Are we leaving pregnant women behind?

Hepatitis C cascade of care during pregnancy at a metropolitan obstetric centre in Melbourne

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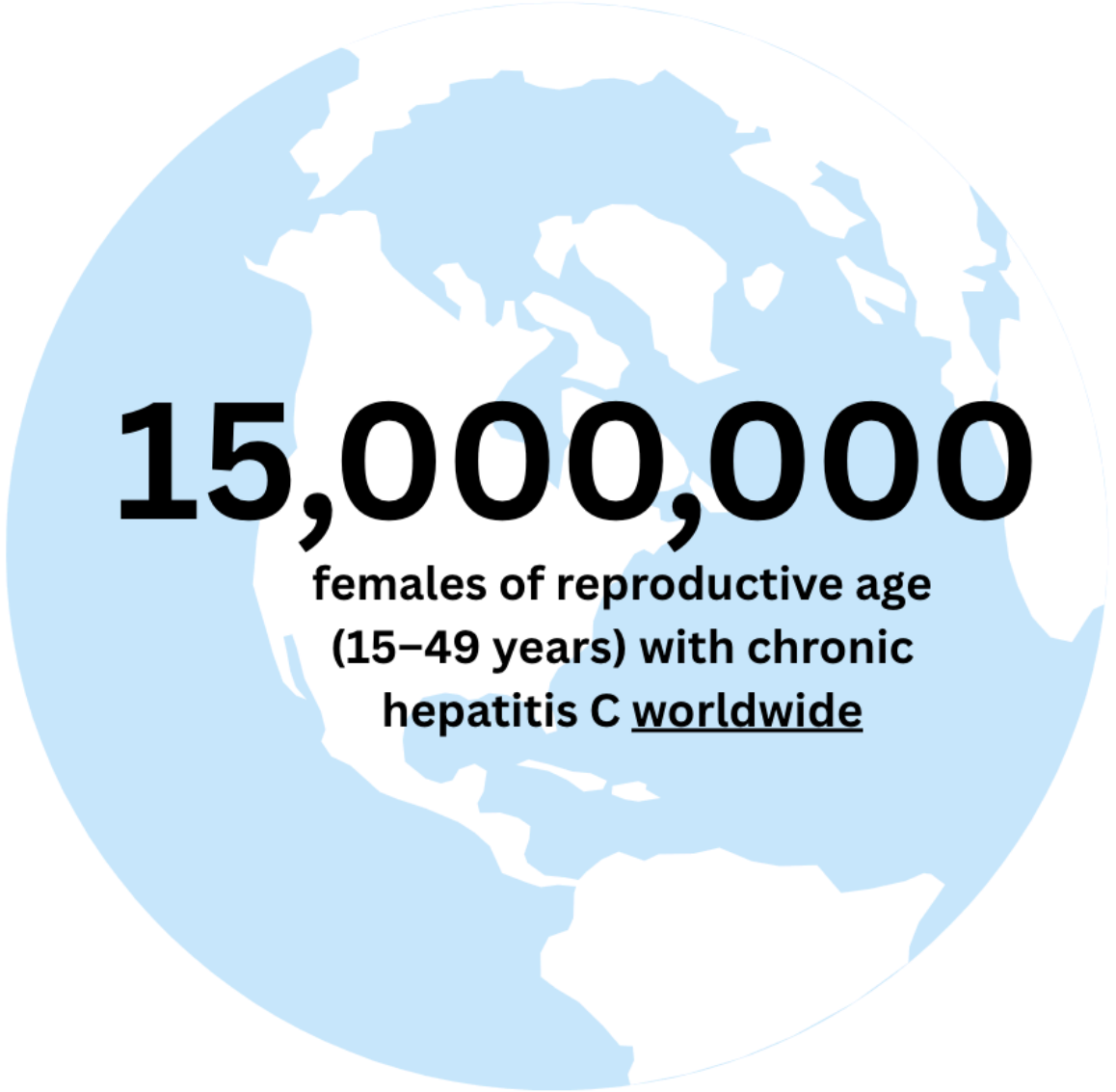
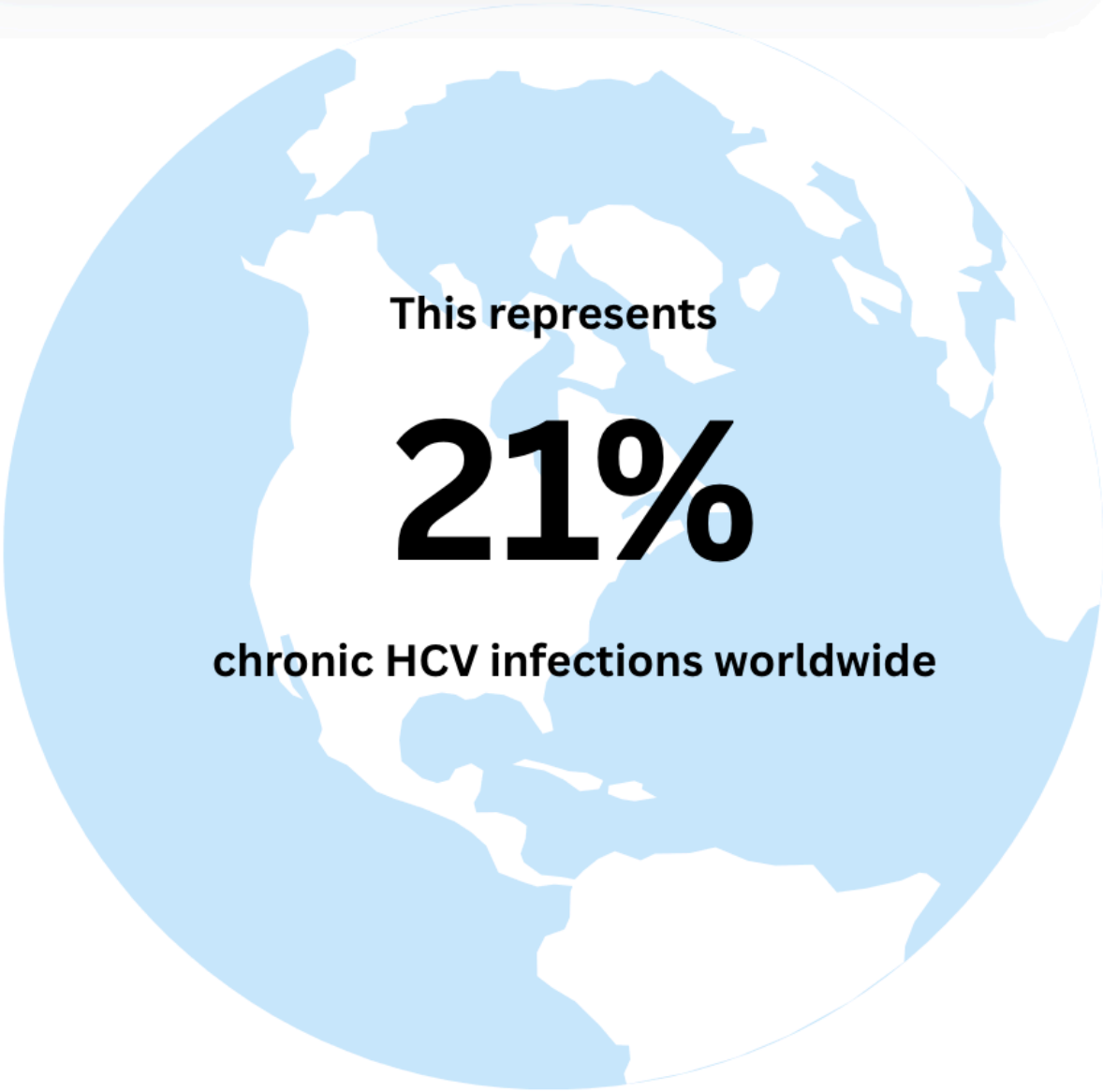
Acknowledgement of country

I would like to echo the acknowledgement of previous speakers and recognise we are meeting on the lands of the Wurundjeri Woi-wurrung people where I am lucky to live and work and I would like to pay my respects to their Elders both past, present, and emerging.

