

# Access to treatment and disease burden



**Robert Flisiak**

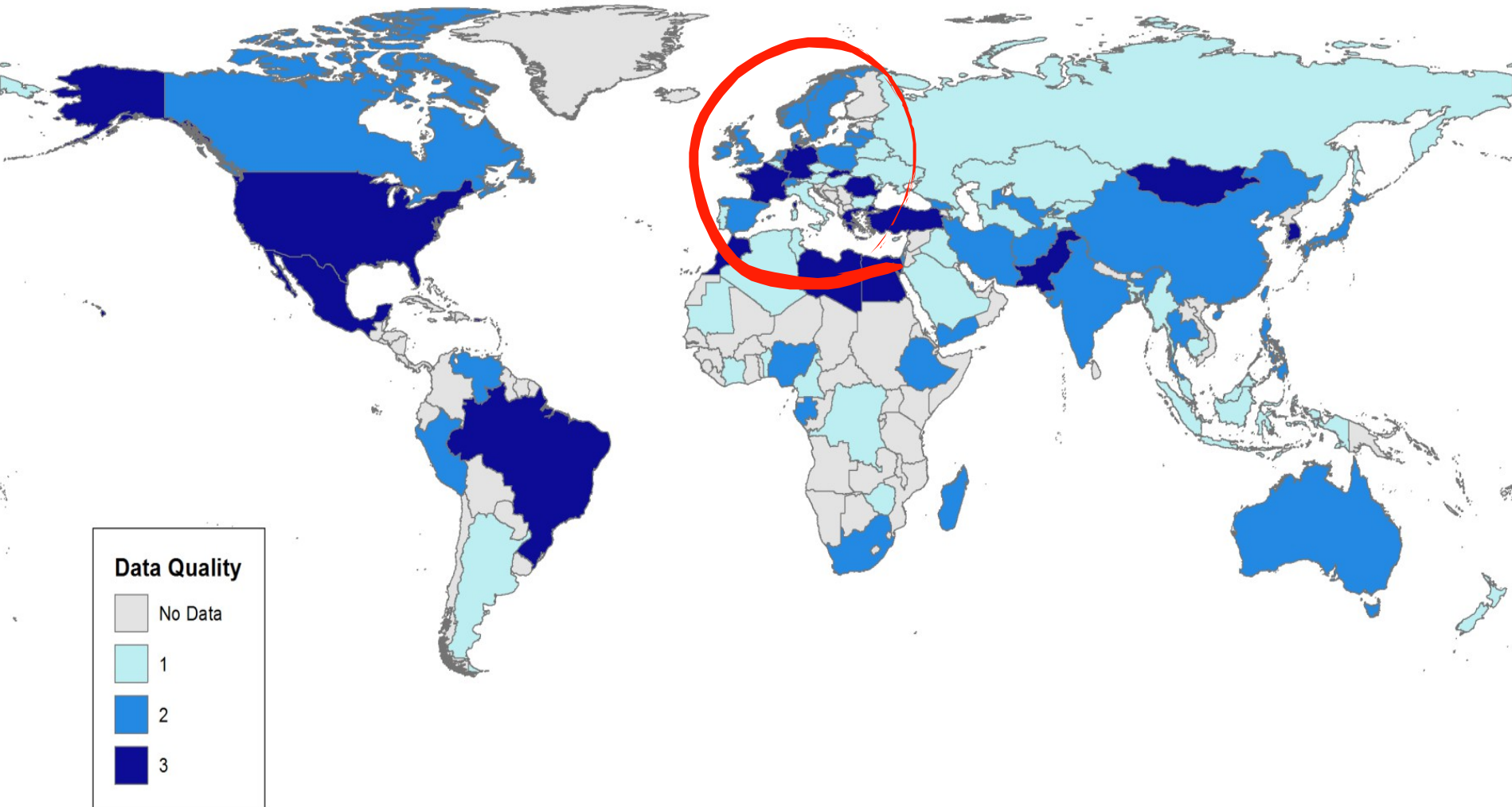
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# Disclosures

