

Does the United States Do It Better? A Comparative Analysis of Liver Allocation Protocols in the United Kingdom and the United States

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NHS Blood and Transplant (NHSBT) is responsible for the procurement and allocation of human organs in the United Kingdom.¹ Its main role is to “ensure that organs donated for transplant are matched and allocated to patients in a fair and unbiased way.”² NHSBT’s liver allocation policies are underpinned by the National Liver Transplant Standards, a document published by the Department of Health in 2005 to oversee patient care, patient assessment, liver allocation and transplantation, education and training, and research and development.³ NHSBT has developed its own liver allocation protocols under the powers assigned to it by the Department of Health, which include a “super-urgent” liver allocation policy, a Liver Allocation Sequence, and pediatric candidate liver allocation protocols.⁴

In the United States, the United Network for Organ Sharing (UNOS) governs the Organ Procurement and Transplantation Network (OPTN), which maintains the national organ transplant database (UNet).⁵ UNOS similarly assures the public that it has “established an organ sharing system that maximizes the efficient use of deceased organs through fair and timely allocation.”⁶ UNOS was formally established by the National Organ Transplantation Act in 1984. In 1999, the U.S. Department of Health and Human Services published the Final Rule, a federal regulation outlining the operation of the Organ Procurement and Transplantation Network, which was launched in 1986. Similar to the United Kingdom, UNOS has also developed its own liver allocation policy, entitled Policy 3.6. This policy implements a unique mortality scoring system for both adult and pediatric liver transplant candidates.

The primary job of both agencies is to allocate human organs to suitable transplant candidates using objective medical criteria. In light of the shortage of livers, NHSBT and UNOS are under considerable pressure to allocate their resources not only to those who *need* them the most but to those who will derive the most *benefit* out of them (referred to hereafter as the need principle and the “best bet” principle). A combination of need and efficiency will ensure that when a candidate is selected for transplantation, the allocation is morally justified *and* economical. Can an organ procurement agency successfully manage the battle between need and efficiency through the creation of ethically balanced organ allocation protocols? For example, do NHSBT and UNOS consider need and efficiency *equally* when allocating livers, or is the need criterion (i.e., medical urgency) often the dominant factor when selecting the appropriate candidate?

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Alternatively, how far can considerations of “best bet” apply, and how ethical are the limits? Particularly vulnerable groups of candidates—such as the very old, the frail, and minority groups—may be particularly vulnerable in the light of economically based allocation policies.

What follows below is a comparative analysis of the national and agency-level liver allocation procedures in both countries and the ethical principles underpinning them.

The United Kingdom: NHS Blood and Transplant

NHSBT is the United Kingdom’s primary organ procurement agency. It is responsible for matching and allocating donated human organs nationwide. There are approximately 8,000 candidates registered on the official National Transplant Database,⁷ and in the period from April 1, 2008 to March 31, 2009 there were 667 successful liver transplants.⁸

National Liver Allocation Guidelines

In 2005, the Department of Health published its National Liver Transplant Standards to support NHSBT’s professional practice. The National Standards include diagnostic, assessment, allocation, transplantation, training, and development objectives. Although it is left up to the NHSBT to incorporate these National Standards into its own policies, the Department of Health does reveal the principles that it believes should underpin the liver allocation process.

First and foremost, the National Standards support the separation of urgent candidates from nonurgent candidates during the selection process: “Because patients referred with fulminate hepatic failure are likely to die within a few days of diagnosis, they receive priority over all other patients in a ‘super-urgent’ category. Patients with primary liver graft failure or early hepatic artery thrombosis are also eligible for ‘super-urgent’ listing” (Standards 3.5 and 3.20).⁹ The Department of Health is also mindful of economical issues when listing candidates: “Patients assessed by experienced psychiatrists as likely to continue their habit are usually regarded as unsuitable for liver transplantation. Based upon the principle that donor livers should be placed according to greatest benefit, it is currently recommended that organs should be allocated to patients who have at least 50% chance of surviving five years post transplant” (Standards 3.11 and 3.13).¹⁰ These statements reveal two things: there is considerable pressure on the Department of Health to allocate its resources efficiently and a candidate’s medical need is a chief allocation priority. On candidate selection, the National Standards list a generous collection of medical factors to be calculated to find a suitable match: “matching for age, size and blood group are important and, other factors being equal, time on the waiting list will then identify the recipient. However, the condition of patients on the waiting list and the quality of the donor liver must also be taken into account. Patients who deteriorate whilst waiting for a liver transplant may become too sick to stand a reasonable chance of surviving the procedure. They might have to be removed from the waiting list” (confirmed by standard 3.19).¹¹ The Department of Health has listed many medical criteria for NHSBT to calculate, allowing for the “best bet” candidate to be found among a rather large pool of candidates. Interestingly, it appears that

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“waiting time” (the “first-come first-served” principle) is withheld as an allocation criteria until two or more equal matches are found. This would ensure that the deciding criterion is impartial and fair.

