

# **Data Speaks: What the numbers tell us about previous quality initiatives and options for the future**

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## Disclosures: Allan Collins Views on care

- Institutional Grants and Contract: NIH, HRSA, Amgen, AMAG Pharma, Akebia, AstraZeneca, DaVita, Fresenius, Hospira, Merck, NxStage, Novartis, Peer Data Coordinating Center, Onyx, ZS Pharma, Keryx, Zoll
- Consulting Epidemiology: Amgen, Bayer, Hospira, NxStage, Relypsa, ZS Pharma
- Clinical Trial Phase 1, 2 & Data Safety Monitoring Committee: Akros, Akebia, Bayer, Lily
- Dialysis Providers: Executive Director Peer Kidney Care Initiative with 6 NPO and 7 FP provider groups

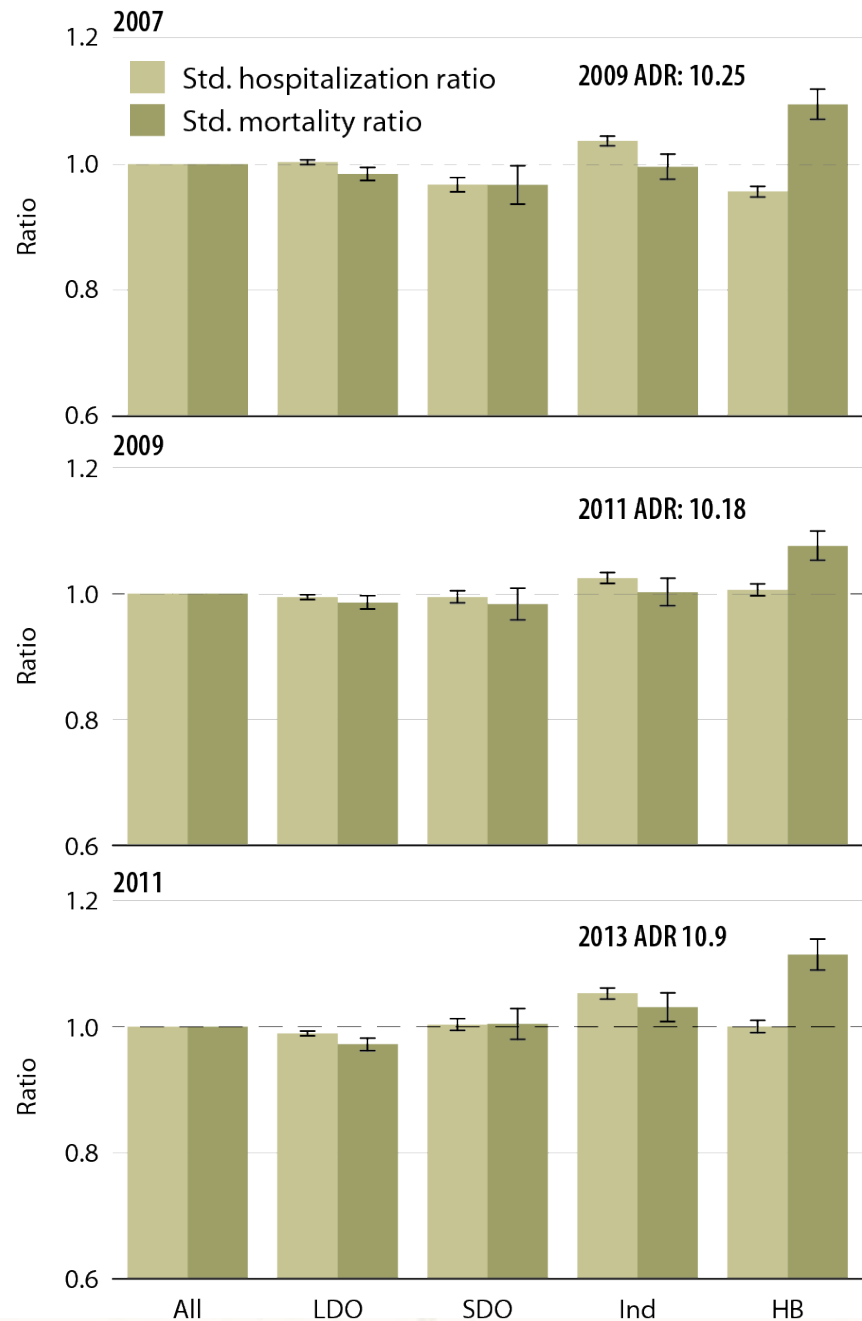
# Approaches to improve outcomes for populations

- **Public Health setting of targets for specific domains of care and outcomes assessed over 5-10 years**
  - **Healthy People 2010 and 2020 Kidney objective targets for 10 years**
  - **WHO NCD objectives to reduce mortality: 10 year target**
    - **20% reduction in NCD deaths by 2020: Objective for 2010**
    - **25% reduction in NCD deaths by 2025: Objective for 2015**
- **Regulatory comparisons of provider performance**
  - **Dialysis Compare: microscopic view on dialysis units**
  - **Quality Improvement Payment (QIP) under the “Bundle” Pay For Performance**
  - **5 Star rating of providers**

# How much progress has been achieved: Long term progress vs narrowing variation

- **Public Health view:** Public reporting of data directed at long term progress
  - **Healthy People 2020 ESRD objectives:** Most of the objectives for 2020 have already been achieved but they have received little attention
    - Objectives show progress across the board
- **Regulatory:** Objective is narrowing of variation in outcomes between providers
  - **Dialysis Compare** rates providers against each other
  - **Based on National Average and bell shaped distribution (Standardized Ratios, 5 Star)**
    - Creates clear winner and losers
    - No assessment of progress over time or regional variation

# SMRs/SHRs in the LDOs, SDOs, independent, and hospital-based units: USRDS data



vol 2 Table 8.1 All-cause standardized mortality ratio, by unit affiliation, 2010–2012

Affiliation	2010	2011	2012
<i>All patients</i>			
<b>Overall</b>	1.02 (1.02-1.03)	1.00 (1.00-1.01)	0.97 (0.97-0.98)
<b>LDO</b>			
Davita	1.05 (1.03-1.06)	1.02 (1.01-1.03)	0.97 (0.96-0.98)
Fresenius	1.03 (1.02-1.05)	1.02 (1.01-1.03)	0.98 (0.97-0.99)
DCI	0.94 (0.91-0.98)	0.92 (0.89-0.96)	0.95 (0.91-0.98)
<b>SDO</b>	1.02 (1.00-1.04)	1.03 (1.01-1.04)	1.00 (0.98-1.01)
<b>Hospital-based</b>	0.93 (0.91-0.95)	0.85 (0.83-0.87)	0.86 (0.84-0.88)
<b>Independent</b>	1.04 (1.02-1.05)	1.01 (1.00-1.03)	1.01 (0.99-1.02)

<i>Black/African American patients</i>			
<b>Overall</b>	0.88 (0.87-0.89)	0.84 (0.83-0.85)	0.81 (0.80-0.82)
<b>LDO</b>			
Davita	0.88 (0.88-0.84)	0.84 (0.83-0.86)	0.80 (0.79-0.82)
Fresenius	0.88 (0.88-0.84)	0.84 (0.83-0.86)	0.80 (0.79-0.82)
DCI	0.88 (0.88-0.84)	0.84 (0.83-0.86)	0.80 (0.79-0.82)
<b>SDO</b>	0.84 (0.80-0.87)	0.84 (0.81-0.88)	0.81 (0.77-0.85)
<b>Hospital-based</b>	0.67 (0.63-0.72)	0.64 (0.59-0.69)	0.61 (0.57-0.66)
<b>Independent</b>	0.83 (0.79-0.87)	0.81 (0.77-0.85)	0.78 (0.74-0.81)

*measures are adjusted for all the above characteristics except*

**There was a major change in the methods to assess Standardized Ratios which favors hospital based units!**

<b>SDO</b>	0.84 (0.80-0.87)	0.84 (0.81-0.88)	0.81 (0.77-0.85)
<b>Hospital-based</b>	0.67 (0.63-0.72)	0.64 (0.59-0.69)	0.61 (0.57-0.66)
<b>Independent</b>	0.83 (0.79-0.87)	0.81 (0.77-0.85)	0.78 (0.74-0.81)

vol 2 Table 8.2 All-cause standardized hospitalization ratio by unit affiliation 2010–2012

Affiliation	2010	2011	2012
	<i>All patients</i>		
<b>Overall</b>	1.01 (1.01-1.02)	1.00 (1.00-1.01)	0.98 (0.98-0.98)
<b>LDO</b>			
Davita	1.02 (1.02-1.03)	1.01 (1.00-1.01)	0.98 (0.98-0.98)
Fresenius	1.01 (1.01-1.02)	1.00 (1.00-1.00)	0.97 (0.97-0.97)
DCI	0.91 (0.90-0.92)	0.91 (0.90-0.92)	0.89 (0.88-0.91)
<b>SDO</b>	1.02 (1.01-1.02)	1.02 (1.02-1.03)	0.98 (0.98-0.99)
<b>Hospital-based</b>	1.07 (1.06-1.08)	1.05 (1.04-1.06)	1.09 (1.08-1.10)
<b>Independent</b>	1.00 (0.99-1.00)	0.99 (0.99-1.00)	0.98 (0.97-0.98)

<b>Hospital-based</b>	1.04 (1.03-1.05)	1.02 (1.01-1.03)	1.06 (1.05-1.08)
<b>Independent</b>	1.00 (0.99-1.01)	1.00 (0.99-1.00)	0.99 (0.98-1.00)

*Black/African American patients*

*body mass index (BMI) at incidence. The White- and Black-specific measures are adjusted*

**The changed methods to assess Standardized Ratios demonstrates hospital based units have disparate results between morality and hospitalizations!**

<b>Hospital-based</b>	1.06 (1.03-1.09)	1.05 (1.03-1.08)	1.11 (1.08-1.14)
<b>Independent</b>	0.97 (0.96-0.99)	0.93 (0.92-0.95)	0.94 (0.93-0.96)

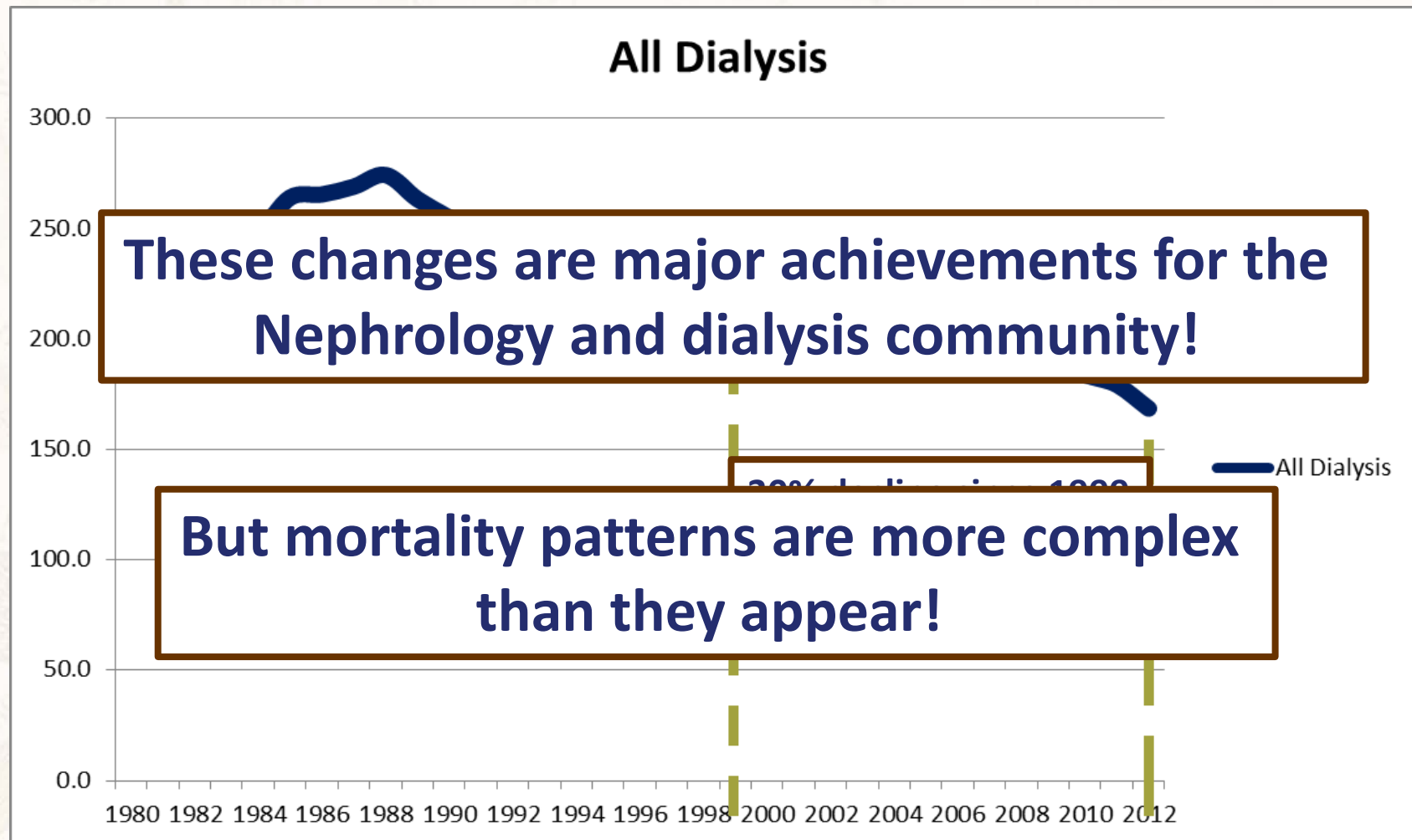
# Standardized Ratios as Static Measures

- The nature of the traditional STD Ratios are cross sectional and measure relative outcomes to a national average
- Any single year for a reported STD ratio generally ignores longer term trends over many years and cumulative trends
- The basic assumptions in using a “National Standard” is that care and outcomes should be universal and access to care is comparable across the US
  - Even if geographic outcomes could have some adjustment, how would they be applicable to local circumstances?
- Different SMR and SHR methods can give different results suggesting comparisons are method dependent!
  - This is a real problem because few would be able to assess it
- **There is an alternative: Assessing trends over time within providers and groups by geography (Provider is their own control)!**

