Access to therapy – the perspective of the prescriber

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Topics

- The course of regular treatment in germany, case presentation
- The patient with cirrhosis, case presentation.
- real resources for adequate diagnostics and treatment
- Doctor as factor for treatment success and cost effectiveness

Case report

- 56 year old woman, IVDU 20 years ago, HCV genotype 1b infection
- No concomittant medication, no medical history
- Transient elastography showed mild fibrosis (6,5kPa)
- ALT 45U/L, AST 36U/L, platelets 240.000/ul, bilirubin 1,2mg/dl, HCV RNA 1.2Mio IU/mL

Case report

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- No conco
- Transient
- ALT 45U/l L,2mg/dl, HCV RNA

EASY CASE!

Avaliable therapies for GT1:

- **Sofosbuvir / Ledipasvir (Harvoni) 8 weeks**
- Sofosbuvir / Ledipasvir (Harvoni) 12 weeks
- Sofosbuvir / Velpatasvir (Epclusa) 12 weeks
- **3D Regime (Viekirax / Exviera) 8-12 weeks?**
- **EBV / GZV (Zepatier) 12 weeks**

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Potential to save money!

Case report

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Time and number of consultations during regular HCV treatment

1st Q 2016	2nd Q 2016	3rd Q 2016	4th Q 2016
Referral medical Hx recording blood tests fibrosis assessment discussion treamtent options discussion lab results introduction AVT baseline prescription →3 visits within 12 weeks	week 4 prescription blood test adherence check week 8 prescription End-of-treatment FU week 4 blood test discussion results →3 visits within 12 weeks	FU week 12 visit blood test discussion results →2 visits within 12 weeks	FU week 24 visit blood test discussion results →2 visits within 12 weeks

Case report

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Up to 10 visits per patient per treatment course

1st Q 2016

Referral
medical Hx recor
blood tests
fibrosis assessme

discussion tream
discussion lab results

introduction AVT
baseline prescription

→3 visits within 12 weeks

End-of-treatment

FU week 4
blood test
discussion results

→3 visits within 12 weeks

→2 visits within 12 weeks

Q 2016

week 24 visit
od test

ussion results

→2 visits within 12 weeks

GASTROENTEROLOGIE AM BAYERISCHEN PLATZ

Case report

- male, 56 Y, BMI 31, HCV GT **3a** infection,
- Therapy experienced, IVDU 1980ies, no OST
- GPT 165U/L, GOT 137U/L, GGT 97U/L, **Thrombo 150/nl, Bilirubin 1,2mg/dl**
- HCV RNA 6 Mio IU/mL at initial presentation
- Fibroscan **12,2 kPa**
- No medical history, no concomittant medication

Case report

- male, 56 Y, BMI 31, HCV GT **3a** infection,
- Therapy experienced, IVDU 1980ies, no OST
- GPT 165U/
- **Bilirubin 1**
- HCV RNA 6
- Fibroscan
- No medical history, no con medication

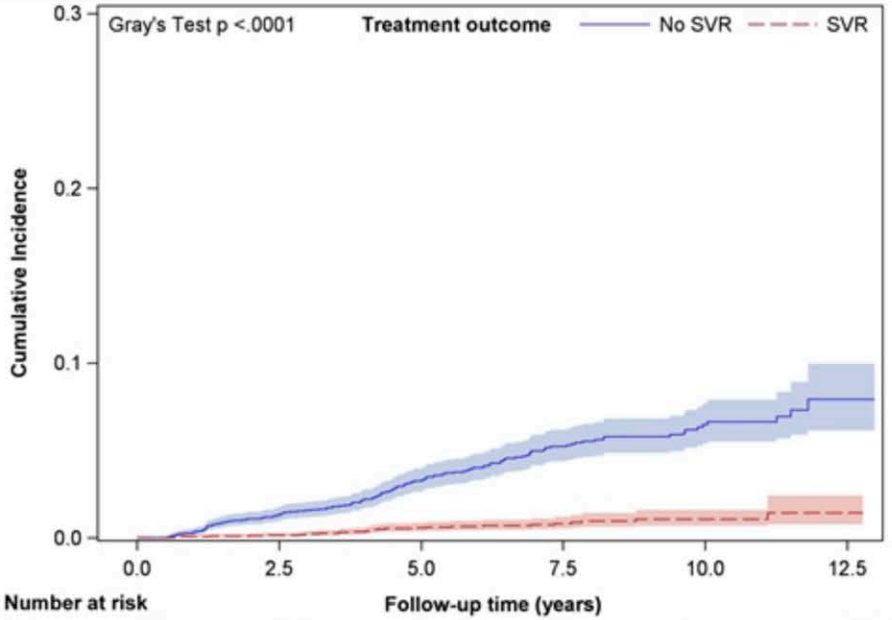
Transient elastography available?

