Treatment of HCV by specialist in private practice

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Disclosures

- Speakers bureau and advisory boards:
  - AbbVie, Bristol-Myers Squibb, Falk, Gilead, Janssen, Merz, Merck Sharp & Dohme

Treatment with DAAs – Situation in Germany

- German guidelines are published in February/May/September 2014 and February 2015
  - "Chronic hepatitis C ….. is an indication"
  - **No limitation related to the stage of fibrosis**

- All DAAs are reimbursed by the social insurance system
  - Price creates political debates
  - AMNOG – influence on treatment selection

- Price and SmPC (Guidelines) with high impact on treatment selection

- **Treatment concentrated in experienced centres, mainly GI**

Treatment with DAAs – Situation in Germany

- About 26000 treatment in 2015
  - Treatment rates declining
  - Treatment possible without any waiting time
  - No need for further expansion

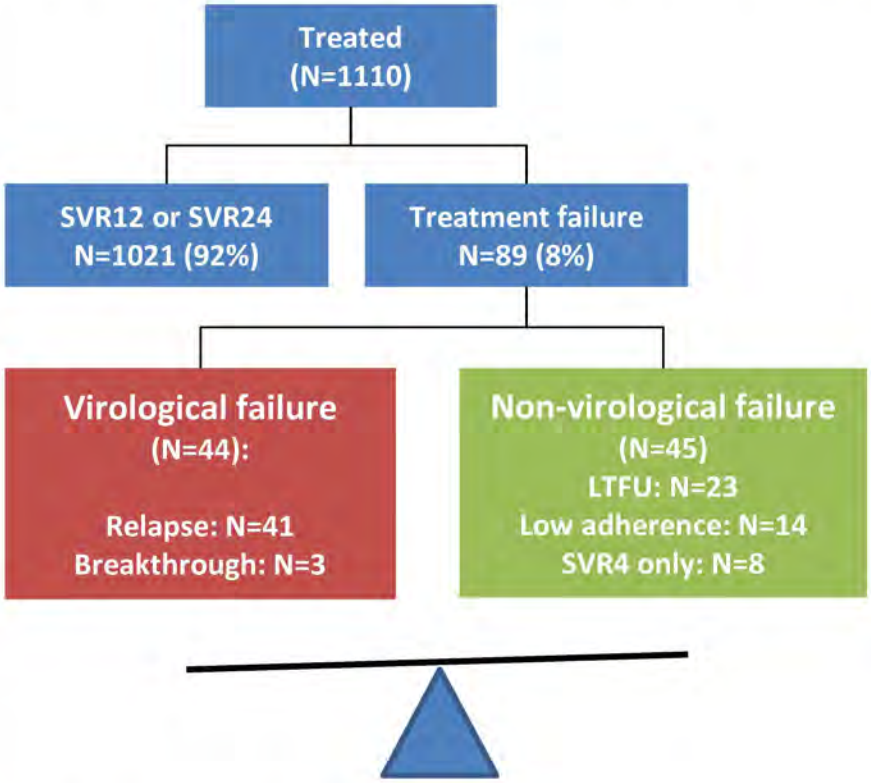
- Most treatment by GI specialists in private practice
  - E.g. treatment rates in BW ≈62% in private practice
  - Slowly uptake by OST – specialists

- Results are excellent
- Even publications derived (mainly from the DHC-R)

HCV therapy failure in a real-life cohort

89 patients out of 1100, enough to think about!

