Next Generation Disease Management:

Saving Healthcare Costs Through Medical Genomics

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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, as safely and as inexpensively as possible.

Comparison w/ other DM cos.

- Cutting-edge medicine (genomics), not out-of-date consensus guidelines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



ACE D/D genotype = overactivity of ACE

- D/D has twice as much activity as ACE I/I;
 1.5 times as much as ACE I/D
- ACE is rate-limiting step for angiotensin II production
- ACE D/D is associated w/ ~150 diseases in whites (75%), ~40% of diseases in blacks
- ACE is the major aging gene

Diseases with Published Outcomes

- CRF due to NIDDM or HTN in white and black men (n=1,000)—published 9/02
- ASPVD due to HTN (n=2)
- COPD (n=1)

Recently published:

– Psoriasis (2), pancreatic cancer (1), WestNile virus encephalitis (8)

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



Avoiding 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



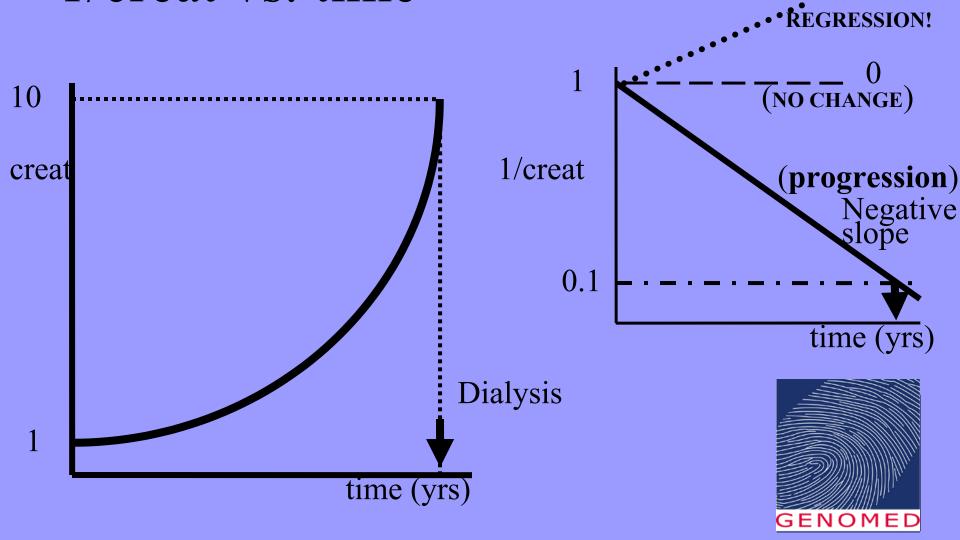
Clinical Results in Diabetic Kidney

Disease



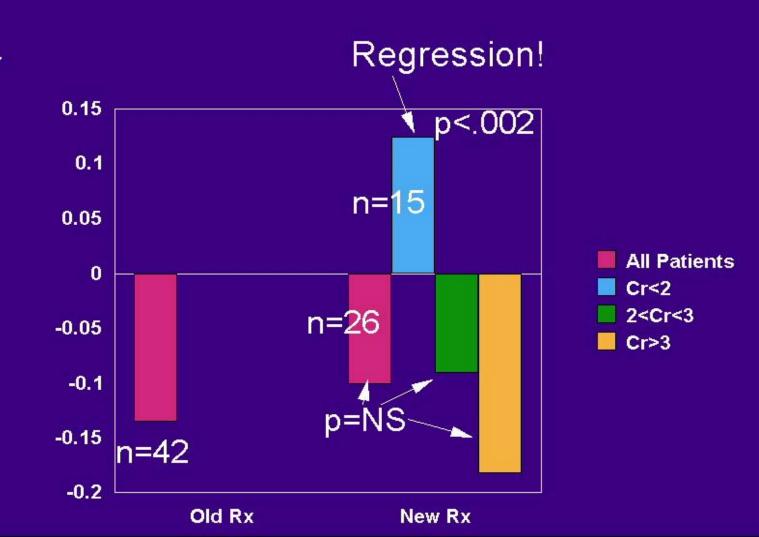
1/creat vs. time





Progression of CRF due to NIDDM: white men

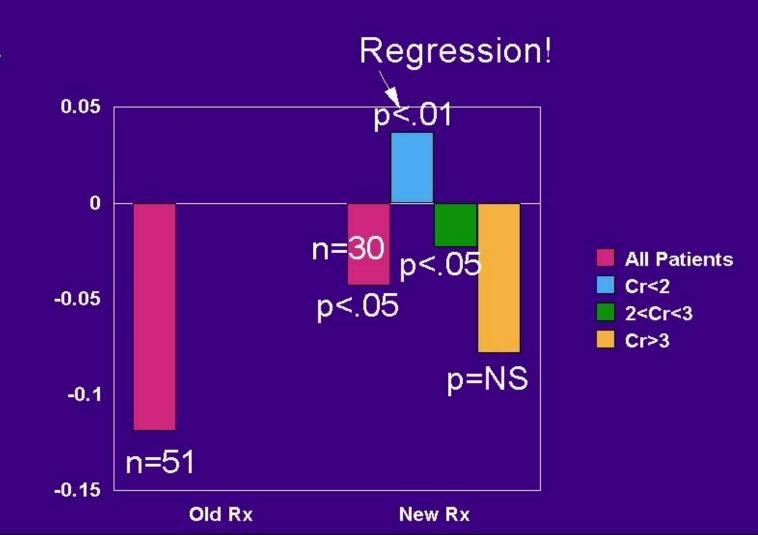
slope 1/cr vs. time



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

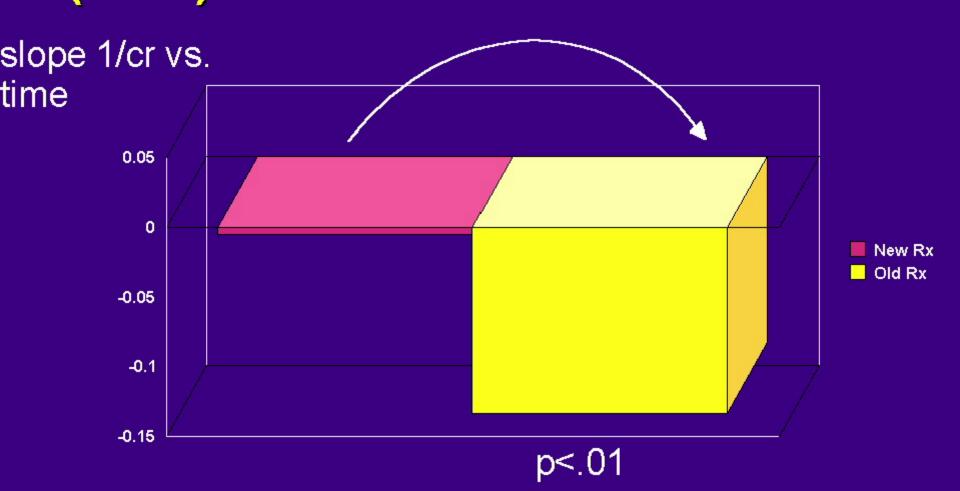
slope 1/cr vs. time



Dose and specific ACE inhibitor are crucial (& patentpending)



Inadvertent Cross-over Design
From New Rx to Conventional Rx
Black men w/ CRF due to NIDDM
(n=21)

