Checklists and Protocols: Lowering Complication Rates in EOS

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

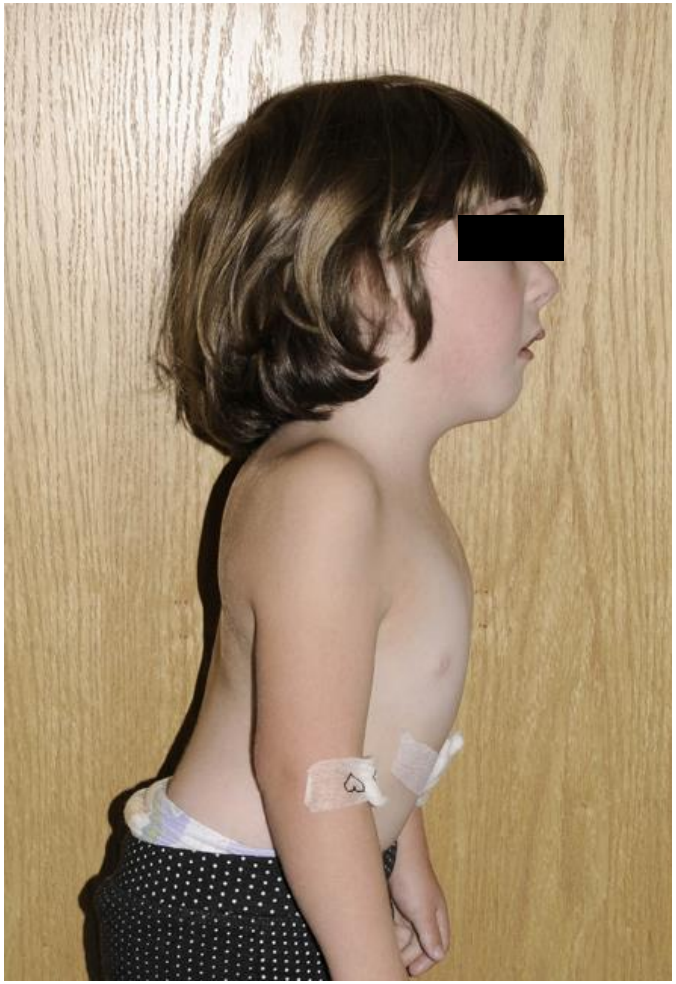
Outline

- 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



Progressive

2005

2007

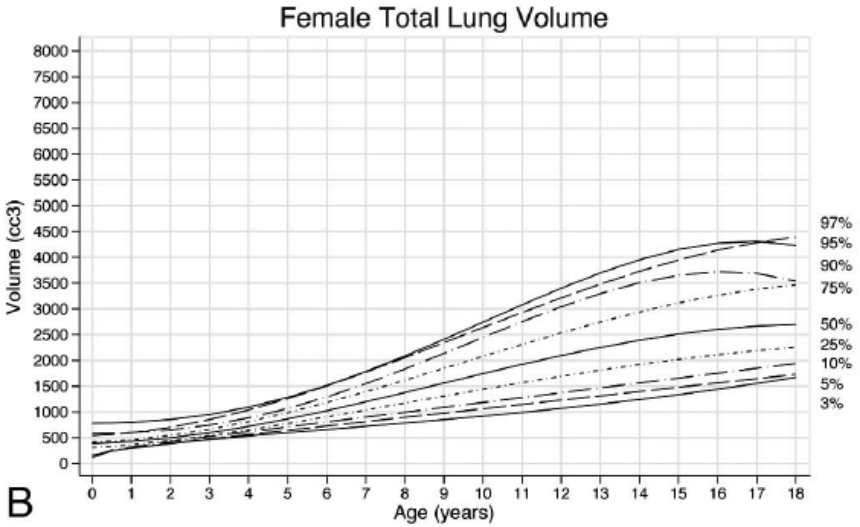
2008


AP


LT


00523765NS086
ge:3 years
Ref:EL-HAWARY R
Rad:
2 May 2008
0:21:23
Vol. 3D-Q03 Pediatric Body
VP:120
hA:50
sec:500
As:25
hk:0.5 mm
Vitre
W/L:321/3

