

Flexible clinicopathological scores with  
optional histopathology for the quality  
assessment of deceased donor kidneys in  
Eurotransplant

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# Disclaimer

Counsel for Sanofi

# Background

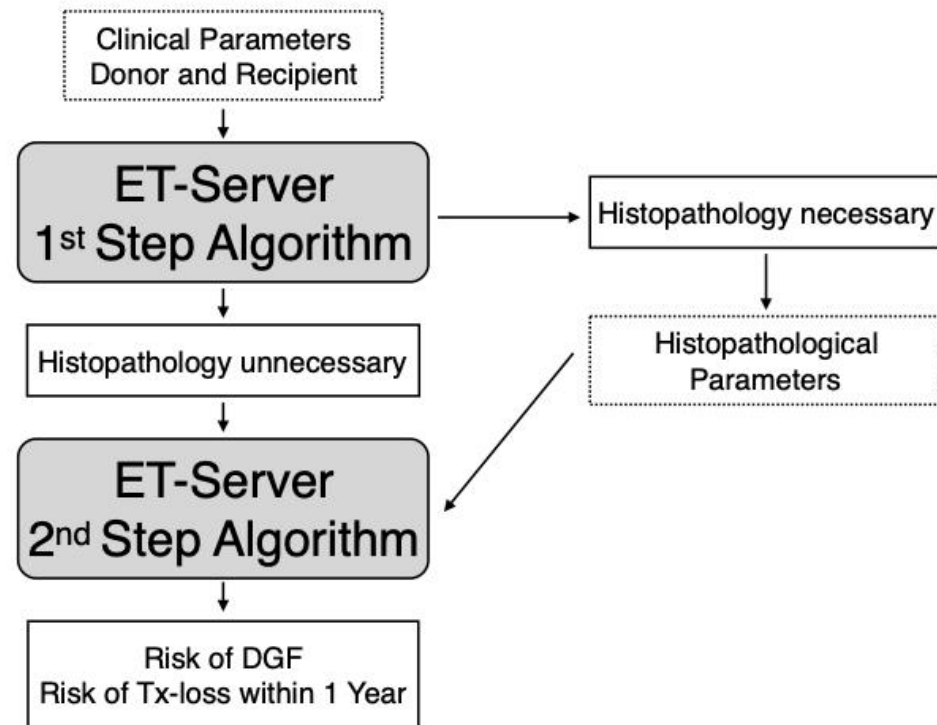
- Severe shortage of donor kidneys in Eurotransplant (ET)
- More patients with ESRD waiting for transplant
- Donors increasingly older and with more morbidity
- Evidence base for acceptance or rejection of a DDK rather thin in ET
- ESOT TLJ-consensus did not even tackle the question of a donor kidney quality score Zaza et al. Transpl Int 2023

# Performance of scores on DSO procurement biopsies (before 2014)

Score		n	AUC for DGF AUC (%)	AUC for death-censored graft loss ≤12 months(%)
Navarro [16]	Score	223	52.5	55.3
	Score >5	223	48.4	56.9
Ortiz [17]	CADI	171	49.1	60.2
Balaz [13]	CIV Score, donor age and cause of death	171	49.0	56.9
Snoeijs [18]	Banff	171	49.7	59.6
	cg+mm+ct+ci+cv+ah+(fraction sclerosed glomeruli*3)			
Remuzzi [19]	Score	223	52.0	56.9
	Grading (Score 0-3/4-6/7-12)	223	50.1	53.2
Paris [14]	Paris Composite Score	223	53.2	54.5
Leuven [15]	Leuven (3-year prediction)	223	45.7	64.3
	Leuven (5-year prediction)	223	43.9	62.2
Port [6]	ECD vs. SCR	223	48.0	61.8
KDRI [27]	KDRI (Median)	223	44.2	62.8
	KDP	223	45.8	61.5
	KDRI	223	41.6	57.9
Schold [7]	Risk Index	222	45.1	60.7
	Grade I-V	222	44.1	60.4
Nyberg [21]	Nyberg Score	223	43.1	60.0
	Nyberg Grading	223	44.5	60.9
EPTS [35]	EPTS Score	120	43.9	63.2
	EPTS Grading	120	46.8	63.4
Jeldres [8]	Jeldres, absolute	223	50.3	56.8
	Jeldres, percent	223	50.3	56.7
Chapal [10]		131	70.9	67.6*
Irish [9]	DGF Score (Irish) without history of transfusion	223	71.2*	52.0

# Aim DDK score for ET

- Two-steps, clinical  $\pm$  histology
- For DGF und 1 year death censored transplant loss (1y-tl)
- Simple
- Based on ET data
- Suited to inform decision on kidney acceptance vs. discard
- Compartmentalised, updateable design



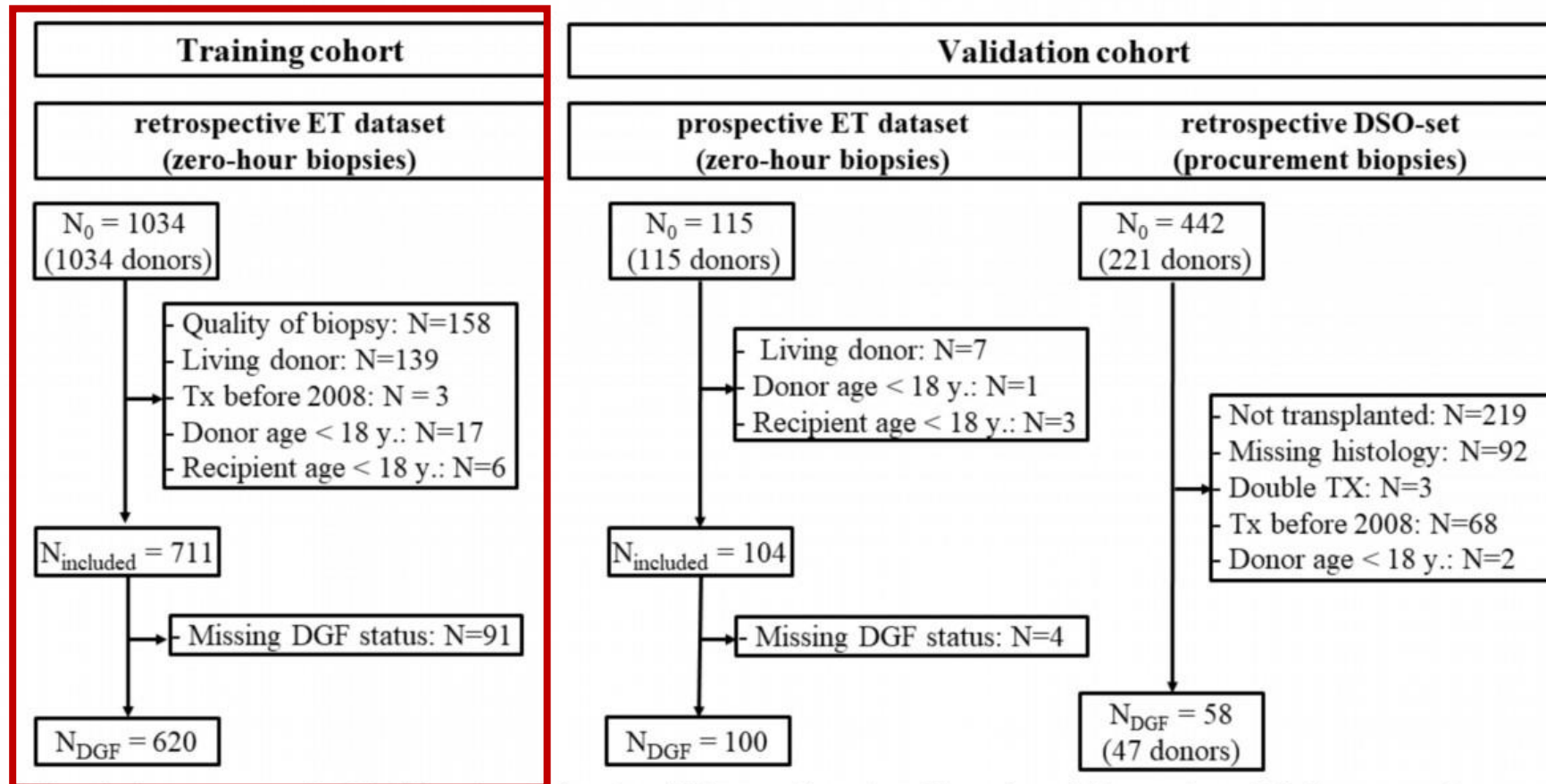
# Study design #1

- Retrospective training set of n=1000 biopsies
- Prospective validation set of n=200 biopsies
- Multicentric Eurotransplant (ET)
- Transplantation from 2008 onwards
- No DCD
- No double-transplant, no multi-organ transplant
- No recipient <18
- Endpoints:  
delayed graft function (DGF), 1-year death-censored transplant loss (1y-tl)

# Study design #2

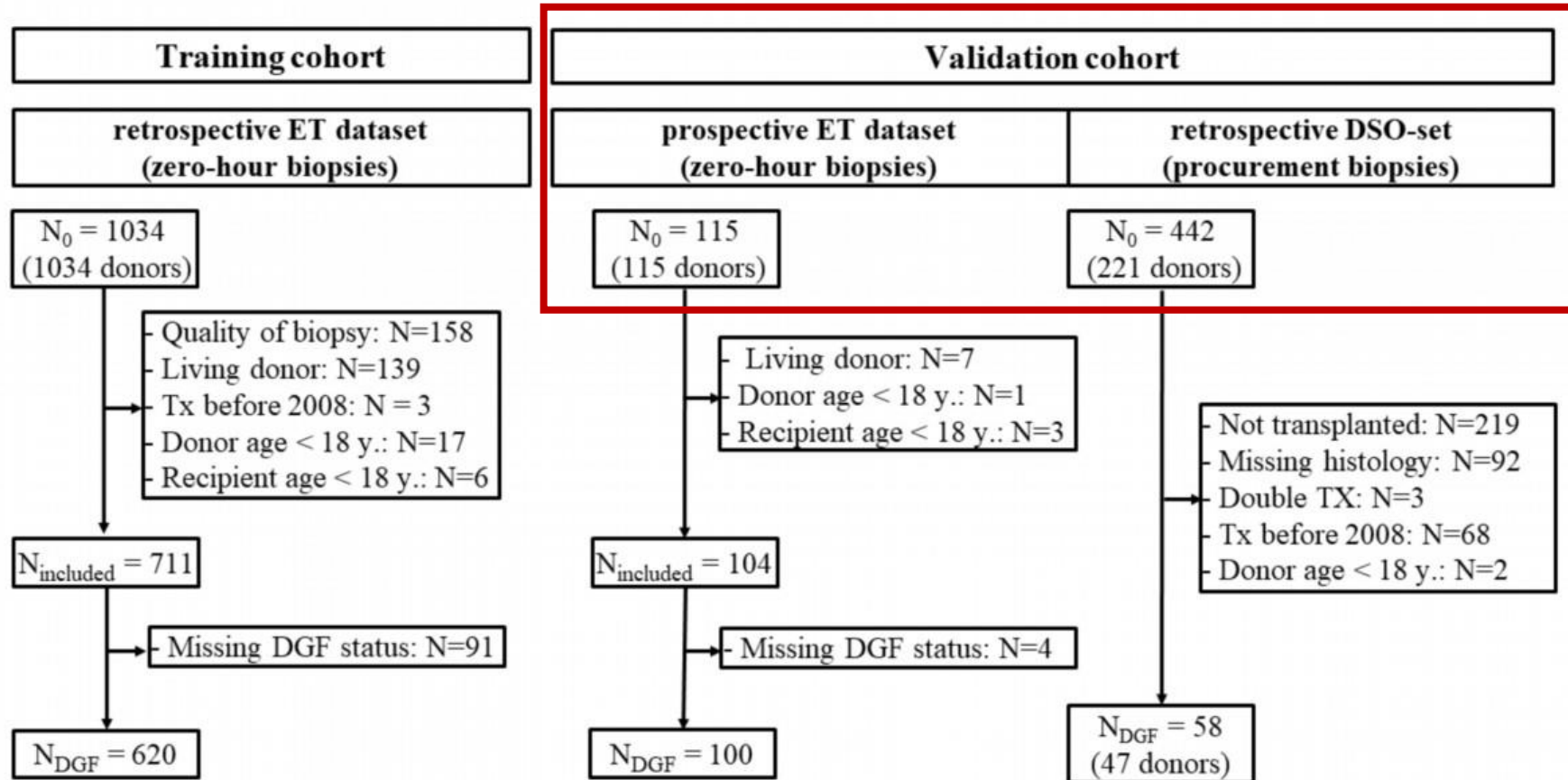
- Only punch or needle biopsies
- Only paraffin histology
- 2 PAS level sections per biopsy
- As x40 whole slide images Histopathology scoring by experienced nephropathologist (JUB) for Banff Lesion Scores, TMA, acute tubular damage, number of arteries, number of glomeruli, ratio of globally sclerotic glomeruli
- Intra- and interrater reproducibility scoring on set of 70 biopsies ongoing

# Training and validation cohorts for DGF



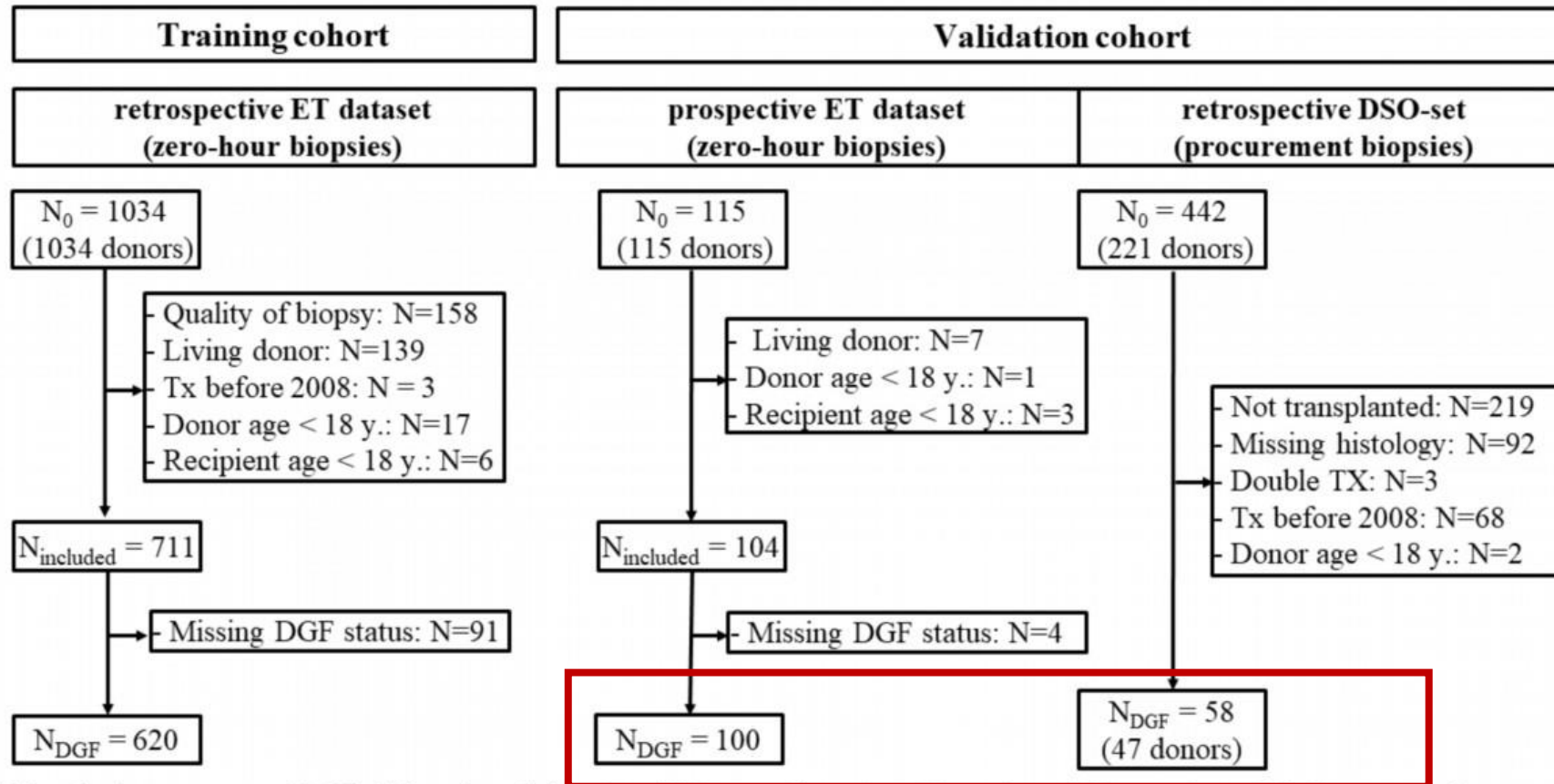
Abbreviations: *y*, years; *DGF*, delayed graft function; *TX*, transplantation; *N* number of observations; *ET*, Eurotransplant; *DSO*, Deutsche Stiftung Organtransplantation [German Organ Procurement Organization]

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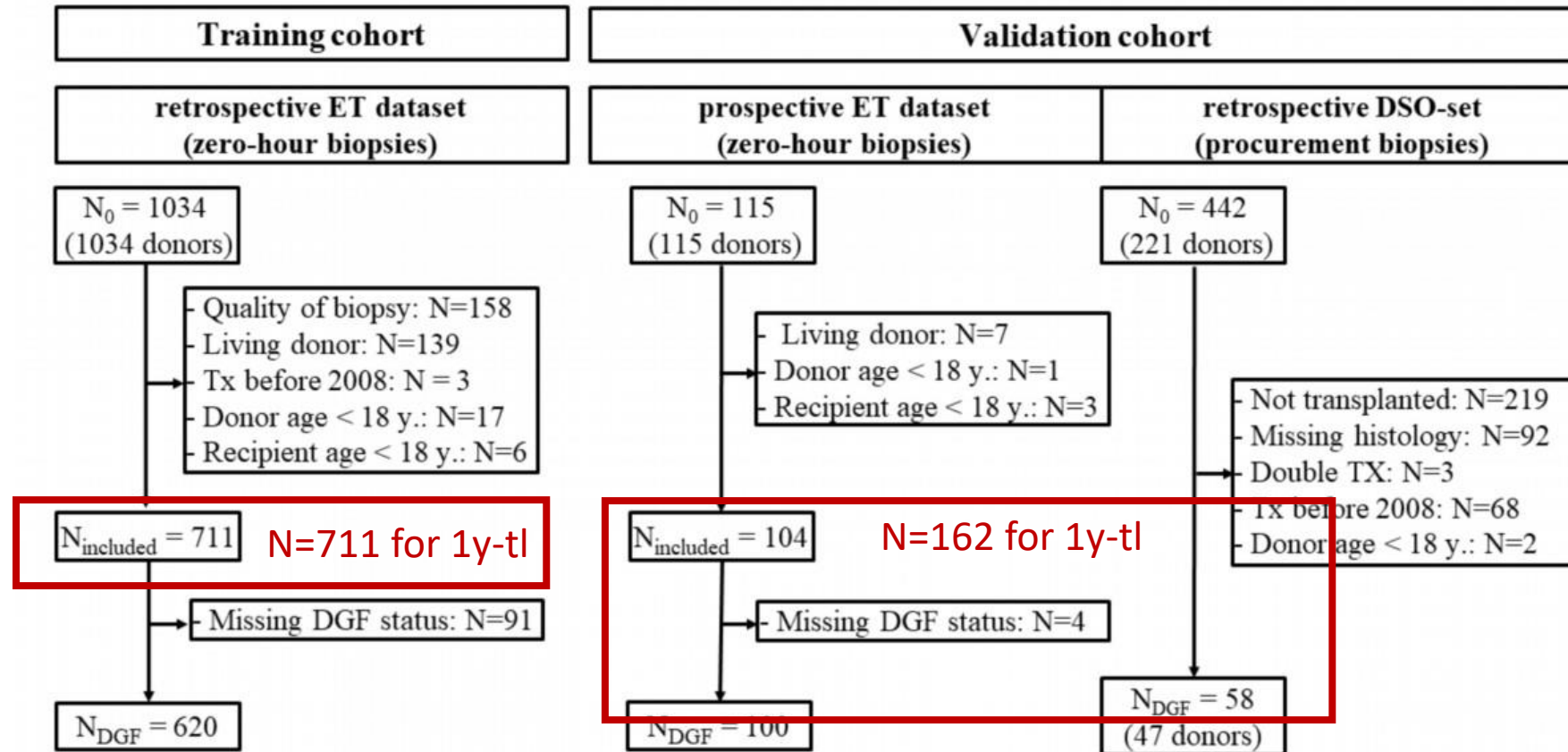
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# Training and validation cohorts for 1y-tl



*Abbreviations: y, years; DGF, delayed graft function; TX, transplantation; N number of observations; ET, Eurotransplant; DSO, Deutsche Stiftung Organtransplantation [German Organ Procurement Organization]*

# Baseline characteristics #1

Fail-set	Overall (%)	Training (%)	Validation (5)	p
<b>N</b>	873	711	162	
<b>DGF no</b>	566 (64.8)	454 (63.9)	112 (69.1)	
<b>DGF yes</b>	212 (24.3)	166 (23.3)	46 (28.4)	0.001
<b>DGF unknown</b>	95 (10.9)	91 (12.8)	4 (2.5)	
<b>1y-tl [Yes] (%)</b>	72 (8.2)	61 (8.6)	11 (6.8)	0.556
<b>Centre 1</b>	50 (5.7)	50 (7.0)	0 (0.0)	<0.001
<b>Centre 2</b>	210 (24.1)	112 (15.8)	98 (60.5)	
<b>Centre 3</b>	63 (7.2)	63 (8.9)	0 (0.0)	
<b>Centre 4</b>	442 (50.6)	442 (62.2)	0 (0.0)	
<b>Centre 5</b>	44 (5.0)	44 (6.2)	0 (0.0)	
<b>Centre 6</b>	58 (6.6)	0 (0.0)	58 (35.8)	
<b>Centre 7</b>	6 (0.7)	0 (0.0)	6 (3.7)	

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# Baseline characteristics #2

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Donor age [y] (median [IQR])	55.00 [44.00, 65.00]	54.00 [44.00, 64.00]	60.00 [45.00, 70.00]	0.003*
Donor BMI [kg/m <sup>2</sup> ] (mean (SD))	26.49 (4.81)	26.20 (4.34)	27.76 (6.36)	<0.001
<i>Donor diabetes no</i>	541 (62.0)	470 (66.1)	71 (43.8)	<0.001
<i>Donor diabetes yes</i>	62 (7.1)	42 (5.9)	20 (12.3)	
<i>Donor diabetes unknown</i>	270 (30.9)	199 (28.0)	71 (43.8)	
<i>Donor hypertension no</i>	331 (37.9)	298 (41.9)	33 (20.4)	<0.001
<i>Donor hypertension yes</i>	339 (38.8)	262 (36.8)	77 (47.5)	
<i>Donor hypertension unknown</i>	203 (23.3)	151 (21.2)	52 (32.1)	
Donor creatinine, last [mg/dl] (mean (SD))	1.04 (0.79)	0.94 (0.49)	1.50 (1.43)	<0.001
<i>Brain death primary</i>	555 (63.6)	479 (67.4)	76 (46.9)	<0.001
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<i>Cerebrovascular accident</i>	433 (49.6%)	379 (53.3%)	54 (33.3%)	<0.001
<i>Subarach. haemorrhage†</i>	14 (1.6%)	0 (0.0%)	14 (8.6%)	<0.001
<i>Traumatic brain injury</i>	94 (10.8%)	93 (13.1%)	1 (0.6%)	<0.001
<i>Unknown cause of death</i>	243 (27.8%)	161 (22.6%)	82 (50.6%)	<0.001
<b>Recipient age [y]</b>	55.0 [46.0, 65.0]	55.0 [45.0, 64.0]	58.0 [50.0, 67.0]	0.004*
<b>Dialysis vintage [y]</b>	3.61 [2.02, 5.94]	3.13 [1.86, 4.85]	8.77 [4.61, 13.32]	<0.001*
<i>Recipient CMV IgG negative</i>	197 (22.6%)	142 (20.0%)	55 (34.0%)	<0.001
<i>Recipient CMV IgG positive</i>	375 (43.0%)	277 (39.0%)	98 (60.5%)	
<i>Recipient CMV IgG unknown</i>	301 (34.5%)	292 (41.1%)	9 (5.6%)	
<b>Recipient PRA peak historic (median [IQR])</b>	0.00 [0.00, 4.00]	0.00 [0.00, 5.00]	0.00 [0.00, 3.00]	0.093*

