Nuffield Council on Bioethics
Forward Look 2013
7th and 8th May

This paper provides summaries of the discussions and presentations at the recent Forward Look meetings, and identifies themes that emerged. Each note is a synthesis of the discussions and does not necessarily reflect the particular views held by individual attendees or the Council itself. Each note concludes with a list of questions and issues the Council may wish to consider in the future.

Scientific research integrity

Emerging themes from presentations and discussions

The problem: 'the ethics of scientific research'

1 The issue of 'scientific integrity' is part of a broader question of 'the ethics of scientific research', under which there are a number of sub-categories, including: research misconduct, fraud, and publication ethics. These issues are part of the same broad area but there are differences in the interests at play in each of them and in the ways that they may be addressed. The term 'research misconduct' is commonly used as a catch-all term for breaches of the ethics of the conduct of science (albeit with the understanding that it is a simplification), and is used in this way in this note.

Extent of misconduct

2 Scientific research is under more scrutiny now than ever before, yet evidence suggests there is more research misconduct than is popularly believed. The biomedical sciences receive considerably more scrutiny than other disciplines. This is likely to be a consequence of the sheer quantity of biomedical research undertaken, as well as the greater, and inherent, 'human interest' although there is no evidence to suggest that there are (proportionally) greater levels of misconduct in this field.

3 The difficulty of adequately defining and identifying research misconduct in all but the most blatant cases makes it difficult to respond to it appropriately. For example:

a) It can be difficult to differentiate between poor record-keeping and deliberate falsification of data.

b) There are often difficulties in determining what constitutes poor practice when working across disciplines: what is perfectly acceptable in one discipline can be outright misconduct in another. For example, the practice of 'salami publishing' the same or very similar data across multiple publications) is often accepted in the social sciences but not the natural sciences.

c) Assigning responsibility for a particular instance of misconduct can be problematic due to the structure of, and relationships within, the organisation responsible for producing the research. For example: is a data error the responsibility of the doctoral student who collated and recorded the data? Or does responsibility lie with the Principle Investigator? Or perhaps the institution within which the work is done should bear some responsibility for applying inappropriate pressure to its employees to produce positive results.

Harms

4 The potentially damaging effects of research misconduct, how it is reported and how it is dealt with are complex issues and should be approached as such. Yet, emphasis is too often inappropriately placed only on reporting and commenting on instances of 'extreme' research misconduct (such as that of Hwang Woo-suk the South Korean researcher at the centre of a controversial claim about human cloning during the mid-2000s). This focus on high-profile examples tends to exaggerate the impact of a few cases and draw attention away attention from less dramatic, but more numerous and pervasive, instances of 'low-level' misconduct – which are, if anything, more damaging to the scientific enterprise.

5 Quantifying the harms of scientific misconduct is difficult. There are some clear-cut instances: in the worst cases, there can be physical harm to research participants or even patients; 'salami publishing' has been shown to skew the results of meta-analyses; investigations into research misconduct are time-consuming and expensive and therefore represent significant opportunity costs; professional reputations can be unnecessarily damaged; and, funders can withdraw resources from promising research areas if controversy develops. Much of the harm is actually in the distortion of scientific record itself. Measuring this distortion is extremely difficult but the cumulative effect can certainly be understood as a harm in itself, if for no other reason than the retardation of scientific progress in important and beneficial areas.

Causes and motivations

6 There are many potential motivations for those who engage in research misconduct, most of which take the form of imbalances in the incentive structure that underlies scientific research and tensions between the priorities of different interested parties.

7 Perhaps the most important problem, certainly in the academic sector, is the nature of the system within which the scientific enterprise operates. That is to say, an increasingly professional, 'industrialised', and competitive global system. A number of factors have led to this industrialisation, but it is understood mainly to be a consequence of a (relatively) small number of individuals and groups competing for a finite and (contextually) small amount of resource, and the 'publish or perish' imperative felt by individual academics. (In the UK, the Research Excellence Framework can be understood as a manifestation of the kind of approach that causes such imperatives.)

8 This has led to claims that the current industrialised and 'market' economy for science inherently incentivises research misconduct; it is in the (narrowly defined) best interests of the participants to 'game' the system to obtain access to greater resources or other benefits. The problem is not the presence of competition itself, but the failure to modulate competition through effective correcting mechanisms that are more obviously desirable and (ideally) present in more transparently competitive market environments. For example, the nature of scientific expertise, and the consequent opacity of professional due diligence, creates a significant imbalance of knowledge between the consumer (the funder, the public etc.) and the supplier (scientists, institutions), that inhibits effective examination of the research output.

9 There are also strong conflicting priorities between the individuals and groups operating within the system, e.g. scientific authors, institutions, journal editors and publishers. All groups wish to produce 'good science' but there are tensions between the different understandings of 'good': (broadly) authors want to produce excellent academic work, improve their standing, acquire funding, and be promoted; institutions want to secure funding and attract high quality staff; journal editors want to publish good papers and improve the standing of their publication; and, publishers want to make money. These aims are not always compatible, even internally – if constant publication is understood as being necessary for career advancement, authors may need to produce more publications than their research warrants, or even 'stretch' research to increase their output. Publishers may exert pressure on editors to sell more copies and, given such pressure, editors may be less rigorous in checking the work submitted to them if its publication might enhance sales or reputation.

