Next Generation DM™

Financial Incentives & Preventive Molecular Medicine

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GenoMed's Mission Statement

- To find the molecular basis of common diseases, and

- To use this information to improve patient outcomes as quickly, safely and inexpensively as possible.

Comparison w/ other DM cos.

- Cutting-edge medicine (genomics), not out-of-date consensus guidelines (“EBM”)
- Ongoing clinical research
- Financial incentivization of MDs
- Constant contact w/ MDs & pts
- We own the Intellectual Property

Who pays for prevention now?

- Nobody
  - Health plans (BCBS) arose in 1920s to reimburse surgeons; have kept their close financial ties to hospitals ever since
  - Health plans make a profit on their volume; have no incentive to decrease volume
  - 20-50% annual turnover means

plans will only help their competitors

if they prevent disease, so none do

Why are financial incentives necessary?

- Physicians are fundamentally anti-innovative
  - "community standard" definition of malpractice; deviation = massive risk (loss of livelihood)
- Medicine is fundamentally anti-innovative
  - **Except for** surgery, devices, procedures, &

    new drugs, which make money &

    raise healthcare costs
  - NOT rigorously outcomes tested

Example of EBM

- Lung volume reduction surgery
  - Panned in NEJM: A Randomized Trial Comparing Lung-Volume–Reduction Surgery with Medical Therapy for Severe Emphysema
    National Emphysema Treatment Trial Research Group N Engl J Med 2003; 348:2059-2073, May 22, 2003. "…Overall, lung-volume–reduction surgery increases the chance of improved exercise capacity **but does not confer a survival advantage over medical therapy**."
  - But reimbursed by CMS!!!!

Example of an EBM Reject

- Not published in *NEJM* or *Lancet*
- Not an RCT
- Not a $50-100 M study

Instead,

- Published in *Diab Tech &Ther* 9/2002
- Consecutive case series, n=1000
- Done w/out support, i.e. for free
- Like pre-WW II medicine

ACE is the major aging gene

- ACE is rate-limiting step for angiotensin II production
- ACE D/D genotype = overactivity of ACE
  - D/D has 2 times as much activity as ACE I/I;

    1.5 times as much as ACE I/D
- ACE D/D is associated w/ ~150 diseases in whites (75%), ~40% of diseases

  in blacks
- ACEI = fountain of youth?

Diseases with Published Outcomes

- CRF due to NIDDM or HTN in white and black men (n=1,000)
- ASPVD due to HTN (case report)
- COPD (case report)

Recently published (Curr Top Med Chem 7/04):

- Psoriasis (2), pancreatic cancer (1), West Nile virus encephalitis (8)

In trials: Cancers, MS, chronic fatigue, Alzheimer's, Parkinson's, etc.

Preventing Kidney Dialysis due to Diabetes or Hypertension

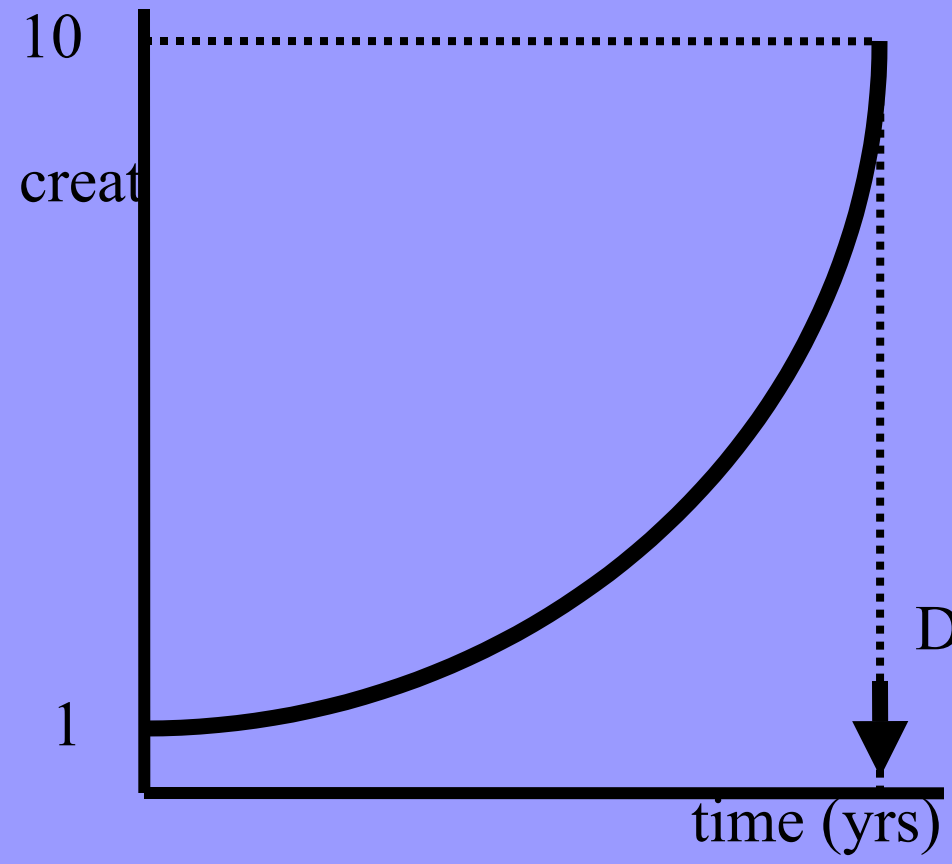
GenoMed can Prevent 90% of Kidney Dialysis

