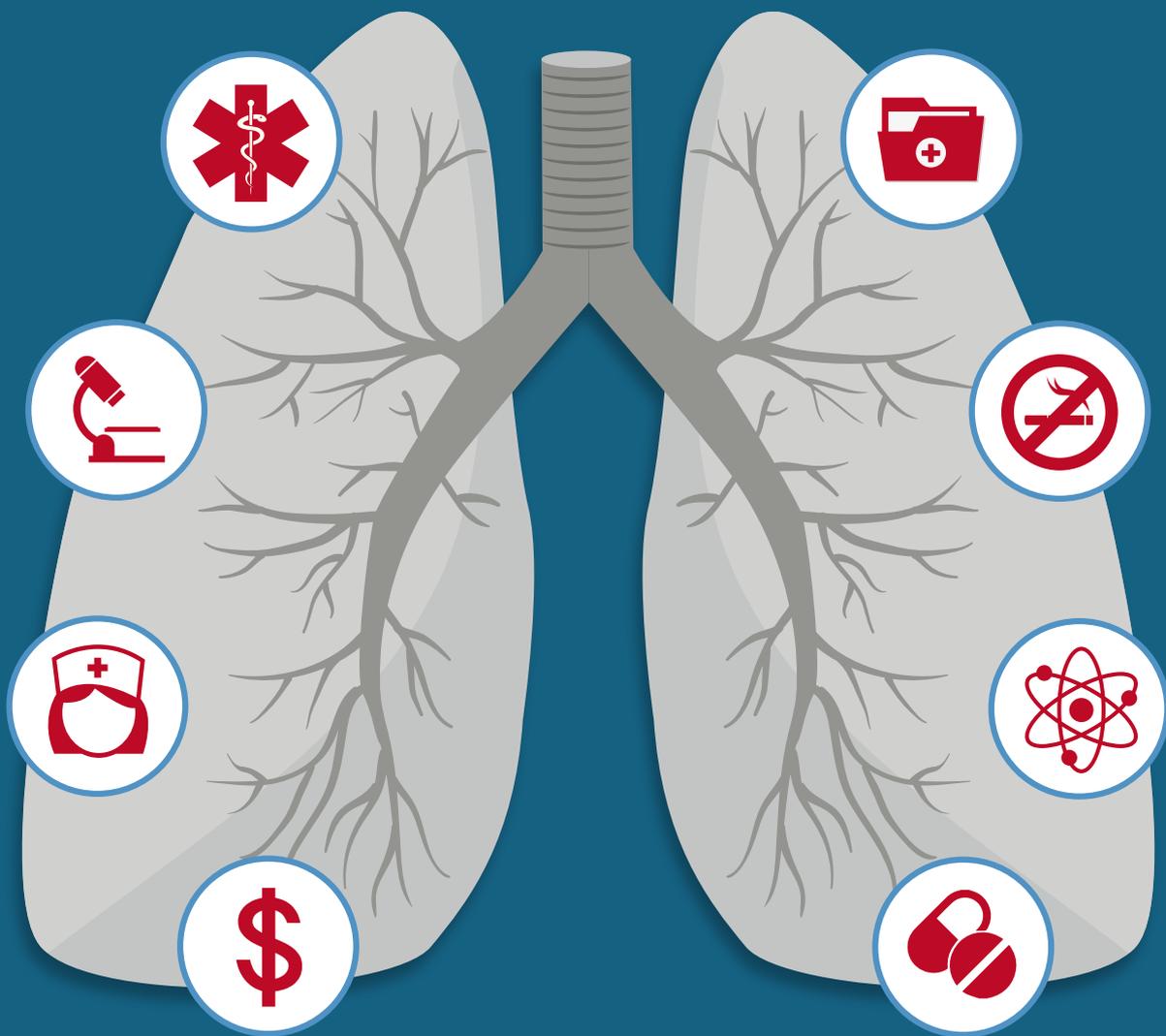


## REDUCING THE BURDEN: The economic and social costs of lung cancer in Italy



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### INTRODUCTION

Lung cancer is one of the world's deadliest diseases. In 2015 it was believed responsible for an estimated 280,000 deaths in the European Union, or 20% of all cancer deaths.<sup>1</sup> In men, lung cancer is the most common kind of fatal cancer. Among women, it is the second most common kind of fatal cancer.<sup>2</sup>

In Italy, the picture mirrors the global trend. Lung cancer is the biggest killer of men and is tied with colorectal cancer for the most deaths in women. Moreover, the impact of lung cancer in Italy has been increasing over the past two decades. Deaths from lung cancer were above 35,000 in 2013, up from fewer than 31,000 in 1990. Lung cancer is expected to be diagnosed in 40,000 cases in 2016, according to the Italian Association of Medical Oncology (AIOM) in its publication "I numeri del Cancro in Italia 2016" (Cancer numbers in Italy 2016). The number of disability-affected life years (DALYs), or years of life lost due to lung cancer, rose above 607,000 in 2013, after falling below 600,000 in 2010.<sup>3</sup>

With this as background, The Economist Intelligence Unit undertook research to assess the economic and social impact of lung cancer in Italy and to compare policy approaches aimed at reducing that impact, including a comparison between Italian strategies and approaches used in neighbouring countries.

*Reducing the burden: The economic and social costs of lung cancer in Italy* presents the results of this research. This white paper was written by The Economist Intelligence Unit (EIU) and sponsored by Roche. It is based on desk research and in-depth interviews with 15 experts in the topic. The EIU would like to thank the following participants in the interview programme (listed alphabetically) for their time and insights:

- Federico Cappuzzo, director of medical oncology, Ospedale Santa Maria delle Croci, Ravenna
- Christos Chouaid, head of thoracic oncology, Centre Hospitalier Intercommunal, Créteil, France
- Francesco De Lorenzo, president of the European Cancer Patient Coalition, and president of the Italian Federation of Volunteer-based Cancer Organisations
- Mina Gaga, president-elect, European Respiratory Society
- Marina Garassino, medical consultant, Medical Oncology Division of the National Cancer Institute of Milan
- G Scott Gazelle, professor of radiology, Harvard Medical School, and professor in the department of health policy management, Harvard School of Public Health
- Claudio Jommi, professor of public management and policy, Centre for Research on Health and Social Care Management, Graduate Business School of Bocconi University, Milan

<sup>1</sup> Malvezzi, M, Carioli, G. *et al.*, "European cancer mortality predictions for the year 2016 with focus on leukaemias" *Annals of Oncology*, Vol 27, January 26th 2016, pp. 725-731. <http://annonc.oxfordjournals.org/content/27/4/725.long>

<sup>2</sup> World Health Organisation, 10 Facts on Cancer. Available at: <http://www.who.int/features/factfiles/cancer/facts/en/index4.html>

<sup>3</sup> Institute for Health Metrics and Evaluation, *Global Burden of Disease*, 2013.

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- Carlo La Vecchia, associate professor of epidemiology, University of Milan, and head of the laboratory of epidemiology, Mario Negri Institute for Pharmacological Research, Milan
- Jessica Menis, clinical research physician, European Organisation for Research and Treatment of Cancer
- Silvia Novello, professor of medical oncology, San Luigi Hospital at the University of Turin, and president, Women against Lung Cancer in Europe
- Carmine Pinto, president of the Italian Association of Medical Oncology (AIOM)
- Georgio Scagliotti, professor of medical oncology, University of Turin, and president, International Association for the Study of Lung Cancer
- Richard Sullivan, director, Institute of Cancer Policy and King's Health Partners Comprehensive Cancer Centre, King's College London
- Kostas Syrigos, head of the oncology department, School of Medicine, University of Athens
- Stefania Vallone, president, Lung Cancer Europe, Italy

The Economist Intelligence Unit bears sole responsibility for the content of this report. The findings and views expressed here do not necessarily reflect the views of the sponsor. Andrea Chipman was the author of this report, and Aviva Freudmann was the editor.