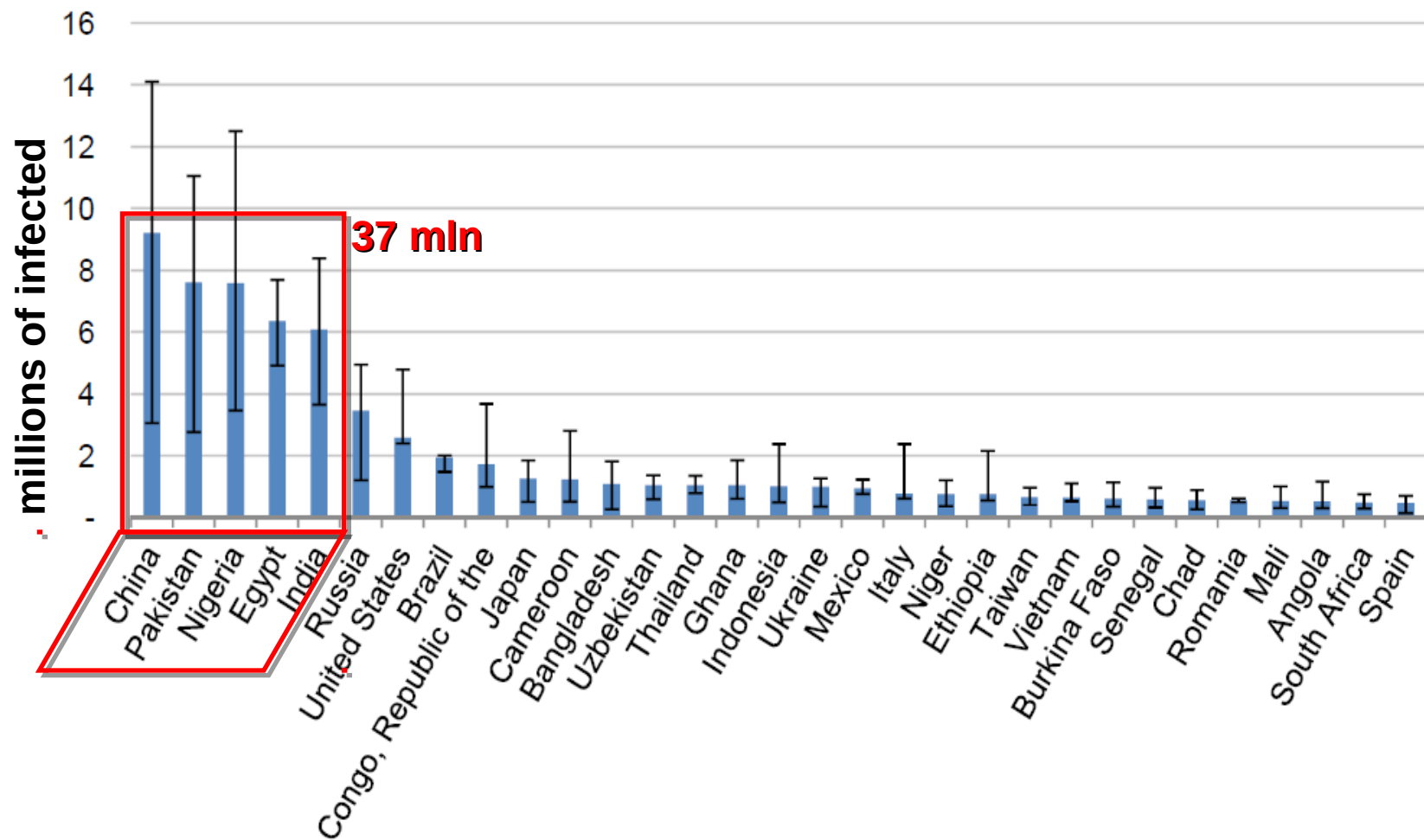
Advisor and/or speaker for

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

# Quality of HCV epidemiological data

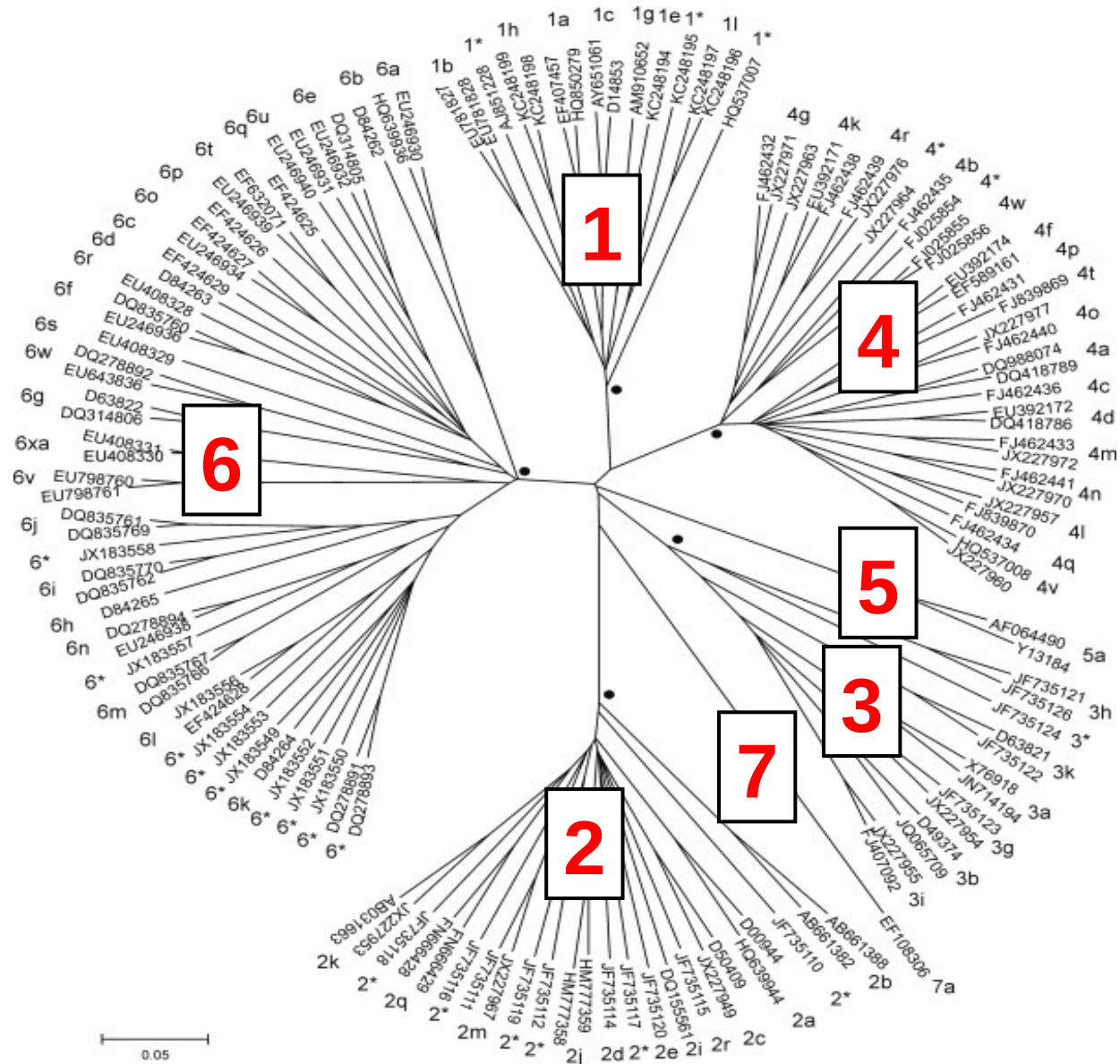


# Number of active HCV infections (HCV RNA positive) in countries responsible for 80% of worldwide infections



Gower, E. i wsp. Global epidemiology and genotype distribution of the hepatitis C virus, *J Hepatology* (2014)

# HCV genotypes

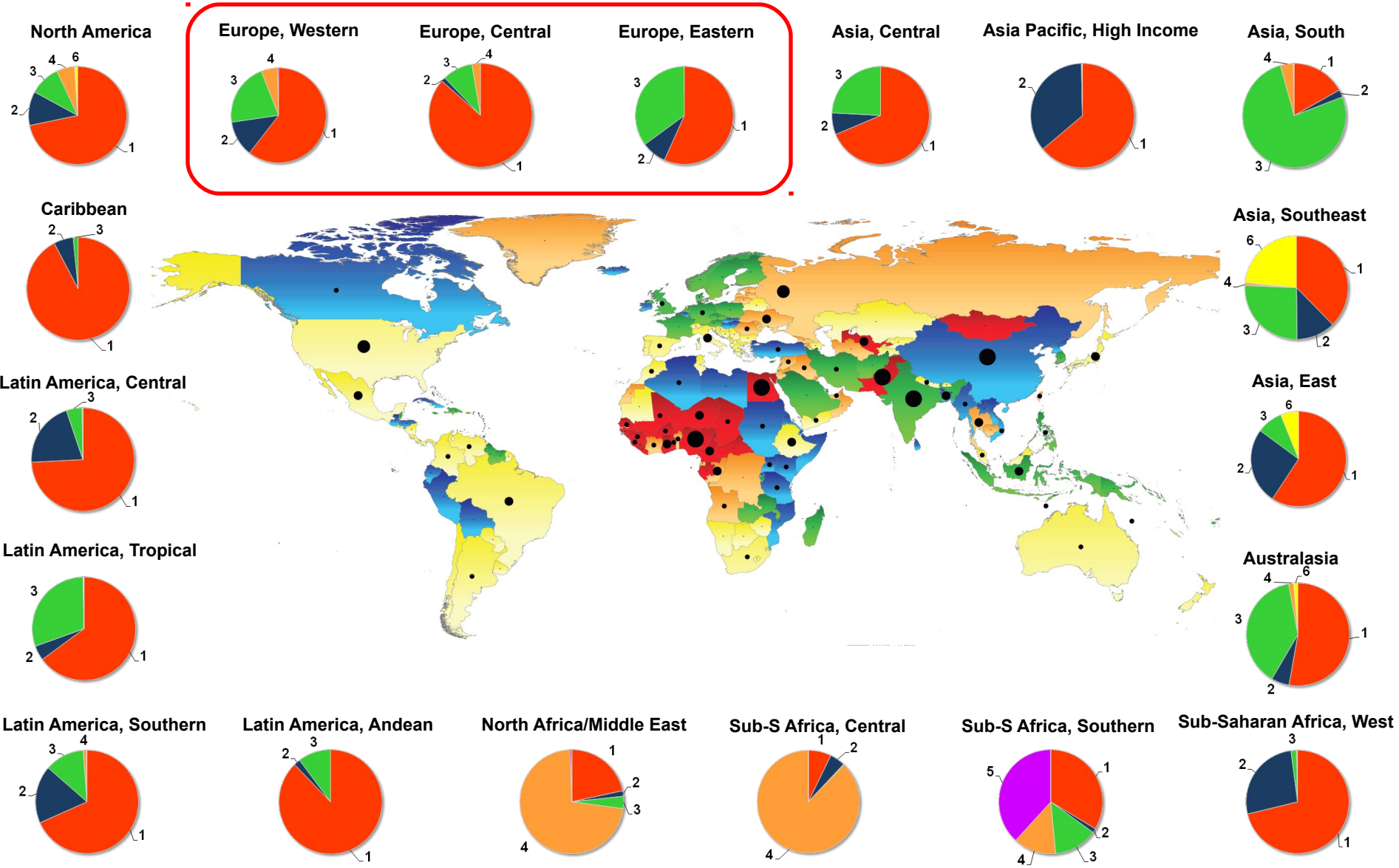


# Global prevalence of HCV genotypes

<b>Genotype 1</b>	48%
<b>Genotype 2</b>	14%
<b>Genotype 3</b>	22%
<b>Genotype 4</b>	13%
<b>Genotype 5</b>	1%
<b>Genotype 6</b>	2%

