

# Hepatitis C:

**Dr Rafael Esteban**

Hospital Universitario Vall d'Hebrón

Barcelona



# CONFLICT OF INTEREST

I have financial relationships to disclose within the past 12 months relevant to my presentation:

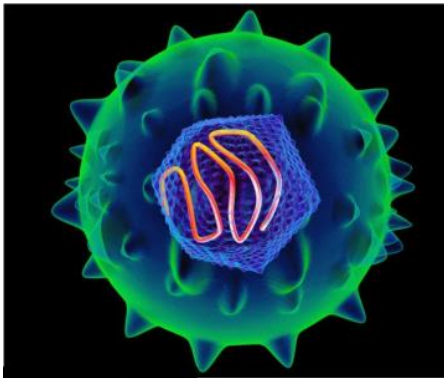
*Consultant and Speaker Bureau  
Abbvie and Gilead,*

# Situación hasta 2000

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Centers for Disease Control and Prevention  
CDC 24/7: Saving Lives, Protecting People™



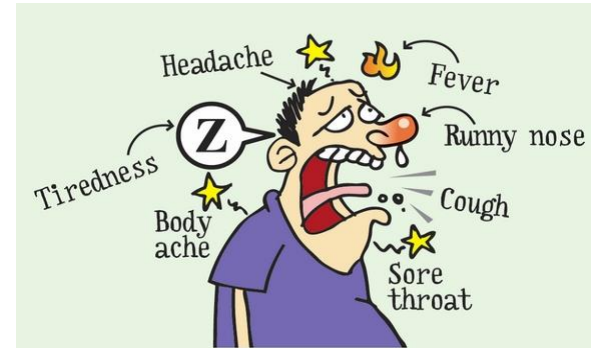
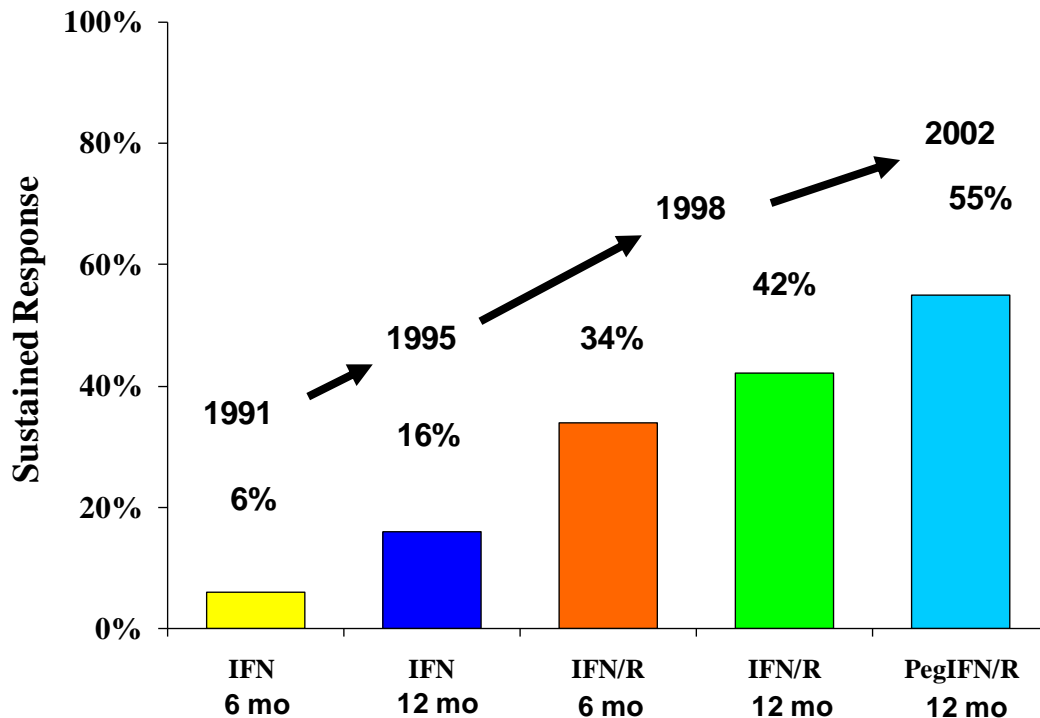
**VHC**

- ✓ Aprox. 170 millones infectados  
**(3% de la población mundial)**
- ✓ Más de 483.000 muertes anuales
- ✓ **Principal indicación de trasplante**
- ✓ **Causa más frecuente de hepatocarcinoma en Europa**

