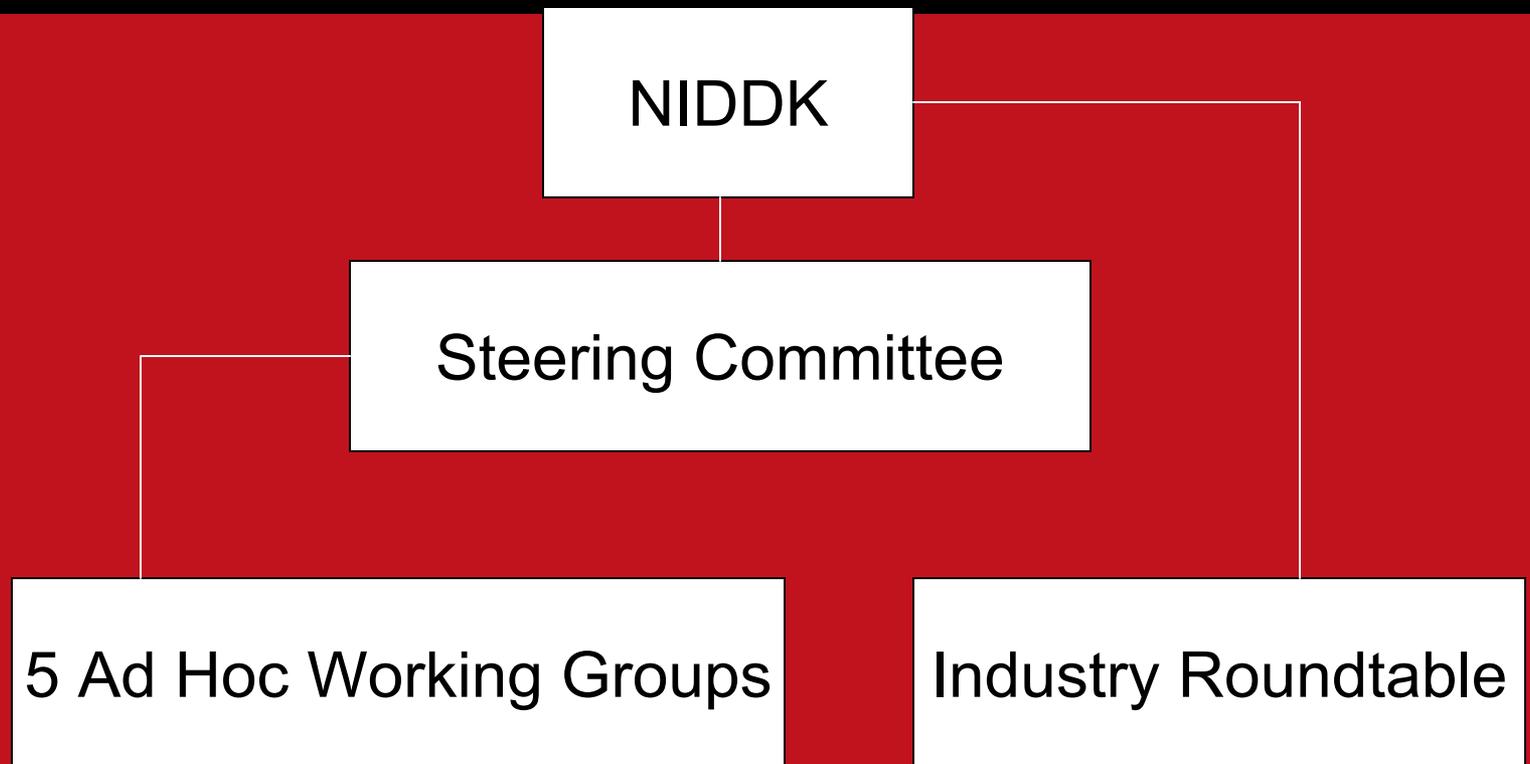


National Kidney Disease Education Program Manufacturers Forum Tom Hostetter

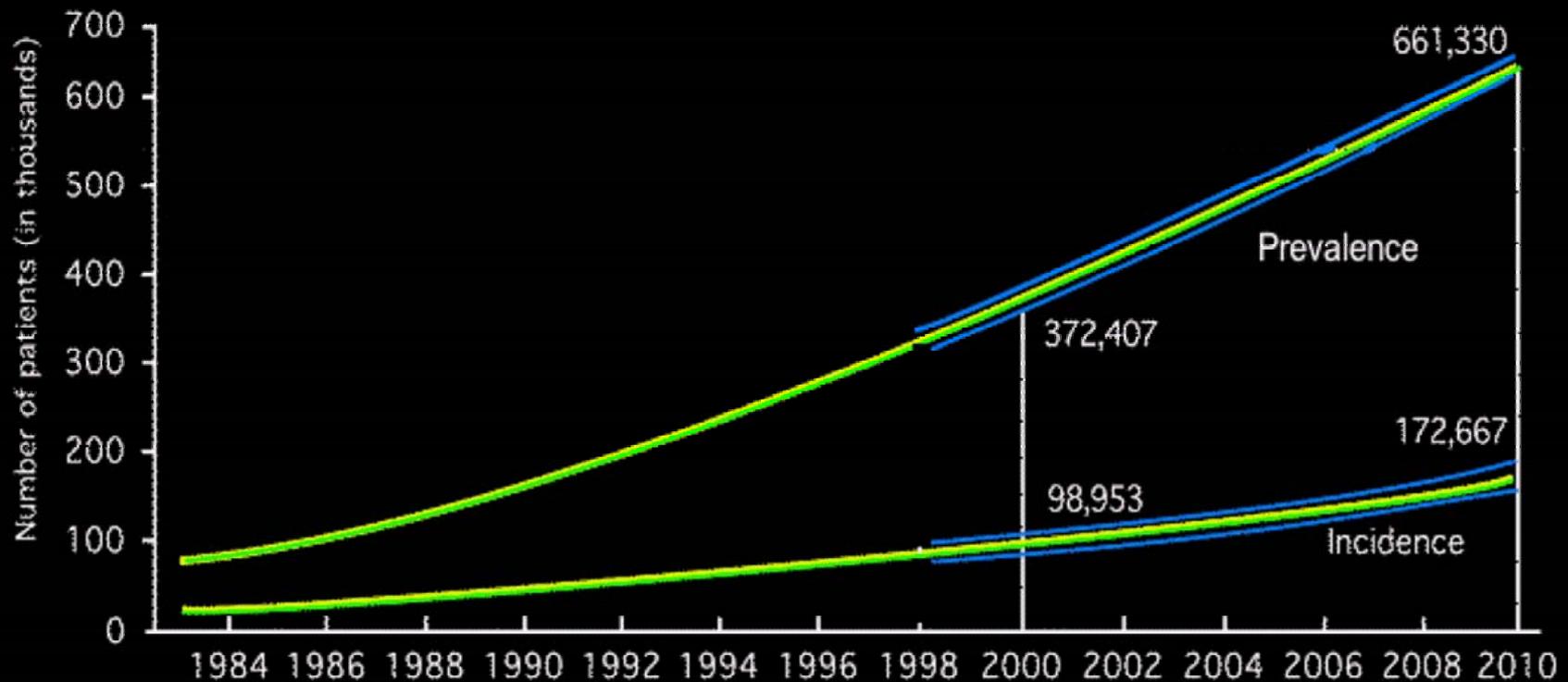
Organizational Structure



Reasons for a National Kidney Disease Education Program