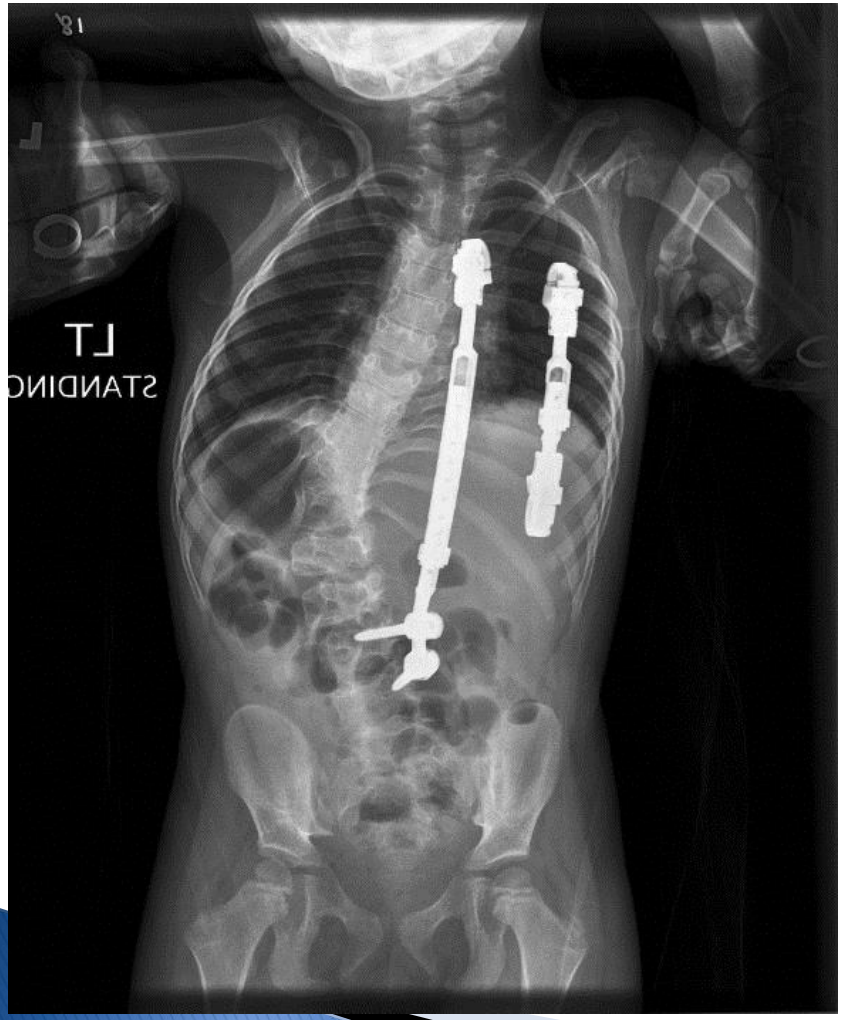
Lung Volume < 3rd %ile

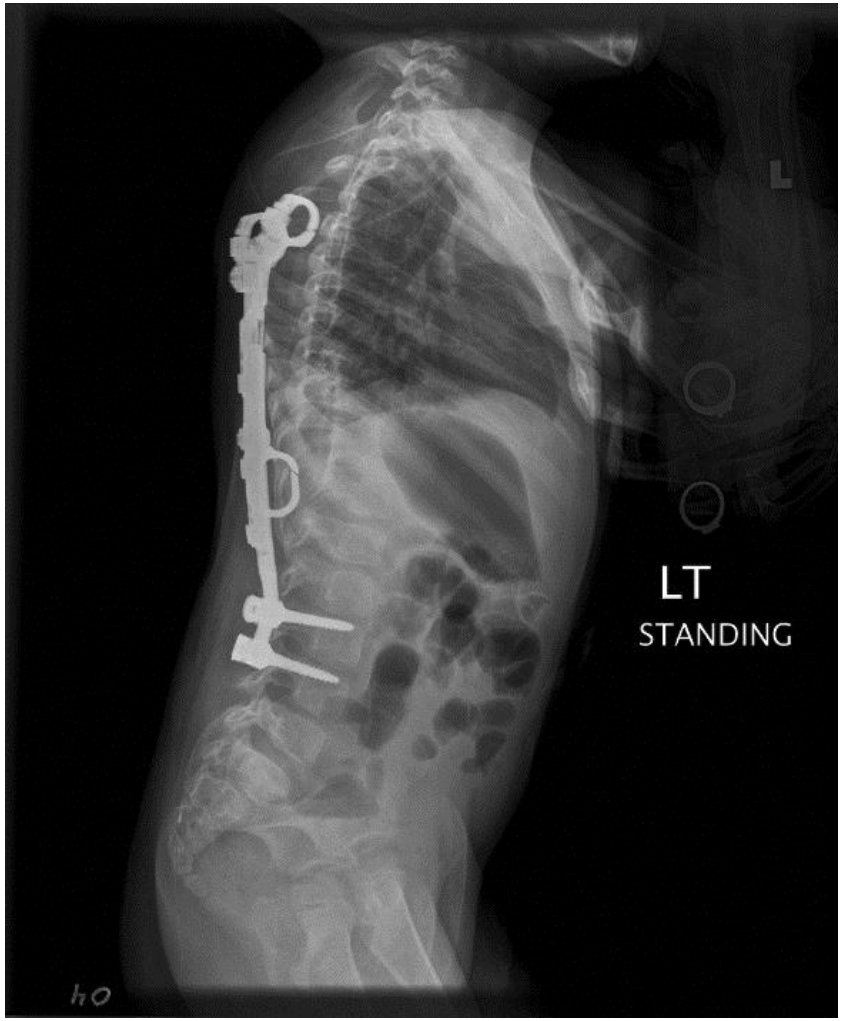


What to do? (2008)

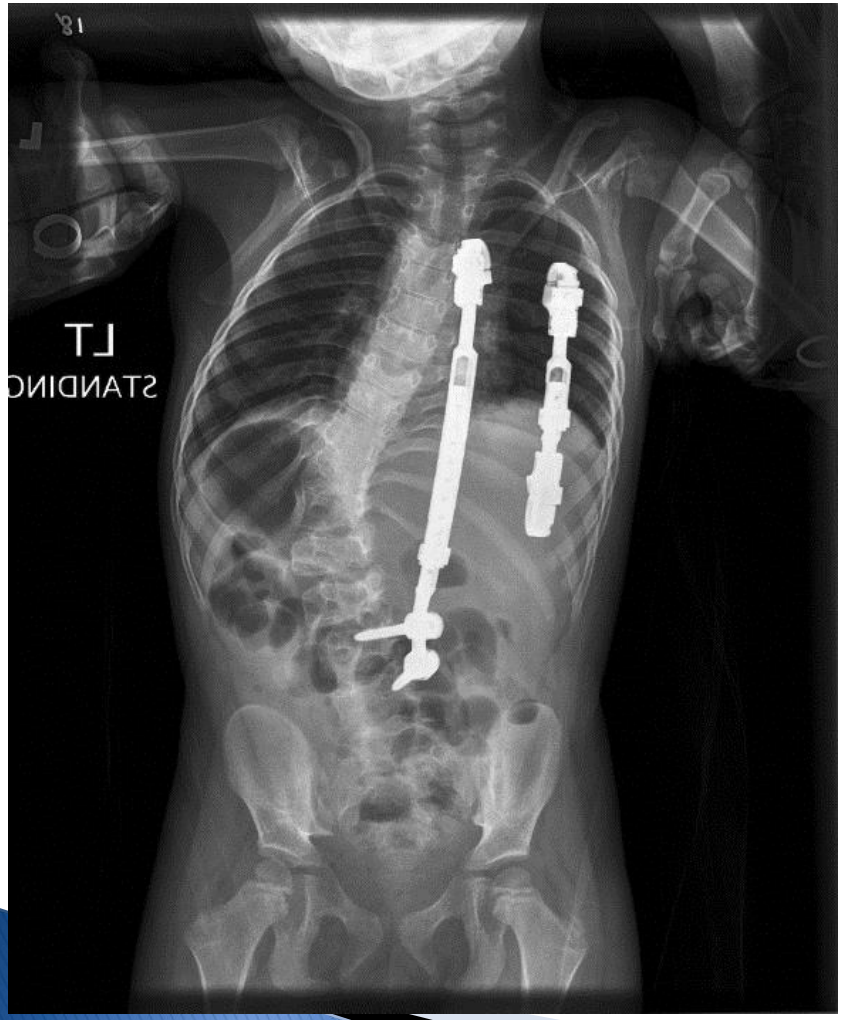
- Observe
- Cast/ Brace
- Distraction Based
  - Growing Rods
  - Rib-Based
- Fusion

