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General Introduction to Policy Papers in the CanCon Project

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This deliverable presents the results of the CanCon Work Package 5 (WP5) Member States (MS) Platform. The Platform was planned in order to involve MS representatives in defining policy proposals according to their own role as key actors in governing cancer control interventions in each country. Nonetheless, the aim was to support policy development based on scientific evidence, taking into account the expertise of board experts and associations' representatives. In this introduction we describe the process carried out and the methods adopted in producing the policy papers for the CanCon Project. More details are reported in a specific paragraph in each document.

1 Objectives

The overall objective of CanCon WP5 was to invite Member States to share their experiences and the different challenges they are facing with respect to cancer control, thus serving as a valuable lesson for others. In addition, sharing knowledge and information can help to solve some of the difficulties that MS are facing in the ever more complex area of cancer prevention and control. This work must be carried out from the perspective of policy makers.

According to the methodological document "Guidance for the preparation of the Position Paper (PP)" the purpose of a PP is to generate support for a topic and its relative issues.

2 What is a position paper?

A position paper (for the final wording of the documents, see below) is an essay that presents an opinion or appraisal of a particular issue. As a deliverable of the CanCon platform, it:

- Summarizes the main points of given topics that make explicit the aspects that MS agree are important;
- Identifies relevant issues in defining policy at the MS level;
- Suggests recommendations or advocates for selected policies.

The PP aims to present the basic, relevant information known about the topic and is intended to conclude with recommendations. The production of the PP that are part of CanCon WP5 was carried out according to the following phases: selection of topics, construction of the core writing group (CWG), search for evidence, selection of relevant issues, discussion about the issues and their treatment in scientific literature, and definition of policy recommendations.

3 Selection of topics

The selection of topics to be addressed was a multi-step process based on several different methods, namely: scoring (ex-ante appraisal) carried out via a survey among MS representatives that included a prioritization of the topics to be dealt with; individual MS willingness to carry out action on a topic; and general suggestions (WP5 meeting discussion).

The survey questionnaire asked MS representatives to score the topics (from a preliminary list defined in the last steering group meeting of the previous Joint Action EPAAC) using the following criteria: relevance (interest for a MS's national cancer policy); estimated added value of EU level cooperation and/or coordination; availability of scientific and/or technological background; and feasibility.

Analysis of survey responses was carried out, grouping the four criteria into two main areas: i) *strategic value* (relevance and estimated added value of EU level coordination) and ii) *scientific feasibility* (availability of scientific technological background and *feasibility*).

Four topics were then selected and included in the agreement with the CHAFEA:

A public health genomics approach to omics in oncology

- An impact evaluation system to assess prevention outcomes
- A system for assessing and promoting the disinvestment process for re-allocation
- Common European objectives for National Cancer Control Plans Group leader

For each of the selected topics, a Core Writing Group (CWG) was formed. The term 'CWG' is used because the topic is carried out on behalf of the platform. The group included: the MS representatives interested in actively participating in the specific paper in question; leading scientific experts in the specific field of science; experts- whether from the MS lead country or not-; and possible stakeholders. A call for experts was carried out.

4 Search for evidence

The aim of this phase was to gather all of the relevant evidence about the specific topic in order to provide a sound scientific and policy base for next steps. WP5 was committed to using the same methodology among the PP, but allowance was made for some differences, because different topics can have specific characteristics to be considered, and likewise MS representatives have different cultures and areas of expertise. Therefore, at the outset each writing group was asked to apply- within the agreed upon common framework- the proper method(s), while taking into account the nature of the topic to be dealt with.

In searching the available evidence, the CWG used recent systematic reviews or country reports (if available) and qualitative data, mainly about the policies already put in place by countries (e.g. national and/or regional legislation, and national and/or regional rules).

A definition was developed for the topic and its main issues, and it was revised according to the results of the systematic scientific reviews and/or expert opinions.

It was asked that implications for National Health Systems (NHS) be as practical and unambiguous as possible. They should not go beyond the evidence that was reviewed and be justifiable by the data presented in the review.

5 Selection of relevant issues

Relevant issues were selected from among each topic. It was important that the main issues be clearly defined and selected in order to receive a fruitful and well-oriented discussion by the Platform.

Because the determination of issue relevance can be a matter of opinion, CWG members were asked to highlight well the criteria for the proposed choice. Among these criteria, feasibility and potential for implementation were recommended as cardinal points.

Any suitable structured method for gaining expert agreement was considered useful, however the WP5 team suggested the Nominal Group Technique.[1]

Based on the requirements for the structure and the aim of a specific position paper, it was decided that comprehensiveness was not a mandatory result.

6 Discussion

Within the framework of systematic interaction with MS representatives, the EU Commission, and experts, three intermediate outputs were planned to be delivered and submitted for discussion on the web and in specific workshops: Draft 1, containing the summary of evidence; Draft 2, with the selection of proposed main issues; and Draft 3, which identified the provisional policy recommendations.

7 Definition of policy recommendations

Policy recommendations make up the core of any position paper, therefore we engaged the Platform in the provisional definition of suggestions as early as possible. Two final comprehensive meetings were carried out in order to harmonize the papers and finalize them with a formal agreement on the recommendations.

Given our awareness of the challenges that producing a position paper could imply, we planned to have some flexibility. Such flexibility has been applied in the following cases:

- Renaming the deliverables: whilst explicitly thought of as a non-mandatory tool for MS, the term *position paper* does not resonate for all countries; therefore we chose the more general term **Policy Paper.**
- Selecting and defining the topics: from the start of the process, we had envisaged the possibility that we would need to deal with the topic of inequalities. Therefore, after we verified the possibility to address the topic, a fifth PP was planned, titled "Equity Mainstreaming in Cancer Control in Europe". Based on discussion- and the suggestions of the Expert Group of the European Commission in particular (see below)- the PP concerning disinvestment for reallocation was renamed and consequently re-shaped, titled "Enhancing the Value of Cancer Care Through a More Appropriate Use of Healthcare Interventions".
- Discussion: the EU expert group was constituted, and it intervened during the implementation of the Joint Action. Involvement of the Expert Group has been carried out at least twice. Also, interactions with a broader audience were held to review advanced drafts during the *European Public Health Conference* in 2016.

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[1] http://www.cdc.gov/healthyyouth/evaluation/pdf/brief7.pdf

Policy Paper on Public Health Genomics in Cancer

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1 Introduction

Genomics and molecular biology have developed rapidly over the last decade, and the pace of advances is set to accelerate in the future. However, claims and counterclaims about the role that genomics might play in improving population health abound. On the one hand, genomics is viewed as the harbinger of a brave new world in which healthcare is transformed by virtue of earlier diagnosis, more effective prevention programs and more precise targeting of therapies to more narrowly specified diseases. On the other hand, genomic medicine has also been said to promote a vision of healthcare that encourages individualism rather than collectivism, and that it may further fragment the risk pooling that underpins social solidarity, and increase the scope for stigmatization and discrimination. Amid these competing visions of the advances that genomic science might entail, there is a critical need for an appropriate policy response.

Healthcare around the world is at a crossroads, with financial pressures undermining the sustainability of health systems. As highlighted by a number of policy documents, such as those produced by the European Steering Group on Sustainable Healthcare and the World Economic Forum, sustainable healthcare requires a shift from treatment of established disease to early diagnosis and disease prevention. It also relies on the need to engage citizens in taking greater responsibility for their own health in order to establish a more participatory healthcare model. The three elements that are a consistent feature of reports seeking to address these issues are: placing the individual citizen at the centre of health systems; an increase in emphasis on early detection and risk reduction, i.e. prevention; and the reorganisation of service in which care is moved from the hospital to the community.

Although it is widely acknowledged that the application of genomics in healthcare has the potential to reduce the burden of disease and improve population health, none of the abovementioned reports explicitly discuss the role of genomics or the life sciences in contributing to solutions to these problems. In fact, the contribution of genomics to health in two main areas is clear: 1) in *personalised medicine*, where *omics* technologies may be used to diagnose disease, indicate the best treatments and monitor continuing disease activity or response, and 2) in *personalised prevention*, where new technologies help in the assessment of risk for disease and preventive medications that could reduce this risk, such as– in some cases– the use of aspirin in colorectal cancer.

It is time for policymakers, health authorities and other public organisations to promote and support resources that enable citizens- individually and cooperatively- to access, understand, interpret and make use of reliable information that supports application of genomics in healthcare. Policy should also help to define metrics to measure stakeholder participation, particularly among citizens and their communities, and to facilitate public dialogue on the value of personalised medicine and the necessary conditions for its success.

2 Aim

Cancer control is a major public health issue. Cancer is strongly driven by genetic modifications in the genome DNA. A new era in science has emerged in the last decade with the field of study of genomics, wherein the aim is to try to better understand health through integrating broad information on the genome of environmental factors such as nutrition, physical fitness and disease. When studied at the population level, this area is generally referred to as *public health genomics* (PHG).

This policy paper provides guidance on three important issues where PHG can substantially advance our understanding of cancer control as well as support policy makers, citizens and cancer patients in particular, in their common fight against cancer. These issues are: first, the importance of strictly regulating stratified screening by genetic testing of high-risk cancer patients; second, key issues to be addressed within the health system when implementing genomics in medical care; and third, how to address direct-to-consumer genetic testing (DTC-GT) within the health system.

3 General recommendations

Establish a framework on the ethical, legal and social requirements related to introducing the use of omics data into the health system.

Increase genetic and preventive literacy of healthcare professionals and citizens to promote responsible use of these novel options.

4 Theme 1: Personalised risk-assessment for stratified prevention (PeRaSP): Standards in genetic testing as a prerequisite for stratified screening and prevention of high-risk patients

Cancer screening (CS) aims to identify cancer at a pre-symptomatic stage in order to improve patient outcomes, i.e. to reduce mortality and morbidity and to improve quality of life. CS programmes implemented so far have been designed to test a target population which is mainly made up of people from the general population with an average risk to develop the disease in a specific age group. Therefore, the screening test being used is appropriate for the majority of individuals in this population.

Genetic screening (GS) is defined as genetic testing for medical purposes that is systematically offered to the entire population or specific segments of the population as a part of **personalised risk-assessment for stratified prevention (PeRaSP)**. Epidemiological studies suggest that about one third of the most frequent solid tumours, i.e. colon, breast and prostate cancer, are associated with inherited risk factors, although only a minor proportion of these factors have been identified so far.

For individuals known to be at higher risk for certain tumour diseases, general CS programmes might not be appropriate or might start too late in life. Therefore, these individuals could potentially benefit from PeRaSP. Using PeRaSP would thus reduce the incidence, morbidity and mortality associated with the disease, however this would require that individuals at risk be identified by GS. As an example, the identification of BRCA or HNPCC gene mutation carriers has already led to the offer of specific prevention programmes, including risk-adjusted screening for early detection and prophylactic surgery or preventive medicines, such as anti-estrogens for breast cancer and aspirin for colon cancer, for risk reduction (29).

Beyond the generally recognised principles for the implementation of CS programmes, additional requirements need to be fulfilled in order to justify PeRaSP. Specifically, any PeRaSP programme based on GS must include appropriate counselling both before and after genetic testing. Counselling should be target-group specific and non-directive, offering people appropriate information to empower them to take informed decisions. In particular, the *right not to know* must be respected, and discrimination and disadvantage must be prohibited. Also, counselling should provide information regarding the phenotype, i.e. the typical clinical presentation linked to the genotype with respect to the natural disease course, subtype and treatment response.

Introducing PeRaSP programs requires careful streamlining with currently implemented population-based screening programs, when common cancer sites are targeted. Also, the cost of introducing PeRaSP programs will need to be evaluated in more detail.

5 Recommendations: Personalised risk-assessment for stratified prevention

Recommendation 1: Develop harmonised common entrance criteria for PeRaSP throughout Europe.

Recommendation 2: Establish and promote specific, multi-disciplinary professional structures for the indication, evaluation and provision of PeRaSP.

Recommendation 3: Increase genetic and preventive literacy of healthcare professionals (i.e. promote literacy on risk assessment, risk communication, clinical interpretation of genetic test results, and indication of preventive measures).

Recommendation 4: Increase genetic and preventive literacy of citizens to promote responsible use of preventive options for cancer and health system resources.

Recommendation 5: Establish new genotype/phenotype databases to enable prospective cohort studies and ensure that Quality Assurance is a prerequisite for the evaluation of effectiveness of PeRaSP (preferably linked to existing cancer registries).

Recommendation 6: Establish a harmonised framework on the ethical, legal and social requirements of PeRaSP in cancer.

6 Theme 2: Requirements and prerequisites for implementation of *omics* in routine molecular diagnosis in oncology

The implementation of genomics and other *omics* technology in somatic mutation profiling for targeted therapies or for linking prognosis to genetic markers such as BRCA 1&2 has become a reality in clinical diagnostics in oncology. Currently, targeted next-generation sequencing (NGS) gene panels are being used in routine diagnosis, and soon whole genome sequencing will become a standard asset. The novel approach represented by the extension of precision and personalised medicine- presumably linked to access to a wide range of (currently) non-reimbursed medicines- poses a great challenge for the sustainability of oncological care. Complex or rare cancers also require the co-evolution of research and care, which supposes the need for the establishment of a new operational framework in healthcare.

Multi-disciplinarity is a key element in the success of such a framework. It implies coordination in the concerted activities of many medical professionals (including oncologists, pathologists, surgeons, radiotherapists, clinical geneticists, and others) public health professionals, IT specialists, biostatisticians, bioinformaticians, molecular/biomedical scientists, epidemiologists, and (population) geneticists.

This level of organisation does not currently exist in most European countries, although a few disparate activities at various levels are ongoing or in the process to being initiated. Considering the major impact the introduction of genomics may have on healthcare services and public health, it is essential that each country develop a system and infrastructure that ensures harmonisation in terms of quality, performance, interpretation and documentation of NGS, to facilitate and support the development and implementation of genomics in daily practice. All disciplines directly involved in the process as well as professionals, scientists, officials and patient/citizen representatives, should be included.

Two key elements of this novel paradigm in healthcare capacity building are: 1) the massive production, collection, storage and integration of different types of data, requiring broad computational capacities for analysis, i.e. big data, and 2) the integration of multi-disciplinary teams as part of a common vision for the 21st century organisation of public health and healthcare services aimed at long-term follow-up of cancer patients (by medical and health professionals, government, industry, and the general public).

In addition, it is clear that introducing this novel paradigm necessitates general acceptance by the European population. Therefore, it is important to maintain a culture of continuous open communication and debate. Raising awareness should take place broadly across society about the possibilities and limits of the approach: in education, from the high school level to highly specialised professional education programs in academic institutions and universities; in the healthcare, social and professional sectors; in the financial world (banking and insurance); in industry at large; and at the government level. Training and education at all levels of society will be the cornerstone in empowering people in their access to and choices regarding the potential benefits provided by these new opportunities.

7 Recommendations: *Omics* in the clinic

Recommendation 1: For each country, establish a system and infrastructure that oversees the rapid evolution of omics and the utility of molecular variants within oncological clinical use.

Recommendation 2: Develop an integrated outcome evaluation framework that links different healthcare information among registries and repositories. This framework should use standardised data formats and data transmission protocols to support development of clinical trials tailored to the personalised genome context.

Recommendation 3: Launch public debate on the limits and use of genomic information for improvement in public health and healthcare. Debate should include citizens, cancer patients, professionals, scientists, industry and government representatives.

8 Theme 3: Direct-to-consumer genetic testing

Since 2007, many companies have been promoting and selling genetic tests directly to consumers through the Internet (1), which have been referred to as direct-to-consumer genetic tests (DTC-GT).

DTC-GT are defined as genetic tests that are both marketed and sold directly to the public- including over the counter- without the supervision of a healthcare professional (18).

The use of DTC-GT has rapidly increased since their first commercialization in 2007 (2), and awareness of citizens on this issue has grown accordingly (3,4). Currently, many commercial tests are being offered in the form of multiplex genetic profiles (5-7).

Currently, three types of DTC-GT are available: 1) tests for one or a few specific conditions, 2) multiple single-nucleotide polymorphism risk assessment tests, and 3) whole human genome sequencing (8).

There is very little regulatory control over DTC-GT in most European countries and the United States (9). Since February 2015, the US FDA has allowed companies to market only limited DTC-GT (10), while in EU the situation varies widely. Regulatory and control mechanisms for DTC-GT in the EU vary among different member states. For instance, although Greece does not have explicit legal provisions for DTC genomics, several other laws, including soft law mechanisms, create the broader legal framework within which DTC genomic services may exist (11). In Belgium, Italy and the UK there is no specific legislation that forbids or regulates the provision of DTC genetic tests, while in France, Germany, Portugal, and Switzerland there is specific legislation that dictates that genetic tests can only be carried out by a medical doctor after the provision of sufficient information and appropriate genetic counselling (12, 13).

There has been debate about whether strict regulations regarding personal genetic services are likely to be enforced in European countries in the near future (14). The Human Genetics Commission (HGC) of the UK made recommendations in 2007, setting up a public consultation regarding DTC-GT in response to controversy over the matter, but the commission has not yet come up with specific regulations (14).

Although there is limited scientific evidence on the potential benefits of DTC-GT (15-17), these genetic tests also have the potential to be harmful as they lack professional counselling services that should accompany them (18). Moreover, the incidental finding of variants of unknown significance (VUS) may raise unnecessary concerns or even inappropriate interventions on the part of consumers. Other relevant issues have been reported, such as privacy protection of data storage, discrimination by employers and health insurers, and lack of delivery of genetic services in terms of diagnostic and/or preventive counselling due to the absence and/or ignorance of the healthcare workforce (19).

In some cases of DTC-GT, there is a lack of transparency about quality control, clinical validity (i.e. the strength of association that determines the test's ability to accurately and reliably identify or predict the disorder of interest) and clinical utility (i.e. the balance between benefit and harm when the test is used to influence patient management) (20).

Furthermore, social inequity and unnecessary follow-up, anxiety, and negative psychosocial consequences have been associated with the use of DTC-GT (21-24). In 2013 the European Parliament published the results of a survey on DTC-GT, reporting that a majority of service providers fail to offer sufficient information to consumers about the nature of DTC-GT, the interpretation of results, and the implications arising from the test itself (25).

In order to support decision making for policy at the European Union level, a systematic review of position statements, policies, guidelines, and recommendations produced by professional organizations or other relevant bodies related to the use of DTC-GT was published (12). In all of the 17 included documents, the potential disadvantages of DTC-GT overweighed the potential benefits.

Concerning the field of cancer, DTC-GT often include only genetic variants with low or no clinical validity and no clinical utility. Consequently, people who are worried about cancer and undergo DTC-GT do not change their risk behaviour, but in fact may adopt unhealthy attitudes (26). Other literature also reports paradoxical behaviour with respect to cancer and dietary interventions (27).

As mentioned earlier, some DTC-GT provide information on known hereditary cancer genes (e.g. BRCA 1&2) (28), stressing the need for counselling. Indeed, people who undergo such DTC-GT might discover inheritance of a highly penetrant genetic variant and therefore have to deal with an incidental finding (29-32).

9 Recommendations: Direct-to-consumer genetic testing

Recommendation 1: In its current form, DTC-GT for cancer risk prediction is unlikely to have any positive impact on the health of citizens. Citizens' and healthcare professionals' awareness and education about DTC-GT is urgently needed.

Recommendation 2: Policy makers should regulate the offering of DTC-GT, with the understanding that legislation should balance consumer protection with freedom of opinion.

Recommendation 3: Each European citizen should have access to organised certified genetic counselling in his own country, provided by the national health system, taking into account the local context of organisation of services.

10 Authorship

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Policy Paper on National Cancer Control Programmes (NCCPs)/ Cancer Documents in Europe

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1 Recommendations at a glance

Throughout this policy paper, the acronym NCCP will be used to refer to National Cancer Control Programmes and / or other cancer documents.

Recommendation 1: Develop an NCCP if your country does not have one.

Recommendation 2: Use the European Guide for Quality National Cancer Control Programmes for the preparation of new NCCPs and for updating existing documents in order to improve quality.

Recommendation 3: Where NCCPs have been prepared but not yet implemented, NCCPs should be implemented as soon as possible.

Recommendation 4: Establish effective communication with the public regarding the implementation and/or evaluation of NCCPs.

Recommendation 5: Establish an institution that will have responsibility for cancer control at the national/regional level, if such an institution does not already exist.

Recommendation 6: Increase the involvement of patients and payers and reimbursement agencies in all stages of the preparation of NCCPs (strategic consulting, drafting, implementation, and evaluation) whenever possible.

Recommendation 7: Learn from strengths, weaknesses and obstacles related to the process of drafting and implementation of NCCPs in other countries.

Recommendation 8: Ensure that your country's NCCP covers all of the key areas that should be included in a quality NCCP, as described in the European Guide for Quality National Cancer Control Programmes.

Recommendation 9: Ensure additional financial resources for the implementation of the NCCP.

Recommendation 10: Ensure availability of detailed instructions for the implementation of the NCCP.

Recommendation 11: Allocate specifically trained human resources for the implementation process, and outline how they will be involved within the NCCP.

Recommendation 12: Ensure a specific objective for every action taken in the NCCP.

Recommendation 13: Make specific alliances with relevant stakeholders, in order to ensure the implementation of the NCCP.

Recommendation 14: Make sure that indicators for evaluation are clearly defined in your NCCP.

Recommendation 15: Make sure to include process and structure evaluation in your evaluation strategy; do not rely on outcome evaluation alone.

EXECUTIVE SUMMARY

The present policy paper is a deliverable of the CanCon Joint Action Member State Platform Work Package 5. In this framework, an Expert Group on National Cancer Control Programmes (referred to in the text as "Expert Group") was established with the task to carry out and analyse a survey regarding NCCPs in Europe in 2016 and to prepare a report and policy paper. The survey report identified the main shortcomings regarding NCCPs in Europe. Standards from the previously published *European Guide for Quality National Cancer Control Programmes* were used to identify these shortcomings (1). This policy paper and its recommendations are meant to serve as an aid for policymakers who wish to improve their cancer control policies.

2 Concepts used in this policy paper

The World Health Organization (WHO) defined a National Cancer Control Programme (NCCP) as "a public health programme designed to reduce cancer incidence and mortality and improve quality of life of cancer patients, through the systematic and equitable implementation of evidence-based strategies for prevention, early detection, diagnosis, treatment and palliation, making the best use of available resources" (2).

Due to the fact that some European countries do not have a single document that addresses cancer at the national level, but instead have several documents addressing cancer at the regional level- which are not necessarily named programmes- the Expert Group agreed to use the term *cancer document/s* in addition to the official term *National Cancer Control Programme*. However, in this policy paper, the acronym NCCP will be used to refer to both National Cancer Control Programmes and other cancer documents.

3 Introduction

National Cancer Control Programmes are key elements in cancer control, and their role in national cancer policies of European countries has grown significantly (2). In 2009 the European Commission called upon all Member States to adopt national cancer plans/strategies by 2013. Based on this recommendation, many countries have decided to take steps and begun to develop their national/regional cancer documents (3).

The first survey on the situation regarding National Cancer Control Programmes in Europe was performed in 2011 under the Joint Action European Partnership for Action Against Cancer (**EPAAC JA** 2011-2013). At that time, a separate Working Group on Cancer Programmes was established and co-chaired by the European Commission and Slovenia. All European Member States, Iceland and Norway were invited to actively participate and contribute to its work. Answers to the abovementioned survey provided input for the comprehensive overview and assessment of the situation in the EU, Iceland and Norway regarding the availability of cancer programmes/documents in 2011.

In 2013 in the framework of the Member State Platform Work Package of the Joint Action European Guide on Quality Improvement in Comprehensive Cancer Control (**CanCon JA** 2013-2017), an Expert Group on National Cancer Control Programmes was established. Members of the group from different countries prepared a survey that was used to conduct an overview the current situation (2016) regarding cancer documents in EU countries, Iceland, Norway, Turkey and Montenegro. On the basis of the answers to the survey, a report was prepared. The report serves as the baseline document for this policy paper. This policy paper is one of the main deliverables of the CanCon Member State Platform.

Why is a policy paper at the European level needed?

Policy papers provide practical recommendations on which the European Commission and Member States can base concrete actions to improve the situation regarding NCCPs/cancer documents and consequent cancer control.

4 Aim

This policy paper aims to shed light on the vital importance of the preparation, adoption, implementation and evaluation of quality National Cancer Control Programmes/cancer documents in all European countries. Health systems can respond to population needs in the field of cancer only through adequate planning (4). The present policy paper provides recommendations that:

1 Enable policymakers to improve or develop their National Cancer Control Programmes/cancer documents,

2 Clearly show which tools to use in the improvement or development of National Cancer Control Programmes/cancer documents,

3 Make National Cancer Control Programmes/cancer documents more comparable and simplify the work of policy analysts who compare plans within European borders.

5 Recommendations with examples

Recommendation 1: "Develop an NCCP if your country does not have one."

