

Evaluation of Surgical Quality
with a Focus on the Standardized Monitoring of
Peri-Operative Thoracic Morbidity and Mortality

By

JELENA IVANOVIC

A THESIS SUBMITTED IN PARTIAL FULLFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE OF MASTER OF SCIENCE IN EPIDEMIOLOGY

Department of Epidemiology and Community Medicine

Faculty of Medicine

University of Ottawa

© Jelena Ivanovic, Ottawa, Canada, 2011

ABSTRACT

Objective: Evaluation of surgical quality ensures consistency of care and facilitates improvements in the quality of care delivered.

Methods: An overview of surgical quality measurement is presented. A system for monitoring thoracic morbidity and mortality (TM&M) at the Ottawa Hospital is introduced and evaluated. Results of a needs assessment survey on the involvement in thoracic surgical research and quality improvement initiatives are presented.

Results: Structure, process, and outcomes reflect different viewpoints on how to evaluate surgical quality. The feasibility of the TM&M system is evaluated using descriptive and univariate statistics, while its inter-rater reliability is assessed amongst the Canadian Association of Thoracic Surgeons.

Conclusions: Outcomes have been fundamental in the evaluation of surgical quality. TM&M classification system advocates for a practice of continuous quality improvement and provides standardized and reliable feedback on surgical outcomes. Results of the needs assessment have built a strong foundation of knowledge on prospective ways to enhance the monitoring of surgical quality.

Word Count: 154

TABLE OF CONTENTS

Abstract	ii
Table of Contents	iii
List of Tables	vii
List of Abbreviations	viii
Acknowledgements	ix
Dedication	x
Co-authorship Statement	xi
1 Introductory Chapter	1
Thesis Objectives	2
References	3
2 First Manuscript Chapter: Methods used to evaluate the quality of surgical	4
care: A review of the literature	
Manuscript Status	4
Abstract	5
Introduction	6
Methods	6
Structure	7
Structural Quality Initiatives	8
Process	9
Initiatives Aimed at Improving the Process of Care	10

Outcomes	11
Quality Initiatives geared towards Improving Surgical Outcomes	13
Multihospital Collaborations for Surgical Quality Improvement	13
New Paradigm for improving the Quality of Surgical Care	13
Concluding Remarks	14
References	16
3 Second Manuscript Chapter: Systematic classification of morbidity and mortality following thoracic surgery	22
Manuscript Status	24
Abstract	25
Introduction	26
Methods	27
Results	30
Comment	37
Acknowledgements	41
References	42
4 Third manuscript Chapter: Testing the reliability and reproducibility of the Ottawa Thoracic Morbidity & Mortality classification system	45
Manuscript Status	46
Abstract	47
Introduction	48
Methods	49

Results	55
Comment	57
Acknowledgements	62
References	63
5 Fourth manuscript Chapter: Assessing the status of thoracic surgical	66
research and quality improvement programs: A survey of the members of the	
Canadian Association of Thoracic Surgeons	
Manuscript Status	67
Abstract	68
Introduction	70
Methods	71
Results	73
Discussion	81
Acknowledgements	84
References	85
6 Concluding Chapter	87
References	90
7 Appendices	91
Appendix A	91
Appendix B	92
Appendix C	93
Appendix D	103

Appendix E 112
Appendix F 124

LIST OF TABLES

Table 3.1	28
Table 3.2	29
Table 3.3	31
Table 3.4	33
Table 3.5	35
Table 4.1	49
Table 4.2	50
Table 4.3	54
Table 4.4	56
Table 5.1	74
Table 5.2	75
Table 5.3	76
Table 5.4	78
Table 5.5	80

LIST OF ABBREVIATIONS

Abbreviation	Long Form	Page Number (first appearance)
ANOVA	Analysis of Variance	30
CATS	Canadian Association of Thoracic Surgeons	50
CTCAE	Common Terminology Criteria for Adverse Events	28
ICU	Intensive Care Unit	28
LOS	Length of Stay	26
M&M	Morbidity and Mortality	13
NSCLC	Non-Small Cell Lung Cancer	55
NSQIP	National Surgery Quality Improvement Program	15
SAS	Statistical Analysis Software	30
SCIP	Surgical Care Improvement Project	12
STS	Society of Thoracic Surgeons	22
TM&M	Thoracic Morbidity and Mortality	ii
TPA	Tissue Plasminogen Activator	55
VATS	Video-assisted Thoracoscopic Surgery	xii

ACKNOWLEDGEMENTS

I offer my enduring gratitude to the faculty, staff, and my fellow classmates in the Department of Epidemiology and Community Medicine, at the University of Ottawa, and to my colleagues at the Ottawa Hospital and the Ottawa Hospital Research Institute.

I owe particular thanks to Dr. Andrew Seely and Dr. Tim Ramsay for their dedication, commitment, and encouragement throughout my master's thesis work.

A special thank you is owed to my family, friends and Alexy, who have been a tremendous source of support throughout my graduate years of education.

DEDICATION

To my parents

CO-AUTHORSHIP STATEMENT

MANUSCRIPT 1: *Methods used to evaluate the quality of surgical care: A review of the literature*

Study conception and design: Ivanovic, Jelena; Seely, Andrew

Data harvest: Ivanovic, Jelena; Villeneuve, Patrick James

Interpretation of data: Ivanovic, Jelena

Writing of the manuscript: Ivanovic, Jelena

Critical review: Seely, Andrew; Ramsay, Tim

Status: Not Applicable

MANUSCRIPT 2: *Systematic classification of morbidity and mortality following thoracic surgery*

Study conception and design: Seely, Andrew; Ivanovic, Jelena

Data harvest: Alhussaini, Ahmed; Threader, Jennifer; Ivanovic, Jelena

Statistical analysis and interpretation of data: Ivanovic, Jelena; Seely, Andrew

Writing of the manuscript: Ivanovic, Jelena

Critical review: Seely, Andrew; Maziak, Donna; Shamji, Farid; Sundaresan, Sudhir; Alhussaini, Ahmed; Ramsay, Tim; Gilbert, Sebastian

Status: Published in the Annals of Thoracic Surgery, 2010;90:936-942.

MANUSCRIPT 3: *Testing the reliability and reproducibility of the Ottawa Hospital Thoracic Morbidity & Mortality classification system*

Study conception and design: Seely, Andrew; Ivanovic, Jelena

Data harvest: Ivanovic, Jelena

Statistical analysis and interpretation of data: Ivanovic, Jelena; Ramsay, Tim; Seely, Andrew

Writing of the manuscript: Ivanovic, Jelena

Critical review: Seely, Andrew; Maziak, Donna; Shamji, Farid; Sundaresan, Sudhir; Gilbert, Sebastien; Alhussaini, Ahmed; Ramsay, Tim

Status: Published in the Annals of Thoracic Surgery, 2011;91:387-393.

MANUSCRIPT 4: *Assessing the status of thoracic surgical research and quality improvement programs: A survey of the members of the Canadian Association of Thoracic Surgeons*

Study conception and design: Seely, Andrew; Ivanovic, Jelena

Data harvest: Ivanovic, Jelena

Statistical analysis and interpretation of data: Ivanovic, Jelena

Writing of the manuscript: Ivanovic, Jelena

Critical review: Seely, Andrew; Maziak, Donna; Gilbert, Sebastien; Shamji, Farid; Sundaresan, Sudhir; Ramsay, Tim

Status: Accepted for publication in the Journal of Surgical Education [In press] July/August 2011;68(4).

Appendix D: *Evaluating the safety and efficacy of VATS lobectomy*

Study conception and design: Seely, Andrew

Data harvest: Alhussaini, Ahmed

Statistical analysis and interpretation of data: Ivanovic, Jelena

INTRODUCTION

Evaluation of surgical quality is of utmost importance for patients, physicians and hospitals. Evaluating surgical quality helps to ensure consistency of care and facilitates in monitoring and improving the quality of surgical care delivered (1). Evaluation of surgical quality can also provide information to the hospital for decision-making and planning (1). Furthermore, resources and staff can be allocated to areas shown to increase patient care and provide support to those areas deemed to make the most difference for patients in terms of quality (1).

According to Donabedian (2), assumptions about the quality of surgical care can be made from three components: structure, process, and outcomes. Structure refers to organizational characteristics of the particular health care setting. Process refers to the perioperative care received by the patient, and finally, outcomes refer to the effects of care on the health status of the patient (2). Surgical outcomes are most commonly used in many ongoing efforts as measures of the quality of surgical care (3), as many consider patient outcomes at the core of surgical practice. There is no doubt that surgeons have to monitor and assess complication rates in order to design and implement systems that minimize them. Continuous regulation with ongoing feedback on the results to the care teams forms the foundation of an efficient monitoring system (4).

In 1992, Clavien and colleagues were the first to introduce an innovative system to grade complications by severity proportional to the effort required to treat the complications (5). This methodology was recently revised and a novel five-tiered classification system was developed with the intent of presenting an objective and reproducible method for reporting complications (6). This system, now known as the Clavien-Dindo classification system, has

been used in several surgical specialties; however, there have been no published abstracts or papers applying the approach of standardizing surgical morbidity following thoracic surgery. The objective evaluation of both the presence and severity of thoracic morbidity and mortality and the prospective monitoring of thoracic surgical volume represents an important means of standardizing surgical outcomes, enabling comparisons between centers and surgeons, and represents a crucial component to ensuring continuous quality improvement and the best practice of care.

Thesis Objectives:

In order to conduct a thorough evaluation of surgical quality, with an emphasis on the monitoring of thoracic-related, peri-operative complications, four thesis objectives have been outlined:

1. Conduct a literature review to identify methods used for the evaluation of surgical quality
2. Refine a thoracic morbidity and mortality (TM&M) classification system and evaluate its feasibility and utility over the first two years of its implementation at the Ottawa Hospital
3. Evaluate the reliability and reproducibility of the TM&M classification system amongst a national cohort of thoracic surgeons using surgical case scenarios
4. Conduct a needs assessment survey to identify surgeons'/institutions' involvement and capacity in thoracic surgical research and quality improvement initiatives across Canada

REFERENCES

1. Kitts J. "TOH Check Up: Measuring Excellence." Accessed on 25 Nov. 2009.
<<http://www.ottawahospital.on.ca/about/reports/indicators/index-e.asp>>.
2. Donabedian A. The quality of care. How can it be assessed? JAMA 1988;260(12):1743-1748.
3. Dimick JB, Weeks WB, Karia RJ, et al. Who pays for poor surgical quality? Building a business case for quality improvement. J Am Coll Surg 2006;202:933-937.
4. Rebaso P, Mora L, Luna A, et al. Continuous monitoring of adverse events: Influence on the quality of care and the incidence of errors in general surgery. World Journal of Surgery 2009;33(2):191-198.
5. Clavien PA, Sanabria JR, Strasberg SM. Proposed classification of complications of surgery with examples of utility in cholecystectomy. Surgery 1992;111:518-526.
6. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: A new proposal with evaluation in a cohort of 6336 patients and results of a survey. Annals of Surgery 2004;240:205-213

MANUSCRIPT 1

Methods used to evaluate the quality of surgical care: A review of the literature

Jelena Ivanovic, BSc;² James Patrick Villeneuve, MD;¹ Tim Ramsay, PhD;² Andrew JE Seely, MD, PhD, FRCSC.^{1,2}

Affiliation:

¹Department of Surgery, Division of Thoracic Surgery, University of Ottawa, the Ottawa Hospital – General Campus, 501 Smyth Road, K1H 8L6, Ottawa, Canada

²Clinical Epidemiology Program, Ottawa Hospital Research Institute, 725 Parkdale Avenue, K1Y 4E9, Ottawa, Canada

Key Words: Quality assurance (healthcare), Outcome and process assessment, Surgical procedures (operative), quality indicators

Corresponding Author: Andrew JE Seely, MD, PhD, FRCSC

Competing Interests: None declared.

Manuscript Status: Not Applicable

ABSTRACT:

Background: An overview of the literature on surgical quality measurement is summarized through a discussion of three important aspects of quality: structure, process and outcomes of care.

Methods: The review of the literature compromised a search of the following electronic databases: MEDLINE, SCOPUS, Web of Science (via Web of Knowledge), Cochrane Library, and PubMed. The search method was applied and adjusted to each selected database and included the following search terms: specialties (surgical/standards); surgical procedures (operative); quality assurance (healthcare); quality control; quality of healthcare; outcome and process assessment (healthcare); and postoperative complications/epidemiology.

Results: A total of 115 abstracts were identified and scanned for relevance. Of the abstracts, 56 reports met the inclusion criteria and were included in the literature review. Provider volume is frequently studied to evaluate the quality of surgical care at the structural level. Important process measures include: the preoperative preparation of the patient, the choice of the surgical intervention, and use of preoperative checklists. Lastly, morbidity and mortality rates remain the most frequently measured and reported surgical outcomes.

Conclusions: Outcomes measurement has been fundamental in evaluating the quality of surgical care. Specifically, most quality initiatives in surgery have focused on measures of morbidity and mortality. Thus, the use of a standardized classification system is fundamental for the reliable evaluation and monitoring of post-operative morbidity and mortality.

INTRODUCTION

The delivery of the best quality care is the collective goal of all health care systems and of those who are employed within these systems. Nevertheless, wide variations in the quality of surgical care can still be found (1), as the provision of surgical care is technologically advanced, highly specialized, and involves invasive procedures performed on high-risk groups of patients (2). Thus, there is a need to identify methods that allow for continuous measurement and evaluation of the quality of surgical care delivered. The measurement and evaluation of surgical quality refers to the methodological review of the surgical speciality with the purpose of identifying shortcomings and raising standards of care (3). Recommendations can then be put forth so that errors are not repeated and standards of practice are maintained or raised (3).

Similarly, Donabedian advocates that the evaluation of quality in health care entails the assessment of specific and measurable elements of practice that are amenable to quantification (4). Donabedian has further opined that the information from which assumptions can be made regarding the quality of care can be arranged under three broad categories: structure, process, and outcome (4). Our objectives were to perform a literature review within this context, namely describing elements of structure, process, and outcomes that have been associated with surgical quality. The three areas clearly overlap to some degree, nonetheless, this triad approach provides a useful means to classify and evaluate surgical quality. Large-scale initiatives that have attempted to improve the quality of surgical care by targeting one or more aspects of the triad will also be discussed and the advantages and disadvantages of these initiatives will be presented as well.

METHODS

The review of the literature compromised a search of the following electronic

databases: MEDLINE, SCOPUS, Web of Science (via Web of Knowledge), Cochrane Library, PubMed and PubMed related articles option. The search method was applied and adjusted to each selected database and included the following search terms: specialties (surgical/standards); surgical procedures (operative); quality assurance (healthcare); quality control; quality of healthcare; outcome and process assessment (healthcare); and postoperative complications/epidemiology. A structured approach to the literature review helped to ensure that important information was not overlooked. A total of 115 abstracts were identified and scanned for relevance. Of the identified abstracts, 56 reports were considered relevant and the full articles were reviewed for further evaluation. The bibliography of each article was reviewed for other potentially relevant papers. The main selection criteria were publications in English since 1988. Other selection criteria included origin of studies, which was limited to U.S., Canada, and Western Europe. Studies were also restricted to surgical care. The selected publications consisted of original research, systematic reviews, evaluative studies, and opinion articles.

STRUCTURE

Structure refers to the characteristics of the settings in which health care occurs (4). Structural measures also include the knowledge and organization of healthcare personnel (5), hospital accreditation, and the availability of medical devices and drugs (6). Relative to surgery, structural measures include the following: the physical plant, the equipment and supplies, the members of the surgical team and their qualifications, and provider volume (2). Surgical wait times are another commonly targeted indicator of the quality of care at the structural level, as longer wait times have been linked with poorer outcomes in several surgical procedures (7). It is important to note that many structural elements are not rapidly

actionable, and ultimately their use a method toward quality improvement is limited (8).

Of the above variables, provider volume is most frequently studied to evaluate the quality of surgical care. Generally, patients can experience lower mortality rates when choosing to undergo surgery at a high-volume institution (7-8). Both, simple common and rare complex surgical procedures performed at high-volume institutions are linked with lower mortality and improved operative outcomes (9 - 20).

The evidence exploring the reason why high volume has been linked with better outcomes is inconclusive. One thought is that practice makes perfect. Performing the same procedure countless times produces familiarity with its complexities and ultimately leads to improved judgment and fewer errors (12). However, it remains unclear whether surgeon or hospital volume is the more important factor in the volume-outcome relationship. For operations that are dependent on surgeon volume, outcomes may well indeed depend primarily on the traits of the surgeon, such as preoperative decision making or surgical skill. For other operations, surgical outcomes may be associated more on institutional-level attributes, such as the careful attention provided by a specialized team involving preoperative preparation, intraoperative care provided by anaesthesiologists, and postoperative critical care (13). Nurse staffing levels and the degree to which intensive care units are closed and/or staffed by intensivists, have consistently been linked to lower hospital mortality rates following surgery as well (21 - 23).

Structural Quality Initiatives

The Leapfrog Group was formed in November 2000 as an effort aimed at improving safety for high-risk surgical procedures (24). The Leapfrog Group has established several quality practices for hospitals, including volume-based hospital referral (25).

Volume-based referral strategies are most appropriate for procedures with the greatest outcome variability between low-volume and high-volume institutions, and for particularly high-risk groups of patients (26). For instance, the Leapfrog Group has set a minimum volume requirement of 500 procedures for coronary artery bypass grafting (26).

Among their advantages, volume-based referral strategies depend mainly on structural measures of quality and thus can be applied to surgical practice easily and inexpensively (13). However, volume-based referral strategies tend to be highly discriminating as they separate both hospitals and their attending staff into winners and losers (13). Thus, volume-based referral strategies need to be complemented with other types of quality improvement initiatives.

PROCESS

Process refers to the act of giving and receiving care (4). In surgery, important process measures include: informed consent, the preoperative preparation of the patient, the choice of the surgical intervention and its execution, use of preoperative checklists, routine postoperative care and efficient clinical handover (27). The interest in process measures has grown because they allow for more specific actions geared towards quality improvement (8). When strictly applied, such processes can have a significant effect on large patient populations (27). For instance, appropriate antibiotics given at the appropriate time decrease the rate of surgical site infections (28 - 30). Supplemental oxygen has also been associated with decreased infection rate (30).

The use of endoscopic procedures has also transformed several aspects of surgical care and has led to the reassessment of traditional care regimens when compared with open procedures. Studies have reported less pain, shorter hospital stay, and decreases in morbidity

rates after laparoscopic surgery (30). Minimally invasive surgery is considered one of the most important techniques for future improvement of postoperative outcomes (30).

Clinical pathways and surgical checklists are also thought to be an important tool to improve care in surgery. Clinical pathways and surgical checklists are standardized and objective care plans outlining the necessary measures to be performed throughout perioperative care (32-34). Clinical pathways and surgical checklists are useful in avoiding a forgotten order and to induce a reproducible expectation for residents, nurses, and other care team members (34), while decreasing the chances of human error.

Initiatives Aimed at Improving the Process of Care

The Surgical Care Improvement Project (SCIP) focuses on four broad areas where the incidence and cost of complications in surgery is high and where there is a significant opportunity for prevention (29). SCIP was created to reduce risks of 1) surgical site infection, 2) venous thromboembolism, 3) cardiac events, and 4) ventilator acquired pneumonia. The process of surgical infection prophylaxis is a measure of surgical quality because the outcome of wound infections is closely linked to the process (29). However, more studies are needed to examine whether increased compliance with SCIP processes will reduce variation in surgical mortality across hospitals.

OUTCOMES

Outcomes measurement has been fundamental in evaluating the quality of surgical care (5). The measurement of surgical outcomes dates back to the early 20th century (35). Surgical outcomes are the most discussed, most cited, and arguably the most relevant of the three categories of care. Essentially, outcome signifies the effects of care on the health status

of patients (4).

Examples of commonly used outcomes in surgery include preventable adverse events, hospital length of stay, hospital readmission, long-term survival, healthcare costs, patient experience – including patient satisfaction, functional health status, and other measures of health-related quality of life, and postoperative morbidity and mortality (M&M).

It is important to differentiate between complications due to patient disease and those due to medical error. Thus, preventable adverse events are caused by medical errors and can be indicative of broader quality issues that are systemic in origin, whereas M&M rates are indicative of quality within an individual division (due to patient's disease) (36).

Hospital length of stay (LOS) is generally reflected by the severity and extent of post-operative morbidity (2). LOS, as a measure of quality of surgical care, has not yet been validated (2).

Hospital readmission refers to patients who experience two or more hospital events within a specified time period (37). Several studies have shown an association between hospital readmission and improper care during the initial hospitalization period (38-39).

Long-term survival after a surgical operation is impacted by the patient's disease, the type of surgical intervention performed, and the patient's response to treatment (2). Therefore, long term survival is unpredictable (2).

Healthcare costs are another indicator of surgical quality. Essentially, high-quality surgery costs less. Poor quality surgery, on the other hand, is more costly because it increases morbidity, requires more resources, and prolongs hospital LOS (2). Cost accounting systems of surgery are not yet well developed (2).

Outcome measurements are becoming more patient centered, as patients are becoming more active in defining surgical quality. Patient outcomes are measures of the

physical, psycho-social, and functional consequences an individual experiences with health, illness, and treatment (40-41). To accurately measure patient experience, the concept to be measured needs to be matched with the available instruments. A major challenge exists in measuring surgical outcomes due to the current lack of diagnosis specific instruments that are relevant to invasive surgical procedures (40). Nonetheless, measuring patient centered outcomes is a cornerstone for evaluating the effectiveness of invasive surgical procedures (40).

Lastly, morbidity and mortality (M&M) rates remain the most frequently measured and reported endpoints (42). M&M rates are often the only data provided as a method of comparing surgical techniques, centers and surgeons (42). Postoperative mortality is simply defined as either in hospital mortality, 30-day mortality, or a combination of the two (2). Postoperative morbidity, on the other hand, refers to adverse events and complications following surgery (2). Surgical adverse events contribute significantly to postoperative morbidity, yet the measurement and monitoring of these adverse events is often vague and of uncertain reliability and reproducibility (43).

Quality Initiatives geared towards Improving Surgical Outcomes

Several ongoing, large-scale initiatives have been developed for measuring and improving surgical outcomes (8). For example, the National Surgical Quality Improvement Program (NSQIP) (44) and the Society for Thoracic Surgeons (STS) database (45), provide hospitals and cardiothoracic surgeons with information on their risk-adjusted M&M rates.