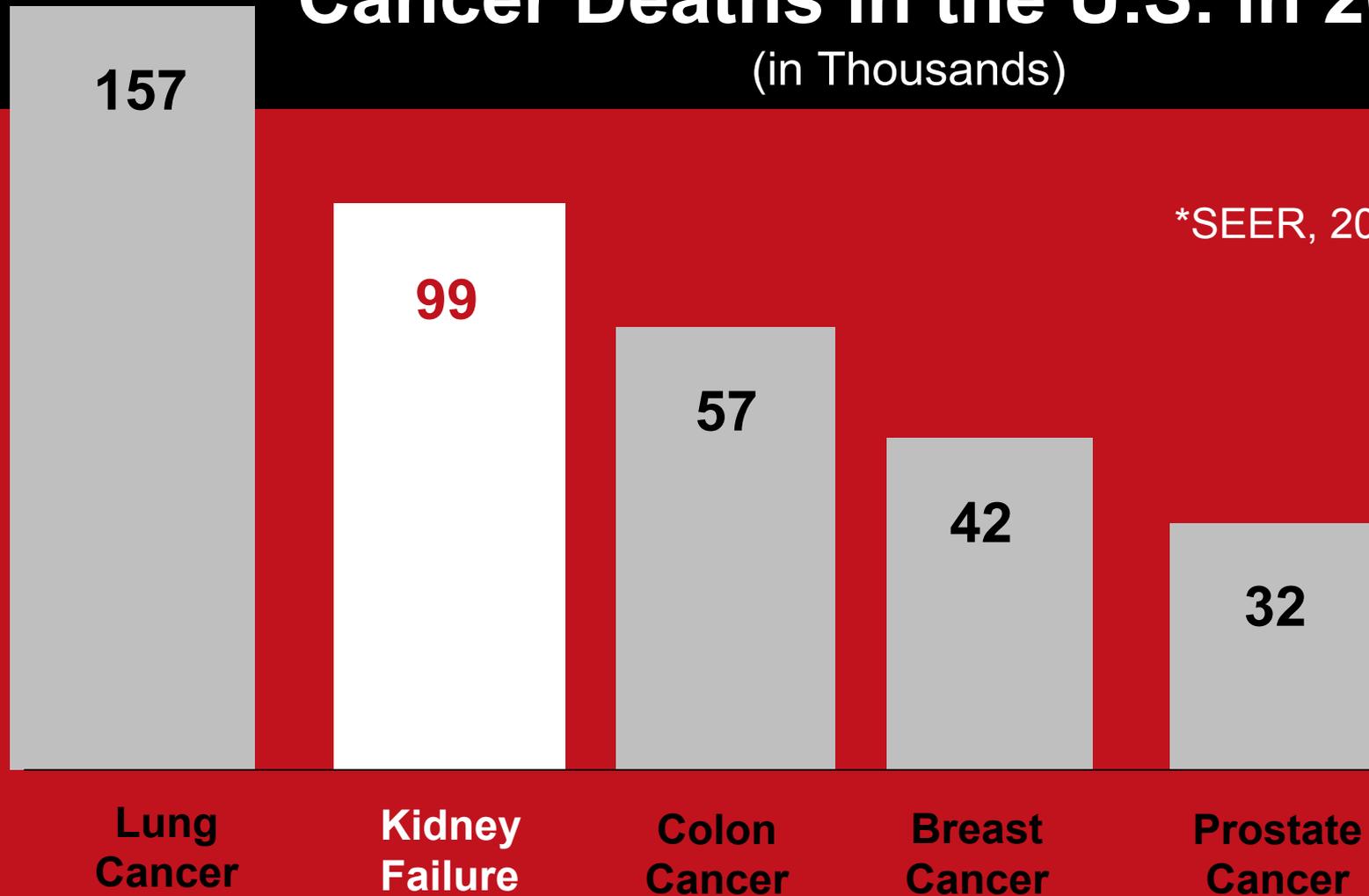
- 1) Kidney failure is a public health problem
- 2) Economical, effective testing and therapy exist
- 3) Testing and therapy are inadequately applied