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<i>Cerebrovascular accident</i>	433 (49.6%)	379 (53.3%)	54 (33.3%)	<0.001
<i>Subarach. haemorrhage†</i>	14 (1.6%)	0 (0.0%)	14 (8.6%)	<0.001
<i>Traumatic brain injury</i>	94 (10.8%)	93 (13.1%)	1 (0.6%)	<0.001
<i>Unknown cause of death</i>	243 (27.8%)	161 (22.6%)	82 (50.6%)	<0.001
<b>Recipient age [y]</b>	55.0 [46.0, 65.0]	55.0 [45.0, 64.0]	58.0 [50.0, 67.0]	0.004*
<b>Dialysis vintage [y]</b>	3.61 [2.02, 5.94]	3.13 [1.86, 4.85]	8.77 [4.61, 13.32]	<0.001*
<i>Recipient CMV IgG negative</i>	197 (22.6%)	142 (20.0%)	55 (34.0%)	<0.001
<i>Recipient CMV IgG positive</i>	375 (43.0%)	277 (39.0%)	98 (60.5%)	
<i>Recipient CMV IgG unknown</i>	301 (34.5%)	292 (41.1%)	9 (5.6%)	
<b>Recipient PRA peak historic (median [IQR])</b>	0.00 [0.00, 4.00]	0.00 [0.00, 5.00]	0.00 [0.00, 3.00]	0.093*

# Baseline characteristics #3

Fail-set	Overall	Training (%)	Validation (5)	p
<i>Cerebrovascular accident</i>	433 (49.6%)	379 (53.3%)	54 (33.3%)	<0.001
<i>Subarach. haemorrhage†</i>	14 (1.6%)	0 (0.0%)	14 (8.6%)	<0.001
<i>Traumatic brain injury</i>	94 (10.8%)	93 (13.1%)	1 (0.6%)	<0.001
<i>Unknown cause of death</i>	243 (27.8%)	161 (22.6%)	82 (50.6%)	<0.001
<b>Recipient age [y]</b>	55.0 [46.0, 65.0]	55.0 [45.0, 64.0]	58.0 [50.0, 67.0]	0.004*
<b>Dialysis vintage [y]</b>	3.61 [2.02, 5.94]	3.13 [1.86, 4.85]	8.77 [4.61, 13.32]	<0.001*
<i>Recipient CMV IgG negative</i>	197 (22.6%)	142 (20.0%)	55 (34.0%)	<0.001
<i>Recipient CMV IgG positive</i>	375 (43.0%)	277 (39.0%)	98 (60.5%)	
<i>Recipient CMV IgG unknown</i>	301 (34.5%)	292 (41.1%)	9 (5.6%)	
<b>Recipient PRA peak historic (median [IQR])</b>	0.00 [0.00, 4.00]	0.00 [0.00, 5.00]	0.00 [0.00, 3.00]	0.093*

# Baseline characteristics #3

Fail-set	Overall	Training (%)	Validation (5)	p
<i>Cerebrovascular accident</i>	433 (49.6%)	379 (53.3%)	54 (33.3%)	<0.001
<i>Subarach. haemorrhage†</i>	14 (1.6%)	0 (0.0%)	14 (8.6%)	<0.001
<i>Traumatic brain injury</i>	94 (10.8%)	93 (13.1%)	1 (0.6%)	<0.001
<i>Unknown cause of death</i>	243 (27.8%)	161 (22.6%)	82 (50.6%)	<0.001
<b>Recipient age [y]</b>	55.0 [46.0, 65.0]	55.0 [45.0, 64.0]	58.0 [50.0, 67.0]	0.004*
<b>Dialysis vintage [y]</b>	3.61 [2.02, 5.94]	3.13 [1.86, 4.85]	8.77 [4.61, 13.32]	<0.001*
<i>Recipient CMV IgG negative</i>	197 (22.6%)	142 (20.0%)	55 (34.0%)	
<i>Recipient CMV IgG positive</i>	375 (43.0%)	277 (39.0%)	98 (60.5%)	<0.001
<i>Recipient CMV IgG unknown</i>	301 (34.5%)	292 (41.1%)	9 (5.6%)	
<b>Recipient PRA peak historic (median [IQR])</b>	0.00 [0.00, 4.00]	0.00 [0.00, 5.00]	0.00 [0.00, 3.00]	0.093*

# Baseline characteristics #3

Fail-set	Overall	Training (%)	Validation (5)	p
<i>Cerebrovascular accident</i>	433 (49.6%)	379 (53.3%)	54 (33.3%)	<0.001
<i>Subarach. haemorrhage†</i>	14 (1.6%)	0 (0.0%)	14 (8.6%)	<0.001
<i>Traumatic brain injury</i>	94 (10.8%)	93 (13.1%)	1 (0.6%)	<0.001
<i>Unknown cause of death</i>	243 (27.8%)	161 (22.6%)	82 (50.6%)	<0.001
<b>Recipient age [y]</b>	55.0 [46.0, 65.0]	55.0 [45.0, 64.0]	58.0 [50.0, 67.0]	0.004*
<b>Dialysis vintage [y]</b>	3.61 [2.02, 5.94]	3.13 [1.86, 4.85]	8.77 [4.61, 13.32]	<0.001*
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<i>Recipient CMV IgG positive</i>	375 (43.0%)	277 (39.0%)	98 (60.5%)	
<i>Recipient CMV IgG unknown</i>	301 (34.5%)	292 (41.1%)	9 (5.6%)	
<b>Recipient PRA peak historic (median [IQR])</b>	0.00 [0.00, 4.00]	0.00 [0.00, 5.00]	0.00 [0.00, 3.00]	0.093*

# Baseline characteristics #4

Fail-set	Overall (%)	Training (%)	Validation (5)	p
<i>HLA-DR mismatch 0</i>	244 (27.9)	207 (29.1)	37 (22.8)	0.021
<i>HLA-DR mismatch 1</i>	477 (54.6)	393 (55.3)	84 (51.9)	
<i>HLA-DR mismatch 2</i>	151 (17.3)	110 (15.5)	41 (25.3)	
<i>HLA-DR mismatch unknown</i>	243 (27.8)	161 (22.6)	82 (50.6)	
Warm ischaemia time [min] (median [IQR]) †	33.00 [0.00, 45.00]	32.00 [0.00, 45.00]	36.00 [22.00, 45.75]	0.012*

# Baseline characteristics #4

Fail-set	Overall (%)	Training (%)	Validation (5)	p
<i>HLA-DR mismatch 0</i>	244 (27.9)	207 (29.1)	37 (22.8)	0.021
<i>HLA-DR mismatch 1</i>	477 (54.6)	393 (55.3)	84 (51.9)	
<i>HLA-DR mismatch 2</i>	151 (17.3)	110 (15.5)	41 (25.3)	
<i>HLA-DR mismatch unknown</i>	243 (27.8)	161 (22.6)	82 (50.6)	
Warm ischaemia time [min] (median [IQR]) †	33.00 [0.00, 45.00]	32.00 [0.00, 45.00]	36.00 [22.00, 45.75]	0.012*

# Baseline characteristics #5

Fail-set	Overall (%)	Training (%)	Validation (5)	p
<i>i0</i>	865 (99.1)	711 (100.0)	154 (95.1)	<0.001
<i>i1</i>	7 (0.8)	0 (0.0)	7 (4.3)	
<i>i2</i>	1 (0.1)	0 (0.0)	1 (0.6)	
<i>t0</i>	865 (99.1)	711 (100.0)	154 (95.1)	<0.001
<i>t1</i>	8 (0.9)	0 (0.0)	8 (4.9)	
<i>g0</i>	850 (97.4)	699 (98.3)	151 (93.2)	<0.001
<i>g1</i>	13 (1.5)	4 (0.6)	9 (5.6)	
<i>g2</i>	8 (0.9)	7 (1.0)	1 (0.6)	
<i>g3</i>	2 (0.2)	1 (0.1)	1 (0.6)	

# Baseline characteristics #5

Fail-set	Overall (%)	Training (%)	Validation (5)	p
<i>i0</i>	865 (99.1)	711 (100.0)	154 (95.1)	<0.001
<i>i1</i>	7 (0.8)	0 (0.0)	7 (4.3)	
<i>i2</i>	1 (0.1)	0 (0.0)	1 (0.6)	
<i>t0</i>	865 (99.1)	711 (100.0)	154 (95.1)	<0.001
<i>t1</i>	8 (0.9)	0 (0.0)	8 (4.9)	
<i>g0</i>	850 (97.4)	699 (98.3)	151 (93.2)	
<i>g1</i>	13 (1.5)	4 (0.6)	9 (5.6)	<0.001
<i>g2</i>	8 (0.9)	7 (1.0)	1 (0.6)	
<i>g3</i>	2 (0.2)	1 (0.1)	1 (0.6)	

# Baseline characteristics #5

Fail-set	Overall (%)	Training (%)	Validation (5)	p
<i>i0</i>	865 (99.1)	711 (100.0)	154 (95.1)	<0.001
<i>i1</i>	7 (0.8)	0 (0.0)	7 (4.3)	
<i>i2</i>	1 (0.1)	0 (0.0)	1 (0.6)	
<i>t0</i>	865 (99.1)	711 (100.0)	154 (95.1)	<0.001
<i>t1</i>	7 (0.8)	0 (0.0)	7 (4.3)	
<i>g0</i>	850 (97.4)	699 (98.3)	151 (93.2)	<0.001
<i>g1</i>	13 (1.5)	4 (0.6)	9 (5.6)	
<i>g2</i>	8 (0.9)	7 (1.0)	1 (0.6)	
<i>g3</i>	2 (0.2)	1 (0.1)	1 (0.6)	

# Baseline characteristics #6

Fail-set	Overall (%)	Training (%)	Validation (5)	p
<i>cv0</i>	321 (36.8)	272 (38.3)	49 (30.2)	0.031
<i>cv1</i>	166 (19.0)	129 (18.1)	37 (22.8)	
<i>cv2</i>	180 (20.6)	135 (19.0)	45 (27.8)	
<i>cv3</i>	205 (23.5)	174 (24.5)	31 (19.1)	
<i>mm0</i>	858 (98.3)	707 (99.4)	151 (93.2)	<0.001
<i>mm1</i>	10 (1.1)	2 (0.3)	8 (4.9)	
<i>mm2</i>	2 (0.2)	1 (0.1)	1 (0.6)	
<i>mm3</i>	3 (0.3)	1 (0.1)	2 (1.2)	
<b>No. of arteries (median [IQR])</b>	3.00 [2.00, 4.00]	3.00 [2.00, 4.00]	3.00 [2.00, 6.00]	0.005*
<b>No. of glomeruli (median [IQR])</b>	26.00 [20.00, 35.00]	29.00 [21.00, 36.00]	19.00 [13.00, 29.00]	<0.001*

# Baseline characteristics #6

Fail-set	Overall (%)	Training (%)	Validation (5)	p
<i>cv0</i>	321 (36.8)	272 (38.3)	49 (30.2)	0.031
<i>cv1</i>	166 (19.0)	129 (18.1)	37 (22.8)	
<i>cv2</i>	180 (20.6)	135 (19.0)	45 (27.8)	
<i>cv3</i>	205 (23.5)	174 (24.5)	31 (19.1)	
<i>mm0</i>	858 (98.3)	707 (99.4)	151 (93.2)	<0.001
<i>mm1</i>	10 (1.1)	2 (0.3)	8 (4.9)	
<i>mm2</i>	2 (0.2)	1 (0.1)	1 (0.6)	
<i>mm3</i>	3 (0.3)	1 (0.1)	2 (1.2)	
<b>No. of arteries (median [IQR])</b>	3.00 [2.00, 4.00]	3.00 [2.00, 4.00]	3.00 [2.00, 6.00]	0.005*
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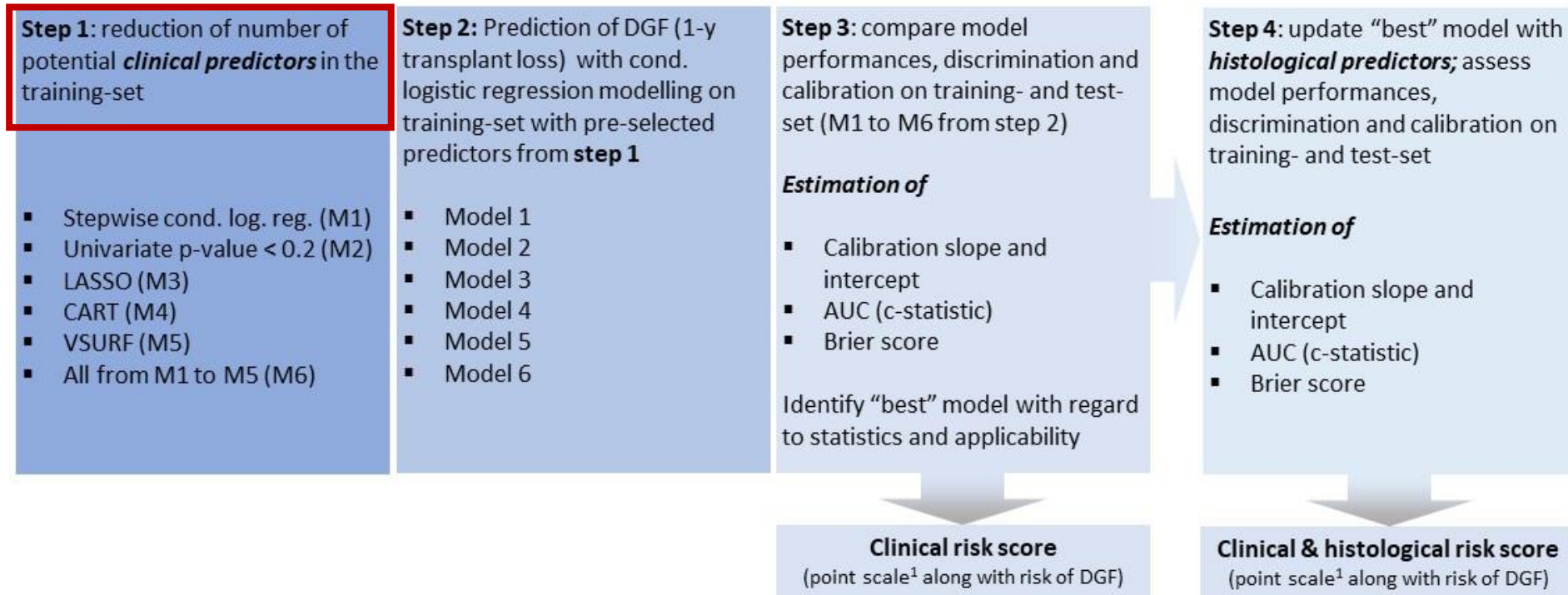
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# Score development



<sup>1</sup> LM Sullivan, JM Massao, RB D’Agostino Sr., “TUTORIAL IN BIostatistics Presentation of multivariate data for clinical use: The Framingham Study risk score functions”; Statist. Med. 2004; 23:1631-1660 (DOI: 10.1002/sim.1742)

# Univariable predictors of DGF training set #1

Variable	No DGF (n=454)	DGF (n=166)	OR (95%-CI)
Donor age in years	15 (3.3)	11 (6.6)	2.08 (0.91-4.59, p=0.073)
Donor BMI (kg/m <sup>2</sup> )	25.69 [23.15, 27.78]	26.15 [24.22, 29.24]	1.07 (1.03-1.11, p=0.001*)
Donor hypertension yes	160 (35.2)	73 (44.0)	1.52 (1.02-2.28, p=0.043)
Donor last serum crea (mg/dl)	0.81 [0.66, 1.05]	0.82 [0.65, 1.10]	1.48 (1.05-2.09, p=0.025)
Recipient BMI (kg/m <sup>2</sup> )	25.51 [22.83, 28.71]	25.25 [23.23, 30.46]	1.04 (1.00-1.08, p=0.043)
Recipient dialysis vintage in years	3.01 [1.65, 4.49]	3.43 [2.13, 5.38]	1.10 (1.03-1.17, p=0.006)
Recipient CMV IgG+	177 (39.0)	77 (46.4)	1.72 (1.04-2.92, p=0.038)
Recipient FSGS primary disease	11 (2.4)	10 (6.0)	2.58 (1.06-6.24, p=0.034)
Recipient hypertensive nephropathy yes	41 (9.0)	5 (3.0)	0.31 (0.11-0.74, p=0.016)

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Donor hypertension yes	160 (35.2)	73 (44.0)	1.52 (1.02-2.28, p=0.043)
Donor last serum crea (mg/dl)	0.81 [0.66, 1.05]	0.82 [0.65, 1.10]	1.48 (1.05-2.09, p=0.025)
Recipient BMI (kg/m <sup>2</sup> )	25.51 [22.83, 28.71]	25.25 [23.23, 30.46]	1.04 (1.00-1.08, p=0.043)
Recipient dialysis vintage in years	3.01 [1.65, 4.49]	3.43 [2.13, 5.38]	1.10 (1.03-1.17, p=0.006)
Recipient CMV IgG+	177 (39.0)	77 (46.4)	1.72 (1.04-2.92, p=0.038)
Recipient FSGS primary disease	11 (2.4)	10 (6.0)	2.58 (1.06-6.24, p=0.034)
Recipient hypertensive nephropathy yes	41 (9.0)	5 (3.0)	0.31 (0.11-0.74, p=0.016)

# Univariable predictors of DGF training set #1

Variable	No DGF (n=454)	DGF (n=166)	OR (95%-CI)
Donor age in years	15 (3.3)	11 (6.6)	2.08 (0.91-4.59, p=0.073)
Donor BMI (kg/m <sup>2</sup> )	25.69 [23.15, 27.78]	26.15 [24.22, 29.24]	1.07 (1.03-1.11, p=0.001*)
Donor hypertension yes	160 (35.2)	73 (44.0)	1.52 (1.02-2.28, p=0.043)
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# Univariable predictors of DGF training set #2

Variable	No DGF (n=454)	DGF (n=166)	OR (95%-CI)
HLA-DR mismatches >1	65 (14.3)	39 (23.5)	2.19 (1.29-3.76, p=0.004)
Cold ischaemia time hour	12.00 [5.74, 16.00]	13.69 [7.97, 19.00]	1.03 (1.00-1.05, p=0.019)
Warm ischaemia time minute	34.00 [0.00, 45.00]	39.00 [0.00, 52.75]	1.01 (1.00-1.02, p=0.008)

# Univariable predictors of DGF training set #2

Variable	No DGF (n=454)	DGF (n=166)	OR (95%-CI)
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# Univariable predictors of 1y-tl training set

Variable	No DGF (n=454)	DGF (n=166)	OR (95%-CI)
DGF	23 (5.1)	33 (19.9)	4.20 (2.36, 7.49, p<0.001) <sup>§</sup>
Donor age in years	54.00 [43.00, 63.00]	62.00 [52.00, 71.00]	1.03 (1.01-1.05, p=0.001)
Donor hypertension yes	225 (34.6)	37 (60.7)	2.41 (1.37-4.39, p=0.003)
Recipient age in years	54.00 [45.00, 63.75]	60.00 [48.00, 67.00]	1.03 (1.01-1.05, p=0.015)
HLA-A mismatches >1	94 (14.5)	14 (23.0)	2.29 (1.04-5.03, p=0.037)
Cold ischaemia time hour	11.00 [0.00, 16.00]	15.00 [9.00, 19.00]	1.05 (1.02-1.09, p=0.002)
Warm ischaemia time minute	27.57 (24.75)	37.92 (28.02)	1.02 (1.01-1.03, p=0.002)
Ratio of globally sclerotic glomeruli	0.03 [0.00, 0.09]	0.05 [0.00, 0.12]	10.94 (1.06-89.89, p=0.032)

