Risk Stratification in Renal Care

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Fresenius Disease Management Optimal Renal Care

Chronic Kidney Disease

- ***Chronic Kidney Disease*** is a rapidly growing problem
- What is needed to address this problem?
  - Identification
  - Stratification
  - Management
    - Physician management
    - Disease management (encompassing the spectrum from population management to intensive case management).

Can *Chronic Kidney Disease* be considered health care's latest epidemic?

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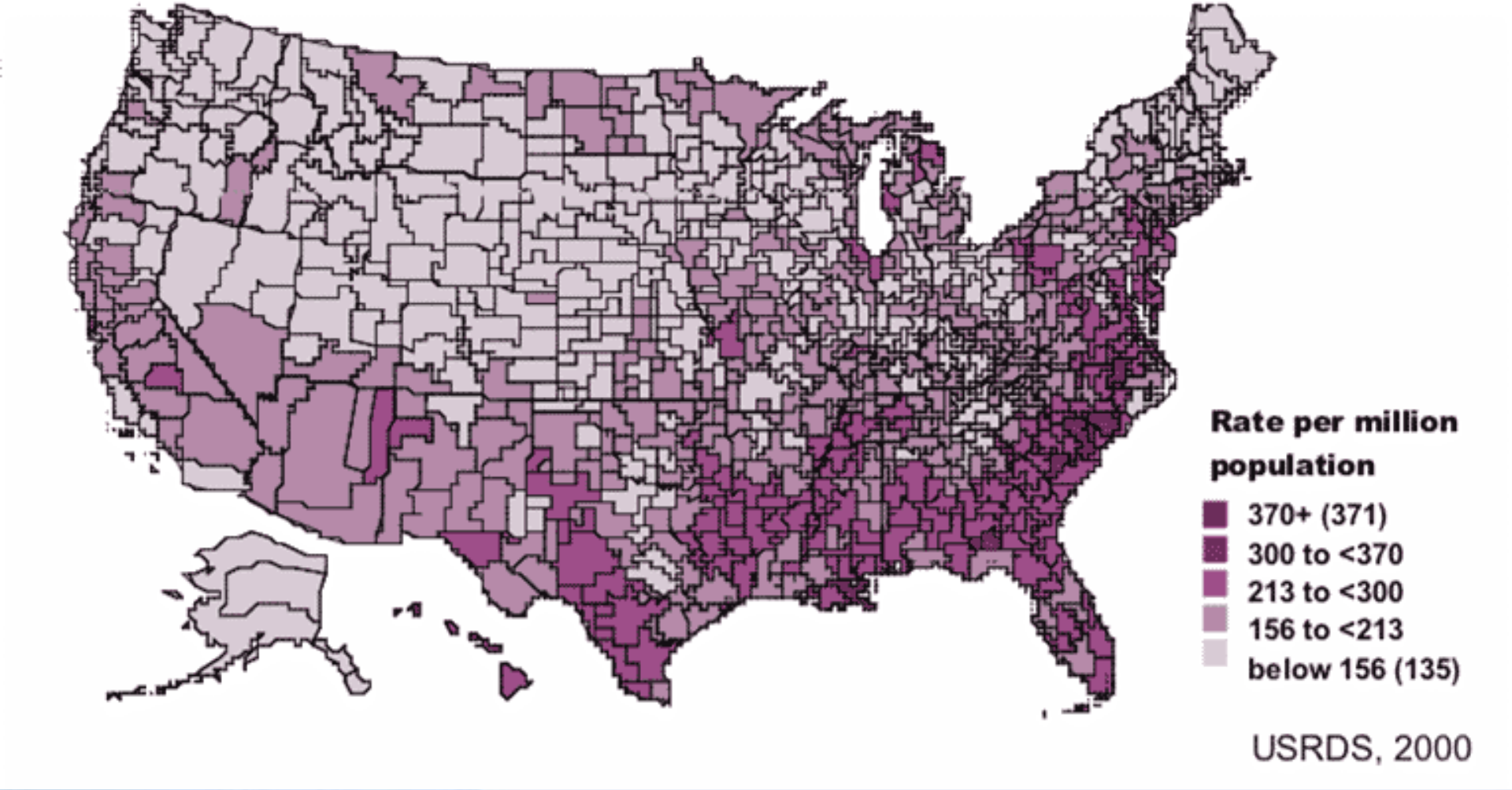
Incidence of CKD - ESRD

