

Tackling reimbursement for radiation oncology and cancer surgery: challenges and options

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Abbreviations

AGNSS	Advisory Group for National Specialized Services (United Kingdom)
AR-DRG	Australian Refined Diagnosis Related Groups
ASCO	American Society of Clinical Oncology
CANCON	Joint Action on Cancer Control
CatSalut	Catalan Health Service (Spain)
CCO	Cancer Care Ontario (Canada)
CRG	Clinical Reference Groups (United Kingdom)
CED	Coverage with Evidence Development
DRG	Diagnosis-related groups
ES-NSCLC	Early-Stage Non-Small Cell Lung Cancer
ECCO	European Cancer Organisations
EMA	European Medicines Agency
ESMO	European Society for Medical Oncology
ESTRO	European Society for Radiotherapy and Oncology
ERNs	European Reference Networks
EU	European Union
EUnetHTA	European Network for Health Technology Assessment
FDA	US Food and Drug Administration
G-DRG	German diagnosis-related groups
HTA	Health Technology Assessment
HRG	Health resource groups
HSM	Highly specialised medicine (Switzerland)
ICO	Institut Català d'Oncologia
IDEAL	Idea, Development, Exploration, Assessment, and Long-term Follow-up
IGZ	Dutch Healthcare Inspectorate
IMPT	Intensity-Modulated Proton Therapy
iPAAC	Innovative Partnership for Action Against Cancer
IVHSM	Inter-cantonal Agreement on Highly Specialised Medicine (Switzerland)
JA	Joint Action
MDT	Multidisciplinary team
MEA	Managed Entry Agreements
NCCN	National Comprehensive Cancer Network
NCPR	National Cancer Peer Review (United Kingdom)
NCRS	National Committee for Reference Centers (Portugal)
NICE	National Institute for Health and Care Excellence
NHS	National Health Service (United Kingdom)
NVvH	Dutch Association of Surgeons
ÖSG	Austrian Structural Plan on Health
PPP	Power Purchase Parity
PROMs	Patient-Reported Outcome Measures
RWD	Real-world data

RIZIV-INAMI	National Institute for Sickness and Disability Insurance (Belgium)
RRI	Relative resource intensity
RTC	Randomized clinical trial
SBRT	Stereotactic body radiation therapy
SD	Standard deviation
SONCOS	Dutch Foundation for Oncologic Cooperation
SRI	Structural relative index
SRS	Stereotactic radiosurgery
TD-ABC	Time-driven activity-based costing
UK	United Kingdom
WP	Work Package
3D-RT	Three-dimensional conformal radiation therapy

Executive summary

The evolving field of cancer therapy poses a real challenge for designing a reimbursement policy that can cope with providing a fair payment of the evidence-based standard of care and with the rapid pace of innovation.

Within the framework of WP8 Challenges in cancer care, a review of the different reimbursement models for cancer surgery and radiation oncology was carried out. Based on this analysis, a meeting with experts, industry and patient representatives were convened to discuss possible alternatives and options that could deal with the need of a fair reimbursement and support to emerging innovation.

The situation so far has been highly uncoordinated with enormous variability across European countries resulting in very different amounts paid for the same therapeutic strategy. In addition to this, the reimbursement policy has not evolved in many countries in the recent decades, only with patches for specific technologies, techniques or treatment approaches, or based on investment in technologies without changing the reimbursement.

It seems reasonable to support a review of the current reimbursement systems that promote a comprehensive perspective, avoid fragmentation, and support valuable innovation. 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. 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. Innovation should be tackled in a two-tier approach: one tier based on considering the common criteria for reimbursement of evidence-based interventions; and another tier for innovative therapies with definitive value yet to be proven. In the case of emerging innovation, we advocate for considering coverage with evidence development to gain information on therapies without alternative option to assess effectiveness and costs. All policy proposals should support the collection of relevant information, including costs, in an information system that could allow for real-world data analysis, when clinical trials are not feasible.

1. Innovative Partnership for Action Against Cancer (iPAAC)

The general objective of the iPAAC Joint Action (JA) is to develop innovative approaches to advances in cancer control. The innovations that will be covered within the JA consist of further development of cancer prevention, comprehensive approaches to the use of genomics in cancer control, cancer information and registries, improvements and challenges in cancer care, mapping of innovative cancer treatments, and governance of integrated cancer control, including a new analysis of National Cancer Control Plans. The development of innovative approaches to cancer control will be supplemented by a Roadmap on Implementation and Sustainability of Cancer Control Actions, which will support Member States in implementation of iPAAC and the Joint Action on Cancer Control (CANCON) recommendations.

Work package 8. Challenges in Cancer Care

Objectives

The aim of the work package is to define strategies to improve the quality of cancer care by optimising the use of healthcare resources and promoting realistic and evidence-based responses to existing needs. While cancer care has evolved, showing better organisation and specificity with regards to treating different cancer diseases, cross-cutting and disease-based challenges remain. Specific objectives are the following:

To review and assess the situation for neglected cancers with a special focus on pancreatic cancer, highlighting the challenges and opportunities for improving detection, diagnosis, and access to expert clinicians in order to increase the quality of care and outcomes, and raising awareness within the EU Policy and Research agenda.

To identify the potential use for and existing barriers to shared information systems, decision support systems, information and communication technologies, and 'big data' in the context of multidisciplinary teams (MDTs) and cancer care management, and its consequences for the implementation of MDTs in EU countries.

To propose a set of measures aimed at improving the sustainability of cancer care in European countries, taking into account the challenges posed by trends in cancer incidence, assessment of clinical effectiveness, efficient resource allocation, affordability, and equitable access to good quality cancer care. This objective includes the task reported in this deliverable (task 8.4.2).

To ensure that pain control is considered a priority in cancer and to distinguish the needs of long-term survivors from those of palliative care patients. Identify evidence-based guidelines and areas for improvement in the implementation of guidelines, education of oncologists and organisation of multidisciplinary approaches, including oncologists, pain and palliative care specialists.

To highlight a homogenous approach to palliative care based on CANCON recommendations, including patient care pathways, national policy and sustainability, innovative therapies, cancer

registries and clinical databases. Identify areas of development and challenges posed by innovative therapeutic approaches such as early integration of palliative care in the oncology care pathways, focusing on the available models of integration and on how palliative care and oncology can respond to the availability of personalised medicine, guiding the use of target therapies and immunotherapies both in clinical practice and in research.

Economics of cancer care

Following the objectives defined above, one of the challenges in cancer care is undoubtedly its sustainability, the introduction of innovations, and allocative efficiency (task 4 of the WP8). The CANCON policy paper ‘Enhancing the value of cancer care through a more appropriate use of health care interventions’ reported that the economic problem of improving the efficiency of the cancer care cannot be separated from the way health services are actually used in clinical practice. Inappropriate use of health services, unexplained variability in clinical practice, and the delivery of interventions of negligible value are responsible for a significant portion of resource wastage. Thus, to address current unmet needs (i.e. the underuse of effective or valuable care) through efficiency gains, health systems need to improve the quality of healthcare delivery, reduce unwarranted variation in practice, and withdraw resources for low-value care.

At the same time, the continuous introduction of new technologies and therapies for diagnosing and treating cancer requires a careful evaluation of their effects on clinical outcomes and their impact on system sustainability. As mentioned in EU documents, there is a need to maintain a balance between innovation, availability, accessibility, and affordability. From a policymaking perspective, one key element in this endeavour is the reimbursement system for new technologies and treatments. Although reimbursement mechanisms are not a panacea, they are an essential component of the policy toolkit for addressing the introduction of new and expensive technologies. Indeed, there are numerous examples of reimbursement mechanisms that have been developed and implemented in recent years, including pay-for-performance, bundled payments, and coverage with evidence development, to name just a few. These alternatives, which are sometime implemented in combination with more traditional reimbursement approaches, could – together with regulatory mechanisms – promote or discourage innovation. Assessing their impact is therefore crucial. At present, most research focuses on new drugs. In addition to evaluating reimbursement arrangements for new health technologies, there is a need to review the different models implemented in therapeutic strategies, such as radiation oncology and complex cancer surgery, in order to gain a broader perspective of reimbursement practices in cancer care.

Task 4.2. To review the recent developments in reimbursement models and experiences in introducing innovative treatments in European health systems, with special focus on radiation oncology and complex cancer surgery as case studies

A workshop with experts, cancer planners and scientific and patient associations discussed the recommendations on reimbursement reviewed in this report in order to improve how innovations are introduced in cancer care.

2. Introduction

Reimbursement is one of the main policy tools to achieve health system aims, namely accessibility, acceptability and quality in the delivery of care (1). It is also a powerful tool for stimulating or disincentivizing health care innovations, although it is not the only one. Other tools include regulations for introducing new health care interventions and health technology assessments (HTA) (2). How a new intervention is reimbursed is also a reflection of its importance, as perceived by the health systems, and this is especially significant for innovations in the clinical arena.

Given its specificity, cancer care has always posed specific challenges to health policy and financing. There is a multitude of epidemiological, clinical and organisational factors to consider, the increasing number of new patients, the dynamics of research and innovation in cancer prevention, diagnosis and treatment. Also, the interactions within multidisciplinary cancer care and the impact of cancer care organization on quality and outcomes are factors to take into account, only to name a few. Financial aspects are also crucial: as the growing cost of new cancer therapies demands an increased share in the health care budget and the gross national product of any country, reimbursement plays a key role in access to both standard and new cancer interventions and influences their uptake in health services (3). In addition, reimbursement can provide important information, for example on the interpretation of variations in cancer care at regional or national level or on the amounts paid for the same therapy in different countries. All these aspects interact, depending on the health system context at national or regional level (4,5) and influence access, quality and sustainability of cancer care now and in the future.

Based on the above considerations, iPAAC decided to assess reimbursement of cancer therapies in its 8th work-package ‘Challenges in Cancer Care’, focusing on radiation oncology and complex cancer surgery. Both therapeutic strategies are the primary curative treatment options for solid organ malignancies and are, along with systemic cancer therapy, essential components of the multidisciplinary approach to cancer treatment (6). However, in terms of published reports on reimbursement and paying mechanisms and their impact on equity of access and quality of care delivery, these loco-regional cancer therapies have been relatively neglected compared with cancer drugs (7). In addition, systematic approaches to health technology assessment (HTA) and attempts to better understand the value and magnitude of benefit of cancer therapies have almost exclusively focused on cancer drugs to date (7-12).

A group of experts in radiation oncology and cancer surgery, in health systems research and policy making and patients and industry representatives were convened. In preparation of a workshop (Barcelona, 27th-28th January 2020), the reimbursement models in European health systems were reviewed, comparing the advantages and disadvantages of each model (see annexes including agenda of the meeting and list of participants, and background document). The present paper reports the discussions held during this meeting, with the aim to give

guidance on how to finance radiation therapy and complex surgery, with particular attention paid on how reimbursement could influence the dissemination of innovation in cancer care.

3. Why do loco-regional cancer treatments deserve specific consideration in the general framework of reimbursement systems?

As mentioned, cancer care has unique characteristics, which impose a specific approach to the organization of care delivery in a way that it achieves good access, quality and outcomes. This section will focus on two core aspects: the multidisciplinary of cancer care and innovations in oncology, with emphasis on radiation and surgical oncology.

First, almost all cancer patients should benefit from a multidisciplinary team (MDT) approach for clinical decision-making and a coordinated sequence of treatments, as it is associated with better quality and care outcomes (13,14). The scope of MDT work is particularly important for complex clinical cases, as cancer care pathways may involve clinical services from different hospitals and the input from a wide set of health professionals dealing with diagnosis over treatment into supportive and palliative care, as well as survivorship aspects (15). These multiple contacts, involving surgical and radiation oncology specialists as part of the entire group of professionals devoted to multidisciplinary oncology care, require an investment in time and coordination of tasks that are underacknowledged in reimbursement processes, with few exceptions such as in Belgium.

Secondly, the pace of cancer innovation and its implementation in daily practice has accelerated in recent years. Besides the increased development and use of novel and expensive systemic agents such as targeted or immunotherapy, similar evolution has taken place in cancer surgery and radiation oncology, with robotic devices and Stereotactic body radiation therapy (SBRT) just to mention some of the most prominent (16,17). Innovation in itself is a broad concept that is not limited to technologies but also how they are used in procedures or interventions and how the health system is organized. Building on Rogers' classic definition of innovation, that is, "*any idea, practice, or object that is perceived as new by an individual or other unit of adoption*" (18), other authors like Greenhalgh have stressed the organizational aspects, defining innovation in health care as "*any novel set of behaviours, routines or ways of working that are discontinuous with previous practices; directed at improving health outcomes, administrative efficiency, cost-effectiveness or users' experience; and implemented by planned and coordinated actions*" (19). In a position paper identifying critical steps towards improved access to innovation in cancer care, the European Cancer Organisations (ECCO) has highlighted interventions that make a meaningful difference to patients, whether these are new therapeutic interventions or organizational changes (20). Both characterisations of health care innovation emphasize the novelty and the benefits to the patients. Reimbursement is relevant in this discussion as it is considered a key barrier to adoption of evidence-based innovations which have the capacity to offer meaningful improvements in cancer outcomes (20).

Despite these broad definitions, in reality, innovation in radiation and surgical oncology is frequently reduced to the mere aspect of new devices. This is however too restrictive, and it is important to distinguish between three different aspects of innovation:

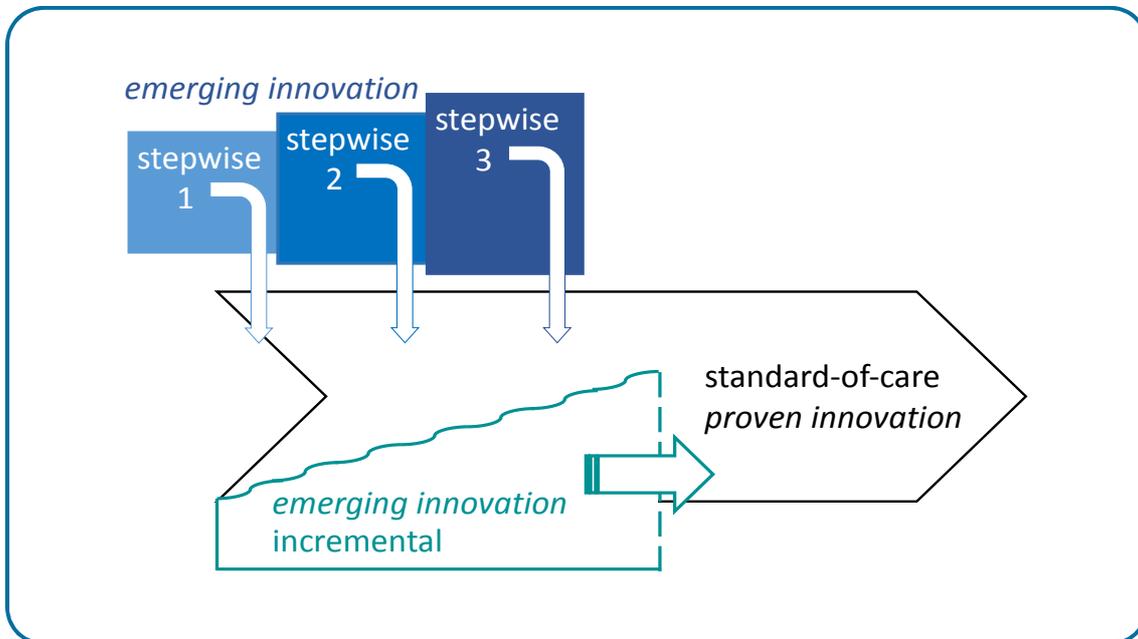
- Innovative technologies, referring to new types of equipment or devices for cancer treatment such as linacs or proton therapy machines for radiotherapy, robotic equipment for surgery or stereotactic radiotherapy;
- *Innovative techniques*, referring to new ways of using technology, such as stereotactic body radiotherapy (SBRT), adaptive radiotherapy or intensity-modulated proton therapy (IMPT), non-invasive surgery (e.g. laparoscopic), or reducing surgery (e.g. sentinel node biopsies); or ablative techniques (using microwaves or radiofrequency);
- *Innovative treatments*, referring to new ways of care delivery for specific indications, such as new combinations with systemic agents or hypofractionated radiotherapy schedules, all or not as a consequence of the availability of novel techniques and/or technologies; the use of radiofrequency ablation in the treatment of oligometastatic disease. Also organizational changes could be considered in this aspect;

When considering specific innovations in radiotherapy or cancer surgery, one should keep in mind which of the above aspects apply, alone or in combination.

In addition, not all innovations generate the same impact. As such, it is useful to distinguish between stepwise and incremental innovations (figure 1) (7,21). *Stepwise innovations* are those that change clinical practice in a significant way for patients and physicians. Some examples are robotic surgery, SBRT, hypofractionated radiotherapy or the introduction of neoadjuvant or radio-chemotherapy for some clinical indications. In contrast, *incremental innovations* involve less obvious changes in clinical practice, such as new immobilization devices, better imaging for patient positioning or better surgical instruments, which are continuously implemented in radiation oncology or cancer surgery (7). This distinction is relevant because the evidence required for each type of innovation could be different, with implications for adapting the health care reimbursement in order to make these innovations accessible (22).

This brings us to a last distinction that should be made between proven and emerging innovation. Both radiation and surgical oncology interventions are highly operator-dependent, requiring training and expertise that translates into learning curves that impact both outcome and costs in the implementation phase of new technologies and techniques (23). The diffusion of technology-related innovation may moreover be hampered by high upfront capital investment to be made by the health care providers, prior to any reimbursement (21,24). Indeed, even if 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 interventions. In view of the dual aim to allow patients appropriate access, and health care

Figure 1. Stepwise and incremental innovations



providers to implement and generate evidence on outcome and costs of these emerging innovations, provisional financing modalities should be considered. In a next step, once innovations have been proven effective and efficient through formal health technology assessment, they should become standard of care, and granted ‘final’ reimbursement. At the other end of the spectrum, once established practices have been superseded by newer developments or become obsolete, and no longer constitute optimal care in the health system, they should not continue to be funded out of the health system funds (‘disinvestment’ or ‘delisting’) (25,26).

To date, however, the introduction of radiation and surgical oncology innovation into clinical practice is very haphazard and not necessarily associated with the level or quality of the evidence, improved clinical outcomes or even its reimbursement. For instance, introducing robotic surgery for prostate cancer could have been motivated by the aim of attracting patients and the additional income that greater demand brings (27). This would make it an example of competition or market driven technology dissemination, based on hospitals’ expectations for a better market position to attract patients in a competitive arena, rather than by evidence of better outcomes for those receiving non-invasive robotic surgery compared to open surgery. In addition, without robust outcome data, patients will use informal sources of information such as reputation and the availability of novel technologies to make decisions regarding health care which can destabilise the health system (28). This provides an example of how a stepwise innovation may have been implemented without considering traditional criteria of evidence of

additional benefit or short-term reimbursement rationality. For instance, in Germany, health services covered by the health system in the outpatient setting need to go through evaluation first (not covered unless allowed), while services in the inpatient setting are reimbursed unless they are explicitly excluded based on HTA (covered unless prohibited). This creates an “innovation-friendly” environment in hospitals, in contrast to the ambulatory health care setting, although this could imply to accept some safety risks due to the lack of systematic assessment of the innovation. Stronger guidance in this field is necessary from a health policy perspective.

