Article:
Culyer, Anthony J (2017) Ethics, priorities and cancer. Journal of Cancer Policy. pp. 6-11. ISSN 2213-5383

https://doi.org/10.1016/j.jcpo.2016.09.007

Journal of Cancer Policy xxx (2016) xxx–xxx

Contents lists available at ScienceDirect

Journal of Cancer Policy

journal homepage: www.elsevier.com/locate/jcpo

Original Research

Ethics, priorities and cancer

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ARTICLE INFO

Article history:
Received 1 September 2016
Accepted 10 September 2016
Available online xxx

Keywords:
Cost-effectiveness
HTA
Equity
Cancer
Prioritization
The bookshelf
Threshold
End of life
Health economics

ABSTRACT

Beginning with the ethical case for maximising the impact of health care resources on health, this article examines nine arguments for exempting cancer treatments from rigorous economic evaluation or for relaxing some of the conditions often required if an intervention is to be provided at public expense. Some of these may have validity under particular circumstances but, in general, if these arguments apply at all they apply also to other treatments for similarly placed patients (for example, those near the end of their lives) and so do not constitute an argument for treating cancer patients as such more favourably than others. The arguments need to be more than merely valid. They need also to have quantitative and qualitative significance.

1. Prioritising

1.1. How ought priorities for public health care spending to be set?

Context always matters, so let us set a context. I shall assume we are thinking about the value of health care interventions – specifically, ones for the benefit of cancer patients, actual or potential (as in preventive interventions) – in a publicly financed health care system. The ultimate payers are therefore taxpayers and the ultimate beneficiaries are cancer patients within that jurisdiction, whether or not they are taxpayers. The ethical issues that arise differ somewhat under conditions of private health insurance financing, but that is not our concern here. The broad questions of prioritisation, chief of which concerns the selection of interventions to be provided publicly and the terms of access to them, are therefore necessarily to be collectively determined and the values embodied in such decisions are, in the same sense *social* values, being made on behalf of a community by publicly accountable "decision makers".

Let us take it as given that no one is in denial that priorities have to be established. This may be done implicitly or explicitly, in camera or under the public's gaze. The second is always preferable unless it damages the integrity of the process.[1] Let us also take it as given that in any period the resources normally[2] available in a national health insurance system are set by some planning process at a high (say, cabinet) level of government, along with other broad decisions regarding expenditure on education, defence, the environment and so on. We shall consider the question at a slightly less high level – that is, at the level of decisions at the top level of a ministry of health – where the decisions are about the allocation of the "budget" as determined by the higher process.[3] Specifically, some of the decisions are about the health care procedures and interventions to be provided. It is these decisions on which we focus. In practice, some decisions may be delegated to a lower or arm's length agency that either sets the priorities or makes recommendations about them. Finally, let us assume that the main purpose of public health insurance is to enhance the health of the population[4] without causing anyone to bankrupt themselves, or even to suffer significant financial hardship. Other objectives commonly include reassurance (e.g. "you're OK"), information provision (e.g. diagnostic utility), certification (e.g. for legitimate absence from work), reduction in uncertainty (e.g. about one's exposure to health risks), social solidarity ("this is *our* health service"), social or national iconography (e.g. "our system represents the 'kind of

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[1] As when the matter is personal and private, or price-sensitive but public.

[2] That is, excluding those set aside for public emergencies.

[3] The private sector analogy is a third party insurer designing a benefits package and anticipating a stream of premium income and co-payments to cover its cost.

[4] This is commonly treated as allocating resources according to need. For why such an approach is not a good idea see [1,2].