per million population, 1990, by HSA, unadjusted



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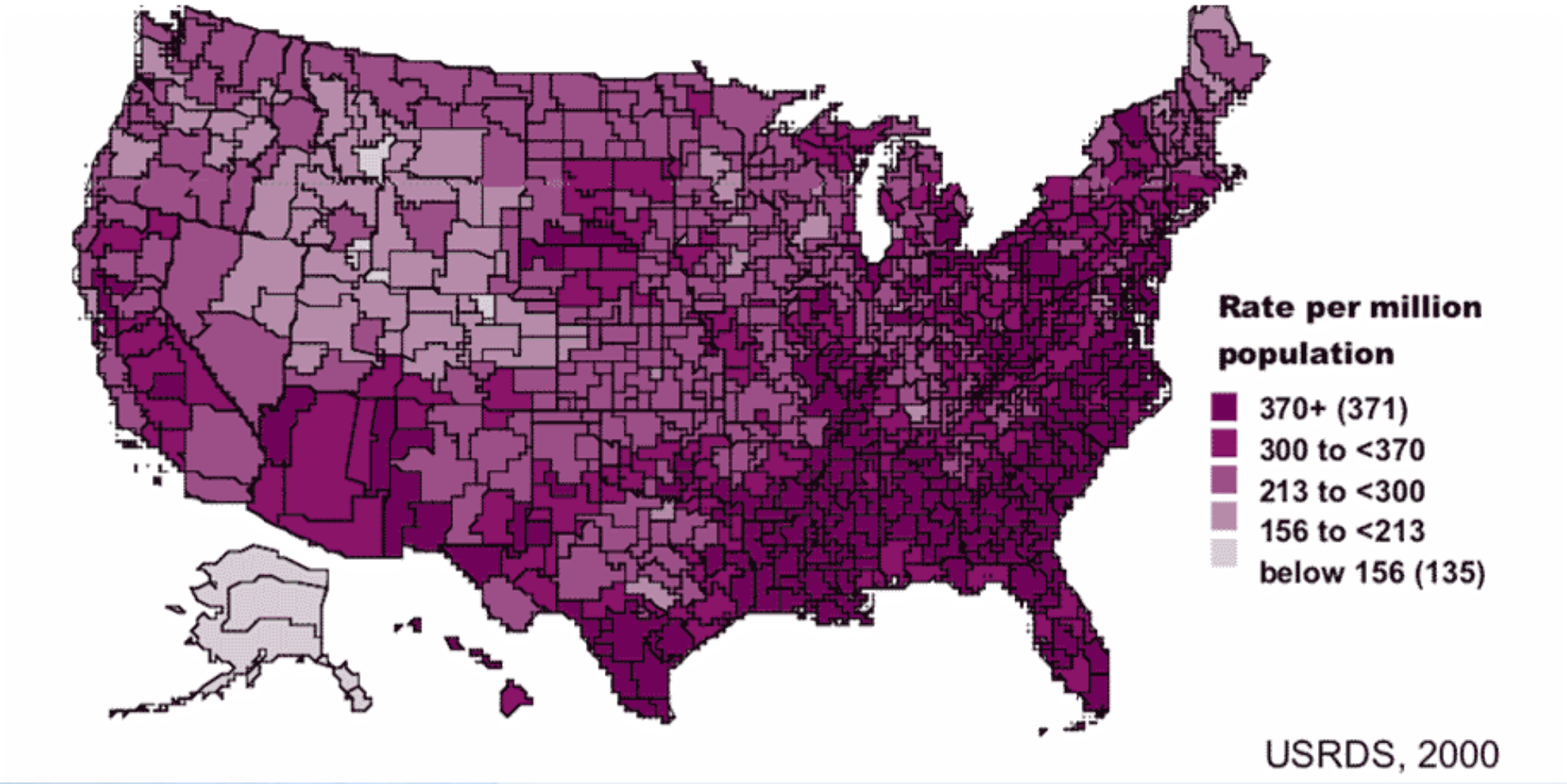
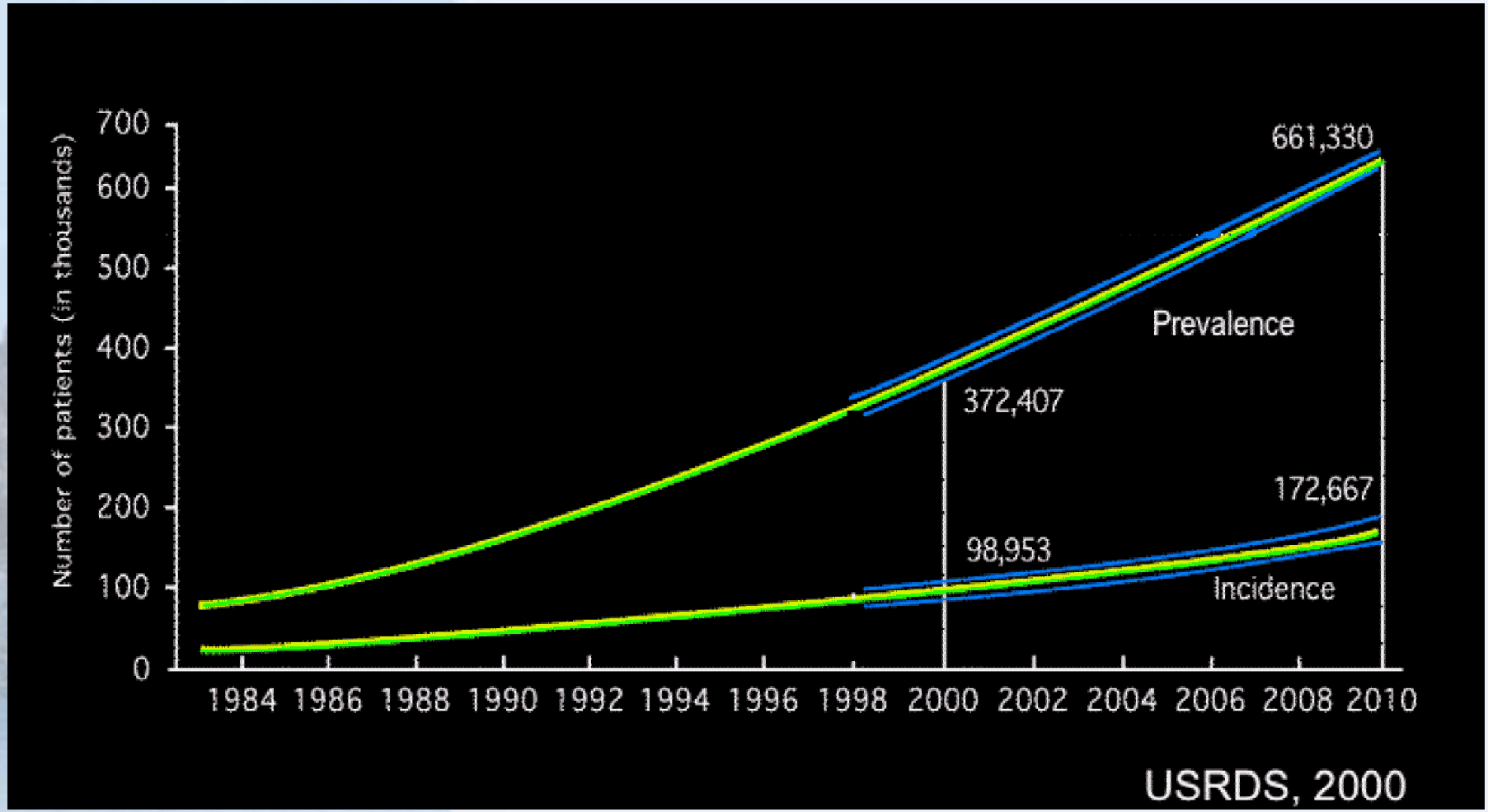
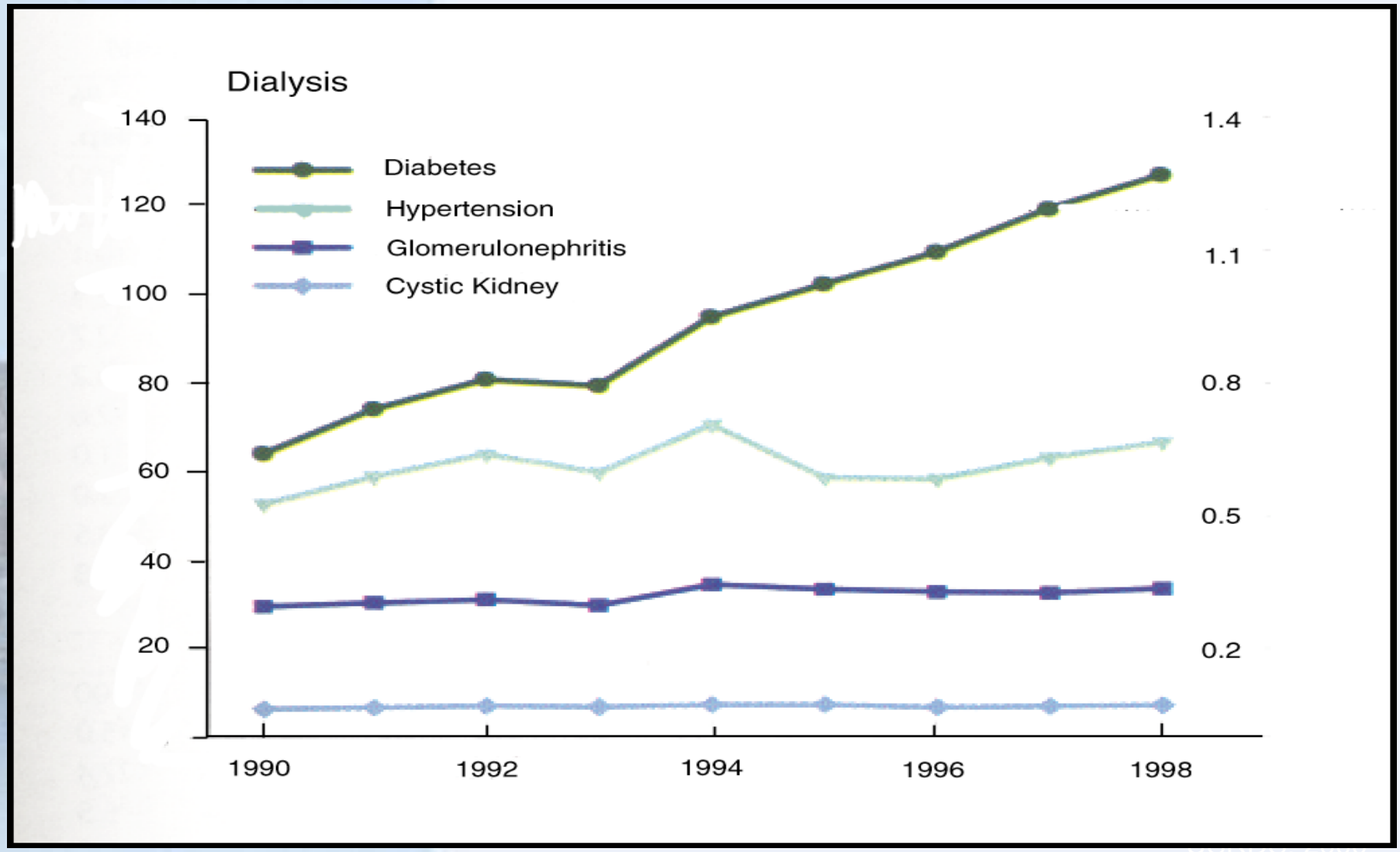


Kidney Failure = ESRD
Can be considered an *epidemic*



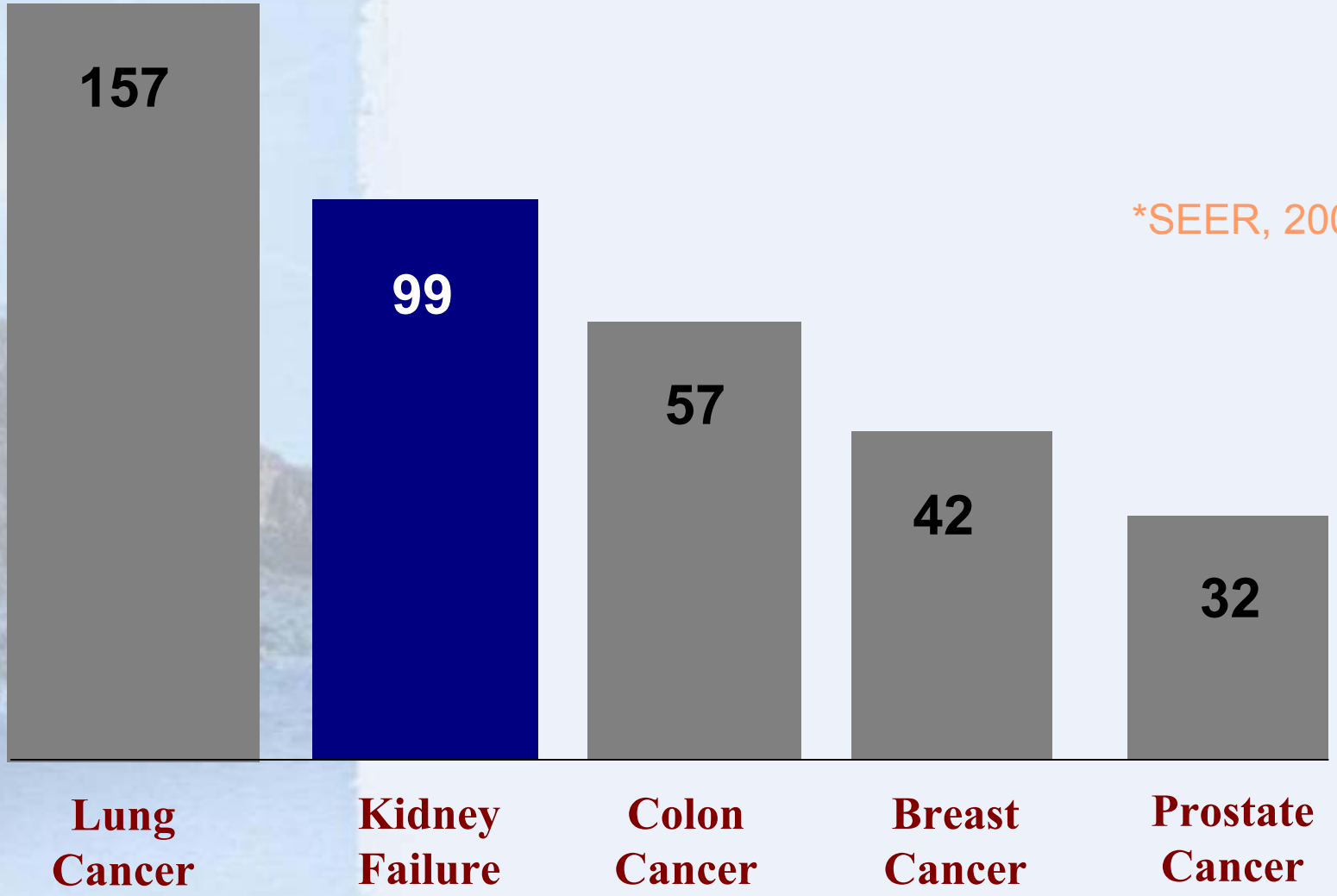
Incident Rates by Primary Diagnosis

(per million population, unadjusted)



Kidney Failure Compared to Cancer Deaths in the U.S. in 2000*

(in Thousands)



*SEER, 2003

Chronic Kidney Disease (CKD)

Defined as:

- Renal dysfunction that persists for more than 3 months.
- Stratified (Stage 1-5) from minimal damage to End-Stage Renal Disease (ESRD)
  - CKD (no renal replacement therapy)
  - Dialysis: Hemodialysis & Peritoneal Dialysis
  - Functioning Kidney Transplant
- Multiple organ effects – most die of CVD before reaching ESRD

Stages of Chronic Kidney Disease

National Kidney Foundation KDOQI

Stage	Description	GFR (ml/min/1.73 m^2)	Action†
	At Increased Risk	>90 (CKD Risk Factors)	Screening, CKD Risk Reduction
1	Kidney Damage with Normal or ↑ GFR	>90	Diagnosis and Treatment, Treatment of Comorbid Conditions, Slowing Progression, CVD Risk Reduction
2	Kidney Damage with Mild ↓ GFR	60-89	Estimating Progression
3	Moderate ↓ GFR	30-59	Evaluating and Treating Complications
4	Severe ↓ GFR	15-29	Preparation for Kidney Replacement Therapy
5	Kidney Failure	<15 or Dialysis	Replacement, if Uremia Present

† Includes actions from preceding stages.

