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## Special article

# Consensus document of the Spanish Society of Liver Transplantation. Waiting lists, liver transplantation, and quality indicators

## Documento de consenso de la Sociedad Española de Trasplante Hepático. Lista de espera, trasplante pediátrico e indicadores de calidad<sup>☆</sup>

Sociedad Española de Trasplante Hepático (SETH)<sup>\*,1</sup>

## ARTICLE INFORMATION

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### 2nd Consensus Meeting of the Spanish Society of Liver Transplantation, November 28, 2008, Madrid, Spain

This document contains the conclusions reached during the 2nd Consensus Meeting organised by the Spanish Society of Liver Transplantation (SETH) in November 2008. In this meeting, access and priority criteria for the waiting list were updated, a set of key questions for children's transplant programmes was addressed, and advances were made in implementing quality measurement systems for liver transplant (LT) programmes.<sup>1</sup>

### Waiting list

#### Systems for measuring the degree of hepatocellular failure

The moment an LT recipient is added to the waiting list (WL) is still a matter of great clinical variability. The most adequate

way to homogenise these criteria is to establish a system to measure the severity of the liver disease. This system has a minimum score which guarantees that the transplant itself will not lead to a higher mortality than that associated with the disease's natural progression, so that the survival rates will clearly increase after the LT. There is unanimous agreement about current measurement systems' usefulness for informing us about patient mortality on the WL. However, we must stress that these measurement systems inform us about the mortality variable without providing additional information about other aspects which have classically been considered when indicating a transplant, such as quality of life, social repercussions, etc.

The Child-Turcotte-Pugh (CTP) score, and more recently, the MELD (Model End Stage Liver Disease) score are references for evaluating the prognosis for cirrhosis patients. While the first is constituted by 3 objective variables and 2 subjective variables, the MELD system uses 3 objective variables without an upper evaluation limit (no ceiling effect).<sup>2</sup> This method is

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a step forward in gaining a better definition of at-risk patient categories and prioritising according to short-term prognosis, according to the "sickest first" policy. One disadvantage of the MELD formula is the decrease in prognostic precision for periods longer than three months. The CTP score offers c statistics which may be even better than the MELD formula for periods longer than 1 year.<sup>3,4</sup> Both the CTP classification and the MELD formula show acceptable accuracy levels for establishing the prognosis for a patient with chronic liver disease, and by these systems, in hospitalised patients, the "c statistic" is 0.84 and 0.87 respectively.<sup>2</sup> Nonetheless, the variables that they employ present a non-negligible interassay variation and may change due to extrahepatic factors such as diuretic treatment, haemolysis or sepsis.

It was recently suggested that adding a sodium measurement to the MELD formula could make it more precise.<sup>5,6</sup> However, this formula is also subject to interassay variations, not to mention the potential manipulation that may inadvertently occur with the use of diuretics. It is also unknown whether or not its use can increase mortality due to neurological causes. Due to all of these reasons, using this formula seems premature as long as we do not have validation data from larger groups with different cohorts.

1. Both the CTP score and the MELD system are adequate methods for measuring the severity of patients' chronic liver disease. However, the scoring systems that are used must be evaluated periodically, and they must be flexible in order to incorporate variables that will increase their precision in the future.

#### **Minimum criteria for accessing the liver transplant waiting list**

In a register study that examined transplantation as a treatment procedure, we were able to identify a cut-off point in the MELD formula after which transplantation has a protective effect. This point falls between a score of 15 and 17.<sup>7</sup> However, according to a recent communication from the same registry, when patients are classified according to disease aetiology, those affected by alcohol-related liver disease, and possibly other causes not related to hepatitis C, may benefit from transplantation when their MELD score is above 12 points. It seems clear that patients with a lower score who receive a transplant face a higher risk of death than candidate cases do.<sup>8</sup> In the same way, case studies and controls have pointed toward a transplant having a protective effect when the CTP score is above eight points.<sup>9,10</sup>

2. Candidates for inclusion in the WL are those patients with advanced-stage liver disease with a MELD score of 12 points or higher, or those placed in category B-8 or higher using the CTP score.

#### **Recommendations for managing the waiting list: prioritising**

The unanimous consensus is that the main criterion in WL management must be the seriousness of the condition and not the time the patient has been on the list. The time factor will only be taken into account in those exceptions in which the passing of time affects progression of the disease in a way

that formulas for measuring the severity of the liver function do not properly reflect (see below).

Evaluation of condition severity will be done according to the MELD formula. Out of all patients on the waiting list, the priority candidates are those with more than a 10% chance of dying while on the list. Under the current organ distribution system, we observe considerable variability in the mean time on the waiting list among different groups. This is an important factor and must be considered, given the close relationship between time on the waiting list and mortality.<sup>11</sup> We therefore believe that 10% risk of mortality may correspond to a MELD score ranging between 15 and 19 points depending on whether the patient spends a shorter or longer time on the waiting list. We must take into account the fact that the MELD score's variability depends on the severity of the patient's condition. High MELD scores may be more variable than lower scores in more stable patients. Using this consensus document, we urge different transplant groups to attempt to identify what the mean waiting time is for each of the different MELD categories.

3. Organ distribution for LT should be done according to the severity of patients' conditions. Patients with more than 10% probability of mortality while on the list (MELD>15–19) should be prioritised. The score should be reviewed on a monthly basis for priority candidates, and quarterly for all other patients on the list.

#### **Limitations and exceptions to the Model End Stage Liver Disease formula**

While condition severity and need for transplant may easily be calculated for patients in whom liver disease will be the cause of death, we also find other diseases and comorbidities requiring a transplant, whether they are associated with liver disease or not, and which cannot be evaluated using the classic prognostic measurement formulas and systems. These are the so-called exceptions. In this document, we assess 2 groups in order to evaluate exceptions properly: firstly, those patients who should be considered for a transplant and do not need to be prioritised, and secondly, patients who may be excluded from the WL due to the progression of the disease or their risk of death. While preparing this article, we have considered scientific evidence and established practices in addition to expert opinions.

##### *Hepatocarcinoma*

We should consider the type of exception in which liver failure is not, per se, the real threat to the patient's life; rather, it is the progression of the tumour to a point at which it cannot be cured.<sup>12</sup> The transplant recommendations and indications for hepatocarcinoma must be adapted to the recommendations listed in the consensus document which was recently prepared by different medical societies.<sup>13</sup> In that document, the Milan Criteria serve as the reference for including patients in a WL. Prioritising and assigning a score to patients who are considered to be at risk for progression is a more complex process. In this consensus meeting, it was unanimously concluded that *high-risk hepatocarcinoma patients, who therefore are candidates for prioritisation, are those*

with a single nodule larger than 3 cm or 2–3 nodules, with alpha-fetoprotein level above 200, or those with nodules smaller than 3 cm for whom adjuvant treatment has failed.