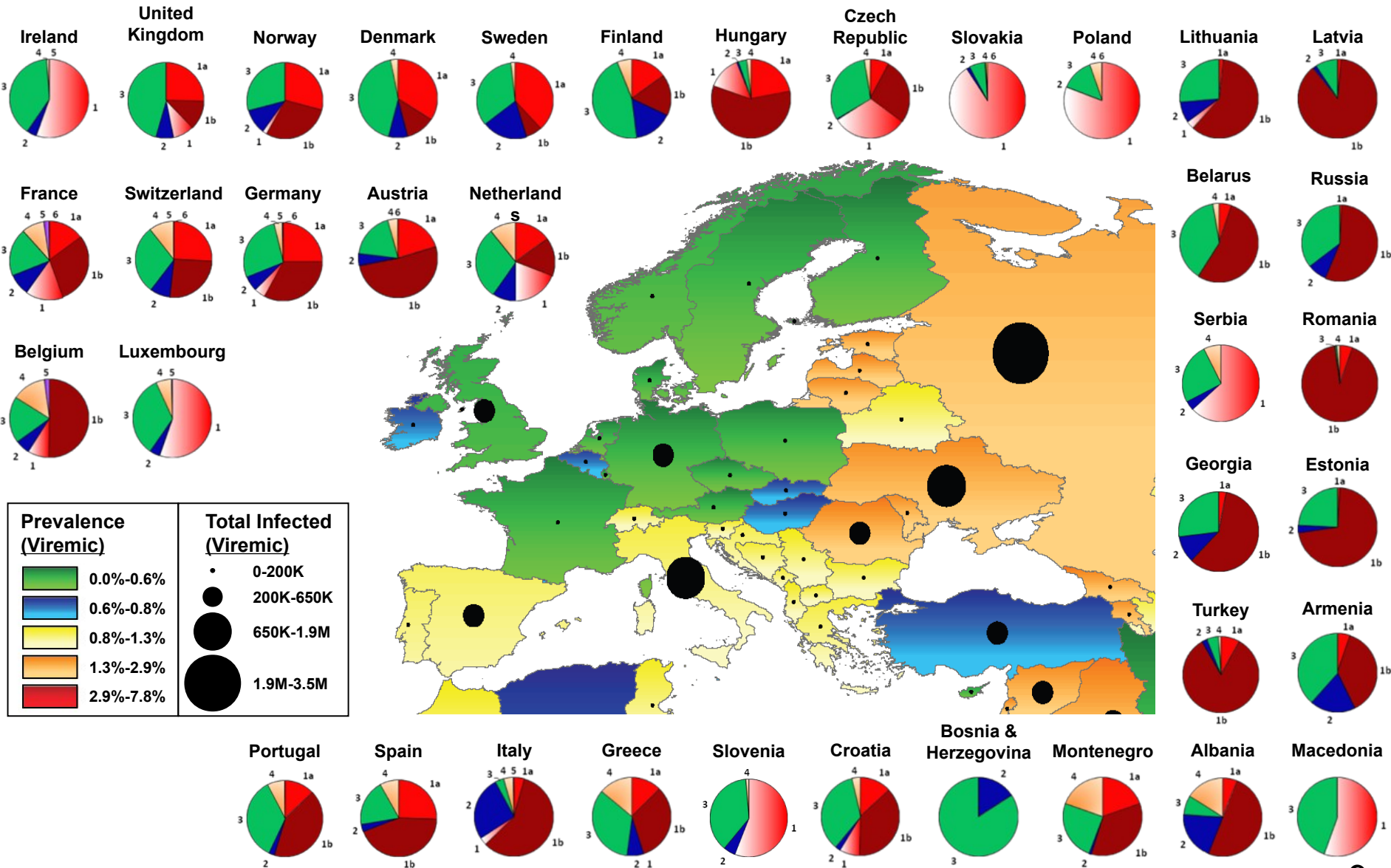
# Distribution of HCV genotypes depending on income

# Global chronic (viremic) HCV prevalence, total number of infections and HCV genotype distribution

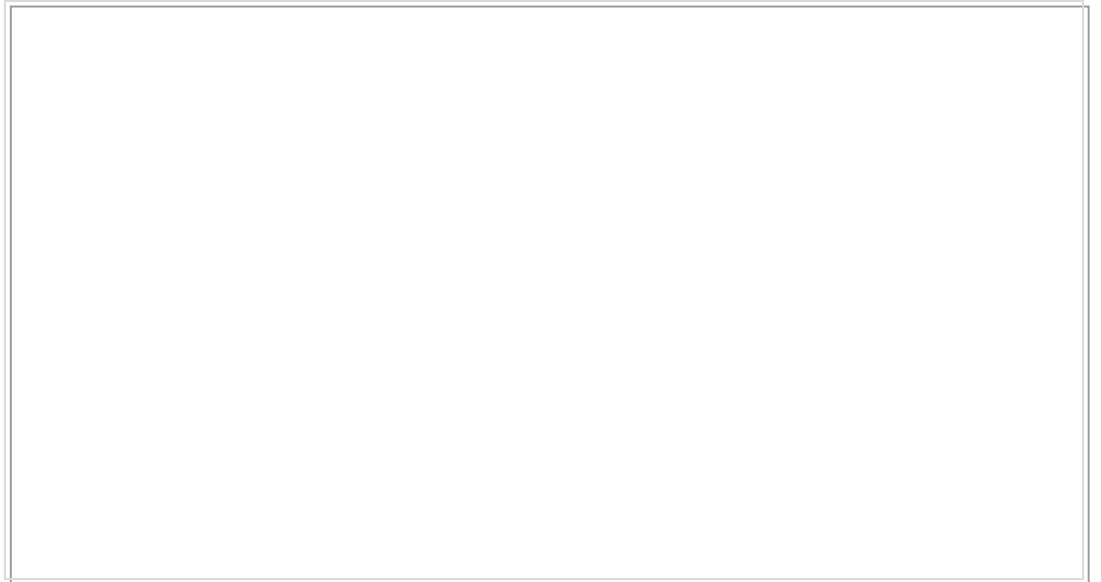
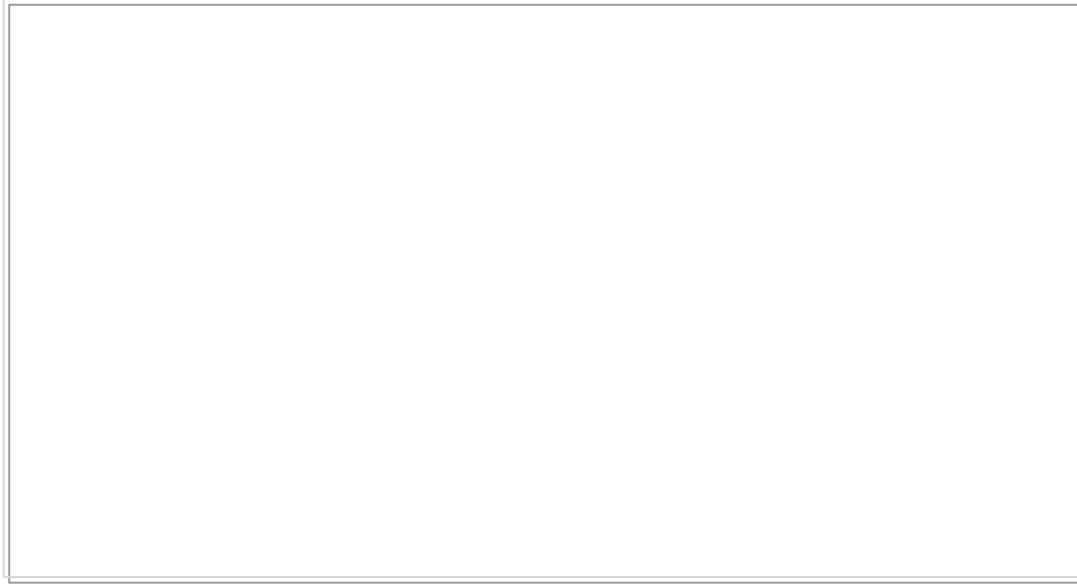