### EXECUTIVE SUMMARY

In addition to ranking among Europe's deadliest diseases, cancer is one of its most expensive. In Italy alone the economic burden of all cancers—including the costs of treatment and the value of lost wages and lost productivity of disease sufferers and their carers—was estimated at €16.5bn (US\$18.4bn) in a 2013 article in *The Lancet Oncology*.<sup>4</sup> Since lung cancer is among the deadliest forms of cancer, it follows that lung cancer is responsible for a large part of that overall financial burden.

Moreover, the incidence of lung cancer is rising in Italy, particularly among women, which is compounding the burden of the disease. "From both the European and the Italian perspective, the cost of diagnosis and treatment is increasing, and that has a downstream impact both on governments and on reimbursement agencies and hospitals," says Jessica Menis, a clinical research physician at the European Organisation for Research and Treatment of Cancer.

On the plus side, Italy, like many of its European neighbours, is improving the ways in which it fights lung cancer, both in a clinical sense and through an array of broader policies. By considering a variety of measures to discourage smoking, and by experimenting with innovative approaches to financing new treatments, Italy is starting to formulate plans to reduce the burden of the disease.

This study, which assesses the burden of the disease and the policies aimed at reducing it, concludes that stronger policies are needed to wage a successful war on lung cancer in Italy. While important advances are being made in benefits coverage and financing clinical innovations, some of the basic ways to tackle the disease receive too little attention. These include recognising the disease's true demographics and strengthening measures to discourage smoking, a major cause of the illness.

Here are other key findings of the research:

- **Lung cancer is costly for the economy and burdensome for society.** Total costs for all forms of cancer in Italy were estimated in 2013 at €16.5bn, Europe's third-highest total after Germany and France. These costs include lost earnings for patients and carers as well as the direct costs of treating cancer patients. Lung cancer is believed to account for the largest portion of the country's total cancer burden.

- **The most effective anti-cancer measure is to curb smoking.** Between 85% and 90% of lung cancer cases are believed to be caused by smoking. It follows that curbing smoking overshadows all other measures in reducing the incidence of the disease. However, the government has taken only feeble measures to raise the cost of cigarettes via taxation, and it has failed to wage a strong public-education effort via schools and communities, or via warning messages on cigarette packages.

- **The demographics of the disease are shifting towards women and the young.** Lung cancer in Italy is typically seen as a disease of older men, but women are increasingly

<sup>4</sup> Luengo-Fernandez, R, Leal, J, Gray, A and Sullivan, R, "Economic burden of cancer across the European Union: a population-based cost analysis", *The Lancet Oncology*, November 2013.

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susceptible, and more patients are now being diagnosed at a younger age. Policymakers have yet to reorient their efforts, including via education and screening, to fully account for this shift.

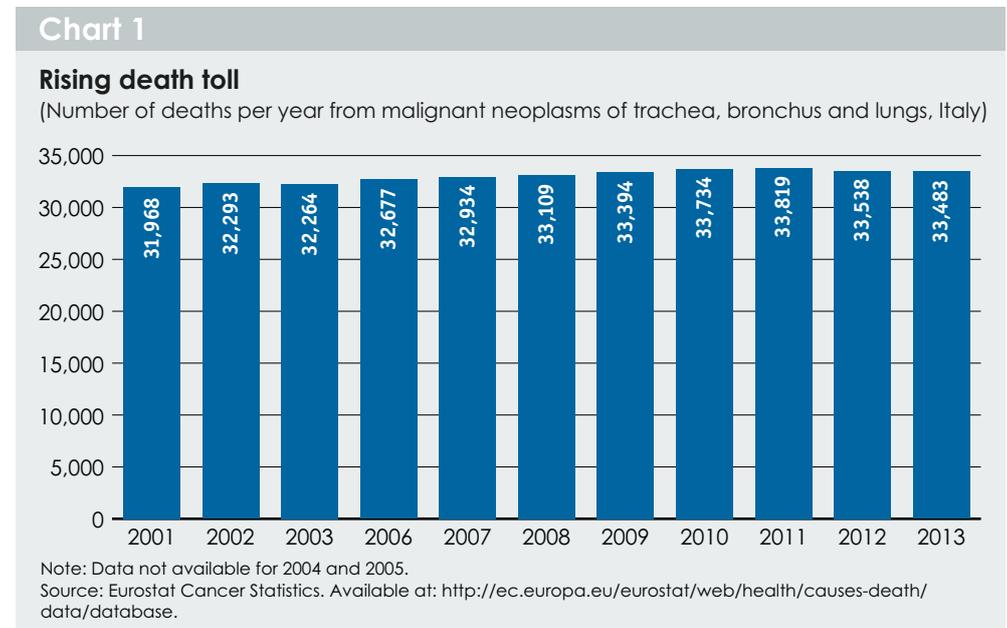
- **A holistic approach involving prevention, screening, treatment and palliative care is most effective in fighting the disease.** France and the UK take such a comprehensive approach. Italy, on the other hand, takes a more piecemeal approach, with a national cancer plan lacking in detail. Implementing Italy's anti-cancer plan is further hindered by a fragmented and uneven healthcare delivery system.

- **Italy suffers from regional inequalities in healthcare funding and quality.** Funding considerations lead to uneven availability of cutting-edge treatments in different parts of the country. This affects all patients, including lung cancer patients.

- **Screening at-risk populations can help to reduce lung cancer rates.** Studies in the US and preliminary trials in Europe suggest that computerised tomography (CT) screening of at-risk patients can aid early detection, which in turn can improve survival rates. Screening is controversial, however, owing to its high costs.

- **Some clinical advances offer hope as well, but costs are a deterrent.** Among the cutting-edge clinical approaches to reducing cancer are the identification of genetic mutations linked with some of the rarer types of lung cancer, and associated therapies. However, the high costs and the narrow group of patients likely to benefit make these techniques and treatments controversial.

# CHAPTER 1: ASSESSING THE BURDEN: WHO IS AFFECTED, AND HOW?



According to pioneering research published in *The Lancet Oncology* in 2013, lung cancer imposes the highest economic costs of all forms of cancer in the 28 states of the European Union. The total cost of lung cancer in the EU at that time was €18.8bn, approximately 15% of the overall EU cancer cost of €126bn. These costs included direct healthcare costs and productivity losses for patients and carers.<sup>5</sup>

<sup>5</sup> Luengo-Fernandez, R, Leal, J, Gray, A and Sullivan, R, "Economic burden of cancer across the European Union: a population-based cost analysis", *The Lancet Oncology*, November 2013. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/24131614>

Lung cancer is similarly costly in Italy and accounts for a large part of the country's total cancer burden, estimated at €16.5bn in 2013. Deaths from lung cancer in Italy reached 33,483 in 2013, up from 31,968 in 2001. (Chart 1). Lung cancer is expected to be diagnosed in 40,000 cases in 2016, according to the Italian Association of Medical Oncology (AIOM) in its publication "I numeri del Cancro in Italia 2016" (Cancer numbers in Italy 2016). The number of disability-affected life years (DALYs), or years of life lost due to lung cancer, exceeded 607,000 in 2013, after falling below 600,000 in 2010. Italy's death toll (number of deaths) from lung cancer is the third-highest in the EU, after Germany and the UK, although its death rate (number per 100,000) compares favourably to that of other European countries. (Chart 2)<sup>6</sup>

