Policy priorities for 2024-2028

Improving cancer care in Belgium

Integral memorandum

All.Can Belgium

Changing cancer care together

Content

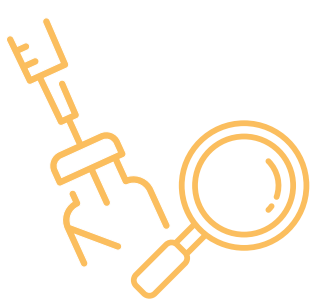
Policy priorities for 2024-2028

Cancer care continues to evolve at an unprecedented speed. This progress offers new hope to cancer patients and their loved ones and allows us to envision an optimistic future in which more cancer types can be cured or pushed into a prolonged remission.

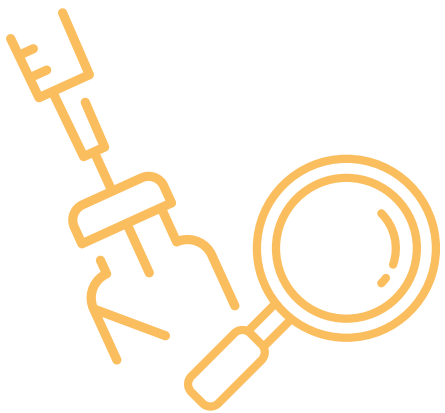
In order to maximize the potential benefits from these continued innovations in cancer care, there is a need for an action plan that integrates and coordinates the different aspects of the fight against cancer. To this end, the Belgian cancer plan was launched in 2008.

However, after more than 15 years, this plan is in need of an update. In this light, All.Can Belgium has formulated a number of policy priorities for the years to come. In brief, these priorities are built around four axes:

1. Invest in primary prevention, early detection, and cancer screening
2. Improve the access to high quality care
3. Facilitate timely access to novel treatment options for cancer patients
4. Support clinical and translational research in oncology to safeguard Belgium's leading position in oncological research




1 Invest in primary prevention, early detection and cancer screening



About 4 out of 10 cancers are caused by known, modifiable lifestyle factors, environmental factors, oncogenic viruses, or occupational hazards.[1, 2] As such, primary cancer prevention continues to be the most efficient long-term cancer control strategy.

In line with this, both the World Health organization (WHO) and the European Union (EU) see primary prevention as a key priority. However, this requires a dedicated and continued political commitment, with an aim to reach everyone in the society.

All.Can Belgium therefore urges policy makers to make continued investments in increasing the awareness on the cancer risk related to lifestyle factors such as smoking, alcohol use, obesity, physical inactivity, and excessive sun exposure.

Nudging

In parallel to improving the cancer-related health literacy among the general public, preventive health programs should be initiated that stimulate a healthy lifestyle ('nudging'). Examples include health score codes on food, taxation on tobacco and alcohol, fiscal incentives for people entering sport clubs, etc.

In addition to this, incentives must be put in place to avoid the use of cancerous environmental factors, such as nickel compounds, benzene, acrylonitrile, radon, or arsenic.

Human papillomavirus

Finally, evidence-based vaccination programs against oncogenic viruses should be put in place. For example, several cancer types, including cervical cancer, are caused by human papillomavirus (HPV), an infectious agent without a non-human reservoir. Since HPV vaccines have a very high efficacy against persistent vaccine-type HPV infection, obtaining very high levels of vaccine coverage will ultimately eradicate HPV types that cause almost all cervical cancer cases. Therefore, continued efforts should be made by Belgian policymakers to maximize the HPV vaccination rate in both girls and boys.