http://dx.doi.org/10.1016/j.jcpo.2016.09.007
2213-5383/

people we are"'), support for manufacturing and innovation (e.g. in supply chain industries), and sometimes even the provision of ineffective but popularly demanded treatments (e.g. by traditional healers, alternative medicine, religion-driven interventions). Each of these objectives makes a claim on the overall budget. Evidently not all of them directly enhance population health and neither do they all have equal merit. That is not to say that the domination of the impact on health is either automatic or overwhelming, only that it takes a powerful moral argument if a sacrifice of population health is to be made for any other objective. The reality therefore is that all these activities have a specific opportunity cost. If the health budget is spent in part on, say, ineffective traditional medicine, it is necessarily spent at the expense of something else. In considering that part of the budget that is for health itself, the opportunity cost (as economists say) is not any old something else, it is – and only can be – health. Thus adding a new clinical procedure, given the budget limit, necessitates disinvesting in another. Assuming that other procedure also to have been an *effective* procedure, the opportunity cost of the new procedure is the consequential loss of health which the old procedure would have generated. If the old procedure was not effective, it had no business being in the benefits package in the first place.

The father of evidence-based medicine, Archie Cochrane, wrote in 1972, "All effective treatment must be free" [3,p. 1]. This does not mean that effective treatments do not use resources – resources that have other good uses, for the treatments in question are not what economists call "free goods"[5]; even if Cochrane's slogan certainly does mean that people should not be exposed to the burden of paying for them individually. That burden is a collective one, requiring fairness in the distribution of the financial burden and equity and efficiency in the choices made about the services to be available. Some of these choices are tough. Many concern cancer. So, how should they be made?

2. Prioritising health care spending – the general case

In order to prioritise one needs to be able to compare. We need some acceptable common measure or indicator of the contribution that each intervention makes to health. It must be common, like change in mortality or life-years gained, or SF-36 (36 item short form survey), or QALYs (Quality-Adjusted Life-Years) or averted burden of disease like DALYs (Disability-Adjusted Life-Years), in order for decision makers to be able to make comparisons of the productivity of each across what may be very different sorts of intervention (surgical and medical, many disease categories, chains of supply, imported or home-produced, etc.). Some interventions are disease specific, like the cancer treatments; some are not disease specific, like interventions to improve childhood nutrition; others may be preventive; yet others diagnostic; while others, like community clinics or hospitals, are examples of general delivery platforms or common generic resources available for delivering treatments for many diseases and interventions. A common outcome measure is needed for them all.

If decision makers cannot make reasonable comparisons they can hardly make reasonable choices. This may seem a self-evident point. However, nearly all (or at any rate a very large number of) the studies of the effectiveness of interventions for health have measures of outcome (e.g. biological, physiological, symptomatic, physical functioning, mental functioning) that ensure comparisons *cannot* be made other than amongst a restricted set of options. Selecting an appropriate outcome measure is no minor task and will

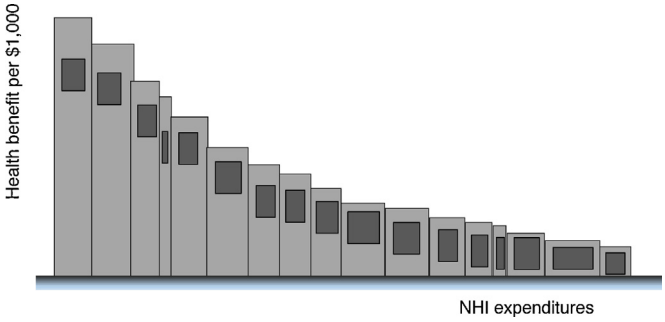

Fig. 1. Health care interventions arranged like books on a shelf.

be contingent on contextual factors like the quality of the available database, the precision required for policy decisions and ethnic and other traditions, for example as to what is understood by "health". What is appropriate in Canada may not be appropriate (or even feasible) in Malawi. I shall assume, however, that these major matters have been settled.

It is helpful to analyse the main issues by use of a model. A model is a simplification of reality which, if it is to be useful, removes all inessentials (i.e. elements that are irrelevant for immediate purposes) enabling one to focus on key issues and relationships. Consider a bookshelf analogy [5] as such a model. Imagine a bookshelf like that in Fig. 1 – a very long bookshelf – of health care interventions, each like a book, and ranked according to its effectiveness per $1,000 (its height), with the most effective on the left and the less effective stretching away on the right. The effectiveness is the discounted expected net improvement in health over the full period for which it endures.[6] The fatness of each book represents the estimated (discounted) cost of providing it. This is a combination of the costs of a specific technology, like a drug, the costs of associated procedures (other medicines, diagnostic services, community services, etc.) for as long as the treatment continues, and the estimated number of people using the intervention in question. The area of each book's spine is evidently a measure of the total health generated by use of that intervention. The maximum possible total health generated by any given rate of expenditure is the entire area under the roofscape of the books up to the given expenditure.