<sup>6</sup> Eurostat Cancer Statistics – Specific Cancers: Table 1: Causes of death – malignant neoplasms of trachea, bronchus and lung, residents, 2012 Health2015B.png. Available at: [http://ec.europa.eu/eurostat/statistics-explained/index.php/File:Causes\\_of\\_death\\_%E2%80%94\\_malignant\\_neoplasms\\_of\\_trachea,\\_bronchus\\_and\\_lung,\\_residents,\\_2012\\_Health2015B.png](http://ec.europa.eu/eurostat/statistics-explained/index.php/File:Causes_of_death_%E2%80%94_malignant_neoplasms_of_trachea,_bronchus_and_lung,_residents,_2012_Health2015B.png)

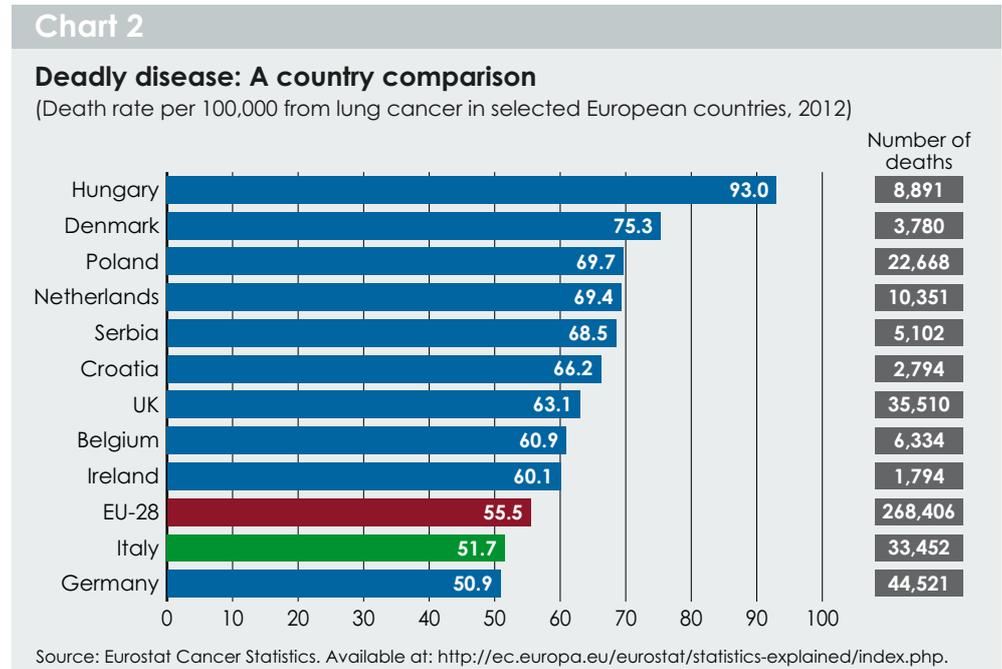
### A women's problem

That is the overall view. A closer look reveals a troubling trend: women account for a rising proportion of lung cancer patients in Italy. Female lung cancer rates rose steadily

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between 2001-10, while the rate for men declined. (Chart 3), and lung cancer is now the second leading cause of death for women. The gap in smoking rates between men and women in Italy, which reached 55 percentage points in the 1960s, was down to 10.9 percentage points by 2014. (Chart 4)



These trends have caught health professionals unawares. Medical providers are less accustomed to recognising the disease in women and in young people and are therefore less likely to screen these populations for lung cancer. "It can be difficult for a general practitioner to understand that there is an increase in this disease among women, and that if there are symptoms indicating the possibility of this disease in a woman, it suggests the need for a diagnostic work-up," says Silvia Novello, professor of medical oncology at San Luigi Hospital at the University of Turin.

Women, too, are only slowly getting the message to take lung cancer seriously. "It's difficult for women to understand that there is a different malignant disease to cope with other than breast cancer or reproductive cancers," says Professor Novello, who is also president of Women Against Lung Cancer in Europe.<sup>7</sup>

Once women have started smoking, they find it more difficult to quit, she adds. "Italy is exactly comparable to other countries in which smoking cessation campaigns are more successful in men than in women, because in women there is a fear of gaining weight [if they stop smoking], together with other psychological aspects. The other problem is that we know that women are more susceptible than men to tobacco carcinogens, and that among lung cancer patients who have never smoked, the vast majority are women."

<sup>7</sup> [www.womenagainstlungcancer.eu](http://www.womenagainstlungcancer.eu)

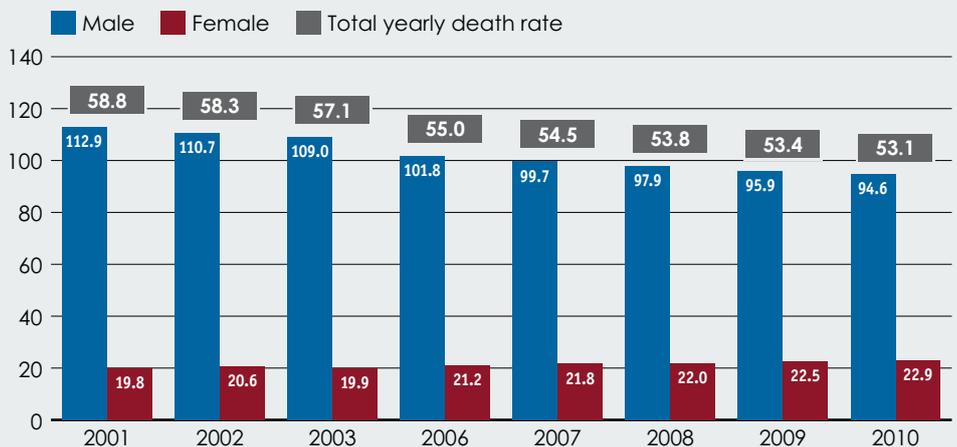
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### Chart 3

#### Diverging trends

(Male and female lung cancer rates per 100,000, Italy, 2001-10)



Note: Data not available for 2004 and 2005.

Source: Eurostat. Available at: <http://ec.europa.eu/eurostat/data/database>.

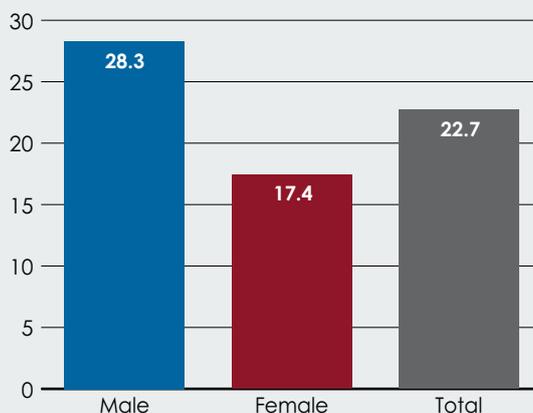
### Younger and poorer

In addition to becoming more female, the profile of lung cancer sufferers in Italy is also becoming younger. In part this is due to a cohort or generational effect, since the generation of women who started smoking in the 1970s is now reaching late middle age. In the past, most lung cancers were diagnosed in elderly patients, but now around 45% of new cases are identified in people under the age of 65.

