

Policy Paper on Enhancing the Value of Cancer Care Through a More Appropriate Use of Healthcare Interventions

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1 Executive summary

Despite the relevant progress made over the last few decades in diagnosing and caring for cancer patients and the potential of therapeutic innovations which are currently in the pipeline, there are legitimate concerns that many oncologic patients currently do not receive appropriate care according to their needs. Indeed, cancer care is not immune from the problem of the persistent overuse or underuse of procedures and interventions, a problem that affects modern medicine in general. Awareness of the relevance of this problem has been growing recently, given that the overall economic context is forcing health systems to function with decreasing resources while introducing costly innovations and maintaining and enhancing quality of care to meet patients' and citizens' expectations. Within this context, this paper focuses on the issue of health services overuse and the delivery of low-value care through the use of interventions or procedures that do not provide any benefit to patients. While low-value care may take different forms in clinical practice- from the use of clearly ineffective interventions to the inappropriate use of potentially effective ones- low-value care always exposes patients to unnecessary risks. It also represents a waste of resources that could otherwise be used to support the adoption of relevant innovations and to sustain patients' access to good quality care.

Taking forward an agenda aimed at reallocating resources from the provision of low-value care towards effective and appropriately used interventions entails adopting a policy framework that garners the support of health professionals, patients and citizens to this end while enhancing the value of cancer care. Also, initiatives must be undertaken to identify health interventions from which to withdraw resources (partially or fully) without reducing the quality of care. Finally, such a policy framework should develop a coherent set of initiatives aimed at fostering the necessary changes in clinical practice.

The assumption that withdrawing support from inappropriate oncologic care can make possible a reallocation of resources large enough to sustain innovation and reduce underuse should not be taken for granted and needs to be empirically assessed. Nevertheless, eliminating or reducing low-value care should be seen as a valuable effort to improve the quality of healthcare for cancer patients. The goal of this paper is to make recommendations to provide guidance for policy makers to adopt policies that enhance the value of cancer care while maintaining a systematic and inclusive approach.

2 Key recommendations at a glance

Recommendation 1: Policies aimed at reducing low-value oncologic care should be appropriately framed, emphasizing the goal of enhancing quality of care, rather than merely reducing healthcare costs. It should be made clear that the effort is not aimed at cutting resources for cancer care.

Recommendation 2: Withdrawing (totally or partially) resources from low-value or inappropriate care should be linked to sustaining patient access to good quality care, addressing both the issue of underuse of existing valuable interventions and access to innovations whose actual clinical value has been properly assessed.

Recommendation 3: The process should include proper consideration and analysis of the views and interests of health professionals and patients, as well as of other contextual factors relevant to the decision to withdraw support for a particular intervention.

Recommendation 4: The need to reduce patients' risk of exposure to low-value care is increasingly acknowledged by organisations of health professionals. Every effort should be made to foster collaboration and partnership between initiatives sharing these goals, among institutions, health professionals and patient associations.

Recommendation 5: Although other forms of evidence should form part of the policy process, research evidence on the safety, effectiveness and cost-effectiveness of oncologic healthcare interventions should be given a pivotal role in the decision making process.

Recommendation 6: The complexity of the scientific techniques and methodologies should be fully acknowledged in support of the policy process, assuring that adequate resources and skills are provided to make the overall attempt at identifying low-value interventions feasible and successful.

Recommendation 7: Multiple sources of information should be used in identifying low-value interventions and in assessing their use in clinical practice. Among the many low-value interventions that could be targeted, priorities should be set to identify those for whom disinvesting- totally or partially- is likely to provide the highest return in terms of benefit for patients and/or reduction of wasted health system resources.

Recommendation 8: Implementation strategies aimed at stopping or reducing the use of low-value interventions should consider the contextual factors that favour or hamper the desired changes. Implementation of initiatives undertaken at a system level could consider the options offered by the use of audit and feedback mechanisms, the cautious use of incentives, and the use of mass media campaigns.

Recommendation 9: It is important to foster collaboration among health systems, given the similarity of problems and challenges faced by individual countries, despite differences in policy and social context, administration, and the organisation of services. Sharing experiences between countries will help to reach a common framework and taxonomy for these policy initiatives. It will support a common methodological approach to the identification of low-value interventions and will offer the opportunity to avoid redundancies and duplications in the scientific and technical aspects of the process.

Recommendation 10: Research that addresses the methods, implications and effects of reducing low-value cancer care should be promoted and supported. Health policies are in need of good quality research that sheds light on health services overuse and its multiple determinants.

Recommendation 11: Every effort should be made to assure patient participation in the process of identification and removal of low-value and inappropriate care.

3 Introduction

The need for an appropriate and clinically rational use of resources in healthcare delivery is certainly not recent. However, it has undoubtedly received new input and attention as the result of a global economic context that constantly promotes solutions that aim to control and contain healthcare costs and allocate resources efficiently while maintaining and improving the quality of services. It has been estimated that approximately 30% of healthcare expenditures in the USA is a waste of resources.¹ A WHO report estimated that waste accounts for 20 to 40 percent of healthcare spending and identified its reduction as a key step towards universal coverage (2).

This strategically significant problem of the sustainability of health systems calls for the need to tackle not only the issue of governing technological innovation processes in the healthcare setting (one of the main drivers behind the escalation of costs), but also to reinforce the capacity to intervene regarding the use of health services in everyday clinical practice (1,3-6). Significant variability in professional practice styles has been frequently observed, which cannot be explained by differences in patient characteristics and needs, suggesting that the use of healthcare interventions¹ is often less optimal than expected and guided by factors other than scientific evidence (7-9).

Indeed, patterns of care are frequently not in line with the scientific knowledge available, which indicates three different problems: failure to use effective/valuable healthcare interventions in patients who might benefit from them (underuse), occurrence of errors when using specific interventions (misuse), and use of interventions that are known to be either ineffective or of little clinical value (overuse). The use of interventions that are indeed effective/valuable, but in clinical indications where their risk/benefit profile is unfavourable, is another common form of overuse. A number of factors are at play in determining variation in the use of health services in general, and overuse in particular, related to the characteristics (competencies, knowledge, attitudes, and beliefs) of clinicians/providers, to those of patients (including their expectations) and of the context (economic, administrative, social) in which care is delivered (7,8,10,11). Therefore, the task of reducing variation in practice styles and reducing over and underuse of healthcare interventions is particularly difficult.

The achievement of a more rational use of healthcare interventions is clearly not an economic challenge alone. It is also an issue of quality of care and concerns how to best assure that patients access the most suitable option of care according to their needs. This is not a new issue, since it has been at the heart of international debate for at least thirty years. Despite significant progress in methodologies for assessing and improving the quality of health services and the significant efforts invested in developing recommendations for clinical practice and designing techniques and instruments aimed at guiding professional and organisational behaviours, the initiatives put forth so far are insufficient for tackling this issue.

