Evaluating Evidence Behind Policy Mandates in Dialysis Care

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Disclosures

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Role of Policy in Dialysis

Medicare covers 65% of all prevalent patients receiving dialysis in the US.
- High costs of dialysis care present significant challenges for federal and state budgets.

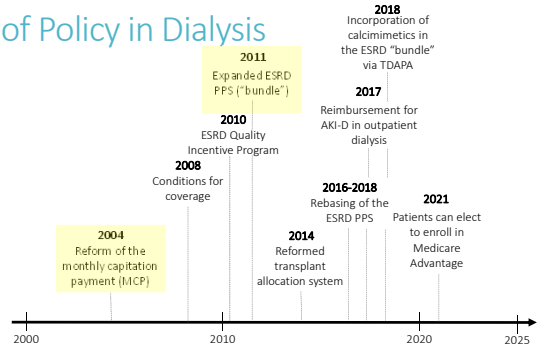
Public payers (Medicare and, to a lesser extent, state governments) tightly regulate the provision of dialysis care

Federal mandates have begun to affect nearly all areas of dialysis care delivery.

Regulation is likely to continue.

It is important that policies are effective in achieving their goals of improving the quality of care delivered and controlling costs.

Role of Policy in Dialysis



Role of Policy in Dialysis

- A perspective published in 2017 outlined key features to consider when assessing evidence supporting policy mandates, including:
  - 1) clearly defining the policy of interest
  - 2) evaluating the policy within the context of a specific goal or goals
  - 3) assessing the magnitude of the policy's effect on the stated goals


PERSPECTIVE

EVIDENCE-BASED HEALTH POLICY

Evidence-Based Health Policy

Katherine Baicker, Ph.D., and Amitabh Chandra, Ph.D.

NEJM 2017

I will review two mandates affecting dialysis care within this framework.

1) Reform of the Monthly Capitation Payment (MCP) for nephrologists providing outpatient dialysis care in 2004.

2) Inclusion of injectable medications into the ESRD composite rate in 2011.

Although these are different in many ways, more than 20 years of combined post-policy follow-up allows a thorough assessment of their effectiveness and highlights keys to making policies effective.

Nephrologist Reimbursement Reform

In July of 2003, the Centers for Medicare and Medicaid Services (CMS) announced that it would change reimbursement to nephrologists for outpatient dialysis care (i.e. MCP).

Moved from a single monthly payment to at tiered fee-for-service beginning in 2004.

Reimbursement varied according to the number of times a physician or advanced practitioner saw a patient.

At the time of its proposal CMS wrote that the objectives of the reform were to:

1) "Align incentives"

2) "Encourage increased frequency of face-to-face visits for patients who require it"

And in doing so:

3) "Improve the quality of care delivered"

Source: Federal Register, 2003

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Nephrologist Reimbursement Reform

Pre-policy evidence:

- Evidence indicated that physicians respond to economic incentives in other areas of medicine.
- Had not been studied explicitly in outpatient dialysis.

Nephrologist Reimbursement Reform

Was the policy effective?

Evidence since the policy was enacted suggest that it effectively led to more frequent visits:

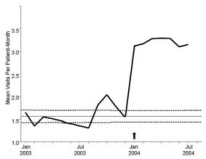
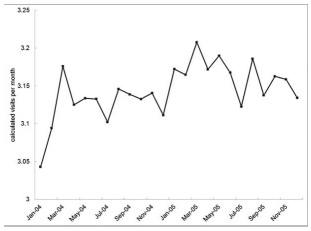


Fig 1. Mean number of visits per patient-month. Control chart analyzing monthly data. Control limits and center lines are based on data before the Medicare reimbursement change. Arrow indicates the start of the new reimbursement policy.

Source: Mentari, AJKD 2005



Source: Erickson, FHEP 2014

Nephrologist Reimbursement Reform

Was the policy effective?

The absence of comprehensive data on the frequency of outpatient practitioner visits before reimbursement reform has prevented overall assessment of the policy on visit frequency.

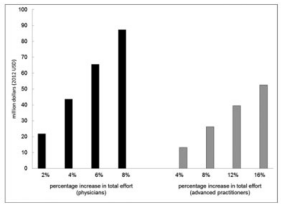


Figure 3.
Range of Estimated Economic Costs of Additional Provider Visits.Note: Economic cost estimates were derived from published data.

Source: Erickson, AJKD 2017

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Nephrologist Reimbursement Reform

Pre-policy evidence:

Small cross-sectional analyses of the associations among nephrologist visit frequency and health outcomes (before and after the 2004 reimbursement reform) were inconclusive. *(McClellan, JASN 1998; Plantinga, JASN 2004; Plantinga; Int J Qual Health Care, 2005)*

Was the policy effective?

