

New Treatment for HCV G4 Towards an End to HCV Epidemic in Egypt

Professor Gamal Esmat

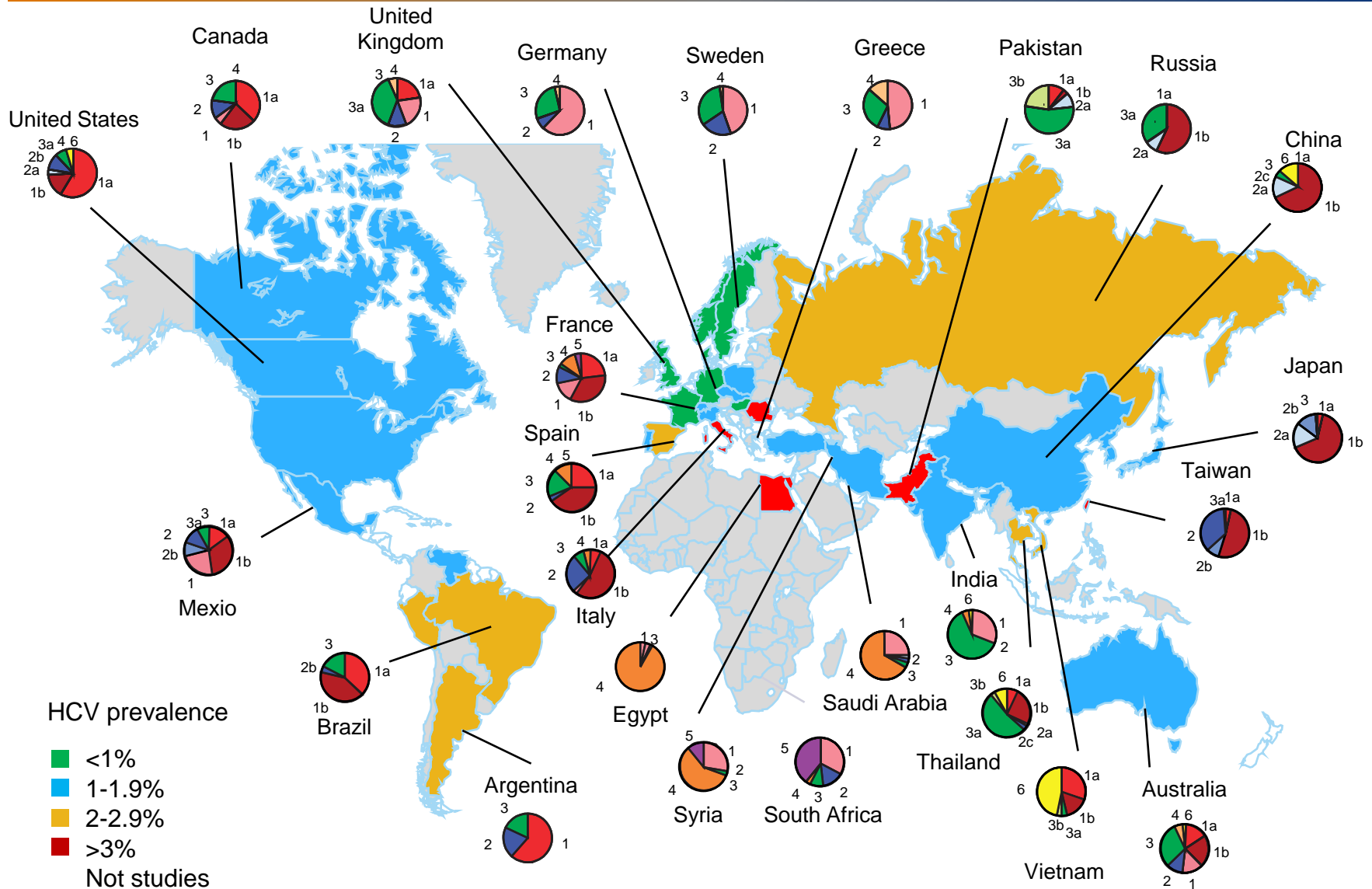
Cairo University Faculty of Medicine

Cairo, Egypt

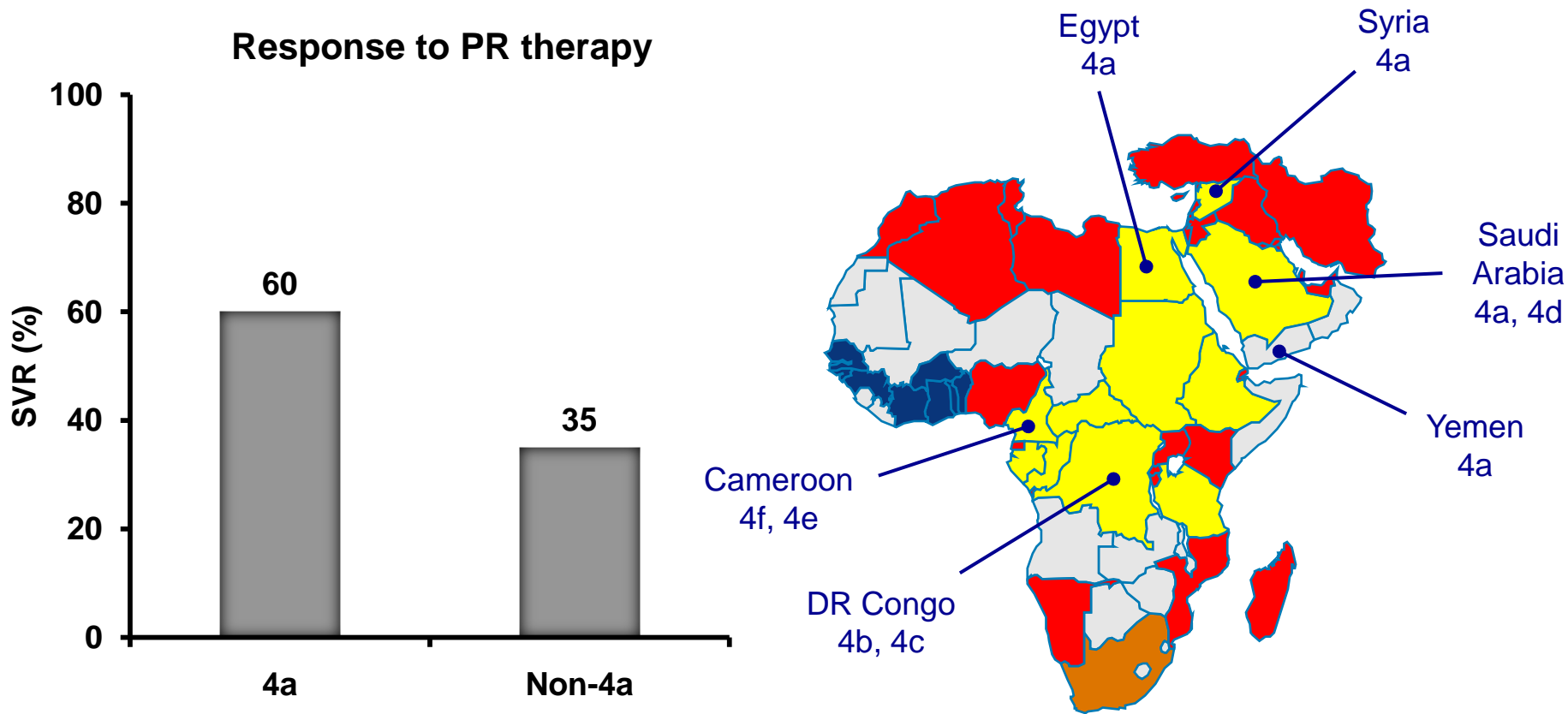
Genotype 4

- HCV genotype 4 accounts for approximately 15% of all cases of chronic HCV worldwide
- Genotype 4 predominates throughout the Middle East and parts of Africa, often in association with a high population prevalence, such as in Egypt
- More than 90% of Egyptian HCV isolates belong to genotype 4
- Phylogenetic analysis of the complete genomic sequence of genotype 4 revealed a closer relationship between genotype 4 and genotype 1 than with other genotypes

