COLLEGE OF ONCOLOGY

Oncology in Belgium
Networks of Expertise

College of Oncology, 2015

Table of contents

1. Introduction

-Reference Centers for (rare or complex) cancers: a must?-

This question is under investigation mostly in recent years and will be addressed shortly within the Ministry of Health and Social affairs.
Reference centers are established in some of the European countries and the representatives of ESMO elaborated a set of 39 recommendations on stakeholder actions and public policies in order to improve (rare) cancer care in Europe[1].
These recommendations can be grouped into six areas:

- Regulatory barriers in (rare) cancer care
- Methodological barriers to (rare) cancer care
- The need for centers of expertise and European reference networks
- Barriers to patients access to care
- Education of health care professionals
- Access to information on (rare) cancers for patients

The European influence and implementation of reference centers brought the Ministry of Health & Social affairs to -in accordance with action 13 of the Belgian Cancer Plan (2008-2010)-assign the KCE in performing a study with the objectives to:

- Establish the threshold to define rare cancers in Belgium
- Define the competences required to manage patients with rare cancers
- Propose scenarios for the organization of care for patients with rare cancers and cancers that require complex care, taking into account the current Belgian situation and relevant foreign experiences.

This report will give

1. An overview of the topics contained in the KCE reports,
2. A comparison with the Oncology Care programs existing since 2003,
3. The advice from the College of Oncology.

The latter will give an opinion on cancer care in general, with a special focus on rare/complex cancers.

[1] http://www.esmo.org/content/download/16802/296577/file/ESMO_Rare_Cancers_recommendations_2010.pdf

2. Background

Based on registration data (2004-2010), the national cancer registry reports that on average almost 62.000 new tumors are diagnosed in the adult population each year in Belgium. Of those, 4.100, i.e. 7%, are considered rare tumors (i.e. with an incidence < 6/100.000). These figures will increase by 3% per yeardue to the increasing numberof inhabitants and the ageing of the population.

The increase in new cancer cases, the complexity of (molecular) subtyping of cancer, the expanding treatment options and the multidisciplinarity ask for a transparent structure of care. Therefore, a Royal Decree was published on March 21, 2003.
The Royal Decree stipulates the care programs for basic oncological care and oncology care programs. Both programs aim at reinforcing the provision of high quality care for cancer patients:

- **Care programs for basic oncological care** focus mainly on diagnosis and less complex treatment. In principle, each hospital that does not have the recognition for an oncology care program has to offer a care program for basic oncological care.
- **Oncology care programs** have to offer more advanced diagnostic options as well as various therapeutic possibilities. The number of care programs that can be installed is not limited.

Since the introduction of cancer programs, the complexity of cancer care has further increased.

Care programs are coherent sets of care services for a well-defined target patient group. Firstly, the program is defined by patient groups treated and the type of care given. Secondly, norms describing infrastructure, number of personnel, minimum activity level, etc., are defined for the care program.
The Royal Decree also stressed the importance of certain additional aspects in the organization of oncological care such as multidisciplinary care and coordination between care in the first line, the care program for basic oncological care, the oncology care program and the palliative setting. In order to get recognition, a hospital must have a multidisciplinary handbook of oncology that includes guidelines with respect to diagnosis, treatment and follow-up of patients, referral agreements and the identity and tasks of all personnel involved. A second tool that must ensure multidisciplinary care is the organization of multidisciplinary oncological consults (MOC) that needs attendance by at least 4 physicians from different disciplines.

The article 27 § h of the Royal Decree (2003) recommends that the multidisciplinary commission has the duty to refer patients with complex or rare tumors to specific care programs as defined in the handbook of oncology.

In February 2005, the National Hospital Council wrote a letter to the Minister of Health and Social Affairs and stated that “reference centers” had several meanings and could be interpreted differently. The Council also formulated several questions which had to be answered before the next steps could be taken.

In 2007, a panel of 11 Belgian oncologists published a White book on the status of several aspects of cancer care in Belgium. These authors formulated innovative recommendations for improvement and anticipation of new challenges, such as the effect of ageing on cancer incidence. This book already recommended to develop and to re-analyse the repartition of the care programs in oncology but also to put in place dedicated programs for rare cancers and pediatric cancers.

After consultation of the field the minister of Public Health and Social affairs launched in March 2008 a first comprehensive National Cancer Plan 2008-2010. The primary objectives of the plan were to reduce cancer-related mortality and morbidity and to improve quality of life of cancer patients and their families through psychological support. The plan focused on three main topics:

- Prevention
- Treatment
- Research and innovative technologies

In the same year (November 7th, 2008) a Royal Decree was published that provided the legal framework for reference centers. The National Hospital Council formulated a first negative advice because too many obstacles were identified to implement the Decree.
The Ministry of Health has repeated its request for advice in 2013. The National Hospital Council published its second advice on this topic in February 2014. This will be discussed in § 5.6 of this document.
On August 8th, 2014, a concrete model for rare diseases was published in a Royal Decree. The content of this publication will be discussed later in this document (§ 5.2).
More than ten years after the implementation of the Royal Decree, the KCE concluded after an extended review that treating patients with a complex or rare cancer in each Belgian hospital is not feasible, nor efficient and ethical anymore. They stated that the quality can only improve if the expertise and the sophisticated infrastructure will be centralized in reference centers.

The College of Oncology reviewed in detail all the existing programs and legal provisions on the national level as well as on the international level, the discussion texts mentioned above and the KCE recommendations. The College of Oncology concludes with recommendations in chapter 7.

3. Rare or complex cancers

3.1 Definition of rare cancer

A rare cancer is defined when the incidence is lower than 6 new cases per 100.000 inhabitants per year (RARECARENet[2]).
A rare cancer is also a cancer difficult to classify under a specific heading.

3.2 Definition of complex cancer

A complex cancer is defined:

- A cancer on a very specific and extremely difficult to reach anatomic location (for instance a brain tumor or an ocular tumor) or otherwise such that the local treatment is difficult and requires specifically trained teams.
- A cancer occurring during a specific condition (for instance a cancer occurring during pregnancy) in as much that the treatment strategy would be drastically different and require special skills
- A cancer requiring a high level of expertise, because of its diagnosis and/or treatment (for instance some soft tissue sarcoma, early stage esophageal cancer because of the frailty of the surgical patient)
- A cancer requiring very high-tech or costly technical infrastructure (for instance HIPEC treatment for tumors of the peritoneum)

3.3 Selected tumor types by KCE

The KCE selected 14 rare or complex cancers which were extensively discussed in multidisciplinary teams and the concrete propositions per tumor type can be consulted in the KCE Report 219As[3].