Consider now Fig. 2. A population health promoter will select the first book on the left and add books (that is, further interventions) moving along the shelf until she exhausts the budget. At that point (B) all the interventions selected will be effective and only the most effective of those that are effective will have been selected. The only services offered under public health insurance are those to the left. The least cost-effective intervention that is included indicates a "threshold" of t_o, a measure the effectiveness-cost ratio of the least effective procedure included in the insured bundle. Any new candidate for inclusion in the insured bundle must be at least as cost-effective as this. At the budget limit, and with only cost-effective interventions being used, the total health generated is area under the roofscape of the books up to the budget limit.

The reason why the interventions on the right are not included is not because they are ineffective. On the contrary, they are all effective. One would have to go a long way to the right before hitting zero productivity or slipping into the zone of iatrogenesis. The trouble

[5] "'Free good' is used in economics to describe a good that is not scarce; more of which is not demanded than is already available at a zero price: as much is available as anyone wants." [4]

[6] A simplification in this model is that each intervention (book on the shelf) has a constant cost and a constant productivity in terms of health. In practice one might expect the marginal cost of rolling out an intervention to rise (as for example, one reaches out to patients groups that are harder to reach) and its marginal benefits to fall (if one prioritizes those most capable of benefiting first). Those assumptions would be inappropriate in a model for analysing the ideal speed and extent of roll-outs but do not affect any of the conclusions reached here.

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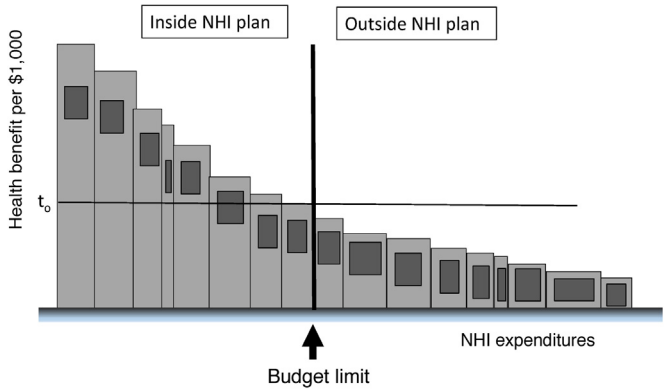

Fig. 2. The threshold that divides included interventions from excluded interventions.

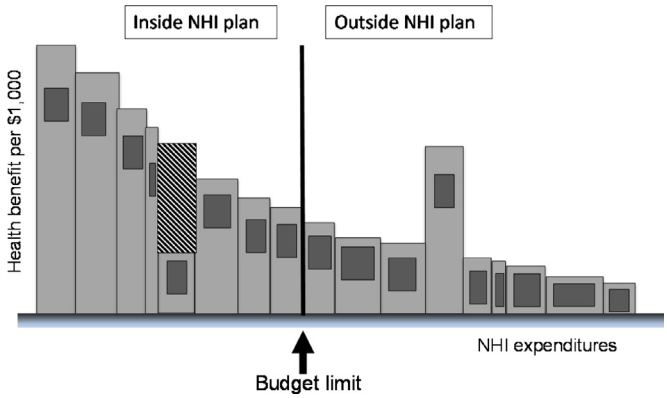

Fig. 3. Health loss from poor technology selection.

with them is that they are not effective enough. The benchmark test for inclusion of further interventions is the cost-effectiveness of the least cost-effective intervention that is included in the plan, t_o, if they fail this test they are not cost-effective.[7] It immediately follows that merely to demonstrate the effectiveness of an intervention is not enough to ensure its inclusion in the insured bundle. Advocates for specific interventions or types of patient need therefore to demonstrate *relative* effectiveness. One way of doing this is to make direct comparisons between interventions, for example a cancer versus a non-cancer treatment. A less cumbersome procedure is to use the threshold, and make comparisons with that.[8] The cost-effectiveness of an intervention cannot be evaluated independently of a threshold.