Global genotype distribution



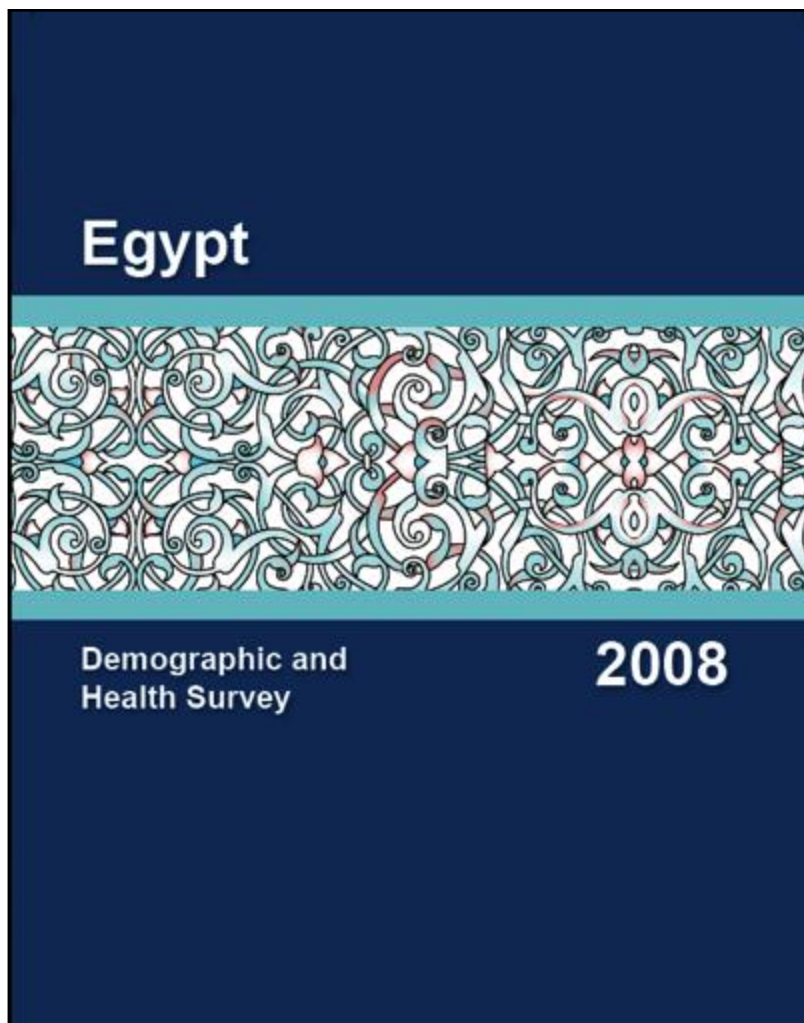
Genotype 4 subtypes



Genotype 4 subtypes respond differently to Peg-IFN/RBV therapy

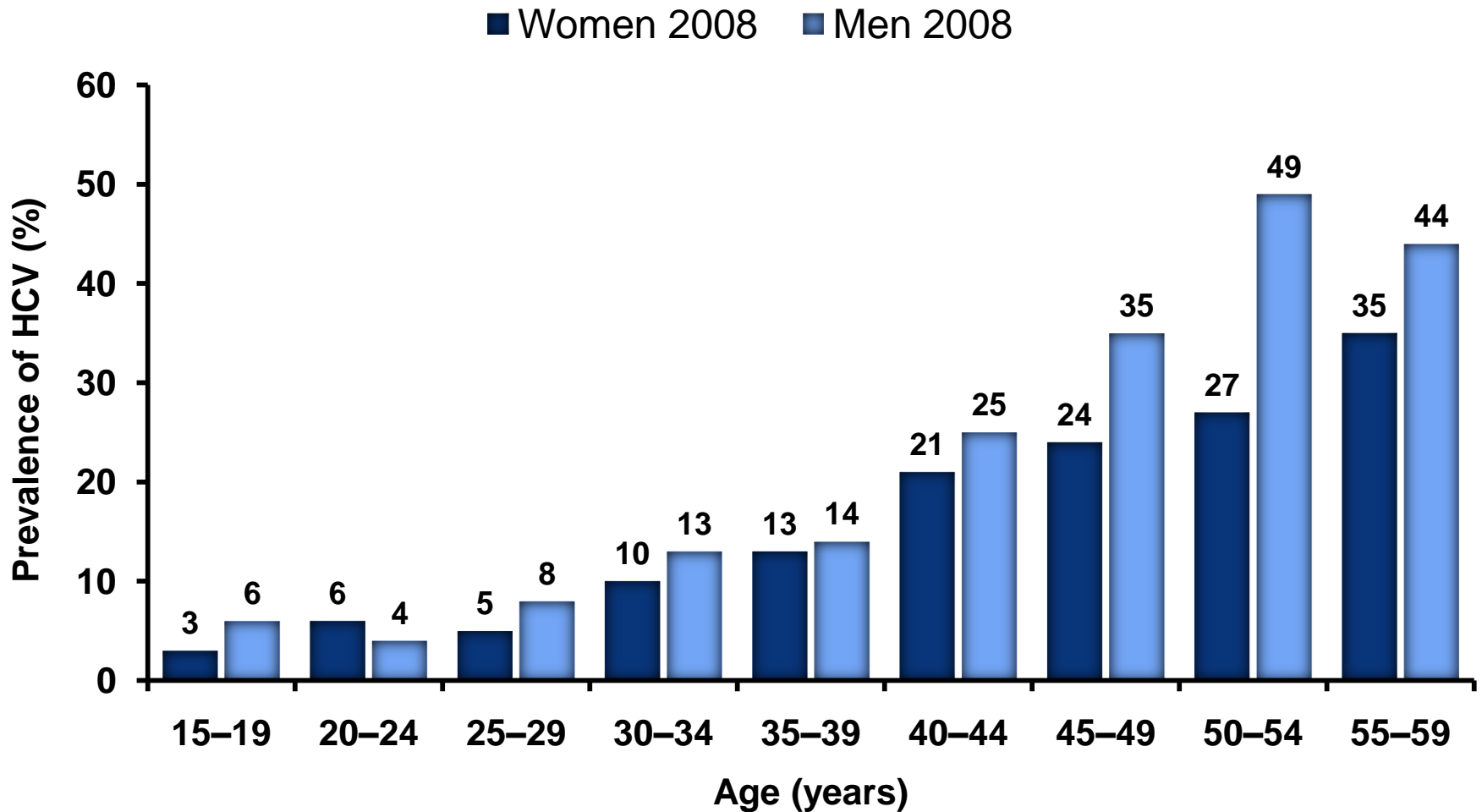
The impact of genotype 4 subtype on the response to DAA therapy is not yet known

