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WP4 INTEGRATION IN NATIONAL POLICY & SUSTAINABILITY

REPORT OF THE IPAAC WP4 CANCER CONTROL POLICY INTERVIEW SURVEY

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PREFACE

The Innovative Partnership for Action Against Cancer (iPAAC) Joint Action brings together 24 Associated Partners (with Affiliated Entities, 44 partners) across Europe whose main objectives are to build upon deliverables of the CANCON Joint Action and to implement innovative approaches to cancer control. A Roadmap on Implementation and Sustainability of Cancer Control Actions will be the main deliverable of this Joint Action.

The iPAAC Work Package 4 (WP4), led by the Belgian Cancer Centre of Sciensano, visited 28 European countries in order to collect examples of innovative approaches for implementing cancer control policies which will to be shared in the Roadmap.

As providing an exhaustive list of the cancer policies in each country was not feasible, semi-structured interviews were conducted with the aim to identify those initiatives that were considered of interest for sharing with other countries by the local stakeholders (i.e., health advisers, healthcare providers, scientists, civil society representatives and healthcare providers). Five domains were prioritized for the discussion: health promotion and prevention; cancer screening; diagnostics and treatment (innovative therapies); cancer care (including rehabilitation and end of life care) and cancer information systems.

As the objective was not to capture a state of play, not all of these five domains were discussed in all 28 countries. The content and extent of the discussions depended mainly on the availability of the local stakeholders at the time of the visit and the time dedicated to the interview. More details on the methodology of this exercise can be found in the iPAAC WP4 working document "iPAAC_WP4_CCPIS_Methodological paper", available on the intranet of the iPAAC website[1].

At no point we did aim to evaluate cancer policy implementation or benchmark the findings from this study. This report is to be considered as a summary description of the discussions and could represent the basis for the development of propositions for further action(s). In addition to describing the innovative implementation activities themselves, many interviewees reported challenges encountered in establishing new actions. Indeed, many practical issues were raised concerning cancer control policy implementation. These challenges are listed in the WP4 working document 'iPAAC_WP4_CCPIS_list of challenges', available on the intranet of the iPAAC website. Importantly, this report describes the perspective of the interviewees and not the country position.

Interestingly, some challenges noted in some countries were motivating factors for developing innovative approaches to overcome the difficulties in others; while for a series of challenges, no concrete solutions were reported. Thus, it is clear that bringing countries together around specific challenges is of great value for knowledge exchange, mutual learning, and identifying further needs or help required to develop solutions.

To the many challenges and solutions identified by the countries, iPAAC WPs5-10 effectively worked to develop support for quality improvement and sustainability of cancer control. In total, more than 300 examples captured as concise one-page summaries have been produced with each of these inspiring examples to be retrievable in the iPAAC Roadmap.

We have been impressed by the warm welcome in most countries and the easy collaboration with our local contact persons who were dedicated and very efficient in the practical organization, including the invitation of key players around the table. But also, and especially in getting the feedback and validation of the Minutes of the interviews. Their help and commitment was invaluable, as well as the input from the iPAAC work package leaders and their teams.

The Belgian Cancer Centre, Sciensano

[1] https://www.ipaac.eu/res/file/outputs/wp4/ipaac_wp4_ccpis_methodological_paper.pdf

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ABSTRACT

From July 2018 to January 2020, the Innovative Partnership for Action Against Cancer (iPAAC) Work Package 4 (WP4) performed a survey among European Union (EU) Member States to capture their experience and challenges regarding the implementation of cancer control policies. In total, 28 countries were visited, and the meeting minutes were inductively coded using NVivo qualitative analysis software to provide the core data for this report[2].

Two important and consistent rationale for action were found: quality and equity. Through all cancer control domains, the objectives are the same: ensure quality and tackle inequities.

When it comes to **primary prevention**, all countries reported having pursued innovative approaches to better inform and communicate with key stakeholders, especially related to children, adolescents and young adults (AYAs) and lower socio-economic groups. A recurrent issue concerns the sustainability of primary prevention actions. A vicious circle exists due to the difficulty in measuring short-term impacts, which in turn, does not provide support for the provision of structural budgets. Register-based collection of structured and validated data of lifestyles and interventions from electronic data sources in health care would be a key to evaluation and to generate evidence-based recommendations.

A second important challenge relates to the interference of the corporate giants of the tobacco, alcohol and food industries. Regulatory actions as well as inter-ministerial and inter-sectorial platforms have proven their efficacy to mitigate the influence of these corporate interests and promote the pursuit and maintenance of healthy lifestyles.

Regarding **cancer screening**, the extent of implementation of screening programs varies widely among EU Member States. The most often reported challenges concern test selection, non-appropriate governance and/or legal frameworks and the effectiveness of population-based screening programs. Some countries, as well as the scientific community, are investigating the possibility of shifting to high-risk stratified screening programme. Some groups have been found to have systematically lower compliance to organized screening programs. Special attention should be given to the means of reaching, informing and inviting these specific populations. The involvement of community health professionals (pharmacists or nurses) and the training of community lay workers have been reported by several countries to better inform the population and raise the participation of target groups to screening.

Cancer diagnostics and treatment are of high importance for both quality and equity. Most countries struggle with controlling the rise of the costs of innovation that put the sustainability of their systems at risk. Also, the rapid pace of some innovations can require regular adjustments in reimbursement schemes and decision-making processes. EU cooperation on these two matters is highly sought and needed.

Cancer care provision and organization is at the heart of action in most EU countries. It regulates the ‚what and how' for cancer patients and their family. Waiting times, lack of cancer care professionals, cultural habits and quality control are recurrent challenges reported by EU countries. In addition, the lack of knowledge and the persistent need to identify best practices, especially for long-term care have been raised. Comprehensive cancer care networks, patient pathways and coordinated activities have been reported as the current ways to improve and ensure quality and equity in the provision of cancer care. More efforts are needed to investigate (evidence-based) improvements that focus on a more patient-centered provision of care, especially for rehabilitation and palliative care. Rare cancers are specific priorities for these networks, especially in relation to European Reference Networks (ERNs).

Cancer information systems intersect all dimensions of cancer control and are mainly organized through cancer registries. However, their mandate and subsequent ability to support evidence-based cancer control policy varies widely. The possibility to link with other health, administrative or socio-economical information sources is key but requires legal, ethical and technical adjustments. Enhancing digitalization, data integration and interoperability 'by design' is crucial and requires global strategies and resources. In a context of increasing prevalence the lack of data on the whole disease trajectory, including quality of life and survivorship, is considered critical. Also, patient and carers

[2] https://www.ipaac.eu/res/file/outputs/wp4/ipaac_wp4_ccpis_methodological_paper.pdf.

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perspectives need to be integrated to ensure meeting their needs and support development of patient-centered interventions.

Overall, EU countries are engaged in many cancer control efforts, with differing foci according to specific national needs, political agendas and resources. However, maximum capacity seem to have been reached in many domains and the support from the European Commission (EC) would help to overcome persistent challenges. Three types of support are required. First support for research, including epidemiology and health services research leading to the identification of best practices and the development of guidance. Second, support for knowledge exchange among EU countries on cancer control policy implementation. Third, legal frameworks, i.e. regulations, have the power to ensure coherent activities and provide binding force to expected good quality practice. To ensure improved effectiveness and cost-effectiveness, these three key types of support need to be organized and developed in parallel, integrated and well documented.

1 BACKGROUND

The main objective of the iPAAC Joint Action is to develop innovative approaches to advances in cancer control. The innovations covered within the Joint Action consist of the (1) further development of cancer prevention, (2) comprehensive approaches to the use of genomics in cancer control, (3) cancer information and registries, (4) improvements and challenges in cancer care, (5) mapping of innovative cancer treatments and (6) governance of integrated cancer control, including a new analysis of National Cancer Control Plans.

The key focus of the Joint Action is on implementation, reflected in the main deliverable: a **Roadmap on Implementation and Sustainability of Cancer Control Actions**, which will support EU Member States in the implementation of innovative cancer control actions and programs through the facilitation of mutual learning, knowledge and experience sharing. This is the responsibility of Work Package 4 (WP4).

In addition to inputs from the IPAAC core work packages (WPs 5-10) which map the six cancer control domains noted above, WP4 conducted a detailed country-specific policy survey, the 'Cancer Control Policy Interview Survey' (CCPIS), in order to collect information on current initiatives and experience in implementing cancer control policies in EU Member States.

This report is a summary of the outcomes of that exercise, providing an overview of the main issues reported by Member States in six cancer control domains and the main results from the associated iPAAC core work packages.

2 METHODOLOGY

A detailed description of the methods used to perform the CCPIS as developed and applied by WP4 is provided in the iPAAC WP4 methodological paper[3].

In short, the CCPIS process consisted of the following key steps:

- Preparation of a 'Country Profile' (CP) document
- Development of the interview guide
- Organization of country visits in collaboration with the iPAAC country representatives
- Country visit and conduct of survey by at least two members of the WP4 team
- Preparation of minutes and summary of country visit (the latter presenting the list of possible country-specific examples to be included in the Roadmap)
- Validation through member-checking of the generated meeting minutes and country visit summaries and examples by the country participants

[3] https://www.ipaac.eu/res/file/outputs/wp4/ipaac_wp4_ccpis_methodological_paper.pdf

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The CCPIS exercise did not aim to be exhaustive. Rather, the aim was to identify themes and topics of interest to be included in the mutual learning platform deliverable for iPAAC, i.e., the 'Roadmap'. Therefore, it should be emphasized that **this report, does not intend to present a comprehensive state of play on cancer control policy of EU Member States**.

Most survey informants were part of governmental institutions (such as national institutes of public health, health ministries, cancer societies, etc.) or clinical institutions (e.g. cancer centers).

Importantly, WP4 mostly met **national representatives rather than regional/local stakeholders**. In many countries the health care system is not fully centrally organized/managed but has been to variable extent decentralized to regional/local authorities.

Due to time constraints and the exploratory nature of this exercise, the country visits could not be extended to multiple regional/local levels.

In general, the CCPIS approach was very well received and supported. In many countries, participants were open and willing to address the gaps or challenges of their current approaches to the implementation and sustainability of cancer control actions.

3 HEALTH PROMOTION AND PRIMARY PREVENTION

3.1 PRIMARY PREVENTION FRAMEWORKS AND RESPONSIBILITIES

3.1.1 The legal force of preventive frameworks

The frameworks in which primary prevention activities are organized are rarely cancer-specific. Several countries reported that their primary prevention strategies started with the fight against cardiovascular diseases (MD) or under an overall plan against non-communicable diseases (15 countries), because of the same risk factors.

For specific cancer-related primary prevention programs, ten countries reported to have it organized or integrated in the framework of National Cancer Control Program (NCCP). Fifteen countries mentioned that these frameworks have a legal force and are therefore supported by legislation. More typically, they often concern specific risk-factors, especially tobacco and alcohol, such as the French *National Smoking Reduction Programme* 2014–2019 (FR[4]) or the Irish Alcohol Act (IE)[5]. In Poland both actions are supported by legislation: the Act amending the Health Protection Against the Effects of Using Tobacco and Tobacco Products[6] and the Act revising the Act on Upbringing in Sobriety and Counteracting Alcoholism and the law on the safety of mass events[7] strongly connected with the act concerning the mental health protection[8](PL).

[4] https://www.ipaac.eu/res/file/reports/wp4/ccpis/plan_cancer_2014_2019_pnrt.pdf

[5] http://www.irishstatutebook.ie/eli/2018/act/24/enacted/en/print#part1

[6] Act of 22 July 2016 amending the Health Protection Against the Effects of Using Tobacco and Tobacco Products http://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20160001331/O/D20161331.pdf

[7] Act of 10 January 2018 amending the Act on Upbringing in Sobriety and Counteracting Alcoholism and the Act on Mass Event Safety http://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20180000310/O/D20180310.pdf

[8] Act of 24 November 2017 amending the Mental Health Protection Act and several other acts http://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20170002439/O/D20172439.pdf

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For example, the informants from the Netherlands presented their national framework for primary prevention, the Dutch Prevention Agreement[9], with common goals and joint decisions (NL).

In Belgium, it has been reported that the different regional and level of authorities worked together on a "Protocol Agreement for Prevention" that is not legally binding but is reported as a political agreement'[10] (BE).

The main disadvantage of not having the fight against the risk factors embedded in law is the lack of authority to first check and monitor the (un)healthy behaviors and second, to act if unhealthy environments are created. This requires first, careful planning on how legislation is put into action and second, the support from the population to these legislative restrictions.

In most countries, we find a combination of two strategies: on one hand, the use of legislation to ban or prohibit unhealthy practices, and on the second hand, non-legally binding initiatives with the involvement of target groups through friendly and educational activities. Importantly, legislation and health education go hand in hand.

Nutrition is recently becoming an important concern, with many efforts to improve dietary habits, especially among children. Fourteen countries reported examples of programs in which schools are targeted, supported and involved for promoting healthy behavior among children and AYAs. Some countries serve at schools - until high school or vocational school is over- free warm meals five days a week according to healthy diet recommendations. Also, healthy snacks are served during long days (FI)[11], including fresh fruits, vegetables and milk from local farmers (PL)[12]. Fourteen countries reported examples of programs in which schools are targeted, supported and involved for promoting healthy behavior among children and AYAs. Both restrictions and incentives are used to promote healthy habits.

While some countries restrict unhealthy snacks and drinks at school premises (as in PL, LT, FI and CY, where e.g. they prohibit dispensing machines for sugary drinks) others are inviting parents to learn about healthy meals (MT, CY). Cooking classes and nutrition information may be part of national curriculum (FI, NO).

An example from Malta is the Lunchbox Campaign13 where schools do organize practical sessions on *what should be included in a health lunchbox* (MT).

In Cyprus, a coherent promotion of healthy nutrition in schools has been organized which offers cooking classes for parents and children, provides healthy breakfasts for socially vulnerable children and has adapted the law for school canteens (CY).

An important challenge when it comes to health promotion and primary prevention frameworks are changes in government (HR, BE, PL). To observe positive changes or impact of preventive actions, it requires extended periods of time. Four of five years are typically not enough time to judge the effectiveness and even less so the efficiency of such measures. Health promotion requires long term efforts, planning and strategy level actions. Therefore, the implementation, sustainability and actual outcomes of preventive activities is put at risk at each change of government, unless there is a national policy to serve at schools free healthy meals and state supports this activity despite government changes.

9 https://www.government.nl/documents/reports/2019/06/30/the-national-prevention-agreement

10 https://overlegorganen.gezondheid.belgie.be/sites/default/files/documents/2016_03_21_-_prevention_-_preventie.pdf

11 https://www.ipaac.eu/res/file/reports/wp4/ccpis/um_casestudyfinland_schoolfeeding_june2019_netti.pdf

12 Regulation the Ministry of Agriculture and Rural Development of 28 August 2020 on the detailed scope of tasks to be carried out by the National Support Centre for Agriculture related to the implementation of the programme for schools in the Republic of Poland

13 https://deputyprimeminister.gov.mt/en/health-promotion/Pages/campaigns/2015/lunchbox-campaign-2015.aspx

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3.1.2 Stakeholders leading or participating in primary prevention

Preventive actions can be governed centrally, but in most EU Member States they are implemented and financed by the local or regional level. In most cases (22 countries), the –federal- state provides the regions with the legal framework//guidelines/recommendations but the responsibilities for the implementation and the funding lie with the regional governments.

Spanish informants reported the existence of guidelines for organizing tobacco counselling in primary healthcare settings, that are prepared by the National Ministry of Health and spread among regional instances (ES).

In some countries, it has been reported that this "top-down approach" is mainly steered by the national institute of public health (NIPH), which then support the local stakeholders by providing guidance and/or materials (BG, HR).

In Bulgaria, there is a structural collaboration between the National Center of Public Health and Analyses (*NCPHA*), the Ministry of Health and the Regional Health Inspectorate (BG). In Latvia also, the National Centre for Disease Prevention and Control provides methodological guidelines and training to the municipalities facilitating the implementation of primary prevention policies and organize exchanges of information and experience between the regions (LV).

Most of the guidance provided by central institutions (ministry or NIPH) are non-binding, i.e., regions can deviate from the prescribed practices without any consequences. In some countries, regional institutes of public health or municipal public health offices are organized in networks (HR, BG, SK). In Serbia and in Poland, the Ministry of Health allocates funds for public health activities including health promotion. Activities are implemented by the network of regional public health institutes under the guidance of the NIPH. Annual work plans are approved and monitored by MoH and NIPH and activities might be adjusted in terms of content (RS, PL).

The organization in networks can also facilitate the run of activities across the country. For example, in Serbia and Croatia, the network of regional institutes of public health is coordinated by the national one. They organize training for health professionals, teachers, social workers, representatives of regional authorities, NGOs, etc. with regards to evidence-based prevention and health promotion.

