

GOVERNMENT GAZETTE

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PLAN

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PARLIAMENTARIANS
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NEW EU
COMMISSIONER
FOR HEALTH AND
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PRIORITIES

THE IMPERATIVE OF
ALZHEIMER'S DISEASE
AWARENESS



GOVERNMENT GAZETTE

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People with Dementia as People with Disability

By Henna Nikumaa



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People with dementia are often treated unequally, as compared with those that have other illnesses or disabilities, with respect to access to disability services. In the European context, which is characterized by relatively strong public welfare provision and quite comprehensive national disability legislation, people with dementia may still find themselves in an unequal position and experience discrimination in terms of access to services.

Article 1 of the UN Convention on the Rights of Persons with Disabilities provides that 'persons with disabilities include those who have long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others'.

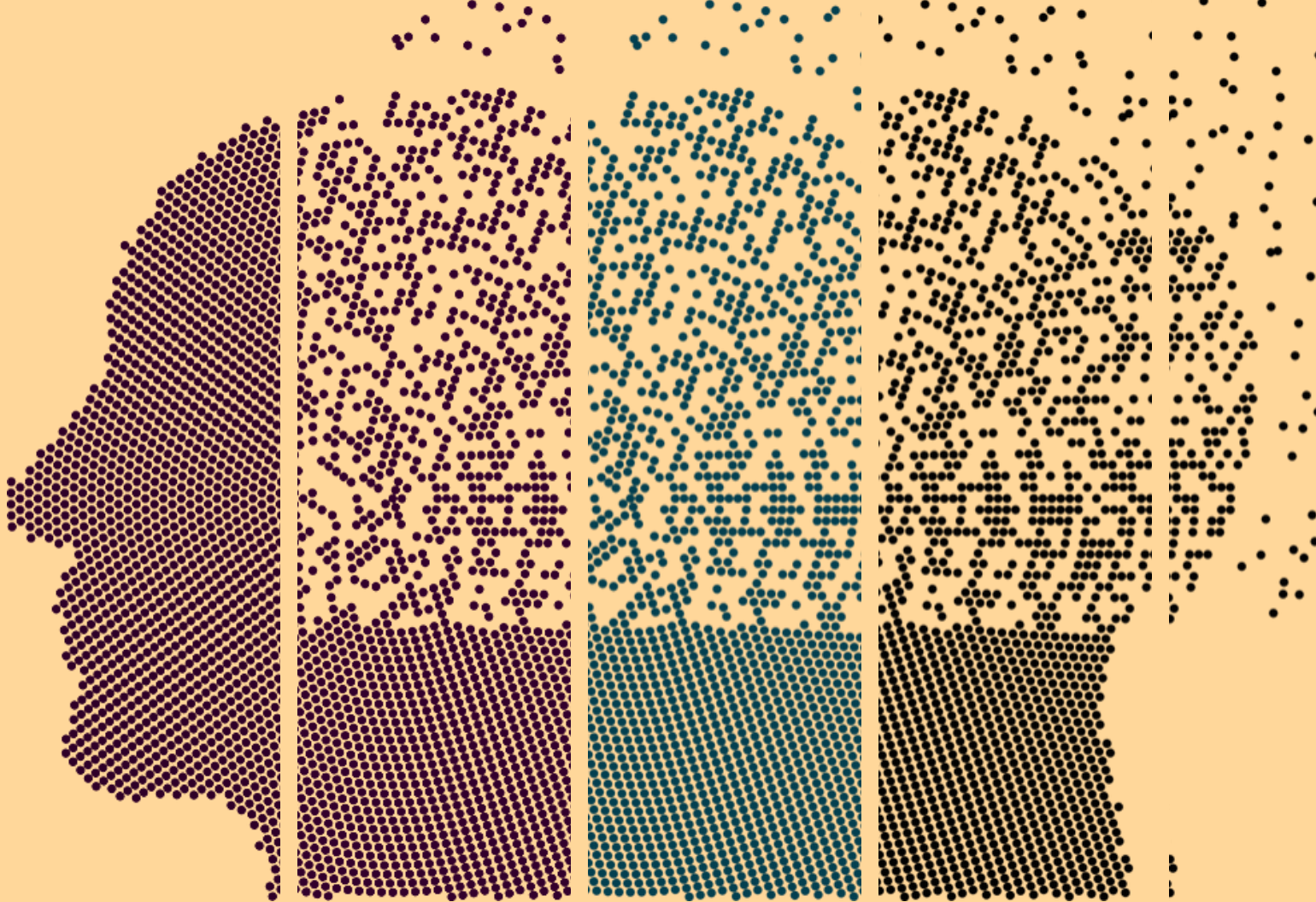
As progressive neurological diseases weaken an individual's physical, psychological, social and legal capacity, it should be clear that the Convention also applies to people with dementia. Dementia causes a cognitive disability, albeit one that is largely invisible. The UN Convention uses a social model of disability, which is based on an evolving conception of disability and does not draw any distinctions between the causes or forms of disabilities. The Convention does not exclude any age, illness or disability groups.

The significance of the unequal situation in which people with dementia find themselves has also been highlighted by Alzheimer's Disease International and Dementia Alliance International, which have called for global recognition of dementia as a disability. People with dementia should be accorded the same rights as those living with other disabilities.

People with dementia should also be able to utilize supported decision-making, which is more commonly used in respect of other disability groups. The diagnosis of a dementing illness neither removes a person's autonomy automatically nor makes him or her legally incompetent. However, as the disease progresses, capacity can deteriorate and it is likely that the person will, at some stage of the disease, lose their legal capacity. Nonetheless, with early diagnosis the period during which a person with dementia is able to make independent or supported decisions could be relatively long. The duration of this period is a significant consideration for legal planning purposes.

Different measures and tools for legal planning are essential elements in securing personal autonomy and equal agency.

Dementia Is a leading cause of disability for older people, but is not usually recognised as a disability in the context of policy, practice or disability legislation.



It is possible to legally prepare for diminishing capabilities, for example through the use of advanced directives, powers of attorney or continuing powers of attorney, and the legal framework for these instruments is reasonably similar in many European countries. Planning for the future is an essential part of anticipating the progression of dementia. However, the legal planning options are still unfamiliar and counselling or information on the matter is not sufficiently available.

Thus legal planning should be an essential part of the counselling given in connection with an early diagnosis of dementia. Ideally, of course, every person should carry out such legal planning when still in full health.

However, if this is not done, legal planning immediately after an early diagnosis is the next best thing.

For this planning, people with recently diagnosed with dementing illness need support. The support methods need to be developed as an aspect of the development of social and health care services. The social and health care professionals in charge of giving counselling when dementing illness is diagnosed need to be educated in terms of the basic knowledge of legal planning relevant to people with dementia.

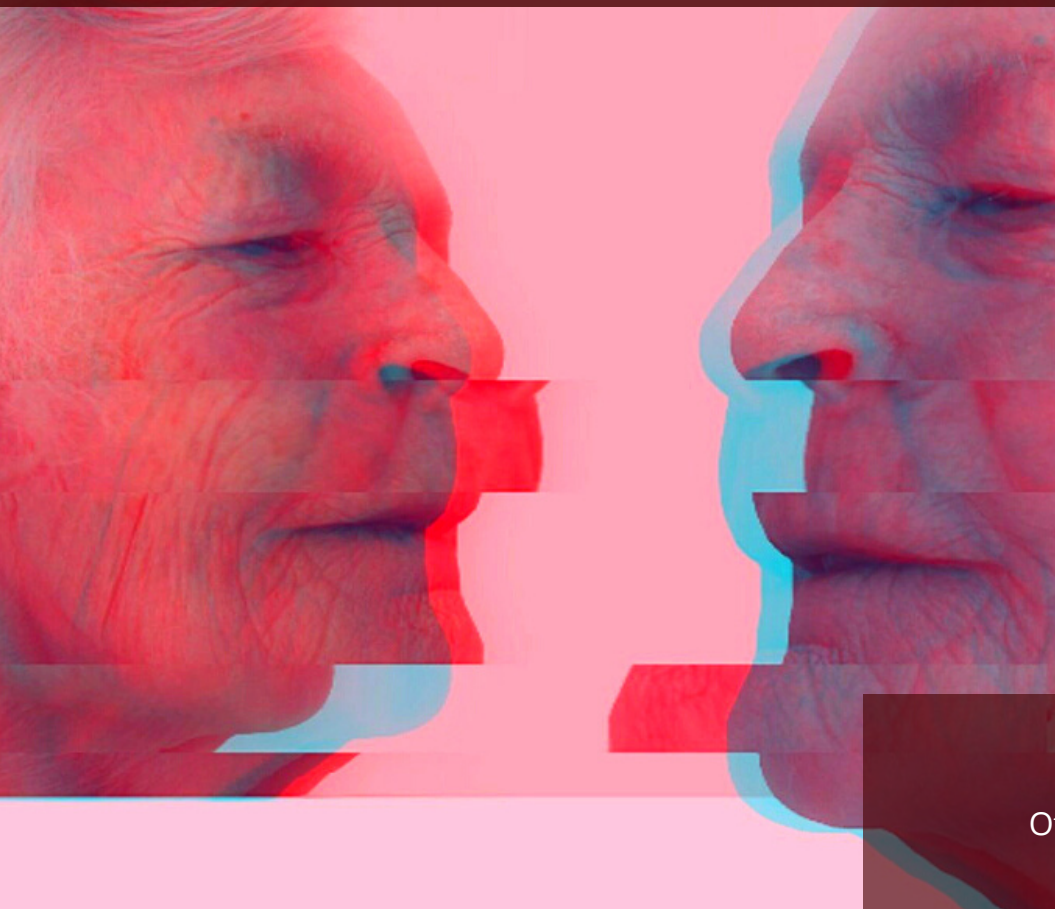
Further research and international comparisons in respect of the rights of people with dementia is needed. This research should focus both on legislative and practical methods and tools, and people with dementia need to be involved in the research. Policies should be developed so that people with dementia are legally treated as disabled. Their autonomy and legal capacity should be supported by means of a variety of tools and legal planning options.

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Living with Alzheimer's Disease

By Alison Lawrence



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In Europe, there are over 11 million people estimated to be living with dementia, of which 60-80% have Alzheimer's Disease (AD) as the underlying cause. Expectations are that this number will rise to over 18 million by 2050[1] [2]. Alzheimer's Disease is a chronic, debilitating, complex and challenging illness that places a significant strain on the quality of life for those affected, patients and caregivers alike. In addition, the growing number of people living with AD places a burden on already stretched healthcare resources with the societal and economic cost of AD in Europe estimated to increase by 43% from 2008 to 2030 to in excess of €250bn[3].

It is clear that providing good quality, patient centred, co-ordinated care for individual patients and aregivers is a priority for governments and health systems.

According to the Alzheimer's Europe Dementia Monitor 2017[1], 21 European countries had published strategies and put in place guidelines. In addition there are initiatives investing in research, raising awareness of AD and working to build dementia friendly communities within the European community.

Whilst the details of country strategies vary there are common themes that aim to improve the quality of life for those living with AD. The strategies and policies acknowledge the essential need to provide good quality, accessible care and treatment care throughout the life course of the disease. Perceived opinion being that if we are able to support people to live well it will ease the economic pressures for governments and health systems.

Not surprisingly there is considerable interest, publicly and among experts, in finding a pharmaceutical intervention that will stop or slow the progression of AD (a disease modifying treatment or DMT). The setbacks in recent years have been well documented and whilst much has been learned at each stage, a breakthrough has yet to be realised. DMTs and the associated requirement for advancement in early detection and diagnosis remain an essential goal.

Yet focusing on this end point runs the risk of losing sight of the not insignificant unmet care and treatment needs for people living with AD and for those not potentially eligible for a DMT in the future.

Perceived opinion being that if we are able to support people to live well it will ease the economic pressures for governments and health systems.

Until such time people with AD and their families require high quality care, support and information to manage the complex challenges they face living with AD. It is essential that we continue to research new treatments and therapeutic strategies for all symptoms, cognitive and behavioural alike, and at all stages of the disease.

Cummings et al[1] noted that “there is a paucity of clinical trials for new treatments targeting the moderate to severe symptoms of AD”.

In addition, this report shows that whilst there is an increase in the total number of agents in research (2017 vs 2018) of the 112 agents in the pipeline as shown on clinicaltrials.gov 34% are symptomatic cognitive enhancers and symptomatic agents addressing neuropsychiatric and behavioural changes – just 8 of which are in phase III specifically for neuropsychiatric and behavioural changes.

Memory difficulties, problems with other aspects of thinking, perception and communication are well recognised and documented symptoms of Alzheimer’s Disease[1]. Asking a family member if their loved one knows who they are over simplifies the complexity of symptoms. Whilst these memory challenges for patients and carers are not without impact on peoples’ quality of life, the behavioural and psychological symptoms of dementia (BPSD), often present the greatest challenge for the person with AD and their carers[2].



BPSD can occur at any stage of AD[1] and is not necessarily a reflection of how a family member may recall a person’s character before the onset of AD. When pausing to contemplate the range of symptoms, such as agitation, anxiety, apathy, depression, wandering, hallucinations, insomnia, incontinence, disinhibition, it is possible to comprehend how distressing it must be for the person with AD and their caregiver.

Studies show that 90%[1] of people living with AD will experience at least one BPSD during their illness and caregivers report[2] these symptoms cause them more stress and distress than cognitive decline. Furthermore, evidence suggests that, if untreated, BPSD can accelerate the decline in quality of life and be the leading factor for people living with AD moving into residential care. Moving into residential care is not only costly it can be stressful as often the move is triggered by a crisis of some kind. Caregivers often have little choice as to where they would like their loved one to live, be cared for and spend the remaining time of their life.

People living with AD and their caregivers are central to developing and implementing services, treatment options and care. The ultimate goal is to ensure that people with AD and their families have a good quality of life and are able to live well at every stage of the illness. For all involved in the research and development of treatment and care; the way in which services are structured and funded, we must take account of the whole of the life course of the illness.

Guidelines and policies must be aligned to a clear patient pathway that enables accessible, patient centred, integrated services at all stages of the disease. Patients and caregivers will live with AD for many years and until there are means to prevent or stop the progression patients and caregivers have the right to have as good a quality of life as possible.

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Alzheimer’s Disease is a chronic, debilitating, complex and challenging illness that places a significant strain on the quality of life for those affected, patients and caregivers alike.

Alzheimer's Disease

By Paola Barbarino



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50 million people are currently living with dementia, with someone developing dementia every 3 seconds. Figures are forecast to increase to 152 million by 2050, with the majority of increase in low- and middle-income countries.

It is ADI's role to advocate for and raise the profile of dementia globally. After 10 years of advocacy, we saw concrete policy action when the WHO implemented its Global action plan on the public health response to dementia 2017-2025, with targets for the advancement of dementia awareness, risk reduction, diagnosis, care and treatment, support for care partners and research. [2] National dementia plans are an essential tool for responding strategically to the global dementia epidemic and for measuring health and care preparedness. However, less than 15% of WHO Member States currently have a national plan.

Much more progress is needed to meet the WHO's target of 75% by 2025. It is my belief that a series of simple policy measures could drastically improve the lives of people living with dementia. There are many that we support but the few listed below should resonate easily in Europe.

1. Countries should share experiences and best practices

There are currently only 30 national plans globally; over half of those are in Europe. However, the existence of a plan doesn't mean it is funded and fully implemented – take Italy as an example. Our report on progress - one year into the plan implementation - revealed that certain areas, such as data sharing, risk reduction and research, are being overlooked in national plans [3]. We also really need more plans in low- and middle- income countries as we know that the majority of people with dementia are living in those.

More sharing of best practice from high income and better resourced countries is needed. I

recently visited South Korea, where they are on their third version of the national dementia plan. They are innovating on many levels and they are funding and resourcing their effort adequately. There are 256 large dementia care centres across the country catering for all stages of dementia. I saw classes for at-risk and early stages, where cognitive training helps reduce the risk of getting dementia or slows down progression. They are pioneering a mobile application called the "Dementia-Free Index" which gives individuals a score based on limiting their lifestyle behaviours that increase their risk of dementia. There is also a widespread dementia awareness education programme.

We really need more plans in low- and middle-income countries as we know that the majority of people with dementia are living in those.

2

INVOLVE PEOPLE LIVING WITH DEMENTIA AND CAREGIVERS IN THE DISCUSSION

The voices of people living with dementia and their carers need to be included in the development and assessment of strategic plans. This is so important as we know the diagnostic experience of people with dementia can be extremely difficult, leading to depression in many cases. We need strong post-diagnostic care, rehabilitation and support, which many people do not get. Involving people with dementia in the drafting of national plans, for instance, can uncover where institutional stigma needs to be addressed and enable person-centred care. We encourage the inclusion of a rights-based approach to the development of national plans, ensuring that they are embedded with human rights and Conventions on the Rights of Persons with Disabilities (CRPD) Articles. The ultimate goal of any policy on dementia (until we have a cure) should be to support people to live positively with dementia, and this can only be achieved by listening to people's lived experiences.

3

DEVELOP A DEMENTIA FRIENDLY SOCIETY

Dementia awareness and friendliness are a prerequisite for any meaningful dementia policy – especially at the global level. The Dementia Friends programme was pioneered in Japan and successfully exported to many countries [4]. Effective dementia friendly initiatives such as this help to alleviate pressure on health systems.

We do need to ask ourselves, however, what a dementia friendly society looks like because only by having a society, not just a community, that homogeneously includes people with dementia will we make any real progress. And I would like to emphasise that dementia friendly initiatives should be locally acceptable and cannot simply be transplanted from one cultural setting to another.

One of the cornerstones of dementia friendliness is access to appropriate healthcare, and we need to ensure that healthcare systems themselves are dementia friendly. A recent report revealed a lack of awareness and specific training in dementia among primary health workers in OECD countries, where primary care doctors correctly identify only around 50-75% of dementia cases [5]. By adequately training primary doctors and not relying too heavily on specialist services, governments can also enhance efficiency and help achieve the goals of universal health coverage (UHC).

4

MAKE CARE ACCESSIBLE

It is a fact that ageing societies will demand advances in care. It is also a fact that people living with dementia have a right to access adequate healthcare and social protection. [6] Governments need to improve mainstream health and specialist services for dementia. Post diagnosis support needs to be addressed, using examples such as Scotland (where people are given at least 1 year of post-diagnostic support) as the basis for inspiration. We must give consumers confidence as people need a guarantee and coordinated services. We also need to build on integrated care given that financial costs associated with dementia are so burdensome on individuals, often intensified by lengthy duration of illness and co-morbidities. The example of Slovenia's government-run care homes - recent recipients of a European award - is one of the best in Europe. In line with SDG target 3.8, governments must pursue sustainable solutions for financing and implementation of dementia services, spanning the continuum of care; risk reduction, early diagnosis, treatment, rehabilitation and palliative care.

5

DEVELOP FLEXIBLE EMPLOYMENT LAWS

The economic costs associated with dementia are huge: US\$1 trillion per year and set to double by 2030. 40% of this cost is attributable to informal or unpaid care, which amounts to the equivalent of 40 million full time jobs; a number that is forecast to reach 65 million by 2030. I urge governments to be innovative in drafting employment laws around flexible working for carers, to reduce the burdens of loss of income and career interruption. Such policy should acknowledge that women are disproportionately affected by dementia; as well as more women developing dementia, 71% of informal carers are female [7]. Singapore is a country that is making steady progress on this front.

6

EDUCATION

Education at primary level can have a lasting impact on children, for example by increasing dementia awareness and influencing healthy lifestyle behaviours from an early age. Many resources are already available for children – we have seen examples from Argentina to Israel. There are, however, fewer examples of dementia education among older cohorts. One example is a pilot project at the Universidad Latina de Costa Rica to provide standardised dementia education. South Korea is really leading the way with a dementia awareness education programme which extends to students, parents, and teachers by including courses in elementary and middle school curriculums.

CONCLUSION

Dementia is a global epidemic requiring global policy responses. The ones outlined above are easily adaptable to multiple country contexts – especially, I would argue, in Europe. Sharing of best practices among countries at different levels of Global plan implementation is essential. High-income countries must take a leading role in this. Developing a dementia friendly society which is appropriate to the country's cultural context is the first step towards effective dementia policy. Governments should also make care accessible; make labour laws flexible to support informal carers and people with dementia as far as possible; and develop strong educational programmes. All of these will help relieve the pressure on health and social systems later in life. Importantly, any policy must directly involve people living with dementia and caregivers; whilst remembering that one size does not fit all, people-centred care is what we all should aspire to.

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Dementia

By Karin Kadenbach



Introduction

The OECD estimates that there are around 9.1 million aged over 60 living with dementia in EU member states and according to 'Dementia:

A Public Health Priority', a report published by the World Health Organisation (WHO) in 2012, it is estimated that by 2030 nearly 14 million people in Europe will have some form of dementia, which is expected to rise to over 18 million by 2050. Research commissioned by Alzheimer Europe and published in

2009 used similar prevalence estimates and projected that the cost of dementia in Europe will exceed €250 billion by 2030.

With no cure and no disease-modifying treatment on the horizon, there is a need of high quality care, support and information, which allows people to continue to live as well as they can with the condition, remaining in their communities for as long as possible.

Dementia as policy priority

To achieve this, a coordinated approach is needed, raising public consciousness about the condition, training health and social care professionals about the best way to provide care and support, whilst fostering research and innovation across academic disciplines.

In 2014, Alzheimer Europe launched the Glasgow Declaration calling for the creation of a European Dementia Strategy, national strategies in every country in Europe, as well as calling on world leaders to recognise dementia as a public health priority and to develop a global action plan on dementia.

In that time, many countries across Europe have published dementia strategies, setting out how they intended to address the condition. Additionally, the World Health Organisation (WHO) launched its 'Global Action Plan' on dementia in 2017, outlining seven 'action areas'

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**With no cure
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1. Dementia as a public health priority.
2. Dementia awareness and friendliness.
3. Dementia risk reduction.
4. Dementia diagnosis, treatment, care and support.
5. Support for dementia carers.
6. Information systems for dementia.
7. Dementia research and innovation.

These themes reflect many of the priorities in the national dementia strategies of EU Member States, whilst also aligning well with some programmes of work and projects at an EU level. This includes the third EU Health Programme (2014-2020) which commits to 'support cooperation and networking in the Union in relation to preventing and improving the response to chronic diseases including cancer, age-related diseases and neurodegenerative diseases...'.¹

The Second Joint Action on Dementia is a three-year project funded through the Health Programme, involving a number of EU Member States. Beginning in 2016, the project aims to promote collaborative actions among Member States to improve the lives of people with dementia and their carers across four areas:

- Diagnosis and Post-Diagnostic Support
- Crisis and Care Coordination
- Residential Care
- Dementia Friendly Communities

The programme aims to provide practical guidance for policymakers developing and implementing their national dementia plans, policies and strategies. In addition, it aims to provide cost-effective and practical examples of the core components of good dementia diagnosis, care and support. Projects such as this have the potential to transform the way care and support are delivered to people across Europe. Such programmes demonstrate the ability of dedicated funding from the EU to support collaboration towards better outcomes for people with dementia.

Dementia research

There has been slow progress on the development of a disease modifying treatment for Alzheimer's disease and other dementias, with a high attrition rate in drug development. However, significant progress has been made in a number of areas, with innovative research improving brain scanning for the condition, the way in which we use biomarkers to detect dementia and developments in data usage. These developments are changing the discussion around diagnosis, as well as expanding our understanding of the condition which may help towards the discovery of a preventative or curative intervention.

The Horizon 2020 research programme has helped drive progress, including funding for collaborations such as the second Innovative Medicines Initiative (2014-2024), funding for projects such as EPAD, AMYPAD, MOPEAD, ROADMAP and PARADIGM. Other funded initiatives include the Joint Programme for Neurodegenerative Diseases Research (JPND), which seeks to increase coordinated investment between participating countries in research aimed at finding causes, developing cures, and identifying appropriate ways to care for people with neurodegenerative diseases.

It is essential that such joint initiatives and research projects, across drug development, detection and diagnosis, as well as high quality care and support for people living with the condition is, continue to be funded through the Horizon Europe research programme.

Conclusion and Policy Recommendations

Given the prevalence of dementia and the anticipated increase amongst the population, it is of utmost importance for Member States and the EU to work together to ensure that dementia is made a priority at both European and national level. Work must take place in coordination, avoiding duplication and ensuring best practice can be shared widely to improve outcomes for people with dementia. In terms of policy recommendations for dementia:

- Each country should have national dementia strategy, with clear measures and processes to oversee its implementation and evaluation, with the EU committing to supporting the WHO's Global Action Plan on Dementia.
- EU institutions must commit to ensuring that in the forthcoming Horizon Europe views dementia research as a priority, committing to funding high quality dementia research both in clinical, basic science and practice-based research.
- The EU Commission must ensure that the place of dementia, and health more broadly, continues to be sufficiently funded – especially if the Commission does not commit to a specific health programme within the next MFF.

Imperative of Alzheimer's Disease Awareness, Early Screening & Diagnosis in Europe



By Dr. Harald Hampel, MD, PhD
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Alzheimer's disease (AD) represents a worldwide fast-growing health epidemic. The global proportion of people aged 65 years or older is growing rapidly and will make up 30% of the general population by 2060 (1, 2). The incidence of age-related diseases - such as cancer and neurodegenerative diseases - will increase dramatically with this extended lifespan. The prevalence of dementia increases with age, affecting approximately 2.5% of people aged 65 to 69 years, and escalating to almost 40% of people aged 90 to 94 years in western Europe (3). By 2050, there will likely be up to 18.9 million patients with dementia in Europe (4).