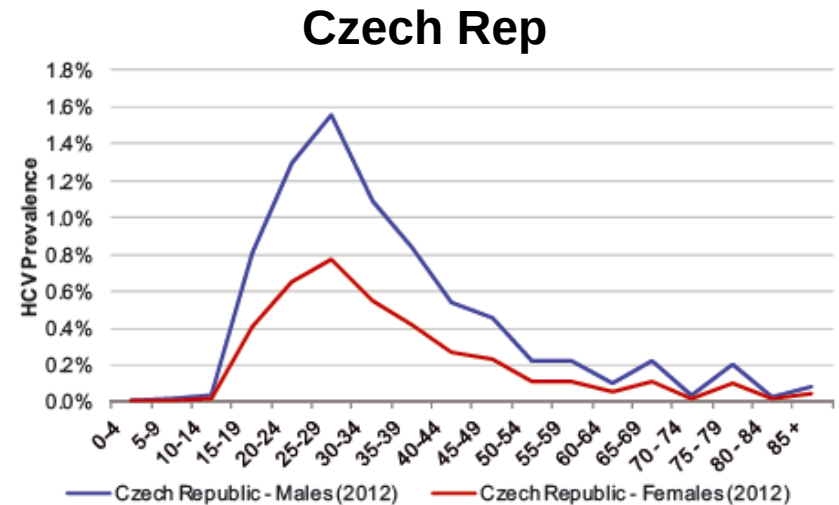
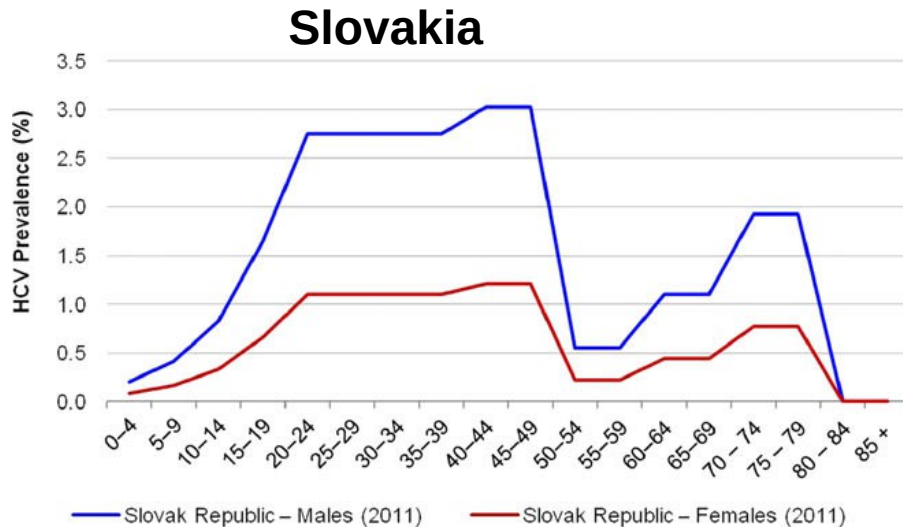
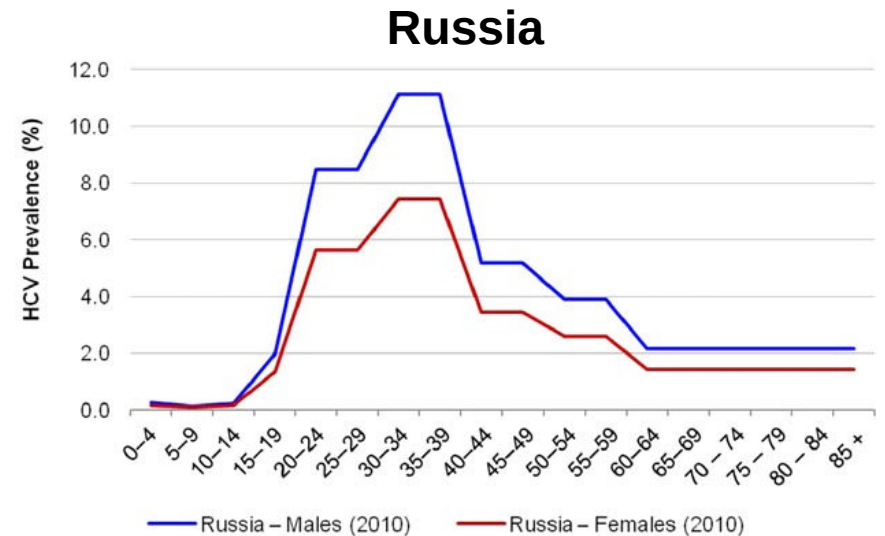
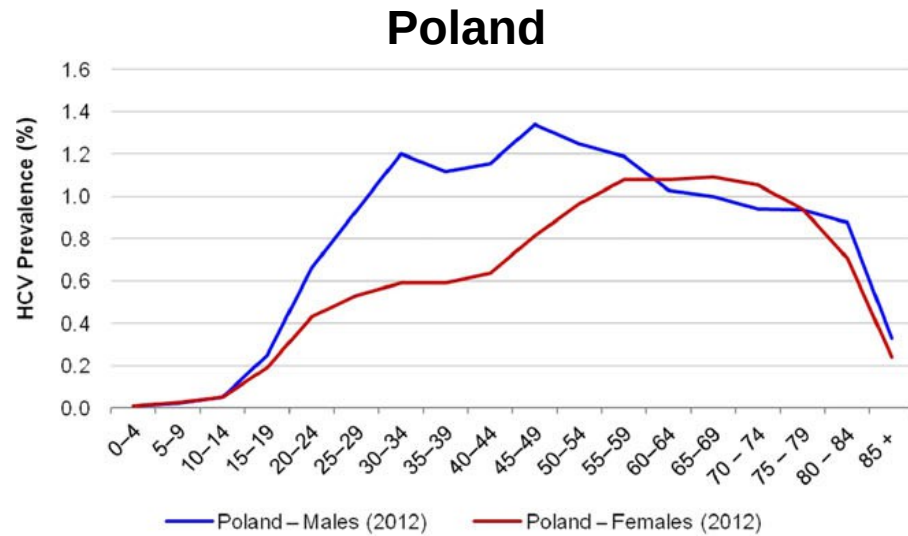
# Chronic (viremic) HCV prevalence, total number of infections and HCV genotype distribution in Europe