Due to the current economic climate, policies have ended up focusing on the problem of the overuse of health services and interventions. From a clinical standpoint, overuse exposes patients to ineffective or even harmful interventions and procedures, hence jeopardising the possibility to achieve the desired clinical results. From an economic perspective, overuse represents a clear source of waste, thus being an inefficient allocation of healthcare resources. This by no means implies that other forms of waste in the healthcare setting do not exist and should not be effectively tackled. Indeed, there may well

¹ By "healthcare interventions" we refer broadly to medications, drugs, diagnostic tests, diagnostic or therapeutic devices, and surgical techniques used by health professional in specific clinical circumstances.

be inefficiencies in the way in which health services are organised in terms of their mode of delivery and administration. However, the nature and the causes of these forms of inefficiency are inherently different from those related to the use (or lack of use) of healthcare interventions in clinical practice; they have different determinants and possibly need different solutions.

4 Tackling the delivery of low-value care

Providing guidance on health services use to assure that patients receive appropriate care according to their needs in the proper clinical setting has been a constant concern of health systems worldwide over the last 30 years. This guidance, with its clinical, economic, and social implications, has been usually provided through guidelines and recommendations aimed at influencing the clinical decision making process. The endeavour towards better quality of care has been largely conceived in terms of improving the connection between research and clinical practice, favouring (through the development of increasingly sophisticated approaches and tools) the transfer of knowledge on the value of healthcare interventions. The aim has been to make health professionals more fully aware of the most appropriate courses of action in specific clinical circumstances. Within the framework of enhancing the transfer of knowledge from research to practice, efforts at improvement simultaneously tackle a number of different problems: the lack of use of interventions of known effectiveness/value, the persistent use of those known to be ineffective or of little clinical value, and the failure to adopt innovative practices emerging from clinical research settings in a timely way. The available empirical knowledge, available via well-designed clinical trials and systematic reviews is eventually translated into practice guidelines and is the key starting point of the process.

This paper does not aim to provide a full analysis of these efforts, their implications and outcomes. However, it is worth noting that growing concerns about controlling healthcare expenditures seem to have prompted a more focused approach regarding the issue of making clinical practice adhere to available evidence on the effectiveness and cost-effectiveness of healthcare interventions. This approach is particularly oriented to tackling the problem of health services overuse and thus focuses attention on the delivery of low-value/inappropriate interventions, defined as:

Interventions that are harmful and/or ineffective/non-beneficial, according to the available evidence,

- a/ Interventions whose effectiveness or clinical value is very low, according to the available evidence,
- b/ Interventions known to be effective or of relevant clinical value, but which are at high risk of inappropriate use (i.e. they should be used selectively, or only for specific clinical indications),
- c/ Interventions known to be effective, but for which better alternatives exist or that provide a better value (i.e. they are not cost-effective).

Overall, the healthcare intervention issues outlined above constitute a significant problem. Established practice- i.e. the healthcare interventions assumed to be the standard of care- frequently turn out to be inferior to their alternatives when tested in clinical trials, a phenomenon- defined as practice reversal- that is not uncommon.^{12,13} Diagnostic procedures have been shown to be used excessively, such that the information obtained makes no contribution to clinical management or leads to diagnosing conditions that do not have an impact on patients' quality or length of life (14,15).

These efforts to improve health service use pursue higher allocative efficiency through the withdrawal of funding from individual items of care qualified as of low-value (i.e. delisting). Low-value interventions include technologies that become obsolete after their adoption as well as those that are adopted and then shown to be ineffective or even harmful when compared to alternatives (practice reversal). The goal is to identify these interventions and eliminate them from clinical practice by withdrawing funding that supports their use. Funding withdrawal is thus the main tool for making clinical practice more appropriate. In practical terms, however, such an approach may be feasible mostly with interventions that are always of low-value, regardless of the clinical indication where they are applied. As such, they can be excluded from the list of items of care for which economic support is provided. More often than not, overuse is represented by more complex issues, in particular by interventions that are indeed valuable and effective but are actually used in the wrong clinical indications. In dealing with this specific aspect of overuse, delisting may not be feasible or desirable, and other policy actions might have to be undertaken to achieve the desired changes in patterns of care, where funding withdrawal is a goal, rather than a means.

5 Examples of initiatives aimed at reducing low-value care

Despite its relevance, overuse is a policy issue that has not been fully explored or addressed (16,17) for a number of technical, cultural and political reasons. However, concerns about the escalating expense of healthcare has stimulated renewed policy attention to the problem. Over recent years a number of health systems have been focusing on low-value care (18). The initiatives that aim to reduce the use of low-value interventions in clinical practice are referred to in various ways (19), including as *decommissioning* (20,21) *de-implementation* (22), and *de-adoption* (19). *Disinvestment for reallocation* has been the most frequently used term, and it is probably the term that makes most explicit the ultimate goal of achieving a better allocation of resources (see Box 1).

Box 1 Definitions of disinvestment for reallocation

“Disinvestment specifically refers to resource allocation decisions based on withdrawing funding from no or low added-value health interventions, freeing up these resources for reinvestment in other health technologies that meet the criteria of safe and cost-effective care.” (Garcia-Arnesto, 2013 (23))

“The process of (partially or completely) withdrawing health resources from any existing health practices, procedures, technologies or pharmaceuticals that are deemed to deliver little or no health gain for their cost, and thus are not efficient health resources allocation.” (Elshaug, 2007 (24); Peirò, 2014 (25); Parkinson, 2015 (26))

“The displacement of non-cost-effective technologies for resources reinvestment or reallocation.” (Joshi, 2009 (27))

“An explicit process of taking resources from one service in order to use them for other purposes that are believed to be of better value.” (Pearson, 2007 (28))

In the United Kingdom the National Institute for Health and Care Excellence (NICE) recently compiled guidance for the containment of healthcare costs. NICE promotes the best clinical practice through the use of cost-effective procedures and opposes the use of procedures that are ineffective or deemed unsustainable. In 2006 NICE launched a process with the UK Cochrane Centre to identify procedures that could potentially be withdrawn based on the findings of Cochrane systematic reviews (29,30). Among the initiatives of NICE, it is worth mentioning the “do not do list”, a searchable database of evidence-based recommendations concerning interventions that should not be used, as they have been shown to have no clinical value (31). In Spain in 2006, a national law acknowledged the importance of the removal of technologies deemed ineffective, inefficient or with an unfavourable risk/benefit ratio. In 2007 two regional health technology assessment (HTA) agencies began a research project to identify, prioritise and assess potentially obsolete technologies. The first guideline for defunding such technologies in healthcare systems was published in 2010, however, the implementation of these policies is still in progress (23,32). In Australia in 2009, the Department of Health and Ageing carried out an assessment of HTA activities and requested a formal review of all procedures currently in use in order to identify healthcare interventions for which funding could be withdrawn (33,34). In the same year, the government funded a research programme with the aim of developing a tool to facilitate the identification of such procedures on the basis of evidence. Also in Australia, the ASTUTE Health study (35) was financed with the same objective. The project includes ethical and economic considerations and involves patients, citizens, clinicians and healthcare decision makers in the tool development process. Disinvestment activities have also been undertaken in Canada (36).

While the above outlines how the problem of reducing waste in clinical practice has been tackled at the institutional level in different countries, initiatives have also been developed concurrently under the aegis of professional bodies. Of these, the Choosing Wisely Campaign in the USA (37-39) is the most remarkable, and is internationally known and has been imitated (40-42). The “choosing wisely approach” is aimed at encouraging clinicians to engage with their patients in discussions about opting for specific interventions whose use is questionable if used outside of specific clinical indications, or to stop using interventions known to be ineffective or of no clinical value. Several specialty societies in different areas have developed short lists of interventions deemed to have these characteristics.