4. Exploring the differences in introducing and reimbursing new interventions in surgical and radiation oncology compared to systemic cancer therapy

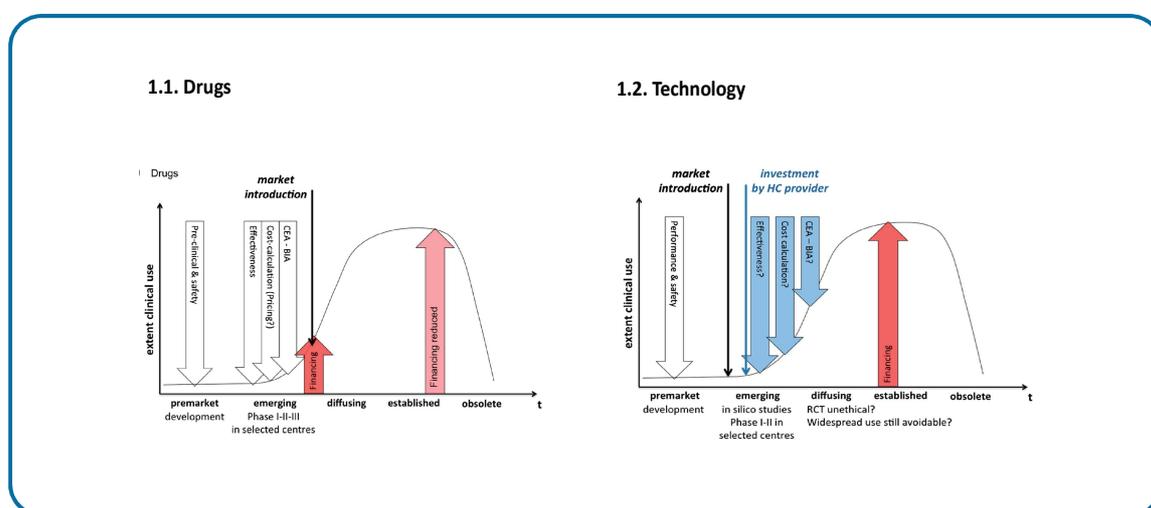
Clinical and policy stakeholders are united in their desire to reimburse effective, evidence-based care and innovation for the treatment of cancer to all who need it. However, it is also imperative that the treatment and its delivery incurs fair and reasonable costs with respect to the outcomes it is expected to deliver. Likewise, there is agreement that the reimbursement system must not disincentivize the adoption of innovations that may add value for the patient or the health system. The main question is how to assess the benefit of innovative loco-regional cancer treatments and the potential for reimbursement mechanisms to influence their dissemination, especially in the case of new technologies and techniques. These points mark a divergence between systemic therapy and radiation and surgical oncology.

Cancer surgery and radiation oncology share the main focus of their therapeutic contribution, namely a loco-regional treatment that can interact concurrently or in sequence with systemic cancer therapy. They are typically oriented to early or locally-advanced disease, are in the majority of cases used with curative intent. Due to their loco-regional action they are usually evaluated in clinical trials focussing on intermediate outcomes, such as local control, short- and long-term toxicity, peri-operative and functional outcomes, in addition to long-term outcomes such as overall survival and quality-of-life. This is in contrast to the outcomes typically addressed in trials for regulatory approval of cancer drugs, where side effects, disease- and progression-free and overall survival dominate. This may in part explain the limited interest from HTA in the evaluation of their impact. Moreover, the smaller number of randomised clinical trials in comparison with systemic therapy, resulting from more restrained research financing, and the low regulatory requirements for introducing any innovative technology or technique (29-31) could be other factors explaining the low profile of HTA for radiation and surgical oncology.

The regulatory process for approving a new medical device or technology in radiotherapy and surgery follows a different process compared to systemic therapy. It requires clinical data, and a demonstration of its safety (32) and technical performance (33-35), prior to putting the device in the market without necessitating the complex process for demonstrating superior efficacy compared to current standards of care as has been established for systemic therapies (figure 2) (29-31). A potentially useful framework has been developed, referred to as the IDEAL (Idea, Development, Exploration, Assessment, and Long-term Follow-up) guidelines. Initially defined for surgery but later adapted to radiation oncology, it provides an interesting methodology to assess innovations and the required generation of evidence. In essence, it proposes the most appropriate study design for each stage in the development of a device or technology. Though interesting, it has not yet been deployed systematically (33-35).

Systemic therapy require a robust and formal approach to the measurement of efficacy prior to regulatory approval – usually through randomized controlled trials – comparing the new drug with the standard treatment. In contrast, a new medical device can enter the market prior to the process of building evidence for its efficacy and comparative effectiveness with decisions on financing and maintaining the innovation depending on available resources and policy-makers’ prerogative (22). Moreover, the discussion about the potential indications and expected outcomes when deciding about its use is often carried out with different levels of evidence. In fact, the number of clinical trials in radiation oncology is quite low, amounting to only 5% of all published radiotherapy research (36). The same is true in the field of cancer surgery (6).

Figure 2. Process of disseminating of drugs (figure 1.1) and health technologies (figure 1.2)



Source: Lievens 2015 (22)

Deciding about the clinical outcomes that should be obtained to evaluate the contribution of any therapeutic intervention to cancer care remains a challenge. For systemic therapy, regulatory mechanisms indicate which clinical outcomes are needed for obtaining authorization for reimbursement. Even so, in many cases oncology drugs are approved without having shown relevant benefits in terms of overall survival or quality of life (37). There are no equivalent regulations for radiotherapy or surgery. As mentioned, the endpoints of clinical trials selected to define changes in clinical practice are often very different from those in systemic therapy. Indeed, an assessment of several practice changing randomized trials using magnitude of benefit scales developed for systemic cancer therapy showed the limitations of these scales when applied to cancer surgery and radiotherapy (7). On the other hand, outcomes such as reduced toxicity or increased efficiency in the delivery of care could be very relevant as well, as demonstrated, for instance in hypofractionation for breast cancer, which has shown similar

clinical outcomes and increased patient satisfaction with fewer fractions (38,39). An innovation like this one, that changes the way radiotherapy is delivered and results in similar efficacy, yet reduced patient burden and increased efficiency, has to be specifically considered in new reimbursement models, because it is often disincentivized with prevailing models employing fraction-based or fee-for-service payments (40).

5. Value-based healthcare: useful approach to inform reimbursement policy for radiation oncology and cancer surgery?

Perhaps the most relevant conceptual change in health policy in recent years has been the emergence of the notion of value-based health care (41) aimed to assess the contribution of a given treatment in terms of benefit for the patient, and to make decisions about its reimbursement. In the reference paper by Porter, value was defined as “*the balance between the outcome associated with a procedure or treatment and the price paid for it*” (41). The main change introduced by this definition has been the idea that the outcome assessment should be focused on the patient, so maximizing value requires a patient-centred approach. This point is very relevant because the value perceived by each actor involved in the health system is different, meaning that government, hospitals, physicians, the private sector, and patients could assign a different value to the same therapy based on their own perspective or method of outcome evaluation.

One of the main unresolved questions of value-based health care in oncology is how to measure the individual contribution of each separate therapeutic intervention. The European Society for Medical Oncology (ESMO), the US National Comprehensive Cancer Network (NCCN), and the American Society for Clinical Oncology (ASCO) have each proposed scales of measurement to assess the magnitude of clinical benefit, predominantly focusing on the context of cancer drugs (8-12). The three scales mainly focused on efficacy obtained from phase II and III trials along with meta-analyses, and included outcome measures of survival, disease-free and progression-free survival, toxicity and safety; while two also considered quality of life. These scales have been extensively analysed, and found to work reasonably well for their purpose, although with some inconsistencies and potential flaws in their application (42). As a consequence, some hospitals and regions have applied these scales in the evaluation process deciding on inclusion of the drug in the hospital formulary or reimbursement. Interestingly, a caveat that has been made following several analyses is the absence of any relationship between the price of the drug approved by the European Medicines Agency (EMA) or the US Food and Drug Administration (FDA) and the magnitude of its benefit scored (36,43-45). Such considerations are relevant to assess how prices of therapies are established and whether and how they should be reimbursed.

The scales were also applied to selected practice changing clinical trials in radiation oncology and cancer surgery (7). Doing so, the radiotherapy and surgery interventions assessed were classified as having limited value or low-grade scores because their contributions consisted of improvements in toxicity, efficiency of the radiotherapy delivery, and quality of life, which the available scales do not – or not sufficiently – contemplate. The limited availability of (randomised) clinical trials in radiation oncology and cancer surgery (36) makes the application of these scales even more difficult. A possible way forward could be to define scores for value

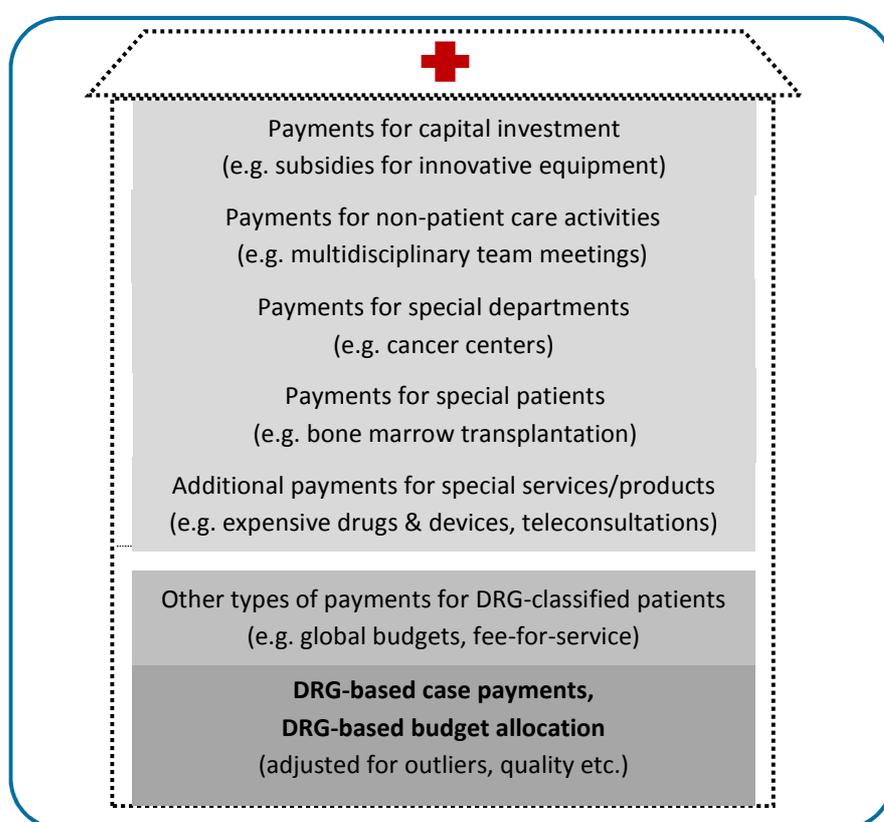
based scales adapted to surgery and radiotherapy, using good quality evidence on safety and clinical outcomes, developed within an IDEAL framework (7).

Seeing their main role in loco-regional treatment, the classic key variable to assess cancer care outcomes, survival, should be accompanied by others like organ preservation, toxicity, late side effects and functional status to render value-based assessments relevant for radiotherapy and surgery. It seems reasonable that the endpoints assessed for value should be consistent with the outcomes they generate and their relevance to cancer patients. As such, a value-based magnitude of clinical benefit scale adapted to radiation oncology and cancer surgery, accounting for a broader range of evidence and for the relevant outcomes in these loco-regional oncology treatments, could provide an additional tool to link reimbursement to value-based care. By providing transparency as to the meaningful benefit considering the evidence, outcome and effect size, such scale could inform reimbursement. This is particularly important for technologies and techniques, where the low regulatory barriers do not provide the necessary guidance. In summary, it offers a potential interesting framework, however its practical implementation is still challenging and will require an effort of defining and evaluating quality indicators before making feasible its introduction in cancer policy (46) .

6. How do health services address reimbursement of radiotherapy and surgery?

Several payment models have been implemented for tertiary hospital care. In figure 3, different options are listed, building on Diagnosis Related Group (DRG)-based payment. For radiation therapy and surgery, two examples of care taking place in the hospital setting, a variety of reimbursement models has been implemented.

Figure 3. Refining hospital payment for complex cancer care



Source: Busse 2011 (48)

Table 1. Advantages and disadvantages of different provider payment models in radiotherapy

Advantages	Disadvantages
<i>Departmental or hospital budget</i>	
<ul style="list-style-type: none"> – Incentives for cost minimization and increased efficiency of service provision at a micro level – Incentives for using hypofractionated schedules 	<ul style="list-style-type: none"> – 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)
<i>Payment per case or episode (DRGs or similar)/radiotherapy treatment</i>	
<ul style="list-style-type: none"> – 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 	<ul style="list-style-type: none"> – 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
<i>Payment per treatment fraction/fee-for-service (FFS)</i>	
<ul style="list-style-type: none"> – 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 	<ul style="list-style-type: none"> – Overuse of fractions and sophisticated technology or techniques – No incentives for administering shorter-than-standard fractionated treatments: palliative treatments, hypofractionated schedules or stereotactic radiotherapy – 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

A review of the reimbursement models for radiation therapy was undertaken (see annex) (40), and the pros and cons of each were compared (table 1). Overall, large variability was observed. Most European health systems reimburse radiotherapy using a budget-based, fee-for-service or fraction-based system; few reimburse services according to an episode-based model. This is a consequence of the approach taken by many health systems that have not changed reimbursement models for years, instead sometimes adding new rules to the existing models when an innovation is 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 the consequence of a disconnection between the reimbursement for the therapy and the outcome delivered (40). In general, there is great variability in amounts reimbursed for the same technique in different countries, even after adjusting for purchasing power parity (PPP). Likewise, there is a lack of specific funding arrangements to foster new treatment approaches such as hypofractionation, which, as mentioned previously, is changing practice and reduces patient burden. This change in treatment delivery 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. This is an excellent example of an innovation that would require a change in reimbursement to support its dissemination, finding the appropriate incentive that balances the efficiency in resource use to the added complexity. Conversely, in a context of overall fixed healthcare budgets, savings obtained through the implementation of hypofractionation could be used to support other interventions which require greater capital infrastructure investment or to meet demand for the increasing burden of disease.

Similar discussion (47) and analyses have been carried out for complex cancer surgery (table 2), although in the context of much less data and research to assess. The main point derived from this analysis is to consider combining a DRG-based reimbursement system with an ‘add-on’ payment for complex cancer surgery (see attached box on DRGs). On the other hand, little variability in reimbursement models for cancer surgery has been found, restricted to differences embedded in the DRG system and adjustments applied to the fees, based on the complexity of each surgical procedure (48). 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 provide 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 and expertise with clinical outcomes (47,49). 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 (50); taking into account each system’s logic of payment mechanisms. 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 (51,52). 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.

Table 2. Advantages and disadvantages of different provider payment models in complex cancer surgery

Advantages	Disadvantages
<i>Hospital budget</i>	
<ul style="list-style-type: none"> – Incentives for cost minimization and increased efficiency of service provision at a micro level 	<ul style="list-style-type: none"> – 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
<i>Payment per case or episode (DRGs or similar)</i>	
<ul style="list-style-type: none"> – Incentives for increasing the efficiency of service provision – Incentives for increasing the cases treated – Incentives for reducing costs (mean cost/case) 	<ul style="list-style-type: none"> – 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 take into account of cost differences between providers who deliver complex services: <ul style="list-style-type: none"> – 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
<i>Fee-for-service (FFS)</i>	
<ul style="list-style-type: none"> – Incentives for quality-supporting activities 	<ul style="list-style-type: none"> – Incentives for overproduction/unnecessary indications and/or surgical procedures – Overuse of sophisticated technology or techniques

DRG and reimbursement in cancer care

DRG-based hospital payment systems are one of the main mechanisms for paying hospitals internationally (50) DRG systems classify hospital cases into a manageable number of clinically meaningful and economically homogeneous groups, based primarily on diagnoses and procedures. Hospitals then either receive a fixed amount per case within a certain DRG (DRG-based case payment), or a budget calculated based on the number and type of DRGs (case-mix) provided in one of the previous years (DRG-based budget allocation). However, some patients have costs that are difficult to predict on the basis of diagnosis and procedures. Beyond the issue of individuality and statistical variation, this may be because their condition is rare and the low number of cases makes it impossible to calculate valid average costs; secondly, multimorbidity is increasing in prevalence and patients may require additional services beyond the scope of the condition that brought them to the hospital (e.g. dialysis).

To account for this variability, countries with DRG systems have developed mechanisms to complement DRG-based payments with other payment mechanisms. These invariably entail the exclusion of certain services from the DRG system and the separate reimbursement of related costs through other mechanisms. Exclusions usually pertain to a) certain patient groups (e.g. patients with severe burns); b) certain services and products (e.g. high-cost drugs & devices); c) certain hospitals or hospital departments (such as cancer hospitals in the USA); and d) outlier cases with considerably higher/lower costs than other patients in the same DRG.

Specifically, for cancer treatment different exclusions can be found in the international comparison. Cancer therapies (drugs) are excluded and reimbursed separately in many countries. Radiotherapy is also a common area for which separate payments apply (e.g. in England, Estonia or France). In Denmark, a range of highly specialized cancer services are reimbursed based on the specialized hospital's own calculations. Denmark has a combined system of outside-DRG payments, wherein highly specialized patients are excluded from the DRG system only when they are treated at specifically designated hospitals. Different countries apply different payment mechanisms for DRG-exclusions, including on a fee-for-service, global or pathology-specific and block grants. Which mechanism is applied usually depends on the overall payment mechanisms typically used to reimburse services in each health system.

So far in this report, reimbursement for cancer surgery and radiation oncology has been considered in isolation from the hospital where the services are delivered. In practical terms, 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 the impact of new human or financial resources deployed to upgrade surgical and radiation technologies, or hamper the implementation of new techniques and treatments.

The rapid development that occurred, especially of new technologies, but also of innovative techniques and treatment schemes, in both complex cancer surgery and radiation oncology, partially explains the fragmented reimbursement landscape. Access to these innovations has not been coordinated in most health systems, although their often higher costs would lend support for more planned action from a cancer policy perspective. Moreover, these new therapeutic approaches are usually complex and have shown a high operator dependency with significant learning curves, which add complexity to their dissemination, and to finding the most appropriate financing. Conversely, health professionals have resisted adoption of some innovations not only because of fear of potential long-term adverse effects and toxicity, but also due to their impact on the organization of service delivery, or negative incentives associated with the reimbursement model applied (53).