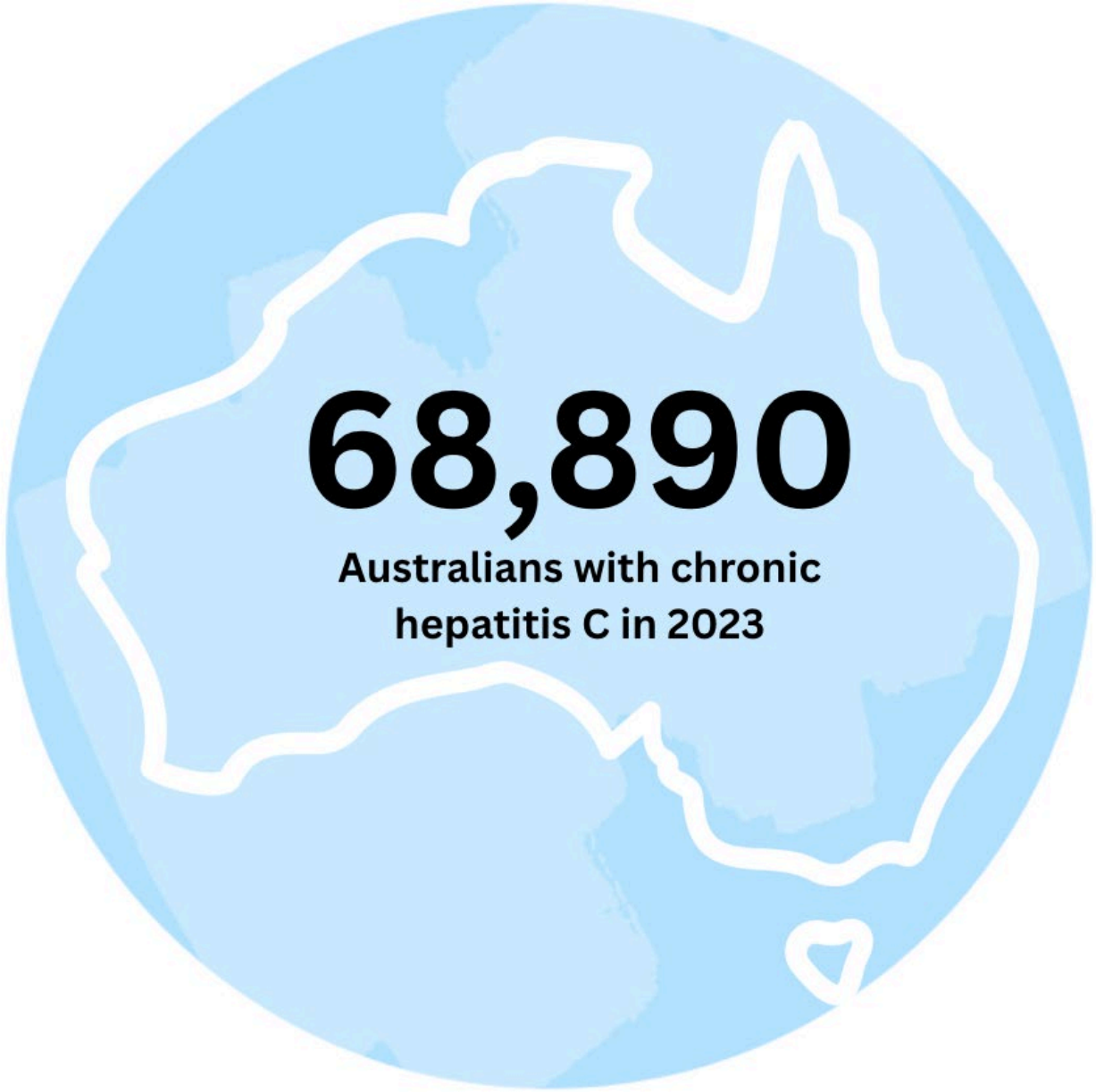
Conflict of Interest

Nil disclosures



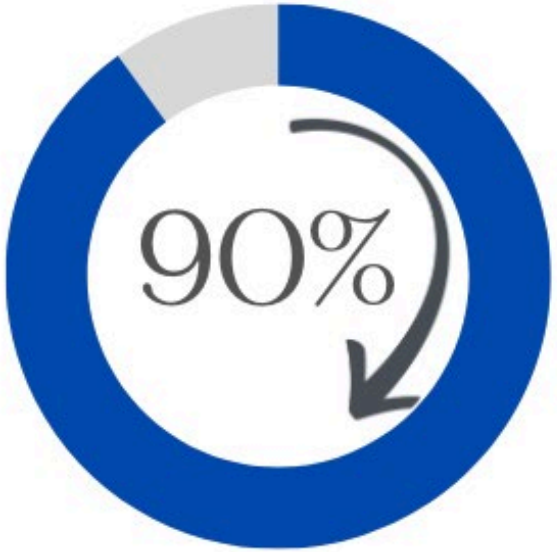


Global prevalence of hepatitis C virus in women of childbearing age in 2019: a modelling study
Dugan, Ellen et al.
The Lancet Gastroenterology & Hepatology, Volume 6, Issue 3, 169 - 184



HIV, viral hepatitis and sexually transmissible infections in Australia: Annual surveillance report 2024
King, J., Kwon J., McManus, H., Gray, R., & McGregor, S.,
The Kirby Institute, UNSW Sydney, Sydney, Australia

Global Viral Hepatitis Elimination Strategy 2030



World Health Organization

Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022-2030. Geneva: World Health Organization; 2022

Are we leaving pregnant people behind?

