Access to Innovation: Hepatitis C and the Egyptian National Experience

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(EGYPT)

Stepwise Solution for LMIC
(Real Life Experience)

- Data and Situation analysis
- Strengthen Surveillance systems
- Knowledge, Awareness and Empowerment (Public, HCWs, Scientific Associations, Philanthropic organisations, NGOs, Politicians, other Stakeholders)
- Government Advocacy
- Development of National Strategies & implementation
- plans
- Improve access.

Situation of HCV in Egypt before 2006

Level 1

Prevalence

- First national viral hepatitis survey in 1996
- Other epidemiological studies

Blood Safety

- Screening of blood for HCV started -1992 (ELISA)

PCR done in Central Banks

- First guideline developed

Surveillance and IC

- National Surveillance system established (1999)
- Assessment of IC policies and first guidelines 2004

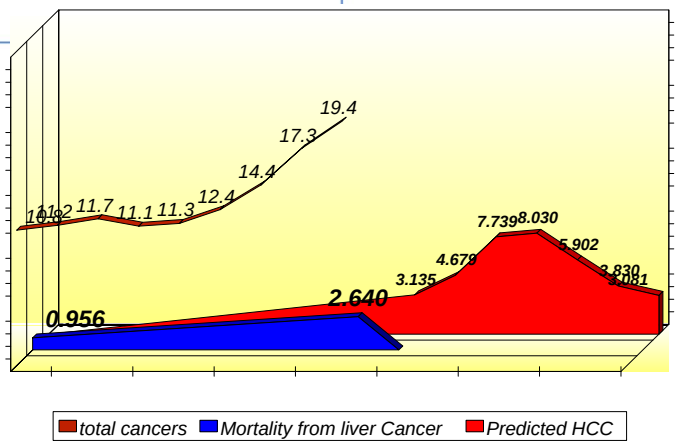
Treatment

-Liver Disease mortality > 40,000/year with increasing HCC

-Treatment not offered by the Government

Vaccination

- HBV vaccination at 2,4,6 months age since 1992
- HCWs and high risk population groups not vaccinated



National Committee for Control of Viral Hepatitis (Established in 2006)

Level 2

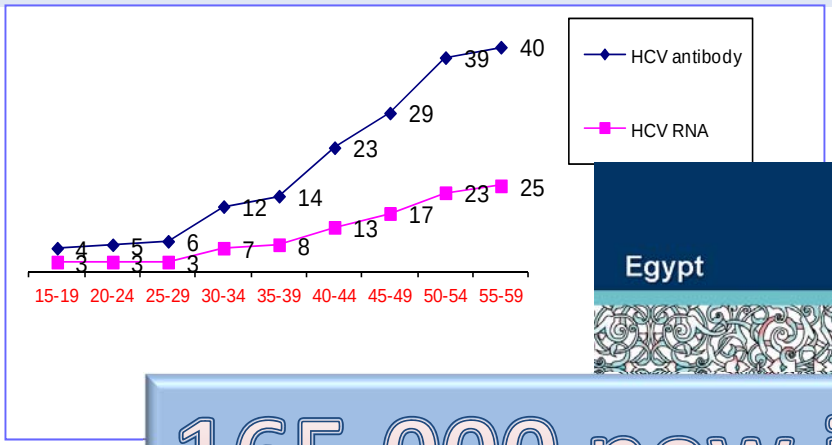
- Targets
  - National Survey & Burden of Disease
  - Develop a National Strategy
  - Treatment Program
  - Prevention
    - Awareness and media Campaign
    - Infection control
  - Clinical Research
  - Management of advanced liver disease (ALD)
- Outcome
  - HCV testing integrated in DHS survey 2008
  - National Strategy published 2008
  - Successful treatment program
  - Limited to university campaign vaccinating 30,000 against HBV
  - IC remained fragmented
  - Research ongoing
  - Management of ALD

Situation Analysis

- 9.8% of population (15-59 Yrs) are chronically infected with Hepatitis C (highest prevalence in the world), in addition modeling projects that 150,000 new cases occur every year.
  - Transmission occurs mostly during medical procedures including unsafe injection.
  - 281 M injections every year, 23 M are considered unsafe (8%)
  - Average number of injections per person/year is 6.8 compared to 2.88 (global)
  - 4.9 needle stick injury/HCW compared 1.2 (global)
  - Informal injection providers contribute to the problem of unsafe injection.

