Checklists and Protocols: Lowering Complication Rates in EOS

Ron El-Hawary, MD, MSc, FRCS(C)
IWK Health Centre
Halifax, Nova Scotia, Canada
Outline

- Complications in Early Onset Scoliosis
  - Past and Present

- Checklists / Protocols
  - LEAN Process of Quality Improvement
    - Standard Work, Value Stream Analysis
  - Published Resources
    - Extended Time out
    - Intra–Operative Neuromonitoring Changes
    - Infection Control
2008

- 3 yo girl with congenital scoliosis
Lung Volume < 3rd %ile
What to do? (2008)

- Observe
- Cast/ Brace
- Distraction Based
  - Growing Rods
  - Rib-Based
- Fusion
Complications?
Complications in Pediatric Spine Surgery Using the Vertical Expandable Prosthetic Titanium Rib

The French Experience

Grégory Lucas, MD,* Gérard Bollini, MD,† Jean-Luc Jouve, MD,‡ Jérome Sales de Gauzy, MD,‡ Franck Accadbled, MD,† Pierre Lascombes, MD,§ Pierre Journeau, MD,§ Claude Karger, MD,¶ Jean François Mallet, MD,¶ Petre Neagoe, MD,** Jérome Cottalorda, MD,† Benoît De Billy, MD,‡‡ Jean Langlais, MD,‡‡ Bernard Herbaux, MD,§§ Damien Fron, MD,§§ and Philippe Violas, MD*

› 54 patients with mean F/U 2 years

› 67% of patients had at least one complication

› 137% complication rate per patient

› 40% complication rate per procedure
Complications of Growing-Rod Treatment for Early-Onset Scoliosis

Analysis of One Hundred and Forty Patients

By Shay Bess, MD, Behrooz A. Akbarnia, MD, George H. Thompson, MD, Paul D. Sponseller, MD, Suken A. Shah, MD, Hazem El Sebai, FRCS, MD, Oheneba Boachie-Adjei, MD, Lawrence I. Karlin, MD, Sarah Canale, BS, Connie Poe-Kochert, RN, CNP, and David L. Skaggs, MD

- 140 Growing Rod Patients
- 58% Complication Rate
- Rate decreased by 13% per each year of patient age at time of initial implant
- Rate increased by 24% per additional surgical procedure
Complications of Growing-Rod Treatment for Early-Onset Scoliosis

Analysis of One Hundred and Forty Patients

By Shay Bess, MD, Behrooz A. Akbarnia, MD, George H. Thompson, MD, Paul D. Sponseller, MD, Suken A. Shah, MD, Hazem El Sebaie, FRCS, MD, Obenenna Boachie-Adjei, MD, Lawrence I. Karlin, MD, Sarah Canale, BS, Connie Poe-Kochert, RN, CNP, and David L. Skaggs, MD
CSSG – Complications

- Multicenter Registry

- 3989 patients enrolled as of October 2017
  - 2142 Complications
  - 54% risk of complications
Growing Instrumentation without fusion
  ◦ All types (traditional, modern)

Unplanned reoperation rate within 20 months of implantation of 29.95% (142/474)
  ◦ Neuromuscular scoliosis
  ◦ Scoliosis > 50°
  ◦ Hyperkyphotic
Traditional Techniques

- Multiple complications with traditional techniques...
What About MCGR?

- Avoids repetitive surgeries
  - Infection
  - Dehiscence
  - Psychological Dysfunction

- Still at risk
  - Neurologic Injury
  - Implant failure
  - Migration
Unplanned Reoperations in Magnetically Controlled Growing Rod Surgery for Early Onset Scoliosis with a Minimum of Two-Year Follow-Up

- 30 patients underwent MCGR (2009–12)
  - 6 institutions
  - Minimum 2 year f/u

- 14 patients (46.7%) unplanned reoperation
  - Mean 23 months after initial surgery (5–48 months)

Kwan et al., Spine 2017
Even with modern devices, there is still a NEED to decrease complications and unplanned return to the operating room.

Standardization.

Checklists/ Protocols.
Standardization

- Standard Work

- LEAN process
  - Management System
  - *Continuous Improvement*
  - i.e. Toyota Production
  - Taichi Ohno
Standard Work (EOS)

- Team Members
  - Surgeons, anesthesiologists, nurses, respirologists, psychology, etc.
Standard Work (EOS)

- **Reason for Improvement**
  - “To help children with spine problems live longer, better lives.”

