

Can religious treatment choices justify additional healthcare expenditure and, if so, are there limits to this?

Abstract

Access to healthcare is generally regarded as a supportive right to the right to life. Freedom to hold a religious belief and to practice that religion is also held to be a right. The practicing of a religion includes the freedom to live in accordance with the tenets of that religion, but this may entail refusing certain healthcare treatments. Where such a refusal leads to a lower share of healthcare resources being consumed, there is no adverse impact on other people who might also require a share of those healthcare resources. However, where that refusal leads to a more expensive treatment being requested in place of the proscribed treatment, Individual Funding Request (IFR) Panels within the NHS have to decide how to balance individual rights with the fair allocation of resources.

This paper considers religious perspectives on healthcare treatments and whether, in respecting these, additional expenditure can be justified. Included within this assessment is a case with extreme characteristics that helps to illustrate the type of problem that such cases present.

The solution proposed is built upon Quality Adjusted Life Years (QALYs) as a tool for assessing the cost-effectiveness of treatments and introduces the concepts of 'individualised QALYs' and 'personalised QALYs', concepts that potentially have much wider applications in individual treatment funding decisions than those for which religious treatment preferences have significance. The use of personalised QALYs allows limits to be set on the acceptable costs of religiously-preferred treatments. These proposals are then tested from a variety of perspectives, including considering the legal implications, to demonstrate that they could be practically applied by IFR Panels in decision making in these difficult and sensitive cases.

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Introduction

This paper is written in the context of the UK National Health Service (NHS). The NHS is a state-funded system with finite resources. It cannot, therefore, provide all treatments that may be desired by all patients. In order to ensure that the limited resources are spent most effectively, the Department of Health determines how to direct resources to different health programmes and the National Institute for Health and Clinical Excellence (NICE) determines which specific treatments should be funded.

The NHS specifically prohibits individual 'top-ups' to pay for treatment; patients may choose to pay for private treatment outside the NHS, but they cannot, within the NHS system, pay a premium for treatments that meet their personal requirements. Patients who wish the NHS to provide treatment that is not routinely offered must make an Individual Funding Request (IFR). There are two main scenarios in which this applies: some conditions are deemed to have an insufficiently-high clinical priority, such as cosmetic conditions and no treatments are routinely provided for these; and some treatments are not provided even for conditions that do have sufficient clinical priority if the treatment cost is too high compared to the clinical benefit, such as drugs that may extend life by a few weeks at exceptionally high cost. In both types of case, one of the key considerations is the cost of treatment compared to the benefit and, in assessing this, the cost per Quality Adjusted Life Year (QALY) is the dominant tool.

IFR decisions are made by Primary Care Trusts (PCTs), generally via panels of clinical, non-clinical (and sometimes lay) members established for this purpose. At the time of writing, Primary Care Trusts will cease to exist in less than a year and their functions will be taken over by Clinical Commissioning Groups (CCGs). Whatever the local NHS structures, IFR decisions within the NHS have always been taken at local level and this is likely to continue.

However, no particular ethical decision-making framework is mandated for IFR Panels and the relevant legal judgements are, in some aspects, unclear.

Some patients hold religious views that mean that certain treatments are not acceptable. If a patient wishes to access a more expensive, religiously-acceptable treatment he or she will have to make an individual funding request to their local PCT. This paper was stimulated by such a case: the patient argued that his religious beliefs prevented the standard treatment being acceptable and instead wanted a treatment to be funded that would otherwise be far beyond what a QALY-based cost-effectiveness assessment would support.

The NHS is guided by the seven key principles in the NHS Constitution, including,

1. The NHS provides a comprehensive service, available to all irrespective of gender, race, disability, age, sexual orientation, religion or belief. It has a duty to each and every individual that it serves and must respect their human rights. At the same time, it has a wider social duty to promote equality through the services it provides and to pay particular attention to groups or sections of society where improvements in health and life expectancy are not keeping pace with the rest of the population.

4. NHS services must reflect the needs and preferences of patients, their families and their carers. Patients, with their families and carers, where appropriate, will be involved in and consulted on all decisions about their care and treatment.

6. The NHS is committed to providing best value for taxpayers' money and the most effective, fair and sustainable use of finite resources. Public funds for healthcare will be devoted solely to the benefit of the people that the NHS serves.¹

In the case of an expensive religiously-motivated treatment request, a number of these principles might be seen to conflict: a service available to all irrespective of religion; respecting human rights; reflecting the preferences of patients; being involved in treatment decisions; providing best value for money; and providing the most effective and fair use of finite resources.

¹ NHS, 'The NHS Constitution', updated March 2012, p.5.

<<http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/nhs-constitution-interactive-version-march-2012.pdf>> Accessed 22 September 2012.

In this paper I explore the issues relevant to the subject of religiously-motivated IFRs and then set out my proposed solution to the decision-making problems that such cases create. I then test this against potential ethical, legal and practical objections to see whether it can really offer a practical solution to help IFR Panels make the difficult decisions demanded of them in these highly sensitive cases.

Religious tolerance in the NHS

The NHS is generally understanding of religious and cultural differences, making positive attempts to make its services meet the preferences of patients rather than adopting the stance that the NHS will dictate what is provided and how it is provided, take it or leave it.

Hospital chaplaincy services accommodate spiritual needs of many faiths¹, but this is just the tip of the iceberg. There is lots of guidance within the NHS to help staff and services meet the religious preferences of patients in terms of, for example, drug treatments, personal care, and diet. This is largely taken for granted within the NHS: staff accept that patients' religious beliefs are important and should be accommodated, both as a matter of individual, non-discriminatory respect and also to help to ensure that people of all faiths can access health services and are not disadvantaged as a group or as individuals. The guidance created for hospitals or by hospitals² helps staff to meet religious preferences, without reference to cost.

However, in providing services and treatments that are compatible with religious preferences, the NHS unquestioningly diverts some of the common healthcare resource to patients with religious faith. This is accepted practice, but sometimes cases arise that cannot merely be accepted because their financial impact is so great.

¹ Department of Health, *NHS Chaplaincy – Meeting the religious and spiritual needs of patients and staff* <http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4073111.pdf> Accessed 22 September 2012.

² e.g. St George's Healthcare NHS Trust, *Transfusion Alternatives for Jehovah's Witnesses* <<http://www.stgeorges.nhs.uk/docs/patient/JehovahsPatInfoBooklet.pdf>> Accessed 22 September 2012.

The case of Joe, the extreme scenario

The case that stimulated this paper has been adapted to preserve patient anonymity. The patient, whom I shall call Joe, is a 40 year old male with evident capacity to make informed decisions about his medical treatment. Joe suffers from the condition ‘paroxysmal nocturnal haemoglobinuria’ (PNH) which is a rare, potentially life-threatening haematological disease (with an incidence of 1-2 cases per million population). The only curative treatment for this condition is stem cell transplant, but this is associated with high rates of mortality for patients with PNH¹. Amongst the other treatments that are used to control various aspects of the condition are regular blood transfusions. In 2007 the United States Food and Drug Administration and the European Medicines Agency approved a new drug, eculizumab as treatment for the condition, the first treatment of its kind to be made available². One consequence of the use of this drug is a reduction in the need for blood transfusions. However, the drug is very expensive, costing approximately £240,000 per year³ and, as the drug does not cure the condition, it has to be taken year-on-year to maintain its effect.

Joe is a Jehovah’s Witness and, in accordance with his religious beliefs, refuses blood transfusions. This affects his quality of life and the severity of the symptoms that result from PNH. Joe requested funding from his local PCT for eculizumab on the basis that this new drug offered the possibility of treatment for PNH for him as one of the few people with this condition, but also that, as a Jehovah’s Witness it would be particularly advantageous for him as he could not accept blood transfusions and so his symptoms were significantly worse than a comparable PNH patient who could accept blood transfusions.

The question for the PCT was therefore twofold, should it fund the drug anyway (given its very high cost) and should the religious objections of Joe to blood transfusions have any

¹ Robert A. Brodsky, ‘Stem Cell Transplantation for Paroxysmal Nocturnal Hemoglobinuria’, *Haematologica*, 95 (2010) pp.855-856.

² NHS National Electronic Library for Medicines, ‘Eculizumab for paroxysmal nocturnal haemoglobinuria’, 14 April 2008
<<http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Drug-Specific-Reviews/Eculizumab-for-paroxysmal-nocturnal-haemoglobinuria/>> Accessed 22 September 2012.

³ *ibid.*

bearing on this decision? It is this latter question that I will consider in a wider context – to what extent can the religious beliefs of a patient justify a disproportionately high share of healthcare resources?

This particular case is an extreme one for two reasons. Firstly, the drug in question is at the extreme end of the scale of treatment cost. It has been described as, ‘the world’s most expensive drug’¹, not only because of its cost per treatment, but because it would potentially be continued for life at £240,000 per year. Secondly, the position of Jehovah’s Witnesses in relation to certain blood transfusions is absolute. Many other religions allow normally-prohibited treatments to be accepted in certain, limited circumstances, but Jehovah’s Witnesses will refuse blood transfusions even if the consequence of this refusal is likely (or certain) to be death.²

An IFR Panel would not wish to make a decision to refuse funding for treatment without sound justification, but similarly cannot simply approve funding, particularly at such a high cost, without considering the impact on the healthcare budget available to support other patients’ treatments. The convergence of the issues of religion and resource use that are starkly illustrated in this case also has relevance for more moderate cases where religious considerations lead to a demand for additional healthcare resource use.

Therefore, even though accepted practice is that the NHS takes religious preferences into account without questioning the cost, when a case demands that cost is taken into account the NHS suddenly finds itself without clear guidance to help in decision-making. This calls into question how such decisions should be made, but also challenges the presumption that NHS resources should be used to accommodate other religious preferences.

¹ Matthew Herper, ‘The World’s Most Expensive Drugs’, *Forbes Magazine*, 22 February 2010
<http://www.forbes.com/2010/02/19/expensive-drugs-cost-business-healthcare-rare-diseases_print.html> Accessed 22 September 2012.

² Watchtower Bible and Tract Society of Pennsylvania, *What Does the Bible Really Teach?* (New York: Watchtower Bible and Tract Society of New York, 2012) pp.126-133.
<<http://wol.jw.org/en/wol/d/r1/lp-e/1102005143?q=blood+transfusion&p=par>> Accessed 22 September 2012

Religious perspectives on medical treatments

I need to firstly identify some of the religious perspectives on treatment options. I am not going to attempt a comprehensive review of the teachings of various religions on medical treatments as this would require a substantial book in its own right. Therefore, this is simply an overview which includes some of the key issues that may face the NHS in making treatment decisions and which also includes examples that highlight some of the particular ethical dilemmas that will be considered later.

I would argue that religious faiths and religious beliefs are distinct from choices. If a religious belief was simply a choice this would entail the ability to simply choose not to have that belief (people's religious beliefs do sometimes change over time, but that process of change is not as simply as choosing a different belief). A religious faith, genuinely held, should be regarded as a fundamental part of a person's identity and this may entail particular beliefs about whether particular treatments are unacceptable – are wrong or sinful.

The Jehovah's Witnesses' refusal to accept blood transfusions is a well-known instance of a religiously-proscribed treatment option,

Does the command to abstain from blood include blood transfusions? Yes. To illustrate: Suppose a doctor were to tell you to abstain from alcoholic beverages. Would that simply mean that you should not drink alcohol but that you could have it injected into your veins? Of course not! Likewise, abstaining from blood means not taking it into our bodies at all. So the command to abstain from blood means that we would not allow anyone to transfuse blood into our veins.¹

Blood transfusions are acceptable in other Christian churches, but that does not mean that their acceptability has simply not been considered,² and within many other religions such as Judaism and Sikhism³. Within Islam, there is a prohibition on the use of blood except in

¹ *ibid.*

² Thomas J. O'Donnell, *Medicine and Christian Morality* (Staten Island NY: Alba House, 1996), p.87.

³ Queensland Government, *Sikh Beliefs Affecting Healthcare*, 2011, p.16.

<http://www.health.qld.gov.au/multicultural/health_workers/hbook-sikh.asp> Accessed 22 September 2012.

situations of dire necessity, “Islamic jurisprudence categorizes any form of blood that flows out of the body as *najas* (impure)”.¹

A patient may also refuse to accept treatment if it involves medicines that have a religiously-unacceptable origin, such as for Hindus, a drug that is derived from animal products or more specifically from cows (because they are sacred) or pigs (because they are unclean).² Similarly a Jewish or Muslim patient may refuse drugs derived from pig products. There are also many other restrictions within Judaism relating to treatment on the Sabbath, such as a ban on consumption of medicines and restrictions on treatments for wounds.³

Many religions have specific teachings in relation to abortion, although these may vary considerably between different branches of a religious faith, such as is the case within Islam⁴, and those without a religious faith may also have equally strong views on abortion.

There are also a range of religious perspectives on end of life care, but it is probably reasonable to summarise these by noting that the general ‘religious’ view is that the patient should be allowed to die peacefully without excessive striving to prolong life. In this, the religious requirement is framed as a more general principle rather than a clear rule about a specific treatment. This principle is reflected in a number of studies on the relationship between religion and treatment options in relation to end of life care. Some studies have focused on how well people cope with terminal illness, how they rate their quality of life or the extent to which their treatment options are affected by their religiosity.⁵ Many consider how religious patients differ from non-religious patients in general – treatment choices may be religiously influenced, but that is not the same as a specifically religiously-endorsed or

¹ Abu F.M. Ebrahim, *Organ Transplantation, Euthanasia, Cloning and Animal Experimentation – An Islamic View* (Leicester: The Islamic Foundation, 2001), p.30.

² Queensland Government, *Hindu Beliefs Affecting Healthcare*, 2011
<http://www.health.qld.gov.au/multicultural/health_workers/hbook-hindu.asp> Accessed 22 September 2012.

³ Sir Immanuel Jakobovits, *Jewish Medical Ethics: A Comparative and Historical Study of the Jewish Religion's Attitude to Medicine and its Practice*, (New York: Bloch, 1975), pp.74-75.