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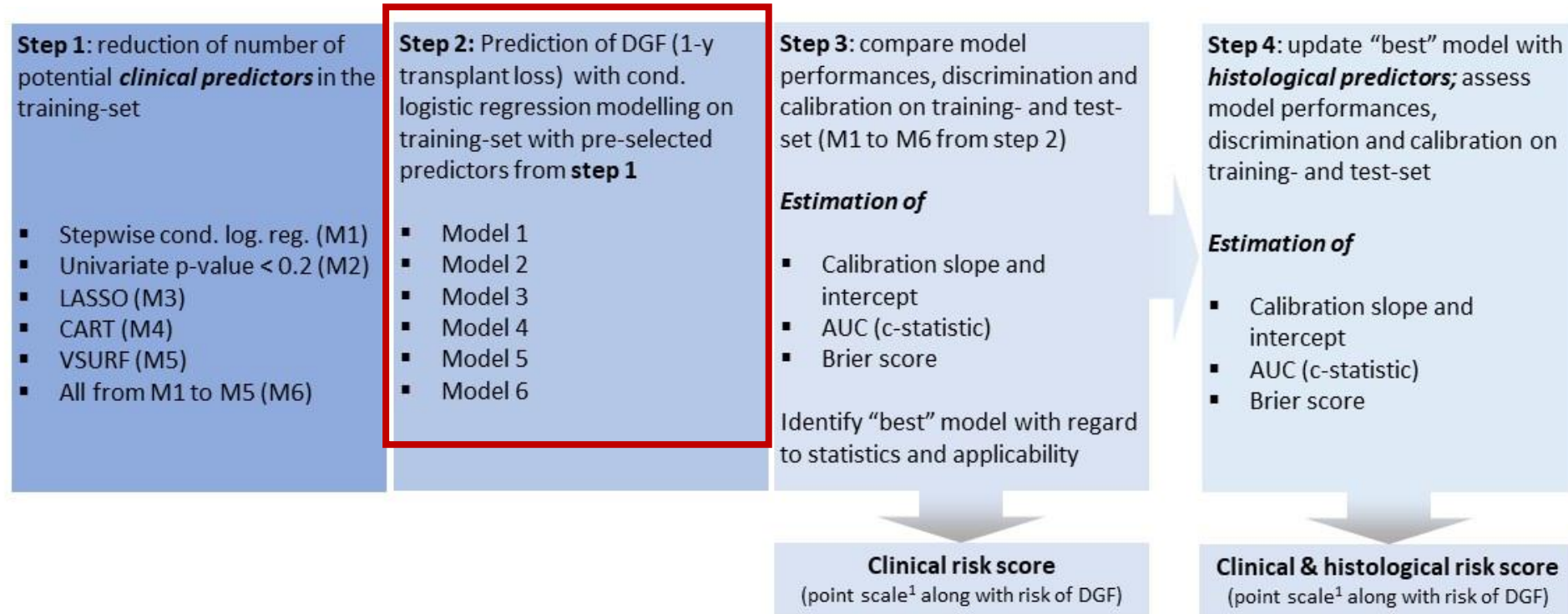
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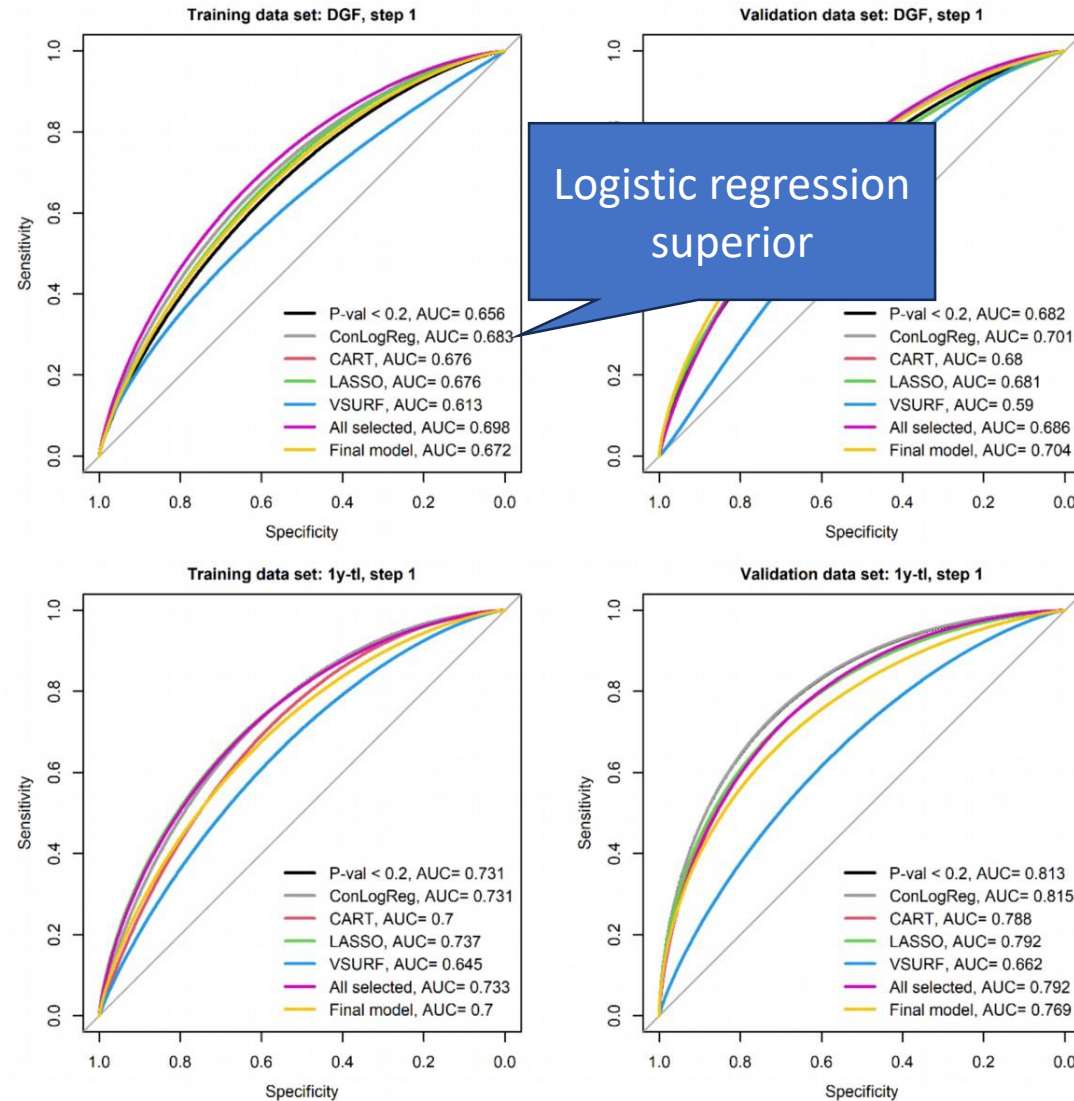
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# Score development

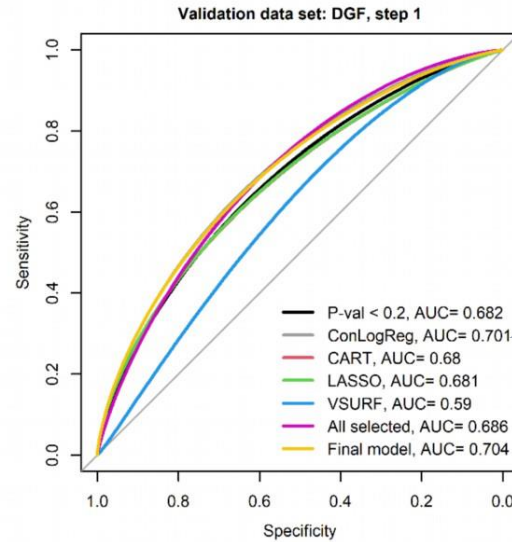
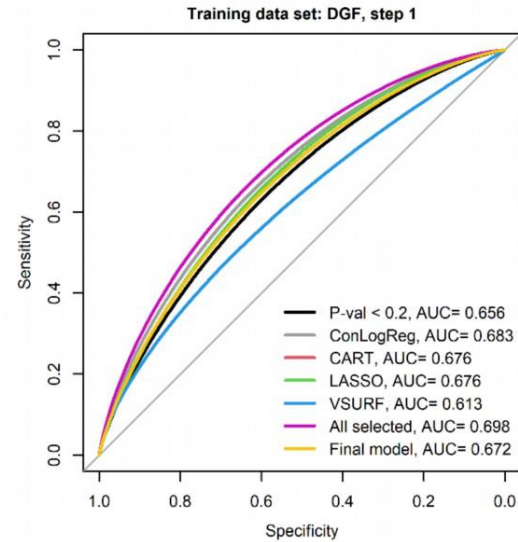


<sup>1</sup> LM Sullivan, JM Massao, RB D’Agostino Sr., “TUTORIAL IN BIostatistics Presentation of multivariate data for clinical use: The Framingham Study risk score functions”; Statist. Med. 2004; 23:1631-1660 (DOI: 10.1002/sim.1742)

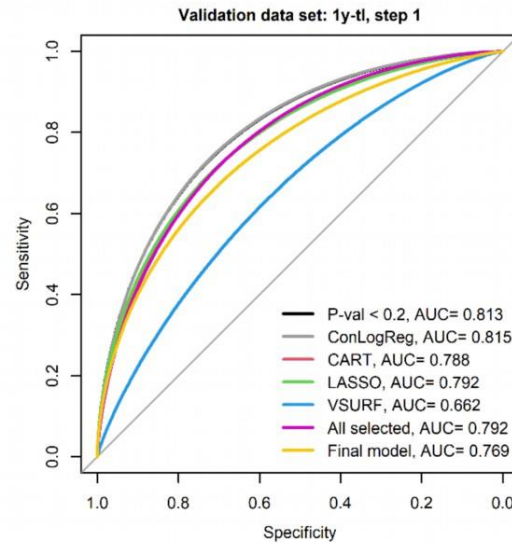
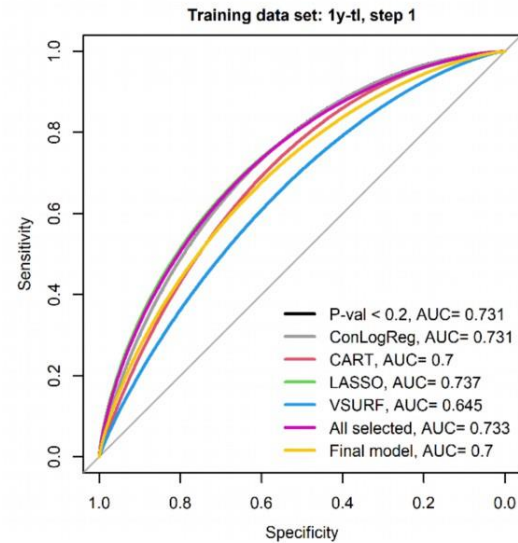
# Performance model 1-6 training set



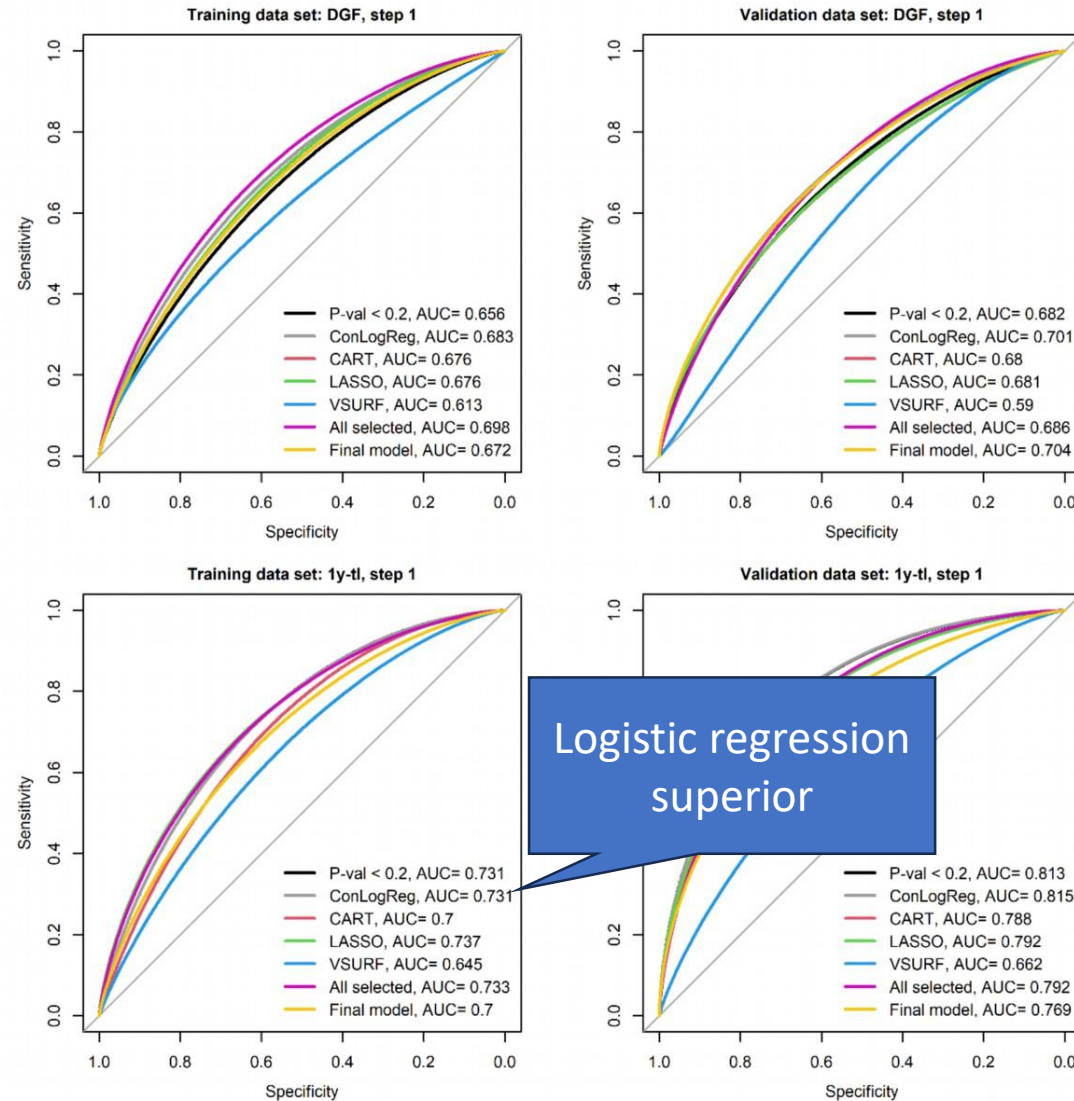
# Performance model 1-6 training set



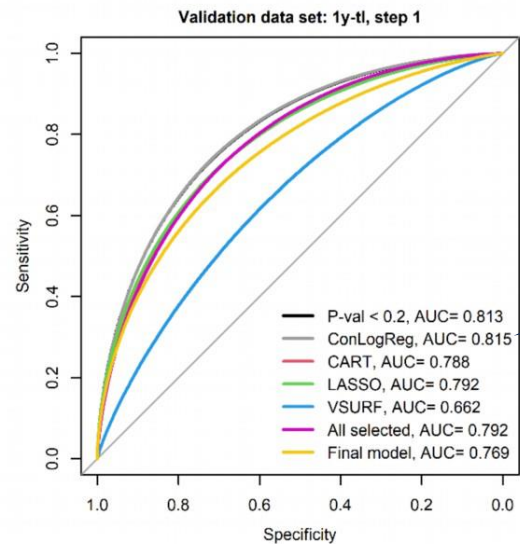
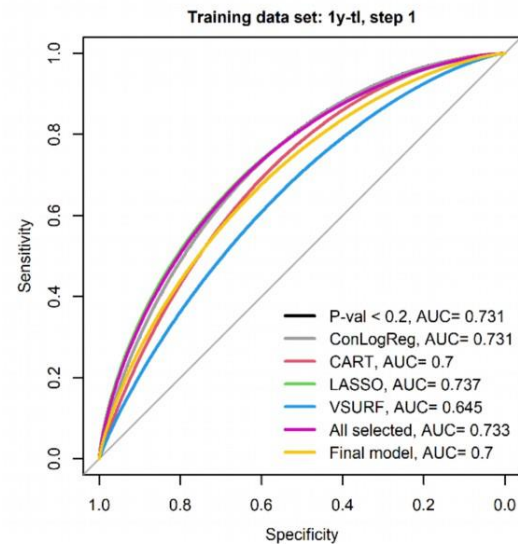
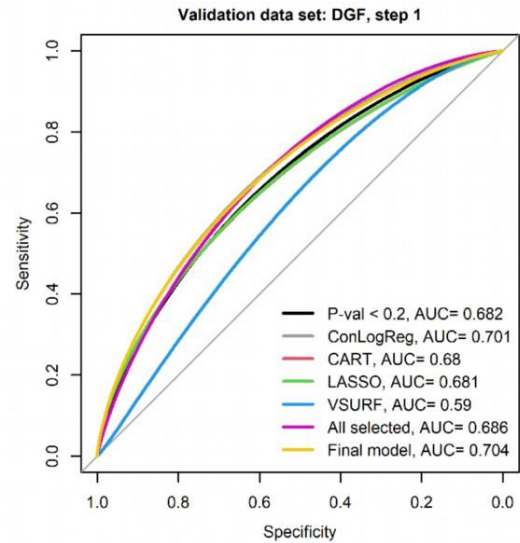
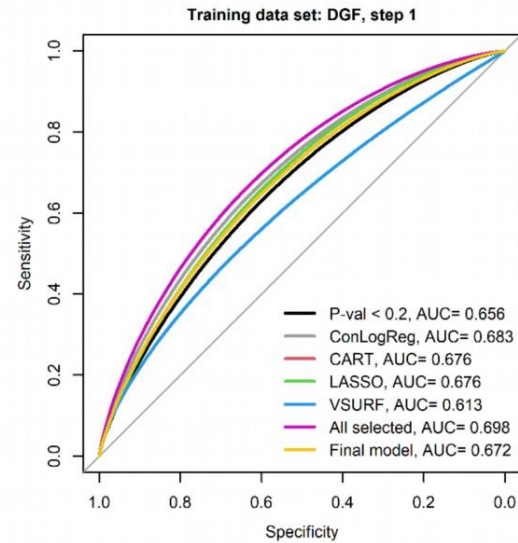
Logistic regression superior



# Performance model 1-6 training set



# Performance model 1-6 training set



Logistic regression superior

# Score development

**Step 1:** reduction of number of potential **clinical predictors** in the training-set

- Stepwise cond. log. reg. (M1)
- Univariate p-value < 0.2 (M2)
- LASSO (M3)
- CART (M4)
- VSURF (M5)
- All from M1 to M5 (M6)

**Step 2:** Prediction of DGF (1-y transplant loss) with cond. logistic regression modelling on training-set with pre-selected predictors from **step 1**

- Model 1
- Model 2
- Model 3
- Model 4
- Model 5
- Model 6

**Step 3:** compare model performances, discrimination and calibration on training- and test-set (M1 to M6 from step 2)

**Estimation of**

- Calibration slope and intercept
- AUC (c-statistic)
- Brier score

Identify “best” model with regard to statistics and applicability

**Clinical risk score**

(point scale<sup>1</sup> along with risk of DGF)

**Step 4:** update “best” model with **histological predictors**; assess model performances, discrimination and calibration on training- and test-set

**Estimation of**

- Calibration slope and intercept
- AUC (c-statistic)
- Brier score

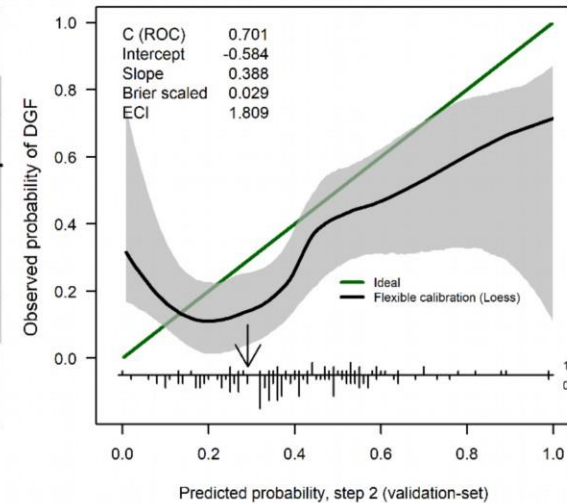
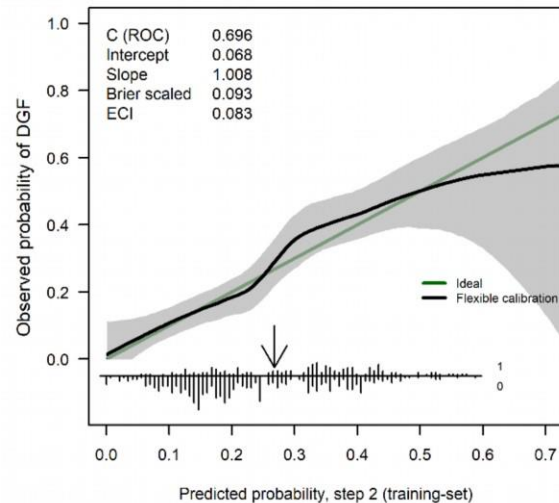
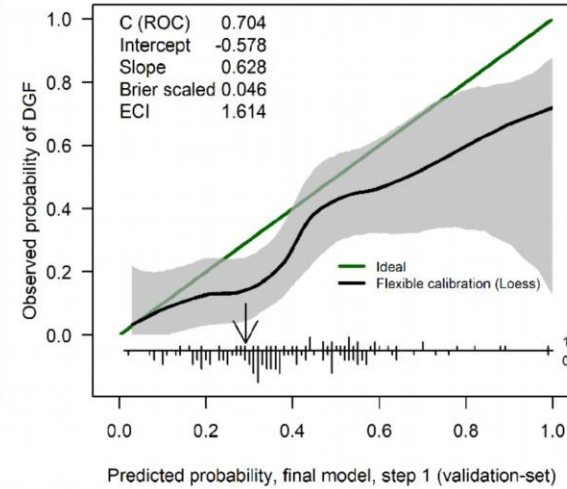
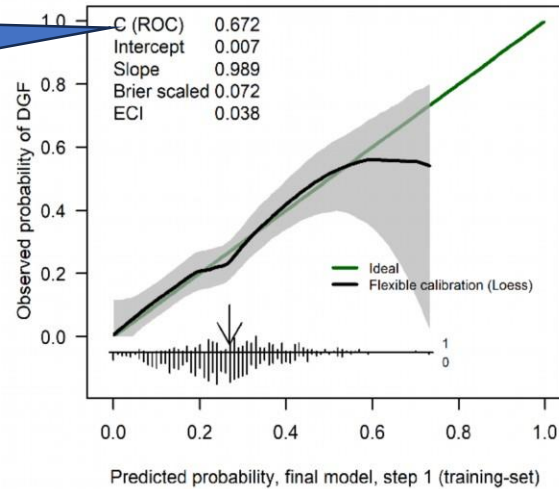
**Clinical & histological risk score**

(point scale<sup>1</sup> along with risk of DGF)

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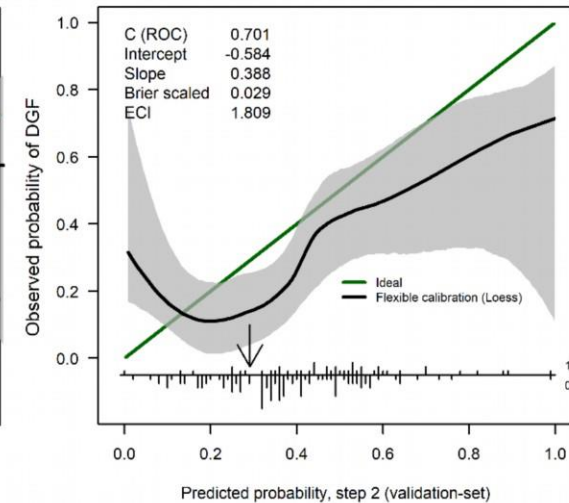
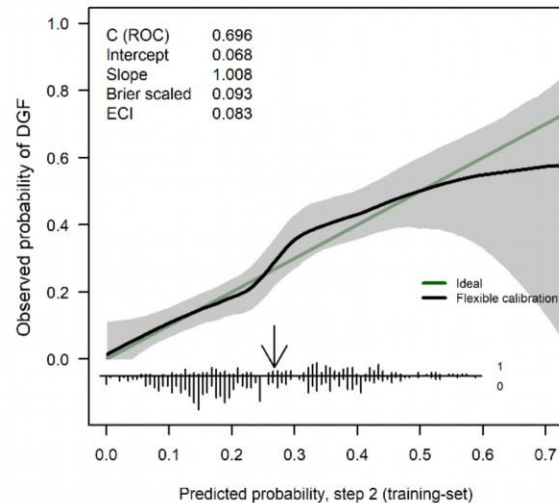
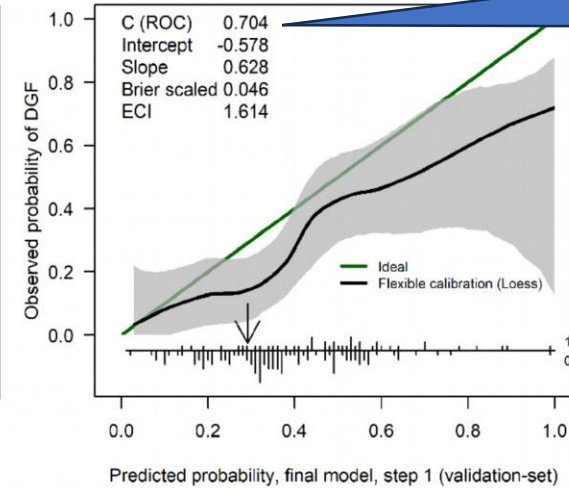
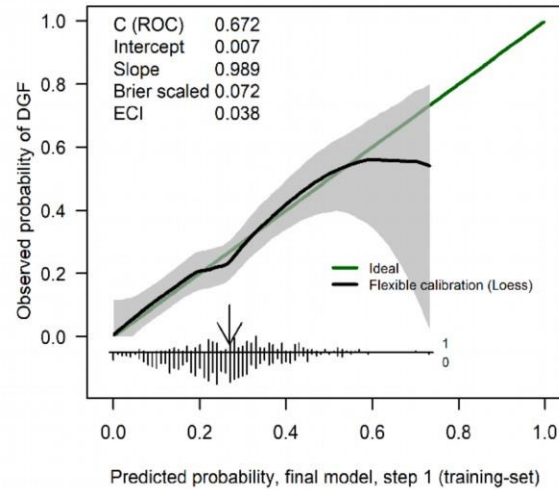
# Performance step 1 and step two for DGF