The decentralization leads to different approaches in primary (cancer) prevention, with different efforts being pursued simultaneously within the countries. However, the decentralized approach has the advantage of strong **community-based engagement**, with pharmacies (IE, PT), schools (reported in 14 countries), NGOs (12 countries), primary healthcare centers (18 countries). These latters have more experience in advising local communities, having their confidence and knowing the socio-economic contexts.

To lessen the inequities that these differences among regions could generate, initiatives are often taken at the federal level to coordinate actions, to share experiences and to develop consensus on "*how to implement*" prevention policies.

For example in Latvia, the National Centre for Disease Prevention and Control provides methodological guidelines, trainings and seminars to municipalities, and organized field visits between regions to exchange their experience (LV).

In Portugal, the Primary Health Care Centers have regional coordinators that is often invited together to the national level, in order to facilitate the collaboration between the regions by, among others, providing guidance for performing primary prevention activities (PT).

These national initiatives aim at decreasing the differences among regions, especially in those countries where resources are not equally distributed across the country (HR, DK, PT).

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Also, for those living in remote and/or rural areas, **mobile units** are organized, including several healthcare professionals and social workers who perform health checks and provide advices or support.

In Hungary as in Poland, the use of mobile units has been reported, which are primarily foreseen for cancer screening and cardiovascular disease screening, but in which the health professionals also take the opportunity to perform health promotion activities (HU, PL).

In Germany, the contract of the coalition parties of the Federal Government is planning for preventive home visits to be funded through the Preventive Health Care Act. The rationale is to prevent early disability and the need for long term care. In some German regions (”Laender”) this approach has been evaluated in pilot projects.

In five countries, **inter-regional coordination platforms** are created to discuss primary prevention policies and to ensure there is a common vision on primary prevention goals (BE, DE, IT, ES, AT).

For example in Austria, authorities representing the provinces, the federal government and the health insurance come together to discuss and decide on priorities for health promotion and public health and the underlying necessary budget. All involved partners have to adopt the legal frameworks resulting from the consensus (AT). Similarly, Germany has a national ”prevention forum”, a yearly event with alls level of stakeholders to advise on the implementation and further development of the ”National Prevention Strategy” (DE). In Belgium, the inter-ministry conference (IMC) involves all ministries responsible for policies that can influence primary prevention and screening activities and aims at finding consensus on priorities for prevention activities (BE).

The Health in All Policies (HiAP) approach is reported by some countries as the approach chosen for health promotion and primary prevention or as an overarching goal (FR, FI, AT, MD, IT, PT)[14].

This approach acknowledges that health policies go across administrative sectors, for instance tax policies are in the domain of finance ministry. The main reported effort in that sense is the organization and support of **inter-ministerial collaboration**, work and discussion; ten countries reported organizing close collaboration between the various ministries responsible for health, education, finance, environment and employment.

Finland reported that it is of great importance to ensure and improve population health and health equity as it includes the impact assessment of policies on health (FI[15]), but also FR, PL and PT reported that, to take into account health in other sectors, they do organize health impact assessments (FR, PT, PL).

Aligned with these inter-ministerial efforts, inter-sectoral work has also been often reported (in sixteen countries). Indeed, the HiAP approach was also often reported in context of adaptation of taxes, involvement of schools or negotiation and cooperation with food industry.

Some countries have dedicated **inter-sectoral committees**, involving the different ministerial departments with local stakeholders, health care professionals, industry and private sector stakeholders, civil society representatives, media, etc. (LT, FI, EL, MT, FR, CY, IE, PT, HR). Mostly these committees or working groups are organized according to a specific risk factor and are considered as advisory bodies developing policy recommendations or guidelines together.

For example in Portugal, the establishment of the sugar tax resulted from a protocol in which it has been agreed to collaborate with the food industry on the reformulation of certain products (PT); while in Poland, the legal Act concerning the sugar tax is signed by the President but already under amendment process due to comments from the beverage industry (PL). In Austria, the health literacy alliance gathers the national MoH, which chairs the alliance, a number of other ministries (including, education, youth, sports), representatives of the Provinces, health and social insurance and organizations performing health literacy interventions within their own sphere of influence (AT).

[14] https://www.ipaac.eu/res/file/reports/wp4/ccpis/health_in_all_policies_book_fi.pdf
[15] https://www.ipaac.eu/res/file/reports/wp4/ccpis/pwp_health_in_all_policies_and_cancer_prevention_eeva_ollila.pdf

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In Serbia, the Office for smoking prevention at the National Institute of Public Health organizes multi-sectorial workshops with, MoH and health professionals to create awareness and to build consensus on the tobacco control evidence-based policy interventions and legislation (RS).

Besides the roles of authorities and institutes of public health, the role of non-governmental organisations (NGOs) in primary prevention has also been reported in several countries (11/28). While some are highly involved in the formulation and/or execution of preventive policies, others focus on funding or conducting research on health determinants and informing the population about them.

Generally speaking, the role of NGOs relates to advocacy for preventive policies; communication and information on risk factors and available tools or support; and patient counselling. For example, a formalized Irish Cancer Prevention network was recently created between the HSE National Cancer Control Programme and the three main NGOs working on prevention. They share initiatives, evidence and studies with the aim to ensure a clear and consistent message (IE).

3.2 CONTENT AND PURPOSES OF PRIMARY CANCER PREVENTION

In most EU countries, primary prevention actions are developed around five major risk factors: tobacco, alcohol, nutrition, obesity and physical activity. Although parts of a common comprehensive programme or strategy, these actions can be classified into three inter-related type of actions:

1. **Regulatory actions** such as taxation, packaging, labelling, availability or prohibition;
2. **Communication and information** campaigns
3. Support to **behavioural change** (also reliant on the two previous)

Most measures and initiatives also favour specific target groups (16/28 countries) which are mainly children or adolescents and young adults (AYAs) and deprived people. For example, the increase in binge drinking, smoking and obesity among AYAs have been reported in several countries which in turn decided to act accordingly.

In five countries the willingness to have a **lifelong approach** (FR, IE, MT, PL, DE), addressing primary prevention needs at each step of the life course and allowing for continuity, comprehensiveness and sustainable approach, has been discussed.

For example, in France interventions take into account the individual's environment across his or her life course so that they can stay healthy over their lifetime; it addresses all health determinants, environmental as well as behavioral; and encompasses the specific needs of different age groups (FR).

Healthy Ireland, a framework for *Improved Health and Wellbeing 2013-2025* is the national initiative to improve the health and wellbeing of the population[16]. It takes a whole-system and life course approach to increase emphasis on prevention, reducing health inequalities, addressing the social determinants of health and empowering people and communities to look after their own health and wellbeing (IE)[17]. Also, Malta reported favoring an inter-ministerial lifelong approach to promote physical activity and healthy diets, notably through *The Healthy Lifestyle Council* (MT)[18]. In Poland the campaign of MoH, 'Planning a long life', organized within the National Cancer Plan, encourages healthy lifestyles and participation in prevention programmes campaing[19] (PL).

[16] https://www.ipaac.eu/res/file/reports/wp4/ccpis/hienglish.pdf
[17] https://www.ipaac.eu/res/file/reports/wp4/ccpis/a_healthy_weight_for_ireland_obesity_policy_and_action_plan_2016_2025.pdf
[18] https://www.ipaac.eu/res/file/reports/wp4/ccpis/healthy_lifestyle_promotion_and_care_act_mt.pdf
[19] http://planujedlugiezycie.pl/

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3.2.1 Regulatory actions

Regulatory actions have two main goals: protection of population from substances which cause cancer and encouraging healthy lifestyles.

Labelling: Many countries provide concrete and specific information through labelling of products (PT, IE, FR, DK, NO, FI, LT, PL). Tobacco, alcohol and food products are the most subject to labelling. Tobacco labelling on packages is well established due to the EU directive on tobacco control.

The use of the *Nutri-score, KeyHole*[20] *or Green apple*[21] have been reported in visited countries (LT, IT, FIN, NO, FR, BE), as well as other initiatives such as the use of **colored symbols** related to the presence of reasonable or unreasonable amounts of salt or sugar. However, Portugal reported that a recent study shows that the message was not clear enough and is currently looking for ways to clarify the content of the labelling (PT).

For example, in Finland, the amount of fat and sodium are reported trough the labelling of food products using a heart symbol (FI).

The use of the Front of Pack labelling, *NutriScore*, to guide consumer choice for better healthy diet has been reported in FR and BE.

An example of a specific cancer-related warning has been found in Ireland regarding the high consumption of alcohol (IE). This results from the observation that a significant number of people are not aware of the link between cancer and specific risk factors (IE, PT, SI).

Serbia launched a contest among universities to develop a symbol for healthy diet products which resulted in having a green apple on a series of food supplies often bought by young people (RS).

Restriction or ban: Bans, prohibition or restrictions mainly concern tobacco and alcohol selling and consumption (in public places), but also publicity and advertisement of these products. Regarding nutrition, some countries have adapted legislation on the types of food permitted in schools (LT, MT, CY, PL).

Norway reported regulations on sunbeds (NO) and in Latvia, the use of sunbeds are forbidden for persons under the age of 18. Also the marketing of sunbeds is restricted, i.e. prohibited to advertise on the benefits of cosmetic tanning for human health, including vitamin D synthesis (LV).

The rise in the use of e-cigarettes presents the need to handle, adapt or foresee legal frameworks for this new consumption. Some countries, as Poland, included this issue in the regulation concerning tobacco use[22] (PL), while other countries acknowledged the challenges of regulating e-cigarettes in the absence of strong evidence (LT, MT, ES, IT).

Tax policy: Price policies regarding tobacco products are more common compared to alcohol or sugar. However, the amount of salt and sugar is increasingly being discussed and underlying legislation adopted in some countries (LT, MT, EL, PL).

European and international regulations have been evocated as helpful frameworks for developing national laws; as in Portugal where the informants referred to the WHO FCTC that has been signed in 2005 and which enforced to change legislation (PT). However, Greece revealed that there are significant matters regarding the application of the law especially in regards to smoke free environments and advertising, sponsoring and promotion of tobacco and related products (EL).

[20] https://ec.europa.eu/food/sites/food/files/animals/docs/comm_ahac_20180423_pres2.pdf

[21] Serbia: Labelling of Packed Food Prodcuts. Tatjana Dekleva and Charis Chaldoupis. *European Food and Feed Law Review* Vol. 3, No. 3 (2008), pp. 191-194

[22] Act of 22 July 2016 amending the Health Protection Against the Effects of Using Tobacco and Tobacco Products http://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20160001331/O/D20161331.pdf

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3.2.2 Communication & information

Communication campaigns and information efforts vary widely among EU countries. They concern all risk factors, using all possible communication channels. The recent initiatives, however, pay attention to the use of innovative approaches, as traditional messages and communication channels seem to have less impact, especially among adolescents and young adults. As a consequence, health authorities are using **social media** and basing their actions on de-normalization and/or de-moralization of unhealthy behaviors. Humor and irony are viewed as indispensable, shifting away from stigmatization approach to a more positive approach, and highlighting alternative behaviors (DK, DE, EL, FR, PL).

For example, a social media campaign in Denmark aims to start a dialogue with youngsters by including funny and clear messages which do not stigmatize or point fingers (DK). Also, in Germany[23], the focus on a positive note has been raised, as for example, the benefits of being smoke free as the central idea behind the *"be smart don't start program"*. The program aims at preventing start smoking among youngsters by organizing social contract between peers at school (DE).

Most preventive campaigns or programs focus on specific target groups: children, adolescents and young adults (involving schools); women; lower socio-economic groups (e.g., migrants, travelling communities), etc.

For example, in Greece, one tries to improve health promotion and screening among elderlies, by informing them and their families through local institutions (EL). France engaged in supporting smoking cessation among young people from lower socio-economic groups using evidence-based approaches, the *Tabado Programme*[24] (FR).

The focus on specific groups is also the purpose of the **opportunistic approach to health promotion,** providing advices and counselling during other health-related moments; for example, while women come for breast or cervical screening or during neighborhood/ community events (IT, EL, HU, PT).

Another example is the *"take all vaccination opportunities"* used by community nurses and pharmacies (PT).

The **EU agenda of events on cancer** is sometimes used for organizing thematic activities (e.g., campaigns or weeks for focus on specific cancers), which provides the opportunity to use and spread EC-developed support tools, materials, rationales, publicity, etc. (LT, RS, MT, IE). Another important EU-communication tool is the **European Code Against Cancer (ECAC)**, which can be used to support the organization of health promotion campaigns thanks to the provision of straight forward evidence-based recommendations. It is also used for advocacy for new measures (LT, DE, ES, MT, IE, PL).

The **digital trend** has clearly influenced cancer prevention communications. While digital communication is used in health campaigns to overcome the frequently reported barriers of reaching youngsters and monitoring of target(s) met, it also results in an overall increase in the amount of information disseminated. This can overwhelm citizens and make it difficult to differentiate between high quality and evidence-based information from less trustworthy information.

For example, in Ireland, some NGOs closely collaborate with government to develop messages spread across the social media platforms, to improve the quality of the communication (IE). Similarly, in Portugal, the government cooperate with the media to streamline the provision of information and e.g. clearly and correctly explain the benefits of the sugar tax to the population (PT).

[23] Bahr, "National Strategy on Drug and Addiction Policy."

[24] https://tabado.fr/le-programme-tabado

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A salient and often reported and discussed example concerns the **HPV vaccination**. In some cases, HPV vaccination has been embedded in national vaccination programs (FI, HU, MT, NO, PT, ES, SE, UK, NL, DE)[25]. In eleven of the visited countries, the HPV vaccination of boys has been discussed with different level of implementation or planning (NO, AT, DK, IT, SK, IE, PT, FI, HU, SE, CZ, HR, DE)[26].

While indeed most countries report that vaccination is organized through primary care centers, pediatricians, or at dedicated vaccination centers, the organization of the HPV vaccination in school settings has been reported in five countries (PL, NO, AT, SK, CY, IE, FI).

The rise of the **anti-vaccine movement** has been reported as an important barrier for HPV vaccination (DK, HR, FR, SK, PT) as it results in the spread of contradictory messages and the consequent erosion of public trust regarding the vaccination.

Some countries aim to overcome this through the training of primary care professionals who help their patients by clarifying the information and beliefs induced by these movements against evidence-based information.

In Portugal, nurses are trained by a coordinator from the national level with the aim to increase the acceptance by the nurses in the health unit (PT). To improve GP's knowledge on HPV vaccination, Latvia launched a three tiered campaign. In the first part, information seminars were organized to increase the *GP's knowledge* on the vaccination; second, *parents* were informed, mostly by means of television campaigns; thirdly, towards the girls older than 14, since they can decide for themselves if they want to have the vaccination or not (LV).

3.2.3 Support for behavioural change

When it comes to therapies for behavioral change, actions are often organized at the primary care level. In most countries, **general practitioners**, **family physicians** and/or **specialized nurses** provide their patients with brief health interventions or refer patients at risk towards dedicated health counselling professionals or settings (LT, SI, DK, MT, CY). In addition, paediatricians and gynaecologists are also often considered/referred as primary care providers and therefore involved in primary prevention activities.

Health counselling is mainly organized through **primary care centers** or specialized counselling centers (as reported in 18 countries). In a few cases the latter has been reported to be reimbursed or/and provided in combination with (reimbursed) pharmaco-therapy (DK, PT). More specifically, *motivational coaching* has been reported as an example of organized behavioral change therapy in four countries (LT, MT, CY, PT, IT).

In Malta, a Network organization for motivational coaching and interviewing for behavioral change in regard to tobacco use and healthy eating is in place (MT). In the Czech Republic,

helplines for smoking patients as well as a Network of Centers for individuals dependent on tobacco are in place (CZ). In Poland, a hotline is available for adults and teenagers[27] (PL).

[25] https://www.ecdc.europa.eu/sites/default/files/documents/Guidance-on-HPV-vaccination-in-EU-countries2020-03-30.pdf

[26] http://www.nzjz-split.hr/index.php/sluzbe/sluzba-za-skolsku-i-adolescentnu-medicinu/80-cijepljenje-protiv-hpv-a;https://www.hzjz.hr/aktualnosti/cijepljenje-protiv-humanog-papiloma-virusa-hpv-2018-2019/

[27] https://116111.pl/problemy/jak-rzucic-palenie,aid,102

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Also, in Lithuania, there is community-based network for counselling on addictions which aims at motivating people to apply for assistance, motivate for behavioral change and providing support to the patient and family during the cessation treatment (LT).

Several do report **capacity building measures to support and facilitate the role of primary care professionals in prevention and health promotion actions** (LT, EL, DE, ES, SE, DK, RS, MT, CY, PT). The use of e-health platforms, provision of guidelines and tools regarding health counselling, the organization of trainings and workshops on motivational coaching are the major reported efforts.

For example, in Lithuania, alcohol brief interventions in primary health care units are performed by GPs and nurses who receive manuals on how cessation counselling services should be performed and receive regular training (LT), which is also the case in Spain, where primary healthcare settings are provided with guidelines for organizing tobacco counselling (ES).