Prevalence of HCV in Egypt



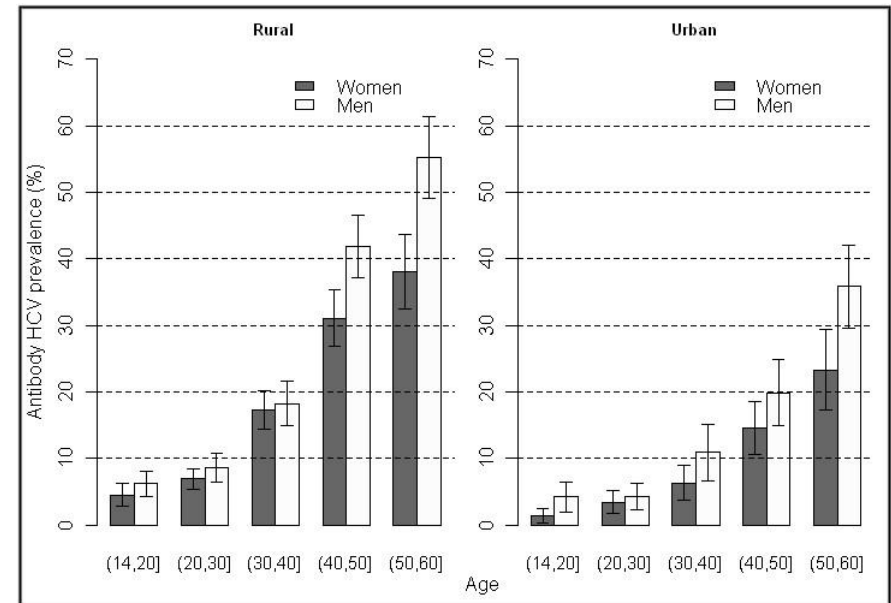
Socioeconomic characteristic	HCV antibody positive, %
Urban-rural residence	
Urban	10.3
Rural	18.0
Place of residence	
Urban Governorates	9.5
Lower Egypt	17.5
<i>Urban</i>	11.8
<i>Rural</i>	19.3
Upper Egypt	14.7
<i>Urban</i>	10.9
<i>Rural</i>	16.4
Frontier Governorates	3.8
Education	
No education	24.0
Some primary	20.4
Primary complete/some secondary	11.5
Secondary complete/higher	10.5
Wealth quintile	
Lowest	18.6
Second	17.1
Middle	16.4
Fourth	11.6
Highest	10.2
Total	14.7

Prevalence of HCV in 2008

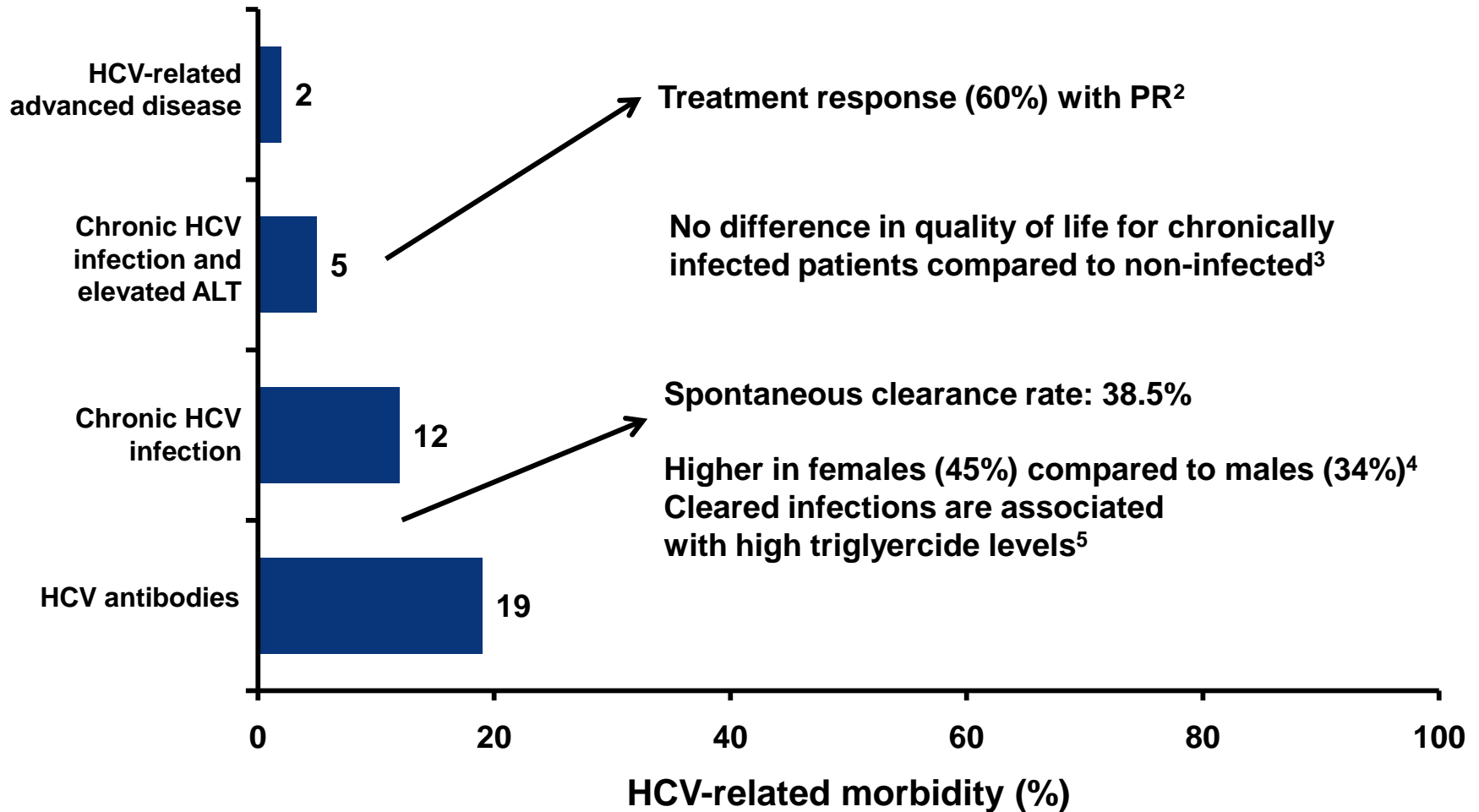


HCV burden in Egypt

- HCV antibody prevalence: 14.7%
- Overall HCV viremia: 9.94%
- 8 million Ch HCV
 - >90 are genotype 4
- Estimated 150,000 new infections per year