4. Prioritisation of high-risk patients should involve assigning an initial MELD score that guarantees a probability of exclusion from the list similar to the exclusion probability for patients without hepatocarcinoma. This score is raised according to patient's time on the WL.

In this article, we urge transplant groups to form local and regional committees for establishing priority criteria according to the consensus guides. Given that certain groups include patients with hepatocarcinoma with expanded criteria (more developed than the Milan criteria), these patients will be referred to such committees in order to be prioritised correctly.

#### *Ascites and hepatorenal syndrome*

For patients with refractory ascites and no deterioration of renal function, there is little evidence that they should be given additional priority on top of that indicated by the baseline MELD score.<sup>12</sup> Type I hepatorenal syndrome (HRS) is a clinical profile associated with high mortality.<sup>14</sup> When prioritising these patients, we recommend using the creatinine level at the time of hospitalisation, prior to the therapeutic intervention for the HRS, in order to calculate the MELD score.

#### *Hepatopulmonary syndrome*

We believe that patients with this condition should necessarily be prioritised given the risk of exclusion from the list due to a decrease in respiratory function. A  $pO_2 < 60$  mm Hg and proof of a shunt should be sufficient criteria for prioritising the patient.<sup>15</sup> Given the condition's progressive nature, time on the WL must be considered.

#### *Portopulmonary hypertension*

No solid evidence exists to show that transplant is the most adequate treatment for portopulmonary hypertension, but it has been observed to improve cases in which the hypervolaemic-hyperdynamic component is predominant. It typically presents with a mean pulmonary artery pressure below 45 mm Hg and with non-elevated pulmonary vascular resistances. Its progression speed with current treatments is unknown. The MELD score is also an inadequate measurement of the prognostic severity associated with each condition. We assume that a mean pulmonary pressure  $> 35$  mm Hg would justify prioritising the patient and conceding additional points so that he/she would remain on the WL. Patients with a mean pulmonary vascular pressure  $> 45$  mm Hg should not be prioritised due to their poor prognosis.<sup>16,17</sup>

#### *Cholangitis*

Some patients with structural problems with the bile duct frequently present cholangitis. Patients with recurrent bacterial infections may have complications (endocarditis, osteomyelitis) that would determine their exclusion from the active list.<sup>18</sup> Therefore, we consider that these candidates should be prioritised, and that furthermore, they should

receive additional points depending on their time on the waiting list.

#### *Oxaluria*

Finding an enzymatic defect in the biopsy is sufficient reason for a patient to be prioritised, although there is no solid evidence to indicate how much priority he or she should have.<sup>19</sup> Time spent on the waiting list should determine if additional points are to be awarded. (See action protocol for children.)

#### *Cystic fibrosis*

Liver disease in cystic fibrosis can be evaluated reasonably well using the MELD score. However, decreased pulmonary function evaluated by FRV (forced respiratory volume) increases pre-transplant mortality, and therefore these patients should be a priority.<sup>20</sup>

#### *Uncommon tumours*

Primary liver haemangioendotheliomas and neuroendocrine tumours confined to the liver call for prioritisation.<sup>21</sup> The rareness of these tumours means that local/regional committees should evaluate these cases one by one.

#### *Familial amyloidotic polyneuropathy*

In this patient group, there are no good methods for analysing mortality or motives for exclusion from the WL. Due to the absence of structural damage in the recipient's liver, we recommend reusing the liver in a domino procedure. Currently available data indicates that potential damage arising from using the liver in a future recipient seems to be negligible. In this situation, prioritisation of the familial amyloidotic polyneuropathy patient will be carried out by assigning the patient the MELD score of his or her liver's recipient.<sup>22</sup>

#### *Small for size syndrome*

This syndrome is the result of insufficient liver mass; it is detected by coagulation disorders, hyperbilirubinaemia and ascites, and is associated with a high mortality rate, meaning that patients must be prioritised and given preference by the local and regional review committees.<sup>23</sup>

#### *Polycystic liver disease*

Diminishing quality of life is a common cause for indicating a transplant in this patient group. However, there are some alternatives before reaching the point of transplant (percutaneous puncture, surgical unroofing, partial hepatectomy, etc). In cases of grave malnutrition evaluated with objective parameters, prioritisation may be considered by regional committees performing individual analyses.<sup>24</sup>

#### *Cholangiocarcinoma*

Patients with well-defined protocols have an acceptable survival rate, provided that they do not exceed 140 days on the WL. Inclusion in the list and a reasonable level of prioritisation should be possible in properly selected cases, within the protocols of well-controlled, well-designed and agreed-upon clinical studies.<sup>25</sup>

### *Budd-Chiari syndrome*

Patients with chronic Budd-Chiari syndrome (BCS) can be prioritised reasonably well using the MELD score if the syndrome presents spontaneously and the patients do not need additional points. Acute BCS patients should be treated according to the policies for fulminant hepatic failure.<sup>26</sup>

### *Other exceptions*

This section includes other conditions for which, due to lacking objective markers to quantify the severity of the disease (as in encephalopathy),<sup>27</sup> the disease decreasing quality of life without increasing mortality (pruritus)<sup>29</sup> or having non-transplant treatment alternatives (digestive haemorrhage)<sup>28</sup> the exceptions are not considered apt for prioritisation, and are therefore given their true MELD score. Mortality prediction for Weber-Rendu syndrome cannot be based on evidence; patients must be evaluated on an individual basis.

### *Re-transplant*

As we see with primary LT, there is a good correlation between the MELD score and WL mortality for the patient waiting for a re-transplant. The MELD system has a poorer correlation with mortality after re-transplant because it is affected by other factors that are not present in the MELD model, such as graft quality, ischaemic time or immunosuppression. Nonetheless, a large quantity of data indicates that retransplantation should be avoided in patients with a MELD score >25 due to the high rate of associated mortality (5-year survival <50%). On the other hand, as stated in the previous consensus document,<sup>1</sup> we support inclusion of the prognostic model proposed by Rosen<sup>30</sup> and suggest avoiding a retransplant in patients with a score >20.5 in the prognostic model proposed by that author. Graft quality is one of the most important factors for a successful LT in general, and for retransplantation in particular. Given the short list of studies analysing the predictive value of donor characteristics, it is difficult to make recommendations about which organs should not be used. However, the following grafts should be used with caution for retransplants: those from elderly patients, those having undergone a long hospital stay, or those with a prolonged ischaemic time.

5. *There is a good correlation between the MELD score and WL mortality for liver re-transplant. On the other hand, re-transplant should be avoided in patients with a MELD >25 and a score >20.5 in the Rosen model.*

### *Combined hepatorenal transplant*

There is a certain amount of controversy in medical literature with regard to the best moment for performing combined hepatorenal transplant. Ever since the MELD formula was implemented in the United States, the number of double transplants has increased significantly. This is probably related to way creatinine is weighted in the formula itself, in conjunction with the lack of clear directions. Recently, a document was published reflecting consensus among different societies which identified the patients who benefit from simultaneous liver and kidney transplantation:

1. Creatinine clearance (preferably measured with the isotopic method) below 30 mL/min.
2. Patients with hepatorenal syndrome or acute renal failure who remain on dialysis during at least 6 weeks.

