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BACKGROUND PAPER

Expensive Life-extending Treatments

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**Forward Look
7-8 May 2013**

Note

The author was commissioned by the Nuffield Council on Bioethics to write this paper in order to inform the Council's discussions about possible future work on this topic. The paper is intended to provide an overview of key clinical, ethical, social, legal and policy issues, but is not intended to offer any conclusions or recommendations regarding future policy and practice. Any views expressed in the paper are the author's own and not those of the Nuffield Council on Bioethics.

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Summary

1. This paper focuses on the implications of extremely expensive biomedical technologies and treatments that may extend the lives of people with incurable diseases.

Outline

2. The paper begins by outlining methods of allocating resources to life-extending technologies in the UK, and the controversy about hyper-expensive treatments to which these methods have contributed. Thereafter it examines ethical concerns about the value of life, the fair distribution of life-extending drugs, and the role of social values in decisions about resource allocation. This is followed by a discussion of pertinent economic and legal concerns. The final section discusses implications for research funding.

Background

3. Many interventions are hyper-expensive, meaning that they have an absolute price that is extremely high, or that they provide comparatively small benefits relative to how much they cost (Hunter and Wilson 2011). A significant class of these expensive interventions is used by patients that have a terminal disease, often adding just a few months to their lives. This paper focuses on concerns about this class of hyper-expensive, life-extending, end-of-life drugs.

Examples of hyper-expensive, life-extending, end-of-life treatments

4. Hyper-expensive treatments are often for extremely rare diseases, referred to as orphan conditions. For example, Soliris is a monoclonal antibody therapy used in the treatment of paroxysmal nocturnal haemoglobinuria. The treatment costs around \$409,500 USD per year and is thought to be the most expensive drug in the world.¹ However, such orphan conditions are by definition extremely rare.
5. Treatments for more common conditions, such as cancers, have caused greater controversy. Because older people make up an increasing proportion of

¹ <http://www.forbes.com/2010/02/19/expensive-drugs-cost-business-healthcare-rare-diseases.html>.
Last accessed 26 March 2013.

society, and the risk of cancer increases with age, cancers are becoming more prevalent. The discovery of effective treatments for other age-related diseases, such as cardio-vascular disease, has contributed to cancer being the leading cause of death in many nations (Sullivan et al. 2011). Indeed 40% of new drug applications are cancer therapies (Trowman et al. 2011).

6. It is thus unsurprising that many life-extending end-of-life treatments are for cancers. Erbitux (colorectal/head and neck), Yervoy (skin), Afinitor / Everolimus (renal/ breast), Perjeta (breast), Arbiraterone (prostate), Provenge (prostate), Herceptin (breast), Avastin / Bevacizumab (several), are some examples of cancer drugs that are extremely expensive.
7. Medical technologies are also increasingly costly. For instance, a year's use of a haemodialysis machine for end stage renal failure is estimated to cost around £20,000.²
8. Due to the impact of the financial crisis, governments are trying to stabilise budgets. Biomedical advances and changing demographics mean that the profusion of life-extending treatments is likely to place further strain on already scarce resources.³

Methods for allocating resources

9. In the UK, the primary responsibility for negotiating competing claims on limited resources falls to the National Institute for Health and Clinical Excellence (NICE). The Quality Adjusted Life Year (QALY) is the central tool for determining which treatments the National Health Service (NHS) will provide. Estimating an intervention's QALY contribution involves judging evidence about the *number of years* (or months) the intervention will add to a person's life, as well as about the *quality of life* the person is likely to experience in the added time.
10. An intervention must be an improvement over the standard treatment, if there is one, in order to be adopted. A cost per QALY ratio informs decisions between two interventions. More expensive treatments that do not substantially increase quality or quantity of life are thus less likely to be provided.
11. In addition most nations have a nominal upper bound, or threshold for cost-effectiveness. Currently, in order to be considered cost-effective in the United Kingdom, an intervention must cost less than £30,000 per QALY (Kirkdale et al. 2010). In this paper, treatments that would exceed this threshold are taken to be hyper-expensive, providing a relatively small benefit for their price.
12. With reference to the cost per QALY ratio and the cost-effectiveness threshold Appraisal Committees decide whether the NHS will provide the treatment,

² <http://publications.nice.org.uk/guidance-on-home-compared-with-hospital-haemodialysis-for-patients-with-end-stage-renal-failure-ta48/evidence-and-interpretation>. Last accessed 26 March 2013.

