ProvenCare Lung Cancer: A Multi-Institutional Improvement Collaborative

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Abstract

Geisinger’s ProvenCare™ Program (for elective coronary artery bypass surgery, total hip replacement, and others) has shown that the principles of reliability science, facilitated by a robust electronic health record and institutional commitment, allow the re-engineering of complicated clinical processes. This eliminates unwarranted variation and promotes the completion of evidence-based elements of care. It has not been established that ProvenCare can be generalized to other institutions. Now, under the auspices of the American College of Surgeons Commission on Cancer, ProvenCare has been adapted to a multi-institutional collaborative for the care of the patient with resectable lung cancer. CA Cancer J Clin 2011;61:382-396. © 2011 American Cancer Society, Inc.

Introduction

The Institute of Medicine has defined quality as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” Implied in this statement is that professionals will provide the right care: not too much care (eg, providing unnecessary tests, medication, and procedures, with associated risks and side effects), not too little care (eg, not providing an indicated diagnostic test or a life-saving surgical procedure), and not the wrong care (eg, prescribing medicines that should not be given together, using faulty surgical technique).

Few would disagree that cancer demands quality care. This is particularly true for lung cancer. Lung cancer remains the most common cause of cancer death in the United States among both men and women. Every year, more Americans die from lung cancer alone than from breast, prostate, colorectal, and ovarian cancers combined. The primary cause of lung cancer is both known and avoidable and, although lung cancer is not a disease exclusive to smokers, tobacco exposure accounts for 85% of all cases. The US Surgeon General declared tobacco a carcinogen in 1964, yet even today more than 36% of all Americans are either current or former smokers. Similar to most cancers, lung cancer is typically silent in early stages and incurable in late stages. At least three-quarters of all lung cancers are detected in an advanced stage and the overall 5-year survival rate is a dismal 15%, which is hardly improved from the rate of 13% reported 35 years ago. Unlike most other leading causes of cancer, however, we do not routinely screen at-risk Americans for the disease. Patients with early stage disease deemed appropriate for potentially curative lung cancer surgery, therefore, represent fewer than 30% of all new cases. Sadly, the current medical literature suggests that delivery of evidence-based surgical care to these patients remains relatively unreliable and variable.
The Case for Change

Unwarranted Variation in Health Care

In 2003, McGlynn et al.9 demonstrated that patients received 54.9% of recommended (“right”) care with only moderate variation in quality-of-care scores among sociodemographic subgroups.10 For adult preventive care, on average only 50% of patients received recommended care. For adult acute care, on average only 70% of patients received recommended care while 30% received care that was not indicated. Among patients with chronic conditions, 60% received recommended care while 20% received contraindicated care.2 In addition, adult patients received only 61.9% of recommended pharmacologic care.11 Children fare less well than the adult population. Overall, only 46.5% of children receive recommended care in the clinical setting.12 This unwarranted inconsistency in care delivery results in widespread variation in procedure rates, health care expenditures, and clinical outcomes.13-15

Unwarranted Variation in Lung Cancer Care

In January 2005, Little et al presented unsettling results from an American College of Surgeons Commission on Cancer patient care evaluation to an audience of the Society of Thoracic Surgeons (STS).8 This national survey took place in 2001 and queried the practices of all surgeons performing lung cancer resections in the United States at accredited Commission on Cancer institutions. By its own estimate, the American College of Surgeons states that 70% of all cancer care in this country is delivered through health care organizations accredited by the Commission on Cancer.16 This national survey demonstrated that almost 12,000 patients had surgery for lung cancer in 2001 (29% of all cases seen that year).

As with other malignancies, clinical staging of lung cancer is critical to the overall management plan. In the absence of demonstrable distant metastatic disease, mediastinal lymph node evaluation is a cornerstone of clinical staging. Once cancer spreads to these lymph nodes, overall cure rates plummet and chemotherapy is indicated. In the study by Little et al., however, only 27.1% of all patients considered for surgery had their mediastinal lymph nodes sampled by mediastinoscopy.8 Of those patients who actually had the mediastinoscopy procedure, lymph node tissue was obtained by the surgeon in only 47%, which is quite low and not standard care.