The increasing incidence of AD will fundamentally overburden all European healthcare institutions and services. It is estimated that the direct and indirect costs in Europe will increase by about 43% between 2008 and 2030 with an absolute value exceeding €250 billion (1),(5). When considering the effect on AD sufferers combined with the medical, financial, ethical, emotional, and physical challenges placed on their loved ones, it becomes shockingly clear that the exponential growth of AD presents a major threat to our societies and Europe and the world at large (6).

There are currently no curative or disease-modifying treatments available for AD. However, there are several drugs with putative or reported disease-modifying effects in late stages of clinical development. These candidate treatments target patients in early clinical stages of AD - the mild cognitive impairment (MCI) stage - before dementia symptoms manifest, and have the potential to significantly delay disease progression. If a new treatment was to become available soon, the 20 million individuals with MCI in the 28 European Union (EU) countries would require systematic multi-stage screening, diagnosis, and treatment as quickly as possible. The goal of treatment would be to avoid progressing to overt dementia with complex behavioral or neuropsychiatric symptoms and severe disabilities including loss of autonomy and independence (7).

There is a high probability that the demand caused by the increasing incidence of AD would outweigh the capacities of the current healthcare systems, and therefore lead to very long wait times to access a required multi-stage diagnostic work-up and subsequent management. Capacity issues can manifest into real clinical problems, as even with the availability of new therapies, not all of the patients who could benefit would access them. Indeed, it is estimated that if these capacity constraints could be overcome we could prevent 1 million AD sufferers from progressing from the initial symptomatic MCI stage to AD dementia (5). It is essential that we begin to establish the required infrastructure across European regions and implement widespread cognitive screening and diagnostic algorithms for accessible early AD detection and diagnosis.

Thus, the healthcare systems and the whole societies must be sensitized to the importance of an early detection and diagnosis of AD in order to implement the expected disease-modifying treatments once they will be available.

In addition, there are several challenges to overcome for accomplishing an efficient large-scale detection of early stages of AD. For example, MCI is a heterogeneous clinical syndrome with multiple potential pathophysiological mechanisms underlying it.

It is estimated that 40% to 60% of individuals aged 58 years and older with MCI have underlying AD pathophysiology. The incidence of MCI due to AD is likely down rated due to the fact that disease-modifying treatments are not available and therefore a considerable number of physicians do not recommend medical examinations for the diagnosis of preclinical / prodromal AD. One potential reason for the current lack of screening and diagnosis of people with MCI due to AD is that many physicians believe that early identification and diagnosis of these individuals is futile. This belief stems from the fact that current treatments only target symptoms of AD but does not take into account the potentially near future availability of disease-modifying treatments (8).

Raising awareness and challenging the notion of the futility of early identification is an immediate imperative in the EU. Early identification of individuals with cognitive impairment can be beneficial even before a disease-modifying therapy is available. This can come in the form of better management of the vast array of treatable components of cognitive impairment as well as from lifestyle interventions that may help slow cognitive decline. It also allows for future financial and personal planning. Finally, for many patients and their families, understanding the source of their cognitive complaints can be comforting or even empowering (8); (9).

Cognitive screening tools ideally, should be quick and easy to use, utilizing both patient and informant assessments, in addition to physician evaluations (9). Several groups have provided valuable recommendations and guidance (8).

However, specific and up-to-date European guidelines informed by currently available tools are still urgently needed to avoid uncertainty among specialists and primary care physicians about how best to detect MCI. A standardization of the neuropsychometric assessment and the harmonization of protocols is of primary importance.

Biomarker-based screening tools will also be crucial for the success of a disease-modifying therapy. Not all individuals with MCI have AD as the underlying pathology (e.g. differentiation from patients with medications and multiple medical syndromes and diseases affecting cognition or major depression) (8). Thus, after screening people for MCI, the underlying brain molecular changes, such as amyloid and tau pathophysiology to confirm a diagnosis of AD, need to be rapidly evaluated (7); (10). The rapid pace of research on the use of blood-based biomarkers to aid in the detection and diagnosis of AD pathophysiology creates the potential for these innovations to revolutionize the future of early and accurate AD identification (7). However, large investments and changes in infrastructure will be required to efficiently integrate upcoming blood-based biomarker panels into clinical practice.

A steep increase in the aged population over the next decades will bring with it an unprecedented and unavoidable EU-wide health crisis. The EU must begin taking immediate, concerted action to face these daunting challenges head-on. Sensitizing health care professionals and the whole society to the emergence of AD in general and an early diagnosis of AD must begin now to optimally prepare the background for the potential near future availability of effective disease-modifying treatments. In parallel, we must invest in the development of simple, globally accessible, time- and cost-effective cognitive and biomarker-based screening tools and establish up-to-date EU guidelines for physicians to follow.

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Shifting mindset and approach to eliminate lung cancer as a cause of death

By Nathalie Varoqueaux



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Every two minutes someone in the EU28 dies from lung cancer; one fifth of all cancer deaths and around 1 in 20 of all deaths across the EU[i]. It is a bleak picture but thankfully not one that necessarily represents the experience of every person diagnosed with lung cancer. At AstraZeneca we believe that a mindset shift is required for lung cancer. Innovations and focused implementation are needed to support earlier diagnosis, deliver curative treatments and ensure high quality care for all. Adopting a mindset that long-term survival and cure are possible in lung cancer will encourage adoption of new approaches to the treatment and care of patients.

Newer treatments for metastatic (or “stage IV”) lung cancer are changing the landscape for patients to live longer and with better quality of life[i].

The growing scientific understanding of cancer driver mutations has supported development of targeted treatments. In recent years, we are seeing “next-generation” treatments showing greater efficacy, lower toxicity, and benefit in new patient populations, compared with the earlier generation treatments[ii][iii].

These developments provide new options for patients and highlight the need for genetic testing at diagnosis to appropriately identify all patients. Further possibilities exist when lung cancer is diagnosed in stages I - III before it has spread around the body. Here it can be treated with curative intent. We want to build on these possibilities and our ambition is to eliminate lung cancer as a cause of death.

Recent new evidence on lung cancer screening[i] is extremely important, providing strong support for implementing screening programmes across Europe.

**Every
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**EUROSTAT, CANCER
STATISTICS**



Formal calls to revise the 2003 EU Council recommendations on cancer screening[i] are welcome but countries shouldn't wait for these changes. Examples of implementation such as in the UK[ii], underpinned by evidence based national guidance[iii] should be replicated by other health systems. We are committed to working with partners to advance the case for adoption of screening and trust this will lead to more patients being diagnosed earlier where, for example in stage 1 disease, 5-year survival is 68% to 92%[iv]. A shift to earlier diagnosis demands a shift in approach to the development of new treatments for lung cancer. This is one of our key priorities for investment in research.

We are working extensively towards new treatment options in stage III disease[i], building on recent approval of a new treatment option in this setting[ii].

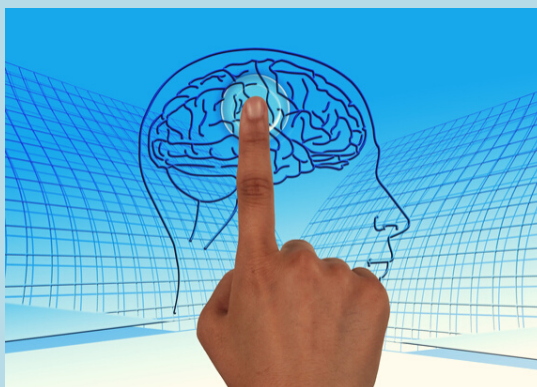
We are also conducting trials to test treatments in earlier disease settings (stages I-III)[iii] where surgery will continue to play a critical role but there is potential for medicines to improve outcomes of patients receiving surgery for their lung cancer.

A further area of exploration is the potential of intervening proactively where there is "minimal residual disease", to improve outcomes among patients who have had a good response to treatment but are at high risk of relapse[iv].

We're proud of our role in developing the first "liquid biopsy"[v] (ctDNA) and this is now actively being investigated as an approach to predict the risk of relapse and to characterize the mechanisms of resistance among people who have received treatment[vi].

Investment in research is a key part of our commitment to the patients of tomorrow. Today's patients need support to ensure they have access to and a good experience of care. We are also working in this area including, for example, providing support programmes for patients facing the challenge of lung cancer[i] and working to address the variations in access to treatment that have been well-described. These are linked to different reimbursement status of treatments and/or different access to biomarker testing[ii].

Our commitment to people with lung cancer, across Europe and beyond, means that we will continue to work with multiple partners to improve both the outcomes that are possible and the outcomes that are delivered in practice across different geographies and health systems.



We're proud of our role in developing the first "liquid biopsy"[v] (ctDNA) and this is now actively being investigated as an approach to predict the risk of relapse and to characterize the mechanisms of resistance among people who have received treatment[vi].

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Fighting lung cancer in the European Union

By Antoni Montserrat Moliner



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Lung cancer causes 1.37 million deaths per year worldwide, which represents 18% of all cancer deaths. Within the European Union, lung cancer is one of the most frequently fatal cancers, leading to over 266 000 deaths yearly and accounting for 20.8% of all cancer deaths. Lung cancer mortality in men from the European Union (EU) peaked in the late 1980s at an age-standardised (world standard population) rate over 53 per 100,000 and declined subsequently to reach 44 per 100,000 in the early 2000s and continued to fall over recent years, to reach a value of 41.1/100,000 in 2005-2009. The fall was similar at all-ages and in middle-aged men (less than 2% per year over most recent years), but was appreciably larger in young men (aged 20-44 years, over 5% per year).

This favourable trend is essentially due to the widespread measures for smoking control and cessation. Smoking can contribute to around 85% of the lung cancer cases[1].

Anti- tobacco policies, especially in middle-aged European men, i.e., in the generations where smoking prevalence used to be high, would lead to appreciable reductions in male lung cancer mortality in the near future. This is particularly urgent in central and eastern European countries.

According to EURO CARE-5 Study[1], lung cancer had a European average five-year relative survival of 13%. The European mean age-standardised 5-year survival for lung cancer is one of the poorest and it's better for women than for men. Geographical differences were small, varying from 9% in the UK and Ireland to 14,8% in central Europe. Age was a strong determinant of survival, ranging from 24,3% for patients aged 15-44 years, to 7,9% for patients aged older than 75 years. However European 5-year survival increased significantly from 11,6% in 1999-2001 to 13,4% in 2005-07, with similar trends in each region.

Risk factors for lung cancer include: Smoking, Exposure to second hand smoke, Exposure to radon gas, Exposure to asbestos and other carcinogens and Family history of lung cancer.

For the European Commission cancer prevention constitute one of our high priorities. The adoption on October 2014, of the last version of the European Code Against Cancer permits to have a key tool for general prevention of cancer with a particular emphasis on some recommendations that could be very efficient in prevention of lung cancer (Do not smoke, Do not use any form of tobacco, Make your home smoke free, Support smoke-free policies in your workplace. Take action to be a healthy body weight. Be physically active in everyday life. Limit the time you spend sitting, Have a healthy diet).



These recommendations are supported by an active policy of the EU. With one in three cancers being preventable, addressing the risk factors (or determinants) is at the forefront of the Commission's strategy to reduce the burden of cancer. The Commission addresses all the key risk factors, e.g. through an ambitious tobacco control policy comprising both robust laws regulating tobacco products and prohibiting the advertising and sponsorship of such products; an award winning pan-EU campaign "Ex-smokers are unstoppable"; strategies and platforms for joint action on alcohol and nutrition & physical activity bringing together Member States and a wide range of stakeholders including NGOs and industry.

The Commission further contributes to cancer prevention by addressing environmental factors such as exposure to carcinogenic and mutagenic substances both indoors (including in the workplace) and outdoors. It does so mainly by developing and implementing legislation on air, soil and water quality and on general chemical exposure (i.e. in water, waste and organic pollutants). A new ongoing revision of the 2004 Directive will permit to set the exposure limit values (maximum amount of substance allowed in workplace air) and/or skin notations (possibility of significantly absorbing substance through the skin) for additional carcinogens.

Lung cancer in women differs from lung cancer in men in many ways. Even though smoking is the number one cause of lung cancer, a higher percentage of women who develop lung cancer are life-long non-smokers. Some of the causes may include exposure to radon, secondhand smoke, other environmental and occupational exposures, or a genetic predisposition. Recent studies suggest infection with the human papilloma virus may also play a role.

New immunotherapy (using the body's own immune cells to attack cancer cells) shows great promise for patients with advanced, non-small cell lung cancer (NSCLC). Personalized medicine is also providing hope by treating a patient already diagnosed with lung cancer with drugs that are effective based on specific characteristics of their tumour.

In order to be recommended for population-based screening, malignant tumours must meet certain scientific criteria: the disease must be common, sensitive to safe and uncomplicated detection and more easily and effectively treated if diagnosed at an early stage. Breast, cervical and colorectal cancer meets these criteria and on this basis, the 2003 Council Recommendation on cancer screening acknowledges both the significance of the burden of cancer and the evidence for effectiveness of breast, cervical and colorectal cancer screening.

At the time, the available evidence did not yet point to an appropriate balance between benefit and harm of population-based screening when it comes to lung, prostate and other cancers.

On 30 April 2015 the European Respiratory Society (ERS) and the European Society of Radiology (ESR) published a joint white paper on lung cancer screening[1] suggesting data supporting the survival benefit for screening of individuals at high risk for early detection of lung cancer using low dose computed tomography (LDCT) including minimum requirements and recommended refinements.

Findings from a recent study, the NELSON study, demonstrate that the use of computed tomography (CT) screening among asymptomatic men at high risk for lung cancer led to a 26 percent (9-41%, 95% CI) reduction in lung cancer deaths at 10 years of study follow-up (at 86% compliance). The NELSON study was a population-based, controlled trial that enrolled 15,792 individuals, who were randomized 1:1 to either the study arm or control arm.

In the framework of the ongoing Joint Action iPAAC (2014-2020) on Innovative Partnership for Action Against Cancer, supported by the EU Health Programme, a specific work package (WP5) will evaluate suggestions on possible prevention and cancer screening programmes.

The objectives of WP5 in iPAAC are to reinforce cancer prevention via population-based screening programmes, further developing the principles of the 2003 EU Council Recommendation on screening, to identify data collaboration partners and to describe the process leading to better implementation of screening and strengthen screening practices with quality criteria and to remove obstacles of early detection of cancer.

CRDs and lung cancer are, to a large extent, preventable, and prevention costs are less than treatment costs. Therefore, education and legislative actions supporting better lifestyle choices and helping to eliminate risk factors will be crucial in reducing CRD burden. Future actions will need to adapt to an ageing population, putting in the centre the patients and their quality of life; make use of innovative technologies and large cohorts to improve disease and risk factors understanding; and capitalise on the advances in knowledge to provide better screening methods and stratified therapies.

Under the Seventh Framework Programme (2007-2013), about 1000 research projects on cancer received funding totalling some €1.6 billion. From which 194 relevant projects related to CRD from which 16% related to lung cancer. Lung cancer and infections with an impact on CRD have been funded for an amount of over €350 million. Under Horizon 2020 (2014-20) the current EU framework programme for research and innovation, 980 cancer research projects so far have been funded for €1.2 billion. Horizon 2020 provides a wealth of opportunities to address unmet research and innovation needs in CRD within the theme "Health, demographic change and wellbeing" (budget €7.6 billion) and elsewhere in Horizon 2020.

For the next long-term EU budget 2021-2027, the Commission today proposed €100 billion for research and innovation. The new programme – Horizon Europe – will build on the achievements and success of the previous research and innovation programme (Horizon 2020) and keep the EU at the forefront of global research and innovation. Horizon Europe is the most ambitious research and innovation programme ever.

The European Commission feels fully concerned by the tremendous impact of lung cancer. They will invest, as much as possible, efforts to contribute to the reduction of cases and for a better prognosis for patients affected.

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Doctors and Governments Must Keep Up the Momentum on Lung Cancer Progress

By Chris Martin



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Lung cancer is a growing global epidemic with 1.6 million deaths annually that will require an international effort to reduce the morbidity and mortality of this tragically lethal disease. More than 60% of lung cancers are diagnosed after the cancer has spread, leading to worse outcomes for patients, whereas early detection and diagnosis can lead to lowered mortality. Implementing a validated tool to reliably find early stage, curable lung cancer is a priority of the International Association of the Study of Lung Cancer (IASLC) in its mission to conquer thoracic cancers worldwide.

And yet, despite lung cancer killing more people than breast, prostate and colon cancers combined, there is no global consensus or standard for lung cancer screening.

This may be our continent's biggest challenge for the next generation. Fortunately, there is hope on the way. In 2018, results from the Dutch-Belgian NELSON lung cancer screening trial presented at the IASLC 19th World Conference on Lung Cancer (WCLC) in Toronto, Canada, support the use of low dose computed tomography (LDCT) screening in high risk individuals as one way to reduce lung cancer mortality.

Still, CT scans have barriers to widespread implementation as a screening tool. Not all patients live close to a center that has the technology and cost can be a factor. I encourage my colleagues to continue to press for better methods to screen more people at risk. One such method is a liquid biopsy. On this front, there is much excitement, too. The possibility of using a non-invasive method to understand and identify molecular targets and mechanisms of resistance for current drugs, both targeted agents and immunotherapies, will be extremely beneficial for patients, as will harnessing these strategies to identify new biomarkers.

The future of liquid biopsies is undeniably exciting, but there is a need to more clearly understand the latest developments.

The effective use of any screening tool for lung cancer hinges on clinicians' ability to diagnose and predict, with near certainty, what therapies might be most effective. Properly staging tumors helps clinicians better treat lung cancer and it allows for more clear clinical trials to move forward.

**The future of
liquid biopsies is
undeniably
exciting**



In 1998, the IASLC established its Lung Cancer Staging Project, an effort to collect a significant, international database of lung cancer cases and their anatomical classifications. In 2017, a new staging system was implemented worldwide to share staging information with our European and international colleagues on a more regular basis. The Second Edition of the IASLC Staging Manual in Thoracic Oncology reports on the latest revisions of the tumor, node and metastasis (TNM) classifications of thoracic malignancies, namely lung cancer, malignant pleural mesothelioma, carcinoma of the esophagus and of the esophago-gastric junction, and thymic epithelial tumors.

The focus on better, more accurate staging along with a renewed and strengthened screening effort, will make all lung cancer specialists around the world better equipped to diagnose and treat lung cancer patients. In just the past decade, tremendous

advances in the treatment of metastatic non-small cell lung cancer (NSCLC) have been made due to the identification of targetable oncogenic molecular drivers on which the tumors are dependent for their growth and survival. Precision oncology—treating the patient with therapies predicted to be effective based on the specific molecular characteristics of their tumor—can add years of quality life for those patients. Ensuring that oncologists worldwide have access to these advances is critical to ensuring that all patients have access to the latest treatments.

Work on this front continues in Europe and North America and we should encourage the support of these ongoing trials to allow our researchers to further hone targeted therapies and identify biomarkers that will indicate receptivity to these new therapies.

For European government officials, all of these recent developments create a serious momentum for real progress screening, diagnosing and treating lung cancer—a momentum that will call for leadership and investment across the continent but also in our own countries.

The IASLC is hosting its 20th World Conference on Lung Cancer in Barcelona September 7-10, 2019.

For more information, visit: <https://www.iaslc.org/events/iaslc-2019-world-conference-lung-cancer-wclc19>.

The focus on better, more accurate staging along with a renewed and strengthened screening effort, will make all lung cancer

For European government officials, all of these recent developments create a serious momentum for real progress

Early detection and Screening of Lung Cancer in Europe: Technological enablers for efficient screening programs

By Lars Rower



Lars Rower

Senior Director EU Affairs
Siemens Healthineers

In 2009, the European Union launched “European Partnership for Action Against Cancer” (EPAAC), the first Joint Action against Cancer, and committed to ambitious goals regarding the reduction of the cancer burden in Europe.[1]

Just recently, the European Peoples Party group of the European Parliament published a roadmap claiming “Nobody [has] to die of cancer in 20 years’ time”. [2]

With more than 250.000 deaths in the EU-28 annually, lung cancer is the leading cause of oncological mortality in the EU. Hence, any action aiming to reduce cancer mortality in Europe will fail, if it does not address lung cancer.

The most promising approach is of course prevention, especially reduction of tobacco usage and smoking cessation programs. Unfortunately, these measures only show long-term effects – the number of deaths from lung cancer even slightly increased between 2008 and 2018.

To improve lung cancer mortality quickly and save thousands of lives across Europe, we need to implement measures that have positive short- to mid-term effects on mortality: Screening programs for lung cancer present a strong, evidence based opportunity to get there. These programs must be combined with smoking cessation and provide additional opportunities for preventive measures. This article highlights the technological innovations that enable efficient LCS programs.

Technological Enablers of Lung Cancer

Screening. A number of large clinical studies showed the benefit of screening a high risk population for lung cancer. Together with innovative treatments, this screening can lead to a significant short-term reduction in lung cancer mortality: The latest large study that reported results was the NELSON study from the Netherlands and Belgium, showing a 26% reduction in lung cancer mortality.

These studies showed that lung cancer screening in selected individuals at high risk is an important part of any strategy to reduce cancer mortality in the EU. Several technological innovations along the pathway of diagnosing and treating lung cancer contribute to making screening a feasible solution to reduce mortality:

- (1) Reduction of the applied radiation dose,
 - (2) Improved diagnostic accuracy and workflow efficiency through automation
 - (3) Availability and capacity of modern Computed Tomography (CT) technology
 - (4) Quality assurance through standardization and remote supervision
 - (5) Innovations in treatment of the found lesions.
- These innovations allow to design LCS programs that ensure the highest standards of security and safety for patients, equal access for patients to the same evidence based standard of care (protocols and procedures), and optimize the clinical outcomes of the screening. In addition, innovations support the medical professionals in efficiently managing the additional workload, and link the screening back to follow-up diagnosis and treatment in case lung cancer nodules are identified.

1 REDUCTION OF THE APPLIED RADIATION DOSE

Every screening program has to balance the benefits of early detection against the risks of conducting the screening procedure. For LCS, the participant's exposure to radiation that is necessary to acquire the CT image represents one of these risks. Modern Computed Tomography (CT) systems are able to conduct lung scans for screening at very low radiation doses. Several technologies were introduced in the past 15 years, including iterative reconstruction and spectral filtering, that enabled chest scanning at effective dose levels of 0.1-0.3 mSv, which is below 1/10 of the global average background radiation.[1] Spectral filtering through tin filtration adapts the spectrum of radiation specifically to this application, thereby eliminating radiation that does not contribute to diagnosis before it reaches the scanned person. Therefore, radiation dose is no hurdle any longer to implementing LCS programs.

2 IMPROVED DIAGNOSTIC ACCURACY AND WORKFLOW EFFICIENCY

Diagnostic accuracy is important to prevent unnecessary invasive interventions as well as too many follow-up examinations. Fortunately, large progress has happened in this area: The NELSON trial first used software for semi-automated volumetry and achieved a significant improvement compared to the previous NLST trial with manual measurements.[1] Since then, an almost revolutionary development in the field of artificial intelligence took place, and many of these technological developments find application in lung cancer screening. Generally speaking, LCS programs can benefit from AI powered solutions by improving the probability to correctly identify and indicate potentially malign nodules. This addresses one of the core weaknesses of "old" screening approaches: The relatively high number of "false positives" that are challenging for overall outcomes of a LCS program and individual participants alike. Although more research about the clinical results of these tools in a screening setting is required, there is strong hope that these tools will lead to even lower rates of patient recalls than today and at the same time relieve the radiologists from repetitive work. Recent lung screening activities already achieve very low rates of unnecessary interventions and much better results than long established screening programs like cervix carcinoma.

The patient management is another critical success factor of cancer screening programs. This also greatly profits from digital approaches: Cloud-based solutions enable seamless data exchange between the participating physicians along the patient journey, and digital solutions simplify risk assessment and the invitation of the appropriate target group. Appropriate safety and security measures are used to restrict access to the data and ensure patient privacy.

3 AVAILABILITY AND CAPACITY OF MODERN CT TECHNOLOGIES

Implementing LCS programs will raise the number of CT screens conducted per year. The amount of additional screens depends on the size of the targeted risk group, the participation level and the intervals of screening. Most European countries have an installed base of CT systems that seems to be sufficient to handle the workload from lung cancer screening programs.

Some countries, where the availability of CT systems is at a critical level, like the UK, have already taken actions to improve the situation. However, a large portion of the installed base does not provide the technological prerequisites for ultra-low-dose screening.[1]

Additionally, the availability of a sufficient workforce in radiology – medical doctors as well as medical technical assistants (MTAs) – is of critical importance to the success of LCS programs. Advanced CT systems reduce the workload by providing higher levels of automation in image processing e. g. by automatically adjusting to the individual patient's physiognomy.

4 QUALITY ASSURANCE THROUGH STANDARDIZATION AND REMOTE SUPERVISION

One of the challenges in any screening program is to ensure high levels of quality over a long period of time in multiple locations. Connecting screening centers and CT systems to a larger "LCS Network" makes it possible to apply digital solutions that contribute to quality assurance e. g. by enforcing and maintaining scan protocols, or supervising image quality as well as image reading. A large part of the CT systems in Europe are already connected to networks, and more will be in the future. The American College of Radiology took the lead in this with their registry, and the European societies are now called to action to provide similar registries. Furthermore, digitalization and connectivity of systems enable not only quality control, but will improve the accuracy of the diagnostic tools through "continuous learning" of the software over time.

5 INNOVATIONS IN TREATMENT OF SMALL LESIONS DETECTED THROUGH SCREENING

Screening for lung cancer leads to a shift from late-stage surgery and radiotherapy to early-stage surgery and radiotherapy. These early stage interventions raise the probability of curative treatment. This eventually causes the positive effect on mortality. However, it remains a challenge to tackle small pulmonary nodules minimally invasively because of their size and the plasticity of the lung. Intra-operative image-guidance seems to be crucial to account for tissue deformation during interventions and the requirement for minimally-invasive approaches. New infrastructure and tools like hybrid operating rooms, endobronchial navigation systems and robotic surgical system have been introduced in the last years. In this new environment more evidence is needed to develop guidelines and therapy pathways.

