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Medical Device Advancements: Balancing Development and Value

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Medical Device Advancement - Balancing Development & Value

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Professor of Surgery CCLCM
Disclosures

- Research Support – Stryker, Zimmer, Salient Surgical Technologies, Orthovita, Cool Systems, Active Implants, DJO, Orthosensor
- Consultant – Stryker Orthopaedics
- Royalties – Stryker, Zimmer, Exactech, Shukla Medical
- Stock Options – Otismed, Custom Orthopaedic Solutions, iVHR
- Board Member – KEF Healthcare
Today - Dramatic and Rapid Change

Inflection Point

- Economics
- Consumerism
- Transparency
- New Players
- Reform
- Demographics
- Technology
Medicare Payment Cuts

Total $415 Billion
What are we facing?

- Governments and health insurers implementing measures to control costs
- Hospital operating on tighter budgets
- Flat or declining reimbursement trends
- Increasing competition in orthopaedic device industry

**TREND TOWARDS PRODUCTS THAT ARE “GOOD ENOUGH” AND COMPETITIVELY PRICED**
Value = \frac{\text{Quality}}{\text{Cost}}

(1) Improve quality without raising costs
(2) Reduce cost without compromising quality
U.S. Hospital Beds

1991: 923,000
2013: 796,000
“A majority of Medicare fee-for-service payments already have a line to quality or value”

“Our goal is to have 85% of all Medicare fee-for-service payments tied to quality or value by 2016, and 90% by 2018”
Payment Structure

Volume-Based → Value-Based

Fee-for-Service → Outcomes
Reimbursement Model Shifting Away from FFS

Increasing Amount of Risk

Fee for Service
Pay for Value
Shared Savings Upside
Shared Savings Downside
Bundles/Episode Risk
Full Capitated Risk
Value-Based Purchasing

Efficiency
Care Outcomes
Patient Experience
Clinical Process

2013: 70% (30% Red, 45% Blue)
2014: 45% (30% Red, 15% Blue)
2015: 30% (30% Red, 0% Blue)
2016: 25% (25% Red, 0% Blue)
Retail Clinics

- Walmart
  - Save money. Live better.
- take care clinic
  - at select Walgreens
- minute clinic
  - the medical clinic in CVS/pharmacy
- TARGET
- The Little Clinic
  - Convenient Neighborhood Medical Care
  - Inside Select Stores
- Kroger
Retail Clinics

2006: 202
2007: 
2008: 
2009: 
2010: 
2011: 
2012: 
2013: 
2014: 2,243
Quality Reports
Quality Metrics
Cost Transparency Companies

- CLEAR HEALTH COSTS BETA
- pokitdok
- FindTheData
- Transparent Healthcare
- CASTLIGHT HEALTH
- CHANGE HEALTHCARE
- CarePilot
- New Choice Health
- Healthcare Blue Book
- OPTIMAL HOSPITAL
- HEALTHSPARQ
- TREO SOLUTIONS
High Deductible Insurance

2009: 19%
2014: 36%
TJA Today

- THA and TKA – Two of the most successful surgeries in improving quality of life
• Reported THA survivorship of 78% (±8%) with end point of revision for any reason
Survivorship TKA

- Long-term follow-up studies have reported implant survivorship as high as 96% at 15 – 20 years (Ma et al JOA 2005; Lachiewicz and Soileau JBJS 2009; Ritter JBJS Br 2009)
Patient Dissatisfaction following TJA

- 15% patients dissatisfied with TKA (NIH Health Consensus panel)
- 7% patients dissatisfied with THA (Anakwe et al. 2010 JOA)

THA and TKA are highly successful procedures, but there are opportunities for improvement. Must be carefully considered in value-based system.
Value?

- Technological advances may (or may not) result in better outcomes
- Results in increased cost
- Cost-effective? Adds value?

![Graph showing health care consumption vs. outcomes](chart.png)
18 years of results with cemented primary hip prostheses in the Norwegian Arthroplasty Register
Concerns about some newer implants

Birgitte Espehaug¹, Ove Furnes¹,², Lars B Engesæter¹,², and Leif I Havelin¹,²
1998-2007

N=37,577 THAs

Except for Spectron/ITH and Link IP/Lubinus SP (I and II), all prostheses had statistically significantly higher revision rates than the Charnley
Incremental vs Transformational Change

- Incremental – modest changes to products, keep a business generally competitive (e.g., alternative hip bearing surfaces, navigation)
- Transformational – large technological advances that propel ahead of competitors, often the result of R&D
Types of Innovation

- **Product/service**
  - New good or service
- **Process**
  - Improved production or delivery
- **Marketing**
  - Improved design or packaging
  - Pricing
- **Organizational**
  - Business practices
- **Business model**
  - New ways to capture value

Evolutionary – incremental
Revolutionary – breakthrough
## Incremental vs Breakthrough

