

**WEF-E
2016**



**ROMA
14 | 15
GIUGNO 2016**

**SESTO WORKSHOP
DI ECONOMIA E FARMACI IN
EPATOLOGIA**



Verso l'eliminazione dell'HCV nelle key populations

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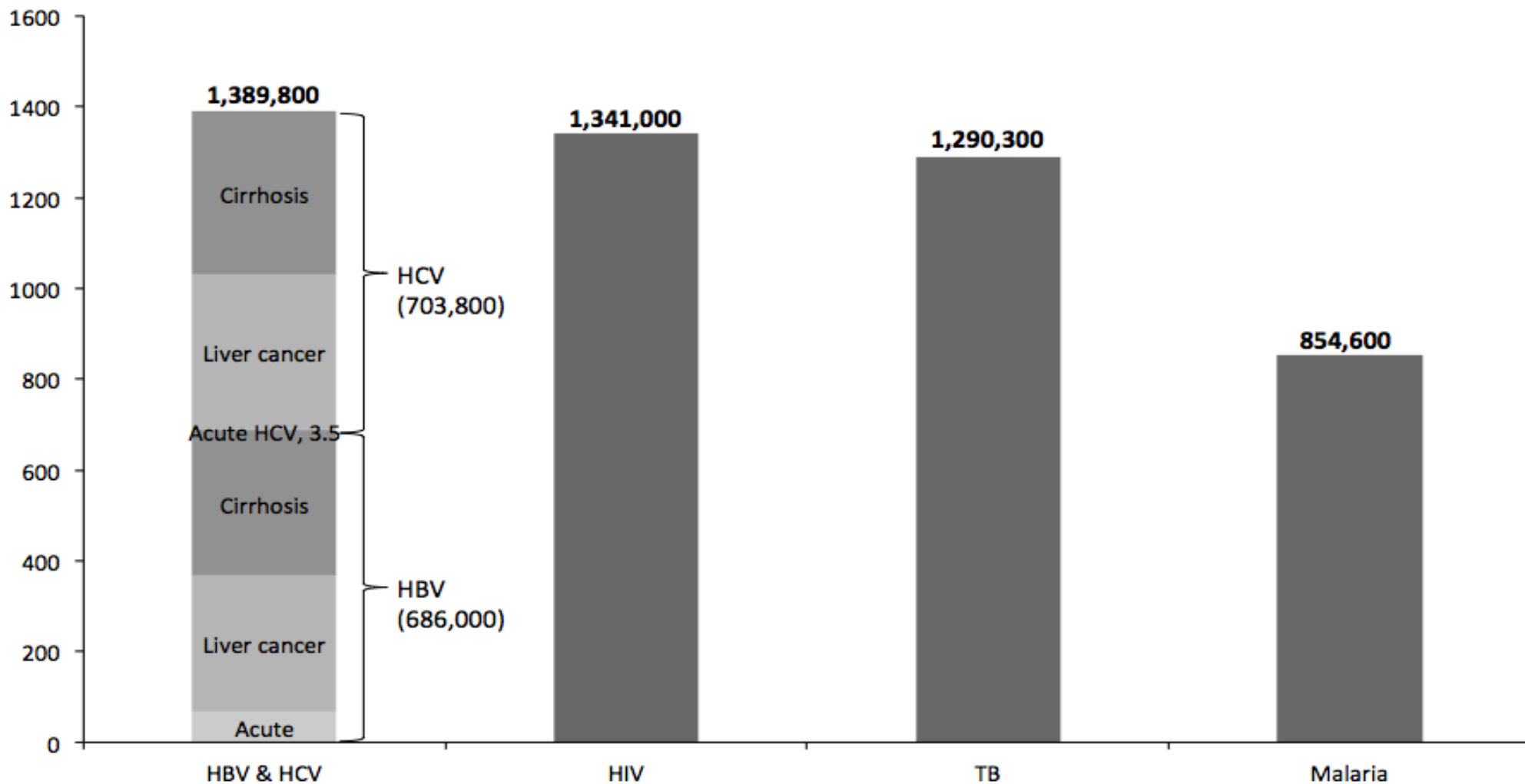
**Fondazione Malattie Infettive
e Salute Internazionale**



