

The new National Liver Offering Scheme

What's changing and how it will affect you

Introduction and background to the scheme

What is the Benefit Score and how does it work?

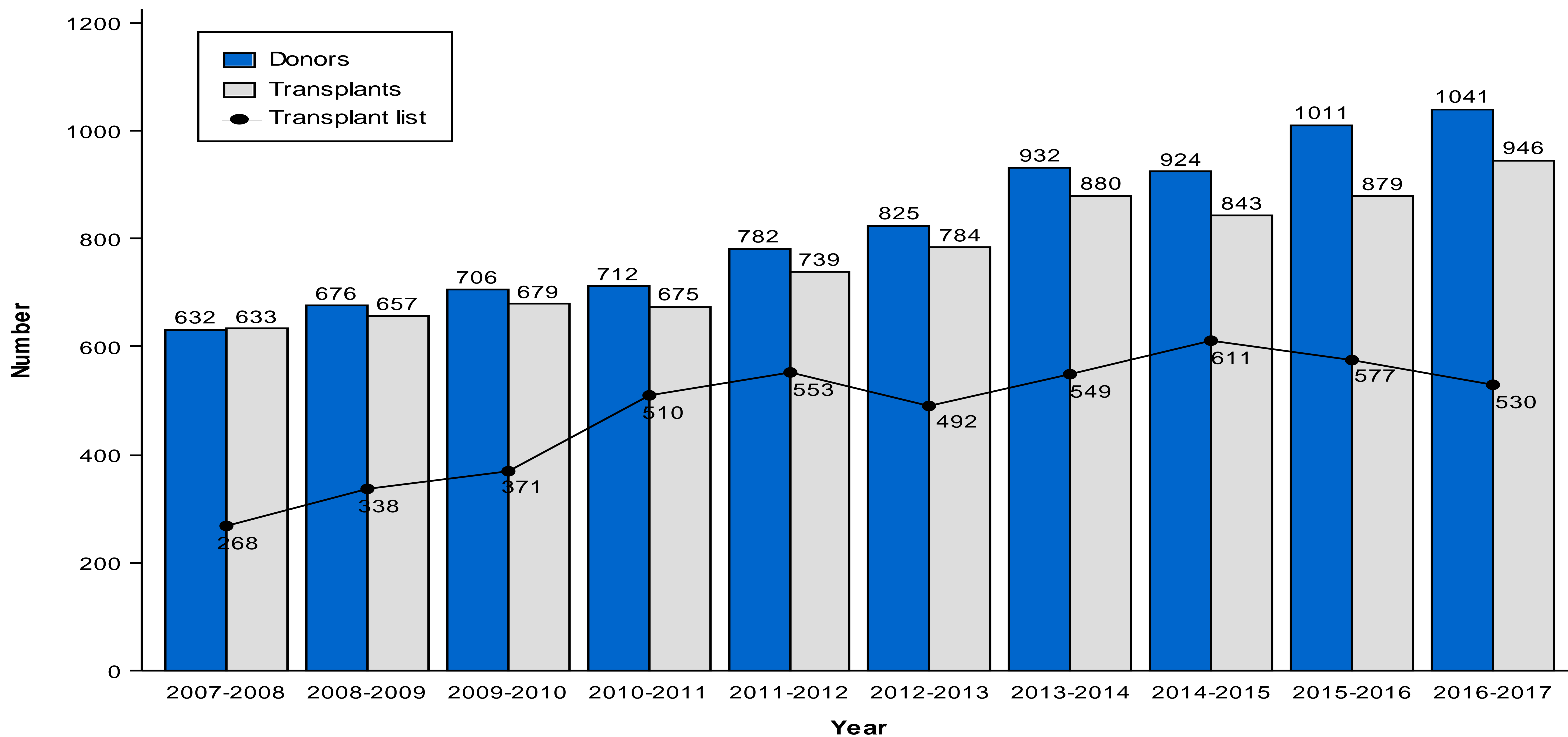
Acknowledgements

Prof. Dave Collett and Rachel Johnson – Statistics & Clinical Studies
Statisticians at NHSBT; Rhiannon Taylor, Cathy Hopkinson, Kerri Barber
Organ Offering FTWU of the Liver Advisory Group (LAG)
Core Group of the LAG

Motivation

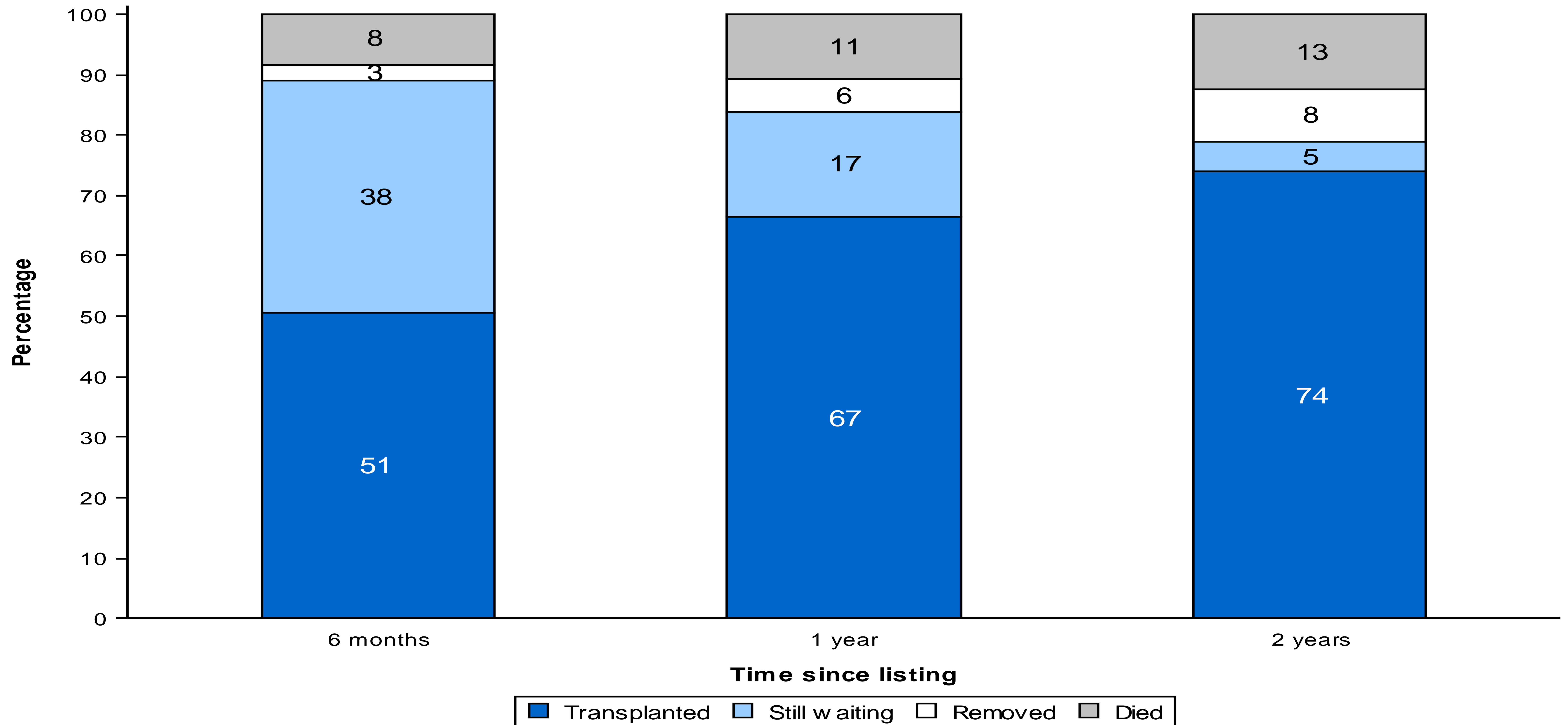
- Introduction of universal allocation schemes within NHSBT
- Assessment of efficacy of transplantation from point of registration
- Imbalance between demand and supply of organs for transplantation from deceased donors

