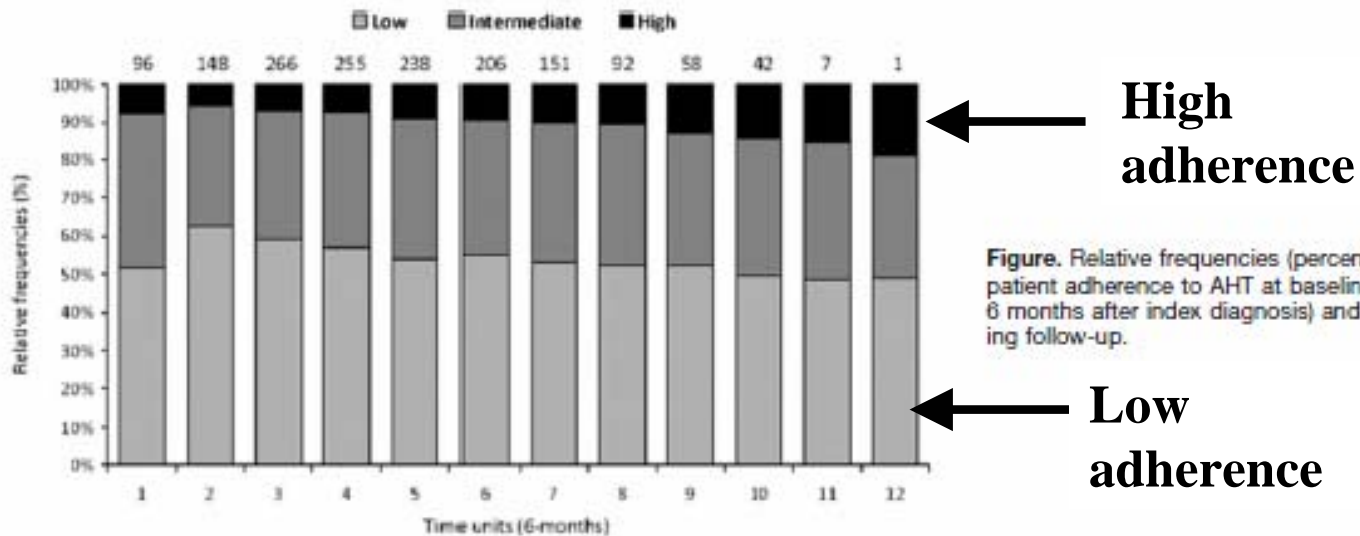


Figure. Relative frequencies (percent) of patient adherence to AHT at baseline (ie, 6 months after index diagnosis) and during follow-up.

\* The number of patients censored within each time-unit is reported above the bars.

# After 4.5 years

**Table 3. Multivariable Analysis of the Association of Patient Characteristics With First-Ever Acute Cardiovascular Event Estimated by Cox Proportional-Hazards Models**

Adherence Within 6 mo After Diagnosis	HR* (95% CI)	P
Model 1†		
Low (PDC <40%)	1.00	<0.001§
Intermediate (PDC, 40% to 79%)	0.87 (0.73–1.03)	0.117
High (PDC ≥80%)	0.50 (0.35–0.69)	<0.001
Model 2‡		
Low (PDC <40%)	1.00	<0.001§
Intermediate (PDC, 40% to 79%)	0.86 (0.71–1.03)	0.109
High (PDC ≥80%)	0.62 (0.40–0.96)	0.032

A total of 659 CVEs were considered in the models.

\*All models were adjusted for clustering by regional health authority.

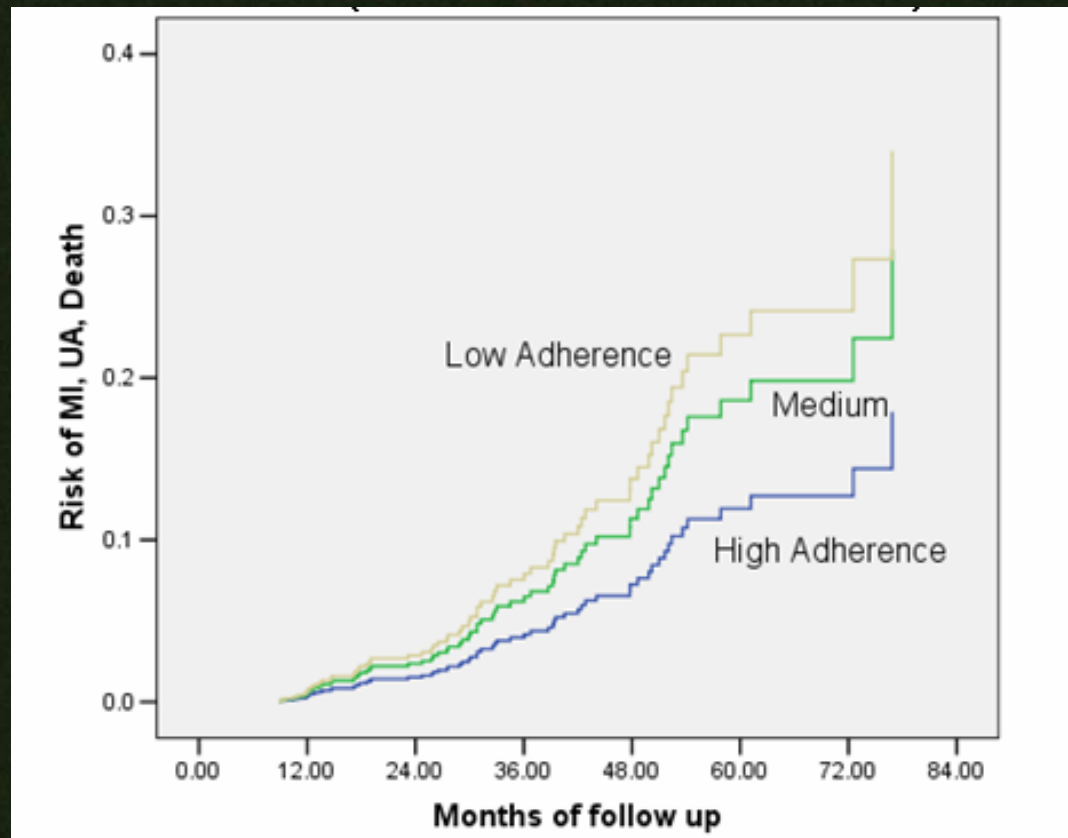
†Model 1: adjusted for age, gender, use of antithrombotics, ≥5 concurrent medications, presence of diabetes mellitus, dyslipidemia, and prior hospitalization. Time-dependent covariates included adherence to AHT, use of combination AHT, antithrombotics, ≥5 concurrent medications, presence of peripheral vascular diseases, diabetes mellitus, and dyslipidemia.

