

How to improve access to therapy ?

A round the World Table: GERMANY

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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 SMV/SOF
- 08/2014 Daclatasvir: DCV/SOF

- 11/2014 Sofosbuvir/Ledipasvir (FDC)
- 1/2015 Paritaprevir/r/Ombitasvir/Dasabuvir (3D)

Germany: Access to Treatment

1. EMA approval
2. Reimbursement by health insurance

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 ?
- Extra HCV Budget „Sonderausgabenvolumen“ for 2015 and 2016 approx. 1.4 Billion €
- Special contracts with Health Insurance Companies

Need for Economic Efficiency by Law:

„Wirtschaftlichkeitsgebot“

- As always there is a need for economic efficiency: Wirtschaftlichkeitsgebot §12 SGB V

§12 Wirtschaftlichkeitsgebot

(1) Die Leistungen müssen ausreichend, zweckmäßig und wirtschaftlich sein; sie dürfen das Maß des Notwendigen nicht überschreiten. Leistungen, die nicht notwendig oder unwirtschaftlich sind, können Versicherte nicht beanspruchen, dürfen die Leistungserbringer nicht bewirken und die Krankenkassen nicht bewilligen.

- If there are various therapies of comparable efficiency lower cost drugs have to be prescribed
- Therefore documentation of therapies for each patient a must (labelling and guidelines to be acknowledged)



Situation of Hepatitis C in Germany:

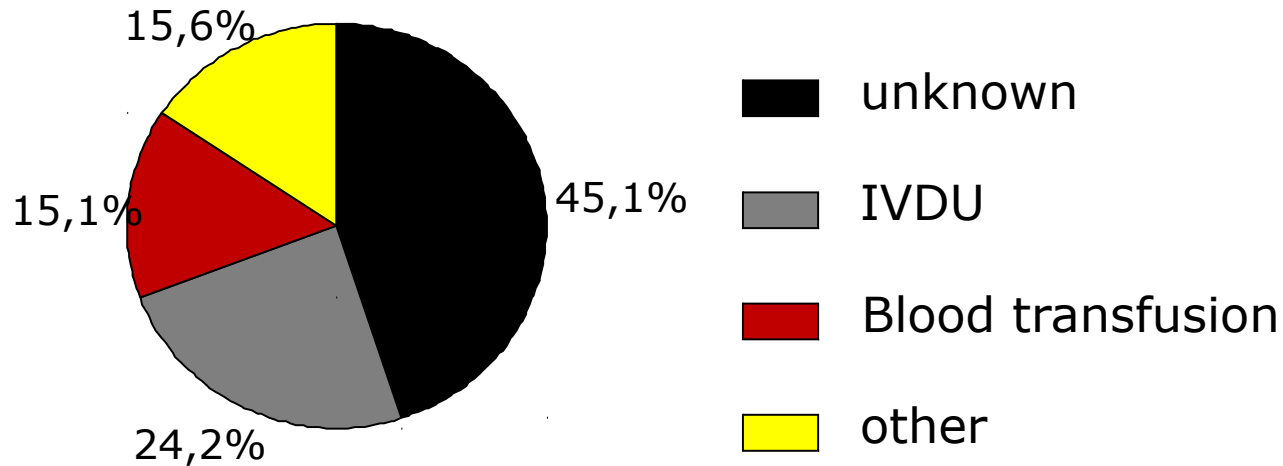
Present Discussion

- Is HCV therapy too costly ?
- Extra HCV Budget „Sonderausgabenvolumen for 2015 and 2016 approx. 1 Billion €
- Special contracts with Health Insurance Companies
- Treatment of „posttransfusion“ HCV patients (independent of fibrosis stage) is no problem in Germany.
- What about risk groups with high risk for re-infection and transmission ?