10 There are more personal and prosaic factors that can motivate people to engage in unethical research practices. Sometimes, it is simply the result of ignorance of the proper procedures and standards. For example, training is often lacking in areas such as publication ethics and much is learnt informally throughout one's career, rather than through formal training. For example, some early-career researchers may simply be unaware that 'salami publishing' can constitute unethical practice in their discipline. Alternatively, a researcher might simply become attached to a particular theory or method and be unable to accept it as incorrect, and therefore select results to fit that belief. Finally, some researchers simply see rules about research integrity as a barrier to their aims, be they personal or academic, and ignore them in order to obtain a result more conducive to their ambitions (yet, science progresses though challenges to orthodoxy, including the meaning and understanding of 'evidence').

Possible solutions

11 There are many potential solutions to the problem of unethical research practice, some general and some specific to the various sub-types. None is a panacea; unethical research practices will never be eliminated entirely but it can be reduced and its influence ameliorated.

12 Most countries respond to the issue with some form of professional self-regulation but some do use direct, external regulation of the field. The UK has a

reputation for limiting external regulation and relying primarily on self-regulation by researchers, with funders, employers and the learned societies playing significant roles. There have been some calls for statutory regulation in the UK but this view has limited support.

13 The effectiveness of regulation is, in any case, limited, for a number of reasons. Most solutions focus on 'classic' research misconduct such as data manipulation, falsification, plagiarism etc., despite the fact these are not the only problems at stake. Statutory regulation tends to over-burden researchers (extra administration etc.) while not being particularly effective at preventing unethical research practices – harsher regulation usually fails to act as a deterrent. Research Ethics Committees focus on a very narrow range of procedural issues and may miss the influence of incentive structures entirely. However, professional self-regulation is not as effective as is often assumed: studies are regularly remain un-replicated, peer review misses many errors, and codes of practice are often ignored.

14 Although rarely an official response, public shaming of researchers following a particularly high profile case is particularly ineffective as it can have the unintended effect of pushing people to cover up indiscretions and possibly stifling legitimate criticism for fear that it will spark a journalistic campaign against an individual researcher. This kind of journalistic attitude is exemplified by groups that seek to track and publicise retractions of scientific papers, an attitude that fails to take into account the fact that retractions are a basic part of the scientific enterprise and are not in themselves problematic. However, it does point to a developing tension between the hitherto 'closed' scientific discourse of costly and obscure journals, and the public sphere, which has different values, standards and norms of behaviour.

15 There are a number of possible improvements to be made to the systems in place to prevent unethical research practices. Primarily, incentive structures must be addressed: the different aims of the various actors within the system should be recognised as such and incentive structures differentiated accordingly. Furthermore, there should be a systematic, 'joined-up' approach to applying appropriate measures and changing attitudes. Possibilities include:

a) Adopting changes to attribution when publishing in order to limit the (perceived) necessity of salami slicing and the 'publish or perish' phenomenon. For example, micro-attribution systems and the use of new technologies such as ORCID.

b) Encouraging open-access publication to lessen the commercial influence on research publication;

c) Embracing a wider range of factors contributing to 'impact' beyond only the consideration of citations;

d) Encouraging training in the relevant areas, but not necessarily through formal means – the majority of professional practice is learned during one's working life, not during education; the place and importance of role models should be considered carefully; and

e) Changing self regulation methods, such as peer-review and data reporting, by adopting new practices such as ‘portable’ peer review, ‘open’ peer view and ‘post-publication’ peer-review.

f) Encouraging researchers to report data clearly when publishing and specifying the relevant data standards to which they have adhered.

Suitability as an area for consideration by the Nuffield Council on Bioethics

16 The main contribution the Council can make to this area is an examination of the ethical implications of the ‘cultural’ factors, including, for example, structuring of incentives for publication, patenting and for certain forms and fashions in research within the current structure of academic science, and possible measures to address these. Such an examination might also include consideration of:

a) Why the ‘culture of science’ is so often ignored despite its ideal form being so well known and understood (i.e. the interplay between the ideal of disinterested academic research and the culturally embedded reality). In so doing, the Council might also examine the changing nature of the scientific enterprise itself and whether the system itself can be altered so that integrity is ‘built in’;

b) The relationship between research and publication; and

c) How new technologies can enable more ethically appropriate research practices.

Aesthetic / cosmetic procedures

Themes from presentations and discussions

Extent of the UK aesthetic surgery industry

1 The UK aesthetic surgery industry is expanding rapidly. In 2005 turnover was £750 million; by 2010 it was £2.5 billion, with a projected turnover of £3.5 billion by 2015. The number of breast augmentations increased from 4,000 in 2004 to 10,000 in 2011.

Defining the ‘problem’

Risk of physical harm

2 The safety of surgical procedures is improved when surgeons perform regularly and frequently, but evidence from aesthetic surgery organisations suggests that some surgeons specialising in aesthetic techniques perform far fewer procedures per year than colleagues performing ‘conventional’ surgery. Of course, surgeons working in low-throughput, private aesthetic surgery clinics may also practise elsewhere, such as within the NHS. However, improved safety is also strongly associated with the frequency with which entire surgical teams train and perform

together, a factor that is difficult to record and is unlikely to be addressed by cross-sector surgical practising.

3 Many potentially dangerous aesthetic procedures can be legally performed with little or no training and are effectively unregulated. These procedures include 'Botox' injections, chemical peels, and dermal fillers and are extremely common. Because they are unregulated, output data is very limited.