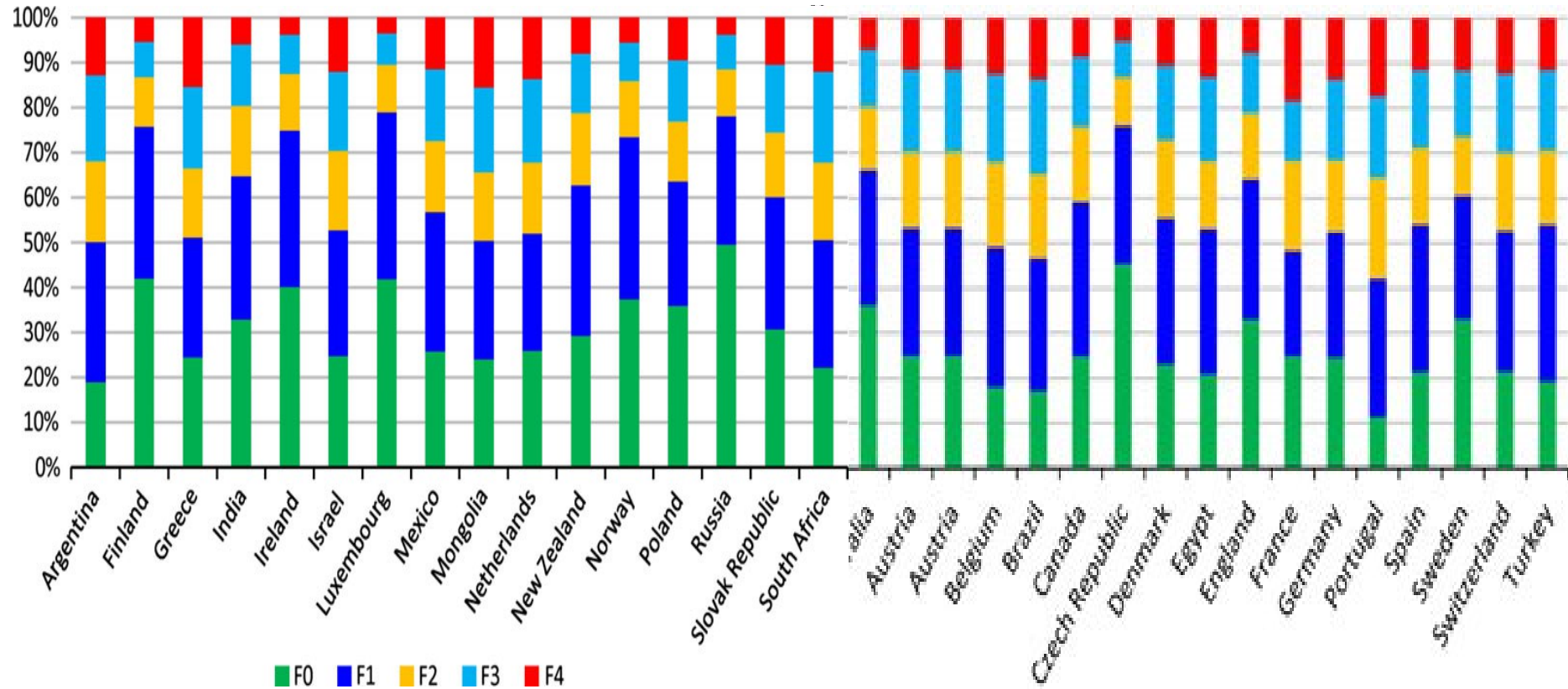
# The age distribution of viremic HCV cases varies by country, with younger populations seen in England, Poland and Sweden



# Distribution of viremic cases by age and gender can be very different



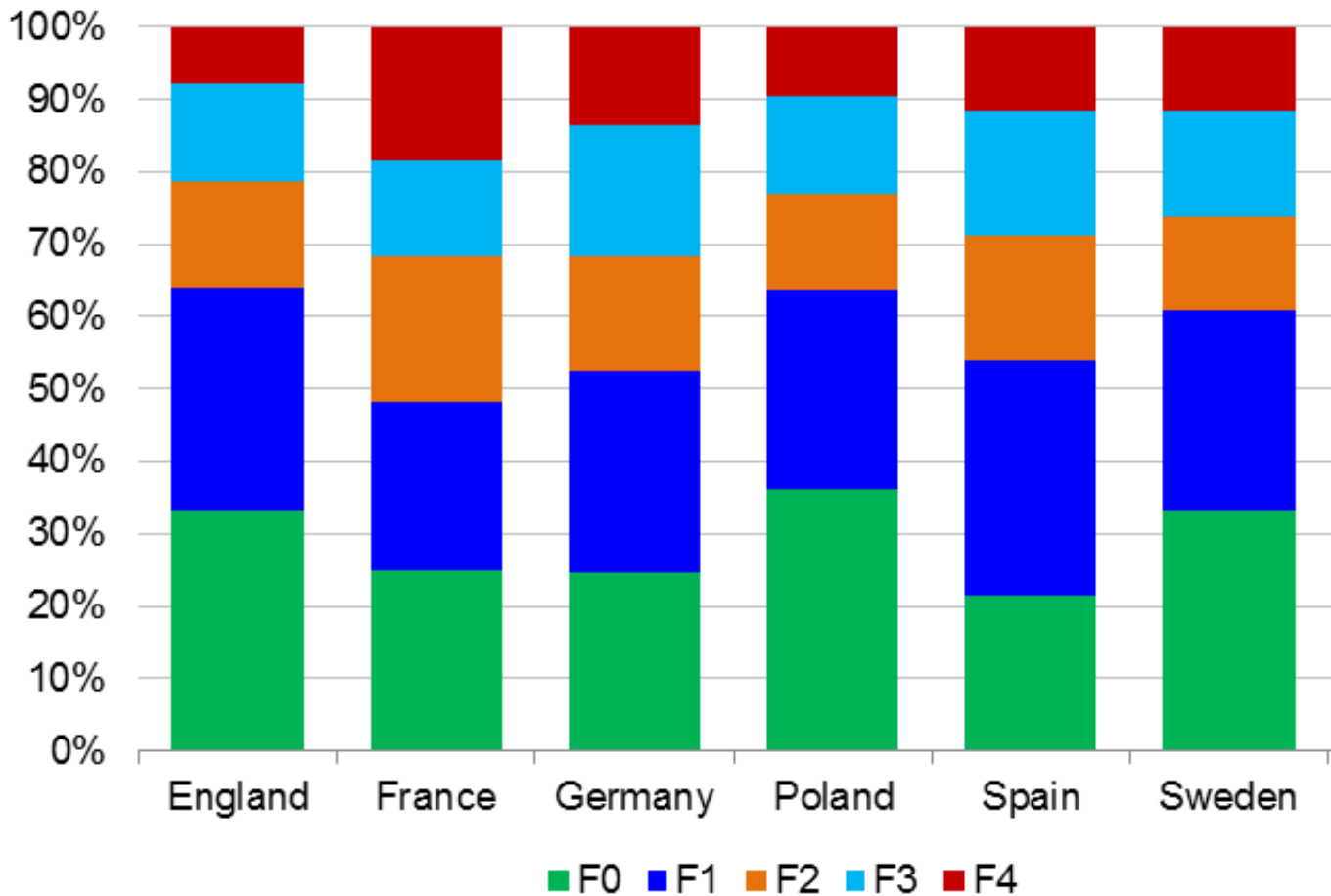
# Worldwide distribution of hepatic fibrosis related to HCV infection



