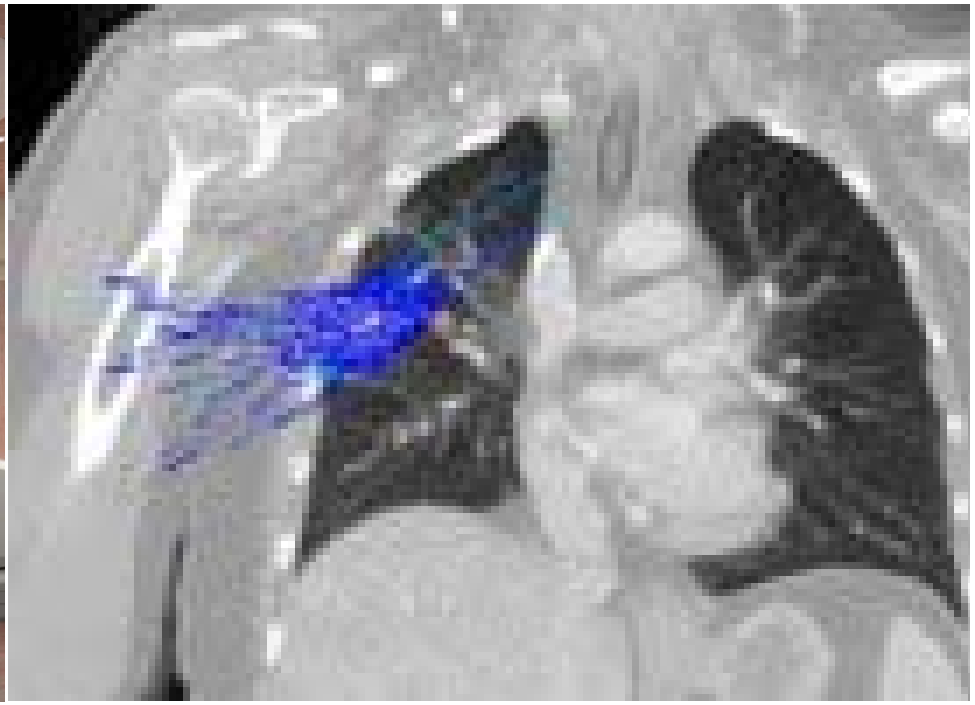
KCE REPORT 198C

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

INNOVATIVE RADIOTHERAPY TECHNIQUES: A MULTICENTRE TIME-DRIVEN ACTIVITY-BASED COSTING STUDY



KCE REPORT 198C
HEALTH TECHNOLOGY ASSESSMENT

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LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
ABC	activity based costing
APBI	accelerated partial breast irradiation
ASTRO	American Society for Therapeutic Radiology and Oncology
BFM-BMF	budget financiële middelen-budget des moyens financiers
CE mark	Conformité Européene-European Conformity
CRT	conformal radiotherapy
CT	computed tomography
DCIS	ductal carcinoma in situ
EIC	extensive intraductal component
ER	estrogen receptor
ESTRO	European Society for Therapeutic Radiology and Oncology
FANC – AFCN	Federal Nuclear Control Agency
FOD – SPF	Federale Overheidsdienst – Service Public Fédéral
FTE	full time equivalent
Gy	Gray
HAS	Haute Authorité de Santé
H&N	head and neck
HDR	high dose rate
HTA	health technology assessment
IMRT	intensity modulated radiotherapy
IORT	intraoperative radiation therapy
kV	kilovolt
LCIS	lobular carcinoma in situ
LVSI	lymphovascular space invasion
MeV	mega electron volt
MOC	multidisciplinary oncology consultation
MV	megavolt
NHS	National Health Service (UK)

NSCLC	non-small cell lung cancer
PET	positron emission tomography
QA	quality assurance
RCT	randomized controlled trial
RFA	radiofrequency ablation
RIZIV – INAMI	Rijksinstituut voor ziekte- en invaliditeitsverzekering – Institut national d'assurance maladie-invalidité
RT	radiation therapy
SABR	stereotactic ablative body radiotherapy
SBPT	stereotactic body proton therapy
SBRT	stereotactic body radiation therapy
SRT	stereotactic radiation therapy (brain), also named stereotactic radiosurgery
VAT	value added tax
WBI	whole breast irradiation

SCIENTIFIC REPORT

1 INTRODUCTION

1.1 Objectives

The primary aim of this study is to calculate the cost of innovative radiotherapy techniques that are being introduced in Belgium. We focus on (1) stereotactic body radiation therapy (SBRT) in selected indications, (2) accelerated partial breast irradiation (APBI) and (3) intraoperative radiotherapy (IORT) as a boost to whole breast irradiation (WBI) schemes. The results will immediately serve as input for a planned research financing of these radiotherapy techniques by the National Institute for Health and Disability Insurance (RIZIV–INAMI). This study is part of a larger project that aims to facilitate the introduction of promising innovative radiotherapy techniques in the Belgian health care system.

The secondary aim is to calculate the costs of the most commonly performed routine radiotherapy treatments. These cost data could support any future rework of the radiotherapy financing in Belgium.

1.2 The study team

The conduct of the cost study was outsourced by KCE to MÖBIUS Business Redesign nv–sa and was conducted in collaboration with 10 Belgian radiotherapy centres. The radiotherapy expertise for performing the cost study was provided by Professor Yolande Lievens, who has published on the subject.[1, 2]

1.3 Radiotherapy and innovation

Radiotherapy in Belgium is offered at 25 hospital-based centres that have been authorized for this activity. Eight of these centres serve one or more satellite centres, which are based in another hospital. The Belgian compulsory health insurance provides coverage for radiotherapy treatments in these centres when performed by one of the 155 recognised radiotherapy specialists. A survey in 2010 showed they accounted for 133 FTEs (personal communication Y. Lievens). Billing of activities is performed using a set of billing codes or “nomenclature”, managed by the RIZIV–INAMI. Adapting this financing system, including the tariffs and the content of the “nomenclature”, is a lengthy process, involving multiple stakeholders. Based on data from the first 9 months of 2012, extrapolated to a full year, the overall amount paid per year for radiotherapy specific

billing codes is 111 million euro. In addition, hospital financing and specific funds for linear accelerators and personnel provided by the FOD–SPF Public Health, amount to about 40 million euro per year.

In contrast to medicines, high-risk medical devices are not clinically validated for specific indications when they obtain a CE mark and enter the European market (KCE report nr 158).[3, 4] It has been questioned whether market entry based on "performance" is appropriate, especially as the term "performance" was not defined by the regulator.[3, 4] The low regulatory barrier creates a challenge for government organisations involved in the financing of high-risk devices that are placed in the market. The case of radiotherapy techniques is even more complex as the innovation often concerns delivering the right radiation dose precisely to the target volume, based on multiple medical devices (software and hardware systems) from different manufacturers that are expected to communicate flawlessly. Furthermore, oncology clinical trials with hard outcomes take many years to conduct. Such large confirmatory clinical trials for innovative radiotherapy techniques in specific indications are often still ongoing when some centres already want to offer these novel therapeutic options to their patients. Evidence based on limited case series can be convincing enough to justify this move. In many other cases, where the evidence based on case series is not yet reassuring, it seems appropriate to only use the innovative technique in the context of a well monitored clinical trial, such that side-effects of the new radiotherapy techniques are timely identified.

Awaiting further clinical validation of specific innovative techniques for specific indications (technique/indication pairs), the Belgian health care knowledge centre (KCE) is working with the RIZIV–INAMI and the FOD–SPF Public Health to facilitate a staged introduction of promising new techniques based on robust cost calculations and the creation of a registry of innovative radiotherapy treatments and their clinical outcome.

1.4 Innovative radiotherapy techniques and their indications

First, the promising innovative radiotherapy techniques and their indications were identified by a working group of interested Belgian radiation oncologists and representatives from KCE, RIZIV–INAMI, FOD–SPF Public Health, and the Federal Nuclear Control Agency (FANC–AFCN). The techniques considered were novel radiotherapy techniques for treating early breast cancer and stereotactic body radiation therapy (SBRT). For both novel strategies of radiotherapy, indications were specified and the current level of evidence was determined based on literature reviews and consensus statements of professional societies. No systematic review of the literature was however performed, which is a limitation of the project.

1.4.1 Novel radiotherapy techniques for treating early breast cancer.

For early stage breast cancer the focus of innovation is on accelerated partial breast irradiation (APBI) as an alternative to whole breast irradiation (WBI) following breast conserving surgery. Also intraoperative radiation therapies (IORT) to deliver a boost to WBI are discussed.

With APBI, the period during which irradiation is scheduled is shortened from 3 to 7 weeks for hypo- and standard fractionated WBI to 1 or 2 weeks, or even to just the stay in the operating theatre. This is convenient for patients.

Targeting the right area with an IORT boost is more straightforward compared e.g. with brachytherapy as boost starting after completion of the WBI, and despite the markers the surgeon may have left behind.

Techniques for APBI identified in the literature range from brachytherapy using radio-isotopes or electrons, to external beam irradiation techniques using MV photons or MeV electrons, or intraoperative radiation therapies (IORT) delivered with kV photons or MeV electrons.[5-8] Different techniques may show tremendous differences in dose delivery, but the clinical relevance of it has not yet been documented.[9] A health technology assessment (HTA) including a systematic review of intraoperative radiotherapy in early breast cancer was reported by the Ludwig Boltzmann Institute, Vienna, 2009.[10] The HTA report concludes that IORT to administer APBI replacing whole breast irradiation (WBI) should still be considered experimental and its use should be limited to trials. A warning

for (too) early adoption of IORT for early breast cancer was published by Sautter et al.[11]

Recently presented US outcome data after brachytherapy were not highly reassuring. Based on a retrospective review of Medicare claims, women who had partial-breast brachytherapy after surgery for invasive breast cancer had more than double the risk for later mastectomy and nearly double the risk for serious complications compared with those who underwent surgery and whole-breast irradiation.[12] At least seven large RCTs are ongoing (www.clinicaltrials.gov):

- First results of an RCT were made public: the Targit RCT comparing IORT Intrabeam (kV photons) with WBI. The results were promising for APBI but long term follow-up is not yet available.
- A large RCT called ELIOT (electron intraoperative therapy) began in 2000 in Italy. The ELIOT RCT compares IORT with MeV electrons (NOVAC-7 system) versus WBI and has long term follow-up data available. However, results have not yet been published for reasons that remain unclear.
- An RCT (trial no. NCT00402519) is ongoing in Europe in 1300 women > 40 years with low-risk stage early stage breast cancer, randomized to WBI or APBI with PDR and HDR brachytherapy.
- An RCT (trial no. NCT00282035) is ongoing in Canada in 2128 women > 40 years with low risk early stage breast cancer, comparing WBI with APBI (3D-CRT).
- A 3-arm RCT (trial no. NCT01247233) in 2800 postmenopausal women > 50 years of age in the US, comparing WBI standard (50Gy in 6.5 weeks + "boost" 16Gy) versus hypofractionated WBI (40/42,5 Gy in 15/16 fractions in 3 weeks) versus APBI (3D-CRT, in 5 days, 40Gy to the tumour bed).
- A 660 patient RCT in women 40 years and older in the US, comparing intensity modulated radiotherapy (IMRT) versus 3D planning for APBI.(trial no. NCT01185132)
- A 4300 patient RCT in women who have undergone surgery for ductal carcinoma in situ or stage I or stage II breast cancer (trial no. NCT00103181). This US trial started in 2005 (NSABP-B-39/RTOG 0413, www.rtog.org). Patients are randomized between WBI and one of three options of partial breast irradiation:
  - 3D CRT (conformal radiotherapy)
  - MIB (Multicatheter interstitial brachytherapy)
  - MammoSite (intracavitary single lumen, balloon catheter brachytherapy)

The American Society for Therapeutic Radiology and Oncology (ASTRO) published a consensus statement on APBI.[13] This ASTRO 2009 consensus suggests three groups of patients where these techniques may be “suitable”, “cautionary” or “unsuitable”.[13]

The GEC-ESTRO Breast Cancer Working Group also recommends three categories guiding patient selection for APBI:

1. a low-risk group for whom APBI outside the context of a clinical trial is an acceptable treatment option; including patients >= 50 years of age with unicentric, unifocal, pT1–2 (=<30 mm) pN0, non-lobular invasive breast cancer without the presence of an extensive intraductal component (EIC) and lympho-vascular invasion (LVI) and with negative surgical margins of at least 2 mm,
2. a high-risk group, for whom APBI is considered contraindicated; including patients =<40 years; having positive margins, and/or multicentric or large (>30 mm) tumours, and/or EIC positive or LVI positive tumours, and/or 4 or more positive lymph nodes or unknown axillary status (pNx), and
3. an intermediate-risk group, for whom APBI is considered acceptable only in the context of prospective clinical trials.(www.estro.org)

Based on the literature the APBI risk categories were defined in a working group, headed by Dr. Luigi Moretti, Institut Bordet (see appendix 1).

Belgian radiotherapy centres have currently invested in the following APBI techniques:

- MeV electrons delivered in a single intraoperative fraction via Mobetron (IntraOp): a mobile external irradiation system which can be placed in a shielded operating theatre for IORT. The entire procedure lasts for about 15 to 20 minutes.[7] Unnecessary radiation to the underlying normal tissue is avoided by mobilizing the mammary gland during surgery and placing a lead plate for shielding on its dorsal surface. The Mobetron can also be used for IORT for other indications.
- 50 kV photons delivered in a single intraoperative fraction via Intrabeam (Zeiss): a smaller device with an applicator that fits in the cavity after lumpectomy, for IORT.
- Multicatheter brachytherapy with high dose range (HDR) Iridium-192 isotope is delivered in 8 fractions over 4 days in one centre. The same technique usually administered in 10 fractions over 5 days was nearly completely discontinued, in another centre. In that centre, the technique is still used when the same breast had already been treated by WBI in the past. Other brachytherapy systems such as balloon catheter radiation (MammoSite) are currently not used in Belgium.

1.4.2 Stereotactic body radiation therapy (SBRT).

SBRT is also referred to as stereotactic ablative body radiotherapy (SABR) and as stereotactic ablative radiation therapy. By using X-ray imaging devices for stereotactic positioning and sometimes implanted markers in the body, radiation oncologists are able to deliver a much higher radiation dose to a precise target than with traditional radiation therapy, while sparing healthy tissue. SBRT can be delivered using various formats with systems that may or may not be dedicated for SBRT. SBRT is under advanced evaluation for the treatment of early-stage non-small cell lung cancer (NSCLC), (oligo)metastases in the liver and lung, as well as (para)spinal tumours. Evidence for additional indications is still very limited.

For patients with T1-2 N0 NSCLC in the periphery of the lung and unfit or unwilling to undergo surgery, SBRT is an accepted alternative for conventionally fractionated external beam radiotherapy (either 3D conformal or IMRT). There is now considerable non-randomised evidence supporting SBRT as superior to conventional RT with respect to local control and survival.[14-16] Ongoing randomized controlled trials of SBRT versus surgery will help determine their relative effectiveness. For the patient SBRT is also more convenient because of fewer treatment sessions (typically 1 to 5 or sometimes up to 10 sessions, instead of the standard 30-35 sessions for 3D conformal RT or IMRT or less protracted hypofractionated schedules).

Four SBRT treatment options can be distinguished for lung tumours. The relative effectiveness of these four options is currently unknown.

- Tracking: the irradiation tracks the tumour while the patient is breathing freely
- Gating: irradiation only when tumour is situated in a well determined window or ‘gate’; rhythm of breathing may be guided by auditive or visual means.
- Breath-hold: breathing is blocked in a predetermined phase of the breathing cycle.
- Free breathing

A recent systematic review on SBRT summarizing the literature published until the end of 2010 identified over 100 case series.[17] Many focused on thoracic cancers. Five large RCTs are ongoing in NSCLC, one in spine metastasis and one in colorectal carcinoma liver metastases (www.clinicaltrials.gov):

- A non-randomized trial (trial no NCT00870116) is ongoing in France (20 patients treated with CyberKnife SBRT, 80 with a linear accelerator SBRT and 20 with conformal RT).
- A 960 patient RCT in the Netherlands of surgery versus SBRT in stage IA NSCLC patients who are fit to undergo primary resection was reduced in size because of a poor enrolment rate (trial no NCT00687986).
- An international RCT comparing CyberKnife SBRT with surgical resection in 440 stage I NSCLC is ongoing (trial no NCT00840749).
- A 420 patient RCT in the US of sublobar resection (+/- brachytherapy) versus SBRT in high risk patients with stage I NSCLC (trial no NCT01336894).

- A 100 patient RCT in Australia of SBRT versus conventionally fractionated radiotherapy for inoperable stage I NSCLC (trial no. NCT01014130).
- A 120 patient RCT in the US comparing (SBRT) with stereotactic body proton therapy (SBPT) for centrally located stage I/II and recurrent NSCLC (trial no NCT01511081).
- A 283 patient RCT in the US of image-guided radiosurgery or SBRT (single dose of 16 Gy) versus external-beam radiation therapy in localized spine metastasis. (NCT00922974)
- A European 300 patient RCT of radiofrequency ablation (RFA) versus SBRT in colorectal carcinoma liver metastases (NCT01233544).

Evaluations of SBRT indications:

- In France, indications for SBRT (lung cancer and spinal tumours) were already defined in 2006.[18]
- The 2010 SBRT evidence review document developed in the UK [19] was selected as reference document for SBRT indications as it provides important guidance on the implementation of the SBRT technique by indication. In addition to the NHS clinical evidence review of SBRT, another (linked) NHS document on SBRT implementation was identified.[20]

MV photon SBRT include, but are not limited to, systems reviewed: [21]

- CyberKnife (Accuray): uses real-time tumour tracking via robotic repositioning; the patient breathes freely without gating or breath-holding techniques
- Hi-Art (TomoTherapy): radiation delivered helically around patient, during treatment: patient immobilization, breath holding and gating
- Vero (Brainlab): uses tumour tracking, and can use multiple inputs for this purpose
- Novalis (BrainLab) and Novalis TX (Varian and Brainlab): respiratory gating and body frame, stops irradiation if intrafraction target movement is detected based on BrainLab imaging.
- Trilogy (Varian): stops irradiation if optical imaging detects movement of patient's surface
- TrueBeam (Varian): uses RapidArc, compensates for tumour motion by synchronizing imaging with dose delivery during a continuous rotation around the patient
- Elekta Axesse (Elekta)

1.4.3 Research funding, registration of activities and clinical outcome.

In the planned RIZIV–INAMI registry project, the monitoring of eligibility criteria and the analysis of side-effects in patients treated with innovative radiotherapy and registered in the cancer registry cannot be as stringent and as frequent as is standard practice in a clinical trial. Therefore, in order to timely capture patient safety signals, technique/indication pairs with a low level of evidence should only be performed in the context of a clinical trial, with a close follow-up of patient safety. For some of the indications there is insufficient evidence to justify the use of APBI or SBRT beyond the clinical trial context. Based on the available evidence, two categories of technique/indication pairs can thus be distinguished (see Table 1). Both can be part of the planned RIZIV–INAMI project. Based on new evidence, both lists will need to be updated on a regular basis by an expert working group during the project.

- Technique/indication pairs with a sufficiently high level of evidence that can be included in the RIZIV–INAMI project without the requirement of a clinical trial setting (of course, patients enrolled in a clinical trial can also be included in the project).
- Technique/indication pairs with a low level of evidence that can only be included in the RIZIV–INAMI project if the patient is already enrolled in a clinical trial. It should be clear that the clinical trial itself is NOT part of the RIZIV–INAMI project. Note that clinically relevant deviations from the technique/indication as defined under 1 also require a clinical trial setting.

For technique/indication pairs where insufficient evidence is available the link to the formal clinical trial in which the patient is enrolled should be provided (electronic link to the protocol registered in a publicly accessible register). Clinical trials can e.g. be sponsored by a university or a scientific radiotherapy organization and should be approved by the local Ethics Committee. They should guarantee close monitoring of eligibility criteria and safety signals.

For technique/indication pairs requiring a clinical trial setting as a precondition for the RIZIV–INAMI project, it should be noted that the RIZIV–INAMI project will not interfere with nor finance any clinical trial related activity such as but not limited to protocol design, obtaining study approval, study monitoring, study analysis and study reporting.

The only items the planned RIZIV–INAMI project will finance are the innovative radiotherapy technique and the obligatory registration at the Cancer Registry. Such financing of "a model to introduce innovative techniques in health insurance based on evaluation of outcomes and costs" is covered by RIZIV–INAMI art 56 §1. All cases included under the RIZIV–INAMI project will have to be registered by the participating centres in a specific registration module (web application) of the Cancer Registry. Set up and monitoring of the registry will be performed by the Cancer Registry. A formal multidisciplinary oncology consultation preceding the registration will be required. All other restrictions of use and obligations of safety reporting as imposed by regulatory agencies (including FANC–AFCN) should strictly be followed. RIZIV–INAMI is planning to provide research funding ("conventies – conventions") for the identified innovative radiotherapy/indication pairs. The funding is planned to be per treatment, based on the cost study detailed in this report. In addition, the funding will be conditional to the completion of a set of relevant variables in the cancer registry for each patient treated using such an innovative technique.

Table 1 – Techniques / Indications and the need for close safety monitoring

Technique	Cancer Indication (for APBI, see Table 5 in appendix, for SBRT see NHS document[19])	Safety monitoring required (clinical trial)
APBI	Breast (low risk group only)	No**
APBI	Breast (medium risk)	Yes
Intraoperative boost	Breast	No**
SBRT	Lung	No
SBRT	Prostate	Yes
SBRT	Renal	Yes
SBRT	Pancreatic	Yes
SBRT	Head & Neck	Yes
SBRT	Primary Hepatic	Yes
SBRT	Hepatic Metastases	No
SBRT	Spinal and paraspinal *	No
SBRT	Oligometastases (other)	Yes
SBRT	Lung Metastases	No
SBRT	Lymph Node Metastases	Yes

** Patients should have "no extraspinal disease activity", replacing "limited disease activity" in the NHS document [19]. Clinical trial needed for kV equipment.*

2 METHODOLOGY

2.1 Why an ABC analysis?

The primary objective of this study is to provide input for a cost-based coverage of innovative radiotherapy treatments. This requires a costing analysis from the perspective of the health care provider, assessing the actual costs incurred on-the-field by the centres.

The cost study was performed using time-driven activity-based costing (TDABC) of all radiotherapy treatments in 10 radiotherapy centres.[22] An important reason for this choice was to limit cost-shifting from routine to innovative therapies. In addition, TDABC enables to detail the different costs for the long list of radiotherapy treatments by allocating personnel and equipment costs based on time measurements. The methodology was considered feasible as radiotherapy is a predictable process of subsequent activities. TDABC based on direct measurements of health care costs and using various methods of data collection for micro-costing have been tried in health care.[23-25] TDABC was applied successfully in the radiotherapy department of the University Hospitals Leuven.[1, 2, 26] The Leuven model was adapted to meet the specific needs of this study.