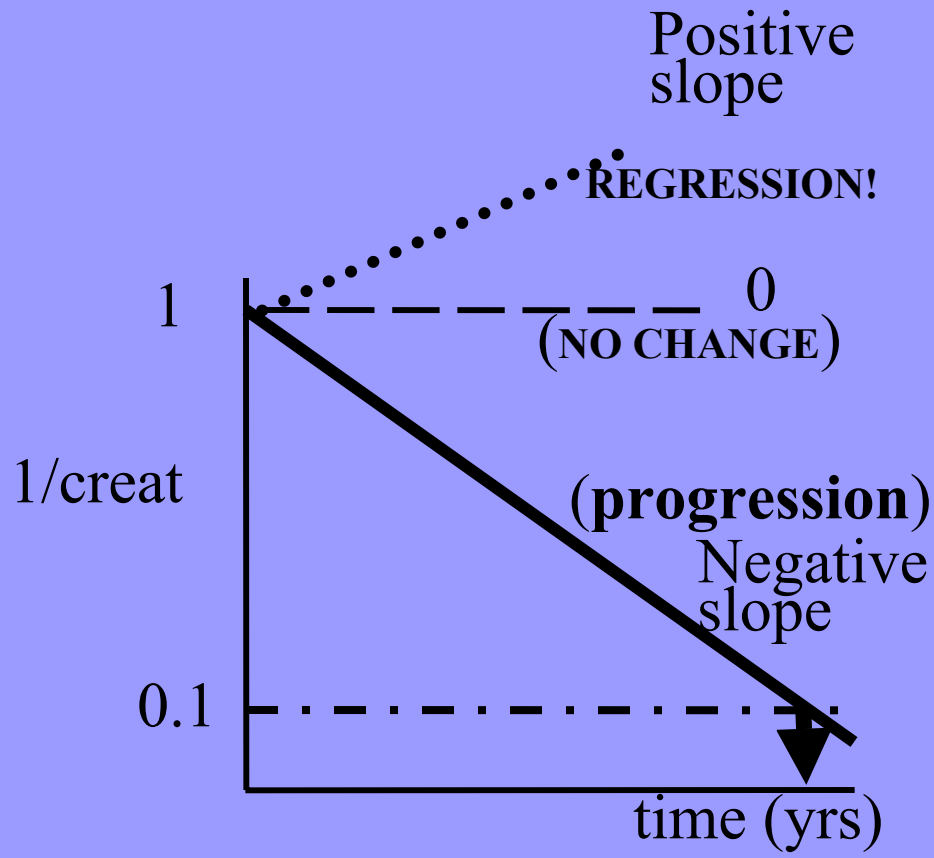
- Due to diabetes or hypertension
- In whites, blacks, and Hispanics
- Our outcomes are the best in the literature
  - 1,000 St. Louis VA patients 1994-1997
  - Ref. Diab Technol & Ther 4(4):519-531, 2002.
  - No adverse events in over 3,000 patient-yrs
- Requires our patent-pending treatment