- **Current Performance**
  - Lack of standardization
  - High risk of complications, UPROR
Value Stream Analysis

CURRENT STATE & WASTE IDENTIFICATION
Variability in decision making with regard to the optimum treatment of certain subsets of patients with early-onset scoliosis reflects gaps in the available evidence.
### Standard Work (EOS)

#### Target Performance

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Measure</th>
<th>Current</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morale/HD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delivery/Access</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost/Productivity</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Value Stream Analysis

FUTURE STATE

- Referral Received
- Triage
- Book Appointment
- Wait
- Reminder of Appointment
- Register
- Tech or Testing
- Clinical Evaluation
- Immediate Treatment
- Care Plan
- Dictate & Sign
- Follow Up Tests / Consults / Rehab
- Book Surgery
- Pre-Op & Tests
- Discharge
Standard Work (EOS)

- Gap Analysis
  - Lack of standardization

- Waste Theme / Root Cause
  - Heterogeneous populations
**Standard Work (EOS)**

- **Counter Measures / Action Plan**
  - Standardize (checklists, protocols)
  - Quality Improvement Dashboards

- **Follow Up Plans**
  - Who?, What?, When?

- **Measurement Tracking**
  - Societies, Study Groups, Industry
Building Consensus: Development of a Best Practice Guideline (BPG) for Surgical Site Infection (SSI) Prevention in High-risk Pediatric Spine Surgery

Michael G. Vitale, MD, MPH,* Matthew D. Riedel, BA,* Michael P. Glotzecker, MD,†
Hirotaka Matsumoto, MA,* David P. Roye, MD,* Behroz A. Akbaria, MD,‡
Richard C.E. Anderson, MD, FACS, FAAP,§ Douglas L. Brockmeyer, MD,∥
John B. Emans, MD,† Mark Erickson, MD,¶ John M. Flynn, MD,#
Lawrence G. Lenke, MD,** Stephen J. Lewis, MD,†† Scott J. Luhmann, MD,**
Lisa M. McLeod, MD, MSCE,+++ Peter O. Newton, MD,§§
Ann-Christine Nyquist, MD, MSPH,/// B. Stephens Richards, III, MD,###
Suken A. Shah, MD,*** David L. Skaggs, MD,††† John T. Smith, MD,####
Paul D. Spongberg, MD, MBA,§§§ Daniel J. Sucato, MD,####
Reinhard D. Zeller, MD,//// and Lisa Saiman, MD, MPH////###

### Consensus (%) ###

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Strongly Agree</th>
<th>Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patients should have a chlorhexidine skin wash at home the night before surgery.*</td>
<td>91</td>
<td>61</td>
<td>30</td>
</tr>
<tr>
<td>2. Patients should have preoperative urine cultures obtained and treated if positive.*</td>
<td>91</td>
<td>26</td>
<td>65</td>
</tr>
<tr>
<td>3. Patients should receive a preoperative Patient Education Sheet.*</td>
<td>91</td>
<td>48</td>
<td>43</td>
</tr>
<tr>
<td>4. Patients should have a preoperative nutritional assessment.*</td>
<td>96</td>
<td>57</td>
<td>39</td>
</tr>
<tr>
<td>5. If removing hair, clipping is preferred to shaving.†</td>
<td>100</td>
<td>61</td>
<td>39</td>
</tr>
<tr>
<td>6. Patients should receive perioperative intravenous cefazolin.*</td>
<td>91</td>
<td>65</td>
<td>26</td>
</tr>
<tr>
<td>7. Patients should receive perioperative intravenous prophylaxis for gram-negative bacilli.*</td>
<td>95</td>
<td>65</td>
<td>30</td>
</tr>
<tr>
<td>8. Adherence to perioperative antimicrobial regimens should be monitored (ie, agent, timing, dosing, redosing, cessation).*</td>
<td>96</td>
<td>61</td>
<td>35</td>
</tr>
<tr>
<td>9. Operating room access should be limited during scoliosis surgery whenever practical.*</td>
<td>96</td>
<td>61</td>
<td>35</td>
</tr>
<tr>
<td>10. Ultraviolet lights need not be used in the operating room.*</td>
<td>87</td>
<td>48</td>
<td>39</td>
</tr>
<tr>
<td>11. Patients should have intraoperative wound irrigation.*</td>
<td>100</td>
<td>83</td>
<td>17</td>
</tr>
<tr>
<td>12. Vancomycin powder should be used in the bone graft and/or the surgical site.†</td>
<td>91</td>
<td>48</td>
<td>43</td>
</tr>
<tr>
<td>13. Impervious dressings are preferred postoperatively.†</td>
<td>91</td>
<td>56</td>
<td>35</td>
</tr>
<tr>
<td>14. Postoperative dressing changes should be minimized before discharge to the extent possible.†</td>
<td>91</td>
<td>52</td>
<td>39</td>
</tr>
</tbody>
</table>
Best Practices in Intraoperative Neuromonitoring in Spine Deformity Surgery: Development of an Intraoperative Checklist to Optimize Response

