con il patrocinio di

REGIONE DEL VENETO
ULSS8 BERICA

con il patrocinio della

CONFERENZA DELLE REGIONI E DELLE PROVINCE AUTONOME

VICENZA
24 MAGGIO 2018

PALAZZO CHIERICATI
Salone d'Onore
Piazza Giacomo Matteotti 37/39

MEDICINA TERRITORIALE E GESTIONE INTEGRATA DELLA CRONICITÀ

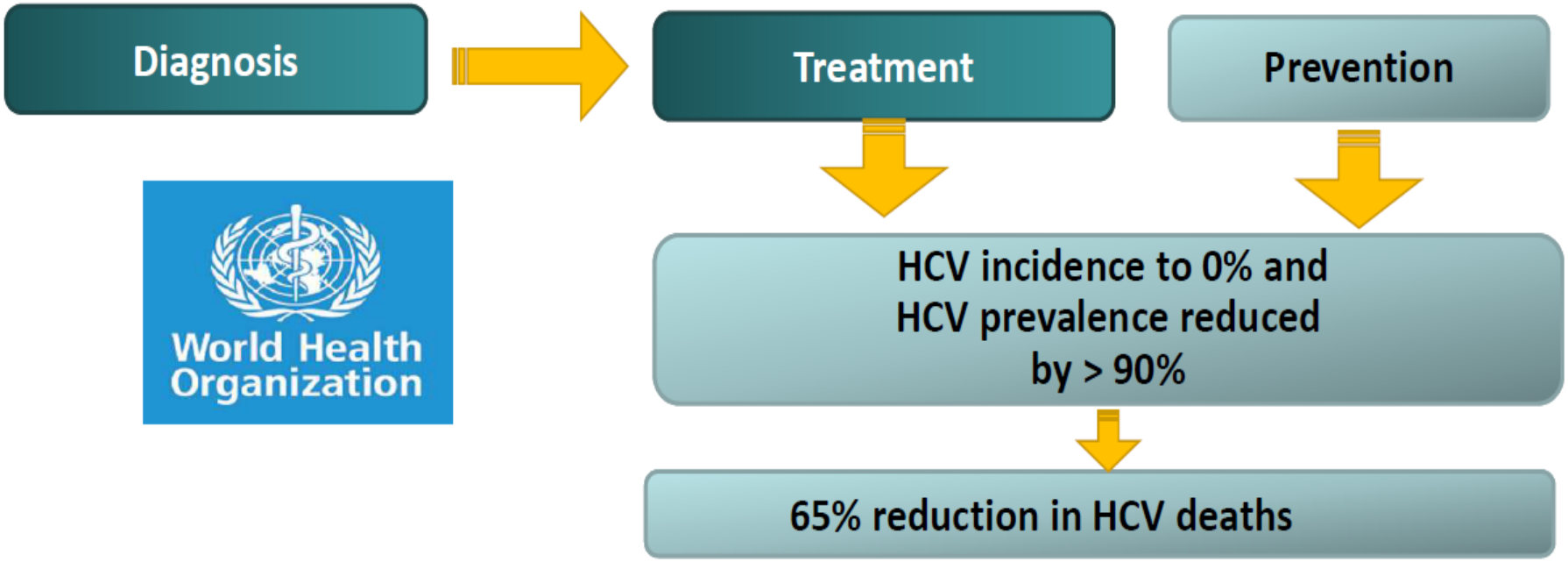
2018 MOTORE SANITÀ
Sanità Universale