³ See Pammolli, Riccaboni, and Magazzini (2012) for evidence that healthcare and welfare expenditure in Europe is increasingly imbalanced towards the elderly.

provide with minor reservations, provide with major reservations, or not provide the intervention. Decisions on expensive drugs made using these procedures have been hotly debated in recent years. As discussed in the following subsection, these debates have resulted in a number of changes, both to the procedures themselves, and to the bodies that are responsible for decisions about expensive drugs.

Controversy about hyper-expensive end-of-life treatments

13. Daniels and Sabin suggest that decisions about expensive life-extending technologies are the 'most difficult and explosive responsibility for any health care system' (Daniels and Sabin 1998). Refusals to provide potentially life-extending drugs due to cost-ineffectiveness have led to emotionally charged controversy. Patient interest groups and the media have conducted high profile campaigns against NICE's perceived 'penny-pinching' at the cost of people's lives.⁴
14. Against this background, the Richards review, compiled by Prof. Mike Richards, suggested a number of measures, including a re-evaluation of the cost/QALY threshold, as well as a reconsideration of the significance of public views on life-extending treatments at the end of life (Richards 2008).
15. In 2009, in response to the Richards report, and public and political pressure, NICE issued supplementary guidance on the issue of life-extending end-of-life treatments. The supplementary advice instructs Appraisal Committees to consider the impact of giving additional weight to QALYs, if a treatment
 - is licensed for treating a patient population not normally exceeding 7000 new patients each year
 - is indicated for the treatment of patients with a diagnosis of a terminal illness and who are not, on average, expected to live for more than 24 months
 - offers a substantial average extension to life (roughly 3 months) compared to current treatment
 - has been assessed by NICE as having an incremental cost effectiveness ratio in excess of the upper end of the range (£30000) normally considered by NICE's Appraisal Committees to represent a cost effective use of NHS resources.

Strong evidence would have to be presented for these claims and no alternative treatment with comparable benefits should be available through the NHS (NICE 2009). These new criteria aimed to reflect the importance attributed to the last months of life, particularly in groups that may be disadvantaged due to the rareness of their condition.

⁴ <http://www.dailymail.co.uk/news/article-1325449/Drug-victory-patients-NICE-stripped-power-ban-life-saving-drugs.html>. Last accessed 27 March 2013.

16. A further step taken by government was to set up an 'Interim Cancer Drugs Fund' of £50 million in 2010.⁵ This was set aside for cancer treatments that were deemed too expensive by NICE. Since then, regional commissioning bodies (initially Primary Care Trusts, now Clinical Commissioning Groups) have been given access to a Cancer Drugs Fund of £200 million, which is used to make treatments available to patients with rarer cancers.
17. As of 2014 there will be a shift to a scheme of value-based pricing. So far the impact of this change on the allocation of funding to life-extending end-of-life drugs, and whether it will be an improvement, is unclear.⁶

Ethical issues

18. Ethical concerns have been raised about healthcare rationing in general, and the use of the QALY in particular. This report focuses on those concerns that are directly relevant to hyper-expensive, life-extending, end-of-life treatments, although some overlap with more general concerns is unavoidable. Key ethical issues concern the value assigned to the last months of life, whether expensive treatments can be fairly provided, and the role of social values in determining which treatment should be provided.

The value of life and death

19. Increased life expectancy has been ranked as 'a crowning achievement of modern civilisation' (Vaupel and Kistowski 2008, 256). Other things being equal, living longer is a good thing for the person concerned. Nonetheless, a highly significant set of problems concerns whether, and the circumstances in which, additional time added by hyper-expensive end-of-life treatments will benefit a person, and the impact they will have on the achievement of a 'good death.'