The selected tumor types were:

- Rare haematological cancers
- Cancers of the central nervous system
- Cancers of the head and neck
- Cancers of the endocrine organs
- Cancers of the endocrine organs/rare thyroid cancers
- Neuroendocrine Tumors (NETS)
- Malignant Pleural Mesothelioma
- Rare cancers of the female genital system

[2] http://www.rarecarenet.eu/rarecarenet/
[3] https://kce.fgov.be/nl/publication/report/organisatie-van-de-zorg-voor-volwassenen-met-een-zeldzame-of-complexe-kanker#.VyDK1PmLRD8

- Cancers occurring during pregnancy
- Cancers of the esophagus
- Cancers of the pancreas
- Rare hepato-biliary cancers
- Cancers of the peritoneum- carcinomatosis
- Cancers of the peritoneum – pseudomyxoma
- Cancers of the peritoneum – peritoneal mesothelioma
- Familial adenomatous polyposis (colorectal cancer)
- Rare malignant skin tumors

4. International Initiatives

Due to their low frequencies, rare cancers are difficult both for clinical decision-making and for the organization of health care. On the one hand, clinical decision-making is hampered by the lack of clinical studies leading to limited available evidence, sometimes of poor quality. On the other hand, the management of rare cancers is more problematic than for common cancers, due to a lack of clinical expertise of oncologists. Also in general, fewer treatments have been developed for rare cancers than for common ones. For these reasons, rare cancers are an important policy concern for public health in Europe. There is an important scope for action at the EU level, both in in sharing the scarce available knowledge and in promoting new research on rare cancers. Several European projects on surveillance, research and organization of care were started recently..

4.1 Initiatives taken by ESMO

The observation that sub-optimal treatment outcomes were relatively common for rare cancers due to a lack of medical expertise in the management of rare cancers, poor referral rates from general practitioners and pathologic misdiagnosis lead the ESMO representatives to elaborate a set of 39 recommendations on stakeholders actions and public policies in order to improve rare cancer care in Europe[1].

4.2 Lessons learned from European Member States

In order to improve the organization of care for patients with rare and complex cancers, several structural and organizational actions have been implemented in several countries.

- **Centers of expertise - reference centers**: Some European Member States have designated centers of expertise for rare cancers, either in the context of a national plan for rare cancers or for rare diseases, either within the context of their current structure of healthcare delivery (e.g. Finland, Norway, Sweden, Germany, Lithuania, Estonia, and Greece). Some countries like France and the United Kingdom have regional centers of expertise for rare cancers covering the national territory, whereas the Netherlands adapted a more centralized approach at the country level. Denmark has two levels of specialized function hospitals: highly specialized functions at the national level and regional function hospitals.

- **Agreement and reference networks:** In France, the management of patients affected by a given group of rare cancers relies on regional or interregional expert centers that together cover the whole national territory and are coordinated at the national level by a single national expert reference center under the supervision of a single coordinating clinician. Each national reference center must set up a network with regional centers of excellence.

In England, the 28 NHS cancer networks bring together the providers of cancer care (organizations that deliver cancer services to patients) and the commissioners of cancer care (organizations that plan, purchase and monitor cancer services) to work together to plan and deliver high quality cancer services for a specific population. In the Netherlands national agreements have been adopted on task allocation, concentration and spread of care with regard to a number of specialties and tumor types, but for many other tumors and complex diagnostic or therapeutic treatments no national agreements have been made. In Denmark the legislation gives the Health and Medicines Authority the right to decide on specialized functions and to approve the installment of functions.

- **Combination of expertise and proximity:** In France, each patient affected by a rare cancer can benefit from the management in the institution of his/her choice, being assured of high quality care from diagnosis to follow-up. This is enabled by the close networks between national reference centers and regional and interregional expert centers. In Denmark, the political environment has agreed that quality and expertise are more important than proximity. Yet, there are up to three Danish hospitals assigned as highly specialized function hospitals even when the yearly case load is less than 50 patients within the country. This is done to ensure a certain level of treatment proximity for the patient and it is also the result of the fact that other criteria than volume, such as complexity of disease and resources, are taken into account when deciding in how many hospitals a certain specialized function should be installed. Hospitals that are not approved to carry out a certain function are actually not allowed to perform these. The NHS cancer Networks in England were also chosen to reflect existing geographical patterns of referral and joint care for cancer patients. They cover populations varying between a half and 3 million people, and roughly following local administrative boundaries. In the Netherlands, the guarantee of expertise is overarching the principle of proximity. The leitmotiv of the Dutch Federation of Cancer Patients Organizations (NFK) is “Kankerzorg dichtbij als het kan, verder weg als het moet”. The most striking example is the concentration of pediatric oncological care in one center (in Utrecht) from 2016 on. To compensate for long distance between home and expert centers, families of (seriously) ill children can stay for a small charge in Ronald McDonald houses, which are situated in the neighborhood or on the premises of certain hospitals.

  Differentiation: In England, the hospitals were assigned through a “top-down” decision approach, one of the three levels of care: (1) primary care, (2) Cancer Units in district general hospitals (designated to deal with referrals from primary care and with the diagnosis, staging, and management of patients with common cancers) and (3) Cancer Centers designated to provide expertise in the management of all cancers, including common cancers and less common cancers by referral from Cancer Units. Also in Denmark, the hospitals were assigned (with regard to cancer care) through a “top-down” approach one of the three levels of care: (1) Main function (not assigned as a specialty function), (2) Regional function (can be assigned to 1-3 hospitals in each of the 5 Danish regions) and (3) Highly specialized function (can be assigned to 1-3 hospitals in

the entire country). Hospitals can receive this designation for a 3-years period. If they do not fulfill the application criteria during the 3-years period, the approval can be withdrawn. In the Netherlands highly specialized clinical care ("topklinische zorg") is concentrated in eight university medical centers (UMCs). These UMCs treat tertiary referral patients ("topreferente patiënten"), i.e. patients with rare and complex pathologies who need highly specialized multidisciplinary care. The aim is to concentrate specialized care, research, education and training at the highest level on a regional level. The less complex parts of care are performed in local shared care centers.

