

## OPERA-C

An Observational Prospective Epidemiological Registry in Australia of HCV Liver Disease

Interim report – Data available as of July 2020

Please note that data presented below included information available as of July 2020. The few discrepancies in numbers between tables and variables are due to data that is currently being checked/cleaned.

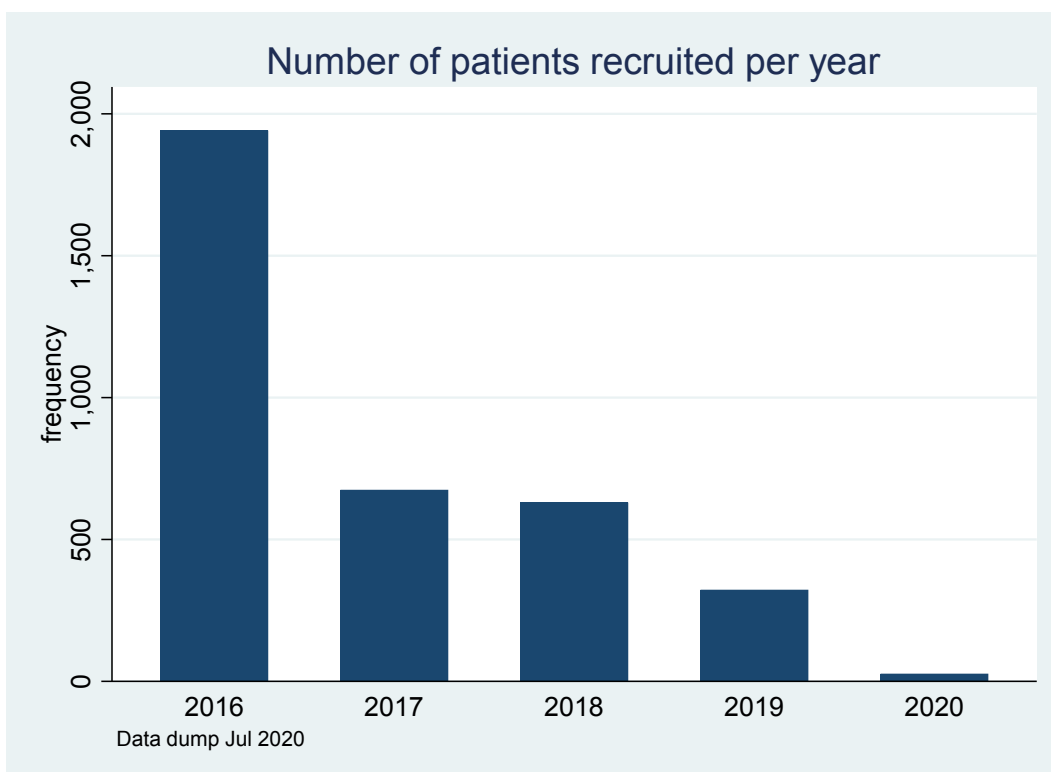
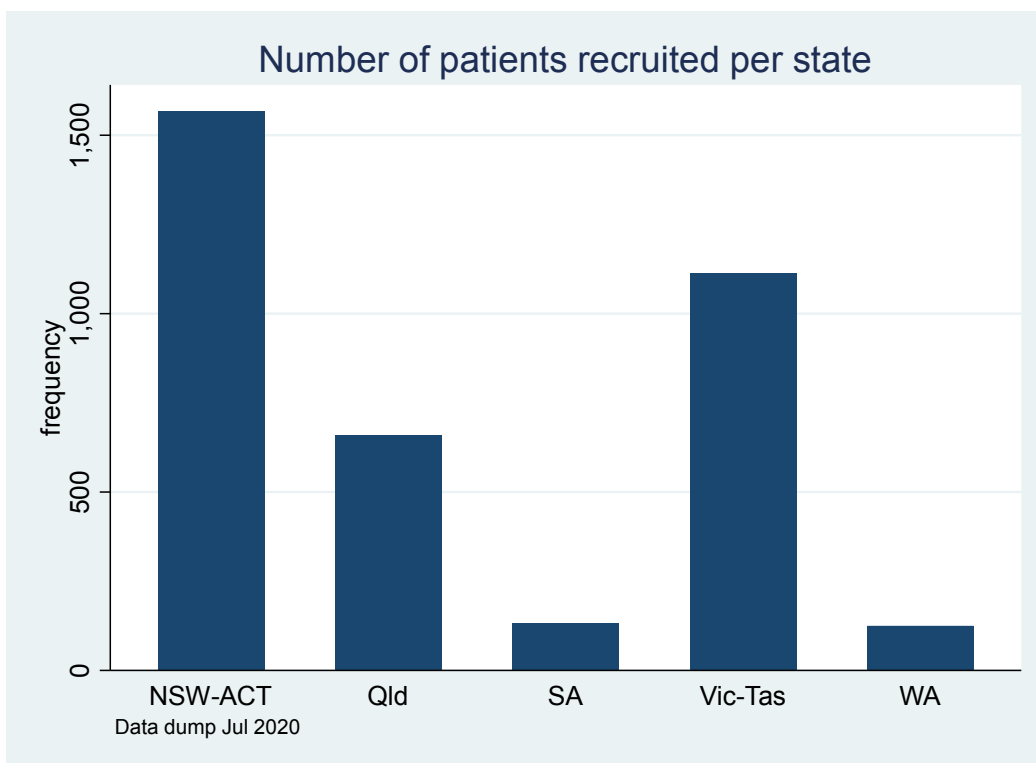
Number of data points		Page																												
<b>Baseline data (at enrolment)</b>	n=3506 patients. The sociodemographic and clinical features of patients included in the Opera-C study thus far are described in this below.	<b>3</b>																												
<b>Follow up data</b>	n=6,994 records	<b>18</b>																												
<b>HCC baseline data</b>	<p>N=139 records</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">HCC status at baseline (HCC form)</th> <th style="text-align: center;">Freq.</th> <th style="text-align: center;">Percent</th> <th style="text-align: center;">Cum.</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">New HCC</td> <td style="text-align: center;">63</td> <td style="text-align: center;">45.32</td> <td style="text-align: center;">45.32</td> </tr> <tr> <td style="text-align: center;">Stable Disease</td> <td style="text-align: center;">51</td> <td style="text-align: center;">36.69</td> <td style="text-align: center;">82.01</td> </tr> <tr> <td style="text-align: center;">Local Recurrence</td> <td style="text-align: center;">10</td> <td