6 The case of cancer care

Cancer care is one of the fields in which healthcare systems’ capacity to cope with modern medicine’s challenges is most tested (43,44). Elements of these challenges include the extremely innovative dynamism of healthcare technologies, the increasing care needs of patients, the overall ageing of the population, the increasing expectations of citizens about the quantity and quality of healthcare services and finally, the pressing need to contain the costs of care (45,46).

Also, particularly in Europe, oncology is an area with persistent and significant differences between countries. These differences are found both in terms of quantity and quality of services offered to citizens and in terms of clinical outcomes (survival) observed in patients (47,48). As patient survival has been shown to be correlated with macro-economic determinants in general, and with investments in health systems in particular,⁴⁷ one might reasonably argue whether these differences across countries have been further widening due to the effects of the economic crisis (49).

Indeed, the spectrum of phases of the clinical management of cancer patients seems to be exposed to some degree of inappropriateness and overuse. Over-diagnosis has been pointed out as a relevant issue in this area (43), where the adoption of increasingly sophisticated diagnostic devices makes possible the detection of small tumours that are unlikely to cause harm if left untreated. Variation among providers and among geographic areas has been shown for surgical interventions (like breast conserving surgery or radical prostatectomy) and chemo or radiotherapy treatments as well. Patient staging and follow-up after primary treatment also appear to be shaped by physicians' excessive reliance on imaging tests, despite recommendations from the Choosing Wisely Campaign that support a more parsimonious use of those technologies (50-54). Lastly, a number of studies have shown overuse of aggressive medical and surgical approaches in patients at the end of life (55), although often patients would be in favour of less aggressive options (56). These findings are paralleled by indications of the potential underuse of appropriate care in the same patients (57). Not unlike other fields of modern medicine- although perhaps with greater intensity and relevance due to the implications of the health needs expressed by patients- overuse and underuse coexist in oncology, like the two faces of a coin.

Although there is evidence that suggests that patients' expectations might not necessarily be a major driver of overuse in cancer care (58), nevertheless, involving patients and their families in the decision making process may be valuable in creating a supportive environment and in achievement of a higher level of appropriateness in clinical practice. Indeed, the Choosing Wisely Campaign is explicitly aimed at encouraging physicians and patients to engage in discussing the best courses of action to be taken in specific clinical circumstances (37,42).

Sharing information with patients about the value of healthcare interventions and making them fully aware of the possible alternative options means not only respecting their dignity and personal autonomy, but also sustaining efforts for a more clinically appropriate provision of care. Nevertheless, many barriers exist to patient engagement in the decision making process. These include being represented by the health profession, lack of time to communicate effectively, insufficient health literacy among patients, and lack of tools and instruments to support patient-physician communication (59).

Thus, it is not surprising that cancer care has been considered an area of clinical practice where higher quality of care is necessary (46), and initiatives have been undertaken by physicians' associations as well as by government institutions in this respect. The abovementioned NICE database of "do not do" recommendations includes a long list of items concerning cancer care. In Italy under the aegis of the Ministry of Health, a working group was established in 2013 with the task of identifying low-value interventions in oncology (60). In addition, over the last few years lists of interventions of low clinical value or at high risk of inappropriate use have been developed and provided by some scientific societies in oncology (40,61-63). Box 2 outlines the interventions qualified as of low value by those initiatives.

Lastly, a systematic search for low-value interventions undertaken in Australia- that used multiple sources of information (literature search, nominations from relevant stakeholders, etc.)- identified over 150 interventions for which there was evidence of low clinical value, and 26 concerned cancer care (33).

Box 2 Outline of the recommendations from oncology speciality societies concerning interventions deemed to be of low clinical value or at high risk of inappropriate use

The American Society of Clinical Oncology Identifies Five Key Opportunities to Improve Care and Reduce Costs: The Top Five List for Oncology (Journal of Clinical Oncology, vol 30: pp 1715, 2012)

Don't use cancer-directed therapy for solid tumour patients with the following characteristics: low performance status (3 or 4), no benefit from prior evidence-based interventions, not eligible for a clinical trial, and no strong evidence supporting the clinical value of further anti-cancer treatment (10-15).

Don't perform PET, CT and radionuclide bone scans in the staging of early prostate cancer at low risk for metastasis (16-18).

Don't perform PET, CT and radionuclide bone scans in the staging of early breast cancer at low risk for metastasis (19).

Don't perform surveillance testing (biomarkers) or imaging (PET, CT and radionuclide bone scans) for asymptomatic individuals who have been treated for breast cancer with curative intent (12,20-23).

Don't use white cell stimulating factors for primary prevention of febrile neutropenia for patients with less than 20% risk for this complication (24).

Choosing Wisely Canada Cancer List: Ten Low-Value or Harmful Practices that Should Be Avoided in Cancer Care (Journal of Oncology Practice, vol 11: pp e296, 2015)

Do not order tests to detect recurrent cancer in asymptomatic patients if there is not a realistic expectation that early detection of recurrence can improve survival or quality of life.

Do not perform routine cancer screening, or surveillance for a new primary cancer, in the majority of patients with metastatic disease.

Avoid chemotherapy and instead focus on symptom relief and palliative care in patients with advanced cancer unlikely to benefit from chemotherapy (e.g. performance status 3 or 4).

Do not perform routine colonoscopic surveillance every year in patients after their colon cancer surgery; instead, frequency should be based on the findings of the prior colonoscopy and corresponding guidelines.

Do not delay or avoid palliative care for a patient with metastatic cancer because they are pursuing disease-directed treatment.

Do not recommend more than a single fraction of palliative radiation for an uncomplicated painful bone metastasis.

Do not initiate management in patients with low-risk prostate cancer (T1/T2, PSA<10 ng/mL, and Gleason score <7) without first discussing active surveillance.

Do not initiate whole-breast radiotherapy in 25 fractions as a part of breast-conservation therapy in women age ≥50 years with early-stage invasive breast cancer without considering shorter treatment schedules.

Do not deliver care (e.g. follow-up) in a high-cost setting (e.g. primary care).

Do not routinely use extensive locoregional therapy in most cancer situations where there is metastatic disease and minimal symptoms attributable to the primary tumour (e.g. colorectal cancer).

Choosing Wisely: The American Society for Radiation Oncology's Top 5 list
(Practical Radiation Oncology, vol 4: pp 349, 2014)

Don't initiate whole-breast radiation therapy as a part of breast conservation therapy in women age ≥ 50 with early-stage invasive breast cancer without considering shorter treatment schedules.

Don't initiate management of low-risk prostate cancer without discussing active surveillance.

Don't routinely use extended fractionation schemes (> 10 fractions) for palliation of bone metastases.

Don't routinely recommend proton beam therapy for prostate cancer outside of a prospective clinical trial or registry.

Don't routinely use intensity modulated radiation therapy (IMRT) to deliver whole-breast radiation therapy as part of breast conservation therapy.