- **Strict criteria for eligibility of reference centers/centers of expertise:** In France, only teaching hospitals authorized for the treatment of cancer (i.e. Centre Hospitalier Universitaire (CHU) and Centre de Lutte contre le cancer (CLCC)) are eligible as national reference centers. The applications to be certified as national reference center are subjected to a double expert assessment, involving international experts. For the regional or interregional expert centers the criteria for selection include multidisciplinarity, activity in relation to rare cancers and involvement in research and publications. In the Netherlands, the SONCOS (Stichting Oncologische Samenwerking, Foundation of Oncological Collaboration) report describes quality standards for 21 cancer treatments in adults, including rare and more common cancers. It is a living document that will be adapted on a yearly basis. In Denmark, candidate hospitals for a specific cancer type follow an application process delivered by the Danish Health and Medicines Authority. They have to prove that they can ensure a care continuum, including surgery, chemo and/or radiation therapy. In England, specialist cancer services are only commissioned if they are already compliant, or if they have demonstrable plans to be compliant within agreed timeframes, with the NICE Improving Outcomes Guidance (IOG). For example, it is expected that providers are fully engaged in the national peer review process, and are working toward full compliance with the necessary specialist cancer standards.

- **Volume Criteria:** In England, a minimum caseload was defined based on the size of the population covered by a network in order to maintain expertise and experience. Volume norms are also described in the GCP guidelines of NICE. In Denmark, volume is only one of three criteria (together with complexity and resource use) used to determine hospital designation. In the Netherlands, volume of surgical interventions is considered a surrogate for high-level processes of care. Consequently, centralization of care is now mandatory for different cancers, whatever their incidence. In addition, volume criteria have also been defined for non-surgical treatments (e.g. melanoma, neuro-endocrine tumors), for specific cancer stage (e.g. metastatic disease) and for non-cancer therapies. Hospitals that do not qualify are not reimbursed.

- **Multidisciplinary treatment planning meetings:** in France, multidisciplinary treatment planning meetings (MDT) are organized at the regional/interregional level as well as at the national level. The regional MDTs represent the first expertise level whereas the national MDT is a second expertise level, to resolve

specific difficulties (e.g. rare cancer cases, patients in whom the cancer progresses). Interactive forums (e.g. web conference) enable European experts to participate in the discussions. In Denmark, multidisciplinary treatment planning meetings have also been implemented as part of the national cancer patient pathways.

- **Clinical guidelines and care pathways:** In France, clinicians involved in centers of expertise actively participate in the development of clinical guidelines for the management of patients with rare cancers. These guidelines are posted on dedicated websites. In 2011, seven rare cancers had been covered by such guidelines. In the Netherlands and England, the comprehensive cancer center (Integraal Kankercentrum Nederland, IKNL) and the National Institute for Health and Care Excellence (NICE) respectively are in charge of the composition of clinical practice guidelines. IKNL looks at the content as well as at the organizational aspects of the care pathway. In the Netherlands, many national multidisciplinary tumor working groups in oncology were installed in order to develop more cohesive plans. In England, Clinical reference Groups are tasked with developing service specifications and policies to ensure compliance with the NICE improving outcomes guidance for rare cancers. All providers are expected to formally adopt, within their own clinical governance processes, the locally agreed pathways, policies and clinical guidelines in the strategic clinical network to which they are affiliated. In addition, providers are required to provide seamless care across organizational boundaries, throughout the whole care pathway. In Denmark, 32 cancer pathways, for common as well as for rare cancer types, have been established by working groups which comprised representatives from all relevant medical societies including general practitioners, oncologists, pathologists and radiologists, together with specialists from the medical fields relevant to the specific cancer, the Danish Multidisciplinary cancer groups (who had a tradition of formulating clinical guidelines), nursing colleges and medical representatives from all five health regions. They cover the full care continuum, starting from a reasonable suspicion of cancer, over diagnosis and treatment up to follow-up. They all describe standard timeframes for the various elements involved in the pathway, in order to avoid unnecessary delays. Each rare cancer patient has a person assigned as a coordinator to ensure a smooth patient centered process. The highly specialized department also takes care of follow-up and control visits.

- **Research:** In France, all national expert centers are involved in fundamental, translational or clinical research on rare cancers, various expert center coordinators are also engaged in international research projects. In parallel, other centers for early phase clinical trials were recognized in order to facilitate access to innovative treatments and their evaluation in early phase clinical trials. Both structures facilitate the inclusion of patients in clinical trials with very short delays, also for patients with very rare cancers. In Denmark research can be carried out on all levels of the health system.

- **Quality improvement and quality control:** In France, apart from databases containing incidence and follow-up data, quality indicators are developed to compare results obtained by the centers of expertise (e.g. rate of surgical re-interventions for R1, delay between diagnosis and discussion in multidisciplinary treatment planning meetings). Also external audits assess the quality of medical data recorded. In the Netherlands a variety of instruments, such as guidelines, visitations and accreditations, outcome registration, case mix adjusted feedback and quality improvement projects is used by the involved parties (i.e. care professionals, professional associations, Comprehensive Cancer Centers (Integraal Kanker Centrum IKC), the Health care inspectorate (Inspectie voor de gezondheidszorg, IGZ), Health insurance companies and patients associations) to improve the quality of cancer care.

- **National anatomopathological reference networks:** In France, the setup of anatomopathological reference networks enabled the double reading of anatomopathological specimens of some rare cancer groups (i.e. soft tissue and visceral sarcomas, malignant pleural mesotheliomas, rare peritoneal tumors, sporadic and hereditary malignant endocrine tumors in adults and lymphomas). The double reading resulted in 11% of cases in an altered treatment plan and for another 7% the diagnosis was adapted.

- **Information for patients:** In the Netherlands and France, several expert centers have set up websites that diffuse up-to-date information to care providers, patients and all other interested. This is realized thanks to the involvement of patients associations. The majority of centers of expertise have a close link with patients associations, who are also actively involved in the development of research protocols (e.g. patient information to obtain informed consent). In Denmark, every patient is assigned a personal coordinator, who ensures a smooth patient centered process. In addition, the e-health platform gives every involved care provider access to every detail of the care pathway, no matter where the care is provided.

- **Patients associations:** Several rare cancer patients associations try to provide a gateway, directing patients to further avenues of specialized care, information and support. In addition, in the Netherlands, the Dutch Cancer Society (Koningin Wilhelmina Fonds voor de Nederlandse Kankerbestrijding) has a website and telephone line for patients who need some help, support or information. On the website "SIB op maat" (SIB stands for "samenstellen informatie over bijwerkingen" – compose information on side effects) health care professionals as well as patients can find information on standard treatment plans, the side effects of oncological treatments and concrete advice. The Dutch Federation of University Medical Centers (NFU) has developed a special website where patients and care providers can identify the appropriate reference center for their pathology.

