ACTA ONCOLOGICA
2019, VOL. 58, NO. 10, 1328–1332
https://doi.org/10.1080/0284186X.2019.1639822

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COMMENTARY

Value-based health care – what does it mean for radiotherapy?

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ARTICLE HISTORY Received 12 April 2019; Accepted 22 May 2019

What constitutes value?

If our aim is value-based radiotherapy, we must first understand and agree what constitutes value.

Generally speaking, value refers to importance, usefulness or (monetary) worth, i.e., determines the relationship between a good or service and the price paid or asked for [1]. In various disciplines – sociology, business management, economics – different views exist: Although aspects regarding utility and monetary exchange are crucial, value is also influenced by cultural and social contexts and connected to experience [2]. In behavioral economics, the 'prospect theory' describes that perceived value may differ when decisions are made under conditions of potential benefits or losses, which may be relevant for patients in non-curative situations [3]. This introduces subjectivity, as the desirability of a good or service and what is considered a fair price may vary with its specific properties, the person concerned, the specific situation, the external circumstances.

In the above, value refers to what one wants to pay or give up to obtain something, not to what it actually costs. In health care, however, cost has been introduced into the value equation: 'An assessed health benefit relative to the cost'. The Institute of Medicine proposed an even broader definition, considering six elements of valuable health and cancer care: safety, effectiveness, patient-centeredness, timeliness, efficiency, equity [4,5]. Others have included yet other aspects, with societal implications beyond patients' value, such as accessibility, quality, acceptability, affordability, social significance, emotional and spiritual meaning [6,7]. The National Institute for Health and Clinical Excellence provides the most operational definition: 'The value of a treatment is based on scientific value judgments, including a clinical and an economic evaluation, and social value judgments, including considerations of efficiency and effectiveness' [6].

A balance between outcomes and costs

We will use the definition of Michael Porter: 'Value is defined as the health outcomes – that matter most to patients – achieved per dollar spent', i.e., an equation with outcomes in the numerator and costs in the denominator [8]. As such, value and economic evaluation can be regarded as two sides of the same coin, both with two dimensions crucial to guide societal decision-making on acceptability and affordability of new healthcare interventions [6,8,9]. But while economic evaluations strictly compare two treatments and provide an absolute value measure, the incremental cost-effectiveness ratio [9,10], Porters value equation is a cost-consequence analysis, with outcomes and costs being evaluated but not aggregated into a single measure [8,10].

The value of a good or service depends on one's willingness to trade for something else that has value. It does not necessarily include a monetary aspect [11]. Let's take the case of radiotherapy for locally advanced lung cancer: The disease extent and patients' comorbidities will be critical in making the choice, in 'valuing' between a potentially curative multimodality approach, with risk of serious side effects, and palliative radiotherapy, with limited toxicity but without chance of long-term survival. Based on such considerations, it has been questioned whether it is correct to define value as Porter did, including costs [8,10]. Assuming we accept his definition, changes in both the numerator and denominator can improve value, although they often are not independent. If, for example, advanced radiotherapy results in better outcome through decreased toxicity, healthcare costs subsequent to treatment are expected to decrease. Likewise, more efficient radiotherapy may not only lower the costs, but also improve local control, quality-of-life and survival, as in stereotactic body radiotherapy for lung cancer [12,13].

Economists believe that consumers are 'utility maximisers' by nature, always choosing the good or service which best satisfies their needs for the lowest cost [14]. Cancer patients may not follow this rationale: Beyond a balanced evaluation of risks and benefits, demands for particular treatments may be driven by hope, even when facing a high likelihood of side effects or limited benefits [15,16]. Defining optimal value for healthcare customers – patients undergoing radiotherapy, but by extension the society as a whole – is therefore not a trivial exercise. Which outcome offered by radiotherapy innovations matters most to patients, and what are the associated costs, during treatment, and in the years thereafter?

