Home-based hematopoietic stem cell transplantation

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Background

Hematopoietic cell transplantation (HCT) has the potential to cure hematologic malignancies and other disorders, but at the risk of toxicities:

- **HLA-identical Sibling**
  - New Malignancy (1%)
  - GVHD (16%)
  - Infection (13%)
  - Other (18%)
  - Organ Failure (5%)

- **Unrelated Donor**
  - Primary Disease (37%)
  - New Malignancy (1%)
  - GVHD (18%)
  - Infection (18%)
  - Other (18%)
  - Organ Failure (8%)

WHY AT HOME?

- Home-based HSCT has the potential to:
  - Reducing exposure to nosocomial pathogens, preventing infections
  - Maintain the gut microbiota, decreasing inflammation and preventing GVHD
  - Improving access to nutrition, activity, social support, and independence, improving quality of life
  - Lower costs

Shifting Risk

- Consumers
- Employers
- Health Plans
- Government Payers

- Physicians
- Medical Groups
- Hospitals
- Other Providers

Source: Pricewaterhouse Coopers | Dixon Hughes
What Is the Patient Centered Medical Home? This is what WE do!

- Defined in pilot programs in 44 states
- Built on 7 fundamental principles
- Focuses on comprehensive patient management
  - Focuses on treatment and management of chronic conditions
  - Manages expense of high cost, perpetual patients (Diabetes, COPD, Hypertension, Asthma)
- Increases access by leveraging physician extenders
- Qualifies for additional incentive based payments

Cornerstone of Accountable Care Organizations

Duke Cancer Institute
A National Cancer Institute-designated Comprehensive Cancer Center

Scientific Rationale

- The human body has ~100 trillion cells; the gut has ~10 x as many microorganisms with ~100 x more genes
- Our gut microbiota has a symbiotic relationship
  - fermenting unused energy substrates
  - fending off harmful bacteria
  - training the immune system
  - regulating gut development
  - producing vitamins and hormones.
- Changes in the gut microbiome have been implicated in diseases from obesity to infections to cancer and graft-versus-host disease.
**Scientific Rationale**

- Patients with GVHD were more likely to have loss of stool flora diversity (right).
- Changing the gut microbiota in murine models of HSCT (bottom) worsens GVHD and survival.

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**Home-based HSCT has been done:**

- Case-control study from the Karolinska Institute
- 36 patients treated at home vs. 54 controls

- Improved survival
  - Trend to improved relapse-free survival
Scientific Rationale

Home-based HSCT has been done:
- less GVHD
- less TRM

Table 2  Grade of acute GVHD and organs affected in patients treated at home or in the hospital

<table>
<thead>
<tr>
<th>Grade of acute GVHD</th>
<th>Home care</th>
<th>Controls</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>11 (33%)</td>
<td>8 (15%)</td>
<td>0.11</td>
</tr>
<tr>
<td>Grade I</td>
<td>19 (53%)</td>
<td>21 (39%)</td>
<td>0.28</td>
</tr>
<tr>
<td>Grade II</td>
<td>5 (14%)</td>
<td>14 (26%)</td>
<td>0.19</td>
</tr>
<tr>
<td>Grade III-IV</td>
<td>1 (3%)</td>
<td>9 (17%)</td>
<td>0.08</td>
</tr>
<tr>
<td>Day of acute GVHD</td>
<td>21 (8-13)</td>
<td>19 (8-40)</td>
<td>0.21</td>
</tr>
</tbody>
</table>

Organs affected by GVHD
- Skin: 25 (100%)
- Liver: 3 (12%)
- Gastrointestinal tract: 4 (16%)

Methods

1. Keep patients at home during the pancytopenic phase after HSCT.
2. How?
   a. Find the proper patient, family and home situation.
   b. Do a site visit and home inspection with caregiver.
   c. Chemotherapy +/- TBI in the hospital, followed by discharge home.
   d. Typical day at home:
      a. Morning house call by an advanced practice provider
         a. History, physical, draw labs
      b. APP brings labs back to the hospital, where they are run
      c. Afternoon house call by a visiting nurse to provide blood transfusions, electrolytes, iv antibiotics, or other interventions
      d. Video link available day or night for patient and family.
Data and Outcomes

• 7 home-based transplants
  – 6 auto (4 myeloma, 2 lymphoma), 1 allo (AML)
  – Age 47-69 (average 60)
  – 6.5-25.5 miles away (average 16.5 miles)
• 129 Days at Home
  – 102 APP and 96 RN visits
  – 72 electrolyte infusions, 23 blood transfusions, 38 days of iv antibiotics
Data and Outcomes

- **Lessons Learned**
  - Blood draw tubes, iv pole, weight scale to be left at home
  - Designated place to work
  - IT infrastructure
    - Cell phone reception
    - IT security
  - Insurance approval and authorization
  - Staff scheduling

- **Safe and Feasible**
Data and Outcomes

- Preservation of bacteroides, a potentially helpful anaerobic bacteria

Results and Next Steps

- Randomized Phase 2 Trial of home-based vs. standard HSCT
  - Allogeneic patients
- Hypotheses:
  - Improve GVHD, infections, TRM, QOL
  - Identify mediators of efficacy (nutrition, exercise, caregiver, etc.)
  - Maintain the gut microbiota
  - Lower costs by reducing complications, length of stay, etc.
Conclusions

- Home-based HSCT is safe and feasible
- Keeping patients at home may help maintain their gut microbiota
- A randomized phase 2 study is currently in process

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