

# Presentation Outline

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## TREAT

**Marc Pfeffer, MD, PhD**

Dzau Professor of Medicine, Harvard Medical School,  
Cardiovascular Division, Brigham and Women's Hospital

## Introduction

**Paul Eisenberg, MD, MPH, FACC**

Global Regulatory Affairs & Safety, Amgen Inc

## Clinical Perspective

**Allen R. Nissenson, MD, FACP, FASN**

Professor of Medicine, Associate Dean, Director,  
Dialysis Program, David Geffen School of Medicine, UCLA

## Benefit/Risk

**Preston Klassen, MD, MHS**

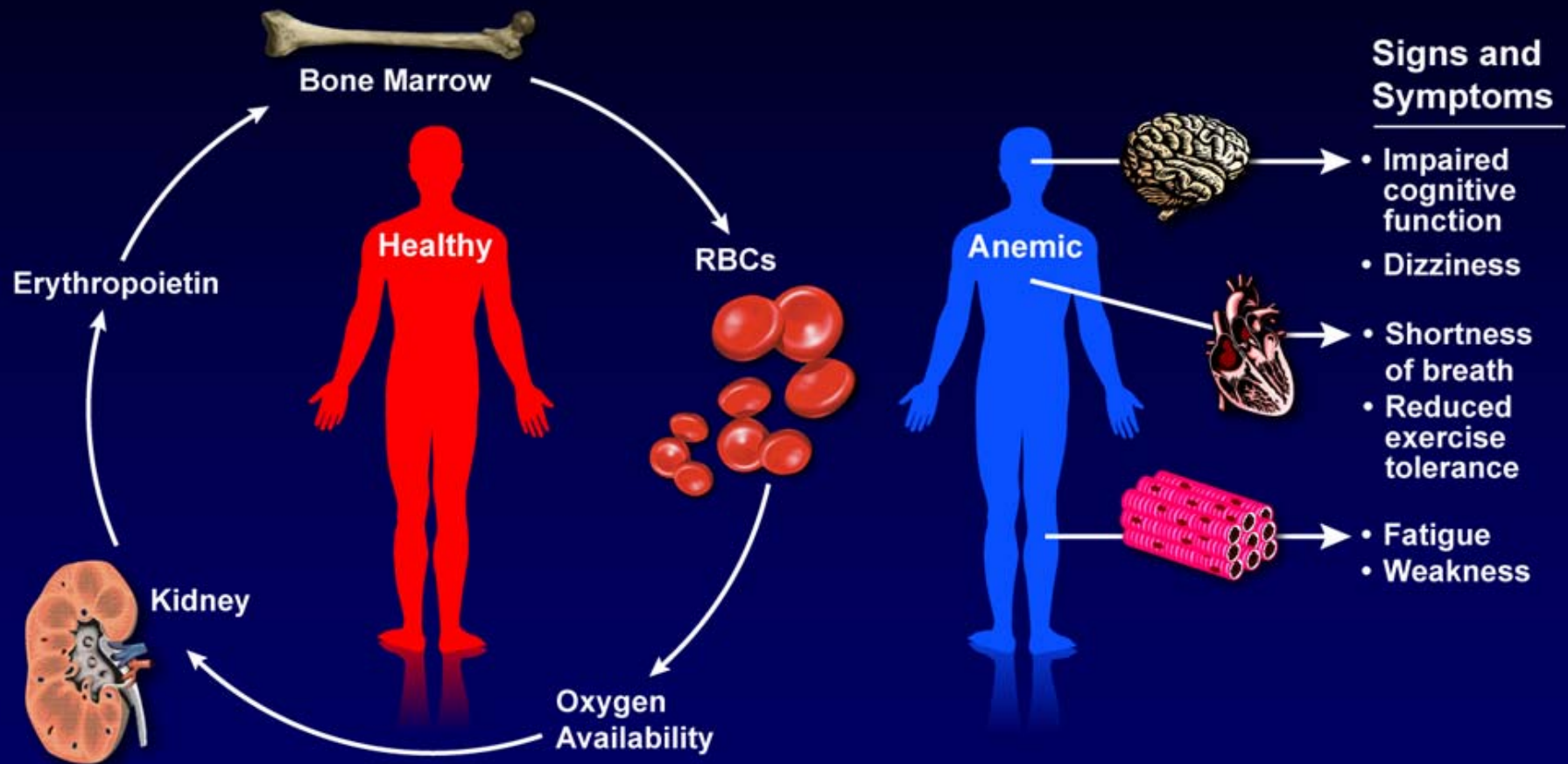
Global Development, Amgen Inc

