Preventing and Documenting Complications after Thoracic Surgery

Andrew JE Seely, MD, PhD, FRCSC
Disclosure

• No relevant commercial relationships or support

• Grant funding from Canadian Partnership Against Cancer

• Biased by interest, commitment and research
Learning Objectives

<p>| | |</p>
<table>
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<tbody>
<tr>
<td>1.</td>
<td>Understand the <strong>importance</strong> of post-operative adverse events (AEs) after thoracic surgery</td>
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<tr>
<td>2.</td>
<td>Understand <strong>principles of documentation</strong> of AEs after thoracic surgery</td>
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<td>3.</td>
<td>Explore means to utilize that data to prevent post operative AEs (&quot;data-driven AE prevention&quot;)</td>
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<td>4.</td>
<td>Understand how to <strong>mitigate barriers</strong> impeding documentation and prevention of AEs</td>
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Literature highlights the dramatic importance of Adverse Events (AEs)

- Post-operative AEs are THE major determinant on clinical & economic outcomes of surgical care
  - Hamel J Am Ger S 2005: VA patients: 15x increase in mortality risk with >1 AE
  - Volanthen Ann Surg 2011: Major complications increase in-hospital costs by 5 times

- Surgical AEs are frequent, and used as a parameter for evaluating quality of surgical care
  - Seely Ann Thor Surg 2010: Esophagectomy ~60% Lobectomy ~30% AE rates
  - Gawande 1999: 66% of all AEs are surgical; Baker 2004: 51% of all AEs are surgical

- Methodologies to better categorize, report, & monitor incidence of AEs are essential for ongoing efforts to minimize their occurrence & impact
Adverse events count.

How do you measure adverse events?

“If you can’t measure it, you can’t improve it.”

Lord Kelvin

“Not everything that can be counted counts, and not everything that counts can be counted.”

--Albert Einstein
Principles of Documenting AEs

Definitions of AE and their severity

Clavien Schema:
Severity of a complication may be measured by the degree of effort and intervention required to reverse or address it.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Complication</td>
<td>Any deviation from the normal post-operative course.</td>
</tr>
<tr>
<td>Grade I</td>
<td>Any complication without need for pharmacologic treatment or other intervention.</td>
</tr>
<tr>
<td>Grade II</td>
<td>Any complication that requires pharmacological treatment or minor intervention only.</td>
</tr>
<tr>
<td>Grade III</td>
<td>Any complication that requires surgical, radiological, endoscopic intervention, or multi-therapy.</td>
</tr>
<tr>
<td>Grade IIIa</td>
<td>Intervention does not require general anaesthesia.</td>
</tr>
<tr>
<td>Grade IIIb</td>
<td>Intervention requires general anaesthesia.</td>
</tr>
<tr>
<td>Grade IV</td>
<td>Any complication requiring ICU management and life support.</td>
</tr>
<tr>
<td>Grade IVa</td>
<td>Single organ dysfunction.</td>
</tr>
<tr>
<td>Grade IVb</td>
<td>Multiorgan dysfunction.</td>
</tr>
<tr>
<td>Grade V</td>
<td>Any complication leading to the death of the patient.</td>
</tr>
</tbody>
</table>

Classification of Surgical Complications
A New Proposal With Evaluation in a Cohort of 6336 Patients and Results of a Survey

Daniel Dindo, MD, Nicolas Demartines, MD, and Pierre-Alain Clavien, MD, PhD, FRCS, FACS

Systematic Classification of Morbidity and Mortality After Thoracic Surgery

Andrew J. E. Seely, MD, PhD, Jelena Ivanovic, BS, Jennifer Threadder, BS, Ahmed Al-Hussaini, MD, Derar Al-Shehab, MD, Tim Ramsay, PhD, Sebastian Gilbert, MD, FRCSC, Donna E. Maziak, MDCM, MS, Farid M. Shamji, MBBS, FRCSC, and R. Sudhir Sundaresan, MD, FRCSC

Department of Surgery, Division of Thoracic Surgery, University of Ottawa, the Ottawa Hospital; and Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada

