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REVIEW ARTICLE

Cost calculation: a necessary step towards widespread adoption of advanced radiotherapy technology

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ABSTRACT

Radiotherapy costs are an often underestimated component of the economic assessment of new radiotherapy treatments and technologies. That the radiotherapy budget only consumes a finite part of the total cancer and healthcare budget does not relieve us from our responsibility to balance the extra costs to the additional benefits of new, more advanced, but typically also more expensive treatments we want to deliver. Yet, in contrast to what is the case for oncology drugs, literature evidence remains limited, as well for economic evaluations comparing new radiotherapy interventions as for cost calculation studies. Even more cumbersome, the available costing studies in the field of radiotherapy fail to accurately capture the real costs of our treatments due to the large variation in cost inputs, in scope of the analysis, in costing methodology. And this is not trivial. Accurate resource cost accounting lays the basis for the further steps in health technology assessment leading to radiotherapy investments and reimbursement, at the local, the national and the worldwide level.

In the current paper we review some evidence from the existing costing literature and discuss how such data can be used to support reimbursement setting and investment cases for new radiotherapy equipment and infrastructure.

The amount of money countries annually spend on health care, in absolute figures and in terms of percentage of their Gross Domestic Product (GDP), has drastically increased over the past decades, rising from 7.3% in 2000 to 9.2% in 2009. Yet, as a consequence of the economic crisis of 2008, the cost curve has started to bend in almost all European countries. Even while the latest OECD health statistics report shows that health spending has recently started to rise again, the pace of growth remains well below pre-crisis rates, especially in Europe [1].

This relative decrease of the healthcare budget has prompted an even higher scrutiny with which healthcare authorities and insurers are evaluating the value for money of new treatments and technologies. Even if the estimated 5% share of the radiotherapy budget in the total oncology budget is modest [2], particularly when considering that on average more than half of all newly diagnosed cancer patients will require radiotherapy in the course of their disease [3,4], resource limitations and tightening budgets make choices on how and where to spend societies' money unavoidable.

Health economic evaluation – weighing the incremental cost to the incremental effect of a new intervention compared to the current standard of care – is the established methodology that supports decision making on assigning the limited resources to different treatments and diseases. Whereas health technology assessment institutions have widely adopted economic evaluations for pharmaceuticals in cancer care, economic analyses for other types of anti-cancer interventions, including radiotherapy and surgery, are far less common. In a recently published systematic literature review, Barbieri et al. found only 29 studies that satisfied their criteria for economic evaluation of radiotherapy applied to breast, prostate, colorectal, cervical and head and neck cancer [5]. Even more worrisome, among these studies, the majority was not able to fulfill all

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methodological criteria requested from a state-of-the-art economic evaluation.

This is in part related to the fact that health authorities are only starting to request cost-effectiveness evidence prior to funding technical innovations in radiation oncology. However, the problem also relates to the typical incremental evolution of these, and other, technologies. Although clinical benefit is expected on the basis of superior biological and physical characteristics, translating into better dosimetric profiles, data for clinical effectiveness of new radiotherapy techniques are scarce and often only become apparent many years after treatment. This makes it hard to collect formal level I evidence [6]. On the other side of the equation, this step-wise evolution, the need to distribute the high investment costs over many years and numerous treatments and the progressive technical modifications taking place over time render cost calculation difficult to pursue as well.

However, regardless of these considerations, a comprehensive economic assessment – both evaluating the cost-effectiveness and the likely impact on the national, regional or local healthcare budgets – is now becoming more frequently mandatory before accepting a new technology on the market and into the reimbursement system [7]. Accurate cost data are a crucial first step in this evaluation. In the following we will discuss how radiotherapy costs can be obtained and how these data not only support the introduction of new and promising radiotherapy techniques and technologies, but can as well ascertain access to radiotherapy in the broader sense.

What do we know about radiotherapy costs?

As mentioned, the existing data suggest that radiotherapy consumes roughly 5% of the total cancer care budget [2]. Unfortunately, more formal and recent data to support this are lacking. In contrast to this, the cost of radiotherapy is often, incorrectly, perceived as being high due to the technologically intense environment requiring significant upfront financial investment in equipment and buildings. However, one should realize that radiotherapy is also labor-intensive, which is deemed to translate into high personnel costs. In an analysis of the limited radiotherapy costing literature available in 2008, Ploquin and Dunscombe demonstrated that in high-income countries human resources consume about 50–60% of the total radiotherapy costs, compared to equipment being limited to about one third of the costs [8]. Based on the latest four studies included in their study, all performed at the turn of the century, the authors calculated the cost of a 21-fraction course of radiation therapy at 3.239€ ± 566€ with an annual increase in radiotherapy cost per patient of about 5.5%.

