

## **THE SECRET WORLD OF LIVER TRANSPLANT CANDIDATE ASSESSMENT**

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### **ABSTRACT**

Organ transplantation is a field entangled with ethical complexities. One of the major controversies subject to debate is resource allocation. The UK's organ procurement agency, NHS Blood and Transplant, must ensure that the limited number of human organs are allocated to the most efficient, yet the most deserving, transplant candidates. NHSBT have published numerous organ allocation protocols to this end, but little of known of the transplant candidate assessment process, which not only plays a pivotal role in selecting suitable transplant candidates for the waiting list, but also plays host to some of the most difficult ethical decisions in medicine. This piece will examine the UK liver transplant candidate assessment process in detail, paying particular attention to the composition of transplant teams, the diverse candidate criteria under examination, and the controversial grounds upon which a candidate can be excluded from transplantation. The limited regulations surrounding transplant teams and the opportunities to discriminate against particularly vulnerable candidates—such as alcoholics and illicit drug users—will also be discussed, and it will be asked if a fair assessment process for all liver transplant candidates can be guaranteed by NHSBT when transplant teams are subject to such a wealth of discretion.

### **INTRODUCTION**

As the UK's organ procurement agency, NHS Blood and Transplant's key role is to ensure that organs donated for transplant are matched and allocated to patients in a fair and unbiased way.<sup>1</sup> In recent years NHSBT and the Department of Health have published several liver allocation protocols and describe a candidate's level of urgency, his blood type, and his position in the Liver Allocation Sequence as key liver allocation criteria.<sup>2</sup> Although NHSBT's current protocols are not without their ethical difficulties, they do provide clear and measurable allocation strategies which encourage transparency and build trust between the organ procurement agency and its current (and prospective) transplant candidates.

Candidate assessment occurs much earlier in the transplantation process and remains largely hidden from view. The scarcity of human organs puts considerable pressure upon organ procurement agencies

to allocate livers efficiently, and a strict assessment process may be the only feasible means of reducing the number of unsuitable candidates put forward for transplantation. During the last six years, NHSBT and the Department of Health have taken steps to standardise the assessment process for liver transplant candidates through the publication of three brief assessment guidelines,<sup>3</sup> but these guides provide little in the way of calculable assessment criteria against which to accurately assess a candidate's physical, psychological, motivational, environmental, financial and social characteristics. There are also no safeguards in place to protect against prejudiced assessment decisions, there are only limited options for redress if a candidate feels he has been unjustly excluded from life-saving treatment, and it is not clear how closely NHSBT governs transplant teams and the liver transplant candidate assessment process. A number of controversial questions therefore remain unanswered.

What follows is a detailed examination of the current liver transplant candidate assessment guidelines in the UK and a discussion as to whether the current system can offer a fair and impartial assessment process for particularly vulnerable liver transplant candidates. A 'universal' assessment strategy will be suggested by way of conclusion to pave the way for much-needed reform.

## **THE DEPARTMENT OF HEALTH**

In 2005 the Department of Health published the National Liver Transplant Standards. This brief document supports NHS Blood and Transplant's professional practice by recommending diagnostic, assessment, allocation, transplantation, training and development strategies. The National Standards focus particularly on the composition of transplant teams and their primary objectives, which are to ensure that candidates who need a transplant are listed for a suitable liver whilst they are fit enough to survive the operation, but not so early that they are exposed to the risks of a transplant prematurely.<sup>4</sup> It is left up to NHSBT to incorporate the following Standards into their own assessment guidelines at their discretion.

### *(i) The National Liver Transplant Standards*

The National Standards begin by explaining how the assessment process can encourage efficient organ allocation:

There are far more patients than there are donor organs, thus the process of assessment is one of making the most appropriate allocation

of a scarce resource. Based upon the principle that donor livers should be placed according to greatest benefit, it is currently recommended that organs should be allocated to candidates who have at least 50% chance of surviving five years post transplant.<sup>5</sup>

This suggestion by the Department of Health does two things: it recommends that considerations of utility should underpin all liver allocations, and it indicates that the primary objective of candidate assessment is to filter out those candidates who possess only a small chance of short-term survival. Creating fair assessment guidelines to reflect these objectives is a task allocated to NHSBT.

Section 2 of the National Standards describes in detail the suggested composition of a transplant team:

The liver transplant team should include: a) liver transplant surgeons, hepatologists, anaesthetists and critical care specialists; b) transplant nurses and recipient coordinators; c) a dietician, pharmacist, physio-therapist, psychiatric liaison nurse, social worker, and chaplain; and d) clinicians involved in liver radiology, histopathology and microbiology.<sup>6</sup>

The structure of a transplant team may therefore be adjusted to meet the needs of the candidate, and each transplant team will adopt a unique approach to assessment depending on the share of specialists. The Department of Health have assured with this recommendation that particularly vulnerable candidates will receive the appropriate social and psychological care for their liver disease, but could a personalised approach to assessment work against a candidate who has contributed to his own liver failure? For example, a substance-abusing candidate may be placed with a largely social transplant team, who will be keen to observe, counsel and rehabilitate the candidate. This may include a detailed examination of the candidate's criminal, social and environmental issues. A candidate in this position may feel 'condemned' by his team before he's had an opportunity to change his behaviour and more likely to be prohibited from transplantation on account of his harmful social conduct. Not only might NHSBT use this flexibility to their advantage to compile transplant teams who will be reluctant to forward 'inefficient' candidates for transplantation, but the Department of Health does not appear to regulate this process: standard 2.1 includes the term '*should include...*', meaning that the decision as to who assesses a candidate and whether that candidate's transplant team will be socially, clinically or psychologically minded is left up to NHSBT to regulate at their discretion.

Further information is provided in the National Standards about the psychiatric liaison nurse, who is particularly important to

candidate assessment as she will deal with the most controversial liver transplant cases (including alcoholic, drug-dependant and mentally ill candidates):

The transplant team should include a psychiatric liaison nurse, experienced in the management of candidates who abuse alcohol and drugs; and responsible for the assessment and counselling of candidates with alcohol or drug abuse problems as well as other candidates with psychiatric problems.<sup>7</sup>

The Department of Health shows considerable compassion and support for a fairer assessment process in this recommendation by allowing for an experienced substance abuse specialist to assess these candidates in an open-minded and understanding way. However, despite the fact that the psychiatric nurse retains one of the most ethically contentious jobs in candidate assessment, the Department of Health has provided no further assessment guidelines to show the nurse how to implement a fair assessment of alcoholic, drug-dependant and mentally ill candidates. The National Standards do assert that: 'there should be written Guidelines and Protocols of Care for candidates undergoing assessment',<sup>8</sup> but it appears that full discretion is handed to NHSBT to develop these protocols.