# Situación hasta 2000

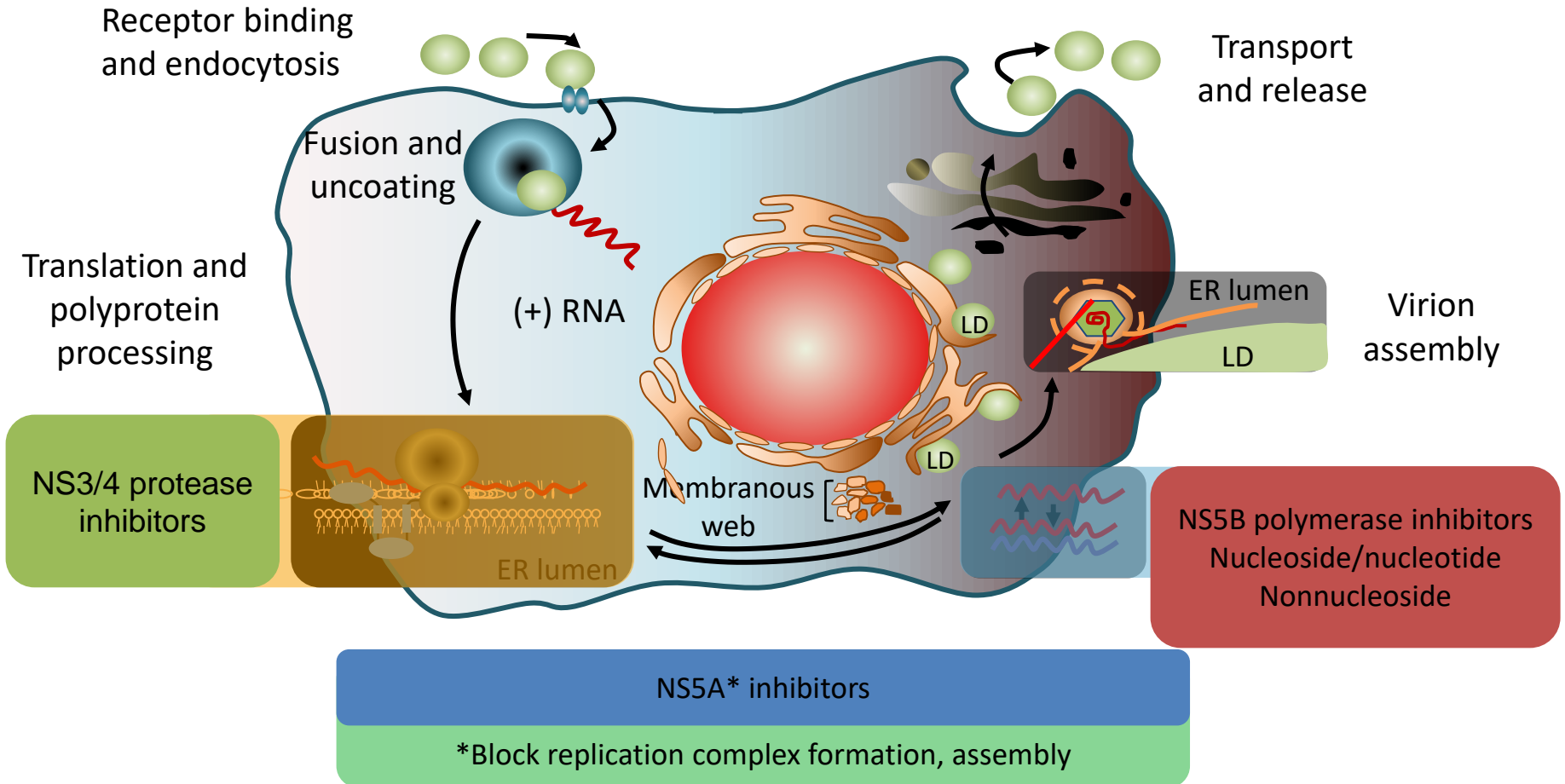


## Tasa de respuesta virológica sostenida con IFN



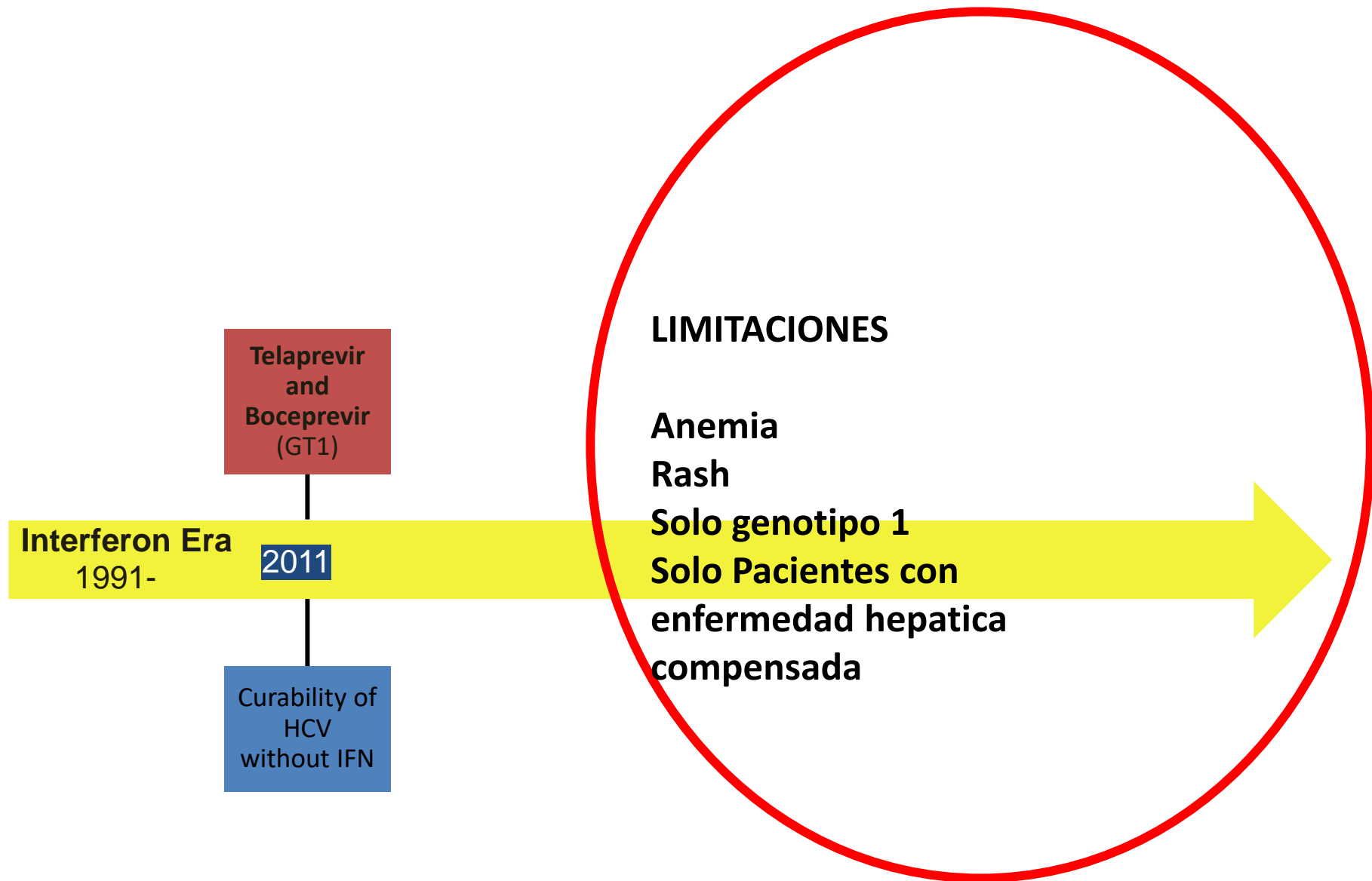
- Múltiples efectos adversos
- Algunos graves
- Frecuentes reducciones dosis
- Abandonos frecuentes
- Interacciones farmacológicas

# HCV Life Cycle and DAA Targets



# The Evolution of HCV Therapy

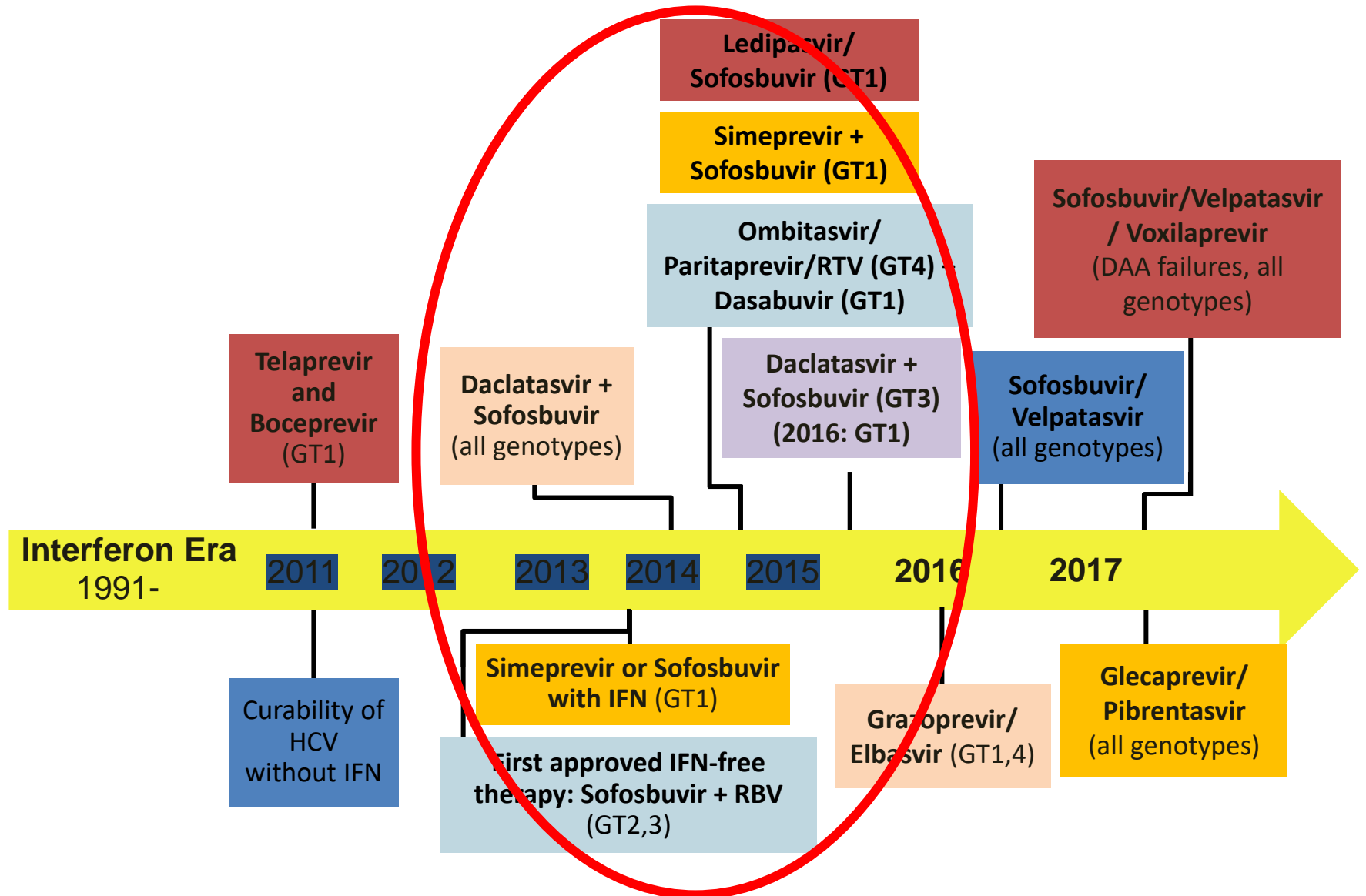
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# 2013