### Chart 4

#### Puffing away

(Male and female smoking rates, current smokers, %, Italy, 2014)



Source: Eurostat. Available at: <http://ec.europa.eu/eurostat/data/database>.

This age profile has serious implications for lost working hours and productivity, both for the patients and for family members who care for them, says Carlo La Vecchia, associate professor of epidemiology at the University of Milan and head of the laboratory of epidemiology, Mario Negri Institute for Pharmacological Research, Milan.

Moreover, lung cancer in Italy, like lung cancer elsewhere in Europe, is closely correlated with lower educational attainment. The reasons, say researchers led by Professor Franco Merletti

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of the University of Turin, is the higher incidence of smoking in this population segment, as well as lower levels of skill in getting the right medical help.<sup>8</sup>

### Counting the economic costs

Illness and premature mortality, tragic as they are, also translate into higher costs for individuals and for society at large. These take the form of direct healthcare costs, reduced productivity and lost wages. Of the total economic cost of all cancers in Italy, estimated at €16.5bn in a 2013 article in *The Lancet Oncology*,<sup>9</sup>

the authors also put direct healthcare costs at €6.9bn, the value of working or leisure time forgone by informal, unpaid carers at €5.5bn, and the lost wages of the patients themselves at €4.1bn (Chart 5). Of the four cancers discussed in that article, lung cancer was responsible for the largest overall economic burden.

Ironically, data on direct healthcare costs for treating lung cancer can appear modest compared with those for treating other forms of cancer, mainly because the healthcare often fails to prolong the life of lung cancer patients. Total expenditure on drugs for lung cancer patients accounts for less than 10% of the total cost of drugs for all types of cancer, says Professor La Vecchia.

Chart 5

### A costly disease

(Economic costs of all cancers in Italy, € m, 2009)



**Total: €16,454 m**

Source: Luengo-Fernandez, R. et al, "Economic burden of cancer across the European Union: a population-based cost analysis". Published online October 14, 2013. Available at: [www.thelancet.com/oncology](http://www.thelancet.com/oncology).

<sup>8</sup> Merletti, F, Galassi, C et al., "The socioeconomic determinants of cancer," *Environmental Health*, Vol. 10, 2011, page 2.

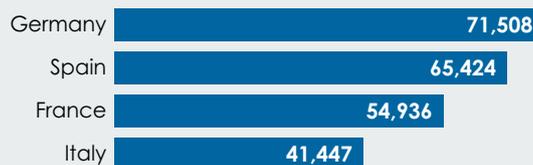
<sup>9</sup> Luengo-Fernandez, R et al., "Economic burden of cancer across the European Union: a population-based cost analysis".

<sup>10</sup> *Ibid.*, page 5.

Chart 6

### Spending modestly

(Per-patient lifetime costs, non-small-cell lung cancer, four countries, €)



Source: Solem, CT, et al, "Resource Utilization Among Advanced Squamous and Non-Squamous Non-Small-Cell Lung Cancer Patients Receiving Second-Line treatment in France, Germany, Italy and Spain: Results of a Retrospective Chart Review".

For the same reason, the costs to the broader economy—measured in terms of lost wages—arising from premature mortality of lung cancer patients are relatively high. The authors of the *Lancet Oncology* article put the EU-wide productivity losses attributable to mortality from lung cancer at just under €10bn, or 23% of productivity losses arising from all cancers.<sup>10</sup>

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In comparison with its European neighbours, Italy spends modestly on healthcare for lung cancer patients. Per-patient lifetime costs attributable to non-small cell lung cancer (NSCLC), which accounts for 85% of all lung cancers, were lower in Italy (€41,447) than in France (€54,936), Spain (€65,424) or Germany (€71,508), according to a study presented at the 2015 conference of the International Society for Pharmacoeconomics and Outcomes Research (Chart 6).<sup>11</sup>

The lower costs in Italy may be because Italian NSCLC patients have, on average, shorter hospital stays than their counterparts in Germany and France. “Only a fifth to a quarter of patients undergo surgery,” Professor La Vecchia says. “About half of these are then treated with chemotherapy or radiation.” On the other hand, ancillary expenditure—such as for hospice, nursing home, assisted or home care—for lung cancer patients were higher in Italy than in France, Germany and Spain.<sup>12</sup>

Despite shorter hospital stays and lower healthcare expenditure for lung cancer patients in Italy, the survival rates of Italian lung cancer patients are slightly better than in Europe overall. For patients diagnosed in 2000-02, the five-year survival rate was 13.4% in Italy, slightly above the European average of 12.6%, but well below the rates of 16.8% in Iceland and 16.3% in Belgium.<sup>13</sup>

The introduction of new treatments, such as immunotherapies, may change both the cost and survival comparisons between Italy and its neighbours. New treatments are driving up healthcare costs and creating significant burdens on healthcare systems, according to Kostas Syrigos, head of the oncology department at Athens University School of Medicine. Dr Syrigos and others note that if new treatments achieve their intended target of making lung cancer a chronic disease rather than a terminal one, governments will need to find new sources of funding to meet the higher costs.

<sup>11</sup> Solem, CT, Penrod, JR et al., “Resource Utilization Among Advanced Squamous and Non-Squamous Non-Small Cell Lung Cancer Patients receiving Second-Line Treatment in France, Germany, Italy and Spain: Results of a Retrospective Medical Chart Review”. Available at: <http://www.ispor.org/ScientificPresentationsDatabase/Presentation/60128>

<sup>12</sup> *Ibid.*

<sup>13</sup> European Lung white book. Available at: <http://www.erswhitebook.org/chapters/lung-cancer/>

<sup>14</sup> *Ibid.*, p. 7.

### **Adding social costs**

Beyond the economic burdens are social costs, which include lost wages and reduced leisure time incurred by unpaid family members responsible for the daily care of lung cancer patients. As noted above, The Lancet Oncology article published in 2013 listed the social cost of all cancers in Italy—that is, the monetary value of working time or leisure time forgone by unpaid carers—at €5.5bn. In a separate study published by the OECD, lung cancer was found to cause the highest informal care costs of any of the cancers studied. In Europe as a whole, according to the OECD, lung cancer was responsible for 16% of the informal care costs of all cancers.<sup>14</sup>

These aggregate cost estimates translate into large burdens on individuals and families. Some recent studies suggest the magnitude of that burden. The Italian Survey of Dying of Cancer (ISDOC) found that 26% of families caring for lung cancer patients had to use all their financial resources to pay for care not covered by the health system. These costs

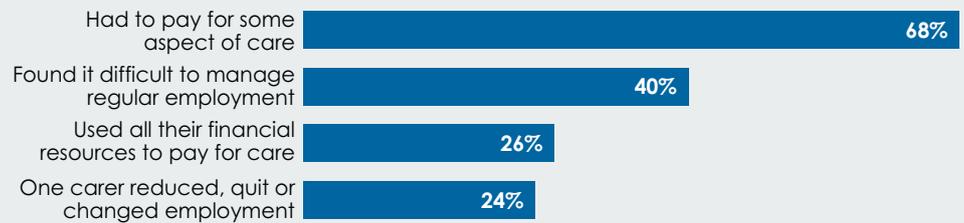
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### Chart 7

#### The burden on families

(Survey of Italian families caring for lung-cancer patients, % respondents)



Source: Dying of Cancer in Italy: impact on family and caregiver; report of The Italian Survey of Dying of Cancer.

included taking patients to medical appointments and helping with the demands of daily living (Chart 7).<sup>15</sup>

The ISDOC also found that 40% of non-professional caregivers of working age found it very or quite difficult to manage their regular employment. In 24% of families surveyed, one patient's relative reduced, quit or changed employment. A striking 68% reported that the patient and/or the family paid for some aspects of care (Chart 7). The biggest cost items were drugs and visits to the doctor not covered by health insurance, home nursing care, medical equipment, and the transport of patients. The burdens on carers were most likely to be found in the south of Italy.<sup>16</sup>

### Some bright spots

Not all is doom and gloom in the lung cancer sphere, however. As of 2010 there were 75,365 survivors of lung cancer in Italy, according to an Italian Tumour Registry study. Some of these individuals were considered cured because they had survived at least 11 years since their initial diagnosis.<sup>17</sup> More generally, survival rates—while low—are inching up, and policymakers are looking into ways to improve support for patients and their families.