Dall'eradicazione dell'HCV alla presa in carico del paziente

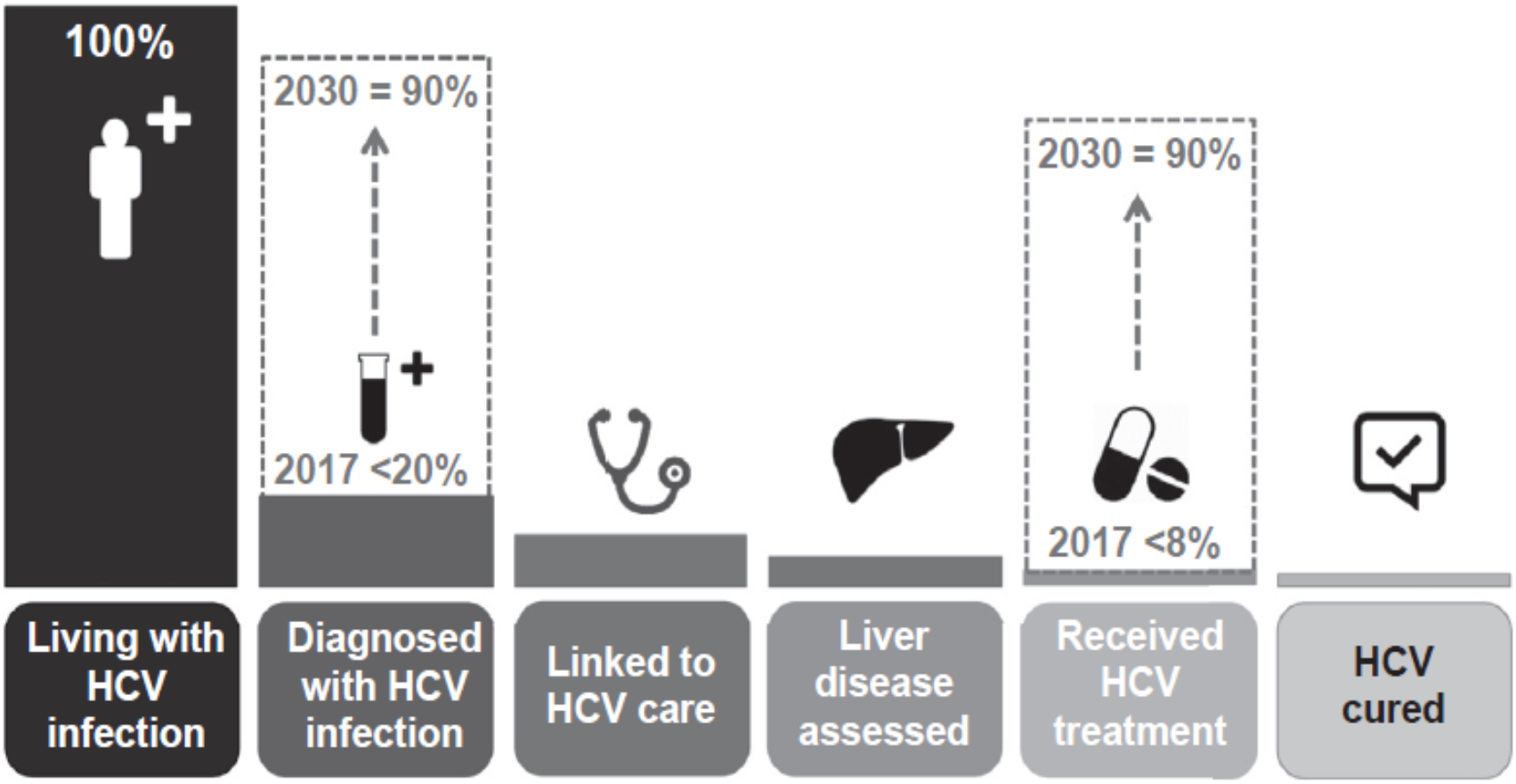
Anna Maria Cattelan
UOC Malattie Infettive
Azienda Ospedaliera di Padova

The Goal of Hepatitis C Elimination by 2030

Elimination of HCV infection in the country through identifying 90% and treating 80% HCV patients strengthened by effective prevention interventions