Section 3 of the National Standards is all about candidate assessment. The following recommendations are put forward by the Department of Health for the assessment of all liver transplant candidates:

Candidates should be assessed by a multidisciplinary team; assessment should be based as far as possible on objective criteria and should include a detailed review of the candidates' physical and psychological condition to determine whether transplantation is indicated as treatment for their liver disease and whether they are sufficiently fit to have a reasonable chance of long term survival; candidates with generally accepted contraindications (e.g. those who continue to abuse alcohol) should not be offered transplantation.<sup>9</sup>

These recommendations are curious in that they encourage objective assessment with a twist. The Department of Health are encouraging objectivity by focusing on a candidate's physical and psychological condition to ascertain his fitness levels, survival rate and suitability for the procedure. These considerations require little in the way of social assessment and will simply distinguish candidates on clinical grounds. However, the final recommendation that patients with 'generally accepted contraindications' should not be offered transplantation at all could lead to a rather blinkered elimination process. What exactly is a 'contraindication' and what makes

contraindications ‘generally accepted’? With regards to candidates who continue to abuse alcohol, does this recommendation include recovering alcoholics, or just candidates who abuse alcohol during the assessment process? If it is the latter, are they excluded for clinical reasons, or on grounds of efficiency? The Department of Health fails to define ‘contraindications’ to transplantation (i.e. the grounds for outright rejection) or provide any guidelines as to how contraindications should be calculated, allowing NHSBT to draft their own ‘generally accepted’ exclusion criteria (examined in detail below). The Department of Health is therefore sending mixed messages in its recommendations. Should the candidate assessment process support a blanket ban upon particular groups of candidates? If not, what form should contraindications to transplantation take? The result is that NHSBT is under significant pressure to define and implement an ethical version of these recommendations.

The Department of Health give alcoholic candidates a particularly difficult time throughout the National Standards, making it clear where they stand on alcoholic assessment:

It is generally accepted that candidates with alcoholic liver disease are likely to develop disease in their new liver if they continue to abuse alcohol. Such candidates are also likely to be non-compliant with medication and clinic visits. Candidates assessed as likely to continue to abuse alcohol are usually regarded as unsuitable for liver transplantation.<sup>10</sup>

It is understandable that the Department of Health wish to exercise caution over alcoholic candidates: public support for organ donation is a great concern for organ procurement agencies and their governing bodies, and there is an expectation that NHSBT will allocate scarce organs to suitable and responsible candidates. However, why are alcoholic candidates ‘usually regarded’ as unsuitable? Is this assumption based on clinical reasons i.e. an accurate assessment is far more difficult, or is it based on grounds of efficiency or social aversion to alcoholic liver transplants? The rationale underpinning this assumption has not been made clear. If the Department of Health *is* publishing unfair social assumptions about the behaviour of a particular group of candidates in its National Standards, these suggestions could translate into a collection of prejudiced assessment protocols at agency-level. NHSBT must therefore ensure that they do not reject alcoholic or drug-dependant candidates simply because they are *assumed* to defy their post-transplant care. It may be that candidates who continue to abuse dangerous substances are inefficient choices for transplantation because they present a very high risk of graft failure, but any contraindications to transplantation should

be clearly underpinned by these clinical calculations, not social or behavioural assumptions. Because NHSBT could not think to incorporate such partial views into any of their formal assessment protocols, they have displayed considerable caution when publishing their assessment guidelines for alcoholic and drug-dependant liver transplant candidates.

In terms of fair and objective candidate assessment, the National Liver Transplant Standards are generally disappointing. The Department of Health has provided little in the way of a foundation for NHS Blood and Transplant to develop their own impartial candidate assessment protocols. Efficiency emerges as a chief consideration for the Department of Health and this is balanced with the need to provide a personal assessment experience with a tailored transplant team, but NHSBT are in receipt of such a wealth of discretion that it is almost impossible to guarantee, on the basis of the Department of Health's recommendations, that all liver transplant candidates will receive a fair and objective assessment. The ambiguity of the National Standards gives NHSBT maximum room to discriminate in the interests of utility. Is the candidate offered any form of redress should his experience be unsatisfactory? The Department of Health provides some vague directions in the event that a candidate should complain about his experience:

The transplant team [may] decide that the candidate is not suitable for transplantation. The reasons for the decision are explained to the candidate, his family and carers. Candidates who disagree with the decision are offered the option of a second opinion at another transplant centre.<sup>11</sup>

This recommendation uses an interesting choice of words. The term 'not suitable' suggests that a candidate is 'inappropriate', and this can be interpreted clinically or ethically. If the term 'not eligible' was substituted, this would suggest that the candidate simply did not meet the necessary clinical criteria. On the point of redress, the candidate is encouraged by the Department of Health to go elsewhere. This is not really redress, as it provides little hope for the excluded candidate and it places no responsibility upon NHSBT to justify their controversial assessment decisions.

As a result of the Department of Health's rather ambiguous recommendations, a considerable amount of direction, power and control is handed to NHSBT. This is reflected in their liver transplant candidate assessment protocols (below). With all of this in mind, it would be rather fitting to finish this section with National Standard 1.10: 'staff in the multidisciplinary team should be trained in communication skills... there should be a policy for breaking bad news'.<sup>12</sup>

## NHS BLOOD AND TRANSPLANT

NHS Blood and Transplant is responsible for the fair and equitable assessment of all its transplant candidates and must publish a whole raft of assessment protocols to ensure that this process is recognised and regulated. Following the Department of Health's National Liver Transplant Standards in 2005, NHSBT published three relevant documents: general protocols for adults undergoing liver transplantation (2009), alcoholic candidate assessment guidelines (2005), and illicit drug-use assessment guidelines (2007).<sup>13</sup> The general protocols from 2009 provide a brief overview of the whole transplantation process with a small section on assessment, whereas the two smaller guidelines from 2005 and 2007 are specifically developed to provide guide transplant teams through the assessment of alcoholic and drug-dependant candidates. NHSBT has the difficult task of ensuring that any protocols produced on the back of the Department of Health's National Standards are fair yet practical. Does candidate assessment improve at agency-level?