Ethical problems

4 The primary ethical concern associated specifically with aesthetic procedures relates to the development and propagation of 'unhealthy' and damaging societal norms relating to 'body ideals'. Such norms can be construed as inherently problematic (psychological harm from unnecessary dissatisfaction with one's own body) and as a driver for accessing potentially physically dangerous procedures (the increase in the pursuit of invasive, medically unnecessary aesthetic surgery). Especially problematic is the inappropriate application of pressure to conform to these norms applied to potentially vulnerable and impressionable groups, such as young people and people with mental health problems (such as body dismorphic disorder and depression).

5 There is evidence to suggest that young girls tend to become increasingly unhappy with the way they look as they grow older. Evidence also suggests that this trend is becoming more prevalent over time: a Girl Guides' Attitude Survey shows more girls reporting feelings of unhappiness with the way they look than in previous years. However, unhappiness with one's body is not a feeling limited to young girls. Such unhappiness is found across ages, genders and socio-economic divides; societal idealization of bodily form is not exclusive to the youthful female physique, although it is probably more acute in this part of the population.

Evidence of harm

6 Despite these ethical concerns, there is a lack of evidence relating to harm (physical or psychological). This is particularly the case regarding long-term outcomes and is primarily a function of the many associated methodological problems in conducting long-term studies in this area (e.g. small sample sizes and very limited access to relevant data, which is mainly, and restrictively, held by private organisations). What is known is that in the short term, people often report satisfaction with the outcome of the procedure. However, there is a well known positive emotional bias relating to products or services on which considerable sums of money have been spent. Thus, short-term, self-reported outcomes should not be taken as a conclusive judgement of satisfaction.

Trivialisation

7 There is a tendency, particularly within the academic, medical and political elite, to trivialise aesthetic procedures and their effects because they are 'merely cosmetic' and thus a low priority. This is a flawed position: it ignores the common and often very serious psychological consequences and motivations for

individuals undergoing aesthetic procedures and also inhibits a proper examination of the nature of the trivialisation of aesthetic ideals. Such trivialisation makes it difficult to obtain funding for research into these areas and may contribute negatively to the psychological wellbeing of those who have undergone aesthetic procedures (i.e. where they are informed, explicitly or implicitly, that their psychological response is unimportant.)

Motivations

8 More is known about why people choose to have aesthetic procedures than about the outcomes of those procedures. Primary motivations appear to be a mix of (and interaction between) psychosocial and socioeconomic factors. For example, patients seeking elective aesthetic procedures sometimes misconstrue them as a simple 'fix' for what are actually complex psychosocial problems that require similarly complex responses (examples include failing relationships, low self-esteem, and poor body-image). Yet, there are difficulties in responding to people with 'problematic' desires for elective aesthetic procedures as, although psychological interventions can help, there are also sociological factors influencing these motivations that need to be addressed.

9 For example, it is arguable that social norms relating to body image are driven by upward comparisons with media-popularised ideals of appearance (literature, television, magazines, pornography etc.) These comparisons can negatively influence perceptions of abnormality and body ideals (e.g. aesthetic dissatisfaction with physiologically normal genitalia), especially considering that such ideals are in fact sometimes physically unachievable (e.g. digital manipulation of images).

10 However, decisions made concerning aesthetic procedures can, simply, be based on non-standard aesthetic norms: people may intentionally seek an 'artificial' physical appearance as a matter of preference. The outcome is not necessarily something that has gone 'wrong', or the decision a result of a body image disorder or other mental health problem. There is no 'true' and ideal physical form. Rather, there are many different aesthetic ideals that shift over time and within different sub-groups. The radical shift in the acceptability of tattoos and body-piercing over the course of the latter half of the 20th century can be understood as an example of this. (However, such forms of body modification are not and never have been part of an overall societal aesthetic and, as such, decisions to adhere to that aesthetic are not subject to society-wide pressure to conform in the same way as – for example – weight loss or breast enlargement procedures.)

Possible responses to problematic motivations

11 There are a number of possible policy responses that might attempt to combat the motivational factors described above:

a) Regulation: the more draconian the regulation, the greater the chance problematic procedures will be sought from unlicensed practitioners or abroad, where standards may differ. Statutory regulation will never fully

eliminate an unwanted procedure, and so other approaches may be favourable.

b) Psychological intervention prior to surgical consultation: if the motivation for an invasive aesthetic procedure is suspected to be based on a psychological problem, such as intense social anxiety due to dissatisfaction with perceived physical appearance, then the primary response should be the management of that anxiety, not the alteration of the person's appearance. Evidence suggests that certain interventions are effective (e.g. cognitive-behaviour therapy) and, ideally, a full assessment by multi-disciplinary team would take place prior to surgical consultation. If such assessment is provided too late in the process, there is a risk that the person seeking the aesthetic procedures might feel that they are simply being unnecessarily inhibited from getting what they want, rather than being involved in a professional and appropriate process.

c) Education: the inappropriate pressure to conform to particular body ideals should be countered by improved education. Possible approaches could include teaching children about body image perception and helping them to recognise over-sexualisation in the media.

Areas for future analysis

12 A number of important areas were identified as being in need of analysis or re-interpretation:

a) Some common questions should be re-interpreted:

I. Questions regarding motivations for accessing aesthetic procedures are more pertinently reformulated as 'why is access increasing?' rather than 'why do people access it?', the latter being a question which has to a large extent already been answered.