In line with the Department of Health’s recommendations, the NHSBT has separated liver transplant candidates into two main categories in their 2009 Protocols and Guidelines for Adults Undergoing Liver Transplantation: super-urgent and elective.¹² Super-urgent candidates must be diagnosed with one of the following medical ailments: paracetamol poisoning, seronegative hepatitis, acute Wilson’s disease, hepatic artery thrombosis, graft dysfunction, or liver failure.¹³ The NHSBT has also incorporated the Department of Health’s economical “50% survival/five year rule” into its 2009 Protocols, stating that candidates who do not meet one of the super-urgent criteria will be accepted for elective transplantation if this rule applies to them in addition to being diagnosed with chronic liver disease or failure, hepatocellular carcinoma, a variant syndrome, or acceptance through the National Appeals Panel.¹⁴ These rather strict admittance criteria by the NHSBT reflect the Department of Health’s firm approach: a candidate must be in grave need, but he must also be an efficient host for an organ. The NHSBT openly expresses throughout its 2009 Protocols that it wishes to measure benefit: “There remains a gap between the number of patients suitable for liver transplantation and the number of donated human livers. Decisions on selection of patients for liver transplantation have to be made on criteria other than just medical need. . . . [S]uch protocols must balance the often competing issues of equity of access for all with overall utility (or benefit in outcome).”¹⁵ It is important that as an organ procurement agency, the NHSBT is seen supporting many resource allocation principles to allow for a varied and balanced organ allocation system. A candidate’s medical need now appears to share the spotlight with considerations of equal access and efficiency—is the NHSBT taking a more objective approach? Not quite. The NHSBT opens an entirely new category of candidates: individuals who are not super-urgent or elective may also be considered for transplantation if “they have an anticipated length of life of less than one year or an unacceptable quality of life,” and the 5-year posttransplant survival rate must come with “a quality of life acceptable to the patient.”¹⁶ This loosening of the strict admittance criteria by the NHSBT and an understanding of unique candidate circumstances show how an application of the need principle can open important doors for particular candidates who would ordinarily be excluded from transplantation.

Regarding the selection of candidates, the NHSBT inserts an interesting directive into its 2009 Protocols: “Other medical and social factors (such as alcohol or drug misuse, age or antisocial life style) are not directly relevant other than whether they affected the 50% survival/five year rule.”¹⁷ The Department of Health stated in its National Standards that “habitual” candidates would not be suitable for transplantation because of their limited benefit,¹⁸ but the NHSBT appears to be actively encouraging the assessment of social factors *if* these factors are expected to scupper a candidate’s efficiency. This highly economical approach is not good news for most candidates: it is difficult to imagine any instance in which a candidate’s antisocial behavior (e.g., substance abuse) or age (e.g., considerably elderly) would *not* have a direct impact on her efficiency as a transplant recipient, particularly if her social behavior contributed to her organ failure. It is understandable that the NHSBT feels a weighty responsibility to ensure longevity

for transplanted organs and guarantee that the selected candidate is strong enough—both physically and mentally—to survive her surgery and postoperative care, but this rather strict application of the “best bet” principle could be interpreted as an overruling of a candidate’s medical need. If a candidate is not physically, mentally, or socially efficient, her level of need (e.g., one day from death) will matter little to the NHSBT. Additionally, the consideration of social factors may also be construed by some as an application of the moral worth principle, which should not, ideally, be a basis for scarce organ allocation.

It has been shown that the Department of Health and NHS Blood and Transplant consider medical need and efficiency to be primary considerations when allocating scarce resources. A combination of need and efficiency is vital to ensure that the gravest of candidates receive their treatment first *and* that they will acquire a significant benefit from it. However, this combination also suggests that super-urgent places will be tightly restricted to those who, with a transplant, could show a 50% chance of surviving for at least 5 years, thus excluding many gravely ill patients from transplantation. This “combined” policy actually demonstrates how the need principle can be “trumped” by the “best bet” principle when an organ procurement agency wishes to promote “sustainable” organ allocation. There is also be a sprinkling of additional principles in the U.K. National Standards, such as the “first-come first-served” principle, to encourage liver allocation in favor of objective selection. However, can the radically impartial “first-come first-served” approach really be in the best interests of transplant candidates?

Agency-Level Liver Allocation Protocols

NHS Blood and Transplant allocates donor livers according to its Liver Organ Sharing Principles, which were first published in 1999 by UK Transplant.¹⁹ The 1999 Principles outline liver allocation procedures for super-urgent candidates, elective candidates (the Liver Allocation Sequence), and pediatric candidates.

Super urgent candidates in the United Kingdom are ranked according to minimal criteria: “the sequence of offers for recipients registered as Super Urgent will be *strictly* in relation to blood group and the time of registration: the blood group compatible patient having been registered the longest at any one time taking priority, and thereafter in reverse chronological order by time of registration.”²⁰ Blood group is the only relevant medical factor to be calculated by the NHSBT when selecting a super-urgent candidate. This criterion will only reveal which super-urgent candidate is the “best bet” for the available organ, not the candidate’s super-urgent status. Some may be closer to death than others. What about the progression of the candidate’s disease? A more needs-based test could include a mortality scoring system to ensure that the gravest of super-urgent candidates will be selected first, although the Department of Health has made it clear that this is not the favored approach in the United Kingdom: “Although prognostic models can predict survival without transplant for a few specific liver diseases, there is no scoring system that has universal applicability. Scoring systems may aid clinical decision-making but should not replace expert clinical judgment.”²¹ The NHSBT distances itself further from a needs-based approach by incorporating registration time into its super-urgent policy. The “first-come first-served” principle does not require any medical calculations,

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making the choice wholly impartial when a transplant candidate is selected. But within in a “super-urgent” category, is not the most urgent candidate selected first? The application of a “first-come first-served” principle to a super-urgent scheme contradicts the very meaning of the category.