Of note, under the umbrella of the Europe's Beating Cancer Plan the EU supports efforts of member states to extend routine HPV vaccination. With this, the EU wants to vaccinate at least 90% of the female EU target population and significantly increase the vaccination rate among boys by 2030.[3]

Inappropriate distribution

In Belgium, we are confronted with an inappropriate distribution of competences between the federal and regional governments. For example, preventive care falls into the scope of the regional entities, while some of the related procedures remain under the responsibility of the Federal State. For example, the regions are in charge of organizing cancer screening programs, while the federal INAMI/RIZIV deals with the reimbursement of the examinations that are used for this screening (e.g., cervical smear test, mammograms). The complex governmental structure in Belgium can make it challenging to organize primary and secondary prevention strategies in a structured and effective way. Therefore, All.Can Belgium urges for a better coordination and cooperation between the regional and federal governments regarding cancer policies.

The treatment of cancer at an early disease stage is less aggressive, less expensive and more effective, resulting in higher long-term survival rates and a better quality of life for patients.[4, 5] In fact, data from a recent meta-analysis show that even a delay of just 4 weeks significantly increases the mortality across different cancer types and treatment modalities, with longer delays being increasingly detrimental.[6]

According to the 2020 WHO Report on cancer, early diagnosis is one of the most effective public health measures in cancer.[7] Two approaches can be used to facilitate an earlier cancer detection: screen for precancerous lesions, or preclinical, asymptomatic cancer in apparently healthy people and invest in the early diagnosis of cancer in patients with early signs or symptoms of disease.[7]

All.Can Belgium urges to strengthen and re-invigorate the existing screening programs for breast, cervical and colorectal cancer among the general population. The latter is also supported by the European Commission, who specifically see the development of a new EU Cancer Screening Scheme for breast, cervical and colorectal cancer screening as a flagship initiative of their 'Europe's beating cancer plan.'[3] With this initiative, the EU wants to ensure that by 2025, 90% of the target population is offered breast, cervical and colorectal cancer screening.

Early diagnosis is one of the most effective public health measures in cancer.

Screening for other cancers

In addition to reinforcing existing screening programs, additional targeted screening programs need to be developed for other cancer types, such as lung or prostate cancer. Specifically for lung cancer, there is now consistent evidence that lung cancer screening by low dose computed tomography in high-risk populations of current and former smokers significantly and substantially improves lung cancer mortality. In this, data show that the number needed to screen (NNS) for one diagnosis of lung cancer is 130–230, with a NNS of 320 to avoid one lung cancer death.[8] As such, these figures actually compare favorably to the NNS for cervical, breast and colorectal cancer screening in Flanders.[9-11]

To improve on the early detection of symptomatic cancer, it is first and foremost important to increase the awareness for these early signs of cancer among primary care physicians and the general public as a whole. To improve this 'cancer literacy' there is a need for consistent, comprehensive, and evidence-based information, adapted to the mindset, culture and beliefs of the target population.

A prime example of this consists of the JUVENTAS project that was initiated by All.Can Belgium to specifically improve the awareness on early signs of breast cancer, testicular cancer, and sarcoma among adolescents and young adults. In addition to an awareness campaign in schools and in the media, this project also includes surveys looking into the cancer knowledge of adolescents and assessing the obstacles they encounter in discussing potential early signs of cancer with their primary physician.

In parallel to this, there is a need for continued investments in our diagnostic capacities. Apart from providing adequate primary care services, this includes suitable access to (molecular) testing and medical imaging.

2 Improve the access to high quality care

Striving for high quality care has become ubiquitous in debates around cancer care in recent years. However, it is important to underscore that patients, loved-ones, and health care providers (HCP) often hold different definitions for 'qualitative care'. In fact, whereas cancer patients and relatives tend to evaluate care based on whether or not their treatment allows them to turn back to normal life as soon as possible, HCPs may focus more on technical competence and how efficient this care is being executed.

For All.Can Belgium, patient-centricity is one of the main criteria by which care should be judged. As such, high-quality cancer care should be provided across the entire care continuum from the time of diagnosis and treatment to rehabilitating survivors and providing end-of-life care. Across this continuum, care should focus on the provision of patient-centered care planning, palliative and psychosocial support for both patients and their caregivers and the prevention and management of long-term treatment-related toxicity.

To maximize the quality, care should be provided by competent, trusted, and multidisciplinary cancer care teams that are aligned with the individual patient needs, values, and preferences.