SUMMARY

Two large randomized controlled trials and several additional studies provide convincing evidence to conduct screening programs for lung cancer. Due to the longitudinal nature of such trials, between the time of the design and the publication of the outcomes of these trials, there are plenty technological innovations that further support effective and efficient screening. These innovations address challenges across the whole participant/patient pathway from invitation management via the image acquisition and reading to minimal invasive surgery. All these technologies are commercially available, and further development will lead to even better results in the future.

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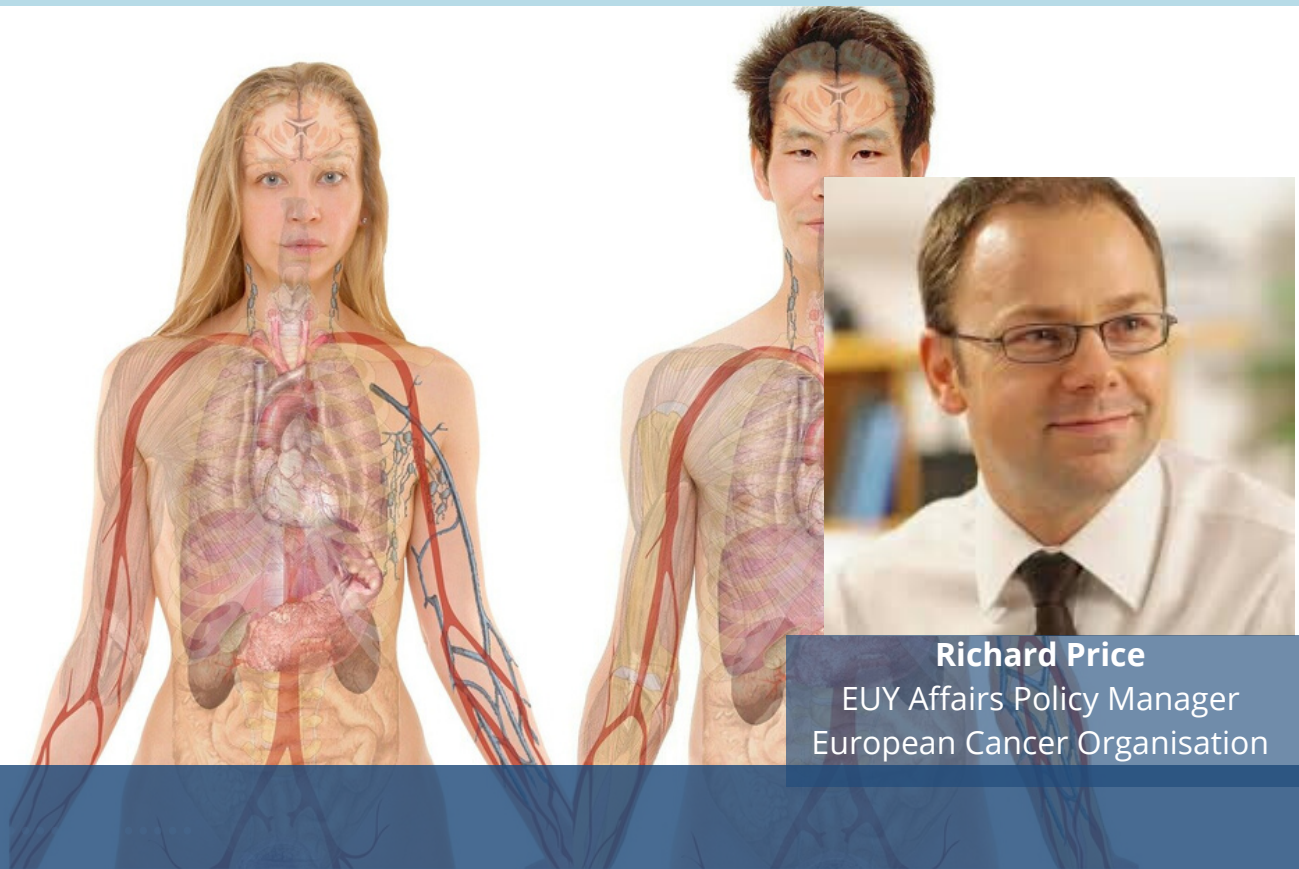
[1] Huber, A., et al., Performance of ultralow-dose CT with iterative reconstruction in lung cancer screening: limiting radiation exposure to the equivalent of conventional chest X-ray imaging. *Eur Radiol*, 2016. 26(10): p. 3643-52.

[1] Horeweg, N., et al., Detection of lung cancer through low-dose CT screening (NELSON): a prespecified analysis of screening test performance and interval cancers. *Lancet Oncol*, 2014. 15(12): p. 1342-50.

[1] According to the Imaging industry association COCIR, more than 50% of the installed base in Computed Tomography in Europe is older than 6 years, more than 20% are already older than 10 years. Website: <https://www.cocir.org/activities/business-innovation/imaging-market-intelligence.html>

ECCO: Bringing patients and healthcare professionals together for better quality lung cancer care

By Richard Price



Richard Price

EU Affairs Policy Manager
European Cancer Organisation

What is the problem with the quality of care provided to patients with lung cancer in Europe, and what needs to be done about it? To these questions the European CanCer Organisation (ECCO) community of 23 member societies and 17 Patient Advisory Committee members is turning attention as it prepares to produce Essential Requirements for Quality Cancer Care (ERQCC) for the lung cancer tumour type.

The ECCO ERQCCs set out consensus articulations of the fundamental components for achieving quality cancer care, including, but not limited to, what is required in respect to:

- Multidisciplinary team working among core and extended groups of professionals, in a dedicated comprehensive cancer centre or unit
- Cancer care pathways
- Time lines of care
- Minimum case volumes
- Audit of outcomes and care
- Performance measurement of outcomes and care
- Quality assurance of outcomes and care
- Professional education needs
- Enrolment in clinical trials

As such, the ERQCC documents should not be understood as traditional guidelines, but rather descriptions of the organisational models of cancer care necessary to achieve best outcomes and care experience for the patient.

ECCO has already published such requirements in respect to colorectal cancer, sarcoma, melanoma and oesophageal and gastric cancer, and is currently progressing similar charters for improvement for breast cancer and prostate cancer. As of February 2018, the ECCO Board of Directors has now instructed that lung cancer be the next tumour type in focus. Ahead of the call for experts and roundtable discussions commencing, we took some time to speak with a leading healthcare professional, as well as a patient advocate, about some particular concerns in respect to lung cancer care that could be addressed by the forthcoming ECCO Essential Requirements project.

Jan Bussink is a Professor of Biological and Molecular Imaging in Experimental Radiotherapy at the Radboud University Nijmegen Medical Centre in the Netherlands.

Reflecting on what quality cancer care means in respect to lung cancer, Professor Bussink identifies provision of information to patients, patient empowerment and patient involvement as key areas for improvement:

“Where we want to get to is personalisation of a patient’s treatment in the fullest sense of the term. That means healthcare professionals enabling patients throughout their care pathway with the information they need to make choices about their treatment. To speak in very practical terms, for patients with stage 1 lung cancer, for example, there is often a choice to be made between surgery and stereotactic ablative radiotherapy (SABR). One can add to this the choices to be made between differing types of surgery. Factors that might influence choice include the rate of growth of the tumour, but also personal choices related to the individual values of the patient, including the impact of different treatments on their daily lives, and those of their families.

To my mind, there is so much more that we might do to improve how we inform patients about these choices and involve them in a meaningful and real way. I look forward to seeing such issues covered in the ECCO Essential Requirements for Quality Cancer Care (lung cancer).”



Dr Anne-Marie Baird represents the Lung Cancer Europe (LuCE) patient advocacy organisation within the ECCO Patient Advisory Committee (PAC), and holds a PhD in Cancer Research from the Department of Clinical Medicine, the University of Dublin, Trinity College. Her views on raising the prominence of patient decision-making in respect to lung cancer care chime with those of Professor Bussink.

“For me, quality cancer care means putting patients at the centre of all decisions relating to their treatment. This means the care team actively listening and acting upon individual patient choices and preferences. Shared decision making and patient centred care doesn’t mean anything unless the patient is truly at the centre, with care organised around them. A quality cancer care pathway should cover patients from diagnosis through to survivorship and end of life care, with research, clinical trial access and psycho-oncology care playing an integral part of the pathway, and not being minor after thoughts.

That’s where I see the Essential Requirements for Quality Cancer Care (lung cancer) as being so important. The clue is in the name, all of these elements constitute quality in cancer care – and they are essential, not optional.”

ECCO will commence the consensus gathering and drafting process for new Essential Requirements for Quality Cancer Care (lung cancer) later in 2018. For queries about the essential requirements programme please contact Sapna Sheth sapna.sheth@ecco-org.eu

The clue is in the name, all of these elements constitute quality in cancer care – and they are essential, not optional

“For me, quality cancer care means putting patients at the centre of all decisions relating to their treatment”

Integrating prevention and early diagnosis: A case of how not if

By Dr Grace McCutchan & Dr Samantha L. Quaife



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Smoking causes over 80% of the 47,235 lung cancer cases diagnosed each year in the UK. Rates of smoking are twice as high in socioeconomically deprived areas compared with affluent areas. Of concern, rates of smoking in deprived communities are staying the same rather than improving.

This will widen existing inequalities in lung cancer mortality and overall life expectancy. In this short report we make five evidence-based recommendations. This favourable trend is essentially due to the widespread measures for smoking control and cessation. Smoking can contribute to around 85% of the lung cancer cases[1].

1. Embed stop smoking services throughout lung cancer pathways
Substantial economic and public health gains will be made by funding existing effective and evidence-based smoking cessation support services, yet these have disappeared in many areas due to funding cuts. Smokers are up to four times more likely to successfully quit with the support of NHS stop smoking services

(www.ncsct.co.uk/publication_Stop_smoking_services_impact_on_quitting.php). Smoking cessation advice, support and referrals to stop smoking services should be offered to smokers at every possible opportunity along the lung cancer pathway. This is consistent with NHS Health Education England's 'Making Every Contact Count' guidance offering brief smoking cessation advice during everyday interactions across health and social care organisations. Research highlights that how the offer of smoking cessation support is broached is key to whether patients consider cessation, where a non-judgemental, compassionate approach to offering smoking cessation support was recommended (McCutchan et al, 2019, BMJ Open). The National Centre for Smoking Cessation and Training (NCSCT) offers free, evidence-based online training to support this 'Very Brief Advice' approach

2. Involve Behavioural Scientists in the design of smoking cessation interventions. Behavioural science provides pragmatic evidence for how to support people to initiate and sustain smoking cessation and reduce the risk of relapse. This includes using specially designed techniques to suit the more complex needs of high-risk populations, such as long-term smokers living in socioeconomically deprived communities. Research shows that smokers living within socioeconomically deprived communities try just as many times to quit (Kotz and West, Tobacco control, 2009) but are less successful due to complex challenges overcoming this addiction. These include higher nicotine dependence (Siahpush et al, Tobacco Control), low quit confidence (Quaife et al, BMC Cancer, 2018), multiple failed quit attempts, and complex social circumstances (Quaife et al, Health Expectations, 2016).

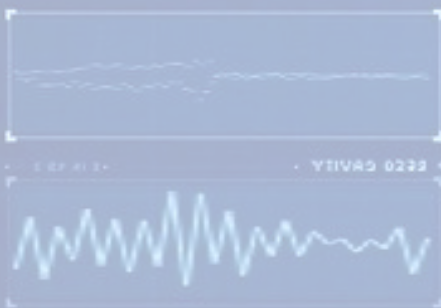
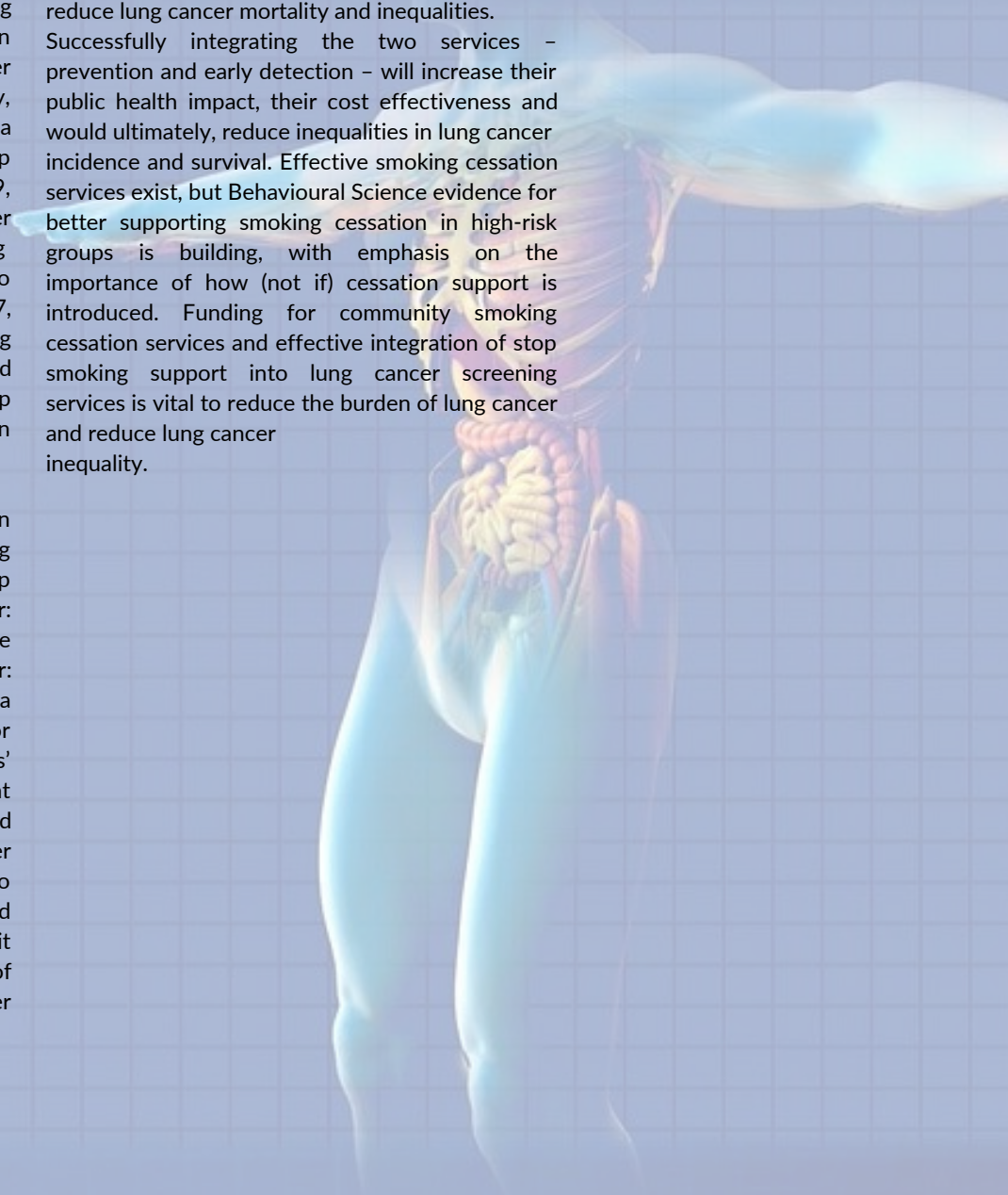
3. Lung cancer screening is an unmissable opportunity to support long-term smokers in quitting Targeted lung cancer screening for high-risk adults is being introduced as part of the NHS 2019 Long Term Plan,



through NHS England's Targeted Lung Health Check programme. This is because screening using low (radiation) dose CT scans has been shown to significantly improve lung cancer mortality by detecting lung cancer at an early, mostly curable stage. Research shows that a high-risk population are willing to receive stop smoking advice at screening (Stevens et al, 2019, Lung Cancer), and that attendance at lung cancer screening results in a larger reduction in smoking cessation rates compared with participants who did not receive screening (Brain et al, 2017, Thorax). At a minimum, smokers attending lung cancer screening should be offered advice and proactive 'opt-out' referrals to existing stop smoking services (an approach already used in other services, such as midwifery).

4. Higher intensity smoking cessation interventions may be more effective in lung cancer screening The Yorkshire Enhanced Stop Smoking Study (trial reference number: ISRCTN63825779), embedded in the Yorkshire Lung Screening Trial (trial reference number: ISRCTN42704678) is the first to test a personalised smoking cessation intervention for lung cancer screening. This includes individuals' CT scan images from screening which highlight healthy and damaged areas of the heart and lungs, delivered by a stop smoking practitioner trained to improve confidence and motivation, to provide non-judgemental encouragement and ongoing support to facilitate successful quit attempts. This intervention, grounded in state-of-the-art Behavioural Science, is currently under trial, with findings expected 2022.

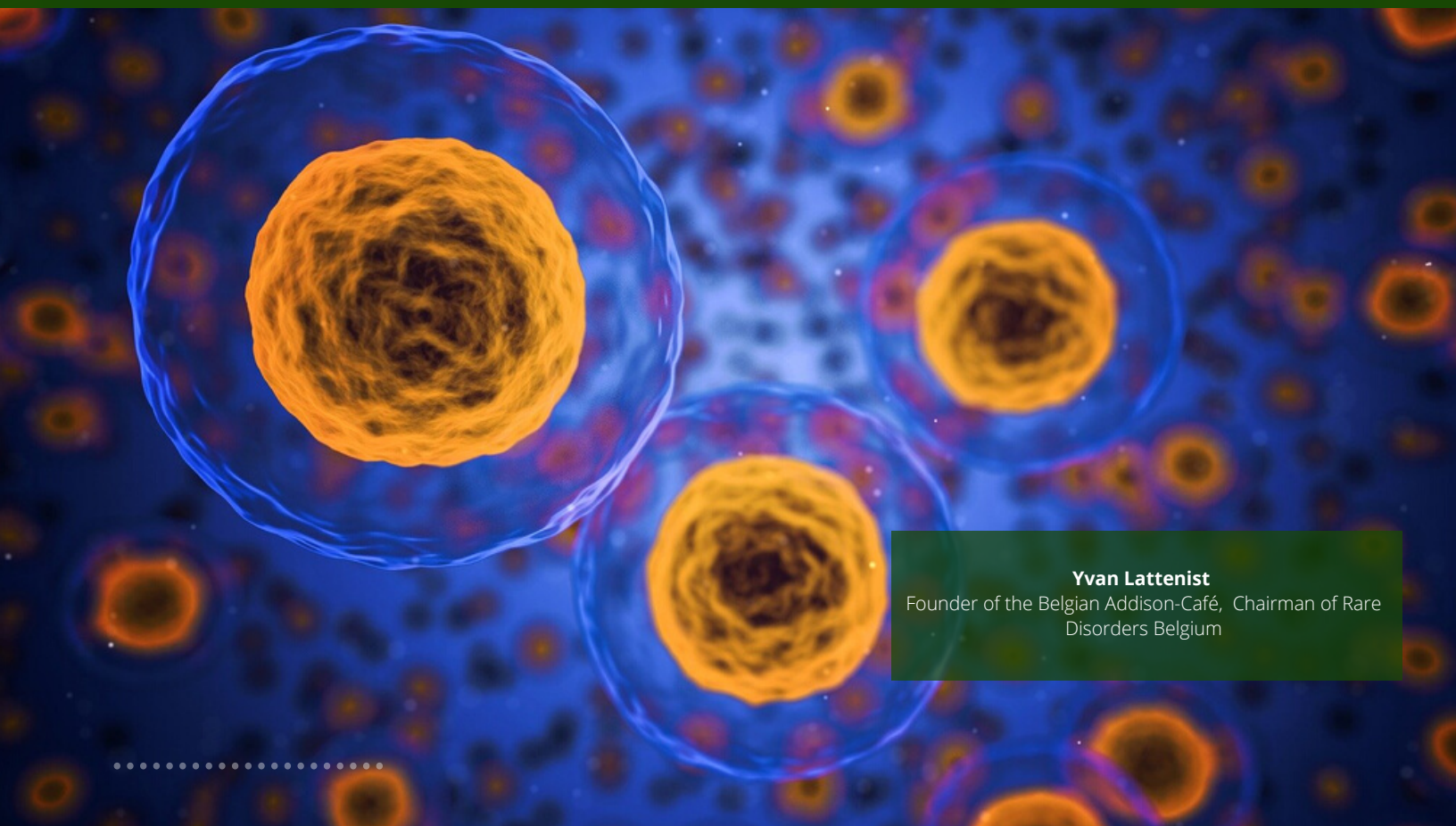
5. Improving prevention for high-risk groups will reduce lung cancer mortality and inequalities. Successfully integrating the two services – prevention and early detection – will increase their public health impact, their cost effectiveness and would ultimately, reduce inequalities in lung cancer incidence and survival. Effective smoking cessation services exist, but Behavioural Science evidence for better supporting smoking cessation in high-risk groups is building, with emphasis on the importance of how (not if) cessation support is introduced. Funding for community smoking cessation services and effective integration of stop smoking support into lung cancer screening services is vital to reduce the burden of lung cancer and reduce lung cancer inequality.



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The patients' voice in the domain of rare diseases

By Yvan Lattenist



Yvan Lattenist

Founder of the Belgian Addison-Café, Chairman of Rare Disorders Belgium

Too little attention is paid to rare diseases as the word "rare" tends to develop the idea that only a small population is concerned: thinking that actions and benefits would be addressed to only a few persons makes it feel illegitimate to devote attention as well as national and European budgets to them. This is in fact a fundamental mistake! Rare diseases affect much more people than one would expect based only on its name: while they only affect, by definition, 1 out of 2.000 persons as a maximum (and rather 1/20.000, or even less: 1/200.000), there are 7.000 different diseases identified in the world, of which as much as 700 have already been identified in a country as small as Belgium. This is

factual: the estimation of the target population in Europe is definitely as large as 27 to 30 million. On top of this, one has to consider that at least one and even two or more people are deeply affected by the daily life requirements of each rare disease patient, as the impact of such illnesses can be a real trauma, in many cases. As a result, there are several people whose lives have changed because of one sick person. These considerations should definitely increase the attention towards a positive attitude in favor

1. of the subject "rare diseases"!

This being said, let's add three important thoughts that deserve attention about the subject matter:

1. the low level of identification of patients with rare diseases: based on some statistics in countries where patient associations are well developed, one estimates that only 10% of the target population is involved in them. This is probably due to the fact that not all patients are ready to meet with peers and share their difficulties. But the current level of penetration of patients' organizations is certainly far too low, because of a lack of awareness: large campaigns should be organized, taking profit, for instance, of the annual international day of rare diseases (February 28th).

2. the whole medical system (including doctors, pharmacists, nurses,...), as well in its training as in its practice, is not prepared to cope with rare diseases. This is a real challenge as paying attention to this unknown matter requires time and humility, resources which are often too scarce, while the probability to ever meet one particular disease in a whole career is very little. As a result, new approaches need to be developed in order to cope with that overall lack of competence: they should involve academic authorities and will probably require new communication strategies with health practitioners.

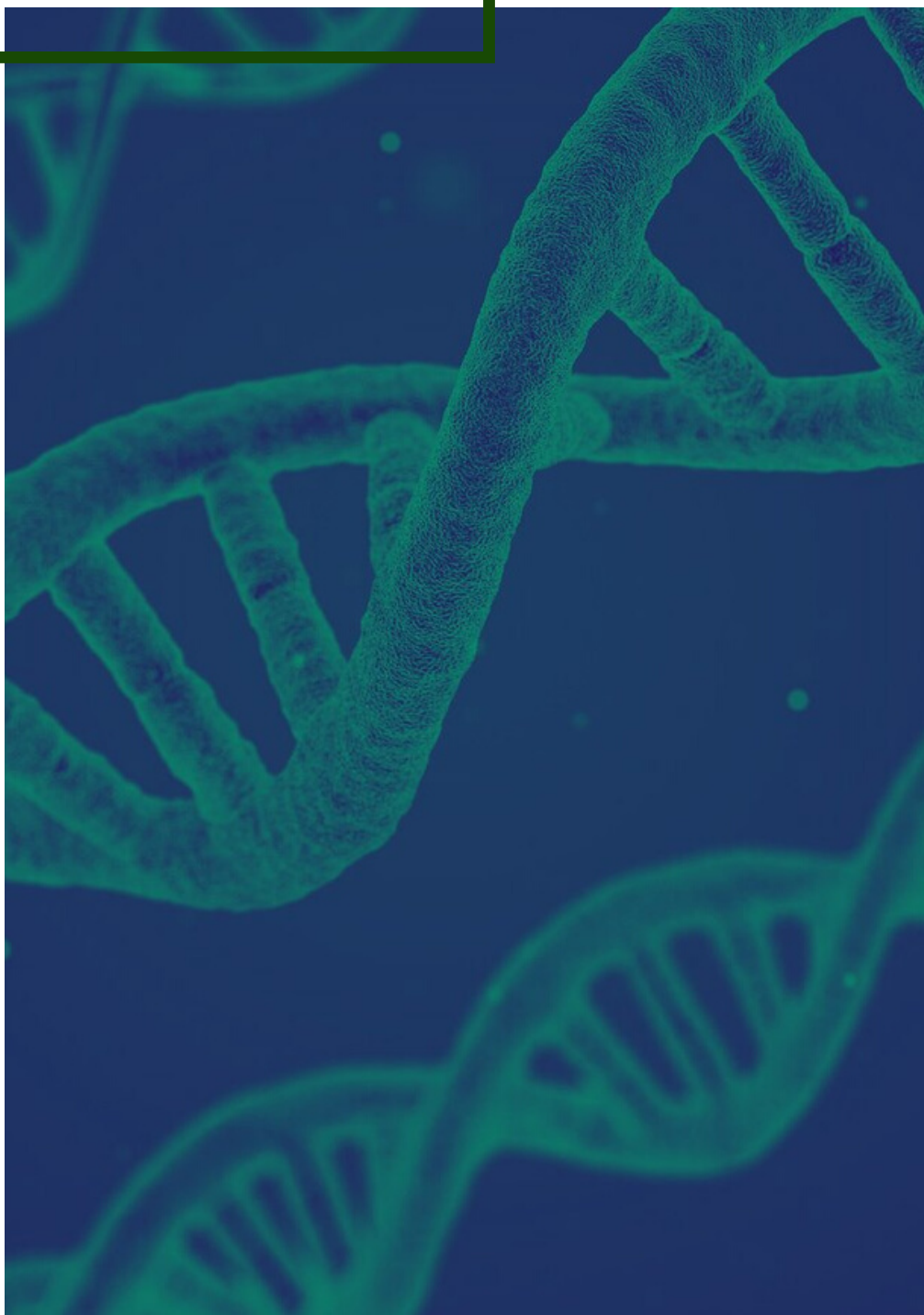
3. finally, a better approach of the rare diseases problematic would bring major enhancements in the healthcare system in general, also in the "non rare" domain, because the approaches required for rare diseases will automatically bring focus on the need for new approaches in general. "Patient Reported Outcome", "Patient Empowerment", "The patient as a partner"... many new ideas which are mandatory in the treatment of rare pathologies, where they have proven to have large positive effects in a limited domain, could now be exported with great benefit for the overall medical system. In addition to this clinical aspect, in the fast growing domain of genetics too, deeper analysis and potential enhancements could find their origin in crossing experiences initiated in the rare diseases domain.