Highlights until 2013

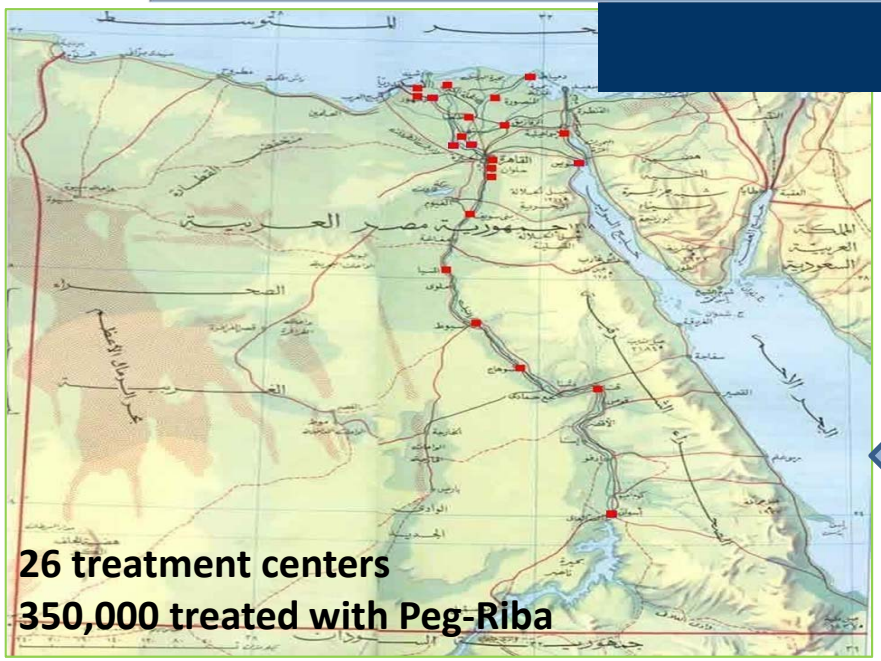
EGYPTIAN NATIONAL CONTROL STRATEGY FOR VIRAL HEPATITIS 2008-2012



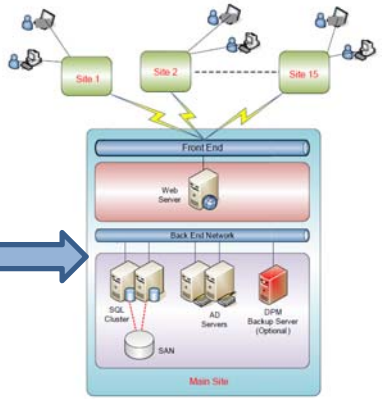
April 2008

Arab Republic of Egypt, Ministry of Health and P
National Committee for the Control of Viral He

165,000 new infections per year



26 treatment centers
350,000 treated with Peg-Riba



Database networking

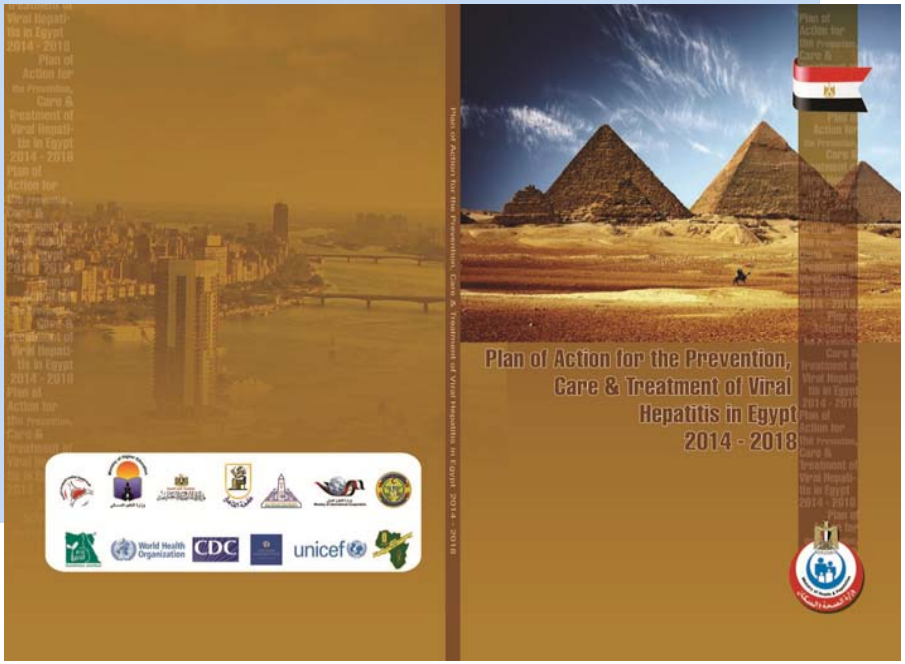
Key to Success in the Continuum of Care in LMIC

(Real Life Experience)

Developments 2011 through 2014

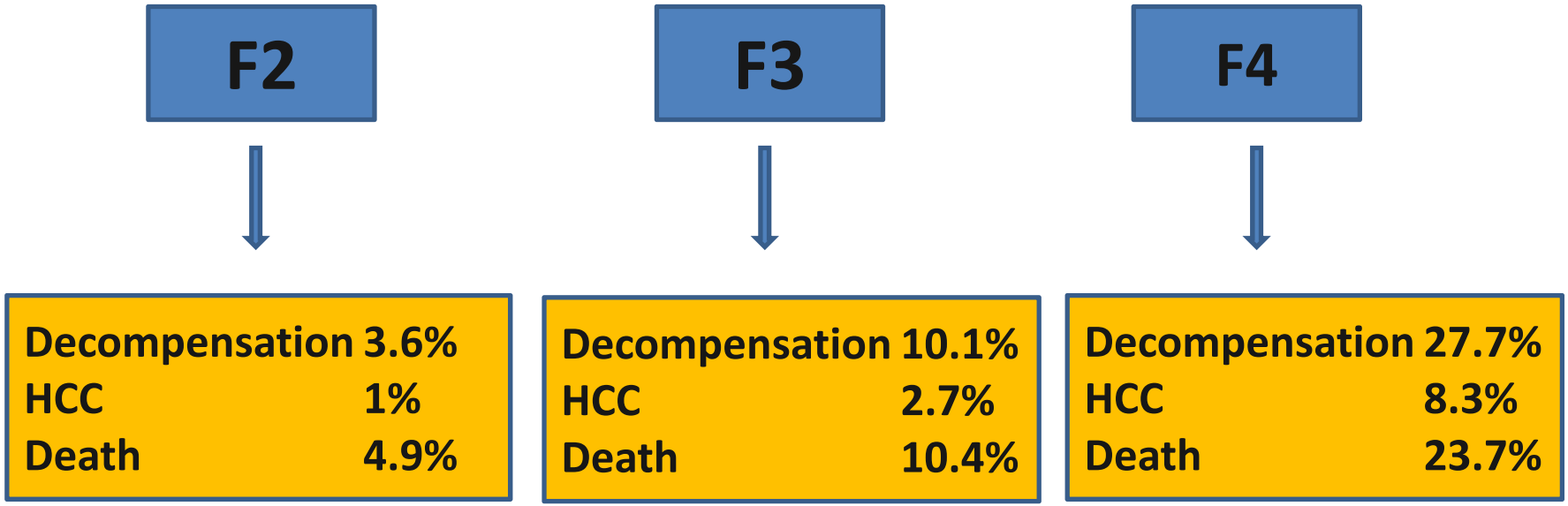
Level 3

- Treatment
  - Clinical trials with DAAs (GT4)
  - Negotiations & registration of Sof 2014
  - Web-based national patient enrolment for DAA treatment (>1.1 million so far)
  - First patient started treatment Oct 16th
  - Other DAAs introduced in 2015
- Prevention
  - Action plan launched Oct 2014
  - Components (Surveillance, IC, Blood safety, Vaccination, IEC, Screening, care and treatment