Furthermore, during the lung resection portion of the procedure, only 58% of patients had their mediastinal lymph nodes sampled. Surgical margins were confirmed intraoperatively by frozen section in only 65% of cases, and the final pathology reports subsequently revealed a positive surgical margin in 7.8% of patients. As a side note, blood transfusion (transfusions are likely a marker of a difficult operation) and having surgery in hospitals with a volume of over 90 lung cancer resections per year (considered high volume) were both associated with better operative mortality. Subsequently, similar data were published from the STS General Thoracic Surgery Database on the surgical management of primary lung tumors. This national database was established in 1999 and initially was used by board-certified thoracic surgeons. By nature of the specialty and the years of training involved, these surgeons generally have expertise in lung cancer. It might be assumed that this group would have better process and outcome metrics than, for example, a general surgeon occasionally practicing elements of thoracic surgery. These initial data were published in 2008 and described 9033 cases entered into the database between 1999 and 2006.17 Once again, the overall rate of use of mediastinoscopy was low at 21% (worse than the previous survey), and only 65% of patients had mediastinal lymph nodes sampled at the time of the actual lung resection (slightly higher than the previous survey). In the end, only 54% of all patients had complete TNM staging documentation in the database and the authors commented specifically on this deficiency.17

At about the same time as the STS report, general thoracic surgeons at the Mayo Clinic in Rochester, Minnesota scrutinized their own efforts against a panel of patient-centered and clinically relevant quality measures in a unique quality initiative published in 2008.18 The various elements they considered were generally accepted among thoracic surgeons as standard care for patients with lung cancer. This small group of highly experienced surgeons at the Mayo Clinic aimed to review various quality indicators in an effort to improve the delivery of care to patients with lung cancer.

Thirteen separate measures were retrospectively reviewed in 333 patients and the percentage
compliance reported. Standard preoperative pulmonary function testing to assess the potential risks of lung surgery, for example, was performed in 74% of patients. Although somewhat low at face value, the actual rate of compliance was likely much higher given that 2 of the surgeons consistently relied on an acceptable alternative method (stair climbing test) rather than spirometry (Dr. Francis Nichols, personal communication, March 2011). Some form of mediastinal lymph node staging was performed in 94% of patients overall, which is arguably good in general terms. A detailed review, however, revealed that only 27% of patients underwent preresection mediastinoscopy (similar to previous studies), while 85% of patients had lymphadenectomy performed during the actual pulmonary resection portion of the procedure (better than previous studies).

The authors emphasized the importance of this internal audit as an overall quality improvement tool into which they had incorporated somewhat unique measures such as follow-up planning and National Quality Forum “never events” (eg, wrong patient, wrong procedure, wrong body part, retention of foreign body, intraoperative or immediate postoperative death of a normal American Society of Anesthesiology Physical Status I patient) in their analysis.

The group of cardiothoracic surgeons at the University of Washington in Seattle recently published a study on the impact of surgeon specialty upon processes of care and long-term survival related to pulmonary resection for lung cancer. Using the large Surveillance, Epidemiology, and End Results (SEER) database, they reviewed the care and outcomes for patients diagnosed with lung cancer between 1992 and 2002. The project “hypothesized that patients under the care of board-certified general thoracic surgeons would have higher survival rates than those under the care of general surgeons, and that differential use of processes of care might explain any observed variation in outcome.” The 5-year survival for this group of patients was indeed higher (by 11%) if their care was delivered by a general thoracic surgeon compared with a general surgeon (probably multifactorial, as explained in greater detail by the authors).

Detailed review of the processes of care, however, again revealed limited compliance with the standards of careful preoperative and intraoperative staging methods. Only 17% of patients had mediastinoscopy, only 29% had positron emission tomography (PET) imaging, and only 23% had lymphadenectomy at the time of surgery. Although general thoracic surgeons were significantly more likely to obtain PET imaging (36%) and to perform lymphadenectomy (33%), these rates of compliance are clearly suboptimal. Rates of operative mortality, prolonged length of stay, reoperation, tracheostomy, and readmission were not significantly different among the different surgeon specialties. Therefore, the authors concluded that the differences in cancer staging accounted for at least some of the improved outcomes.

The preceding information demonstrates that patients with lung cancer are not receiving generally agreed upon evidence-based care.

Eliminating Unwarranted Variation

Reliability Science

The adoption of clinical practice guidelines was promoted as a means to reduce unwarranted variation and achieve better outcomes and lower costs. Such guidelines, however, are often ignored or poorly applied. They are frequently criticized for:

- Recommending too little or too much.
- Contradicting dogma or providing reasons for insurers to deny coverage for specific drugs or devices.
- Allowing third parties (pharmaceutical and medical device companies) who have a financial stake in the outcome to provide funding for development.

Leape et al, however, suggest that physicians are more likely to follow guidelines that are evidence-based and developed by experts in the field.