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Accurate costs are crucial in determining the value of healthcare – and radiotherapy – interventions, but consistent evidence is limited and confusion remains between the costs borne by healthcare providers and the price paid by patients or insurers [14,17–19]. Time-driven activity-based costing (TD-ABC), proposed to optimize healthcare costing [19], has been applied to radiotherapy, in real life as in theoretical models [19–24]. The ESTRO-HERO (Health Economics in Radiation Oncology) TD-ABC cost-accounting model can provide insight into the actual resources consumed in the radiotherapy care pathway, in the associated costs and in radiotherapy resources and costs embedded in the broader multidisciplinary environment [25]. Porter indeed defines costs as 'the total costs involved in the full cycle of care for the patient's medical condition'; hence, to optimize value, one should reduce the total costs of cancer care, not just those of individual treatments or services [8,26,27].

Similar complexity holds for capturing near- and long-term outcome [8]. Value being multidimensional, one outcome measure can by no means give a true representation of the results of a healthcare intervention. This is especially true for cancer care. Although it is commonly accepted that oncology innovations should aim for patients to live longer and better [6,28], various tumor types and stages will define different sets of multidimensional outcomes, together defining patient benefit. In addition, risk factors and comorbidities, patient circumstances and preferences, as healthcare system characteristics and capabilities, may impact the relative importance of these outcomes.

Although radiotherapy should be seen in the broader context of cancer care, it is useful to elaborate what may best capture patient outcome during and after radiotherapy. Porter defined health outcomes in a three-tiered hierarchy, each with two levels. While top tiers are generally most important, lower levels or tiers may become more relevant depending of the patients or interventions [8]. Figure 1 illustrates how this structure could apply to radiotherapy.

Tier 1 considers the 'health status achieved or retained'. 'Survival' is included as first-level outcome, being a fundamental goal, not in the least for cancer patients [8]. It may, however, not be optimal for loco-regional cancer treatments, especially if patients experience prolonged survival, the technology itself and concurrent treatments evolve over time, and the multimodality approach makes it difficult to associate survival with one specific treatment [29–32]. Moreover, maximizing survival may not be the most important objective for all patients. Hence, the second level: 'the degree of health or recovery achieved or retained', which includes quality-adjusted survival, and radiotherapy-specific endpoints such as functional status or organ sparing [8].

Tier 2 relates outcomes to the 'process of recovery', including 'the time required to achieve recovery' and 'the disutility of the care or treatment process' [8]. Avoidance of treatment interruptions would apply here, as would shorter overall treatment time and lower treatment burden, with possibly quicker return to previous activities. The second level would include radiotherapy-related acute toxicity [30].

Tier 3, the 'sustainability of health', encompasses 'recurrences of the original disease or longer-term complications', and 'new health problems created as a consequence of treatment' [8]. For radiotherapy, endpoints such as long-term local control or organ-specific progression-free survival, sustained functional status and late side effects, should be considered here [30,31].

Even if included in lower tiers, side effects – especially long term – and how they impact on health-related quality-of-life, are crucial in the evaluation of new radiotherapy treatments, techniques and technologies [8,30]. Symptoms, side effects and quality-of-life should therefore be incorporated in the assessment of any radiotherapy innovation and best measured by directly asking patients about their experience through patient-reported outcomes (PRO), thus quantifying value from a patient perspective [14,33,34].

Multiple roads to evidence

It is undisputable that efficacy remains best to provide unbiased outcome under ideal conditions. Yet, the design and reporting of randomized controlled trials (RCT) may render their results of lesser relevance to clinical practice. Patient selection to conform to strict inclusion criteria, for example, may hamper external validity and applicability, and overlook the need for personalized, not population-based, outcomes [35,36]. RCTs represent a specific challenge in radiotherapy due to the large scope of innovations involved. This is reflected in a mere 2% of radiotherapy research being devoted to RCTs [37]. While new treatments investigating altered fractionation or drug-radiotherapy combinations should favor RCTs, other innovations, such as new positioning devices, may require less stringent appraisal. Moreover, high upfront capital investments and rapid incremental evolution in software and hardware may hamper RCTs as the sole methodology to evaluate new radiotherapy technologies [29–31].

Blended evidence generation is therefore needed [29–31]. One novel method is the model-based approach applying parallel proton- and photon-planning. Based on personalized estimates of predicted long-term toxicity, patients are allocated to one technology or the other and subsequently followed in a standardized manner [38–40]. Although developed for evidence generation in particle therapy, this approach could also be used to appraise other emerging technologies [38,41].