The current study follows the guidelines of the KCE "Manual for Cost-Based Pricing for Hospital Interventions"[27] and uses its average data concerning physician, personnel and overhead costs. The costs calculated are based on observed resource use, not on predefined normative, efficient or standard resource use. They may or may not be optimal.

Although the focus was on innovative radiation therapies, the cost exercise was extended to the complete radiotherapy department, including all radiation treatments and breast brachytherapy treatments. Non-breast brachytherapy treatments, however, were not considered in this study. This choice also implies that no direct measures were made for any activities performed by other hospital departments, e.g. surgery.

Cost analyses can also serve as input for decision-making on pricing and reimbursement in the context of health economic evaluations. The aim of the analysis is then to assess whether a particular service is good value for money, and both costs and outcomes will be assessed. When costs are calculated for the purpose of health economic evaluations, the perspective of the health care payer is recommended and a longer time horizon should be considered.

The philosophy and concepts of ABC find their origins in the manufacturing sector of the United States during the 1970s and 1980s. Robin Cooper and Robert S. Kaplan, also known from the Balanced Scorecard, brought attention to the ABC methodology in a number of articles published in *Harvard Business Review* in 1988.[28-30] Cooper and Kaplan described ABC as an approach to solve the problems of traditional costing methods. These traditional costing systems are often unable to determine accurately the costs of products and related services, especially when there are multiple products sharing common costs. The ABC methodology consists of three classes of entities: resources (or costs), activities and cost objects (products or services or treatments). An accurate cost per cost object is calculated by assigning resources to activities through "resource drivers" (in practice often time percentages are used) and consequently assigning activity costs to cost objects through "activity drivers" (e.g. number of times an activity is performed or number of fractions). The eventual cost calculation is done by simply adding up all assigned costs per cost object.[31]

2.2 Selection and participation of radiotherapy centres

Ten Belgian radiotherapy centres were invited to participate to the cost study. They were selected to be representative of all 25 centres but preference was given to centres that had started with the innovative techniques under study. The centres included 2 pilot, 1 co-pilot and 7 other centres. A mix was ensured in terms of university versus non-university hospitals, region (Flanders, Wallonia, Brussels) and ownership (public versus private non-profit). Both centres with and without satellite centres were included. All ten centres accepted to participate. For 4 of the centres (2 university and 2 non-university centres) one or more satellite centres were included in the analysis. The list of participating centres is shown in appendix 2. All centres received a participation fee of € 5000 to cover their costs incurred for filling out the data.

2.3 Definition of radiotherapy treatments

Radiotherapy treatments are defined as a combination of an indication (mainly the tumour type), a technique and the number of fractions used. A treatment consists of a preparation phase followed by the irradiation under the format of a single or multiple fractions plus a potential boost. During several years after treatment, the patient may return for follow-up consultations. However, these follow-up consultations do not always occur in radiotherapy departments and are therefore not part of the treatment as defined for this project. Similarly, activities preceding the treatment (e.g. cancer diagnosis or multidisciplinary consultations) are not part of the treatment process as defined for this project. The treatment cost also does not encompass the cost of future treatments in case the patient relapses, the cost of treating adverse effects of radiotherapy, or costs outside the health care sector such as productivity costs or incapacity allowances.

2.4 Time-Driven ABC of radiotherapy

The method of time driven activity based costing [22] estimates the cost of each treatment based on the time needed to perform the activities that compose the treatment. We combined both bottom-up and top-down approaches. Bottom-up calculations were done for personnel and equipment based on time data. A top down calculation was done for the overhead. We proceeded according to the following steps.

First, a **list of treatments** (ABC products) was needed. Each centre first produced its own list of treatments offered, together with the yearly number of patients per treatment. These lists contained about 50 to 70 different treatments, providing a variable level of detail of target organ and technique and variable groupings of fraction numbers per treatment. In order to analyse selected treatments across the centres expert help was provided by a radiation oncologist (Y.L.) and centres were contacted to provide more detail where needed.

Next we **listed the activities** that compose the treatments. This was done by visiting the pilot centres and discussing the treatment process with specialists (see paragraph 2.5).

The following step consisted of collecting **costs and resource use information** (see paragraph 2.6). This required determining which costs pertained to radiotherapy and which costs did not. It also required determining which costs would be precisely calculated (the most important costs responsible for the large majority of costs) and which costs would only be approximated (less significant costs).

The last step consisted of **allocating the costs** to the treatments (see paragraph 2.7). This occurred in two successive steps. First, personnel and equipment costs were allocated to the activities. Second, activities, materials and overhead were allocated to treatments.

The next paragraphs explain into more detail how these steps were carried out.

2.5 Activities

The activities included in the treatment process comprised all patient related activities from the intake consultation to releasing the patient after all radiotherapy sessions had been completed.

Activities performed by radiotherapy personnel can be grouped in several categories.

Care related activities

- Radiotherapy **patient related activities** performed for a specific patient (e.g. intake consultation)
- Radiotherapy support activities performed for multiple patients (e.g. meetings, equipment maintenance)
- Non-radiotherapy care related activities performed in order to treat non-radiotherapy patients (e.g. time spent on consultations for other patients). These were out of scope.

Non-care related activities are activities that are not part of routine patient care (e.g. teaching or research, mainly at university hospitals). Among these activities, some were out of scope for one or several of the following reasons:

- Activity is financed by another source (university, national cancer plan, other), e.g. teaching and research activities or activities/personnel receiving financing by the national cancer plan, e.g. a psychologist.
- Activity is not part of the radiotherapy treatment as we defined it, e.g. multidisciplinary consultation, follow-up consultations.

- Activity is not a radiotherapy activity, that is, it is not performed in order to treat radiotherapy but other patients, e.g. chemotherapy activities, multidisciplinary consult of non-radiotherapy patients.
- Activity is part of the overall radiotherapy treatment but is performed outside of the radiotherapy department and by non-radiotherapy personnel. Examples include surgical activities for intraoperative forms of radiotherapy and for placing gold markers (prostate).

Note that by "out of scope", we mean that the cost of the activity was not allocated to radiotherapy treatments. In order to estimate the time consumed by in scope activities, we also requested estimations of the time spent on some of the out of scope activities.

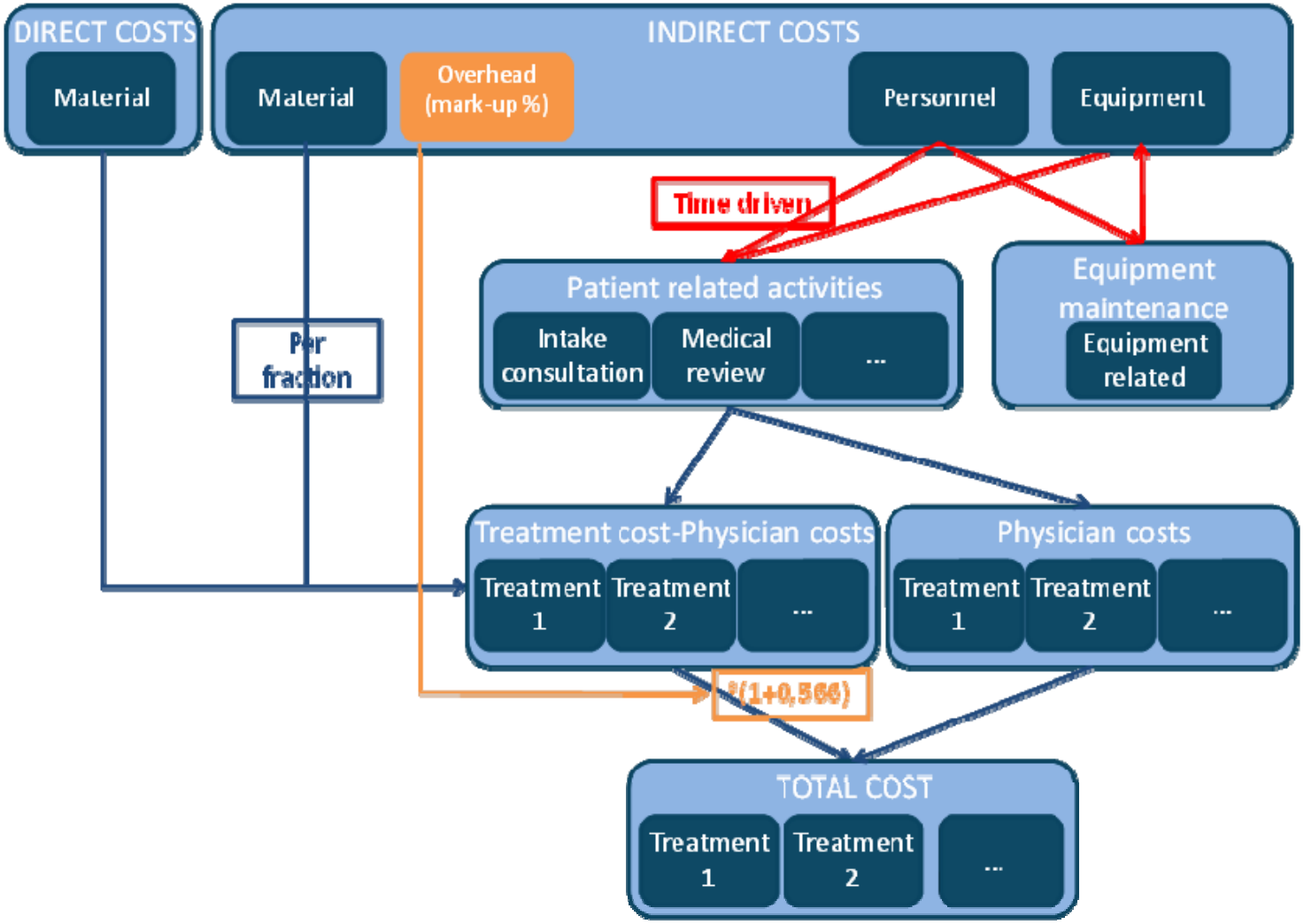
The generic list of activities composing an external radiotherapy treatment can be consulted in appendix 3. In general, we used a completely generic activity list. In a few centres, some minor adaptations had to be made in order to fit their specific work processes.

2.6 Costs and resource use

Radiotherapy costs were split into indirect and direct costs. In this report, indirect costs are defined as costs that cannot directly be assigned to a single treatment, but have to be allocated to the treatments through activities. Four different types of indirect costs were distinguished: personnel (including physician) costs, equipment costs, indirect material costs and overhead. In our model the only direct costs are material costs such as the costs of masks and markers. They are directly assigned to a specific treatment and to a specific patient (costs are based on the year 2011 and include Value Added Tax (VAT). Cost information was extracted from the centres' accounting systems and supplier contracts. In case the 2011 data were not representative (e.g. because new equipment was installed in 2012), 2012 data were used instead. In case the innovative technique was not yet in use in Belgium, but the investment had been planned in a study centre, we used precise estimates of the costs they would incur. This approach was used only in a single centre for an innovative technique (APBI Intrabeam) for which we could not obtain cost data otherwise.

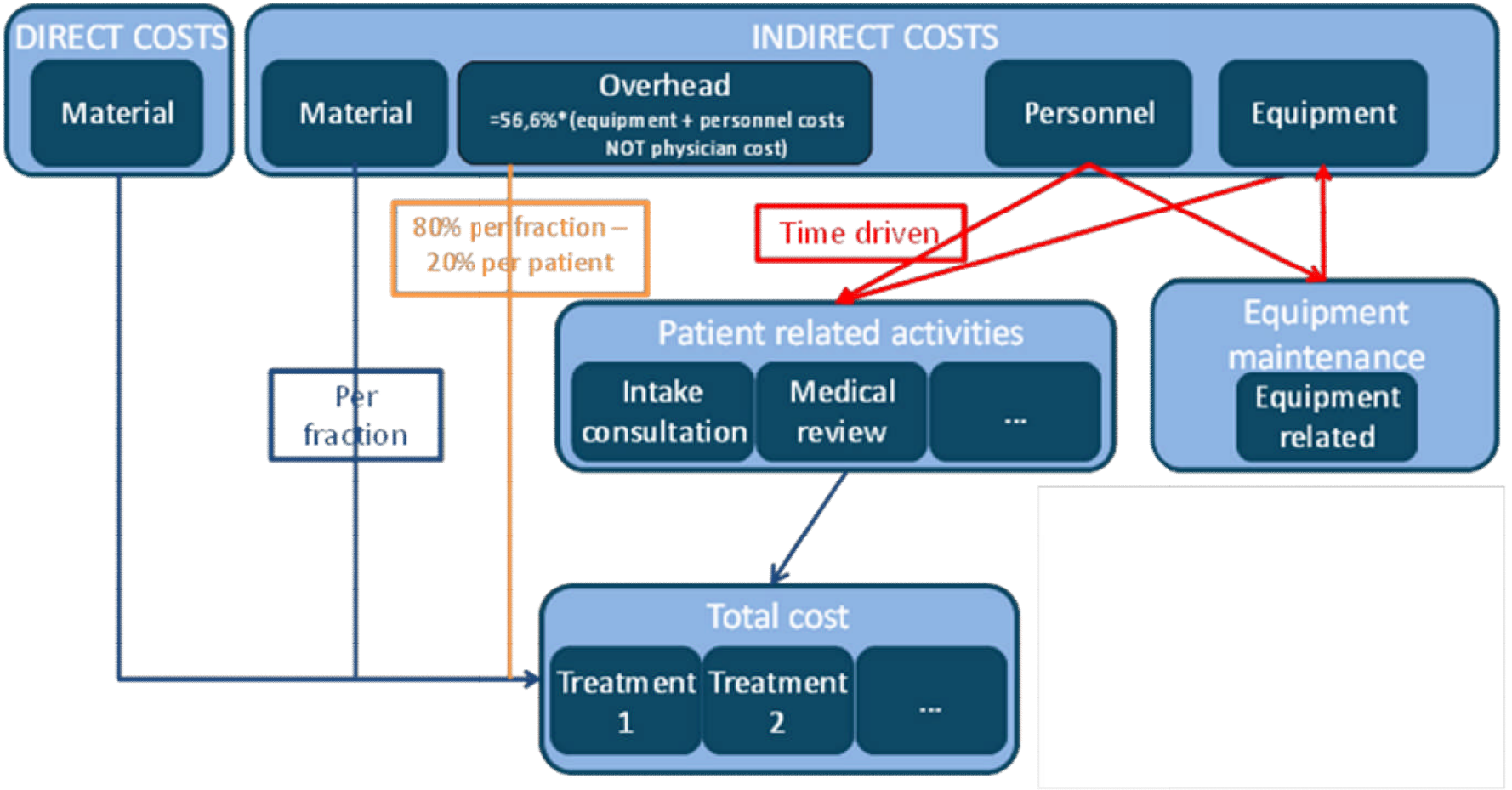
Figure and figure 2 show an overview of the applied ABC framework. Two models are shown here which differ only in the manner in which overhead costs are allocated. In both diagrams, the topmost part shows the different types of costs. The lower part of the diagrams shows how these costs were distributed amongst the different treatments using cost and activity drivers. In this paragraph we focus on the cost inputs. In a next paragraph we will focus on the allocation of the costs to the treatments.

Figure 1 – Time-driven activity-based costing of radiotherapy costs, overhead mark-up option



"treatment cost – physician cost": treatment cost minus the personnel cost of physicians

Figure 2 – Time-driven activity-based costing of radiotherapy costs, overhead 80/20 option



2.6.1 Personnel cost

In accordance with the KCE manual,[27] the following personnel categories were analysed separately:

- senior radiation oncologists (including chief radiation oncologist),
- junior radiation oncologists (i.e. radiation oncologists in training),
- physicists who calculate the radiation plans and are responsible for equipment quality assurance,
- dosimetrists or planners who calculate the radiation plans and
- nurses (including head nurse).
- Physician cost per half day and personnel costs per hour were derived from the KCE manual (see table 2).[27] For precise details we refer to the KCE manual.

Table 2 – Inputs from KCE manual

Input parameter	Value
Cost per productive hour – radiotherapy nurses	€ 40.16
Cost per productive hour – dosimetrists/planners	€ 37.32
Cost per productive hour – physicists	€ 51.57
Number of productive hours per year per FTE	1605
Cost per productive half day – senior radiation oncologists	€ 531.62
Number of productive half days per year – senior radiation oncologists	482
Overhead rate (% of direct costs excluding physician cost)	56.6%

2.6.2 Equipment costs

The following types of equipment were included in the model: simulators, treatment machines, verification systems, dosimetrical equipment, planning systems, positioning devices, imaging equipment, stereotactic frames, gating modules and other equipment. In some cases, machines could be integrated (e.g. positioning devices, imaging equipment and treatment machines).

The yearly cost of equipment is based on its purchase price from which all discounts were subtracted. The number of useful years was based on the actual lifetime of the equipment with a minimum of 5 years for software equipment and 10 years for all other equipment. The cost of upgrades and updates as well as external and internal maintenance and quality assurance were also included.

2.6.3 Indirect material costs

Indirect material costs comprise all consumables used in the radiotherapy department (bandages, paper for the examination table …) that could not be linked to a specific patient. The value of this cost was very limited in all centres. They were based on the cost accounts 600 and 601. Note that cleaning products, linen, electricity, office materials etcetera are included in the overhead.

2.6.4 Pharmaceuticals, radio-isotopes and gold markers

No expensive pharmaceuticals or radio-isotopes were included in the cost analysis as they are financed separately from the radiotherapy activity and generally not registered on the cost accounts of the radiotherapy department. The use of pharmaceuticals is very limited in radiotherapy. Antiemetic drugs may be administered to a minority of patients for radiotherapy-induced nausea and vomiting. Use of other pharmaceuticals is rare. Radio-isotopes used for brachytherapy are also reimbursed separately from the radiotherapy activities. In order to obtain a full cost of interventions that include brachytherapy, the cost of the radioisotope is thus to be added. For more information on the cost of radio-isotopes we refer to KCE report 79.[32] Gold markers can be used during 3D Conformal, IMRT (Intensity Modulated Radiation Therapy) and IGRT (Image Guided Radiation Therapy) treatments to provide real-time localization of moving volumes. For prostate carcinoma treated with IGRT the implanted gold markers are reimbursed by RIZIV-INAMI specific billing codes for implants. In hindsight, we noted that the cost of these markers had been included in the treatment costs in one of the centres. The cost of the marker placement intervention was however never included.

2.6.5 Overhead

Overhead was estimated by the KCE cost manual general overhead rate.[27] Overhead includes costs of all administrative personnel, blue-collar workers and engineers, top and middle management, all depreciations (except on medical equipment), general, cleaning, maintenance (except of medical equipment), heating, financial and administration costs. The general overhead rate is 56.6% of all costs minus physician costs.

2.6.6 Direct costs

Direct costs can be traced to a specific patient. They consist of the cost of masks (or other fixation systems) or markers which can directly be assigned to a patient undergoing a specific treatment. In order to allocate these costs the unitary cost of each type of direct material was provided by the centres.

2.7 Cost allocation

2.7.1 Time based allocation of personnel and equipment costs to patient related activities

Allocation of personnel and equipment costs to activities was based on time registrations and estimates for patient related activities. In figure 1, this is represented by the red arrows. For all activities that were expected to have a significant impact on the treatment cost (Table 2), either because they are repeated several times or because they require expensive equipment, actual times were registered by the personnel of the radiotherapy department during 4 weeks. Time registrations were made in each centre by technique/indication pair by activity and by personnel type. Given the 4-week period, not all treatments (products) or not all activities of that treatment occurred during this period and could thus be measured. Consequently, a number of time measurement extrapolations were done by the project team to estimate the lacking time data.

Table 3 – Activities with time registrations

Simulation	Delineation*	Planning	Treatment delivery
Make immobilisation system	Image fusion	Make radiation plan	Positioning
Inject contrast product#	Organs at risk delineation	Finalize plan	Imaging
Simulation with basic imaging	Target volume delineation	Cross control	Irradiate patient
Additional imaging (if performed by radiotherapy personnel)		Dosimetrical checks	
Gating preparation			

**Some centres provided estimates for these activities for the radiation oncologist*
#Where feasible, if not, the incremental time was calculated based on the simulation time with and without contrast

A standard algorithm was developed and used for this extrapolation, detailed in appendix 8.3. Briefly, for the purpose of extrapolations, the time of the following activities was assumed to be organ dependent: simulation, image import and fusion, delineation of target volume and organs at risk. For the other activities, including planning and treatment delivery, we assumed that the most important determinant of time spent was the technique. When we were confronted with missing data for innovative techniques the centres were asked for a time estimate.

Appendix 5 to appendix 9 present the templates used to gather information in each radiotherapy centre.

Based on the time registrations and estimates the number of hours the equipment was used during one year was calculated. This was done bottom-up starting from the duration of each activity, the frequency of this activity for each patient and the number of patients per year. With the total number of hours and the cost of each piece of equipment, the cost per hour was calculated.

The total yearly productive time of personnel was calculated as follows:

the number of FTEs

x an estimated percentage of in scope activities for each personnel category (estimated at each centre separately)

x the yearly productive time from the KCE manual (1605 hours for personnel and 482 half days for physicians).

In order to correctly allocate the yearly in scope productive time of personnel, the initial time estimates and measurements had to be rescaled. By productive time we understand the working time minus training, sick leave and other absences paid by the employer. Rescaling the time input allows adjusting for:

- radiotherapy support activities, such as weekly meetings, morning discussions and training activities exceeding the 3 days estimated in the KCE manual
- imperfections of the time measurements and estimates
- idle time, such as coffee and toilet breaks

Instead of rescaling the number of minutes per activity, another equivalent method is to rescale the cost per minute of the personnel performing the activity. Both methods yield exactly the same result. However, the latter solution was much easier to implement and therefore selected to perform the cost calculations.

Activities such as equipment quality assurance or maintenance activities were linked to the equipment used. The cost of these activities was added to the cost of the equipment (red arrow going up from “Equipment maintenance” to “Equipment”) and thus, redistributed amongst patient related activities.

Other support activities, not related to specific equipment, were assigned to the patient related activities by the rescaling factor.

2.7.2 Allocating activities, materials and overhead to treatments

Allocating RT patient related activities

Once the cost of each activity had been calculated, we had to know how often each activity is performed for each patient. For example, an SBRT treatment of the lung in 5 fractions is composed of 1 intake consultation, 1 medical review … Therefore the cost of an SBRT treatment equals 1 time the cost of intake consultation + 1 time the cost of medical review + … . This information on activity consumption by the treatments was provided by each centre. The allocation of activities to treatments is represented by the blue arrows coming out of “Patient related activities” (Figure 1).

Allocating indirect material costs

Indirect material costs were allocated using the number of fractions as a resource driver. Indirect material is a small cost item (<1%) and therefore the allocation rule is not critical for the final results.