Several risk-adjusted databases were launched in the late 1980s in an effort to understand the relationship between clinical practice and quality outcomes. The Northern New England Cardiovascular Disease Study Group (NNECVDSG) (1987), the Veterans Administration (VA) National Surgical Quality Improvement Program (NSQIP) (1987), the STS National Adult Cardiac Surgery Database (1989), and the Vermont Oxford Network (VON) (1989) each compiled extensive data sets on specific patient populations and through analysis began to link best practice to best clinical outcomes. There are
indications that routine feedback of risk-adjusted data on local performance from these databases to providers heightens awareness and leads to self-examination and self-assessment, which in turn improves quality and outcomes.22

Clinical guideline development and data feedback strategies have resulted in some clinical outcome improvements, but both are dependent upon individual provider adoption and integration into daily practice. As McGlynn et al9 and others have shown, the systems in which these providers practice cannot reliably guarantee patients will receive 100% of the recommended care at a clinical encounter. Reliability is defined as a system’s ability to provide failure-free operation over time. Industry has used reliability principles to improve the rate at which complex industrial processes produce expected outcomes while achieving higher levels of safety.23 The nuclear power and aviation industries are often cited as examples of complex systems that reliably produce their expected outcome (successful flights, electricity) with extremely low failure rates. For health care, reliability is successfully delivering all evidence-based components of care for a specific disease (or surgical intervention) every time, one patient at a time.

Nolan,23 Resar,24 and others propose that by adopting and adapting reliability principles found in industry, health care systems can design better processes that reliably deliver the care patients expect. Their 3-tiered strategy for process and procedure redesign is: 1) prevent failure, 2) identify and mitigate failure, and 3) redesign the process based on the identification of critical failures.23

Prevent Failure
Prevention of failure begins with the adoption by caregivers of a uniform process of care. Agreement on standard guidelines, specified processes, tools, techniques, order sets, etc is the basic framework on which reliable systems are built. Measuring adherence to the components of the process and creating timely feedback mechanisms heighten provider awareness and promote compliance with the agreed upon standards.

Identify and Mitigate Failure
The second tier of the strategy is focused on identifying instances in which the standard approach is not used and, therefore, designing into the care pathway “guardrails” that help eliminate such variations in the way tasks are performed. Most reliable systems are error-proofed by employing a variety of the following “guardrails”:25:

- Reminders: checklists or alarms that prompt specific actions.
- Differentiation: color, size, and numeric differentiation to make the right choice distinguishable.
- Constraints: making the desired action the default or restricting the performance of certain actions.
- Affordances: visual or sensory clues that ensure the product or tool is used correctly or that the action is performed as agreed upon.

Redesign of Critical Failures
The third tier of the strategy can only be implemented when the first 2 tiers are complete. Once a standardized process with “guardrails” is in place, further analysis of the process and structure in which the processes operate must be undertaken. This analysis is intended to “surface” weaknesses in the design that might lead to future failure. Once identified, mitigation strategies must be designed and built into the process.

ProvenCare: The Future State of Care
In 2005, Geisinger Health System’s (GHS) executive leadership accepted the challenge to demonstrate that a large integrated health care delivery system, enabled by an electronic health record (EHR), could successfully re-engineer a complicated clinical process, reduce unwarranted variation, and reliably deliver evidence-based care for patients with a specified clinical condition. Starting with elective coronary artery bypass grafting (CABG), they demonstrated that an improvement model that embeds evidence-based medicine into the workflow, applies the principles of reliability science (standardization, error proofing, and failure mode redesign) to the care redesign process, employs effective data feedback strategies, and engages patients in their care results in the right care delivered 100% of the time with better patient outcomes.26,27 This model was named ProvenCare and was subsequently applied to elective total hip replacement and cataract surgery.28 In 2007, GHS applied the model to percutaneous coronary intervention (PCI),28 in which multiple microsystems were required to work together to
develop a reliable pathway. A clinical microsystem is a "small group of people who work together on a regular basis to provide care to discrete subpopulations of patients. It has clinical and business aims, linked processes and a shared information environment, and it produces performance outcomes."29 These linked microsystems formed a new PCI mesosystem to support the work of providing care to this population. A mesosystem is "an interrelated set of peer microsystems that provide care to certain patient populations or support the care provided to these populations."29 The intentional “joining” of care microsystems into ProvenCare mesosystems (CABG, total hip replacement, etc) through reliability science-driven redesign has enabled GHS to deliver evidence-based care every time, one patient at a time.

GHS’s ProvenCare demonstrates that linking several improvement concepts (evidence-based guidelines, data feedback, reliability science) in a single design model can effectively reduce unwarranted variation in care delivery.

Expanding Generalizability

Application of the ProvenCare model to other areas of care within the GHS has been successful. However, the model had not been generalized to other health systems to validate its robustness and applicability for reducing unwarranted variation. To test this assumption, GHS partnered with the American College of Surgeons Commission on Cancer to assemble a workgroup from other health care systems to discuss joining together to apply the model to non-small cell lung cancer. This workgroup became a collaborative called the American College of Surgeons Commission on Cancer National Pilot Study for ProvenCare Lung Cancer.