HCV-related morbidity among adults in Zwyat Razin (N=2425)¹



1. Mohamed MK, et al. J Med Virol 2006;78:1185–9; 2. Males S, et al. Antivir Ther 2007;12:797–803

3. Schwarzinger M, et al. Hepatology 2004;40:1434–31; 4. Bakr I, et al. Gut 2006;55:1183–7

5. Marzouk D, et al. Gut 2007;56:1105–10

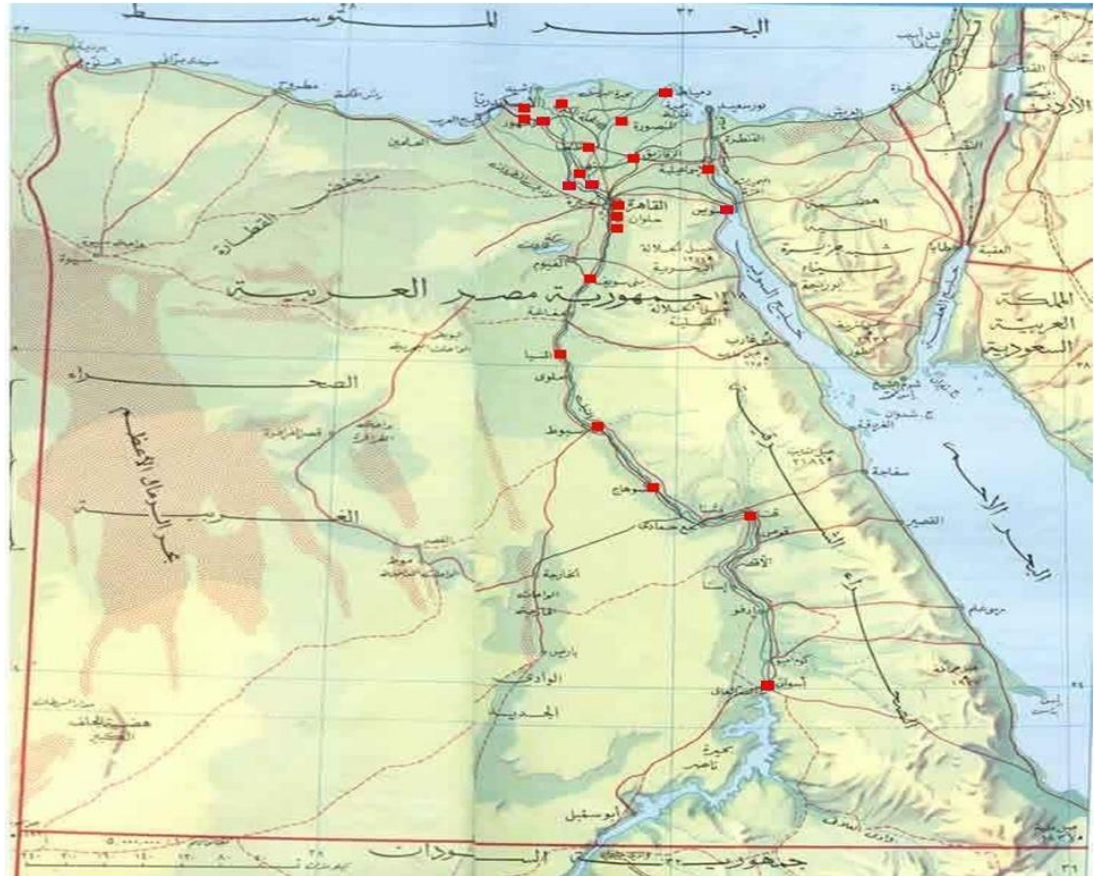
23 national treatment centres opened between 2007–13

EGYPTIAN NATIONAL CONTROL STRATEGY FOR VIRAL HEPATITIS 2008-2012



April 2008

Arab Republic of Egypt, Ministry of Health and Population
National Committee for the Control of Viral Hepatitis