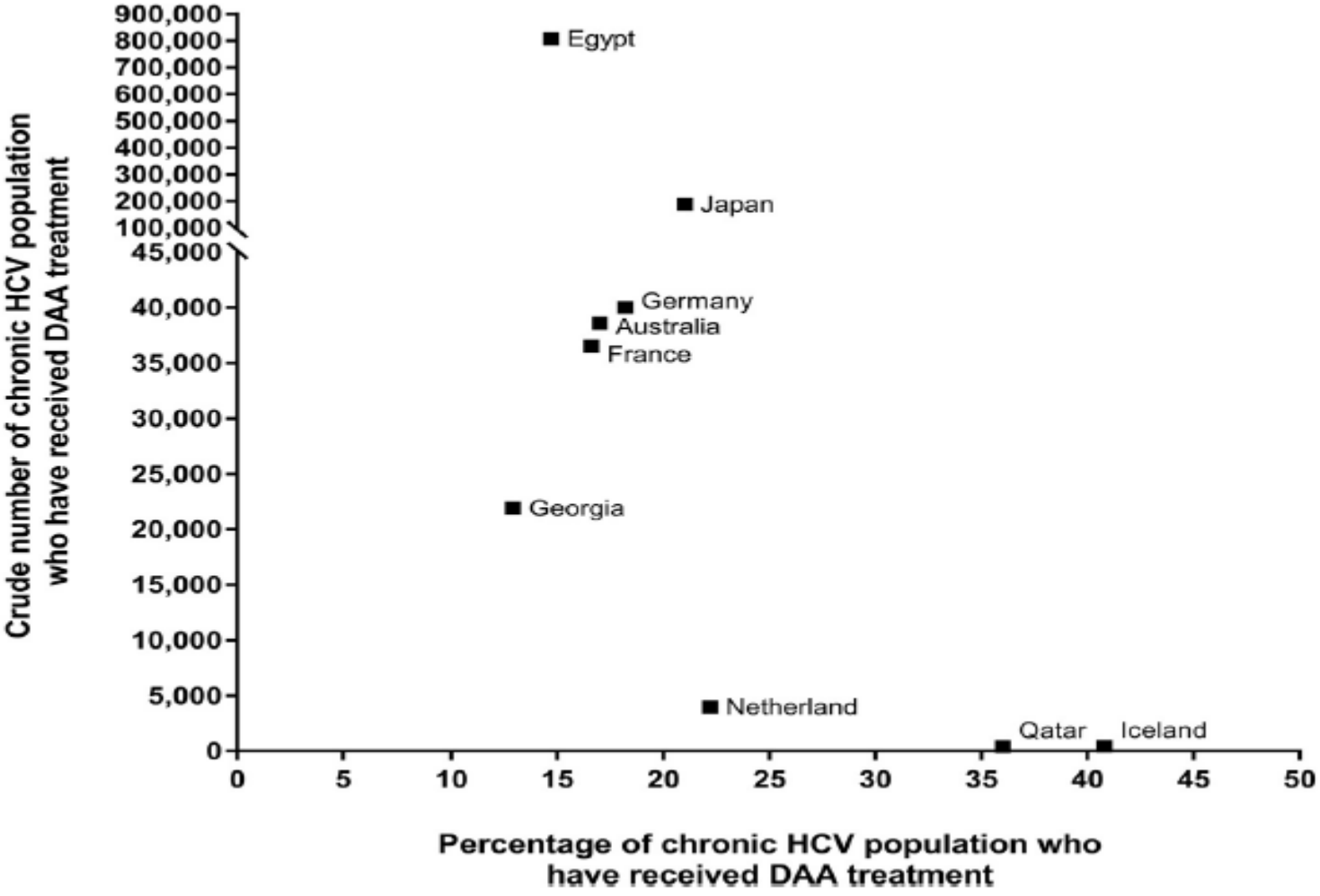


Global gaps to reach WHO 2030 elimination goals



Infect Dis Clin N Am 32 (2018) 425–445

9 countries considered to be "on-track" for HCV elimination (2015-2016)



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"Access for all" is critical for HCV eliminatio

- In 2016, Australia became one of the first countries to make "access f public health priority
- Several DAA regimens subsidised since March 2016 (LDV/SOF, SOF PrOD), with more to follow in late 2016 (EBR/GZR) and 2017 (SOF/V
- No restrictions based on liver disease stage or drug and alcohol use
- No cap on number of patients treated per year
- Risk-sharing arrangement with pharma, therefore expenditure is capp
- 5 year contract ($1 billion over 2016-2020)
- Broad practitioner base: GI/hepatologists/ID/other specialists/GPs
- Retreatment (including for reinfections) allowed