‡Model 2: model 1 additionally weighted by the inverse estimated propensity scores.

§P values for the overall comparison between models with and without adherence to AHT using the log-likelihood ratio test.

- **38% fewer CV events in high adherence group**

# In Saskatchewan...



**Are there logical solutions to  
this problem of non-  
adherence??**

# Solution #1



# Solution #2



Research article

Open Access

## A test of financial incentives to improve warfarin adherence

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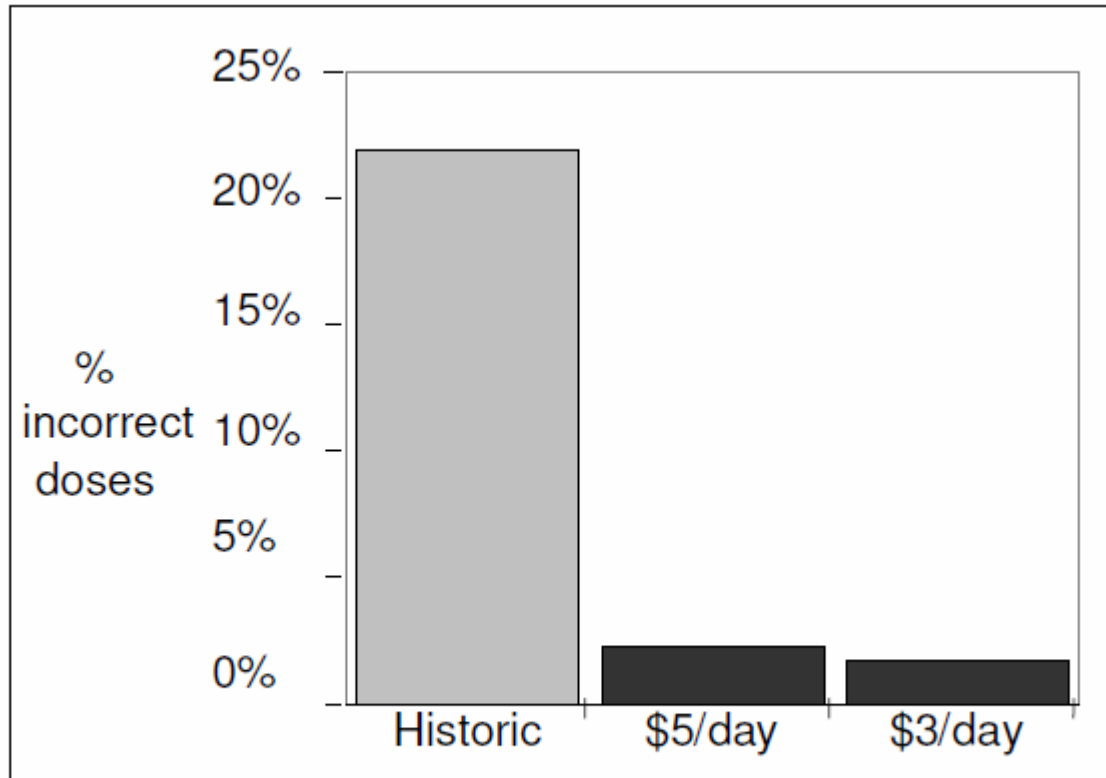
BMC Health Services Research 2008, 8:272 doi:10.1186/1472-6963-8-272

Accepted: 23 December 2008

# Methods

- **10 subjects attending a warfarin clinic**
- **Given a MEMs system**
- **For correct use**
  - **2 in 5 chance at a \$10 reward**
  - **1 in 100 chance at \$100 reward**