Kidney Failure Is a Rapidly Growing Problem



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

(in Thousands)



*SEER, 2003

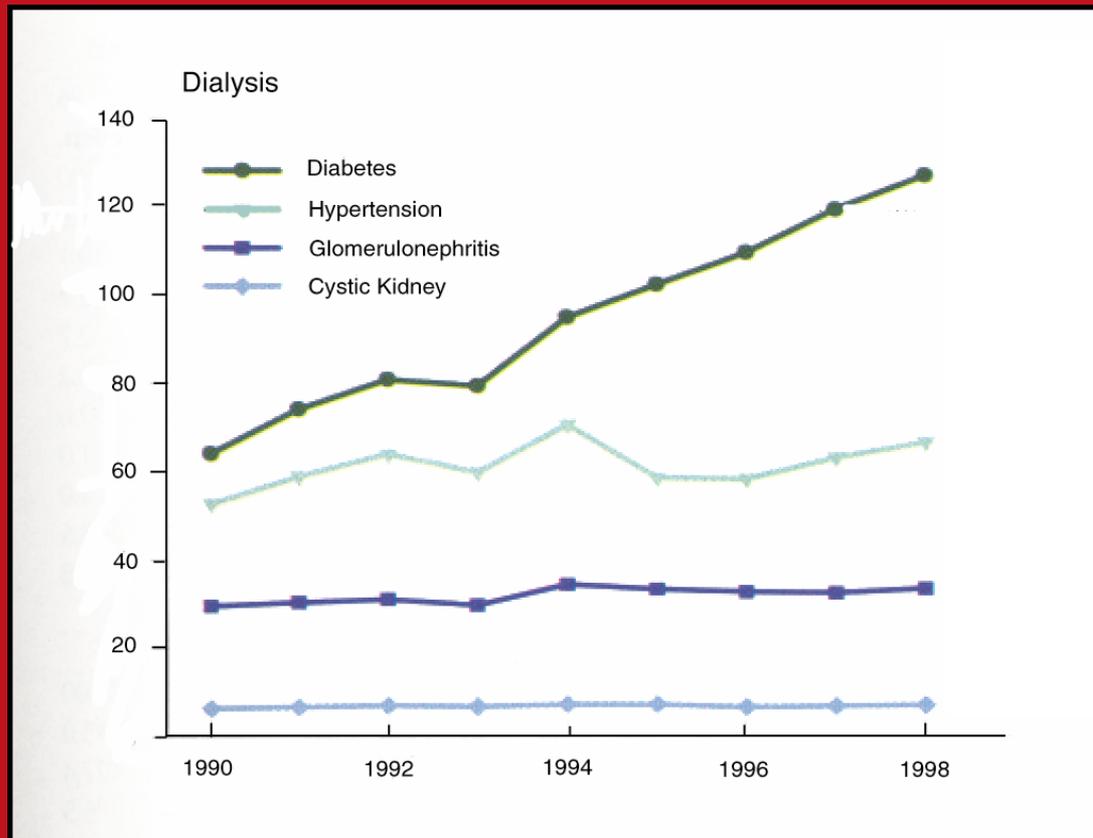
Prevalence of Renal Insufficiency in U.S.

GFR (ml/min/1.73 m²)	59-30	29-15	< 15
Number of People	7.6 Million	360,000	> 300,000

More than 8 million Americans have substantial kidney impairment and 10 million more have albuminuria.