The criteria applied for reimbursing radiation and surgical oncology have changed little over the past 20 years, with a few exceptions. The main changes are briefly described here:

- Specific investments have been made for implementing new equipment. This applied for robots (e.g. in Swedish hospitals) or new facilities for proton therapy (e.g. in Denmark), through targeted investment (infrastructure/equipment) or for supporting the initial dissemination of these technologies with a specific additional budget in the reimbursement. Criteria for these investments are sometimes better explained by contextual factors related to the health system or interactions with policy makers, rather than by any rational approach. In addition to this, other investments have been made for massive upgrading of technologies in radiation oncology, thanks to a private donor (for example in Spain) or through European support schemes (for example in Bulgaria).
- In the field of surgery, some specific add-on fees to the reimbursement based on DRGs have been associated with policies centralizing complex cancer surgery (54). This is an incentive/disincentive more relevant probably 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 attached box from Catalonia, Spain).
- For specific tumors sites, a list of quality indicators has been developed, which would allow to link the outcomes in these indicators to the reimbursement fee received (see case study from United Kingdom).

- Coverage with Evidence Development (CED) or Managed Entry Agreements (MEA) 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) (32, 55). A robust pre-market testing of these technologies or techniques should always be a required starting point of any CED.

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 (58) 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 (59). 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. The diversity of approaches for changing the financing of surgical and radiation oncology interventions demonstrate the variability in options considered, generally applied in a quite unsystematical manner, and the importance of developing a more comprehensive approach to address the challenges posed by these therapeutic strategies.

Using reimbursement mechanisms to accelerate and consolidate a centralisation policy for highly complex cancer diseases: A case study from Catalonia, Spain

Centralisation policies aim to increase the quality of highly complex cancer care while also preserving equity in patient access. In Catalonia (pop. 7.5 million), Spain, implementation of the centralisation policy began in 2012 for 20 surgical procedures and cancer diseases, based on a model combining the accreditation of centres with clinical audits.¹ Of the 64 publicly financed hospitals, more than 50 have offered cancer treatments over the past three decades—especially those needing surgery—, contributing to wide population access to these services. However, many of these treatments required extensive clinical experience, and they were administered with little to no coordination among tertiary centres.

The centralisation policy was implemented progressively, one pathology at a time, through the convergence of different programme components. The first was population-based clinical audits, which assessed quality in different centres based on clinical variables agreed on by expert clinicians. These audits established the basis for the second programme component, namely, decisions on minimum caseload thresholds and designated centres. Thus, a caseload above a cancer-specific threshold was considered to indicate an acceptable level of quality; for example for sarcoma, this policy led to consolidating service provision from 20 centres to 3, and for oesophageal surgery, from 18 to 5.^{2,3} The third component consisted of setting patient pathways guiding referrals from the non-designated hospitals to the designated ones. As a result, improved clinical outcomes were shown in cancer of the pancreas, oesophagus, liver and rectum; in rectal cancer, these included fewer emergency surgeries, more lymph node examinations, less locoregional recurrence and reduced mortality at three months and one and two years.¹

Nonetheless, the broad scope of the policy, aimed at creating a specific quality framework for highly complex cancers, gave rise to implementation problems such as long delays (up to two years) before some non-designated hospitals adopted the new regulations. The health authorities addressed this implementation challenge by introducing a fourth programme component, namely, conditional cash transfers, that withdrew hospitals' reimbursement rights for procedures performed in non-authorized centres. At the same time, reimbursements were increased for centralised procedures in order to improve the management and funding of these activities in authorised hospitals. Disincentive for non-authorized hospitals and reimbursement adds-on for highly complex procedures were critical levers in accelerating the adoption of the regulation.

¹ Prades J, Manchon-Walsh P, Solà J, Espinàs JA, Guarga A, Borrás JM. Improving clinical outcomes through centralization of rectal cancer surgery and clinical audit: a mixed-methods assessment. *Eur J Public Health* 2016;26(4):538-42.

² Manchon-Walsh P, Espinàs JA, Prades J, Aliste L, Pozuelo A, Benaque A et al. Evaluation of the concentration process of highly specialized digestive oncological surgery in Catalonia. Barcelona: Catalan Agency for Health Information, Assessment and Quality (CAHIAQ), n. 21; 2016.

³ Manchon-Walsh P, Espinàs JA, Prades J, Torrents A, Aliste L, Pozuelo A et al. Evaluation of the concentration process of highly specialized digestive oncological surgery in Catalonia. Barcelona: Catalan Agency for Health Information, Assessment and Quality (CAHIAQ), n. 28; 2018.

Coverage with evidence development: a case study from Belgium

Decisions regarding population coverage of new technologies at the time of regulatory approval may be difficult due to remaining uncertainty about both clinical and economic benefits. Similar considerations apply to new techniques, ensuing from the described learning curves, often present in the context of radiotherapy and surgery. In search for innovative financing models, Coverage with Evidence Development (CED) programs have gained interest, as they allow early access to innovative health care interventions, while supporting the collection of clinical and economic data.

In Belgium, a CED program has been applied to facilitate access and support reimbursement for SBRT (stereotactic body radiotherapy). While SBRT had become an accepted treatment modality for certain primary cancers (e.g. early-stage non-small cell lung cancer (ES-NSCLC) not amenable to surgery), and there was growing interest in SBRT for oligometastatic disease, the Belgian radiation oncology community asked for its inclusion in the reimbursement system in 2011. This request was not granted, because of remaining uncertainty about its clinical safety and benefit, and due to questions regarding its cost, cost-effectiveness and budget impact in the Belgian health care system. Yet, in consultation with the National Institute for Sickness and Disability Insurance (RIZIV-INAMI) and the Belgian health technology assessment body (the Knowledge Centre), a CED program was initiated (56,57).

First, the provider cost in Belgium was determined by running a costing exercise in 10 operational radiation oncology departments, which determined the level of financing within the CED program. Inclusion of patients in the project was based on the indication, either primary tumor or oligo-metastatic disease, defined as a maximum of 3 active lesions. Some indications (e.g. ES-NSCLC) were considered sufficiently supported by evidence so that the mere registration and data collection in the CED program was sufficient for financing; for other cases (e.g. most types of oligo-metastatic disease), where the evidence was less well established, additional inclusion in a clinical trial was mandatory. Data registration and collection focused on clinical and technological aspects and was performed through the Belgian Cancer registry.

Actual data collection started in autumn 2013. By the end of 2017, 17 out of the 24 radiation oncology departments in Belgium had participated, and 1759 res. 1468 SBRTs for primary tumor res. oligometastases were available for analysis. After evaluation of the outcome and technical aspects, in comparison to available literature evidence, and ensuing discussion between the RIZIV-INAMI and the radiation oncology community, SBRT has been accepted for formal reimbursement as of January 2020.

Several lessons can be drawn from this experience:

- the complexity of the process suggests that this approach may be most suitable for stepwise innovations, although incremental innovations (such as evolving image-guided radiotherapy) for which clinical trials may be even more difficult to perform, could also be considered;
- the introductory phase should cover enough hospitals to assess variability in practice and provide access to patients with such a promising indication;

Coverage with evidence development: a case study from Belgium (cont'd)

- there should be a well-defined set of data to be collected, and a system enabling data collection. Collaboration with the national cancer registry, as in this example, has been found advantageous;
- a formal audit procedure at a pre-defined time point should be defined;
- one of the most interesting findings was the range of costs for the same indication across hospitals in the country, which demonstrates the relevance of assessing variability in practice, not only on the clinical but also on the administrative – and costing – side of the outcomes;
- it should be borne in mind that such a program may take time – 10 years in this example – to reach a recommendation (acceptance of reimbursement for SBRT). Yet, a large number of patients got access to SBRT through a growing number of centers participating in the project.

Reimbursement case study – an example from the National Health Service (UK) in Prostate Cancer

The case study below using prostate cancer radiotherapy in the UK as an example, demonstrates the challenges to publicly funded hospitals in adopting innovation within radiation oncology. In particular, the need to first of all have robust evidence to demonstrate variation in the quality of care in order to identify areas that need improvement. In addition, the difficulties in deciding which innovations to adopt to improve patient outcomes in the absence of comparative effectiveness data, or a framework to assess the “value” of innovation when considering their costs. Finally, current reimbursement systems are inflexible, which makes the adoption of “high” value innovation challenging if the new innovation comes at increased costs.

In the NHS in England and Wales, outcomes of care for four common cancer types are reported publicly at the individual hospital level for bowel, oesophageal and prostate cancer. The transparency afforded through this approach offers the opportunity for benchmarking best practice, identifying outlying performance, supporting patient choice and defining “high value” pathways of care.

The National Prostate Cancer Audit in England and Wales (UK), is the first national reporting programme internationally to assess outcomes for men treated radically with surgery or radiotherapy for prostate cancer <https://www.npca.org.uk/provider-results/>. Medium-term outcome indicators of toxicity and function are reported un-blinded at the individual centre level. These indicators capture bowel, urinary and sexual function of individual patients using linked hospital datasets as well as PROMs, collected as part of a national survey.

Since starting in 2019, the programme has fostered new approaches to quality improvement and provides a means for individual hospitals to compare their levels of toxicity to other providers, in particularly identifying centres considered to be outliers according to statistically derived limits (i.e. rates of toxicity 2-3 SD above the mean).

However, whilst having the opportunity to review processes of care and identifying where improvements can be made, this process has highlighted the difficulties in implementing and deciding which innovation to adopt to achieve meaningful improvement in patient outcome as presented in the case study below.

One centre considered an “outlier” due to higher rates of bowel toxicity evaluated three different options to improve the accuracy of targeting the tumour and to reduce the dose of radiation to organs at risk. i.e. the bladder and bowel.

These included:

1. Insertion of fiducial markers into the prostate to reduce set-up error during treatment and support a reduction in treatment margins
2. Insertion of a rectal spacer and fiducials with a view to improving localisation and reducing coverage of the rectum in the radiation field
3. MRI fusion to facilitate contouring of the target organ (i.e. prostate) and organs at risk to improve consistency of treatment planning and accuracy.

¹Aggarwal A, Nossiter J, Parry M, et al. Public reporting of outcomes in radiation oncology: The National Prostate Cancer Audit. *The Lancet Oncology* (2020) in press.

7. Leveraging factors to support improved reimbursement

Some health system developments should be taken into account as leveraging factors in any future change of the reimbursement system in general, the most relevant being real world data, and, more specifically for Europe, the development of European Reference Networks for rare cancers.

Data from electronic clinical records and administrative claims, or so-called *real-world data*, are increasingly used by payers, health services researchers and clinicians to assess health services utilization and related outcomes, including medical devices uptake regulatory decisions, health technology assessment and reimbursement (60). It is evident that linking population-based cancer registries to these data sources could be extremely useful for assessing the utilization of radiotherapy or surgery, evaluating gaps and unmet needs, modelling future needs, and analysing the outcomes associated with therapy (6,61). Moreover, these data can also be used to assess adherence to clinical guidelines, the type of treatment administered and its impact on hard outcomes such as recurrence or survival. Such possibilities support the progressive use of real-world data in cancer planning, priority setting and outcomes assessment.

Although the data available for analysis is still very limited in cancer care in general, and more specifically in terms of certain key outcomes such as quality of life, patient-reported outcome measures (PROMs), or adverse effects, the field is growing rapidly, and better data availability in the near future is likely (62-66). There are several examples of their use: to develop outcome indicators by using large data sets and PROMS (64-65) or to apply these indicators to demonstrate publicly quality of care at hospital level (66). However, interoperability and data standardization still challenge many health systems (44). The consistency and systematic recording of these data is not yet firmly established, so these aspects will need progressive development in order to expand their potential use. It is of interest that WP7 of iPAAC is exploring the linkage of cancer registry data with administrative and reimbursement information in order to assess the economic impact of cancer treatment and the relative costs of each therapy from a population perspective. This can inform reimbursement through two mechanisms: it can be used as an evidence base for understanding the value of a new technology (65) and as a way of rewarding performance or quality of care delivery. By benchmarking best performance, the approach to treatment in these centres can become a marker for reimbursement (see case study from UK).

Another interesting initiative at the European level is the consolidation of European Reference Networks (ERNs) for rare cancers (paediatric, hereditary syndromes, rare adult cancers and haematological malignancies). ERNs comprise a network of reference centres, designated by national governments due to their experience in rare cancers and evaluated externally by the European Commission. One of the initial activities is the development of clinical guidelines for diagnosing and treating these tumours (67-68). This process offers an opportunity to detect gaps in therapeutic knowledge, evaluate new therapies through sufficiently large clinical trials,

and organize clinical databases that could be useful in assessing new procedures or therapies using a real-world data approach. These databases could also allow exploration of the effectiveness of standards of care for rare cancers that may not have been properly evaluated with a clinical trial approach due to insufficient case volume or logistical difficulties.

Both the use of real-world data and the expansion of ERNs could improve data coverage to include most or all of the process and care outcomes for all tumour types, including rare ones. These data could also enable the assessment of the variability in clinical practice and its potential budgetary impact and effect on patient and treatment outcomes, information that is very relevant for reimbursement.

8. Proposed avenues for improving reimbursement in radiation oncology and cancer surgery

All reimbursement models face substantial challenges, which may further be amplified in the context of radiation oncology and cancer surgery, 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, essentially 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 (40). 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.

Principles to be considered in the (re)designing of the reimbursement model for loco-regional cancer treatments

- 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

It is time to rethink what a reasonable approach to reimbursement would look like, taking into account the experience developed so far and the challenges ahead. Some principles that could be considered while (re)designing reimbursement for loco-regional cancer treatments could be as those listed below (modified from a personal presentation at the workshop on 28/1/2020).

Taking into account these criteria, the following proposals could be useful in progressing towards a better reimbursement model (Figure 4).

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 radiation oncology and cancer surgery should be based on time-bound episodes of care. The episode defined should include: initial consultation, planning of the intervention and associated activities, delivery of the intervention, management of immediate follow-up consultations to assess the short-term outcome. Quality indicators, such as surgical reinterventions due to complications or acute radiotherapy induced toxicity, should be also included in the definition. This approach should consider radiotherapy and surgery separately but factor in the potential effect of systemic therapy due to differences in 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 treatment and time, therefore seems the most achievable approximation of a bundled payment system.

This proposed approach based on episodes of care implies that any reimbursement system for radiotherapy based on fractions as a unit of measure should be adapted due to the disincentives for rational treatment.

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 resource impact of treatment complexity and duration/density (for example, for radiotherapy the number of fractions). The level of 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.

The time-driven activity-based costing (TD-ABC) model for evaluating the costs of an intervention could support the definition of appropriate reimbursement per episode of care, as its use enables greater accuracy and transparency in estimating the costs of health care (69,70).

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.
4. Quality management should 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.
5. 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, 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 radiation oncology, because they deal with the entire oncology clinical decision-making. A separate financing entity should be developed to foster MTDs.
6. 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 fulfill the requirements of evidence-based practice.
7. 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.
8. Research activities as well as pre- and postgraduate education should be disentangled from the reimbursement system.

Financing emerging innovation

Emerging innovation poses a challenging question to any reimbursement system (figure 4). A clinical and economic evaluation should be undergone before accepting it as a proven therapy. The question is how to build a solid case for accepting/rejecting innovation when data from clinical trials is not available and low regulatory barriers exist.

There are several issues that need to be dealt with:

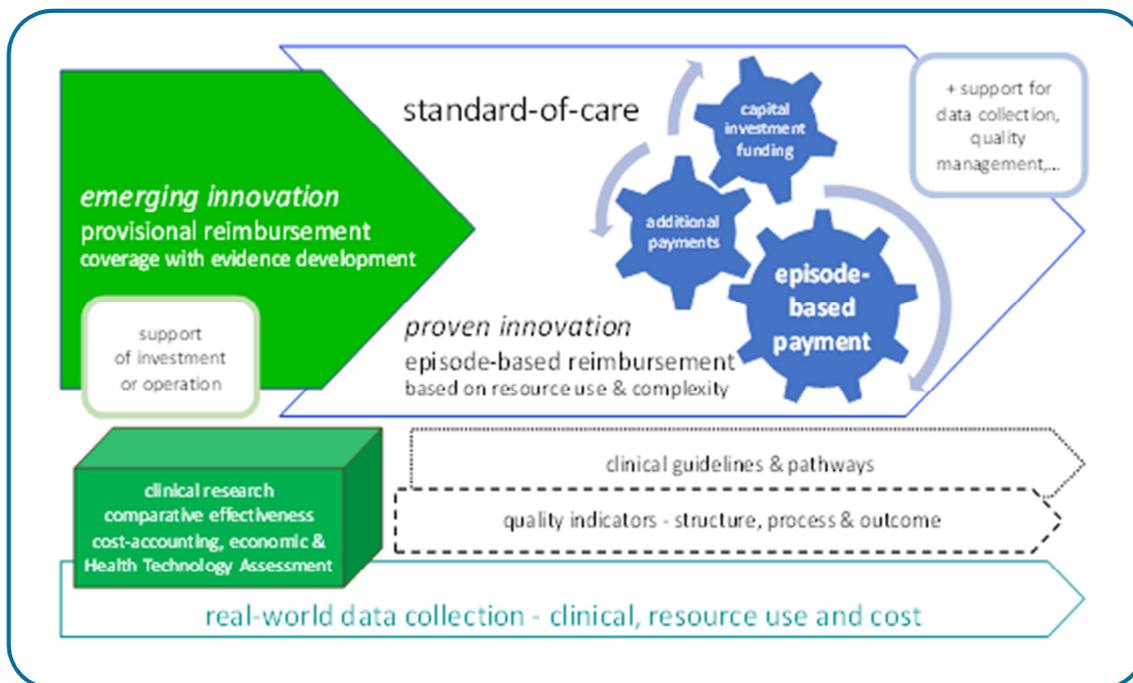
- How to generate evidence? Clinical trials are the gold standard although they are usually problematic in these therapies for two kind of reasons. First, lack of resources devoted to fund them (71). Secondly, although there have been good examples of RCTs resulting in practice changes for many therapeutic approaches in these fields (72), in a context of limited research investment and 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, in many cases the technology is implemented (73,74) without proper evaluation of clinical outcomes. We contend that evaluation is necessary both in incremental and stepwise innovation combining clinical and economic evaluation, in addition to a robust pre-marketing safety testing. Real-world data (RWD) collected systematically, with good quality and covering all cases, not a selection of them, could be a feasible alternative between accepting the intervention at face value or planning trials that would only provide results when the intervention is fully implemented. Due to the different relevance of the stepwise innovation, this problem could have worse consequences in this case than in incremental innovation. RWD should however form a key complement to all different kinds of evidence 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 multistakeholder 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. It should be borne in mind that the dissemination process in the health service of emerging innovative treatments are prone to learning effects, which could not only play a confounding role in the outcomes observed, but would also impact the costing analysis, hence the need for a specific temporary financing approach in this period.

Coverage with Evidence Development (CED) should be proposed as a practical approach which combines practical use and access to the innovation with formal evaluation, when clinical trials are not feasible. 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 any innovation. Its performance is more difficult, as the clinical benefits stemming from new radiotherapy treatments, techniques, and technologies are only perceived 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 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.