Treatment – overall cohort



Baseline characteristics– overall cohort N=1110

Age, Median (range)	53.6 (19–82)
Males, n (%)	660 (59.5)
Genotype, n (%)	
1a	352 (31.7)
1b	393 (35.5)
2	48 (4.3)
3	250 (22.5)
4	67 (6.0)
Fibrosis stage: Metavir Score, (%) (FibroScan®)	
F0–3	775 (69.8)
>F3 (>12.3 kPa)	335 (30.2)
Previous treatment status	
Naïve, n (%)	729 (65.7)
Experienced, n (%)	381 (34.3)

Petersen, et al. AASLD 2016; Poster #2019

F: fibrosis stage; LTFU: lost to follow-up

Therapy failure with HCV in real life – ITT analysis

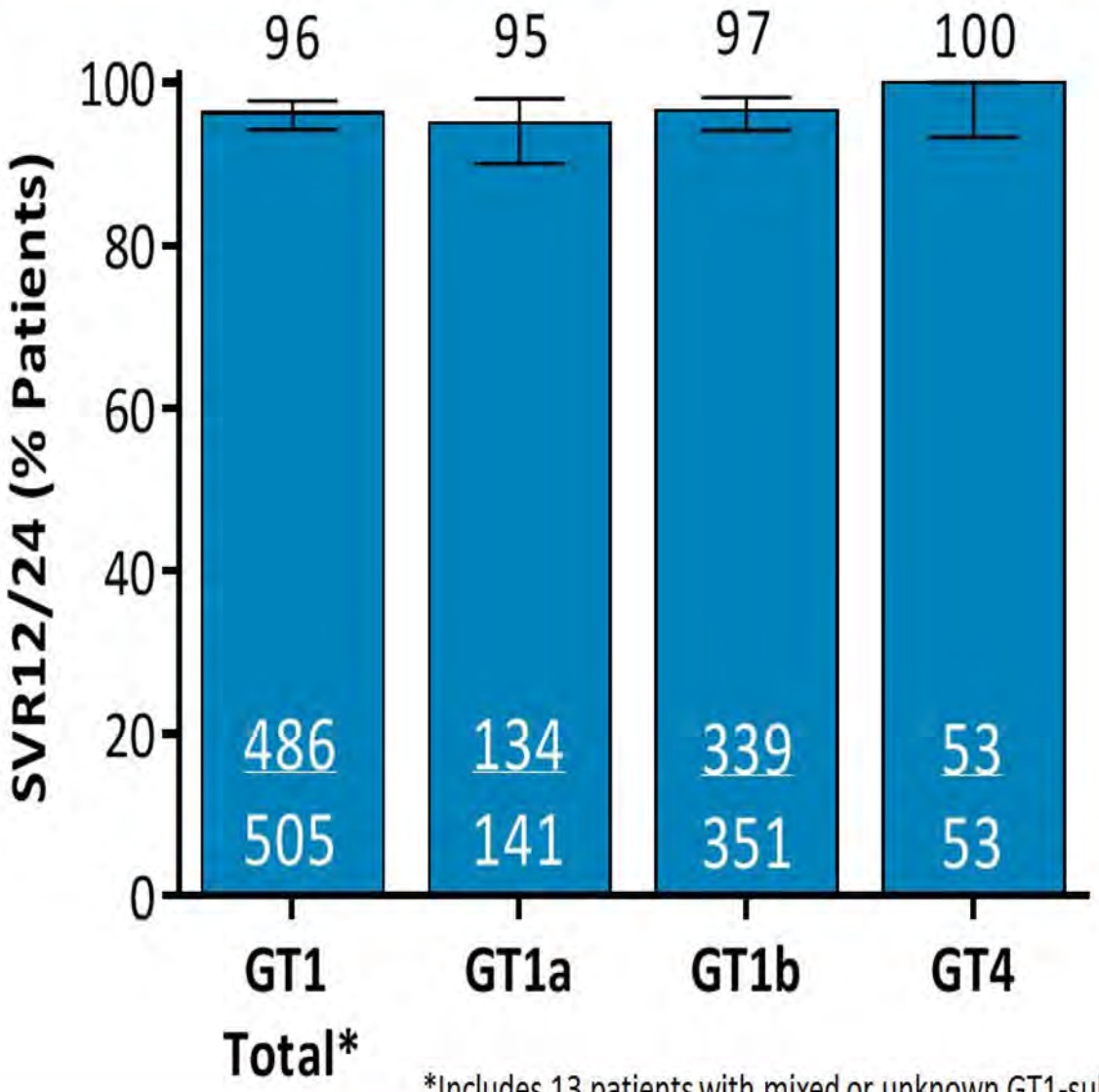
Logistical regression analysis of virological failure N=44