The NSQIP, for example, was created as a program that originated in the Veteran's Administration Hospitals in the United States as a quality improvement tool for surgical care (45). The NSQIP uses clinical information from medical records to risk-adjust hospital mortality rates. One of the advantages of this type of system includes extensive clinical

information on over one million patients for risk-adjusted analyses on 30-day outcomes of surgical care (45). Since the NSQIP has been implemented, marked improvement in surgical quality has been documented – M&M rates have declined, patient satisfaction has improved, and lengths of stay have decreased (46).

The NSQIP and STS database offer inter-institutional benchmarking, however, they are less applicable as a continuous quality improvement measure for an individual surgical program, as understanding and improving the delivery of a particular operation may require measures tailored to that operation (8), such as proper evaluation of the burden of illness of individual complications and subsequent patient impact. Moreover, the measurement and monitoring of postoperative morbidity is much less efficient than of mortality due to the lack standardized definitions within the NSQIP and STS database (47).

New Paradigm for Improving the Quality of Surgical Care

The use of standardised, valid and reliable definitions is fundamental to the accurate measurement and monitoring of surgical adverse events (43). This notion has in part encouraged a movement toward a new paradigm for improving the quality of surgical care, involving the continuous surveillance and evaluation of surgical adverse events. Continuous and objective analysis and discussion of surgical M&M is the foundation of quality assurance. Continuous monitoring of surgical M&M: i) allows for benchmarking; 2) identifies areas in need of improvement; 3) improves knowledge transfer; 4) facilitates staff and resident education; 5) enables prospective research; and 6) evaluates effectiveness of interventions.

Clavien and colleagues were the first to introduce an innovative system to grade complications by severity proportional to the effort required to treat the complications (48).

This system, now known as the Clavien-Dindo classification system, was validated in 2004 in a large cohort of patients, who underwent a number of general surgical procedures, and has been used in several surgical subspecialties (49-54). This system of reporting is precise, simple, and reproducible, and serves as a continuous means of evaluating the completeness of M&M reporting and monitoring of surgical quality (42).

CONCLUDING REMARKS:

Surgical care quality is a multidimensional construct, as such, it is important to consider and understand the relationships between structure, process of care, and surgical outcomes. The three areas are interrelated, as quality assessment is only possible because good structure increases the likelihood of good process, and good process increases the likelihood of good outcome (4). To date, however, most quality improvement initiatives in surgery have focused on measuring outcomes, in particular, postoperative morbidity and mortality (8). There is thus a clear need for surgeons to accept a single and standardized grading system that has been demonstrated on scientific evaluation to be valid and reliable (44). A standardized and objective system of surgical complications is the foundation (55), on which relative performance measures could be compared, existing performance measures could be assessed, and gold standards could be recognized and realized (56).

REFERENCES:

1. Chow A, Mayer EK, Darzi AW, et al. Patient-reported outcome measures: The importance of patient satisfaction in surgery. *Surgery* 2009;146(3):435-443.
2. Khuri SF, Daley J, Henderson W et al. Relation of surgical volume to outcome in eight common operations: Results from the VA National Surgical Quality Improvement Program. *Annals of Surgery* 1999;230(3):414-429.
3. Dunn DC. Surgical Audit. *National Medical Journal of India* 1992;5(2):50-51.
4. Donabedian A. The quality of care. How can it be assessed? *JAMA* 1988;260(12):1743-1748.
5. Birkmeyer JD, Stukel TA, Siewers AS, et al. Surgeon volume and operative mortality in the United States. *N Engl J Med* 2003;349:2117-2127.
6. Gruen RL. Monitoring and improving quality in surgery. *ANZ Journal of Surgery* 2008;78(11):940-942.
7. Kawakami J, Hopman WM, Smith-Tryon R, Siemens DR. Measurement of surgical wait times in a universal health care system. *Can Urol Assoc J* 2008;2(6):597-603.
8. Birkmeyer JD, Dimick JB, Birkmeyer NJO. Measuring the quality of surgical care: Structure, process, or outcomes? *Journal of the American College of Surgeons* 2004;198:626-632.
9. Birkmeyer JD, Siewers AE, Finlayson EVA, et al: Hospital volume and surgical mortality in the United States. *N Engl J Med* 2002;346:1128-1137.
10. Birkmeyer JD, and Dimick JB. Potential benefits of the new Leapfrog standards: Effect of process and outcomes measures. *Surgery* 2004;135:569–75.

11. Dimick JB, Pronovost PJ, Cowan JA, and Lipsett PA. Surgical volume and quality of care for esophageal resection: Do high-volume hospitals have fewer complications? *Annals of Thoracic Surgery* 2003;75:337– 341.
12. Feliberti EC, and Perry RR. Volume as a marker of surgical quality. *Journal of Surgical Oncology* 2007;96(7):539-540.
13. Birkmeyer JD, and Dimick JB. Understanding and reducing variation in surgical mortality. *Annual Review of Medicine* 2009;60:405-415.
14. Dudley RA, Johansen KL, Brand R, et al. Selective referral to high volume hospitals: estimating potentially avoidable deaths. *JAMA* 2000;283:1159–66.
15. Halm EA, Lee C, Chassin MR. Is volume related to outcome in health care? A systematic review and methodologic critique of the literature. *Ann Int Med* 2002; 137:511–20.
16. Houghton A. Variation in outcome of surgical procedures. *Br J Surg* 1994;81:653–60.
17. Porter GA, Soskolne CL, Yakimets WW, et al. Surgeon-related factors and outcome in rectal cancer. *Ann Surg* 1998;227:157-167.
18. Hillner BE, Smith TJ, and Desch CE. Hospital and physician volume or specialization and outcomes in cancer treatment: Importance in quality of cancer care. *J Clin Oncol* 2000; 18:2327-2340.
19. Begg CB, Reidel ER, Bach PB, et al. Variations in morbidity after radical prostatectomy. *N Engl J Med* 2002;346:1138-1144.
20. Chowdhury MM, Dagash H, and Pierro A. A systematic review of the impact of volume of surgery and specialization on patient outcome. *The British Journal of Surgery* 2007;94(2), 145-161.
21. Aiken LH, Clarke SP, Sloane DM, et al. Hospital nurse staffing and patient mortality, nurse burnout, and job dissatisfaction. *JAMA* 2002;288:1987–93.

22. Pronovost PJ, Dang D, Dorman T, et al. Intensive care unit nurse staffing and the risk for complications after abdominal aortic surgery. *Eff Clin Pract* 2001;4:199–206.
23. Pronovost PJ, Angus DC, Dorman T, et al. Physician staffing patterns and clinical outcomes in critically ill patients: a systematic review. *JAMA* 2002;288:2151–62.
24. The Leap Frog Group. Available at: <http://leapfroggroup.org>. Accessed Nov. 12, 2010.
25. McCafferty M H, and Polk HC Jr. Patient safety and quality in surgery. *Surgical Clinics of North America* 2007;87(4):867-881.
26. Shahian DM, and Normand SL. The volume-outcome relationship: from Luft to Leapfrog. *The Annals of Thoracic Surgery* 2003;75(3):1048-1058.
27. Fink AS, Itani KM and Campbell DC Jr. Assessing the quality of surgical care. *Surgical Clinics of North America* 2007;87(4):837-852.
28. Bratzler DW, Houck PM. Antimicrobial prophylaxis for surgery: An advisory statement from the National Surgical Infection Prevention Project. *Am J Surg* 2005;189:395–404.
29. Bratzler DW. The surgical infection prevention and surgical care improvement projects: Promises and pitfalls. *American Surgeon* 2006;72(11):1010-1016.
30. Dellinger EP, Hausmann SM, Bratzler DW, et al. Hospitals collaborate to decrease surgical site infections. *Am J Surg* 2005;190:9–15.
31. Kehlet H, Wilmore DW. Multimodal strategies to improve surgical outcome. *American Journal of Surgery* 2002;183:630-641.
32. Ronellenfitch U, Rossner E, Jakob J, et al. Clinical pathways in surgery: Should we introduce them into clinical routine? A review article. *Langenbeck's Archives of Surgery* 2008;393(4):449-457.
33. Polk HC. The evolution of guidelines toward standards of practice. *Am Surg* 2006;72:1017–20.

34. de Vries EN, Hollmann MW, Smorenburg SM, Gouma DJ, Boermeester MA. Development and validation of the SURgical Patient Safety System (SURPASS) checklist. *Qual Saf Health Care* 2009;18:121–126.
35. Neuhauser D, Ernest Amory Codman MD. *Qual Health Care* 2002;11:104-105
36. Healy MA, Shackford SR, Osler TM, Rogers FB, Burns E. Complications in surgical patients. *Arch Surg* 2002;137:611-618.
37. Corrigan JM and Kazandjian VA. Characteristics of multiple admissions. *American Medical Record Association* 1991;62(3):37-47.
38. Ashton CM, Wray NP, Dunn JK, et al. Predicting readmission in veterans with chronic disease: development and validation of discharge criteria. *Med Care* 1987;25:1184-1189.
39. Benbassat J, and Taragin M. Hospital readmissions as a measure of quality of health care: Advantages and limitations. *Archives of Internal Medicine* 2000;160(8): 1074-1081.
40. Ireson CL, and Schwartz RW. Measuring outcomes in surgical patients. *American Journal of Surgery* 2001;181(1):76-80.
41. Mitchell PH, Heinrich J, Moritz P, and Hinshaw AS. Outcome measures and care delivery systems. *Med Care* 1997; 35(Suppl):NS1–NS5.
42. Martin RC 2nd, Brennan MF, Jaques DP. Quality of complication reporting in the surgical literature. *Ann Surg* 2002;235:803-813.
43. Bruce J, Russell EM, Mollison J, Krukowski ZH. The measurement and monitoring of surgical adverse events. *Health Technol Assess.* 2001;5(22):1-194.
44. Khuri SF, Daley J, Henderson W, et al. The Department of Veterans Affairs' NSQIP: The first national, validated, outcome-based, risk-adjusted, and peer-controlled program for

- the measurement and enhancement of the quality of surgical care. National VA surgical quality improvement program. *Annals of Surgery* 1998;228(4):491-507.
45. Society of Thoracic Surgeons. 2007. (Accessed January 18, 2010, at www.sts.org/sections/stsnationaldatabase.)
 46. Hall BL, Hamilton BH, Richards K, et al. Does Surgical Quality Improve in the American College of Surgeons National Surgical Quality Improvement Program: An Evaluation of All Participating Hospitals. *Annals of Surgery* 2009;250: 363–376.
 47. Grover FL, Shroyer AL, Hammermeister KE. Calculating risk and outcome: the Veterans Affairs database. *Ann Thorac Surg* 1996;62:S6–11.
 48. Clavien PA, Sanabria JR, Strasberg SM. Proposed classification of complications of surgery with examples of utility in cholecystectomy. *Surgery* 1992;111:518-526.
 49. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: A new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Annals of Surgery* 2004;240:205-213.
 50. DeOliveira ML, Winter JM, Schafer M, et al. Assessment of complications after pancreatic surgery: A novel grading system applied to 633 patients undergoing pancreaticoduodenectomy. *Annals of Surgery* 2006;244:931-939.
 51. Gonzalgo ML, Pavlovich CP, Trock BJ, et al. Classification and trends of perioperative morbidities following laparoscopic radical prostatectomy. *The Journal of Urology* 2005;174:135-139.
 52. Kocak B, Koffron AJ, Baker TB, et al. Proposed classification of complications after live donor nephrectomy. *Urology* 2006;67:927-931.

53. Tamura S, Sugawara Y, Kaneko J, et al. Systematic grading of surgical complications in live liver donors according to Clavien's system. *Transplant International: Official Journal of the European Society for Organ Transplantation* 2006;19:982-987.
54. Mazeh H, Samet Y, Abu-Wasel B, et al. Application of a novel severity grading system for surgical complications after colorectal resection. *Journal of the American College of Surgeons* 2009;208: 355-361.
55. Jacques DP. Measuring morbidity. *Annals of Surgery* 2004;240:214-215.
56. Andrew N, Tolson D, and Ferguson D. Building on Wenger: Communities of practice in nursing. *Nurse Educ Today* 2008;28:246 –252.

INTERFACE

It is important to standardize the definition of both presence and severity of surgical complications, as well as perform continuous quality monitoring. However, the lack of standardization in evaluating morbidity after thoracic surgery has severely hampered meaningful comparisons over time. The following article describes the first step of the creation of a system to monitor thoracic surgical quality. The Clavien-Dindo classification system, which has been used in other surgical specialties, was adapted to the thoracic surgical setting. Additionally, peer review, questionnaire, and surgeon experience were used to develop the thoracic morbidity and mortality (TM&M) classification system. The TM&M system relies on the therapy used to correct a specific complication. Grade I and grade II complications include minor deteriorations from the normal postoperative course that require either no intervention or pharmacologic therapy, respectively. Grade III complications require interventional treatment. Grade IV complications are life-threatening complications with ICU management. Grade V complications result in the death of a patient.

Additional aims of the study were to evaluate the feasibility and utility of the TM&M system over the first two years of its implementation at the Ottawa Hospital. All patients undergoing thoracic surgery between January 2008 and December 2009 were prospectively evaluated. Topics such as overall grade and severity of thoracic surgical complications, common complications for major thoracic procedures, impact of complication grade on readmission rates and length of stay, burden of illness of individual complications, change in complications over the 2-year time period, and incidence of complications in subgroups, are considered in the manuscript.

Morbidity and mortality conferences have been greatly enhanced by the improved quality of statistical reporting of thoracic surgical complications. With the TM&M classification system fully in effect at the Ottawa Hospital, the thoracic oncology team plans to continue to build upon a strong commitment to surgical quality.

MANUSCRIPT 2

Systematic classification of morbidity and mortality following thoracic surgery

Andrew JE Seely, MD, PhD, FRCSC;^{1,2} Jelena Ivanovic, BSc;² Jennifer Threader, BSc;¹
Ahmed Al-Hussaini, MD;¹ Derar Al-Shehab, MD;¹ Tim Ramsay, PhD;² Sebastian Gilbert,
MD, FRCSC;¹ Donna E Maziak, MDCM, MSc, FRCSC;^{1,2} Farid M Shamji, MBBS,
FRCSC;¹ R Sudhir Sundaresan, MD, FRCSC.¹

Affiliation:

¹Department of Surgery, Division of Thoracic Surgery, University of Ottawa, the Ottawa Hospital – General Campus, 501 Smyth Road, K1H 8L6, Ottawa, Canada

²Clinical Epidemiology Program, Ottawa Hospital Research Institute, 725 Parkdale Avenue, K1Y 4E9, Ottawa, Canada

Keywords: Database, Outcomes (includes mortality, morbidity), Patient safety, Perioperative care, Surgery (complications)

Corresponding Author: Andrew JE Seely, MD, PhD, FRCSC

Manuscript Status: Published in The Annals of Thoracic Surgery, 2010;90:936-942.

ABSTRACT:

Background: Objective reporting of postoperative complications is the foundation of surgical quality assurance. We developed a system to identify both presence and severity of thoracic morbidity and mortality, and evaluated its feasibility and utility over the first two years of its implementation.

Methods: The system was based on the Clavien-Dindo classification, in which the severity of a complication is proportional to the effort to treat it. Definitions were developed by peer review and questionnaire. All patients undergoing thoracic surgery (01/2008-12/2009) were prospectively evaluated.

Results: 953 patients (mean age 61, range 14-95) underwent thoracic surgery, of whom 369 (29.3%) patients had at least one complication. Grades I and II include minor complications requiring no therapy or pharmacologic intervention only. Grades III and IV are major complications that require surgical intervention or life support. Grade V complications result in patient death. Grade I, II, III and IV complications comprised 4.9%, 63.9%, 21.1% and 7.8% of all complications; overall mortality rate (Grade V) was 2.2%. The most common complications were prolonged air leak (18.8%) and atrial fibrillation (18.2%) following pulmonary resection, and atrial fibrillation (11.5%) after esophagectomy/gastrectomy. Prolonged air leak led to a major complication (13%), readmission (17%) or prolonged hospital stay (29%) to a greater extent than atrial fibrillation (3%, 2% and 7%, respectively).

Conclusions: This standardized classification system for identifying presence and severity of thoracic surgical complications is feasible, facilitates objective comparison, identifies burden of illness of individual complications, and provides an effective method for continuous surgical quality assessment.

INTRODUCTION:

Objective analysis and discussion of surgical morbidity and mortality (M&M) is the foundation of quality assurance. However, defining and measuring quality is a particularly difficult undertaking (1). Mortality is well defined in the medical literature and is a comparable surgical outcome, whereas morbidity rates have been poorly reported; thus, limiting comparisons among surgeons, procedures, and centers, and within the same center over time (2 – 4). To enable such comparisons, data on surgical outcomes must be acquired in a standardized and transparent format (2). Short-term surgical outcomes, such as hospital length of stay (LOS), 30-day mortality rate, operating time, and approximate blood loss, are regularly reported in the data collected; yet, conclusive assessments of surgical procedures have remained limited by the lack of agreement on how to define and classify complications by severity (5).

Most surgeons depend on regular review of complications at M&M conferences to evaluate experience, analyze complications and receive feedback regarding quality improvement measures undertaken to minimize risk (6). However, data from M&M conferences are neither systematically collected, nor stored in a standardized and reproducible fashion (7). These shortcomings of traditional methods for quality assurance have partly encouraged a movement toward a new paradigm for improving surgical care quality (8).

In 1992, Clavien and colleagues introduced an innovative system to grade complications by severity proportional to the effort required to treat the complications (2). This methodology was recently revised and a novel five-tiered classification system was developed with the intent of presenting an objective and reproducible method for reporting

complications after general surgery (9). This system, now known as the Clavien-Dindo classification system, has been validated in a large cohort of patients, who underwent a number of general surgical procedures, and has universal applicability (10 – 14). However, there have been no published abstracts or papers applying the approach of standardizing surgical morbidity following non-cardiac thoracic surgery.

Thus, our aims were to develop a classification system to grade presence and severity of thoracic morbidity and mortality (TM&M), which would enable us to compare surgical procedures and subgroups of patients, and simultaneously allow us to evaluate the feasibility of the system over the first two years of its implementation at the Ottawa Hospital, a high-volume, single academic thoracic surgery center. The Ottawa Hospital serves a population of 1.35 million people and thoracic surgical care is consolidated at one campus by five thoracic surgeons and one resident. We hypothesized that a standardized system for classifying thoracic-related post-operative complications would function as a basis to inform the individual surgeon regarding M&M rates following thoracic surgery.

METHODS:

Ethical Concerns:

Research on complex diseases raises ethical issues concerning informed consent, privacy, and patient confidentiality. The Ottawa Hospital Research Ethics Board approved the collection of thoracic morbidity and mortality data, through waived consent (refer to Appendix A).

Development and Classification of Surgical Complications:

The TM&M system was developed according to the Clavien-Dindo classification schema (9) of surgical adverse events (Table 3.1).

Table 3.1. Classification of complications following thoracic surgery

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

Definitions of surgical adverse events were modified according to complications in patients following non-cardiac thoracic surgery through peer review and questionnaire, and adjusted based on surgeons' experience. A complication was defined as any deviation from the normal postoperative course. For each of the following systems: pulmonary, pleural, cardiac, renal, gastrointestinal, neurological, wound, and other, complications were described associated with the specific grading system (refer to Appendix C). The Common Terminology Criteria for Adverse Events (CTCAE version 3.0) (15) was also used to refine some definitions.

Patients:

The TM&M classification system was applied to a cohort of 953 consecutive patients undergoing non-cardiac thoracic surgery at The Ottawa Hospital from January 1, 2008 to December 31, 2009. Demographics and indications for operation are shown in Table 3.2. There were 520 male (54.5%) and 433 female (45.5 %) patients with a mean age of 61 years

(range, 14–95 years). While 592 patients (62.1%) had a malignant disease, the remaining 361 patients (37.9%) had a range of benign lung, esophageal and other thoracic-related diseases.

Table 3.2. Demographics and preoperative diagnoses for patients (n = 953)

Demographics		
Mean age (in years), range	60.9	14 – 95
Gender	n	% of Total Cases
Males	520	54.5
Females	433	45.5
Preoperative Diagnosis		
Lung	n	% of Total Cases
Malignant	441	46.3
Benign	148	15.5
Esophagus		
Malignant	83	8.7
Benign	175	18.4
Other		
Malignant	68	7.1
Benign	38	4.0

Data Collection:

Daily data collection of M&M was carried out by a senior thoracic surgical resident and the thoracic surgery research coordinator using the TM&M form. Weekly lists of operative procedures along with related complications were compiled and further validated by attending staff. These complications were then discussed at monthly M&M conferences. A database for complication reporting was developed; data entered included gender, age and preoperative diagnosis. Surgical details entered were type of operation, including whether it was a video assisted or open operation. The grading of complications was prospectively applied to each patient according to severity and effort required to treat the complication (Table 3.1), but risk adjustment was not done at this time. Access to the database was protected by password and limited.

Statistical Analysis:

Descriptive statistical analyses were performed to analyze surgical volume and M&M rates after non-cardiac thoracic surgery. Incidence of complications in different subgroups was analyzed using the Chi-square test or Fisher's exact test. Correlations between complication grade and hospital length of stay was analyzed using analysis of variance (ANOVA). A *p* value of less than 0.05 was considered significant. Data was analyzed using SAS version 9.2 software.

RESULTS:

Overall Grade and Severity of Thoracic Surgical Complications

During the study period, a total of 953 patients (mean age 61, range 14-95) underwent a thoracic surgical procedure, of which 369 (29.3%) patients had at least one complication. As suggested by Clavien et al., 2009, our goal was to record only the most severe complication pertaining to the affected system, when those complications of a lower grade are a step in the process leading to the more serious outcome (16). Thus, grades I and II are minor complications, and comprised 4.9% and 63.9% of all complications, respectively. Grade III and IV are considered major complications and comprised 21.1% and 7.8% of all complications, respectively. Overall mortality rate (Grade V) was 2.2%. Distribution of complications by grade and by major surgical procedure is presented in Table 3.3. Of the 229 lobectomies performed, 96 (41.9%) were done by video-assisted thoracoscopic surgery.