All.Can Belgium has identified 9 priorities that can help to further optimize the cancer care quality in Belgium.

1. Recognition of reference centers and centers of excellence

Given the complexity of cancer management anno 2023 it is no longer reasonable, efficient, or ethical to offer care for every tumor type in every hospital. This is especially true for rare cancers or complex situations (e.g., cancer and pregnancy). To improve the quality of care and decrease the current dispersion of cancer expertise in Belgium, continued efforts should be made to further establish and certify reference centers with multidisciplinary teams of recognized experts for a larger number of rare and/or complex cancers.[12]

In fact, there is a large body of high-quality evidence convincingly showing an improved short- and long-term outcome when complex procedures are performed in high-volume hospitals.[13-15] Already in 2014, the Belgian Health Care Knowledge Centre (KCE) argued for the development of reference centers for 14 rare or complex cancers.

In this, reference centers are responsible for the diagnostic confirmation, the elaboration of the treatment plan and the complex parts of the treatment (e.g., complex surgery or radiotherapy), whereas peripheral centers can still perform less complex, well-described parts of the treatment, performed in close collaboration with the reference center.

Combining expertise and proximity

The formation of networks between reference centers and peripheral centers ('shared care model') allows for a better care delivery, combining expertise and proximity. Embedding these reference centers within the European reference networks (ERN) allows for a further exchange of expertise. Through international networking Belgian reference centers will not only increase their expertise but also their research potential, with a positive impact on the participation rate in clinical trials.

In the meantime, reference centers have been set-up for a couple of rare cancers (i.e., pancreatic, and esophageal surgery), but for most of the identified rare cancers this is not yet the case. All.Can Belgium therefore urges for the further implementation of reference centers for all rare or complex cancer types.

In fact, All.Can Belgium believes that the reference center concept should not be limited to rare cancers alone as it may also lead to improved outcomes for patients with more common cancers. For example, data from a recent KCE report show that breast cancer patients who are being treated in a center without a breast cancer certification have a markedly higher chance of dying from their disease than patients who are treated in a coordinating breast clinic.[16] As such, it seems wise to also concentrate crucial steps in the management of more common cancers, such as breast or lung cancer, in certified centers of excellence.

The concept of reference centers may also improve outcomes for patients with more common cancers.

2. Educate a sufficient number of specialized caregivers

Data from the Belgian Cancer Registry show a continuously increasing incidence of cancer over the last decades.[17] To ensure that the growing number of cancer patients receive the best possible care it is important that the number of oncologists, radiotherapists, onconurses, etc. adequately reflect this growing cancer incidence. Therefore, efforts should be made to educate a sufficient number of specialized caregivers.

In addition to this, there is a need for an advanced nursing practice curriculum which focusses on the clinical and psychosocial needs encountered in the care for cancer patients. However, before we can make this a reality, we need to find a consensus on the competences these professionals must master and on the role they can play in coordinating the multidisciplinary care for our patients.

3. Develop guidelines for psychosocial care of cancer patients

The significant impact of cancer on the lives of patients and their families is not limited to symptoms and treatment side effects, but may extend to a wide range of psychological, emotional, social, cultural, and spiritual aspects of life.[18] Despite a growing recognition that psychosocial care is an essential component of comprehensive cancer care, evidence suggests that the psychological needs of many patients remain unmet.[19]

Nevertheless, data show a clear relationship between psychosocial morbidity and maladaptive coping, a reduced quality of life, impaired social relationships, suicide risk, longer rehabilitation times, poor treatment adherence, and possibly also a shorter survival. As such, psychosocial care requires special attention in the care for cancer patients.[18, 19] In this, several studies have shown the positive health impact of a wide range of psychosocial interventions.[20-22]

Unfortunately, financial and organizational barriers continue to stand in the way of a routine implementation of psychological care programs in the management of cancer patients. As such, there is need for psychosocial care guidelines that help care teams to timely detect and address the psychosocial needs of cancer patients and tackle potential barriers to the provision of care to patients of different linguistic and cultural backgrounds.