Figure 4. Reimbursement of incremental and stepwise innovation



EU may help Member States by providing guidance to improve their reimbursement systems. For instance, the EU, with the support of the European Network for Health Technology Assessment (EUnetHTA) could develop a model for evaluation/renewal of reimbursement processes to improve efficiency and clinical outcome, which could consider the proposals made in this report. A multistakeholder approach would also provide additional insights including but not limited to scientific societies, patients, industry, insurers, hospitals, social carers.

Conclusion

The evolving field of cancer therapy poses a real challenge for designing a reimbursement policy that can cope with providing a fair payment of 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 amounts paid for the same therapeutic strategy. In addition to this, the reimbursement policy has not evolved in many countries in the recent decades, only with patches for specific technologies, techniques or treatment approaches, or based on investment in technologies without changing the reimbursement.

Although cancer drugs have attracted most of the policy discussion, cancer surgery and radiation oncology also have important challenges ahead. It seems reasonable to support a review of the current reimbursement systems that promote a comprehensive perspective, avoid fragmentation, and support valuable innovation. 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. 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. Innovation should be tackled in a two-tier approach (figure 4): one tier based on considering the common criteria for reimbursement of evidence-based interventions; and another tier for innovative therapies with definitive value yet to be proven. In the case of emerging innovation, we advocate for considering coverage with evidence development to gain information on therapies without alternative option to assess effectiveness and costs. All policy proposals should support the collection of relevant information, including costs, in an information system that could allow for real-world data analysis, when clinical trials are not feasible.

The key role played by cancer surgery and radiation oncology 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 cancer therapy.

Glossary

Budget-based payment

Hospitals receive a fixed income for providing health care over a certain time period, usually one year. Input measures or output measures (those related to the volume of activity) can be used to determine the size of the budget.

The budget for financing radiotherapy or surgery activities is part of the global hospital budget. In the case of radiotherapy, systems also have the option of establishing a specific budget for radiation oncology services, separate from the rest of hospital services.

Payment per case or episode (episode-based payment)

Hospitals are reimbursed according to the number and type of cases treated. The centre receives a fixed sum for every case attended, independently of the number of care activities or services provided in each treatment. This is largely a prospective model, since prices are determined ex ante and independently of real patient costs. The most well-known model is based on the diagnosis-related group (DRG) classification system.

Diagnosis-related groups (DRGs)

Measure of hospital products based on the determination of patient groups that are homogeneous in terms of resource consumption. All patients assigned to their DRG are expected, on average, to use the same amount of resources. Generally, the tariffs paid are based on the mean costs of each DRG at a national level.

Payment per radiotherapy treatment (or Course)

The radiotherapy service receives a lump sum for each treatment administered. This amount covers the cost of preparing and administering the complete radiotherapy treatment. It could be considered an episode-based reimbursement using the course of treatment as unit of measurement

Payment per fraction or per diem

Centres receive a lump sum per fraction of treatment, which covers all activities related to the administration of treatment as well as the cost of its preparation.

Fee-for-service

All diagnostic and therapeutic activities and services that constitute an episode of care are paid separately. The price of each service is determined ex ante.

Value-based payment

A type of reimbursement for medical services that ties payments for care delivery to the quality of care provided and rewards providers for both efficiency and effectiveness.

Bundled payments

Lump sums for covering all services comprising a care episode during a given period of time (usually ranging from one month to one year). It covers the full healthcare cycle for an acute medical condition, as well as defined time periods in the case of chronic diseases and primary care.

Coverage with evidence development

Coverage of a treatment or technology conditioned on data gathering through a clinical trial or registry to determine its effectiveness.

Managed entry agreements

Arrangements between firms and healthcare payers that allow for coverage of new medicines while managing uncertainty around their financial impact or performance.

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Annex 1

Workshop iPAAC

WP8 Challenges in cancer care.

Innovation and reimbursement models in radiation oncology and cancer surgery: towards value-based cancer care

Background

Reimbursement is one of the major policy tools that drives the way that health care is delivered in European health care systems. Reimbursement could be defined as the ‘way that money is allocated to the provider of care by payers of health care’. Different models of reimbursing cancer care exist in Europe, but the major debates have been focused on the reimbursement and cost of the drugs without almost no reference to radiotherapy or surgery.

The fact is that reimbursement systems for radiation oncology or surgery have not evolved in the last decades, only modified for reimbursing specific new treatments that require new equipment or complex planning of treatments, with few exceptions. These partial changes often modify the original rationality of the initial payment system. However, radiation oncology and cancer surgery delivery have changed in a very remarkable way, with major contributions to the improvement of outcomes in cancer care, both in local control of the disease and global survival.

New approaches proposed such as bundled payments models could have major impact on the payment and incentives to deliver these therapies, if applied in our health care systems. Also, the need to frame the contributions of the cancer treatments from the value-based care perspective requires an assessment of the potential of this approach to the evaluation of innovative treatments and how to interact with the classic reimbursement systems.

With these considerations in mind, in this workshop we would like to explore the potential contributions of reimbursement systems to the rational adoption and delivery of innovation in radiotherapy and surgery, how to define valuable innovations in these therapies and how to pay for them. In summary, we would like to explore the interconnection of three pillars: innovation, value-based care and reimbursement

Objective of the workshop

The aim of this workshop is to identify critical aspects of health policy and to explore potential options for supporting innovative treatments in radiation oncology and cancer surgery from a reimbursement perspective.

Methodology

A group discussion with experts, based on presentations made by participants. A report of the discussions with conclusions and recommendations, if participants agree on them, will be written and circulated among cancer plans of the countries involved in iPAAC (24 out of 27 of EU) and the Commission. If recommendations are agreed on, they will be included in the roadmap of the iPAAC to be delivered to the partners.

Workshop iPAAC – WP8

DRAFT PROGRAMME

Barcelona, 27-28 January 2020

8.30-9.00	Registration
9.00-9.30	Welcome and introduction to the workshop. <i>JM Borrás, Y Lievens (Tour de table)</i>
9.30-10.00	Background: reimbursement models in Europe. <i>J Corral</i>
10.00-10.45	Innovations in cancer surgery. <i>Peter Naredi</i>
10.45-11.30	Innovations in radiotherapy. <i>Ajay Aggarwal</i>
11.30-12.00	Coffee
12.00-12.45	Innovations and reimbursement: a perspective from the industry. <i>COCIR</i>
12.45-14.00	Lunch
14.00-14.45	Value based radiotherapy: how to define it. <i>Y Lievens</i>
14.45-15.30	Value based cancer surgery: how to define it. <i>R Audisio</i>
15.30-16.15	Do patients follow the technology? Implications for policy. <i>A Aggarwal</i>
16.15-17.00	General discussion

19.00h DINNER

8.30-9.15	How to reimburse innovation of medical devices. Y Lievens/N Pourel
9.15-10.00	How to stimulate innovation in drugs to meet patient needs, and how to reimburse them. D Pantali
10.00-10.45	Reimbursement, innovation and health care: a health policy perspective. J Figueras
10.45-11.15	Coffee
11.15-12.00	Patients perspective. ECPC
12.00-13.00	What's next? Wrap up and next steps. JM Borrás and Y Lievens
13.00-14.00	Lunch

Annex 2

LLISTA PARTICIPANTS REIMBURSEMENT MEETING BARCELONA

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Dimitra Pantelli	European Observatory on Health Systems and Policies
Valeria Wehner	Varian Medical Systems Deutschland
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Joan Prades	Institut Català d'Oncologia
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Annex 3



Economics of cancer care: reimbursement to improve introduction of innovations in cancer care

Reimbursement models in radiation oncology and complex cancer surgery in Europe

Deliverable related to the Task 8.4.2
WP8 Challenges in Cancer Care

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Co-authors: Yolande Lievens, Josep Maria Borràs

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Abbreviations

AGNSS	Advisory Group for National Specialized Services (United Kingdom)
AR-DRG	Australian Refined Diagnosis Related Groups
ASCO	American Society of Clinical Oncology
CANCON	Joint Action on Cancer Control
CatSalut	Catalan Health Service (Spain)
CCO	Cancer Care Ontario (Canada)
CRG	Clinical Reference Groups (United Kingdom)
DRG	Diagnosis-related groups
ESMO	European Society for Medical Oncology
ESTRO	European Society for Radiotherapy and Oncology
EU	European Union
G-DRG	German diagnosis-related groups
HRG	Health resource groups
HSM	Highly specialised medicine (Switzerland)
ICO	Institut Català d'Oncologia
IGZ	Dutch Healthcare Inspectorate
IMRT	Intensity Modulated Radiation Therapy
iPAAC	Innovative Partnership for Action Against Cancer
IVHSM	Inter-cantonal Agreement on Highly Specialised Medicine (Switzerland)
JA	Joint Action
MDT	Multidisciplinary team
MeSH	Medical subject headings
NCCN	National Comprehensive Cancer Network
NCPR	National Cancer Peer Review (United Kingdom)
NCRS	National Committee for Reference Centers (Portugal)
NICE	National Institute for Health and Care Excellence
NHS	National Health Service
NVvH	Dutch Association of Surgeons
ÖSG	Austrian Structural Plan on Health
PPP	Power Purchase Parity
RRI	Relative resource intensity
SBRT	Stereotactic body radiation therapy
SONCOS	Dutch Foundation for Oncologic Cooperation
SRI	Structural relative index
SRS	Stereotactic radiosurgery
TDABC	Time-driven activity-based costing
WP	Work Package
3D-RT	Three-dimensional conformal radiation therapy

Executive summary

Introduction

WP8 is dedicated to defining strategies to improve the quality of cancer care by optimising the use of healthcare resources and promoting realistic and evidence-based responses to existing needs. The continuous introduction of new technologies and therapies for diagnosing and treating cancer requires a careful evaluation of their effects on clinical outcomes and their impact on system sustainability. From a policymaking perspective, one key element is the reimbursement system, an essential component of the policy toolkit for introducing new and expensive technologies. However, most research focuses on new drugs. In addition to evaluating reimbursement arrangements for new health technologies, there is a need to review the different models implemented in therapeutic strategies, such as radiation oncology and complex cancer surgery, in order to gain a broader perspective of reimbursement practices in cancer care.

The aims of this literature review are to identify models for reimbursement and uptake of innovation among EU countries; assess their potential impact on accessibility, affordability, and equity; identify models for reimbursement in radiation oncology and complex cancer surgery in the European context; and finally, to analyse the distinct incentives for implementing each reimbursement model.

Methods

First of all, the main provider payment models used in the field of health care were described, and secondly, the systems for hospital payment in the European context. A literature review was then undertaken; 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. The advantages and disadvantages associated with the use of different payment models were then described narratively, along with the regulations around minimum volumes in complex cancer surgery in the European context and their implications in reimbursement policies. Finally, we briefly describe the evolution of payment systems used in oncology.

Results

The provider payment or reimbursement model is one of the main determinants of successfully achieving general health system objectives, like availability, accessibility, acceptability, and quality. The payment system in a given country shows how the health care system of that country pays for specific treatment strategies, including cancer care or radiotherapy.

The payment models used in radiotherapy in Europe are as follows: hospital or departmental budget, payment per case or episode (diagnosis-related groups (DRGs) or similar), payment per radiotherapy treatment, payment per day of hospital stay (per diem), payment per fraction, and fee-for-service. The different payment models show significant variation in terms of their implementation at national or regional level, the criteria used to evaluate the complexity of care, and the amounts paid and incentives created. Moreover, the financial incentives generated by different payment models have an impact on clinical practice, as they affect the fractionation schemes and determine the complexity of the treatments. Finally, the choice of a payment model in the field of radiation oncology becomes very important in relation to the introduction of new technologies and the rising cost of treatments, which has led to the development of payment models denominated 'coverage with evidence development' that assess the uncertainty associated with the introduction of new technologies.

The literature review on European payment models in complex cancer surgery yielded very limited evidence related to this issue. Most references came from grey literature; the provider payment models used to reimburse complex surgery include the global budget, payment per case or episode (e.g. DRGs), payment per diem, and fee-for-service. In the case of payment per case/episode or per diem, additional payments or special reimbursement rates were observed for complex surgery.

Based on the evidence relating improved patient outcomes to more experience in specific surgical procedures, regulations on minimum volumes were introduced for numerous complex surgeries as a measure to improve the quality of health care. In cases where these standards are not met, measures vary between countries. Some deny authorisation for practicing the surgical procedure at hand, while others withhold reimbursement from low-volume hospitals for the procedures.

As a result of the growing costs in oncology, a certain consensus has emerged around the need to reorient payment models towards those based on outcomes or on prospective bundled payments. The use of time-driven activity-based costing (TDABC) enables greater accuracy and transparency in estimating the costs of health care, so it can serve as a basis for making decisions on future investments and reimbursement for treatments, supporting the early but controlled adoption of new radiotherapy technologies in clinical practice.

The impact of the reimbursement systems is one of the aspects to be addressed within the framework of cancer plans as a key avenue for achieving the established health policy objectives.

1. Introduction

Innovative Partnership for Action Against Cancer (iPAAC)

The general objective of the iPAAC Joint Action (JA) is to develop innovative approaches to advances in cancer control. The innovations that will be covered within the JA consist of further development of cancer prevention, comprehensive approaches to the use of genomics in cancer control, cancer information and registries, improvements and challenges in cancer care, mapping of innovative cancer treatments, and governance of integrated cancer control, including a new analysis of National Cancer Control Plans. The development of innovative approaches to cancer control will be supplemented by a Roadmap on Implementation and Sustainability of Cancer Control Actions, which will support Member States in implementation of iPAAC and the Joint Action on Cancer Control (CANCON) recommendations.

Work package 8. Challenges in Cancer Care

Objectives

The aim of the work package is to define strategies to improve the quality of cancer care by optimising the use of healthcare resources and promoting realistic and evidence-based responses to existing needs. While cancer care has evolved, showing better organisation and specificity with regards to treating different cancer diseases, cross-cutting and disease-based challenges remain. Specific objectives are the following:

- To review and assess the situation for neglected cancers with a special focus on pancreatic cancer, highlighting the challenges and opportunities for improving detection, diagnosis, and access to expert clinicians in order to increase the quality of care and outcomes, and raising awareness within the EU Policy and Research agenda.
- To identify the potential use for and existing barriers to shared information systems, decision support systems, information and communication technologies, and 'big data' in the context of multidisciplinary teams (MDTs) and cancer care management, and its consequences for the implementation of MDTs in EU countries.
- To propose a set of measures aimed at improving the sustainability of cancer care in European countries, taking into account the challenges posed by trends in cancer incidence, assessment of clinical effectiveness, efficient resource allocation, affordability, and equitable access to good quality cancer care.

- To ensure that pain control is considered a priority in cancer and to distinguish the needs of long-term survivors from those of palliative care patients. Identify evidence-based guidelines and areas for improvement in the implementation of guidelines, education of oncologists and organisation of multidisciplinary approaches, including oncologists, pain and palliative care specialists.
- To highlight a homogenous approach to palliative care based on CANCON recommendations, including patient care pathways, national policy and sustainability, innovative therapies, cancer registries and clinical databases. Identify areas of development and challenges posed by innovative therapeutic approaches such as early integration of palliative care in the oncology care pathways, focusing on the available models of integration and on how palliative care and oncology can respond to the availability of personalised medicine, guiding the use of target therapies and immunotherapies both in clinical practice and in research.

Task 8.4: Economics of cancer care

Another challenge in cancer care is undoubtedly its sustainability, the introduction of innovations, and allocative efficiency (task 4). The CANCON policy paper ‘Enhancing the value of cancer care through a more appropriate use of health care interventions’ reported that the economic problem of improving the efficiency of the cancer care cannot be separated from the way health services are actually used in clinical practice. Inappropriate use of health services, unexplained variability in clinical practice, and the delivery of interventions of negligible value are responsible for a significant portion of resource wastage. Thus, to address current unmet needs (i.e. the underuse of effective or valuable care) through efficiency gains, health systems need to improve the quality of healthcare delivery, reduce unwarranted variation in practice, and withdraw resources for low-value care. At the same time, the continuous introduction of new technologies and therapies for diagnosing and treating cancer requires a careful evaluation of their effects on clinical outcomes and their impact on system sustainability. As mentioned in EU documents, there is a need to maintain a balance between innovation, availability, accessibility, and affordability. From a policymaking perspective, one key element in this endeavour is the reimbursement system for new technologies and treatments. Although reimbursement mechanisms are not a panacea, they are an essential component of the policy toolkit for addressing the introduction of new and expensive technologies. Indeed, there are

numerous examples of reimbursement mechanisms that have been developed and implemented in recent years, including pay-for-performance, bundled payments, and coverage with evidence development, to name just a few.

These alternatives, which are sometime implemented in combination with more traditional reimbursement approaches, could – together with regulatory mechanisms – promote or discourage innovation. Assessing their impact is therefore crucial. At present, most research focuses on new drugs. In addition to evaluating reimbursement arrangements for new health technologies, there is a need to review the different models implemented in therapeutic strategies, such as radiation oncology and complex cancer surgery, in order to gain a broader perspective of reimbursement practices in cancer care.

Task 4.2. To review the recent developments in reimbursement models and experiences in introducing innovative treatments in European health systems, with special focus on radiation oncology and complex cancer surgery as case studies

The aims of this literature review are, firstly, to identify models for reimbursement and uptake of innovation among EU countries as well as their potential impact on the accessibility, affordability, and equity, and secondly, to identify the distinct incentives and barriers for implementing each model in a context of multidisciplinary cancer management.

A workshop with experts, cancer planners and scientific and patient associations will discuss the recommendations on reimbursement reviewed in this report in order to improve how innovations are introduced in cancer care. The Institut Català d'Oncologia (ICO) will coordinate the workshop and the corresponding report in cooperation with scientific societies, experts and patient representatives.

Milestones to be reached by this task 4.2

M 8.2: Methodology of evaluation of reimbursement of complex surgery and radiation oncology, with a map of the pros and cons of different approaches completed, M 12

The target group of the specific milestone

Policymakers and cancer plans.

2. Objectives and research questions

2.1. Main research questions

- What are the recent developments in reimbursement models in cancer care in Europe?
- What reimbursement models have been used in radiation oncology and complex cancer surgery?
- What are the incentives for and barriers to implementing each model in a context of multidisciplinary cancer management?

2.2. General and specific research objectives

Overall aim

- To analyse the different reimbursement models that have been used in radiation oncology and complex cancer surgery in the European context.

Specific aims

- Identify reimbursement models and innovation uptake in European countries and assess the potential impact of each model on accessibility, affordability, and equity of service provision.
- Identify models for reimbursement in radiation oncology and complex cancer surgery in the European context.
- Analyse the distinct incentives for implementing each reimbursement model.

3. Methods

The report begins by describing the features of the main payment models used in the field of health care and the hospital payment systems used in the EU.

We then review the literature related to the payment or reimbursement systems currently used in radiation oncology and complex cancer surgery in April 2019, using the PubMed platform. We used a combination of medical subject headings (MeSH) terms and keywords to identify English-language publications related to the topic ‘payment systems in radiation oncology’ and the topic ‘payment systems in complex cancer surgery’ published from the year 2000. No country filter was applied (see Appendix A). We searched only the title and abstract fields and then screened the references of the publications retrieved. We also performed a grey literature search (Figures 1 and 2).