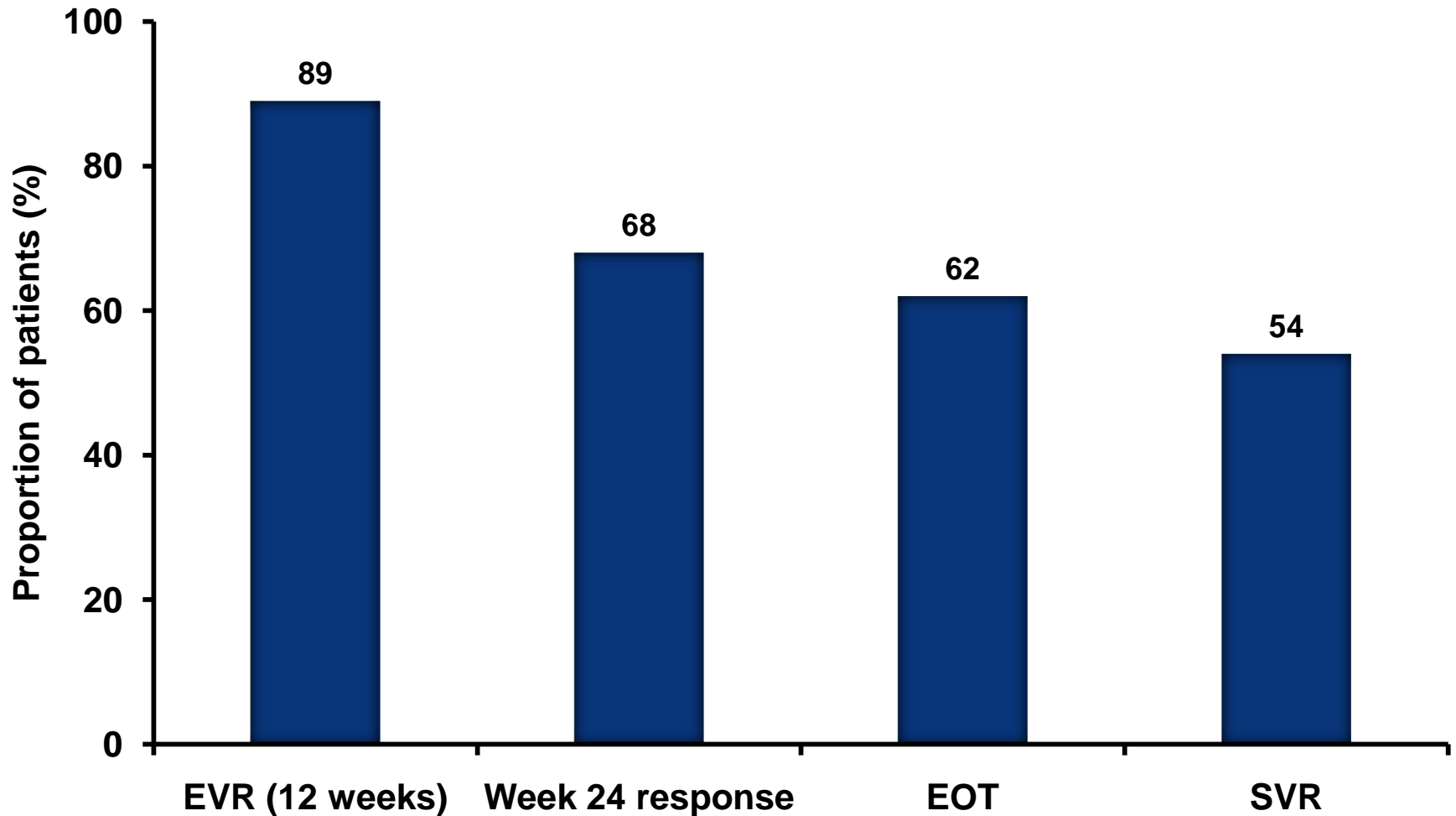


Total number of patients treated with Peg-IFN (2007–13): **350,000**

Annual number of new patients treated: **45,000**

Annual budget from the Ministry of Health: **\$90 million**

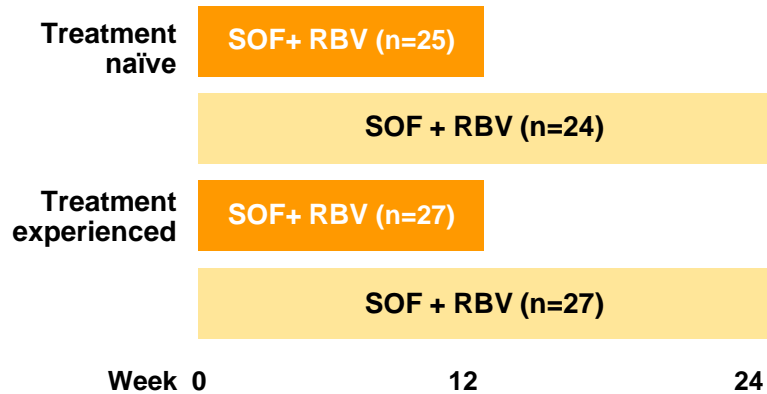
National HCV Treatment Program: response rates of treated patients



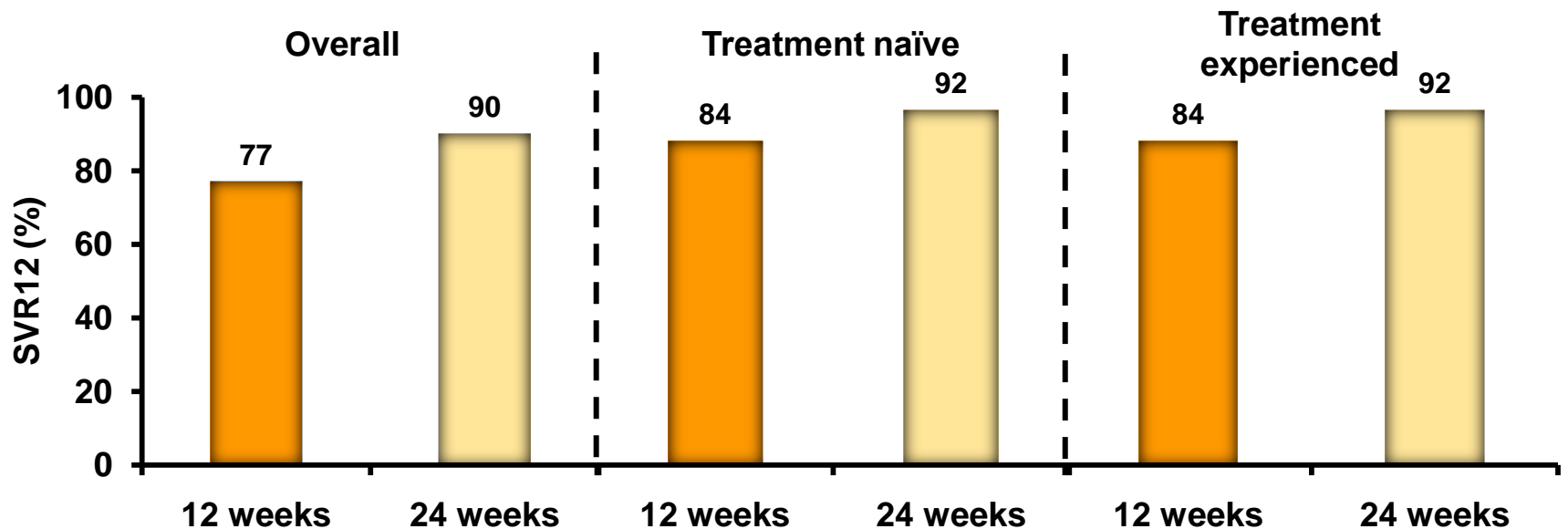
National HCV Treatment Program: positive outcomes