The Liver Allocation Sequence was first created by UK Transplant as a means of allocating donor livers to all other liver transplant candidates.²² The process is described in UKT’s 1999 Principles:

The liver allocation sequence will be used to advise designated centres²³ of the availability of a donor organ, *regardless of whether a patient of the appropriate blood group is registered from their unit on the National Transplant Database at the time*. The sequence will be sequenced according to each centre’s transplant activity, based on a rolling 4-week period. The centre with the least number of transplants during this period will appear top of the sequence, down to the centre with the most number of transplants. Offers will be made to non-designated centres in accordance with the liver allocation sequence only when a suitable blood group recipient is registered from their unit on the National Transplant Database.²⁴

This unique Sequence is curious. An elective candidate will only become available for selection if (i) he is placed in an underresourced designated center or (ii) he is placed in a nondesignated center (considered *after* designated centers) and he is a blood match. Why would an organ procurement agency expressly ignore blood match when searching for a transplant candidate? Why implement this policy for underresourced centers only? Should underresourcing have an influence on organ allocation, or take precedence over finding the “best bet” candidate? The Liver Allocation Sequence may be an example of the justice principle, which claims that resources should be shared out impartially using objective and fair criteria. The Liver Allocation Sequence achieves total impartiality through its center rota, enabling all transplant centers to acquire an equal share of livers, but it becomes *too* impartial when ignoring candidate blood match. Blood match is vital in organ transplantation to ensure a successful graft. Ideally, the allocation of livers should depend upon relevant medical characteristics, such as progression of disease, mortality status, and blood, age, size, and tissue match. A blind, justice-based policy such as the Liver Allocation Sequence, which selects eligible candidates through the identification of underresourced centers, is not in the best interests of transplant candidates, unless there were enough “one-size-fits-all” livers to go around.

Once a donor liver completes the Sequence and arrives at a transplant center, a candidate must be selected for transplantation: “There may be many factors such as the quality and size of the liver and blood group, the health of the patient and pressures on beds and staff, which will influence the choice of recipient. When equal post-transplant outcome is anticipated then the sicker patient would normally be transplanted first.”²⁵ The number of allocation principles listed by the NHSBT is extensive and shows a substantial departure from the previous justice-based policy. In particular, it is encouraging to see medical need (i.e., patient health and urgency) working together with efficiency (i.e., quality of liver and blood group) to select the appropriate candidate. Medical need appears to be the overriding concern when two candidates are anticipated to have similar

postoperative success. It is unfortunate that these diverse criteria are only calculated *after* the donor liver has been allocated to an underresourced center through the Sequence, where it may have ignored a blood-matching candidate at a more local, well-resourced center. “Pressures on beds and staff” is a slightly worrying criteria. This consideration casts an eye far beyond the candidate’s immediate need or efficiency to measure the social and economical needs of other patients and their hospital trusts. It is not known whether such wide considerations should exert an influence over organ allocation policies, but staffing problems and bed pressures could establish a postcode lottery of organ allocation if incorporated into formal policies. This would be dreadfully unfair for all transplant candidates.

It has been shown that the NHSBT is especially keen to allocate organs according to the “best bet” principle: “Where possible the donor should be matched to the recipient who is expected to obtain the largest transplant benefit from the procedure (difference between survival with and without transplantation).”²⁶ This can be seen clearly in the United Kingdom’s super-urgent scheme, which implements the strict “50% survival/five year” rule. The super-urgent scheme may be open to additional scrutiny by only allocating livers according to blood match and waiting time. A mortality scoring system could help to stratify candidates according to their level of need *inside* the super-urgent category, thus allowing for more accurate selections. Waiting time also fails to represent who truly *needs* or would *benefit* from an organ transplant, as most candidates who dwell for several weeks or months on a transplant waiting list may not be gravely urgent cases. In practice, therefore, we see in the NHSBT’s agency-level protocols what we observed in the Department of Health’s National Standards: a combination of need, efficiency, and justice. These principles are vital to allow for equitable organ allocation policies, but this arrangement will only support candidates if they are considered to be the “best bet” for a donor organ at the time of selection. In other words, regardless of a candidates’ urgency or waiting time, his economical status will prevail as the NHSBT’s organ allocation priority.

The perplexing Liver Allocation Sequence leaves an important ethical question unanswered: can an organ procurement agency ever justify ignoring a local or well-resourced blood-matching candidate simply to uphold a radically impartial strategy of resource allocation? It is rather frustrating to find that once a liver has been allocated to an underresourced center through the Sequence, only *then* are vital medical criteria calculated to select the most urgent, most efficient candidate. What of the local, blood-matching candidate who was excluded by the Sequence? Why are only nonurgent candidates subjected to this fluctuating and justice-based allocation policy? If the NHSBT feels pressure to publish equitable and unbiased protocols, they need not worry, as it is completely acceptable for an organ procurement agency to be partial and selective when allocating such a personal and scarce medical resource. Bearing the scarcity in mind, is this radically impartial approach really in the best interests of transplant candidates?

The United States: The United Network for Organ Sharing

UNOS is the primary organ procurement agency in the United States. It is responsible for matching and allocating donated human organs nationwide. There are approximately 106,621 candidates registered on UNet,²⁷ and in the

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period from January 1, 2009, to December 31, 2009, there were 6,320 successful liver transplants.²⁸

National Liver Allocation Guidelines

The National Organ Transplantation Act of 1984 is brief, but it clearly outlines the primary objective of UNOS: “[UNOS] shall have a system to allocate donated organs equitably among transplant patients according to established medical criteria.”²⁹ There are further objectives listed in the Act for the Organ Procurement and Transplantation Network: “The OPTN shall assist in the nationwide distribution of organs equitably among transplant patients, and shall carry out studies and demonstration projects for the purpose of improving procedures for organ allocation and transplantation among populations with special needs, including children and individuals who are members of racial or ethnic minority groups, and among populations with limited access to transportation.”³⁰ These primary objectives establish two goals: (i) the equitable distribution of organs and (ii) the appropriate care of minority candidates. The first goal is founded upon the principle of justice. The second goal shows an application of the need principle, promoting a “reaching out” to minority candidates who are traditionally excluded from complex medical care on social, age, financial, or racial grounds. The mention of minority candidates at a national level also reinforces the impetus upon UNOS to design policies that are “fit for all.” Regarding efficiency, the 1984 Act clearly requires UNOS to measure “medical criteria” (noted above) when allocating organs, and this “best bet” approach has been enshrined in Policy 3.6 (in detail below).