Figure 1. Identification of eligible studies in radiation oncology

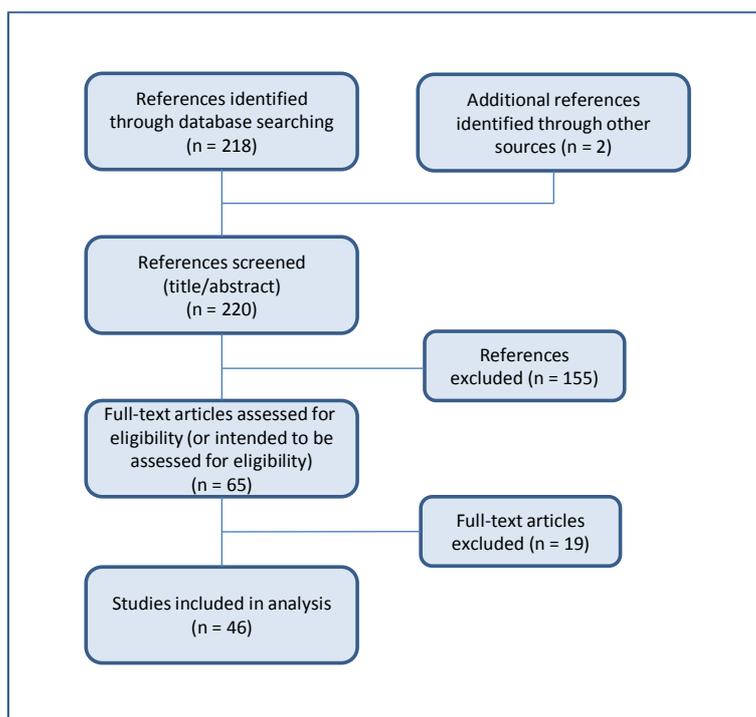
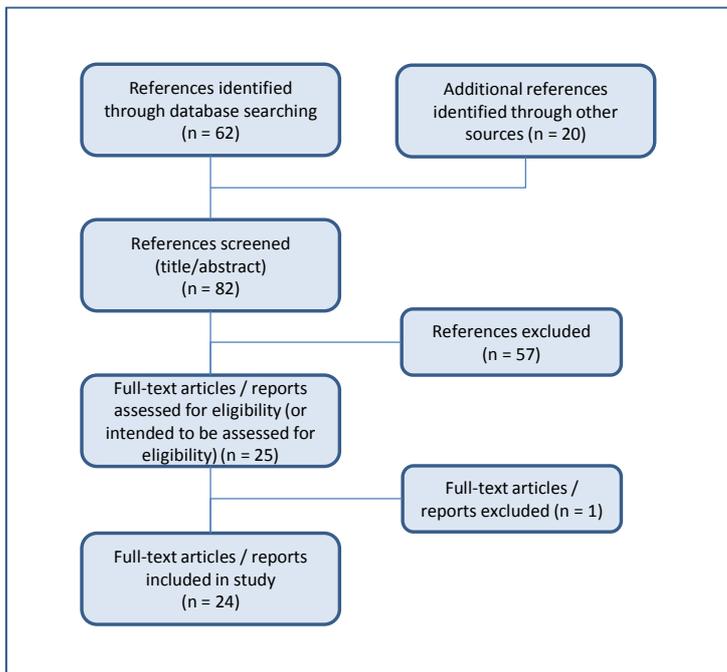


Figure 2. Identification of eligible studies in complex surgery



The advantages and disadvantages associated with the use of different payment models were then described narratively, along with the regulations around minimum volumes in complex cancer surgery in the European context and their implications in reimbursement policies. Finally, we briefly describe the evolution of payment systems used in oncology.

4. Provider payment models

The provider payment or reimbursement model is one of the main determinants of successfully achieving general health system objectives, like availability, accessibility, acceptability, and quality (1,2). The payment system of a given country provides information on how the health care system of that country pays for specific treatment strategies, such as cancer care or radiotherapy. The different payment models show significant variation in terms of their implementation at national or regional level, the criteria used to evaluate the complexity of care, and the amounts paid and incentives created, so the choice of payment system depends on the specific conditions of each country (3-5).

4.1. Definition of provider payment models

Provider reimbursement or payment models are mechanisms through which the payer reimburses the provider for services provided in the health care sector. Providers can be individuals/professionals (general practitioners, specialists, nurses, etc.) or institutions (hospitals, nursing homes, home health agencies, etc.) (1).

Although in some situations the concepts of reimbursement and real cost of a treatment are used interchangeably, in fact costs are based on the real consumption of resources, while reimbursement is the result of negotiations between the providers and funders of health care (6,7).

4.2. Characterisation of payment models

The payment model classification used by Jegers *et al.* (4) classifies models as: fixed or variable, and retrospective or prospective.

4.2.1. Fixed and variable models

Models can be classified as fixed or variable depending on the relationship between service provision and payment thereof, i.e. the additional revenue obtained by a provider for producing one additional unit (procedure, admission, patient-day, etc.) (4). In fixed models, payment does not vary with changes in provision. The provider receives a fixed sum that is determined *ex ante* and is unrelated to production; there is no payment for extra production units. Consequently, these models generate incentives to minimise costs by reducing the

number and intensity of care activities, possibly affecting the quality of care. Access to services may also be affected, since this type of model generates incentives to exclude patients with the highest expected costs. In variable models, meanwhile, payment does vary with changes in activity. The provider is paid for each additional unit produced, which generates incentives to increase production. This overproduction can lead to the provision of services that are not necessarily of any clinical benefit.

4.2.2. Retrospective and prospective models

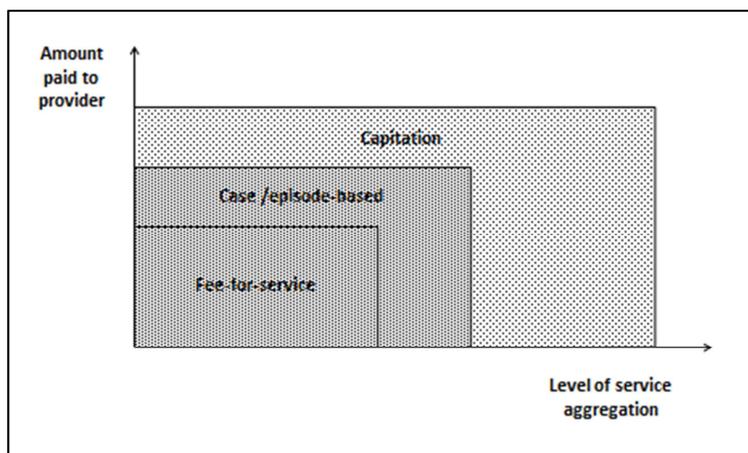
Models can be classified as retrospective or prospective according to the relationship between provider revenue and production costs (4). In retrospective models, production costs are reimbursed ex post. Consequently, providers have incentives to increase costs with the aim of increasing revenue. All financial risk rests with the payer (8). In prospective models, provider reimbursement is determined ex ante and is unrelated to production costs, which means the provider assumes all financial risk. Compared to retrospective models, prospective models generate more incentives to increase efficiency and cost containment, and to reduce the marginal cost per unit of reimbursement. These models also generate incentives to shift costs by referring patients to other providers, potentially increasing the total cost of care at a macro level (9). Furthermore, access to services may be affected in patients whose expected costs are higher than the corresponding prices. These incentives are greater where payments are not cost-neutral, i.e. where the expected marginal cost exceeds the marginal revenue of an additional production unit (4).

4.2.3. Other considerations

Another feature of the models relates to whether payment is based on the inputs used or the outputs produced (10). In the former case, the payer reimburses the costs of providing services. An example is a hospital receiving funding through a budget to cover operating costs. In the latter case, payment varies according to the number of medical activities or services, days of hospitalisation, cases treated, etc. These units are defined at different levels of aggregation. At the most disaggregated level, the provider is paid for each medical act or service separately (fee-for-service). The most aggregated level covers all medical activities and services provided to a patient in a given time period (capitation) (Figure 3). In these models,

prices are determined prospectively, regardless of whether payments are prospective or retrospective.

Figure 3. Dimensions of output-based payment models



Source: Langenbrunner 2009

4.3. Main provider payment models

The most widely used payment models for reimbursing professionals are: fee-for-service, capitation, and salary-based payment. The most widely used models in the hospital setting are: payment per diem, payment per case or episode, and global budgets (4). Each payment model generates specific financial incentives, and since no model is inherently better than any other, the choice of the model depends on the aims pursued and the type of provider.

4.3.1. Fee-for-service

In these models, all diagnostic and therapeutic activities and services that constitute an episode of care are paid separately. The price of each service is determined ex ante (4).

This is a variable model, since providers can increase their revenue by increasing production. It has the advantage of ensuring access to services, at least while marginal revenue is greater than or equal to the marginal costs of these services. On the other hand, this model promotes overproduction even where the health benefits generated are insignificant and – when prices are very low in relation to costs – it creates incentives to cut back on the resources (inputs) used in each service (8,10).

At the macro level, it is very difficult to control the growth of spending. In these models, annual payments cannot be made ex ante, since they depend on the volume of services provided by all hospitals (open-ended models).

Defining the list of reimbursable services and corresponding prices is a complex process. In addition, prices generally stay the same over long periods of time and thus fail to reflect the evolution of technological development costs. This can lead to a suballocation of resources because prices do not reflect the cost-effectiveness of each procedure. The administrative requirements of this model are significant, since services can be provided only with prior authorisation (4).

4.3.2. Capitation

Providers receive a lump sum for each patient on a periodic (usually annual) basis. Their total revenue depends on the number of patients under their care and is independent of the volume of services provided. This can encourage providers to maximise patient enrolment (4).

Capitation generates incentives to reduce per-patient costs by eliminating unnecessary services and focusing on prevention and health promotion when these activities are more cost-effective than ex-post treatment. Another advantage of this system is that the funder knows the costs ex ante.

However, this model type may promote risk selection, i.e. favouring patients whose care costs are expected to be low, to the detriment of patients whose care costs are expected to be high. A partial solution could be differentiating capitation payments according to patient age, sex, chronic diseases and other socioeconomic factors, or establishing some sort of risk adjustment.

Geographical capitation is a kind of capitation payment for primary care physicians, in which the revenue of these professionals depends on the number of patients in their catchment area. This model is more fixed than standard capitation payments because the physicians have no incentives to enrol more patients, and revenue can be modified in neither the short nor long term (4).

4.3.3. Salary-based payment

Professionals receive a fixed income to treat patients in a certain time period. The sum is independent of the number of patients attended and services provided (4). As with the capitation models, salary-based payment entails the risk of underuse and patient referral. Another disadvantage of this model is the relatively small incentive to provide continuous patient follow-up. Finally, this system discourages coordination of care among different providers (8).

4.3.4. Payment per diem

This type of payment is used to reimburse hospital operating costs. In this type of system, physicians play a decisive role in reimbursement, as they determine how long patients stay in hospital.

This is generally a variable model and can be either retrospective or prospective (4). In retrospective models, a price is set based on the costs and number of patient-days of the previous year. This system covers the historical costs of the hospital, since reimbursement is based on real costs. If total costs increase in a given year, the price will increase for the following year. In prospective models, prices are determined ex ante, which means providers have incentives to reduce average costs per patient-day by cutting down on the resources (inputs) used (10). In both cases, there are incentives to increase the average length of stay.

This model also promotes unnecessary admissions and discourages the development of outpatient surgery. Finally, using this payment model generates incentives to increase hospital capacity (number of beds) (10).

4.3.5. Payment per case or episode

Hospitals are reimbursed according to the number and type of cases treated. This is largely a prospective model, since prices are determined ex ante and independently of real patient costs. The most well-known model is based on the diagnosis-related group (DRG) classification system.

This model is considered a compromise between the variable and fixed model (4). Providers have incentives to increase productivity (11), increase the number of episodes treated, and reduce their duration; but also to reduce costs by shortening hospital stays, using lower-cost

resources (inputs), and diminishing the quality of care (4,10). This model is associated with a greater risk of hospitals specialising in healthier, lower-cost patients and dividing diagnostic/preoperative and surgical procedures over several hospital admissions to increase revenue. To counteract this effect, a regulation could be put in place whereby hospitals are not reimbursed when they readmit patients during a certain time period after discharging them. Finally, there is a greater risk of diagnostic upcoding in order to increase revenue.

4.3.6. Budget-based payment

Hospitals receive a fixed income for providing health care over a certain time period, usually one year. Input measures or output measures (those related to the volume of activity) can be used to determine the size of the budget (4). In the former case, the budget is based on hospital capacity, measured by number of beds or number of specialists. The budget is defined by multiplying the number of beds by the corresponding prices. In the latter case, the budget is determined using units such as patient-days, admissions, outpatient visits, or cases. This is a prospective model, since the payment amount is determined ex ante and is not related to the provider's real costs. It is also possible to combine these measures. For example, in the Netherlands, the budget is based on the number of patients treated in the hospital catchment area, the capacity of the hospital (measured by number of beds and specialists) and the negotiated activity of the hospital (4).

Under this model the provider assumes all the financial risks of service provision. As a result, it generates incentives to minimise costs, possibly resulting in underprovision of services and reduced quality of care. It may also lead to access barriers for patients with greater expected costs (8).

The budget is normally based on historical costs, which means this model risks institutionalising inefficiencies because hospitals with higher costs receive more resources than more efficient hospitals (1,12). Finally, this system discourages coordination of care among different providers (8).

4.3.7. Mixed payment models

Given the disadvantages of capitation-based and pure DRG-based payment models, in the study conducted by Ellis and McGuire in 1986, the authors proposed a mixed payment model, in which hospitals are reimbursed according to the volume of cases/patients and the volume

of care activities or services. The main advantage of these systems is that the payment can be disaggregated to some extent without going as far as the fee-for-service model. In addition, the partial use of per-patient payment could reduce incentives for risk selection.

Furthermore, it is possible to design a prospective per-case payment model combined with a global budget, with the aim of controlling overall costs and promoting care productivity (1). This type of model was implemented in several hospitals in Norway from 1991 to 1993. In these cases, 70% of the payment was made through a global budget to fund the fixed hospital costs, while the remaining 30% was reimbursed through a per-case model, thus covering variable costs. Where total fixed costs are covered independently of the level of activity, there is little incentive to increase efficiency in healthcare provision. A 60:40 combination could solve this problem (1). Another alternative is a capitation-based payment model combined with fee-for-service, in which the incentive to overuse services generated by the fee-for-service model is compensated by the incentive to reduce the use of resources promoted by the capitation-based model. This type of payment model has been implemented in the Netherlands to pay office-based doctors.

5. Hospital payment models in Europe

Until the end of the 1990s, most European countries reimbursed hospitals through global budgets, fixed prices per admission, or fixed prices per diem, based on the number of bed-days. Since then, and with the aim of increasing efficiency and cost containment in a context of significant technological innovation and growing complexity of cases, many of these countries have begun to incorporate per-case payments in their hospital payment models (11). Table 1 lists the hospital payment models used in selected EU countries.

Table 1. Hospital payment models in selected EU countries

Country	Payment model
Austria	DRG-based budget allocation (96%) and per diems
Belgium	Payment per case (45%) + payment per procedure (41%) + payments for drugs (14%)
Bulgaria	Payment per case and global budget
Croatia	Per diem and global budget
Czech Republic	Prospective global budget (75%) + per case (15%) + per procedure (8%)
Denmark	Prospective global budget (80%) + payment per case/DRG (20%)
Estonia	Payment per case/DRG (39%) + fee-for-service (33%) + per diem (28%)
Finland	Payment per case/DRG
France	Payment per case/DRG (80%) (macro-level price control) and global budgets + additional payments
Germany	Payment per case/DRG (within global budgets) (80%) + global budgets + additional payments
Greece	Payment per case/DRG + global budgets + per diem + additional payments
Hungary	Payment per case/DRG
Ireland	DRG-based budget allocation (80%) + global budgets + additional payments
Italy	Payment per case/DRG and global budgets
Lithuania	Payment per case

Country	Payment model
Luxembourg	Prospective global budget
Netherlands	Payment per case/DRG (within global budgets for 67% of DRGs) (84%) + global budgets + additional payments
Poland	Payment per case/DRG (60%) + global budgets + additional payments
Portugal	DRG-based budget allocation (NHS), Payment per case/DRG (health insurance) (80% NHS + health insurance) + additional payments
Romania	Payment per case and global budget
Slovakia	Payment per case/DRG
Slovenia	Global budgets and case-based payment
Spain	Line-item budget, DRG-based budget allocation + global budget + fee-for-service + additional payments (Catalonia)
Sweden	Payment per case/DRG (55%) + global budget
UK	Payment per case/DRG (60%) + global budgets + additional payments

Sources: Langenbrunnen *et al.*, 2005 (13), Cylus 2010 (11), Cots *et al.*, 2011 (14), Economou *et al.*, 2017 (15)

6. Provider payment models in radiation oncology in Europe

The diversity of payment models generates regional variability in the availability and access to cancer treatment, especially chemotherapy and radiotherapy (16). Moreover, the financial incentives generated by the different payment models used in radiation oncology have an impact on clinical practice, as they affect the choice of fractionation schemes and determine the complexity of treatments, for instance regarding the amount of isodose calculations performed, the use of shielding blocks or the number of fields irradiated (17-26). Finally, the choice of a payment model in the field of radiation oncology becomes very important in relation to the introduction of new technologies and the rising cost of treatments (27-28), which has led to the development of payment models denominated ‘coverage with evidence development’, which assess the uncertainty associated with the introduction of new technologies (29-30).

The literature review on European payment models in complex cancer surgery yielded very limited evidence related to this issue. In 1996, Kesteloot *et al.* (12) sent surveys to radiation oncologists and administrators in different European countries, comparing the main characteristics of the payment systems used in radiation oncology along with their organisation and financing. In 2000, Lievens *et al.* (17) sent questionnaires to 565 radiotherapy centers included in the 1997 directory of the European Society for Radiotherapy and Oncology (ESTRO), comparing the reimbursement systems for radiotherapy in different western European countries and analysing the impact of these differences on the administration of palliative radiotherapy for bone metastasis (17-18). In a forthcoming paper (31), the same authors update the information on reimbursement systems used at a national level in the European context and present a more detailed analysis of the reimbursement for different treatments with a curative intent for cancers of the breast, prostate and lung as well as for brain metastasis (palliative radiotherapy and cranial stereotactic radiosurgery). In other studies, Schmidberger (32) describes the payment system for radiotherapy in Germany, while Palazzi *et al.* (27) estimates the mean reimbursement per patient in 30 centres of the Lombardy region based on information from regional authorities.

In Bulgaria, Hadjieva (33) analysed the changing patterns of radiotherapy treatment after implementation of 15 projects valued at EUR 100 million, financed by the European Fund for Regional Development under the Operational Programme ‘Regional Development’ 2007–2013.