### *(i) Protocols for Adults Undergoing Liver Transplantation (2009)*

NHSBT begins its general liver transplant protocols with an encouraging objective: 'livers donated for transplantation should be considered a national resource and therefore guidelines for their use needed to be agreed publicly and followed nationally'.<sup>14</sup> This statement allows for candidates to feel 'involved' in the development of liver transplant protocols and it promotes a feeling of transparency. NHSBT can build vital public trust through the guarantee of clear, accessible and patient-friendly transplant guidelines.

In terms of candidate assessment, NHSBT's 2009 protocols clearly outline what a typical transplant team will investigate:

Candidates should be accepted for transplantation only if they have an estimated probability of being alive 5 years after transplantation of at least 50% with a quality of life acceptable to the candidate. Other medical and social factors (such as alcohol or drug misuse, age or anti-social lifestyle) are relevant if they affect the above criteria.<sup>15</sup>

The recommendation by the Department of Health that a candidate must show a 50% chance of surviving five years post transplant<sup>16</sup> has been expanded considerably by NHSBT to include a controversial 'quality of life' criterion and anti-social characteristics. Why has NHSBT chosen to add these elements and what affect does it have on the candidate's chances of transplantation?

'Quality of life' is a notoriously difficult factor to measure in clinical terms, even if it is the candidate who makes the decision. An 'acceptable' quality of life is not defined by NHSBT, and a personal criterion such as this will inevitably vary from candidate to candidate. Perhaps NHSBT felt the need to incorporate the candidates' view into the assessment process to allow for more vulnerable candidates to be considered for transplantation? Reservations have been raised in the past about a Quality Adjusted Life Years approach to allocating scarce medical resources.<sup>17</sup> How can a transplant team accurately measure 'quality of life' in a way that is fair to a candidate, yet ensures that no groups of candidates are met with a distinct disadvantage (i.e. all elderly candidates are excluded on the grounds that their quality years have passed)? There would be little point in allocating an organ to a candidate who is not expected to benefit from it or survive any longer than a few days, but the word 'quality' alludes to the measurement of worth, and the result of a 'quality of life' decision would be to label any inefficient, minority, frail or undesirable candidates as 'worthless'. NHSBT cannot be seen to reject candidates simply because they have past their best.

Anti-social characteristics were briefly mentioned in the National Standards in the guise of alcoholism. NHSBT has inevitably incorporated anti-social characteristics into its 2009 protocols (above), but according to NHSBT these factors will only be assessed if they affect the candidate's 50% chance of surviving five years post transplant. How is it possible for a transplant team to conclusively prove that a candidate's liver failure is due to his or her anti-social behaviour? Some cases may be obvious (such as alcohol-induced liver disease) but other cases may be less clear (such as heavy drug use coinciding with unexpected liver failure). Additionally, just how many anti-social factors can a transplant team attribute to liver failure? NHSBT has provided further details regarding the assessment of non-medical factors in section 3 of its 2009 protocols:

Other factors which will need to be considered will include the reason which gave rise to the primary cause of liver failure (for example, alcohol-induced liver diseases); a history of illegal drug use or of self-inflicted, medical or psychiatric conditions; and the patient's age.<sup>18</sup>

NHSBT have widened the Department of Health's 'five year' recommendation significantly to allow for further social, psychological, environmental, criminal and self-inflicted conditions to be incorporated into the assessment process. For the purposes of efficient liver allocation, a meticulous approach to assessment is logical: it will guarantee that the most efficient candidates are selected for transplantation and it will ensure that those who have caused their

own liver failure through self-inflicted alcohol and drug abuse will not be forwarded for a liver transplant. However, these guidelines are woolly. Transplant teams have no definitive standard against which to measure the gravity of these non-medical factors in a way that is fair and consistent. An investigation into the real cause of a candidate's liver failure will also be an uncomfortable experience for many candidates, feeling as though they are being subjected to a rigorous personal examination and judged solely in light of their unhealthy lifestyle choices. NHSBT does not expressly state that any non-medical factors are a *complete* contraindication to transplantation, but they make it clear that a candidate's reckless behaviour is open to scrutiny by the transplant team.

Alcoholism is one anti-social factor that causes particular concern for organ procurement agencies. A candidate who continues to abuse alcohol will not only put his new liver at risk, but he will be placed in direct competition with other liver transplant candidates who have not caused their own liver failure. This moral issue generates great public anxiety.<sup>19</sup> The Department of Health were quite clear in the National Standards when it came to the assessment of alcoholics: alcoholism is a 'generally accepted' contraindication and should be a barrier to transplantation.<sup>20</sup> NHSBT have showed considerable caution when re-drafting this recommendation into their 2009 protocols. In an attempt to avert any apparent prejudice, NHSBT present the following alcohol assessment policy:

A multi-disciplinary approach is required to select candidates who are likely to comply with follow-up schedules and not return to a damaging pattern of alcohol consumption after transplantation and may include psychological/psychiatric assessment.<sup>21</sup>

NHSBT have moved away from the postulation that all alcoholics should be automatically excluded from liver transplantation and instead suggest that alcoholic candidates should be subject to a detailed social and psychiatric assessment. In the National Standards, this task is allocated to an experienced psychiatric liaison nurse to allow for a tailored assessment experience. Perhaps NHSBT believe that a multi-disciplinary transplant team would be better suited to dealing with such complex individuals? This is more beneficial for particularly vulnerable candidates: a nurse may focus only on social issues, whereas a well-rounded team will place more emphasis on medical utility.

Frustratingly, NHS Blood and Transplant have come no further forward in providing clear assessment regulations for transplant teams when incorporating the Department of Health's ambiguous National Standards into its assessment protocols. The 'quality of life'

criterion simply adds a new ethical complication to the assessment process which may be especially problematic for a small handful of candidates who transplant teams consider to possess an already substandard quality of life.