National studies found that more frequent visits are associated with:

- *Slightly fewer hospitalizations (Slinin, JASN 2012)*
- *More substantial reductions in 30-day hospital readmissions (Erickson, JASN 2014)*
- *Earlier placement of AV fistulas (Erickson, JASN 2015)*

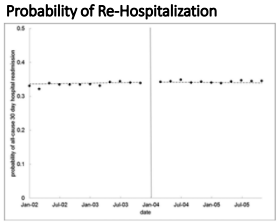
But,

- *More frequent visits were not associated with improvements in mortality (Slinin, JASN 2012)*
- *May have led to unnecessary spending on vascular access care. (Erickson, CJASN 2015)*

Nephrologist Reimbursement Reform

There is no evidence that a policy of paying for more visits led to any benefits.

Probability of Re-Hospitalization



- Similar absence of benefit from payment reform in studies examining:
  - Mortality or listing for kidney transplant *(Erickson, FHEP 2014)*
  - All hospitalizations *(Erickson, AJKD 2017)*
  - Kt/v, albumin, hemoglobin, phosphorus, calcium, catheter use, UF volume, skipped or shortened treatments, hospital admissions, health related quality of life or satisfaction. *(Mentari, AJKD 2005)*

Source: Erickson, AJKD 2017

Nephrologist Reimbursement Reform

At the time of its proposal CMS wrote that the objectives of the reform were to:

1) "Align incentives" **??**
2) "Encourage increased frequency of face-to-face visits for patients who require it"

And in doing so:

3) "Improve the quality of care delivered" **No**

Yes, but the magnitude and scope of this success is unknown

Expanded ESRD PPS

After the approval of EPO by the FDA in 1989, growing use in erythropoietin stimulating agents (ESAs) in dialysis combined with trials demonstrating potential safety concerns about their use in patients with kidney disease led policy makers to try to curb their use.

The Medicare Improvements for Patients and Providers Act of 2008 required CMS to add injectable medications administered during dialysis to the Composite Rate bundle of dialysis services beginning in 2011.

In 2010, CMS summarized 3 primary objectives of this policy:

1) reduce the overuse of profitable separately billable drugs, particularly EPO
2) through flexibility offered, increase desirable quality of care
3) target payment to facilities with more costly payment and access to services.

Assumes that providers change ESA dose in response to

Assumes that health outcomes will improve from changes in ESA use.

Source: Federal Register, 2010.

Expanded ESRD PPS

Pre-Policy Evidence: Economic Incentives and ESA Use

Analyses of claims immediately following coverage demonstrated lower-than-expected use of EPO, attributed to the fixed per-treatment reimbursement schedule and issues around coverage for home dialysis. *(Griffiths, Health Care Financ Rev. 1994)*

Legislation in 1990 eliminated early disincentives, leading to decades of increasing ESA use.

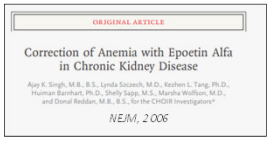
Beginning in 2005, CMS made several changes reimbursement for injectable medications (including ESAs) in dialysis in an effort to curb their use.

A 2006 GAO report of Medicare claims suggested that providers decreased use of injectable medications, but that the policy was not sufficient.

Expanded ESRD PPS

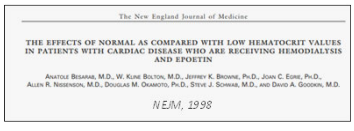
Pre-Policy Evidence: Health Consequences from Lower ESA Use

One small randomized, controlled trial of patients with ESRD followed by two large trials of patients with CKD indicated that more EPO use does not improve patient health and may be harmful.


ORIGINAL ARTICLE

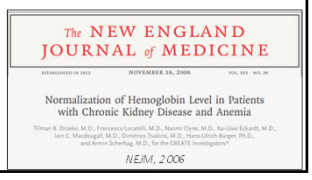
Correction of Anemia with Epoetin Alfa in Chronic Kidney Disease

NEJM, 2006


The New England Journal of Medicine

THE EFFECTS OF NORMAL AS COMPARED WITH LOW HEMATOCRIT VALUES IN PATIENTS WITH CARDIAC DISEASE WHO ARE RECEIVING HEMODIALYSIS AND EPOETIN

NEJM, 1998


The NEW ENGLAND JOURNAL of MEDICINE

NOVEMBER 16, 2006

Normalization of Hemoglobin Level in Patients with Chronic Kidney Disease and Anemia

NEJM, 2006

Change in ESA Use Following Expanded PPS

Was the policy effective?

