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## Executive summary

Health Council of the Netherlands. Searchlight on radiotherapy. A vision for 2015. The Hague: Health Council of the Netherlands, 2008; publication no. 2008/27

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### Burden of disease through cancer

Cancer, after cardiovascular disease, constitutes the second most important cause of death in the Dutch population with over 30 percent of all deaths (40 000 cases per year in 2005). Every year approximately 75 000 people are diagnosed with a *de novo* case of cancer (incidence), the frequency being almost equal in men and women. Moreover, around 400 000 people every year are affected in some way by the disease (prevalence), either by being diagnosed, getting treated, declared cured, or being alive with the disease. It is estimated on the basis of both epidemiological and demographic trends, that this incidence will continue to rise in the coming years, reaching around 95 000 new cases per year in 2015, and with almost 700 000 people having their health affected in some way by cancer.

### The role of radiotherapy

The treatment of patients with cancer usually includes surgical intervention, chemotherapy, or radiotherapy. A combination of these three modalities is often applied. Radiotherapy is an important treatment option and may be intended for both cure or palliation; in the latter case the priority lies with preserving and enhancing the quality of the remaining life span. On the basis of international comparative research one may conclude that about half of all new cancer patients will qualify for radiation therapy, as both primary or secondary treatment, and

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often in combination with other treatment modalities. In recent years data from the Dutch National Cancer Registry indeed show that in the Netherlands some 45 to 47% of the patients will get radiotherapy at some stage of their disease. For the main indications (tumors of the breast, lung, prostate, and rectum), the proportion of patients that will undergo radiotherapy is even higher (50 to 80%), but for other indications too (such as cancers of stomach, bladder, pancreas and CNS) the application of radiotherapy is on the rise.

### Planning the capacity for radiotherapy

Since many years the aim in the Netherlands has been to make the capacity for radiation treatment correspond as best as possible with the estimated growth of the number of new cancer cases in the population. Both epidemiological trends (changes in the incidence) as well as demographic trends (aging of the population) are taken into account. Data from the National Cancer Registry form the basis for this extrapolation. In this way the expected number of new radiation patients, as well as the total number of radiation treatments can be calculated. This in turn becomes the input for calculating the numbers of linear accelerators and radiation bunkers needed, as well as the number of physicians, physicists and support staff. In the past 20 years it has been shown that this planning model achieves reliable outcomes on which to base the planning of radiotherapy infrastructure.

### License to practice radiotherapy (certificate of need)

In the Netherlands hospitals that want to practice radiotherapy should obtain a license from the minister of health. The law on specialized medical interventions (WBMV) sums up the criteria (such as volume, minimum quality requirements, and catchment area needed) that centers must comply with to qualify for this license. The minister of health will review his decision to admit new centers against the background of a specific planning vision document (Planningsbesluit) that gives recommendations for the desired degree of concentration and accessibility of new centers needed. At present there are 21 fully operational radiotherapy centers in the Netherlands. According to the Health Council expert committee, this number ensures adequate accessibility for practically all patients today. However, the current planning vision document (that expired in 2005) badly needs updating: its planning horizon should be extended to the year 2015.

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## Present state of radiotherapy in the Netherlands

Today, the facilities for radiotherapy (number of centers, linear accelerators and staff) in the Netherlands are just sufficient to enable treatment of the actual number of patients. Moreover, the accessibility of the centers is good (>90% of patients are able to reach a nearby center within one hour), and waiting times are relatively short. Before this favorable situation could be achieved, however, a problematic backlog in the capacity and waiting lists for radiotherapy had developed at the end of the nineties, and had to be dealt with. An accelerated policy procedure was put in motion to make up for the arrears and bring the capacity for radiation treatment to the desired level (between 2000 – 2010). This step-up operation could be achieved only with the close cooperation of all parties involved, and by giving top-priority to the realization of new radiation facilities. According to the Health Council expert committee the lesson to be learned from this history is that the planning for expanding the radiotherapy capacity needed in the coming years (at least till 2015) should start timely, and that plans should be carried into effect without delay.