The morality of proper use of a threshold comes from its impact on people's health, which may be taken as having a moral worth that usually trumps that of non-health objectives of health care systems. If interventions on the right of the threshold are allowed to replace any on its left, population health falls. In Fig. 3 books on the shelf have been swapped from either side of the budget line. The cross-hatched area is the loss of life and/or quality of life from having the wrong things in the plan.[9] Decision makers are typically ignorant as to whether they have the right things assigned to either side of the vertical budget line but so long as they always replace interventions having lower productivity per dollar with ones that have higher productivity per dollar, they will be moving in the right direction and, if they also ensure that those that are included have a productivity per dollar that is higher than the effectiveness-cost ratio t_o, then they can be confident of extracting even more health from their health dollars.

There is the converse: if the low productivity intervention is already in the bundle, then the cross-hatched area represents the health gain from eliminating it and replacing it with the more productive technology on the right. Note the politically difficult and somewhat counterintuitive fact: disinvestment, even in effective technologies, can *increase* health provided there is complementary investment of the right kind.

3. Cancer care: costliness and effectiveness

Many oncological treatments have received approval for inclusion of public health insurance plans in recent years and some have not. Both the reasonableness of their prices and the value of their impact on the health of patients are controversial. The launch prices of new cancer drugs, which include uplifts on direct production and distribution costs for "overhead" R&D costs, have increased over time in real terms [6]. Bae and Mullins [7] note an estimated average annual cost of end-stage breast cancer treatment of $94,000. The same authors also report widely differing thresholds across US institutions and third party payers, from incremental cost-effectiveness ratios (ICERs) of $6000–$745,000 per Quality-Adjusted Life-Year (QALY). The mean was $139,000 and the median $56,000. For non-cancer treatments the range was $54,000–$332,000 with a mean of $50,000 and a median of $31,000 per QALY. They compared these ICERs with threshold norms for what counts as "cost-effective" of $50,000–$100,000. The implications are evident: cancer treatments in general are substantially less cost-effective than non-cancer treatments, they are substantially more costly, they vary greatly, and many exceed the conventional range of cost-effectiveness.

Variation in the willingness of an agency (or a country) to pay, as reflected in a threshold value or range is, of course, to be expected, not least because willingness to pay is normally higher when per capita incomes are higher and more generous benefits can be purchased. In the National Health Service (NHS) in England and Wales, the conventional range of £20,000–£50,000 has often been exceeded by cancer drugs, and some have been denied to NHS patients as a result. Public controversies arising from such decisions were met (in part) by the creation of a special Cancer Drugs Fund in 2011, even though the National Institute for Health and Care Excellence (NICE) already allowed a higher cost-per-QALY threshold for end-of-life drugs. There was in effect a dual threshold: one for cancer treatments and one for all the rest. Maynard and Bloor delivered a harsh criticism: "The Cancer Drugs Fund not only undermines NICE decision making and weakens incentives for companies to price their products at a level that is affordable and justified by health improvements, but also singles out a particular disease for favourable treatment in an essentially arbitrary manner. The emotive power of this disease led politicians to capture support by singling it out for preference" [8,p. 137].[10]

It is to be expected that the regulated seek to "capture" the regulator [9,10]. One way in which this can be achieved is through exploiting the softer elements in a regulatory process. For example, most agencies charged with identifying cost-effective clinical

[7] What is to be judged cost-effective is thus context-dependent – it depends on the budget as well as other things.

[8] We abstract, as previously stated, from the effectiveness of interventions of all kinds on the non-health objectives of health care systems and their budgets.

[9] In practice, the area indicated in Fig. 3 is likely to overstate the health loss. See [5].

