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Performed 1998-2002

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FOR LIVER TRANSPLANTATION

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Note: Analyses contained in this report were provided by University Renal Research and Education Association in collaboration with the University of Michigan, as contractor for the Scientific Registry of Transplant Recipients (SRTR) to the Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, US Department of Health and Human Services. The conclusions rendered by the Workgroup do not necessarily represent the positions of the SRTR, the Organ Procurement and Transplantation Network, or the U.S. government.
INTRODUCTION

Organ transplantation has progressed, in a relatively brief period of medical history, from an experimental to a standard treatment for end stage organ failure. The replacement of a diseased heart, liver, or kidney with a functional transplant has become the preferred approach to restoring the well-being of a patient. However, while the number of patients who are medically suitable to undergo organ transplantation has dramatically risen, the supply of deceased organ donors has remained insufficient to provide for the increasing demand. Thus, organ procurement and transplant professionals have considered other ways of addressing this organ shortage, such as the transplantation of organs from living donors, or from deceased donors whose medical characteristics are not ideal.

The ideal deceased donor of an organ has been identified as a donor less than 40 years of age who has no characteristics which may predispose his or her organs to graft failure after transplantation. Currently, ideal deceased liver donors provide approximately one third of all livers transplanted in the United States. All other deceased liver donors present a continuum of increased risk of graft failure compared to the ideal donor. The Expanded Criteria Donor (ECD) designation is meant to describe a deceased donor with substantially increased risk of graft failure compared to the ideal donor.

The following deceased donor characteristics have been associated with increased risk of graft failure and have been used to describe the ECD:

- Medical history of systemic illness such as malignancy;
- Social history of exposure to transmissible infectious disease;
- Pre-donation course of hemodynamic instability;
- Serological evaluation of viral infection;
- Evidence of less than optimal organ function prior to surgical recovery;
- Adverse intra-operative recovery events;
- Post-recovery biopsy results;
- Age; and
- Cause of death.

The transplantation of liver allografts (an organ or tissue transplanted from one individual to another of the same species, i.e., human to human) from ECDs is increasing, not only in the New York region, but also in most regions of the United States. As the waiting list for liver transplants continues to grow (and the availability of livers from ideal donors remains largely unchanged), there is increasing need to use expanded criteria donor livers (ECDLs). Until now, there has been little medical guidance in determining the more suitable ECDL for transplantation or in the development of selection criteria for the most appropriate recipient. Furthermore, guidance to improve the informed consent of potential recipients of these organs is essential.

Thus, Commissioner of Health, Antonia C. Novello, M.D., M.P.H., Dr. P.H., assembled a Workgroup of national experts to address the use of liver allografts from ECDL. Since the outcome of this Workgroup would have implications not only for New York State but also for the nation, the membership was chosen accordingly. It included the President-Elect of the Organ Procurement and Transplantation Network (OPTN)/United Network for
Organ Sharing (UNOS), a representative from the Scientific Registry of Transplant Recipients (SRTR), members of the OPTN/UNOS Liver and Intestinal Transplantation Committee, a liver transplant recipient, ethicists, organ procurement organization representatives, transplant physicians from across the nation, representatives from the five liver transplant programs in New York State, and a federal government representative.

The Department of Health’s positive experience with the Committee on Quality Improvement in Living Liver Donation, that produced a seminal report on live adult liver transplantation in 2002, set the precedent for the Department to utilize the same approach in studying this issue. The Workgroup convened in June, August, and October of 2004. This current report represents the completion of the diligent work of the Workgroup and is presented as guidance on the use of ECDL for the liver transplant community. The members of this Workgroup believe that these recommendations will serve as a reference of data and experience for the rest of the country. The Workgroup acknowledges, however, that the recommendations of this report may be revised as advances in ECDL transplantation occur in the future.

**BACKGROUND**

The Workgroup identified three important issues in the use of ECDL:

- To identify characteristics of ECDL;
- To determine if there should be a separate allocation system for ECDL; and
- To determine what information should be shared with a potential liver transplant recipient to achieve informed consent when an ECDL is offered.