Considering all this, we believe that there is evidence on the fact that the whole matter of rare diseases deserves a better approach: it is time to pave the road for another set of initiatives, involving a large number of potential shareholders with a methodology that clearly starts from the patient's perspective.

TOO LITTLE ATTENTION IS
PAID TO RARE DISEASES AS
THE WORD "RARE" TENDS TO
DEVELOP THE IDEA THAT
ONLY A SMALL POPULATION
IS CONCERNED

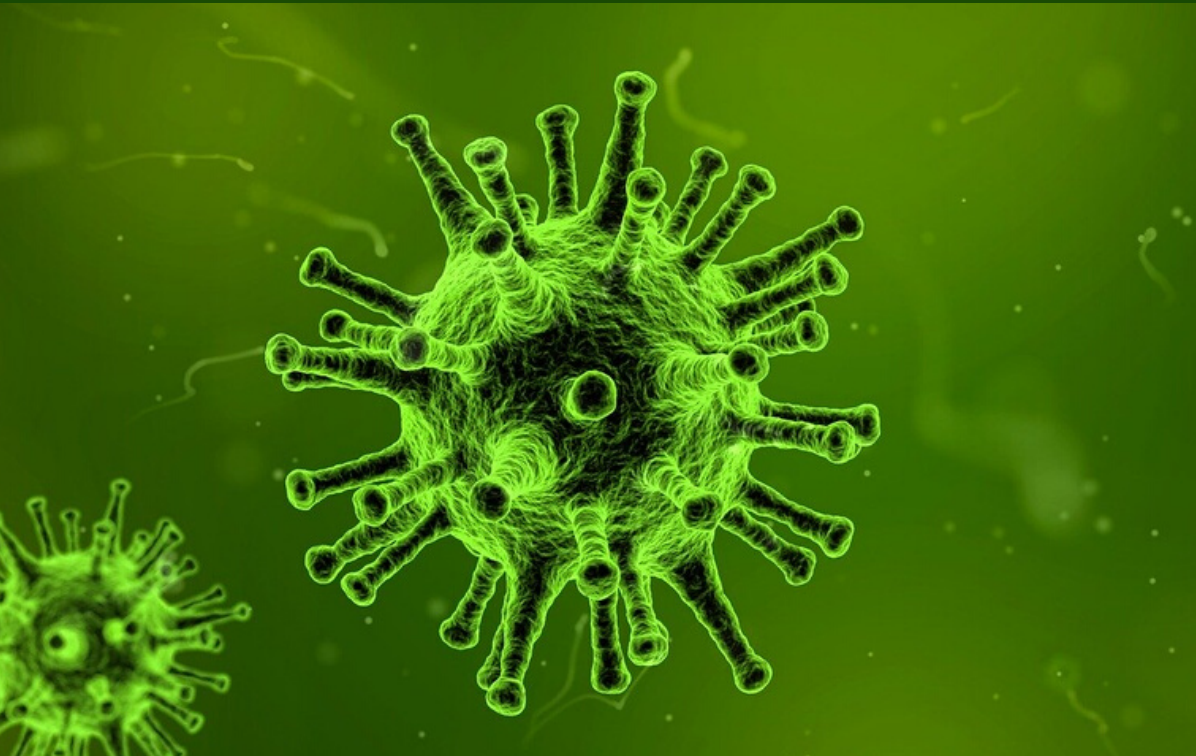
Many associations, of varying sizes, are caring about these pathologies in Europe; they are building and realizing major things, for many different diseases. Each one struggling in its domain, with its own resources and energy, they have succeeded in developing an important expertise, including knowledge of best practices and working recipes, as well as potential pitfalls.

This wealth of information should now be shared amongst them, in a more structured way, through an effective networking, not only by a few words exchanged, for instance, during lunchtime at some annual plenary sessions. It's time to put acts together! But this effort requires more support: it should not rely only on the goodwill of a few people who, by the way, deserve greater consideration for what they did up to now. As they would be ready to share and extend their knowledge on a broader scale, they need means that should be made available by politicians who are ready to invest in this exciting domain, encompassing so many aspects of health and welfare.



Time for a new, more balanced partnership between industry and all stakeholders on access

By Jim Lennertz



Jim Lennertz
VP and GM Commercial
Operations BioMarin

Despite great progress over the last two decades, most of the 7,000 rare diseases known today have no treatment, nor any promise of one. On 17 November 2018, the 2nd EU Rare Diseases Roundtable debated two topics of major importance for the 35 million or more people living with a rare disease across the European Union. One was how to encourage research, innovation and the development of new medicines. The other was how to ensure that, whenever treatments have been developed, patients can gain timely access to them regardless of where they live.

Both aspects neatly capture the mission that all of us at BioMarin have been pursuing relentlessly over the past 21 years. Our goal is to bring new treatments to market that will make a big impact on small patient populations. We focus on developing first-in-class and best-in-class therapeutics that provide meaningful advances to patients who live with serious and life-threatening rare genetic diseases, and many of whom are children with unmet medical needs. We know patients are waiting, which is why we bring medical innovation as quickly as possible to market

However, it is a well-documented fact that access to orphan medicines in Europe today remains far from ideal. Research conducted in the early 2010s by EURORDIS-Rare Diseases Europe highlighted that one in three people living with a rare disease in Europe had no access at all to the orphan medicine they needed, regardless of its prior approval by the European Medicines Agency (EMA). Another third had access, but only after a delay of months or even years following the medicine's approval. EURORDIS concluded that, "if an innovative medicine is approved but does not reach all the patients who need it, it fails in its primary objective". As an organisation absolutely dedicated to research and one that reinvests nearly 50 % of its annual turnover into R&D, we agree. It can be tempting to point to the list price of rare disease medicines as the crux of the access problem. While it is true that the price of orphan medicines may sometimes be higher than those for more prevalent diseases, this is largely correlated to the technical difficulty and increased risk of developing often very complex therapies for complex diseases with limited populations. The majority of rare diseases is still not completely understood, and they are

Additionally, in its own milestone position paper from January 2018, "Breaking the Access Deadlock", EURORDIS points out that not only are the prices of many of the orphan medicines commercialised in Europe to date fairly uncontroversial when compared to those of non-orphan medicines, but that the share of national pharmaceutical budgets spent on funding rare disease treatments remains very low. It is important to keep sight of facts like these to ensure a fair and balanced discussion about access.

Diabetes prevention is among the most important Public Health strategies in Hungary

Imre Rurik and Péter Kempler



Prof Dr Imre Rurik

President
Hungarian Society of Nutrition

Péter Kempler

President
Central European Diabetes
Association
& Hungarian Diabetes Society

Metabolic disorders represent a significant burden for the Hungarian population, for the capacity and financing of the health care system, deteriorate the quality of life, and are responsible for premature mortality [1].

The pathological consequences of diabetes

Diabetes affects the arteries, is the main reason of coronary heart disease and other “macrovascular” complications in the vessels of the brain and lower extremities, together with “microvascular” alterations in the retina and in the kidney, combined with neuropathy.

Conditions responsible for diabetes

Although options for genetic and hereditary origin become clearer, obesity represents the most important reason. Obesity could be a consequence of some endocrine disorders, a side-effect of certain drugs, although it mainly has a simple energetic reason: the energy-intake with foods and drinks is constantly higher than the expenditure. The energy expenditure of people is usually lower than in the previous decades, especially in urban settings. Nutritional habit usually did not follow these lifestyle changes [2].

Higher portion sizes, higher energy density of foods and drinks are responsible for that. Two thirds of the whole Hungarian population is overweight nowadays, half of them being obese [3].

Epidemiology

According to the most recent available data, 727.000 people in Hungary have been diagnosed with diabetes. 20% of the population above the age of 60 has type 2 diabetes. The number of incident cases with newly registered T2DM decreased from 76.645 to 29.122 between 2001 and 2016. Beside them, almost the same numbers of persons are living with diabetes (prediabetics), without having appropriately diagnosed [4].

Screening

The early diagnoses of DM could be improved by regular screening activities of family physicians. Its methodology and legislations are already available. Hungarian general practitioners usually perform well, supported by the occupational physicians.

Diabetes care in Hungary

In the recent Hungarian health care system, there is no professional institution of

care, although there is a well-developed network of specialist's services under the umbrella of the Hungarian Diabetes Association, with wide range of capacity and professional level. There is a type of qualification (licence of diabetes care) achieved by internists and general practitioners, who provide dedicated services for diabetic patients.

The Hungarian National Diabetes Programme, prepared by the Hungarian Diabetes Association was launched in 2011, defining

eight important target points, improvement in quality indicators of diabetes care: decrease the average HbA1c level, the blindness of diabetic origin, the number of patients with nephropathy who need dialysis, the number of lower limb amputations, the number of macrovascular complications (myocardial infarction, stroke, peripheral atherosclerosis). Initiatives were described for the primary care based screening for diabetes, for the early detection of pre-diabetes and gestational diabetes. Achievements in these fields could stop the increase of diabetes-revalence in Hungary [5]

“Education for the general population could be supported by legal regulations: Effective campaign in the broadcast and media”

Available treatments in diabetes care In Hungary, almost all of the medications and drugs developed and approved for the treatment are available, although there are many restrictive regulations in the prescription, based mainly on financial reasons. There are scientific evidences, that diabetes could be improved with effective decrease of body weight, even with bariatric surgery, blood-sugar value could be decreased to the normal range, and the antidiabetic medication could be stopped.

Options for prevention

Appropriate nutrition and healthy lifestyle with physical activity are the key points of prevention. There are many data and epidemiological evaluations supporting that Type2 diabetes could be prevented or at least significantly delayed. According to our recent knowledge, the most effective ways of prevention are regular physical activity, considering the age-related characteristics and the maintenance of the normal body-weight index (BMI).

Education at all levels is needed In the curriculum of primary and secondary schools, more space and higher number of hours should be allocated for sharing knowledge and improve skills related to healthy nutrition. Students are expected getting education about the components of foods, food-safety and healthy technologies available for cooking. Explanations and reasons why to avoid or decrease the consumed amount of some foods and beverages should also be provided. Variety of choices in the school-canteens and buffet should be in accordance with this knowledge, besides providing optimal conditions for water drinking instead of consuming sweetened drinks.

Curriculum should also contain information about the advantages of continuous, life-long physical activities. It is a great pedagogical success in Hungary, that daily physical exercise hours were incorporated into the curriculum of primary schools.

Although available infrastructure and personal staff of schools are different, continuous support will help the maintenance and development in the future.

Government and local municipalities are expected to improve opportunities and increase available facilities for physical activity in the leisure time. Education for the general population could be supported by legal regulations: Effective campaign in the broadcast and media, where the ratio/percent in broadcasted time and in surface of the printed media/journals are regulated, determining the space dedicated for health related education.

Food manufacturers and trade are expected to establish partnerships in this effort, even forced by regulations to product and sale healthy foods [6].

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Data collection as an important step forward

By Raimund Weitgasser



Raimund Weitgasser
Austrian Diabetes Association
(ÖDG)

Austria has as well as other European countries undertaken the effort to establish a National Diabetes Strategy (ÖDIS) to improve Diabetes Prevention, Diagnosis and Treatment. The aims for action following discussions and input by the main stakeholders led by the Ministry of Health can be summarized in six main topics:

1. Increase diabetes-related health competence by promotion and extension of the National Action Plans for Physical Activity (NAP.b) and Nutrition (NAP.e)
2. Improve factors for prevention like the attenuation of a diabetogenic environment.
3. Raise individual competence in persons with established diabetes coping with the disease.
4. Extension and maintenance of Integrated Care models like the already implemented Disease Management Type 2 Diabetes (DMP Typ 2 Diabetes, Therapie Aktiv“).
5. Improve and enlarge the competence of HCPs, support networks, enhance transparency.
6. Generate knowledge and support evidence-based quality assessed actions

The Austrian Diabetes Association (ÖDG), one of the main contributors to the ÖDIS, supports these goals within an action plan which could also be used as an example for Europe wide efforts to improve diabetes prevention and care. To extract meaningful content for all European countries a survey and compilation on already developed, established or implemented national diabetes plans would thus be helpful. In addition this could help to sort out failed developments and put the focus on successful actions irrespectively of different health care systems in different countries. Furthermore the mandatory oral glucose tolerance test for all pregnant women in Austria may serve as a role model for high-quality diabetes care in Europe.

As a basis for all actions we regard diabetes registries containing a small but relevant data set comparable to already established registries in Sweden, Denmark or Scotland an absolute necessity for all European countries. These data could then be used to back decisions on a governmental and political level as well as directions for epidemiological and translational research. A common view on diabetes in Europe would then contribute to joint political efforts and actions. We strongly advise EU parliamentarians to support screening and evaluating national diabetes plans and enforce the implementation of a European Diabetes Registry.

DIABETES



Making 21st century support for people with diabetes a reality — harnessing the tech revolution

By Brigitte Klinkenbijn



Brigitte Klinkenbijn
Global Market Access, Dexcom.

Technical opportunities for managing the prevention and treatment of Europe's estimated 60+ million People with Diabetes (PwD) are changing rapidly. There is a revolution taking place in this tech field in medicine. Despite this, across Europe, government commitment and investment in outcomes-improving technologies has been sadly lagging behind. As has been seen across this year's roundtable, the speed in adopting new technologies and the unlocking of appropriate funding has consistently failed to deliver more access to individualised self-monitoring and -management opportunities for PwD.

This need not be the case. The example of Continuous Glucose Monitoring (CGM) has been shown to transform the lives of PwD where it has been clinically and economically adopted. European health policymakers should seize this opportunity to improve the lives of many more PwD.

Modernising support for People with Diabetes

The vast majority of PwD still rely on blood glucose monitoring (BGM) methods that are fast becoming out-dated and invasive. Daily living with diabetes relies on careful monitoring, i.e. regular testing of glucose level and appropriately responding to the monitoring results. The traditional BGM home testing kit, better known as a 'finger-stick' - uses a lancet to take a small amount of blood from the tip of the finger.

Until recent years this has simply been an inevitable part of daily life no matter how invasive, painful and inconvenient. Though effective up to a point, BGMs only supply a snapshot of glucose levels. This does not give PwD enough data to manage the myriad factors that impact on their health. This year's roundtable identified the slow pace of adopting and delivering new technologies like CGM as a barrier to more effective diabetes treatments. Systems developed by Dexcom, a pioneering company in connected CGM technology, enable PwD to monitor glucose in real time, in other words, as it happens.

CGM systems operate with a sensor inserted into the interstitial fluid (under the skin) where glucose levels are continuously monitored 24 hours a day and transmitted to a smart device (like a phone) CGM technology is transformative for people with diabetes². By giving a real time impression of glucose levels and by sending alerts if moving into dangerous low or high glucose levels, CGM lowers the acute risks of distressing and potentially fatal events^{3,4}.

As the alerts are delivered immediately, these systems are particularly popular with parents or carers of vulnerable PwD monitoring remotely, during the day as well as overnight^{5,6}.

CGM is not simply a modern and compassionate replacement for 'finger-sticks'. It is an efficient and reliable self-management technology which enables true understanding of the intricacies of diabetes metabolism^{7,8}. By examining up to date glucose data, users can determine how stress, exercise and food impact on their glucose levels. This gives patients the opportunity to adopt a lifestyle to better control their condition.

Many governments around Europe have adopted programmes to prevent the devastating effects of diabetes but this has not been universal

Treatment can then be individualised to optimise the outcome for the patient, without having to resort to the costliest options^{9,10,11}. In actively using CGM systems the need for acute medical care and hospital admissions is lessened³. But more than that, they allow PwD to take charge of their condition and its treatment, potentially preventing long term debilitating and costly diabetes complications^{1,12}.

Making access to CGM a reality for all PwD
Many governments around Europe have adopted programmes to prevent the devastating effects of diabetes but this has not been universal, and the suboptimal use of new technologies is symptomatic of a lack of wider investment in diabetes. Health ministries have traditionally been resistant to implement new approaches based on the cost of CGM systems alone. As evidence on the true health and quality of life benefit of CGM grows, we as industry-partners, diligently work towards a needed shift in mindsets to realise the impact of these preventative technologies,

while empowering individuals with diabetes. Governments across Europe should take a more holistic approach to the real cost offsets of CGM technology, as it has shown to reduce pressures on acute health care provision. We see fewer in-patient admissions, and less need for emergency treatment, as PwD and health care professionals embrace the added value CGM brings.

In the past 20 years we have seen a transformation in the way that diabetes can be managed. We know that better glucose control can prevent acute, and postpone long term diabetes complications. To help see this achieved we would suggest the following steps be taken:

That programmes of reimbursement are instituted to ensure that CGM technology is as widely available as possible that governments accept that investments made today in diabetes may reap long term health benefits.

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IMPROVING THE FUTURE OF DIABETES

BAYER STATEMENT FOR GOVERNMENT GAZETTE



Diabetes is a chronic disease with about 60 million people affected in the EU, causing significant public health issues and burden of disease for individual patients. Despite the large number of people affected by the disease, public and political awareness of the issue is rather low, partly because of the nature of this chronic disease which has mainly long term health consequences and in diabetes type II immediate subjective disease burden may be low.

While innovative oral treatments for diabetes and new insulins have been developed in recent years, timely access to these medicines has not kept pace. Digital treatment support and new devices allow for more physiological treatment adaptation, improved education and better guideline adherence.

Similarly, advances in prophylactic measures including improvements in food composition are still in its infancy. This has also a major impact on the prevalence and incidence of the disease, leading to an increasing number of later stage complications of diabetes.

These are largely due to cardiovascular pathologies leading e.g. to diabetic foot syndrome, diabetic kidney disease, significant increase in risk for cardiac events, peripheral neuropathia and loss of vision. Bayer believes that there are 3 areas of major influence on the future and long term impact of diabetes for society and individuals.

1. Prevention of the disease and prevention/ delay of complications Higher public and political awareness of the magnitude of the current and future problem is urgently needed through appropriate measures. These should include better education of people at risk, patients and care givers, changes in food composition and diets and more widespread use of advanced technologies.
 2. Improved health outcomes Improvement of therapeutic outcomes can be achieved through better guideline adherence, more widespread use of innovative medicines that have shown to improve outcomes and continuous monitoring of therapeutic effects with the help of real life outcome data. Access to outcome improving therapy includes reimbursement of such therapies based on economic evaluations and models with longer and broader perspective across budget areas and legislative periods.
-



Implementation of widespread data acquisition in registries for better steering of therapeutic outcomes and improved quality control of care needs to be implemented as well.

3. Earlier diagnosis and better treatment of the devastating complications of diabetes Based on the large number of patients at risk there is a significant prevalence and increasing incidence in complications resulting from yearlong diabetic metabolism and less than optimal treatment and behavior. Over 50% of patients with diabetes die from cardiovascular events such as stroke and myocardial infarction. 10-20% of the patients develop diabetic nephropathy which finally can lead to dialysis; about 10% develop serious visual impairment and 1-2% become blind.

Furthermore peripheral vascular problems such as diabetic foot syndrome and peripheral neuropathia also have debilitating consequences.

As such, individual suffering and the health-economic burden are expected to increase over the next years. Breaking this development will require major efforts in prevention, therapy of diabetes as such, earlier diagnosis and better therapy of the complications. Preventative measures for diabetes will at the same time contribute to the prevention of cardiovascular diseases in general.

Bayer stresses that the above can only be achieved with a strong stakeholder collaboration including policymakers, patients, healthcare professionals and industry and stands ready to contribute to the discussion to ensure that patients across Europe get rapid access to the latest, effective and lifesaving treatments and medicines.

Bayer calls on policymakers to keep Europe as a center of excellence for medical research through incentives and rewards mechanisms for Research and Development of new medicines, by recognizing the value of health data to foster medical research as well as driving the debate towards outcomes-based healthcare systems to improve quality of care and contribute to the sustainability of healthcare systems.



iCPS Diabetes Europe Roundtable

Diabetes – the silent killer – advances almost imperceptibly not only in the body but also in political discussion. Since its symptoms are hard to identify, half of the people with the disease remain undiagnosed¹ and outside the estimated population of 58 million Europeans currently affected by diabetes. Although 25 percent of the global diabetes healthcare spending is allocated to prevention and research in the European region, it is expected that by 2045 the number of European living with diabetes will increase to 67 million. Even if this rising trend is affected by a variety of factors, it still suggests there is progress to be made both in the implementation of national plans and in enhancing European Union (EU) cooperation. Great inequalities exist in the tackling of diabetes among member states. While several countries have made progress towards developing a systematic policy response to the diabetes burden, overall investment in and implementation of comprehensive strategies for the prevention and treatment of diabetes has varied.

In an effort to build a more holistic approach to the prevention and treatment of this disease, it is pertinent to tackle the persisting gaps and missed opportunities in the EU battle against diabetes. In order to review the current progress of diabetes management in Europe and address the complications in managing the fatal disease, the International Centre for Parliamentary Studies brought together eminent parliamentarians, healthcare professionals, academic experts and industry stakeholders in a high-level policy roundtable on May 8th, 2019 in Brussels.

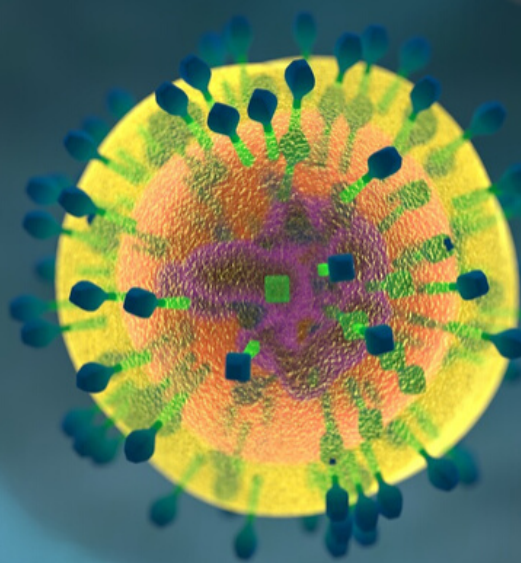
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Closing the gaps in European HIV Response

By Eleni Kakalou



Eleni Kakalou

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National Health System, Greece
Policy Advisor for the Board of
Directors*

Greece has a concentrated HIV epidemic that has been stabilized around 5 cases of HIV infection per 100,000 population per year. In 2011 an outbreak among PWIDs in central Athens became a major driver of the epidemic that peaked at 9.2 cases per 100,000 population per year in 2012 before decreasing again in 2015. Currently, one third of new HIV cases are diagnosed in the community through use of rapid diagnosis testing (RDT) at Checkpoints run by an NGO of PLWHA called "POSITIVE VOICE". Clinical care is free and accessible to all including migrants, refugees and asylum seekers. Main priorities are the increase of HIV testing either in Health Care settings or the community, implementation of PrEP, introduction of self-testing and models of expansion of testing services targeting especially the most vulnerable populations such as PWIDs, migrants, refugees, asylum seekers, homeless, sex workers, victims of trafficking and prisoners. Reinforcing early linkage to care and long-term retention for people with multiple vulnerabilities especially migrants and PWIDs, are among areas in need of improvement. Strengthening harm reduction services and integrating them into the system

of HIV prevention and care remains both a challenge but also a necessity for containing and reversing the epidemic among PWIDs.

Introducing new tools, innovations, developing eHealth services both for supporting clients and patients but also for collecting better data to guide interventions and policy, is the main way to improve diagnosis and care. Societal interventions to reduce stigma and improve health education strategies are a prerequisite for all other efforts. Normalizing HIV disease, away from fear, guilt or moralistic approaches to sexuality is the only way to achieve the elimination of HIV disease in future generations. Linking HIV prevention with a comprehensive mid and long-term policy for sexual and reproductive health, could be a way to reduce stigma and create synergies. Sensitive public health policies for interrupting transmission -such as partner notification- should be examined through a perspective of human rights and medical anthropology. Different cultural realities within Europe might warrant flexible policies of proven efficacy and impact.

Public and private partnerships and state funding to civil society groups with pre-qualification standards and rigorous quality control,

and accountability, could be the only way to close remaining gaps especially among the hardest to reach populations.