In Portugal, there is an area in the electronic clinical record, which supports the health professionals to do the assessment of risk behaviors and result are registered in the patient electronic record (PT). In Cyprus, there is an exchange of experience and knowledge via *peer coaching platform among health care professionals* involved in cessation and counselling programs (CY).

Beyond primary health care settings, **schools** are increasingly involved in the improvement of health literacy among students and to encourage healthy lifestyles. Not only children and AYAs but also parents and teachers are reported to be included in healthy behavior counselling or training.

In Spain, the national level is organizing contests among schools, regions or enterprises to stimulate health promotion regarding healthy nutrition and physical activity (ES).

The MoH of the Czech Republic initiated a national strategy on health literacy, including a new National Health Information Portal navigating the patient through the health care system. It includes different modules such as primary prevention or screening (CZ).

The targeting of vulnerable groups to increase their access to cessation support has been reported by five countries (IE, DK, CY, FR, MT). This is mainly organized by means of training health care professionals in identifying vulnerable patients, by reimbursing the cessation support, or by reaching them in day to day settings, such as schools.

For example, in Ireland, the Health Service Executive staff work in conjunction with the Irish Cancer Society to deliver and support the *Quit* programme which, among other population cohorts, targets female smokers from disadvantaged areas (IE). Portugal reported having organized an initiative that

Pre-prepare food baskets for lower socio-economic families with instructions fiches to stimulate a healthier diet at the household level (PT).

Besides the involvement of schools, the inclusion of work environment to health promotion and has been reported in 4 countries (FI, MT, AT IE). Malta launched a competition among workplaces to encourage the organization of healthy initiatives (MT)[28].

In primary prevention, reducing risk factors with proven strategies is important. The European Code against Cancer (ECAC) has been discussed in some countries (LT, DE, ES, MT, IE, PL), but is applied inconsistently in practice; also countries more often organizes prevention around the major risk factors for all non-communicable diseases (e.g., cardiovascular disease is often the starting point or rationale to have it organized).

In general, outcomes of preventive actions are monitored indirectly (e.g., by estimation of the percentage of smokers) while the use of electronic platforms for health brief interventions, counselling and referral has been reported in Spain and Portugal (SP, PT).

Portugal monitors lifestyles in the population through the results from the brief interventions and questioning performed by the GP and the registration of results through the E-Health information platform (S-Clinic) and the electronic patient report (PT).

[28] https://deputyprimeminister.gov.mt/en/health-promotion/Pages/campaigns/2019/World-Obesity-Day.aspx

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3.2.4 Monitoring and evaluation

Very few countries reported having structural register-based data collection of primary prevention action outcomes or systematic **register-based data of lifestyles and behaviors** (SI, ES ,PT).

For those which monitor lifestyles it is often done by primary health care professionals during regular health checks (SI, ES, PT), although not systematic nor including all risk factors. However, several countries assess these aspects through the organization of health interview surveys. In Germany there is a cross-sectoral and multi-disciplinary "Prevention Report" of the National Prevention Conference which is published at a four yearly interval. The overarching aim of the report is the evaluation of the national prevention strategy over time. It also maps the overall health status of the population and the need for prevention activities.

The results are in some cases registered in patient files and/or sent to institutions in charge of analyzing the data. These institutions are often departments of NIPHs, statistical institutes or dedicated observatories as for example the Obesity Observatory in LV and in ES .

They are also often in charge of preparing a state of play of the risk behaviors and to provide recommendations on actionable measures.

Importantly, data collection regarding the lifestyles, although not widely disseminated organized, also allows the monitoring of needs and long-term evaluation of the impact of measures (FI, LT, FR, PT, PL) In Portugal, the National Barometer on Physical Activity aims at monitoring physical activity behavior, facilities, policies, promotion policy, using the PAT TOOL and surveys (PT).

The lack of systematic collection of data about lifestyles or regular measurement in the population leads to the lack of evidence supporting the continuation of preventive activities. Effectiveness of such measures are very challenging to assess, challenging in turn their sustainability.

3.3 CHALLENGES FOR IMPLEMENTING PRIMARY PREVENTION ACTIONS

Tackling **social inequities** in primary prevention has been a widely discussed issue in the visited countries (15). Therefore, some Member States reported to target socially, but also geographically vulnerable groups through specifically tailored prevention policies (SE, MT, IE, SK, HU), by e.g. providing specific financial incentives or adjusted communication campaigns to accommodate the lower **health literacy** of some target groups.

Besides reaching vulnerable groups, the challenge of structurally targeting and **monitoring equity** in prevention policies is a persistent challenge for several countries; also, being specific in reaching and/or targeting some groups must be considered in light of prevailing ethical issues.

Cultural habits and beliefs are also important challenges for authorities. To understand their mechanisms and to overcome them, **anthropological studies**, or public engagement campaigns (IE, FR, DK, LU) can help. Also, the **training of lay workers** playing a significant role in the community has been used to mitigate the impact of cultural barriers (SK, SE, DK, LT).

The industry interference is an important challenge in many countries. The ubiquity of the lobbyists/industries does not only concern the tobacco industry, but also the sugar and alcohol industries that represent a challenge for policy makers. This is especially true in countries with local industrial production or representing important income, whereby actions against prevailing risks factors has economic consequences (IT, LU, MT). Some countries reported interest in a cross border or EU approach in regard to negotiations with industry on restrictions and regulations. This would overcome barriers such as the difference in price and regulation between neighboring countries. The main reported attempt to control the influence of industry is inter-sectoral work. Regarding nutrition, communication and cooperation with the food industry and private retailers are ongoing in several countries (LT, FIN, NO, ES, FR, EL, MT, DK, PT, PL).

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In Lithuania, the MoH signed an agreement with the association of, restaurant chef' to elaborate healthy recipes for schools, which can be found online (LT).

In Denmark supermarkets took the initiative to decrease the visibility of tobacco in their shops. In other Nordic countries (NO, SE, FI, IE) tobacco legislation stipulates point-of-sale display ban for tobacco products in retail stores.

Research on primary prevention. Some examples of research or monitoring efforts were reported during the country visits (11 countries). In these cases, ministries commission studies from NIPHs or universities. **Cost-effectiveness studies** are the most typically required studies to inform the long-term sustainability of actions (FI, PT).

Italy for example reported having organized the **genotyping of samples from HPV positive women** to assess the effectiveness and efficiency of the different vaccines (IT).

Environmental exposure is the most challenging risk factor for health authorities, as very limited evidence is usable to inform the development of concrete policy actions; six countries reported to address environmental risk factors in their policy (SI, EL, MD, FR, IT, HR, IE, NO).

Budget adequacy: The long time periods that primary prevention actions need to prove their effectiveness and efficiency, and the added challenge of the multifactorial impacts on health, makes it difficult to justify longstanding or structural budgets for primary prevention activities; which in turns represents a risk for the sustainability of such programs (ES, PT, NL, HR, DK, PL).

Capacity building is essential but can require considerable resources, such as the training of professionals, organizing systematic electronic monitoring and setting up networks for referrals.

3.4 WP5 INPUT

In health promotion and prevention, commercial determinants play a major role and should not be ignored. Although few countries made references to EU regulations and legislation, it should be mentioned that several EU-level regulations are the rationale for national policies.

Indeed, cancer is a major health issue as referred in Article 168 TFEU, which gives the EU the competence to support, coordinate or supplement the actions of the Member States for the protection and improvement of human health.

The most known and used are probably the Tobacco products directive and the Tobacco tax directive, explaining the wide implementation at national levels of tobacco products legislation.

When it comes to labelling, as from December 2016, the Regulation (EU) No 1169/2011 requires the vast majority of pre-packed foods to bear a nutrition declaration.[29]

Some products are regulated by EU-level measures, for instance ban on snus within EU, with exemption of Sweden[30].

Regarding e-cigarette and the difficulty expressed by some countries in regulating it, it should be mentioned that some countries regulate it similarly as cigarettes[31], because there is no evidence supporting the claims that these products do not damage health[32]. **For instance Finland has a goal of not letting children to be dependent on toxic nicotine products and for this reason has strictly regulated the use of e-cigarettes and prohibited flavors in liquids for e-cigarettes (FI).**

[29] https://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation/nutrition-labelling_en

[30] European Union, Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco. *Official Journal of the European Communities*, 2014 L 127/1 (29/04/2014)

[31] https://www.euro.who.int/en/health-topics/disease-prevention/tobacco/news/news/2020/5/strong-legislation-helps-defeat-e-cigarettes-in-finland

[32] https://www.who.int/news-room/q-a-detail/e-cigarettes-how-risky-are-they; https://ec.europa.eu/health/tobacco/ecigarettes_en

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In cancer prevention, avoiding premature deaths, saving health care costs and human suffering are also drivers for action. Although not reported during the interviews, importantly, one of the main drivers for cancer prevention is that **risk reduction has the potential to prevent around half of all cancers,** especially if implemented with evidence-informed policies like the European Code Against Cancer is recommending.

The iPAAC WP5 also emphasizes that communication campaigns and information should be part of comprehensive programmes to be effective. Communication alone is not enough to change behaviors. A specific task of iPAAC WP5 is to plan sustainability to 12 evidence-based strategies of cancer prevention, the 4th edition of the European Code Against Cancer[33].

In the framework of research, monitoring and evaluation, it should be also noted that the health surveys can be used in evaluation of impacts of the health interventions and in fact, taking into account that there are interviews performed already over decades the overall data size is substantially large and enables with linkage studies to asses also the achievements up to mortality or disease endpoints. Furthermore, during 2000s there is a growing interest to combine biobanking in the population health surveys.

[33] https://cancer-code-europe.iarc.fr/index.php/en/

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4 CANCER SCREENING

4.1 CANCER SCREENING FRAMEWORKS AND RESPONSIBILITIES

The organization of the three EU Council recommended screening programs for breast, cervical and colorectal cancers are established practices in the majority of EU Member States, although organized in diverse ways, being in different phases of the implementation process (i.e. from piloting to fully implemented).

In countries where screening is organized by the federal level, a specific **legal framework** (as reported in LT, FI, SE, DE, ES, DK, LV, IT, NO, NL) typically exists that specifies target groups; screening intervals; types of invitation; types of test; etc. In Germany, the Cancer Screening and Registries Act was adopted in 2013. It provides the overarching legal framework for organized screening programmes considering existing European Guidelines for quality assurance in screening programmes as currently for breast, cervical und colorectal cancer. The German legal framework determined the transfer of the former opportunistic screening programmes for colorectal and cervical cancer into nationwide organized quality assured screening programmes. As of January 2020 Germany has established organized screening programmes for breast, cervical and colorectal cancer.

The role of **national steering committees** was discussed in eleven countries (SI, NO, AT, ES, SE, DK, IT, RS, HR, CY, IE, NL) as governance platforms for the screening programs, mostly including scientific communities and experts responsible to provide technical support and recommendations. Some countries report to include representatives of medical societies, insurance companies and NGO's.

For example in Slovakia, within the Ministry of Health (MoH), a screening committee serves as an advisory board in which members are the State secretary of the MoH, Director of NHIC, Director of NOI, cancer care experts, representatives of the insurance companies, professional medical societies, including the Slovak Society of Gastroenterology and Slovak Society of Oncology, which plays a supporting role in design and implementation of the screening programs (SK). In the Netherlands, **the importance of involving stakeholders in discussion about implementing and executing the nationwide colorectal cancer screening program has been reported**. Changes in one phase (might) have consequences for a preceding or following phase. That's why is it of utmost importance that stakeholders have consensus about these changes (NL).

In more decentralized screening contexts, the regions or local entities have the responsibility to decide on practical organization and implementation aspects of screening programmes. In these countries, **inter-regional platforms** are typically in place to discuss general aspects of the organization and limit differences and possible inequities among regions (DE, BE, ES, IT, AT, NO). For example in Germany the technical organization and management of the screening programmes fall into the remit of the Federal Joint Committee. In this context, the management of German screening programmes is regulated by way of directives on a sub-legal level. The Federal Joint Committee is the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany. For example in Spain, the implementation of new screening programs in the country is discussed in the Public Health Committee and in the Commission of Benefits, Insurance and Financing, which are committees established at the inter-territorial council (ES).

In Norway, interregional steering committees has been established for screening programs, and all four health regions are involved in the planning and each is responsible for the organization of the cancer screening initiatives (NO).

Regardless of centralized or decentralized approaches, cancer screening policies across EU countries reveal a wide range of activities that are reported and often shared among the different levels of authority: the setup of (quality) criteria for laboratories which can perform the analysis of the tests; the certification/authorization of screening units/centers; health technology assessment (HTA) of tests to be used; the most effective approaches for screening invitations and reminders; the most appropriate procurement processes for acquiring screening tests; etc.

For example, in Latvia, three state colposcopy centers were appointed as reference centers for follow-up of a positive cytology test. This was accompanied with a certification process and additional seminars regarding the colposcopy. The certificate can be obtained after following a theoretical course, a practical training and when a minimum threshold of colposcopies performed in a year (LV). In Norway, a set of minimum quality criteria are suggested for the endoscopists who will perform the colonoscopies.

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A structured system for endoscopy training is established (NO).

An important challenge has been raised in countries where both private and public sectors can perform screening tests; there seems to be higher incentives directed to the private sector (CY, LV, LT). Also, the **certification of laboratories** is often a sensitive issue (HR, DK, ES, FI, SE), as different tests could be used in different regions.

Because the tests themselves evolve and require evolving expertise to use and interpret results, eleven countries reported issues for the certification of laboratories or criteria for analyzing the tests (LT, SI, NO, FI, NL, IT, ES, DK, HR, LV,). Three countries reported that the challenge is mainly due to the resistance of pathologists and small labs which cannot fulfill the quality criteria (BE, HR, IT).

Another important issue concerns the **linkage of screening results with cancer registry data** and information (DE, IT, SK, CY, LV, IE, CZ, BE). Although it is crucial for program monitoring and evaluation, the country visits highlighted the difficulties in achieving this due to a lack of appropriate resources directed to such activities, lack of development of legal frameworks for the linkage and interoperability issues. Slovakia for example reported to be currently preparing a legal framework for linking cancer registry data with cancer screening data that meets GDPR requirements (SK). In Norway, cancer screening programs are organized at the Cancer Registry which allows frequent linkage between cancer registry and screening registry files for improved program evaluation (NO). In Germany, the Cancer Screening and Registries Act of 2013 created the legal framework for the establishment of nationwide clinical cancer registries complementing the already existing epidemiological cancer registries. The registries provide standardised and valid data for the linkage of screening results within the scope of scientific programme evaluation.

When it comes to capacity building and the resources required, a key feature for screening programs is the management of persons that are positive for the screening tests.

Some countries reported a lack of specialists able to further investigate patients (DK, SK, HR, MD), or a lack of specific **procedures to follow-up patients with positive test results** (HR).

When it comes to **the lack of specialists**, some countries decided to train paramedical staff to perform specific tests, such as colonoscopies and removal of polyps, pap smears or the reading of bone fractures to allow specialists to focus on mammography, mainly performed by specialized and trained nurses (DK, EL, SE, NL).

These countries reported having observed decreases in waiting times and in costs without associated reductions in quality. For example, in Denmark, nurses can follow a two years education program to learn how to perform the colonoscopy and remove the polyps (DK). Similarly, in Hungary, trained nurses can take pap-smear samples and can send it for cytological examination (HU).

The lack of specialists has been reported by some countries as a consequence of a **brain drain**, with oncology not being the only medical specialty impacted (HR, MD).

When it comes to guidelines, most countries reported using the EU guidelines for screening programs but were expecting **updates** soon.

4.2 UPTAKE & PARTICIPATION IN CANCER SCREENING PROGRAMS

Notwithstanding the European guidelines and recommendations on the implementation of population-based screening programs, low participation rates for screening programs remain an issue in many countries. Several factors influencing the participation rate have been raised, including:

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- inappropriate invitation procedures
- lack of (evidence-based) communication on harms & benefits
- systematic coverage gaps (e.g., groups which are difficult to reach: not fluent in the national language; living in remote areas; low health literacy; non-permanent residents)
- extent of wide-spread opportunistic screening
- deficits in the acceptance of nature and type of test

4.2.1 The target groups

Many visited countries reported struggling with the important practical differences in reaching these groups (NO, DK, MT, SK, HR, CY, LV, IE, NL.). The type and format of invitation and information provided is tailored to the age, health literacy and socio-economic status of the people to be invited. Also, the screening tests may be different based on these characteristics (e.g., human papillomavirus (HPV) test vs. Pap smear among young/older women).

In addition, several countries reported having to adjust the age range for screening based on new evidence, resources and capacity or availability of tests (IT, CY, DK, NO, MT).

