Anti-viral treatment levels among treatment-eligible people living with chronic hepatitis B in Australia: The REACH-B Study

Hajarizadeh B[1], Carson J[1], George J[2], Cowie B[3,4], Davies J[5], Hanson J[1,6], Tu T[2,7], Tran L[4,7], Tu E[1], Erratt A[1], Carter J[1], Allard N[4,8], Monaghan R[1], Mascarenhas L[9], Howard S[10], Nelson R[11], O'Beirne J[12], Wong I[13], Hasan T[13], Martinello M[1,14], Dore G[1,15], Matthews G[1,15], on behalf of the REACH-B Study Group

1. The Kirby Institute, University of New South Wales (UNSW), Sydney; 2. Storr Liver Centre, Westmead Hospital, and The Westmead Institute for Medical Research, University of Sydney, Sydney; 3. Royal Melbourne Hospital, Melbourne; 4. WHO Collaborating Centre for Viral Hepatitis, and the Peter Doherty Institute for Infection and Immunity, Melbourne; 5. Menzies School of Health Research, Darwin; 6. Cairns and Hinterland Hospital and Health Service, and Torres and Cape Hospital and Health Service, Cairns; 7. Hepatitis B Voices Australia, Melbourne; 8. Cohealth, Melbourne; 9. Utopia Refugee and Asylum Seeker Health, Melbourne; 10. Broome Health Campus, WA Country Health Service Kimberley, Broome; 11. The Queen Elizabeth Hospital and Royal Adelaide Hospital, Adelaide; 12. Sunshine Coast University Hospital, Sunshine Coast; 13. Blacktown Mt Druitt Hospital, Sydney; 14. Justice Health and Forensic Mental Health Network NSW, Sydney; 15. St Vincent's Hospital, Sydney

UNSW Kirby Institute

UNSW SYDNEY

Background

- An estimated **205,550 people were living with chronic HBV in Australia** in 2022, among whom **13% were receiving treatment**
- The WHO target for HBV elimination includes treating **80% of the people living with chronic HBV who are eligible for treatment by 2030**.
- Australian representative data on HBV care cascade, including proportion eligible for antiviral therapy is lacking.
- HBV treatment eligibility criteria are highly varied between clinical guidelines

Background: HBV treatment indications

REACH-B

			EASL 2017	AASLD 2018	APASL 2015	WHO 2015	GESA 2022	PBS 2024
HBeAg +	HBV DNA	> 2,000	●	○	○	○	○	○
		> 20,000	○	●	●	●	●	●
	ALT	> 1× ULN	●	○	○	●	●	●
		> 2× ULN	○	●	●	○	○	○
HBeAg -	HBV DNA	**> 2,000**	●	●	●	○	●	●
		> 20,000	○	○	○	●	○	○
	ALT	> 1× ULN	●	○	○	●	●	●
		> 2× ULN	○	●	●	○	○	○
Liver fibrosis			**≥ F2**	**≥ F2**	≥F2 if ALT↑		**≥ F2**	

ALT ULN threshold	Male	40	35	40	30	30	NA
	Female	40	25	40	19	19	NA

Background: HBV treatment indications

REACH-B

WHO and Chinese Medical Association

Regardless of HBeAg status

		CMA 2022	WHO 2024
HBV DNA	Detected	●	○
	> 2,000	○	●
ALT	> 1× ULN	●	●
ALT ULN threshold	Male	30	30
	Female	19	19

WHO recommendation:

Where there is no access to HBV DNA, treatment is recommended in individuals with persistently abnormal ALT levels alone.

In those with chronic HBV and any of the following criteria (regardless of ALT or HBV DNA levels):

Liver fibrosis ≥ F2	●	●	WHO definition of F2: APRI>0.5 or TE>7KPa
Family Hx of HCC or cirrhosis	●	●	
Age >30	●	○	
Comorbidities (e.g. diabetes, MAFLD)	○	●	