Definitions

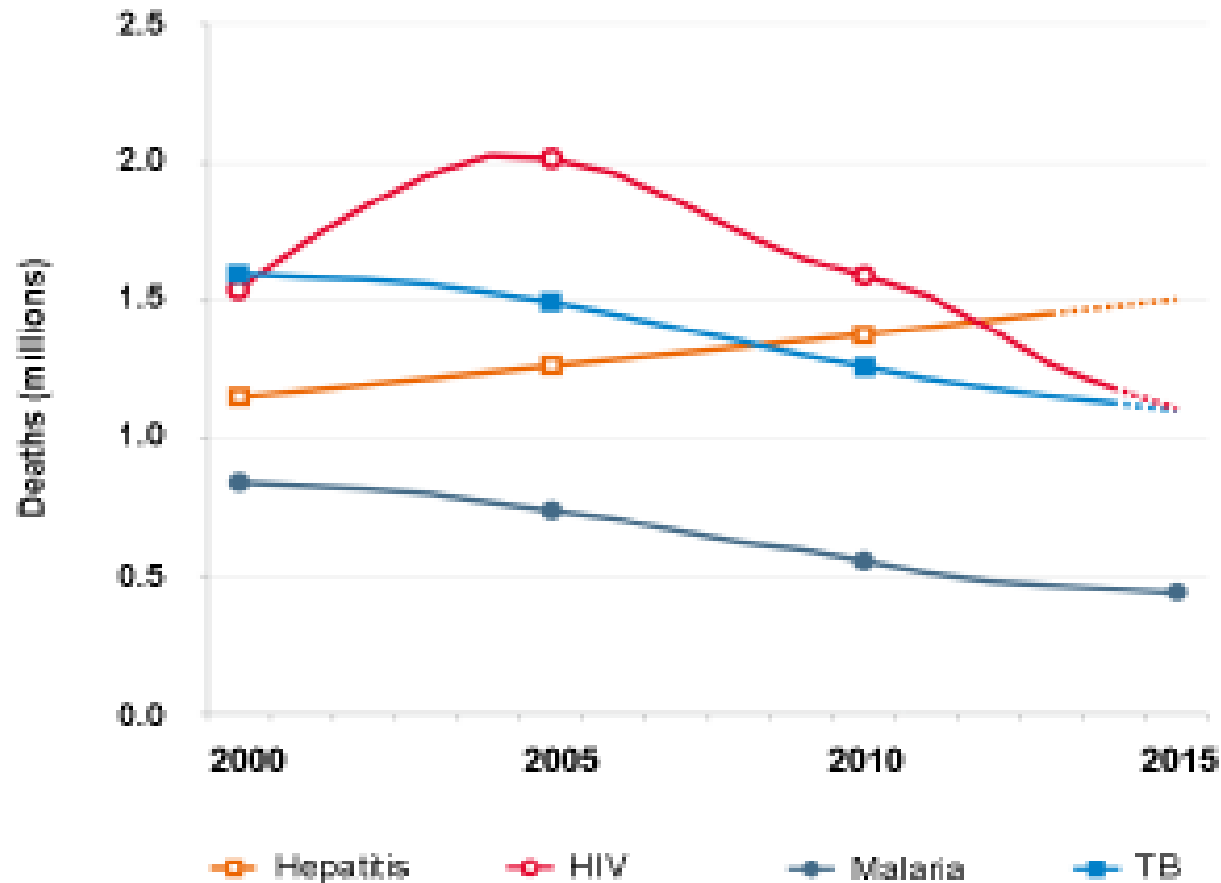
- ▶ **Eradication** refers to the complete and permanent **worldwide reduction to zero new cases** of an infectious disease through deliberate efforts, with **no further control measures required** (e.g. **smallpox**).
- ▶ **Elimination** refers to the reduction of the incidence of infection caused by a specific agent to zero **in a defined geographical area** as a result of deliberate efforts, but **requires the presence of continued measures to prevent re-establishment** of transmission (e.g. **poliomyelitis**).
- ▶ As such, **eradication of HCV infection would represent a considerably greater challenge compared to elimination.**