## Risk Management

**Paul Eisenberg, MD, MPH, FACC**

Global Regulatory Affairs & Safety, Amgen Inc

# Anemia in CRF



# Anemia Treatment was a Rescue Therapy in Pre-ESA Era

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- **Anemia of CRF was major source of functional impairment**
- **Treatment of anemia was important unmet medical need**
  - Available options were inadequate
    - **Blood transfusions (average 6-8 units per patient/yr)**
    - **Parenteral iron therapy**
    - **Androgen therapy**

Eschbach, *Kidney Int*, 1989.

Eschbach, *Ann Intern Med*, 1989.

Churchill, *Am J Kidney Dis*, 1992.

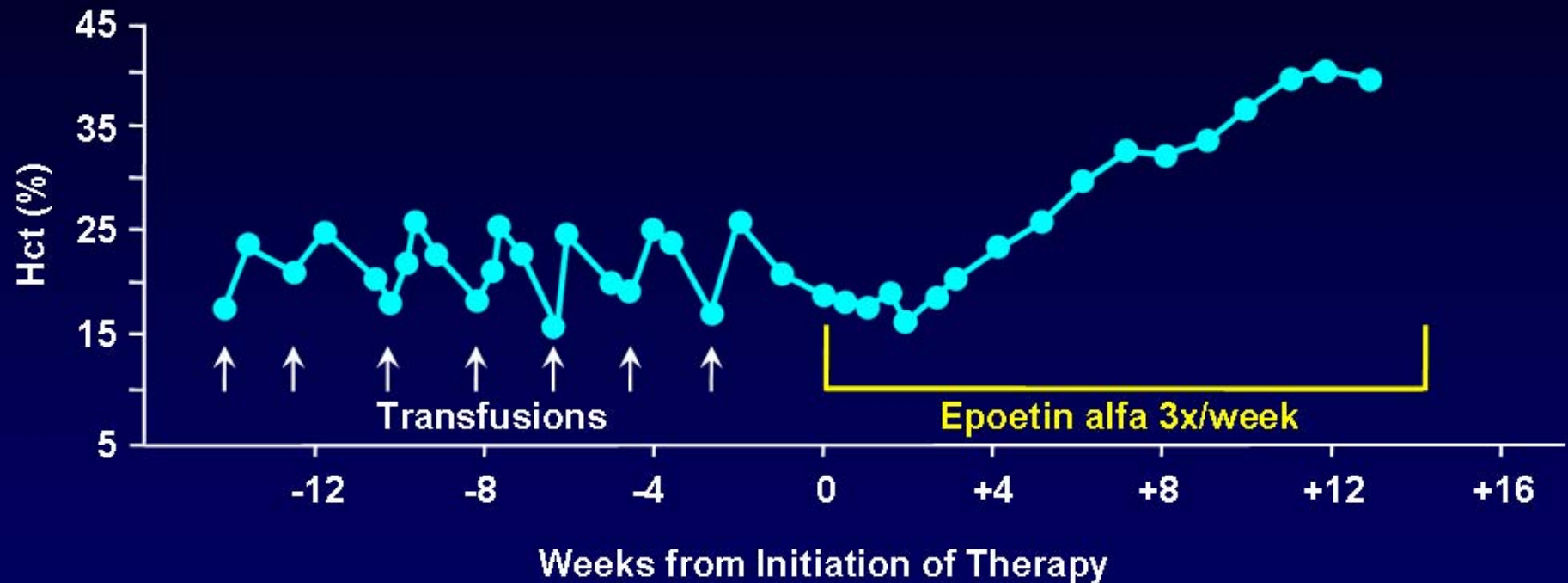
Winearls, *Nephrol Dial Transplant*, 1998.