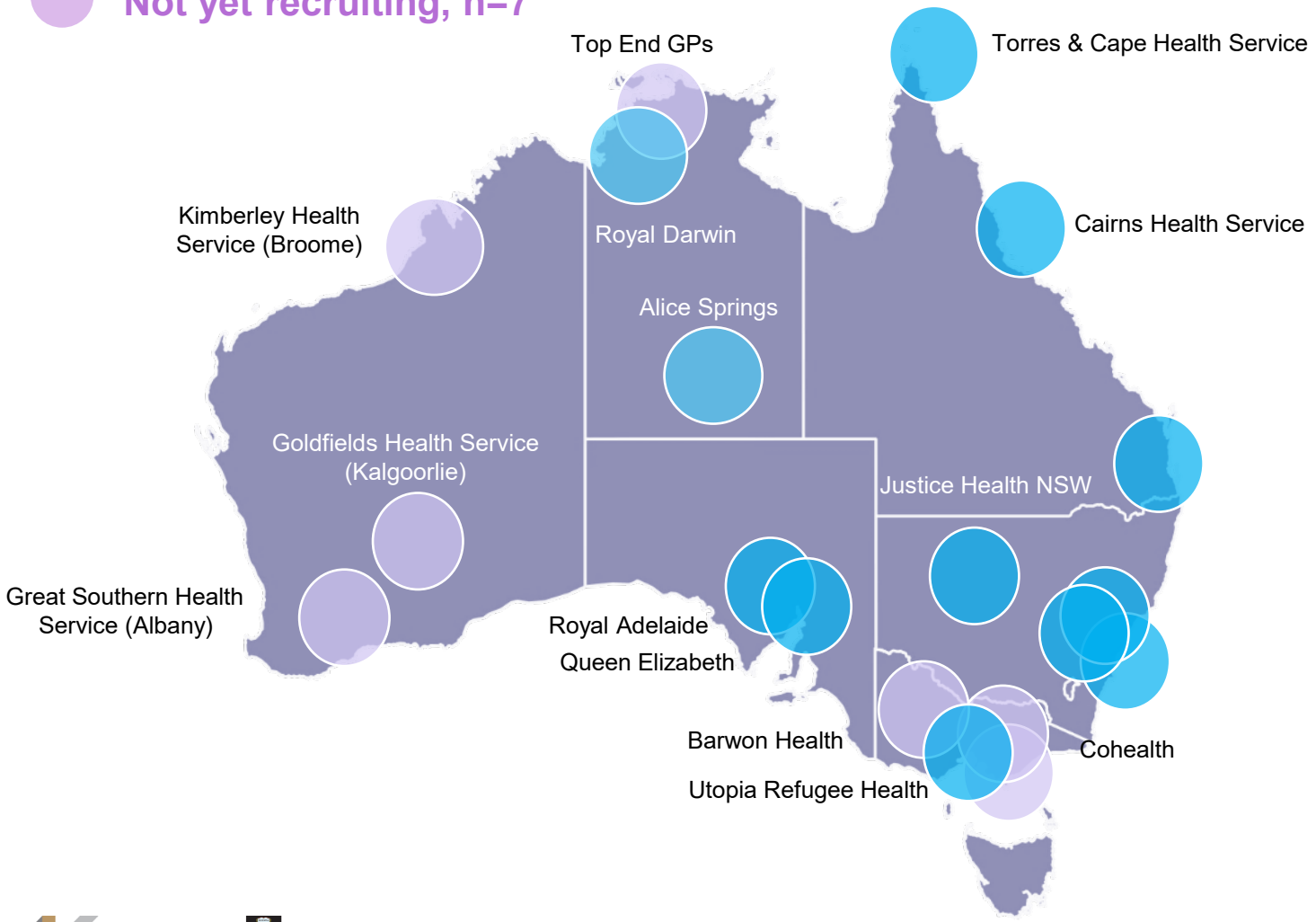
Objectives

- **The Real-world Assessment of people living with Chronic Hepatitis B in Australia (*REACH-B Study*)** is an observational cohort study of people living with chronic HBV in Australia from a national network, including a diverse range of services. Some of the aims of the REACH-B study include:
  - To evaluate socio-demographic and clinical characteristics of people with HBV
  - To evaluate proportion of people with HBV receiving guideline-based HBV clinical care
  - To monitor HBV treatment uptake and adherence
- This analysis evaluated baseline characteristics and receiving guideline-based HBV treatment in the REACH-B study (until July 2024)

Methods

Recruiting, n=12

Not yet recruiting, n=7



- Demographic, clinical care, treatment, and laboratory data are collected from medical records
- Data are collected at enrolment and follow-up visits (at least annually)
- By 08 July 2024:
  - 3,306 participants recruited
  - 1,193 participants completed at least one follow up visit

Results: Baseline characteristics

3,306 participants recruited from ***11 sites*** in 6 jurisdictions:

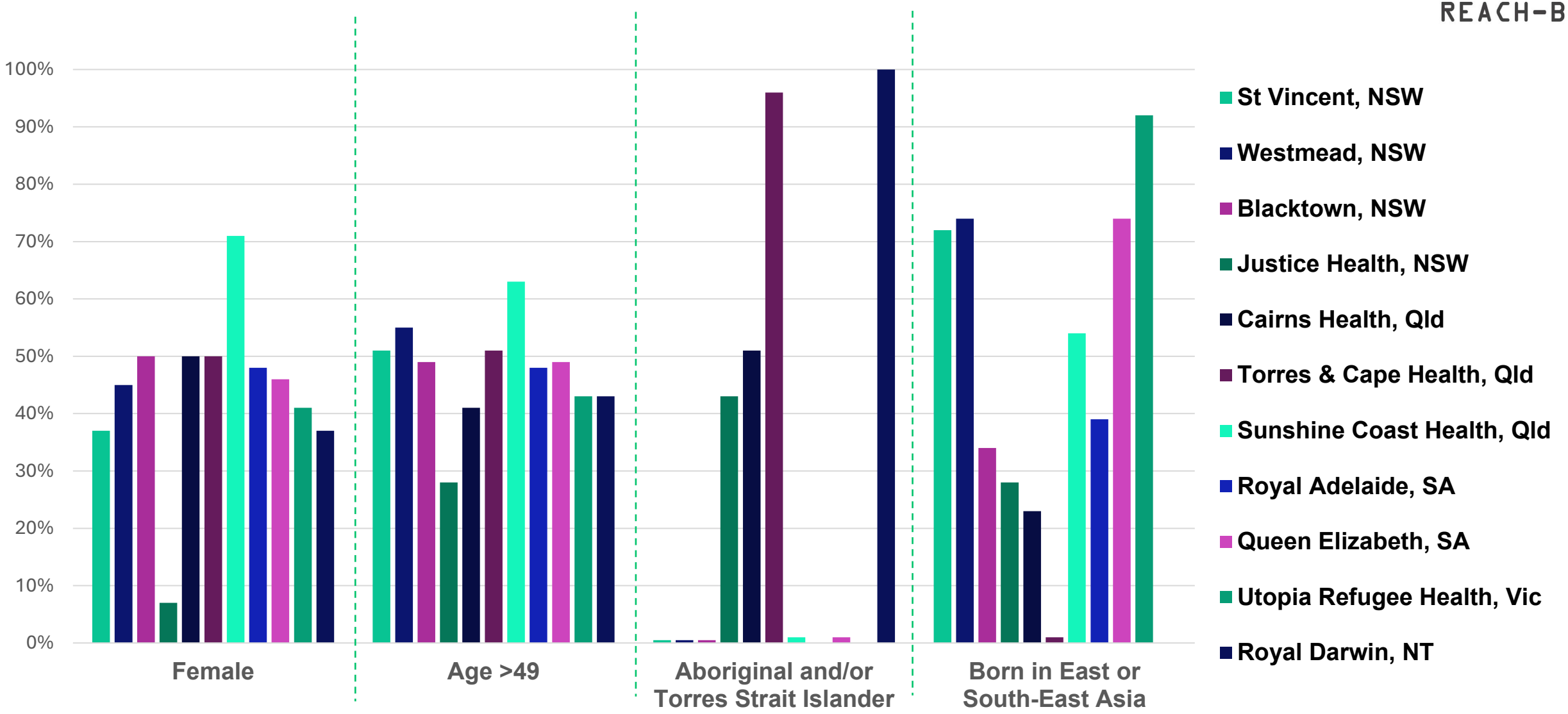
- NSW (4 sites)
- Qld (3 sites)
- SA (2 sites)
- Vic (1 site)
- NT (1 site)

