HCV Epidemiology & Burden Disease

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HCV in Brazil: a “puzzle to solve....

What we don’t know | What we know

Work in progress: Modeling
Still need a Registry Study
Prevalence: 1-1,9%
HCV prevalence (and projections)

Genotype 1: 70%
Genotype 3: 30%

Age matters!

Drug users: 39.5-69.6%; 3.0-84.8% HIV+ve.

Epidemiology:

<table>
<thead>
<tr>
<th>Factor</th>
<th>Hepatitis B (%)</th>
<th>Hepatitis C (%)</th>
</tr>
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<tbody>
<tr>
<td>Transfusion of blood</td>
<td>8.1</td>
<td>23.9*</td>
</tr>
<tr>
<td>Hemodialysis</td>
<td>4.5*</td>
<td>2.3</td>
</tr>
<tr>
<td>Injectable Medicines</td>
<td>1.8</td>
<td>9.5*</td>
</tr>
<tr>
<td>STD's</td>
<td>22.3*</td>
<td>10.1*</td>
</tr>
<tr>
<td>Blood/secretion exposure</td>
<td>5.4</td>
<td>9.7</td>
</tr>
<tr>
<td>Drug users (injecting)</td>
<td>12.5</td>
<td>9.2</td>
</tr>
<tr>
<td>Drug users (inhaled)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>More than 3 sexual partners/year</td>
<td>0</td>
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Cruz CRB et al. Arq Gastroenterol 2009

- Previous surgery: 25.3%
- Blood transfusion: 24%
- Injectable Medicines: 19.3%
- STD's: 10.1%
- Blood/secretion exposure: 9.7%
- Drug users (injecting): 9.5%
- Drug users (inhaled): 7.9%
- More than 3 sexual partners/year: 9.2%
Brazil (2007):

- Diagnosed ~ 10%
- Treated ~ .79%

Low SVR rates in real life settings (~30%)
2002 - 2012: need to improve!

Adapted Datasus
Hospitalizations due HCV: liver diseases stay longer and cost more.


But...what really matters? Is it possible to change??
Sinergy Trial (NIH Study): design

Hard to treat population*, all oral, short duration, naïve.

* 88% African-American, 72% male, 70% genotype 1a, 70% high viral load, 82% non-CC haplotype, 25-35% > F3

http://www.natap.org/2014/CROI/croi_110.htm
Sinergy Trial (NIH Study): results.

No side effects, no discontinuations.

http://www.natap.org/2014/CROI/croi_110.htm
Probably possible to change....
An evolving landscape...

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<th>Acute Infection:</th>
<th>Before 90’s</th>
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<td>Expansion (high)</td>
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<td>Lower Expansion (high selected sets)</td>
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<td>Does it exist?</td>
<td>Low</td>
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<td>Low/Moderate</td>
<td>High but.. access?</td>
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...and a race against the clock!
Target populations are changing!

Before 90's  |  90's: the IFN Era  |  2000's: the PegIFN Era  |  After 2012: the DAA Era  |  And beyond...

General Population
PWID Poverty

General Population
PWID Poverty

General Population
PWID Poverty

General Population
PWID Poverty

How much eager to fight for the patients will the Society be?

Need a comprehensive policy NOW!
Science is almost all done! Now the challenge is to provide access (diagnostic and therapy)!
Science done! Now to become affordable
1996-2008: 12 years!

2011-2013: 2 years from PI 1 to PI 2 + NUC (SOF)!

HCV

We learn a lot with ART Development!
Dramatic shift on HIV related death rate after HAART.
## An evolving landscape

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An evolving landscape

**Acute Infection:**
- Before 90's: Expansion (high)
- 90's: the IFN Era: Expansion (high)
- 2000's: the PegIFN Era: Lower Expansion (high selected sets)
- After 2012: the DAA Era: Decrease (high selected sets)

**Chronic Infection:**
- Expansion (high)
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- Expansion (high)

**Disease:**
- Expansion (modest)
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- Expansion (high)
- Expansion (high)

**Death:**
- Low
- Expansion (modest)
- Expansion (high)
- Expansion (high)

**Cure:**
- Does it exist?
- Low
- Low/Moderate
- High

Access
An ideal landscape (access): a new beginning!

