Adopting Integrated Care Pathways in Non–Small-Cell Lung Cancer

From Theory to Practice

Gianpiero Fasola, MD, Simona Rizzato, MD,* Valentina Merlo, MD,* Marianna Aita, MD,* Tino Ceschia, MD,† Francesco Giacomuzzi, MD,‡ Emilio Lugatti, MD,§ Stefano Meduri, MD,‖ Angelo Morelli, MD,¶ Maurizio Rocco, MD,# and Valeria Tozzi, PhD***

Introduction: Integrated care pathways (ICPs) have been proposed as effective strategies for quality improvement. To date, limited data are available that detail the methodology to design an optimal care pathway for patients with non–small-cell lung cancer (NSCLC). The main aim of this study was to assess the quality of health care delivered to lung cancer patients referred to a hub university hospital.

Methods: All professionals involved with the management of NSCLC patients, in cooperation with health care researchers, identified 11 quality indicators and associated benchmarks. These were used to estimate the quality and efficiency of health care delivered to a cohort of 175 NSCLC patients.

Results: The gap between "desired" and "actual" performance has been measured by benchmarking current practice against key quality indicators. Diagnostic workup, multidisciplinary team care and medical treatment of advanced disease have emerged as areas of good performance. Conversely, the management of early-stage disease offers room for improvement, in terms of both accuracy of nodal staging and surgical timeliness.

Conclusions: Analyzing the process of caring for NSCLC patients is feasible and offers room for improvement. Acquired knowledge may be shared with hospital administrators, guide the revision of ICPs, and enable the delivery of consistent, high-quality clinical standards.

Key Words: Health care indicators, Integrated care pathways, Non–small-cell lung cancer, Quality improvement.

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Lung cancer is the most common cancer and the leading cause of cancer death in men worldwide. In women, it is the fourth most frequent cancer and the second leading cause of cancer death.[1] The management of patients with suspected or known lung cancer is becoming increasingly complex, because state-of-the-art care requires input and coordination among many different specialty competencies.

So far, limited data exist detailing how these patients flow through the health care system, the sequence of activities performed, and the delays and barriers that may interfere with the patient journey, from the point of diagnosis onward. Inadequate literature exists describing well-tested methodologies to develop an optimum care plan for this specific patient group. The wide availability of evidence-based guidelines and the institution of multidisciplinary teams and meetings has improved both clinical effectiveness and service coordination among hospital departments, but does not automatically translate into the development of leading-edge care models.[2]

Integrated care pathways (ICPs) are structured, multidisciplinary care plans for a specific clinical condition, which describe the tasks to be pursued, their timing, sequence, and the professionals and departments involved.[3] ICPs are emerging as strategies of improvement from the perspective of professionals, organizations, and patients, and they may encourage the enforcement of clinical guidelines in routine practice. They provide a means to improve multidisciplinary communication and care planning, to optimize the safety and quality of care, and to increase patient satisfaction. This approach also allows for systematic collection and clinical data extraction for audit purposes, promoting the identification of research and development questions.[4] ICPs are particularly meaningful in teaching hospitals, because they support a continuous process for quality improvement, through the adoption of innovations coming from research and teaching.[5]

The selection of proper quality-of-care indicators is a critical step in the development of ICPs. Quality indicators have been defined as "measurable elements of practice performance for which there is evidence or consensus that they can assess the quality of care."[6] In other words, they represent milestones against which to measure a patient's progress along a care pathway by comparing them with literature-derived standards or stakeholder values. Once developed, ICPs should

*Departments of Oncology, †Radiation Therapy, ‡Nuclear Medicine, §Pulmonology, ‖Radiology, ¶Thoracic Surgery, and #Pathology, S. Maria della Misericordia University Hospital, Udine, Italy; and **CERGAS (Center for Research on Health and Social Care Management), Bocconi University, Milan, Italy.

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Address for correspondence: Gianpiero Fasola, MD, Department of Oncology, S. Maria della Misericordia University Hospital, P.le S. Maria della Misericordia 15–33100 Udine, Italy. E-mail: fasola.gianpiero@aoud.sanita.fvg.it

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be shared and supported by hospital administrators, reflecting the organization's aims and philosophy, and being delivered within the framework of its strategic plan.