style="text-align: center;">7.19</td> <td style="text-align: center;">89.21</td> </tr> <tr> <td style="text-align: center;">Hepatic recurrences (new Lesion/s)</td> <td style="text-align: center;">14</td> <td style="text-align: center;">10.07</td> <td style="text-align: center;">99.28</td> </tr> <tr> <td style="text-align: center;">34</td> <td style="text-align: center;">1</td> <td style="text-align: center;">0.72</td> <td style="text-align: center;">100.00</td> </tr> <tr> <td style="text-align: center;">Total</td> <td style="text-align: center;">139</td> <td style="text-align: center;">100.00</td> <td></td> </tr> </tbody> </table>	HCC status at baseline (HCC form)	Freq.	Percent	Cum.	New HCC	63	45.32	45.32	Stable Disease	51	36.69	82.01	Local Recurrence	10	7.19	89.21	Hepatic recurrences (new Lesion/s)	14	10.07	99.28	34	1	0.72	100.00	Total	139	100.00		Not included in this report
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<b>HCC follow up data</b>	N= 384 records on 115 patients. This dataset has not been analysed.	Not included in this report																												
<b>PBS</b>	PBS data is available for 3,323 patients included in Opera-C. Information covers the period between 01 MAY 2015 to 30 SEP 2019. The data contains <b>350,910 records</b> .	<b>21</b>																												
<b>MBS data</b>	MBS data is available for 3,378 patients included in Opera-C. Information covers the period between 01 MAY 2015 to 30 SEP 2019. The data contains <b>488,399 records</b> .	<b>25</b>																												