The experiences of these European Member States also illustrate some limitations:

- In spite of well-designed initiatives to improve the organization of care for patients with rare cancers, the implementation may be inconsistent (e.g. when guidance in service reconfiguration is not properly followed, when established cancer centers turn out to be too small), which may result in perpetuating variations in service quality.
- The high specialization and centralization of care may lead to increased demand (and hence longer waiting lists) for trained site-specialists, although this might be overcome (as in Denmark) by legislation that determines maximum timeframes.
- When quality controls (e.g. audits and accreditations) remain informal and/or confidential, their impact is limited. Failure to meet standards or observe agreements has only minor consequences, when the only ones who are made aware of shortcomings and areas for improvement are the care professionals directly concerned. This is different when one has to give account to the public.
- Early diagnosis and appropriate referral of rarer cancers are a challenge for the primary health care setting, but may be improved with the implementation of pathways that describe clear referral criteria (including pathway for patients with uncharacteristic symptoms).
- Single institution monopoly on specific care programs with lack of competitive peer pressure could lead to loss of quality in the longer run. It would be good to have always at least two alternatives.

5. Belgian cancer care

Since 2003, Belgium has implemented several oncology care programs in order to improve the quality of care for cancer patients. After 10 years of implementation the College of Oncology and the KCE decided to evaluate these current programs.

5.1 Evaluation of the existing oncology care programs

5.1.1. Care programs for basic oncological care/oncology care programs

In 2013, 106 hospitals were registered with a care program for basic oncological care and/or an oncology care program; 87 hospital sites with programs for basic oncological care and 84 hospital sites with an oncological care program.
A survey was conducted by the College of Oncology in 2013, 10 years after the implementation of the Royal Decree.
The College of Oncology asked 143 hospitals to answer several questions on the care programs. 95 hospitals answered the questionnaire and the results of the research are well described in the thesis of Annelies Van Steirtegem, 2013.

- Legal standards of the medical framework are not always respected;
- Some disciplines are not represented within the care programs;
- Standards/norms on sensitization are not taken into account (risk/danger of treatments);
- There is a heterogeneity of implementation on quality standards/norms;
- There are differences in the implementation of standards between care programs for basic oncology care and oncology care programs as well as differences between the Flemish and the French-speaking hospitals;
- There is a lack of control on the organization of oncological care programs.

5.1.2. Research done by the KCE on MOCs (October 2014)

In Belgium, MOCs have been reimbursed since 2003 for all cancer types. It was one of the first examples of the reimbursement of shared intellectual activity involving different specialties. Today there is a consensus that MOCs have improved the quality of care by strengthening the communication between the different health professionals, and that this practice should be facilitated as much as possible. At present, however, little is known about the variability between hospitals in the organization of the MOCs, to which extent new cancer patients are effectively discussed, and to which extent these discussions are really efficient, specific and patient-centered.

One year after the introduction of the reimbursement, only 50% of newly diagnosed cancer patients were discussed during a formal MOC and increased to 79% in 2010 (76% Brussels, 81% in Flanders and 74% in Wallonia). The implementation of the MOC still has some gaps to tackle:

- Some patients die very soon after the confirmation of the diagnosis and were never discussed;

- MOCs are not mandatory for every new cancer case but only in some very specific situations that are precisely described in the Royal Decree;
- For those patients who do not fall within these legal criteria, no guidelines exist stipulating which patients have to be referred to MOCs;
- Rare cancers are significantly less frequently discussed during MOC meetings;
- Some patients are less frequently discussed for other (debatable) reasons (e.g. elderly patients).

One of the legal responsibilities of the coordinator of the oncological care program is the transfer of cancer cases to the Belgian Cancer Registry. In 2011, 86% of the cancer cases were recorded at the BCR. Hence, there is room for improvement. One way of improvement would be to make a MOC obligatory for each cancer patient and linking reimbursement of care to this MOC (College of Oncology).

To obtain a more holistic picture of the patient, MOC meetings should theoretically be composed of medical, paramedical and psycho-social staff and have sufficient administrative support. The report concluded that the attendance of a data manager and nurses was only mentioned by 55-65% of the respondents. Only 12% of the respondents reported regular presence of a GP in the MOCs. Several reasons can explain the low attendance rate, e.g. the timing of the invitation, the timing of the MOC during the day and the travel time. A videoconference can be a solution, although efforts in that direction have not been very successful.

The report described several issues related to the MOC reimbursement where there is still room for improvement:

- The high administrative burden;
- Legislation on follow-up MOC subject to interpretation leading to highly variable practices;
- Second opinion MOCs are rarely reimbursed.

5.1.3. Stakeholders feedback

In this paragraph we will only summarize the feedback from the stakeholders on the existing programs during the KCE research (2013 - published in March 2014):

- Laboratories: The actual network of pathology laboratories is fragmented and there are too many low-volume laboratories. As a result, there is a lot of heterogeneity in materials used by laboratories and in the additional tests performed, which leads to varying levels of quality.
- Transparency: Patients, GPs and relatives often do not know where to find sufficient expertise when diagnosed with a rare and/or complex cancer.
- Regulations: at this moment there are no regulations for healthcare providers at which phase or in which situation they have to refer patients to someone who has more expertise. Patients can only thrust that they are taken care of by an experienced professional (team), but they have no means to check that.

5.2 Concrete Model for rare diseases

A concrete model for rare diseases was recently published in the Royal Decree (August 8th, 2014) and can be used as an example for the rare/complex cancer model although a lot of similarities are seen with the published Royal Decrees on cancer care (2003).

Art 1: Life-threatening or chronic debilitating diseases with a prevalence of less than 5/10.000 inhabitants
Art 2: The network "rare disease" proposes at least one care program (center of expertise) where patients can be treated and followed.
Art 3: The network "rare disease" includes a team of caregivers from:

- general hospitals without the recognition "rare diseases"
- hospitals with the recognition "rare diseases"
- hospitals with the center of expertise on rare disease
- centers for human genetics

Art 4: They have to assign a coordinator
Art 5: European and international networks
Art 6:

- The network committee has representatives from the departments discussed in art. 3 and a representative from the patient associations.
- The network committee has the following tasks:
    - take care on the agreements
    - define modalities on process controls and quality monitoring
    - define the meetings on the care programs
    - define the meetings with the caregivers who are not part of the network
    - multidisciplinary quality handbook
    - organize meetings with other networks "rare diseases"
    - sensitization campaigns towards the public
- The network committee has to come together 1x year to realize the projects

5.3 Future concrete Models proposed in the KCE Report

The KCE report 219 describes three different models

- Model 1: Reference Centers exclusively (from diagnosis to follow-up). One a patient is suspected of the cancer, he/she should be referred to a Reference Center. A network with other Reference centers or with specific expert working in other centers is encouraged.