Advanced cirrhosis + GT 3 + treatment experienced	**Significant**
Time at end of treatment (end of 2014 vs. end of 2015)	**Significant**
Genotype	Not significant
Cirrhosis vs. non-cirrhosis	Not significant
Treatment-naïve vs. treatment-experienced	Not significant
Age	Not significant
Race	Not significant
Viral load	Not significant
HIV co-infection	Not significant

Petersen, et al. AASLD 2016; Poster #2019

ITT: intention-to-treat

SVR Rates AbbVie 3 D – Data from the DHC-R- mainly from private centers organized in the BNG



Overall SVR rates were high, ranging between 95% and 100% across GT1 and GT4

*Includes 13 patients with mixed or unknown GT1-subgenotype infection, all of whom achieved SVR

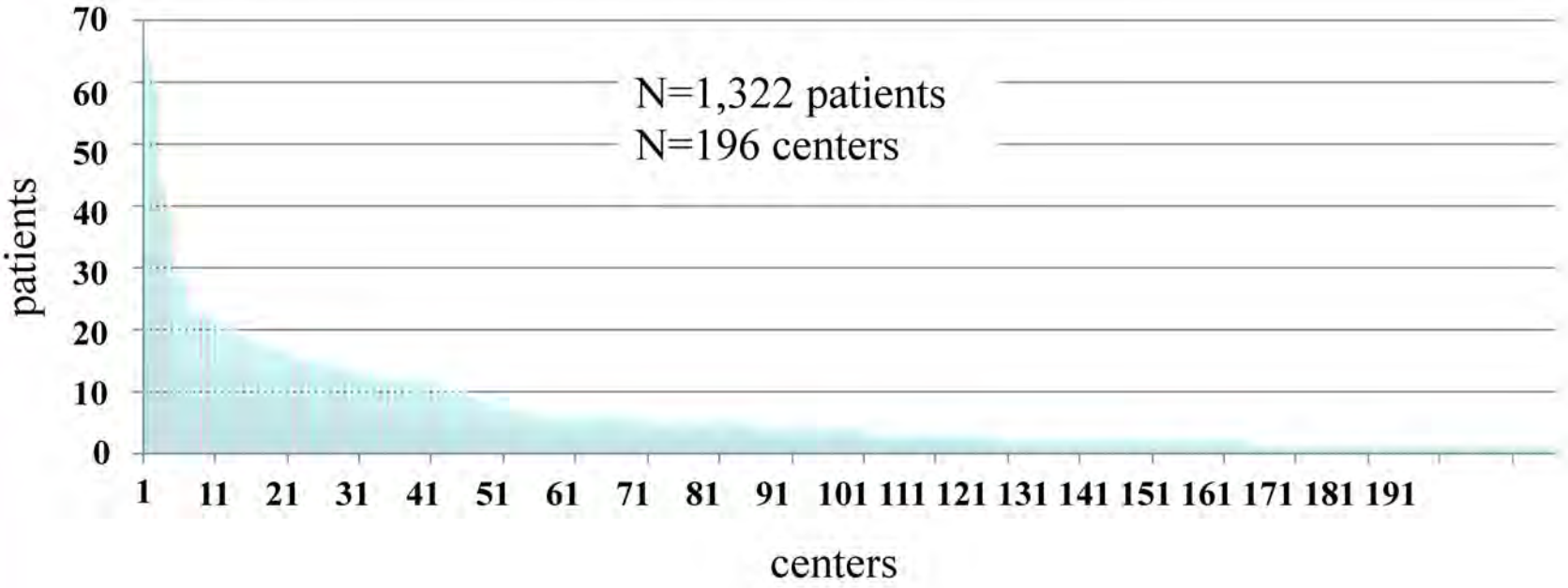
Treatment with DAAs in private practice

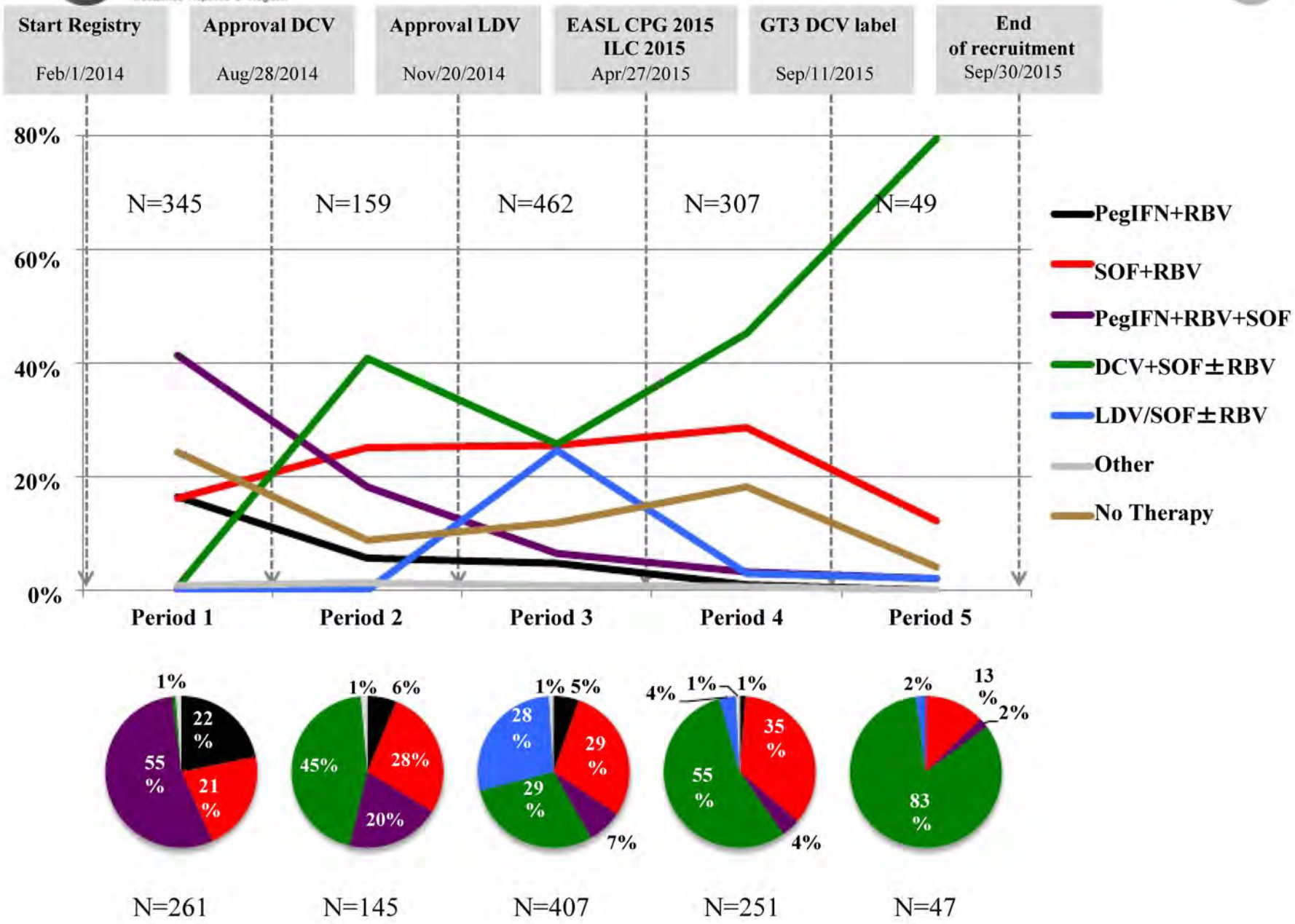
- Very fast reaction to publications and new data
  - High quality of patient care
  - Very sensitive to price changes