Public sector would lack the flexibility, adaptability, appetite for innovation that NGOs and civil society groups usually exhibit, along with remarkable resilience and ability to get acceptance among hard to reach groups or communities. What's more patient groups, civil society and NGOs can drive patient or client empowerment and societal change. Digital tools and eHealth could also play a pivotal role in enhancing the impact of such actors in the community. The EU through its different political and scientific platforms could guide member states to co-ordinate their actions so that the epidemic is being tackled in a dynamic continuum in an area with porous borders that do not stop disease transmission. Designing a coherent policy on Human and Social Rights as well as legal protections - especially for the incorporation of eHealth and digital data surveillance-, could help member states untangle many challenges that slow efforts to use all available tools and innovations safely and effectively. Allocating enough resources for epidemiological and operational research is also important to guide policy all over the continent.

European-African partnership to fight the HIV pandemic. A strategy for 'zero-HIV for Europe' can only be sustained with continued research investments to combat HIV globally

By Dr Ole F. Olesen



Dr Ole F. Olesen

Director of International Cooperation for
Europe, European & Developing
Countries Clinical Trials Partnership

Treatment of HIV/AIDS is one of the most significant achievements in medical history over the last decades. HIV infection has gone from an almost certain death sentence to become a chronic condition that can be managed with proper and adjusted pharmaceutical intervention. The HIV pandemic is not beaten however. HIV-infection remains incurable and HIV remains a global threat to all generations everywhere. The clinical management strategies and health care systems need to evolve to support the new priorities for combating HIV.

Despite decades of European integration, the health care systems in Europe remain highly fragmented. Exchange of health care information, pharmaceutical legislation, prescription of pharmaceutical products, availability of diagnostic options and health insurance remain largely bound within national borders. Limited access to health care, including HIV treatment, for undocumented immigrants and internal migrants is a further area of concern. Taking together, several unnecessary obstacles are therefore preventing an effective delivery of health care to European citizens, and this is obviously true also for HIV prevention and treatment.

More efforts and fewer barriers are needed to facilitate collaboration, exchange of data, experiences and best practices between HIV researchers and clinicians across Europe.

At the same time, results from research conducted outside Europe, in regions with a high incidence of HIV-infection and common comorbidities, such as sub-Saharan Africa, may usefully inform the European response.

The European & Developing Countries Clinical Trials Partnership (EDCTP) funds clinical research conducted in sub-Saharan Africa by partnerships of European and African research institutions. While the challenges in combatting HIV in sub-Saharan Africa are huge in comparison with Europe, the end goal is nevertheless the same, namely to ultimately end HIV. The struggle with HIV in sub-Saharan Africa and in Europe is a common and a global problem. In a globalised world, HIV cannot be treated as a regional issue but should be seen in the wider, global context.

Amazing success has been achieved in combatting HIV, but there is still more to be done. While a zero-HIV strategy may seem within sight in Europe, the devastating nature of the HIV pandemic in sub-Saharan Africa means that a global zero-HIV strategy is not within reach in the foreseeable future. We need therefore to maintain a high level of research and collaboration to uphold and continue progress towards more effective and accessible treatment and prevention. A strategy for 'zero-HIV for Europe' can only be sustained with continued research investments to combat HIV globally.

Over the last 15 years, EDCTP has achieved significant progress in bringing together researchers and institutions in Europe and Africa to advance medical interventions and improved clinical management against HIV. EDCTP-funded studies on HIV

**Stigma
adhering to
HIV-infection,
legal and/or
social
discrimination
based on sexual
orientation or
gender
identification
create situations
of
under-diagnosis**

have made vital contributions to the development of antiretroviral drug formulations tailored to children and facilitating their widespread introduction in Africa. Other studies were carried out in the prevention of mother-to-child transmission of HIV and in the detection and treatment of opportunistic fungal infections, which are responsible for one in five HIV-related deaths. The EDCTP-funded REMSTART trial[1] provided a key contribution to the newest WHO Guidelines on Advanced HIV Disease[2].

Although tools for prevention or control of HIV have become available, access is a serious problem in many places in both Africa and Europe. Testing and self-testing are often out of reach and Pre-exposure prophylaxis (PrEP) is only piecemeal introduced thus far. Lack of proper medical supervision is mentioned as a European problem while in sub-Saharan Africa a political movement for universal health care and health care system strengthening is slowly gaining some momentum.

The political and social dimensions of HIV infection loom large in both Africa and Europe. Sustained development is essential as the pandemic is driven by poverty at regional, national and in-country levels.

Stigma adhering to HIV-infection, legal and/or social discrimination based on sexual orientation or gender identification create situations of under-diagnosis.

cause denial of access to testing and treatment and drive

HIV-transmission. Adolescents are vulnerable groups everywhere and sexual health education is hardly effective regarding HIV/AIDS in many countries. Migration and special populations such as prisoners or people in migratory or mobile trades (transport, fishing, mining) present specific challenges that are relevant to both Europe and Africa. HIV in coinfection with, for example, tuberculosis or sexually transmitted infections is prevalent in Africa and Europe, together with an ageing population of people living with HIV in comorbidity with non-communicable diseases. HIV-treatment of pregnant women, infants and adolescents needs also special attention. There is a vast amount of experience on this within the EDCTP-funded research consortia that conduct this kind of clinical research in sub-Saharan Africa.

An overriding theme is the need for an integrated and collaborative approach. The need for cooperation between different actors is essential in both Europe and Africa. Political commitment, sustained research investments and cooperation between public institutions and between countries is necessary to improve access to HIV prevention, care and treatment for all.

[1] S. Mfinanga et al., Cryptococcal meningitis screening and community-based early adherence support in people with advanced HIV infection starting antiretroviral therapy in Tanzania and Zambia: an open-label, randomised controlled trial. *Lancet*. 2015 385, 2015, pp 2173-82. doi: 10.1016/S0140-6736(15)60164-7. *Epib* 2015 Mar 10

[1] Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy, July 2017. Geneva: World Health Organization; 2017.



Roadmap for eliminating HIV/AIDS in Switzerland

By Federal Commission for Sexual Health (FCSH)



Switzerland has a concentrated HIV/AIDS epidemic particularly affecting men who have sex with men (MSM) as well as heterosexual women from abroad. 445 new HIV diagnoses in 2017 constituted a historic low and a decrease of 16% compared to the previous year. At the end of 2017, around 16,600 HIV-positive persons were living in Switzerland. Of those, an estimated 15,000 (90%) were diagnosed, 14,400 (96%) were undergoing HIV treatment, and in 13,800 cases (96%) virus replication was successfully suppressed. In other words, Switzerland has reached the 90-90-90 treatment targets of the Joint United Nations Programme on HIV/AIDS set for 2020.

In 2021, the Federal Government of Switzerland is to decide on a new National Programme on HIV and Other Sexually Transmitted Infections. Based on its mandate, the Federal Commission for Sexual Health (FCSH), an extra-parliamentary expert panel, recommends to the Federal Government that the future national programme target the elimination of HIV/AIDS in Switzerland.

The FCSH takes the view that an elimination of this epidemic would be

beneficial not only for thousands of individuals but for society at large.

It could save some CHF 400 million in direct therapy and treatment costs over the next 50 years. To reach elimination, the FCSH considers an annual decrease in the number of new cases by 30% as necessary and feasible. It suggests the following definition for the term of “elimination”: “Stopping HIV transmissions and AIDS cases among people living in Switzerland as a result of deliberate and ongoing efforts and measures as well

as effective surveillance to prevent reintroduction”. The following narrative of HIV/Aids-elimination is suggested: “Every new HIV infection is preventable and every HIV-related death is avoidable. Missed HIV prevention and treatment opportunities must be regarded as public health emergencies, and efforts to quickly fill gaps in service provision for all people living with and vulnerable to HIV infection must be

prioritized. Programmes to eliminate HIV and other STIs should be embedded in a broader context of sexual health. This will not only improve the integration of disease control services in health-promoting settings and thus improve the former’s acceptability and accessibility, it will also promote people’s rights and empower them to make

healthy choices and prevent further stigmatisation of key populations.” To reach “elimination” the FCSH suggest four overarching operational goals:

1. Accountability: All stakeholders – state actors on all federal levels, non-profit organisations, for-profit organisations – fulfil their lawful duties to make core services and tools for HIV elimination accessible to all people living in Switzerland on a non-discriminatory basis. Service provision is respectful of human rights and medical ethics and does not lead to the stigmatisation of people with, at risk of or vulnerable to HIV.

2. Access to Key populations: Key populations most likely to be exposed to or to transmit HIV and those particularly vulnerable to HIV and AIDS, such as MSM, people using oral chemoprophylaxis (PrEP), migrant populations from high-prevalence countries, people who inject drugs, sex workers, transgender people, refugees and populations in closed settings, are provided priority services and tools that are tailored to their particular risks, vulnerabilities and needs

- Integrated access: Persons at risk of or vulnerable to HIV and AIDS are identified by sexual health

and other health services and through community and outreach activities and are given access to core services and tools.

- Universal access: All people living in Switzerland have unrestricted access to all core services and tools without risk of incurring financial hardship.

3. Sustainability: Elimination processes are sustainable because they build on the participation of key populations, scientific evidence, innovation and broad political support.

4. Surveillance response: Based on a reverse-engineering approach, a surveillance system monitors success or failure along the whole continuum of prevention and care and informs all stakeholders on the elimination progress and on the impact of measures, with a focus on accountability, access and uptake. Analysis and interpretation of data shed light on the social contexts and constructs of the success or failure of prevention efforts. Surveillance allows for the translation of findings into timely action for measures to interrupt transmission.

In view of tackling STIs other than HIV, the FCSH observes that the currently unprecedented decrease in new HIV infections in Switzerland is paralleled by an increase in all other STIs largely due to increased testing among the same key populations as for HIV. Consequently, all concentrated endeavours to eliminate HIV/AIDS as proposed in FCSH's Roadmap for eliminating HIV/AIDS in Switzerland will also have a major and dynamizing spin-off effect on the successful control and eventual elimination of other STIs in Switzerland.

"Service provision is respectful of human rights and medical ethics and does not lead to the stigmatisation of people"



PARLIAMENTARIANS FIGHT TO END AIDS IN EUROPE

UNITE



For UNITE, the Global Parliamentarians Network to End HIV/AIDS, Viral Hepatitis and other Infectious Diseases, efforts towards the elimination of HIV/AIDS as a public health threat in Europe requires an urgent positioning of HIV in both the public and political agenda. With political awareness and advocacy, Members of Parliament (MP's) and other policymakers have the potential to influence:

- Increase access to HIV care throughout the whole cascade from health promotion, prevention, affordable treatment to achieve viral suppression, towards a focus on quality of life and well-being for virally suppressed people living with HIV to continuously manage co-morbidities (1);
- Suggest changes of laws towards the elimination of stigma and discriminatory policies and increase of access and usage of services by most people in need. Laws that protect PLHIV and respect human rights standards are required;
- Boost the emergence and strengthening of community and peer-led initiatives that ease the uptake of prevention, testing and treatment of HIV;

- Focus on strategies to decrease the burden of HIV among key populations such as women, sex workers, people who inject drugs, migrants, prisoners, and gay men and other men who have sex with men, which constitute the most infected groups in countries such as Bosnia and Herzegovina, Latvia, Azerbaijan, Ireland and Lithuania (2);

- Increase of domestic funds addressed to innovative diagnosis and therapeutic tools, tailored to local needs. Funding can be addressed to public entities but also to community-based organizations (CBO), who in most countries lack basic means to advance in the implementation of their activities. However, CBO need to keep their financial independence and engage with the private sector, beyond the pharmaceutical and diagnostics industries. This can be possible if a percentage of total funds were to come from private sectors partnerships;

The elimination of HIV as a public health threat in Europe requires the engagement of MPs to increase leadership and accountability that will drive changes in laws and will influence policies, health budgets approvals, and alignment with the UN 2030 Sustainable Development Goals.

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Being in the interface between governments and their constituencies, MPs engagement can bring impact in the elimination of HIV. Thus, there is a need to engage MPs in taking action against HIV and promote the understanding of their critical leadership role in controlling the epidemic of HIV, ensure the increase of sustainable financing, and eliminate marginalization and impoverishment of PLHIV, especially in urban settings.

To reach these ambitious goals, initiatives and tools towards strengthening the engagement of MPs are required. The existing handbook directed to MPs engagement into HIV control dates back from 2007. Elaborated in a joint effort the Inter-Parliamentary Union (IPU), the United Nations Development Programme (UNDP) and the Joint United Nations Programme on HIV/AIDS (UNAIDS), Taking Action Against HIV. A Handbook for Parliamentarians (3), needs to be updated to include:

- Focus on strategies to decrease the burden of HIV among key populations such as women, sex workers, people who inject drugs, migrants, prisoners, and gay men and other men who have sex with men, which constitute the most infected groups in countries such as Bosnia and Herzegovina, Latvia, Azerbaijan, Ireland and Lithuania (2);
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The elimination of HIV as a public health threat in Europe requires the engagement of MPs to increase leadership and accountability that will drive changes in laws and will influence policies, health budgets approvals, and alignment with the UN 2030 Sustainable Development Goals.

A Comprehensive View on Breast Cancer Management in Europe

By Didier Verhoeven



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Caregivers delivering care to breast cancer patients must provide the highest quality possible within their existing financial and personnel resources. Due to the complexity of the pathway, this should be delivered by a multidisciplinary team working in a breast cancer unit/centre.

Although the basics in diagnosis and treatment are well known, providing, monitoring, and assessing the quality of the breast cancer care offered is challenging for most sites. To address all these problems the book : “BREAST CANCER : GLOBAL QUALITY CARE” was recently produced and is now in production

by Oxford University Press (Ref.). Launching will be end of the year (probably October). Some participants of the meeting were actively involved (Didier Verhoeven as leading editor, Robert Mansel as co-editor , Lynda Wyld, Lieve

Wierinck and Luis Teixeira as faculty members) The authors provide thorough descriptions of high-quality breast cancer care, define targets to strive for, methods to assess one's care, and ideas on how to improve within one's resources.

A global view of quality of breast cancer care shows specific best practices applicable to many centres operating in various health care systems with different financial and political situations.

Foundation hallmarks of innovation, communication, patient-centred care, multidisciplinary, and budget considerations guide specific recommendations for each component of care. This book provides a comprehensive overview that takes into account global and local considerations so that optimally “integrated” breast cancer care can be organised.

Individually, each component of care (e.g. imaging, surgery, systemic treatment, genetic assessment, etc.) is discussed from both theoretical and practical aspects. Each discipline may identify a desired level of care that is possible, while the local resources define what is achievable.

After 10 years of extensive work with a lot of expert meetings devoted to quality management, organization of breast cancer care, guidelines

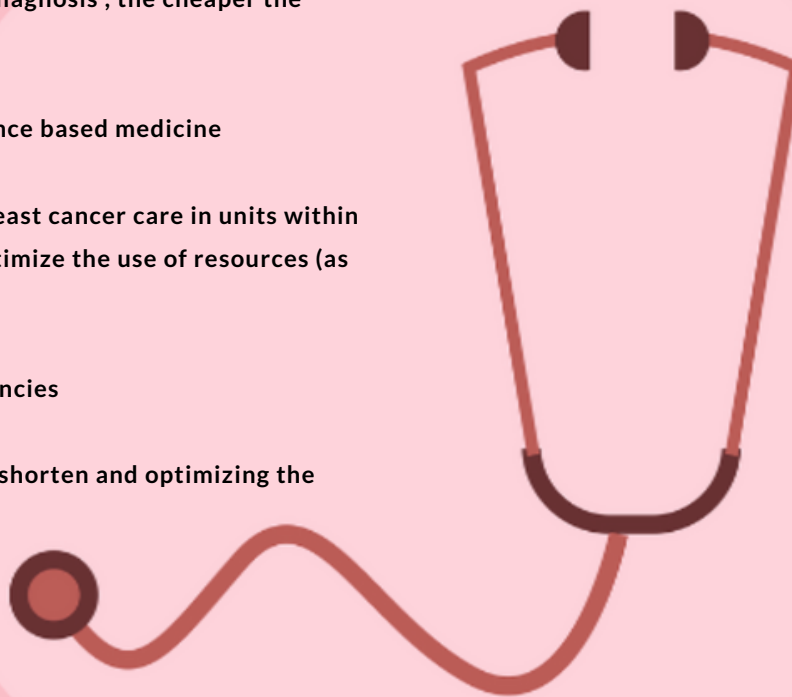
and the influence of local economics and resources in breast care these experts decided to publish their knowledge to provided astute assessment of these issues which will be valuable for those around the globe. All aspects from epidemiology , to quality management, media aspects, economics and health technology are included in a short and comprehensive way with clear messages. 125 top-experts coming from 25 countries over the five continents worked together to explain in a comprehensive but easy way, all you need to know if you want to start a breast center, wherever you live.

Ten key conclusion were put forward:

- Cancer registries are important because they provide insight of the burden of cancer.
- Multidisciplinary teams and integrated care are most important. The multidisciplinary meeting is the key element of the breast unit, it is the jewel on the crown. The place where all the players must join and meet : surgeons, medical and radiation oncologists, pathologists, radiologists, breast nurses. The conference must lead to a clear treatment plan, taken into account the different aspects, as socio-economic considerations, innovations and clinical trials.
- A strong primary care presence should be promoted globally.
- Resource -stratified guidelines and adherence must be identified.
- Information to patients should be given at the right time and in the right amount.
- Breast cancer research must be efficient and guided by targeted and personalised treatments
- Quality management of breast cancer by accreditation programs and continuous education should be daily practice.
- New information technology must be integrated in daily care.
- Health economic analysis will provide insight and reflection on the organisation of the care.
- National cancer plans must engage authorities to work on the breast cancer burden.

Furthermore some important aspects to save money are:

- **Avoid overtreatment and over-diagnosis , for example by personalization of treatment**
- **The earlier the diagnosis , the cheaper the treatment**
- **Promotes evidence based medicine**
- **Organize the breast cancer care in units within networks, to optimize the use of resources (as radiotherapy)**
- **Reduce inefficiencies**
- **Try to simplify, shorten and optimizing the treatment**
- **Promote ambulatory care (financially)**
- **Organize a Quality management , but cut also in the administrative burden!**



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Dr Lorenza Marotti
Executive Director of Eusoma

Breast Centre is the place where breast cancer is diagnosed and treated; it has to provide all services necessary from genetics to prevention, to the treatment of the primary tumour, to care of advanced disease, to palliation and survivorship and psycho-social support.

Eusoma since 2000 has published a milestone document on the requirements of a specialist Breast Centre, which has been pivotal for the setup of Breast Centre not only in Europe but also overseas and has been taken into consideration by national Authorities to define the organization of breast cancer management in their countries.

Despite this, as highlighted in the EBCC-10 Manifesto (EJC 72 (2017) 244-250), still too many European Countries have not deliberated on the management of Breast Cancer, missing the 2016 deadline for all patients in European Countries to access specialist multidisciplinary breast cancer units or centre.

Requirements are important referring tools and, as such, need to be regularly up-dated. In this view, Eusoma, with the endorsement of the European CanCer Care Organisation (ECCO) as part of the ECCO project "The Essential Requirements for Quality Cancer Care" - ERQCC, has finalised the updating of the paper "The requirements of a specialist Breast Centre" (EJC2013;49,3579-3587),

with the contribution of European experts and representative of ECCO member discipline societies involved in the management of Breast Cancer Care.

This document will contain the updating of the existing Eusoma requirements taking into consideration changes in organization and care in the past 5 years and will also include sections on epidemiology, challenges in breast cancer and quality and audit processes.

Multidisciplinary approach, based on dedicated health professionals and quality control are two essential aspects of a specialist breast Centre, which has to offer harmonised quality care, regardless in which European country a person lives.

Multidisciplinary approach is based on the concept that not a single specialist but a group of specialised and dedicated experts will take shared decision on the diagnosis and care to be delivered to each patient.

Therefore, each Breast Centre must hold weekly multidisciplinary case management meeting to discuss diagnostic preoperative and postoperative cases and any other issue related to breast cancer patients, which need multidisciplinary discussion.

As highlighted in literature, this approach results into a great impact on patient survival. A 2012 UK observational cohort study (Kesson EM et al Br. Med J 2012; 344:e2178), evaluating the effects of multidisciplinary approach on nearly 14.000 women, showed that this approach was associated with a 18% lower mortality at 5 years.

Quality control is an essential tool to monitor the activity of the Breast Centre, the compliance with the adopted recommendations and protocols, the performance with regard to Quality Indicators.

It is necessary that each Breast Centre collects its data in a database and has within the team a data manager, i.e. a person qualified and trained to be responsible of the breast Centre data.

The data manager works under the supervision of the breast Centre clinical lead, organises audit meeting, monitors the trend of the Quality Indicators, keeps the team informed on that and takes part in the, at least yearly audit meeting, where all the team together discusses on the breast centres performance, on the need for any changes, improvements. Again, with a multidisciplinary approach, the team identifies the necessary corrective actions, which might be not only clinical but also organizational or structural and therefore needs the involvement of the hospital management.



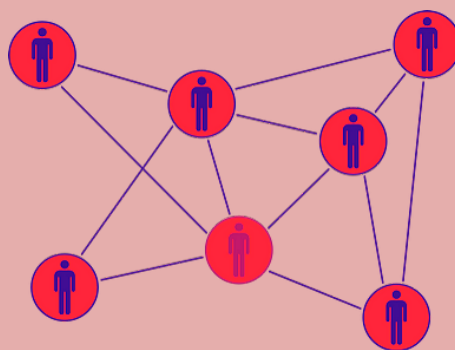
Quality control is very important not only for the single Breast Centre but also for the entire scientific community, because the benchmarking of the results of the different centres represent a helpful resource in the up-dating of national and international guidelines, in identifying new quality indicators or amendments of the existing ones.

Collecting data is essential for the scientific research at the breast centre, to allow to develop specific project and to publish local experience or to join national and international project.

There is evidence on the benefit of external audit, i.e. certification or accreditation, to better performance and outcomes, and this is true also for a breast centre.

Therefore, it is advised that a Breast Centre undergo a voluntary certification/accreditation process based on the offer at national or international level such as for example German Cancer Society and German Senology Society, National Accreditation program for Breast Centre (NAPBC) run by the American College of Surgeons, Breast Centre Certification, accredited scheme based on the Eusoma requirements and Quality Indicators.

The contribution of policymakers and politicians to make sure that all women in Europe are treated in specialist breast centres is fundamental. Only joint forces from health professionals, patients' advocates, policymakers and politicians can ensure that breast cancer patients have access to specialist breast centres in any European countries.



Exercise as Medicine for Cancer Survivors

By Dr. Yvonne Wengström, Dr. Sara Mijwel, Dr Kate Bolam



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Advances in anti-cancer treatments mean that more people with cancer are living longer, but many people aren't living as well as they could be. Cancer survivors may experience considerable morbidity, increased risk of losing independence as they age, and significantly reduced quality of life. These effects also place unnecessary economic burden on the health care system. Addressing the detrimental effects of cancer and its treatment has been consistently identified as a central component of survivorship care.

Numerous systematic reviews and meta-analyses have concluded that regular exercise is a safe and effective intervention to counteract many of the adverse physical and psychological effects of cancer and its treatment. Consistent evidence from epidemiological studies suggests that being more physically active after a cancer diagnosis reduce the risk of cancer specific death and cancer recurrence in for certain cancer types. The increasing body of evidence has led international exercise organizations such as The American College of Sports Medicine (ACSM) and Exercise and Sports Science Australia (ESSA) to develop guidelines on exercise for cancer survivors. The ACSM guideline was published almost a decade ago with an update due in 2019. While the message for cancer survivors to be physically active and reduce sedentary behaviors such as prolonged sitting is important, evidence supporting

exercise guidelines arises from interventions that are appropriately prescribed and monitored, and research continues to add insight to the precautions, adaptations, and optimal prescriptions for exercise in people with cancer. Appropriate exercise is an effective intervention for the long-term management of cancer and should be put forward as a critical element of survivorship care.

Need for an Exercise

Medicine Model of Care The current evidence of the various health benefits of exercise support a paradigm shift in oncological care. Survivorship guidelines released by the American Society of Clinical Oncology specify exercise as a core component of high quality survivorship care. Survivors have clearly indicated a desire to participate in appropriately designed and supervised exercise programs; however, no such services are routinely available for cancer survivors in most countries. The challenge is to develop a sustainable model of care that is affordable and effective. Including exercise as an established and standard component of cancer survivorship may help to reduce some of the barriers to exercise, such as unequal access to evidence-based information, lack of access to exercise equipment, facilities, and exercise specialists. Additionally, creating a standardized model of care for exercise in cancer survivorship will minimize the risk of missing the patients groups who are less likely to ask about exercise or to ask questions about their health in general.

Throughout the literature larger effects have been observed for interventions delivered at exercise facilities by appropriately qualified allied health professionals. Exercise should be prescribed and delivered under the direction of a qualified exercise physiologists, specialists or physiotherapists in order to maximize safety and therapeutic effect. These health professionals have expertise in understanding and identifying potential exercise contraindications and considerations and are able to use their clinical judgement in complex clinical scenarios. While not all people with cancer will require ongoing supervision, these practitioners will allow for exercise to be prescribed in line with evidence-based guidelines to help individuals with cancer meet exercise recommendations, which is important for the health, function, quality of life and, potentially, survival of people with cancer. We now have enough evidence for the positive effects of exercise during and after treatment for breast cancer and it is time to take responsibility to make exercise as medicine available and part of treatment for women.

