



LVAD therapy as destination therapy in the centre of europe

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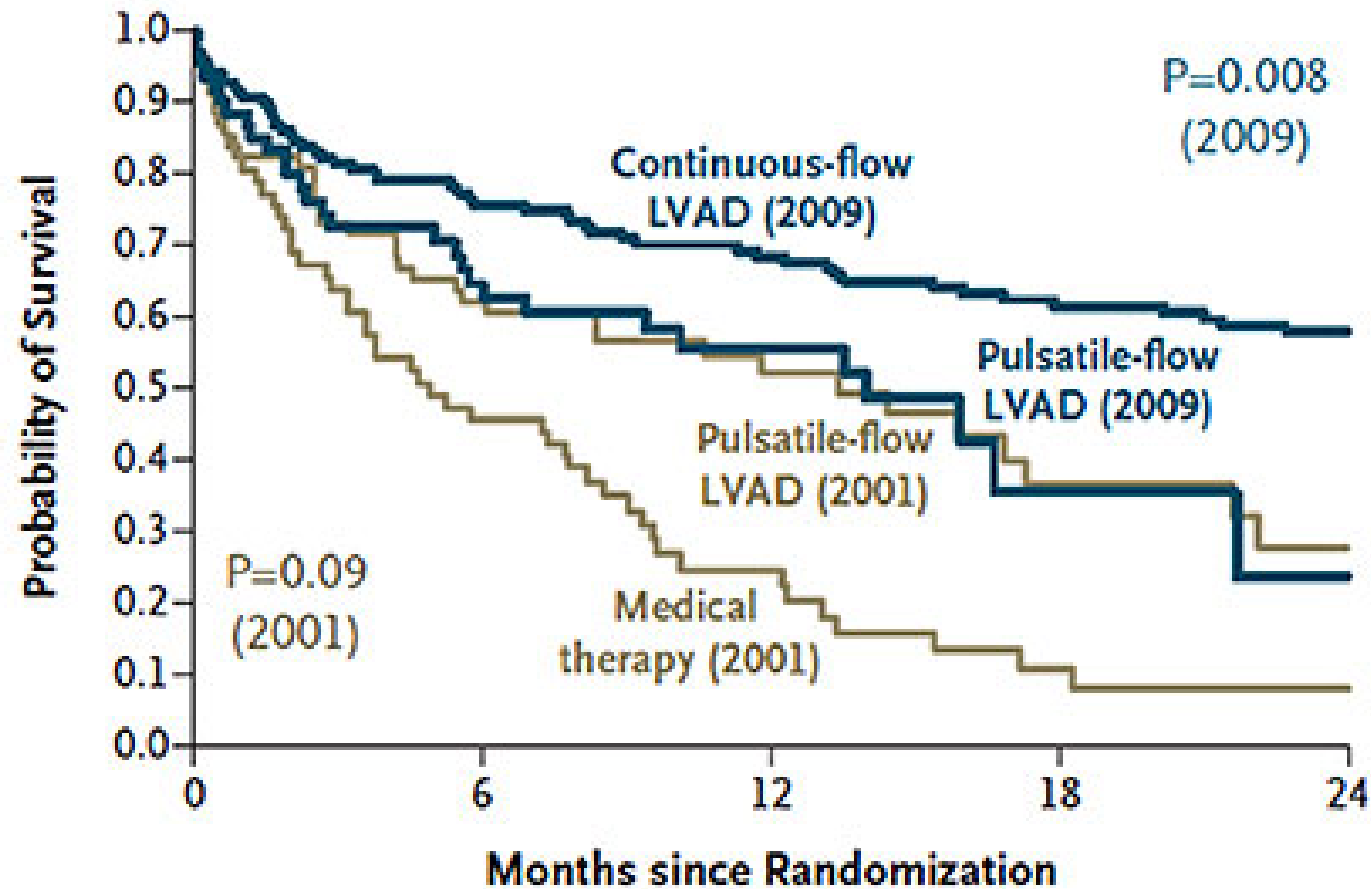