Available therapies for GT3 and CPT A cirrhosis

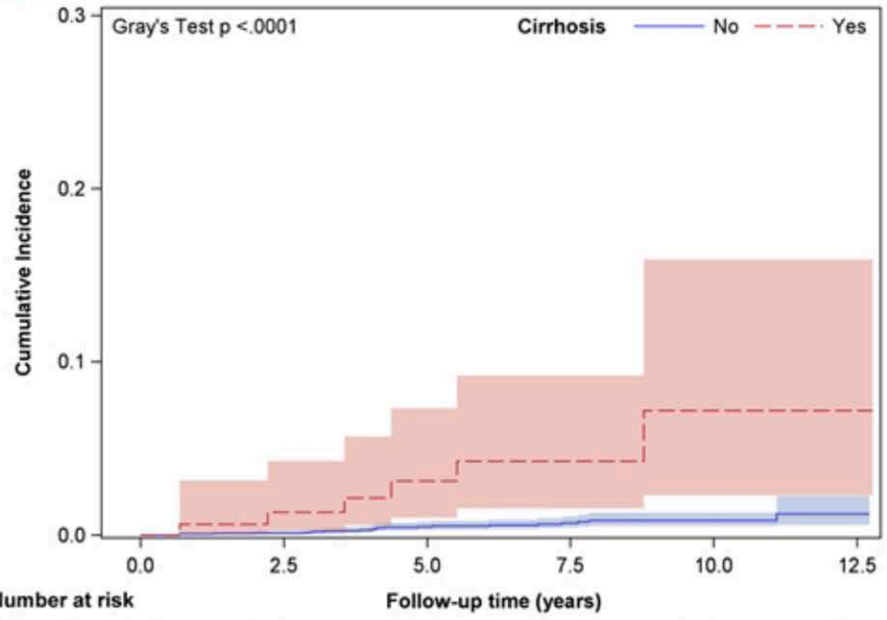
- **Sofosbuvir / Velpatasvir (Epclusa) 12 weeks**
- Sofosbuvir (Sovaldi) / Daclatasvir (Daklinza) 12-24 weeks
- Sofosbuvir (Sovaldi) / Ribavirin 24 weeks