NCCPs are designed to reduce cancer incidence and mortality and improve quality of life of cancer patients, therefore they represent key elements of cancer management and control. In 2011 under the EPAAC JA, when the first survey on the situation regarding National Cancer Control Programmes in Europe was conducted, some countries reported having no NCCP. In 2016 the situation regarding the development of NCCPs improved, however, there are still countries without an NCCP.

Example related to Recommendation 1: Development of an NCCP in Austria, Iceland and Luxembourg.
In 2011 under the EPAAC JA when the previous survey on the situation regarding National Cancer Control Programmes in Europe was conducted, Austria, Iceland and Luxembourg reported that they did not have a national cancer document. In 2016 all three countries reported that they had prepared a national cancer document: Austria prepared a strategy, Luxembourg prepared a plan, and Iceland prepared a draft document.

Recommendation 2: Use the European Guide for Quality National Cancer Control Programmes for the preparation of new NCCPs and for updating existing documents in order to improve quality.

NCCPs should be constantly improved and updated, and they should be considered to be living documents. Every country should- from time to time- evaluate the quality of their NCCP and try to improve and update the existing documents. The *European Guide for Quality National Cancer Control Programmes* is a guide that shows the elements that should ideally be present in high-quality NCCPs. The guide also shows which aspects of cancer management and control should require special attention from policymakers (1).

Example related to Recommendation 2: Use of the European Guide for Quality National Cancer Control Programmes in the preparation of the National Cancer Plan in Romania and in improvement of the quality of an already existing NCCP in Belgium.
Romania presented the new National Cancer Plan in 2016. The key tool used in the preparation of the plan was the *European Guide for Quality National Cancer Control Programmes*. Romania reported being satisfied with the use of the Guide, which was very useful for their work, as was their participation in the EPAAC and CanCon Joint Actions. Belgium reported that they will use the guide to modify and improve their plan in 2017.

Recommendation 3: Where NCCPs have been prepared but not yet implemented, NCCPs should be implemented as soon as possible.

The implementation of an NCCP is a demanding and conscientious process that requires the determination of certain institutions and bodies (for example Ministries of Health or other Ministries, Institutes of Public Health, coordinators, cancer societies and others) to carry it out.

Example related to Recommendation 3: Implementation process of a new National Cancer Plan in Luxembourg.
In Luxembourg the National Cancer Plan was adopted in July, 2014. Afterwards, the structures for its implementation were created (the National Cancer Platform and National Cancer Institute), responsibilities were determined, and an additional budget for the implementation of different measures was allocated.

Recommendation 4: Establish effective communication with the public regarding the implementation/evaluation of NCCPs.

Establishing effective communication with the public regarding the implementation/evaluation of NCCPs is of key importance. The most common ways of communicating with the public include websites, publications in different journals and scientific conferences, and other media such as print, radio or television. Several methods of communication with the public should be used to ensure communication is effective.

Example related to Recommendation 4: Establishment of effective communication with the public regarding the implementation and/or evaluation of the NCCP in France.
France reported the use of several methods of communication with the public regarding the implementation/evaluation of the NCCP. These included websites, public papers, journals, conferences, and an annual report to the President of France- which is available on the website.

Recommendation 5: Establish an institution that will have responsibility for cancer control at the national/regional level, if such an institution does not already exist.

It is advisable to establish a new institution to be responsible for cancer control at the national or regional level. It could be an institute or cancer control centre.

Example related to Recommendation 5: Establishment of the French National Cancer Institute (INCa) to be responsible for cancer control at the national level.
In France the National Cancer Institute (INCa) was established in 2005, with the task to carry out cancer control at the national level. At that time, the first French cancer control plan was adopted. In Finland, the National Comprehensive Cancer Control Centre was established in April, 2016.

Recommendation 6: Increase the involvement of patients and payers and reimbursement agencies in all stages of the preparation of NCCPs (strategic consulting, drafting, implementation, and evaluation) whenever possible.

The professional community, as well as Ministries of Health and Governments, are significantly involved in all stages of the preparation of NCCPs, including strategic consulting, drafting, implementation and evaluation in most European countries. However, the involvement of patients, patient organisations and payers or reimbursement agencies is not adequate. It is recommended that they be involved whenever possible.

Example related to Recommendation 6: Inadequate involvement of patients in the implementation of the NCCP in Belgium, the Czech Republic and Sweden.
Some countries inlcuding Belgium, the Czech Republic and Sweden identified the inadequate involvement of patients in the implementation of their NCCPs as a weakness.

Recommendation 7: Learn from strengths, weaknesses and obstacles related to the process of drafting and implementation of NCCPs in other countries.

Almost all countries cope with certain issues in the process of drafting and implementation of their NCCPs. Specific issues that countries have encountered in the process of drafting and implementation of the NCCP, as well as the strengths and weaknesses of their solutions, are described in the report, based on the analysis of data from the survey on NCCPs, carried out in 2015 (CanCon JA deliverable).

Example related to Recommendation 7: The report based on the analysis of data from the survey- carried out in 2015 (CanCon JA)- on NCCPs/cancer documents will be available online at www.cancercontrol.eu, so that policymakers can learn from the examples of other countries.

Recommendation 8: Ensure that your country's NCCP covers all of the key areas that should be included in a quality NCCP, as described in the European Guide for Quality National Cancer Control Programmes.

A high quality NCCP/cancer document should cover all of the most important areas: primary prevention, health promotion, cancer screening, early detection, diagnosis, treatment, psychosocial oncology care, survivorship, rehabilitation, palliative and end of life care, governance (management and planning of cancer services), financing, cancer resources (human resources, infrastructure, health technology, and cancer-specific expenditure), cancer data and information, research, access to innovative cancer treatments, patient orientation/patient empowerment and epidemiological trends (1).

Example related to Recommendation 8: Based on the information collected on NCCPs, a large number of countries have already recognised the importance of including all of the key elements/areas in an NCCP; one-third of surveyed European countries include all key areas. The elements are described in the *European Guide for Quality National Cancer Control Programmes* (1).

Recommendation 9: Ensure additional financial resources for the implementation of the NCCP.

Budgetary restrictions can influence decisions and priorities related to NCCPs, and thus it is not always possible to respect the key priorities of the NCCP. It is important to ensure a specific budget for the implementation of different measures planned in the NCCP.

Example related to Recommendation 9: Twelve countries (among them Belgium, Germany, Hungary, and Luxembourg) ensured additional financial resources for the implementation of different measures planned in the NCCP.

Recommendation 10: Ensure availability of detailed instructions for the implementation of the NCCP.

Implementation of an NCCP is a complex and demanding process. Detailed instructions for the implementation are of great help to experts who are responsible for implementing NCCPs.

Example related to Recommendation 10: Some European countries have ensured detailed instructions for the implementation of their NCCP.
European countries are conscious of the complexity of the implementation process of an NCCP, and some of them have ensured the availability of detailed instructions for the their implementation (for example Lithuania, Malta, Poland, Norway, and England).

Recommendation 11: Allocate specifically trained human resources for the implementation process, and outline how they will be involved within the NCCP.

It is recommended that specific human resources be allocated to the implementation process of the NCCP. Human resources that are specifically trained in the implementation of the NCCP should be planned to assure the success of the process.

Example related to Recommendation 11: Some European countries have allocated specifically trained human resources to the implementation process.
In some European countries (Belgium, Luxembourg, Sweden, and England) additional, specifically trained human resources were allocated to the implementation process. In France, for example, most of INCa human resources contributed to the implementation of the NCCP. Only a few European countries (for example the Czech Republic and France) have specified this in the NCCP.

Recommendation 12: Ensure a specific objective for every action taken in the NCCP.

It is important to closely link the actions taken in the NCCP to its objectives. It is recommended that a specific objective be ensured for every action taken in the NCCP.

Example related to Recommendation 12: Some European countries ensure specific objectives for every action taken in the NCCP.
Some European countries (for example Austria, Cyprus, Denmark, Finland, and Italy) ensured a specific objective for every action taken in the NCCP. In some countries (for example Belgium) there was not a specific objective for every action taken in the NCCP, but they specified them for specific actions (for example screening in some regions in Belgium).

Recommendation 13: Make specific alliances with relevant stakeholders, in order to ensure the implementation of the NCCP.

In order to ensure the implementation of the NCCP, specific alliances with relevant stakeholders should be made. It is advisable to make alliances with academia, scientific societies, health care professionals, universities, patients, cancer societies, cancer registries, industry, local municipalities, cancer charities, or other related institutions.

Example related to Recommendation 13: Alliances with stakeholders in order to ensure the implementation of the NCCP in Lithuania.
In Lithuania professional and patient organizations, universities and local municipalities are included in the NCCP 2014–2025 implementation.

Recommendation 14: Make sure that indicators for evaluation are clearly defined in your NCCP.

Indicators are important in order to provide for the ongoing assessment of the implementation process and the objective evaluation of the targets set out by the NCCP. It is recommended that indicators be clearly defined in the NCCP.

Example related to Recommendation 14: Indicators for evaluation are clearly defined in NCCPs in some European countries.
In Austria, Slovenia and Estonia indicators for evaluation are clearly defined in their NCCPs.

Recommendation 15: Make sure to include process and structure evaluation in your evaluation strategy; do not rely on outcome evaluation alone.

In order to improve the monitoring and evaluation of NCCPs, it is recommended that process and structure evaluation be carried out in addition to outcome evaluation, which is the most frequently used method of evaluation in Europe. The added value of using all three different types of evaluation is a more in-depth understanding of the process and structures that lead to the desired outcome.

Example related to Recommendation 15: Some European countries evaluate their NCCPs by outcome, by process and by structure.
To assure accurate results, Belgium, Cyprus, Denmark, Germany, Italy, Lithuania, Luxembourg, Spain, Sweden, Turkey and Wales evaluate their NCCPs using all three methods of evaluation: by outcome, by process and by structure.

6 Authorship

This policy paper represents the joint work of members of the Expert Group on National Cancer Control Programmes in the framework of the CanCon Joint Action Member State Platform. Members of the Expert Group on National Cancer Control Programmes are (in alphabetical order): Tit Albreht, National Institute of Public Health, Slovenia; Karen Budewig, Ministry of Health, Germany; Patricia Fitzpatrick, University College Dublin, Ireland; Marjetka Jelenc, National Institute of Public Health, Slovenia; Aneta Modrzynska, Ministry of Health, Poland; Francois Schellevis, NIVEL (Netherlands Institute for Health Services Research), the Netherlands; Branko Zakotnik, Institute of Oncology, Slovenia and Elisabete Weiderpass, Karolinska Institute, Sweden.

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Policy Paper on Enhancing the Value of Cancer Care Through a More Appropriate Use of Healthcare Interventions

R. Grilli, J. Espin, F. Florindi and F. De Lorenzo

CONTENTS

1 Executive summary

Despite the relevant progress made over the last few decades in diagnosing and caring for cancer patients and the potential of therapeutic innovations which are currently in the pipeline, there are legitimate concerns that many oncologic patients currently do not receive appropriate care according to their needs. Indeed, cancer care is not immune from the problem of the persistent overuse or underuse of procedures and interventions, a problem that affects modern medicine in general. Awareness of the relevance of this problem has been growing recently, given that the overall economic context is forcing health systems to function with decreasing resources while introducing costly innovations and maintaining and enhancing quality of care to meet patients' and citizens' expectations. Within this context, this paper focuses on the issue of health services overuse and the delivery of low-value care through the use of interventions or procedures that do not provide any benefit to patients. While low-value care may take different forms in clinical practice- from the use of clearly ineffective interventions to the inappropriate use of potentially effective ones- low-value care always exposes patients to unnecessary risks. It also represents a waste of resources that could otherwise be used to support the adoption of relevant innovations and to sustain patients' access to good quality care.

Taking forward an agenda aimed at reallocating resources from the provision of low-value care towards effective and appropriately used interventions entails adopting a policy framework that garners the support of health professionals, patients and citizens to this end while enhancing the value of cancer care. Also, initiatives must be undertaken to identify health interventions from which to withdraw resources (partially or fully) without reducing the quality of care. Finally, such a policy framework should develop a coherent set of initiatives aimed at fostering the necessary changes in clinical practice.

The assumption that withdrawing support from inappropriate oncologic care can make possible a reallocation of resources large enough to sustain innovation and reduce underuse should not be taken for granted and needs to be empirically assessed. Nevertheless, eliminating or reducing low-value care should be seen as a valuable effort to improve the quality of healthcare for cancer patients. The goal of this paper is to make recommendations to provide guidance for policy makers to adopt policies that enhance the value of cancer care while maintaining a systematic and inclusive approach.

2 Key recommendations at a glance

Recommendation 1: Policies aimed at reducing low-value oncologic care should be appropriately framed, emphasizing the goal of enhancing quality of care, rather than merely reducing healthcare costs. It should be made clear that the effort is not aimed at cutting resources for cancer care.

Recommendation 2: Withdrawing (totally or partially) resources from low-value or inappropriate care should be linked to sustaining patient access to good quality care, addressing both the issue of underuse of existing valuable interventions and access to innovations whose actual clinical value has been properly assessed.

Recommendation 3: The process should include proper consideration and analysis of the views and interests of health professionals and patients, as well as of other contextual factors relevant to the decision to withdraw support for a particular intervention.

Recommendation 4: The need to reduce patients' risk of exposure to low-value care is increasingly acknowledged by organisations of health professionals. Every effort should be made to foster collaboration and partnership between initiatives sharing these goals, among institutions, health professionals and patient associations.

Recommendation 5: Although other forms of evidence should form part of the policy process, research evidence on the safety, effectiveness and cost-effectiveness of oncologic healthcare interventions should be given a pivotal role in the decision making process.

Recommendation 6: The complexity of the scientific techniques and methodologies should be fully acknowledged in support of the policy process, assuring that adequate resources and skills are provided to make the overall attempt at identifying low-value interventions feasible and successful.

Recommendation 7: Multiple sources of information should be used in identifying low-value interventions and in assessing their use in clinical practice. Among the many low-value interventions that could be targeted, priorities should be set to identify those for whom disinvesting- totally or partially- is likely to provide the highest return in terms of benefit for patients and/or reduction of wasted health system resources.

Recommendation 8: Implementation strategies aimed at stopping or reducing the use of low-value interventions should consider the contextual factors that favour or hamper the desired changes. Implementation of initiatives undertaken at a system level could consider the options offered by the use of audit and feedback mechanisms, the cautious use of incentives, and the use of mass media campaigns.

Recommendation 9: It is important to foster collaboration among health systems, given the similarity of problems and challenges faced by individual countries, despite differences in policy and social context, administration, and the organisation of services. Sharing experiences between countries will help to reach a common framework and taxonomy for these policy initiatives. It will support a common methodological approach to the identification of low-value interventions and will offer the opportunity to avoid redundancies and duplications in the scientific and technical aspects of the process.

Recommendation 10: Research that addresses the methods, implications and effects of reducing low-value cancer care should be promoted and supported. Health policies are in need of good quality research that sheds light on health services overuse and its multiple determinants.

Recommendation 11: Every effort should be made to assure patient participation in the process of identification and removal of low-value and inappropriate care.

3 Introduction

The need for an appropriate and clinically rational use of resources in healthcare delivery is certainly not recent. However, it has undoubtedly received new input and attention as the result of a global economic context that constantly promotes solutions that aim to control and contain healthcare costs and allocate resources efficiently while maintaining and improving the quality of services. It has been estimated that approximately 30% of healthcare expenditures in the USA is a waste of resources.[1] A WHO report estimated that waste accounts for 20 to 40 percent of healthcare spending and identified its reduction as a key step towards universal coverage (2).

This strategically significant problem of the sustainability of health systems calls for the need to tackle not only the issue of governing technological innovation processes in the healthcare setting (one of the main drivers behind the escalation of costs), but also to reinforce the capacity to intervene regarding the use of health services in everyday clinical practice (1,3-6). Significant variability in professional practice styles has been frequently observed, which cannot be explained by differences in patient characteristics and needs, suggesting that the use of healthcare interventions[1] is often less optimal than expected and guided by factors other than scientific evidence (7-9).

Indeed, patterns of care are frequently not in line with the scientific knowledge available, which indicates three different problems: failure to use effective/valuable healthcare interventions in patients who might benefit from them (underuse), occurrence of errors when using specific interventions (misuse), and use of interventions that are known to be either ineffective or of little clinical value (overuse). The use of interventions that are indeed effective/valuable, but in clinical indications where their risk/benefit profile is unfavourable, is another common form of overuse. A number of factors are at play in determining variation in the use of health services in general, and overuse in particular, related to the characteristics (competencies, knowledge, attitudes, and beliefs) of clinicians/providers, to those of patients (including their expectations) and of the context (economic, administrative, social) in which care is delivered (7,8,10,11). Therefore, the task of reducing variation in practice styles and reducing over and underuse of healthcare interventions is particularly difficult.

The achievement of a more rational use of healthcare interventions is clearly not an economic challenge alone. It is also an issue of quality of care and concerns how to best assure that patients access the most suitable option of care according to their needs. This is not a new issue, since it has been at the heart of international debate for at least thirty years. Despite significant progress in methodologies for assessing and improving the quality of health services and the significant efforts invested in developing recommendations for clinical practice and designing techniques and instruments aimed at guiding professional and organisational behaviours, the initiatives put forth so far are insufficient for tackling this issue.

Due to the current economic climate, policies have ended up focusing on the problem of the overuse of health services and interventions. From a clinical standpoint, overuse exposes patients to ineffective or even harmful interventions and procedures, hence jeopardising the possibility to achieve the desired clinical results. From an economic perspective, overuse represents a clear source of waste, thus being an inefficient allocation of healthcare resources. This by no means implies that other forms of waste in the healthcare setting do not exist and should not be effectively tackled. Indeed, there may well

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1 By "healthcare interventions" we refer broadly to medications, drugs, diagnostic tests, diagnostic or therapeutic devices, and surgical techniques used by health professional in specific clinical circumstances.

be inefficiencies in the way in which health services are organised in terms of their mode of delivery and administration. However, the nature and the causes of these forms of inefficiency are inherently different from those related to the use (or lack of use) of healthcare interventions in clinical practice; they have different determinants and possibly need different solutions.

4 Tackling the delivery of low-value care

Providing guidance on health services use to assure that patients receive appropriate care according to their needs in the proper clinical setting has been a constant concern of health systems worldwide over the last 30 years. This guidance, with its clinical, economic, and social implications, has been usually been provided through guidelines and recommendations aimed at influencing the clinical decision making process. The endeavour towards better quality of care has been largely conceived in terms of improving the connection between research and clinical practice, favouring (through the development of increasingly sophisticated approaches and tools) the transfer of knowledge on the value of healthcare interventions. The aim has been to make health professionals more fully aware of the most appropriate courses of action in specific clinical circumstances. Within the framework of enhancing the transfer of knowledge from research to practice, efforts at improvement simultaneously tackle a number of different problems: the lack of use of interventions of known effectiveness/value, the persistent use of those known to be ineffective or of little clinical value, and the failure to adopt innovative practices emerging from clinical research settings in a timely way. The available empirical knowledge, available via well-designed clinical trials and systematic reviews is eventually translated into practice guidelines and is the key starting point of the process.

This paper does not aim to provide a full analysis of these efforts, their implications and outcomes. However, it is worth noting that growing concerns about controlling healthcare expenditures seem to have prompted a more focused approach regarding the issue of making clinical practice adhere to available evidence on the effectiveness and cost-effectiveness of healthcare interventions. This approach is particularly oriented to tackling the problem of health services overuse and thus focuses attention on the delivery of low-value/inappropriate interventions, defined as:

Interventions that are harmful and/or ineffective/non-beneficial, according to the available evidence,

a/ Interventions whose effectiveness or clinical value is very low, according to the available evidence,

b/ Interventions known to be effective or of relevant clinical value, but which are at high risk of inappropriate use (i.e. they should be used selectively, or only for specific clinical indications),

c/ Interventions known to be effective, but for which better alternatives exist or that provide a better value (i.e. they are not cost-effective).

Overall, the healthcare intervention issues outlined above constitute a significant problem. Established practice- i.e. the healthcare interventions assumed to be the standard of care-frequently turn out to be inferior to their alternatives when tested in clinical trials, a phenomenon-defined as practice reversal– that is not uncommon.[12,13] Diagnostic procedures have been shown to be used excessively, such that the information obtained makes no contribution to clinical management or leads to diagnosing conditions that do not have an impact on patients' quality or length of life (14,15).

These efforts to improve health service use pursue higher allocative efficiency through the withdrawal of funding from individual items of care qualified as of low-value (i.e. delisting). Low-value interventions include technologies that become obsolete after their adoption as well as those that are adopted and then shown to be ineffective or even harmful when compared to alternatives (practice reversal). The goal is to identify these interventions and eliminate them from clinical practice by withdrawing funding that supports their use. Funding withdrawal is thus the main tool for making clinical practice more appropriate. In practical terms, however, such an approach may be feasible mostly with interventions that are always of low-value, regardless of the clinical indication where they are applied. As such, they can be excluded from the list of items of care for which economic support is provided. More often than not, overuse is represented by more complex issues, in particular by interventions that are indeed valuable and effective but are actually used in the wrong clinical indications. In dealing with this specific aspect of overuse, delisting may not be feasible or desirable, and other policy actions might have to be undertaken to achieve the desired changes in patterns of care, where funding withdrawal is a goal, rather than a means.

5 Examples of initiatives aimed at reducing low-value care

Despite its relevance, overuse is a policy issue that has not been fully explored or addressed (16,17) for a number of technical, cultural and political reasons. However, concerns about the escalating expense of healthcare has stimulated renewed policy attention to the problem. Over recent years a number of health systems have been focusing on low-value care (18). The initiatives that aim to reduce the use of low-value interventions in clinical practice are referred to in various ways (19), including as *decommissioning* (20,21) *de-implementation* (22), and *de-adoption* (19). *Disinvestment for reallocation* has been the most frequently used term, and it is probably the term that makes most explicit the ultimate goal of achieving a better allocation of resources (see Box 1).

Box 1 Definitions of disinvestment for reallocation

“Disinvestment specifically refers to resource allocation decisions based on withdrawing funding from no or low added-value health interventions, freeing up these resources for reinvestment in other health technologies that meet the criteria of safe and cost-effective care.” (Garcia-Arnesto, 2013 (23))

“The process of (partially or completely) withdrawing health resources from any existing health practices, procedures, technologies or pharmaceuticals that are deemed to deliver little or no health gain for their cost, and thus are not efficient health resources allocation.” (Elshaug, 2007 (24); Peirò, 2014 (25); Parkinson, 2015 (26))

“The displacement of non-cost-effective technologies for resources reinvestment or reallocation.” (Joshi, 2009 (27))

“An explicit process of taking resources from one service in order to use them for other purposes that are believed to be of better value.” (Pearson, 2007 (28))

In the United Kingdom the National Institute for Health and Care Excellence (NICE) recently compiled guidance for the containment of healthcare costs. NICE promotes the best clinical practice through the use of cost-effective procedures and opposes the use of procedures that are ineffective or deemed unsustainable. In 2006 NICE launched a process with the UK Cochrane Centre to identify procedures that could potentially be withdrawn based on the findings of Cochrane systematic reviews (29,30). Among the initiatives of NICE, it is worth mentioning the "do not do list", a searchable database of evidence-based recommendations concerning interventions that should not be used, as they have been shown to have no clinical value (31). In Spain in 2006, a national law acknowledged the importance of the removal of technologies deemed ineffective, inefficient or with an unfavourable risk/benefit ratio. In 2007 two regional health technology assessment (HTA) agencies began a research project to identify, prioritise and assess potentially obsolete technologies. The first guideline for defunding such technologies in healthcare systems was published in 2010, however, the implementation of these policies is still in progress (23,32). In Australia in 2009, the Department of Health and Ageing carried out an assessment of HTA activities and requested a formal review of all procedures currently in use in order to identify healthcare interventions for which funding could be withdrawn (33,34). In the same year, the government funded a research programme with the aim of developing a tool to facilitate the identification of such procedures on the basis of evidence. Also in Australia, the ASTUTE Health study (35) was financed with the same objective. The project includes ethical and economic considerations and involves patients, citizens, clinicians and healthcare decision makers in the tool development process. Disinvestment activities have also been undertaken in Canada (36).

While the above outlines how the problem of reducing waste in clinical practice has been tackled at the institutional level in different countries, initiatives have also been developed concurrently under the aegis of professional bodies. Of these, the Choosing Wisely Campaign in the USA (37-39) is the most remarkable, and is internationally known and has been imitated (40-42). The "choosing wisely approach" is aimed at encouraging clinicians to engage with their patients in discussions about opting for specific interventions whose use is questionable if used outside of specific clinical indications, or to stop using interventions known to be ineffective or of no clinical value. Several specialty societies in different areas have developed short lists of interventions deemed to have these characteristics.

6 The case of cancer care

Cancer care is one of the fields in which healthcare systems' capacity to cope with modern medicine's challenges is most tested (43,44). Elements of these challenges include the extremely innovative dynamism of healthcare technologies, the increasing care needs of patients, the overall ageing of the population, the increasing expectations of citizens about the quantity and quality of healthcare services and finally, the pressing need to contain the costs of care (45,46).