# Complications of Blood Transfusions in Patients with CRF

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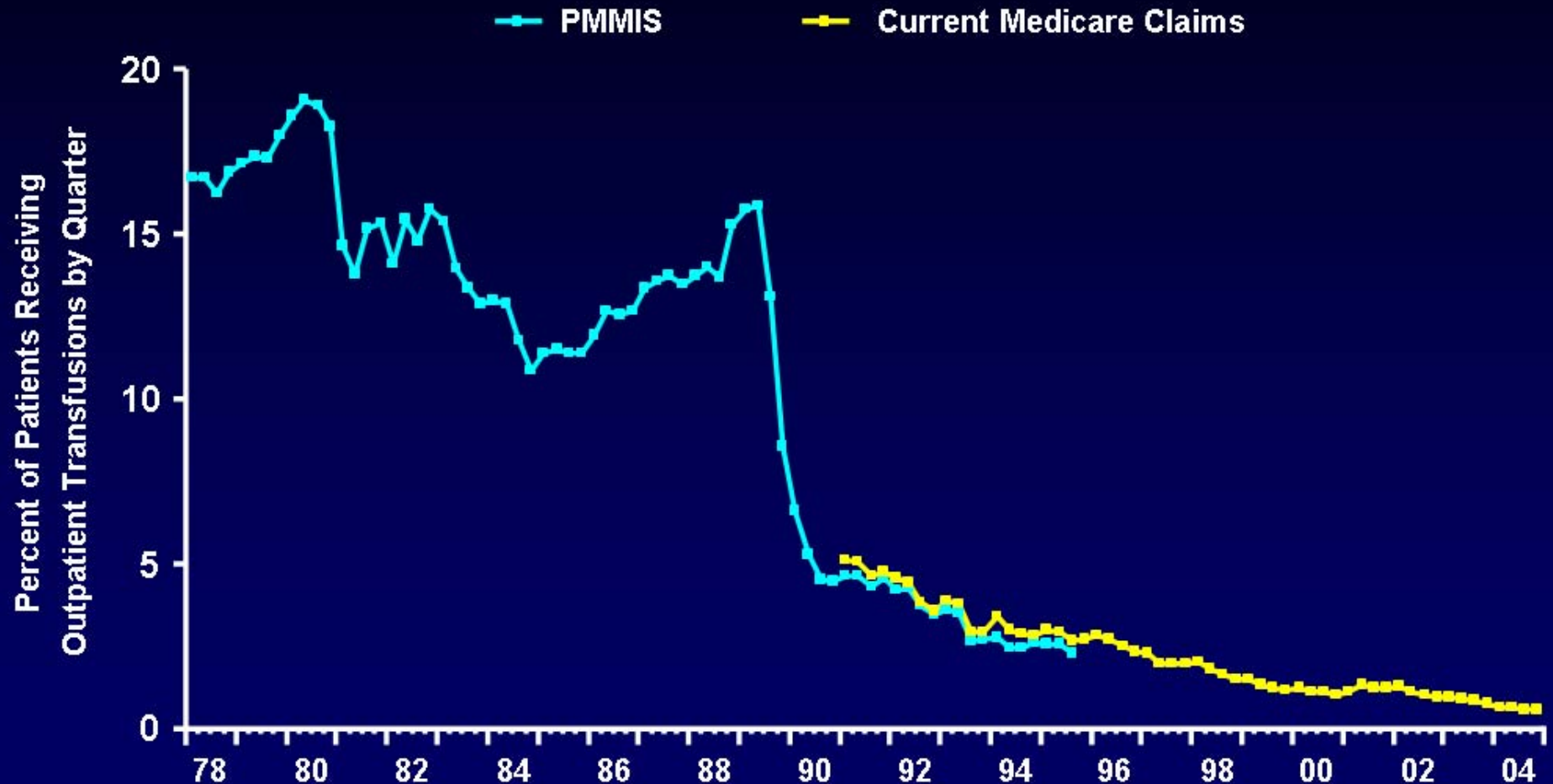
- **Volume overload and pulmonary edema is common and requires concomitant dialysis therapy**
- **Allo-immunization increases with transfusion and reduces opportunity for kidney transplantation**
- **Iron overload**
- **Hyperkalemia**
- **Infection**