Cummulative incidence HCC according to SVR and cirrhosis

Cumulative incidence of HCC by SVR



Cumulative incidence post SVR by cirrhosis

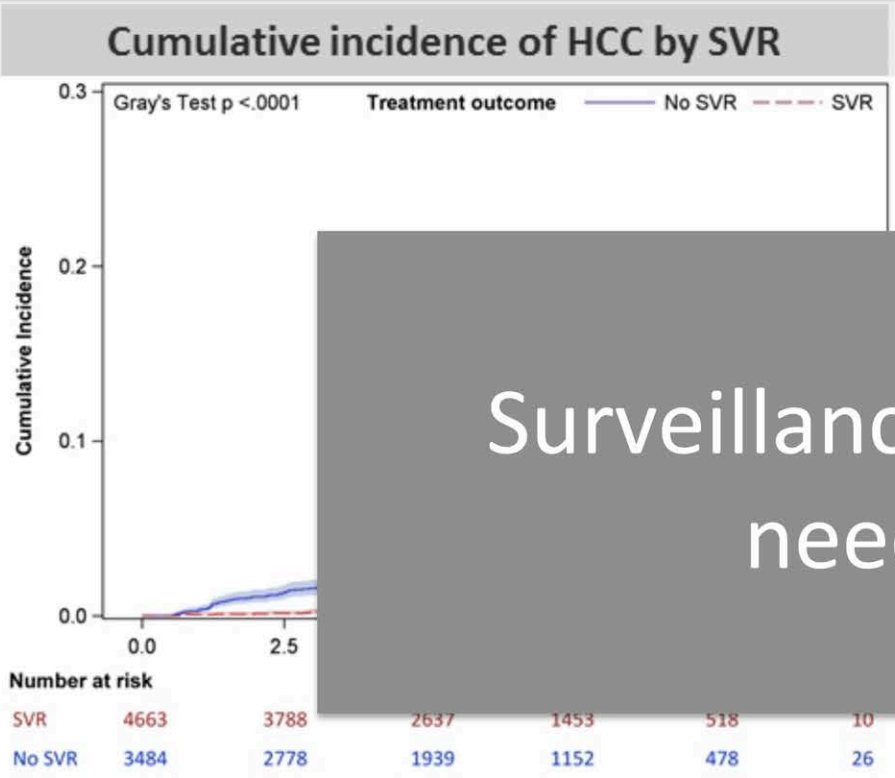


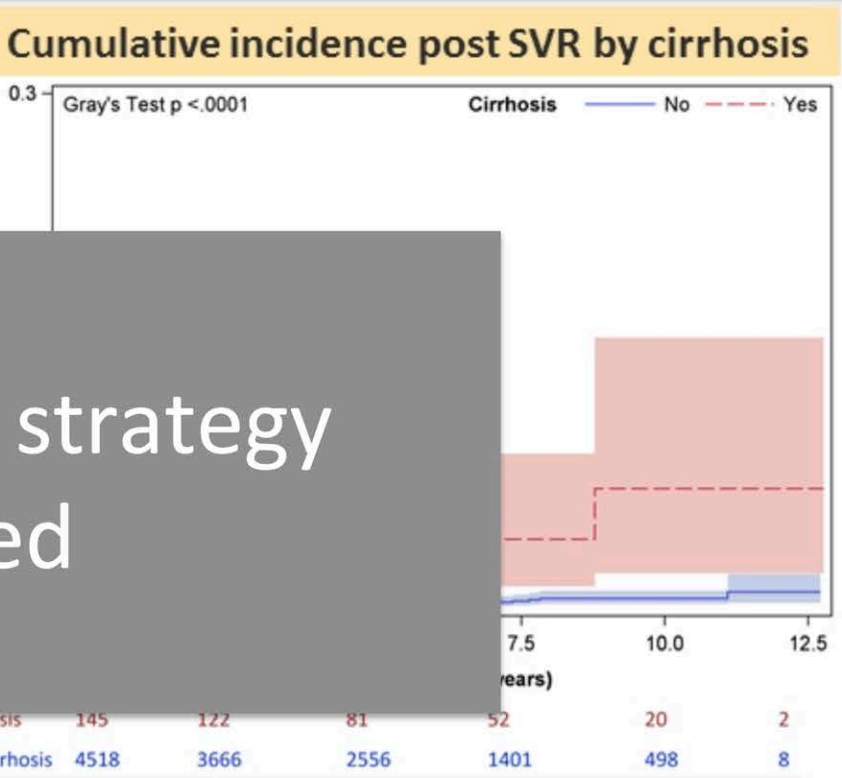
	N	HCC	Incidence rate
SVR	4663	29	1.1/1000 PY
No SVR	3484	145	7.2/1000 PY

	Incidence rate (95%CI)/ 1000 PY	
	SVR	No SVR
Cirrhosis	7.0 (3.2, 15.6)	20.1 (13.7, 29.5)
No Cirrhosis	0.9 (0.6, 1.3)	6.3 (5.3, 7.5)