Formation of the Collaborative Model

The early collaboratives evolved out of narrowly focused research databases. In 1987, a voluntary research consortium, composed of clinicians, hospital administrators, and research scientists, began to gather data on patients who had undergone CABG in New England. This consortium became known as the NNECVDSG. Cardiac catheterization results, comorbidity, demographic and historical data, and other related data were compiled beginning in 1987. In 1990, the NNECVDSG concluded that observed differences in mortality rates across member institutions were not attributable to differences in case mix but rather had other causes.30 The group decided to investigate what might explain these differences and to launch an intervention that became the foundation of many collaborative models that were to follow. Their intervention features 3 basic components:

- Feedback of outcome data to participating members.
- Training of all intervention teams in the techniques of continuous quality improvement.
- Team site visits to share knowledge and techniques.

All participating sites reported that the intervention resulted in changes in the process and systems of care. The observed outcomes of 6488 consecutive patients during the postintervention period indicated 74 fewer deaths than would have been expected. The 24% reduction in the hospital mortality rate was statistically significant (P = .001), and the authors of the published report concluded that a regional model for continuous improvement of surgical care is feasible and effective.31

The VON was established in 1989 with the goal of improving the care for newborn infants through a coordinated program of research, education, and quality improvement initiatives. It maintains a clinical database on very low-birthweight infants (401-1500 g) born to or admitted within 28 days of birth to member hospitals. The database demonstrated the presence of variation in mortality, morbidity, and length of stay for very low-birthweight infants among individual neonatal intensive care units (NICUs). One such variation, widely divergent nosocomial bacterial infection rates, was the impetus to launch a collaborative-like initiative in 1995. VON incorporated findings from the NNECVDSG study and expanded the methodology. Six member NICUs joined the initiative, which included:

- Multidisciplinary collaboration.
- Database feedback.
- Quality improvement training.
- Member site visits.
- Benchmarking against top performers.
- Best practice sharing.
- Performance evaluations.
After 1 year, the overall nosocomial infection rate declined from 26.3% to 20.9% \( (P = .007) \); however, the author noted that there was variation among the group with respect to whether improvement occurred and the magnitude of improvement achieved.\(^3^2\)

The VA compiled a database of 417,944 major surgical procedures performed between 1991 and 1997 in an effort to provide reliable risk-adjusted morbidity and mortality rates to hospitals within its system. With a focus on improving the quality of care for veterans, the NSQIP was initiated in 1994. Functioning like an internal collaborative, the methodology used included:

- Development of a robust database tool with data feedback to participating hospitals.
- Analysis of data by clinical experts with recommendations made in accordance with preset guidelines.
- Dissemination of information about the processes and structures of top performing hospitals to collaborative members.

During the study period (October 1, 1991 through September 30, 1997), the collaborative achieved reductions in 30-day mortality (3.1% to 2.8%; 9.6% decrease) and 30-day morbidity (17.4% to 10.3%; 40% decrease) for noncardiac surgeries performed in VA system hospitals.\(^3^3\)

The Breakthrough Collaborative Model

Conceptualized in 1994, the Institute for Healthcare Improvement (IHI) Breakthrough collaborative model was designed to accelerate improvement in health care and to overcome the slow pattern of diffusion of health care innovations. The foci for improvement were not derived from extensive narrowly defined databases but rather through a process of interviews and surveys of national clinical, administrative, and policy leaders. These “suggestions” were then evaluated using 3 criteria\(^3^4\):

- Does current prevailing practice deviate from the best evidence-based medicine?
- Will improvement produce clearly positive results by reducing costs and improving quality?
- Had the possibility of breakthrough improvement been demonstrated by at least some “sentinel” organizations?

From this analysis, the IHI identified 10 topics for the focal points of the Breakthrough Series. A key concept of the Breakthrough model that differed from the previous models was the matching of subject matter experts in a specific clinical area and quality improvement application experts with a specific collaborative focus. The methodology follows these basic steps:

- Topic selection (see above).
- Faculty recruitment and creation of the Change Package, in which subject content experts and quality improvement experts are matched with the topic. The faculty develops a model for ideal care and ideas for specific changes that, when locally applied, may significantly improve performance (the Change Package).
- Organization enrollment, in which organizations join the collaborative through an application process. Multidisciplinary teams are appointed, and Senior Leaders are expected to guide and support their team through the collaborative initiative.
- Learning sessions. There are multiple learning sessions in each collaborative. Teams meet face-to-face to learn quality improvement concepts and techniques. In later sessions, formal instruction is enhanced through team sharing of innovative changes.
- Action periods. Sequenced after each learning session, the action period is when teams apply their improvement skills to test and implement changes at their institution. Data gathering and analysis are emphasized in an effort to quantify positive change. Teams are supported by the faculty through site visits, telephone conferences, and assessments.
- Summative congress. Upon completion of the initiative, the work is documented and results are presented both internally and externally if significant change has been achieved.