New York State has four organ procurement organizations (OPOs), and is unique since it shares deceased donor livers on a statewide basis. During the deliberations, the representatives from the five New York State liver transplant centers offered their experience with ECDL. The center representatives suggested that the donor and recipient populations in New York State are different as compared to the rest of the nation. The New York State transplant community had the following perspective regarding their patient population:

- New York liver transplant patients undergo transplantation of ECDL at a greater frequency than the rest of the country;
- Recipients in New York State are sicker at the time of transplant than those in the rest of the country; and
- Despite these circumstances, the outcomes of liver transplantation in New York State are comparable to the rest of the country.

To determine if the New York centers’ perceptions were valid, the Workgroup requested that the Scientific Registry of Transplant Recipients (SRTR) provide a comparative analysis of the use of ECDL in New York, with the rest of the nation. The SRTR is the federal contractor responsible for the ongoing evaluation of the scientific and clinical status of solid organ transplantation including kidney, heart, liver, lung and pancreas transplants. The SRTR comparative analysis is discussed later in this report.
IDENTIFYING CHARACTERISTICS OF EXPANDED CRITERIA DONOR LIVERS (ECDL)

The potential benefits of characterizing an ECDL were identified as:

- Permit a comparative profile of center/regional practices regarding acceptance of ECDL and recipient selection for these grafts.
- Provide physicians with important information to make judgments regarding the risk of graft failure for their specific patient, versus the benefit that may be derived by transplantation.
- Build public trust by providing information regarding the potential for success, complications and risks associated with the use of these organs.

The potential drawbacks of characterizing an ECDL were seen as:

- Potentially limiting the availability of deceased donor livers, impacting recipients on the waiting list based on an arbitrary standard that could curtail or limit the transplantation of livers based on a clinical matching of donor and recipient characteristics.
- Potentially inhibiting development of future innovative practices.

Although there has been presentation of data at the national level about the ECDL (1), there is no nationally accepted definition of an ECDL. Consequently, the Workgroup reviewed data on clinical characteristics that may affect graft survival to help identify what characteristics are indicative of an ECDL. The SRTR has used a relative risk (RR) of graft failure of 1.7 or greater as an arbitrary indicator of an ECD kidney (2). For liver transplantation, the RR compares the risk of graft failure (including death) using a liver from any given donor to that of a liver from an ideal donor (i.e., under 40 years old and having no donor characteristics significantly associated with graft failure). For example, a liver graft with an RR of 1.7 has a 70% greater chance of failure as compared to a liver from an “ideal” donor (RR=1.0). The Workgroup members accepted an RR \( \geq 1.7 \) as a working definition of ECDL for its deliberations. All donors with an RR greater than 1.0 are non-ECD and those with an RR greater than 1.7 are ECD.

The characteristics identified by the SRTR in their analyses that were associated with a significantly higher risk of liver graft failure include (see Table 1): increased donor age, partial or split livers (a deceased donor liver which is split and used to transplant two recipients), donors after cardiac death (DCD), black race, cerebral vascular accident (CVA) as the cause of death (COD), and COD other than trauma, CVA or anoxia. While each of the above characteristics is associated with significant risk, none individually reach the threshold of RR \( \geq 1.7 \). It is important to emphasize that none of these characteristics alone would result in a donor being classified as an ECD. It is only when any one of these characteristics is paired with at least one other characteristic of the following Table that the RR may be greater than 1.7.
### Table 1

List of Donor Factors Found to be Significantly Associated with Graft Failure

<table>
<thead>
<tr>
<th>Factor</th>
<th>RR</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donor Age 40 to 49</td>
<td>1.16</td>
<td>0.0006</td>
</tr>
<tr>
<td>Donor Age 50 to 59</td>
<td>1.30</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Donor Age 60 to 69</td>
<td>1.51</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Donor Age 70 or Above</td>
<td>1.63</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Partial / Split Liver</td>
<td>1.53</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>DCD Liver</td>
<td>1.52</td>
<td>0.0006</td>
</tr>
<tr>
<td>Donor COD Other*</td>
<td>1.20</td>
<td>0.0168</td>
</tr>
<tr>
<td>Donor COD CVA</td>
<td>1.15</td>
<td>0.0001</td>
</tr>
<tr>
<td>Donor Race Black</td>
<td>1.19</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>

*Cause of Death is not one of the following: trauma, CVA, or anoxia.

The matrix below (Table 2) demonstrates the combinations of donor characteristics that cumulatively result in a graft failure RR $\geq 1.7$. For example, a donor age 60 or older who also has other risk factors has an RR $> 1.7$. Since there are many potential combinations of donor characteristics, ECDL represents a spectrum of risk. Since the risk in a particular case depends on the values for each of the factors, a specific RR cut-off for what is an acceptable or unacceptable donor would be arbitrary and might disadvantage patients, especially those with a much higher risk of death without a transplant.