[10] In countries, like South Africa, which have dual systems of health care, there will be (implicitly) dual thresholds and an important strategic issue becomes the harmonisation of standards (and therefore thresholds) over time

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interventions address the many uncertainties that can attach to process design, scientific evidence and the value content of decision rules through the use of consultative and deliberative methods. These open up many opportunities for special interests to bias decisions [11] as well as for the agencies to protect themselves against such biases. The harder elements too may come under sustained pressure. In the UK, NICE's cost-effectiveness threshold has met with sustained arguments from industry for its raising. The Association of British Pharmaceutical Industry's Paul Catchpole maintained that the threshold that NICE applies is too low and out of step with what the general public perceive is appropriate to pay for life extending cancer medicines: "a sustainable solution must now be found which empowers NICE to approve more new cancer medicines using different criteria and different values that reflect in practice more closely those that are used by today's NHS to make investment decisions" (reported in [12]). The objective of industry might well – and not unreasonably – be to have more cancer medicines approved, but the objective of the health care system is more usually to put them to a fair test of cost-effectiveness. A manufacturers' strategy that accepted this would place its emphasis on increasing the overall health care budget, thereby indirectly lowering t_o and raising the cost-effectiveness threshold.[11]

NICE had from its early days been explicit about the value judgments that were embodied in its decisions [13]. It created the Citizens Council in part to ensure that social value judgments had a full discussion and consideration. The justification for the Cancer Drug Fund was in part that NICE received a report from its Citizens Council recommending the use of fifteen further criteria in addition to cost-effectiveness [14]. The argument adduced by the Department of Health in 2010 was on grounds of the "possibility" that society values benefits to patients with cancer more highly than benefits to other kinds of patient [15]. There is, however, little evidence for this possibility actually being the case [16,17]. Further, the Committee of Public Accounts of the British parliament complained that the government "do not have the data needed to assess the impact of the Fund on patient outcomes, such as extending patients' lives, or to demonstrate whether this is a good use of taxpayers' money" [18,p. 3]. The Fund was an under-researched political reaction to the fact that NICE judged NHS resources to be better spent on treatments for *non-cancer* patients. The government overrode a careful and respected decision-making process with an ad hoc one that led to uncontrolled expenditures, reintroduced "post-code prescribing" into the NHS [19,18] and substituted cost-ineffective care for cost-effective care.

4. Can cancer be exempted from the criteria?

The moral question inevitably arises: what justifications might be offered for including cost-ineffective interventions like that represented by the cross-hatched rectangle in Fig. 3, well below the effectiveness-cost threshold? The effectiveness-cost ratio is the reciprocal of the more familiar cost-effectiveness ratio. The same question might therefore be put thus: what justifications might be offered for including cost-ineffective interventions like that represented by the cross-hatched rectangle, *well above* the cost-effectiveness threshold?

4.1. Argument 1: the whole health maximisation assumption underlying the approach is misconceived. health care is about more than just promoting health. other objectives commonly include financial protection (e.g. from the out-of-pocket expense of costly interventions), innovation, and all those listed earlier

However, these alternative reasons for having public health insurance afford no special status for cancer. For example, insurance provides protection for all health care expenses covered under a public plan including many other costly procedures. The mere fact that cancer treatments are often very costly (in terms of the health necessarily forgone) is no argument unless they can deliver an expected health gain that counts for more. And the fact that they deliver *some* health gain (i.e. are effective) is, as we have seen, not a sufficient justification for their inclusion.

4.2. Argument 2: innovation is stifled by the strict application a cost-effectiveness threshold that is too low

Innovation is desired across all disease areas, provided it is innovation that leads to real and substantial health benefits that are realizable at affordable cost. Innovation is already rewarded (or at least encouraged) through the patent system and with special pricing and profit regulatory schemes in most countries. To win on an innovation argument a case has to be made that cancer R&D is inherently more innovative than other clinical R&D and that this renders it worth the additional sacrifice of other people's health and lives. The innovation argument is frequently adduced by pharmaceutical manufacturers and may be one reason why the UK government introduced its special Cancer Drugs Fund in 2011. This decision missed two wonderful opportunities: first to explain to manufacturers and to the public that the kind of innovation wanted was not for the invention of extremely expensive interventions of small benefit, rather for inventions of the opposite kind; second to make clear to everyone the opportunity cost argument that lies at the core of the case for agencies such as NICE and CADTH (the Canadian Agency for Drugs and Technologies in Health), namely that you can spend health care resources only once and a million dollars spent on a particular technology should never be at the expense of a higher, or more certain, health gain that could have been obtained through an alternative use of those dollars – never, that is, without a careful marshalling of good reasons for sacrificing the health of some for the benefit of others. Achieving public understanding of both kinds would have been marks of true leadership.