Psychosocial care can have a positive impact on the health of cancer patients.

4. Maximize personalized medicine approaches in oncology

The recognition that each patient with cancer is unique is not a new concept in oncology. In fact, each patient presents with specific preferences, needs, tolerances, and unique tumor characteristics.[23] This understanding has led to an increasingly personalized management of patients, taking into consideration the inter- and intra-tumor variability in gene expression, differences in tumor (immune) microenvironment, and the lifestyle or comorbidities of the individual patient.

In this respect, a personalized treatment strategy specifically tailors the therapy towards the oncogenic drivers of the tumor and tumor immune environment of the patient. Furthermore, personalized medicine also considers the potential therapy-induced toxicity. In this way, the biggest chance for a qualitative tumor response is combined with the preservation of organ function and quality of life.[24]

The basis for a personalized treatment selection process in oncology is formed by the efficacy and safety results established through clinical trials. However, these clinical trial data do not address all possible scenarios resulting in considerable data gaps. All.Can Belgium believes that real-world data (RWD) can play a vital role in filling these gaps.

Importance of real-world data

For example, RWD can produce valuable insights into treatments and their efficacy in daily clinical practice, identify better biomarkers, allow for a broader capture of treatment-related toxicities, and produce valuable data on treatment sequencing. An improved collection and sharing of RWD should therefore be a priority for authorities and the medical community as a whole in the years to come.

Determining the biomarker status is often a prerequisite for an effective personalized therapy. Unfortunately, the current registration and reimbursement processes for complex diagnostic companion tests are inadequate. In brief, there is a lack of coordination between the review process of the companion diagnostic and the medicine in question. This can cause time lags, especially if a medicine has been approved via an accelerated pathway, potentially limiting the access for patients to an effective targeted therapy.

Therefore, All.Can Belgium underscores the need to better align the registration and reimbursement processes used for medicines and companion diagnostics. Only then patients will fully reap the potential benefits of the personalized treatment revolution in oncology.

To provide the best care, we need to better align the evaluation of therapies and their companion diagnostic tests.

5. Promote practical healthcare solutions for patients

A patient-centered cancer care requires continued investments in optimizing the treatment journey. For example, many patients and their loved-ones experience regular travelling to cancer treatment centers as inconvenient and time-consuming. In this, a high travel burden can lead to delays in the treatment of cancer and is associated with a worse prognosis and a greater quality of life impairment.[25]

Therefore, efforts should be made to organize the treatment or patient follow-up outside of the oncology ward, closer to the patient's home (e.g., home-based, in primary care centers, through satellite or mobile cancer units, etc.). In this, however, it is important to organize things in close collaboration with the treating reference center. By allowing a more 'flexible care' wherever possible, patients can decide where they want to receive their treatment, leading to an improved quality of life, while simultaneously reducing pressure on HCPs and hospitals.[26] In the same spirit, the COVID pandemic has demonstrated how telemedicine can be useful to allow patients to have access to care without having to leave their home.

Apart from thinking about innovative ways to bring the treatment closer to patients and investments into tools that allow for remote patient follow-up, we should also think about ways to improve the 'treatment experience' within hospitals. In this light we see a vital role for clinical nurse specialists or onconurses. In fact, data show that being cared for a by a specialized onconurse is associated with better experiences of involvement in treatment decisions and care coordination.[27]

Patients who are being cared for by a specialized onconurse feel more involved in their treatment.

6. Ensure a holistic approach towards cancer care

Cancer patients and cancer survivors face many physical, psychological, social, spiritual, and financial issues throughout their disease course. Therefore, it is important to stimulate a shift from a disease-focused cancer care to a more holistic approach, in which more attention is paid to psychosocial aspects, quality of life, patient empowerment and survivorship.