Allocating overhead costs

Two scenarios for overhead allocation were analysed. Unless specified, the cost presented here is the average of the two scenarios.

In scenario A, the “mark-up” option (as depicted in figure 1), the overhead formula are applied at the treatment–level. This means that for each treatment the costs minus the physician cost are multiplied by 56.6%. The first diagram therefore includes an extra row, splitting up the cost of the patient related activities into the “treatment cost minus physician cost” and the “physician cost”. This is because the overhead mark-up rate of 56.6% is calculated only on the treatment cost minus physician cost. By applying

this method, however, more overhead is allocated to “expensive” products than to “cheap” products. This may not always reflect actual overhead costs. For example, with this method, stereotactic treatments, which are relatively expensive treatments in proportion to the number of fractions, receive a relatively large overhead cost, although one could expect a lower overhead given the smaller number of fractions.

Therefore a second scenario (scenario B) was also analysed (second diagram or figure 2). In Scenario B, the “80/20” option, the 56.6% are calculated at the departmental level. This resulted in a departmental overhead-pool, which was consequently allocated to the treatments based on a combination of the number of fractions (80%) and number of patients (20%). This method results in higher overhead costs for the treatments with high number of fractions and lower overhead for the treatments with low number of fractions. The rationale for the 80/20 split is given in Table 17 in appendix.

Note that both approaches for calculating overhead costs yield the same result when calculating an average cost of all treatments of a centre.

2.8 Total cost per treatment

The total cost for each treatment was obtained by applying the following formula:

$$\text{Cost of 1 treatment} = \sum_{\text{Activities}} (\text{activity consumption} * \text{cost per activity}) + \text{allocated indirect material costs} + \text{direct material costs} + \text{allocated overhead costs}$$

2.9 Data collection templates

In order to be able to analyse the data efficiently, it was essential that all centres delivered the data in the same format. To this end standard templates were provided to all centres. The templates were based on the experience with the (co-)pilot centres and can be consulted in appendix 5 to appendix 9.

3 RESULTS

The cost analysis covered all radiation treatments and rendered a considerable amount of data. Not all data are presented in this report however.

The first section of this chapter will present the different centres in terms of number of full time equivalents (FTE) as well as in terms of number of patients per indication. This should allow the reader to have a good understanding of the size and product mix of the centres composing the sample. The second section will then show some overall results (for all treatments). After this each section, we focus on the innovative techniques and the most common radiotherapy treatments, being lung, breast, head and neck, prostate, rectum and palliative.

The aim of this report is not to discuss results for named centres. Therefore the name of the centres will not be mentioned in the graphs. Centres are identified by a single letter and the letter is not the same in the different tables and figures.

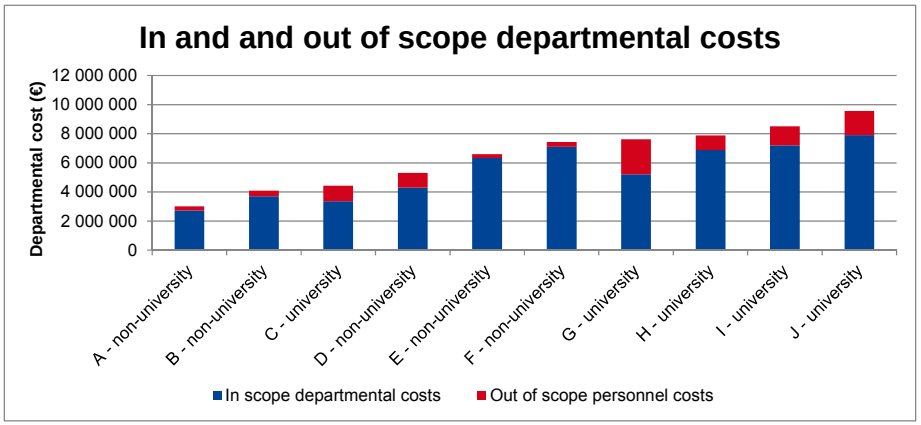
The reported average cost of radiotherapy treatments in a given centre takes into account the number of patients treated with each treatment (it is a weighted average and the weighting factor used is the yearly number of patients per treatment). However, when we report an average cost across several centres, a normal average of the (weighted average) costs in each centre is calculated. The reason is that we did not want to give more weight to centres treating more patients than to smaller centres.

3.1 Centre's profile

The aim of this section is to give the reader a better idea of the type of centres composing the sample. More specifically, it will present the number of FTEs of each centre as well as the patient mix of each centre.

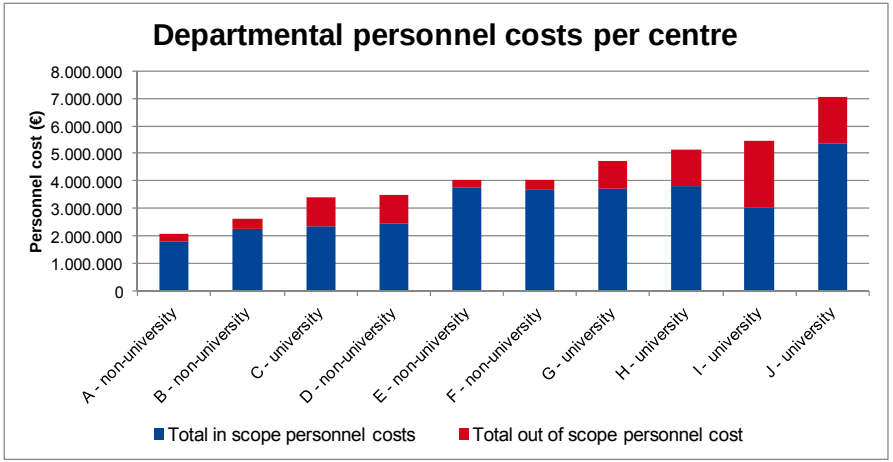
Figure 3 shows the total costs of each radiotherapy department, excluding overhead costs and excluding research funded personnel. The blue bars represent the costs that were "in scope" in the context of this study. This means that they have been allocated to treatments. "Out of scope" costs (red bars) are supported by the centres but were not taken into account when calculating total treatment cost. They are mainly composed of personnel costs (time spent on out of scope activities). In Figure 3 we see a clear difference between non-university centres and university centres where the out of scope personnel costs are higher. For the most part, this is due to additional research and teaching activities performed by personnel of the university centres (and funded by the centres themselves).

Figure 3 – Yearly departmental total cost with and without out of scope activities, by centre (excluding research funded personnel, personnel financed by National Cancer Plan and overhead)



The next graph (Figure 4) shows total personnel cost per department, split into "in scope" and "out of scope" personnel cost. Note that in some university centres, the "out of scope" personnel costs represent a relatively large portion of total personnel costs (up to 44% for centre I).

Figure 4 – Yearly departmental personnel cost with and without out of scope activities, by centre (excluding research funded personnel, personnel financed by National Cancer Plan and overhead)



Next, we present the number of FTEs (in scope) in each centre (Figure 5).

For nearly all functions there is a large spread in the number of FTEs with the minimum number of FTEs for a specific function being about a third of that of the maximum number of FTEs for that function. This was to be expected, however, as the centres were selected specifically for their variety in size.

Figure 5 – Number of FTEs per function in each centre

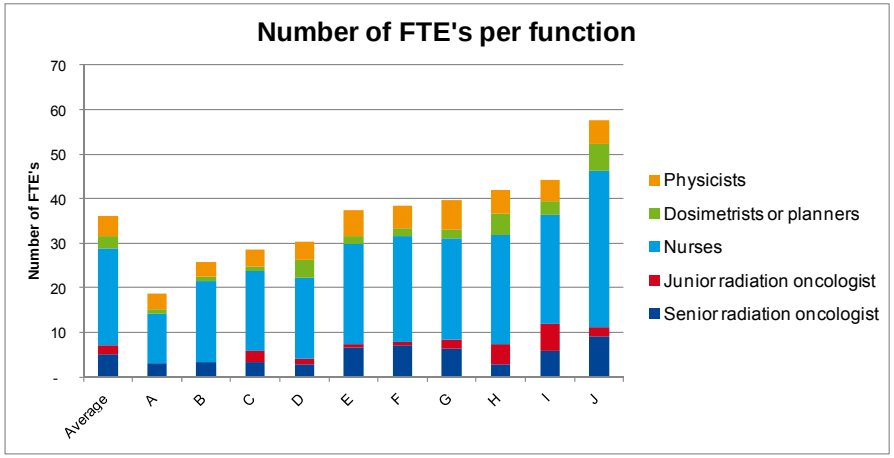


Figure 6 shows the number of patients per indication and figure 7 the proportion of each indication in the total patient population of each centre.

The variety in size between centres can be appreciated in the next figure (Figure 6). Figure 6 shows the number of patients per indication and per centre. Again, the range from the smallest centre (A) to the largest (J) is relatively large with the smallest centre (A) treating nearly three times less patients than the largest (J).

Next, in Figure 7, we can see that the first six categories (breast, palliative lung, prostate, head and neck and rectum) are the most frequent indications. Taken together they represent 80% of the patient population of the 10 centres. This is why our analyses focus on these indications.

Figure 6 – Yearly number of patients by indication, by centre (2011 or 2012)

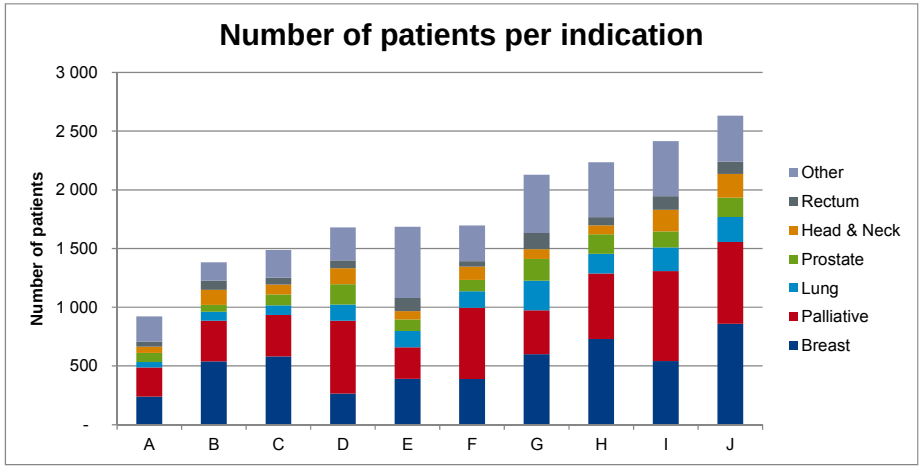
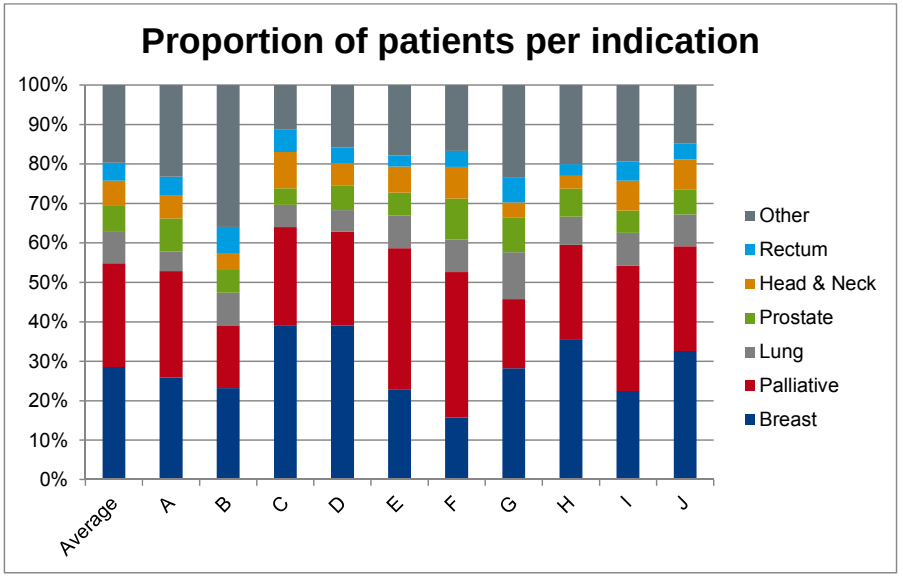


Figure 7 – Proportion of patients by indication, by centre (2011 or 2012)

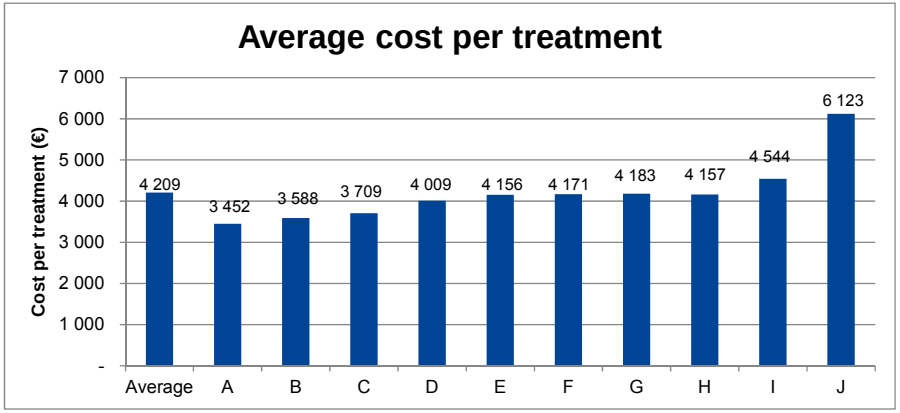


3.2 Average cost over all treatments

This section will focus on some overall analyses made for all treatments. Note that both methods of calculating overhead (mark-up % per treatment and global overhead divided 80% per fraction and 20% per patient) will yield the same results when considering all treatments. Also note that boost irradiations are not considered a separate treatment.

The first graph (Figure 8) shows the average cost per treatment in the different centres. While the results of most centres are relatively similar, centre J has much higher costs. This is mostly due to low equipment utilization for some of its accelerators. Additionally, the number of patients per FTE in centre J is lower than average for all functions. Both of these factors have a significant impact on cost.

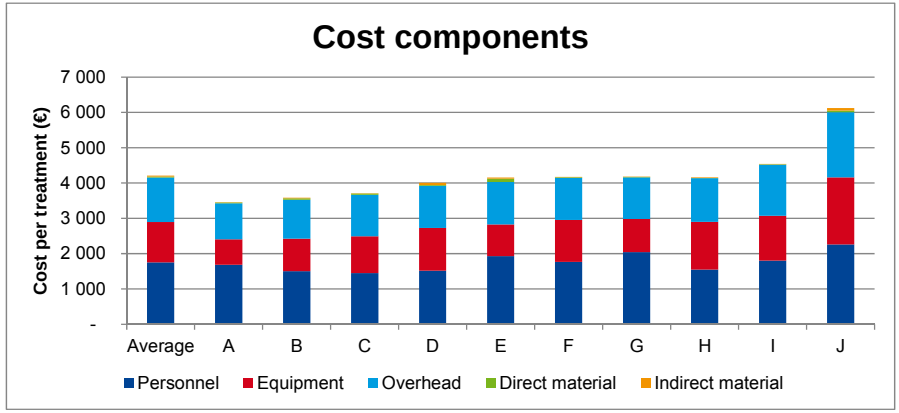
Figure 8 – Average cost per treatment



The total cost of a treatment can also be divided into its components. This is shown in figure 9. This figure clearly shows that the bulk of the costs is composed of personnel, equipment and overhead costs. Direct and indirect material costs, on the contrary, are relatively insignificant.

We also see that the composition of cost is relatively similar across centres. On average personnel represents 41% of total treatment cost, while equipment costs only represents 27% of the treatment cost. Overhead is a fixed percentage (56.6%) calculated either at treatment level or globally, for the entire department. Nevertheless, overhead is always calculated as a percentage of the other costs (personnel costs minus physician costs, equipment costs and material costs). Therefore on average, overhead will always represent approximately a third of the total costs per treatment.

Figure 9 – Cost components

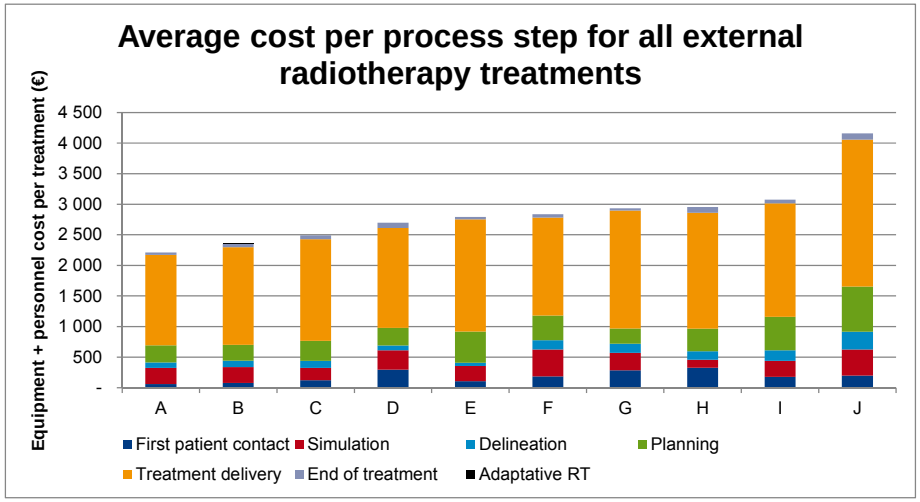


The next graph (figure 10) shows which part of the process has the greatest impact in terms of cost. Note that only personnel and equipment costs can be linked to a particular part of the process. Therefore material and overhead costs are not included in the next graphs.

Depending on the centre, the treatment delivery accounts for 57% to 68% of total equipment and personnel costs with the overall average being 63%. Clearly “Treatment delivery” is the most expensive part of the process. This was to be expected as the treatment sessions occur during this phase. The sessions require the most expensive pieces of equipment (accelerators) and are repeated several times.

After “Treatment delivery” the most expensive phases of the process are “First patient contact”, “Simulation” and “Planning”. A detailed overview of the activities comprised in each activity group can be found in appendix 3. “First patient contact” is expensive mostly because it takes up physician time. “Simulation” on the other hand, is expensive due to the cost of the simulator. Finally the cost of “Planning” comes from the fact that planning is very time consuming.

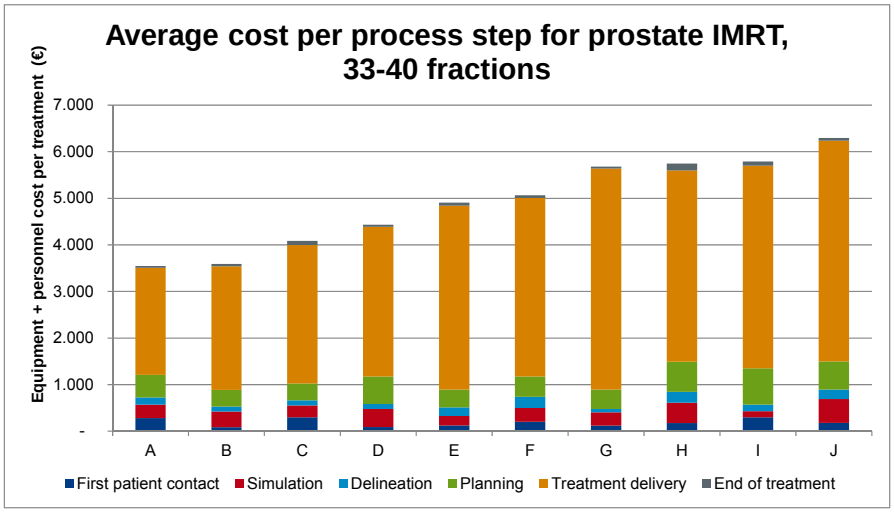
Figure 10 – Personnel + Equipment cost per process step



Even though the total cost is relatively similar for all centres, we see some differences in the costs of each individual phase, especially for "First patient contact" and "Simulation". In order to see if the differences are due to difference in treatment mixes between the centres (proportion of patients per indication) or to differences in process, we can do the same analysis for a single treatment.

The result for IMRT prostate treatment with standard fractionation is shown in the next graph (figure 11). The results at treatment level are relatively similar to the global results. There are still large cost differences for "First patient contact" and "Simulation". This seems to indicate that the differences in the cost of each process step are probably not due to a difference in product mix between the centres but, instead, that they are due to a difference in the process itself. For example, if we look at centre A and B in figure 11, we see that the cost of "First patient contact" of centre B is lower than that of centre A. The cost of "Simulation", on the other hand, is higher. The rationale behind such a difference could be that, in centre B, fewer explanations are given by the radiation oncologist during the consultation and that these explanations are given later, during the simulation phase.

Figure 11 – Personnel + Equipment cost per process step for IMRT prostate cancer



3.3 SBRT, focus on the lung

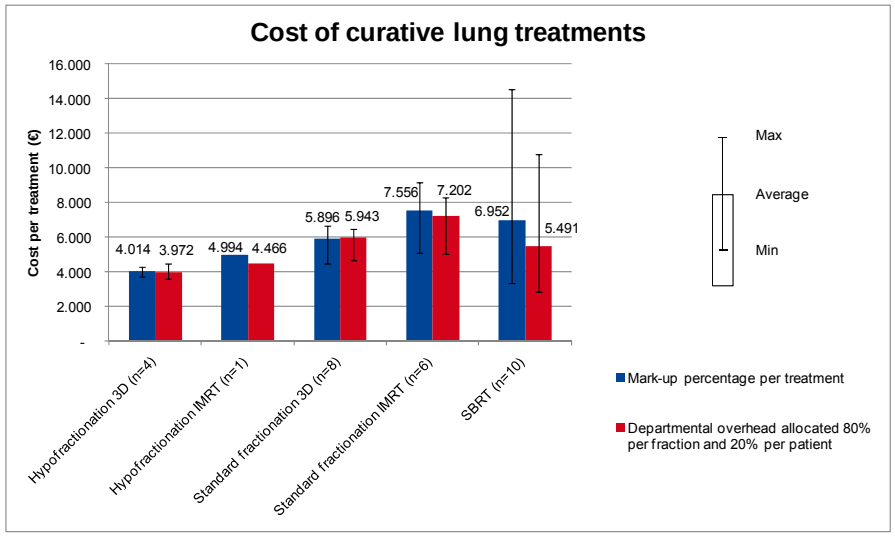
Among the innovative treatments studied, the evidence for SBRT for the treatment of lung cancer is probably most developed, despite the lack of randomized trial results. This is reflected in the fact that all ten participating centres offer at least one variant of SBRT for lung cancer. The number of SBRT treatments in other indications was however considered too low to report costs.

This section will focus on the cost of different types of treatments with curative intent for lung cancer. The treatments are grouped based on their fractionation scheme and on the technique used. Three techniques can be distinguished: 3D-CRT (3D), IMRT and SBRT. For 3D and IMRT we can also distinguish between hypofractionation (12 to 20 fractions) and standard fractionation (30 to 35 fractions).

