Access to Innovation: Hepatitis C and the Egyptian National Experience

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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**

**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

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Graph showing trends in total cancers, mortality from liver cancer, and predicted HCC from 1987 to 2022.
National Committee for Control of Viral Hepatitis (Established in 2006)

**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
• 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

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

**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

- **F2**
  - Decompensation: 3.6%
  - HCC: 1%
  - Death: 4.9%

- **F3**
  - Decompensation: 10.1%
  - HCC: 2.7%
  - Death: 10.4%

- **F4**
  - Decompensation: 27.7%
  - HCC: 8.3%
  - Death: 23.7%

Fried M, AASLD 2014
Saleem M AASLD 2014
Cost Effectiveness Chart

<table>
<thead>
<tr>
<th>SVR %</th>
<th>P/R 48</th>
<th>P/R/SOF 12 WK</th>
<th>R/SOF 24 WK</th>
<th>*R/SOF 12 WK</th>
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<tbody>
<tr>
<td>100%</td>
<td>12,000 L.E</td>
<td>9600 L.E</td>
<td>12,600 L.E</td>
<td>6600 L.E</td>
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<td>90%</td>
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*CNAÏVE, NON CIRRHOTIC, LOW VIREMIA,
Flow Chart for the Treatment Procedure

1. Appointment
2. Evaluation clinic
3. Physician (checklist)
4. Realtime data in NNTC
5. Data entry from centers
6. Enrollment sheet
7. Final Decision Regimen
8. Decision sent online
9. Start ttt, FUP sheet
Online registration system

Register using your national number (ID):

Name:

Father's name:

Mother's name:

Identification number option:

Mobile number:

Enter your mobile number and submit.
Registry data first 4 days
Sep 28th 2015 (1222229 registered)
Registration according to Governorate
Gender Distribution (%)

- Males: 64.09%
- Females: 35.91%
Age Distribution (%)

- >60 years: 16.56%
- 18-30 yrs: 7.54%
- 31-40 yrs: 13.31%
- 41-50 yrs: 26.48%
- 51-60 yrs: 36.01%
Number of patients on DAAs since October 2014

129,249

- Under therapy: 38,246 (29.59%)
- Finished Courses: 91,003 (70.41%)
Antidiversion Plan

• Patient QR code Encrypted

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

• Patient QR code Unencrypted
899 patients started triple therapy
Before 1/1/2015

Relapse rate 11%

SVR 86%

DC, 8
Positive, 91
NA, 27
Negative, 773
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)

- 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)

Total Infected Cases (Viremic) - Egypt

| Basecase | Increased Efficacy & Treatment | Increased Efficacy & Treatment-No Incidence Reduction |

<table>
<thead>
<tr>
<th>Year</th>
<th>2014</th>
<th>2030</th>
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<th>2014</th>
<th>2030</th>
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<tr>
<td>Base Case</td>
<td>6,000,000</td>
<td>4,420,000</td>
<td>-26%</td>
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<tr>
<td>Increased treatment &amp; SVR, reduce incidence</td>
<td>6,000,000</td>
<td>285,000</td>
<td>-95%</td>
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<tr>
<td>Increased treatment &amp; SVR, without incidence reduction</td>
<td>1,250,000</td>
<td>-79%</td>
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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

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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