4.3. Argument 3: the use of standard outcome measures, like the EQ-5D QALY or averted DALYs, underestimates the health benefits of cancer treatments

It is possible that these measures omit some aspects of benefit to patients that are not captured in the QALY/DALY algorithms, but it is far from clear whether this confers an unfair disadvantage in cancer relative to other diseases and, if it does, precisely what the omitted element is and how significant it is judged to be. One of the important reasons for having patients and informal carers involved, as in England and Wales, in the decisions about inclusion or exclusion from benefit packages is precisely to check that the outcome measure matches the kinds of concerns of those most intimately involved (that is, patients and their informal carers). If there are omissions in particular cases, this participation allows them to be spotted and may make a case for giving such cancer treatments lower hurdles – but the case needs to be made convincingly and preferably in a quantified or well-researched qualitative way.

[11] Their argument would still be biased unless they found some way of demonstrating that a smaller budget for education, transport and other publicly financed services, or for taxpayers' private consumption, was justifiable.

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4.4. Argument 4: the assessment of benefit excludes the beneficial effects that treatment and its consequences have on those who care for cancer patients

If these effects are indeed neglected, are genuine benefits and there are no additional actual burdens, and if they are substantial, then this argument would carry weight. Again their qualitative and quantitative significance needs to be convincingly demonstrated and not merely asserted. In England and Wales, NICE routinely considers any such effects that are judged to be of significance and requires their quantification. Of course, not all regulatory agencies may be as thorough as this.

4.5. Argument 5: the opportunity cost argument is weak. there are always efficiency savings that can be found in any system which mean that the alleged sacrifice of health represented by the threshold is spurious. the actual sacrifice is much smaller

It is true that no system will be perfectly efficient but it does not follow that health opportunities are not forgone when resources are devoted to particular interventions. The answer to an empirical question must be empirical enquiry. What does the evidence say about the actual sacrifices? Such evidence as we have [20] suggests strongly that the conventional thresholds used (for example in the UK) are already *too high*, so raising them still further would increase the loss of health elsewhere in the system by introducing cost-ineffective treatments. More to the point, however, there is no reason to suppose that the health losses imposed elsewhere in the system by any given expenditure on cancer care are either larger or smaller than the same sum spent on any other treatment or combination of treatments. The efficiency savings argument cannot be one for cancer as a special case. If there is a case, it is that the opportunity cost argument overstates the health cost of *all* treatments.

4.6. Argument 6: cancer is a scary disease and people who suffer from it deserve to have access to treatments that would fail a conventional cost-effectiveness test

There is no doubt that most people live in fear of cancer, but people also live in fear of many diseases, and the fact that they are fearful (as distinct from being able to be offered remedies that remove the fear because they are effective either in preventing the disease or relieving its consequences) is not a good reason for denying cost-effective health care to others, be they fearful or unfearful. If there are effective ways of relieving fear, they may be justifiably included but not if the only source of relief comes from a modest reduction in symptoms not justified by its cost and possibly better achieved through alternatives, like palliation.

Childhood cancer may be viewed as demanding special sympathy but, if so, the same relaxation of the strict criteria of evaluation should apply on grounds of horizontal justice to similarly placed children suffering from other diseases.