Department of
Health Policy

“LVAD AS DESTINATION THERAPY IN BELGIUM: UNMET NEEDS AND POLITICAL BIAS”

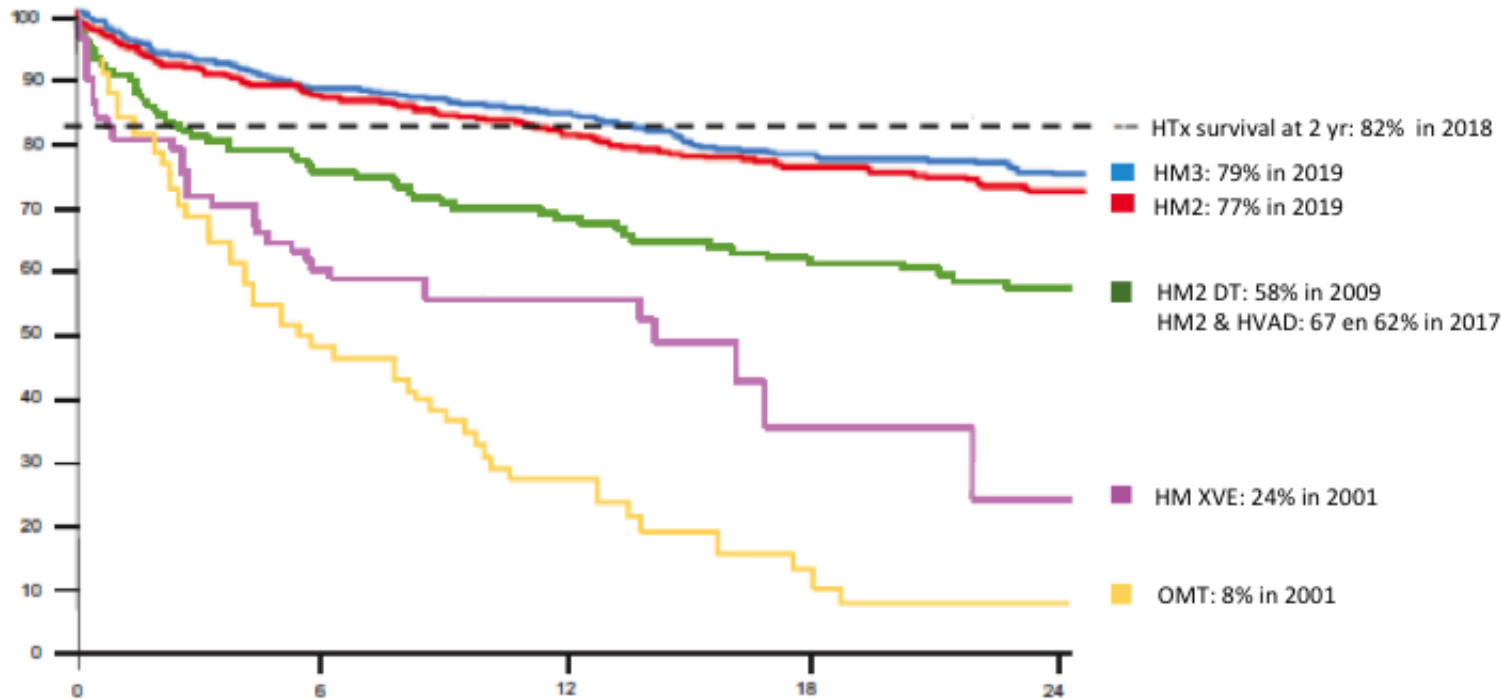


1. LVAD as disruptive HF treatment



Fang N Engl J Med 2009

1. LVAD as disruptive HF treatment



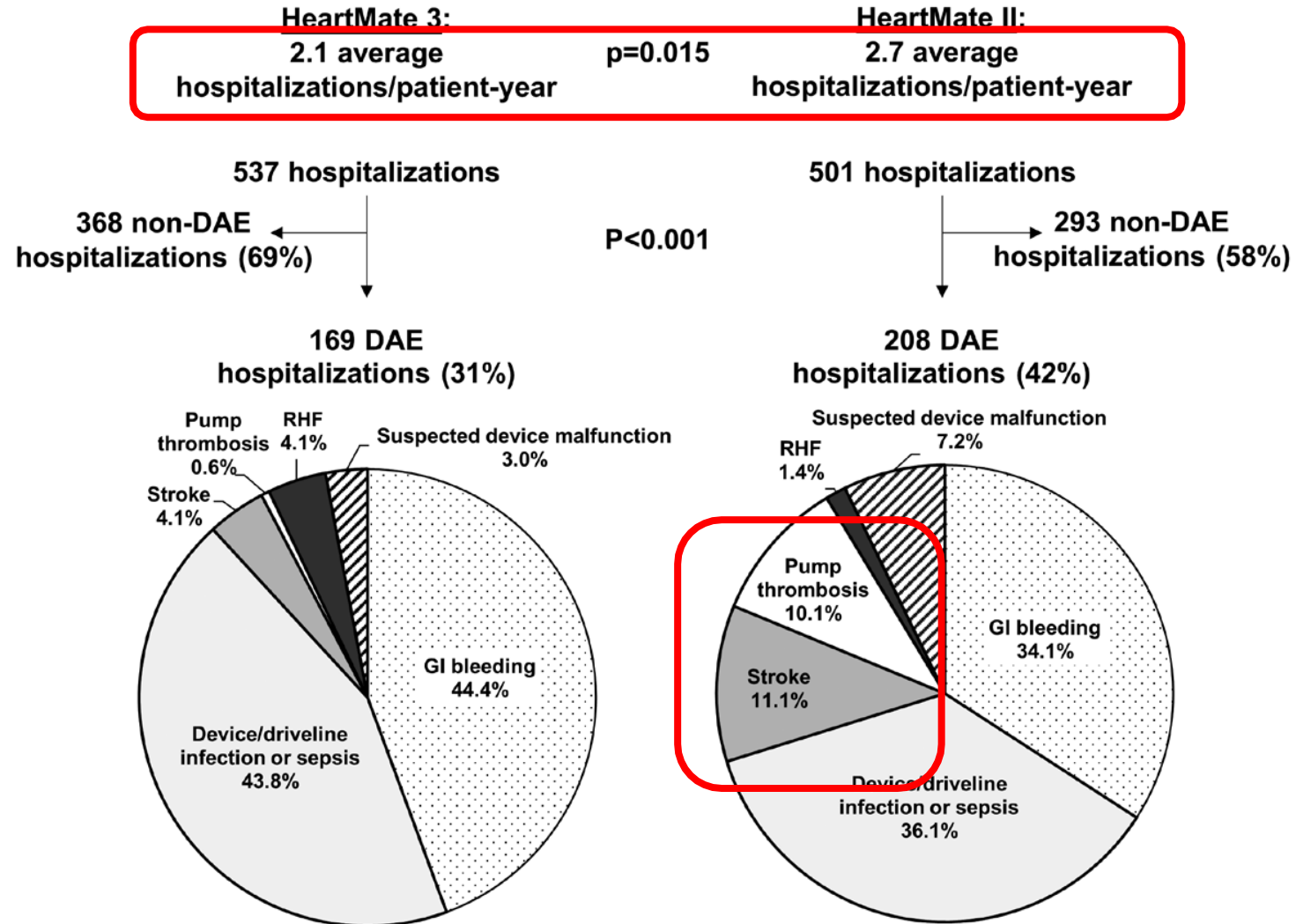
- Kaplan-Meier curves of survival after LVAD implantation according to landmark randomised controlled trials. Survival probability after 2 years was retrieved from the latest available publication of the International Society of Heart Lung Transplantation (Khush KK et al. J Heart Lung Transplant. 2018;37:1155-1166). The Kaplan Meier curve is adapted from Sidhu K et al. after written permission from the corresponding author (Mehra MR).