- Governmental appreciation of the magnitude of HCV problem in Egypt
- National guidelines for treatment of chronic HCV
- Ministry of Health and universities cooperation
- Treatment for more than 350,000 patients
- >90% governmental funding
- Data to answer a lot of questions

IFN-free therapy in HCV genotype 4 in treatment-naïve and -experienced patients



- Randomized, open-label, multi-centre study conducted in Egypt of the safety and efficacy of all-oral SOF + RBV in Egyptian patients with HCV GT 4, 103 patients
- SOF 400 mg + weight-based RBV dosing (1000–1200 mg)
- Male (67%), cirrhosis (17%), 52% high viral load (>800,000 IU/ml), *IL28B* non-CC (81%)

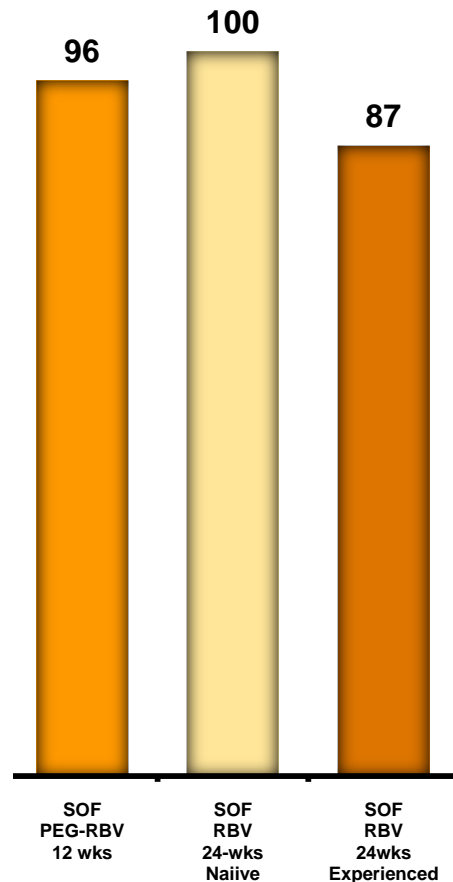


Naïve patients, with \leq F2 Fibrosis, low viral load (<600,000 IU/mL): 100% SVR with 12 weeks treatment

Resource-limited settings: the Egyptian example



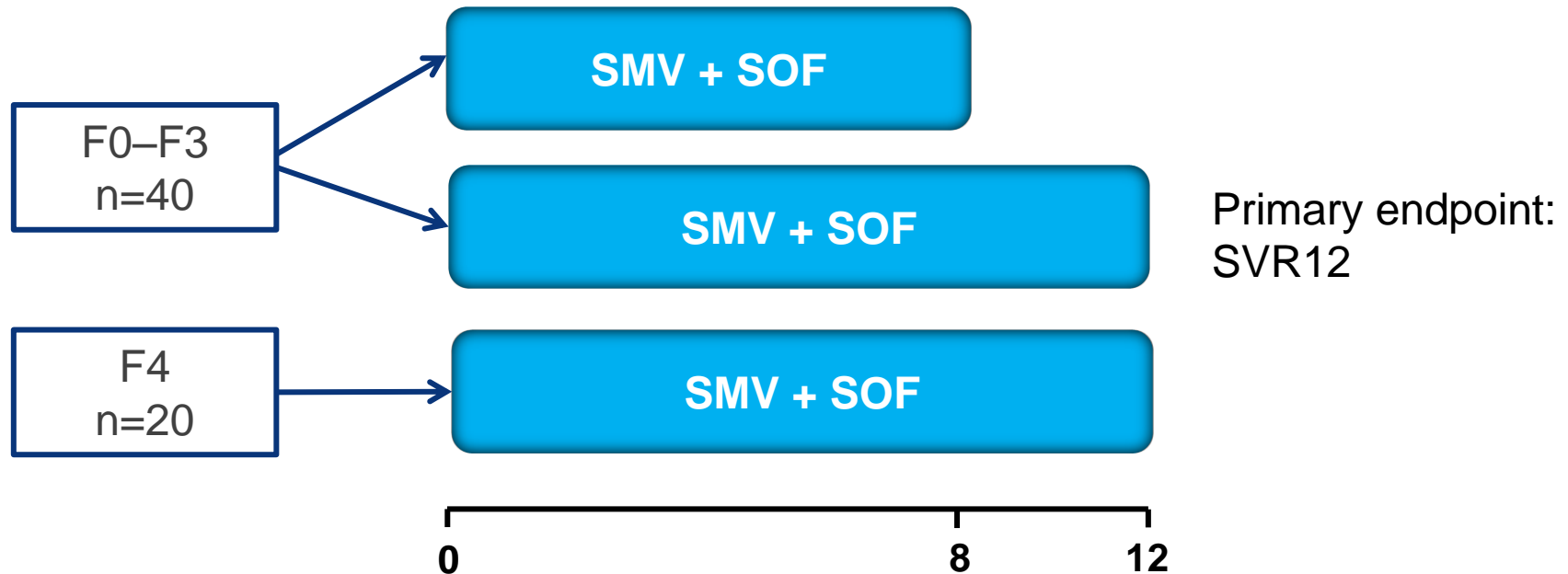
- Currently: SOF based therapy
 - SOF-PEG-RBV 12 wks for IFN eligible patients
 - SOF-RBV 24 weeks for IFN-ineligible patients
- Total estimate 6-7 Mill 95% G4
- Gilead access program reduced cost drastically
- National treatment program started October 2014