4.7. Argument 7: for some cancer patients a costly and not very effective treatment may offer a "last chance" to someone in despair. such a situation might exist if no intervention of any kind existed for these patients or if the patient suffered from a rare form of cancer

Whether there truly is no alternative treatment is a matter of fact which needs to be established. If the proposed treatment is simply ineffective, then the last chance is illusory and such patients needs to be counselled accordingly; if it is cost-ineffective, then the judgment has to relate first to the extent to which despair, as a matter of fact, is reasonably to be expected to be relieved and, second, whether it is worth the sacrifice of the health of other people that giving the treatment would necessarily entail. There may be a case here – provided that the despair is indeed likely to be relieved. This is, plainly, a judgment call that those responsible for making decisions about the inclusion of treatments in a benefits package need to consider. It seems, however, a flimsy[12] ground for sacrificing health benefits elsewhere.

In the case of rare cancers, the question arises of the moral status of rarity per se. Do rare cancer sufferers deserve greater sympathy than other cancer sufferers and, if so, do they also deserve greater sympathy than others with rare non-cancer diseases? If it is not the rarity per se but the fact, say, that much less is known about the effectiveness of treatments in relatively unresearched rare disease territory, then a judgment needs to be formed as to the acceptability of the risk of delivering ineffective or cost-ineffective care. Such matters plainly require considerable deliberation but common horizontal justice again requires that similar treatment be accorded to non-cancer patients with rare or under-researched conditions.

4.8. Argument 8: cancer is a "severe" disease and should accordingly be given a higher priority than less severe diseases

If this argument is accepted, it plainly has consequences for the treatment of all diseases classed as "severe", again on grounds of horizontal justice. Severity seems generally to be conceived as a serious and progressive condition expected to lead to premature death. It is related to more general philosophical arguments for giving priority to those who are "worse off" (classically [21]). There are several difficulties with the severity argument [22] but chief amongst them is that it is indifferent to the effectiveness of the treatment and completely blind to its opportunity cost. As a consequence, ineffective treatments for severe cases would command a higher priority for funding in a benefits package than highly effective interventions for less severe conditions. For the same reason, providing relatively cost-ineffective treatments would deny care to others whose conditions were judged to be insufficiently severe, despite the availability of highly effective and relative cheap interventions.

4.9. Argument 9: many cancer patients have a short life expectancy even with treatment. a quasi-utilitarian argument might cite the law of diminishing marginal value: even small gains for such people are to be valued more highly than the same gains of equivalent quality of life for people with an already long expectation of life. alternatively, there is the more direct emotional appeal "Our moral response to the imminence of death demands that we rescue the doomed" [22]

This "rule of rescue" argument [23,24] makes two intuitive appeals but has two important caveats. First, the strength of the argument is much weakened if the additional time, short though it may be, is in fact of poor quality and even of a worse quality than would be the case under normal palliative care. Second, the end-of-life argument applies to all with short life expectancies whether or not they are cancer patients. These other patients also include non-cancer end-of-life patients who could benefit from cost-ineffective treatments not currently in the benefits package but which, were these patients to receive similar end-of-life weightings as cancer patients, might be included. Again, assessing these claims and identifying those potentially affected are empirical, not rhetorical, questions whose answers are currently not clear. Claims concerning them from self-interested sources like manufacturers and cancer lobbying groups ought to be treated with the

[12] I do not wish to imply that all qualitative arguments are flimsy, only that this one is.

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same scepticism that should attach to all biased vested interest claims on resources. Such evidence as there is does not support the idea that the public in general supports the end-of-life argument [16,17].

5. The burden of proof

These arguments fall into two broad groups. Some are questions of social value: how should we value health gains of particular kinds and should we value them differently according as they accrue to different people? Others are questions of fact: would information about the quantitative size of the effects in question lead us to conclude that cancer is indeed a special case? The burden of proof in both cases lies with those making the assertion that cancer is, indeed, special. That burden of proof is not impossible to bear. But merely to assert the arguments listed here is not good enough: until the empirics are done Maynard and Bloor's [8] charge of arbitrariness will stand.

Ethical approval

none required.

Conflict of interest

none declared.

Acknowledgments

I have benefitted from comments by Karen Bloor, Bengt Jönsson and Alan Maynard. Needless to say, they are responsible neither for the analysis nor its conclusions.

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Please cite this article in press as: A.J. Culyer, Ethics, priorities and cancer, J Cancer Policy (2016), http://dx.doi.org/10.1016/j.jcpo.2016.09.007