NHSBT has, however, made a direct move to embrace all candidates with all kinds of problems into the assessment process, including alcoholic, drug-dependant, self-inflicting and mentally-ill candidates. With this compassionate undertaking comes a responsibility to develop detailed and comprehensive assessment guidelines to ensure that every candidate receives an objective and consistent assessment experience, but transplant teams still appear to possess complete discretion as to how, and against what criteria, candidates are assessed. When a candidate's lifestyle choices, attitudes, criminal history, environment, habits and motivations are exposed under the microscope for detailed scrutiny, NHSBT cannot currently guarantee that the outcome will be impartial because transplant teams have no definitive benchmarks against which to consistently measure these non-medical factors. Transplant teams may argue that these meticulous examinations are crucial for economical reasons, but judgments regarding a candidate's anti-social behaviour will creep into murky territory. Another issue arising from the 2009 protocols which will be a particular concern for candidates is who do transplant teams answer to if it emerges that a candidate's exclusion is based on social or behavioural grounds? Perhaps the Department of Health could step in?

NHSBT has taken further steps to support the assessment of alcoholic and drug-dependant candidates. Further assessment guidelines published in 2005 and 2007 allow for transplant teams to employ a far more tailored (and far more critical) assessment strategy for these difficult candidates, which are outside of the ambit of the National Standards. It is not clear why these additional guidelines have been created, although public pressure to allocate livers sensibly may have exerted a strong influence.

*(ii) Recommendations for liver transplant assessment of alcohol-dependant candidates (2005)*

In 2005, the Liver Advisory Group (LAG) published assessment guidelines for candidates with alcohol-related liver disease.<sup>22</sup> NHS Blood and Transplant have endorsed these guidelines to combat the potential risk of recurrent disease and poor compliance leading to graft loss, and recommend that transplant teams employ a careful assessment of psychosocial and substance use factors for candidates with a diagnosis of alcohol-related liver disease.<sup>23</sup> The guidelines are

brief, but they contain various contraindications to listing (i.e. grounds for exclusion to transplantation) and are intended to work alongside NHSBT's 2009 liver transplant protocols (above) to enhance liver transplant success rates.

The Liver Advisory Group (in conjunction with NHSBT) begin the 2005 alcoholic guidelines by suggesting that any alcoholic candidate assessment should include a careful attention to risk factors associated with predicting a relapse to drinking.<sup>24</sup> Calculating a candidate's risk of relapse is incredibly difficult and may require a detailed psychological examination to uncover the candidates' personal reasons for becoming alcohol-dependant. Unfortunately, 'risk factors' are not defined by the guidelines, but it is anticipated that they will include any social, criminal, emotional, psychological, employment, financial and physical factors which may influence a candidate during his waiting period and beyond. Without a scale of reference in place to accurately measure these factors, a transplant team are potentially free to initiate a comprehensive investigation into a candidate's private life. This will be extremely uncomfortable for many candidates, and may expose areas of his or her life that have no impact of graft success (such as a previous criminal conviction). With these concerns in mind, the Liver Advisory Group admit that the use of *specific* factors to predict a relapse is not appropriate because of weak evidence, and that further research is required to identify factors that can *reliably* predict a poor outcome in terms of graft function and survival.<sup>25</sup> However, the Liver Advisory Group still remind transplant teams that:

Robust criteria for predicting a return to heavy drinking and its consequences on graft function must: i) discriminate consistently and be clinically meaningful; ii) be objective and measureable; iii) be fair; iv) cannot be, or likely to be, modified.<sup>26</sup>

If risk factors must be reliable to provide an accurate prediction of relapse, should transplant teams be left with only a vague framework with which to create their own assessment criteria? Perhaps the likelihood of relapse should not be assessed until reliable risk factors can be provided by an endorsing body? The Liver Advisory Group do not provide any more guidance on alcoholic candidate assessment, preferring to focus on contraindications instead (below). These assessment criteria are therefore disappointingly vague considering their objective to combat the potential risk of recurrent disease or poor compliance leading to graft loss. It is also extremely difficult to identify any other factors that are 'clinically meaningful, objective, measureable, fair and cannot be modified' other than a candidate's age and blood type. How do transplant teams ensure that their

assessments of alcoholic candidates are consistent, fair and clinically meaningful when they have no clear, objective, calculable risk factors at hand when assessing the candidate? The good news, incorporated from the Department of Health's National Standards, is that candidates admitted for assessment where alcohol has contributed to their liver disease will be assessed by a specialist in substance misuse.<sup>27</sup> This will ensure a more understanding and compassionate assessment experience, but candidates may still fear that their transplant teams will find it relatively easy to 'predict' a relapse on little medical evidence.

The four contraindications to transplantation are interesting. It was agreed by the Liver Advisory Group that there were several factors, each of which precluded listing for a transplant, because a poor outcome for the graft was likely.<sup>28</sup> It is encouraging to see utility as the primary reason for excluding alcoholic candidates from transplantation as opposed to social or moral reasons, although this does not provide much hope for gravely ill, minority, elderly or non-rehabilitated candidates.

The first contraindication to transplantation is alcoholic hepatitis, which does not cause any significant ethical problems. The second contraindication to transplantation is more than two episodes of non-compliance with medical care where there was not a satisfactory explanation, but this should not be confined to management of their liver disease.<sup>29</sup> This is a strange request from the Liver Advisory Group. It appears that a candidate's medical history may be meticulously examined for non-compliance to *any* medical treatment. Is it fair to exclude a candidate from transplantation on the grounds that he did not comply to unrelated medical care in the past? Admittedly, any past non-compliance may help a transplant team to shed some light on a candidate's motivation levels, but to request a 'satisfactory explanation' is particularly pretentious. Perhaps it would be better to simply *consider* a candidate's past non-compliance rather than asking the candidate to *justify* his bad behaviour like a naughty school-child? This could lead to NHSBT 'punishing' the candidate by excluding him from life-saving treatment. The third contraindication to transplantation is a return to drinking following full professional assessment and advice (this includes permanent removal from the list if found to be drinking while listed).<sup>30</sup> From a clinical point of view, this ground for exclusion is justified; abstinence from alcohol whilst awaiting a liver transplant is vital as it allows the candidate to detoxify his body; it enables a more successful graft, and it demonstrates the candidate's motivation and dedication towards his post-transplant care. From an ethical point of view however, by *permanently* excluding from transplantation a candidate who is found to be drinking whilst on the waiting list, are NHSBT again seeking to punish candidates

for their socially unacceptable behaviour? Why permanent removal? Perhaps it might be more rehabilitative to place relapsing candidates on a 'pending' waiting list, or monitored over time in accordance with a long-term approach to assessment?