One can easily understand that radiotherapy costs tend to evolve with time: more complex treatment strategies typically require more time, hence more dedicated personnel and equipment. The Leuven radiotherapy department compared its costs between 2000 and 2009. The increase in average treatment cost was 34%, which is, interestingly, well in line with the overall evolution in healthcare expenses in Belgium at the time. However, analyzing the data into more detail, cost increases were most obvious for complex treatments, such as intensity-modulated radiotherapy (IMRT), which had been recently introduced, costing up to 88% more than conformal approaches. The cost increases were clearly related to the higher resource demands of these novel treatment approaches, especially for quality assurance, such as image guidance [9].

Similar correlations between treatment complexity and higher costs were also observed in the cost calculation project of the Belgian Health Care Knowledge Centre (KCE), carried out in 10 operational radiotherapy centres. However, other factors such as hypofractionation and more optimal resource use were conversely identified to have a positive impact on the costs [10,11]. In this era of rapidly evolving technology, paralleled with increasing automation and shortening fractionation schedules, it is difficult to make firm a priori assumptions on how the interplay of different factors will impact on the actual costs.

In need of a standardized costing methodology

Another, more theoretical problem that arises when analyzing radiotherapy costs, is the lack of a standardized methodology. This was already observed in the review paper of Ploquin and Dunscombe, but is even more striking in the ongoing systematic literature review performed in ESTRO's Health Economics in Radiation Oncology (HERO) project [12]. This systematic review objectivises a large variation in type and source of cost inputs, in scope of the analysis and in costing methodology used [13]. This makes it hard, or even impossible, to derive valid overall conclusions on the actual cost of radiotherapy treatments. Such problems are not uncommon in healthcare cost accounting: according to Kaplan and Porter "the biggest problem with health care is that we are measuring the wrong things the wrong way". We can therefore not overestimate the necessity to accurately measure the costs, before embarking on the comparison with treatment outcome [14].

Any accurate costing system should account for the total costs of all resources used by a patient as he or she migrates through the treatment process. Grossly speaking, two validated cost accounting methods have been frequently used in radiotherapy costing: micro-costing (MC) and (time-driven) activity-based costing (TD-ABC).

MC uses very detailed unit estimates of consumed resources, typically obtained from time-and-motion studies, to compute the cost in a bottom-up approach. It provides a thorough insight into a well defined radiotherapy treatment or activity, but, due to its precision and focus, tends to disregard the overall picture.

TD-ABC, on the contrary, combines a bottom-up and top-down approach to allocate the indirect radiotherapy resource costs, such as personnel, equipment, buildings and overhead, to the radiotherapy treatments. It does so by using an intermediary allocation step of the resources to the radiotherapy activities, followed by allocating activity costs to the treatments. In other words: activities consume resources to produce treatments. ABC was developed in the manufacturing industry of the 1980s to optimize cost calculation in case of high product complexity and diversity [15]. As such, it has also been found well suited to obtain insight in radiotherapy treatment costs, to capture the impact of different activities performed in the radiotherapy process, to evaluate resource consumption and possible productivity improvements and to evaluate radiotherapy costs over time [9,16].

Kaplan and Porter have suggested TD-ABC to be the answer to the methodological shortcomings encountered in nowadays' healthcare cost accounting [14].

It's always too early...

Another concern, which is inherently linked to the incremental nature of technology evolution, is that it is difficult to define the correct timing to calculate the costs. As Martin Buxton said in the law named after him: "It is always too early to evaluate a technology, until, suddenly it is too late".

The level of resource use is known to be related to the time frame in which the measurement is performed, e.g. the introduction phase of a new technology. The learning phase typically entails higher costs, whereas these tend to come down once the technology has been fully implemented. A French study analyzed the impact of learning effects in the case of IMRT. Costs were assessed from the perspective of the healthcare providers and compared to the reimbursement. Learning effects explained 42% of the variance between centers, and there was a substantial decrease in treatment costs after the implementation phase. The mean treatment cost was 6.332€ in centers with a previous experience of IMRT, compared to 14.192€ in centers implementing IMRT for the first time. As a matter of comparison, the reimbursement was 6.987€ [17].