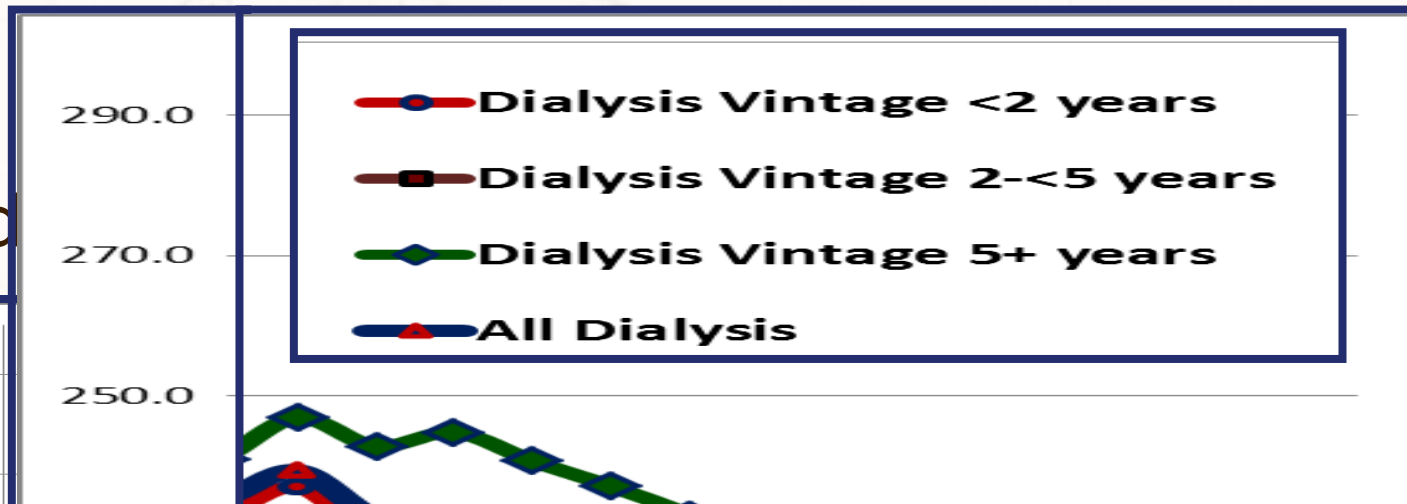


# Trends in Prevalent Dialysis Death Rates 1980-2012: USRDS 2014 ADR Ref Tables H.4

Rates 1980-2012: USRDS 2014 ADR Ref Tables H.4

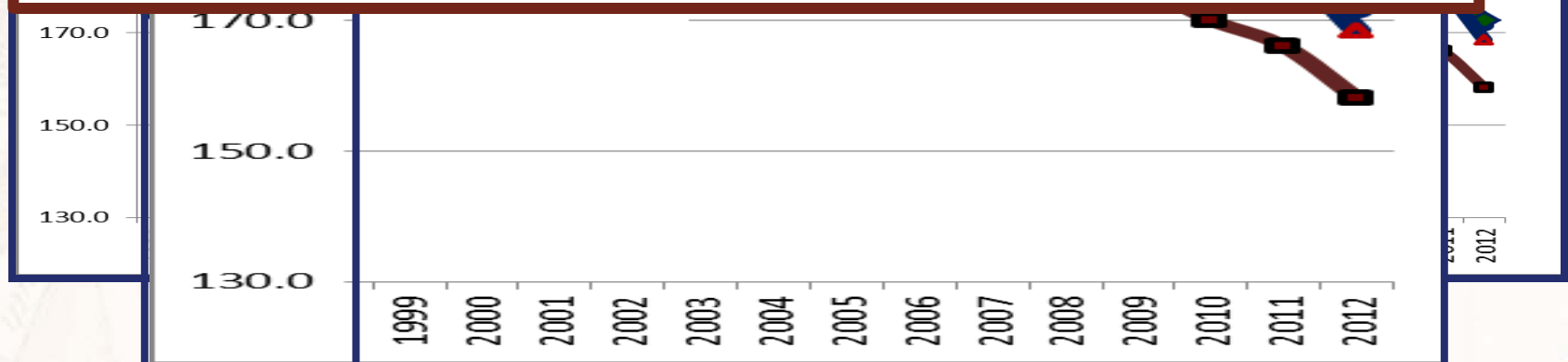


Trend



The trends are similar across vintage but not proportional.

The change is less in the low vintage group and greater with longer vintage



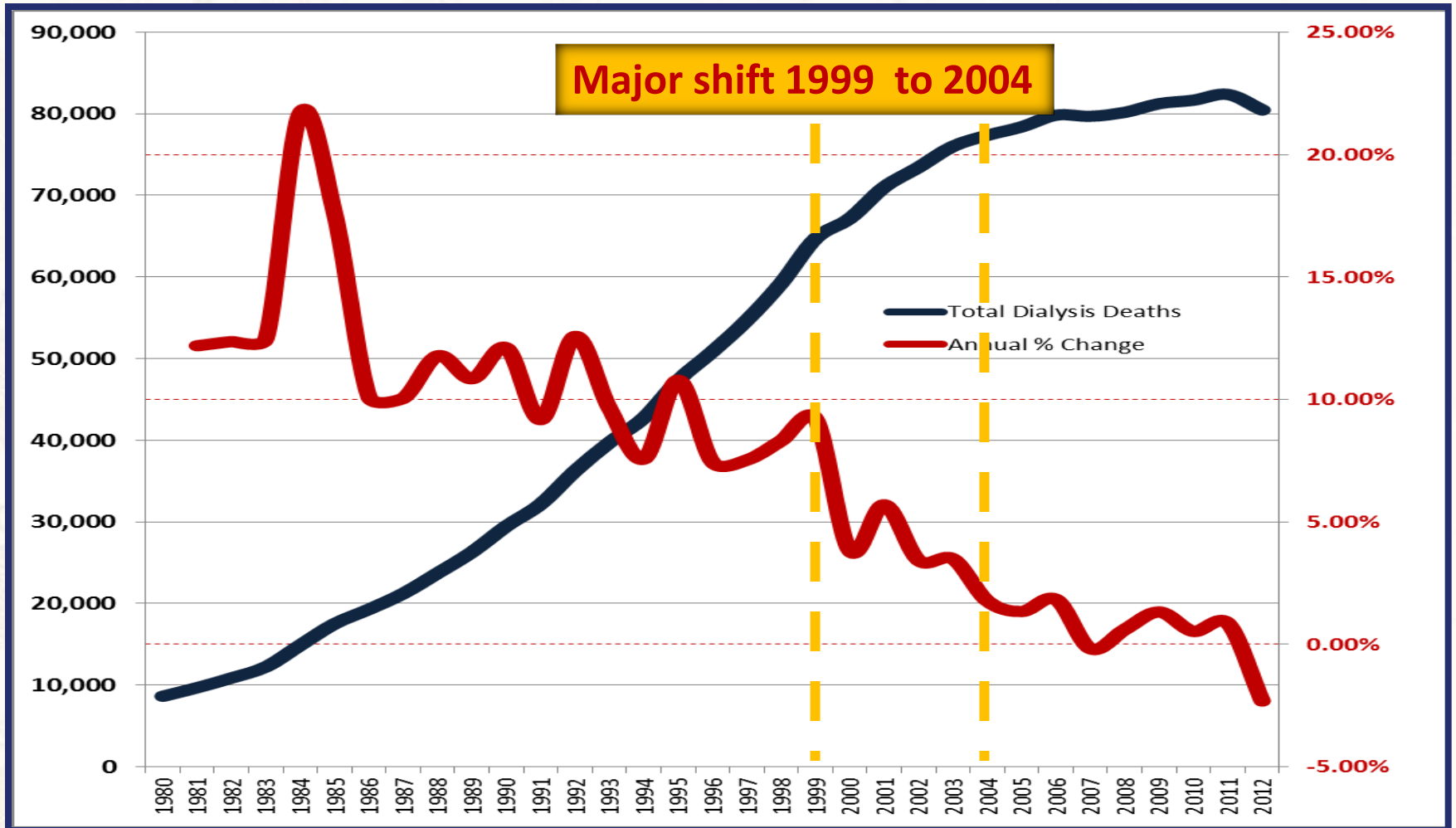
## Trends in outcomes over time

- There has been a major shift in patient mortality over the last 12 years.
- The average US dialysis population death rates are falling such that the relative position of any provider or group of providers may not change over time despite major improvements in outcomes!
- The steady reduction in death rates create challenges in understanding how these observations impact the yearly traditional STD Mortality Ratios.
- One example of major change is the absolute death rates and placement rates of vascular accesses.

## Assessing outcomes: back to the basics

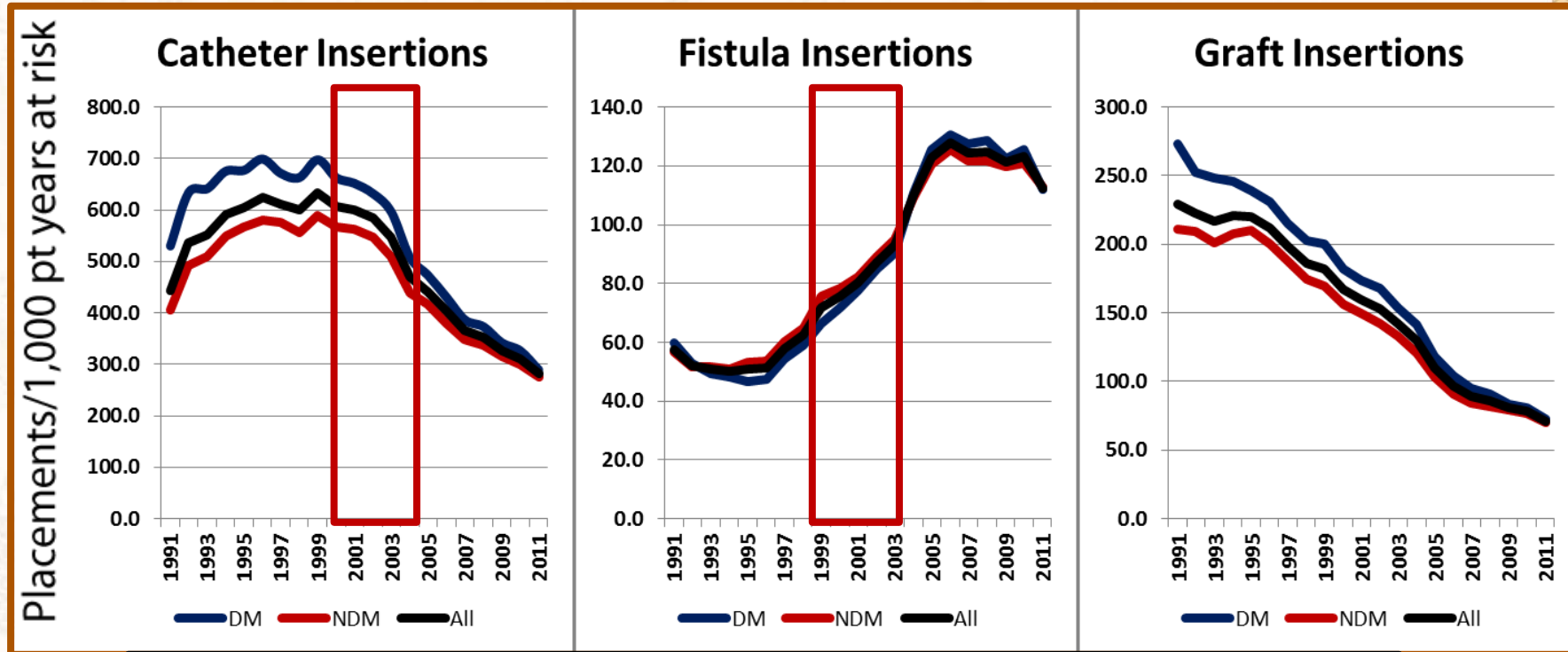
- Start with the trends in absolute death counts
- Compare time sequences with other clinical events
- Assess outcomes across various groups that may be sensitive to mortality and morbidity
- And compare trends within groups over time with minimal adjustments to determine the minimum changes based on age gender, race and cause of ESRD

# Trends in Total Dialysis Deaths 1980 to 2012: USRDS 2014 ADR Ref Table H.3



# Trends in vascular access placement rates: 1991 to 2011

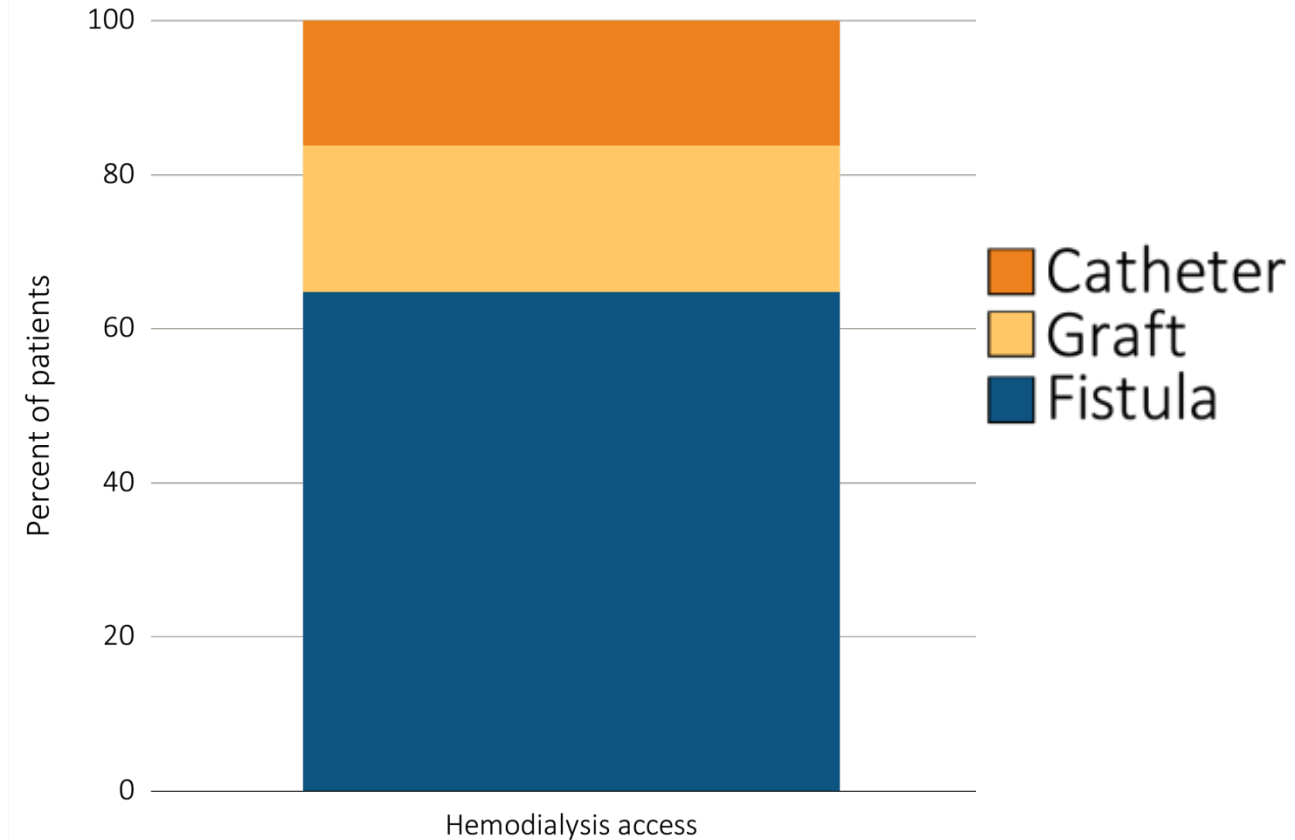
2013 USRDS ADR Ref. Tables Updated by CDRG