Also, particularly in Europe, oncology is an area with persistent and significant differences between countries. These differences are found both in terms of quantity and quality of services offered to citizens and in terms of clinical outcomes (survival) observed in patients (47,48). As patient survival has been shown to be correlated with macro-economic determinants in general, and with investments in health systems in particular,47 one might reasonably argue whether these differences across countries have been further widening due to the effects of the economic crisis (49).

Indeed, the spectrum of phases of the clinical management of cancer patients seems to be exposed to some degree of inappropriateness and overuse. Over-diagnosis has been pointed out as a relevant issue in this area (43), where the adoption of increasingly sophisticated diagnostic devices makes possible the detection of small tumours that are unlikely to cause harm if left untreated. Variation among providers and among geographic areas has been shown for surgical interventions (like breast conserving surgery or radical prostatectomy) and chemo or radiotherapy treatments as well. Patient staging and follow-up after primary treatment also appear to be shaped by physicians' excessive reliance on imaging tests, despite recommendations from the Choosing Wisely Campaign that support a more parsimonious use of those technologies (50-54). Lastly, a number of studies have shown overuse of aggressive medical and surgical approaches in patients at the end of life (55), although often patients would be in favour of less aggressive options (56). These findings are paralleled by indications of the potential underuse of appropriate care in the same patients (57). Not unlike other fields of modern medicine- although perhaps with greater intensity and relevance due to the implications of the health needs expressed by patients- overuse and underuse coexist in oncology, like the two faces of a coin.

Although there is evidence that suggests that patients' expectations might not necessarily be a major driver of overuse in cancer care (58), nevertheless, involving patients and their families in the decision making process may be valuable in creating a supportive environment and in achievement of a higher level of appropriateness in clinical practice. Indeed, the Choosing Wisely Campaign is explicitly aimed at encouraging physicians and patients to engage in discussing the best courses of action to be taken in specific clinical circumstances (37,42).

Sharing information with patients about the value of healthcare interventions and making them fully aware of the possible alternative options means not only respecting their dignity and personal autonomy, but also sustaining efforts for a more clinically appropriate provision of care. Nevertheless, many barriers exist to patient engagement in the decision making process. These include being represented by the health profession, lack of time to communicate effectively, insufficient health literacy among patients, and lack of tools and instruments to support patient-physician communication (59).

Thus, it is not surprising that cancer care has been considered an area of clinical practice where higher quality of care is necessary (46), and initiatives have been undertaken by physicians' associations as well as by government institutions in this respect. The abovementioned NICE database of "do not do" recommendations includes a long list of items concerning cancer care. In Italy under the aegis of the Ministry of Health, a working group was established in 2013 with the task of identifying low-value interventions in oncology (60). In addition, over the last few years lists of interventions of low clinical value or at high risk of inappropriate use have been developed and provided by some scientific societies in oncology (40,61-63). Box 2 outlines the interventions qualified as of low value by those initiatives.

Lastly, a systematic search for low-value interventions undertaken in Australia- that used multiple sources of information (literature search, nominations from relevant stakeholders, etc.)- identified over 150 interventions for which there was evidence of low clinical value, and 26 concerned cancer care (33).

Box 2 Outline of the recommendations from oncology speciality societies concerning interventions deemed to be of low clinical value or at high risk of inappropriate use

The American Society of Clinical Oncology Identifies Five Key Opportunities to Improve Care and Reduce Costs: The Top Five List for Oncology (Journal of Clinical Oncology, vol 30: pp 1715, 2012)

Don't use cancer-directed therapy for solid tumour patients with the following characteristics: low performance status (3 or 4), no benefit from prior evidence-based interventions, not eligible for a clinical trial, and no strong evidence supporting the clinical value of further anti-cancer treatment (10-15).

Don't perform PET, CT and radionuclide bone scans in the staging of early prostate cancer at low risk for metastasis (16-18).

Don't perform PET, CT and radionuclide bone scans in the staging of early breast cancer at low risk for metastasis (19).

Don't perform surveillance testing (biomarkers) or imaging (PET, CT and radionuclide bone scans) for asymptomatic individuals who have been treated for breast cancer with curative intent (12,20-23).

Don't use white cell stimulating factors for primary prevention of febrile neutropenia for patients with less than 20% risk for this complication (24).

Choosing Wisely Canada Cancer List: Ten Low-Value or Harmful Practices that Should Be Avoided In Cancer Care (Journal of Oncology Practice, vol 11: pp e296, 2015)

Do not order tests to detect recurrent cancer in asymptomatic patients if there is not a realistic expectation that early detection of recurrence can improve survival or quality of life.

Do not perform routine cancer screening, or surveillance for a new primary cancer, in the majority of patients with metastatic disease.

Avoid chemotherapy and instead focus on symptom relief and palliative care in patients with advanced cancer unlikely to benefit from chemotherapy (e.g. performance status 3 or 4).

Do not perform routine colonoscopic surveillance every year in patients after their colon cancer surgery; instead, frequency should be based on the findings of the prior colonoscopy and corresponding guidelines.

Do not delay or avoid palliative care for a patient with metastatic cancer because they are pursuing disease–directed treatment.

Do not recommend more than a single fraction of palliative radiation for an uncomplicated painful bone metastasis.

Do not initiate management in patients with low-risk prostate cancer (T1/T2, PSA<10 ng/mL, and Gleason score <7) without first discussing active surveillance.

Do not initiate whole-breast radiotherapy in 25 fractions as a part of breast–conservation therapy in women age ≥50 years with early-stage invasive breast cancer without considering shorter treatment schedules.

Do not deliver care (e.g. follow-up) in a high-cost setting (e.g. primary care).

Do not routinely use extensive locoregional therapy in most cancer situations where there is metastatic disease and minimal symptoms attributable to the primary tumour (e.g. colorectal cancer).

Choosing Wisely: The American Society for Radiation Oncology's Top 5 list
(Practical Radiation Oncology, vol 4: pp 349, 2014)

Don't initiate whole-breast radiation therapy as a part of breast conservation therapy in women age ≥50 with early-stage invasive breast cancer without considering shorter treatment schedules.

Don't initiate management of low-risk prostate cancer without discussing active surveillance.

Don't routinely use extended fractionation schemes (> 10 fractions) for palliation of bone metastases.

Don't routinely recommend proton beam therapy for prostate cancer outside of a prospective clinical trial or registry.

Don't routinely use intensity modulated radiation therapy (IMRT) to deliver whole-breast radiation therapy as part of breast conservation therapy.

American Society of Clinical Oncology 2013 Top Five List in Oncology (Journal of Clinical Oncology, vol 31: pp 4362, 2013)

Do not give patients starting a chemotherapy regimen that has a low or moderate risk of causing nausea or vomiting antiemetic drugs intended for use with a regimen that has a high risk of causing nausea or vomiting.

Do not use combination chemotherapy (multiple drugs) instead of chemotherapy with one drug when treating an individual for metastatic breast cancer unless the patient needs a rapid response to relieve tumour-related symptoms.

Avoid using PET or PET-CT scanning as part of routine follow up care to monitor for cancer recurrence in asymptomatic patients who have finished initial treatment to eliminate the cancer, unless there is high-level evidence that such imaging will change the outcome.

Do not perform PSA testing for prostate cancer screening in men with no symptoms of the disease when they are expected to live fewer than 10 years.

Do not use a targeted therapy intended for use against a specific genetic aberration unless a patient's tumour cells have a specific biomarker that predicts an effective response to the targeted therapy.

7 Methods

The development of this document was based on the following considerations.

- Key features of policies aimed at addressing the issue of low-value care were drawn from available and recently conducted reviews on the topic (18,19,64-66), and from discussions with experts in the field in the context of a seminar held in Rome on February 2, 2016. In this workshop the findings from a systematic review on health services overuse were presented by the main authors (Michel Wilson and Moriah Ellen from McMaster University, Hamilton, Ontario) (67,68). In that event, the following themes were identified as worth addressing as policy themes in the policy document:
    - Key issues to be considered at the policy framing stage
    - Methodological issues
    - Implementation
    - International collaboration
    - Research to support reallocative policies
    - Patient engagement

Individual papers related to the themes outlined above were retrieved from the scientific literature. PUBMED was searched for articles published in English in peer-reviewed journals and reporting the word "disinvestment" in the title or abstract. Relevant documents/reports published by health technology assessment agencies were also retrieved, identified either through the reference lists of published papers, or through Google searches (keywords: disinvestment, healthcare). Overall, 80 articles (23,69-133) and 14 grey-literature documents (5,18,27,32,34,36,60,64,67,134-138) were retrieved, published during the period from 1994 to 2015.

Relying on the information gathered through the steps described above, a first version of the paper was drafted and then circulated for comments and suggestions by a group of experts. Comments were also obtained from the European Cancer Organisation (ECCO) and from EU Member States.

8 Goals

This document should not be seen as a methodological paper, nor is it intended to be a technical "manual" on how to carry out initiatives aimed at reducing the delivery of low-value care. When methods and technical aspects are mentioned, it is to highlight the complexity of the process to be undertaken and its implications. The aim of this paper is to support policy makers and decision-makers at the health system level, making them aware of the elements that should be considered when developing policies oriented towards promoting appropriate use of healthcare interventions.

In line with the above, the recommendations provided should therefore be considered as general guidance, aimed at highlighting the aspects to be taken into account when developing policies aimed at reducing low-value care, in order to maximise their likelihood of success with the support and cooperation of professionals, patients and citizens.

9 Theme 1: Issues to be considered in framing policy

Withdrawing resources from ineffective/low-value care is a complex endeavour, entailing different steps to be undertaken, decisions to be made and actions to be taken at various levels of health systems, therefore involving a plurality of actors. As such, tackling low-value care and inappropriateness in clinical practice should be properly seen as a policy process (20 24), rather than a merely technical exercise.

Therefore, a key issue is for these policies to be framed to favour the participation of all relevant stakeholders in supporting a common agenda. In particular, gaining the support and active contribution of health professionals' organisations and of patient and citizens' associations is of utmost importance to the success of these initiatives. Thus, it is particularly important to adopt an understandable terminology during the policy development stage, one that is fully consistent with the policy objectives and involved actors. *Disinvestment for reallocation* could be a less than optimal term for conveying the meaning and ultimate goals of these policies, both to health professionals and lay people (139).

Although frequently used- and perhaps mitigated by the "for reallocation" specification- the word *disinvestment* appears to be unsatisfactory to many in order to fully capture and make explicit the policy goals to be achieved. In particular, the term's focus on economic issues evokes the action of withdrawing resources from specific healthcare interventions. In the current economic context, with many countries already experiencing a substantial reduction in public resources to sustain their health systems, there is a strong need to distinguish initiatives aimed at reducing low-value care from policies aimed at merely cutting healthcare costs. This could be instrumental in achieving the desired support from health professionals, patients and citizens.

While disengaging resources from low-value interventions in order to use them for the delivery of high-value care is the desired effect of disinvestment for reallocation policies, the primary goal is to improve the quality of care by reducing the use of interventions/procedures not providing any benefit to patients and possibly even causing harm. Thus, these policies should be defined in more effective terms, conveying to relevant stakeholders (health professionals, patients, and citizens) a more clear and unambiguous message concerning their objectives. For instance, they could possibly highlight that health service overuse and adoption of low-value interventions represents a waste and an opportunity to recover resources to apply elsewhere.

Lastly, as others have already pointed out (140), *disinvestment* may suggest a complete removal or withdrawal of a technology/intervention from clinical practice, while in many instances the objective is rather to achieve a more selective and clinically appropriate use. In the context of the overall evaluation of the initiatives undertaken to date at the international level, some have proposed *de-adoption* as an alternative to *disinvestment* (19). However, the term *de-adoption* highlights only one of the issues at stake, the complete or partial removal from clinical practice of specific healthcare interventions or procedures. In many other instances, the problem is not de-adopting in absolute terms, rather it relates to a different use (i.e. a more selective, appropriate use) of individual interventions or procedures. The appropriate terminology must unambiguously reflect the true goal of the policy.

Reducing waste in clinical practice as a way of improving quality of care is the ultimate goal of these policies, which aim to promote a higher level of clinical appropriateness in the provision of care for cancer patients. From the beginning of policy development, there should be explicit focus on what should be eliminated or reduced in clinical practice as well as interventions whose delivery should be promoted. It is important to describe the specific reallocative goals of these policies, addressing the issue of health services underuse through the identification of valuable healthcare interventions whose accessibility for patients might be still unsatisfactory. At the same time, actions aimed at reducing resource waste should be directly linked to the promotion of innovation, such that health professionals and patients are encouraged to look at disinvestment as a strategy to redirect resources towards patients' access to innovations. Although it might be overoptimistic to state that removing or reducing low-value care will provide sufficient resources to contribute to the cost of innovations, testing the truth of this assumption should be a part of the disinvestment process. This can take place by estimating the actual value of low-value interventions in clinical practice and the frequency of their use. Actions to reduce low-value care should be included in policies aimed at strengthening health system capacity to govern the use of new technologies in clinical practice, distinguishing those that provide real value to patients.

Reallocative decisions based upon withdrawal of resources from low-value care should be based primarily on sound scientific evidence in addition to information on contextual factors. In other words, colloquial evidence helps shape policy processes (141,142). Also, stakeholder voices should be taken into account, in particular, a proper consideration and analysis of the opinions, beliefs and values of those who will be affected is necessary (143).

While the value of patient engagement will be extensively addressed later in this paper, it is worth mentioning here the utmost importance of the contribution of health professionals. In general, health professionals are a primary determinant of the quality of care delivered to patients. Although health professionals' decisions and actions are inevitably conditioned by the resources available within specific clinical settings (i.e. technical equipment, etc.), as well as by healthcare administration and management, their skills and competency in identifying patient needs and expectations and in avoiding unnecessary interventions is at the core of good quality care (4,144). Promoting a clinically appropriate use of healthcare interventions is one of the foundational values of the medical profession, and the Choosing Wisely movement itself represents growing physician awareness of the need for reduction in inappropriate and/or low-value care (42).

More specifically, it is important that initiatives to reduce provision of low-value care exploit the quality improvement efforts undertaken with the support of authoritative and representative professional bodies. Initiatives like Choosing Wisely are a case in point, as they share the goal of removing interventions deemed to be of low clinical value from clinical practice. As such, they should be seen not only as concurrent efforts focused on the same objectives, but possibly as merging initiatives, with reciprocal advantage to be gained from their integration. Indeed, institutional disinvestment initiatives can rely on the lists of low-value interventions produced by speciality societies as a useful starting point for targeting aspects of care where inappropriate use is a relevant problem. This is also supported by the engagement of authoritative professional bodies, the credibility of the process and favours the implementation of their decisions. Professional bodies can also gain from partnership with institutions, assuring that key clinical considerations do not end up being overlooked in the process, and that the degree of clinical autonomy required to take into account patients' needs is effectively safeguarded. In addition, institutions are certainly better equipped to promote the implementation of changes required to improve quality.

Recommendations

Recommendation 1: Policies aimed at reducing low-value care should be appropriately framed, emphasizing the goal of enhancing quality of care, rather than merely reducing healthcare costs. It should be made clear that the effort is not aimed at cutting resources for cancer care.

Recommendation 2: Withdrawing (totally or partially) resources from low-value or inappropriate cancer care should be linked to sustaining patient access to good quality care, addressing both the issue of underuse of existing valuable interventions and access to innovations whose actual clinical value has been properly assessed.

Recommendation 3: The process should include proper consideration and analysis of the views and interests of health professionals and cancer patients, as well as of other contextual factors relevant to the decision to withdraw support for a particular intervention.

Recommendation 4: The need to reduce patients' risk of exposure to low-value care is increasingly acknowledged by organisations of health professionals. Every effort should be made to foster collaboration and partnership between initiatives sharing these goals, among institutions, health professionals and patient associations.

10 Theme 2: Methodological aspects

The implications of methodological aspects related to identification of low-value interventions should be considered throughout the policy process. Indeed, the adoption of a sound methodological approach is a key to the value of the initiative, especially for maximizing the likelihood of correct identification of aspects of care where there is room for improvement through withdrawing- completely or partially- support to interventions that do not provide any benefit to patients and therefore represent a waste of resources.

Insofar as no methodological approach has been defined as the standard for these efforts, it seems that the majority of the experiences undertaken so far have relied on Program Budgeting Marginal Analysis (PBMA) or on the health technology assessment (HTA) approach (65). HTA entails a systematic evaluation of the different issues (medical, economic, social, and ethical) concerning adoption and use of a healthcare intervention.145 It is an exercise largely based upon a systematic appraisal of the available information on safety, effectiveness, cost-effectiveness, and patterns of use. PBMA is an economic evaluation technique that is suitable for setting priorities among different alternatives of funding allocation, based upon cost-effectiveness principles of analysis of marginal costs vs. marginal benefit (88,114,129,131,146,147).

From a policy-making perspective, whatever the methodology adopted, the process will benefit from being sustained by multiple sources of information, in particular:

- Research information on safety, effectiveness, and cost-effectiveness of healthcare interventions is of high importance. Disinvestment should be an evidence-informed process. Reliance on sound scientific evidence is key to providing credibility to the effort, which is required for tackling the potentially sensitive issues concerning the withdrawal of interventions already well entrenched in clinical practice.
- The limitations of research should also be acknowledged as well. Evidence on the yield of healthcare interventions might be lacking, of poor quality, difficult to interpret or controversial (148). While it seems wise or even obvious to suggest that these efforts should focus primarily on interventions whose evidence base is less controversial and unambiguously indicates their lack of clinical value, it could also be that these interventions are not widely used in clinical practice and, as such, do not represent a priority (i.e. they have already been "spontaneously" abandoned) (29 30).
- Other sources of information should be considered in the identification of interventions that are seen as complementary rather than alternative to a systematic assessment of the scientific evidence available on safety, effectiveness, and cost-effectiveness of interventions. Examples are reported in Table 1, and include information drawn from consultation with patients and health professionals. Analysis of routinely available databases- or from ad hoc studies on patterns of care- can also provide valuable information on the frequency of use of interventions. In particular, evidence of significant variation in the use of specific procedures/interventions across geographic areas within a jurisdiction, or across providers, can be a starting point for focusing on areas of care that represent areas of potential overuse (and underuse as well) (149). In general, assessment of the frequency of use of healthcare interventions is of crucial importance to gain a better understanding of the clinical and economic burden represented by low-value interventions.
- As will be addressed in greater detail in the implementation section of the paper, disinvesting from healthcare interventions already in use in clinical practice can be particularly challenging. Therefore, disinvestment efforts should be focused, prioritizing items where substantial improvements– both in terms of benefit to patients and resource retrieval– can realistically be achieved. Examples of priority criteria- related to the characteristics of the interventions, to their frequency of use, and clinical and economic implications- are reported in Table 2.
- As equity implications should also be a concern, the methodological process should include an assessment of whether policy decisions discriminate against any disadvantaged or vulnerable group. For this purpose, the Equality Impact Assessment (EqIA) was proposed in the United Kingdom in 2008 and revised in 2009 (150). The EqIA should ensure that a policy is as equitable as possible. It should consider the impact of health policies on people of different age groups, social and economic groups, ethnic backgrounds, sexual orientations, and religions/beliefs as well as people with disabilities. The EqIA is an integral and essential part of the policymaking and management processes and must inform and influence decisions and actions. In the UK, EqIA has been applied to cancer care in order to reduce inequalities in health services and outcomes (https://www.cancerresearchuk.org/sites/default/files/taskforce_equality_impact_assessment.pdf).

- Overall, the technical complexity of the methodologies to be used should be fully acknowledged. Every effort should be made to assure that disinvestment for reallocation policies are designed and conducted taking into account the range of competencies required at the different stages from multiple disciplines. Tackling low-value care is indeed, to a large extent, a multidisciplinary effort, involving a number of different technical and scientific competencies and skills. In particular, the technical work that represents the backbone of the disinvestment process requires the clinical expertise of health professionals, experts in the evaluation of health technologies, professionals with statistical and literature review skills, health economists and social scientists, as well as experts in quality improvement. As the ultimate goal of these initiatives is to promote changes in clinical practice towards a more appropriate use of healthcare services, the support from implementation scientists is also relevant.

Table 1 Examples of approaches to the identification of interventions to be targeted by policies aimed at reducing low-value care

Conditions for which interventions are assessed	Source
• Availability of new evidence on safety, effectiveness and/or cost-effectiveness. • Evidence of variation in clinical practice among geographic areas or providers, suggesting differences in clinical opinion about the value of interventions. • Temporal variations in volume, showing significant increase or decrease in utilisation rates. • Communication from patients, consumer advocacy and support groups, and community groups, highlighting negative (or ineffective) experiences following treatment. • Consultation with clinical, nursing, allied health and technical staff, healthcare administrators and funders. • Nomination through a process involving individuals, associations, and colleges. • In situations where a new intervention is assessed and is considered a potential replacement of another, the latter is considered and assessed for disinvestment. • Technology use (with reimbursement) outside of evidence-based indications. • Long-established technologies that have never had their cost-effectiveness assessed. • In situations where practice is inconsistent with clinical practice guidelines.	151
• Ongoing consultation with clinical speciality groups. • Use of routine data to identify variations in the use of technologies and/or associated outcomes. • Use of routine data to identify technologies with high budget impact. • Monitoring published studies and systematic reviews. • Routine identification of technology candidates for optimisation within the context of the assessment of new technologies. • Feasibility (i.e. identification of barriers and opportunities for disinvestment in order to select candidates with most potential for change and impact).	140

Table 2 Examples of criteria for prioritising interventions to be targeted by policies aimed at reducing low-value care

Criteria	Source
• The cost of the technology has a significant overall budget impact.	28
• There are effective alternative technologies of demonstrated cost-effectiveness that may be currently underused.	
• Elimination of the technology may reduce risks to patient safety.	
• The impact of disinvestment will not be borne largely by specific vulnerable populations such as the disabled, elderly or children.	
• The ascribed benefit of the technology is small, i.e. it is not used to treat very severe or life-threatening conditions.	
• There is evidence that the technology causes an overall worsening of health.	115 136
• There is unacceptable potential risk for patients or the environment.	
• The level of discomfort produced by the technology or the level of its invasiveness has a high negative impact.	
• There is no scientific evidence to show that the technology improves health.	
• Potential productivity and cash-releasing savings.	29
• Potential impact on quality of clinical care delivered to patients and on clinical outcomes.	
• Potential impact on patient safety.	
• Potential impact on patient and carer experience.	

Recommendations

Recommendation 5: Although other forms of evidence should be part of the policy process, research evidence on the safety, effectiveness and cost-effectiveness of healthcare interventions should have a pivotal role in the decision making process.

Recommendation 6: The complexity of the scientific techniques and methodologies to be used in support of the policy process should be fully acknowledged, assuring that adequate resources and skills are provided to make the overall attempt at identifying low-value interventions feasible and successful.

Recommendation 7: Multiple sources of information should be used to identify low-value interventions and to assess their actual use in clinical practice. Among the many low-value interventions that could be targeted, priorities should be set to identify those for whom disinvesting- totally or partially- is likely to provide the highest return in terms of benefit for patients and/or reduction in wasted resources for the system.

11 Theme 3: Implementation

The ultimate goal of the policy process is to promote clinical appropriateness and eliminate (or reduce) the use of ineffective interventions to support better clinical outcomes and a more efficient reallocation of resources. In general, the implementation of policies aimed at reducing low-value care can represent a complete withdrawal of funding (i.e. delisting) for interventions when they have been shown to be clearly ineffective and/or harmful. In these cases- especially in terms of interventions already well integrated in daily clinical practice- such a disinvestment process is likely to face resistance from professionals and/or patients. Also, the counterforce of vested interests has the potential to affect the decision to withdraw resources. Thus, consensus is needed from relevant stakeholders to ensure that policies reducing the provision of low-value care will be able to overcome expected resistance to change and to ensure that attention is paid to the issue of implementation.

Indeed, the complexity of withdrawing resources from specific interventions can be even greater when it implies- rather than the mere delisting- the introduction of a different (i.e. more selective) pattern of use of the interventions at stake. This is the case in terms of interventions that- although potentially useful- are used inappropriately in clinical indications. In these circumstances, a key issue concerns how to change healthcare providers' behaviour to achieve a more selective and appropriate use. As has been extensively demonstrated by a large body of research, developing guidelines and recommendations is not sufficient to change clinical practice.152 Therefore, it is not surprising that the provision of recommendations supporting the abandonment of low-value care has been shown to be insufficient (153-155).

