Today’s Presenters

Julie Schulz, MD, MPH
Vice President, Clinical Engagement and Effectiveness Lumere

Simon Kerr
Category Advisor
Lumere
Agenda

• Orthopedics market landscape

• Hip and knee implants

• Ancillary devices
Orthopedics and spine are key service lines

DEVICE EXPENSE ACROSS SERVICE LINES

Orthopedics/Spine 21%
Cardiac 16%
Interventional 11%
Nursing 7%
Neuro 4%
General Surgery 9%
Other (ENT, GI, Urology, Critical Care, etc.) 32%
Joints 10%
Spine 8%
Trauma 2%
Other 1%

Source: Lumere analysis, ENT = Ear, nose, and throat; GI = Gastrointestinal.
Joint replacement demand grows while site of care evolves

DEMAND FOR JOINT REPLACEMENT

<table>
<thead>
<tr>
<th>Year</th>
<th>Hips</th>
<th>Knees</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PROJECTED IP AND OP JOINT REPLACEMENT

- Inpatient
- Outpatient

Sources: Orthopedic Network News, Sg2; IP: inpatient, OP: outpatient.
Joint replacement accounts for ~10% of a health system’s device expense

KNEES
- ~45% of joint replacement spend
- 120+ devices
- 25+ vendors
- 4 Lumere device groups

HIPS
- ~35% of joint replacement spend
- 350+ devices
- 20+ vendors
- 7 Lumere device groups

OTHER
- ~20% of joint replacement spend
- Includes bone cement, shoulders, ankles, small joints
- 20+ vendors
“Big 4” vendors dominate 90+% of U.S. hip and knee implant market

HIP AND KNEE IMPLANT MARKET

- Smith & Nephew (10%)
- DePuy Synthes (J&J) (23%)
- Stryker (25%)
- Zimmer Biomet (35%)
- Others (20+) (7%)

RECENT M&A ACTIVITY

- 2011: Synthes acquired by J&J, formed DePuy Synthes
- 2013: MAKO acquired by Stryker
- 2013: Wright’s hips/knees acquired by MicroPort
- 2014: Biomet acquired by Zimmer, formed Zimmer Biomet
- 2014: Wright and Tornier merged
- 2016: Blue Belt Technologies acquired by Smith & Nephew
- 2016: Tornier’s hips/knees acquired by Corin
- Could Smith & Nephew be acquired next?

Source: Orthopedic Network News; J&J = Johnson & Johnson; M&A = mergers and acquisitions.
Hip and knee implant pricing is not rational

THERE IS NOT A STRONG CORRELATION BETWEEN SPEND VOLUME AND BETTER PRICES IN JOINT REPLACEMENT

Source: Lumere analysis.
Orthopedic device companies enjoy extremely high gross margins

<table>
<thead>
<tr>
<th>Company</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>5-year Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith &amp; Nephew</td>
<td>74.1%</td>
<td>74.7%</td>
<td>74.8%</td>
<td>75.3%</td>
<td>72.8%</td>
<td>74.3%</td>
</tr>
<tr>
<td>Zimmer Biomet</td>
<td>74.8%</td>
<td>72.6%</td>
<td>73.4%</td>
<td>70.0%</td>
<td>69.0%</td>
<td>72.0%</td>
</tr>
<tr>
<td>Stryker</td>
<td>67.9%</td>
<td>66.7%</td>
<td>65.7%</td>
<td>66.4%</td>
<td>66.2%</td>
<td>66.6%</td>
</tr>
<tr>
<td>Apple</td>
<td>41.9%</td>
<td>37.4%</td>
<td>39.3%</td>
<td>40.1%</td>
<td>38.5%</td>
<td>39.4%</td>
</tr>
<tr>
<td>Tesla</td>
<td>7.3%</td>
<td>22.7%</td>
<td>27.6%</td>
<td>22.8%</td>
<td>23.9%</td>
<td>20.9%</td>
</tr>
<tr>
<td>General Motors</td>
<td>7.1%</td>
<td>11.6%</td>
<td>8.9%</td>
<td>12.0%</td>
<td>12.8%</td>
<td>10.5%</td>
</tr>
</tbody>
</table>

Source: TradingView
Orthopedic care providers need to adapt to the evolving value-based care landscape

### STATUS OF APMs UNDER CMS

<table>
<thead>
<tr>
<th>Payment Model</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bundled Payment Care Initiative (BPCI) Advanced</td>
<td>Active</td>
</tr>
<tr>
<td>BPCI Models 2, 3, 4</td>
<td>Active</td>
</tr>
<tr>
<td>Comprehensive Care for Joint Replacement</td>
<td>Active with modifications</td>
</tr>
</tbody>
</table>