Additional value for a patient's final months?

20. The QALY assigns equal value to all years spent in full health. Early on in the life of the QALY, concerns were expressed that it does not place sufficient weight on later years in life. John Harris, for example claims that additional time at the end of life can be 'valuable in enabling the individual to put her affairs in order, make farewells and so on, and this can be important' (Harris 1987, 120–121). This suggests some grounds for giving a patient's last months extra consideration when determining the cost-effectiveness of life-extending drugs for people with incurable illness.
21. In their supplementary guidance on 'Appraising life-extending, end-of-life treatments,' NICE attempts to account for the importance of a patient's final

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http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_117970. Last accessed March 26 2013.

⁶ <http://blogs.bmj.com/bmj/2012/12/21/james-raftery-qalys-and-value-based-pricing>. Last accessed March 26 2013.

months by making provision for extra weight to be given to QALYs at the end of life. Given the criteria outlined above – small patient population, short life expectancy, and no comparable treatment – months added to the end of life can be accorded greater significance in deciding whether to provide a treatment.

22. However, both the empirical and ethical basis for this extra weight have been questioned. Despite the actions of patient groups and the media, it is not clear that most people want the final months to be granted extra value (Dolan 2009). Nor is it obvious that such weighting is justified by ethical theory.

The value of living with an incurable disease

23. It is not always true that additional months spent undergoing therapy for a terminal disease will be of significant benefit. Extending a period of illness may be expensive for a patient. It may also be emotionally distressing for both the patient and her family. Arguably treatment may be so bad that it does not add to the value of a patient's life. Up to a fifth of cancer patients treated with chemotherapy in the last month of life will achieve little benefit, and may experience a significant decrease in quality of life due to the toxicity of treatments (Braga 2011).
24. With their supplementary guidance, NICE invites Appraisal Committees to assume in some cases 'that the extended survival period is experienced *at the full quality of life* anticipated for a healthy individual at the same age' (NICE 2009). As a result, the Committee could potentially ignore poor quality of life in the final months. The effect of this clause may be to privilege length of life over quality of life in assessing hyper-expensive drugs for people in their last months.

Value for whom?

25. At present, QALYs are based on public, as opposed to patient evaluations of health states. Because people that assign values to health states are usually not experiencing the health state themselves, it is likely that their judgement of the (negative) value of a health condition will differ from individuals that are in the health state (Dolan 2009).
26. There are at least two features that make this particularly problematic in the case of life-extending end-of-life treatments: first, individual valuations of health states that would be experienced under treatment may differ; second, the *time of life* in which a health state occurs does not form part of the assessment of life-extending interventions. These features mean that the QALY is unlikely to reflect a patient's own valuation of months at the end of her life.

Autonomy, informed consent and a good death

27. End-of-life treatments may stand in the way of a person's desire for a 'good death'. For instance, an overwhelming majority of people state that they would prefer to die at home (Townsend et al. 1990). Aggressive therapy may impede

this wish when end-of-life treatment requires hospitalisation. If patients were aware that additional months are likely to be a burden rather than a benefit, they might prefer palliative care, or assisted dying options.

28. Physicians are often reluctant to give a realistic prognosis in end-of-life situations and prognosis is consistently overestimated (Glare et al. 2003). Knowing how long one is likely to live can be highly significant in helping one to achieve a good death. In report commissioned by the *Lancet*, Sullivan and colleagues point out that

a substantial percentage of cancer-care spending occurs in the last weeks and months of life, and that in a large percentage of cases, such care is not only futile, but contrary to the goals and preferences of many patients and families if they were adequately informed of their options. (Sullivan et al. 2011)

Indeed a recent study of 1274 stage IV lung and colon cancers found that many people receiving aggressive end-of-life treatment for cancer mistakenly believed that they might be cured. 69% of lung cancer patients and 81% of colon cancer patients did not understand that they were unlikely to be cured by chemotherapy (Weeks et al. 2012).