The aim of this study was to map the existing health care pathway of non–small-cell lung cancer (NSCLC) patients referred to the University Hospital of Udine from January 1, 2008 to December 31, 2008; to use a number of selected, relevant indicators to measure overall process performance; and to identify opportunities for improvement and a model to guide the design of tailored ICPs. The ultimate aim is the construction of a directional dashboard allowing for the routine monitoring of the hospital performance as a result of the introduction of ICPs.

MATERIALS AND METHODS

This study applied a methodological framework derived primarily from the work by Ouwens et al.,[7] although its retrospective nature entailed less patient involvement in the sharing of performance indicators. The study was conducted in a teaching institution that is a result of the merger of a regional hospital and a university hospital. With almost 1000 beds, this hospital consists of 14 integrated departments, covers nearly all major specialties, and is a regional referral center serving a population of approximately 1 million inhabitants in the northeast of Italy.

This study project was developed collecting data and information from both expert panels and the hospital information system. Two working groups were established. The first was a steering committee, consisting of both professionals and health care researchers who were involved in study planning and operational organization, performed a critical data evaluation, and guided the tailored revision of current clinical pathways. The second was a professional focus group of specialists involved in the management of NSCLC patients, i.e., medical oncologists, pulmonologists, radiologists, thoracic surgeons, pathologists, nuclear medicine physicians, and radiotherapists. As a multidisciplinary group, these professionals have met on a regular basis for 20 years to discuss selected cases, share information, and jointly agree on the best management plan for an individual patient. Health care researchers from Bocconi University, Milan, were invited to join these meetings to lead the focus group in an additional final session.

The specific contribution offered by the team of health care experts mainly concerned the methodological approach to the research. Indeed, health care researchers helped clinicians to identify current practices and processes and to map them in a flowchart, i.e., a graph using codified symbols to depict the order of steps in a particular process. Furthermore, they supported the selection and operalization of quality or performance indicators.

The following activities were carried out by the focus group:

1. Mapping of the existing local care process. Group members graphically depicted in an organizational map the order of steps in the current care pathway of NSCLC patients, from the first hospital visit to the follow-up phase. Because of the need for different management strategies, separate flowcharts were drawn up for patients with early, locally advanced, and metastatic disease, respectively. The map aimed to detail the temporal sequence of care and activities performed, the role and responsibilities of each unit involved, and the relationships between different individuals and departments. The care process was divided into three phases—diagnosis and staging, treatment, and follow-up—to improve the level of detail.
2. Selection of quality-of-care indicators. Among 21 initially available indicators, 11 were selected based on three main properties, i.e., validity—the ability to assess both clinical and organizational aspects of current care, feasibility of automatic data extraction from the hospital information system, and reliability—the reproducibility of measurement over time. An additional reason for their selection was the availability of a corresponding benchmark, which was derived from previous studies, international professional guidelines, ICP-specific literature, or according to the experts' opinion. Indeed, because of the limited availability of evidence on organizational standards, related indicators and benchmarks were developed using group-facilitation techniques designed to explore the level of consensus among a group of experts and to aggregate judgments into refined agreed opinions.[6]
3. A retrospective analysis of the quality level of existing care pathways. One hundred and seventy-five NSCLC patients, who were referred consecutively to the Department of Oncology of Udine University Hospital from January 1 to December 31, 2008, were identified. Patient age, sex, pathological diagnosis, disease stage, and performance status were recorded. Data were collected on all the diagnostic, staging and treatment procedures performed. The care processes were reviewed from 3 months before diagnosis to 12 months after, and their quality level assessed by applying selected indicators.

RESULTS

Figure 1 illustrates an example of process mapping, showing the management flowchart for IIIA-N2 patients. As previously mentioned, separate diagrams were drawn for patients with disease stage I, II and selected IIIA; IIIA-N2; selected IIIB (i.e., no pleural effusion and no supraclavicular node involvement); and IIIB-IV (American Joint Committee on Cancer tumor, node, metastasis (TNM) staging system, 6th edition, 2002).[7] Diagnosis, treatment by stage, and follow-up phases were analyzed separately. Distinct graphs were also drawn to represent the follow-up of patients with active versus no evidence of disease, respectively.

As shown, common and predictable events are arranged on two axes. The vertical axis represents the temporal sequence of health activities and their causal relationship. Involved hospital units and the relationships among different individuals and departments are plotted on the horizontal axis. Codified symbols are used to indicate the starting and ending points of the pathway, and clinical episodes, critical decision-making moments, and document management, respectively (Fig. 1).

