

**Hepatitis C Disease Burden
and
Strategies to Minimize its Consequences
in the Future**

*Assumptions and Outputs
for Romania*

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OUTLINE

- The big burning picture of HCV disease:
 - *prevalence, incidence, demographics*
- Disease control strategies in order to minimize the future HCV disease burden
 - ✓ increasing the pool of diagnosed people
 - ✓ increasing access to therapy
 - ✓ increasing the level of therapy/treatment efficacy

THE MAGNITUDE OF HCV INFECTION

worldwide

- A global public health issue - significant *morbidity and mortality*
- Up to 180 million individuals chronically infected worldwide (2.5-3% of the world's population) (WHO 2015)
- 350,000-500,000 people die annually of HCV-related causes
- 15 - 17 million persons (2% of adults) HCV infection in the Europe region (WHO 2015)
- Long-term HCV infection translates in a **heavy burden of liver-related morbidity and mortality**
- Hepatitis C the leading cause of **liver cirrhosis, cancer, transplantation**

But it's not all about prevalence!

- **Silent epidemic**
- 75% of infected people are *not aware* of their HCV-positive status and remain *undiagnosed*
- Diagnosed as ***advanced HCV-associated liver disease - cirrhosis, liver cancer***
- Only 3-5% of infected individuals receive treatment annually worldwide
- Causing a large economic impact - costs for patient and society
- **Costs increase with disease progression**

HCV historical epidemiology in Romania:

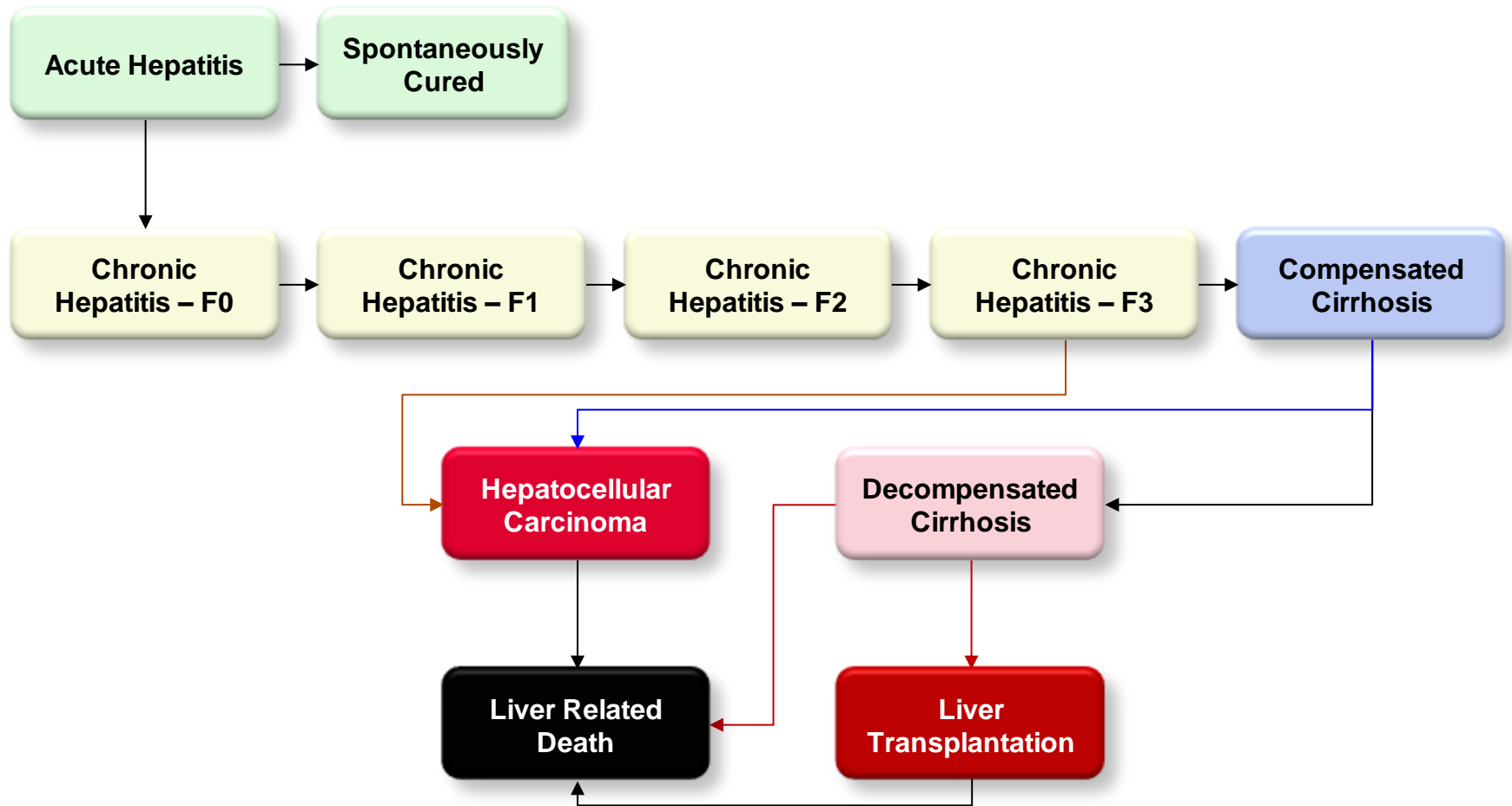
Prevalence & demographics *at a glance*

	N or/and %	Comments														
Country Population	19.6 million															
HCV Infection Prevalence	<ul style="list-style-type: none"> • 3.23% seroprevalence in adult general population in Romania • 86% viremic cases 	A nationwide cross-sectional survey in general adult population conducted between 2006-2008 through a multistage random cluster sampling method														
Genotype distribution	<table border="1"> <tr> <td colspan="2">1</td> <td rowspan="2">2</td> <td rowspan="2">3</td> <td rowspan="2">4</td> <td rowspan="2">OT HER</td> </tr> <tr> <td>1a</td> <td>1b</td> </tr> <tr> <td></td> <td>99.1%</td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	1		2	3	4	OT HER	1a	1b		99.1%					Genotype 1 is almost exclusively
	1		2					3	4	OT HER						
	1a	1b														
	99.1%															
HCV route of transmission	<p>Nosocomial</p> <p>Sexual & perinatal – few cases</p> <p>IVDU – increasing in younger subjects</p>	Major risk factor: unsafe blood supply & unsafe medical procedures in the past														
HCV gender distribution	<ul style="list-style-type: none"> • Female 3.94% • Male 2.95% 	Female gender significantly more affected														
Age groups	<p>19-29: 1.61%</p> <p>30-39: 1.04%</p> <p>40-49: 3.85%</p> <p>50-59: 4.35%</p> <p>60-69: 5.39%</p>	A significantly increased risk in subjects >40 (born 1937-1975)														
Regional/by counties	<ul style="list-style-type: none"> • 4.25% Moldavia • 3.35% Walachia • 2.63% Transylvania 	Significant regional differences														

