Clinical Trials

Smarter studies Global impact Better health



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Background

- Risk of vertical transmission of hepatitis C virus (HCV) is ~6%, ¹ and evidence suggests HCV negatively affects pregnancy and infant outcomes.
- Direct acting antivirals (DAA) have a very good safety profile and very high efficacy but are not yet approved for use during pregnancy/breastfeeding.
- A phase I trial (n=8) showed sofosbuvir-ledipasvir in pregnancy was well tolerated, achieved 100% maternal cure and no vertical transmission.²
- Ukraine has high burden of HCV with ≈ 2 million people anti-HCV positive, and high prevalence among women living with HIV (≈33%) and people who inject drugs (\approx 55%), of whom \approx 25% are women of childbearing age.
- There are scarce data on the acceptability of universal antenatal HCV screening and, if DAAs were approved for use in pregnancy, the potential acceptability of treatment in pregnancy in women in high burden settings such as Ukraine.³

Aims

The aims of this study were to assess:

- 1. the acceptability of free universal antenatal HCV screening
- 2. potential uptake of DAA treatment in the scenario of DAAs being approved for use in pregnancy.

Participants and methods

Inclusion Criteria:

Pregnant or postpartum (<6 months since delivery) women attending 3 antenatal clinics/maternity hospitals in Ukraine, including a specialist infections centre. Women were included irrespective of HCV status.

Methods:

- Women were invited to complete a survey and provide basic data on their HCV and HIV status and potential HCV risk factors
- HCV infection was defined as self-reported ever HCV antibody or PCR positive. HIV was also self-reported
- Acceptability of HCV testing and DAA treatment in pregnancy were summarised by HCV/ HIV status

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HCVAVERT survey in pregnant and post-partum women in Ukraine indicates hepatitis C screening and treatment would be highly acceptable during pregnancy

Results – participant characteristics 150 women participated, with median age 33 [IQR 28,37] years (Table) 60 (40%) had HCV mono-infection, 23 (15%) HCV/HIV co-infected, 67 (45%) were HCV uninfected or had unknown HCV status Table: Characteristics of participants by HCV / HCV+/ HIVn=60 **Kiev AIDS Center** 0 (0) Centre Kiev Maternity 37 (62) 23 (38) Odessa Maternity 32 [28, 36] Age, years Relationship Married/co-habiting 56 (93) status Not married/co-habiting 4 (7) < Secondary 7 (12) Education level ≥ Secondary 53 (88) 16 (27) Full-time or student Employment Part-time 13 (22) status 31 (52) Unemployed Pregnant 28 (47) No previously Yes 32 (53) Ever injected Yes 4 (7) drugs 56 (93) No

Results – acceptability

- 97% of women supported universal antenatal HCV testing, with no difference by HCV or HIV status (Figure 1)
- 78% would take DAAs in pregnancy if they were safe and approved for use (75%, 65%, 85% for HCV+/HIV-, HCV+/HIV+, HCV-/HCV status unknown) respectively), while 22% of women preferred to start treatment after delivery/breastfeeding (Figure 2)
- Among women who considered DAAs in pregnancy acceptable, 68% would take DAAs only if they prevented vertical transmission or had other potential benefits for their baby and 32% would take them for maternal cure regardless.

References

1 Benova L, et al. Vertical transmission of hepatitis C virus: systematic review and meta-analysis. Clinical infectious diseases. 2014;59(6):765-73 2 Chappell CA et al. Ledipasvir plus sofosbuvir in pregnant women with hepatitis C virus infection: a phase 1 pharmacokinetic study. Lancet Microbe, 2020. 1(5): p. e200-e208. 3 Pronyuk, K., Results of implementation of the State Program on elimination of viral hepatitis C in Ukraine: achievements and challenges, in 5th CEE Meeting on Viral Hepatitis and HIV. 2019: Vilnius, Lithuania.