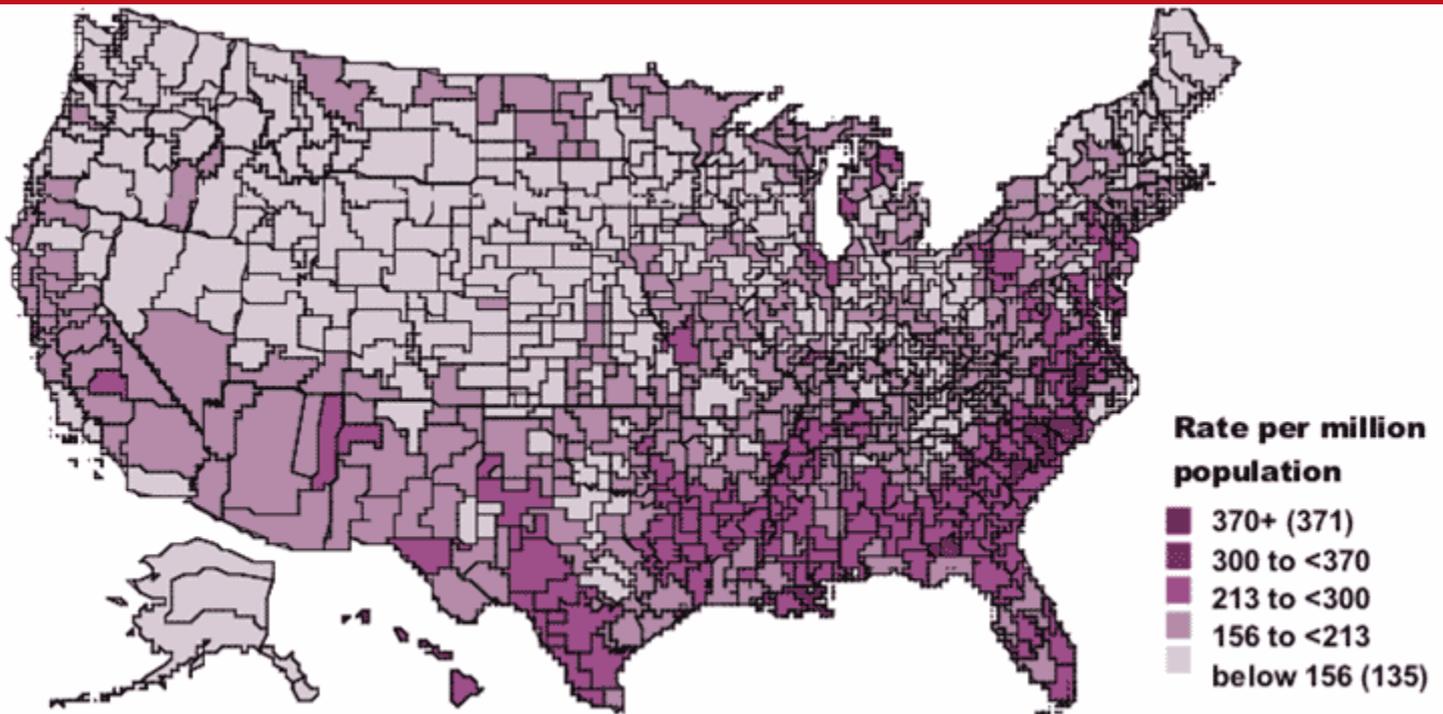
Incident Rates by Primary Diagnosis

(per million population, unadjusted)



Incidence of Kidney Failure

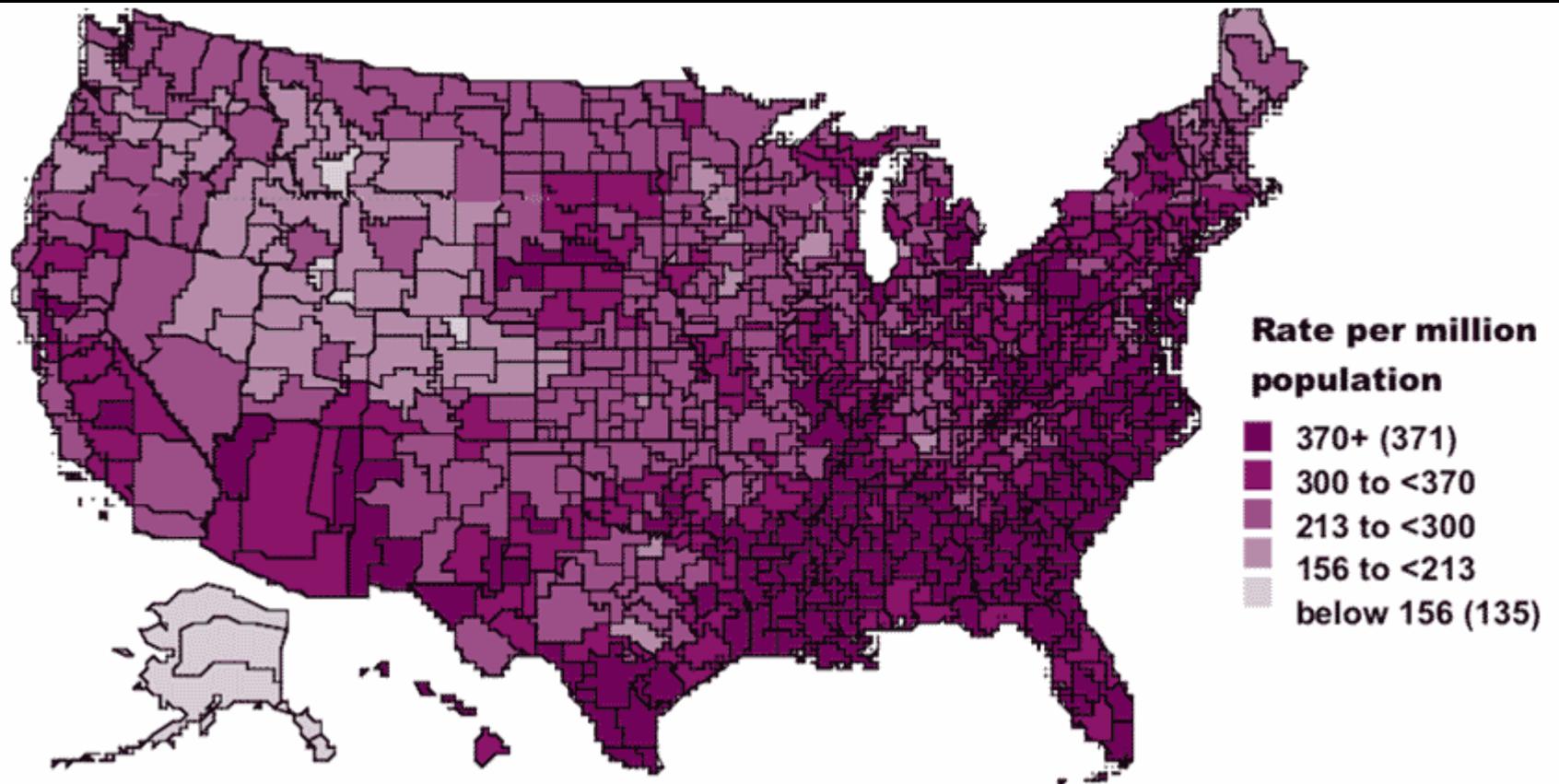
per million population, 1990, by HSA, unadjusted