II. In determining the appropriate regulation of aesthetic procedures, it is better to ask 'should doctors perform the procedures?' rather than 'should people be allowed to access them?' The consent model for aesthetic procedures is reversed from that of conventional, medically necessary surgery as the patient directly requests a particular procedure, rather than seeks a remedy to a particular ailment.

b) The 'elite' paternalistic approach to norms of beauty: failing to adhere to elite norms is not intrinsically unethical.

c) The reasons underlying the development and propagation of societal expectations and body-ideals should be examined closely, as they are often overlooked when criticising the influence of (for example) the media in the application of inappropriate pressure to conform; media is reflexive and does not only apply top-down pressure.

d) Does regulation (not simply prohibition), provide tacit acceptance of aesthetic procedures generally? Similar issues arise, for example, in the field of 'alternative medicine'.

e) Are some aesthetic procedures so beyond the pale that they must be prohibited entirely? If so, why?

f) Most debate focuses on decisions that affect only the individual making the decision. However, decisions affecting third parties should also be addressed, such as a parent consenting to surgery to reduce the physical signs of Down's syndrome in their child.

Suitability as an area for consideration by the Nuffield Council on Bioethics

13 During the discussion, a number of themes were identified as being uniquely suited to consideration by the Nuffield Council on Bioethics:

a) The underlying ethical issues related to aesthetic procedures have not been well examined. The Council might explore the specific moral problems associated with aesthetic procedures: are they morally unique? Are they morally more problematic than other forms of body modification, such piercings or tattoos? What, if anything, ethically separates 'acceptable' aesthetic surgery (such as facial reconstruction following burns) from morally problematic procedures?

b) Motivations and the interaction between the individual and society: what is choice, what is undue and inappropriate societal pressure, and what is the result of a psychological pathology?

c) What are the relevant moral and legal rights and responsibilities and where do they lie: patient, professional and institution?

d) On what criteria should outcomes be assessed?

e) Triviality: why is the area of aesthetic surgery often considered to be of trivial importance? Can and should this be rectified?

f) To avoid going over well-trodden ethical ground (such as female genital mutilation and circumcision), the Council might focus specifically on individual decisions and the relevant procedures, rather than on decisions about procedures for others (i.e. children).

Expensive life extending treatments

Defining expensive life extending treatments

1. **Expensive treatments:** In the NHS the expensiveness of a treatment is generally considered in relation to its effectiveness. Cost-effectiveness assessments consider the value of the health benefits derived from a new therapy against the value of the benefits lost elsewhere. For example, it may ask whether the health benefits accrued by one person from an expensive treatment are disproportionate to the treatment benefits lost by another person in the healthcare system due to the cost of the first treatment. Based

on this type of calculation a treatment is relatively less "expensive" when its benefits are greater.

2. **Life extending treatments**: "Life extending" refers to a group of drugs or therapies that extend life expectancy in patients with a particularly short life expectancy. A significant number of these examples are found in relation to cancer, for example, the well known breast cancer drug Herceptin®. However, there are many other therapies that could be seen to extend life even if they are not "directly" life extending. For example, it could be argued that biologics used to treat rheumatoid arthritis reduce mortality associated with the disease and are therefore life extending.

3. The National Institute for Health and Care Excellence (NICE)[1] uses quality adjusted life years (QALYs) to assess the cost-effectiveness of treatments. The calculation used to work out a QALY takes into account the trade-off between length of life and quality of life. QALYs, as used by NICE, do not discriminate between different types of treatment or the age of the person being treated; the treatment only needs to be effective. NICE's working rule with regard to expensive treatments has been that drugs that cost more than £30,000 per QALY gained will generally be considered too expensive/not cost-effective enough to justify NHS provision.

Changes to NICE policy regarding life extending treatments

4. In 2009 some important changes were made to the way NICE assesses expensive drugs that are life extending. These changes followed the publication of a report written by the National Cancer Director, Professor Sir Mike Richards, for the Secretary of State for Health. The report, *Improving access to medicines for NHS patients,* was undertaken to examine policy relating to patients who chose to pay for drugs that were not available through the NHS. One of the report's findings was that stakeholders felt that drugs to treat patients in the last months or years of life should be regarded as having high priority. The report also recommended that NICE should assess what measures could be taken to make available drugs used at the end of life that did not meet cost-effectiveness criteria.

5. In response to this recommendation NICE developed a policy which meant that end of life (EOL) therapies would be given greater weighting (1.6) in the QALY calculation. The criteria for this additional weighting are that:

    - the patient group has a life expectancy of less than 24 months
    - the therapy extends life by more than three months

    Most of the NICE drugs that have been approved since this policy was introduced in 2009 have been treatments for cancer.

[1] NICE is responsible for assessing whether treatments are cost-effective in England and Wales and whether they should be funded by the NHS.

Opportunity costs

6. Since the introduction of the extra weighting for EOL treatments in 2009 the net effect on population health of paying for these drugs has been estimated at between 6,000 QALYs (if the NHS sets its QALYs at £30,000) and 15,100 QALYs (if they are set at £20,000).

7. It can be difficult to compare the opportunity cost to unidentified people with the benefits accrued by identified people who require access to expensive life extending treatments. For example, providing expensive treatments might mean less investment in building new hospitals, training doctors or higher thresholds for access to other drugs such as the biologics mentioned earlier for the treatment of rheumatoid arthritis.

8. Another concern is the possibility that NICE's EOL policy might lead to investments in very expensive life extending treatments (such as cancer drugs) rather than other life-enhancing treatments (such as deep brain stimulation), as the latter are less likely to be funded under these arrangements. It was suggested in discussion that any incentives for industry should be provided at the development stage and that the NHS should not be prepared to pay for less effective therapies.