Michael G. Vitale, MD, MPH\textsuperscript{a}, David L. Skaggs, MD\textsuperscript{b}, Gregory I. Pace, BA\textsuperscript{a}, Margaret L. Wright, BS\textsuperscript{b}, Hiroko Matsumoto, MA\textsuperscript{a,c}, Richard C.E. Anderson, MD\textsuperscript{c}, Douglas L. Brockmeyer, MD\textsuperscript{d}, John P. Dormans, MD\textsuperscript{e}, John B. Emans, MD\textsuperscript{f}, Mark A. Erickson, MD\textsuperscript{g}, John M. Flynn, MD\textsuperscript{g}, Michael P. Glotzbecker, MD\textsuperscript{h}, Kamal N. Ibrahim, MD\textsuperscript{i}, Stephen J. Lewis, MD\textsuperscript{j}, Scott J. Luhmann, MD\textsuperscript{k}, Anil Mendiatta, MD\textsuperscript{k}, B. Stephens Richards, III, MD\textsuperscript{l}, James O. Sanders, MD\textsuperscript{m}, Suken A. Shah, MD\textsuperscript{n}, John T. Smith, MD\textsuperscript{o}, Kit M. Song, MD\textsuperscript{p}, Paul D. Sponseller, MD\textsuperscript{q}, Daniel J. Sucato, MD, MS\textsuperscript{l}, David P. Roye, MD\textsuperscript{r}, Lawrence G. Lenke, MD\textsuperscript{l}

### Checklist for the Response to Intraoperative Neuromonitoring Changes in Patients with a Stable Spine

<table>
<thead>
<tr>
<th>Control of Room</th>
<th>Anesthetic/Systemic</th>
<th>Technical/Neurophysiologic</th>
<th>Surgical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraoperative pause; stop case and announce to the room</td>
<td>Optimize mean arterial pressure (MAP)</td>
<td>Discuss status of anesthetic agents</td>
<td>Discuss events and actions just prior to signal loss and consider reversing actions</td>
</tr>
<tr>
<td>Eliminate extraneous stimuli (e.g., music, conversations, etc.)</td>
<td>Optimize hematocrit</td>
<td>Check extent of neuromuscular blockade and degree of paralysis</td>
<td>Remove traction (if applicable)</td>
</tr>
<tr>
<td>Summon ATTENDING anesthesiologist, SENIOR neurologist or neurophysiologist, and EXPERIENCED nurse</td>
<td>Optimize blood pH and pCO\textsubscript{2}</td>
<td>Check electrodes and connections</td>
<td>Decrease/remove distraction or other corrective forces</td>
</tr>
<tr>
<td>Anticipate need for intraoperative and/or perioperative imaging if not readily available</td>
<td>Seek normothermia</td>
<td>Determine pattern and timing of signal changes</td>
<td>Remove rods</td>
</tr>
<tr>
<td></td>
<td>Discuss POTENTIAL need for wake-up test with ATTENDING anesthesiologist</td>
<td>Check neck and limb positioning; check limb position on table especially if unilateral loss</td>
<td>Remove screws and probe for breach</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Evaluate for spinal cord compression, examine osteotomy and laminotomy sites</td>
</tr>
</tbody>
</table>

**Ongoing Considerations**

- REVISIT anesthetic/systemic considerations and confirm that they are optimized
- Wake-up test
- Consultation with a colleague
- Continue surgical procedure versus staging procedure
- IV steroid protocol: Methylprednisolone 30 mg/kg in first hr, then 5.4 mg/kg/hr for next 23 hrs

*Data of Revision: 3/26/2014*
Development of Consensus-Based Best Practice Guidelines for Postoperative Care Following Posterior Spinal Fusion for Adolescent Idiopathic Scoliosis

Nicholas D. Fletcher, MD,* Michael P. Glotzbecker, MD,† Michelle Marks, PT, MA,‡,§ and Peter O. Newton, MD¶, Harms Study Group