References;

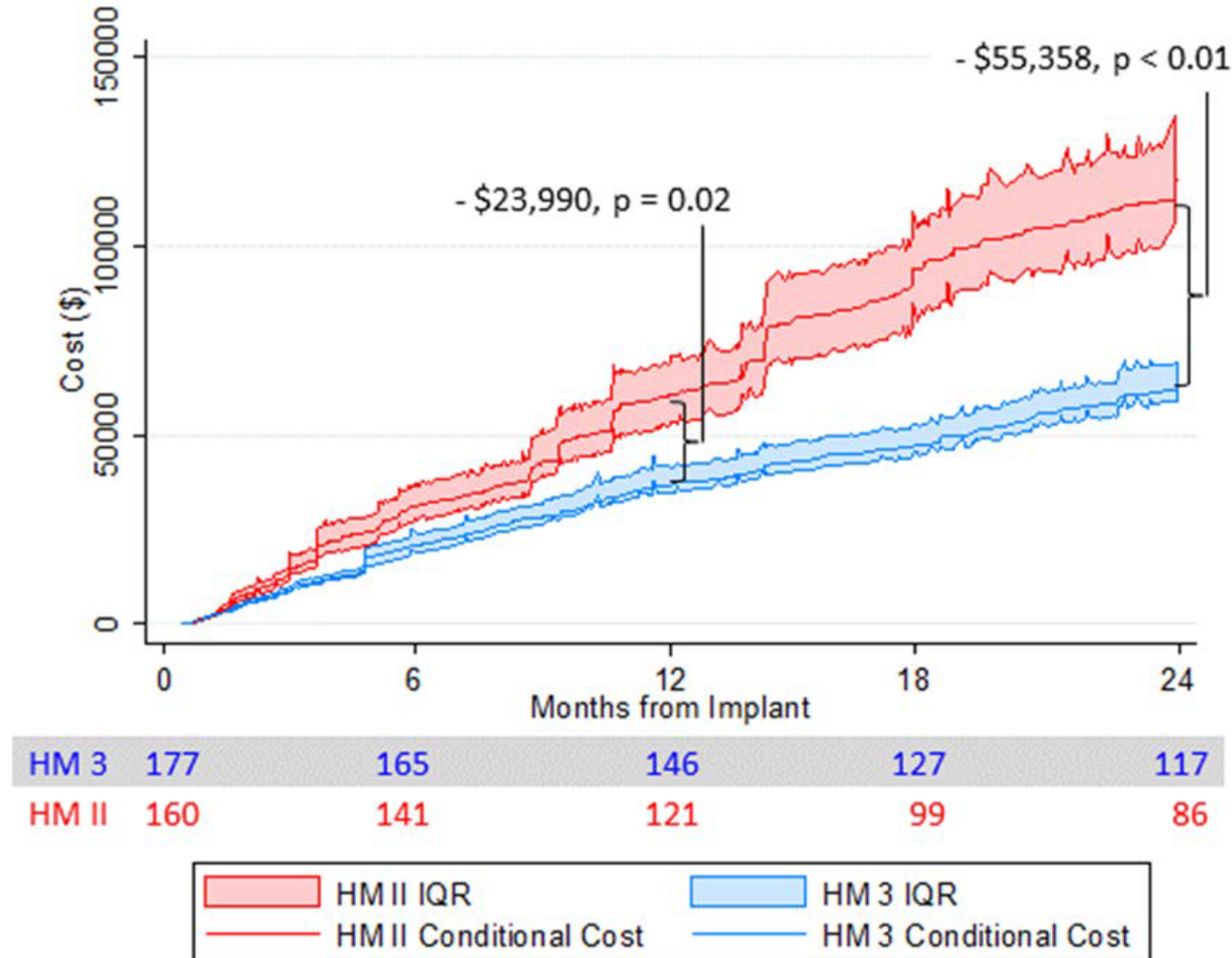
- Rose EA et al. N Engl J Med. 2001; 345:1435-1443,
- Slaughter MS et al. N Engl J Med. 2009;361:2241-2251,
- Rogers JG et al. N Engl J Med. 2017;376:451-460,
- Mehra MR et al. N Engl J Med. 2019; 380:1618-1627

