Änderung der Richtlinie gemäß § 16 Abs. 1 S. 1 Nrn. 2 u. 5 TPG für die Wartelistenführung und Organvermittlung zur Lebertransplantation

Ergebnis Fachanhörungsverfahren, Stand 01.11.2024

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Leiden, October 31, 2024
Reference: 24043LAC24/mz

Subject: Stellungnahme Institution erste Lesung der Richtlinie Leber 25-09-24

Dear colleague,

Please find below our reply to the request for *Stellungnahme erste Lesung der Richtlinie Leber 25-09-24*.

In sentence 984 *III.6.4 Elektive Allokation bei Kindern und Jugendlichen (< 18 Jahre)* we see that besides the foreseen change in the pediatric age definition from 16 to 18 years, changes have been made in the accumulation of pedMELD points and the freezing of the pedMELD points after reaching the age of 18.

For these last 2 changes we would like to stress that the pedMELD score is an international score used for pediatric recipients in all countries. Therefore, changes in the score itself should be made with international consensus after discussion in the ELIAC.

Accumulation of points in the pedMELD score
The accumulation of points in the pedMELD score currently distinguishes between pediatric patients <12 and ≥12 years of age, the first group receiving a higher initial pediatric MELD equivalent than the second group:

1) pediatric recipients <12 years of age receive an initial pediatric MELD equivalent to 35% probability of 3-month mortality on the waiting list and 90-day upgrades of 15%
2) pediatric recipients ≥12 years of age receive an initial pediatric MELD equivalent to 15% probability of 3-month mortality on the waiting list and 90-day upgrades of 10%.

The proposed change in the Richtlinie describes to abolish this difference in the two pediatric groups. If international consensus is found to abolish this difference in pedMELD score for the two pediatric groups, international consensus is required on how pedMELD score buildup is applied to all pediatric patients under the age of 18.

Frozen pedMELD points
Currently, the accumulated pedMELD points are ‘frozen’ after reaching the age threshold; no further automated upgrades are performed and the pedMELD score is maintained until delisting.

The highest valid MELD at time of matching i.e. either labMELD, pediatric MELD or exceptional MELD score is applied in the match.
The decision to abolish the frozen pedMELD should be made with international consensus.

Adjustment of Standard Exceptions
As described in the ELAS Manual paragraph *5.2.3.7 Pediatric SE and reaching of age threshold,* there are two pediatric Standard Exceptions (SE) with an age threshold:
1) SE PH1 (Oxalosis) with an age threshold <1yr,
2) SE biliary atresia with an age threshold <2yr,

If a pediatric patient with one of these SE's reaches the age threshold, the exceptional MELD is frozen at the time the patient reaches the age threshold. This frozen exceptional MELD is kept until transplantation. It should be decided whether these SE's need adjustment as well.

Effect of the intended changes in the pedMELD score
If the intended changes in the pedMELD score would be implemented in the current wording, it would result in an advantage of German pediatric patients ≥12 years of age on the waiting list for international offers over non-German pediatric patients, resulting from higher points in comparison to a non-German pediatric patient of the same age. And to a disadvantage for German patients that reach the age of 18 versus non-German patients of the same age due to losing the frozen pedMELD.

For Eurotransplant, the proposed change would result in an extensive IT implementation, which would require us to revise our priorities and timing of implementation.

We propose discussing the intended changes within the ELIAC first, in order to reach a broadly supported decision before implementation.

Kind regards,

Marieke de Rosner, MD
Medical Staff

Erwin de Buijzer, MD MBA
Medical Director

Kommentar zur geplanten Änderung

Richtlinie gem. § 16 Abs. 1 S. 1 Nrn. 2 u. 5 TPG für die Wartelistenführung und Organvermittlung zur Lebertransplantation

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Die vorgesehene RL-Änderung beruht auf den im Literaturverzeichnis zitierten Arbeiten. In diesen Publikationen war die 90-Tage-Mortalität Zielpunkt der Modellierung. Aus einer ET-Datei der Jahre 2010-2015 (n=10518; davon 7919 Patienten mit MELD-Allokation) ergibt sich hinsichtlich der Wartelistenbewegungen folgendes Bild:

WL-Mortalität (nur MELD-Patienten; n=7919; ET 2010-2015)			
	<=90 Tage	Tag 91 bis Entfernung von WL	Gesamt
Deceased/Rem	1092	1523	2615
Transplanted	2764	1809	4573
Summe	3856	3332	7188
WL-Mortalität (%)	28,3	45,7	36,4

Dec/Rem = Deceased/Removed: unfit for transplantation
Transpl = Transplanted

Danach ist nicht nur die WL-Mortalität wesentlich höher als in diesen Publikationen, sondern es versterben auch 58 % der WL-Patienten nach dem 90. Tag, die nach der zitierten Literatur nicht berücksichtigt wurden. Die Analyse kann somit für Deutschland genau wie der MELD-Score (ebenfalls 90-Tage-Mortalität) nur marginal wissenschaftlich sein, da sie der Realität in unserem Land nicht entspricht. Es macht nach meiner Ansicht wenig Sinn, ein fraglich wissenschaftliches Allokationssystem durch ein anderes fragliches System zu ersetzen.

31.10.2024