IHI collaboratives typically involve from 12 to 40 organizations that work together for 12 to 15 months. The IHI states that between 1995 and 2003, it sponsored over 50 collaborative projects involving over 2000 teams from 1000 health care organizations.

Does the Collaborative Model Work?

The rapid adoption of the Breakthrough collaborative model shortly after it was introduced was impressive, considering the lack of comparative evidence that the collaborative concept was more effective than other methods for achieving and
spreading improvement. In 2002, a group of researchers involved in evaluating collaboratives in the United States, United Kingdom, and Sweden concluded:

- Collaboratives provided professional and organizational development that professionals valued.
- Interprofessional cooperation within the team and in the organization was enhanced.
- For some teams (approximately 30%), significant clinical performance was achieved more quickly than might have occurred normally; however, an estimated 30% of the organizations may drop out of the collaborative before they finish.
- Achievements of the team can be limited if a lack of senior leadership support or an unsupportive culture exist.

In his 2004 article, Mittman argues that the acceptance and reliance on the collaborative model to drive improvement is not supported by evidence but by shared beliefs and anecdotal affirmations that overstate their effectiveness. He goes on to state that: 1) most published articles in this area may be biased in favor of positive findings; 2) most published assessments of the collaborative model use uncontrolled pretest/posttest designs that do not account for secular trends (that is, trends that were not caused by the intervention and that occurred to a similar degree in nonparticipating institutions); 3) measurements often lack objective measures of clinical practice or outcome changes; and 4) systematic overweighing of evidence and observations confirm prior expectations and beliefs. Mittman, however, does concede that the collaborative method may facilitate accurate recognition and diagnosis of clinical quality problems. Collaboratives, by providing teams with the knowledge and skills to implement solutions and by generating energy and commitment to address these problems, may be the appropriate solution in some situations. Newton et al reached similar conclusions.

In an effort to evaluate the effectiveness of health care collaboratives in improving care, Schouten et al conducted a systematic review of the literature. They identified 1104 articles, of which 72 were selected for analysis. Frequently articles were eliminated because the intervention lacked structured activities facilitating the exchange of ideas and information between participating teams or did not employ the model for improvement. Sixty of the 72 articles (83%) used an uncontrolled study design; 50 of this group were based on the Breakthrough Series. Conclusions on the effectiveness of these collaboratives were difficult to reach because the study design of these reports often relied on post-measurement, did not account for secular trends, used self-report measures, and sometimes only included anecdotal information. Six of the 12 remaining articles were controlled before and after studies based on the Breakthrough Series, and 2 were randomized controlled trials. Significant improvements were noted in 5 of the 6 controlled before and after studies and in one of the 2 randomized trials.

Schouten et al conclude that the strength of the quality improvement collaborative seems to be the efficient use of experts and peers and the exchange of best practices to facilitate and guide improvement. Furthermore, the evidence underlying the collaborative strategy is positive but limited, and the effects cannot be predicted with certainty.

### A New Hybrid: The ProvenCare Collaborative

The American College of Surgeons Commission on Cancer National Pilot Study for ProvenCare Lung Cancer collaborative structure was designed to incorporate the valuable components of previous collaboratives while at the same time addressing some of their shortcomings. Its focus is to eliminate unwarranted variation in the delivery of evidence-based care to patients diagnosed with non-small cell lung cancer.

### History

In 2009, David Winchester, MD, Medical Director of Cancer Programs for the American College of Surgeons Commission on Cancer, met with one of us (G.D.S.) to discuss the practicality of translating GHS’s internal ProvenCare model to a multi-institutional platform for cancer care. If feasible, this would represent the first such ProvenCare for cancer and the first collaborative multi-institutional model. Plans were made for an organizational meeting at a central location. This meeting was held in Chicago in August 2009, with invitees chosen to represent a variety of hospital settings (academic and community, EHR and paper medical record, group and individual practitioner) in order to demonstrate that the model is generalizable.
At the first meeting in August, members were educated about ProvenCare, process redesign, and principles of collaboration. Scientific study design was discussed, as was possible linkage to data from the STS General Thoracic Surgery Database. Much of the meeting was consumed by discussion of the evidence-based elements of care for elective pulmonary resection, proposed elements for discussion having been developed by 2 of us (M.R.K. and M.A.F.) and distributed prior to the meeting.