Worldwide deaths from HCV, HBV, HIV, tuberculosis, and malaria in 2013



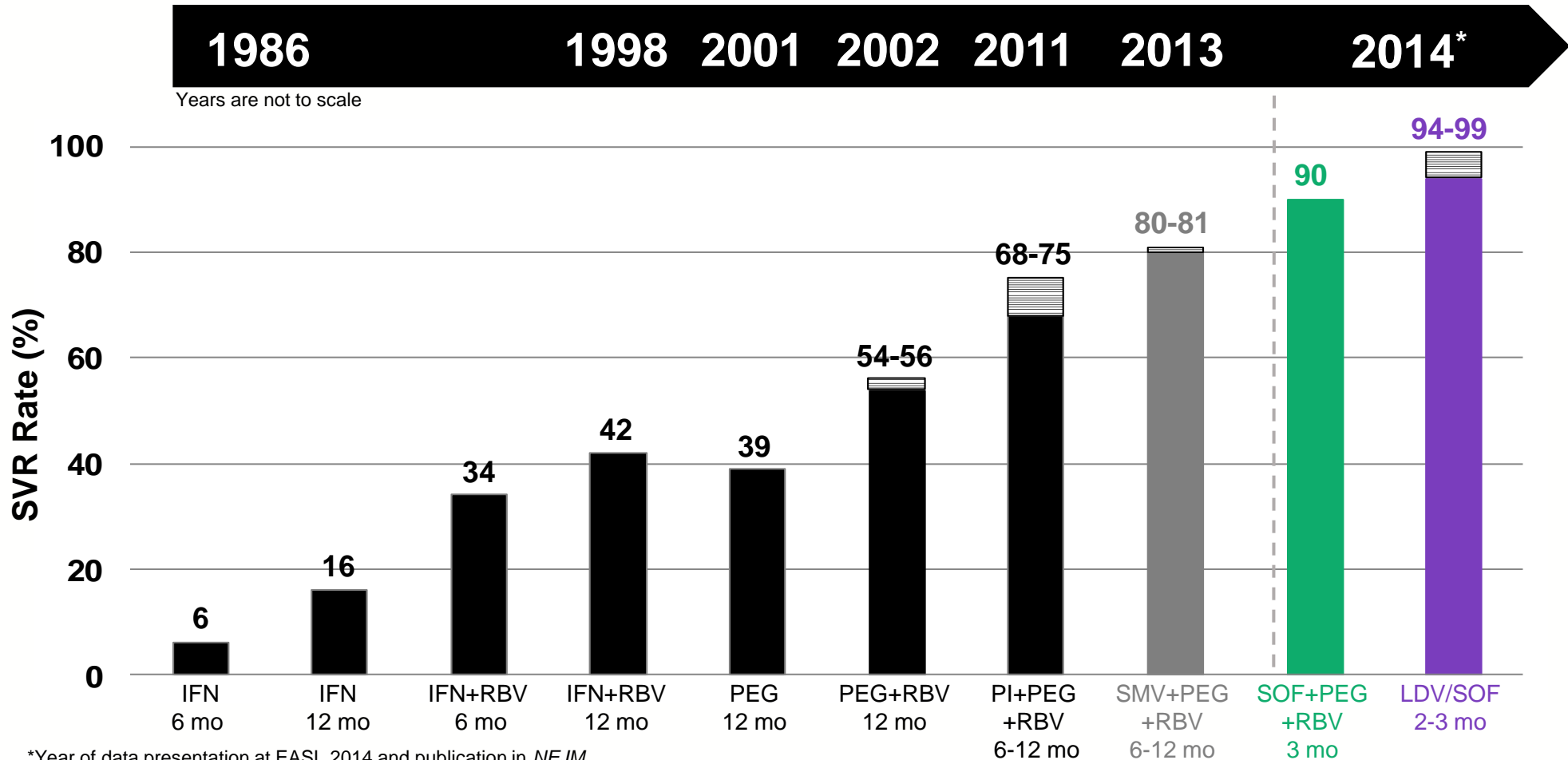
Global Burden of Disease report, Lancet 2014, 385: 117-171

Estimated global number of deaths due to viral hepatitis, HIV, malaria and TB, 2000–2015



Source: Global Burden of Disease and WHO/UNAIDS estimates, see <http://ihmeuw.org/3pms>, <http://ihmeuw.org/3pmt> (accessed 2 April 2016).