To facilitate data capture across Europe, ESTRO and the European Organization for Research and Treatment of Cancer (EORTC) have bundled the forces of a large group of professionals with the know-how and infrastructure to perform large-scale oncology research in the E2-RADIatE (EORTC-ESTRO RADiotherapy Infrastructure for Europe) initiative. E2-RADIatE has the ambition to be an efficient research framework for radiation oncology, generating robust real-world evidence (RWE) on the role of radiotherapy in cancer treatment by supporting multiple prospective cohort studies [42].

RWE can also be extracted from registries or administrative datasets [29]. While it may overcome some of the

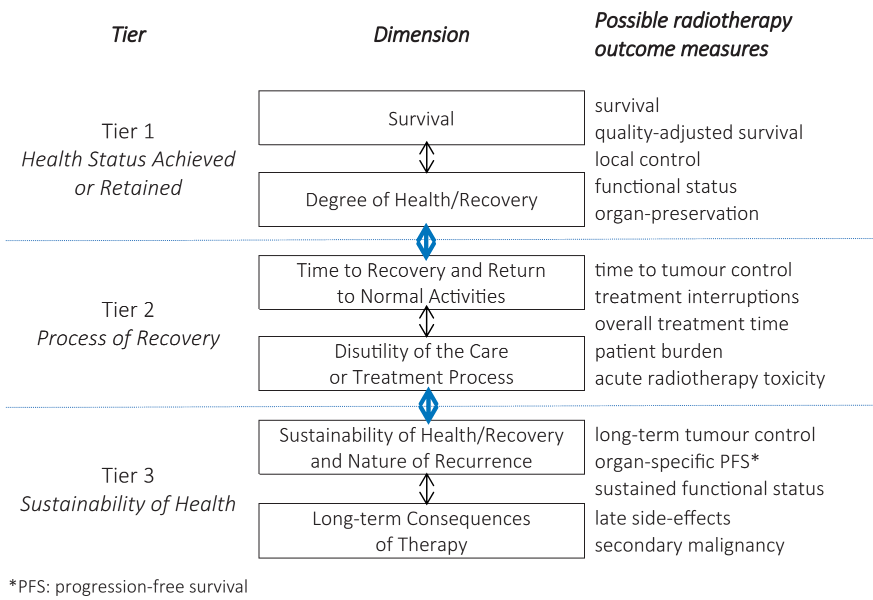

Figure 1. Three-tiered outcome hierarchy applied to radiation oncology.

described challenges of radiotherapy research, additional validation and methodological work may be needed. Moreover, RWE should not be seen in isolation, but as part of a multifaceted, practice-oriented approach to clinical effectiveness research. Complementing other data sources, RWE may generate hypotheses for clinical trials, translate efficacy into effectiveness representative of actual practice and patient populations, and allow for data capture over a long-term perspective [43,44].

Future perspectives for value-based radiation oncology

Ever-rising cancer care costs have triggered interest in value-based oncology, with value frameworks specifically developed to appraise value in oncology. The ESMO Magnitude of Clinical Benefit Scale, ASCO Value Framework and NCCN Blocks have been extensively discussed concerning their development, methodologies used and results generated. Although it has been argued that these frameworks vary in value assessment of specific drugs and do not truly capture value to support population-level decision-making, their merit lies in proposing strict methodologies evaluating outcome, all or not in combination with costs, and in putting value on the international oncology agenda [7,45–48].

Initially developed for drugs, these frameworks are inappropriate for value assessment of non-systemic cancer treatments [30]: They do not capture the most relevant outcomes and are not easily applicable to the multitude of radiation and surgical oncology interventions. In addition, limited patient focus and involvement, evidence generated by clinical trials only and insufficient cost evaluation have all been mentioned as points of concern [30].

Defining core endpoints [49–55] and a value scale for loco-regional oncology through multistakeholder collaboration is imperative [30], considering following aspects:

1. *intervention types:* stepwise versus incremental technological innovations;
2. *evidence levels* beyond RCTs, considering requirements per intervention type [38–40,43];
3. *intervention intent,* determining endpoints and relevant clinical improvement;
4. *endpoint categorization* in survival-related endpoints; functional outcomes, acute and late toxicity and complications; economic and operational endpoints including resource use, costs and quality.