For example, IT decided to still use the pap smear for women between 25 and 30 due to the problem of over diagnoses with the HPV-test (IT). Cyprus reported to offer the HPV test as a follow-up test or a triage test but not to women under 35 years of age, due to the high amount of false positives with HPV as primary test (CY). Denmark reported to perform HPV testing in elderly women, since they were more difficult to invite for pap smear (DK). In Norway, HPV testing has been used since 2005, as a triage after slightly abnormal cytology. From 2015 pilot was initiated for gradual implementation of HPV primary screening for women from the age of 34 years. Currently, a pilot study performed on HPV self-sampling, to test whether it could improve screening attendance in under-screened women (NO). In The Netherlands it is already possible to receive the PHV self-sampling (NL).

The age range of invited women to cervical cancer screening is being gradually extended in Malta and the invitations are presently being issued to women in the 25 to 35 age cohort every 3 years (MT).

These changes and pilots mean regular revision and lead to a certain degree of uncertainty and challenges for monitoring and evaluation.

Also, there has been recent questioning among the scientific and policy communities about the **cost-effectiveness of population-based screening programs**, especially regarding the fact that participation rates for the main screening programs seem to have reached a plateau regardless of additional attempts to increase participation. The organization of several pilot studies have also been reported in order to investigate the potential to shift to **high risk-stratified screening**.

Also, **genetic screening** is under discussion in several EU Member States (15). The underlying legal frameworks, medical services and ethical requirements related to data protection are the main issues discussed. The introduction and reimbursement of genetic screening for the BRCA and other genes clinical testing for high risk women has been reported in some countries (CY, EL, IT, MT, DE).

4.2.2 Invitation procedures

Most countries invite the specific target groups by means of a postal invitation letter, some reported to include information booklets or infographics. Latvia reported being currently reformulating the invitation letter, based on the results from a study which showed how the invitation letter was not easy to understand (LV).

The first challenge regarding the process of invitations for screening relate to the **(electronic) identification** of the target population (HR, LV, MT). It can be quite straightforward in some countries, but in others, especially where residency is not unique, up-to-date demographic data is challenging to obtain.

To increase participation rates, some countries reported to involve the GP's in the invitation process or in information provision (LT, EL, MD, IT, LV, IE, HU, DK), with sometimes trainings for GP's regarding the **communication on screening harms & benefits**. This

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is the case for example in Moldova (MD) and in Hungary where the National Public Health Center supports the GPs in referral, by providing updated information on screening through an information system which enhances the communication & information sharing with screening centers (HU). In Greece also, there is an EU training program on oncology expertise for GPs in which emphasis is given on skills for early detection and patients' post-treatment follow-up (EL).

Broadly, Ireland reported organizing training and material for health care professionals on communication about the programmes, including e-learning module on understanding cancer screening, which is available free of charge to healthcare professionals (IE, NO).

Croatian respondents reported that primary care providers do not always have access to information on whether their patients have been invited for screening or if they participated in a screening program (HR).

Four countries reported to organize **mass media awareness and communication campaigns** to increase the knowledge on harms and benefits of the screening programs. The informant from Slovenia and Latvia reported the regular use of multiple communication channels to increase the participation rate to the three screening programmes (SI, LV).

In Norway, different media channels are used in the #sjekkdeg campaign to reach young women. An online blog was launched by The Norwegian Cancer Society (NCS) in cooperation with a young female cervical cancer patient and blogger in 2015. Several external players also participated, including a café-chain, a clothing store-chain with clothes for young women, a pharmacy-chain, in addition to a patient organization and the association for Norwegian GPs (NO).

Some countries reported the use of **field nurses** who can provide correct and further information to reluctant patients (especially the elderly) and also, they can report on incorrect demographic information (HR, ES).

Also, **telephone contacts** for (systematic) the non-responding people are used; as well as personalized invitations with information leaflets; invitations specifying the exact date and time of appointment; and reminder letters for some groups (FI, NO, NED, SW, RS, MT, HR, CY, LV, IE). As for primary prevention, **community (lay) workers** are trained, to reach and inform targeted risk groups, especially women in some communities who are not participating and could be at risk (SW,SK).

Ireland reported the involvement of pharmacies in a pilot project to invite the target group to the colorectal cancer screening programme (IE).

In Slovakia, the training of Roma mediators to improve their access to healthcare, including cancer screening has been reported (SK).

In Sweden, the role of the doulas has been described, who are ambassadors supporting women in vulnerable communities and who are trained by health officers (SE). However, Sweden also reported to use **a combination of different efforts** to raise the participation, as for example, letters posted in the laundries.

For remote and/or rural areas, four countries reported to organize **mobile units** that include physicians, nurses and social workers (NO, HU, LV, PT, EL).

Portugal reported to use especially to reach and invite seasonal workers and lower socio-economic group to cancer screening programs (PT).

In these efforts to create awareness on the screening programs and aiming to increase the participation rate, the cooperation and role of NGOs has been reported by 6 countries (LT, NO, NL, SK, CY, IE).

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To ensure implement changes based on evidence, France and Norway engaged in studies[34,35] to understand the barriers to screening attendance (FR, NO[36]). In the Netherlands, for the colorectal cancer screening programs a feasibility study[37] is organized before introducing new techniques and tests (NL).

The selection of the most appropriate testing method for screening programs is becoming increasingly more complex as scientific evidence is evolving and not always clear (and as discussed in 18/28 countries visited). Three exercises have been reported in order to determine which screening test(s) should be used for specific target groups: (1) randomized controlled studies; (2) cost-benefit analyses or comparative harms/benefits studies (using discrete-choice experiments); and (3) health technology assessments (HTA).

Pilot studies that have been reported in EU Member States mainly related to the use of different testing schemes, e.g., faecal immunochemical test (FIT) vs. faecal occult blood test (FOBT) vs. colonoscopy for colorectal cancer screening; and cytology vs. HPV test for cervical cancer screening (NO, DK, SK, DE, CY, NL, PL[38]). In addition, the triage of HPV positive women is also under discussion/piloting in several countries (NO, DK, CY, LV, IE).

In Spain, it has been reported that regions do organize tenders for the choice of tests to be used, but that the minimum quality standards requirements are provided by the national level (ES). Belgium reported to have prepared a Roadmap for the introduction of HPV testing in the cervical cancer screening program (BE)[39]. Germany reported to have finished a ten year pilot offering the HPV test in addition to pap smear as primary test for women between 30 - 70 with sub-pilots on triage of those positive (DE).

In Norway, the HPV test was implemented as a triage test for low-grade cytology results since 2005. A pilot study, in which the HPV test is offered as the primary screening test for women between 34 and 69 started in 2015, and is currently being rolled out to almost whole country (NO).

Where regions or municipalities are responsible for the practical organization of screening programs, they also have to launch procurement processes to select screening tests. This leads to potential differences in the tests used among regions with the price most often being the main rationale for their choice.

In the Czech Republic, BRCA 1 & 2 genetic testing & follow-up is organized at the Masaryk Memorial Cancer Institute which has a cancer risk clinic[40]. The cancer risk clinic offers genetic counselling, NGS germline mutation testing (including BRCA 1 & 2, APC, Lynch) and a prevention program tailored to each mutation carrier, including primary and secondary prevention, as for example surgical prophylactic procedures or intensive follow-up[41] (CZ).

34 https://www.e-cancer.fr/Institut-national-du-cancer/Democratie-sanitaire/Concertation-citoyenne-sur-le-depistage-du-cancer-du-sein

35 https://pubmed.ncbi.nlm.nih.gov/29304944/

36 https://login.kreftregisteret.no/eurpub/article/27/5/873/,DanaInfo=academic.oup.com,SSL+3914734
https://login.kreftregisteret.no/10.1016/,DanaInfo=doi.org,SSL+j.ypmed.2016.11.018

37 https://www.rivm.nl/bibliotheek/rapporten/225082001.pdf

38

39 https://cogi-congress.org/wp-content/uploads/2018/11/HPW_2018_final.pdf

40 https://www.linkos.cz/english-summary/klinicka-onkologie-journal/2016-01-15-supplementum-1-en/retrospective-ngs-study-in-high-risk-hereditary-cancer-patients-at-masaryk-memor/

41 https://www.prolekare.cz/en/journals/clinical-oncology/2012-supplementum/diagnostics-of-breast-cancer-in-high-risk-women-our-own-experience-38593

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Also, the EU project MyPEBS (personal breast cancer screening)[42] is running in five countries: BE, UK, Israel, IT and FR. In Finland, there is currently a new program being gradually launched. It provides a biennial invitation at ages of 60-74 which is accompanied by a risk-based questionnaire for all patients regarding symptoms, lifestyle (alcohol use, smoking, BMI) and cancers among relatives (FI).

4.3 OPPORTUNISTIC TESTING

Several visited countries reported facing various implications of opportunistic screening testing in one or more of the three main screening programs (LT, SI, FI, BG, MT, IT, HR, CY, LV, RS, BG,BE).

Different **reimbursement models** for covering the cost of a screening test when performed inside or outside a screening program does seem to have an impact on the amount of opportunistic screening present in a country. Five countries reported explicitly to not reimburse screening performed outside the population-based program (IT, SI, MT, IT, CY, LV).

However, several countries reported that the rather low cost of screening tests presents challenges for reducing opportunistic testing, regardless of reimbursement model, with one extreme case where a cervical cancer screening program was stopped because opportunistic screening was routinely the preferred option (HR). Also, it seems that young women have greater access to opportunistic screening testing given regular contacts and visits with their gynaecologists (FI, MT, IT). In most countries, the extent of opportunistic screening is not monitored nor regularly documented, which makes it difficult to have a clear estimation of its impact (FI, BG, LV, LT, CY). For example, Italy reported retrieving the information on opportunistic screening via a structured survey, *the PASSI survey* 43, which is based on a sample of the population, every year and collects information on different aspects of health care, including screening (IT).

The **role of health professionals and individual beliefs** seem to be the main forces behind opportunistic testing. Three levers have been identified to decrease this practice. Fist, a better provision of **information** and active **involvement** of health care professionals in the development and implementation of screening programs. For example, Italy decided to provide trainings to GPs which aims to modify their habits (IT).

Second, a better communication with citizens, especially the targets groups using contemporary and relevant **communication** channels (MT); and third, better designed reimbursement schemes that incentivize participation in organized screening (SI, IT, CY, LV). Combined efforts to address the varying impacts of opportunistic screening are key to successful implementation of screening programs.

4.4 SCREENING REGISTRIES AND RESEARCH

Sixteen of the 28 visited countries reported to have already established cancer screening registries, which are sometimes linked or integrated into broader cancer registries.

The screening registries are mostly used for the planning, follow-up and evaluation of screening programs and for conducting research on cost-effectiveness and cost-benefit of screening programs, as e.g. performed in France for cervical screening[44] (FR).

Hungary and Bulgaria reported to have used the World Bank support to setup their cancer registries (HU, BG). In Italy, a national center for screening monitoring (Osservatorio Nazionale Screening –ONS) is in charge (by the MoH) of promoting the screening program nationwide since 2004. This Observatory is constituted by a network of expert centers (IT).

[42] https://mypebs.eu/

[43] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2483542/

[44] https://bmjopen.bmj.com/content/7/10/e014626

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Six countries reported performing process evaluation aiming to enhance the organization of the screening programs (FI[45], NO, ES, IT, NL, LV, BE). The registration and evaluation process can be influenced by legal or technical barriers, such as the mandate to collect and link data and/or the interoperability between registries. Moldova reported international collaboration for evaluation and improvement of national screening programs (MD).

As mentioned in the previous chapter on primary prevention, in most countries, information systems and processes to monitor HPV vaccinations in girls is ongoing, or in the planning phase. A related issue, is the challenge of linking this information with cervical cancer screening data. In Croatia, a pilot project is testing a new IT-tool which should structure the results from the HPV test and PAP screening (HR), while Italy works on integrating population-based screening and vaccination information systems (IT).

Finding the best organizational scheme, taking into account the national contextual features, cost-effectiveness and the preferences of some stakeholders is often a difficult exercise that crystallizes pragmatic/political compromises preventing yet optimal cost-effectiveness. Again, stakeholder involvement in the design of the screening programs can help to ensure broader support and compliance (IT, HR, ES, DK, IE, AT, SI, SE, SK, CY, NO).

4.5 POSSIBLE NEW CANCER SCREENING PROGRAMS OPPORTUNITIES

Our country visits identified prostate, gastric and lung cancer screening as highest on the agenda to be implemented (LT, HU, ES, EL, SE, IT, HR). Most countries are still looking for evidence including results of cost-effectiveness studies to inform decisions to launch such screening programs. At the moment, especially for lung cancer screening, several pilot programs and feasibility studies are running in several Member States (IT, HR, HU, PL). In Hungary, there are pilot programs planned on the early detection of oral cancers. A screening program for lung cancer, using low-dose tomography is tested in an implementation trial, which is about to be completed (HU). In Lithuania, prostate cancer screening is in place since 2006. The target population are men aged 50-69. Men aged to 59, for which the PSA is lower than 1 ng/ml, and men aged from 60, for which their PSA is lower than 2 ng/ml are invited once every 5 year. The participation rate was 28,3 % in 2018. The reimbursement in private sector occurs only if they are contracted to national health insurance funds (LT).

An important issue for many countries, especially regarding prostate cancer screening, is the ability to provide an acceptable answer to patient advocacy groups and representatives who strongly and vigorously advocate for new screening programs. To overcome this challenge, in Sweden for example, prostate cancer- model for structured testing has been (by PSA) initiated. There is this no formal invitation letter but men are invited to a 'study' with an appointment to a doctor and receive standardized information on prostate cancer and the PSA test for which benefits and harms are explained. It is up to the patient to decide if they want to undergo the test or not (SE).

4.6 REPORTED CHALLENGES TO CANCER SCREENING PROGRAM IMPLEMENTATION

An important barrier to the implementation of screening programs (or even the modification of some program features) can be the **resistance of healthcare professionals** underestimating the efficiency of a well running screening programme (BE, HR, IT, SK, MT). Indeed, since 1960s the test for preventing cervical cancer has been available but yet there are many countries who do not use this opportunity for mortality reduction. Most countries overcome these problems by involving impacted professionals in all stages of the design and implementation of screening programs; but also all actors which will have to handle the changes and work at the implementation.

For successful implementation of screening programs and to ensure compliance of health professionals and target groups, there is a need for access to trustworthy and up-to-date scientific evidence.

This touches upon the challenge of translating scientific information to easily under-

[45] https://www.ipaac.eu/res/file/reports/wp4/ccpis/finnish_cancer_registry_oct18_2018.pdf

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stood messaging. Training health care professionals on communication skills, and more sophisticated use of the media are reported solutions to overcome this challenge (IT, IE, MD, LV).

Moldova reported that the family doctor (GP) plays an important role regarding the participation to all three screening programs. They are reimbursed if their patient is diagnosed with cancer; which stimulates them to encourage the participation to the screening program among their patients. Further, education programs and guidance to the GP's is provided (MD).

In Ireland, the Royal College of Physicians has developed an e-learning module on understanding cancer screening, funded by the Health Service Executive, and this is available free of charge to healthcare professionals.

4.7 WP5 INPUTS

When it comes to legal framework, an appropriate list of aspects that legal frameworks on cancer screening programmes should cover has been presented in the Cancon guide[46] (chapter 4), where it has been indicated that the available national legal frameworks are often inappropriate to support screening organisation and coordination, and quality assurance.

While many countries reported issues regarding the choice of tests and the effectiveness of population-based screening programs, it should be mentioned that cancer screening is by definition a public health measure targeting asymptomatic population and a chain on measures, not merely a test.

Some countries reported to explore the possibility to shift to high-risk group stratified screening.

However, all screening programmes with evidence target high-risk groups, are defined by age or results in screening tests (for example positive HPV test or precancerous change in pap-smears). Some high-risk groups cannot be defined from population reliably, for example smokers for lung cancer screening and in some screening trials (prostate cancer) harms have exceeded benefits despite of mortality reduction. Some groups have been found to systematically escape from the organized programs. Special attention should be given to the means of reaching, informing and inviting them.

Moreover, countries need to have appropriate governance developed, taking care e.g. of the required evaluation, and policy-making criteria. In the policy-making criteria one important aspect would be health economic assessments (although indicated in Cancon that it is often lacking) and also the required threshold values have often not been developed in the MSs.

The examples provided in this report do not present a comprehensive state of play on cancer control policy of EU MSs but they rather identifies themes and topics of interest to be included in the mutual learning platform foreseen, i.e. Roadmap. However, in order to be added to EU platforms, all measures identified should be tested and based on science.

[46] https://cancercontrol.eu/archived/uploads/images/Guide/042017/CanCon_Guide_4_Screening_LR.pdf

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5 DIAGNOSTICS AND TREAMENT

The interview guide section addressing ”diagnostics and treatment” includes questions that relate to the introduction of innovative therapies: the role of HTA (if any) and price setting.

In three countries (FR, BG and NO), diagnostics and treatment were not discussed due to a lack of time or unavailability of expert(s) to participate in the interview. However, insights from these countries have been added from the work of Work Package 6 and 9.