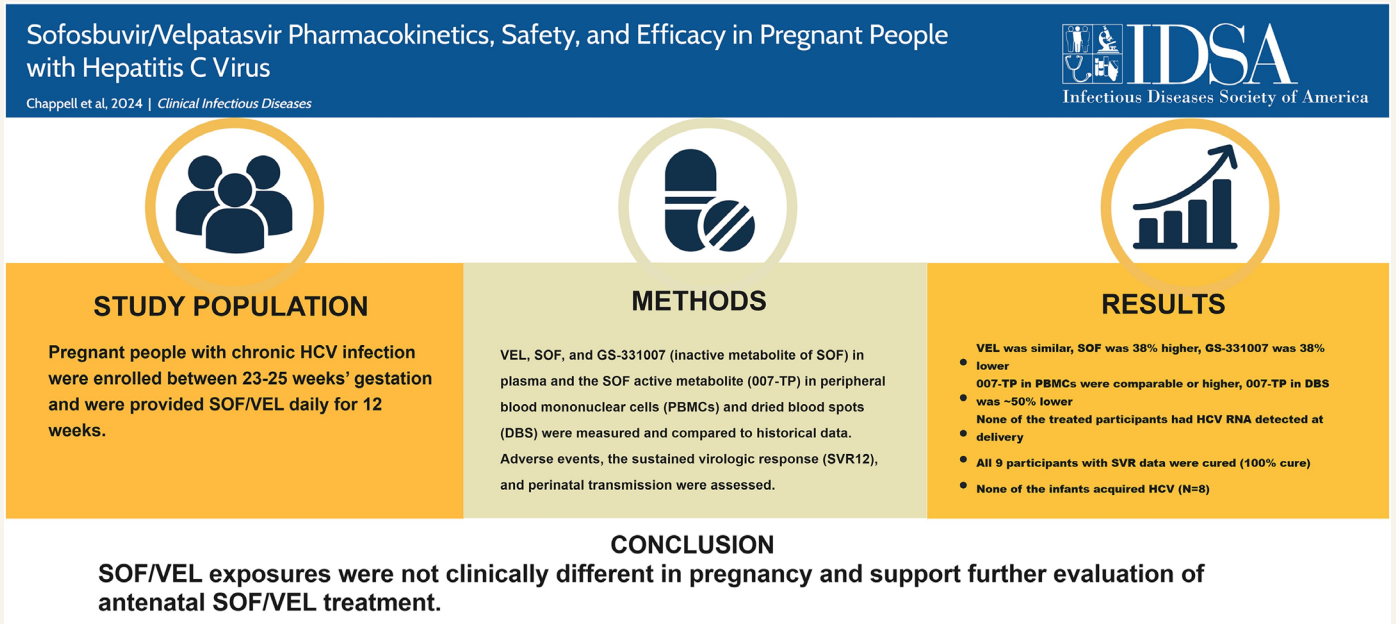
DAA's currently contraindicated in pregnancy and breastfeeding

Opportunity to engage in hepatitis C treatment WHILE linked in with maternity care and undergoing regular follow up

Decreases risk of vertical transmission

Progresses WHO Hep C elimination goals

Pharmacokinetic studies of DAAs in pregnancy



Clinical Infectious Diseases

Ledipasvir plus sofosbuvir in pregnant women with hepatitis C virus infection: a phase 1 pharmacokinetic study

Catherine A Chappell, Kimberly K Scarsi, Brian J Kirby, Vithika Suri, Anuj Gaggar, Debra L Bogen, Ingrid S Macio, Leslie A Meyn, Katherine E Bunge, Elizabeth E Krans, Sharon L Hillier

Summary

Background Hepatitis C virus (HCV) infection is increasing among pregnant women because of the opioid epidemic, yet there are no interventions to reduce perinatal HCV transmission or to treat HCV during pregnancy. Physiological changes in pregnancy alter the pharmacokinetics of some medications; thus, our aim was to compare the pharmacokinetic parameters of ledipasvir 90 mg plus sofosbuvir 400 mg during pregnancy with non-pregnant women.

Lancet Microbe 2020; 1: e200–08
Published Online
July 27, 2020
https://doi.org/10.1016/S2666-5247(20)30062-8

Department of Obstetrics, Gynecology, and Reproductive

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Treatment In Pregnancy for Hepatitis C

CGHE launched the TiP-HepC project in order to increase collaboration and understanding about treatment in pregnancy for hepatitis C. The project consists of a case registry, a webinar series, and a community of practice. Read on to learn more about how you can get involved.

Contribute cases to TiP-HepC registry here

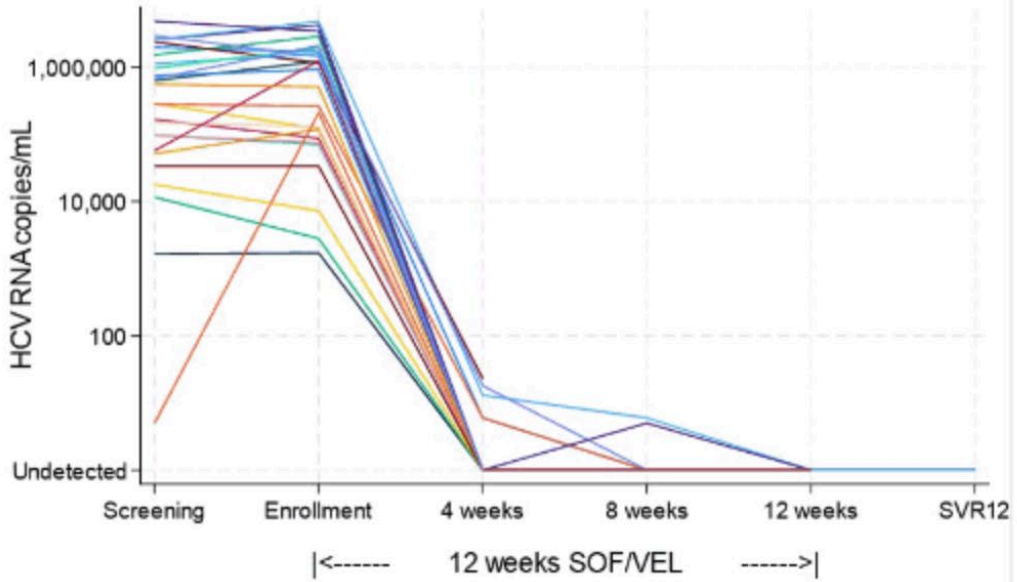
Hepatitis C in pregnancy and the TiP-HepC registry
Gupta, Neil et al.
The Lancet Gastroenterology & Hepatology, Volume 7, Issue 7, 598 – 599
https://www.globalhep.org/projects-research/treatment-pregnancy-hepatitis-c

Safety, Tolerability, and Outcomes of Sofosbuvir/Velpatasvir in Treatment of Chronic Hepatitis C Virus during Pregnancy: interim results from the STORC study Nov 2023

Conclusions

The interim data from the STORC study provide preliminary reassurance regarding the safety

Figure 3. HCV viral response to SOF/VEL during pregnancy



15 participants had HCV RNAs assessed at delivery and all (100%) were undetectable.

ongoing.

