



# Evidence-Based ONCOLOGY™

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## ALSO IN THIS ISSUE



### VALUE-BASED PURCHASING AND MORE.

A session of the Institute for Value-Based Medicine® (IVBM) in Nashville, Tennessee, offered highlights of where value-based purchasing works and where it doesn't, as well as an overview of where the Oncology Care Model (OCM) has succeeded and where it needs work, [SP350-SP351](#).

### RADIATION ONCOLOGY.

Miranda Lam, MD, presented the attendees at IVBM with data and issues surrounding CMS' proposal for the mandatory Radiation Oncology Model, [ajmc.com/link/4408](#).



LAM

**COA PAYER EXCHANGE SUMMIT.** Community Oncology Alliance (COA) invites shared stories of success with the OCM as well as challenges as practices weigh the future of 2-sided risk in Tyson's Corner, Maryland, [SP356-SP358](#).

**AMCP NEXUS.** Data collaboration, genomic testing, and the review of the pharmaceutical pipeline were highlights of the Academy of Managed Care Pharmacy (AMCP) Nexus 2019 meeting in National Harbor, Maryland, [SP358-SP361](#).

### MULTIPLE MYELOMA DISPARITIES.

New results show that novel therapies for multiple myeloma take longer to reach African American and Hispanic patients, [SP370](#).



## COMMENTARY

### Empower Physicians to Fight Financial Toxicity With Biosimilars

*Kathy Oubre, MS*

**ONCOLOGY PRACTICES SEE THE TOLL** financial toxicity<sup>1</sup> exacts on patients and their families every day. The financial burdens of cancer treatment are damaging even when they don't directly affect care—and research shows that all too often, they do. Patients struggling under the burdens of cancer care are more likely to be nonadherent with their prescribed treatment regimen, failing to fill prescriptions, delaying office visits, and forgoing critical diagnostic tests.<sup>2</sup> More affordable care is better care, and payers should empower providers to steer patients toward superior-value options whenever available. When it comes to oncology biologics, this means giving providers the power to prescribe biosimilars.

CONTINUED ON SP374 »

## ONCOLOGY CARE FIRST

### Can Cancer Care Lead the Way Toward a Value-Based Future?

*Keely Macmillan, MPH*

**THE 2019 MEDICARE TRUSTEES REPORT** forecasts insolvency of the Hospital Insurance Trust Fund in 2026, sooner than prior projections.<sup>1</sup> A significant contributor to this unsustainable healthcare cost curve for Medicare beneficiaries is cancer-related spending.<sup>2</sup> To address this challenge, Medicare is engaging oncologists through new, value-based programs to identify ways to reduce inefficiency and unwarranted variation in spending.

On November 1, 2019, CMS released an informal request for information (RFI) on Oncology Care First (OCF), the highly anticipated successor to the current Oncology Care Model (OCM), which sunsets in 2021. The RFI, which solicits feedback through the extended deadline of December 13, 2019, is an important step in the development of successful models with robust engagement.<sup>3</sup>

CONTINUED ON SP377 »

## ADVOCACY PERSPECTIVE

### Improving Survival in Lung Cancer: Commitment of The Lung Ambition Alliance

*Giorgio Scagliotti, MD, PhD*

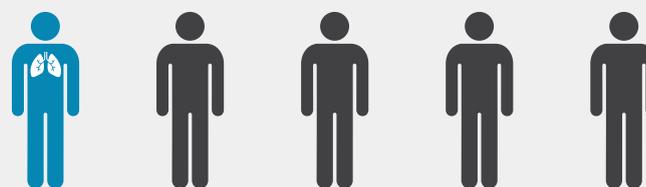
**FOR TOO LONG**, lung cancer has had one of the worst prognoses of any cancer. It is the leading cause of cancer-related deaths worldwide (**Figure 1**); only 1 in 5 people with lung cancer will be alive 5 years after diagnosis.<sup>1,2</sup>

New advances are creating the opportunity to transform the diagnosis, treatment, and management of lung cancer. However, survival rates have improved only modestly and are lagging behind those of other common cancers (**Figure 2**).<sup>3</sup> The time for us to act is now: to come together as a community, to bend the lung cancer survival curve faster, and to significantly improve patient outcomes in this devastating disease.

CONTINUED ON SP387 »

Approximately **1 in 5** cancer deaths are attributed to **lung cancer**.