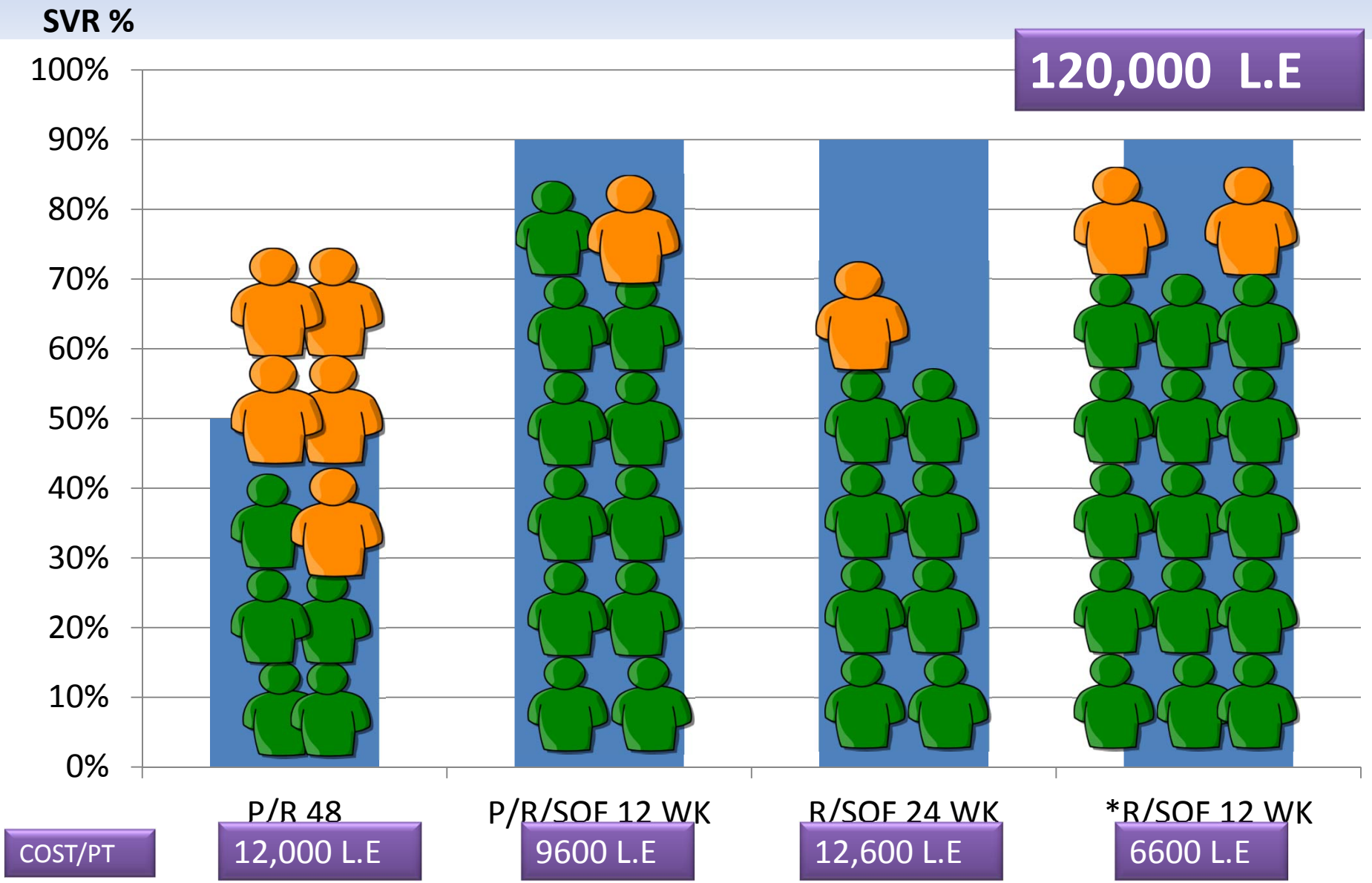
What Happens Without Therapy?

4 years follow up of 2120 patients



Fried M, AASLD 2014
Saleem M AASLD 2014

Cost Effectiveness Chart



*NAÏVE, NON CIRRHOTIC, LOW VIREMIA,

Flow Chart for the Treatment Procedure

Appointment

Evaluation clinic

Physician (checklist)