A more detailed national framework in place to manage the allocation of donor organs in the United States is the Final Rule, which was published in 1999 to establish the roles, administrative duties, and organ allocation objectives of the OPTN.³¹ Organ allocation objectives are provided in specific detail at section 121.8 and are split up into sections: policy development, allocation performance goals, and allocation performance indicators. According to “policy development,” the OPTN Board of Directors must develop equitable allocation policies that are “based on sound medical judgment, achieve the best use of donated organs, [are] designed to avoid wasting organs, to avoid futile transplants, and to promote patient access to transplantation.”³² There appears to be a slight ethical contradiction to these objectives. If the OPTN must allocate organs to the “best” candidates according to the “best bet” principle (which, by its very nature, does not support equality), how can the OPTN also promote “access to transplantation” that is underpinned by impartiality? Perhaps the Department of Health and Human Services is encouraging the OPTN to open its doors to a wide variety of candidates in accordance with the need principle, and then to allocate organs efficiently and realistically according to the “best bet” principle. The OPTN manages to achieve this complex balance under Policy 3.6 (below).

According to “allocation performance goals,” the OPTN must, when developing organ allocation policies, meet the following criteria:

- (1) standardize the criteria for determining suitable transplant candidates through the use of minimum criteria, expressed through objective and measurable medical criteria, for adding individuals to, and removing

candidates from, organ transplant waiting lists; (2) setting priority rankings, expressed through objective and measurable medical criteria, for patients or categories of patients who are medically suitable candidates for transplantation to receive transplants. These rankings shall be ordered from most to least medically urgent; (3) distributing organs over as broad a geographic area as feasible in order of decreasing medical urgency.³³

The Final Rule shows a strong allegiance to the “best bet” principle in these economical goals. The OPTN must use minimal, objective, measurable, medical criteria to allocate organs, alluding to the selection of the best, most efficient candidate for transplantation. This strict scheme will, in turn, ensure that the OPTN will reduce wastage. The only medical criterion that is minimal, measurable, *and* objective is a blood test result, which can be used to calculate urgency (a needs-based criteria). The Department of Health and Human Services also encourages the OPTN to rank candidates according to level of urgency, which is reflective of the need principle. This ethical balance is encouraging, but it must be remembered that in addition to these seemingly even-handed goals, the OPTN must still avoid “wasting organs” or conducting “futile transplants.” Hardly any room remains for maneuver or for the inclusion of “borderline” criteria, such as “waiting time” or “pressures on beds and staff,” as was observed in some U.K. protocols (above). UNOS and the OPTN have successfully developed a needs-based scoring system in line with the Final Rule objectives, which calculates a candidate’s level of urgency according to measurable medical criteria (more below).

The last relevant section in the Final Rule, entitled “allocation performance indicators,” describes how the U.S. Secretary of Health and Human Services will oversee the OPTN and its policies:

For each organ-specific policy, the OPTN shall provide to the Secretary data to assist the Secretary in assessing organ procurement and allocation, and access to transplantation. Such data shall include: risk-adjusted total life-years pre- and post-transplant, risk-adjusted patient and graft survival rates following transplantation, risk-adjusted waiting time and risk-adjusted transplantation rates, as well as data regarding patients whose status or medical urgency was misclassified and patients who were inappropriately kept off a waiting list or retained on a waiting list.³⁴

The Secretary of Health will use the above data to measure just how well the OPTN (and each transplant center) is meeting the objectives listed under “allocation performance goals” (described above). This section of the Final Rule reveals a collection of ethical priorities. First, by confirming that the OPTN is regulated by a higher body to which it must justify its policies and procedures and through an express commitment by the Secretary of Health to assess organ allocation policies in relation to their application of objective, measurable, medical criteria, the Final Rule illustrates a strong allegiance to the needs of transplant candidates (the need principle). Second, the collections of data listed above (which will reach the Secretary in statistical form) give the impression that the U.S. organ transplantation system is very goal driven. To put it another way, this section could be translated as exclaiming: “the OPTN must be efficient, . . . it must meet its goals, . . . it must minimize waste, . . . it must meet its targets, . . . it

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must calculate “best bet.” This strict economical approach could influence UNOS and the OPTN when allocating organs and drafting policies (similar to the “50% survival/five year” rule in the United Kingdom). If this is the case, UNOS and the OPTN should be mindful so as to not undermine the needs of candidates when striving to meet their economical goals.

It has been shown that the Department of Health and Human Services in the United States places an overwhelming burden on UNOS/the OPTN to be objective, resourceful, and efficient when allocating scarce organs. The National Organ Transplantation Act of 1984 lists “equitable distribution” and “appropriate care of minority patients” as key priorities for the OPTN, but these are overwhelmed by a push for efficiency and practicality in the Final Rule. The expectation of UNOS and the OPTN to avoid wasting organs and to allocate organs to the “best bet” candidates adds considerable pressure to draft policies that are calculated and minimal. UNOS and the OPTN must therefore be doubly sure that any agency-level strategies maintain support for the best interests of the candidate.