<table>
<thead>
<tr>
<th>Metric</th>
<th>Incremental</th>
<th>Breakthrough</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding</td>
<td>$$</td>
<td>$$$$$$$</td>
</tr>
<tr>
<td>Market size</td>
<td>Varies depending on funding needed</td>
<td>&gt;500MM</td>
</tr>
<tr>
<td>Time needed</td>
<td>Shorter</td>
<td>Longer</td>
</tr>
<tr>
<td>Adoption &amp; exit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Value at exit</td>
<td>Less</td>
<td>More</td>
</tr>
<tr>
<td>Major risks</td>
<td>Window of opportunity</td>
<td>Technical/clinical unknowns</td>
</tr>
<tr>
<td></td>
<td>Execution quality &amp; critical path</td>
<td>Market adoption hurdles</td>
</tr>
<tr>
<td></td>
<td>Competition</td>
<td>Reimbursement</td>
</tr>
<tr>
<td>Success factors</td>
<td>Focused execution, management experience,</td>
<td>Patents, franchise value,</td>
</tr>
<tr>
<td></td>
<td>manufacturing economics</td>
<td>market adoption, standard of</td>
</tr>
<tr>
<td></td>
<td></td>
<td>care, investor expectations</td>
</tr>
<tr>
<td>Patent protection</td>
<td>Less</td>
<td>More</td>
</tr>
<tr>
<td>Competition</td>
<td>More</td>
<td>Less</td>
</tr>
</tbody>
</table>
Hepatitis C Treatment

- Hep C drug Sovaldi approved by FDA in Dec 2013, cures over 90% of patients
- 1K per pill, or 84K for 12-week treatment regimen
- Medicare coverage under Part D
- National Health and Nutrition Examination Survey estimates that 350K Medicare beneficiaries have hep C
- Medicare spent $4.5 billion in 2014 – 15 times more than the year before on older treatments ($286 million in 2013)
Hepatitis C Treatment

- Gilead developed and introduced another hep C drug in 2014 – Harvoni (combination of Sovaldi and second drug, $94,500)
- AbbVie introduced Viekira Pak Dec 2014 ($83,000)
- Battle for payers - Insurance providers negotiating with drug companies for discounts
### U.S. Average 2011 Billed Charges Per Transplant

<table>
<thead>
<tr>
<th>Transplant</th>
<th>30 Days Pre-transplant</th>
<th>Procurement</th>
<th>Hospital Transplant Admission</th>
<th>Physician During Transplant</th>
<th>180 Days Post-transplant Admission</th>
<th>Immuno-suppressants</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Only</td>
<td>$47,200</td>
<td>$80,400</td>
<td>$634,300</td>
<td>$67,700</td>
<td>$137,800</td>
<td>$30,300</td>
<td>$997,700</td>
</tr>
<tr>
<td>Single Lung</td>
<td>$10,300</td>
<td>$73,100</td>
<td>$302,900</td>
<td>$33,500</td>
<td>$117,700</td>
<td>$23,700</td>
<td>$561,200</td>
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<tr>
<td>Double Lung</td>
<td>$21,400</td>
<td>$90,300</td>
<td>$458,500</td>
<td>$56,300</td>
<td>$142,600</td>
<td>$28,200</td>
<td>$797,300</td>
</tr>
<tr>
<td>Heart-Lung</td>
<td>$56,800</td>
<td>$130,500</td>
<td>$777,700</td>
<td>$81,000</td>
<td>$169,100</td>
<td>$33,300</td>
<td>$1,148,400</td>
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<tr>
<td>Liver</td>
<td>$25,400</td>
<td>$71,000</td>
<td>$316,900</td>
<td>$46,600</td>
<td>$93,900</td>
<td>$23,300</td>
<td>$577,100</td>
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<tr>
<td>Kidney</td>
<td>$17,000</td>
<td>$67,200</td>
<td>$91,200</td>
<td>$18,500</td>
<td>$50,800</td>
<td>$18,200</td>
<td>$262,900</td>
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<tr>
<td>Pancreas</td>
<td>$17,000</td>
<td>$65,000</td>
<td>$108,900</td>
<td>$17,800</td>
<td>$61,400</td>
<td>$19,300</td>
<td>$289,400</td>
</tr>
<tr>
<td>Intestine</td>
<td>$55,100</td>
<td>$78,500</td>
<td>$787,900</td>
<td>$104,100</td>
<td>$146,600</td>
<td>$34,600</td>
<td>$1,206,800</td>
</tr>
</tbody>
</table>

- CMS spends $27 billion annually on the care of renal failure patients, approximately 13% of which are transplants (Englesbe et al. *Am J Transplant* 2009)

Data from Milliman Research Report, Dec 2014
TKA as Commoditized Product

- Continue to drive prices lower OR
- Package additional “value” that the customer is not willing to pay for (e.g., disposable cutting guides, preoperative planning)

Llewellyn et al, Capturing the new “value” segment in medical devices, Jan 2015
What Will Hospitals Pay For?

Products with:

- Existing human data
- Level I studies
- Reproducible published studies in peer-reviewed literature
- Cost-benefit studies
• Vanderbilt University – Medical Economic Outcome Committee (MEOC)

• “A clinician-driven process that standardizes and utilizes evidence-based, clinically sound, financially responsible methodologies for introduction or consolidation of new supplies, devices and technology within the medical center to provide the highest quality of patient care”
Final Thoughts

- Significant concerns about future “value” of US healthcare.
- 22% believe costs will grow without improving quality.
- Align competition with value - energy and expertise must be directed at the right problems.
- Incremental changes to existing technology will not suffice. Need breakthrough technology with proven effect on quality.

Harvard’s Forum on Healthcare Innovation, 2014
Cleveland Clinic

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