Scientists have also made progress in recent years in identifying specific rare genetic mutations that cause cancer in some of the estimated 15-20% of lung cancer patients who have never smoked, says Giorgio Scagliotti, professor of medical oncology at the University of Turin. "That leads us to believe that in the near future you can make lung cancer in this tiny minority of patients a chronic disease."

Moreover, several trials, both in untreated and already treated patients with advanced non-small cell lung cancer found that immunotherapy can increase survival rates, according to Dr Menis. While some basic screening for potential immunotherapy candidates is common across Europe, the Italian health system does not reimburse it. Nor does Britain, where the National Institute for Health and Care Excellence (NICE)—

<sup>15</sup> Rossi, P, Beccaro, M et al., "Dying of cancer in Italy: Impact on family and caregiver", The Italian Survey of Dying of Cancer, *Journal of Epidemiology and Community Health*, 2007, page 550.

<sup>16</sup> *Ibid.*, pp. 550 and 552.

<sup>17</sup> "Cancer prevalence in Italy: Patients living with cancer, long-term survivors and cured patients," Associazione Italiana Registri Tumori (AIRTUM), 2010 Report. <http://www.registri-tumori.it/cms/?q=Rapp2010> Cure rate was based on the fact that these patients were in remission and had been diagnosed at least 11 years before the study.

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which evaluates the cost-effectiveness of new treatments—recently rejected the reimbursement of immunotherapy owing to its high cost.

Recent cohort studies, meanwhile, have used data from Italian regions with a high incidence of lung cancer to improve knowledge about risk factors, in order to target screening at high-risk populations. Genetic epidemiologists involved in the Environment and Genetics in Lung Cancer Etiology (EAGLE) project, a population-based study of cancer in the Lombardy region of northern Italy, looked at tobacco use and environmental factors—such as occupational exposures to toxins from manufacturing and farming—to rank significant risks.

Among their findings were that certain genes make patients more susceptible to a particular subtype of lung cancer. They aim to use “behavioural, biomarker and genomic tools” to predict who is at high risk of contracting lung cancer and therefore might be a candidate for screening.<sup>18</sup> “We have got much more molecular insight in the last ten years than in the previous 20,” says Professor Scagliotti, who is also president of the International Association for the Study of Lung Cancer.

<sup>18</sup> Fisher, V and Loukissas, J, “Exploring the causes and course of lung cancer in Northern Italy,” National Cancer Institute, Division of Cancer Epidemiology & Genetics.

# CHAPTER 2: REDUCING THE BURDEN: PREVENTION AND TREATMENT

With the burden of lung cancer on the rise, Italy's medical establishment faces the task of reducing the incidence of the disease and improving survival rates for those who do fall victim to it. They face these challenges at a time of strained budgets and rising demand for new and expensive treatments.

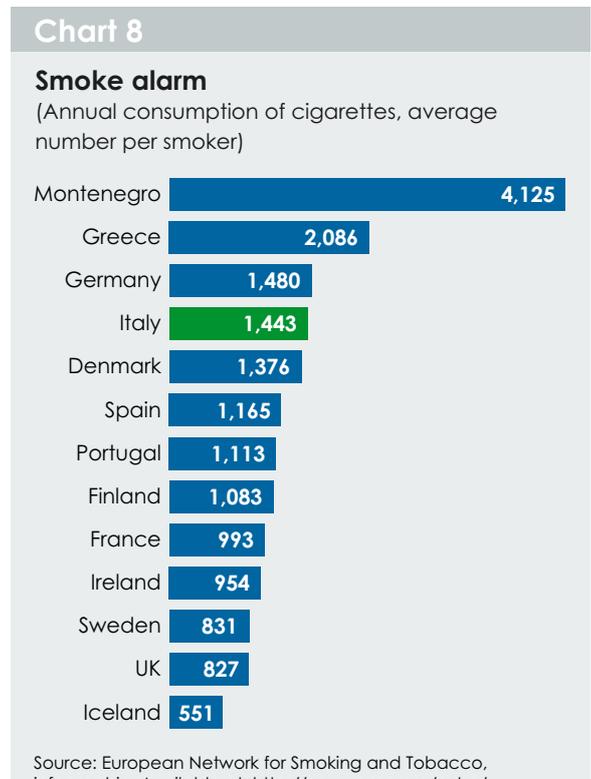
As with any disease, the most effective approach to lung cancer is to minimise its incidence in the first place; in addition, there needs to be an improvement in diagnosis and treatment. An effective strategy, therefore, has two main aspects: strengthening anti-smoking programmes in an effort to reduce the rate of cancer; and stepping up screening and awareness programmes, on the basis that early detection, diagnosis and treatment tend to improve patients' survival chances.

### First target: Cigarettes

Italian smokers consume over 1,400 cigarettes a year per head—nearly four cigarettes a day on average, and more cigarettes than are consumed by smokers in the UK, France, Ireland and most of the Nordic countries (Chart 8).<sup>19</sup> The incidence of smoking is significant, since the most important means of fighting lung cancer is to reduce the rate of smoking.

About 80% of lung cancer is caused by smoking, says G Scott Gazelle, professor of radiology at Harvard Medical School and professor of health policy at Harvard School of Public Health. "The thing that many countries are doing right is making it harder and harder to smoke. The countries that really want to take on lung cancer have to be willing to take on smoking."

A big part of taking on smoking is making cigarettes more



<sup>19</sup> European Network for Smoking and Tobacco Prevention, "Towards a smoke free Europe" infographic. Available at: <http://www.ensp.org/extra/smoke-free-europe/infographic.html>

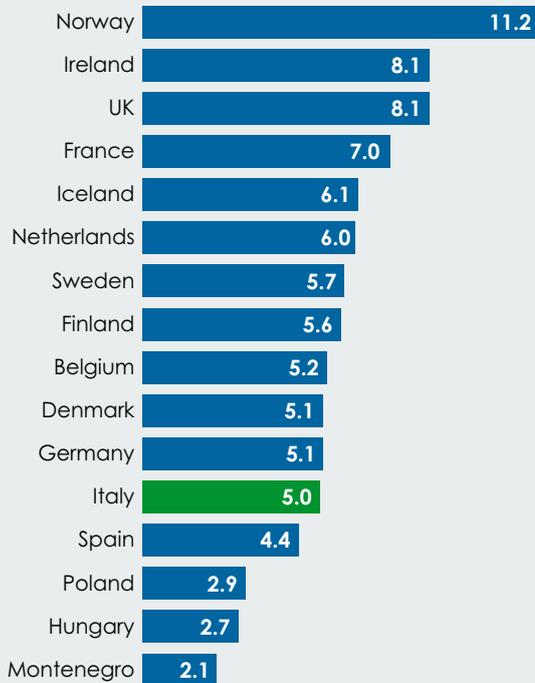
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Chart 9

### Cheap smokes?

(Price of a pack of a leading brand of cigarettes in selected European countries, €)



Source: <http://cigarettesprices.strikingly.com>, a website built by <https://cigs4us.biz/>, an online vendor of cigarettes.

expensive by applying excise taxes. Here, efforts have been weak at best. The Italian Association of Oncologists is proposing an excise tax of only 1 euro cent per package. That is unlikely to make much difference, particularly since cigarettes are relatively cheap in Italy: a pack of cigarettes costs about €5 in Italy, compared with €7 in France and €8.10 in the UK (Chart 9). The rise in cigarette prices has been relatively modest, too, at 38% in Italy since 2005, compared with more than 200% in Turkey and Romania over the same period (Chart 10).<sup>20</sup>

Marina Garassino, a medical consultant in the Medical Oncology Division of the National Cancer Institute of Milan, notes that Italy introduced smoking cessation programmes later than the US or UK. She adds that policymakers are reluctant to increase prices substantially, in part due to UK data suggesting that higher prices simply encourage smokers to roll their own cigarettes.