There is a great deal of research evidence available on how to change health professionals' behaviours and drive quality improvement efforts. The Cochrane Review Group on Effective Practice and Organisation of Care provides valuable information on the effectiveness of different approaches. The group continuously updates systematic reviews which are made available through the Cochrane Library (http://www.cochranelibrary.com). While this information represents a useful resource for the design and implementation of quality improvement initiatives and for efforts aimed at increasing appropriateness in healthcare delivery, available evidence should be critically interpreted with respect to the extent to which it is "generalizable" to disinvestment policy and its impact on clinical practice. Overall, although several instruments, tools and approaches to influence clinical practice have been developed and tested, none of them has been shown to be unequivocally effective. While many examples of successful approaches are documented in the literature, failures are even more common. Thus, there is no *magic bullet* when it comes to changing healthcare providers' behaviour (156). A careful in-depth analysis of the type of behaviour to be changed and its determinants should be undertaken prior to choosing the most appropriate approach. Also, the importance of non-scientific factors should be considered in analysing the determinants of the identified behaviours. Although ideally medical practice should be based on sound empirical evidence in choosing the most appropriate course of action for patients, in a practical sense, behaviours are influenced not only by science, but also by social, political and economic factors. Scientific literature has shown how these factors influenced the persistence of radical mastectomy in the surgical management of breast cancer vs. the adoption of breast conserving approaches (157).

Moreover, the promotion of changes in healthcare settings that aim to withdraw resources from low-value interventions might well take a perspective quite different from the one frequently adopted in most of the relevant literature, whose focus has been predominantly promoting the adoption of "innovative" practice. In contrast, disinvesting entails the challenge of relinquishing something already in practice, rather than taking-up something new. Scholars and researchers have pointed out this difficulty, recognising that "de-implementation" might have different determinants and require a different set of actions to be achieved (22).

Although we do not provide an in-depth description and analysis of the literature on changing health providers' behaviours, we believe it is worth considering those aspects related to actions to be taken at the macro system level, which are more likely to be related to the roles and responsibilities of policy makers, the target audience of this paper.

In particular, the following issues are worth mentioning:

- Efforts should be made to make quality of cancer care as transparent and assessable as possible, with attention paid to the issue of measuring the provision of low-value care (158) This is indeed a critical issue with both technical and policy implications. While technical aspects concern the development of process indicators to measure to what extent the frequency of use of specific interventions is appropriate, the policy aspects call for the adoption of arrangements and tools that reinforce healthcare providers' accountability for the quality of care delivered to cancer patients.

  Development of well-conceived, evidence-based process indicators that measure appropriateness is required to overcome the intrinsic limitations of analysis of patterns of care. These analyses are often limited to measures of the frequency of use and the degree of variation across providers. Variations in practice patterns are a proxy for inappropriate use. While variability in provider behaviour- when dealing with patients with similar healthcare needs- may suggest the existence of a problem of overuse (and possibly of underuse as well), it may also show the way in which healthcare providers take into account individual patients' preferences and needs. Separating positive from *negative variation* is particularly difficult,7 especially when these analyses have to rely on relatively incomplete information concerning the clinical circumstances in which health services are used, as is often the case when these analyses rely on administrative data. Lack of detailed information on individual patient characteristics may prevent a full understanding of their actual clinical needs and therefore hamper any assessment of the appropriateness of use of the procedures/interventions considered.

Taking full advantage of the widespread use of electronic medical records, as well as the information made available by cancer registries (where they exist) might offer major opportunities for enhancing our analytical capacity to explore quality of care dimensions relevant to disinvestment policies, and to disentangle their determinants (159).

Development of such a capacity has several implications of utmost importance. For instance, allowing a critical appraisal of the current policy relevance of the recommendations made by specialty societies on "do not use" interventions, or cautious use of interventions, such as those outlined in Box 2 on cancer care, is important. Failure to measure the rate of use in clinical practice of the interventions indicated in the recommendations hampers the policy usefulness of the endorsement of professional bodies and prevents knowledge of the frequency (i.e. the relevance) of the problem. Finally, it weakens- from the outset- the implementation of the recommendation. Also, it prevents any efforts to make health providers accountable. Translation of these recommendations into measurable process indicators is a complex task, characterised by the need to capture information on patient and intervention characteristics that is usually not accessible unless a local audit exercise is conducted (which can be resource intensive). Better analytical capacity in assessing quality of care necessitates relying to a greater extent on change-behaviour approaches known to be effective.

Use of various performance feedback systems targeted at healthcare providers has become an increasingly common approach within quality improvement initiatives/programs or regulatory efforts. These systems are favoured by the presence of ICT in healthcare settings, which make large amounts of data on healthcare use patterns and outcomes relatively more accessible and usable. Performance feedback refers to the systematic (i.e. formally structured) provision of performance summaries to providers (individual health professionals, teams, services, organisations) over a specified period of time.160 Performance assessment relies on process and/or outcomes indicators, and the feedback summary may take different forms. It usually provides for benchmarking of the observed performance with external frames of reference and standards. Suggestions have been put forward related to how these reports should be developed and structured and on the desirable features of a good performance feedback procedure, according to the knowledge available and the opinions of experts in the field.161 Evidence from systematic reviews on performance feedback interventions shows significant variation in their effect, according to a number of factors. Overall, they make clear the substantial potential of these approaches in changing health providers' behaviours (160).

- Economic incentives targeted to healthcare providers are often one of the options considered to promote desired changes in clinical practice (162-170). Surely, policies based on these tools may well be able to induce providers to discontinue, reduce, or increase the rate of use of specific procedures/interventions, according to a desired goal. However, economic incentives have remarkable limitations and problematic aspects, and their adoption should therefore be cautious (171).

  Firstly, that incentives can influence rates of adoption and use of an intervention does not necessarily mean that they impact the appropriateness of use. Indeed, the relationship between rate of use and appropriateness seems to be an issue not yet fully explored by research. The limited evidence available so far suggests that the relationship may not be linear as one would expect (172). In other words, it cannot be assumed that inappropriateness is necessarily higher where rates of use are higher as well.

This implies that economic incentives aimed at reducing the volume of activities for specific interventions or procedures can indeed be effective in lowering the quantity (i.e. the rate of use) without necessarily affecting quality (i.e. reducing the proportion of patients receiving inappropriate care). The other implication is that approaches to influence clinicians' decisions should be careful in preserving a degree of necessary discretion, which is an important component of clinical practice (7,8).

Secondly, the effects of economic incentives are often lower than expected and have limited duration over time (173,174). In general, the relationship between economic incentives and professional conduct is much more complex than imagined, and it is not necessarily true that by increasing the incentive, the expected effect on professional conduct increases at the same rate. There is a threshold above which incentives lose their effectiveness (for example, because the professional has reached his/her desired level of economic remuneration). Furthermore, the economic aspect is just one of the many motivational levers that inspire professional conduct. Professionals have their own intrinsic motivations to improve, as well as a personal moral code that induces them to "do the right thing", often regardless of the economic reward. From this point of view, over-intensive and indiscriminate use of economic incentives has the negative effect of monetising behaviours, whose motivation is rooted in professional ethics (175,176). Policies should consider the adoption of rewards and incentives that are not necessarily or exclusively economic (173), and may possibly be more able to sustain intrinsic motivations and professional values.

- Mass media have been shown to be effective in shaping patterns of healthcare use (177). Notwithstanding, it is fair to remark that studies support the effectiveness of mass media in changing the volume of health services use, while there is no robust evidence showing their effect on quality. Nevertheless, although the available evidence does not allow a full understanding of the key determinants of their effectiveness, the adoption of approaches relying on mass media as a tool to convey to the general public the meaning and goals of disinvestment initiatives should be considered in order to create a favourable context for the changes to be made. Of course, it should be remembered that communicating to health professionals and citizens in a clear and unambiguous way about the goals of disinvestment initiatives is important, as mentioned earlier. In devising and conducting mass media campaigns, support from health professionals and patient associations is of crucial relevance in order to maximise the chances of achieving the desired goals.

Recommendations

Recommendation 8: Implementation strategies aimed at stopping or reducing the use of low-value interventions should consider the contextual factors that favour or hamper the desired changes. Implementation initiatives undertaken at a system level could consider the options offered by the use of audit and feedback mechanisms, the cautious use of incentives, and use of mass media campaigns.

12 Theme 4: International collaboration

It is important to promote collaboration among health systems on policies aimed at reducing low-value care. While differences may exist across countries in terms of the health policy context, administration, organisation of services, and values, the problems to be addressed can be surprisingly similar and common. Inappropriateness in clinical practice, overuse and underuse of healthcare interventions are largely ubiquitous, although the main determinants of those problems may be different according to the context. Nevertheless, sharing experiences between countries may have a great beneficial effect, at least in helping to reach a common framework and taxonomy, and possibly a common methodological approach to the identification of low-value interventions.

The experience developed in Europe thus far by EUnetHTA, a network formed by health technologies assessment agencies from several European countries (http://www.eunethta.eu/), has already shown the benefit offered by cross border collaboration. For each individual country there are increased opportunities to rely on technical products developed elsewhere but with trustable, transparent, scientifically sound, and agreed upon methods and approaches. It is considered important, therefore, to mention the relevance that cross border collaboration could have for eliminating/reducing low-value care. Some European institutions have informally already started to establish collaborative relationships, and this type of effort should be encouraged and sustained.[2] Specific areas that could benefit from increasing the level of international collaboration include the development of common methods for the identification of low-value interventions, as well as the systematic sharing of the output of these efforts. Making lists of low-value interventions available to other countries provides the opportunity to explore to what extent these interventions are used in other local contexts. In addition, although implementation must be linked to each individual policy and the administrative, organisational, and cultural context in which it is developed, sharing experiences may help improve knowledge on how to overcome barriers to change in clinical practice.

Recommendations

Recommendation 9: It is important to foster collaboration among health systems, given the similarity of problems and challenges faced by individual countries, despite differences in policy and social context, administration, and the organisation of services. Sharing experiences between countries will help to reach a common framework and taxonomy for these policy initiatives. It will support a common methodological approach to the identification of low-value interventions and will offer the opportunity to avoid redundancies and duplications in the scientific and technical aspects of the process.

13 Theme 5: The need for policy relevant research

The development of a shared research agenda on how to tackle low-value care and its implications can be seen as a desirable outcome that an international collaborative effort on this theme could make possible.

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[2] Promoted by the National Health Care Institute in Amsterdam, some HTA agencies/organisations (from The Netherlands, Belgium, France, Italy, Germany, Austria, Switzerland) are currently participating into the "IZZI - Appropriate Care Network", where experiences in tackling health services overuse and its implications are shared and discussed.

Research could fruitfully address several aspects concerning the design and conduct of these initiatives, and provide relevant information on the characteristics and determinants of the problems to be faced. The scientific credibility, as well as the feasibility of policies aimed at withdrawing resources from low-value care, could benefit a great deal from relying on sound research that supports its methodological development and that guides its efforts in changing clinical practice through the provision of information on the key determinants of health services overuse.

Indeed, attempting to reduce low-value care means facing issues often neglected or overlooked by current health services research (16). Indeed, few studies on patterns of care have focused on the problem of overuse (17). As others have made clear, such a paucity of information on this issue is remarkably at odds with its policy relevance (10).

Lastly, research should also be considered as a tool to assess the actual impact of the policy initiatives undertaken (178) providing information on their effects on patterns of healthcare use, as well as on their acceptability by health professionals, patients, and citizens.

Recommendations

Recommendation 10: Research that addresses the methods, implications and effects of reducing low-value cancer care should be promoted and supported. Health policies are in need of good quality research that sheds light on health services overuse and its multiple determinants.

14 Theme 6: Patient engagement

The European Cancer Patients' Bill of Rights sets out the irrevocable rights of all European cancer patients to fast access to the best care available (http://ecpc.org/activities/policy-and-advocacy/policy-initiatives/138-european-bill-of-cancer-patients-rights). Notwithstanding the undeniable right of all cancer patients to access adequate cancer care, there are still unacceptable inequalities in cancer outcomes across Europe, as documented by the European Cancer Patient Coalition (ECPC) in its strategic policy document *Europe of Disparities in Cancer* (179). The participation of patients and patient representatives in the decision making process on disinvestment represents a key factor in ensuring that disinvestment policies meet their target, namely that disinvestment will not increase existing levels of inequality. On the contrary, it could build the bases for more sustainable and innovative management of the resources allocated to cancer care. To ensure the meaningful contribution of patients, it is necessary to consider the following factors, which will be further developed in the following paragraphs:

- Appropriateness of treatment versus disinvestment policies,
- Engaging in a public debate on disinvestment to inform citizens,
- Involvement of patients in all of the steps of HTA and
- Disinvestment's final aim: making room for innovation.

Appropriateness of treatment and disinvestment for reallocation policies

Notwithstanding the increasing cost of cancer care, the safety and outcomes of patients should remain the top priority for action by European health systems. For this reason, disinvestment should not be used as a scapegoat in order to cut healthcare services based on their financial performance. Disinvestment policies must be implemented in a way so as not to increase existing inequalities in cancer care in Europe. Disinvestment interventions should increase access to quality treatments. In fact, it is not sufficient to provide better treatments if they are not accessible to the majority of the patient population.

Disinvestment must improve the capacity of health systems to treat patients across a given country, rather than simply improve outcomes in few cancer centres. Therefore, it is important to ensure that disinvestment policies be paired with the full implementation of the Cross Border Healthcare Directive. Health systems' capacity to treat patients locally should not be hampered. If disinvestment policies recommend centralisation of healthcare services, health ministries must put balancing measures in place to ensure that they are fully accessible by the population, even those living in remote regions of the country. The same argument is valid for low-value procedures that can be highly beneficial for a small portion of the cancer patient population: crucial interventions for rare cancer patients should not be the object of disinvestment policies, at least not until the European Reference Network has the capacity to absorb and satisfy the needs of these patients.

Opening a public debate on disinvestment for reallocation to inform citizens

To ensure the success of disinvestment for reallocation policies, it is necessary to create public engagement and awareness that allows patients and civil society to both understand and endorse the decisions related to disinvestment. This step is crucial to obtain a general consensus on the necessity of disinvestment, therefore paving the way for implementation.

Priority setting and disinvestment procedures may trigger an adverse reaction by the population, if not well prepared and communicated properly. For this reason, it is advisable not only to involve patients and their representatives in decision making processes related to disinvestment, but also to lay the groundwork for such decisions through communication campaigns run in partnership with patient organisations, aimed at explaining the core principles behind disinvestment. The objective of the communication campaign should be to inform citizens about the advantages related to disinvestment, building trust in the disinvestment methodology and providing key elements to understand the criteria for the selection of treatments to be included in disinvestment policies.

Enhanced communication between decision makers and civil society on disinvestment should also aim to solve cultural issues related to disinvestment. Particularly important for the relationship between patients and healthcare professionals is the issue of defensive medicine, by which resources are wasted on diagnostic tests or treatments that are not necessarily the best option for the patient, but are an option that mainly serves to protect the physician against the patient as a potential plaintiff.

Involvement of patients in all of the steps of HTA

As the decision regarding disinvestment strategies is national, involvement of patient representatives should be a part of the process. The European Commission has demonstrated how decision makers can embed patients in consultative bodies (as in the Expert group on Cancer Control and in the collaborative partnership in the Joint Action CanCon). The same model should be used at the national level to include local cancer patient organisations in the decision making processes.

It is therefore crucial to identify patient experts and patient advocates at the local level able to meaningfully provide input in certain parts of the decision making process on disinvestment. Expert patients and their representatives should be involved in the process of HTA in order to embed the patient point of view before disinvestment strategies are put in place. Increasing patients' familiarity with HTA is a pre-requisite for ensuring that patients can meaningfully contribute to the debate on disinvestment. ECPC and other large umbrella organisations have a role to play in educating national patient organisations. On the other hand, medical associations and member states have to dedicate human and financial resources to ensuring that patients can meaningfully be integrated in the process of disinvestment, making them true partners within the process.

The final aim: making room for innovation

For many cancer patients, innovation in cancer care represents the only hope to fight the disease. Overall survival for many types of cancer has increased substantially: more than one fifth of all cancer patients are considered cured, since their life expectancy is equal to that of the average population. However, these impressive results have not been achieved in all tumour types, including some of high incidence (lung, stomach).

The successes in fighting cancer are based on better understanding of the biology of the tumours. It is therefore necessary to increase the resources allocated to research and development of innovative treatments, particularly for those cancer types for which the survival rates are very low (pancreas, rare tumours).

From the patient perspective, the main objective of disinvestment strategies should be to save and redirect resources to ensure patient access to meaningful and affordable innovation. Innovation in cancer care must aim to resolve existing inequalities, rather than increase the divide between EU countries/regions or within the same country. The rising costs of innovative treatment require that European health systems find sustainable ways to fund access to innovation. Cancer patients must have a role in evaluating which innovations are most meaningful, by being equal partners in the HTA process and in defining disinvestment priorities.

Recommendations

Recommendation 11: Every effort should be made to assure patient participation in the process of identification and removal of low-value and inappropriate cancer care.

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Policy Paper on Tackling Social Inequalities in Cancer Prevention and Control for the European Population

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Cancer treatment, survivorship and rehabilitation policies

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Recommendation 10: Ensure equitable access to high-quality surgical care in all European Union Member States.

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Recommendation 13: Develop national cancer rehabilitation and survivorship policies, underpinned by an equity perspective.

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S.R. 13.3: Integrate employment programmes into follow-up survivorship care, with additional emphasis among socially vulnerable groups, to support return to work after acute treatment.

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2 Executive Summary

Europe is characterised by unacceptable disparities in access to cancer care and by significant social inequalities between and within European countries, which deeply impact cancer incidence, survival and mortality. Wide social inequalities in cancer incidence and survival exist both between and within European countries. All European Union Member States are affected by inequalities in cancer care between various population groups. Survival is often much lower in Southern and Eastern European countries than the European average. Important geographic differences in survival also exist within Western and Northern European countries, indicating that access to quality cancer care is not uniform across all European regions and that more privileged groups have better outcomes, due to a combination of lower exposure to risk factors, better access to screening programmes, better access to health services, and better capacity to absorb the social and financial consequences of cancer. Disadvantaged groups in all EU countries are at higher risk for most of the common cancers.

Social inequalities in cancer outcomes also have significant financial consequences for individuals and their families, and major economic consequences for Member States and the European Union. These costs account for 15% of social welfare system costs and 20% of the overall cost of health systems in the EU. Social inequalities in cancer are thus not only unethical, but also have significant consequences for the financial sustainability of healthcare budgets in all EU Member States. Since social inequalities in cancer have common roots, both across the continent of Europe and between social groups within the European population, they should be addressed at the European level. The European Union can play a crucial role in addressing inequalities in cancer care, by planning joint actions in all EU countries and by implementing effective measures to minimise inequalities in cancer incidence and survival.

This policy paper is one of the deliverables of the Joint Action on Cancer Control (CanCon), an initiative of the European Commission with partners from 17 European countries. It provides practical recommendations on which the European Commission and Member States can base concrete actions designed to reduce social inequalities in cancer. These recommendations reflect the analysis of contributing experts regarding the challenges facing EU Member States. They reflect the shared learning that can be achieved from the approaches that individual Member States have already taken to address some of these challenges. The recommendations are also informed by a survey completed by Member States. The policy paper includes 13 general recommendations, grouped into 3 main focus areas: capacity-building; primary and secondary prevention; and cancer treatment, survivorship and rehabilitation.

The first area of focus of the recommendations describes actions that the EU can take to support capacity-building for cancer control and prevention. There is a need to strengthen cancer prevention and control policies across the EU, by developing valid indicators of equity and then formulating objectives that are specifically designed to improve equity in cancer outcomes. EU countries can also build upon the Health in all Policies approach, and adopt a Health Equity Impact Assessment framework to promote the assessment of the impact of current and new policies, programmes and health services on social inequalities in cancer. This process requires the engagement and empowerment of patients and communities, to ensure that socially vulnerable groups are fully involved. Capacity-building can also be supported by promoting professional expertise and the exchange of good practices to tackle cancer inequalities at the EU level. European research programmes that can help deliver equity in cancer prevention and control should also be developed.

The second area of focus aims at promoting equity in primary and secondary prevention policies. The implementation of proportionate universalism policies to develop and maintain living environments that facilitate compliance with the European Code Against Cancer is recommended. Furthermore, actions must be implemented to improve equity in access to and compliance with cancer screening programmes. These actions and policies must be addressed to the whole population, but with additional emphasis on socially vulnerable groups.

The third area of focus relates to the promotion of equity in access to cancer care and to survivorship and rehabilitation services. Equity in access to timely, high-quality and multi-disciplinary cancer care is essential. This requires an integrated model of cancer care management, and inclusion of equity as a quality criterion in cancer care guidelines. Equity in access to high-quality surgical care is also recommended, with particular efforts to be made in establishing benchmark standards for surgical oncology and providing information to patients on the volume of surgeries performed at each cancer centre.

Investments in radiotherapy equipment and training are also necessary to ensure sufficient radiotherapy capacity across the EU. Unacceptable inequalities exist in access to systemic therapy (including essential chemotherapies and innovative personalised medicines), which can be targeted by harmonising Health Technology Assessment procedures across Member States. Finally, Member States should adopt and implement national cancer survivorship plans. These plans should become an integral component of each patient's care pathway. They should also include programmes designed to enhance return to full employment and financial incentives to ensure reintegration of cancer survivors into active life.

Concepts and glossary of terms used in this document

Social inequalities in health: refer to differences in health that are systematic, socially produced, unnecessary and avoidable and are considered unfair and unjust (1). The European Commission recommends using the term social inequalities in health instead of social inequities in health, because it is more readily understood by the general public, and the term health inequities does not have a direct translation in all languages (2). These inequalities exist both between countries and/or regions and among social groups (3).

Equity in health: implies that each person should attain his/her full health potential and that no one should be disadvantaged from achieving this because of their social position or other socially determined circumstances. This refers to every citizen and not just to a particularly disadvantaged population segment (1).

Place of residence (including municipalities, regions and countries):
The habitual place of residence of each cancer patient at the time of diagnosis is the geographic basis of cancer registration from which all metrics of cancer incidence, prevalence and survival are derived. It is also a stratifying factor for socially determined circumstances. The role of the place of residence in determining health goes beyond socioeconomic status. Many of the differences in health outcomes related to place of residence are avoidable if the necessary infrastructure is in place. When the difference is related to distribution of services such that services are not available to populations living within certain areas, this can be considered unfair (4). Other socially stratifying factors that are determinants of health include: race/ethnicity, culture, language, occupation, sex and gender, religion, education, socioeconomic status, and social capital (4)..

Social gradient in health: the social gradient runs from the top to the bottom of the socio-economic spectrum. The social gradient in health means that health inequalities affect everyone (3).

Socially vulnerable groups: refer to subgroups of the population that- because of their position in the social structure- are at higher risk of multiple exposures to cancer risk factors, both clustered cross-sectionally and accumulated longitudinally throughout the life course (5) (e.g. people with mental, physical, and/or psychosocial disabilities, illiterate persons, refugees, prisoners etc.)

Social inequalities in cancer: refer to health inequalities that span the full cancer continuum and involve social inequalities in the prevention, incidence, prevalence, detection and treatment, survival, mortality, and burden of cancer and other cancer-related health conditions and behaviours (6).

Proportionate universalism approach: based on universal action but with a scale and intensity that are proportionate to the level of disadvantage (7).

3 Introduction

There is an urgent need for policies that support improved cancer prevention and control to be at the top of the European public health agenda. In 2012 approximately 3,450,000 European citizens were diagnosed with cancer, with over 1,750,000 dying from cancer (8). In 17 out of 28 EU countries, cancer has now overtaken cardiovascular disease as the leading cause of premature death (9). Cancer also places a significant social and economic burden on European citizens and societies.

In addition to these statistics, there are unacceptable social inequalities that exist across Europe in terms of cancer prevention, care, survival, and rehabilitation. There are also social inequalities- including geographical inequalities- related to cancer incidence, survival and mortality both between and within European countries (10-13). The situation is particularly challenging in Eastern Europe, with survival for many cancers below the European average (11). Western and Northern European countries also show inequalities in cancer care. This is reflected in lower survival from lung, colorectal and ovarian cancers in the UK and Denmark when compared to Norway and Sweden (14).

Social inequalities in cancer also occur within European countries (15-17). Social inequalities refer to the way in which differing social circumstances across the lifespan generate a social gradient in health through a myriad of complementary mechanisms (18). In terms of cancer, this means that more privileged groups have better outcomes because they have fewer risk factors for cancer, can take advantage of new interventions and screening programmes more quickly, have easier access to health services, and can minimise the social and financial consequences of cancer when it occurs (19). For example, disadvantaged groups are at greater risk for cancers of the lung, stomach, upper aero-digestive tract, and cervix (20). Lower participation in cancer screening programmes and delayed diagnosis has been reported for those with lower socio-economic status (21-23). Socially vulnerable groups, such as people with mental health problems, a physical handicap, children and adults with intellectual and or psychosocial disabilities, illiterate persons, refugees, and prisoners, also suffer from social inequalities in cancer (24-27). Social inequality is also associated with comorbidity, because socially vulnerable groups have greater exposure to multiple risk factors, which makes them more vulnerable to both cancer and other diseases.

