

How to improve access to therapy? around the world table

Poland



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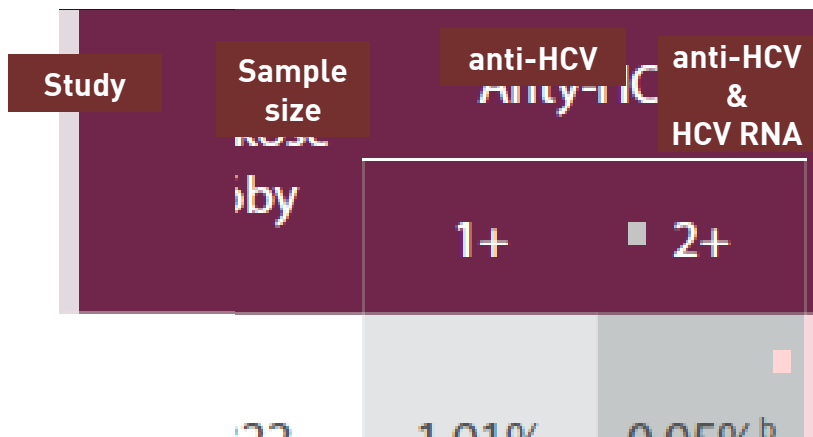
Disclosures

Advisor and/or speaker for

AbbVie, Bristol-MyersSquibb, Gilead, Janssen, Merck,
Novartis, Roche

Situation of hepatitis C in Poland

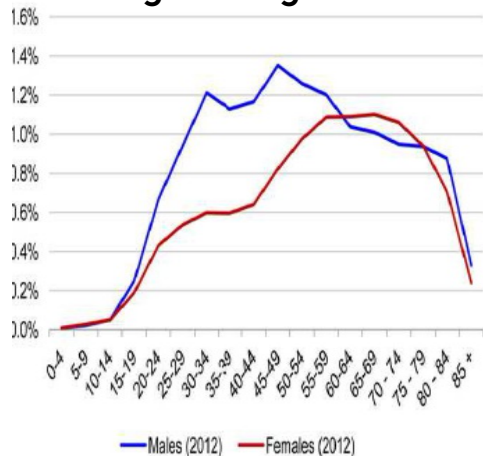
Prevalence of anti-HCV and HCV RNA



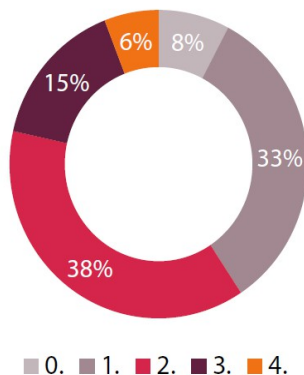
Risk factors for anti-HCV positivity

| | OR (95% CI) | P |
|--|-------------------|--------|
| Sex male vs. female | 1.74 (1.32, 2.29) | <0.001 |
| Age > median | 0.77 (0.59, 1.02) | 0.07 |
| Number of hospital admissions > median | 1.75 (1.31, 2.34) | <0.001 |
| Endoscopic procedures | - | >0.1 |
| Dialysis | - | >0.1 |
| Surgical procedures | - | >0.1 |
| Blood transfusions before 1992 | 2.88 (2.08, 3.98) | <0.001 |
| History of tattooing and/or piercing | - | >0.1 |
| Intravenous drug use | 6.13 (3.8, 10.0) | <0.001 |

Age and gender



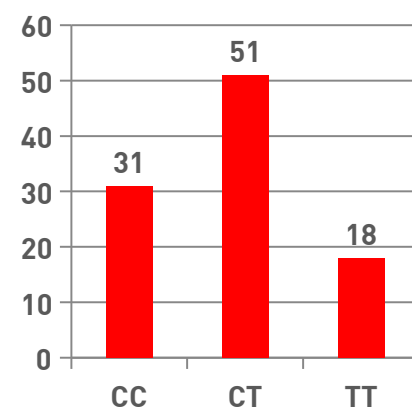
Fibrosis stage



HCV genotypes



IL28B genotypes



Flisiak R, et al. Eur J Gastroent Hepatol 2011; 23: 1213-1217.