# Daily adherence (avg 3 months)



**Figure 1**  
Adherence under lotteries compared to historic controls.

# INR control

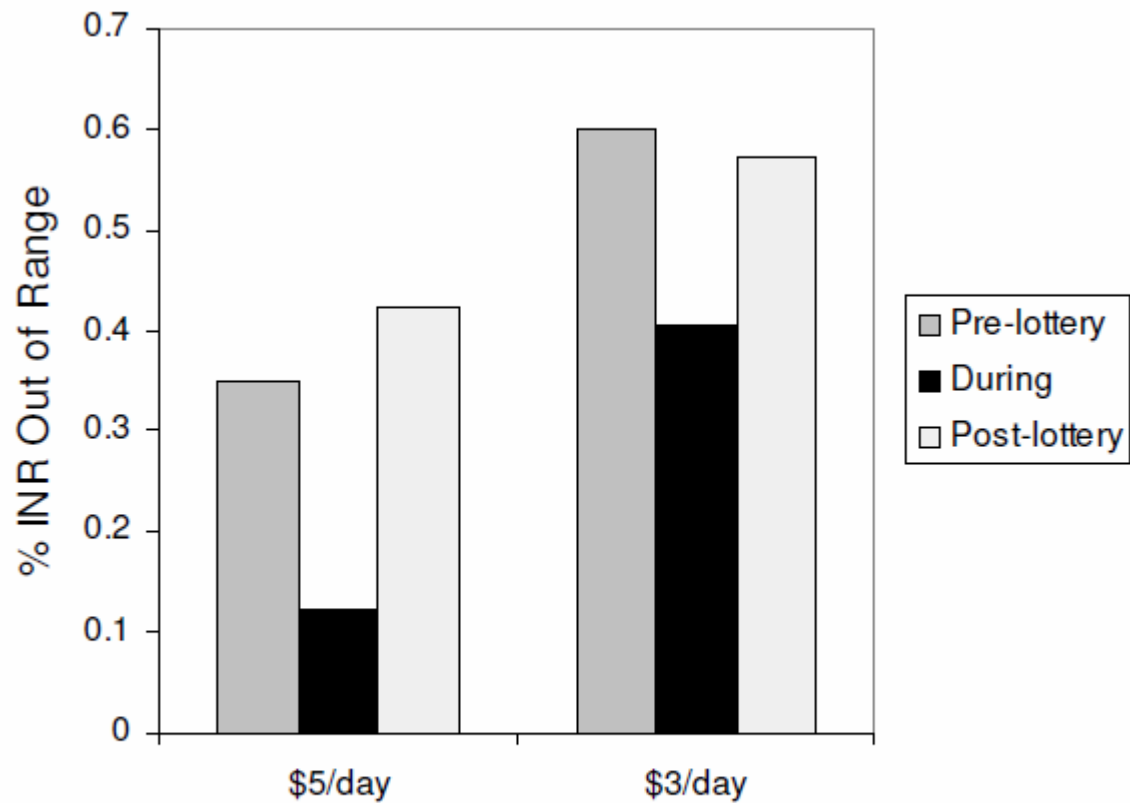


Figure 2  
Differences in time out-of-range INRs while in lottery compared to pre-enrollment.

SPECIAL ARTICLE

## A Randomized, Controlled Trial of Financial Incentives for Smoking Cessation

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ABSTRACT

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**BACKGROUND**

Smoking is the leading preventable cause of premature death in the United States. Previous studies of financial incentives for smoking cessation in work settings have not shown that such incentives have significant effects on cessation rates, but these studies have had limited power, and the incentives used may have been insufficient.

# Show me the money

- \$100 for completing a smoking-cessation program
- \$250 for stopping within 6 months
- \$400 for abstinence at 1 year

# Results

- **Enrollment in a smoking cessation program**
  - Money group → 15.4% (67 / 436)
  - Control group → 5.4% (24 / 442)
- **Confirmed stopping at 3 or 6 months**
  - Money → 20.9%
  - Control → 11.8%
- **Continued success at 15 – 18 months**
  - Money → 9.4%
  - Control → 3.6%

Maybe there's something to this  
but...



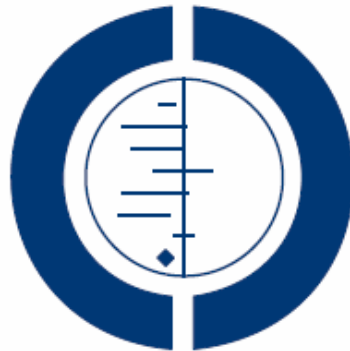
# Solution #3

- **The traditional way**

# “Scientific” interventions to help non-adherence

**Interventions for enhancing medication adherence (Review)**

Haynes RB, Yao X, Degani A, Kripalani S, Garg A, McDonald HP



**THE COCHRANE  
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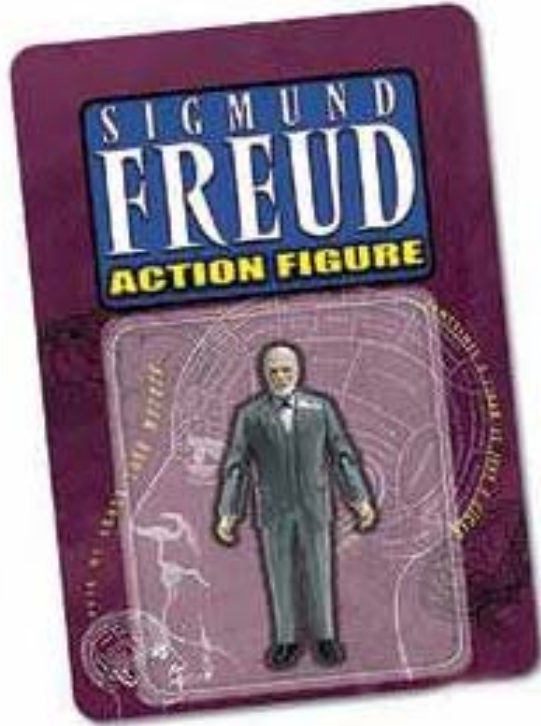
Cochrane  
2005 issue 4

# Authors' conclusions

***“Current methods of improving adherence for chronic health problems are mostly complex and not very effective, ....”***

Other possibilities?

**Tell me  
about your  
mother.**



**Behavioural interventions are  
logical**

# If the problem is...

<p>Knowledge</p>	<p>Lack of understanding of heart failure concepts as they relate to diet and drug therapy</p> <p>Lack of understanding of the relationship of hypertension or diabetes management to heart failure management</p> <p>Lack of understanding of drug-specific information</p> <p>Needs further drug-specific information</p> <p>Needs diet-specific instruction, especially relating to low-sodium diets</p>	<p>Explain fundamentals of heart failure and its management to patient in terms he or she can understand.</p> <p>Provide patient education materials as needed to clarify concepts.</p> <p>Explain how poor management of hypertension and diabetes contribute to worsening of heart failure.</p> <p>Provide patient with the handout on the importance of blood pressure medicines† or importance of diabetes medicines‡.</p> <p>Explain in terms patient can understand the rationale for the use of the icon system, how various icons belong to a specific medication type, and how these icons and colors map to the patient education materials.</p> <p>Use the approach espoused by Lorig (55). Namely, tell patients what you want them to do, show them how to do it, provide written instructions, and ask them how they plan to do it.</p> <p>Explain in terms patient can understand the rationale for needing a specific medication and its relationship to the other medications.</p> <p>Provide patient with appropriate handout.</p> <p>Ask patient about salty foods he or she eats and verbally provide patient with the names of alternatives that contain less salt.</p> <p>Provide patient with “Healthy Heart”§ handout.</p>
<p>Beliefs</p>	<p>Patient does not believe he or she needs the medication</p> <p>Lack of perceived self-efficacy</p>	<p>Provide verbal and written education materials.</p> <p>Discuss patient’s beliefs with his or her physician.</p> <p>Work with the patient to help him or her better manage the drug regimen.</p> <p>Build his or her confidence in medication management routines.</p>
<p>Expectations</p>	<p>Patient’s needs are not being met according to data from the Expectations Questionnaire</p>	<p>Discuss patient’s expectations with him or her.</p> <p>Determine whether drug-related expectations are realistic (e.g., desire for a prescription for unwarranted medications).</p> <p>Refer disease management expectations to primary care physician and nurse.</p>