⁴ Donna Bowen, *Contemporary Muslim Ethics of Abortion*, in Brockopp, Jonathan E., ed., *Islamic Ethics of Life* (Columbia: University of South Carolina Press, 2003), pp.51-52.

⁵ Tracy A Balboni, et al, ‘Religiousness and Spiritual Support Among Advanced Cancer Patients and Associations With End-of-Life Treatment Preferences and Quality of Life’, *Journal of Clinical Oncology*, 25 (2007), pp.555-560.

religiously-forbidden treatment choice. The religiously-influenced treatment choices may include choice of treatment location (home, care home or hospice), additional non-medical treatments (e.g. aromatherapy) or attitudes to prolongation of treatment (e.g. tube feeding, IV fluids, medical ventilation).¹ Many studies have found little differences between religious and non-religious patients, apart from different attitudes to the prolongation of life.²

One of the more common medical procedures with a religious significance is circumcision. However, when done for religious rather than therapeutic reasons, I do not regard this as a healthcare treatment. Religious circumcision is only apparently within the scope of religiously-motivated treatment because it is performed by a surgeon, but no illness is treated and the procedure is performed for religious rather than health reasons. For this reason, most PCTs within the NHS do not fund circumcision for non-clinical reasons and a PCT could justify a refusal to approve an IFR on this basis.³

Where, from a particular religious perspective, any of the above treatment options are generally believed to be wrong, this does not mean that they are always unacceptable in practice.

How flexible are religious rules in relation to treatment?

We may accept that religious faith should be regarded as stronger than a choice and fundamental to a person's identity, but still regard some individual behaviours or religious practices as equivalent to choices – particularly in cases where the formal position within that religion is to regard the behaviour or practice as a matter of conscience or choice rather than an absolute obligation. For example, in Islam, the practice of *salat*, praying 5 times per day, is obligatory, but *where* this takes place is a matter of choice even though it is regarded as better to pray in a mosque. In Roman Catholicism sins may be mortal or venial and venial

¹ O. Heeren et al, 'Religion and end of life treatment preferences among geriatric patients', *International Journal of Geriatric Psychiatry*, 16 (2001), pp. 203-208.

² Shane Sharp, Deborah Carr and Cameron Macdonald, 'Religion and End-of-Life Treatment Preferences: Assessing the Effects of Religious Denomination and Beliefs', *Social Forces*, 91 (2012), pp.275-298.

³ NHS Choices, 'Circumcision' <<http://www.nhs.uk/Conditions/Circumcision/Pages/Introduction.aspx>> Accessed 22 September 2012.

sins, although they should be avoided, are less serious than mortal sins; that is not to say that it is entirely acceptable to choose to commit a venial sin, but it is also not entirely forbidden to do so. Similarly, in relation to religious views of medical treatments, some treatment options may be generally forbidden but be permissible in certain circumstances, others may always be prohibited. Most religions allow normal prohibitions to be set to one side in cases of dire necessity or to save a human life (including the patient's own life).

Within Islam, medicines containing pig-derived products may be consumed if there is no alternative:

It is permissible to seek treatment with what is forbidden in case of dire necessity. What proves this is the general evidence about the permissibility for a person to consume what is forbidden in case of dire necessity. Allaah Says (what means): '...while He has explained in detail to you what He has forbidden you, excepting that to which you are compelled.' [Quran 6:119]

The above verse and other verses are evidence about the permissibility of consuming what is forbidden when in dire necessity, provided there are no permissible medicines that can serve instead of this. In addition to this, a trustworthy doctor should inform you that this medicine is useful for that kind of disease, and that there is no other permissible alternative.¹

Similarly, the Islamic prohibition on the use of blood may be set to one side in cases of dire necessity or to secure recovery even though it is generally thought better to avoid blood transfusions.²

Within Judaism similar considerations apply. The principle of *pikuach nefesh* in Jewish law requires that the usual obligations to comply with almost any religious law are overridden if a human life is in danger and this, '...applies to both an immediate threat and a less grave danger that has the potential of becoming serious'.³ The principle of *pikuach nefesh* goes

¹ Islamweb, 'Fatwa No:106469, Taking a Medicine Derived from Pig Material', 31 March 2008
<<http://www.islamweb.net/emainpage/index.php?page=showfatwa&Option=Fatwald&Id=106469>>
Accessed 22 September 2012.

² Abu F.M. Ebrahim, *Organ Transplantation, Euthanasia, Cloning and Animal Experimentation – An Islamic View* (Leicester: The Islamic Foundation, 2001), p.37.

³ Ariel Scheib, 'Pikuach Nefesh', *Jewish Virtual Library*
<http://www.jewishvirtuallibrary.org/jsource/Judaism/pikuach_nefesh.html> Accessed 22 September 2012.

even further in effectively forbidding compliance with normal laws when a human life is at risk,

...there is, therefore, absolutely no virtue in observing laws at the risk of life. Such conduct, rather, is branded as both sinful and foolish...According to many authorities, a seriously sick person who refuses a cure because it would involve a breach of the law should be forced to submit to it, since such a refusal amounts to a 'piety of madness'.¹

In contrast, the Jehovah's Witness will refuse transfusion treatment even if such a refusal leads to loss of life. The position is stated as follows:

What if a Christian is badly injured or is in need of major surgery? Suppose doctors say that he must have a blood transfusion or he will die. Of course, the Christian would not want to die. In an effort to preserve God's precious gift of life, he would accept other kinds of treatment that do not involve the misuse of blood. Hence, he would seek such medical attention if that is available and would accept a variety of alternatives to blood.

Would a Christian break God's law just to stay alive a little longer in this system of things? Jesus said: 'Whoever wants to save his soul [or, life] will lose it; but whoever loses his soul for my sake will find it.' (Matthew 16:25) We do not want to die. But if we tried to save our present life by breaking God's law, we would be in danger of losing everlasting life. We are wise, then, to put our trust in the rightness of God's law, with full confidence that if we die from any cause, our Life-Giver will remember us in the resurrection and restore to us the precious gift of life.—John 5:28, 29; Hebrews 11:6.²

This is considerably more rigid than the positions within Islam or Judaism. Not only is there no dire necessity or *pikuach nefesh* exemption, but the consequence of breaching the prohibition is of maximum severity, to be placed, 'in danger of losing everlasting life'.

Despite the range of religious rules and beliefs in relation to medical treatments, these do not apparently present us with particular ethical challenges in most cases as a respect for patient autonomy determines that we should respect people's beliefs and their informed

¹ Sir Immanuel Jakobovits, *Jewish Medical Ethics: A Comparative and Historical Study of the Jewish Religion's Attitude to Medicine and its Practice*, (New York: Bloch, 1975), p.52.

² Watchtower Bible and Tract Society of Pennsylvania, *What Does the Bible Really Teach?* (New York: Watchtower Bible and Tract Society of New York, 2012) pp.126-133.
<<http://wol.jw.org/en/wol/d/r1/lp-e/1102005143?q=blood+transfusion&p=par>> Accessed 22 September 2012.

treatment choices. However, wider ethical issues are raised when treatment choices that are driven by religious beliefs have an impact on the use of healthcare resources.

Religiously-motivated treatment choices and resource implications

Treatment decisions are effectively individual resource-allocation decisions – at the point that a treatment plan is confirmed there is a concomitant commitment of resources – but such decisions are usually made without specific reference to cost or cost-effectiveness at that time. There are a number of scenarios within which religious beliefs influence a patient's willingness to accept a particular treatment and these do have resource implications.

In some cases the patient may refuse treatment that might otherwise be provided and therefore reduce his/her consumption of shared healthcare resources. Examples noted above include a refusal to accept blood transfusions or a refusal to accept medicines with a religiously-unacceptable origin.

However, to refuse a treatment is not the same as to refuse all treatments; and often the refusal to accept a religiously-unacceptable treatment is accompanied by a request for an alternative, religiously-acceptable treatment. Given that the NHS attempts to deliver the most clinically-effective treatment for the cost, the standard treatment is likely to be amongst the most cost-effective (the cost-effectiveness ratio of clinical effectiveness to cost is discussed in some detail later). Therefore, where a religiously-acceptable alternative to the standard treatment is requested, it is likely that this will be less clinically-effective or more expensive – in either case, the cost-effectiveness is likely to be reduced. A treatment for a condition that would usually involve a drug that is derived from religiously-unacceptable sources may be refused and another, religiously-acceptable drug be requested at additional cost. An alternative to transfusion may be requested, either by the use of intra-operative autologous blood transfusion, the administration of drugs that reduce the need for blood transfusion or via different operating techniques that are more expensive,

but which minimise blood loss.¹ These alternatives to blood transfusion generally involve additional cost.

There are scenarios within which the religious considerations might either result in additional resources being consumed or in fewer resources being consumed. These will include situations that involve a decision to switch off a life support machine. There may be a wide range of religious positions in such scenarios, from an acceptance that using 'extraordinary' rather than 'ordinary' means to sustain life is wrong² and that therefore the patient should be allowed to die peacefully, through to a refusal to allow life-sustaining machines to be turned-off even for patients in a persistent vegetative state, potentially resulting in enormous costs.³ In such emotionally-charged circumstances, it may sometimes be unclear whether the position taken really is religiously-motivated. It may be that in some cases the position taken by a relative of the patient is equally motivated by emotional distress. These cases also have the added complication that there will probably be a relative rather than the patient himself or herself involved in the treatment decision and it may be the relative's rather than the patient's religious views that are being considered. This is also a problem for decision-makers in cases where the parents of a sick child have strong religious views about the treatment for their child. I will not discuss these cases here as the issues raised about parental responsibility, and dependant patient capacity and autonomy are beyond the scope of the issues that I am addressing. However, it should be the case that the considerations in this paper that apply to decision-making in relation to individual patients may help in cases where the focus is the treatment of a dependant.

Where a patient refuses treatment for religious reasons and the consumption of healthcare resources by that patient is reduced, a greater share of resources is then available for other people. These others will include those who share the patient's religious views and would support the decision and those of other religious faiths or no faith whose views may

¹ St George's Healthcare NHS Trust, *Transfusion Alternatives for Jehovah's Witnesses* <<http://www.stgeorges.nhs.uk/docs/patient/JehovahsPatInfoBooklet.pdf>> Accessed 22 September 2012.

² Thomas J. O'Donnell, *Medicine and Christian Morality* (Staten Island NY: Alba House, 1996), pp.49-79.

³ Over \$800,000 in the case of Helga Wanglie, cited in Julian Savulescu, 'Desire-Based and Value-Based Normative Reasons', *Bioethics*, 13 (1999), pp.405-413.

coincide or differ from those of the patient. Whatever their views, there can be no objection from these others that their opportunity to benefit from these shared resources has been reduced.

However, where a more expensive treatment is desired for religious reasons than would be provided to others in similar clinical circumstances an agreement to that funding request will adversely affect others' opportunity to benefit from the shared resources. We must therefore decide whether to commit the additional resources to these treatments or to refuse to offer a religiously-acceptable treatment option.

It should be noted that as new treatments are developed, different religious objections may gain greater significance. Until recombinant human insulin analogues were developed, insulin was derived from animal sources, usually pigs or cows.¹ This was deemed acceptable to Muslims and Jews under dire necessity or *pikuach nefesh* principles² as without insulin the diabetic patient would die. Once non-animal insulin was made available there was a religiously-acceptable alternative, but it was more expensive and so would have required a willingness within the healthcare system to meet the additional cost. Since then, recombinant human insulin analogues have become cheaper and have largely taken over from animal-derived insulin, so generally there is no longer a religious objection to the standard treatment. Currently, the majority of drugs of porcine origin (or that use porcine gelatine as an excipient) are not much cheaper than the non-porcine alternatives, so the religiously-acceptable alternatives are freely prescribed when requested.³ Therefore, the scenario where an IFR for a non-porcine drug might be made and not granted on cost-effectiveness grounds would be relatively unusual in 2012. One exception that is foreseeable in the next few years is the use of porcine collagen as a surgical mesh. This is currently an expensive option and so the religiously-acceptable alternative would not

¹ A. Teuscher, *Insulin – A Voice for Choice* (Basel: Karger, 2007), pp. 10-13.

² From this point onwards I will use the term 'dire necessity' to encompass Islamic dire necessity, Jewish *pikuach nefesh* and all similar principles unless a specific distinction needs to be drawn.

³ G. Mynors, et al, *Drugs of Porcine Origin and Clinical Alternatives*

<<http://www.keele.ac.uk/pharmacy/npcplus/medicinespartnershipprogramme/medicinespartnershipprogrammepublications/drugsofporcineoriginandclinicalalternatives/drugs-of-porcine-origin.pdf>>

Accessed 22 September 2012.

require additional funding. However, range of operations in which this is used is increasing and the cost is reducing, so there may come a time when this is deemed to offer better cost-effectiveness than the alternatives in specific surgical circumstances.

Nevertheless, that does not make these considerations so unusual that PCTs can regard these scenarios as merely theoretical. New drugs are always being developed and with increased use of genetic modification it is possible that a new porcine drug might come onto the market at any time. Furthermore, stem cells are often proclaimed to be the next 'big thing' in clinical technologies and these will bring religious controversies with them. Some religious patients may find these acceptable, based on their religions' teachings about the age at which an embryo is regarded as a human life, but it is likely that there would be objections from others.

PCTs need frameworks for decision-making that are based on sound principles and which can be used in range of religious treatment scenarios. A framework that served solely to support decision-making in relation to alternatives to blood transfusions for Jehovah's Witnesses might address the most financially-significant IFR scenario that has a religious dimension today, but it might not be fit for the treatments of tomorrow. It would also be unacceptable and would be greeted with scepticism if PCTs adopted or amended their decision-making frameworks for treatments with religious significance only once presented with those new treatments. The framework in this paper is designed to be effective in all such scenarios and to give consistency across a range of religions and treatments.

A religious justification for consuming additional healthcare resources is a particular challenge in a predominantly secular society where the majority of people entitled to access the shared resources will not share the religious views of the patient in question. It will be argued that every 'health pound' could and should be used to get maximum health benefit and that we should have equal access to the benefits that those health pounds can purchase.