Figure 12 shows the average cost per treatment. Not all centres offered every type of treatment. The "n" represents the number of centres offering the treatment and on which the average cost is based. The error bars represents the minimum and maximum cost that can be found amongst all the centres offering that treatment. The average cost of hypofractionation

in our sample is lower than that of standard fractionation. Similarly we can also note that, amongst the centres in our dataset, the average cost of 3D is lower than that of IMRT. For most types of lung treatments, the results are relatively similar across centres: the range between the minimum and the maximum is relatively small. For SBRT treatments, however, this range is much larger. Also, the overhead allocation method chosen has a significant impact on costs.

Figure 12 – Average cost of lung cancer treatments with curative intent, by technique and fractionation scheme



In order to give a better understanding of the variability of costs amongst centres, the next graphs show the detailed results per type of lung treatment (if n>1).

Figure 13 shows the cost of 3D hypofractionated lung treatments amongst the different centres. Only four centres offer this treatment but their costs are very similar. There is little impact of the overhead allocation method.

Figure 13 – Cost of 3D hypofractionated lung cancer treatment, by centre

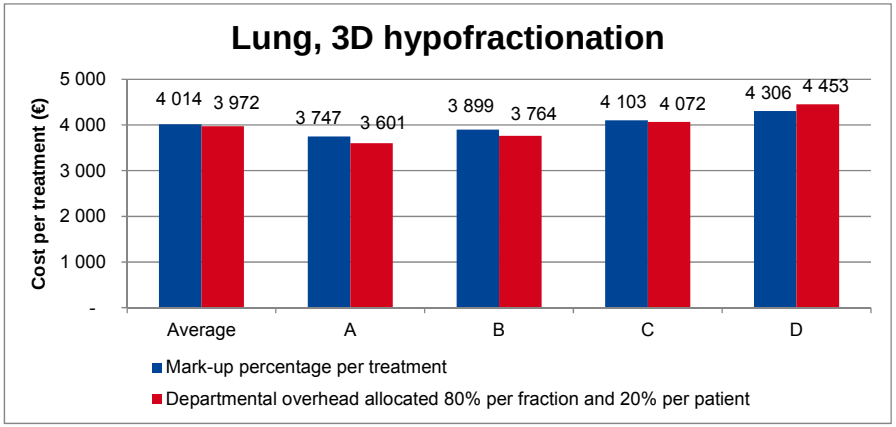
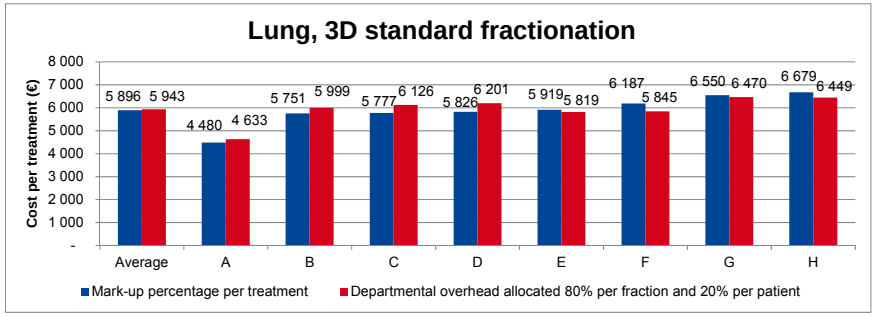


Figure 14 gives an overview of the cost of 3D standard fractionated lung treatments amongst the centres. Most centres (8 out of 10) offer this treatment. The variability here is a little higher, mostly because of centre A which has a lower cost than the other centres. This is due to the lower equipment cost in that centre. This lower equipment cost of A can be explained both by the lower absolute yearly cost of their equipment and by the higher utilization of the equipment in that centre. Personnel costs for standard 3D lung treatment in centre A are not particularly low however.

Again, for these treatments the manner in which overhead is calculated does not have a very important impact on the cost per treatment.

Figure 14 – Cost of 3D standard fractionated lung cancer treatment, by centre



The next graph (Figure 15) shows the costs of IMRT standard fractionated lung cancer treatments. The difference between the centres is larger here with the cost of centre F being nearly double that of centre A. Also for centre E and F, we can see that the choice of the overhead method has an impact on the total cost per treatment. This is because the personnel and equipment cost per fraction for this treatment is high relative to that of other treatments in these centres. Indeed, with the mark-up percentage per treatment method, the greater the equipment and personnel costs of the treatment, the greater the amount of overhead it gets allocated.

Figure 15 – Cost of IMRT standard fractionated lung cancer treatment, by centre

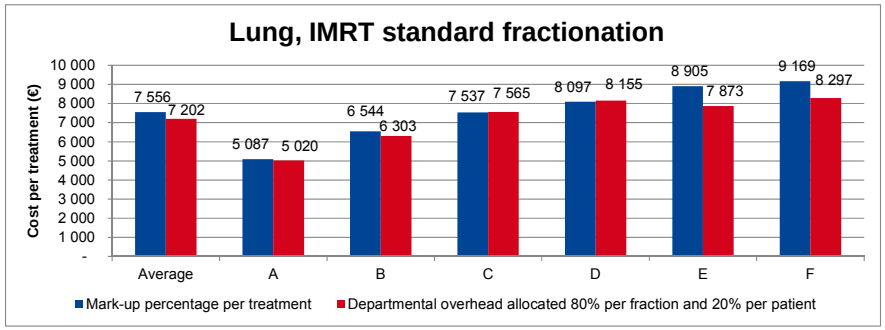


Figure 16 shows the cost of SBRT lung treatments in the different centres. All ten centres in the sample had one form of SBRT treatment for lung. However the technique used differs across the centres. Most centres have free breathing SBRT but two use gating technology and two other use tracking technology. Each colour in the graphs below represents a different centre except for the first bar of each technique (red) which is the average for that type of SBRT technique. Furthermore, one centre (light blue) can do free breathing and tracking. This is why there are a total of 11 bars representing different centres.

Looking at the graphs below it is clear that there is a large spread in treatment costs depending both on the centre and on the SBRT technique. This is true no matter which overhead allocation method is chosen. Depending on the centre, higher costs are due to more expensive equipment and/or greater personnel costs. For example, in centres where nurses are the only ones present during the irradiation session, the cost is much lower than in centres where the radiation oncologist, the physicist and the nurses are present during the entire session.

Next, the cost per treatment also varies with the choice of overhead allocation method. Indeed in the first graph, the overhead is allocated to each treatment by taking a fixed percentage of that treatment's equipment and personnel cost (mark-up percentage method). The equipment and personnel cost per fraction of SBRT treatments being high, the overhead cost of these treatments is high too. In the second graph, the departmental overhead of the centre is divided amongst the treatments based on the number of fractions and the number of patients. The overhead cost per patient will therefore be low if the number of fractions is low. As this is the case for stereotactic treatments, the overhead cost in the second graph is much lower than in the first.

Since overhead represents about a third of total treatment cost (see figure 9) the choice of the overhead method can have a significant impact.

Figure 16 – Cost of SBRT for lung cancer, by centre (average of SBRT fractionation schemes offered at the centre)

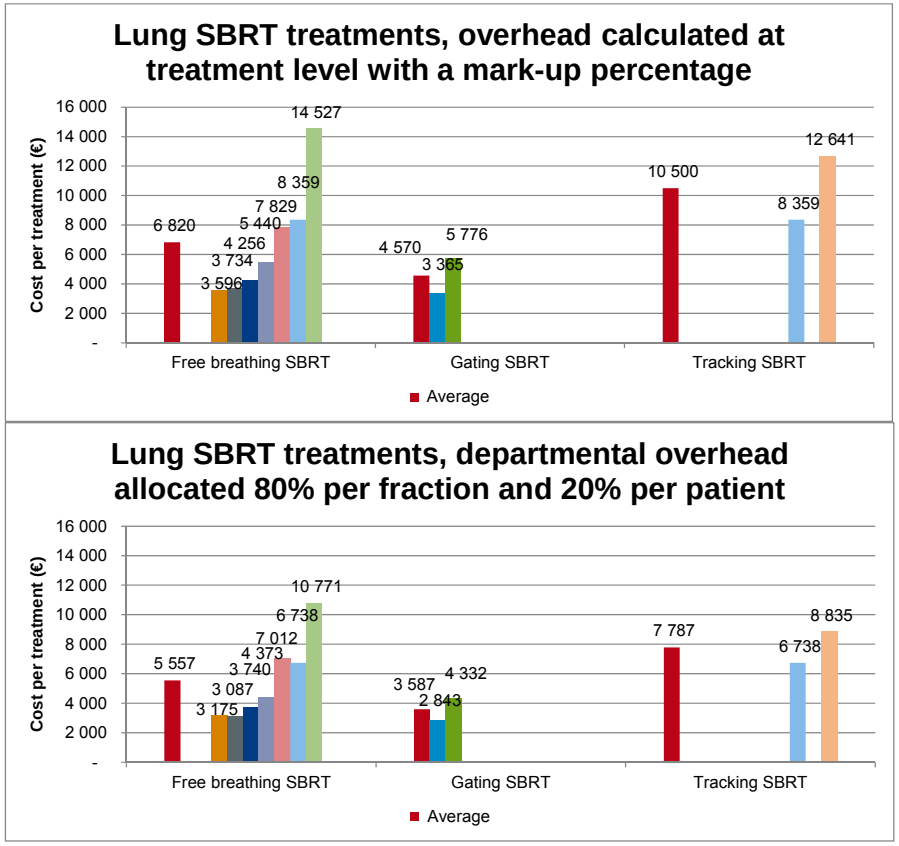
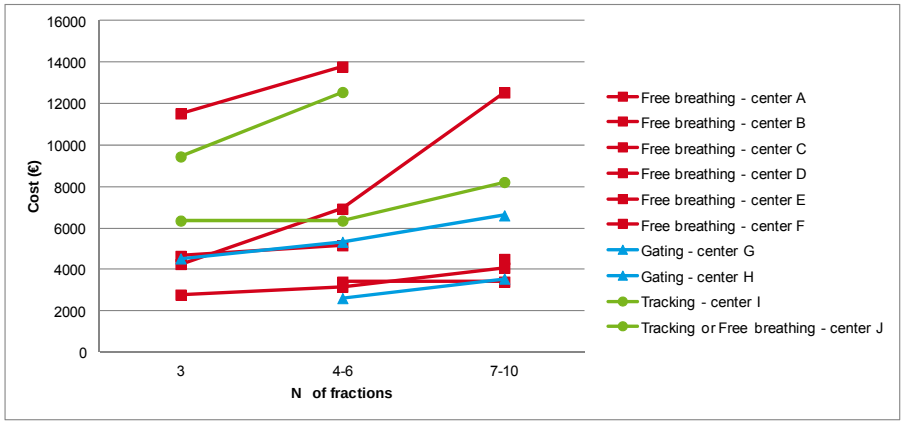


Figure 17 – Cost of SBRT for lung cancer per centre, by technique and fractionation*



**Average of overhead mark-up and 80/20 scenarios; if the reported fractionation overlapped with two categories, the same cost is used for both*

3.4 SBRT of spinal, liver, pancreas, bone and oligometastases

Costs for SBRT spinal (3 fractions) were obtained in a single centre only and concern very few patients. The cost varied between € 3352 and € 3794, depending on the overhead allocation rule used.

Costs for SBRT of liver cancer were obtained in 5 centres, but only a single centre reported to treat over 10 patients per year. No distinction was made between hepatocellular carcinoma and liver metastases. The fractionation ranged from 3 to 10. The median cost among the 5 centres was € 4233 (range: € 2490 euro to € 8714) and € 5119 (range € 3037 to € 12421), for overhead allocation rules 80/20 and mark-up per treatment, respectively. As for SBRT lung, the technique, closely linked to the centre, seems to be a more important determinant of the SBRT cost than the fractionation. Averaging the amounts based on different overhead allocation rules, we obtain an overall average cost of € 5586 (median cost is € 4527).

Costs for SBRT of pancreatic cancer were obtained in 2 centres, each reporting the treatment of only very few patients per year. Ten fractions

were delivered in both centres. The costs varied from € 4227 to € 6456, and from € 4282 to € 7276, for overhead allocation rules 80/20 and mark-up per treatment, respectively. This results in an overall average cost for SBRT of pancreatic cancer of € 5341. This cost is only slightly higher than the overall average of € 4927 found for the 6 centres (range € 3903 to € 7200) that perform treatment of pancreatic cancer in 25 to 30 fractions with 3D-CRT or IMRT.

Costs for SBRT of bone were obtained in 2 centres and concern very few patients. One centre delivered 3 fractions with 4D tracking at a cost between € 8204 and € 9628. The second centre used IMRT for delivering a single high dose fraction at a cost between € 2129 and € 2241.

Costs for SBRT of oligometastatic disease were obtained in 2 centres, but only a single centre reported to treat over 10 patients per year. The fractionation was 3, 5 and 10 in one centre and 10 in the second centre. The costs, reported for both overhead allocation rules, were between € 3148 and € 3536 for 3 fractions, € 3781 and € 4243 for 5 fractions and from € 4051 to € 6100 for 10 fractions.

3.5 Breast cancer

This section focuses on the different forms of primary breast cancer radiation therapies with curative intent, with a focus on APBI and IORT boost techniques. Schemes including specific irradiation of lymphatic nodes were excluded. The first graph shows the average cost per treatment across centres by technique and fractionation scheme. The following graphs show the cost depending on whether or not a boost is administered and the type of boost. Figure 18 shows the average cost of breast irradiation treatments by technique and fractionation scheme. Again, the error bars represent the minimum and maximum cost amongst the centres offering that kind of treatment.

The first thing that is apparent is the large range in costs. Differences in cost result mostly from different fractionation schemes, hypofractionation (fractions 13 to 20) versus standard fractionation (25 fractions), and from differences in technique, 3D, 3D with gating, IMRT and APBI. Note that there are large differences in the costs of the different APBI treatments. These are explained into more detail below (with the explanations of Figure 19).

There are some differences in average cost depending on the overhead calculation method applied. The greatest differences are seen for APBI treatments. Indeed the overhead method which consists of dividing the global overhead amongst treatments depending on the number of fractions (for 80%) and the number of patients (for 20%) will result in low overhead for APBI treatments where the number of fractions is considered to be equal to 1 for IORT and 8 for HDR interstitial multicatheter brachytherapy.

Figure 18 – Average cost of breast cancer treatments, by technique and fractionation

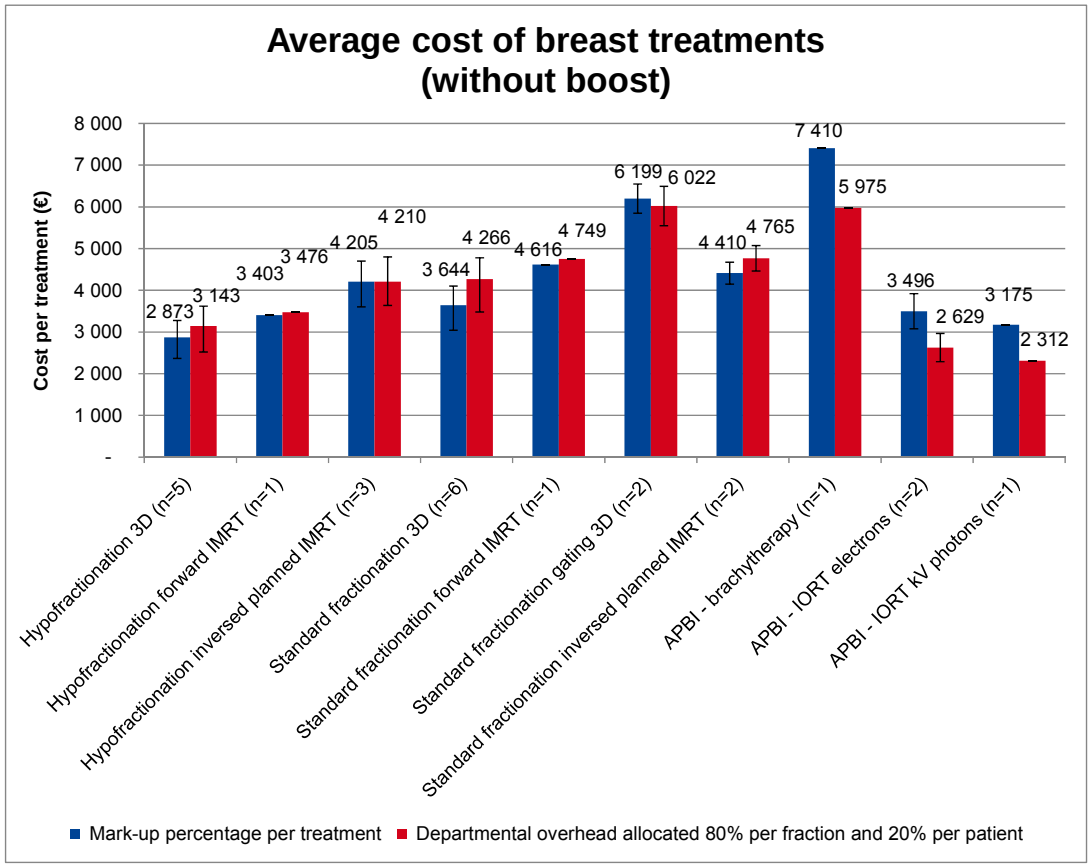


Figure 19 shows the cost of different types of APBI treatments. Each form of APBI is only performed in one centre except for APBI with an electron boost which is performed in two centres. Again, note that the number of centres on which the calculations are based is low.

HDR interstitial multicatheter brachytherapy.was performed in a centre where the number of patients treated this way is low. This means that the equipment is not fully utilized and that the resulting cost per patient is very high. All other things being equal, if the number of patients undergoing APBI by brachytherapy in that centre were to increase fourfold, the brachytherapy equipment utilization would still be at approximately 3% of full utilization and the cost of APBI by brachytherapy would be reduced to € 6122 (mark-up percentage per treatment for overhead calculation) or € 5144 (global overhead divided 80% per fraction and 20% per patient). The cost is thus high because the HDR treatment machine is used only for a few breast cancer treatments each year but also because multiple highly qualified specialists are present during the eight treatment sessions. The cost of the Iridium isotope and any costs for the surgical department are not included.

The cost of MeV electrons and KV photon IORT APBI are rather similar and lower than for brachytherapy. However, also for these two forms of IORT the cost of the surgical department was not included. These surgical department costs will depend on the extra time the surgery will take and should consider the cost of the nurses, the surgeon, the anaesthesiologist, the anatomical pathologist and the (shielded) operating room. For information, based on the KCE cost manual the direct costs of the operating theatre, anaesthesia and sterilization department can be estimated by 156 euros per hour and per nurse. (If the intervention requires two nurses, the cost per hour must be doubled.) This cost covers medical equipment, staff except for physicians and drugs, pharmaceutical products and consumables.[27] The cost of a general surgeon, anaesthesiologist and anatomical pathologist is respectively € 363, € 441 and € 458 per half day. On top of the direct costs excluding physicians, the general overhead rate of 56.6% applies.

Figure 19 – Cost of APBI treatments

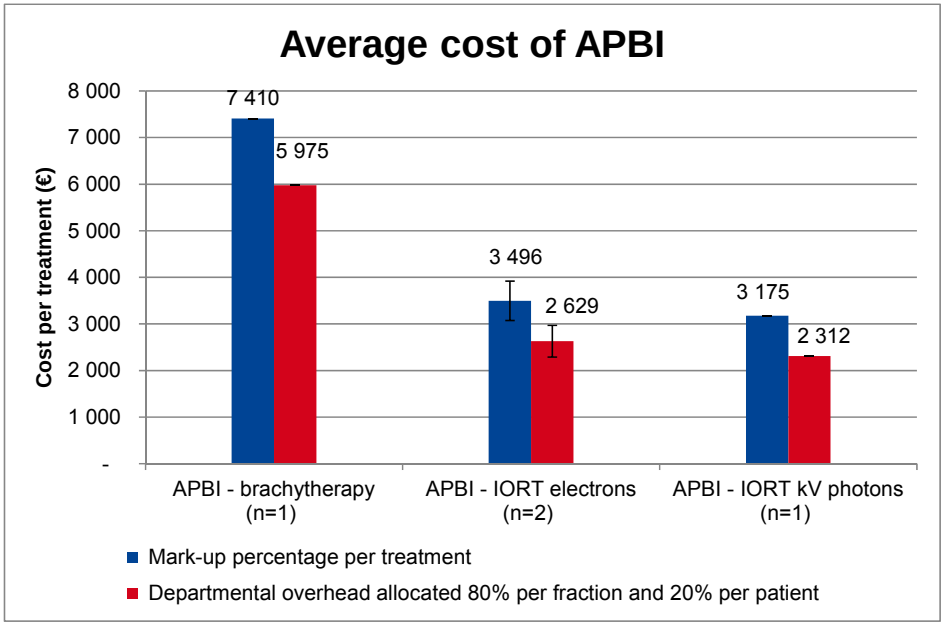


Figure 20 shows the cost of 3D breast hypofractionation as well as the cost of possible boosts. The first category represents the cost of 3D hypofractionation without boost. Five of the ten centres perform this type of treatment and their costs are relatively similar.

Looking at the cost of the boosts we can see that there is a great difference in costs depending on the type of boost: the cost of an external boost (not intraoperative) is clearly lower than that of a boost with brachytherapy.

In general, the spread between the minimum and the maximum is relatively small.

Note that the costs of surgery (personnel, room, equipment,…) are not included in the cost of the IORT boost. Only radiotherapy costs were considered in this study.