How should we prioritise health care?

9. In a publicly funded healthcare system such as the NHS one of the most significant questions is how therapies should be rationed and on what basis you should give priority to some groups over other groups?

10. **End of life:** The current policy operated by NICE in relation to EOL therapies implies that more should be spent on preserving life when it is known that there is less of it. However, it was reported that recent research funded by NICE found that this is not necessarily the case. Some attendees at the meeting felt that a plausible case might be made for the beginning of life being prioritised over end of life.

11. It was reported that some research indicates that the significant priority for patients and families experiencing end of life scenarios was good palliative care including pain management and death at home. Another concern was that people should have sufficient time to "put their house in order", which might indicate that the suddenness of onset is also an important factor when deciding who should have access to life extending treatments. It was also suggested that there is a good argument for preparing people to stop expecting treatment earlier than they currently do.

12. **Rarity**: There was some discussion about whether the EOL treatment debate overlapped with the "rare disease" debate in that small patient groups are more easily identified than others patient groups; this identification can make

it more difficult to justify limiting how much should be spent on life extending treatments for them.[2]

13. Another point raised in relation to rarity was the possibility that as drugs for more common conditions become increasingly specialised/stratified, candidate populations for each one will become smaller. For example, a cancer drug that only treats specific forms of bowel cancer may lead to a particular form of bowel cancer being identified as "rare", even though bowel cancer is relatively common. If the treatments are cost-effective there is no clear reason why they would not be paid for by the NHS, which raises cost control issues.

14. Historically, rare (orphan) conditions have struggled to incentivise the development of therapies, in part due to small market size. However, there is a parallel problem relating to the difficulty of collecting data for small patient populations, which means that there is often an absence of robust cost-effectiveness data for orphan therapies.

15. **Age:** Although NICE does not include age in its QALY calculations there are arguments for factoring age into treatment costs. For example, should the QALYs gained by a 95 year old be worth the same as those gained by a 25 year old? The concept of "fair innings" has been proposed as relevant to how QALYs might be adjusted to reflect age.

Challenging the NHS

16. For healthcare rationing decisions to be considered fair they must be open to challenge. Patients who believe that they have been unfairly denied treatment can apply for judicial review. However, any such challenge must be based on the grounds that the decision-maker – likely to be a GP commissioner or NHS England– has acted illegally, irrationally or unfairly. It was reported that a challenge to the denial of treatment is much more likely to succeed if it addressed process rather than human rights. In most cases, judicial review has involved the claim that a patient's circumstances were exceptional, and that the commissioner's exceptionality review process was flawed. People have to be able to make the claim that their experience was exceptional. Almost all judicial review to date has involved expensive drugs.

17. It is possible to apply for judicial review of a decision on the grounds that it infringes rights under the Human Rights Act 1998. However, Article 2 (the right to life) does not give patients the right to be provided with any expensive life-prolonging treatment. Also, there is no right to receive treatment, although the Act provides grounds to challenge unfair treatment.

18. It was suggested that if expensive life extending treatments were not available through the NHS, they would still be available to those who were able to pay for them privately, leading to an inequitable healthcare system. It was also

[2] The Rule of Rescue can be a desire to help an identified person at all costs or an ethical imperative that we should do all we can to save an identified life which is in some way endangered.

suggested that if this were to happen, a market for specialist insurance policies would be likely to develop to cover hyper- expensive treatments. Such policies might be cheaper than full health insurance but they would still be unaffordable to the majority.

Questions to consider:

- Is the question really about end of life or are there other aspects of social value incorporated such as age, burden of illness and rarity?
- Why do we focus on extending life rather than improving quality of life?
- Is “life extension” sufficiently nuanced? Are there other important factors to consider other than therapies?
- Why may life extension for one group more valuable than another?
- How should policy decisions be informed?

Anti-ageing therapies

19. Biogerontology is a field that coves basic research into the ageing process. The ageing process is a complex, flexible and manipulable interaction of genetics, environmental, behavioural and social influences. Currently there are no safe anti-ageing medicines. However, researchers working in this area claim that it may be possible to achieve life extension by up to seven years in humans accompanied by reduced morbidity.

Biogerontology Research

20. Biogerontology research has had some success in extending life in smaller organisms such as yeast, fruit flies, nematodes and mice. Using a variety of methods including mutations, drugs and dietary restriction, researchers claim to have achieved varying degrees of success such as a 100 per cent lifespan increase in mice and a 10 fold lifespan increase in nematodes. The inference is that these findings could be replicated to some extent in humans.

21. Some biogerontology researchers argue that it is much more effective to address the ageing process through a “holistic” rather than disease focused approach. Possible methods of treatment will include drugs, genetic interventions and stem cells.

Potential ethical problems

22. Ethicists such as Leon Kass have claimed that the experience of ageing is an important aspect of living a full life, that physical ageing is imbued with “the meaning of finitude” and that there is an important “naturalness” to the life cycle. However, these may not be viewed as compelling reasons not to develop anti-ageing therapies.

23. Some of the other arguments for not developing anti-ageing therapies include various disruptive societal effects which relate to how these therapies might be used. For example, the risk of exacerbating issues relating to over population, increasing ageism through negative associations and the

polarisation of existing health inequalities due to access and affordability are all potential risks. The latter is particularly relevant as the majority of people are unlikely to have access to anti-ageing therapies, especially as they are would be highly personalised. However, there may be potential benefits related to demographic change, such as older people continuing to be active members of society for longer, due to reduced morbidity.