Social inequalities in cancer can have their origin in childhood, when social conditions can influence longer-lasting exposures that may lead to increased risk of developing cancer in later life. Behavioural risk factors can be transferred from parents to children, and there is significant evidence that a healthy lifestyle is influenced by positive experiences in early childhood (18, 28, 29). This implies that improving social conditions in early life is likely to confer health benefits for the rest of an individual's lifetime (30).

Unacceptable inequalities exist in the provision of cancer care. A significant proportion of European citizens have inadequate access to surgery, radiotherapy and systemic therapies. These treatments have been shown to prolong lives and can achieve long-term cures (31, 32). Access to innovative treatments, including personalised medicine, a number of which have demonstrated substantial therapeutic benefit, is also denied to a significant number of European citizens (33).

Cancer care and control does not stop when initial treatment ends. Living with and beyond cancer must be underpinned by cancer policies that support survivorship and rehabilitation. For many people who survive cancer, transitioning to a normal and productive life can be extremely challenging. It may also involve suffering from discrimination because of perceived stigma related to the disease. Socially disadvantaged groups face greater unmet need for rehabilitation services (34), and they have more difficulties returning to work (35).

Social inequalities in cancer outcomes also have significant financial consequences for individuals and major economic consequences for Member States and the European Union. They account for 15% of social welfare system costs and 20% of the cost of health systems in the EU (36). The societal burden of cancer in Europe is also reflected in huge losses in productivity due to early death (€42.6 billion a year) and lost working days (€9.43 billion a year) (37). Analysis of GLOBOCAN figures from 30 European countries confirms the significant lost productivity costs due to premature cancer-related mortality (38).

The economic burden of home or family care of cancer patients is substantial (39) and might be even more costly in terms of time spent in caregiving, learning caregiving skills and sacrifice of leisure time in families without resources to hire a formal caregiver (40). Caregiving also leads to reduced working hours (41), wage penalties (42), and disbursements for medical treatments (43). As female family caregivers report higher levels of stress and burden than male caregivers (44), caregiving for cancer patients is also related to gender inequality.

A central tenet of this paper is that social inequalities in cancer are not only financially intolerable but unethical. The EU thus has a responsibility to patients and the wider population to take measures to address these inequalities, both for the 3 to 4 million citizens who develop cancer every year, and more generally for the entire European population, up to half of whom will be expected to develop cancer at some point in their lives.

Social inequalities in cancer have common roots, both across the continent of Europe and among different social groups within the population. They should therefore be addressed at the European level, through strengthened collaboration between Member States, European institutions and key European and national stakeholders. Policy makers, health and social care professionals, and civil society must become aware of the unfair and avoidable nature of these inequalities. There are many examples that show the way in which EU-level cooperation can be of added value in cancer control, for example the European Partnership for Action Against Cancer (45).

This policy paper is a product of Work Package 5 (WP5) of the Cancer Control Joint Action initiative of the EU. It provides practical recommendations on which the European Commission and Member States can build and implement concrete actions to reduce social inequalities in cancer. It aims to promote equity-oriented policy making related to cancer prevention and control by highlighting practical actions to tackle social inequalities in cancer at the European and national levels, thus ensuring that reducing social inequalities in cancer is a top priority within European and national strategies on cancer prevention and control, especially through the National Cancer Control Plans.

These recommendations reflect contributing experts' analysis of the current challenges that are faced by EU Member States and the shared learning that can be achieved from the approaches which individual Member States have taken to address these challenges. In addition, the recommendations are informed by a survey that was sent to Member States (see Table 1). A call for experts was launched in July, 2015 by the European Commission, and 23 experts were selected in order to review the policy paper drafts. A literature review was performed between September and October of 2015 to identify evidence of cancer inequalities and any regional, national and European-wide strategies designed to tackle them.

In 2016 Member States were surveyed on their experiences in tackling social inequalities in cancer. We received 7 completed surveys, and the information was incorporated into this policy paper with the reference "Member States Survey, 2016". Examples identified from the literature review have been included to illustrate all of the recommendations in this paper. Information provided by Member States in the survey was used to complement these examples.

Table 1. Survey sent to Member States to determine the current situation and collect experiences on tackling social inequalities in cancer.

1. Has the equity perspective been included in the cancer control plan or cancer policy of your country?

Yes ☐ Partially ☐ No ☐ Short comment ………………………………

(in all questions of this survey these answer options were included)

2. Has evidence of cancer inequalities in your country been assessed?

3. Have any information gaps in cancer inequalities been identified in your country?

4. Have the cancer policies related to health promotion and prevention targeted health inequalities?

5. Is the cancer policy/strategy of your country linked to a "Health in all Policies" strategy? (working beyond the health sector)

6. Has a cancer trans-disciplinary working group been organised, including inequalities experts?

7. Are the cancer professionals of your country being trained to address special needs of vulnerable groups in the population?

8. Have community and patient participation mechanisms been implemented during the process of cancer policy development?

9. Has equity been embedded in every cancer programme or service at the level of public health and healthcare provision? (For example by using an equity assessment tool)

As causes of cancer inequalities are multiple and inter-related, the action to tackle them needs to be interconnected across levels and sectors. Therefore, we are also interested in examples of actions and policies to address health inequalities carried out in your country. Regarding this issue, we have available the following information extracted from a complete study carried out by Sir Michael Marmot and published in the report: "Health inequalities in the EU — Final report of a consortium." Consortium lead: Sir Michael Marmot. European Union 2013 http://ec.europa.eu/health/social_determinants/docs/healthinequalitiesineu_2013_en.pdf

Please check the following figure, explained in the table, and answer the question below.
From your knowledge and experience in your ministry:

10. Does the response to health inequalities in your country remain in the same cluster?

Yes ☐ No ☐

☐ It has improved

☐ Now It is in cluster: 1, 2, 3

☐ It has worsened

☐ Now It is in cluster: 1, 2, 3

If you have any good experience related to health inequalities responses that could be shown as an example, please write a short description or send us any document attached or link:

Cluster	Cluster	Countries
Cluster 1 — Relatively positive andactive response to health inequalities	Countries in this group have at least one national response to health inequalities (often alongside a number of regional initiatives) or all regions of a country have a regional HI-focus policy. Other supporting policies tend to have explicit aims to reduce health inequalities.	Denmark, Finland, Ireland, Netherlands, Norway, Slovenia, United Kingdom
Cluster 2 — Variable response to health inequalities	Countries in this group do not have an explicit national policy on health inequalities, but they have either at least one explicit regional response to health inequalities or a number of other policies with some focus on health inequalities and explicit aims to reduce them.	Belgium, Bulgaria, Croatia, Czech Republic, Estonia, France, Germany, Iceland, Italy, Latvia, Lithuania, Luxembourg, Poland, Portugal, Spain, Sweden
Cluster 3 — Relatively undeveloped response to health inequalities	Countries in this group have no specifically focused national or regional policy responses to health inequalities. Policies do not have explicit health inequality reduction targets, though they may imply actions to reduce them through universal or targeted measures acting on the social determinants of health or access to healthcare services.	Austria, Cyprus, Greece, Hungary, Malta, Romania, Slovakia

Although research groups that analyse data on social inequalities in cancer do exist in many countries, results are not pan-European, and a formal commitment by governments or governmental agencies to monitor and act on social inequalities in cancer is very rare.

This policy paper has 13 general recommendations that focus on 3 main areas: capacity-building; primary and secondary prevention; and cancer treatment, survivorship and rehabilitation. Each general recommendation includes a background based on evidence, specific recommendations, and examples identified through the Member States Survey, experts' knowledge, and the literature review.

This policy paper advocates for the need to explore the basis for social inequalities in cancer in Europe, and makes recommendations for policy makers that focus on addressing social inequalities that exist across the cancer continuum. Each Member State should adapt the recommendations to their specific policy needs, based on knowledge of the cancer profile of the population and the economic and social context.

4 Recommendations

Capacity-building for cancer prevention and control

Recommendation 1: Embed equity within the cancer prevention and control policies in all European Union Member States.

Including equity targets in cancer prevention and control policies raises awareness at all levels of action. Initiatives that tackle health and cancer inequalities such as those undertaken by the Commission on the Social Determinants of Health (46) have influenced the policy agenda at many levels. Universal coverage requires that every individual within a country or region can access the same range of optimal quality services, according to needs and preferences, regardless of income level, social status, or residency, and that people are empowered to use these services. It extends the same scope of benefits to the whole population (46). A recent review of National Cancer Control Plans in Europe concluded that key goals to achieve equity are notably absent and that there is no explicit mention of how equity goals will be met, (47) thus highlighting the challenge that EU nations face.

Well intentioned universal policies and welfare programmes may inadvertently worsen social inequalities (5, 48-50) because more privileged groups are better equipped to take advantage of new knowledge and have access to interventions at an earlier stage (51, 52). To reduce the steep social gradient in health, a proportionate universalism approach (7) is needed. Actions must be universal, but with a scale and intensity that is proportionate to the level of disadvantage. In this approach health services are universally available, not only for the most disadvantaged, and they are able to respond to the level of presenting need (7). It is essential to identify barriers to equity in cancer, to define goals to improve equity and to identify the obstacles faced by specific groups allowing the subsequent design of tailored strategies to address these barriers and needs (1, 53).

S.R. 1.1: Formulate specific objectives that aim to tackle social inequalities in cancer across the whole population with additional emphasis on socially vulnerable groups.

Examples:
The third National Plan Against Cancer 2014-2019 in France promotes equity in prevention, care, rehabilitation and cancer research. Objectives related to equity include:

"[…]To combat inequality in uptake of and access to screening, and to increase the efficiency of programmes, in order to reduce avoidable deaths and the more severe treatments associated with delayed care", and "[...]To reconstitute and analyse patient care trajectories by shedding light on their association with risk factors (behavioural, environmental, or professional) and social determinants (level of education, employment, income level, etc.) so as to reduce inequality and adapt public policy to needs."[1]

As reported by the Member States Survey (2016) the National Cancer Strategy in Spain focuses on gender inequalities in cancer. In Poland, the National Health Programme aims to undertake actions targeted at reducing health inequalities in all areas of the healthcare system, including cancer control. Austria has a specific target that aims to provide equity in health promotion and care to the whole population independent of age, sex, origin and socioeconomic background.

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[1] Available at http://www.e-cancer.fr/Expertises-et-publications/Catalogue-des-publications/Plan-cancer-2014-2019.

S.R. 1.2: Include indicators of social inequality within the quality criteria established for cancer prevention and control programmes.

Example:
Most European health systems are based on the principle of equity (54). However, it is difficult to find indicators that systematically measure results according to socio-economic variables. Some examples exist in which institutions have included equity as a quality criterion: for example, every hospital and long-term care home in Ontario is required to submit formal Quality Improvement Plans (QIPs) (54). This simple requirement signals a commitment to high-quality care across the health system, and it has positive implications for an equity-oriented quality strategy. By introducing equity as an element of the QIP process, institutions will be encouraged to incorporate equity as an essential element of quality, and best practices can be shared. For example, in "Measuring-Up" (a yearly report on the health of Ontarians and how the health system is performing), inequalities are highlighted both regionally and amongst different populations. The institution also believes that equity cannot just be implicit in its work–equity needs to be explicitly reflected in its quality efforts (55).

Recommendation 2: Align cancer prevention and control policies with a Health in all Policies approach.

The many causes of social inequalities in cancer are inter-related, so the actions to tackle the causes must also be interconnected, both across sectors and across intervention levels (56). The Health in all Policies approach involves coordinating policy sectors to address the social determinants of health that are the root causes of social inequalities in cancer (46, 57). The existence, and long-term persistence, of social inequalities in cancer and other non-communicable diseases suggests a prolonged failure of society to develop and implement policies to foster healthy household and community environments, facilitate healthy lifestyles and diet, and to deliver high-quality healthcare to all citizens (58). For an effective impact on the cancer-related social gradient in health, the involvement of non-health sectors is also needed, especially from the many sectors that have a direct impact on health, including education, social policy, environment, labour and immigration, housing, urban and regional planning, transportation and active mobility, and the economy (59, 60). A successful Health in all Policies approach could be facilitated in several ways. However, it is of primary importance that there are mechanisms of engagement such that different sectors that impact health are committed to working to support health and health equity (60), including citizens. Concerted and coordinated action on the social determinants of health requires strong political leadership at the local, national and international levels (60).

S.R. 2.1: Create a multi-sectoral working group that includes experts on social inequalities in health to embed a Health in all Policies approach within cancer policies.

Example:
From the Member States Survey (2016): Under a new 2015 law on public health, the next National Health Programme in Poland will be a multi-sectoral action coordinated by many ministries and governmental agencies. The Steering Committee of this programme will monitor and coordinate the actions undertaken during implementation of the programme, including the Minister of Health and the Undersecretary of State in other ministries. The Council on Public Health, including healthcare experts, will serve as an opinion-giving and advisory body of the Minister of Health for issues related to the programme. In this way, a focus by non-health ministries and sectors on the social determinants of health can help to provide a wider perspective on equity issues.

S.R. 2.2: Assess the impact of current and new policies, programmes and health services on social inequalities in cancer.

Example:

The "Apprendre et Agir pour Réduire les Inégalités Sociales de Santé" in Toulouse (France) is a health equity impact assessment umbrella programme to analyse and modify interventions related to cancer- which are already underway- in terms of their potential impact on health inequalities. It relies on partnership between researchers and other actors in the health field, including policy makers. Many partners have rallied around this program, which has been shown to be feasible and acceptable by partners and health actors (61).

S.R. 2.3: Produce a report on social inequalities in cancer, and make it available to the public.

Examples:

The National Cancer Equality Initiative (62) in England published a report on inequalities in cancer titled Reducing Cancer Inequality: Evidence, Progress and Making it Happen (2010). It compiled the most accurate figures in order to identify gaps in knowledge, and thus to increase awareness about social inequalities in cancer.

In England a study (2013) analysed the effectiveness and the equity impacts of town-wide cycling initiatives, showing that after a major investment in more deprived areas, the situation improved in all studied areas, with larger relative changes in deprived areas (63).

Recommendation 3: Adopt a Health Equity Impact Assessment framework.

Knowledge is crucial to inform policies designed to influence population health and welfare, particularly in terms of policy effectiveness, efficiency, and equity (64). Information on the social determinants of cancer risk and outcomes in a population can be used to monitor trends and allow for comparison of the ways in which cancer affects different social groups (46). Long-term monitoring of cancer inequalities contributes to the evidence base for comprehensive policies on cancer control. Population-based cancer registries can support a wide range of studies on cancer inequalities in the EU, although not all cancer registries collect individual socio-economic data (65); in some cases, area-based indicators have been used (66). Difficulties have also arisen in gaining access to data for research, due to national legislation on confidentiality, which anticipated the approval of the European regulation on protection of data (67). It is therefore important to harmonise data gathering and processing to address inequalities in cancer, in order to foster comparisons of cancer incidence and survival trends. Although research groups analysing data on social inequalities in cancer do exist in many countries, the results do not cover all of Europe, and formal commitments by governments and governmental agencies to monitor social inequalities in cancer are rare.

Health Equity Impact Assessment is a useful tool to develop public policies designed to promote equity in health (68, 69). It aims to identify potential health impacts (positive or negative) of a plan, policy or programme on socially vulnerable or disadvantaged groups within the general population. Several tools have been designed to provide systematic steps for health policy makers, programme planners, and researchers to assess their initiatives through the lens of a health equity perspective (70-72).

S.R. 3.1: Assess the evidence on social inequalities in cancer and identify any gaps in knowledge.

Example:
Results from the Member States Survey (2016) suggest that social inequalities in cancer have been assessed mainly in terms of geographic or regional differences in incidence and mortality within a country (Spain, Poland and Lithuania). Spain also reported that inequalities in cancer have been assessed by gender. Austria reported the identification of gaps in information on social inequalities in cancer, and has also partially assessed these inequalities.

S.R. 3.2: Introduce a unique national identifier to facilitate safe record linkage between different databases in each European country in order to monitor cancer inequalities.

Example:
In the framework of the Turin Longitudinal Study (Italy), the cancer registry, screening programmes, and breast cancer treatment regional databases have been individually linked to socio-economic indicators from the census through an anonymous unique regional code, thus providing detailed information about social inequalities in access to screening and in cancer incidence, treatment and survival in Turin (73-75).

S.R. 3.3: Collect information on patients' reported outcome measures (PROMs), and link this information with cancer registry data.

Example:
The patient reported outcome measures (PROMs) of the National Health Service of England is a mandatory national data collection system, the purpose of which is to gather key information on the health status of patients before and after their operation. A report titled Quality of Life of Cancer Survivors in England was published in 2012 (75), piloting a survey using PROMs. This survey was commissioned by the Department of Health as part of the National Cancer Survivorship Initiative (NCSI). The survey was conducted by the Quality Health Department in conjunction with three cancer registries in England. The first aim was to assess the feasibility and acceptability to cancer survivors of collecting information on quality of life (QoL) with PROMs. The second aim was to assess the overall QoL of representative samples of cancer survivors with four different tumour types (breast, colorectal and prostate cancer, and non-Hodgkin lymphoma) at four different time points after diagnosis (approximately one, two, three or five years) (76).

S.R. 3.4: Use the Health Equity Impact Assessment tool to assess systematically the impact of policies on social inequalities in cancer.

Example:
A paper from England gives an example of how this tool can be used by urban planners, health policy decision makers and other municipal authorities to support the health and equity assessment of policies and interventions affecting air pollution. These tools aim at identifying the various modifiable factors that can be mobilised to increase the positive impact of policies and interventions. It can be used by those who may not necessarily have or need a sophisticated epidemiological model (77).

Recommendation 4: Engage and empower communities and patients in cancer prevention and control activities.

The Ottawa Charter for Health Promotion (78) highlighted the importance of effective community action in setting priorities for health, including in decision making and the development and implementation of strategies to improve the health of citizens. Subsequent publications have reinforced this perspective (78-81). Community participation is a means and a necessary step to improve the health of the population and to increase the capacity for interventions related to the social determinants of health. Empowerment has been found to improve the social acceptability of interventions and cancer-related outcomes (82). This requires a shift in emphasis, from provision of information to the population, to fostering their participation in decision making processes. This, in turn, requires in-depth knowledge of the population, to facilitate outreach and engagement on the part of health professionals, community workers and lay health advocates. Providing a voice to the population can help ameliorate social inequalities by incorporating the needs of different social groups into cancer programmes.

Patient-centred care in cancer requires a multi-level approach, in order to understand patients' concerns, needs and expectations, all of which can change during the many stages and cycles of diagnosis and treatment (83). There are many aspects related to patients in the process of cancer care; the individual patient's view of his or her disease, as well as the treatment process; the interaction with the family, friends and caregivers; the relationship with the surrounding society and culture (84), and finally, communication barriers with the healthcare provider, especially with respect to unmatched health belief models and understanding of treatment goals (85, 86). Empowerment is fundamental to the principles and approaches of patient-centred care. Healthcare providers should adopt a partnership style with patients. They should provide healthcare that is respectful of patients, in order to support informed patient decision making (87).

S.R. 4.1: Involve communities and patient associations in decision making processes.

Examples:

The principles of the European Cancer Patients' Bill of Rights (BoR) promote three main rights for all cancer patients in Europe.

1 The Right of every European citizen to receive the most accurate information and to be proactively involved in his/her care.

2 The Right of every European citizen to equal and timely access to appropriate specialised care, underpinned by research and innovation.

3 The Right of every European citizen to receive care in health systems that ensure improved outcomes, patient rehabilitation, best quality of life and affordable healthcare.

The Bill of Rights, developed by the European Cancer Concord (a coalition of patient groups and healthcare professionals) and the European Cancer Patient Coalition (ECPC), is a beacon for the work of many national and local patient associations in Europe and represents a useful stepping stone for the implementation of truly patient-centred cancer care in Europe (88, 89).[2]

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[2] Available at: http://www.ecpc.org/activities/policy-and-advocacy/policy-initiatives/138-european-bill-of-cancer-patients-rights.

The Member States Survey (2016) showed that in Spain, cancer patient associations are members of the Monitoring and Evaluation Committee of the National Cancer Strategy, and they participate actively in the elaboration, implementation and evaluation of the strategy. Austria reported that a patient representative had been involved during the entire development period of the National Cancer Framework Programme.

S.R. 4.2: Ensure that socially vulnerable groups are involved in the design, implementation and evaluation of health policies related to cancer prevention and control.

Example:
A literature review identified numerous cases where cancer patients were engaged in health policy and planning in the UK, Scotland and in other countries. The participation of patients from minority ethnic groups was specifically sought out in the United States and in Australia (90).

S.R. 4.3: Ensure that all patients receive up-to-date and accurate information and are proactively involved in their care.

Example:
In the UK, Evans (91) identified the different forms that user involvement can take in cancer services and explored the necessary elements for effective patient engagement. They found a range of factors that influence cancer service users' participation in service development and delivery that can be taken into account in European countries.

Recommendation 5: Promote the exchange of good practice and support development of professional expertise in social inequalities in cancer in all European Union Member States.

Encouraging exchange of good practice and sharing expertise between countries to tackle social inequalities in cancer is vital to long-term improvement in cancer outcomes (92).

Better training for cancer professionals is required to support a shift towards improved equity in cancer care and to help guarantee the right to health for the whole population. The Social Determinants of Health approach (46) and education about the importance of achieving equity should form part of the educational curricula for undergraduate and postgraduate degrees in all disciplines that play a role in cancer prevention, care and rehabilitation.

S.R. 5.1: Foster exchanges of professional experience in all European Member States in tackling social inequalities in cancer.

Example:
The EUROCOURSE action (Europe Against Cancer: Optimisation of the Use of Registries for Scientific Excellence in Research) (93) aims to develop necessary standards to support use of registry data in research. This is part of the infrastructure to streamline data collection by European cancer registries, in order to provide better cancer statistics for Europe. Best practices will be documented and recommendations will be drafted on the issues of ethics, evaluation of the effectiveness of screening programmes using data from cancer registries, and the design of population-based genetic studies using biobanks.

S.R. 5.2: Provide appropriate training for cancer prevention, care, and rehabilitation professionals to tackle social inequalities in cancer.

Example:
The French National Cancer Institute (INCa) has hosted a "Cancer equity task force" for several years. This think tank gathers professionals from virtually all INCa services and cancer-related professional groups. It has helped foster reflection about how to improve equity and how to ensure that measures included in the cancer plan are equitable by design.

Recommendation 6: Support the development of European research programmes that help deliver equity in cancer prevention and control in all European Union Member States.

There are enormous differences in research capacity across Europe, both between countries and between disciplines (94). Research on social inequalities in cancer is underfunded, both in Member States and across the European Union. Adequate support for research is crucial to generate evidence for evidence-based decision making (46). Data and evidence on the social determinants of health may come from many disciplinary backgrounds and methodological traditions, including social history, economics, social policy, politics, sociology, environmental science, and epidemiology. This pluralistic approach is essential in order to produce systematic studies of the effects of policies on social inequalities in cancer (95).

Cancer research in Europe is of a high standard, but fragmentation and lack of sustainability are the greatest barriers to implementing innovation in cancer care. Integration of research data from many data sources across the complete continuum of cancer care represents a powerful research tool for Europe but is difficult to achieve. Solving this problem would substantially improve the study of inequalities in cancer outcomes between countries (96). Standardisation of data collection, interoperability between cancer information systems and support of internationally standardised protocols are pre-requisites for success. This would enable more effective evaluation of prevention policies, as well as mapping variations in the standards of care and in cancer survival. Data on patient values and preferences could also be added to the database to incorporate the cancer patient's perspective (97, 98).

Example:
In the Member States Survey (2016), France reported that it supports research designed to improve understanding of factors and processes that create inequalities across the cancer continuum (e.g. higher exposure of lower social classes to cancer risk factors such as smoking etc.) This is one of the equity objectives in the National Plan on Cancer.

Primary and secondary cancer prevention policies

Recommendation 7: Implement proportionate universalism policies to develop and maintain living environments favouring compliance with the European Code Against Cancer.

Social inequalities in cancer related to incidence and mortality are associated with the socially patterned distribution of the main modifiable risk factors for the most common types of cancer: smoking, alcohol, diet and exercise, viral infections, occupational exposures and reproductive behaviours (99-101). These risk factors are largely avoidable or preventable, but they are disproportionately prevalent in poor and disadvantaged communities. The European Code Against Cancer focuses on actions that individual citizens can take to help prevent cancer (102).

Many population health interventions focus on unhealthy behaviours that are key contributors to the cancer burden, but successful cancer prevention requires various levels of action (individual, legislative, etc.) supported by government policies (102, 103). Without targeted prevention programmes, intervention or communication campaigns can inadvertently contribute to widening inequalities via the so called "Inverse Prevention Law" under which more educated or affluent groups of society can more readily access or interpret messages about prevention or screening and are better able to act on them to change their behaviour and reduce their risk (48, 104).