Subsequent conference calls were held with members of the Collaborative, during which these elements were finalized. A Webinar was conducted to inform member hospitals’ administrators and chief executive officers. Two additional in-person meetings were held in Chicago, in January and May of 2010. At these meetings, participants discussed reliability science, incorporation of the EHR into the redesign process, and patient involvement; a shared

TABLE 1. Patient Compact

The Geisinger lung cancer surgery team has your health and safety as its chief concern. That is why we established the Geisinger Lung Cancer Program. Our team is committed to providing all of the care steps necessary to ensure the highest quality care before, during and after your lung cancer operation. Your active participation is one of the most important parts of this program. Medical research has shown that the more involved you are in your own care—and the stronger the partnership between you and your caregivers—the better your results will be. We believe that you will get the best result when you, your family and your Geisinger surgery team are all active partners in your care.

I commit to:

COMMUNICATING WITH MY SURGERY TEAM

✔ I will call my surgery team when I don’t understand something, when anything worries me, or if anything unexpected occurs, knowing that my surgery team will work with me until I am satisfied.

✔ I will discuss all of my current medicines, non-prescription products, vitamins or herbs as well as all of my current and past medical problems, recognizing how important this information is in guiding my care and making me safer.

INVOLVING FAMILY AND LOVED ONES

✔ I will have a trusted family member or loved one present with me during my operation and clinic visits to help support me during my care.

✔ I will work with my surgery team to develop a sensible plan for my transition from the hospital.

COMPLETING IMPORTANT CARE STEPS

✔ I will alert my surgery team before I stop or start any new medications so that we can discuss how any change might impact my care.

✔ I will use my spirometer and complete my breathing exercises as directed before and after surgery.

✔ I will follow my after-surgery precautions and instructions because I know that by following these I will be more likely to have a better recovery from my operation.

✔ I will work with my surgery team to develop a sensible schedule for my after-surgery care and follow-up clinic visits.

I realize that my decisions and my behavior have a significant positive impact on my recovery. Because I want to become and stay healthy, I fully accept my role as a partner in the Geisinger Lung Cancer Program.

[ PATIENT NAME ]

Date

I commit our team to provide all of the care steps necessary to ensure the highest quality care before, during and after your lung cancer operation.

[ PHYSICIAN NAME ]
Web-based database was finalized. Throughout these months, 2 of us (S.A.B. and K.E.M.) hosted coaching calls to assist member institutions and teams. On July 1, 2010 the project “went live” and patients were enrolled thereafter.

Members

The 6 members of the Collaborative (Fig. 1) were invited by the Commission on Cancer based upon diversity of setting and resources:

- Duke Raleigh Hospital, Raleigh, North Carolina.
- Geisinger Health System, Danville, Pennsylvania.
- Kern Medical Center, Bakersfield, California.
- NorthShore University Health System, Evanston, Illinois.
- Northwestern University Medical Center, Chicago, Illinois.
- University of Washington Medical Center, Seattle, Washington.

Among the 4 academic medical centers, 2 are urban (both National Cancer Institute [NCI]-designated Comprehensive Cancer Centers), one is suburban, and one is rural (an NCI-designated Community Cancer Center). Of the 2 community medical centers, one is suburban and university-affiliated and one is county-owned with a solo thoracic surgeon, no EHR, and minimal information technology support.

Teams at each institution included a thoracic surgeon(s), administrator, nurse, information technician, and in some cases advanced practitioner, respiratory technician, quality officer, thoracic oncology coordinator, and clinical research coordinator. Members were supported by Dr. Winchester and Connie Bura, Administrative Director, from the Commission on Cancer; Howard Tanzman, Director of Information Technology of the American College of Surgeons; and Jane Han, Manager of Quality Initiatives of the STS.

Collaborative Rules

Each team developed a Global Aim Statement. GHS’s is virtually identical to all others:

“We aim to improve the reliable delivery of evidence-based care for patients undergoing resection for lung cancer at Geisinger.”

“The process begins with the first clinic visit and ends with a written plan for ongoing care and/or surveillance for our patients.”

By working on this process we expect to:

- Decrease our complication and mortality rates.
- Increase the efficiency of our process.
- Increase the proficiency in providing evidence-based care.
- Eliminate unwarranted variation of care by all staff.

“It is important to work on this now because lung cancer is the #1 cancer killer of females and males in the US. Surgical resection offers the only cure, and the smoking and age demographic trends in NE Pennsylvania suggest that more of this care will be provided by caregivers in the Geisinger system.”