GI: Gastroenterologist; GP: general practitioner; ID: infectious di

STAYING ON TRACK FOR HEPATITIS C VIRUS ELIMINATION IN AUSTRALIA

- **community awareness campaigns**
  - **“spread the word” through social networks**
- **the SCALE-C (Strategies for hepatitis C testing and treatment in Aboriginal communities that Lead to Elimination) PROJECT: a community-based model of care that includes point-of care HCV testing and noninvasive liver disease assessment**
- **Projects to encourage and train additional prescribers (an estimated 9,760 patients having been prescribed DAA by general practitioners by June 2017)**
- **Maintenance of “high levels” of harm reduction framework**

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Che cos'è

L'epatite C è una malattia del fegato provocata dal virus HCV

Il virus può causare sia l'epatite acuta, sia quella cronica

Con il tempo l'infezione da HCV può indurre cirrosi e tumore al fegato

IN ITALIA

almeno **800** mila
Le persone infette con il virus dell'epatite C*

circa **160** mila
Le persone che non sanno di essere infette*

122.090
I pazienti trattati fino ad oggi (1/1/2015- 5/3/2018)

Fonte: Oms; Aifa; Associazione EpaC; Università di Palermo; (*stima)

NEL MONDO

71 milioni
Le persone con epatite C cronica

circa **399** mila
Le persone che ogni anno muoiono di epatite C, per lo più a causa di cirrosi e tumore al fegato

95-100%
La quota di persone con infezione da epatite C, curabile con i farmaci antivirali

74%
I casi in cui il virus può causare malattie extra-epatiche (renali, cardiovascolari, autoimmuni, depressione)

PROGETTO « ELIMINAZIONE HCV IN VENETO»

- **IDENTIFICAZIONE DELL' 80 % DEI SOGGETTI CANDIDABILI A TERAPIA**
- **TRATTAMENTO DELL' 80% DEI SOGGETTI ELEGGIBILI**
- **RIDUZIONE DELL' 80% DELLA PREVALENZA**

Identificazione di fasi e tempi per la realizzazione

STIME HCV NELLA POPOLAZIONE GENERALE DEL VENETO

HCV-RNA POSITIVI DA PROIEZIONE 2002 (Alberti et al Ann. Int. Med)

