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Review Article

Innovation, value and reimbursement in radiation and complex surgical oncology: Time to rethink

Josep M. Borras [a,b,c,*], Julieta Corral [b,c], Ajay Aggarwal [d], Riccardo Audisio [e], Josep Alfons Espinas [b,c], Josep Figueras [f], Peter Naredi [g], Dimitra Panteli [h], Nicolas Pourel [i], Joan Prades [b,c], Yolande Lievens [j]

[a] University of Barcelona; [b] Catalonian Cancer Plan, Department of Health; [c] Bellvitge Biomedical Research Institute (IDIBELL), Barcelona, Spain; [d] Guy's and St. Thomas' Hospital NHS Trust, United Kingdom; [e] Department of Surgery, Sahlgrenska University Hospital, University of Gothenburg, Sweden; [f] European Observatory on Health Systems and Policies, Belgium; [g] Department of Surgery, Sahlgrenska University Hospital, University of Gothenburg, Sweden; [h] Department of Health Care Management, Technische Universität Berlin, Germany; [i] Institut Sainte Catherine, Avignon, France; [j] Department of Radiation Oncology, Ghent University Hospital & Ghent University, Belgium

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ABSTRACT

Background and purpose: Complex surgery and radiotherapy are the central pillars of loco-regional oncology treatment. This paper describes the reimbursement schemes used in radiation and complex surgical oncology, reports on literature and policy reviews.

Material and methods: A systematic review of the literature of the reimbursement models has been carried out separately for radiotherapy and complex cancer surgery based on PRISMA guidelines. Using searches of PubMed and grey literature, we identified articles from scientific journals and reports published since 2000 on provider payment or reimbursement systems currently used in radiation oncology and complex cancer surgery, also including policy models.

Results: Most European health systems reimburse radiotherapy using a budget-based, fee-for-service or fraction-based system; while few reimburse services according to an episode-based model. Also, the reimbursement models for cancer surgery are mostly restricted to differences embedded in the DRG system and adjustments applied to the fees, based on the complexity of each surgical procedure. There is an enormous variability in reimbursement across countries, resulting in different incentives and different amounts paid for the same therapeutic strategy.

Conclusion: A reimbursement policy, based on the episode of care as the basic payment unit, is advocated for. Innovation should be tackled in a two-tier approach: one defining the common criteria for reimbursement of proven evidence-based interventions; another for financing emerging innovation with uncertain definitive value. Relevant clinical and economic data, also collected real-life, should support reimbursement systems that mirror the actual cost of evidence-based practice.

Reimbursement is one of the main policy tools to achieve the health system aims of accessibility, acceptability and quality of care [1,2]. It is powerful in stimulating or disincentivizing the clinical introduction of health-care innovations in addition to health technology assessments (HTA) and regulatory decisions [3]. In addition, it can also be used as a tool for cost-containment. How a new intervention is reimbursed typically gives a reflection of its importance, its value, as perceived by the health systems.

Although the challenges posed by reimbursement to health policy and financing are not restricted to cancer care, it has specific features. It could be mentioned factors as the ever-increasing patient numbers, the dynamics of research and the swift adoption of innovations in cancer prevention, diagnosis and treatment. The importance of strong multidisciplinary collaboration and the impact of cancer care organization on quality and outcomes are also factors to consider [4,5]. Financial aspects are equally crucial: the growing cost of new cancer therapies demands an increased share in the health-care budget and the gross national product of any country. This is becoming unsustainable, and results in inequitable availability and access to optimal care [6,7].

The pace of introducing innovative interventions in clinical cancer practice has accelerated in recent years and deserves specific consideration. Besides the incessant development and use of novel and expensive systemic agents, similar evolution has taken place in

* Corresponding author at: University of Barcelona - Hospital Duran i Reynals, Gran Via de l'Hospitalet, 199, 08908-Hospitalet del Llobregat, Barcelona, Spain.
E-mail address: jmborras@iconcologia.net (J.M. Borras).

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cancer surgery and radiation oncology, resulting in a broad portfolio of new devices and treatment approaches [8,9]. The decision which innovative interventions to reimburse, when and how, has become increasingly difficult and relevant, as reimbursement is considered a key barrier to the adoption of innovations offering meaningful improvements in cancer outcomes [2,10]. Developing reimbursement systems that are able to capture the continuous evolution in cancer care and correctly cover for the cost of evidence-based interventions, thus supporting sustainable – yet equitable – availability and access, has never been more crucial [2].

To address this need, the Joint Action on Innovation Partnership Action Against Cancer (iPAAC), a multistakeholder action supported by the European Union (EU) and 24 EU countries (www.ipaac.eu) convened an expert group to tackle the issue of reimbursement in radiation and complex surgical oncology, also considering its relationship with how to support innovation. The group included experts in the field of radiation oncology, cancer surgery, cancer control and health policy experts and included representatives from the industry and patient associations. The objective was to propose a set of policy measures to assess how Radiation oncology and cancer surgery should be reimbursed as to support sustainable access to valuable. First, a systematic literature review on radiotherapy and complex cancer surgery reimbursement was undertaken. Then a policy review defined the actual and innovative reimbursement systems for these treatments, upon which key criteria were proposed to improve their reimbursement in European health systems.