Enrollment sheet

Data entry from centers

Realtime data in NNTC

Final Decision Regimen

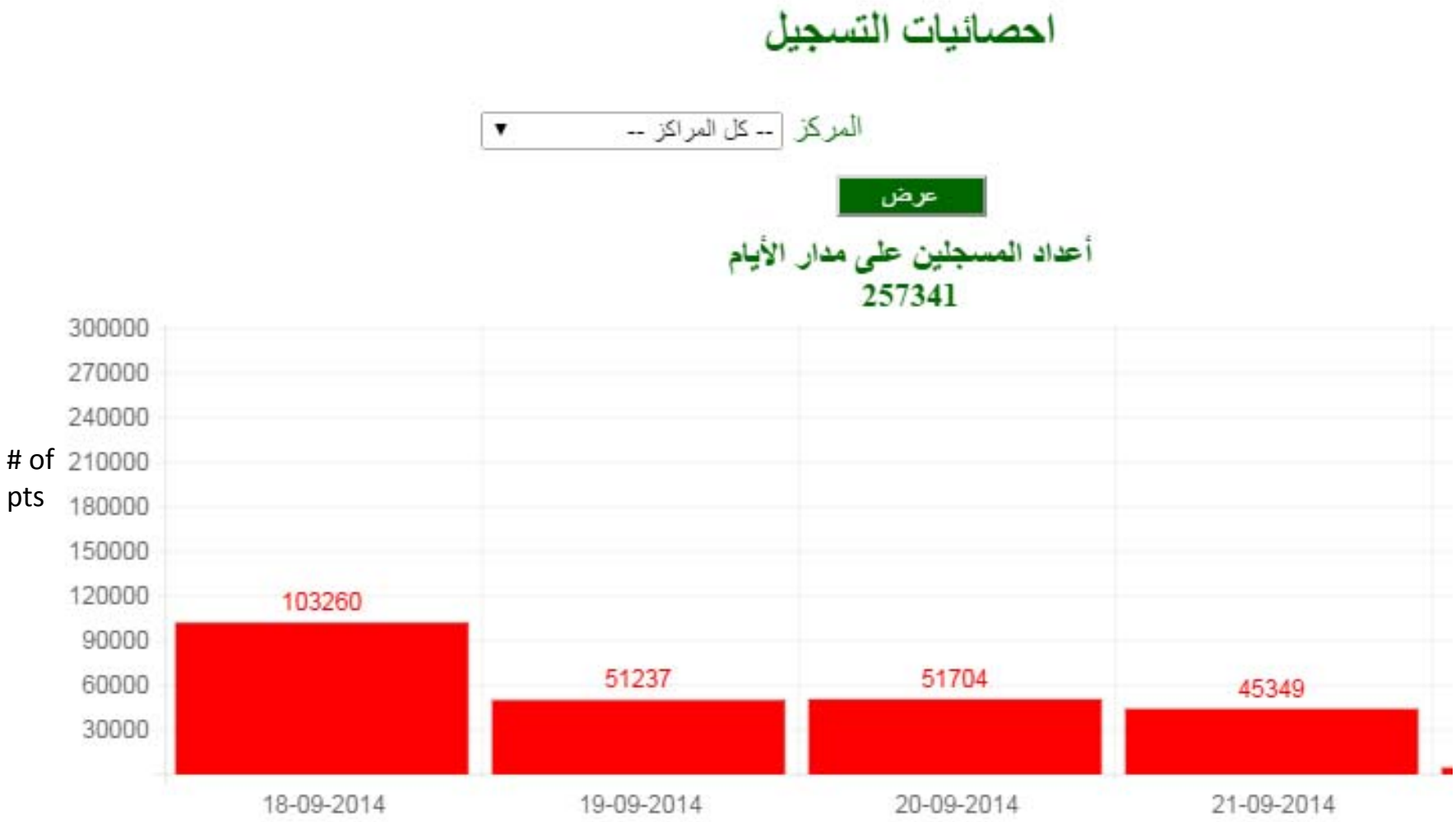
Decision sent online

Start ttt, FUP sheet