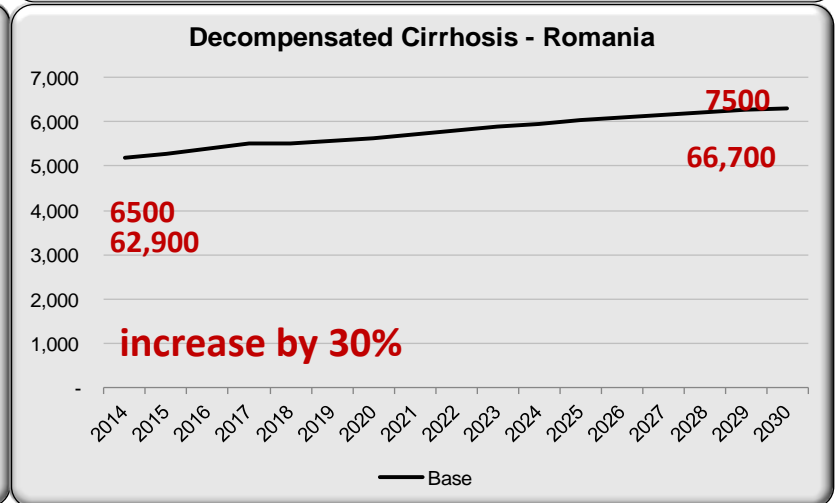
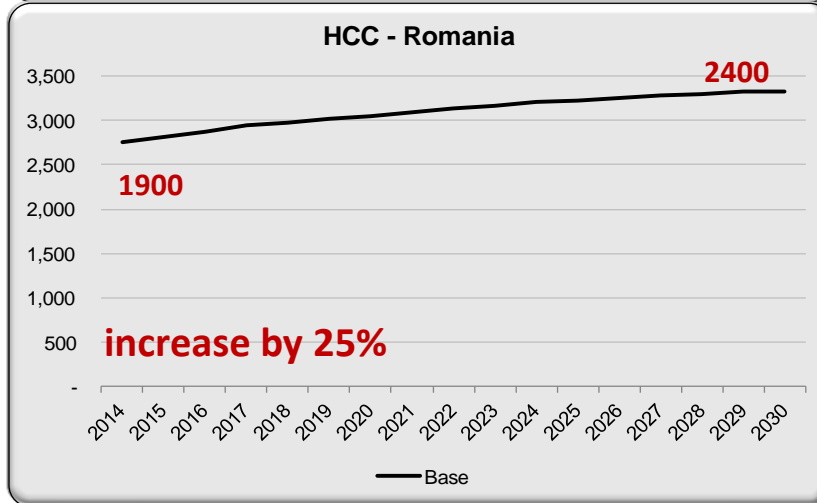
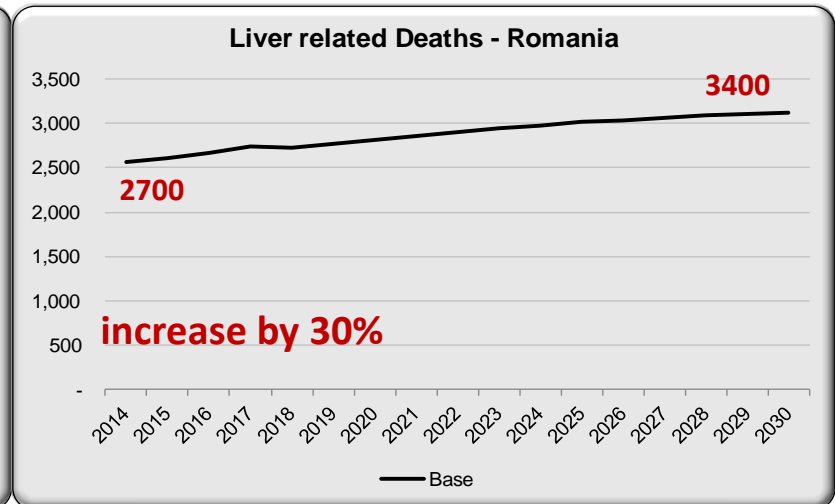
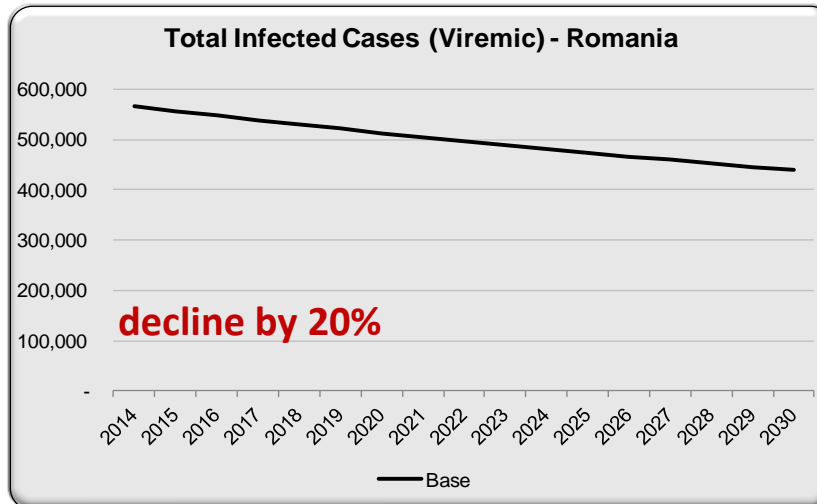
Historical epidemiology in Romania: Current HCV burden