5.1 PERSONALIZED MEDICINE

In many countries, focus on precision medicine has been left to the pharmaceutical industry. Moldova reported for example that Next Generation Sequencing is performed for breast, colorectal cancer and lung but only in the context of clinical trials. From 2020, it will be introduce into routine diagnostic practice (MD).

However, five countries (BE, FI, DK, DE, EL) reported to have installed or to be in the phase of establishing genome centres or expert groups, to manage needs. For example in Finland, the National Genome Center will be established as soon as the parliament approves the proposal for *a Genome Center Act*. It will maintain population’s genome database and grant access to national users for health care, research and innovation purposes. According to the proposal, the Centre will be hosted by the National Institute of Health and Welfare (FI). Denmark also reported being currently working under the framework of the National Strategy for personalized medicine (2017-2020) and developing a National Genome Registry (DK)[47]. Greece reported the ongoing implementation of the Precision Medicine Network[48], including associated clinic-biological information about the samples as well as genomic data produced within HPMN-GR that will be stored in databases tailored-made to this purpose, following all national and international guidelines, compliant with the GDPR and meeting ISO27001 standards for security (EL). In Belgium, a Roadbook for developing and piloting a new legal framework was created which included 10 actions (BE).

Some countries like France have had such structures in place for several years, as for example their French horizon scanning system (HSS) with a scoring approach (FR).

But in most countries, these activities are still at an early stage, focusing mainly on preparing the legal basis and providing technical support (DE, FI, EL, MD, DK, AT, MT, BE, PL).

The involvement of health authorities in the matter is especially important to control two aspects: the costs of therapies (as explicitly reported in BG, ES, BE, LT) and the ethics related to the use and registration of genomic information. Finland report that a national law imposes the anonymization of the results for the use of non –medical specialists and social welfare institutions (FI).

When it comes to cost control, most countries recognize their inability to afford these growing costs[49] and the reluctance of their governments to engage in some activities that would lead to important increase of budgets dedicated to cancer diagnostics and treatment (BE, EL, LV, LT, MT, MD, PT, IT). Some examples of EU cooperation in the procurement of (innovative) drugs have been reported, such as the BeNeLuxA initiative (BE, NL, LU, AT)[50], the Valetta Declaration (MT, CY, FR, UT, EL, PT, ES) or V4[51] (PL, SK, HU, CZ).

Five countries expressed expectation for having a general EU framework that would allow more cooperation for the price setting of innovative therapies (BE, SI, FI, MD, IE).

[47] https://eng.ngc.dk/

[48] https://oncopmnet.gr/?page_id=2921&lang=en

[49] https://apps.who.int/iris/bitstream/handle/10665/277190/9789241515115-eng.pdf?ua=1

[50] https://beneluxa.org/collaboration

[51] http://www.visegradgroup.eu/article-title-190201

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Also, importantly, many countries reported major **procedural constraints for the introduction and use of new therapies** (MT, ES). At the moment, most countries overcome this challenge by using other channels (AT, EL, FI, LT, IT, SK, SI, BE), such as special funds for emergencies, off-label use, clinical trials, or compassionate use.

However, these channels do not allow the same level of security for the prescription or the same equity of access to anti-cancer drugs and might not fit the future needs related to personalized medicine (also addressed by iPAAC WP9 in the report *Reference frameworks linked with the access to innovative immunotherapies*). Therefore, revision of these procedures will be required.

In Germany, the law reforming the pharmaceutical market (Arzneimittelmarkt-Neuordnungsgesetz – AMNOG), which took effect in January 2011, stipulates the principle of free pricing at market launch, but imposes a systematic and formal assessment of the "added therapeutic benefit" of new medicinal products in order to negotiate the value based reimbursement within twelve months after market launch.

Horizon scanning mechanisms are already used in some countries to foresee the arrival of new drugs, either by the companies (IE) or through joint initiatives (MT, BE, NL, LU, AT, IT, CY, FR, UT, DK, UK, SE, PT, NO, EL, PT, ES). EU collaboration and cooperation in this field will be unavoidable and the support of the EC is a highly reported expectation[52].

Also, the involvement of the pharmaceutical industry in covering some of the costs of tests that are linked to their therapies has been reported as an issue (FI, BG) that needs to be discussed at the EU level.

Another reported challenge is the knowledge and expertise necessary to implement these technologies (IE, BE, IT). An issue is the interpretation of results that vary from one laboratory or professional to another, leading to differences in therapeutic decisions. Therefore, it has been reported that these new therapies will have to come with concrete and detailed procedures and guidelines including algorithms, etc. (BE, ES).

Regular training of involved healthcare professionals is also anticipated as well as expertise platforms to share knowledge, needs, experiences, questions, etc.

Importantly, BE, FI and DK reported to have engaged in public consultations to better prepare for informed consent of patients regarding the provision of results of genetic testing, while other countries, like ES, reported that patient informed consent is a challenge and suggested an EU perspective is needed on this matter.

5.2 HEALTH TECHNOLOGY ASSESSMENT (HTA) AGENCIES

Health Technology Assessment (HTA) is an evidence-based process that allows competent authorities to determine the relative effectiveness of new or existing technologies. HTA focuses specifically on the added value of a health technology in comparison with other new or existing health technologies. HTA can cover both clinical and non-clinical aspects of a health technology, depending on the healthcare system.

HTA is very differently organized across EU Member States, with variations in the institutions hosting the HTA function (e.g., ministries, NIPHs, universities), but also the extent to which formalization of HTA use has been established (the role and organization of HTA has been discussed in 15 countries). However, overall, HTA is typically organized at the national level, whatever the prerogatives of the regions (although in one country, FI, we found out that HTA can also be led by hospitals).

When an HTA agency is in place, its main prerogative lies in the evaluation of new medicines or medical devices. Most countries have strict pathways/procedures for the introduction of new medicines or new medical devices (in some cases also including biomarkers) to the market, which usually require a positive recommendation from the HTA agency to be authorised (as reported in PL, SE, FI, HR, EL, EL, MT, PT, NL).

Spain (ES) reported an interesting process for the prioritization of the topics to be investigated and requiring HTA: the PriTec platform[53].

[52] https://ihsi-health.org/partners/

[53] https://eunethta.eu/wp-content/uploads/2018/02/WP7-Activity-1-Report.pdf

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Differences among EU Member States are found in the authorisation processes for off-label uses or for rapid access to new therapies (BE, EL, NO, PT), particularly in the case of rare diseases. EU countries do have special procedures to handle these requests or even special funds to cover these needs (e.g., in BE). Several countries described high administrative burdens and complexity (ES, AT, EL, MT, PT, SK, IE, LT, SI), potentially delaying access to drugs or devices and impacting on the prognosis of cancer patients.

More specifically, Belgium reported to have prepared a convention for reimbursement of genetic expression profiling tests (GEP) in Breast Cancer e.g. Oncotype Dx and Mammaprint, etc. (BE).

The management of the (positive) list of medicines (i.e., those being reimbursed without prior-authorisation) also varies among countries, with the revision of the list occurring at regular intervals or continuously (i.e., in real-time).

The main challenge for HTA agencies is to reduce the length of the overall assessment process (including the following stages: enter a request, approve the request, perform the study/assessment, provide a recommendation).

5.3 INPUTS FROM WP6 AND WP9

5.3.1 WP9 input

INTEGRATION OF INNOVATIVE THERAPIES INTO CLINICAL PRACTICE GUIDELINES

Several challenges related to the integration of innovative therapies into clinical practice guidelines have been highlighted through WP9 and are addressed in the deliverable entitled *"Innovative cancer therapies in clinical practice guidelines"*.

First of all, the difficulty to **produce and maintain updated guidelines** has been raised, especially in the context of the rapid evolution of innovative new cancer drugs. Defining the best place in the cancer treatment strategies implies to select the best treatment for a given clinical situation and patient. When several innovative therapies are developed in parallel in the same settings of patients, direct comparative data between these new therapies are usually not available and it can thus be very challenging to select the most appropriate therapy. The experts consulted by the WP9 on this topic thought for a large majority of them (90%) that having a public fund to sponsor studies comparing innovative therapies launched in parallel could be helpful to support healthcare professionals in defining the position position new therapies as part of cancer treatment strategies.

WP9 work revealed a divergence of opinions regarding the acceptability of providing recommendations for off-label indications. In some circumstances, such as for small groups of patients, specific biomarker expressions, paediatric populationsSeveral experts interrogated by the WP9 agree to say that there are situations for which off-label recommendations could be tolerated in a clinical practice guideline, especially for small groups of patients, specific biomarker expression, paediatric population, or when there is no other therapeutic alternative. This was the example for the use of checkpoint inhibitors for MSI-H tumours, and more especially for MSI-H colorectal tumours, for which there is currently no indications approved in Europe despite scientific evidence showing positive efficacy and safety results. However, from governmental body and national agency it seems to be harder to include off-label recommendations in CPG than for medical societies.

Furthermore, the low visibility of European clinical practice guidelines in oncology was pointed out during the stakeholder consultations. Therefore, iPAAC WP9 recommends strengthening the collaboration of clinical guidelines providers in Europe **with the implementation of a central platform/repository of guidelines to facilitate awareness and use.**

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ACCESS TO INNOVATIVE IMMUNOTHERAPIES

Inequities across European countries have been observed regarding access to innovative immunotherapies, such as checkpoint inhibitors and CAR-T cells. The WP9 deliverable *"Reference frameworks linked with the access to innovative immunotherapies"* addresses challenges related to reimbursement restrictions as well as early access programs for unapproved indications. Three main factors leading to reimbursement restrictions for innovative therapies were identified:

- the low level of scientific and medical evidence supporting marketing authorization,
- missing data on direct comparisons with alternative therapies;
- high costs.

Increasing and framing the use of real-life data to further assess new treatments arriving on the market could help address providing early and secured access to innovative therapy. For instance, implementing conditional approval or conditional reimbursement systems (such as managed entry agreements or pay-for-performance systems) are interesting schemes to consider as it can enable the collection and the assessment of additional safety and efficacy data while the patient can already receive the treatment outside clinical trials. It will also be important to increase collaborations and implement actions which help control the rise of prices of innovative therapies. Implementing that enables early access programs for innovative therapies can help bridging the gap between EMA approval and definition of the price as well as decision for reimbursement in member states. It is also an instrument for incentivising innovation and reimbursement decisions. To facilitate the implementation of such programs, two main aspects stood out from the work conducted by the WP9: the need to have clearly defined pathways and the need to have strong discussion among the different stakeholders involved (see details in the deliverable: *Reference frameworks linked with the access to innovative immunotherapies*). For instance, the French early access program called ATU[54] enables secured access to innovative therapies after a preliminary review of the benefit/risk ratio and clear definition of the target population, while allowing additional collection of data in real-life settings.

When considering access to a new drug, it is also important to consider access to potentially related diagnostic tests that impact on prescribing decisions, where applicable, to ensure that personalized medicine is properly positioned.

ENSURING EFFECTIVE AND EFFICIENT ANTICIPATION OF INNOVATIVE CANCER THERAPIES AND THEIR POTENTIAL IMPACTS ON HEALTHCARE SYSTEMS

Horizon scanning systems (HSS), also called early awareness alert systems have shown strong value in anticipating clinical, organizational and economic impacts of innovative therapies. Considering that half of ongoing clinical development involves anti-cancer drugs, it becomes even more relevant to have appropriate tools and methodologies for this therapeutic area.

The iPAAC WP9 task 3 deliverable, entitled *"Horizon scanning systems applied for cancer control in Europe"*, highlights the methodologic specificities that should be considered for innovative anti-cancer drugs in horizon scanning systems with a focus on immunotherapies, gene and cell therapies, as well as biomarkers. Remaining challenges in this area are also described in the deliverables with potential perspectives to be further considered.

Some implemented HSS have also been shown to be strong assets for anticipating personalized medicine. When applicable, it is important to foresee biomarkers and potential related diagnostic tests before arrival of the new drug on the market. For instance, the INCa HSS has developed a specific methodology to identify innovative therapies in parallel with their potential associated biomarkers and related diagnostic tests if applicable.

[54] https://www.ansm.sante.fr/Activites/Autorisations-temporaires-d-utilisation-ATU/Qu-est-ce-qu-une-autorisation-temporaire-d-utilisation/(offset)/1

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ENSURING EFFECTIVE AND EFFICIENT REAL-LIFE MONITORING OF INNOVATIVE THERAPIES

Implementing effective and efficient systems to enable the long term follow-up of innovative therapies in real-life settings has been identified as an important asset to provide early and/or secured access to innovative therapies, while continuing to gather comprehensive data on safety, efficacy and proper use.

Task 4 of iPAAC WP9 highlights the most innovative initiatives enabling monitoring of patients treated with CAR-T cells in real-life settings in Europe. Indeed, these gene and cell therapies face unique challenges with complex therapeutic courses, complex manufacturing processes and high costs. Conditional reimbursement models requiring the additional collection of specific data such as treatment response and patient status after treatment help to control the costs of innovative therapies. Remaining challenges which would require further European collaboration will also be raised in the associated deliverable.

5.3.2 WP6 input

Given that several large surveys of both patients, citizens and professionals' attitudes towards genomics have been conducted in the past few years (DDD-study and 'Your DNA, your say' within Genomics England and a survey of 11,000 participants within the SIENNA project)[55] , iPAAC WP6 decided to shift its attention to public consultation initiatives on ethical, legal and societal issues (ELSI) in genomics. Recently, Genomics England, the French National Committee on Bioethics (CCNE), the SIENNA consortium and Sciensano all independently organized some form of public consultation on the issue. Within the IPAAC joint action, we will provide an overview of the main findings and strengths and weaknesses of different strategies. Additionally, we will report extensively on the findings from three patient and citizen initiatives organized by Sciensano at the national level (focus group study with cancer patients, a citizen forum and an online discussion platform). These initiatives show the need for a clear ethical and legal framework that inspires trust in populations to share their genomic data. All these initiatives show that it is possible to engage patients and citizens on genomics and to develop useful recommendations and principles based on careful deliberation. In the UK, citizens talked about 'renegotiating the social contract', building on altruism, solidarity and reciprocity as core values. In France, the citizens expressed fundamental distrust about the (future) use of genomic data and asked for strong informed consent policies and strict privacy protection. In Belgium, the citizens referred to the precautionary principle: genomic technologies can be a huge common good, but they also imply many risks (loss of privacy, genetic discrimination, limiting autonomy,…). A good ELSI framework, co-constructed by citizens and all other stakeholders, can maximize the benefits and minimize the risks and harms related to genomics in society.

The constant gain of knowledge about genetic and non-genetic risk factors must be considered and incorporated into clinical practice, especially in light of the difficulties to generate evidence by classic RCTs. Ultimately, existing screening programs should be assessed regarding whether they can be complemented by an institutionalized **multi-step risk-adjusted learning screening system.** Such a system should be constantly evaluated regarding forthcoming insight into new genetic and other particularities, allowing generating stratified screening strategies, and at the same time offering up-to-date genetic risk-assessment tools within a clinical setting. In iPAAC WP6 a proposal has been developed for a new paradigm for application of genetic information in preventive as well as therapeutic care.

Four Member States (BE, FR, IT and UK) committed to participate in documenting experiences in their country with the organized introduction of genomics in their healthcare system. During the CCPIS and through real-time information tracking, information on genomics medicine plans were retrieved from some other member states: Sweden, Finland, Denmark and Greece. In addition, Estonia has implemented a genomic medicine plan but unfortunately no further information from this country was received within our initiative.

[55] https://www.sienna-project.eu/

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IPAAC WP6 also performed a literature review regarding the DTC-GT legislation in the EU Member States and on citizens' knowledge, attitudes and behaviors towards DTC-GT.

Our systematic review showed that European citizens have a moderate level of awareness toward DTC-GT and a high interest in purchasing the tests. The citizens were motivated to purchase the DTC-GT mainly because of the possibility to discover the personal risk for the development of a common disease. Therefore, our findings highlight the importance of tracking the citizens' perceptions and misperceptions, in order to develop recommendations related to their educational needs. Educational and counselling strategies should be provided on the national levels aiming to increase the general publics' understanding of genetic information in order to make appropriate health decisions.

Also, a review on core curriculum requisites for health care professionals in the field of cancer genetics and genomics and the evaluation of competencies via Delphi survey involving a group of experts has been performed. The combined results will contribute to set-up an online distance course for healthcare professionals involved in cancer genomics.

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6 CANCER CARE

6.1 ORGANIZATION AND CONTEXT OF CANCER CARE

6.1.1 Legal frameworks and cancer care programs

Quality of cancer care is at the heart of the action of many governments; it concerns the technical provision of care, but also its organization due to the intrinsic multidisciplinary nature of cancer care[56].

In terms of legal frameworks for ensuring quality, they concern the assessment of the process and outcomes of care, compulsory organization of care pathways, compliance with guidelines, and the certification of care centres, etc.