Prescription-taking skills	<p>Pharmacist's assessment suggests an inability to read instructions on prescription label</p> <p>Pharmacist's assessment suggests an inability to comprehend instructions</p>	<p>Literacy problem: Review prescription-specific icon system on each medication-specific pamphlet.</p> <p>Explain medication administration timeline.</p> <p>Vision problem: Find a font size that the patient can adequately read and use it on the medication-specific pamphlet.</p> <p>Blind: Use raised lettering or Braille on prescription lids and container.</p> <p>Review prescription-specific icon system on each medication-specific pamphlet.</p> <p>Explain medication administration timeline on the medication pamphlets.</p>
Communication skills	<p>Patient finds it difficult discussing problems with his or her physician</p> <p>Patient forgets what his or her physician says</p> <p>Patient does not agree with physician's treatment</p>	<p>Determine gaps in patient's knowledge and treatment plan and provide patient with a list of questions to ask the physician by phone or at his or her next visit.</p> <p>Ask patient to have physician or nurse write down his or her instructions.</p> <p>If the patient forgets or loses the instruction list, encourage him or her to call physician.</p> <p>Medicine not effective: Encourage patient to discuss alternative treatments with his or her physician.</p> <p>Side effects: Encourage patient to discuss problem with physician. Pharmacist should call physician to describe the side effect and determine alternative treatment.</p> <p>Other: Encourage patient to work closely with his or her physician and explain the reason for his or her disagreement with the physician's choice of treatments. Pharmacist should call the patient's physician to explain the situation depending on the nature and magnitude of the problem.</p>
Supervision	Patient lives alone and has no one to supervise self-administration of medications	<p>Provide motivation for patient to take medications and use aids to improve adherence and reminders.</p> <p>Call patient to follow up and show him or her that you care that he or she takes his or her medication.</p> <p>Coach patient on taking his or her medications.</p> <p>If no improvement, contact physician and possibly social services.</p>
Perceived health	<p>Patient does not realize the severity of his or her illness</p> <p>Patient with mild disease is frightened about his or her fate</p>	<p>Establish the severity of the disease.</p> <p>Educate patient about the importance of treating heart failure and associated comorbid conditions to prevent or slow the progression of the disease.</p> <p>Provide disease- and drug-specific education pamphlets.</p> <p>Provide disease- and drug-specific education pamphlets.</p> <p>Be optimistic with patient.</p> <p>Encourage patient to discuss his or her feelings with his or her physician and nurse.</p>
Cognitive function	Patient does not remember to take medications	Provide reminders, such as patient-specific calendar to mark when they

Tools to help

# Health Belief Model

Concept	Definition	Application
Perceived <b>Susceptibility</b>	-belief regarding the <b>chance of getting a condition</b>	Define the population at risk/risk level Personalize the risk based on person's characteristics of behavior Make perceived susceptibility more consistent with an individual's actual risk
Perceived <b>Severity</b>	-belief of <b>how serious</b> a condition and its consequences	Specify consequences of the risk and the conditions
Perceived <b>Benefits</b>	-belief in the <b>efficacy of the advised action</b> to reduce risk or seriousness of impact	Define action to take: how, where, when; clarify the positive effects to be expected
Perceived <b>Barriers</b>	One's belief about the tangible and psychological <b>costs</b> of the advised action	Identify and reduce perceived barriers through reassurance, correction of misinformation, incentives, assistance

# Theory of Reasoned Action / Planned Behaviour

Construct	Definition
Behavioral Intention	Perceived likelihood of performing the behavior
<i>Attitude</i>	
Direct Measure	Overall evaluation of the behavior
Indirect Measure	
Behavioral belief	Belief that behavioral performance is associated with certain attributes or outcomes
Evaluation	Value attached to a behavioral outcome or attribute
<i>Subjective Norm</i>	
Direct Measure	Belief about whether most people approve/disapprove of the behavior
Indirect Measure	
Normative belief	Belief about whether each referent approves/disapproves of the behavior
Motivation to Comply	Motivation to do what each referent thinks

# If those weren't enough...

- **Social cognitive theory**
- **Theory of planned behaviour – Perceived behavioural control**
- **Transtheoretical model (stages of change)**
- **Relapse prevention**
- **And many more...**

# The Morisky scale

## ■ eAppendix A. The 8-Item Morisky Medication Adherence Scale

Question	Response Options
1. Do you sometimes forget to take your high blood pressure pills?	Yes/No
2. Over the past 2 weeks, were there any days when you did not take your high blood pressure medicine?	Yes/No
3. Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?	Yes/No
4. When you travel or leave home, do you sometimes forget to bring along your medications?	Yes/No
5. Did you take your high blood pressure medicine yesterday?	Yes/No
6. When you feel like your blood pressure is under control, do you sometimes stop taking your medicine?	Yes/No
7. Do you ever feel hassled about sticking to your blood pressure treatment plan?	Yes/No
8. How often do you have difficulty remembering to take all your blood pressure medication?	Never/Almost Never/Sometimes/Quite Often/Always

Adapted from Morisky et al.<sup>13</sup>

# Adherence Estimator

	Agree completely	Agree mostly	Agree somewhat	Disagree somewhat	Disagree mostly	Disagree completely
I am convinced of the importance of my prescription medication	0	0	7	7	20	20
I worry that my prescription medication will do more harm than good to me	14	14	4	4	0	0
I feel financially burdened by my out-of-pocket expenses for my prescription medication	2	2	0	0	0	0

ADD UP THE TOTAL NUMBER OF POINTS FROM THE CHECKED BOXES

Score	Interpretation
0	Low risk for adherence problems (> 75% probability of adherence)
2-7	Medium risk for adherence problems (32-75% probability of adherence)
8+	High risk for adherence problems (< 32% probability of adherence)

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# Evidence for these tools / theories in health care?