How many patients in the U.S. are affected by CKD?

Percent of Tested Patients and Estimated U.S. Individuals with CKD

Data source	GFR 30-59 *K/DOQI Stage 3*	GFR 15-29 *K/DOQI Stage 4*	GFR < 15 (no RRT) *K/DOQI Stage 5*
NHANES (K/DOQI Analysis)[1]	4.3% 7,600,000	0.2% 400,000	
KP SO CA[2]	4.75%	0.27%	0.04%
Southwestern U.S. Health Plan[3]	4,2000,000 in U.S. with CKD (conservative definition)		

1 K/DOQI Work Group: Am J Kidney Dis 2002; 39: S50.
2 Rutkowski M, et al:J Am Soc Nephrol 2002; 13:463A.
3 Nissenson AR, et al: Am J Kidney Dis 2001; 37:1177-1183.

What Can Be Done About It?

- Managing End-Stage Kidney Disease (ESRD) on RRT
  - Disease Management interventions based upon risk stratification
    - ESRD Managed Care Demonstration Project (Medicare)
    - Optimal Renal Care; Renaissance Renal Management Services
- Managing Earlier Stages of Chronic Kidney Disease (CKD)
  - Identification & Stratification: K/DOQI Staging Guidelines
  - Stage-specific Approach to Management
    - Population Management in early Stages
    - Case / Care Management pre-dialysis / pre-kidney transplant
  - CKD Disease Management Programs that manage co-morbid conditions (CVD; diabetes; hypertension)
    - Prepare for dialysis and/or transplant when needed
- Evidence of Improved Outcomes from Key Interventions

Risk Stratification and Prediction of Hospitalization and Mortality

Overview of Optimal Renal Care Risk Stratification Process

Risk Stratification Tool

Optimal Renal Care Risk Stratification:

- Predicts hospitalization; mortality
- Partially built upon the Index of Coexisting Disease (ICED) Risk Stratification
- 6 Additional components:
  - Utilization (Time since last acute care episode)
  - Psychosocial variables such as social support structure (lives alone; no support system)
  - Adherence with medical regimen
  - Specific Clinical indicators
  - Co-morbid conditions
  - Age

Risk Stratification Tool

- Has identified *Predictive Components* of co-morbid conditions for the kidney patient
- Has defined *Time Dependence* of stratification and re-stratification
  - Assigns types and frequency of interventions based on risk stratification score
  - Predicts hospitalization and mortality over time
- Demonstrates changes of *Risk Stratification* over time
  - Reports outcomes of initial and ongoing risk stratification outcomes
  - Manage components that predict change

ORC Stratification Results

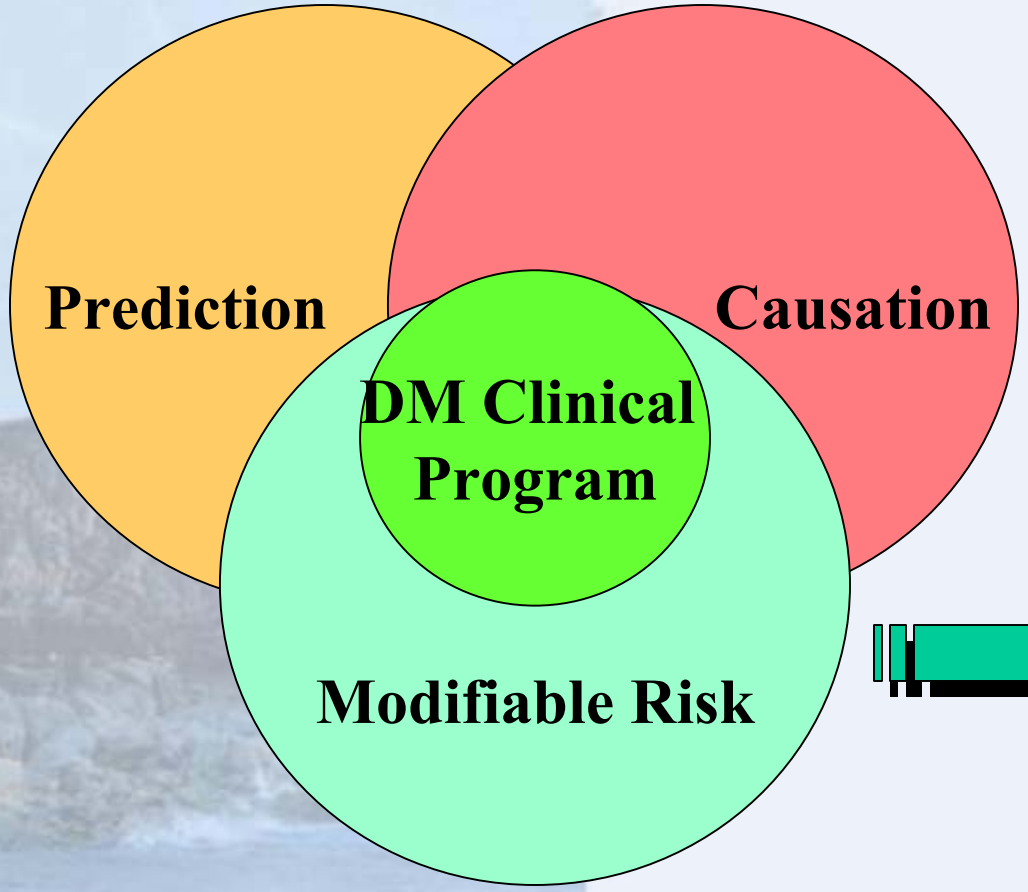
Levels

- Low Risk
- Medium
- High

Frequency of re-stratification

- Quarterly (every 90 days)
- More frequently based upon:
  - Member specific care plan
  - Hospital utilization; SNF utilization
  - Specific care coordination activities
  - Clinical judgment

Global Assessment Drives Risk Scoring



Dialysis Prescription (HD orders, anemia, Bone D, etc)

Unified Care Plan

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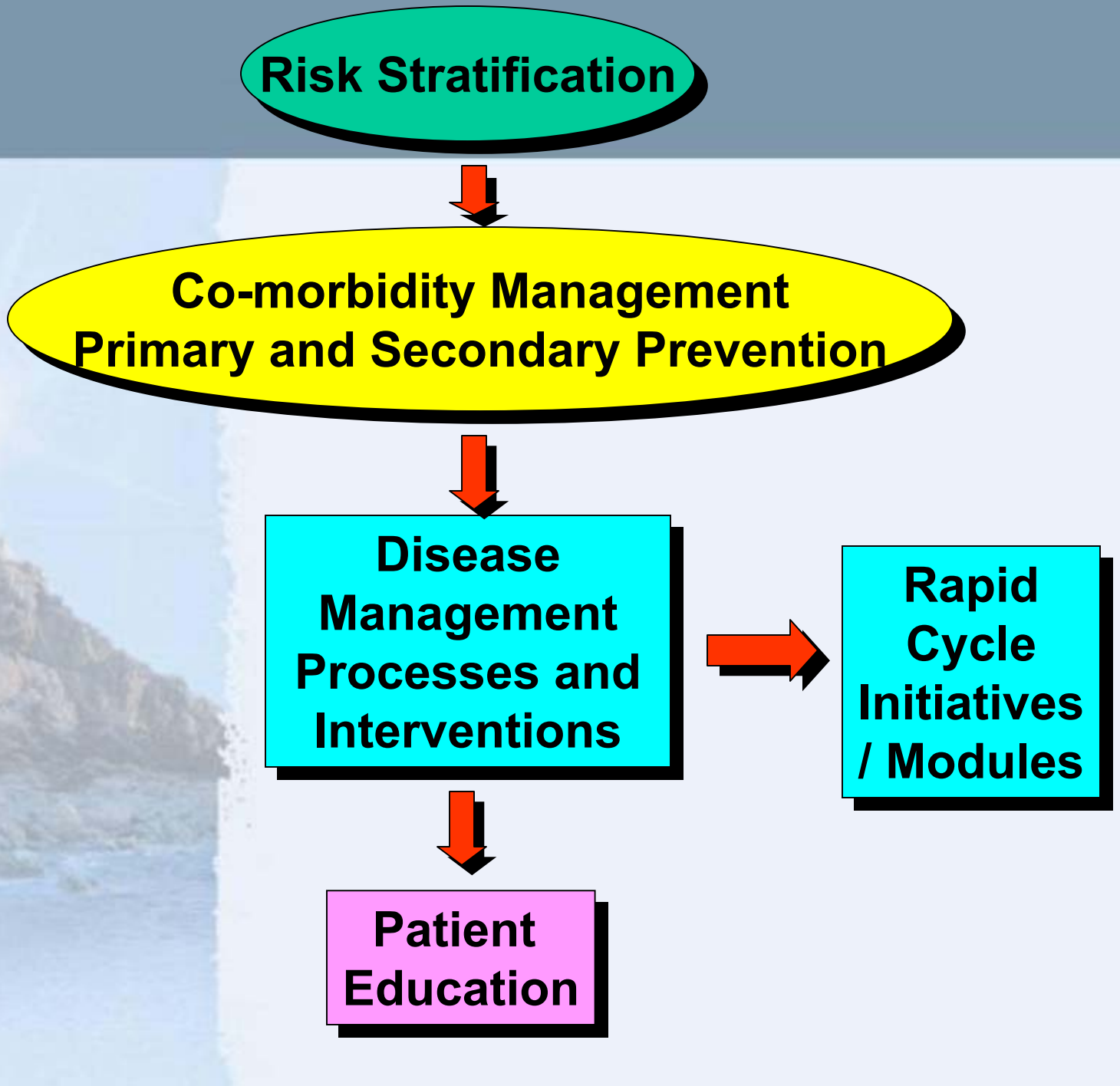