Figure 20 – Cost of hypofractionation for 3D breast cancer treatments

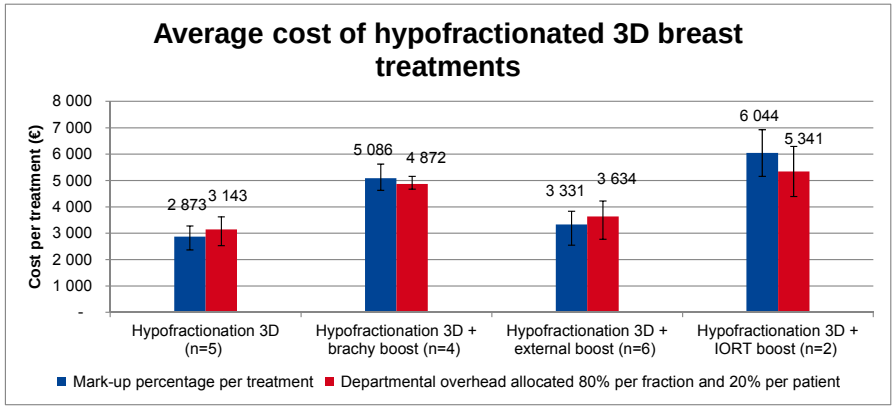
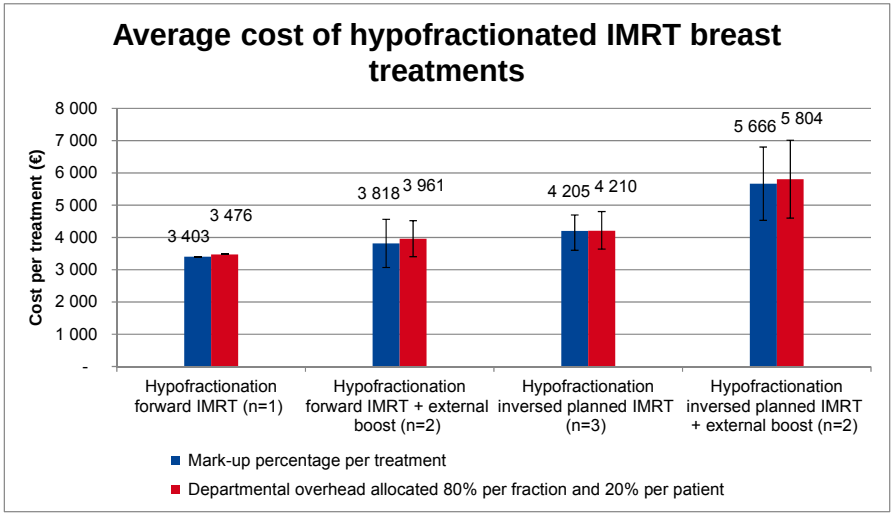


Figure 21 shows the results for hypofractionated IMRT breast treatments. It looks like the cost of forward IMRT is much lower than that of regular IMRT. However, given the limited number of centres performing that type of treatments, the results are very sensitive to the personnel and equipment costs of the individual centres.

Figure 21 – Cost of hypofractionation for IMRT breast cancer treatments



The next graph shows the costs for 3D standard fractionation for breast. Note that the type of treatment that is performed in the greatest number of centres is actually not the standard 3D treatment without boost but the standard 3D treatment with an external boost.

While the results are relatively similar across centres for 3D without boost or for 3D with a brachytherapy boost, the difference between the minimum and the maximum is much higher for 3D with an external boost. This is mostly due to one centre that has much higher personnel costs than the others. The difference in personnel costs in that centre comes from the fact that more time is spent by physicians on administrative tasks and medical review meetings.

Figure 22 – Cost of standard fractionation for 3D breast cancer treatments

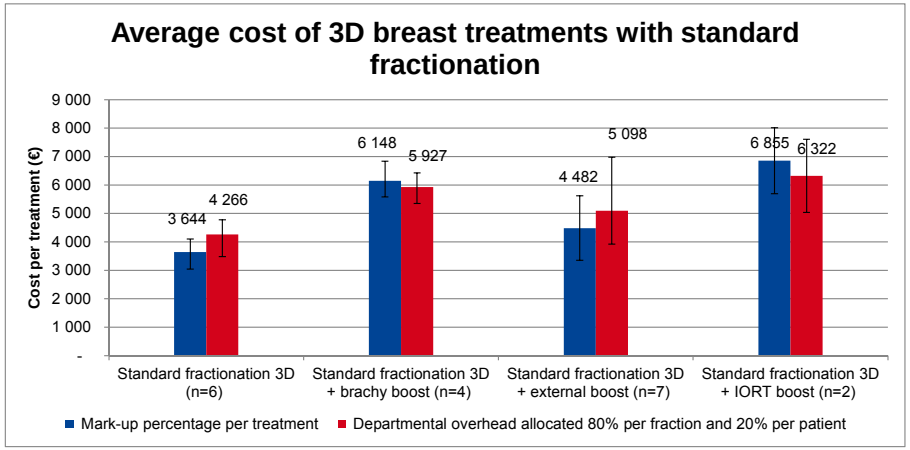
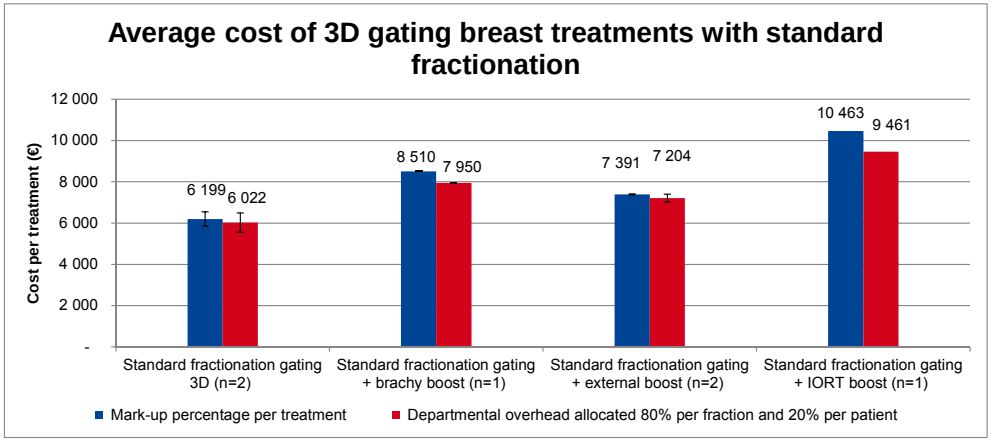


Figure 23 shows the costs of 3D breast treatments with gating. Other types of respiratory guided techniques are used in Belgium but they were not specified separately in the centre's product lists. Only gating was defined as a separate product. This is why only gating results are presented here.

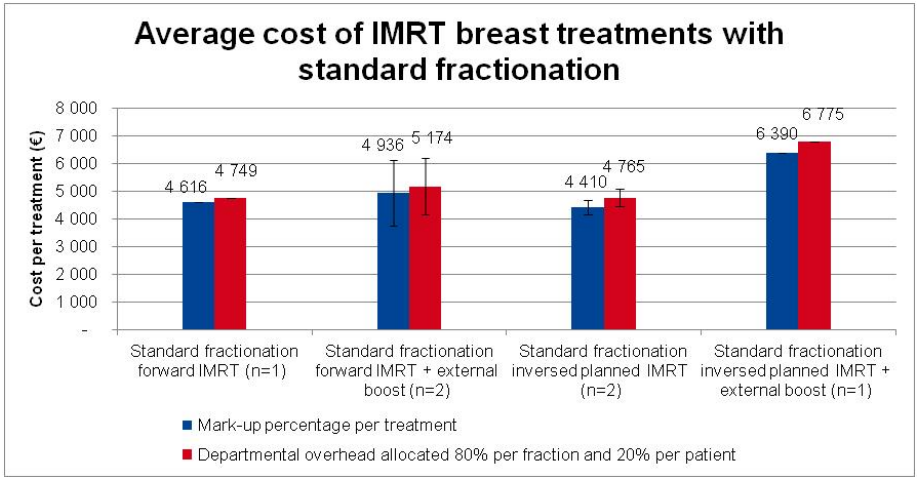
Overall, the results are relatively similar across the centres but given the small number of centres performing this treatment one has to be careful before drawing conclusions.

Figure 23 – Cost of standard fractionation for 3D/IMRT breast treatments with gating



The results for IMRT breast treatments with standard fractionation are also relatively similar across centres but, again, the small number of centres does not allow drawing any conclusions.

Figure 24 – Cost of standard fractionation for IMRT breast cancer treatments

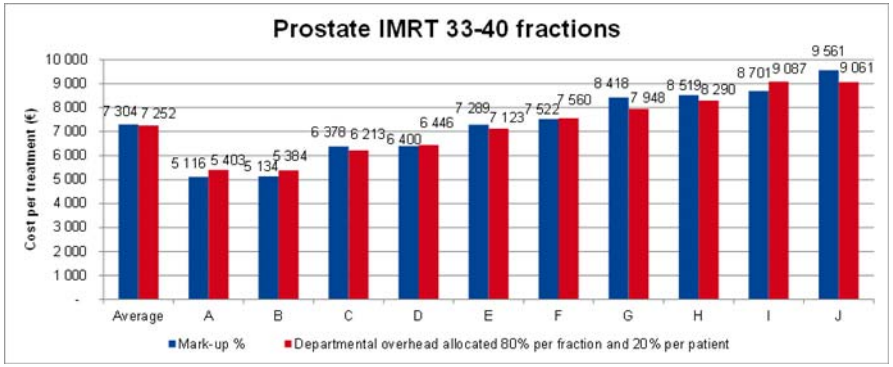


3.6 Prostate cancer

After breast cancer and lung cancer, prostate cancer was the most common target for radiation therapy. This section will focus on the cost of standard fractionated IMRT for prostate cancer. In addition to head and neck cancer, prostate cancer is an important indication of IMRT.[33]

Figure 25 shows the cost of IMRT prostate treatment in all ten centres. There are important cost differences between centres with the lowest cost and centres with the highest costs. At the lower end, we have centres A and B while centres I and J are at the higher end. These cost differences have several causes: the low costs of centre A are mostly due to high personnel efficiency (which reduces the cost per minute of personnel) and high machine utilization. Centre B on the other hand, takes very little time for a prostate IMRT treatment session. At the other end of the spectrum, centre I has generally high personnel costs per minute. Furthermore the duration of the simulation and planning is very high in that centre. Finally in centre J prostate patients can be treated on three different machines. The first two have average costs per minute but the last one has a very high yearly cost as well as a low utilization level. And because the number of fractions for standard fractionated IMRT treatments is high, this has a large impact on the total treatment cost. Finally, note that the total treatment cost does not vary much between with the choice of overhead calculation method.

Figure 25 – Cost of IMRT prostate cancer treatment with standard fractionation



3.7 Head and neck cancer

The average cost of head and neck IMRT is relatively high. This is mostly due to the equipment cost that is generally higher for head and neck (H&N) IMRT treatments than for other IMRT treatments with similar fractionation schemes. Personnel cost is also slightly higher for H&N IMRT but there, the difference is not as large. This high cost per fraction is why the difference in costs between both overhead allocation methods is large for the last (most expensive) centres.

Figure 26 – Cost of IMRT Head and Neck treatments

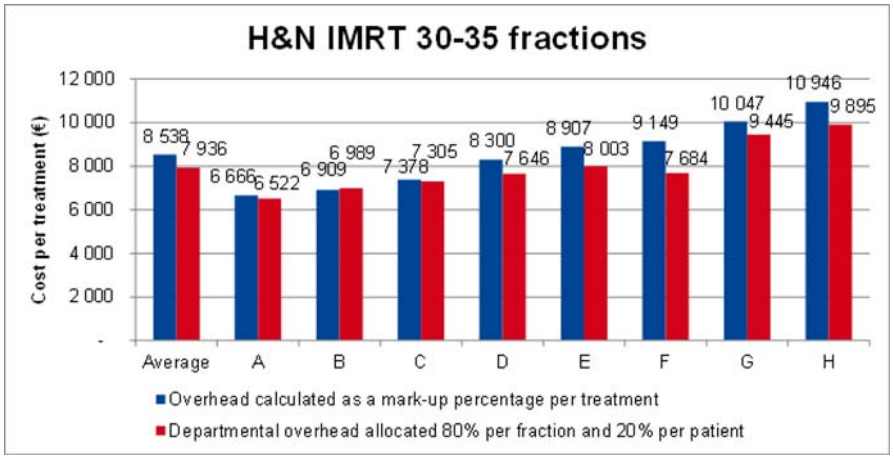
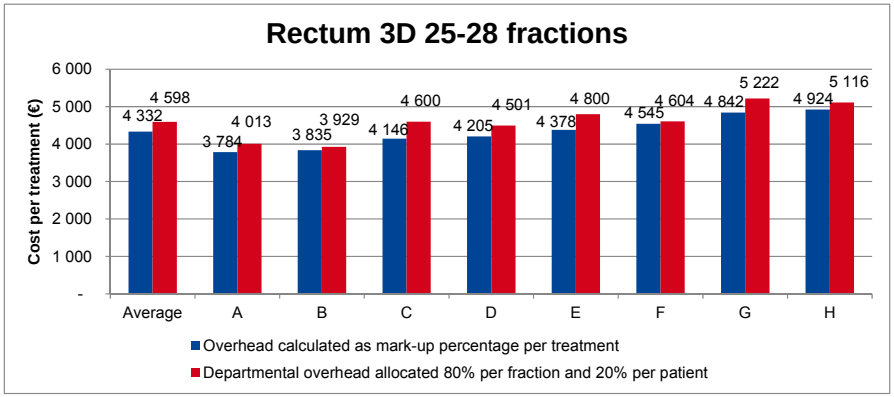


Figure 27 – Cost of 3D Rectum Cancer Treatments



3.8 Rectum cancer

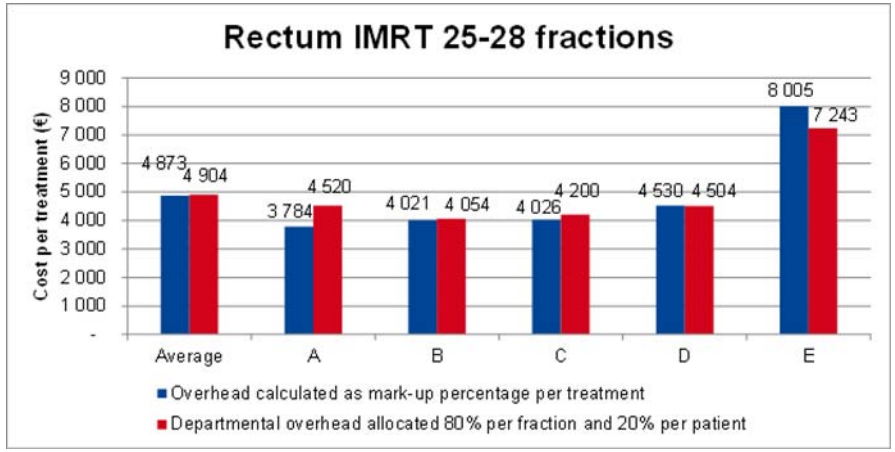
This section focuses on the cost of standard fractionation for rectum cancer.

Eight of the ten centres perform 3D rectum treatments and only five perform IMRT rectum treatments. The cost of 3D treatments is impressively consistent across the centres.

For IMRT, the costs are also very similar amongst all centres except for centre E (Figure 28). The reason for this higher cost of centre E is that the treatment session takes approximately 30% longer and that the cost per minute of the accelerator is higher.

Finally, note that the cost of 3D is generally lower than that of IMRT.

Figure 28 – Cost of IMRT Rectum Cancer Treatments



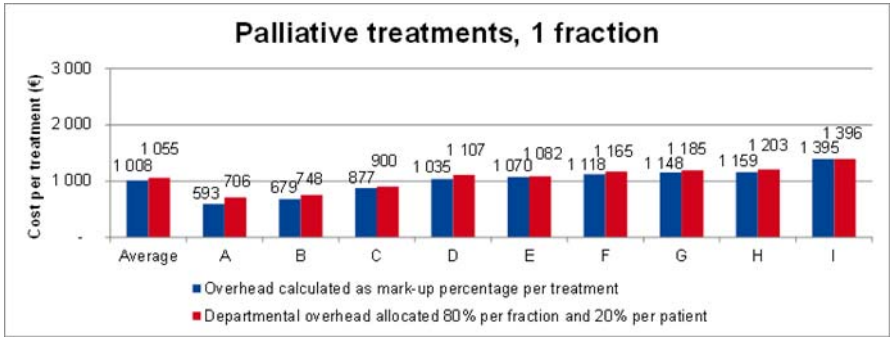
3.9 Palliative radiotherapy

This section focuses on palliative treatments which represent approximately 25% of all treatments. Usually palliative treatments are administered using 3D techniques although in some cases, IMRT is used.

Figure 29 focuses on palliative treatments that are administered in a single fraction. All centres except one perform this treatment, all using 2D or 3D external radiotherapy. The main goal of these treatments is pain relief, not to deliver an ablative dose to the tumour. Clearly the cost of palliative radiotherapy is lower than the cost of radiotherapy with curative intent. This is mostly due to the low number of fractions and to the use of less complex treatment techniques.

Note that the results of the centres are relatively homogeneous and that there are no obvious outliers. Furthermore, the choice of the overhead method does not have a significant impact on the total cost of the treatment. Centre I uses IMRT.

Figure 29 – Cost of palliative cancer treatments in a single fraction

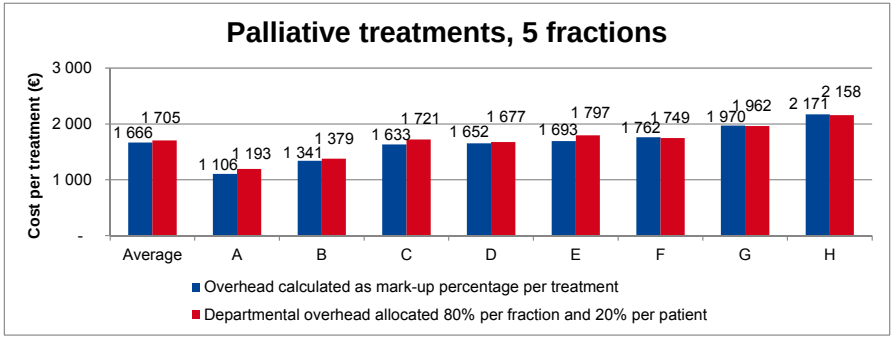


The next graph (Figure 30) shows the results for palliative treatments in five fractions. As expected, the costs for this type of treatment are higher than those of single fractionation. However because only a single simulation and planning are made for all fractions, the cost is not multiplied by 5. On average, the cost of palliative treatments in five fractions is only approximately 50% higher than with a single fraction.

Most centres administer this treatment using 2D or 3D. Centre H however uses IMRT for some patients and 2D or 3D for others.

Again, the costs are relatively consistent amongst the different centres and the choice of the overhead method does not have a significant impact on the total cost of the treatments.

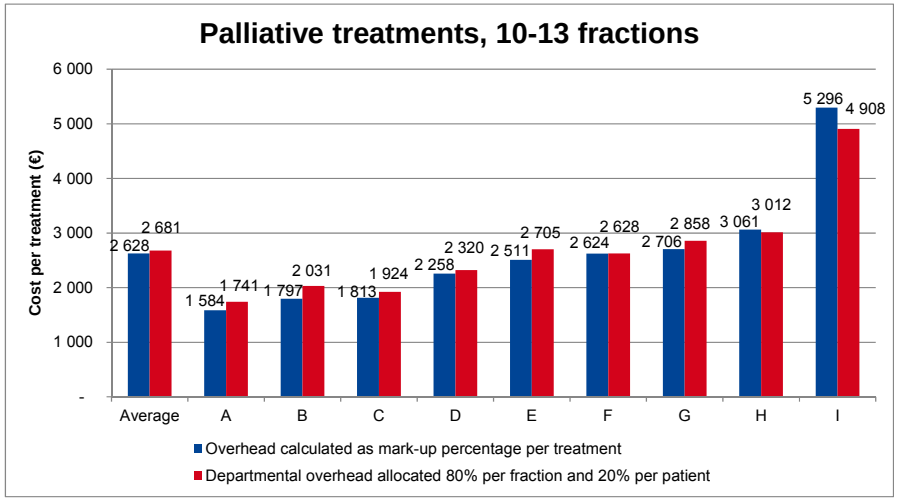
Figure 30 – Cost of palliative cancer treatments in 5 fractions



Finally figure 31Figure 31 shows the costs of palliative treatments in 10 to 13 fractions. Again, due to the higher number of fractions, the cost per treatment is higher.

With this fractionation scheme (10-13 fractions) most centres use 2D or 3D irradiation. However some centres also use IMRT for part of their patients (centres A and G). Only centre I systematically uses IMRT. Combined to the fact that the cost per minute of centre I's accelerators is higher than average, this results in higher costs for centre I.

Figure 31 – Cost of palliative treatments in 10-13 fractions



3.10 Cost determinants and efficiency

During this project a large amount of data on the in and outputs of radiotherapy was gathered. This data collection served primarily to estimate the cost of treatment, in function of indication, technique, fractionation scheme and type of equipment. These data could however also be used to investigate other determinants of costs, such as efficiency and quality delivered. As the study was not designed for this purpose, only exploratory analyses were conducted. Others have reported general efficiency analyses covering all Flemish radiotherapy departments [34].

First, we looked at average treatment cost as a function of the overall treatment volume (both in terms of number of patients and fractions) at the centre. No clear relationship was observed (data not shown). Despite the variation between the volume of the centres, one should keep in mind that the centre with the lowest number of patients still treated nearly 1000 patients per year. This could be the cause of the apparent lack of relation between the volume of a centre and its average treatment cost. Indeed, it has been reported that centres with under 1000 patients per year could significantly benefit from volume driven efficiency gains, but that the room for improvement is much smaller in larger centres.[1]

Second we checked the impact of overall patient volume on FTEs (by personnel type) per patient treated.

Figure 32 shows the ratio of FTEs-in-scope per patient (y-axis) in function of the number of patients (x-axis) for all centres. A value of 1.2% of nurse FTE time means that the sum of all in scope activities by a nurse (or rather nurses) for a scheme of radiotherapy amounts to a time that corresponds to 1.2% of the time a full time nurse has available in a year. A linear regression line was added for each personnel category. The figure shows no clear tendency towards economies of scale. For nurses and physicists the slope of the regression line is negative, but for radiation oncologists and dosimetrists or planners, the slope of the regression line is positive. A negative slope of the regression line means a trend of economies of scale, however, the sample is small (n=10) to draw robust conclusions from. The same can be observed in figure 33 that depicts the ratio of FTEs-in-scope per fraction.