	N or/and %	Comments
HCV Disease Burden		
<ul style="list-style-type: none"> Leading cause of chronic hepatitis liver cirrhosis 	<ul style="list-style-type: none"> 64% 59% 	
HCC	49.5% out of HCC cases diagnosed in tertiary centers	
<i>Special populations</i>		
Chronic Kidney Disease	>11→20%	
HIV/HCV co-infection	~40-50% out of HIV+ population	
HCV diagnosis rate	16%	Low
Treated	60,000 2002-2015 Peg/RBV 5850 2016 DAA's	<i>>56,500 treated between 2002-20015 w/ Peg/RBV (~50% SVR in real life)</i> <i>A very fey in clinical trials and EAP</i> 99% SVR

HCV-related disease progression over time



Trends in epidemiology of HCV-related diseases in Romania *the next 15 years*

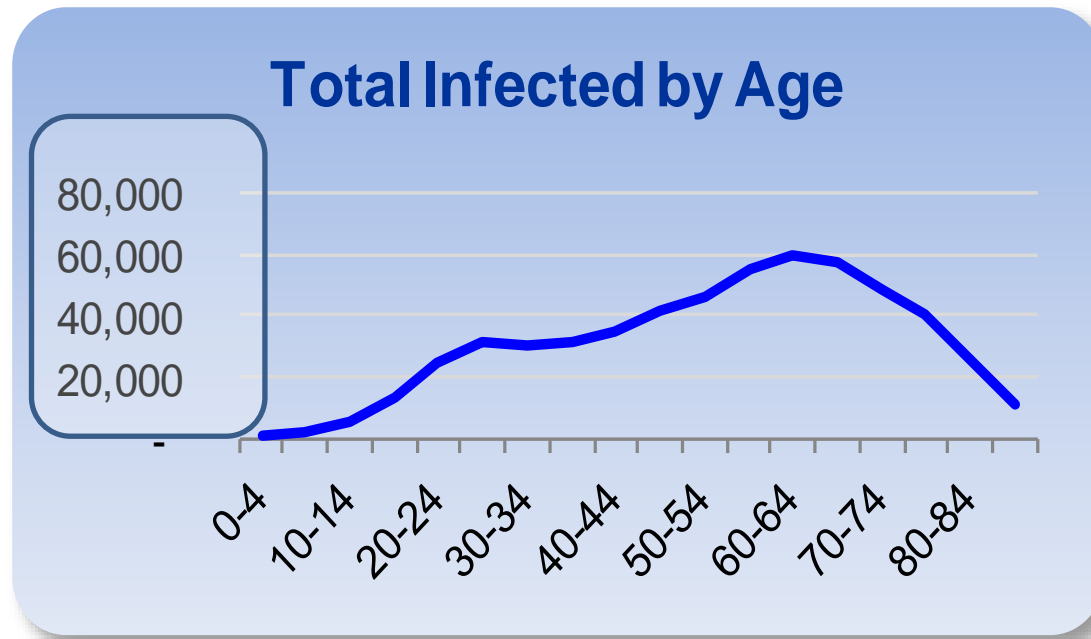


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Increasing diagnosis/screening

WHO SHOULD BE SCREENED FOR HCV INFECTION: Birth cohort screening



HCV infected population - 2015

- An aggressive screening programme
- *The birth cohort screening*

**A NATIONAL SCREENING
PROGRAMME
HCV**

2017

European Structural Funds

Operational Programme

Human Resources Development

Increasing access

*“... costs of the new antiviral agents DAAs
are
as breathtaking as
their effectiveness”*