Table 3.3. Total complications for all cases and for three major surgical procedures

Complication Grade		Major Surgical Procedure			All Cases (n = 1260)
		Lobectomy (n = 229)	Pneumonectomy (n = 33)	Esophagectomy/ Gastrectomy (n = 51)	
Minor	Grade I	12 (7.5)	0 (0)	2 (3.8)	22 (4.9)
	Grade II	112 (69.6)	17 (54.8)	29 (55.8)	287 (63.9)
Major	Grade IIIa	21 (13.0)	1 (3.2)	5 (9.6)	63 (14.0)
	Grade IIIb	5 (3.1)	3 (9.7)	8 (15.4)	32 (7.1)
	Grade IVa	7 (4.3)	8 (25.8)	8 (15.4)	30 (6.7)
	Grade IVb	1 (0.6)	0 (0)	0 (0)	5 (1.1)
Mortality	Grade V	3 (1.9)	2 (6.5)	0 (0)	10 (2.2)
Total # Complications		161	31	52	449
Total # Patients with Complications		113 (49.3)	18 (54.6)	27 (60.8)	369 (29.3)

Common Complications for Major Thoracic Procedures

The most common complications and their frequency are presented in Tables 3.3 and 3.4 for patients who underwent a lobectomy, pneumonectomy, or an esophagectomy/gastrectomy.

Grade I complications accounted for 7.5% of all lobectomy complications, with pneumothorax being the most common grade I complication. Grade II complications made up the majority of lobectomy complications with a total of 69.6%; prolonged air leak (22.4%) and atrial fibrillation (17.4%) were the most common grade II complications. Atrial fibrillation classified under grade II was defined as requiring medical therapy only (e.g. beta-blockers) for heart rate control. Prolonged air leak classified under grade II was defined as persistent air leak beyond five (5) days. Next, grade IIIa complications made up 13.0% of lobectomy complications, with pneumothorax being the most common complication requiring placement of an additional pleural tube. Postoperative bleeding requiring re-exploration was the most common grade IIIb complication. Respiratory failure was the most

common grade IVa complications. A total of 3 (2.4%) deaths occurred in patients undergoing a lobectomy due to respiratory failure, pneumonia, and gastrointestinal bleeding.

A similar trend in complication rates was noted for patients who underwent a pneumonectomy or an esophagectomy/gastrectomy, with grade II complications compromising the majority of complications. Atrial fibrillation (22.6%) was the most common Grade II complication after pneumonectomy. There were 2 (6.5%) deaths in the pneumonectomy group due to pneumonia.

An array of grade II complications occurred in patients who underwent an esophagectomy/gastrectomy, amongst which atrial fibrillation (11.5%) was the most common. There were no deaths in this group.

Table 3.4. Most common complications resulting from a major thoracic procedure

Grade	Lobectomy (n = 161)			Pneumonectomy (n = 31)			Esophagectomy/Gastrectomy (n = 52)		
	Complication	n	%	Complication	n	%	Complication	n	%
I	Pneumothorax	2	1.2	--			Elevated White Blood Cells	1	1.9
	Delirium	2	1.2	--			Elevated Platelets	1	1.9
	Social Issues	2	1.2	--			--		
	Other	6	3.7	--			--		
II	Prolonged air leak	36	22.4	Atrial Fibrillation	7	22.6	Atrial Fibrillation	6	11.5
	Atrial Fibrillation	28	17.4	Pneumonia	2	6.5	Urinary Tract Infection	4	7.7
	Delirium	7	4.3	Low Hemoglobin	2	6.5	Wound Infection	3	5.8
	Other	41	25.5	Other	6	19.4	Other	16	30.8
IIIa	Pneumothorax	6	3.7	Urinary Tract Infection	1	3.2	Esophageal Leak	1	1.9
	Subcutaneous Emphysema	3	1.9	--			Urine Retention	1	1.9
	Prolonged air leak	1	0.6	--			Urinary Tract Infection	1	1.9
	Other	11	6.8	--			Other	2	3.8
IIIb	Postoperative Bleeding	2	1.2	Empyema	2	6.5	Anastomotic Leak	5	9.6
	Subcutaneous Emphysema	1	0.6	Hiatus Hernia	1	3.2	Ischemia	1	1.9
	Leak Anastomosis	1	0.6	--			Jejuno Necrosis	1	1.9
	Other	1	0.6	--			Other	1	1.9
IVa	Respiratory Failure	4	2.5	Respiratory Failure	3	9.7	Myocardial Infarction	2	3.8
	PAL	1	0.6	Pulmonary Edema	1	3.2	Anastomotic Leak	1	1.9
	MI	1	0.6	Pneumonia	1	3.2	Respiratory Failure	1	1.9
	Other	1	0.6	Other	3	9.7	Other	4	7.7
IVb	Renal Failure	2	0.6	--			--		
V	Respiratory Failure	1	0.6	Pneumonia	2	6.5	--		
	Pneumonia	1	0.6	--			--		
	Gastro Intestinal Bleeding	1	0.6	--			--		

Impact of Complication Grade on Readmission Rates and Prolonged Hospital Stay

Between May 1, 2009 and December 31, 2009, data were collected to evaluate the effect of complication grade on the risk of prolonged length of hospital stay and readmission to hospital for all cases. Patients with lower grade complications (i.e. grade II) were less likely ($p < 0.05$) to have prolonged hospital stay when compared to patients with higher grade (i.e. III and IV) complications. During this time period, a number of patients were readmitted to the hospital, but readmission rates did not reach statistical significance.

Burden of Illness of Individual Complications

The TM&M classification system offers a comprehensive and objective evaluation of the impact of individual complications on patients. Atrial fibrillation (18.8%) and prolonged air leak (18.2%) compromised the majority of grade II complications following pulmonary resection, and thus, require more careful attention. The majority of prolonged air leak complications following pulmonary resection were grade I or II (87%), Grade IIIa and IIIb were 9% and 2%, respectively, and Grade IV was 2%. Upon evaluation of all complications secondary to air leak after pulmonary resection, 97% of all atrial fibrillation was Grade II, with 1 patient (3%) experiencing a Grade IVa complication (Table 3.5). In addition, since we began evaluating if complications led to prolonged hospital stay or re-admission, we found air leak led to 17% rate of re-admission, and 29% prolonged hospital stay, compared to 2% and 7% for atrial fibrillation. Thus, despite similar incidence after pulmonary resection, we identified air leak as having a significantly greater burden of illness than atrial fibrillation as defined by more severe complications, re-admissions and longer stay.

Table 3.5. Evaluating the burden of illness of individual complications, January 2008 to December 2009, and readmission rates and prolonged length of stay for patients (n = 41) who underwent pulmonary resection, May 2009 to December 2009.

Complication	Total (%)	Grade (%)						Readmission (%)		Prolonged LOS (%)		
		I	II	IIIa	IIIb	IVa	IVb	V	Yes (%)	No (%)	Yes (%)	No (%)
Air Leak	46 (100)	1 (2)	39 (85)	4 (9)	1 (2)	1 (2)	0 (0)	0 (0)	7 (17)	9 (22)	12 (29)	4 (10)
A. Fibrillation	36 (100)	0 (0)	35 (97)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	1 (2)	11 (27)	3 (7)	8 (20)
Pneumothorax	8 (100)	2 (2)	0 (0)	6 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	1 (2)	0 (0)
MI	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	1 (2)	1 (2)	0 (0)
Pneumonia	12 (100)	0 (0)	8 (67)	0 (0)	0 (0)	1 (8)	0 (0)	3 (25)	0 (0)	2 (5)	2 (5)	0 (0)

Complications by Grade and by System

Grade II complications accounted for the majority (63.9%) of complications in patients who underwent a thoracic surgical procedure. When broken down by system, cardiac (27.5%), pleural (19.2%), and pulmonary (14.3%) complications accounted for the majority of grade II complications. A total of ten deaths occurred with an overall mortality rate of 2.2%. Of the ten patients that had a fatal outcome, six patients died from complications that were pulmonary in nature. An additional two patients died from cardiac complications. The remaining two patients died from other causes.

Impact of Complication Grade on Length of Stay (LOS)

The influence of complication grade on hospital LOS was analyzed for major thoracic procedures. Patients were followed throughout their hospital course. For example, patients undergoing lobectomy are placed on a clinical pathway and their expected LOS is 5 days if no complications occur post-operatively. We found that LOS was significantly longer (ANOVA, $p < 0.05$) for patients with higher grade complications undergoing a lobectomy procedure. The median length of hospital stay in patients with grade I complications was 5.5 days (range 5 to 11 days), with grade II 8 days (range 3 to 42 days), with grade IIIa 8 days (range 3 to 23 days), grade IIIb 7.5 days (range 5 to 14 days), grade IVa 31 days (range 19 to 114 days), and grade IVb 43 days (1 patient). Postoperative mortality was defined as in-hospital mortality: 1 patient died of respiratory failure on postoperative day 32, 1 patient died of pneumonia on postoperative day 5, and 1 patient died of gastrointestinal bleeding on postoperative day 49.

Change in Complications Over the 2-year Time Period

To determine whether the frequency of minor (grades I and II) and major (grades III and IV) complications have changed over time, we analyzed all patients who underwent a

lobectomy, pneumonectomy, and an esophagectomy/gastrectomy between January 1, 2008 and December 31, 2009, in three-month intervals. The dispersion of minor and major complications for the three major procedures was not statistically significant. Despite this, the TM&M classification system has provided our department with an objective evaluation of thoracic surgical complications and has facilitated effective M&M review.

Incidence of Complications in Subgroups

Overall complication rate was not statistically different in patients undergoing a lobectomy or patients undergoing a pneumonectomy procedure (49.3% versus 57.6%; $p = 0.38$). However, there was a significantly higher grade IVa complication rate in patients undergoing a pneumonectomy compared to those patients undergoing a lobectomy (24.2% versus 2.2%; $p < 0.05$).

Overall complication rate was not statistically different in patients undergoing video-assisted thoracoscopic surgery or patients undergoing an open lobectomy (53.1% versus 45.1%; $p = 0.23$).

Regardless of type of procedure, there was a significantly higher complication rate in patients older than 71 years of age compared to those patients younger than 70 years of age (62.1% versus 40.1%; $p < 0.05$). Particularly, patients older than 71 years of age experienced significantly more grade II complications (44.4% versus 23.4%; $p < 0.05$) in comparison to patients younger than 70 years of age. No differences in major complications occurred between the two age groups.

COMMENT:

An objective evaluation of surgical care quality is of utmost importance for patients, physicians, and hospitals. Evaluating the outcome of patient care is helpful in improving the

quality of surgical care delivered. Thus, any system that is developed for this purpose must be simple, reproducible, and applicable to any surgical specialty at any medical institution. A uniform system would permit comparison of outcomes between surgical procedures, between different institutions, and allow for knowledge transfer for improvement in one's own institution. The implications are wide-ranging, as all disciplines would be empowered to work towards the same goal of improving surgical in-patient outcomes.

The development of the TM&M classification system and the accompanying TM&M database has facilitated systematic monitoring, reporting and evaluation of postoperative complications across all thoracic surgical procedures performed at the Ottawa Hospital. To assess the validity and reproducibility of the modified classification, a 31-item, web-based questionnaire was sent to all active members of the Canadian Association of Thoracic Surgeons in August 2009. The first part of questionnaire consisted of an introduction to the TM&M classification system along with definitions of the severity grades. The second part of the questionnaire showed 20 case-based examples along with postoperative adverse events to be classified in accordance to the proposed classification system. Lastly, respondents were assessed on their personal judgments about the classification system. A statistically significant degree of agreement was obtained among the survey respondents which will be reported separately.

The TM&M classification system is complementary to several ongoing, large-scale programs designed specifically to measure and improve surgical outcomes (17), such as the National Surgical Quality Improvement Program (NSQIP) (18) and the Society for Thoracic Surgeons (STS) database (19), which provide hospitals and cardiothoracic surgeons with information on their risk-adjusted M&M rates, respectively. These initiatives offer inter-institutional benchmarking, however, they are less applicable as a continuous quality

improvement measure for an individual thoracic surgical program, as understanding and improving the delivery of a particular operation may require measures tailored to that operation (17), such as proper evaluation of the burden of illness of individual complications and subsequent patient impact. Incorporation of a standardized complication grading system, such as the TM&M, into large organizational databases would allow identification of areas for improvement for surgeons and institutions. It would provide a common denominator for the implementation of quality improvement programs to reduce the incidence of complications following thoracic surgery.

By using the TM&M system as a continuous measure of quality, we have now embarked on several initiatives to further improve complication rates related to thoracic procedures. A comparison was performed at our institution to evaluate postoperative outcomes after lobectomy by video-assisted thoracoscopic surgery versus open thoracotomy performed on thoracic oncology patients (refer to Appendix D). We further plan to utilize this continuous TM&M classification system as a backbone for prospective monitoring of essential surgical information, upon which to add additional clinical data collection tools. While the use of a reliable and continuous system of evaluation of presence and severity of complications after thoracic surgery is necessary, it is not sufficient for a comprehensive evaluation of surgical quality. Monitoring of wait times, efficient resource utilization, patient experience and satisfaction are all dimensions of surgical care quality improvement.

We recognize several important limitations to this type of classification system. Reported morbidity bears little importance without an understanding of the medical impact of that morbidity (20). It is as important to precisely document the complication as it is to analyze it and relate it to pre-existing risk factors, intra-operative difficulties, and lack of hospital resources. While it is important to recognize the financial implications for prolonged

length of stay in the hospital, it is equally important to determine the exact reason for such occurrence. Similarly, for all complications seen in the thoracic surgical population, the cause must be identified, the severity of the complication assessed and the steps necessary to rectify quickly should be undertaken. The attribution of cause of morbidity is an additional dimension of morbidity reporting that we have not endeavoured to record systematically, as it is based on judgement, and customarily requires peer discussion during M&M conferences. Our results indicate that atrial fibrillation and prolonged air leak have a different burden in different patients; but risk-adjustment, to account for the different case-mix was not performed at this time. Thus, future modifications to the TM&M classification system are planned, including a measure of the etiology of complications which may be useful for attributing cause as knowledge about risk factors is fundamental to compare outcomes among risk-adjusted populations.

Whereas complications may reflect both patient and health care factors, the ability to save patients once complications arise is much more closely related to the quality of health care (21). A failure to rescue rate may not be correlated with postoperative adverse events, but represents a limitation of the TM&M classification system to counter the occurrence and progression of complications.

Indeed, collecting TM&M data is inherently a collegial activity. It requires participation of the senior residents on a daily basis, weekly confirmation by attending staff, and monthly discussion at M&M conferences. The presence and grade of a complication is not always clear, and frank collegial discussion enhances the validity of the data. Our experience has been that M&M conferences have greatly been enhanced by improved quality of statistical reporting of all complications, while maintaining individual patient case presentations.

We conclude that a prospectively collected, standardized classification system for accurately identifying and grading thoracic surgical complications in all cases is feasible to implement, facilitates objective comparison between surgical procedures and patients, and between surgeons and centers, identifies burden of illness of individual complications, and thus, provides an effective tool for continuous surgical quality assessment.

ACKNOWLEDGEMENTS:

The authors would like to gratefully acknowledge funding from the Department of Surgery at the Ottawa Hospital, Dr. Lorenzo Ferri (McGill University) for his suggestion to initially explore the Clavien-Dindo classification system, and to Dr. Jack Kitts, president and CEO of The Ottawa Hospital for his encouragement of this project.

REFERENCES:

1. Donabedian A. The quality of care. How can it be assessed? JAMA 1988;260:1743-1748.
2. Clavien PA, Sanabria JR, Strasberg SM. Proposed classification of complications of surgery with examples of utility in cholecystectomy. Surgery 1992;111:518-526.
3. Clavien PA, Camargo CA Jr, Croxford R, et al. Definition and classification of negative outcomes in solid organ transplantation: Application in liver transplantation. Ann Surg 1994;220:109-120.
4. Clavien PA, Sanabria JR, Mentha G, et al. Recent results of elective open cholecystectomy in a North American and a European center: Comparison of complications and risk factors. Ann Surg 1992;216:618-626.
5. Martin RC 2nd, Brennan MF, Jaques DP. Quality of complication reporting in the surgical literature. Ann Surg 2002;235:803-813.
6. Murayama KM, Derossis AM, DaRosa DA, et al. A critical evaluation of the morbidity and mortality conference. American Journal of Surgery 2002;183:246-250.
7. Antonacci AC, Lam S, Lavarias V, et al. A morbidity and mortality conference-based classification system for adverse events: Surgical outcome analysis: Part I. Journal of Surgical Research 2008;147:172-177.
8. Feldman L, Barkun J, Barkun A, et al. Measuring postoperative complications in general surgery patients using an outcomes-based strategy: Comparison with complications presented at morbidity and mortality rounds. Surgery 1997;122:711-720.
9. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: A new proposal with evaluation in a cohort of 6336 patients and results of a survey. Annals of Surgery 2004;240:205-213.

10. DeOliveira ML, Winter JM, Schafer M, et al. Assessment of complications after pancreatic surgery: A novel grading system applied to 633 patients undergoing pancreaticoduodenectomy. *Annals of Surgery* 2006;244:931-939.
11. Gonzalzo ML, Pavlovich CP, Trock BJ, et al. Classification and trends of perioperative morbidities following laparoscopic radical prostatectomy. *The Journal of Urology* 2005;174:135-139.
12. Kocak B, Koffron AJ, Baker TB, et al. Proposed classification of complications after live donor nephrectomy. *Urology* 2006;67:927-931.
13. Tamura S, Sugawara Y, Kaneko J, et al. Systematic grading of surgical complications in live liver donors according to Clavien's system. *Transplant International: Official Journal of the European Society for Organ Transplantation* 2006;19:982-987.
14. Maze H, Samet Y, Abu-Wasel B, et al. Application of a novel severity grading system for surgical complications after colorectal resection. *Journal of the American College of Surgeons* 2009;208: 355-361.
15. Trotti A, Colevas AD, Setser A, et al. CTCAE v3.0: Development of a comprehensive grading system for the adverse effects of cancer treatment. *Semin Radiat Oncol* 2003;13:176-181.
16. Clavien PA, Barkun J, DeOliveira ML et al. The Clavien-Dindo classification of surgical complications: Five-year experience. *Annals of Surgery* 2009;250:187-196.
17. Birkmeyer JD, Dimick JB, Birkmeyer NJO. Measuring the quality of surgical care: Structure, process, or outcomes? *Journal of the American College of Surgeons* 2004;198:626-632.
18. Khuri SF, Daley J, Henderson W. The Department of Veterans Affairs' NSQIP: The first national, validated, outcome-based, risk-adjusted, and peer-controlled program for the

measurement and enhancement of the quality of surgical care. *Ann Surg* 1998; 228:491-507.

19. Society of Thoracic Surgeons. 2007. (Accessed January 18, 2010, at www.sts.org/sections/stsnationaldatabase.)
20. Grobmyer SR, Pieracci FM, Allen PJ, et al. Defining morbidity after pancreaticoduodenectomy: Use of a prospective complication grading system. *Journal of the American College of Surgeons* 2007;204:356-364.
21. McKee M, Coles J, James P. 'Failure to rescue' as a measure of quality of hospital care: The limitations of secondary diagnosis coding in English hospital data. *Journal of Public Health Medicine* 1999;21:453-458.

INTERFACE

The definition of a surgical complication and the classification of its severity is very subjective and not transparent. Lists of specific complications, although useful, cannot be analyzed in a meaningful way, nor compared across multiple studies or sites. The subsequent manuscript is a next step to validate the application of the TM&M classification system through a national survey of the members of the Canadian Association of Thoracic Surgeons. Using kappa statistics, the degree to which different raters gave consistent grades of the same case scenario were assessed. Surgeons were asked to select the most severe grade of complication for each case (one choice per case) based on the proposed schema of definitions. Personal judgments relating to the TM&M classification system were assessed as well.

MANUSCRIPT 3

Evaluating the reliability and reproducibility of the Ottawa Thoracic Morbidity & Mortality classification system

Jelena Ivanovic, BSc;² Ahmed Al-Hussaini, MD;¹ Derar Al-Shehab, MD;¹ Jennifer Threader, BSc;¹ Patrick James Villeneuve, MDCM, PhD, FRCSC;¹ Tim Ramsay, PhD;² Donna E Maziak, MDCM, MSc, FRCSC;^{1,2} Sebastian Gilbert, MD, FRCSC;¹ Farid M Shamji, MBBS, FRCSC;¹ R Sudhir Sundaresan, MD, FRCSC;¹ Andrew JE Seely, MD, PhD, FRCSC;^{1,2}

Affiliation:

¹Department of Surgery, Division of Thoracic Surgery, University of Ottawa, the Ottawa Hospital – General Campus, 501 Smyth Road, K1H 8L6, Ottawa, Canada

²Clinical Epidemiology Program, Ottawa Hospital Research Institute, 725 Parkdale Avenue, K1Y 4E9, Ottawa, Canada

Key Words: Learning aids, Outcomes (includes mortality, morbidity), Patient safety, Practice guidelines, Statistics

Corresponding Author: Andrew JE Seely, MD, PhD, FRCSC

Competing Interests: None declared.

Manuscript Status: Published in the Annals of Thoracic Surgery, 2011;91:387-393.

ABSTRACT:

Background: Minimizing adverse events after surgery is widely recognized as an important indicator of quality; yet no consensus has been reached on how to standardize the reporting of adverse events following surgical procedures. Our objectives were to develop a standardized classification system to monitor both presence and severity of thoracic morbidity and mortality, and test its reliability and reproducibility amongst a national cohort of thoracic surgeons.

Methods: To assess the Thoracic Morbidity and Mortality (TM&M) classification system (based on the Clavien-Dindo classification of adverse events), a 31-item questionnaire was sent to all members of the Canadian Association of Thoracic Surgeons in August 2009, consisting of a general description of the TM&M severity grades, 20 case-based questions of postoperative adverse events to be classified, and questions regarding personal judgments. We derived descriptive and quantitative information using weighted Kappa statistics.

Results: 52 (54.7%) thoracic surgeons completed the questionnaire; 41 (78.8%) of the respondents were affiliated with an academic teaching hospital. A total of 1326 individual weighted Kappa statistics were calculated for all distinct pairs of raters, of which 1152 (87%) were greater than 0.81, a range which is interpreted as “almost perfect agreement.” A further 174 (13%) were in the range between 0.61 and 0.8, interpreted as “substantial agreement.” All results were statistically significant ($p < 0.05$). The classification system was regarded as straightforward (98% of the respondents), reproducible (94%), logical (92%), and useful (98%).

Conclusions: The modified classification system appears to offer objective, reliable and reproducible reporting of TM&M, and thus may assist continuous quality improvement in thoracic surgery.

INTRODUCTION:

Morbidity and mortality (M&M) rates are frequently used as indicators of quality in surgical care (1). Thus, accurate and objective reporting of postoperative M&M is essential in order to implement and follow improvements in quality of surgical care (2). Reporting of postoperative adverse events has traditionally been accomplished at M&M conferences, and through retrospective case series within the surgical literature. Unfortunately, these approaches are susceptible to selection bias and have resulted in underreporting (3). To date, no consensus has been reached among surgeons on how to quantify presence or severity of postoperative adverse events.