In this, decision makers in the management of cancer patients should collaborate with all relevant stakeholders to ensure all patients have access to holistic, integrated supportive care. It is crucial to put psychological wellbeing on an equal footing with physical health, providing easy access to psychological support for patients who need it. Results of an All.Can survey show that more than two thirds (69%) of respondents indicate a need for psychological support during or after their cancer care, but that a third of them lacked that support.[28] This clearly illustrates that there is still considerable room for improvement.

Risk of malnutrition

In addition to this, also nutritional support should be an integral part of a holistic cancer care. In fact, malnutrition is a frequent

problem in cancer patients, which leads to prolonged and repeated hospitalizations, increased treatment-related toxicity, reduced response to cancer treatment, impaired quality of life, a worse overall prognosis, and the avoidable waste of healthcare resources.(29)

Despite the availability of international guidelines for nutritional support in cancer patients, a considerable gap remains between nutritional support requirements and actual delivery of nutrition care, with varying attitudes among HCPs. As such, there is a continued need for a growing awareness on the importance of nutrition in an oncological setting. Importantly, this nutritional support needs to be safeguarded throughout the patient journey: during treatment, at end-of-life and for cancer survivors.

Due to an ageing population and an improved early detection and treatment of cancer, the number of cancer survivors is continuously growing. Therefore, it is important to transform our current care model to better address the specific physical, psychosocial, and supportive care needs of cancer survivors. Apart from a thorough surveillance for recurrence, this requires an increased attention for long-term effects of certain therapies (e.g., lymphoedema, osteoporosis, etc.) and common psychosocial issues of cancer survivors (e.g., fear of recurrence, fatigue, altered sleep and cognition, effects on sex and intimacy). In this respect, patients also deserve support to direct them back to their workplace.

In addition to this, efforts should be made to mitigate the risk of recurrence or new cancer by stimulating a healthy lifestyle among cancer survivors. Finally, cancer survivors have a 'right to be forgotten'. In fact, long after recovering from cancer, cancer survivors are requested to report their former medical condition to commercial companies, such as life insurance companies or funeral insurance companies. The right to be forgotten is explicitly recognized in Belgium, with a time limit of 8 years (5 years for patients younger than 21 years of age at the time of diagnosis) and the European Union set the objective to have this implemented in all EU members states by 2025.

At the other end of the spectrum, adequate palliative support should be offered to patients with a life-threatening cancer. By timely addressing the specific physical, emotional, practical, and spiritual needs that arise when faced with a life-threatening condition, we can markedly improve the quality of life of patients and their caregivers.

In this, it is important to underscore that palliative care should not be restricted to the very end of the disease journey, but should be offered across the different disease stages, from diagnosis to the end of life. In fact, literature shows that early palliative care consultations can improve symptoms, quality of life, and even disease outcomes for patients with cancer. When palliative care is initiated early in the treatment process, patients experience less distress and gain more control over the delivery of their care.(30) Therefore, palliative care should be fully integrated within the cancer care continuum and involve a truly multidisciplinary team of professionals, including doctors, nurses, dieticians, pharmacists, occupational therapists, physical therapists, chaplains, psychologists, and social workers.(31, 32)

Palliative care should be offered across the different disease stages, from diagnosis to end of life.

7. Strive for a patient-centered, multidisciplinary, and integrated cancer care

Throughout their cancer journey, patients are managed by a wide range of healthcare providers and undergo multiple treatment modalities. In this multidisciplinary setting, every specialist approaches the patient from their own perspective. While this approach ensures the best outcome for patients, it also comes with a risk for ambiguity about responsibilities and roles of the different specialists within the care team and a lack of clarity on who does what for patients. Therefore, efforts should be made to improve role clarity, both within the treatment team and towards patients.