Good diagnostic discrimination

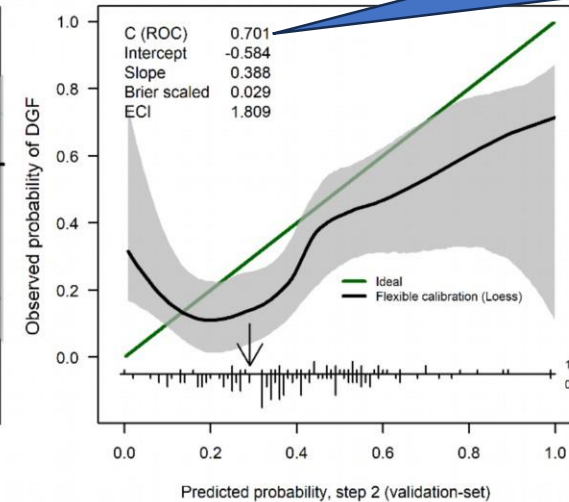
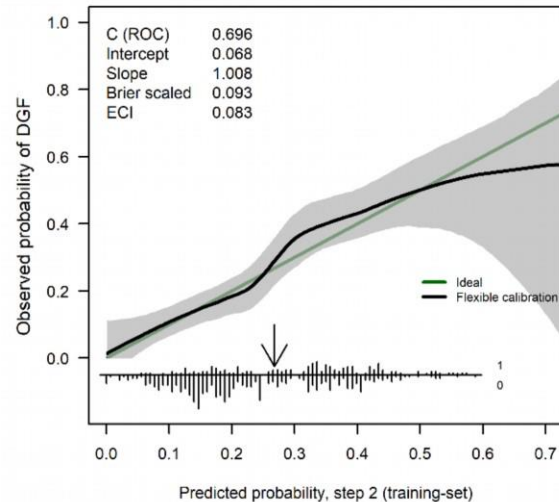
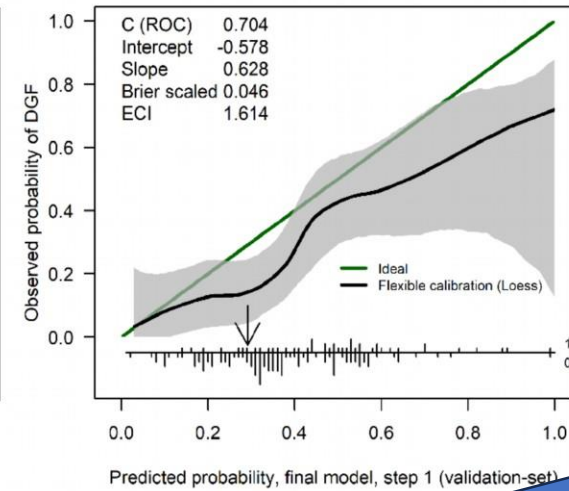
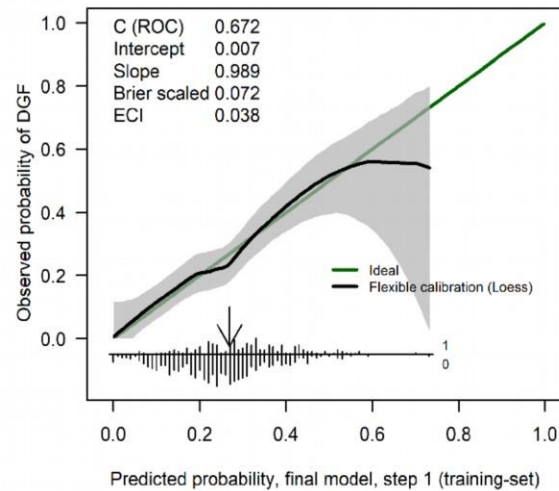


# Performance step 1 and step two for DGF

Good diagnostic discrimination



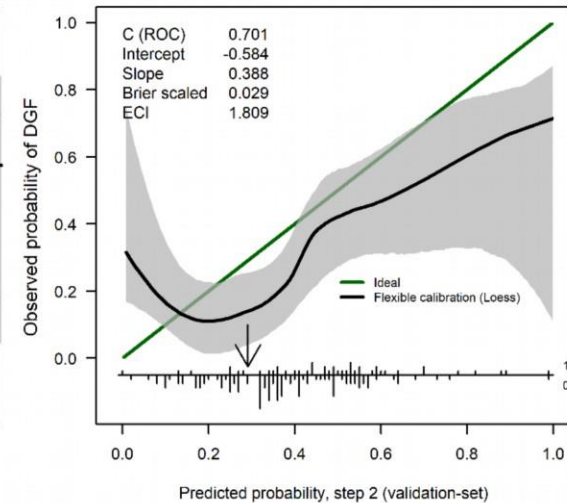
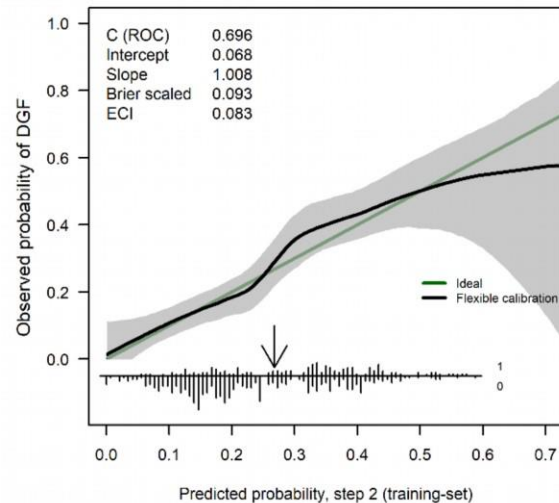
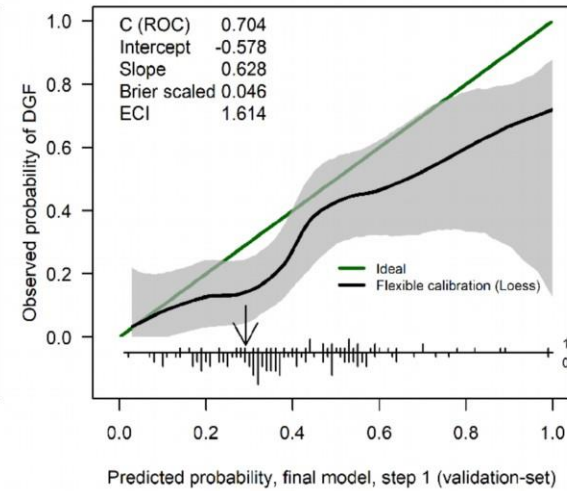
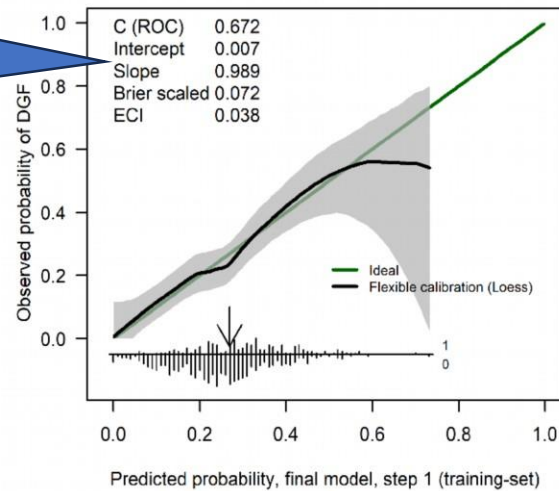
# Performance step 1 and step two for DGF



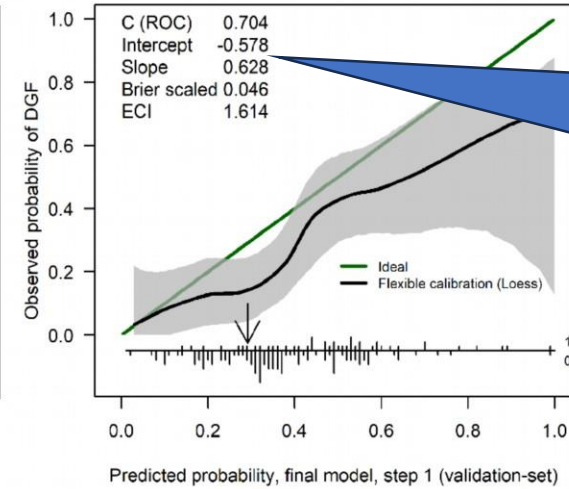
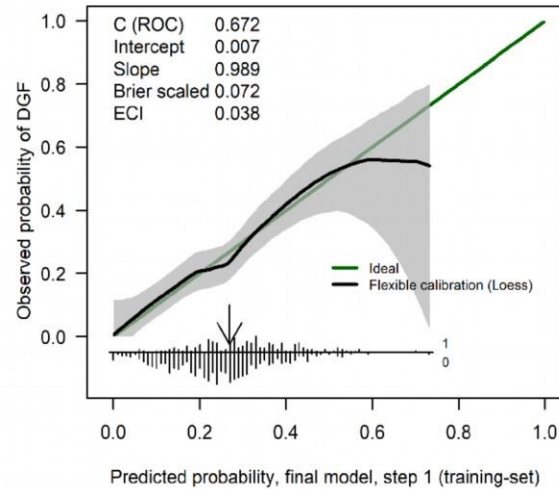
Not improved by  
histology on  
validation set

# Performance step 1 and step two for DGF

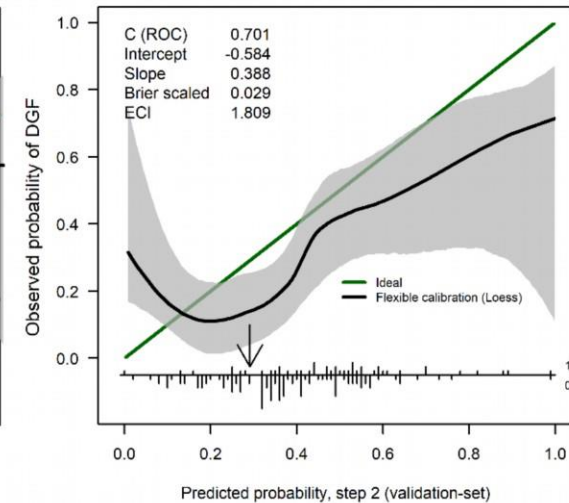
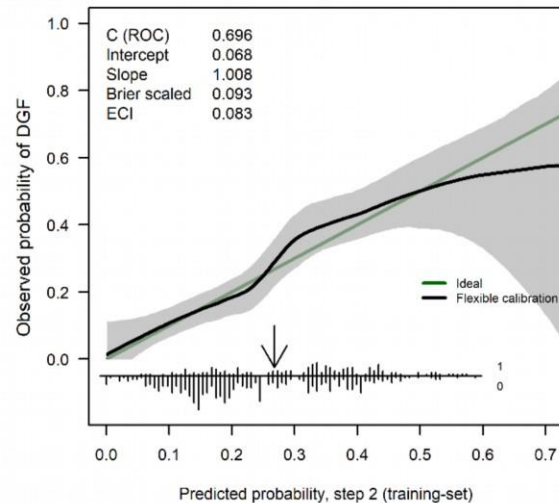
Calibration  
intercept and  
slope very good  
on training set



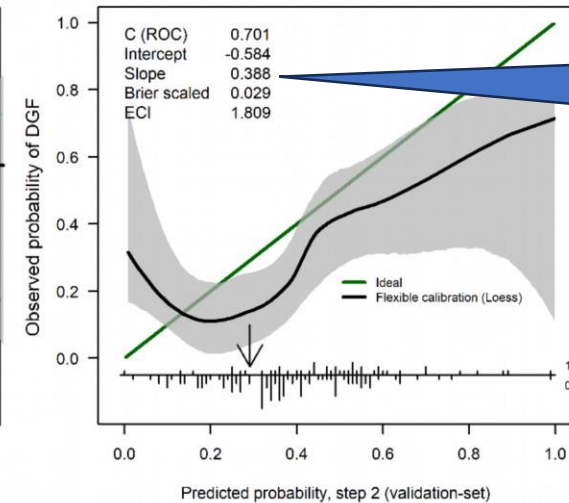
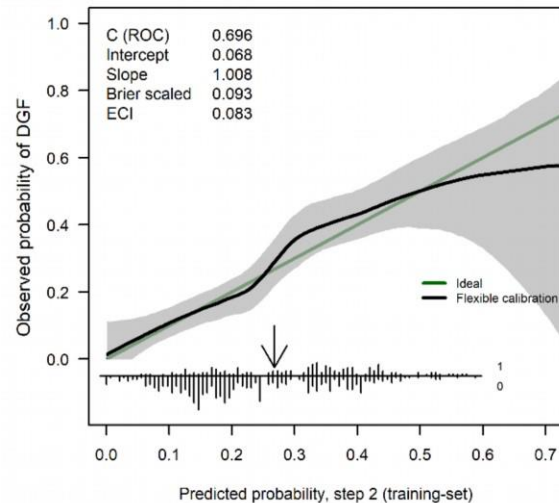
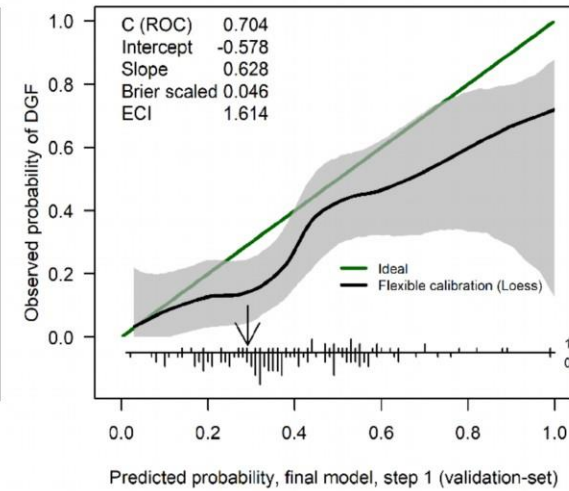
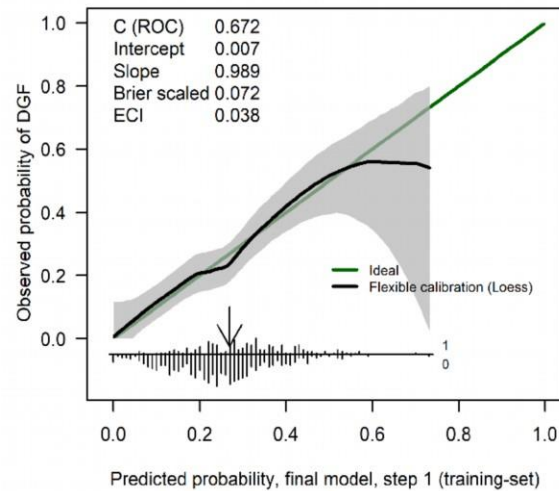
# Performance step 1 and step two for DGF



Intercept and slope dropped on validation set: underestimation of risk



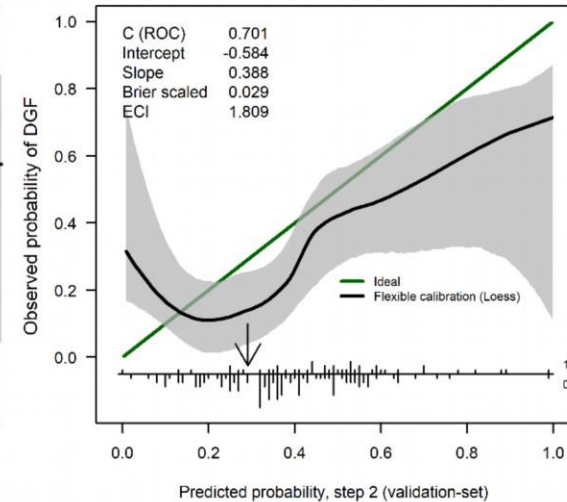
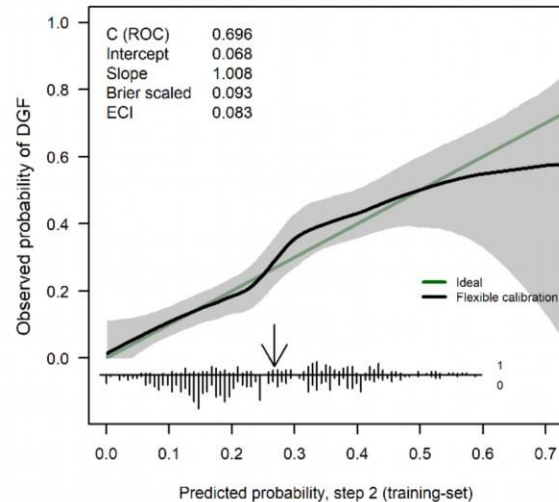
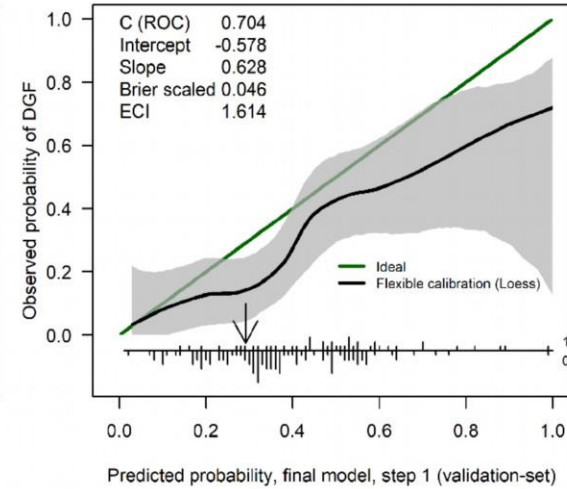
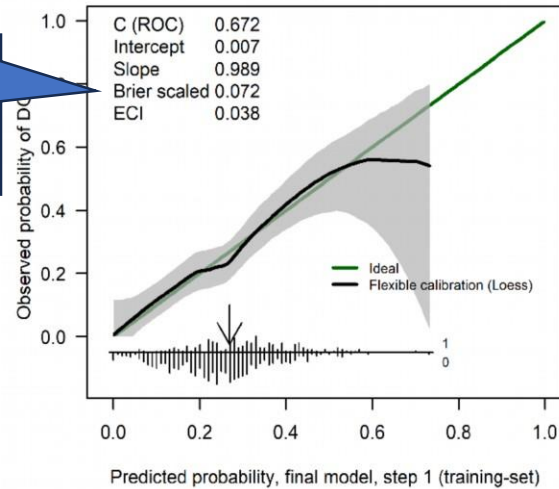
# Performance step 1 and step two for DGF



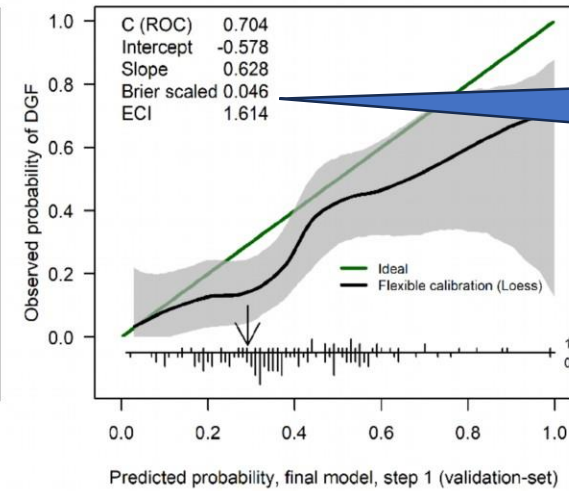
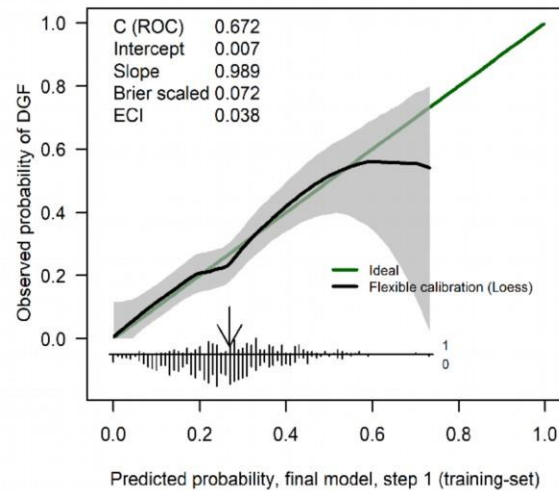
Intercept and slope dropped with histology

# Performance step 1 and step two for DGF

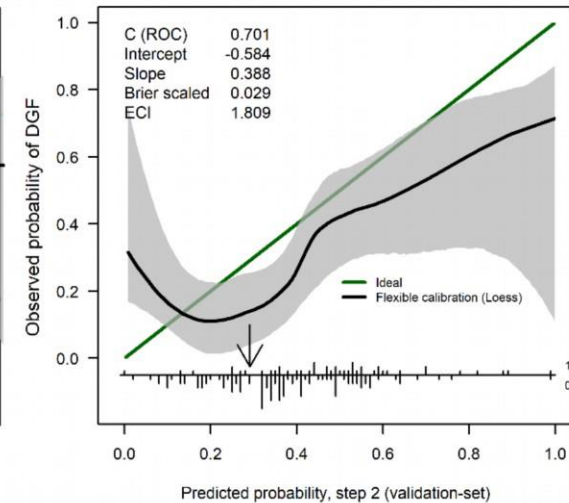
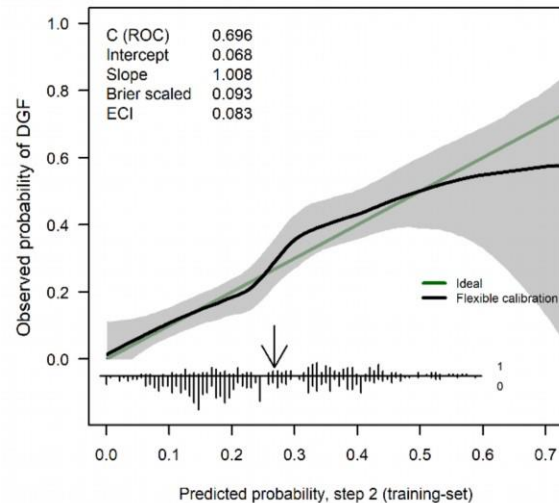
Scaled Brier score reflects C (ROC)



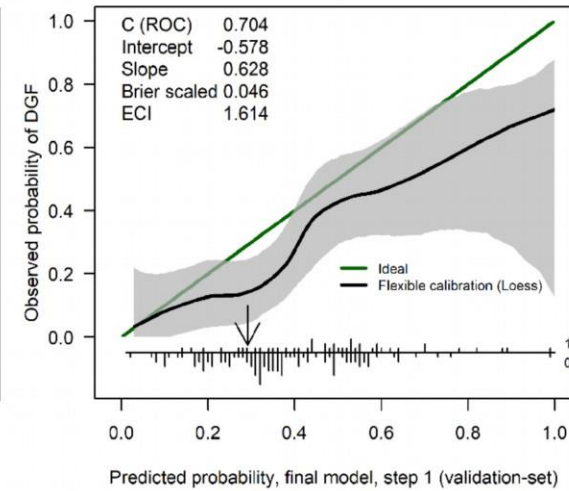
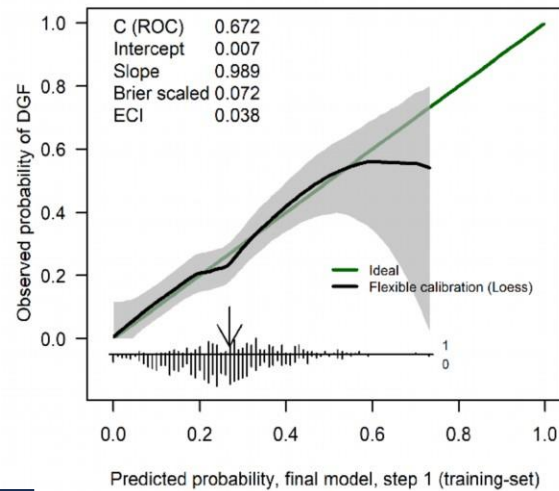
# Performance step 1 and step two for DGF