SP387



Source: World Health Organization, International Agency for Research on Cancer, Latest global cancer data: Cancer burden rises to 18.1 million new cases and 9.6 million cancer deaths in 2018. [who.int/cancer/PRGlobocanFinal.pdf](#). Accessed November 22, 2019.

## ADVOCACY PERSPECTIVE

# Improving Survival in Lung Cancer: Commitment of The Lung Ambition Alliance

Giorgio Scagliotti, MD, PhD

## CONTINUED FROM COVER

For more than 45 years, the International Association for the Study of Lung Cancer (IASLC), with our membership of nearly 6500 lung cancer experts worldwide,<sup>4</sup> has been working tirelessly toward a world without lung and other thoracic cancers. The task is immense as lung cancer is, and to add strength to our efforts we recently joined with other leading organizations in the lung cancer space to create a powerful force for change: The Lung Ambition Alliance (“The Alliance”).

The Alliance unites the IASLC, the Global Lung Cancer Coalition, AstraZeneca, and Guardant Health with a common goal: to one day eliminate lung cancer as a cause of death. To achieve this bold goal, we will start by doubling the 5-year survival in lung cancer by 2025.

Improving survival rates in lung cancer is both complicated and multifactorial; thus, our plans must be varied and dynamic to address each barrier to ensure optimal outcomes. We need to move beyond existing prevention efforts to target every point in the patient journey with innovative and effective strategies. This includes establishing early diagnosis through broader screening guidelines, developing more innovative medicines, and ensuring the best quality of care and support for patients and families.

The Alliance has identified 3 priority areas that align with critical points in the patient journey, and we are already undertaking several flagship projects, focused on these priority areas, to create positive change in the lung cancer landscape.

## Increasing Lung Cancer Screening and Early Diagnosis

Late diagnosis is a key reason that survival rates for lung cancer are so poor.<sup>5</sup> Forty percent of patients are diagnosed after cancer has already spread beyond the lung.<sup>6</sup> To significantly shift the survival curve, we must diagnose and treat patients at earlier stages of disease. Because early-stage disease is often asymptomatic, this can be done only by improving lung cancer screening.

The IASLC has focused on improving lung cancer screening for some time. In October 2018, we issued a statement supporting the findings of the Dutch–Belgian NELSON (Nederlands-Leuven Longkanker Screenings Network) Randomized Lung Cancer Screening Trial<sup>7</sup> and the National Lung Screening Trial (NLST).<sup>8</sup>

The landmark 2011 NLST was the first large-scale trial to show that lung cancer screening with low-dose computed tomography

(LDCT) can significantly reduce mortality. The NLST enrolled more than 50,000 patients, aged 55 to 74 years,<sup>9</sup> who were current smokers with >30 pack-years of cigarette smoking history or who had quit smoking in the past 15 years.<sup>10</sup> Results showed that participants who received LDCT scans had a 20% lower risk of dying from lung cancer than participants who received standard chest x-rays, and 50% of lung cancers detected by LDCT were stage I disease.<sup>11,12</sup>

However, in addition to highlighting the obvious advantages of screening, the NLST also revealed flaws in real-world national screening programs.<sup>13</sup> First, CT scanning is associated with a high rate of false-positive results. In the NLST, 24.2% of the results from the CT scans performed were positive, and more than 96% of nodules uncovered were later deemed to be false positives,<sup>14</sup> causing unnecessary stress and concern to thousands of patients. In addition, for those patients who did test positive, further procedures were required to confirm the diagnosis, including additional scanning or a biopsy, which can be invasive and carry serious risks. Finally, perhaps the biggest barrier to large-scale screening programs is the limit that national insurance coverage and reimbursement policies place on which patients are eligible to receive screening.