- Minimal – especially as they relate to drug use, adherence, and outcomes
- However, they are very logical

## Blackburn's beefs

- Focus on the patient as if they are the only player
- They are very logical

# How dependable is logic in health care?

- **We used to think..**
  - ACE and ARBs were a good combination
  - Coronary stenting was superior to drugs
  - Glitazones would save lives in diabetes
  - Intensive blood sugar reduction would save lives in diabetes
  - Estrogen would reduce CV risk
  - Digoxin would save lives and BB would kill people with heart failure
  - Antiarrhythmic drugs would save lives after MI
  - Converting atrial fibrillation patients would be beneficial

Is the logic regarding blood sugar and cardiovascular risk more or less reliable than the logic regarding human behaviour and motivation?

What if we were to keep things  
simple?

# Self-reported Medication Adherence and Cardiovascular Events in Patients With Stable Coronary Heart Disease

## *The Heart and Soul Study*

Anil K. Gehi, MD; Sadia Ali, MD, MPH; Beeya Na, MPH; Mary A. Whooley, MD

**Background:** Nonadherence to physician treatment recommendations is an increasingly recognized cause of adverse outcomes and increased health care costs, particularly among patients with cardiovascular disease. Whether patient self-report can provide an accurate assessment of medication adherence in outpatients with stable coronary heart disease is unknown.

**Methods:** We prospectively evaluated the risk of cardiovascular events associated with self-reported medication nonadherence in 1015 outpatients with established coronary heart disease from the Heart and Soul Study. We asked participants a single question: "In the past month, how often did you take your medications as the doctor prescribed?" Nonadherence was defined as taking medications as prescribed 75% of the time or less.

**Results:** Of the 1015 participants, 83 (8.2%) reported nonadherence to their medications, and 146 (14.4%) developed cardiovascular events. Nonadherent participants were more likely than adherent participants to develop cardiovascular events during 3.9 years of follow-up (22.9% vs 13.8%,  $P = .03$ ). Self-reported nonadherence remained independently predictive of adverse cardiovascular events after adjusting for baseline cardiac disease severity, traditional risk factors, and depressive symptoms (hazards ratio, 2.3; 95% confidence interval, 1.3-4.3;  $P = .006$ ).

**Conclusions:** In outpatients with stable coronary heart disease, self-reported medication nonadherence is associated with a greater than 2-fold increased rate of sub-

# Estimating adherence

- 1,015 patients with CHD from hospitals in California
- 1 question:

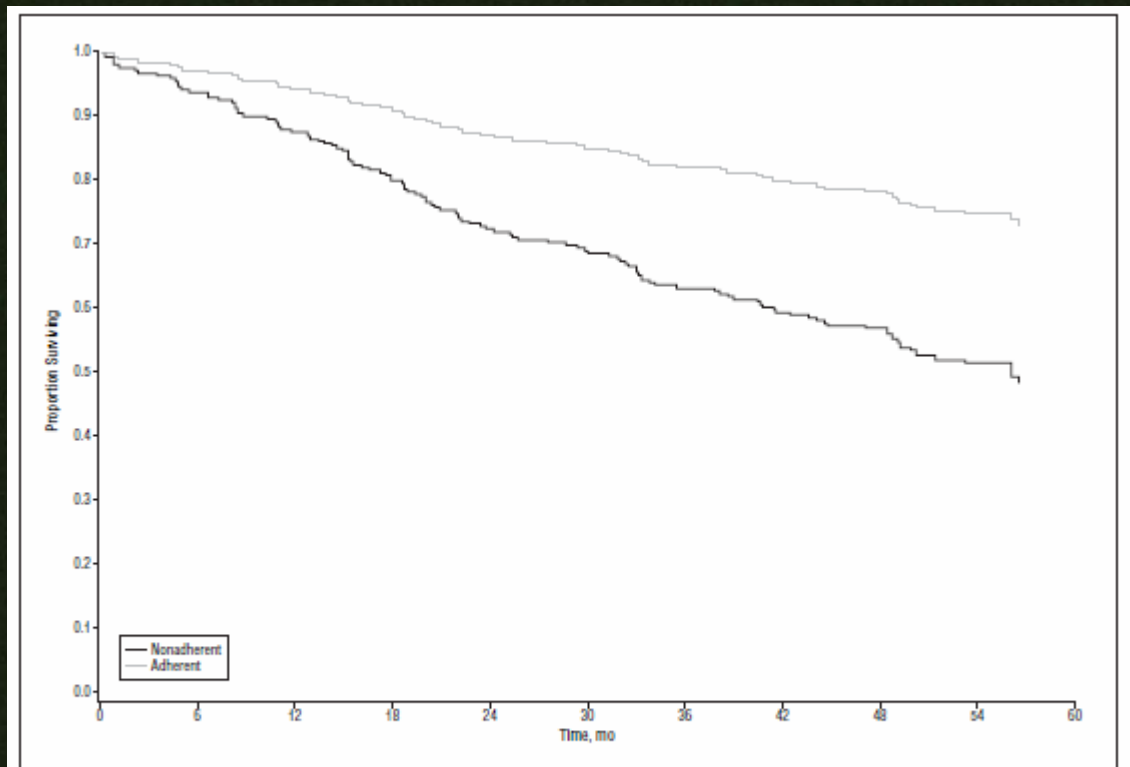
“In the past month, how often did you take your medications as the doctor prescribed?”