German Hepatitis C Registry

Patient characteristics (30.6.2015) 5437 patients

Mode of transmission



OST	604
HIV-coinfected	432
Viral load >6 IU/ml	557

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

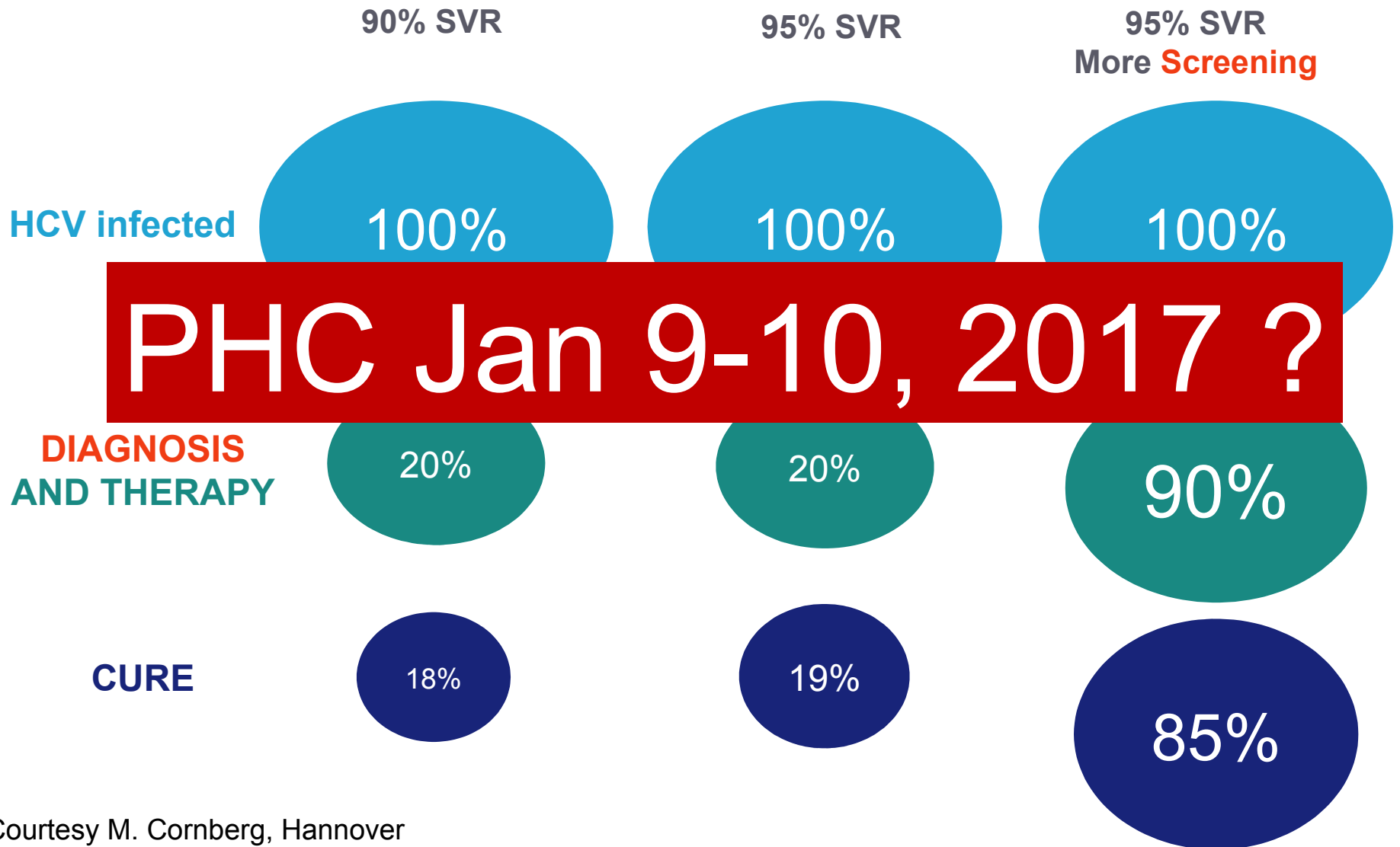
Germany: How to improve access to HCV therapy

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
 - Hoener zu Siederdisen 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 !**
- 5. Education networks for primary care physicians of OST patients and other risk groups**

Screening is more important than SVR 90% versus 95%



Courtesy M. Cornberg, Hannover