Radiation and surgical oncology: Common concepts of innovation and value

Cancer surgery and radiotherapy are two main pillars in the multidisciplinary approach to cancer care. About half of all cancer patients require radiotherapy at least once over the course of their disease, similarly it is estimated that surgery should be used in up to 60% of cancer cases [11–14]. Both modalities share the main focus of their therapeutic contribution as loco-regional treatments that can interact concurrently or sequentially with systemic cancer therapy. They are typically oriented to early or locally advanced disease, and in the majority of cases used with curative intent. [15] Still, their impact on symptoms and quality-of-life in the palliative setting may also be substantial.

New surgical or radiotherapy devices or technologies are often mistaken as the proxy for the innovation taking place in these disciplines. The way in which both new and established technologies are used to deliver innovative treatment techniques is however equally important. In turn, more advanced techniques will foster the development of new surgical or radiotherapy treatment approaches, allowing better integration with novel oncology drugs. Another distinction to bear in mind is that while some new interventions may represent a stepwise change, impacting clinical practice in a significant way for patients and physicians, others may evolve more steadily over time, representing incremental changes [16]. A last distinction relates to whether the innovation is sufficiently supported by a strong evidence-base. Both radiation and surgical oncology interventions are highly operator-dependent, requiring training and expertise that translates into learning curves impacting both outcome and costs in the implementation phase of new technologies and techniques [17]. The diffusion of technology-related innovation may moreover be hampered by high upfront capital investment, prior to any reimbursement [18,19]. Even if such emerging innovations may show potential benefit for patients, the limited and uncertain evidence initially available will typically preclude them from formal uptake into reimbursement to the extent that the reimbursement system relies on evidence-based or proven interventions (see box with definitions of the different types of innovations in the supplementary material) [20].

It is not straightforward to define the value of innovative loco-regional cancer treatments, which typically aim at better local control and organ function sparing, while decreasing (long-term) toxicity and patient treatment burden. As a consequence, clinical trials often primarily focus on these intermediary outcomes, more so than capturing overall survival and quality-of-life, which may take more time to mature [16]. In addition, the described incremental evolution and operator dependency may by itself hamper the generation of randomised evidence. This is why oncology value-scales, first and foremost developed to define the value of new cancer drugs – assessed in randomised controlled trials with side effects and disease-free, progression-free and overall survival dominating – are not simply transferable to non-systemic treatment strategies [16,21–24]. It seems reasonable that the endpoints assessed for value should be consistent with the broad range of outcomes innovative cancer surgery and radiotherapy generate and their relevance to cancer patients. Moreover, a more blended approach to evidence generation should be deployed. As such, a value-based magnitude of clinical benefit scale adapted to radiation oncology and cancer surgery, providing transparency as to the meaningful benefit considering the evidence, outcome and effect size, could help inform which new loco-regional cancer interventions to reimburse and introduce in clinical practice. Therefore, a new project is initiated by ESTRO, aimed at developing a framework to define and assess the value of radiotherapy innovations and to support clinical implementation and equitable access [25].

This would be particularly relevant for the field of radiation and surgical oncology, where the low regulatory barriers to date do not provide the necessary guidance. Indeed, the regulatory process for approving a new medical device or technology in radiotherapy and surgery follows a different process compared to systemic therapy. While some clinical data are requested, putting the device in the market mainly requires demonstration of its safety and technical performance [26–29], without necessitating the complex process of demonstrating superior efficacy when used to deliver certain techniques or treat certain indications, compared to current standards of care [30–32]. The IDEAL (Idea, Development, Exploration, Assessment, and Long-term Follow-up) guidelines, initially defined for surgery but more recently adapted to radiotherapy, provide an interesting methodology to assess technical innovations and generate evidence. It has however not yet been deployed systematically, nor has it been integrated in regulatory processes [27–29]. Moreover, while health technology assessments (HTA) have become a prerequisite for reimbursement in some countries, these HTA processes still lag behind those required for systemic therapies [17–19,33–35]. It has been proposed to align HTA of drugs and technologies, but neither the concept nor the methods on how to adopt HTA for technologies has been accepted at a European level [30–32].

This paper describes the concepts shared by radiation and complex surgical oncology, reports on literature and policy reviews, to conclude with recommendations of this task force.

Material and methods

A systematic review of the literature of the reimbursement models has been carried out separately for radiotherapy and complex cancer surgery. Using searches of PubMed and grey literature, we identified articles from scientific journals and reports published since 2000 on provider payment or reimbursement systems currently used in radiation oncology and complex cancer surgery.