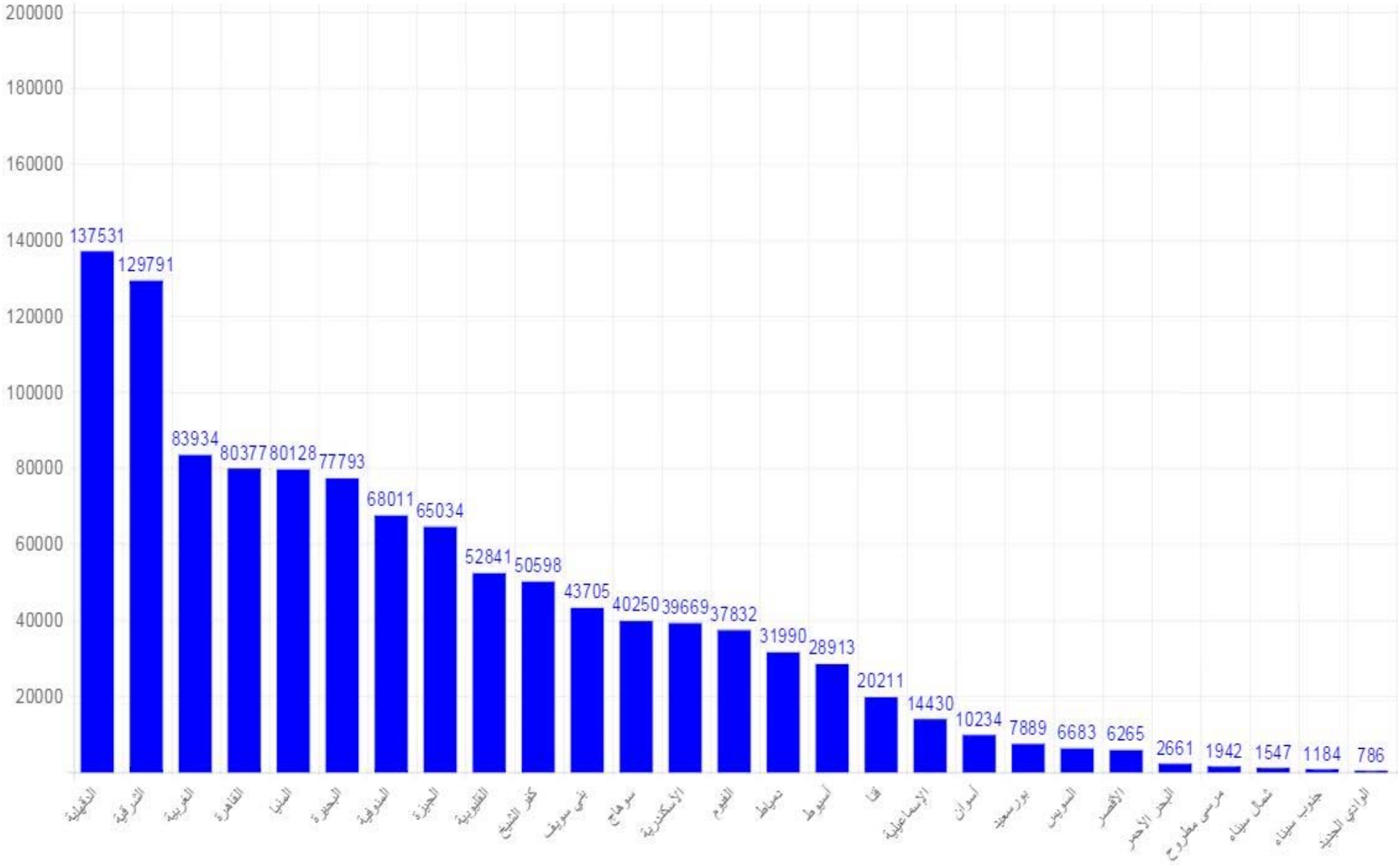
Online registration system

Registry data first 4 days

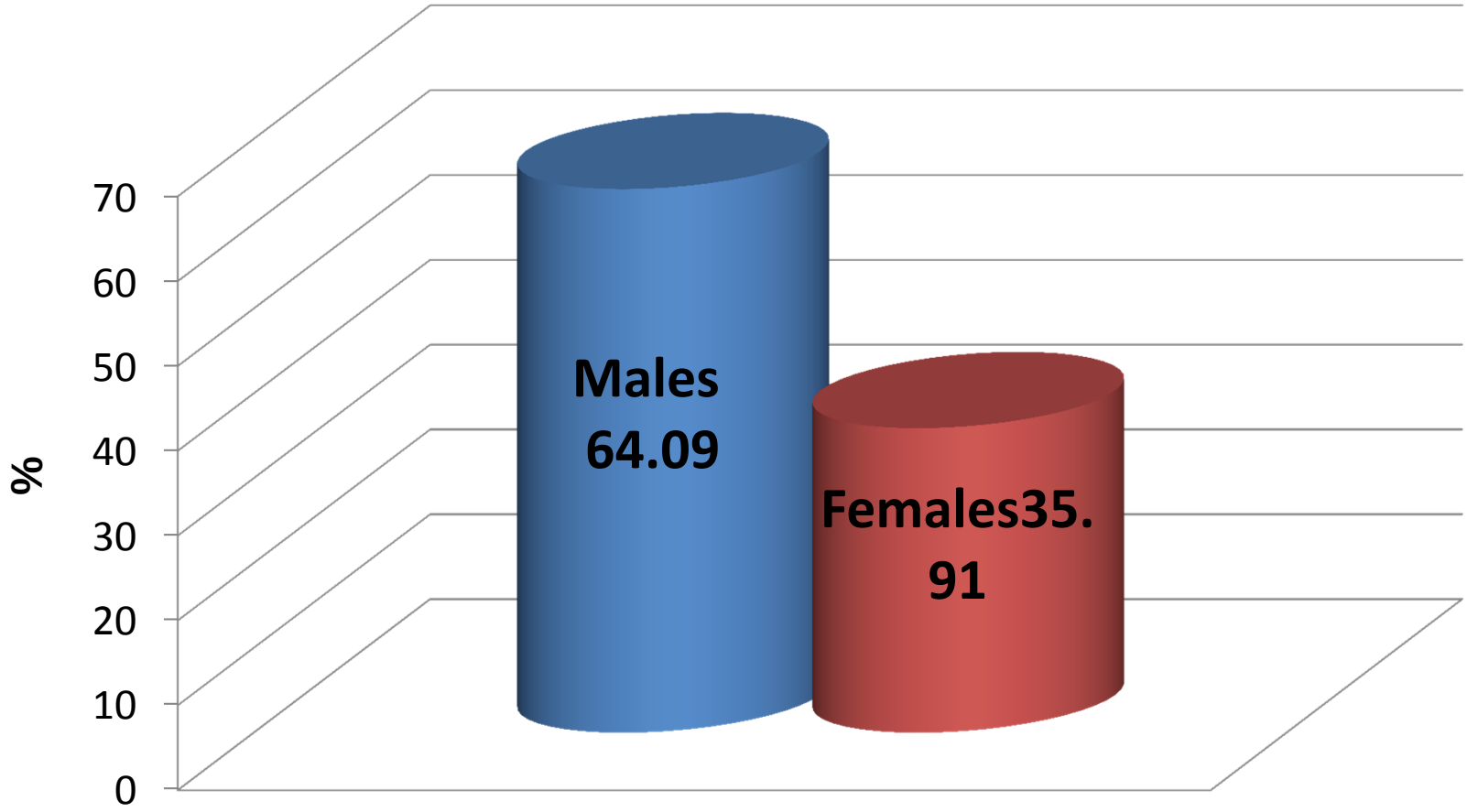
Sep 28th 2015 (1122229 registered)