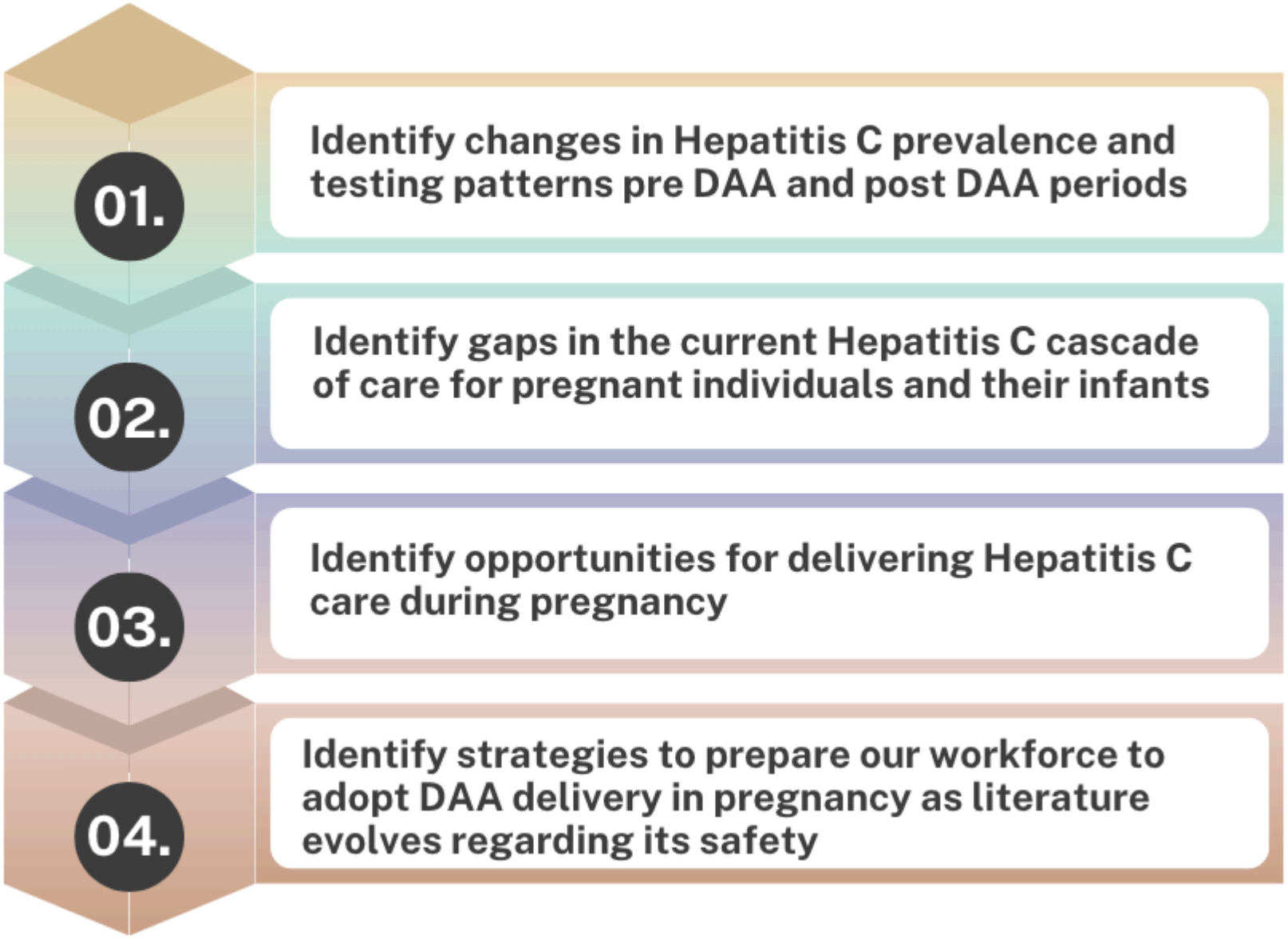
Ongoing research

SUMMARY

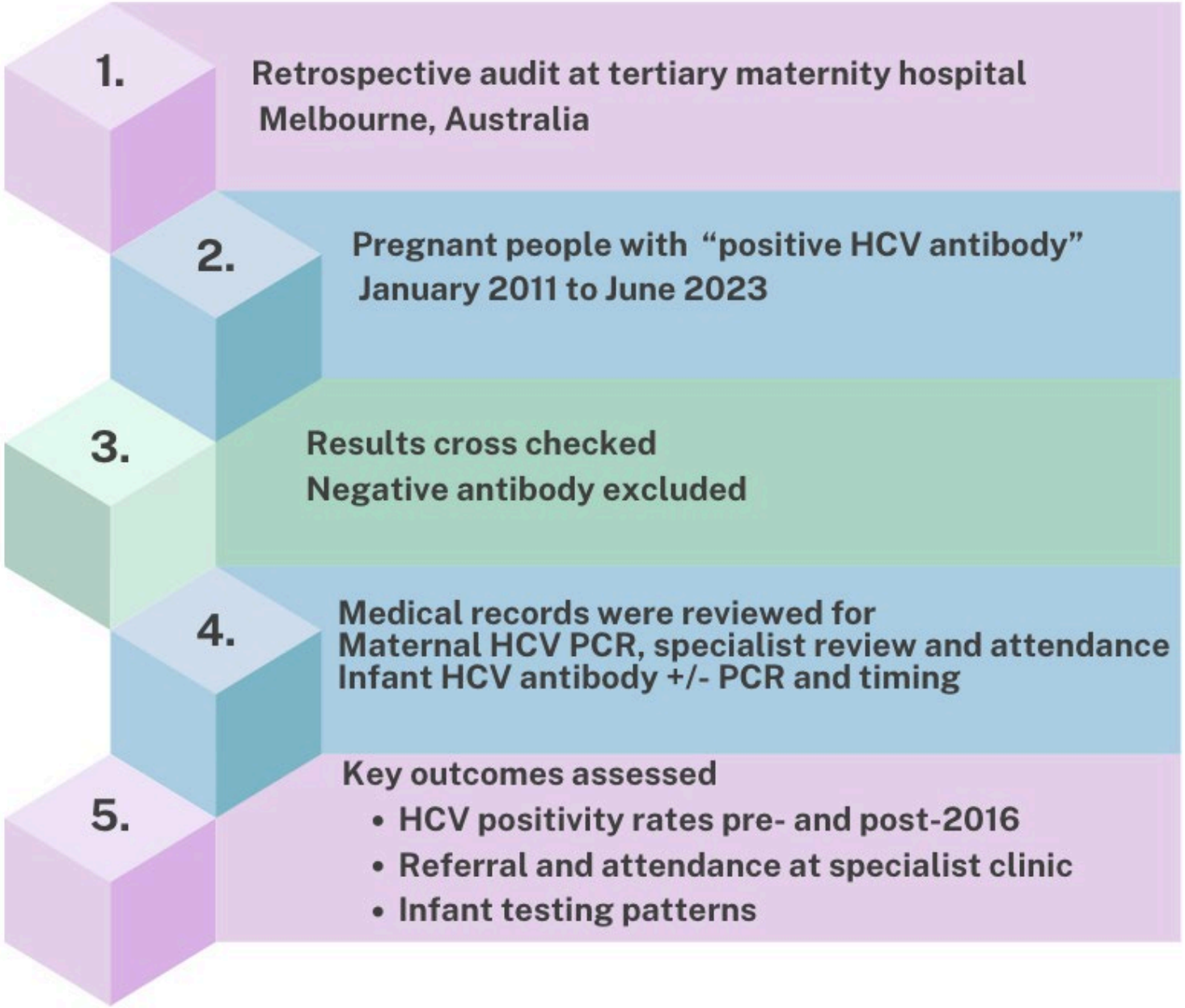
IMPAACT 2041 is a Phase I/II Study of the Pharmacokinetics and Safety of Glecaprevir/Pibrentasvir in Women with Hepatitis C During Pregnancy. The study is designed to evaluate the pharmacokinetics and safety of GLE/PIB during pregnancy and postpartum, and will follow pregnant women and their infants through three months postpartum. Site selection was completed in July 2023 and was opened to IMPAACT sites located in the United States only. Only US sites were invited to participate due to the expected availability of GLE/PIB.