# Epoetin alfa Introduced Paradigm Change: Partial Hb Restoration Instead of Transfusion Rescue



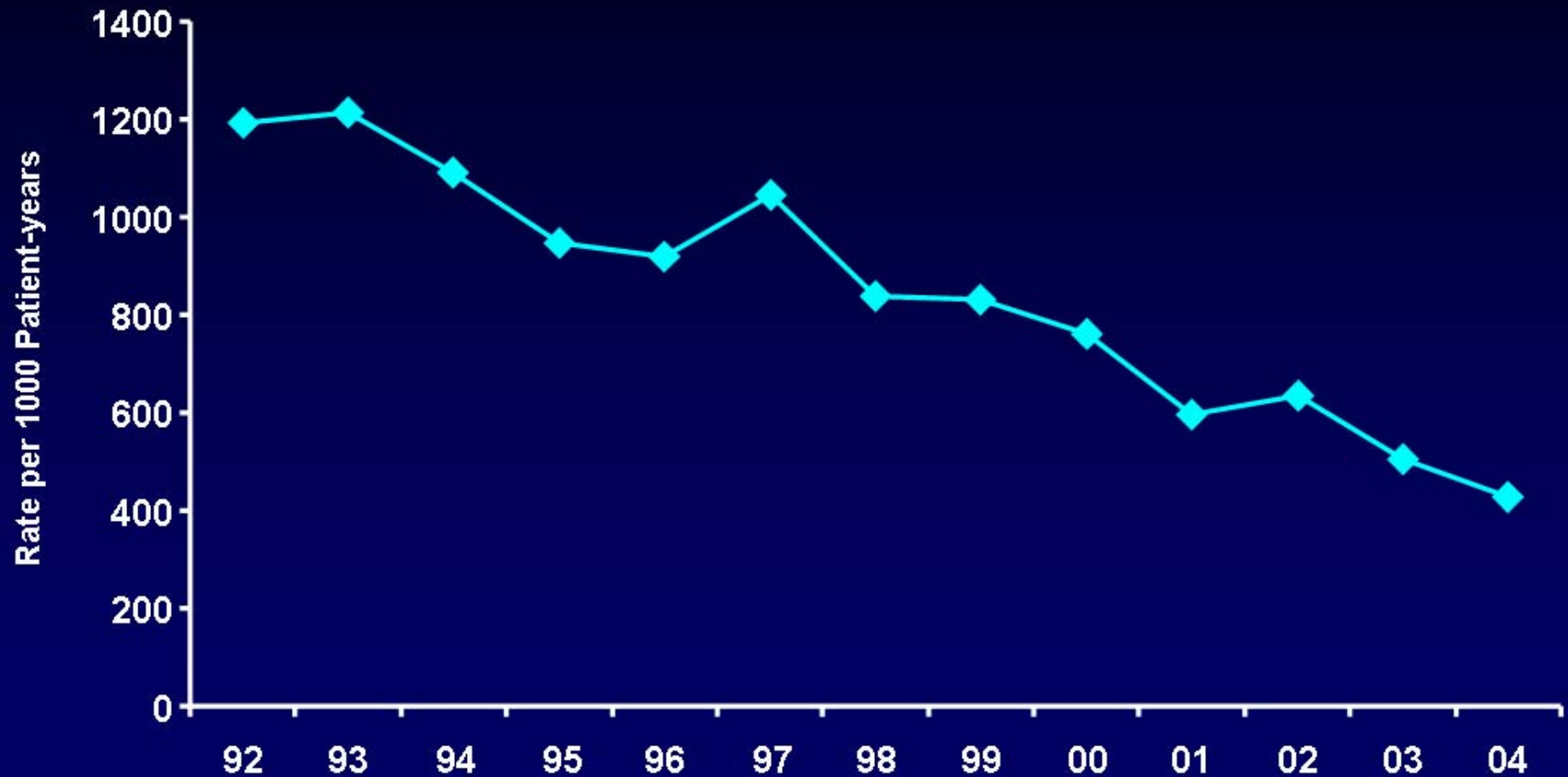
Adapted from: Eschbach, *N Engl J Med.* 1987