So when should radiotherapy costs be calculated, and by whom? The industry seldom invests in performing cost calculation or economic evaluation studies. To date, a new radiotherapy machine, e.g. must be able to deliver radiation, and precisely and safely do so. However, no indication-specific proof of (cost)-effectiveness is requested before market launch. In contrast to the situation in cancer drugs, which typically undergo the entire effectiveness and economic evaluation cycle prior to market introduction and reimbursement, the risk of investment and the burden of clinical and economic evaluation typically rest on the shoulders of the radiotherapy healthcare providers. Due to the delayed initiation of evidence generation, (if any) typically performed by the radiation oncology professionals after investment in new equipment is done, formal reimbursement often arrives late in the life cycle of a new technology, with the risk of becoming obsolete shortly thereafter as newer technologies emerge. The differences between drugs and technologies, in timing of evidence generation, in responsibilities and in financial endorsement of new treatments, are illustrated in Figure 1.

Reimbursement setting, a challenging problem

In addition to the impact of the learning phase, other factors induce variations in computed costs that do not always reflect justified variations in resource use.

One is the suboptimal use of expensive resources as observed in the example of radiosurgery in Australia: assuming the dedicated use of a Gamma Knife or a linear accelerator to deliver 150 radiosurgical interventions annually resulted in an incremental cost for the former of only AU$209 (approximately 148€) per patient. However, in a scenario where the linear accelerator would be used to full capacity by allowing other treatments, the extra cost per Gamma Knife treatment would increase to AU$1.673 (1.182€) [18]. Similar observations were made for SBRT delivered with the CyberKnife compared to standard linacs in Belgium [10,11]. Regardless of the necessity to build and maintain expertise to ensure high quality in complex radiotherapy treatments, more centralization with access of a minimum number of patients will have a positive effect on the costs.

Similar to other situations with high investment costs, economies of scale indeed have an impact on radiotherapy costs, as some resources (e.g. simulators) will have a higher share in the individual