Questions

- Are the benefits of longevity brought about by such therapies likely to accrue?
- Which groups are likely to benefit from anti-ageing therapies?
- If there is a potential longevity dividend, how can it be achieved?

Discussion

24. **Palliative care**: It was suggested that QALYs should be applied to palliative care as well as life extending therapies. However, the challenge in assessing palliative care is that the views of the dying person are often missing or unexpressed. There was also some discussion about the usefulness of QALYs to assess the comparative cost-effectiveness of high-tech treatments versus good nursing and palliative care at the end of life.

25. **Assessing QALYs:** QALYs necessarily make trade-off decisions about rationing; they do this in quite a crude way in order to aid comparison. However QALYs may not work so well at the level of individuals rather than groups of patients. QALYs are used to make both economic and moral decisions about which person gets a drug.

26. **Price setting:** There was some discussion about the role of the pharmaceutical industry in setting prices and whether more needs to be done to challenge the very high costs of some drugs.

27. Value based pricing (VBP) will be introduced into the NHS in 2014. The intention is that there will be a negotiation with the pharmaceutical industry about what the price of a drug should be based on what the "value" is considered to be. However, there are difficult questions that need to be answered such as "what is value?" At the moment the decision to pay for a drug is largely based on cost-effectiveness but VBP may introduce other "value" based considerations such as age, rarity and quality. NICE will be responsible for the full value assessment of medicines once VBP is introduced and it will have to reassess how they are going to make these valuations.

28. **Framing:** Some concern was expressed that direct and indirect lobbying from industry and charities puts organisations such as NICE under pressure and makes it difficult for them to regulate effectively. When issues such as end of life are framed by certain groups of people with a specific agenda, such as patient lobbyists, it can narrow the discussion, a trend that is likely to continue as drugs are increasingly targeted at specific groups.

29. **Empirical data needed:** It was suggested that there needs to be more evidence to support policy decisions about EOL treatments and that empirical evidence should inform decision making about who/what should be sacrificed. Most people are willing to sacrifice some quality for quantity but the important question is about how these might be traded off against each other.

Cross-border care

Introduction

Emerging themes from presentations and discussions

Data and evidence limitations

1 There are limitations in the evidence and data currently available regarding the extent of cross border treatment. For example, although instruments such as the International Passenger Survey[3] suggest that the rate of medical tourism in the UK is rising, and that both large numbers of people from outside the UK and also UK citizens themselves 'cross borders' to receive various sorts of health care, there are limitations to this method of recording people's purposes in travelling (for example, passengers submitting responses which are incomplete). Similarly, the 2007 European Commission (Eurobarometer) survey which obtained information about the number of European citizens who travelled to other Member States for medical treatment, did not ask questions about the types of treatment they received (for example, whether the treatments were emergencies, or elective procedures). Nor did it distinguish between treatments that were self-funded, publicly-funded, or funded by insurance companies.[4]

2 Despite limitations in the data available, completed surveys do offer a partial picture of patients who cross borders. For example, a Freedom of Information (FOI) request to 28 NHS Foundation Trusts elicited data from 18 of those Trusts on the financial benefits received as a result of incoming medical tourists. These 18 trusts reported a combined income of £42 million, with Great Ormond Street Hospital reporting the largest income (£20 million). Within the Trusts who were able to answer the FOI request, this indicates significant profit: while only six per cent of private patients were inbound medical tourists, their care generated 35 per cent of total private income. However, the fact that these data are incomplete suggests that some, or indeed most, UK hospitals may have a limited idea of how to address treatment of overseas patients in a strategic way.

3 There is also evidence from polls regarding attitudes to cross border treatment, with one poll finding that 32 per cent of respondents felt that the expansion of the

[3] Office for National Statistics (2013) *International Passenger Survey (IPS) methodology*, available at: http://www.ons.gov.uk/ons/guide-method/method-quality/specific/travel-and-transport-methodology/international-passenger-survey/index.html.

[4] European Commission (2007) *Cross-border health services in the EU: analytical report* (Brussels: European Commission). The survey found that three per cent of UK citizens had treatment in the EU during the previous 12 months.

NHS into global contexts will benefit UK patients.[5] The European Commission survey also found that 54 per cent of UK residents were willing to travel abroad for treatment. However, there remain clear gaps in data, such as more precise information on the number of patients who travel between countries (and indeed which countries); for what specific purpose they travel; what motivates or encourages them to travel; their experiences of quality and safety; the development of industry in cross-border care contexts; and economic considerations.

Motivations to travel

4 It is important to understand *why* people travel abroad for medical treatment in order to identify how best to approach treatments undertaken abroad from a policy perspective. The European Commission report identified a number of motivators underpinning decisions to travel abroad for treatment, including faster treatment, cheaper treatment, better quality treatment, treatments from specialists, and treatments that are unavailable in their home nation. One example of people travelling for faster treatment is the 2001 NHS pilot project where UK patients travelled to Belgium, France and Germany for more immediate ophthalmic and orthopaedic treatment.[6]

5 In the context of motivating factors, the language used to describe those who travel abroad for treatment should be used sensitively: in particular it was suggested that travelling abroad for treatments such as bariatric surgery for weight loss, or for cosmetic procedures, may not necessarily perceived as a choice (rather as the only option), and hence it is not appropriate to regard these as 'elective' procedures. Patients may also choose to travel to a country with which they have a former connection (for example, they may have lived there in the past, or may have family members who live there).