35.000-40.000

TRATTATI ED ERADICATI DAL 2002 (IFN e DAA) : 10.000

STIMA HCV-RNA POSITIVI 25.000-30.000

DEI QUALI CON DIAGNOSI NOTA 11.000-12.000

DEI QUALI GIA' REGISTRATI SU NAVIGATORE 3000

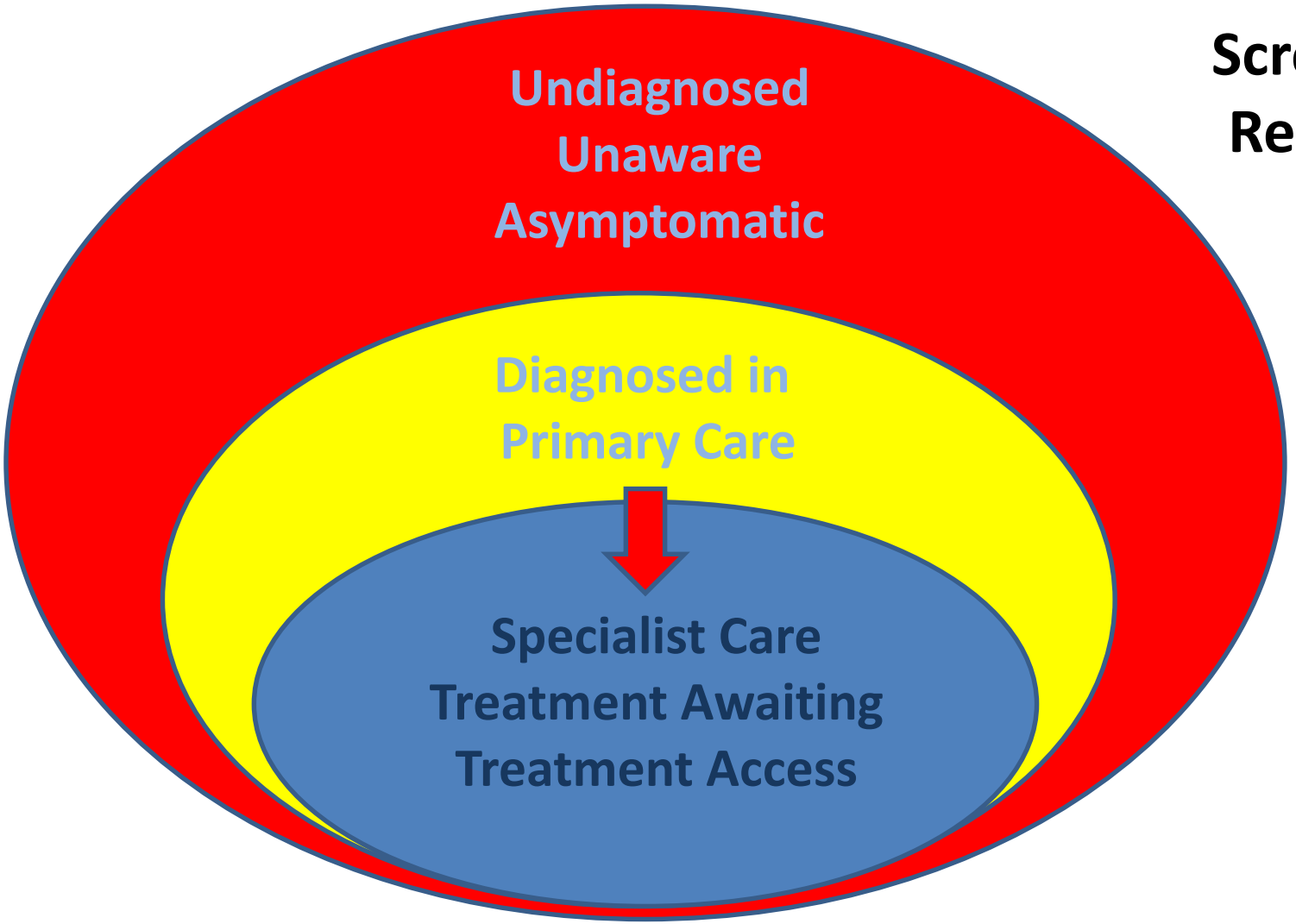
↓

CON DIAGNOSI NOTA MA NON RIFERITI ALLA RETE : 8000-9000

ANCORA DA DIAGNOSTICARE : 14.000-19.000

TARGET DI TERAPIE x ELIMINAZIONE HCV : 12.500-16.000

HCV POPULATION



Screening Required

Population targets

- HCV in PWID
- HCV in jail population
- HIV/HCV population
- HCV in "high risk" MSM
- HCV in "other" population
  - "Baby boomers"
  - Patients with comorbidities (diabetes, CKD, CVD, etc)

Population targets

HCV in PWID
HCV in jail population
HIV/HCV population
HCV in "high risk" MSM

Relative small numbers but high risk of HCV transmission

HCV in "other" population

- "Baby boomers"
- Patients with comorbidities

Large numbers but very low risk of HCV transmission

Soggetti con coinfezione HIV/HCV
Azienda Ospedaliera di Padova
(Marzo 2018)

Pazienti con infezione da HIV in carico presso il Ns Centro: **1592**

- **HCV Ab+: 23,9%**
- Dei quali:
    - **HCV-RNA non rilevabile: 91%**
    - **Ancora da trattare** (o in trattamento o in attesa di SVR12): **9%**

-

Marzo 2018:

Trattati o in trattamento con DAAs: 192 pz (da Aprile 2015)

Età mediana 55,3 aa (IQR 30-63); M/F=3,2:1

STADIO DI FIBROSI:

- **76** pazienti F0-F1 (criteri AIFA 7 e 8, criterio 3)
- **29** pazienti F2 (di cui 9 trattati con 3D+RBV ad uso compassionevole)
- **32** pazienti F3 (criterio AIFA 4)
- **55** pazienti F4 (criterio AIFA 1)