29. It is important that patients receive adequate information about the likely *extent* of life extension, and the impact of expensive treatment on *quality* of life. Better communication with physicians would improve patients' chance of having the type of death that they would choose (Mack et al. 2012). In addition to impacting on individual well-being, such steps may also have implications for health expenditure, both for the patient and for health services.
30. The points above suggest ways in which hyper-expensive treatments, or the grounds on which they are evaluated, may reduce a patients' welfare and the quality of her choices. The following section examines issues concerning the fair distribution of life extending technologies.

Fairness

31. It is possible to distinguish between the *size* of a health benefit and the *distribution* of that benefit (Parfit 1997). *Maximising* theories suggest that we should simply aim for the greatest health benefit regardless of its distribution. In general, however, large disparities in lifespan are thought to be unjust, or unfair. Expensive life-extending technologies raise several concerns regarding the fairness of their distribution. If they are not provided by healthcare services, they may increase existing disparities in lifespan between wealthier and poorer groups. If they are provided, they may disadvantage groups who do not have life-limiting illness. Moreover, if treatments are only provided for small sub-groups with particular diseases, larger groups may receive inferior treatments.

Non-provision and unfair lifespans

32. The gap between the life expectancies of wealthier and poorer groups is already large. If life-extending technologies are not provided by healthcare services, they may only be available to the very wealthy, further increasing this gap. This undermines several principles of fairness.
33. Applied to life expectancy, strict *egalitarian* principles hold that societies should aim for roughly equal lifespans, even if this means preventing those better off in lifespan from accessing treatments. If only the wealthy live longer, principles of equality are violated. *Prioritarian* principles hold that societies should aim to benefit those who are worst off in terms of life expectancy. Non-provision would mean that very little benefit would accrue to the worse off. *Sufficientarian* principles hold that society should ensure that people have *enough* lifespan (Parfit 1997). This might be cast in terms of a 'fair innings' of around 75-80 years (Williams 1997). Non-provision of life-extending technologies might mean that many people do not reach a sufficiency threshold.

Partial provision, fairness and autonomy

34. One option is to provide partial coverage of expensive treatments. Several alternatives to full public provision have been suggested in order to mediate between the public burden and opportunity costs (discussed below) of expensive drugs on the one hand, and patients' desire for the most effective treatment on the other. For example employing 'top-up payments' would require the NHS to pay the cost of the standard treatment towards the patient's preferred alternative, while the patient would reimburse the NHS for the additional expense.
35. However, those with greater wealth may still benefit more. This could conflict with the principle of solidarity enshrined in NHS's stated goal of 'high quality care for all.' The value of a patient's ability to autonomously choose higher quality treatment sits uneasily with values like equality and solidarity.⁷

Public provision and opportunity costs

36. An 'opportunity cost' is the cost, or lost benefit, of an alternative not chosen. In the current case the opportunity cost is the benefit lost to other patients when more is spent on patients who are closer to death. These opportunity costs are thought to be amongst the most important arguments against hyper-expensive treatments.
37. Provision of additional funds by the Cancer Drugs Fund, or in accordance with the NICE Supplementary Guidance, is likely to deprive others of beneficial treatments. Moreover, since treatments for other ailments are within the cost-effectiveness range those that are deprived would be a greater number, and would also benefit *more*. This seems unfair (Raftery 2009).

⁷ See Richards 2009 for an evaluation of various alternatives in light of NHS principles.

38. Arguably, though, those who have a short time to live are worse off. Thus, in accordance with the prioritarian principle of fairness discussed above, it is acceptable to provide them with the greatest degree of benefit. If so, perhaps it is fair to improve the well-being of those with a terminal disease by providing them with life-extending treatments (assuming these are good for them).
39. Towse has suggested a lack of evidence about opportunity costs means that it is justified to raise levels of spending (Towse 2009). There is thus an important empirical question about who loses out due to spending on expensive life-extending technologies.