Table 2

| Donor Profile | Donor Age (Years) |< 40 | 40-49 | 50-59 | 60-69 | $\geq 70$
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Ref.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any factor*</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any 2 or more factors</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DCD or Partial/Split</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>(DCD or Partial/Split) + 1 other factor</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

*Factors: Partial/Split Liver, DCD, Donor Race = Black, COD = CVA, COD = Other, not one of: trauma, CVA, anoxia

By replacing the X’s in the above matrix with the actual range of RRs and the one-year graft survival rates for the patients receiving these transplants, the calculated risks and associated predicted graft survival rates for recipients of each category of ECDL can be examined (see Tables 3 & 4).
### Table 3

**ECD Matrix with Ranges of Donor RR's for Each Cell**

<table>
<thead>
<tr>
<th>Donor Profile</th>
<th>Under 40</th>
<th>40-49</th>
<th>50-59</th>
<th>60-69</th>
<th>70+</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>1.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cod-Other or Cod-Stroke or Black</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Cod-Other + Race-Black) or (Cod-Stroke + Race-Black)</td>
<td></td>
<td>1.74-1.82</td>
<td>1.88-1.96</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DCD or Partial/Split</td>
<td>1.74-1.76</td>
<td>1.96-1.99</td>
<td>2.28-2.31</td>
<td>2.46-2.50</td>
<td></td>
</tr>
<tr>
<td>(DCD or Partial/Split) + at least one other factor</td>
<td>1.73-3.31</td>
<td>2.00-3.81</td>
<td>2.25-4.30</td>
<td>2.62-4.99</td>
<td>2.83-5.40</td>
</tr>
</tbody>
</table>

*Source – SRTR – January 1, 1998 to December 31, 2002*

The matrix immediately above (Table 3) shows the RR range for each combination of donor characteristics. The RR for these donors ranges from 1.73 to 5.40 depending on the donor’s age and the combinations of other risk characteristics.
### Table 4

**ECD Matrix with 1-Year Graft Survival Rates and 95% Confidence Intervals (Adjusted to Average Liver Transplant Recipient)**

<table>
<thead>
<tr>
<th>Donor Profile</th>
<th>Donor Age (Years)</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Under 40</td>
<td>40-49</td>
<td>50-59</td>
<td>60-69</td>
<td>70+</td>
</tr>
<tr>
<td>None</td>
<td>82.8 (82.3 - 83.4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>n=17,164</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cod-Other or Cod-Stroke or Black</td>
<td>76.3 (74.5 - 78.2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>n = 1,445</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Cod-Other + Race-Black) or (Cod-Stroke + Race-Black)</td>
<td>77.9 (74.1 - 82.0)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>n = 290</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DCD or Partial/Split</td>
<td>61.6 (48.9 - 77.6)</td>
<td>86.9 (74.1 - 100.0)</td>
<td>68.8 (41.0 - 100.0)</td>
<td>38.0 (9.9 - 100.0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>n = 34</td>
<td>n = 17</td>
<td>n = 6</td>
<td>n = 3</td>
<td></td>
</tr>
<tr>
<td>(DCD or Partial/Split) + at least one other factor</td>
<td>75.2 (69.1 - 81.9)</td>
<td>74.1 (64.3 - 85.5)</td>
<td>72.4 (56.9 - 92.0)</td>
<td>56.6 (37.2 - 86.3)</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>n = 129</td>
<td>n = 51</td>
<td>n = 20</td>
<td>n = 14</td>
<td>n = 0</td>
</tr>
</tbody>
</table>


According to the data above, a donor age 50-59 who was a DCD or partial/split graft carries a RR of 1.96 – 1.99 (96% to 99% higher risk of graft failure than an ideal donor). The associated mean one-year graft survival with a donor liver of this nature used for a transplant candidate with average characteristics is 86.9%. However, these survival data do not necessarily predict the outcome for a given recipient with “non-average” characteristics.
Workgroup members concluded that, based on their clinical experience, there are other characteristics that may indicate a potential for a higher rate of liver graft failure, not identified by the SRTR analysis, most probably due to lack of available data or a small number of cases. These characteristics are:

- Significant steatosis (fat)
- Serum sodium >170 at the time of procurement
- Positive hepatitis serology
- Donor malignancy (cancer)

Further data collection and research will be necessary to determine whether these characteristics impact the ECD matrix.
THE NEW YORK STATE EXPERIENCE

As noted earlier, the transplant community in New York State (UNOS Region 9) has had the perception that New York centers transplant ECDL more frequently and into higher MELD score patients than the rest of the country. Thus, the Workgroup requested that the SRTR provide data for the following questions:

- When compared to the rest of the nation, did New York State centers transplant a higher or lower percentage of ECDL (predicted RR > 1.7)?

**Answer:** Yes, New York State centers transplanted a higher percentage of ECDL (24.7%) as compared to the rest of the nation (13.4%). (Table 5).

- What was the percentage of “ideal” deceased donor liver transplants in New York State?

**Answer:** The percentage of “ideal” liver transplants in New York State was 21.8% of all livers transplanted, which was less than the rest of the nation at 35.0% (Table 5).

### Table 5

<table>
<thead>
<tr>
<th></th>
<th>Region 9 (N=1,512)</th>
<th>Rest of Nation (N=18,511)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Percent</td>
</tr>
<tr>
<td>ECD</td>
<td>373</td>
<td>24.7</td>
</tr>
<tr>
<td>Ideal</td>
<td>330</td>
<td>21.8</td>
</tr>
<tr>
<td>Other Non-ECD*</td>
<td>809</td>
<td>53.5</td>
</tr>
</tbody>
</table>

*Other Non-ECD – a donor with an RR > 1.0 but <1.7
Ref. Category in ECD Matrix
Source - SRTR - January 1, 1998 to December 31, 2002
What was the mean RR of deceased donor liver transplants in New York State?

**Answer:** The mean RR of ECD deceased donor liver transplants performed at New York centers ranged from 1.88 to 1.91 (Table 6).

The mean RR of Non-ECD deceased donor liver transplants performed in New York centers ranged from 1.26 to 1.35 (Table 6).

### Table 6

<table>
<thead>
<tr>
<th></th>
<th>Region 9 (N=687)</th>
<th>Rest of Country (N=8407)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Year</td>
<td>n</td>
</tr>
<tr>
<td>ECD</td>
<td>2002</td>
<td>77</td>
</tr>
<tr>
<td></td>
<td>2003</td>
<td>101</td>
</tr>
<tr>
<td></td>
<td>2004</td>
<td>29</td>
</tr>
<tr>
<td>Non-ECD*</td>
<td>2002</td>
<td>188</td>
</tr>
<tr>
<td></td>
<td>2003</td>
<td>225</td>
</tr>
<tr>
<td></td>
<td>2004</td>
<td>67</td>
</tr>
</tbody>
</table>

* Non-ECD – a donor with a RR>1.0 but < 1.7
Source – SRTR – April 1, 2002 to March 31, 2004
What was the overall retransplant rate by ECD/Non-ECD for New York State liver transplant recipients as compared to the rest of the country?

Answer: The chart below shows the percentage of retransplants for both ECD and Non-ECD in New York State compared to the rest of the country. New York State centers had a higher rate of retransplantation, during the time period cited, than the rest of the country for both types of grafts. Recipients in New York State, as well as those in the rest of the country, that received ECD liver allografts had twice the rate of retransplantation as those who received a Non-ECD. (Figure 1).

Figure 1

• What were the retransplant rates by ECD/Non-ECD for New York State (Region 9) and the rest of the country by OPTN region?

**Answer:** There are 11 OPTN/UNOS organ-sharing regions. The percent of liver retransplantation for ECDL recipients in Region 9 exceeded every other OPTN region except Region 3.

**Figure 2**

![Bar chart showing retransplant rates by OPTN region and ECD/Non-ECD status.](chart.png)
The chart below represents the number of liver allografts derived from donors outside of New York State compared to liver allografts transplanted in other regions, which were derived from donors outside their respective regions. New York State used a higher percentage of both Non-ECD and ECD originating from outside their local region than the rest of the country.

**Figure 3**

Distribution of Donor Origin for ECD and Non-ECD Transplants

SUMMARY OF NEW YORK STATE DATA PROVIDED BY THE SRTR

Based on data provided by the SRTR, the following observations can be cited regarding ECDL transplantation in New York State:

- New York State recipients of ECDL and Non-ECDL had a similar distribution by age, gender, race, and diagnosis as the rest of the country (as indicated by SRTR data not included in this report).