Interventions to promote healthy behaviours are a potentially powerful contribution to the primary prevention of cancer. Among risky behaviours, smoking is certainly the risk factor that accounts for the highest burden of disease in cancer and in general morbidity. Social inequalities in smoking follow the so-called "smoking epidemic", with higher socio-economic classes adopting this habit very early and successively abandoning it, while smoking becomes progressively more common among lower socio-economic groups (105). In women, these patterns have usually lagged 10–20 years behind those of men. Various countries are in different stages of this epidemic, therefore there are quite different patterns in the social gradient by gender across Europe. Unfortunately, however, there is some evidence that general tobacco control policies are more effective among higher socioeconomic groups, and they may therefore contribute to widening inequalities unless specific targeted actions are undertaken (106). Research is needed to develop interventions that explicitly focus on socially vulnerable groups.

S.R. 7.1: Ensure that tobacco and alcohol control policies, as well as other interventions promoting healthy behaviours, are addressed to the whole population with additional emphasis on socially vulnerable groups.

Examples:

A recent project supported by the EU Public Health Programme aimed at evaluating the implementation of the EU Strategy on nutrition, overweight and obesity, has assessed the equity impact of interventions encouraging healthy diet and physical activity.[3] The report found some evidence that providing healthy foods at schools can reduce the social gradient in unhealthy diets and is an effective strategy in the long term. More generally, actions developed under the life-course approach, focusing on crucial stages of life (e.g. gestation and early childhood) have great potential to reduce inequalities in obesity, which are increasingly affecting women more than men, and also affect children.

A systematic review of interventions to promote healthy eating that evaluate the differential impacts by socioeconomic position found that upstream policies- such as those that combine taxes on unhealthy foods with subsidies for healthy foods- appeared to decrease social inequalities. By contrast, individual interventions, especially dietary counselling, seemed to increase social inequalities in dietary fat intake (106).

The Hungarian government's public school food policy mandates a reduction in unhealthy foods such as salt and red meat and an increase in the proportion of healthy foods such as vegetables and fruit.[4] Among other actions (development of standards and guidelines, restrictions on marketing of food or sweet drinks on school premises, etc.), the programme includes provision of food at

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[3] Available at http://ec.europa.eu/health/nutrition_physical_activity/docs/pheiac_nutrition_strategy_evaluation_case_study_en.pdf.

[4] Available at https://ec.europa.eu/jrc/sites/jrcsh/files/jrc-school-food-policy-factsheet-hungary_en.pdf

schools. The programme is free for socially vulnerable groups of children during the school term as well as during school holidays. In parallel, more time has been devoted to physical education in primary and secondary schools in order to reduce obesity and improve general health.

Recommendation 8: Improve equitable access and compliance with cancer screening programmes.

Population-based screening programmes reduce mortality from cancer of the breast, cervix and large bowel (colon and rectum). Socio-economic and geographic inequalities in access to timely diagnosis and high-quality treatment are likely to be key determinants of inequalities in cancer survival, especially for cancers with a good prognosis (23). Evidence suggests that population-based screening programmes that include comprehensive quality assurance of diagnostic services and personalised invitations to all individuals in the eligible target population (107) ensure greater equity in access to timely and high-quality diagnosis than is possible with opportunistic screening (108, 109). Population-based screening programmes are more effective at channelling screen-detected patients into a protected, effective and evidence-based pathway of care (75). However, social inequalities in participation in cancer screening still arise within population-based screening programmes. For example, participation rates are often lower in lower socioeconomic groups (110), minority ethnic groups (111), people with intellectual disability (112), and people living in underprivileged areas (108, 110-116). Participation in and the performance of population-based screening programmes varies widely between countries (117-120), indicating inequalities in access to and the effectiveness of some of these programmes (116-122).

Some strategies have been shown to enhance access to screening among lower socioeconomic groups (7, 120). These strategies include offering free testing, elimination of geographical barriers to access (such as introducing mobile screening units), greater involvement of primary care physicians, and communication strategies tailored to specific groups of the population in which uptake of screening is known to be poor.

S.R. 8.1: Provide screening processes that address the whole population with additional emphasis among socially vulnerable groups.

Example:
The Reference Centre for Epidemiology and Cancer Prevention in Piedmont (Italy) coordinates the regional programme for female cancer and colorectal cancer screening. To promote participation in cervical cancer screening of immigrant women, the programme undertook initiatives aimed at improving the quality of communication and access to screening facilities. A multi-disciplinary team was created including medical doctors, community health workers, members of associations working in the field of immigration and cultural mediators. Leaflets and posters in eight languages (Romanian, Russian, Arabic, Chinese, Albanian, English, French and Spanish) were produced and disseminated in clinics, pharmacies, medical offices, cultural centres and associations in Piedmont and were included in a wider mass campaign with posting on regional transport systems (buses, trams, trains).[5]

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[5] Available at: http://www.cpo.it/en/articles/show/prevenzione-serena-integration-also-in-prevention/.

S.R. 8.2: Ensure the development and implementation of guidelines for quality assurance in cancer screening, which must include equity as a quality criterion.

Example:
The two main goals of the European Commission Initiative on Breast Cancer (ECIBC) are to develop the European guidelines for breast cancer screening and diagnosis and the voluntary European Quality Assurance scheme for Breast Cancer Services. The Quality Assurance Scheme Development Group is working on the definition of quality requirements and indicators that will address quality domains related to clinical effectiveness, facilities, resources and workforce, personal empowerment and experience, and safety. Equity is a transversal item that has been included as a quality indicator (121).

Cancer treatment, survivorship and rehabilitation policies

Recommendation 9: Ensure equitable access to timely, high-quality and multi-disciplinary cancer care.

The European Action Against Cancer (EPAAC) (www.epaac.eu) has set out the need for multi-disciplinary cooperation to improve the care of cancer patients. Multi-disciplinary care has rapidly become a standard approach to the management of cancer patients since 2000 (123). A multi-disciplinary team (MDT) can be defined as a team of medical and health professionals who manage patients with a specific type or group of tumours, such as brain tumours or lymphomas. The MDT is characterised by professional collaboration, evidence-based clinical decision-making and coordination of the delivery of care throughout the cancer patient pathway. Furthermore, MDTs should encourage an active role of patients and caregivers in cancer management. Cancer care is increasingly complex, and MDTs involve a growing number of specialist disciplines, including areas as diverse as psychosocial support, genetics and frailty. In this context, consensus decision making becomes particularly important (124). A systematic review showed that multi-disciplinary cancer teams produce better clinical and process outcomes for cancer patients, in terms of survival and reduced waiting time from diagnosis to treatment, reducing social inequalities in care (125).

Organisational models of cancer care have a great impact on outcomes. The EPAAC and CanCon projects have examined organisational models designed to improve outcomes. One literature review of networks as an organisational model has suggested that they have the potential to improve the quality of healthcare services, equity of access, knowledge transfer and the cost-effectiveness of health services. Networks also have the potential to provide more patient-centred services.

Socio-economic disadvantages in access to optimal treatments exist across Europe. Well-documented examples of lack of access to optimal treatment exist for lung, colon, pancreas, prostate, oesophageal and breast cancer in different European countries (126-128). Patients in lower socioeconomic classes show higher levels of comorbidity and lower levels of adherence to treatment, which greatly affect survival (129). The EUROCARE Project (11) and International Cancer Benchmarking Partnership (14) indicated lower survival for patients over 65 years of age, reflecting a potential ageism in the delivery of cancer care and possible widening of the survival gap between older and younger patients in Europe. In many European countries there is increasing evidence that older patients are under-treated and that this lack of equity in access to cancer care is leading to poorer outcomes (130). This may have an even greater impact in countries without universal health coverage.

In addition to implementing the EPAAC recommendations on multi-disciplinarity in cancer care, two other key factors play a role in facilitating equitable access to multi-disciplinary care: patient navigation programmes and clinical practice guidelines.

Patient navigation programmes are increasingly being used to address inequalities in healthcare, and in cancer care in particular. Successful patient navigation includes instrumental interventions to identify and meet patients' needs (e.g. insurance, transportation, information) and relationship interventions to enhance the interaction between patients and clinicians. It has been shown to be effective in helping women to access cancer screening, to receive more timely diagnostic resolution after an abnormality has been detected during breast or cervical cancer screening, to initiate treatment sooner, to receive appropriate treatment, and to improve quality of life after a cancer diagnosis. The patient navigation model has been most widely adopted in the USA, but several schemes have been implemented in the UK and the Nordic countries, in collaboration with oncology nurses (131). In other EU countries, cancer patient associations may arrange for volunteers to provide navigation services where the health-care institution cannot provide this intervention. Collaboration between cancer patient organisations, hospitals and universities could promote training and education for patient advocates or survivors as volunteer patient navigators. This could improve the integration of patient navigators into the cancer care pathway.

The implementation of clinical practice guidelines that have been developed through international consensus among clinicians can help reduce social inequalities in cancer by minimising differences in the quality of care. This requires equal access to screening, early diagnosis and treatment. The many factors that can act as barriers to the effective implementation of clinical guidelines need to be addressed. These include provision for training of specialists who are expected to deliver guideline-compliant treatment, and formal guidance on organisational aspects of their implementation.

S.R. 9.1: Implement an integrated model of cancer care management, whereby primary and secondary care are seamlessly linked.

Example:

The chapter on integrated care in the CanCon Guide developed within Work Package 6 (WP6) uses as an example of better access to quality cancer care the creation of Comprehensive Cancer Care Networks (CCCN) at the national level. CCCNs reconcile the expertise of high-volume specialised referral centres with the greater accessibility of general hospitals and of other healthcare institutions (imaging centres, community care centres, etc.) as well as of primary care providers (general practitioners, home nurses, and others). In terms of social inequalities, the contributors to the CCCN could facilitate access to quality cancer care for patients who may be less likely to seek specialised healthcare in existing comprehensive cancer centres. CCCNs may effectively address territorial inequality in access. Access points to a CCN should be clearly defied; i.e. access points should be as close as possible to where patients reside, and uniformly optimal care should be provided as close to home as possible.

An analysis of physician utilisation by income in 21 OECD countries, drawing on data from national surveys or the Community Household Panel, reported no inequalities in primary care physician visits and an inequality in specialist consultations that favoured those with high incomes (132).

S.R. 9.2: Implement measures to ensure access to and use of appropriate treatments that are addressed to the whole population with additional emphasis on socially vulnerable groups.

Examples:
The patient navigator experience addresses emotional, informational and instrumental barriers to treatment (133-136). A review of cancer patient navigation identified four major areas in which patient navigators can intervene, building on the construct of social support, including 1) overcoming health system barriers, including coordination, scheduling and help with paperwork (i.e. instrumental support); 2) providing health education, including written information, discussion and answering questions (i.e. informational support); 3) addressing patient barriers, such as lack of transportation, financial and insurance barriers, lack of childcare, low literacy and language translation (i.e. instrumental support); and 4) providing psychosocial support (i.e. emotional support) (133).

In a public health system financial difficulties may be associated with cancer patient outcomes such as quality of life and survival. A group of Italian researchers pooled data from 16 multicentre trials in lung, breast and ovarian cancer (a total of 3,670 patients). They analysed the patients' reported financial difficulties following cancer treatment (so-called "financial toxicity"), and found that 22% of patients reported financial toxicity that was significantly associated with an increased risk of death (approximately 20%) (137).

S.R. 9.3: Ensure the development and implementation of guidelines in all involved disciplines, which must include equity as a quality criterion.

Example:
The Centre for Clinical Practice at NICE is committed to eliminating unlawful discrimination, advancing equality of opportunity, and fostering good relations. "Positively equal" was designed as an essential tool to help inform consideration of equality issues as a systematic and integrated part of the clinical guideline development process (138).

Recommendation 10: Ensure equitable access to high-quality surgical care in all European Union Member States.

Surgery is a key component of multi-disciplinary cancer care and contributes significantly to improved survival in Europe. It is estimated that 80% of all new cases of cancer in 2015 will require surgery, some several times (31). However, variations in the quality of surgery delivered and unequal access to appropriate surgical interventions across Europe leads to significant differences in cancer outcomes between groups of people within countries and between countries (24, 25).

Complex treatment of cancer requires a minimum number of procedures to be performed, appropriate infrastructure, and human resources at the Member State and EU levels. The best opportunity for ensuring improved outcomes relies on delivery of surgical care in cancer centres where specialised surgical oncologists perform a sufficient number of procedures with appropriate complexity (based on the number of cases treated per year (139) in an environment with access to other treatment modalities (radiotherapy, chemotherapy) and appropriate supportive care (140).

This is particularly true for rare cancers and cancers requiring highly complex surgery (e.g. cancers of the lung and pancreas). In these cases, patients should be treated in centres of excellence in order to ensure that they benefit from high-quality surgical expertise, thus increasing their chances of survival. In this respect, the creation of a European Reference Network (ERN) on rare cancers, foreseen by the Cross-border Healthcare Directive, could represent an important development (141).

It remains a priority to strengthen surgical systems through investment in public sector infrastructure, education, and training (31) and by facilitating patients' access to cancer centres with a high annual volume of surgical procedures for cancer. Access to innovative surgical procedures should also be implemented, provided that efficient innovation is sustainable and brings sufficient added value to cancer patients (31). Investments in innovative surgical procedures should be paired with solid analysis and reallocation of resources to ensure overall sustainability of cancer care. The CanCon Policy Paper on *"Enhancing the Value of Cancer Care Through a More Appropriate Use of Healthcare Interventions"* defines this practice as a systematic attempt at identifying low-value items of care that represent an inappropriate use of healthcare resources. At the same time, disinvestment requires developing coherent initiatives aimed at eliminating or reducing their use, with the general expectation of supporting the use of more effective procedures and interventions and sustaining the adoption of valuable diagnostic and therapeutic innovations. In implementing disinvestment policies, a critical factor influencing their success is a balanced, patient-centric evaluation of the equilibrium between the cost of health services and the benefit to patients. To achieve this goal, adequate resources and skills should be put in place by Member States to identify low-value interventions and to design disinvestment plans. Those plans should be based on the key criteria of multi-disciplinarity and consultation, in particular with patients and their organisations.

S.R. 10.1: Establish optimal benchmarking standards for surgical oncology in all European Union Member States to help reduce current inequalities experienced by cancer patients.

Examples:

A study on breast cancers diagnosed in the period from 1996 to 1998 revealed large differences in care for breast cancer across Europe. Delivery of "standard-of-care" surgery ranges from 78% (France) to 9% (Estonia), and inequalities were evident, even between countries with medium to high expenditure on health. National protocols had been developed and disseminated during the late 1990s, but standardised European guidelines were still not available (32).

The European Registry of Cancer Care (EURECCA) (140) is an international multi-disciplinary platform of clinicians and epidemiologists aiming to improve the quality of cancer care by ensuring data registration, promoting and incorporating feedback, forming plans for improvement and sharing knowledge of performance and science. The mission of EURECCA is to achieve and assure high-quality multi-disciplinary cancer management in Europe, accessible to all patients through the development and support of an international quality assurance structure- which is an audit structure- using anonymous patient data and compliant with national and international laws.

S.R. 10.2: Promote the creation of national information sources on the volume of surgeries per cancer centre, to provide patients with accurate activity data to aid in their choice of surgical centre.

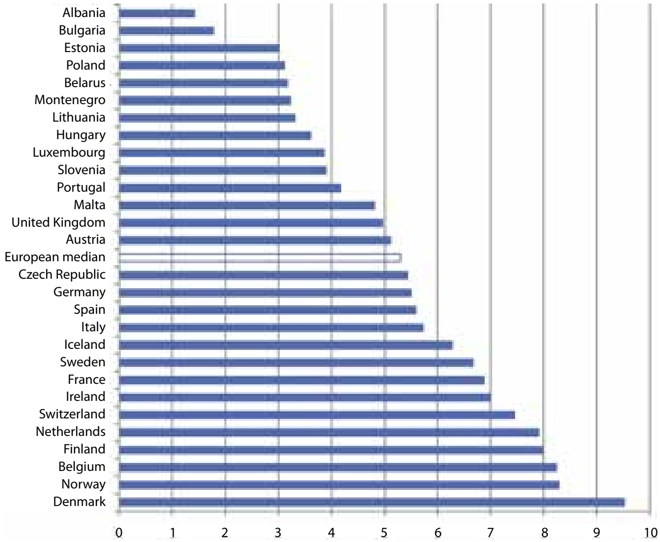
Example:

The Italian Oncoguida[6] is an information service produced by the Italian Association of Cancer Patients (AIMaC) in collaboration with the Italian Institute of Health and the Italian Ministry of Health. Oncoguida provides detailed, patient-oriented information on Italian hospitals and cancer centres providing cancer care, including volume of surgeries performed per tumour site, availability of psychological and physical rehabilitation services and contact details of patient associations involved at the hospital level. The Oncoguida should act as a blueprint for other Member States to produce similar national directories.

Recommendation 11: Ensure availability of sufficient radiotherapy capacity with appropriate technology innovation in all European Union Member States.

Radiotherapy is a key pillar of treatment and is essential in more than half of all cases of cancer, to cure localised disease, palliate symptoms and control disease in incurable cancers. A large discrepancy exists between the actual and the optimal availability and use of radiation therapy between European countries (142-145), as well as between socio-economic groups (146). When staffing levels or access to modern radiotherapy equipment are evaluated, the results are similar (144, 145) and show unequal access to cancer care for European patients. These deficiencies are experienced not only in Southern and Eastern European countries (particularly Bulgaria, Macedonia and Romania), but also in some Western European countries such as Portugal and the UK (Figure 1, Figure 2).

Figure 1 Number of radiotherapy units per million inhabitants.



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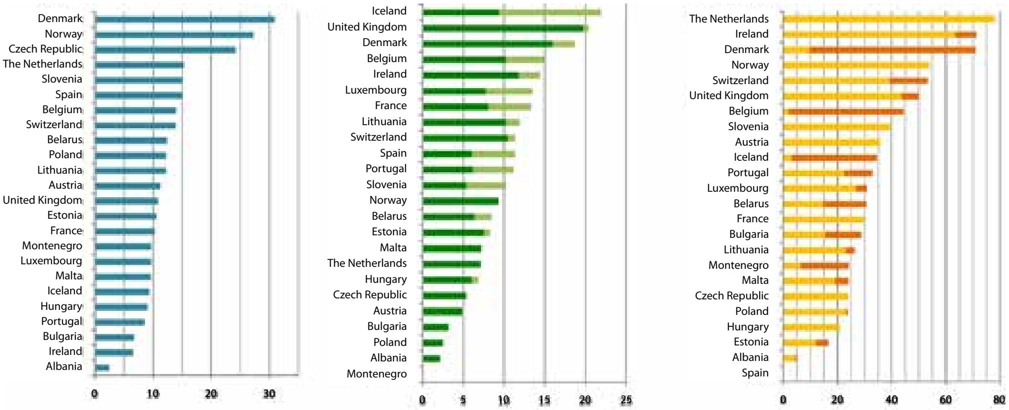
[6] http://www.oncoguida.it/html//home.asp

Figure 2 Figure 2 : Number of radiation professionals per million inhabitants



a. ROS per million inhabitants

b. MPs and DOs per million inhabitants
MP: dark green – DO: light green

c. RTTs and RNs per million inhabitants
RTT: yellow – RN: orange

ROs: radiation oncologists; **MPs:** medical physicist; **DOs:** dosimetrists: **RTTs:** radiation therapists **RNs**: radiation nurses

Recommendation 12: Ensure that all patients have timely access to appropriate systemic therapy.

While many cytotoxic medicines have been shown to be effective treatments for cancer patients, there are significant social inequalities in access to these treatments across Europe. A recent survey indicated that over 50% of European hospital pharmacists have experienced significant shortages in access to life-preserving and life-sustaining cytotoxic regimens (ranging from 33% in Northern Europe to 59% in Western and Southern Europe and 65% in Eastern Europe) (147). Unfortunately, information on the causes of medicine shortages is not currently consistently collected and reported across Europe, thus it is difficult to develop potential solutions.

Increased understanding of disease biology is fuelling a "personalised cancer medicine" revolution (148). However, providing innovative treatments in a timely fashion to European cancer patients is hampered by a pricing/reimbursement approach that differs markedly between individual European countries, thus accentuating inequalities between countries in access to optimal cancer care (33). In many EU countries cancer patients have experienced extended delays in access to innovative treatments due to the lengthy decision-making process for pricing and reimbursement. Such decisions are normally due within 180 days from the European Medicine Agency (EMA) decision on market authorisation, in line with the relevant EU binding regulation. In certain cases (149), this has led to significant discrepancies in access, which may have a detrimental effect on survival, although more research is required in this area (150).

S.R. 12.1: Promote access to innovative therapies that deliver value-based, effective care, by harmonising Health Technology Assessment in all Member States.

Examples:
For some essential cancer drugs, there are marked differences in time to approval/reimbursement in all EU Member States, which vary from few days from the EMA market authorisation to more than 12 years from EMA approval (149). In 10 out of 28 EU countries, it has taken 2 years or more to provide some drugs to patients in the metastatic setting, further demonstrating the unacceptable

delays in accessing this essential cancer drug. One of the reasons for such delays relates to the heterogeneity of procedures and methodologies used by Member States to assess relative effectiveness (REA) and cost-effectiveness of new medicines.

More than 5,000 patients annually with metastatic melanoma in Europe do not have access to new life-saving drugs. A recent study presented at the European Society of Medical Oncology (2016) reported unacceptable differences in access to lifesaving innovative melanoma medicines across Europe. At least 70% of patients with metastatic melanoma in Western Europe were treated with innovative medicines. In Central Europe only 41% of patients had access to these innovative drugs, while only 10% of patients had access to these medicines in Southern and Eastern European countries (150).

Recommendation 13: Develop national cancer rehabilitation and survivorship policies, underpinned by an equity perspective.

The end of cancer treatment does not signal the end of cancer care. It is important to raise awareness of potential late effects of cancer treatment and of early detection of cancer recurrence and secondary tumours. Key elements in the prevention of cancer recurrence include the maintenance of a healthy body weight, healthy diet and physical exercise. Avoidance of the use of tobacco, excess sun exposure, and alcohol are also important elements, just as they are for primary prevention. Rehabilitation is a key component to ensure that cancer survivors have the best chance of returning to a normal life. Rehabilitation must be understood to include not only physical rehabilitation, but also psychological, cognitive, sexual, spiritual and professional rehabilitation. These principles must be enshrined in every National Cancer Control Plan in the form of Survivorship Care Plans to ensure the fullest possible recovery of all cancer survivors. This is especially important for those in situations of social vulnerability, because they face greater challenges in terms of access to care and health behaviours.

Many cancer survivors are at risk for loss of employment, which can lead to significant financial and social burdens, and reduction in quality of life. Surviving cancer patients may suffer unacceptable discrimination in relation to employment and other areas of society, including access to insurance, mortgage approval and social re-integration (151). Geographical and social isolation may make it more difficult for rural or otherwise socially vulnerable patients to access social and practical support. European and national authorities have a role to play, by allocating adequate financial resources to support services and in implementing adequate survivorship and rehabilitation services for all social groups, as well as in informing the public and raising awareness.

It has been shown that cancer survivors with a low socio-economic position are more often unemployed (25) or take early retirement, which can act as a substitute for disability leave or unemployment (153). Emerging research also suggests the existence of social inequalities in the ability of cancer survivors to return to work (154). Working conditions and psychosocial conditions of a manual job can act as additional barriers (155). Furthermore, women often become informal caregivers to family members with cancer and are more at risk of unemployment and early exit from the labour market.

Examples:

A few best practices have shown good results in reintegrating cancer survivors into an active life (152). Those practices should be shared across the EU. For example, in 2016, France introduced a new policy under the national cancer plan, giving cancer survivors the right to obtain loans or insurance without surcharge or restriction, once a certain period has passed since their diagnosis. Furthermore, the same French NCP legislates that survivors of malignancy in childhood (0-14 years) whose treatment finished 5 or more years prior and adults with any cancer whose treatment finished 15 years prior are not required to declare the disease when applying for a mortgage or health insurance.

S.R. 13.1: Make survivorship and rehabilitation an integral component of the patient care pathway from the time of diagnosis.

Examples:

Attenuating the economic consequences of cancer to support the living standards of patients and their families is an imperative that should make use of various levers. The French National Cancer Plan (2014-2019) provides a reduction in the patient's contribution toward the cost of breast reconstruction and an increase in the reimbursement rate for wigs and mammary prostheses.[7]

In Italy, a new regulation facilitates claims for social security or invalidity/handicap benefits when submitted by cancer patients (156). As a result, the time to disability and handicap recognition has been reduced from 12 months to just 15 days, which means economic and societal benefits are payable at an earlier stage. Claims are submitted online by family doctors, which speeds up processing and guarantees equal treatment of individuals nationwide. This allows the National Social Security Body to pay out the relevant benefits within four months (157).

S.R. 13.2: Raise awareness about late effects, with the aim of providing recommendations to all patients and tailoring information specifically for socially vulnerable groups.