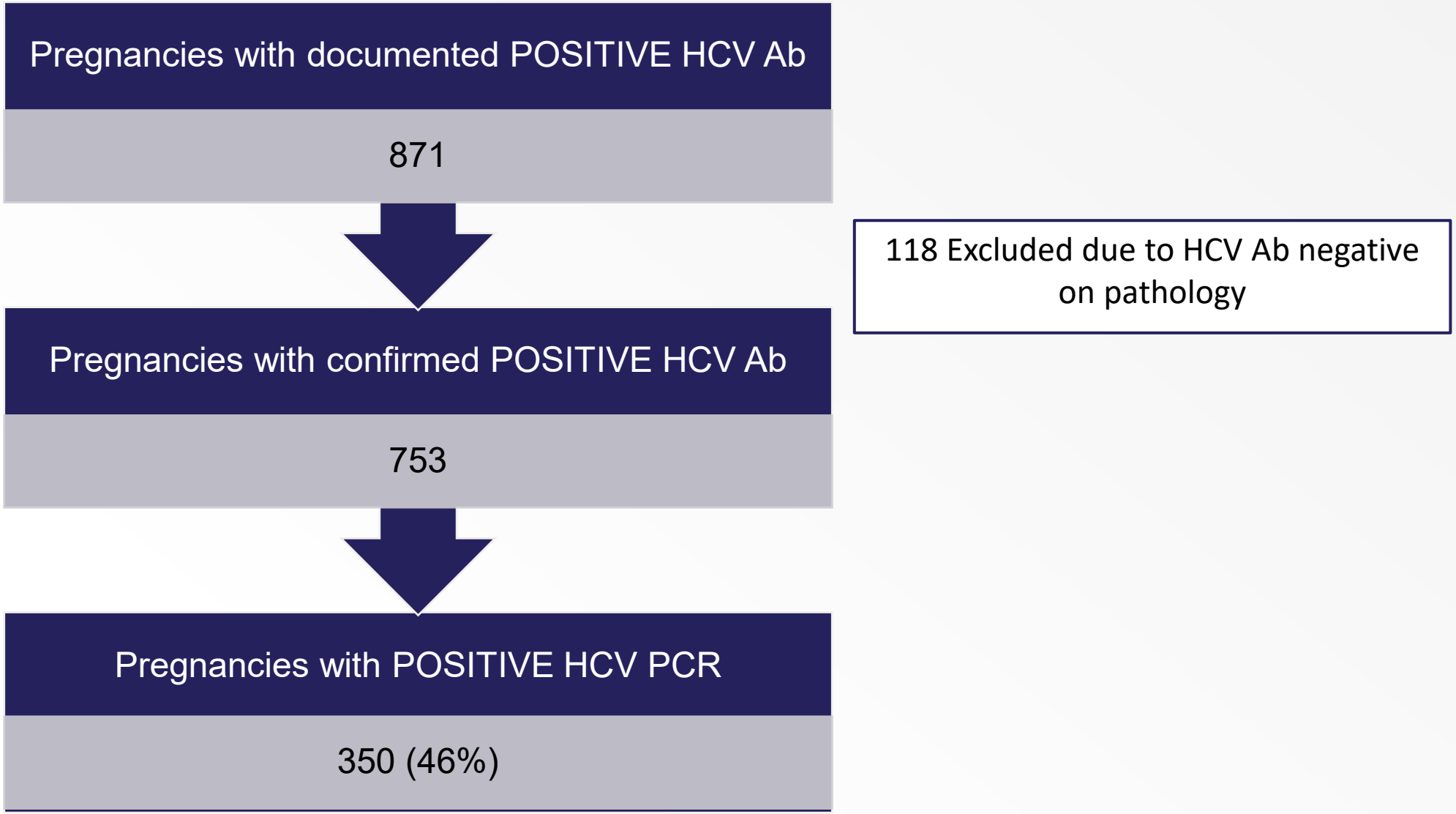
Eke A et al. IMPAACT 2041: Phase I/II Study of the Pharmacokinetics and Safety of Glecaprevir/Pibrentasvir Initiated in Pregnancy in People with Hepatitis C with and without HIV. National Institutes of Health https://www.impaactnetwork.org/studies/impaact2041.

Aims


01.
Identify changes in Hepatitis C prevalence and testing patterns pre DAA and post DAA periods
02.
Identify gaps in the current Hepatitis C cascade of care for pregnant individuals and their infants
03.
Identify opportunities for delivering Hepatitis C care during pregnancy
04.
Identify strategies to prepare our workforce to adopt DAA delivery in pregnancy as literature evolves regarding its safety

Methods


1.
Retrospective audit at tertiary maternity hospital
Melbourne, Australia
2.
Pregnant people with "positive HCV antibody"
January 2011 to June 2023
3.
Results cross checked
Negative antibody excluded
4.
Medical records were reviewed for
Maternal HCV PCR, specialist review and attendance
Infant HCV antibody +/- PCR and timing
5.
Key outcomes assessed
• HCV positivity rates pre- and post-2016
• Referral and attendance at specialist clinic
• Infant testing patterns