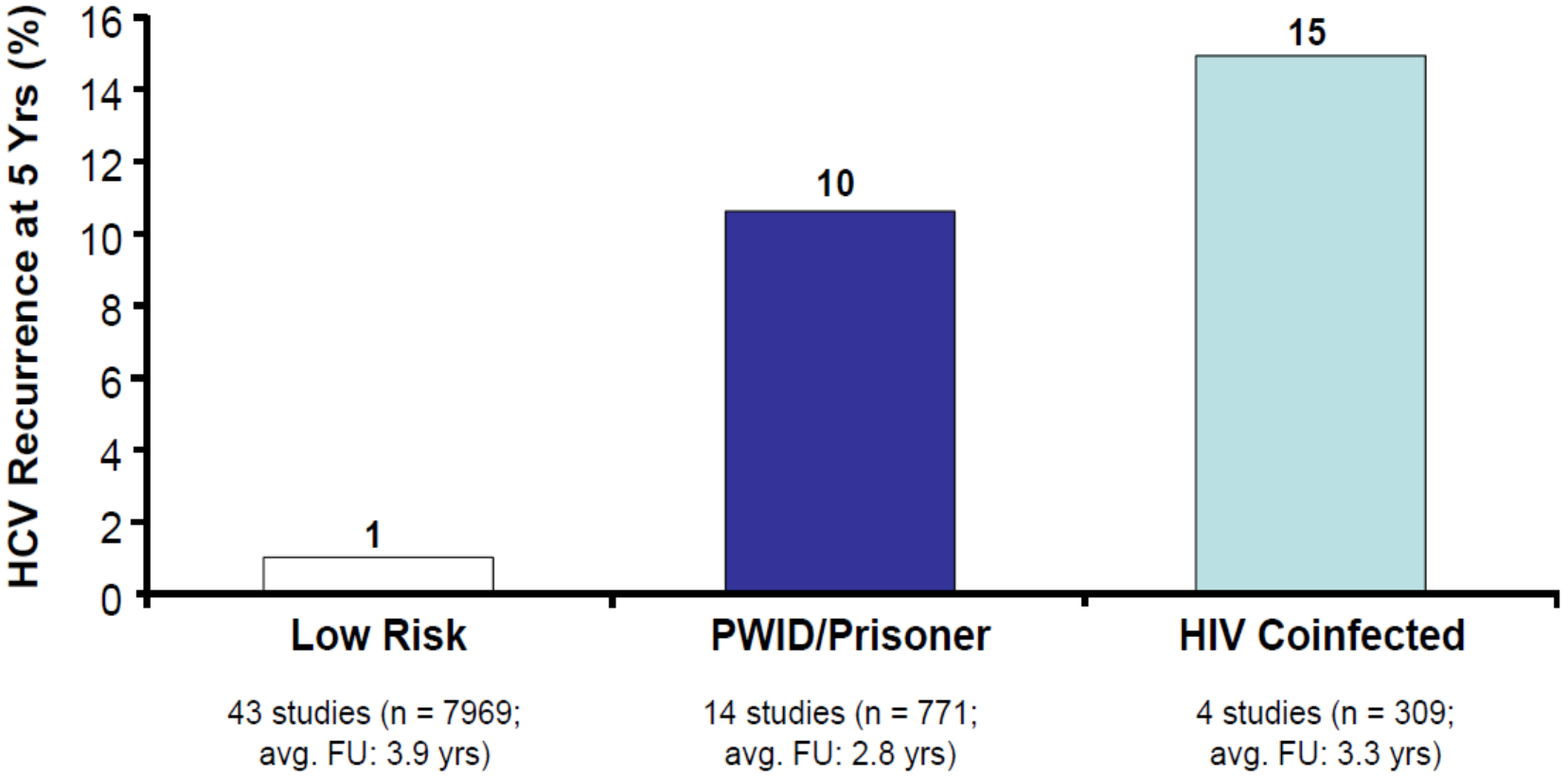
171 pazienti hanno completato il trattamento

158 pazienti hanno già raggiunto il controllo a 12 settimane dal termine della terapia

→ SVR 12 nel 98,3% (analisi OT)