Study sites:

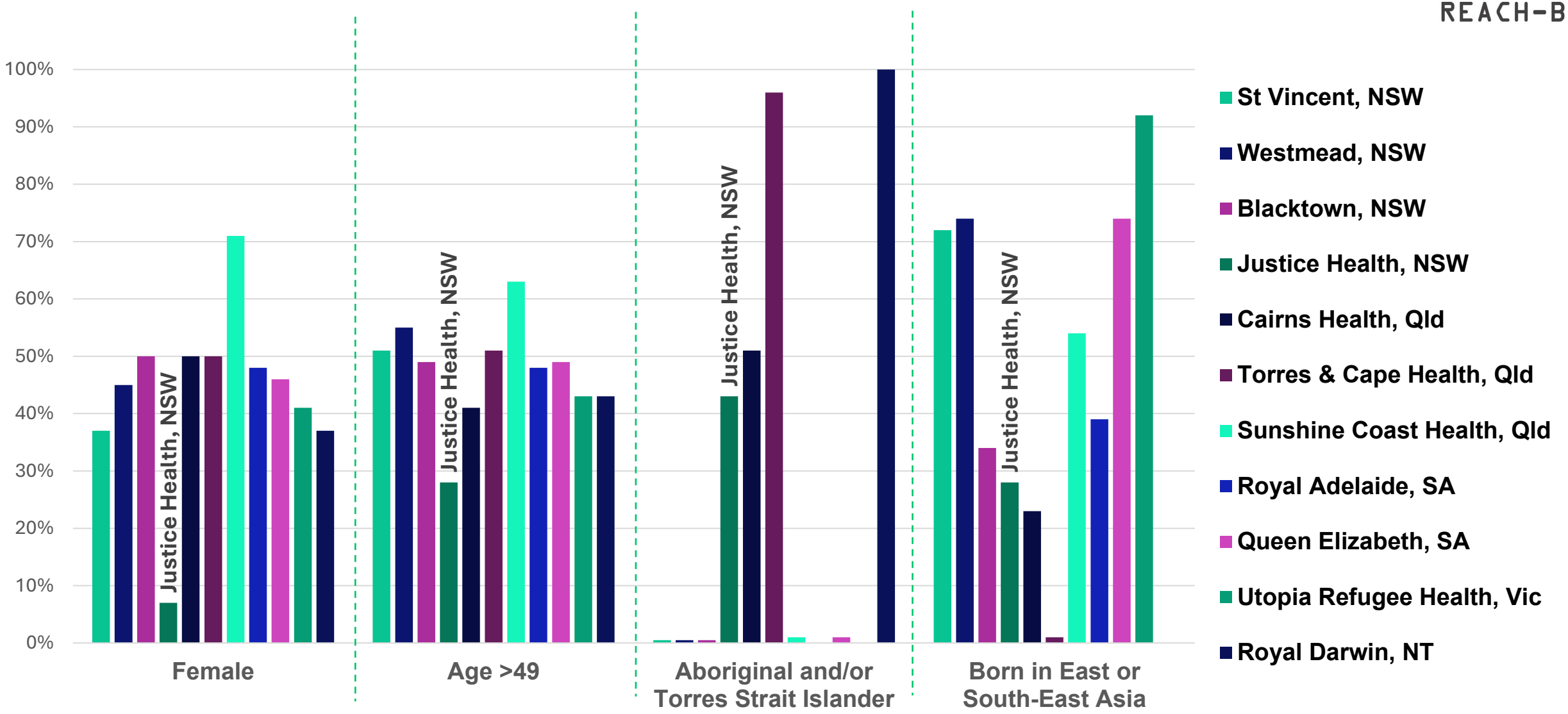
- Viral hepatitis specialist services (n=5), including community outreach (n=4)
- Primary care clinic (n=1)
- Justice Health clinic (n=1)

Baseline characteristics	n=3,306
Female	1463 (44%)
Median age (IQR)	49 (39, 60)
Aboriginal or Torres Strait Islander	918 (28%)
Region of birth	
Aus/NZ/Europe/N America	1138 (34%)
East/South-East Asia	1594 (48%)
South Asia / Middle-East	195 (6%)
Africa	187 (6%)
Pacific	127 (4%)
Other / Unknown	65 (2%)
Most likely mode of HBV infection	
Mother to Child / via family	1657 (50%)
Injecting drug use	84 (3%)
Sexual transmission	35 (1%)
Other	44 (2%)
Unknown	1519 (45%)