American Society of Clinical Oncology 2013 Top Five List in Oncology (Journal of Clinical Oncology, vol 31: pp 4362, 2013)

Do not give patients starting a chemotherapy regimen that has a low or moderate risk of causing nausea or vomiting antiemetic drugs intended for use with a regimen that has a high risk of causing nausea or vomiting.

Do not use combination chemotherapy (multiple drugs) instead of chemotherapy with one drug when treating an individual for metastatic breast cancer unless the patient needs a rapid response to relieve tumour-related symptoms.

Avoid using PET or PET-CT scanning as part of routine follow up care to monitor for cancer recurrence in asymptomatic patients who have finished initial treatment to eliminate the cancer, unless there is high-level evidence that such imaging will change the outcome.

Do not perform PSA testing for prostate cancer screening in men with no symptoms of the disease when they are expected to live fewer than 10 years.

Do not use a targeted therapy intended for use against a specific genetic aberration unless a patient's tumour cells have a specific biomarker that predicts an effective response to the targeted therapy.

7 Methods

The development of this document was based on the following considerations.

- Key features of policies aimed at addressing the issue of low-value care were drawn from available and recently conducted reviews on the topic (18,19,64-66), and from discussions with experts in the field in the context of a seminar held in Rome on February 2, 2016. In this workshop the findings from a systematic review on health services overuse were presented by the main authors (Michel Wilson and Moriah Ellen from McMaster University, Hamilton, Ontario) (67,68). In that event, the following themes were identified as worth addressing as policy themes in the policy document:
 - Key issues to be considered at the policy framing stage
 - Methodological issues
 - Implementation
 - International collaboration
 - Research to support reallocative policies
 - Patient engagement

Individual papers related to the themes outlined above were retrieved from the scientific literature. PUBMED was searched for articles published in English in peer-reviewed journals and reporting the word “disinvestment” in the title or abstract. Relevant documents/reports published by health technology assessment agencies were also retrieved, identified either through the reference lists of published papers, or through Google searches (keywords: disinvestment, healthcare). Overall, 80 articles (23,69-133) and 14 grey-literature documents (5,18,27,32,34,36,60,64,67,134-138) were retrieved, published during the period from 1994 to 2015.

Relying on the information gathered through the steps described above, a first version of the paper was drafted and then circulated for comments and suggestions by a group of experts. Comments were also obtained from the European Cancer Organisation (ECCO) and from EU Member States.

8 Goals

This document should not be seen as a methodological paper, nor is it intended to be a technical “manual” on how to carry out initiatives aimed at reducing the delivery of low-value care. When methods and technical aspects are mentioned, it is to highlight the complexity of the process to be undertaken and its implications. The aim of this paper is to support policy makers and decision-makers at the health system level, making them aware of the elements that should be considered when developing policies oriented towards promoting appropriate use of healthcare interventions.

In line with the above, the recommendations provided should therefore be considered as general guidance, aimed at highlighting the aspects to be taken into account when developing policies aimed at reducing low-value care, in order to maximise their likelihood of success with the support and cooperation of professionals, patients and citizens.

9 Theme 1: Issues to be considered in framing policy

Withdrawing resources from ineffective/low-value care is a complex endeavour, entailing different steps to be undertaken, decisions to be made and actions to be taken at various levels of health systems, therefore involving a plurality of actors. As such, tackling low-value care and inappropriateness in clinical practice should be properly seen as a policy process (20–24), rather than a merely technical exercise.

Therefore, a key issue is for these policies to be framed to favour the participation of all relevant stakeholders in supporting a common agenda. In particular, gaining the support and active contribution of health professionals' organisations and of patient and citizens' associations is of utmost importance to the success of these initiatives. Thus, it is particularly important to adopt an understandable terminology during the policy development stage, one that is fully consistent with the policy objectives and involved actors. *Disinvestment for reallocation* could be a less than optimal term for conveying the meaning and ultimate goals of these policies, both to health professionals and lay people (139).

Although frequently used- and perhaps mitigated by the "for reallocation" specification- the word *disinvestment* appears to be unsatisfactory to many in order to fully capture and make explicit the policy goals to be achieved. In particular, the term's focus on economic issues evokes the action of withdrawing resources from specific healthcare interventions. In the current economic context, with many countries already experiencing a substantial reduction in public resources to sustain their health systems, there is a strong need to distinguish initiatives aimed at reducing low-value care from policies aimed at merely cutting healthcare costs. This could be instrumental in achieving the desired support from health professionals, patients and citizens.

While disengaging resources from low-value interventions in order to use them for the delivery of high-value care is the desired effect of disinvestment for reallocation policies, the primary goal is to improve the quality of care by reducing the use of interventions/procedures not providing any benefit to patients and possibly even causing harm. Thus, these policies should be defined in more effective terms, conveying to relevant stakeholders (health professionals, patients, and citizens) a more clear and unambiguous message concerning their objectives. For instance, they could possibly highlight that health service overuse and adoption of low-value interventions represents a waste and an opportunity to recover resources to apply elsewhere.

Lastly, as others have already pointed out (140), *disinvestment* may suggest a complete removal or withdrawal of a technology/intervention from clinical practice, while in many instances the objective is rather to achieve a more selective and clinically appropriate use. In the context of the overall evaluation of the initiatives undertaken to date at the international level, some have proposed *de-adoption* as an alternative to *disinvestment* (19). However, the term *de-adoption* highlights only one of the issues at stake, the complete or partial removal from clinical practice of specific healthcare interventions or procedures. In many other instances, the problem is not de-adopting in absolute terms, rather it relates to a different use (i.e. a more selective, appropriate use) of individual interventions or procedures. The appropriate terminology must unambiguously reflect the true goal of the policy.

Reducing waste in clinical practice as a way of improving quality of care is the ultimate goal of these policies, which aim to promote a higher level of clinical appropriateness in the provision of care for cancer patients. From the beginning of policy development, there should be explicit focus

on what should be eliminated or reduced in clinical practice as well as interventions whose delivery should be promoted. It is important to describe the specific reallocative goals of these policies, addressing the issue of health services underuse through the identification of valuable healthcare interventions whose accessibility for patients might be still unsatisfactory. At the same time, actions aimed at reducing resource waste should be directly linked to the promotion of innovation, such that health professionals and patients are encouraged to look at disinvestment as a strategy to redirect resources towards patients' access to innovations. Although it might be overoptimistic to state that removing or reducing low-value care will provide sufficient resources to contribute to the cost of innovations, testing the truth of this assumption should be a part of the disinvestment process. This can take place by estimating the actual value of low-value interventions in clinical practice and the frequency of their use. Actions to reduce low-value care should be included in policies aimed at strengthening health system capacity to govern the use of new technologies in clinical practice, distinguishing those that provide real value to patients.

Reallocative decisions based upon withdrawal of resources from low-value care should be based primarily on sound scientific evidence in addition to information on contextual factors. In other words, colloquial evidence helps shape policy processes (141,142). Also, stakeholder voices should be taken into account, in particular, a proper consideration and analysis of the opinions, beliefs and values of those who will be affected is necessary (143).