Example:

Cancer survivors' follow-up, late effects management and tertiary prevention need to be anticipated, personalised and implemented into care pathways, with active participation of survivors and relatives. The CanCon recommendation on survivorship and rehabilitation provides solid evidence on the need to create personalised survivorship care plans (SCPs) to provide clear information to cancer survivors. In particular, the role of the general practitioner (GP) has been demonstrated to be crucial to ensure more equitable and simple access to key information on survivorship. In the Netherlands, a recent study demonstrated that cancer patients prefer to discuss diet, fatigue, relationship difficulties, sexuality, return to work and physical fitness with the GP rather than with their oncologist (158). SCPs can be managed according to different models of care coordination with a common starting point of an MDT specialist follow-up having a holistic and integrated approach to survivors' health.

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[7] Available at http://en.e-cancer.fr/The-Cancer-Plan-2014-2019

S.R. 13.3: Integrate employment programmes into follow-up survivorship care, with additional emphasis on socially vulnerable groups, to support return to work after acute treatment.

Examples:

The employment provisions of the Equality Act 2010 (UK) protect anyone who has- or has had- a disability (including people affected by cancer). The act requires employers to make reasonable adjustments for employees with a disability, and it also includes important provisions to prevent discrimination arising from disability, including indirect discrimination and discrimination against carers.

A major achievement in Italy in the field of job protection for cancer survivors and their families is a regulation passed in 2003 (159) prescribing the opportunity for cancer patients who work in the private sector to switch from a full-time to a part-time position while they are under treatment, and to revert to a full-time position in due course according to their needs and capability. The same right has been extended to public employees (160). Family members of cancer patients are given priority for part-time applications as long as there are positions available.

S.R. 13.4: Develop financial incentives to help employers introduce adaptations to work environments/situations in order to accommodate survivors' return to work.

Example:

In Denmark, two municipalities were involved in an individually tailored occupational rehabilitation intervention (controlled trial) for cancer survivors, focusing on enhancing readiness for return to work. The trial showed that the intervention (implemented in one of the two municipalities) provided benefit to the patients, by delivering timely occupational rehabilitation that was much earlier initiated than in the control group. Furthermore, the active involvement of the employers was also instrumental in the rapid reintegration of patients in the workplace. Vulnerable cancer survivors particularly benefitted from this approach, and the effects of social inequality on workability were reduced (152).

5 Conclusions

Unacceptable inequalities in cancer prevention, treatment and care, and survivorship still affect millions of cancer patients across Europe. This paper provides evidence-based recommendations to address those factors related to inequalities in cancer care for which strong pan-European collaboration is required. This paper proposes an equity-oriented approach to developing policies for cancer prevention and control, based on universal action, but with a scale and intensity that are proportionate to the level of disadvantage of the population in question. We thus highlight practical actions to tackle social inequalities in cancer at the European and national levels in the form of 13 recommendations that span the areas of capacity building; primary and secondary prevention; and treatment, survivorship and rehabilitation. The recommendations are based on a review of available scientific evidence in addition to experiences identified through our survey of Member States.

Our recommendations can serve as a guide for action for national and European policy makers to tackle social inequalities in cancer prevention and control in Europe. However, implementation of the recommendations will require appropriate resources, first and foremost to adapt the recommendations to each country, thus respecting the profile of the population and the social and economic context of each country.

While social inequalities in cancer in Europe are significant and formidable, important experience exists in addressing them, supporting the urgent need for action highlighted by patient organisations consulted during the drafting of this paper. The role of European institutions is also extremely important, particularly cancer institutions. Several Member States have already taken action in this direction, and their efforts can serve to strengthen and expand work on reducing social inequalities in cancer. Despite the principles of subsidiarity, which places healthcare as a shared competence between Member States and the European Union, the European Code Against Cancer and the Equity Joint Action strongly impacted the development and implementation of national cancer plans. For the recommendations to be successful, it is necessary that social inequalities in cancer are placed at the top of the European public health agenda, therefore maximising the impact of future EU initiatives on cancer.

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Policy Paper on
An Impact Evaluation System to Assess Prevention Outcomes

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CONTENTS

1 Background

Cancer no longer lags behind cardiovascular disease as an important cause of death in Europe (Nick Townsend et al. Cardiovascular disease in Europe: epidemiological update 2016. European Heart Journal 2016). In fact, cancer has overtaken cardiovascular disease as the main cause of death in 12 European countries (Belgium, Denmark, France, Italy, Luxembourg, the Netherlands, Portugal, Slovenia, Spain, UK, Norway, and Israel), highlighting the importance of a coordinated European effort towards prevention.

Up-to-date cancer incidence and mortality data in Europe are a key resource in both planning and assessing the impact of cancer control programmes at the country and regional levels. Europe carries a significant load of the global cancer burden, representing one quarter of all cases. There were an estimated 3.45 million new cases of cancer (excluding non-melanoma skin cancer) and 1.75 million deaths from cancer in Europe in 2012. The most common cancer sites were the female breast (464,000 cases), followed by colorectal (447,000), prostate (417,000) and lung (410,000). These four cancers represent half of the overall burden of cancer in Europe. The most common causes of death from cancer in Europe in 2013 were cancers of the lung (353,000 deaths), colorectal (215,000), breast (131,000) stomach (107,000), liver (62,000), bladder (52,400) and kidney (49,000) (Ferlay 2013).

Maintaining a healthy weight, staying physically active throughout life, consuming a healthy diet, stopping smoking and reducing alcohol intake can substantially reduce the lifetime risk of developing cancer, as well as influence overall health and survival after a cancer diagnosis. Thus many national and international guidelines on cancer prevention point to improving lifestyles and diet as a means to address the disease and promote health.

In this paper according to the Evidence Base Medicine the key points and primary cancer prevention evidence reviewed is classified according to the following scale: a= consistent, good-quality patient-oriented evidence; b = inconsistent or limited-quality patient-oriented evidence; and c = consensus, disease-oriented evidence, usual practice, expert opinion, or case series. (http://www.aafp.org/afpsort.xml).

1 Achievement and maintenance of a healthy weight throughout life

   a/ It is well documented that overweight and obesity are significant risk factors for cancers of the breast (post-menopausal), colorectum, endometrium, liver, oesophagus, pancreas, prostate and kidney *(Bergström 2001; Vainio 2002; Kushi 2006; Kushi 2007; Wahnerfriend 2008, Amling et al. 2005);*

   b/ Overweight and obesity are risk factors for multiple myeloma and non-Hodgkin's and Hodgkin's lymphoma, and cancers of the cervix, gallbladder, gastric cardia, ovary, advanced prostate and leukaemia (*Bergström 2001; Vainio 2002; Kushi 2006; Lindblad 2005; Patel 2005; Amling 2005; Wahnerfriend 2008; Latino-Martel 2016, WCRF 2016*);

2 A plant-based diet high in fruits, vegetables, and whole grains and low in saturated fats and red and processed meats

   a/ There is consistent evidence that high intake of red and processed meats and animal fat in general are associated with risk for colorectal cancer (*Kushi 2006, U.S. Department of Health and Human Services 2008, Latino-Martel 2016*);

   b/ Evidence suggests that plant-based diets with high levels of fruits, vegetables and whole grains are protective for some cancers (*Kushi 2007; U.S. Department of Health and Human Services 2008, Erinosho 2015*).

3 Regular physical activity of at least 30 minutes per day and at least five days per week

a/ Consistent evidence indicates that physical activity offers significant protection for cancers of the breast, colon and endometrium (*Vainio 2002; Kushi 2006; Boyle 2003; U.S. Agency for Healthcare Research and Quality 2004, Latino-Martel 2016*).

4 Avoid alcohol consumption

a/ Consistent evidence exists that high alcohol intake is associated with increased risk for kidney, liver, esophagus, pancreas and head and neck cancers. Alcohol intake also is significantly associated with risk of breast cancer (*Kushi 2006; American Cancer Society 2007*).

5 Tobacco smoking cessation

a/ Cigarette smoking causes cancers of the lung, oral cavity and pharynx, larynx, esophagus, bladder, kidney, pancreas, stomach, uterine cervix, penile and acute myeloid leukaemia. Smoking avoidance and smoking cessation result in decreased incidence and mortality from cancer (*Kvaavik 2010; van Dam 2008; American Cancer Society 2007*).

A call for public policy and community action make up a significant component of the primary prevention guidelines (Boyle 2003, Vainio 2002, CDC 2004, Weinhouse1991, Byer 2002, Kushi 2007).

2 Search for evidence

This CanCon policy paper deals with the outcomes of prevention in relation to diet and nutrition, physical activity, alcohol consumption and tobacco control.

Topic definition

The questions posed in this document include:

- What policies and interventions are currently implemented for prevention of cancer?
- Which indicators are used to measure the effectiveness of interventions in scientific research?
- Which indicators are present in the information systems for surveillance at the European Level?
- Is it possible to compare scientific and surveillance indicators?

A systematic review of review studies published in the scientific literature over the last 5 years (2010-2015) was undertaken to assess interventions throughout the world.

Methodological approach and definitions

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement was adopted to conduct the review (Moher 2009).

a/ Ethical approval

As a review article, this document does not require ethnical approval.

b/ Literature search strategy

Scientific literature was systematically searched for peer-reviewed studies that examined the impact of policies on healthy diet and nutrition, moderation of alcohol consumption, regular physical activity and tobacco control. Relevant literature published in peer reviewed journals was identified through keyword searches in relation to policy and health promotion and health impact for each determinant (diet, tobacco smoking, alcohol consumption and physical activity). PubMed, Scopus and Cochrane Library electronic databases were queried using search algorithms (for details see specific annexes).

- Annex 1: Diet and nutrition
- Annex 2: Physical activity
- Annex 3: Alcohol consumption
- Annex 4: Tobacco control

All annexes can be found as supplemental information at the website www.cancon.eu

These databases were consulted for relevant peer reviewed publications in English between January 1st, 2010, and June 1st, 2015.

Initial screening of the documents retrieved was conducted by one reviewer and involved consideration of the title and abstract. Second, a full text examination was conducted, and articles were checked against the inclusion and exclusion criteria (reported below and in the specific annexes). Finally the retrieved articles' references were reviewed to identify secondary references meeting the inclusion criteria. After eliminating articles that did not meet the inclusion criteria, the remaining studies were collected and their characteristics summarized.

c/ Inclusion and exclusion criteria

Eligible study designs included narrative or systematic review and meta-analysis. Studies focused on a specific population were excluded, e.g. categories of patients (asthmatic, HIV positive, etc.), ethnic groups (such as American Indians, Indios).

For more detailed information of inclusion and exclusion criteria for each topic, see the annexes (1-4).

d/ Information collection

The full-text of the papers meeting the inclusion criteria were retrieved, and two investigators independently reviewed articles and compiled relevant data into a standardized data extraction form. A third reviewer resolved any uncertainties that arose during the process.

The following study characteristics were extracted, where applicable:

1/ Authors, year of publication
2/ Study design: systematic review, meta-analysis
3/ Types of policy or intervention (see below *"Classification of policies and interventions in macro-areas/ groups*)
4/ Setting (national level, clinical setting, school, etc.)
5/ Target population (general population, adults, adolescent)
6/ Indicators

e/ Classification of policies and interventions

What constitutes a policy vs. an intervention?

- *Intervention* refers to a scientific trial in the classical sense, or an action realized at local level (school, local health units, interventions of health promotion not delivered by an institution, such as "Let's Move" (http://www.letsmove.gov/) or "Race for the Cure"(http://www.komen.it/raceforthecure/).
- *Policy* refers to prevention actions set out at institutional (ministerial or regional) levels or by government, such as national laws or campaigns.

In the areas of tobacco and alcohol prevention, WHO classifications for policies and interventions were used (WHO FCTC 2003; WHO 2010). For nutrition and physical activity the classification was performed using the policy interventions described in the papers selected for the review. In terms of nutrition outcomes, the distinction between policies and interventions was difficult to determine, since differences between action at the local or national levels often were not clear. Detailed tables that describe the selected papers in terms of policy and intervention typologies are provided in the annexes (1-4).

The following schemes were adopted for categorization:

NUTRITION

INTERVENTIONS / POLICIES[a]
Provision and food access (food environment policies)
Taxation/fiscal policy/ food price policies/ monetary subsidies
Food marketing/labelling
Food marketing/advertising
Food marketing/mass media campaigns/promotion
Community interventions
Mixed community interventions
Education and environmental policies/interventions
Education/ awareness/ behavioural interventions

[a] Review articles were searched for both interventions and policies (both were included). Categorizing the two types of actions was difficult, since some items could be referred to as both a policy and an intervention.

PHYSICAL ACTIVITY

INTERVENTIONS	POLICIES
Counselling	Mass media campaigns
Advertising	Education/awareness
Education	Advertising/promotion
Promotion	

ALCOHOL

INTERVENTIONS	POLICIES
Therapy and/or counselling	Advertising, promotion, sponsorship
Education and/or awareness	Availability
Brief interventions (BI)	Drinking and driving
Screening	Education and/or awareness
	Policies on the alcohol industry
	Packaging and/or labelling
	Price and tax related
	Protection from exposure
	Monitoring

TOBACCO CONSUMPTION

INTERVENTIONS	POLICIES
Therapy/counselling	Therapy/counselling
Educational/awareness	Education/awareness
Protection from exposure	Protection from exposure
Bans on advertising, sponsorship	Bans on advertising, sponsorship
	Price and tax measures
	Packaging/labelling
	Availability[a]
	Mass media campaigns

[a] Restricting access to youth/ minors, regulating tobacco outlet density, tobacco retailer licensing.

f/ Quality assessment

Methodological quality was assessed for meta-analysis using the AMSTAR tool (Shea 2007).

g/ Assessment of effectiveness

The effectiveness of the policy/intervention was assessed only for meta-analysis studies. The main results were synthetized in tables. The percentages, OR or RR with their relative 95% confidence intervals or p-value were reported.

h/ Feasibility of indicator implementation at the European level

The indicators found in the scientific literature that measure the effectiveness of the policies/ interventions were compared with the indicators present in European information databases: EUROSTAT, Health for All Europe (HFA) and European Core Health Indicators (ECHI). The Health Behaviour in School-aged Children (HBSC) survey was analysed to evaluate the specific indicators for adolescents and was presented in a separate section.

i/ Analysis of results

A synthesis of results is reported in the present document for each cancer determinant.

In particular the following tables are shown:

- Lists of the reviews stratified by typologies of policies and interventions
- Lists of indicators applied to monitoring policies or interventions in the scientific literature
- Description of indicators in areas of interest (behaviour, knowledge and health)
- Description of effective policies/interventions (meta-analysis only)
- Comparison of data indicators by European information systems (EUROSTAT, ECHI, HFA)
- Geographical distribution of the indicators in the EU28 and availability of the data

Results

A – DIET AND NUTRITION

(for details see ANNEX 1 in supplemental information)

This summary presents the evidence collected regarding available policies/interventions that aim to create a healthy food environment and support individuals' ability to make healthy food choices to prevent cancer related to unhealthy diets. A number of these policies are crucial in changing the dietary patterns of the population. The scientific literature describes the following:

1. Policies that support a healthier composition of foods:

These policies support changes to the composition of staple foods, thus having a direct influence on the nutrient intake of the population (e.g. reducing saturated fatty acid content of oil; limiting energy-dense foods). Governments should use incentives to reward companies for promoting healthier foods and beverages.

2. Multi-sectorial policies that facilitate the adoption of healthy diet:

Accessibility policies: those that aim to make healthy foods more accessible by reducing their price in relation unhealthy foods through fiscal measures.

Availability policies: both policy and environmental interventions targeting the built environment through increasing the availability to healthy foods and beverages (and reducing availability of unhealthy foods) in schools, worksites (e.g. in the cafeteria or in vending machines) and communities (e.g. strategies that influence availability at grocery stores, in vending machines, and at cafeterias and restaurants to support healthier choices).

This also includes policies that improve access to supermarkets and healthful food and limit access to fast-food restaurants, and those that address neighbourhood deprivation, reduction of disparities and promotion of more equitable access to healthy foods.

3. Community-wide, multi-component programs/interventions:

These include programs to promote changes in individual behaviour, increased knowledge and self-monitoring (e.g. those conducted as a part of a national or global campaign to promote healthy lifestyles). They may address **dietary education and/or knowledge of the whole population** through:

- Long-term, intensive mass media campaigns
- Educational programs to support the purchase of healthier foods
- National health brands or logos to support consumers in making healthy food choices
- Advertisements including labelling and/or health warnings on healthy/unhealthy products
- Computer/web-based and e-health interventions or telephone/mobile counselling interventions with interactive personalized feedback (that can target high-risk groups)
- School-based or university curriculum that addresses healthy eating and body image
- Workplace interventions

4. Primary, secondary and/or tertiary prevention programs/interventions conducted in the primary healthcare setting targeting people that have an unhealthy diet, are overweight/ obese and/ or have an both an unhealthy diet and a consequent chronic disease such as type 2 diabetes, cardiovascular disease and/ or cancer. The intensity of interventions ranges from mild (e.g. in primary prevention programs), including providing printed educational materials, telephone counselling, and internet consultations, to intense (e.g. in secondary prevention), where patients are regularly monitored in their participation in intensive educational nutrition programmes (that also involve the family) or where participants receive live-in rehabilitation services.

A total of 28 papers were reviewed (published from January 2010 to June 2015), 5 of which were meta-analyses (Table 1).

A total of 26 indicators were found, and the majority concerned nutritional behaviours (Tables 2 and 3).

The main results related to the effectiveness of policies/ interventions were summarised (meta-analysis studies only) (see supplemental information).

Table 1 Distribution of the number of papers and indicators for each type of intervention/ policy

Area (policies / interventions)	Number of papers	Number of indicators
Provision and food access (food environment policies)	5	19
Taxation/fiscal policies/ food price policies/ monetary subsidies	7	17
Food marketing/labelling	3	2
Food marketing/advertising	2	5
Food marketing/mass media campaigns/ promotion	3	11
Community interventions	5	6
Mixed community interventions	1	1
Education and food environment policies/interventions	1	2
Education/awareness/behavioural interventions	1	3

Table 2 Distribution of indicators by type of outcome: health, behaviour or knowledge
One indicator can be used in one or more areas.

Indicator area	Number of indicators
Knowledge	11
Behaviour	40
Health	22
Total	73

Table 3 Description of all indicators reported for interventions/ policies

Indicators for monitoring the effect of interventions/policies	Frequency
Change behaviours:	50
1) Attitude towards healthy foods	
2) Increase in frequency and amount of healthy foods (a) (increase in purchases of fruit, vegetables etc.)	
3) Reduction of fat intake (reduction in purchases of foods with a high fat content)	
4) Reduction of high-fat snacks (reduction in purchases, availability)	
5) Less saturated fat intake (reduction in purchases of foods with a high saturated fat content)	
6) Reduction in calories consumed (reduction in purchases, availability)	
7) Reduction in sodium intake (reduction in purchases, availability)	
8) Beneficial increased consumption of dietary fibre, fruit and vegetables (increase in purchases, availability)	
9) Change in diet in favour of a healthier diet with an increase in fruit, vegetables and fibre (in the general population and setting) (increase in purchases, availability)	
10) Change in primary school diet or at worksites in favour of a healthier diet with a greater consumption of vegetables and fruit (increase in purchases, availability)	
11) Changes in cafeteria food content, foods: soft-drinks/ sugary beverages, fat, vegetables, breakfast, and snacks/ desserts (increase in purchases, availability)	
12) Weight related behaviours	
13) Behaviours (e.g. food preparation, mealtime, snacking)	
14) Frequency of purchase of healthy foods	
15) Nutrition purchase	
Knowledge/ awareness	10
1) Related to a healthy diet (more vegetables and fruit consumption, more fibre consumption, and less saturated fat content and calories consumed)	
2) Related to healthy foods	
3) Related to the purchase of healthy foods	
Body weight reduction:	5
1) BMI	
2) Overweight and obesity	
Reduction in blood pressure	2
Reduction in blood glucose	2
Reduction in blood cholesterol	2
Metabolic risk factors for NCDs	1
Chronic disease	1
Attitude	2

[a] Heathy foods or healthy diets refer to a high consumption of fruit and vegetables and fibre and a decrease in unhealthy foods such as those with high calories or high levels of saturated fats or sodium.

General considerations on diet and nutrition

EVIDENCE

The results from the systematic review of the literature and meta-analysis regarding the following intervention/policies show that any type of intervention targeted at the specific population represents a cost-effective approach, in detail:

a/ Interventions to promote healthy diet in primary care are effective, especially those that increase fruit and vegetable consumption with a decrease in total fat intake, and as a consequence a decrease in serum cholesterol.

b/ Primary school diet and physical activity policies have a positive influence on the reduction of body weight and in increasing physical activity.

c/ Social media interventions for diet and exercise behaviours show a significant decrease in dietary fat consumption, despite no significant differences in changes in physical activity and weight.

d/ Tailored multi-component preschool-based interventions for increasing fruit and vegetable consumption in children aged 5 years and under report an increase in mean child consumption of fruit and failed to significantly increase child consumption of vegetables.

POLICY RECOMMENDATIONS

The review of the literature clearly defines the interventions/policies that have been demonstrated to be of proven efficacy/effectiveness, and therefore Member States should consider implementing them.

The recommendations related to indicators for nutrition are as follows:

a/ When a decision on the implementation of a policy/intervention has been made, Member States should consider at least three dimensions for monitoring the impact of the policy in the short term:

   i. Changes in terms of a healthy diet: the increase in healthy food consumption, especially fruit and vegetables, and the decrease in total fat intake, (especially saturated and hydrogenated trans fats), sodium, calories and the reduction in sugar;

   ii. Changes in body weight and in the prevalence of overweight and obesity (monitoring BMI);

   iii. Serum cholesterol reduction, blood glucose, blood pressure as well as the other dietary-related health status and nutritional and metabolic diseases (i.e. chronic disease, ischaemic heart disease and cerebrovascular diseases etc.).

b/ If these indicators cannot be monitored annually, we recommend considering the revision of these indicators (EUROSTAT, Health for All) to ensure the best match between policy/intervention and annual monitoring (example: increase in healthy food consumption, especially fruit and vegetables, decrease in total fat intake, decrease in sodium consumption, decrease in calorie intake, prevalence of overweight and obesity (monitoring BMI), serum cholesterol reduction (prevalence of hypercholesterolemia/hyperlipidemia), blood glucose reduction (prevalence of diabetes/hyperglycemia), blood pressure (prevalence of hypertension), other dietary-related health status and nutritional and metabolic diseases (i.e. chronic disease, ischemic heart disease and cerebrovascular diseases etc.).

c/ In the meantime, if these indicators cannot be monitored annually, an observational study for monitoring is recommended in order to assess impact after the implementation of the policy at the national level.

INFANTS, CHILDREN, AND ADOLESCENTS: EVIDENCE AND RECOMMENDATIONS

This systematic review highlights the "school" setting, with large-scale intervention (for example at regional or multi-centre levels). Outcomes concerning behaviour are the most studied.

The main interventions/policies reported in the scientific literature on adolescents/children with an evidence of effectiveness were:

- School-based programs for diet and nutrition
- Food promotions in general
- Advertising of food and beverage products and brand mascots and cartoon media characters that influence children's diets
- Food environment interventions related to eating behaviours that regulate food availability in schools (with greater access to the consumption of healthy foods such as fruits and vegetables and less access to unhealthy foods) and the use of taxes or subsidies to influence purchasing decisions
- Meaningful partnerships of diverse school communities within obesity prevention interventions

No effectiveness or unclear evidence was found for policies or interventions related to multi-component programmes including home visiting programs and multi-component preschool-based interventions. The measures applied to assess the outcomes were the same as those included in the evidence on the general population: "childhood overweight and obesity", "body weight reduction" and "children's food preferences, choices, knowledge and food intake/healthy diets". Specifically: "children's food intake, especially for energy-dense and nutrient-poor foods (e.g. cookies, candy or chocolate)"; "increased children's fruit or vegetable intake, reducing fat and calorie intake, and changing cafeteria food content, foods: soft-drinks/sugary beverages, fats, vegetables" and the "increase in the consumption of promoted products (fruits, vegetables and low-fat snacks sold in supermarkets, cafeterias, vending machines, farmers' markets or restaurants)".

Based on a comparison with the items included in the World Health Organisation collaborative cross-national survey "Health Behaviour in School-aged Children" on dietary habits in those aged 6-17 years, the items proposed are: "levels of daily fruit consumption", "soft-drink consumption", and- in addition- in the Health Behaviour in School-aged Children Survey, there are "eating breakfast on weekdays" and "frequency of having evening meals with the family" indicators.

B – PHYSICAL ACTIVITY PROMOTION

(for details see ANNEX 2 in supplemental information)

According to the WHO (2004) document "Global Strategy on Diet, Physical Activity and Health" physical activity promotion and improving diet is recognized as an effective strategy for reducing deaths and the disease burden worldwide.