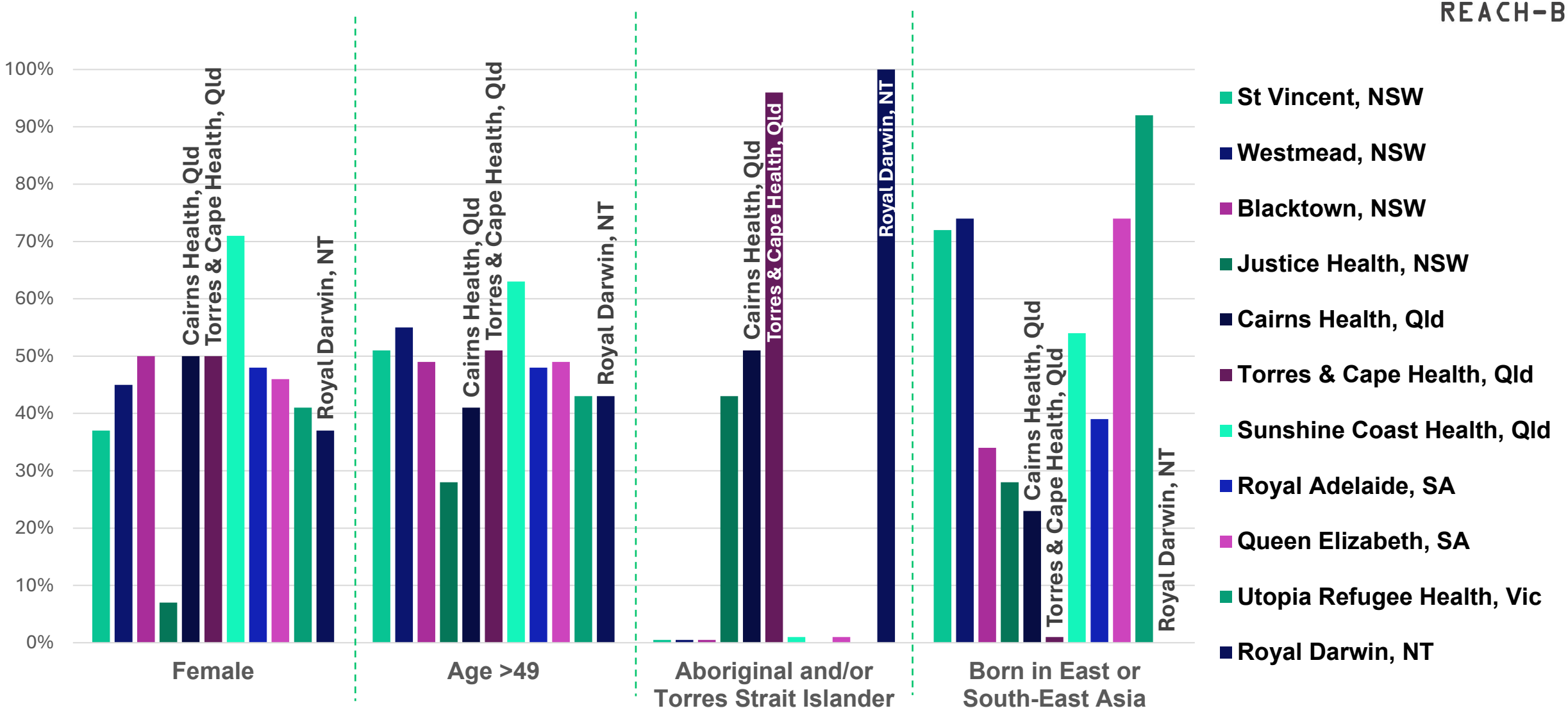
Results: Baseline characteristics



Results: Baseline characteristics



Results: Baseline characteristics



Results: Clinical data

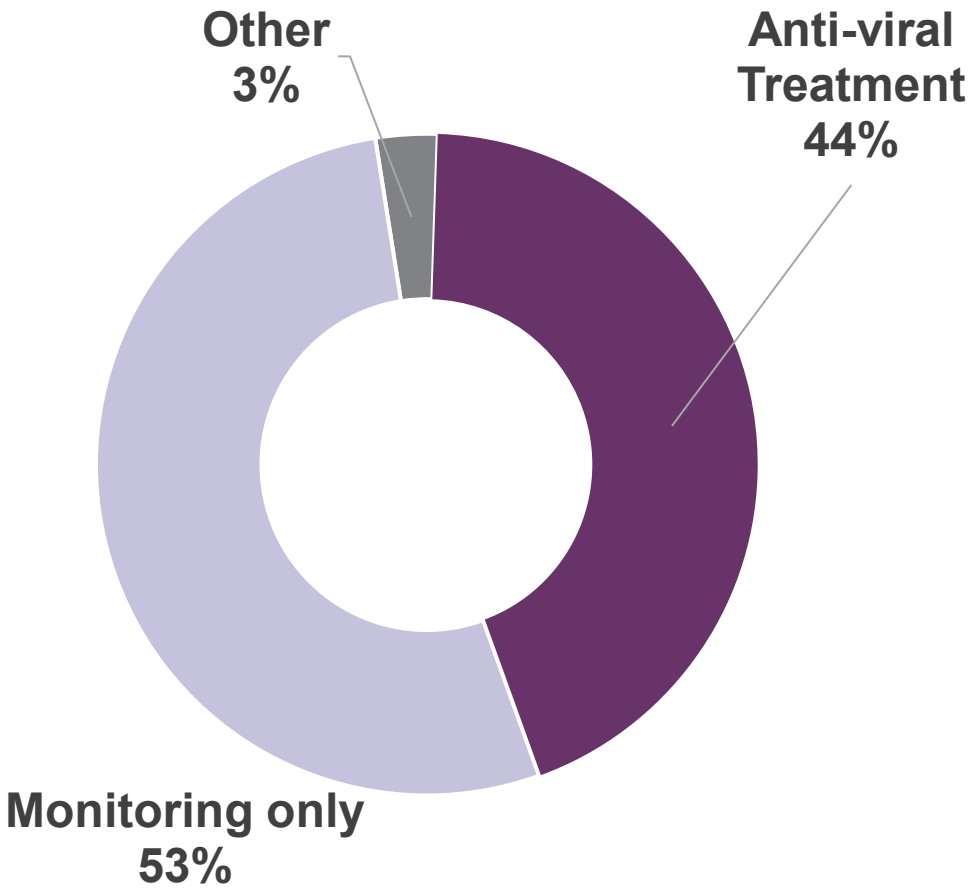
Clinical data	n=2,413
HBeAg positive	346 (14%)
Elevated ALT (F>19, M>30)	1446 (60%)
Cirrhosis	160 (7%)
HBV DNA	
Undetected or <20 IU/mL	1275 (53%)
20-2,000	726 (30%)
2,000-20,000 IU/mL	214 (9%)
>20,000 IU/mL	198 (8%)
HIV co-infection	32 (1%)
HDV co-infection	
HDV Ab negative	822 (34%)
HDV Ab and RNA positive	21 (1%)
HDV Ab positive / RNA not available	28 (1%)
HDV Ab and RNA not available	*1542 (64%)*