**Deceased donor liver programme in the UK, 1 April 2007 - 31 March 2017,
Number of donors, transplants and patients on the active transplant list at 31 March**



Source: Transplant activity in the UK, 2016-2017, NHS Blood and Transplant

**Post-registration outcome for 1029 new elective liver only registrations made in the UK,
1 April 2014 - 31 March 2015**



Source: Transplant activity in the UK, 2016-2017, NHS Blood and Transplant

New national offering scheme

- The development of a national set of rules to offer livers to named adult patients on the elective liver waiting list
- Initially, from donors after brain death (DBD)
- In future, from donors after circulatory death (DCD)

Liver offering arrangements in the UK

Current liver offering scheme

‘Local’ transplant centre receives the first offer. Transplant centre allocates by blood group compatibility, size match and greatest need (i.e. sickest patient).



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New scheme

Livers are offered nationally to **named patient predicted to gain the most survival benefit from receiving the particular liver graft on offer.**



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‘Local’ transplant centre receives the first offer. Transplant centre allocates by blood group compatibility, size match and greatest need (i.e. sickest patient).

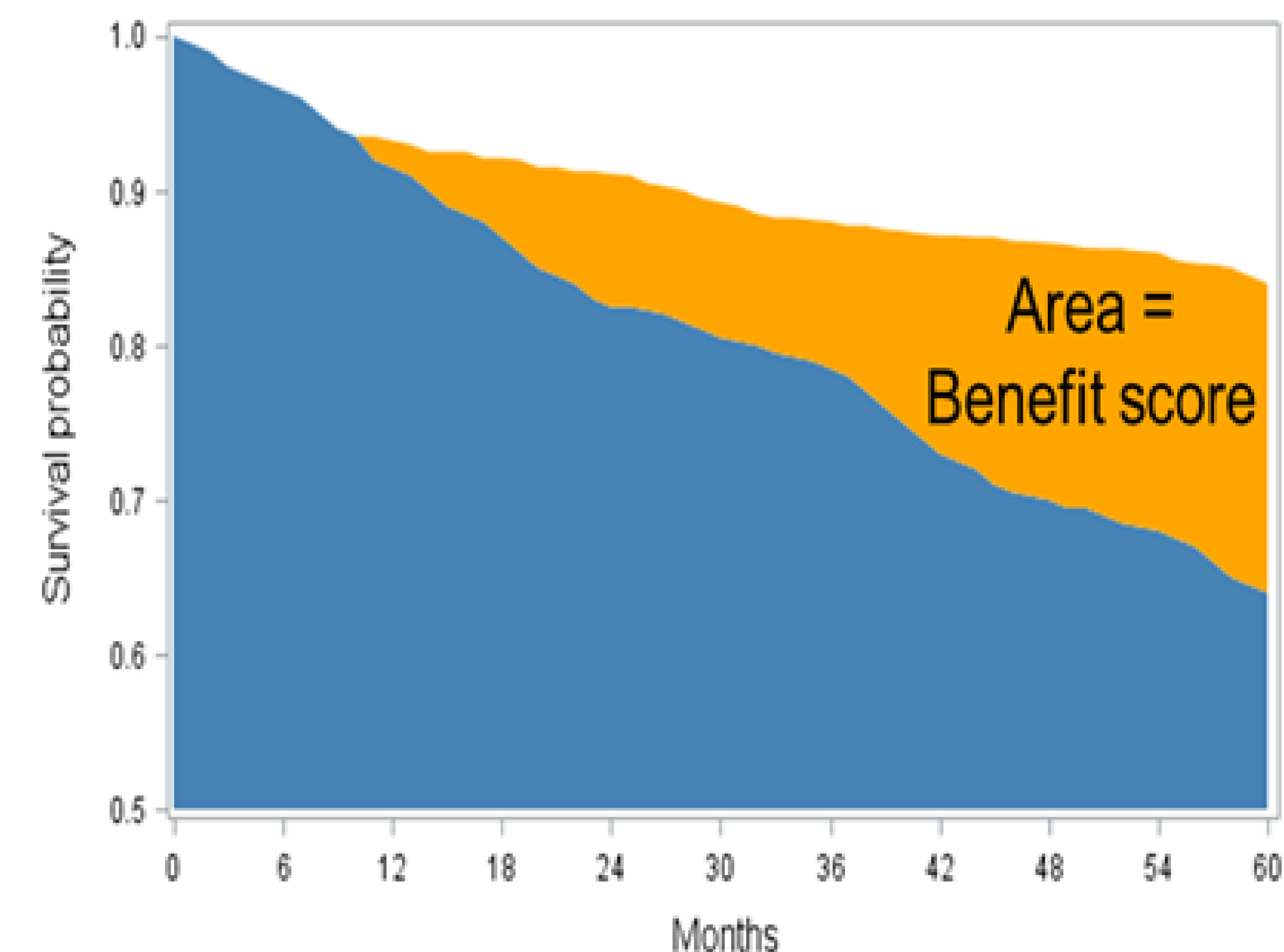
New scheme

Livers are offered nationally to **named patient predicted to gain the most survival benefit from receiving the particular liver graft on offer.**



For each patient and the particular liver graft on offer:

The **benefit score** is calculated by measuring the difference between the area under the waiting list survival curve (**blue shading**) and the area under the post-transplant survival curve (**orange shading**) over a 5-year interval



A total of 21 recipient and 7 donor factors are integrated in the score, such as:

- | | |
|---|----------------------|
| recipient age | donor age |
| gender | cause of death |
| indication for transplantation | BMI |
| number of tumours | history of diabetes |
| renal support | whole or split liver |
| donor-recipient blood group compatibility | |

TRANSPLANT (SURVIVAL) BENEFIT SCORE

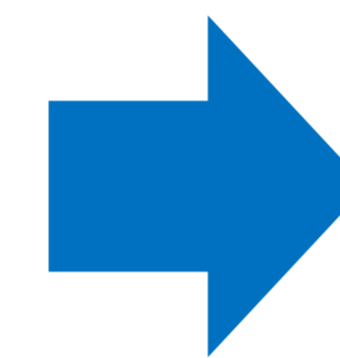
- Demonstrating superiority
- Developing the score

Timeline

2007	Working Group established within NHSBT Liver Advisory Group (LAG)
2009	LAG agreed examination of a national offering scheme
2010	Different offering schemes proposed and discussed with stakeholders
2012	Liver consensus conference held <ul style="list-style-type: none">- Concluded <i>transplant benefit</i> scheme most appropriate but further work was needed
2013	New Fixed-Term Working Group (FTWG) set-up by LAG
2014	<i>Transplant benefit</i> based offering recommended to LAG as the optimum
2014 - 2015	Stakeholder scrutiny period – including patient groups.
May 2015	LAG approved the recommendation of <i>transplant benefit</i> based core offering, in principle, together with <i>proportional offering</i> for variant syndrome patients.
2015 - 2018	After disbandment of the FTWU, the LAG Core Group has continued developing all other aspects of offering outside core offering.