- Model 2: Shared care between Reference centers and local hospitals. For example, the first contact is taken with a Reference center (diagnostic step and MOC), and then the patient can be referred back to the referring hospital (for treatment, palliative care, follow- up).

- Model 3: An alternative model that needs to be developed

5.4 Future recommendations proposed by KCE

To improve the quality of care and to decrease the dispersion of expertise and experience, Reference Centers with multidisciplinary teams of recognized clinical and technical expertise in specific rare/complex cancers should be established and certified.

The formation of networks or functional relationships between Reference Centers and Peripheral Centers (shared care models) will allow a delivery of care combining expertise and proximity.

In Peripheral Centers, only less complex well-described parts of the diagnosis and treatment can take place, and they should be performed under supervision of the Reference Center. A Peripheral Center should get guidelines about when they have to confer with a Reference Center about a rare/complex cancer patient.

The most fundamental benefit patients can expect from shared care networks organized around Reference Centers is a better chance of survival, lower relapse rates and lower complication rates.

5.4.1. Reference Centers: Recommendations by KCE

- To become recognized as Reference Center, hospitals should meet strict criteria in addition to those specified in the oncology care program legislation. These criteria should ensure that recognized Reference Centers truly apply a multidisciplinary approach and have sufficient expertise in the rare cancers they are recognized for.

- Reference Centers need more specifically skilled medical and paramedical staffing than required by the programs in oncology. In addition, they should be equipped in function of the rare/complex cancer they are certified for.

- Specialized multidisciplinary oncological consults (MOC) should ensure optimal management of patients with rare/complex cancers. The panel should involve medical and paramedical experts with a specific expertise in the management of patients with the cancer in question (diagnostic and therapeutic strategies, supportive care). The composition of the panel of experts will vary according to the cancer types discussed and the phase in the disease.

- Reference Centers have to ensure that care is based on the patients' needs and values. In order to guarantee that patients are actively involved in the clinical pathway they are offered, a liaison coordinator should be appointed.

- In order to halt the dispersion of care and to increase concentration of resources and expertise in rare and complex cancer care, it is recommended to impose minimum caseloads for Reference Centers and medical specialists. These norms

should be based on Belgian incidence data and international guidelines and should allow for a run-in period. Within a reasonable time frame it should be realized that every patient with a suspicion of rare/complex cancer is referred to a Reference Center in the early diagnostic phase.

- Reference Centers should only be certified if they meet specific requirements regarding expertise, experience and infrastructure. The quality of care provided in Reference Centers should be evaluated on a regular basis, so that "static and lifelong" certification of centers can be avoided.

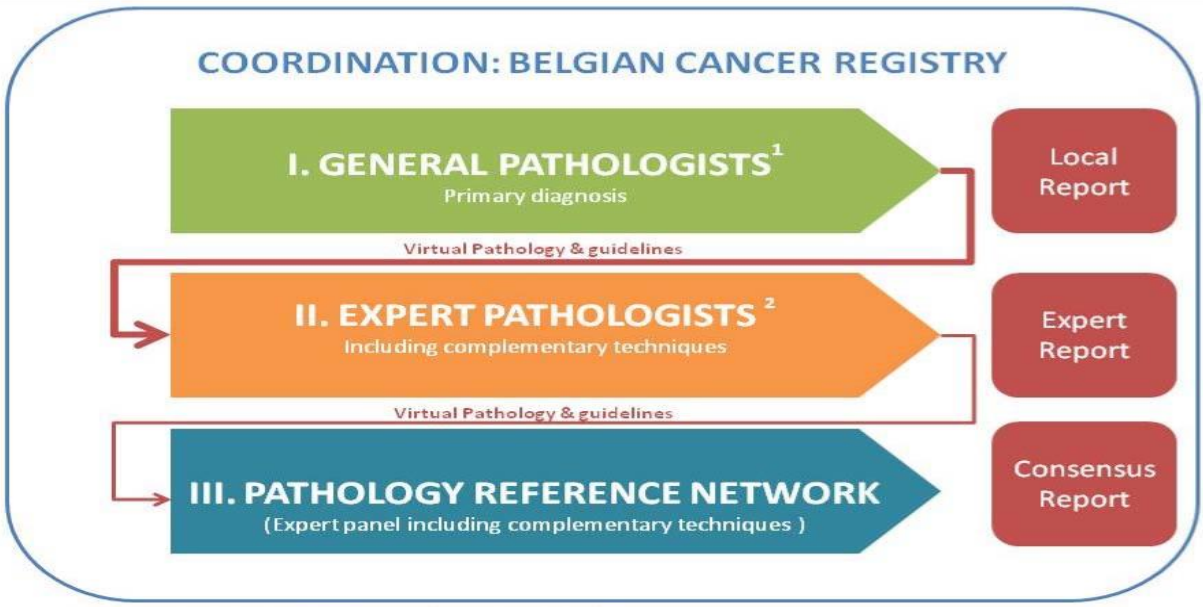
- Reference Centers should be actively involved in clinical research to stay on the cutting edge of their field. In order to disseminate their medical expertise, they should also be implicated in continued education of health care professionals.

- Healthcare professionals from Belgian Reference Centers should collaborate actively with colleagues from international Reference Centers. In case of (ultra)-rare cancers and highly complex procedures for which there is insufficient expertise in Belgium referral partnership should be set up.

- The formation of networks or functional relationships between Reference Centers and Peripheral Centers that allow a delivery of care combining expertise and proximity (shared care model) is highly recommended. Service Level Agreements (SLA) between the physicians and centers involved have to address patient referral/back referral and patient follow-up. To facilitate the transition of patients between Reference and Peripheral Centers, a liaison coordinator has to be appointed. Each patient with a rare/complex cancer should be discussed during a multidisciplinary meeting in the Reference Center, as first intent or as second opinion before any therapeutic intervention. Also in cases of relapse or recurrence, the patient should be discussed again during a multidisciplinary meeting in the Reference Center.

- The networks and functional relationships between Reference Centers and Peripheral Centers should ensure continuity and coherence in the follow-up and rehabilitation of the patient after the specialized treatment.

- A three-step model of diagnostic confirmation of pathology findings is recommended for rare cancers.