In patients with acute renal failure who are not on dialysis, simultaneous renal transplant is not justified, since the one-year survival rate is 81.5% and only 1.5% need a kidney transplant.<sup>31</sup>

### *Donor-recipient pairing*

At this moment, there is no scientific evidence that would recommend pairing the recipient's indication and condition severity with the donor characteristics. However, in the light of a recently published study, LT with pairing between high-risk or suboptimal donors and recipients with less severe conditions can potentially increase the recipients' risk of mortality. In contrast, the recipients with the most severe conditions and highest waiting list mortality rates would benefit from any donor.<sup>32</sup>

### *Final recommendation*

Prognosis evaluation systems must be flexible systems that are open to incorporating new variables that improve their accuracy. In this way, different programmes' effectiveness and efficiency can be improved. The clinical variability for indicating transplants and the special treatment for exceptions are both considerable. Therefore, we must make an effort to reduce existing inequalities in LT access among Spain's different autonomous communities and among different transplant centres in the same autonomous community.

6. *We recommend implementing common priority lists in similar geographic areas in order to reduce unequal access to transplants.*

In addition, referring back to a previous recommendation,<sup>1</sup> the implementation of coordinated WL management models will require cooperation from the autonomous government through the transplant coordination offices. Application of these coordinated programmes would imply establishing control mechanisms enabling us to supervise results, revise criteria and audit compliance.

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## **2. Paediatric liver transplant. Prioritising the waiting list**

### *Introduction*

The objectives of including a paediatric patient on the transplant WL are as follows: 1) avoiding patient death; 2) avoiding suffering associated with advanced liver disease; and 3) avoid conditions and effects associated with the prolonged evolution of a liver disease for which there is no effective medical or surgical treatment (intolerable pruritus, intellectual delay, growth retardation). If LT is to be implemented at the

proper moment, considering the peculiarities of indicating a transplant in children, transplant access should be expanded by using complementary options: promoting cadaver donation, split liver transplantation and live donation.

The process of choosing a transplant candidate among registered patients at a transplant centre regards clinical severity as its main concern. The sickest children are prioritised. In children, ideal donor-receptor size is considered in cases of similar clinical severity. Giving priority to liver disease patients in a poorer clinical state enables us to decrease their mortality. Post-transplant survival analyses indicate that this policy has no negative repercussions on procedure results according to data from the United States<sup>33</sup> and Brussels.<sup>34</sup>

Breaking down the assignment of donors to recipients in a centre is not complicated. The largest paediatric programmes in the world perform between 20 and 40 procedures annually. This number enables us to have a good knowledge of each patient's characteristics and aids in the selection process. Managing organ distribution in a country or region according to the recipients' condition severity requires keeping a general recipient list and having an accepted system for evaluating urgency.

### Objectives of the consensus document

To analyse the circumstances associated with mortality on the paediatric transplant waiting list and recommend new prioritisation criteria directed at decreasing this mortality.

#### Background

**Transplant indication.** The favourable post-transplant survival rate in children, above 70% when the procedure began in the 1980s and higher than 90% in the last decade, has given rise to a change in the attitude toward the treatment of paediatric liver disease. With chronic liver disease, the risk of mortality due to the disease is not the factor that determines having a transplant; rather, it is the perceived quality of life affected by a liver disease that cannot be resolved with any other treatment and which has evolved to the point at which it compensates for the risk of premature mortality associated with a transplant.

The risk of mortality must be estimated in order to: a) determine the moment of the transplant before the child experiences extremely severe or damaging complications, and b) prioritise patients on the transplant WL.

*Transplant prioritisation by estimating risk of mortality on the waiting list PELD (Paediatric End stage Liver Disease) Model for chronic liver disease*

In 1999, the Institute of Medicine required that liver transplant specialists in the United States create a scoring system for evaluating risk of mortality in patients on the transplant WL, thus enabling them to establish norms for prioritising transplant access based on liver disease severity.

To this end, we collected clinical and analytical data from children (under 18) from the database belonging to Studies

of Paediatric Liver Transplantation (SPLIT), a consortium of centres in the United States and Canada that since 1995 has recorded data from patients when they are added to the transplant WL and every 6 months after their inclusion. The analysis was carried out using data from patients with a chronic liver disease and waiting for a first transplant. An initial model searched for pre-transplant mortality predictors based on information from 884 cases, including 41 deaths. A second model was developed for predicting death or need for admission in intensive care before the transplant. This model contained data from 779 children who were not admitted to the ICU at the time when they were added to the list; 74 died or were admitted to the ICU.<sup>35</sup>

The main variables predicting the prognosis three months after inclusion in the list were age and lack of growth. The most strongly associated factors were age of less than 1 year and a Z score of weight or height below -2 (2 standard deviations below the average for age and sex). The glomerular filtration rate calculated from the creatinine level did not have an influence.

In the model for validation with the ROC (Receiver Operating Characteristic) curve, we included the analytical variables identified as having an influence on mortality/ICU admission in the univariate analysis and the subsequent multivariate analysis. Multivariate analysis showed the following factors as significant: age, bilirubin and INR (for death only), and bilirubin, INR (International Normalised Ratio), lack of growth, and albumin (for death or ICU admissions). The scoring system that best predicted death before three months (AUC [Area Under Curve] ROC, 0.92) or death/ICU admission (AUC, 0.82) was based on bilirubin, albumin, INR, lack of growth, and age.<sup>35</sup> The formula is as follows:

$$\begin{aligned} \text{PELD} = & 0.436 \text{ age}(<1 \text{ year}) - 0.687 \log \text{ albumin g/dL} \\ & + 0.480 \log \text{ total bilirubin mg/dL} + 1.857 \log \text{ INR} \\ & + 0.667 \text{ growth retardation (z} < -2). \end{aligned}$$

Laboratory values of less than 1 are rounded up to 1 when calculating PELD. The score for children included in the list before reaching one year of age maintains the value assigned to age <1 year until they reach 24 months.