to be started early: before creatinine is 2 mg/dl

Clinical Results in Diabetic Kidney Disease

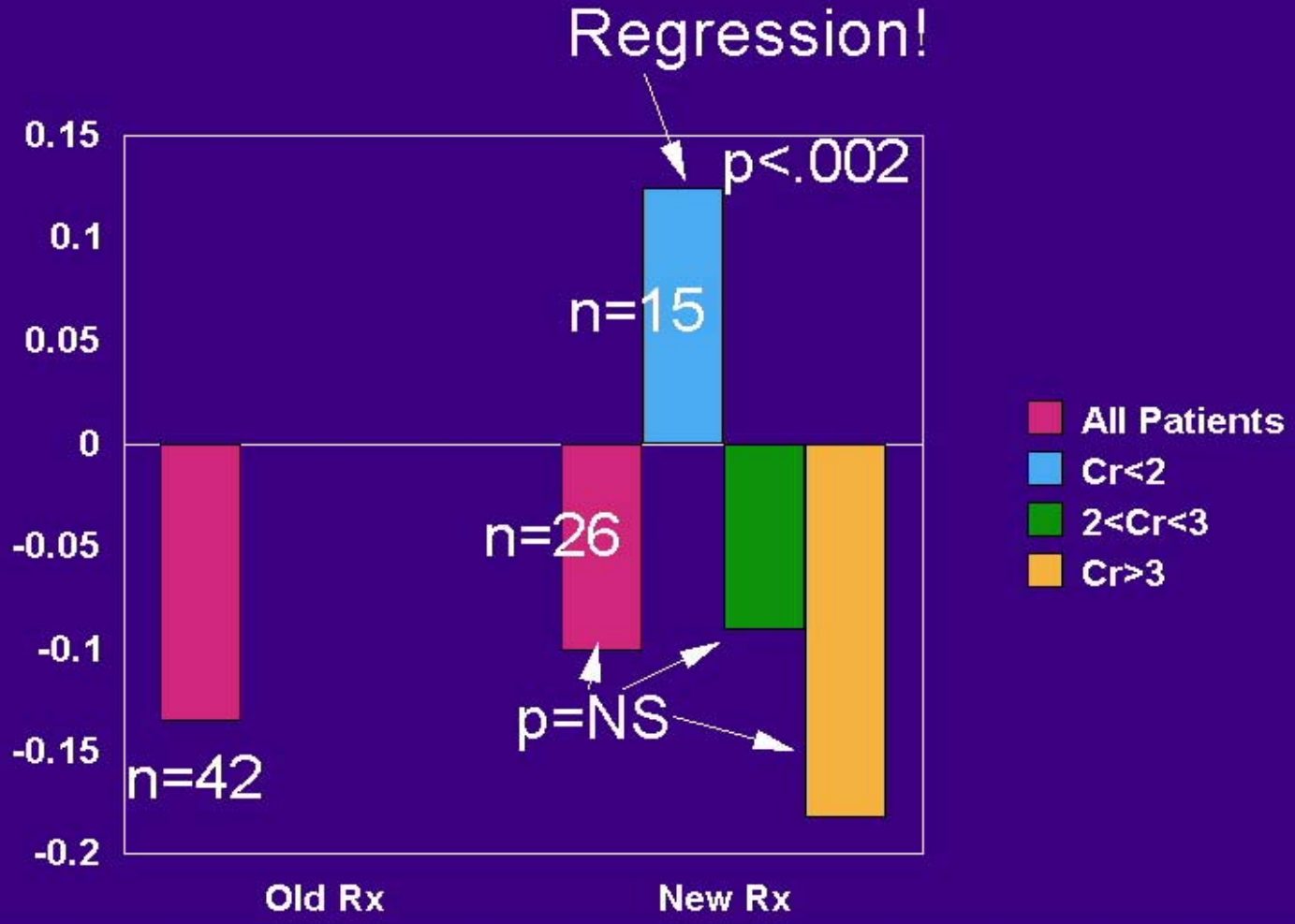
1/creat vs. time





Progression of CRF due to NIDDM: white men