USRDS, 2000

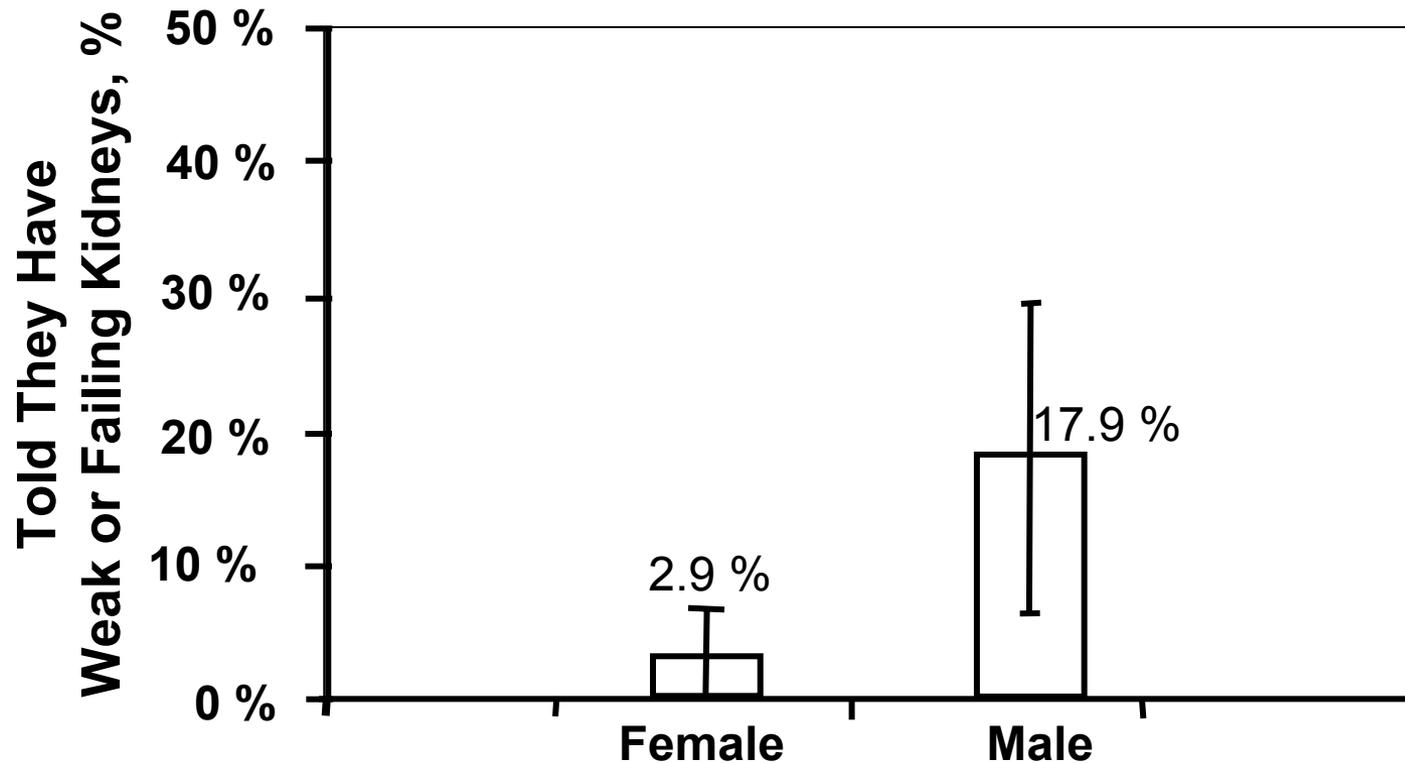
Incidence of Kidney Failure

per million population, 2000, by HSA, unadjusted



USRDS, 2000

Less Than 20% of People with CKD Are Aware



Who To Test for Chronic Kidney Disease

Regular testing of people at risk

- Diabetes
- Hypertension
- Relative with kidney failure

How To Test for Chronic Kidney Disease

- “Spot” urine albumin to creatinine ratio
- Estimate GFR from serum creatinine using the MDRD prediction equation

Note:

24 hour urine collections are NOT needed

Diabetics: should be tested once a year.

Others at risk: less frequently as long as normal.

Primary Care Providers Must Be Engaged

- 1) 7.6 million people with GFR 30-60 ml/min/1.73m²
- 2) About 4,500 full-time nephrologists
- 3) Nearly 2,000 new patients per nephrologist

Therefore, 7 new patients per day per nephrologist

At What Level of Creatinine Does a 65-Year-Old Diabetic, Hypertensive White Woman Weighing 50 Kilograms Have CKD?

