Proposed Inclusion of Oral-Only Drugs in ESRD Bundled Payment System

May 18, 2010

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Agenda

- Concerns of Renal Community and Congress
- Technical Challenges with Data
- Potential Impact on Patients and Providers
- Absence of Baseline Quality Data
- Delay May Allow Time to Address Challenges

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Renal Community and Congressional Concerns

- Vast majority of posted public comments from renal community oppose CMS proposed inclusion of orals in bundle
  - Majority submitted comprehensive concerns, including inadequate payment, incomplete data, significant legal and operational barriers, and negative impact on quality of care to patients

- Congressional concerns about inclusion of oral-only drugs in bundle
  - Senator Baucus has called for delay
  - 40 House Tri-Caucus Members opposed provision
  - Congressman Lewis, Senators Conrad, Bennett, Nelson
  - 11 Democrats on House Ways and Means
  - PPACA requires GAO study on operational challenges and potential harm to patients

Technical Challenges with Inadequate Data on Utilization and Cost of Oral-only Drugs

- CMS acknowledges in proposed rule that it has inadequate data
  - $14 payment per treatment for oral drugs is grossly insufficient
  - Dialysis providers report actual cost of $45-80 per treatment
- CMS has data on only two-thirds of Medicare ESRD patients that have Part D coverage
  - > Only data on federal costs of LIS and non-LIS beneficiaries
  - > Lack one-third with retiree drug subsidy, private insurance, no insurance
- Data only reflects federal government expenditures; fails to account for spending in "donut hole," deductibles, coinsurance or free drug from manufacturers
- Shortchanging facilities will force facilities to self-fund costs, or "stint" on care

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Provider Cost Versus Medicare Payment: Medicare Data on Phosphate Binder & Calcimimetic Drug Spending

	Part D: PDP		No Spending Data			Total
	LIS Beneficiaries	Non-LIS Beneficiaries	Retiree Rx Subsidy	Private Coverage	No 3rd Party Ins	
# Beneficiaries	Complete	Complete	Complete	Missing	Missing	Partial
Drug Spend*	Complete	Partial	Missing	Missing	Missing	Partial
Covered Spend*	Complete	Partial	Missing	Missing	Missing	Partial
Plan Cost*	Complete	Partial	Missing	Missing	Missing	Partial
LIS Cost*	Complete	N/A	N/A	N/A	N/A	Complete
Medicare Cost*	Complete	Partial	Missing	Missing	Missing	Partial
Total Drug Spend	Complete	Partial	Missing	Missing	Missing	Partial
SubTotal Medicare	Complete	Partial	Missing	Missing	Missing	Partial
SubTotal Beneficiaries	Complete	Missing	Missing	Missing	Missing	Partial

*Per beneficiary per year cost

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Part D Spend: Too Much Insurance Risk Placed on Individual Facility

- Based on individual clinical considerations, ESRD patients have 3 types of phosphate binder and calcimimetic spending:
  - 1 out 3 have Low Cost, using multi-source or no drugs
  - 1 out 2 have High Cost, using 1 single source drug
  - 1 out 5 have Very High Cost, using 2 single source drugs
- ESRD facilities too small to have stable "risk pools"
  - Average facility dialyzes only 68 patients/week
  - Small changes in patients cause BIG winners and losers
- Greatly complicates setting appropriate payment and outlier policy – annual costs range from $0 to $10,000+

Financial Risk on Facilities Will Create Clinical Risk to Patients

- Placing financial risk on facilities creates conflict between appropriate patient care and their economic interest
  - Currently, prescribing is without consideration of facility cost (or revenue)
  - Facilities will newly have financial incentives under bundling proposal
  - Physicians may feel pressure to prescribe lowest cost – not most clinically appropriate – products