“All of the time” (100%),

“Nearly all of the time” (90%),

“Most of the time” (75%) or less

# Maybe 1 question is all you need?



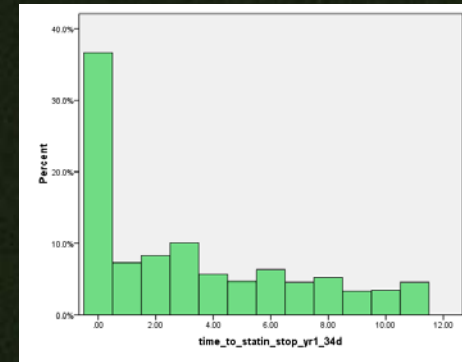
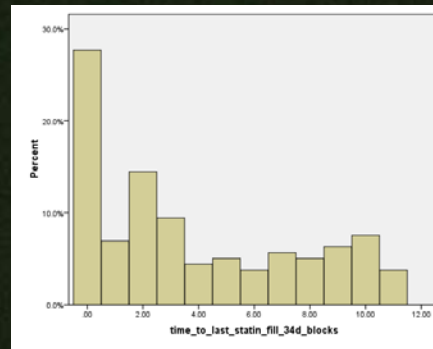
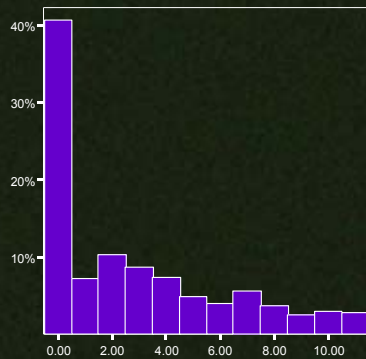
**Figure 2.** Proportion surviving without a cardiovascular event (myocardial infarction, stroke or coronary heart disease death) by self-reported medication adherence at baseline, adjusted for age, sex, race, educational level, smoking, diabetes mellitus, hypertension, depressive symptoms, number of cardiovascular medications, use of  $\beta$ -blocker, use of statin, left ventricular ejection fraction, weekly angina, high-density lipoprotein cholesterol level and low-density lipoprotein cholesterol level ( $P=.006$ ).

Do we need to ask everybody whether they are non-adherent?

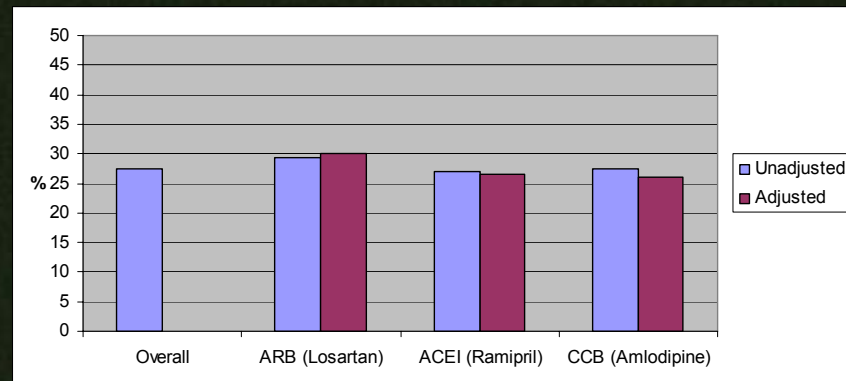
- **Likely not practical**
- **Who are the most at risk?**

# The new user !!!

## Statins



## Antihypertensives



Where is the holy grail in all this?

# The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

JANUARY 30, 2003

VOL. 348 NO. 5

## Multifactorial Intervention and Cardiovascular Disease in Patients with Type 2 Diabetes

Peter Gæde, M.D., Pernille Vedel, M.D., Ph.D., Nicolai Larsen, M.D., Ph.D., Gunnar V.H. Jensen, M.D., Ph.D.,  
Hans-Henrik Parving, M.D., D.M.Sc., and Oluf Pedersen, M.D., D.M.Sc.

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### ABSTRACT

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#### BACKGROUND

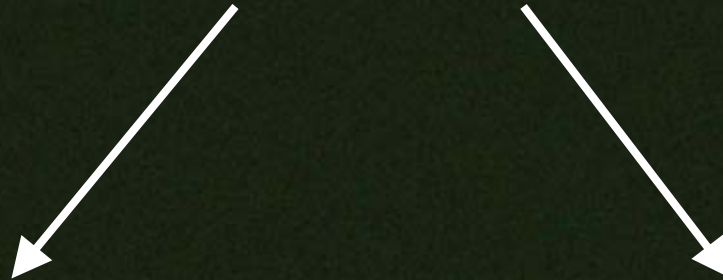
Cardiovascular morbidity is a major burden in patients with type 2 diabetes. In the Steno-2 Study, we compared the effect of a targeted, intensified, multifactorial intervention with that of conventional treatment on modifiable risk factors for cardiovascular disease in patients with type 2 diabetes and microalbuminuria.

#### METHODS

From the Steno Diabetes Center, Copenhagen (P.G., P.V., N.L., H.-H.P., O.P.); Herlev County Hospital, Herlev (N.L.); Amtssygehuset Roskilde, Roskilde (G.V.H.J.); and the Faculty of Health Science, Aarhus University, Aarhus (H.-H.P., O.P.) — all in Denmark. Address reprint requests to Dr. Pedersen at the Steno Diabetes Center, Niels