5.5 Stakeholders opinions, suggestions and concerns

Several stakeholders were invited and provided feedback toward the KCE. The KCE team collected the feedback and summarized these in the KCE report 219.

The following paragraph will summarize the questions and the answers.

5.1.4. Is there an agreement on the organization of care around reference centers for rare and/or complex cancer?

Results: The majority of stakeholders expressed the absolute necessity to centralize expertise for rare and/or complex cancers in a small number of hospitals.

Proponents of the new organization model around reference centers are mainly found among patient's organizations, representatives of university hospitals, sick funds, RIZIV/INAMI and the scientific association "Fund Rare Diseases and Orphan Drugs".

Opponents are mainly found among representatives of non-university hospitals. Some of the opponents are actually in favor of the identification of reference centers for rare cancers although they fear that the centralization idea will be extended to all cancers requiring complex treatments. They also admit the added value of a multidisciplinary management of rare cancer patients in reference centers that can guarantee the expertise and required facilities, although they insist that also non-university hospitals will be eligible to become recognized as reference centers.

Legislation and regulation stakeholders (FOD/SPF, Cancer Center, and Representative of the Minister) expressed no official opinion on this topic.

5.1.5. Why opting for reference centers for rare and/or complex cancers? What are the opportunities of this organization of care?

Pro Argument:

- The improved quality of care if care for patients with rare and/or complex cancers will be organized in centers with multidisciplinary expertise.
- Will lead to better diagnosis, as every reference center should have a close collaboration with a reference laboratory in pathology.
- The confirmed diagnosis should be approved by a team of two or more (expert) pathologists, all taking responsibility for the final conclusion in the pathology report. This is essential for the correct diagnosis of rare cancers and should be used as starting point for the referral of patients to expert centers.
- Patients will be offered a better quality of care in reference centers as the multidisciplinary team has expertise and can build up routine.
- Patients seen in reference centers will have better access to complex and new targeted therapies and they will benefit from adequate surveillance of (adverse) treatment effects.
- Patients in reference centers will have a better outcome at the end.
- Transparency: The identification of reference centers would lead to improved transparency of the location of high level care for patients and their caregivers. (Information available on websites, flyers,…).
- Improved efficiency of the healthcare system, avoiding dilution of complex expertise and costly infrastructure (by concentrating human and technical resources and expertise, an optimal allocation of resources for a limited number of patients).

5.1.6. Why not opting for reference centers for rare and complex cancers? What are the threats of this organization of care?

Cons:

- Travel distances for patients and relatives become longer will also imply higher costs for care (reimbursement of travel costs and the provision of accommodation for close relatives should be considered). A Survey of the Belgian patient organization and the medical specialists agree that quality of care is much more important than proximity.
- Increased waiting times.
- Potential loss of financial revenues. A fee-for-service payment for most medical acts, does not encourage referral of patients. Referring patients to more specialized physicians in reference centers, implies a loss of financial resources, for themselves, but also for related services in the hospital.
- A fear for decreased ability to care for patients with rare conditions if specialists working in non-reference centers have to focus mainly on common situations.

5.1.7. How to organize the network between reference centers and peripheral centers? (and how to adapt clinical pathways?)

All stakeholders in favor of the organizational model recommend the formation of networks between reference centers and peripheral centers.

- Reference center: responsible for diagnostic confirmation, the elaboration of the treatment plan and the complex parts of the treatment;
- Peripheral center: responsible for the implementation of certain parts of the treatment plan;
- A care coordinator has to be assigned to the process between both centers. Onco-coaches (financed by the Cancer Plan) can accomplish this mission; this person will also facilitate the logistics of the referral;
- Number of reference centers is based on the yearly incidence;
- European or international reference centers will be contacted if Belgium has insufficient treatment modalities experiences for certain pathologies.

5.1.7.1. The importance of identifying qualified medical staff

In order to avoid that patients with rare cancers are being diagnosed and/or treated by a medical staff that does not have sufficient skills and/or experience, it is suggested to add "addenda" to the specialists. (RIZIV/INAMI registration number which identifies extra training and expertise in certain sub specialties).

The reimbursement of certain procedures could be made conditional on the fact that they are performed by qualified specialists.

5.1.7.2. The importance of the multidisciplinary approach

With regard to the registry of the MOC some stakeholders suggest to add specific items related to rare tumors to the questionnaire sent to the BCR (e.g. second reading of slides).

A larger (suggested by law) panel of specialists, involved in the diagnosis and the treatment of rare cancer patients, should join the MOC discussions.

In addition to the MOCs, it is also recommended to install super MOCs, allowing experts from several reference centers to discuss more difficult cases.

5.1.8. What are the main obstacles for an organization of care around reference centers?

- The correct diagnosis : mainly based on pathological analysis of a tissue sample.
- Implementation of new clinical pathways (to describe and define per cancer type at what stage of the clinical pathway referral can be best performed).
- Advances in molecular biology.
- Linguistic and ideological/philosophical differences between centers.

- No standard electronic patient filing system (IT systems for data sharing across the country will be essential).
- Timelines for advice.

5.1.9. How to evaluate the quality of care?

Quality surveillance:

- Audits are essential to improve the quality of care and should be performed by independent (auditing) specialists.
- The college of Oncology judge and can be judged, it is difficult for them to evaluate the quality of care delivered by themselves and by their colleagues. Otherwise, the college can be an organ of advice based on their daily practice experience.
- Quality indicators need to be set (exist already for breast, testis, oesophagus, stomach, rectum).
- Reference centers need to be evaluated on a regular basis.
- Reference centers should have the obligation to register their patient volumes, their processes and outcomes within strict timelines. (They can lose their recognition if they don't fulfill this rule).

5.1.10. How to proceed next? What would be the legal basis to recognize reference centers?

The Royal Decree of March 2003 stipulates that a number of specialized care programs have to be developed that focus on patients with cancers and they need a complex multidisciplinary approach and/or extremely specialized expertise and/or that are very rare. A separate care program for the organization of pediatric cancer was published in August 2014.

Several stakeholders emphasize that this Royal Decree is a good starting point for an improvement in the organization of cancer care in Belgium. They suggest adding specific norms to the current norms of this Royal Decree, with specific focus on the management of patients with rare cancers and cancers requiring complex care. However, the sixth phase of the federal reform will transfer the authority of setting norms entirely to the communities. Therefore, the recognition by means of a convention with RIZIV/INAMI may be more pragmatic manner to recognize reference centers in the near future. In this way, uniform norms can be adopted for Belgium as a whole. A number of stakeholders recommend limiting the reimbursement of diagnosis and rare cancer treatment to reference centers, which is actually already the case for a limited number of treatments. If conventions are installed with NIHDI (RIZIV/INAMI), the candidate Reference Centers should reflect in advance whether this will be financially sustainable as conventions only pay on a fee-per-patient basis. Hence, if a center does not obtain the number of patients described in the threshold, there is no payment at all for any of the patients seen in the center. Also, it has to be realized that conventions often have a temporary perspective whereas arrangements described in a Royal Decree are long-lasting.