- High number of medical education programs
  - Driven by BNG
  - Expert system “Hepdata”

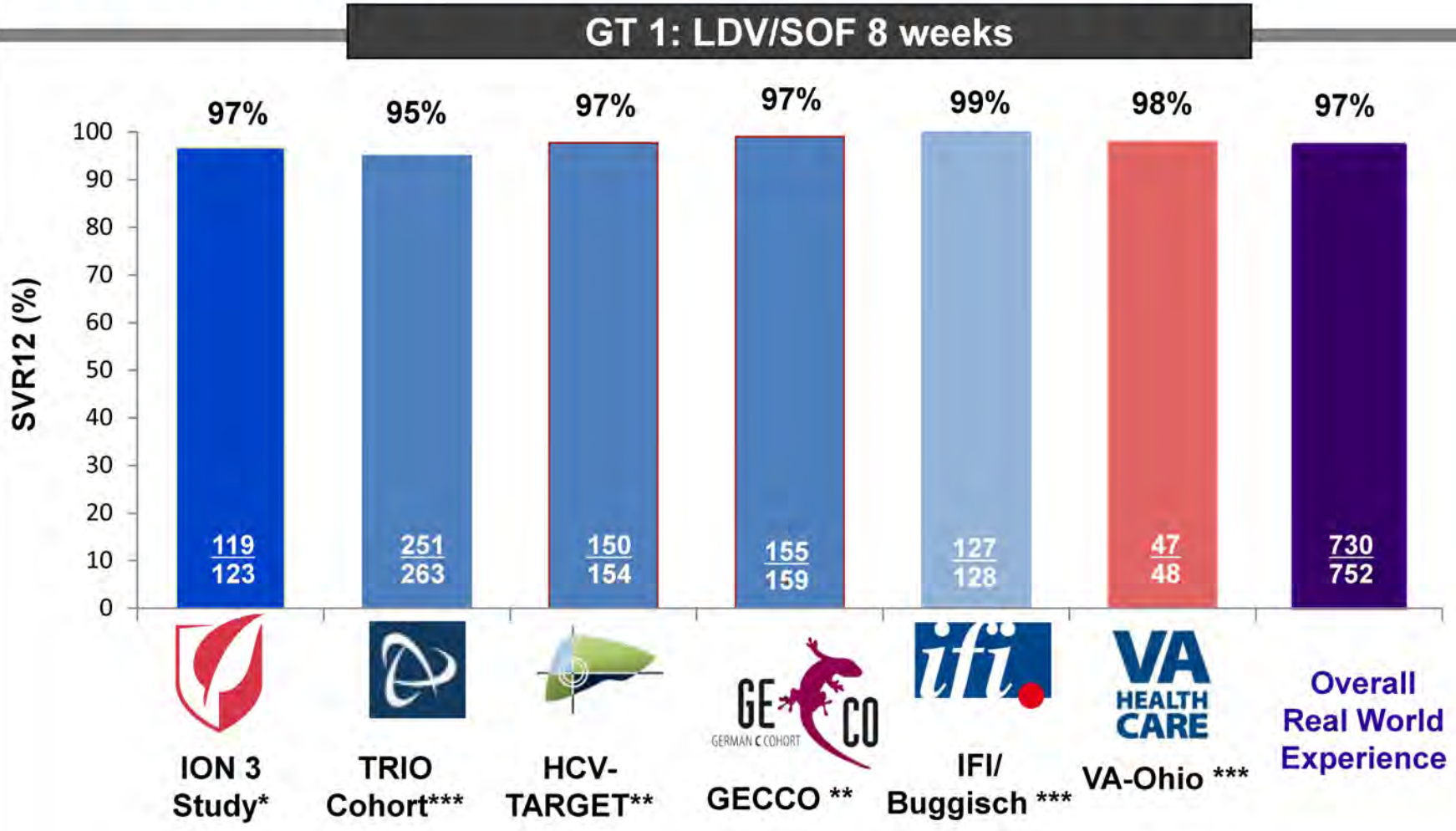
- High motivation to generate data from “Real world”

