The Executive Order - What Proportion of New Incident ESKD Cases Should be Treated with Dialysis Versus Transplantation: Practical, economic, and logistic considerations

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Disclosures

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• Consulting on transplant-related matters for Fresenius Medical Care, North America

• Owns shares and options in OmniLife.ai (IT platform)

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Learning Objectives

• Describe how a shift in payment models and outcomes metrics aimed at OPOs, transplant centers, dialysis facilities, and nephrology practices, largely driven by proposals under the rubric of the Executive Order, are shaping a framework for designing a population-health approach to patients with advanced CKD and ESKD;

• Comprehend how the ethical, economic, and operational constraints of this landscape contours a defensible and achievable policy prescriptions for expanding access to transplantation for as many patients as may benefit;

• Articulate what might count as “success” in achieving a fully integrated, value-based model of care across the continuum of CKD, ESKD, and kidney transplantation.
Overview

The common frame: “Who should be transplanted when not all can be?”
- Lofty, detached, dessicated utilitarian calculations, decorated with “principles”
- Ignorant of/indifferent to a myriad of social contexts

A better frame = Thinking about patients’ access to transplant in context
- Context: Past, and forthcoming regulatory/payment regimes and threats
- Context: Access to/actual transplant is just a part of a broader continuum of lived disease process over an entire lifetime = “Total Renal Life”

A better system of care = Creating a patient-responsive, quality focused, and financially sustainable model of care across continua of kidney disease-states.
“What’s past is prologue” -- Past

Transplant:
• Past allocation disputes (KPSAM, KDPI, Top 20%)
• Intense regulatory focus by CMS and payors (2007-2019)
• Recent allocation disputes DSA -> Geography: Liver -> Kidney

General sense we have been nibbling around the edges. “Lost two decades”

Nephrology/dialysis:
• Attention to $$ -- Volume -> Value – ESCOs
• Emphasis on: Care coordination, home therapies.....transplant?
• Absence of consensus of the role of neph/DO in the transplant process
“What’s past is prologue” -- Prologue

Transplant:
• Old scoring systems → Big Data and AI decision tools
• Relaxation of regulatory controls - ? Whether payors keep up
• Living donor reform; Immuno bill; OPO rules

But, transplant centers mostly left out of new payment models

Nephrology/dialysis:
• ESCOs – 12/31/2020 – EO payment models :: Negotiating VBCs with payors
• Emphasis on: Value not volume, home therapies, “access” to transplant
• Nephs/DOs beginning to define their own role in transplant process
• Evolving relationships with/demands on individual/consortia of Tx Centers
Threat assessment – Transplant centers and OPOs

- 21st Century Cures Act
  - 15% increase ESRD patients in MA plans
- New allocation system = Substantial disruption in expected organ availability across markets
- New OPO rules – OIG inquiry
- Workforce challenges
  - 74% Nephrology ABIM pass rate
- Private payors /= regulators
- Centers not ready for risk-sharing in a value-based world

Pivert K. ASN Data Brief; Seaborg E. Kidney News Online
Advancing American Kidney Health

EO July 20, 2019: Mandatory model and 4 voluntary models
ETC – ESRD Treatment Choices - **Mandatory** model – **ON HOLD**
Four **voluntary** models: Includes attributed CKD 4, CKD 5, ESKD
Kidney Care First (KCF): Capitated payments for attributed CKD 4 and 5
• Reduction in ESRD MCP payments = 2-3 visits/month
3 Comprehensive Kidney Care Contracting (CKCC) models
Upside only; 2-sided risk on 50%; 100% of total costs of care (Tx costs out)
Tx bonus: $2500/$5000/$7500 – “Tx provider” part of contracting entity
Nephrology practices respond

Applications deadline 22 Jan; Hundreds received; Decision TBD;
Rise of population health management consortia
• Both LDOs; Some CINs; Several startups
• Designed to take 2-sided risk on all attributed pts with CKD IV, CKD V, ESKD
• Designed to engage EO models and private payors
• Tx “carved out” except for transplant bonus - ? Transplant centers involved
• Smaller nephrology practices :: Align with larger practices/consortia

Where will transplant centers fit in?
A place for transplant centers in value-based contracting

Longevity, QoL, and $$ benefits of transplantation vs dialysis well understood

What’s missing:

• **A new rubric** which understands disease states as a continuum, not a category
  – Viewing Tx as a category and not a continuum ignores costs of graft failure in QALY and $$

• **Sussell et al**: Economic burden of graft failure
  – $78,079 additional costs of graft failure = $1.38B annualized;
  – QALY losses of 29,289 patient years/annual cohort of transplants
  – Costs of re-transplant = $154,643; Death w/ Function = $153,506; D w/ Failed graft = $249,284

• **Policy and payment models** which incent reorganization around new rubric
  – Incents longevity of transplant and safe transitions from transplant -> dialysis
The “Total Renal Life” (TRL): New population health rubric

PHM = Responsibility for the TRL
- Continuum of shifting disease states over time
  - Exposes and explodes utility of “care silos”
- Useful in exploring gaps in continuity
  - Tracking pt transplant education, referral, evaluation, post-waitlist surveillance;
  - Management of advanced “Tx-CKD”;
  - Long-term Tx management generally;
  - Modality education, Fix “surgical deserts”;
  - Identify/intervene on SDOH factors;
Combining TRL rubric with Intent-to-treat model

Intent to treat captures Triple Aim:
- Better patient experience, better population health, lower costs
TRL captures the continuum of experience of disease states over time
- TRL offers a temporal dimension to I-t-T
- Patients will cycle through these disease states and need expert management and continuous surveillance to enjoy successful transitions
TRL + ITT - Expanding access to transplantation

What does “access” mean? What should it mean?