### What is needed for 2015?

The professional organization of radiotherapists/oncologists in the Netherlands (NVRO) has recently published new estimates for the future need of radiotherapy facilities (by 2015): actual and future epidemiological and demographic trends, as well as ongoing scientific developments have been taken into account. These estimates show that an increase of about 50% (as compared to 2005) in the capacity of radiotherapy infrastructure (number of linear accelerators, medical and technical staff) is needed in order to be able to satisfy the expected demand for radiotherapy. This means that the number of radiation treatments is expected to grow from 60 000 in 2005 to around 79 000 in 2015, which requires linear accelerator capacity to grow from 100 units in 2005 to 158 units in 2015, accompanied by the necessary increase of medical, technical and supporting staff. In addition, a shift towards more labor-intensive and complex treatments is expected, which in turn requires an increase in multidisciplinary consultation, resulting in extra workload for the radiation oncologists and physicists involved. The Health Council expert committee subscribes to these viewpoints laid down in the calculations and recommendations that underpin the new estimates published by the NVRO.

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## New developments in radiotherapy

Scientific and technological developments continue to contribute to the quality and effectiveness of radiotherapy. Primary goals in this respect are: to strive for as precise as possible radiation of the target volume (tumor tissue) in order to achieve local tumor control, while at the same time keeping the radiation dose as low as possible to spare surrounding healthy tissue and vulnerable organs and structures. Much attention is given to efforts to avoid and limit any radiation-induced complications in the short and long run. The aim here is to minimize the compromising effects of radiation on the quality of life. These strategies require the use of novel imaging technologies (e.g. CT, PET, MRI), combined with advanced radiation modalities, such as: intensity-modulated radiotherapy (IMRT), image-guided radiotherapy (IGRT), stereotactic radiation and proton-beam radiation. A general observation is that these new developments may result in a significant increase of treatment quality, but that they also lead to heavier demands on both personnel and equipment, and to possible cost increases. Routine application of effective new techniques however may lag behind if the capacity for radiotherapy is under strain for longer periods of time.

## Quality criteria for radiotherapy centers

In the past decades the Netherlands have seen positive developments in the field of radiotherapy: this treatment has become an integral part of a multidisciplinary approach to cancer and forms an important link in the chain of patient care (through close cooperation with regional cancer care organizations). Another trend that results from this is a growing sub-specialization in the fields of oncology and radiotherapy; this development requires a sufficient yearly patient volume to be seen and treated in order to build and maintain the necessary special expertise. Research has shown that there is a direct association between the volume of patients treated and the expertise of the individual physician and the center as a whole; this correlates strongly with the quality and outcome of the care provided. The efforts in the Netherlands to ensure an adequate patient volume have resulted in the establishment and development of relatively large-size radiotherapy centers, that form part of or collaborate with hospitals that feature extensive oncology facilities.

Practically all Dutch radiotherapy centers meet the recommended criteria for minimum volume of a radiotherapy department (following nationally and internationally accepted standards), namely: at least four linear accelerators and a

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staff consisting of at least eight FTE doctors and three FTE physicists. This provides the means to treat a yearly volume of at least 2700 cancer patients. Each center should have a catchment area of about 500 000 population to achieve this. Around one-third of the present 21 centers in the Netherlands today has a capacity of six or more linear accelerators. International comparison shows that the Netherlands are in a favorable position with respect to the infrastructure and capacity of its radiotherapy centers, and also that a number of countries have recently initiated policies that closely resemble the Dutch approach (i.c. national planning, minimum criteria for capacity of infrastructure and staff, concentration of radiotherapy in high-volume centers).

### Quality assurance policies

Quality assurance and enhancement has always been a crucial focus of attention in radiotherapy. Until now, this concerned mainly the physical-technical and radiation-safety aspects of radiotherapy, but recently more attention has been given to the quality of the actual care itself (treatment outcomes and complication rates), and also to the overall care process. Quality control systems that are now being developed, focus on the quality and strength of the whole chain of care and the separate organizational processes that make it up. An important aspect is the development of radiotherapy-specific performance indicators, that is: aspects of care that can be measured and quantified, and give an indication of its quality, safety and effectiveness. The professional organizations in radiotherapy have recently embarked on the development and application of such performance indicators, in close collaboration with the Dutch central organization for quality assurance (CBO). The Health Council expert committee wants to emphasize the fact that development of a comprehensive quality assurance policy in radiotherapy still has a long way to go, and that the application of performance indicators as a quality assurance instrument should not give rise to unrealistic expectations in the short run.