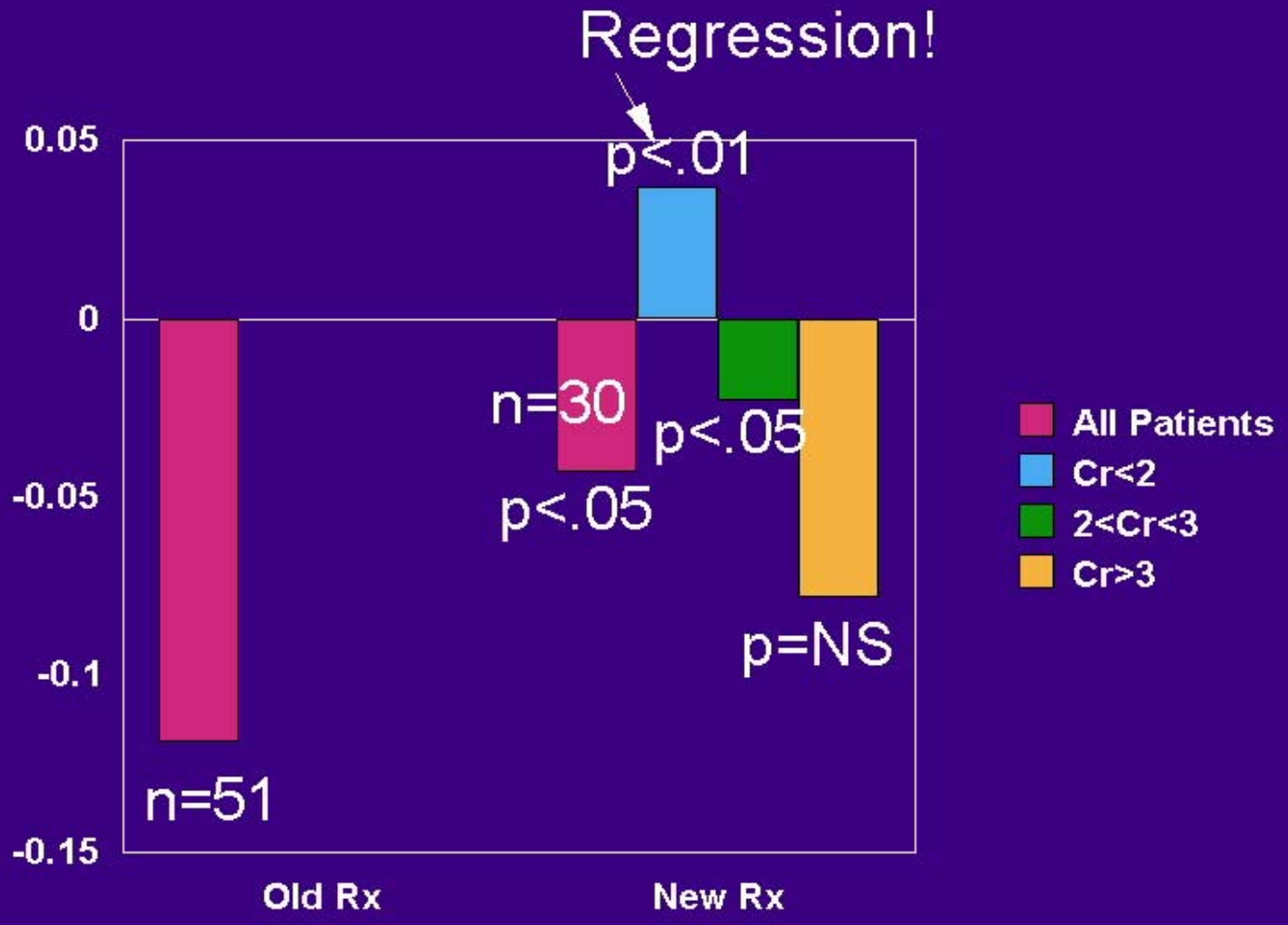
slope 1/cr vs. time



The blue bar means kidney disease has regressed, i.e. progression to end-stage kidney disease has been reversed.