In 1992, Clavien and colleagues were the first to introduce the idea of severity grading of surgical adverse events as a way of assessing the degree of injury caused by that event (4). This classification system was modified in 2004 in order to increase its accuracy and acceptability in surgical practice and renamed as the Clavien-Dindo classification system (5). The principle underlying the Clavien-Dindo classification system assumes the severity of an adverse event is proportional to its impact on a patient and the degree of effort to correct it. Since its modification, the Clavien-Dindo classification system has been avidly used as a tool for quality assessment in surgery, and has broad applicability in clinical practice (6-10). To date, however, no attempts have been made to apply the approach of standardizing surgical adverse events following thoracic surgery.

Therefore, the goals of the current study were to first develop a classification of surgical adverse events based on our experience of thoracic morbidity and mortality (TM&M) and to assess the acceptability of the classification through peer review and questionnaire in a single academic thoracic surgery center (The Ottawa Hospital); and

second, to assess the reproducibility and reliability of the classification through a survey of all active members of the Canadian Association of Thoracic Surgeons (CATS). We hypothesise that a graded classification system for evaluating morbidity and mortality following thoracic surgery is an objective, reproducible and practical tool to monitor and analyze adverse events.

METHODS:

Single Center (Internal) Development of the TM&M Classification System

The TM&M classification system was developed in a single academic thoracic surgery center, the Ottawa Hospital, according to the Clavien-Dindo classification proposed in 2004, which grades adverse event on a severity scale between grades I to V based on the effort required to treat the event (Table 4.1).

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

Grades I and II include events that deviate from the normal postoperative course but require either no intervention or pharmacologic therapy, respectively. A Grade III event

requires medical intervention, without general anaesthesia (IIIa), and with general anaesthesia (IIIb). Grade IV events are life-threatening and require ICU management due to single organ dysfunction (IVa) or multi-organ dysfunction (IVb). Grade V events result in death of the patient. For each of the following systems: pulmonary, pleural, cardiac, renal, gastrointestinal, neurological and wound, adverse events were defined associated with a specific grade (Table 4.2). The Common Terminology Criteria for Adverse Events (CTCAE version 3.0) (11) was also used to refine a number of definitions. Specific definitions were further refined by peer review and questionnaire, and modified according to potential adverse events in patients following thoracic surgery. This was an iterative process that required consensus among the five practicing thoracic surgeons, and the two thoracic surgical residents, who form a large thoracic oncology program in Ontario.

Table 4.2. Clinical examples of postoperative adverse event based on severity grades

Grade	Organ System	Examples
I	Pulmonary	<i>Atelectasis</i> : requiring no intervention other than additional chest physiotherapy
	Pleural	<i>Effusion</i> : asymptomatic, no intervention indicated
	Anastomotic	<i>Anastomotic leak</i> : transient, no therapy added
	Cardiac	<i>Atrial fibrillation</i> : converting after correction of electrolytes
	Renal	<i>Urinary tract infection</i> : no intervention required other than removal of foley
	Gastrointestinal	<i>Constipation</i> : no intervention required
	Neurological	<i>Confusion</i> : transient, new or worsened; no intervention required
	Wound	<i>Hematoma</i> : no intervention required
II	Pulmonary	<i>Atelectasis</i> : requiring endo-tracheal suctioning
	Pleural	<i>Effusion</i> : requiring medical therapy (e.g. diuretics) for CHF and drainage
	Anastomotic	<i>Anastomotic leak</i> : medical therapy (e.g. antibiotics) added
	Cardiac	<i>Atrial fibrillation</i> : requiring medications (e.g. beta-blockers) for heart rate control
	Renal	<i>Urinary tract infection</i> : Requiring medical therapy only (e.g. antibiotics)
	Gastrointestinal	<i>Constipation</i> : nasogastric intubation, stool softeners, laxatives, dietary modification, or enema
	Neurological	<i>Confusion</i> : requiring medical intervention
	Wound	<i>Hematoma</i> : transfusion, evacuation or aspiration. Opening of wound at bedside

Table 4.2. Clinical examples of postoperative adverse event based on severity grades (continued)

Grade	Organ System	Examples
IIIa	Pulmonary	<i>Atelectasis</i> : endoscopic or radiological intervention, or non-invasive ventilation for < 24 hrs
	Pleural	<i>Effusion</i> : endoscopic, radiological or bedside pleural interventions performed
	Anastomotic	<i>Anastomotic leak</i> : intervention required (opening of wound)
	Cardiac	<i>Atrial fibrillation</i> : symptomatic, requiring a cardio-version or a device (e.g., pacemaker)
	Renal	<i>Urinary tract infection</i> : endoscopic, radiological or bedside interventions performed
	Gastrointestinal	<i>Constipation</i> : obstipation with manual evacuation indicated
	Neurological	<i>Confusion</i> : prolonged hospitalization indicated; danger to self or others
	Wound	<i>Hematoma</i> : interventional radiology indicated
IIIb	Pulmonary	<i>Atelectasis</i> : operative intervention required under general anaesthesia
	Pleural	<i>Effusion</i> : surgical intervention performed under general anaesthesia
	Anastomotic	<i>Anastomotic leak</i> : intervention required under general anaesthesia
	Cardiac	<i>Atrial fibrillation</i> : intervention required under general anaesthesia
	Renal	<i>Urinary tract infection</i> : surgical intervention performed
	Gastrointestinal	<i>Constipation</i> : surgical intervention performed under general anaesthesia
	Neurological	<i>Confusion</i> : N/A
	Wound	<i>Hematoma</i> : surgical intervention performed
IVa	Pulmonary	<i>Atelectasis</i> : respiratory compromise requiring intubation and positive pressure ventilation
	Pleural	<i>Effusion</i> : life-threatening; debilitating; organ failure present
	Anastomotic	<i>Anastomotic leak</i> : leads to single organ failure
	Cardiac	<i>Atrial fibrillation</i> : single organ failure (e.g. CHF, hypotension, syncope, shock)
	Renal	<i>Urinary tract infection</i> : life-threatening; debilitating; organ failure present
	Gastrointestinal	<i>Constipation</i> : life-threatening consequences (e.g., obstruction, toxic megacolon)
	Neurological	<i>Confusion</i> : N/A
	Wound	<i>Hematoma</i> : life-threatening consequences; major urgent intervention indicated

Table 4.2. Clinical examples of postoperative adverse event based on severity grades (continued)

Grade	Organ System	Examples
IVb	Pulmonary	<i>Atelectasis</i> : concomitant multiorgan complications
	Pleural	<i>Effusion</i> : concomitant multiorgan complications
	Anastomotic	<i>Anastomotic leak</i> : leads to multiple organ failure
	Cardiac	<i>Atrial fibrillation</i> : concomitant multiorgan complications
	Renal	<i>Urinary tract infection</i> : concomitant multiorgan complications
	Gastrointestinal	<i>Constipation</i> : concomitant multiorgan complications
	Neurological	<i>Confusion</i> : N/A
	Wound	<i>Hematoma</i> : concomitant multiorgan complications

Multicenter (External) Testing of Reproducibility and Reliability of the TM&M Classification System – Survey of the Members of the Canadian Association of Thoracic Surgeons

The Canadian Association of Thoracic Surgeons (CATS) was approached for a multi-center evaluation of the TM&M classification system. The membership of CATS includes full-time practitioners of general (non-cardiac) thoracic surgery, along with qualified general and cardiovascular surgeons whose practice includes more than 50% thoracic surgery (12).

To assess the reproducibility and reliability of the modified classification, an electronic questionnaire was designed with 31-items (refer to Appendix E). The CATS master file, provided by the executive committee, was used in developing a mailing list of the target surgeons. This list was based on data collected from individual members and included all thoracic surgeons with a valid e-mail address. An initial email was sent with a link to the survey at the start of August 2009, and 3 reminder emails were sent each week thereafter. Eligible candidates, who did not have valid email addresses, were sent a questionnaire package by postal service. The questionnaire was estimated to take less than 15

minutes to complete. The Ottawa Hospital Research Ethics Board approved this study (Refer to Appendix A). As a token of gratitude, each survey respondent received a \$10 gift certificate to any Tim Horton's coffee shop across Canada. The questionnaire consisted of three parts including: i) an information sheet with the TM&M classification system along with definitions of the severity grades; ii) 20 case-based questions asking respondents to classify postoperative adverse events in accordance to the proposed classification system (Table 4.3 shows several case examples placed in order from lowest to highest grade of severity); and iii) questions regarding personal judgments about the classification system. In the second part of the questionnaire, the 20 case-based scenarios were placed randomly with regards to their complication grade. The 20 case scenarios were chosen to have an even representation of minor (Grades I – II) and major case examples (Grades IIIa – V). Respondents were asked to choose the most severe grade of complication for each case (one choice per case). A pilot study was performed using the survey with five thoracic surgeons and two thoracic surgical residents at the Ottawa Hospital prior to mailing. At the time the survey was conducted, CATS had a total of 95 members.

Table 4.3. Examples of clinical cases and their respective severity grades	
Grade	Clinical Case
I	A RUL lobectomy was performed on a 54-year-old patient for lung cancer, the patient developed a prolonged air leak but required no further intervention beside observation.
II	A 47-year-old patient suffered from atrial fibrillation on the second day following pneumonectomy for malignant mesothelioma. IV Metoprolol and Digoxin were given, the patient reverted to sinus rhythm.
IIIa	A 22-year-old patient underwent VATS bullectomy and pleurectomy for recurrent spontaneous pneumothorax. The patient suffered from prolonged air leak and persistent pneumothorax, which was treated by insertion of another chest tube.
IIIb	An 84-year-old patient underwent total thyroidectomy for a retrosternal goiter. The patient developed stridor and hypoxia. An immediate operation was done to evacuate the hematoma and control the bleeding.
IVa	A 69-year-old patient suffered from ARDS following right lower lobectomy for NSCLC. The patient was transferred to ICU and required intubation for 2 weeks, eventually the patient recovered and was extubated.
IVb	An esophagectomy and gastric pull up was performed on a 50-year-old patient. On day 8, the patient showed signs and symptoms of sepsis and anastomotic leak. The patient was taken to the OR for drainage and lavage. Thereafter, the patient was transferred to ICU, where he developed ARDS and acute renal failure which required dialysis. Eventually the patient recovered.
V	A 62-year-old patient underwent a redo fundoplication for recurrent hiatal hernia. The patient developed a massive pulmonary embolism, which was treated with TPA. The patient was transferred to ICU where he died following a cardiac arrest.

Statistical Analysis

All survey data collected was carefully entered using quality control and verification measures into a secure database. Replies were kept anonymous. Weighted kappa statistics were calculated to assess the inter-rater reliability among the survey respondents. For each inter-rater comparison, calculations were performed to establish the proportion of observed agreement (Po), the proportion of expected agreement (Pe), and the kappa value. A

distribution of kappa scores was calculated for the five grades. This score yielded a weighted calculation of all of the paired kappa scores for each case scenario and was used to indicate general agreement among the surgeons. The same calculation was applied for the minor and major case scenarios. The level of agreement among the raters was evaluated using the system put forth by Landis and Koch, 1977 (13), in which a kappa value of 0.21 to 0.4 reflects fair agreement, a value of 0.41 to 0.60 reflects moderate agreement, a value of 0.61 to 0.80 reflects substantial agreement, and a value of 0.81 or more reflects almost perfect agreement. Data were analyzed using R statistical software.

RESULTS:

Response Rate

From the 95 members, 52 surveys were completed (54.7%) within the designated timeframe permitted for response, which was 4 weeks. The majority of respondents were affiliated with a university teaching hospital (78.8%, $n = 41$) and practised in Ontario (32.7%, $n = 17$) or Quebec (15.4%, $n = 8$). Ontario and Quebec are the most densely populated provinces in Canada with populations of approximately 12.2 million and 7.6 million, respectively. In terms of geographical distribution, the characteristics of the sample were representative of the whole. Of the 52 completed surveys, 8 (15.4%) were completed by members practicing outside of Canada. Most surgeons had been in practice for less than 10 years (51.0%, $n = 26$). Fifty-one respondents (98.1%) indicated that they were a full-time staff member at their institution, one resident completed the survey.

Inter-rater Agreement

The weighted Kappa statistic assesses agreement between two raters on an ordered scale. With 52 raters, a total of 1326 individual weighted Kappa statistics were calculated for all distinct pairs of raters (Table 4.4). Of those 1326 weighted Kappa statistics, 1152 (87.0%) were greater than 0.81, a range which is interpreted as “almost perfect agreement.” Furthermore, 173 (13.0%) were in the range between 0.61 and 0.8, interpreted as “substantial agreement.” Thus, all of the statistics indicated at least substantial agreement. All results were statistically significant ($p < 0.05$) indicating that we should reject the null hypothesis that the ratings are independent (i.e. $\kappa = 0$) and accept the alternative that agreement is better than one would expect by chance.

Table 4.4. Inter-rater agreement

Range/Agreement	Overall Agreement		Minor Complications		Major Complications	
	n	%	n	%	n	%
0.81 to 1.0/Almost perfect	1152	87.0	428	32.2	992	74.8
0.61 to 0.8/Substantial	174	13.0	455	34.3	265	20.0
0.41 to 0.6/Moderate	0	0	265	20.1	47	3.5
0.21 to 0.4/Fair	0	0	178	13.4	22	1.7
Total	1326	100	1326	100	1326	100

All results were statistically significant ($p < 0.05$).

The level of inter-rater agreement was also calculated among minor and major clinical case examples. A factor that has to be considered in the interpretation of kappa coefficients is the number of categories (14). For the minor clinical case examples (grades I and II), a total of 428 (32.2%) individual weighted Kappa statistics were greater than 0.81. A further 455 (34.3%) individual weighted Kappa statistics were in the range between 0.61 and 0.8; and 265 (20.0%) in the range between 0.41 and 0.6 which is a range interpreted as

“moderate agreement.” The remaining 178 (13.4%) individual weighted Kappa statistics were in the range between 0.21 and 0.4 which is a range interpreted as “fair agreement.”

A more pronounced increase of kappa coefficients was observed with increasing numbers of categories. Thus, for the clinical case examples with major complications (grades IIIa, IIIb, IVa, IVb and V), a total of 992 (74.8%) individual weighted Kappa statistics were greater than 0.81. A further 265 (20.0%) individual weighted Kappa statistics were in the range between 0.61 and 0.8; and 47 (3.5%) in the range between 0.41 and 0.6. The remaining 22 (1.7%) individual weighted Kappa statistics were in the range between 0.21 and 0.4.

Personal Judgments

Respondents were asked to agree or disagree with several statements regarding their personal judgments of the TM&M classification system. Of the 52 respondents, 49 (98.0%) considered the TM&M classification system as straightforward to understand. A total of 48 respondents (94.1%) considered the TM&M classification system as reproducible; that is, different surgeons would tend to agree on the classification of individual patient events. A total 47 respondents (92.2%) considered the TM&M classification system as logical; that is, it accurately reflects level of severity of adverse events. Lastly, 50 respondents (98.0%) consider the TM&M classification system useful in their patients; that is, it will be helpful to evaluate both presence and severity of surgical adverse events.

COMMENT:

In the surgical community, M&M rates have been established as critical outcome measures and indicators of quality (2). However, conflicting approaches of reporting postoperative adverse events make the use of these rates unreliable for quality assessment. In addition, the absence of standardized definitions and a generally accepted classification

scheme to grade surgical adverse events has further hindered appropriate evaluation of surgical outcome data (15). Specifically, expressions such as minor, moderate, major, or severe have been inconsistently applied by surgeons and medical institutions to classify surgical adverse events (16). An objective system for monitoring and accurately reporting postoperative adverse events is fundamental in order to advance performance in thoracic surgery and collect reliable data for benchmarking.

To test the reproducibility of the TM&M classification system, clinical case examples were created by the thoracic oncology team at the Ottawa Hospital and sent to all members of the Canadian Association of Thoracic Surgeons. The consistency of a surgeons' rating is an important consideration in outcome assessment. These ratings often fall on an ordinal scale, making the kappa coefficient an appropriate measure of reliability for such data (14). A high level of agreement was calculated among the 52 survey respondents for the 20 case scenarios, indicating that the TM&M classification system is consistent among surgeons' opinion and can be applied to multifaceted case examples. One explanation for the lower proportion rate of Kappa scores among the minor case scenarios (i.e. grades I and II) can be attributed to the number of categories. The proportion of kappa statistics that were greater than 0.81 was lower when two categories were presented, as agreement by chance was more likely among the raters. A more pronounced increase of kappa coefficients was observed among the major case scenarios (i.e. grades IIIa, IIIb, IVa, IVb, and V) due to increasing numbers of categories. As the number of categories increased, the likelihood of agreement by chance was reduced among the raters. The increase of kappa coefficients with the number of categories is a preferred outcome, since as the number of categories increases, so does the proportion of the variability in the true variable captured by the imperfect ordinal variable (17). Through the application of severity grades, the TM&M classification system has

provided standardized measures for discriminating what may represent a minor as opposed to major adverse event following thoracic surgery.

The presented results demonstrate that the TM&M classification system can be utilized in its current state for use in clinical research and for quality improvement. Since initiating the TM&M classification system in January 2008 at the Ottawa Hospital, daily data collection of M&M has been carried out by a senior thoracic surgical resident and the thoracic surgery research coordinator using the TM&M form (refer to Appendix B). Weekly lists of operative procedures along with related adverse events are compiled and further validated by all attending staff present. Complications are then presented and discussed at monthly M&M conferences – allowing for regular and active reporting of adverse events. A secure database for adverse event reporting was developed and has since been used to compare surgical procedures and subgroups of patients, allowing us to evaluate the feasibility of the system over the first two years of its implementation at the Ottawa Hospital (18). The TM&M classification system advocates for a practice of continuous quality improvement, advances the development of quality improvement programs, can be used to improve the quality of retrospective studies (as it does not rely on the original surgeon to grade the adverse event as such), and facilitates an open forum for ongoing medical education on surgical quality assurance. Moreover, our 2-year experience indicates that the TM&M classification system is feasible, facilitates objective comparison, accurately identifies burden of illness of individual adverse events, and provides an effective method for continuous surgical quality assessment (18).

There are many other potential applications of this system. For example, video-assisted thoracic surgery (VATS) is a relatively new technology that has become the standard of care for minimally invasive thoracic procedures. However, controversy surrounds the

safety, reproducibility, and oncologic efficacy of VATS lobectomy (19). Awareness of this controversy inspired us to initiate a comparison between VATS and open lobectomy procedures at our institution. The TM&M classification system was utilized for reporting the difference in presence, severity and types of postoperative morbidity in patients undergoing VATS versus open lobectomy (20) (refer to Appendix D).

We further plan to utilize this continuous TM&M classification and reporting system as a backbone for prospective monitoring of essential surgical information, upon which to add additional clinical data collection tools. The TM&M classification system provides a strong base with which we can build a system to continuously monitor and improve the overall quality of thoracic surgical care. Expanding the TM&M classification system to include clinical data on all time points on the continuum of care, starting with patient referral to at least a two year follow-up post surgery, would help improve continuous assurance of care. A reduction in adverse events and death can be achieved by the exchange of information and analysis of morbidity and mortality between hospitals (21). Additionally, standardized collection and electronic storage of patient information can provide a dataset to enable prospective clinical research (22).

Other future refinements to the TM&M classification system are planned, including a measure of the etiology of surgical adverse events and determination of whether the event was preventable. Additionally, patients with prolonged hospital stay and those who are readmitted to the hospital form a small proportion of thoracic patients at our institution, and may highlight quality of care problems. To monitor and further our understanding of those patients who are readmitted to the hospital, the TM&M classification system can be made capable of linking hospital re-admissions and eventually, hospital re-admissions with out-of-hospital services as well (23).

We recognize important limitations of the use of a survey instrument for evaluating the reproducibility of the proposed system. Our overall response rate was 54.7%. As such, it is possible that our group of respondents was not representative of thoracic surgeons as a whole. While the use of a reliable and continuous system of evaluation of presence and severity of adverse events after thoracic surgery is necessary, it is not sufficient for a comprehensive evaluation of surgical quality. Monitoring of wait times, efficient resource utilization, patient experience and satisfaction are all dimensions of surgical care quality improvement.

We conclude that the TM&M classification system appears reliable, reproducible and may represent a feasible tool for quality evaluation in surgery. The objective evaluation of both the presence and severity of TM&M and the prospective monitoring of thoracic surgical volume represents an important means of standardizing evaluation of outcomes, enabling comparison between centers and surgeons, and represents a crucial component to ensuring best practice of care. We hope that utilization of this system in future studies can enable improvements in thoracic surgical quality.

Web-Archive:

The Ottawa TM&M system is freely available online and can be found at the following website: <https://sites.google.com/site/ottawatmtool/home>. This web-archive includes the definitions of all the complications according to grade and to the affected system. A copy of the survey can be found as well.

ACKNOWLEDGEMENTS:

The authors would like to gratefully acknowledge the entire membership of the Canadian Association of Thoracic Surgeons for their participation in the questionnaire, in addition to their feedback and encouragement of this project.

REFERENCES:

1. Dimick JB, Weeks WB, Karia RJ, et al. Who pays for poor surgical quality? Building a business case for quality improvement. *J Am Coll Surg* 2006;202:933-937.
2. Veen EJ, Steenbruggen J, Roukema JA. Classifying surgical complications: A critical appraisal. *Archives of Surgery* 2005;140:1078-1083.
3. Grobmyer SR, Pieracci FM, Allen PJ, et al. Defining morbidity after pancreaticoduodenectomy: Use of a prospective complication grading system. *Journal of the American College of Surgeons* 2007;204: 356-364.
4. Clavien PA, Sanabria JR, Strasberg SM. Proposed classification of complications of surgery with examples of utility in cholecystectomy. *Surgery* 1992;111: 518-526.
5. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: A new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Annals of Surgery* 2004;240:205-213.
6. DeOliveira ML, Winter JM, Schafer M, et al. Assessment of complications after pancreatic surgery: A novel grading system applied to 633 patients undergoing pancreaticoduodenectomy. *Annals of Surgery* 2006;244:931-939.
7. Gonzalzo ML, Pavlovich CP, Trock BJ, et al. Classification and trends of perioperative morbidities following laparoscopic radical prostatectomy. *The Journal of Urology* 2005;174:135-139.
8. Kocak B, Koffron AJ, Baker TB, et al. Proposed classification of complications after live donor nephrectomy. *Urology* 2006;67:927-931.
9. Tamura S, Sugawara Y, Kaneko J, et al. Systematic grading of surgical complications in live liver donors according to Clavien's system. *Transplant International: Official Journal of the European Society for Organ Transplantation* 2006;19:982-987.