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Validation of the Risk Stratification Process

Tulane University Validation

Goals

- Validate ORC Additive ICED-Based Risk Stratification
  - Hospitalization, Mortality
- Identify Predictive Components
- Determine Time Dependence of Stratification
  - Hospitalization, Mortality
- Changes of Risk Stratification over Time
  - Outcomes of patients who changed risk stratification
  - Components that predict change

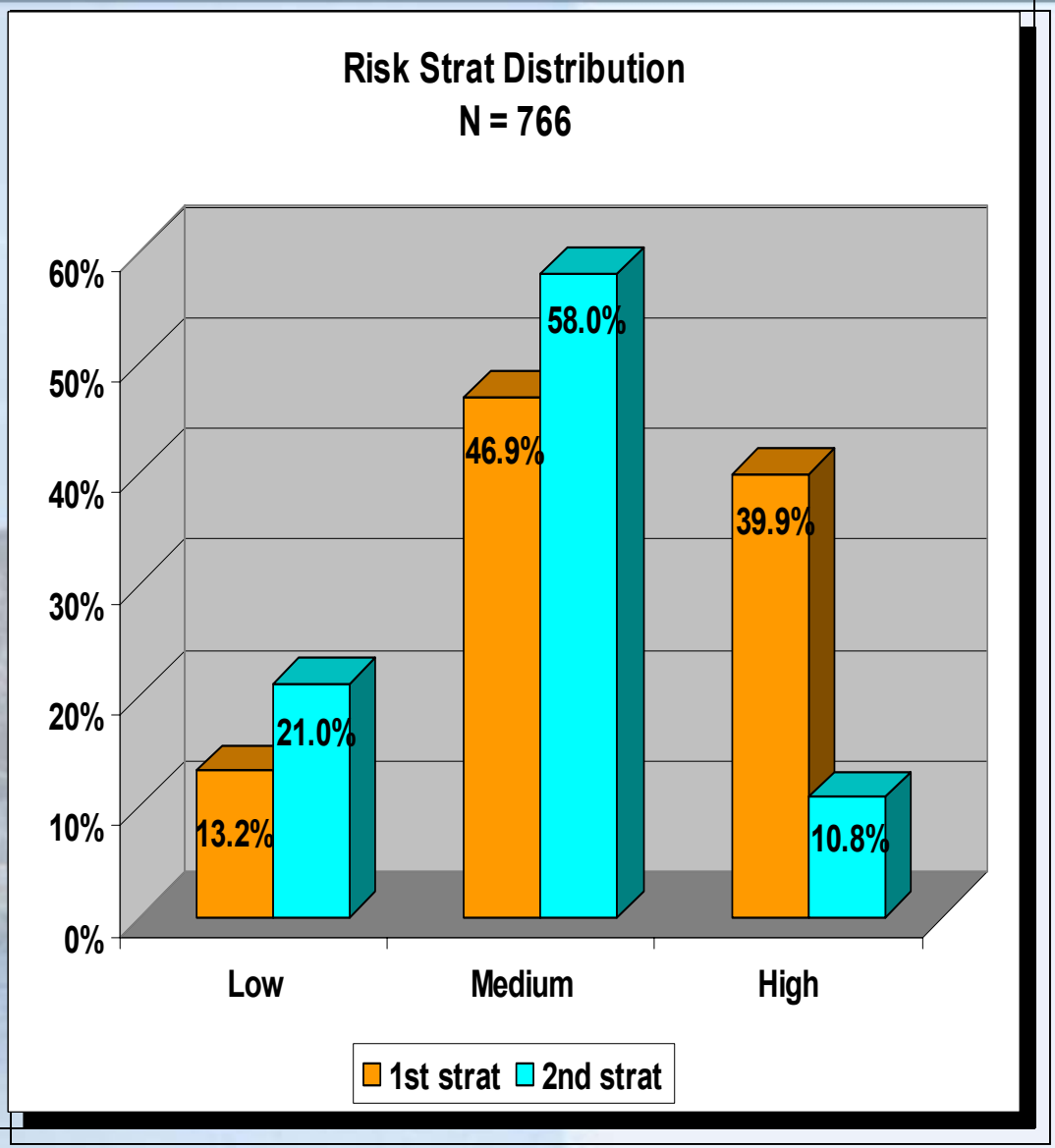
Study Design

- Retrospective analysis
  - 965 patients in 8 health plans who had an initial risk stratification
- Data collected prospectively
- Endpoints
  - Time to first hospitalization
  - Hospitalizations over time
  - Mortality

Patient Demographics

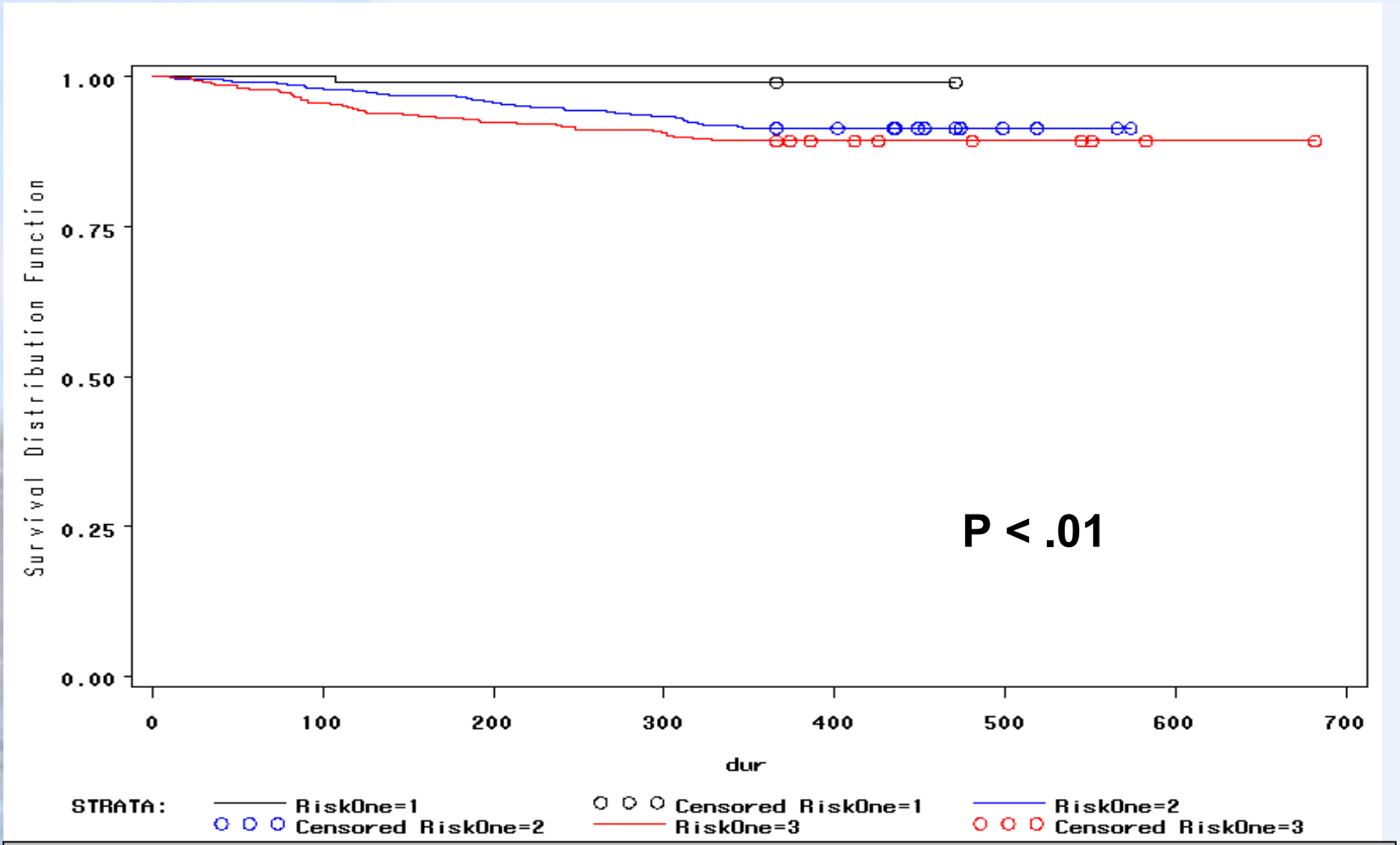
Study Population	
N = 965	
Age	
Time on dialysis	
Male	57.70%
Female	42.30%
% Diabetic	52%