Progression of CRF due to NIDDM: black men

slope 1/cr vs. time

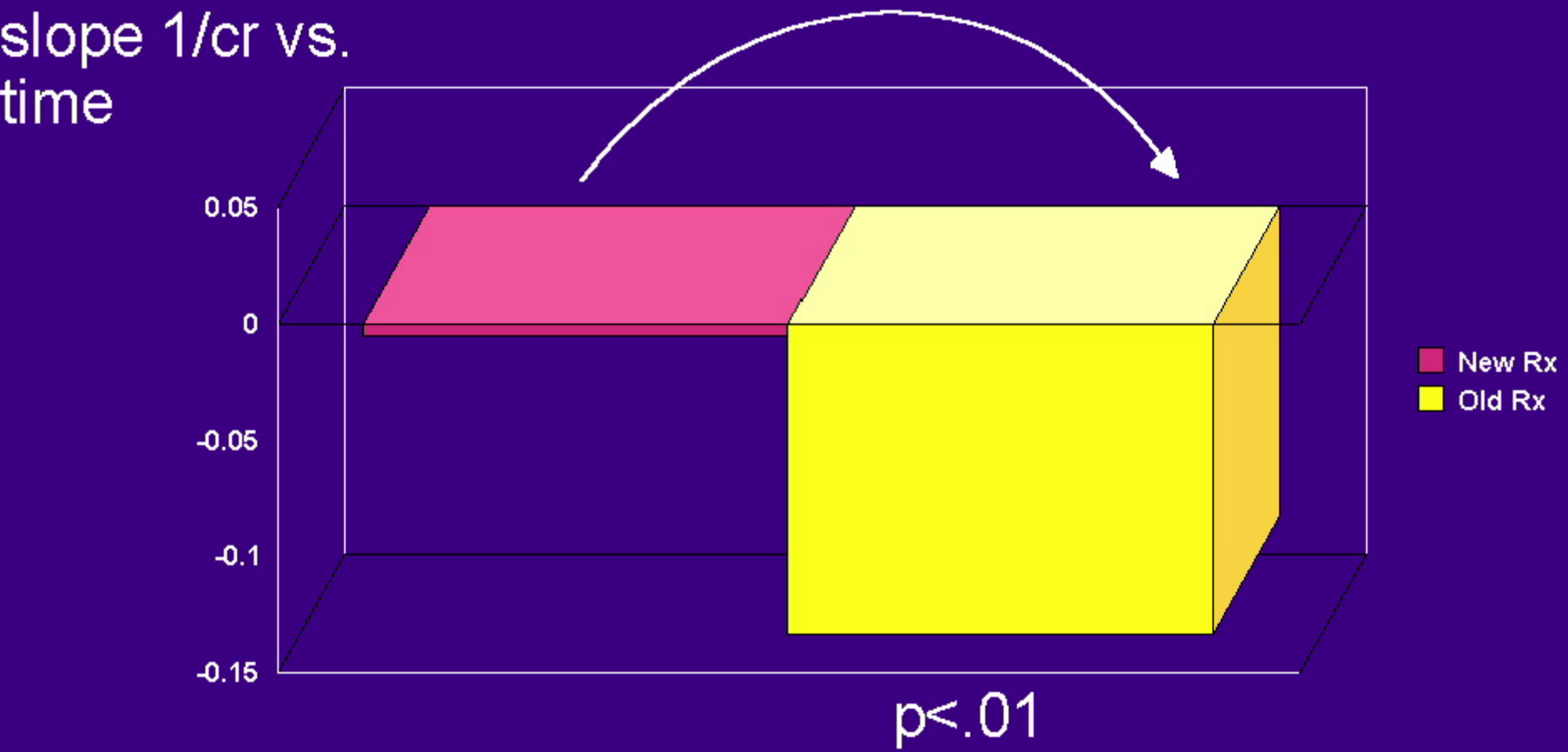


Dose and specific ACE inhibitor are crucial (& patent-pending)