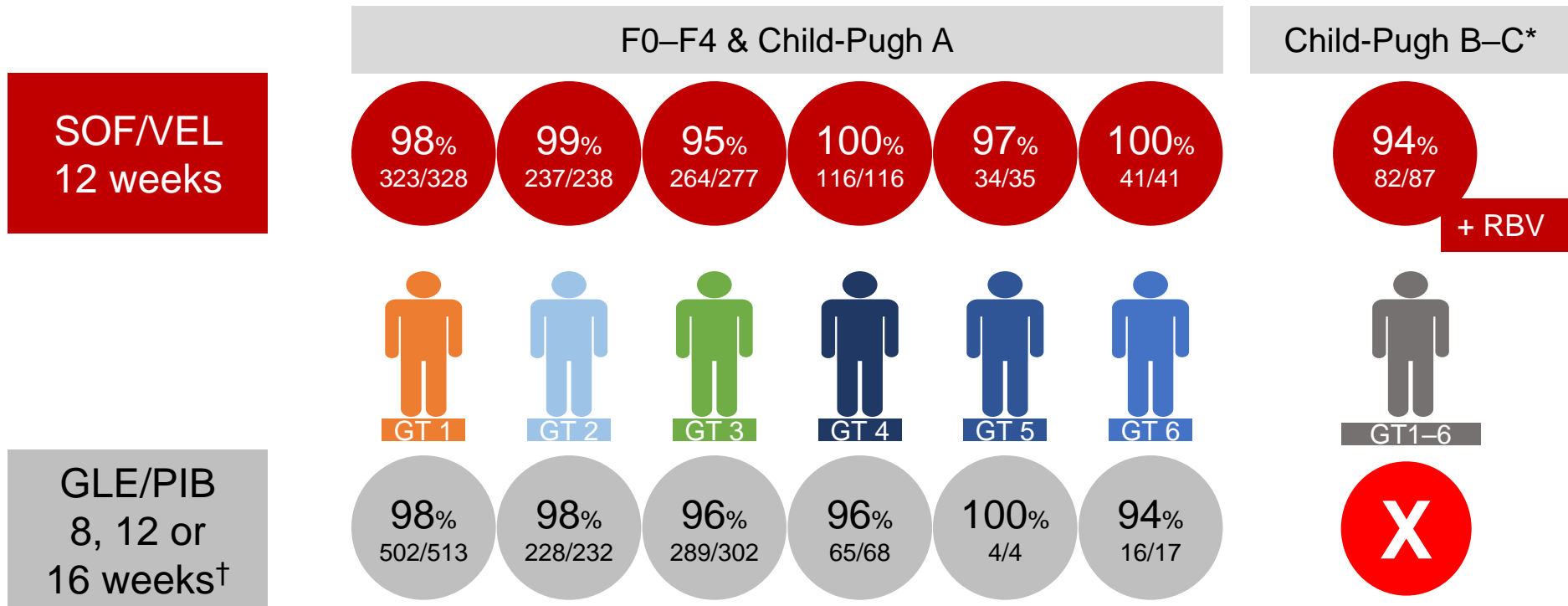


# The Evolution of HCV Therapy





# Pangenotypic therapies for almost all patients



\*Safety and efficacy of SOF/VEL have not been assessed in patients with CTP class C cirrhosis. <sup>†</sup>As approved in the EU SmPC. These are not head-to-head studies and direct comparisons cannot be made.

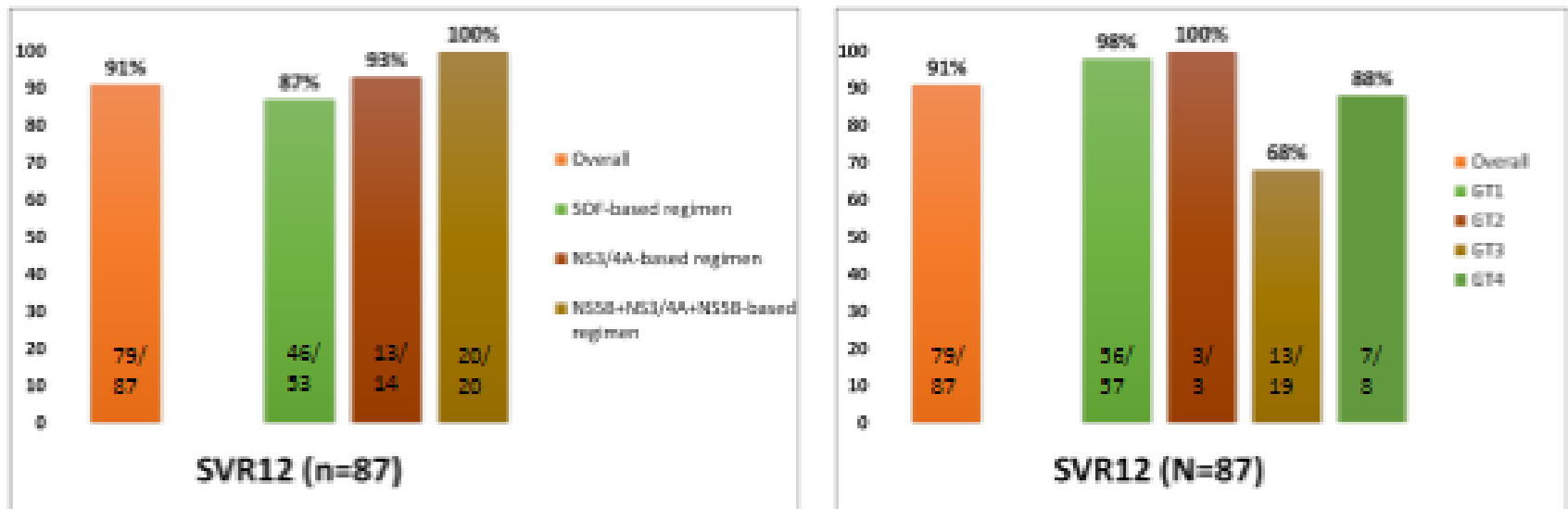
CTP: Child–Turcotte–Pugh

Agarwal K, et al. ILC 2016; Poster #SAT-195; Gane E, et al. AASLD 2017; Oral #74; Puoti M, et al. ILC 2017; Poster #SAT-233; Gilead Sciences Ltd. EPCLUSA ▼ (sofosbuvir/velpatasvir), SmPC, March 2018; AbbVie Ltd. MAVIRET ▼ (glecaprevir/pibrentasvir), SmPC, February 2018

# Real-life effectiveness and safety of velpatasvir/sofosbuvir/voxilaprevir for previously DAA treated patients with chronic hepatitis C

- Prospective multicentric study DAA previously treated subjects at 28 Spanish hospitals (2014-2017)
- Retreated with SOF/VEL/VOX for 12 weeks.