The preliminary results of analysis of systematic reviews and meta-analyses concern the following intervention/policies according to the WHO recommendations (Tables 4A and 4B):

1 After-school programs can improve physical activity levels and other health-related aspects;

2 Tertiary education students within the university/college setting are ideal targets for lifestyle interventions aimed at improving health behaviours;

3 Interventions that increase the proportion of time students spend in moderate-to-vigorous physical activity in school physical education lessons;

4 Interventions aimed at both parents and children had a significant effect on physical activity, but not on BMI;

5 Some workplace physical activity interventions can improve both health and important worksite outcomes;

6 The evidence from this review suggests that, when implemented alone, school diet and physical activity related policies appear insufficient to prevent or treat overweight or obesity in children, however, they do appear to have an effect when developed and implemented as part of a more extensive intervention program;

7 The synthesis of evidence indicates that several attributes of urban environments are associated with physical activity, including land-use mix and cycling infrastructure;

8 Increasing self-efficacy for physical activity;

9 Self-monitoring, group-based components, and motivational signs to encourage stair use were identified as promising strategies to increase physical activity;

10 Evidences supports the effectiveness of face to-face interventions for promoting physical activity;

11 Lifestyle interventions with a behavioural programmes aimed at changing diet and physical activity thinking patterns provide a significant and clinically meaningful decrease in overweight in both children and adolescents compared to standard care or self-help in the short- and the long-term through global, national, and regional public health policies and action;

12 There is no specific legislative framework regarding physical activity policy;

13 There is a need to include mass media in policy action in order increase the interest of policy makers in physical activity;

14 Policies adopted should be monitored closely; indicators must be established and used to monitor the implementation process;

15 Increased physical activity concerns many sectors: children, seniors, workplaces, and health, therefore, it is important that to act at the global level;

16 The recommendations made by the States based on WHO recommendations should report concrete objectives.

A total of 55 papers (systematic reviews and meta-analysis) were analysed, published from 2009 to 2015, and a total of 56 indicators were found (see supplemental information).

Table 4A Distribution of the number of papers and indicators for each type of intervention

One paper can be used in one or more area.

Macro area (interventions)	Number of papers	Number of indicators
Advertising	1	1
Counselling	6	14
Education	9	17
Promotion	15	36

Table 4B Distribution of the number of papers and indicators for each kind of policy

Macro area (policy)	Number of papers	Number of indicators
Promotion	1	4
Education	11	19
Advertising	6	2

Table 5A Distribution of indicator type for intervention outcomes: advertising, counselling, education, promotion or mass media campaign

Area of interest of indicators	Number of indicators
Education	17
Promotion	36
Counselling	14
Advertising	1

Table 5B Distribution of indicator type for policy outcomes: advertising, counselling, education, promotion or mass media campaign

Area of interest of indicators	Number of indicators
Education	19
Promotion	4
Advertising	2

Table 6A Description of all indicators reported among interventions

Indicators	Frequency
Time and frequency of physical activity	13
MVPA	11
BMI	7
Total energy expenditure (kcal/week)	3
Systolic and diastolic pressure	3
Lipid profile	5
Adverse events	3
Aerobic capacity	3
Quality of life (SF-12)	2
Weight loss	2
VO2 max	2

MVPA: Moderate to Vigorous Physical Activity
BMI: Body Mass Index

Table 6B Description of all indicators reported among policies

Indicators for monitoring policies	Frequency
BMI	3
Overweight	1
CDC Growth Charts	1
Fat mass index (FMI)	3
MPVA	1
BMI/SDS (deviation score)	1
Healthy Fitness Zone (HFZ)	1
Frequency	1
IPAQ Instrument	1
Precede model: facilitating factors	1
Trans theoretical model (TTM)	1
EPAQ Instrument	1

MVPA: Moderate to Vigorous Physical Activity
BMI: Body Mass Index

General considerations on physical activity promotion

EVIDENCE

The results from the systematic review of the literature and meta-analysis regarding the following intervention/policies show that:

a/ A socio-ecological model for environmental urban facilities increases the level of physical activity and improves public health outcomes. This model of health promotion considers the complex interplay between individual, relationship, community, and societal factors.

b/ Multiple-component physical activity programs encourage exercise participation, self-efficacy, and adherence over time.

c/ School-based physical education and after school programmes improve blood pressure, lipid profile, BMI, school achievement, and MPVA.

d/ In child care centres the education and training of staff is useful to promote physical activity.

e/ Interactive computer-based interventions are effective for weight loss and weight maintenance.

f/ Group counselling increases self-reported physical activity. Individual counselling improves lipid profile, BMI, and self-reported physical activity.

g/ Community walking groups increase the time and frequency of physical.

h/ Worksite health promotion improves lipid profiles, BMI, and decreases job stress and absenteeism.

i/ Interventions of proven efficacy/effectiveness include:

  i. Environmental urban facilities using a socio-ecological approach
  ii. School-based physical education
  iii. One to one or group counselling
  iv. Worksite health promotion

POLICY RECOMMANDATIONS

Scientific evidence shows that it is possible to devise a set of indicators on physical activity and compile a database that enables the integration and comparability of the data collected.

In particular, we recommend that:

a/ The indicators chosen should be adopted by all countries in order to unify goals and monitoring activities.

b/ In addition to choosing effective indicators based on scientific evidence, it is necessary that States base recommendations on those of the WHO and report concrete objectives.

c/ The indicators highlighted in the literature are in line with those reported by EUROSTAT, Health for All and ECHI. This is an important factor that facilitates the implementation of policies.

d/ An indicator is optimal if it can be measured in the living environment, and in school, after school, worksite, and urban environments: BMI, level of physical activity, total energy expenditure (kcal/week), waist circumference, and time spent in moderate to vigorous physical activity (MPVA).

INFANTS, CHILDREN, AND ADOLESCENTS: EVIDENCE AND RECOMMENATIONS

The systematic review highlights that physical education and physical activity promotion in school seem to be the best approach to increase movement in children and adolescents. School is the ideal setting to develop a positive attitude of children and adolescents towards regular physical activities. The main interventions/policies reported in the scientific literature on adolescents/children with evidence of effectiveness included:

- Physical education in school curriculum
- Health education in school with the involvement of teachers and family
- School-based interventions targeting both physical education and healthy diet
- Child care policies and practices
- Promotion through Internet, smart-phone, mail, telephone
- Interactive computer-based interventions
- One to one counselling

It is important to create an appropriate school environment where physical activity can be practised and encouraged through the building of playing fields and sports halls. Moreover, all actions aimed at making physical activity more attractive to children and young people should be promoted, because the school environment alone is not enough. In a multi-component approach, family and teachers should also be involved in promotion efforts, and urban facilities and environmental facilities should be suitable to encourage children's movement and physical activity.

a/ No effectiveness or unclear evidence was found for policies or interventions related to advertising, community-wide campaigns, mass media campaigns and group counselling.

b/ The indicators more studied were BMI, level of physical activity, total energy expenditure (kcal/week), waist circumference, and time spent in moderate to vigorous physical activity (MPVA).

c/ Concerning the World Health Organisation collaborative cross-national survey "Health Behaviour in School-aged Children" in those aged 6-17 years, one item on physical activity is considered: "How many boys and girls achieve the recommended 60 minutes of MVPA daily?" The same indicator on time spent in MVPA is found in the review as well.

C – ALCOHOL CONTROL

(for details see ANNEX 3 in supplemental information)

Alcohol is a recognized risk factor for oncologic diseases; in particular the Acetaldehyde associated with consumption of alcoholic beverages is considered carcinogenic. In 2012 the International Agency for Research on Cancer (IARC) confirmed alcohol as carcinogenic to humans (Group 1). The association between alcohol consumption and neoplasms of the mouth, pharynx, larynx, esophagus, pancreas, kidney, liver, and breast has been confirmed (Larc monography 100-E, 2012).

In 2010 the WHO developed the WHO Global Strategy to Reduce Harmful use of Alcohol («WHO | Global strategy to reduce harmful use of alcohol», s.d.) to promote policies and interventions to control alcohol consumption. In this document WHO pinpointed 10 areas of possible intervention to control the consumption of alcohol. We reviewed the scientific evidence to find the most effective policies and interventions as well as the indicators used in scientific literature to monitor their effects.

Our review provides information on the effectiveness of the following policies and interventions addressing alcohol consumption:

1 Health service response, in particular we focused on screening programs to detect alcohol addiction, programs of therapy and/or counselling, and brief Interventions;

2 Community action including education, awareness and prevention programs that are school or family based or multi-component;

3 Drunk driving countermeasures;

4 Availability of alcohol;

5 Marketing of alcoholic beverages, including limitations on advertising, promotions, sponsorship, and the legislation on packaging;

6 Pricing policies;

7 Reducing the public health impact of illicit alcohol and informally produced alcohol;

8 Monitoring systems.

A total of 34 articles published from January 2011 to June, 2015 were included. We evaluated systematic reviews and meta-analyses, and quantitative results of meta-analyses are shown in Tables 7-6 (see supplemental information). Seven meta-analyses have been performed in the last five years on this issue. Nevertheless, a huge body of individual studies and systematic reviews have been performed, and they suggest that the control of alcohol spread implies a range of measures, including policies at the national and local levels to prevent the onset of the alcoholic behaviour and to promote and support recovery from alcohol addiction.

Moreover, interventions at the local level that are tailored to specific population targets (e.g. children, adolescents, elderly people, and pregnant women) actively support national policies. Monitoring the effectiveness of policies and interventions in the field of alcohol consumption will be fundamental both for evaluating improvements in the risk profile of the population and for developing evidence to continually improve interventions.

Table 7A Distribution of the number of papers and indicators for each kind of intervention

*One paper can be included in one or more area.

Macro area of intervention	Number of papers*	Number of indicators
Brief Intervention	4	15
E-health interventions	1	3
Education/ awareness	10	41
Screening	1	1
Therapy/counselling	5	30
Universal family-based prevention programs	1	6
Universal multi-component prevention programs	1	6
Universal school-based prevention programs	1	10

Table 7B Distribution of the number of papers and indicators for each type of policy

*One paper can be included in one or more area.

Macro area of policy	Number of papers*	Number of indicators
Advertising, promotion, sponsorship	2	12
Availability	3	28
Drunk driving	2	5
Education/awareness	1	1
Encourage alcohol industry	1	1
Illegal alcohol	1	12
Monitoring	1	1
Packaging/labelling	2	10
Price and tax	6	25
Protection from exposure	2	3

Table 8 Distribution of indicator of type of outcome: health, behaviour or knowledge

*One indicator can be used in one or more outcome.

Typology of indicator*	N
Knowledge	4
Behaviour	16
Health	13

Table 9A Description of indicators more frequently reported among interventions (out of total=21)

Intervention indicator	N
Consumption	20
Consumption frequency	15
Consumption quantity	9
Abstinence	7
Alcohol related problem	6
Binge drinking	4
Drunk driving	4
Initiation age	4
Protective behaviours	4
Blood alcohol content	3
Knowledge	3
Incidence of drunkenness	2
Prevalence of drinkers	2

Table 9B Description of all indicators reported among policies (total=18)

Policy indicator	N
Consumption	15
Alcohol-related injuries	10
Violence	8
Alcohol-related diseases	7
Crime	4
Knowledge	4
Abuse	3
Blood Alcohol Concentration	3
Toxic effects	3
Unrecorded alcohol consumption	3
Awareness	2
Social disorder	2
Age of initiation	2
Number of outlets	2
Alcohol production	2
Risk perception	2
Sexually transmitted infections	2
Youth drinking	2

General considerations on alcohol control

EVIDENCE

The results from the review of systematic reviews and meta-analyses regarding the following intervention/policies show that:

a/ Health service response

Assessment of the effectiveness of screening programs to detect alcohol addiction, harmful drinking and therapy and/or counselling is difficult because of the lack of scientific evidence on some of these approaches, the heterogeneity of the interventions performed, the populations targeted and the indicators adopted in the evaluations.

Brief interventions are effective in reducing alcohol consumption, alcohol related injuries, alcohol related diseases and binge drinking, and the WHO supports their implementation.

b/ Community action

Summarizing education and/or awareness programs is difficult because of the heterogeneity of the interventions performed, the populations targeted and the indicators adopted in the evaluations. Nevertheless, provision of social norm information for alcohol misuse in university and college students is effective in reducing binge drinking. Motivational interviewing for alcohol misuse in young adults reduces the quantity and the frequency of alcohol consumption. School-based preventive interventions in adolescents reduces the prevalence of students' drinking alcohol and the frequency and quantity of alcohol consumption. E-health interventions may represent an important innovative option. They seem to obtain high levels of compliance, increase patients' motivation and prevent relapse in alcohol dependent patients.

c/ Drunk driving counter-measures

Enhanced enforcement of BAC seems to be effective in reducing blood alcohol levels and road accidents.

d/ Availability of alcohol

Limiting the hours of alcohol availability and the density of alcohol outlets seems to reduce alcohol consumption, sales and social violence in the areas of restriction. An increase in the minimum age of sale reduces alcohol consumption and alcohol-related injuries.

e/ Marketing of alcoholic beverages

Evidence suggests that marketing campaigns by alcohol producers increase alcohol consumption and positive beliefs about alcohol. Restricting or banning alcohol advertising is effective in reducing alcohol consumption in adults and adolescents. Forbidding sponsorship of social and sporting events seems to reduce alcohol consumption. The impact of health information on packaging on awareness and behaviours has not been shown, but packaging may be an important tool to inform customers about alcohol-related risks.

f/ Pricing policies

Increasing the price of alcohol seems to be effective in reducing alcohol consumption production, the number of retail outlets, alcohol-related diseases, dependence and abuse.

g/ Reducing the public health impact of illicit alcohol and informally produced alcohol

Several options are available to reduce alcohol production and the consequences of illegal production, but few studies have been performed on this issue. The main actions that can be undertaken are: mass media campaigns to inform about health risks, increasing internal and cross-border controls, and abolishing the tax exemption for denatured alcohol.

POLICY RECOMMENDATIONS

a/ Implement at the Member State level evidence that has been demonstrated to be of proven efficacy/effectiveness.

b/ Policies should be designed considering the different needs of populations exposed to different levels of risk. Primary, secondary and tertiary prevention should be implemented as well as brief interventions to treat alcohol consumption.

c/ When a decision on the implementation of a policy/intervention has been made, Member States must consider at least three dimensions for monitoring the impact of the policy in the short term:

i. Alcohol consumption by- at minimum- gender and age

ii. Prevalence of high risk drinkers

iii. Alcohol related injuries

and two dimensions for monitoring the impact of policies in the long term:

iv. Prevalence of alcohol-related diseases

v. Mortality for alcohol-related diseases

d/ Monitoring of the policies' effectiveness through EUROSTAT official indicators, or through the European Information System on Alcohol and Health (GISAH) is important, as suggested by the European Action Plan to Reduce the Harmful use of Alcohol 2012–2020.

e/ If the suggested indicators cannot be monitored annually at the national level, we recommend performing an observational study after the policy's implementation.

INFANTS, CHILDREN, AND ADOLESCENTS: EVIDENCE AND RECOMMENDATIONS

According to the systematic review, interventions targeting children or adolescents were in the areas of education and awareness- to prevent alcohol consumption- and therapy or counselling for those who already had begun consuming alcohol. The settings were mainly schools, families or community health departments. At the national level, the policy specifically targeting young people relates the area of protection from exposure, and in particular to the ban on alcoholic beverage sales to people under a certain age. Policies targeting the general population (e.g. in the area of packaging and labelling) may particularly impact the young population. According to our review, the interventions or policies that are effective in children and adolescents are warning labelling on alcohol products, the ban of alcoholic beverage sales to children and adolescents, the use of serious educational games, and some alcohol education and life skills training, including coping strategies and problem solving skills.

Indicators adopted in the scientific literature in the area of knowledge/awareness include: awareness of alcohol-related health risks and perception of harm; in the area of alcohol consumption behaviour- in terms of frequency and quantity- frequency of drunkenness, drunk driving, alcohol initiation age, and binge drinking; in the area of alcohol-related health consequences, the indicators are the Global Symptom Index scores and mental health status, alcohol related harms and road accidents.

The WHO Health Behaviour in School-aged Children (HBSC) Study identifies three key indicators to monitor alcohol behaviour among children and adolescents : weekly drinking, drunkenness initiation age and number of times being drunk.

D – TOBACCO CONTROL

(for details see ANNEX 4 in supplemental information)

According to the WHO (2003), the policies for community interventions to control tobacco consumption by changing social norms are a good investment. Currently the policies realized worldwide represent a synergy between are a public health approach, a health systems approach, surveillance and research.

The interventions/policies related to effectiveness on tobacco control were obtained from review of the scientific literature (systematic reviews and meta-analyses) and reported, according to the WHO categorization, as follows:

1 Smoke-free workplaces represent a cost-effective approach;

2 There are mixed conclusions to be drawn from articles on price and tax measures: some articles underscore high effectiveness in reducing demand, but other papers conclude that "a regressive measure today will probably achieve only a moderate reduction in tobacco use in the future, as smoking is becoming a phenomenon associated with poorer and less-educated people";

3 Health warnings on tobacco products- picture-based advertisements on standardized packaging are effective at discouraging smoking;

4 Establishing the effect of mass media campaigns is difficult, as they are mostly guided by other measures such as tax increases;

5 Regarding interventions:

a/ School/university based interventions;

b/ Telephone/mobile counselling;

c/ Internet counselling, group-delivered behavioural interventions to achieve long-term smoking cessation, incentives, physician advice;

d/ Expert systems, tailored self-help materials and individual or group counselling:

Interventions of type D appear to be as effective in a stage-based intervention as they are in a non-stage-based form. The evidence is inconclusive for other types of stage-based interventions, including telephone counselling, interactive computer software, and training of physicians or lay supporters.

The control of the spread of tobacco and smoking requires a range of measures included in policies at the national level. It also requires intervention at the local level, such as counselling to improve motivation to quit and interventions to prevent starting to smoke. The success of these measures depends on their synergistic use in the broader context of a comprehensive tobacco-control strategy.

A total of 47 papers (systematic reviews and meta-analyses) were analysed, and a total of 66 indicators were found.

The policies and interventions were categorized into macro areas (Tables 10A-10B). The majority of interventions were focused on "protection from exposure" and "therapy/ counselling". Whereas policies were focused on "price and tax measures" and "protection from exposure".

Many indicators have been identified in the scientific literature (Annex 4 in supplemental information) to measure effectiveness, those most used are shown in Tables 11A and 11B. Table 12 reports the distribution of different areas of interest related to indicators: health, behaviours and knowledge. To measure effectiveness, the polices/interventions were studied only for meta-analysis studies published in 2010-2015 (N=18). The quality and the main results are reported in supplemental information.

The indicators most frequently reported in the scientific literature were compared to the existing indicators at the European level (EUROSTAT, ECHI and HFA). Tables 14 and 15 (see supplemental information) describe the indicators found in different systems and their availability within the different European regions (see supplemental information). The total number of different indicators found was 66. Forty related to policies and 43 related to interventions.

Some limitations should be mentioned. When the indicators differed in terms of the definition of smokers, or age or gender, they were classified as the same indicator, i.e. prevalence of smoker includes: prevalence of heavy smokers, prevalence of daily smokers, prevalence of subjects that have smoked 100 cigarettes in their lives, etc.

Another limitation is that some indicators combined different situations: for example the "quitting smoking" indicator includes different settings and target populations (adolescents, heavy and/or long-term smokers, low income populations, low education populations and the general population), different measurements (rates or percentages or frequencies) and different follow-up times (1 month, 6 months, one year, etc.)

Lastly, the EUROSTAT website published only the most robust indicators; other indicators are surely collected (such as the number of cigarettes smoked and type of product), but in this report they were not included.

Table 10A Distribution of the number of papers and indicators for each type of intervention

*One paper can be used in one or more area.

Macro area (interventions)	Number of papers	Number of indicators*
Availability	1	1
Ban on advertising/sponsorship	8	8
Combined approach	2	5
Education/awareness	9	15
Mass media campaign	3	7
Protection from exposure	8	12
Therapy/counselling	17	17

Table 10B Distribution of the number of papers and indicators for each type of policy

*One paper can be used in one or more area.

Macro area (policy)	Number of papers	Number of indicators*
Availability	3	6
Ban on advertising/sponsorship	5	5
Combined approach	1	1
Mass media campaign	5	5
Packaging/labelling	4	5
Price and tax measures	10	11
Protection from exposure	10	17
Therapy/counselling	2	2

Table 11A Description of indicators most frequently reported among interventions (out of total =42)

Indicator	Frequency
Quit rate	10
Quitting smoking (measure not specified)	7
Abstinence in late pregnancy	6
Smoking cessation prevalence	6
Smoking initiation prevalence	6
Smoking prevalence	6
Reduction of second hand smoke exposure	4
Reduction of tobacco consumption	4

Table 11B Description of indicators most frequently reported among policies (out of total=40)

Indicator	Frequency
Smoking prevalence	13
Tobacco consumption	12
Quit smoking	4
Smoking initiation prevalence	3

Table 12 Distribution of indicator by type of outcome: health, behaviour or knowledge

*One indicator can be used in one or more area.

Area of interest of indicators	Number of indicators
Knowledge	9
Behaviour	52
Health	9
Total*	66

General considerations on tobacco control

EVIDENCE

The main intervention/policies reported in the scientific literature were:

1. Smoke-free workplaces represent a cost-effective approach;
2. Price and tax measures give positive results in the reduction of smoking prevalence, even if of moderate impact;
3. The health warning on tobacco products and the pictorial warnings are quite effective in discouraging smoking;
4. Mass media campaigns cannot be easily monitored;
5. Interventions of proven efficacy/effectiveness include:
   - i. School/university based interventions,
   - ii. Counselling, telephone/mobile counselling,
   - iii. Internet counselling, group-delivered behavioural interventions to achieve long-term smoking cessation, incentives, physician advice;
   - iv. Expert systems, tailored self-help materials and individual counselling, appear to be as effective in a stage-based intervention as they are in a non-stage-based form. The evidence is inconclusive for other types of stage-based intervention, including telephone counselling, interactive computer software and training of physicians or lay supporters.

POLICY RECOMMENDATIONS

The literature clearly defines the interventions/policies that have been demonstrated to be of proven efficacy/effectiveness, and therefore the Member States are recommended to implement them.

As far as the set of indicators related to tobacco, we recommend that:

a/ When a decision on the implementation of a policy/intervention has been made, Member States must consider at least three dimensions for monitoring the impact of the policy in the short term:

   - i. Tobacco smoking prevalence
   - ii. Quit rate
   - iii. Initiation rate

b/ If these indicators cannot be annually monitored, we recommend considering revising the indicators (EUROSTAT, Health for All) for the best fit between a policy/intervention and monitoring*

c/ In the meantime, if these indicators cannot be annually monitored, we recommend performing an observational study after the implementation of the policy at the national level.

INFANTS, CHILDREN, AND ADOLESCENTS: EVIDENCE AND RECOMMENDATIONS

The systematic review shows that policies in the school setting are the most referenced, followed by policies at the national level. The outcomes concerning behaviour are the most studied. The main interventions/policies reported in the scientific literature related to adolescents/Children with evidence of effectiveness were:

- School-based programs for smoking prevention, health promotion
- Smoke-free air regulations and enforcement
- Smoking bans in workplaces, public space, etc.
- Voluntary home smoke-free policies
- Increase in taxes on tobacco products

No effectiveness or unclear evidence was found for policies or interventions related to incentives, competitions, lotteries or punishment, and sanctions, especially in high-school students.

The measures applied to assess the outcomes were the same included in the Evidence on the General Population, and they are: smoking prevalence, smoking initiation prevalence. Instead the " tobacco use initiation" seems to be preferred to the indicator "quit rate".

In comparison with the items included in the World Health Organization collaborative cross-national Health Behaviour in School-aged Children Survey on tobacco consumption in those aged 6-17 years, the item related to smoking is: "How often do you smoke tobacco at present? % of boys and girls that replied 'at least once a week' ".

Summary list of indicators extracted from “Policy Recommendations”

A – NUTRITION

- Changes towards a healthy diet
  - Increase in frequency and amount of healthy foods (fruit, vegetables)/average amount of fruits and vegetables available per person per year (kg)
  - Decrease in total fat intake (especially saturated and hydrogenated trans fats) sodium, calories, and reduction in sugar
- Changes in body weight and in the prevalence of overweight and obesity (monitoring of BMI)
- Reduction in serum cholesterol level, blood glucose level, blood pressure as well as other dietary-related health status and nutritional and metabolic diseases

B – PHYSICAL ACTIVITY

- BMI
- Level of physical activity
- Total energy expenditure (kcal/week)
- Waist circumference
- Time spent in moderate to vigorous physical activity (MPVA) weekly
- Fat mass index (FMI)

C – ALCOHOL

- Alcohol consumption by- at minimum- gender and age
- Prevalence of high-risk drinkers
- Alcohol related injuries
- Prevalence of alcohol-related diseases
- Mortality for alcohol-related diseases
- Frequency of binge drinking among adolescents

D – TOBACCO

- Tobacco smoking prevalence
- Quit rate
- Initiation rate
- First use of tobacco (for adolescents)

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4 Authorship

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6 Annexes

For annexes and supplemental information see website of the Joint Action Cancon: www.cancercontrol.eu under Policy paper "An Impact Evaluation System to Assess Prevention Outcomes"