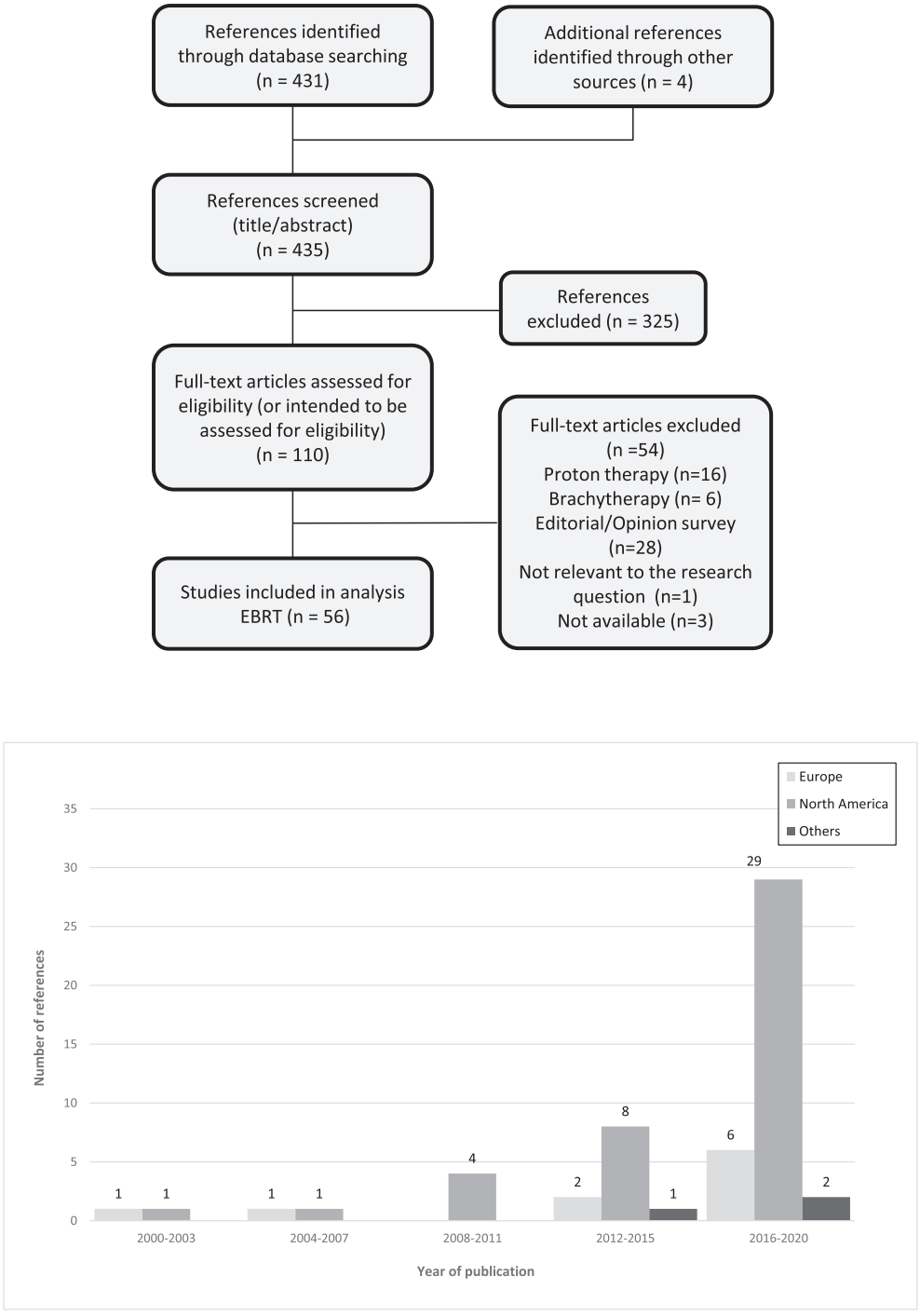

Fig. 1. Literature review on radiotherapy reimbursement. (a) PRISMA Flowchart for radiotherapy. (b) Studies on external beam radiotherapy reimbursement, by region of origin and year of publication.

The PRISMA flowcharts and the available papers are presented in Figs. 1 and 2. The search terms and the list of the papers included in the review are presented in the supplementary data.

Results

How do health services address reimbursement of radiotherapy and cancer surgery to date?

a) Systematic literature review of the current evidence

A total of 56 papers reported on radiotherapy reimbursement with a focus on external beam radiotherapy, in the 20 years of the analysis. More than three quarters of the papers (n = 43) were based on the North American experience and 3 come from countries outside Europe or North America. The analysis of payment to professionals, hospitals or the variability in reimbursement