While the value of patient engagement will be extensively addressed later in this paper, it is worth mentioning here the utmost importance of the contribution of health professionals. In general, health professionals are a primary determinant of the quality of care delivered to patients. Although health professionals' decisions and actions are inevitably conditioned by the resources available within specific clinical settings (i.e. technical equipment, etc.), as well as by healthcare administration and management, their skills and competency in identifying patient needs and expectations and in avoiding unnecessary interventions is at the core of good quality care (4,144). Promoting a clinically appropriate use of healthcare interventions is one of the foundational values of the medical profession, and the Choosing Wisely movement itself represents growing physician awareness of the need for reduction in inappropriate and/or low-value care (42).

More specifically, it is important that initiatives to reduce provision of low-value care exploit the quality improvement efforts undertaken with the support of authoritative and representative professional bodies. Initiatives like Choosing Wisely are a case in point, as they share the goal of removing interventions deemed to be of low clinical value from clinical practice. As such, they should be seen not only as concurrent efforts focused on the same objectives, but possibly as merging initiatives, with reciprocal advantage to be gained from their integration. Indeed, institutional disinvestment initiatives can rely on the lists of low-value interventions produced by speciality societies as a useful starting point for targeting aspects of care where inappropriate use is a relevant problem. This is also supported by the engagement of authoritative professional bodies, the credibility of the process and favours the implementation of their decisions. Professional bodies can also gain from partnership with institutions, assuring that key clinical considerations do not end up being overlooked in the process, and that the degree of clinical autonomy required to take into account patients' needs is effectively safeguarded. In addition, institutions are certainly better equipped to promote the implementation of changes required to improve quality.

Recommendations

Recommendation 1: Policies aimed at reducing low-value care should be appropriately framed, emphasizing the goal of enhancing quality of care, rather than merely reducing healthcare costs. It should be made clear that the effort is not aimed at cutting resources for cancer care.

Recommendation 2: Withdrawing (totally or partially) resources from low-value or inappropriate cancer care should be linked to sustaining patient access to good quality care, addressing both the issue of underuse of existing valuable interventions and access to innovations whose actual clinical value has been properly assessed.

Recommendation 3: The process should include proper consideration and analysis of the views and interests of health professionals and cancer patients, as well as of other contextual factors relevant to the decision to withdraw support for a particular intervention.

Recommendation 4: The need to reduce patients' risk of exposure to low-value care is increasingly acknowledged by organisations of health professionals. Every effort should be made to foster collaboration and partnership between initiatives sharing these goals, among institutions, health professionals and patient associations.

10 Theme 2: Methodological aspects

The implications of methodological aspects related to identification of low-value interventions should be considered throughout the policy process. Indeed, the adoption of a sound methodological approach is a key to the value of the initiative, especially for maximizing the likelihood of correct identification of aspects of care where there is room for improvement through withdrawing- completely or partially- support to interventions that do not provide any benefit to patients and therefore represent a waste of resources.

Insofar as no methodological approach has been defined as the standard for these efforts, it seems that the majority of the experiences undertaken so far have relied on Program Budgeting Marginal Analysis (PBMA) or on the health technology assessment (HTA) approach (65). HTA entails a systematic evaluation of the different issues (medical, economic, social, and ethical) concerning adoption and use of a healthcare intervention.¹⁴⁵ It is an exercise largely based upon a systematic appraisal of the available information on safety, effectiveness, cost-effectiveness, and patterns of use. PBMA is an economic evaluation technique that is suitable for setting priorities among different alternatives of funding allocation, based upon cost-effectiveness principles of analysis of marginal costs vs. marginal benefit (88,114,129,131,146,147).

From a policy-making perspective, whatever the methodology adopted, the process will benefit from being sustained by multiple sources of information, in particular:

- Research information on safety, effectiveness, and cost-effectiveness of healthcare interventions is of high importance. Disinvestment should be an evidence-informed process. Reliance on sound scientific evidence is key to providing credibility to the effort, which is required for tackling the potentially sensitive issues concerning the withdrawal of interventions already well entrenched in clinical practice.
- The limitations of research should also be acknowledged as well. Evidence on the yield of healthcare interventions might be lacking, of poor quality, difficult to interpret or controversial (148). While it seems wise or even obvious to suggest that these efforts should focus primarily on interventions whose evidence base is less controversial and unambiguously indicates their lack of clinical value, it could also be that these interventions are not widely used in clinical practice and, as such, do not represent a priority (i.e. they have already been “spontaneously” abandoned) (29 30).
- Other sources of information should be considered in the identification of interventions that are seen as complementary rather than alternative to a systematic assessment of the scientific evidence available on safety, effectiveness, and cost-effectiveness of interventions. Examples are reported in Table 1, and include information drawn from consultation with patients and health professionals. Analysis of routinely available databases- or from ad hoc studies on patterns of care- can also provide valuable information on the frequency of use of interventions. In particular, evidence of significant variation in the use of specific procedures/interventions across geographic areas within a jurisdiction, or across providers, can be a starting point for focusing on areas of care that represent areas of potential overuse (and underuse as well) (149). In general, assessment of the frequency of use of healthcare interventions is of crucial importance to gain a better understanding of the clinical and economic burden represented by low-value interventions.
- As will be addressed in greater detail in the implementation section of the paper, disinvesting from healthcare interventions already in use in clinical practice can be particularly challenging. Therefore, disinvestment efforts should be focused, prioritizing items where substantial improvements– both in terms of benefit to patients and resource retrieval– can realistically be achieved. Examples of priority criteria- related to the characteristics of the interventions, to their frequency of use, and clinical and economic implications- are reported in Table 2.
- As equity implications should also be a concern, the methodological process should include an assessment of whether policy decisions discriminate against any disadvantaged or vulnerable group. For this purpose, the Equality Impact Assessment (EqIA) was proposed in the United Kingdom in 2008 and revised in 2009 (150). The EqIA should ensure that a policy is as equitable as possible. It should consider the impact of health policies on people of different age groups, social and economic groups, ethnic backgrounds, sexual orientations, and religions/beliefs as well as people with disabilities. The EqIA is an integral and essential part of the policymaking and management processes and must inform and influence decisions and actions. In the UK, EqIA has been applied to cancer care in order to reduce inequalities in health services and outcomes (https://www.cancerresearchuk.org/sites/default/files/taskforce_equality_impact_assessment.pdf).

- Overall, the technical complexity of the methodologies to be used should be fully acknowledged. Every effort should be made to assure that disinvestment for reallocation policies are designed and conducted taking into account the range of competencies required at the different stages from multiple disciplines. Tackling low-value care is indeed, to a large extent, a multidisciplinary effort, involving a number of different technical and scientific competencies and skills. In particular, the technical work that represents the backbone of the disinvestment process requires the clinical expertise of health professionals, experts in the evaluation of health technologies, professionals with statistical and literature review skills, health economists and social scientists, as well as experts in quality improvement. As the ultimate goal of these initiatives is to promote changes in clinical practice towards a more appropriate use of healthcare services, the support from implementation scientists is also relevant.