Year	intervention	Primary outcome	study size	DT (%)	Mean age (y)	Result of primary outcome (%)	2-year survival (%)	ref
2001	OMT vs HeartMateXVE	survival	129	100	68±8,2 66±9,1	8 23	8	1
2009	HeartMateXVE vs HeartMate II	2-year survival free from disabling stroke or device failure	200	100	63±12 62±12	11 46	24 58	2
2017	HVAD vs HeartMate II		446	100	64±11,6 66±10,2	55,4 59,1	60,2 67,6	3
2019	HeartMate II vs HeartMate III		1028	61,4 60,5	59±12 60±12	64,8 76,9	77 79	4

2. Evolution of LVAD complications



3. Evolution of LVAD treatment costs



4. LVAD as destination therapy: ICER

costs of LVAD therapy in Belgium, Germany, the Netherlands and the UK

	Belgium	Germany	The Netherlands	The UK
Health care institution	KCE		Zorginstituut Nederland	NHS
Year of publication	2016		2015	2017
ICER (euro/QALY)	83 000	Not calculated	107 600	91 000 £
ICER threshold	54 000		/ ¹	20 – 30 000 £

¹: no strict threshold was stated, judging that for expensive treatments (>30 000 euro/QALY) more stringent evaluation, evidence, benefits and total budget impact are needed.