## Rate of SVR12 according to genotype and previous DAA



# Beneficios del tratamiento



Mejoría de la enfermedad hepática



Mejoría de las manifestaciones extrahepáticas y sus costes asociados



Mejoría calidad de vida del paciente

# Global Call for HCV Elimination

- WHO vision: *“A world where viral hepatitis transmission is stopped and everyone has access to safe, affordable, and effective treatment and care”*

## 2030 Targets

90% Diagnosed

80% Treated

65% Reduced mortality

- Feasible by scaling up key interventions:
  - Hepatitis B vaccination and treatment
  - Safe injection practices and safe blood
  - Harm reduction for PWID
  - Safer sex (including condom promotion)
  - Hepatitis C cure

# We have the tools— the challenges are access and implementation

Harm reduction



Direct-acting  
antivirals

Screening

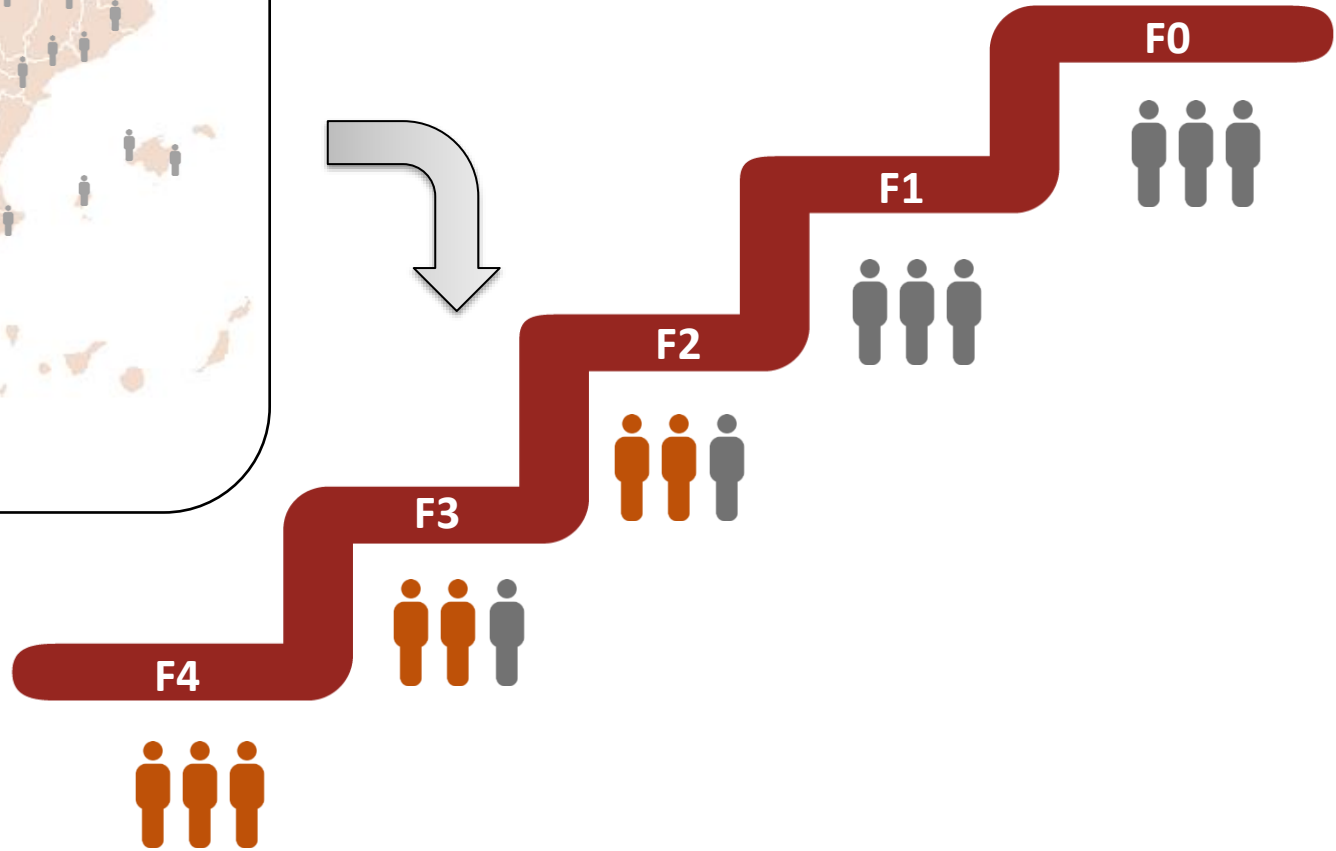
# Point of care testing for antHCV antibodies and HCV RNA



# Plan estratégico para el abordaje de la Hepatitis C en el Sistema Nacional de Salud. Situación actual

Pacientes con VHC

## Tratamiento universal del VHC



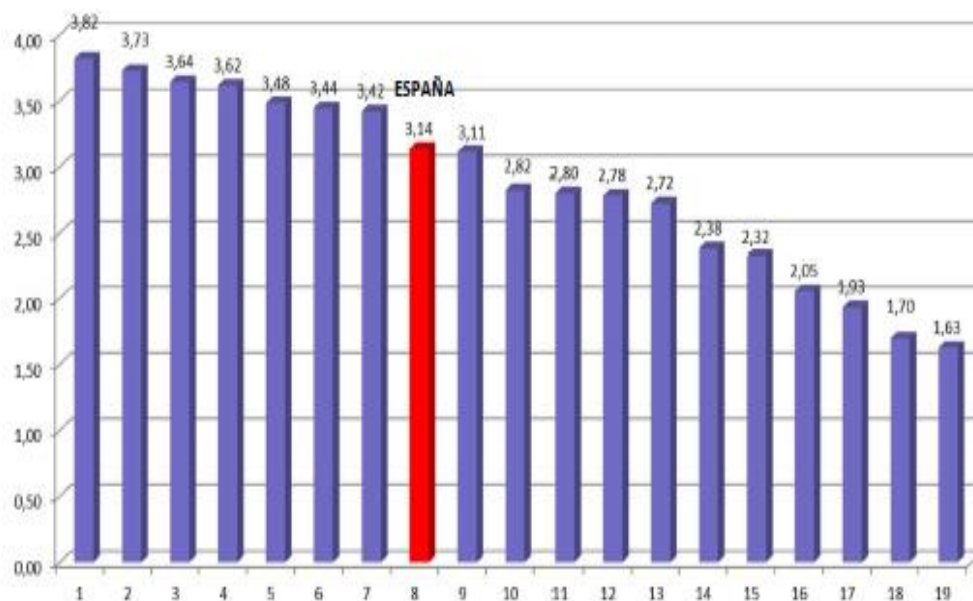
## PACIENTES TRATADOS POR COMUNIDAD AUTÓNOMA

### 1 ENERO 2015 – 31 DICIEMBRE 2020

Pacientes tratados

146.668

TOTAL PACIENTES PONDERADO SEGÚN POBLACIÓN  
(DATOS INE \* 1,000)