SVR Rates over the years in the treatment of HCV infection



*Year of data presentation at EASL 2014 and publication in *NEJM*

Adapted from Strader DB, et al. *Hepatology* 2004;39:1147-71. INCIVEK [PI]. Cambridge, MA: Vertex Pharmaceuticals; 2013. VICTRELIS [PI]. Whitehouse Station, NJ: Merck & Co; 2014. Jacobson I, et al. EASL 2013. Amsterdam. The Netherlands. Poster #1425. Manns M, et al. EASL 2013. Amsterdam. The Netherlands. Oral #1413. Lawitz E, et al. APASL 2013. Singapore. Oral #LB-02; Afdhal N, et al. *N Engl J Med* 2014; 370: 1889-98; Kowdley K, et al. *N Engl J Med* 2014; 370: 1879-88.

Diamo qualche numero

- An estimated **130-170 million people worldwide (2-3% of the population) are currently infected.**

Because most infections are asymptomatic, **up to 75-90% of HCV-positive individuals are unaware** of their infections: **a silent epidemic**

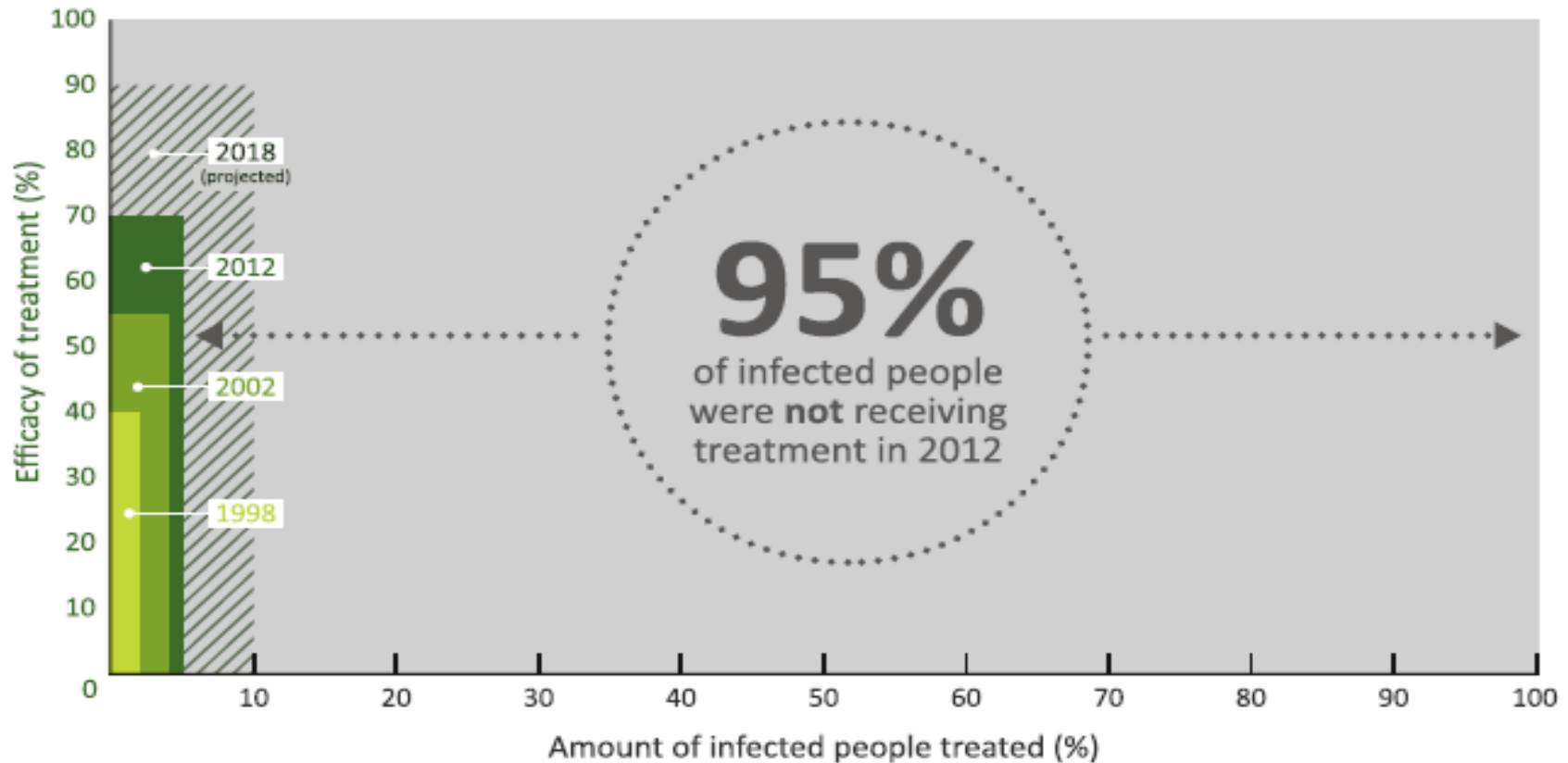
- **Over 350.000 deaths have been attributed to HCV infections annually,** most caused by cirrhosis and HCC