77% Said:

Creatinine > 1.5 mg / dl

$$\text{GFR} = 37 \text{ ml/min} / 1.73 \text{ m}^2$$

$$\text{Ccreat} = 30 \text{ ml/ min}$$

Creatinine = 1.0 for GFR = 59 ml/min/1.73 m²

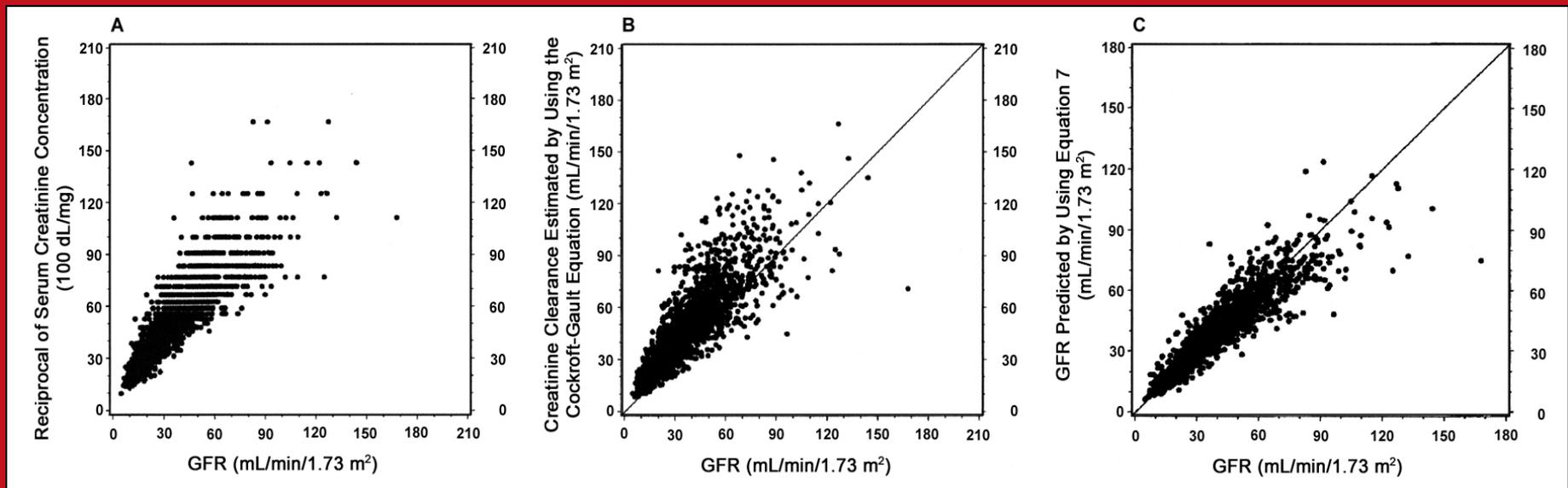
Laboratory Working Group

- **Routinely report estimated GFR**
 - IHS, VA, many other systems
 - Quest and LabCorp
 - France and coalition of willing
- **Program to standardize and improve serum creatinine measurements**

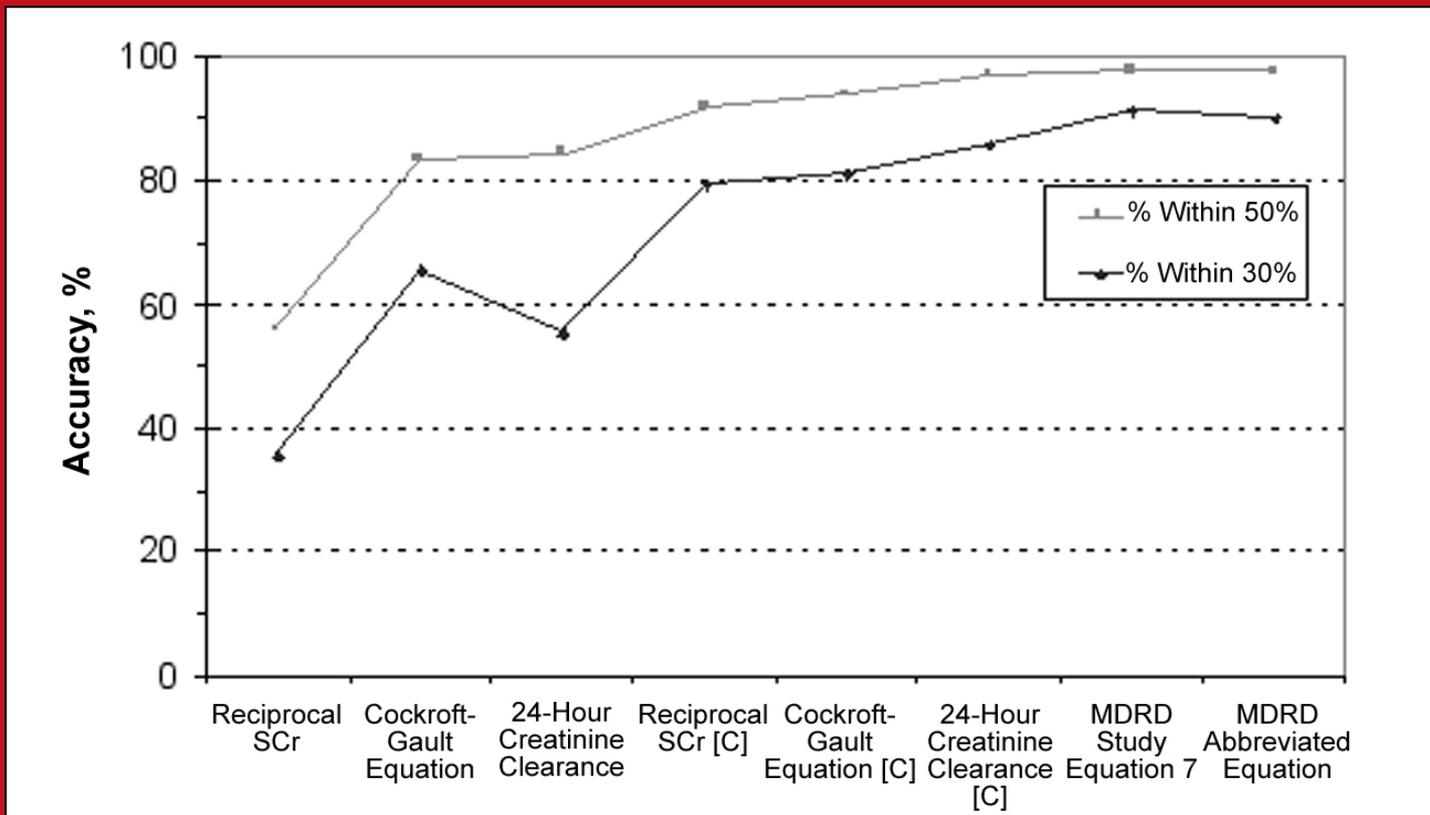
MDRD Study 4-Variable Formula for Estimating GFR