### “BUNDLED” AVERAGE TARGET PRICE EXPECTED TO DECREASE OVER TIME

Source: OrthoIndex analysis, 2016; CMS = Centers for Medicare and Medicaid Services; TKA = total knee arthroplasty.
The time for evidence-based care is now

**Episode of care (~90 days)**

### PRE-OPERATIVE
- Patient selection/indications
- Patient expectations
- Prehabilitation

### PERI-OPERATIVE
- Implant selection
- Ancillary device utilization

### POST-OPERATIVE
- Multimodal analgesia
- Early mobilization
- VTE prophylaxis

### POST-ACUTE
- Discharge disposition
- Communication
- Patient motivation and education
- Avoidance of ED visits/readmission

VTE = venous thromboembolism; ED = emergency department.
Optimizing implant selection can drive significant cost savings while maximizing clinical outcomes

Episode of care (~90 days)

- Implant selection
- Ancillary device utilization
Transformative innovation (“new technology”) in hip and knee implants is lacking

1980-1990
- Mobile-bearing tibial components
- OXINIUM femoral components
- BIOLOX ceramic femoral heads
- Cross-linked polyethylene

2000-2009
- Custom implants and cutting guides
- Advanced porous coatings
- Antioxidant (e.g. vitamin E) cross-linked polyethylene

2010-PRESENT
- Minimal innovation
- What is next?

OXINIUM is a trademark of Smith & Nephew; BIOLOX is a trademark of CeramTec.
Recent new technologies in hip and knee arthroplasty have been disappointing

Appraisal of evidence base for introduction of new implants in hip and knee replacement: a systematic review of five widely used device technologies
Nieuwenhuijise MJ, Nelissen RG, Schoones JW, Sedrakyan A

Conclusion: We did not find convincing high quality evidence supporting the use of five substantial, well known, and already implemented device innovations in orthopaedics. Moreover, existing devices may be safer to use in total hip or knee replacement. Improved regulation and professional society oversight are necessary to prevent patients from being further exposed to these and future innovations introduced without proper evidence of improved clinical efficacy and safety.

Do “premium”: joint implants add value?: analysis of high cost joint implants in a community registry
Gioe TJ, Sharma A, Tatman P, Mehle S

Conclusion: In this time frame, premium implants did not demonstrate better survival than standard implants. Revision indications for TKA did not differ, and infection and instability remained contributors. Longer followup is necessary to demonstrate whether premium implants add value in younger patient groups.

Sources: The BMJ, September 2014; Clinical Orthopaedics and Related Research, January 2011. TKA = total knee arthroplasty.
New technologies in hip arthroplasty have not consistently led to improved clinical outcomes

<table>
<thead>
<tr>
<th>Technology</th>
<th>Price premium</th>
<th>What does the evidence say?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dual mobility acetabular systems, e.g. ADM from Stryker</td>
<td>$150</td>
<td>See Technology Spotlight (next slide)</td>
</tr>
<tr>
<td>Antioxidant acetabular liners, e.g. E1 from Zimmer Biomet</td>
<td>$400</td>
<td>Lower liner oxidation, no evidence of improved clinical outcomes</td>
</tr>
<tr>
<td>Ceramic femoral heads, e.g. BIOLOX delta from many vendors</td>
<td>$400</td>
<td>May improve implant survivorship particularly in active patients</td>
</tr>
</tbody>
</table>

Source: Lumere analysis. Prices are approximate. Photo credit AAOS.
Technology Spotlight: Dual mobility acetabular systems

WHAT DOES THE EVIDENCE SAY?

• Similar hip scores (pain, function) but lower dislocation rates compared to standard systems.

• May be appropriate ($150 price premium) for patients at elevated risk for dislocation, particularly in revision cases.

Sources: American Joint Replacement Registry 2016 Annual Report (left); Lumere analysis (right); photo credit Zimmer Biomet (right).
New technologies in knee arthroplasty have not consistently led to improved clinical outcomes

<table>
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<tr>
<th>Technology</th>
<th>Price premium</th>
<th>What does the evidence say?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxidized zirconium, e.g. OXINIUM from Smith &amp; Nephew</td>
<td>$600</td>
<td>No evidence of improved clinical outcomes</td>
</tr>
<tr>
<td>Antioxidant tibial inserts, available from several vendors</td>
<td>$300</td>
<td>Lower liner wear compared to standard poly, no comparative clinical study</td>
</tr>
<tr>
<td>Mobile-bearing components, e.g. Attune Rotating Platform from DePuy Synthes</td>
<td>$700</td>
<td>No evidence of improved clinical outcomes</td>
</tr>
</tbody>
</table>

Source: Lumere analysis. Prices are approximate. Photo credit Zimmer Biomet.
Technology Spotlight: Antioxidant polyethylene tibial inserts

WHAT DOES THE EVIDENCE SAY?