**Dialysis Catheter placement rates are  
at their lowest level since 1991**

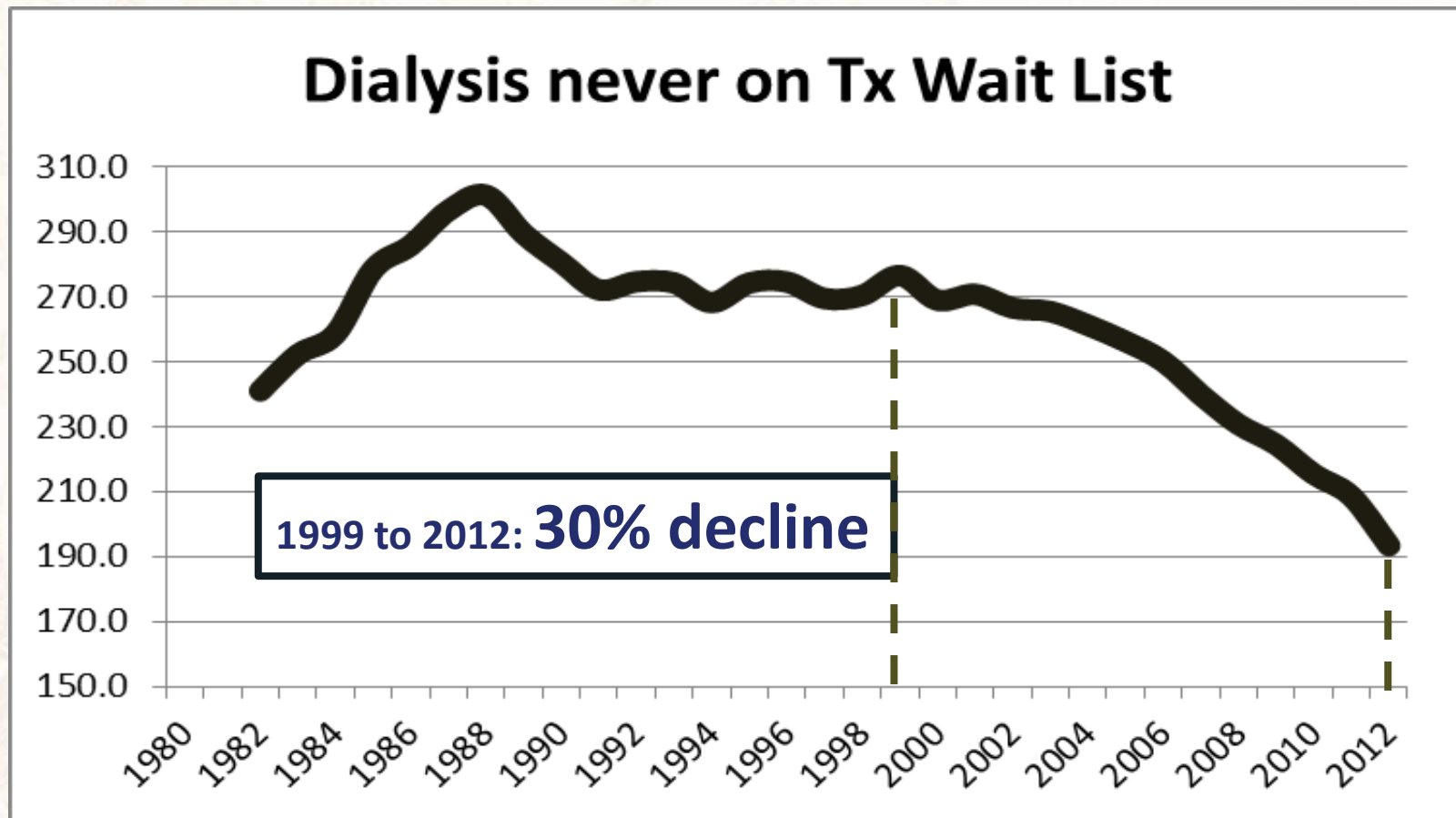
vol 2 Figure 3.1(c) Clinical indicators: Percentage of prevalent patients meeting clinical care guidelines on dialysis adequacy, percentage distribution of achieved mean Hgb among prevalent HD and PD patients, and percentage distribution of VA

## Prevalent Vascular Access distribution 2013



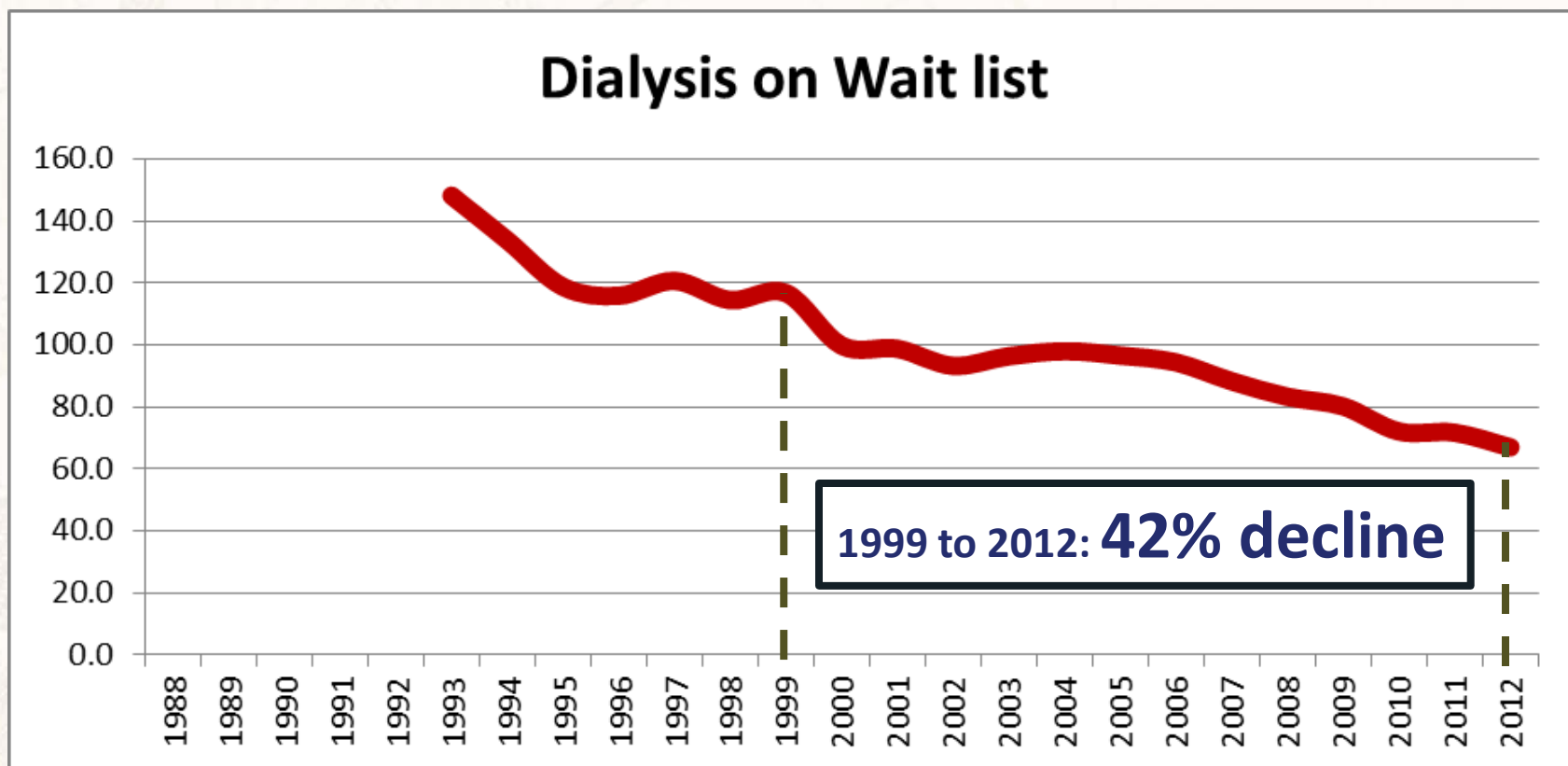
Data Source: CROWNWeb clinical extracts for December 2013. Panel c: HD patients initiating treatment for ESRD at least 90 days prior to December 1, 2013, who were ≥18 years old as December 1, 2013, and who were alive through December 31, 2013. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; Hgb, hemoglobin; Kt/V, see Glossary; PD, peritoneal dialysis; URR, urea reduction ratio; VA, vascular access.