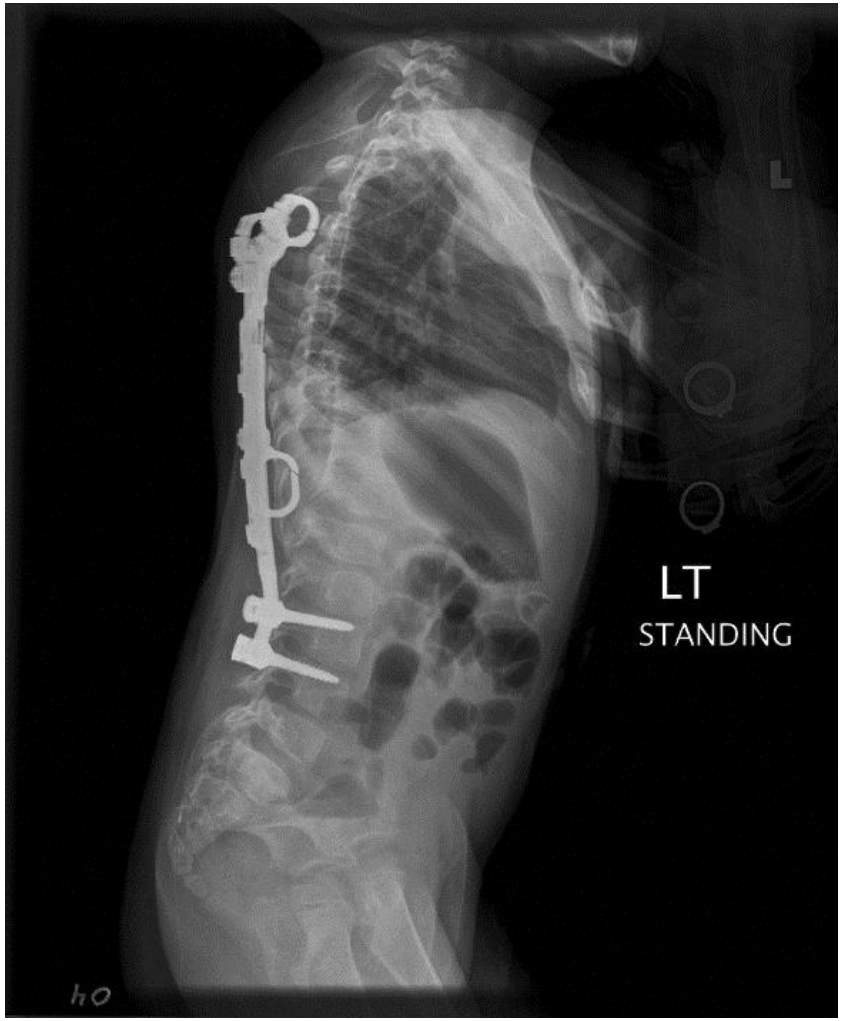
Oct 2008 – Insertion





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,†† Benoit 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

SPINE Volume 38, Number 25, pp E1589-E1599

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, Oheneba Boachie-Adjei, MD, Lawrence I. Karlin, MD, Sarah Canale, BS, Connie Poe-Kochert, RN, CNP, and David L. Skaggs, MD