The PELD value can be calculated automatically on hepatology or liver transplant websites. A higher value reflects an increased probability of patient death within the next three months. Once the formula was established, considering events such as ascites, varicose haemorrhage and encephalopathy did not improve its predictive ability. The explanation for this fact is that those complications determine mortality depending on the baseline liver disease severity.<sup>35</sup> The PELD score's predictive ability for death on the transplant waiting list was validated by using the score in a large transplant centre with an area of 0.89 below the ROC curve.<sup>36</sup>

#### *Applying the PELD score in children: first experience in the United States*

A system based on 2 severity codes and designed to decrease the risk of death has been used in the United States since February 2002. On the one hand, we have the Status 1 priority

group, which includes patients whose death is projected in a very short time frame (7 days) and which mainly includes patients in acute liver failure; however, it may also include severely decompensated patients with chronic liver disease by means of petition to a committee which analyses each case. The other candidates receive transplants in turn according to their PELD score upon being added to the WL. A committee may decide to add points to the PELD score for patients with liver diseases whose risk is not properly graded under this system (hepatoblastoma or metabolic disorders with a risk of damage to another organ). In the United States, the donor assignment system does not prioritise paediatric use of organs from child donors. Competition for organs with adults (a much more numerous group; there is roughly one child per 17 adults) offers a partial explanation for the high percentage of children whose doctors request an evaluation for them to be placed in the Status 1 category "as an exception".

The SPLIT consortium's experience between 2002 and 2003 showed a significantly different mean PELD score between the most severe models of paediatric liver disease: fulminating liver failure (PELD=24.6), severe liver disease included in the Status 1 category due to being of particular risk (PELD=19.6) and children classified as Status 1 "as exceptions," that is, after having obtained additional points from a regulatory committee that evaluated the particular circumstances of their condition that were not reflected by the PELD score (PELD=14).<sup>33</sup>

Forty point three percent of patients on the list of child transplant candidates in the United States are classed in the Status 1 category (strictly for patients whose death is projected within the span of seven days, or "exceptional cases"), and the rest (60%) have a PELD<10. A retrospective analysis of the PELD score in children waiting for a transplant evaluated in Belgium showed a mean PELD score of 13.3. The value distribution was as follows: PELD>32.7 in 5%, PELD from 23.1 to 32.7 in 11%, PELD from 13.3 to 23 in 24%, PELD from 3.6 to 13.3 in 47% and PELD<3.6 in 13%.<sup>34</sup>

#### *Revision of groups with transplant priority*

The analysis of the 2002-2003 experience in the United States reached the conclusion that the priority group Status 1 included children with different risks of imminent mortality competing with one another. It found an equivalent risk of mortality for children with acute liver failure and children with chronic liver disease and a PELD score  $\geq 25$ . Children included in the Status 1 group "as exceptions" had a mortality equivalent to that of children with a PELD score of 22-26. Those who died on the waiting list waited an average of 4-5 days (for children with acute liver failure), while those who died with a chronic liver disease (including "exceptional cases" waited an average of 18-24 days.<sup>37</sup>

In 2005 the system was changed, and the following patients are now given Status 1 priority<sup>37</sup>:

**Status 1A: common for adults and children:** Fulminant hepatic failure must be present (including classic acute failure, Wilson's disease with acute decompensation, and failure of the previous graft due to thrombosis or primary damage), and

the patient must be in the ICU and meet at least one of the following criteria:

- a) mechanical ventilation;
- b) kidney failure with haemofiltration/haemodiafiltration,
- c) INR>2.

**Status 1B: children only.** Must be admitted to the ICU with a chronic liver disease, PELD score >25 and meet at least one of the following criteria:

- a) mechanical ventilation;
- b) haemorrhage (>30 cc/kg transfused in the previous 24 hours);
- c) kidney failure with haemofiltration/haemodiafiltration,
- d) Glasgow coma scale <10.

In the system for assigning paediatric donors (understood in the United States as those younger than 18), priority order is as follows:

1. Status 1A recipients
  - paediatric, local.
  - paediatric, regional.
  - adult, local.
  - adult, regional.
2. Status 1B recipients
  - local.
  - regional.
3. Children aged 0-11, regional
  - order determined by PELD.
  - (1st >15 local, 2nd >15 regional)

#### **Framing the problem in Spain**

In Spain, the National Transplant Organisation (ONT) holds the list of recipients and has a specific coding system (*Urgencia 0* [Emergency 0]) that prioritises candidates on a national level. "Urgencia 0" is only for those patients with acute liver failure and urgent retransplantation candidates (in children, graft failure within 30 days of transplant).

Patients not in the *Urgencia 0* group follow the transplant order established by the transplant team based on the organs offered by the ONT, which has a policy of giving successive turns to hospitals in each community, with preference given to using the donor organ in the centre whose turn comes up. In Spain, paediatric donors (under 15 years of age) are preferred for child recipients, and children can only receive organs from adult donors if they are classed as *Urgencia 0*. Under this system, the mortality rate on the waiting list for a paediatric liver transplant in 2007 in Spain was 7%.

In Spain, there is a concept of a "priority" paediatric candidate with chronic liver disease who may be granted access to a transplant through an agreement with the hospital whose turn it is to be assigned a valid donor. The main difficulty with the current system is providing fast access to transplants for children in very advanced states of chronic liver disease with complications (similar to that established in the United

States as Status 1B). Another existing difficulty is providing transplant access to children with particular needs, such as those with tumours (to avoid extension contraindication and to synchronise the moment of the transplant with phases with no haematological complications from chemotherapy), children with metabolic disorders and a risk of irreversible neurological damage and those needing combined organ transplants.

Up until now, optimisation of transplant access has focused on developing live-donor transplant programmes. The medical and surgical evaluation of the donor and compliance with legal requirements result in a waiting time of approximately one month before the live-donor transplant takes place. Building up this programme is controversial, because if we use donor organs in an optimal manner and split them between two recipients where a donor is ideal, live donation may be unnecessary. However, it does present true advantages: it allows for scheduling in stable patients, and improves access to cadaver donors for patients who do not have, want, or are faced with a technical contraindication for a live-donor transplant. The possibility of a live donor, added to the common practice of a split transplant, could serve to eliminate pre-transplant mortality.<sup>38</sup>

In this moment, it is thought to be necessary to establish a national priority system for access to cadaver donors which includes children with chronic liver disease and a high risk of mortality.

### Conclusions by the consensus meeting

In Spain, considering the number of liver transplants that are performed and the percentage of donation present, no child should die while on the WL for a transplant. We recommend implementing the following measures:

1. *Matching donor age to recipient age:* That is, considering all donors 16 years old or younger to be paediatric donors.
2. *Implementing and focusing on split transplants:* this way, all donors who meet the characteristics for being optimal split transplant donors should be offered to paediatric LT groups in order to increase the liver graft pool. It is widely known by all Spanish LT groups that the results obtained with this type of transplant are comparable to those obtained when a whole organ is implanted. The yearly number of donors who meet the requirements for this type of transplant is not very high, but it is high enough to offer a solution for the mortality rates signalled by the paediatric LT groups. Therefore, we need cooperation from the rest of the adult transplant groups and the creation of a list of low-weight adult recipients who would receive the right lobe after the donor organ is divided. This list will be sent to the ONT and the right lobes will be assigned in the same manner as the whole organs. The procedure in the donor would be carried out by two harvest teams (paediatric and adult), or else the paediatric team would send the graft to the corresponding centre after completing the split (similar to the procedure for a liver-pancreas extraction).