- Quality metrics should be in place to track utilization of drugs or clinical outcomes before facilities are responsible for orals
  - Without baseline data on metabolic bone disease (MBD) markers, CMS will not be able to detect under-treatment or deterioration of quality of care
  - There are no reporting requirements for lab values for Ca, Ph, and PTH, or quality measures to treat to target goals

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Additional Negative Impact on Patients

- Patient safety and access to care would be at risk
  - ESRD patients would lose patient protections for access and appeals processes in Part D plans
    - > Such as 2 drugs required on formulary in each therapeutic class
  - Drug utilization review by Part D plans would be incomplete and could endanger patients by missing drug-drug interactions with phosphate binders and calcimimetics

- Increased out-of-pocket costs for many ESRD patients
  - Non-Duals and LIS beneficiaries
  - Loss of "catastrophic" protection provided by Part D
  - Low income dialysis population very sensitive to copays

Negative Impact on Providers and Innovation of New Therapies

- Dialysis facilities face many operational obstacles
  - Not licensed under state laws to dispense outpatient drugs
  - Costs for meeting complex requirements under various state laws to become a retail pharmacy or contracting for services not addressed by CMS
  - Will likely make rural, independent facilities less competitive

- Manufacturers will have diminished incentives to develop new therapies and technologies
  - There is no process to recognize clinical practice changes and account for new drugs

Why Control of the Mineral Bone Disorder Parameters is Important?

- Cardiovascular (CVD) mortality is the leading cause of death among ESRD patients
- High serum phosphorus is a significant independent risk factor for cardiovascular (CV) mortality and needs to be controlled:
  - Factors associated with increased relative risk of mortality in dialysis patients include:
    - > Serum P: <3.0 and >5.0 mg/dL
    - > Serum Ca: >9.5 mg/dL
- Decisions on how to control phosphorus levels is critically important, because calcium-based binders lead to significantly greater vascular calcification of ESRD patients
- Risks of CVD and CV calcification are far greater in ESRD patients than in the general population:
  - > Arterial calcification increases mortality risk
  - > CV mortality rate is 10-20x greater in dialysis patients
  - > All dialysis patients should be evaluated for vascular calcification
  - > Factors associated with coronary artery calcification include:
    - Serum P; Ca intake from binders; Ca x P product; Duration of dialysis; Age
- High plasma PTH is associated with increase risk of mortality