In the majority of cases, such as drugs derived from non-porcine products, the religiously-acceptable treatment option is likely to have a relatively small additional cost and the

impact on others' opportunity to benefit will be immaterial (although, as will be discussed later, some would find even this to be questionable or unacceptable). However, there are cases, such as the case of Joe where the religiously-acceptable treatment with 'the world's most expensive drug' is at the extreme end of treatment costs, where to accede to the religiously-motivated request would give that patient a disproportionately high share of resources with a detrimental impact on the resources available to others. If Joe uses £240,000 every year he will have gained access to money that could have been spent on others and will have done so for reasons that do not apply to others. In other words, he has gained special access to a shared resource because of his religious beliefs and this special access seems unfair.

We are not all entitled to an equal share of healthcare resources – we do not each have a virtual account with the NHS which is credited with a sum at birth, allowing us to spend against it throughout our lives while we remain in credit, but giving us some difficult budgeting choices to ensure that we don't use it all up too soon. This would itself be unjust as I might be blessed with good health and have quite a lot of credit in my account to use on minor ailments or to keep to one side in case of future need; whereas another person might, through no fault of their own, suffer from a condition requiring expensive treatment and find that their virtual account was going to be inadequate. Joe is in this category – he is unfortunate enough to have a condition that gives significant need for treatment resources. Even if he had had a virtual account with few withdrawals in his younger years due to the health benefits of his religious lifestyle (as discussed in the following paragraph), once he developed PNH he would soon have become overdrawn. Instead of having a virtual account, we are all entitled to expect that the NHS will meet our needs – whether these are small or large and we should expect that our rights of access to such resources are equal. According to Aristotle's 'formal principle of equality' on which many conceptions of justice are built, '...equals should be treated equally, and unequals treated unequally in proportion to the relevant inequalities'. If our health needs are unequal we should expect unequal access to resources proportionate to our unequal needs, but if our health needs are equal, we should expect equal access. Yet the religious patient wants special, unequal access.

In response, many religious people might object to the use of shared healthcare resources for services that they would not accept, such as abortion services. They would argue that those with no religious beliefs or with different beliefs are consuming a disproportionate share of resources that reduces the resources available for everyone for other treatments.¹ Alternatively, the religious patient might argue that religions have a positive net impact on the health of the population and therefore on the healthcare resources available to all – via promotion of abstinence from harmful activities such as excessive alcohol consumption; via social support programmes; and in the form of institutions with religious connections, such as many hospices. Furthermore, as well as these institutional contributions to reducing healthcare resource consumption for the benefit of all, there is evidence that individuals with a religious faith have better physical and mental health and increased longevity.² The religious individual may reasonably argue that their faith and the institution that they support results in them taking a lower share of resources than others and that this should be set against their occasional requests for additional expenditure.

However, we can't make IFR decisions on the basis of the characteristics of the group to which the patient belongs. That would, by definition, be discriminatory. A PCT will have to decide for an individual patient whether their religious views should have an influence on a treatment funding decision and this will be a decision about that individual that will not be determined by those wider 'religious group' considerations.

Religious beliefs and IFR Panels

In IFR decisions, one of the key principles is objectivity. It is partly for this reason that multi-member panels are used rather than lone individuals making these decisions. In being objective, the panel should be able to ensure that decisions are consistent and that the natural human sympathy for an individual patient in need does not inevitably lead to

¹ Supporters of the use of healthcare resources for abortion could argue that the provision of abortion services reduces the healthcare costs related to obstetric services. In response, it could be argued that this would mean that all healthcare treatments that prolong life and so increase subsequent healthcare costs should be avoided. Whether a foetus qualifies as 'someone' would be the next stage of this argument, which I shall not pursue here.

² Joseph T. Young, *Disease, Social Causation*, in Ritzer, George, ed., *Blackwell Encyclopedia of Sociology* (Oxford: Blackwell Publishing, 2007).

treatments being approved that consume a disproportionate share of resources, disadvantaging other patients (and potential patients) that are 'invisible' at the point of that decision. However, there is a risk in the adoption of a position of apparent objectivity that the panel members may not sufficiently empathise with the personal beliefs of the patient concerned. The panel members will bring with them their own set of values and will attempt to ensure that these do not distort their decisions, but in attempting to be 'objective' they may fail to fully appreciate the impact that a decision may have on the patient, given that patient's values and beliefs.

In a largely secular society, the significance of faith to a person of faith may be underestimated by people without strong (or any) religious convictions. This is likely to be more marked when dealing with unfamiliar or minority religious beliefs. Jehovah's Witnesses do not represent a particularly large religion in the UK, with approximately 130,000 members.¹ Although they regard themselves as Christian, in some countries they are regarded as a non-Christian sect and in others they have been persecuted. They are also commonly regarded unsympathetically whether in relation to their views (such as predictions of Armageddon or the prohibition on blood transfusions) or practices (such as refusing military service and door-to-door preaching).² My view is that people would be more personally sympathetic to a Jewish patient wanting to avoid porcine products in medicines than they would to a Jehovah's Witness wishing to avoid blood transfusions. Whether this would be due to Jehovah's Witnesses being regarded as more of a 'fringe' religion, due to disagreements with their scriptural interpretations, or because a refusal to accept a blood transfusion appears more extreme is hard to judge.

However, lack of sympathy with the religious beliefs of a patient should not lead to a dismissing of those beliefs. A Jehovah's Witness who believes firmly that to accept a blood transfusion is a sin that will lead to the loss of eternal life will clearly be gravely concerned

¹ BBC, 'Jehovah's Witnesses at a Glance', 2009
<<http://www.bbc.co.uk/religion/religions/witnesses/ataglance/glance.shtml>> Accessed 22 September 2012.

² Allan S. Evans, Riley E. Moynes and Larry Martinello, *What man Believes: A Study of the World's Great Faiths* (Whitby, Ontario: McGraw-Hill Ryerson, 1973), p.361.

by such treatment. This is evidenced by the Jehovah's Witnesses who refuse potentially life-saving treatments and would prefer to die than to accept a blood transfusion.

This degree of commitment is unlike the majority of objections to treatment options of people with non-religious beliefs or values that we might commonly encounter. In secular terms, there are vegetarians and vegans who will refuse some animal-based medicines, there may be others who will generally avoid any conventional medicines as it is a requirement that they are tested on animals. Some of these people may refuse treatment even if such treatment would be urgent and life-saving or even if the life of their child was at risk, but such extreme responses are probably unusual. I have certainly never encountered them in my experience of IFR cases.

At this point, having explored the issues, the question arises as to whether there is any reason that the secular majority should take notice of these religious beliefs? The answer, it seems to me, is that morally they should.

Religious beliefs, treatment preferences, rights and justice

Beauchamp and Childress', 'four principles of biomedical ethics'¹ have attained the status of a cornerstone of medical ethics. These principles are as follows:

1. Respect for autonomy – a patient has the right to choose (or refuse) their treatment in an informed way.
2. Beneficence – to act in the patient's best interest.
3. Non-maleficence – effectively, 'first, do no harm'.
4. Justice – the fair distribution of health resources.

The need for four principles illustrates the inadequacy of using a single principle for decision-making, hence the accepted ethical and legal position that a PCT must make decisions based on all relevant factors taken together². Clearly, respecting religious views

¹ Thomas L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 4th edn (New York: Oxford University Press, 1994).

² Daphne Austin, *Priority Setting: managing individual funding requests*, NHS Confederation, 2008
<<http://www.nhsconfed.org/publications/prioritysetting/Pages/Prioritysetting.aspx>> Accessed 22 September 2012.

of treatment is consistent with the principle of autonomy and, depending how widely we define 'best interest' and 'harm', is consistent with the principles of beneficence and non-maleficence. The key principle that may be challenged is that of justice,

Justice refers to the fair, equitable, and appropriate treatment in light of what is due or owed to persons. Distributive justice refers to fair, equitable, and appropriate distribution in society determined by justified norms that structure the terms of social cooperation.¹

In order to answer the question of whether it is just to direct additional healthcare resources to address religious treatment preferences, I will look at how this might be answered by John Rawls given the central position of his works, 'A Theory of Justice'² and 'Justice as Fairness: A Restatement'³ in modern political philosophy. John Rawls' 'original position' thought experiment asks what principles of justice one would establish from behind a 'veil of ignorance' that prevents the parties knowing anything about their particular characteristics: ethnicity, wealth, social status, abilities, personality and so on. He concludes that each person should have equal rights to basic liberties,

...political liberty...together with freedom of speech and assembly; liberty of conscience and freedom of thought; freedom of the person along with the right to hold (personal) property; and freedom from arbitrary arrest and seizure as defined by the concept of the rule of law.⁴

He also concludes that society should be structured to ensure equal opportunities and to allow inequalities as long as they benefit the most disadvantaged in society (on the condition that this does not conflict with the other principles).

The provision of healthcare supports citizens' equality of opportunity and allows them to use their other rights and freedoms. For this reason, Rawls regards, 'a basic level of healthcare provided for all' as one of the, 'three main institutions of a property owning democracy'.⁵ Although having a religious faith would be a basic liberty (liberty of conscience and freedom of thought), it is not a basic liberty to have one's religious requirements supported by common resources.

¹ Thomas L. Beauchamp and James F. Childress, p.327.

² John Rawls, *A Theory of Justice*, original edn (Cambridge MA: Harvard University Press, 1971).

³ John Rawls, *Justice as Fairness: A Restatement* (Cambridge MA: Harvard University Press, 2001).

⁴ John Rawls, *A Theory of Justice*, p.61.

⁵ John Rawls, *Justice as Fairness: A Restatement*, p.176.

Although Rawls uses the veil of ignorance to establish basic rules of justice rather than to test specific scenarios, it is a useful way to consider what influence we would wish our possible religious views to have on the distribution of healthcare resources. If I might hold a religious belief that would lead me to prefer death to accepting a treatment that could save my life, I would surely want this to be taken into account. What would be the point of a just allocation of life-preserving healthcare resources if my beliefs would lead me to prefer death than to access such resources? If there were other, non-religious factors that were similarly important, it would also be just to take these into account. One would not be prepared to take the risk that one might hold such religious beliefs and be unable to access religiously-acceptable treatment and so be faced with death as the alternative. Rawls takes the view that, 'if the parties assume that their basic liberties can be effectively exercised, they will not exchange a lesser liberty for an improvement in economic well-being'.¹ Even libertarian critics of Rawls (such as Robert Nozick²) who regard Rawls' views from behind the veil of ignorance as too risk averse, might support taking such an absolute religious preference into account rather than gamble that one might not hold such beliefs and so could benefit from a marginally larger share of resources as a result.³ One would not be prepared to risk being poor and unable to afford the additional treatment cost if the consequence would be death. This position makes no assumptions about the nature of the specific religious beliefs. I am assuming a theoretical consensus that a belief worth dying for should be respected, not a specific exposition of what that belief might be. However, there are some arguments within, 'Justice as Fairness: A Restatement' that might be interpreted as challenging this position and these merit further attention.

In 'Justice as Fairness: A Restatement', Rawls states,

...we view democratic citizens not only as free and equal but as reasonable and rational, all having an equal share in the corporate political power of society, and all equally subject to the burdens of judgement. There is, therefore, no reason why any

¹ *ibid.* pp. 151-152.

² Robert Nozick, *Anarchy, State and Utopia* (New York: Basic Books, 1974).

³ I regard this as a reasonable assumption of the libertarian position on the basis that a religious faith is not a choice. If it was equivalent to a choice then the libertarian view would be that the religious person should expect no support from others in the pursuit of his/her personal choices.

citizen, or association of citizens, should have the right to use the state's power to favor a comprehensive doctrine, or to impose its implications on the rest (p.191)

This could be interpreted as prohibiting the distribution of common goods to support an absolute religious preference as this would involve indirectly 'imposing the implications on the rest'. Conversely, the secular majority do not have the right to impose secular implications on a religious minority – instead a consensus is required. However, beyond the basic liberties, Rawls concludes that social and economic goods can be unequally distributed if this benefits the disadvantaged in society. We could regard the Jehovah's Witness as disadvantaged by his/her beliefs as without these beliefs a standard treatment could be accepted and it would therefore be just to allow the unequal distribution of goods in his/her favour to support the religiously-acceptable treatment. I do not wish to imply that the faith of a Jehovah's Witness or any religious person should be regarded as an impairment in a wider sense – this is merely a disadvantage in the narrow context of being unable to accept particular healthcare treatments.

This is supported later in the same section,

Any such authority [that attempts to impose its doctrine on others] is therefore without reason, contrary to person's fundamental interests in developing and exercising their moral powers and in pursuing their particular (permissible) conceptions of the good. Reasonable comprehensive doctrines recognise this fact and with it that all have an equal liberty of conscience (p.192)

Here, it is not just that the holding of a belief is a basic liberty, but also that the 'pursuing [of] their particular (permissible) conceptions of the good' is a 'fundamental interest'. However, we should be clear that the just distribution of common goods is secondary to basic liberties and at some point too much resource going to support a particular religious practice would contravene this. Rawls takes the position that justice is served by each person having, 'an equal right to the most extensive basic liberty compatible with a similar liberty for others'¹ which can be contrasted with a libertarian view that justice is served by more minimal rights, such as merely to hold resources justly or to justly acquire them². A libertarian might argue that a religious patient cannot therefore call on the resources of others to support his/her particular beliefs, perhaps with the exception of where death is

¹ John Rawls, *A Theory of Justice*, original edn (Cambridge MA: Harvard University Press, 1971), p.60.

² Robert Nozick, *Anarchy, State and Utopia* (New York: Basic Books, 1974), pp.150-153.

the alternative. Certainly, where only minimal rights are to be regarded as just, one would argue that from behind a veil of ignorance I would not choose that less absolute religious preferences would be taken into account. If these were taken into account, fewer resources would remain for everyone else, so I might decide to 'take my chance' and accept that I would have to sacrifice some other goods in order to make a personal contribution to top-up what the state provides for me to enable me to be provided with healthcare compatible with my religious beliefs. Would I wish to give everyone the right to choose a particular life-saving treatment according to mere religious preferences? – probably not. I might forgo the right to have what I would prefer and accept the treatment if such acceptance amounted to (merely) a venial sin (or equivalent). Would I wish to give everyone the right to choose a particular life-enhancing (rather than life-saving) treatment according to absolute religious rules? – probably not. I might forgo the right to the improvement in my condition and reject the treatment to allow me to live according to my beliefs.