Figure 32 – FTEs-in-scope per patient as a function of the number of patients

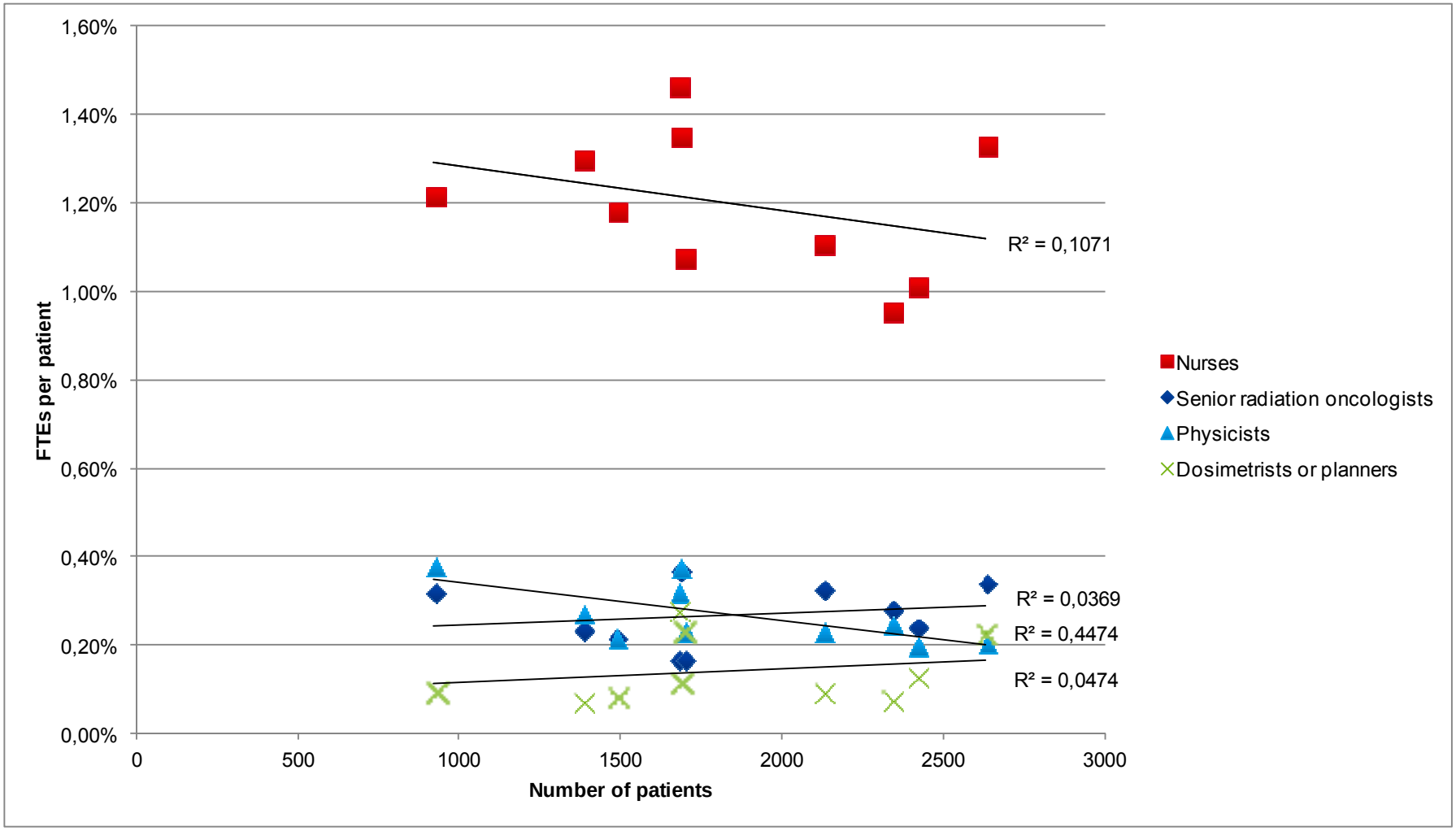
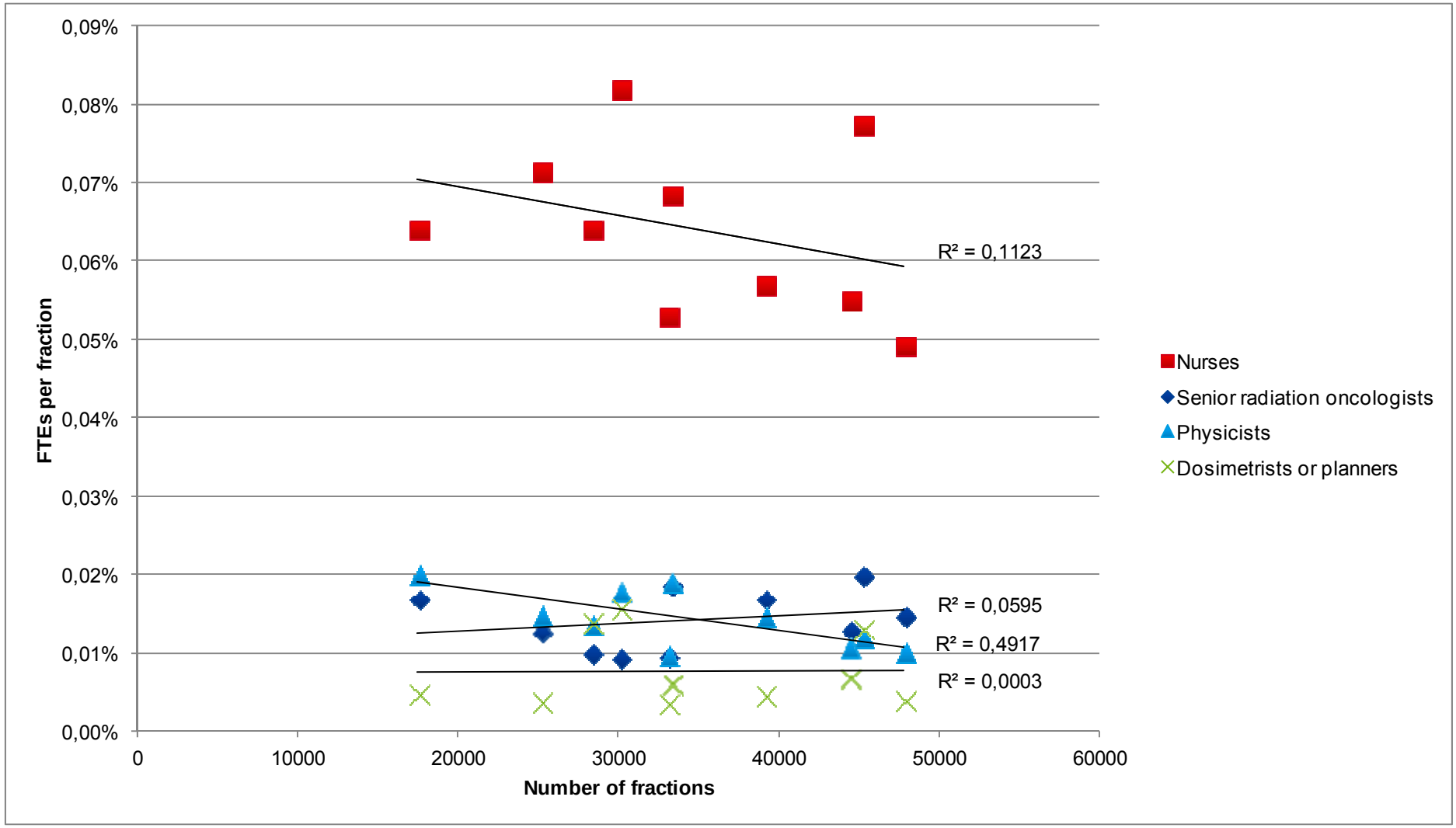


Figure 33 – FTEs-in-scope per fraction as a function of the number of fractions



4 DISCUSSION OF THE RESULTS

To our knowledge this is the first time a time-driven activity-based costing study of radiation therapy is performed in multiple hospitals. We did benefit from the accumulated experience of repeated ABC studies performed at the radiotherapy department of Leuven university hospital.[1, 2]

4.1 The 10 centres and the overall results

The 10 centres studied can be considered representative for the 25 Belgian radiotherapy centres: they included 5 university and 5 non-university centres. One or more satellite centres of 2 university and 2 non-university centres were also included in the study.

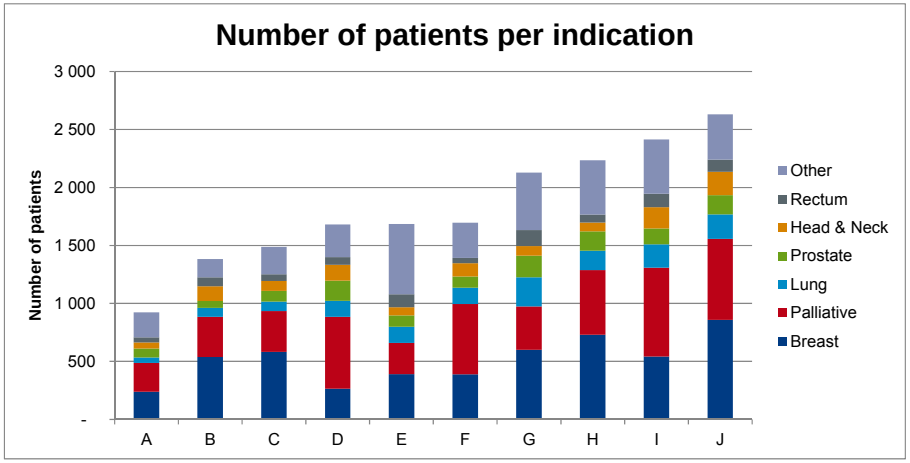
The 10 centres treated in total 18 265 patients per year (2011 or 2012) at a total cost of nearly 78 million euros, or € 4 266 per treatment on average (Table 3). The largest indication group for radiotherapy is breast cancer with 5 133 patients. The proportion of breast cancer patients treated with curative intent varies between 20% and 40% (Figure 5). The indication groups breast, palliative, lung, prostate, head and neck, and rectum account for 80% of all treatments.

The 10 radiotherapy centres studied each have an in-scope yearly cost of 3 to 8 million euros (excluding overhead costs), with in-scope cost for personnel cost varying from 1.8 to 5.2 million euros. This corresponds to 18 to 58 in-scope FTEs per centre. About 60% of the in scope FTEs are nurses, followed by physicists, senior radiation oncologists, dosimetrists and planners, and junior radiation oncologists.

Table 4 – Patients treated and cost of radiotherapy for 10 centres

Treatment group	Average cost	Patients in 10 centres		Total cost in 10 centres	
	(euro)	(N/year)	(%)	(Mio euro)	(%)
Breast	4675	5133	28%	24,0	31%
Head Neck	7153	1131	6%	8,1	10%
Prostate	6995	1250	7%	8,7	11%
Lung	5422	1458	8%	7,9	10%
Rectum	4810	834	5%	4,0	5%
Other	4392	3620	20%	15,9	20%
Palliative	1916	4839	26%	9,3	12%
Overall	4266	18265	100%	77,9	100%

Figure 34 – Yearly number of patients by indication, by centre



4.1.1 General findings

Cost of personnel is 50% higher than the equipment cost in radiotherapy departments

An important finding is that despite the high cost of the equipment used in radiotherapy, the personnel cost is higher than the equipment cost in all centres. On average personnel cost represents 41% of total treatment cost, while equipment cost only represents 27% of the treatment cost. Direct and indirect material costs are relatively insignificant. Overhead accounts for about a third of the total cost per treatment.

Treatment delivery is the most expensive part of the process

Only personnel and equipment costs can be linked to a particular part of the process. Therefore, material and overhead costs are not included in the percentages presented in this section. Depending on the centre, the "treatment delivery" accounts for 57% to 68% of total equipment and personnel costs with the overall average being 63%. This was to be expected as the most expensive pieces of equipment (linear accelerators) are used during this phase. Treatment delivery will typically make up a larger part of the total cost of standard fractionation schemes compared with hypofractionation schemes. However, larger radiation doses delivered per fraction add to the complexity of treatment delivery (more imaging, more QA, more use of IMRT or 4D techniques, more highly qualified personnel present for more time) and longer time slots blocked for the activity.

After "Treatment delivery" the most expensive phases of the process are "First patient contact", "Simulation" and "Planning". "First patient contact" is expensive mostly because it takes up physician time. "Simulation" on the other hand, is expensive due to the cost of the simulator. The cost of "Planning" is high because it can be very time consuming, depending on the degree of software automation.

Resource use and practices vary within and between centres

The 10 centres show important variations in preparation and delivery of radiotherapy. Resource use and practices vary within and between centres. The collected data demonstrate sensitivity of costs to these differences. As up to date internationally accepted quality criteria for radiotherapy may not exist, it is difficult to judge which practices and resource use reflect best practice. Resource use may differ in terms of personnel mix, personnel load and equipment. Tasks are not always performed by the same type of personnel across the centres. At some centres and for some treatments, physicians are present during the complete treatment delivery session, whilst at other centres and for other treatments, they are only present for part of the activity. If we would compare the Belgian situation to the situation in the Netherlands, the differences might even be greater, as e.g. dosimetrists in the Netherlands have a broader role. Further research is needed to determine which option is economically most efficient while assuring high quality radiotherapy.

Costs may also vary within a single centre based on the type of resource used. Generally, multiple treatment machines, verification systems and planning systems are in place. Some have a high level of automation, thus improving efficiency.

Instability of the data and unexpected variations between treatment costs within a centre may occur if only a single time measurement was made for the activity or if only the most commonly used treatment machine is linked to a given treatment. In most centres however, for treatments that could be performed on different linear accelerators (linacs), an average usage rate of the machines concerned was used, thus creating somewhat more robust treatment costs.

Importance of overhead allocation rules

This study was the first to apply the recently published KCE manual of cost studies. We applied the general overhead rate of 56.6% as recommended. However, this approach of a general overhead rate deals with a number of limitations.

First of all, it is a general overhead rate which was calculated for hospital interventions regardless of medical discipline. It is not known to what extent the overhead differs between different medical disciplines with e.g. low versus high equipment intensity (e.g. geriatrics versus radiotherapy), low versus high personnel and physician intensity.

Secondly, final results are very sensitive to the way the overhead is allocated within the radiotherapy department. In the first scenario the total overhead is split over the treatments weighted by the (non-physician) treatment cost. In the second scenario total overhead is allocated weighted 80% per fraction and 20% per patient treated, as this better reflects the overhead activities. However other scenarios are also possible. For instance, it would be possible to take into account not only the number of fractions but also the average duration per fraction. For stereotactic treatments with a low number of fractions, the average length of a fraction is indeed longer and this implies larger overhead costs. Also, if SBRT is used more frequently in the future, fewer fractions in total will absorb the total overhead which will not decrease accordingly. The reality will therefore likely be somewhere in between the two scenarios presented in detail in the full report. In the synthesis we show the average of the results based on the two scenarios.

Importance of fixed versus actual equipment lifetime

We based the number of useful years of the equipment on the actual lifetime with a minimum of 10 years. What would have been the impact on the treatment cost of introducing a fixed lifetime of 10 years for the equipment? When increasing lifetime on all equipment with e.g. 20% (from 10 to 12 years), the total treatment cost decreases by 4.4%. When decreasing the lifetime on all equipment with e.g. 17% (from 12 to 10 years), the total cost increases by 5.4%.

Centres tend to have a mix of linear accelerators with a varying actual lifetime that only rarely exceeds 10 years. Therefore, the overall cost increase associated with the use of a fixed equipment lifetime of 10 years (instead of using the actual lifetime with a minimum of 10 years) was only 1.2%. It was 0 to 1% for 7 centres, 2% for 2 centres and 5% for the one centre with an exceptionally “old” set of linear accelerators.

Out of scope activities

The proportion of the personnel cost that was considered out of scope was much larger at university centres compared with non-university centres. In university centres this out of scope time will likely consist of time spent on teaching and research, including clinical research overlapping with the treatments included in this cost study. However, there are important variations for the fraction “out of scope” between university centres (20% to 44%). We left it to the centres to define the time spent by each personnel type on out of scope activities, without providing specific guidance on where to draw the cut-off line between clinical research and patient care. In hindsight, such guidance might have reduced the between centre variation. Of course, time measurements of all activities of each individual, linked to specific machine use time would have been a possible solution, but difficult to implement within the time and budgetary constraints of this project. A possible consequence of the approach we used is that in centres with a high fraction “out of scope”, the real treatment cost may have been underestimated. On the other hand, it can be assumed that educating junior radiotherapy specialists in university centres increased the time spent per activity and thus the cost.

We limited the measurements of activities to those performed by the radiotherapy department. For radiotherapy treatments that involved some surgical activities (placement of gold markers for some forms of prostate radiotherapy, IORT boost for breast cancer radiotherapy, or IORT APBI), we cannot provide a calculated overall cost per treatment. We have however listed the costs per hour (or half a day) for specific activities of the departments of surgery and pathology.

4.1.2 Cost determinants and efficiency

During this project a large amount of data on the inputs and outputs of radiotherapy were gathered. This data collection served primarily to estimate the cost of treatment, in function of indication, technique, fractionation scheme and type of equipment. This data could however also be used to investigate other determinants of costs, such as efficiency and quality delivered. As the study was not designed for this purpose, only exploratory analyses were conducted. Others have reported general efficiency analyses covering all Flemish radiotherapy departments.[34]

First, we looked at average treatment cost in function of the overall treatment volume (both in terms of number of patients and fractions) at the centre. No clear relationship was observed. Despite the variation between the volume of the centres, one should keep in mind that the centre with the lowest number of patients still treated nearly 1000 patients per year. This could be the cause of the apparent lack of relation between the volume of a centre and it's average treatment cost. Indeed, it has been reported that centres with less than 1 000 patients per year could significantly benefit from volume driven efficiency gains, but that the room for improvement is much smaller in larger centres.[1]

Second, we checked the impact of overall patient volume on FTEs (by personnel type) per patient treated. There is a tendency towards economies of scale for nurses and physicists.

Personnel efficiency

We used average data for personnel and physician cost, thus reducing variation and facilitating a comparison of their efficiency. However, measurement of personnel efficiency is complex as more personnel for an equal output does not necessarily mean lower efficiency. More personnel may imply more quality, more patient information, more mutual consultations, or stricter adherence to the personnel norms etcetera. Fewer personnel may on the other hand be due to understaffing because of an unfilled position. We therefore opted not to focus on simple input-output ratios such as number of FTEs per treatment or fraction. A good way of measuring personnel efficiency is through an idle time analysis, measuring and analysing waiting and other unproductive times. Our analysis however did not include such elements. Nevertheless, we could make a number of observations. A first observation is that the presented personnel cost figures seem to be sensitive to the learning curve. For instance, at some centres, the physician is present during the whole treatment session for the innovative technique(s), whilst for routine techniques this is rarely the case. It is clear that personnel costs of innovative techniques may decrease once the centre progresses further on the learning curve.

The presented personnel cost figures also appear highly sensitive to the type of equipment used. Personnel time needed for fully automated planning systems for instance is considerably lower than for systems requiring more user interventions. High cost sophisticated systems on this other hand may take longer for treatment delivery, further increasing costs, When one examines personnel efficiency, it should thus take into account the type of equipment used as well.

Equipment efficiency

Departments that work with a set of fully compatible machines have an advantage in terms of equipment efficiency over centres which have invested in different brands that are not always compatible. Occupancy rates were estimated for all equipment but not presented in the report as they were based on the same opening hours for all centres and some centres expressed their concerns that the data were therefore not correct. We opted not to adapt the occupancy rate to the individual opening hours of each centre as this would not provide comparable data either. When longer opening hours are combined with higher volume, they may lead to more intensive and thus more efficient use of the equipment. However, longer opening hours may also boost personnel costs as personnel outside the shifts is more expensive and as extra personnel may be needed to ensure the overlap between the shifts. Therefore, it is not easy to determine which centre uses its equipment in the most efficient way. Merely looking at equipment costs does not provide an answer to this question either as low equipment costs may not only be due to high occupancy rate but also to old equipment.

It was not investigated whether smaller satellite centres are less efficient than their main or larger centres. In case the satellite centres were included in the analyses, they were treated in conjunction with the head centre. On one hand it can be expected that the occupancy rate of equipment in small satellite centres is lower than in larger centres as there

are fewer patients, on the other hand often only one type of equipment is installed in the satellite which guarantees use of the available equipment. There may be both economies of scale and diseconomies of diversification. Quality of care should not be forgotten either: is less choice in equipment a limitation to deliver the best possible care or not? In case of satellite centres, physicians sometimes need to commute between centres during the day. The cost linked to this commuting time is estimated to be minimal as centres generally try to limit this time as much as possible by assigning full day work slots in a single centre to the physicians.

Future use of the data set

More analyses of the cost of less common radiotherapy treatments as well as probabilistic sensitivity analyses of specific treatment costs could further contribute to a better understanding of the cost determinants. However, we believe that the study aims have been achieved with the analyses as presented in this report, and that the next steps of the overall RIZIV-INAMI project should not be delayed awaiting further analyses of the very large set of data collected.

4.2 Cost of SBRT compared with other modalities

4.2.1 Focus on the lung

Among the innovative treatments studied, only SBRT of the lung was offered at all 10 participating centres. The number of lung SBRT treatments per centre per year varied between 7 and 73. The number of SBRT treatments in other indications was lower. We compare SBRT of the lung with routine radiotherapy with curative intent for lung cancer. The treatments are grouped based on their fractionation scheme and on the technique used. Three techniques can be distinguished: 3D-CRT (3D), IMRT and SBRT. For 3D and IMRT we can also distinguish between hypofractionation (12 to 20 fractions) and standard fractionation (30 to 35 fractions).

Figure 35 – Cost of lung cancer treatments with curative intent, by technique and fractionation scheme

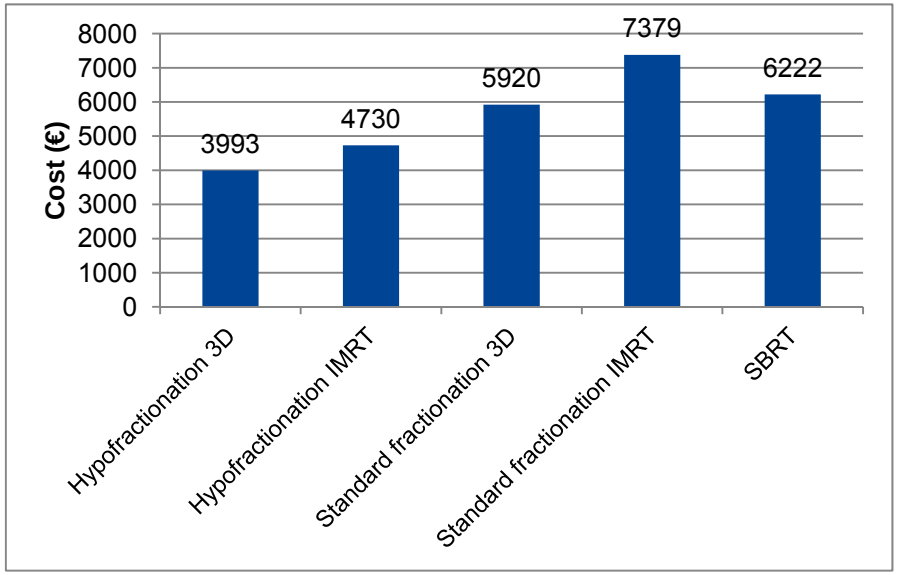


Figure 35 shows the average cost per treatment. Not all centres offer each type of treatment. The average cost of hypofractionation in our sample is lower than that of standard fractionation. The average cost of 3D is lower than that of IMRT. For most types of lung treatments, the results are relatively similar across centres: the range between the minimum and the maximum is relatively small. For SBRT treatments, however, this range is much larger. Costs of SBRT of lung cancer differ significantly by centre, by technique, and by fractionation (Figure 17). Centre and technique are often linked. It is not obvious how to disentangle the various drivers of the SBRT cost: the technique itself; the cost of the system(s) used and its occupancy level; the duration of specific activities and the personnel present, in particular senior radiation oncologists and physicists.