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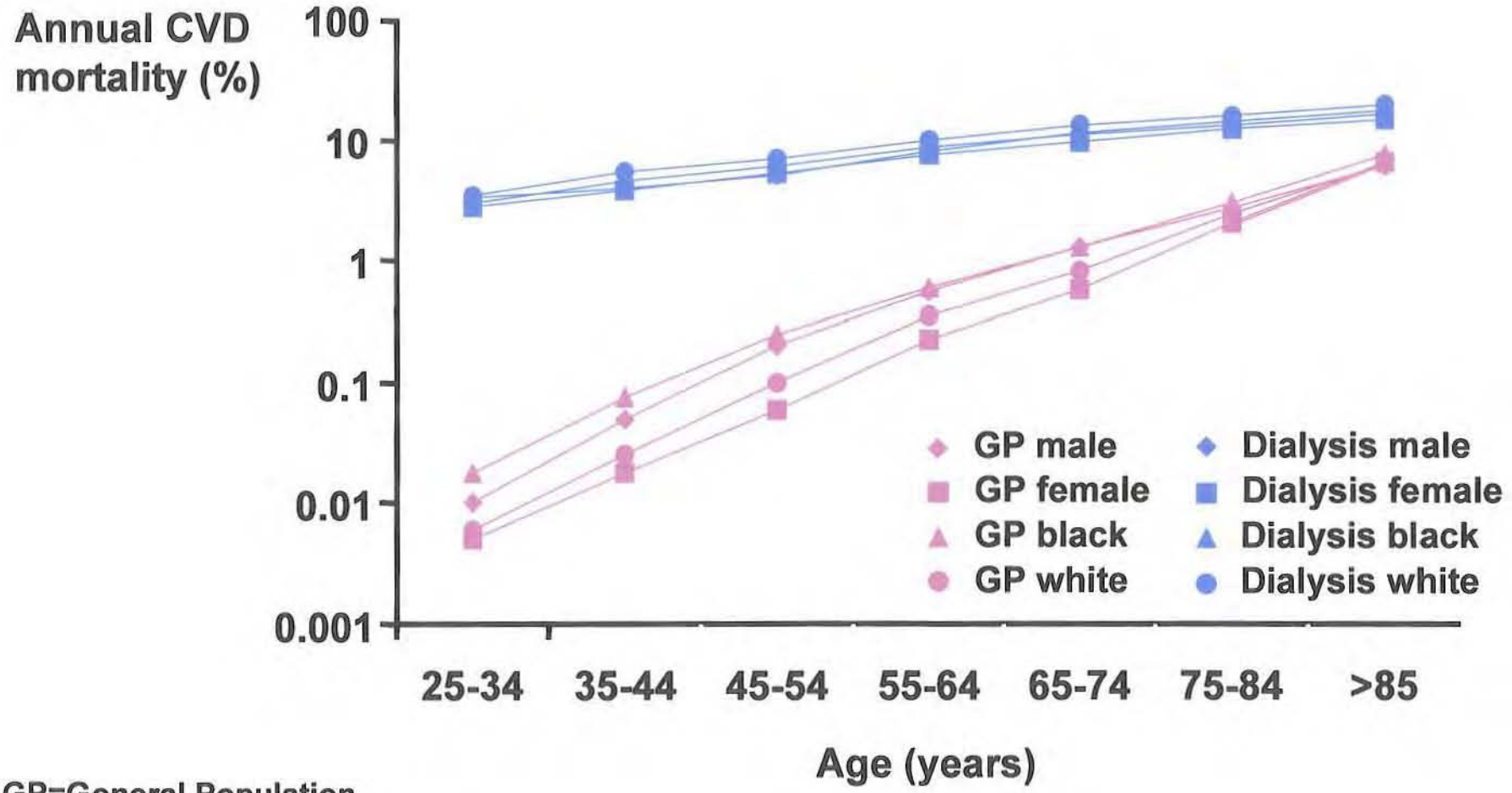
End Stage Renal Disease is strongly associated with Cardiovascular Mortality



GP=General Population
ESRD=End-Stage Renal Disease

Foley RN, Parfrey PS, Sarnak MJ. *Am J Kidney Dis*. 1998;32(suppl):S112-S119.