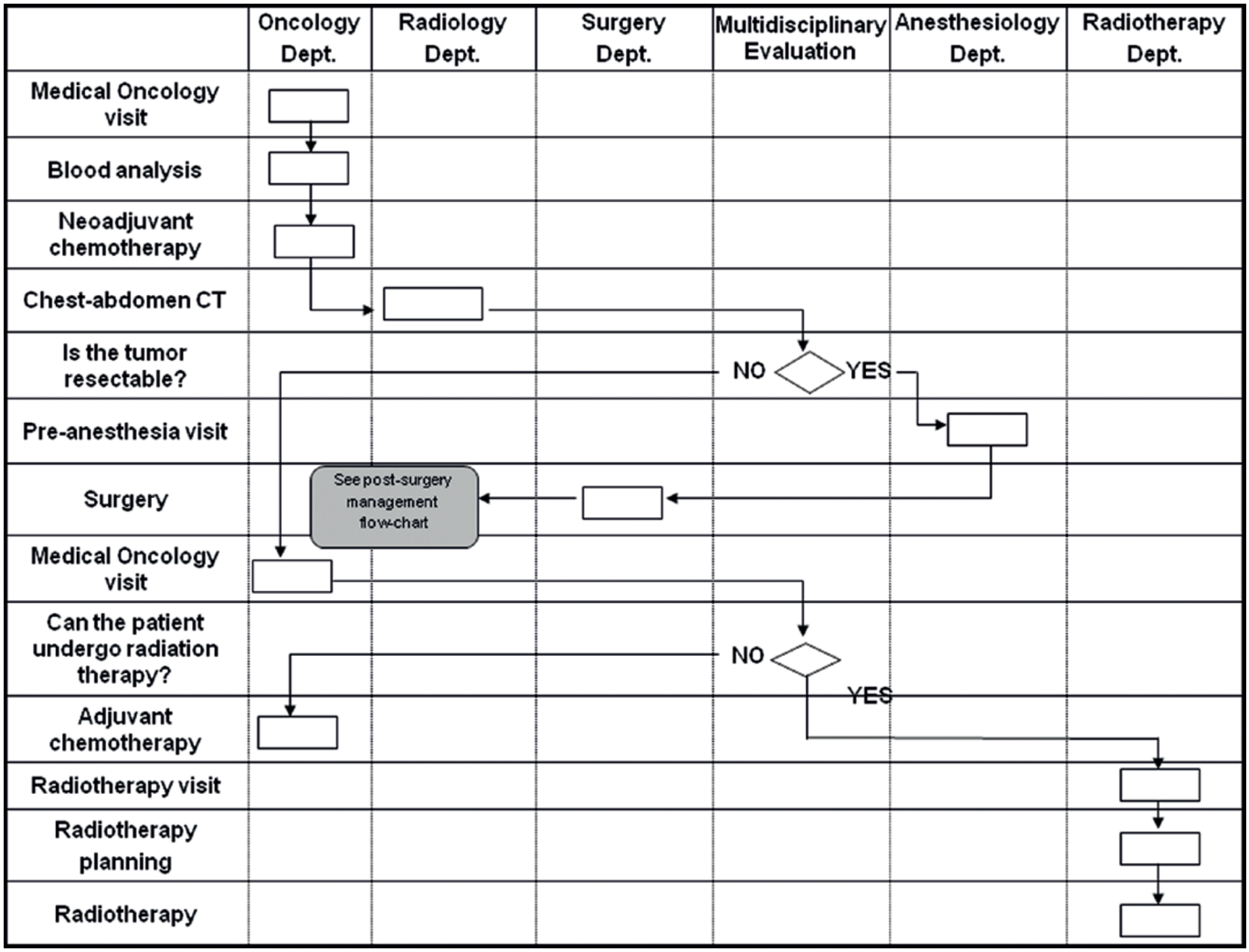

FIGURE 1. Flowchart of the management steps of stage IIIA-N2 patients demonstrating an example of the local care process.

Once developed, the map may be analyzed in light of selected indicators to identify problem areas such as duplication, delays, service shortfalls and nonadherence to guidelines. A list of selected indicators and their description is provided in Table 1. Associated benchmarks were derived from specific literature,[8–18] if available, or produced by consensus among the focus-group experts.