This model has begun to be implemented in Andalusia, due to the cooperation of all of the transplant groups and the regional coordinators.

3. *Implementing the PELD system:* given the experience gained after implanting the MELD system and the benefits it has provided in the area of reducing WL mortality, we feel that we should do the same for the paediatric population and that all paediatric transplant groups should use this system.
4. *Prioritising on the WL:* once the PELD system has been implemented, WL prioritisation will be done according to the PELD score, differentiating between the following groups:
  - PELD<15: the local transplant unit evaluates transplant order.
  - PELD 15–22: inclusion in the centre's priority WL.
  - PELD 22–25: inclusion in the autonomous community's priority WL.
  - PELD>25 with a complication that requires admission to the ICU: inclusion on the national paediatric priority list during seven days, after which the patient will be considered "Urgencia 0".
  - Urgencia 0 (acute organ failure; post-transplant complication): given national priority.

"Special cases" included on the local priority WL:

- a) metabolic disorders with neurological effects;
- b) tumours;
- c) cystic fibrosis;
- d) recipients younger than 1 year and weighing less than 10kg;
- e) combined transplant recipients.

If these patients do not receive a transplant within a month, they will be placed on the national paediatric priority list.

5. *Need for a common list on a national level:* we feel it necessary to create a national paediatric priority WL like the Urgencias 0 list. Such a list would include recipients with a high risk of mortality while on the WL.
6. *Assignment of organs and grafts:* paediatric and adult donors who meet the requirements for a split transplant will be offered first to recipients on the national paediatric priority list. For split transplants, the right lobe will be assigned according to the existing criteria.  
In the event of not having any paediatric recipients on the national priority WL, organs obtained from paediatric donors assigned to each group should be implanted in recipients of equal weight with the highest PELD score. If the donor's weight is correct, a split transplant for two paediatric recipients will be considered.

## 3. Liver transplant quality indicator manual

### Introduction

In 2005, the Spanish Society of Liver Transplantation (SETH) held a consensus seminar in order to ensure

continuous improvement of quality and results in LT units. The seminar was divided into work groups made up of professionals belonging to that society who debated different matters or current relevance for the practice of LT.

One of the work groups took charge of developing a set of quality indicators that can be monitored to provide periodic measurement and evaluation of pertinent aspects for the provided service. This development consisted of determining a set of relative indicators for these units, and defining and standardising them. The intention was to identify aspects of the care process that should be defined and evaluated, and generate open debate among those professionals interested in improving the quality of the service provided. These results were published in the SETH Consensus Document in 2008.<sup>1</sup>

In a second seminar held in 2008, professionals selected indicators with the desired degree of reliability, validity and precision. To that end, the indicators were subjected to a pilot study and critical analysis by an improvement task force. This document summarises the 1st SETH Consensus Meeting, the tasks carried out based on the defined list of indicators, the 2nd Consensus Meeting and the conclusions reached, which are the result of teamwork and cooperation between professionals sharing the same concern: quality in LT.

### Methodology

The project to design and validate LT quality indicators was developed in three stages:

- a) 1st SETH Consensus Meeting;
- b) Pilot experience and analysis of results obtained;
- c) 2nd SETH Consensus Meeting.

The first SETH Consensus Seminar, held in November 2005, was divided into 4 task forces made up by members of that society. The groups debated the following:

- a) access to WL;
- b) limits on transplant indications;
- c) WL prioritisation;
- d) quality indicators in LT.

The task force which focused its debate on LT quality indicators, known as "Group 4: Quality and Accreditation in Liver Transplantation" was formed by the following members of SETH:

1. Coordinators:
  - Pardo, Fernando (SETH)
  - Clemente, Gerardo (SETH)
  - Pérez Lázaro, Juan José (Andalusian School of Public Health)
2. Participants
  - Barneo Serra, Luis (Hospital Central of Asturias)
  - Charco, Ramón (Hospital Clinical of Barcelona)
  - Fraga, Enrique (Reina Sofía)

- Lozano, Ricardo (Zaragoza)
- Martínez, Jorge (Xeral of Santiago)
- Meneu, Juan Carlos (12 de Octubre)
- Gómez Fleitas, Manuel (Hospital Valdecilla)
- Santoyo, Julio (Carlos Haya)
- Soriano, Arturo (Tenerife)
- Villar, Jesús (Virgen de las Nieves)

Firstly, they approached identifying and prioritising LT indicators. To do so, they used a modified Delphi method in which each component of the group of experts listed what medical factors should be measured for the LT process. Based on this anonymous method, they generated true repetitions and controlled feedback for the questions being debated. When the information was combined, they undertook a task of synthesis and selection to obtain a reasonable set of possible indicators.

Subsequently, professionals were asked to participate in a group activity to prioritise the obtained results, which gave us the level of agreement among professionals for each indicator.

The selected indicators were as follows:

- a) post-liver transplant in-hospital mortality;
- b) perioperative mortality;
- c) rate of liver retransplantation;
- d) rate of early reintervention;
- e) transplant patient survival;
- f) existence of an established screening protocol for de novo neoplasias;
- g) existence of an established protocol for detecting and treating cardiovascular risk factors;
- h) informed consent;
- i) complications with live liver donors;
- j) patients evaluated in 30 days or less after making an appointment with the Functional Liver Transplant Unit (UFTH);
- k) percentage of lack of primary liver function;
- l) refusal rate for livers without an objective justifiable reason;
- m) satisfaction of the transplant patient.

A complete data sheet was designed for each of these indicators, following the indications of the Joint Commission on Accreditation of Healthcare Organisations. The sheets specified each indicator's definition and formulation, offered an explanation of terms, and designated the study population, indicator type, data source, standard and comments. They were subsequently published in the SETH Consensus Document.<sup>1</sup>

Following the initial step of identifying, prioritising and defining the indicators obtained, and with a view to evaluating reliability, validity and precision aspects for each indicator, we developed a pilot study and analysis of the results obtained in different centres and institutions in which professionals actively participated in the project.

The first launch consisted of collecting information for the defined indicators at these centres, identifying difficulties, and subsequently analysing obtained data.



### 1) Data collection

In this step, we selected the data referring to each indicator in different hospitals, with cooperation from the following professionals:

- Bárcena Marugan, Rafael (Hospital Ramón y Cajal);
- Citores Pascual, Miguel Ángel (Hospital Universitario Río Hortega);
- Clemente Ricote, Gerardo (Hospital Gregorio Marañón);
- Cuervas-Mons Martínez, Valentín (H. U. Puerta de Hierro-Majadahonda);
- Fuster Obregón, José and Dr Calatayud (Hospital Clínico);
- Garrote Lara, Daniel and Dr. Granero (H. U. Virgen de las Nieves);
- Gómez Bravo, Miguel Ángel (H. U. Virgen del Rocío);
- Gómez Gutiérrez, Manuel (Hospital Juan Canalejo);
- Miyar, Alberto (H. U. Central of Asturias);
- Pardo, Fernando (Clínica Universitaria of Navarra),
- Solórzano Peck, Guillermo and Dr Montero, José Luis (Hospital Infanta Cristina).