5.1.11. How to proceed next? On which basis should reference centers be identified?

- Hospitals should not be recognized or certified as reference centers for all rare/complex cancers.
- There is a need to define a set of norms (evidence-based).
- Include quantitative criteria e.g. patient volume, volume of surgical interventions, number of MOCs, number of referral MOCs, diagnostic confirmation (double reading of slices in pathology, or other diagnostic and staging tests), dedicated medical and paramedical staff, particular attention to patients information.
- Another option is recognition based on demonstrated results (better outcomes, better quality of care) rather than norms.
- One sickness fund proposed to start from those centers which have already built a certain know-how and expertise, and then fully evaluate in the coming years those recognized centers based on criteria mentioned above.

5.1.12. How to proceed next? Who are the main actors for a change?

All stakeholders have a role to play if a new organization of care for patients with rare and complex cancers has to be installed:

- Regulators: identification of instruments able to introduce a change (regulation, accreditation, financing);
- Healthcare practitioners and medical associations can play a major role in identifying specific criteria to be fulfilled by reference centers;
- Financing bodies (sick funds and private insurance companies);
- Patient associations;
- Scientific institutions.

The KCE concluded that all the ideas described above, should fit in a comprehensive change in the organization of care for patients with rare cancers. It is expressed by several stakeholders that if only some aspects are taken care of, the impact of change may be very limited. If changes are made, they should be seen as vital links in a chain of change.

5.6 Advice National Hospital Council (February 13th, 2014)

After the publication of the Royal Decree in 2007, the National Hospital Council gave a negative advice because too many obstacles were identified to implement the article. The ministry of Health repeated its request for advice in 2013.

The National Hospital Council (NHC) recently published their second advice on this topic and advices that we have to distinguish between rare tumors and tumors which need a complex treatment.

1. Rare tumors

The NHC concludes that specific regulations on reference centers or reference networks for rare tumors are recommended. This implementation leads to a better diagnosis, a more efficient care. These centers will be asked to demonstrate in a transparent way their best results. Every regulation must be supported with a consensus from a team of care givers working in the domain of prevention, diagnosis, therapy and research. There must be clear guidelines on the identification of experts, the concentration of the expertise, the networks between experts and the referrals.
Reference centers can be implemented relatively quickly. The MOC must be adapted and supported in order to discuss each cancer patients. The selection of reference centers must be done in an objective way and international experts must be assigned.

2. Complex tumors

Complex tumors can be treated in well organized and structured hospitals with a dedicated team a good registration and quality control.

In General:

- Registration

The NHC asks all care givers to inform the cancer registry with the following information: clinical parameters, structural indicators, results indicators for all cancer patients. The College of Oncology and Radiotherapy must be clear on which data must be registered and the experts must propose general and specific indicators. All these data will be centralized in the cancer registry. The data will be monitored, validated, analyzed and communicated on a regular basis.

- Quality and care givers

The quality system must set clear objectives. The caregivers must define clear guidelines on diagnosis, treatment and follow up. The Colleges of Oncology and Radiotherapy will evaluate the quality of care based on these results and will support the collaboration and discuss room for improvement. The authorities must support the collaboration between the different colleges. They also will give incentives as well as penalties in order to optimize the quality.

- Communication

There is a need for electronic patient file. The modern telecommunication can improve the collaboration between hospitals, physicians and generalists. This must be a high priority.

- Finance

The government must pay attention on an efficient financing of structures, resources and physicians who will improve the quality of care.

6. SWOT matrix

6.1 *Current organization*

The KCE published the SWOT analysis of the existing program in the KCE report 219.

Strengths

Legal framework

- Existing care programs in oncology (basic/advanced/children);
- Existing reference centers for rare diseases;
- Concept of reference centers foreseen by/described in the Hospital act;
- The European directive on patient's rights in cross-border healthcare (2011/24/EU) asks each Member State to designate Reference Centers, especially for rare diseases, in the context of the European Reference Networks.

Diagnosis, treatment and follow-up

- MOC: healthcare providers have an increased awareness of the importance of a multidisciplinary approach; additional reimbursement codes for specific situations (new case, new event, altered therapeutic strategy and yearly follow-up);Second opinion/peer-review: two successful pilot projects in Belgium in sharing data for peer-review (pathology revision in rectum cancer and review of target volumes for radiotherapy).

Quality of care evaluation

- Ongoing accreditation process in many hospitals, but on a voluntary basis and without (financial) incentives;
- Cancer registry (data and expertise);
- Ongoing development of quality indicators in oncology.

Patient centeredness

- Good and rapid access to care (everywhere).

Weaknesses

Legal framework

- No evaluation yet of the programs of care in oncology (no minimal criteria, self-declared expertise) and hence no consequences if care is suboptimal;
- Previous negative advise from the National Hospital Council regarding centers of reference (year 2005);
- No legal rule to prevent specialists and hospitals from delivering treatment to every patient with (rare) cancer (even if they lack expertise);
- No criteria and control institution for current programs.

Diagnosis, treatment and follow-up

- Dispersion of expertise in diagnosis and treatment;
- MOC: high variability in frequency, types of cases discussed, involvement of specialists, time devoted to MOC;
- Heterogeneity in expertise of pathology laboratories;

- Rare use of second opinion/peer-review in pathology (no digital equipment, reluctance of profession, cost involved, fear of peer-review, no reimbursement);
- Few clinical practice guidelines to support practice.

Quality of care evaluation

- Legal mission of the College of Oncology, but not fulfilled so far (judge and being judged);
- No systematic quality monitoring;
- No impact of positive/negative evaluation (incentives/disincentives);
- Convergence of actions taken by different organizations/institutions.

Patient centeredness

- No information/identification of reference centers;
- No systematic referral mechanism.

Opportunities

Legal framework

- The Royal Decree of March 21st, 2003 foresees specific royal decrees for rare/complex cancers (no concrete realization so far);
- By order of the Minister of Health renewed consultation of the members of the National Hospital Council (NRZV/CNEH) with regard to the installation of reference center.