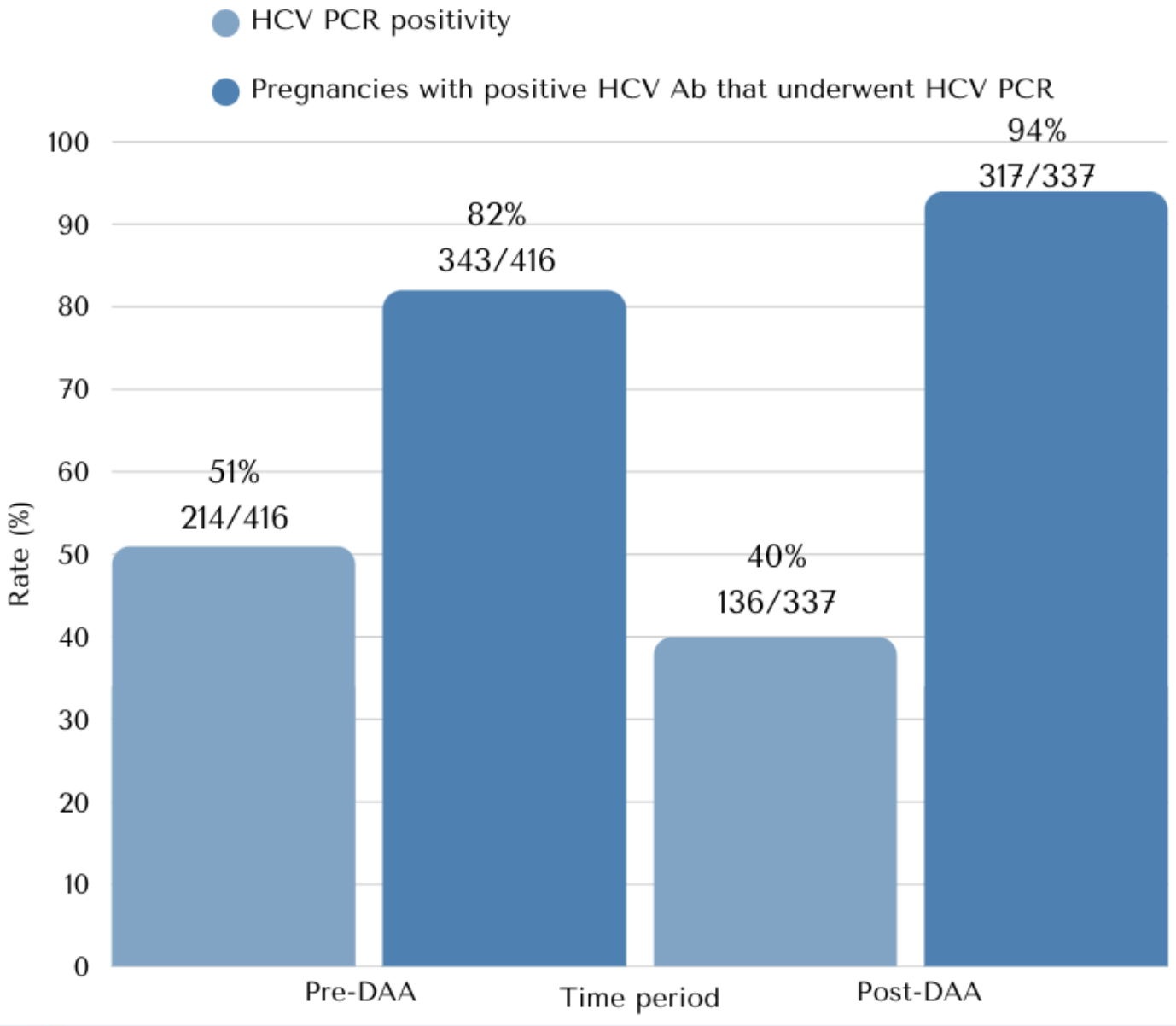


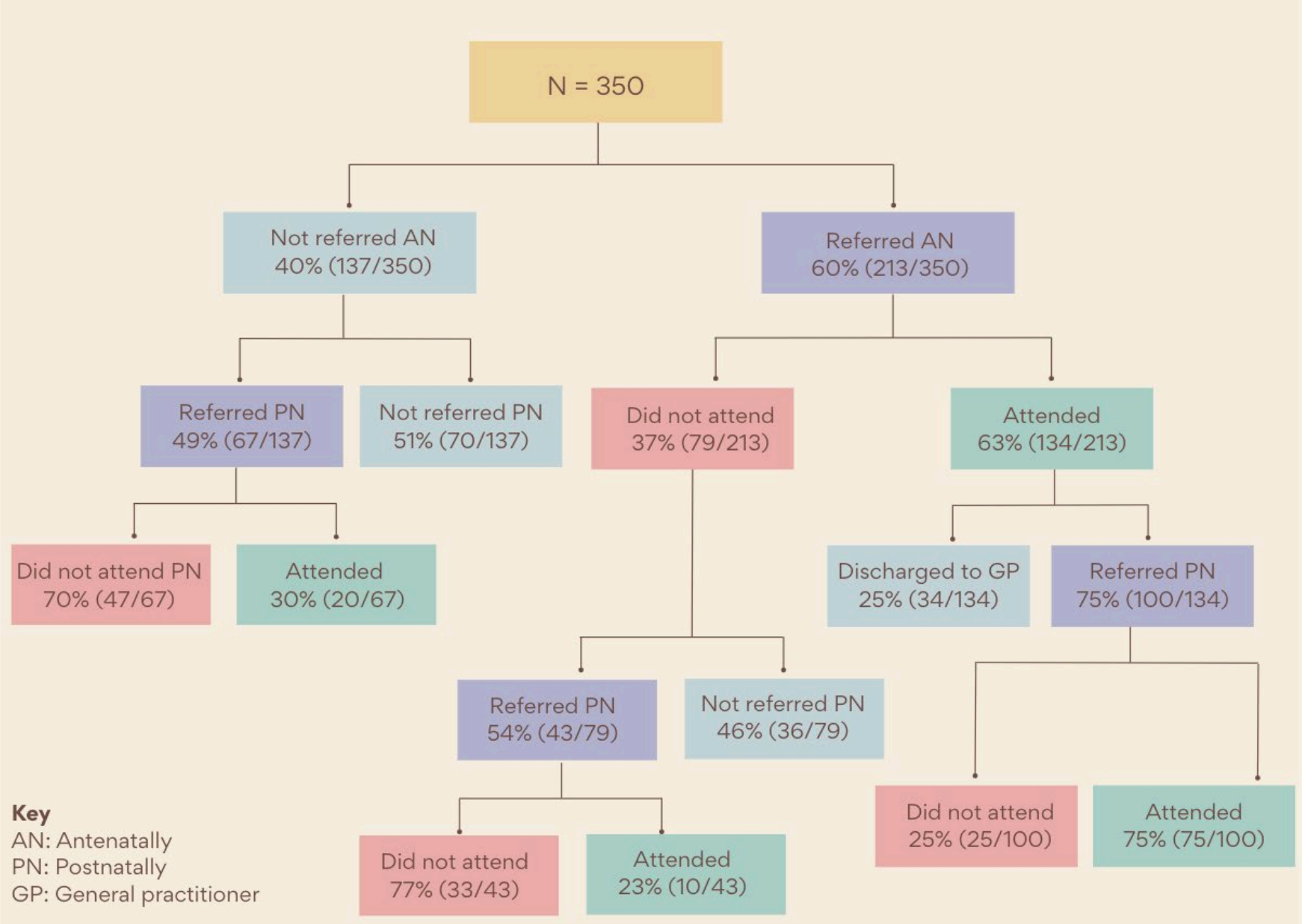
Flowchart of study population

Baseline demographics of pregnant individuals with HCV (HCV PCR positive)