In some cases, the **concentration of cancer care** is viewed as an important attribute of care quality (where higher volumes of cases typically aligns with better outcomes), mainly related to complex surgery and rare cancers (NO, ES, MD, BE, DK, IE, NL). In the framework of its National Cancer Control Programme, Germany developed quality criteria for certification of centres (DE)[57].

However, concentration of care was rarely reported as being both supported by legal frameworks and linked to reimbursement. It can likely be explained by the reality that in many countries, professionals are attached to one hospital and legal developments or formal agreements could be required to work collaboratively in broader care networks. If their practice is no longer permitted due to a care concentration rationale, hospitals would be reimbursed less for these interventions and professionals could have to be relocated or develop their clinical practice partially in different hospitals (sometimes in another region).

A few countries reported having initiated the development of legal framework for cancer care concentration such as Moldova (MD). An example of both a legal framework and financial incentives for the concentration of complex care can be found in Catalonia (ES); Ireland (IE) is also pursuing this approach, where a plan is currently being rolled out (2020) for the centralisation of complex surgery. Moreover, a pilot for the concentration of complex surgery (in oesophagus and pancreas cancer) has been reported in Belgium (BE). In Denmark (DK), it was also reported that, in the previous Danish National Cancer Programs, I, II, III, IV (2000-2005-2010-2016)[58], strong centralization of surgery took place with a strong role for regional decision making. However, the decision on the **criteria** for activity thresholds has been reported as an important and contestable challenge for implementation of care concentration policies, in DK, as well as in Croatia, which in addition seems to also have faced a lack of political commitment (HR).

Organizational frameworks exist mainly to ensure alignment with **ethical requirements**, such as the (secondary) use of personal data (FI), but also to provide healthcare providers (professionals and clinical institutions) with (quality) criteria or minimum requirements necessary for the provision of cancer care (e.g. 'oncological care programs' in BE and the CSUR (Centros, Sevicios y Unidades de Referencia del Sistema Nacional de Salud -Reference Centres, Services and Units from National Health Service) for cancer in ES.

When it comes to quality, several countries reported struggles with the design and organization of **clinical quality assessment**. Often, these struggles were related to a lack of supporting legislation, resources or the lack of willingness of key stakeholders (mainly healthcare providers) to support structured care quality assessments (as explicitly mentioned in BE and HR).

[56] http://epaac.eu/images/Wp_7_Healthcare/Policy_Statement_on_Multidisciplinary_Cancer_Care_02-12.pdf

[57] https://www.ipaac.eu/res/file/reports/wp4/ccpis/cccn_germany_criteria_for_ccc.pdf

[58] Ulrik Lassen, "Danish Comprehensive Cancer Center - an Introduction"

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6.1.2 The role of stakeholders

OVERARCHING ADMINISTRATIVE AND SCIENTIFIC CANCER INSTITUTES

With increased complexity of cancer control and the speed and breadth of evidence generation, several countries decided to concentrate knowledge management of cancer control[59] into **cancer institutes,** as administrative institutions (e.g. INCa in FR, the Cancer Centre in BE, the National Cancer Institute in LU, the Regional Cancer Centres in SE, the Hellenic National Cancer Institute in EL, the Finnish Cancer Society in FI, the National Institute of Oncology in PL, etc.). An interesting example is *Terveysportti* (FI), which was developed by the Finnish Medical Society and provides up-to-date care and treatment recommendations in electronic form.

Depending on the size of the countries and the overall spread of competencies, these are organized at either the regional or federal level. Their role is different from HTA agencies as they are mainly involved in supporting the implementation of cancer control policies and providing support to government and a range of stakeholders. They are typically involved, to varying extents, in coordinating policy implementation, assessing policy actions and initiatives, and facilitating inter-regional discussions.

HEALTHCARE PROFESSIONALS

An important stakeholder group is clearly **health care professionals**. In addition to the provision of care, they ensure the development and update of guidelines (FI, NO, MD, DK, DE, PL). In some cases, this has been recognized as a challenge, as authorities sometimes need to find incentives for physicians to participate in this important work. The role of general practitioners/family physicians was often discussed and reported in all steps of the cancer pathways (NO, MD, DK, HR, IE, SI). They are often the source of the initial suspicion of cancer, refer patients for diagnostic exams or tests, and coordinate follow-up care. Therefore, good communication, including information sharing tools, among primary care and hospital sectors is key to ensure quality and continuity of care.

The country visits also highlighted, the **role and voice of health professionals vis a vis government and policy making** and the different and sometimes contradictory challenges this presents. Some countries reported the important and substantial involvement of physicians in policy making (e.g. as explicitly mentioned in HR and MT), with some having privileged relations and lobbying for their advantages. In other countries, healthcare professionals are more distant from the decision-making processes and there is desire to see their experience and expertise used for the development of measures concerning their work. An informant from FI expressed the need for having, at both EU and national levels, a platform bringing together healthcare professionals and policy-makers to set common goals and priorities and to create awareness among government decision makers about healthcare professionals' perspectives and ideas. In Germany, The Federal Joint Committee (G-BA) is a public legal entity comprising, along with the National Associations of Statutory Health Insurance Physicians and Dentists, other leading umbrella organizations of the self-governing German healthcare system: the German Hospital Federation, and the National Association of Statutory Health Insurance Funds. Thus, it is is the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany. In addition, patient representatives participate in all sessions and actively take part in the decision-making process of the Federal Joint Committee; they are entitled to put topics on the agenda but not to vote. The Federal Joint Committee issues directives for the benefits catalogue of the statutory health insurance funds for more than 73 million insured persons and thus specifies which services in medical care are reimbursed by the Statutory Health Insurance.

CIVIL SOCIETY

The role of NGOs has been widely discussed and reported during the country visits; not only for advocacy but also related to direct support for patients, especially regarding palliative and survivorship care (FI, LU, NL, EL, MT, MD, IT, HR, IE, ES, NO, PL, DE). In some cases, they are also involved in funding cancer research (FI, BE, DE, NO,NL).

[59] Excluding cancer registries; multidisciplinary approach to achieve organizational objectives by creating, sharing, using and managing cancer-related knowledge and information

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6.1.3 Financial resources

Budgets for cancer care mainly relate to three domains: (1) funding the clinical work; (2) financing the products (medicines, tests and materials); and (3) funding research (mainly university-based work).

A principal mechanism in addition to government funding is **health insurance**. This can be organized as state compulsory insurance, private sector insurance, or often a varying mix of both. In most countries, both insurance mechanisms are available, but in some cases, the specific nature of this mix has been reported as contributing to inequities. For example, informants from the Netherlands reported exploring a more "value-based" financing system[60] (NL). In Belgium (BE), the NIHDI[61] set up conventions with hospitals which link financing with quality criteria.

In Germany, the SHI[62] covers comprehensive medical care, including pain therapy, palliative care and rehabilitation on the basis of up-to-date evidence (DE), however, the funding of follow-up care and rehabilitation is still challenging in many countries.

For that reason, Denmark decided that a legal framework was necessary and an agreement was made with the unions of health professionals (DK).

A nice example has been found in Finland with the "*Health Sector Growth Strategy*"[63] which aims at strengthening the operating environment and improve Finland's position as an internationally renowned forerunner in health sector research and innovation, and at the same time, an improvement is sought in people's health and wellbeing through the opportunities offered by research and technology (FI).

6.2 CANCER CARE

6.2.1 Rare and paediatric cancer care

Rare cancers are recognized as a specific problem, which has involved in some cases singular organizational approaches. The development of European Reference Networks (ERN) with three networks devoted to cancer and another one partially (adult, paediatric, haematology and rare hereditary genetic syndromes) has triggered a growing interest in the diagnosis and care of these patients and the development of EU guidelines within the framework of ERNs for rare cancers. This initiative, jointly with the recommendations of the Joint Action on Rare Cancers (JARC)[64] are relevant aspects that were reported in most countries.

Cancer care for children (i.e., paediatric cancer care) is almost always reported and given specific attention, most notably through the European Reference Network for Paediatric Oncology[65], discussed during the Austrian visit[66]. In most countries, paediatric cancer care is concentrated in a few hospitals (mainly academic health centres) with Denmark reporting that one hospital is being built only for children, with an architecture that has been specifically created for children and their families (DK).

There is also the example of the collaborative network named the *Nordic Society of Paediatric haematology and Oncology* from which some units are part of the ERN (NO, DK, SE, FI). In Spain, one can find a formal agreement to concentrate paediatric cancer care (ES), and similarly in Moldova, where all cases are treated in the National Oncological Institute (MD), and in Ireland which has one paediatric cancer centre (IE).

[60] https://www.bcg.com/publications/2018/how-dutch-hospitals-make-value-based-health-care-work
[61] National Institute for Heath Disability and Insurance
[62] Statutory Health Insurance
[63] https://tem.fi/en/health-sector
[64] https://jointactionrarecancers.eu/
[65] https://paedcan.ern-net.eu/
[66] https://www.ipaac.eu/res/file/reports/wp4/ccpis/bmasgk_childhood_cancer_092019_at.pdf

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6.2.2 Cancer care networks

Out of the 28 visited countries, 16 recognized that an efficient way of organizing cancer care is by establishing comprehensive cancer care networks[67]. The country visits identified several models of such an approach[68], with two main options highlighted: (1) networks that link existing **hospitals**[69] or/and (2) networks that link **healthcare professionals**. In both cases, a **legislative basis** was/is needed and many challenges are presented, such as the **funding** of the care pathways in such networked structures (IT, NL) and the (digital) **sharing of information** (NL); all centres or professionals need to have access and contribute to patient files.

Network governance is another challenge, specifically how decisions are made about both clinical care of individual patients and network administration.

Two examples have been explored and described within the iPAAC Joint Action by the iPAAC WP10: the Lower Silesian Voivodship Oncology Network (PL) and the German Charité Network for Oncology (DE).

Cultural habits and the centrality of **physicians perceived role** and **lack of cooperative capacity** in some countries makes it difficult to implement networks, which require that decisions and responsibilities are shared (e.g.,., minimum activity levels) and **multidisciplinary work** is a core principle (IT, DK, FI, NL).

Networks also require a mentality shift for patients that relates to, in many countries, being used to the free choice of hospitals and healthcare professionals (as explicitly mentioned in BE and NL). The referral logic that a network could impose can be perceived as a restriction of the freedom of choice. In this context, **information and communication** about the benefits, the rationale and the organization of networks among health professionals and patients is key for the successful implementation of cancer care networks.

6.2.3 Patient pathways

Most countries recognize the importance of defining cancer care pathways, with legally binding effects, especially for quality and cost control purposes (and as explicitly reported by NO, IE, FI, MD, DK, MT, SE). However, the development, implementation and application of these care pathways is a challenge for many EU countries. It is notable that Denmark and Norway, as the pioneering countries, already have a 25 **cancer-specific** patient pathways (DK, NO). Because of the potential need for a high number of pathways (if tumour-specific), France decided to develop an overall pathway to be adapted to each individual case (FR). An important aspect is linking these pathways to existing guidelines, which in turn can allow the authority to monitor guideline compliance (NO)[70].

An often-reported incentive for creating care pathways are **reduced waiting times** (NO, DK, MT, SE). Wait times have often been reported as a recurrent complaint of civil society that puts policy-makers under pressure. Defined pathways have been recognized as a possible way of controlling waiting times, capturing data at each stage and allowing for the calculation of intervals between stages.

A challenge that has been reported when considering the development of pathways is **comorbidities** (DK). This is especially true for elderly patients for whom clinical options can be affected by the presence of one or multiple comorbidities. For all patients, personal goals need to be taken into account, but this is especially relevant for older cancer patients with comorbid diseases. The implementation of geriatric oncology approaches to patient pathways is a challenge in many countries.

[67] https://cancercontrol.eu/archived/uploads/images/Guide/042017/CanCon_Guide_5_Control_LR.pdf

[68] Previous survey performed in the framework of the JA CanCon by INT: https://cancercontrol.eu/archived/guide-landing-page/CANCON_Final_Report_Annex%206.10_CCCN%20Survey.pdf

[69] https://www.ipaac.eu/res/file/reports/wp4/ccpis/um_casestudyfinland_schoolfeeding_june2019_netti.pdf

[70] Jolie Bolvig Hansen, "Clinical Practice Guidelines – Cancer." Ministry of Health and Social Affairs, "Cancer Care in Sweden.Pptx."

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6.3 PALLIATIVE CANCER CARE

The organization and provision of palliative care has been very often discussed during the country visits (21/28)[71]. Nine countries reported the integration of palliative care provision in healthcare services (FI, NO, NL, EL, DE, MD, DK, MT). In Finland, it has been reported that palliative care centres use the Edmonton Symptom Assessment System[72,73], ESAS[74] (FI).

Three countries reported that specific palliative care plans, acts or strategies do exist (EL, ES, DE). The latter focusing mainly on the rights of palliative patients and its organization with a strong focus on end-of-life care and requirements for the structures which welcome palliative patients (i.e., outpatient services, such as hospices).

The main implementation challenge relates to the **transition from hospital to home care or to a long term care facility,** and the regular communication that this requires (NO, EL, ES, SE). Also, funding for this communication and exchange or the provision of advice by hospital specialists is difficult to organize, especially when there is a need to visit patients at home. For patients living in rural areas, the challenge is even greater. Two countries reported to have mobile units specialized in palliative care provision (MD, DK).

The provision of support for carers and families (especially during nights) has been reported as challenging with few options for families of palliative patients. Besides a lack of resources (ES, EL, HR, MT) another challenge is that **few professionals are trained in palliative care**, especially paediatric palliative care (ES, HR). Moldova reported having organized an educational program for GPs and pharmacists regarding the oral use of opioids (MD).

In Portugal in 2012, the law of palliative care rights has been signed. This law states that the MoH has to ensure qualitative palliative care for patients. This entails training for health professionals, and a network which is coordinated at the national level but implemented by the five regions (PT).

Some countries decided to finance the foreign training opportunities for their professionals who want to go abroad, especially to the United States, or UK (DK, MT). Belgium has worked with a group of field experts (nurses and medical oncologists) on the development of paediatric palliative care guidelines (BE).

6.4 SURVIVORSHIP AND PSYCHOSOCIAL CARE

The most important challenge for after care is the **lack of knowledge**, evidence and guidelines, although Spain reported that the recommendations from CanCon[75] should be used for local advocacy and improvements (ES). A group of NGOs in Portugal are now working together with the health professionals to create new guidelines for after care provision. They also provide social & emotional support to family and patients (PT).

The subsequent challenge is the **training** of healthcare professionals in the provision of after cancer care. This is due to the fact that it is a relatively recent preoccupation and that the shift in minds, culture and budgets still needs to be pursued.

71 Arias-Casais and EAPC Press, *EAPC Atlas of Palliative Care in Europe 2019*.

72 http://cancercaresoutheast.ca/edmonton-symptom-assessment-system-esas

73 https://www.albertahealthservices.ca/frm-07903.pdf

74 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5337174/

75 https://cancercontrol.eu/archived/uploads/images/Guide/042017/CanCon_Guide_7_Survivorship_LR.pdf

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Germany mentioned that the results from a report of the Robert Koch Institute[76] highlighted that despite the large and growing number of cancer survivors, there is a lack of information on the long-term care needs and use among cancer survivors (DE). In Denmark, the authorities provided funds through the National Cancer Program to the Danish Health Authority (DHA) to study the late effects and to municipalities to develop programs such as 'Good life after Care 2017-2020' (DK).

Austria reported that in Italy, a decision support database is in place. In the future, the aim is that Austria – together with 6 other countries- would link with this database. A future integrated registry function is envisaged allowing to capture also future events and episodes during the survivors life span possibly related to previous cancer treatments. Big data generation in this context including PROM's is planned as a tool for research for better understanding of patient's needs to assure best possible quality of life and as a guidance to develop treatment and care optimization (AT). In Ireland, a national survivorship steering group provides governance to projects and initiatives within the Survivorship Programme. This group includes members of the multi-disciplinary clinical oncology team, advocates, health service managers and cancer patients which bring the patient perspective (IE).

At the policy and decision-making level, the main incentive and rationale to engage in the provision of better after (cancer) care is the pursuit of better **quality of life and equity**. Germany and the Netherlands[77] reported working groups and task forces involving all relevant stakeholders to develop recommendations for better organization of cancer survivorship, including recommendations on research activities (NL, DE). In Ireland, emphasis has been put on the **role of community-based cancer groups** who are involved in cancer groups, writing guidelines and participating in survivorship programs (IE); while informants in Italy reported that, for the new national cancer program, the cancer survivorship component was written by **patient associations** (IT).