- Deceased donor livers transplanted in New York State were older than those in the rest of the country (as indicated by SRTR data not included in this report).

- In New York State, and the rest of the country, those that received an ECDL had nearly twice the rate of retransplantation compared to those who received a Non-ECDL (Table 5).

- New York State had a higher retransplant rate than the rest of the country (Figure 1).

- Liver allografts were transplanted in New York State into a higher proportion of hospitalized and ICU-bound patients than in the rest of the country.
  - 35% of recipients in New York State were in the ICU at the time of transplant compared to 21% for the rest of the country.
  - 26% of recipients in New York State were hospitalized at the time of transplant compared to 13% for the rest of the country.

The study collected information regarding patients hospitalized in the ICU between 1998 and 2002 to determine their severity of illness. Since then a standard of medical urgency (severity of illness) has been developed nationally by determining a Model for End Stage Liver Disease (MELD) score, so that an objective and consistent determination of illness could be provided for each patient. MELD is a numerical scale, ranging from 6 (less ill) to 40 (gravely ill), that is used for adult liver transplant candidates. It gives each candidate a ‘score’ (number) based on three laboratory values, and the score is predictive of the risk of death in the absence of a liver transplant within the next three months.

A MELD score is calculated using a relatively simple formula that relies on three readily available objective variables: serum creatinine, total bilirubin and INR (international normalized ratio).

The current liver allocation system directs deceased donor livers to candidates with the highest (most medically urgent) MELD scores.
What were the liver allograft survival outcomes for recipients in New York State as compared to the rest of the country?

**Answer:** The chart below shows the graft survival for patients undergoing liver transplantation in New York State as compared to the rest of the country.

**Table 7**

*United Network for Organ Sharing*

*Organ: Deceased Donor Liver Alone*

*Kaplan-Meier Graft Survival for Primary Transplants Performed: 1998-2002*

<table>
<thead>
<tr>
<th>Area</th>
<th>Number of Transplants</th>
<th>Year Post-Transplant</th>
<th>Survival Rate and 95% Conf. Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Region 9</td>
<td>1408</td>
<td>1</td>
<td>80.59 [78.45,82.72]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>67.95 [65.31,70.58]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5</td>
<td>62.07 [58.99,65.16]</td>
</tr>
<tr>
<td>U.S. Overall</td>
<td>20056</td>
<td>1</td>
<td>82.50 [81.96,83.03]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>73.92 [73.28,74.55]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5</td>
<td>67.48 [66.70,68.27]</td>
</tr>
</tbody>
</table>

*Based on OPTN data as of January 28, 2005*

*Data subject to change based on future data submission or correction.*
• What were the patient survival outcomes for recipients in New York State as compared to the rest of the country?

**Answer:** The chart below shows the survival rates for patients undergoing liver transplantation in New York State as compared to the rest of the country.

**Table 8**

*United Network for Organ Sharing*

*Organ: Deceased Donor Liver Alone*

*Kaplan-Meier Patient Survival for Primary Transplants Performed: 1998-2002*

<table>
<thead>
<tr>
<th>Area</th>
<th>Number of Transplants</th>
<th>Year Post-Transplant</th>
<th>Survival Rate and 95% Conf. Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Region 9</td>
<td>1408</td>
<td>1</td>
<td>86.83 [84.93,88.73]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>75.22 [72.66,77.78]</td>
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<tr>
<td></td>
<td></td>
<td>5</td>
<td>70.18 [67.12,73.24]</td>
</tr>
<tr>
<td>U.S. Overall</td>
<td>20056</td>
<td>1</td>
<td>87.46 [86.98,87.93]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>80.02 [79.42,80.61]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5</td>
<td>74.25 [73.48,75.01]</td>
</tr>
</tbody>
</table>

*Based on OPTN data as of January 28, 2005*

*Data subject to change based on future data submission or correction.*
WORKGROUP CONCLUSIONS

After extensive deliberations regarding the above data pertaining to an ECDL, the Workgroup concluded the following:

- Liver transplants from ECDLs are not unacceptable but carry a higher risk of graft failure as compared to liver transplants from “ideal” donors. In absolute terms, if an “ideal” donor liver carries a 5% risk of graft failure, then a liver procured from a donor with characteristics defining an RR of graft failure = 2.0 would have a 10% risk of graft failure.