Four offering schemes were investigated

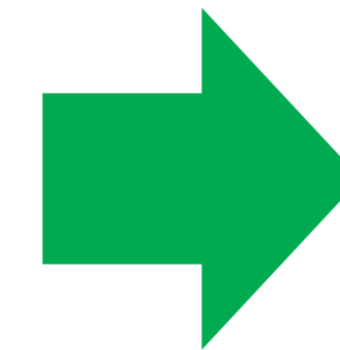
1.Need: Liver offered to patient with shortest predicted **survival time without a transplant**.



Survival without a transplant model

Adult 'non-urgent' liver-only UK registrations
Cancer cohort (n=660), 2009 to 2012
Non-cancer cohort (n=3859), 2006 to 2012

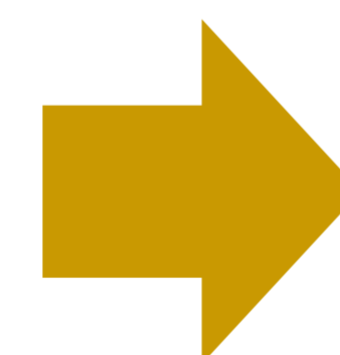
2.Utility: Liver offered to patient with longest predicted **survival after transplantation**.



Survival after transplantation model

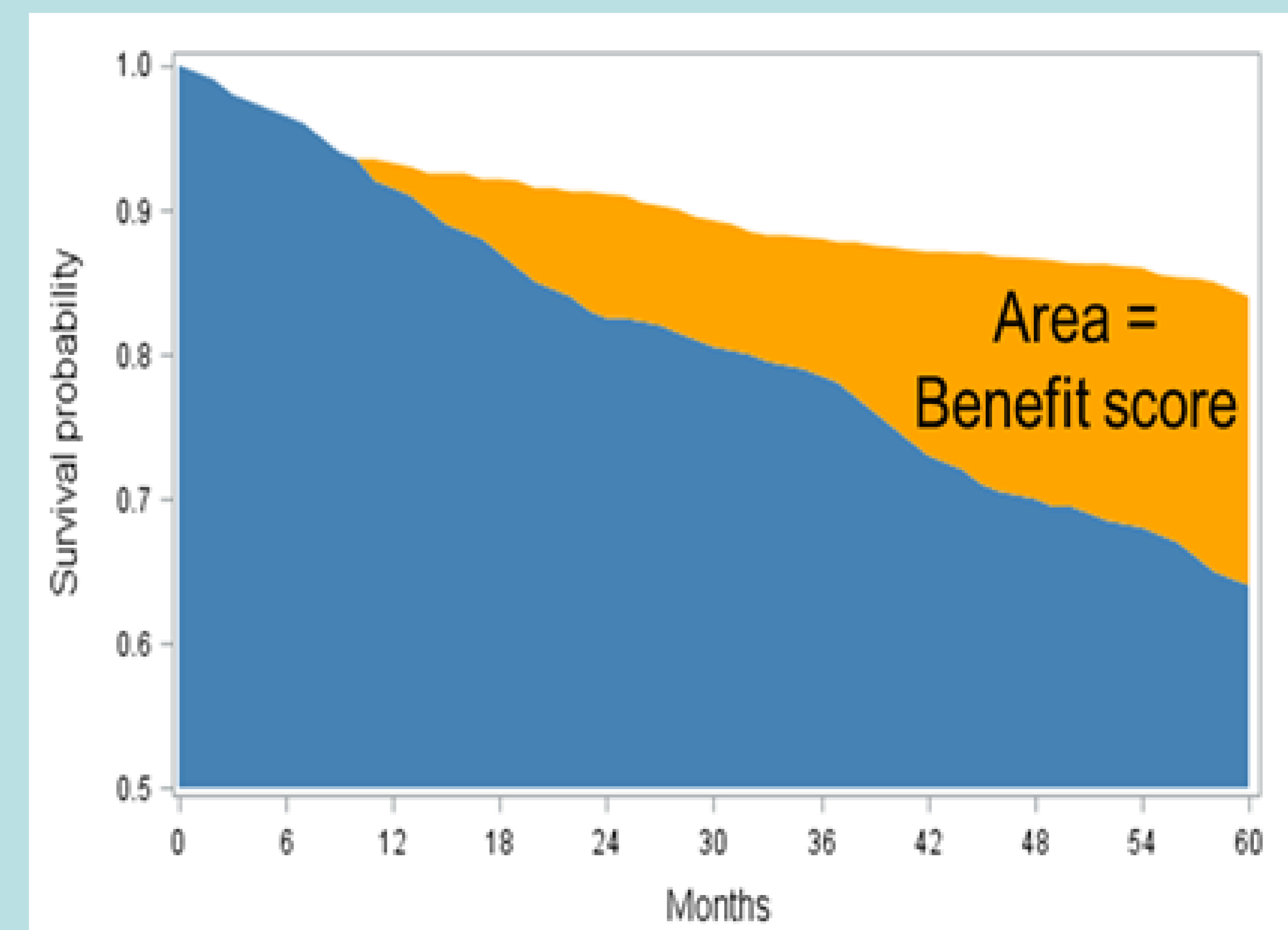
Adult 'non-urgent' liver-only transplants
Cancer cohort (n=430), 2009 to 2012
Non-cancer cohort (n=2495), 2006 to 2012

3.Benefit: Liver offered to patient predicted to gain most **net benefit** (difference in predicted survival with and without transplant).



Transplant benefit

Area between the two survival curves



4.Status quo.

Factors predicting transplant list survival

Non-cancer

Recipient aetiology

Age

Gender

Creatinine, bilirubin, INR, sodium

Renal replacement therapy

In/outpatient

Registration year

[Interactions between factors]

Hepatocellular carcinoma

Recipient age

Gender

HCV

Renal replacement therapy

Creatinine, bilirubin, INR, sodium

In/outpatient

Registration year

Max AFP level

Max size tumour

Number tumours

[Interactions between factors]

Factors predicting post transplant survival

Non-cancer

Recipient aetiology
Age, gender, HCV
Creatinine, bilirubin, INR, Na, K, albumin
Renal replacement therapy
In/outpatient
Prior abdominal surgery
Encephalopathy, ascites, diabetes
Waiting time
Donor age, cause of death, diabetes, BMI
Blood group, liver meets split criteria
[Interactions between factors]

Hepatocellular carcinoma

Recipient age
Gender
HCV
Renal replacement therapy
Creatinine, bilirubin, INR, Na, K, albumin
Recipient diabetes
In/outpatient
Prior abdominal surgery
Encephalopathy, ascites
Waiting time
Max AFP level
Max size tumour
Number tumours
Donor age, cause of death, diabetes, BMI
Blood group, liver meets split criteria
[Interactions between factors]