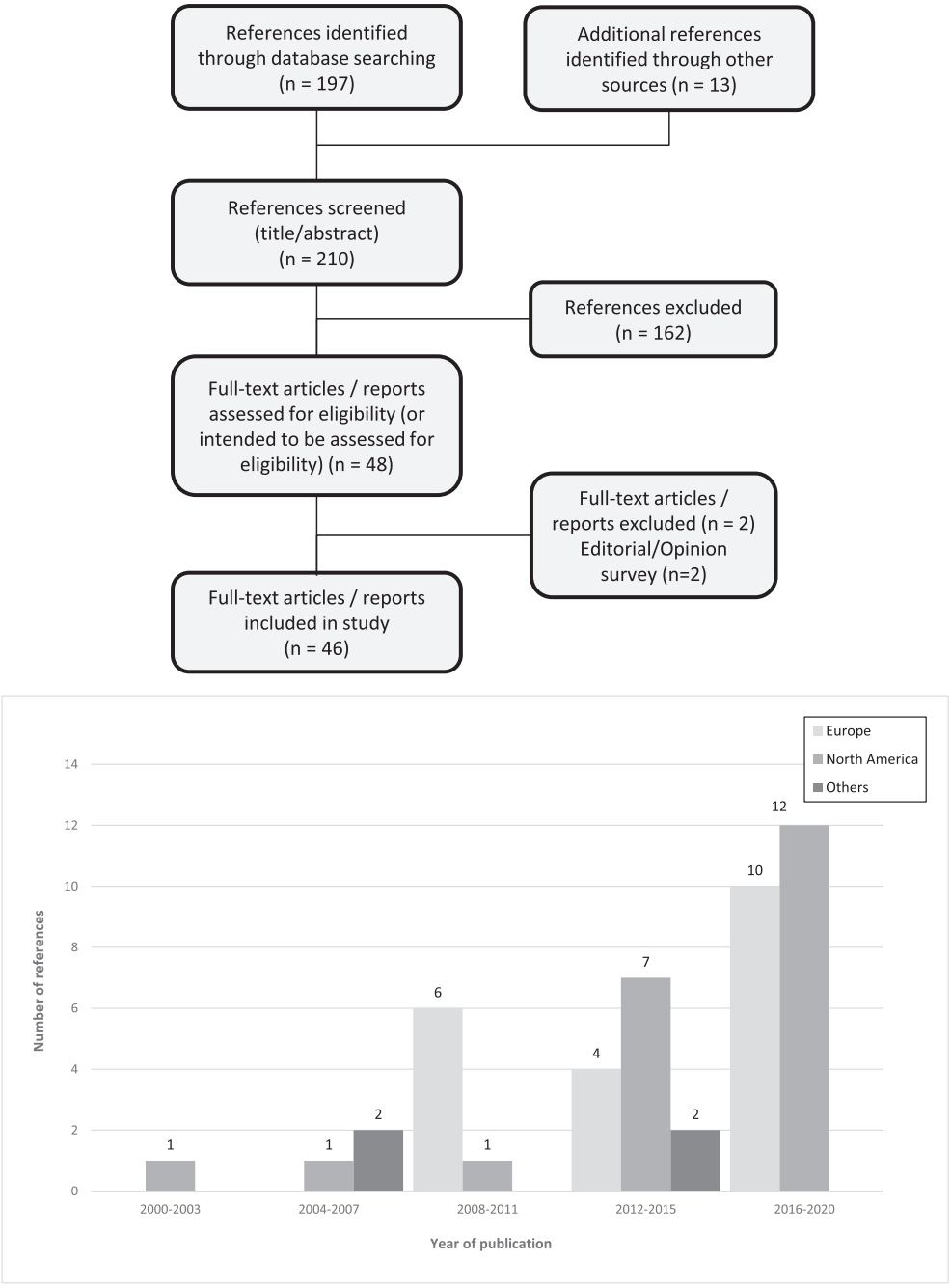

Fig. 2. Literature review on reimbursement of complex cancer surgery. (a) PRISMA Flowchart for cancer surgery. (b) Studies on complex cancer surgery, by region of origin and year of publication.

according to different models has been extensively evaluated in the US literature. Many papers focused on assessing payment for specific innovative techniques, such as Image-guided radiation therapy (IGRT) or Intensity modulated radiotherapy (IMRT). Only two papers allowed for a cross-country analysis of the impact of reimbursement models: one was restricted to hypofractionation in breast cancer radiotherapy [36]; the other assessed the different models of reimbursement in European countries, as well as the fees for specific treatments and the overall radiotherapy budget [16]. In general, the two described exceptions set aside, this review showed that the limited number of papers devoted to radiotherapy reimbursement approached the issue in a fragmented manner, based on specific techniques or tumour sites, without any aim to comprehensively analyse the reimbursement for radiotherapy in a holistic manner [2,36].

In the case of complex cancer surgery, the number of papers dealing with reimbursement over the last two decades is similar (n = 46). The proportion of papers published with an exclusive interest in North America is only about half (n = 22), while 4 papers are from other regions of the world. Again, almost all papers were oriented to the analysis of specific techniques or procedures, such as cytoreductive surgery with HIPEC, or to therapies for specific tumour sites (specifically head and neck, lung, rectum, oesophageal, pancreatic and liver surgery). Interestingly, some papers focused on the DRG-system and assessed the impact of top-up payments in addition to DRG-based reimbursement [37], or the DRG

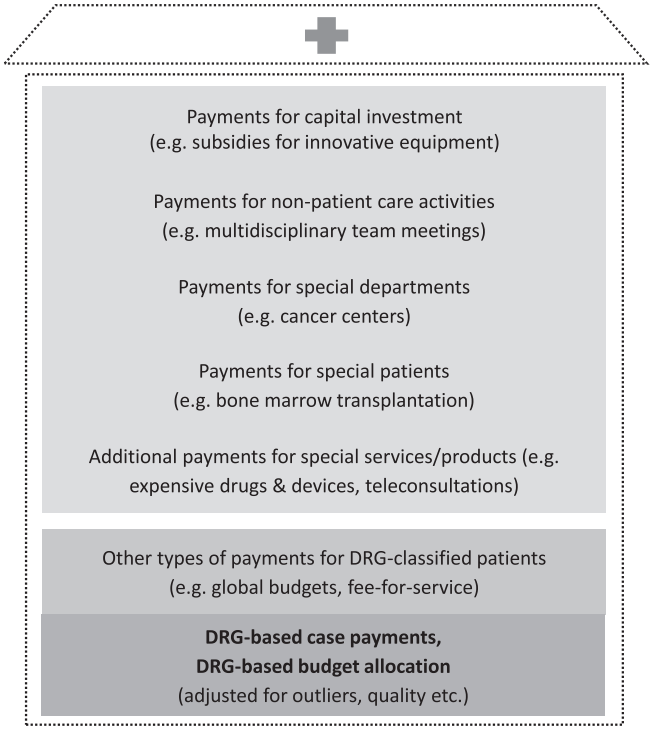

Fig. 3. Refining hospital payment for complex cancer care. Source: Busse 2011 [39].