Agency-Level Liver Allocation Protocols

In line with the objectives set down in the Final Rule, UNOS has developed a liver allocation protocol entitled Policy 3.6. It employs a unique mortality scoring system to separate transplant candidates into two categories: Status 1A and MELD.

Policy 3.6 outlines its objectives as follows:

Each candidate will be assigned a status code or probability of candidate death derived from a mortality risk score corresponding to the degree of medical urgency, calculated in accordance with the Model for End-Stage Liver Disease (MELD). Livers will be offered to candidates with an assigned Status of 1A in descending point sequence with the candidate having the highest number of points receiving the highest priority. Following Status 1, livers will be offered to candidates based upon their probability of candidate death derived from assigned MELD scores in descending point sequence with the candidate having the highest probability ranking receiving the highest priority.³⁵

Policy 3.6 is similar to NHS Blood and Transplant’s Liver Organ Sharing Principles (1999) in that it separates super-urgent candidates (Status 1A) from all other candidates (MELD). However, UNOS prefers to implement a similar allocation strategy—a mortality scoring system—to *both* groups of candidates, a significantly different approach to NHSBT’s Liver Allocation Sequence, which saw an impartial justice-based strategy applied to nonurgent candidates only. The objectives of Policy 3.6 therefore indicate that medical need is a significant allocation priority for UNOS, regardless of the category into which a candidate is slotted, and shows a strong allegiance to the need principle. However, the scoring systems for both groups of candidates require further analysis.

A candidate with fulminant liver failure who has less than 7 days left to live will be categorized as Status 1A (i.e., super-urgent). Similar to the United Kingdom, fulminant liver failure is strictly defined in the United States as hepatic failure, transplant failure, hepatic artery thrombosis, or acute Wilson’s disease. Alternatively, any candidates not meeting these criteria may have their

case reviewed by the Regional Review Board and be upgraded to Status 1A in this way.³⁶ This strategy is supportive of candidate need. Local and regional Status 1A candidates are grouped together, and livers are allocated to this wide pool of candidates first, before being offered to MELD candidates (in detail below) and then finally to national Status 1A candidates.³⁷

Status 1A candidates are stratified according to points accrued, and this is where Policy 3.6 begins to incorporate a wider variety of ethics. Blood match is vital to Status 1A candidates to ensure that they are an efficient match to the donor liver, and those with the same ABO blood type as the donor receive 10 points. Candidates who are compatible but not identical receive 5 points, and incompatible candidates receive 0 points.³⁸ This is a considerably strict application of the “best bet” principle—the better the match, the more economical the candidate, the higher the score, the more likely the transplant—and although it does not completely exclude less efficient candidates from transplantation, they are ranked lower on what appears to be a sliding scale of efficiency. Surprisingly, the other primary consideration when selecting Status 1A candidates is waiting time. According to Policy 3.6, Status 1A candidates will attract waiting time points based on their length of tenure in that status. For example, the person waiting the longest in blood group O will attract 10 points and so on in descending order.³⁹ This is a noteworthy incorporation of the “first-come first-served” principle, which traditionally disregards medical need and efficiency as allocation criteria. However, it is only used by UNOS in this instance as a final means of distinguishing all Status 1A candidates who are an identical blood match to the donor. Finally, in addition to urgency status (need), blood match (“best bet”), and waiting time (“first-come first-served”), livers are also allocated to Status 1A candidates according to donor size.⁴⁰

Policy 3.6 appears to promote equality and equal access by reserving preference for urgent, blood matching, long-awaiting candidates. There is little room for discrimination because medical criteria underpin most of the Status 1A selection process. UNOS shows a commitment to a combination of ethical allocation principles, which in turn supports the best interests of the candidates *and* the organ. UNOS also prefers to incorporate waiting time as an impartial calculation when selecting a precise candidate, but a diversion from “need” may not be the best option when selecting Status 1A candidates. Perhaps UNOS could design tighter medical criteria to distinguish candidates based on closeness to death, as opposed to how long they have waited. For example, out of all Status 1A candidates (who all have 7 days left to live), some will inevitably be closer to death than others. Can this be calculated in any way to provide more “justified” organ allocations?

Following Status 1A, Policy 3.6 creates a unique scoring system based on a statistical formula, which accurately measures a candidate’s risk of mortality and level of urgency. Formally known as the MELD score (Model for End Stage Liver Disease), it is a numerical scale that assigns each candidate a “score” based on how urgently she or he requires a liver transplant, ranging from 6 (less ill) to 40 (gravely ill).⁴¹ The score is calculated using the results of three blood tests: bilirubin, which measures how effectively the liver excretes bile, INR prothrombin, which measures the liver’s ability to make blood clotting factors, and creatinine, which measures kidney function (often associated with severe liver disease).⁴² Additional points are not accrued in MELD as they are in Status 1A for blood match and waiting time, but these factors are considered *alongside*

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the MELD score in order to stratify MELD candidates inside their score bracket. For example, once a MELD score is allocated (e.g., 30), candidates are stratified inside their score bracket by blood type similarity (e.g., type O), and then lined up by waiting time.⁴³ Livers are allocated to candidates with MELD scores of 15 or above locally first, *then* regionally (not grouped together as in Status 1A). Livers are then allocated to candidates with scores of less than 15 locally and then regionally. Finally they are allocated nationally to all candidates.⁴⁴