HCV-infected individuals have **2.4 times the risk of all-causes mortality,** **26.5 times the risk of liver-related mortality**

- Despite increases in treatment efficacy, **estimates of uptake are low,** ranging from 10-25% in North America to 40-45% in Europe

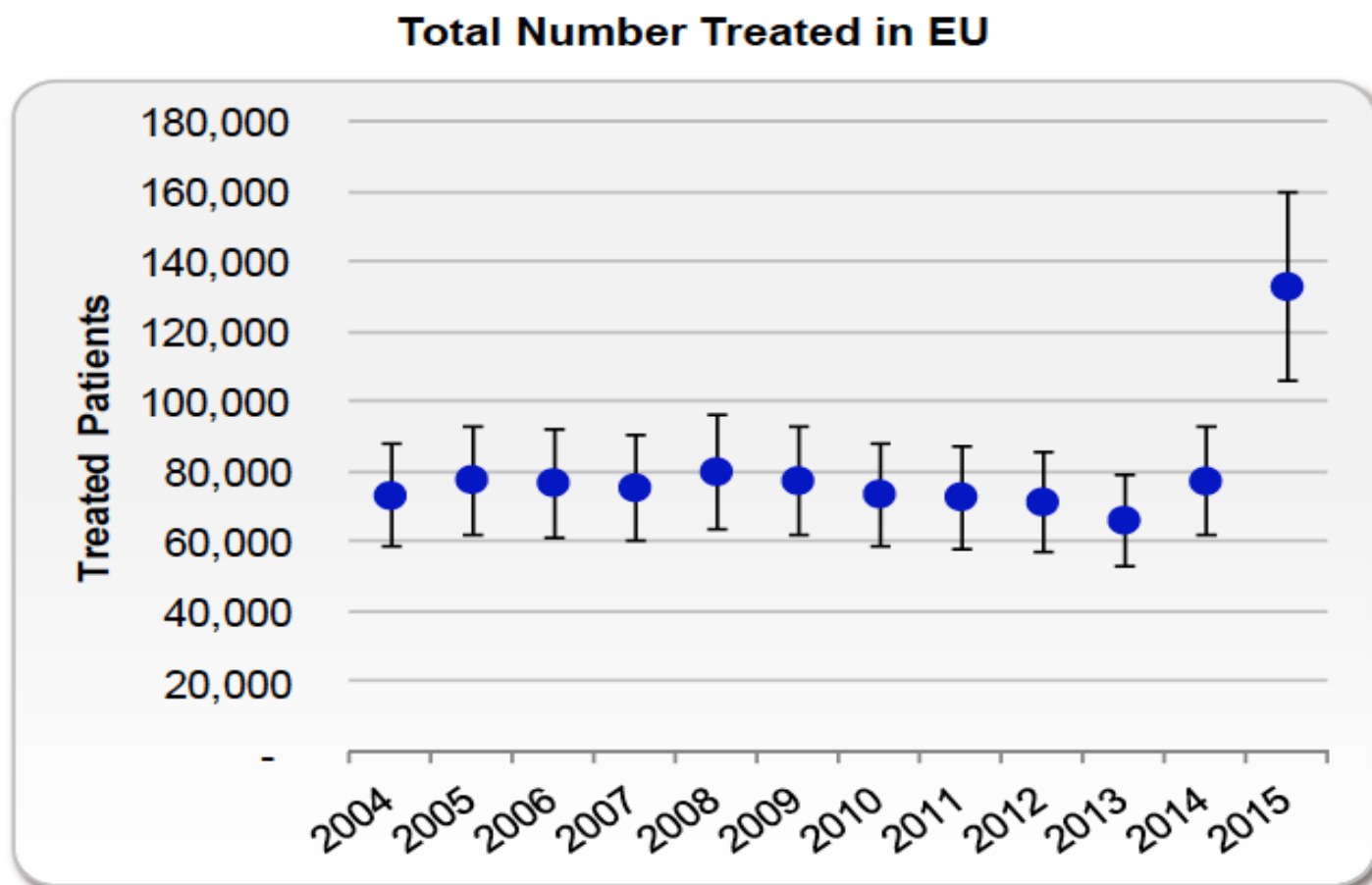
New **all oral DAA treatment** are expected to **increase dramatically uptake** of treatment and probably **eliminate specialist referral**