2,413 participants

with available data on:
HBV DNA; ALT; HBV clinical management

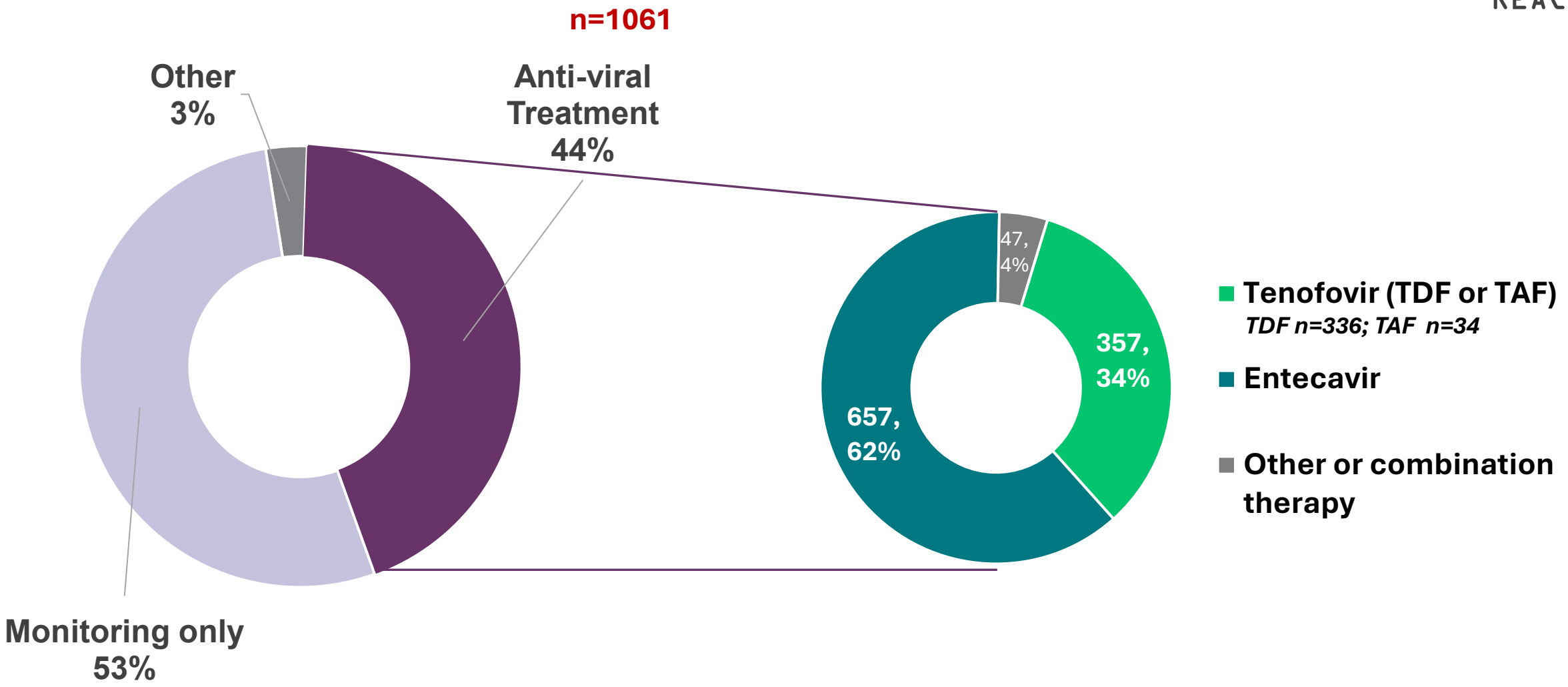
ALT ↑ *F>19, M>30*	ALT ↑ *F>25, M>35*	ALT ↑ *F/M >40*
55%	39%	21%
61%	44%	23%
64%	46%	29%
83%	71%	48%