10. Mazeh H, Samet Y, Abu-Wasel B, et al. Application of a novel severity grading system for surgical complications after colorectal resection. *Journal of the American College of Surgeons* 2009;208: 355-361.
11. Trotti A, Colevas AD, Setser A, et al. CTCAE v3.0: Development of a comprehensive grading system for the adverse effects of cancer treatment. *Semin Radiat Oncol* 2003;13:176-181.
12. Darling GE, Maziak DE, Clifton JC, et al. The practice of thoracic surgery in Canada. *Canadian Journal of Surgery* 2004;47:438-445.
13. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977; 33: 159-174.
14. Brenner H, Kliebsch U. (1996). Dependence of weighted kappa coefficients on the number of categories. *Epidemiology* 1996;7:199-202.
15. Martin RC 2nd, Brennan MF, Jaques DP. Quality of complication reporting in the surgical literature. *Annals of Surgery* 2002;235:803-813.
16. Clavien PA, Barkun J, DeOliveira ML et al. The Clavien-Dindo classification of surgical complications: Five-year experience. *Annals of Surgery* 2009;250:187-196.
17. Sim J, and Wright CC. The Kappa statistic in reliability studies: Use, interpretation, and sample size requirements. *Physical Therapy* 2005; 85:257-268.
18. Seely AJE, Ivanovic J, Threader J, et al. Systematic classification of morbidity and mortality after thoracic surgery. *The Annals of Thoracic Surgery*. 2010;90:936-942.
19. Gharagozloo F, Tempesta B, Margolis M, et al. Video-assisted thoracic surgery lobectomy for stage I lung cancer. *The Annals of Thoracic Surgery* 2003;76:1009-1015.
20. Villeneuve PJ, Alhussaini A, Al-Shehab D, Threader J, Ivanovic J, Gilbert S, Maziak DE, Shamji F, Sundaresan S, and Seely AJE. Video assisted thoracoscopic lobectomy:

Short-term outcomes and safety. 13th Annual Meeting of the Canadian Association of Thoracic Surgeons, Quebec City, September 2010.

21. Campbell DA Jr., Dellinger EP. Multihospital collaborations for surgical quality improvement. *JAMA* 2009;302:1584-1585.
22. Mittnacht AJ, Wax DB, Srivastava S, et al. Development and implementation of a pediatric cardiac Anesthesia/Intensive care database. *Seminars in Cardiothoracic and Vascular Anesthesia* 2008;12:12-17.
23. Corrigan JM, Kazandjian VA. Characteristics of multiple admissions. *American Medical Record Association* 1991; 62: 37-47.

INTERFACE

The subsequent manuscript assesses the degree of involvement and participation in thoracic surgical research as well as surgical quality improvement conducted across Canadian institutions through a membership survey of the Canadian Association of Thoracic Surgeons. Questions focused on clinical research programs and research activity, research funding, database use and interest, and other methods of quality monitoring.

The ideas presented in the following study provide a complementary component to the TM&M classification system and to continuous quality improvement in thoracic surgery. Moreover, the future of surgical quality assessment is envisioned through the development of a national, multihospital thoracic surgery database. Multihospital databases have the potential to improve practice effectiveness, standardize surgical outcomes, enable inter-institutional comparison, and promote research in the thoracic surgical speciality. The following manuscript builds upon these principles, providing useful statistics and feedback regarding measures of quality and efficiency of thoracic surgical care across Canadian institutions.

MANUSCRIPT 4

Assessing the status of thoracic surgical research and quality improvement programs:

A survey of the members of the Canadian Association of Thoracic Surgeons

Jelena Ivanovic, BSc;² Donna E Maziak, MDCM, MSc, FRCSC;^{1,2} Sebastien Gilbert, MD, FRCSC;¹ Farid M Shamji, MBBS, FRCSC;¹ R Sudhir Sundaresan, MD, FRCSC;¹ Tim Ramsay, PhD;² Andrew JE Seely, MD, PhD, FRCSC.^{1,2}

Affiliation:

¹Department of Surgery, Division of Thoracic Surgery, University of Ottawa, the Ottawa Hospital – General Campus, 501 Smyth Road, K1H 8L6, Ottawa, Canada

²Clinical Epidemiology Program, Ottawa Hospital Research Institute, 725 Parkdale Avenue, K1Y 4E9, Ottawa, Canada

Key Words: Thoracic surgery, quality assurance, needs assessment, statistics/numerical data

Corresponding Author: Andrew JE Seely, MD, PhD, FRCSC

Competing Interests: None declared.

Manuscript Status: Accepted for publication in the Journal of Surgical Education [In press] July/August 2011;68(4).

ABSTRACT:

Objectives: Assessing the degree of involvement and participation in thoracic surgical research as well as surgical quality improvement conducted across Canadian institutions is difficult as there exists no common data collection system and no prior studies. As a pilot investigation, we designed and conducted a membership survey of the Canadian Association of Thoracic Surgeons (CATS) to evaluate the extent of participation in research and quality improvement processes among thoracic surgeons.

Design, Setting, and Participants: A 45-item needs assessment survey was sent to all national members of CATS (n = 86) in August 2009. Questions primarily focused on clinical research programs and research activity, research funding, database use and interest, and other methods of quality monitoring.

Results: The 49 completed surveys represented a 57.0% response rate from surgeons at 28 institutions across Canada. Research in basic and clinical science is conducted by 17.0% and 80.9% of the respondents, respectively. The annual budget of research funds is most commonly between \$5,000 to \$50,000. 72.0% (n = 18) of institutions do not have a formal surgery quality assessment program and 92.3% (n = 24) do not participate in a national or international thoracic surgery database. Ten institutions (38.6%) have local thoracic surgery database for quality monitoring. Other systems of monitoring surgical quality include formal morbidity and mortality rounds (69.2%; n = 18 institutions), formal evaluation of surgical wait times (73.1%; n = 19 institutions), and patient satisfaction surveys (71.4%; n = 10 institutions). 97.8% of surgeons would be willing to share data on morbidity and mortality with other centers, and 73.1% have a high or very high level of interest in participating in a national thoracic surgery quality database.

Conclusions: A high level of interest and participation exists in thoracic surgery research. However, more robust quality improvement processes are needed for thoracic surgical oncology services. A national thoracic surgery quality improvement database offers a potential means to improve practice effectiveness, standardize surgical outcomes, and promote thoracic research across Canada.

INTRODUCTION:

Surgical practice is characterized by a strong culture of quality assurance and improvement. In surgery, quality assurance is defined as: the process whereby the profession ensures that standards of medical care are upheld and raised when necessary.¹ Quality assurance has been at the forefront for surgeons in all specialties and to this day it remains a primary objective of their professional careers.¹ Surgeons have advanced a highly refined system of sustaining and improving the quality of their practice - this is achieved through formal morbidity and mortality (M&M) conferences, where open collegial discussion not only helps to facilitate the improvement of surgical outcomes but also enhances surgical education of trainees. Furthermore, surgeons are required to attend conferences and self-study projects in order to maintain competency. This is to meet the standards defined by the Royal College of Physicians and Surgeons of Canada.¹

It is increasingly important to monitor and compare the quality of health care delivery among different institutions. In the United States, a number of state and federal programs have been implemented to explicitly monitor and improve thoracic surgical outcomes. The National Surgical Quality Improvement Program (NSQIP)² of the Department of Veterans Affairs and the Society of Thoracic Surgeons (STS)³ database are two examples of initiatives that provide hospitals and thoracic surgeons with information on risk-adjusted M&M rates from cardiothoracic surgical practices nationwide. This aggregate information provides a national standard to benchmark individual results and promote quality improvement.³ NSQUIP and STS databases provide the next level of quality improvement programs – enabling standardization and inter-institutional comparison. M&M conferences help an individual surgeon and a division, whereas the larger initiatives represent a broader, collective means to enhance quality.

Thoracic surgery is one of the smallest subspecialty groups in all Canadian surgery (Schieman, 2010)⁴ and is largely performed in high volume academic centers, where specialized care is required to manage complex diseases. Accordingly, the lack of a common data collection system in Canada is the very reason for the little information available to determine the full scope of thoracic surgical research, the resources and funding required for it, and programs designed for thoracic surgical quality improvement. There is a need for quality initiatives relating to thoracic oncology services, both benign and malignant, in order to improve surgical outcomes and improve efficiency of care.⁵ Increased volumes of thoracic surgery are expected in Canada in the near future due to a growing and aging population, and the rapidly rising cost of medical care, further accentuate this imperative.

In a pilot investigation, to better understand the current state of Canadian thoracic surgical research and initiatives aimed at quality improvement, a needs assessment survey was designed and sent to all national members of the Canadian Association of Thoracic Surgeons (CATS) in August 2009.

METHODS:

Survey Instrument

A 10-page, web-based needs assessment survey, was developed by the division of thoracic surgery at the Ottawa Hospital. <http://surveymonkey.com> (Portland, Oregon) was used to create the web-based questionnaire. Questions primarily focused on clinical research programs and quality monitoring in thoracic surgery. Several questions were also asked relating to thoracic surgical manpower and thoracic surgical volumes. All survey items were self-reported. Survey items contained: 1) open-ended responses; 2) Likert-type formats (5-point scales); and 3) dichotomous yes/no responses. The survey instrument could be completed without reference to any other source material, but respondents were able to refer

to their own institutional databases as necessary to ensure accuracy of case numbers required for some questions. The Ottawa Hospital Research Ethics Board approved this study (Appendix A).

Study Population and Survey Administration

The membership of CATS includes full-time practitioners of general (non-cardiac) thoracic surgery, along with qualified general and cardiovascular surgeons whose practice includes more than 50% thoracic surgery.⁶ This study involved a survey of all active members of CATS practicing in Canada; thus, a total of 86 surveys were mailed in August 2009. Nine international members were excluded from the study in order to have the appropriate and applicable group survey answers for specific questions. The CATS master file, provided by the executive committee, was used in developing a mailing list of the target surgeons.

An initial email was sent with a link to the survey at the start of August 2009, and three reminder emails were sent each week thereafter. Eligible CATS members, who did not have valid email addresses, were sent a survey package by postal service. As a token of gratitude, each survey respondent received a \$10 gift certificate to any Tim Horton's coffee shop across Canada.

Statistical Analysis

All survey data collected were carefully entered using quality control and verification measures into a secure database. Partially completed surveys were included in the statistical analysis and proportional data were analyzed with regards to the number of respondents who answered a particular question. The primary data analysis consisted of descriptive statistics, including the calculation of frequencies, means, and standard deviations using SAS 9.2 software (SAS Inc., Cary, NC). Only data that had actually been entered onto the survey

instrument by respondents who were actively engaged in the practice of thoracic surgery were extracted and analyzed. No information from other sources was considered.

RESULTS:

Response Rate and Demographics

From the 86 national members, 49 surveys were returned completed (57.0%) within the time frame permitted for response, which was 4 weeks. The 49 surveys cited 28 participating centers. Individual questions varied in the number of responses. Of the 86 national CATS members, 27 (31.4%) are also members of the STS.

Thoracic Surgical Manpower Available for Research

In all surgical specialties, including thoracic surgery, an adequate number of practicing surgeons is necessary to meet the needs of the patient population, and an objective evaluation of manpower plays an essential role in strategic planning and surgical quality assessment.⁶ Survey results indicate that 3 (± 1 ; range 1 – 6) is the average number of full-time thoracic surgeons at each institution that provide perioperative care (Table 5.1). Eight institutions (28.6%) have a residency training program, five institutions (20.0%) have a formal residency research program – implying that residents are required to complete at least one project before completion of residency, and 10 institutions (47.6%) require their residents to perform research at some point during their residency (Table 5.1).

Table 5.1. Survey questions relating to thoracic surgical manpower

Survey Item	Mean or Frequency	
	Total Respondents (%)	Total Institutions (%)
<i>Thoracic Surgical Manpower</i>		
1. What is the number of full-time thoracic surgery staff members at your institution?	N/A*	3±1
2. Do you have a residency training program? Yes	N/A	28 8 (28.6)
3. If you have a residency training program, how many thoracic surgery residents are at your institution?		8
1 resident per year	N/A	1 (12.5)
1 resident every two years		6 (75.0)
2 residents per year		1 (12.5)
Other		0 (0)
4. Do you have a formal residency research program? Yes	N/A	25 5 (20.0)
5. Are your residents required to perform research at some point during their residency? Yes	N/A	21 10 (47.6)

*Not applicable

Clinical Research Programs and Research Activity

Twenty-one institutions (75.0%) are directly involved in research. The average number of active research studies per institution is between one to five studies (n = 17; 63.0%) (Table 5.2). More specifically, eight respondents (17.0%) personally participate in basic science research, 23 respondents (47.9%) participate in tumour banking, and 38 respondents (80.9%) personally participate in clinical research, of which: 35 respondents (92.1%) participate in retrospective chart reviews, 25 respondents (65.8%) participate in prospective observational studies, and 25 respondents (65.8%) participate in randomized control trials (Table 5.2). Areas of expertise or strong interest in clinical research include minimally invasive surgery, critical care medicine, quality of care, and clinical

Table 5.2. Survey questions relating to clinical research programs

Survey Item	Mean or Frequency	
	Total Respondents (%)	Total Institutions (%)
<i>Clinical Research Programs</i>		
1. Are you directly involved in research?	49	28
Yes	37 (75.5)	21 (75.0)
2. If you answered yes to the above question, please check all that apply:	37	
Principal investigator	22 (59.5)	
Co-investigator	19 (51.4)	N/A*
Collaborator	26 (70.3)	
Participant	18 (48.6)	
Other	2 (5.4)	
3. Do you have a thoracic surgery research director?	48	
Yes	18 (37.5)	N/A
4. Are you currently a thoracic surgery research director?	48	
Yes	4 (8.3)	N/A
5. Do you have a clinical research coordinator?	49	
Yes	23 (46.9)	N/A
6. If yes, what is their contract?	24	
0.2 FTE (1 day per week)	3 (12.5)	
0.4 FTE (2 day per week)	2 (8.3)	
0.6 FTE (3 day per week)	4 (16.7)	N/A
0.8 FTE (4 day per week)	2 (8.3)	
1.0 FTE (5 day per week)	13 (54.2)	
7. Do you personally participate in basic science research?	47	
Yes	8 (17.0)	N/A
8. If you answered yes to the above question, please check all that apply :	8	
Molecular biology, genomics	2 (25.0)	
Intracellular pathways, signalling, proteomics	3 (37.5)	
Cell cultures	3 (37.5)	N/A
Animal models	4 (50.0)	
Human tissue	6 (75.0)	
Other	2 (25.0)	
9. Do you participate in tumour banking?	48	
Yes	23 (47.9)	N/A
10. Do you personally participate in clinical research?	47	
Yes	38 (80.9)	N/A
11. If you answered yes to the above questions, please check all that apply .	38	
Retrospective chart reviews	35 (92.1)	
Prospective observational studies	25 (65.8)	N/A
Randomized control trials	25 (65.8)	
Other	0 (0)	
12. What is the average number of active research studies that are ongoing at your centre in a given year?		27
0 studies		4 (14.8)
1 – 5 studies	N/A*	17 (63.0)
6 – to studies		2 (7.4)
11 – 20 studies		2 (7.4)
> 20		2 (7.4)
13. What percentage of research studies have the principal investigator that is an attending thoracic surgeon at your institution?		24
< 25%	N/A	19 (79.2)
25 – 50%		2 (8.3)
50 – 75%		1 (4.2)
> 75%		2 (8.3)

*Not applicable

epidemiological research. Areas of expertise or strong interest in basic science research include clinical trials in lung cancer, lung cancer genomics, and regenerative medicine.

Funding Opportunities

Survey results indicate that 17 institutions (63.0%) have research accounts with funds that are available to support existing or potential research projects (Table 5.3). Sources of research funds are equally received from grants, department, and industry. The annual budget of research funds is between \$5,000 to \$50,000 at most institutions (70.6%; n = 12) (Table 5.3).

Table 5.3. Survey questions relating to funding opportunities

Survey Item	Survey Item	
<i>Funding Opportunities</i>	Total Respondents (%)	Total Institutions (%)
1. Are there research accounts with funds available to support existing or potential research projects at your institution?	N/A*	27
Yes		17 (63.0)
2. What is the source of these research funds (<i>check all that apply</i>)?		21
Grants	N/A	10 (47.6)
Department		10 (47.6)
Industry		10 (47.6)
Other		7 (33.3)
3. What is the annual budget of your research accounts?		17
Up to \$5,000		2 (11.8)
\$5,000 – \$50,000	N/A	12 (70.6)
\$50,000 – \$100,000		3 (17.6)
\$100,000 to \$500,000		0 (0)
> \$500,000		0 (0)

*Not applicable

Database Use and Interest

The CATS membership survey revealed that of the 21 (75.0%) institutions that are directly involved in research, 10 (38.5%) have a local thoracic surgery database (Table 5.4). Surgeons from 20 institutions (76.9%) expressed a high or very high interest in initiating or

improving their local thoracic surgical database. The majority of institutions do not participate in a national or international thoracic surgery database (92.3%; n = 24). However, 19 institutions (73.1%) have a high or very high level of interest in participating in a national thoracic surgery database. Similarly, 17 institutions (65.4%) have a high or very high level of interest in initiating or improving on a national thoracic surgery database (Table 5.4).

Quality Monitoring

Survey results revealed that the majority of institutions (73.1%; n = 19) do not have a formal surgery quality assessment program, but do however monitor M&M regularly (69.2%; n = 18), and would be willing to share data on M&M with other centers (100.0%; n = 26) (Table 5.4). Evaluation of thoracic M&M takes place through monthly conferences at some institutions (42.3%; n = 11). Retrospective evaluation of morbidity on selected patient populations is performed at 17 institutions (65.4%) (Table 5.4).

To better comprehend the burden of illness on the delivery of thoracic surgical oncology services, surgeons were asked about wait time monitoring. Survey results revealed that 19 institutions (73.1%) have a formal evaluation of surgical wait times. Specifically, regular feedback regarding wait times is received at 18 institutions (72.0%) (Table 5.4). Monthly and quarterly conferences indicate the frequency of regular feedback regarding surgical wait times at most institutions (88.9%; n = 16) (Table 5.4).

Table 5.4. Survey questions relating to database use and interest and quality monitoring

Quality Monitoring	Survey Item	Mean or Frequency	
		Total Respondents (%)	Total Institutions (%)
1.	Do you have your own local thoracic surgery database?	47	26
	Yes	22 (46.8)	10 (38.5)
2.	Rate your level of interest in initiating or improving your local thoracic surgical database.	47	26
	Very low	1 (2.1)	1 (3.8)
	Low	0 (0)	0 (0)
	Neutral	8 (17.0)	5 (19.2)
	High	23 (48.9)	12 (46.2)
	Very high	15 (31.9)	8 (30.8)
3.	Do you participate in a national or international thoracic surgery database?	47	26
	Yes	2 (4.3)	2 (7.7)
4.	Rate your level of interest in initiating or improving on a national thoracic surgery database.	46	26
	Very low	0 (0)	0 (0)
	Low	5 (10.9)	2 (7.7)
	Neutral	10 (21.7)	7 (26.9)
	High	16 (34.8)	8 (30.8)
	Very high	15 (32.6)	9 (34.6)
5.	Rate your level of interest in participating in a national thoracic surgery database.	47	26
	Very low	0 (0)	0 (0)
	Low	1 (2.1)	1 (3.8)
	Neutral	10 (21.3)	6 (23.1)
	High	21 (44.7)	10 (38.5)
	Very high	15 (31.9)	9 (34.6)
6.	Do you have a formal surgery quality assessment program?	46	25
	Yes	18 (39.1)	7 (28.0)
7.	Do you monitor morbidity and mortality (M&M) regularly?	47	26
	Yes	36 (76.6)	18 (69.2)
8.	Please rate the frequency of the evaluation of thoracic surgery morbidity and mortality (M&M) at your institution.	47	26
	Weekly	4 (8.5)	2 (7.7)
	Monthly	24 (51.1)	11 (42.3)
	Quarterly	9 (19.1)	5 (19.2)
	Infrequently	9 (19.1)	7 (26.9)
	Never	1 (2.1)	1 (3.8)
9.	Would you be willing to share data on M&M with other centers?	46	26
	Yes	45 (97.8)	26 (100)
10.	Do you perform retrospective evaluation of morbidity on selected patient populations?	47	26
	Yes	34 (72.3)	17 (65.4)
11.	Is there a formal evaluation of surgical wait times at your institution?	47	26
	Yes	36 (76.6)	19 (73.1)
12.	Do you receive regular feedback regarding wait times?	47	25
	Yes	35 (74.5)	18 (72.0)
13.	If yes, how often?	35	18
	Monthly	14 (40.0)	8 (44.4)
	Quarterly	17 (48.6)	8 (44.4)
	Biannually	1 (2.9)	1 (5.6)
	Annually	1 (2.9)	0 (0)
	Other	2 (5.7)	1 (5.6)
14.	Are there other systems of monitoring surgical quality? (<i>Check all that apply</i>)	23	14
	NSQIP	8 (34.8)	7 (50.0)
	Patient satisfaction surveys	17 (73.9)	10 (71.4)
	Other	6 (26.1)	3 (21.4)

Provision of Thoracic Surgical Oncology Services

Surgical quality is closely tied to the volume of thoracic surgical procedures performed at an institution. Study results indicate that 183 (± 127.4 ; range 40 – 600) is the average number of anatomic pulmonary resections performed at each institution per year, and 25 (± 16.1 ; range 0 – 50) is the average number of esophagectomies performed at each institution per year, across Canada (Table 5.5).

Minimally invasive thoracic surgery is available and used at 25 institutions (96.2%). Survey results reveal that up to 50% of lobectomies are performed via video-assisted thoracoscopic surgery (73.1%; n = 19 institutions). Similarly, 25-50% of paraesophageal hernias are repaired via laparoscopy (37.5%; n = 9 institutions) (Table 5.5).