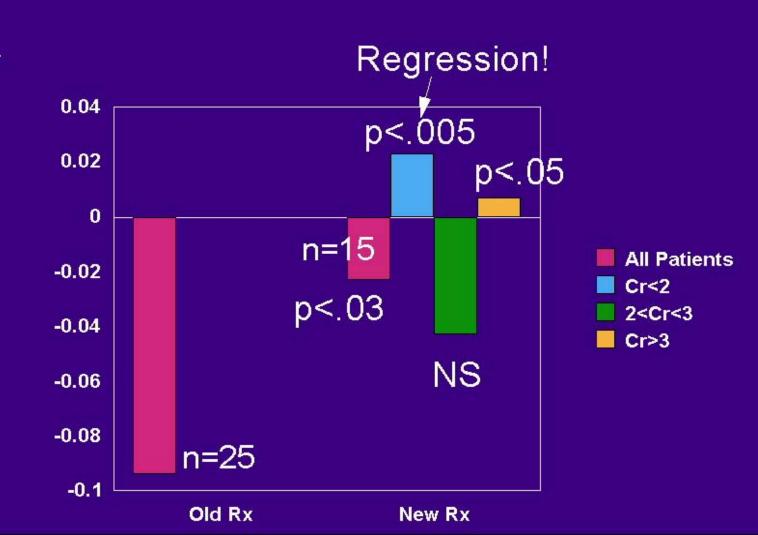


Chronic Kidney Disease due to High Blood Pressure



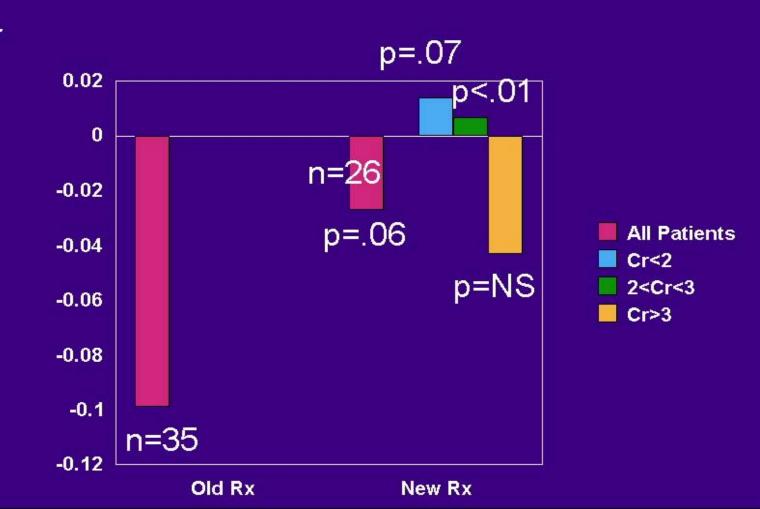
Progression of CRF due to HTN: white men

slope 1/cr vs. time



Progression of CRF due to HTN: black men

slope 1/cr vs. time

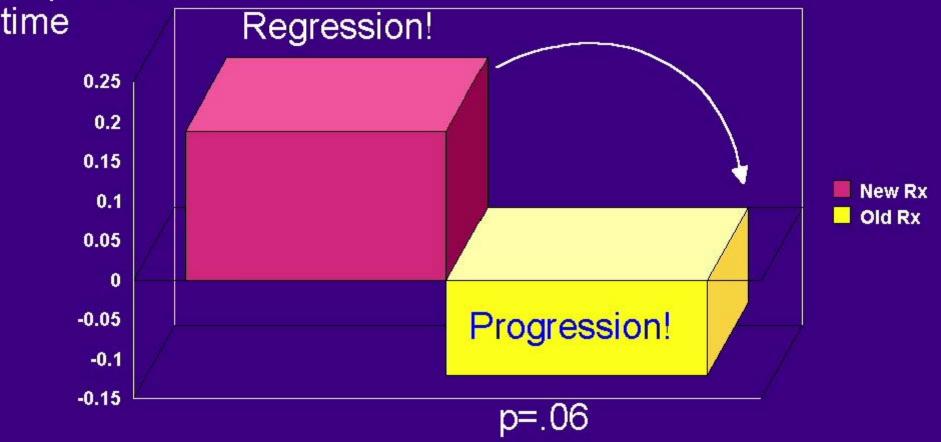


Again, dose of ACE inhibitor is crucial

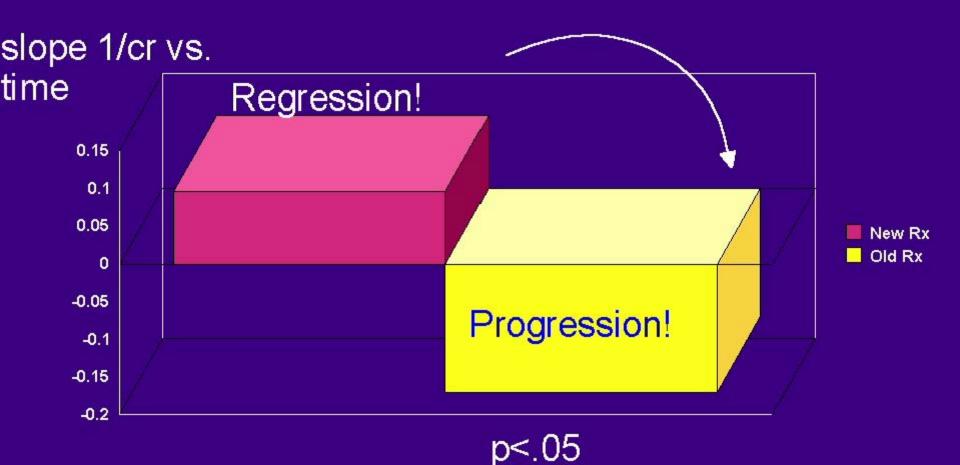


Inadvertent Cross-Over Design From New Rx to Conventional Rx White men w/ CRF due to HTN

(n=22) slope 1/cr vs.



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 dialystenomed
 than whites

 Next Generation DMTM

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

GENOME

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)

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2,000 \text{ with } 1.5 \le \text{Cr} \le 2
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1,000 with
$$2 \le Cr \le 3$$

$$1,200 \text{ with Cr} > 3$$



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



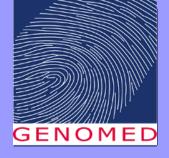
GenoMed's Clinical Outcomes Improvement Program (COIP®)

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/y Ext Generation DMTM

GenoMed's Clinical Outcomes Improvement ProgramTM

- Additional Patients
 - Any pt w/ NIDDM, IDDM, or HTN
 - Goal: Delay <u>all</u> complications
 - COPD
 - Psoriasis
 - -WNV
- Cost: \$800/pt/yr



For questions, please contact:

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