Therefore, even if it was agreed by both liberals and libertarians that we should support a religious belief that requires preferring death to accepting a religiously-incompatible treatment, a) the extension of that support to less absolute religious requirements might be challenged; and b) the amount of additional support that would be acceptable would surely have some limit. Rawls requires that a consensus is reached from behind the veil of ignorance, but it is difficult to see how this could be achieved for points 'a' and 'b'. The NHS is, in its essence, more liberal/Rawlsian than libertarian/'Nozickian' and so it might be consistent to adopt a liberal position and endorse 'a' – to support non-absolute religious requirements from shared resources, but even limiting our philosophical approaches in this way still does not give us a solution to 'b' – the limits of this support.

We face a similar difficulty if we consider accepted modern statements of rights. Having a religious faith and living according to its rules is widely accepted as a right. Article 18 of the United Nations' Universal Declaration of Human Rights¹ states,

¹ United Nations, *United Nations Universal Declaration on Human Rights*
<<http://www.un.org/en/documents/udhr/>> Accessed 22 September 2012.

Everyone has the right to freedom of thought, conscience and religion; this right includes freedom to change his religion or belief, and freedom, either alone or in community with others and in public or private, to manifest his religion or belief in teaching, practice, worship and observance.

This goes beyond the holding of a religious faith, to a right to practical 'observance' which I interpret as including living by the rules of the religion, including in treatment choices.

Article 29 (2) then states,

In the exercise of his rights and freedoms, everyone shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society.

One might take the view that the religious adherent should take notice of others' rights to healthcare resources and not limit those rights by the exercising of his or her own right to religious freedom. Taking Article 18 and Article 29 (2) together, we are again faced with the incomplete position that religious views should be respected but with resource limitations that are unclear.

My conclusion, at this point, is that,

1. Religious objections that are absolute (in that death would be preferred to contravening the rules) should be respected and supported by an unequal allocation of shared resources.
2. There should be limits to this or others' rights to life or basic liberties might be compromised.
3. Religious objections that are not absolute (in that they may be overcome in some circumstances, such as dire necessity) should be respected.
4. These have a lesser claim on shared resources and so lower limits should apply.

The challenge is therefore to establish these limits. To do this, I need to consider how the principles of distributive justice are enacted within the NHS to see whether these can be extended to address religious objections to treatment options.

QALYs and resource allocation

The just allocation of resources within the NHS, when formally considered, is determined by the use of Quality Adjusted Life Years (QALYs). These may be criticised, but this paper is focused on 'real world' decision-making and the 'real world' for the NHS is that QALYs are accepted. However, they do not obviously lend themselves to the consideration of religious treatment options. In order to address whether and how QALYs can be used in relation to treatment options with religious implications, I firstly need to consider the concept of QALYs in more detail and then extend QALYs beyond their conventional uses.

The concept of the QALY is explained as follows,

The essence of the QALY is that it takes a year of healthy life expectancy to be worth 1, but regards a year of unhealthy life expectancy as worth less than 1. Its precise value is lower the worse the quality of life of the unhealthy person.¹

QALYs are one way of determining how healthcare resources should be spent to ensure that those limited resources give maximum health benefit. There are three potential ways that QALYs are used in resource allocation:

1. To determine which treatment to give to a particular patient or how to share resources between individual patients (micro allocation).
2. To determine which group of patients to treat or which conditions to give priority in terms of funding (macro allocation).
3. To determine which treatment to use to treat a particular condition. Depending on one's perspective this is sometimes described as a form of micro allocation and sometimes as a form of macro allocation. I regard it as a form of macro allocation because it operates at a population level rather than an individual level and because it is so closely linked to the other forms of macro allocation (we can less easily determine which group of patients to treat or which conditions to give priority to unless we know which treatment we are proposing to use).

¹ Alan Williams, 'The Value of QALYs', *Health and Social Service Journal*, 95 (1985), p.3-15 (p.3).

The majority of the *practical applications* of QALYs in resource allocation relate to macro allocation. In the UK the Department of Health determines that funding should be targeted at those conditions (such as coronary heart disease or cancer) that will have the maximum impact on the health of the population and the National Institute of Health and Clinical Excellence (NICE) assesses the costs and benefits of specific treatments and recommends or mandates their use in the NHS. However, many of the *criticisms* of QALYs relate to their use in micro resource allocation, apparently valuing one human life above another.

In the NHS in the UK, QALYs have become a fundamental part of macro resource allocation. The incremental cost per QALY is a key consideration for NICE, with a 'willingness to pay' threshold of £30,000 per QALY¹, that is, the additional amount of money that it is worth spending to produce an additional Quality Adjusted Life Year. In addition, in cases where NICE is yet to pronounce, local Drugs and Therapeutics Committees will use QALY data (where they are available) to produce local policies in relation to the funding of new treatments.

When comparing the cost effectiveness of different independent programmes of healthcare, a simple Cost Effectiveness Ratio (CER) is calculated for each programme and the programmes are ranked accordingly. However, when considering different treatments for the same condition, the Incremental Cost Effectiveness Ratio (ICER) is used: this calculates the additional QALY benefits gained per unit of cost comparing one treatment with another. The least effective intervention is initially given a CER compared to 'no treatment' and then the incremental gain or loss of the alternative treatments are calculated compared to this base CER. Treatments that give less benefit per unit of cost are excluded until the most effective treatment per unit of cost is identified.² ICERs are preferred to CERs because if we simply used CERs we might approve a treatment because it was within a given 'cost per QALY' threshold even though a cheaper and more effective treatment was available. The preference for the use of ICERs rather than simple CERs will be of significance later in this paper.

¹ Rudolf Klein and Jo Maybin, *Thinking about Rationing* (London: The Kings Fund, 2012).

² Ceri Phillips and Guy Thompson, *What is Cost Effectiveness?*, Hayward Medical Communications, 2009
<<http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/Cost-effect.pdf>> Accessed 22 September 2012.

The status of QALYs in the NHS is not shared in all healthcare systems. In the USA, the Patient Protection and Affordable Care Act (PPACA) (more commonly known as 'Obamacare') aims to significantly extend health insurance coverage to create a 'safety net' healthcare funding system that, for the economically disadvantaged, is closer to the NHS than the pre-PPACA system in the USA. This Act also established the Patient Centered Outcomes Research Institute (PCORI) to review research and provide information to Medicare about which treatments are effective. Although this sounds similar to the role of NICE in the UK in relation to the NHS, the PPACA explicitly prohibits PCORI from using QALY-type cost-effectiveness assessments, stating that PCORI,

...shall not develop or employ a dollars per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs.¹

The extent to which this prohibition is ethically, economically, religiously or politically motivated may be debated, but this does illustrate that QALYs have a degree of acceptance in the UK that is not the case elsewhere.

I should probably state at this point that, in my view, some consideration of the relative cost effectiveness of different treatments at a macro level is an essential part of a state healthcare system. QALYs are subject to a number of ethical criticisms, and one criticism in particular will be discussed in the next section, but whatever the imperfections of QALYs as a tool for resource allocation decisions, I believe that some such tool is required. Whatever our discomfort about using numerical calculations to determine whether it is 'worth' treating people and saving lives, the alternative approaches that are apparently less cold, such as medical tradition, the judgement of doctors or health technology industry pressure have even less to recommend them.

¹ United States Government, *Patient Protection and Affordable Care Act*, 2010, Section 1182e. <<http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>> Accessed 22 September 2012.

In contrast to macro resource allocation decisions which are largely the preserve of the Department of Health or NICE, micro resource allocation decisions are primarily made by PCT IFR Panels in considering whether a treatment that is not routinely offered should be approved for an individual patient. These Panels suffer from inadequate national guidance and inconsistent legal judgements about how such decisions should be made (this is considered later) and there is significant inconsistency between PCTs.

A Department of Health survey of PCTs conducted in 2008 estimated from its responses that some 26,000 applications for exceptional funding had been received by PCTs in the previous year, on average 177 requests per PCT, though there was significant variation between areas (from one PCT receiving just one request to another receiving 1,017 applications) (Richards 2008). On average, nearly two-thirds of requests for cancer treatments (64 per cent) and three-quarters of requests for non-cancer treatments (74 per cent) were approved, but agreements to fund such requests also varied widely, from one PCT not granting any approvals to six PCTs approving funding for 100 per cent of their requests.¹

PCTs therefore need more help to structure these decisions, in particular to balance the need of the individual patient with the statutory requirement for PCTs to use their limited available resources to meet the health needs of their overall population. Despite this requirement, even the use of QALYs or similar tools in such decisions is not formally mandated by the Department of Health or the NHS. Nevertheless, many PCTs do use QALY assessments (where they exist) for the following reasons:

1. As NICE uses QALYs ICERs a PCT will want to be assured that its own threshold for approving treatments will be consistent with that used to determine whether other treatments should be provided by the NHS.
2. If a treatment is due to be considered by NICE, the PCT will aim to make a decision for a patient that will be consistent with NICE once it does pronounce and not find that a treatment has been refused that NICE subsequently recommends.
3. Without QALYs (or a similar tool) it may be difficult to consider the cost effectiveness of a treatment and without this, the IFR decision-making may be based on clinical effectiveness, human sympathy or other factors that may make a decision insufficiently-rounded to meet the requirement that PCTs use resources reasonably and effectively for the population for which the PCT is responsible.

¹ Mike Richards, *Improving Access to Medicines for NHS Patients: A report for the Secretary of State for Health by Professor Mike Richards*, (London: Department of Health, 2008), cited in Rudolf Klein and Jo Maybin, *Thinking about Rationing* (London: The Kings Fund, 2012), p.25.

4. Many pharmaceutical companies publish their own QALY assessments and these make it practically possible to consider QALY ICERs.

However, QALYs are primarily calculated to inform macro resource allocation policy decisions and to assume that these calculations can simply be applied to IFRs can lead to concerns.

QALYs have been referred to pejoratively as ‘moral mathematics’ because they are perceived to put a financial value on an individual human life. I view this criticism as misleading when used in relation to QALY calculations in the context of macro resource allocation. If we did not do such analyses, we might be seen not to be giving a human life a financial value, but we would instead be indirectly valuing some people’s lives more highly than others by allowing some patients to consume excessive resources which would result in other patients being denied treatment. Criticisms of QALYs tend to focus on an individual patient being denied treatment and to ignore the other patients who would not receive treatment because the first patient had consumed excessive resources. Such criticisms sometimes use individual micro resource allocation scenarios to imply shortcomings in population-wide macro resource allocation uses of QALYs. This is because QALYs are seen to fit more comfortably in macro resource allocation decisions than in micro resource allocation decisions. When PCTs extend the use of QALYs to micro allocation IFR decisions they leave themselves vulnerable to the criticism that they are putting a value on a particular human life by using QALY assessments to determine whether to fund the requested treatment. However, even in these circumstances, I think it preferable and more accurate to view the decision that is being made as follows:

1. DECISION 1: A treatment is deemed to be not cost effective for the population, under a macro resource allocation policy.
2. Therefore, this treatment will not be made available.
3. An individual patient requests this treatment.
4. DECISION 2: The PCT must consider whether there are circumstances about this case that justify overturning the macro resource allocation policy.
5. One part of this decision-making may involve considering the QALY ICER of the treatment.

Described in this way, no treatment is actually *refused* under this individual assessment as the treatment has already been refused in advance via the macro resource allocation policy (Decision 1). The default position following 'Decision 1' is that the patient will *not* be treated and this is a population decision, not an individually-focused one. A decision to fund (Decision 2) is then a decision to overturn the population-wide policy in this particular instance. In deciding the case we do not deny treatment, instead we give an opportunity for this individual case to be funded. It may be an 'omission' to allow the population-wide decision to stand, but it is an 'act' to overturn it.

It may be questioned whether this acts/omissions distinction is really meaningful, like any such distinction. Whatever one's view of this, I think that this is a more accurate presentation of the decision that is to be made.

From a macro resource allocation perspective, the overturning of the case for an individual is defensible. The macro resource allocation policy decision has been made, securing resources for the population as a whole. The impact on the wider population if the treatment is funded in an individual case is minimal. Clearly, if IFR decisions are made that in significant numbers go against the policy, then there may be an impact on the wider population, but that would be because the policy was not being followed. If the policy is followed, but occasional decisions are made that justify breaking the policy in individual circumstances, the treatment for an individual can be secured without anything other than a negligible impact on other 'invisible' patients.

Individualised and personalised QALYs

At this point I would like to introduce two terms: individualised QALYs and personalised QALYs.¹ Both these concepts have significance when we try to use QALYs that work well for population-wide macro resource allocation decisions in the very different circumstance of micro resource allocation decisions that IFR Panels have to make.

¹ I initially introduced the term, 'individualised QALY' and briefly discussed the concept in an assignment entitled, 'Give a critical ethical assessment of the concept of the QALY and of the uses to which it is put in health care resource allocation' for the 'MAME 0620: Ethical Issues in Resource Allocation' module of The University of Wales, Trinity St David Medical Ethics MA. I have further developed those ideas here.

Individualised QALYs

In practice, QALY scores are based on population-level information: the average benefit (in terms of health gain) of the treatment based on evidence of its clinical-effectiveness, compared to the cost of the treatment. The benefit and cost calculations are subject to the criticism that we should not generalise from population averages to individuals. In contrast, I use the term ‘individualised QALY’ to describe a QALY assessment that takes account of the response of an individual to treatment and the cost of treatment of that individual.