Economic endpoints should formally be included, crucial as they are to guide societal decisions on acceptability and affordability of new treatments. Data generation and capture can be facilitated by dedicated tools and infrastructure (e.g., ESTRO-HERO TD-ABC, E2-RADIatE) [6,25,42]. Likewise, operational and quality endpoints are critical in radiation oncology [30]: procedural volume, professional qualification and expertise, availability and diversity of high-tech medical devices, learning curves following the rapid evolution of techniques and technologies may all impact outcome. Including aspects of the Donabedian model, i.e., structure and process indicators, along with outcomes, should therefore be considered for a value scale for radiation oncology [14].

Finally, value frameworks should address unmet medical need and timely access to promising new treatments. They should be flexible in clinical endpoints, data generation and integration of new evidence, practice patterns and medical progress as well as incorporate patient preferences. In the present rigid data capture environment, this is hardly achievable. However, broader integration of data available in various healthcare and insurance registries, along with better interoperability of radiotherapy-specific IT networks, should in time allow a flexible framework combining data from clinical trials, dedicated infrastructures and real life [56].

In conclusion, value-based healthcare has gained interest, yet multiple questions remain, not in the least in the context of radiation oncology. Issues regarding endpoints and evidence generation required to value new radiotherapy treatments, techniques and technologies should be addressed through multistakeholder collaboration, including the patients' perspective.

Disclosure statement

No potential conflict of interest was reported by the authors.