- Antioxidant tibial inserts have only been evaluated compared to UHMWPE or XLPE in vitro.

- Price premium ($300) is not warranted until improved clinical outcomes are demonstrated.

ACETABULAR LINER MATERIAL UTILIZATION BY YEAR IN USA

Sources: American Joint Replacement Registry 2016 Annual Report (left); Lumere analysis (right); photo credit Ortho Development (right)

Appropriate utilization of ancillary devices should not be overlooked

Episode of care (~90 days)

- Implant selection
- Ancillary device utilization
“Premium” ancillary devices add significant cost

<table>
<thead>
<tr>
<th>“Premium” device</th>
<th>Non-“premium” alternative</th>
<th>Additional cost for “premium” device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotic loaded bone cement</td>
<td>Plain bone cement</td>
<td>$500 per case</td>
</tr>
<tr>
<td>Bipolar sealer w/ saline (e.g. Aquamantys)</td>
<td>Traditional electrocautery</td>
<td>$500 per case</td>
</tr>
<tr>
<td>Custom femoral and tibial cutting guides</td>
<td>Traditional femoral and tibial cutting guides</td>
<td>$1,000 per case</td>
</tr>
<tr>
<td>Robotic surgery (e.g. MAKO)</td>
<td>Manual surgery</td>
<td>$1M+ upfront capital plus service/disposables</td>
</tr>
</tbody>
</table>

Source: Lumere analysis; Photo credit (top to bottom): Stryker, Medtronic, Zimmer Biomet, Stryker.
Clinical evidence shows when use is appropriate

### EXAMPLES OF “PREMIUM” ANCILLARY DEVICES WITH ALTERNATIVES

<table>
<thead>
<tr>
<th>“Premium” device</th>
<th>Non-”premium” alternative</th>
<th>What does the evidence say?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotic loaded bone cement</td>
<td>Plain bone cement</td>
<td>TKA: no clinical benefit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>THA, rev. TKA: may reduce infections</td>
</tr>
<tr>
<td>Bipolar sealer w/ saline (e.g. Aquamantys)</td>
<td>Traditional electrocautery</td>
<td>Primary TKA: no benefit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>THA, rev. TKA/THA: reduced blood loss</td>
</tr>
<tr>
<td>Custom femoral and tibial cutting guides</td>
<td>Traditional femoral and tibial cutting guides</td>
<td>TKA: no clinical benefit</td>
</tr>
<tr>
<td>Robotic surgery (e.g. MAKO)</td>
<td>Manual surgery</td>
<td>UKA/THA: no clinical benefit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TKA: no published data available</td>
</tr>
</tbody>
</table>

Source: Lumere analysis; photo credit (top to bottom): Stryker, Medtronic, Zimmer Biomet, Stryker; TKA = total knee arthroplasty; THA = total hip arthroplasty; UKA = unicompartamental knee arthroplasty.
Improving patient care using Enhanced Recovery After Surgery (ERAS)

Episode of care (~90 days)

- Multimodal analgesia
- Early mobilization
- VTE prophylaxis

VTE = venous thromboembolism; ED = emergency department.
Multimodal analgesia drive faster recovery with early ambulation

- Incorporates multiple, non-opioid pharmacological agents
- Promotes early ambulation and recovery
- Reduces opioid consumption
- Multidisciplinary team must align on optimal protocol

Source: Lumere analysis.
Technology Spotlight: Exparel (liposomal bupivacaine) for pain relief following joint replacement

What does the evidence say?

• There is no consistent evidence for improvement of pain scores with Exparel compared to BPV/RPV-based regimens

• Exparel results in lower opioid consumption compared with BPV-based techniques, but similar consumption compared with RPV-based techniques

• Due to lack of impact on hospital stay and the availability of more cost-effective regimens, Exparel ($300) use may not be warranted

Source: Lumere analysis; BPV and RPV-based techniques include drug cocktails, peripheral nerve blocks, periarticular injections, and local infiltration; BPV: bupivacaine, RPV: ropivacaine
Three key takeaways

**VALUE-BASED CARE**
- Value-based care is here to stay, particularly in orthopedics.
- Managing costs while maintaining quality is paramount to success, particularly in outpatient setting.

**IMPLANTS**
- Implants are commoditized and make up ~50% of the costs associated with the inpatient MS-DRG.
- “Premium” implants can add considerable costs without providing improved clinical outcomes.

**PATIENT CARE**
- Use clinical evidence to standardize peri-op and post-op patient care.
- Clinical evidence is critical to achieving cost and quality targets in the inpatient and post-operative settings.
Questions?