Example Change in Risk Stratification



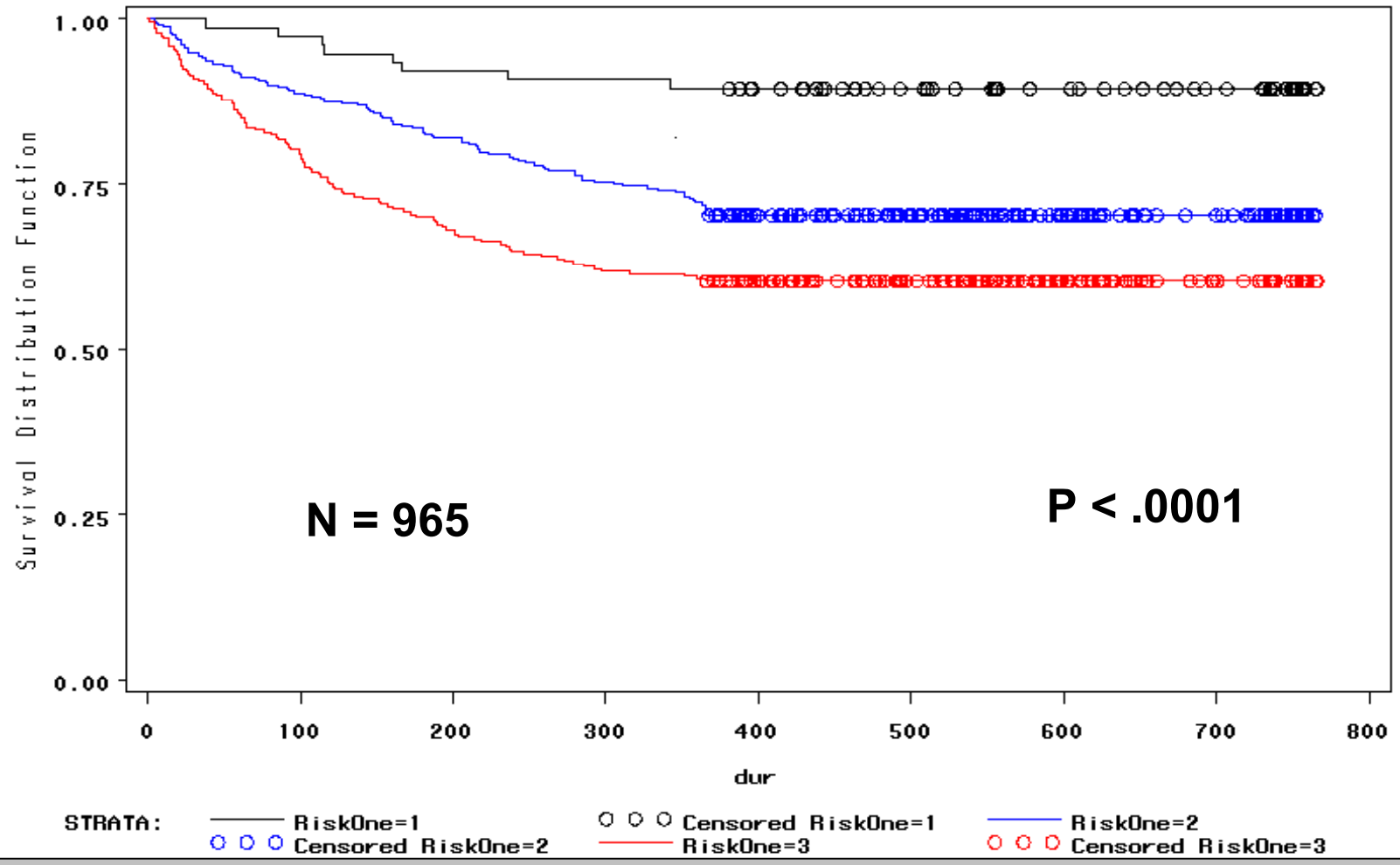
First and Second Risk Level	
Stayed Same	48.0%
Changed	52.0%
Decreasing	47.3%
Increasing	4.7%
Low	
Stay Low	9.1%
Become Medium	2.2%
Become High	0.0%
Medium	
Stay Medium	30.6%
Become Low	16.1%
Become High	2.5%
High	
Stay High	8.3%
Become Low	6.0%
Become Medium	25.2%

Risk Stratification and 365 Day Patient Survival



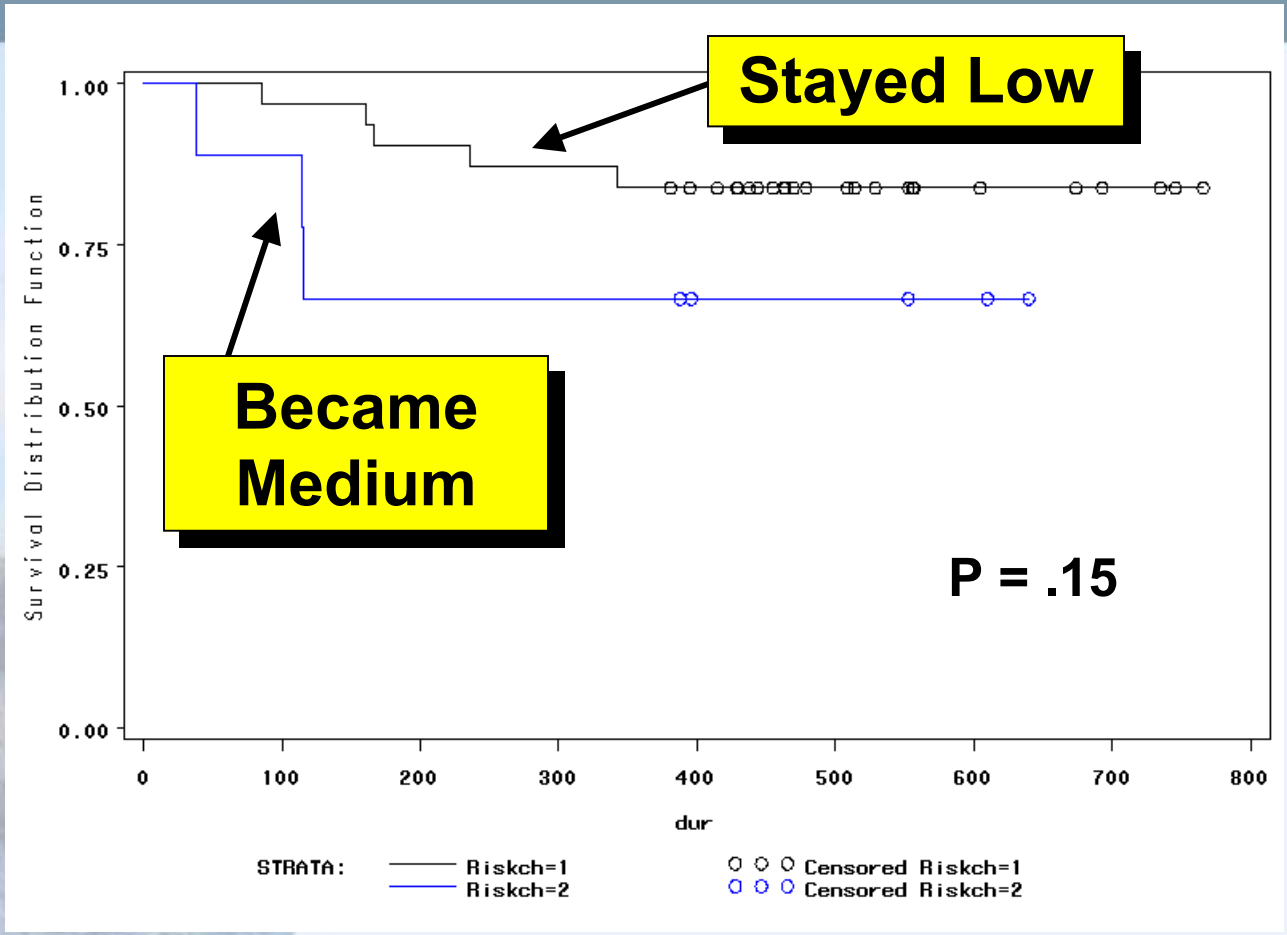
- Stratification predicts mortality
- Low mortality for a dialysis population

Risk Stratification and 365 Day Hospitalization



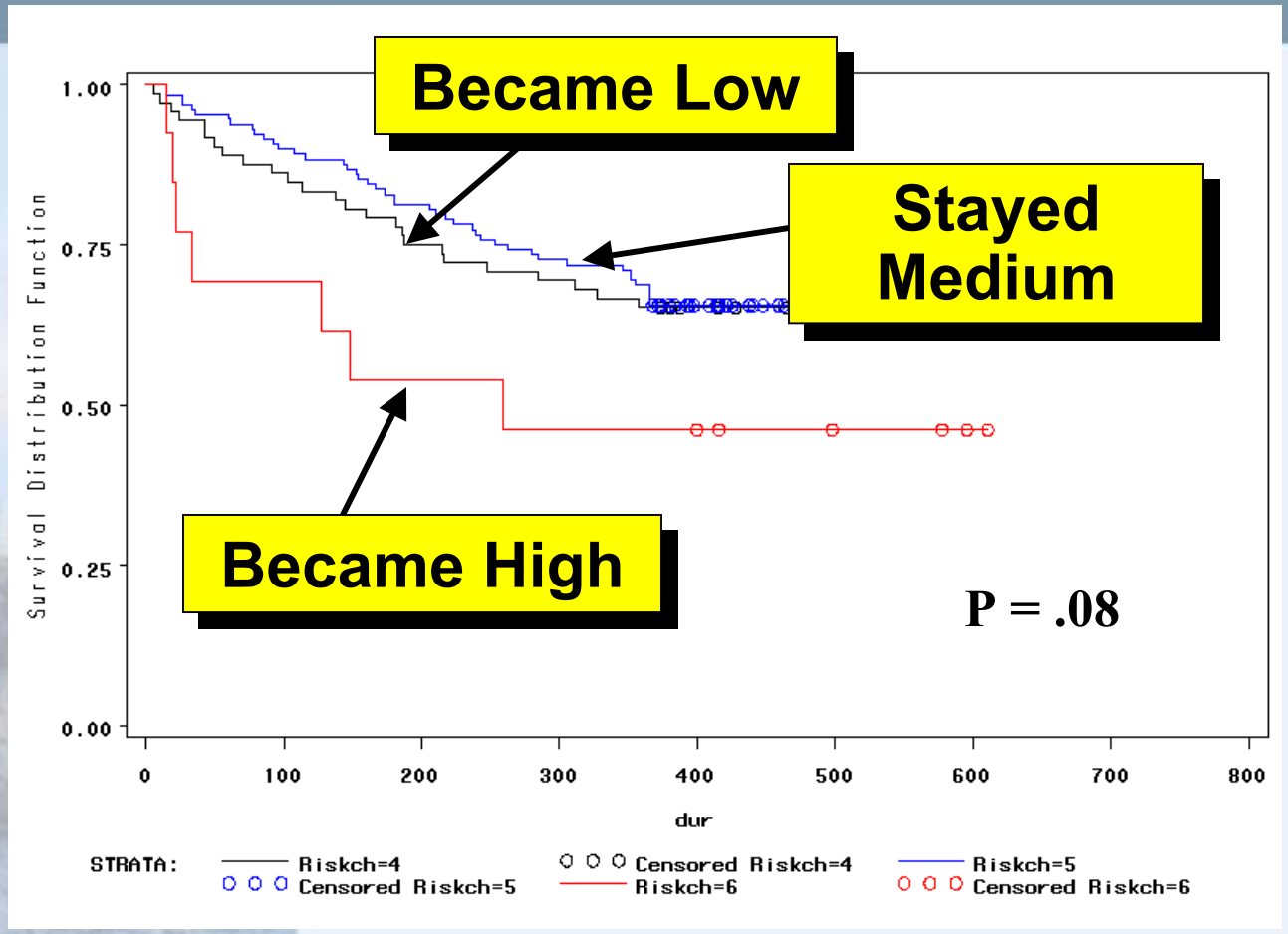
- Stratification predicts hospitalization risk