Based on the provided documents, in addition to gathering information about indicators we also detected difficulties in the information gathering process, measurement impossibilities for certain indicators (for which it is too expensive, imprecise or complicated), different interpretations of the same definition, and different methods for measuring the same indicator.

### 2) Analysis of the data obtained

Once the information was obtained from participating hospitals, it was subjected to exhaustive analysis. The data identifying each centre and each indicator was necessarily codified.

The team mainly performed 2 types of analysis:

**Analysis by indicator:** This provides us with a means of comparing the indicator among participating centres and to the established standard.

In this case, we see that all hospitals met the standard established for the I3 indicator – (liver retransplantation rate) given that all have a rate of less than 10%. However, we can see how hospitals H2, H6 and H11 have much lower rates than H3 and H10; these last have rates that approach the upper limit established by the standard (Figure 1).

**Analysis by hospital:** this study is of considerable internal value for each centre, and allows each one to view its strong and weak areas. The analysis distinguishes between indicators which should not exceed a certain value according to the standard, and indicators for which the standard should not fall below a certain value.

We can take the diagrams obtained for hospital H1 as an example:

The diagram on the left shows us that hospital H1 meets indicators I8.2 (complications with live liver donors: morbidity), I3 (liver retransplantation rate) and I4 (early reintervention rate), since its scores fall below the maximum established value, and does not meet indicators I1 (hospital mortality) and I11 (primary malfunction rate), since the scores exceed the maximum established standard value (Figure 2).

The diagram on the left shows us that this hospital meets indicator I7 (informed consent), I8.1 (live liver

donor complications: mortality) and I5.1 (1-year survival of transplant patient) given that the measurements are equal to the minimum established value. It does not meet I9 (percentage of patients studied in under 30 days), I5.2 (3-year transplant patient survival) and I5.3 (5-year transplant survival) since it does not reach the respective values for those standards.

We do not have available information for the other indicators - I5.4, I10 and I12, and for I2 there is no established standard, so we cannot examine a centre's compliance.

The 2nd Liver Transplant Consensus Meeting, held in November 2008, was also divided into 4 groups. On this occasion, the groups addressed the following:

- a) WL;
- b) paediatric transplantation;
- c) high-risk patients: HIV;
- d) quality and accreditation.

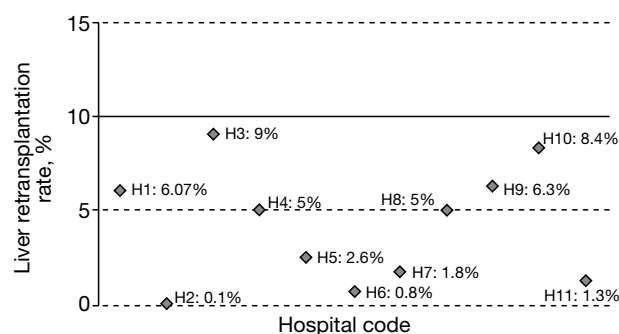
In this second seminar, "Group 4: LT quality and accreditation" consisted of the following SETH members:

#### 1. Coordinators:

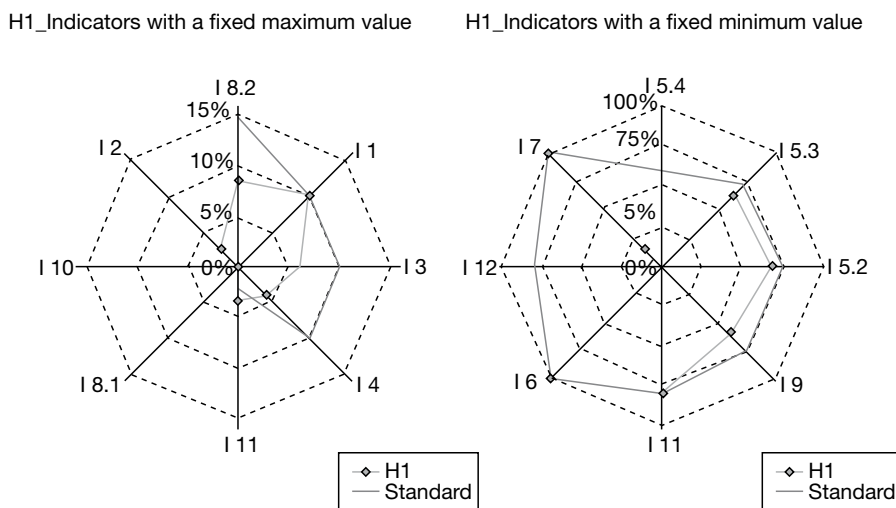
- Clemente Ricote, Gerardo (SETH);
- González-Pinto Arrillaga, Ignacio (SETH),
- and Pérez Lázaro, Juan José (EASP).

#### 2. Participants

- Bárcena Marugan, Rafael (Hospital Ramón y Cajal);
- Casanovas Taltavull, Teresa (Hospital Vall d'Hebrón);
- Citores Pascual, Miguel Ángel (Hospital U. Río Hortega);
- Cuervas-Mons Martínez, Valentín (Hospital U. Puerta de Hierro-Majadahonda);
- De la Rosa, Gloria (ONT);
- Fuster Obregón, José (Hospital U. Clinic);
- Garrote Lara, Daniel (Hospital U. Virgen de las Nieves);
- Miras López, Manuel (Hospital U. Virgen de la Arrixaca);
- Ramos Rubio, Emilio (Hospital U. Bellvitge);
- Rufian Peña, Sebastián (Hospital U. Reina Sofía);
- Serrano Aullo, Trinidad (Hospital Clínico U. Lozano Blesa);
- Solórzano Peck, Guillermo (Hospital U. Infanta Cristina),
- and Soriano Benítez de Lugo, Arturo (Hospital U. Ntra Señora de la Candelaria)



**Figure 1 – Analysis by indicator.**



Nota: información no disponible para los indicadores I 5,4, I10 e I 12

**Figure 2 - Analysis by indicator.**

Their work focused on evaluating and calibrating the defined indicators. To this end, they presented the datasheets for each indicator and the analysis of the obtained information.

The resulting debate and consensus addressed the following matters:

- validity of the data obtained: difficulties with gathering information, clarity problems or ambiguities found in indicator definitions, exceptions that must be considered, data quality and its repercussion in results, variability of certain indicators, possible modifications to the criteria, standards, information sources, etc;
- reliability of the results: intraobserver and interobserver reproducibility and variability; comparability of data, whether the indicators provide a proper evaluation of the characteristic to be measured, etc;
- significance of the hospital sample in which the pilot study was completed and the coverage they provide to the study population;
- indicator sensitivity or specificity, that is, whether this group of indicators exposes all problems with quality, or reveals factors that are not quality problems.