Conditions with a small treatment group

40. Provision of hyper-expensive, life-extending treatments might be regarded as relatively unproblematic when the disease being treated is very rare. In the first place, a smaller population is unlikely to result in an unsustainable total cost. It may also not result in severe opportunity costs.
41. Moreover, due to smaller uptake, it is reasonable for pharmaceutical companies to charge more. Not funding such treatments would reduce incentives to develop interventions with a smaller number of users. It would also be unfair for patients to be denied treatment simply because their ailment is rare.
42. On the other hand, making provision for people with rarer diseases, as the NICE supplementary guidance does, may introduce unfair 'special pleading.' Sometimes an expensive drug would benefit patients with a rare disease and those with a more common disease. In such cases it may be unfair to provide the treatment only to those with the rarer disease. The smaller size of the patient group to which they belong appears to be a morally irrelevant reason to grant greater benefits (Jackson 2010).

Personalised medicine

43. The above type of concern is likely to be exacerbated as a result of 'personalised medicine.' A person's genotype can have an impact on the efficacy of a particular treatment. As a result, an expensive treatment may provide greater benefit to a group with a particular genetic make-up. Thus, it may exceed a cost-effectiveness threshold for people with one genotype, but not for a targeted group. This may already be the case for Bevacizumab in the treatment of different types of breast cancer (Fleck 2010).
44. Given the increasing prevalence of pharmacogenomic approaches, agencies such as NICE will be presented with a growing number of cases in which patients with nominally the same disease will be given different treatments that are known to have different degrees of benefit. In such cases it will be necessary to explain to patients why they will be denied a treatment, while others are provided it, even though they would benefit, albeit unequally.

The significance of age

45. The majority of patients receiving treatment for terminal diseases will be elderly. Bioethicist Daniel Callahan has argued that the pursuit of aggressive life-extending therapies in the aged is both unethical and economically unsustainable. He claims that medicine should aim to help people achieve a 'natural' human lifespan. Beyond this point, care offered should purely be palliative (Callahan 1988; Callahan 2009).
46. By contrast, Harris argues that including age as a factor for decisions about resource allocations is unacceptably ageist (Harris 1987, 121). Denying treatment on the grounds of QALYs appears more likely to affect the elderly. Since years in later old age are typically less healthy, these years are judged as having a lower QALY value. However, the elderly are more likely to have diseases that would be treated by expensive end-of-life treatments. The upshot is that the elderly are more likely to have a disease, and may be less likely to receive treatment for it (Harris and Regmi 2012; Harris 2005).
47. The NICE 2009 supplementary guidance provides further fuel for critics. The guidance holds that the Appraisal Committee should consider the

impact of giving greater weight to QALYs achieved in the later stages of terminal diseases, using the assumption that the extended survival period is experienced at the full quality of life *anticipated for a healthy individual of the same age*. (NICE 2009)

Appraisal Committees are empowered to disregard *actual* health states that would result from treatments and instead consider aggregate, age-relative health states. Arguably this represents a departure from valuing health states, and ends up granting a value to life years *based on age, rather than health*.
48. The concession to weight the last months has a further implication. If Appraisal Committees grant extra weight to the last months of terminally ill patients because of the significance of these last months, perhaps the same reasoning should justify granting extra weight to treating old people in their last years. Failing to do so may be inconsistent unless morally relevant reasons are provided.

Social values

The rule of rescue

49. The 'rule of rescue' has been defined as the view that

We ought to attempt to rescue an individual when we are reasonably confident that our efforts can help, and when the individual's death is imminent and our failure to act is reasonably expected to result in that person's death. (Jecker 2013)

It seems likely that social pressure to provide expensive end-of-life treatments is an instantiation of the rule of rescue.

50. As mentioned, in their supplementary advice on end-of-life treatments, NICE agree to give extra weight to end-of-life conditions. Arguably this may be a concession to a public endorsement of the rule of rescue. If it is, this represents a departure from NICE's *Social Value Judgements* document, which is clear that

applying the rule of rescue may mean that other people will not be able to have the care or treatment they need... The Institute has not therefore adopted an additional rule of rescue. (NICE 2005, 21)

51. Part of the motivation for the *Social Value Judgements* document is to make the basis for decisions transparent. If exceptions are being made in the case of end-of-life treatments these should be made explicit and justified.
52. This is especially important, since it has been argued that the rule of rescue is unjust on the grounds that it privileges emotional reactions towards those with the resources to make their conditions public (Jecker 2013). In addition, it may distract attention and funding away from programs that would *prevent or postpone* illness that causes death.