That paper argued that reimbursements for radiotherapy covered just 25% to 50% of the operating costs, constituting an inadequate level of reimbursement. Reimbursement for three-dimensional conformal radiation therapy (3D-RT) is EUR 900, and for intensity-modulated radiation therapy (IMRT), just EUR 1500. Moreover, despite the availability of radiosurgery and stereotactic body radiation therapy (SBRT), these techniques are not reimbursed. In a paper on changes in radiotherapy in Lithuania, Mineikyte *et al.* (34) drew similar conclusions, reporting that the mean reimbursement for 3D-RT is EUR 571, and for IMRT, EUR 860. In Slovenia, too, Jeraj *et al.* (35) sustains that molecular imaging plays a central role in radiotherapy treatments, but its generalised use is limited by the reimbursement models used.

In papers by Van de Werf (36) and Lievens (6,37), the authors argue that the available economic studies in the field of radiotherapy do not accurately capture the real costs of these treatments because of the high variability in the cost inputs, the scope of the analyses, and the costing methods used. Moreover, the estimates based on time-driven activity-based costing support the design and establishment of reimbursement schemes allowing investments in new equipment and infrastructure and the introduction of innovative techniques in clinical practice. Bonastre (38) analysed the impact of learning effects on the variability of costs for new health technologies in a prospective payment system, based on the case of IMRT in 99 patients diagnosed with head and neck cancer who were included in a prospective study of IMRT in nine centres in France.

Outside Europe, Santos (26) reviewed the clinical records of patients treated with radiotherapy for uncomplicated bone metastasis between March 2006 and March 2014 in a centre in south-eastern Brazil, concluding that the type of reimbursement influences the prescription of radiotherapy in patients with bone metastasis.

The rest of the references found correspond to studies in the United States. Several studies analyse the reforms implemented in the payment systems for radiotherapy to reorient them towards value-based models (39-42), the existing variability in reimbursements for radiotherapy provided through Medicare across the country (28), and the relationship between financial incentives generated by reimbursement models and physicians' clinical practice (23,25,43,44). Other studies analyse the impact of reimbursements on the use of IMRT (20,24), brachytherapy (22,45), palliative radiotherapy (19,46,47), intraoperative radiotherapy (21), and other techniques (48,49), as well as the use of hypofractionation as a way to increase the value of the treatments (50,51). Several studies analyse the

reimbursement received by radiation oncologists and physicists (52-60) and the reimbursements for radiotherapy in testicular cancer (61). Finally, one study examines how membership in managed care networks affects the uptake of new technologies in hospitals (62).

6.1 Main payment models used

The main payment models used in radiation oncology in Europe are (31):

- Departmental or hospital budget
- Per case or episode (DRGs or similar schemes)
- Per radiotherapy treatment
- Per diem
- Per fraction
- Fee-for-service

6.1.1. Departmental/hospital budget

The budget for financing radiotherapy activities is part of the global hospital budget. Systems also have the option of establishing a specific budget for radiation oncology services, separate from the rest of hospital services. This type of model is also used to finance the procurement of equipment, although generally it does not permit the incorporation of cutting-edge technology (12,17).

Under this model, the hospital assumes all financial risks in the provision of services, which generates incentives to minimise costs, potentially through an underprovision of services, for example in shielding blocks, isodose calculations, and simulations. This can have negative impacts on the quality of care. Lievens *et al.* (17) reported that the payment model was statistically correlated with the fractionation scheme and the complexity of care, as measured by the use of shielding blocks, although not in the case of the production of isodose distributions and in the field set-up. Specifically, the authors observed shorter fractionation schemes and less complex treatments (i.e. fewer shielding blocks used) in centres receiving case-based reimbursements in comparison to a fee for service.

Because budgets are usually calculated based on historical budgets, the centres with the highest costs receive more resources than those that are more efficient, so this kind of reimbursement system can institutionalise inefficiencies (12).

Lievens *et al.* (17) also noted that the most common payment method used is the global budget, as 69% of the centres used some kind of budget for financing radiation therapy activities. Furthermore, there were differences according to whether the centre was public or private. The percentage of private centres using a budget was 55%, while in university

hospitals, it reached 83%. Finally, the investigators found an association between the size of the hospital, the type of payment model used, and the type of fractionation: the biggest centres were reimbursed through a budget and/or payments per case or radiotherapy treatment, and this model was associated with the use of shorter fractionation schemes. In their most recent study, Lievens *et al.* (31) reported that in 2017, radiotherapy activities were totally or partially financed through budgets in 83.3% (n = 20) of the 24 European countries included in the study.

6.1.2. Payment per case or hospital episode

The centre receives a fixed sum for every case attended, independently of the number of care activities or services provided in each treatment. This model is used to reimburse radiotherapy treatments undertaken in inpatients using a case- or episode-based rate. Measures are calculated using hospital 'products' (DRGs or similar), defined by the diagnosis and weighted according to the procedure, age, sex, circumstances of discharge, and the presence of complications or comorbidities.

The main advantage of this model is that it incentivises hospitals to increase efficiency in the provision of services (11). However, it also generates incentives for increasing the cases or episodes treated, limiting costs by reducing the length of hospital stay, substituting inputs for those with a lower cost, or decreasing the quality of care (4,10). Another of its disadvantages is the risk of diagnostic upcoding in order to increase revenues. In 2017, Lievens *et al.* (31) found that only 1 of the 24 European countries studied financed radiotherapy activity based on the number of cases or episodes.

6.1.3. Payment per radiotherapy treatment

Under this model, the radiotherapy service receives a lump sum for each treatment administered. This amount covers the cost of preparing and administering the complete radiotherapy treatment. The incentives that this model generates are similar to those under the case- or episode-based model: increasing the radiotherapy treatments administered and reducing the costs by providing fewer medical acts or services and decreasing the quality of care (23). The potential reduction of medical acts or services is smaller than that generated through budget-based payments (12).

Lievens *et al.* (17) observed that centres receiving reimbursements for activities based on cases or a global budget used shorter fractionation schemes and less complex treatments (i.e. lower use of shielding blocks) than those paid per service. This study also noted the incentive for diagnostic upcoding in order to increase revenues. While in the 2000 study, 35% of the centres used this payment model to finance radiotherapy activity, by 2017, the same authors reported that this proportion had dropped to 8.3%, representing just two countries that used this payment system in combination with other models (17,31).

6.1.4. Payment per fraction or per diem

Centres receive a lump sum per fraction of treatment, which covers all activities related to the administration of treatment as well as the cost of its preparation. The advantage of this payment model is that it covers the real costs of the treatment and, when done prospectively, it generates incentives to reduce the mean costs per fraction of treatment administered. However, this model incentivises the overuse of fractions and sophisticated technologies (32). Moreover, it does nothing to incentivise hypofractionation techniques that use smaller fractions and a lower total dose over the course of the treatment (and consequently, lower revenues per patient) or the use of stereotactic radiotherapy (50,32). In some cases, this model is used to reimburse treatment received by inpatients through a per diem rate. In 2017, Lievens *et al.* (31) found that 3 of the 24 included countries in Europe financed radiotherapy activity by means of payments per fraction or per diem.

6.1.5. Fee-for-service

Radiotherapy activity is financed through fees paid for each medical act or service administered. This means that every medical act, whether it be a simulation, plan, fixation, or treatment session, is paid separately (17). Generally, this is combined with other types of fees for activities (or budget) to cover the total cost of radiotherapy treatment.

The model uses variable rates and has the advantage of guaranteeing access to services, at least when the marginal revenues of the services match their marginal costs (4). Moreover, incentives are created for activities and overprovision of services (23,44). The centres do not face restrictions on providing additional services, even when the marginal benefit of the services is negligible (4). In the case of radiotherapy, the incentivisation towards the overuse of services translates to a larger number of fractions, a larger total dose, and a greater use of

shielding blocks (17). As a consequence, the use of this payment system does not incentivise the administration of shorter-than-standard treatments (for example, palliative treatments), hypofractionation techniques, or stereotactic radiotherapy (Johnstone 2019). This payment model also incentivises the use of more complex irradiation techniques (17,44).

Additionally, the fee-for-service scheme can result in a suballocation of resources, as the tariffs do not reflect the cost-effectiveness of the procedures. Indeed, they are fixed for long periods of time and do not reflect the evolution of costs and benefits associated with technological developments. This point is more relevant in the field of radiation oncology, where the technological component is crucially important (4).

In their paper from the year 2000, Lievens *et al.* (17) reported that 46% of the European centres studied used a fee-for-service component (although not necessarily alone) for financing radiotherapy activity. By 2017, this proportion had fallen to 33.3% (8/24 countries). This type of model is also used in the United States to reimburse physician practice in oncology as well as in other clinics and hospitals throughout the country (23,44,54).

6.1.6. Comparison of payment models used in radiation oncology

Table 2 compares the payment models used to finance radiotherapy activities in Europe, listing the advantages and disadvantages associated with implementing each model.

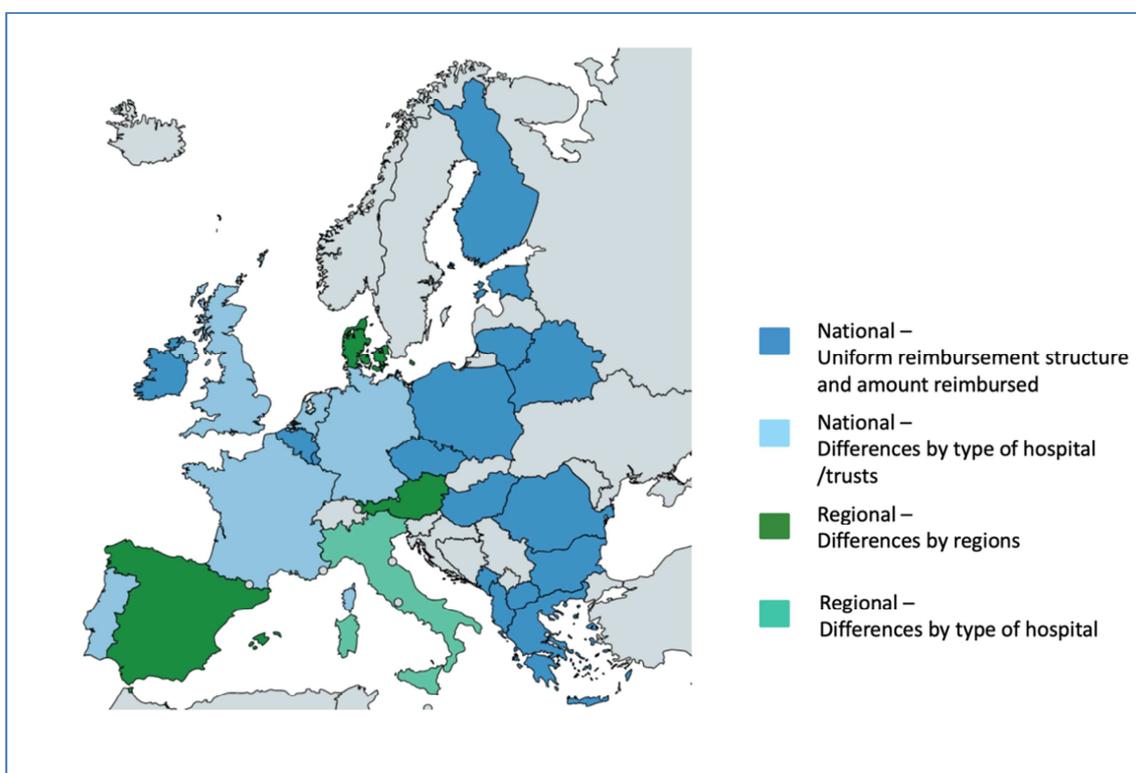
Table 2. Advantages and disadvantages of different provider payment models in radiotherapy

Payment model	
<i>Advantages</i>	<i>Disadvantages</i>
Departmental or hospital budget	
<ul style="list-style-type: none"> – Incentives for minimising costs at a micro level – Incentives for using hypofractionation techniques 	<ul style="list-style-type: none"> – Underprovision of services: deterioration in the quality of care – Lower complexity in treatments, less use of shielding blocks – Institutionalisation of inefficiencies in centres with higher costs
Payment per case or episode (DRGs or similar)	
<ul style="list-style-type: none"> – 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 per case) – Incentives for using hypofractionation techniques 	<ul style="list-style-type: none"> – Underprovision of services: reduction in hospital stay, use of lower-cost inputs, decrease in quality of care – Diagnostic upcoding
Payment per radiotherapy treatment	
<ul style="list-style-type: none"> – Incentives for increasing the efficiency in the provision of services – Incentives for increasing the number of cases treated – Incentives for reducing costs (mean cost per case) – Incentives for using hypofractionation techniques 	<ul style="list-style-type: none"> – Underprovision of services: use of lower-cost inputs or decrease in quality of care – Lower complexity in treatments, less use of shielding blocks – Diagnostic upcoding
Payment per treatment fraction	
<ul style="list-style-type: none"> – Coverage of real costs of treatment – Reduction of mean cost per treatment fraction in case of prospective rate: reduction of resources per fraction 	<ul style="list-style-type: none"> – Overuse of fractions and sophisticated technology – No incentives for administering shorter-than-standard treatments: palliative treatments, hypofractionation techniques or stereotactic radiotherapy
Fee for service	
<ul style="list-style-type: none"> – Guarantees access to services 	<ul style="list-style-type: none"> – Overuse of fractions – Use of more complex irradiation techniques – No incentives for administering shorter-than-standard treatments: palliative treatments, hypofractionation techniques or stereotactic radiotherapy – Suballocation of resources: tariffs do not reflect cost-effectiveness of procedures

6.2. Characterisation of payment models in radiation oncology by country

Figure 4 shows the organisational structure of publicly financed provider payment systems in radiation oncology in Europe, based on the paper by Lievens *et al.* (31). In some countries, public financing also covers private services. Additionally, provider payment systems in radiotherapy activity are mainly organised on a national level.

Figure 4. Sources of financing and organisational structure of provider payment models for radiation oncology in Europe



Source: Lievens *et al.*, 2019 (31)

In their 2019 study, Lievens *et al.* (31) observed a wide variety of payment models in the 26 included countries (table 3). In 76.9% (n = 20), radiotherapy activity is partially or totally financed through budgets. In 34.6% of these countries (n = 9), the budget is based on the number of treatments administered or activities performed, while in 26.9% (n = 7), the budget is used to finance investments in equipment. In addition, 34.6% (n = 9) of the countries use a fee-for-service model, while just one country finances radiotherapy through case- or episode-

based payments, three countries combine case-based payments with other models, and three countries finance radiotherapy per fraction or per diem.

Belgium

This country uses a fee-for-service system to pay for radiotherapy, along with a budget to finance a portion of the activities, the basic operational costs, and the equipment. This budget is calculated based on measures of activity.

The equipment budget is based on the number of treatment units under 10 years old in current use, the type of equipment, and the level of utilisation, as measured by the number of patient simulations per treatment unit (12).

Hungary

The Ministry of Health funds 95% of the system, while the hospital assumes the remaining 5% of the costs. The hospital budget, in conjunction with a departmental budget based on payment per treatment, is used to finance the procurement of equipment. The departmental budget is based on a maximum number of treatments administered, after which no additional treatments are financed. For its calculation, each treatment is considered to comprise 14 fractions; the same amount is paid for all treatments from 5 to 14 fractions. If a patient receives 25 fractions, this is considered two treatments in the budget calculation. For fewer than 5 fractions, the insurer pays a proportional part of this amount.

Poland

Poland uses a payment-per-treatment model, which is independent from the number of patients treated annually. The health system also uses a limited budget, negotiated annually, for patients who are not treated according to a predefined timeline, creating an incentive for centres to provide prompt service on a strict timeline. The budget for purchasing equipment is national, and services can put in requests to replace obsolete machines.

Spain

Depending on the region, funding for radiotherapy activity is based on budgets or paid per treatment. In Catalonia, the regional health authority uses payments per treatment, according to four levels of complexity. Assuming that the radiotherapy units are working at maximum capacity and that there is a certain caseload, the budget is established as follows: 75% is paid

through a global budget, independently of the number of patients treated, while the remaining 25% varies according to the number of treatments administered (case-based payments). As in Portugal, agreements exist for referring patients from the public to the private sector in case of long waitlists.

United Kingdom

Scotland and Wales use hospital budgets to reimburse radiotherapy activities, while England uses a fee-for-service system. However, in some regions of England, certain indications are reimbursed using a treatment-based rate, for example for SBRT in lung cancer.

Table 3. Description of provider payment models in radiation oncology by country

Country	Hospital budget	Departmental budget	Per case or episode	Per radiotherapy treatment	Per diem/fraction	Fee-for-service
Albania	✓					
Austria		✓ (based on activities)				
Belgium	✓ (based on number and type of treatments) ✓ (equipment)					✓
Bulgaria		✓ (equipment)		✓		
Czech Republic		✓ (based on activities)				
Denmark		✓ (based on activities)				
Estonia						✓
Finland	✓				✓	
France						✓ (Public) ✓ (Private: field)
Germany						✓
Greece		✓ (Public: based on activities) ✓ (Public: equipment)				✓ (Private)
Hungary	✓ (equipment)		✓ (based on number of 14 fraction treatments)			
Ireland	✓					

Country	Hospital budget	Departmental budget	Per case or episode	Per radiotherapy treatment	Per diem/fraction	Fee-for-service
Italy	✓ (Public)	✓ (Private: based on activities)				
Lithuania						✓
Luxembourg	✓ (equipment)					✓
Macedonia	✓ (based on number of treatments)					
Montenegro	✓					
Netherlands						✓
Poland	✓ (based on number of treatments)	✓ (equipment)				
Portugal				✓ (inpatient)	✓ (outpatient)	
Romania	✓ (equipment)		✓ inpatient		✓ outpatient	
Spain		✓		✓		
UK	✓ (Scotland, Wales)					✓ (England)

Source: Lievens *et al.*, 2019 (31).

6.3. Comparison of payment per radiotherapy treatment in cancers of the breast, prostate, and lung and in brain metastasis

Lievens *et al.* (31) compared payment per radiotherapy treatment by country and technique used with regard to the indications for cancers of the breast, prostate, and lung, plus brain metastases (palliative radiotherapy and cranial stereotactic radiosurgery; Fig. 5). According to the authors, there is substantial variability in relation to the reimbursements received by providers for all indications analysed, but especially for the specific reimbursement for rotational IMRT, as well as for the complex activities like movement management in some countries. In radiotherapy to the brain, the differences observed related to the combined effect of the treatment intent and complexity.