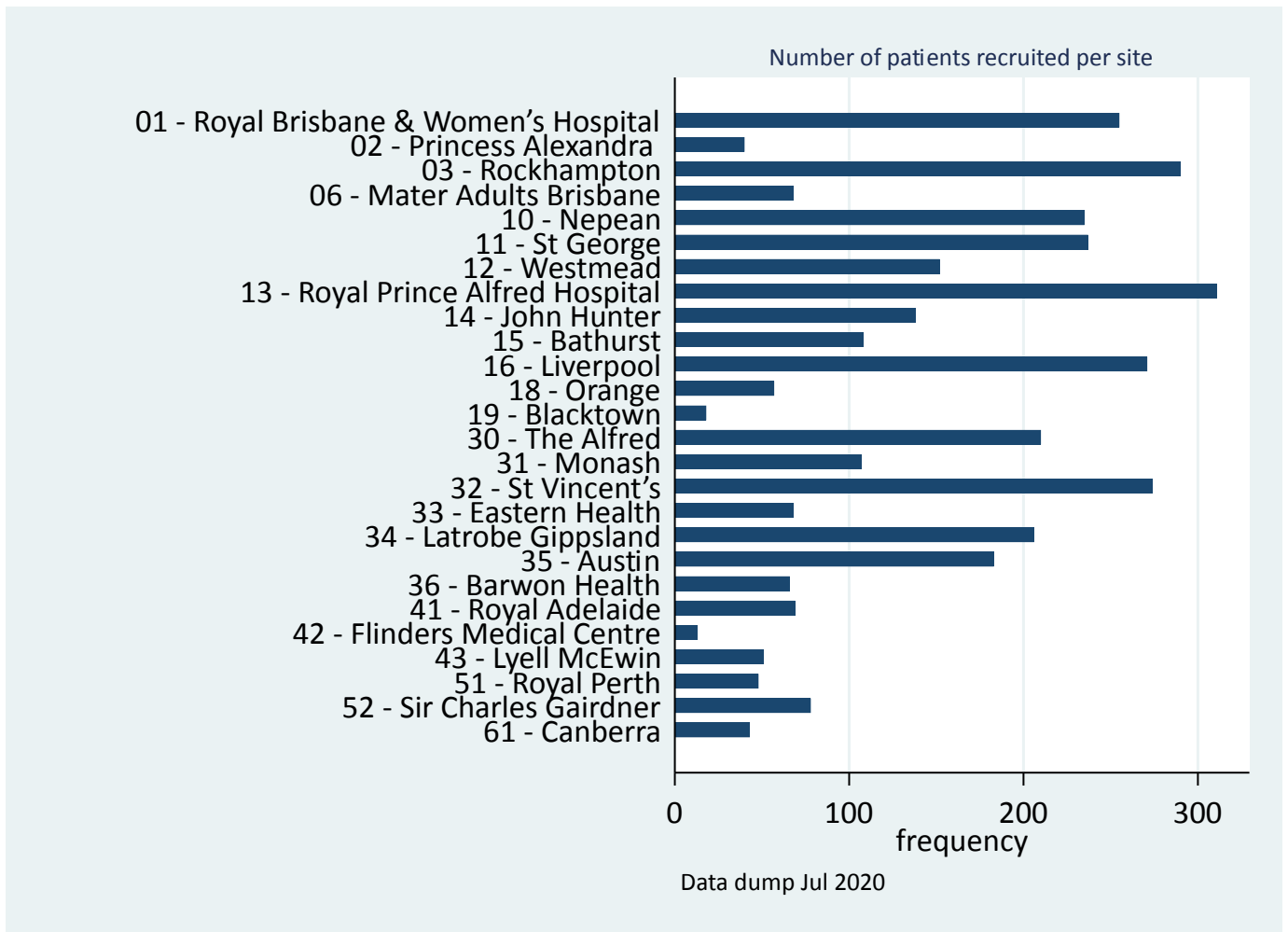
Information obtained at baseline

There were 3,596 patients enrolled in the Opera-C study when the data used for this report was extracted from the study's database. See below the distribution of patients by site, state and year of enrolment.