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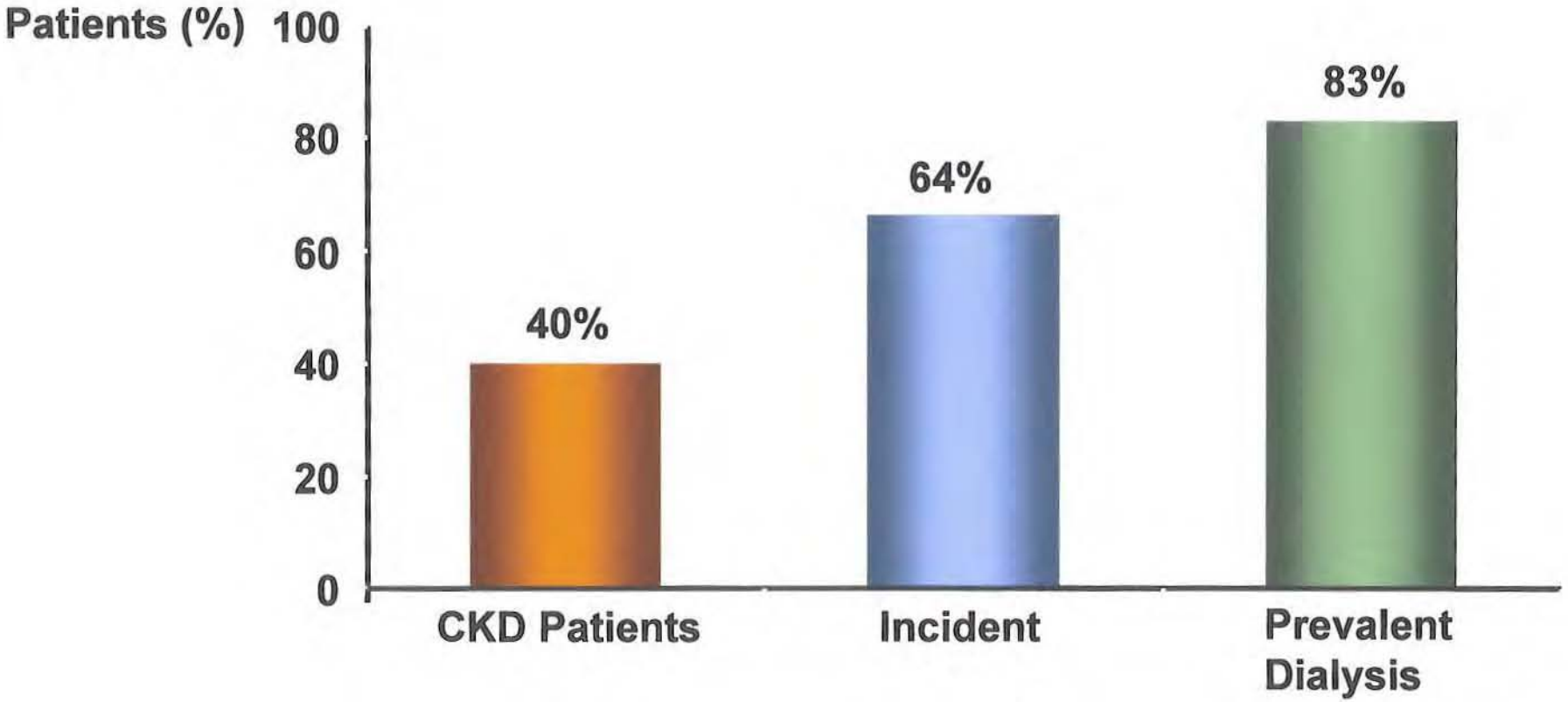
Prevalence of Coronary Artery Calcification



Russo D, Palmiero G, De Blasio AP, Balletta MM, Andreucci VE. *Am J Kidney Dis*. 2004;44:1024-1030.
Spiegel DM, Raggi P, Mehta R, et al. *Hemodial Int*. 2004;8:265-272.
Chertow GM, Burke SK, Raggi P. Treat to Goal Working Group. *Kidney Int*. 2002;62:245-252.