For example, in the United States, guidelines were adopted by the US Preventive Services Task Force based on data from NLST, and lung cancer screening has been recommended since 2014. However, these guidelines have been enforced only in high-risk individuals (Table 1, SP384), which means that they are utilized by only about 8% of those dying from this disease annually.<sup>15</sup>

Outside the United States, few countries have screening policies. After reviewing the NLST results, many countries continued to wait for data from a study outside of the United States to confirm the findings before they considered implementing screening. Confirmation finally became available in 2018, when results from the 10-year follow-up of NELSON were presented at the IASLC 19th World Conference on Lung Cancer. With 15,822 participants, the NELSON trial was the largest-ever European lung cancer CT screening trial. The study was designed to determine the effect of stringent referral criteria and increasing screening intervals on the characteristics of screen-detected lung cancers. The study confirmed the findings of the NLST and helped to address key

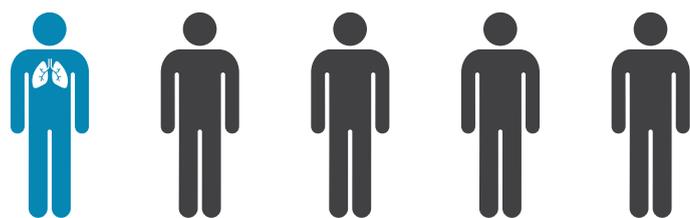


## SCAGLIOTTI

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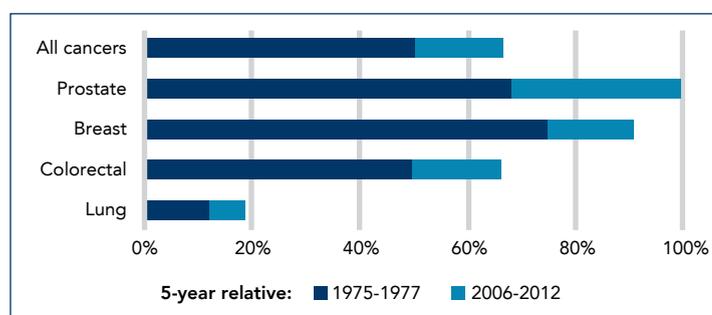
FIGURE 1. Lung Cancer and Death<sup>2</sup>

Approximately **1 in 5** cancer deaths are attributed to **lung cancer**.



Source: World Health Organization, International Agency for Research on Cancer, Latest global cancer data: Cancer burden rises to 18.1 million new cases and 9.6 million cancer deaths in 2018. <http://www.who.int/cancer/PRGIobocanFinal.pdf>. Accessed November 22, 2019.

FIGURE 2. Lung Cancer Survival Lags Behind That of Other Common Cancers<sup>3</sup>



Shown are 5-year survival rates for the 4 most common US cancer diagnoses. Darker shade indicates 5-year relative survival rate in 1975-1977; lighter shade indicates 5-year relative survival rate in 2009-2015 for all ages, all stages of diagnosis.

Source: National Cancer Institute: Surveillance, Epidemiology, and End Results Database. Cancer Stat Facts: Lung and Bronchus Cancer. [seer.cancer.gov/statfacts/html/lungb.html](http://seer.cancer.gov/statfacts/html/lungb.html). Accessed November 22, 2019.

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TABLE 1. Current Lung Cancer Screening Guidelines<sup>15</sup>

In the United States, high-risk patients eligible for payer coverage for screening must meet these criteria:
Aged between 55 and 80 years
30 pack-year smoking history
Currently smoke or have quit within the past 15 years

Source: US Preventive Services Task Force. Lung Cancer: Screening. www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lung-cancer-screening. Accessed November 22, 2019.

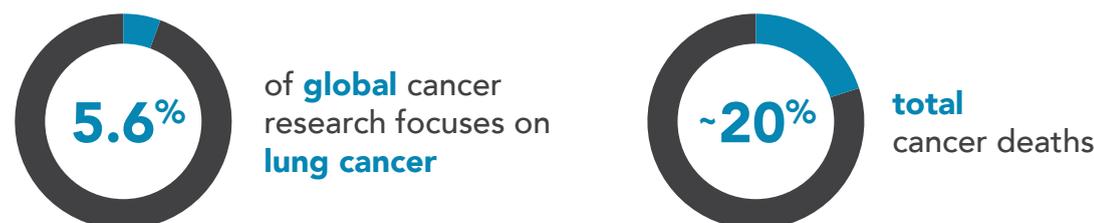
TABLE 2. Findings From NELSON<sup>16</sup>

	Stage I	Stage II	Stage III	Stage IV
Current practice*	26%	9%	25%	40%
<b>NELSON Lung Cancer Stage Distribution</b>				
First	64.9%	9.5%	18.9%	6.8%
Second	75.9%	6.9%	13.7%	3.4%
Third	72.2%	3.9%	19.5%	3.9%
Fourth	60.9%	15.2%	10.8%	13.0%

- Interval 1 year
- Interval 2 years
- Interval 2.5 years

\*In NELSON, computed tomography screening took place at baseline and after 1, 2, and 2.5 years. Results showed that with appropriate screening, patients were most likely to be diagnosed in the stage I setting. Source: EpiCast Report: NSCLC Epidemiology Forecast to 2025. GlobalData. 2016.