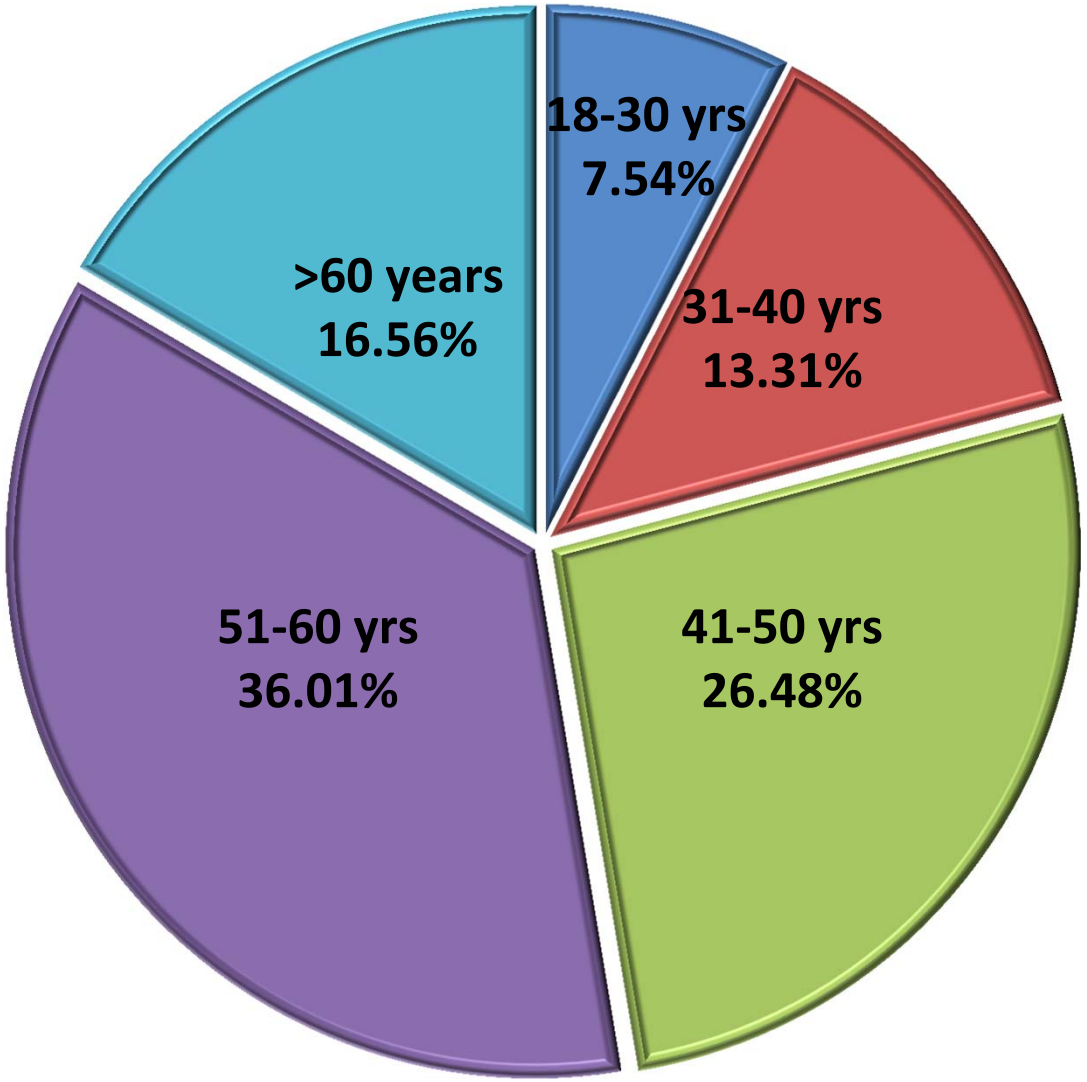
Registration according to Governorate



Gender Distribution (%)

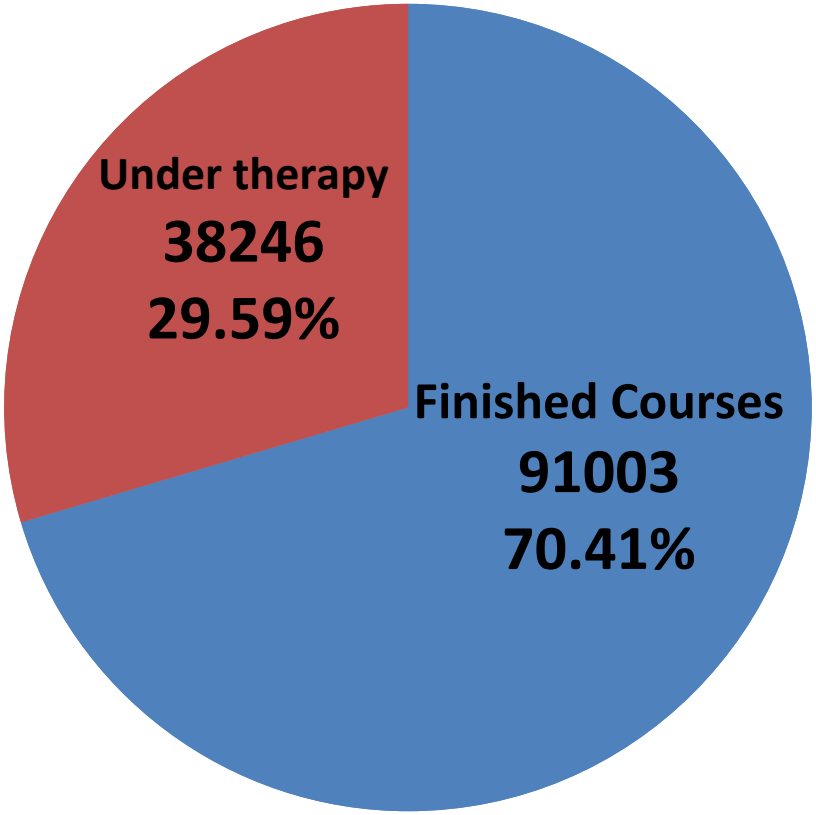


Age Distribution (%)



Number of patients on DAAs since October 2014

129.249



Antidiversion Plan

- Patient QR code Encrypted

PE:nk»Îhó~j#B`«ý7!%ÃÛA*Ó&ý£ÊfRúÍÜî T±;6ü<FMçà»®=\Ûìû^Ñv-á]ÌôÄÆ$àI»±ÊÈ¶\±¾#§¹Æt&ñb1èË#'³ñ?P zk1íOt£Uèò¼VÙs)µ;jzy³U2Fìú +½T;