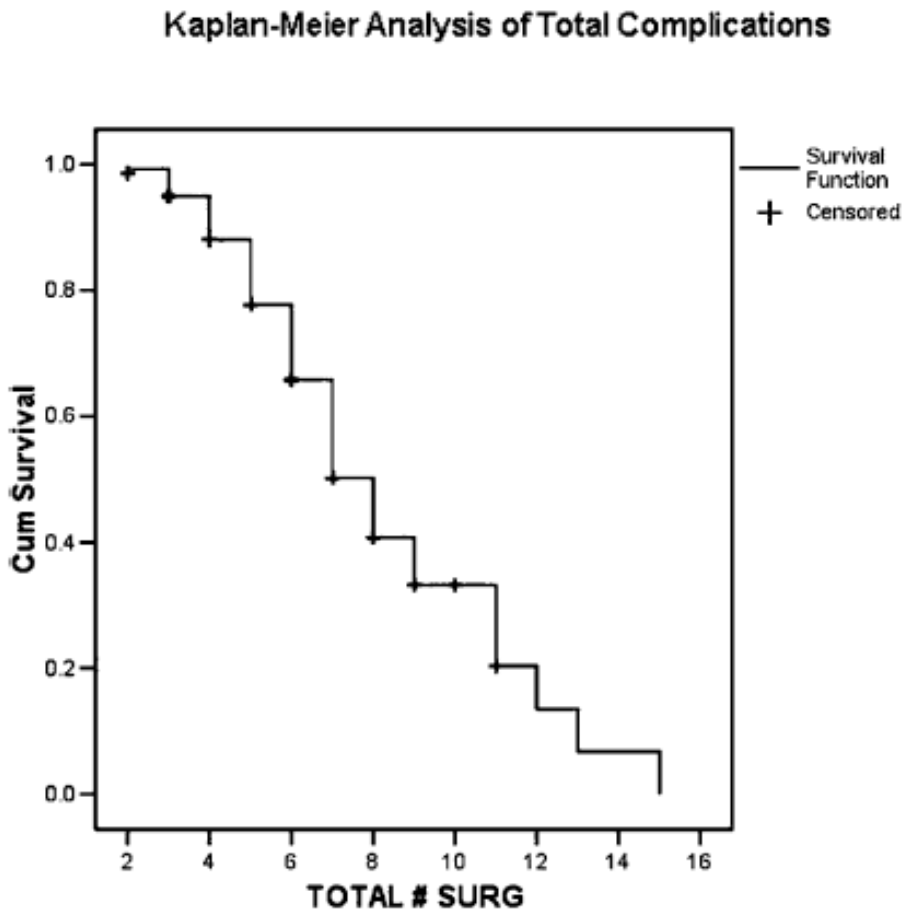
- 140 Growing Rod Patients
- 58% Complication Rate
- Rate decreased by 13% per each year of patient age at time of initial implant
- Rate increased by 24% per additional surgical procedure

J Bone Joint Surg Am. 2010;92:2533-43

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, Oheneba Boachie-Adjei, MD, Lawrence I. Karlin, MD, Sarah Canale, BS, Connie Poe-Kochert, RN, CNP, and David L. Skaggs, MD



J Bone Joint Surg Am. 2010;92:2533-43

CSSG – Complications

- Multicenter Registry
- 3989 patients enrolled as of October 2017
  - 2142 Complications
  - 54% risk of complications

CHILDREN'S SPINE STUDY GROUP

Unplanned Return to OR for EOS Children: A Comprehensive Evaluation of all Diagnoses and Instrumentation Strategies

Jason Anari, John Flynn, Michael Vitale, John Smith, Jaime A. Gomez, Children's Spine Study Group

Paper #22, ICEOS 2017

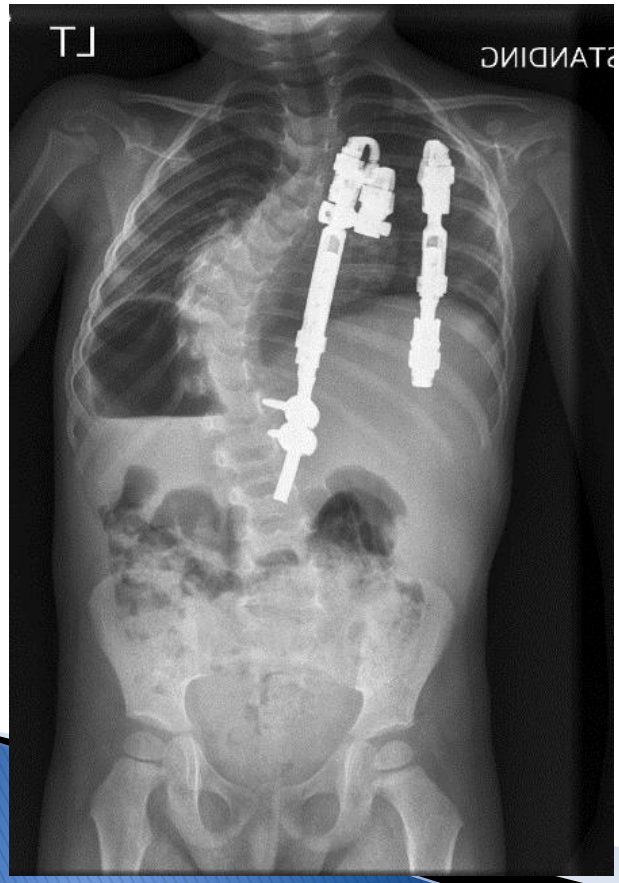
- Growing Instrumentation without fusion
  - All types (traditional, modern)

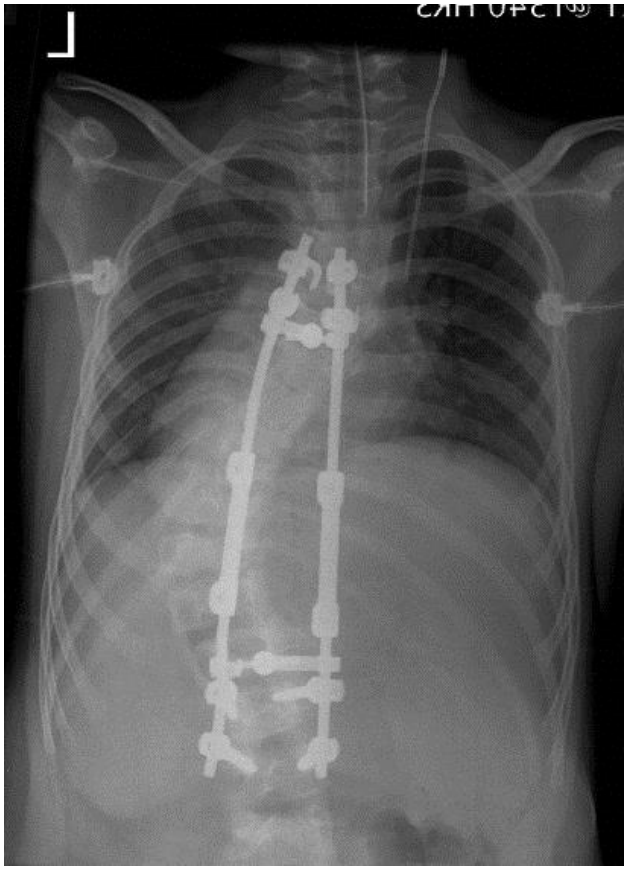
- Unplanned reoperation rate within 20 months of implantation of 29.95% (142/474)
  - Neuromuscular scoliosis
  - Scoliosis > 50º
  - Hyperkyphotic