Several countries have prepared initiatives on specific survivorship-related issues (e.g., psychological care, physical activity, work-related issues) or fund ad hoc projects (DK, DE, MT). For example in Malta, *a Nurse Survivorship Coordinator* (Practice Nurse) has been recruited with the Cancer Care Pathways Directorate[78] whose role is to develop a survivorship survey tool, to carry out a research project to identify the needs, gaps and services required (MT). In Ireland, a *National Cancer Survivorship Needs Assessment*[79] has been published to guide the actions that need to be taken to achieve good outcomes for cancer patients and their families. The aim is to improve quality of life of cancer patients in the post-active treatment period. Priorities are identified in the Assessment, by healthcare professionals, scoping research and patient and public consultation (IE). In the region of Vienna, *a survivorship center* was recently created to enable transition to appropriate health care provider and psychosocial structures. The aim is patient empowerment throughout a lifelong "cancer" journey from diagnosis, treatments to long-term follow up facilitating healthy life years and eventually in case of resistant cancer, appropriate palliative care (AT). Still in Austria, the survivorship passport[80] has been initiated in the context of the NCCP. The planning and preparation for implementation lasted one year and involved all stakeholders. The passport will provide information on cancer treatment and will provide a personalized surveillance programme for late effects related to the various cancer treatment exposures. The plan is to embed it in the future e-health system (ELGA) with standardized reports, including recommendations (AT). In Ireland[81], the survivorship coordination is performed by a Survivorship Working Group who are working to develop a Patient Treatment Summary and Care Plan for patients. It aids coordinating and standardization of surveillance, prevention, information and self-management.

After care and long-term care has become an important area of health services research over the last decade. In most countries, there are pilot studies, scientific projects (including Horizon 2020 projects)[82] or tests that are ongoing and that look specifically at

[76] http://www.krebsdaten.de/Krebs/DE/Content/Publikationen/Krebsgeschehen/Krebsgeschehen_download.pdf

[77] https://taskforcecancersurvivorshipcare.nl/

[78] https://deputyprimeminister.gov.mt/en/ccp/Pages/home.aspx

[79] https://www.hse.ie/eng/services/list/5/cancer/profinfo/survivorship-programme/needs%20assessment.html

[80] https://siope.eu/news/austrian-cancer-plan-integrates-survivorship-passport/

[81] https://www.hse.ie/eng/services/list/5/cancer/profinfo/survivorship-programme/acute%20sector%20cancer%20survivorship%20services.pdf

[82] https://cordis.europa.eu/search/en?q=contenttype%3D'project'%20AND%20programme%2Fcode%3D'SC1-DTH-01-2019'&p=1&num=10&srt=%2Fproject%2FcontentUpdateDate:decreasing

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the provision and organization of long-term care. Slovenia reported that a special multi-disciplinary working group of national experts defined guidelines and prepared a pilot project for breast cancer survivorship (SI).

The main challenge is that care needs to be **tailored to the specific needs of the patient**. Overall long-term care plans or pathways can be defined, but not all patients need all types of after care, as particularly stressed by the Belgian Round Table on After Care[83] (BE). Indeed, after care can have implications for tertiary prevention (e.g., dietary counselling, smoking cessation support, physical activity); psychological support; and social support (including work-related issues). An iconic initiative is the French '*Droit à l'oubli*' (FR[84]) that has raised interest in some countries which are exploring the feasibility of implementing the initiative in their own countries (LU, BE). This measure aims at suppressing the additional insurance costs for patients (not only cancer, but also chronic and disabled) who ask for a loan.

An important barrier for accessing survivorship care is the lack of **financial coverage** for its main components such as psycho-oncological care, due to varying findings regarding its effectiveness. Therefore, there is a need to **establish basic standards** and to define mechanisms and practices, including across different disciplines, that have proven positive impacts on the long-term quality of life and socio-professional reintegration.

6.5 COORDINATION

To offer comprehensive cancer care and to ensure that all patients benefit from the array of services that they need, **coordination** is key. It is typically organized at the hospital level, ensuring a coherent clinical pathway, or at the community level, where general practitioners/family physicians, nurses or specialized social workers take on the role of cancer care coordinators and ensure that the follow-up needs of patients are covered. The first approach (hospital as principal coordinator) is more common in the countries visited than the second approach (primary care provider as principal coordinator), which is difficult to organize in practice. Efficient coordination also requires strong **information technology support**. For example, patient records, analysis of results, and appointments ideally should be centralized into one digital platform, accessible by patients and their carers. In most countries, multiple patient files often exist in different locations that are not easily connected or linked (typically hospital databases, primary care provider files and other health information platforms).

The use of ICTs and hospital health information systems (HIS) are directly transforming the informational and decision-making processes (e.g. through virtual MTMs), but they are also indirectly driving the incorporation of other functions (e.g. access to molecular diagnoses), which also leads to changes in these processes. Digital and dynamic interaction of teams within their ecosystem (the hospital and beyond) will continue to gradually transform the MDT model away from discussions and decision-making from within an isolated room. Opening MTMs to professionals and teams in other institutions, and to patients through registries that influence these processes in real time (e.g. PROMs), entails profound changes in clinical decision-making, as does the uptake – so far limited – of operating systems that facilitate these processes [85]. Still, the reality is that numerous obstacles and conditions limit ICTs' role in MDT tasks. The problems of interoperability of computer systems, both within and between hospitals, is a clear example, as is the resistance of some professionals against, for instance, properly using electronic health records (EHRs). However, the biggest challenge is probably the fact that hospital information systems are structured around types of clinical reports and services rather than around care processes, plus the massive generation of unstructured data (namely free text pdfs).

[83] https://www.collegeoncologie.be/sites/collegeoncologie.be/files/inline-files/FRrapport_tableronde_soinsaprescancer.pdf

[84] PDF AREAS

[85] Innovation Partnership for Action Against Cancer (iPAAC) Joint Action. Multidisciplinary teams (MDTs) and the potential impact of new technologies and systems for improving integrated cancer care r. Specific task 8.3, Work Package 8 of the iPAAC

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6.6 PATIENT EMPOWERMENT

An important issue concerns the need for **accurate information** for patients about the available services that they could draw upon when needed. But patients and their carers also need to be able to **recognize their needs**, which means, the ability to assess their own symptoms and seek appropriate support.

In Austria, the survivorship passport has to be established, in a first step for children and adolescents and will then be technically implemented in the ELGA application (e-health system), with standardized reports and recommendations. Patients will have access to their history of treatment and surveillance recommendations, which will support the empowerment of the patient (AT). In Germany, patient empowerment is a cross-sectional topic in the National Cancer Plan. Furthermore, one area for action in the Cancer Plan is exclusively dedicated to "the strenghthening of patient orientation" for a more focused patient-centred approach. In this context, the experts of the Cancer Plan developed specific recommendations with a view to improve the availability of quality assured and target group specific information, advice and support for cancer patients and their families. Other objectives of the activities include for example further developing communication skills of health care providers and shared decision making. The Cancer Information Service (KID) of the German Cancer Research Centre (DKFZ) in Heidelberg is one of the key stakeholders in this field. The Cancer Information Service offers comprehensive advice on all cancer related issues. Importantly, the above activities within the German National Cancer Plan initiated a general debate about the fundamental importance of "health competence". As a consequence the "Alliance of Health Competence" was created in 2017, followed by a "National Action Plan for Health Competence" in 2018[86].

In most countries, this type of patient empowerment has been left to civil society, which in turn cannot ensure equitable or systematic provision of information. In some countries, **civil society** (NGOs) is very powerful, well organized and recognized, with remarkable initiatives that seem to fill gaps within existing systems (FI, NO, IT, NL, LU). Unfortunately, there are limited controls possible at that level and **inequities** can be created.

To organize the provision of useful information, Denmark reported to have organized an anthropological study[87] (by municipalities) on patient experience in order to identify difficulties for patients understanding their own care pathways (DK) and to assess the impact of patient literacy on how the patient pathway is understood. The patients reported a lack of information and coordination. More generally, **patient reported outcome and experience measures** (PREMs and PROMs) have to be organized more systematically[88] in order to adapt the procedures and anticipate appropriate information and support requirements. The Belgian Centre for Knowledge expertise in healthcare, KCE, provided a detailed report in the use of PROMs and PREMs in care and policy[89] (BE). Sweden and the Netherlands[90] reported to have some PROMs organized, registered and integrated in the cancer registry or in the clinical cancer quality registry (SE, NL) and a review conducted in iPAAC work package 10 identified ongoing programs in five countries (NL, DK, DE, UK, AT) that collect PROMs multicentrically in routine cancer care and that allow for both comparing providers and individual treatment decision making. Although these programs are typically confined to a few or a group of tumors, like bladder or childhood cancers, they serve as good examples for future initiatives[91]. Austria also reported plans to develop personalized care plans for survivors and the introductionon of patient reported outcomes (AT). Important challenges regarding the implementation of PROMs and PREMs concern costs and the resources required to maintain a PROM/PREM col-

[86] https://www.bundesgesundheitsministerium.de/ministerium/meldungen/20181/februar/nationaler-aktionsplans-gesundheitskompetenz.html

[87] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5585953/

[88] https://www.oecd.org/els/health-systems/Recommendations-from-high-level-reflection-group-on-the-future-of-health-statistics.pdf

[89] https://www.nivel.nl/sites/default/files/bestanden/KCE_use_of_PROM_PREM.pdf

[90] https://ascopubs.org/doi/abs/10.1200/JCO.2017.35.15_suppl.6570

[91] Herrmann A, Scheibe M, Einhart N, Schmitt J, Kowalski C (2019) *Implementation of patient-reported outcome assessment in routine cancer care – a systematic review of multicentric programs in Europe*. Report to the European Union Innovative Partnership for Action Against Cancer Joint Action, Brussels.

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lecting infrastructure that produces high quality data. In addition, patients and providers need to get used to the routine use of PROMs and PREMs to tap the ful potential of standardized patient-reported data.

6.7 THE USE AND DEVELOPMENT OF CLINICAL PRACTICE GUIDELINES (IN ONCOLOGY)

Regarding the development of clinical practice guidelines, most countries reported the involvement and responsibilities of healthcare professionals, mainly focused on the adaptation of international guidelines, such as European Society for Medical Oncology (ESMO) guidelines.

However, guidelines do not always deal exclusively with clinical practices but also with overall organization of (oncological) care both within and outside of hospitals. The typical problem faced is when the resources available within a country do not match the guideline recommended care which is the unfortunate reality when unequal cancer care systems have varying resources and catalogue of covered services. In both cases, there are some initiatives that have been taken to monitor or influence the use of guidelines, and to consider consequences of their lack of implementation (NO, DK, DE, SE[92]). Some examples have been reported of links between the compliance with care guidelines and reimbursement (SE, DE, NO), especially when the aim is political, e.g., decrease in the delay between diagnosis and treatment (DK).

[92] https://www.ipaac.eu/res/file/reports/wp4/ccpis/cancer_care_in_sweden.pdf

6.8 IPAAC WP8 AND WP10 INPUTS

6.8.1 WP 8 Challenges in cancer care

The iPAAC WP 8 deals with several challenges faced by the health systems not covered in other WPs. The **shared approach** is the need to improve the organization of cancer care to continuously improving outcomes, focusing on the following cross-cutting challenges:

- to assess the potential ways to improve quality of care and outcomes and raising awareness on neglected cancers, using pancreatic cancer as case study;
- to identify potential use and existing barriers for Information technologies in the context of Multidisciplinary cancer team management;
- to propose measures to improve sustainability of cancer care in Europe, with specific focus on radiation oncology and complex cancer surgery, evaluating the pros and cons of different reimbursement systems and their potential impact on access to innovation. Also, the efficient use of resources in cancer care to support high value clinical practices is analysed;
- palliative cancer care integration with oncology clinical pathways is assessed and proposed improvements in the models of more integrated care. Also, pain control and ways to increase guidelines implementation are evaluated; in combination with proposed improvements in multidisciplinary approaches to better pain control.

The approach to these challenges has been based in several of them on CANCON documents. From this perspective, the iPAAC WP8 activities are aligned with the priorities and measures proposed in previous Joint Actions and in other cases fill the gaps perceived in the global perspective of cancer control, such as the case of neglected cancers. The discussions and deliverables of the WP8 with practical recommendations so far are briefly described:

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Neglected cancers: Given its emerging nature as a policy problem, it should be referred the case for "neglected cancers", a group of cancer diseases which have an important public health impact but no effective treatments or high-visibility research efforts. Neglected cancers have been defined as non-rare cancers with moderate incidence (< 20 per 100,000 person-year), a high mortality/incidence ratio (≥ 0.7), and low survival (relative survival ≤ 40% at 1 year and ≤ 30% at 3 or 5 years after diagnosis), due to either biological aggressiveness, late diagnosis, or lack of effective treatments (ref 1)[93]. The list of neglected cancer includes tumours of the gallbladder and biliary tract, stomach, liver, brain, central nervous system, and pancreas. However, pancreatic cancer is the most representative, as it has the highest mortality/incidence ratio and the lowest survival at one, three and five years after diagnosis; nowadays, it is the fourth cause of cancer death in Europe. By delineating a policy arena concerned specifically with neglected cancers, which – like common and rare cancers – would need to be addressed through a comprehensive strategy, a door was opened for EU stakeholders to consensus policy recommendations and healthcare quality standards. *The Bratislava Statement on Pancreatic Cancer Care*, with 21 recommendations addressing health systems capabilities, and the ECCO *Essential Requirements for Quality Cancer Care* in pancreatic cancer, are significant steps in the effort to fight neglected cancers diseases.

Information and Communication Technologies (ICTs) and MDTs: Health systems have increasingly recognised MDTs as a core element for high-quality care, heightening the need for their efficient and effective functioning. At the same time, the last decade has seen a boom in ICT innovations that complement or directly substitute some of the processes tied to MDT activities, becoming an important factor in generating opportunities that favour integrated cancer care. While EPAAC focused on MDTs' development as professional and organisational entities, iPAAC served to assess the impact of ICT and health information systems (HIS) on daily MDT tasks and to characterise their limitations and the new challenges posed by their adoption. As a result, 10 instruments or functionalities were identified as critical in transforming the way MDTs obtain information, communicate and make decisions.

Sustainability of cancer care: CANCON discussed the need to combine efficiency improvement with an analysis of the utilisation of health resources in clinical practice. Inappropriate use, unexplained variations clinical practice and interventions of low value are associated with inefficient use of resources. How to address these challenges and, at the same time, to cope with the continuous flow of innovations requires a careful evaluation of their effects on outcomes and their impact on system sustainability is one of the objectives explored in this task. In parallel, reimbursement systems for radiation oncology and complex cancer surgery are evaluated in order to assess their pros and cons of existing systems. A policy perspective will be developed to propose a framework that could allow improving reimbursement and introducing innovation in these therapies, mostly oriented at loco-regional treatment.

Palliative care integration: The increasing recognition of the role of palliative care for advanced patient is yet combined with incomplete accessibility to high quality services for all EU citizens with lack of common policy for the integration of palliative care in the oncology care continuum. CANCON recommendations are a starting point of this analysis and areas of development and improvement will be identified. The issue of early palliative care integration in cancer care is an issue that deserves specific analysis and action from cancer plans perspective. Another, cross-cutting challenge is pain management, in this area the analysis of prevalence data in Europe shows the need for continuous and consistent action and a priority in the continuity of care between oncology and palliative care. The implementation of the measurement of symptom assessment, including pain, should impact at the clinical skills and resources dedicated to symptom control. Dissemination of the guidelines is also a key priority.

[93] Innovation Partnership for Action Against Cancer (iPAAC) Joint Action. Definition of neglected cancers: the case for pancreatic cancer. Specific task 8.1, Work Package 8 of the iPAAC.

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6.8.2 WP10 Governance of Integrated and Comprehensive Cancer Care

The results from the iPAAC WP10 tasks concern

- a method for the derivation of tumor-specific quality indicators (task 3),
- tumour-specific patient pathways (task 2)
- patient reported Outcomes (task 4)
- a tumour-specific set of standards (task 5) which summarises the guideline-based requirements that enable comprehensive and high-quality care of oncological patients
- implementation of of the tumor-specific set of standards, including the application of quality indicators, patient pathways and PRO's, which will be verified by an on-site audit. . The results of the certification should be used to identify areas with potential for improvement and to continuously improve quality in oncology.

Importantly, the tasks of WP10 are consistent with the challenges discussed during the country visits, so that the iPAAC results, when applied in member states, will be an important contribution to the further development of oncological treatment. In detail, that means:

- **Legal frameworks:** with the **application of quality indicators** (task 3, WP 10) and with the help of on-site monitoring whether and how the set of standards is implemented in Comprehensive Cancer Care Networks (task 5, WP 10); the quality of cancer care becomes visible and manageable and controlled at the political level.
- **The role of actors:** representatives of the CCCNs, which are networks of various medical disciplines and professional groups such as psycho-oncologists or social workers, are the contact point **for the further development of the guidelines or for constructive cooperation** with government (task 5, WP 10)
- **Cancer Care Networks and Coordination:** WP10 offers a definition for CCCNs. Within these networks, which can consist of one or more hospitals, the practitioners work together on an inpatient and outpatient basis. All areas and all phases are covered from the patient point of view: from early diagnosis, through diagnosis and therapy, to aftercare and palliation. At the heart of the work are the **interdisciplinary tumour conferences**, in which treatment plans for patients are defined based on guideline recommendations. For this purpose, all treatment partners must have access to the clinical data of patients, and other formats for the exchange of data must be defined, for example, in the context of quality circles, further training courses, etc.
- **Patient pathways:** a methodology has been defined that allows for the **integration of guideline-based pathways into the hospital information system**. By integrating quality indicators into the path, the quality of treatment can be monitored and evaluated in real time. Extensions of waiting times can thus be addressed directly.
- **Palliative care:** WP10 provide requirements for the **early integration of palliative care** and tumour-specific concepts for outpatient and inpatient palliative/ hospice care. Thus, the entire treatment chain is addressed and, above all, the interfaces between the areas are organised.