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I have cancer, but I want to work

By Fatima Cardoso¹, Lieve Wierinck, Karen Benn, Barbara Wilson, Richard Sullivan, Donatella Decise, Sonia Ujupan, Vincent Clay, Roberta Ventura and Marc Beishon, on behalf of the ABC Global Alliance



Introduction

The ABC Global Alliance (www.abcgloballiance.org) is a multistakeholder organization, launched in 2016, for tackling the many issues faced by people with advanced breast cancer (ABC). The Alliance is a continuation of the work developed through the ABC International Consensus Conference created in 2011, responsible for the ESO-ESMO International Consensus Guidelines for the management of Advanced Breast Cancer and its advocacy efforts. Many studies revealed substantial gaps in care, access to resources, support, and treatment outcomes for ABC patients. The alliance's aim is to improve and extend the lives of women and men living with ABC in all countries worldwide, raise awareness about ABC and lobby worldwide for the improvement of the lives of ABC patients.

Costs of cancer have an important impact on the global economy and encompass direct and indirect costs. The latter are most related to loss of productivity due to the inability to continue or return to work from many cancer patients and survivors. Cancer has an enormous impact in the personal, social and working relationships of people. To address the cancer burden in Europe, it is crucial to address disparities and harmonise standards for all Europeans. Many people want to continue working for financial security and to have a helpful distraction from their illness, and they should expect flexible support from their employers, as the effects of cancer treatment such as pain and fatigue can differ at various times. European and national politicians and policymakers need to implement consistent and flexible policies to enable cancer patients and cancer survivors to return to work.

Scale of the issue

One out of 8 to 10 women will have breast cancer in their lifetime, and the number of annual deaths will rise to more than 800,000 globally by 2030, about 43% more than the 560,000 deaths recorded in 2015. In Europe, there is a breast cancer diagnosis every 2.5 minutes and a death every 6.5 minutes. The latest Globocan 2018 data show that, in Europe, more than half a million women (and some men) are diagnosed with breast cancer annually and about 140,000 die from this disease each year.

About a third of those diagnosed with early stage breast cancer will later have a relapse/recurrence, even if diagnosed early and with access the best available therapies. It is unfortunately unknown how many advanced cancer patients currently exist in Europe since the majority of cancer registries do not record the occurrence of recurrence, but only incidence and mortality. This makes it harder to allocate resources and to implement the needed changes to address the needs of these patients. Recently, the European Network of Cancer Registries (ENCR), which focuses on finding ways to integrate data from Europe's cancer registries, started to be run at the European Commission's Joint Research Centre. It is crucial that the JRC includes mandatory collection of data on metastatic recurrences in breast and other cancers. The ABC Global Alliance has made a thorough needs assessment of ABC patients and defined 10 priority goals to be addressed and achieved during the current decade: the ABC Global Charter. These goals include doubling of median survival, increasing access to multidisciplinary care, include ABC in cancer registries, improving communications and information, and reducing stigma. Last but by no means least among the goals is "help patients with ABC continue to work by implementing legislation that protects their rights to work and ensure flexible and accommodating workplace environments", which given the rising incidence of breast cancer will mean more women (and some men) having to negotiate workplace arrangements.

Working with employers and employees

Work is an important part of one's identity, it fulfils the need for social structure and provides financial stability, a sense of normality and of purpose. But treatment and medication can cause fatigue, cognitive dysfunction, pain and other symptoms, and the path to getting better is not smooth; there are good days and weeks, but also bad times, and getting back to "normal" is often not possible. Cancer is life changing – physically and emotionally – it would be wrong to think otherwise.

Three important aspects to keep in mind are:

- 1) It is possible for most people with cancer, including those with advanced cancer, to continue to work;
- 2) Information must be given to employers and employees on what to expect during and after cancer treatment and how to manage at work. This means regular communication about the side-effects of treatment and having the flexibility to make adjustments for a gradual and successful return to work;
- 3) There must be a consistent EU-wide framework that supports all people with cancer who face discrimination in the workplace. As an example, the UK Equality Act 2010, while not fully taken onboard by every employer, does a lot to protect cancer survivors against discrimination at work and to support their return to work, through for example, the requirement for employers to make reasonable workplace adjustments.

Employment/return to work issues facing people with ABC

The EU's Employment Equality Framework Directive 2000 is the legislative framework that should protect people with both early and advanced cancer from discrimination. But it is an EU Directive and not an EU Regulation, and while it must go onto the statute books of the EU member states, each country has the flexibility to define what constitutes disability, and therefore whether or not cancer fits their definition.

Some countries, such as the Nordic countries, Netherlands, Ireland, France, Belgium and the UK do give cancer patients the ability to "register" as disabled and therefore to benefit from this legislation for their working rights, among other things. However, in many European countries, formal protection is either non-existent or the situation is legally ambiguous, and there are no data on how many cancer patients return to work or how easy they find it to do so.

There are also big disparities in how countries help people to return to work after long-term illness – here the Scandinavian countries are good, offering cancer survivors a return to work plan. Europa Donna, the European Breast Cancer Coalition, did a short survey of people with metastatic breast cancer about their experiences and support in their countries for employment and return to work. It found that, according to the survey respondents, a majority of the 35 countries represented do indeed have disability discrimination legislation that protects cancer patients, and some countries also have other legislation which protect people living with cancer from discrimination. A majority also said there is information available on social security and welfare, and on leave of absence and return to work, and on working part time, although the latter is mostly dependent on the employer. Surveyed advocates and patient advocate also reported that pressure from employers and colleagues can discourage return to work, and there is stigma and lack of awareness of living and working with cancer.

There is some movement at EU level. A report from the European Parliament, "On pathways for the reintegration of workers recovering from injury and illness", (2017/2277 (INI)), now includes amendments on cancer. In May 2018, a group of MEPs led by Rory Palmer (UK) launched the European Dying to Work campaign, which aims to protect terminally ill workers from dismissal; as it stands, there are no specific protections for terminally ill employees. Also, in 2018, MEP Deirdre Clune (Ireland) proposed a pilot project to the European Commission on collecting data on the number of people with metastatic cancer in the workplace, using breast cancer as a model; however, this project has not yet been funded. The aim of the project is to assist in designing better policies and service provision.

Costs and value in cancer care

There are big threats to achieving equitable care for breast cancer and other diseases – social inequalities, which are rising in Europe, and the impact of technology such as new drugs and imaging, which must be subject to guidelines and also must have an experienced healthcare workforce that can deliver appropriate care. Breast cancer and colorectal cancer, due to their incidence, are the two cancers that particularly determine economic burden and whether policy response can control costs.

Economic impact is framed by direct healthcare costs and informal costs, balanced against productivity losses – and the figures are substantial. In Europe, total costs for breast cancer are over €14 billion, made up of 43% healthcare, 22% informal care, and 35% productivity lost to mortality and morbidity. Productivity loss of people unable to work is one of the biggest concerns for employers, although these figures also show the sheer cost that advanced cancer has on societies as people are lost to the disease. Several studies have shown that the percentage of indirect costs related to cancer is superior to the direct costs of treating the disease. Tackling the problem of loss of productivity would benefit substantially Europe and the World's economy.

Reports and projects

Previous published reports have highlighted the problem of loss of productivity angle. The Cancer in the Workplace report, published by the Economist Intelligence Unit in collaboration with Bristol-Myers Squibb in 2016, assessed the challenges that cancer poses for employers and reported that loss in productivity of cancer survivors who were unable to return to paid work in the UK was £5.3 billion in 2010. In a survey, productivity loss was ranked highest among the concerns of employers, followed by rising insurance premiums and the cost of days off sick. Notably, high among the concerns was the ability of managers to support employees with cancer. The report also surveyed employees and, encouragingly, when asked whether they feel confident that their employer would support them during the period of illness and up to 1 year thereafter, around 75% of respondents said that they would be fairly confident or very confident. This figure is higher among respondents in large companies. However, in a more recent survey in the Netherlands, it was small, family owned businesses that offered the most support, ahead of larger companies and the public sector.

The Policy Roadmap on Addressing Metastatic Breast Cancer report, published by a multi-stakeholder steering committee and Eli Lilly & Company, raised awareness on clinical, economic and societal burden of metastatic breast cancer and issued some recommendations, that include:

1) provide wider support systems and decision-making tools for metastatic breast cancer patients for coping with their diagnosis, handling their disease, managing their treatment's side-effects, and organising their lives to allow for minimal disruption; 2) the European Commission should use the European Pillar of Social Rights as a policy framework to initiate adequate measures to ensure member states provide patients and informal carers with employment regulations that sufficiently protect their work-life balance; 3) increase recognition of the role of informal carers and formalise their rights and access to available support systems.

The two Novartis-led projects Here & Now and My Time, Our Time have focused on the needs of ABC patients. In 2013, 40% of women in Europe with advanced breast cancer who were surveyed were working and of those, 25% worked full-time; about 50% of patients had to change their work situation due to advanced breast cancer and 37% had to give up work temporarily or altogether. As a consequence, 56% of patients experienced a decline in household income as a result of being ill.

The road to a better normal: Breast cancer patients and survivors in the EU workforce is a recent report published by the Economist Intelligence Unit in collaboration with Pfizer and showed that societal and medical trends in Europe are intersecting to increase the number of breast cancer patients and survivors who are likely to want to work. In the past 15 years the proportion of European women aged 50-64 in employment has risen steadily, so that now a majority (59.6%) of that group are active in the labour force. The rate at which breast cancer patients and survivors return to work is highly uneven, suggesting substantial room for improvement. National return-to-work rates for breast cancer patients and survivors who were in a job at the time of diagnosis ranged from 43% in the Netherlands to 82% in France. Breast cancer and treatment side-effects make returning to work harder, but they are far from the only issues. Important non-medical barriers also impede a return to work, including lack of employer or colleague support, the extent to which work is physically demanding, and the level of education of the women involved. Such factors overlap to make specific populations vulnerable, particularly working-class women.

In addition to the summarized reports, it is important to consider that there are substantial numbers of self-employed women who do not have a formal workplace to return to, and face financial difficulties in particular. Younger women with breast cancer are likely to be most affected.

Conclusion

Returning or maintaining a productive professional life is a crucial factor for cancer patients and cancer survivors. Reducing the costs associated with loss of productivity due to cancer would substantially decrease the economic burden of this disease in all countries.

The majority of cancer patients and survivors want and/or need to return to work but they face several limitations as a consequence of disease and treatments and need flexibility and understanding in their work environment. Some employers are willing to provide such flexibility but would need incentives and support.

The public sector should lead by example, but government employers are often the worst at supporting return to work. Organisations may respond better to incentives to adopt flexible policies rather than penalties and financial support is crucial to enabling flexibility for employers that find it hard to support unpredictable patterns of absence for cancer patients. Replacement income from welfare that switches in on days when an employee cannot work would help solve this.

Legislation protecting the right to return to work part time or with flexible hours, coupled with financial support and/or tax exemption for employers who apply that legislation, could be a solution to protect both employees and employers. Doing so, would substantial decrease the burden of cancer on each country's healthcare budget.

The 5-year prevalence (i.e. people who had a diagnosis of breast cancer in the last 5 years and are still alive) of breast cancer in Europe is over 2 million people. When considering all cancers, there are over 12 million people who had a diagnosis of cancer in the last 5 years and are still alive, the majority of whom are in their most productive years (40's, 50's and 60's). Europe cannot afford to lose this wealth of workforce.

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European Commission Initiative on Breast Cancer (ECIBC)

By Luciana Neamțiu



Luciana Neamțiu
European Commission
Joint Research Centre

Breast cancer is the most common cancer among women in the European Union (EU). Data from the European Cancer Information System (ECIS), managed by the European Commission's Joint Research Centre (JRC), indicate that more than 400,000 new cases were diagnosed in 2018. Indicators of quality of care and patient experience and of accessibility to breast cancer centres were showing discrepancies among Member States and within Member States; these discrepancies push the Commission to launch the ECIBC with the view to tackle these inequalities through updating the previous European Guidelines for quality assurance in breast cancer screening and diagnosis, reflecting the latest scientific developments with the aim to improve and harmonise the quality of breast cancer services and to overcome inequalities in accessing care across Europe. The ECIBC is operated by the EC-JRC under the umbrella of collaboration with the EC Directorate General for Health and Food Safety (DG SANTE). It involves today 35 participating countries across Europe. In addition to representations of all EU Member States, also Iceland, Macedonia, Montenegro, Norway, Serbia, Switzerland and Turkey are collaborating on the European Commission's initiative. The ECIBC objectives are achieved through the development of: (1) new European breast guidelines on screening and diagnosis, and (2) of an associated quality assurance scheme with particular attention

on the patients' needs, using the latest scientific evidence available. The ECIBC covers the entire breast cancer care pathway, from screening of asymptomatic women to diagnosis, treatment, rehabilitation, management of recurrence and palliative care.

(1). The European Breast Guidelines are developed using Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology. The GRADE Evidence-to-Decision framework is granting full transparency about the process followed for each ECIBC recommendation. These recommendations focus on many crucial aspects of breast screening and diagnosis, for example: when and how often women should attend mammography screening, which technology should be used, how women should be invited to ensure high population coverage, how results should be communicated, how more vulnerable parts of populations should be addressed and which diagnostic methods should be used. ECIBC's recommendations aim to guide healthcare professionals and policymakers to plan, organise, and deliver effective and equitable breast cancer services. At the same time, the recommendations can also help women to be better informed on their care options.

The ECIBC recommendations are being published online* as they are progressively developed. Guidelines developers and screening programmes organisers of several countries have already expressed their interest to either adopt

and/or adapt ECIBC recommendations for their own National or regional programmes, such as from countries of the European Union (Bulgaria, Czech Republic, Greece, Estonia, Italy, Malta, Romania, Slovakia, Spain, United Kingdom) as well as from Armenia, Bahrain, Brazil, China and Macedonia.

(2). The ECIBC Quality Assurance (QA) Scheme will, once finalised in 2020, cover the entire breast cancer care pathway, from screening to palliative care. The QA scheme sets quality criteria needed to guarantee that breast cancer care is effective and safe when implemented in breast services.

The ECIBC working groups include health care professionals as well as patients and patient advocates, such as Europa Donna – The European Breast Cancer Coalition, who participate in every phase of the discussion and development of both the guidelines and the quality assurance scheme. Moreover, several calls for feedback were posted on the ECIBC website in the recent years which outcome was considered during the activities of the various working groups to ensure that the various stakeholder needs are properly considered during the development of ECIBC.



The implementation of the ECIBC scheme into National contexts is voluntary. Therefore, the European Commission initiative has been developed in a flexible and adaptable way to allow local guideline developers to make best use of ECIBC by incorporating individual recommendations into local programmes or adopting ECIBC in total in breast services.

2019 will be an important year for ECIBC: the work on recommendations development will be finalised and the ECIBC will experience the first practical applications of the QA scheme to be ready for the final roll-out of the ECIBC scheme in 2020.

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The European Breast Cancer Coalition raising Awareness of Breast Cancer

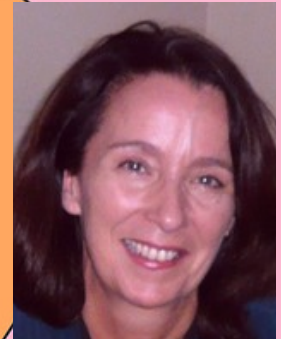
By Susan Knox & Karen Benn



EUROPA DONNA - The European Breast Cancer Coalition is an independent, non-profit organisation whose members are affiliated groups from countries throughout Europe. The Coalition works to raise awareness of breast cancer and to mobilise the support of European women in pressing for improved breast cancer education, appropriate screening, optimal treatment and care and increased funding for research. EUROPA DONNA has national groups in 47 member countries



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CEO EUROPA
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There are currently 404,920 new cases of breast cancer in the EU each year and 98,735 deaths¹. High quality early detection, followed by treatment in a specialist breast unit is still the best way to ensure living a full life after breast cancer. As Europe's breast cancer advocacy organisation, Europa Donna (ED) seeks to ensure that all European women have information about, and access to, early detection through mammography screening programmes set up in accordance with the EU Guidelines and access to care and treatment in Specialist Breast Units as defined in EU guidelines. Our efforts over the last 20 years have been dedicated to making women aware of the services they should have the right to receive through consistent education, information and policy programmes.

While much has been achieved many inequalities still exist between countries. See our website www.europadonna.org for policy and other initiatives undertaken.

Central to overcoming inequalities is training advocates from our member countries on current best practice so that they can take this information back to their countries and advocate for implementation locally. Europa Donna has been conducting training programs for advocates since 2001. Each year advocates from all our member countries are invited to participate in advocacy training courses, advocacy leader conferences and most recently advocacy conferences for women



for mammography screening and how specialist breast units should be set up and conducted. Now this training includes a module on the ECIBC - European Commission Initiative on Breast Cancer. Europa Donna had been advocating for a Europe wide program such as this and has been following this initiative closely since its inception in 2013. Susan Knox, ED's CEO, serves on the Guideline Development Group for the new EU Guidelines and Karen Benn, ED Deputy CEO, serves on QASDG Quality assurance scheme development group working on the QA scheme. Both serve as individual experts and not as ED representatives, in accordance with EC rules.

The GDG Guidelines Development Group, has recently published its first recommendations on screening which are available at <http://ecibc.jrc.ec.europa.eu>. Europa Donna is now actively promoting the implementation of these important EU guidelines and has begun by publishing "The Europa Donna Advocates Guide to the ECIBC".

with MBC (metastatic breast cancer). In this way we ensure that advocates have the most up to date information on all aspects of early detection, breast cancer diagnosis, breast cancer surgery, imaging, and current treatments available for the disease. They are informed about evidence-based guidelines

and/or adapt ECIBC recommendations for their own National or regional programmes, such as from countries of the European Union (Bulgaria, Czech Republic, Greece, Estonia, Italy, Malta, Romania, Slovakia, Spain, United Kingdom) as well as from Armenia, Bahrain, Brazil, China and Macedonia.

(2). The ECIBC Quality Assurance (QA) Scheme will, once finalised in 2020, cover the entire breast cancer care pathway, from screening to palliative care. The QA scheme sets quality criteria needed to guarantee that breast cancer care is effective and safe when implemented in breast services. The ECIBC working groups include health care professionals as well as patients and patient advocates, such as Europa Donna - The European Breast Cancer Coalition, who participate in every phase of the discussion and development of both the guidelines and the quality assurance scheme. Moreover, several calls for feedback were posted on the ECIBC website in the recent years which outcome was considered during the activities of the various working groups to ensure that the various stakeholder needs are properly considered during the development of ECIBC. This is currently being used in all our training courses to ensure that advocates know the content of these new guidelines and understand how they were developed so that they can advocate for them effectively in their own countries.



. The ECIBC provides concrete evidence-based recommendations that can and should be implemented by all countries. When it is completed the ECIBC will delineate the entire breast cancer pathway including diagnosis, treatment, follow up and rehabilitation etc thus providing an outline of what breast services should be provided to women across Europe. The ECIBC will only be valuable if it gets implemented, so our main priority today is working toward that goal. We see that it is included in all of our training programs, conferences, information materials, as well as in key European scientific conferences such as EBCC of which we are a co-organiser with EORTC and EUSOMA. It is now imperative that all policy makers active both at the European level and the National level join together to ensure the implementation of the ECIBC in all countries.

Another key priority for advocates and for policy makers is ensuring that high quality research is carried out in Europe.

Europa Donna's role and involvement in research is broad and a number of our organisational goals are dedicated to breast cancer research. Our involvement in the EU and international research agenda spans policy, education and direct involvement in research; this includes promoting relevant research trials that address important questions from the patient's point of view; being the informed link between professionals and prospective trial

participants, representing patients' needs and the consumer perspective, thereby adding balance; advocating for the dissemination of study results and availability of effective drugs across all countries.

In terms of policy, ED has always advocated for increased funding for all types of BC research, including ensuring that the EU Resolutions on Breast Cancer of 2003 and 2006, and Written Declarations on Breast Cancer of 2010 and 2015, include a commitment to high-quality, multi-institution, independent breast cancer research. ED's extensive education and information programmes, including attending EU breast cancer conferences and meetings ensures that ED's members, and patient advocates in its member countries, remain abreast of the latest scientific research and are trained to understand

and participate actively and effectively on research committees. Effective advocacy involvement means that Europa Donna advocates must be included from the outset of the research. Advocates are not there to "rubber stamp" trial protocols; they need time to study materials in advance, ask questions and participate actively in order to ensure credibility, independence, and provide real consumer perspective. To this end Europa Donna has conducted education programs for advocates and has published 3 booklets on research engagement that can be found on our website

<https://www.europadonna.org/research/>.

ED has been also been directly involved in the European research agenda for many years.

We are the patient advocacy partner of BIG, the Breast International Group, which is a consortium of more than 50 institutions and academic breast cancer research groups headquartered in Brussels. Through the BIG consortium we are currently serving on the steering committees of the MINDACT trial, the Olympia trial, and the AURORA research programme; in addition, ED representatives serve on the BIG Survivorship taskforce.

Europa Donna has also collaborated for many years with other EU consortia who receive EU funding, frequently through DG Research's programmes, including the Horizon 2020. We are currently engaged as consortium partners, or as external advisors, in 4 Horizon 2020 funded projects, PREFERABLE, BOUNCE, Mesi-strat and MyPEBS. ED also has a representative on the Steering committee of EBCTCG - Early Breast Cancer Trialists' Collaborative Group, and on the ethics committee of IBCSG - International Breast Cancer Study Group; in addition, ED representatives are involved at an advisory level in the IBCSG's POSITIVE trial. Europa Donna's involvement in clinical trials and studies can influence numerous areas including: ensuring that the research answers an important question of interest and use to patients and the public, leading to better and more user-friendly trial design, and ensuring that patient-oriented information, including consent forms, is presented in clear, comprehensible language, leading to a better understanding by potential trial participants. Finally Europa Donna has a key role to play in explaining clinical trials and research in general to the public, to policy makers and to other stakeholders.

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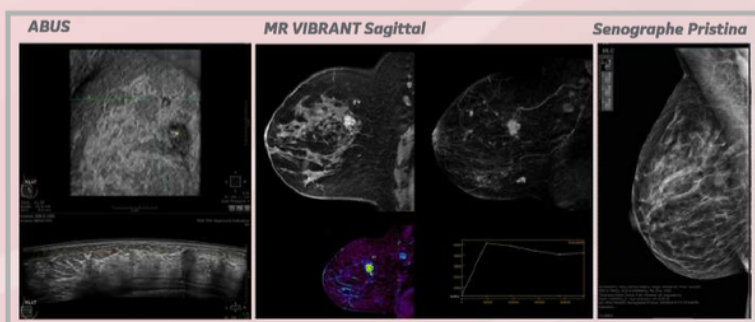
Multi-modality approach for early breast cancer

The value of breast cancer screening and early cancer detection has been proven by a wide range of clinical evidence with the aim to improve outcomes. Mammography continues to be highly accessible and the primary method of detection with a wealth of evidence on accuracy and cost-effectiveness in screening and has shown a great mortality rate reduction when integrated into population-based screening programs. However, breast imaging is not a single modality specialty. MRI and ultrasound are quickly becoming elevated to the same standard of care particularly for women at high risk. There is an urgent need for clinical studies that show the optimal screening and diagnostic pathway based on a patient individualised risk profile. For example, mammography screening is less effective in women with dense breast tissue. Women with dense breasts may be 4-6x more likely to get breast cancer¹, 71% of breast cancers occur in dense breasts² and up to 50% of breast cancers will be missed in extremely dense breasts³.

Evidence exists for the benefit of implementing additional screening tools, such as Automated Breast Ultrasound (ABUS). The European Asymptomatic Screening study⁴ demonstrated a 57% relative increase in invasive cancer detection rate in women with dense breasts by keeping a stable recall rate of 2.3%, when ABUS is used as an adjunct to 2D mammography. ABUS Invenia™, the only FDA approved Ultrasound screening technology was successfully implemented into a high-volume screening workflow for this trial in St. Görans Hospital in Sweden.

In the past decade other screening and diagnostic tools have emerged in adjunct to 2D mammography. One such screening tool, known as 3D mammography, offers an innovative imaging of the breast. The 3D mammography technique offers multiple images of the breast, providing additional diagnostic information. There are key aspects of this new imaging mode that impact the patient, including dose exposure. The Senographe Pristina™ technology has been designed to deliver 3D mammography images at the same dose level as a standard 2D mammography examination. Studies in Europe show that 3D mammography detects 90%⁵ more cancers than 2D mammography alone, with a similar recall rate. This higher detection rate may have a beneficial impact on cancer diagnosis.

Another diagnostic tool, Contrast Enhanced Spectral Mammography (CESM), uses a dual energy technique enabling visualization of contrast uptake within the breast tissue; enabling imaging of the angiogenesis phenomena that can be associated with development of a tumor in the breast. It can be used as an adjunct to an inconclusive diagnostic after Mammography or Ultrasound and may help to determine if a finding seen on the inconclusive diagnostic corresponds to an area of the breast with contrast uptake; potentially highlighting a lesion.



Senographe Pristina

The multimodality approach offers opportunities; for example risk adaptive screening approach could be a potential future solution and is currently under investigation in several clinical trials (MyPEBS, BRAID trial), but more needs to be done. To facilitate the generation of evidence to support adoption of multimodality imaging a standardized repository to capture screening programs, clinical outcomes and key success factors could be created to foster bestpractices across the member states.

Investment is also required in research to develop AI capabilities to improve early detection of breast cancer and improve radiologist's workflow.

Early cancer detection is very important to get a better clinical prognosis for the women and to lower the mortality rate. In addition, cancer detection and more efficient diagnosis is likely to reduce downstream treatment costs. For example, in Belgium, the average cost of treating a patient with stage I breast cancer is almost half of the cost of treating a patient with stage IV disease: €19,827 versus €35,201 (Gentile 2018).