DHC-R shows most treatments are run in centers with experience and more patients (G 3 data from 200 centers)




Start Registry
Feb/1/2014
Approval DCV
Aug/28/2014
Approval LDV
Nov/20/2014
EASL CPG 2015
ILC 2015
Apr/27/2015
GT3 DCV label
Sep/11/2015
End
of recruitment
Sep/30/2015
80%
60%
40%
20%
0%
N=345
N=159
N=462
N=307
N=49
PegIFN+RBV
SOF+RBV
PegIFN+RBV+SOF
DCV+SOF±RBV
LDV/SOF±RBV
Other
No Therapy
Period 1
Period 2
Period 3
Period 4
Period 5
1%
22 %
55 %
21 %
1%
6%
45%
28%
20%
1%
5%
28 %
29 %
29 %
7%
4%
1%
1%
35 %
55 %
4%
2%
13 %
2%
83 %
N=261
N=145
N=407
N=251
N=47

8 week treatment option -
In Germany evaluated mainly in private practice.



*Post hoc analysis ** Per Protocol *** ITT analysis

Kowdley KV, et al. N Engl J Med 2014;370:1879-88; Curry M, et al AASLD 2015;
Terrault N, et al AASLD 2015; Buggisch P, et al. EASL 2016; Christensen, et al. CROI 2016; Marshall et al. AASLD 2015

Majority of patients eligible get 8 weeks - different from international experiences

	zwei Kriterien erfüllt		alle Kriterien erfüllt		Total	
	N	%	N	%	N	%
LDV/SOF 8 W	127	10.7%	839	65.5%	976	33.4%
LDV/SOF 12 W	874	73.7%	410	32.0%	1508	51.7%
LDV/SOF/RBV 8 W	2	0.2%	2	0.2%	5	0.2%
LDV/SOF/RBV 12 W	183	15.4%	29	2.3%	430	14.7%
Total	1186	100.0%	1280	100.0%	2919	100.0%

Treatment should be done by specialists !

Buggisch, DGVS 2016,

Treatment with DAAs in private practice – Problems

- Still a lot uncertainty about the decisions of GBA – after negotiation !
  - Fear of "Regress"
  - Several specialist do not treat anymore ("risk too high")

- "Strukturverträge" are highly welcomed but….
  - Very slowly
  - Not universal in every state
  - Every health insurance (> 120) with different rules