4. Demographic, health care and end-stage HF policies in the centre of Europe (2019)

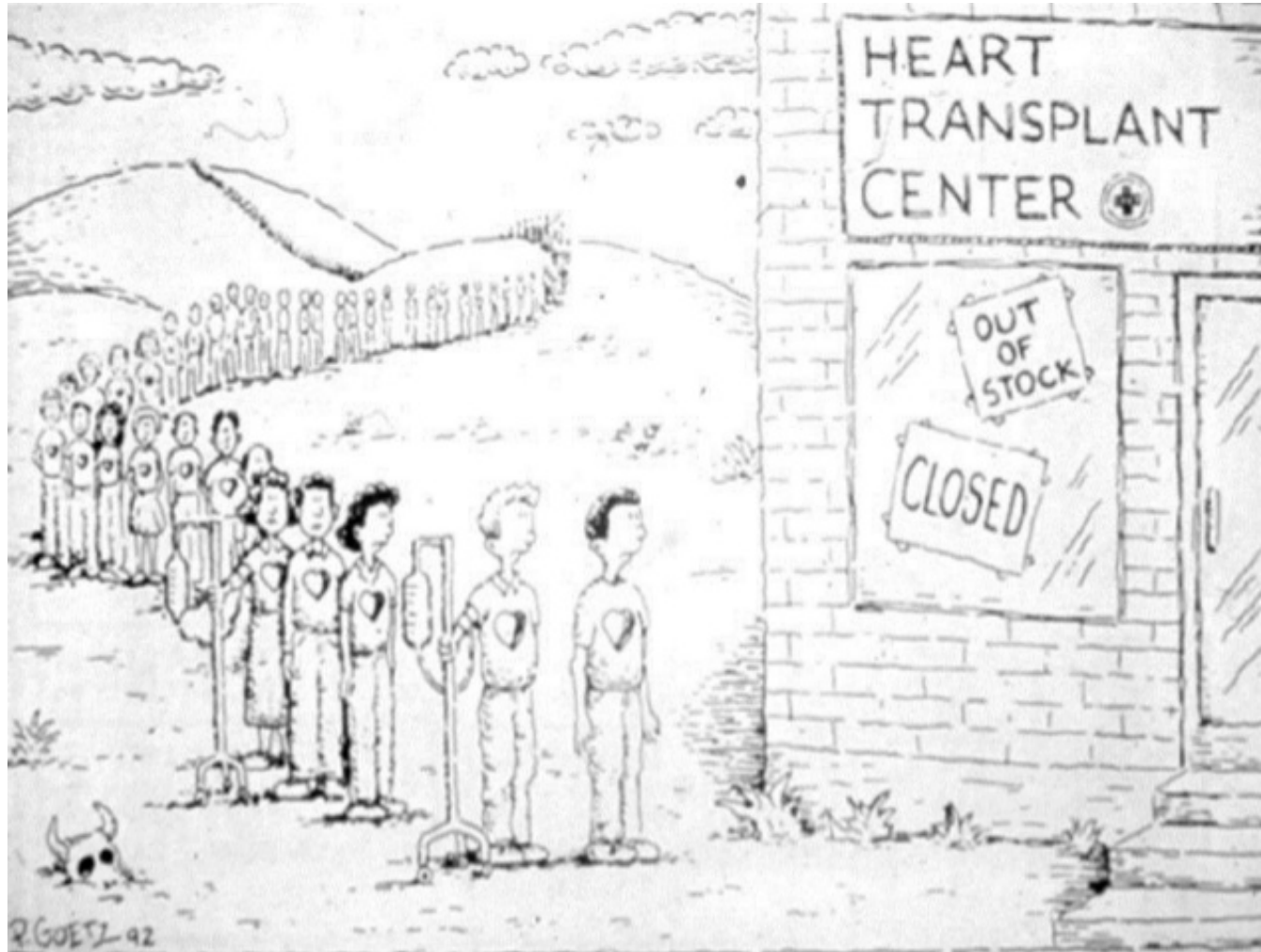


	Belgium	Germany	The Netherlands	UK
Inhabitants (million)	11,35	82,79	17,08	66,04
Life expectancy (y)	81,1	80,8	81,4	80,4
Health care expenditure (% GDP) ¹	10,04	11,14	10,36	9,76
Health care budget per capita (\$)¹	4149	4869	4742	3958
Health care system	Bismarck	Bismarck	Bismarck	Beveridge
Organ transplant organisation	Eurotransplant	Eurotransplant	Eurotransplant	NHS blood and transplant
Default organ donation legislation	opt out	opt in	opt in*	opt in*
LVAD as destination therapy	no	yes	yes	no