The two highest costs calculated for SBRT had different main drivers. In one case it was a dedicated system (CyberKnife). Some linear accelerator systems used for SBRT indeed have a cost that is higher than that of standard linac systems. High cost SBRT systems include Vero (Brainlab),

CyberKnife (Accuray), Hi-Art (TomoTherapy). The “multipurpose” level of such systems varies but forms an important element in the cost calculation. The cost of radiation treatments delivered using “dedicated“ systems may be higher compared with modified “multipurpose” linear accelerator systems, especially if a low demand results in a low machine occupancy rate of the dedicated system. This has been reported for the dedicated Gamma Knife system for stereotactic brain irradiation, which may be cost competitive only if demand for these services is high enough to fully use the equipment working time.[35]

For the CyberKnife system, and based on our ABC data, the treatment cost was found to be high for three reasons. First the cost of the machine is somewhat higher than the average non-dedicated linac. Second, because it is a dedicated SBRT machine and only few indications are supported by minimal clinical evidence, patients should be selected from a wider catchment area. The CyberKnife machine occupation level is a critical determinant of cost. Increasing the occupation level from the current 30% to 90% would nearly cut the cost in half of SBRT lung delivered in 3 or 5 fractions.

Third, even at full capacity, the CyberKnife technique will remain somewhat more costly compared with other SBRT modalities as the time the machine takes to deliver the treatment dose while tracking the tumour in real time takes longer compared with other systems.

Any clinical benefit of the higher cost of SBRT with a dedicated system over lower cost modalities to deliver SBRT is yet to be demonstrated. If such benefit is demonstrated and if this proves to be cost-effective, centralization of treatments could be justified in a country with short driving distances. Access to the minimum number of patients to build and maintain the necessary expertise may be an even more important reason to centralise complex treatments such as SBRT lung. For decision makers it is not obvious how to select the few centres where such treatments should be centralized. Obligatory high-quality accreditation together with a minimum volume level to build and maintain expertise could be criteria. Centres taking the financial risk of already investing in such techniques already now develop expertise but without any guarantee of being selected later on.

Centralisation is also a must if one wants to offer e.g. hadron therapy in Belgium. The need for centralization in oncology contrasts with the opening of satellite centres to the existing 25 centres for radiotherapy, leading to low patient numbers, and a decrease in specialization with a potential negative impact on quality while increasing costs.

In the second centre with a high cost for SBRT there was a high level of presence of the senior radiation oncologist during lengthy treatment sessions, most probably reflecting an early phase in the learning curve. In both cases costs are expected to drop considerably with increasing volume and experience, respectively. So these costs should not be considered a good basis for reimbursement or research funding in the long term.

The lowest costs for SBRT were found in centres where the time measures for SBRT and IMRT activities were rather similar, as well as the systems used to deliver the irradiation. Low costs driven by a low cost of a set of old linear accelerators or driven by understaffing are not a good basis for reimbursement either.

The average cost of SBRT of the lung (€ 6 222) is very similar to the cost of standard fractioned 3D-CRT of the lung. For a given technique and centre, SBRT of the lung delivered in 3 fractions is less costly compared with SBRT delivered in 7 to 10 fractions. The differences in cost between centres was remarkable and deserve further study, especially as no such major differences were present for more standard treatments.

4.2.2 SBRT of spinal, liver, pancreas, bone and oligometastases

The average cost for SBRT of liver (3 to 10 fractions) and pancreas (10 fractions) were € 5 586 (based on 5 centres) and € 5 341 (2 centres) respectively. This cost is only slightly higher than the overall average of € 4 927 found for the 6 centres that perform treatment of pancreatic cancer in 25 to 30 fractions with 3D-CRT or IMRT.

The cost for SBRT spinal was € 3 573 for 3 fractions, obtained in a single centre only and concerning very few patients. Costs for SBRT of bone were obtained in 2 centres and concern very few patients. The cost varies from € 2 185 for a single fraction to € 8 916 euro for 3 fractions delivered using SBRT with tracking.

Costs for SBRT of oligometastatic disease were obtained in 2 centres, but only a single centre reported to treat over 10 patients per year. The fractionation was 3, 5 and 10 in one centre and 10 in the second centre. The costs were € 3 342 for 3 fractions, € 4 012 for 5 fractions and from € 5 076 for 10 fractions.

4.3 Breast cancer, focus on APBI and IORT boost

When selecting the centres for the cost study, we succeeded to include the three Belgian centres that showed some activity in APBI, but mainly use IORT as a boost. We analysed costs of the different forms of primary breast cancer radiation therapies with curative intent, with the innovation focus on APBI and IORT boost techniques. Schemes including specific irradiation of lymphatic nodes were excluded. Figure 36 shows the average cost of breast irradiation treatments by technique and fractionation scheme.

The cost of MeV electrons and kV photon IORT APBI is rather similar and about half the cost of APBI using brachytherapy.

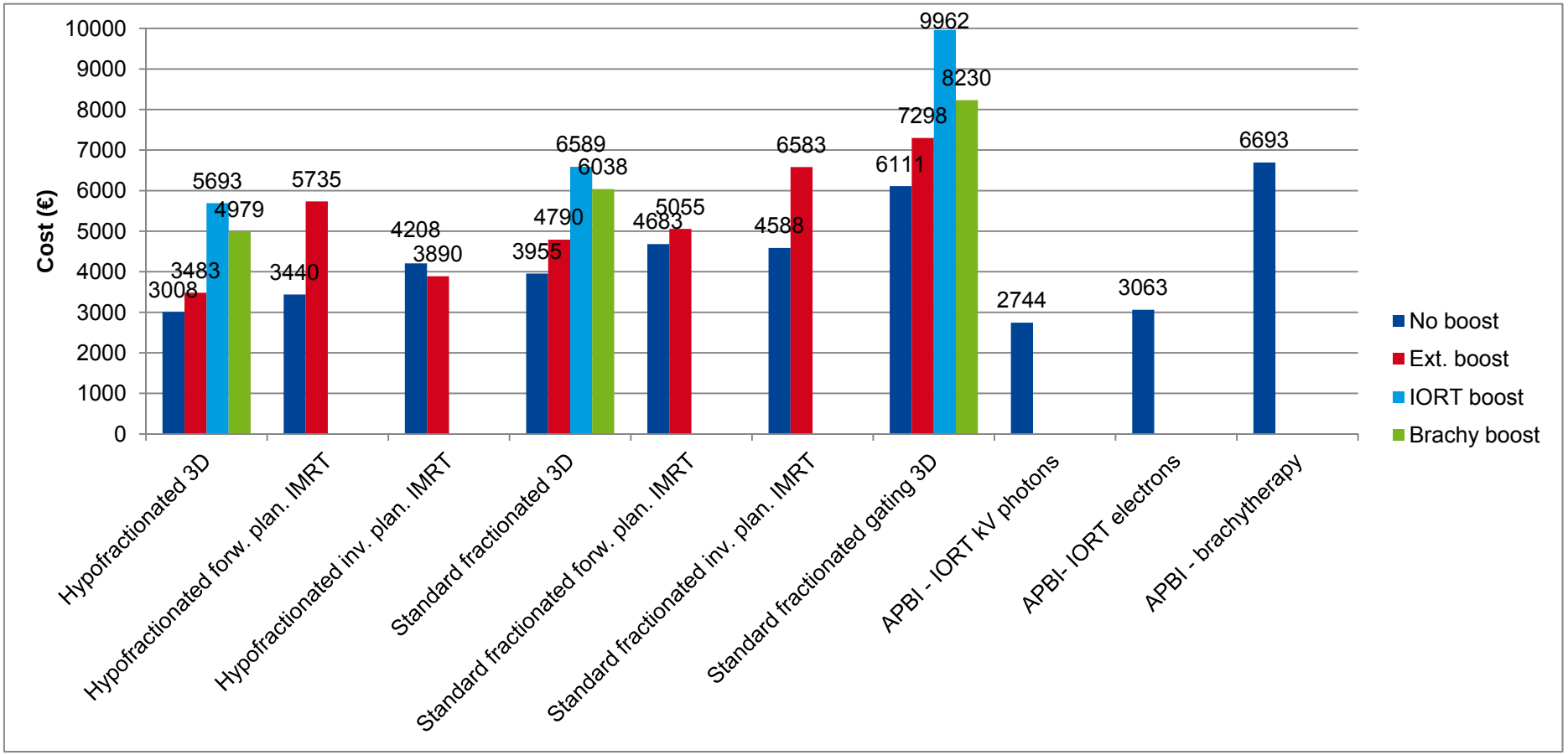
The average cost of intraoperative single fraction APBI delivered as MeV electrons using a mobile linear accelerator system (Mobetron) was € 3 063 and € 2 744 if delivered as kV photons (Intrabeam). The entire procedure of APBI with MeV electrons has been reported to last for about 15 to 20 minutes.[7] Unnecessary radiation to the underlying normal tissue is avoided by mobilizing the mammary gland during surgery and placing a lead plate for shielding on its dorsal surface. This shielding is not needed for APBI with kV photons.

As discussed above, our calculated costs do not include any additional cost of the surgical department. This will depend on the extra time, if any, the surgery will take and should consider the cost of the nurses, the surgeon, the anaesthesiologist, the anatomical pathologist and the (shielded) operating room. Sometimes, IORT can be performed while the surgeon has to wait for the pathology result of the sentinel node, thus not extending the surgery time. Based on the KCE cost manual the direct costs of the operating theatre, anaesthesia and sterilization department can be estimated: € 156 per hour and per nurse present. This cost covers medical equipment, staff except for physicians and drugs, pharmaceutical products and consumables.[27] The cost of a general surgeon, anaesthesiologist and anatomical pathologist is respectively € 363, € 441 and € 458 per half day. On top of the direct costs excluding physicians, the general overhead rate of 56.6% applies. Based on these considerations we can deduce that the additional cost, if any, is relatively low compared to the cost of the radiotherapy itself.

We found a relatively high cost of over € 6 693 for APBI using HDR interstitial multicatheter brachytherapy delivered in 8 fractions of 15-20 minutes over 4 days, starting about 6 weeks after surgery. The cost was measured in a centre where the number of patients treated this way is low. This means that the equipment is not fully utilized and that the resulting cost per patient is very high. All other things being equal, if the number of patients undergoing APBI by brachytherapy in that centre were to increase fourfold, the brachytherapy equipment utilization would still be low and the cost of APBI by brachytherapy would be reduced to € 5 633. The cost is also high because highly qualified specialists (radiation oncologist and physicist) are present during the eight treatment sessions..

Brachytherapy for breast cancer in Belgium is mainly used as a boost after hypo- or standard fractionated WBI. This boost is delivered a few weeks after the end of the WBI. Both HDR and pulsed dose rate (PDR) techniques are used. Placement of 5 up to 12 catheters can be done by the senior radiation oncologist using local anesthesia or with assistance of a surgeon and anesthesiologist under general anesthesia. A correct placement may be guided by clips left in place during the breast surgery. After simulation the patient is placed in a shielded room. HDR brachytherapy using an 0.6 x 3.5 mm Iridium rod and a machine for remote afterloading is performed in 15-20 minutes. The 10-12 Curie source of ^{192}Ir costs € 5 500 (excl. VAT) and needs to be replaced 4 times a year. PDR brachytherapy uses a 1 Curie source with afterloader delivers a total dose of 15 Gy in pulses of 10 minutes per hours for 24 hours. The patient is hospitalized for 1 or 2 nights in a dedicated room. Removing the catheters does not require a general anesthesia. Hospitals invoice isotopes in various ways as described in detail in KCE report no. 79.[32]

Figure 36 – Cost of breast cancer treatments by technique, fractionation and type of boost



Only observed combinations of technique and boost are presented; lymph node irradiation schemes were excluded.

It was not always possible to calculate the exact additional cost of delivering a boost to a specific WBI schedule. Some centres systematically perform a boost so that if we compare the average cost of treatments with boost to the average cost of treatments without boost, we are comparing averages that are based on different sets of centres. Taking this remark into account, the cost of an external beam radiotherapy boost is about € 500 to € 1 500. This additional cost is much lower than the cost of a brachytherapy boost (€ 2 000 to € 2 500 euro), an IORT kV boost (2000 € to € 2500) or an IORT MeV boost (€ 2 500 to € 4 000).

4.4 Cost of other common treatments

The IMRT costs we report here are clearly higher for prostate cancer (€ 7 278 for 33-40 fractions) and head and neck cancer (€ 8 237 for 30-35 fractions) than for IMRT for rectum cancer (€ 4 889 for 25-28 fractions) and standard fractionated WBI (€ 4 587 for 25 fractions). The cost difference can in part be explained by a different fractionation.

IMRT, as an innovative intervention, was the subject of KCE report no 62 published in 2007.[33] No cost study was performed for IMRT at that time. However, the sum of fee for service (article 18), investment costs (A3), operational departmental and point lump sums (B3) was € 5 288 euro for IMRT in 2003. This estimate of the financing is however incomplete as will be discussed in the next section.

In comparison, the cost of a course of 25-28 fractions of 3D-CRT for rectum carcinoma is € 4 465.

Palliative treatments on average cost less compared with radiotherapy with curative intent: € 1 079 (1 fraction), € 1 686 (5 fractions) and € 2 655 (10 to 13 fractions).

4.5 Costs, financing and budget considerations

Breast radiotherapy at large accounts for 28% of the patients treated and 31% of the total radiotherapy costs. The number of patients receiving radiotherapy as a palliative treatment is similar (26%) but these treatments account for only 12% of the total costs.

The average costs of APBI (except using brachytherapy) is lower compared with existing radiotherapy modalities, while IORT as a boost has a higher cost compared with other boost modalities. For lung and pancreas cancer, the cost of SBRT is only slightly higher compared with existing treatments. SBRT is proposed for oligometastatic disease, including vertebral metastases, and liver metastases. Some of these metastases are currently treated with (lower cost) palliative intent radiotherapy, some are currently not treated with radiotherapy. A budget increase will be needed if these additional indications are to be treated with SBRT.

The large overhead rate and the complexity of hospital financing hamper a one-to-one comparison of cost with the current complex financing structure. Radiotherapy specific financing consists of the A3 and B3 components of the hospital financing (BFM-BMF) and the radiotherapy billing codes.

The A3 financing of about € 90 000 per year per linear accelerator is much lower than the real cost. We observed that the cost (including VAT) per linear accelerator, with or without a limited or extended service contract, varies from less than € 250 000 euro per year (if in use for more than 10 years) to over € 500 000 euro per year (for the more expensive linear accelerators with extended service contract). Note that the VAT level of radiotherapy devices is 21% whereas it is only 6% for medicines. It should also be noted that specific financing of linear accelerators, as is the case in Belgium, creates a disadvantage for APBI techniques that are not based on this technique.

As there are no legal allocation keys for allocating the general hospital financing components A1, A2, B1, B4 financing to radiotherapy, no perfect one-to-one match is possible between the presented cost and the financing. For the D-beds linked to the radiotherapy department there is also financing through the BFM-BMF, mainly the B2 part. The investment costs and general care activities for these beds, however, are not included in this cost analysis.

The large variety in treatments administered (in terms of fractionation and dose), treatment strategies used and equipment choices often leads to a large variety in cost results for a single indication. The design of an optimal financing structure poses a big challenge for the national health care payer. Previous research suggests that reimbursement policies influence radiotherapy practice.[36, 37] This has also been reported for the IMRT of breast cancer in the US.[38] Financing should therefore be guided by the real costs of the treatment, as calculated in this study, and designed to encourage the most cost-effective treatment schemes. One should take

care no incentives are created to adjust the technique or fractionation scheme in function of the billing codes instead of the patient's needs.

4.6 Introducing innovations in health care

As mentioned in the introduction radiotherapy equipment has a low regulatory barrier (CE mark) to enter the European market. At market entry there is most often no clear clinical indication that is supported by clinical evidence.[3, 4] Furthermore, new sophisticated radiotherapy machines have a high investment cost.

Costs of interventions (or better their coverage by the health care payer) are an important input for cost-effectiveness analyses. Effectiveness is often derived from RCT based efficacy data, but in the case of novel radiotherapy treatments such data will not be available in the near future. Government and health care payers have to make sure these costly RCTs are conducted, as they provide the high level evidence needed for decision making. Evidence generation outside of a clinical trial context may also be important but is a concept that is not straightforward to implement.

The initial diagnosis of cancer and the treatment plan proposed by the multidisciplinary oncology consultation (MOC) is registered at the Belgian cancer registry. Also an additional MOC may take place each time an important oncology management decision is made. Some radiation oncologists felt that the participation to the MOC is underfinanced. This report does not provide an answer to this question as this activity was out of the scope of this study. The functioning and financing of the MOC meetings is however the subject of another ongoing KCE project.

Another activity, reportedly underfinanced, is the long term patient follow-up visit. Tariffs for follow-up visits are lower for a radiation oncologist compared with a medical oncologist, creating a financing-driven shift of this activity out of the radiotherapy department in some hospitals. Patients referred from other hospitals most often receive follow up after radiotherapy at the referring hospital. This hampers the registration of endpoints such as local disease progression, which is not always the subject of a new MOC that would trigger an additional registration. In addition, long term side-effects of the radiotherapy are often not communicated back to the radiotherapist.

APPENDIXES

APPENDIX 1. RISK CATEGORIES FOR APBI

Table 5 – Risk categories for APBI

	Suitable/Low-risk	Caution/intermediate-risk	Unsuitable/high-risk
Age (years)	≥ 50	> 40-50	≤ 40
BRCA1/2 Mutation	Not present	Not present	Present
Tumour size (cm)	≤ 2	≤ 3	> 3
T stage	pT1-2	T0, pT1-2	pT2-4
Margins (mm)	Negative ≥ 2	Close < 2	Positive
Grade	≤ 2	Any	Any
ER	All (Positive only?)	All	All
Multicentricity	Unicentric	Unicentric	Multicentric
Multifocality	Unifocal	Multifocal (total size 2.1-3.0 cm)	Multifocal (> 3cm total size)
Histology	Invasive ductal, mucinous, tubular, medullary & colloid	Invasive lobular	Any
DCIS	Not allowed	Yes (≤ 3cm)	If >3 cm in size
EIC	Not allowed	Not allowed	Present
Associated LCIS	Allowed	Allowed	/
LVSI	Not allowed	Not allowed (Limited/focal only?)	Present (Extensive?)
N stage	pN0	pN0	pNx, pN1-3
Neoadjuvant	Not allowed	Not allowed	If used

APPENDIX 2. PARTICIPATING CENTRES

Table 6 – List of participating radiotherapy centres

Centre	Any satellite centres	Type of centre	Region
CHU de Liège	Yes, Sart-Tilman, La Citadelle and St-Joseph are included	University	Wallonia
UZ Gent	No	University	Flanders
GZA Sint-Augustinus	Yes, AZ Nikolaas, Sint-Niklaas is included	Non-university	Flanders
UZ Brussel	Yes, ASZ Aalst is included	University	Brussels
Institut Jules Bordet	Yes, but not included in cost study	University	Brussels
UZ Leuven	No	University	Flanders
OLV Aalst	No	Non-university	Flanders
Jessa Ziekenhuis	Yes, ZOL Genk is included	Non-university	Flanders
Jolimont	No	Non-university	Wallonia
Sainte-Elisabeth Namur	Yes, but CH Mouscron not included in cost study	Non-university	Wallonia

APPENDIX 3. ACTIVITIES COMPOSING THE TREATMENTS

The list of activities performed by radiotherapy personnel was determined through interviews with the three (co-)pilot centres. This was an iterative process. A first list of activities was set up, then additional information from the other centres was added, each centre also reviewed the process and provided feedback. After 2 to 3 reviews by each centre, the radiotherapy process was finalized.

Table 7 – External radiotherapy treatment activities

Process step	Sub process
First patient contact	Create and/or fill in patient file (except if done by administrative personnel)
	Intake consultation
	Set appointments (except if done by administrative personnel)
	Medical review
Simulation	Make immobilization system
	Inject contrast product
	Simulation with basic imaging (split into multiple activities for centres with a non-integrated simulator)
	Additional imaging (PET CT, MRI) only if performed by radiotherapy personnel
	Gating preparation
	Treatment prescription
	Administrative tasks (except if performed by administrative personnel)
Delineation	Image fusion
	Target volume delineation
	Indicate organs at risk
Planning	Make radiation plan
	Clinical check radiation plan
	Finalize plan
	Cross control
	Medical review
	Delineation of reference images
	Dosimetrical checks
Secondary simulation for adaptative radiotherapy	Secondary simulation for adaptative radiotherapy
Deliver treatment session	Pre-treatment check and prepare imaging
	Delineation of reference images
	Equipment QA per patient for specific treatments
	Positioning (online matching is included)
	Imaging
	Irradiate patient
	Off-line checks (in vivo dosimetry)
	Off-line checks (matching)
	Evaluation CT
	Regular review patient file
	Consultation
End of treatment	Release patient

Table 8 – Intraoperative radiotherapy (with MeV electrons) treatment activities*

Process step	Sub process
First patient contact	Create and/or fill in patient file (except if done by administrative personnel)
	Intake consultation
	Set appointments (except if done by administrative personnel)
	Medical review
Radiation preparation	Preparation and pre-simulation
Position patient for radiation	Insert applicators
	Prepare to move patient
	Position patient and equipment
	Simulation and calibration of the radiation equipment
Deliver radiation treatment	Irradiate patient
	Quality control
Wrap up radiotherapy	Call anaesthetist and surgical oncologist
	Place patient back and remove equipment
	Equipment sterilization
	Patient administration

**Surgical activities are not included in this list*

Table 9 – Intraoperative radiotherapy (with kV photons) treatment activities*

Process step	Sub process
First patient contact	Create and/or fill in patient file (except if done by administrative personnel)
	Intake consultation
	Set appointments (except if done by administrative personnel)
	Medical review
Radiation preparation	Preparation quality control
	Probe adjustment
	Dynamic offsets test
	PDA source check
	PAICH output check
	Transport X-ray source to operating theatre
	Fixation Intrabeam X-ray source on stand
Preparing patient for radiation	Applicator selection
	Stand preparation and applicator fixation
	Insert applicator
	Dose prescription and verification
Deliver radiation treatment	Irradiate patient
Wrap up radiotherapy	Call anaesthetist and surgical oncologist
	Remove equipment
	Equipment sterilization
	Patient administration

**Surgical activities are not included in this list*

Table 10 – Brachytherapy treatment activities

Process step	Sub process
First patient contact	Create and/or fill in patient file (if done by nurse)
	Intake consultation
	Set appointments (if done by nurse)
	Medical review
	Order single use brachytherapy material (if done by non-administrative, RT personnel)
Operation room procedure	Prepare patient and material
	Anesthetize patient (if done by RT personnel)
	Clinical examination
	Imaging in OR and insert applicator
	Recovery room (if done by RT personnel)
Simulation	Simulation for breast brachytherapy
Delineation	Target volume delineation
	Organs at risk delineation
Planning	Make radiation plan
	Cross control
	Clinical check radiation plan
Treatment delivery	Prepare treatment delivery
	Anesthetize patient (if done by RT personnel)
	Connect patient and give explanations
	Imaging during breast brachytherapy treatment
	Irradiate by breast brachytherapy (time spent by RT personnel)
	End of treatment
	Write and send letter
End of treatment	End of treatment consultation

APPENDIX 4. IN SCOPE ACTIVITIES AND OUT OF SCOPE ACTIVITIES

Table 11 – Activity classification

	CARE related activities			NON-CARE related activities
	RT Patient related activities	**RT support activities**	**Care related, non RT activities**	
In Scope	• All patient related activities from first patient contact to end of treatment if performed by radiotherapy personnel (non-administrative)	• Creating and maintaining the quality system (time spent by RT personnel not funded by the National Cancer Plan) • Quality assurance and maintenance of equipment • Overhead • Staff meetings • Transport between sites (if multiple satellite centres) • Time spent starting up the equipment or closing it down • …		
Out of scope	• Multi-disciplinary consultation (MOC/COM) for RT patients • Follow-up consultations • Time spent on RT patients by non-radiotherapy personnel • Activities performed by personnel funded by the National Cancer Plan (dietician, psychologist, social nurse) except if the social nurse replaces the radiotherapy nurse…	• Activities performed by personnel funded by National Cancer Plan (quality coordinator) • …	• Multi-disciplinary consult (MOC/COM) for non RT patients • Pneumo • Time spent on chemotherapy patients • Time spent on brachytherapy patients (except breast) • …	• Research • Teaching • Self-study • …

APPENDIX 5. PERSONNEL COSTS

Appendix 5.1. Special cases

Some special cases were addressed as follows:

Nurses that partly perform administrative tasks

It was assumed that hospitals register this personnel fully as nursing personnel, not as administrative personnel. Consequently, no part of this cost was considered being included in the overhead. The nurse cost was added fully to the personnel cost.