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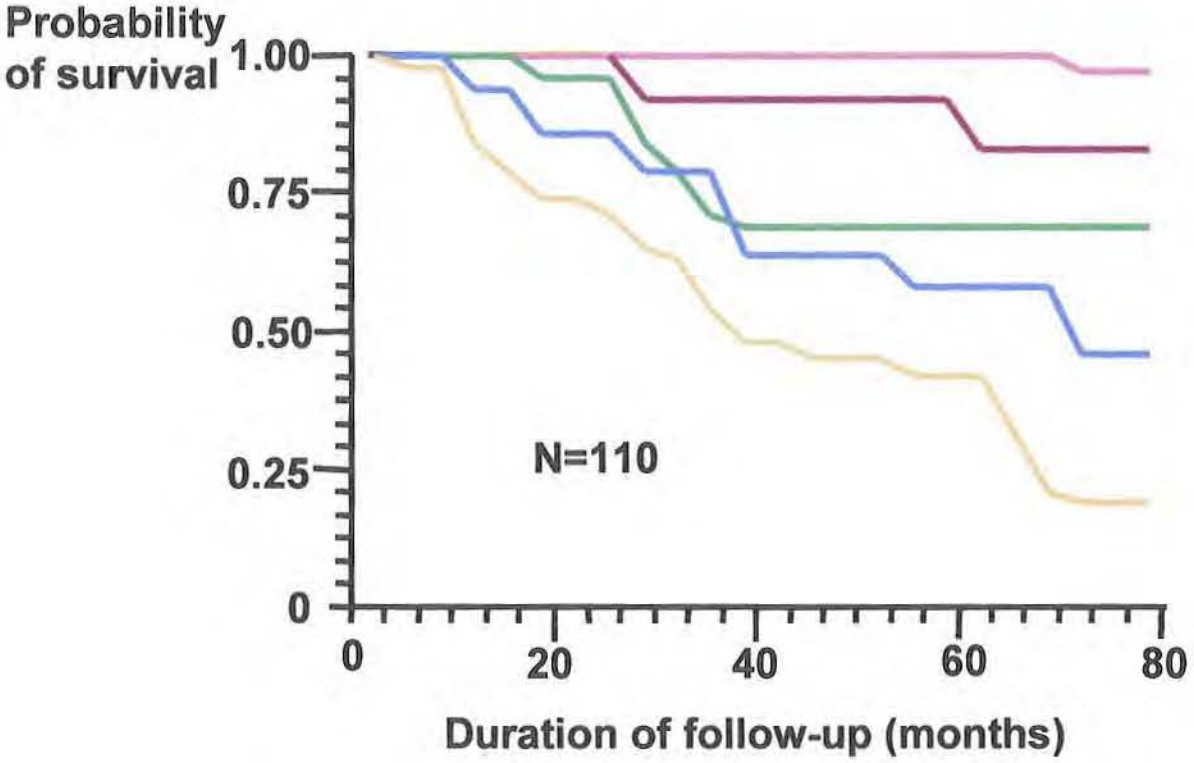
Arterial Calcification Increases Mortality Risk†



73% risk of all-cause mortality in patients with 4 arterial sites calcified

†Determined by ultrasonography; measurement sites: Carotid artery, abdominal aorta, iliofemoral axis, and legs

Probability of all-cause survival according to calcification score: $P<0.0001$ ($\chi^2=42.66$) for each increase in number of arteries calcified

Blacher J, Guerin AP, Pannier B, Marchais SJ, London GM. *Hypertension*. 2001;38:938-942.

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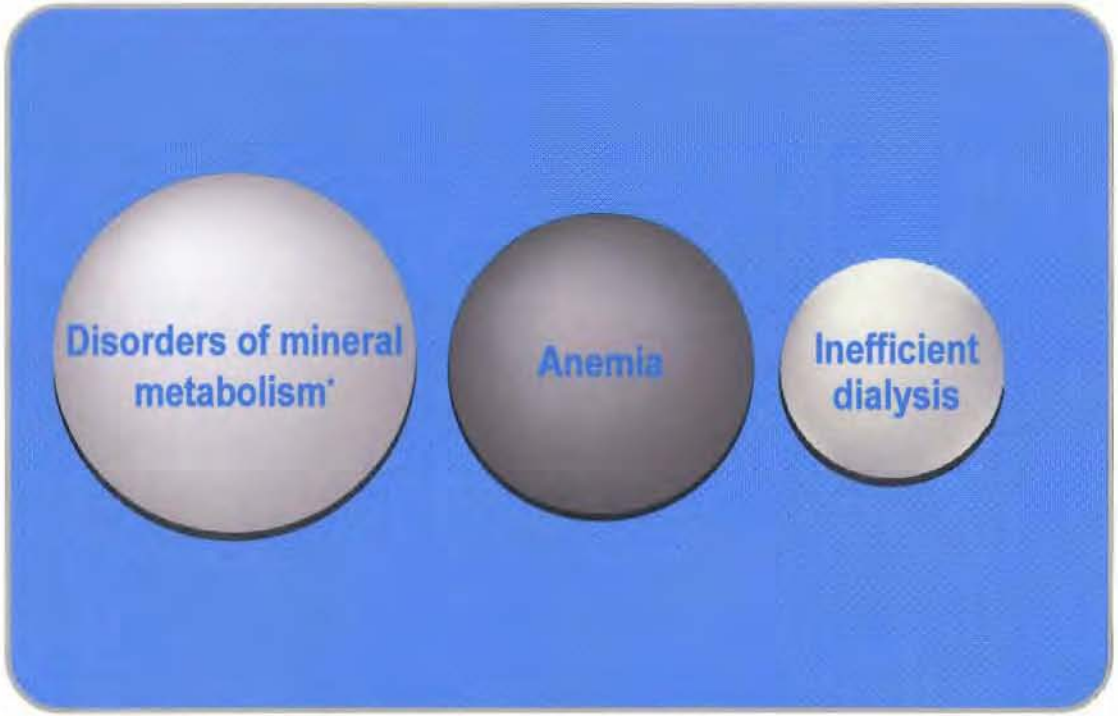
Disorders of Mineral Metabolism are Associated with Higher Rates of Mortality* than other facets of care that are monitored