CHILDREN'S SPINE STUDY GROUP

Traditional Techniques

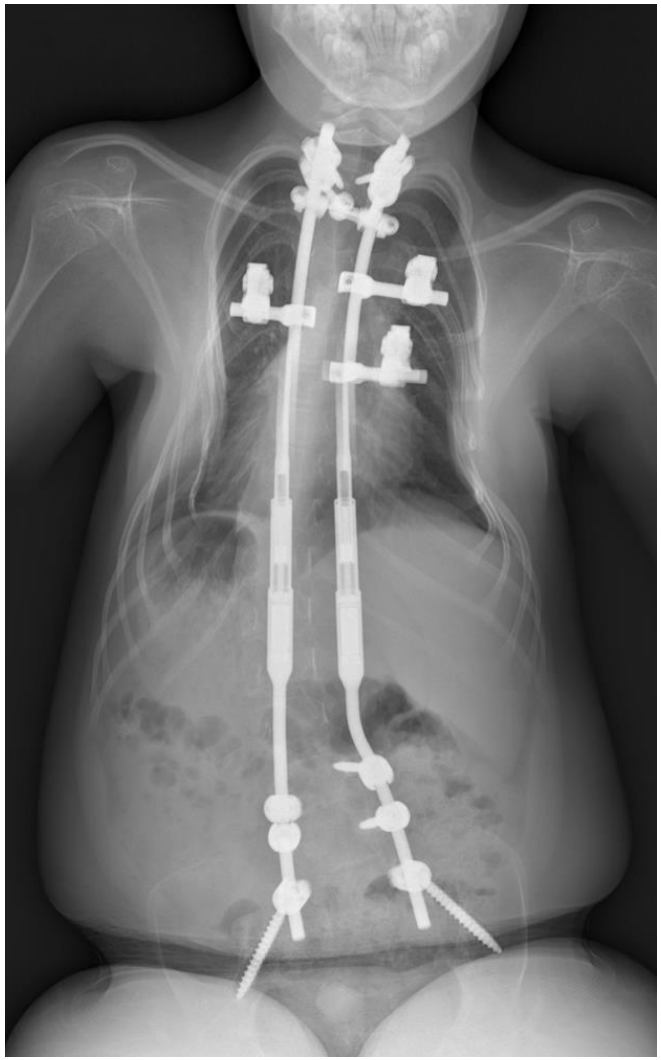
- Multiple complications with traditional techniques…





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)

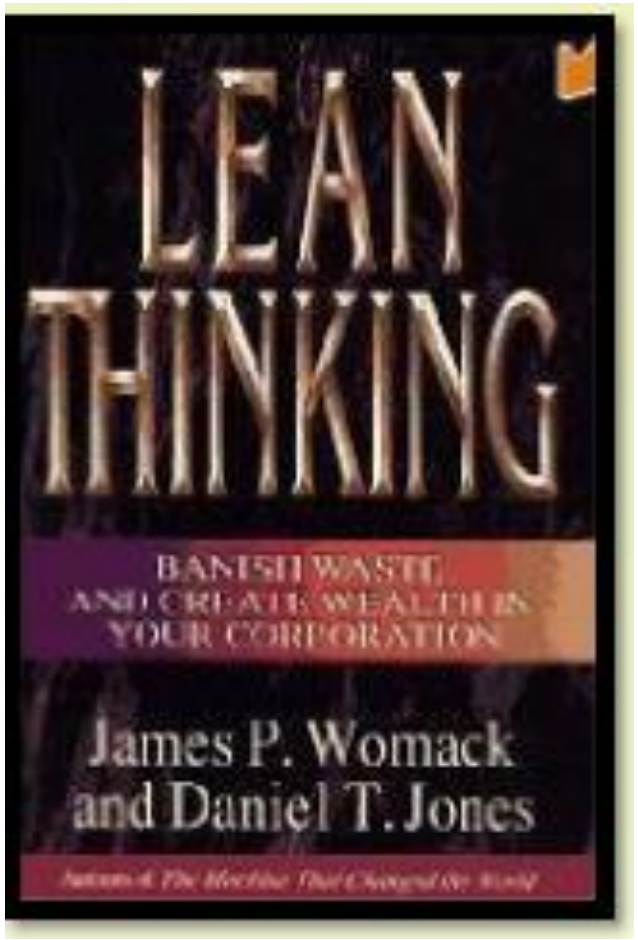
Kwan et al., Spine 2017

State of the Art

- 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)