Inadvertent Cross-over Design

From New Rx to Conventional Rx

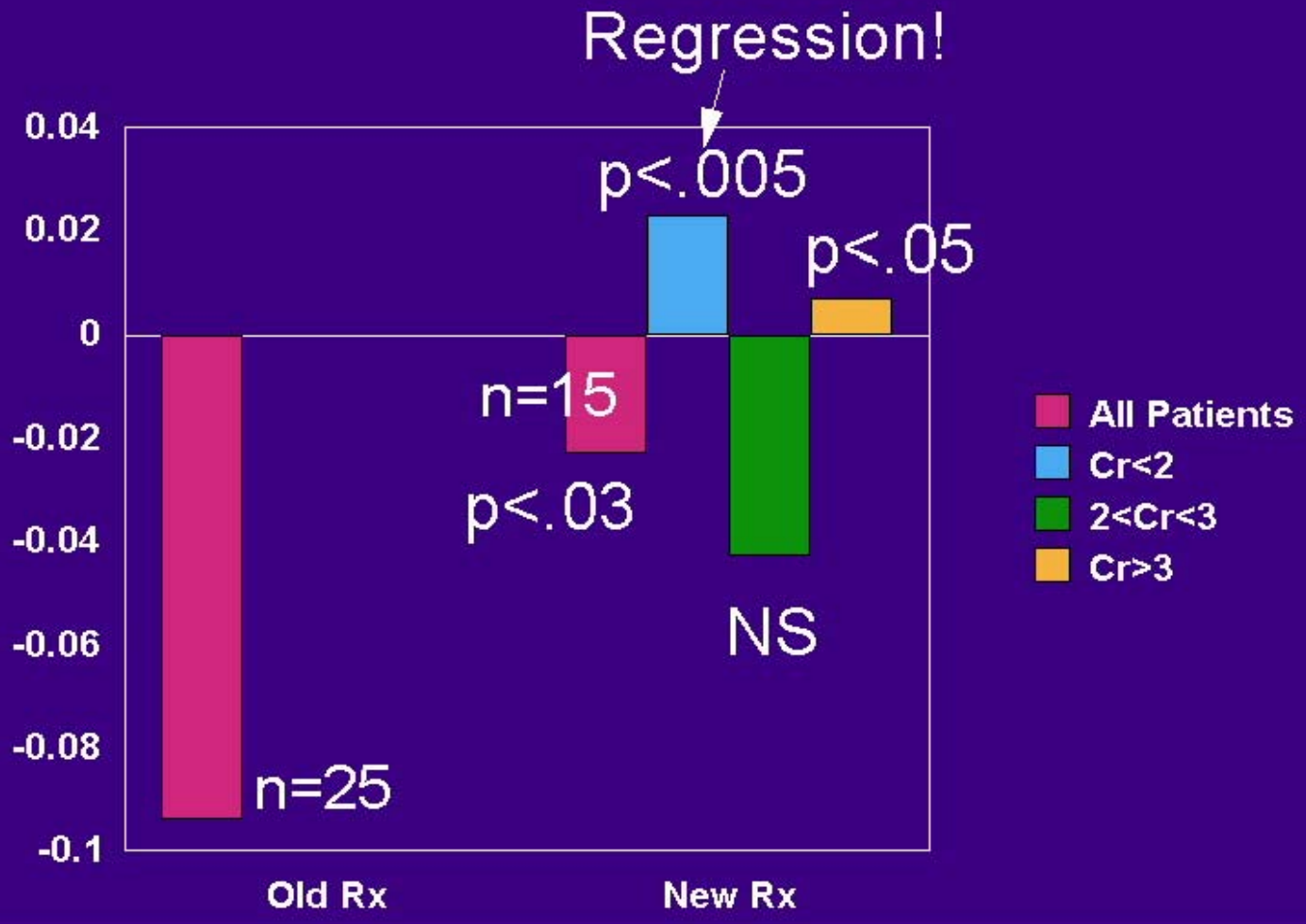
Black men w/ CRF due to NIDDM (n=21)