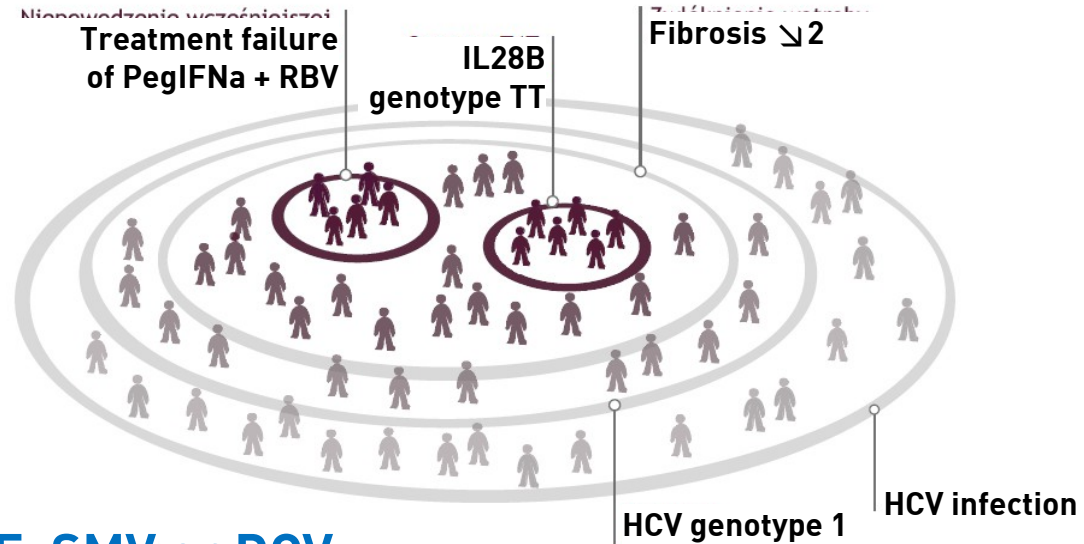
Godzik P, et al. Epidemiol Rev 2012; 66: 575-580.

Crucial problems that complicate the optimal management of patients

- 1) Elastography is not allowed by National Health Fund (NFZ) for enrollment to reimbursed treatment of genotype 1 infected patients (liver biopsy necessary)

Genetic selection for triple therapy (BOC or TVR)

(reimbursed for 20% HCV population only)



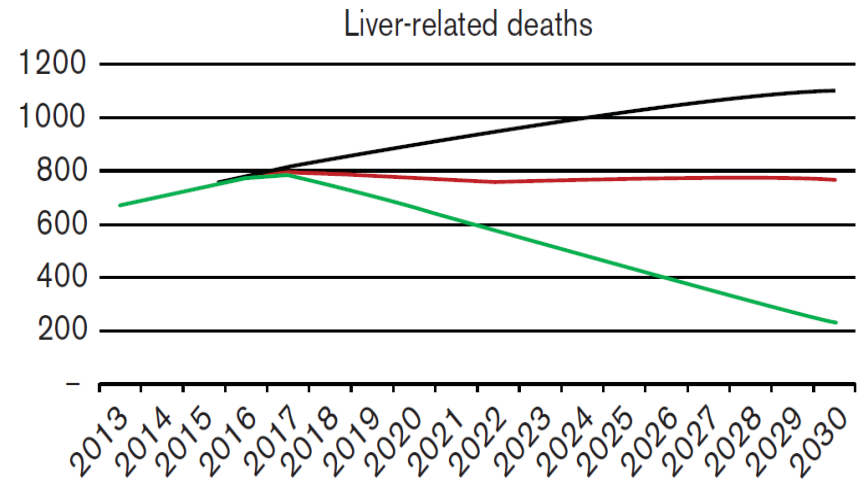
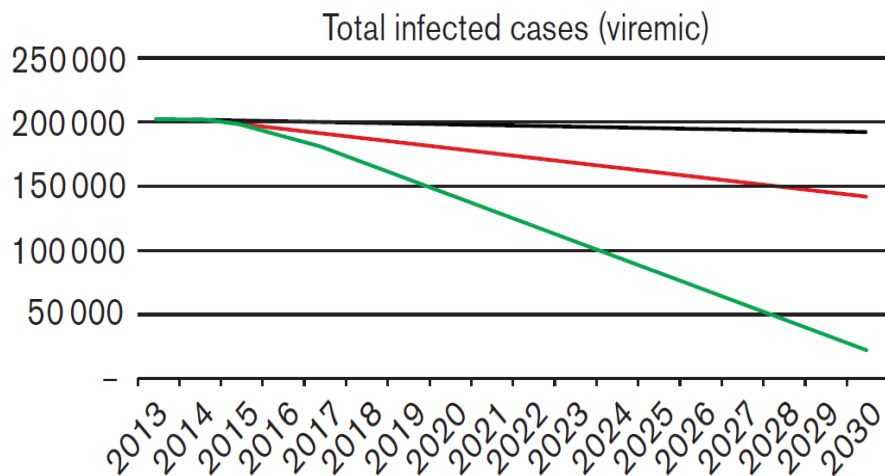
3) No reimbursement of

- IFN based treatment with SOF, SMV or DCV
- IFN-free regimen
 - 3D (PRV/OBV/DSV) - ongoing managed access program
 - DCV/ASV - access expected
 - SOF/LDV - not offered
 - combination of SOF with SMV or DCV not allowed ...

... long lasting reimbursement approval procedures by regulatory authorities.
for BOC and TVR it took →20 months (approved in mid 2013)

How to improve access to therapy

- Inclusion of anti-HCV testing in the set of reimbursed procedures for GPs.
- Exclusion from the HCV therapy reimbursement program (covered by NFZ).
 - IL28B based genetic selection
 - obligatory liver biopsy
- Improvement of regulations for reimbursement approval, to speed up procedures.
- Need of „compassionate use regulations”.



| | | | |
|------------------|--------------|--------------------------|---------------|
| | — Baseline | — Control disease burden | — Elimination |
| diagnosed | 3 000 | 5 000 | 15 000 |
| treated | 3 000 | 5 000 | 15 000 |