When calculating population-level QALYs, we use clinical research evidence to average the cost of treatment and the response to treatment with the published cost per QALY being the average cost required to achieve the average response for the research population.¹ However, when a patient is treated, that individual patient’s costs and response to treatment can be assessed. The costs will vary as a result of severity of illness, general health and physical fitness, genetic predispositions, co-morbidities, weight and other individual factors; and the response of a patient to treatment may vary from cure to marginal benefit, no benefit or even harm. NICE will not recommend some treatments for NHS provision based on average QALY ICERS even though some individual patients may have a better than average response for below average cost. For these patients, their individual QALY ICER may actually fall within the NICE threshold. With NICE’s reliance on QALY assessments, there has been a recent trend towards pharmaceutical companies offering Patient Access Schemes to the NHS. For example, offering to reimburse the NHS for cancer drug costs if patients do not respond and treatment is discontinued – improving the ratio of benefits to costs to the point that the NICE ICER threshold of £30,000 per QALY is achieved. This means that the NHS will prescribe and the pharmaceutical company will be able to sell its products for patients who do respond. Patient access schemes do not use the term

¹ We assume that the research population is representative of the wider population to which the treatment will be applied, ignoring that research populations often exclude patients who are perceived in advance to be at risk of an adverse reaction to treatment. Clinical trials also often include patients who thought most likely to benefit. Furthermore, medical technology companies may choose not to publish trials that show no benefit. All of this can distort the conclusions and the resulting QALY ICERS.

‘individualised QALYs’, they simply focus on how they can bring the QALY ICER to within acceptable levels. However, in essence, they are using individualised QALYs.

Of course, using individualised cost and response data would not always improve access to treatment: sometimes this would mean that some treatments that fall within the NICE QALY ICER for the average patient would be deemed to fall above that threshold if individually assessed for patients with high costs and poor responses. A treatment with a drug that is given in a dose per kilogram of body mass will cost more for an obese patient than for the average patient and if the patient has obesity-related co-morbidities the response to treatment may be less good. Unsurprisingly, although companies have developed patient access schemes to recognise individualised QALYs and encourage treatment that would not otherwise be provided, they have not developed schemes to offer discounts to the NHS where the treatment has been approved by NICE, but at a poor individualised cost per QALY for particular patients.

Without individualised QALYs, we treat unequal people as if they are equal. Patients who require high costs or have a poor response will consume a disproportionately high share of resources compared to patients who require lower costs or who have a better response to treatment.

Importantly, it is possible in practice to calculate individualised QALYs by replacing the population average cost and expected response with that of the individual – this is not just a theoretical concept that cannot be applied. For example, the ranizumab patient access scheme¹ operates so that the NHS has the drug costs reimbursed for patients with wet age-related macular degeneration who need more than 14 treatments as this brings the ICER to within £30,000 per QALY. The cost per treatment for an individual patient is known, the response to treatment for the individual patient can be assessed (in this case via visual acuity tests) and so the cost of the QALY gain for an individual can be calculated by adjusting the published population-average cost and QALY data. A similar approach could be used in

¹ National Institute for Health and Clinical Excellence, ‘Patient Access Scheme Submission Template (Ranizumab)’, October 2009 <<http://www.nice.org.uk/nicemedia/live/13125/55330/55330.pdf>> Accessed 22 September 2012.

the absence of a patient access scheme where the population-wide QALY ICER, average cost and average treatment response are published and the individual's cost and response to treatment can be assessed. Therefore, we can use individualised QALYs to support the micro resource allocation decisions that IFR Panels have to make. The use of individualised QALYs in this way is implicitly recognised in the NHS, within the NHS Confederation's definition of 'exceptionality',

The patient is significantly different to the general population of patients with the condition in question; and the patient is likely to gain significantly more benefit from the intervention than might normally be expected for patients with that condition.¹

However, individualised QALYs do not help in the case of a religious objection to treatment as this is not a matter of cost or patient response, it is a matter of a personal 'quality' perspective and for that 'personalised QALYs' are required.

Personalised QALYs

Personalised QALYs similarly address the criticism of the generic application of the population-wide calculation of QALYs, but instead of considering the costs and responses of individuals to treatment, I use the term 'personalised QALYs' to describe how individuals value different quality states of health. The Quality weightings used in QALYs are intended to address population-wide decision making via macro resource allocation and it is clearly consistent that population-wide weightings should be used for population-wide decisions. However, when QALYs are used as one factor to help IFR Panels make individual micro resource allocation decisions, the population-based quality weightings may not apply.

Where population-wide QALYs do have a benefit is in allowing consistency of decision-making and consistency is very important for decision-making panels. Consistency is seen as important as a means to ensure fairness. However, fairness should be characterised by 'equitable' treatment rather than 'equal' treatment of individuals – where equitable includes the concept of meeting need rather than merely equal distribution.

¹ Adapted from Dr Henrietta Ewart by the NHS Confederation, *Priority Setting: managing individual funding requests*, 2008, p.4.
<<http://www.nhsconfed.org/publications/prioritysetting/Pages/Prioritysetting.aspx>>
Accessed 22 September 2012.

The population-based Quality weightings that are a strength in population-level resource allocation decisions might actually become a weakness at the individual level as they assume that each person's Quality weighting will be the same. This is untrue for a variety of reasons (and if it was true, there would be no need to ask more than one person to create a valid Quality weighting). Some of the reasons do not necessarily indicate a different 'real' Quality valuation of a health state, they merely indicate an error or inconsistency in the Quality assessment by different individuals because of different perspectives. For example, people affected by a condition will often to measure their quality of life differently than the general population because their perspective on the condition is different and they may physically and psychologically adapt to their condition which changes their assessment of how their quality of life is affected.¹

Another reason is that people genuinely will value different states of health differently than others even if all the above issues of perspective are addressed, and this is where the concept of personalised QALYs becomes relevant. Under personalised QALYs I would weight different states of health according to my personal preferences. The loss of the fourth finger of the left hand would not be deemed to have a significant impact on quality of life under population-wide QALY assessments, but for a concert violinist whose career and personal pleasure is partly dependent upon this finger, the Quality weighting for living without this finger might be significantly lower and therefore the QALY benefits of treatment to preserve that finger would be significantly higher than the population-based QALY would suggest.

The individualisation and personalisation of QALYs is further supported by the principle of patient autonomy – a patient is not able to be autonomous if he/she is forced to make decisions based on information that applies to patients other than himself/herself.

¹ John Brazier et al., 'Should patients have a greater role in valuing health states?', *Applied Health Economics and Policy*, 4 (2005) pp.201-208.

As an illustration of personalised QALYs,

A treatment for arthritis costs £50,000 and is estimated to give the patient no additional years of life, but will improve the quality of those years from a weighting of 0.6 without treatment to 0.8 with treatment for the remainder of the patient's life (estimated to be 5 years).

- QALYs without the treatment are: 5 years x 0.6 = 3.0 QALYs
- QALYs with the treatment are: 5 years x 0.8 = 4.0 QALYs
- The treatment gives a gain of 1.0 QALYs at a cost of £50,000, an ICER of £50,000 per QALY. This is above the NICE £30,000 per QALY threshold and would not meet this cost effectiveness criterion.

We could personalise the QALYs by stating that, based on other published Quality weightings of health states, the violinist whose left hand is arthritic would personally weight this as so significant that each year of life without treatment would only be weighted as 0.4:

- QALYs without the treatment are: 5 years x 0.4 = 2.0 QALYs
- QALYs with the treatment are: 5 years x 0.8 = 4.0 QALYs
- The treatment gives a gain of 2.0 QALYs at a cost of £50,000, an ICER of £25,000 per QALY. This would then be below the NICE £30,000 per QALY threshold and would meet this cost effectiveness criterion.

This would not automatically justify a decision by the IFR Panel to fund treatment for this patient, but it would indicate that a decision to fund could be reasonable and that the case would merit further discussion.

Whereas practical resource allocation decisions, such as those employed in Patient Access Schemes, might use individualised QALYs (although without explicitly doing so, nor using this term), I have been unable to find a practical example of the use of personalised QALYs (whether using this or any other term). Some papers do suggest that patient-determined QALYs are used at the doctor-patient interface when discussing treatment choices¹: patients

¹ Milton C. Weinstein, George Torrance and Alistair McGuire, 'QALYs – The Basics', *Value in Health*, 12 (Supplement 1) (2009) pp.5-9

will take decisions on whether to accept treatment or not, given the risks and impact on quality of life. For example, continuing to accept frequent night-time urination and the risks of bladder stones in preference to the post-surgical impotence risks of TURP (transurethral resection of the prostate) surgery. However, to describe this as a patient's personal QALY assessment of the options is an overstatement of such a conversation.

Whereas individualised QALYs can be calculated in practice, a problem with personalised QALYs is that to calculate them in IFR decision-making scenarios would be almost impossible: there would have to be the time and expertise to do this; the weightings would have to be validated in some way, such as assessing them a number of times at intervals; and most problematically, a patient applying for a particular treatment to be funded would be likely to skew his/her responses to make it more likely that the desired outcome was achieved. Therefore, even though personalised QALYs might be intuitively attractive, they may appear to be limited in their practical application. Yet despite this, they may help in the case of religious objections to treatment.

Personalised QALYs and religiously-motivated treatment choices

In the case of a religious objection to treatment, the personalised Quality weighting will not relate to the health state achieved by treatment, but to the religious Quality disadvantage of the treatment itself. A treatment that contravenes a religious prohibition will have a lower Quality value than one that is compatible with the patient's religious views.

When we then ask a Jehovah's Witness to personalise QALYs, we get the answer that treatment by blood transfusion is equivalent to something that would give no years of life and that a treatment that avoids blood transfusion therefore has a significant personalised QALY advantage. To express this another way, each year of life gained by a blood transfusion would have a personalised value of zero – as the patient would choose no years of life over any years of life gained by such treatment. This can be illustrated as follows:

A religiously-unacceptable treatment (Treatment A) would be life-saving, costs £20,000 and is estimated to give the patient 5 additional years of life of full quality (1.0 quality weighting).

- QALYs without the treatment are: 0 years = 0.0 QALYs
- QALYs with the treatment are: 5 years x 1.0 = 5.0 QALYs
- The treatment gives a gain of 5.0 QALYs at a cost of £20,000, an ICER of £4,000 per QALY. This is within the NICE £30,000 per QALY threshold and would meet this cost effectiveness criterion.

We could personalise the QALYs for the patient with an absolute religious objection by stating that, at one extreme, the quality of years gained by accepting 'Treatment A' would have a zero quality weighting:

- QALYs without the treatment are: 0 years = 0.0 QALYs
- QALYs with the treatment are: 5 years x 0.0 = 0.0 QALYs
- The treatment gives a gain of 0.0 QALYs at a cost of £20,000 and would not be worth considering.

An alternative, religiously-acceptable treatment ('Treatment B') would be life-saving, costs £84,000 and is estimated to give the patient 3 additional years of life of full quality (1.0 quality weighting).

- QALYs without the treatment are: 0 years = 0.0 QALYs
- QALYs with the treatment are: 3 years x 1.0 = 3.0 QALYs
- The treatment gives a gain of 3.0 QALYs at a cost of £84,000, an ICER of £28,000 per QALY. This is within the NICE £30,000 per QALY threshold and would meet this cost effectiveness criterion.

However, when we compare the two treatment options under ICER methodology, 'Treatment B' would never be funded for a patient without religious objections. Relative to 'Treatment A', 'Treatment B' costs an additional £64,000 and gives 2 years less of additional life. However, for the patient with religious objections to

‘Treatment A’, it is possible, in the extreme case, that the treatment would be justified under a personalised QALY ICER assessment.

Interestingly, in doing this we do not give the Jehovah’s Witness patient any additional value for the non-transfusion treatment. The difference between the Jehovah’s Witness patient and the ‘other’ patient is not in the personalised QALY valuation of the religiously-acceptable treatment, it is in the valuation of the unacceptable treatment and therefore the QALY ICER that the acceptable treatment gives relative to that unacceptable treatment.

This treats the religious objection as so fundamental that for a Jehovah’s Witness a life lived after a blood transfusion would have no value. There may be many years of life with a rewarding job, warm family relationships, great charitable deeds done for others and so on, but we would apparently be saying that for the Jehovah’s Witness this life would have no value. Whilst this may seem incredible to someone from outside this faith, this is, in effect, what the Jehovah’s Witness patient who refuses a treatment in the understanding that he or she will die without this treatment is prepared to accept.

For the Jehovah’s Witness patient this is equivalent to stating that there can be no transfusion treatment, that this not an option that is available. This is the effect of the personalised QALY when the treatment is absolutely prohibited within the religion to such an extent that death is to be preferred. However, in the case of a less-absolute religious objection this merely marks the theoretical outer limit of the personalised QALY. In such a case in particular, this would not dictate that the decision to fund treatment should be based on that QALY assessment, but it may help as one element contributing to that decision. The more flexible the religious prohibition and the higher the incremental cost per QALY, the less likely will the PCT be to overturn the population-wide policy to not fund the treatment and instead agree to make an exception to this policy. The more rigid the religious prohibition and the lower the incremental cost per QALY, the more likely will the PCT be to fund the requested treatment.

The religious patient or the healthcare professional might object that a financial limit is being set by a PCT in the knowledge that if this is exceeded for the religiously-acceptable

treatment this forces the patient to choose death and that this is setting a value on a human life. This is equally an objection to the use of QALYs in any macro or, more starkly, micro resource allocation decision. As the NHS accepts and uses QALYs to assess clinical and cost effectiveness it is consistent to adopt the same approach for the religiously-unacceptable treatment scenario. Otherwise we would be indirectly valuing the life of the religious patient more highly than another patient whose treatment choices are limited by NICE QALY ICER assessments.

It would be desirable to be able to refine the personalised QALY in the same way that we can for the individualised QALY. This is unnecessary for the Jehovah's Witness who wants to avoid blood transfusions as we can give the transfusion treatment a quality weight of zero. However, for other treatments that a religious patient would prefer to avoid for religious reasons, the personalised Quality weighting would be less than for a person with no religious objection, but greater than zero. However, the precise value would be difficult to assess. One approach might be to reflect the way that NICE consider QALY ICER thresholds:

In practice NICE has operated on the basis that a cost per QALY of less than £20,000 is acceptable, that a cost per QALY of between £20,000 and £30,000 needs justification, and that if the cost exceeds £30,000, it's thumbs down.¹

We could therefore give the religiously-unacceptable treatment a weighting of zero and agree to fund the religiously-acceptable treatment if it had an ICER of £20,000 per QALY or lower, would reject it if it had an ICER of £30,000 per QALY or higher and would have to consider the religious justification between £20,000 and £30,000. We could have a general policy that a religious preference that would be excusable under a dire necessity principle would have to have a QALY ICER of £20,000 or below, but one that was absolute, such as the Jehovah's Witness objection to blood transfusions would be accepted if it had an ICER of up to £30,000. There might still be exceptional circumstances that would lead us to vary from these rules in a specific case, but these parameters could constitute our assessment of the consideration of what was acceptable in pursuit of distributive justice.