(Jay H. Hoofnagle & Averell H. Sherker; NEJM 2014; 370: 1552-1553)

PARADIGM OF THERAPY in Romania

2015-2016

- ✓ **Restricted access:**
 - **5800** p reimbursed therapy
 - *F4 and a part of F3*
 - **Inadequate** options for sp populations:
NO
 - *decompensated cirrhosis*
 - *transplant recipients*
- ✓ **Treatment option**

Only 1 option:
Viekirax/Exviera

2017-2018

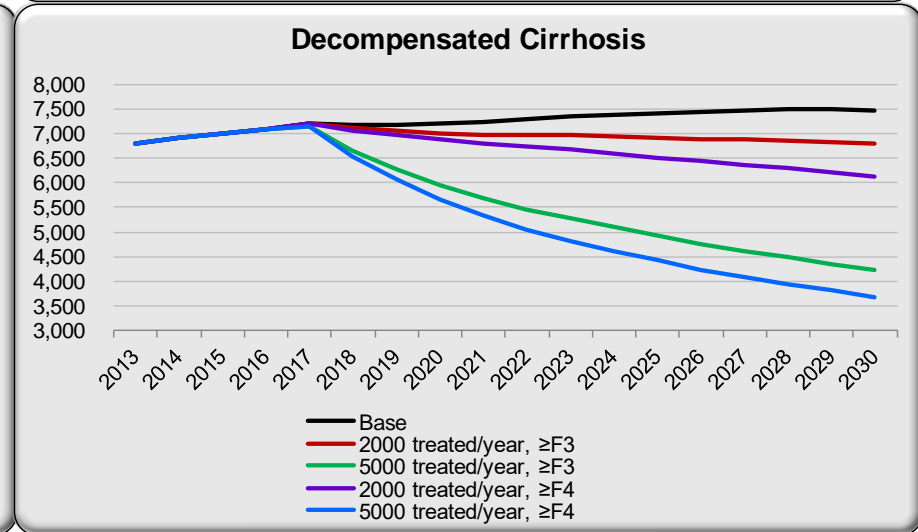