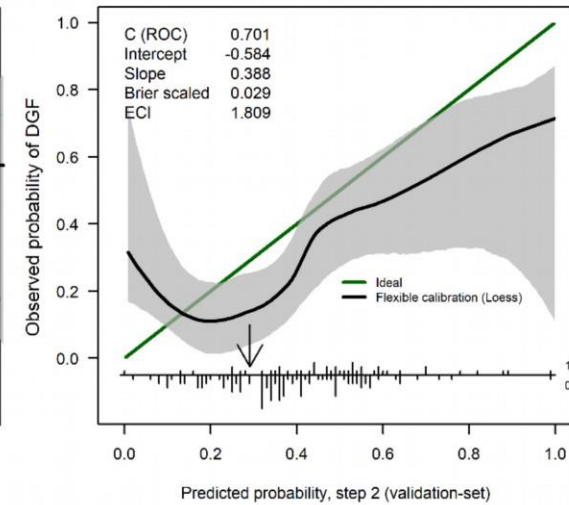
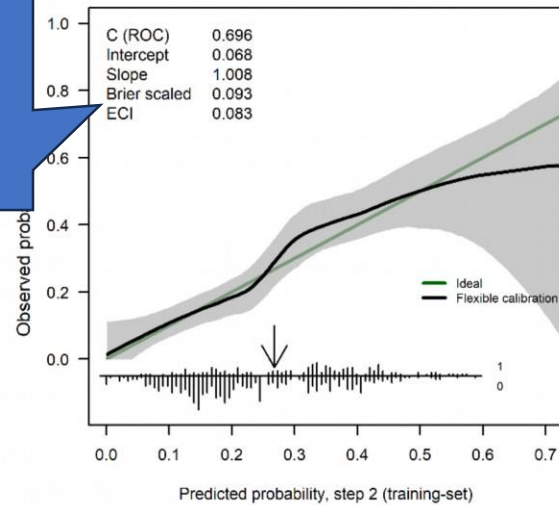
Also on validation set



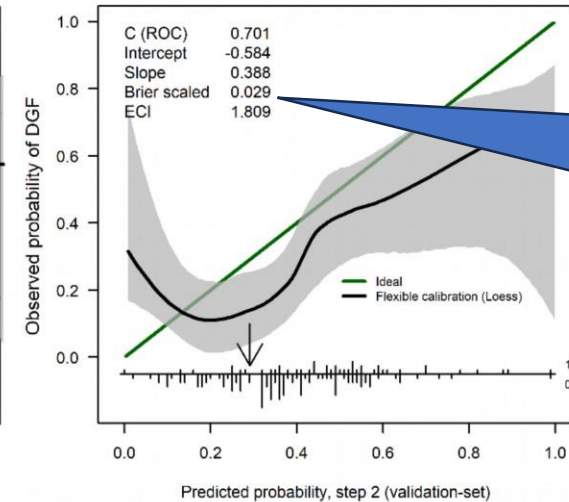
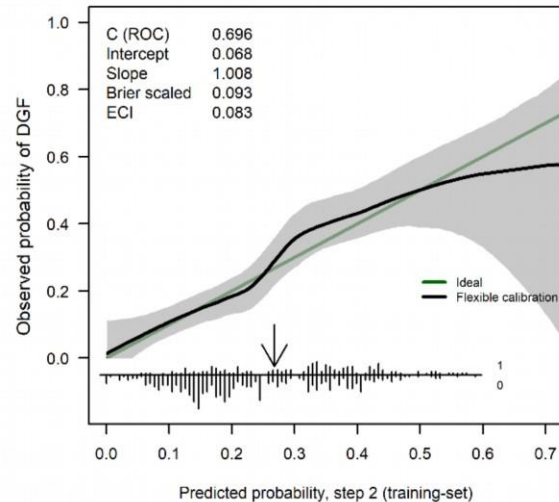
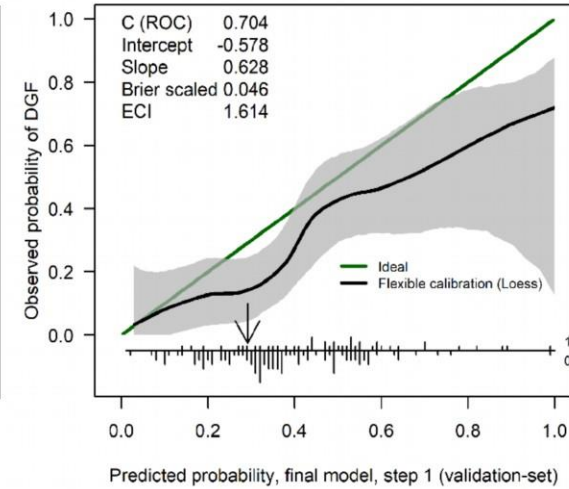
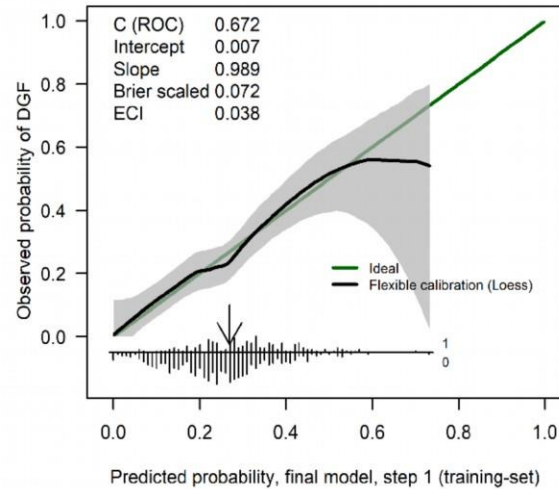
# Performance step 1 and step two for DGF



Brier score still reflects C (ROC)



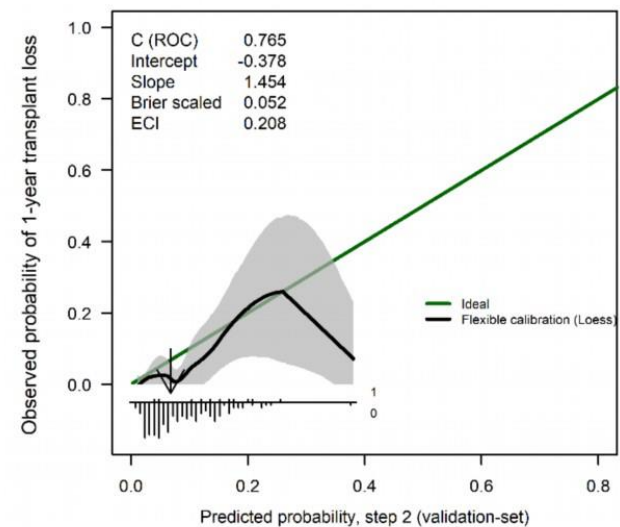
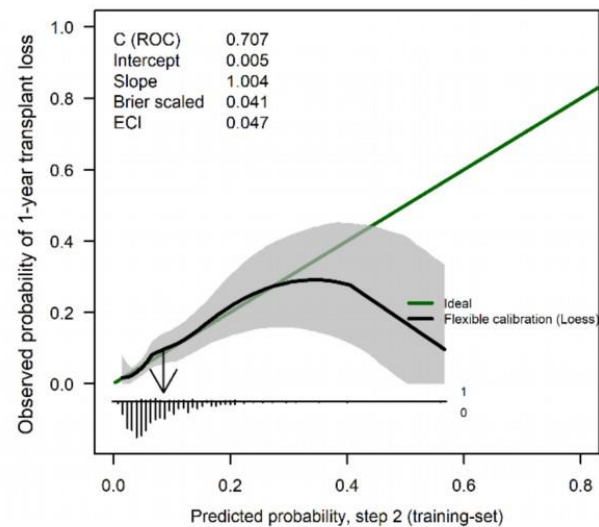
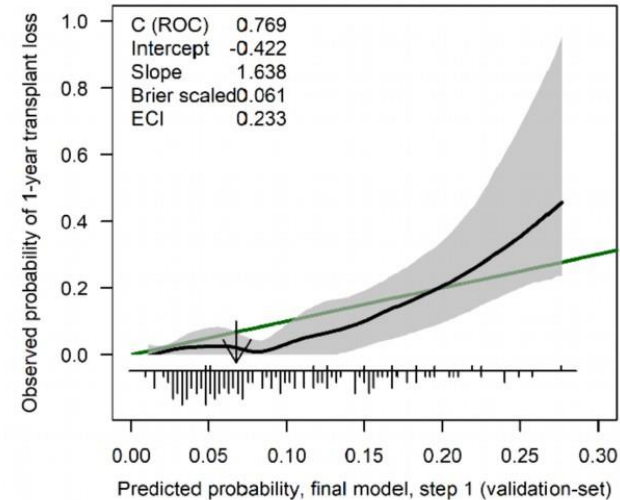
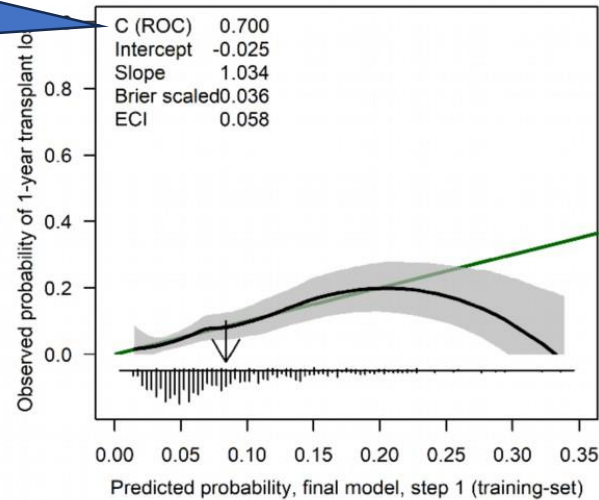
# Performance step 1 and step two for DGF



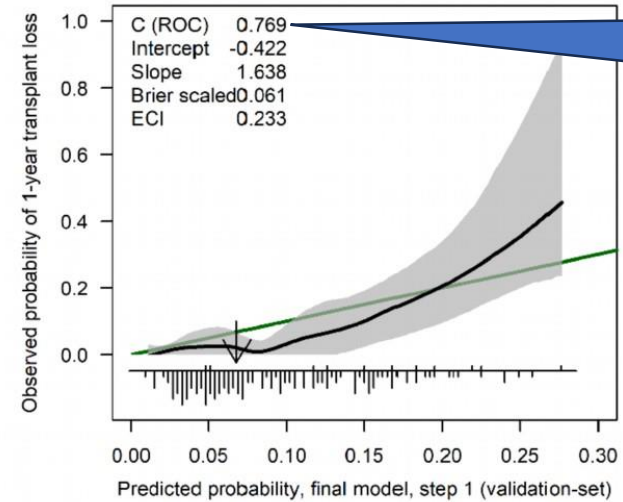
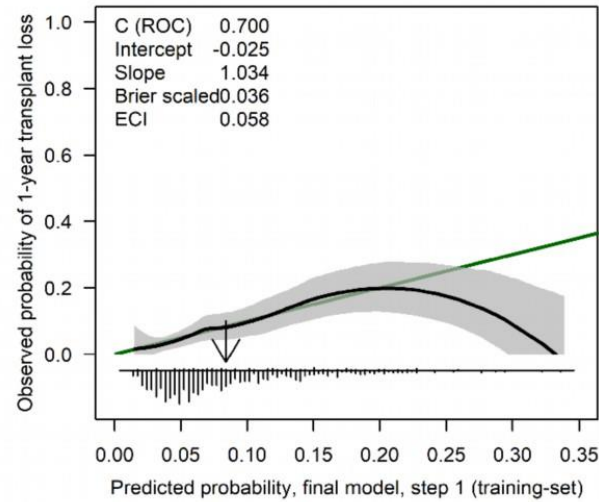
..also on validation set with histology

# Performance step 1 and step 2 for 1y-tl

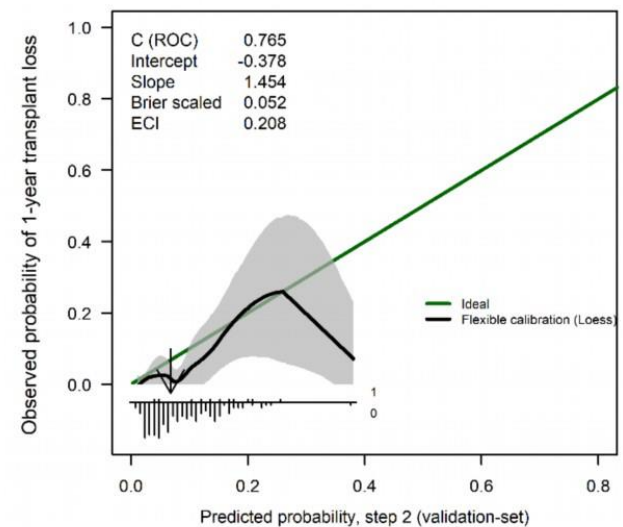
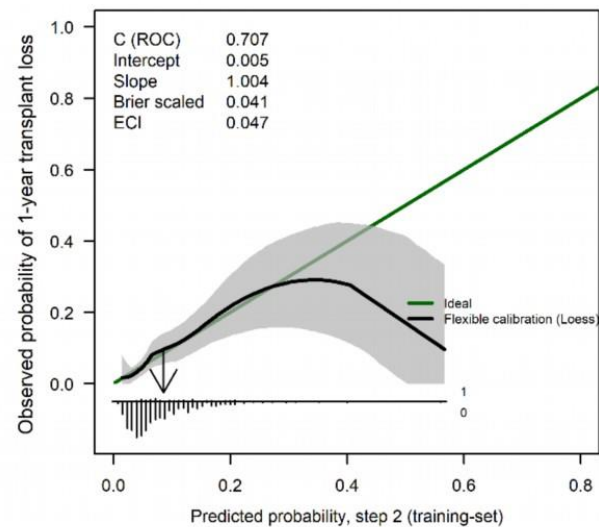
Good diagnostic discrimination



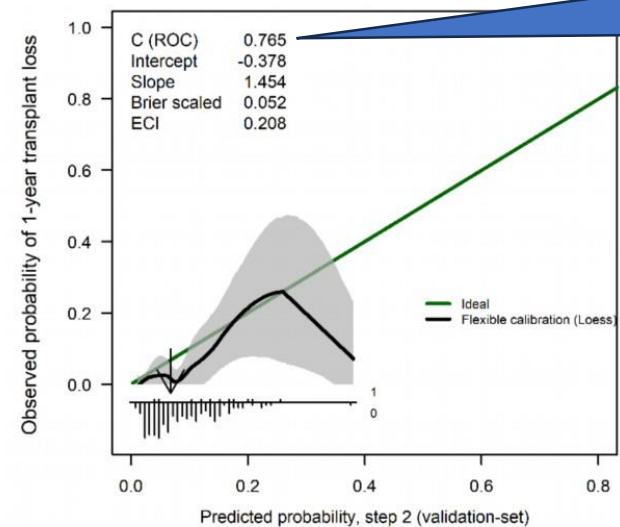
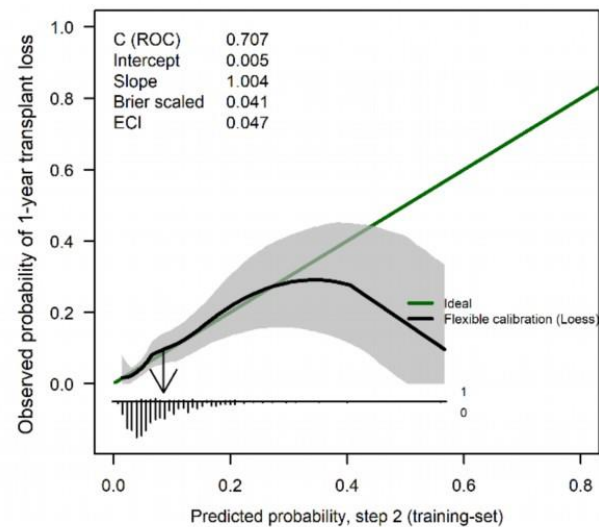
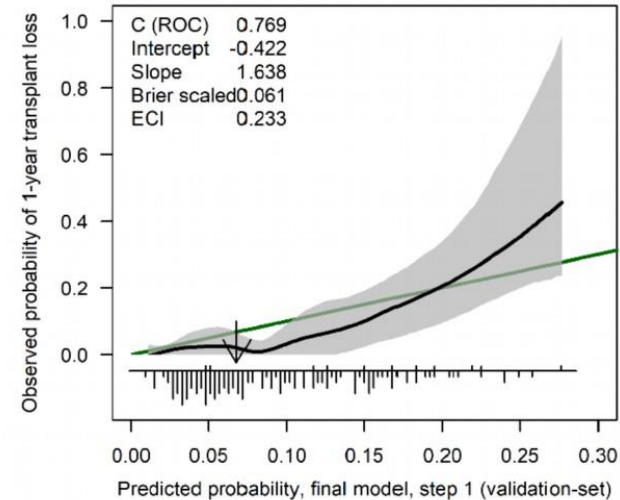
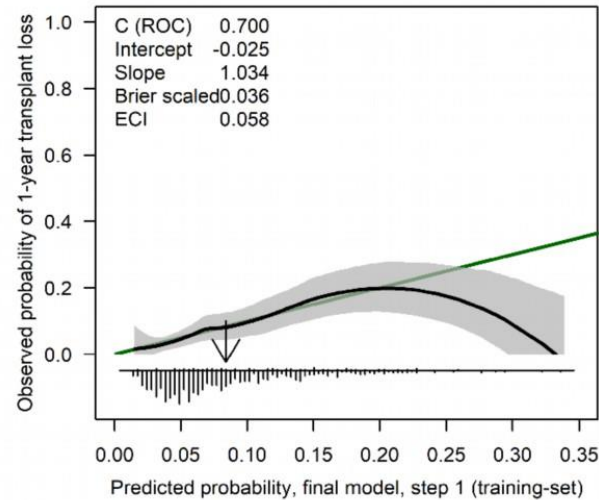
# Performance step 1 and step 2 for 1y-tl



Good diagnostic discrimination

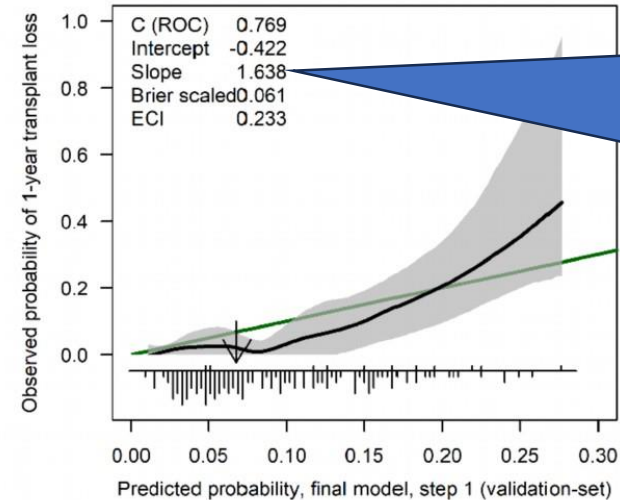
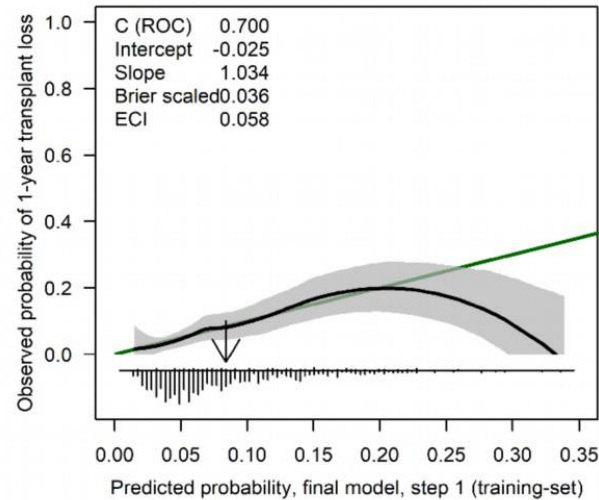


# Performance step 1 and step 2 for 1y-tl

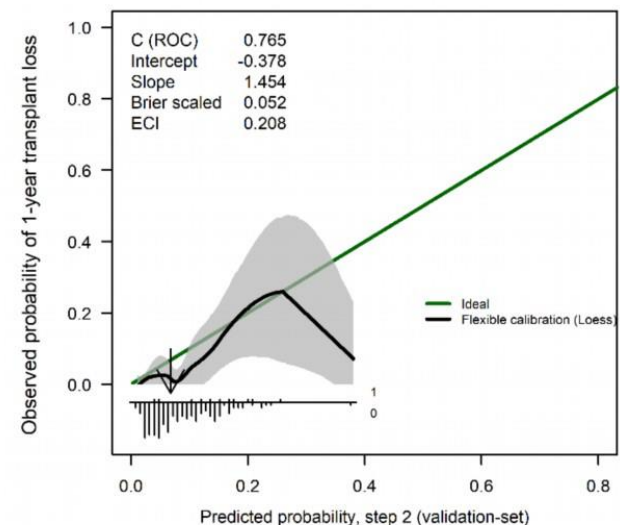
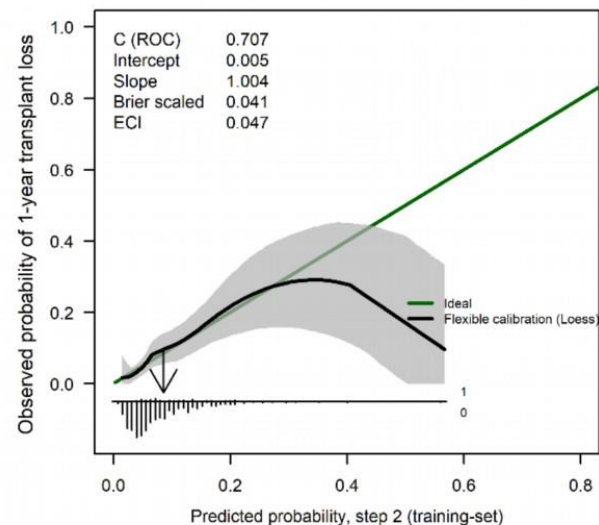


