# Patients Will Be Safe With
# A-L-L Heart Protection

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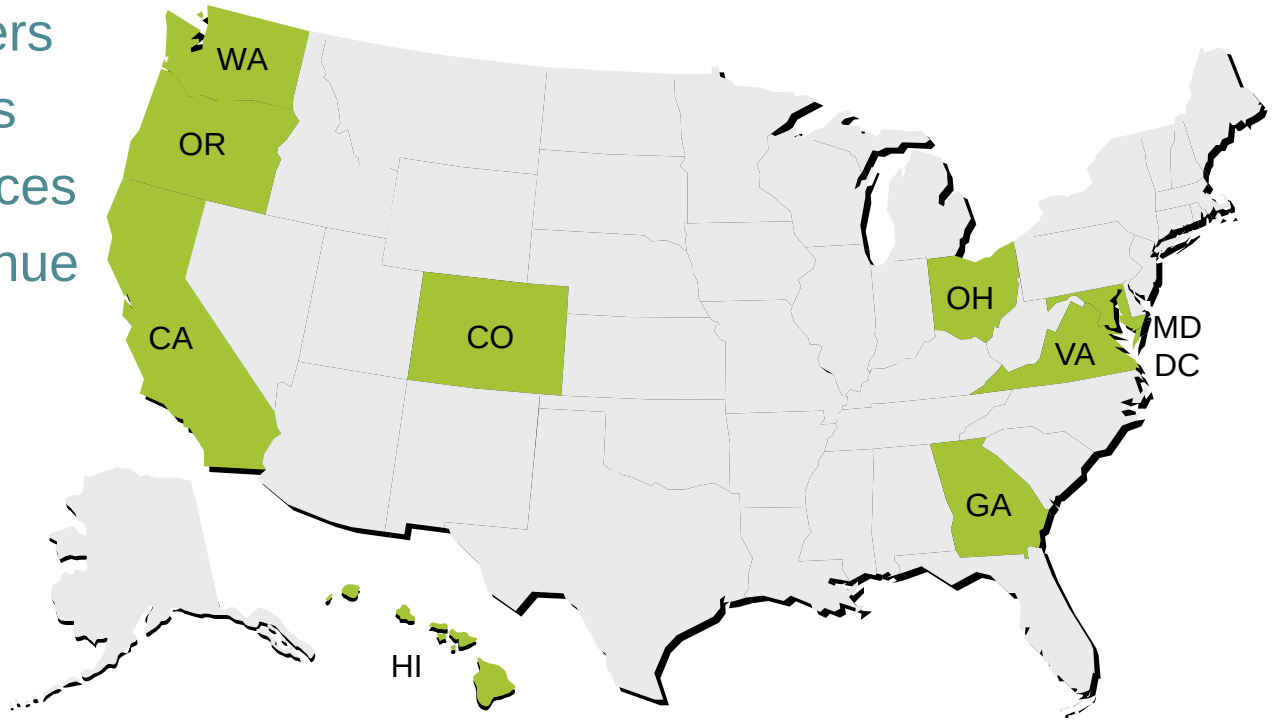
# Lets Discuss..

- How A-L-L evolved: What…
  - was the problem?
  - did modeling predict?
  - happened?
  - Is left to do?
- Is there polypill interest in Kaiser?
  - What didn't work?
- Why a CVD prevention polypill makes sense

# Kaiser Permanente: A Health Maintenance Organization

- Serving 9 states

- ~9 million members
- 15,000 physicians
- ~600 medical offices
- $44 billion/y revenue



# The Problem:

- In yr 2000 Kaiser's **cholesterol** clinic targeted a Decrease in MI's & Strokes by lowering cholesterol
  - Archimedes* analyzed results: No significant decrease because it was:
    - **Ineffective** by trying to treat all who walked in with **high cholesterol**, rather than outreach to **high CVD** risk pts
    - **Inefficient** by not dropping MI rates enough **just treating cholesterol**
- So next..