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References

[1] Oxford English Dictionary. Available from: http://www.oed.com, cited 2019 April 2.
[2] Boztepe S. User value: competing theories and models. Int J Des. 2007;1:55–63.
[3] Kahneman D, Tversky A. Prospect theory: an analysis of decision under risk. Econometrica. 1979;47:263–291.
[4] Institute of Medicine Committee on Quality of Health Care in America. Crossing the quality chasm: a new health system for the 21st century. Washington DC (US): National Academies Press; 2001. ISBN-10: 0-309-07280-8.
[5] Levit L, Balogh E, Nass S, et al. Board on Health Care Services, Institute of Medicine Committee on Improving the Quality of Cancer Care: addressing the challenges of an aging population. Delivering high-quality cancer care: charting a new course for a system in crisis. Washington DC (US): National Academies Press; 2013. ISBN-13: 978-0-309-28660-2.
[6] Ramsey S, Schickedanz A. How should we define value in cancer care? Oncologist. 2010;15:1–4.
[7] Campolina AG. Value-based medicine in oncology: the importance of perspective in the emerging value frameworks. Clinics (Sao Paulo). 2018;73:e470s.
[8] Porter ME. What is value in health care? N Engl J Med. 2010;363: 2477–2481.
[9] Gold MR, Siegel JE, Russell LB, et al. Cost-effectiveness in health and medicine. New York: Oxford University Press; 1996.
[10] Waldeck AR, Botteman MF, White RE, et al. Importance of economic perspective and quantitative approaches in oncology value frameworks of drug selection and shared decision making. J Manag Care Spec Pharm. 2017;23:S6–S12.
[11] Wheeler SB, Spencer J, Rotter J. Toward value in health care: perspectives, priorities, and policy. N C Med J. 2018;79:62–65.
[12] Ball D, Mai GT, Vinod S, et al. Stereotactic ablative radiotherapy versus standard radiotherapy in stage 1 non-small-cell lung cancer (TROG 09.02 CHISEL): a phase 3, open-label, randomised controlled trial. Lancet Oncol. 2019;20:e112–e123.
[13] Lagerwaard FJ, Aaronson NK, Gundy CM, et al. Patient-reported quality of life after stereotactic ablative radiotherapy for early-stage lung cancer. J Thorac Oncol. 2012;7:1148–1154.
[14] Teckie S, McCloskey SA, Steinber ML. Value: a framework for radiation oncology. J Clin Oncol. 2014;32:2864–2870.
[15] Aggarwal A, Sullivan R. Affordability of cancer care in the United Kingdom–Is it time to introduce user charges? J Cancer Pol. 2014; 2:31–39.
[16] Gaskin DJ, Kong J, Meropol NJ, et al. Treatment choices by seriously ill patients: the health stock risk adjustment model. Med Decis Making 1998;18:84–94.
[17] Lievens Y, Borras JM, Grau C. Cost calculation: a necessary step towards widespread adoption of advanced radiotherapy technology. Acta Oncol. 2015;54:1275–1281.
[18] Defourny N, Dunscombe P, Perrier L, et al. Cost evaluations of radiotherapy: what do we know? An ESTRO-HERO analysis. Radiother Oncol. 2016;121:468–474.
[19] Kaplan RS, Porter ME. How to solve the cost crisis in healthcare. Harv Bus Rev. 2011;89:47–64.
[20] Lievens Y, van den Bogaert W, Kesteloot K. Activity-Based costing: a practical model for cost calculation in radiotherapy. Int J Radiat Oncol Biol Phys. 2003;57:522–535.
[21] van de Werf E, Verstraete J, Lievens Y. The cost of radiotherapy in a decade of technology evolution. Radiother Oncol. 2012;102: 148–153.
[22] Lievens Y, Obyn C, Mertens AS, et al. Stereotactic body radiotherapy for lung cancer: how much does it really cost? J Thorac Oncol. 2015;10:454–461.
[23] Yong JH, Beca J, O'Sullivan B, et al. Cost-effectiveness of intensity-modulated radiotherapy in oropharyngeal cancer. Clin Oncol. 2012;30:532–538.
[24] Atun R, Jaffray D, Barton M, et al. Expanding global access to radiotherapy. Lancet Oncol. 2015;16:1153–1186.
[25] Defourny N, Perrier L, Borras JM, et al. National costs and resource requirements of external beam radiotherapy: a Time-Driven Activity-Based Costing model from the ESTRO-HERO project. Radiother Oncol. 2019;138:187–194. DOI:10.1016/j.radonc.2019.06.015
[26] Gupta D, Karst I, Mendelson EB. Value-based reimbursement: impact of curtailing physician autonomy in medical decision making. AJR Am J Roentgenol. 2016;206:276–279.
[27] Porter ME, Marks CM, Landman ZC. OrthoChoice: bundled payments in the county of Stockholm. Harvard Business School Supplement 714-515, June 2014. (Revised April 2015.)
[28] Yu PP. Challenges in measuring cost and value in oncology: making it personal. Value Health 2016;19:520–524.
[29] Lievens Y. Access to innovative radiotherapy: how to make it happen from an economic perspective? Acta Oncol. 2017;56: 1353–1358.
[30] Lievens Y, Audisio R, Banks I, et al. Towards an evidence-informed value scale for surgical and radiation oncology: a multi-stakeholder perspective. Lancet Oncol. 2019;20:e112–e123.
[31] Smith GL, Ganz PA, Bekelman JE, et al. Promoting the appropriate use of advanced radiation technologies in oncology: Summary of a National Cancer Policy Forum Workshop. Int J Radiat Oncol Biol Phys. 2017;97:450–461.
[32] Sharma RA, Fumi L, Audisio RA, et al. Commentary: how will interventional oncology navigate the "valleys of death" for new medical devices? " Br J Radiol. 2018;91:20170643.
[33] Basch E, Abernethy AP, Mullins CD, et al. Recommendations for incorporating patient-reported outcomes into clinical comparative effectiveness research in adult oncology. J Clin Oncol. 2012; 30:4249–4255.
[34] McCloskey SA, Kuplian P, Asch S, et al. Adapting the PRO-CTCAE for patient reporting of toxicity in radiation oncology. Int J Radiat Oncol Biol Phys. 2012;84:99–100.
[35] Tannock I, Amir E, Booth CM, et al. Relevance of randomised controlled trials in oncology. Lancet Oncol. 2016;16:e560–e567.
[36] Brown MM, Brown GC, Sharma S. Evidence-based medicine to value based medicine. Chicago, IL: AMA Press; 2005.
[37] Aggarwal A, Lewison G, Rodin D, et al. Radiation therapy research: a global analysis 2001-2015. Int J Radiat Oncol Biol Phys. 2018;101:767–778.
[38] Pignol JP, Janus C. The evaluation of innovation in radiation oncology-what can we do and what should we do? Acta Oncol. 2015;54:1251–1253.
[39] Langendijk JA, Lambin P, De Ruysscher D, et al. Selection of patients for radiotherapy with protons aiming at reduction of side effects: the model-based approach. Radiother Oncol. 2013; 107:267–273.