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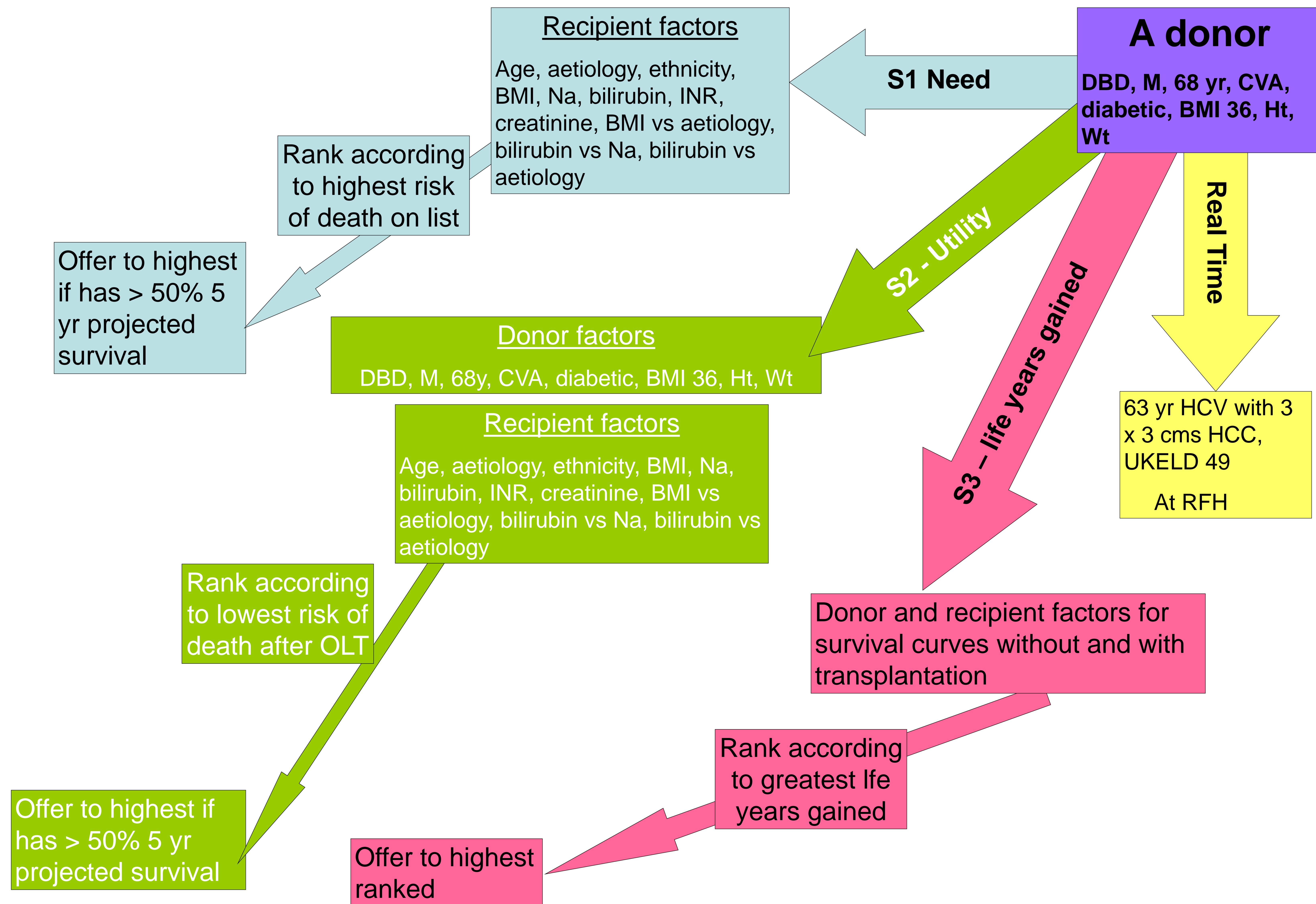
Primary outcomes

Total number of deaths on the waiting list.

Cumulative years of expected patient survival both on the list and post transplant.

Estimate survival from the point of registration, not solely from the point of transplantation

Referred to as population-life- (or patient-) years



Simulation results

Mortality and patient-years associated with the current liver allocation scheme and the simulated allocation schemes based on the simulation period, 1 January 2013 to 31 December 2013 (1287 registrations; 629 DBD and DCD donors)

	No (%) died/ removed ¹	Patient-years
Current scheme	93 (7%)	4581
Need (M1)	48 (4%)	5187
Utility (M2)	95 (7%)	4779
Transplant benefit (M3)	48 (4%)	5262

¹ Removed due to condition deteriorated

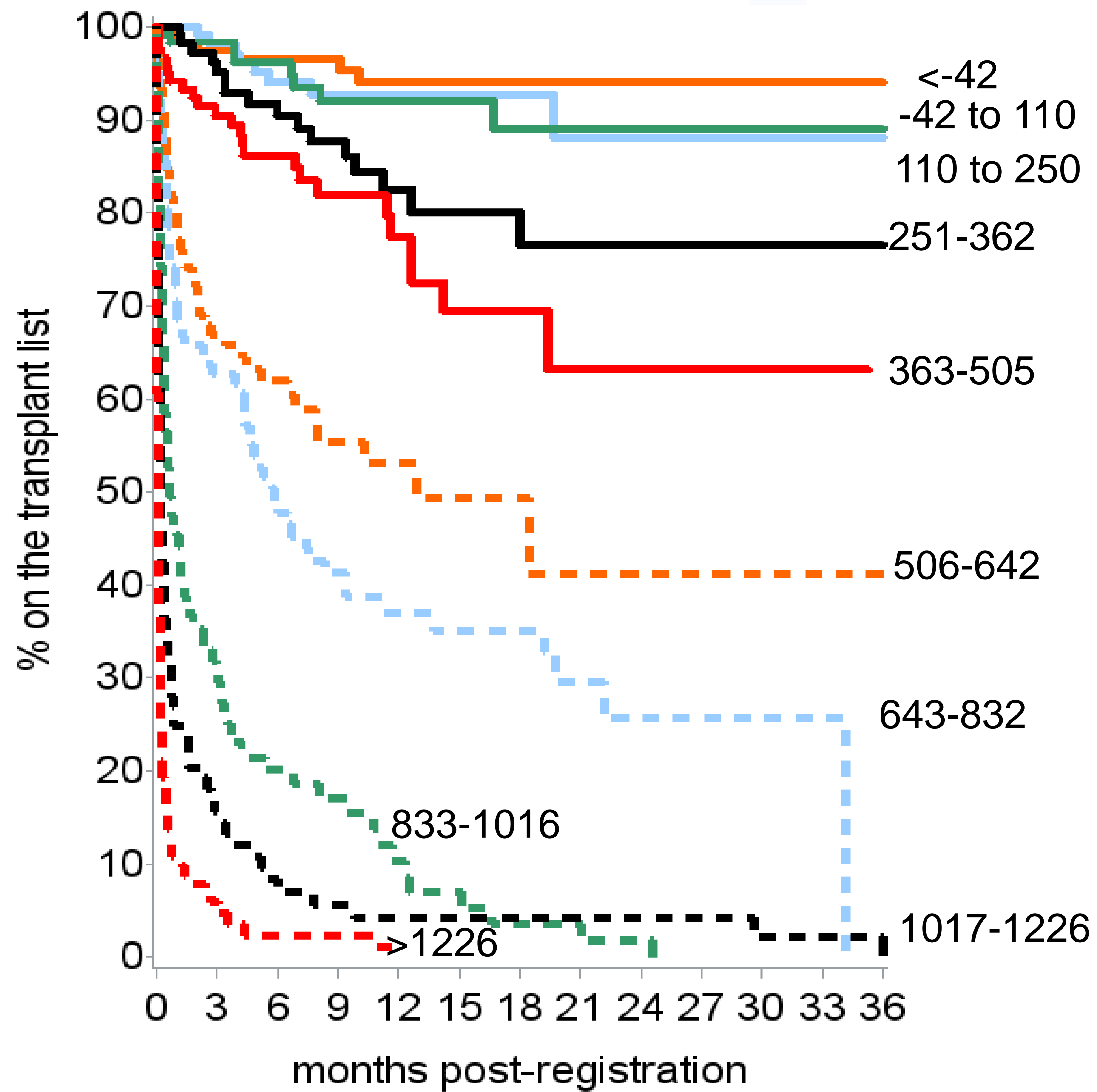
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IMPACT OF PARAMETERS ON TBS