Freely available at www.ottawatmm.org

Evaluating the Reliability and Reproducibility of the Ottawa Thoracic Morbidity and Mortality Classification System

Jelena Ivanovic, BS, Ahmed Al-Hussaini, MD, Derar Al-Shehab, MD, Jennifer Threadder, BS, Patrick James Villeneuve, MDCM, PhD, Tim Ramsay, PhD, Donna E. Maziak, MDCM, MS, Sebastian Gilbert, MD, FRCSC, Farid M. Shamji, MBBS, FRCSC, R. Sudhir Sundaresan, MD, FRCSC, and Andrew J.E. Seely, MD, PhD

Freely available at www.ottawatmm.org

Measuring Surgical Quality: Comparison of Postoperative Adverse Events with the American College of Surgeons NSQIP and the Thoracic Morbidity and Mortality Classification System

Jelena Ivanovic, MSc, Andrew J.E. Seely, MD, PhD, FRCSC, Caitlin Anstee, BA, Patrick James Villeneuve, MDCM, PhD, FRCSC, Sebastien Gilbert, MD, FRCSC, Donna E. Maziak, MDCM, MSc, FRCSC, FACS, Farid M Shamji, MBBS, FRCSC, Alan J Forster, MD, FRCPC, MSc, R Sudhir Sundaresan, MD, FRCSC, FACS

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The use of the Thoracic Morbidity and Mortality system for the internal analysis of performance: a case-matched temporal audit†

Michele Salati*a, Cecilia Pompili*a, Majed Refai*a, Francesco Xiumè*a, Armando Sabbatini* and Alessandro Brunelli*a,b

## Thoracic Surgery
### Procedure-Specific Adverse Event Profiles

<table>
<thead>
<tr>
<th>Complication Grade</th>
<th>Lobectomy (n=791)</th>
<th>Pneumonectomy (n=72)</th>
<th>Esophagectomy (n=159)</th>
<th>Gastrectomy (n=94)</th>
<th>All Cases (n=4203)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Minor</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>87 (11.0)</td>
<td>4 (5.6)</td>
<td>9 (5.7)</td>
<td>3 (3.2)</td>
<td>213 (5.1)</td>
</tr>
<tr>
<td>II</td>
<td>268 (33.9)</td>
<td>39 (54.2)</td>
<td>120 (75.4)</td>
<td>27 (28.7)</td>
<td>1195 (28.4)</td>
</tr>
<tr>
<td><strong>Major</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IIIa</td>
<td>73 (9.2)</td>
<td>5 (6.9)</td>
<td>60 (37.7)</td>
<td>13 (13.8)</td>
<td>421 (10.0)</td>
</tr>
<tr>
<td>IIIb</td>
<td>21 (2.6)</td>
<td>7 (9.7)</td>
<td>30 (18.9)</td>
<td>9 (9.6)</td>
<td>246 (5.9)</td>
</tr>
<tr>
<td>IVa</td>
<td>24 (3.0)</td>
<td>9 (12.5)</td>
<td>22 (1.4)</td>
<td>4 (4.3)</td>
<td>159 (3.8)</td>
</tr>
<tr>
<td>IVb</td>
<td>5 (0.6)</td>
<td>0 (0)</td>
<td>6 (3.8)</td>
<td>0 (0)</td>
<td>32 (0.76)</td>
</tr>
<tr>
<td><strong>Mortality</strong> V</td>
<td>10 (1.3)</td>
<td>4 (5.6)</td>
<td>7 (4.4)</td>
<td>1 (1.1)</td>
<td>60 (1.4)</td>
</tr>
<tr>
<td><strong>Total # Complications</strong></td>
<td>488 (61.7)</td>
<td>68 (94.4)</td>
<td>254 (159.7)</td>
<td>57 (60.6)</td>
<td>2326 (55.3)</td>
</tr>
<tr>
<td><strong>Total # Patients with Complications</strong></td>
<td>243 (30.7)</td>
<td>37 (51.4)</td>
<td>97 (61.0)</td>
<td>27 (28.7)</td>
<td>829 (19.7)</td>
</tr>
</tbody>
</table>