# Trends in Deaths/1,000 Pts Yrs for dialysis Pts never on Tx Wait List: USRDS 2014 ADR Ref Table H.5

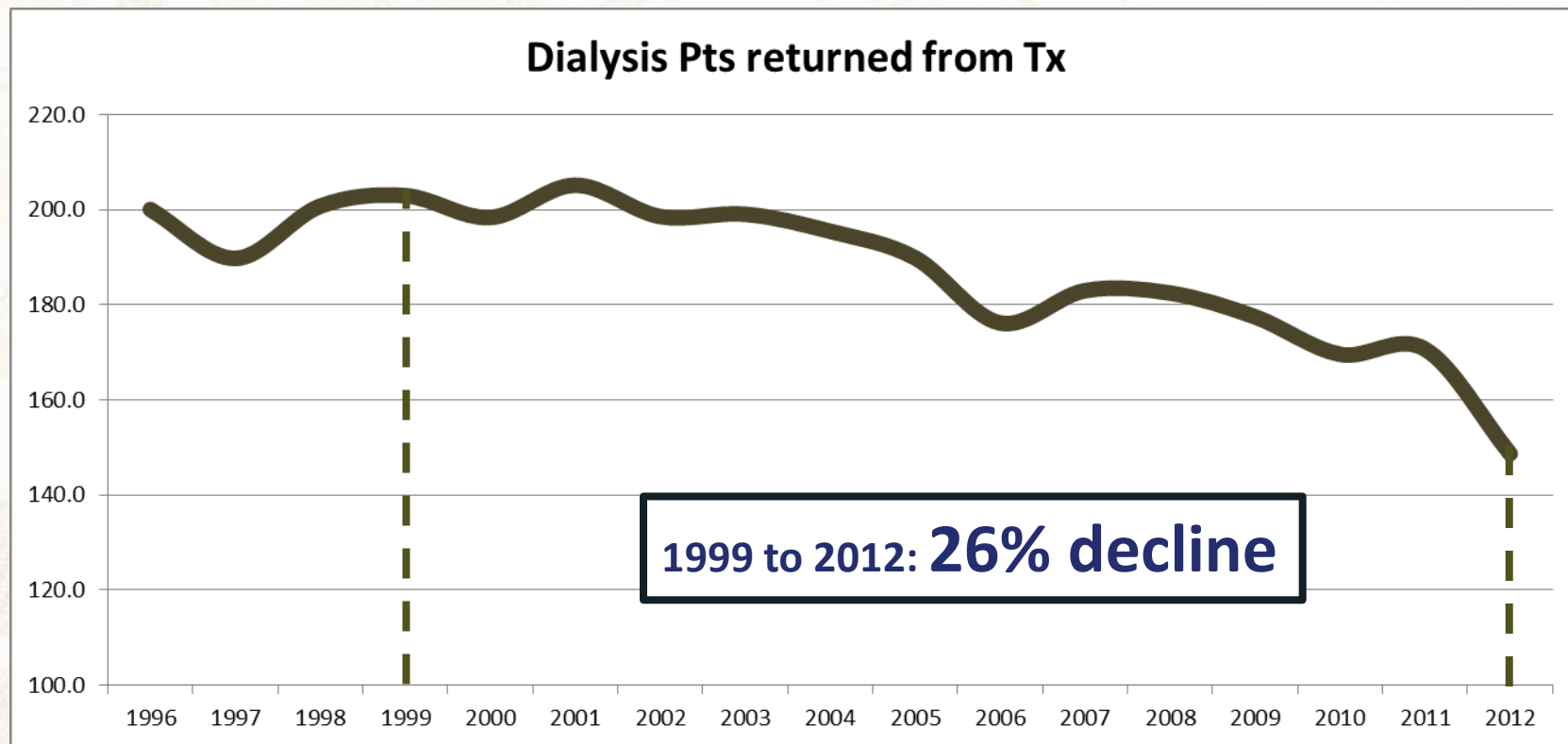




# Trends in Deaths/1,000 Pts Yrs for dialysis Pts on Tx Wait List: USRDS 2014 ADR Ref Table H.6



# Trends in Deaths/1,000 Pts Yrs for dialysis Pts that returned from Tx: USRDS 2014 ADR Ref Table H.7

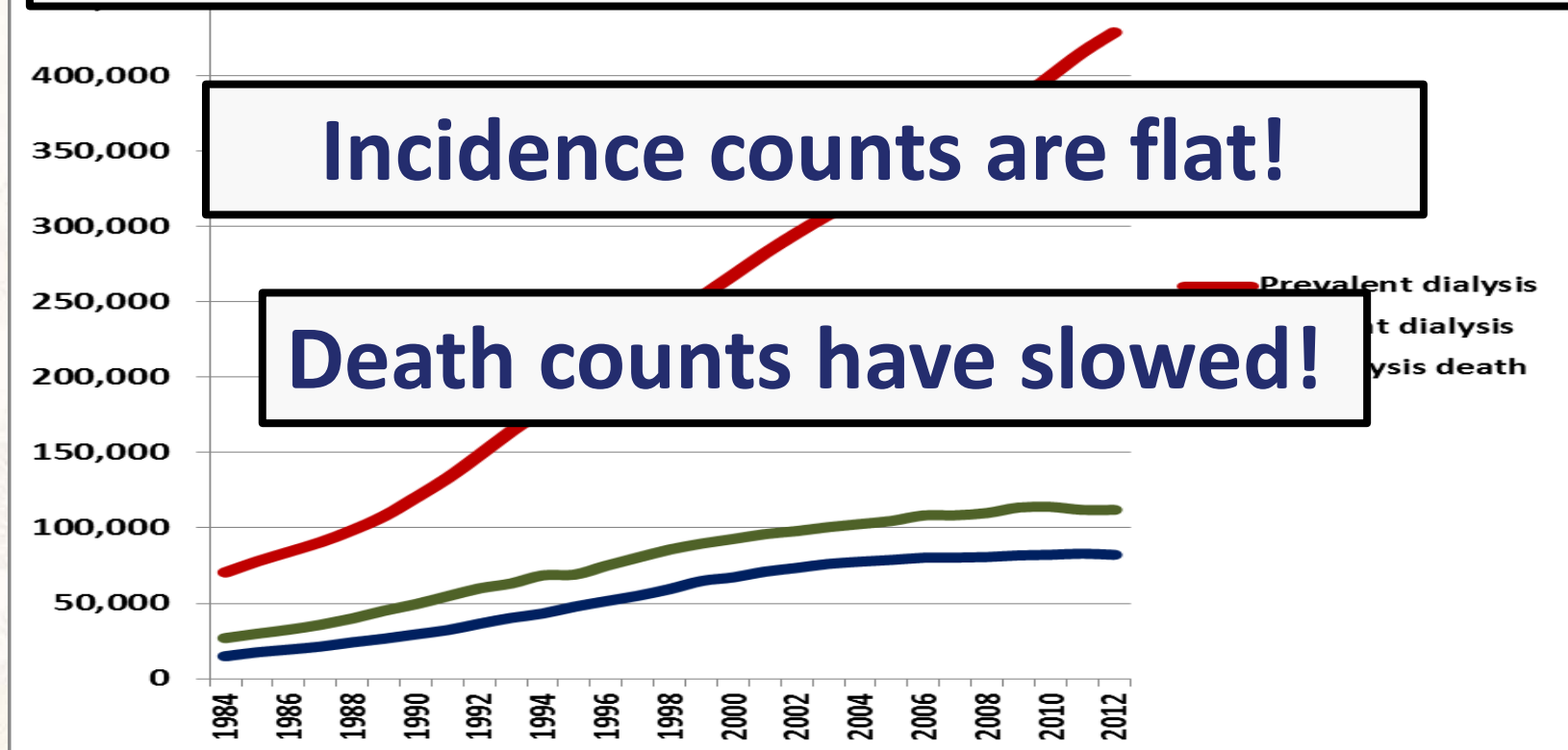


# Changing Death rates and growth of the Dialysis Patients

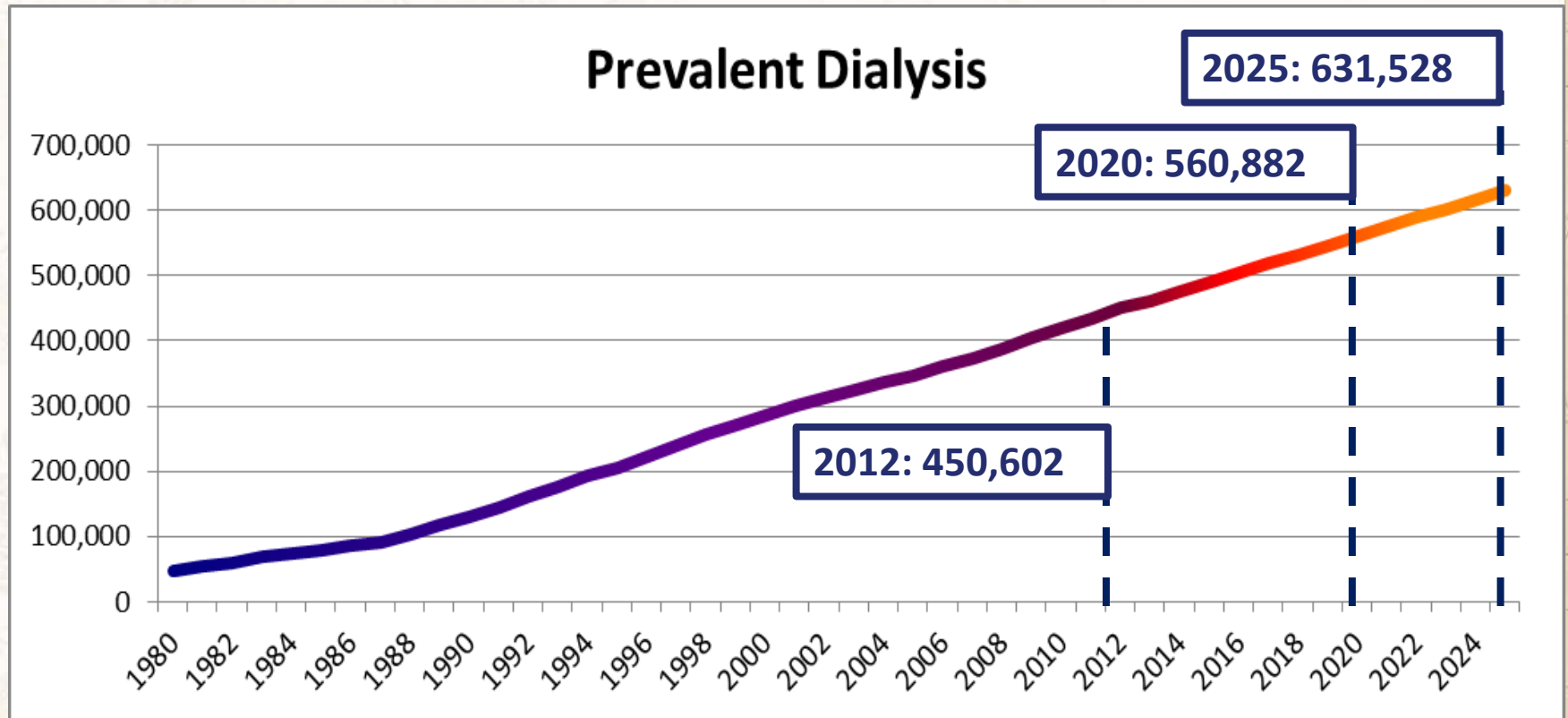
- The falling death rates are wide spread across all groups including those on the Transplant Wait list, Never on the Wait list and those returning from a failed Kidney transplant
- The declining death rates was greatest in those on the transplant wait list (42% from 1999 to 2012)
- These trends are not recognized by the SMRs across providers
- What do these trends mean for future growth of the dialysis program?

# Trends in Prevalent Dialysis, Incident ESRD and Dialysis Death counts 1984 to 2012

**Prevalent Dialysis growth is linear!**



# Projected growth of dialysis 2012 to 2025: Approx. +3%/yr (simple auto-regression) USRDS 2014 Ref Table D.4 data thru 2012



## Dialysis growth and assessing outcomes

# The alternative view from the new Peer Kidney Care Initiative

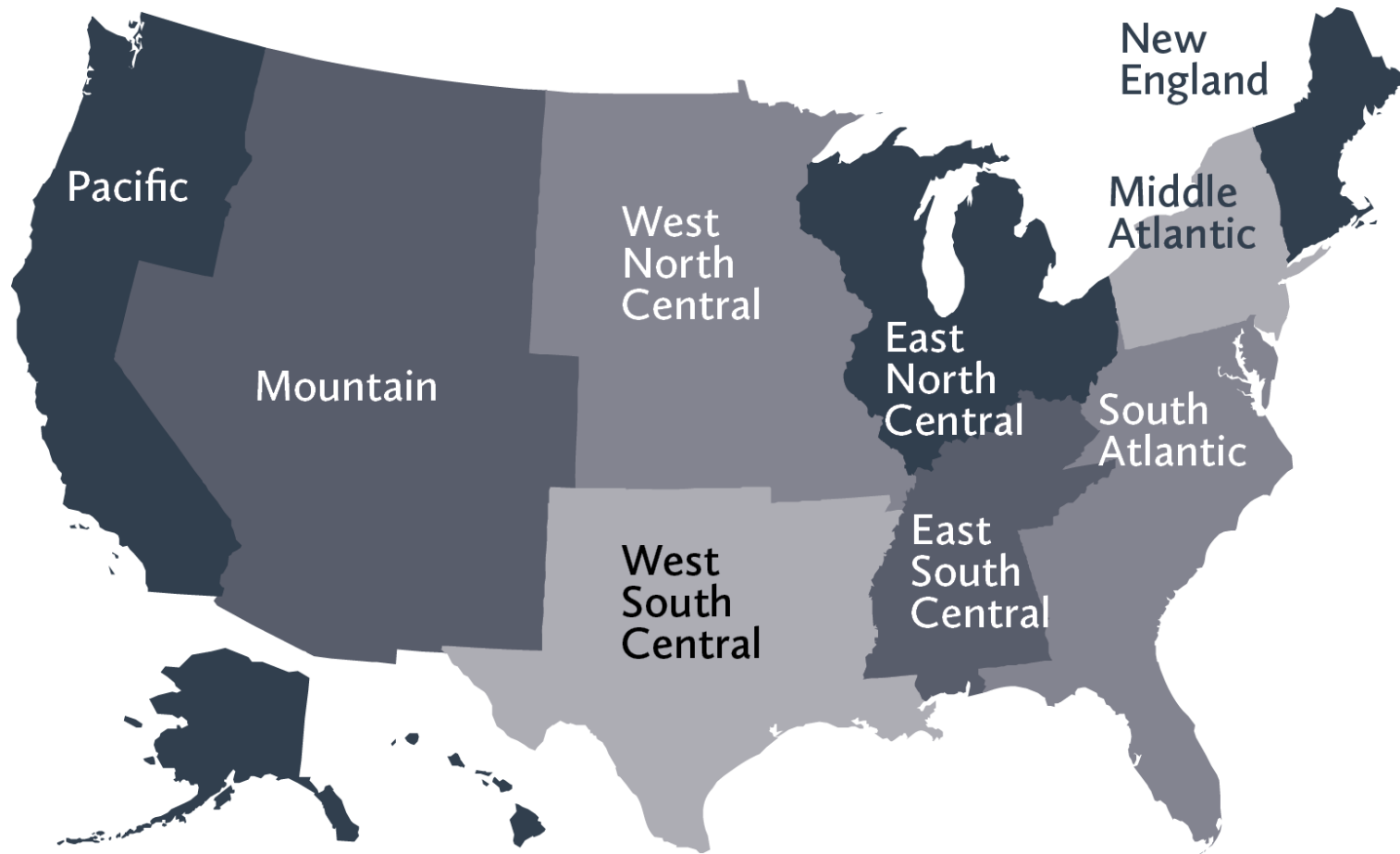
The mix of the prevalent population is shifting over time.

- The shifting vintage of the prevalent populations creates challenges in adjustments and the rate of change in the death rates is not the same across vintage groups.

# Data From the Peer Kidney Care Initiative

- In March of 2014 the Dialysis CMO group was presented information showing a 30% reduction in mortality yet their relative positions in Standardized Ratios changed little over the past 10 years
- The CMO group (6 NPO and 7 FP) engaged CDRG to develop a full report with details on targeted areas to improve outcomes using Medicare data under a consortium research contract
- The thematic development showed Trends in outcomes, Geographic Variation in events and Seasonal Differences in major outcomes

# U.S. Census Divisions





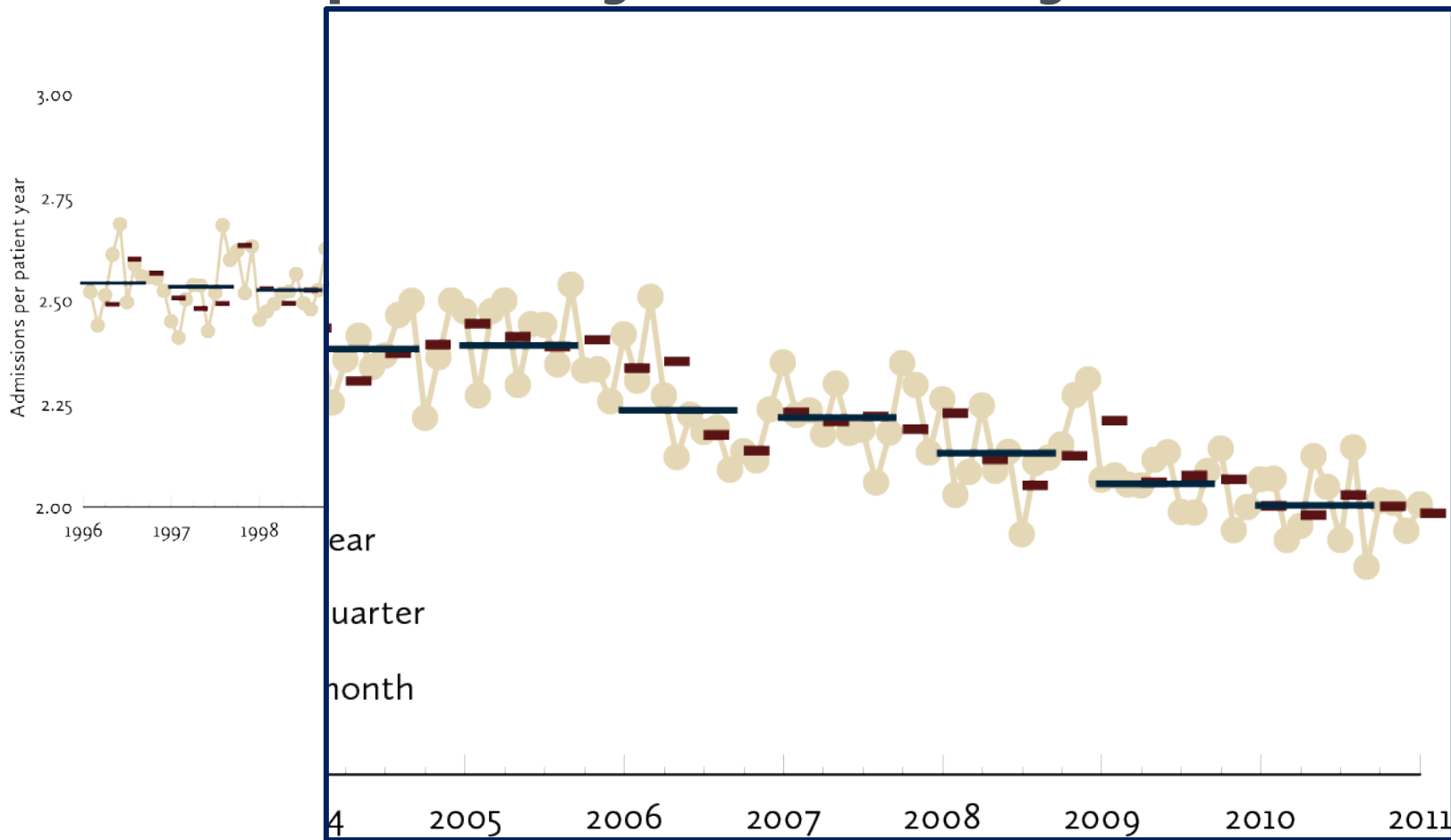


Peer Report:

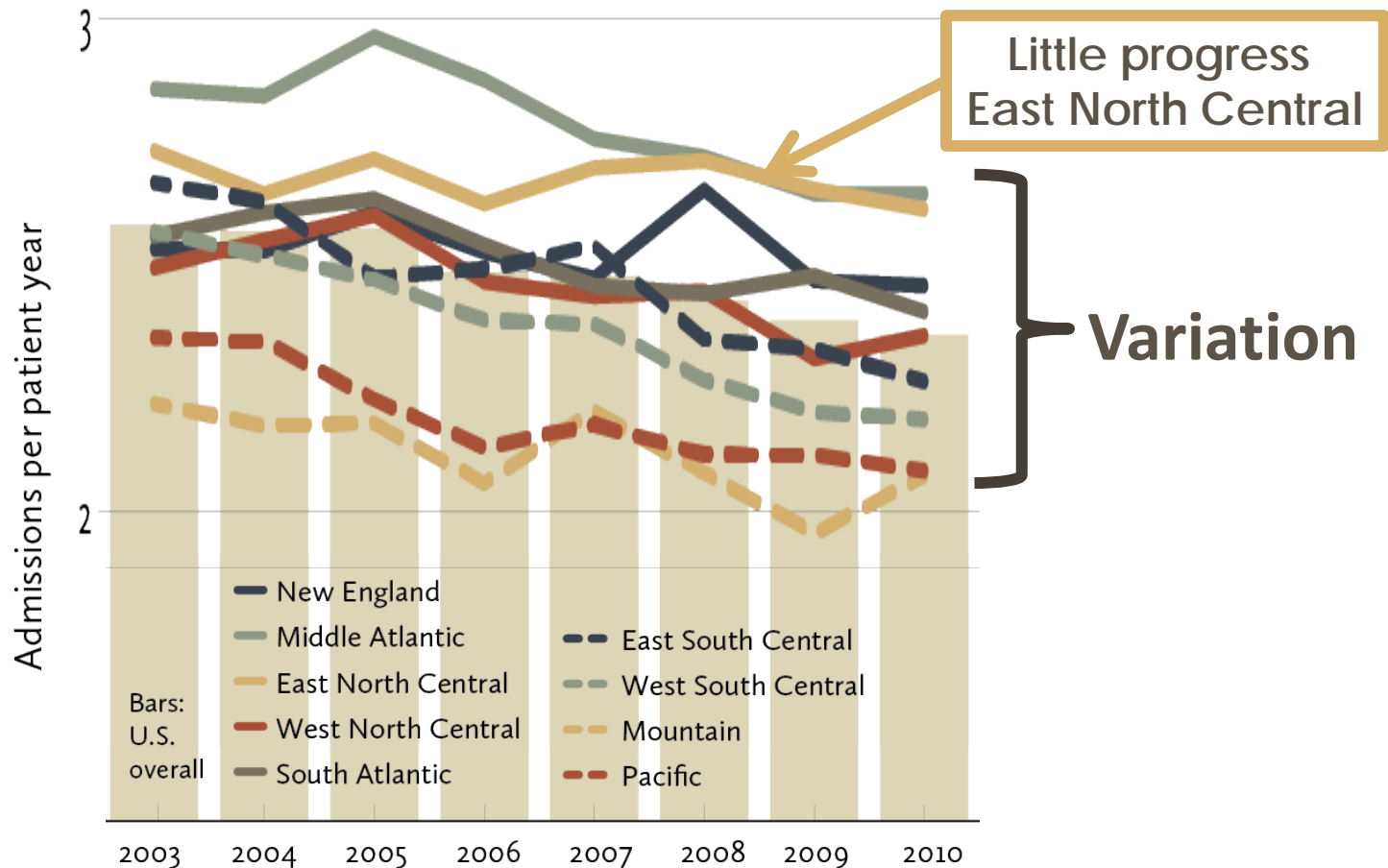
## Hospitalization

Trends, Geographic  
Variation and  
Seasonality

# First-year hospital admission rates among incident dialysis patients, by annual, quarterly, & monthly cohorts






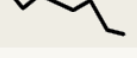



# First-year hospital admission rates among incident dialysis patients, overall & by U.S. Census Division



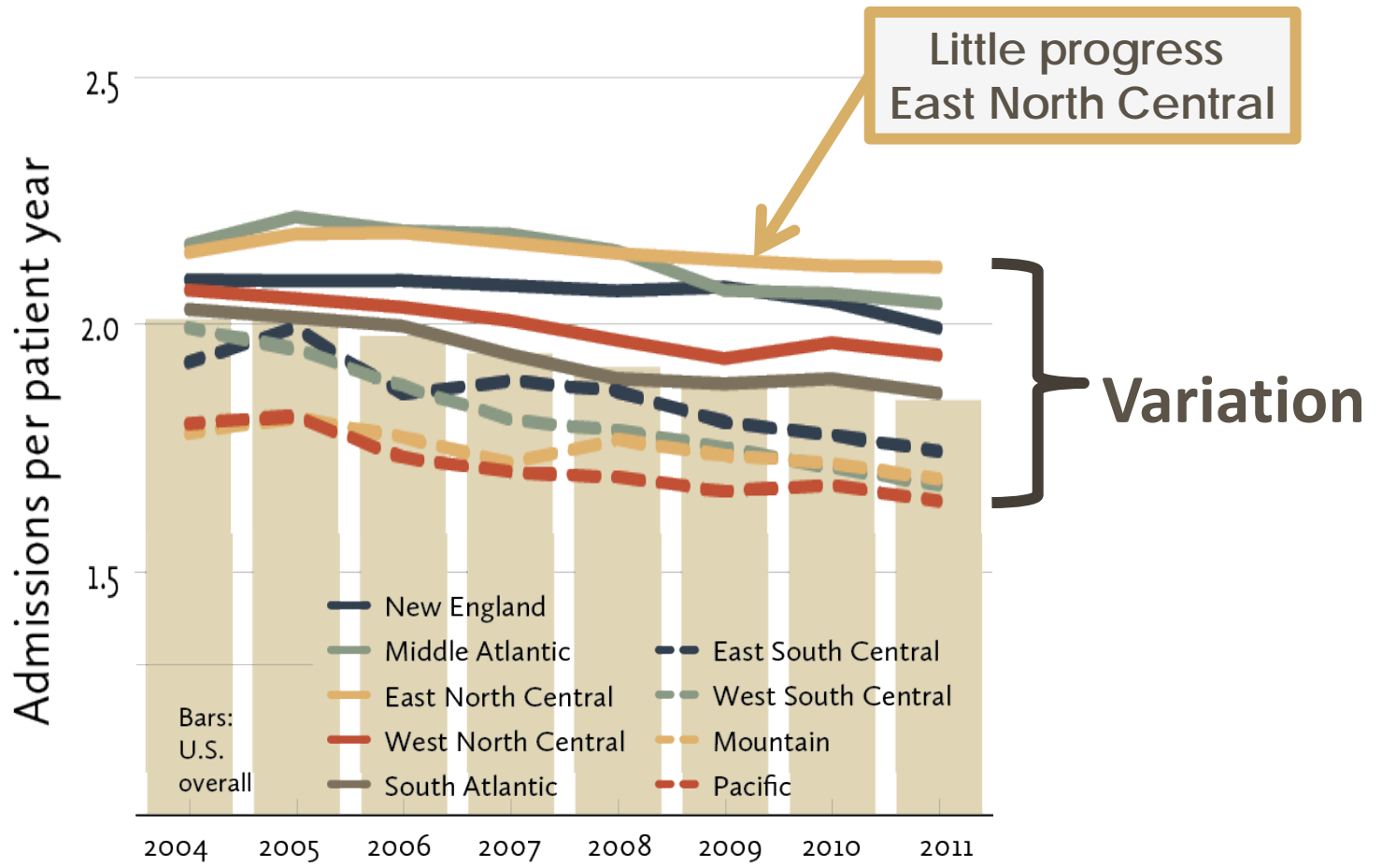
# First-year hospital admission rates among incident dialysis patients: Division 3, East North Central

After first Medicare-covered dialysis session in freestanding facility. Admissions per patient year; APC, Annual Percent Change. Maps show 2010 rates.

DIV	2003	2004	2005	2006	2007	2008	2009	2010	APC	
All	2.73	2.64	2.71	2.62	2.70	2.71	2.65	2.61	-0.3	
Illinois	2.83	2.86	2.84	2.74	2.79	2.79	2.75	2.73	-0.6	
Indiana	2.36	2.20	2.49	2.23	2.43	2.54	2.32	2.46	0.8	
Michigan	2.70	2.63	2.73	2.60	2.73	2.81	2.77	2.70	0.4	
Ohio	2.94	2.81	2.78	2.88	2.87	2.76	2.85	2.69	-0.7	
Wisconsin	2.51	2.25	2.42	2.32	2.23	2.35	1.98	1.92	-3.1	

- ✦ First-year hospital admission rates have fallen 0.3 percent per year in the East North Central states, the smallest rate of decline among all U.S. Census Divisions.
- ✦ Rates in Indiana and Michigan actually tended to increase between 2003 and 2010.
- ✦ Rates in Wisconsin, however, have decreased 3.1 percent per year, one of the ten largest rates of decline in the country.

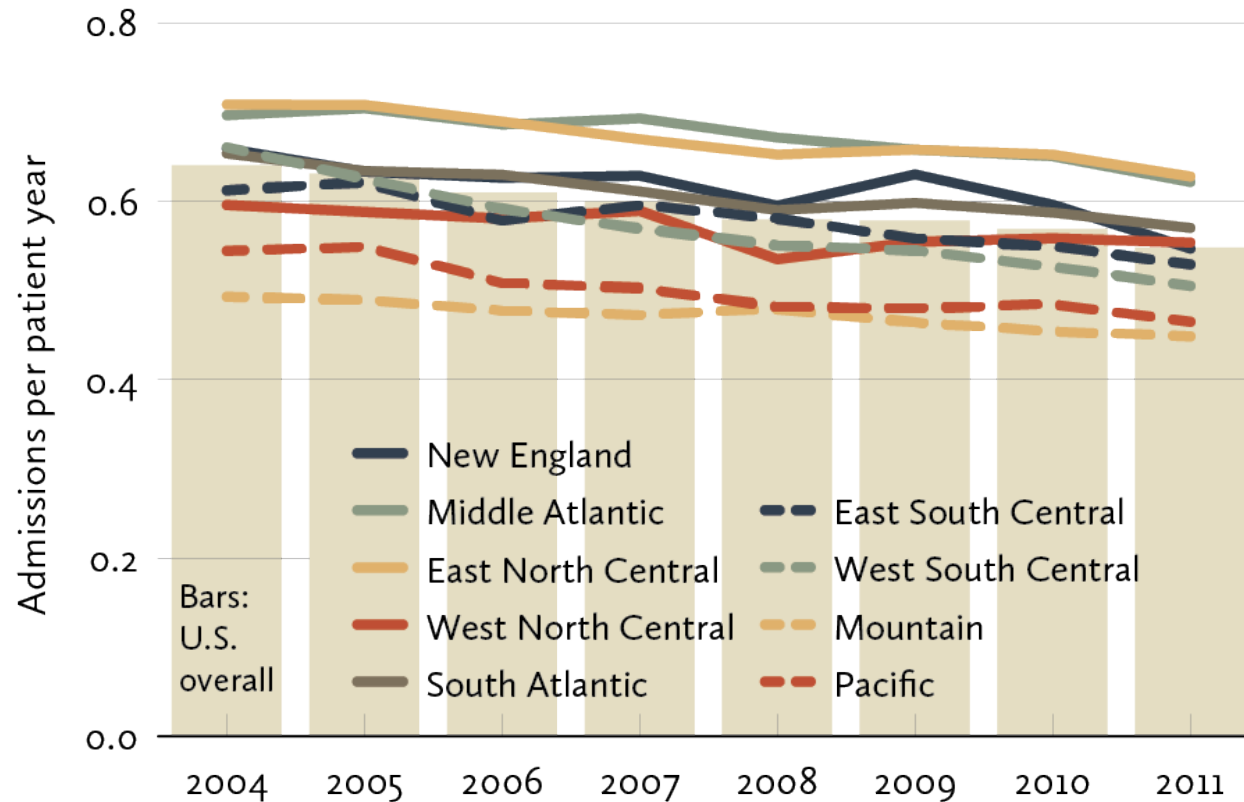
# Hospital admission rates among prevalent dialysis patients, overall & by U.S. Census Division





The  
**East North  
Central** states  
have seen the  
**least**  
**improvement**  
in hospitalization rates

# Cardiovascular disease as the primary discharge diagnosis among prevalent patients: Admission rates, overall & by U.S. Census Division