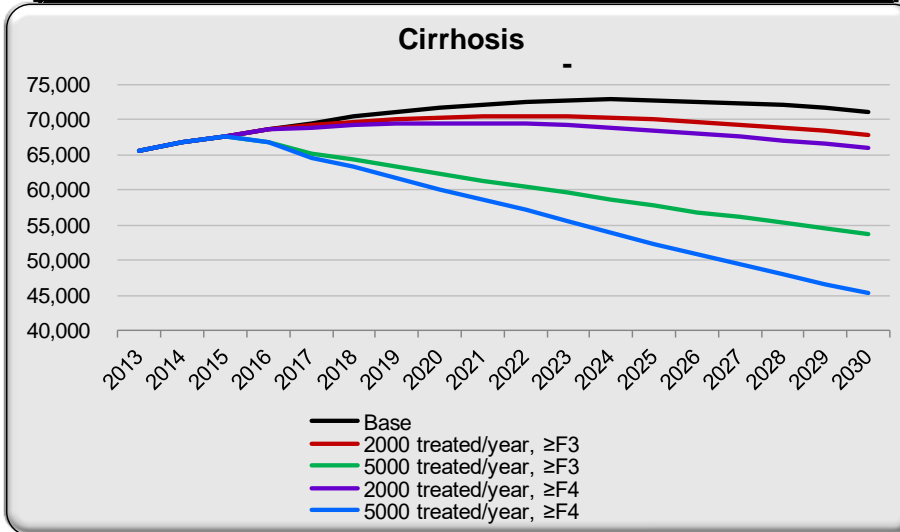
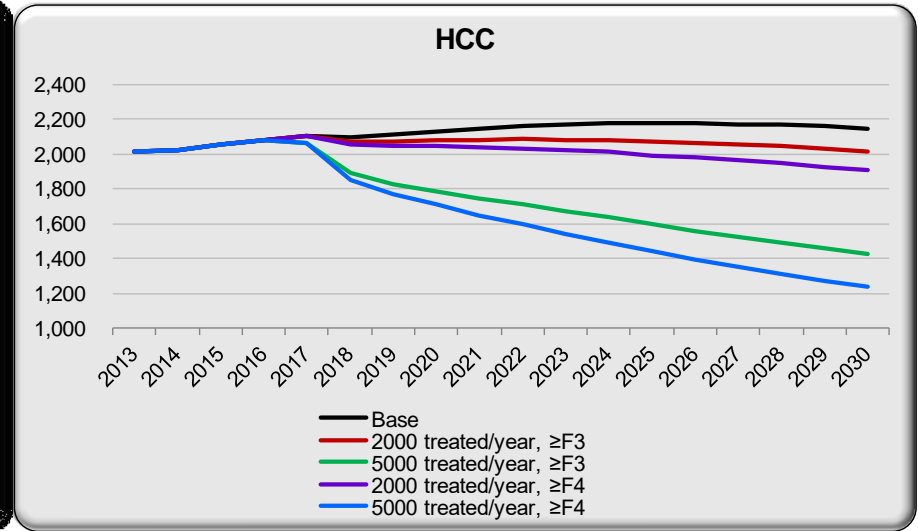
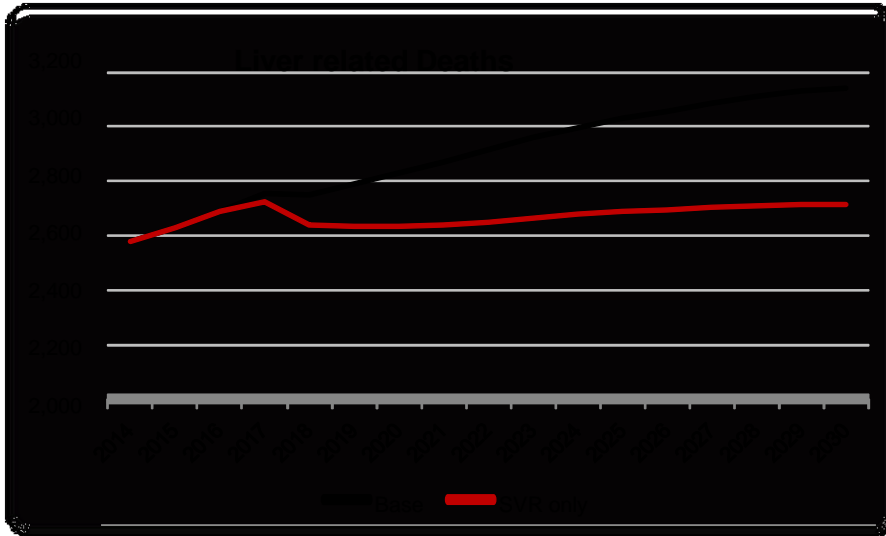
- ✓ **Restricted access:**
 - **10,000** p reimbursed therapy
 - *F4, F3 and a part of F2*
 - **Adequate** options for sp populations:
YES
 - *decompensated cirrhosis*
 - *transplant recipients*
 - *dialysis*
 - *medical perssonel*
- ✓ **Treatment option**