Policymakers have stepped carefully around the price issue. "The influence of the Ministry of Health on cigarette smoking has been inadequate," says Professor La Vecchia. "They don't understand that if they increase the price through more taxation, they will decrease health costs."

Equally important to raising the price is campaigning strongly against smoking, particularly among children. Primary schools should be

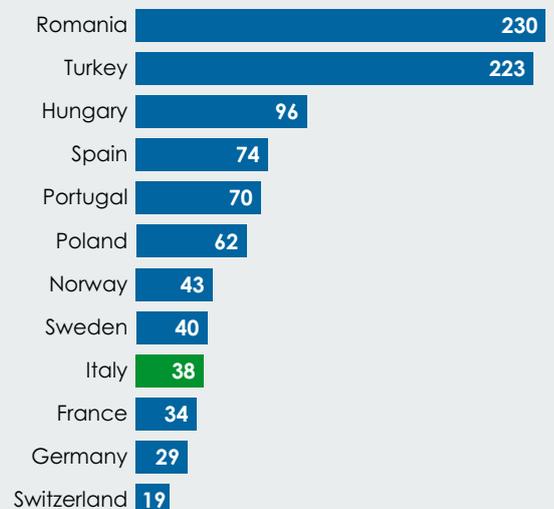
the focus of such campaigns, according to Professor Scagliotti. By the time students reach high-school and university age, it is too late, he says. Professor Novello of the San Luigi Hospital agrees. "When you address children between 11 and 13 years of age, you find that half the class has already tried a cigarette," she notes.

Programmes targeted at teenage girls would be particularly effective, according to Dr Garassino. "If they start to smoke when they are 13

Chart 10

### Expensive habit

(Rise in cigarette prices, 2005-15, %)



Source: European Network for Smoking and Tobacco, infographic. Available at: <http://www.ensp.org/extra/smoke-free-europe/infographic.html>.

<sup>20</sup> Ibid.

and 14, they will unfortunately be the patients of the future, and we must avoid that," she adds.

Other measures include printing strong warnings on cigarette packages, including graphic images showing the health consequences of smoking. Italy has been slow to adopt this technique. While Australia introduced such "shock images" in 2003, they were not used in Italy until May 2016.

There is evidence that such measures produce results. A presentation by Carmine Pinto, president of the Italian Association of Medical Oncology (AIOM), to the Italian Ministry of Health in early 2016 found a 2% average decrease in lung cancer incidence since 1999 among men, correlating with a similar decrease in tobacco use.<sup>21</sup> In women, by contrast, the trend was in the opposite direction, with a 2.6% annual increase in new cases of cancer related to increased tobacco use.<sup>22</sup>

### **Early detection**

With lung cancer, as with other diseases, awareness among the population of potential warning signs is key to early detection and treatment, and these, in turn, are key to boosting survival rates among those who contract the disease.

When it comes to promoting awareness and encouraging people to seek an early diagnosis, Italy might profit from the experience of neighbouring countries. Although survival rates from lung cancer in Italy are currently slightly better than the European average, there is room for improvement. A comparison of Italy with neighbouring countries shows significant differences in response time when a person suspects he or she may have a lung problem.

"There is a very big discrepancy between countries in Europe in patient care; patients have totally different gaps between the suspicion of a diagnosis and confirmation of a diagnosis, gaps in availability of care and testing, and differences in the waiting period before biopsies are performed or before treatment is initiated," says Mina Gaga, president-elect of the European Respiratory Society. "For example, liquid biopsies or molecular testing may not be available, and waiting times for surgery or radiotherapy may be very long. Lung cancer is a deadly cancer, and mostly we pick it up at an advanced stage, when the disease is incurable."

Public awareness campaigns aimed at speeding up the seeking of medical advice are relatively uncontroversial, as the costs associated with them are usually not prohibitive. What is more controversial is the widespread use of computed tomography (CT) scanning—an imaging procedure that uses special X-ray equipment to create detailed pictures of areas inside the body—to screen large numbers of people who may be at risk from lung cancer.

<sup>21</sup> Pinto, C, "The Cancer numbers in Italy 2016: incidence, mortality and survival for cancer in Italy in 2016," power point presentation to the Ministry of Health, Rome, September 27th 2016, Slide 25.

<sup>22</sup> *Ibid*, Slide 26.

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Two recent studies highlight the benefits of CT screening. The Nelson Study, a collaboration between Dutch and Belgian researchers, found that increasing the frequency of screening could help to reduce the number of missed cancers.<sup>23</sup> Separately, the National Lung Screening Trial (NLST), including research from the US National Cancer Institute, found a mortality reduction of around 20% for those who had undergone lung cancer screening.<sup>24</sup>

The findings have sparked a debate among cancer specialists about the uses of scanning. "I'm sure the CT scan is a good tool to make an earlier diagnosis, but I'm not so sure it is the only tool to reduce mortality," says Professor Novello. She notes that one recent trial, done within the context of a screening programme using low-dose CT scans, showed that the biggest impact on mortality comes from smoking cessation.<sup>25</sup>

The cost of CT scans are an even bigger cause of controversy. Italy's health service does not reimburse regular use of CT scanning for lung cancer. The cost-effectiveness of this technique has been the subject of a "15-year debate", notes Professor Gazelle of Harvard University, who is also a founder of the Institute of Technology Assessment at Massachusetts General Hospital.

"It's pretty clear that there is a benefit, although not a large benefit," Professor Gazelle says. He notes, however, that CT screenings cost US\$150,000 per quality-adjusted life year (QALY), compared with around US\$20,000-30,000 per QALY for breast or colon cancer screening. Since lung cancer is widespread, the costs of such screening can mount quickly. "If you do a CT, more than half of patients will have a positive initial result and need some sort of follow-up. You could end up with doing annual CTs on 50m people and follow-up CTs on half of them."

One answer is finding ways to target screening at the specific groups most likely to need it. The development of new chemical signatures to identify patients at high risk could narrow down the population that would benefit from regular screening, notes Dr Garassino.

Micro RNA diagnostics—using biomarkers to identify the best candidates for early screening—can help with targeting, Professor Gazelle says. But cost-effectiveness is a relative thing, he adds. "If you could just reduce smoking by a few percentage points a year, it completely dominates the benefit you could get from screening, and it's so much more cost-effective."