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- **Patient empowerment:** the starting point for the patient pathway or for the recommendation of therapy is always the **individual stage of a tumour**. Combined with patient-specific needs, it is important to take into account **co-morbidities, preferences** and individual life situations such as employment, the need for family care, and the supply of aids. For this reason, **patient reported outcomes should be recorded**, which reflect not only the quality of life but also the function. (e.g. after surgery). The set of standards includes the organization of a multi-professional network that enables access to psychosocial care right from the start, if the patient's situation requires it. Furthermore, patient representatives are obligated to be involved in the CCCN. The provision of information to patients (e.g.,through patient guidelines, patient events, CCCN websites) are components of an effective CCCN that works in the interests of those affected, and. which can be guaranteed by implementing a consistent set of standards.

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7 CANCER INFORMATION SYSTEMS

All visited countries reported having a cancer information system. However, the level of implementation and coverage of cancer registration are very different among EU Member States (from 25% to 100% in countries with national cancer registries).

7.1 EUROPEAN FRAMEWORKS AND INITIATIVES

In this field an important stakeholder is the *European Network of Cancer Registries* (ENCR), the collaborative network of European Cancer Registries (https://encr.eu), active since 1990 to promote quality and harmonisation of data collection standards, training for cancer registry personnel and regular dissemination of information on cancer burden in Europe. ENCR is supported by the European Commission and the ENCR Secretariat is hosted at the European Commission's Joint Research Centre (JRC) from 2012. An outcome of the past Joint Action on Cancer (EPAAC) is also the decision to support through the JRC the development of a "*European Cancer Information System*" (ECIS), building on existing experience, competence and cooperation of cancer registries associated to ENCR, together with other key stakeholders in the cancer information domain.

The ECIS web application and website (https://ecis.jrc.ec.europa.eu/) is conceived for accessing cancer burden indicators derived from cancer registry data across Europe in a unique platform, overcoming the fragmentation of different (often non comparable) information sources. It reports incidence and mortality at national and registry level, as well as national survival estimates

The WP4 therefore mainly focus on the challenges faced by the CIS and their needs.

7.2 LINKING CLINICAL DATA WITH OTHER INDIVIDUAL INFORMATION

7.2.1 Legal requirements

The **linkage of cancer information systems** to other health or demographic information systems has been discussed in thirteen countries. Data linkage between cancer registries and all other health (or administrative) information systems is not so easy and does imply legal, ethical and technical issues. In most cases, these linkages are performed on ad-hoc basis, for specific studies which receive approval from (national) ethical committees.

Indeed, in addition of the provision of the classical epidemiological indicators, linkage and extended mandate would allow cancer registries to better inform the decision-making process. For example, some countries reported "Cancer Screening and Registries Act" that created the legal and financial framework necessary for setting up clinical cancer registries on a nationwide scale. Thirteen countries discussed their legal frameworks for the use of personal (health related) data.

While in some countries linkage is not yet in place, in others, **legal frameworks** and/or interoperability among health and demographic information system do allow the linkage of data (six countries), or are in a planning phase (two countries); one country having mentioned the existence of a legal framework specifically for the secondary use of health care and social registry data and another one reported being currently investigating the Dalzell model[94] to maximize linkage and accessibility of the CR to other data sources (IE).

[94] https://amstat.tandfonline.com/doi/abs/10.1080/10618600.2018.1458624

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7.2.2 Financial resorces and digitalisation

The challenge that the **financial and human resources dedicated to cancer information registration and management** represents has been discussed in six countries. Importantly, although all EU Member States report having a form of cancer registries, not all are structurally funded and the extent of their mandates also vary widely. The level of regionalization of the countries has also an important impact on the cancer registration, especially if funded by the local level. The federal State has in most case to fund an additional 'national' infrastructure to collect all the data. The most reported underlying challenge is the understanding of policy makers on the importance of having an accurate cancer information system. Few of them are aware of its added value and the need of extending its mandate to capture and reporting not only basic information (incidence and mortality) but also to link with other health information systems.

These challenges relate to the digitalization required in hospitals systems, or to the need of regions to apply for funding at the Ministry of Health, the training and use of data managers. In one country it has been reported that although all healthcare facilities are in the information network and its IT-platform (also private hospitals), the professionals have to be pro-active to register and that there is no binding measure for registration.

Delay in data collection and reporting has been discussed in six visited countries (ES, SE, BG, IE, NO, SK). The underlying reported reasons were the need of linking different sources of information (ES) or the manual registration (SE, BG, IE, NO, SK), although SE, NO and SK reported to be currently working on a new web-based system or IT infrastructure.

7.2.3 Screening, quality and costs of care, survivorship

Integration between screening registries and cancer registries cannot be given for granted in most countries, thus limiting the assessment of preventive programs effectiveness. Croatia informants regret the **non-interoperability with the screening registries** (HR), while e.g. in Slovenia, the Cancer Registry (CR) is also responsible for the management of the results from the screening, collects **performance indicators of the screening** programs and interprets them (SI, BE).

Two countries discussed the need of expanding the overall data collection to allow better monitoring of health programs (ES,NL). Germany reported more specifically the **lack of information regarding the long-term care situation** and **needs of cancer survivors** (DE), which has also been reported in Denmark where patients move across sectors and different providers but the information did not move along (DK).

Concerning this, the Finnish informants described how The *"MyKanta"* (a patient personal health record platform)[95] gives access to medical professionals to all data of the patient, e.g. **allowing doctors to send the diagnoses to nurses for follow up**. Above that, the KANTA is completely controlled by patients whom give their consent for data sharing (FI). Hungary reported the possibility to **share imaging data and pathological data** between the hospitals, so that the staff of NIO (National Cancer Institute) could perform virtual multidisciplinary team meetings to discuss the treatment plan of the patient (HU).

To monitor **delays in cancer care pathways** (CCP), the Danish Health Data Authority monitors the CCP timeframes with data from the Danish National Patient Register; they analyze the data and link to clinical registries, since 2012 (DK).[96] Sweden is similarly organizing the registration and monitoring the timeframe (including PREM) of **standardized cancer care pathways** starting from reasonable suspicion to the start of first treatment; including criteria for reasonable suspicion; maximum time scale between the measures; national clinical care guidelines; interdisciplinary groups (SE).

[95] https://www.kanta.fi/en/my-kanta-pages

[96] Ministry of Health and Social Affairs, "Cancer Care in Sweden.Pptx."

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Also in Sweden, the mandate of the national Clinical Cancer Quality Registry includes the evaluation of **adherence to guidelines** and to make comparisons and to improve quality (SE). In Portugal, the CR even performs **effectiveness studies** and provides information for the **evaluation of the reference centers** (PT). In Germany, the German Cancer Society (GCS/DKG) works together with the independent and palliative care certification institute OnkoZert for the **benchmarking of hospital quality of care**, based on aggregated data provided by the hospitals (DE)[97]. Belgium performs quality of care assessments for a number of tumors as well, including benchmarks and individual feedback to all the hospitals in Belgium. In the Czech Republic, it has been reported that, based on the outcomes from CanCon, they are developing **quality indicators** for inpatient and outpatient care, as well as accreditation forms and process for cancer centers (CZ).

As established by law in March 2019 in Greece, the patient registries are expected to serve as a tool for more effective **patient monitoring** as well as more efficient **management of health resources**. These registries will be interconnected and will cooperate with the Clinical (Therapeutic) Protocols, the Electronic Prescription system as well as the registries of EU countries, e.g. registry of efficacy and safety data collection using CAR-T cell therapies (EL). In all these initiatives, the role of the cancer registries is crucial as data provider, support for interpretation and data analyzing. Ireland reported that the Cancer registry (NCR) collaborate with other organizations, promoting research, and also produce anlaysis themselves on the incidence and prevalence of cancer in Ireland (IE).

Austria reported to have launched a survey in acute hospitals, rehabilitation centers and specialist societies (AT). Moreover, big data generation in this context (including PROMs) is planned as a tool for research for a better understanding of patient's needs to assure best possible **quality of life** and as a guidance to develop treatment and care optimizations. A unique example has been found in Sweden, with the **National Quality Registry for Palliative Care** (SE)[98].

The CCPIS collected several examples of **cancer-related data** collection and sharing that have been used to better inform the decision and policy making or improve quality of care[99].

The Cyprus Cancer Association is involved in an epidemiological study on obesity with a focus on the relation between dietary habits and cancer incidence (CY). In Spain, the Observatory for Obesity[100] monitors the trends, especially among children and makes policy recommendations (ES).

7.2.4 Genomics and personalised medicine

Coming to the management of **genetic information** for personalized medicine, Spain expressed the willingness of having an EU perspective on "what happens afterwards" with the information (ES), while Belgium reported having it centrally organized (BE) but did not yet started with analyzing.

Denmark also reported having already developed an IT infrastructure where results of all omics tests are registered, but that only aggregated data can be used for research (DK). But also in Finland, the National Genome Center[101] will maintain population's genome database and grant access to national users for health care, research and innovation purposes (FI).

97 Simone Wesselmann, "Structures of Oncological Care in Germany, DKG Certification."

98 http://kvalitetsregister.se/englishpages/findaregistry/registerarkivenglish/nationalqualityregistryforpalliativecare.2196.html

99 Ministry of Health of the Republic of Lithuania, "Lithuanian EHealth System."

100 http://www.aecosan.msssi.gob.es/AECOSAN/docs/documentos/nutricion/NAOS_Strategy.pdf

101 https://stm.fi/en/genome-center

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In Greece, an e-Infrastructure and tools for the collection, management and analysis of bioinformatics data have already been developed, supporting the (a) scaling of the number of diagnostic analyses that can be provided for medical applications and (b) the provision of services for the analysis of large-scale experiments (EL)[102].

7.3 IPAAC WP7 INPUT

iPAAC WP7 on "*Cancer Information and Registries*" addresses several cancer information needs reported by the countries in the survey interview. WP7 activities are focused on **population-based cancer registries** and aim at developing methods and tools to expand information derived from cancer registries to support decision making. The action is oriented at optimising the **integration of registry data with external health, administrative and socio-economic data sources** (to derive additional indicators) and at better exploiting already available registry data to address lack of information on cancer **prevalence and survivors needs**.

The outcomes of WP7 activities include:

i. procedures to integrate cancer registries datasets with external health and administrative data sources to derive 'real world' indicators on different domains: **quality of care** and adherence to protocols (tasks 7.2), **patterns of care and related costs** (task 7.3), late effects and **survivorship** of Adolescents and Young Adults (AYA) patients (task 7.4);

ii. a complex **ICT model** to integrate the national cancer registry of the Czech Republic with multiple administrative and health data sources to support health services governance and quality improvement (task 7.5);

iii. iii) delivery of population-based indicators on **cancer survivors** in Europe to support research on survivorship. Comparable national cancer prevalence estimates, so far not available, will integrate the range of indicators accessible in the ECIS web-platform (task 7.6).

The definition of appropriate **legal settings**, compliant to GDPR -and to additional national rules is necessary to mantain the present activities and to advance the scopes of cancer information systems. In iPAAC WP7 this step was crucial in piloting the ICT model interconnecting multiple clinical and administrative data sources with the national registry in the Czech Republic (task 5), and in the study pilots for granting access (for instance through **data sharing agreements**) to data sources not routinely accessed by the registries and necessary to expand their information (tasks 2,3,4).

[102] https://oncopmnet.gr/?page_id=2863&lang=en

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8 OVERALL CHALLENGES

The iPAAC WP4 identified a list of challenges that (1) have been (explicitly) raised by the informants during the interviews and (2) challenges that have been derived from the inductive coding of the interviews. In addition, the iPAAC WP leaders have also identified challenges in cancer control (policy) implementation in which they have worked for quality improvement.

8.1 HEALTH PROMOTION AND PRIMARY PREVENTION

Regarding prevention policies, many countries reported the important but lacking **resources** to ensure the sustainability of actions, as well as **comprehensive and legal frameworks** supporting the activities. *Health in All Policies*[103] and the *Economy of Well-being*[104] have been recognized by the experts as means to ensure coherent approach, taking into account all risk factors, stakeholders and levers to organize health promotion.

More specifically, a series of challenges have been raised by informants from the 28 visited countries:

- unequal financial and human resources and related effort consented among regions;
- socio-economic and health literacy differences among communities
- sustainability of programmes suffering from changes in governments
- industry interference and (national) income associated to the production of unhealthy products

8.2 CANCER SCREENING

Most of the reported challenges related to (the implementation of) cancer screening do relate to non-appropriate and/or not complete frameworks, as recommended by the results from the previous Joint Action CanCon[105].

More specifically, the most recurrent challenges that have been reported concern:

- the engagement of health professionals
- the delays and waiting times for further investigation with the positively tested patients
- uptake and the informed decision of target groups to participate
- the evaluation of screening programs, especially the cost-effectiveness
- the management and decision regarding new tests available on the market

8.3 DIAGNOSTIC AND TREATMENT

The insurance of the provision of the ”best care as possible” often means dealing with huge amount of new knowledge, trying to remain up to date and evidence-based. Cancer innovations is also experienced as putting at risk the sustainability of healthcare and social security systems because of constantly and significantly raising costs.

International collaboration for the knowledge management (e.g. Horizons scanning initiatives) and price negotiation have been recognized as a way of mitigating these difficulties.

[103] https://www.who.int/healthpromotion/frameworkforcountryaction/en/

[104] https://www.oecd.org/about/secretary-general/the-economy-of-well-being-iceland-september-2019.htm

[105] https://cancercontrol.eu/archived/guide-landing-page/guide-cancer-screening.html#a4.

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Country informants reported specific challenges:

- Slowness and heaviness of new drug introduction of the healthcare systems
- The affordability of new drugs and innovations in cancer care
- The informed consent of patients regarding new diagnostic technologies (NGS)

8.4 CANCER CARE

The provision of cancer care is highly related to the general organization of the healthcare system, the role of health professionals and the socio-economic status of the country. Because of this reality, overall recurrent challenges are difficult to identify without linking them to contextual features. For example, the organization of comprehensive cancer care networks, the geographical disparities and access of small communities, the consequences of the brain drain, are important challenges experienced by countries when implementing cancer control, that do relate to their own context.

Therefore, we present here below a list of challenges that can be understood as ”recurrently reported” but which have different rationale behind and implications in the visited countries.

- The lack of (evidence-based) guidelines for survivorship care
- The organization of cancer care pathways that are linked to guidelines and reimbursement and which can be monitored and evaluated; and which take into account comorbidities
- Communication and coordination between the different lines of care, especially in the context of after care and palliative care; including IT tools to support the collaboration
- The provision of survivorship care in rural areas and to lower socio-economic groups
- The funding of psychosocial care; too often left to the civil society

8.5 CANCER INFORMATION SYSTEMS

Although all countries reported some form of cancer information systems, the extent, content and possibilities were found to vary a lot. The main underlying reason do relate to the (existence of not of) legal framework and mandate of cancer registries.

Technical, ethical, legal and social implications of the expansion of cancer registries has been reported as challenging although seen as key for better informing cancer policy decision-making. It does require resources to digitalize the existing processes and to update or setup (local) information systems, ensuring interoperability. Policy makers usually undervalue the importance of information systems and a comprehensive strategy is lacking in this field.

The list of recurrent challenges or information needs is:

- mandate for cancer registries to collect information on the whole disease trajectory
- lack of resources (human and financial) to enhance CIS
- interoperability and integration of information from multiple care providers (patient- rather than provider- centered information systems), overcoming silo-structure
- lack of information on the whole clinical pathway for quality of care evaluation
- lack of information on cancer survivorship (burden, conditions and needs of survivors)

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8.6 CROSS-CUTTING ISSUES AND CHALLENGES

Against these domain-specific challenges, some transversal issues have been raised during the interviews:

- The involvement of patients in the (policy and care) decision-making process
- The translation of professionals and expert needs to policy makers
- Improve the effectiveness of communication and coordination across sectors
- The difficulty to implement comprehensive approaches and frameworks
- The need of having an EU platform to exchange about cancer control policy implementation
- The (health) continuous education of all actors: health professionals, patients (empowerment and health literacy) and policy-makers