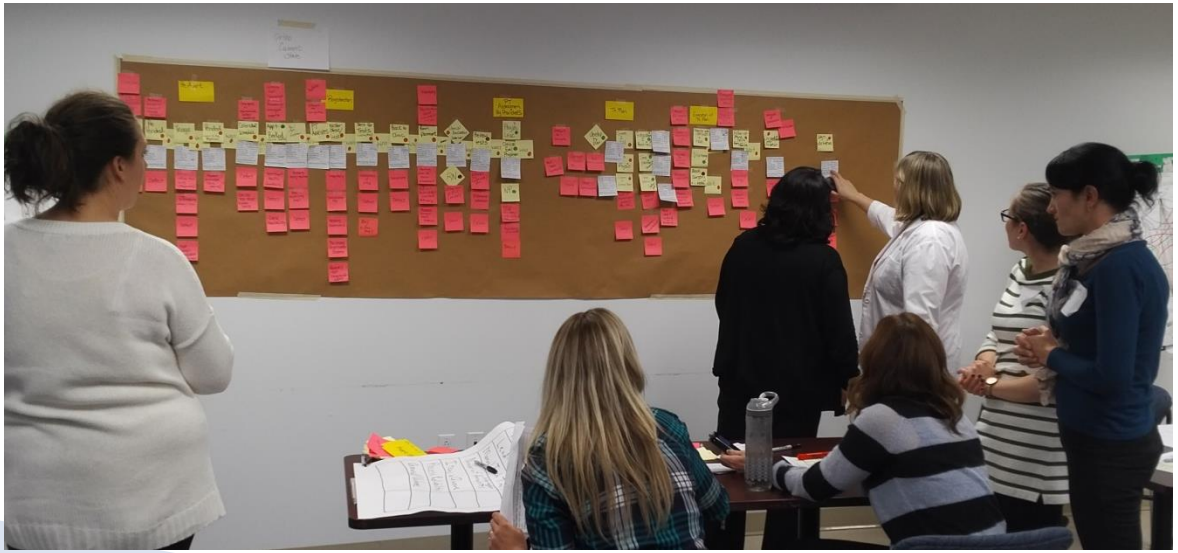
- Team Members
  - Surgeons, anesthesiologists, nurses, respirologists, psychology, etc.

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



Value Stream Analysis – EOS

Evaluating the Extent of Clinical Uncertainty Among Treatment Options for Patients with Early-Onset Scoliosis

"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."

J Bone Joint Surg Am. 2013;95:e67(1-10)

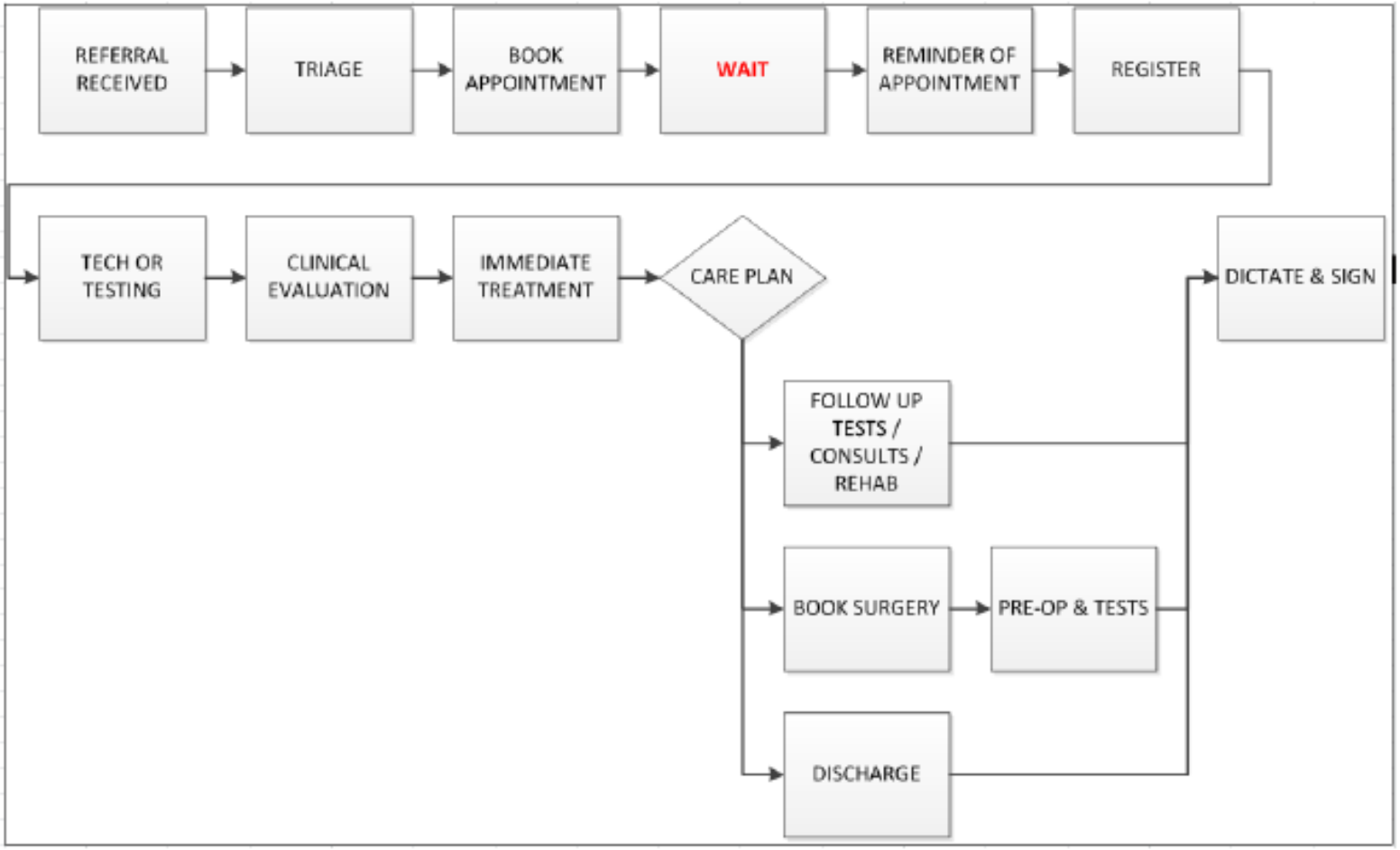
Standard Work (EOS)

- Target Performance

Dimension	Measure	Current	Target
Morale/HD			
Quality			
Delivery/Access			
Cost/Productivity			

Value Stream Analysis

FUTURE STATE



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

Best Practice Guidelines

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. Glotzbecker, MD,† Hiroko Matsumoto, MA,* David P. Roye, MD,* Behrooz A. Akbarnia, 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. Sponseller, MD, MBA,§§§ Daniel J. Sucato, MD,## Reinhard D. Zeller, MD,‖‖‖ and Lisa Saiman, MD, MPH¶¶¶###*