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01/2015-12/2016: 2704 esophageal resections

“The overall incidence of complications was 59% with the most common individual complications being pneumonia (14.6%) and atrial dysrhythmia (14.5%). Anastomotic leak, conduit necrosis, chyle leaks, recurrent nerve injury occurred in 11.4%, 1.3%, 4.7%, and 4.2% of cases, respectively. Readmissions occurred in 11.2% of cases and 30- and 90-day mortality was 2.4% and 4.5%, respectively.”
Principles of AE Documentation

- Clear definitions
- Ensure inter-observer reliability
- Measure incidence and severity
- Harmonize with international databases
- AEs require prospective collection
  - Daily entry and weekly review of AEs
- Documentation enabled with software tools
AEs worsen Patient Experience

Impact of Adverse Events and Length of Stay on Patient Experience After Lung Cancer Resection

Emma J. M. Grigor, BSc, Jelena Ivanovic, PhD, Caitlin Anstee, BA, Zach Zhang, BSc, Sebastian Gilbert, MD, Donna E. Maziak, MD, MSc, Farid M. Shamji, MD, Sudhir Sundaresan, MD, Patrick J. Villeneuve, MD, PhD, Tim Ramsay, PhD, and Andrew J. E. Seely, MD, PhD

- Patients had lung cancer resection, recurrence free
- Single-center, 288 survey respondents (70% response rate)
- 61% no AE, 39% ≥1AE, 18% prolonged length of stay (PLOS)

Results: presence of any AEs contribute to worse patient experience, much stronger signal if AEs lead to PLOS

Ann Thorac Surg 2017;104:382–8
All grades of severity of postoperative adverse events are associated with prolonged length of stay after lung cancer resection

JCTVS, 2018 Feb;155(2):798

Zach Zhang, a Fargol Mostofian, BHSc, a Jelena Ivanovic, MSc, PhD, b,c Sebastien Gilbert, MD, FRCSC, a,c,d Donna E. Maziak, MDCM, MSc, FRCSC, FACS, a,b,c,d Farid M. Shamji, MD, FRCSC, a,d Sudhir Sundaresan, MD, FRCSC, FACS, a,c,d Patrick J. Villeneuve, MDCM, PhD, FRCSC, a,d and Andrew J. E. Seely, MD, PhD, FRCSC a,b,c,d

- 1041 pulmonary resections for cancer
- Prolonged LOS defined as procedure-specific >75%’ile
- Results: Even minor AEs (Grade I & II) increase LOS

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Age≥85</td>
<td>3.6</td>
<td>1.1 – 11.7</td>
<td>0.04</td>
</tr>
<tr>
<td>Surgical approach:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thoracotomy</td>
<td>2.0</td>
<td>1.4 – 2.9</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Converted</td>
<td>2.3</td>
<td>1.2 – 4.5</td>
<td>0.02</td>
</tr>
<tr>
<td>Post-operative AE identified by the TM&amp;M:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade I</td>
<td>6.4</td>
<td>3.6 – 11.5</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Grade II</td>
<td>6.3</td>
<td>4.2 – 9.5</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Grade III</td>
<td>12.5</td>
<td>7.5 – 20.7</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Grade IV</td>
<td>25.0</td>
<td>8.9 – 69.8</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>
Infectious AEs increase risk of cancer recurrence

- 892 pulmonary resections for lung cancer; all Stage 1 or II
- 2008-2015; mean f/u 26 months
- Major infectious complications (i.e. bacteremia, pneumonia, empyema) were associated with increased risk of ca recurrence (HR 1.71; CI 1.05-2.81).

L Baker et al, Annals of Surgical Oncology, in review
How to transform AE documentation into AE prevention on a systemic level?
AE documentation for AE prevention?

• Long history: Ernest Codman (इन्डियन)
  • "We believe it is the duty of every hospital to establish a follow-up system, so that as far as possible the result of every case will be available at all times for investigation by staff, trustees, administration, or by other authorized investigators or statisticians."