Extensive data on the administration of injectable medications, including ESAs, were recorded on Medicare claims before and after the expanded ESRD payment bundle, enabling rapid monitoring of utilization changes.

The DOPPS Practice Monitor was initiated in 2010 to monitor effects of bundled payments on dialysis care.

Change in ESA Use Following Expanded PPS

Was the policy effective?

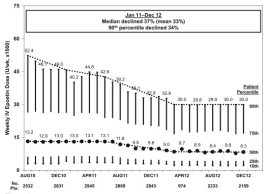


Figure 4

Distribution of prescribed weekly intravenous (IV) epoetin dose, August 2010 to December 2012. Values for each month reflect the average IV epoetin dose prescribed to patients during 1 week of each study month (restricted to 1,000-400,000 U/mo) in facilities providing renal medication records for at least 10 patients.

Adapted with permission of Arbor Research Collaborative for Health from the April 2013 update to the DOPPS Practice Monitor.

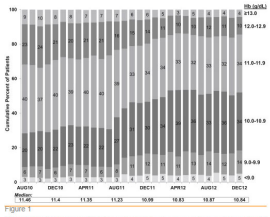


Figure 1

Hemoglobin (Hb) level distribution in the DPM national sample from August 2010 to December 2012. Based on 1,744 to 3,836 patients per month among facilities providing laboratory records for at least 10 patients.

Adapted with permission of Arbor Research Collaborative for Health from the April 2013 update to the DOPPS Practice Monitor.

Douglas, AJKD 2013

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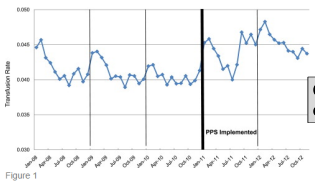

Figure 1

Percentage of Medicare dialysis patients receiving 1 or more red blood cell transfusion, January 2008 to November 2012, standardized to 30-day months. The x-axis represents the time period. The bold vertical black line represents the starting date of the prospective payment system (PPS).

Hirth, AJKD 2014

Quality of life not studied in detail

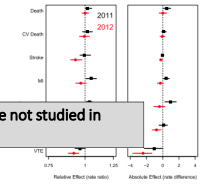

Figure 3. Rate ratio (RR) and absolute rate differences and their associated 95% confidence intervals for all outcomes for the individual years 2011 and 2012, comparing observed versus expected are shown. Relative effect (rate ratio) and absolute effect (rate difference) of observed to expected rates of all-cause death, cardiovascular (CV) death, stroke, MI, the composite endpoint, heart failure (HF), and VTE in 2011 and 2012. Expected rates are based on 2005–2010 data. *Composite endpoint describes rates of all-cause death, stroke, and MI.

Chertow, JASN 2016

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Source: Federal Register, 2010.

Targeting Payments

Pre-policy evidence:

Two reports before enactment of the policy suggested that existing databases could be leveraged to adjust facility reimbursement for differences in patient resource use. *(Wolfe, UM-KECC 2002;* Leavitt, Report to Congress 2008).

Was the Policy Effective?:

Payment adjustment methods have had limitations.

Issues related to under-reporting of comorbidities and changes in practice patters led CMS to revise its model for adult case-mix adjustment in 2016.

A 2013 GAO report suggested that small volume and rural payment adjusters are not targeting facilities that need them.

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Important Differences Between Mandates

	Nephrologist Reimbursement Reform	ESRD Expanded Payment Bundle
Amount and quality of prior evidence supporting the policy interventions.	Several conflicting small observational analyses.	One small and two large RCTs.
Differences in data collection in order to evaluate the policies.	No data on practice patterns prior to the policy.	Immediate data collection, enabling meaningful reform within 5 years.
	No policy evaluations until 9 years after the policy, increasing disruption and costs from reform.	
Differences in clarity of states goals:	Unclear goals have complicated efforts to evaluate policy.	Clearly stated objectives have facilitated policy evaluation.

Conclusions

Evaluation of two federal mandates in dialysis care highlights the importance of clearly-stated objectives, evidence-based policy, and monitoring.

The federal government's prominent role in financing dialysis care, combined with high costs means that dialysis care will continue to be highly regulated.

It is critical that clinical and research communities work closely with policy-makers to:

1) guide policy objectives.
2) build the evidence base available to draw upon.
3) build systems of data collection that allow for rapid policy evaluation.

Thank You

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