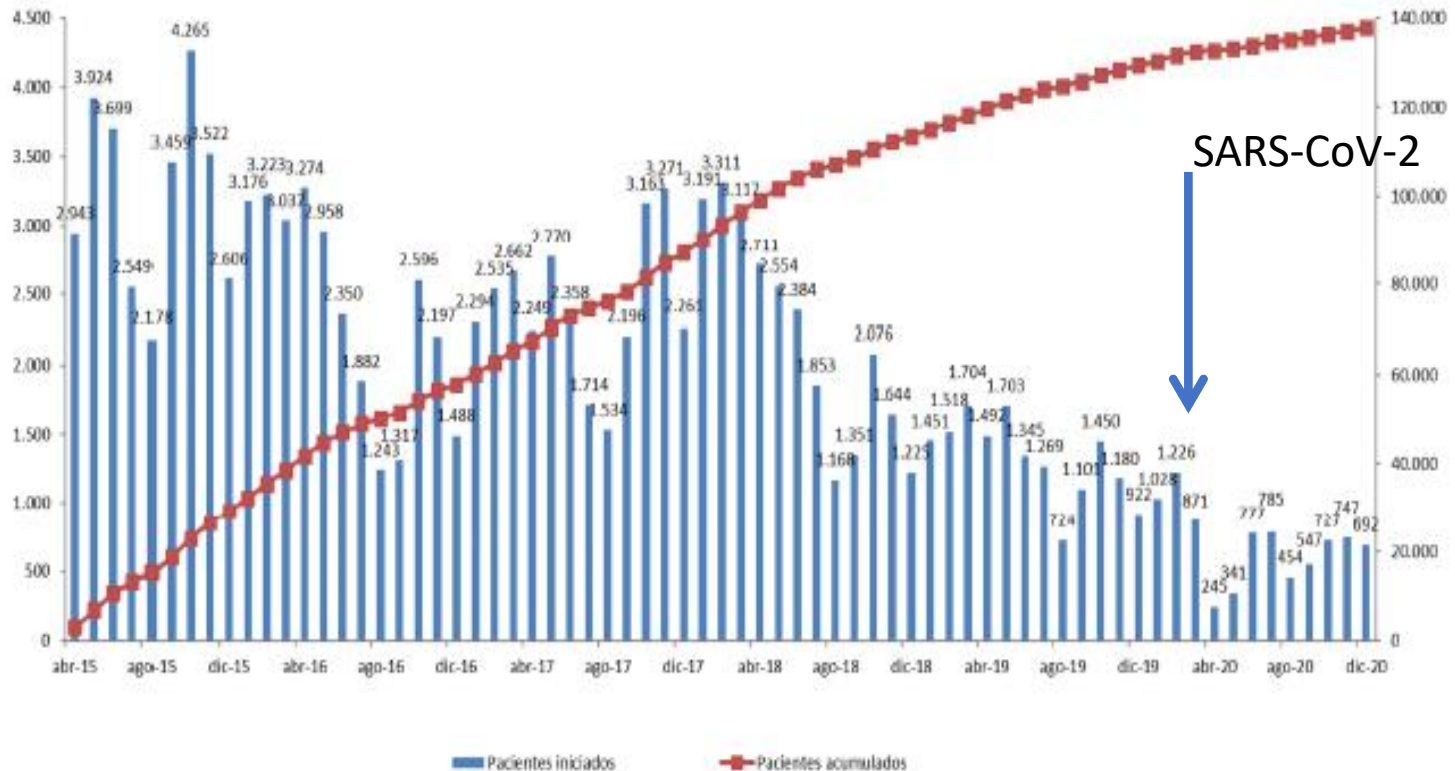
\*Población INE enero 2014 x 1.000 para el periodo 2015-2018 y Población INE enero 2018 x 1.000 a partir de 2019.

Fuente: Datos presentados por las CCAA mensualmente



## PACIENTES QUE INICIAN TRATAMIENTO MENSUALMENTE DESDE EL INICIO DEL PEAHC

Media de 1.997 pacientes inician tratamiento/mes

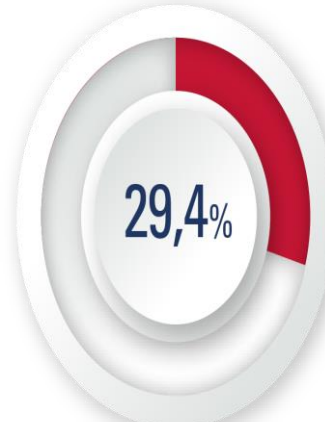


# 2º Estudio de seroprevalencia de infección por el VHC en España (2017-2018)



**Infección activa por el VHC previamente documentada<sup>1</sup>**

Búsqueda activa de pacientes diagnosticados no tratados



**Infección activa por el VHC no diagnosticada<sup>1</sup>**

Cribado de pacientes no diagnosticados

Se puede calcular que **unas 76.457 personas** en la población general tendrían **infección activa en España**, de las cuales **53.979 tendrían ya un diagnóstico<sup>1</sup>**

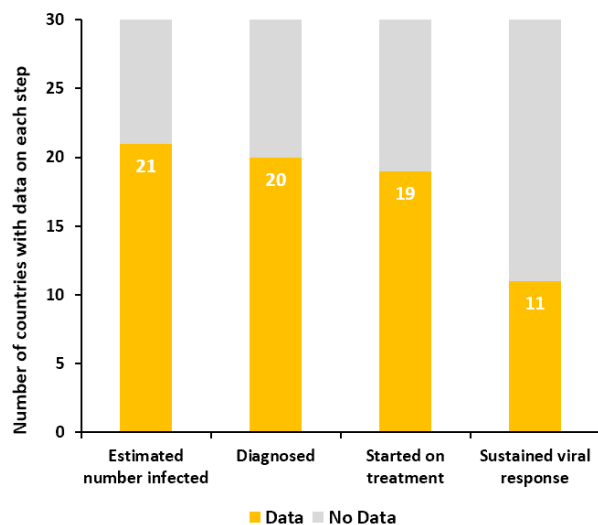
**VHC:** virus de la hepatitis C.

1. Ministerio de Sanidad, Secretaría General de Sanidad, Dirección General de Salud Pública, Calidad e Innovación. Guía de cribado de la infección por el VHC, Julio 2020. Disponible en: [https://www.mscbs.gob.es/gl/ciudadanos/enfLesiones/enfTransmisibles/sida/docs/GUIA\\_DE\\_CRIBADO\\_DE\\_LA\\_INFECCION\\_POR\\_EL\\_VHC\\_2020.pdf](https://www.mscbs.gob.es/gl/ciudadanos/enfLesiones/enfTransmisibles/sida/docs/GUIA_DE_CRIBADO_DE_LA_INFECCION_POR_EL_VHC_2020.pdf).