Chronic Kidney Disease due to High Blood Pressure

Progression of CRF due to HTN: white men

slope 1/cr vs. time



Progression of CRF due to HTN: black men

slope 1/cr vs. time

Again, dose of ACE inhibitor is crucial

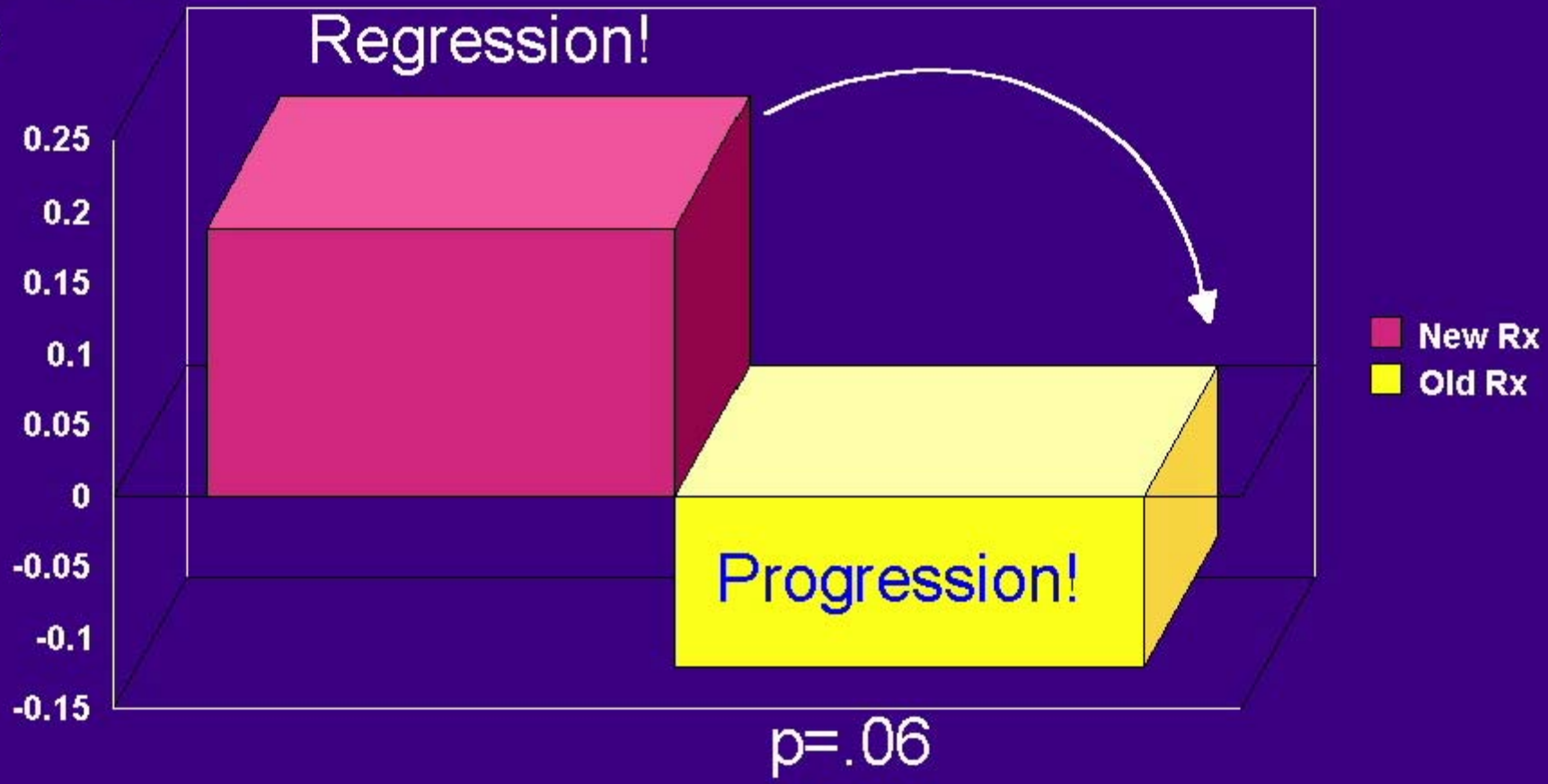
Inadvertent Cross-Over Design

From New Rx to Conventional Rx

White men w/ CRF due to HTN

(n=22)