Collaborative Engagement Rules were promulgated and agreements signed. Rules included the appointment of appropriate personnel and financial resources,
## TABLE 2. ProvenCare™ Lung Cancer: All Patients Considered for Resection With Proven or Suspected Lung Cancer

| EVIDENCE ELEMENTS |
|-------------------|
| **PREADMISSION ELEMENTS** |
| 1. Treatment options will be discussed and patient preferences determined. |
| 2. Maintain beta-blockade through the perioperative period for all patients already on them. |
| 3. Determine and document preoperative use of aspirin/clopidogrel. |
| 4. Withhold warfarin for 5 d prior to surgery. |
| 5. Spirometry performed within 180 d prior to surgery and surgeon documents awareness of result. |
| 6. EKG performed within 180 d prior to surgery (if age ≥ 50 y) and surgeon documents awareness of result. |
| 7. Documentation of smoking history. |
| a. Yes/no. |
| b. If yes, then pack-y. |
| c. If yes, then smoking cessation counseling initiated. |
| 8. Chest CT imaging performed within 60 d prior to surgery and surgeon documents awareness of result. |
| 9. PET scan imaging performed within 60 d prior to surgery and surgeon documents awareness of result. |
| 10. Brain MRI obtained for any patients with clinical stage IIIA or greater disease and surgeon documents awareness of result. |
| 11. Multidisciplinary evaluation performed for any patients with stage IIIA or greater disease and surgeon documents awareness of result. |
| 12. If any prior biopsy has been performed, then a copy of the pathology report is available in the medical record and has been reviewed by the surgeon. |
| 13. Clinical performance status is measured (Zubrod and ASA systems). |
| 14. Clinical disease stage is established, discussed with the patient, and documented in the medical record. |
| 15. Patient activation (signed contract). |

| INPATIENT OPERATIVE ELEMENTS |
|-----------------------------|
| 1. Warfarin will be withheld 5 d preoperatively (if applicable). |
| 2. Preoperative antibiotics will be given. |
| 3. The appropriate antibiotic will be selected. |
| a. First choice: first-generation cephalosporin. |
| b. Second choice (allergy): vancomycin or clindamycin. |
| 4. A cervical mediastinoscopy will be performed in all patients with clinical stage IB (T2) or greater disease unless the mediastinal lymph nodes have been previously pathologically evaluated. |
| 5. At least 3 mediastinal lymph node stations sampled or dissected during resection. |
| 6. DVT prophylaxis will be accomplished preoperatively and maintained during the perioperative period using mechanical, pharmacologic, or both methods. |
| 7. Documentation of hair removal method, if done (clip, not shave). |
| 8. A universal protocol, as defined by The Joint Commission (formerly known as The Joint Commission on Accreditation of Health Care Institutions) (including surgical time out), will be performed in the operating room prior to the procedure. |
| 9. Bronchoscopy must have been performed prior to attempted resection. |
| 10. For stage T1b or greater disease (> 2-cm lesion), pulmonary resection will be accomplished in an anatomic fashion. |
| 11. If a pneumonectomy is performed, surgeon documents consideration of sleeve resection. |

| INPATIENT POSTOPERATIVE ELEMENTS |
|---------------------------------|
| 1. Although an R0 is the goal of every resection, if a pathology report reveals a positive margin, this shall be documented and the implications and alternatives for further care will be reviewed. |
| 2. Antibiotics will be discontinued within 24 h of surgery end time. |
| 3. Smoking cessation counseling will be reinforced. |
| 4. A structured postresection pulmonary toilet regimen will be used. |
a time guarantee for multidisciplinary team members, completion of a readiness assessment, sharing of data in a transparent and Health Insurance Portability and Accountability Act (HIPPA)-compliant manner, Institutional Review Board approval, and joint initial publication of results. A shared Web site was initiated.

Patients eligible for inclusion are all patients with non-small cell lung cancer who agree to be part of the study and who undergo resection for cure. Neoadjuvant treatment is allowed. Patients are excluded if the intent of the operation is palliation.

Patient Engagement
A fundamental component of ProvenCare is patient engagement. To that end, each patient signs a Patient Compact (Table 1) and marks each quadrant of a Patient Value Compass (Fig. 2). The latter encourages the patient and family to consider what is most important to them during their care and thus informs the care team. This information helps the provider develop a more patient-centered plan of care. Smoking cessation is facilitated. Postoperatively, every patient receives a written oncology plan documenting type of cancer, pathologic stage of cancer, name of operation, a plan for further treatment if indicated, and a plan for follow-up surveillance.