With this premise, the care pathway of 175 NSCLC patients who were admitted to the University Hospital of Udine over the study period was retrospectively reviewed. Main patient characteristics are summarized in Table 2. Briefly, 71% were men, the mean age was 68 years, and most (80%) were classified as having locally advanced or metastatic disease.

The information systems of both the whole hospital and of the oncology unit, which provides a full suite of department-specific information, were queried to retrieve critical information. Selected indicators were applied to measure the quality of health care delivered to the study population (Table 1).

The median time from first admission to the Pulmonary Unit (PU) to the first visit with a medical oncologist (indicators 1a–1b) was different for patients with stage I–IIIA disease ($n = 29$; 84 days) and those with advanced disease ($n = 85$; 28 days), corresponding to the upper and lower bounds of their respective benchmark time intervals.[8,11]

Timeliness of cancer diagnosis was measured as median time from both first bronchoscopy to pathological diagnosis (indicator 3; $n = 131$) and from first admission to the PU to pathological diagnosis (indicator 4; $n = 116$). Results compared well against external benchmarks, with median times of 5 versus 7 days and 16 versus 15 to 20 days, respectively.[10–14]

The median time from computed tomography-positron emission tomography (CT-PET) to surgery in potentially resectable patients (indicator 2; $n = 25$) was within the benchmark values (23 days, interval values 14–28 days),[12–15] whereas scores of overall surgical timeliness—measured as the median time from pathological diagnosis to surgery (indicator 5a; $n = 19$)—performed poorly against literature benchmarks (50 versus 28–35 days).[8,11,15] As for the medical

TABLE 1. Selected quality indicators and corresponding benchmarks.

Indicator	N of patients	Median/ percentage	Benchmark/ benchmark interval values
1a - Time from 1st admission to the Pulmonary Unit to 1st oncology visit (stage I-IIIA), days	29	84	56–84 (B)
1b - Time from 1st admission to the Pulmonary Unit to 1st oncology visit (stage IIIB-IV), days	85	28	28–42 (B)
2 - Time from CT-PET to surgery, days	25	23	14–28 (B)
3 - Time from the 1st invasive diagnostic procedure to pathological diagnosis, days	131	5	7 (B)
4 - Time from 1st admission to the Pulmonary Unit to pathological diagnosis, days	116	16	15–20 (A)
5a - Time from pathological diagnosis to surgery, days	19	50	28–35 (B)
5b - Time from pathological diagnosis to chemotherapy, days	104	26	14–21 (B)
6 - Patients who underwent a cervical mediastinoscopy following a CT-PET before surgery, %	37	3 (%)	80–100 (A)
7 - Patients for whom there was evidence of a multidisciplinary evaluation, %	175	50 (%)	55 (A)
8 - ECOG PS > 1 patients receiving a doublet chemotherapy, %	9	0 (%)	0 (A)
9 - Patients receiving more than three treatment lines, %	104	0 (%)	0 (A)
10 - Per-patient yearly number of oncology visits, average number	104	18	16 (A)
11 - Patients who received an active medical treatment within 30 days of death, %	104	16 (%)	20 (B)

PS: performance status
(A) According to evidence based guidelines or to ICP-specific literature; (B) According to expert consensus.

TABLE 2. Main patients' characteristics.

Characteristics	N = 175	Range/ Percentage
Average age* (years)	68	40–88
Male/Female	125/50	71%/29%
Disease stage*		
I	19	11%
II	16	9%
III	44	25%
IV	96	55%
First treatment		
Surgery	40	23%
Radiation therapy	6	3%
Chemotherapy	89	51%
No treatment	29	17%
Not applicable#	11	6%

*At first medical oncology visit
#First treatment performed at another center

treatment of patients with advanced disease, the median time from pathological diagnosis to chemotherapy (indicator 5b; $n = 104$) was slightly higher than the benchmark upper value (26 days versus benchmark interval values of 14–21 days).[8,11,15]

A CT-PET was performed within 3 months before radical surgery in 23 of 37 patients with early disease. Of three patients with positive mediastinal nodes on CT-PET, none underwent invasive nodal staging. Conversely, a mediastinoscopy was performed in one patient despite negative PET findings. Overall, 3% of potential surgery candidates underwent a cervical mediastinoscopy after a CT-PET (indicator 6).[8,12] The proportion of patients receiving a multidisciplinary evaluation (indicator 7; $n = 175$) seemed well aligned to the benchmark,[8,12] as well as the yearly number of consultations for each patient started on medical treatment (indicator 10; $n = 104$).[17]