Table 5.5. Survey questions relating to provision of thoracic surgical oncology services

Survey Item	Mean or Frequency	
	Total Respondents (%)	Total Institutions (%)
<i>Provision of Thoracic Surgical Oncology Services</i>		
1. Indicate the average number of anatomic pulmonary resections performed at your institution per year.	N/A*	183± 127.4
2. Indicate the average number of esophagectomies performed at your institution per year.	N/A	25±16.1
3. Indicate the average number of OR days available to your thoracic surgery division per week.	N/A	4±1.5
4. Is minimally invasive thoracic surgery performed at your institution?	47	26
Yes	46 (97.9)	25 (96.2)
5. What is the percentage of lobectomies done by video-assisted thorascopic surgery?	47	26
< 25%	18 (38.3)	12 (46.2)
25 – 50%	19 (40.4)	7 (26.9)
50 – 75%	5 (10.6)	4 (15.4)
> 75%	5 (10.6)	3 (11.5)
6. What is the percentage of paraesophageal hernias repaired via laparoscopy?	46	24
< 25%	11 (23.9)	7 (29.2)
25 – 50%	18 (39.1)	9 (37.5)
50 – 75%	5 (10.9)	0 (0)
> 75%	12 (26.1)	8 (33.3)
7. Which of the following do you perform routinely in the staging of lung cancer? (Check all that apply)	47	26
CT scan chest and abdomen	47 (100)	26 (100)
Mediastinoscopy	34 (72.3)	18 (69.2)
PET/CT	29 (61.7)	18 (61.5)
MRI of the brain	9 (19.1)	5 (19.2)
CT head	25 (53.2)	11 (42.3)
EBUS (Endobronchial Ultrasound)	10 (21.3)	5 (19.2)
EUS (Esophageal Ultrasound)	3 (6.4)	2 (7.7)
8. Which of the following do you perform routinely in the staging of esophageal cancer? (Check all that apply)	46	25
CT scan chest and abdomen	46 (100)	25 (100)
Mediastinoscopy	0 (0)	0 (4.0)
PET/CT	29 (63.0)	17 (68.0)
MRI of the brain	0 (0)	0 (0)
CT head	18 (39.1)	9 (36.0)
EBUS (Endobronchial Ultrasound)	3 (6.5)	2 (8.0)
EUS (Esophageal Ultrasound)	18 (39.1)	12 (48.0)

*Not applicable

DISCUSSION:

This is the first study of this nature that has concentrated exclusively on the need for research and quality assessment of a contemporary workforce in the specialty of thoracic surgery. To evaluate clinical research and funding, and methods of quality assessment, we designed a comprehensive, web-based survey and sent it to a national thoracic surgery association. A response rate of 57.0% was generated and reflects the importance of this work to the thoracic surgical workforce. The results of the study offer current and previously unavailable information and provide a better understanding of thoracic surgical research and quality monitoring processes.

Through a consensus based approach, an expert panel has agreed that the practice setting should have an adequate volume of thoracic surgery to preserve the skills of surgeons in both complex cancer surgery and thoracic surgery.⁵ Survey results indicate that thoracic surgeons across Canada perform a significant number of general thoracic procedures on significant case volumes each year to preserve their surgical skills as well as to uphold institutional quality standards. Moreover, hospitals providing oncological and benign thoracic services should have sufficient infrastructure support for surgeon participation in both local and national databases to maintain ongoing clinical research.⁵ Survey results indicate that most institutions are involved in research, and many surgeons are avid participants in basic and clinical research through involvement in retrospective chart reviews, prospective observational studies, and randomized controlled trials. However, more robust quality improvement processes are needed for thoracic surgical services, in particular, as the disease burden in Canada requiring thoracic oncology services is likely to increase as our population ages and baby boomers enter their senior years.⁷ Quality assurance in the thoracic surgical speciality must evolve and engender greater participation, as 72.0% of Canadian

institutions do not have a formal surgery quality assessment program and 92.3% of institutions do not participate in a national or international thoracic surgery database. Nevertheless, surgeons from 19 institutions (73.1%) are willing to participate in and lead quality processes, and possess a high level of interest in initiating a national thoracic surgery database (65.4%).

To ensure consistent quality in the thoracic surgical speciality, an ongoing commitment to continuous quality improvement is essential. Continuous quality improvement, in healthcare, is the repetitive cycle of outcomes and process measurement, design and implementation of interventions to improve the processes of care, and re-assessment to evaluate the effect on quality of care.⁸ One way for thoracic surgeons to continuously evaluate and improve upon their practice is to compare themselves with evidence-based national guidelines through data generated from large patient databases. The development of a national database is progressively being recognized as fundamental to the practice, review and quality assessment of thoracic oncology services across Canada. A system of regular review of perioperative patient care is crucial for the attainment of optimal patient outcomes. A national database would enhance multidisciplinary communication, and allow for design and implementation of programs to improve surgical quality locally and nationally. Our results indicate that 97.8% of surgeons are willing to share data on M&M, representing 100% of all institutions. Moreover, prospective research using a national database can help to answer questions that previously could not be answered due to inadequate sample sizes.¹⁰ For instance, if surgeons do not know the rate of atrial fibrillation or prolonged air leak after lobectomy, how can they monitor their effort to improve it and document it? How does an institution's mortality for esophagectomy compare with other institutions in the same region? How are surgeons doing among their colleagues? Active

participation in a national database can lead to quality improvements in thoracic surgical care and facilitate objective comparison between common surgical procedures, and between surgeons and centers over time.⁹

We recognize several limitations of the use of a survey instrument for evaluating research and quality improvement process in thoracic surgery across Canada. First, the question of how complete, accurate, and representative is the data set must be addressed. This membership study only reflects a snapshot in time and overlooks the various interacting factors affecting the numbers of actively practicing thoracic surgeons. Recall bias also is a relevant concern that may compromise the accuracy of results, as survey responses can be highly dependent on how a question is worded.

Although, demographics and case volume have been previously studied in Canada, information on methods of quality assessment has been limited; thus, limiting opportunities for comparison and evaluating trend over time. Future needs assessment studies must continue to monitor the trends that have already been documented so that appropriate and strategic initiatives can be planned and implemented.

The analysis captured in this report provides an overview of the extent of participation in thoracic surgical research and the methods used for the evaluation of thoracic surgical quality in Canada. The information rendered enhances our ability to strategically plan. Implementation of a national database and the collection of valid data at the national level may be of value for future quality assessment processes in thoracic surgery. Data are essential to document the efficacy and quality of thoracic surgical procedures that are performed and a national database is a necessary tool for quality assurance and for the continued success of thoracic surgical practice. We hope that the results of our membership survey will play an essential first step in that process.

ACKNOWLEDGEMENTS:

The authors gratefully acknowledge the members of the Canadian Association of Thoracic Surgeons for their input and encouragement of this project.

REFERENCES:

1. Gumpert JR. Why on Earth do surgeons need quality assurance? *Ann Roy Coll SurgEng.* 1988;70:85-92.
2. Khuri SF, Daley J, Henderson W. The Department of Veterans Affairs' NSQIP: The first national, validated, outcome-based, risk-adjusted, and peer-controlled program for the measurement and enhancement of the quality of surgical care. *AnnSurg.* 1998; 228:491-507.
3. Caceres M, Braud RL, and Garrett HE Jr. A short history of the Society of Thoracic Surgeons National Cardiac Database: Perceptions of a practicing surgeon. *Ann Thora Surg.* 2010;89:332-339.
4. Schieman C, Kelly E, Gelfand G, et al. Thoracic surgery training in Canada according to the residents: The Thoracic Surgery Resident Survey, of the Canadian Thoracic Manpower and Education Study (T-Med). *J Surg Educ.* 2010;67(5):325-334.
5. Sundaresan S, Langer B, Oliver T, et al. Standards for thoracic surgical oncology in a single-payer healthcare system. *Ann Thorac Surg.* 2007;84,693-701.
6. Darling GE, Maziak DE, Clifton JC, et al. The practice of thoracic surgery in Canada. *Can J Surg.* 2004;47:438-445.
7. Shemin RJ, Dziuban SW, Kaiser LR, et al. Thoracic surgery workforce: Snapshot at the end of the twentieth century and implications for the new millennium. *Ann Thorac Surg.* 2002;73:2014-2032.
8. Ferguson TB Jr. Peterson ED, Coombs LP, et al. Use of continuous quality improvement to increase use of process measures in patients undergoing coronary artery bypass graft surgery: A randomized controlled trial. *JAMA: JAMA.* 2003;290:49-56.

9. Wright CD, Edwards FH. The Society of Thoracic Surgeons General Thoracic Surgery Database. *AnnThorac Surg.* 2002;83:893-894.

CONCLUSION

Defining, monitoring and improving quality and efficiency of care is at the forefront of health care research. Surgeons have advanced a highly refined system of sustaining and improving the quality of their practice through the measurement and evaluation of: 1) structure of care - as it relates to the type of setting the care takes place in; 2) processes of care – such as, the perioperative preparation of the patient; and 3) outcomes of care - via formal M&M rounds, where open collegial discussion not only helps to facilitate the improvement of surgical outcomes, but also enhances surgical education of trainees.

The TM&M classification system, based on the Clavien-Dindo classification system, builds upon the above principles, providing objective and standardized feedback on surgical adverse events for an individual division of thoracic surgery at the Ottawa Hospital. The TM&M classification system advocates for a practice of continuous quality improvement, advances the development of quality improvement programs, and facilitates an open forum for ongoing medical education on surgical quality assurance. The TM&M classification system has potential for widespread adoption by providing a critical component to continuous quality improvement in thoracic surgery.

To evaluate the reliability and reproducibility of the TM&M classification system, a 31-item questionnaire was sent to all members of the Canadian Association of Thoracic Surgeons in August 2009, consisting of 20 case-based questions of postoperative adverse events to be classified. The response rate of the survey may not have been optimal; however; efforts were made to increase participation in the survey. Results indicate a high level of agreement among the survey respondents for the 20 case scenarios, further indicating that the TM&M classification system is consistent among surgeons' opinion and can be applied to

different case examples. Personal judgements of survey respondents show that the TM&M classification system is straightforward to understand, reproducible, and useful.

The next step of the project called for a needs assessment of the Canadian thoracic surgical speciality as it has become increasingly important to compare the quality of surgical care delivery across Canadian institutions. This time, a 45-item speciality-focused survey was mailed to all national members of Canadian Association of Thoracic Surgeons in August 2009. Questions focused on thoracic surgical manpower, clinical research programs and funding opportunities, methods used for the evaluation of surgical quality (i.e. database use and interest, and quality monitoring), and the provision of thoracic surgical oncology services. The results of this study have provided a strong foundation of knowledge upon which we can, with time, enhance the monitoring of quality of care at the national level.

Future plans are in place for the development of a Thoracic Surgical Quality Monitoring System (TSQMS). This novel system will be a natural extension of the TM&M classification system, with the intent to seamlessly integrate all patient interactions with clinical staff at the Ottawa Hospital, by recording and reporting: (i) minimal essential clinical data on all time points on the continuum of care, starting with patient referral to two years follow-up post surgery; (ii) other measures of quality of care (e.g. wait times, patient experience); and (iii) measures of efficiency of care (e.g. patient flow over time, length of stay). Using hand-held tablet PCs or Apple's iPad to record the above information, the next step will be to initiate and evaluate the TSQMS. By including essential clinical data in addition to a broadened definition of quality, there is a capacity to greatly enhance an already successful model.

The health care system places high importance on sustaining and improving the quality of surgical care and patient satisfaction. Thoracic surgeons are being challenged to

achieve this within the framework of a patient population that is increasing in severity of disease (1). The work outlined in this thesis was prepared to achieve these goals.

REFERENCES

1. Sundaresan S, Langer B, Oliver T, et al. Standards for thoracic surgical oncology in a single-payer healthcare system. *The Annals of Thoracic Surgery* 2007;84,693-701.

APPENDIX A (Ethics Approval)



Ottawa Hospital Research Ethics Boards / Conseils d'éthique en recherches

<http://www.ohri.ca/ohreb>

Wednesday, July 15, 2009

Dr. Andrew Seely

Dear Dr. Seely:

Re: Protocol # 2007862-01H An Automated System for Continuous Monitoring and Reporting of Complications and Thoracic Surgical Volume at The Ottawa Hospital

Thank you for the letter of June 24, 2009 from Jennifer Threader, enclosing documentation we had requested in previous correspondence. The following documentation is approved:

- Protocol Amendment Report, dated March 30, 2009
- Revised Protocol (Including Changes), received April 15, 2009
- TM&M Questionnaire Package, received June 25, 2009


Ethical approval remains in effect until January 20, 2010.

Yours sincerely,

Raphael Saginur, M.D.
Chairman

RS/hm

APPENDIX B (Thoracic Surgery Morbidity and Mortality Assessment Tool)

4850307298  ID CODE: Length of stay: Patient Initials:

Report Date: / / Date discharge home: / /

Thoracic Surgery Morbidity and Mortality Assessment Tool (TM&M)

Complication	Grade I No treatment	Grade II RX Any new medication	Grade III (Intervention) Bronch, pigtail, cardioversion, BiPAP, pacemaker, etc.		Grade IV Life support Intubation, dialysis, pressors, etc.		Grade V Death	Patient Readmitted?	Prolonged LOS?
			Grade III a No general anest.	Grade III b General anesthesia	Grade IV a Single organ disf.	Grade IV b Multiorgan disf.			
P U L M O N A R Y	Atelectasis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Pneumonia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Cardiogenic edema	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	ARDS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P L E U R A L	Empyema	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Effusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Chylothorax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Hemothorax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Prolonged air leak	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	BP Fistula	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SubQ emphysema	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
A N A S T	Leak	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Dehiscence	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C A R D I A C	Atrial arrhythmia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Heart block	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Ischemia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Hypertension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	CHF	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Cardiac effusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
R E N A L	UTI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Renal Insufficiency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Retention	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
G A S T R I C	C-Difficile	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Non-infect. Diarrhea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Constipation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Vomiting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Ileus	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
N E U R O	Confusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Mood alteration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Seizure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Cerebro-Vascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
W O U N D	Infection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Hematoma	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Seroma	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Dehiscence	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (e.g. social conditions that prolonged hosp.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

APPENDIX C (TM&M Classification System)

Pulmonary							
Complication	Minor Complication		Major Complication				Grade V
	Grade I	Grade II	Grade III		Grade IV		
			Grade III a	Grade III b	Grade IV a	Grade IV b	
Atelectasis Condition in which part of the lung becomes airless and contracts	Requiring no intervention other than additional chest physiotherapy	Requiring endotracheal suctioning	Endoscopic or radiological intervention performed, or non-invasive ventilation (BiPAP) for < 24 hrs	Operative intervention required under general anaesthesia	Respiratory compromise requiring intubation and positive pressure ventilation	Concomitant multiorgan complications	Death
Pneumonia Inflammation of one or both lungs which is usually caused by infection	--	Requiring antibiotic therapy	Endoscopic or radiological intervention performed, or non-invasive ventilation (BiPAP) for < 24 hrs	Operative intervention required under general anaesthesia	Life-threatening consequences (e.g., septic shock, respiratory failure, or hypotension)	Concomitant multiorgan complications	Death
Inflammatory Lung Injury Includes ARDS, TRALI, ALI or non-cardiogenic pulmonary edema	--	Requiring O ₂ and other medical therapy	Endoscopic or radiological intervention performed, or non-invasive ventilation (BiPAP) for < 24 hrs	Operative intervention required under general anaesthesia	Symptomatic and requiring drugs and non-invasive ventilation (e.g. BiPAP) for > 24 hrs; or requiring intubation and ventilation	Concomitant multiorgan complications	Death

Pleural							
Complication	Minor Complication		Major Complication				
	Grade I	Grade II	Grade III		Grade IV		Grade V
			Grade III a	Grade III b	Grade IV a	Grade IV b	
Empyema Collection of pus within a naturally existing anatomical cavity	--	Requiring medical therapy (e.g. antibiotics)	Endoscopic, radiological or bedside pleural interventions performed	Surgical intervention performed under general anaesthesia	Life-threatening; debilitating; organ failure present	Concomitant multiorgan complications	Death
Effusion Collection of pus that accumulates in the pleural cavity	Asymptomatic, no intervention indicated	Requiring medical therapy (e.g. diuretics) for CHF. Drainage is required if postoperative effusion is large	Endoscopic, radiological or bedside pleural interventions performed	Surgical intervention performed under general anaesthesia	Life-threatening; debilitating; organ failure present	Concomitant multiorgan complications	Death
Chylothorax Type of milky fluid resulting from lymphatic fluid accumulating in the pleural cavity	--	Requiring medical therapy (e.g. TPN, drainage for 7 days)	Require TPN, or endoscopic, radiological or bedside pleural interventions performed	Surgical intervention performed under general anaesthesia	Life-threatening; debilitating; organ failure present	Concomitant multiorgan complications	Death
Hemothorax Blood in the pleural cavity resulting from an injury to chest	--	Requiring medical therapy. Requiring drainage at > 300 cc/hr for 3 hrs.	Endoscopic, radiological or bedside pleural interventions performed.	Surgical intervention performed under general anaesthesia.	Life-threatening; debilitating; organ failure present.	Concomitant multiorgan complications.	Death
Pneumothorax A collapsed lung; caused by accumulation of air or gas in the pleural cavity	No intervention required.	Requiring medical therapy only or prolonged (>5 days) pleural drainage	Endoscopic, radiological or additional bedside pleural interventions performed.	Surgical intervention performed under general anaesthesia.	Life-threatening; debilitating; organ failure present.	Concomitant multiorgan complications.	Death
Prolonged Air Leak (air > 5 days) A pocket of air between the two layers of pleura caused by a tear in the lung	No intervention required.	Requiring medical therapy only or prolonged (>5 days) pleural drainage	Endoscopic, radiological or additional bedside pleural interventions performed	Surgical intervention performed under general anaesthesia	Life-threatening; debilitating; organ failure present	Concomitant multiorgan complications	Death
Prolonged Pleural Drainage Fluid > 5 days	No intervention required	Requiring medical therapy only or prolonged (>5 days) pleural drainage	Endoscopic, radiological or additional bedside pleural interventions performed	Surgical intervention performed under general anaesthesia	Life-threatening; debilitating; organ failure present	Concomitant multiorgan complications	Death

Continued

Pleural							
Complication	Minor Complication		Major Complication				
	Grade I	Grade II	Grade III		Grade IV		Grade V
			Grade III a	Grade III b	Grade IV a	Grade IV b	
BP Fistula Abnormal communication between a bronchus and the pleural cavity; usually caused by necrotizing pneumonia or empyema	--	Symptomatic, medical management indicated	Symptomatic, requiring: tube thoracostomy, endoscopic (e.g., stent), closure	Operative intervention with thoracoplasty, chronic open drainage or multiple thoracotomies indicated	Life-threatening; debilitating; organ failure present	Concomitant multiorgan complications	Death
Sub-Cutaneous Emphysema Gas or air is present in the subcutaneous layer of the skin	No intervention required	Requiring medical therapy only	Endoscopic, radiological or bedside pleural interventions performed	Surgical intervention performed under general anaesthesia	Life-threatening; debilitating; organ failure present	Concomitant multiorgan complications	Death

Anastomotic							
Complication	Minor Complication		Major Complication				
	Grade I	Grade II	Grade III		Grade IV		Grade V
			Grade III a	Grade III b	Grade IV a	Grade IV b	
Leak Breakdown of a suture line in a surgical anastomosis with leakage of gastric or intestinal fluid	Anastomotic leak – transient, no therapy added	Anastomotic leak – medical therapy (e.g. antibiotics) added	Anastomotic leak – intervention required (opening of wound)	Anastomotic leak – intervention required under general anaesthesia	Anastomotic leak – leads to single organ failure	Anastomotic leak – leads to multiple organ failure	Death
Dehiscence/ Conduit Failure Fecal discharge from the wound and/or drain.	--	Anastomotic dehiscence – medical therapy (e.g. antibiotics) added	Anastomotic dehiscence – intervention required (opening of wound)	Anastomotic dehiscence – intervention required under general anaesthesia	Anastomotic dehiscence – leads to single organ failure	Anastomotic dehiscence – leads to multiple organ failure	Death
Delayed Emptying Partial paralysis of the stomach resulting in food remaining in the stomach for a longer period of time than normal	No intervention required	Requiring medical therapy only	Endoscopic or radiological interventions performed	Surgical intervention performed under general anaesthesia	Life-threatening; debilitating; organ failure present	Concomitant multiorgan complications	Death

Cardiac							
Complication	Minor Complication		Major Complication				
	Grade I	Grade II	Grade III		Grade IV		Grade V
			Grade III a	Grade III b	Grade IV a	Grade IV b	
Atrial Fibrillation Irregular heart rhythm involving the two upper (atria) of the heart	Converting after correction of electrolytes. No other intervention required	Requiring medications (e.g. beta-blockers) for heart rate control	Symptomatic, requiring a cardio-version or a device (e.g., pacemaker)	Idem.	Associated with single organ failure (e.g. CHF, hypotension, syncope, shock)	Concomitant multiorgan complications	Death
Heart Block Partial or complete interruption of impulse transmission from the atria to the ventricles	Asymptomatic, intervention not indicated	Requiring medications (e.g atropine)	Symptomatic, requiring a device (e.g. pacemaker)	Idem.	Associated with single organ failure (e.g. CHF, hypotension, syncope, shock)	Concomitant multiorgan complications	Death
Ischemia Restriction in blood supply, due to factors in the blood vessels, leading to damage or dysfunction of tissue	Elevation Troponin, asymptomatic	Requiring angina medications (e.g. beta blockers, NITRO)	Requiring percutaneous coronary intervention (PCI)	Requires urgent cardiac surgery for aorto-coronary bypass grafting	Associated with single organ failure (e.g. CHF, hypotension, syncope, shock)	Concomitant multiorgan complications	Death
Hypertension High blood pressure; a generally symptomless medical condition in which the blood pressure is chronically elevated	Defined as persistent BP mean > 80 mmHg). No intervention required	Recurrent or persistent requiring one or more additional drug therapy	Requiring intensive care admission if malignant type HTN	Idem.	Single-organ failure	Concomitant multiorgan complications	Death
Cardiac Effusion or Pericarditis The presence of an abnormal amount of fluid in the pericardial space; inflammation of the pericardium, often with fluid accumulation	No intervention required	Medical therapy adequate	Requiring pericardiocentesis	Require operative drainage	Single-organ failure	Concomitant multiorgan complications	Death
CHF The quantity of blood pumped by the heart each minute (cardiac output) is insufficient to meet the body's normal requirements for oxygen and nutrients	No intervention required	Symptomatic and requiring additional medical therapy: diuretics, beta-blockers, nitrates, calcium channel blockers, ACE inhibitors, phosphodiesterase inhibitors, calcium blockers	Symptomatic and requiring drugs and non-invasive ventilation (e.g. BiPAP) for < 24 hrs	Requires ventricular assist device, ventricular reduction surgery, or heart transplant indicated	Symptomatic and requiring drugs and non-invasive ventilation (e.g. BiPAP) for > 24 hrs; or requiring intubation and ventilation	Concomitant multiorgan complications	Death