Janjua et al. AASLD 2016

Cummulative incidence HCC according to SVR and cirrhosis





Surveillance strategy needed

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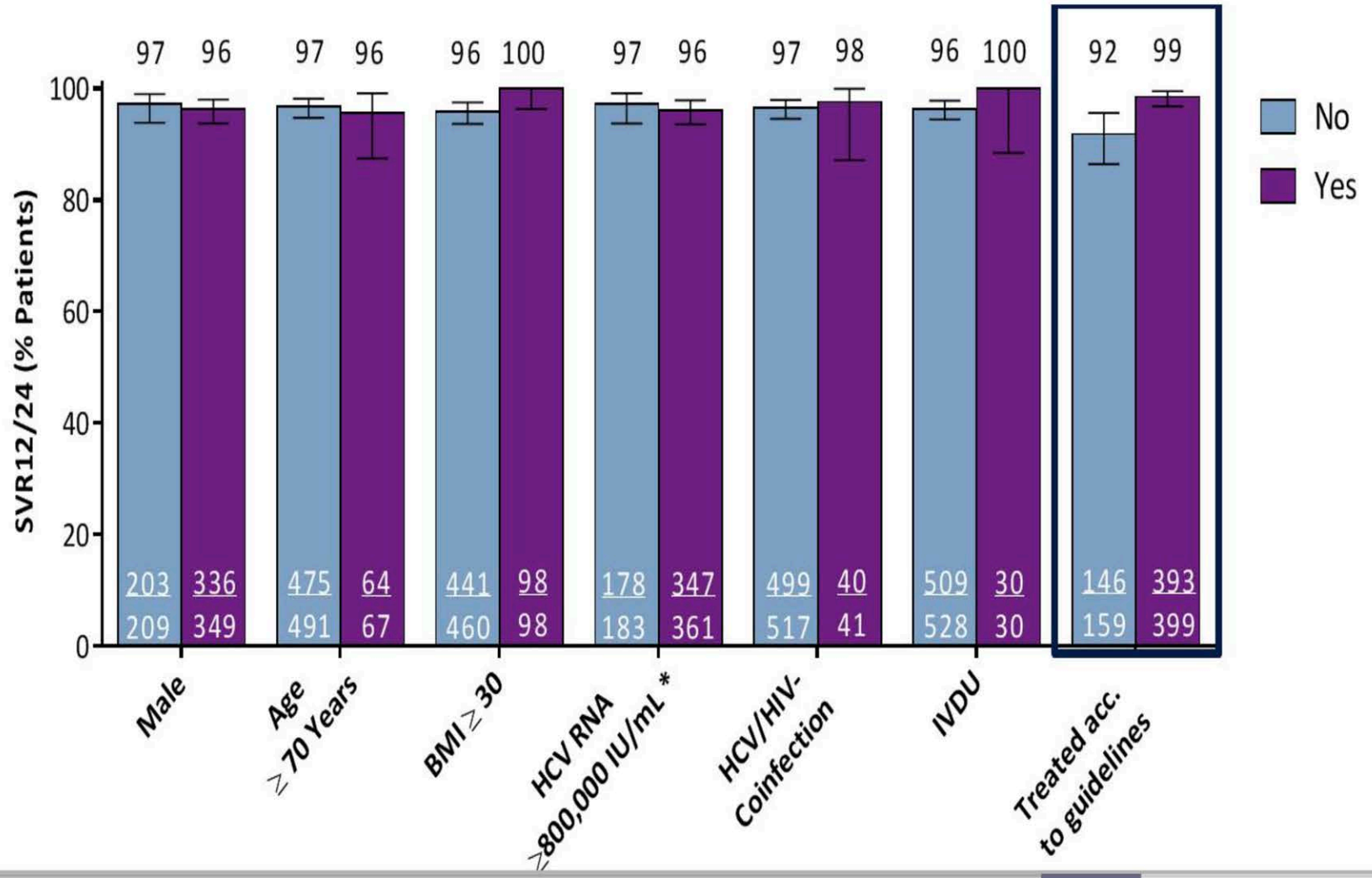
Janjua et al. AASLD 2016

Real resources for diagnostics and therapy in germany today

- In general, GP and specialist receive an „all inclusive rate“ (Fallpauschale) every 3 months within a given budget (RLV) per patient
  - Additional visits not paid (HCV: up to 10 per tx course)
  - Non-invasive fibrosis assessment in HCV (Fibroscan) not paid
- HCC surveillance: ultrasound should be performed on regular basis: belongs to „all inclusive rate“ (not paid)