$$\text{GFR (ml/min/1.73 m}^2\text{)} = 186 \times (P_{\text{cr}})^{-1.154} \times (\text{Age})^{-0.203} \times (0.742 \text{ if female})$$
$$\times (1.210 \text{ if African American})$$

Estimates of GFR vs. Measured GFR Among MDRD Study Baseline Cohort



Accuracy of Different Estimates of GFR in Adults



MDRD EQUATION

In adults, the best equation for estimating glomerular filtration rate (GFR) from serum creatinine is the MDRD equation.^{1, 2}

$$\text{GFR (ml/min/1.73m}^2\text{)} = 186 \times (\text{P}_{\text{cr}})^{-1.154} \times (\text{Age})^{-0.203} \times (0.742 \text{ if female}) \times (1.210 \text{ if African American})$$

The equation requires 4 variables:

- serum creatinine
- age
- sex
- African American or not

Since a patient's race is often not available to clinical laboratories, a good alternative is to report estimated GFR values for both African Americans and non-African Americans (see Sample Reports below). Note that the equation **does not require weight** because the result is reported normalized to 1.73m² body surface area, which is an accepted average adult surface area.

REPORTING VALUES

We presently recommend reporting values above 60 ml/min/1.73m² merely as "above 60 ml/min/1.73m²" not as an exact number such as 92 ml/min/1.73m². For values below 60 ml/min/1.73m², the report should give the numerical estimate such as "32 ml/min/1.73m²" (see Sample Reports below).

There are 3 reasons for this recommendation:

1. The equation has been most extensively evaluated in people with some degree of renal insufficiency.
2. Inter-laboratory differences in calibration of the creatinine assay have their greatest impact in the near normal range and therefore lead to greater inaccuracies.³
3. Quantification of GFR below 60 ml/min/1.73m² has more clinical implications than above that level.