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Primary Author:

Prof. Dr. med. Mathias Goyen

Currently the Chief Medical Officer Europe for GE Healthcare, Mathias is responsible for leading medical, clinical and evidence generation strategies for product modalities in Europe. Together with his team he provides leadership in healthcare economics and outcomes research and comparative effectiveness research to develop customer value propositions for new and existing products

Mathias began his career as a diagnostic Radiologist working at Essen and Hamburg/Germany. He was appointed Professor of Diagnostic Radiology at the University of Hamburg/Germany in 2010. Mathias' previous experience also includes 5 years as Managing Director of UKE Consult and Management GmbH, a subsidiary of the University Medical Center Hamburg where he was responsible for the overall consulting and foreign business of the University Medical Center Hamburg. Together with the leadership team of the hospital Mathias established a Comprehensive Cancer Center linking clinical medicine with new oncologic research strategies.

Mathias holds a medical degree from the University of Bochum, Germany. He has been secretary general of the German-Chinese Society of Medicine, Berlin, since 2005. Mathias lives in Essen/Germany with his family.

Recommendations to reshape policy making

By Pedro Moutinho-Ribeiro

Pedro Moutinho-Ribeiro

Member of the Board of Portuguese Society of Gastroenterology (SPG) Vice-President of Portuguese Group of Ultrasounds in Gastroenterology (GRUPUGE)

It was with great pleasure and enthusiasm that, on behalf of the Portuguese Society of Gastroenterology, I have participated in the Pancreatic Cancer Europe Roundtable 2019, promoted by the International Centre for Parliamentary Studies (ICPS), held in Brussels, on the past 9th of July.

The roundtable, superiorly chaired by Dr. Francesco Sclafani, was a very participated one, with all the delegates having the opportunity to give their opinions and inputs in all proposed topics for debate, namely analyzing the current policy framework of Pancreatic Cancer in the EU and member states; improving prevention, diagnosis and patient treatment; and fostering research, innovation and drugs development. At the end, recommendations were proposed contemplating these various issues.

I myself, as a clinician who deals everyday with pancreatic cancer patients, not only in the moment of the diagnosis and staging of the disease, but also in the management of late stage symptoms, alleviating pain and pruritis, have focused my strong recommendations in the premalignant phase of this dismal disease. In fact, it is with concern that we testify the increasing incidence of pancreatic cancer, that is not being accompanied by a desired increased rhythm in the knowledge of its biology, early diagnosis and effective treatment. For this reason, it is not with surprise that pancreatic cancer is expected to be the second cause of cancer related deaths by 2020.

In our opinion, it is not enough to diagnose and treat the disease in its earlier stages, as the survival rates, even in these patients, are far from being reasonable. Strong efforts should be made to detect the disease before it appears. In other words, awareness campaigns should take place, not only for the general population but also for the medical community itself, to alert for the existence of high-risk groups of individuals that should be identified and properly orientated. Belonging to this group are those with family history of pancreatic cancer or harboring a genetic hereditary syndrome predisposing for its occurrence (e.g. Peutz-Jeghers syndrome, hereditary pancreatitis, Lynch Syndrome, etc) those with pancreatic mucinous cystic lesions, those suffering from chronic pancreatitis, and, more recently recognized, patients developing new onset (<36months) diabetes after the age of 50y.

Besides the recognition of this population at increased risk for developing pancreatic cancer, it is extremely important to try to stratify these subjects in order to identify those who will really benefit from a tight surveillance strategy. This objective, in our opinion, can only be achieved if a “magic” biomarker (or a panel of biomarkers) could be validated for selecting patients or healthy individuals, harboring a condition with high risk of progression to cancer, but that could be recognized in a “safe” premalignant phase. Posteriorly, these subgroup of selected “very high”-risk patients should be screened and surveilled properly, and, when indicated, treated effectively before cancer development.

Having said so, it is our pure desire that research on this matter could be encouraged and be a primordial target for financial funding, at a national and international levels.

Other secondary, but also very relevant, topics to be considered in the recommendation aims are: prevention campaigns, namely alerting for the importance of tobacco smoking as the most important risk factor for the development of pancreatic cancer; facilitation the access of newly diagnosed or high risk patients to a network of centers of reference in this pathology; the need to have well-structured multidisciplinary teams (MDT), with high qualified and dedicated professionals; the need to contemplate in these MDT aspects related to nutrition and psychological support, since from the beginning of patient management; Constant lobbying, at various levels, for funding research from biology to cure; Stimulate data collection, data sharing and collaborative studies all over the world.

Finally, personally and in the name of the Portuguese Society of Gastroenterology, we do

want to thank and emphasize the value this kind initiatives held by of ICPS and look forward to contributing in upcoming ones.

Pancreatic cancer patients deserve our continuous hope and efforts!



BY ANDRÉ DESCHAMPS, CHAIRMAN EUROPA UOMO

Facts

A questionnaire amongst our members in 24 European states showed that:

- Less than 50% of all men are aware of the disease
 - PSA-led early detection is promoted by healthcare professionals in only 50% of the countries
 - Depending on the country, between 20 and 60% of all PCa diagnosis is done in the metastatic phase.
 - A multidisciplinary approach is partially available, not all treatments are available in all countries.
- Inequality of care is the norm.

False economies

Some countries are still discouraging PSA-led early detection and claim that they do not harm their citizens with this. The arguments are mostly: less costs, avoiding over treatment and that this policy has no influence on mortality rates. If you compare the high cost of treatment per life year for treatment in a metastatic phase (50.000€) with the cost of early treatment (5000€) it is clear that the cost saving long term is non existent. Overtreatment has been and is still a problem. But it does not need to be. The scientific methods are available to avoid it. Active surveillance disconnects diagnosis of cancer and subsequent treatment.

Statistics show that the mortality rate decrease which was seen a few years ago has stopped declining. In some countries we see (figures 2015 and 2016) a significant increase in primary detection in Stage IV (advanced and metastatic PCa). This must be reflected in the mortality rate in the years to come.

Quality of life

Even more important is the quality of life of the patient. Unfortunately, men cannot influence whether or not they develop PCa, neither whether or not it will be a slow developing low risk or highly aggressive cancer. What men (and policy makers) can influence is an early detection of the cancer. If you are diagnosed in an early stage, your quality of life is affected, but to a far lesser extent than detection in a metastatic phase. Especially when treatment is carried out in a cancer centre with experienced surgeons and radiotherapists. Detection in a metastatic phase means a life time of hormone treatment which often has the following side effects: impotence, fatigue, osteoporosis, loss of libido and in a later treatment phase chemotherapy.

A new strategy

We as patients urge our politicians and policy makers to adopt a change in strategy based on three pillars. All three must be implemented at the same time to assure the best treatment and quality of life with a reduced overall cost. These pillars are:

1. *Increase awareness*

It will be necessary to launch awareness campaigns as was done for breast and colon cancers. Men and their relatives need to be aware that PCa exists and that curative treatment is possible, especially when detected at an early stage.



2. Promote informed PSA led early detection

It is important that informed men are actively encouraged by the government and health care professionals to test their PSA level. The scientifically based advice on when to test is described in the newly published EAU guidelines

3. Assure treatment in multidisciplinary cancer centres

Considering the best outcome for men, treatment in a cancer centre with multidisciplinary approach is a must. Studies have shown that the extent and severity of the side effects of treatments are a function of the experience of the surgeon and or radiotherapist. We expect cancer centres to measure the patient-related outcomes and have them published and freely accessible for patients. Different initiatives have been taken to establish prostate cancer centres. Germany for instance, has developed its own requirements. From a patient point of view, as long as the general idea is maintained and all treatments are assured we can live with these developments.

Active surveillance

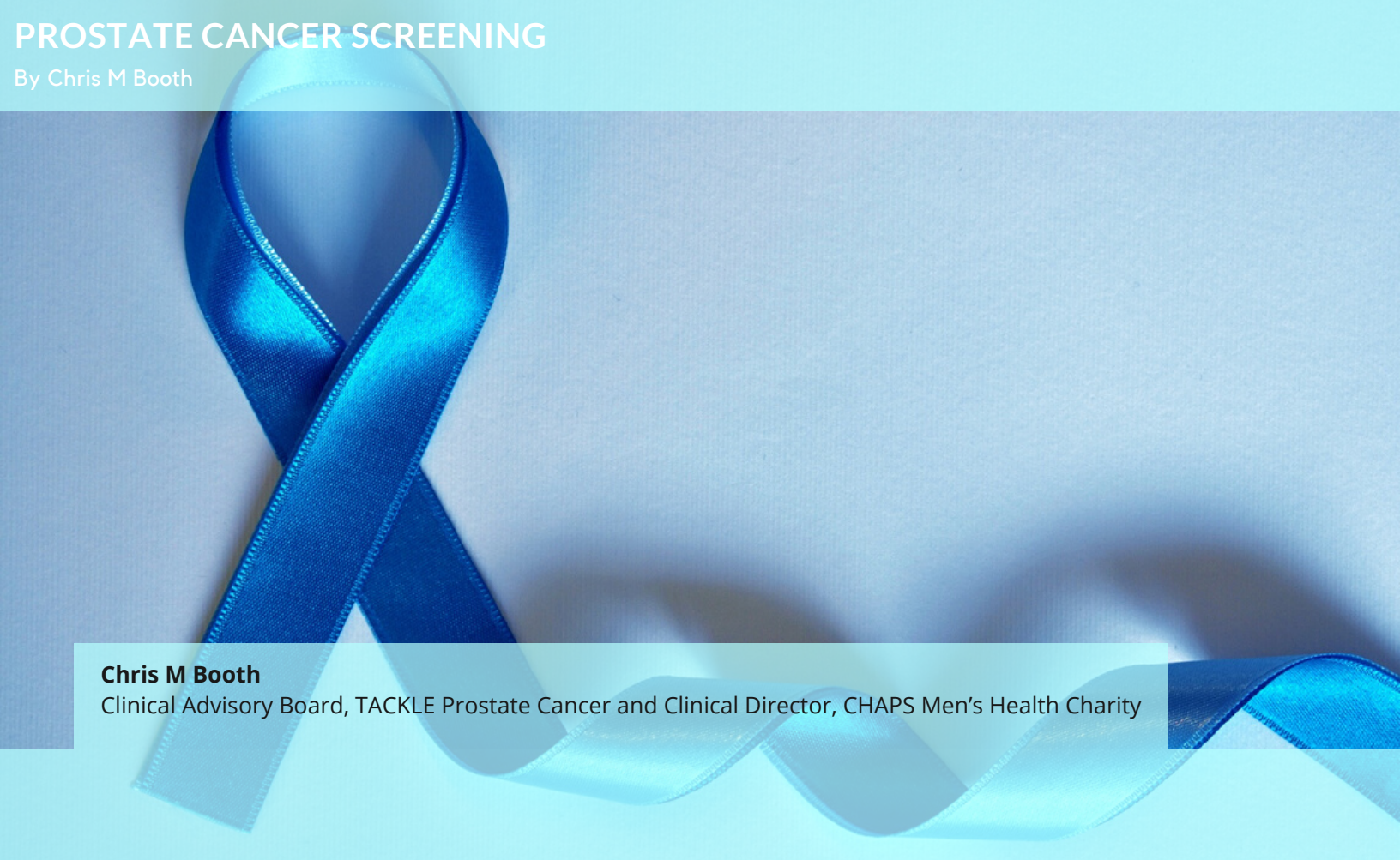
The development of active surveillance treatment for men with low-risk PCa is essential in order to avoid over-treatment and to assure an optimal quality of life for the patient during the years he can stay in that program.

Generally there is a belief that this treatment can be valid for up to 30% of the patients – those with low or intermediate risk.

Conclusion

Since the PSA test has been used, men have not had to wait for their prostate cancer to become metastatic in order to get a diagnosis. This early diagnosis was and is not always done and depends on the knowledge of men and the healthcare policy. We also know now that many men with low risk cancer might have avoided or postponed treatment with its life-changing consequences.

We now have the means and the scientific knowledge to do better. By re-focussing our efforts we can learn from the mistakes within the success of the past few decades. The emergence of a more informed and organised patient population stands ready to do its part.



PROSTATE CANCER SCREENING

By Chris M Booth

Chris M Booth

Clinical Advisory Board, TACKLE Prostate Cancer and Clinical Director, CHAPS Men's Health Charity

This is a synopsis of the latest expert information on screening and early diagnosis of PCa given to the European Parliament. To see the full EPAD programme and report, go to: <http://epad.uroweb.org/programme/epad-2019-presentations/>

Background

The UK lags well behind its European neighbours for early diagnosis and cure of Prostate Cancer (PCa). Every year 47,000 UK men are diagnosed with PCa and nearly 12,000 die from it¹. It is our commonest male cancer and second commonest male cancer killer with deaths now exceeding those for breast cancer.

As there is no way of preventing PCa, our efforts should be to detect it early when it is confined within the prostate and thus curable. The only practical way to do this is with the blood test PSA (Prostate Specific Antigen); there is no other simple, cheap marker on the horizon.

Since its widespread introduction as a PCa screening tool in the early 1990s, the death rate from PCa has fallen consistently in all countries making significant use of the test. Unfortunately this came at the cost of substantial over-diagnosis and over-treatment of non-aggressive, insignificant PCa that has possibly outweighed the benefits of early diagnosis and cure for many other men. This problem was highlighted by the United States Preventive Services Task Force who decreed in 2012 that these harms outweighed the benefits³.

As a consequence there has been a downturn in screening both in the USA and the UK, where the death rate has stopped falling and the presentation of cases of metastatic PCa has risen^{4,5}, raising the spectre of the pre-PSA era when most men presented with advanced, incurable disease. This is unacceptable.

EAU Policy Paper on PSA Screening for PCa

The longest, clinically valid trial evidence on the benefits and harms of PCa screening comes from Europe. The speakers at this event presented clear, objective evidence showing that the benefits now easily outweigh the harms. They then lucidly outlined strategies to implement life-saving, cost-effective screening programmes.

http://epad.uroweb.org/wp_content/uploads/EAU_policy-briefing_PSA.pdf

What follows is therefore not mere opinion, but hard, objective, scientific evidence from screening studies running for up to 20 years.

The Facts

- Since 2012, death rates from PCa in the USA and UK are rising.
- PSA-based screening trials have reduced PCa mortality by up to 64%.
- After 20 years' follow-up the number of patients needed to screen and to diagnose PCa have fallen to 101 and 10 respectively to prevent 1 PCa death – figures substantially lower than for diagnosing colorectal cancer and breast cancer.
- Quality of life studies show that early treatment of PCa lowers the risk of complications such as incontinence and impotence whereas treatment of metastatic disease has a disproportionately negative effect on quality of life for both the sufferer and his partner.
- Early measurement of PSA in a man's 40s can largely define his lifetime risk of dying from PCa. Low risk men with consistently low PSAs (<1ng/ml) can stop screening in their 60s as subsequent risk of death from PCa is only 0.2%.
- Early PSA measurement should be linked to family history, ethnicity and freely available risk calculators to further define lifetime risk.
- Second line biomarkers provide further information that assists identification of aggressive PCa.

MORE SUPPORT AND FUNDING SHOULD BE DIRECTED TO PCA SCREENING PROGRAMMES AND RESEARCH. THE EVIDENCE IS CLEAR. THE ONLY THING LACKING IS THE POLITICAL WILL.

- mpMRI scans should now be used before biopsy to better target significant disease and avoid the need for biopsy where significant disease is unlikely to exist.
- Active surveillance is a proven, safe, management option for “insignificant”, low-grade, low-volume PCa.
- In the UK treatment options are determined jointly by multi-disciplinary teams and informed patients to avoid over-treatment, the rate of which has fallen to 4%.
- The cost of early curative treatment is approximately €15,000¹⁸ compared with approximately €300,000 for long-term treatment of advanced PCa¹⁹.

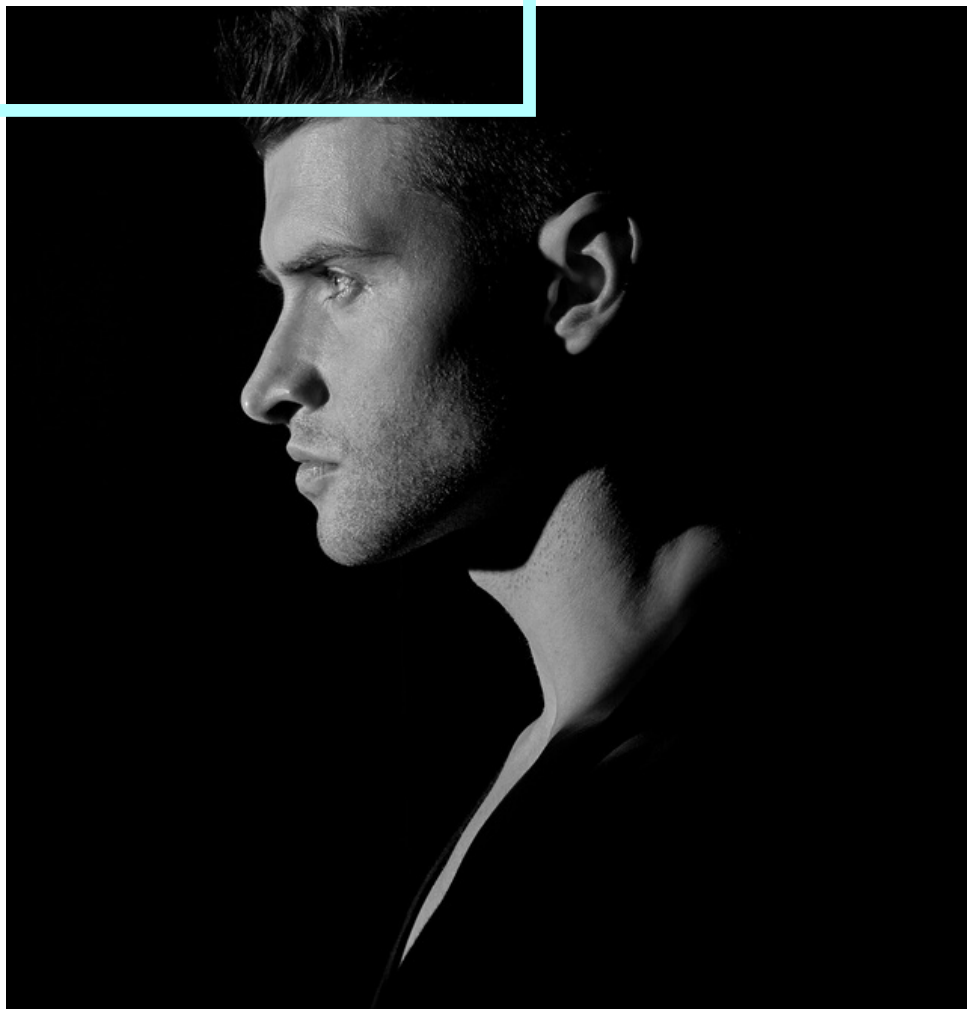
Conclusion

The UK cannot continue to overlook PCa, our commonest male cancer, now that the twin threats of over-diagnosis and over-treatment are clearly outweighed by PSA-based screening programmes coupled to recent advances in clinical practice.

The UK does not require further screening trials but should implement proven screening strategies based on multi-disciplinary international guidelines.

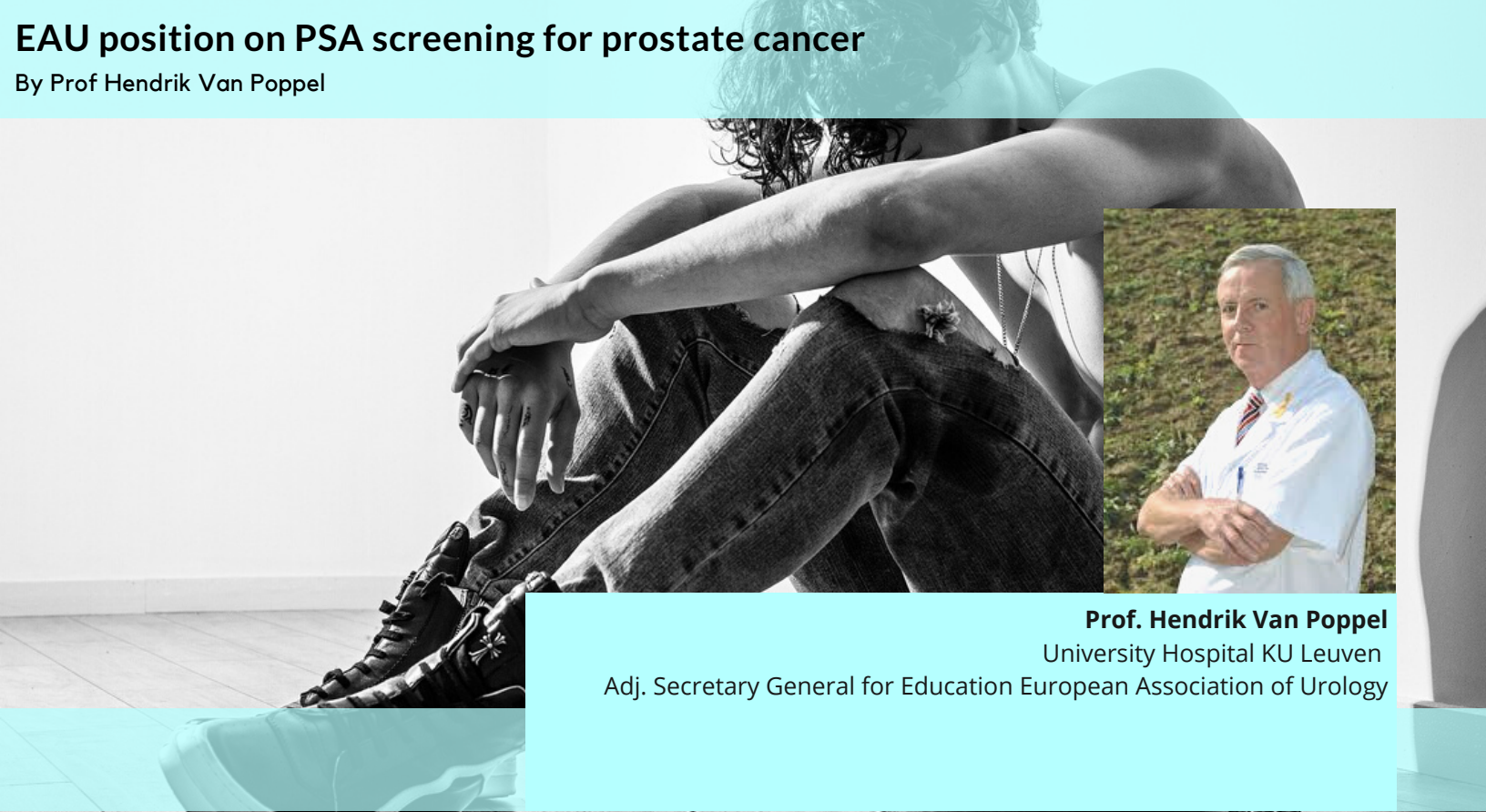
More support and funding should be directed to PCa screening programmes and research.

The evidence is clear. The only thing lacking is the political will.



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EAU position on PSA screening for prostate cancer

By Prof Hendrik Van Poppel



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The European Association of Urology (EAU) has for many years invested in the design of guidelines for healthcare providers. This includes guidelines on prostate cancer, the most common male cancer, which have been endorsed by all urological National Societies in the European Union and in total by 58 urological national associations from across the world, and have been translated in more than 30 languages. Alongside this, for the past couple of years the EAU's Patient Information Initiative has been working on producing educational information for patients, which are now translated in around 20 languages thanks to the support of the national urological societies.

Interaction with patient organisations and policy makers started with the European Prostate Cancer Awareness Day (EPAD) in 2015 in collaboration with Europa Uomo, the Prostate Cancer Patient Coalition, and ECPC, The European Cancer Patient Coalition. Two years later the EAU launched, together with the patient organisations, a white paper on "Recommendations to lower the risk and mortality rate of the most frequent cancer in men" in an event in the European Parliament on the second European Prostate Cancer Awareness Day (EPAD), hosted by MEP Alojz Peterle and MEP Marian Harkin both being Members of Parliament Against Cancer (MAC's). On this occasion awareness and screening for prostate cancer was picked-up by Dr. Vytenis Andriukaitis,

EU Health Commissioner, who went on to give his support for the inclusion of prostate cancer screening in a new EU Joint Action on Cancer.

More recently, the EAU has developed a policy paper on PSA screening for prostate cancer entitled "Has the time come to reconsider structured population-based screening for prostate cancer?", that was launched during the third EPAD hosted by Dubravka Šuica, MEP in the European Parliament on the 23 of January 2019.

Over the years the EAU has been working closely in collaboration with the International Centre for Parliamentary Studies (iCPS) and was offered to chair the latest roundtable on Prostate Cancer Europe 2019 in Brussels on the 2 of April 2019. On this occasion the EAU presented its views on the necessity to reintroduce in Europe early detection strategies to substantially decrease prostate cancer mortality, save the lives and improve the quality of life of thousands of men around Europe.

Benefits of early detection

There is no debate that PSA (Prostate Specific Antigen) can be used for early detection and its use in population-based screening has resulted in stage migration at diagnosis and a decrease in prostate cancer deaths. A recent publication after 19 years of follow-up in the Rotterdam Cohort of the European Randomized study of Screening for Prostate Cancer (ERSPC) showed a

more than 50% reduction of metastatic disease and of prostate cancer mortality. However, population-based screening risks over-diagnosis and over-treatment and therefore its implementation has been largely discouraged. Indeed, incidental prostate cancer can be found in more than 50% of men at autopsy but one cannot forget that 11% of all male cancers are prostate cancer related.