Predicting Hospitalization



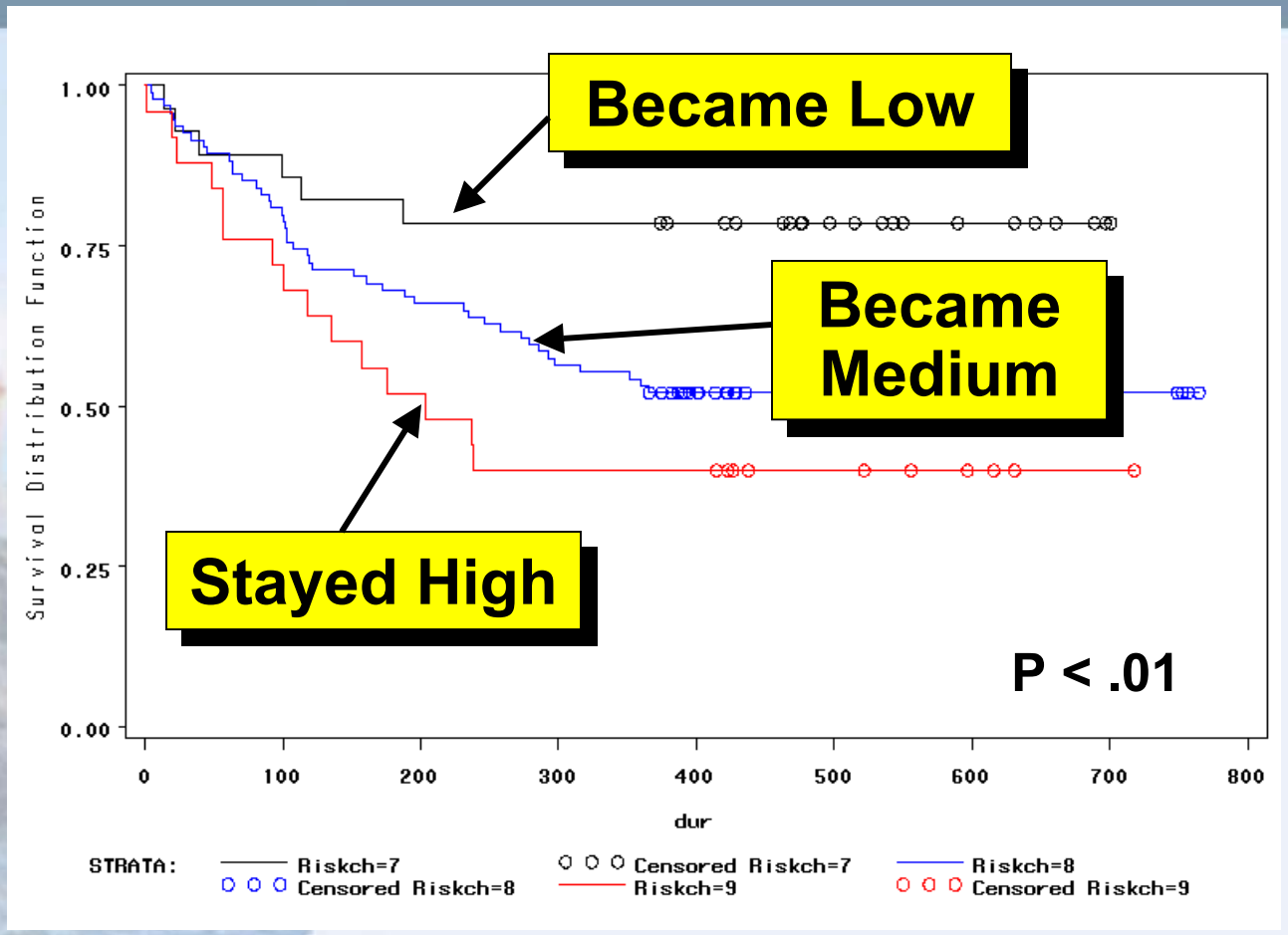
Patients who increased from low to medium risk had a trend toward earlier hospitalization

Predicting Hospitalization



Patients who increased from a medium to high risk had poorer outcomes from the onset

Predicting Hospitalization



High risk patients who decreased risk level at 90 days had longer time to hospitalization

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Sample Risk Stratification Co-Morbid Conditions Outcomes

Co-Morbid Condition	Members With	Percent With
Hypertension	259	86.3%
Diabetic Insulin Dependent	125	41.7%
Diabetic Diet Controlled	51	17.0%
Congestive Heart Failure	102	34.0%
Ischemic Heart Disease	100	33.3%
Opthalmologic Conditions	85	28.3%
Musculoskeletal Connective Tissue Disease	77	25.7%
Peripheral Vascular Disease	74	24.7%
Nonvascular Nervous System Disease	73	24.3%
Anticoagulation Conditions	66	22.0%
Gastrointestinal Disease	62	20.7%
Cardiac Arrhythmias	60	20.0%
Other Heart Disease	55	18.3%
Cerebral Vascular Disease	48	16.3%
Malignancy	38	12.7%
Respiratory Disease	37	12.3%
Hepatobiliary Disease	26	8.7%
Hematologic Conditions	22	7.3%
Urinary Tract Disease	18	6.0%
HIV AIDS	6	2.0%

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Expanding the risk stratification and intervention link

Chronic Kidney Disease

Pre-renal replacement therapy

Why?

Costs of Kidney Failure Are High (in $billions for 2000)

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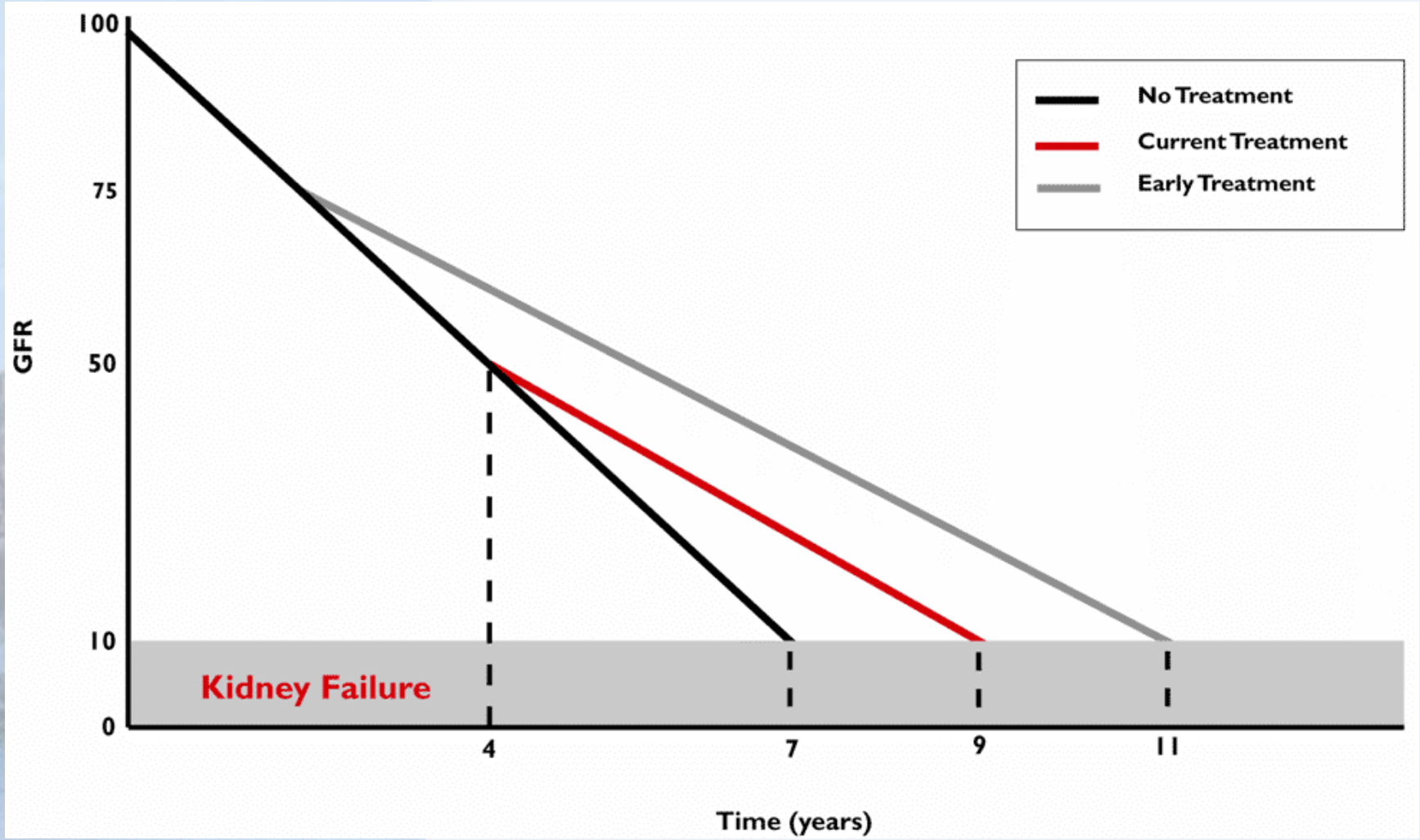
Early Treatment Makes a Difference