Site Name	Freq.	Percent	Cum.
13 - Royal Prince Alfred Hospital	311	8.65	8.65
03 - Rockhampton	290	8.06	16.71
32 - St Vincent's	274	7.62	24.33
16 - Liverpool	271	7.54	31.87
01 - Royal Brisbane & Women's Hospital	255	7.09	38.96
11 - St George	237	6.59	45.55
10 - Nepean	235	6.54	52.09
30 - The Alfred	210	5.84	57.93
34 - Latrobe Gippsland	206	5.73	63.65
35 - Austin	183	5.09	68.74
12 - Westmead	152	4.23	72.97
14 - John Hunter	138	3.84	76.81
15 - Bathurst	108	3.00	79.81
31 - Monash	107	2.98	82.79
52 - Sir Charles Gairdner	78	2.17	84.96
41 - Royal Adelaide	69	1.92	86.87
06 - Mater Adults Brisbane	68	1.89	88.77
33 - Eastern Health	68	1.89	90.66
36 - Barwon Health	66	1.84	92.49
18 - Orange	57	1.59	94.08
43 - Lyell McEwin	51	1.42	95.49
51 - Royal Perth	48	1.33	96.83
61 - Canberra	43	1.20	98.03
02 - Princess Alexandra	40	1.11	99.14
19 - Blacktown	18	0.50	99.64
42 - Flinders Medical Centre	13	0.36	100.00
Total	3,596	100.00	

state	Freq.	Percent	Cum.
NSW	1,538	42.77	42.77
Vic	1,111	30.90	73.67
Qld	659	18.33	91.99
SA	132	3.67	95.66
WA	125	3.48	99.14
ACT	29	0.81	99.94
Tas	2	0.06	100.00
Total	3,596	100.00	





The demographic characteristic of patients included in the study are described below (overall and by type of recruitment site).

		Total
		N=3,596
Age at OPERA-C enrolment		52.05407 (10.50451)
Gender	F	1,225 (34.1%)
	M	2,371 (65.9%)
Ethnicity	Caucasion	3,159 (87.8%)
	Asian	232 ( 6.5%)
	ATSI	108 ( 3.0%)
	other	63 ( 1.8%)
	Missing	34 ( 0.9%)
State (at recruitment)	NSW-ACT	1,567 (43.6%)
	Qld	659 (18.3%)
	SA	132 ( 3.7%)
	Vic-Tas	1,113 (31.0%)
	WA	125 ( 3.5%)
Rurality of residence (ARIA+) 3 groups	Major city	2,679 (74.5%)
	Inner regional	773 (21.5%)
	Outer regional/Remote/Very remote	142 ( 4.0%)
Socioeconomic advantage and disadvantage (IRSAD) 5 groups	Q1 most affluent	703 (19.6%)
	Q2	501 (13.9%)
	Q3	550 (15.3%)
	Q4	658 (18.3%)
	Q5 most disadvantaged	1,180 (32.9%)

Data are presented as mean (SD) for continuous measures, and n (%) for categorical measures.

		Secondary	Tertiary	p-value
		N=506	N=3,090	
Age at OPERA-C enrolment		49.8857 (9.937716)	52.40926 (10.55361)	<0.001
Gender	F	181 (35.8%)	1,044 (33.8%)	0.38
	M	325 (64.2%)	2,046 (66.2%)	
Ethnicity	Caucasion	452 (89.3%)	2,707 (87.6%)	<0.001
	Asian	9 ( 1.8%)	223 ( 7.2%)	
	ATSI	34 ( 6.7%)	74 ( 2.4%)	
	other	2 ( 0.4%)	61 ( 2.0%)	
	Missing	9 ( 1.8%)	25 ( 0.8%)	
State (at recruitment)	NSW-ACT	165 (32.6%)	1,402 (45.4%)	<0.001
	Qld	289 (57.1%)	370 (12.0%)	
	SA	51 (10.1%)	81 ( 2.6%)	
	Vic-Tas	1 ( 0.2%)	1,112 (36.0%)	
	WA	0 ( 0.0%)	125 ( 4.0%)	
Rurality of residence (ARIA+) 3 groups	Major city	52 (10.3%)	2,627 (85.0%)	<0.001
	Inner regional	361 (71.5%)	412 (13.3%)	
	Outer regional/Remote/Very remote	92 (18.2%)	50 ( 1.6%)	
Socioeconomic advantage and disadvantage (IRSAD) 5 groups	Q1 most affluent	7 ( 1.4%)	696 (22.5%)	<0.001
	Q2	28 ( 5.5%)	473 (15.3%)	
	Q3	55 (10.9%)	495 (16.0%)	
	Q4	163 (32.3%)	495 (16.0%)	
	Q5 most disadvantaged	252 (49.9%)	928 (30.1%)	

Data are presented as mean (SD) for continuous measures, and n (%) for categorical measures.