TBS score at
transplant and
time waiting

Example of TBS score for PBC patient

Recipient Details	Values			Donor Details	Values
Age (years)	52			Age (years)	53
Sex	Female			Weight (kg)	76
Primary Liver Disease	Primary biliary cirrhosis			Time in ICU (days)	2
Secondary Liver Disease	Not reported			Cause of Death	Intracranial haemorrhage
Tertiary Liver Disease	Not reported			BMI (kg/m ²)	26
Number of previous transplants	0			History of diabetes	No
HCV Status	No			Donor Type	DBD
Serum Creatinine (µmol/l)	63			Blood Group	O
Serum Bilirubin (µmol/l)	74				
INR	1.2			Transplant Details	
Serum Sodium (mmol/l)	138			Blood group compatibility	Identical
Serum Potassium (mmol/l)	4.2			Liver meets split criteria	Does not meet split criteria
Serum Albumin (g/l)	31				
Renal replacement therapy	Not required				
Inpatient Status	Outpatient				
Registration Year	2017				
Previous upper abdominal surgery	No				
Encephalopathy grade	Not present				
Ascites	No				
Waiting Time (days)	68				
Diabetes	No				
Blood Group	O				

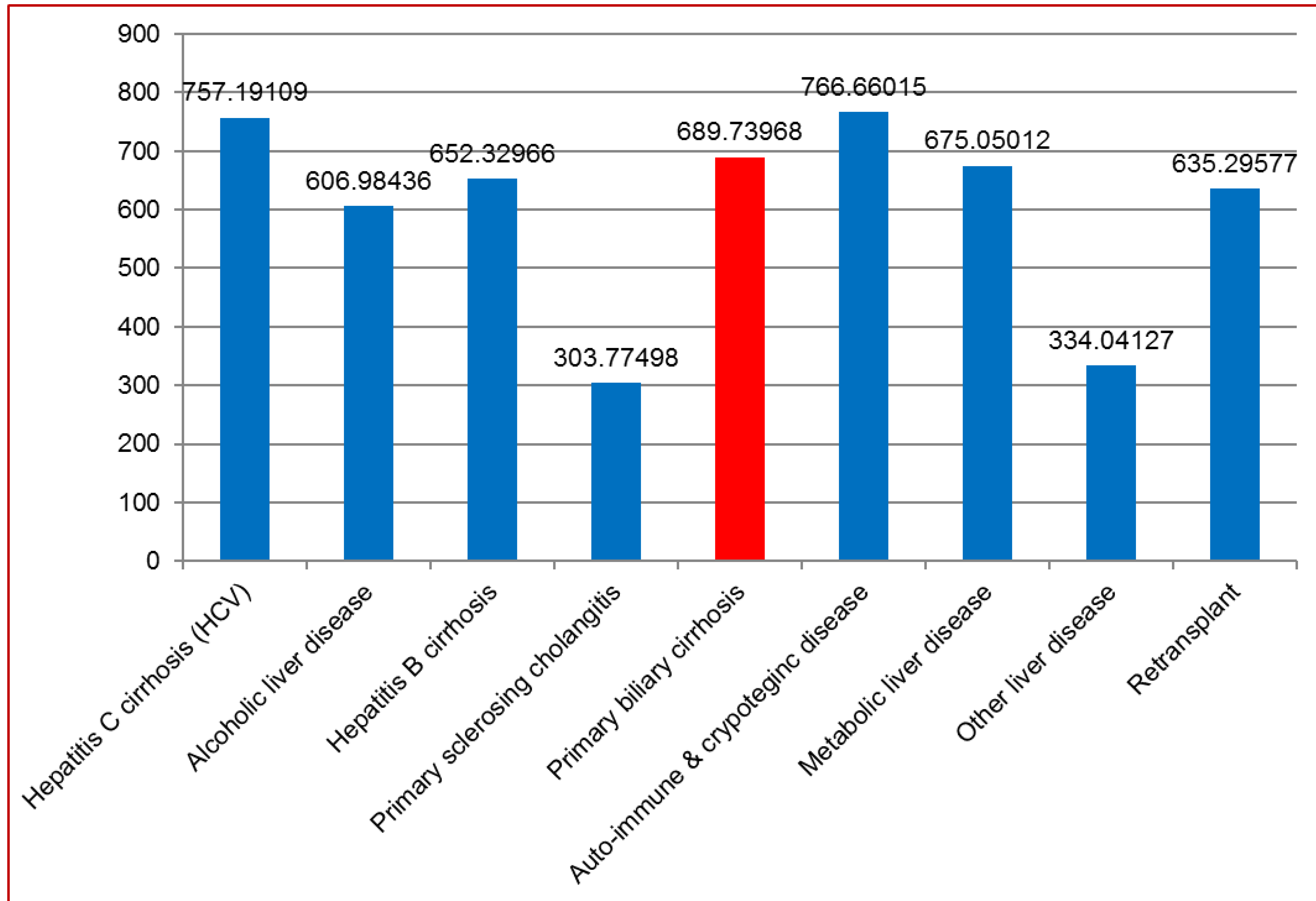
**Transplant Benefit Score
(TBS) = 689.73968**

Example of TBS score for PSC patient

Recipient Details	Values			Donor Details	Values
Age (years)	52			Age (years)	53
Sex	Female			Weight (kg)	76
Primary Liver Disease	Primary sclerosing cirrhosis			Time in ICU (days)	2
Secondary Liver Disease	Not reported			Cause of Death	Intracranial haemorrhage
Tertiary Liver Disease	Not reported			BMI (kg/m ²)	26
Number of previous transplants	0			History of diabetes	No
HCV Status	No			Donor Type	DBD
Serum Creatinine (μmol/l)	63			Blood Group	O
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INR	1.2			Transplant Details	
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Serum Albumin (g/l)	31				
Renal replacement therapy	Not required				
Inpatient Status	Outpatient				
Registration Year	2017				
Previous upper abdominal surgery	No				
Encephalopathy grade	Not present				
Ascites	No				
Waiting Time (days)	68				
Diabetes	No				
Blood Group	O				

**Transplant Benefit Score
(TBS) = 303.77498**

Impact of recipient aetiology on TBS score for a patient with identical characteristics