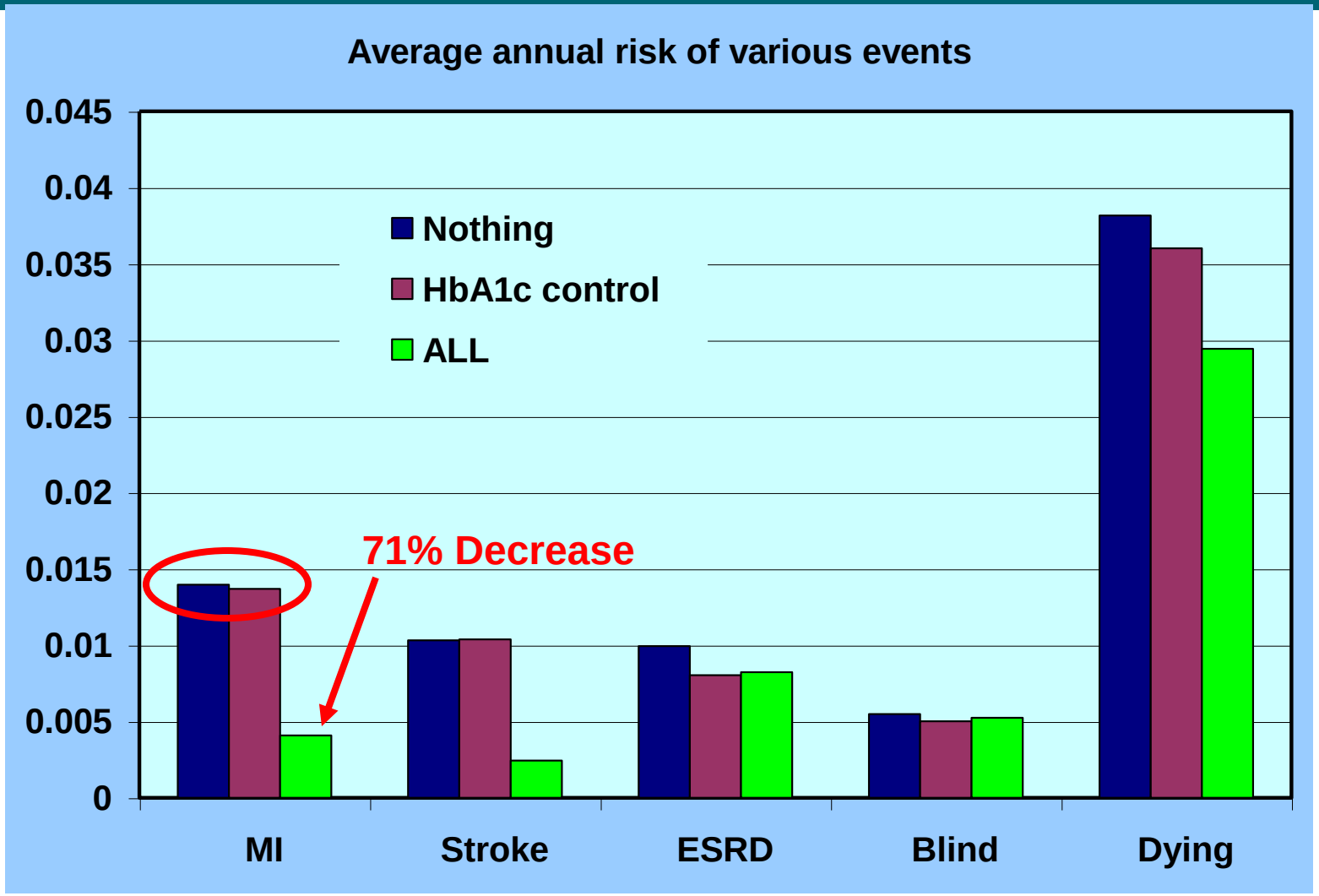
http://archimedesmodel.com/sites/default/files/Cost-Effectiveness-Archimedes.pdf