Results: Clinical data

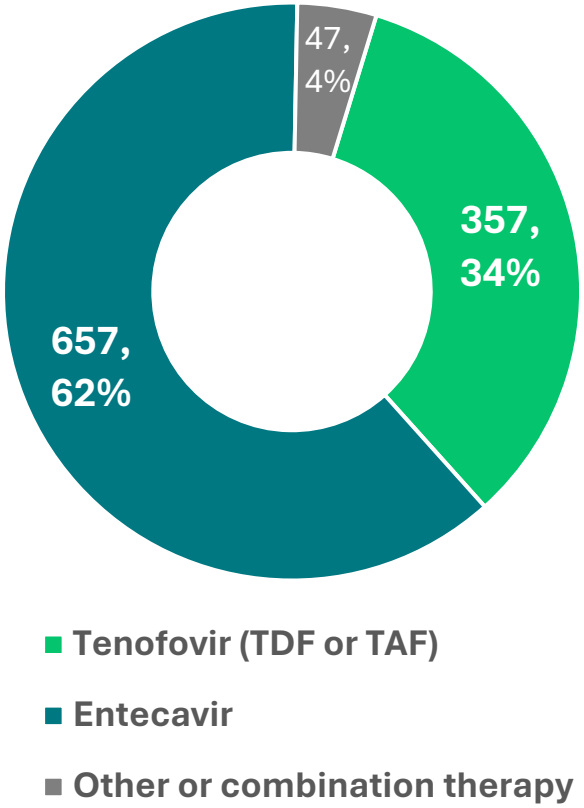


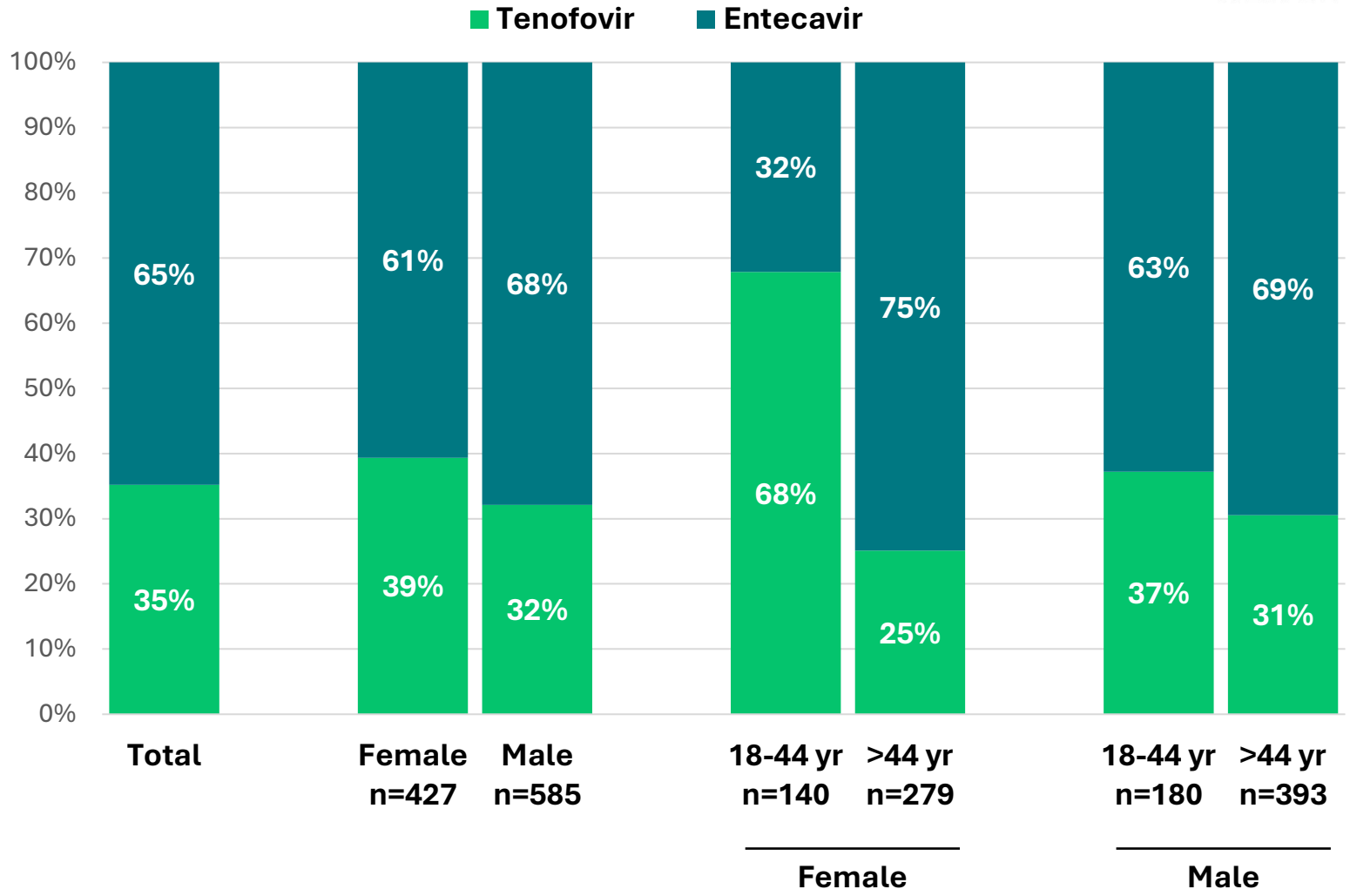
	Monitoring n=1,279	Treatment n=1,061
HBeAg positive	108 (8%)	224 (21%)
Elevated ALT (F>19, M>30)	764 (60%)	633 (60%)
Cirrhosis	21 (2%)	136 (13)
HBV DNA Undetected or <20 IU/mL 20-2,000 2,000-20,000 IU/mL >20,000 IU/mL	 375 (29%) 609 (48%) 174 (14%) 121 (10%)	 881 (83%) 91 (9%) 31 (3%) 58 (5%)
HIV co-infection	4 (<1%)	28 (3%)

