How to improve access to therapy?

A round the World Table: GERMANY

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Paris Hepatitis Conference, 12 & 13 January 2015
Situation of Hepatitis C in Germany

- Low endemic area

- Prevalence still under debate: 0.4 % in healthy blood donors

- Still to convince that HCV is a major health burden

- Peak of endstage liver disease still ahead:
  - Cirrhosis
  - HCC
  - Liver transplantation
HCV drugs available in Germany

- 2001: PEG-IFN a2a / RBV
- 2002: PEG-IFN a2b / RBV

- 05/2011: Boceprevir/P/R
- 07/2011: Telaprevir/P/R

- 01/2014: Sofosbuvir: SOF/P/R or SOF/R
- 05/2014: Simeprevir: SMV/P/R or IFN intol + SOF
- 08/2014: Daclatasvir: DCV/SOF

- 11/2014: Sofosbuvir/Ledipasvir (FDC)
Latest recommendations: DGVS 12 September 2014

after DCV before SOF/LDV !!!
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after DCV before SOF/LDV !!!

MONTHLY UPDATE NEEDED !!

April 2014: www.easl.eu

12 September 2014: www.dgvs.de
Germany: Access to Treatment

- Health insurance coverage:
  - regular social health insurance (~ 80 %)
  - private health insurance (< 20 %)
Germany: Access to Treatment

- Health insurance coverage:
  - regular social health insurance (~ 80 %)
  - private health insurance (< 20 %)

- Social welfare

- Special populations
  - refugees
  - prisoners

- Clinical trials
Germany: Access to Treatment

1. EMA approval

2. Reimbursement by health insurance
Germany: Nomenclature

1. **AMNOG**: Arzneimittelneuordnungsgesetz

2. **GB-A**: Gemeinsamer Bundesausschuss

3. **IQWiG**: Institut für Qualitätssicherung und Wirtschaftlichkeit im Gesundheitswesen
Germany: Access to Treatment

- Pricing according to the AMNOG law

- 1 year drug price according to pharmaceutical industry

- After first year pricing as a results of
  - GB-A judgement whether new therapy has additional benefit (Zusatznutzen) over standard of care (SOC) based on IQWiG (Institut für Qualitätssicherung und Wirtschaftlichkeit im Gesundheitswesen) evaluation
  - Final pricing following negotiations with the pharmaceutical industry based on GB-A judgement
Situation of Hepatitis C in Germany:

Present Discussion

- Is HCV therapy too costly?

- Prioritization of HCV therapies
  - F3/F4?
  - Transplant populations: all? HCC/Child A? Child B/C post LTX?
Germany: How to improve access to HCV therapy

1. Guidelines and recommendations

2. Definition how and who should treat HCV: primary care physician versus specialized centers
Germany: How to improve access to HCV therapy

1. Guidelines and recommendations

2. Definition how and who should treat HCV: primary care physician versus specialized centers

3. Improved eligibility and tolerability of novel IFN free therapies:
   - Maasoumy et al Plos One 2013
   - Siederdissen et al Liv Int 2014
Germany: How to improve access to HCV therapy

1. Guidelines and recommendations

2. Definition how and who should treat HCV: primary care physician versus specialized centers

3. Improved eligibility and tolerability of novel IFN free therapies

4. Effective screening programmes !
All HCV patients: 
- 100% PEG-IFN/RBV
- 100% 95% SVR
- 100% Cure
- 100% 95% SVR
- 100% And increase of diagnosis

DIAGNOSIS and therapy: 
- 20% PEG-IFN/RBV
- 20% 90% SVR
- 20% Cure

Cure: 
- 10% PEG-IFN/RBV
- 19%
- 85% 90% SVR
Strategies to manage hepatitis C virus (HCV) disease burden

Old standard Peg-IFN/RBV

SVR 90%

SVR 90%, Increase of Treatment uptake by 75%
The Global Viral Hepatitis Summit

15th International Symposium on Viral Hepatitis and Liver Disease

- Public Health
- Basic Science
- Prevention
- Diagnosis
- Treatment

Joint Meeting with
12th International HepNet Symposium (German Liver Foundation) and 1st International Hepatitis Symposium of the German Center for Infection Research (DZIF)

Professor Michael P. Manns, MD
Congress President

Berlin, Germany
June 26–28, 2015

www.isvhld2015.org