The fourth and final contraindication to transplantation is concurrent or consecutive illicit drug use (except occasional cannabis use).<sup>31</sup> It is interesting that only highly dangerous illegal drugs—such as heroin or cocaine—are viewed as contraindications. Cannabis use is known to cause high blood pressure, paranoia, panic attacks and loss of co-ordination in users<sup>32</sup> and may also connect to social, environmental, financial, employment and criminal justice issues. Why has the Liver Advisory Group made allowances for cannabis use? It may be that candidates who abuse highly dangerous substances such as heroin are assumed to be more likely to display anti-social behaviour and not comply with post-transplant care, but there are no reliable clinical indicators to support this assumption.

The Liver Advisory Group/NHSBT may have made matters a little more difficult with their 2005 alcoholic guidelines. In order to combat the risk of recurrent disease, poor compliance and graft loss they have listed four seemingly clinical contraindications to transplantation, but these contraindications simply encourage a highly subjective and meticulous examination of a candidate's personal and social life. Social prejudices appear to be scattered throughout the alcoholic contraindications with NHSBT seeking to strictly punish (i.e. permanently exclude) candidates who have not behaved in an acceptable way, and because the Department of Health played no part in developing these additional guidelines, NHSBT are free from strict supervision or radical reform.<sup>33</sup> As a result, transplant teams seem free to exclude difficult candidates from transplantation on ambiguous and undetermined grounds, and the recommendation that their decision must be 'clinically meaningful, objective, measurable and fair' means little when no further guidelines are provided to guarantee a more consistent assessment strategy. Primary concerns centre around contraindications two (permanent exclusion failing a satisfactory explanation for past non-compliance) and three (permanent exclusion for drinking whilst listed), which encourage transplant teams to take a heavy-handed approach to candidates who are still perfectly suitable for a graft as long as they remain abstinent for a set amount of time and can prove to the substance abuse specialist that they are dedicated to their post-transplant care. Additional concerns relate to the lack of consistent decisions and the wealth of discretion awarded to transplant teams when assessing such personal matters. Reliable and detailed standards would make it exceptionally difficult for a transplant teams' biased views (or the views of a particular specialist) to be incorporated into the candidate assessment process.

However, there is some good news for candidates in the form of redress for unwelcome decisions: ‘if a possible recipient is found by the multi-disciplinary team not to be a suitable candidate then the opportunity for a second opinion from a second liver transplant unit should be offered’.<sup>34</sup> This may only provide limited hope for a candidate who feels he or she has been discriminated against and it will have no regulatory affect on the conduct of transplant teams, but it does illustrate a desire on the part of NHSBT to accommodate as many candidates as possible.

*(iii) Recommendations for liver transplant assessment of candidates who use illicit drugs (2007)*

In 2007, the Liver Advisory Group published further assessment guidelines for liver transplant candidates who were involved in illicit drug use.<sup>35</sup> These guidelines, compared to the alcohol guidelines of 2005, are much more painstaking when assessing a candidate’s personal circumstances. There may be three explanations for this: (a) illicit drug use is highly damaging to the liver; (b) it may reveal problems with the candidate’s state of mind; and (c) the general public may not condone their donated organs to be allocated to illicit drug users. What is also unique about the 2007 drug guidelines is that contraindications to transplantation are followed by *potential* contraindications to transplantation, as if to make doubly-sure that a candidate’s circumstances are meticulously scrutinised.

The 2007 drug guidelines begin with a clear direction from the Liver Advisory Group to transplant teams that no stone should be left unturned when assessing illicit drug using candidates:

Any candidate considered to have a significant drug taking history should be assessed by a specialist in substance misuse. The term ‘significant’ must be interpreted by the clinical, multi-disciplinary team. Assessment should include problematic or dependant use as well as recent use. It should also identify substance use and stability within the candidate’s wider social support network, and take into account mental health and criminal justice issues as appropriate.<sup>36</sup>

It becomes clear from this direction that the assessment of drug using candidates will involve much wider psychological and social considerations than those of other candidates. The ‘stability’ of the candidate’s social circle is a particularly unusual criterion to measure to ascertain whether a candidate can successfully undergo a medical procedure, and the examination of criminal justice issues will be an uncomfortable leap out of the ambit of medicine for some candidates.

The 2007 drug guidelines may therefore make a small handful of candidates feel very vulnerable to biased decisions.

The 2007 drug guidelines list five contraindications to transplantation. The first contraindication recommends that candidates who display ongoing intravenous use of illicit or non-prescribed substances will be excluded from the waiting list.<sup>37</sup> Interestingly, in NHS Blood and Transplant's 2009 liver transplant protocols (based on the Department of Health's National Liver Transplant Standards), continued intravenous drug use is listed a contraindication to transplantation owing to the possible risk of infection in a immunosuppressed candidate,<sup>38</sup> but there is no indication in the 2007 drug guidelines that this contraindication is underpinned by a clinical ideology. Is this merely an oversight by the Liver Advisory Group, or do they believe that all contraindications to transplantation in drug abuse assessment guidelines will be accepted as correct without the need for clinical justification? Perhaps NHSBT could make it clearer that any assessment guidelines adopted for the use of assessing drug using candidates are based on medical grounds? The second contraindication is similar to the 2005 alcohol guidelines in that a candidate who shows two or more incidents within 2 years of unexplained and significant non-compliance with treatment not necessarily confined to the management of liver disease will be excluded from transplantation.<sup>39</sup> As explained earlier, this alludes to NHSBT 'punishing'—through exclusion from life-saving treatment—candidates who can not justify their non-compliant behaviour.