**Lancet 360, 6 July 2002

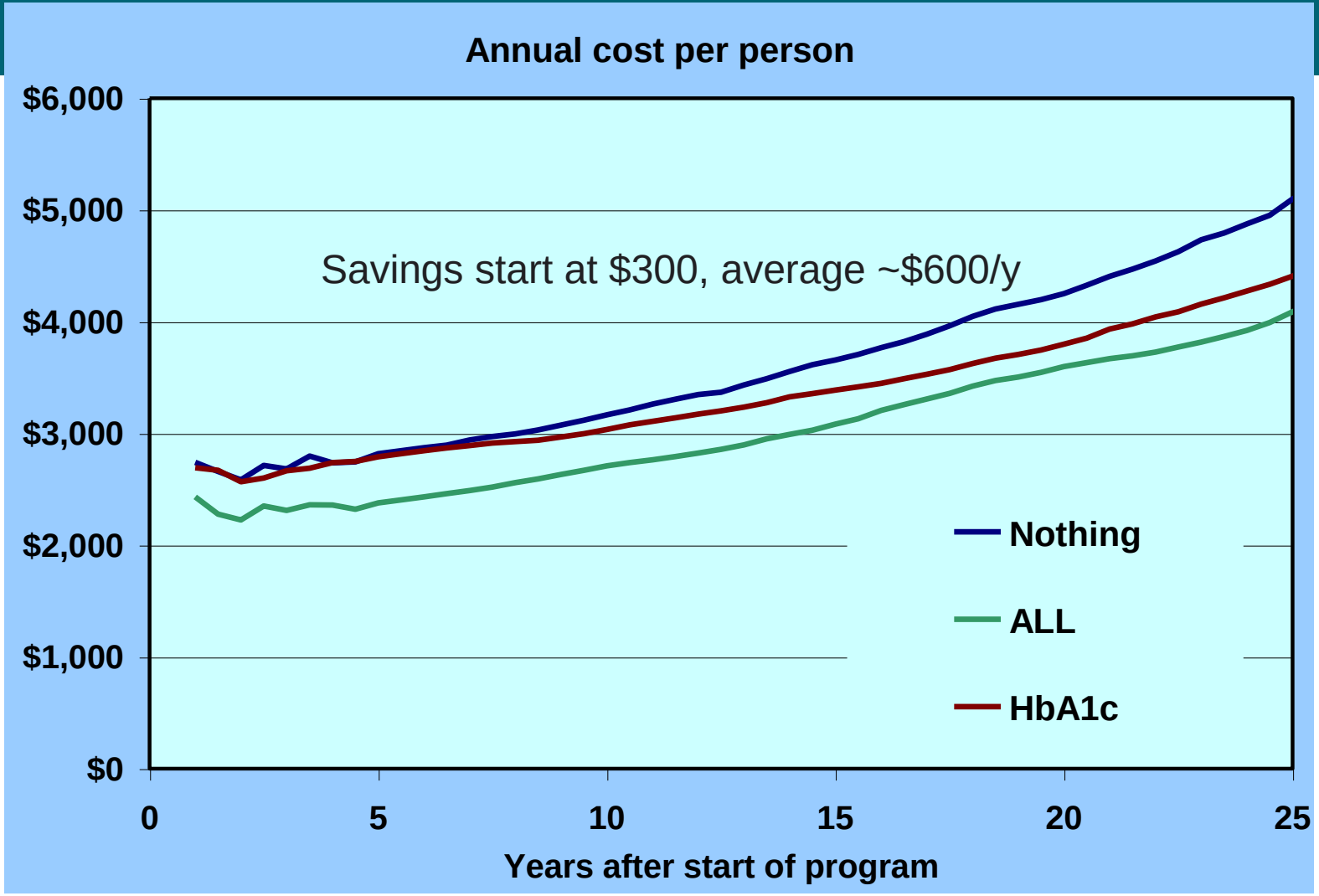
# Archimedes Modeled a Program that Could