Table 1 Examples of approaches to the identification of interventions to be targeted by policies aimed at reducing low-value care

Conditions for which interventions are assessed	Source
<ul style="list-style-type: none"> • Availability of new evidence on safety, effectiveness and/or cost-effectiveness. • Evidence of variation in clinical practice among geographic areas or providers, suggesting differences in clinical opinion about the value of interventions. • Temporal variations in volume, showing significant increase or decrease in utilisation rates. • Communication from patients, consumer advocacy and support groups, and community groups, highlighting negative (or ineffective) experiences following treatment. • Consultation with clinical, nursing, allied health and technical staff, healthcare administrators and funders. • Nomination through a process involving individuals, associations, and colleges. • In situations where a new intervention is assessed and is considered a potential replacement of another, the latter is considered and assessed for disinvestment. • Technology use (with reimbursement) outside of evidence-based indications. • Long-established technologies that have never had their cost-effectiveness assessed. • In situations where practice is inconsistent with clinical practice guidelines. 	151
<ul style="list-style-type: none"> • Ongoing consultation with clinical speciality groups. • Use of routine data to identify variations in the use of technologies and/or associated outcomes. • Use of routine data to identify technologies with high budget impact. • Monitoring published studies and systematic reviews. • Routine identification of technology candidates for optimisation within the context of the assessment of new technologies. • Feasibility (i.e. identification of barriers and opportunities for disinvestment in order to select candidates with most potential for change and impact). 	140

Table 2 Examples of criteria for prioritising interventions to be targeted by policies aimed at reducing low-value care

Criteria	Source
<ul style="list-style-type: none"> • The cost of the technology has a significant overall budget impact. • There are effective alternative technologies of demonstrated cost-effectiveness that may be currently underused. • Elimination of the technology may reduce risks to patient safety. • The impact of disinvestment will not be borne largely by specific vulnerable populations such as the disabled, elderly or children. • The ascribed benefit of the technology is small, i.e. it is not used to treat very severe or life-threatening conditions. 	28
<ul style="list-style-type: none"> • There is evidence that the technology causes an overall worsening of health. • There is unacceptable potential risk for patients or the environment. • The level of discomfort produced by the technology or the level of its invasiveness has a high negative impact. • There is no scientific evidence to show that the technology improves health. 	115 136
<ul style="list-style-type: none"> • Potential productivity and cash-releasing savings. • Potential impact on quality of clinical care delivered to patients and on clinical outcomes. • Potential impact on patient safety. • Potential impact on patient and carer experience. 	29

Recommendations

Recommendation 5: Although other forms of evidence should be part of the policy process, research evidence on the safety, effectiveness and cost-effectiveness of healthcare interventions should have a pivotal role in the decision making process.

Recommendation 6: The complexity of the scientific techniques and methodologies to be used in support of the policy process should be fully acknowledged, assuring that adequate resources and skills are provided to make the overall attempt at identifying low-value interventions feasible and successful.

Recommendation 7: Multiple sources of information should be used to identify low-value interventions and to assess their actual use in clinical practice. Among the many low-value interventions that could be targeted, priorities should be set to identify those for whom disinvesting- totally or partially- is likely to provide the highest return in terms of benefit for patients and/or reduction in wasted resources for the system.

11 Theme 3: Implementation

The ultimate goal of the policy process is to promote clinical appropriateness and eliminate (or reduce) the use of ineffective interventions to support better clinical outcomes and a more efficient reallocation of resources. In general, the implementation of policies aimed at reducing low-value care can represent a complete withdrawal of funding (i.e. delisting) for interventions when they have been shown to be clearly ineffective and/or harmful. In these cases- especially in terms of interventions already well integrated in daily clinical practice- such a disinvestment process is likely to face resistance from professionals and/or patients. Also, the counterforce of vested interests has the potential to affect the decision to withdraw resources. Thus, consensus is needed from relevant stakeholders to ensure that policies reducing the provision of low-value care will be able to overcome expected resistance to change and to ensure that attention is paid to the issue of implementation.

Indeed, the complexity of withdrawing resources from specific interventions can be even greater when it implies- rather than the mere delisting- the introduction of a different (i.e. more selective) pattern of use of the interventions at stake. This is the case in terms of interventions that- although potentially useful- are used inappropriately in clinical indications. In these circumstances, a key issue concerns how to change healthcare providers' behaviour to achieve a more selective and appropriate use. As has been extensively demonstrated by a large body of research, developing guidelines and recommendations is not sufficient to change clinical practice.¹⁵² Therefore, it is not surprising that the provision of recommendations supporting the abandonment of low-value care has been shown to be insufficient (153-155).

There is a great deal of research evidence available on how to change health professionals' behaviours and drive quality improvement efforts. The Cochrane Review Group on Effective Practice and Organisation of Care provides valuable information on the effectiveness of different approaches. The group continuously updates systematic reviews which are made available through the Cochrane Library (<http://www.cochranelibrary.com>). While this information represents a useful resource for the design and implementation of quality improvement initiatives and for

efforts aimed at increasing appropriateness in healthcare delivery, available evidence should be critically interpreted with respect to the extent to which it is “generalizable” to disinvestment policy and its impact on clinical practice. Overall, although several instruments, tools and approaches to influence clinical practice have been developed and tested, none of them has been shown to be unequivocally effective. While many examples of successful approaches are documented in the literature, failures are even more common. Thus, there is no *magic bullet* when it comes to changing healthcare providers’ behaviour (156). A careful in-depth analysis of the type of behaviour to be changed and its determinants should be undertaken prior to choosing the most appropriate approach. Also, the importance of non-scientific factors should be considered in analysing the determinants of the identified behaviours. Although ideally medical practice should be based on sound empirical evidence in choosing the most appropriate course of action for patients, in a practical sense, behaviours are influenced not only by science, but also by social, political and economic factors. Scientific literature has shown how these factors influenced the persistence of radical mastectomy in the surgical management of breast cancer vs. the adoption of breast conserving approaches (157).

Moreover, the promotion of changes in healthcare settings that aim to withdraw resources from low-value interventions might well take a perspective quite different from the one frequently adopted in most of the relevant literature, whose focus has been predominantly promoting the adoption of “innovative” practice. In contrast, disinvesting entails the challenge of relinquishing something already in practice, rather than taking-up something new. Scholars and researchers have pointed out this difficulty, recognising that “de-implementation” might have different determinants and require a different set of actions to be achieved (22).

Although we do not provide an in-depth description and analysis of the literature on changing health providers’ behaviours, we believe it is worth considering those aspects related to actions to be taken at the macro system level, which are more likely to be related to the roles and responsibilities of policy makers, the target audience of this paper.

In particular, the following issues are worth mentioning:

- Efforts should be made to make quality of cancer care as transparent and assessable as possible, with attention paid to the issue of measuring the provision of low-value care (158) This is indeed a critical issue with both technical and policy implications. While technical aspects concern the development of process indicators to measure to what extent the frequency of use of specific interventions is appropriate, the policy aspects call for the adoption of arrangements and tools that reinforce healthcare providers’ accountability for the quality of care delivered to cancer patients.

Development of well-conceived, evidence-based process indicators that measure appropriateness is required to overcome the intrinsic limitations of analysis of patterns of care. These analyses are often limited to measures of the frequency of use and the degree of variation across providers. Variations in practice patterns are a proxy for inappropriate use. While variability in provider behaviour- when dealing with patients with similar healthcare needs- may suggest the existence of a problem of overuse (and possibly of underuse as well), it may also show the way in which healthcare providers take into account individual patients’ preferences and needs. Separating positive from *negative variation* is particularly difficult,⁷ especially when these analyses have to rely on relatively incomplete information concerning the clinical circumstances in which health services are used, as is often the case when these analyses rely

on administrative data. Lack of detailed information on individual patient characteristics may prevent a full understanding of their actual clinical needs and therefore hamper any assessment of the appropriateness of use of the procedures/interventions considered.