[40] KNAW. Evaluation of new technology in health care. In need of guidance for relevant evidence. 2014. Amsterdam, KNAW. Available from https://www.knaw.nl

[41] Verkooijen H, Kerkmeijer LGW, Fuller CD, et al. R-IDEAL: a framework for systematic clinical evaluation of technical innovations in radiation oncology. Front Oncol. 2017;7:59.

[42] Weber DC, Grau C, Lim PS, et al. Bringing Europe together in building clinical evidence for proton therapy – the EPTN-ESTRO-EORTC endeavor. Acta Oncol. 2019;58:1340–1342.

[43] Burock S, Meunier F, Lacombe D. How can innovative forms of clinical research contribute to deliver affordable cancer care in an evolving health care environment? Eur J Cancer. 2013;49:2777–2783.

[44] Sujenthiran A, Nossiter J, Charman SC, et al. National population-based study comparing treatment-related toxicity in men who received intensity modulated versus 3-dimensional conformal radical radiation therapy for prostate cancer. Int J Radiat Oncol Biol Phys. 2017;99:1253–1260.

[45] Bentley TGK, Cohen JT, Elkin EB, et al. Measuring the value of new drugs: validity and reliability of 4 value assessment frameworks in the oncology setting. J Manag Care Spec Pharm. 2017;23:S34–S48.

[46] Shah-Manek B, Galanto JS, Nguyen H, et al. Value frameworks for the patient-provider interaction: a comparison of the ASCO value framework versus NCCN evidence blocks in determining value in oncology. J Manag Care Spec Pharm. 2017;23:S13–S20.

[47] Cheng S, McDonald EJ, Cheung MC, et al. Do the American Society of Clinical Oncology value framework and the European Society of Medical Oncology Magnitude of Clinical Benefit Scale measure the same construct of clinical benefit? J Clin Oncol. 2017;35:2764–2771.

[48] Del Paggio JC, Sullivan R, Schrag D, et al. Delivery of meaningful cancer care: a retrospective cohort study assessing cost and benefit with the ASCO and ESMO frameworks. Lancet Oncol. 2017;18:887–894.

[49] Avery KNL, Chalmers KA, Brookes ST, et al. Development of a core outcome set for clinical effectiveness trials in esophageal cancer resection surgery. Ann Surg. 2018;267:700–710.

[50] McNair AGK, Whistance RN, Forsythe RO, et al. Core outcomes for colorectal cancer surgery: a consensus study. PLoS Med. 2016;13:e1002071.

[51] Ong WL, Schouwenburg MG, van Bommel ACM, et al. A standard set of value-based patient-centered outcomes for breast cancer: the International Consortium for Health Outcomes Measurement (ICHOM) Initiative. JAMA Oncol. 2017;3:677–685.

[52] Zerillo JA, Schouwenburg MG, van Bommel ACM, et al. An international collaborative standardizing a comprehensive patient-centered outcomes measurement set for colorectal cancer. JAMA Oncol. 2017;3:686–694.

[53] Martin NE, Massey L, Stowell C, et al. Defining a standard set of patient-centered outcomes for men with localized prostate cancer. Eur Urol. 2015;67:460–467.

[54] Morgans AK, van Bommel ACM, Stowell C, et al. Development of a standardized set of patient-centered outcomes for advanced prostate cancer: an international effort for a unified approach. Eur Urol. 2015;68:891–898.

[55] Mak KS, van Bommel ACM, Stowell C, et al. Defining a standard set of patient-centered outcomes for lung cancer. Eur Respir J. 2016;48:852–860.

[56] Allen JD, Stewart MD, Roberts SA, et al. The value of addressing patient preferences. Value Health. 2017;20:283–285.