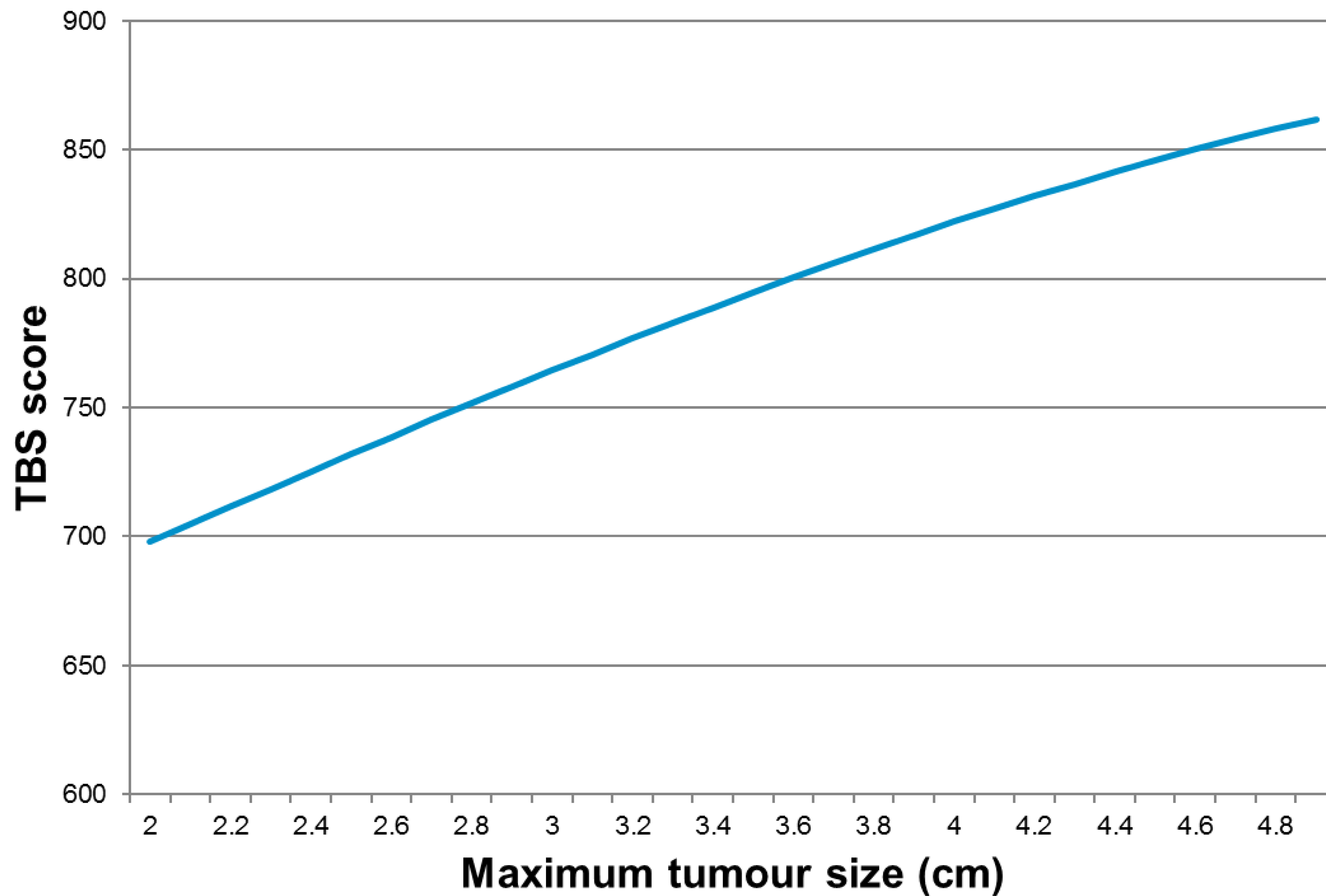


Example of TBS score for cancer patient

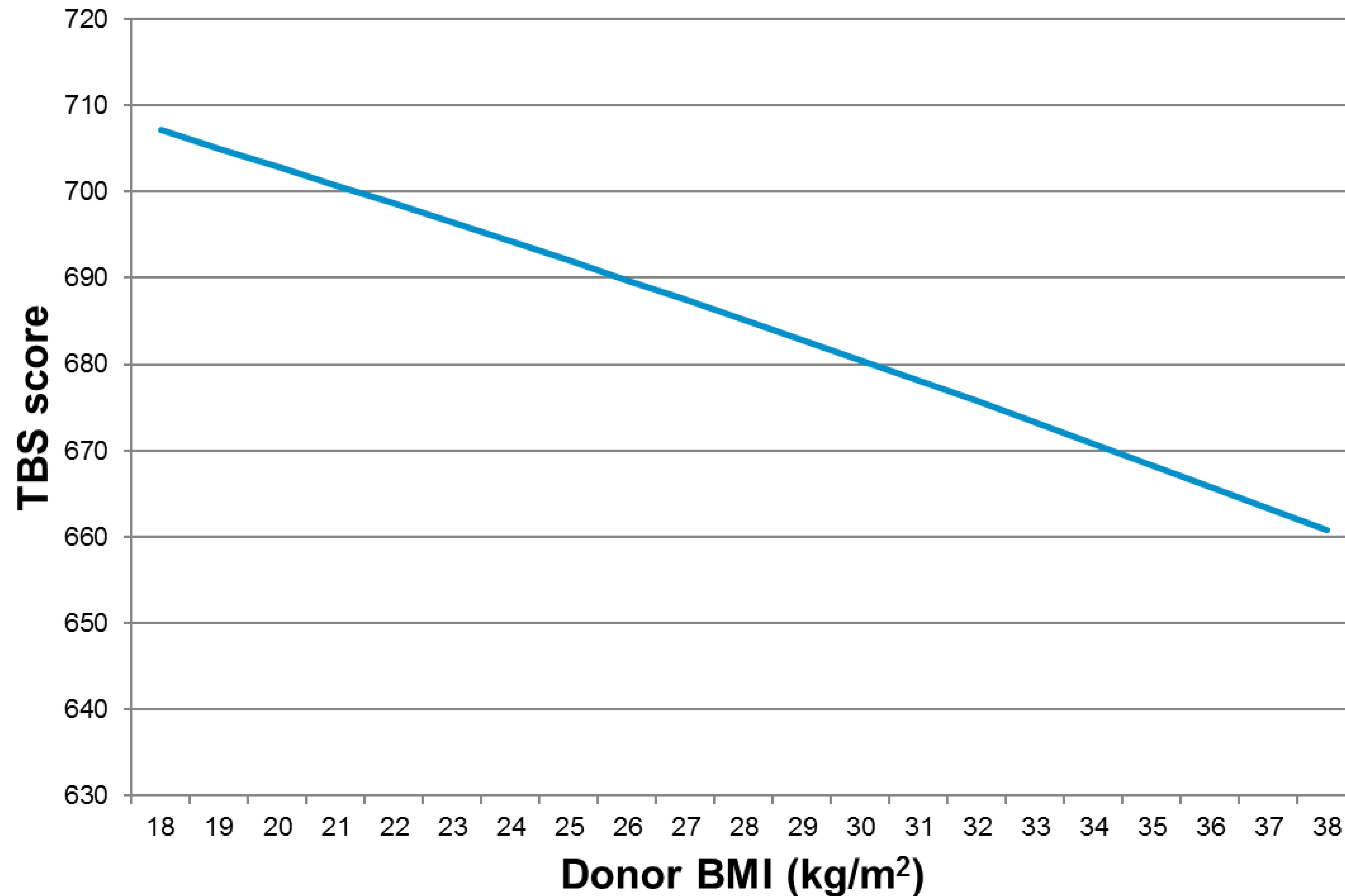
Recipient Details		Values	Donor Details	
Age (years)		52	Age (years)	53
Sex		2	Weight (kg)	76
Primary Liver Disease		Hepatocellular carcinoma - cirrhotic	Time in ICU (days)	2
Secondary Liver Disease		Hepatitis C cirrhosis	Cause of Death	Intracranial haemorrhage
Tertiary Liver Disease		888	BMI (kg/m ²)	26
Number of previous transplants		0	History of diabetes	No
HCV Status		Yes	Donor Type	DBD
Serum Creatinine (μmol/l)		63	Blood Group	O
Serum Bilirubin (μmol/l)		74		
INR		1.2	Transplant Details	
Serum Sodium (mmol/l)		138	Blood group compatibility	Identical
Seum Potassium (mmol/l)		4.2	Liver meets split criteria	Does not meet split criteria
Serum Albumin (g/l)		31		
Renal replacement therapy		Not required		
Inpatient Status		Outpatient		
Registration Year		2017		
Previous Upper Abdominal Surgery		No		
Encephalopathy grade		Not present		
Ascites		No		
Waiting Time (days)		68		
Diabetes		No		
Blood Group		O		
If Patient has cancer				
Maximum AFP level (iu/ml)		6		
Number of tumours		1		
Maximum tumour size		3		