Taking full advantage of the widespread use of electronic medical records, as well as the information made available by cancer registries (where they exist) might offer major opportunities for enhancing our analytical capacity to explore quality of care dimensions relevant to disinvestment policies, and to disentangle their determinants (159).

Development of such a capacity has several implications of utmost importance. For instance, allowing a critical appraisal of the current policy relevance of the recommendations made by specialty societies on “do not use” interventions, or cautious use of interventions, such as those outlined in Box 2 on cancer care, is important. Failure to measure the rate of use in clinical practice of the interventions indicated in the recommendations hampers the policy usefulness of the endorsement of professional bodies and prevents knowledge of the frequency (i.e. the relevance) of the problem. Finally, it weakens- from the outset- the implementation of the recommendation. Also, it prevents any efforts to make health providers accountable. Translation of these recommendations into measurable process indicators is a complex task, characterised by the need to capture information on patient and intervention characteristics that is usually not accessible unless a local audit exercise is conducted (which can be resource intensive). Better analytical capacity in assessing quality of care necessitates relying to a greater extent on change-behaviour approaches known to be effective.

Use of various performance feedback systems targeted at healthcare providers has become an increasingly common approach within quality improvement initiatives/programs or regulatory efforts. These systems are favoured by the presence of ICT in healthcare settings, which make large amounts of data on healthcare use patterns and outcomes relatively more accessible and usable. Performance feedback refers to the systematic (i.e. formally structured) provision of performance summaries to providers (individual health professionals, teams, services, organisations) over a specified period of time.¹⁶⁰ Performance assessment relies on process and/or outcomes indicators, and the feedback summary may take different forms. It usually provides for benchmarking of the observed performance with external frames of reference and standards. Suggestions have been put forward related to how these reports should be developed and structured and on the desirable features of a good performance feedback procedure, according to the knowledge available and the opinions of experts in the field.¹⁶¹ Evidence from systematic reviews on performance feedback interventions shows significant variation in their effect, according to a number of factors. Overall, they make clear the substantial potential of these approaches in changing health providers’ behaviours (160).

- Economic incentives targeted to healthcare providers are often one of the options considered to promote desired changes in clinical practice (162-170). Surely, policies based on these tools may well be able to induce providers to discontinue, reduce, or increase the rate of use of specific procedures/interventions, according to a desired goal. However, economic incentives have remarkable limitations and problematic aspects, and their adoption should therefore be cautious (171).

Firstly, that incentives can influence rates of adoption and use of an intervention does not necessarily mean that they impact the appropriateness of use. Indeed, the relationship between rate of use and appropriateness seems to be an issue not yet fully explored by research. The

limited evidence available so far suggests that the relationship may not be linear as one would expect (172). In other words, it cannot be assumed that inappropriateness is necessarily higher where rates of use are higher as well.

This implies that economic incentives aimed at reducing the volume of activities for specific interventions or procedures can indeed be effective in lowering the quantity (i.e. the rate of use) without necessarily affecting quality (i.e. reducing the proportion of patients receiving inappropriate care). The other implication is that approaches to influence clinicians' decisions should be careful in preserving a degree of necessary discretion, which is an important component of clinical practice (7,8).

Secondly, the effects of economic incentives are often lower than expected and have limited duration over time (173,174). In general, the relationship between economic incentives and professional conduct is much more complex than imagined, and it is not necessarily true that by increasing the incentive, the expected effect on professional conduct increases at the same rate. There is a threshold above which incentives lose their effectiveness (for example, because the professional has reached his/her desired level of economic remuneration). Furthermore, the economic aspect is just one of the many motivational levers that inspire professional conduct. Professionals have their own intrinsic motivations to improve, as well as a personal moral code that induces them to "do the right thing", often regardless of the economic reward. From this point of view, over-intensive and indiscriminate use of economic incentives has the negative effect of monetising behaviours, whose motivation is rooted in professional ethics (175,176). Policies should consider the adoption of rewards and incentives that are not necessarily or exclusively economic (173), and may possibly be more able to sustain intrinsic motivations and professional values.

- Mass media have been shown to be effective in shaping patterns of healthcare use (177). Notwithstanding, it is fair to remark that studies support the effectiveness of mass media in changing the volume of health services use, while there is no robust evidence showing their effect on quality. Nevertheless, although the available evidence does not allow a full understanding of the key determinants of their effectiveness, the adoption of approaches relying on mass media as a tool to convey to the general public the meaning and goals of disinvestment initiatives should be considered in order to create a favourable context for the changes to be made. Of course, it should be remembered that communicating to health professionals and citizens in a clear and unambiguous way about the goals of disinvestment initiatives is important, as mentioned earlier. In devising and conducting mass media campaigns, support from health professionals and patient associations is of crucial relevance in order to maximise the chances of achieving the desired goals.

Recommendations

Recommendation 8: Implementation strategies aimed at stopping or reducing the use of low-value interventions should consider the contextual factors that favour or hamper the desired changes. Implementation initiatives undertaken at a system level could consider the options offered by the use of audit and feedback mechanisms, the cautious use of incentives, and use of mass media campaigns.

12 Theme 4: International collaboration

It is important to promote collaboration among health systems on policies aimed at reducing low-value care. While differences may exist across countries in terms of the health policy context, administration, organisation of services, and values, the problems to be addressed can be surprisingly similar and common. Inappropriateness in clinical practice, overuse and underuse of healthcare interventions are largely ubiquitous, although the main determinants of those problems may be different according to the context. Nevertheless, sharing experiences between countries may have a great beneficial effect, at least in helping to reach a common framework and taxonomy, and possibly a common methodological approach to the identification of low-value interventions.

The experience developed in Europe thus far by EUnetHTA, a network formed by health technologies assessment agencies from several European countries (<http://www.eunetha.eu/>), has already shown the benefit offered by cross border collaboration. For each individual country there are increased opportunities to rely on technical products developed elsewhere but with trustable, transparent, scientifically sound, and agreed upon methods and approaches. It is considered important, therefore, to mention the relevance that cross border collaboration could have for eliminating/reducing low-value care. Some European institutions have informally already started to establish collaborative relationships, and this type of effort should be encouraged and sustained.² Specific areas that could benefit from increasing the level of international collaboration include the development of common methods for the identification of low-value interventions, as well as the systematic sharing of the output of these efforts. Making lists of low-value interventions available to other countries provides the opportunity to explore to what extent these interventions are used in other local contexts. In addition, although implementation must be linked to each individual policy and the administrative, organisational, and cultural context in which it is developed, sharing experiences may help improve knowledge on how to overcome barriers to change in clinical practice.

Recommendations

Recommendation 9: It is important to foster collaboration among health systems, given the similarity of problems and challenges faced by individual countries, despite differences in policy and social context, administration, and the organisation of services. Sharing experiences between countries will help to reach a common framework and taxonomy for these policy initiatives. It will support a common methodological approach to the identification of low-value interventions and will offer the opportunity to avoid redundancies and duplications in the scientific and technical aspects of the process.