• Rich legacy of effective data-driven QI programs in several surgical associations
  • E.g. STS, NSQIP, ESTS

• I will present unproven opinions regarding five principles focused on data-driven AEs prevention
AE documentation for AE prevention?

Establish goals and values

Patient-centered objectives and goals.

Collegial, collaborative, positive culture.

Assume shared professional will to improve.
Enable self-assessment with anonymized peer comparison

- “Know where you stand”

Focused on individual procedures and adverse events.

- E.g. air leak and lobectomy
- E.g. esophagectomy anastomotic leak
Combining Positive Deviance and Evidence

**Data** → **Identify Positive Deviance**

Experience → Discuss best practice

**Relevant Literature** → **Evidence**

Discuss best evidence

**Community of Practice** → **Collegial discussion**

Standardize & improve care

**Consensus recommendations**

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* (Ann Thorac Surg 2015;100:1188–95)

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Targeted Risk Mitigation

AE documentation for AE prevention?

Targeted risk mitigation to reduce AEs in specific high risk group

Identify patients with increased risk of specific AE

Pre-op care, OR, post op care

Recovery

Targeted risk mitigation to reduce AEs in specific high risk group
AE documentation for AE prevention?

Address Barriers

- Time ➢ Dedicated efficient group discussion time
- Technology ➢ Integrate AEs into clinical documentation
- Priorities ➢ Highlight value, encourage research
- Psychology ➢ Encourage curiosity, willingness to learn

Knowledge (t) = $1 / \text{Ego (t)}$

“Less the ego, more the capacity to augment knowledge”
Summary

1. Understand the importance of post-operative AEs after thoracic surgery
   - Worse experience, LOS, cost, oncology outcomes

2. Understand how to document adverse events (AEs) after thoracic surgery
   - Clear definitions, prospective dedication

3. Explore innovative means to utilize that data to prevent post operative AEs
   - Set the stage, self-assessment, positive deviance integrated with evidence, targeted risk mitigation

4. Understand barriers impeding documentation and prevention of AEs
   - Time, technology, priorities, psychology
Acknowledgements

- Jenn Artz, Caitlin Anstee, Johanna Petersen
- CATS: C Finley, T Waddell, L Ferri, N Safiedine
- Colleagues: D Maziak, F Shamji, S Gilbert, J Villeneuve, S Sundaresan
- CATS, CPAC
Feedback: Positive Deviance:

Using Surgeon-Specific Outcome Reports and Positive Deviance for Continuous Quality Improvement

Jelena Ivanovic, MS, PhD, Caitlin Anstee, BA, Tim Ramsay, PhD, Sebastien Gilbert, MD, Donna E. Maziak, MDCM, MS, Farid M. Shamji, MBBS, R. Sudhir Sundaresan, MD, P. James Villeneuve, MDCM, PhD, and Andrew J. E. Seely, MD, PhD

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• Divisional positive deviance (PD) seminars (n=7 seminars; 09/13-09/14; duration 1.5-2 hrs each)
• REB approved, mixed methods study
• Group discussion – discuss best experience and evidence
• Group agreement – adopt group recommendations
• Longitudinal evaluation on impact of specific AEs

(Ann Thorac Surg 2015;100:1188–95) © 2015 by The Society of Thoracic Surgeons
Observing the impact of Surgeon Self-Assessment and Positive Deviance in reducing Adverse Events

Longitudinal study: Observed reduction in rates of atrial fibrillation (AFIB), prolonged alveolar air leak (PAAL), and anastomotic leak (AL) 6, 9 and 12 months before and after PD seminars
Another problem – regional variation

Findings:

• Regionalization improves care; high volume centers have better outcomes
• “Lack of unified approach for the provision of surgical cancer care”
• “There are significant disparities in patterns of practice and patient outcomes for surgical cancer care across Canada.”
• “Nationally implemented standards should be developed for each cancer surgery”
• “A national benchmarking process for each specialty should be supported”

• C Finley, L Schneider, S Shakeel
• 171 page report

Approaches To High-Risk, Resource Intensive Cancer Surgical Care In Canada