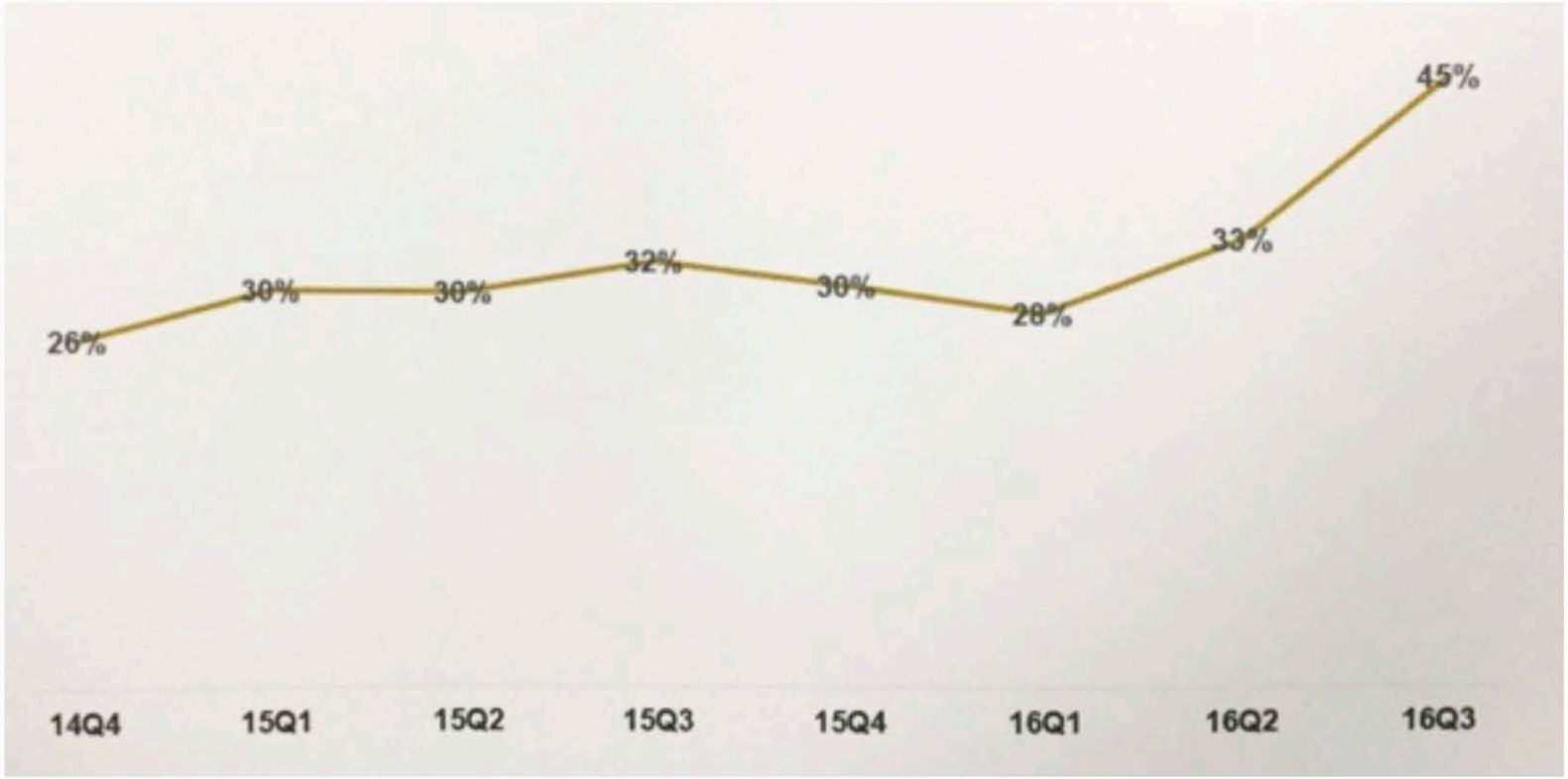
Real life experience with 3D regimen in germany: DHR



Hinrichsen et al. EASL 2016

Real life experience: rate of treatment shortening in the US

- Rate of eligible patients who receive 8 weeks Harvoni according to time product is licensed