Results: Clinical data



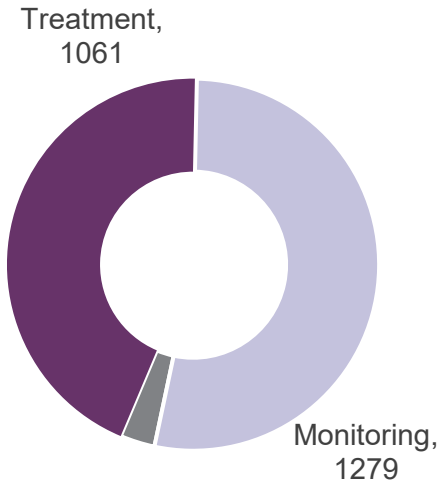
Results: Clinical data

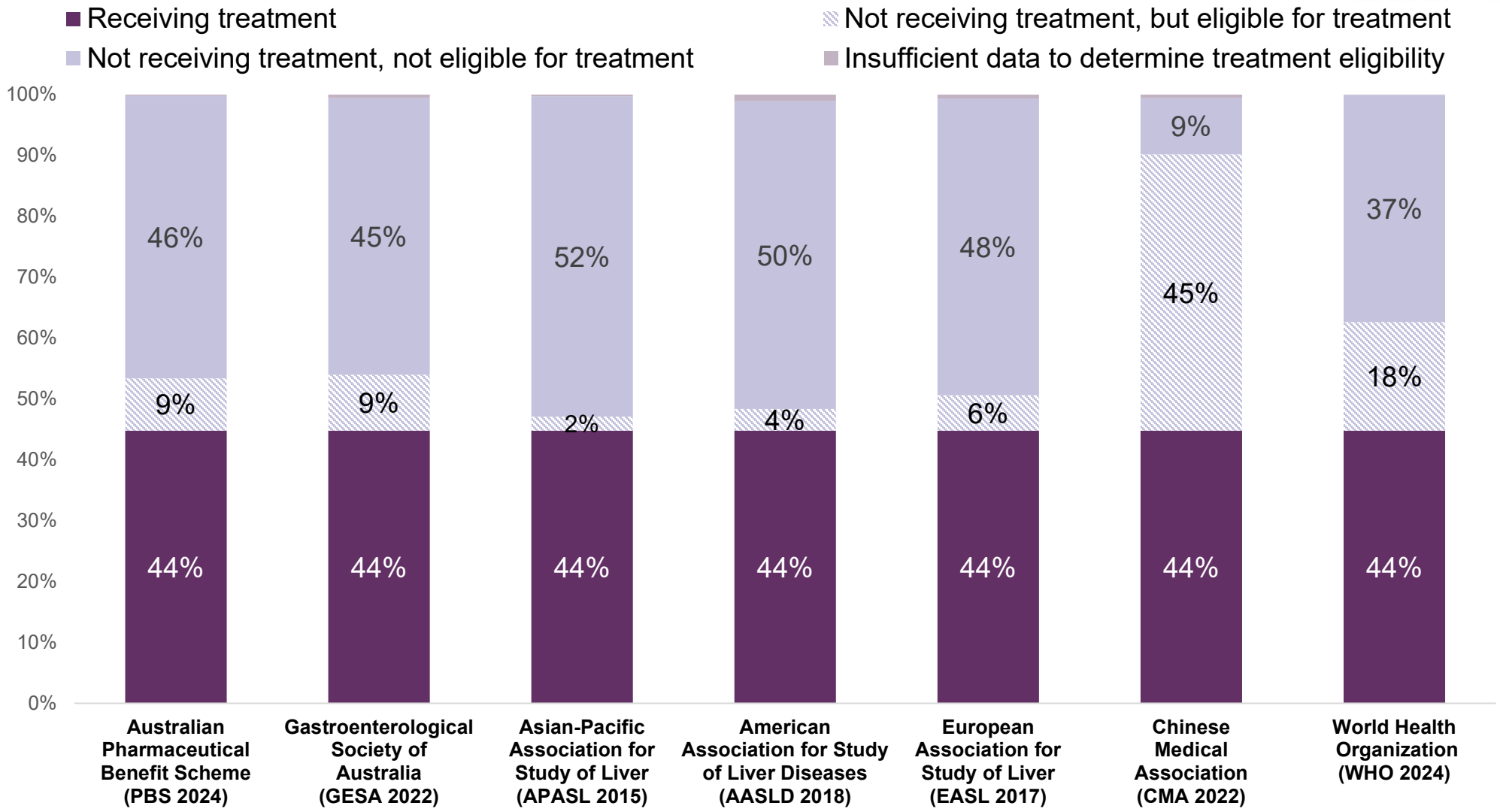




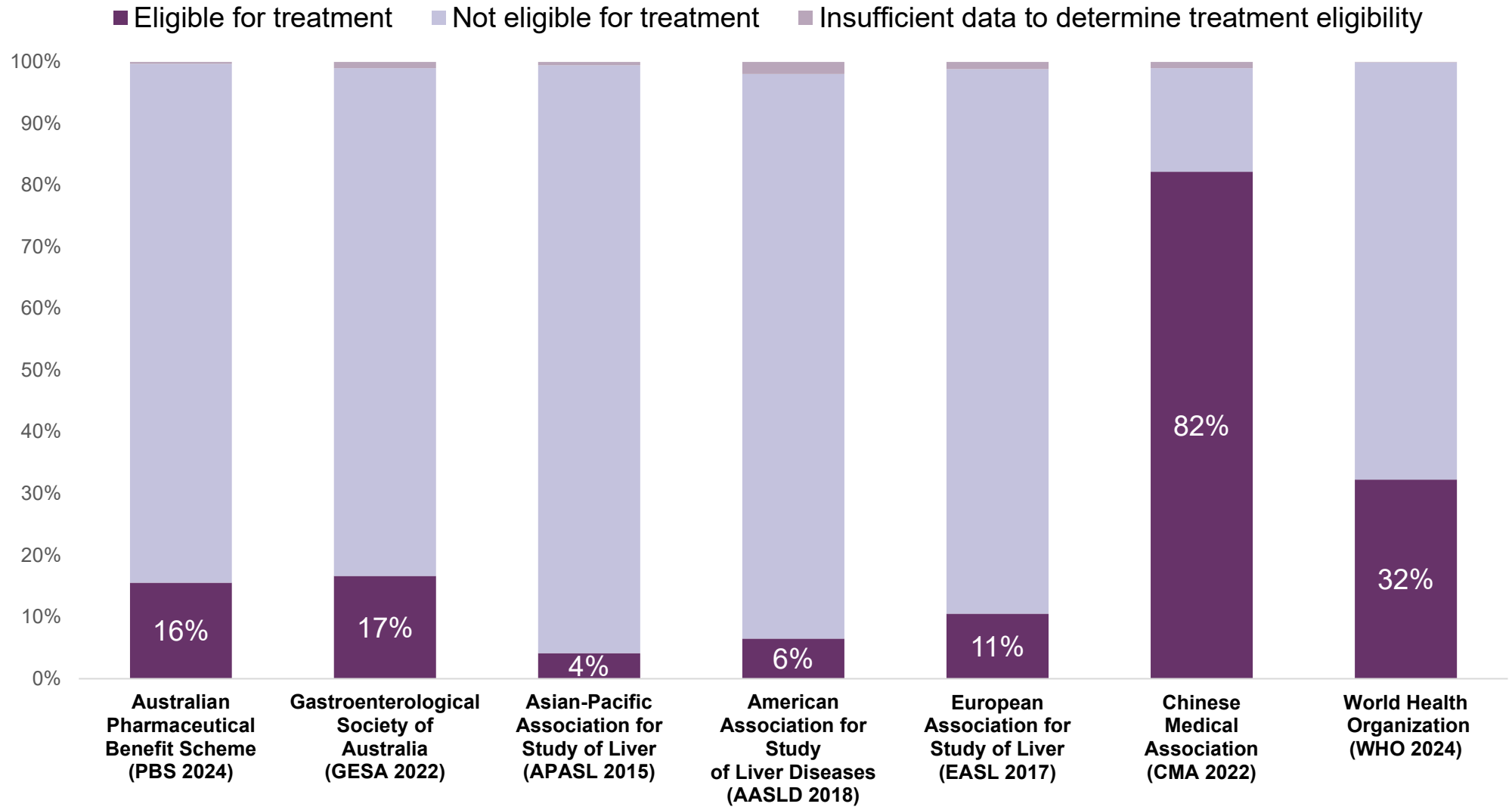
Higher proportion of Tenofovir therapy in women in child-bearing age (18-44 years) could be explained by Tenofovir being the first line treatment in pregnancy.