- "Rabattverträge" are secret, economic action impossible

- No answers if special questions– e.g. retreatment

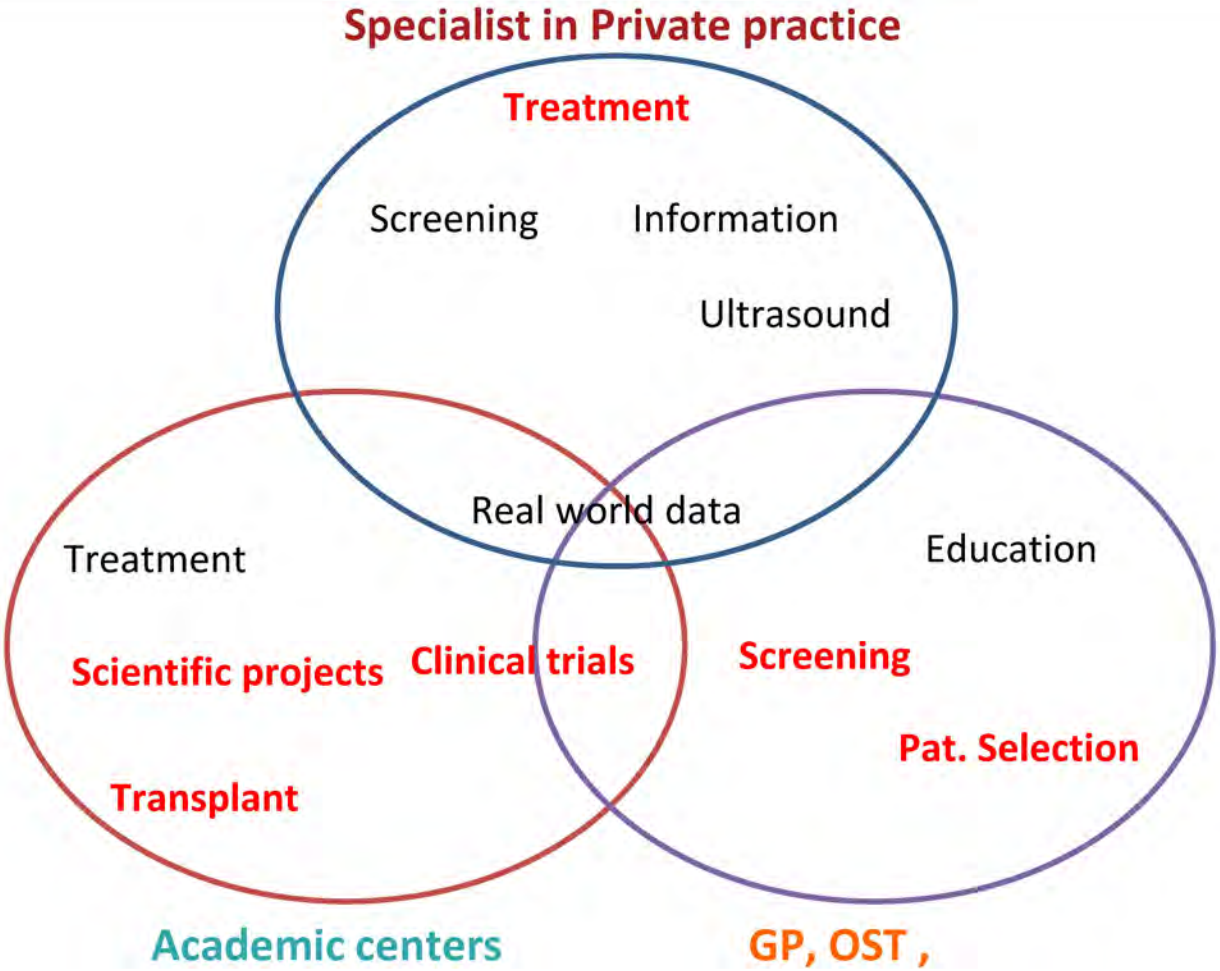
Treatment with DAAs in private practice – Problems

- Reimbursement for the treatment is very low, not economic
  - Between 15-35 Euro / 3 month
  - Fibroscan/ARFI is not reimbursed at all
- Screening strategies are necessary
  - Should be done by specialist
  - Screening not really reimbursed
  - Contrast ultrasound best method but not paid
- Education in risk groups necessary but time consuming

Treatment with DAAs in private practice – future requests

- Frequent and competent communication with payers
  - Clear rules
  - Reimbursement for screening
- Further tight connection with university based centers
  - Scientific projects only possible with academic centers
  - Network with liver transplant centers
- Network with OST experienced physicians
- Network with GPs especially in special groups (Migrants)
- Screening strategies to identify HCV infected patients

HCV treatment – work done by all players



Summary

- Treatment in Germany is not a problem
- Treatment capacity in the hands of specialists is large enough, and well organized
- Reimbursement and GBA decisions/negotiations need improvement
- Network necessary including health insurances, GPs, and social workers
- Reinfection and patient education are important
- Screening and Surveillance are the problem for the future