No improvement with histology on validation set

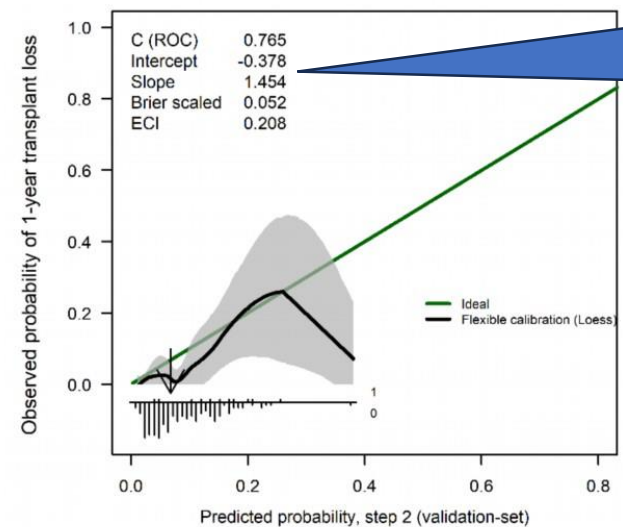
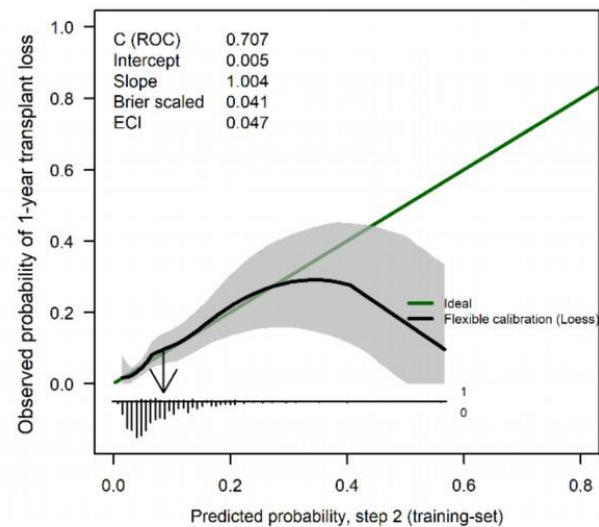
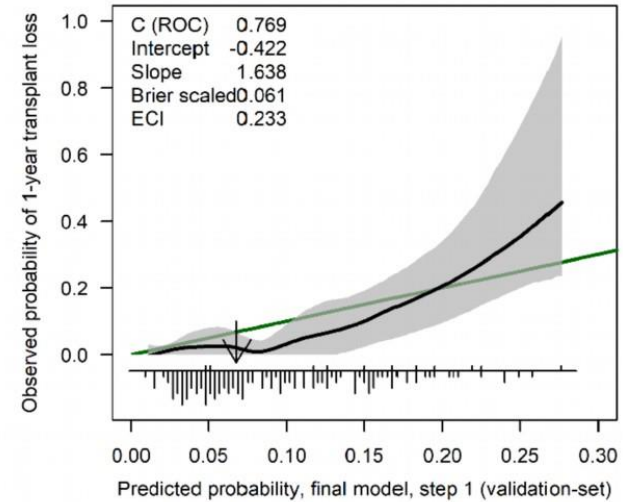
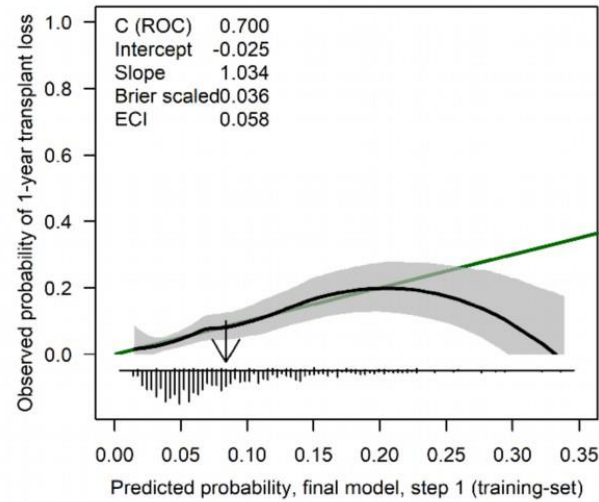
# Performance step 1 and step 2 for 1y-tl



Drop in intercept,  
increase in slope,  
underestimation  
of risk for small  
risks, increasing  
overestimation  
for high risks



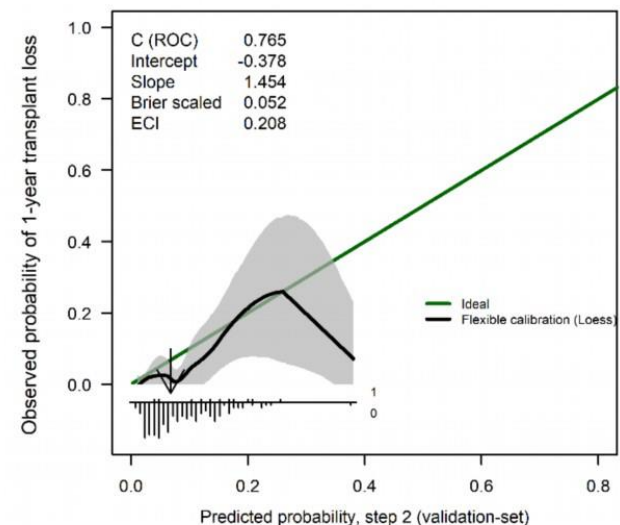
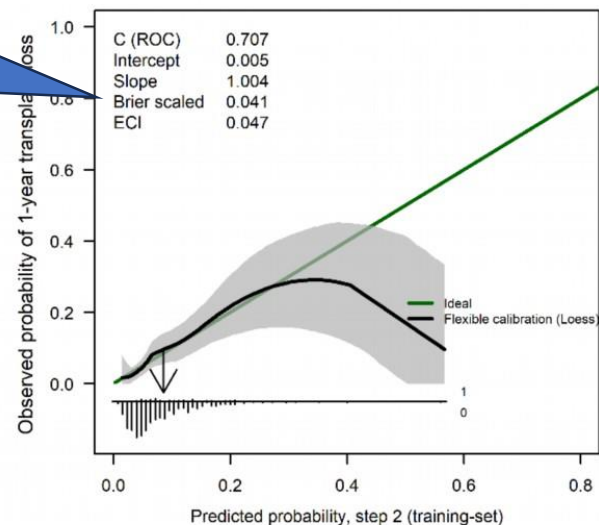
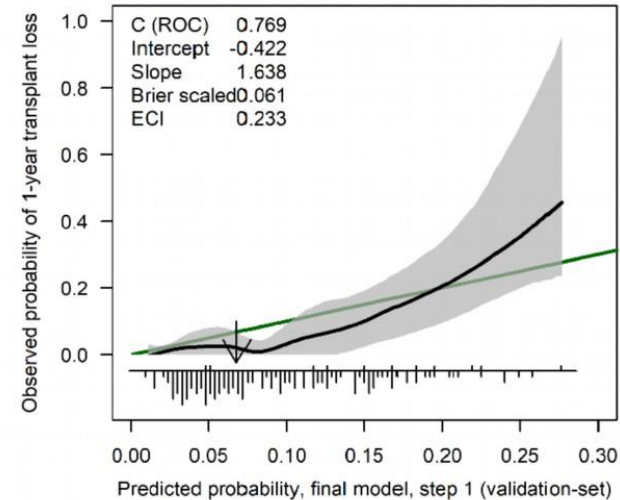
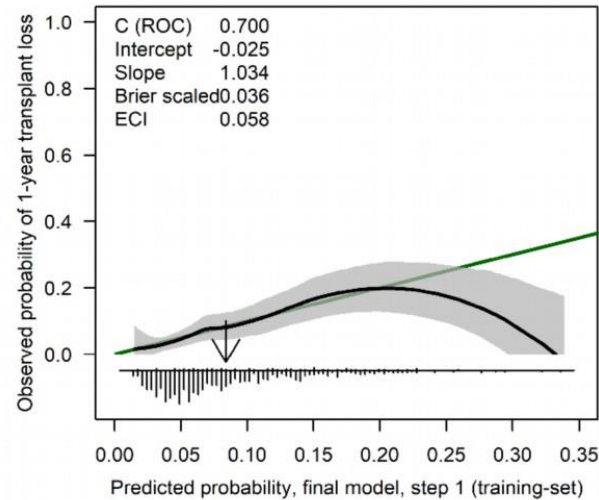
# Performance step 1 and step 2 for 1y-tl



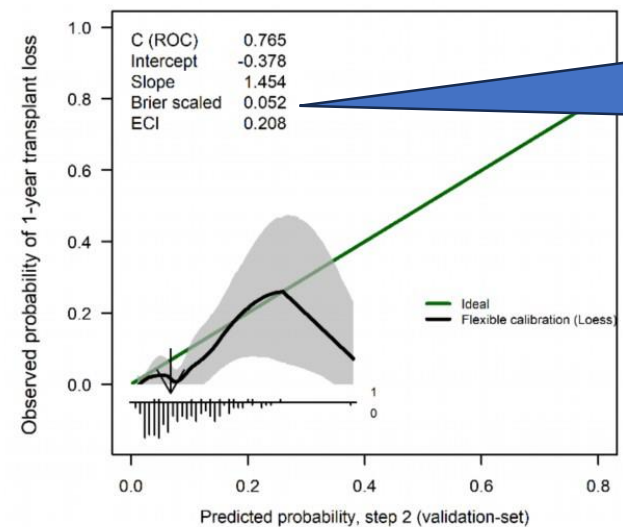
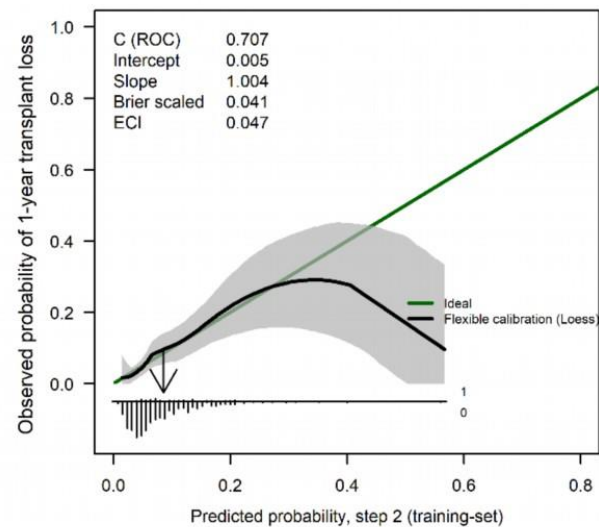
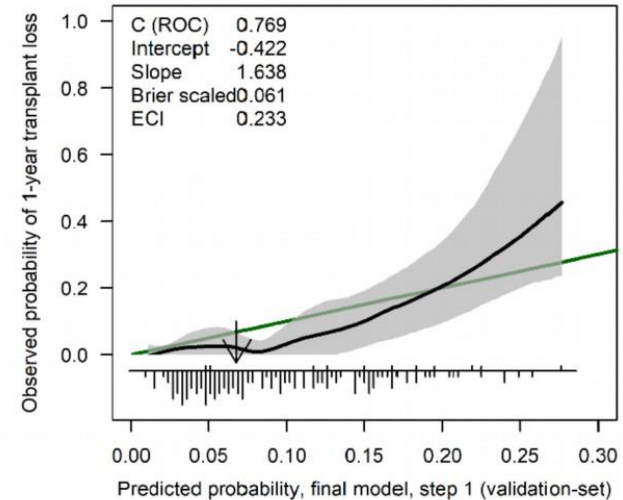
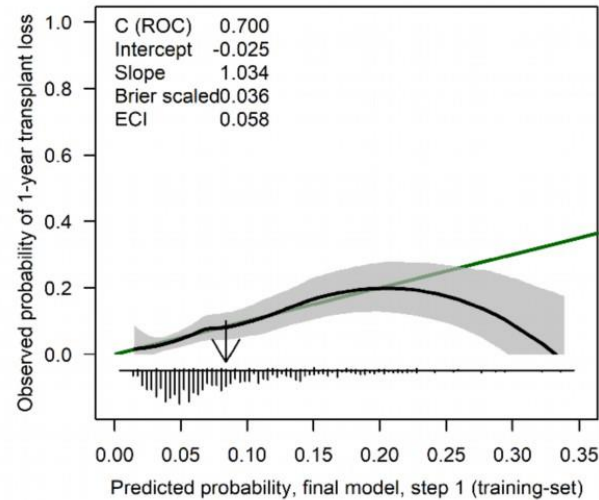
Mitigated by the addition of histology in validation set

# Performance step 1 and step 2 for 1y-tl

Addition of histology improved Brier score

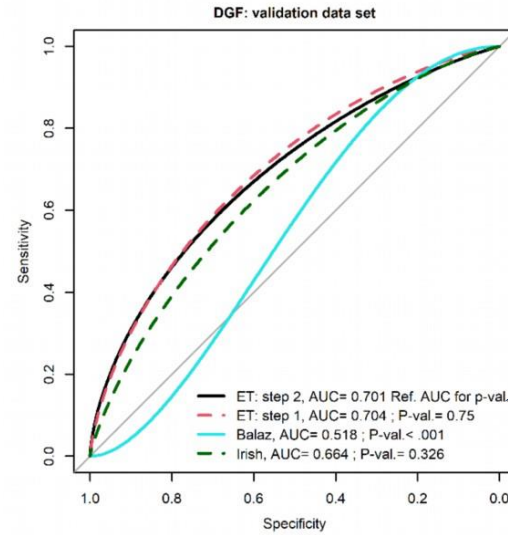
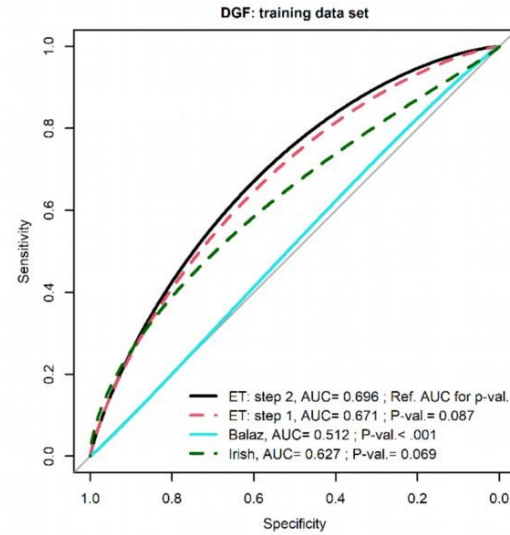


# Performance step 1 and step 2 for 1y-tl

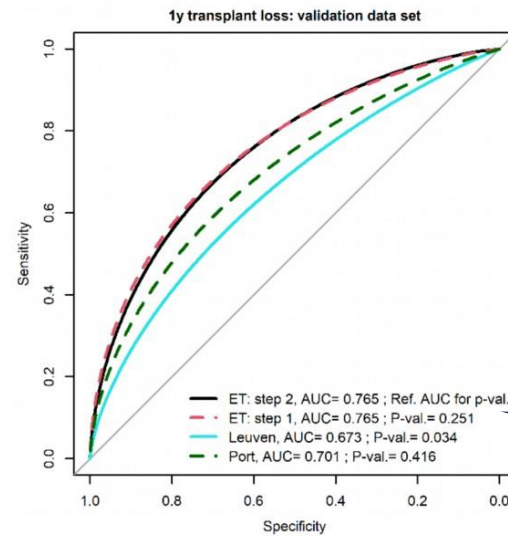
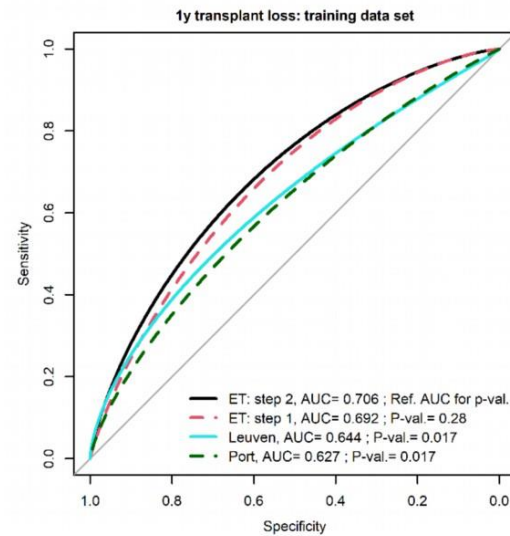


.. which still reflects C (ROC)

# Comparison against established scores



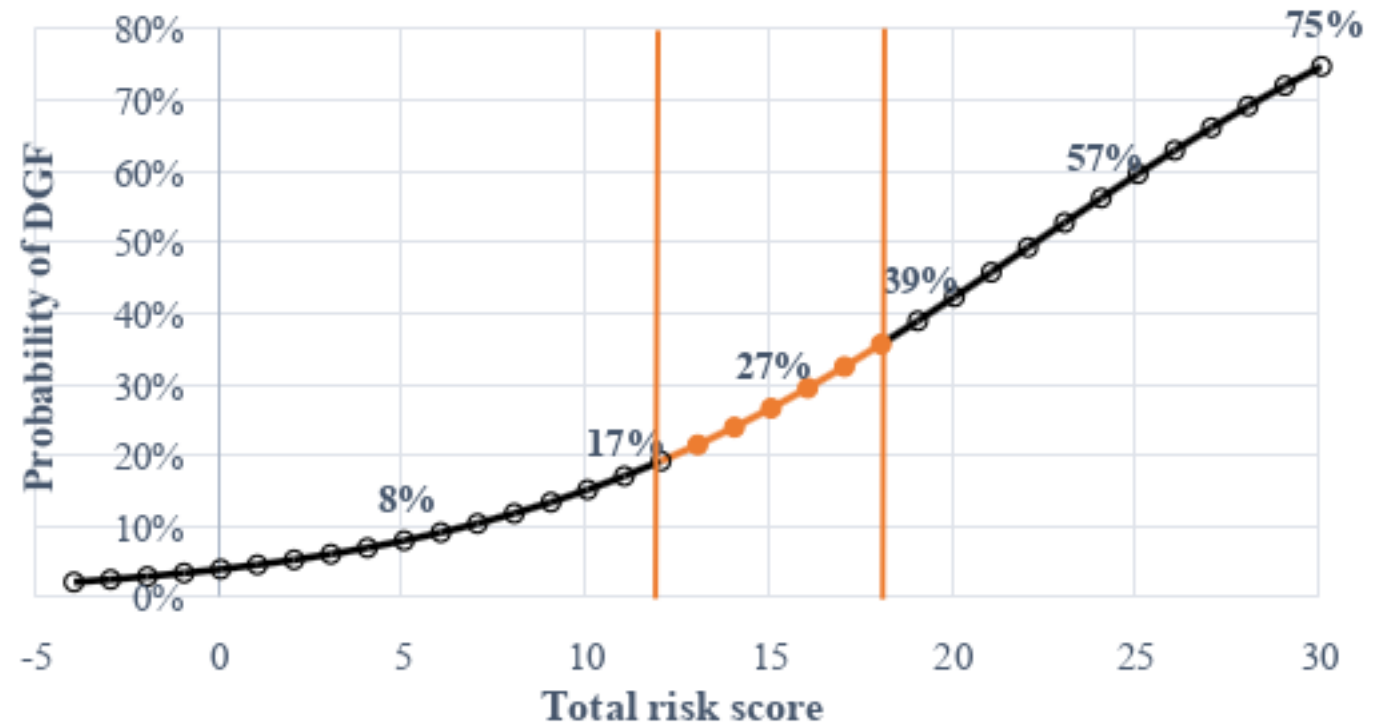
Our scores superior on validation set for DGF



.. and for 1y-tl

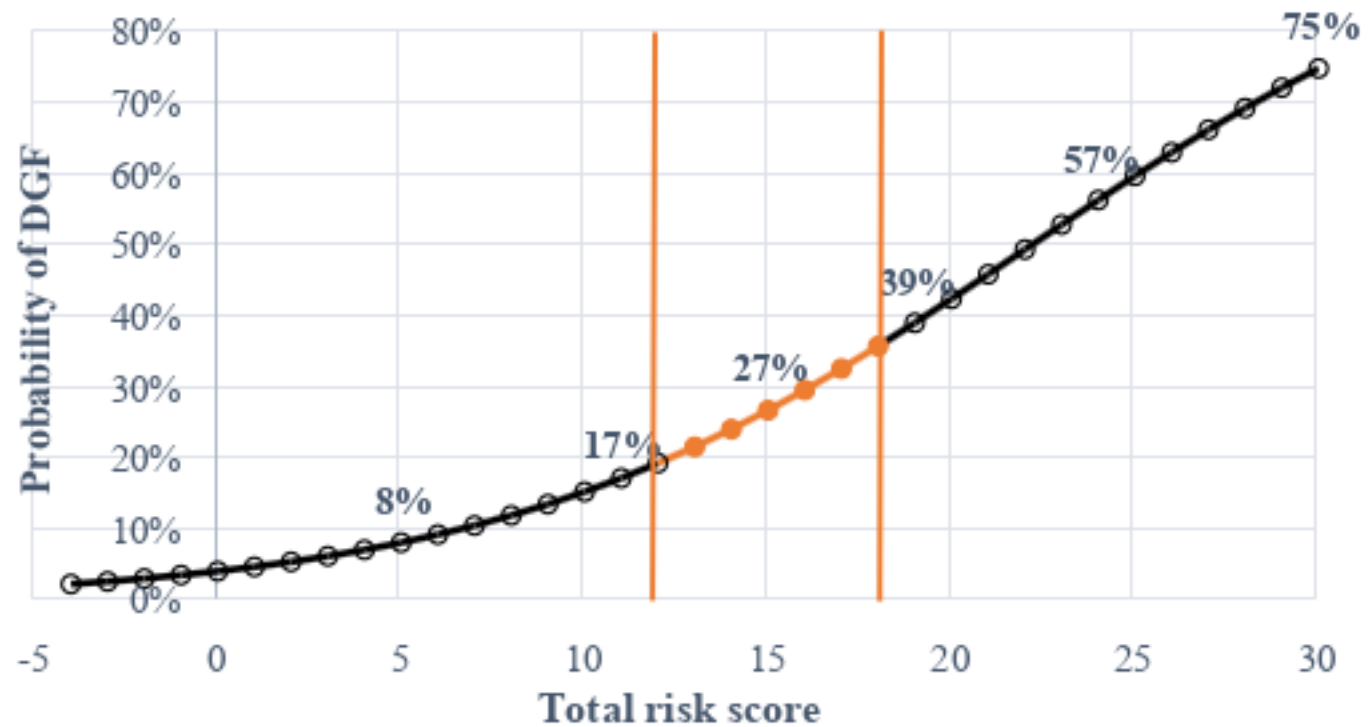
# Score application for DGF prediction

Risk factor	Addition to risk score					Risk score
<i>Donor BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30		>= 30	
	-2	0	+3		+6	
<i>Recipient BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30		>= 30	
	-2	0	+2		+3	
<i>Recipient CVM IgG</i>	Negative			Positive		
	0			+5		
<i>Number of HLA-DR mismatches</i>	Less than two			Two		
	0			+6		
<i>Dialysis vintage in years</i>	< 1	1 to < 3	3 to < 4		4 to < 6	>= 6
	0	+1	+2		+3	+5
<i>Cold ischaemia time in hours</i>	< 2	2 to < 6	6 to < 10	10 to < 14	14 to < 18	>= 18
	0	+1	+2	+3	+4	+5
<b>Total score without histological assessment</b>	- 4 to 11 points		12 to 18 points (18% to 36% risk)		19 to 30 points	
	Low risk		Medium risk: histological assessment advised		Increased risk	
<i>Number of glomeruli</i>	< 20	20 to < 30		30 to < 40	>= 40	
	0	-2		-4	-7	
<i>Banff cv</i>	cv0, cv1 or cv2			cv3		
	0			+5		
	<b>Total score =</b>					