- **easily** identify high CVD risk pts with:
  - Diabetes age ≥55yo or
  - Prior heart attack or stroke
- ensure they are offered daily dose of:
  - Aspirin 75-325 mg
  - Lovastatin 40mg
  - Lisinopril 20 mg

# Archimedes Modeling of A-L-L & A1C in Diabetes

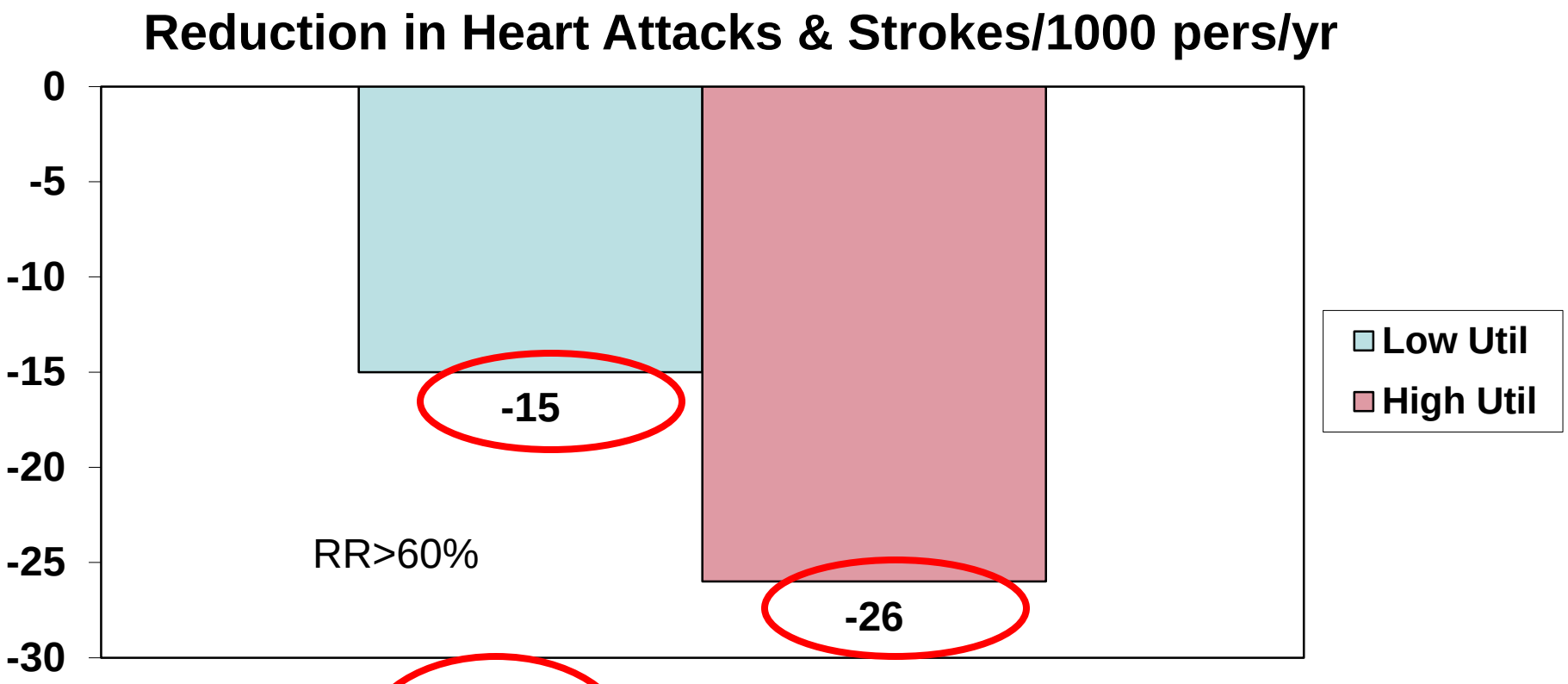