CKD Is Not Being Recognized or Treated (NKDEP)

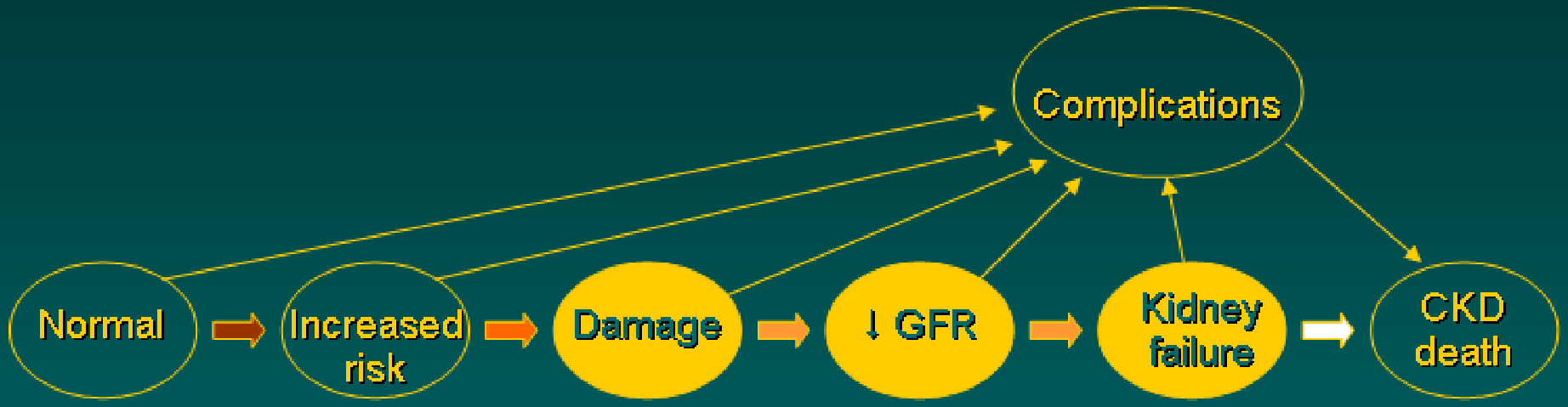
- Only 10% of Medicare beneficiaries with diabetes receive annual urine albumin tests
- Patients are referred late to a nephrologist, especially African American men
- Less than 1/3 of people with identified CKD get an ACE Inhibitor

McClellan, et al., 2000
Kinchen, 2002
McClellan et al.,1997

Parallels Between Hypertension in 1972 and Kidney Disease in 2004 (NKDEP)

- Recent documentation of effective therapy
- Treatment of a silent disease to reduce risk for a disastrous outcome
- Simple screening
- Advantages for patients, physicians, industry

Stages in Progression of CKD and Therapeutic Strategies



Background

- Chronic kidney disease (CKD) is a worldwide public health problem
- There is a rising incidence and prevalence of kidney failure, with poor outcomes and high cost
- There is an even higher prevalence of earlier stages of CKD

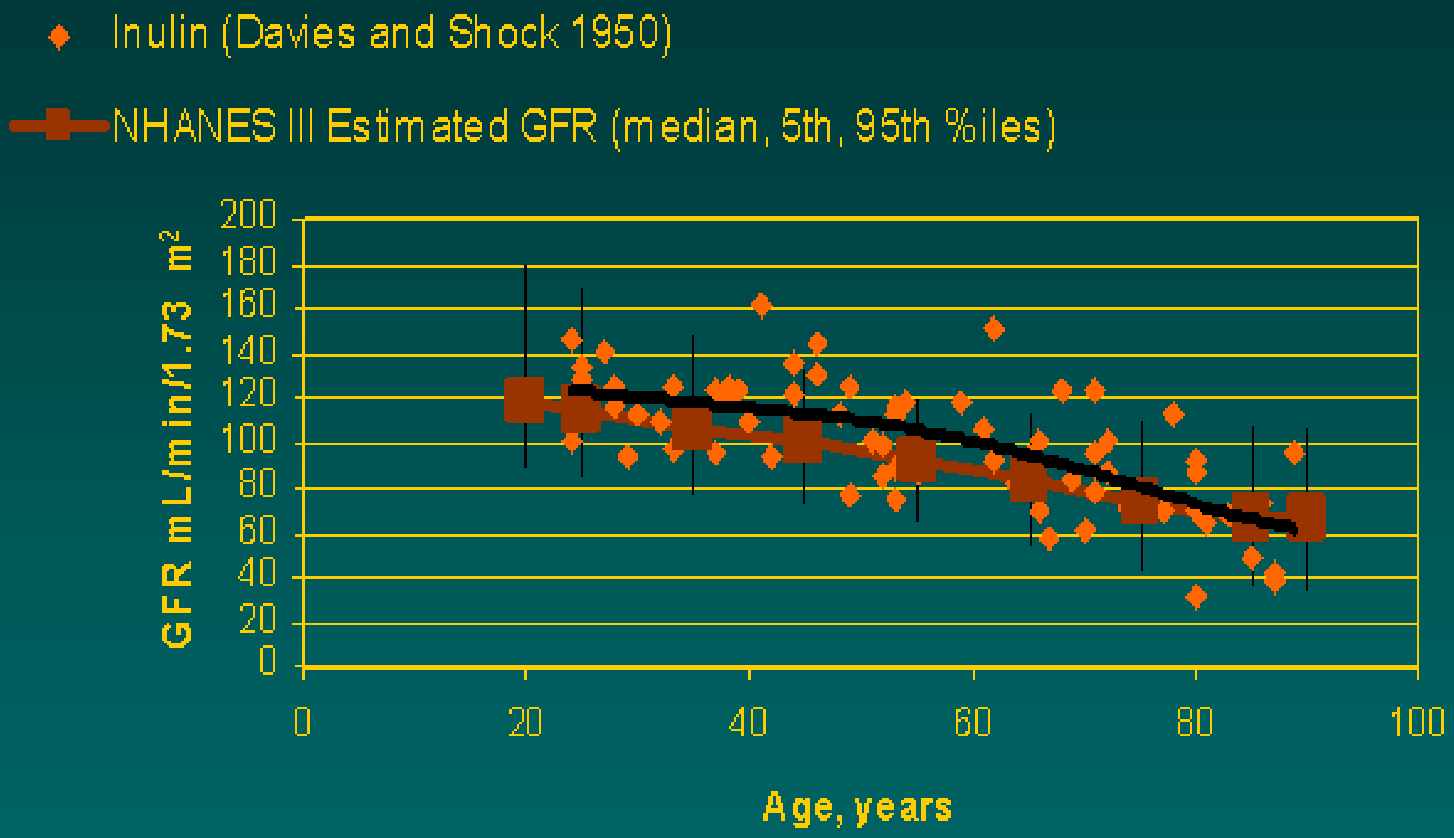
Background (cont'd)

- Adverse outcomes of CKD can often be prevented or delayed
- Earlier stages of CKD can be detected through laboratory testing
- Treatment of earlier stages of CKD is effective in slowing the progression toward kidney failure and correcting complications associated with progressive loss of kidney function
- Treatment of cardiovascular disease risk factors should be effective in reducing cardiovascular disease events, both before and after the onset of kidney failure

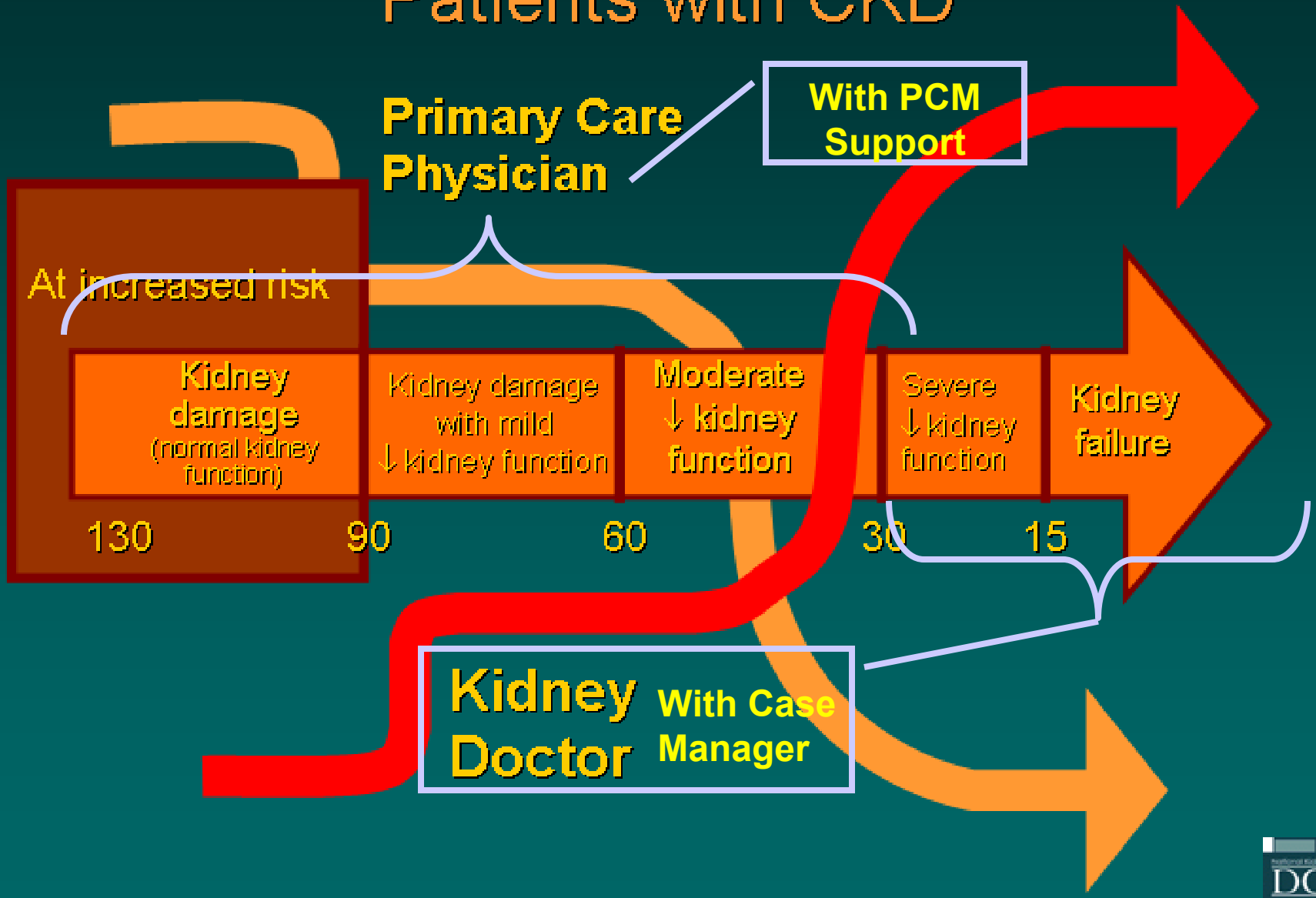
Background (cont'd)