FIGURE 3. Research Funding Does Not Reflect Lung Cancer Burden<sup>2,31</sup>



Sources: GLCC Calls for Rapid Increase in Funding to Address 'Worldwide Scandal' of Lack of Lung Cancer Research. Global Lung Cancer Coalition. lungcancercoalition.org/global-briefing.html. Accessed 22 November 2019; World Health Organization, International Agency for Research on Cancer, "Latest global cancer data: Cancer burden rises to 18.1 million new cases and 9.6 million cancer deaths in 2018." www.who.int/cancer/PRGloboCanFinal.pdf. Accessed November 22, 2019.

questions, including how to minimize false positives. In NELSON, LDCT screening led to a 26% reduction ( $P = .0003$ ) in lung cancer deaths in men and a 39% reduction ( $P = .0054$ ) in women after 10 years, and it confirmed that we can increase the number of patients diagnosed with early-stage lung cancer. Compared with other trials, the screen-detected lung cancers of the NELSON trial were relatively more often diagnosed at stage I, when there is curative possibility, and less often at stage IIIB-IV, when the prognosis has significantly worsened. Findings from NELSON are summarized in **Table 2**.<sup>13,16</sup>

We now have the data and insights we need to act and implement national-level LDCT screening programs for people at high risk for lung cancer. However, despite growing evidence from lung cancer CT screening studies, few countries, districts, or regions have implemented LDCT screening for lung cancer. In countries where they do exist, policies vary from region to region, and too few sites are set up to implement screening effectively, too few patients are offered screenings, and there is low uptake.<sup>16-18</sup>

The Lung Ambition Alliance will focus its efforts and programs on addressing the potential barriers to the uptake of screening. We will promote greater understanding and awareness of the strong evidence of the benefits of implementing screening of

high-risk populations with LDCT, as supported by findings from the NLST and NELSON studies.<sup>19</sup> By doing so, we hope to encourage the adoption of national screening guidelines and policies. We will also continue to explore methods beyond CT scans to improve diagnosis rates of the diseases and to reduce false positives.

One of the foundational programs of The Alliance is advancing screening with the Early Lung Imaging Confederation (ELIC), a potentially practice-changing global resource for lung cancer researchers and care teams. ELIC is a new cloud-based screening registry that is designed to accelerate improvements in the multidisciplinary detection and management of early-stage lung cancer.<sup>13,20</sup> It uses new and emerging artificial intelligence and deep learning techniques to facilitate detailed analysis of gathered CT data to improve the reliability of clinical decision support with CT screening, and to assist in the development of precise quantitative disease biomarkers.<sup>21</sup>

ELIC was developed in 2018 by the IASLC with the intention of creating a large, globally accessible, privacy-secured network of shared CT lung cancer images and associated biomedical data.<sup>21</sup> In December 2018, the IASLC announced the completion of a 4-month pilot project which showed ELIC's potential to bring significant improvements

to lung cancer screening by creating a viable environment for the analysis of large collections of quality-controlled CT lung cancer images.<sup>20</sup> Phase 2 of the project is currently underway, in which additional "data spokes" are being added to make the registry of images more robust and powerful, and quantitative algorithm experiments are being run on data from 6 sites. Once this is complete, ELIC will expand out to a fully operational system and conduct numerous experiments of the internationally curated data.

Delivering Innovative Medicine

We are at a critical moment in the fight against lung cancer. Medical innovations and an increased understanding of the underlying biology of lung cancer are already shifting what is possible in treatment. The key challenge now is to accelerate treatment advances for people with lung cancer today, and for the millions who will be diagnosed in the future. However, several barriers remain to be overcome.

