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

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

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

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:

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.

Source: Erickson, AJKD 2017

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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, CAIN 2015)

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

- 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)

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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.


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.

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.

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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.

Douglas, AJKD 2013

Quality of life not studied in detail

Chertow, JASN 2016
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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 patterns 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

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


Centers for Medicare and Medicaid Services: Medicare program; revisions to payment policies under the physician fee schedule for calendar year 2004; proposed rule. Federal register 69: 30035–30068, 2004

Centers for Medicare and Medicaid Services: Medicare program; revisions to payment policies under the physician fee schedule for calendar year 2004; proposed rule. Federal register 68: 63195–63919, 2003


References
