Post-Transplant Patient Education and Medication Adherence

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Objectives

At the end of this presentation, you will be able to:
• Understand post-kidney transplant medication education and counseling
• Discuss the importance of medication adherence and compliance
• List and describe risk factors and potential barriers to medication nonadherence and noncompliance
• Identify various interventions and strategies to prevent nonadherence
• Examine current and future Medicare immunosuppressant drug coverage

Overview of Kidney Transplantation
• Most patients with end-stage renal disease (ESRD) stem from conditions such as:
  • Diabetes (diabetic nephropathy)
  • Hypertension (hypertensive nephrosclerosis)
  • Glomerular disease
• Transplantation is the primary treatment option for most ESRD patients
• Transplant patients live an average of 10 to 15 years longer than patients on dialysis

Management of Transplant Patients
• Immunosuppressive therapy is most important component
• Complex regimen of drugs
• Lifelong immunosuppressive
• Primary cause of kidney transplant failures
  ➢ Lack of adherence to immunosuppressive medications
Patient Education Workflow

- Pre-transplant education session
  - Living donors
  - Deceased donors
- Post transplant nurse coordinators
  - Roles
  - Education booklet
  - Wound care
  - General info
  - Appointment follow up
  - Medication delivery/pillbox
- Inpatient pharmacist counseling
  - Importance of medications
  - Side effects
  - Pain
  - Expectations
  - Duration of anti-infective prophylaxis
  - Medication reconciliation
    - Discontinue ESRD meds
      - i.e. phosphate binders, Sensipar

UNOS Bylaws: Transplant Clinical Pharmacist

- Evaluates, screens and identifies medication related issues for potential transplant recipients
- Evaluates transplant recipients and their family members on transplant medications and adherence to medication regimen
- Prepares and assists with discharge planning for all transplant recipients
- Acts as liaison between patient and patients' families and other health care team members
- Communicates all transplant recipient medication issues and concerns to appropriate members of the transplant team
- Assists with designing, implementing, and monitoring of comprehensive care plans with other team members (i.e. transplant coordinators, financial coordinator, social worker, dietitian, etc.)

UNOS= United Network for Organ sharing

Typical Post-Transplant Medication Regimen

- Anti-rejection medications
  - Tacrolimus (Prograf)
  - Mycophenolate mofetil (CellCept)
  - +/- Prednisone
- Anti-infective medications
  - Antibacterial
    - Sulfamethoxazole/Trimethoprim (Bactrim DS) or alternative if allergic
  - Anti-viral
    - Valganciclovir (Valcyte)
- Medications for other conditions and Supplements as needed
  - Anti-hypertensives
  - Anti-hyperglycemics
Transplant Patient Education

• Why patients need these medications
  • Anti-rejection medications
    • Lowers body’s natural defense (immune system) against illness and new organ
    • When the body’s immune system fights against organ/allograft, it is known as rejection
    • Thus, these medications stop the body from rejecting the new organ
  • Anti-infective medications
    • Anti-rejection medications increases risk of becoming sick from infections due to the decrease in immune system
    • Taking an antibacterial and antiviral can help prevent certain potential infections

• Cytomegalovirus (CMV)
  • Related to herpes virus
  • Most people have previously been exposed to CMV
  • In immunocompromised patients, latent virus may become active
    • Can affect many organ systems
      • Eyes
      • Lungs
      • Gastrointestinal tract
      • Liver
  • May increase risk of rejection
  • Symptoms of nausea, vomiting, and diarrhea, abdominal pain

• BK virus (polyoma virus)
  • Most people have been previously exposed
  • Latent virus
  • Symptoms are similar to the common cold

Mycophenolate REMS program

Non-adherence

Intentional

Non-intentional

Missing doses

Altering doses

Forgetting doses
Why is this so important?

