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Original article

Economic data for particle therapy: Dealing with different needs in a heterogeneous landscape

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ABSTRACT

Background: In the light of scarce resources to be allocated for cancer care and a steady stream of costly innovations in all modalities applied to treat cancer, particle therapy needs to demonstrate its cost-utility balance to allow its positioning in the context of competing modalities. In the continuous evolving particle therapy landscape, the timely availability of appropriate economic data is crucial.
Methods: Economic data collection and compilation for particle therapy needs to follow health economic standards. Costing related analyses particularly need attention as clinical outcome data follow international standards to provide comparability. Among others, perspective, time horizons and cost categories are critical.
Results: In this report from the "Health Economics Work Package" of the European Particle Therapy Network, the approaches commonly applied in health economic assessments are described and tailored to the specific needs of particle therapy. Data collection for cost calculation, economic evaluation and budget impact analysis are discussed.
Conclusion: The presented data are intended to serve as a guidance for economic data collection, bearing in mind that in each specific case, the heterogeneous requirements of national health systems will need to be considered and assessments adapted accordingly.

The incessant growth in healthcare spending, outpacing the contributions from income growth in many countries, is putting the healthcare budgets under permanent pressure [1]. Especially in high-income countries, health expenditure on cancer care represents a major challenge. In the European Union, for example, expenses on cancer more than doubled during the past two decades, amounting to €83.2 billion in 2014 [2]. Besides the budget of cancer drugs, recently under high scrutiny, the rapid diffusion of new technologies has since long been recognized as an important cost-driver of increasing healthcare costs [3,4]. In a situation of limited budgets, weighing costs and outcomes has become a standard approach to guide the decision-making on new healthcare interventions. Before introduction and implementation in clinical care, new treatments or technologies do not only have to prove that they outperform the actual standards of care in terms of clinical benefit for the patient, they also need to prove that the additional resources invested – and costs made – are well spend.

Particle therapy is a typical example of a financially demanding technology. It has been the topic of hefty debates based on uncertainty about its impact on patients' outcome as well as cost. Although the technology is not new, until recently its availability for clinical use remained limited, which in part may explain the limited amount of high-level clinical evidence. In addition, economic data are equally sparse. Yet, with a complexity deemed to translate into higher investment and operational costs in comparison to photon beam radiotherapy, it is crucial from a departmental and societal point of view to define whether the investment is worthwhile, whether and for which patients it is cost-effective, and what is the expected impact on the budget.

The recent technological advances and development of turn-key facilities has sparked the rise of particle therapy centers across Europe, many of which have recently started operation, while others are in the planning or building phase with operation foreseen in the years to come. Recognizing the enormous challenge and opportunity this brings to produce the long-awaited clinical and economic evidence; the vast majority of European particle centers have gathered under the umbrella of the European Particle Therapy Network (EPTN). The goal of EPTN, since May 2017 endorsed as a Task Force of the European Society for Radiotherapy and Oncology, is to contribute to a better understanding of the value of particle therapy as a radiotherapy modality in the context of usual radiotherapy care.

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In this report from EPTN-WP 7 on health economics, we discuss what data are required to demonstrate the sustainability of particle therapy from an economic perspective. Although it is well-understood that economic data should go hand in hand with information on clinical outcome to allow healthcare decision-making, this paper will focus on the former, discussing the costs, cost-effectiveness and budget impact of particle therapy.

Economic data in a heterogeneous landscape

In addition to the seventeen particle centers in operation in Europe to date – displaying a variable profile in terms of numbers and types of patients served, in technical capabilities, in operational parameters – nineteen particle projects are currently in planning or under construction [5,6]. Departments at different stages of implementation and operation do not only need different economic data to support investment and operation, but will also be able to generate other types of economic results. In addition, particle treatments and technologies are constantly evolving, sometimes stepwise (e.g. introduction of scattered beams or new modes of image guidance), but most often, as is typically the case in radiotherapy, incrementally [7]. In parallel, clinical indications for particle therapy are also changing. Although some 'standard indications' have historically been put forward (e.g. pediatric or base of scull tumors), it is now more widely accepted that the clinical benefit of particle therapy may be highly dependent on specific patient and tumor characteristics.

Bearing this in mind, economic data collection and analysis will require the flexibility to continuously adapt to the evolving technological capabilities and the patient population served, which will both impact on investment and operational parameters. In addition, the accuracy of the economic data collected will be dependent on the implementation phase of the particle center. Three subsequent phases can be defined: the planning phase, the preparatory phase and the operational phase.