6 Despite a range of motivating factors, it may be argued that it is likely to remain the case that only a small proportion of the UK's patient population will travel abroad for treatment, given that many people prefer to receive health care and treatment near their homes, where their families and friends may care for them following treatment.

Finance

7 A further motivational factor for patients who travel abroad for treatment may be financial. Financial motivations may be personal (e.g. patients who self-fund treatment abroad), or public (e.g. where patients are sent abroad by health agencies using cross-national purchasing agreements, for example in order to meet waiting list targets).

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5 68 per cent of respondents answered 'no' to the question: "Will expansion of the NHS abroad benefit UK patients?" In total, 438 votes were cast. See: BMJ (2013) *Poll archive*, available at: http://www.bmj.com/about-bmj/poll-archive.

6 York Health Economics Consortium (2002) *Evaluation of treating patients overseas: final report* (York: University of York).

8 Patients who self-fund may do so because of high treatment costs in their home nation. For example, some people may wish to have a cosmetic procedure which is not ordinarily available through the NHS. Similarly, dental treatments which may only be available privately in the UK may be cheaper in other countries. Other treatments, however, may be available through the NHS, but only to a limited extent, such as IVF and bariatric surgery. Patients may also be incentivised to travel abroad for treatment, with some providers of cosmetic procedures offering buy-one-get-one-free 'deals'. However, it must not be assumed that cost is the only factor in motivating patients to travel abroad for treatment. For example, for patients who seek to access fertility treatment abroad, cost may be a part of their motivation, but other factors such as the availability of egg and sperm donors may also be relevant.

9 The potential need for continuing care where UK patients travel abroad for treatment may also raise financial issues at a broader public level. For example, in cases where continuing care is needed following treatment abroad, a question may be raised as to whether the NHS has a duty to provide this care, especially where it would not have sanctioned the initial treatment. If, on the other hand, a duty to provide the initial treatment is found to exist, then issues of reimbursement of the patient's costs clearly arise. This type of payment issue arose in a recent case where a patient travelled to France for a hip replacement operation in order to avoid the long waiting list present at her primary care trust (PCT). Following the operation, a case was brought against the PCT's commissioner, arguing that the PCT had a duty to pay for her care. In its judgment, the European Court of Justice held that the right to obtain care elsewhere in the EU at NHS expense was only available if the treatment was 'normal' in the sense that it had been sufficiently tried and tested by international medical science, and could not be provided in the home country without "undue delay."[7] The involvement of the courts in decisions about payment for treatment may highlight a symptom of a bigger problem in public health care systems; namely that, in introducing market principles, concepts of solidarity may be undermined.

Exploitation

10 Exploitation may be relevant to three different contexts (see also the section on 'equity' below). The first concerns potential exploitation of the health systems of home nations by overseas visitors not entitled to access NHS care (as opposed, for example, to patients from abroad explicitly seeking private care, as discussed in paragraph 12 above); the second concerns the potential exploitation of third parties; and the third concerns the potential exploitation of patients themselves. Each of these forms of exploitation may clearly interact with the others.

11 On the first concern Jeremy Hunt, the Secretary of State for Health, was recently reported to have stated that "anyone with a 'questionable' residency status should be issued with only a temporary NHS number. It would mean that if they tried to access anything other than accident and emergency departments, they

[7] Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health [2003] EWHC 2228 (Admin).

would be charged." These claims were made as part of an article titled "*How I'll weed out the health tourists, by Hunt*."[8] However, data in this area are limited, and therefore concerns that those who travel from outside the UK may 'fleece' the NHS need to be tempered until there is solid evidence to support it. Such claims that visitors may exploit the NHS sit against a backdrop of a UK system that has generous rules for people who can receive treatment through the NHS, namely that any person who is "ordinarily resident in the UK" (i.e. people who come to the UK on a sporadic basis for employment, etc.) may receive treatment free of charge. Such a system contrasts with insurance-based systems.

12 The second context in which exploitation may arise is where patients travel abroad for treatment that involves donations from third parties; for example, egg donors or organ donors. In the case of egg donors, women may travel to countries such as Spain to receive treatment, but egg donors themselves are likely to be from Eastern European countries. Again, however, monitoring the countries from which women who donate eggs come from is very difficult as there is no central European register for egg donors, or indeed sperm donors.

13 The third context may recognise that patients themselves may be exploited particularly given the lack of international measures of safety that might make comparisons in treatment and care possible. An example in crossborder fertility treatment is found in anecdotal accounts of women travelling to Greece for IVF treatment and having seven embryos implanted.[9] Patients may also come from a diverse spectrum of income and education, and therefore be vulnerable to exploitation in a variety of ways.

Scientific and 'testing' tourism: risks and safety

14 Patients may choose, or be encouraged, to access treatments in other countries that would not be otherwise available in their home nation. For example, in a UK context, such treatments may not have received NICE approval, or may still be at early stages of research (for example, some stem cell treatments). Such restrictions may encourage patients to travel to regimes where regulation is less strict, particular with respect to the claims made about new research. Individual patients will also often not be in a position to access information about poor safety records in particular clinics. In addition, issues may arise when reading and obtaining patients' notes as it may be logistically difficult to transfer files between health practices in different countries.