### Future developments in radiotherapy

The Health Council expert committee has tackled the question how to best prepare and implement the expansion of the capacity in radiotherapy that is needed for 2015. After completion of the recent round one is now confronted with several options. Further expansion of the already existing radiotherapy centers is in accordance with the policy of concentration that was established long ago. This could also take the form of starting new satellite centers, originating from already

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existing mother-centers. An essential requirement will be that mother-center and satellite together form one center, guided by a uniform medical care and quality assurance policy. Complex treatment planning and preparation can take place in the main center, while the actual radiation treatment is performed at the satellite location. The satellite should have a minimum capacity of two linear accelerator units. A final option is the establishment of additional new radiotherapy centers. This could be a solution especially in regions that today have a tight capacity for radiotherapy or where the accessibility is suboptimal (extended travel times). The Health Council expert committee takes the view that new centers should also comply with the accepted minimum criteria for volume, and should have access to their own catchment area of 500 000 inhabitants.

#### Should the licensing requirement be lifted?

Radiotherapy in the Netherlands has since decades been regulated on the basis of a statutory licensing system (Specific Medical Procedures Act – WBMV) giving the minister of health the authority to designate centers. The minister has now put to the Health Council the question whether there exist any decisive reasons that would argue against terminating the central regulation of radiotherapy by the government. This issue refers to his intentions to amend the application of the above mentioned act in general, as well as to ongoing changes in the health care system that should lead to more emphasis on market forces and stronger competition between health care providers.

In order to be able to answer this question, the Health Council expert committee has conducted an analysis of the different effects of applying the WBMV Act, and has carefully identified and weighed the potential advantages and disadvantages of terminating the licensing system. In summary, the committee draws the following conclusions:

- 1 Central regulation by the health minister, by applying the WBMV Act, has until today contributed significantly to the positive development of the quality and effectiveness of radiotherapy in the Netherlands.
  - 2 The same holds true for the system used to estimate the future need for treatment capacity, based on epidemiological and demographic data and trends, and for the policy putting emphasis on the concentration of radiotherapy infrastructure in relatively large centers.
  - 3 The quality of radiotherapy benefits strongly from the promotion of centers that meet minimum criteria for volume of infrastructure and medical and technical staff, which is a requirement for providing safe and (cost)effective
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care. Efforts to develop a dedicated comprehensive quality assurance system for radiotherapy have been initiated, but its completion and application will take many more years.

- 4 To deregulate the current oversight (by lifting the statutory licensing requirement and ending the a priori review of new centers) in fact means that there will be a major shift of responsibility for both planning and quality assurance policies, from the central government to the professional organizations and other stakeholders (health inspectorate, health insurance agencies, hospital managers and patient organizations). In order to fulfill this task responsibly these stakeholders should have access to suitable instruments (such as: an accreditation system, and the authority to audit the quality of centers). A crucial requirement is that there should be a priori review of center quality.
- 5 The committee concludes that all things considered, a possible deregulation may create opportunities for radiotherapy to continue to develop positively as to quality and accessibility of care. However, lifting the statutory licensing requirement also carries the risk that the much-needed coordination between centers at the national and regional level will crumble away, and that the need for concentration and effective use of costly resources will be disregarded. To avoid these risks certain safeguards have to be installed.

On the basis of their careful analysis the expert committee makes the following recommendations regarding the future development of radiotherapy, and the issue of lifting the licensing requirement in a responsible way:

- 1 To ensure that the capacity for radiotherapy is well-tuned to the expected demand, the present system of national and regional planning should be continued, apart from the issue of whether the government should take the primary responsibility for this.
  - 2 A policy focusing on maintaining and enhancing quality, by having the radiotherapy facilities concentrated in a limited number of centers (compliant with minimum requirements for volume and staff), should also be continued.
  - 3 Deregulation (lifting the licensing requirement) can only be implemented in a responsible way after a comprehensive quality assurance system (including accreditation and a priori quality audit of centers) has been put into place. This will require a transitional period of about three to four years, during which the current legislation (licensing system) should stay in force.
  - 4 If it should appear that the above mentioned quality assurance system cannot be implemented successfully, or that abolishing the licensing requirement would have harmful effects on the present day quality of radiotherapy care,
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then continuation of the current legal framework should be the preferred option.

- 5 The committee urges that in the near future efforts should start to carry into effect the plans for increasing the capacity for radiotherapy in the period up to 2015. This initiative should be taken separate from a decision to deregulate.
- 6 In view of the fact that proton-beam radiotherapy for the time being is still in a phase of early development where many research questions remain unanswered (e.g. indications, effectiveness and cost-effectiveness), the committee recommends that, at least for the coming years, the licensing requirement should apply to this facility.