# Steno-2

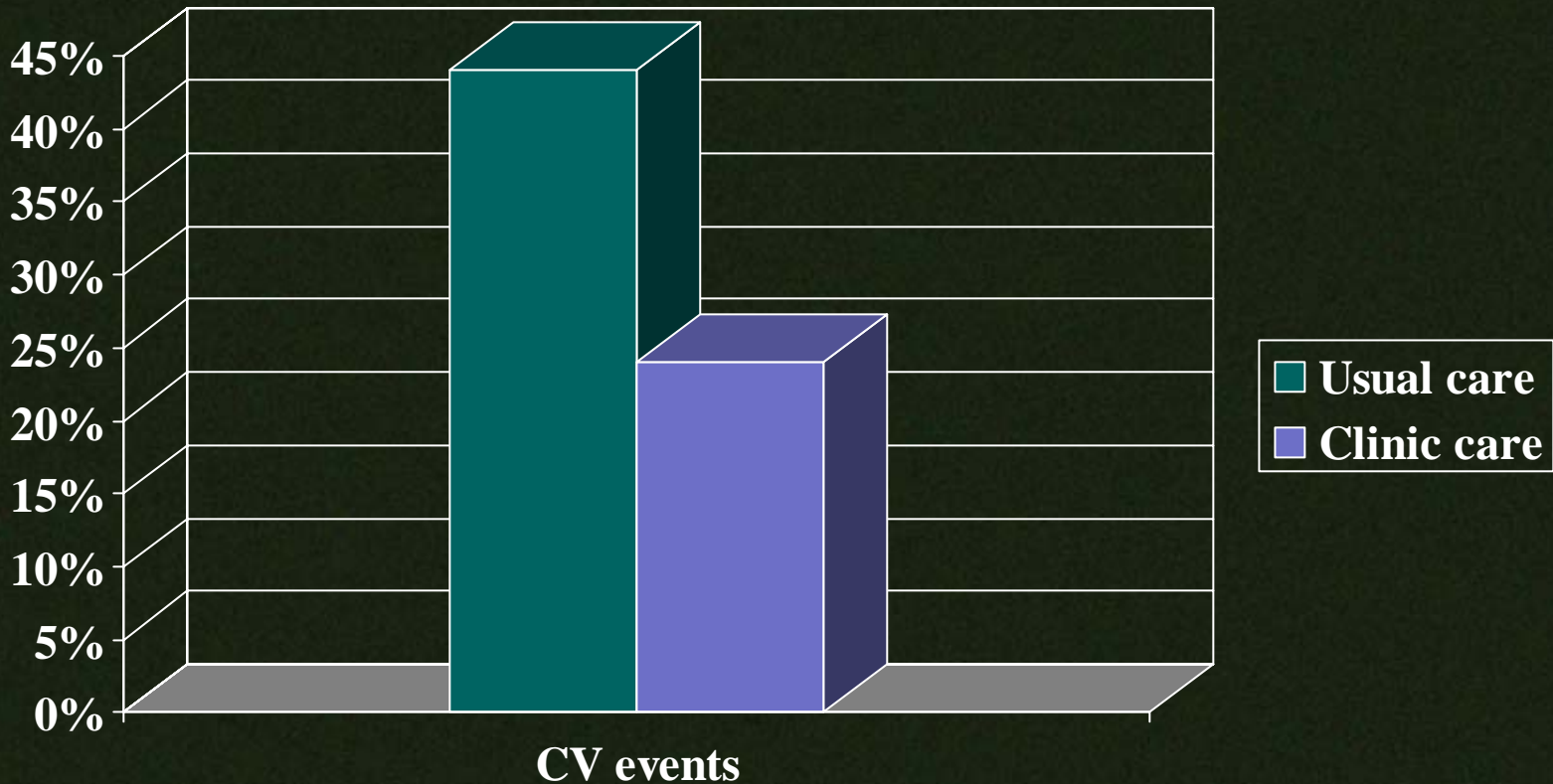
**160 diabetic patients with  
microalbuminuria**



Standard care  
from family doctor  
(n=80)

Specialized care  
from a diabetes  
clinic (n=80)

# % of patients experiencing a CV event

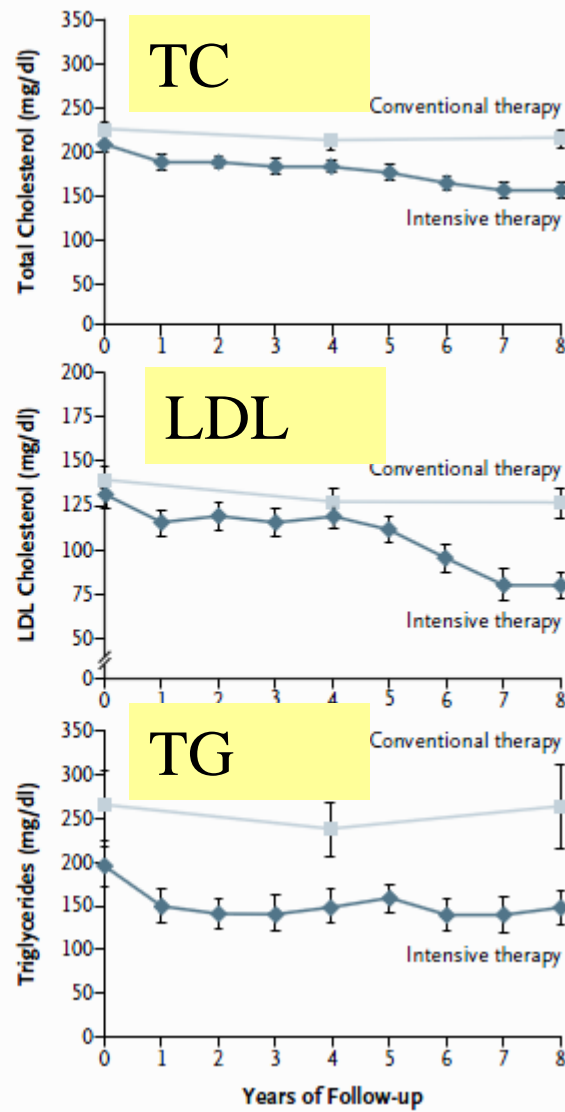
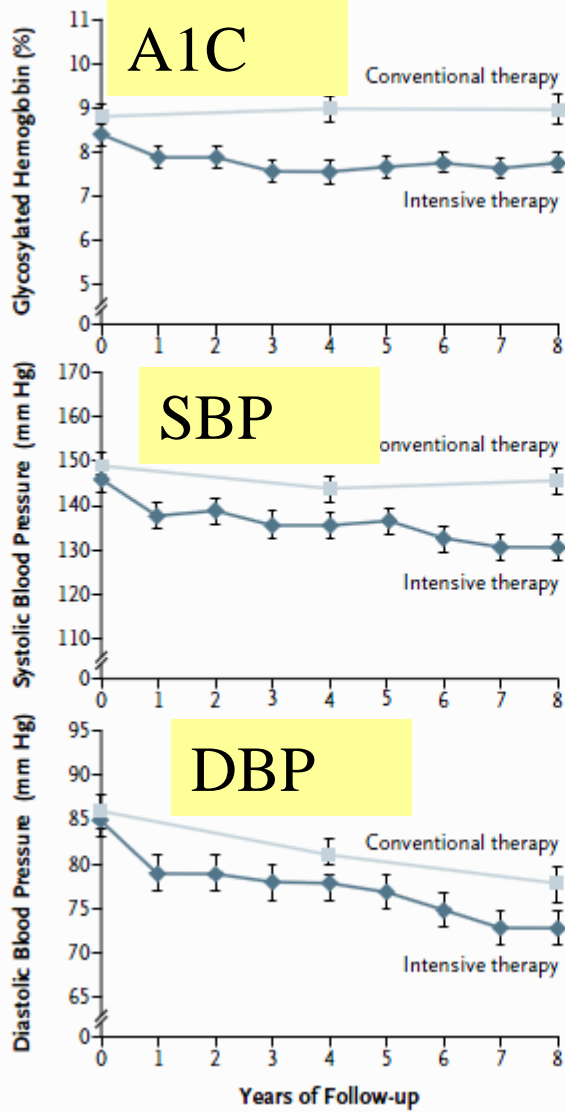