AASLD, 2016

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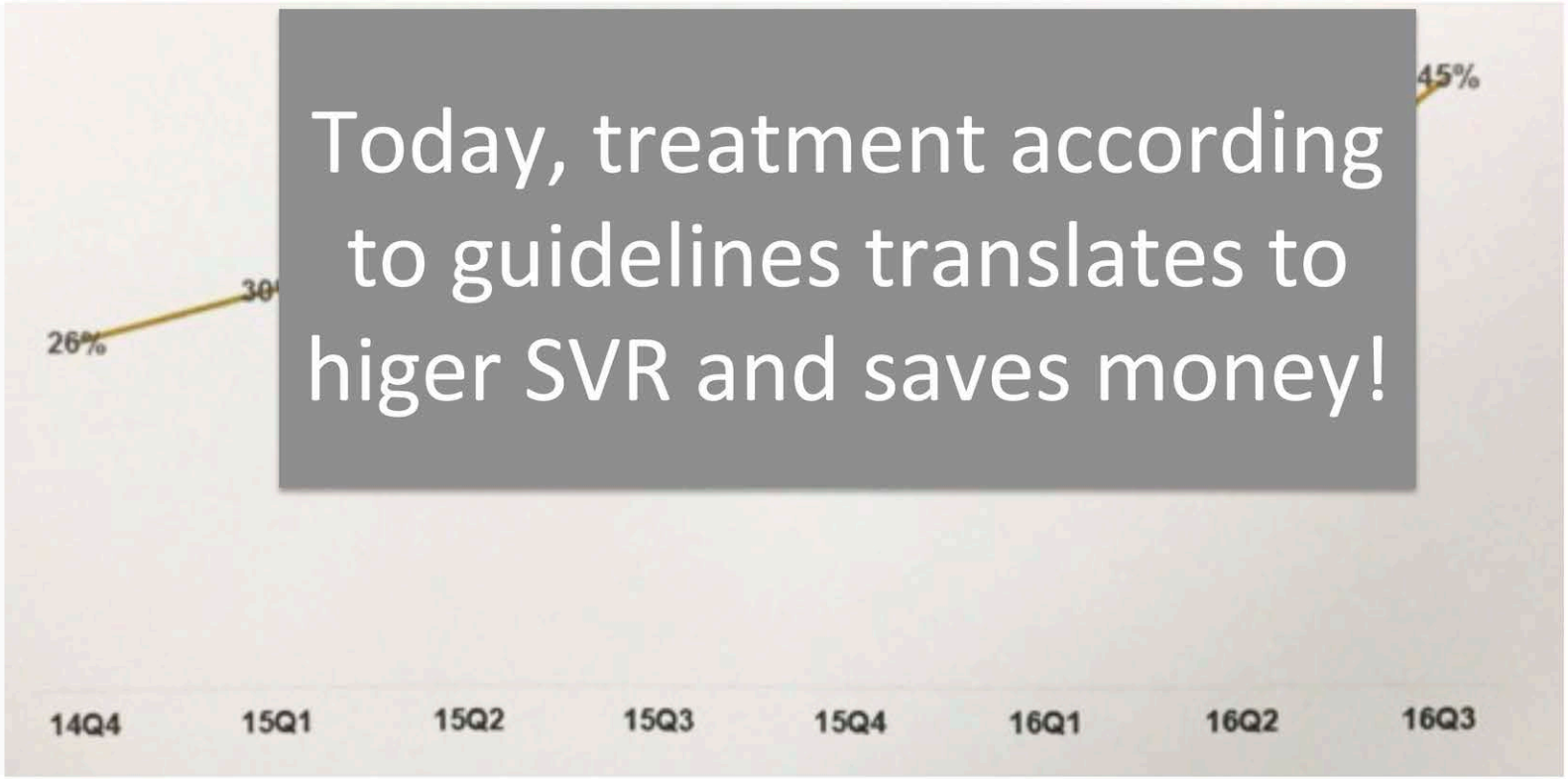

AASLD, 2016

Summary

- Dysbalance between pre-requisites for high quality treatment for HCV and todays resources/reimbursements in germany
- Treatment by specialists (infectiologists, GI specialists, OST-prescriber) to achieve high SVR rates and to save money
- Regional agreements with health insurance companies are promising (e.g. AOK Strukturvertrag) but limited and may change
- National spread of non-budgeted remunerations (as for HIV) is missing (e.g. agreements for quality standards with KV)