• Wait-listing is not access to transplant - Wait-listing = access to waiting list
• ITT = Transplant confers better quality, longer quality, less cost = PH optimal
• TRL = Desirability, type, and timing of transplant + Optimal non-Tx existence/time

What could population health management with ITT + TRL look like?
• Elimination of silos of care = Surveillance, coordination, assuming risk across TRL;
• “Patient activation” – Delivering what patients want across TRL = Ask them;
• Early (CKD IV) education about transplant, living donors, and “expanded” donors;
• “Optimal” time for referral, evaluation, wait-listing; Effective stepwise surveillance;
• Appropriate management of Tx CKD -> CKD quality, optimal starts, Tx-referral.
## Access to transplant in practice – Start over

<table>
<thead>
<tr>
<th>Old approach</th>
<th>New approach</th>
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</thead>
<tbody>
<tr>
<td>Neph and DU // Separate from Center</td>
<td>Neph + DU + Tx center</td>
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<tr>
<td>Limited pt tracking</td>
<td>IT platform tracking start-to-finish;</td>
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<tr>
<td>Limited pt communication</td>
<td>Multi-directional communication;</td>
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<tr>
<td>Often fractured transitions of care</td>
<td>Uniformity in transitions of care:</td>
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<tr>
<td>High rates of suboptimal starts</td>
<td>• Anemia, BP, volume, bone dz;</td>
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<td>High mortality; High cost</td>
<td>• Modality selection, dialysis access;</td>
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<td>Worse QoL</td>
<td>Identify and collaborate on tougher barriers to care (SDOH)</td>
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Thinking differently about the waiting list

Old approach: Maximize CKD/ESKD referrals (PPPW), expansion of waiting list

Drawbacks:
• Years of waiting, surveillance problems, redundant and $ testing, false hope

New approach: Just-in-time waitlist inventory (Abecassis)
• Refer/eval/list: + living donor, pre-emptive, “high risk donor” candidates
• All others: Refer/eval/list within 12-18 months of median waiting time
• Smaller waiting list :: Meaningful testing :: Easier to track :: Truth in advertising
• Substantially lower pre-transplant costs
• For those not listed: Focus on help with living donation and RRT with high QoL.
Novel cross-collaborations serving all patients

Multi-purposing existing bricks-and-mortar: “One-stop shopping”

- Combine dialysis unit, transplant clinic, access center, CKD clinic, ”donor hospital,” lab, pharmacy, patient education and mentoring, remote-monitoring home base;
- Transportation hub; MSW financial counselling resources; Employment and Voc Ed
- ASTS – Dialysis access competency as requirement for transplant surgical fellowship
- Transplant surgeons – Commitment to addressing regional “surgical deserts” for ESKD

Immunosuppression – Stark law exception for an “all-inclusive” pharmacy:

- Remote monitoring of refills, pill-packs, drug-interactions, door-delivery;
- Combine with on-site VS monitoring and home-based lab checks -> IT dashboard.

Policy solidarity

- Collaborations to fix the problems with MA plans :: Cures Act;
- All-inclusive (TRL + ITT) value-based contracting with public and private payors
Replace the Medicare Cost Report and the DRG

• Antiquated means of paying for therapy of choice
• Leaves transplant centers financially dependent on all the wrong line items
• DRG is manifestly inadequate for all but living donation

Alternative: Pay for transplant based on savings compared to ICHD (3 yr ~$280K)*

• Shared savings = SAC + DRG + Immunos + Labs + professional fees
  – $ Bonus system for > 3-year death uncensored graft survival
• Incents silo elimination, other cost-saving measures (e.g. “Novel collaborations”), offers a check on expanding organ utilization “too far.”
• Use Medicare savings as basis for global case rates for MA and private payors

*Sussell AJT 2020 early view
Barriers

• Pervasive and mutual misunderstanding, mistrust, and moral sanctimony;
• Complexity of new payment models :: Hard to understand shifted incentives
• (Often reasonable) aversion to the risk of novel approaches:
  – Transplant centers just not ready to take on any 2-sided risk on total costs of care;
  – Siloed physicians and surgeons mostly satisfied with their current roles;
  – Failed efforts may prove expensive (e.g. negative ‘Hotspotting’ study in NEJM);
  – Will Triple Aim wins = Quadruple Aim (includes clinician well-being) losses?
• Regulators and payors will have difficulty keeping up with change;
• Understanding failure of individual interventions =/= global failure of strategy;
• Efficiencies :: Consolidation :: Surveillance -> Expense of choice and privacy
Overcoming barriers

• “Peace in our time” – Open-minded leaders needed! Listening/learning tour
• Understanding complex incentives = Collaboration on shared goals:: TRL/ITT
  – Bring transplant center personnel directly into CKD clinics and dialysis facilities
  – Bring general nephrologists into “transplant late-CKD” dedicated clinics
• Mitigating (reasonable) aversion on part of Centers to value-based contracting
  – Pilot time-limited collaborations with nephhs/DO consortia who are taking downside risk
  – Agreements that reward more transplants, fill holes in Centers’ balance sheet (DRG)
• Common ground -- United front on common goals with regulators and payors
• Sharing success/failures in population health management (Hotspotting)
• Struggle out loud with patient choice, patient privacy concerns.
What success could look like

1. “Cocoon of care” for all patients across the total renal life continuum;
2. Full alignment of nephrologists, dialysis providers, and transplant centers;
3. Through alignment, a unified front with regulators, payors, and employers;
4. Expanded access to actual transplantation, tempered by cost and quality;
5. Feedback loop to identify and fix problems and unintended consequences;

....all in service to:

Creating a patient-responsive, quality focused, and financially sustainable model of care across continua of kidney disease-states.
Thank you
References