system in use (for Catalonia, Spain) along with its potential limitations [38]. Also worth mentioning is the comprehensive review carried out using an HTA perspective on reimbursement in different European countries [39]. Furthermore, some papers discussed the need for centralization, in which case reimbursement was considered as a potential incentive for supporting such policy. In this respect it should be considered that several payment models have been implemented for tertiary hospital care. In Fig. 3, different options are listed, building on Diagnosis Related Group (DRG)-based payment (see also the case on DRGs in the supplementary material).

b) Policy review: addressing the widening gap between clinical practice and reimbursement

Most European health systems reimburse radiotherapy using a budget-based, fee-for-service or fraction-based system; while few reimburse services according to an episode-based model [2]. This is a consequence of the fact that many health systems have not reviewed their reimbursement models for years, but instead limited themselves to adding new rules to the existing models when an innovation was adopted. The specific reasons for this reside in the health system context of each country, but the result in general is that reimbursement is misaligned with standards of care and provider costs, with a resulting disconnection between the reimbursement and the outcome delivered [2]. A list of pros and cons of each reimbursement system is presented (Table 1).

A striking example of the disconnect between reimbursement and evidence-based practice in the field of radiation oncology is the lack of specific funding arrangements to foster hypofractionation, which is changing practice and reduces patient burden by limiting the number of sessions for each treatment course [36]. This change in treatment delivery also translates into a more efficient use of resources, without requiring any additional change in infrastructure, even if it typically entails a higher degree of complexity and more advanced quality control as well in the treatment planning as in the treatment delivery phase [40]. This is an excellent example of an innovation with benefit for patients, but it requires a change in reimbursement to support its dissemination, finding the appropriate incentive that balances the efficiency in resource use to the added complexity. This has not yet been achieved [2]. Conversely, in a context of overall fixed healthcare budgets, savings obtained through the implementation of hypofractionation could also be used to support other interventions which require greater capital infrastructure investment or more human resources, or to meet the demand for the increasing burden of disease.

Table 1
Advantages and disadvantages of different reimbursement models in radiation oncology.

Advantages	Disadvantages
Hospital budget	
– Incentives for cost minimization and increased efficiency of service provision at a micro level – Incentives for using hypofractionated schedules	– May lead to underprovision of services: use of lower-cost inputs or decrease in quality of care – Lower treatment complexity – Institutionalization of inefficiencies in centres with higher costs, if budgets are calculated based on historical costs (Kesteloot, 1996)
Payment per case or episode (DRGs or similar)/radiotherapy treatment	
– Incentives for increasing the efficiency of service provision – Incentives for increasing the cases treated and reducing the length of treatment – Incentives for reducing costs (mean cost/case) – Incentives for using hypofractionated schedules	– May lead to underprovision of services: use of lower-cost inputs or decrease in quality of care (although not so relevant than with a hospital budget) – Lower treatment complexity – Diagnostic upcoding
Payment per treatment fraction/fee-for-service (FFS)	
– Coverage of real costs of treatment feasible (Schmidberger, 2017) – Incentive for reducing mean cost per treatment fraction in case of prospective rate; reduction of resources per fraction – FFS: incentives for quality-supporting activities	– Overuse of fractions and sophisticated technology or techniques – No incentives for administering shorter-than-standard fractionated treatments: palliative treatments, hypofractionated schedules or stereotactic radiotherapy (unless a dedicated payment for each stereotactic fraction is foreseen) – Suballocation of resources: tariffs do not reflect cost-effectiveness of procedures and the evolution of costs associated with technological developments, which could cause the suballocation of resources because price does not reflect the cost-effectiveness of the procedure

Similar analyses on pros and cons of the models have been carried out for complex cancer surgery (Table 2). The systematic review has shown that there is little variability in reimbursement models for cancer surgery, mostly restricted to differences embedded in the DRG system and adjustments applied to the fees, based on the complexity of each surgical procedure [41]. Add-on payments can counteract the negative incentive of DRG-systems to undertreat these cases, as well as to reduce the risk for providers and offer the necessary backdrop for improved quality of care (see box on Catalonia case study). Highly differentiated DRG groupings, on the other hand, while potentially better capturing the average costs of the patients requiring complex surgery, might not discourage from gaming the system or upcoding. In several European countries, complex cancer surgery is usually associated with the concentration of these procedures in designated centres, due to the observed association between complex procedures

Table 2
Advantages and disadvantages of different reimbursement models in complex surgical oncology.

Advantages	Disadvantages
Hospital budget	
– Incentives for cost minimization and increased efficiency of service provision at a micro level	– May lead to underprovision of services: use of lower-cost inputs or decrease in quality of care – Institutionalization of inefficiencies in centres with higher costs, if budgets are calculated based on historical costs
Payment per case or episode (DRGs or similar)	
– Incentives for increasing the efficiency of service provision – Incentives for increasing the cases treated – Incentives for reducing costs (mean cost/case)	– May lead to underprovision of services: use of lower-cost inputs or decrease in quality of care (although not so relevant than with a hospital budget) – Diagnostic upcoding – It does not consider cost differences between providers who deliver complex services: – Implementation of supplementary or separated (inside or outside DRG system) payments in order to improve the extent to which tariffs reflect the actual provider's costs when this is not sufficiently differentiated in the DRGs design – Refinement of the DRGs to which patients are assigned
Fee-for-service (FFS)	
– Incentives for quality-supporting activities	– Incentives for overproduction/unnecessary indications and/or surgical procedures – Overuse of sophisticated technology or techniques

and expertise with clinical outcomes [42]. Special arrangements for the payments of such centres, which account for the particularities of the treatment they provide, are in place or have been recommended, taking into account each system's logic of payment mechanisms [39]. Criteria on minimum volumes per hospital or per surgeon were introduced for numerous complex surgeries as a measure to improve the quality of surgical care. In cases where these standards are not met, criteria applied to comply with them vary between countries. Some deny authorisation for practicing the surgical procedure at hand, while others withhold reimbursement from low-volume hospitals for the procedures [43,44]. This is an example of how reimbursement can be used to support cancer surgery practice in designated hospitals, while disincentivising it in non-designated hospitals.