Contraindications 3 and 4 are unique to the 2007 drug guidelines and require:

A current failure to comply with the assessment and treatment process for transplantation, refusal to provide consent for gaining access to information pertaining to drug treatment and prescribing, and a recent past history of cross dependency (substituting from one drug to harmful/problematic use of another), within the last 2 years.<sup>40</sup>

The Liver Advisory Group advance a rather biased view in this contraindication: (a) illicit drug users will not comply with the assessment process; (b) they will not comply with the treatment process; and (c) they will refuse to allow the medical team to access their medical records. It is unusual to see patients being excluded from medical treatment on the grounds of their unruly behaviour, but it is even more unusual for a national health organisation to expressly presuppose that a particular group of candidates will sabotage their own chances of survival. Why is this contraindication applicable to drug using candidates but not alcoholics or mentally ill candidates? No clinical rationale is presented to support this contraindication

which would, in turn, make the contraindication applicable to other groups of candidates too. Perhaps one possible explanation for this contraindication is the public pressure exerted upon organ procurement agencies to allocate livers sensibly?. It also seems a little odd that a candidate will be excluded from transplantation if he or she switches from one harmful drug to another within a 2 year period. There seems little point in distinguishing between a candidate who abuses several different substances from a candidate who abuses just one. Apart from indicating that the former candidate may have displayed a lack control over his drug use in the past, it is difficult to ascertain how switching from one illicit drug to another can justify a further ground for excluding a candidate from transplantation. What must surely matter is the candidate's *current* drug use and how that will affect his liver graft presently? If a candidate is a suitable clinical match to a donor liver, NHSBT will find it hard to argue based on these 'anti-social' grounds that they are not discriminating against drug using candidates when excluding them from transplantation.

The fifth and final contraindication to transplantation states that the length of abstinence from illicit drugs should not be less than 6 months, and the candidate must engage in an optimum substance misuse treatment programme.<sup>41</sup> This contraindication gives candidates the opportunity to prove that they are dedicated towards their treatment, and it gives their bodies a chance to recover from the effects of drug use.

Uniquely, the 2007 drug guidelines include *potential* contraindications, which allow transplant teams to examine additional characteristics which *may* jeopardise a candidate's graft success (this is not confirmed), but it is left up to the transplant team to decide whether the particular characteristic *is* a contraindication to transplantation or not. Three of the seven potential contraindications listed in the guidelines are particularly controversial:

- (i) insufficient social support network to remain abstinent from illicit drugs, and where it is not possible to work with the candidate to facilitate a suitable and acceptable social support package; (ii) lack of motivation to move away from drug using culture/area within the confines of opportunity; and (iii) reluctance to agree to drug treatment and after-care or to sign a treatment agreement.<sup>42</sup>

In real terms, according to the Liver Advisory Group, a transplant team may therefore exclude a drug using candidate from transplantation if: (i) he does not have a supportive social group of friends; (ii) he can not feasibly sustain a support package in his current area; (iii) he does not show a desire to move into a better area; and (iv) he is reluctant to agree to drug treatment. These liver transplant assessment

guidelines are beginning to read like a drug rehabilitation programme. With the exception of criterion (iv), which places the onus upon the candidate to behave in a socially acceptable manner, criteria (i), (ii) and (iii) isolate the candidate's social environment as a barrier to transplantation. In terms of efficiency, it is logical that the candidate should show dedication towards his aftercare programme and that he can rehabilitate himself for graft success, but to expect him to remove himself from his environment, culture and social circle at the first possible opportunity—presumably to a 'better area' to become a 'better person'—seems wholly prejudiced of NHSBT. How would a transplant team clinically and fairly assess these criteria in a way that was objective and consistent to the candidate? As long as the candidate abstains from his drug use six months prior to transplantation, shows the motivation to continue his aftercare programme and is a clinical match to the donor liver, all further considerations about *any* candidate's social life and culture should not come within the ambit of medical assessment.

As with the 2005 alcohol guidelines, the Liver Advisory Group/NHSBT presents a controversial collection of guidelines which make more complicated an assessment process that was already fraught with ethical difficulties. The most problematic criteria by far in the 2007 drug guidelines is the examination of a candidate's social circle, and in particular the 'substance use and stability within the patient's wider social support network.' It is not practically possible to objectively assess this criteria in a way that clinically renders the candidate suitable or unsuitable for a liver transplant. Short of tracking down individuals who are in no way related to the transplantation and examining their lifestyle choices and behavioural problems, transplant teams are unable to consistently assess a candidate's social network in a way that could fairly influence their decision. Another significant concern is the level of prejudice that emerges in the potential and actual contraindications. We again see an supposition by the Liver Advisory Group/NHSBT that substance abusing candidates will intentionally sabotage their own chances of survival through refusal, reluctance and non-compliance. The additional requirement that a drug using candidate should enjoy a sufficient social network in order to secure a 'suitable and acceptable social support package' is simply discriminatory. These highly subjective criteria will be a significant concern for drug using candidates who experience liver failure, whether their predicament was caused by their anti-social behaviour or not. Interestingly, no reference made in the 2007 drug guidelines to a 'second opinion' or any other form of redress. Is this merely an oversight, or are drug users simply too much of a risk for organ procurement agencies?

## CONCLUSION: A WAY FORWARD?

NHS Blood and Transplant must ensure that all potential transplant candidates are offered a fair and unbiased assessment experience. The Department of Health's National Liver Transplant Standards fail to provide NHSBT with any firm regulatory or ethical guidance to ensure an impartial assessment experience for liver transplant candidates, and with only the ambiguous National Standards available to support the development of agency-level assessment protocols, NHSBT and the Liver Advisory Group have been free to draft most of the guidelines from scratch. This liberty is reflected in the assessment protocols for regular candidates (2009), alcoholic candidates (2005) and drug-using candidates (2007).

At first glance, NHSBT's 2009 protocols are encouraging in that they develop the National Standards to include more candidates, but this initiative creates a further problem: an all-inclusive approach requires comprehensive assessment criteria to ensure that all candidates are assessed fairly, objectively and in conjunction with their special needs. NHSBT appears to simply hand all power to transplant teams to choose how, and against what criteria, all individuals are assessed. Depending on the cause of the candidate's liver failure and the specialists assigned to his case, a candidate's transplant team may therefore examine (and nominate as a contraindication to transplantation) the following factors: urgency, motivation, utility, sociology, justice, employment, equality, psychology, environment or morality. NHSBT can not, therefore, guarantee that when a candidate's array of characteristics are placed under the microscope for a detailed examination, the outcome will be impartial and objective. Transplant teams have no definitive benchmarks against which to consistently measure these non-medical factors. Candidates who are gravely ill, elderly or self-inflicting are particularly vulnerable to the inconsistent decisions of 'tailor made' transplant teams as they present further ethical quandaries, and transplant teams are themselves vulnerable to public pressure, making strict decisions much more likely.