In addition to this, it is important to better integrate healthcare providers assisting patients in the in- and outpatient setting. For example, the current involvement of primary-care physicians in the management of cancer patients is limited. Nevertheless, they can have a meaningful role in the early identification of cancer, introducing patients to the team, and follow-up after hospital discharge. In addition, they are primarily involved in the management of a series of unrelated comorbidities and symptoms when the patient is at home, and their involvement can help in prompting the identification of treatment-related side effects when the patient is discharged from hospital.[33]

The same holds true for physiotherapists, dieticians, psychologists, or other specialists that are involved in the care for cancer patients outside the walls of the hospital. All.Can Belgium beliefs that a multidisciplinary, patient-centered cancer care, with a good collaboration and communication between healthcare providers in the in- and outpatient setting will lead to better outcomes, more patient-involvement, and a better quality of life for patients.

8. Ensure equity

Ideally, everyone should have an equal opportunity to prevent cancer, find it early, and get proper treatment and follow-up. Unfortunately, however, literature shows that ethnic minorities continue to experience healthcare disparities and poorer clinical outcomes.[34, 35] Similar inequalities are also encountered according to gender, age, socioeconomic status, sexual orientation, patients in rural areas, or the presence of disabilities.[35]

All.Can Belgium urges for continued efforts to promote equal access to high quality cancer care to all patients, regardless of where they live, whether they can afford it, their ethnicity, or any other personal circumstance. These efforts could consist of ensuring a broad geographic accessibility to cancer services and the adoption of practices that improve equitable participation in research activities.[36]

In addition to this, literature shows that a diverse clinical workforce can result in a bigger sensitivity and attention for care inequalities.[37, 38] To better counter the inequalities in cancer care it will also be important for scientific and clinical communities to share their efforts, experience, best practices, lessons learned, and solutions around this theme.

9. Invest in a better integration of oncology within the different internal medicine specialties

Cancer and its treatment can have a profound impact on different organ systems in the human body. Therefore, All.Can Belgium urges for a continued investment in the development of oncology specializations within the different internal medicine subspecialties.

For example, cardio-oncology is an emerging field of interest that focuses on the detection, monitoring, and treatment of cardiovascular disease occurring as a side effect of chemo- and radiotherapy. It is well-established that both these treatment modalities can cause cardiac dysfunction, representing a major cause of morbidity and mortality among cancer patients and survivors. Especially given the availability of more and more effective and potentially curable cancer treatments, adequate management of cardiovascular disease is becoming increasingly important to safeguard the survival benefit obtained from the cancer therapy. Similarly, onconephrology is an emerging subspecialty within the field of nephrology that recognizes the important intersections of kidney disease with cancer.

In this light, All.Can Belgium urges for a better collaboration between oncologists and other internal medicine specialists and for an increased awareness for the potential (long-term) effects of cancer and its treatment on other organ systems. The latter is of particular importance for people who survived cancer during their childhood or adolescence.

Collaboration between oncologists and other internal medicine specialists contributes to good cancer care.

3 Facilitate timely access to novel treatment options for cancer patients

The management of cancer is evolving at an ever-accelerating speed, leading to an earlier cancer detection and an increasing treatment personalization. While these innovations hold great potential for patients, incorporating them into clinical practice in a timely manner continues to be challenging.

Specifically for Belgium, this challenge is amply illustrated by disappointing data on the availability of innovative drugs. According to the European Federation of the Pharmaceutical Industry, a total of 41 oncological drugs received an European Medicines Agency (EMA) marketing authorization between 2017 and 2020.[39] In January 2021, only 66% of these drugs were reimbursed in Belgium. While this 66% exceeds the average of 55% across the entire European Union, Belgium is lagging behind most other Western European countries in this ranking.

The Belgian situation is even more dissatisfying when looking at the time between the EMA marketing authorization of a new drug and reimbursement. In Belgium, this process takes 598 days on average, referring Belgium to a disappointing 25th place in the European ranking. Furthermore, this metric is getting worse over time from 395 days in 2017 to 440 days in 2019 and 598 days in 2021.[40] Given this situation, ensuring access to existing treatment options for patients and an accelerated approval of innovative treatment options should be a top priority in the years to come.

The Belgian government recognizes that we urgently need to improve the availability to existing and innovative treatment options for patients with cancer and is currently working on a new reimbursement procedure. This gives us the opportunity to replace outdated reimbursement processes and assessment tools to facilitate faster patient access to innovation.