Several allocation principles are highlighted in the MELD scoring system. To allocate a liver to MELD candidates, the highest MELD score is sought first, ensuring that medical need is the overarching priority. Because there may be several candidates with a MELD score of 38, blood match is the next chief selection criteria: “within each MELD score, donor livers shall be offered to transplant candidates who are ABO-identical with the donor first.”⁴⁵ This blood-matching strategy will ensure that the selected MELD candidate is the “best bet” for the donor liver. Waiting time is calculated next to guarantee that the blood-matching candidate has been selected impartially. Regular MELD tests are taken during a candidate’s tenure on the waiting list to make sure that the candidate’s score accurately reflects his or her level of need. It follows from this that a candidate’s score may fluctuate frequently. This does not affect the candidate’s access to a donor liver; it simply provides the candidate with an accurate measurement of his medical need and restratifies all candidates according to up-to-date test results. Policy 3.6 states on this fluctuating issue that: “waiting time accrued while listed as a lower MELD score will not be counted toward liver allocation if the candidate is upgraded to a higher MELD score. If the candidate’s score decreases again, s/he would keep the waiting time gained at the higher score.”⁴⁶ The calculation of waiting time in MELD is another application by UNOS of the “first-come first-served” principle. However, because waiting time is calculated *after* need and efficiency for both MELD and Status 1A candidates, it may simply be considered as a distinguishing tool and nothing more. The MELD policy by UNOS therefore demonstrates the need principle, the “best bet” principle, and the “first-come” principle working together in the interests of the candidate.

It has been shown that despite the goal-driven objectives exposed in the Final Rule, Policy 3.6 places candidate need at the top of the agenda by assigning a Status 1A label to a candidate or estimating a candidate’s mortality score first and calculating blood match and waiting time thereafter. The Final Rule encourages the OPTN in particular to allocate organs based on “minimal, measurable and objective criteria” and to “rank candidates according to urgency.” This has been done specifically through the MELD scoring system (and to an extent through the Status 1A points system). The combination of need, efficiency, and the “first-come first-served” principle works well to ensure that the most urgent candidate will also be the “best bet” and will be impartially selected. With waiting time as a mere distinguishing tool, Policy 3.6 has shown to be supportive of a candidate’s best interests and guarantees the fairest possible allocation of donor livers.

Final Thoughts: Which Organ Procurement Agency Implements the Most Ethically Balanced Policy, and What Can Be Learned from Its Approach?

In the United Kingdom, the Department of Health and NHS Blood and Transplant have demonstrated support for the resource allocation principles of need,

“best bet,” and justice. The Department of Health’s National Liver Transplant Standards and the NHSBT’s several liver allocation protocols show a strong allegiance to the “best bet” principle when prioritizing transplant candidates (i.e., the “50% survival/five year” rule). However, the U.K. system is not without its ethical quandaries. It has been shown that efficiency will override medical need in the United Kingdom when a candidate becomes too frail (ironically when his or her *real* need for a transplant increases), and the “super-urgent” scheme only allocates livers according to blood match and waiting time without implementing a further mortality scoring system. Perhaps the calculations to determine urgency in the United Kingdom could be a little more precise. An additional difficulty in the United Kingdom is the Liver Allocation Sequence, which allocates livers to underresourced transplant centers first, before searching for a blood match thereafter. Under this justice-based policy, a local and more compatible candidate would lose out to a remote, less urgent candidate. This is ethically problematic: it does not support the best interests of the particularly deserving liver transplant candidates.

The United Kingdom’s liver allocation system differs considerably from the U.S. system. On a national level in the United States, we see goal-driven economic objectives outlined by the U.S. Department of Health and Human Services in the Final Rule, and at the agency level, objective, medical selection criteria are implemented by the United Network for Organ Sharing in Policy 3.6. What is particularly special about Policy 3.6 is that a candidate’s urgency is calculated using strict medical criteria, leaving no room for maneuver or discrimination, and it employs a balanced mix of allocation principles. The only issue that remains unclear about Policy 3.6’s needs-based approach is how UNOS still manages to avoid “futile” transplants as requested by the DHHS in the Final Rule. Candidates who are labeled as either a Status 1A or MELD 35–40 may not be the most efficient candidates, so where is the line drawn in the United States between need and efficiency? Could the United Kingdom’s strict “50% survival/five year rule” be an economical addition to Policy 3.6 for UNOS? If so, does this mean that the United Kingdom is getting it right?

The main procedural and ethical difference between the NHSBT and UNOS is the way in which they separate and categorize liver transplant candidates. The NHSBT isolates nonurgent candidates by placing them into the independent Liver Allocation Sequence, whereas UNOS connects both Status 1A and MELD candidates by selecting them according to the same allocation principle (the need principle via considerations of mortality) and stratifying them on the same sliding scale of urgency.

The “super-urgent” liver transplant category in the United Kingdom is rather narrow, listing only six qualifying medical conditions.⁴⁷ If a U.K. candidate falls outside of these criteria, he is placed into the Liver Allocation Sequence. The Sequence is deliberately ignorant of blood match until an underresourced center is selected. The NHSBT has underpinned this Sequence with a justice-based policy, which aims to allocate livers impartially. The justice principle is important in medicine to ensure that resource allocation policies do not discriminate in any way (i.e., that allocation is blind), but in the field of organ transplantation, the medical resource is exceedingly limited, so measuring a candidate’s *need* and *match* to the organ first will yield much fairer results. To this end, the MELD scoring system in the United States is quite unique in that it strictly calculates

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a candidate's medical need (thus excluding social and emotional factors) and it enables UNOS to stratify candidates according to blood match and waiting time (an additional application of the "best bet" and "first-come first-served" principles). Considering the scarcity and complexity of the resource, this may be the most ethically balanced liver allocation strategy that an organ procurement agency could implement. It is of little surprise that the United Kingdom's Liver Advisory Group has begun to trial a UKELD scoring system in the United Kingdom, despite the U.K.'s Department of Health stating that there is "no scoring system with universal applicability."⁴⁸ The UKELD score is based on the MELD scoring system, using blood tests to calculate the mortality risk of the candidate. In the United Kingdom, UKELD is currently used to select cases for the waiting list, not for organ allocation, but Alexander Gimson, Chair of the U.K. Liver Advisory Group, has advised that a new strategy is being piloted: "For various reasons the [Sequence] may be a dissatisfactory allocation system. For this reason, we are developing a new universal Liver Transplant Allocation Scheme for the United Kingdom. We will be testing in a real time simulation model the benefit of allocating organs on the basis of need, utility and finally on the basis of transplant benefit the number of net life years gained from transplantation." (personal communication, Alexander Gimson, Chair of the U.K. Liver Advisory Group, March 2010).