Figure 5. Reimbursement levels for the clinical indications breast, prostate, lung and brain (PPP, 2016 EUR)

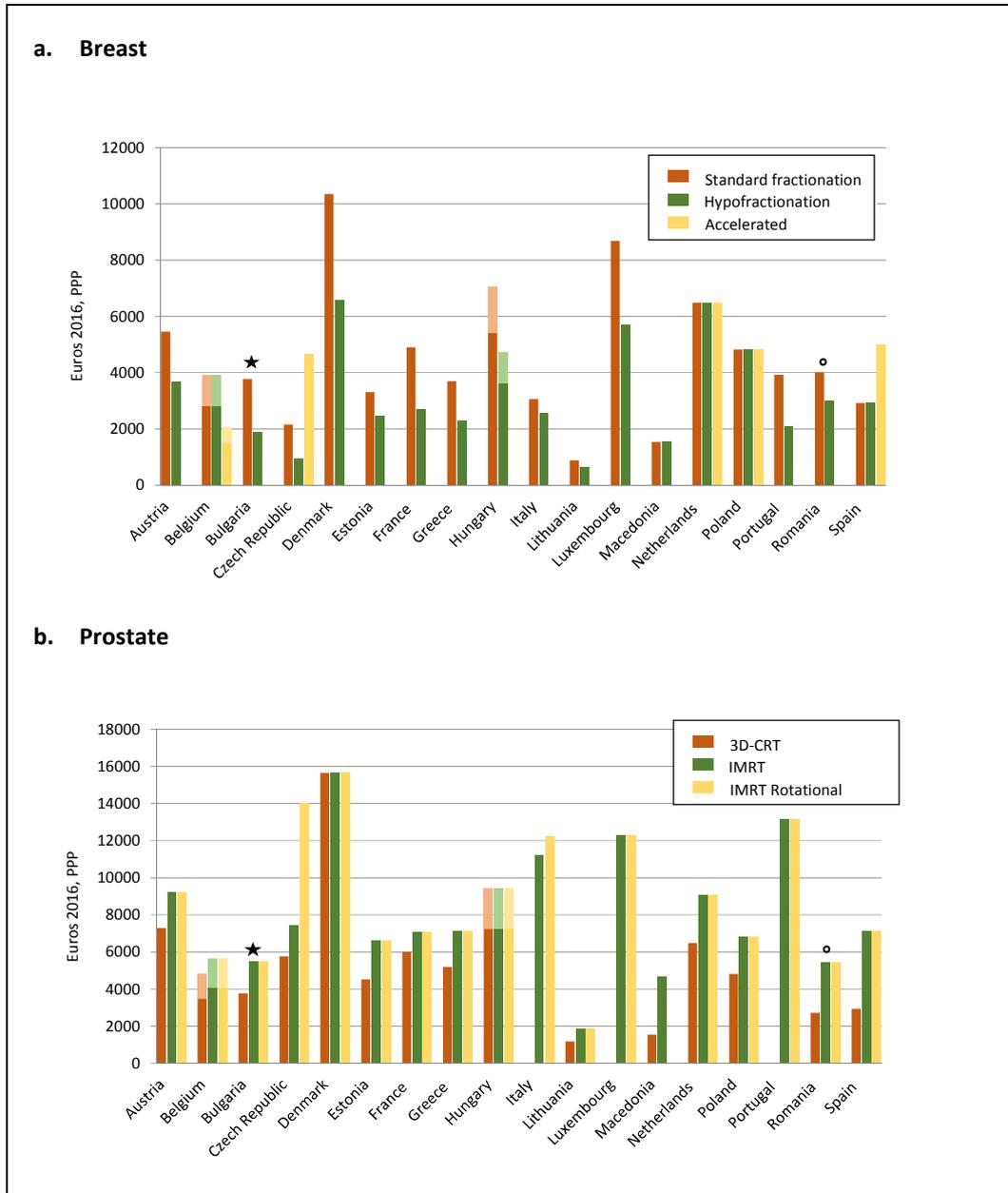
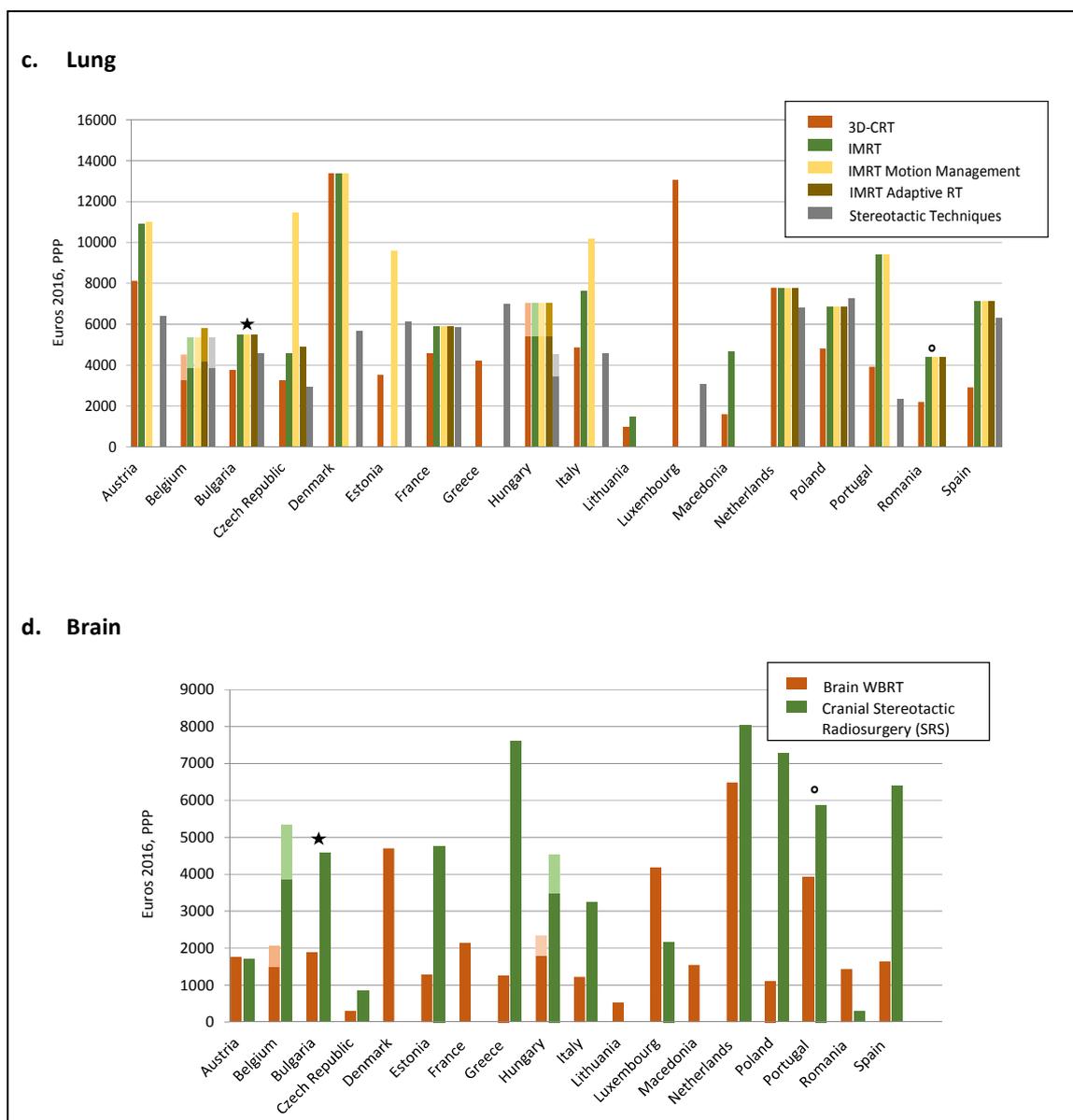


Figure X. Reimbursement levels for the clinical indications breast, prostate, lung and brain (PPP, 2016 EUR) (Cont.)



Source: Lievens *et al.*, 2019 (31).

All figures were converted for purchasing power parity in Euro, for the year 2016.

Averages were computed for the following number of fractions:

- breast standard, regardless of technique: 25 fractions; breast hypofractionation: 15 fractions; extreme hypofractionation: 5 fractions;
- prostate standard, regardless of technique: 37 fractions;
- lung standard, 3D-CRT and IMRT, regardless of additional complexity: 30 fractions; SBRT: 3 fractions;
- WBRT: 10 fractions; SRS: typically 1 fraction, except if specified differently by the country.

Fees per fraction are not displayed.

In three countries, a separate equipment budget exists, not included in the fees. In Belgium and Hungary, an additional amount has been added to these reimbursement fees, estimated from the proportion of the equipment budget in the total radiotherapy expenses. In Bulgaria, a recent capital investment was made through a European co-operative programme for Regional Development of EU countries 2007-2013, which cannot be traced to the reimbursement. This is denoted with the *.

In Romania, about 70% of the capital investment (hospital budget for equipment) is derived from the reimbursement fees. In public hospitals, the remaining 30% of the hospital equipment budget comes from own funds, this is highlighted by the °.

Belgium: all breast and prostate treatments were assumed to receive a simultaneous integrated boost. Data are based on the strict interpretation of the actual reimbursement system, which dates from 2001 without adaptation to changing clinical and technical evidence. It may therefore not completely reflect reality.

The Netherlands: fees for insured patients are negotiated between institutes and their healthcare insurer company, hence are confidential. The data displayed are officially calculated averages from the Dutch Health Authority [retrieved from <https://www.opendisdata.nl/> on 5/7/2019]. For lung treatment schedules, except for stereotactic techniques, an average between two type of tariffs is displayed under the assumption that half of the treatments are done with a simulation CT while the other half is done with a PET-CT (reimbursement dependent on type of imaging).

Portugal: data are based on the Portaria n.234-2015 guideline and represent an average reimbursement which can vary from hospital to hospital.

Spain: mean fee calculated for a patient referred to a private hospital based on the official fee published in specific regions of Spain.

Abbreviations:

3D-CRT: 3D conformal radiotherapy, IMRT: intensity-modulated radiotherapy, SBRT: stereotactic body radiotherapy, WBRT: whole brain radiotherapy, SRS: stereotactic radiosurgery, CT: Computed Tomography scan, PET-CT: combined Positron Emission Tomography and Computed Tomography scan

7. Provider payment models in complex surgery in Europe

The literature review on European payment models in complex cancer surgery yielded very limited evidence related to payment models for complex surgery in Europe. Most references came from grey literature.

Bojke *et al.* (63) analysed the existing approaches for adjusting payments in order to offset the disadvantages of using the DRG payment system in cases of complex health care. Moreover, two reports were found on establishing top-up payments in different areas of health care, both published by the UK Department of Health and Social Care (64,65). We also identified the working papers from the University of York which underpin the establishment of these payments (66,67).

Other studies identified deal more generally with reimbursements for highly specialised services in Germany (68,69) and specific reimbursements for complex surgery in a Spanish region (70-78). Finally, some studies assess regulations on minimum volumes as a measure to improve the quality of health care, mentioning certain economic implications involved in this type of process (79-82).

The papers identified in the PubMed search correspond to analyses of reimbursements for specific complex surgical procedures in hospitals in Germany and the United States. Stellwag *et al.* (83) compares the costs and reimbursement for pylorus-preserving pancreatic head resection due to pancreatic head adenocarcinoma versus a procedure considered standard (in this case, elective laparoscopic cholecystectomy) in a university hospital in Germany. The authors concluded that complex pancreatic surgery is not adequately reimbursed in university hospitals, and additional financing is needed to complement the DRG system, along with a review of the tariffs paid in these cases. Hoefert and Lotter (84) analyse the reimbursement of three surgical options for tongue cancer, including tumour resection and different reconstructive surgeries, through the hospital payment system in Germany from 2006 to 2016.

In the United States, two papers analysed the costs and marginal benefits of pancreatic and hepatic surgery in two hospitals in the country. Kachare *et al.* (85) estimated the costs and marginal benefits of pancreatic surgery between 2008 and 2012 in Vidant Medical Center (North Carolina). Considering only the direct costs, the marginal benefit for the surgeries offered was positive. However, this balance reversed once the indirect costs were incorporated. For their part, Knechtle *et al.* (86) analysed the marginal benefits and costs of three gastrointestinal surgical procedures (pancreaticoduodenectomy, hepatectomy, and

colectomy) carried out between September 2009 and August 2012 in a university hospital in the south-western United States. The authors also estimated the impact of complications on the marginal costs and benefits, finding that cases with surgical complications were more costly but also received higher reimbursements. The use of the fee-for-service model does not generate incentives for improving the quality of care, as the surgical procedures subject to the highest level of reimbursement are those that have the most complications.

7.1. Main payment models used

Based on the literature review conducted, the most common provider payment models used to reimburse complex surgeries are global budgets, case- or episode-based payments (DRGs or similar), per diem payments, and the fee-for-service model. In the case of case-based or per diem payments, cases with complex surgeries were subject to an additional top-up sum or a special tariff (63-69,72-76).

Additionally, Knechtle *et al.* (86) confirmed that the fee-for-service system does not generate incentives for improving the quality of care. Under this model, the surgical procedures that receive the highest reimbursements are those resulting in the most complications.

Diagnosis-related groups

Diagnosis-related groups (DRGs) are a measure of hospital products based on the determination of patient groups that are homogeneous in terms of resource consumption. This implies that all patients assigned to their DRG are expected, on average, to use the same amount of resources. Generally, the tariffs paid are based on the mean costs of each DRG at a national level.

For this payment system to work correctly, either the variation of costs within each DRG should be unrelated to observable patient characteristics, or patients should be randomly distributed among hospitals. If the treatment costs in patients receiving complex care are higher than those in other patients assigned to the DRG, this situation produces a systematic variation in the costs associated with a particular group of patients and hospitals. In these cases, the payment system may penalise hospitals that take on patients with more costly needs, disincentivising hospitals from assuming cases with higher expected costs (63). The larger the differential in the proportion of patients requiring complex care, the higher the financial penalty.

In these cases, there are two approaches for adjusting the reimbursement level to offset the disadvantages of this payment system (63). The first is based on a recalculation of the rate for each DRG in order to determine a top-up payment for patients who receive complex care and to reduce the rate for the rest of the patients assigned to the same DRG. The rate differential would have to reflect the estimated cost differential for each specific type of complex care. This option is easy to implement because it does not require any change in the patient classification system.

The second approach is based on a refinement of the DRGs to which patients are assigned. This option is more appropriate when the patients who receive complex care are concentrated in a few DRGs. If the patients are distributed over many DRGs, the subdivision into an even larger number would result in very few patients belonging to each group. If this refinement of DRGs is combined with a policy for centralising complex services in a small number of hospitals, there is a risk that a single hospital becomes responsible for all the patients in a particular DRG. In this case, that hospital would solely determine the rate for the DRG, and a payment system intended to be prospective would end up being retrospective, based on real costs. Therefore, the option of refining DRGs is less advisable when patients requiring complex care are distributed over a larger number of DRGs. The refinement of DRGs (or lack thereof) depends on the cost differential and the degree of concentration considered necessary between hospitals and DRGs (63).

7.2. Characterisation of payment models for complex surgery in selected countries

This section describes the payment models for complex surgery in selected countries in Europe.

Germany

The payment model used in Germany has been based on DRGs since 2003 – specifically, the Australian Refined Diagnosis-Related Groups (AR-DRGs). A classification algorithm is applied to the hospital discharge data set in order to assign cases to different DRGs, based on the following criteria: primary diagnosis, secondary diagnoses, clinical intervention, patient characteristics (sex, age, weight (in newborns)), cause of the discharge, and length of hospital stay. The German DRGs (G-DRGs) are used in all acute care hospitals for all types of services, and since 2013, also for care in psychiatric, psychotherapy and psychosomatic medicine departments.

The costs of the procedures are used as a basis for calculating reimbursements in the G-DRG system (84). The German DRG Institut calculates the cost weights based on retrospective expenses and claims data collected in hospitals in Germany over the previous two years. Each hospital sends the Institut annual claims data as well as structural data, for example the hospital's institutional code and ownership, number of beds, number of residents, personnel costs, and total costs. The information on costs is calculated using sample data from the hospitals that participate in a voluntary data exchange programme.

The G-DRGs cover the costs of human resources, materials, and catering, though not the capital costs. Additionally, there are certain complex or costly services and very expensive medicines that are not covered by the G-DRG, which are reimbursed through complementary schemes (68). Since 2005, and in the case of highly specialised services, hospitals can negotiate an additional reimbursement (per case or per diem) if they can demonstrate that the service in question cannot be adequately reimbursed through the G-DRG or if it is not included in the section on supplementary tariffs in the Case Fee Catalogue (69).

Spain

Since 1997, the hospital payment system in the Autonomous Community of Catalonia has been based on DRGs. The tariffs paid to hospitals depend on two specific indicators: the relative resource intensity index (RRI) and the structural relative index (SRI). The SRI reflects the structural level of the hospital, while its use of resources (the RRI) is defined by the mean relative weights of the DRG discharges compared to the mean weight in the public network. The Catalan Health Service (CatSalut) establishes tariffs for each RRI and SRI (RRI and SRI prices), along with the weights for each measure (70).

$$\text{Discharge price} = (\text{SRI} \times P_{\text{SRI}} \times 0.65) + (\text{RRI} \times P_{\text{RRI}} \times 0.35)$$

The current weights (65% for the SRI and 35% for the RRI) do not generate incentives for the hospital to increase the complexity of the cases treated. Although there is a difference in the DRG weights of the discharges, the final result is practically the same in terms of reimbursements.

Starting in 2012, a policy for reorganising highly specialised oncology activities began roll-out. This policy regulated the centralisation of complex surgeries for cancers of the oesophagus, stomach, pancreas, liver (metastasis and primary liver tumours), and rectum, plus benign brain tumours and peritoneal carcinomatosis (72-75,77-78) in an effort to improve quality and

clinical outcomes as well as efficiency in the provision of these surgical procedures. In parallel, specific tariffs were established for the reimbursement of these procedures (76).

United Kingdom

The UK uses a case-based payment system called the National Tariff Payment System, in which the tariffs paid to providers reflect the mean costs for each health resource group (HRG). HRGs are a measure of hospital output, and they are homogeneous in terms of resource consumption. This implies that all patients assigned to the same HRG are expected to require the same mean resource use. Moreover, all cost variations within HRGs are expected to be random among patients and hospitals (65). But if the cost variation is systematic and associated with a certain patient group, the payment system may disincentivise centres from treating them, or penalise them if they do (64).

As the national tariffs are calculated on the basis of the mean costs for each HRG, these do not take into account the differences in existing costs among the few providers that take on the most complex cases. In 2005, top-up payments were established for these cases for the purpose of recognising the cost differences and improving the concordance between the tariffs paid and the real costs of the health care.

To establish the payments, an adjustment (called a top-slice) is made to the total amount of money allocated to national prices, and the money is reallocated to providers of specialised services (65). The design and calculation of the top-up payments for specialised services, and the determination of which services to include, were developed by the Centre for Health Economics at the University of York in 2011 (66-67).

The top-up payments are applied only for hospital care; they covered the following areas: in 2017–2019: the spine, neurosciences, orthopaedics, paediatrics, cancer, and respiratory and cardiac diseases.

7.3. Centralisation – regulation of minimum volumes

Based on evidence correlating patient outcomes with experience in a given surgical procedure, minimum volume regulations have been introduced for a number of complex procedures in order to improve the quality of care (79-80). The literature published on this topic is extensive. Beginning with the study undertaken by Luft in 1979 (87), a large body of evidence demonstrates the relationship between the volume of services and patient outcomes, especially in highly specialised procedures (88). In general, hospitals that perform more complex interventions show better outcomes in terms of postoperative mortality than hospitals sustaining a lower volume of the same intervention (88-90). Several studies focusing on oncological surgery in this sense have generated scientific evidence in support of centralising surgical procedures like pancreatectomy and oesophagectomy (80).