# A-L-L Reduces Cost in Patients With Diabetes



# Kaiser Observed Effect of the "L-L" Bundle was Significant

70,000 pts started bundle over 3 yrs, compared to 100,000 with usual care

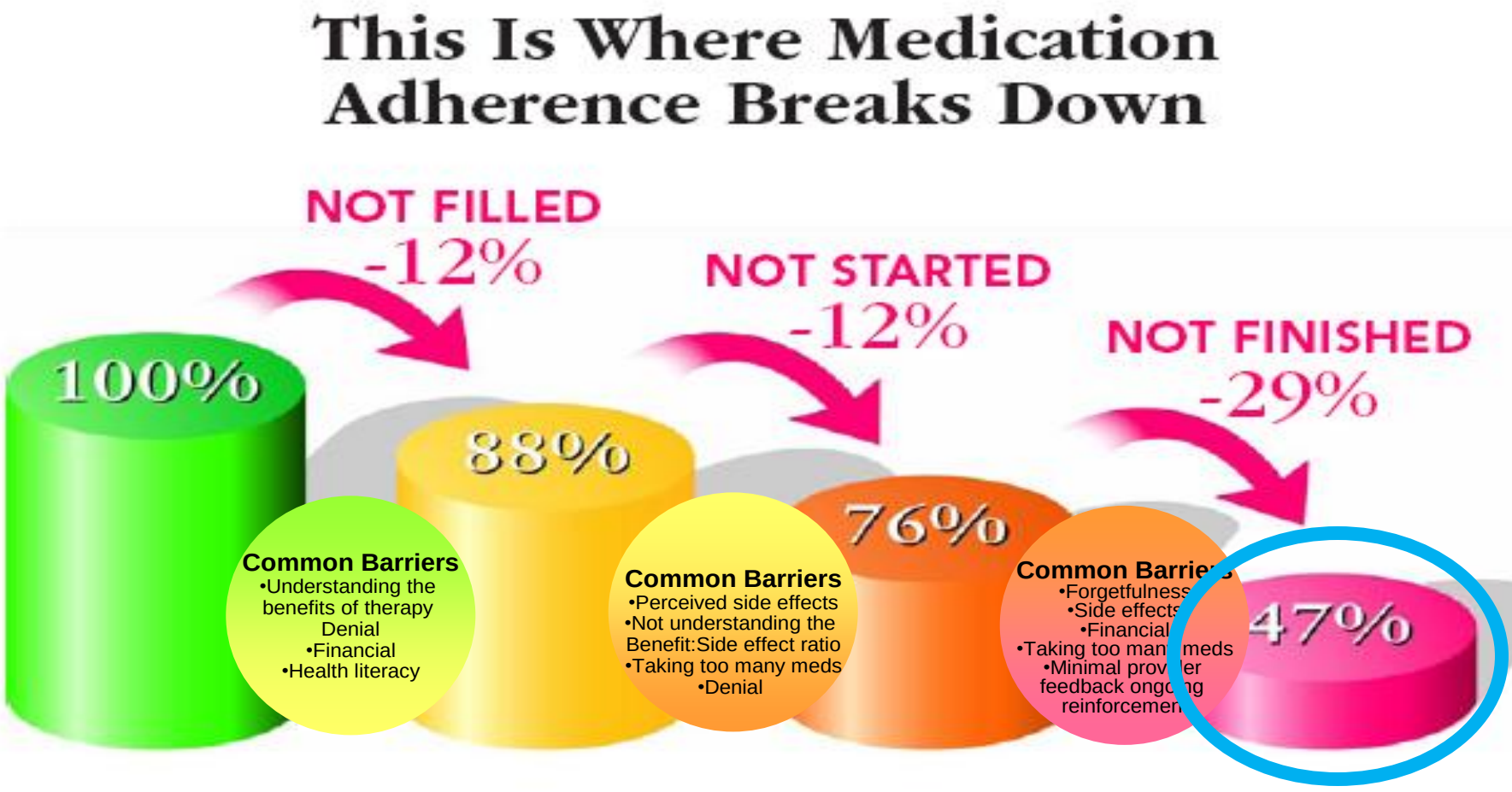



- Even 1 day of 5 utilization was significant
- But taking it 2/3 of the time was much more beneficial