This diverse mix of allocation principles is good news for all U.K. liver transplant candidates.

Despite the innovative MELD scoring system, a rather large uncertainty emerges in Policy 3.6.. What of the "wasteful" and "futile" transplants that the U.S. Department of Health and Human Services expressly prohibit in the Final Rule?⁴⁹ UNOS has developed a needs-based liver allocation system without describing in any real detail how Policy 3.6 will manage waste. It is not ideal for an organ procurement agency to allocate livers according to candidate need only. Needs-based allocation policies may overlook economical, social, or criminal justice issues during candidate selection. Candidates who are significantly diseased or considerably elderly will have the highest need. Candidates who have caused their own liver disease through years of substance abuse may be placed before all other candidates due to skyrocketing MELD scores. These inefficient candidate selections may anger the public. The NHSBT implements a strict "50% survival/five year rule" which can be traced back to the U.K. Department of Health's National Standards,⁵⁰ confirming that U.K. candidates falling below this threshold will be removed from the national waiting list.⁵¹ Can this be implemented by UNOS in some way? At what point does a U.S. transplant candidate become futile, and on what grounds can he be excluded from life-saving treatment? When he shows a 60% chance of survival? 30%? Or are futile candidates excluded from UNet altogether? Both the National Transplantation Act of 1984 and the Final Rule do not reveal at which precise point a candidate's level of efficiency should override his medical urgency. As a result, UNOS has emerged rather elusive on this matter compared to the United Kingdom, which is honest about its "50% survival/five year rule" from the outset. UNOS shows a limited desire to incorporate efficiency into its allocation strategies by positioning "blood type" considerably high on their list of candidate selection priorities for both Status 1A and MELD candidates, but this merely skims the surface of the "best bet" resource allocation principle. Many other

considerations must be calculated in order to combat “futile” and “wasteful” allocations and to find the most economically, physically, socially, financially, and mentally suitable candidate. Perhaps these factors are assessed in more detail during the earlier candidate assessment process. UNOS may have genuinely decided not to implement the economical demands of the Final Rule. Perhaps they are quite happy to simply measure medical urgency and to stratify candidates according to blood type and waiting time only. Alternatively, futile and wasteful candidates may be removed from UNet on a discretionary basis. This would be rather disappointing, as UNOS has shown considerable potential in Policy 3.6 to develop fair and ethical organ allocation strategies that are open, honest, and transparent.

Both countries have felt the need to develop unique liver allocation protocols: the Liver Allocation Sequence in the United Kingdom and Policy 3.6 in the United States, but closer inspection has revealed that these protocols are underpinned by entirely different resource allocation principles. It can be learned from the United Kingdom that a blind and impartial resource allocation ethic such as the justice principle may not be in the best interests of candidate when the resource in question is scarce and personal (i.e., the resource must *match* the recipient, requiring blood match and size match to be calculated in addition to urgency). The separation of transplant candidates into different liver allocation sequences may also isolate those who are ordinarily considered to be the “best bet” candidate from receiving their life-saving medical resource. The United States, however, can assure (as best as it can) that all liver transplant candidates are selected according to their real needs, such as their medical urgency, their blood match, and their waiting time (in that order). The best interests of the gravely ill candidates *and* the likelihood of posttransplant success are considered as equally valuable outcomes (although economical objectives appear to be limited). UNOS also combines all liver transplant candidates on the same sliding scale of urgency, ensuring that lower MELD candidates do not feel excluded from transplantation through being exposed to a separate resource allocation strategy. The United Kingdom is now adopting a UKELD scoring system, illustrating considerable support for the United States’s needs-based approach to liver allocation.

AU1 Notes

1. See <http://www.organdonation.nhs.uk>—the official Web site—for up-to-date policies, current practices, self-help guides, statistics, and transplantation and donation information.
2. See note 1, under “about us.”
3. 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>.
4. Pediatric liver allocation is outside of the ambit of this article, but both countries include pediatric allocation policies within their adult protocols.
5. See <http://www.unos.org> and <http://optn.transplant.hrsa.gov/>—the official Web sites—for further information regarding federal guidelines and organ allocation policies (last accessed 1 Jan 2011).
6. See <http://www.unos.org> under “Who we are” (last accessed 1 Jan 2011).
7. Statistic correct in March 2010.
8. See NHSBT’s official Web site for donation and transplantation statistics from their Transplant Activity report: http://www.organdonation.nhs.uk/ukt/statistics/transplant_activity_report (last accessed 1 Jan 2011).