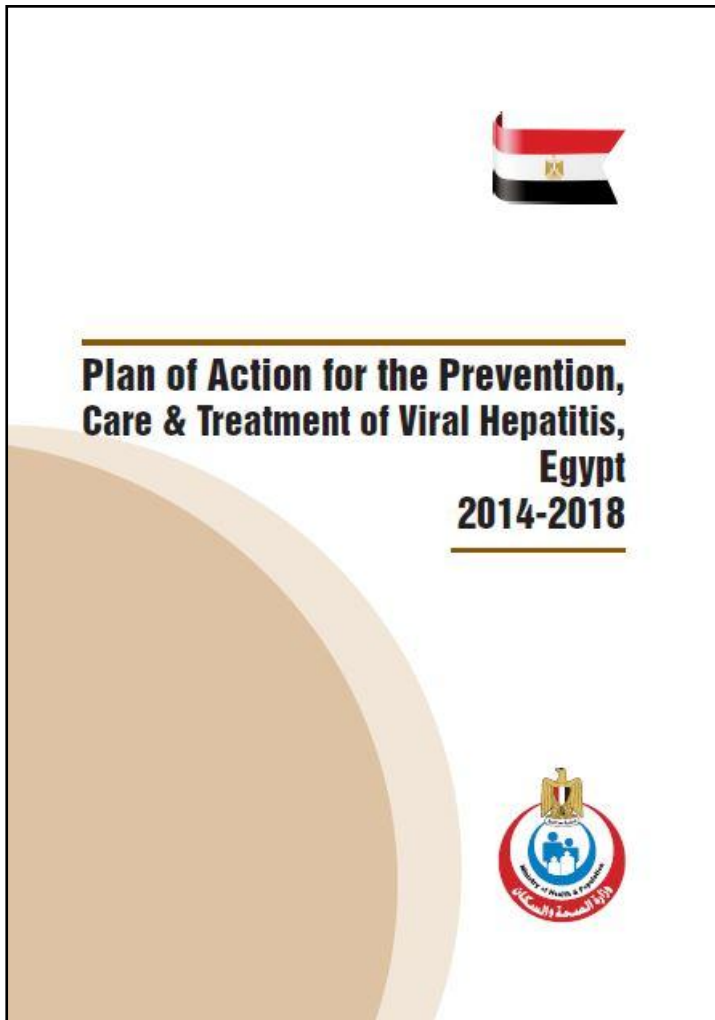
- 738,000 registered for evaluation
- Of them 202521 were evaluated
- In 2014
 - 40,000 F3 and F4 selected for treatment 20%
 - 15,000 started treatment,
 - 33% SOF+PEG-RBV
 - 67% SOF+RBV
- Of those who reached Week 4
 - 99% >2 log₁₀ reduction in viral load
 - 82% RNA <LLQ (<15 IU/ml)
 - 81.3% SOF-RBV
 - 83.3% SOF-PEG-RBV

OSIRIS: SMV + SOF in genotype 4 HCV infection in treatment-naïve and treatment-experienced patients (N=60)

- Phase 2, partly randomized, open-label, multicentre study (Egypt)



National Plan of Action: conclusions



- Increase policymakers' commitment to supporting the policy change necessary to prevent viral hepatitis transmission.
- Educate healthcare workers to prevent transmission of viral hepatitis in Egypt.
- Increase public awareness of viral hepatitis prevention.
- Promote safe injection practices in the community.

Mass treatment: improving access to therapy in Egypt

- Availability of other DAAs in Egypt with a reduced price like sofosbuvir
- Implication of national program for HCV screening
- Increasing the treatment centers to be more than 50 centres this year
- Simplification of the treatment guidelines aiming for faster evaluation and less investigations
- Extension of treatment to F2 defined as:
 - Previous LB with >F1
 - Fib4 >2.5
 - Fibroscan > 8
- Raising fund from NGOs for evaluation and treatment of HCV patients