Although this may be a tidy solution, I am left a little dissatisfied by it. The £20,000 and £30,000 thresholds are, to some extent, arbitrary and to use these as the foundation of an

¹ Rudolf Klein and Jo Maybin, *Thinking about Rationing* (London: The Kings Fund, 2012), p.11.

ostensibly ethical approach to religiously-motivated treatment decisions seems a little trite. However, this is consistent with the practical reality of how NICE assesses other treatments and so, despite its arbitrariness, it puts treatments with a religious implication on a more level playing field with other treatments than is currently the case. When all options are arbitrary, no particular option can be condemned for being arbitrary more than any other. Unless we are unprepared to set any limits, we may have to accept this limitation. Nevertheless, I will return to my sense of dissatisfaction later.

This would mean that there would be circumstances within which a religious person might have treatment funded at a greater cost than someone without religious objections. Even though the personalised QALY ICER would be within the £30,000 threshold, this would not be the cheapest treatment that could be offered so the non-religious person could still object. However, the treatment would be within what was deemed to be a reasonable cost per QALY ICER for any other treatment to be funded and we would have to accept that individual circumstances mean that the cheapest treatment cannot be offered to everyone – some patients respond less well to treatment, some patients have phobias (e.g. of the confined space within a closed MRI scanner and request an open scanner instead), some patients require more staff time for reassurance, and in this particular case some patients have particular religious beliefs.

How would we now assess the case of Joe?

Given that the NICE ICER threshold is £30,000 per QALY, the case of Joe instantly presents us with a clear answer without the need for personalised consideration of religious objections to some treatment alternatives. The annual cost of the drug is so high that even in a scenario that maximises its ICER, it would inevitably be beyond the NICE threshold. The maximising scenario would be one in which:

- Without the drug Joe will die.
- With the drug Joe would live a fully-functioning, maximum health quality life, with a Quality weighting of 1.0.

This would give an ICER of 1.0 QALY for every year that the treatment added to the life of the patient. However, because treatment must be given every year to maintain the benefit, this would give a cost of £240,000 per QALY. This is well beyond the NICE ICER QALY threshold even without any consideration of alternative treatments that might be dismissed for religious reasons. Therefore, there is no circumstance within which this drug could come within the NICE threshold.

However, PCTs do not (and should not) generally make decisions based solely on considerations of cost effectiveness. Although cost effectiveness may be an important consideration, there is not a simple formulaic approach to decision-making because individual case circumstances must also be taken into account. However, in Joe's case, even the overriding 'rule of rescue' cannot be called upon: his is not a life or death case which requires an urgent decision and for which the treatment has a high probability of success. As he is not in this position, the cost-utility ratio would be so poor that the other factors that a PCT might consider would almost certainly be overwhelmed and funding for treatment would be refused.

Nevertheless, there will be treatments that are far less costly where a religious objection may become significant and personalised QALYs do offer a way to address these that should be satisfactory from the perspective of the patient, the IFR Panel and the wider society with its limited healthcare resources. Having developed this solution, I would like to subject it to some criticisms and to see whether there are alternative approaches that could improve upon it.

Other ethical approaches

The practical implications of religious objections to treatment are considered within the NHS, with generally sympathetic, religiously and culturally-respectful advice on how to adapt treatment to accommodate religious views. Whether in relation to immovable objections such as Jehovah's Witnesses refusing blood transfusions or potentially discretionary scenarios, such as avoiding porcine-based medicines, the focus is on making it clear to patients and clinicians which products are forbidden and what alternative products

are available. Following an extensive review, I could not find any detailed discussion of the issues of health economics and equitable distribution of resources within the NHS in relation to a range of religious objections to treatment. This may be because it would be perceived as discriminatory to ignore the views of patients from particular ethnic or religious groups; or because other barriers to healthcare already exist for some minority ethnic groups and establishing additional religious barriers would be further impair their access.

Cases of Jehovah's Witnesses refusing blood transfusions are often discussed in the medico-legal literature. Many papers focus on the difficult cases of a Jehovah's Witness parent refusing treatment for a child where the court may decide that it is in the child's best interest to have the treatment against the patient's wishes. However, this cannot be applied to adults who have autonomy and so who cannot be compelled to accept treatment.

Very few papers consider the health economics of such cases in any detail, apart from merely considering that the additional resources used by a Jehovah's Witness might be depriving someone else of treatment. In his paper 'The Cost of Refusing Treatment and Equality of Outcome'¹, Julian Savulescu does produce an ethical consideration of this scenario, focusing on the use of erythropoietin to boost red blood cells in advance of surgery to allow the patient to avoid blood transfusions. He argues that Jehovah's Witnesses should be refused this more expensive treatment. This conclusion is primarily based on the opportunity cost for other patients of the additional resources being consumed. However, I believe that his conclusions can be challenged for a number of reasons.

Firstly, his position is based primarily on the argument that others are denied treatment if the costs for Jehovah's Witnesses are higher.² He does not consider QALY ICERs or anything else that would set an acceptable limit on this additional cost. The logical consequence of this would be that anyone who wanted a more expensive treatment would be denied it, even if it was only trivially more expensive. The phobic patient would not have their phobia

¹ Julian Savulescu, 'The Cost of Refusing Treatment and Equality of Outcome', *Journal of Medical Ethics*, 24 (1998), pp.231-236.

² *ibid.*, p.232.

taken into account when requesting a closed MRI scanner, the patient who wanted kidney dialysis in hospital rather than at home would be denied that option, we would make no allowance for additional costs related to privacy (e.g. avoiding mixed sex accommodation) and so on. All healthcare decisions would be purely based on cost-effectiveness with no allowance for personal choice. This may be a defensible position from a theoretical perspective, but is beyond what most patients or medical practitioners would accept and it conflicts with the principles of the NHS Constitution outlined in my 'Introduction'. Crucially, it also treats 'cost-effectiveness' as having an objectivity that it lacks – as noted previously, the quality valuation of a health state is derived from average valuations of quality of life. A patient who would accept some adverse impacts on his or her lifestyle (see the prostate example earlier in this paper) and choose one intervention over another would not be permitted to make that choice if the wider population took a different view of the quality weighting and the patient's preferred option was therefore deemed to have a lower QALY ICER. Furthermore, because this would be a strict determinant, it would not allow for exceptions and in practical terms, the UK courts have ruled that a 'blanket ban' on treatments that allows for no exceptions is unacceptable (see 'Legal implications', below). However, I do recognise that ethicists have a role in determining what is right, not just what is practical or acceptable and that Savulescu may argue that he is partly performing this role.

Secondly, Savulescu argues that Jehovah's Witnesses are 'responsible' for their refusal to accept blood transfusions and draws a parallel with them being responsible for their choices not to smoke or drink¹ (in this he misrepresents the Jehovah's Witnesses' position on alcohol consumption which is permitted in moderation). As discussed previously, to equate a religious belief with a lifestyle 'choice' is not really defensible. I think that it is also worth noting that the other cases that Savulescu considers are all unsympathetic cases in which there is a strong element of personal responsibility (e.g. an alcoholic who refuses detoxification). Cases where more expensive treatment preferences have other motivations, such as a frail elderly patient who wants (more expensive) hospital dialysis rather than home dialysis to save his wife having to take on an additional burden of clinical care, are not considered. I think that the conclusions are partly driven by an objection to

¹ Julian Savulescu, 'The Cost of Refusing Treatment and Equality of Outcome', *Journal of Medical Ethics*, 24 (1998), pp.231-236 (pp.232-233).

wider society being expected to compensate for failures in individuals' personal responsibility.

Thirdly, he argues that,

justice is prior to autonomy. It is only when the range of alternatives which society should offer us has been set that we can choose the option which we think is best for ourselves. We are only as free as the constraints of cooperative social existence allow.¹

In my view, as outlined above, I believe that either a liberal or libertarian view of justice would be met by people being treated with additional resources when the alternative would be to choose to die in accordance with one's beliefs. Society cannot justly decide on a range of alternatives if they limit people's fundamental rights.

In another paper, responding to John Harris², Savulescu³ considers whether distributive justice is best served by Desire Based (DB) or Value Based (VB) reasons for action. Savulescu takes a clear consequentialist position that we should consider the value of a decision as its justification rather than the justification being linked to desire. Undoubtedly he would regard my approach as leading to unjust outcomes as it takes the desire of the patient into account (if desire and religious belief can be equated) and so patients with lesser or different desires would be potentially prevented from accessing the same benefits. However, as noted above, the relative desire for different health outcomes is what defines the Quality of QALYs, so if we accept QALYs it is not possible to separate desire from the value of the outcome in this way. Harris might be more sympathetic to my approach as he does regard taking account of personal reasons for healthcare decisions as leading to distributive justice.

¹ *ibid.*, p.233.

² John Harris, 'Justice and Equal Opportunities in Health Care', *Bioethics*, 13 (1999) pp.392-404.

³ Julian Savulescu, 'Desire-Based and Value-Based Normative Reasons', *Bioethics*, 13 (1999) pp.405-413.

Just as I would regard alternative approaches based purely upon consequentialist theory as unsatisfactory if applied in practice to IFR decisions, I need to consider whether my proposals have anything other than a theoretical significance.

Practical implications

Quality Adjusted Life Years are an example of applied ethics – translating normative consequentialist ethics into a tool for practical implementation. In the realm of macro resource allocation via the Department of Health and NICE, QALYs are used in practice and have a significant impact on the NHS. However, in relation to IFR decisions with a religious component, I need to consider the implications of my proposals for real world implementation.

The Department of Health has delegated the IFR decision-making processes and criteria to PCTs, but this is not an entirely satisfactory position, as is accepted even by the Department of Health itself¹. Delegating the development of decision-making criteria to local organisations implies that there are local differences that would justify different criteria being applied in different areas. While that may be true in terms of populations having different health priorities depending on demographic or social characteristics (e.g. dementia or HIV), at the level of individual decision-making, localism is a recipe for a ‘postcode lottery’. PCTs merely have a set of guiding principles which they are required, ‘to take account of’², rather than these being legally mandated. These principles include,

PCTs should define clearly, and then consistently apply, standard criteria for decision-making. Decisions should be based on the best available evidence, take into account the appropriate ethical frameworks and comply with statutory requirements.³

Ethical considerations have been discussed earlier in this paper, so I will now consider how my approach fits with statutory legal requirements. IFR decisions do sometimes result in

¹ Department of Health and National Prescribing Centre, ‘Defining guiding principles for processes supporting local decision making about medicines’, January 2009, p.3.

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_093433.pdf > Accessed 22 September 2012.

² Ibid., p.5.

³ Ibid., p.19.

legal challenges and PCTs are mindful of the legal risks of flaws in their processes or decisions.

Legal implications

The key source that has informed this section is a recent paper by Amy Ford, 'The Concept of Exceptionality: A Legal Farce'.¹ Her paper helpfully pulls together the key legal cases relating to exceptional treatment funding decisions and the ethical issues surrounding these judgements. There are some references to religious views of treatment, but only insofar as these cases illustrate wider principles. However, even without a specific focus on the position in relation to religious treatment preferences, there are some key points that are relevant.

Firstly, although there have been conflicting judgements, the patient's response to treatment can be considered a relevant factor in IFR decisions:

[The patient] was young and fit compared to other patients in her cohort, had suffered negative reactions to alternative treatment, and had appeared to benefit from the new drug without common side effects. In her case, the increased likelihood of benefiting from the drug in question was considered a relevant factor.²

This would mean that individualised QALYs can be taken into account and perhaps should be taken into account. While this does not, in itself, have direct implications for the use of religiously-personalised QALYs, the acceptance that population-wide assessments are inadequate would support my proposals.

Secondly, PCTs cannot have a policy that purports to offer the opportunity for exceptional cases to be funded when no cases could ever be found to be exceptional, 'it is not sufficient for PCTs to have a policy that theoretically allows for exceptions, when in reality a blanket ban is being enforced.'³ Again, although this does not have direct implications for my proposals, it would require a PCT to consider a non-standard treatment for religious reasons even if the population-wide QALY ICER was above a threshold.

¹ Amy Ford, 'The Concept of Exceptionality: A Legal Farce', *Medical Law Review*, 20 (2012), pp.304-336.

² R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust, cited in Amy Ford, p.325.

³ Amy Ford, pp.308-309.

Thirdly, all relevant factors in an IFR should be considered ‘in the round’¹, rather than the decision being based on one factor or on each factor taken individually. Although my proposals are compatible with this judgement, they might create some difficulties in practice. In my experience, there is a tendency for IFR Panels to rely on QALY assessments (when available) as a principal factor in deciding whether or not to fund a treatment. While other factors are considered, QALY ICERs do carry particular weight. If QALY ICERs are available, they give an apparently scientific and quantified basis to the decision that therefore appears more defensible than the personal judgement that has to be exercised when considering the decision from other perspectives – ‘Is the patient exceptional?’, ‘Is there a risk of bias due to how articulately the request is expressed?’, ‘Is the treatment purely ‘cosmetic’ or does the desire for treatment constitute a psychological clinical need?’. If we offer the personalised QALY ICER merely as an outer limit of cost-effectiveness, we risk this being treated instead as an absolute value that will determine the decision without other factors of the case being considered ‘in the round’. This is something that IFR Panels would have to guard against.