Evidence Development and Consensus
ProvenCare elements are selected based on evidence published in the literature and on consensus of experienced clinicians. Other clinicians might quibble with one or more elements, as we all did, but ultimately all members had to agree that the elements were reasonable and could be potentially followed 100% of the time in 100% of our cohort of patients.
A total of 38 elements were developed, and divided into Preadmission, Inpatient Operative, Inpatient Postoperative, and Postdischarge elements (Table 2). These address patient education and involvement in their care, preoperative patient assessment and proper lung cancer staging, compulsive perioperative care, anatomic resection and intraoperative staging, postoperative pain control and respiratory care, referral to medical oncology as appropriate, and a written oncology care plan (Fig. 3). Some teams have developed robust EHR tools (navigators, templates, flow sheets, order sets, alerts) to support the project (Figs. 4, 5, and 6), some are using paper checklists, and some a hybrid of each.

Data relating to compliance with the elements are entered into the shared Collaborative database. In the case of institutions that belong to the STS

This cohort includes all patients considered for resection for proven or suspected non–small cell lung cancer; patients who subsequently did not undergo resection or were found at operation to have a diagnosis other than lung cancer would be dropped from the study.
database, data are linked to the STS data for each patient in order to facilitate outcomes analysis. Institutions that do not belong will enter outcomes data directly to the shared database. Patient Value Compasses will be collected preoperatively and again at one month postoperatively for possible study of changes secondary to the care experience.

Two categories of outcomes will be studied: 1) compliance with the elements of care, and 2) clinical outcomes. A third category will be optional for individual institutions: 3) cost data and/or “pay for performance” arrangements with payors.

The primary outcome will be compliance with the elements of care, that is, can we reliably provide best practices for every patient who undergoes resection of lung cancer. All-or-none compliance will be the chief metric, since it most closely reflects the interests and desires of patients, it fosters a system perspective, and it is a sensitive measure of assessing process improvements. The Cochran-Armitage test for trend will assess process adherence to ProvenCare. Understandably, these are measures of process redesign rather than clinical outcome.

The secondary outcome will be clinical, that is, does the ProvenCare process result in decreased morbidity and...
mortality in patients undergoing resection for lung cancer. We plan to use a valid, concurrent cohort as a comparator (control) group for the ProvenCare study (experimental) group spanning the duration of the trial. The STS General Thoracic Surgery Database with quality-assured annotated clinical information serves as the control cohort. Other comparator groups may include the American College of Surgeons Commission on Cancer National Cancer Data Base, the NCI’s SEER program database, and the Nationwide Inpatient Sample data set. Analyses of the data will include, but not be limited to, pre- and postintervention comparisons, comparative outcomes during stages of the ProvenCare process design timeline, trend analysis, and concurrent matched cohort analysis with comparative databases (Fig. 7). The anticipated study population sample size is 1093 patients accrued from the 6 sites.

Some of the patient characteristics to be controlled include age, gender, comorbidities (eg, diabetes, coronary artery disease, renal disease), Zubrod score (also known as the Eastern Cooperative Oncology Group performance status score), lung cancer stage, and type of operation. Postoperative morbidities will include pneumonia, myocardial infarction, stroke, bleeding, reintubation, pulmonary embolus, and others. Mortality, length of stay, and discharge to home will be included. Although this pilot study is focused on short and intermediate outcomes, cancer outcomes can be studied. These could include disease-free survival and overall survival at various follow-up intervals.

The third category of outcomes study, cost and “pay for performance” payor contracts, has been instructive in ProvenCare CABG at GHS and will likely be equally valuable here. Such arrangements will be unique to the individual institutions and will not be shared among institutions. GHS, for example, has worked concurrently with our finance department and with our arms-length insurance partner (Geisinger Health Plan) to identify all costs that might be included in an episode of care for a patient undergoing lung cancer resection and to develop risk-based pricing. These costs begin with the preoperative visit when a decision is made to admit the patient for resection and continue through the postoperative visit when the written oncology plan is discussed with the patient. Complications and readmissions within 90 days that are related to the resection are also identified. Just as Geisinger provides a warranty for elective CABG patients, which are shown to be win-win for both provider and insurer, we will work with Geisinger Health Plan and other payors to develop a “pay for performance” arrangement for lung cancer resection.

Conclusions

Intelligence, education, and experience of providers are insufficient to ensure the elimination of unwarranted variation and the completion of evidence-based care for the patient with resectable lung cancer. Institutional commitment, a robust EHR, and the principles of reliability science enabled GHS to re-engineer complicated clinical processes and reduce unwarranted variation for CABG, total hip replacement, cataract surgery, PCI, and, more recently, neonatal care: a program collectively known as ProvenCare.

But can ProvenCare be taken beyond a single institution? Is an EHR necessary for success? In short, can ProvenCare and similar programs based on the same principles be generalized? Our test is this pilot study, the ProvenCare Lung Cancer Collaborative.

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