Continued

Cardiac							
Complication	Minor Complication		Major Complication				Grade V
	Grade I	Grade II	Grade III		Grade IV		
			Grade III a	Grade III b	Grade IV a	Grade IV b	
Cardiac Herniation Post Intra-Pericardial Resection Sudden cardiogenic shock caused by torsion of the heart	--	--	--	Requires surgical repair	Single organ dysfunction	Concomitant multiorgan complications	Death
Venous Thrombosis Blood clot that forms within a vein	Non-occlusive, requires no therapy	Requires anti-coagulation.	Requires IVC filter	Requires surgical procedure	Single organ failure	Concomitant multiorgan complications	Death
Pulmonary Embolism The occlusion of one or more pulmonary arteries by thrombi that originate elsewhere, typically in the large veins of the lower extremities or pelvis	Non-occlusive, requires no therapy	Requires anti-coagulation	Requires IVC filter	Requires surgical procedure	Single organ failure	Concomitant multiorgan complications	Death

Renal							
Complication	Minor Complication			Major Complication			
	Grade I	Grade II	Grade III		Grade IV		Grade V
			Grade III a	Grade III b	Grade IV a	Grade IV b	
UTI Bacterial infection that affects any part of the urinary tract	No intervention required other than removal of foley	Requiring medical therapy only (e.g. antibiotics)	Endoscopic, radiological or bedside interventions performed	Surgical intervention performed	Life-threatening; organ failure present	Concomitant multiorgan complications	Death
Renal Insufficiency Abnormal kidney function in which the kidneys are unable to adequately excrete toxic substances from the body. Biochemically, it is typically detected by an elevated serum creatinine	No intervention required	Requiring medical therapy only (e.g. diuretics)	Requiring dialysis	Surgical intervention performed	Life-threatening; organ failure present	Concomitant multiorgan complications	Death
Cystitis An inflammation of the urinary bladder	Asymptomatic, intervention not indicated	Requiring medical therapy only (e.g. bladder irrigation)	Requiring transfusion; IV pain medications	Catastrophic bleeding; major non-elective intervention indicated	Life-threatening; organ failure present	Concomitant multiorgan complications	Death
Urinary Retention A lack of ability to urinate	No intervention required	Requires short term re-catheterization (<72 hrs)	Requires long term re-catheterization (>72 hrs) or D/C home with catheter	Surgical intervention required	Life-threatening; organ failure present	Concomitant multiorgan complications	--

Gastrointestinal							
Complication	Minor Complication		Major Complication				
	Grade I	Grade II	Grade III		Grade IV		Grade V
			Grade III a	Grade III b	Grade IV a	Grade IV b	
Infectious Diarrhea Infection of the digestive system by a bacterium, virus, or parasite that results in frequent bowel motions producing excessive amounts of liquidy feces	--	Requiring antibiotics	Endoscopic, radiological or bedside interventions performed	Surgical intervention performed under general anaesthesia	Life-threatening; debilitating; organ failure present	Concomitant multiorgan complications	Death
Non-infectious Diarrhea Increase in the volume, wateriness, or frequency of bowel movements	No intervention required	Requiring anti-diarrhoeal treatment	Endoscopic, radiological or bedside interventions performed	Surgical intervention performed under general anaesthesia	Life-threatening; debilitating; organ failure present	Concomitant multiorgan complications	Death
Constipation Difficult or infrequent passage of stool, hardness of stool, or a feeling of incomplete evacuation	No intervention required	Requiring nasogastric intubation, use of stool softeners, laxatives, dietary modification, or enema	Obstipation with manual evacuation indicated	Surgical intervention performed under general anaesthesia	Life-threatening consequences (e.g., obstruction, toxic megacolon)	Concomitant multiorgan complications	Death
Nausea Unpleasant feeling of needing to vomit; awareness of afferent stimuli (including increased parasympathetic tone) to the medullary vomiting center	No intervention required	Requiring nasogastric intubation, and prokinetics (e.g. Maxeran, Erythromycin, Graval)	Tube feedings, nasogastric intubation, or TPN indicated \geq 24 hrs	Surgical intervention performed under general anaesthesia	Life-threatening; debilitating	Concomitant multiorgan complications	Death
Vomiting Expulsion of the contents of one's stomach through the mouth and sometimes the nose	No intervention required	NPO. Requiring nasogastric intubation and prokinetics (e.g. Maxeran, Graval)	Tube feedings, nasogastric intubation, rectal intubation, or TPN indicated \geq 24 hrs	Surgical intervention performed under general anaesthesia	Life-threatening; debilitating; organ failure present	Concomitant multiorgan complications	Death
Ileus Disruption of the normal propulsive gastrointestinal motor activity; occurs most commonly after abdominal surgery, when the intestines have been manipulated	No intervention required	NPO. Requiring nasogastric intubation. IV fluids indicated > 24 hrs	Tube feedings, or TPN indicated \geq 24 hrs	Surgical intervention performed	Life-threatening; debilitating; organ failure present	Concomitant multiorgan complications	Death
GI Bleeding Bleeding that starts in the gastrointestinal tract, which extends from the mouth to the anus	--	Transfusion, PPI infusion, or other medical therapy	Requires endoscopy.	Surgical intervention performed	Life-threatening; debilitating; organ failure present	Concomitant multiorgan complications	Death

Neurological							
Complication	Minor Complication		Major Complication				
	Grade I	Grade II	Grade III		Grade IV		Grade V
			Grade III a	Grade III b	Grade IV a	Grade IV b	
Confusion/ Delirium An acute and relatively sudden (developing over hours to days) decline in attention-focus, perception, and cognition	Transient. New or worsened; no intervention required	Requiring medical intervention	Prolonged hospitalization indicated; danger to self or others	--	--	--	Death
Seizure An abnormal electrical discharge that occurs within the brain's cortical gray matter and interrupts normal brain function; typically causes altered awareness, abnormal sensations, focal involuntary movements, or convulsions	--	Requiring medical intervention (e.g. anti-convulsants)	Poorly controlled seizure disorder, with breakthrough generalized seizures despite medical intervention	--	Status epilepticus, intractable epilepsy, requiring mechanical ventilation	--	Death
Cerebro-Vascular Accident Death of some brain cells due to lack of oxygen when the blood flow to the brain is impaired by blockage or rupture of an artery to the brain	No intervention required	Requiring medical intervention (e.g. anticoagulants, ASA)	Radiological or bedside interventions performed	Surgical intervention performed	Life-threatening; requiring intensive-care	Concomitant multiorgan complications	Death

Wound							
Complication	Minor Complication		Major Complication				
	Grade I	Grade II	Grade III		Grade IV		Grade V
			Grade III a	Grade III b	Grade IV a	Grade IV b	
Infection Colonization of a host organism by a foreign species	--	Requiring medical therapy (e.g. antibiotics)	Endoscopic, radiological or bedside interventions performed	Surgical intervention performed	Life-threatening; debilitating; organ failure present	Concomitant multiorgan complications	Death
Hematoma A collection of blood outside the blood vessels, generally the result of hemorrhage	No intervention required	Transfusion, evacuation or aspiration. Opening of wound at bedside	Interventional radiology indicated	Surgical intervention performed	Life-threatening consequences; major urgent intervention indicated	Concomitant multiorgan complications	Death
Seroma A pocket of clear serous fluid that sometimes develops in the body after surgery	No intervention required	Opening of wound at bedside	Transfusion, interventional radiology indicated	Surgical intervention performed	--	--	--
Dehiscence A previously closed wound reopening	--	--	Requiring intervention	Surgical intervention performed	Life-threatening consequences	Concomitant multiorgan complications	Death

APPENDIX D (VATS vs. Open Lobectomy)

Objective: Video-assisted thoracic surgery (VATS) is a relatively new technology that has become the standard of care for minimally invasive thoracic procedures. However, controversy surrounds the safety and oncologic efficacy of VATS lobectomy. The TM&M tool was utilized for reporting presence and severity of complications during the initiation of a VATS lobectomy learning curve, and compared to open lobectomy controls. The types of postoperative morbidity in patients undergoing lobectomy, was further analyzed, in order to deduce if there is an advantage gained by the minimally invasive VATS procedure.

Methods: A retrospective review of all patients undergoing thoracic surgery for lung cancer at the Ottawa Hospital was conducted to identify those patients who underwent elective pulmonary lobectomy for clinical stage I and II non-small cell lung cancer (NSCLC). All consecutive VATS lobectomies performed in the Ottawa Hospital since January 2006 until August 2010 were age-matched (± 5 years) and stage-matched with a control cohort of open lobectomy cases. Data on patient demographics, co-morbidities, pulmonary function, pathological stage, operative procedure and time, blood loss, type and grade of postoperative complications, and hospital length of stay were recorded and will be analyzed retrospectively.

Results: The responsibility of the master's candidate was to analyze the data using frequency counts for categorical variables, such as presence of co-morbid conditions, and as mean, median and range for continuous variables, such as operating room time, surgery time, and length of stay. Differences between VATS and open lobectomy groups were analyzed using the Student's t-test for continuous variables and the χ^2 or Fisher exact tests for categorical variables. Stratified analyses were performed to examine variations in complication rates according to age at surgery (<71 – 80, >81). A p value of < 0.05 was considered significant.

Data was analyzed using SAS 9.2 software. Results are presented below in tables D.1 to D.8, and figures D.1 and D.2.

Table D.1. Patient Characteristics

Characteristics	VATS (n = 120)	Open (n = 120)	p Value
Age (range), years	66.7 (44 - 84)	67.3 (48 - 88)	Matching variable
Gender			0.19
Female, n (%)	61 (50.8)	71 (59.2)	--
Male, n (%)	59 (49.2)	49 (40.8)	--
Clinical Stage			Matching variable
IA	62	71	--
IB	38	29	--
IIA	16	14	--
IIB	1	3	--
IIIA	3	3	--
IIIB	0	0	--
COPD, n (%)	19 (15.8)	19 (15.8)	--
Cardiac Disease, n (%)	17 (14.2)	16 (13.3)	0.87
Diabetes Mellitus, n (%)	20 (16.7)	13 (10.8)	0.19
Hypertension, n (%)	50 (41.7)	56 (46.7)	0.44
% predicted FEV ₁ (range)	2.06 (.96 – 4.34)	2.15 (0.81 – 4.0)	0.42

Based on the student's t-test for continuous variables and the χ^2 or Fisher exact tests for categorical variables.

Note: Patient characteristics did not differ between patients undergoing a VATS lobectomy or patients undergoing an open lobectomy procedure.

Table D.2. Perioperative Data

Characteristics	VATS (n = 120)	Open (n = 120)	p Value
Pathology			
Adenocarcinoma (%)	72 (60)	67 (55.8)	0.51
Squamous Cell Carcinoma (%)	31 (25.8)	32 (26.7)	0.88
Large Cell Lung Carcinoma (%)	5 (4.2)	10 (8.3)	0.18
Other (%)	12 (10)	11 (9.2)	0.83
Mean Tumor Diameter (range), cm	2.68 (.5 - 11)	2.76 (0.7 – 7.4)	0.89
Length of Stay, days	7.76 (2 - 86)	8.16 (3 – 53)	<0.05*
Mean O.R. Time, min	273.18	239.13	<0.05*
Mean Surgery Time, min	220.04	178.24	<0.05*
Mean Blood Loss, cc	170.27	230.56	<0.05*
Conversion, n (%)	7 (5.8)	--	--
Required Transfusion, n (%)	4 (3.3)	6 (5.0)	0.51
# N1 LN Sampled, mean (range)	7.1 (0 - 21)	5.99 (1 - 23)	0.21
# Positive, median (range)	0 (0 - 10)	0 (0 - 3)	<0.05*
# N2 LN Sampled, mean (range)	1.5 (0 - 6)	1.5 (0 - 8)	0.87
# Positive, median (range)	0 (0 - 3)	0 (0 - 3)	0.69
Preop Mediastinoscopy, n (%)	49 (40.8)	52 (43.3%)	0.69
Preop Anterior Mediastinotomy, n (%)	2 (1.7)	6 (5)	0.15
Complications, n (%)	52 (43.3)	57 (47.5)	0.52
Death, n (%)	4 (3.3)	2 (1.7)	0.68

Based on the student's t-test for continuous variables and the χ^2 or Fisher exact tests for categorical variables.

Note: There was a statistically significant difference between groups in terms of mean length of stay, with patients undergoing a VATS lobectomy procedure having a shorter LOS ($p < .0001$). There was a statistically significant difference between groups in terms of mean O.R. time, with patients undergoing an open lobectomy procedure having a shorter O.R time ($p = 0.0016$). There was a statistically significant difference between groups in terms of mean surgery time, with patients undergoing an open lobectomy procedure a having a shorter surgery time ($p = 0.0061$). There was a statistically significant difference between

groups in terms of mean blood loss, with patients undergoing a VATS lobectomy procedure experience less blood loss ($p < 0.0001$).

Table D.3. Severity of Complications

Characteristic	VATS (n = 120)	Open (n = 120)	p Value
Complications/patient, n (%)			
0	68 (56.7)	62 (51.7)	0.43
1	35 (29.2)	38 (31.7)	0.67
2	10 (8.3)	13 (10.8)	0.51
> 3	7 (5.8)	7 (5.8)	--
Max Grade, n (%)			
I	4 (3.3)	2 (1.7)	0.68
II	34 (28.3)	42 (35.0)	0.27
IIIa	7 (5.8)	8 (6.7)	0.79
IIIb	2 (1.7)	0 (0)	0.50
IVa	1 (0.8)	4 (3.3)	0.37
IVb	0 (0)	1 (0.8)	0.31
V	4 (3.3) [^]	2 (1.7) [×]	0.68

Based on the χ^2 or Fisher exact tests for categoric variables.

Note: Overall complication rates were not statistically different between patients undergoing a VATS lobectomy or patients undergoing an open lobectomy procedure.

[^]Causes of death: MI, pneumonia, ARDS, cardiac arrest

[×]Causes of death: cardiac perforation, respiratory failure

Table D.4. Complication Profile

Type, n (%)	VATS (n = 120)	Open (n = 120)	p Value
Pulmonary	18 (15)	14 (11.7)	0.45
Pleural	45 (37.5)	33 (27.5)	0.10
Cardiac	15 (12.5)	26 (21.7)	0.06
Renal	3 (2.5)	4 (3.3)	0.70
Gastrointestinal	3 (2.5)	2 (1.7)	0.65
Neurological	4 (3.3)	6 (5)	0.52
Wound	0 (0)	2 (1.7)	0.50
Other	2 (1.7)	2 (1.7)	--

Based on the x2 or Fisher exact tests for categoric variables.

Note: Complication rates among the different systems were not statistically different between patients undergoing a VATS lobectomy or patients undergoing an open lobectomy procedure.

Table 5. Median length of stay for uncomplicated and complicated cases

Complication Grade	VATS (n = 120)		Open (n = 120)		p Value
	n	Median LOS, days	n	Median LOS, days	
Uncomplicated Cases	68	4	61	5	<0.05*
Complicated Cases					
Grade I	4	5.5	2	17.5	0.02
Grade II	34	7	41 [^]	7	0.04*
Grade IIIa	7	9	8	15.5	0.46
Grade IIIb	2	5.5	0	--	--
Grade IVa	1	86	4	16	--
Grade IVb	0	N/A	1	42	--
Grade V	4	18.5	2	7.5	0.08

Based on the student's t-test for continuous variables.

[^]1 outlier removed (LOS = 144)

Note: Patients who underwent a VATS lobectomy and who experience no complications had a significantly shorter length of stay as compared to uncomplicated open lobectomy cases (p

<.0001). Patients with grade I and II complications who underwent an open lobectomy procedure experienced a significantly higher length of stay ($p = 0.0170$; $p < 0.0001$, respectively) as compared to patients with grade I and II complications who underwent a VATS lobectomy.

Table D.6. Incidence of complications in different age groups of patients undergoing VATS

Patient Outcomes	Controls		Stratified by Age		
	< 70 (n = 77), %	71 – 80 (n = 36), %	p Value	> 81 (n = 7), %	p Value
Uncomplicated Cases	46 (59.7)	18 (50)	0.3303	4 (57.1)	0.89
Complicated Cases					
Grade I	1 (1.3)	2 (5.6)	0.2377	1 (14.3)	0.16
Grade II	19 (24.7)	13 (36.1)	0.2087	2 (28.6)	0.82
Grade IIIa	6 (7.8)	1 (2.8)	0.3029	0 (0)	0.44
Grade IIIb	2 (2.6)	0 (0)	0.3292	0 (0)	0.67
Grade IVa	0 (0)	1 (2.8)	0.0008*	0 (0)	--
Grade IVb	0 (0)	0 (0)	--	0 (0)	--
Grade V	3 (3.9)	1 (2.8)	0.7644	0 (0)	0.59

Based on the χ^2 or Fisher exact tests for categoric variables.

Note: There was no difference in terms of uncomplicated cases among the different age groups. However, there was a significantly higher grade IVa complication rate in patients between 71 and 80 years of age undergoing a VATS lobectomy compared to younger patients (< 70 years) ($p < 0.05$).

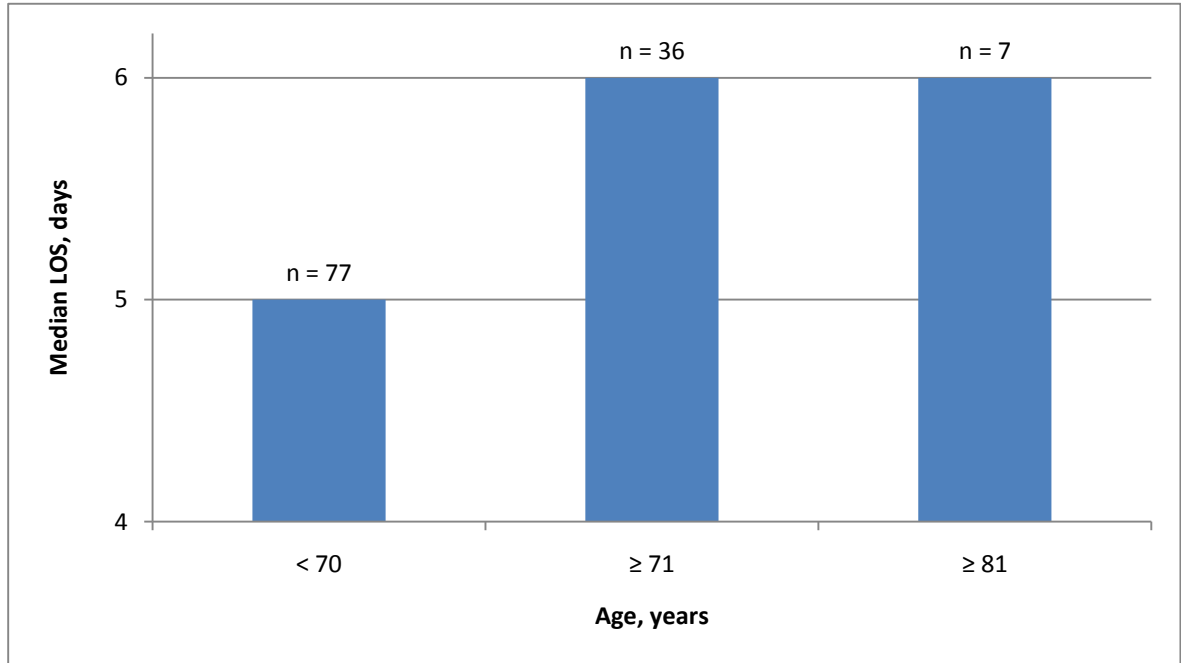


Figure 1. Median length of stay as a function of age for patients undergoing a VATS procedure. There was no difference in length of stay among patients of different age groups (ANOVA, $p = 0.18$).

Lobe	VATS (n = 120)	Open (n = 120)	p Value
RUL	48 (40)	40 (33.3)	0.28
RML	7 (5.8)	11 (9.2)	0.33
RLL	19 (15.8)	15 (12.5)	0.46
LUL	28 (23.3)	29 (24.2)	0.88
LLL	18 (15)	25 (20.8)	0.24

Based on the χ^2 or Fisher exact tests for categoric variables.

Note: There was no difference in the distribution of resections by lobe performed by VATS or open lobectomy.

Table D.8. Dividing the cases chronologically by dates to compare OR and surgical times for VATS lobectomy.

Cases	OR Time	Surgical Time
1 – 20	299.2	237.3
21 – 40	265.5	217.9
41 – 60	253.2	203.8
61 – 80	241.7	190.9
81 – 100	273.6	222.4
101 – 120	306.8	249.8
p value	<0.05*	<0.05*

Based on ANOVA which tests the equality of means when sample sizes are equal.

Note: OR time and surgical time significantly differed among the groups of cases undergoing VATS lobectomy.

Table D.9. Dividing the cases chronologically by dates for number of complications.

Cases	Total number of complications, n (%)		p Value
	VATS (n = 120)	Open (n = 120)	
1 – 20	23 (19.2)	12 (10)	0.04*
21 – 40	17 (14.2)	16 (13.3)	0.85
41 – 60	11 (9.2)	23 (19.2)	0.03*
61 – 80	14 (11.7)	12 (10)	0.68
81 – 100	7 (5.8)	7 (5.8)	--
101 – 120	11 (9.2)	19 (15.8)	0.12

Based on the χ^2 or Fisher exact tests for categoric variables.

Note: The initial 20 VATS cases experienced significantly more complications than patients who underwent an open lobectomy during the same time period ($p = 0.04$). The opposite effect is seen in VATS cases 41 – 60 whom experienced significantly less complications than patients who underwent an open lobectomy during the same time period ($p = 0.03$). There were no differences in terms of complication rates in the other time periods.