Finally, a high-quality level was detected when indicators of appropriate medical treatment (indicators 8, 9, and 11) were measured. No patients with Eastern Cooperative Oncology Group performance status ≥ 2 (indicator 8; $n = 9$) received a two-drug combination.[13,14,16] All patients received a maximum of three treatment lines (indicator 9; $n = 104$), corresponding to the benchmark value;[13,14,16] only 16% of patients (benchmark value, 20%) received an active medical treatment within 30 days of death (indicator 11; $n = 104$).[18]

DISCUSSION

International health systems have been under significant pressure in recent years, facing a precarious balance between resource supply and service demand. Cancer care systems are particularly challenged by additional factors, including an aging and growing population, increasing cost of drugs and technology, and projected workforce shortages.[19] Sullivan et al.[20] detail how urgent solutions are needed, including a reengineering process of the macroeconomic basis of cancer costs, a transparent regulatory system and, importantly, a greater education of policy makers. The US Congress seems to have taken up the challenge: Title VIII of the American

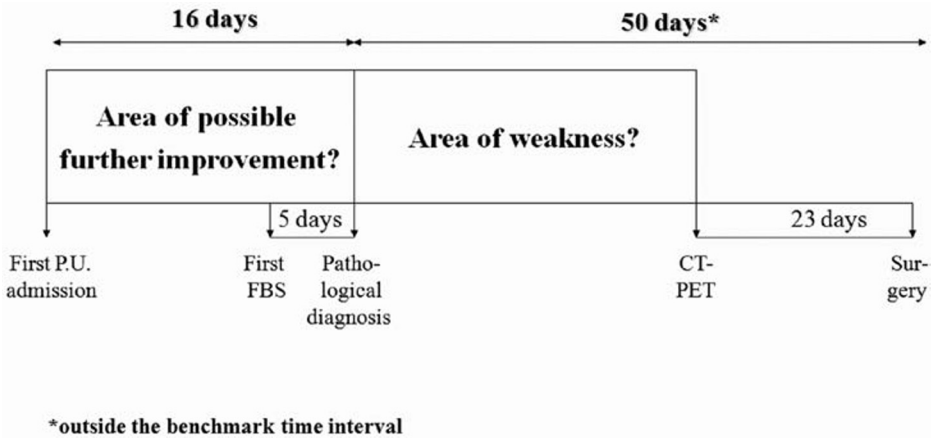

FIGURE 2. Time interval from first admission to the pulmonary unit of patients with early disease to surgery demonstrating areas of weakness and room for improvement. PU, pulmonary unit; FBS, fibrobronchoscopy.

Recovery and Reinvestment Act of 2009 authorizes the expenditure of $1.1 billion to conduct research comparing "clinical outcomes, effectiveness, and appropriateness of items, services, and procedures" related to the world of health care.[21] Several reports exist of significant benefits associated with the introduction of ICPs into clinical practice,[4] including an opportunity for health care cost reductions.[22]

Cancer patients frequently experience fragmented health care journeys and suffer from a lack of continuity of care.[23] Their management is often planned only as far as the next consultation, rather than being scheduled for the whole sequence of events that are foreseen from the point of diagnosis, with consequent higher costs and loss in time and efficiency.[24] Integrated disease management has emerged as an innovative strategy to deliver high-quality health care and align affordability with principles of equitable and universal access.[4]

Our study shows the feasibility of process mapping as a tool to elicit the delivery of care at every step of the lung cancer patients' journey in a hub university hospital; to monitor its alignment to international guidelines; and to develop proposals for a revised pathway, ensuring services are delivered in a coherent and timely manner. In our experience, such activity also allows cancer specialists to acknowledge the professional skills acquired as a multidisciplinary group and the emergence of both a clinical and an organizational know-how. Together with process mapping, the identification and selection of proper quality indicators is an essential step toward drafting a revised care pathway, because quantifying adherence to performance indicators may provide the foundation for quality improvement.[22,25]