Economic and legal issues

Economic issues

53. Fewer new-borns and longer lives mean that dependency ratios – the ratio of dependent people to workers – are already rising in both the developed and developing world. A society in which the use of life-extending technologies is widespread will be much older. This has led to fears about aggravated economic crises due to an increasingly unhealthy and economically dependent population. Francis Fukuyama, for instance, points to the possibility of a

national nursing home scenario, in which people routinely live to be 150 but spend the last fifty years in a state of childlike dependence on caretakers. (Fukuyama 2002, 69)

This dystopian concern may seem overstated. However, the Office of National Statistics already predicts that GDP may have to increase by as much as £11bn by 2032 in order to fund the pensions system, and by an additional £3.4bn to finance long term care.⁸

54. Such predictions cast doubt on the idea that indefinite increases in life expectancy should be a social priority, unless they can be matched by concomitant increases in working life expectancy and healthy life expectancy. It is questionable whether continued investment in drugs that extend life *at the end of life* can achieve these increases. This provides social grounds for rebalancing funding priorities to favour research into interventions that can increase healthy lifespan.

⁸ <http://www.ons.gov.uk/ons/rel/hsg/health-statistics-quarterly/no--52---winter-2011/the-effect-of-lengthening-life-expectancy-on-future-pension.html>. Last accessed March 26 2013.

Value-based pricing (VBP)

55. A new system of value-based pricing is due to be introduced in the UK as of January 1st 2014. Under the new scheme, maximum prices for treatments will be set by the Department of Health rather than by NICE. Price thresholds for different diseases will be based on the value to the patient and society of treating the disease. This value is a function of the burden of the disease or disability on the patient, the seriousness of the condition, and the therapeutic, innovation and perhaps social effects of the intervention beyond existing best practice.
56. The shift to value-based pricing should mean that the supply of innovative treatments from pharmaceutical companies will better reflect national health needs.⁹
57. A further change accompanying the new scheme is that NICE's power to make mandatory recommendations about funding treatments has been removed. Instead NICE will make recommendations that Clinical Commissioning Groups can accept or reject.

Concerns about VBP

58. The additional power given to local authorities has given rise to concerns that the new policy will lead to 'postcode prescribing'. People might be unable to access treatments due to the budgeting decisions of their regional health authority. This in turn might lead to a kind of internal medical tourism and migration for people seeking life-extending drugs.
59. More details on the impact of value-based pricing on expensive life-extending end-of-life treatments should be available when the policy comes into full effect. When it does, it would be useful to have a framework for ethically appraising its implications.

Legal issues

60. Controversies about life-extending end-of-life treatments have given rise to a number of legal cases. The most immediately relevant of these concern the use of treatments for off-label indications. End-of-life treatments will often have effects on more than one disease. Often pharmaceutical companies will not attempt to gain approval to treat these additional effects because gaining approval for a new indication would reduce a company's profits (as in the case of Bevacizumab discussed below).
61. In the UK, however, it is legal to prescribe treatments 'off-label,' that is, for illnesses for which they have not been approved. This has occurred extensively with Bevacizumab, which is licensed for various cancers. The drug has been recommended off-label to treat age-related macular degeneration (AMD), a

⁹ See Claxton et al. (2008) for a discussion of the motivations for, and potential problems with, value-based pricing.

disease that severely impairs vision. Bevacizumab is far cheaper than Lucentis, the standard treatment for AMD.