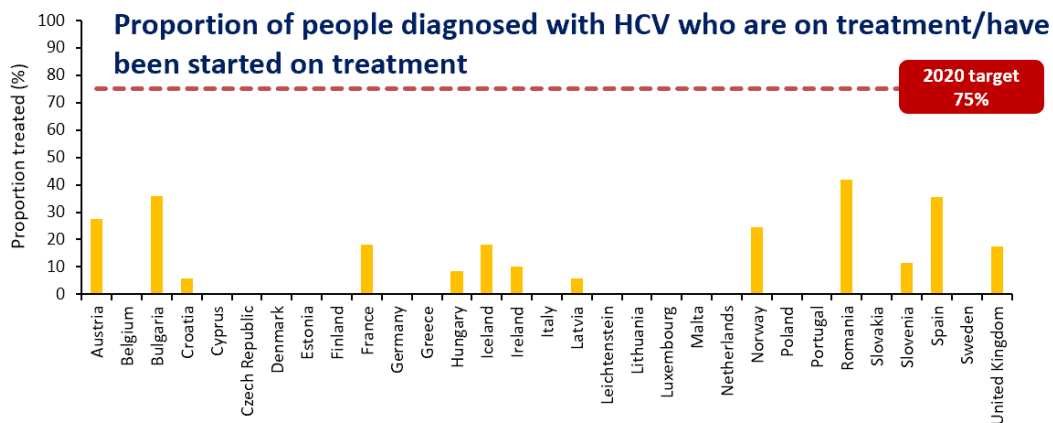
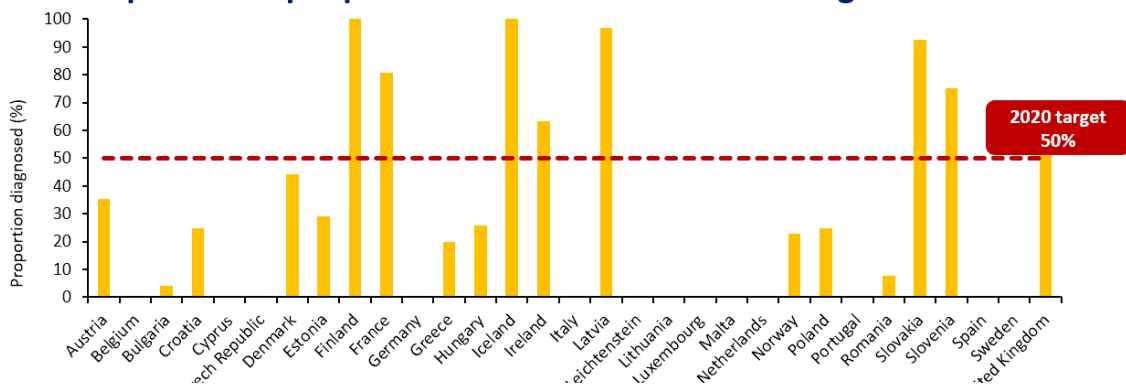
Último acceso: septiembre 2020.

# Monitoring the responses to hepatitis C epidemics in the EU/EEA Member States, 2019

Number of countries reporting data for each stage of the continuum of care



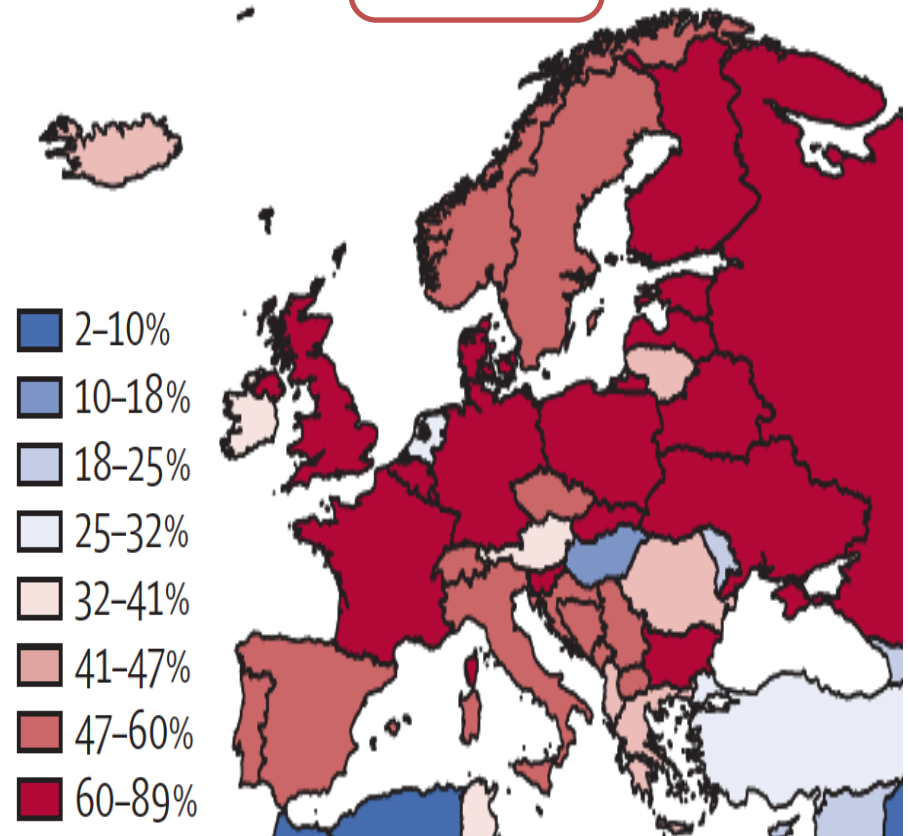
Proportion of people with HCV who have been diagnosed



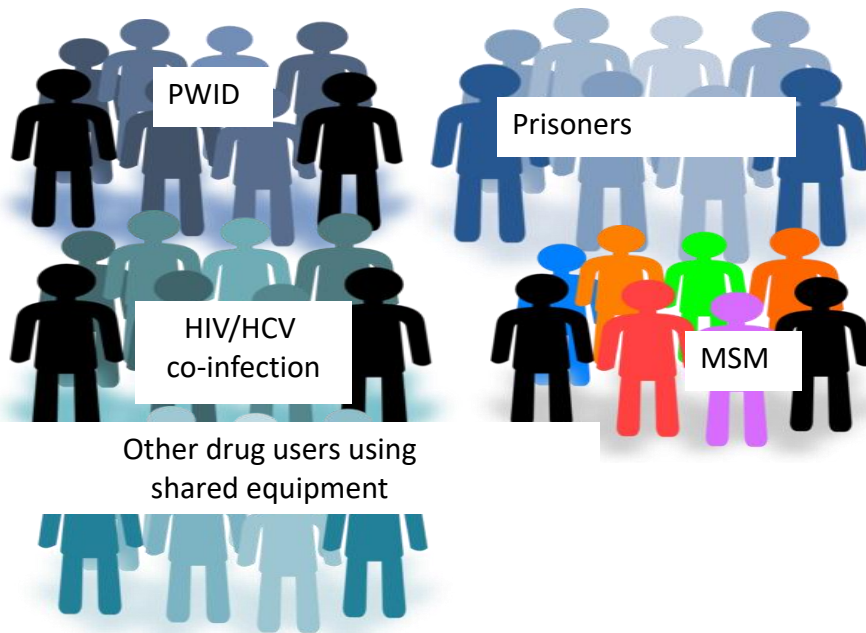
# Proportion of HCV disease burden attributable to injecting drug use