And fourthly, there have been conflicting judgements in relation to whether social factors, such as the patient being a carer for a vulnerable person, should be taken into account in IFR decision-making. Key criticisms of the inclusion of social factors include that they cannot always be validated and that to take them into account would be unfair to all other patients for whom equivalent factors would be unknown.² However, when faced with difficult decisions that involved social factors, some judgements have included the opposite conclusion,

A PCT facing financial limitations could, reasonably, choose to fund cancer treatment for a woman caring for a disabled child, whilst not funding it for another with different personal circumstances.³ (p.319)

¹ *ibid.*, p.326

² *ibid.*, p.320

³ Amy Ford, p.319.

The legal conclusions in relation to 'social factors' may be contradictory, but this point does demand a further discussion. Should religiously-motivated objections to treatment be regarded as social factors?

Treatment decisions and 'social factors'

Amongst the type of case with significant social factors that are not related to religious objections where special access to resources might be requested are the following: Should a mother of young children be treated preferentially to a single person with no dependants? Should the child protection social worker have preference over the investment banker? Does a criminal have less right to access healthcare than a victim of crime?

As a brief consideration of the above examples would demonstrate, the ethical issues are complex: Are all lives of equal value? Is the value of a life influenced by its importance to other people? Can we judge the value of a life at a point in time when its social concomitants may change over the years? Do people lose their rights to access social goods by violating social rules? One's judgements on these matters will be affected by one's political and ethical principles and there will be arguments for and against each proposition, partly influenced by the position of the NHS as a taxpayer-funded healthcare system.

One objection to personalised QALYs might be that they bring social factors into funding decisions that should focus on clinical matters. As soon as we allow the musician to personalise the Quality weighting of a health state and value his or her fingers more highly than the average person, we apparently bring wide-ranging social factors such as occupation, interests and social relationships into the decision-making process.

Upon initial consideration, it would appear that religious beliefs are social factors. They are not clinical or financial factors and they are one of many wider social influences upon a person. Indeed, in the sociological study of disease, religion is sometimes explicitly categorised as a social factor¹. However, the term 'factor' is so flexible that we are misled if

¹ For an example, see Joseph T. Young, *Disease, Social Causation*, in Ritzer, George, ed., *Blackwell Encyclopedia of Sociology* (Oxford: Blackwell Publishing, 2007).

we regard religion or religious beliefs as social factors in the context of IFR decisions. In the IFR context, social factors affect perceived individual merit or worth, so the mother of a disabled child or a wounded soldier may argue that their social circumstances make them more worthy of additional funding for treatment. This is why including social factors in IFR decisions is controversial. In contrast, religious beliefs affect the personal value attributed to different treatment options. The religious person is not saying that their religion gives them an additional worth to be taken into account, they are saying that their beliefs affect the value of different treatments. This *treatment* is worth more to me than to other people, it is not that my social role makes *me* worth more than other people. In this, religious beliefs are like other personalised QALY considerations, such as the violinist's valuation of his fourth finger. A religious person may separately argue, in common with anyone else, that they also have social factors that should influence the decision to fund treatment, but that is a different consideration.

It is possible that personal views of treatment might overlap with social factors. For example, a person might value a particular treatment option more highly as it might allow them to regain mobility more quickly to allow them to resume their role in caring for a disabled child. Where the reason for a high personalised QALY weighting relates to a social factor it is unclear how the courts would regard this.

If social factors have clinical implications (e.g. lifestyle choices affecting chances of successful treatment) then they should be taken into account, not because they affect individual worth, but because they become indirect clinical factors, affecting the response to treatment and the quality and quantity of life years gained.

I can envisage a secular challenge to this approach: this is a question of health economics and the health benefit relative to the cost – and, as such, there is a place for clinical and financial considerations, but no place for social or religious considerations: 'Render therefore unto Caesar the things which are Caesar's; and unto God the things that are God's' (Matthew 22:21) – and this is a matter for Caesar. However, this ignores that QALYs are built on people's non-clinical, non-financial assessments of the quality of different health states. The concept of the personalised QALY is not primarily a religious one, it is one

built upon the personal valuation of treatments and health states – this is neither a matter for God nor Caesar, it is a matter for the individual patient.

Is this discrimination?

According to the Equality and Human Rights Commission,

Health and social care services should meet the needs of people from all backgrounds. You should not be treated less favourably than anyone else because of your religion or belief, or because you have no religion or belief.¹

There are two questions to answer here: is the religious person discriminated against if they are refused a religiously-acceptable treatment and is the non-religious person discriminated against if they are not offered the same treatment options as the religious person? If either of these is the case then an IFR Panel would find it difficult to accept my proposals.

The answer to the above questions partly depends upon whether the religiously-acceptable treatment is more favourable (i.e. is a more effective treatment) than the unacceptable treatment. If the religiously-acceptable treatment is less effective (as will often be the case, given that more effective treatments are preferred by clinicians unless they breach cost effectiveness thresholds) then the non-religious person can claim no discrimination. In this scenario, I would argue that the religious person can also claim no discrimination. He/she is being given access to an additional treatment option to respect his/her beliefs. There may be a further challenge where there is a more clinically-effective religiously-acceptable treatment available at additional cost compare to the religiously-acceptable treatment that has been offered. However, given that the basis of the decision to offer the treatment (the QALY ICER calculation) would be the same as applied to a non-religious person, I think that this could be defended.

If the religiously-acceptable treatment is more clinically-effective, I would also contend that as the basis of the decision to offer the treatment (the QALY ICER calculation) would be the

¹ Equality & Human Rights Commission, 'Health and Social Care'
<<http://www.equalityhumanrights.com/advice-and-guidance/your-rights/religion-and-belief/when-and-where-could-religious-discrimination-take-place/health-and-social-care/>>
Accessed 22 September 2012.

same for all patients, this could be defended. The decision-making would be non-discriminatory in process even if it could be questioned in terms of outcome. The other consideration, as noted previously, is that the IFR Panel has to make decisions on an exceptional basis, taking all relevant factors together: 'One of the few very clear principles to emerge from judicial review of decision making by PCTs in exceptional circumstances is that all features that might contribute to the determination of exceptionality should be considered in their totality, rather than individually'¹. The non-religious patient would find it hard to demonstrate that 'in the round' they should be treated as an exception, whereas the religious patient does have such a case.

How can we know a patient's religious beliefs?

There is a wide spectrum of beliefs and practices between denominations within religions (Sunni and Shia Muslims; orthodox and reform Jews; Catholics and Protestants) and a similar spectrum between sects within denominations and between individuals. Moreover, within Judaism and Islam, there is a tradition of scholarly interpretation of religious texts that means that the followers of different schools of thought or individual scholars may have different beliefs or practices. These differences may be less marked in religions which have a formal central authority on matters of faith (such as the magisterium or the Pope in Catholicism and the Governing Body of Jehovah's Witnesses). However, although 'Loyalty in faith to Jesus and his church is measured by fidelity to the Catholic church's authoritative moral interpretations'², different views are still manifested: in relation to medical ethics, '[McCormick] insists that the magisterium is not exempt from the ordinary process of inquiry in ethics'.³ It may be difficult, therefore, to say that for a particular patient that death is preferable to accepting a blood transfusion or where a patient's judgement of how 'dire' a situation of apparent 'dire necessity' would have to be to justify accepting porcine-based medicines. It would be impractical to subject a patient to a religious examination and an IFR Panel would not be equipped to do this. In that case, should we assume that the

¹ Amy Ford, 'The Concept of Exceptionality: A Legal Farce', *Medical Law Review*, 20 (2012), pp.304-336 (p.325).

² Lisa Cahill, *On Richard McCormick: Reason and Faith in Post-Vatican II Catholic Ethics*, in Verhey, Allen and Stephen E. Lammers, eds., *Theological Voices in Medical Ethics* (Grand Rapids, Michigan: Eerdmans, 1993) p.84.

³ *Ibid.*, p.84.

more widely accepted position represents that of the patient or should we accept at face value the patient's representation of his/her views?

Similarly, a patient who claims to subscribe to the Jedi religion and requests a more expensive treatment (or perhaps a cosmetic treatment that is not normally provided) would not be regarded as having a 'true' religious faith. I might hold that this is a reasonable response, but others might have the same response to a Scientologist, Christian Scientist or Jehovah's Witness. At some point the ability of an individual or a panel of individuals to judge what is a genuine faith, a genuine requirement of that faith or a genuinely-held personal belief becomes impossible.

The criticism that a patient's willingness to accept a religiously-prohibited treatment cannot be judged is justified, but it is often easier to criticise a proposition than to develop a better one. This criticism equally applies to other, unverifiable, aspects of a patient's presentation of their case for exceptional funding: for example, in cosmetic cases, does the patient's appearance really cause them great distress? At some point the IFR Panel has to accept the patient's claims and unless these are so far out of line with the mainstream beliefs and practices of the patient's professed religion that there is genuine doubt about the case, the personalisation of QALYs in accordance with the patient's presentation of their views is a reasonable position to adopt.

We should also remember that the Panel is required by the Department of Health, by established ethical frameworks and by legal judgements to consider the case in the round. The personalised QALY may be a significant factor in the decision, but it is not the single determinant of that decision.

Cultural transferability

We should note that some of the responses to these ethical issues are highly culturally-dependent. In the UK we have a separation of Church and State and we are not a society with a single religion held by the vast majority of citizens. If we were a society where Church and State were not separate or a society with that separation, but with an almost

unanimous adherence to a single religious creed, the responses to religious views of treatment might be very different. Firstly, the view might be taken that religious views must be taken into account in treatment decisions; and secondly, religiously-proscribed treatments might be excluded from the state healthcare system as the state would find it very difficult to construct a religiously-unacceptable policy that relied upon dire necessity justifications to make the treatment acceptable. However, even in such a society, members of other religions might still have their own views of treatment that would not apply to the majority religion and these cases would deserve fair consideration.

Despite the separation of church and state, the NHS strives to be inclusive and non-discriminatory. However, an argument could be made that it should be more clearly and objectively secular. My view would be that attempting an absolute, objective, secular approach would be the wrong aspiration. Religion is something of importance to many people, as are family relationships, social relationships, morality, animal welfare, cultural interests and many other social and psychological factors. A state that determined that its institutions should be entirely removed from these considerations would not be a state that would serve its people well as people.

A unresolved problem and a cynical solution?

I have considered the practical implications of my proposals and subjected them to scrutiny from a range of perspectives. I may have constructed a defensible case by building on ethically sound principles, but when I take a look at what I have created some matters are still left unresolved.

I am satisfied that religious treatment preferences should be respected. I am also satisfied that using personalised QALYs to direct additional resources to a religiously-acceptable treatment, when there is an absolute objection to the standard treatment, is justified as long as the standard QALY ICER limit is used (£30,000 per QALY as used by NICE). However, neither allowing non-absolute religious objections to result in additional resource consumption, nor setting the ICER limit for these at £20,000 per QALY, are entirely satisfactory. There is, however, a possible solution to this.

If we refuse to accept religious objections as a justification for additional use of healthcare resources, the Muslim and Jewish patient, for example, can rely on the principle of dire necessity or *pikuach nefesh* respectively and can accept the religiously-proscribed treatment as the NHS will offer no alternative. However, if the NHS does take religious objections into account when considering whether to fund a particular treatment, then the Muslim or Jewish patient will not be in a position where dire necessity or *pikuach nefesh* applies and so the excess costs may be incurred by the NHS. Therefore, in order to preserve maximum funding for the whole population and spread it most equitably, the NHS could refuse to take account of religious objections where a dire necessity principle would allow the religiously-incompatible treatment to proceed. Jewish and Muslim patients would thereby be permitted to accept religiously-proscribed treatments and we would therefore do them no clinical harm.

In contrast, I have concluded that the NHS should take religious objections into account where they are entirely inflexible. When faced with a Jehovah's Witness, we will be aware that a refusal to provide religiously-compatible treatments will result in a refusal to be treated and potentially great harm, so we will take account of the religious prohibition. This is brought into stark contrast when we consider that the specific treatment that is absolutely forbidden to Jehovah's Witnesses, blood transfusion, is also forbidden in Islam unless really necessary. Could the NHS sustain a position where a Muslim could not access alternatives to blood transfusion in circumstances where they would be provided to a Jehovah's Witness?

To do this would appear to cynically exploit a more moderate religious position and to fail to give that position any respect whatsoever, as if to say, 'If you're not prepared to die for your belief, we'll ignore it entirely and treat you just like anyone else with no religious concerns'. This is worthy of further exploration. Is it ethically defensible to take an approach where such a policy is dependent upon the anticipated responses of individuals to it? I will call my proposal that allows personalised QALYs in the case of a non-absolute religious objection and sets the ICER limit of the religiously-acceptable treatment at £20,000 per QALY, the

‘sympathetic position’; and the approach that allows only for absolute religious objections the ‘cynical position’. The arguments for and against these options are as follows:

In favour of the sympathetic position are the following,

1. The proposed approach is not a *carte blanche* to fund any religious treatment preference. The preferred treatment would have to come within a lower personalised QALY ICER threshold than other treatments or the treatment would not be provided. This is not excessively sympathetic, it is merely a balanced position.
2. If we do not respect personal preferences, the concept of autonomy is fundamentally undermined. Autonomy would become simply the minimal right to refuse the most cost-effective treatment.
3. Forcing a patient to accept a proscribed treatment may still cause significant distress even if it is permitted under a principle of dire necessity. The religious patient may decide to take greater risks with their health (or quality of life in terms of pain and disability) by avoiding that treatment or choosing a less effective one.
4. If we take account only of absolute religious preferences and do not respect the more moderate ones that allow for dire necessity, we encourage a hardening of positions over time which might create a conflict between religious groups and the NHS. The consequences of being too narrowly consequentialist may be worse in the long term. One can envisage the scenario where the advice from religious organisations to patients would be to absolutely refuse all religiously-unacceptable treatments as this would force the NHS to offer the religiously-acceptable alternative.

In favour of the cynical position are the following,

1. We must preserve the maximum resources for those in most clinical need. If we take account of religious preferences we may find that someone with a greater clinical need cannot have treatment.
2. All consequentialist ethics are dependent upon responses – we determine what is morally right by anticipating the aggregate value of the consequences of an action.

QALYs are themselves consequentialist and therefore if we are content to use QALYs, we should be content to base a decision on the anticipated responses of patients to that decision. If we can reasonably assume that a refusal to take notice of religious preferences will result in no harm (as that refusal will create a situation where dire necessity can be invoked), we do the consequentialist 'right' thing.