- Acute Infection:
  - Decrease (high selected sets)

- Chronic Infection:
  - Stable (decrease)

- Disease:
  - Stable (decrease)

- Death:
  - Decrease

- Cure:
  - High

After 2012: the DAA Era

- Acute Infection:
  - Decrease (high selected sets)

- Chronic Infection:
  - Decrease (decrease)

- Disease:
  - Stable (decrease)

- Death:
  - Decrease

- Cure:
  - High

2014 & beyond: DAA Era & IFN free

- Acute Infection:
  - Decrease (high selected sets)

- Chronic Infection:
  - Decrease

- Disease:
  - Decrease

- Death:
  - Decrease

- Cure:
  - High

Vaccine?
Science is almost all done! Now the challenge is to provide access (diagnostic and therapy) ... and simplicity!
Access to diagnosis and therapy plus simplicity = opportunities and inclusion

**Today: the disease**
- Treat “ill” people ie “F2”, F3 and F4
- But not so ill: advanced disease, comorbidities, elderly people
  - Excluded: HIV-HCV, incarcerated, PWID, homeless, comorbidities, certain genotypes and previous non responders
- HAVE TO HAVE: several and complicated laboratory and other diagnostics tools, a place to treat, a team approach, a hospital to go (ie: side effects), other drugs to treat side effects and a huge budget

**Soon: the infection**
- Treat “infected” people
- Treat all*: mild to severe, single to multiple diseases
- Inclusion will be the rule: HIV-HCV, incarcerated**, PWID**, homeless, comorbidities, pangenotype and previous failures
- HAVE TO HAVE: simple tools (point of care), an average clinic, compliance and, still, a huge budget (or not: State policies, affordable drugs and partnerships)

* Potentially all
** Opportunity to do DOT!!!
Simplifying the model of care

- International guidelines (including for resource constrained settings)
- Low cost/technology diagnostics
  - Point of care antibody testing
  - Dried blood spots for HCV RNA testing
- Expansion of non-invasive disease staging

Adapted from Mehta SH, 2014
And simplifying the medical care
This is no longer a simple medical decision: this is too heavy to be on our shoulders

- IFN based (and even PI first generation): by far inadequate
- IFN free: still beginning but much better
- Pragmatic vs Need to treat
- How to not become a “companie’s hostage”
- Using (in favor) the Natural History of disease
  - Not all patients need to be treated “now”
Good short-term survival with compensated cirrhosis

91% 5-year and 79% 10-year survival in Child’s A cirrhosis (ie. most compensated patients can actually wait…)

Fattovich et al Gastro 1997
Key Actors

- Government (MOH)
- WHO & Brazilian new WHO resolution
- Pharmaceutical and Diagnostics Companies
- NGO & Advocacy (including official)
- Scientific Societies
- Media
Manufacturing an immunobiologic agent

Sometimes works.....

Sometimes not!

Difficult to obtain a good generic agent
Manufactoring an antiviral agent

Always works.....

Need to push for generic agents or fair prices!
What we learned with HIV drugs?

Advocacy plus...

Generics!
We don’t need to be a hostage to the Market anymore!

Unlimited profits! Partnership is better!

Accelerating Medicines Partnership

The Accelerating Medicines Partnership (AMP) is a bold new venture between the National Institutes of Health (NIH), 10 biopharmaceutical companies and several non-profit organizations to transform the current model for developing new diagnostics and treatments by jointly identifying and validating promising biological targets of disease. AMP will begin with three to five year pilot projects in three
Brazil is doing what have to do!

PORTARIA CONJUNTA Nº 1, DE 5 DE MARÇO DE 2014

Institui o Comitê Interinstitucional para Acompanhamento das Ações Estratégicas de DST, Aids e Hepatites Virais, no âmbito do Ministério da Saúde e Agência Nacional de Vigilância Sanitária.

Art. 1º Fica instituído o Comitê Interinstitucional para Acompanhamento das Ações Estratégicas de DST, Aids e Hepatites Virais para promover ações articuladas entre entes do Sistema de Vigilância em Saúde.

Art. 2º Compete ao Comitê:

I - acompanhar sistematicamente o plano estratégico de implantação dos insumos estratégicos relacionados às DST, aids e hepatites virais;

II - discutir tecnicamente a incorporação de novas tecnologias para prevenção, diagnóstico e tratamento das DST, aids e hepatites virais; e
After starting IFN free Era

Epidemiology
- Potential to a dramatic change
- Harm Reduction: key to avoid reinfection among selected people
- Vaccine: still necessary among selected people (PWID, poverty)

Burden
- Potential to a dramatic change
- Less deaths and complications
- Need to have a Global approach to avoid/minimize therapy exclusions and preventable infections/reinfections
We saw that before: a changing scenario and a new way to think!

- **HIV**: lethal disease to a chronic disease with functional “cure”
- **HCV**: chronic and potentially lethal disease to a curable infection
  - Therapy as dual prevention: infection & disease
- Not only a therapeutic change but an entire new approach and action plan!
David Capistrano taught us the correct questions:

( ) “Is it possible?”

( ) HOW TO MAKE IT HAPPEN?
David Capistrano teached us the correct questions:

(    )“Is it possible?”

( X ) HOW TO MAKE IT HAPPEN?

Few weeks after the 1996 Vancouver Conference the first city in Brazil (before the country!) to buy 200 therapies for public patients was Santos, in where he was the mayor.
Once you choose hope, anything's possible.

- Christopher Reeve
Everything new: deal with the burden (liver disease) and modify epidemiology (treat infection)!

Thank you for your attention!