Dore GJ, Ward JW., Thursz. J Viral Hepatitis, 2014, 21, (Suppl. S1), 1–4

Wedemeyer H, Dore GJ, Ward JW. J Viral Hepatitis, 2015, 22, (Suppl. S1), 1–5

# Countries with a younger HCV infected population tend to have a larger proportion of F0 and F1 patients

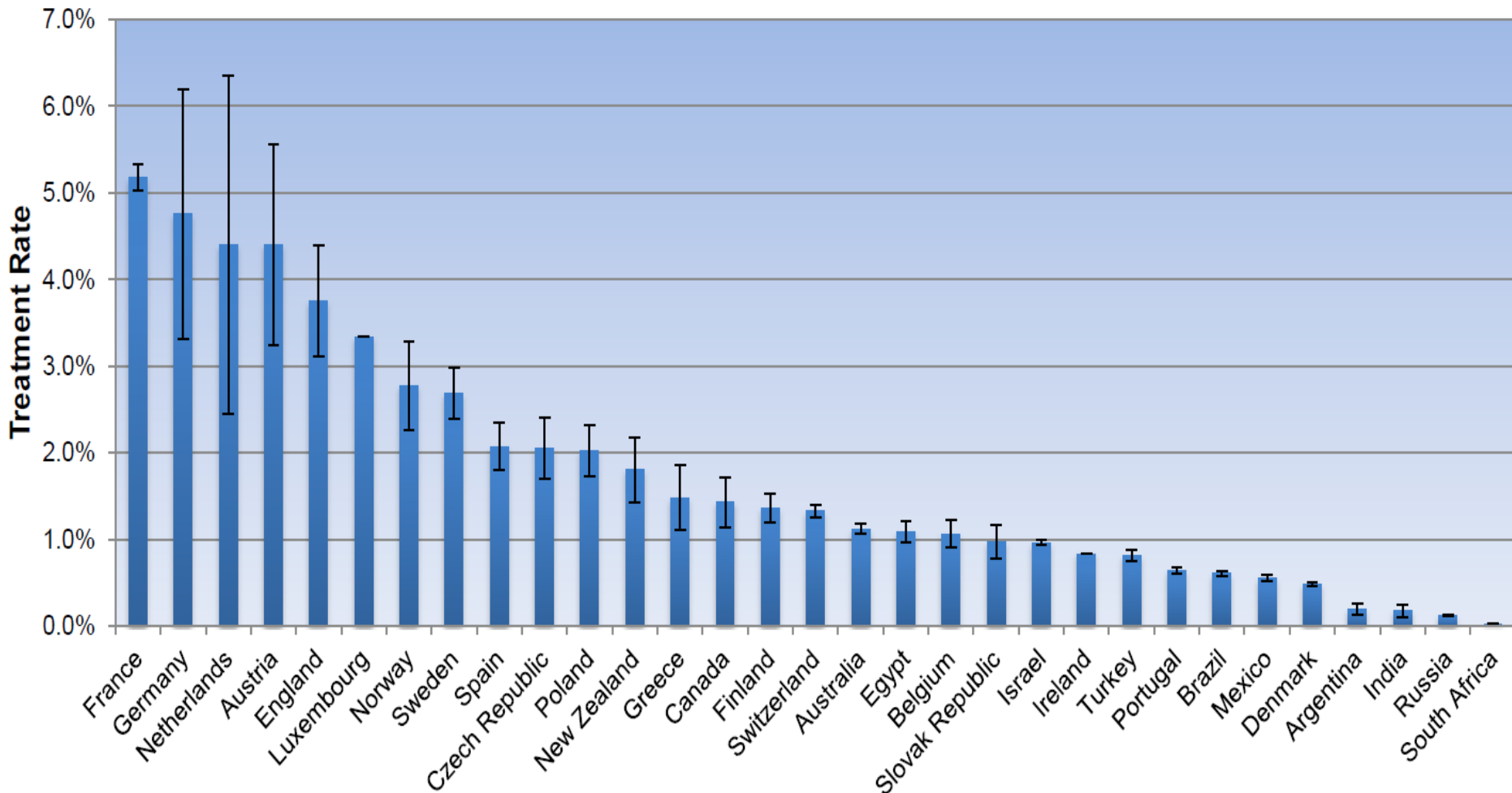


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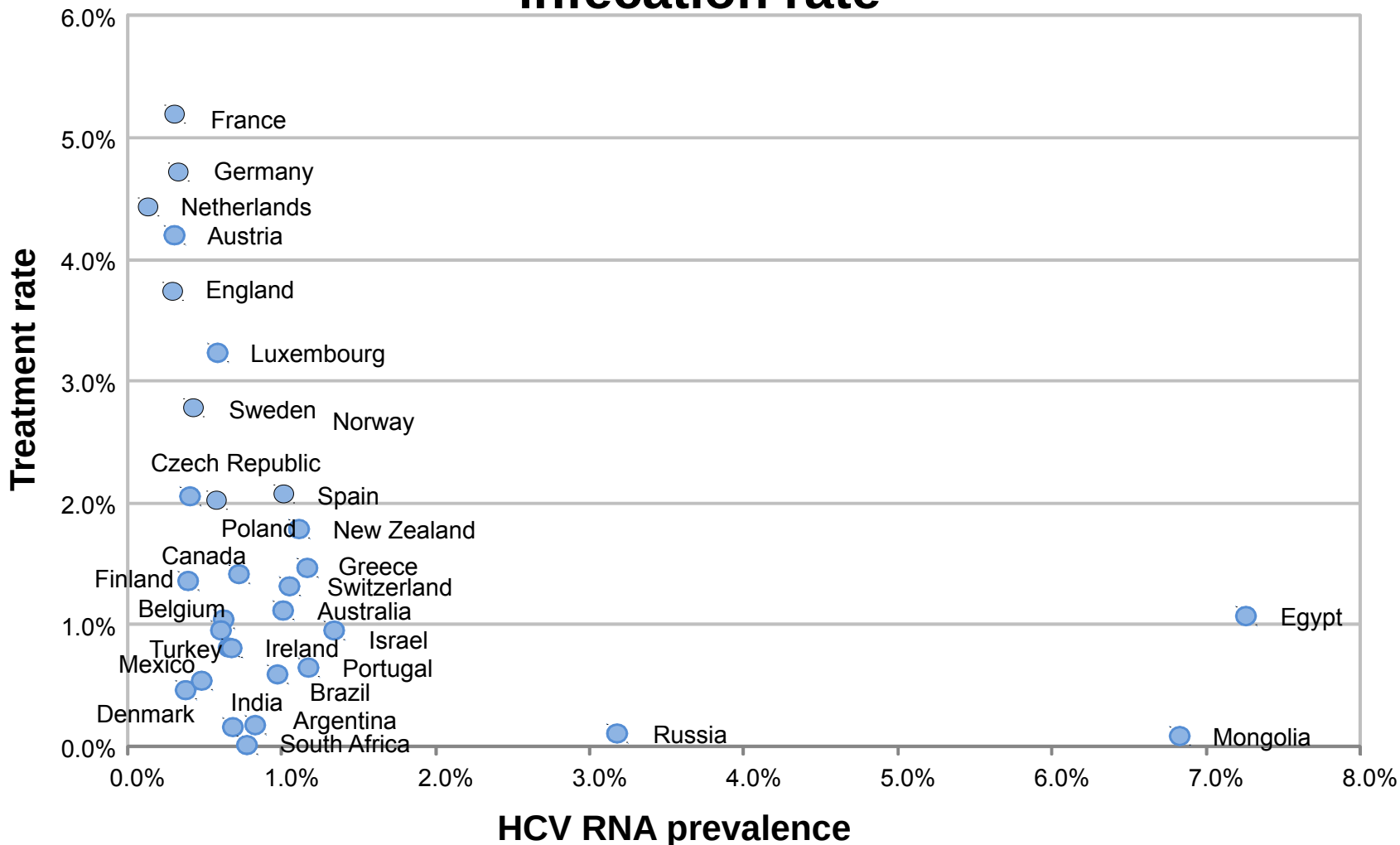
# Treatment rate in particular countries in 2013