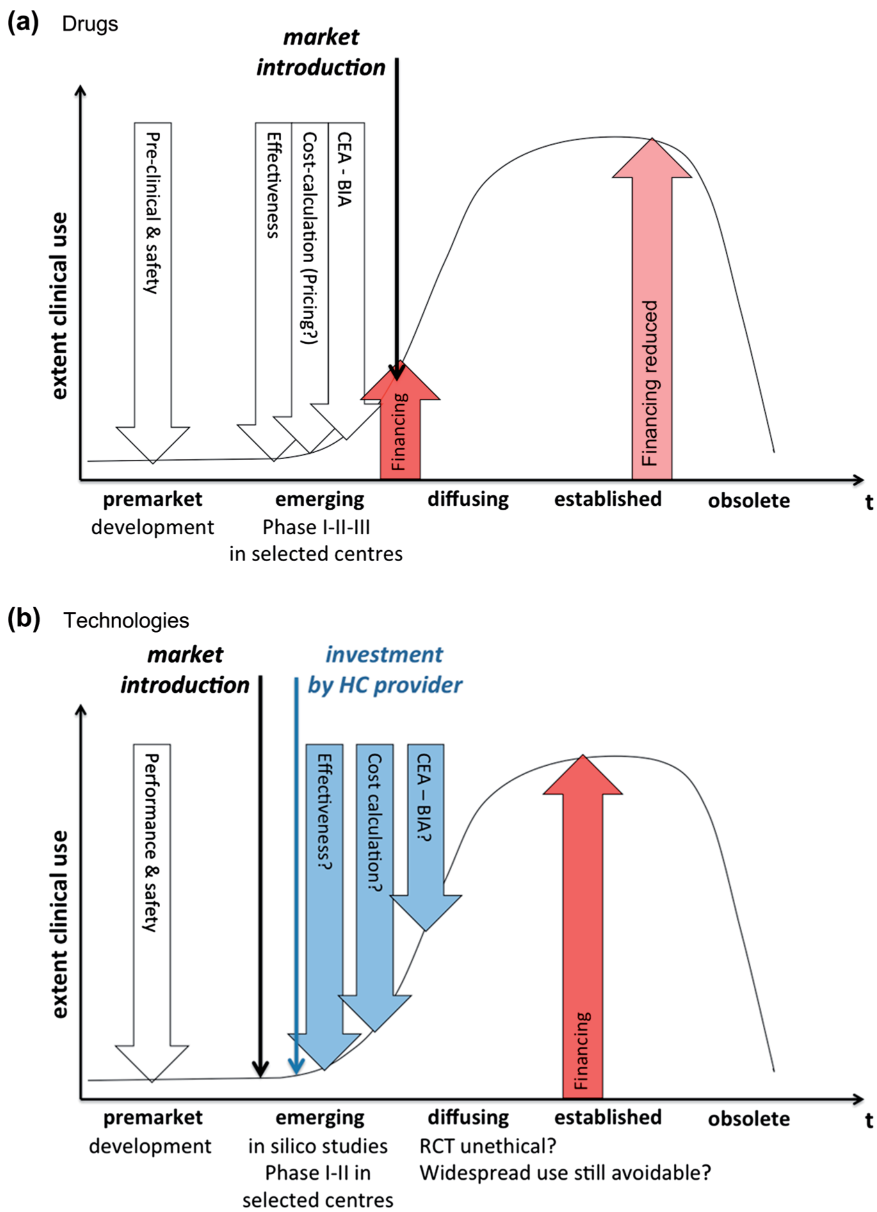

Figure 1. Product life cycle: differences between drugs and technologies in timing of evidence generation, in responsibilities and in financial endorsement of new treatments. Responsibilities of the industry are shown in black/white; responsibilities of (radiation oncology) health care providers are shown in blue. BIA, business impact analysis; CEA, cost-effectiveness evaluation.

treatment cost in small departments. Analyzing the costs in function of varying facility size, it was found that the cost in a facility treating less than 1600 patients per year started to rise, culminating in a 50% higher cost in departments treating less than 400 patients annually [19]. Comparable observations as these made in Canada, were found in Belgium, be it with a lower cut-off point of about 1000 patients per annum [20]. The differences amongst jurisdictions can be explained by the specific legal requirements regarding radiotherapy resource availability.

The above examples clearly demonstrate that, in contrast to what is often believed, real life treatment costs are not at all constant: they vary with time, practice, productivity, department size and costs of resources. In order to avoid undesired incentives towards inadequate utilization or reduced quality of care in case of over- or underfinancing, charges billed or reimbursements paid should ideally reflect the actual costs made to deliver state-of-the-art radiotherapy. However, this is rarely the case, as it is difficult to develop a reimbursement system that accurately grasps the variability in resource costs by type of treatment and is moreover flexible enough to adjust for the technological evolution over time [21].

In the absence of level I evidence, the Belgian obligatory health insurance did not yet accept SBRT for reimbursement. However, in order not to withhold patients from receiving this promising new technology, a coverage with evidence development project was launched for innovative radiotherapy treatments, with a special focus on SBRT. The appropriate financing level in this project was defined using real-life cost data obtained from a comprehensive TD-ABC program of standard and innovative radiotherapy treatments. In this study, the overall average cost of SBRT for lung cancer (6.221€) was in the same range as that of standard fractionated three-dimensional conformal radiotherapy (3D-CRT) and IMRT (5.919€, res. 7.379€). But the inter-center cost variation was much larger, reflecting the use of different technologies, variation in resource utilization and stages in the learning curve (Figure 2) [10,11].

How should one then decide upon an appropriate and fair financing level? Neither the most advanced technique with the highest cost, nor the cheapest approach, potentially mirroring understaffing, less appropriate equipment and/or quality levels, are good bases for reimbursement setting. In this project, the provisional financing was determined close to the average cost. In return for coverage, the radiotherapy centers commit themselves to evidence collection in collaboration with the Belgian cancer registry, with the aim to collect real-life data on indications, techniques, practice patterns and outcome, as well as on budgetary impact. This useful post-market information is expected to ultimately translate into a formal reimbursement scheme for those indications that continue to show value. However, additionally, the cost calculation program collected an invaluable amount of cost data of a wide range of radiotherapy treatments, data that can further be used to recalibrate the currently outdated reimbursement system to the actual state-of-the-art [10].

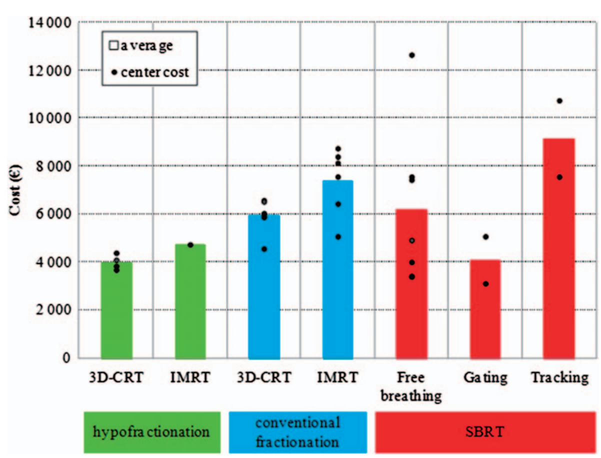

Figure 2. Average costs of standard fractionated radiotherapy, hypofractionated radiotherapy and stereotactic body radiotherapy in lung cancer, per center and for all 10 evaluated centers.