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

J Pediatr Orthop • Volume 33, Number 5, July/August 2013

Best Practices in Intraoperative Neuromonitoring in Spine Deformity Surgery: Development of an Intraoperative Checklist to Optimize Response

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

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

GAIN CONTROL OF ROOM

- ❑ Intraoperative pause: stop case and announce to the room
- ❑ Eliminate extraneous stimuli (e.g. music, conversations, etc.)
- ❑ Summon ATTENDING anesthesiologist, SENIOR neurologist or neurophysiologist, and EXPERIENCED nurse
- ❑ Anticipate need for intraoperative and/or perioperative imaging if not readily available

ANESTHETIC/SYSTEMIC

- ❑ Optimize mean arterial pressure (MAP)
- ❑ Optimize hematocrit
- ❑ Optimize blood pH and pCO_2
- ❑ Seek normothermia
- ❑ Discuss POTENTIAL need for wake-up test with ATTENDING anesthesiologist

TECHNICAL/NEUROPHYSIOLOGIC

- ❑ Discuss status of anesthetic agents
- ❑ Check extent of neuromuscular blockade and degree of paralysis
- ❑ Check electrodes and connections
- ❑ Determine pattern and timing of signal changes
- ❑ Check neck and limb positioning; check limb position on table especially if unilateral loss

SURGICAL

- ❑ Discuss events and actions just prior to signal loss and consider reversing actions:
  - ❑ Remove traction (if applicable)
  - ❑ Decrease/remove distraction or other corrective forces
  - ❑ Remove rods
  - ❑ Remove screws and probe for breach
- ❑ Evaluate for spinal cord compression, examine osteotomy and laminotomy sites
- ❑ Intraoperative and/or perioperative imaging (e.g. O-arm, fluoroscopy, x-ray) to evaluate implant placement

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

Date of Revision: 2/26/2014

M.G. Vitale et al. / Spine Deformity 2 (2014) 333–339

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

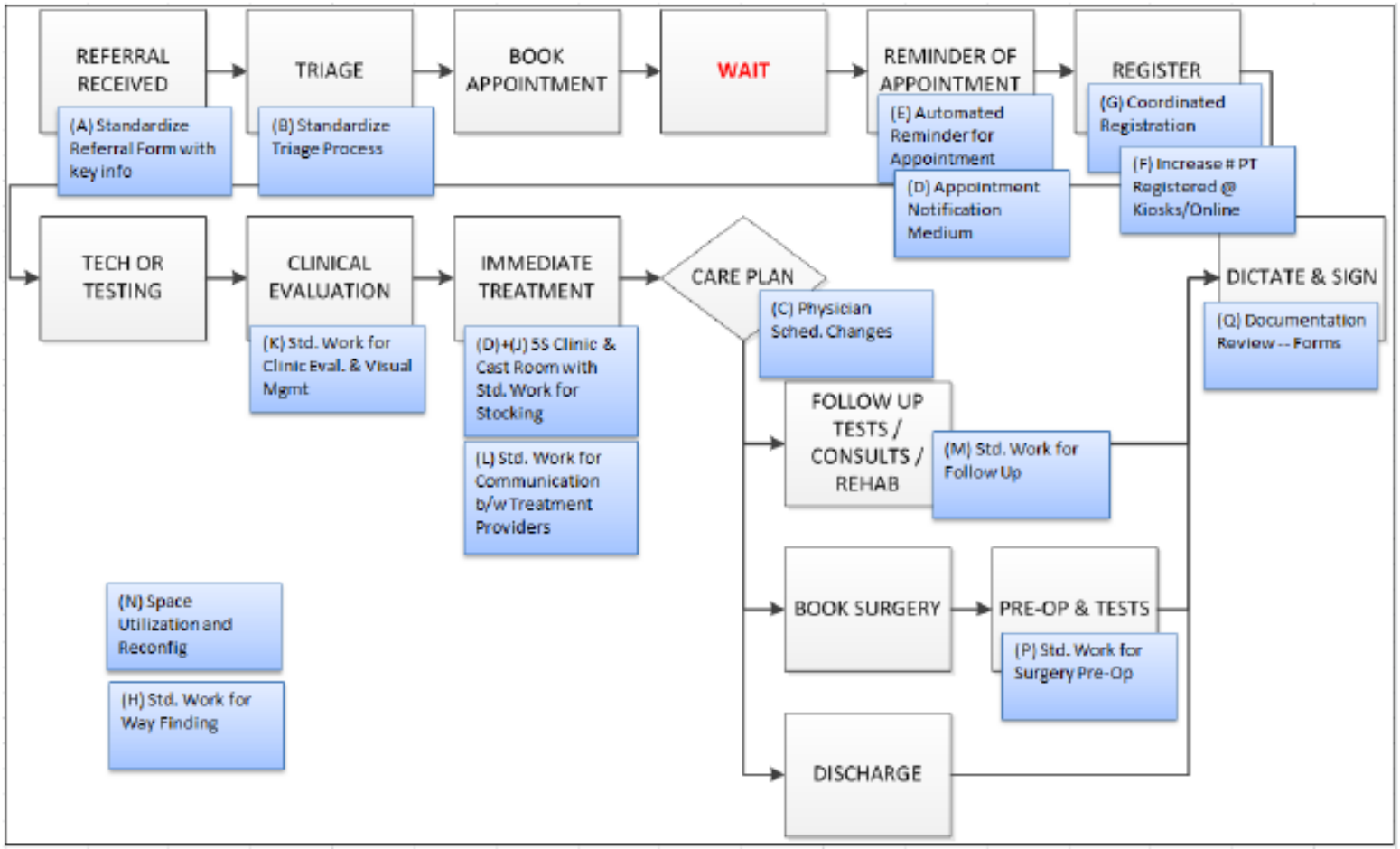
TABLE 1. Final Best Practice Guidelines: Consensus Recommendations for Postoperative Care Following PSF for AIS