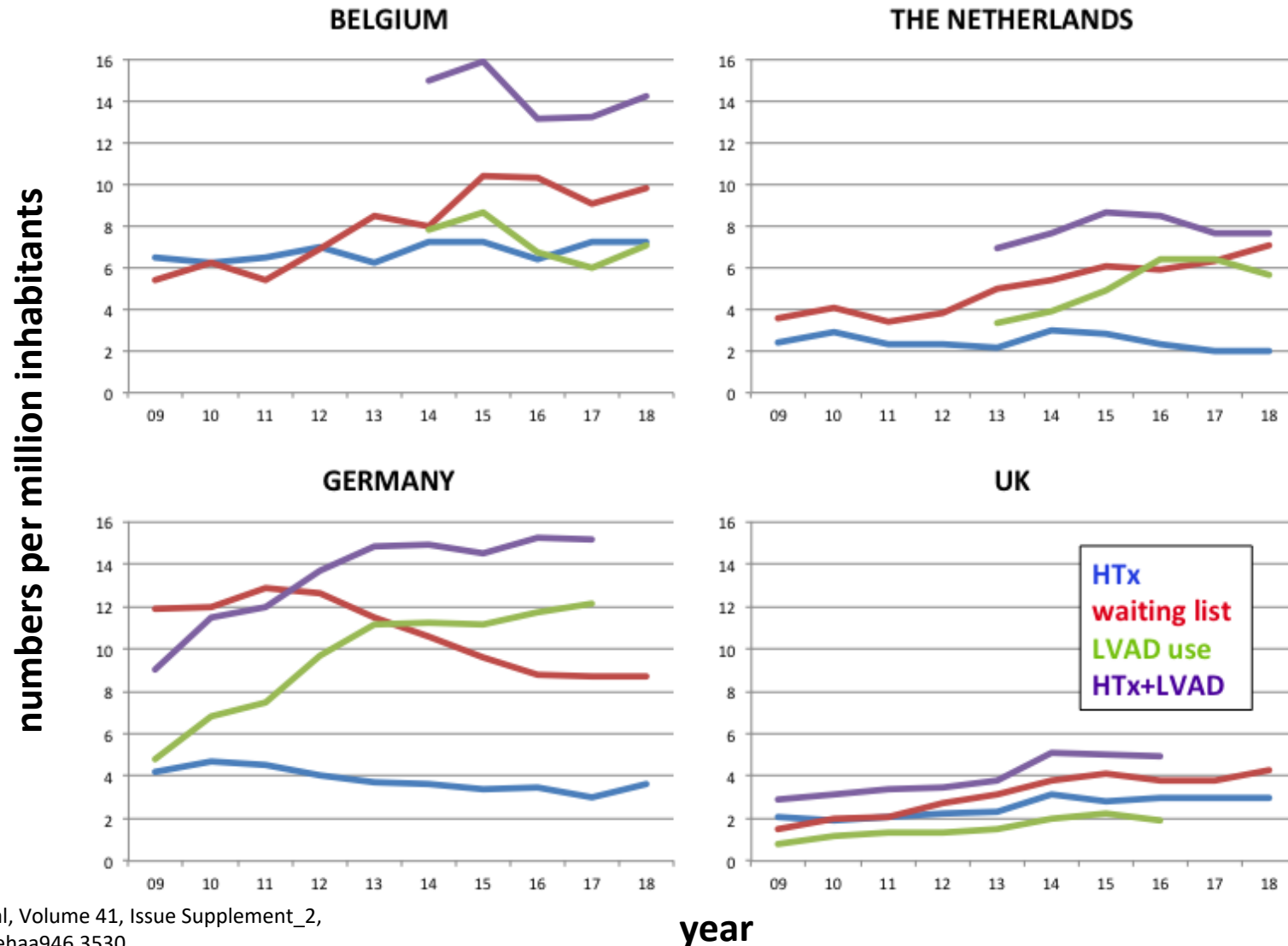
law are voted and changed to opt out as of 2020, yet the impact of this change is legislation has to be evaluated in the coming yers. Off note, Whales has already introduced an opt out legislation.

¹: source: World Bank, Health care expenditure. Latest available data 2016 for all countries

4. Assessing unmet needs in HF



6. End-stage HF treatment utility



HTx: heart transplant
LVAD: left ventricular assist device

7. LVAD as destination therapy

- Although high transplant rates, there is an increasing mismatch between available organs and patients on the waiting list
- LVAD use is high, despite “non-DT” policy – suggesting ‘de facto’ use of LVADs in DT
- The need of LVAD as DT should be assessed in combination with transplant rates; this number is estimated at **14.9 per milion inhabitants**
- A limited additional number of LVADs is needed to cover the needs of the Belgian population (calculated at **+/-8 per year**)
- health care budget impact of DT use, both absolute and relative, is likely to be significantly lower than calculated by the KCE in 2016
- Health care resource use in other domains has not been evaluated with the same strict criteria as compared to HF – **political bias**



8. Unmet needs in end-stage HF



	Belgium	The Netherlands	The UK
Latest HTx rate (per mln)	7,2	2,0	3,0
Latest combined HTx and LVAD rate (per mln)	14,2	7,7	4,9
Average difference in advanced heart failure therapies compared to Germany (per mln)	0,7	7,2	10,0
Unmet needs in advanced heart failure (in patients per year not receiving advanced heart failure therapies)	8	123	660