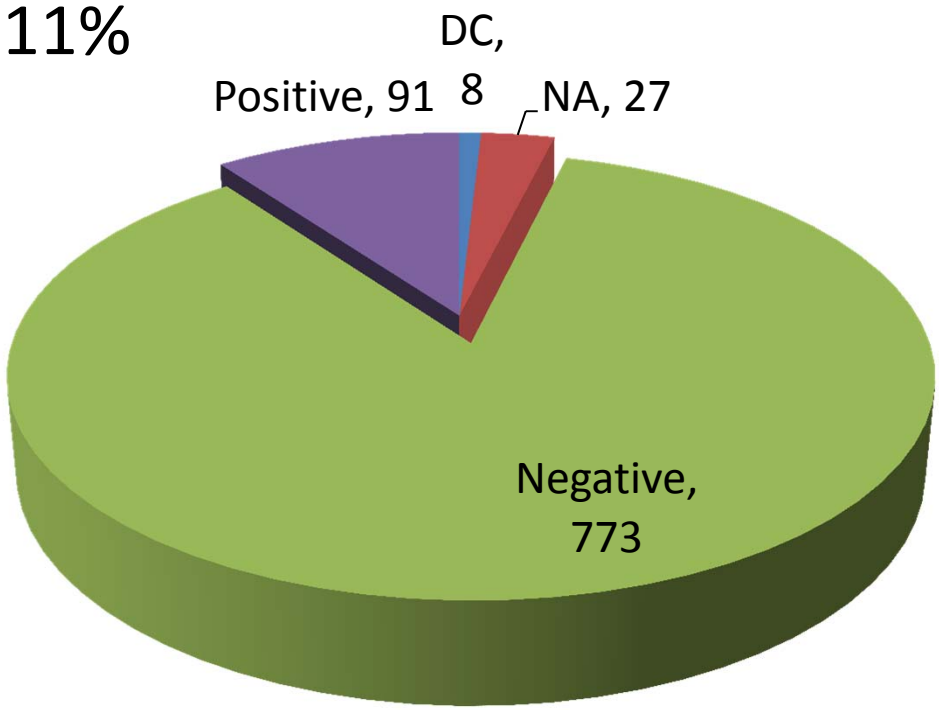
- Patient QR code Unencrypted

Patient Name: Mohamed Fawzy
Patient Address: 20 Salah Salem Street, Heliopolis,Cairo, Egypt
Invoice date: 01/08/2016
Invoice Number: 6375627
Bill to Party: National Liver Institute in Cairo
Payer: Ministry of health
PCR count: 6575778
Product Name: Sovaldi 400MG
Product Code: 255363
Batch Number: AB 3223
Expiry Date: 01/08/2018

899 patients started triple therapy
Before 1/1/2015

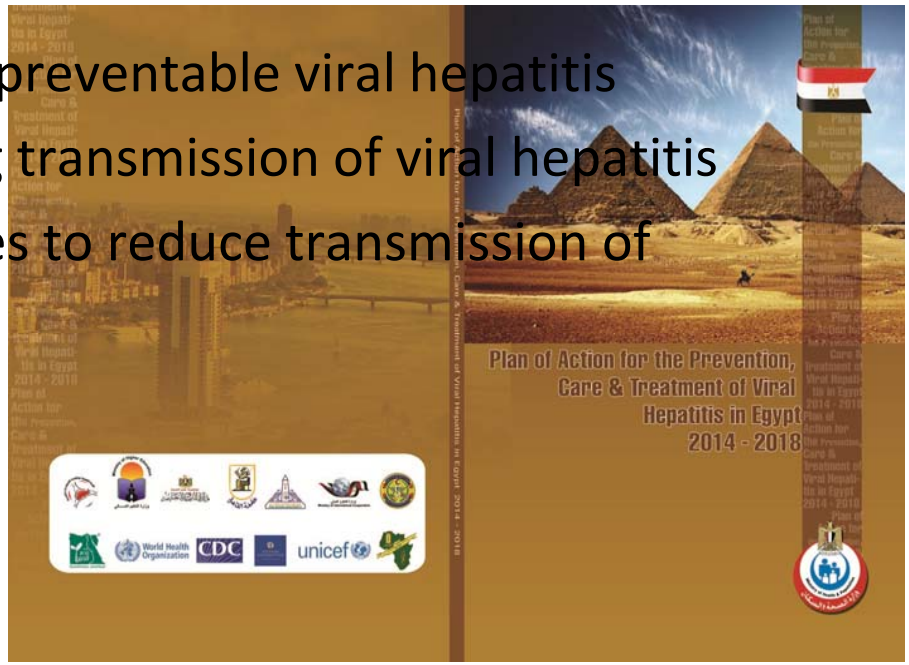
Relapse rate 11%

SVR 86%



Components of the Viral Hepatitis Action Plan

1. Strengthening surveillance to detect viral hepatitis transmission and disease (acute and chronic)
2. Promoting Infection Control Practices to Reduce Transmission of Viral Hepatitis
3. Improving blood safety to reduce transmission of viral hepatitis
4. Eliminating Transmission of vaccine-preventable viral hepatitis
5. Role of care & treatment in reducing transmission of viral hepatitis
6. Educating providers and communities to reduce transmission of viral hepatitis
7. Research Agenda for Viral Hepatitis



Access to Diagnosis & Prevention
(Current Activities)