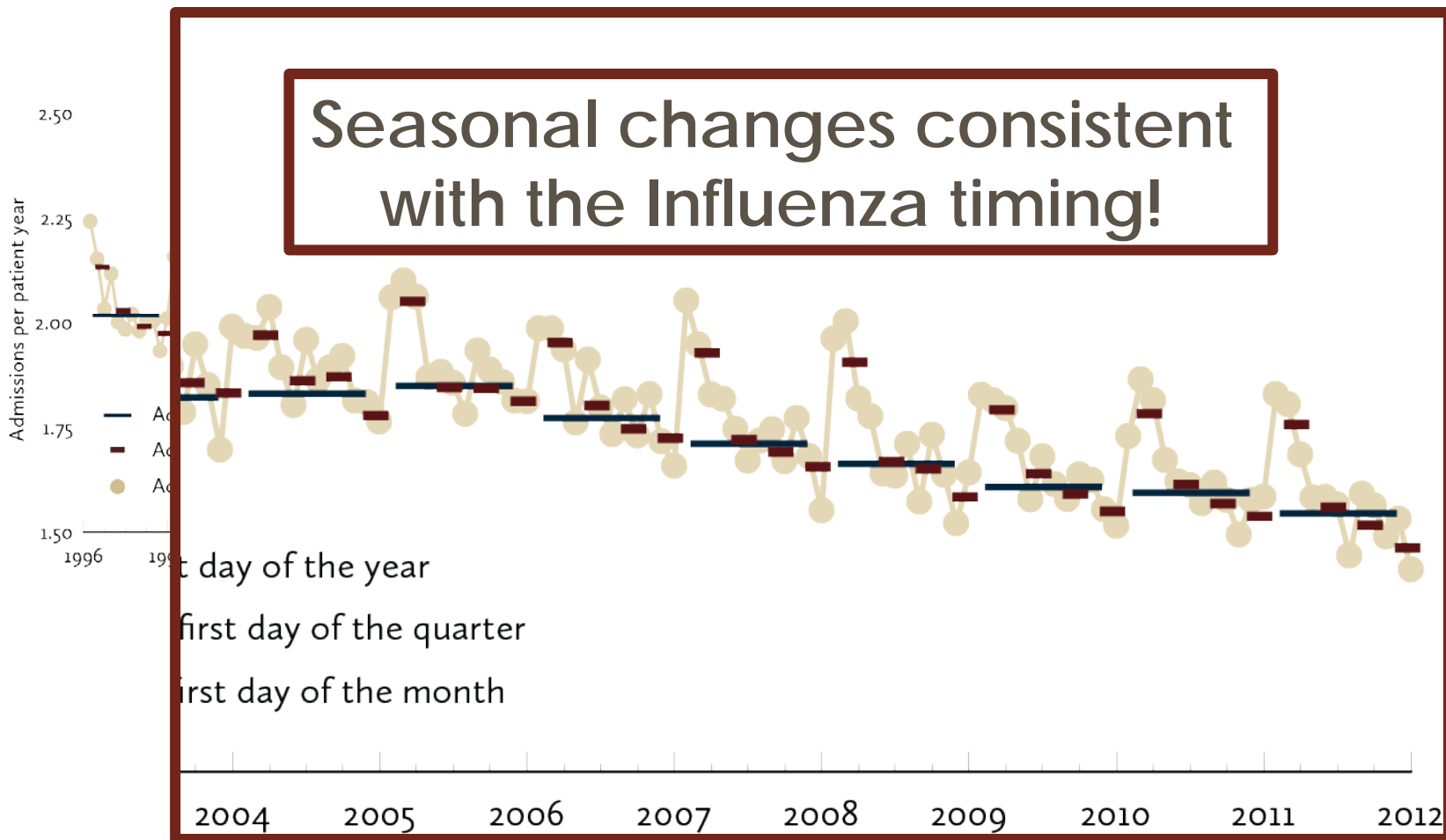


# Trends show progress and geography matters

- **Considerable progress has been achieved overall**
- **Geographic differences are important and can help target efforts for States and ESRD Networks quality initiatives**
- **There is more!**



# Hospital admission rates among prevalent dialysis patients, by annual, quarterly, & monthly cohorts

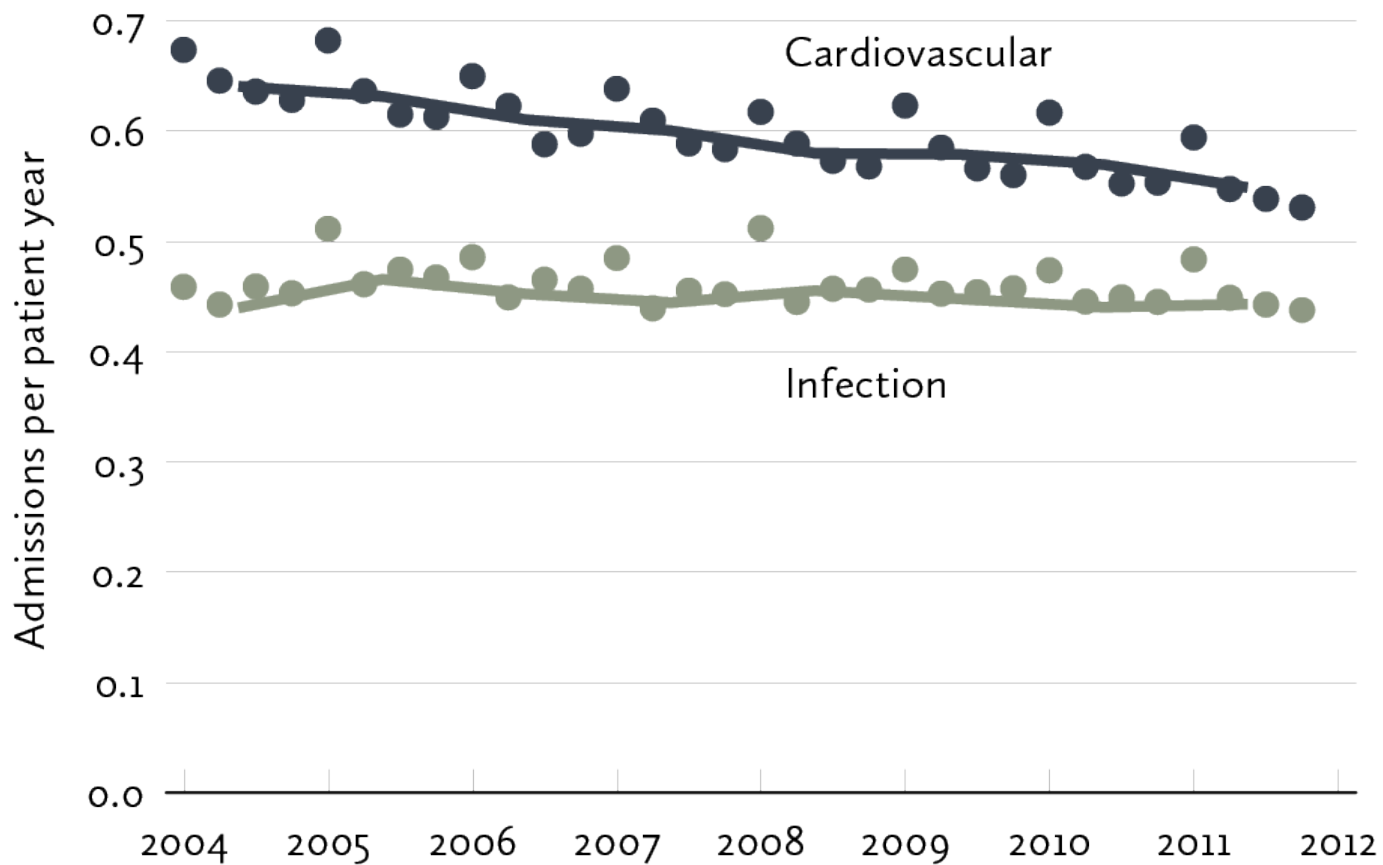




# Hospitalizations Overall: Trending and progress are the central issue

- There are clear geographic differences in event rates over time
- Seasonal differences are also marked and may relate to the reported Influenza seasonal disease
  - Incident population do not show seasonality because they enter at different times of the year
- Trends in event rates should be a major focus within providers and regions to ensure progress is made across the board!

# Hospital admission rates among prevalent dialysis patients, within quarter & year

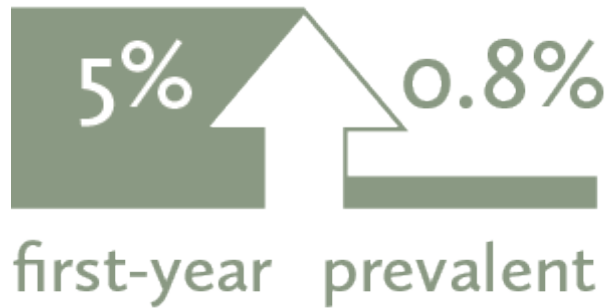


# Hospital admission rates for Cardiovascular Disease



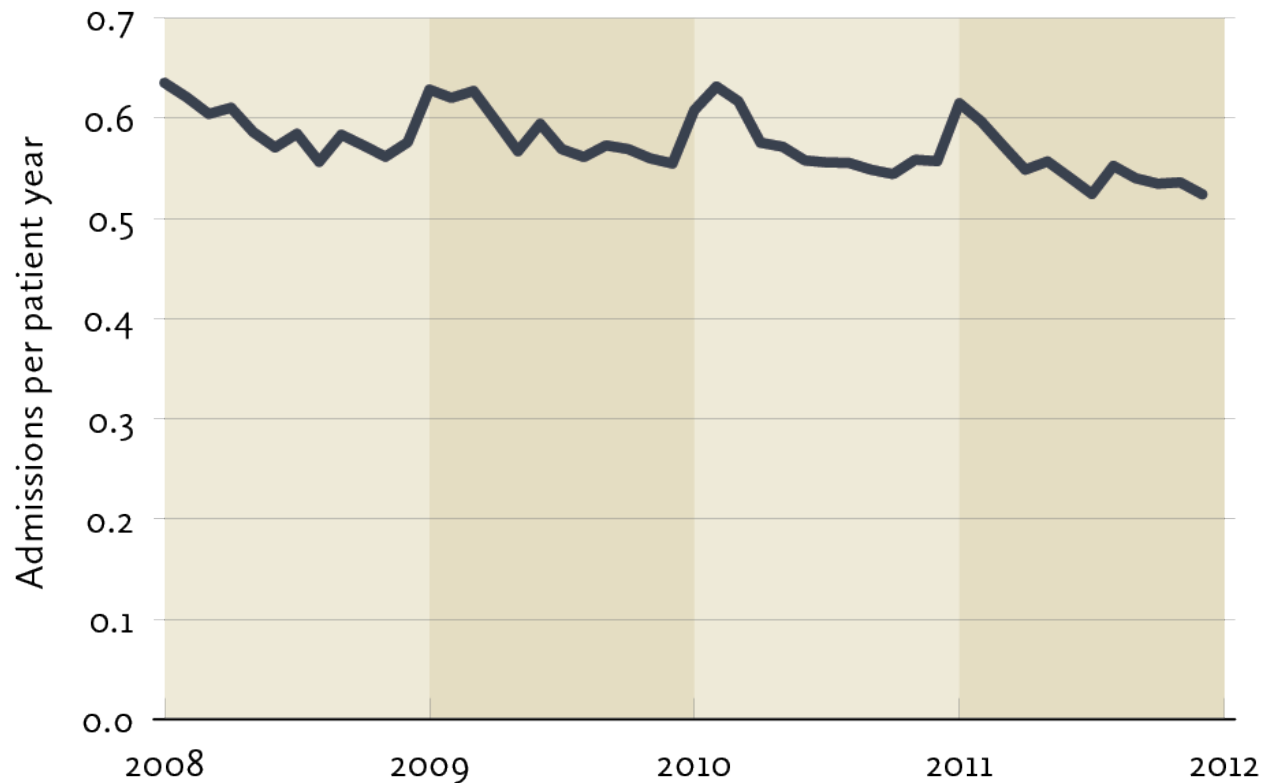
overall admissions per patient year have fallen since 2003/2004

# Hospital admission rates for Infections



and admissions for **infection** are **higher** as well

# Cardiovascular disease as the primary discharge diagnosis among prevalent patients: Admission rates, within calendar month