- In a retrospective analysis of data from 40,538 patients on thrice-weekly hemodialysis **
- Disorders of mineral metabolism were associated with[1]:
  - 1.5 times the mortality risk than anemia
  - 3 times the mortality risk than inefficient dialysis



*High phosphorus (≥5 mg/dL), high calcium (≥10 mg/dL), high PTH (≥600 pg/mL) individually and in combination.

**as of January 1, 1998 and with 12 to 18 months of follow-up

1. Block GA, Klassen PS, Lazarus JM, Ofsthun N, Lowrie EG, Chertow GM. Mineral metabolism, mortality, and morbidity in maintenance hemodialysis. *J Am Soc Nephrol*. 2004;15:2208-2218.

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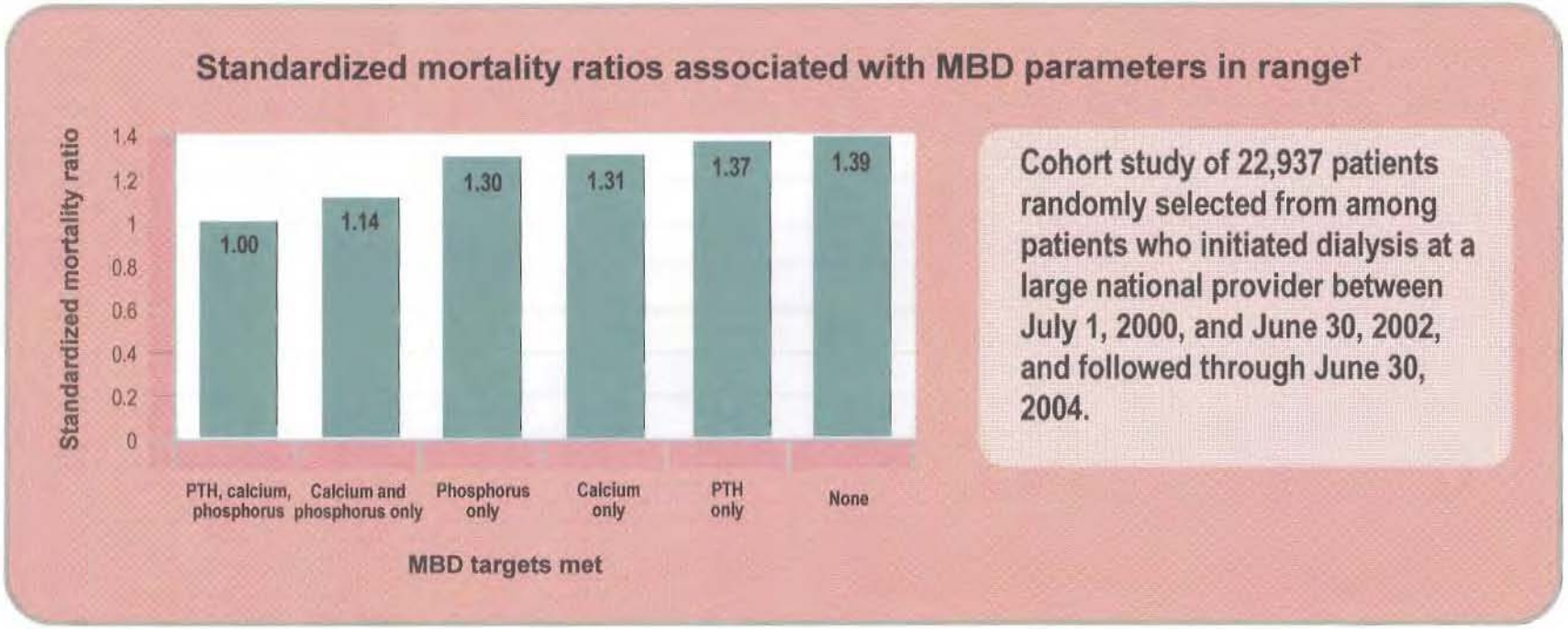
Mineral Bone Disorder (MBD) parameters within KDOQI* target ranges† are associated with improved survival in hemodialysis