Physicist with an engineering degree

It was assumed that hospitals register this type of personnel as physicists (function-based instead of degree-based registration). Consequently, their cost was not considered to be part of the overhead cost and it was included in the personnel cost.

Note that some centres make a distinction between engineers and physicist. In these centres, the engineers maintain the equipment and the physicists calculate plans and perform dosimetrical checks (amongst other things). In these cases, the cost of the engineers was not included in the personnel cost (it was assumed to be part of the overhead cost). The cost of the physicists, however, was included.

Logistic employee partly performing nursing tasks

It was assumed that hospitals register this logistic employee as “salaried personnel”. Consequently it was part of overhead and was not added to the personnel cost.

Appendix 5.2. Personnel cost per minute

For personnel other than physicians, the following data from the KCE manual was used in order to calculate the yearly cost per FTE:

- 1605 productive hours per year per FTE
- € 40.16 / productive hour for radiotherapy nurses
- € 37.32 / productive hour for dosimetrists/planners
- € 51.57 / productive hour for physicists

For the junior radiation oncologists in training, the personnel cost was based on their minimum legal salary (€ 20 500*1.5769 (index)), increased by a factor to take into account the employer costs on top of the gross wage (35.4% based on the KCE cost manual).

For senior radiation oncologists, the cost per half day and the number of half days per year from the KCE manual were used:

- 482 productive half days per year per FTE
- € 531.62 per half day

The number of hours per half day was asked to each centre. This is just informative as it does not influence the treatment cost. Indeed, the cost allocation of all personnel types was done as follows:

- Annual cost/FTE = 482 * cost per half day (KCE cost manual)
- Annual cost of the centre = Annual cost/FTE * number of FTEs in scope
- Personnel cost per minute = Annual cost / number of minutes of work by that type of personnel per year
- Where, the number of minutes of work per year is calculated bottom up from the number of patients of each type and the number of minutes per patient.
- Personnel cost per treatment = cost / minute for that type of personnel * number of minutes for that treatment by that type of personnel

The only determining inputs are therefore the cost per half day (provided by the KCE cost manual), the number of half days per year per FTE (provided by the KCE cost manual), the number of FTEs in scope (provided by the centres), the number of minutes of physician work per year (based on the estimations and time measurements in each centre).

Table 12 – Template for calculating the number of FTE in scope

Function	Number of FTE in 2011
Senior radiation oncologists	
Junior radiation oncologists (in training)	
Physicists (equipment QA and maintenance + plan calculations)	
Dosimetrists or planners (only plan calculations)	
Nurses	

Note that personnel financed by research funds were not included.

Table 13 – Template for personnel time allocation

	CARE related activities			NON-CARE related activities
	RT Patient related activities	RT support activities	Care related, non RT activities	
In Scope	____%	____%		
Out of scope	____%	____%	____%	____%

APPENDIX 6. EQUIPMENT COSTS

The cost per hour of each piece of equipment was calculated in the following manner:

Calculating the total annual cost for each type of equipment:

We requested the **purchasing cost** (VAT included) of the equipment. The purchasing cost is the nominal purchasing price from which all discounts have been subtracted. For example, when buying a piece of equipment, the supplier may offer a rebate. Or, even if he does not offer a rebate on the price itself he may offer to finance technicians for some predetermined duration. In this case, the personnel cost borne by the supplier was subtracted from the initial purchasing price of the equipment.

The purchasing cost was **indexed** at a rate of 0%. The option of non-indexation was based on the observation that the price of equipment appeared more dependent on the options taken rather than on the purchase year. The evolution of a number of output price indices were also consulted:

- OECD Output price indices for investment goods for US, UK, JP, IT, DE, FR, Euro area and EU. However these indices were too general ("investment goods") to draw conclusions for radiation equipment.
- Belgian Output price index of the domestic and non-domestic market for the manufacturing of radiation, electromedical and electrotherapeutic equipment (26.60). However this index was too local (Belgian) to draw conclusions for the international suppliers of radiation equipment.

The **yearly cost** was based on the number of years of use. From the information provided by the pilot centres, a good estimation appeared to be 5 years for software equipment and 10 years for all other equipment. However, when the equipment was older than 5 or 10 years, we used its actual age.

We also added the cost of **external maintenance or quality assurance** to the yearly equipment cost.

The cost of **upgrades and updates** was also included in the equipment cost. This was done for all upgrades/updates performed during the lifetime of a machine.

Finally the cost of **equipment related support activities** was also included in the yearly cost.

Equipment related support activities are performed by radiotherapy personnel. They consist of:

- Maintenance activities performed by the centres (e.g. planned preventive maintenance, unplanned breakdowns, …)
- Quality assurance activities performed by the centres
- Starting up and shutting down the equipment

The cost of equipment related support activities is determined by the hourly wage cost of the personnel performing the activities and by the time they spend on these activities.

Note that some machines or software are used for breast brachytherapy treatments as well as for non-breast brachytherapy treatments. In this case, we only allocated part of the total cost of the machine to breast brachytherapy treatments. In order to do so, we requested the percentage of time that the machine is used for in scope treatments (external radiotherapy + breast brachytherapy) and the percentage of time that the machine is used for out of scope treatments. This percentage was then used to calculate the fraction of the equipment cost that should be allocated to the treatments.

Dividing the total annual cost by the number of minutes that the equipment is used per year (bottom-up calculation similar to that of personnel: see appendix 5.2).

Table 14 – Template for equipment costs

Equipment type *	Equipment name	Purchase cost	Purchase year	External maintenance cost (in 2011)	Time spent on equipment related support activities (hours/year)	Function performing the equipment related support	% of time used for external radiotherapy or breast brachytherapy (as opposed to other brachytherapy treatments)
Simulator 1							
Treatment machine 1							
Treatment machine 2							
Verification system							
Dosimetrical equipment 1							
Dosimetrical equipment 2							
Dosimetrical equipment 3							
Dosimetrical equipment 4							
Planning system 1							
Planning system 2							
Positioning device 1							
Positioning device 2							
Imaging equipment							
Stereotactic frames							
Gating modules							

** Note that the list of equipment presented here is an example: each centre provided its own list of equipment.*

APPENDIX 7. MATERIAL COSTS

Indirect material costs include all consumables used in the radiotherapy department that cannot be linked to a specific patient (e.g. bandages, paper for the examination table…). Direct material costs on the other hand only include materials that are used for one specific patient (e.g. masks, markers…).

The following tables (Table 15 and Table 16) show the templates that were used to gather information on the material costs.

Table 15 – Template for indirect material costs

Total indirect material cost in 2011 (incl. VAT)	_____€

Table 16 – Template for direct material costs

Material*	€ per unit (incl. VAT)
Type 1 masks	
Type 2 masks	
Markers	
Other	

* This list is an example: each centre provided its own list of direct materials.

APPENDIX 8. ALLOCATING PERSONNEL AND EQUIPMENT COSTS TO ACTIVITIES

Appendix 8.1. Allocating personnel costs to activities

In order to allocate personnel costs to activities, information concerning the function(s) performing each activity and on the duration of the activity was required. This information was partly measured (for activities with a significant impact on costs) and partly estimated (all other activities).

The templates used to gather this information are shown in figure 37.

Figure 37 – Template used for personnel cost allocation (partly)

Process step	First patient contact																			
Sub process	Create and/or fill in patient file (if done by nurse)					Intake consultation					Set appointments (if done by nurse)					Medical review (time per patient)				
Functions	Senior radiation oncologist	Junior radiation oncologist	Nurse	Physicist	Dosimetrist/Planner	Senior radiation oncologist	Junior radiation oncologist	Nurse	Physicist	Dosimetrist/Planner	Senior radiation oncologist	Junior radiation oncologist	Nurse	Physicist	Dosimetrist/Planner	Senior radiation oncologist	Junior radiation oncologist	Nurse	Physicist	Dosimetrist/Planner
Number of people performing the activity																				
palliative 5 fractions - mask + CT																				
palliative 6 fractions - mask + CT																				
palliative 8 fractions - mask																				
palliative 10 fractions - mask																				
palliative 13 fractions - mask																				
benigne gynaecomasty																				
palliative 2 fractions + mask																				
palliative 5 fractions + mask - CT																				
palliative 10 fractions + mask																				
pancranial 15 fractions																				
brain 3D 28 fractions																				
brain 3D 15 fractions																				
brain 3D 30 fractions																				
pancranial + rachis																				

Appendix 8.2. Assumptions when calculating activity duration

We assumed that the time of a patient related activity is the same for equipment and for personnel. For example, when performing a CT scan, the time that the scanner is used for the patient equals the time that the radiotherapy personnel needs to perform the scan.

In the case where several functions work together on a same activity (e.g. the radiation oncologist is also present for part of the CT scan), we assumed that they are working in parallel (and not sequentially). Therefore, when several functions spend time on a same activity, we calculated the total duration of the activity by taking the maximum of these times. The only exception to this principle is for the activities composing the radiation session (positioning the patient, imaging and irradiating the patient). For these activities we assumed that the time spent by the nursing personnel determines the activity duration.

Appendix 8.3. Time measurement extrapolation analysis

Time measurements were made over a period of 4 weeks in each centre. The technique/indication pair for each activity and for each personnel type was also registered. However, the level of detail of this information varied significantly from centre to centre. Furthermore, during the 4-week period, not all products were measured. Consequently, a number of extrapolations were done by the project team to estimate the missing time data.

Different techniques were grouped for the purpose of these extrapolations:

- 3D conformal radiotherapy (3D-CRT) was grouped with 2D radiotherapy. Boosts with photons or electrons were also classified as 3D.
- Total body irradiation was a separate technique, considered as 3D if no specific values were provided.
- Intensity modulated radiotherapy (IMRT) grouped all types of intensity modulation, including step-and-shoot and sliding window techniques as well as rotational IMRT (Rapid Arc, VMAT and tomotherapy).
- Stereotactic body radiation therapy (SBRT) and brain stereotactic radiotherapy (SRT) were grouped if no specific measurements or estimates by the centre were available. If no specific SBRT or SRT values could be obtained, IMRT values were used instead.
- APBI: time estimates were provided separately by the centre for APBI

Indications were typically grouped by target organ. For breast cancer (as a larger group) the whole breast irradiation indication was considered to be a separate subgroup from boost and radiotherapy that includes lymphatic nodes (subgroup breastN). If no time measurement for an activity was available the value for whole breast irradiation (without lymph nodes) was taken instead.

Pancranial irradiation is categorized separately from brain tumour irradiation.

For the extrapolation of the time measurement results, **activities** were grouped in two categories:

1. Activities for which the time was considered to be determined primarily by the target organ or indication. These include:
   - Simulation activities
   - Image import and fusion
   - Delineation of target volume and organs at risk
2. All other measured activities, including planning and treatment delivery, for which we assumed that the most important determinant of time spent was the technique.

The time measurements were performed for each personnel type: for nurses, physicists, dosimetrist/planner, junior radiation oncologist and senior radiation oncologist. If a given personnel type participated to an activity in less than 5% of the cases, we assumed that they were not involved in the activity at all.

For each centre, for each activity and for each personnel type, the following rules (in a fixed sequence) were followed for calculating the activity duration. As soon as a value was obtained using a given rule the remaining rules were not applied.

	Weighted average of all time measures as indicated					
Activity group	Sequence of rules	Technique group (3D/IMRT vs SBRT/SRT)	Technique subgroup (3D vs IMRT ; SBRT vs SRT	Indication group (brain, pancranial, lung, breast, ..)	Indication subgroup (breast, breastN, boost)	Estimate by centre
Simulation, image import and fusion, delineation of target volume and organs at risk (time assumed to be organ dependent)	1	same	same	same	same	
	2	same	same	same		
	3 (3D, IMRT)	same		same		
	3 (SBRT, SRT)					x
	4 (SBRT, SRT only)	same	same			
	5	same*				
Planning and treatment delivery activities (time assumed to be technique dependent)	1	same	same	same	same	
	2	same	same	same		
	3 (SBRT, SRT)					x
	4	same	same			
	5	same*				

**use IMRT values if no SRT or SBRT data available (highly exceptional)*

As indicated above, if no time measurement was obtained in the centre for the technique/indication/activity/personnel type, the value was obtained as follows:

- For the activities of simulation, image fusion, delineation of target volume and organs at risk (time assumed to be organ dependent):
  - If no time measurement was available for a particular treatment (combination of technique, indication and fractionation), the average of all measurements of non-stereotactic treatment(s) with the **same indication/activity/personnel type** was taken.
  - If this approach was not successful, the average of all measurements from all (non-stereotactic) treatment(s) for the **same activity/personnel type** was taken.
- For stereotactic treatments, the centre was asked for an estimate. If this estimate was not available, other SBRT treatments were used as a proxy for the SBRT treatment with missing values. If no measures for SBRT treatments were available, SRT measurements were used as a proxy (and vice versa).
- For the **planning and treatment delivery activities** without time measurement, the average of all measurements with the **same technique/activity/personnel type** was taken. It was assumed that the technique (e.g. IMRT versus 3D-CRT) rather than the indication or organ was the major determinant of the time spent for planning and delivery.

Again, for stereotactic treatments, the centre was asked for an estimate. If this estimate was not available, other SBRT treatments were used as a proxy for the SBRT treatment with missing values. If no measures for SBRT treatments were available, SRT measurements were used as a proxy (and vice versa).

Appendix 8.4. Allocating equipment costs to activities

In order to allocate equipment costs to activities, information was required concerning:

- the equipment used for each activity.
- the duration of the activity.

The information concerning the activity duration was provided by the same time estimations and measurements as for personnel cost allocation: we assumed that equipment was used for the entire duration of an activity. The information indicating which equipment was used for which activity was provided by each centre through the following templates (Figure 38).

Figure 38 – Templates used for equipment cost allocation (partly)

Process step	First patient contact																																					
Sub process	Create and/or fill in patient file (if done by nurse)															Intake consultation															Set appointments (i							
Functions	Simulator 1	Treatment machine 1	Treatment machine 2	Verification system	Dosimetrical equipment 1	Dosimetrical equipment 2	Dosimetrical equipment 3	Dosimetrical equipment 4	Planning system 1	Planning system 2	Positioning device 1	Positioning device 2	Imaging equipment	Stereotactic frames	Gating modules	Simulator 1	Treatment machine 1	Treatment machine 2	Verification system	Dosimetrical equipment 1	Dosimetrical equipment 2	Dosimetrical equipment 3	Dosimetrical equipment 4	Planning system 1	Planning system 2	Positioning device 1	Positioning device 2	Imaging equipment	Stereotactic frames	Gating modules	Simulator 1	Treatment machine 1	Treatment machine 2	Verification system	Dosimetrical equipment 1	Dosimetrical equipment 2	Dosimetrical equipment 3	Dosimetrical equipment 4
palliative 5 fractions - mask + CT																																						
palliative 6 fractions - mask + CT																																						
palliative 8 fractions - mask																																						
palliative 10 fractions - mask																																						
palliative 13 fractions - mask																																						
benigne gynaecomasty																																						
palliative 2 fractions + mask																																						
palliative 5 fractions + mask - CT																																						
palliative 10 fractions + mask																																						
pancranial 15 fractions																																						

APPENDIX 9. ALLOCATING ACTIVITIES, MATERIALS AND OVERHEAD TO TREATMENTS

In order to allocate activities and direct materials to treatments, we requested the following data from each centre:

1. Activity consumption by each treatment, that is, how often each activity is performed per treatment. This information was gathered using the template shown in figure 39.
2. The consumption of direct material by each treatment. This information was gathered using the template shown in figure 40.

Finally indirect material costs were allocated per fraction and overhead costs were allocated according to the rules explained in paragraph 2.6.2. In order to allocate these costs we needed to know the number of fractions and the number of patients treated by each centre during 2011. This was done by using the template shown in figure 41.

Figure 39 – Template used for collecting information on activity consumption (partly)

Process step	First patient contact				Simulation							Delineation		
Sub process	Create and/or fill in patient file (except if done by	Intake consultation	Set appointments (except if done by administrative	Medical review	Make immobilization system	Inject contrast product	Simulation with basic imaging	Additional imaging (PET CT, MRI) only if performed by	Gating preparation	Treatment prescription	Administrative tasks (except if performed by administrative	Image fusion	Target volume delineation	Organs at risk delineation
palliative 5 fractions - mask + CT														
palliative 6 fractions - mask + CT														
palliative 8 fractions - mask														
palliative 10 fractions - mask														
palliative 13 fractions - mask														
benigne gynaecomasty														
palliative 2 fractions + mask														
palliative 5 fractions + mask - CT														
palliative 10 fractions + mask														
pancranial 15 fractions														

Figure 40 – Templates used for collecting information on direct material consumption (partly)

	Number of units of direct material per patient			
Treatments	Mask type 1	Mask type 2	Marker	...
palliative 5 fractions - mask + CT				
palliative 6 fractions - mask + CT				
palliative 8 fractions - mask				
palliative 10 fractions - mask				
palliative 13 fractions - mask				
benigne gynaecomasty				
palliative 2 fractions + mask				
palliative 5 fractions + mask - CT				
palliative 10 fractions + mask				
pancranial 15 fractions				
brain 3D 28 fractions				
brain 3D 15 fractions				
brain 3D 30 fractions				

Figure 41 – Template for filling in the number of patients and the number of fractions per treatment

Treatments	Number of patients in 2011	Number of fractions in 2011
palliative 5 fractions - mask + CT		
palliative 6 fractions - mask + CT		
palliative 8 fractions - mask		
palliative 10 fractions - mask		
palliative 13 fractions - mask		
benigne gynaecomasty		
palliative 2 fractions + mask		
palliative 5 fractions + mask - CT		
palliative 10 fractions + mask		
pancranial 15 fractions		
brain 3D 28 fractions		
brain 3D 15 fractions		
brain 3D 30 fractions		
pancranial + rachis		
stereotaxy		
breast tangential		

Appendix 9.1. Allocating overhead to treatments

Table 17 – Overhead sub items and hypotheses on most relevant allocation key (patient or fraction)

Overhead subitem	%	Patient/fraction
General; Maintenance and cleaning (except maintenance of medical equipment); Heating; Laundry; Catering and dietetics; Infection control; Mortuary; Mobile emergency unit	25%	fraction
Administrative personnel	25%	patient + fraction
Salaried personnel (labourer, technician, technical or industrial engineer and civil engineer in maintenance)	17%	fraction
Depreciations (except on medical equipment)	13%	
Central nursing personnel (e.g. Infection control unit)	7%	
Central paramedical personnel	2%	
Central scientific personnel (scientific: biochemists, pharmacists, physicists, psychologists, …)	0.6%	
Financial	3%	
Administration	7.5%	patient (+ fraction)

APPENDIX 10. CURRENT RADIOTHERAPY SPECIFIC FINANCING

Appendix 10.1. B3 financing

The B3 financing is supposed to cover the costs of nursing and technical personnel, administrative and general costs, cost of consumables, maintenance cost of the equipment and rooms of the radiotherapy department.

The amount financed is a lump sum in function of the number and type of acts performed by the centre. The number of points are calculated according to the formula Σ number of acts x number of points per act

The number of points per act is as follows:

- simple external radiation sequence from 1 to 10 fractions for a category 1 patient: 1 point (444113-444124)
- simple external radiation sequence from 11 to 35 fractions for a category 2 patient: 2 points (444135-444146)
- complex external radiation sequence for a category 3 patient: 2.5 points (444150-444161)
- complex external radiation sequence for a category 4 patient: 3 points (444172-444183)

The financed B3 budget is as follows: (index 01/07/2005)

points	B3 financing
<1125	226.688 EUR
>1124 points and <1875	294.694 EUR
>1874 and <2625	383.102 EUR
>2624 and < 3375	498.713 EUR
>3374 and <4125	648.327 EUR
>4124 and <4875	841.012 EUR
>4874	further increase of 179,30 EUR per point

Appendix 10.2. A3 financing

The A3 part is supposed to cover the investment costs of the medical equipment of the radiotherapy service. The A3 part depends on the number of linear accelerators in use and on the number of points calculated for the B3 part. The activity determines the maximum number of linear accelerators eligible for financing, but only the number of accelerators in use is entitled to financing. For each radiation machine there is an A3 financing amount of 90000 EUR minus 2150.97 EUR (since January 1st, 2012). Machines can be financed during a period of 10 years after the acquisition of the machine.

points	Number of radiation machines
<1125	1
>1124 points and <1875	2
>1874 and <2625	3
>2624 and < 3375	4
>3374 and <4125	5
>4124 and <4875	6
>4874	An extra radiation machine is calculated for each extra 750 points

Appendix 10.3. Billing codes

Current billing codes are listed in the following Table.

Billing codes
treatment preparation
personalised immobilisation
simulation
second simulation
2D+-planning / calculation ME
3D-planning (standard)
3D-planning (intensive)
individual shielding
treatment delivery
Category 1 (extern simple)
Category 2 (extern complex standard fractionation)
Category 3 (extern complex hypofractionation)
Category 4 (extern complex stereotactic treatment)
Category 5 (simple brachytherapy)
Category 6 (standard brachytherapy)
Category 7 (complex brachytherapy)
image guidance at start
in vivo

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