treatment rate = number of treated annually / estimated total number of viremic



# HCV RNA prevalence and treatment rate

## Treatment rate is high in countries with relatively low infecation rate



# Cascade of HCV care, based on 2013 data

Sweden

**81%**

**2.8%**

Germany

**57%**

**4.8%**

England

**35%**

**3.8%**

France

**68%**

**5.2%**

Spain

**48%**

**2.4%**

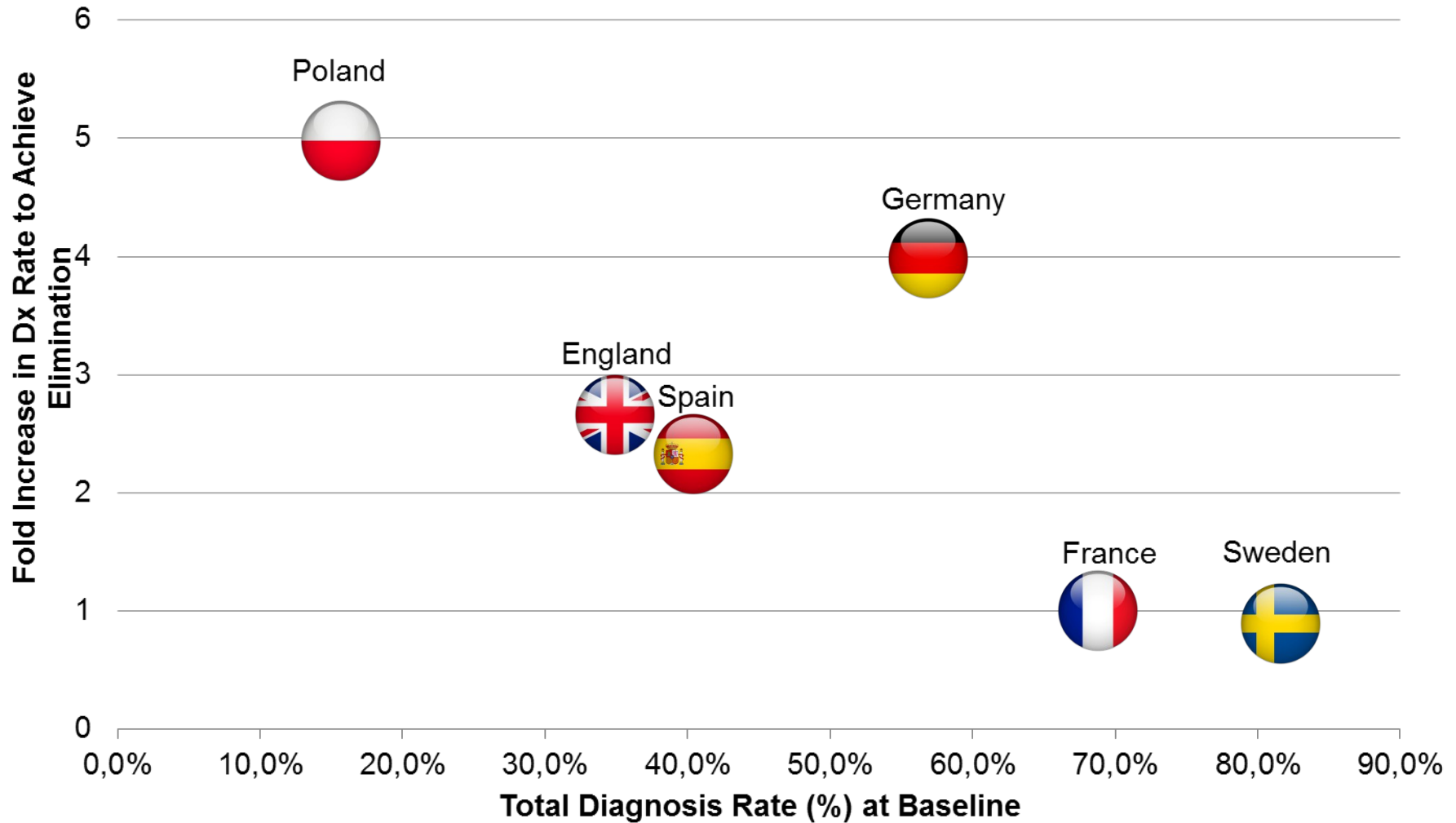
Poland

**15%**

**2.0%**

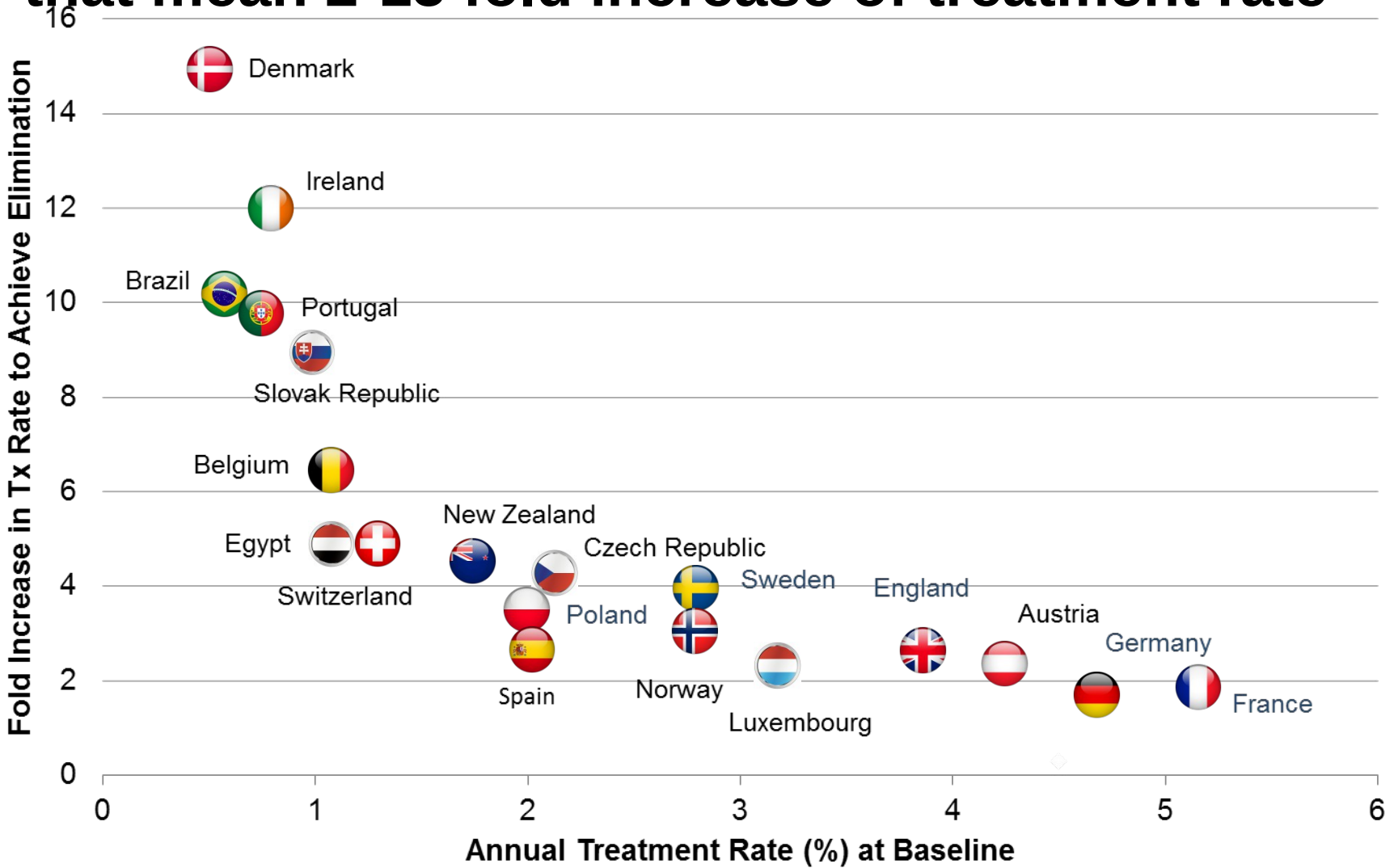


# Fold increase in annual diagnosis rate required to achieve HCV elimination (>90% reduction) by 2030



# A treatment rate of approximately 10%/year is necessary to achieve HCV elimination (>90% reduction) by 2030

that mean 2-15 fold increase of treatment rate



## EASL Recommendations on Treatment of Hepatitis C 2015

European Association for the Study of the Liver\*

# Approved HCV drugs in the European Union in 2015

Product	Presentation	Posology
PegIFN- $\alpha$ 2a	Solution for injection containing 180, 135 or 90 $\mu$ g of PegIFN- $\alpha$ 2a	Once weekly subcutaneous injection of 180 $\mu$ g (or less if dose reduction needed)
PegIFN- $\alpha$ 2b	Solution for injection containing 50 $\mu$ g per 0.5 ml of PegIFN- $\alpha$ 2b	Once weekly subcutaneous injection of 1.5 $\mu$ g/kg (or less if dose reduction needed)
Ribavirin	Capsules containing 200 mg of ribavirin	Two capsules in the morning and 3 in the evening if body weight <75 kg or Three capsules in the morning and 3 in the evening if body weight $\geq$ 75 kg
Sofosbuvir	Tablets containing 400 mg of sofosbuvir	One tablet once daily (morning)
Simeprevir	Capsules containing 150 mg of simeprevir	One capsule once daily (morning)
Daclatasvir	Tablets containing 30 or 60 mg of daclatasvir	One tablet once daily (morning)
Sofosbuvir/ledipasvir	Tablets containing 400 mg of sofosbuvir and 90 mg of ledipasvir	One tablet once daily (morning)
Paritaprevir/ombitasvir/ritonavir	Tablets containing 75 mg of paritaprevir, 12.5 mg of ombitasvir and 50 mg of ritonavir	Two tablets once daily (morning)
Dasabuvir	Tablets containing 250 mg of dasabuvir	One tablet twice daily (morning and evening)