**HCV**

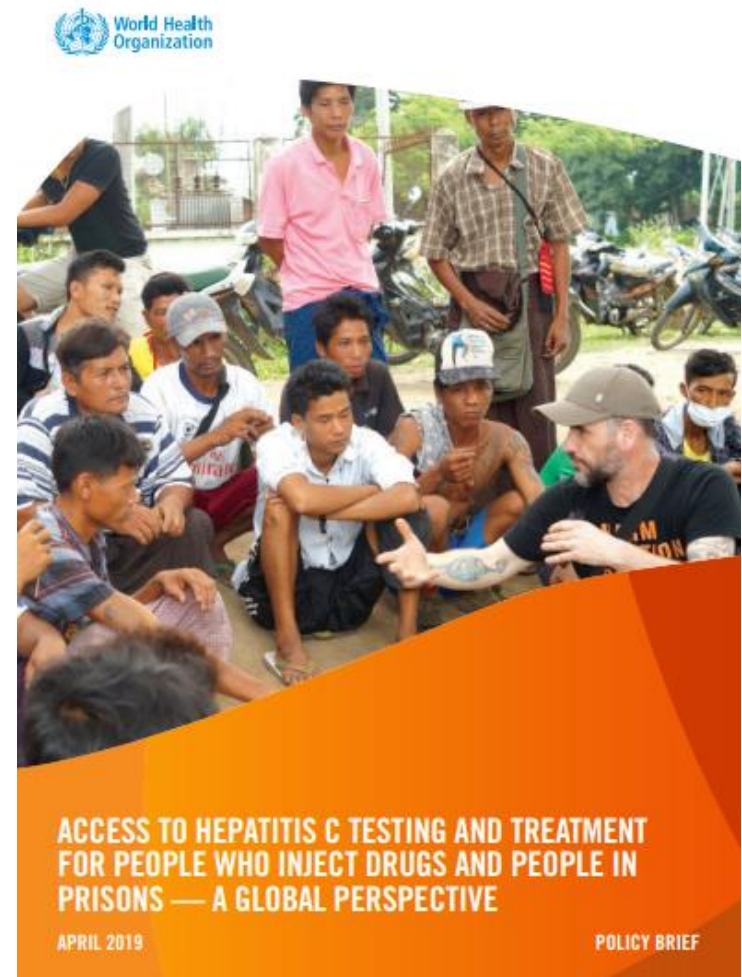
	1990		2013	
	Mean DALYs 1990	Population attributable factor	Mean DALYs 2013	Population attributable factor
Western Europe	376 000	44%	705 000	64%
Eastern Europe	73 000	32%	605 000	68%
Global	2 095 000	23%	7 046 000	38%



# People who inject drugs is a critical population for HCV elimination

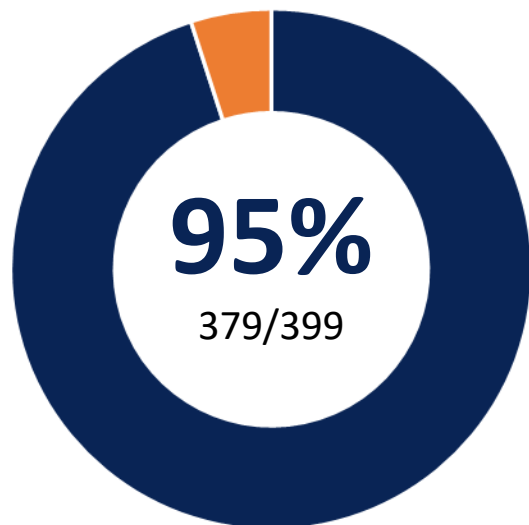


- High HCV prevalence
- Outside the National Health System
- Limited access to HCV therapy



## SOF/VEL Minimal Monitoring (MinMon) Strategy for HCV treatment

### Sustained virological response\*



- 17 with virological non-response\*\*
- 1 sample prior to SVR window opening and no follow-up after
- 2 lost to follow-up



### Remote contact:

- Week 4: 99% (396/399)
- Week 22: 84% (335/399)



### Unplanned visits

- 15 (3.8%) participants recorded 21 unplanned visits<sup>†</sup>

### Adverse and serious adverse events



- **23 participants (5.8%) reported AEs**
  - 5 attributed to SOF/VEL
  - 1 resulted in SOF/VEL discontinuation



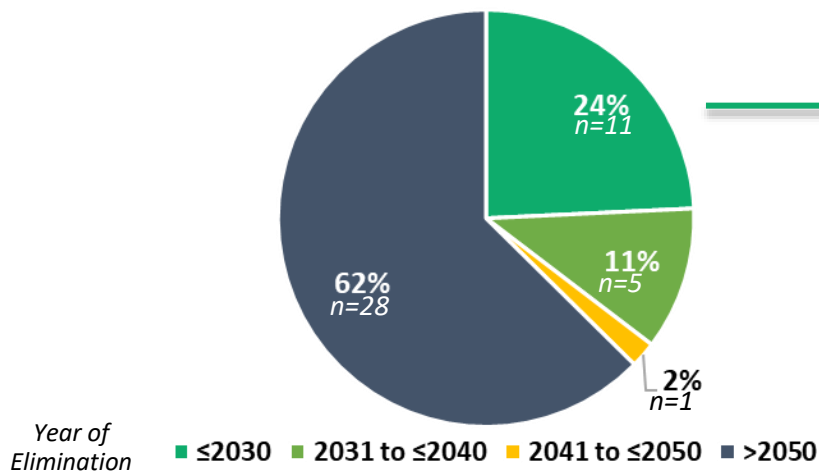
- **14 participants (3.5%) reported SAEs**
  - 0 attributed to SOF/VEL
  - 0 resulted in SOF/VEL discontinuation

**The MinMon approach to HCV treatment delivery with SOF/VEL was simple, safe and achieved SVR comparable to current clinical standards in treatment naïve persons without decompensated cirrhosis**

# Global Timing of HCV Elimination in High-Income Countries

Updated analysis of timing of HCV elimination based on a Markov disease progression model for 45 high-income countries

Country Status Towards WHO's 2030 HCV Elimination Targets



11 Countries Are On Track to Eliminate HCV by 2030

- 🇮🇸 2021 Iceland
- 🇪🇸 2021 Spain
- 🇸🇪 2024 Sweden
- 🇫🇷 2025 France
- 🇨🇭 2025 Switzerland
- 🇯🇵 2027 Japan
- 🇦🇺 2028 Australia
- 🇮🇹 2029 Italy
- 🇨🇦 2030 Canada
- 🇩🇪 2030 Germany
- 🇬🇧 2030 United Kingdom