3. We do the religious person a favour in not permitting the treatment and allowing them to invoke a dire necessity principle. This preserves more healthcare resource for them as well as for others.
4. In respecting the religious rules of Jehovah's Witnesses we are not simply respecting the views of individual people, we are allowing an undemocratic, non-UK religious elite to determine how resources are used. If we allow even more religious preferences to be taken into account, we further disadvantage our citizens as a result of rules created by those who are either not part of our society or who are part of our society, but with no democratic mandate to determine how state resources are used.

In principle, I think that the cynical position is the better one for the wider population that is served by the NHS when considered simply in terms of health (and this should be the primary concern of the NHS). The majority of patients with religious objections could cite dire necessity if required and so still be able to access the standard treatment. The NHS would therefore be able to cure more disease, prevent more suffering, extend more lives by more years and improve the quality of those years of life.

However, I don't think that it is acceptable to hold this position in a society (and healthcare system) where autonomy and respect for the individual are such significant social and political values. Therefore, I would support the sympathetic position. Arbitrary as it may be, a QALY ICER limit of £20,000 for a non-absolute religious preference balances the beliefs that are of personal importance to the individual with the implications for other citizens. We can also reassure a supporter of the cynical position that IFR decisions should not be made on the basis of this sole consideration. This is therefore not a rule for IFR Panels to apply, but will merely provide a guide in relation to one of the factors that should be taken into account.

Conclusion

The NHS adopts a generally tolerant position in relation to religious preferences, even when there are resource implications. There is a *de minimus* level of additional resource requirement, below which we simply accept the cost implications as part of offering a non-discriminatory universal service.

Above this level there is currently no accepted way to draw a line between an acceptable level of resources to support a religious treatment preference and an unacceptable and disproportionate consumption of resources to which others have a just claim. Therefore, a line should be drawn. If not, one PCT might deny that religious preferences have any influence, refuse a treatment and allow a patient to choose death in preference to the PCT spending a small amount of money; and another PCT might allow any religious preference to determine treatment, however costly, and be forced to deny others more cost-effective treatments due to lack of remaining resources.

I have offered an ethically defensible, legally acceptable and practically implementable solution. This states that religious preferences should be taken into account. It also states that people with religious preferences do not have any additional worth, but do have a right to have their treatment preferences evaluated via personalised QALYs, a right that should also be extended to non-religious cases in which personalised QALY valuations are significant. The QALY ICER threshold for approving non-absolute religious objections should be lower than that for absolute religious objections and these thresholds can be set in a way that makes them consistent with existing QALY ICER thresholds used across the NHS. Individualised and personalised QALYs are not the answer to IFR decisions, but they are tools that offer patients just consideration of their individual circumstances and offer PCTs a framework for decision making that they currently lack.

Bibliography

- Austin, Daphne, *Priority Setting: Managing Individual Funding Requests*, NHS Confederation, 2008
<<http://www.nhsconfed.org/publications/prioritysetting/Pages/Prioritysetting.aspx>>
Accessed 22 September 2012
- Balboni, Tracy A. et al, 'Religiousness and Spiritual Support Among Advanced Cancer Patients and Associations With End-of-Life Treatment Preferences and Quality of Life', *Journal of Clinical Oncology*, 25 (2007) 555-560
- Banner, M., *Christian Ethics and Contemporary Moral Problems* (Cambridge: Cambridge University Press, 1999)
- BBC, 'Jehovah's Witnesses at a Glance', 2009
<<http://www.bbc.co.uk/religion/religions/witnesses/ataglance/glance.shtml>>
Accessed 22 September 2012
- BBC Radio 4, 'Treating a Jehovah's Witness', *Inside the Ethics Committee*, 11 May 2005
<http://www.bbc.co.uk/radio4/science/ethicscommittee_20050511.shtml>
Accessed 22 September 2012
- Beauchamp, Thomas L. and James F. Childress, *Principles of Biomedical Ethics*, 4th edn (New York: Oxford University Press, 1994)
- Brazier John, et al., 'Should patients have a greater role in valuing health states?', *Applied Health Economics and Policy*, 4 (2005) 201-208
- Brockopp, Jonathan E., ed., *Islamic Ethics of Life* (Columbia: University of South Carolina Press, 2003)
- Brockopp, Jonathan E. and Thomas Eich, eds., *Muslim Medical Ethics: From Theory to Practice* (Columbia: University of South Carolina Press, 2008)
- Brodsky, Robert A., 'Stem Cell Transplantation for Paroxysmal Nocturnal Hemoglobinuria', *Haematologica*, 95 (2010) 855-856
- Cohen, Randy, 'Pork: The Other White Medicine', *New York Times*, 18 August 2009
<<http://www.nytimes.com/2009/08/23/magazine/23fob-ethicist-t.html>> Accessed 22 September 2012
- Department of Health, *NHS Chaplaincy – Meeting the religious and spiritual needs of patients and staff*
<http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4073111.pdf> Accessed 22 September 2012

- Department of Health and National Prescribing Centre, 'Defining guiding principles for processes supporting local decision making about medicines', January 2009
<http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_093433.pdf> Accessed 22 September 2012
- Dorff, Elliot, J. and Louis E. Newman, eds., *Contemporary Jewish Ethics and Morality, A Reader* (Oxford, Oxford University Press, 1995)
- Ebrahim, Abu F.M., *Organ Transplantation, Euthanasia, Cloning and Animal Experimentation – An Islamic View* (Leicester: The Islamic Foundation, 2001)
- Equality & Human Rights Commission, 'Health and Social Care'
<<http://www.equalityhumanrights.com/advice-and-guidance/your-rights/religion-and-belief/when-and-where-could-religious-discrimination-take-place/health-and-social-care/>> Accessed 22 September 2012
- Evans, Allan S., Riley E. Moynes and Larry Martinello, *What man Believes: A Study of the World's Great Faiths* (Whitby, Ontario: McGraw-Hill Ryerson, 1973)
- Family Law Week, 'The NHS Hospital Trust v A [2007] EWHC 1696 (Fam)', *The Family Law Week*, 2007
<<http://www.familylawweek.co.uk/site.aspx?i=ed826>> Accessed 22 September 2012
- Ford, Amy, 'The Concept of Exceptionality: A Legal Farce', *Medical Law Review*, 20 (2012), 304-336
- Harris, John , 'Justice and Equal Opportunities in Health Care', *Bioethics*, 13 (1999) 392–404
- Harris, John, 'QALYfying the Value of Life', *Journal of Medical Ethics*, 13 (1987), 117-123
- Heeren O. et al, 'Religion and end of life treatment preferences among geriatric patients', *International Journal of Geriatric Psychiatry*, 16 (2001) 203-8
- Herper, Matthew, 'The World's Most Expensive Drugs', *Forbes Magazine*, 22 February 2010
<http://www.forbes.com/2010/02/19/expensive-drugs-cost-business-healthcare-rare-diseases_print.html> Accessed 22 September 2012
- Ihsan, Abdul H., 'Pig Based Pharmaceuticals', *The Halal Index*, Volume 1, 2010-2011
<<http://www.scribd.com/doc/55812138/The-Halal-Index-Pig-Based-Pharmaceuticals-Vol1-SAMPLE>> Accessed 22 September 2012
- Islamweb, 'Fatwa No:106469, Taking a Medicine Derived from Pig Material', 31 March 2008
<<http://www.islamweb.net/emainpage/index.php?page=showfatwa&Option=FatwaId&Id=106469>> Accessed 22 September 2012
- Jakobovits, Immanuel, Sir, *Jewish Medical Ethics: A Comparative and Historical Study of the Jewish Religion's Attitude to Medicine and its Practice*, (New York: Bloch, 1975)

- Klein, Rudolf and Jo Maybin, *Thinking about Rationing* (London: The Kings Fund, 2012)
- Kuhse, Helga and Peter Singer, eds., *Bioethics. An Anthology* (Oxford: Blackwell, 2006)
- Mahoney, Jack, *Bioethics and Belief* (London: Sheed & Ward, 1984)
- McGann, Michael, 'Equal Treatment and Exemptions – Cultural Commitments and Expensive Tastes', *Social Theory and Practice*, 38 (2012) 1-32
- McGregor, Maurice, 'Cost-utility analysis: Use QALYs only with great caution', *Canadian Medical Association Journal*, 168 (2003), 433-434
- Mynors, G. et al, *Drugs of Porcine Origin and Clinical Alternatives*
 <<http://www.keele.ac.uk/pharmacy/npcplus/medicinespartnershipprogramme/medicinespartnershipprogrammepublications/drugsofporcineoriginandclinicalalternatives/drugs-of-porcine-origin.pdf>> Accessed 22 September 2012
- National Institute for Health and Clinical Excellence, 'Patient Access Scheme Submission Template (Ranizumab)', October 2009
 <<http://www.nice.org.uk/nicemedia/live/13125/55330/55330.pdf>>
 Accessed 22 September 2012
- National Prescribing Centre, *Local Decision-making Competency Framework*, 2012
 <http://www.npc.nhs.uk/local_decision_making/resources/LDM_comp_framework.pdf> Accessed 22 September 2012
- Newdick, C., *Who Should We Treat? Rights, Rationing and Resources in the NHS*, 2nd edn (Oxford: Oxford University Press, 2005)
- NHS, 'The NHS Constitution', updated March 2012
 <<http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Document/s/nhs-constitution-interactive-version-march-2012.pdf>>
 Accessed 22 September 2012
- NHS Choices, 'Circumcision'
 <<http://www.nhs.uk/Conditions/Circumcision/Pages/Introduction.aspx>>
 Accessed 22 September 2012
- NHS Confederation, *Priority Setting: managing individual funding requests*, 2008
 <<http://www.nhsconfed.org/publications/prioritysetting/Pages/Prioritysetting.aspx>>
 Accessed 22 September 2012

- NHS National Electronic Library for Medicines, 'Eculizumab for paroxysmal nocturnal haemoglobinuria', 14 April 2008
 <<http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Drug-Specific-Reviews/Eculizumab-for-paroxysmal-nocturnal-haemoglobinuria/>> Accessed 22 September 2012
- Nozick, Robert, *Anarchy, State and Utopia* (New York: Basic Books, 1974)
- O'Donnell, Thomas J., *Medicine and Christian Morality* (Staten Island NY: Alba House, 1996)
- Phillips, Ceri and Guy Thompson, *What is Cost Effectiveness?*, Hayward Medical Communications, 2009
 <<http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/Cost-effect.pdf>> Accessed 22 September 2012
- Queensland Government, *Hindu Beliefs Affecting Healthcare*, 2011
 <http://www.health.qld.gov.au/multicultural/health_workers/hbook-hindu.asp>
 Accessed 22 September 2012
- Queensland Government, *Sikh Beliefs Affecting Healthcare*, 2011
 <http://www.health.qld.gov.au/multicultural/health_workers/hbook-sikh.asp>
 Accessed 22 September 2012
- Rawls, John, *A Theory of Justice*, original edn (Cambridge MA: Harvard University Press, 1971)
- Rawls, John, *Justice as Fairness: A Restatement* (Cambridge MA: Harvard University Press, 2001)
- Ritzer, George, ed., *Blackwell Encyclopedia of Sociology* (Oxford: Blackwell Publishing, 2007)
- Rogers John, ed., *Medical Ethics, Human Choices – A Christian Perspective* (Scottsdale, Pennsylvania: Herald Press, 1988)
- St George's Healthcare NHS Trust, *Transfusion Alternatives for Jehovah's Witnesses*
 <<http://www.stgeorges.nhs.uk/docs/patient/JehovahsPatInfoBooklet.pdf>> Accessed 22 September 2012
- Savulescu, Julian, 'Desire-Based and Value-Based Normative Reasons', *Bioethics*, 13 (1999) 405-413
- Savulescu, Julian, 'The Cost of Refusing Treatment and Equality of Outcome', *Journal of Medical Ethics*, 24 (1998), 231-236
- Scheib, Ariel, 'Pikuach Nefesh', *Jewish Virtual Library*
 <http://www.jewishvirtuallibrary.org/jsource/Judaism/pikuach_nefesh.html>
 Accessed 22 September 2012

- Sharp, Shane, Deborah Carr and Cameron Macdonald, 'Religion and End-of-Life Treatment Preferences : Assessing the Effects of Religious Denomination and Beliefs', *Social Forces*, 91 (2012) 275-298
- Syrett Keith, *Law, Legitimacy and the Rationing of Health Care* (Cambridge: Cambridge University Press, 2007)
- Teuscher, A., *Insulin – A Voice for Choice* (Basel: Karger, 2007) pp 10-13
- Turner, Bryan, ed., *The New Blackwell Companion to the Sociology of Religion* (Chichester: Wiley-Blackwell, 2010)
- United Nations, *United Nations Universal Declaration on Human Rights*
<<http://www.un.org/en/documents/udhr/>> Accessed 22 September 2012
- United States Government, *Patient Protection and Affordable Care Act*, 2010
<<http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>>
Accessed 22 September 2012
- Verhey, Allen, ed., *Religion and Medical Ethics* (Grand Rapids, Michigan: Eerdmans, 1996)
- Verhey, Allen and Stephen E. Lammers, eds., *Theological Voices in Medical Ethics* (Grand Rapids, Michigan: Eerdmans, 1993)
- Watchtower Bible and Tract Society of Pennsylvania, *Blood, Medicine and the Law of God* (New York: Watchtower Bible and Tract Society of New York, 1961)
- Watchtower Bible and Tract Society of Pennsylvania, *What Does the Bible Really Teach?* (New York: Watchtower Bible and Tract Society of New York, 2012)
<<http://wol.jw.org/en/wol/d/r1/lp-e/1102005143?q=blood+transfusion&p=par>> Accessed 22 September 2012
- Weinstein, Milton C., George Torrance and Alistair McGuire, 'QALYs – The Basics', *Value in Health*, 12 (Supplement 1) (2009) 5-9
- Williams, Alan, 'The Value of QALYs', *Health and Social Service Journal*, 95 (1985), 3-15