In contrast to the situation of photon beam therapy in high-income countries, where questions regarding investment are often related to renewing, upgrading or expanding existing capacity, particle therapy centers typically start de novo. This means that the clinical need and economic feasibility and sustainability of a particle project in a certain region or country has to be evaluated in order to motivate financial investment and allow discussions on potential reimbursement. Economic data supporting such *planning phase* often have to rely on estimates from experts and from other projects, hence early-stage cost and economic modeling – and related decision-making – may have to deal with a lot of uncertainty [8]. After approval of the project, in the *preparatory phase,* encompassing building of the premises, training of the personnel and commissioning of the equipment, uncertainties about investment costs and initial timing will decrease. As a consequence, prior assumptions may have to be adapted to the actual reality, potentially translating into a different cost picture. It is only in the *operational phase* that real-life data on patient population treated and operational parameters will become available. Yet even here, an evolution of these parameters is expected between the start of operation and operation at full capacity, with impact on the costs, and consequently, cost-effectiveness.

Costs

Failure to gain reliable information on what it costs to deliver patient care has been put forward as one of the causes of the actual healthcare crisis [9]. Radiotherapy does not make an exception to this general observation: accurate radiotherapy resource costs are scarce. In addition, the vast heterogeneity in the methodologies used, the inputs included and the outputs reported makes it hard to derive formal conclusions and calls for the development of a well-defined and generally accepted cost accounting methodology for radiotherapy [10].

Pragmatically, reimbursement figures or charges are frequently (mis)used as a proxy for real costs, where on the contrary, the very costs should inform negotiations on reimbursement levels [10]. Indeed, ideally reimbursement should reflect the resource costs incurred, in other words, the quantity and quality of resources consumed for a treatment or intervention. Defining reimbursement in such a manner is however hard to accomplish, also in radiotherapy, as it requires continuous alignment to real cost data, which again should truthfully adapt to the changes in resource consumption and to the incremental nature of the radiotherapy progress [11]. In such a context of uncertainty, it may be preferable to implement provisional financing systems that support the broader generation of clinical and economic evidence, commonly referred to as 'coverage with evidence development' programs [7,12].

Conventional cost accounting methods, such as micro-costing (MC) and activity-based costing (ABC), have been strongly recommended to generate accurate cost data, indispensable to correctly inform healthcare decision-making [9,10]. Both methodologies provide the required insight into the resource costs of new and changing healthcare interventions [13].

MC is an analytical bottom-up costing method that combines detailed data on the resources utilized with their unit costs. It is especially useful to gain understanding about the cost of very specific treatment strategies or process steps [14,15]. It is, however, too complex to calculate costs in a wider perspective, such as the cost of new treatments or technologies against the background of entire radiotherapy departments or countries.

ABC assigns resource costs to the treatments via the process steps performed during treatment. Originally developed to better allocate indirect costs and to better capture the impact of product diversity in the manufacturing industry, it has been introduced in healthcare in the early years 2000. More recently, the original ABC, rather complex to develop and maintain, further evolved into time-driven activity-based costing (TD-ABC), which only requires knowledge on two parameters at each process step: the cost of each of the resources used and the quantity of time the patient spends with each of these resources. TD-ABC studies have been performed to calculate the cost of particle and photon beam radiotherapy, differentiating among specific indications, operational models and technical scenario's [8,16–22]. It is also the methodology adopted by the ESTRO Health Economics in Radiation Oncology project [23].

Various costing models have been used to evaluate the impact of different cost inputs (e.g. equipment costs or salaries), different patient population mixes, different operational parameters (e.g. treatment times or fractionation schedules) [8,22,24,25]. The impact of fractionation, however, is best appreciated using TD-ABC: non-conventional costing models typically make the simple assumption that the entire treatment cost scales linearly with the number of fractions, whereas the relative impact of other costs, of treatment preparation or quality assurance, for example, are well-known to increase with decreasing fraction number [8,25]. Cost accounting models can factor in some degree of time-bound factors, e.g. equipment cost can be depreciated over its estimated life-time, hence define the annual amortization costs. However, although cost calculations can be performed at any stage of implementation of a project, they typically assume a steady state, that is, costs are calculated at a certain point in time, most often full operation. As a result, they are less well suited to investigate the impact of delays in the preparatory phases of project implementation.

Financial business models (BM), on the contrary, will factor in the required time for and potential delays in different project

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