SAMPLE REPORTS

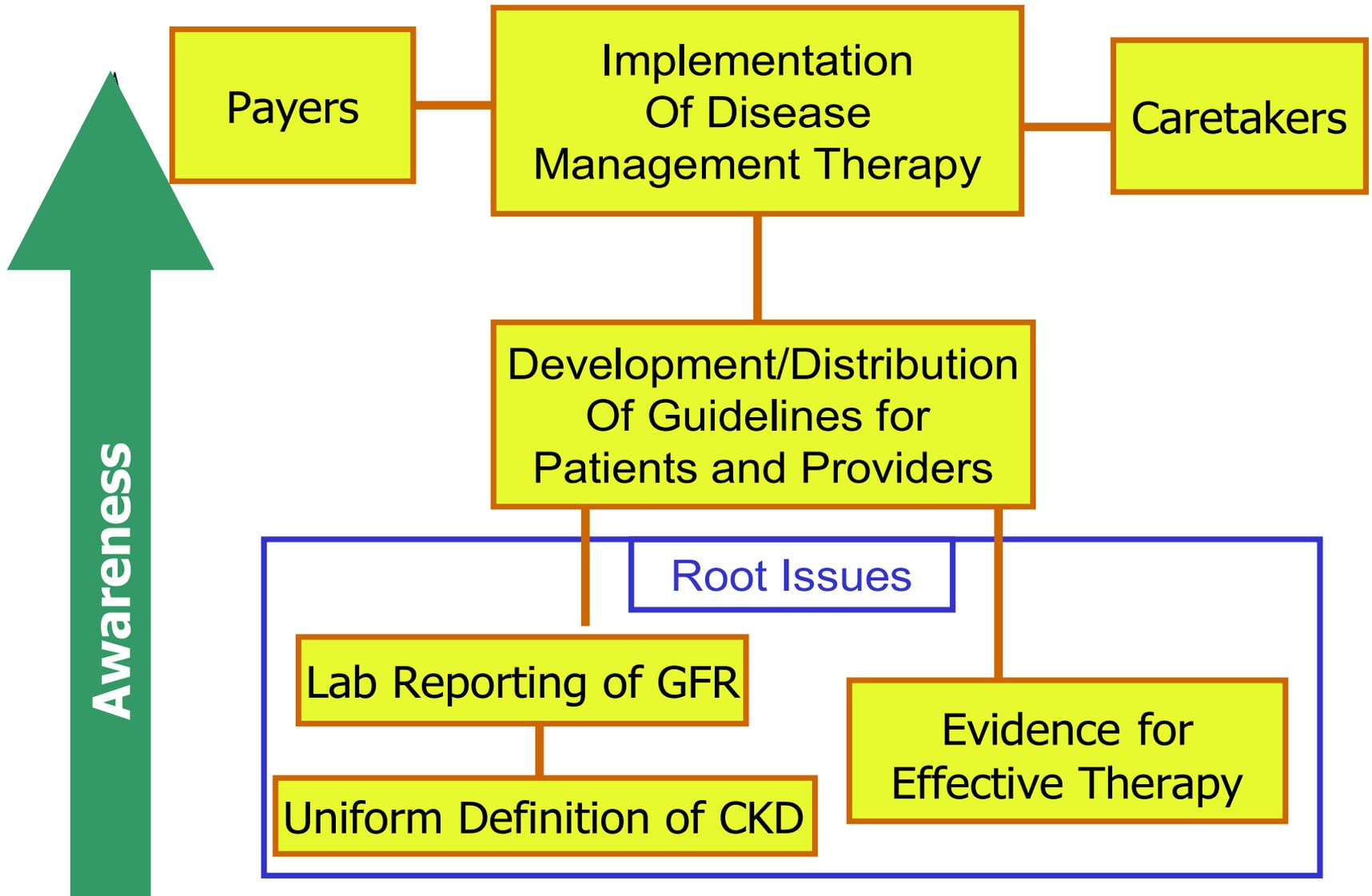
<p>55-year old man Serum creatinine = 1.1 mg/dl Estimated GFR greater than 60 ml/min/1.73m²</p>	<p>Normal Range for GFR estimate for Age and Sex</p> <table border="0" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Age (year)</td> <td colspan="3" style="width: 85%;">Men GFR (ml/min/1.73 m²)</td> </tr> <tr> <td></td> <td style="width: 20%;">Mean</td> <td style="width: 20%;">-2 SD</td> <td style="width: 20%;">+2 SD</td> </tr> <tr style="border-top: 1px solid black;"> <td>50-59</td> <td>93</td> <td>56</td> <td>130</td> </tr> </table>	Age (year)	Men GFR (ml/min/1.73 m ²)				Mean	-2 SD	+2 SD	50-59	93	56	130
Age (year)	Men GFR (ml/min/1.73 m ²)												
	Mean	-2 SD	+2 SD										
50-59	93	56	130										

<p>60-year old woman Serum creatinine = 1.8 mg/dl Estimated GFR = 31 ml/min/1.73m² if non-African American Estimated GFR = 37 ml/min/1.73m² if African American</p>	<p>Normal Range for GFR estimate for Age and Sex</p> <table border="0" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Age (year)</td> <td colspan="3" style="width: 85%;">Women GFR (ml/min/1.73 m²)</td> </tr> <tr> <td></td> <td style="width: 20%;">Mean</td> <td style="width: 20%;">-2 SD</td> <td style="width: 20%;">+2 SD</td> </tr> <tr style="border-top: 1px solid black;"> <td>60-69</td> <td>75</td> <td>45</td> <td>104</td> </tr> </table>	Age (year)	Women GFR (ml/min/1.73 m ²)				Mean	-2 SD	+2 SD	60-69	75	45	104
Age (year)	Women GFR (ml/min/1.73 m ²)												
	Mean	-2 SD	+2 SD										
60-69	75	45	104										

<p>60-year old man Serum creatinine = 1.4 mg/dl Estimated GFR = 55 ml/min/1.73m² if non-African American Estimated GFR greater than 60 ml/min/1.73m² if African American</p>	<p>Normal Range for GFR estimate for Age and Sex</p> <table border="0" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Age (year)</td> <td colspan="3" style="width: 85%;">Men GFR (ml/min/1.73 m²)</td> </tr> <tr> <td></td> <td style="width: 20%;">Mean</td> <td style="width: 20%;">-2 SD</td> <td style="width: 20%;">+2 SD</td> </tr> <tr style="border-top: 1px solid black;"> <td>60-69</td> <td>81</td> <td>49</td> <td>113</td> </tr> </table>	Age (year)	Men GFR (ml/min/1.73 m ²)				Mean	-2 SD	+2 SD	60-69	81	49	113
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	Mean	-2 SD	+2 SD										
60-69	81	49	113										

Why an Emphasis on Creatinine?

- 1) Serum creatinine is much more frequently ordered than quantitative urinary albumin
- 2) Serum creatinine is harder to interpret than albuminuria
- 3) Ordering urinary albumin presupposes concern for CKD



Manufacturers Forum

Summary

- 1) CKD is a large and poorly recognized condition
- 2) Because CKD is largely asymptomatic, laboratory diagnosis is critical
- 3) Provision of a GFR estimate from serum creatinine is possible and desirable