13 Theme 5: The need for policy relevant research

The development of a shared research agenda on how to tackle low-value care and its implications can be seen as a desirable outcome that an international collaborative effort on this theme could make possible.

² Promoted by the National Health Care Institute in Amsterdam, some HTA agencies/organisations (from The Netherlands, Belgium, France, Italy, Germany, Austria, Switzerland) are currently participating into the "IZZI - Appropriate Care Network", where experiences in tackling health services overuse and its implications are shared and discussed.

Research could fruitfully address several aspects concerning the design and conduct of these initiatives, and provide relevant information on the characteristics and determinants of the problems to be faced. The scientific credibility, as well as the feasibility of policies aimed at withdrawing resources from low-value care, could benefit a great deal from relying on sound research that supports its methodological development and that guides its efforts in changing clinical practice through the provision of information on the key determinants of health services overuse.

Indeed, attempting to reduce low-value care means facing issues often neglected or overlooked by current health services research (16). Indeed, few studies on patterns of care have focused on the problem of overuse (17). As others have made clear, such a paucity of information on this issue is remarkably at odds with its policy relevance (10).

Lastly, research should also be considered as a tool to assess the actual impact of the policy initiatives undertaken (178) providing information on their effects on patterns of healthcare use, as well as on their acceptability by health professionals, patients, and citizens.

Recommendations

Recommendation 10: Research that addresses the methods, implications and effects of reducing low-value cancer care should be promoted and supported. Health policies are in need of good quality research that sheds light on health services overuse and its multiple determinants.

14 Theme 6: Patient engagement

The European Cancer Patients' Bill of Rights sets out the irrevocable rights of all European cancer patients to fast access to the best care available (<http://ecpc.org/activities/policy-and-advocacy/policy-initiatives/138-european-bill-of-cancer-patients-rights>). Notwithstanding the undeniable right of all cancer patients to access adequate cancer care, there are still unacceptable inequalities in cancer outcomes across Europe, as documented by the European Cancer Patient Coalition (ECPC) in its strategic policy document *Europe of Disparities in Cancer* (179). The participation of patients and patient representatives in the decision making process on disinvestment represents a key factor in ensuring that disinvestment policies meet their target, namely that disinvestment will not increase existing levels of inequality. On the contrary, it could build the bases for more sustainable and innovative management of the resources allocated to cancer care. To ensure the meaningful contribution of patients, it is necessary to consider the following factors, which will be further developed in the following paragraphs:

- Appropriateness of treatment versus disinvestment policies,
- Engaging in a public debate on disinvestment to inform citizens,
- Involvement of patients in all of the steps of HTA and
- Disinvestment's final aim: making room for innovation.

Appropriateness of treatment and disinvestment for reallocation policies

Notwithstanding the increasing cost of cancer care, the safety and outcomes of patients should remain the top priority for action by European health systems. For this reason, disinvestment should not be used as a scapegoat in order to cut healthcare services based on their financial performance. Disinvestment policies must be implemented in a way so as not to increase existing inequalities in cancer care in Europe. Disinvestment interventions should increase access to quality treatments. In fact, it is not sufficient to provide better treatments if they are not accessible to the majority of the patient population.

Disinvestment must improve the capacity of health systems to treat patients across a given country, rather than simply improve outcomes in few cancer centres. Therefore, it is important to ensure that disinvestment policies be paired with the full implementation of the Cross Border Healthcare Directive. Health systems' capacity to treat patients locally should not be hampered. If disinvestment policies recommend centralisation of healthcare services, health ministries must put balancing measures in place to ensure that they are fully accessible by the population, even those living in remote regions of the country. The same argument is valid for low-value procedures that can be highly beneficial for a small portion of the cancer patient population: crucial interventions for rare cancer patients should not be the object of disinvestment policies, at least not until the European Reference Network has the capacity to absorb and satisfy the needs of these patients.

Opening a public debate on disinvestment for reallocation to inform citizens

To ensure the success of disinvestment for reallocation policies, it is necessary to create public engagement and awareness that allows patients and civil society to both understand and endorse the decisions related to disinvestment. This step is crucial to obtain a general consensus on the necessity of disinvestment, therefore paving the way for implementation.

Priority setting and disinvestment procedures may trigger an adverse reaction by the population, if not well prepared and communicated properly. For this reason, it is advisable not only to involve patients and their representatives in decision making processes related to disinvestment, but also to lay the groundwork for such decisions through communication campaigns run in partnership with patient organisations, aimed at explaining the core principles behind disinvestment. The objective of the communication campaign should be to inform citizens about the advantages related to disinvestment, building trust in the disinvestment methodology and providing key elements to understand the criteria for the selection of treatments to be included in disinvestment policies.

Enhanced communication between decision makers and civil society on disinvestment should also aim to solve cultural issues related to disinvestment. Particularly important for the relationship between patients and healthcare professionals is the issue of defensive medicine, by which resources are wasted on diagnostic tests or treatments that are not necessarily the best option for the patient, but are an option that mainly serves to protect the physician against the patient as a potential plaintiff.

Involvement of patients in all of the steps of HTA

As the decision regarding disinvestment strategies is national, involvement of patient representatives should be a part of the process. The European Commission has demonstrated how decision makers can embed patients in consultative bodies (as in the Expert group on Cancer Control and in the collaborative partnership in the Joint Action CanCon). The same model should be used at the national level to include local cancer patient organisations in the decision making processes.

It is therefore crucial to identify patient experts and patient advocates at the local level able to meaningfully provide input in certain parts of the decision making process on disinvestment. Expert patients and their representatives should be involved in the process of HTA in order to embed the patient point of view before disinvestment strategies are put in place. Increasing patients' familiarity with HTA is a pre-requisite for ensuring that patients can meaningfully contribute to the debate on disinvestment. ECPC and other large umbrella organisations have a role to play in educating national patient organisations. On the other hand, medical associations and member states have to dedicate human and financial resources to ensuring that patients can meaningfully be integrated in the process of disinvestment, making them true partners within the process.

The final aim: making room for innovation

For many cancer patients, innovation in cancer care represents the only hope to fight the disease. Overall survival for many types of cancer has increased substantially: more than one fifth of all cancer patients are considered cured, since their life expectancy is equal to that of the average population. However, these impressive results have not been achieved in all tumour types, including some of high incidence (lung, stomach).

The successes in fighting cancer are based on better understanding of the biology of the tumours. It is therefore necessary to increase the resources allocated to research and development of innovative treatments, particularly for those cancer types for which the survival rates are very low (pancreas, rare tumours).

From the patient perspective, the main objective of disinvestment strategies should be to save and redirect resources to ensure patient access to meaningful and affordable innovation. Innovation in cancer care must aim to resolve existing inequalities, rather than increase the divide between EU countries/regions or within the same country. The rising costs of innovative treatment require that European health systems find sustainable ways to fund access to innovation. Cancer patients must have a role in evaluating which innovations are most meaningful, by being equal partners in the HTA process and in defining disinvestment priorities.

Recommendations

Recommendation 11: Every effort should be made to assure patient participation in the process of identification and removal of low-value and inappropriate cancer care.

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