Lower mortality was observed when all 3 parameters (phosphorus, calcium and PTH) were in target range than when fewer than all three were in target range



Adapted from Danese et al .[1]

* KDOQI: Kidney Disease Outcomes Quality Initiative

† PTH (150-300 pg/mL); calcium (8.4-9.5 mg/dL); phosphorus (3.5-5.5 mg/dL).

1. Danese MD, Belozeroff V, Smirnakis K, Rothman KJ. Consistent control of mineral and bone disorder in incident
2. hemodialysis patients. *Clin J Am Soc Nephrol*. 2008;3:1423-1429.

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Current Clinical Guidelines for Management of Mineral Bone Disorder

CKD Stage	Target PO_4
5 Dialysis	KDIGO: Towards Normal (2.7-4.6 mg/dL) KDOQI: 3.5-5.5 mg/dL

CKD Stage	Target Ca
5 Dialysis	KDIGO: Maintain Normal (8.4-9.5 mg/dL) KDOQI: 8.4-9.5 mg/dL

CKD Stage	Target PTH
5 Dialysis	KDIGO: Maintain 2-9 times the upper limit of the assay KDOQI: 150-300 pg/mL

National Kidney Foundation. K/DOQI clinical practice guidelines for bone metabolism and disease in chronic kidney disease. *Am J Kidney Dis.* 2003;42(suppl):S1-S201.

Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease-mineral and bone disorder (CKD-MBD) *Kidney Int.* 2009;76(suppl 113):S1-S130.

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New* Biotrends Syndicated Market Research captures potential negative consequences

- **Impact of Bundling:**
  - 71% of medical directors believe that bundling will have a negative impact on patient outcomes
    - > Increased from 43% in June 2009
  - Patients most likely to be negatively impacted include:
    - > Sicker, older, African American, rural and incident dialysis patients
  - Medical directors and renal administrators believe they will get 30% of their cost savings from adjusting their management of CKD-MBD

- **Patient's Best Interest:**
  - Nephrologists believe that non-calcium based binders do differ significantly from calcium–based binder in long term safety, mortality and calcification
  - Nephrologists anticipate use of calcium based binders will increase if phosphate binders are included in the bundle
  - 51% of medical directors believe that an increase in use of calcium based binders as a result of the bundled payment system is not in the patient's best interest

***Biotrends syndicated research February 2010.**

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