With regard to gastrointestinal surgery, Vonlanthen *et al.* (81) observed that of the 18 European countries studied, 11 (61.1%) had defined minimum hospital volumes for certain procedures, while just 1 had defined a minimum caseload for surgeons (table 4). If the minimum volume standards are not met, different countries implement a variety of measures (82). Some countries, for example Germany, deny the centres authorisation to practice the surgical procedure in question, while in other countries, like Austria, the consequences are not fully explicit. In the Netherlands, adherence to the standards defined by the Dutch Foundation for Oncological Cooperation (SONCOS, in Dutch) are used in price negotiations between hospitals and insurance companies. In 2011, minimum volume standards were established in the negotiations with hospitals for tumours of the pancreas, oesophagus, and urinary bladder. Moreover, low-volume hospitals were excluded from reimbursement procedures (80,82). In Catalonia (Spain), reimbursements are also denied for interventions performed in non-authorised centres (81). Appendix B provides additional information on centralisation policies for complex surgical interventions in selected countries in Europe and elsewhere.

Table 4. Requirements for minimum volumes by centre (resections/year)

Country	Oesophagus	Pancreas	Liver	Rectum	Surgeon volume	Legally enforced?
Austria	10	10	10 (20 ²⁰¹⁸)	10 (15 ²⁰¹⁸)	ND	Yes
Belgium	ND	ND	ND	ND	ND	
Czech Republic	ND	ND	ND	ND	ND	
Denmark	80-100	>100	>200	>120	ND	
Finland	ND	ND	ND	ND	ND	
France	30	30	30	30	ND	Yes
Germany	10	10	ND	ND	ND	Yes
Greece	15	20	30	ND	ND	
Hungary	10	20	30	20	ND	
Ireland	ND	ND	ND	ND	ND	
Italy	20	50-100	20	50	ND	
Netherlands	20	20	20	20	ND	Yes
Poland	ND	ND	ND	ND	ND	
Portugal	20	20	20	20	ND	
Romania	ND	ND	ND	ND	ND	
Spain	6	11	11	15	ND	Yes
Sweden	ND	ND	ND	ND	ND	
United Kingdom	60	80	150	ND	Defined	

Source: adapted from Vonlanthen *et al.*, 2018 (81).

ND: not defined

8. Evolution of payment models in oncology

Bundled payments

As a result of the growing costs in oncology, a certain consensus has emerged around the need to reorient payment models towards those based on outcomes or on prospective bundled payments (13,40,91). Bundled payments are lump sums for covering all services comprising a care episode during a given period of time (usually ranging from one month to one year). The bundled payment covers the full healthcare cycle for an acute medical condition, as well as defined time periods in the case of chronic diseases and primary care. These sums are not divided into separate pay-outs for human resources or facilities, nor for short hospital stays. However, DRGs can be a starting point for developing bundled payment models (92).

Input-based payment models (salaries, budgets, etc.) do not allow much flexibility for responding to specific needs or changes related to technology or treatment patterns. The more bundled the payment, the more incentives providers have to contain the overprovision of services, increase efficiency, introduce technological innovations that allow cost savings, administer less costly treatments, etc. On the other hand, providers are also incentivised to decrease the rigour and quality of care and cherry pick patients expected to incur lower costs. Thus, it is necessary to define a mixed payment model that balances different objectives, like cost containment and quality of care, progressing towards value-based models in which providers have to focus on improving health care while still maintaining their awareness of the costs of the services provided (86). In that sense, bundled payments incentivise competition among different providers to create value where it really matters – at the level of the individual patient (92).

Reimbursements made through bundled payments are based on the cost of efficient and effective health care. They should provide a marginal amount over the total costs of a provider considered to be efficient, that is, centres that use effective and efficient administrative and clinical processes throughout the care cycle. On the other hand, this type of payment should not provide any positive margin for providers offering low-value services, for example those that achieve poor outcomes, show a suboptimal use of their capacity, or incur high costs. Bundled payments can be adjusted to reflect variations in the setting, like the differentials in the salaries of clinical and administrative personnel and in public services and infrastructure costs (92).

The methodology of time-driven activity-based costing (TDABC) allows providers to measure the real costs of treatment at the patient level (45,92). This method combines bottom-up and top-down approaches to assign indirect costs of treatments, such as those related to personnel, equipment, facilities, and overhead costs (6,93). An intermediate step is used to assign resources to activities and then to assign the costs of the activities to the treatments. In other words, all clinical and administrative activities during a care episode are first mapped out, and specific resources associated with those activities (personnel, equipment, facilities, materials, overhead) are identified, along with the estimated time needed for their performance. Secondly, the costs per available minute are calculated for each type of service. The total cost of treatment is calculated by multiplying the resource time by the resource cost per minute of each activity. The use of TDABC methodology enables greater accuracy and transparency in estimating the costs of health care, so providers can increase the value of the health services offered, determining the treatments that generate the best outcomes at the most sustainable cost (45,92).

The costs of innovation

In the payment systems used to date, the incorporation of new technologies has implied the introduction of patches, added according to the context of the negotiation, such as in cases of extracranial or image-guided stereotactic radiosurgery, which has a special tariff. The availability of new technologies poses the need to use precise, exhaustive costing methods that can inform future decision-making on investments and reimbursements. Given the existing variability in both the type and the source of cost inputs, as well as in the target of the analysis and the methodologies used, there is no standard way to estimate costs (6,93). In addition to assessing the acceptability of a new technology, budget impact studies are needed to evaluate their sustainability (30,94). In the field of radiotherapy, budget impact and cost-effectiveness analyses are more difficult to perform, as the clinical benefits stemming from new radiotherapy treatments, techniques, and technologies are only perceived in the long term, while the costs of these innovations are higher in the implementation and learning phase. In these cases, learning effects are an important confounder in cost analyses, prompting the need for specific reimbursement mechanisms (38). Moreover, new technologies in radiotherapy – in contrast to what occurs with pharmacological treatments – do not require clinical efficacy studies before their introduction to the market. These particularities around the introduction of new technologies contribute to increasing the knowledge gaps related to the value of the innovation (30).

In the pursuit of providing value-based health care, generating knowledge on the benefits of new treatments is problematic, as these are measured using clinical trials, and little work is undertaken to assess the value of care from the patient perspective. In this context, the European Society for Medical Oncology (ESMO), the American Society of Clinical Oncology (ASCO), and the National Comprehensive Cancer Network (NCCN) have developed tools to define the value of oncology treatments. The lack of emphasis on the patient perspective and the dependence on traditional endpoints used in clinical trials (overall survival, disease-free survival, safety, and health-related quality of life) make these studies inapplicable to radiotherapy treatments. It is necessary to develop a more generalised framework of analysis that considers outcomes based on daily clinical practice and centred on the patients, for instance symptom control, preservation of organs, and perioperative complications, among others (51,95).

Finally, clinicians' interpretation of evidence on adverse effects can differ. This circumstance may have an impact on the introduction of innovations and, consequently, on clinical practice (96).

9. Concluding comments

- Healthcare provider payment models are a major determinant of a health system's efficiency and quality, as decisions on costs and level of production are made by professionals and healthcare centres.
- There are different payment or reimbursement models in radiotherapy, which show significant variations with regard to their implementation at national or regional level, the criteria for evaluating the complexity of the care, and the amounts paid and incentives created (31).
- The financial incentives generated by the different payment models used for radiotherapy have an impact on clinical practice, affecting the choice of fractionation schemes and the complexity of treatments provided. Furthermore, the choice of a payment model in the field of radiation oncology becomes very important in relation to the introduction of new technologies and the rising cost of treatments, which has led to the development of payment models denominated 'coverage with evidence development' in order to assess the uncertainty associated with the introduction of new technologies (29,30).
- Payment models need to be regulated through the establishment of control mechanisms to ensure the objectives of quality, access, and efficiency. For example, global or departmental budgets can favour an efficient, high-quality model if the budget is sufficiently large to guarantee an adequate level of services for every patient. If the financial allocations are too low, the incentives for providing good-quality services are diminished, no matter what payment system is used (8,17).
- As a result of the growing costs in oncology, a certain consensus has emerged around the need to reorient payment models towards those based on outcomes or on prospective bundled payments. As this type of model requires greater technical capacity, the case-based/DRG model may require an intermediate step (92).
- Reimbursements made through bundled payments are based on the cost of efficient and effective health care. In that sense, the use of time-driven activity-based costing (TDABC) enables greater accuracy and transparency in estimating the costs of health care, so it can serve as a basis for making decisions on future investments and reimbursement for treatments, supporting the early but controlled adoption of new radiotherapy technologies in clinical practice (17,18).

- The impact of the reimbursement system is one of the questions that should be investigated within the framework of a cancer plan, thus achieving the established health policy objectives (97).

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Appendix A

Literature review – search strategy

Payment systems in radiation oncology

Tables A1 and A2 present the key words and exclusion criteria used during the literature search on payment systems in radiation oncology.

Table A1. Search terms

Searches	Search terms
1	payment[Title/Abstract] OR reimbursement[Title/Abstract]
2	radiotherapy[Title/Abstract] OR radiotherapy treatment[Title/Abstract] OR radiation oncology[Title/Abstract] OR radiation therapy
3	English[Language]
4	2000[Date - Publication]

Table A2. Exclusion criteria

Exclusion criteria
- Studies not on radiation oncology
- Economic or cost-effectiveness studies of radiotherapy treatments
- Editorials
- Studies not relevant to the research questions
- Full text inaccessible

Payment systems in complex oncological surgery

Tables A3 and A4 present the key words and exclusion criteria used during the literature search on payment systems in complex oncological surgery.

Table A3. Search terms

Searches	Search terms
1	payment OR reimbursement
2	complex OR tertiary
3	surgery OR surgical OR surgical procedures
4	cancer OR neoplasm OR neoplasms OR oncology OR oncological
5	English[Language]
6	2000[Date - Publication]

Table A4. Exclusion criteria

Exclusion criteria
<ul style="list-style-type: none">- Studies on oncological but not complex surgery- Studies on complex but not oncological surgery- Costing studies of surgical procedures at a hospital level- Studies not relevant to the research questions- Full text inaccessible

Appendix B

Centralisation – regulation of minimum volumes

This appendix describes the regulations on minimum volumes in complex surgery in more detail for a selected group of European countries, based on studies by Vonlanthen *et al.* (81) and Morche *et al.* (82). A review of centralisation policies in the European context was undertaken, although not an exhaustive review of the regulations by country.

Austria

To ensure the quality of care, minimum standard volumes were defined in the country's health plan (ÖSG, in its German abbreviation) for procedures with enough supporting scientific evidence demonstrating that high-volume hospitals achieve better outcomes. The procedures included surgeries on the pancreas, oesophagus, and liver (82). The standards are determined in consensus by experts and are updated annually (81). The minimum volumes range from 10 to 25 cases per year and centre, as a mean measure of the previous three years. In case the minimum is not met, different states implement a variety of measures, although the real consequences are not sufficiently explicit.

Denmark

The Danish health authority regulates and coordinates highly specialised services, including complex hepato-pancreato-biliary and gastrointestinal interventions. Specialised and highly specialised interventions are performed in one to four centres in the country. Despite the small size of the country's population, the minimum number of cases is among the highest in Europe (for example, oesophageal surgery 80–100/year; pancreatic surgery > 100/year) (81).

France

All medical services require administrative authorisation, and special procedures require an exceptional authorisation (81). In centres performing oncological surgery, a minimum annual number of 30 procedures has been established for breast, gastrointestinal, urological, and thoracic cancers, and of 20 procedures for gynaecological and ear-nose-throat cancers, decreasing the number of centres with a very low case volume. However, Vonlanthen *et al.* (81) notes that centralisation has not been fully implemented; in pancreatic and hepatic surgery, centralisation is unfeasible for high-volume centres due to resource shortages.

Germany

In 2003, minimum volumes were established for complex surgery in order to counter the risks to quality of care posed by changing the payment system to an activity-based model in 2001; complex oesophageal and pancreatic surgeries were among the procedures included (79). For tumours at both of these sites, the minimum volume established was 10 cases/year. Failing to meet this cutoff could lead to withdrawal of the authorisation to carry out these surgeries (82). More than half of the hospitals in the country failed to fulfil the minimum cutoffs established, particularly the many small and non-specialised centres characterised by their overcapacity.

Hungary

This country does not follow any centralisation policy. Specialised surgical procedures are covered only through the health insurance funds in Hungary if they are included in the catalogue of the Hungarian College of Surgeons and authorised by the Ministry of Health. The College of Surgeons defines minimum volumes for oesophageal, pancreatic, hepatic, gastric and rectal resections, although there is no firm legal basis.

Italy

Since 2009, the National Outcomes Programme has been responsible for evaluating Italian hospitals and monitoring the volume standards (81). Moreover, the Italian Society of Surgery has initiated a process to define the criteria for identifying hospitals with the capacity to perform complex gastrointestinal surgeries, and it has made specific proposals for oesophageal, hepatic, pancreatic, and colorectal surgery. The establishment of minimum volumes does not have a legal basis; rather, it comes in the form of recommendations.

Netherlands

There are two nongovernmental organisations involved in establishing minimum volume standards for hospitals: the Dutch Foundation for Oncologic Cooperation (SONCOS) and the Dutch Association of Surgeons (NVvH) (82). SONCOS publishes an annual report on quality standards in multidisciplinary cancer treatment, including minimum standards for gastrointestinal cancer and lung cancer surgery, among others. In 2003, standards were established for oesophageal surgery, and in 2010, for pancreatic surgery. For most groups of

procedures, the minimum volume defined is 20 annual cases. These standards are established in cooperation with different professional associations and updated annually (81).

Adherence to the standards defined by SONCOS is considered in price negotiations between hospitals and insurers. Starting in 2011, minimum surgical volumes have been established in negotiations with hospitals for tumours of the pancreas, oesophagus and urinary bladder, along with exclusions for low-volume hospitals. This situation increased the pressure on hospitals to re-evaluate their position in the field of surgery (80,82).

For their part, the NVvH publishes a report on the standardisation of surgical treatments that includes some of the standards from the SONCOS report. In cases of malpractice, the Dutch Healthcare Inspectorate (IGZ, in its Dutch abbreviation) applies these indicators, and if the malpractice stems from a lack of experience, authorisation to practice the surgical procedure in question may be withdrawn.

Portugal

The Ministry of Health and the National Committee of Reference Centres (NCRS) are responsible for regulating complex health care. In 2014, national legislation established reference centres with the highest competencies in medical care for clinical situations that require a concentration of human and technological resources, whether due to the low prevalence of the disease, the complexity of the diagnosis and treatment, or the cost. These reference centres have been established for hepato-pancreato-biliary, oesophageal, and rectal surgery, among other subspecialties. The NCRS is charged with both the regulation and the monitoring of the reference centres.

Spain

Although a clear centralisation policy does not exist at a national level, some regions have implemented these types of measures in cancer care. In the Autonomous Community of Catalonia, the Catalan Health Service (CatSalut) launched a process to centralise gastrointestinal cancer surgery in 2005 (72), assigning complex cancer interventions to a very limited number of centres based on criteria of minimum case volumes and specialisation. Other targets of centralisation included peritoneal carcinomatosis surgery and retroperitoneal and neuroendocrine tumours (73-75). The Catalan cancer plan includes annual audits, whose results are shared with each audited centre. Moreover, reimbursement is denied for interventions undertaken in non-authorised centres (81).

Different studies have reported reductions in mortality rates in oesophageal and pancreatic surgery (72). Moreover, the audits have shown quality improvements in both the short and the long term in rectal cancer surgery (77-78).

United Kingdom

Currently, the provision of specialised and highly specialised services is concentrated in just a few hospitals (81). The networks specialising in cancer care are based on a hub-and-spokes model and cover an area of 2 to 4 million inhabitants. Resections of the liver, pancreas, oesophagus, and lower rectum, as well as bariatric surgery, are considered specialised services and commissioned directly by NHS England. In April 2013, the National Institute for Health and Care Excellence (NICE) assumed responsibility for evaluating highly specialised health technologies through the Advisory Group for National Specialized Services (AGNSS). Their recommendations include the establishment of minimum volume standards for multidisciplinary teams, although from a legal standpoint adherence is not mandatory.

In 2012, 20 Clinical Reference Groups (CRGs) offering specialised services through NHS England agreed on quality indicators for each area, with NHS England monitoring adherence. Policies for monitoring the NHS trusts have been designed to verify compliance with the volume indicators and the specific qualitative criteria for highly specialised services. In addition, a national programme for guaranteeing the quality of cancer care in the NHS was implemented, called the National Cancer Peer Review (NCPR). This programme stipulates minimum volumes for resections of the gastrointestinal tract, colon, rectum, liver, and pancreas, among other quality indicators.

NHS England can impose economic sanctions on providers that breach the conditions of their contracts. At the same time, providers demonstrating good compliance may receive a bonus. If the care provided is shown to be unsafe or of poor quality, the National Inspectorate Care Quality Commission may take appropriate measures, including shutting down the centre.

In Scotland, studies showing improved outcomes in patients treated by specialists in high-volume centres led to the establishment of managed clinical networks, coordinated by an executive board in order to organise specialised units within the network (81).

Other cases

Outside of the European Union, experiences in Canada and Switzerland are also worth examining.

In Ontario (Canada), Cancer Care Ontario (CCO) established minimum volume standards in organisational guidelines with the objective of improving surgical quality (82). These evidence-based standards were developed by a multidisciplinary panel of specialists in the region. In 2004, minimum volumes were established for thoracic interventions and subsequently introduced for surgeries of the oesophagus, liver, pancreas, and biliary tract. Compliance is not mandatory from a legal perspective; however, in its supporting role in the implementation of the guidelines, the CCO established financial agreements and penalties for poor adherence. Although these agreements are not binding, the CCO can withdraw payment for cases if the hospital does not conform to the stipulations in organisational guidelines. As in previous years, the CCO can pay hospitals for assuming additional cases in excess of budgetary provisions in order to reduce wait lists, and it can also stop financing certain cases if the implementation is not carried out. This penalisation is exceptional and individualised in nature.

In the case of Switzerland, the cantons collaborate in the development of a national, highly specialised medicine (HSM) strategy, within the framework of an Inter-cantonal Agreement on Highly Specialised Medicine (IVHSM) from 2009. This programme encompasses planning and allocation of resources and healthcare services, as well as the establishment of minimum volumes for different groups of procedures, with the objective of guaranteeing quality and improving patient safety (82).

In 2011, hospital services were assigned for a period of about three years, during which time the centres must meet the minimum volume standards for certain interventions. In 2016, the HSM established minimum volume standards for five groups of procedures: oesophageal, pancreatic, liver, and deep rectal resections, plus complex bariatric surgery, for which scientific evidence has shown lower postoperative mortality in higher-volume centres. These standards range from 15 to 25 cases per year and centre, although during a two-year transition period, the minimum number of annual cases was 10.

To request a new authorisation or renew an existing one, hospitals must meet the HSM's specific requirements for the group of procedures in question, including minimum volumes. Otherwise, the procedures will not be assigned to those hospitals.