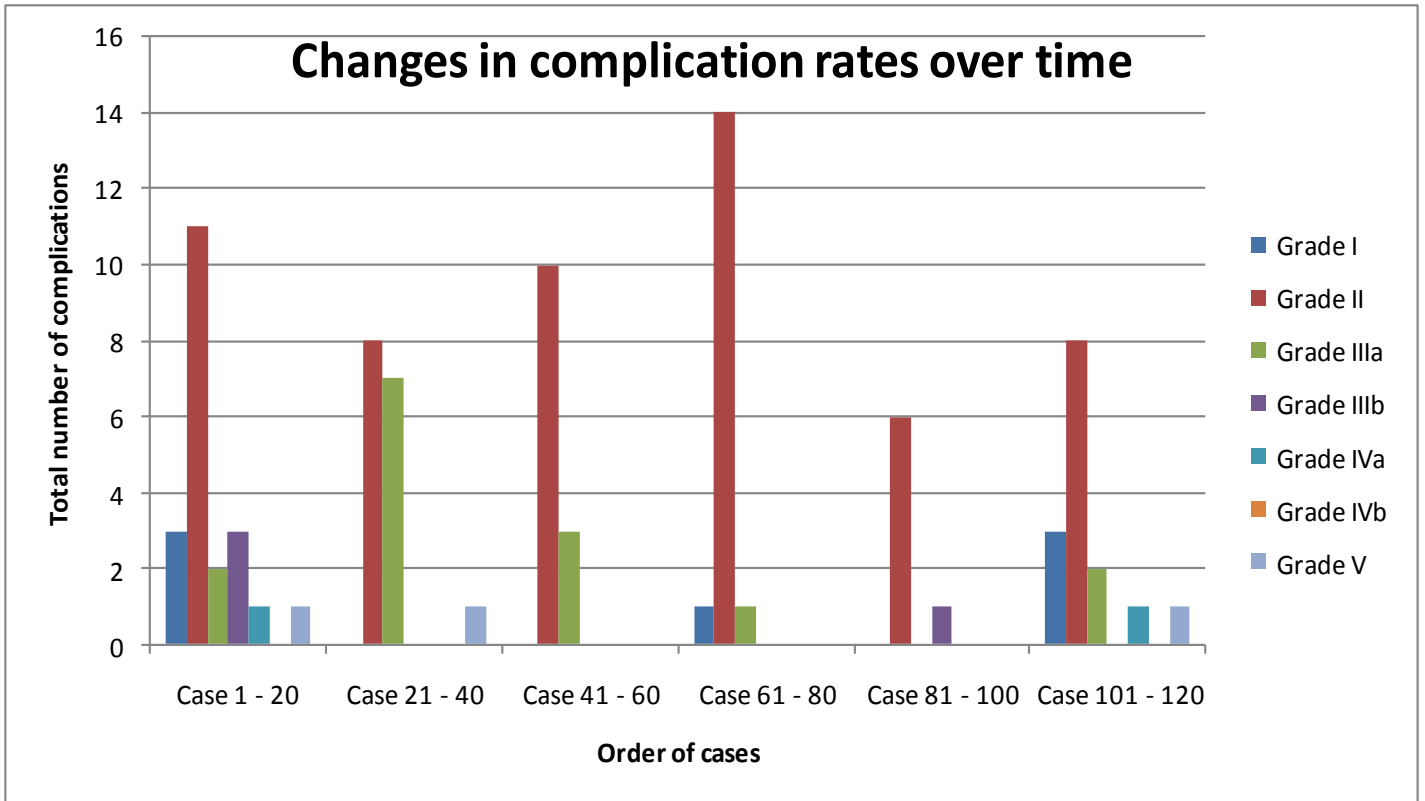


Figure D.2. Changes in complication rates over time for patients undergoing VATS lobectomy. Minor complications (grades I and II) are the most common types of complication seen over time.

Classifying Thoracic Morbidity and Mortality (TM&M)

1. Introduction

Minimizing complications after surgery is widely recognized as an important indicator of quality; however, there is a lack of consensus on how to collect and analyze outcomes following surgical procedures.

We have designed a graded classification schema for evaluating thoracic morbidity and mortality (TM&M), according to the classification schema of surgical adverse events proposed by Clavien. We believe that the TM&M is an objective, reproducible and practical tool to analyze complications after thoracic surgery. To validate the TM&M, we have created 20 case-based examples along with postoperative adverse events to be classified in accordance to the proposed grading system.

The questionnaire is brief, and will take less than 15 minutes to complete. By completing this questionnaire, your feedback will be valuable in the evaluation and validation process of the TM&M tool. Your comments will help in the future development of standards of quality assessment and reporting following thoracic surgery.

Participation in this research study is voluntary. You have the right to withdraw at anytime or refuse to participate entirely. All information provided will remain confidential and will only be reported as group data with no identifying information.

As a token of appreciation, you will receive a \$10 gift certificate to Tim Horton's for completing the questionnaire.

If you have any questions or concerns, please contact Dr. Andrew Seely, Principal Investigator, at 613-737-8899 Ext 74892 or aseely@ottawahospital.on.ca.

Classifying Thoracic Morbidity and Mortality (TM&M)

2. Monitoring Complications following Thoracic Surgery

As per the Clavien system, the following definition of complication and overall classification scheme will be used:

Classification of Complications following Thoracic Surgery	
Grade	Definition
Grade I	Any complication without need for pharmacologic treatment or other intervention.
Grade II	Any complication that requires pharmacological treatment or minor intervention on
Grade III	Any complication that requires surgical, radiological, endoscopic intervention, or mu
Grade IIIa	Intervention does not require general anaesthesia.
Grade IIIb	Intervention requires general anaesthesia.
Grade IV	Any complication requiring ICU management and life support.
Grade IVa	Single organ dysfunction.
Grade IVb	Multiorgan dysfunction.
Grade V	Any complication leading to the death of the patient.
Complication	Any deviation from the normal postoperative course.

Classifying Thoracic Morbidity and Mortality (TM&M)

3. Thoracic Surgical Cases

Please choose the most severe grade of complication for each case (one choice per case).

Classification of Complications following Thoracic Surgery	
Grade	Definition
Grade I	Any complication without need for pharmacologic treatment or other intervention.
Grade II	Any complication that requires pharmacological treatment or minor intervention on
Grade III	Any complication that requires surgical, radiological, endoscopic intervention, or mu
Grade IIIa	Intervention does not require general anaesthesia.
Grade IIIb	Intervention requires general anaesthesia.
Grade IV	Any complication requiring ICU management and life support.
Grade IVa	Single organ dysfunction.
Grade IVb	Multiorgan dysfunction.
Grade V	Any complication leading to the death of the patient.
Complication	Any deviation from the normal postoperative course.

1. A RUL lobectomy was performed on a 54-year-old patient for lung cancer, the patient developed a prolonged air leak but required no further intervention beside observation.

I II IIIa IIIb IVa IVb V

2. A 65-year-old patient developed bilateral atelectasis associated with fever. Following total esophagectomy, patient required oxygen supplementation, aggressive physiotherapy, nasopharyngeal trumpet, and tracheal suctioning. The patient subsequently recovered.

I II IIIa IIIb IVa IVb V

3. A 47-year-old patient suffered from atrial fibrillation on the second day following pneumonectomy for malignant mesothelioma. IV Metoprolol and Digoxin were given, the patient reverted to sinus rhythm.

I II IIIa IIIb IVa IVb V

4. A 22-year-old patient underwent VATS bullectomy and pleurectomy for recurrent spontaneous pneumothorax. The patient suffered from prolonged air leak and persistent pneumothorax, which was treated by insertion of another chest tube.

I II IIIa IIIb IVa IVb V

Classifying Thoracic Morbidity and Mortality (TM&M)

5. A 68-year-old female underwent an open lobectomy for non-small cell lung cancer (NSCLC). The patient developed atrial fibrillation, which spontaneously resolved. The patient required no further intervention beside observation.

I

II

IIIa

IIIb

IVa

IVb

V

Classifying Thoracic Morbidity and Mortality (TM&M)

3. Thoracic Surgical Cases

Please choose the most severe grade of complication for each case (one choice per case).

Classification of Complications following Thoracic Surgery	
Grade	Definition
Grade I	Any complication without need for pharmacologic treatment or other intervention.
Grade II	Any complication that requires pharmacological treatment or minor intervention only.
Grade III	Any complication that requires surgical, radiological, endoscopic intervention, or medical treatment.
Grade IIIa	Intervention does not require general anaesthesia.
Grade IIIb	Intervention requires general anaesthesia.
Grade IV	Any complication requiring ICU management and life support.
Grade IVa	Single organ dysfunction.
Grade IVb	Multiorgan dysfunction.
Grade V	Any complication leading to the death of the patient.
Complication	Any deviation from the normal postoperative course.

6. A gastrectomy and Roux-en-Y gastro-jejunostomy was performed on a 66-year-old patient. On post-operative day 12, the patient was readmitted due to abdominal pain and fever. A CT scan showed intra-abdominal abscess which was treated with IV antibiotics and a CT-guided percutaneous drain insertion.

I II IIIa IIIb IVa IVb V

7. An 84-year-old patient underwent total thyroidectomy for a retrosternal goiter. The patient developed stridor and hypoxia. An immediate operation was done to evacuate the hematoma and control the bleeding.

I II IIIa IIIb IVa IVb V

8. A right pneumonectomy was performed on a 60-year-old patient for lung cancer. On day 5 post-operation, the patient suffered from productive cough and decrease of fluid level on pneumonectomy side on CXR. The patient was managed accordingly and taken to the operating room and closure of BPF was performed.

I II IIIa IIIb IVa IVb V

9. A 58-year-old patient suffered from anuria in the course of severe sepsis secondary to empyema post-left upper lobectomy. A dialysis was temporarily performed, after which the patient's renal function recovered.

I II IIIa IIIb IVa IVb V

Classifying Thoracic Morbidity and Mortality (TM&M)

10. A 69-year-old patient suffered from ARDS following right lower lobectomy for NSCLC. The patient was transferred to ICU and required intubation for 2 weeks, eventually the patient recovered and was extubated.

I

II

IIIa

IIIb

IVa

IVb

V

Classifying Thoracic Morbidity and Mortality (TM&M)

3. Thoracic Surgical Cases

Please choose the most severe grade of complication for each case (one choice per case).

Classification of Complications following Thoracic Surgery	
Grade	Definition
Grade I	Any complication without need for pharmacologic treatment or other intervention.
Grade II	Any complication that requires pharmacological treatment or minor intervention on
Grade III	Any complication that requires surgical, radiological, endoscopic intervention, or mu
Grade IIIa	Intervention does not require general anaesthesia.
Grade IIIb	Intervention requires general anaesthesia.
Grade IV	Any complication requiring ICU management and life support.
Grade IVa	Single organ dysfunction.
Grade IVb	Multiorgan dysfunction.
Grade V	Any complication leading to the death of the patient.
Complication	Any deviation from the normal postoperative course.

11. An esophagectomy and gastric pull up was performed on a 50-year-old patient. On day 8, the patient showed signs and symptoms of sepsis and anastomotic leak. The patient was taken to the OR for drainage and lavage. Thereafter, the patient was transferred to ICU, where he developed ARDS and acute renal failure which required dialysis. Eventually the patient recovered.

I II IIIa IIIb IVa IVb V

12. A 70-year-old male underwent a left lobectomy. Three days after the procedure, the patient was transferred to ICU due to increased respiratory effort and hypoxia. The patient was intubated and a large pericardial effusion was diagnosed, it was drained percutaneously. The patient was extubated and recovered.

I II IIIa IIIb IVa IVb V

13. A 62-year-old patient underwent a redo fundoplication for recurrent hiatal hernia. The patient developed a massive pulmonary embolism, which was treated with TPA. The patient was transferred to ICU where he died following a cardiac arrest.

I II IIIa IIIb IVa IVb V

Classifying Thoracic Morbidity and Mortality (TM&M)

14. A 50-year-old man underwent a right intrapericardial pneumonectomy and mediastinal dissection after which he developed atrial fibrillation. The patient was immediately started on IV amiodarone, and required ICU admission. Atrial fibrillation was reverted to sinus rhythm and the patient's condition improved.

- I II IIIa IIIb IVa IVb V

15. A 63-year-old patient underwent a bullectomy. Approximately 48 hours after the surgery, the patient experienced an acute increase in chest pain and became tachycardic. Portable chest x-ray revealed a large right-sided pneumothorax. Chest tube placement was performed, and the patient stabilized.

- I II IIIa IIIb IVa IVb V

Classifying Thoracic Morbidity and Mortality (TM&M)

3. Thoracic Surgical Cases

Please choose the most severe grade of complication for each case (one choice per case).

Classification of Complications following Thoracic Surgery	
Grade	Definition
Grade I	Any complication without need for pharmacologic treatment or other intervention.
Grade II	Any complication that requires pharmacological treatment or minor intervention on
Grade III	Any complication that requires surgical, radiological, endoscopic intervention, or mu
Grade IIIa	Intervention does not require general anaesthesia.
Grade IIIb	Intervention requires general anaesthesia.
Grade IV	Any complication requiring ICU management and life support.
Grade IVa	Single organ dysfunction.
Grade IVb	Multiorgan dysfunction.
Grade V	Any complication leading to the death of the patient.
Complication	Any deviation from the normal postoperative course.

16. A 70-year-old female patient underwent total esophagectomy, gastric conduit reconstruction and feeding jejunostomy. After verifying an intact anastomosis, the patient experienced recurrent vomiting after initiation of PO diet. An upper GI demonstrated failure of gastric emptying. Tube feeding was continued for four weeks after which the patient was able to tolerate PO intake.

- I II IIIa IIIb IVa IVb V

17. A 64-year-old man underwent an extended thymectomy. Two weeks after surgery, the patient was admitted again for pneumonia. The patient was treated with IV antibiotics and subsequently recovered.

- I II IIIa IIIb IVa IVb V

18. A 37-year-old man underwent a thoracic laminectomy. Substantial bleeding occurred during surgery. Chest radiograph demonstrated a right-sided pneumothorax. Placement of a chest tube resulted in immediate drainage of 900 mL of blood. The patient received 2U of blood transfusion. The chest tube was subsequently removed, and the patient was discharged.

- I II IIIa IIIb IVa IVb V

Classifying Thoracic Morbidity and Mortality (TM&M)

19. A 65-year-old man with history of heart disease underwent lobectomy. On post-operative days 2 and 3, the patient required additional diuretic therapy and occasional BiPAP to control congestive heart failure.

- I II IIIa IIIb IVa IVb V

20. A 44-year-old man underwent an esophagectomy. On postoperative day 5, routine chest x-ray showed moderate pleural effusion. The patient underwent a pigtail insertion under transthoracic echocardiogram guidance. Total parental nutrition (TPN) and drainage resulted in the resolution of pleural drainage and the patient was discharged.

- I II IIIa IIIb IVa IVb V

Classifying Thoracic Morbidity and Mortality (TM&M)

4. Personal Judgments

1. Do you think the TM&M classification is straightforward to understand?

Yes No

2. Do you think that the TM&M classification is reproducible (i.e. different surgeons will tend to agree on the classification of individual patient complications)?

Yes No

3. Do you think that the TM&M classification is logical (i.e. it accurately reflects level of severity of complications)?

Yes No

4. Would you consider the TM&M classification useful in your patients (i.e. it will be helpful to evaluate both presence and severity of surgical complications)?

Yes No

5. Please indicate positive aspects of the TM&M classification.

6. Please indicate negative aspects of the TM&M classification.

Classifying Thoracic Morbidity and Mortality (TM&M)

5. Thank You!

Thank you for your participation in completing this brief questionnaire on the classification of thoracic morbidity and mortality (TM&M). Your feedback, along with a national cohort of other thoracic surgeons, will be valuable in the evaluation and validation process of the TM&M tool. Your comments will help in the future development of standards of quality assessment and reporting following thoracic surgery.

1. Please indicate whether you are a:

- Resident Staff Member

2. Please indicate the number of years that you have been in practice.

- 1 - 5 years 6 - 10 years 11 - 15 years 16 - 20 years > 20 years

3. Please indicate your province of practice.

4. Please describe the type of center you practice in.

- Community Hospital (Non-academic)
 Academic Teaching Hospital (Without Thoracic Surgery Residency Program)
 Academic Teaching Hospital (With Thoracic Surgery Residency Program)

5. Are you interested in further information regarding the TM&M tool?

- Yes No

If yes, please provide your name and a valid e-mail address:

Evaluation of Thoracic Surgical Research

1. Introduction - Canadian Association of Thoracic Surgeons

This questionnaire is designed to be completed by surgeons who currently hold a membership in the Canadian Association of Thoracic Surgeons.

This questionnaire is supported by the Executive of the Canadian Association of Thoracic Surgeons in an effort to build a coherent vision for the evolution of Canadian thoracic surgical research. The questionnaire further aims to evaluate methods of quality assessment and the provision of thoracic surgical services. The questionnaire will take approximately 5 minutes to complete. Please contact Dr. Andrew Seely (aseely@ohri.ca) if you have any questions or comments.

Participation is entirely voluntary. Your refusal to participate will not result in any penalty or prejudice. All information provided will remain confidential and will only be reported as group data with no identifying information. By completing this questionnaire, consent to participate is implied.

All study data will be coded with an independent study number. The Ottawa Hospital Research Ethics Board and the Ottawa Hospital Research Institute may review your relevant study records for audit purposes. The study data will be kept for 15 years after the termination of the study and then destroyed.

If you have any questions about your rights as a research participant, you may contact the chairman of the Ottawa Hospital Research Ethics Board at 613-798-5555, extension 14902.

Thank you very much for your participation!

Evaluation of Thoracic Surgical Research

2. Thoracic Surgical Manpower

1. What is the number of full-time thoracic surgery staff members at your institution?

2. Do you have a residency training program?

Yes No

3. If you have a residency training program, how many thoracic surgery residents are at your institution?

1 resident per year 1 resident every two years 2 residents per year

Other (please specify)

4. Do you have a formal residency research program?

Yes No

5. Are your residents required to perform research at some point during their residency?

Yes No

Evaluation of Thoracic Surgical Research

3. Clinical Research Programs and Funding Opportunities

1. Are you involved directly in research?

Yes No

2. If you answered yes to the above question, please check all that apply:

- Principal investigator Collaborator
 Co-investigator Participant
 Other (please specify)

3. Do you have a thoracic surgery research director?

Yes No

4. Are you currently a thoracic surgery research director?

Yes No

5. Do you have a clinical research coordinator?

Yes No

6. If yes, what is their contract?

- 0.2 FTE (1 day per week)
 0.4 FTE (2 days per week)
 0.6 FTE (3 days per week)
 0.8 FTE (4 days per week)
 1.0 FTE (5 days per week)

7. Do you personally participate in basic science studies?

Yes No

Evaluation of Thoracic Surgical Research

8. If you answered yes to the above question, please check all that apply:

- Molecular biology, genomics Animal models
 Intracellular pathways, signalling, proteomics Human tissue
 Cell cultures
 Other (please specify)

9. Do you participate in tumour banking?

- Yes No

10. Do you personally participate in clinical research?

- Yes No

11. If you answered yes to the above question, please check all that apply.

- Retrospective chart reviews Prospective observational studies Randomized control trials
 Other (please specify)

12. What is the average number of active research studies that are ongoing at your centre in a given year?

- 0 studies 1 - 5 studies 6 - 10 studies 11 - 20 studies > 20 studies

13. What percentage of research studies have the principal investigator that is an attending thoracic surgeon at your institution?

- < 25% 25 - 50% 50 - 75% > 75%

Evaluation of Thoracic Surgical Research

14. Research Funding:

Are there research accounts with funds available to support existing or potential research projects at your institution?

Yes No

15. What is the source of these research funds? (Check all that apply)

Grants Department Industry Other

16. What is the annual budget of your research accounts?

Up to \$5,000 \$5,000 to \$50,000 \$50,000 to \$100,000 \$100,000 to \$500,000 > \$500,000

17. What are the areas of expertise or strong interest in clinical research at your institution? (List up to 3)

18. What are the areas of expertise or strong interest in basic science research at your institution? (List up to 3)

Evaluation of Thoracic Surgical Research

4. Methods to Evaluate Quality of Surgical Care

1. Do you have your own local thoracic surgery database?

Yes No

2. Rate your level of interest in initiating or improving your local thoracic surgical database.

Very Low Low Neutral High Very High

3. Do you participate in a national or international thoracic surgery database?

Yes No

4. Rate your level of interest in initiating or improving on a national thoracic surgery database.

Very Low Low Neutral High Very High

5. Rate your level of interest in participating in a national thoracic surgery database.

Very Low Low Neutral High Very High

6. Do you have a formal surgery quality assessment program?

Yes No

7. Do you monitor morbidity and mortality (M&M) regularly?

Yes No

8. Please rate the frequency of the evaluation of thoracic surgery morbidity and mortality (M&M) at your institution.

Weekly Monthly Quarterly Infrequently Never

Evaluation of Thoracic Surgical Research

5. Provision of Thoracic Surgical Oncology Services

1. Indicate the average number of anatomic pulmonary resections performed at your institution per year.

2. Indicate the average number of esophagectomies performed at your institution per year.

3. Indicate the average number of O.R. days available to your thoracic surgery division per week.

4. Is minimally invasive thoracic surgery performed at your institution?

Yes No

5. What is the percentage of lobectomies done by video-assisted thorascopic surgery?

< 25% 25 - 50% 50 - 75% > 75%

6. What is the percentage of paraesophageal hernias repaired via laparoscopy?

< 25% 25 - 50% 50 - 75% > 75%

7. Staging: Which of the following (or all) do you perform routinely in the staging of lung cancer?

- CT scan chest and abdomen
- Mediastinoscopy
- PET/CT
- MRI of the brain
- CT head
- EBUS (Endobronchial Ultrasound)
- EUS (Esophageal Ultrasound)

Evaluation of Thoracic Surgical Research

9. Would you be willing to share data on morbidity and mortality (M&M) from your center with other centers?

Yes No

10. Do you perform retrospective evaluation of morbidity on selected patient populations?

Yes No

11. Is there a formal evaluation of surgical wait times at your institution?

Yes No

12. Do you receive regular feedback regarding wait times?

Yes No

13. If yes, how often?

Monthly Quarterly Biannually Annually Other

14. Are there other systems of monitoring surgical quality? (Check all that apply)

NSQUIP

Patient satisfaction surveys

Other (please specify)

Evaluation of Thoracic Surgical Research

8. Which of the following do you perform routinely in the staging of esophageal cancer?

- CT scan chest and abdomen
- Mediastinoscopy
- PET/CT
- MRI of the brain
- CT head
- EBUS (Endobronchial Ultrasound)
- EUS (Esophageal Ultrasound)

Evaluation of Thoracic Surgical Research

6. Thank You!

Thank you for completing this questionnaire. Your feedback and comments, along with a national cohort of other thoracic surgeons, will be valuable in the understanding of the current status of Canadian thoracic surgical research.

If you would like to be directly involved in the development of a CATS research program, please include your e-mail in the space provided.