# National treatment guidelines

	<b>Germany</b>	<b>France</b>	<b>Spain</b>	<b>Bulgaria</b>	<b>Croatia</b>	<b>Czech Rep</b>	<b>Estonia</b>	<b>Hungary</b>	<b>Latvia</b>	<b>Lithuania</b>	<b>Poland</b>	<b>Romania</b>	<b>Russia</b>	<b>Slovakia</b>	<b>Slovenia</b>	<b>Ukraine</b>
<b>Created by the national scientific medical association</b>	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
<b>Created by the authority (ministry, government, etc.)</b>			x			x		x	x	x	x	x		x		x
<b>Created by the private insurance companies</b>	x	x				x										

# Therapeutic options reimbursed by public health care

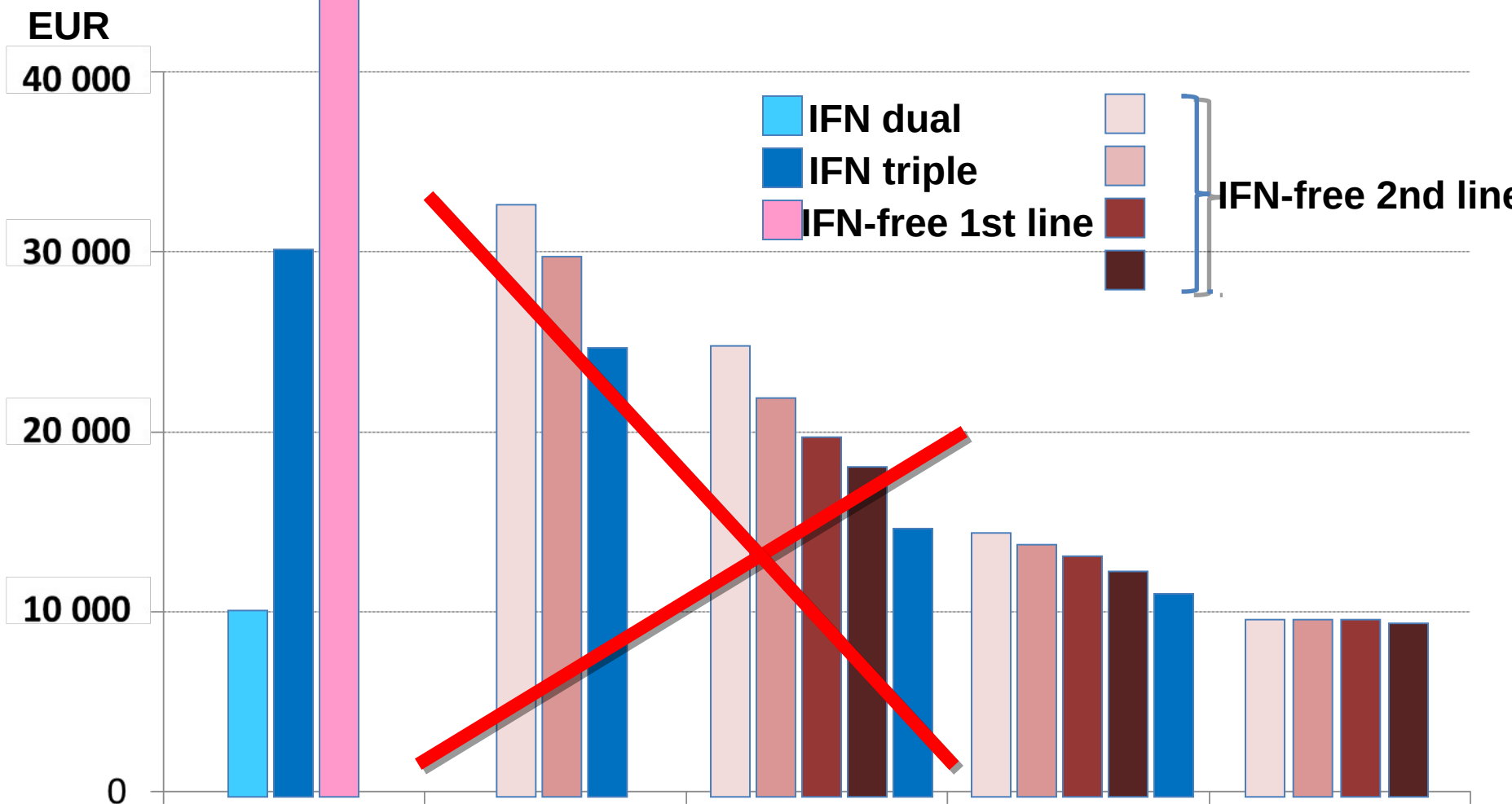
	Germany	France	Spain	Hungary	G. Britain	Czech Rep	Slovakia	Poland	Croatia	Estonia	Lithuania	Russia	Latvia	Bulgaria	Romania	Slovenia	Ukraine
<b>PegIFN+RBV</b>				X	X	X	X	X	X	X	X	X	X	X	X	X	X
<b>BOC+PegIFN+RBV</b>					X	X	X	X	X	X	X	2)					
<b>TVR+PegIFN+RBV</b>					X	X	X	X	X	X		2)					
<b>SOF+PegIFN+RBV</b>					X	X	X										
<b>SMV+PegIFN+RBV</b>					X	X	X	X				2)					
<b>DCV+PegIFN+RBV</b>					X												
<b>SOF+RBV</b>	X	X	X		1)			3)									
<b>SOF+SMV+/-RBV</b>	X	X	X		1)			3)									
<b>SOF+DCV+/-RBV</b>	X	X	X		1)												
<b>SOF+LDV+/-RBV</b>	X	X	X	X	1)			3)									
<b>PRV/OMBr+DBV+/-RBV</b>	X	X	X	X	1)			X									
<b>ASV+DCV+/-RBV</b>								X									

- 1) IFN-free regimen reimbursed for patients with decompensated cirrhosis
- 2) Triple therapy reimbursed for selected professional groups
- 3) Expected by the end of 2015

# Priority to reimbursed treatment

	Germany	France	Spain	G. Britain	Bulgaria	Croatia	Czech Rep	Estonia	Hungary	Latvia	Lithuania	Poland	Romania	Russia	Slovakia	Slovenia	Ukraine
<b>Fibrosis</b> (more advanced has priority)					X	X	X	X	X	X	X		X	X	X	X	X
<b>treatment history</b> (non-responders have priority)						X		X	X	X	X				X	X	X
<b>IL28B</b> (TT has priority)																	
<b>extrahepatic manifestations</b>							X		X		X				X	X	
<b>HIV co-infection</b>							X	X	X					X		X	X
<b>Priority for fibrosis stage</b>																	
<b>F1</b>								X	X								
<b>F2</b>		X	X					X	X	X							X
<b>F3</b>		X	X		X	X	X	X	X	X	X		X		X	X	X
<b>F4</b>		X	X	X	X	X	X	X	X	X	X		X	X	X	X	X

# Predicted costs of reimbursed HCV treatment in Poland



# Conclusions

- 1. Recent epidemiological data from Europe represents good quality but it is not a case in all countries.**
- 2. Europe can be divided into regions of low prevalence – western, central and northern, moderate prevalence – southern and high prevalence – eastern part of the continent.**
- 3. Predominant genotypes are 1 and 3.**
- 4. Reimbursement of HCV treatment according to EASL guidelines is very divergent across the region, from reimbursement of PegIFN/RBV treatment only to IFN-free regimen for all patients.**