Better ability to identify the patients who could benefit from immunotherapy could ultimately lead to savings if it allows more of them to return to productive work, according to Christos Chouaid, head of thoracic oncology at the Centre Hospitalier Intercommunal in Créteil, France. He adds, however, that Italy may have to prepare for increased healthcare costs in the meantime.

"The cost of advanced lung cancer [treatment] is currently around €60,000, while immunotherapy can increase some patients' direct costs to €150,000 because they

<sup>23</sup> Horeweg, N, Scholten, ET et al., "Detection of lung cancer through low-dose CT screening (NELSON): a prespecified analysis of screening test performance and interval cancers," *The Lancet Oncology*, Vol. 15, No 12, November 2014.

<sup>24</sup> The National Lung Screening Trial Research Team, "Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening", *The New England Journal of Medicine*, August 4th 2011.

<sup>25</sup> Pastorino U et al., PLEN04.07: Stopping Smoking Reduces Mortality in Low-Dose Computed Tomography (LDCT) Screening Volunteers, International Association for the Study of Lung Cancer, 16th World Conference on Lung Cancer, Denver, Colorado, 6-9 September 2015, [http://wclc2015.iaslc.org/wp-content/uploads/2015/11/WCLC-2015-Abstract-Book\\_vF\\_FOR-JTO-Website\\_Low-res\\_REV-NOV-2015.pdf](http://wclc2015.iaslc.org/wp-content/uploads/2015/11/WCLC-2015-Abstract-Book_vF_FOR-JTO-Website_Low-res_REV-NOV-2015.pdf)

live longer," he says, noting that some patients are living more than two years with the treatment. France manages these costs by only using immunotherapies to treat lung cancer and melanoma, he adds.

### **Systematising treatment**

Yet more controversy surrounds the question of how to deliver effective treatment—as measured by survival rates and improved quality of life—at reasonable cost. Among the solutions offered is to consolidate treatment in specialised, high-volume centres, where expertise is concentrated and unit costs are reduced.

Italy has few such centres compared with the UK, for example. But healthcare policymakers are increasingly committed to reorganising Italy's hospital system along these lines, Dr Garassino says. The aim is to direct patients in need of high-intensity care to more specialised centres and alleviate the pressure on smaller hospitals, potentially freeing up more money in the long term.

"You might need 5-10 years to define centres of excellence for surgery," Dr Garassino explains. "You would need to define either a [minimum] number of surgeries performed or the existence of a multidisciplinary team." Italy already has around 350 oncology centres, which could be integrated into more specialised centres of surgical excellence, she adds.

A leading proponent of surgical care is Richard Sullivan, director of the Institute of Cancer Policy and the King's Health Partners Comprehensive Cancer Centre at King's College London. He points to studies<sup>26</sup> showing that centralised, high-volume treatment locations can shorten hospital stays and improve outcomes for lung cancer patients.<sup>27</sup> "High-volume centres have better outcomes, so all patients do well," Professor Sullivan says. "If you have lung cancer, you don't want to be treated in a low-volume centre."

Specialised surgery centres can improve survival rates, particularly if their surgeons are backed by national audits showing what works and what doesn't. However, he adds: "When you look at hard numbers, we've made glacial progress [on survival rates]. Well over half of the economic burden of lung cancer is ... due to premature mortality."

### **Integrating patient care**

Other experts say that high-quality surgical centres are only part of the answer to improving outcomes, and that Italy and other countries must create a more integrated medical approach to treatment.

Because lung cancer is often related to smoking, patients frequently have cardiovascular problems and other illnesses, such as chronic obstructive pulmonary disease as well, according to Dr Gaga of the European Respiratory Society. "These patients often have more than one problem, and this can prevent them from going into

<sup>26</sup> Moller, H, Sharma, Riz SP *et al.*, "High lung cancer surgical procedure volume is associated with shorter length of stay and lower risks of re-admission and death: national cohort analysis in England," *European Journal of Cancer*, September 2016, Volume 64, pp. 32-43.

<sup>27</sup> *Ibid.*

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surgery or having certain treatments that can further affect their health, their lungs and the ability to breathe, their heart and kidneys. These problems also affect their quality of life. We need to review patients very carefully, and we need multidisciplinary teams."

Such teams should include not just oncologists, surgeons and radiotherapists, but also pulmonologists and internal medicine specialists, pathologists and molecular biologists, toxicologists, psychologists and nurses, according to both Dr Gaga and Dr Menis. Having a good medical knowledge of the patient as well as discussions with the patient is important because only then can treatment be targeted and also suit the patient's expectations.

Moreover, lung cancer tumours can change in the course of treatment, so regular follow-up and very often repeat biopsies are necessary, Dr Gaga adds. "There is a huge need for understanding who the patient is, how lung cancer evolves, and provision of targeted treatment. The cost of doing this is very high and cannot be met by many countries."

According Dr Menis, the hospital system needs to be reorganised to better support accurate targeting of patients needing treatment. She adds that such a reorganisation is likely to require additional funding.

### CHAPTER 3: COMPARING STRATEGIES: THE FIGHT AGAINST LUNG CANCER

Beyond reducing the burden of lung cancer—by preventing its appearance as much as possible and by improving the outcomes for those who do contract the disease—there is a broad array of measures for managing the war on cancer more effectively. These include providing more useful support for patients and their families; distributing such support more equitably across the country; pressing ahead with research aimed at improving medical outcomes in a cost-effective way; and integrating these diverse policies into an effective, synergistic package.

#### *Supporting patients and their families*

While Italy's health service generally pays for medicines, surgery and other treatments, families take on a significant amount of daily care duties for lung cancer patients, says Claudio Jommi, professor of public management and policy at the Centre for Research on Health and Social Care Management at the Graduate Business School of Bocconi University in Milan. Others interviewed for this paper point out that so-called "informal costs" make up a sizeable amount of the economic impact of lung cancer and other cancers in Italy.

The policy challenge inherent in this situation is to compensate the carers in an equitable way. Patients' advocates have had some successes in recent years in easing patients' access to paid care. They have also won rights for patients and carers to move from full-time to part-time work, and then back to full-time work when they are able to do so, according to Francesco De Lorenzo, president of the Italian Federation of Volunteer-based Cancer Organisations (FAVO). Private employees won these rights in 2003, and public employees in 2009.

In addition, FAVO has successfully lobbied to require regional governments to ensure that patients can get a doctor's appointment within 15 days of requesting it. It has also campaigned successfully for a unified procedure to evaluate disability claims, and for a rule requiring healthcare providers to submit claims online to benefits organisations on patients' behalf. A further victory for the group is a requirement for the national health insurance system to pay benefits, including social security and disability benefits, to patients within 15 days of submission of a claim.

Meanwhile, FAVO is lobbying parliament to fund rehabilitation for cancer patients who have recovered and are trying to return to normal life. "Payers don't understand that they save money [this way], because otherwise these patients will live on disability pensions," Professor De Lorenzo says. Moreover, FAVO wants banks to remove barriers to

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lending to lung cancer survivors, and insurers to offer coverage that used to be denied when the disease was considered inevitably fatal.

An underlying problem is the regional disparity in Italy in the availability of screening and medical treatment. Patients in northern regions such as Lombardy and Piedmont generally have better access than those in the south. The health system often struggles to impose budgetary discipline across the country, but its tools are blunt, says Dr Pinto of the AIOM. "We are very able to contain costs, but we need a general improvement in the management of cancer control strategy from diagnosis to treatment," he says.

Italy's 21 regions, however, have their own evaluation systems. In addition, there are local rules for introducing medicines and deciding when these can be used. This adds up to a patchwork of availability of treatment and uneven access to cutting-edge therapies.