- CKD is under-diagnosed and under-treated, resulting in lost opportunities for prevention
- One reason is the lack of agreement on a definition and classification of stages in the progression of CKD

“Normal” GFR vs. Age



Co-Management of Patients with CKD



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Early Detection of CKD

Interventions that delay progression	Prevention of uremic complications	Modification of comorbidity	Preparation for RRT
ACE inhibitors	Malnutrition	Cardiac disease	Education
BP control	Anemia	Vascular disease	Informed choice of RRT
Blood sugar control	Osteodystrophy	Neuropathy (in diabetics)	Timely access placement
Protein restriction ?	Acidosis	Retinopathy (in diabetics)	Timely initiation of dialysis

Pereira, Kidney International, Vol 57 (2000), p. 353

Management To Prevent Progression of CKD to Kidney Failure

Proven & Accepted Interventions

Delay CKD progression and/or slow progression of CVD

- Improved glycemic control in diabetics
- BP control
- ACEI/ARB in DM and in non-DM with proteinuria
- Anemia management (New evidence)
- Protein Restriction (with Dietitian guidance)
- Timely nephrologist referral
- Multidisciplinary team management
- CV risk reduction (usual measures)

CKD Program: Patient Tracking

Pre-interview Data Collection

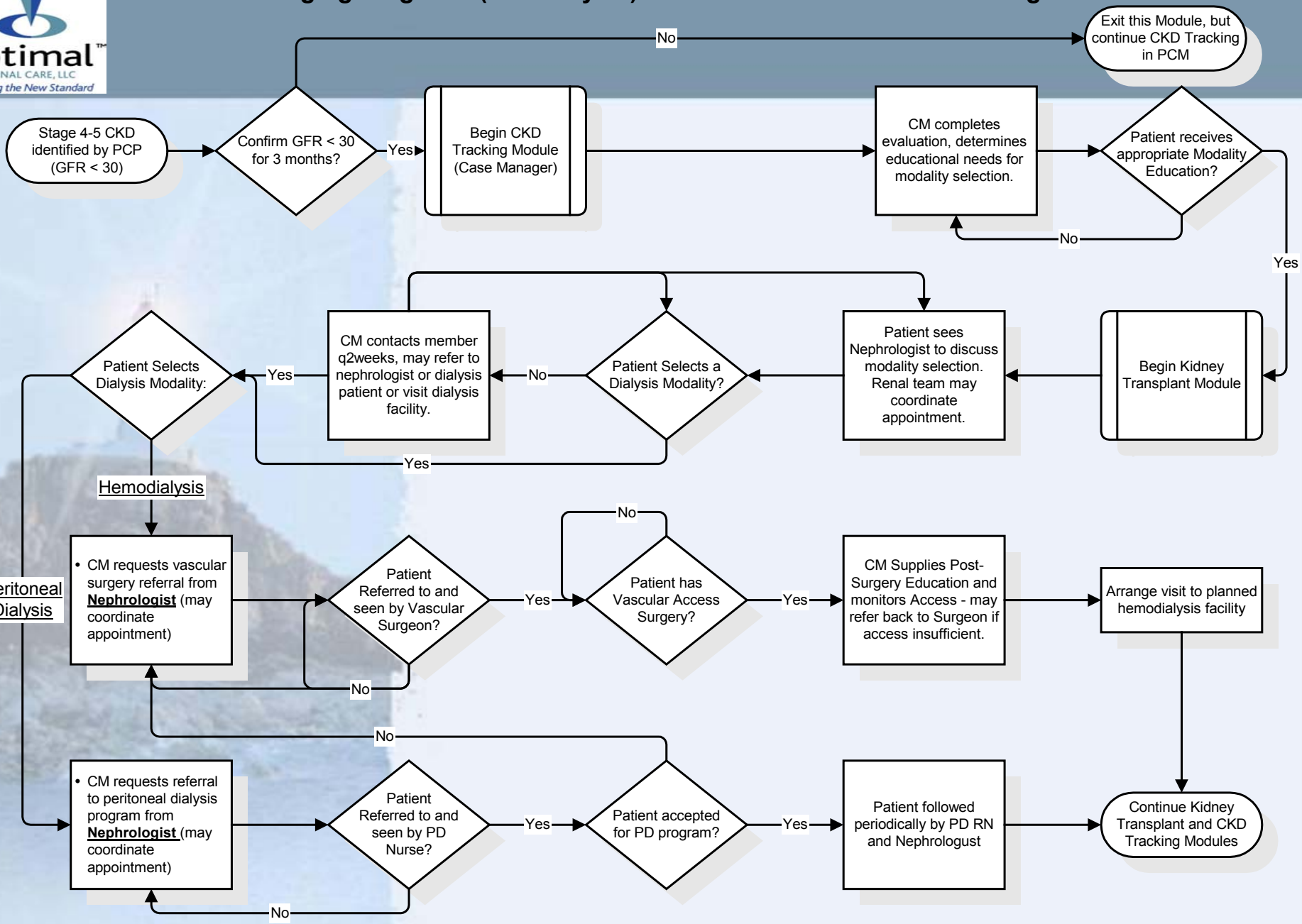
Test or screening procedure	Result	Date	Time Frame
Creatinine level or GFR			3 months
PTH level			6 months
Calcium level			3 months
Phosphorus level			3 months
Hemoglobin			1 month if on EPO 3 months if not on EPO
Serum Albumin			3 months
Fasting Lipid Profile			12 months
HgbA1C for Diabetics only			
Hepatitis B Vaccination Series			Once
Hepatitis B Surface Antibody			1 month after complete Hep B vaccine series
Pneumococcal Vaccination (Pneumovax)			Once when less than 65 Once over age 65 if 5 or more years since last vaccination
Influenza Vaccination			Each Fall
Preventative Health Visit to PCP			1 year

CKD Program: Patient Tracking

Interview Data Collection

Information item from patient	Answer	Criteria	Discipline for follow up if needed
Last visit to Nephrologist		3 months	Nephrologist's Office
Last visit to PCP		12 months	PCP's Office
Modality Selection Made or changed		Committed to a dialysis modality	ORC Social Worker and/or Nephrologist, PD nurse
How is Blood Pressure?		Usually < 140/90, if not: • Alert nephrologist and have patient call nephrologist • Taking meds, if not why? (Pharm or SW) • Restricting salt?	Nephrologist ORC Pharmacist ORC Social Worker ORC Dietitian
Home BP Monitoring? If no, are you interested in doing Home BP monitoring?		No	Give information about HIP Class.
If takes EPO, getting follow up at ORC-HIP Program?		All Stage 4 CKD patients should be managed at HIP Home EPO program	ORC Pharmacist
Are you eating well? Is weight dropping? Do you have dietary questions		No problems	ORC Dietitian
How are you dealing with CKD? How is your family reacting? Do you have enough help at home? Are you feeling more sad or anxious? Are you sleeping well? Are you still working or going to school?		Doing OK	ORC Social Worker
Are you smoking? If yes, are you thinking about quitting?		No	Give information about HIP smoking cessation program
Are you on cholesterol lowering medication? If so, are you following the program?		No No	ORC Pharmacist ORC Social Worker ORC Dietitian
If you are diabetic, are you followed by the HIP diabetes program?		No	Refer to HIP diabetes case manager
Review Test/procedure table with patient		Patient has met all criteria	If not, suggest follow up as appropriate, notify physicians and other disciplines.

Managing Stage 4-5 (Pre-Dialysis) Patients - Case for a Case Manager



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Conclusion

Risk Stratification and Renal Care

- **ESRD Managed Care Demonstration Project (Medicare)**
  - Disease Management can be Cost-effective in ESRD
    - Interventions based on risk stratification acuity level
- **ESRD Quality Improvement is Critical to Long-term Success**
  - Speeds improved outcomes such as:
    - Vascular access outcomes; Reduction of extremes of blood pressure; reduction of fluid volume overload/heart failure; glycemic control
- **The US Renal Disease Care Management Marketplace**
  - Optimal Renal Care Approach to ESRD
- **Earlier Stages of CKD**
  - Sizable problem – Costly, semi-preventable, not well managed
  - Staging Care and applying proven interventions
  - Managing co-morbid conditions (CVD)