Results: HBV treatment indication



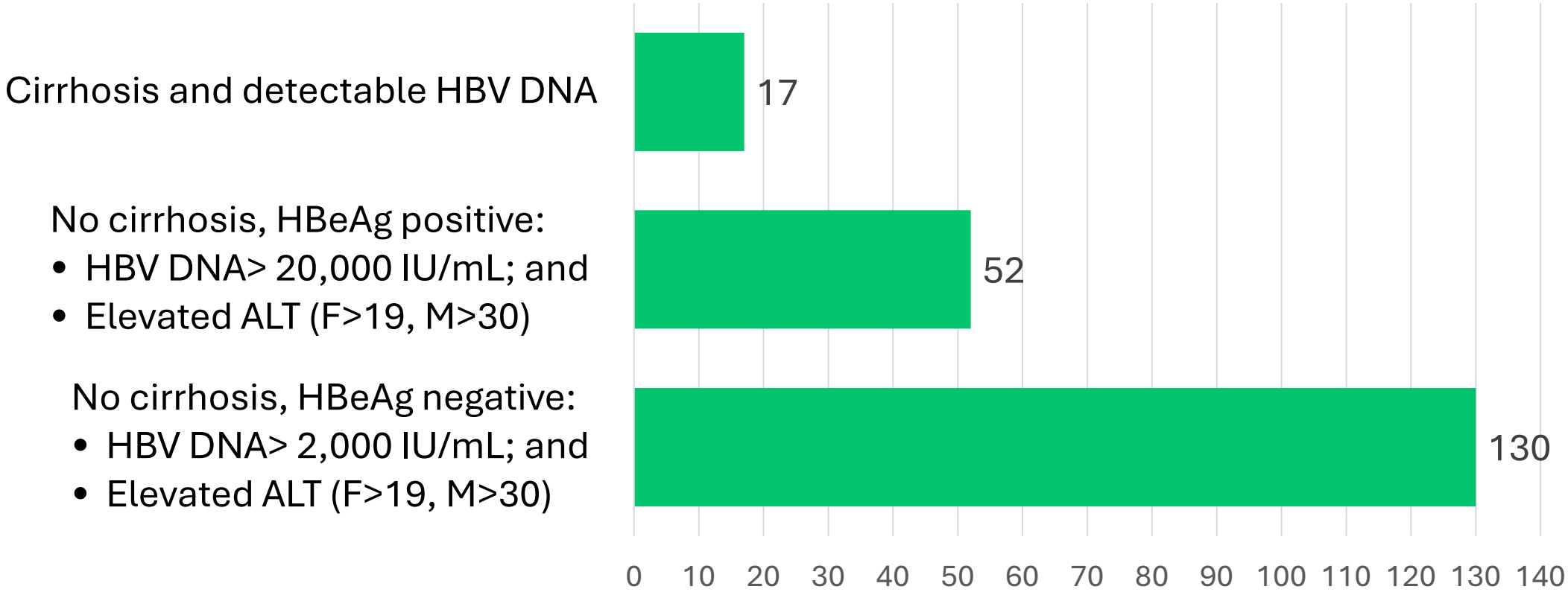


Results: HBV treatment indication



Results: Eligible but not on treatment (PBS 2024)

199 participants who were eligible for treatment based on PBS criteria were not initiated on treatment at the time of data collection



Results: Eligible but not on treatment (PBS 2024)

	Cirrhosis n=17	No cirrhosis, HBeAg+ n=52	No cirrhosis, HBeAg- n=130
Female	9 (53%)	31 (60%)	67 (52%)
Median age (IQR)	58 (50, 62)	38 (25, 46)	46 (35, 57)
HBV DNA			
Detected, <20 IU/mL	6 (35%)	0	0
20-2,000	8 (47%)	0	0
2,000-20,000 IU/mL	1 (6%)	0	94 (72%)
>20,000 IU/mL	2 (12%)	52 (100%)	36 (28%)
Median ALT (IQR)	29 (21, 44)	46 (30, 56)	38 (26, 48)
Elevated ALT (F>19, M>30)	13 (76%)	52 (100%)	130 (100%)
Elevated ALT (F>25, M>35)	9 (53%)	43 (83%)	95 (73%)
Elevated ALT (F/M >40)	5 (29%)	30 (58%)	52 (40%)

Conclusion

- The majority of people with HBV who are eligible for treatment based on the PBS criteria are currently receiving it.
- Greater adherence to PBS treatment criteria could slightly increase treatment uptake, though substantial changes are not anticipated.
- Variations in treatment eligibility criteria across clinical guidelines with the broadest treatment criteria in WHO and Chinese guidelines. Compared to the PBS, broadening criteria to follow WHO guidelines would increase proportion of REACH-B participants eligible for treatment from 53% to 62%.
- As the REACH-B study expands, a more comprehensive evaluation will assess factors predicting lack of treatment despite eligibility.

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Chief Investigator: Gail Matthews

Principal Investigators & Protocol Steering Committee:

Greg Dore
Behzad Hajarizadeh
Jacob George
Ben Cowie
Jane Davies
Josh Hanson
Thomas Tu
Lien Tran
Colette McGrath
Marilou Capati
Sarah Straw
Isabelle Purcell
Nicole Allard
Rob Monaghan
Lester Mascarenhas
Stephanie Howard
Renjy Nelson
James O'Beirne
Ian Wong
Marianne Martinello
Amanda Wade
Georgina Trotter
Lloyd Nash

Study Coordinator:

Jessica Carter