**Transplant Benefit Score
(TBS) = 764.40852**

Impact of maximum tumour size on TBS score for a cancer patient



Impact of donor BMI on TBS score for a Primary Biliary Cirrhosis patient



VARIANT SYNDROMES AND PROPORTIONAL OFFERING

Changes in list of variant syndrome conditions

Removed

Diuretic resistant ascites
Chronic hepatic encephalopathy



From December 2017, considered as variant syndromes in the context of Chronic Liver Disease (CLD). *Patients with DRA and/or CHE to be listed under the CLD criterion for registration and offered alongside CLD/Hepatocellular Carcinoma cases.*

Newly added

~~Familial amyloid polyneuropathy~~
~~Familial hypercholesterolaemia~~



Familial amyloidosis



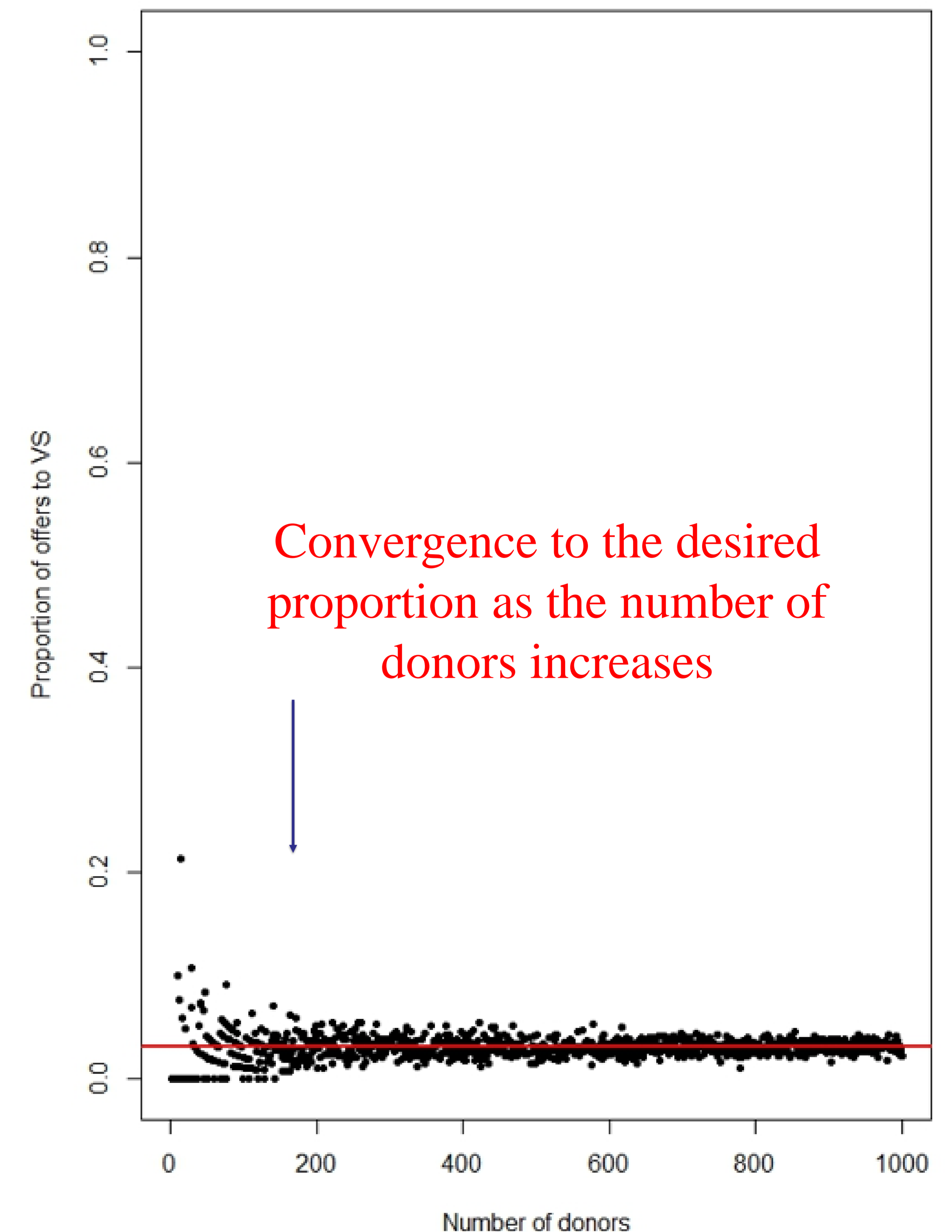
Primary hypercholesterolaemia

Nodular regenerative hyperplasia
Hereditary haemorrhagic telangiectasia
Glycogen storage disease
Ornithine transcarbamylase deficiency

Primary hyperoxaluria type 1
Maple syrup urine disease
Porphyria
Amyloidosis - other

Proportional offering

- When an offering sequence for a DBD adult donor is generated, the algorithm will automatically decide whether to offer to the CLD/HCC list of recipients or the variant syndrome (VS) list.
- The decision is based on a probabilistic rule with:
 - 97% probability of selecting the CLD/HCC list
 - 3% probability of selecting the VS list
- The 3% probability is based on *the proportion of new variant syndrome registrations* to the elective liver transplant list over the course of a year.
- This probability will be reviewed by NHSBT on a regular basis.



POST-LAUNCHING MONITORING COMMITTEE

- LAG has endorsed a proposal to set up a committee to monitor liver offering following the introduction of the new scheme.
- Committee being set up by the Associate Medical Director, ODT.
- Will include representation from:
 - Hepatologist
 - Lay member
 - LAG Core Group liaison
 - Transplant surgeon
 - Patient group
- NHSBT Statistics & Clinical Studies will provide full statistical support.

Summary

1. NHSBT is introducing formal national offering schemes in all organ transplantation
2. Statistical model has been developed to predict outcome waiting for a transplant and post transplant. From these, a *transplant benefit score* (TBS) is calculated
3. The TBS score is predicted to reduce waiting list mortality and increase overall population survival
 - The new scheme could save an additional 45 lives per year on the waiting list relative to current offering arrangements
4. Other aspects of offering will also change, e.g. proportional offering to VS
5. The new National Liver Offering Scheme will be introduced in March 2018

FULL DETAILS:

- Liver Transplantation: Selection Criteria and Recipient Registration Policy
- Deceased Donor Liver Distribution and Allocation Policy

<https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/>

The New National Liver Offering Scheme

Old scheme

Transplant centres are offered livers on a rota, the **local centre receives the first offer**



Centres are **ranked** based on recent **transplant activity**



Most centres then allocate the liver using the **UKELD score**



New scheme

Transplant Benefit Score (TBS)

The difference between expected survival with the transplant and expected survival whilst on the waiting list

Now includes:

- Dual listing for adult and paediatric organs
- Simultaneous liver and kidney registration
- Variant syndrome registrations
- Specific cancer patient matching

Why change?

- Improved equity of access across the UK
- Greater priority to those that will benefit the most
- To **maximise the survival** from the point a patient is registered



To achieve this, livers must be **offered to individual patients on a national level**

What changes?