3 options:
**Viekirax/Exviera or Zepatier
or Harvoni**

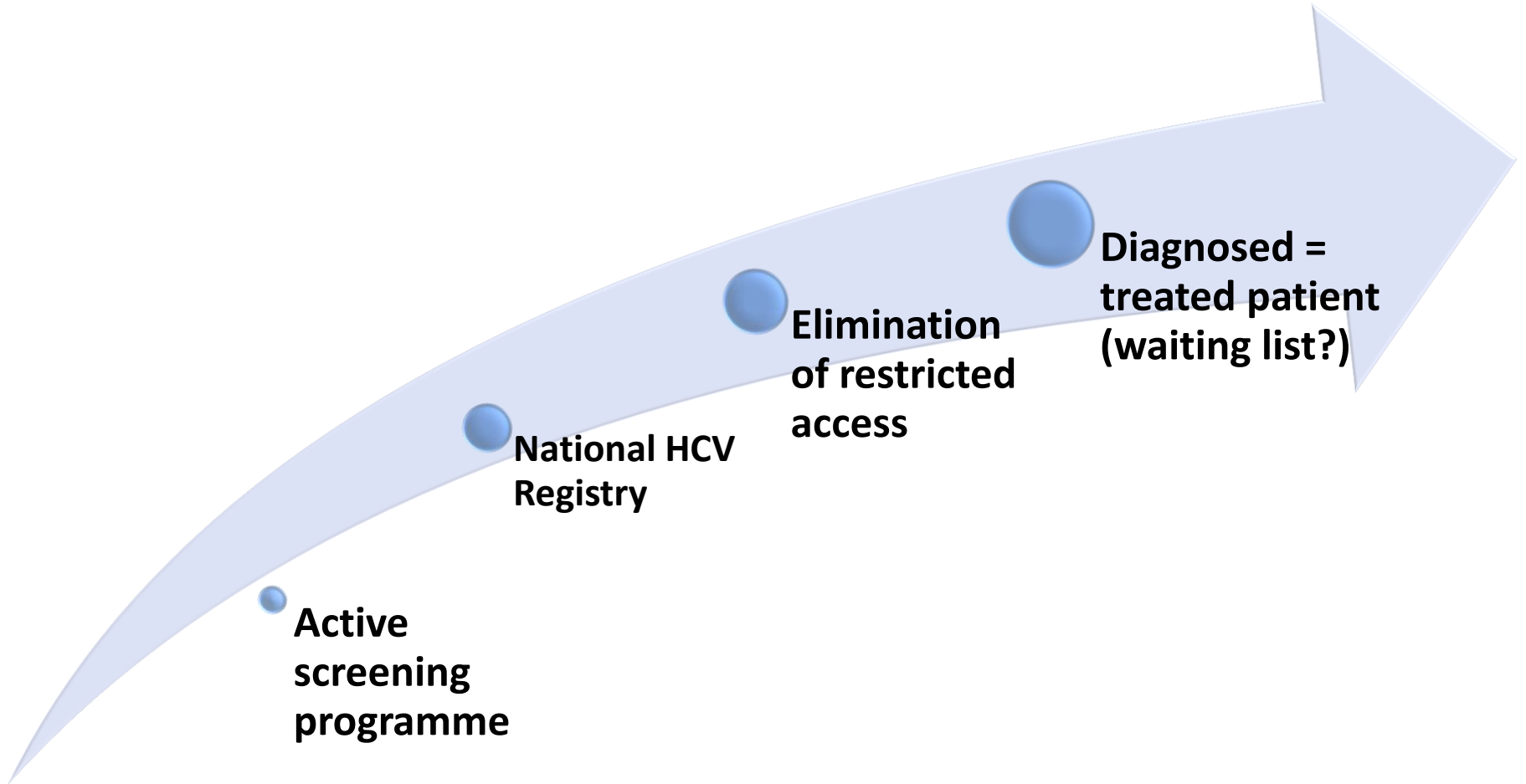
✓ **Limited prescription/settings:**

Academic Centers of Gastroenterology/Hepatology and Infectious Diseases

TREATING 5000-10,000 HCV/year Predictable Outcomes



HOW TO IMPROVE THE THERAPY UPTAKE?



CONCLUSIONS

- Increasing diagnosis
 - Access to therapy
 - High treatment efficacy
 - Education in order to prevent (re)infection
-
- Increase capacity of screening- *birth cohort screening*
 - Increase capacity of treating more patients
 - *Treatment providers/setting/resources*
 - Adoption of new, more efficacious therapies for hepatitis C