First, it is important that patients receive a timely and accurate diagnosis. Barriers to accurate and timely lung cancer staging represent a lost opportunity to guide patients on the appropriate treatment path. The IASLC has led in the creation of lung cancer staging standards for years. With the support of The Alliance, the IASLC is working to standardize international lung cancer staging guidelines and deepen insights into disease progression. Insights from this effort will inform the 9th edition of the Tumor, Node and Metastasis staging system, the most common method for staging lung cancer, and will guide physicians in identifying the right treatment for the right patient at the right time.<sup>21</sup>

Secondly, testing for biomarkers plays an important role in guiding selection of patients for precision medicine therapies. However, currently, many patients who may be eligible for precision medicines, and the improved outcomes they may offer, are not being tested for biomarkers at diagnosis.<sup>22-27</sup>

The Alliance will champion initiatives focused on biomarker discovery and on improving access to high-quality diagnostic approaches like liquid biopsy, as well as the increased uptake of precision medicine approaches in earlier settings where there is greater potential for cure. We are currently exploring several projects in this area, including those that will investigate the validation of surrogate endpoints and identification of predictive biomarkers to accelerate the development of new treatments.

Third, the emergence of precision medicine is making prolonged clinical response a realistic goal of lung cancer therapy. To further improve lung cancer survival outcomes, however, we must explore the potential for precision medicines in earlier stages (stages I-III) where there is a greater chance of cure.<sup>28,29</sup> As part of its Major Pathologic Response Project, The Alliance is working to validate surrogate endpoints and identify predictive biomarkers to accelerate the delivery of innovative medicines.<sup>30</sup>

Lastly, poor survival outcomes in lung cancer may also be tied to the disparity in lung cancer research funding compared with other cancer types (**Figure 3**).<sup>2,31</sup> Lung cancer is consistently

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underfunded relative to societal health cost and economic costs.<sup>31</sup>

In the United States, funding for lung cancer research in 2016 was only about half that of breast cancer research.<sup>32</sup> The National Cancer Institute's funding for lung cancer research was \$321 million in 2016, compared with \$545 million and \$208 million for breast cancer research and colorectal cancer research, respectively.<sup>33</sup>

The Alliance will work to improve awareness and understanding of lung cancer, to reduce stigma in the hope that this correlates to a level of public funding for lung cancer research that matches the urgency of the disease and the current promise of medical innovations.

At the IASLC 2019 World Conference on Lung Cancer in Barcelona in September 2019, The Alliance announced the official launch of an international survey, conducted by Ipsos MORI, which will invite general practitioners, lung cancer specialists, and the public from 7 countries across 3 continents to share their perceptions around lung cancer. The survey will help generate insights and aid The Alliance in developing tailored patient solutions as well as advocacy initiatives. The survey will also establish a barometer by acting as a benchmark to help track the impact of Alliance programs over time. The results of this survey are expected in 2020.

### Improving Quality Care

The Alliance's final priority area recognizes that people with lung cancer need support on their journey of care. We, as a lung cancer community, need to work with advocates and policymakers to deliver projects to address the healthcare challenges most urgent to patients. Patients need access to the multidisciplinary team they require to manage their condition; health systems and insurers need to have an urgency to act instilled in them to provide patients with access to the best possible treatment.

To this end, The Alliance is committed to implementing benchmarking and quality improvement processes in the management of lung cancer. We will identify projects to ensure that patients have a better experience in their journey and achieve better outcomes. The Alliance has launched a new grants program, the Initiatives in Lung Cancer Care (ILC<sup>2</sup>), to engage with the global community and encourage ambitious in-country solutions that can potentially transform patient care and improve survival rates in lung cancer. The ILC<sup>2</sup> program is an open call, inviting registered patient organizations around the world to submit proposals for projects that can potentially transform patient care and improve survival within their home countries.<sup>4</sup> The program recognizes the high variation in lung cancer management around the world as well as the specific, localized barriers to quality care that must be considered when developing patient-centric solutions to address them.

The Alliance began accepting grant applications in November 2019 and will evaluate and select submissions that meet the criteria for funding.

### Changing Lung Cancer Survival

The Alliance is only a few months old, but the efforts of each individual partner go back decades.

This is just the start of an essential process of change that must be taken together by the lung cancer community to ensure that we succeed in transforming lung cancer from a disease with poor patient outcomes to a disease that can be treated successfully, offering new hope to families and communities around the world.

This is a movement designed to grow, welcoming all those who believe that by breaking siloes, facilitating dialogue, and collaboratively searching for new solutions we can accelerate the extraordinary potential of today's science and technology.

We will bend the survival curve in lung cancer, together. ♦

#### AUTHOR INFORMATION

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