Discussion

The criteria applied for reimbursing radiation and surgical oncology have changed little over the past 20 years, in spite of the important evolution and innovation that occurred in these loco-regional cancer treatments. This has created a growing divide between the actual practice, sensing a strong impetus to adopt the evolving evidence, and the financing, lagging behind and often disincentivising the adoption of innovation. There have been a few exceptions trying to introduce change in this static situation. Some noteworthy examples from Europe are:

- Specific financial schemes for implementing new equipment: this has been applied for robots (e.g. in Swedish hospitals) or new facilities for proton therapy (e.g. in Denmark), through targeted investment in infrastructure and/or equipment; or by supporting the initial dissemination of these technologies with a specific additional budget in the reimbursement system. Criteria for these investments or budgets are sometimes better explained by contextual factors related to the health system or interactions with policy makers, rather than by any rational approach.
- Specific add-on fees in the field of surgery: they were defined as a complementary payment to the reimbursement based on DRGs and have been associated with policies centralizing complex cancer surgery [45]. This type of incentive/disincentive is probably more relevant for the hospital managers than for the surgeons, who may not have seen this additional income translated in the budget of their surgical department (see also the example from Catalonia, Spain, in the supplementary material).
- Definition of quality indicators: for specific tumour sites, a list of quality indicators has been developed, allowing to link outcomes in these indicators to the reimbursement fee received (see case study from United Kingdom in the supplementary material).
- Coverage with Evidence Development (CED) or Managed Entry Agreements (MEA): these methods have also been applied to promising technologies and techniques for which the quality of the evidence was judged insufficient to formally include them in the reimbursement system (see case study from Belgium in the supplementary material) [46].

Beyond the context of Europe, bundled payments for the entire radiotherapy treatment have been introduced in the USA using short-term outcomes (like patient satisfaction or quality of treatment delivery) instead of indicators like survival, which cannot be attributed to a specific treatment within the multidisciplinary approach to cancer and require long-term evaluation. A 90-day period has been contemplated to finance the episode of care [47] in Medicare. In practice, this can be seen as an episode-based model of reimbursement, a more restricted format of a bundled payment. Such a bundled payment model has been applied in some surgical procedures outside of oncology, e.g. hip and knee replacement, with events such as reinterventions or complications as quality indicators [48]. An important caveat is that the administrative costs of introducing this approach in the USA have been similar to the savings obtained through this reimbursement model per se, and its relationship with better outcomes is still unclear [49].

Another point is that reimbursement for cancer surgery and radiation oncology has been considered in isolation from the hospital where the services are delivered. In the usual management of health services, this means that hospital managers could potentially redirect additional funds disbursed for centralizing complex cancer care to other underfunded areas of the hospital, effectively cross-subsidizing other clinical units, although the reverse direction could also take place. This could limit new human or financial resources deployed, needed to upgrade surgical and radiation technology or hamper the implementation of new techniques and treatments.

One last specific aspect that should be considered is the role of the private sector in the diffusion of innovations. Proton therapy is exemplary in this respect, especially in the US, where the private sector has played a major role in its dissemination. Also, robotic surgery is a technology with a relevant dissemination associated with policies of hospital competition and patient choice; showing that reimbursement could be a tool to create incentives for the adoption of new technologies, even without strong evidence supporting their superior outcomes [50].

Policy proposals for improving reimbursement in radiotherapy and cancer surgery

All reimbursement models face substantial challenges, which may further be amplified in the context of radiation and surgical oncology, due to their specific characteristics described before. In order to avoid the predictable complexity of implementing a new reimbursement model, most health care systems have taken a conservative attitude, only introducing changes in the reimbursement system when the policy context supports additional increases in reimbursement for a new intervention – be it a technology, technique or treatment scheme [2]. This may however result in an inconsistent approach across interventions and health care systems, which is not optimal for coping with the challenges posed by accelerated innovation in loco-regional cancer therapies. Also, the effort made in recent years in increasing quality and safety in the delivery of care is an additional, usually not well recognized, difficulty posed to the reimbursement system. The result of these non-strategic, improvisational regulatory patches is a growing imbalance between the pace of innovation in technology, novel therapeutic interventions and organizational changes in the delivery of cancer care, on the one hand, and the financing that supports or disincentivizes them, on the other.