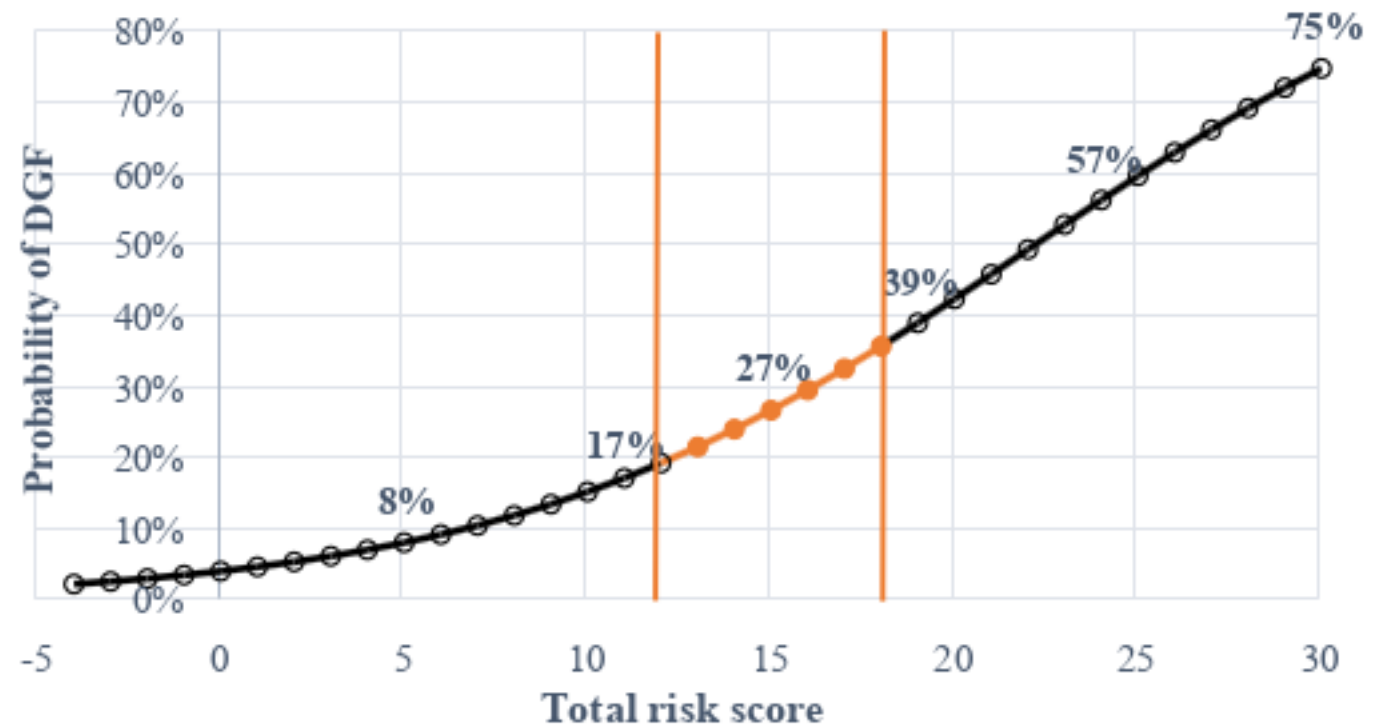
# Score application for DGF prediction

Risk factor	Addition to risk score					Risk score
<i>Donor BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30		>= 30	3
	-2	0	+3		+6	
<i>Recipient BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30		>= 30	
	-2	0	+2		+3	
<i>Recipient CVM IgG</i>	Negative			Positive		
	0			+5		
<i>Number of HLA-DR mismatches</i>	Less than two			Two		
	0			+6		
<i>Dialysis vintage in years</i>	< 1	1 to < 3	3 to < 4		4 to < 6	>= 6
	0	+1	+2		+3	+5
<i>Cold ischaemia time in hours</i>	< 2	2 to < 6	6 to < 10	10 to < 14	14 to < 18	>= 18
	0	+1	+2	+3	+4	+5
<b>Total score without histological assessment</b>	- 4 to 11 points		12 to 18 points (18% to 36% risk)		19 to 30 points	
	Low risk		Medium risk: histological assessment advised		Increased risk	
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	0	-2		-4	-7	
<i>Banff cv</i>	cv0, cv1 or cv2			cv3		
	0			+5		
	<b>Total score =</b>					



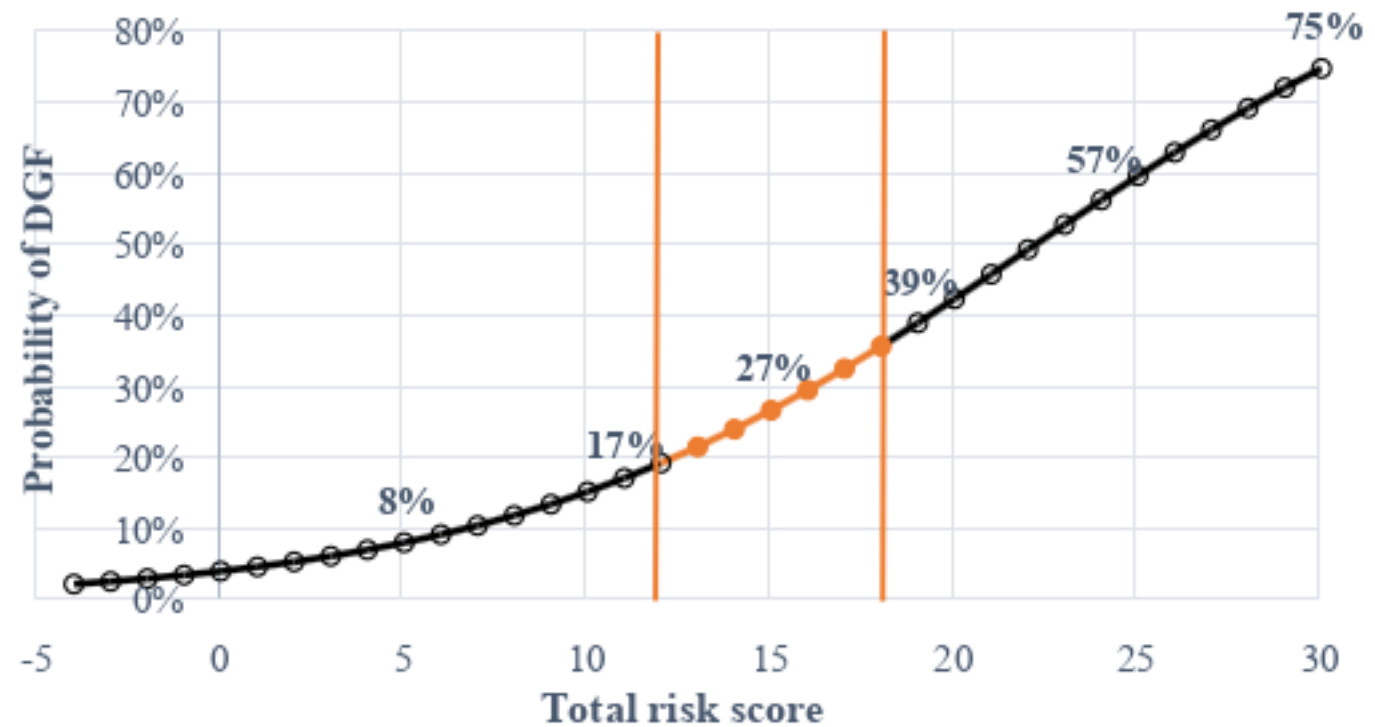
# Score application for DGF prediction

Risk factor	Addition to risk score					Risk score
<i>Donor BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30		3
	-2	0	+3	+6		
<i>Recipient BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30		2
	-2	0	+2	+3		
<i>Recipient CVM IgG</i>	Negative			Positive		
	0			+5		
<i>Number of HLA-DR mismatches</i>	Less than two			Two		
	0			+6		
<i>Dialysis vintage in years</i>	< 1	1 to < 3	3 to < 4	4 to < 6	>= 6	
	0	+1	+2	+3	+5	
<i>Cold ischaemia time in hours</i>	< 2	2 to < 6	6 to < 10	10 to < 14	14 to < 18	>= 18
	0	+1	+2	+3	+4	+5
<b>Total score without histological assessment</b>	- 4 to 11 points		12 to 18 points (18% to 36% risk)		19 to 30 points	
	Low risk		Medium risk: histological assessment advised		Increased risk	
<i>Number of glomeruli</i>	< 20	20 to < 30	30 to < 40	>= 40		
	0	-2	-4	-7		
<i>Banff cv</i>	cv0, cv1 or cv2			cv3		
	0			+5		
	<b>Total score =</b>					



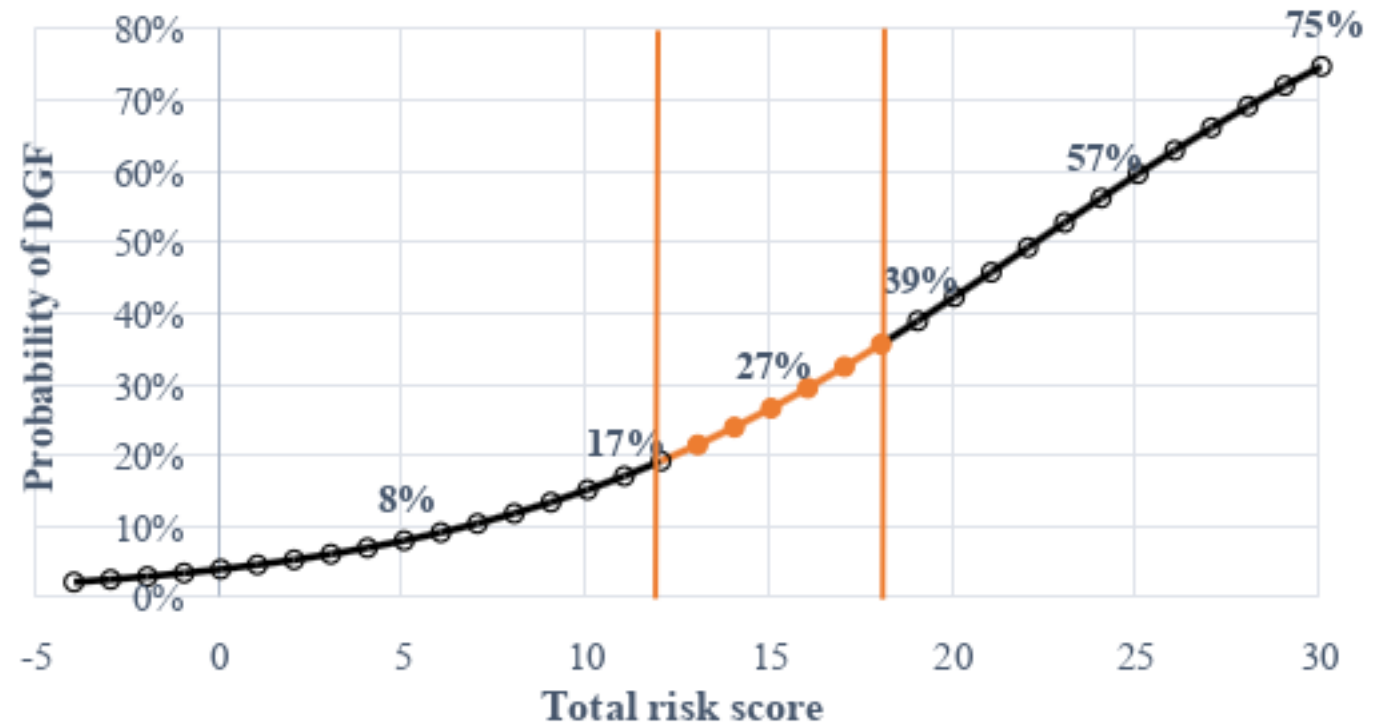
# Score application for DGF prediction

Risk factor	Addition to risk score					Risk score
<i>Donor BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30		3
	-2	0	+3	+6		
<i>Recipient BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30		2
	-2	0	+2	+3		
<i>Recipient CVM IgG</i>	Negative		Positive			5
	0		+5			
<i>Number of HLA-DR mismatches</i>	Less than two			Two		
	0			+6		
<i>Dialysis vintage in years</i>	< 1	1 to < 3	3 to < 4	4 to < 6	>= 6	
	0	+1	+2	+3	+5	
<i>Cold ischaemia time in hours</i>	< 2	2 to < 6	6 to < 10	10 to < 14	14 to < 18	>= 18
	0	+1	+2	+3	+4	+5
<b>Total score without histological assessment</b>	- 4 to 11 points		12 to 18 points (18% to 36% risk)		19 to 30 points	
	Low risk		Medium risk: histological assessment advised		Increased risk	
<i>Number of glomeruli</i>	< 20	20 to < 30	30 to < 40	>= 40		
	0	-2	-4	-7		
<i>Banff cv</i>	cv0, cv1 or cv2			cv3		
	0			+5		
	<b>Total score =</b>					



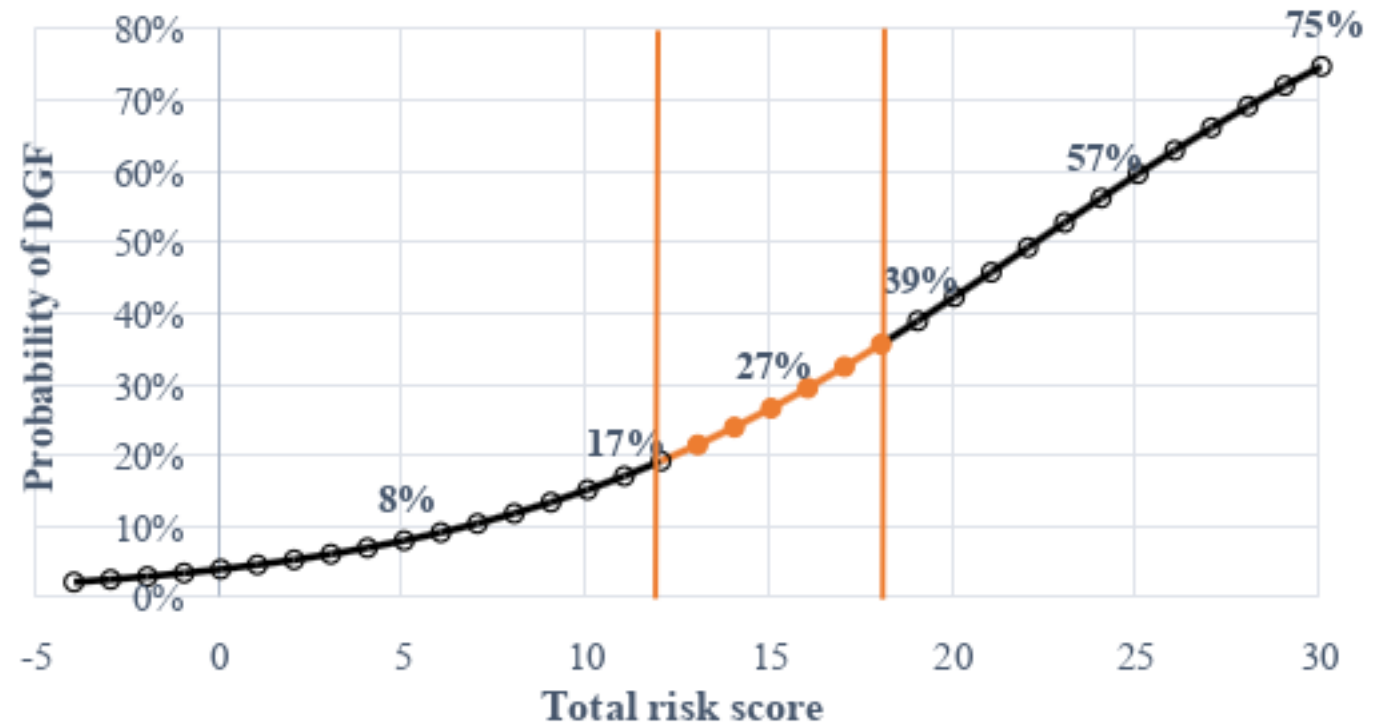
# Score application for DGF prediction

Risk factor	Addition to risk score					Risk score
<i>Donor BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30		3
	-2	0	+3	+6		
<i>Recipient BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30		2
	-2	0	+2	+3		
<i>Recipient CVM IgG</i>	Negative			Positive		5
	0			+5		
<i>Number of HLA-DR mismatches</i>	Less than two			Two		0
	0			+6		
<i>Dialysis vintage in years</i>	< 1	1 to < 3	3 to < 4	4 to < 6	>= 6	
	0	+1	+2	+3	+5	
<i>Cold ischaemia time in hours</i>	< 2	2 to < 6	6 to < 10	10 to < 14	14 to < 18	>= 18
	0	+1	+2	+3	+4	+5
<b>Total score without histological assessment</b>	- 4 to 11 points		12 to 18 points (18% to 36% risk)		19 to 30 points	
	Low risk		Medium risk: histological assessment advised		Increased risk	
<i>Number of glomeruli</i>	< 20	20 to < 30	30 to < 40	>= 40		
	0	-2	-4	-7		
<i>Banff cv</i>	cv0, cv1 or cv2			cv3		
	0			+5		
	<b>Total score =</b>					



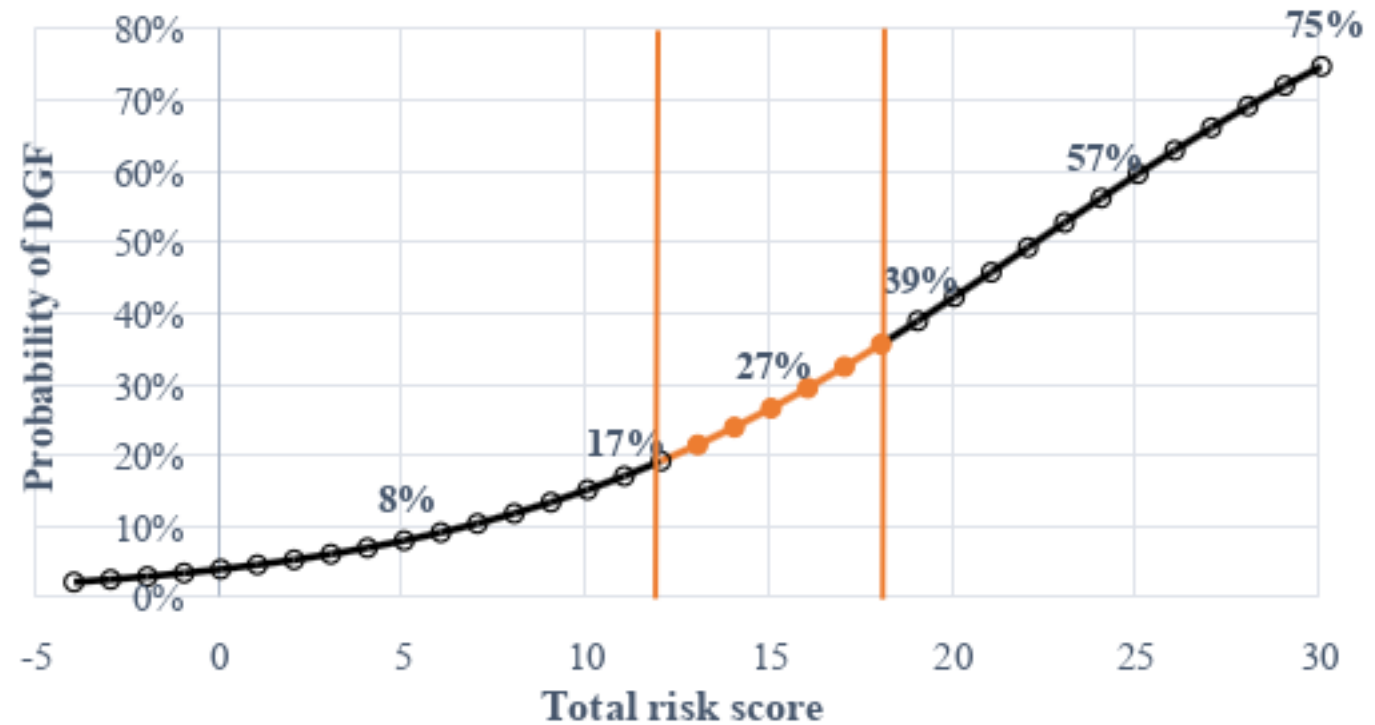
# Score application for DGF prediction

Risk factor	Addition to risk score				Risk score		
<i>Donor BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30	3		
	-2	0	+3	+6			
<i>Recipient BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30	2		
	-2	0	+2	+3			
<i>Recipient CVM IgG</i>	Negative		Positive		5		
	0		+5				
<i>Number of HLA-DR mismatches</i>	Less than two		Two		0		
	0		+6				
<i>Dialysis vintage in years</i>	< 1	1 to < 3	3 to < 4	4 to < 6	>= 6	3	
	0	+1	+2	+3	+5		
<i>Cold ischaemia time in hours</i>	< 2	2 to < 6	6 to < 10	10 to < 14	14 to < 18	>= 18	
	0	+1	+2	+3	+4	+5	
<b>Total score without histological assessment</b>	- 4 to 11 points		12 to 18 points (18% to 36% risk)		19 to 30 points		
	Low risk		Medium risk: histological assessment advised		Increased risk		
<i>Number of glomeruli</i>	< 20	20 to < 30	30 to < 40	>= 40			
	0	-2	-4	-7			
<i>Banff cv</i>	cv0, cv1 or cv2		cv3				
	0		+5				
	<b>Total score =</b>						



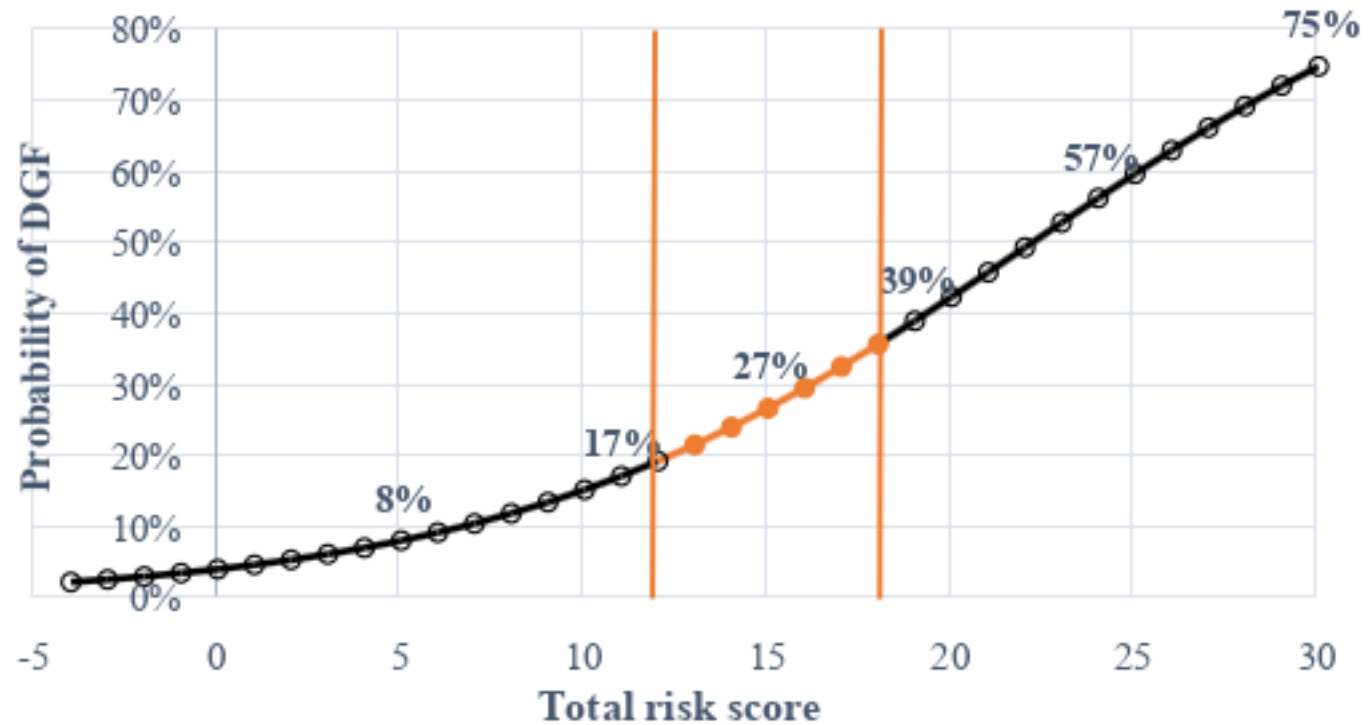
# Score application for DGF prediction

Risk factor	Addition to risk score					Risk score
<i>Donor BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30		3
	-2	0	+3	+6		
<i>Recipient BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30		2
	-2	0	+2	+3		
<i>Recipient CVM IgG</i>	Negative			Positive		5
	0			+5		
<i>Number of HLA-DR mismatches</i>	Less than two			Two		0
	0			+6		
<i>Dialysis vintage in years</i>	< 1	1 to < 3	3 to < 4	4 to < 6	>= 6	3
	0	+1	+2	+3	+5	
<i>Cold ischaemia time in hours</i>	< 2	2 to < 6	6 to < 10	10 to < 14	14 to < 18	3
	0	+1	+2	+3	+4	
<b>Total score without histological assessment</b>	- 4 to 11 points		12 to 18 points (18% to 36% risk)		19 to 30 points	
	Low risk		Medium risk: histological assessment advised		Increased risk	
<i>Number of glomeruli</i>	< 20	20 to < 30	30 to < 40	>= 40		
	0	-2	-4	-7		
<i>Banff cv</i>	cv0, cv1 or cv2			cv3		
	0			+5		
	<b>Total score =</b>					