<table>
<thead>
<tr>
<th>TABLE 1. Final Best Practice Guidelines: Consensus Recommendations for Postoperative Care Following PSF for AIS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
</tr>
<tr>
<td>1. Patients may be admitted to a general floor rather than the PICU.</td>
</tr>
<tr>
<td>2. A PCA pump should be used postoperatively.</td>
</tr>
<tr>
<td>3. An epidural is not necessary for management of postoperative pain.</td>
</tr>
<tr>
<td>4. Primary transition to oral narcotics should occur on a target date (i.e., POD#1) rather than based on a clinical threshold (i.e., passing flatus).</td>
</tr>
<tr>
<td>5. Muscle spasm medications (i.e., diazepam) should be used postoperatively.</td>
</tr>
<tr>
<td>6. Gabapentin should be used in the perioperative period.</td>
</tr>
<tr>
<td>7. Ketorolac should be used to minimize narcotic needs.</td>
</tr>
<tr>
<td>8. Clear liquids can be started as tolerated postoperatively.</td>
</tr>
<tr>
<td>9. A bowel regimen should be used beginning on POD#1.</td>
</tr>
<tr>
<td>10. Antiemetics should be given postoperatively.</td>
</tr>
<tr>
<td>11. A drain should be used postoperatively.</td>
</tr>
<tr>
<td>12. The patient may begin sitting on the side of the bed on POD#1.</td>
</tr>
<tr>
<td>13. The patient may begin ambulating on POD#1.</td>
</tr>
<tr>
<td>14. Physical therapy should see the patient twice daily beginning POD#1.</td>
</tr>
<tr>
<td>15. Chewing gum may be used to increase gastric motility.</td>
</tr>
<tr>
<td>16. Intraoperative, without postoperative radiographs, may suffice to evaluate implant placement and location.</td>
</tr>
<tr>
<td>17. Patients may be discharged before having a bowel movement.</td>
</tr>
<tr>
<td>18. Hospital discharge may occur on postoperative 2 or 3 assuming that pain is controlled on oral medications, the patient has cleared PT, and is tolerating a regular diet, regardless of whether the patient has had a bowel movement.</td>
</tr>
<tr>
<td>19. The patient should be contacted about their progress in the first week after surgery.</td>
</tr>
</tbody>
</table>
Barriers

- External force controlling their decisions
  - Encroaching on their autonomy

“The practice of medicine is an art, not a trade; a calling, not a business...”
Barriers

- Take away from the quality of patient care
- Cognitive aids as a sign of weakness
Using Standardized OR Checklists and Creating Extended Time-Out Checklists

LLOYD A. HEY, MD, MS; THOMAS C. TURNER, BS

Expanded Time Out

Surgical team confirms
- Radiology studies match patient information
- Patient name, medical record number, date of birth
- Operative consent is read aloud
- Patient's operative site is marked and in correct location
- Prep is dry from application to draping
- Hardware and biologics are present and correct
  - Truss
  - Transforaminal lumbar interbody fusion
  - 2 to 4 mm crushed cancellous bone (40 to 80 mL)
  - Anterior lumbar interbody fusion
  - Bone morphogenic protein-2 is ready
  - Removal equipment (e.g., specific hardware type and universal set are open)
  - Need for revision screws
- Hourly cell saver reporting and family call log with family name and phone number are on whiteboard
- Safety zone is identified and displayed

Surgeon confirms
- Operative level of pathology, if applicable, and laterality
- That information matches patient confirmation obtained in the preoperative area

Anesthesia team confirms
- Patient allergies
- Antibiotic dosage, time frame, and time of repeat dosing
- Any positioning concerns
- Tranexamic acid administered when IV is started

Neuromonitoring team confirms
- Any concerns
- The checklist for patient response to intraoperative neuromonitoring is complete

Surgical team
- Performs preincision time out
- Starts surgery timer
Acceptance

- Culture / Environment
- Unity
- Change their thinking
- Quality evaluation (dynamic)
- Buy in (i.e. Lean process)
Summary

- Surgery has lagged behind other fields in the areas of quality and safety.

- Surgeon champions have already started build consensus and define best practice guidelines for adolescent scoliosis.

- Similar processes should be applied to the field of early onset scoliosis.
Summary

Formalized processes directed by:

- Study Groups (CSSG / GSSG)
- Societies (SRS / POSNA)
- Delphi Approaches
- Lean Principles
Thank You