New forms to capture the data needed for the TBS



3 month sequential data collection to keep the forms up to date

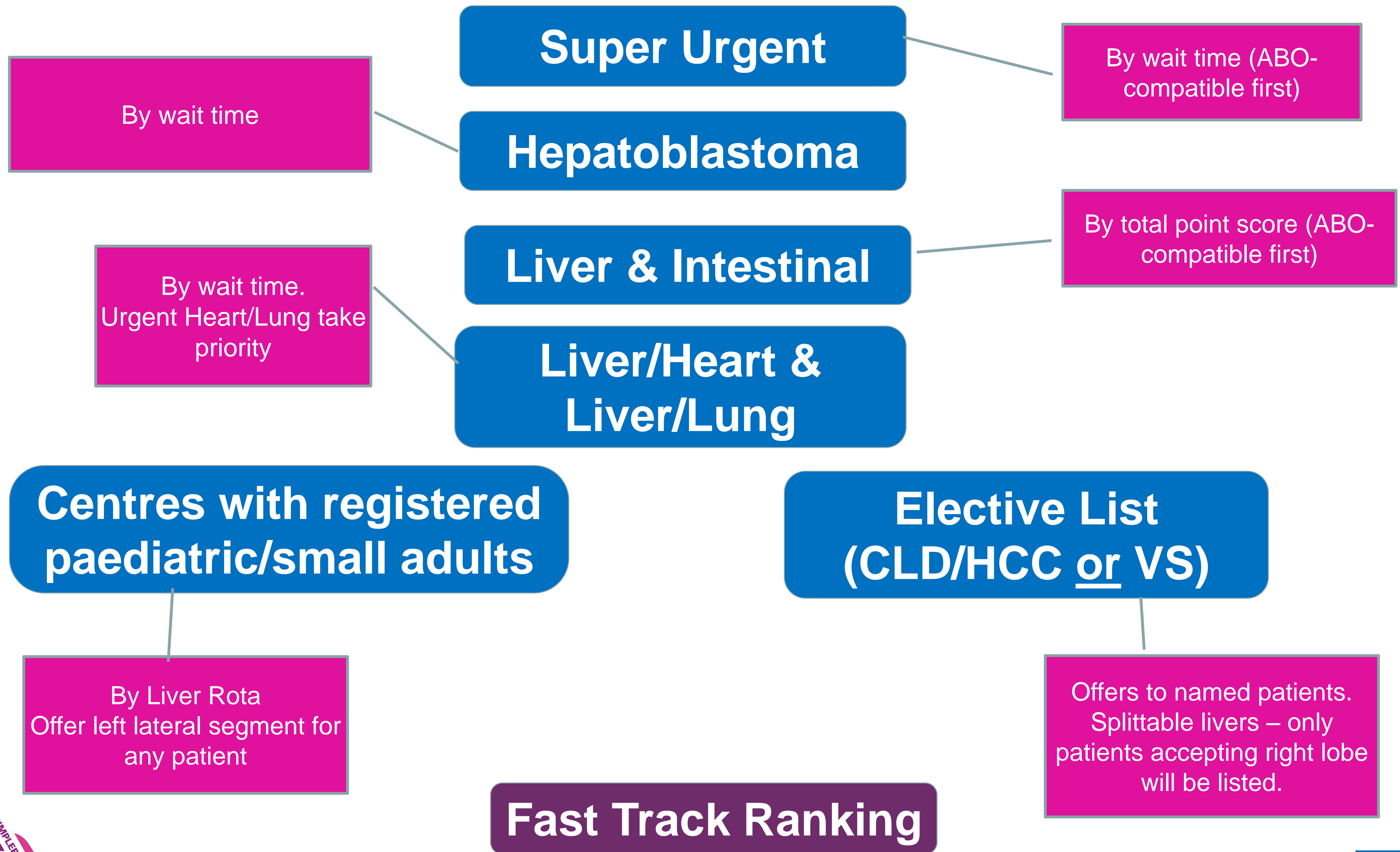


Liver offering to be completed by **ODT Hub Operations**



National Liver Offering Scheme Matching, Allocation and Offering

How will the DBD Offering Scheme work?



Fast track trigger points

- Three declines for donor or function reasons
- Five hours after offering begins

Organ Offering from Hub Operations

Offers made by SMS text or pager

- LIVER OFFER: Case 86829, Donor 150996, Hospital NOTTINGHAM QMC, HC0886. Full offer for S/U Joe Bloggs, DOB 01/01/81, please see EOS.
- LIVER OFFER: Case 86829, Donor 150996, Hospital NOTTINGHAM QMC, HC0886. Full offer for Joe Bloggs, DOB 01/01/81, and Provisional offer for Jane Doe, DOB 02/02/82, please see EOS.
- LIVER OFFER: Case 86829, Donor 150996, Hospital NOTTINGHAM QMC, HC0886. Full offer of L Lobe for any recipient, please see EOS.

Hub Operations rather than SNODs making offers

- First full offer to be given without provisional offers – from the second offer we will do full and provisional offers down the sequence
- No Clinical Information contained in the SMS offer – directed to view EOS
- No details about why another centre has declined
- No details about other organs offered or about theatre time
- Offering to intestinal recipients without HLA may mean we offer unnecessarily
- What information would you like to see on the CDDF ??
- What information would you like to see given at the time of named offering ??
- What information would you like to see on a fast track offer ??

Anticipated Issues with the new system

- Livers will be accepted out of region more often
- Fewer organs will be transported by the NORS team
- Flights will be needed more regularly
- NORS teams must take priority if there are limited flights available
- Organs may be declined late due to logistical reasons
- Cold Ischaemic times may increase
- We will be monitoring this very closely, but just because something is difficult, doesn't mean we shouldn't do it

Update on registration forms and sequential updates

Registrations and Sequential Data Capture Update

What's Happened Since November?

- Head of Information Services, Mike Gumn, visited every liver transplant centre in the country to provide training on the new forms
- Released the new forms on 20/12/17
- Loaded the patient data you provided by spreadsheet onto the database and processed it

What's Next?

- By the launch of the scheme every patient needs to have at least 1 sequential update in the system
- By mid-April every patient will need to have had an update in the previous 3 months
- This will need to be sustained for every adult patient
- Are you ready to send updates for every patient at least once every three months?

Getting ready for the launch of the National Offering Scheme

- NHSBT have produced a report which we will issue monthly
- In the weeks before and after the launch we will send it more often to help you keep on top of your sequential data

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Getting ready for the launch of the National Offering Scheme

- NHSBT have produced a report which we will issue monthly
- First task is to ensure that all patients with a blank "Date of latest sequential form" have one submitted via ODT Online. Deadline is 16/03/18.
- Next task is to ensure that all patients are up to date for their SDC. Deadline is 13/04/18

Out of Hours Registration Support

Your Concerns

- Elective registrations are not processed out of hours
- This is the case for all organ groups that do names allocation
- Concern that this would mean that very sick patients would miss out on offers

What have we done

- Agreed that ODT Hub Ops will process new registrations and sequential updates out of hours
- Run from Friday evening until Monday Morning and Bank Holidays
- Won't run during weekdays evening

How do I submit a registration or sequential update out of hours?

- Submit the registration or sequential update on ODT Online/NTxD
- Phone ODT Hub Ops on 01179757580 let them know you have submitted a form
- ODT Hub ops will phone you back to confirm that the registration has been processed or to discuss any issues with the registration
- If problems cannot be resolved a patient will not be registered

The new National Liver Offering Scheme

What's changing and how it will affect you

Thank you for listening

Any Questions?