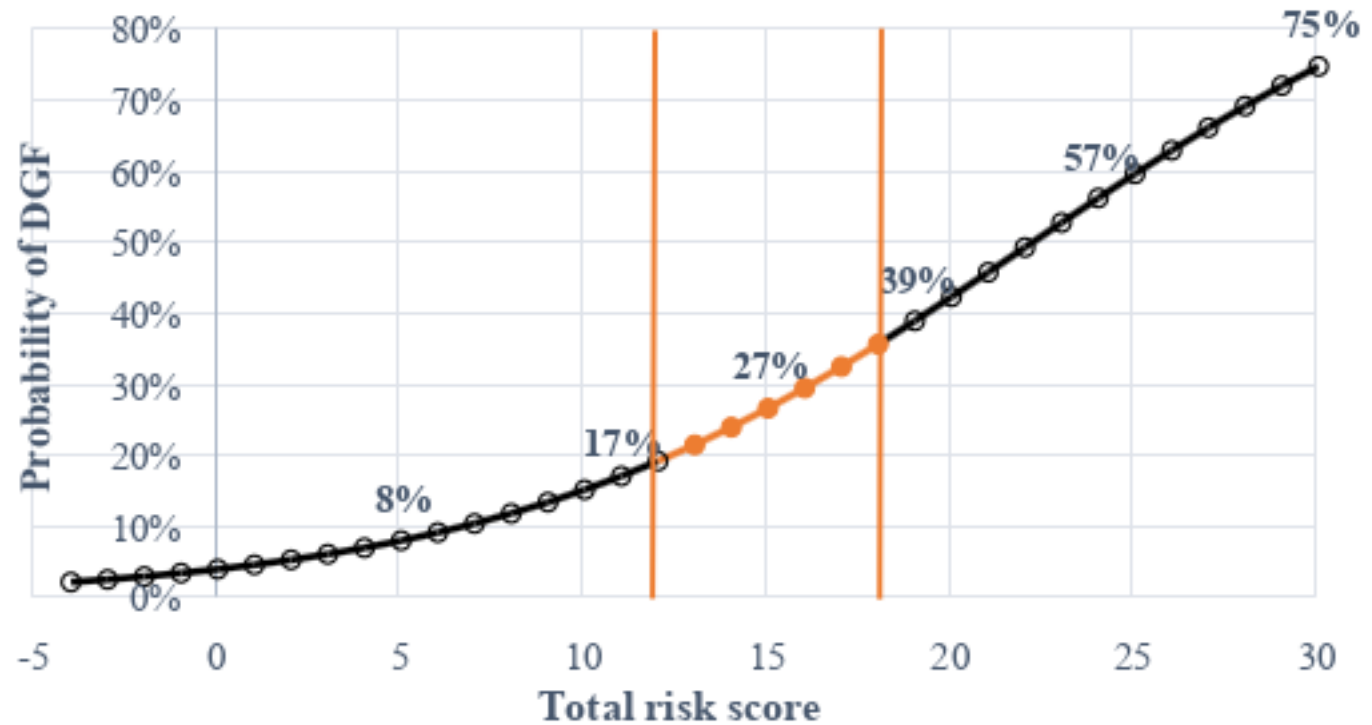
# Score application for DGF prediction

Risk factor	Addition to risk score					Risk score	
<i>Donor BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30		3	
	-2	0	+3	+6			
<i>Recipient BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30		2	
	-2	0	+2	+3			
<i>Recipient CVM IgG</i>	Negative			Positive		5	
	0			+5			
<i>Number of HLA-DR mismatches</i>	Less than two			Two		0	
	0			+6			
<i>Dialysis vintage in years</i>	< 1	1 to < 3	3 to < 4	4 to < 6	>= 6	3	
	0	+1	+2	+3	+5		
<i>Cold ischaemia time in hours</i>	< 2	2 to < 6	6 to < 10	10 to < 14	14 to < 18	>= 18	3
	0	+1	+2	+3	+4	+5	
<b>Total score without histological assessment</b>	- 4 to 11 points		12 to 18 points (18% to 36% risk)		19 to 30 points		16
	Low risk		Medium risk: histological assessment advised		Increased risk		
<i>Number of glomeruli</i>	< 20		20 to < 30		30 to < 40		>= 40
	0		-2		-4		-7
<i>Banff cv</i>	cv0, cv1 or cv2			cv3			
	0			+5			
	<b>Total score =</b>						



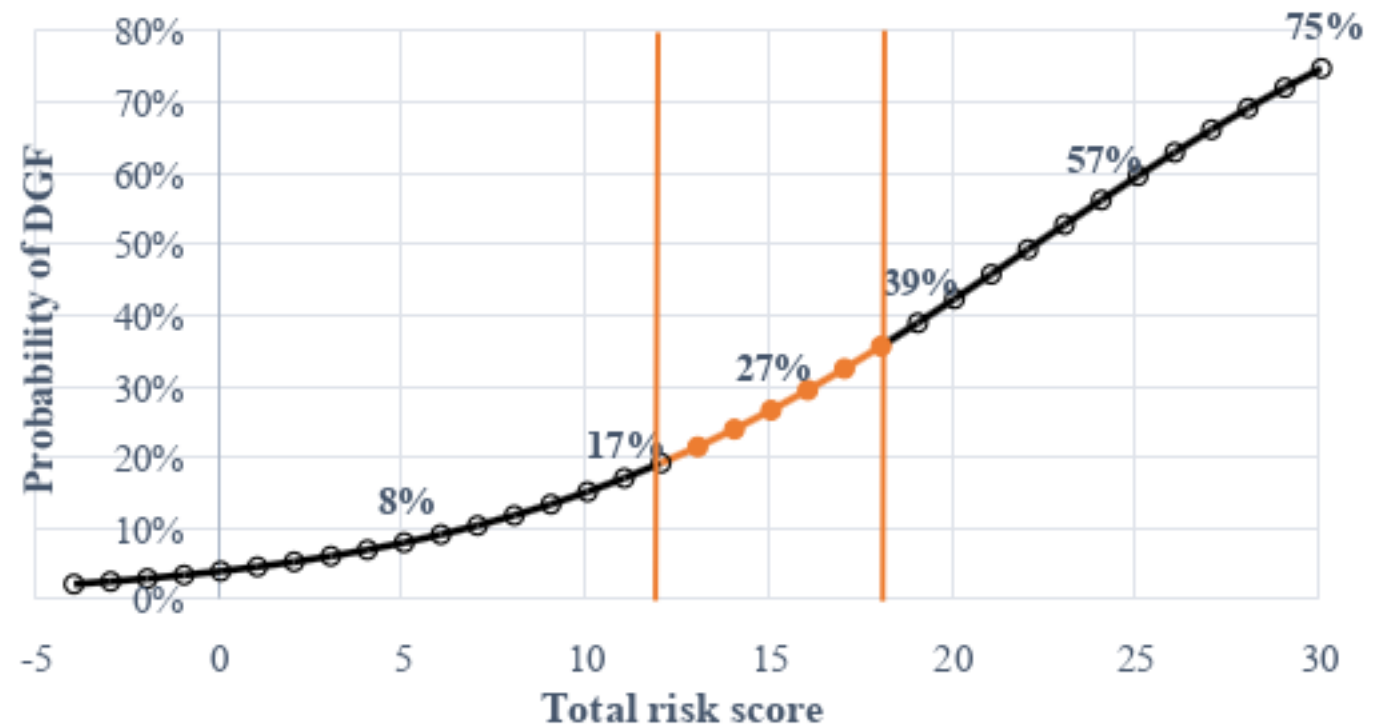
# Score application for DGF prediction

Risk factor	Addition to risk score					Risk score
<i>Donor BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30		>= 30	3
	-2	0	+3		+6	
<i>Recipient BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30		>= 30	2
	-2	0	+2		+3	
<i>Recipient CVM IgG</i>	Negative			Positive		5
	0			+5		
<i>Number of HLA-DR mismatches</i>	Less than two			Two		0
	0			+6		
<i>Dialysis vintage in years</i>	< 1	1 to < 3	3 to < 4		4 to < 6	3
	0	+1	+2		+3	
<i>Cold ischaemia time in hours</i>	< 2	2 to < 6	6 to < 10	10 to < 14	14 to < 18	3
	0	+1	+2	+3	+4	
<b>Total score without histological assessment</b>	- 4 to 11 points		12 to 18 points (18% to 36% risk)		19 to 30 points	16
	Low risk		Medium risk: histological assessment advised		Increased risk	
<i>Number of glomeruli</i>	< 20	20 to < 30		30 to < 40	>= 40	
	0	-2		-4	-7	
<i>Banff cv</i>	cv0, cv1 or cv2			cv3		
	0			+5		
	<b>Total score =</b>					



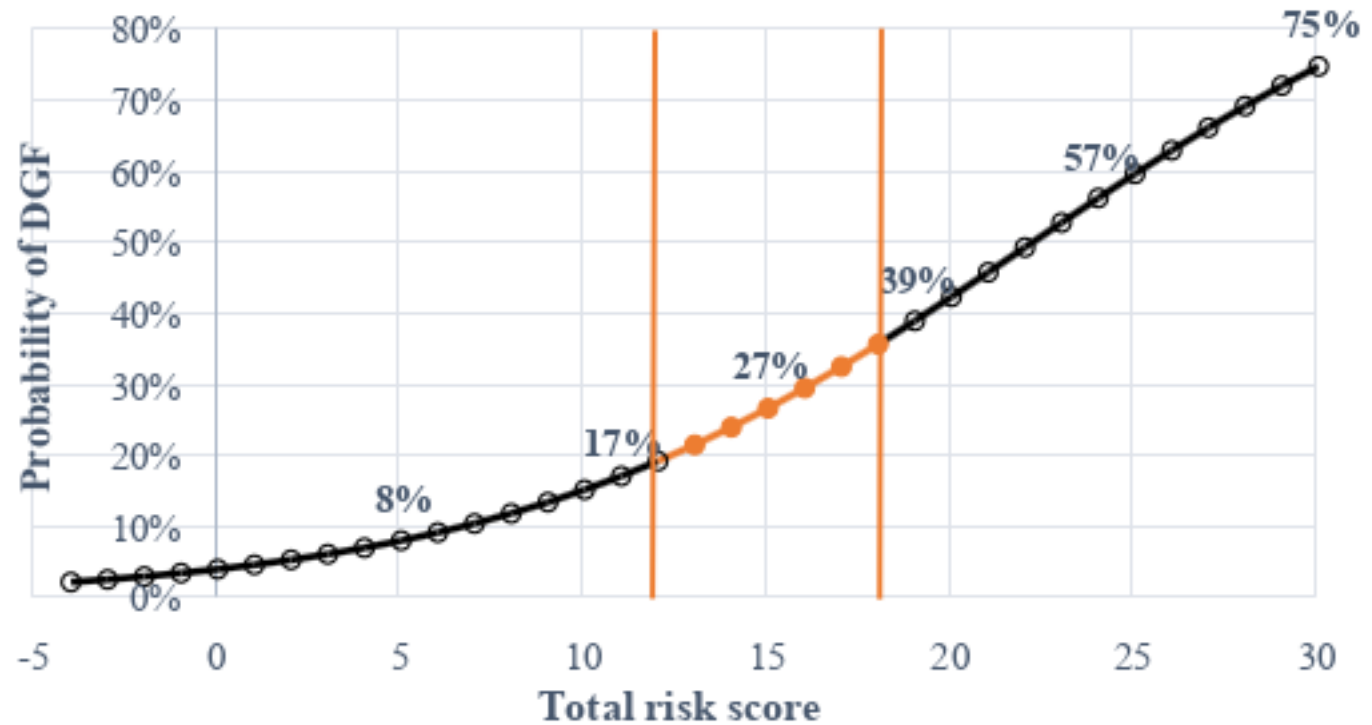
# Score application for DGF prediction

Risk factor	Addition to risk score					Risk score	
<i>Donor BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30		3	
	-2	0	+3	+6			
<i>Recipient BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30		2	
	-2	0	+2	+3			
<i>Recipient CVM IgG</i>	Negative			Positive		5	
	0			+5			
<i>Number of HLA-DR mismatches</i>	Less than two			Two		0	
	0			+6			
<i>Dialysis vintage in years</i>	< 1	1 to < 3	3 to < 4	4 to < 6	>= 6	3	
	0	+1	+2	+3	+5		
<i>Cold ischaemia time in hours</i>	< 2	2 to < 6	6 to < 10	10 to < 14	14 to < 18	>= 18	3
	0	+1	+2	+3	+4	+5	
<b>Total score without histological assessment</b>	- 4 to 11 points		12 to 18 points (18% to 36% risk)		19 to 30 points	16	
	Low risk		Medium risk: histological assessment advised		Increased risk		
<i>Number of glomeruli</i>	< 20	20 to < 30	30 to < 40	>= 40		-2	
	0	-2	-4	-7			
<i>Banff cv</i>	cv0, cv1 or cv2			cv3			
	0			+5			
	<b>Total score =</b>						



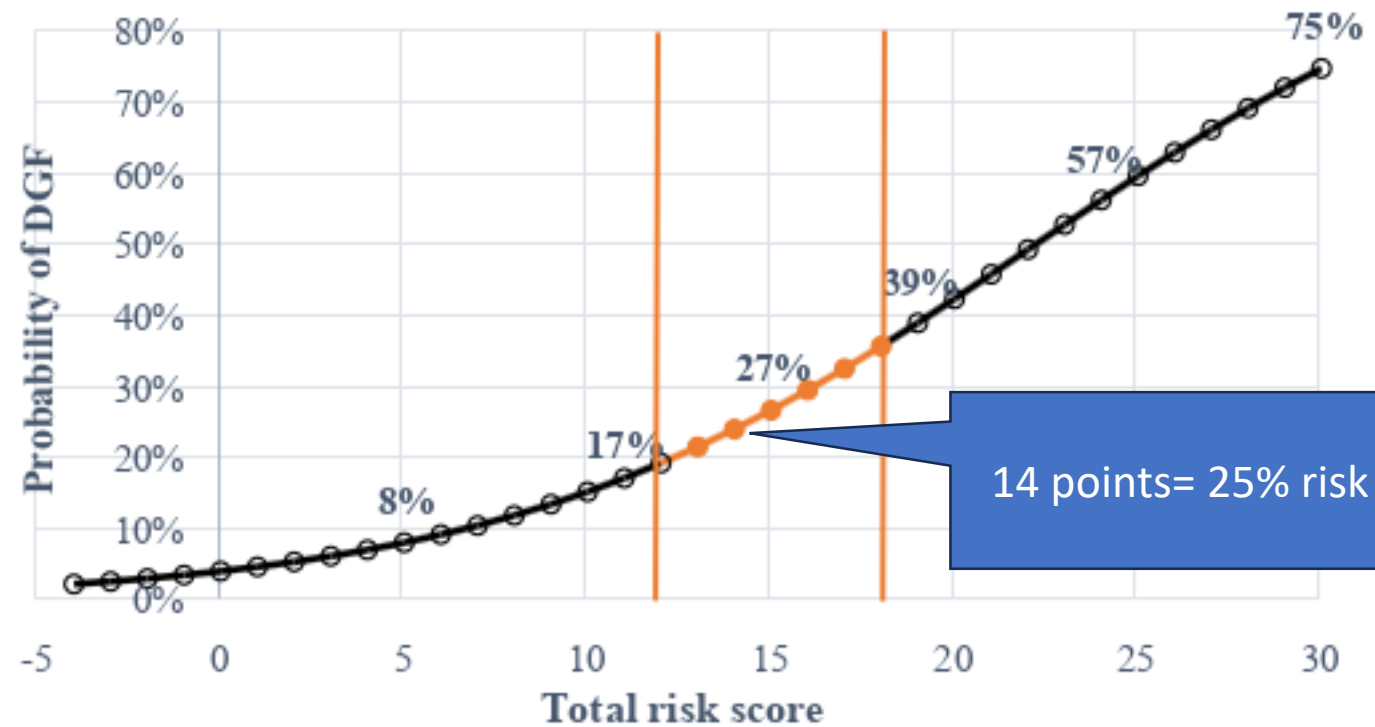
# Score application for DGF prediction

Risk factor	Addition to risk score					Risk score	
<i>Donor BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30		3	
	-2	0	+3	+6			
<i>Recipient BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30		2	
	-2	0	+2	+3			
<i>Recipient CVM IgG</i>	Negative			Positive		5	
	0			+5			
<i>Number of HLA-DR mismatches</i>	Less than two			Two		0	
	0			+6			
<i>Dialysis vintage in years</i>	< 1	1 to < 3	3 to < 4	4 to < 6	>= 6	3	
	0	+1	+2	+3	+5		
<i>Cold ischaemia time in hours</i>	< 2	2 to < 6	6 to < 10	10 to < 14	14 to < 18	>= 18	3
	0	+1	+2	+3	+4	+5	
<b>Total score without histological assessment</b>	- 4 to 11 points		12 to 18 points (18% to 36% risk)		19 to 30 points	16	
	Low risk		Medium risk: histological assessment advised		Increased risk		
<i>Number of glomeruli</i>	< 20		20 to < 30	30 to < 40	>= 40	-2	
	0		+2	-4	-7		
<i>Banff cv</i>	cv0, cv1 or cv2			cv3		0	
	0			+5			
	<b>Total score =</b>					<b>14</b>	



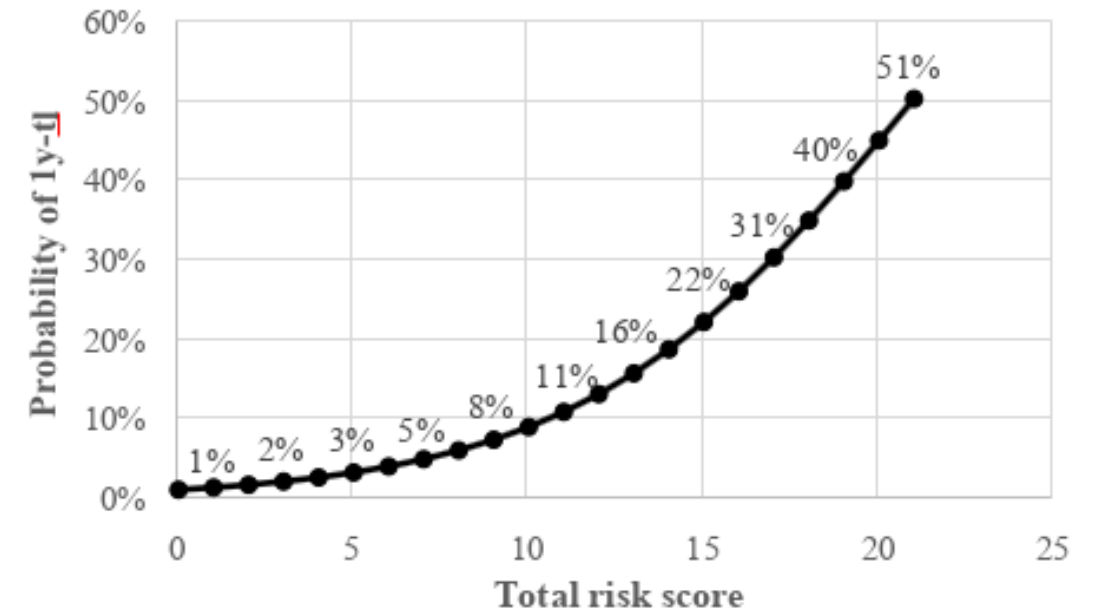
# Score application for DGF prediction

Risk factor	Addition to risk score					Risk score	
<i>Donor BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30		3	
	-2	0	+3	+6			
<i>Recipient BMI (kg/m<sup>2</sup>)</i>	< 18.5	18.5 to < 25	25 to < 30	>= 30		2	
	-2	0	+2	+3			
<i>Recipient CVM IgG</i>	Negative			Positive		5	
	0			+5			
<i>Number of HLA-DR mismatches</i>	Less than two			Two		0	
	0			+6			
<i>Dialysis vintage in years</i>	< 1	1 to < 3	3 to < 4	4 to < 6	>= 6	3	
	0	+1	+2	+3	+5		
<i>Cold ischaemia time in hours</i>	< 2	2 to < 6	6 to < 10	10 to < 14	14 to < 18	>= 18	3
	0	+1	+2	+3	+4	+5	
<b>Total score without histological assessment</b>	- 4 to 11 points		12 to 18 points (18% to 36% risk)		19 to 30 points	16	
	Low risk		Medium risk: histological assessment advised		Increased risk		
<i>Number of glomeruli</i>	< 20		20 to < 30	30 to < 40	>= 40	-2	
	0		2	-4	-7		
<i>Banff cv</i>	cv0, cv1 or cv2			cv3		0	
	0			+5			
	<b>Total score =</b>					<b>14</b>	



# Score application for 1y-tl prediction

Risk factor	Addition to risk score						Risk score
	<i>Donor age in years</i>	< 30	30 to < 40	40 to < 50	50 to < 60	>= 60	
	0	+1	+3	+4	+6		
<i>Sum of HLA-A, -B and -DR mismatches</i>	0	1	2	3	4 or 5	6	
	0	+1	+2	+3	+4	+5	
<i>Cold ischaemia time in hours</i>	< 2	2 to < 6	6 to < 10	10 to < 14	14 to < 18	>= 18	
	0	+1	+2	+3	+4	+5	
<b>Total score without histological assessment</b>							
<i>Banff ct</i>	ct0 or ct1			ct2 or ct3			
	0			+6			
	<b>Total score =</b>						



# Conclusion

- Our flexible, simple scores with optional histopathology are not inferior to established scores for use in ET
- Limited role for conventional histopathology
- Modular, updateable scores are ideal suited to accommodate e.g. DCD, pump perfusion and to different environments
- Validation/adaptation on/to external datasets (Italy; UK? US?) desirable
- Machine learning for extraction of histopathology information?

# Thank you!

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