In Belgium, the advice whether or not to reimburse a new drug comes from the Belgian Commission for Reimbursement of Medicines (CRM). After its evaluation, the CRM can advise for a definitive or temporary reimbursement or advise not to reimburse the medicine in question. In case of a temporary

The voices of patients and doctors are largely absent in reimbursement negotiations for pharmaceuticals.

reimbursement, the reimbursement process is transferred to a working group convention for further negotiation on the solidity of the scientific data and the potential budget impact.

Rather than to wait for more solid evidence before making a definite reimbursement decision, managed entry agreements (MEA) allow to grant early access to pharmaceutical products, while at the same time collecting the relevant data to assess (cost-) effectiveness, controlling the budget impact, monitoring the (rational) use in clinical practice, or generate real life safety and efficacy data. As such, a broader use of this MEA system or other creative access solutions can help to speed up access to innovative treatment options for patients.

During reimbursement negotiations, the interests of patients who want access to safe, innovative, and promising therapies and the interests of physicians who would like to provide these innovative and promising therapies need to be offset against the interests of the industry who wants to sell their products and the interest of payers who wish to take the right decisions in view of the sustainability, equity, and quality of the healthcare system.

Surprisingly, however, the voices of patients and physicians are currently largely absent in these negotiations. As physicians and patients can often sketch a clearer picture of the potential added clinical benefit of an innovative treatment it seems interesting to also imply representatives of medical umbrella organizations (e.g., the Belgian Society for Medical Oncology) or patient organizations during the reimbursement procedure.

Before patients can receive a new treatment, regulators such as the EMA balance the potential added clinical benefit with the tolerability of a new treatment. After EMA approval is being granted, governmental bodies ('payers') of the different European member states assess whether they consider this new treatment option eligible for reimbursement.

Whereas regulatory agencies largely base their decisions on a trade-off between the added value of a novel therapy compared to the current standard of care, payers focus on allocating a set

healthcare budget to those treatments that will likely yield the best outcome in terms of mortality, morbidity, and quality of life (QoL).

As a result, payers and regulators use different parameters in their evaluation of novel treatment modalities. In this, overall survival (OS) continues to be the gold standard for payer-decisions. While OS is indeed a crucial endpoint in the oncological setting, a stringent focus on OS data can stand in the way of a rapid access to new medicines that can improve the outcome of cancer patients. For example, in early disease stages it can take a (very) long time for OS data to mature. In addition to this, the use of subsequent lines of therapy, both in the early and the advanced setting, can make it challenging to root out the true OS effect of a given treatment.[41, 42]

Other evaluation parameters

To overcome this, regulatory agencies are increasingly accepting alternative oncology-related endpoints, such as progression- (PFS) or disease-free survival (DFS) when evaluating a new treatment. Of note, these endpoints are not only relevant from a clinical point of view but are also very important for patients. In fact, for many patients, being disease or progression-free for an extended period of time is an important treatment objective. However, payers continue to primarily focus on OS data in their decision-making process, which can lead to a delayed access to regulatory-approved treatments.[43]

The ever-increasing pace at which new anticancer therapies are being developed in combination with an earlier detection of cancer will make it increasingly more challenging to demonstrate mature OS data at the time of regulatory approval.

Recently, several tools have been developed that can help to mitigate the uncertainties that come with reimbursing an agent in the absence of mature OS data.[44] The most relevant of these tools for the European situation consists of the magnitude of clinical benefit scale developed by the European Society of Medical Oncology (ESMO-MCBS).[45, 46]

Progression- and disease-free survival

Through a rational, structured, and consistent approach the ESMO-MCBS wants to give a clear reflection of the magnitude of clinical benefit that can be expected from a new oncological therapies. In this, the ESMO-MCBS scale does not only look at OS data, but also considers threshold hazard ratios for PFS and DFS, response rates, QoL and toxicity data. Furthermore, also the prognosis of the condition in which the new treatment will be used is taken into consideration.[45, 46]

To improve and speed up the access to innovative anticancer drugs it seems reasonable to value oncology-relevant end-points other than OS in the reimbursement assessment of novel treatment modalities. When a strong treatment effect is seen on an intermediate endpoint such as DFS or PFS, a detriment in OS is (very) unlikely. In fact, when the hazard ratio for such an intermediate endpoint is much better than the thresholds used in ESMO-MCBS, one could even argue that withholding access to this drug based on OS immaturity is unethical.