In this seminar, the definitions of certain standards were perfected, and values for those standards were adjusted or determined based on the best scientific evidence, or where not available, upon the real situations observed in this initial experience. We determined which indicators were not to be developed because of finding a minimum or correlated effect, and defined certain indicators that were thought to be necessary for evaluating the direct quality of the LT process and which were not listed in the initial group of indicators.

#### **Liver transplant quality indicators**

*Early post-liver transplant mortality*  
Code 02

**Definition.** Percentage of transplant patients who die in the first month following the transplant.

**Rationale.** Results indicator which monitors early post-transplant mortality and allows us to focus on analysing causes, relationship with the candidate evaluation process, donor characteristics, procedure and recent post-operative care.

**Formula/format.** Number of transplant patients who died in the first month following transplant/total transplant patients  $\times 100$  in the same period.

**Explanation of terms.** Includes patients who died from the moment the LT began (operating theatre, ICU and hospital ward).

**Population.** All patients who received an LT.

**Type.** Percentage-based result.

**Data source.** Clinical documentation BMDS (Basic minimum data set).

Software application from hospital admissions

Mortality commission and clinical history for qualitative analysis.

**Standard.** Below 10%.

**Comments.** This parameter should be measured quarterly.

*Perioperative mortality*

Code 03

**Definition.** Percentage of transplant patients who die from the moment the surgery begins up to the first 24 hours after the operation.

**Rationale.** Intended to show the transplant mortality rate for the first 24 hours. Cause study. Lists complications presented by recipients (portal vein thrombosis, incidental multifocal or vascularly invasive hepatocarcinoma, severe cardiovascular complications unknown before the transplant, complications of anaesthesia, or surgery) compared with the total transplant number.

**Formula/format.** Number of mortalities during the first 24 hours after transplant/total number of transplant recipients  $\times 100$  in the same period.

**Explanation of terms.** Includes transplant patients who died in the operating theatre, during reanimation or in the ICU.

**Population.** All patients who received an LT.

**Type.** Percentage-based result indicator.

**Data source.** Transplant unit records at each centre.

**Standard.** Not established (based on the RETH database, it would be possible to establish  $<5\%$ )

**Comments.** The objective is to determine whether the deaths that occur are related to the recipient's clinical condition, arise from unexpected findings that were not detected by the pre-transplant evaluation, or are due to intraoperative complications.

To be evaluated on a monthly basis.

*Early liver retransplantation rate*

Code 04

**Definition.** Percentage of liver retransplants indicated in the first 7 days globally for each transplant series that uses cadaver donors.

**Rationale.** Intended to evaluate the frequency and causes of early retransplantation.

Detects improper selection of recipients and donors (cadaver) and the technical problems caused by severe graft dysfunction.

**Formula/format.** Number of liver retransplants indicated in the first week post-LT/ total number of transplants in the series  $\times 100$  in a certain period.

**Explanation of terms.** Patients who receive a second LT in the first week post-transplant.

**Population.** The entire series of transplant patients. Transplants performed with non-cadaver grafts are excluded.

**Type.** Percentage-based results.

**Data source.** Data from each transplant series. Clinical histories.

**Standard.** Below 8%.

**Comments.** This could be a quality indicator for the immediate post-transplant period. Should be evaluated every six months.

*Late liver retransplantation rate*

Code 04\_2

**Definition.** Percentage of liver retransplants, excluding any indicated in the first week, out of the total of each transplant series.

**Rationale.** Intended to evaluate the frequency and causes of late retransplantation. Detects long-term consequences of technical and medical problems (inappropriate immunosuppression protocols or viral recurrence prophylaxis).

**Formula/format.** Number of liver retransplants indicated after the first week post-LT/total number of transplants in the series  $\times 100$  in a certain period.

**Explanation of terms.** Patients who receive a second LT.

**Population.** The entire series of transplant patients.

**Type.** Percentage-based results.

**Data source.** Data from each transplant series. Clinical histories.

**Standard.** Below 6%.

**Comments.** This is a quality indicator in the post-transplant phase and a long-term activity indicator.

It should be evaluated twice yearly.

*Early reintervention rate*

Code 05

**Definition.** Percentage of transplant patients who require an unplanned second operation in the 15 days following the surgery, due to a complication with the primary surgery.

**Rationale.** Evaluates the frequency of technical problems with the transplant and the surgical complications that may arise. Complications and reoperations may occur despite use of proper surgical technique.

**Formula/format.** Number of transplant patients requiring reoperation in the first 15 days/number of transplant patients  $\times 100$  in a certain period.

**Explanation of terms.** All surgical procedures (excluding percutaneous or endoscopic techniques and patients who died prior to the study period) performed under general anaesthesia due to a LT-derived complication which appeared in the first 15 days post-transplant.

**Population.** All patients who undergo LT.

**Type.** Percentage-based result.

**Data source.** BMDS.

**Standard.** Below 9%.

**Comments.** To be evaluated quarterly.

*Transplant patient survival*

Code 11

**Definition.** Survival rate for transplant patients within a series, following after 1, 3, 5, and 10 years post-transplant.

**Rationale.** Intended to show whether the survival results after one, three, five and ten years post-transplant meet the published standards in order to identify problems and implement solutions for any deficiencies.

**Formula/format.** Numerator: number of live transplant patients at the time of each cut or analysis (1, 3, 5, 10 years).

**Denominator.** number of transplant patients at the beginning of the period.

Actuarial survival curves at 1, 3, 5, and 10 years.

**Explanation of terms.** Transplant patients who are still alive 1, 3, 5, and 10 years after their surgery. Includes all deaths that are not related to the process.

**Population.** All patients who undergo LT.

**Type.** Percentage-based result indicator.

**Data source.** Clinical histories of transplant patients. Annual reports by transplant centres. Spanish National LT Registry.

Standard. Overall survival rate of 80% at 1 year, 75% at 3 years, 70% at 5 years, and 60% at 10 years.

*Cardiovascular risk factor detection and treatment*  
Code 17

**Definition.** Presence in each transplant centre of an established protocol for detecting, treating and following up on cardiovascular risk factors which may appear in the post-transplant phase (obesity, diabetes, hypercholesterolaemia and hypertriglyceridaemia, arterial hypertension [AHT]). Beginning in the sixth month post-LT.

**Formula/format.** Absence or presence of the abovementioned protocol.

Dichotomic: Yes/No

Obese, diabetic, hyperlipidaemic, hypertensive transplant patients alive six months after the LT surgery  $\times 100$  in a certain period.

**Explanation of terms.** A protocol is understood to be any written, detailed medical action plan regarding evaluating patients to actively search for cardiovascular risk factors. Intended to identify patients with such factors.