It is time to rethink what a reasonable approach to reimbursement would look like, considering the experience gained so far and the challenges ahead as well as the distinction between standard evidence-based practice and emerging innovation. Some principles that could be considered are:

- Support for evidence-based care and associated activities
- Endorsement of innovation associated with meaningful benefit in clinical outcomes
- Recognition of physicians' intellectual activity and multidisciplinary tasks
- Support for quality of care, reducing variation not related to clinical aspects of care
- Avoidance of under- and over-provision of care
- Support for centralizing cancer care based on improvement of outcomes
- Promotion of efficiency
- Reimbursement based on actual costs
- Ability to adapt to dynamic changes in therapeutic approach
- Clarity and transparency

The proposed approach to reimbursing innovation should be tackled in a two-tier approach (Fig. 4): one tier based on considering the common criteria for reimbursement of evidence-based, proven interventions; and another tier for emerging innovative therapies with definitive value yet to be proven.

a) Reimbursement of standard of care interventions, including proven innovation

Interventions that are considered standard of care, based on prior clinical and economical evidence, including proven innovations that have a solid evidence-base and are cost-effective, should be supported by a reimbursement system that safeguards access for all cancer patients with an indication to these interventions. The following aspects are suggested to be taken into consideration when developing or updating a reimbursement system for radiation and surgical oncology:

1. Reimbursement for radiotherapy and cancer surgery should be based on time-bound episodes of care. The approach could be to define an episode including the initial consultation, the planning of the intervention and associated activities, the delivery of the intervention and the management of immediate follow-up consultations to assess short-term outcome. Early post-treatment events, such as surgical reinterventions due to complications or acute radiotherapy-induced toxicity, should be covered. This approach should consider radiotherapy and surgery separately, but factor in the potential effect of associated systemic therapy due to its impact on resource utilization, short-term outcomes, and adverse effects.

Bundled payments covering the entire cycle of care of a cancer patient are difficult to achieve, due to the large variability in disease entities and cancer stages, courses of disease and comorbidities determining the specific multidisciplinary approach chosen, ensuing in a large variability in the resources consumed. The described episode-based approach, with a more limited scope in

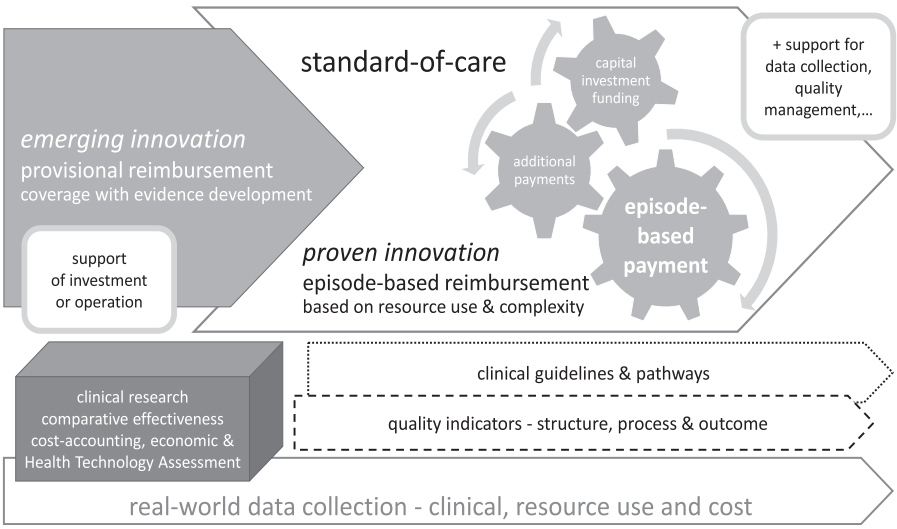

Fig. 4. Reimbursement of innovative non-systemic oncology treatments: a two-tier approach for reimbursement of emerging and proven cancer treatments. In the case of emerging innovation, provisional reimbursement is advocated for, either along clinical trials or in the real-world setting, to generate the clinical and economic evidence needed to prove the value of the new intervention while safeguarding access. Once an innovation is proven and becomes standard-of-care, adequate reimbursement using an episode-based approach should be considered, while further collection of data on adherence to guidelines and quality aspects should be persued.

treatment and time therefore seems the most achievable approximation of a bundled payment system.

2. Reimbursement levels should be based on resource use, needed to provide care following evidence-based clinical guidelines and standards of care, actual costs and required expertise, not (solely) on tumour site or clinical indication. In essence they should mirror the combined impact of treatment complexity and duration/density (e.g., for radiotherapy, a decrease in number of fractions will typically require a higher level of complexity and quality assurance).

The resources utilized, costs and clinical outcomes should be monitored with an information system, to avoid variability in clinical practice not medically explained by patient characteristics.

Time-driven activity-based costing (TD-ABC), a method for evaluating the costs and resource use of an intervention, enabling greater accuracy and transparency of the costs of interventions, could support the definition of an appropriate reimbursement per episode of care [51,52].

3. Information systems should be aligned with the clinical and administrative data collection required to support the characterization of the care episode, adherence to clinical guidelines, and allow a calculation of the costs incurred. The information systems and related data collection should be included in the reimbursement system.
4. Quality management should also be supported through the reimbursement system. The information systems in place should be used to assess the variability related to aspects other than clinical differences in disease presentation, thereby enabling targeted actions to reduce variation in clinical practice. Monitoring of clinical outcomes, including those reported by the patient, should be supported as a means to evaluate quality of care.

In this context, it is important to mention that peer review systems set in place to improve the quality of the radiotherapy practice should be covered through the reimbursement system. In contrast, multidisciplinary team (MDT) meetings, well-recognized for improving quality of care, should also be reimbursed appropriately but not included in the episode of care for surgery or radiotherapy, because they deal with the entire oncology clinical decision-making. A separate financing entity should be developed to foster MDTs.