# Why Did A-L-L Work in Kaiser?

- We readjusted the **evidence-based** bundle & an **opt-out** population strategy until it was **incontrovertibly** supported by:
  - Administration:  Big impact AND **cost savings** & easier implementation
  - Practitioners: Big impact, **much easier that "treat & titrate"** & medication "indicator" easy
  - Patients: Big impact & **easier & more effective than lifestyle**, >60% effect

# What's Left To Do? Adherence




American Heart Association 2009, *Statistics You Should Know,* http://www.americanheart.org/presenter.jhtml?identifier=107.

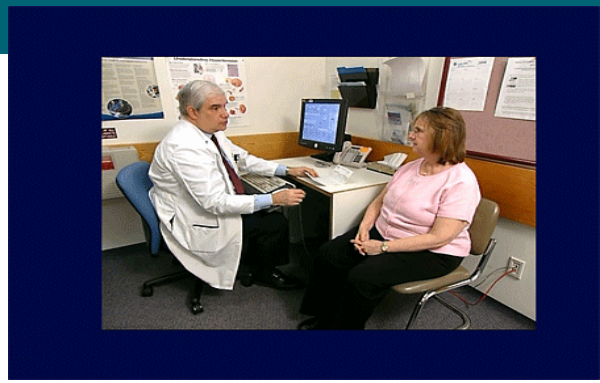
# **Barriers** to medication adherence

## Patient-related

- Forgetfulness
- Lack of knowledge
- Value of therapy
- Cultural/Ethnic
- Denial
- **Financial**
- Health literacy
- Social support

## Medication-related

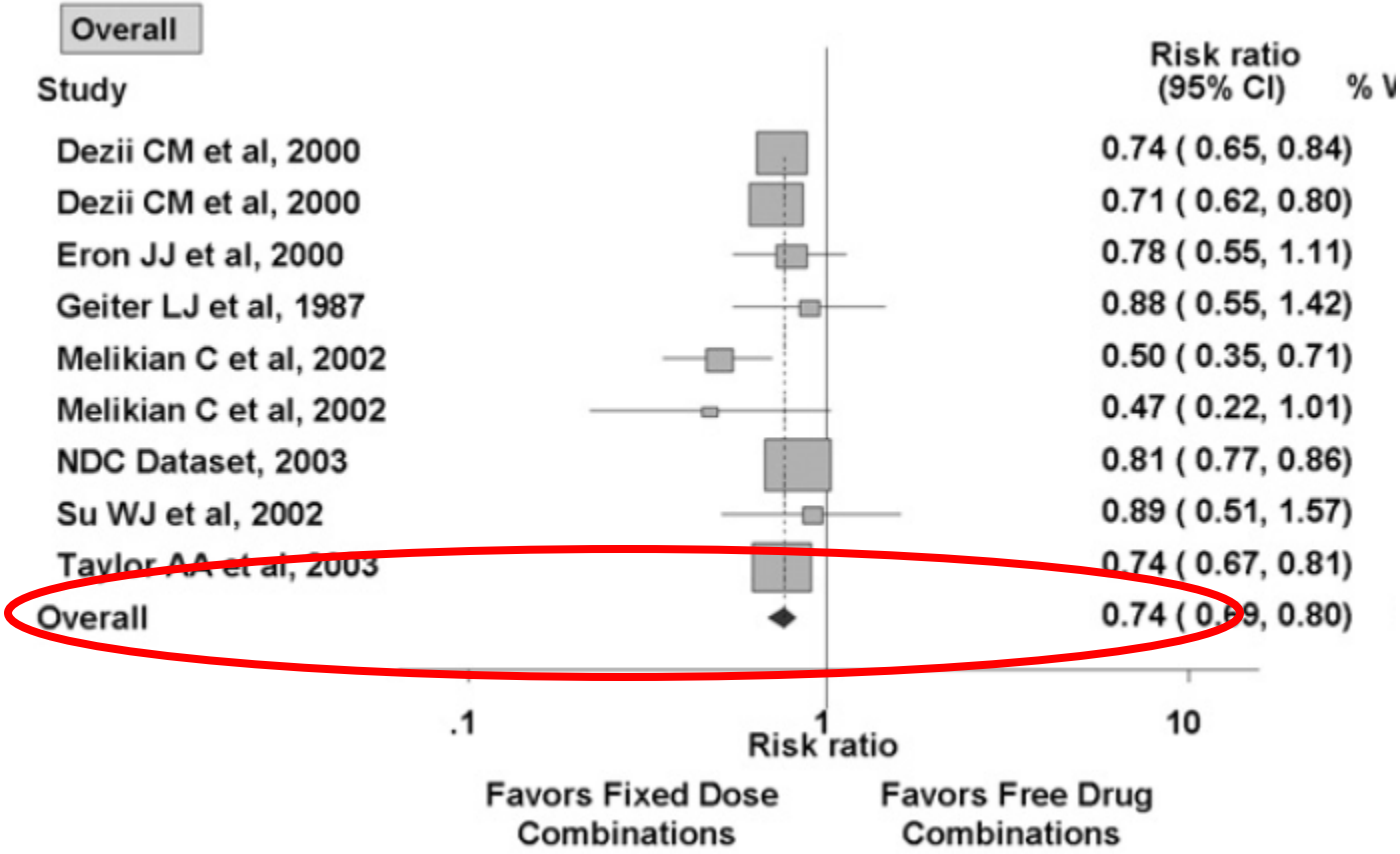
- **Complex regimens**
- Side effects
- **Taking multiple medications**
- Length of therapy