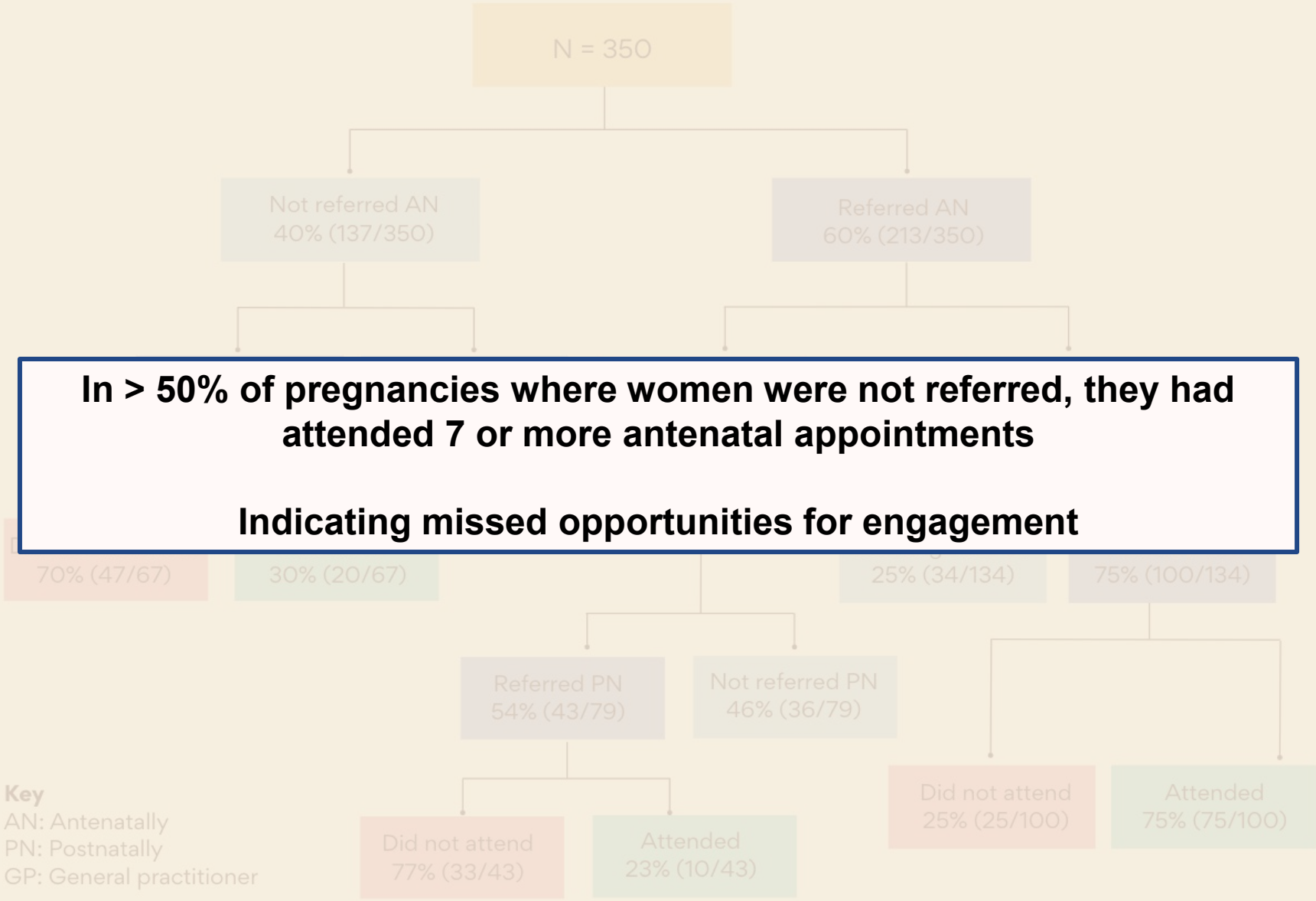
Demographic Characteristic	Pre-2016	Post-2016	p value
	N = 214	N = 136	
Aboriginal and Torres Strait Islander Status			p = 0.66
Yes	12 (6%)	8 (6%)	
No	198 (93%)	127 (93%)	
Unknown	4 (1%)	1 (1%)	
Interpreter Requirements			p = 0.21
Required	19 (9%)	18 (13%)	
Not required	165 (77%)	104 (76%)	
Unknown	30 (14%)	14 (10%)	
Hepatitis B Surface Antigen (HbsAg)			p = 0.69
Positive	8 (4%)	4 (3%)	
Negative	200 (93%)	129 (95%)	
Unknown	5 (2%)	3 (2%)	
HIV Co-Infection			p = 0.19
Yes	1 (1%)	1 (0.5%)	
No	195 (91%)	130 (96%)	
Unknown	18 (8%)	5 (4%)	
Country of Birth			p = 0.002
Australia	154 (72%)	83 (61%)	
Other	15 (7%) Cambodia	6 (4%) Sudan	
	9 (4%) Vietnam	6 (4%) Vietnam	

Results


HCV PCR positivity
Pregnancies with positive HCV Ab that underwent HCV PCR
Rate (%)
100
90
80
70
60
50
40
30
20
10
0
51%
214/416
82%
343/416
40%
136/337
94%
317/337
Pre-DAA
Post-DAA
Time period



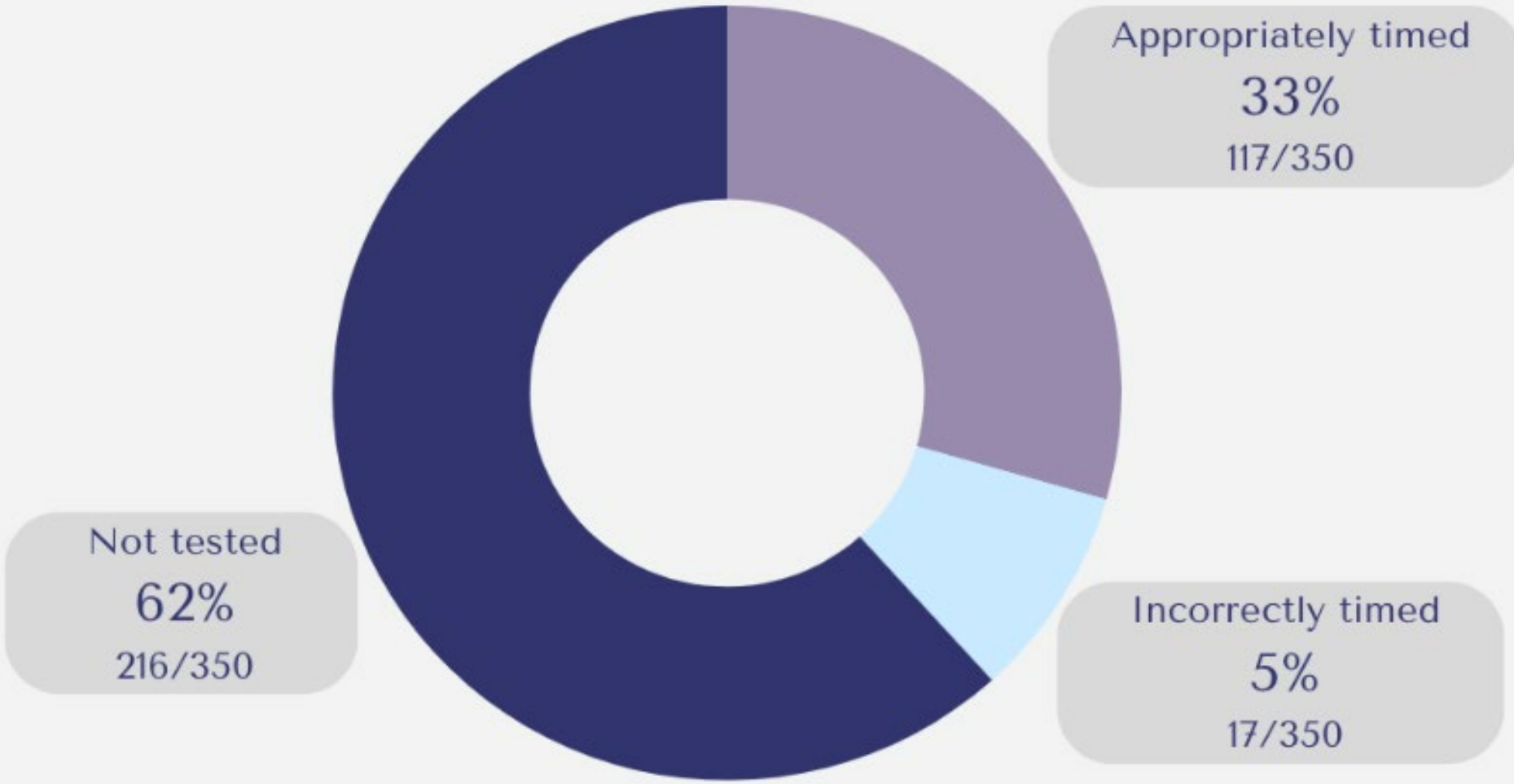
Referral and attendance patterns of pregnant patients with positive HCV PCR