The disparity between potential HCV treatment efficacy and projected HCV treatment effectiveness



J. Grebely et al. Antiviral Research, 2014

The number of treated patients increased in 2014 and 2015 after a period of warehousing patients



Source: Polaris Observatory (www.centerforda.com/polaris)

WHO Policy for HCV

- **Sustainable Development Goals for 2030** includes **specific mention of viral hepatitis**.
- **WHO** is currently developing the **first global strategy** addressing viral hepatitis with a goal of **eliminating viral hepatitis** as major public health threat by 2030.
- **WHO** → comprehensive normative and policy guidance to countries in strengthening their efforts to combat hepatitis.
 - **first-ever WHO guidelines for hepatitis treatment** were released in **2014** addressing screening, care and treatment of persons with hepatitis C infection.
 - updating its **hepatitis C treatment guidelines in 2016**
 - **full updated WHO guidelines EASL2016 13-17 April in Barcelona, Spain**



GUIDELINES FOR THE SCREENING, CARE AND TREATMENT OF PERSONS WITH HEPATITIS INFECTION APRIL 2014

1. **Screening to identify persons with HCV infection:**

How : HCV serology testing

Whom: population with high HCV prevalence or history of HCV risk exposure/ behaviour.

2. **Confirm the diagnosis of chronic HCV infection:**

How: NAT for HCVRNA

3. **Screening for alcohol use and counselling** to reduce moderate and high levels of alcohol intake

4. **Assessing degree of liver fibrosis and cirrhosis+**

How: APRI/FIB4 → Fibrotest Fibroscan

5. **Assessing for HCV treatment**



Updated WHO Guidelines (2016)

- It is recommended that **direct-acting antiviral (DAA) regimens be used** for the treatment of persons with hepatitis C infection rather than regimens with pegylated interferon/ribavirin.
- For patients with HCV **genotype 3 infection with cirrhosis**, and patients with **genotypes 5 and 6 infection with and without cirrhosis**, **sofosbuvir/pegylated interferon and ribavirin is still recommended as an alternative treatment option**
- **Boceprevir- or telaprevir-containing regimens are no longer recommended** for the treatment of persons with hepatitis C infection.