62. However, Novartis, a pharmaceutical company with distribution rights for both drugs refuses to licence Bevacizumab for the treatment of AMD. Nonetheless, NICE has called for head-to-head comparison between the Bevacizumab and Lucentis to determine their relative effectiveness (Rafferty and Lotery 2007). Moreover, a number of Clinical Commissioning Groups in the UK provide funding for the cheaper alternative. In response to these trends, Novartis is currently seeking judicial review to prevent the off-label prescription of their drug (Rhodes et al. 2012).
63. It is highly likely that there will be more cases in which a company attempts to protect profits on expensive treatments by keeping cheaper products unlicensed. Such legal action could have significant implications for the cost of life-extending drugs.

Research funding

Research into compressing morbidity

64. Many concerns about life-extending interventions focus on their impact on *healthy lifespan* (healthspan) and *morbidity*. Interventions that increase healthspan or compress morbidity are, for the most part, ethically unproblematic. However, interventions that extend morbidity potentially pose problems both for individuals and for society. In many cases life-extending, end-of-life drugs will be of the latter type. This suggests a reason to increase research funding for interventions that can postpone or prevent diseases without prolonging disease states.

The holistic treatment of ageing

65. Many hyper-expensive end-of-life treatments are for age-related diseases like cancer. As a result numerous gerontologists argue that, rather than piecemeal treating of individual diseases, research should focus on interventions that slow or halt the ageing process itself (Miller 2002; Olshansky et al. 2007). Doing so may lengthen lifespan whilst at the same time increasing healthspan. This could present significant benefits for individuals and, in light of the economic considerations above, for society.
66. However, biogerontologists Speakman and Mitchell note that this type of

holistic preventative approach to all age related disease... is very much more in the Eastern philosophy of medicine where treatments are often directed at the whole system rather than particular disorders, and the emphasis is more on prevention than treatment. It is difficult to see how the western system of medicine and medical regulation could cope (Speakman and Mitchell 2011).

The need to gain approval for individual diseases, and the fact that ageing itself is not regarded as a disease, mean that pursuing such a holistic approach faces significant obstacles.

67. It may be desirable to fund research that investigates whether impacting on ageing itself might lead to preventive interventions, and the extent to which these could be accommodated in western health systems.

Conclusions

68. Hyper-expensive treatments used to extend lifespan in the last months of life raise complex ethical issues concerning the well-being of patients, whether the treatments can and should be fairly distributed, and their impact on social values. Often the same values appear to provide reasons both for and against the use or provision of such treatments. A clear and coherent framework is needed to provide guidance to patients, physicians, and policy makers. Such guidance would also provide a timely basis for assessing the new value-based pricing system to be employed from 2014.

Summary of key questions

Patients and physicians

- If patients regard additional months as having greater value (how) should policies reflect this in resource allocation?
- How do life-extending treatments impact on patients' prospects for a good death?
- How are end-of-life treatments represented to patients and what impact does this representation have on their uptake?
- How can communication of the effects of life-extending drugs between patients, physicians and their families be improved at what is always a very difficult time?

NICE

- Should patients' own evaluations inform the values accorded to health states used for quality of life judgements?
- In what circumstances is it justified to provide hyper-expensive treatments, bearing in mind opportunity costs and the need to be fair to other patients?
- What are the opportunity costs of providing expensive treatment? Who will not get treatment due to the provision of hyper-expensive treatments?
- Should the size of a treatment group impact on whether a treatment is provided by health services?
- Does the rule of rescue play a part in decisions to increase funding for end-of-life treatments? Is this rule justified?
- On what basis, if any, is it justified to treat older people differently in resource allocation?
- In what circumstances is it morally justified and / or legal to recommend treatments for off-label indications?

Government

- What impact will the demographic change to ‘greyer’ societies have on the uptake of expensive life-extending technologies?
- Is the burden of hyper-expensive treatment tolerable for society? Is there a tipping point at which such treatments cannot be afforded?
- Are existing decision-making bodies, such as NICE and Clinical Commissioning Groups appropriate for decisions about end-of-life treatment?
- Should more research funding be channelled towards prevention, potentially at the expense of funding for interventions that prolong terminal diseases?
- Is it reasonable to fund research into interventions that modulate the ageing process rather than individual diseases associated with ageing?

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