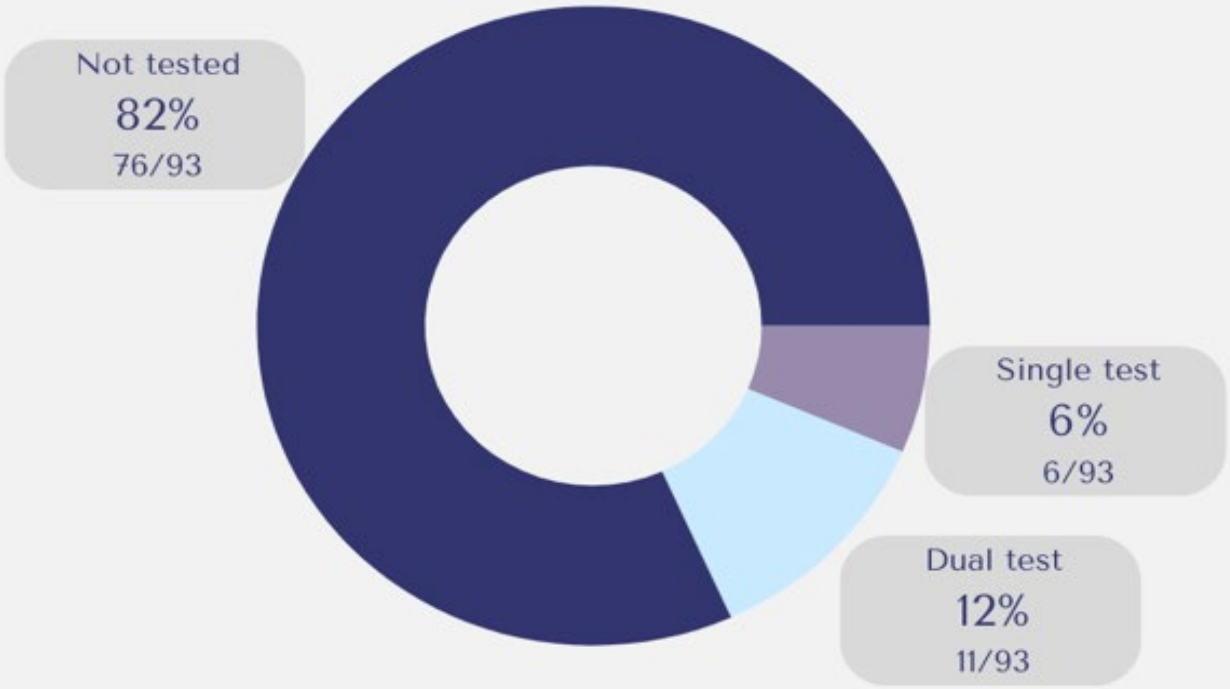
In > 50% of pregnancies where women were not referred, they had attended 7 or more antenatal appointments

Indicating missed opportunities for engagement

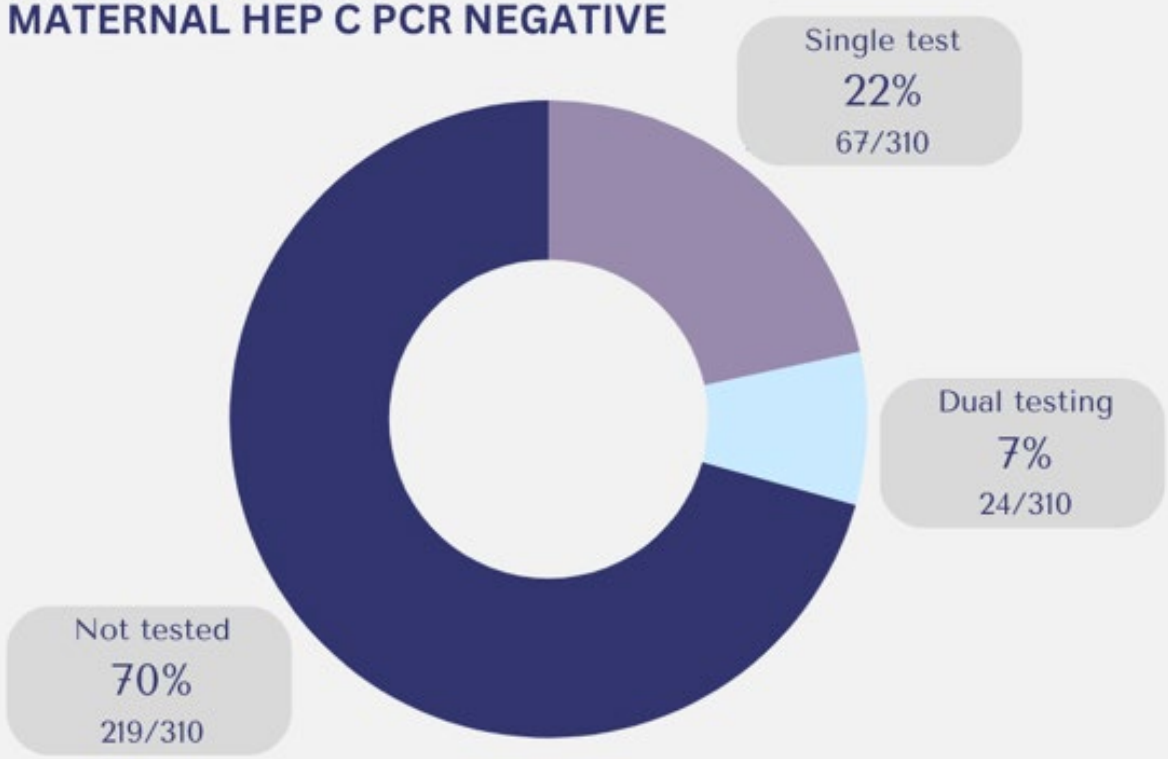
INFANT TESTING
MATERNAL HEP C PCR POSITIVE



INFANT TESTING
MATERNAL HEP C PCR UNKNOWN



INFANT TESTING
MATERNAL HEP C PCR NEGATIVE



Discussion

1

Integration of Hepatitis C care into routine antenatal appointments

- Mothers known to prioritise the health of their infant
- Good engagement with antenatal care
  - opportunity for obstetricians, midwives, drug and alcohol teams to start discussions
- Prescribers are no longer required to complete S100 courses

2

Timely infant testing

- Understanding of recommendations and difference between tests
  - Hepatitis C antibody vs PCR
- Prevention unnecessary testing

Strengths

Large sample size of 753 pregnancies

Time period of over a 12 years (2011–2023)

Captures longitudinal trends before and after the introduction of DAAs

Use of real-world data from a tertiary maternity hospital

Offers a timely review of barriers and opportunities to support the use of DAAs in pregnancy as literature starts to evolve regarding safety

Limitations

Retrospective audit - data collection is dependent on existing medical records, which may be incomplete or lack key details

Reasons for non-referral and lack of specialist clinic attendance incomplete

Individuals who may have followed up with their GPs for treatment missed

Single hospital study which may limit generalisability

Does not capture patient perspectives on why specialist clinic were missed

Key Actions and Takeaways

Although Hep C prevalence is decreasing, this audit highlights gaps in maternal referrals to specialist clinic and infant testing

We need to prepare our workforce so when DAA's in pregnancy are approved, there are no delays in adopting practice

Hep C treatment needs to be delivered at the point of maternity care. This is key to advancing WHO elimination goals

Pregnancy as an exclusion criteria in clinical trials is detrimental to pregnant people and their infants and delays the progress of public health goals

Acknowledgements

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People living with hepatitis C without whom we would not be able to perform this research