	Total	Strongly Agree	Agree
1. Patients may be admitted to a general floor rather than the PICU.	90	78	12
2. A PCA pump should be used postoperatively.	100	62	38
3. An epidural is not necessary for management of postoperative pain.	95	62	33
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).	100	57	43
5. Muscle spasm medications (*i.e.*, diazepam) should be used postoperatively.	100	62	38
6. Gabapentin should be used in the perioperative period.	81	9	72
7. Ketorolac should be used to minimize narcotic needs.	86	53	33
8. Clear liquids can be started as tolerated postoperatively.	95	71	24
9. A bowel regimen should be used beginning on POD#1.	100	23	67
10. Antiemetics should be given postoperatively.	81	38	43
11. A drain should be used postoperatively.	81	14	67
12. The patient may begin sitting on the side of the bed on POD#1.	100	100	0
13. The patient may begin ambulating on POD#1.	86	86	0
14. Physical therapy should see the patient twice daily beginning POD#1.	86	67	19
15. Chewing gum may be used to increase gastric motility.	86	14	68
16. Intraoperative, without postoperative radiographs, may suffice to evaluate implant placement and location.	100	81	19
17. Patients may be discharged before having a bowel movement.	95	47.5	47.5
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.	95	42	53
19. The patient should be contacted about their progress in the first week after surgery.	91	52	39

SPINE Volume 42, Number 9, pp E547–E554

Value Stream Analysis

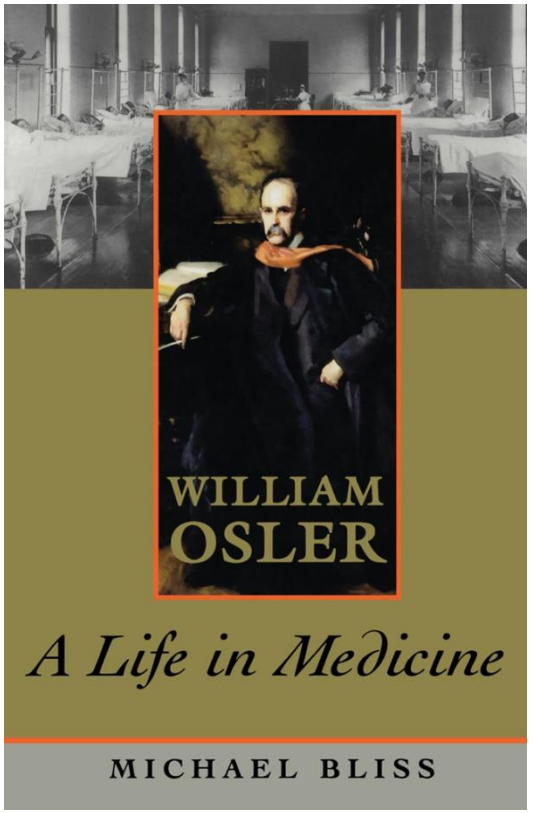
IMPROVEMENT ACTION PLANS



Barriers

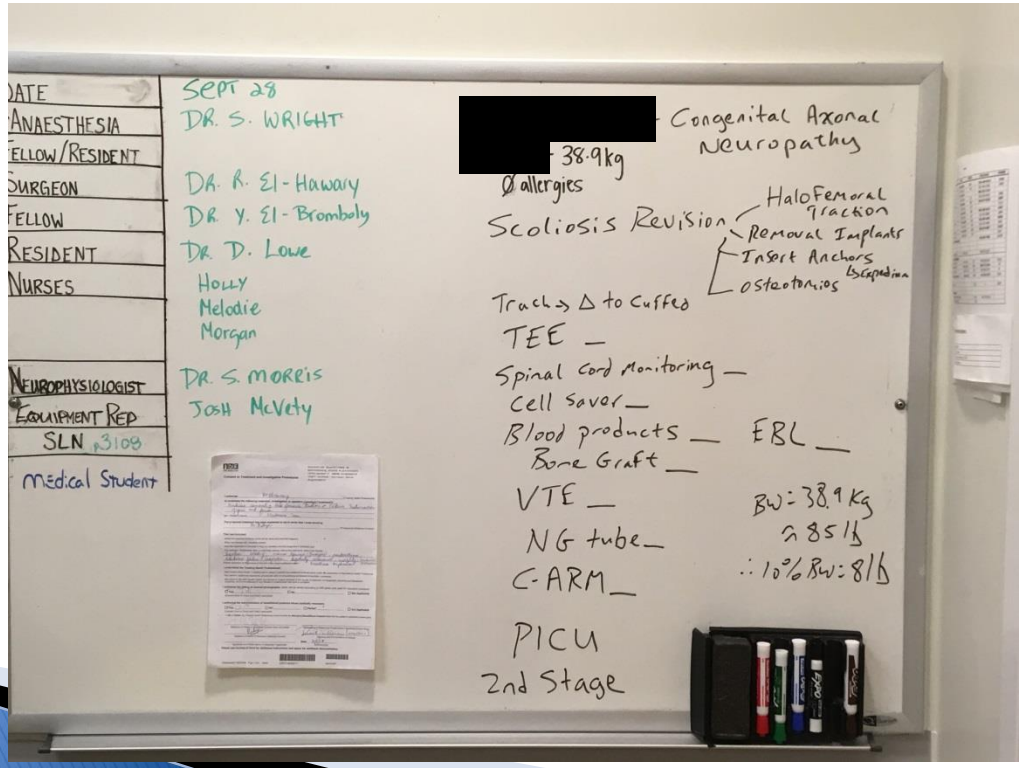
- External force controlling their decisions
  - Encroaching on their autonomy

"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 on 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 (eg, 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

AORN Journal September 2016, Vol. 104, No. 3

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