- Patients are on life-long immunosuppressive regimens
- Non-adherence and non-compliance is associated with a 60% increased risk of kidney transplant failure
  - Increase graft rejection episodes
  - Increase hospitalizations
  - Increase costs
  - Increase poor long-term kidney outcomes

WHO classification of risk factors for non-adherence

- Socio-economic factors
  - Age
  - Gender
  - Nationality
  - Live alone/with others
  - Employment status
  - Perceived adequacy of one's financial situation
  - Level of education

- Patient- / disease-related factors
  - Health beliefs/behaviors
  - Vaccination status
  - Smoking history
  - Alcohol use
  - Depression

- Treatment-related factors
  - Lack of health insurance or health benefits

Additional factors

- Influence of personal characteristics
- Predictor of health-related behavior
- Previous dialysis-dependent patients
- Perceived susceptibility to rejection
- Frequency of drug dosing
  - Once vs Twice daily
Measuring nonadherence

- Electronic medication monitoring
  - Gold standard
  - Limitations:
    - Lack of certainty that med or correct dose was taken
- Self-reporting
- Drug levels
  - Compliant with medications prior to known lab draw
    - However, patient may have missed a dose or two
- Difficult to quantify nonadherence
  - Inconsistent methodology
  - Honest disclosure of self-reporting

Medication Adherence Secondary Outcomes

<table>
<thead>
<tr>
<th>Study, duration, number of participants</th>
<th>Interventions</th>
<th>Measurement</th>
<th>Results</th>
<th>Measurement</th>
<th>Results</th>
</tr>
</thead>
</table>
| Chisholm & Burns (2013) 15 months, C: n = 74, I: n = 76 | Informational: non-adherence consequences, Behavioral: identify tools/strategies Patient motivation | Pharmacy refill records, Monthly healthcare screening questionnaire | T-test Adherence score:
6 months: I: 0.80, C: 0.86
9 months: I: 0.81, C: 0.81 | % patients requiring hospitalization:
I: 6.4%
C: 7.5% |
| Chisholm (2001) 21 months, C: n = 12, I: n = 12 | Usual care (C) vs. intervention (I) | Pharmacy refill records | Mean compliance rates:
I: 96%
C: 82% | Serum drug concentrations of IS | % patients within target serum levels:
I: 64%
C: 48% |

Overcoming barriers of Nonadherence

A combination of interventions via team approach is the most helpful long-term strategy

- Pharmacist-led medication counseling
- Individualized and patient-tailored education
- Open-ended questions regarding adherence
- Repetitive teaching
- Medication scheduling
- Weekly pillboxes
- Refill reminders
Transplant Patient Education

• Medication List
  • Every patient should have an up-to-date medication list that includes:
    • Names and doses of medications
    • How often
    • Indication
    • Name of prescriber
    • Allergies
    • Medication conditions
  • Bring list to every clinic appointment

• Medication Pillbox

Other considerations

• Once vs Twice daily dosing
  • Drug holidays

• Belatacept (Nulojix™)

• Steroid free protocols

• Calcineurin-inhibitor (CNI) minimization

• Valganciclovir (Valcyte®) mini-dosing

• Generics vs Brand medications

• Pipeline transplant medications

• Novel technology: New ingestible sensor system

Barriers to Medication Adherence

• Access to immunosuppressive agents
  • Medicare benefits
  • Financial
  • Direct relationship between loss of insurance coverage and allograft failure

Disparities in Kidney Transplant Outcomes

Risk Factors for Worse Graft Function
Disparities in Kidney Transplant Outcomes\textsuperscript{15}

- Immunological risk factors
- Non-immunological risk factors
  - Comorbidities
  - Time on dialysis
  - Ethnic characteristics and organ characteristics
  - Socioeconomic status
  - Medication adherence
  - Access to care and health policies\textsuperscript{*}

Medicare Coverage of Immunosuppressant drugs

Medicare Part B History\textsuperscript{17}

- 1993-95 Medicare and Medicaid services gradually extended coverage
  - 3 years after kidney transplantation
- 2011-Present
  - Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act
Medicare Part B

Part B Premiums
• The standard Part B premium amount in 2017 is $134 (or higher depending on your income)
• If you pay your Part B premium through your monthly Social Security benefit, you’ll pay less ($109 on average).

Part B deductible & coinsurance
• You pay $183 per year for your Part B deductible
• After your deductible is met, you typically pay 20% coinsurance

Medicare Part B: What does this all mean?