# Transfusions Dramatically Reduced in Dialysis Patients Since Introduction of ESAs



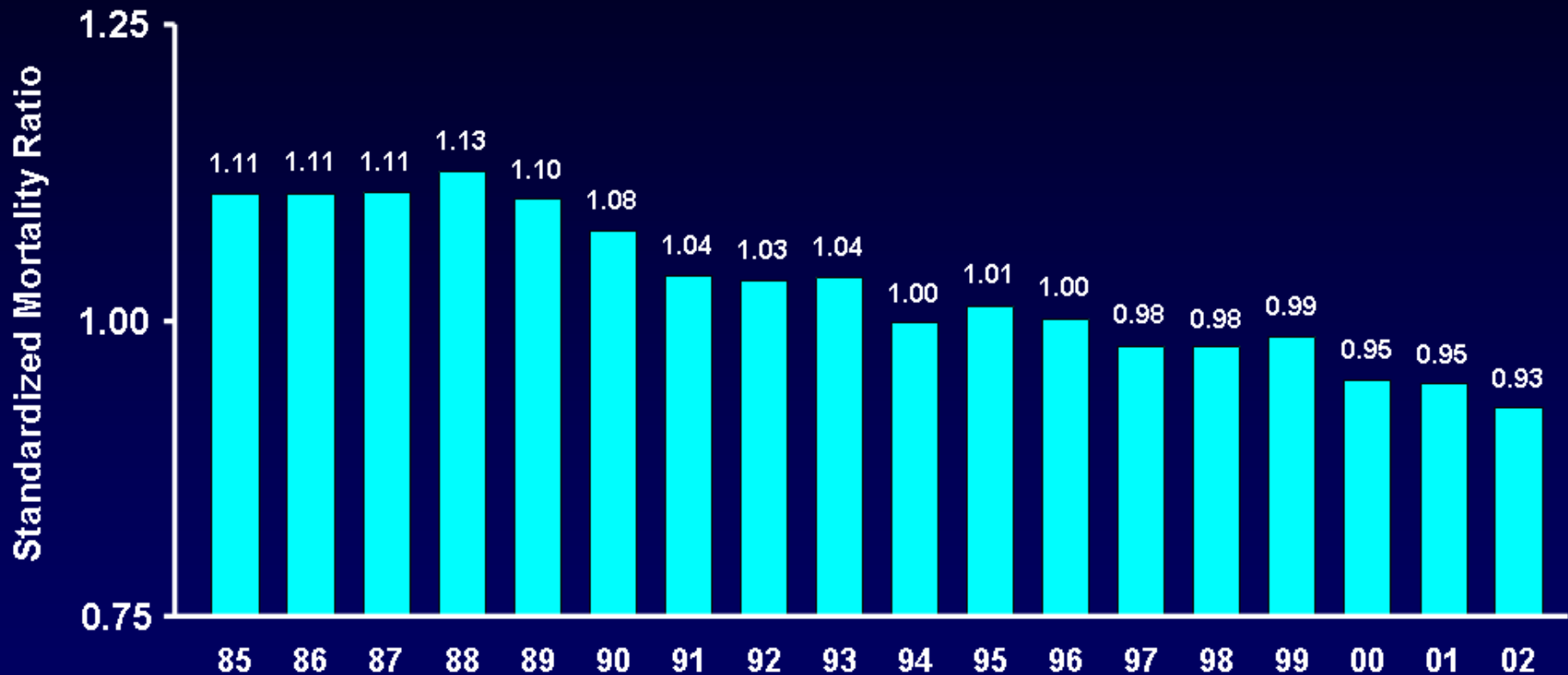
PMMIS= Healthcare Financing Administration Program Medical Management and Information Systems

# Transfusions Reduced in Non-dialysis CKD Patients Since Introduction of ESAs



5% General Medicare Denominator File.

# Standardized Mortality Ratio Has Decreased 17% Since Introduction of EPO





# Patient Well-Being: The Clinician's Journey

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- Initial patient reports of dramatic improvements
- Patient requests to come off transplant lists and not to pursue home dialysis
- Patient reported outcomes studies
- Functional capacity studies

# Nephrology Community Has Over 18 Years of Experience with ESAs

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- **ESAs fundamentally changed practice of nephrology**
- **ESAs enhance patient well-being**
- **Returning to a pre-ESA approach to anemia would set back the care of CRF patients nearly 2 decades**
- **A legitimate scientific debate continues over the appropriate target Hb for populations of patients**

# Nephrology Community Has Over 18 Years of Experience with ESAs

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- **Recent revisions to evidence-based clinical practice guidelines for anemia have incorporated important safety information regarding higher Hb targets**
- **For an individual patient, benefits must be weighed against the risks**
  - Nephrologists and patients are in the best position to work together to optimize anemia management
- **Clinical trial in dialysis targeting Hb  $\leq 10$  g/dL would lack equipoise**
- **Extensive clinical experience of nephrologists and patients *matters***