Therefore, a temporary reimbursement decision based on intermediate endpoints could give Belgian cancer patients earlier access to promising life-saving medicines. Awaiting final reimbursement, more mature data can be gathered to confirm and solidify the earlier results on intermediate endpoints and better assess the tolerability of the treatment at hand in a real-world setting.

Another way to improve the access to treatment for cancer patients relates to the off-label use of medicines. While off-label use of medicines is generally discouraged, it is quite common in oncology.[47] In fact, many 'old', off-patent and low-cost cancer medicines remain off-label for new indications, despite the availability of convincing phase III evidence supporting their use.[48]

However, as these medicines are no longer patent protected, manufacturers lack a financial incentive to proceed with a regulatory application for these new indications. This can lead to prescription and reimbursement obstacles and an impaired access to established therapies. This is especially relevant for healthcare settings that strictly limit medications reimbursement to their licensed indications (as is the case for Belgium).[49]
To avoid this, All.Can Belgium urges that reimbursement criteria for a certain medicine should include all clinical indications for which adequate data are available.

Importantly, when revisiting the Belgian reimbursement process it is important to make it future proof and integrated into the European context. In doing so, we can work on Belgium's preparedness to guarantee patient access to new therapies and avoid delays in patient access to oncology therapies due to European regulation.

The off-label use of medicines can help various cancer patients, but occurs infrequently in Belgium.

4 Support clinical and translational research in oncology

Belgium continues to be an attractive location for clinical trials, ranking second in Europe in terms of the number of clinical trials per capita in 2017. The reasons for Belgium's attractiveness as a clinical trial location are manifold, including the expertise of the authorities, the quality of the research centers, investigator expertise, access to scientific advice, and short start-up timelines.[50]

All.Can Belgium wants Belgium to maintain this leading position in clinical research and therefore urges for a better coordination of clinical cancer research at national and international level with a reinforced collaboration between academic and industry research.

Furthermore, there is a need for more structural support for academic clinical research. This could consist of initiatives to promote a centralized and structured data collection, support data sharing between hospitals, ensure interoperability of digital data or support the appropriate use of digital health technologies in clinical trials (e.g. eCRF). By investing in these fields, Belgium can safeguard its leading position as an ideal location for clinical research, offering Belgian patients the chance to be treated with the most innovative treatments.

Finally, to maintain Belgium's leading position in oncology research it will be important to anticipate European decisions that could reduce Belgium's attractiveness for the performance of clinical trials. For example, in January 2022, the EU Clinical Trials Regulation was launched, harmonizing the submission, assessment and supervision processes for clinical trials in the European Union. In parallel, the 'Accelerating Clinical Trials in the EU' (ACT EU) initiative was launched to further strengthen Europe's position as a clinical trial location.

This new EU legislation is levelling the playing field in Europe when it comes to attractiveness of different Member States as a clinical trial location. For a country to differentiate itself it will therefore become important to make the right strategic choices. Specifically for Belgium, gaining expertise in innovative clinical trial designs represents an opportunity to achieve this goal.

Conclusions

Continued innovations in cancer care have significantly improved the outcome for patients with cancer over the last decades. While the pace of this innovation has been impressive, we must ensure that it is paralleled by a similar upsurge in the interest for patient-centricity and by necessary changes in the organization of our healthcare system.

To this end, All.Can Belgium has formulated a number of short-term priorities that can help us to achieve these ambitious goals and ultimately improve the survival and well-being of cancer patients.

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