<table>
<thead>
<tr>
<th>Immunosuppressive Drug</th>
<th>AWP (30-d AWP)</th>
<th>Annual AWP</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tacrolimus</td>
<td>$2,054.00</td>
<td>$2,054.00</td>
<td>20%</td>
</tr>
<tr>
<td>Mycophenolate Mofetil</td>
<td>$2,260.00</td>
<td>$2,260.00</td>
<td>20%</td>
</tr>
<tr>
<td>Prednisone</td>
<td>$7.00</td>
<td>$7.00</td>
<td>20%</td>
</tr>
</tbody>
</table>

$4,321 total per person
Medicare Part D 17

- Part D went into effect in 2006 and has been administered by private health plans.
- In situations where a beneficiary receives a transplant prior to enrolling in Medicare, immunosuppressive drugs are not covered by Part B but will be covered under Part D.

Medicare Part D Gap 17

Future

- Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act “Immuno Bill”
- Affordable Care Act
- Assistance Programs

Immuno Bill 18

- S.1454/H.R. 2969 was first introduced (112th congress)
- Proposed to amend Medicare to extend ISD coverage beyond 36 mo
- Would allow individuals to be eligible for Medicare Part B solely for the purpose of drug coverage
- Has “died” in the senate finance committee twice
- Recently re-introduced in House 9/22/16 and the Senate 11/30/16
  - H.R. 6139 and S.3487
  - Bill was not enacted
Immuno Bill

- A no brainer?
- Cost of transplant vs dialysis

Kidney transplant = $32,914
PD = $64,175
HD = $87,561

Immuno Bill

- Why the hesitation?
  - The financial health of Medicare programs will be partly determined by cost savings associated with the ACA over the next decade
  - Political pressure/lobbyists from industry has opposed any shifting of payment away from dialysis to transplant antirejection drugs
  - Additional expenditures and disease-specific ESRD entitlement have been questioned by some policymakers when other disease-specific programs lack similar benefits

ACA = Affordable Care Act

Economic Impact of ESRD care and ISD coverage

Medicare Part D ~ $305 million
Medicare Part B ~ $460 million

ESRD = End Stage Renal Disease

Table 6: High Expenditures Medicare Part D Drugs for Which Spending on Medicare Beneficiaries Exceeded Two-thirds of Total U.S. Spending, 2010

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug Name</th>
<th>Conditions Treated</th>
<th>Spent on Total U.S. Spending (Billions) 2010</th>
<th>Spent on Medicare Beneficiaries (Billions) 2010</th>
<th>Percentage of Medicare Spending on Total Spending 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cancer</td>
<td>Preventing and treating cancer (including oral cancers)</td>
<td>297</td>
<td>200</td>
<td>67.1</td>
</tr>
<tr>
<td>2</td>
<td>Psoriasis</td>
<td>Psoriasis, atopic dermatitis (including oral lesions)</td>
<td>184</td>
<td>128</td>
<td>69.7</td>
</tr>
<tr>
<td>3</td>
<td>Anemia (ESRD use)</td>
<td>Anemia, kidney failure (including chronic kidney disease)</td>
<td>163</td>
<td>102</td>
<td>62.7</td>
</tr>
<tr>
<td>4</td>
<td>Infections (infections)</td>
<td>Infections (including HIV/AIDS)</td>
<td>87</td>
<td>57</td>
<td>66.6</td>
</tr>
<tr>
<td>5</td>
<td>Cancer</td>
<td>Preventing and treating cancer (including oral cancers)</td>
<td>113</td>
<td>70</td>
<td>62.3</td>
</tr>
</tbody>
</table>

Source: GAO analysis of Centers for Medicare & Medicaid Services and RED BOOK data. | GAO-16-594
Medication Assistance Programs

- Texas Kidney Healthcare
- Rx Assist, RxHope, Together Rx Access Card
- AZ&Me Prescription Savings Program
- VALCYTE® (valganciclovir): co-pay card

Medication Assistance Programs

- Social worker/case manager
- Drug assistance programs
- Pre-transplant screening (financial)
References:


2. The United Network of Organ Sharing Bylaws. Attachment 1 to Appendix B of the UNOS Bylaws; Designated Transplant Program Criteria. UNOS-Appendix B-Attachment I--XIII-93 June 28-29, 2011