Early detection saves lives, raises quality of life of patients, and lowers costs for healthcare systems

Over the years, the decrease in cancer mortality from all kinds of cancers has been most pronounced for prostate cancer. Obviously, early detected disease can be perfectly cured and treatment of early disease has less side-effects, leads to less incontinence and impotence after radical prostatectomy and means there may be no need of hormonal treatment in case of radiotherapy. The treatment of more advanced disease has more side-effects and a negative impact on quality of life. Finally, the treatment of metastatic disease and of castration resistant prostate cancer is extremely expensive. While surgery and radiotherapy on average will each cost €5,000 and medical castration €11,000, the available new drugs for metastatic and castrate resistant prostate cancer amount to €240,000. So the cost saving from early detection and treatment is enormous.



Nevertheless, the implementation of early detection has been discouraged for several reasons.

Firstly, prostate cancer is not supposed to be a fatal disease; patients usually die from other causes, even though they may have prostate cancer.

Secondly, treatment can lead to many side-effects while a number of men would never suffer from the disease. Thirdly, in the past, prostate cancer diagnosis automatically led to active treatment because we were unable to discriminate between significant and insignificant cancers.

The consequences, however, of doing less early detection and screening are dramatic. In the United Kingdom prostate cancer is nowadays mostly diagnosed in more advanced stages where cure is more difficult to achieve and where treatment impacts severely on quality of life. In the United States more patients are primarily diagnosed in a metastatic, incurable stage and overall, the ever decreasing mortality from prostate cancer has come to a stop. In fact, in some countries like the United States, prostate cancer mortality is now rising, with today more men dying from prostate cancer than before. In some European countries, prostate cancer mortality has become the second cause of cancer death in men.

The EAU in collaboration with the Patient Organisations should not let this happen because of the important progress that has been made in recent years.

The way forward: risk adapted, population based prostate cancer screening

We are now able to avoid over-diagnosis by better use of PSA (PSA density, PSA velocity...) by the use of novel molecular biomarkers and by the use of multiparametric MRI before biopsy.

This imaging technique ignores insignificant cancers and detects a higher amount of significant tumours that can be accurately biopsied.

This leads to substantial reduction in the number of biopsies. Moreover, we have seen a dramatic decrease in overtreatment as nowadays, clinicians use active surveillance in a majority of their low and intermediate risk prostate cancer patients.

Structured, risk adapted population-based prostate cancer screening is also financially feasible. A PSA determination costs around €10, an MRI will cost between €135 up to €500 depending on the country where it is performed.

As mentioned, treatment of early detected significant cancers will be around €5,000. With the new diagnostic and treatment strategies, there will be an enormous cost saving: fewer biopsies, less complications in biopsies and less complications in early treatments.

Moreover, there is less over-diagnosis, avoiding overtreatment, less costly treatment of castrate refractory disease and significantly less prostate cancer deaths which increases the professional life spent.

Since the 2003 Council Recommendations on cancer screening, the European Commission has supported national programmes for screening for breast, cervix and colorectal cancer, but not for prostate cancer. Prostate cancer continues to remain out of the scope of European action, although the yield and the costs through PSA screening are equal or even more favourable than for the three cancers where screening is EU supported.

The numbers needed to diagnose and the numbers needed to treat to save one patient's life are comparable or better than for breast cancer. Had it not been for the issues of over-diagnosis and over-treatment, we would have saved the lives of tens of thousands of European men.

In conclusion, early detection saves lives and prostate cancer deaths can easily be dramatically reduced. Obviously the male population needs to be informed and the EAU is preparing adequate patient information for healthy men who need to decide whether or not they want to have an eventual prostate cancer detected early through PSA.

Cleverly used medical tools and technologies today avoid over-diagnosis and active surveillance avoids over-treatment, therefore we need to join efforts to ensure that early detection programmes for prostate cancer are supported in the European Union Member States.

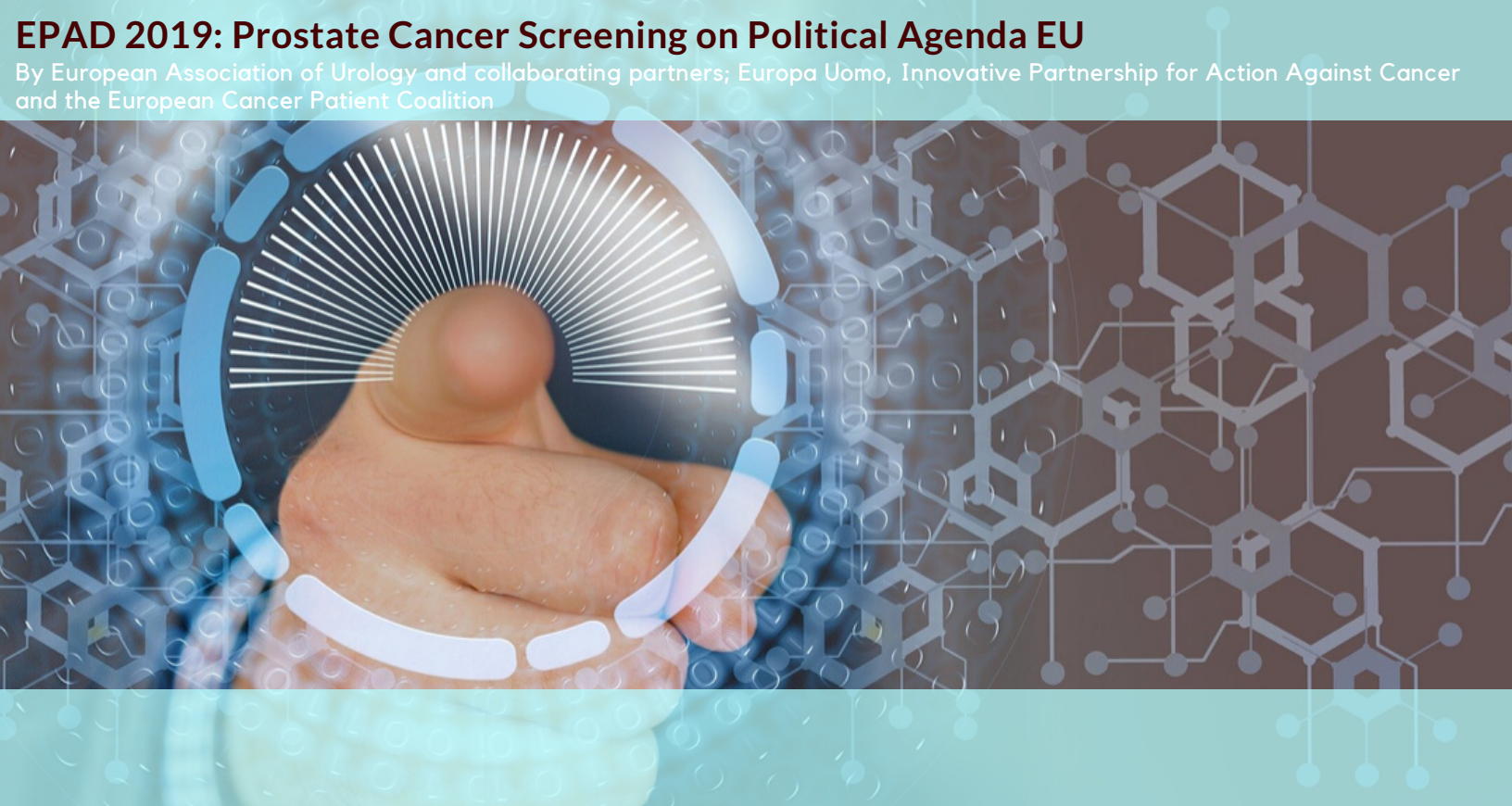
This is why the EAU and patient organisations are currently running a pledge campaign for new and returning MEPs to the European Parliament. #EUPledge4prostatecancer is building momentum on more EU action on prostate cancer, including early detection.

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EAU Policy paper on PSA Screening, EAU Policy Paper on PSA Screening



EPAD 2019: Prostate Cancer Screening on Political Agenda EU

By European Association of Urology and collaborating partners; Europa Uomo, Innovative Partnership for Action Against Cancer and the European Cancer Patient Coalition

After years of decline, prostate cancer mortality has increased last years in several countries. The late detection of advanced prostate cancer, often due to a lack of awareness, is likely a reflection of this revised trend. Although it is well-known that Prostate Specific Antigen (PSA) tests in population-based screening programmes reduce the prostate cancer mortality rate, the discussion on overdiagnosis and overtreatment continues. A good reason for the European Association of Urology (EAU) to publish a policy paper on this topic and invite European influencers to rediscuss the need for population-based prostate cancer screening programmes at a European level during the European Prostate Cancer Awareness Day (EPAD) 2019.

On 22 January 2019 policy makers, scientific experts, European associations working in the urological field and representatives of European patient groups with an interest in prostate disease gathered at the European Parliament to debate the latest evidence and case studies demonstrating the efficacy of prostate cancer screening. The Policy Paper on population-based PSA screening for prostate cancer was officially launched during the meeting and formed the starting point of the discussion. The event was hosted by the Members of European Parliament (MEP) Ms Dubravka Šuica, Member of the “MEPs against Cancer” group (MAC) and Ms Lieve Wierinck and was focussed on how early diagnosis will improve outcomes in European PCa patients.

Scientists, patient representatives, urologists and politicians covered key topics such as the latest evidence, consequences of not performing PSA screening, overdiagnosis and overtreatment in a well-attended session.

PSA History

After Prof. Chris Chapple (GB) and MEP Dubravka Šuica (KR) welcomed all attendees and stressed out the importance of the discussion, Prof. Monique Roobol (NL) introduced the 35-year history of PSA by comparing it to a scenic drive from The Netherlands to Italy. “The easy ride that started in flat Holland in the late 80s was quickly followed by gradually climbs at high speed in Germany”, Roobol begins. “Then the high (but very difficult to drive) summits and beautiful valleys of Switzerland arrived, representing PSA testing practices in the new millennium and the decline in metastatic disease and related mortality. Entering Italy’s Po valley is comparable to PSA testing rates in the US after the recommendations of the USPSTF, where mortality rates start to increase again. The question is what will we do next? Will we take a left turn and slowly disappear into the sea like Venice or return to the valleys in Switzerland?”

Risk-adapted Screening

Prof. Peter Albers (DE) explains why we should adopt structured population-based PSA screening for prostate cancer by comparing screening programmes for other types of cancer. “Registry data have shown that death from

prostate cancer has overruled death from colorectal cancer and is now the second most cause of cancer-related death in men behind lung cancer. Still, despite the significant public health burden, relatively little is performed on prostate cancer screening at EU level, particularly in comparison to breast, cervical and colorectal cancers”, says Albers. “The aim of future PSA screening programmes should be focussed on reducing overdiagnosis. Risk-adapted screening will prevent unnecessary screening in 90% of men, is cost-effective and will still identify 1-2% of men with early PCa.”

Lessons learned in Sweden

In Sweden, prostate cancer is a major public health problem, according to Prof. Per-Anders Abrahamsson. “Mortality results from a 14-year follow-up in the Goteborg study showed that prostate cancer deaths were reduced with 44% in a randomised population-based screening trial and the absolute mortality still continues”, states Abrahamsson. According to the former EAU Secretary General it’s all about finding a balance in maximising benefits and minimising harms. His five golden rules for transforming PSA screening are the first step to success.

Quality of Life

“Early detection of PCa is not only about decreasing mortality rate, but it’s also about Quality of Life”, says André Deschamps, chairman of Europa Uomo. Their study shows



that a minority of European men (48%) is aware of the risks of PCa. Looking at health care professionals, about half of the GPs promote PSA testing. Deschamps states: "Early treatment for prostate cancer lowers the risk of incontinence and impotence significantly, while treatment at metastatic phase has a negative effect on the quality of life. Hence, there is a big opportunity to improve the quality of life if early detection is achieved in combination with avoidance of overtreatment." Deschamps pleads for a new strategy based on increasing awareness at EU level, promote PSA led screening with treatment in specialised cancer centres.

Costs vs Savings

The main advocate of the policy paper and event in the European Parliament, Prof. Hein Van Poppel (BE) discussed the consequences of less screening. "In the United Kingdom, 4 out of 10 prostate cancer diagnoses are currently diagnosed at a locally advanced or metastatic stage. In the United States, after a documented long decline of death rates of prostate cancer, prostate cancer mortality is increasing for the 1st time since early 1990. Moreover, an increase in the number of patients with metastatic and advanced disease has been observed at the same time. This all has happened in parallel with PSA screening decline", says Van Poppel. "The total costs of prostate cancer care sums up to €240,000 in the lifetime of a metastatic patient", Van Poppel continues. "These costs are applicable in case of late detection. Early detection equals €5,000 per patient on average. If we wouldn't have had the overdiagnosis issues, we would have saved the lives of thousands of men."

Lack of Guidelines at EU level

Since PSA screening ultimately reduces the rate of men with metastatic PCa at diagnosis and, in turn, mortality, different organisations have reconsidered their views on screening. The European Association of Urology (EAU) released its recommendations on early detection in the year 2013. According to Prof. Nicolas Mottet, the chairman of the EAU Guidelines panel for prostate cancer, the

way to find aggressive prostate cancer at an early stage is an early diagnosis.

With the upcoming EU elections, the new college of Commissioners should be empowered by the European Parliament and Member States to support Member States with European guidelines on prostate cancer screening.

Hitting the Target

It is clear that early diagnosis is the remedy, but how to select those men that benefit from early testing to prevent overdiagnosis? Prof. Monique Roobol explains the benefits of risk stratification in combination with new developments as MRI and targeted biopsy. "Hitting the target has never been this easy", she says. "With coordinated we will be able to improve mortality reduction, avoid unnecessary testing and overdiagnosis, but also uncertainty, anxiety and costs!"

Call to Action

After all the presented evidence, the European Union can no longer continue to overlook the most common cause of cancer in men in Europe which developed to be the number two cancer killer in men. Urgent action is required to ensure the new Commission is mandated to support EU Member States in prostate cancer screening in their national cancer plans. EAU Policy Coordinator, Michelle Battye (GB), makes a statement with the following recommendations for call to action:

1. The 2003 Council Recommendations on population-based screening need to be urgently reviewed, with prostate cancer added to the list of cancers to be addressed.
2. Member States should already support a policy update on prostate cancer screening through their work on the EU Joint Action, the Innovative Partnership for Action Against Cancer (IPAAC).
3. MEPs should ensure that European action on Prostate Cancer screening is included in the group manifestos as they prepare for Europe elections.
4. The new college of Commissioners mandated in 2019 should be empowered by the European Parliament

and Member States to support member States with European guidelines on prostate cancer screening

5. Member States should bring good practice on prostate cancer screening to the Steering Group on Health Promotion, Disease Prevention and Management of non-communicable diseases 6. European Commission encouraged to channel more support and funding to Prostate Cancer screening and research

PCa Screening in Joint Action

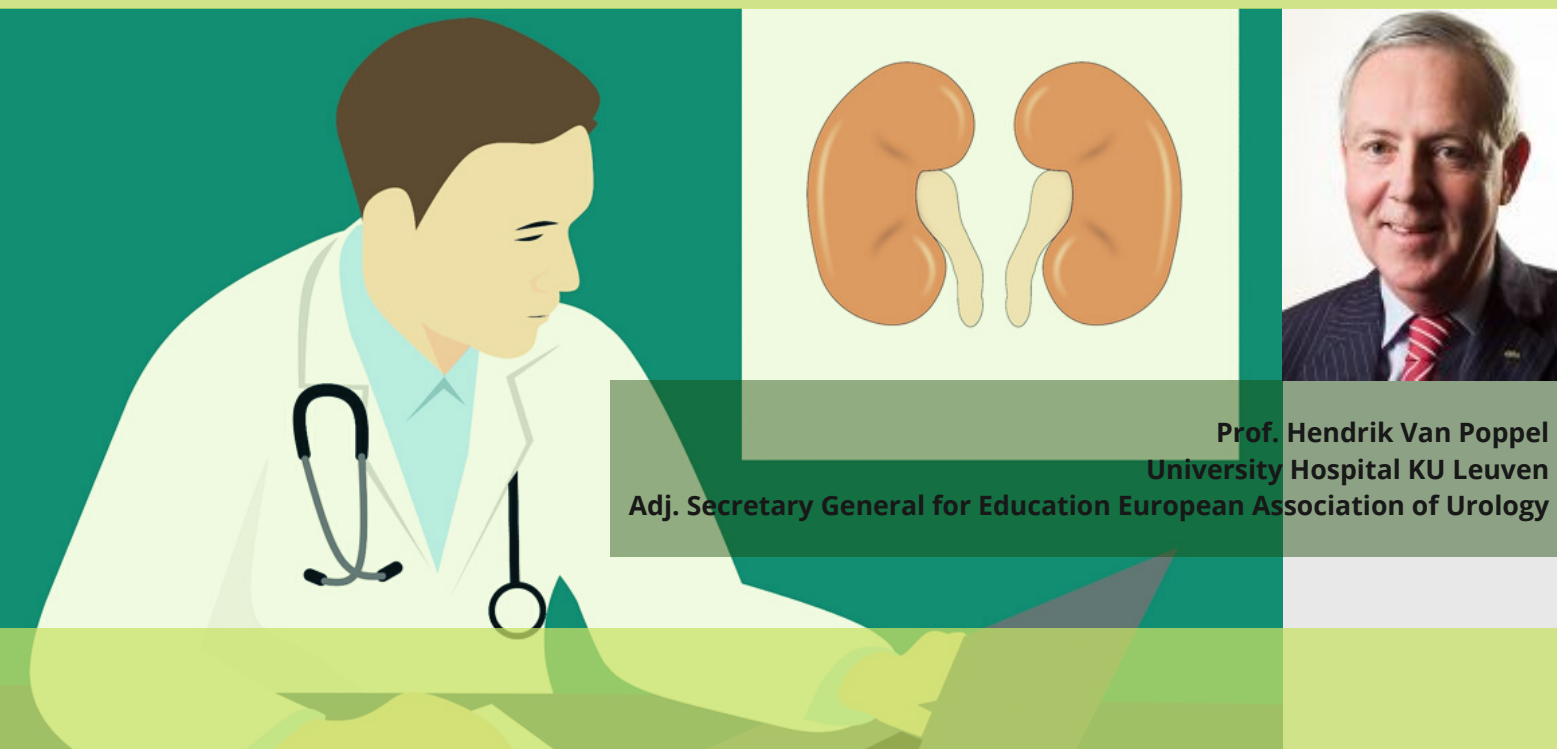
Dr Tit Albreht (SL), coordinator of Innovative Partnership for Action Against Cancer (iPAAC) Joint Action, reflects on early detection and screening from a political point of view. He raises the need to continue to work on reducing stigma about cancer to help improve, among other issues, early detection, but identifies also some challenges like the complexity of targeted screening and identification of gaps. Nevertheless, he is committed to adding prostate cancer screening on the Roadmap on Implementation and Sustainability of Cancer Control Actions. This important step is the opening to implementing recommendations on prostate cancer screening at a European level.

MEP Lieve Wierinck endorsed this commitment by Albreht: "Evidence in PSA screening for early detection of prostate cancer is clear. We now need to take action. I will encourage my fellow MEPs to put this topic on their agenda for the upcoming EU elections", Wierinck concluded.

The Policy Paper on PSA Screening for Prostate Cancer can be downloaded at epad.uroweb.org

Joint forces at EU level to Improve Kidney Cancer Care

By Hein Van Poppel



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As one of the most lethal genitourinary cancers, a greater recognition of kidney cancer as a European healthcare problem is a principal requirement. During the Kidney Cancer Europe Roundtable organised by the International Centre for Parliamentary Studies (ICPS), caregivers, researchers, industry and patient organisations gathered in Brussels to join forces to establish a better management of kidney cancer in Europe.

Kidney cancer is of particular significance in Europe as it has among the highest incidence in the world, particularly in Eastern Europe. In 2012, the Czech Republic showed the highest incidence rates (34.9/100 000 in men and 15.0/100 000 in women). The incidence rates have been slightly increasing over time in some European countries and have remained stable in others. The International Agency for Research on Cancer (IARC) projects a 22% increase worldwide by 2020. The roundtable, superiorly chaired by Dr. Francesco Sclafani, was a very participated one, with all the delegates having the opportunity to give their opinions and inputs in all proposed topics for debate, namely analyzing the current policy framework of Pancreatic Cancer in the EU and member states; improving prevention, diagnosis and patient treatment; and fostering research, innovation and drugs development. At the end, recommendations were proposed contemplating these various issues.

Significant differences in the incidence of kidney cancer in European countries underscore the importance of primary prevention, early detection and effective treatment to ensure an increased quality of life. European action is urgently required to reduce the burden of kidney cancer on patients and society and to ensure equal access to diagnostic tools and innovative treatments across different European countries and regions.

The Kidney Cancer Europe Roundtable, chaired by Professor Hein Van Poppel of the European Association of Urology (EAU), was attended by politicians, like Mr. Francis Zammit Dimech of MEPs Against Cancer, representatives of patient organisations like the European Cancer Patient Coalition (ECPC) and the International Kidney Cancer Coalition (IKCC), academia and clinicians. During the event the Scientific and Policy Briefing paper on Kidney Cancer was also launched. This initiative by the EAU aims to stimulate a closer collaboration and knowledge sharing by EU Member States and across the healthcare sector. It addresses key challenges in improving patients' outcomes.

Awareness & Prevention

It has been estimated that up to half of the overall burden of all cancers can be prevented. Despite the increasing incidence of kidney cancer, the causes are poorly understood. The three most established modifiable risk factors of developing kidney cancer are cigarette smoking, obesity and high blood pressure.

There is an important role for the EU to raise greater awareness for kidney cancer, highlighting the risk factors, but also sharing knowledge about the first symptoms. In the early stage of the disease, there are no clear symptoms to indicate the presence of kidney cancer. If the cancer does show symptoms like blood in urine, lower back pain, weight loss or fatigue, it's usually a sign that it is already at an advanced stage.

A meaningful dialogue between the doctor and patient can be established by educating patients and their families with reliable patient information based on the latest scientific evidence, expert recommendations, and the needs of patients. The EAU Patient Information Initiative aims to provide every urological patient in Europe with access to the highest-quality patient information. Well-informed patients are better equipped to talk about issues that worry them, to share the information about the way they experience their condition and treatment, leading to better care.

International Differences in Mortality

Increased use of imaging techniques in Western countries has increased the detection of early stage disease, and has also already proven to reduce mortality rates in these countries. Equal access to diagnostic tools like MRI across different European regions will allow timely and accurate treatment which will lead to increasing number of kidney cancer survivors.



Deprived healthcare infrastructure and resources, lack of skilled healthcare professionals and complex regulatory and reimbursement pathways are barriers that should be tackled at EU level to achieve a patient-centred multidisciplinary approach for kidney cancer patients in Europe.

Innovative healthcare technologies and the setting of standards at an international level like the EAU Clinical Guidelines are essential to continuously improve the lives of Europeans affected by kidney cancer. Despite the financial pressures on the healthcare systems, the EU should continue to fund research in innovations in uro-oncology.

Future Research for Personalised Treatment

The European Commission has funded about 1,000 cancer-related projects with 1.5 billion euros from 2007 to 2013. Only 21 projects were dedicated to kidney cancer since 2002, which indicates a disproportional underrepresentation of allocated funds to renal cancers.

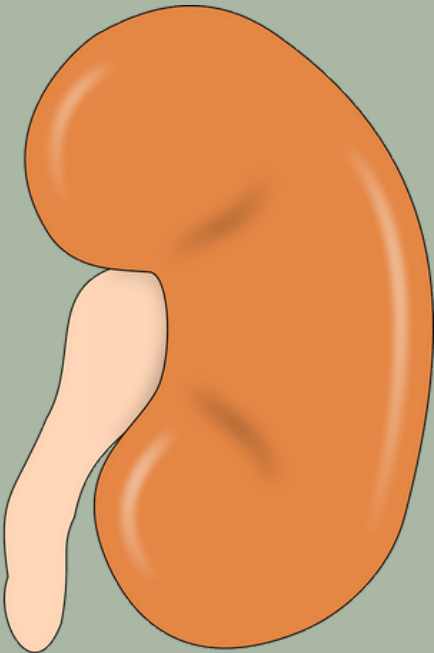
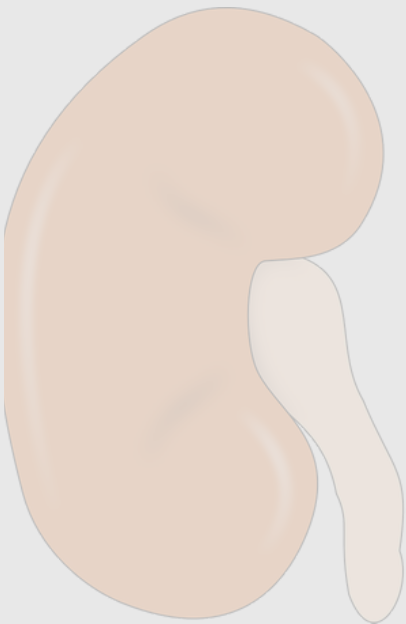
New research on the risk factors, diagnostics and personalised treatment is beneficial to decrease the high degree of inequalities in kidney cancer care and survival all over Europe. With new developments like the effect of gene mutations linked to kidney cancer, effective biomarkers that predicts the treatment response and immune checkpoint inhibitors, the future of kidney cancer care looks promising.

Collaboration to move forward

A close collaboration of multiple specialists is required to ensure the best outcome at lower costs. Unfortunately, in low-income countries this patient-centred multidisciplinary care is often not available.

The scientific and policy paper on kidney cancer was well received by all those who attended and it led to several commitments. It was agreed to work together on a World Kidney Day, led by IKCC. The accompanying campaign should focus on lifestyle recommendations to prevent kidney and other cancers and must be actively advertised to the patient organisations as much as possible.

The EAU will continue to address the most demanding issues on urological care through its publications, scientific and educational activities until all patients with kidney cancer have timely access to innovative treatments that are also affordable.



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