"The biggest problem in Italy is the lack of fast approval of treatment and equal access to treatment because we have a fragmentary system," says Stefania Vallone, president of Lung Cancer Europe.

### **Improving medical outcomes**

Beyond making access more equitable, Italy's medical system needs a better method of evaluating the cost-effective use of different treatment options. For this purpose, data on medical outcomes are crucial. Italy's National Oncology Plan lists a variety of goals, including improving the comprehensive management of patients and equalising treatment across the regions, but it does not say how the medical establishment—doctors, hospitals and policymakers—will measure medical outcomes. Moreover, while the plan mentions several specific cancers, including breast, cervical and colorectal, it does not refer specifically to lung cancer.<sup>28</sup>

This approach compares unfavourably with England's 101-page *Improving Outcomes: A Strategy for Cancer*. The policy roadmap deals with prevention and early diagnosis,

**Table 1 Improving medical outcomes: The English example**

*England's 2011 'Strategy for cancer'*

Prevention and early diagnosis

Quality of life and patient experience

Treatment methods

Reducing inequalities in outcomes for different treatment stages and social groups

Source: UK Department of Health, "Improving Outcomes: A Strategy for Cancer", January 2011

Italy's National Oncology Plan lists a variety of goals, including improving the comprehensive management of patients and equalising treatment across the regions. However, it does not say how medical outcomes will be measured, and does not refer specifically to lung cancer.

Source: Italy National Oncology Plan 2010-2012, renamed "Technical Policy Document on the Reduction of the Cancer Disease Burden – for the years 2010-2013," page 16.

<sup>28</sup> Italy National Oncology Plan 2010-2012, renamed "Technical Policy Document on the Reduction of the Cancer Disease Burden – for the years 2010-2013," page 16.

<sup>29</sup> UK Department of Health, *Improving Outcomes: A Strategy for Cancer*, January 2011.

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quality of life and patient experience, treatment methods, and reducing inequalities in outcomes across all stages of treatment and for different groups in society (Table 1).<sup>29</sup>

Italy is considering a similar approach, including a focus on outcomes, but the structure of the healthcare system can get in the way. "The ongoing programmes in Italy are regional networks for optimising prevention, diagnosis and treatment," notes Dr Pinto.

Better targeting of treatment would be one step towards this goal, Ms Vallone says. In France, she notes, healthcare providers employ platforms where they can test for a number of different mutations at the same time.

"There are places in Italy where most of the physicians are aware of the possibility of testing their patients for mutations, but there are still places where it doesn't happen, and in any case, we test only for one mutation at a time," she says.

### **Integrating diverse policies**

Making sure that treatment yields improved outcomes will require a detailed, integrated national approach that combines prevention, screening, treatment and palliative care. The World Health Organisation (WHO) points to integration of these elements as a key to fighting cancer.<sup>30</sup>

Although such multidisciplinary teams are common in larger teaching hospitals in Italy, they are not available everywhere in the country, Ms Vallone points out.

"If you are talking about a very small hospital, there isn't even a thoracic surgeon, but just a general surgeon, and not a thoracic oncologist, but just an oncologist," she says.

### **Table 2 Integrating prevention, screening, treatment, and palliative care: The French example**

*Priorities of French Cancer Plan 2014-19*

Prevention

Early diagnosis

Equal access to quality medicines and innovations

Comprehensive care of patients

Source: French Cancer Plan 2014-2019, available at: <http://en.e-cancer.fr/The-Cancer-Plan-2014-2019>

In Italy, while multidisciplinary teams combining prevention, screening, treatment and palliative care are common in larger teaching hospitals, they are not available everywhere in the country.

"If you are talking about a very small hospital, there isn't even a thoracic surgeon, but just a general surgeon, and not a thoracic oncologist, but just an oncologist. You need to find the right person dedicated to the disease, because otherwise it can delay the diagnosis, and then you can't treat it properly."

- Stefania Vallone, president, Lung Cancer Europe, Italy

<sup>30</sup> WHO, *National cancer control programmes: policies and managerial guidelines*, 2002.

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“You need to find the right person dedicated to the disease because otherwise it can delay the diagnosis, and then you can't treat it properly.”

One way of bridging this gap would be to train more healthcare workers with specialist expertise in lung cancer, Ms Vallone adds, noting that in countries such as the UK and the Netherlands specialist thoracic nurses have the expertise to help patients undergoing chemotherapy. In addition, she says, palliative care could be introduced earlier in the treatment, when metastatic disease is first diagnosed, rather than at the very end of life.

An example of an integrated approach is offered by the French plan to fight cancer. The detailed plan includes building qualitative indices of medical outcomes to evaluate progress, and taking the interests of cancer patients and carers into account when other national initiatives, such as workforce planning, are formulated.

France's comprehensive approach to cancer management has evolved over the past decade, driven by those with direct experience with cancer, says Professor Chouaid. “We had a very strong mobilisation of patients and their families, asking for a clear public health involvement in cancer. It's patients and their families who have taken the problem into the public space.” France's national plan is reviewed every four years, with oncologists, patients and public-health services leaders making quality assessments. As a result, patient satisfaction levels remain high, Professor Chouaid adds.

France's 2009-13 cancer plan outlined 30 general aims and 118 specific actions. It called for the fight against cancer to take into account other public-health policies that affect cancer patients, and for stringent monitoring to ensure that measures are implemented and evaluated effectively.<sup>31</sup> The latest French plan for 2014-19 sets out four priorities: prevention; early diagnosis; equal access to quality medicines and innovations; and comprehensive care of patients (Table 2).<sup>32</sup>

Yet Professor Chouaid acknowledges that France, like Italy, could do even better at tackling lung cancer. “Our screening programmes don't work as well as they should compared with northern countries,” he says. “We spend a lot of money for care, but we don't have the health culture of prevention.”

<sup>31</sup> French National Cancer Plan 2009-2013, Marseille, November 2nd 2009, pp. 3-5.

<sup>32</sup> French Cancer Plan 2014-2019. Available at: <http://en.e-cancer.fr/The-Cancer-Plan-2014-2019>

### CONCLUSION

The fight against lung cancer in Italy is acquiring larger dimensions as the weight of the lung cancer burden becomes clear. In Italy, lung cancer is the biggest killer of men and is tied with colorectal cancer for the most deaths in women. The profile of lung cancer patients in Italy is changing: it is becoming more female, younger, and poorer. Devising strategies to fight the disease must take into account that the targets of these measures are changing.

In combating this disease, policymakers' first priority must be confronting Italian smoking habits, since smoking is responsible for the vast majority of lung cancers. Reducing smoking will require better educational outreach—above all to young children before they consider starting to smoke—and will entail a greater willingness on the part of government to raise cigarette excise taxes.

But anti-smoking measures are hardly the only weapon against the disease. Using technology to screen for cancers—possibly relying on new information concerning risk factors to decide whom to screen—can aid early detection, which improves the chances for effective treatment. Relying on outcomes data for different treatment paths can help to ensure the most effective courses of treatment for those who do contract the disease.

Beyond that, ensuring equitable access to innovative medicines may contribute to better survival rates across the country; at a minimum, it will ensure that patients have an equal chance at survival regardless of where they live. Streamlining bureaucratic procedures to ensure that patients and their caregivers receive needed support will also reduce the burden of lung cancer—not least for the patients themselves and their families. And finally, an integrated approach—involving reducing the incidence of cancer, screening at-risk populations and following up with effective treatment—will help to reduce the mounting economic and social costs of the disease.

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