# What was the key to success?

- 
- 
- 
- 
- 
- 

**They just took more drugs**

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**A**

# Success?

- **Adherence did not seem to be problematic**
  - “Clinical follow up” every 3 months to reach goals
  - A real team working together

But not everyone can work in a  
multidisciplinary clinic...



# The CPATCH Study

*Community Pharmacists Assisting  
in Total Cardiovascular Health*



**Saskatchewan  
Ministry of  
Health**



**MERCK FROSST / Schering**  
Pharmaceuticals

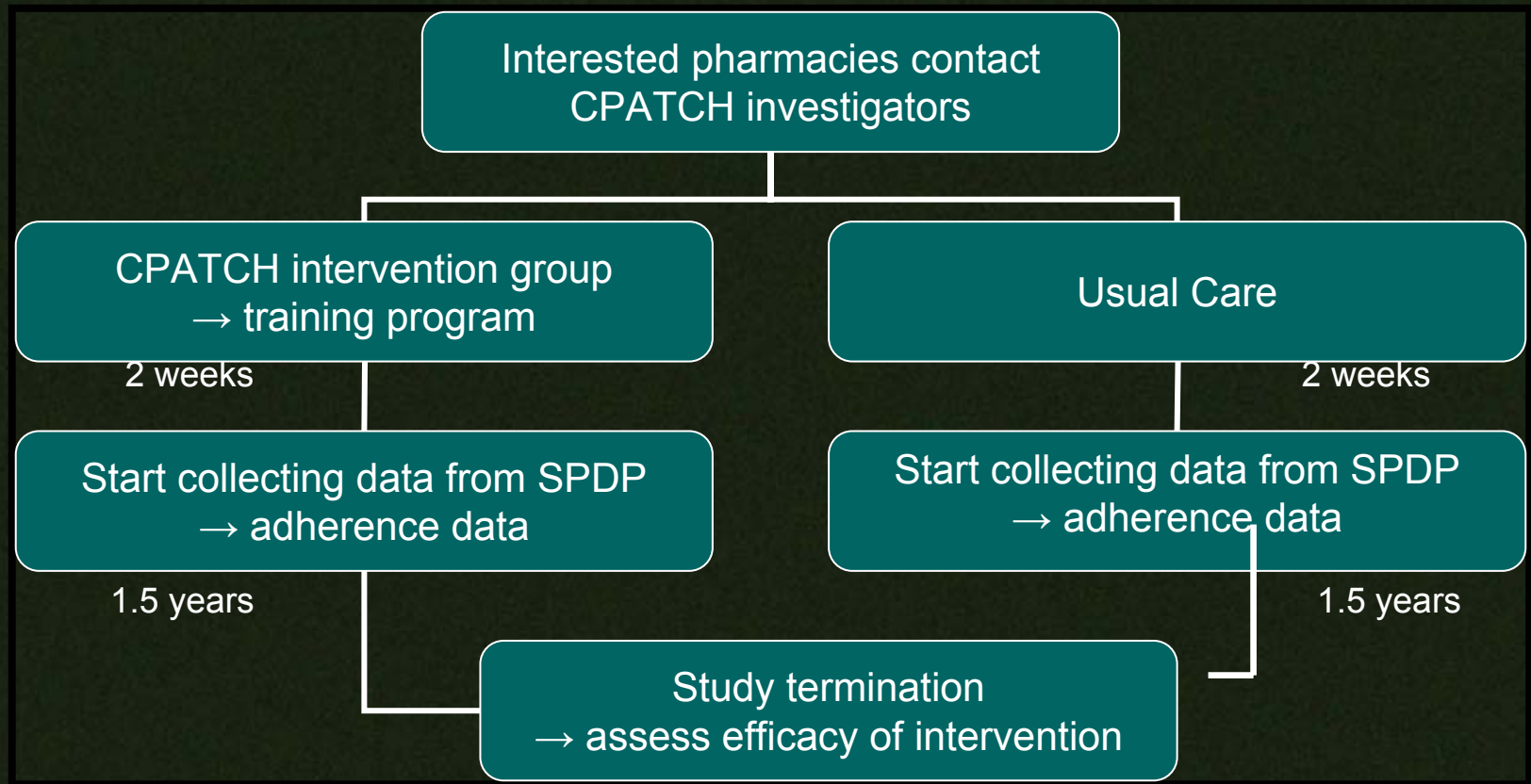
# CPATCH

- **The study of “regular Joe’s”**
- **How much can us regular Joe’s influence probability of becoming non-adherent**

# Basic elements

- **Many people are already adherent**
- **New users need to be prepared, not counseled..**
  - for what “Aunt Betty” is going to say
  - for what the internet will say
- **Need to get to them first**
  - So they never say --- Why didn't they tell me that??
- **Docs need to be notified**

# CPATCH Design



Maybe someday pharmacy will look like this...



But we still have much to learn about our own back yard.



# Questions?