5. Periodic reassessment should be made feasible in view of adapting the reimbursement system to the evolving standards of care, and, if appropriate, discontinue reimbursement for specific interventions that do no longer fulfil the requirements of evidence-based practice.
6. The reimbursement model should be understandable by policy makers and commensurate with the information system in place and with the monitoring capacity of the health system. For instance, a limited number of different types/levels of episodes of care, with add-ons for reimbursement of interventions with specific characteristics, could cover all therapeutic options in radiation and surgical oncology and could provide a reasonable framework for reimbursement.
7. Research activities as well as pre- and postgraduate education should be disentangled from the reimbursement system. Although these are key activities supporting innovation and quality, their funding should be differentiated from the reimbursement for treatment.

b) Financing emerging innovation

Emerging innovation poses a challenge to any reimbursement system. As clinical and economic evaluation should be accomplished before accepting any innovation as a proven therapy, the question is how to build a solid case for accepting/rejecting an innovation while data from clinical trials are not available and low regulatory barriers exist. There are several issues that need to be dealt with.

How to generate evidence?

Although randomised clinical trials (RCT) are the gold standard, they may be problematic to undertake in loco-regional cancer therapies for several reasons. First, there is an acknowledged lack of funding for research in radiotherapy or cancer surgery [53]. But there are also methodologic issues. Although there have been good examples of RCTs resulting in practice changes for many therapeutic approaches in these fields [54], in a context of quick progression of innovation, there are circumstances where it may be too late to evaluate an innovation as many clinicians consider the intervention under consideration accepted by consensus in the clinical practice. Consequently, technologies and techniques may be implemented without proper evaluation of clinical outcomes, especially if mitigating late toxicity is the target [55,56]. Correct evaluation is necessary both in incremental and stepwise innovations, although the impact may be more important for the latter. Evidence should combine clinical and economic evaluation, in addition to robust pre-marketing safety testing.

Real-world evidence data (RWD) collected systematically from clinical and administrative databases, with good quality and covering the entire population for which the intervention applies, could be a good compromise between accepting the intervention at face value or planning trials that would only provide results when the intervention is fully implemented. RWD should form a key complement to a blended approach to evidence generation, including different kinds of evidence besides RCTs, such as phase 2 trials, new pragmatic approaches to trial design or observational studies. HTA agencies seem the most adequate institutions to define their relative place in evidence generation and should carry out this task within a multi-stakeholder perspective.

How to finance this evidence generation?

Budgets should be allocated to a proper assessment of innovation with relevant impact on clinical care. This can be done through support of the initial investment needed to buy a new technology, or through support of the operating costs, or a combination of both. However, the dissemination process of emerging innovative treatments in the health service is prone to learning effects, which could not only play a confounding role in the clinical outcomes observed, but would also impact the costing analysis, hence the need for a temporary financing approach in this period.

Coverage with Evidence Development (CED) could be proposed as a practical approach which combines clinical use and access to the innovation with formal evaluation of both effectiveness and costs, when clinical trials are not feasible [57]. If the period of innovation evaluation is expected to be significant, the programme should include enough centres to provide reasonable access to the innovation and speed up the time for making a final decision based on real-world data.

How to evaluate the evidence?

A combination of comparative effectiveness assessment and economic evaluation should be the ideal target. Economic analysis

is a key component of any evaluation, including those aimed at deciding about reimbursement, and it should not be restricted to cost-effectiveness analysis. Budget impact analysis is a necessary companion to any economic evaluation, defining the budgetary requirements for an innovation. Its performance is more difficult, as the clinical benefits stemming from new radiotherapy treatments, techniques, and technologies may only be achieved in the long term, while the costs of these innovations are higher in the implementation and learning phase.

How to make the transition to the formal reimbursement?

It is important that the evaluation should be submitted to the decision makers after a review, including from clinicians with expertise in the field. The final decision should be made by the payer, after receiving the advice from the HTA agency or the institution in charge of coordinating the evaluation process.

Conclusion

The evolving field of cancer therapy poses a real challenge for designing reimbursement policies that can cope both with providing a fair payment for the evidence-based standard of care and with the rapid pace of innovation. The situation so far has been highly uncoordinated with enormous variability across European countries resulting in very different systems applied and amounts paid for the same therapeutic strategy. In addition, in many countries, the reimbursement policies have not evolved in parallel with the evidence-based innovation, only with ad-hoc coverage for specific technologies, techniques or treatment approaches, or investments for technologies without changing the reimbursement.

Although cancer drugs have attracted most of the policy discussion, surgical and radiation oncology also have important challenges ahead. Both therapeutic strategies share the focus on a loco-regional treatment approach with the need to assess outcomes such as local control or functional outcomes, strongly associated with quality of care, within a broader scope of evidence generation.

It seems reasonable to support a review of the current reimbursement systems, in view of promoting a comprehensive perspective, avoiding fragmentation and supporting valuable innovation. In order to deal with these challenges, we contend that reimbursement policy should be based on a combination of episodes of care as the basic unit for reimbursement with additional financing to address the specificities of the concerned intervention and other needs of quality assurance and data collection, set in the context of multidisciplinary care.

The key role played by surgery and radiotherapy in cancer treatment deserves a careful policy that supports standard of care treatments as well as promising innovation, submitted to the need to build evidence to define its role in multidisciplinary cancer therapy.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.radonc.2021.08.002.

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