Our internal benchmarking process has highlighted the management of NSCLC patients with early disease as the most critical area, in both clinical and organizational dimensions. Because this patient group may have a better long-term prognosis, maximum effort should be made to ensure them the delivery of ready and well-coordinated services, despite the high complexity of procedure requirements. In our analysis, the median time from first admission to the PU of patients with early disease to the first visit with a medical oncologist (indicator 1a)—which may influence a patient's chance of receiving adjuvant treatment—was 84 days, corresponding to the upper bound of the benchmark time interval. As the median time from CT-PET to surgery (indicator 2) seems to be well aligned to the benchmark, one could speculate that most organizational problems correlate with delays in the diagnostic/staging procedures preceding PET (Fig. 2). Another possible explanation is a time delay between surgery and referral to oncology consultation. In a retrospective review, 50% of NSCLC patients who underwent radical surgery were referred to medical oncology for consideration of adjuvant chemotherapy. Where stated, reasons for not referring were as follows: postoperative complications ($n = 15$), comorbidities ($n = 10$), patient refusal ($n = 9$), surgeon's decision ($n = 6$), disease progression ($n = 3$), advanced age ($n = 3$), other cancer ($n = 1$), and time delay believed too long ($n = 1$).[26] These findings emphasize that previously reported delays or surgeons' negative attitude[27] toward the benefits of adjuvant chemotherapy may still persist despite multidisciplinary meetings and published guidelines on waiting-time targets.[28]

Surgical timeliness (indicator 5a) represents a further critical area. This may be associated both with the process weaknesses highlighted in Figure 2 and with a disproportion between the number of skilled surgeons and operating sessions and the increase in patient volume.

Results for indicator 6 suggest that the surgical journey of lung cancer patients through the hospital environment also suffers from a lack of appropriateness, with no surgical candidate with positive PET findings undergoing mediastinoscopy. Accurate mediastinal staging is the hallmark of a sound thoracic oncology program and represents the primary tool for making treatment decisions for NSCLC patients.[29] Current guidelines advocate mediastinoscopy as the gold standard staging technique in patients with positive CT/PET findings. In a retrospective study of NSCLC patients having undergone single (CT only), bi- (CT and PET or CT and mediastinoscopy), or tri-modality (CT, PET, and mediastinoscopy) staging, the significant increase over time in the use of bi- and tri-modality staging seemed to be mostly the consequence of a growing use of PET, whereas invasive staging decreased from 9% to 8% (p trend 0.005). Recent scientific evidence that a high negative predictive PET value reduces the need for invasive staging is a possible explanation of such trends, but alternative reasons may be a limited

access to adequately trained thoracic surgeons, or the false perception that PET may be a proper and safer staging substitute.[30] A relative paucity of experienced surgeons and of available surgical sessions have been identified by our internal auditing as main reasons for the poor performance of indicator 6.

Finally, some opportunities for improvement may be identified in the timeliness of both staging procedures in patients with advanced disease (indicator 5b), and of cancer diagnosis (indicator 3). Indeed, despite the observation of short waiting times from first bronchoscopy to tumor diagnosis, the authors believe that the onsite assessment of bronchoscopy samples by a cytopathologist might significantly improve the diagnostic yield, reducing the rate of specimen inadequacy and the need for repeat examinations, as well as costs and patient discomfort.[31]

This study has demonstrated that good performance levels have been achieved in the area of medical treatment of patients with advanced disease (indicators 8, 9, and 11). These results gain particular importance in terms of quality assurance, because corresponding indicators are based on level 1 evidence and show high consistency across national and international guidelines.

It is worth noting that the proportion of NSCLC patients for which there was retrospective evidence of a multidisciplinary evaluation was near optimal (50%, versus a benchmark value of 55% —indicator 7). This is an essential finding because multidisciplinary team meetings are widely accepted as a means to significantly impact on the quality of patient care by improving communication flow among team members; optimizing management strategies, waiting times and cost effectiveness; providing opportunities for education and learning to its members; and fostering the identification of suitable patients for inclusion in clinical trials.[32] However, limited evidence exists correlating multidisciplinary teams' management with improved clinical outcomes, particularly with survival.[33]

Indicator 10, which refers to the number of per-patient yearly consultations, seems slightly higher than the corresponding benchmark value. However, the number was derived from a database also including breast and colorectal cancer patients, who are less frequently diagnosed with advanced disease and may be assumed to require fewer medical reevaluations. The yearly number of per-patient visits is an exquisite organizational indicator; indeed, we have previously demonstrated that it represents the main variable of a simple model allowing the forecast of the human resource needs of a cancer unit. It may be argued that the identification of leading determinants of health care expenditures other than drug costs may be important in setting priorities for resource allocation and in revealing significant opportunities for cost saving.[17]

This study presents some limitations. First, it is a retrospective review covering a limited 12-month period and including a relatively small sample of 175 patients, although these figures are not so far from those presented by Ouwens et al.,[8] with 276 newly diagnosed patients analyzed during a 6-month period.