Diagnosis, treatment and follow-up

- Improvement in quality of care;
- Confirmation of diagnosis (second opinions);
- Increasing financing of MOC (first consultation, follow-up, supplementary MOC);
- To make a MOC obligatory for each cancer patient linking reimbursement of care to this MOC;
- Development and interest in e-health technologies;
- Improved efficiency of the healthcare system.

Quality of care evaluation

- Performed by independent experts/authorities, preferably not involved in the delivery of care (e.g. Cancer Center, Cancer Registry);

Patient centeredness

- More transparency of the healthcare system: better information to patients. GPs and external specialists (Orphanet, patients associations websites).

Threats

Legal framework

- It takes a long time to publish a Royal Decree on reference centers in pediatric haemato-oncology;
- Care programs and the recognition of centers will be transferred to the regions/communities in the 6th phase of the reform of the state. This may also delay the legislative work.

Diagnosis, treatment and follow-up

- Dreaded loss of income for health providers who refer their patients;
- Extra costs related to double reading (e.g. time, additional analyses);
- Need for new clinical pathways (who refers? when and to whom?).

Quality of care evaluation

- Reference centers ready to take extra workload.

Patient centeredness

- Decreased accessibility of care: higher travel costs for patient and relatives.

7. Advice of the College of Oncology

In several meetings, the College of Oncology discussed in depth the analysis described in the previous sections. In general, the oncologic care in Belgium is at a high quality level. A framework of oncology organization exists, a cancer register is in place and a constantly evaluated cancer plan supports the quality. This results in an overall good outcome (top 10) for most of the tumors when compared to other countries at a European level.

The model of oncology care programs (2003) was an excellent initiative, but not all goals have been reached. Especially, the interaction between care programs is still missing in certain regions. Second opinions between centers and inter-institutional expert consultation are not yet routine, rather the exception.

Over the years, several publications focused on volume/outcome for certain tumors. It's clear that volume plays a role, and an **experienced multidisciplinary approach, networks and specialized dedicated teams** are the most important tools to improve quality of care. Implementation of such dedicated teams requires a government supported and sponsored plan.

The model that is proposed in this section is based on **patient-oriented care** within a network of experienced cancer workers.

Networks of expertise can be organized in several ways, but based on the Belgium context an organized network with a central role of an Academic center as coordinator is the most acceptable, preferentially geographically the most proximal if quality is ensured. Universities are already today the main seat for research and innovation. The university centers should then, in the second tier with peer decisions, decide for which specific indications a further centralization (at National or European level) is warranted .

The access of patients to the best expertise and the comfort of patients by maximizing treatment in the proximity, if possible, are important, even more so in patients with advanced cancer.

A key point in an adequate functioning of the network is **quality**. All members of the network can perform certain predefined parts of the care if they meet the quality standards identified at the level of the College of Oncology with support of the KCE and the Cancer Registry. Examples of quality indicators are stage-specific survival, the discussion rate at
MOCs, the availability of data on morbidity and mortality per network, the involvement in clinical trials, the link with tumor banking, the volume, the 24/7 coverage of patients by experts,… Moreover, organized quality evaluation within the network forms the base of a high performant network.

One of the major tasks of the coordinator (academic center) of the network is to **define the expertise for all tumor types within the network**. The coordinator (Academic

center), in consultation with the members, define the expertise for all tumor types within a given network. This may include partial relocation of specific experts which may require a harmonization of social statutes or other topical government initiatives to promote this (stimulating or coercive). A major obstacle in the organization of cancer care nowadays is for instance the difference in the incomes of specialists working at the reference center and their peers in the peripheral centers.

Networks also need a coordination support to monitor patient flows within the network. The patient flow can exceed the regional network if expertise of another network is necessary. One coordinator per network seems to be the minimum.

Multidisciplinary team meetings are already very important to guide cancer care and are mostly organized locally. **Super MOCs** between the partners and experts of the network need to be created which allows certain predefined (complex) cases to be discussed. SuperMOC's also advice on the location of the different parts of the treatment, locally or more centrally. Academic centers should further mutually coordinate agreements on the further centralization of the care of selected cancer types.

Intensive interaction between centers in the framework of a regional/academic network can only work if new specific political measures are taken including administrative and financial incentives for collaboration.

Experience with rare and complex cancers could in the future also be inspirational for the management of more common cancers. The proposed organizational adaptations will also benefit clinical and translational research and thus foster the international position of Belgian Oncology.

In Conclusion:

Creation of oncologic care networks with, if quality is ensured, preferentially regional academic center anchoring, based on:

- Identification and Implementation of network Quality Indicators (collaboration with Cancer Center);
- Intra- and internetwork collaboration and communication;
- Reorganization of experience within the networks;
- Quality control within the network;
- MOCs and Network MOCs (Super MOCs) with possibility of Tele MOC;
- Revision of oncology care financing with specific incentives for enhanced collaboration.

Annex: list of abbreviations

BCR: Belgian Cancer Registry (www.kankerregister.org)

CHU: Centre Hospitalier Universitaire (Fr)

CLCC : Centre de Lutte Contre le Cancer (www.unicancer.fr)

ESMO: European Society of Medical Oncology (www.esmo.org)

FOD/SPF : Federale Overheidsdienst / Service Public Fédéral (www.health.belgium.be)

GP: general practitioner

HIPEC: hyperthermic intraperitoneal chemotherapy

IGZ: Inspectie voor de Gezondheidszorg

IKC: Integraal Kanker Centrum

IKNL: Integraal Kankercentrum Nederland (www.iknl.nl)

KCE: Federaal Kenniscentrum van de Gezondheidszorg (https://kce.fgov.be/nl)

MOC: multidisciplinary oncological consults

NETS: Neuroendocrine Tumors

NFK: Nederlandse Federatie voor Kankerpatiënten (www.kanker.nl)

NFU: Nederlandse federatie van universitair medische centra (www.nfu.nl)

NHC: National Hospital Council

NHS: National Health Service

NICE: National Institute for Health and Care Excellence (www.nice.org.uk)

NIHDI: National Institute for Health and Disability Insurance

RARECARENet: Information Network on Rare Cancers (www.rarecarenet.eu)

RIZIV/INAMI: Rijksinstituut voor ziekte- en invaliditeitsverzekering / Institut national d' assurance maladie-invalidité (www.riziv.fgov.be)

SIB: samenstellen informatie over bijwerkingen

SONCOS: Stichting Oncologische Samenwerking (www.soncos.org)

SWOT: Strengths, Weaknesses, Opportunities, Threats