## Mode of acquisition

		Total
		N=3,596
Mode of HCV Acquisition 1	IDU	2,051 (57.0%)
	Tattoo	224 ( 6.2%)
	Transfusion	245 ( 6.8%)
	IDU/Tattoo	325 ( 9.0%)
	IDU/Tat/Trans	34 ( 0.9%)
	Tattoo/Transfusion	21 ( 0.6%)
	Other	28 ( 0.8%)
	IDU/Transfusion	16 ( 0.4%)
	Unknown	513 (14.3%)
	Sexual	26 ( 0.7%)
	Needlestick injury	31 ( 0.9%)
	vertical transmission	20 ( 0.6%)
	Vaccination	35 ( 1.0%)
	Medical Procedure	24 ( 0.7%)
	missing	3 ( 0.1%)
Mode of HCV Acquisition 2	Other	20 (24%)
	Sexual	39 (46%)
	Needlestick injury	10 (12%)
	vertical transmission	2 ( 2%)
	Vaccination	8 (10%)
	Medical Procedure	5 ( 6%)
Mode of HCV Acquisition - ever IDU	No	1,166 (32.4%)
	Yes	2,427 (67.5%)
	missing	3 ( 0.1%)
Mode of HCV Acquisition - ever transfusion	No	3,277 (91.1%)
	Yes	316 ( 8.8%)
	missing	3 ( 0.1%)
Mode of HCV Acquisition - ever Tatoo	No	2,989 (83.1%)
	Yes	604 (16.8%)
	missing	3 ( 0.1%)
Mode of HCV Acquisition - ONLY sexual	No	3,569 (99.2%)
	Yes	27 ( 0.8%)
Mode of HCV Acquisition - ONLY needle stick	No	3,565 (99.1%)
	Yes	31 ( 0.9%)
Mode of HCV Acquisition - ONLY vaccine	No	3,567 (99.2%)
	Yes	29 ( 0.8%)
Mode of HCV Acquisition - ONLY medical/dental procedure	No	3,561 (99.0%)
	Yes	35 ( 1.0%)

Data are presented as n (%).

Details of hepatitis C virus (HCV) diagnosis and previous treatment of patients included in the study

		Total
		N=3,596
Genotype known?	Yes	3,557 (98.9%)
	Unknown	39 ( 1.1%)
HCV Genotype result (5 groups)	1	1,924 (53.5%)
	2	168 ( 4.7%)
	3	1,352 (37.6%)
	Genotype 4, 5 or 6	97 ( 2.7%)
	>1 genotype	16 ( 0.4%)
	genotype unknown	39 ( 1.1%)
HCV Genotype Subtype	a	2,407 (66.9%)
	b	509 (14.2%)
	c	19 ( 0.5%)
	d	1 ( 0.0%)
	5	1 ( 0.0%)
	6	1 ( 0.0%)
	8	2 ( 0.1%)
	a b	22 ( 0.6%)
	a c	12 ( 0.3%)
	genotype unknown	39 ( 1.1%)
	blank	451 (12.5%)
	missing	122 ( 3.4%)
	a c d	10 ( 0.3%)

		Total
		N=3,596
Had previous HCV tx?	0	2,828 (79.1%)
	1	745 (20.9%)
Total number of previous HCV treatments	0	2,828 (78.6%)
	1	583 (16.2%)
	2	135 ( 3.8%)
	3	22 ( 0.6%)
	4	2 ( 0.1%)
	5	1 ( 0.0%)
	6	1 ( 0.0%)
	missing	24 ( 0.7%)
TX_previous_USE	DAA only	47 ( 6.3%)
	DAA + PEGIFN/IFN/RBV	18 ( 2.4%)
	PEGIFN/IFN/RBV - no DAA	611 (82.0%)
	RCT not brought forward	11 ( 1.5%)
	RCT unknown drug	12 ( 1.6%)
	unknown/missing	46 ( 6.2%)
Last HCV treatment response	SVR	19 ( 0.5%)
	Relapse	299 ( 8.4%)
	Non Responder	350 ( 9.8%)
	Unknown	73 ( 2.0%)
	Never treated	2,828 (79.1%)
	Missing	4 ( 0.1%)