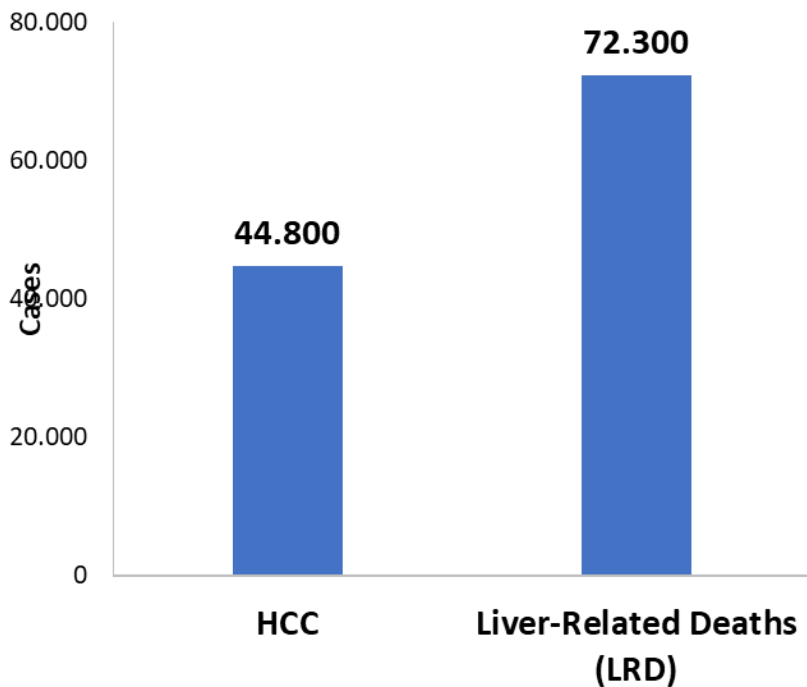
**Only 11 (24%) of 45 high-income countries are on track to eliminate HCV by 2030**  
**Among them, 8 out of 11 are from EU/EEA**



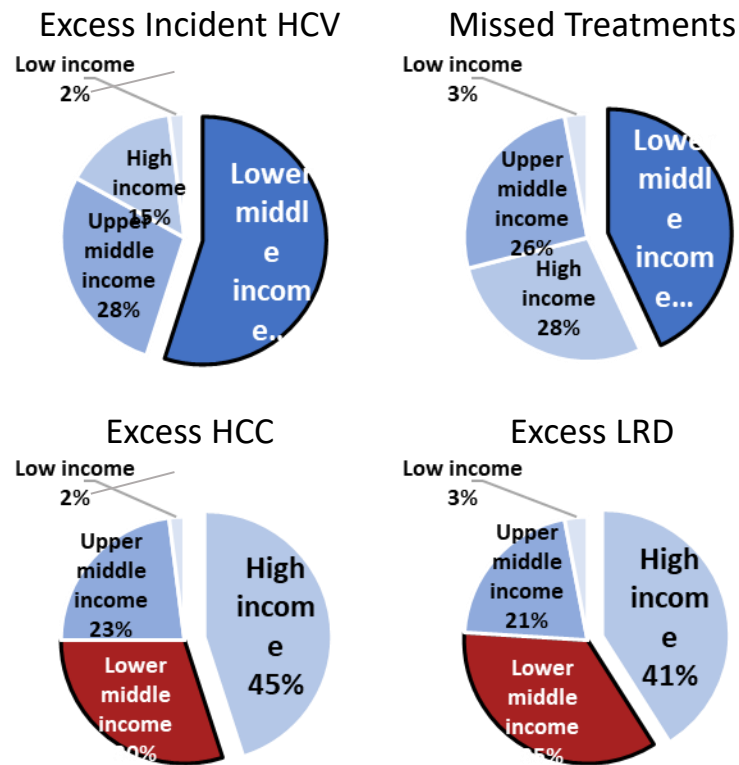
# Global Impact of COVID-19 on Global and Regional HCV Elimination Efforts

Modeling of the incremental change in HCV liver-related deaths and HCC following a one-year delay in HCV elimination program progress

Excess Cases by 2030 with a 1-Year Delay Scenario



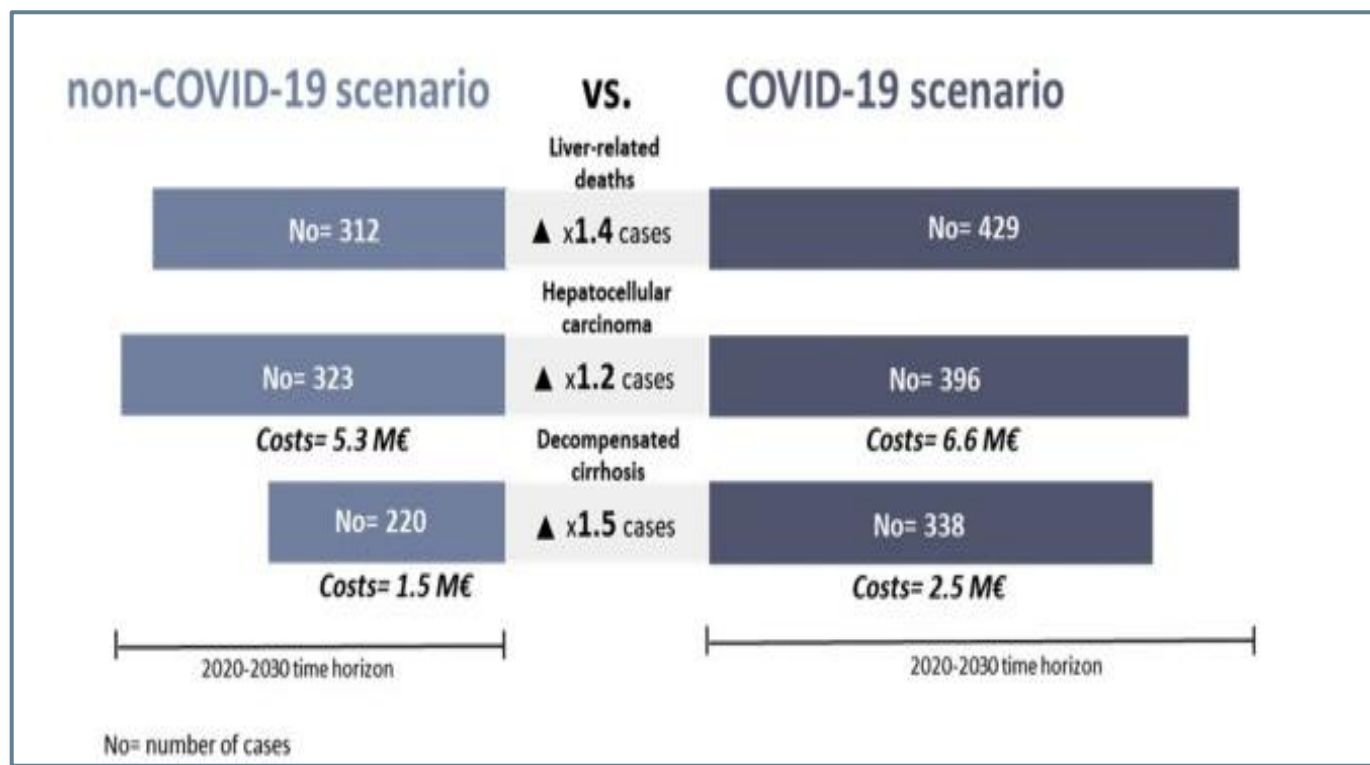
Impact of COVID-19 by Country-Level Income, 2020-2030



To mitigate the impact on viral hepatitis programming and reduce excess mortality from delayed treatment, policy makers should prioritize hepatitis programs as soon as it becomes safe to do so



# Impact of the COVID 19 Pandemic on HCV Elimination in Spain



**El retraso en los programas de eliminación del VHC se asociará con un aumento de la morbilidad y la mortalidad relacionadas con el VHC en los próximos 10 años.**

COVID-19: enfermedad por coronavirus 2019; AAD: antivirales de acción directa; VHC: virus de la hepatitis C; OMS: Organización Mundial de la Salud.

*Harvey J. Alter, Michael Houghton y Charles M. Rice  
Premio Nobel de Fisiología o Medicina en 2020*

