

## 1 INTRODUCTION

- The prevalence of HCV antibody and HCV-RNA among Egyptian females aged 15-59 years is 8.1% and 5.5 % respectively<sup>1</sup>.
- Treatment of women of childbearing age (WoCBA) should be prioritized to minimize the risk of mother to child transmission (MTCT)<sup>2</sup>.
- Although pregnant females are excluded from DAAs treatment protocols, a minority may accidentally become pregnant while on treatment despite vigilant contraception.

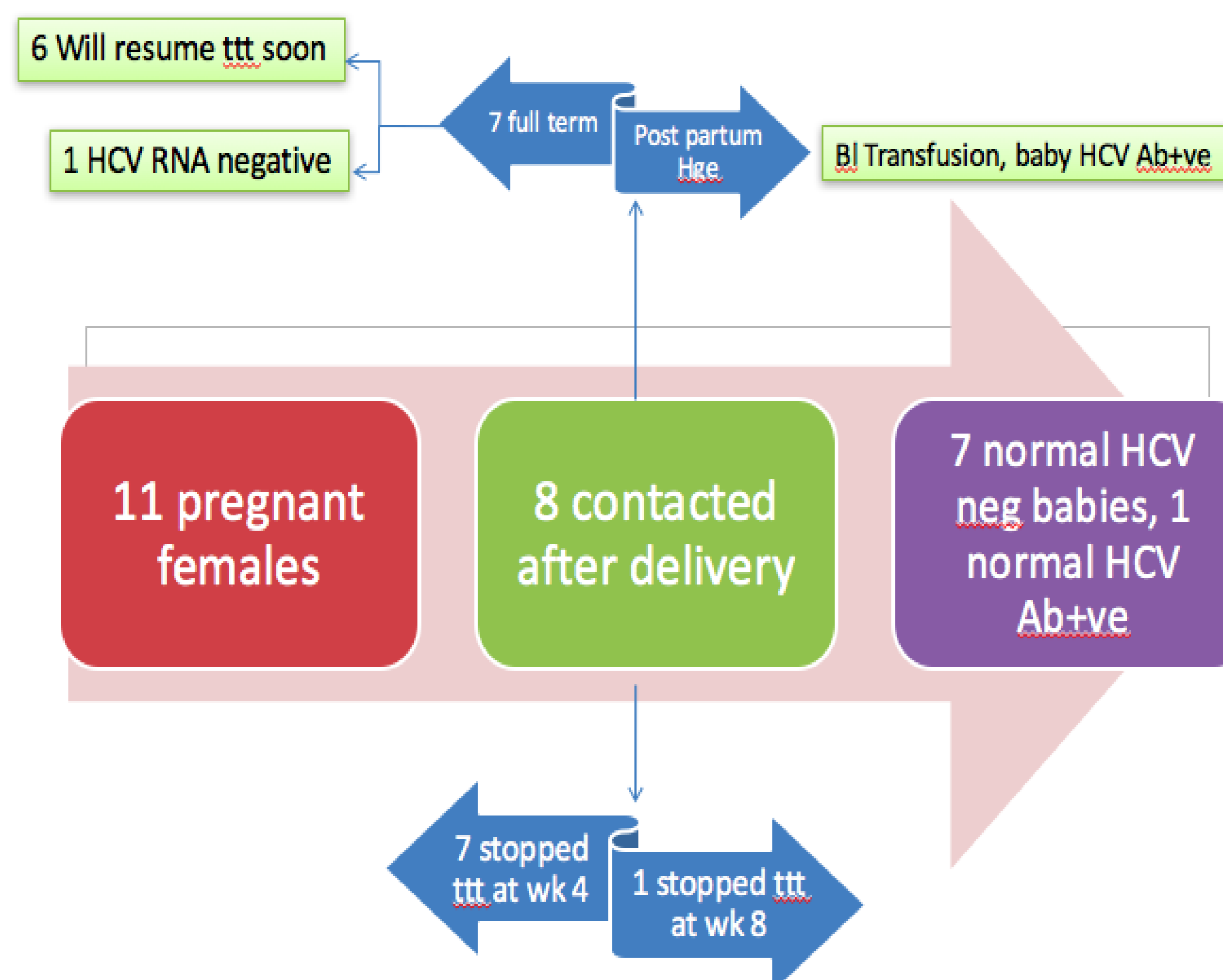
## 2 AIM

- We aimed to assess the pregnancy outcome in WoCBA with chronic HCV who accidentally got pregnant while receiving DAA therapy through the Egyptian national program for control of viral hepatitis.