- The use of RR of graft failure as the criterion of defining ECDL is arbitrary; and not an absolute predictor of recipient outcome.

- The precise RR of a particular donor should be determined to make a medical judgement on the donor suitability for a given recipient (while considering his/her simultaneous medical urgency). Judgment necessitates a continual reassessment of the recipient’s medical condition at the time of a donor offer with the simultaneous quality assessment of the donor organ being offered. Not accepting a donor liver from an ECD may result in the death of a medically urgent patient because another donor liver may not become available in the immediate future.

The Workgroup developed a list of ECDL donor characteristics that transplant physicians may use in their decision making. These characteristics include, but are not limited to:

<table>
<thead>
<tr>
<th>CHARACTERISTIC</th>
<th>BASED ON</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donor Age</td>
<td>SRTR data analysis</td>
</tr>
<tr>
<td>Partial/split liver</td>
<td>SRTR data analysis</td>
</tr>
<tr>
<td>DCD liver</td>
<td>SRTR data analysis</td>
</tr>
<tr>
<td>Donor COD other*</td>
<td>SRTR data analysis</td>
</tr>
<tr>
<td>Donor COD CVA</td>
<td>SRTR data analysis</td>
</tr>
<tr>
<td>Donor race/black</td>
<td>SRTR data analysis</td>
</tr>
</tbody>
</table>

*Cause of Death not one of the following: trauma, CVA, or anoxia.

Other characteristics, such as steatosis (fat), serum sodium greater than 170, positive hepatitis serology and donor malignancy were discussed by the Workgroup as characteristics potentially indicating a higher rate of graft failure.

The Workgroup concluded that the data analyses included in this report will be helpful to practitioners deciding which ECDL are appropriate for transplantation.

The second Workgroup issue was to address the allocation of ECDL. The conclusion of the Workgroup was that a separate allocation policy for ECDL should not be developed for the following reasons:
• The decision to transplant an ECDL should be determined by the recipient’s medical condition at the moment of an organ offer versus the risk of waiting for the next organ offer from another future donor of unknown quality.

• Since the waiting list is not a static entity, and the characteristics of donors are not the same from offer to offer, allocation policy should not restrict the availability of organs to individual candidates and should not supersede clinical judgment in assessing risks and alternatives for individual candidates.

The third issue the Workgroup considered was the information that should be shared with a potential liver transplant recipient to achieve informed consent. A discussion of the transplant alternatives, including the transplantation of an ECDL, should be included early in the informed consent process, so that the recipient has time to consider the information in a non-urgent context. Obviously, this would be difficult to do if a candidate’s first presentation is at a time of medical urgency. Non-urgent candidates should otherwise retain informational materials to which they can refer to when making an informed decision at the time of a donor offer. The inclusion of family members spouses and/or a significant other in the informed choice discussion should be encouraged, because they may be called upon to give consent if the recipient’s medical condition renders them unable to consent. Potential recipients should be permitted to change consideration of receiving an ECDL at any time during the process.

The Workgroup recommends the following stages of consent be used for all liver transplant candidates.

1. **Initial phase:**

   During the initial transplantation evaluation phase the following information should be discussed with the potential recipient:

   • the quality of the deceased donor pool,
   • the characteristics of an ECDL,
   • the possibility of live donor transplantation for appropriate candidates at centers that perform this procedure.

   This informed choice discussion should include:

   • the use of donors with varying degrees of risk of failure when compared to the ideal donor,
   • the risks/benefits/alternatives of using such a donor versus waiting for the next donor in the context of the waiting candidates’ severity of disease and mortality risk.
The MELD score outlined earlier in this report can be helpful to define the risk of death on the list and the risk of waiting in comparison to the benefit of the transplant (with or without a graft from a donor with an increased RR).

2. **Ongoing education:**

   The transplant physician and/or transplant coordinator should provide ongoing education to the recipient while they await transplantation.

   As the candidate’s medical condition evolves, the ECDL option should be readdressed at appropriate intervals.

3. **Final consent at time of transplant.**

   At the time of the proposed transplantation, final consent should be obtained as the physicians have a more precise assessment of the risks associated with undergoing an ECDL transplant versus the risk of waiting for the next available donor.

References