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9. See note 3, The National Liver Transplant Standards 2005, at Introduction and Topic 3: Assessment, Access to the Waiting List and Organ Allocation. Standards 3.5 and 3.20.
10. See note 3, The National Liver Transplant Standards 2005, at Standards 3.11 and 3.13.
11. See note 3, The National Liver Transplant Standards 2005, at Standard 3.19.
12. 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. Part 4: Selection Criteria, paragraph 4.1; available at http://www.organdonation.nhs.uk/ukt/about_transplants/organ_allocation/liver/liver.jsp (last accessed 1 Jan 2011).
13. See note 12, NHS Blood and Transplant and the Liver Advisory Group 2009, confirmed by paragraph B Part 4.1.1 of UK Transplant's Organ Sharing Principles. Operating Principles for Liver Transplant Units in the UK and Republic of Ireland. July 1999. Paragraph B: Super Urgent Liver Scheme (added in October 2005); available at http://www.organdonation.nhs.uk/ukt/about_transplants/organ_allocation/liver/liver.jsp (last accessed 1 Jan 2011).
14. See note 12, NHS Blood and Transplant Protocols and Guidelines 2009, Part 4: Selection Criteria, paragraph 4.1.2.
15. See note 12, NHS Blood and Transplant Protocols and Guidelines 2009, Summary, p. 1; and Introduction, p. 2, paragraph 1.5.
16. See note 12, NHS Blood and Transplant Protocols and Guidelines 2009, Summary, p. 1. See also: Part 2: The Need for Transplantation. P. 3, paragraph 2.2; and Part 3: Assessment. P. 6, paragraph 3.3.
17. See note 12, NHS Blood and Transplant Protocols and Guidelines 2009, Summary, p. 1.
18. See note 3, The National Liver Transplant Standards 2005, at Standards 3.11 and 3.13.
19. See note 13, Liver Organ Sharing Principles 2005.
20. See note 13, Liver Organ Sharing Principles 2005, paragraph B.4. Super Urgent Liver Scheme Ranking, part 4.1. Emphasis added.
21. See note 3, The National Liver Transplant Standards 2005, Introduction.
22. See note 13, Liver Organ Sharing Principles 2005, Paragraph E: Liver Allocation Sequence (added in April 2006).
23. A "designated centre" is a center designated by the NSCAG to carry out particular grafts. They are headed by "zonal retrieval centres" for the purpose of the Sequence.
24. See note 13, Liver Organ Sharing Principles 2005, Paragraph C.4: The Liver Centre Rota (added in April 2006). Parts 4.1, 4.1.1, 4.1.2, and 4.1.3. Emphasis added.
25. See note 12, NHS Blood and Transplant Protocols and Guidelines 2009, Part 6: Allocation of Donor Livers. Paragraph 6.2. Pp. 11–12.
26. See note 12, NHS Blood and Transplant Protocols and Guidelines 2009, Paragraph 6.3. P. 12.
27. Statistic correct in March 2010.
28. See UNOS's official Web site for transplantation statistics from their Data section: <http://optn.transplant.hrsa.gov/latestData/rptData.asp>.
29. The National Organ Transplantation Act. 1984. As amended by the Charlie W. Norwood Living Organ Donation Act in January 2008. Section 273: Organ procurement organisations. Part (b) (3) (E); and section 274: Organ procurement and Transplantation Network. Part (b) (2) (B).
30. See note 29, The National Organ Transplantation Act 1984. Section 274: Organ procurement and Transplantation network. Part (b) (2) (D) & (N).
31. Title 42–Public Health. Chapter I–Public Health Service, Department of Health and Human Services. Part 121–Organ Procurement and Transplantation Network. 1999.
32. See note 31, Title 42 1999, section 121.8. Allocation of organs. Parts (a) (1), (2), and (5).
33. See note 31, Title 42 1999, Parts (b) (1), (2) & (3).
34. See note 31, Title 42 1999, Part (c) (3).
35. UNOS. Policy 3.6: Allocation of Livers. Updated November 2009. Paragraph 3.6 (p. 1); available at http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_8.pdf (last accessed 17 Feb 2011).
36. See note 35, UNOS 2009, Paragraph 3.6.4.1.
37. See note 35, UNOS 2009, Paragraph 3.6 (p. 1).
38. See note 35, UNOS 2009, Paragraph 3.6.2.
39. See note 35, UNOS 2009, Paragraph 3.6.3.
40. See note 35, UNOS 2009, Paragraph 3.6.1. This includes both Status 1A candidates and MELD candidates.
41. The MELD/PELD scoring system has been in effect since February 2002.

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42. UNOS has created an informative MELD/PELD brochure for transplant candidates that provides information about the blood tests, calculations, and liver allocation. See Questions & Answers for Transplant Candidates about MELD and PELD; available at <http://www.unos.org/resources>.
43. See note 35, UNOS 2009, Policy 3.6, Paragraph 3.6 (p. 1) and paragraph 3.6.3.
44. See note 35, UNOS 2009, Paragraph 3.6 (pp. 1 and 2).
45. See note 35, UNOS 2009, Paragraph 3.6.2.
46. See note 35, UNOS 2009, Paragraph 3.6.3. See also note 42, Questions & Answers document, p. 3.
47. Including paracetamol poisoning and Wilson's disease. See note 12, NHS Blood and Transplant Protocols and Guidelines 2009, Part 4: Selection Criteria, paragraph 4.1. Also see note 13, Liver Organ Sharing Principles 2005, Paragraph B: Super Urgent Liver Scheme (added in October 2005).
48. See note 3, The National Liver Transplant Standards 2005, Introduction.
49. See note 31, Title 42, Section 121.8. Allocation of organs. Parts (a) (1), (2), and (5).
50. See note 3, The National Liver Transplant Standards 2005, Introduction and Topic 3: Assessment, Access to the Waiting List and Organ Allocation. Standards 3.11 and 3.13.
51. See note 12, NHS Blood and Transplant Protocols and Guidelines 2009, Summary, p. 1.