## 3 METHODS

- This retrospective study included **58059** females in childbearing period (18-45 years) enrolled to receive DAA therapy between October 2014 and March 2016.
- Demographic, clinical and laboratory baseline data were collected in addition to, ultrasound assessment of the liver.
- **Pregnancy test** was confirmed negative for all WoCBA before starting therapy.

## 4 RESULTS



- The mean age of the studied group (WoCBA) was (37.16 ±6.31 years), 93.1% were treatment naïve and 10.7% were cirrhotic.

- **Sofusbuvir** and **daclatasvir** with or without ribavirin was the main treatment regimen in this group (80.6%) with 96.7% SVR.

- We report **11** of the WoCBA who commenced DAAs and discontinued treatment for accidental pregnancy. **Eight women** could be contacted and 3 were unreachable.

- All were naïve patients treated with SOF/DAC regimen for 12 weeks.

- **7** discontinued therapy at week 4; one discontinued SOF/DAC at week 8 (HCV-RNA negative and maintained SVR).

- **7** women reported full term non interventional deliveries of normal weight newborns with no congenital anomalies.

- One woman reported postpartum hemorrhage and received blood transfusion.

Baseline Characteristics Pregnant Women (n=11)

	Mean ± SD
Age yrs	29 ± 6
BMI	27 ± 3
ALT IU/L	49 ± 26
AST IU/L	45 ± 23
S albumin mg/dl	4 ± 0.2
HCV RNA IU/L (median) (Min-Max)	441500 (10000 – 6390000)
AFP ng/dl	3 ± 2
WBCs <sup>^</sup> 10 <sup>3</sup> μl	7 ± 2
HB g/dl	12 ± 2
PLT <sup>^</sup> 10 <sup>3</sup> μl	246 ± 67
INR sec	1.1 ± 0.2
Glucose mg/dl	88 ± 14
Fib-4	0.8 ± 0.3

- All **8** infants were tested for HCV antibodies at 18 months, only one was **+ve** with low viremia.

- All those women were advised to check HCV-RNA and restart treatment if proved positive.

## 5 CONCLUSIONS

- This is the first report of accidental pregnancy during treatment with Sofosbuvir and Daclatasvir (AU TGA Category B3)<sup>3</sup> with delivery of healthy infants with no congenital anomalies.
- Although one delivery was complicated by post partum hemorrhage it could not be linked to the DAA therapy.
- Only one clinical trial is registered for evaluation of safety of Ledipasvir/Sofosbuvir during pregnancy (category B) and efficacy in prevention of MTCT of HCV (NCT02683005).
- WoCBA with HCV infection should be prioritized in the cascade of care and treatment, while more data on the safety of DAAs during pregnancy is required to prevent MTCT.

## 6 REFERENCES

- 1- Egypt Health Issues Survey-The Demographic Health Survey Program 2015. <https://dhsprogram.com/pubs/pdf/FR313/FR313.pdf>
- 2- El-Sayed MH <https://easl-ilf.org/news/treatment-children-adolescents-essential-fulfil-whos-elimination-goals/>.
- 3-<https://www.drugs.com/pregnancy/daclatasvir.html>

## 7 CONTACT

**Manal Hamdy El-Sayed**

Professor of Pediatrics and Director of Clinical Research Center, Ain Shams University, Cairo, Egypt

[manalhelsayed@yahoo.co.uk](mailto:manalhelsayed@yahoo.co.uk)