## Provider-related

- Poor relationship and / or poor communication with healthcare provider
- Disparity between provider and patient around cultural / religious beliefs
- Lack of feedback and ongoing reinforcement from the provider
- Providers / pharmacists emphasizing negative aspects of the medication (side effects with minimal solutions) vs benefits

# And Polypill Combinations ~25% Better Adherence




American Journal of Medicine 2007 120, 713-719

# There is Polypill Interest in a Large HMO

- Cautious comments by specialists in charge of HTN/DM CVD:
  - Our present system works well
  - Its not consistent with the latest guidelines
- Population leaders
  - In poor populations cost is more important, consider it there
  - Poor adherence improves 25% with pill combinations, use where adherence is poor

# What About Upper Administration?

- One top leader suggests use where it improves quality & value
- Another top leader mentioned **strong** support for FDA approval of polypill and blister packs
  - Wants it NOW, willing to try to overcome remaining issues
  - Would like to quickly & easily vary pill contents
  - Has already tried to get started…..

# What Happened When Kaiser Tried to Do a

- Polypill with a generic company: insurmountable barriers
  - Cost and time for prospective testing & FDA approval too long
  - Too many combinations to be tested [8]
  - Relatively low potential volume increased per pill cost

- Blister pack: a very difficult, small implementation showed
  - multiple cultural barriers with pharmacy, providers and patients but
  - Other issues: labeling, storage, & no economies of scale like automatic packaging but
  - The biggest barrier was regulation:
    - 2 mon limit on pre-packing created a 1 month dispencing vs 3 month usual med supply. It failed

# Why Does a CVD Prevention Polypill Make Sense NOW?

- There millions of high CVD risk people yet to start on multi-drug combinations
- Of those started on the meds, the 50% 1 yr adherence could improve 25%
- Evidence suggests a polypill will overcome real barriers, decreasing morbidity and mortality starting almost immediately in CVD pts, &
  - Risks of M&M from combinations appear much smaller than benefit
- So to develop it, if not now…. When?

# Questions, Comments, Concerns?