15 Circumstances may also arise where patients make use of treatment services abroad, but without travelling (or indeed, without knowing that they are, in fact, subject to services in countries other than their home nation). Specifically, these situations will be where a patient's test samples are sent abroad for analysis. An example of this policy can be seen in the Irish Department of Health's decision to

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8 MailOnline (19 April 2013) *How I'll weed out the health tourists, by Hunt: Minister acts after Mail highlights abuse of NHS*, available at: http://www.dailymail.co.uk/news/article-2311350/Jeremy-Hunt-How-Ill-weed-health-tourists.html.

9 See also: Lawlor DA and Nelson SM (2012) Effect of age on decisions about the numbers of embryos to transfer in assisted conception: a prospective study *The Lancet* **379(9815)**: 521-7.

send smear tests abroad for analysis to reduce waiting times.[10] This underlines the fact that remote services, as well as treatments, can take place abroad.

Inter-country skills and qualifications

16 Where particular treatments are increasingly sought abroad, there is a potential risk that expertise may be lost in specific areas of medicine; similarly if patients are discouraged from having a certain treatment in a certain geographical area (for example by routine referrals abroad), that area will then receive fewer patients who need that treatment. This clearly leads to the potential for unsafe services owing to lack of expertise, or local services becoming non-viable because of too few patients. However, while some countries may lose expertise, other countries may gain it – especially those which have a so-called 'booming' market in certain specialised treatments.

17 As well as expertise which may be gained or lost within countries' borders, the significance of harmonised qualifications and registrations should also be underlined, as well as the importance of patient knowledge when choosing to travel abroad for treatment. For example, when physicians operating in non-UK contexts advertise themselves as 'GMC-registered', patients may not always know what this means in practice. A further issue concerns patient safety. For example, patients may access treatment in clinics which have poor safety records which are not in the public domain. In addition, issues may arise when reading and obtaining patients' notes as it may be logistically difficult to transfer files between health practices in different countries.

Equity

18 The issue of equity, or 'fairness', may be relevant in several contexts – both positive and negative – of cross-border treatments.

19 The argument may be made that medical tourism offers poorer countries the chance to encourage doctors, who might otherwise move away from their home nation, to stay and practice medicine rather than move to practices in higher income countries. An example of this phenomenon can be seen in Tunisia, where medical tourism reportedly yields the second highest amount of foreign currency, and is the second largest employer in the country.[11] In contrast, however, it could be argued that the success of medical tourism in middle-income countries may 'crowd out' domestic patients and the treatments and services on offer to them. For example, in Thailand, where medical tourism generates a value added approximately equal to 0.4 per cent of the GDP,[12] it has been reported that the concentration of doctors in the public sector has fallen, with many moving to the private sector. However, it may be argued that the shortage of quantitative

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10 Independent.ie (6 June 2007) *Outsourcing health still sending smear tests abroad*, available at: http://www.independent.ie/irish-news/outsourcing-health-still-sending-smear-tests-abroad-26295578.html.

11 Africa News (7 April 2009) *Healthcare tourism in Tunisia*, available at: http://www.africanews.com/site/Healthcare_tourism_in_Tunisia/list_messages/24185.

12 World Health Organization (2011) *The effects of medical tourism: Thailand's experience*, available at: http://www.who.int/bulletin/volumes/89/5/09-072249/en/.

evidence means that the wider impact on fair systems within countries remains unknown. It was also suggested that we currently have a poor understanding of the role of the private sector in the provision of health care and in business practices in low income counties.

20 Within a UK context, it might be noted that the NHS has recently been encouraged to become more entrepreneurial, and to gather income from private sources. However, such revenue gathering is subject to strong reporting requirements, namely that if trusts take advantage of opportunities, those activities must benefit NHS patients.

21 The issue of the care of the UK's ex-pat communities may also raise concerns in relation to equity. For example, those who live as ex-pats in Spain and Greece may be UK citizens, but they may not necessarily be eligible for NHS care (eligibility being based on ordinary place of residence). Moreover, UK residents who travel abroad for treatment may potentially feel that they are treated inequitably if they are refused follow-up care once they return to the UK. Questions arise as to what the duties of a solidarity-based NHS might be in these circumstances, and whether, for example, it should provide adequate information about potential pitfalls of travelling abroad for treatment.

Public/private distinctions

22 A private health contract gives a person a right to expect what is promised by the terms of the contract. However, the NHS does not promise this type of substantive right; instead, its focus is on *procedural* rights, as specified by the NHS Constitution (i.e. to have access to a system that works, and is a 'good' system).

23 It was suggested that in Germany, by contrast, a two-tier health insurance system operates where every citizen pays a flat rate for basic health insurance and is guaranteed access to particular services, but may also be required to make additional payments if he or she requires treatments that sit outside the basic insurance scheme.

Future questions

24 Based on the outcomes of the discussions and themes summarised in this document, a number of questions arise which may be of relevance for the Council's future work. These include:

- How might the lack of data detailing the number of people who cross borders for treatment, and their motivation(s) for doing so be tackled?
- Should the UK's NHS profit – or aim to profit – from treatments undertaken on patients from non-UK countries?
- What duties arise for the UK in protecting both UK citizens travelling abroad for treatment, and those who donate bodily material to them (for example, eggs or organs)?

- Does the introduction of market principles impact on solidarity in healthcare in an invidious way? (For example, when comparing developed and developing countries)
- Should safeguards be in place where patients may be encouraged to travel abroad for experimental, or untested, treatments?