Second, some robust indicators of the quality of care, such as perioperative mortality, postoperative length of stay, or the proportion of surgical patients with stage II–III NSCLC who were administered adjuvant chemotherapy, are lacking. Unfortunately, the reliability and feasibility of automatic extraction of specific data may be compromised by some level of uncertainty in disease and/or procedure codes within the hospital information system. As for the number of patients undergoing adjuvant medical treatment after radical surgery, the analysis was further hampered by the fact that, even though our Thoracic Surgery Unit is a regional referral center, several patients may be subsequently treated and followed up in local cancer units other than ours. Still, these drawbacks may also be seen as an opportunity for improvement, contributing to the identification of system inadequacies and unreliable behavior, and stimulating the search for solutions.

Third, this is a single-center study, whereas an accurate assessment of quality indicators probably requires pooling data from multiple sources across a broad region. However, it should be considered that our hospital represents the region's leading medical center and serves as the referral facility for the vast majority of lung cancer patients of this geographical area. Rather, in an ongoing study we are making an effort to include in the analysis all phases of the continuum of care, from initial diagnosis suspicion to post-treatment/postdischarge care. As shown by Lo et al.[10] some benefit may arise from focusing on the whole continuum of care, such as an earlier disease diagnosis.

In any case, it should be pointed out that the visit to a pulmonologist represents the first step of the care pathway for nearly all the lung cancer patients who are referred to our university hospital. This direct-access modality has been the item of an official meeting between hospital representatives and local general practitioners, and is regulated by a formal agreement document.

In general, at each phase of their journey, patients encounter a new set of clinicians: general practitioners during the prevention and screening phases; pulmonologists, radiologists, and surgeons in the diagnostic phase; and oncologists, radiation oncologists, and surgeons at the time of treatment. After treatment, patients often return to primary-care settings and encounter specialists in rehabilitation and palliative care.[34] Quality of care may be impaired by both breakdowns in specific types of care delivered to patients at different points of their history and during the transitions between these types of care.[35]

Finally, our study focused on professional- and organizational-quality indicators, with less attention posed on patients' perspective and no direct involvement of patients or their caregivers, a factor that the specific literature identifies as substantial for a comprehensive development of ICPs.[36] Patient recommendations should be incorporated into evidence-based clinical guidelines for a patient-centered management of cancer and translated into quality indicators.[37] Measuring the level of patient centeredness of cancer care will be a primary aim of a future prospective study currently being planned at our institution.

The strengths of this study lie mainly in its level of analysis. Indeed, for the first time the health care pathways of NSCLC patients have been distinguished and analyzed by stage, improving the level of detail and easing the identification of specific problem areas, which may require differently targeted strategies of improvement. This study has been conducted in an almost fully computerized hospital, a feature which has expedited the identification of a suitable cohort of patients and assisted in the selection of indicators that might be easily retrieved from the hospital medical record system.

These projects—arising from the desire of further focusing on clients' needs—have the potential to exert a profound influence on the participants of multidisciplinary meetings; moreover, the presence of different professional figures, specifically management experts and researchers promotes the development of a new, interprofessional perspective, providing opportunities to learn and reflect critically on one's own knowledge base.

Once key areas for improvement were identified and considerable time was spent to evaluate and select suggestions for change, focus-group members developed an amendment proposal to the existing care process. The document was submitted to and evaluated by the steering committee for ease of use, effectiveness, and final acceptance. It will soon enter into a negotiating process between physicians and health care executives for its official endorsement and adoption by the organization.

In conclusion, our study demonstrates that the introduction of the general principles of ICP methodology in a teaching hospital is feasible and allows the assessment of the quality level of the health care delivered to a specific patient group/population. This knowledge may be shared with hospital managers and executives with the aim of reengineering care delivery focusing on processes, people, and technologies.

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