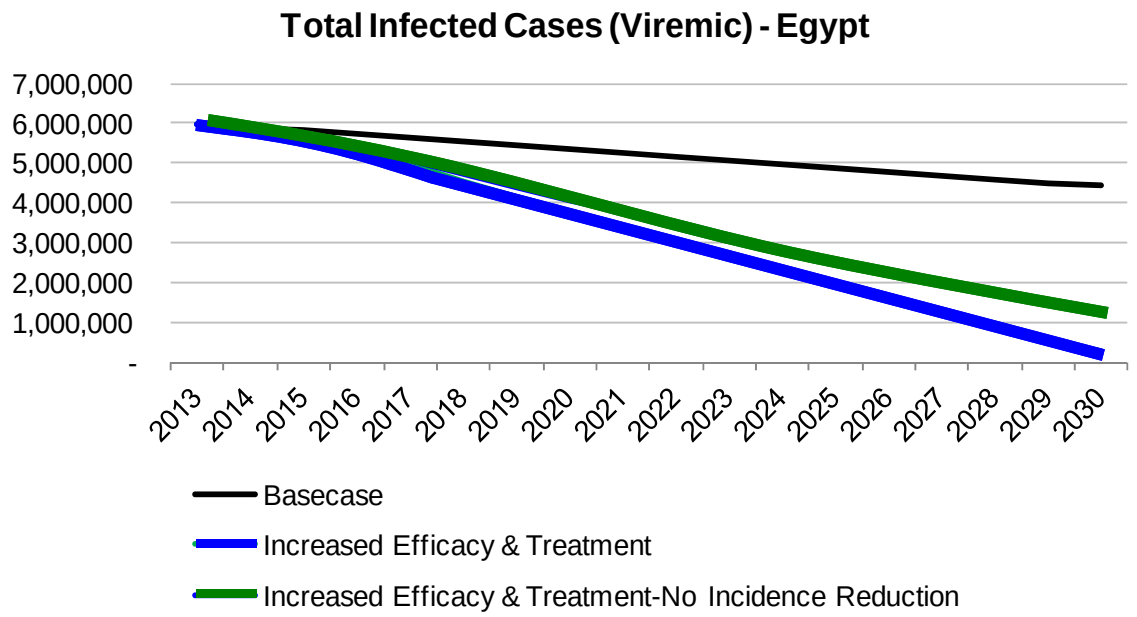
Level 3

- Undergraduate practical infection control course (Didrot University/Claude Bernard)
- Postgraduate phlebotomy practical courses
- **Tech transfer for safety engineered devices**
- Introduction of HCV core antigen (improve blood safety)
- Injection safety and Media awareness campaigns
- Aswan and Suez Canal area demonstration models
- National Screening Program (HCV-RNA prevalence 15-59 years dropped to 7%)
- Phasing population-based screening

Financial Structure

- Self sustained infrastructure for personnel, IT and data management, administration..etc
- Patients' treatment support (Government expenses, national insurance, cash and philanthropic organisations)
- Prevention (limited resources): IC, Blood Safety, Vaccination, IEC…(Governmental and non-governmental and other stakeholders)

Proposed VH Control Strategy for Egypt (Control to Elimination)



	2014	2030	
Base Case	6,000,000	4,420,000	-26%
Increased treatment & SVR, reduce incidence		285,000	-95%
Increased treatment &SVR, without incidence reduction		1,250,000	-79%

Wedemeyer et al. JVH, In Press

HCV Control to Elimination (90/90/90)

Prevention and Cure

(10-15 years plan)

All Egyptians offered safe blood, injections and health services	>90% Access Diagnosis	>90% Access to Treatment	>90% Cured

Scaling up the continuum of care and treatment (12 months)

- Scaled up nationwide treatment centers from 26 to 44 in different Governorates
- Updating guidelines 6 monthly
- >1000 HCWs trained in specialised liver units
- Capacity building for data management
- Increased numbers treated from 60 to 130,000
- Registration of all approved DAAs
- Improving diagnostics and planned stepwise screening program
- Injection safety program with tech transfer

Short term Achievables and Challenges

Level 3

Immediate implementation

- Scaling-up treatment
- Capacity building for a sustainable program
- HBV birth dose implementation
- Strengthening all components
- Non-traditional interventions (AD syringes)
- Updated IC and Blood safety guidelines
- Community mobilisation and empowerment

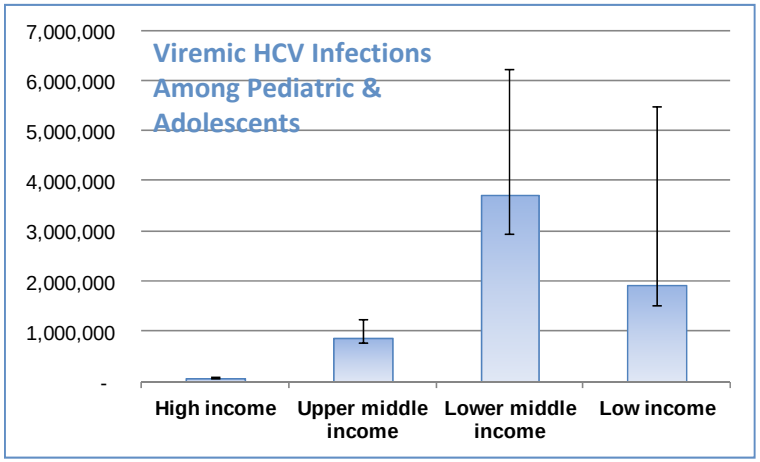
Challenges

- Scaling up screening
- Monitoring and management
- Prequalification of diagnostics and therapeutics
- Budget constraints
- Behavioral changes take time
- Fragmented health care system
- Changing Governments
- Generics (IPR, proven efficacy, quality assurance, stymied innovation….etc)

Discussion Points

- Access to cheap prequalified diagnostics and therapeutics
- Define target population groups in different countries (public, HCWs, patients & their families….)
- **Access of medicine in remote areas**
- **Access of treatment in children**
- **Financial Constraints**
- Stigma, discrimination and social impact
- Availability of global funds for viral hepatitis (Global policies)

Globally, 6.6 million children & adolescents are estimated to be infected with HCV



85% of these infections are in low and lower middle income countries

El-Sayed and Razavi, EASL 2015

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