HIV status			
HCV+/ HIV+ n=23	HCV- or unknown n=67	Total n=150	p-value
n (%) or median [IQR]			
12 (52)	39 (58)	51	
3 (13)	17 (25)	57	< 0.001
8 (35)	11 (16)	42	
35 [30, 37]	33 [27, 37]	33 [28, 37]	0.647
16 (70)	62 (93)	134	0.004
7 (30)	5 (7)	16	
5 (22)	0 (0)	12	0.002
18 (78)	67 (100)	138	
6 (26)	33 (49)	55	
4 (17)	10 (15)	27	0.074
13 (57)	24 (36)	68	
3 (13)	30 (45)	61	0.013
20 (87)	37 (55)	89	
7 (30)	2 (3)	13	<0.001
16 (70)	65 (97)	137	

Results – acceptability continued...

Figure 1: Acceptability of free universal HCV testing in pregnancy

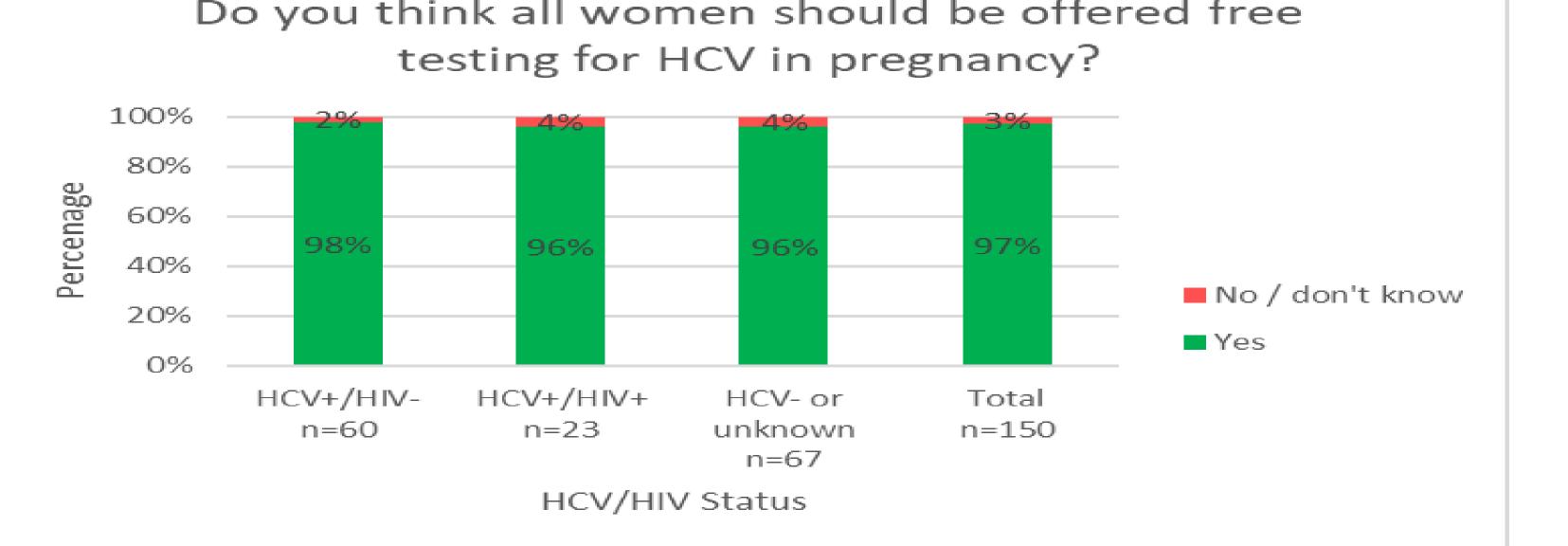
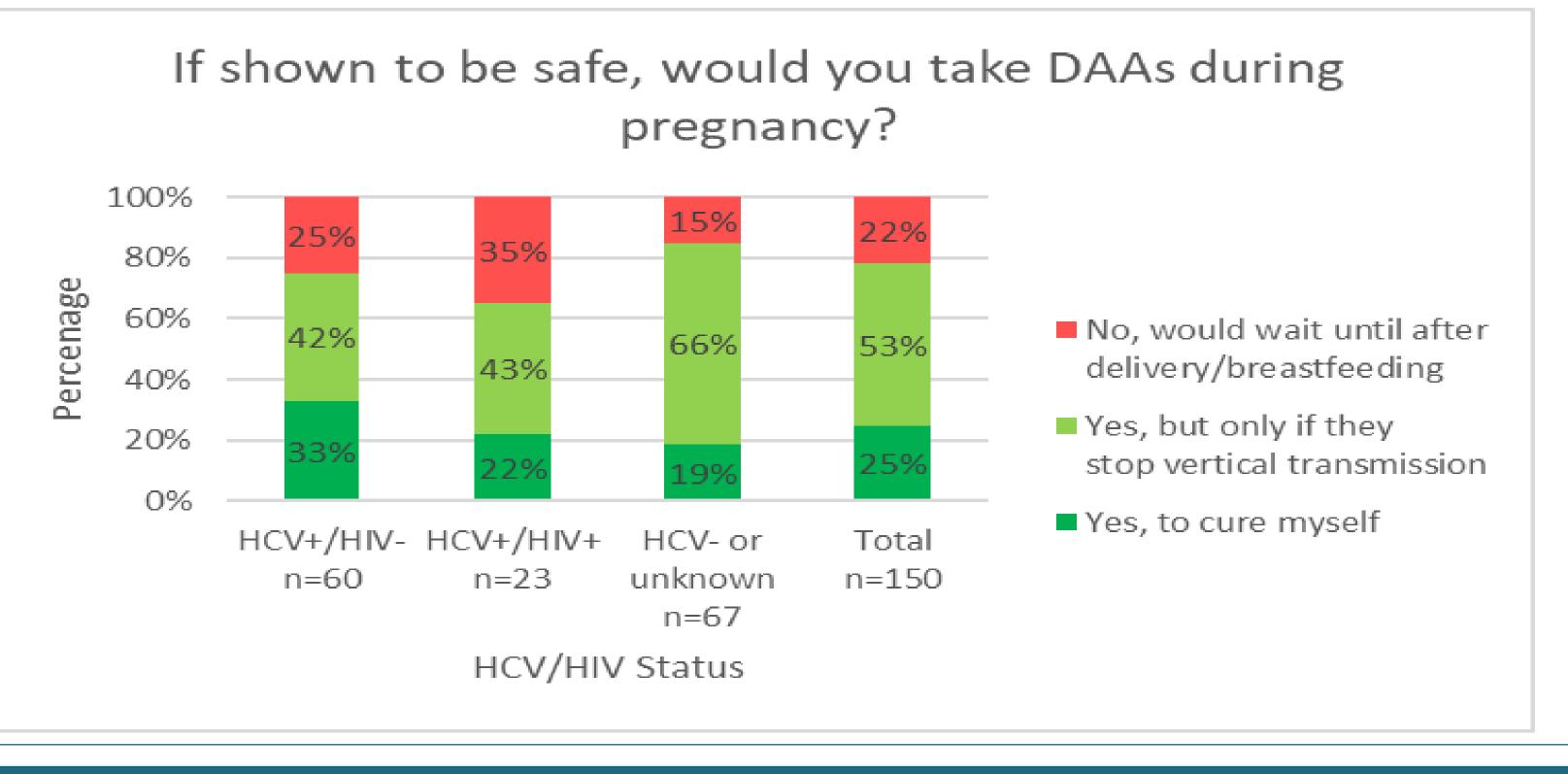


Figure 2: Acceptability of DAAs in pregnancy, if known to be safe



Conclusions

Funding

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Do you think all women should be offered free

Among pregnant and post-partum women in Ukraine, there was very high acceptability of universal HCV screening in pregnancy

Additionally, DAAs, if approved for use in pregnancy, were acceptable for maternal cure and/or prevention of vertical transmission

Acceptability of DAAs was high regardless of HCV/HIV status, but was highest (85%) among women without HCV or with unknown HCV status Phase II/III trials to evaluate the safety/efficacy of DAAs during pregnancy and breastfeeding are urgently required