The bigger picture: investing in Hadrons... and the world

If it is already difficult to argument for financing new technologies embedded in existing radiotherapy services, where the investment and development costs are somehow buffered by the entire departmental operation, it becomes all the more difficult to make a case for new, high-cost facilities, requiring substantial initial investment in infrastructure and training of dedicated personnel. Hadron therapy centers are the archetypical example.

In the real-life studies shown previously, the costs were calculated at a certain time point for fully operational radiotherapy centers. To analyze the financial implications of setting up a facility over time, however, different periods have to be taken into account: a building and commissioning phase where investments are made and initial personnel is trained, a ramp-up phase after start-up of the facility in which progressively more patients are treated and more personnel is hired, and a final phase at full operation. To model the financial implications of such a phased introduction of new technology, another costing approach is necessary. In the context of a feasibility study for a Belgian Hadron Therapy Center, both the treatment cost and the required reimbursement were modeled with a business model (BM) and compared to TD-ABC, considering different technical solutions, patient populations and financing methods. Both calculation models were shown to be valid and provide different, yet complementary perspectives on the cost of Hadron therapy [22]. In addition to the TD-ABC cost information calculated for a center in steady state of operation, the BM shed light on the long-term consequences of the initial investments and training, typically requiring important loans. Disregarding the impact of the latter, average TD-ABC costs (range: 16.059€–46.443€) were 10–15% lower than those calculated with the BM (range: 18.400€–51.200€). Moreover, the BM demonstrated that these projects with high up-front investments are extremely sensitive to delays in commissioning and varying interest rates. Such information is important to aid healthcare policy makers in their decisions regarding the appropriateness of financial investments and the choice for specific technical solutions, accounting for the socio-economic situation of the country and the patient populations to be served.

A yet bigger challenge is to optimize access to radiotherapy worldwide. While even in Europe large variation exists in access to radiotherapy services [23], the situation is clearly dramatic in low- and middle-income countries. About 57% of the total number of cancer cases occur in these countries, but up to more than 50% of all cancer patients lack access to treatment in middle-income countries, whereas this proportion is more than 90% in low-income countries [24]. Given the many other health-care challenges these countries are facing and their competing demands for healthcare resources, to advocate for investing in radiotherapy is a difficult undertaking. Under the auspices of the Union for International Cancer Control (UICC), a Global Task Force on Radiotherapy for Cancer Control has been set up with the aim to support such an investment case for global access to radiotherapy. In collaboration with key organizations, such as ESTRO, CARO, CCORE, IAEA and AAPM, the benefits of optimal access to radiotherapy are defined and the required investment and operational costs to make this happen, computed. By balancing benefits and costs, the opportunity for investing in radiotherapy is being documented and articulated. The final aim of this project is to support those responsible for investing in making sound and validated decisions so that radiotherapy can take up its central role in effective cancer control plans to the benefit of millions of cancer patients worldwide [25].

In conclusion, although there remain many uncertainties and methodological issues to tackle in the costing of radiotherapy treatments and services, it is clear that we cannot escape from our responsibilities. Accurate cost accounting is a first and unavoidable step paving the way for economic evaluations, reimbursement setting and investment frameworks for radiotherapy. The Health Economics in Radiation Oncology (HERO) project of the European Society for Radiotherapy and Oncology has the overall aim to develop a knowledge base and a model for health economic evaluation of radiation treatments at the European level [12]. To accomplish these objectives, the HERO project already addressed radiotherapy availability and needs in Europe, in close collaboration with the European National Societies of radiotherapy. The results of these first two work packages have demonstrated a large variation in radiotherapy recommendations and available resources, departments, equipment and staffing [26–28], as well as of the optimal utilization proportion of external beam radiotherapy by country [4,29]. The next step is to build further on these data by developing a cost-calculation model for radiotherapy, tailored towards the European country level. It is projected that accurate and country-based information on the cost of radiotherapy indications and techniques will facilitate reimbursement negotiations, provide budgetary estimates for radiotherapy optimization in various jurisdictions and support the evaluation of value for money of radiotherapy. As such, it will represent yet another building block reinforcing the development of effective cancer plans in Europe [30].

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