slope 1/cr vs. time

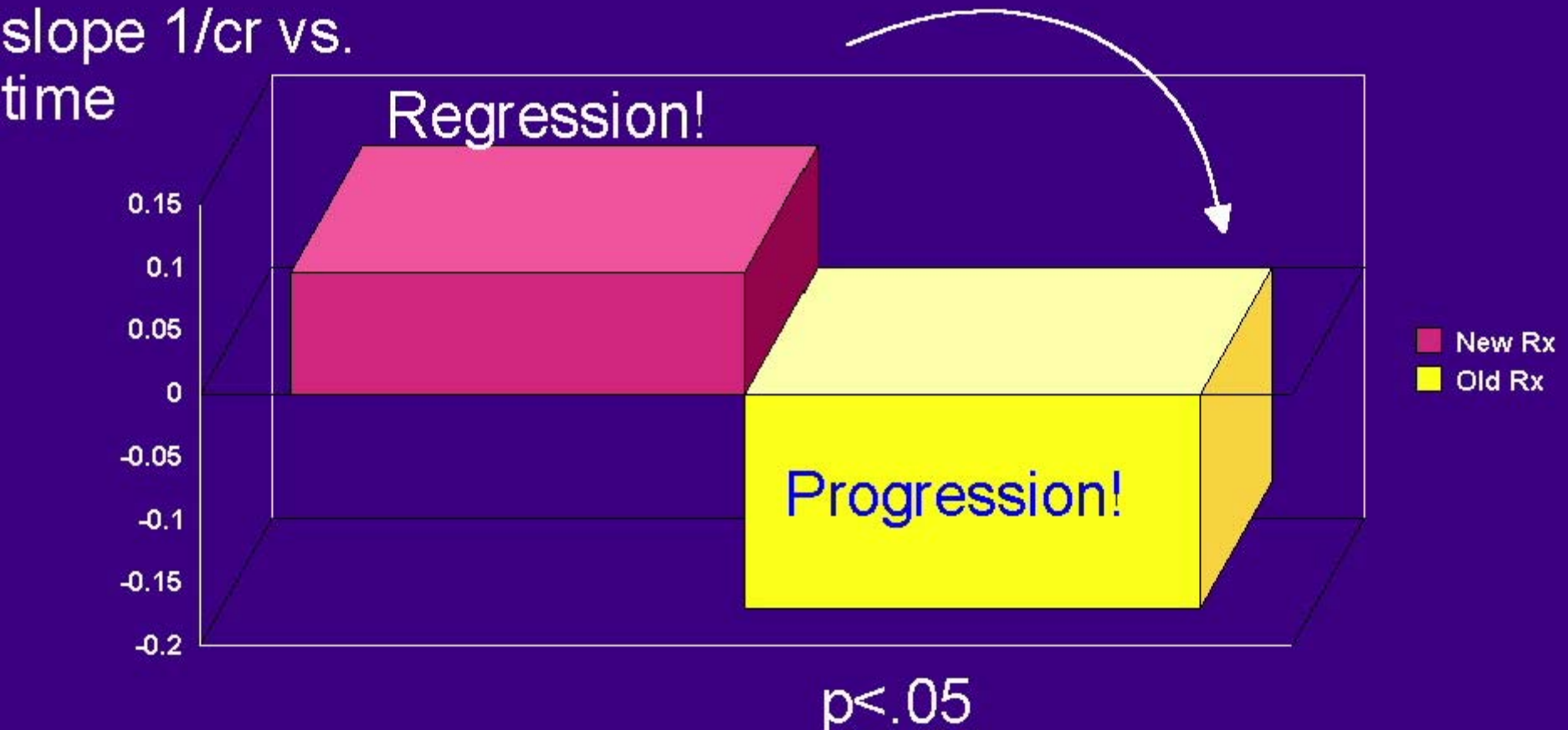


Inadvertent Cross-over Design

From New Rx to Conventional Rx

Black men w/ CRF due to HTN

(n=13)



Preventing Dialysis: Population Health Statistics

- 20 million adults with diabetes, and 60 million with hypertension in US
- 11 million Americans (14% of 80 million) have serum creatinine ≥ 1.5 mg/dl (~25% of all IDDM/NIDDM pts, ~10% of all HTN patients)
- Diabetes has been leading cause of dialysis since late 1980s
  - The incidence of diabetes is increasing
  - Hispanics have even higher prevalence than blacks
- Among patients with diabetes or hypertension, blacks have 4-6 times higher risk of dialysis than whites

Dialysis Facts

- Dialysis w/in 4 yrs once creatinine = 2 mg/dl
- Death w/in 4 yr for 55 yr old man starting dialysis; usually unable to work
- 200,000 dialysis pts cost $18 B in 2001 (i.e. $90K per patient per yr)
- 300,000 pts projected in 2010 (“ESRD epidemic”) ***at a cost of >$150K/pt/yr***

- ***Healthcare plan must pay for first 3 yrs of dialysis***

- **ROI: spend $ 800 /yr to avoid spending $ 150,000 /yr**

Typical Health Plan Population

For 100,000 adult patients:

- Assume 30% have NIDDM or HTN (30,000 patients)
- 14% of these will have Cr ≥ 1.5 (4,200 patients)
  - 2,000 with 1.5 ≤ Cr ≤ 2
  - 1,000 with 2 ≤ Cr ≤ 3
  - 1,200 with Cr > 3

Opportunity

- "Immediate": Delaying ESRD in CRF/HTN
  - Identify 480 patients with 3 < Cr < 4
    - 2.3 years until payoff begins
    - **Annualized ROI: 17 to 20**

- Longer-term: Preventing ESRD in HTN & NIDDM
  - Identify 3,000 patients with Cr < 3
    - 4 to 6 years until payoff begins
    - **Annualized ROI: 3.8 to 11.5**

GenoMed's Clinical Outcomes Improvement Program (COIP®)

- Patients
  - NIDDM, IDDM, or HTN & 1.5 ≤ Cr ≤ 4 mg/dl
- Physicians
  - Learn GMED's approach
  - Select suitable patients (with GMED's help)
  - Obtain patient approval for participation in GenoMed's COIP®
  - Prescribe GMED's Rx to willing patients
  - Report patient outcomes to GMED
  - Are paid $25 per patient per quarter by GMED
- Cost: $800/pt/yr

GenoMed's Clinical Outcomes Improvement Program™

- Additional Patients
  - Any pt w/ NIDDM, IDDM, or HTN
    - Goal: Delay all complications
  - COPD
  - Psoriasis
  - WNV
- Cost: $800/pt/yr
- 2,000 pts → extra $200K/yr

For questions, please contact:

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