NHSBT has endorsed two further assessment guidelines by the Liver Advisory Group for the fair assessment of alcoholic and drug using candidates. These additional guidelines, which are meant to bring clarity and consistency to the assessment process, lack the meticulous detail required to assess complex cases. Those who have caused their own liver to fail through alcohol or drug abuse face a much more painstaking assessment process than those who have not, regardless of any promises of the contrary (e.g. NHSBT's official website states: 'we ensure that organs donated for transplant are matched and allocated to patients in a fair and unbiased way'<sup>43</sup>). Alcoholic candidates face a difficult assessment process, and

although a second opinion at another unit is offered (which could vaguely resemble 'redress' for unfairly rejected candidates), NHSBT's 2005 alcohol assessment guidelines appear to mirror the Department of Health's rather negative attitude towards alcoholic candidates by excluding them from transplantation on behavioural grounds. Drug using candidates face further prejudiced obstacles during assessment, including the examination of *potential* contraindications to allow for an even more scrupulous assessment of the candidate's personal life. Not only are drug-using candidates anticipated to sabotage their chances of survival by refusing to provide access to medical records and not complying with medical care, with no method of redress listed for drug using candidates, the overall assessment outlook for these individuals is unwelcoming. NHSBT claim to distance themselves from prejudice by promising fair and equal access to organs, but the examination of a candidate's social network is unquantifiable and unfair and renders particular candidates victims of their own social circumstances. These candidates may also resent the label of 'substance abuser' (used in the 2007 guidelines), and they may feel condemned to months of counselling, delays and discrimination for their social problems before a fair assessment process can even begin. So what can be done?

It may be that the segregation of complex candidates is causing the problem: NHSBT's current assessment guidelines are too ambiguous to deal with complex candidates, leading to the separation of alcoholic and drug using candidates from the standard assessment process and the development of separate assessment guidelines to deal with this. Perhaps a 'universal' assessment strategy could be created to apply to all liver transplant candidates, so that a patients' drug and alcohol abuse could be viewed as a clinical factor in an extensive assessment process rather than a social problem that underpins the whole assessment strategy. There would then be no need to produce separate guidelines for specific candidates which create delays, alienation and prejudice. A new universal protocol would, of course, need to be meticulous and complex in clinical terms, allowing for the fair exclusion of candidates who pose a direct health risk to their new liver. It would also require objective and measurable assessment criteria to allow for the objective examination of all clinical factors (which could include limited access to aftercare), and there should be an express prohibition of the examination of social or psychological issues unless they would directly (i.e. clinically) cause the graft to fail.<sup>44</sup> An assurance could also be provided that NHSBT will look into any allegations of prejudice by transplant teams. This universal and clinical policy would efficiently remove inefficient candidates from the transplantation process without publically assessing them separately from other candidates.

One would have hoped that when drafting such contentious protocols, NHSBT would have adopted a much more meticulous approach to detail. This is almost inevitable when considering that NHSBT is under no immediate pressure from any higher authority to ensure that the candidate assessment process is as comprehensive as it should be.

## NOTES

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- 1 See [www.organdonation.nhs.uk](http://www.organdonation.nhs.uk) (date last accessed 3rd November 2010). This is the official website for up-to-date policies, current practices, self-help guides, statistics, and transplantation and donation information.
- 2 The Department of Health: National Liver Transplant Standards. National Specialist Commissioning Advisory Group (NSCAG). August 2005. Available at: <http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance> (date last accessed 3rd November 2010); NHS Blood and Transplant and the Liver Advisory Group: Protocols and Guidelines for Adults Undergoing Deceased Donor Liver Transplantation in the UK. Protocols and Guidelines. September 2009; and Operating Principles for Liver Transplant Units in the UK and Republic of Ireland. July 1999, both available at: [http://www.organdonation.nhs.uk/ukt/about\\_transplants/organ\\_allocation/liver/liver.jsp](http://www.organdonation.nhs.uk/ukt/about_transplants/organ_allocation/liver/liver.jsp) (date last accessed 3rd November 2010).
- 3 NHS Blood and Transplant 2009 Protocols. See note 2 above.; Liver Advisory Group Alcohol Guidelines: UK Liver Transplant Group Recommendations for Liver Transplant Assessment in the Context of Alcohol-related Liver Disease. November 2005; and Liver Advisory Group Drug Guidelines: Version 1: UK Liver Transplant Group Recommendations for Liver Transplant Assessment in the Context of Illicit Drug Use. May 2007. All available at: [http://www.organdonation.nhs.uk/ukt/about\\_transplants/organ\\_allocation/liver/liver.jsp](http://www.organdonation.nhs.uk/ukt/about_transplants/organ_allocation/liver/liver.jsp) (date last accessed 3rd November 2010).
- 4 The Department of Health: National Liver Transplant Standards. See note 2 above, introduction.
- 5 See note above.
- 6 See note 2 above, topic 2: The Specialist Multidisciplinary Team, national standard 2.1.
- 7 See note above, national standards 2.8.4, 2.8.5 and 2.8.6.
- 8 See note 2 above, national standard 2.8.17
- 9 See note above, national standards 3.1, 3.2, 3.5, 3.9, 3.10 and 3.13.
- 10 See note 2 above, introduction.
- 11 See note above, introduction, outcome (d), and national standard 1.11.
- 12 See note 2 above, national standard 1.10.
- 13 NHS Blood and Transplant and the Liver Advisory Group: Protocols and Guidelines for Adults Undergoing Deceased Donor Liver Transplantation in the UK. Protocols and Guidelines. September 2009; Liver Advisory Group Alcohol Guidelines: UK Liver Transplant Group Recommendations for Liver Transplant Assessment in the Context of Alcohol-related Liver Disease. November 2005; and Liver Advisory Group Drug Guidelines: Version 1: UK Liver Transplant Group Recommendations for Liver Transplant Assessment in the Context of Illicit Drug Use. May 2007. All available at: [http://www.organdonation.nhs.uk/ukt/about\\_transplants/organ\\_allocation/liver/liver.jsp](http://www.organdonation.nhs.uk/ukt/about_transplants/organ_allocation/liver/liver.jsp) (date last accessed 3rd November 2010).