**Population.** Transplant centres.

**Type.** Structure indicator.

**Data source.** Clinical guides or transplant protocol for each transplant unit.

*Patients evaluated in less than 30 days after contacting the Functional Liver Transplant Unit*  
Code 34

**Definition.** Percentage of patients evaluated by the Liver Transplant Unit (whether or not they were placed on the WL after the evaluation) in less than 30 days after making an appointment.

**Rationale.** To evaluate the efficiency of the assessment process for deciding whether or not to include a patient in the WL. Delays in a patient's evaluation process frequently occur due to organisational reasons at the unit or health care centre. Decreasing delays lowers patient anxiety and understanding the delays allows us to improve the decision-making process.

**Formula/format.** Number of patients with an evaluation completed in fewer than 30 days after making a transplant evaluation appointment/number of patients referred for transplant evaluations  $\times 100$  in a set period of time.

**Explanation of terms.** Patients given an initial appointment at the transplant unit.

Elapsed time from the evaluation was requested to the decision being made by the transplant recipient evaluation committee.

Number of patients who have completed the evaluation and for whom a decision is reached in 30 days or fewer compared with the total number of patients referred for evaluation.

**Population.** All of the patients referred to transplant units for evaluation and placement on the WL.

**Type.** Process indicator.

**Data source.** Study of the case histories of all patients being evaluated by the liver transplant unit and a review of times

between the evaluation and reaching the decision of what action to take with the patient.

**Standard.** Percentage of patients assessed in 30 days or less:  $\geq 75\%$ .

*Appearance of primary liver function failure*  
Code 36

**Definition.** Percentage of transplant patients who develop lack of primary graft function.

**Rationale.** Understanding the rate of "lack of primary graft function" as an indicator of team communication, coordination, dexterity and experience with regard to cold and warm ischaemia times, the quality of the implanted liver, technical factors, logistics, team coordination, etc.

**Formula/format.** Transplant patients who develop a "lack of primary graft function" which causes retransplantation or death/total transplanted patients  $\times 100$  in a certain period.

**Population.** Transplant patients.

**Type.** Result indicator.

**Data source.** Transplant unit records, clinical history.

**Standard.** Below 2%.

**Comments.** This measurement should be made on a quarterly basis.

*Rate of liver refusal without an explainable objective cause*  
Code 37

**Definition.** Percentage of livers that are refused after they are accepted with no justifiable objective cause (histological factor showing an existing abnormality in the donor liver or abnormality detected by the surgeon in charge of the donor team and present in the clinical history) that the transplant team can explain.

**Rationale.** To evaluate whether the refusal rate for donor livers is acceptable, based on the current criteria for accepting donor organs. The purpose is to detect unjustified refusals and increase treatment options for patients on the WL.

**Formula/format.** Number of rejected livers/number of implantable livers  $\times 100$  in a certain period.

**Population.** All whole or partial donations meeting inclusion criteria for being implanted.

**Type.** Process indicator.

**Data source.** Transplant unit records and those belonging to the ONT.

**Donor protocol.** Anatomical pathology at time of implantation. Clinical document with the reasons for excluding a donor, signed by the surgeon responsible for organ harvest. Analysis of refusal causes. Evolution of refused livers subsequently implanted by another group.

**Standard.** Implemented following the first analyses.

*Rate of refused livers*  
Code 37\_1

**Definition.** Percentage of livers refused by the transplant team after a donor is proposed.

**Rationale.** To evaluate whether the refusal rate for proposed livers is acceptable, based on the current criteria for accepting

donor organs. The purpose is to detect unjustified refusals and increase treatment options for patients on the WL.

*Formula.* Number of refused livers/number of implantable livers  $\times 100$  in a certain period.

*Population.* All of the whole livers made available for implantation.

*Type.* Process indicator.

*Data source.* Transplant unit records and those belonging to the ONT.

*Donor protocol.* Analysis of reasons for refusal. Evolution of refused livers subsequently implanted by another group.

*Standard.* Not established.

*Transplant patient satisfaction*

Code 40

*Definition.* Administering a satisfaction survey to a group of transplant patients.

*Degree of overall satisfaction among liver transplant patients.*

*Rationale.* To evaluate the quality perceived by the transplant patient with regard to the overall care received during the LT process.

*Formula/format.* Measuring overall user satisfaction by assigning a score to each item in the survey.

*Population.* All transplant patients.

*Type.* Result indicator.

*Data source.* Analysis of surveys filled out by patients and family members.

*Standard.* Completing the survey.

*Percentage of satisfied/very satisfied respondents above 80%.*

*Comments.* Should be measured yearly.

### Recommendations

During the process of evaluating the initial set of defined indicators, some of those indicators were suppressed as it was

believed that they did not directly assess the quality of the LT process. However, due to the contributions of collected data referring to those indicators and the positive implications that they may have, our conclusion is to recommend using the following:

#### *De novo neoplasia detection protocol*

We feel that there should be a common consensus protocol in all centres, but as this is not likely to occur, it might be enough if each one had its own individual protocol.

#### *Protocol for cardiovascular risk factor detection and treatment*

Action in this area will improve patient survival both qualitatively and quantitatively.

#### *Informed consent*

We recommend having written information about what the patient should expect in LT, which would preferably be uniform and common to different LT units. This allows the patient to understand his or her situation, risks and future.

The following task force was gathered to create this document: Dr Rafael Barcena, Dr Teresa Casanovas, Dr Daniel Garrote, and Dr Ignacio González. This group's work will be evaluated by the Andalusian School of Public Health.

#### *Complications in the live liver donor*

This involves analysing morbidity in transplants with live donors (in both the donor and recipient) and detecting deviations in excess of the published complications.

Given that performing a transplant with a live donor is not a widespread activity, it has been decided that the process is considered to be different from that with a cadaver donor. All of the criteria established for cadaver donors must be evaluated in live donor LTs.

## Appendix. Participants in the task forces

### Waiting list group

#### Coordinators:

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Santiago Tomé Martínez de Rituerto

#### Participants:

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Manuel de la Mata García

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Hospital Reg. U. Carlos Haya, on behalf of SETH

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#### Paediatric liver transplant group

##### Coordinators:

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##### Participants:

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 Hospital U. 12 de Octubre  
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 Hospital U. La Fe

##### Quality indicators group

##### Coordinators:

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 Hospital U. Central de Asturias, on behalf of SERTH  
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##### Participants:

Rafael Bárcena Marugan  
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 Miguel Ángel Cítores Pascual  
 Valentín Cuervas-Mons Martínez  
 Gloria de la Rosa  
 José Fuster Obregón  
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 Hospital U. Puerte de Hierro-Majadahonda  
 ONT  
 Hospital Clínic of Barcelona  
 Hospital U. Virgen de las Nieves  
 Hospital U. Virgen de la Arrixaca  
 Hospital U. of Bellvitge  
 Hospital Clínico U. Lozano Blesa  
 Hospital U. Infanta Cristina  
 Hospital U. Ntra. Sra. de la Candelaria

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