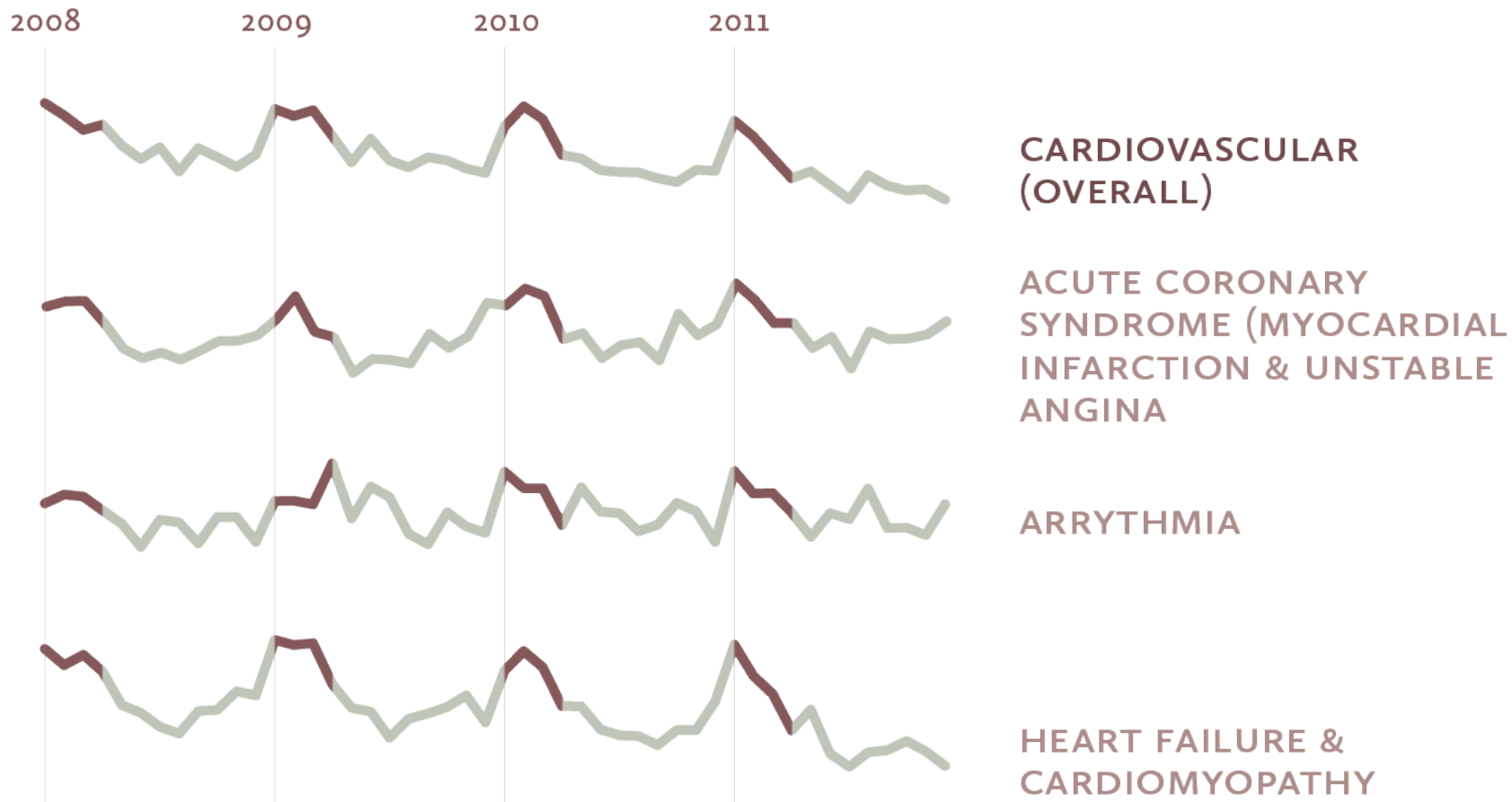




In the prevalent dialysis population,  
hospitalization rates for many causes

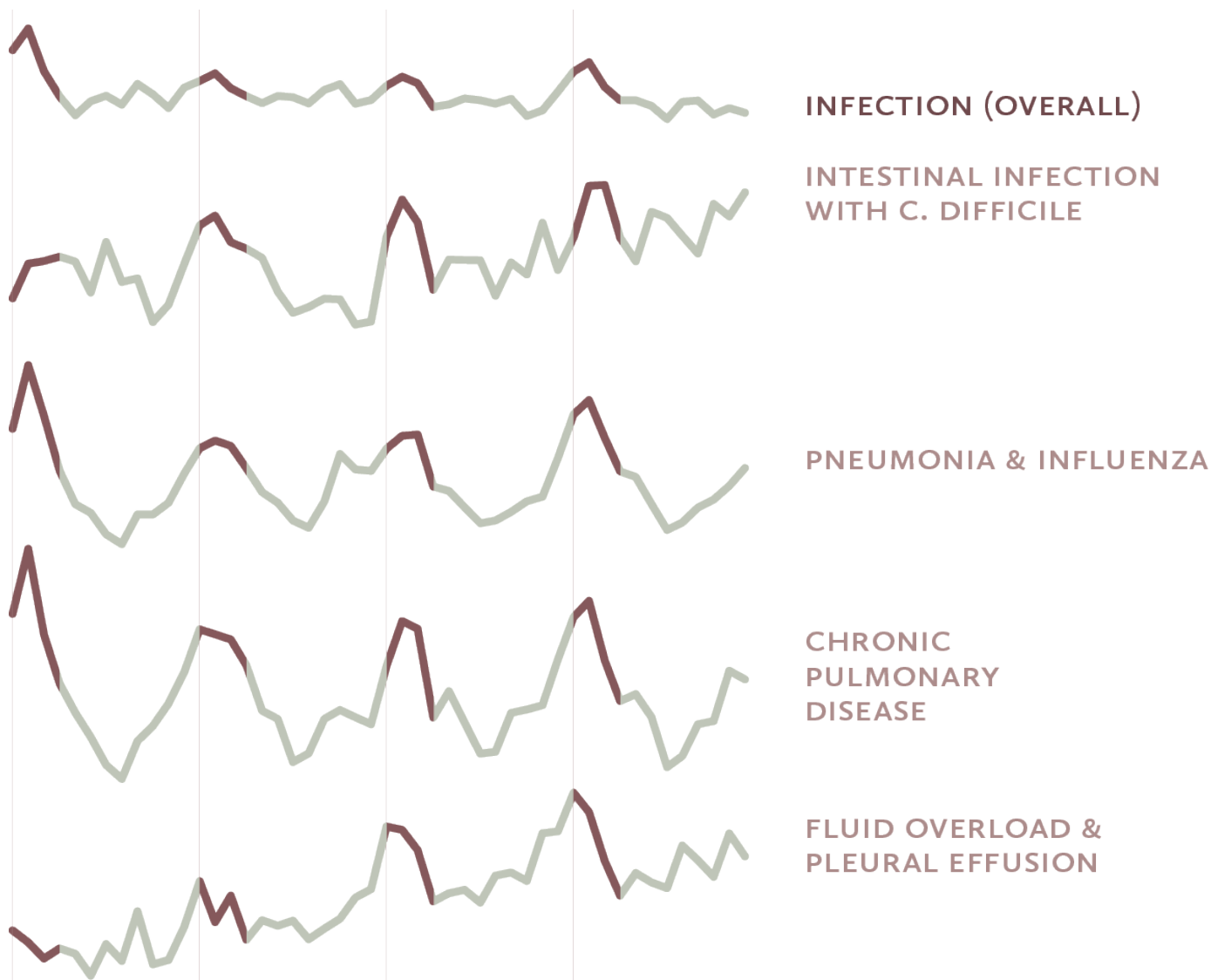
**peak** in January,  
February, & March

# Seasonality of major morbidity in dialysis

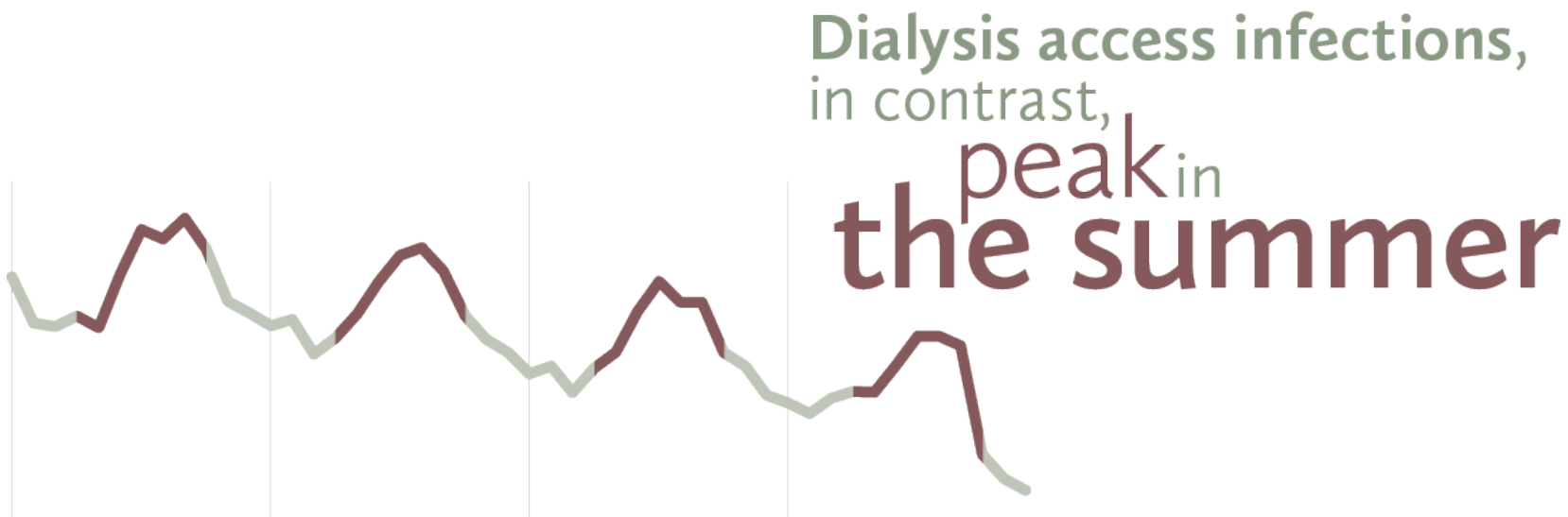




# Seasonality of major morbidity in dialysis



# Seasonality of major morbidity in dialysis





# Hospitalization patterns

- **Geographic variation is striking and needs attention**
- **Seasonal changes in hospitalizations are wide spread across the major organ systems**
- **The relationship between the seasonal events and the influenza season with virulence needs to be recognized**
  - **Improved prevention is needed: vaccination with high intensity dosing**
  - **Respiratory infection control procedures may be needed**
- **Pragmatic Clinical Trials are needed to test procedure efficacy**

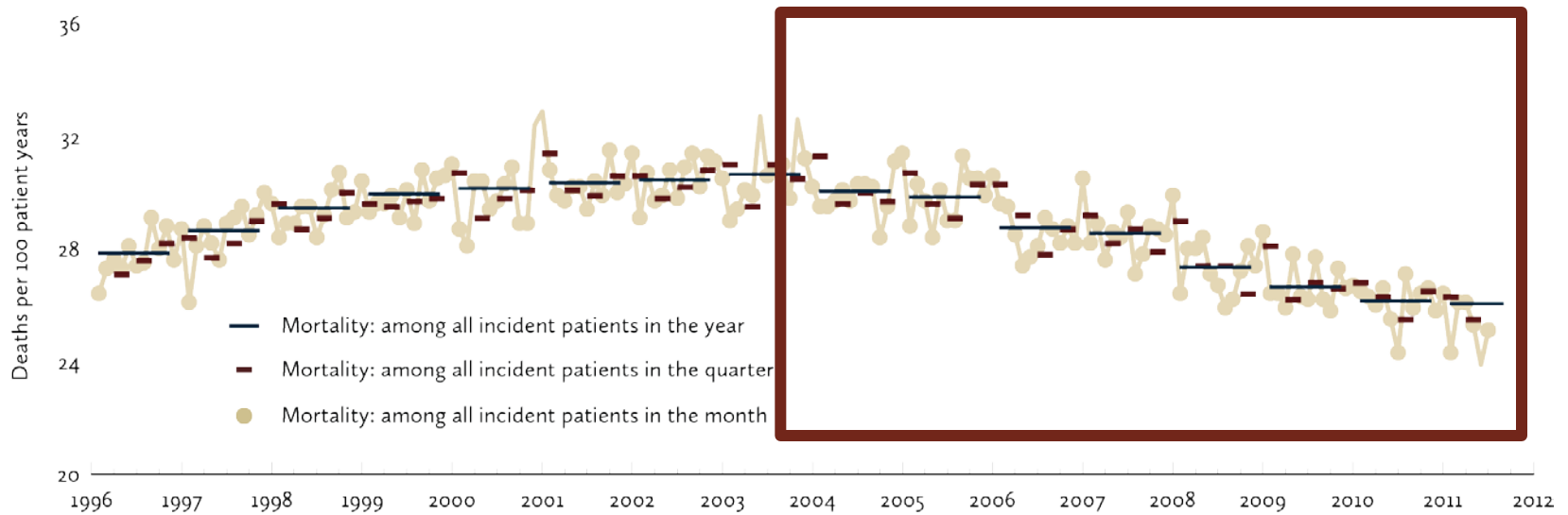


Peer Report:

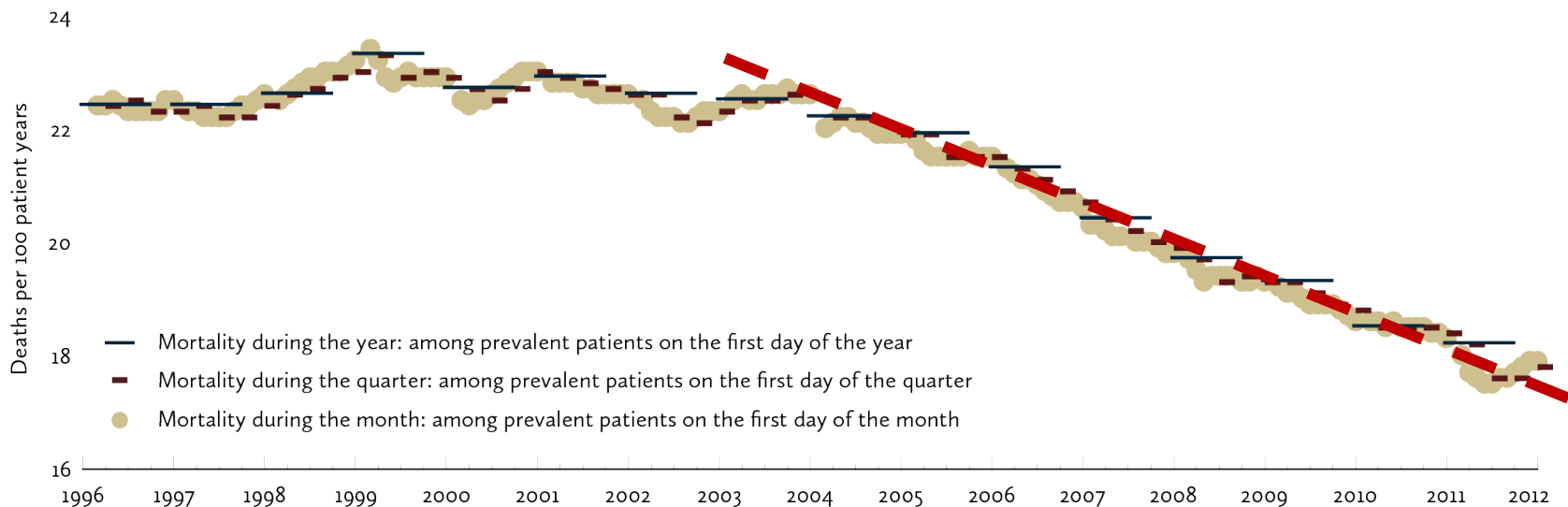
## Mortality

Trends, Geographic  
Variation and  
Seasonality

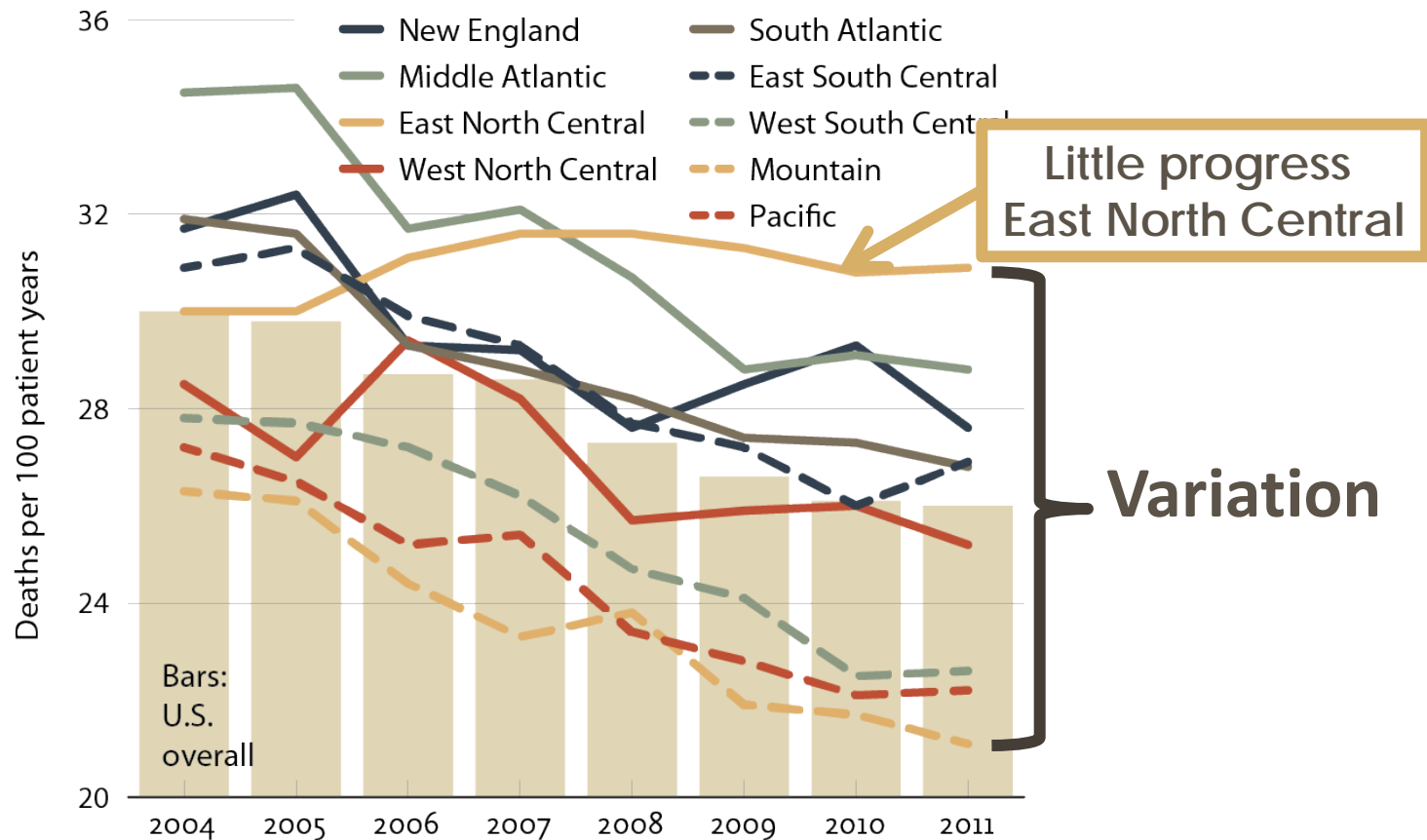
# First-year mortality in incident dialysis patients, by incident year, quarter, & month



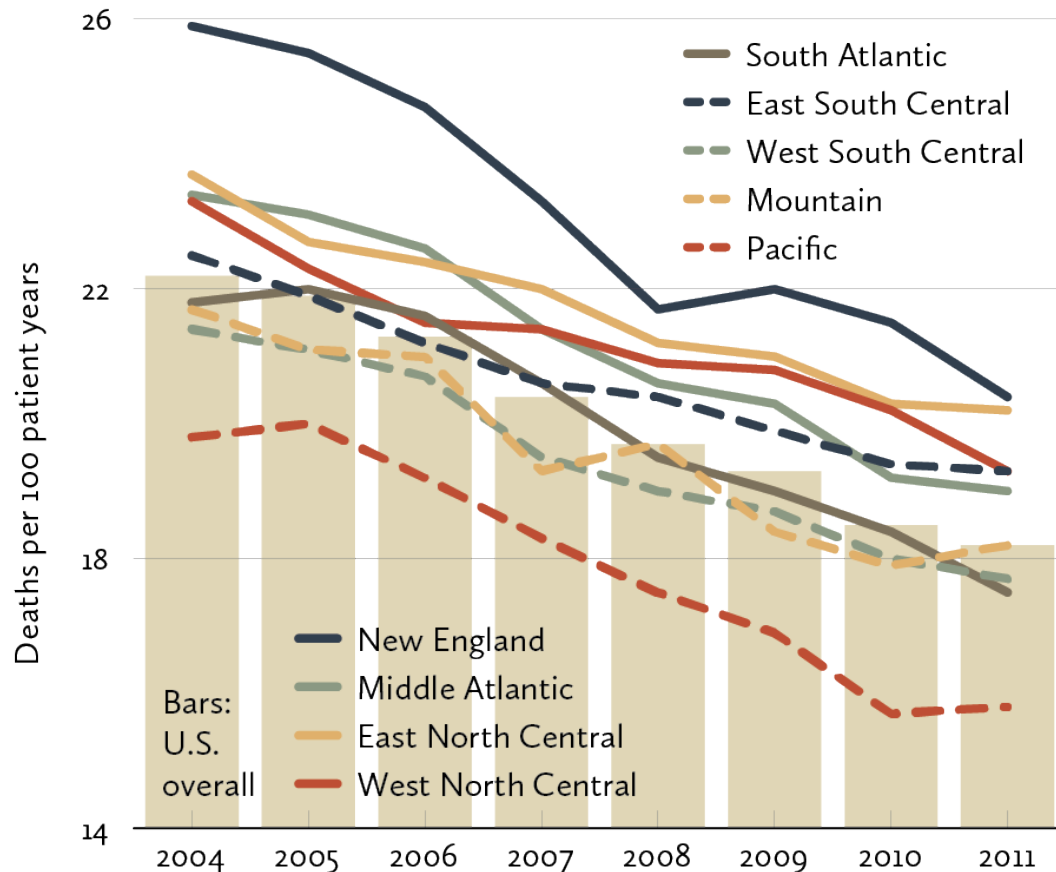
# Unadjusted mortality in prevalent dialysis patients, by year, quarter, & month



# First-year mortality in incident dialysis patients, by U.S. Census Division



# Unadjusted mortality in point prevalent dialysis patients, by U.S. Census Division



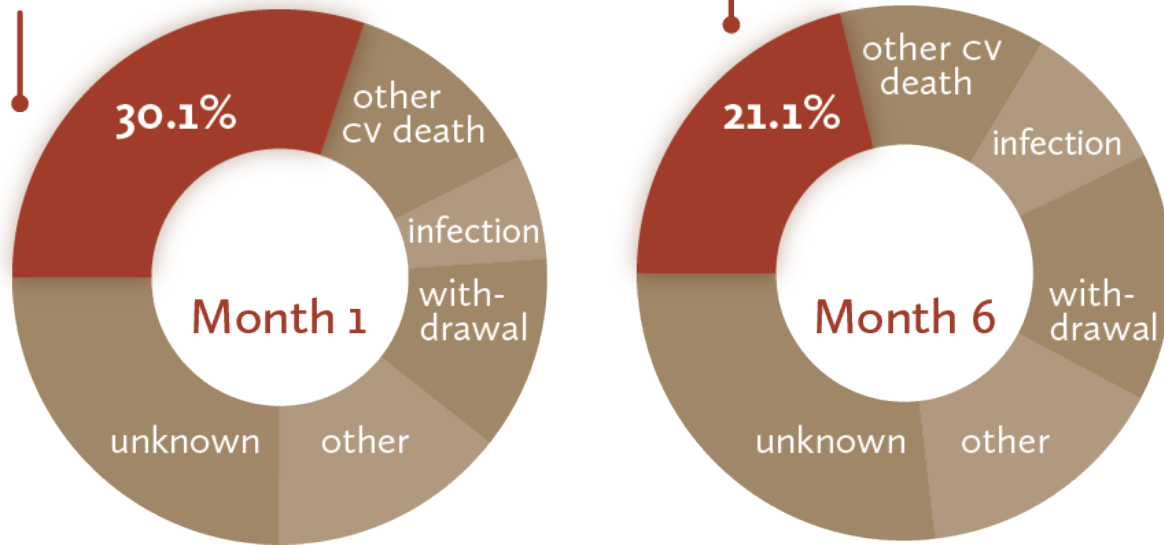




# Trends in Mortality

- **Regional differences in first year incident based and prevalent mortality rates are greater than previously considered**
- **The East North Central Census Division has issues with not only hospitalizations noted above but also incident based first year mortality**
  - **Regional and State level assessments are needed**
  - **Provider groups need to improve regional outcomes by defining specific action areas**

Sudden cardiac death

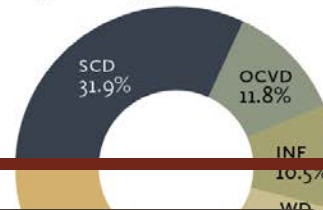


# Cause of death in prevalent dialysis patients

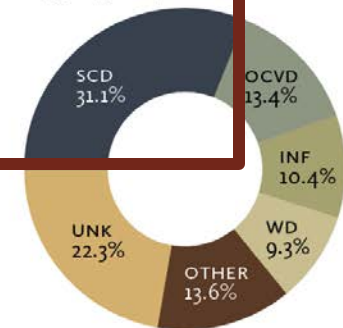
Overall



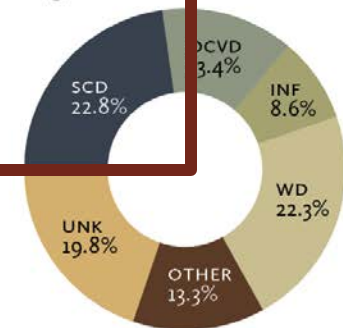
Age 18-44



Age 45-64



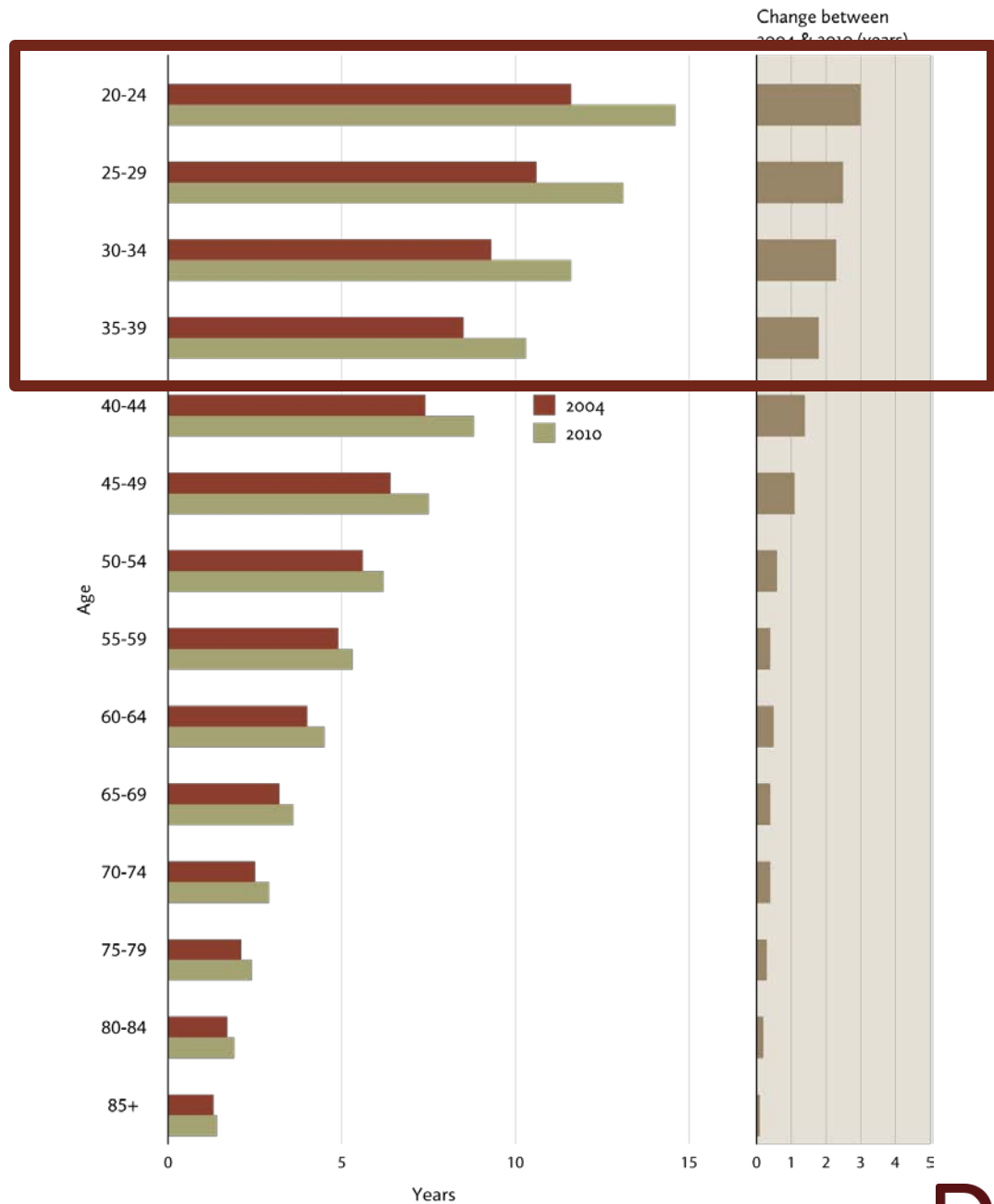
Age 80+



**Sudden Cardiac Death is a major issue and is highest in the younger population which should have better survival**

Sudden cardiac death  
 Other cardiovascular death  
 Infection  
 Withdrawal  
 Other known cause  
 Unknown cause

# Expected remaining lifetimes in incident dialysis patients



## Declining Mortality Rates

- The impact on patient survival is substantial and varies by age group
- The increase of three year survival in the 20-24 year old patients is an important achievement but more needs to be done across all age groups
- The lowering of the death rates since 2003 has extended the lives of over 50,000 dialysis patients

# Mortality Trends and Targets for Improvement

- The steady decline in mortality rates are not addressed by cross sectional Standardized Ratios of providers
- In fact, the improvements in mortality and hospitalization rates may leave providers with little change in their position compared to others because everyone is moving
- Trends in outcomes are a better public health assessment tool and are used by Healthy People 2020 and WHO to set targets for improvement and assess progress.

# Recommendation to consider: trends and targets within providers

- Trends and targets should be a new focus of quality efforts
- Historical trends should define the extent of improvement within providers over a prior 5 year period
- Targets should be set for the next 5-10 years
- All providers should be given a one year period to implement focused programs to address the range of areas to be improved
- The clock assessing providers future progress should start with regional and provider group yearly tracking of progress prospectively
- Percent improvement within a provider or group is the direct measure with the provider working as their own control

# Recommendation to consider: trends and targets within providers

- We need to evolve the approach to assess outcomes as there is still substantial geographic variation in outcomes
- The alternative Public Health approach provides a longitudinal assessment of progress by setting targets and assessing progress prospectively
- Local assessment is a core issue to ensure all populations and regions make long term improvements



**Thanks for your consideration**