- 14 NHS Blood and Transplant 2009 Protocols. See note 13 above. Summary, at page 1.
- 15 See note above.
- 16 The Department of Health: National Liver Transplant Standards. See note 2 above, introduction.
- 17 See Alan Williams, 'The Value of QALY's', (1985), *Health and Social Service Journal* 94; Souzy Dracopoulou (ed), 'Economics, QALY's and Medical Ethics: A Health Economist's Perspective', *Ethics and Values in Health Care Management*, (1998), Routledge, London; John Harris, 'QALYfying The Value of Life', (1987), 13 *Journal of Medical Ethics* 117; and Peter Singer, 'Double Jeopardy and the Use of QALY's in Health Care Allocation' (1995), 21 *Journal of Medical Ethics* 144.
- 18 NHS Blood and Transplant 2009 Protocols. See note 13 above, paragraph 3.2, at page 4.
- 19 For further academic discussion about alcoholic and smoking transplant candidates, see: Jonathan Glover, *Causing Death and Saving Lives*, Penguin London, (1977); Tom Beauchamp and James Childress, *Principles of Biomedical Ethics*, 5th Edition, Oxford University Press, (2001); Tony Hope, David Sprigings, and Roger Crisp, "'Not clinically indicated": patients' interests or resource allocation?' *British Medical Journal*, (2003), 6 Feb., Vol. 306; Martin Benjamin, 'Transplantation for Alcoholic Liver Disease: the ethical issues', *Liver Transplantation and Surgery*, (1997), vol. 3, No. 3, May; J.L. Nelson, *Hippocrates' Maze: Ethical Explorations of the Medical Labyrinth*, Rowman & Littlefield NY, (2003); John Harris, 'Could we hold people responsible for their own adverse health?' (1995), 12 *Journal of Contemporary Health Law and Policy* 147 and 'Organ Procurement: dead interests, living needs', (2003), *Journal of Medical Ethics* 130; Robert Blank, *Rationing Medicine*, Columbia University Press New York, (1988); Roger Higgs, 'Human frailty should not be penalized', *British Medical Journal*, Vol. 306, 17 Apr. 1993; and Peter A. Ubel, 'Transplantation in Alcoholics: separating prognosis and responsibility from social biases', *Liver Transplantation and Surgery*, Vol. 3, No. 3, May 1997; Ranaan Gillon, 'On giving preference to prior volunteers when allocating organs for transplantation', (1995), 21 *Journal of Medical Ethics*, 195; Stephanie Eaton, 'The subtle politics of organ donation: a proposal', (1998), 24 *Journal of Medical Ethics* 166; Hugh McLachlan, 'Smokers, virgins, equity and health care costs', (1995), 21 *Journal of Medical Ethics* 209; Burra and Lucey, 'Liver transplantation in alcoholic patients' (2005) 18 *Transplant International* 491; Oniscu et al., 'Equity of access to renal transplant waiting list and renal transplantation in Scotland' (2003) 327 *British Medical Journal* 1261; Cohen, 'Alcoholics and liver transplantation' (1991) 265 *Journal of the American Medical Association* 1299; and Neuberger and James, 'Guidelines for selection of patients for liver transplantation in the era of donor-organ shortage' (1999) 354 *The Lancet* 1636.
- 20 The Department of Health: National Liver Transplant Standards. See note 2 above, national standards 3.1, 3.2, 3.5, 3.9, 3.10 and 3.13.
- 21 NHS Blood and Transplant 2009 Protocols. See note 13 above, paragraph 3.2.1., page 4.
- 22 Liver Advisory Group Alcohol Guidelines: UK Liver Transplant Group Recommendations for Liver Transplant Assessment in the Context of Alcohol-related Liver Disease. November 2005. Available at: [http://www.organdonation.nhs.uk/ukt/about\\_transplants/organ\\_allocation/liver/liver.jsp](http://www.organdonation.nhs.uk/ukt/about_transplants/organ_allocation/liver/liver.jsp) (date last accessed 3rd November 2010).
- 23 See NHS Blood and Transplant's official website under 'about transplants' and 'organ allocation': [www.organdonation.nhs.uk/ukt/about\\_transplants/organ\\_allocation/liver](http://www.organdonation.nhs.uk/ukt/about_transplants/organ_allocation/liver) (date last accessed 3rd November 2010).

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- 24 Liver Advisory Group 2005 Alcohol Guidelines. See note 22 above, 'Assessment', page 1.
- 25 See note above, 'Contraindications to listing', pages 1-2.
- 26 As above.
- 27 See note 24 above.
- 28 See note 22 above, 'Contraindications to listing', page 1.
- 29 As above.
- 30 See note 28 above, bracketed text included in policy.
- 31 As above.
- 32 See [www.talktofrank.com](http://www.talktofrank.com)—the UK Government's drugs website belonging to [www.drugs.gov.uk](http://www.drugs.gov.uk) (date last accessed 3rd November 2010).
- 33 The Department of Health do make provisions for additional guidelines to be developed by other agencies. The Department of Health: National Liver Transplant Standards. See note 2 above, national standard 2.8.17.
- 34 Liver Advisory Group 2005 Alcohol Guidelines. See note 22 above. 'Second opinion', page 3.
- 35 Liver Advisory Group Drug Guidelines: Version 1: UK Liver Transplant Group Recommendations for Liver Transplant Assessment in the Context of Illicit Drug Use. May 2007. Available at: [http://www.organdonation.nhs.uk/ukt/about\\_transplants/organ\\_allocation/liver/liver.jsp](http://www.organdonation.nhs.uk/ukt/about_transplants/organ_allocation/liver/liver.jsp) (date last accessed 3rd November 2010).
- 36 See note above, paragraph 2, 'Assessment', page 1.
- 37 See note 35 above, paragraph 2.1, 'Contraindications', point I, page 2.
- 38 NHS Blood and Transplant 2009 Protocols. See note 13 above, paragraph 3.2.2., page 4.
- 39 Liver Advisory Group 2007 Drug Guidelines. See note 35 above, paragraph 2.1, 'Contraindications', point II, page 2.
- 40 See note above, points III and IV, page 2.
- 41 See note 35 above, paragraph 2.1, 'Contraindications', point V, page 2.
- 42 See note above, paragraph 2.2, 'Potential contraindications', pages 2–3.
- 43 See [www.organdonation.nhs.uk/ukt/about\\_us](http://www.organdonation.nhs.uk/ukt/about_us) (date last accessed 3rd November 2010).
- 44 A psychiatric liaison nurse could help with this.