Clinical Infectious Diseases

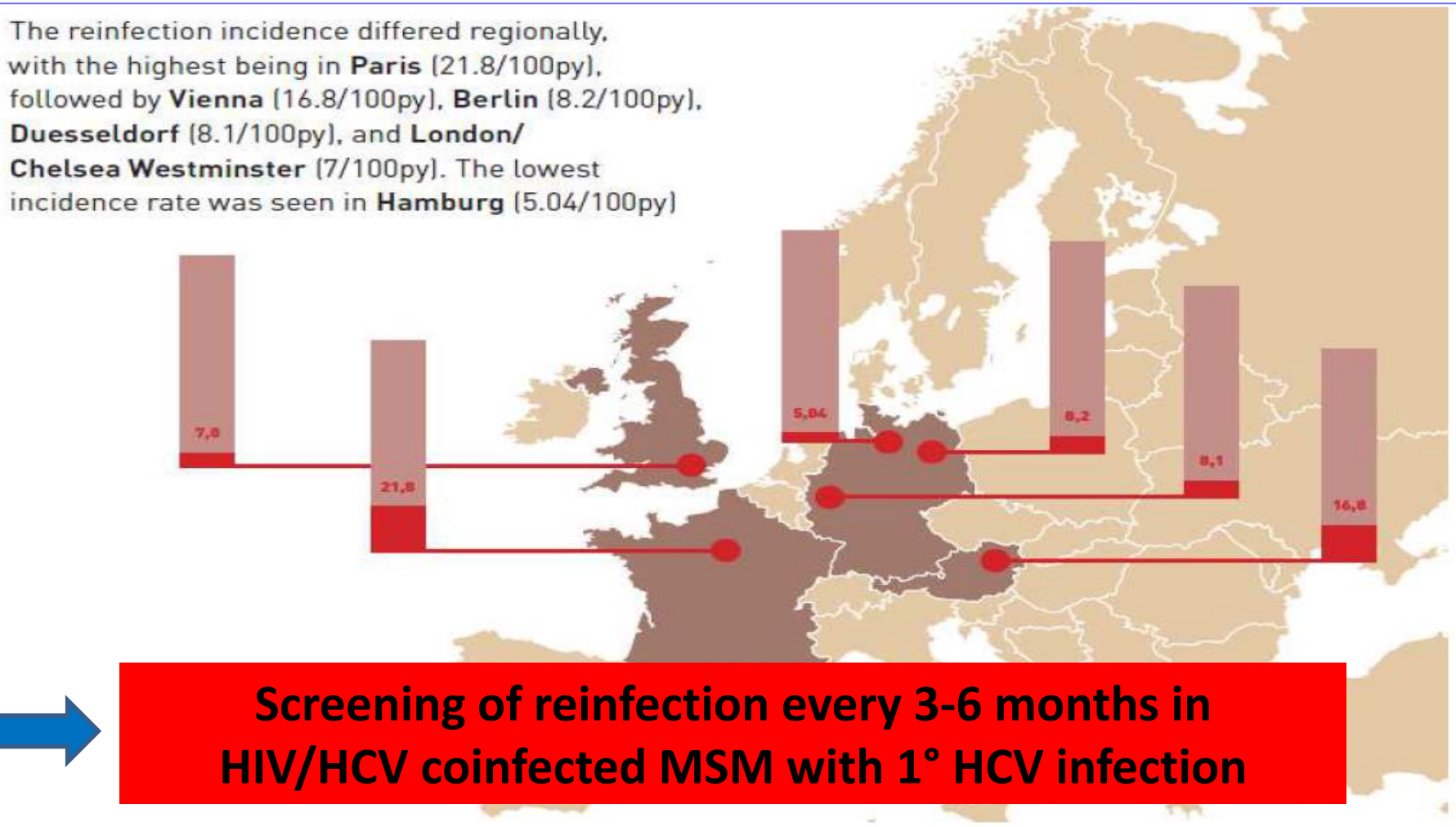
HCV Reinfection Over 5 Yrs by Study Population



Simmons B, et al. Clin Infect Dis. 2016:62:683-694.

HCV reinfection incidence among HIV+MSM in Western Europe

overall 606 cases. Rate of reinfection was 7.3/100 py (95% CI 6.2-8.6);
149 pts (25%) presented a reinfection, 30/70 (43%) presented with a 2° reinfection, 5 with a 3° and 1 with a 4°.



Screening of reinfection every 3-6 months in HIV/HCV coinfected MSM with 1° HCV infection

Ingliz P el al. J Hepatolo 2017; 66(2): 282

Fondazione Icona
ITALIAN COHORT NAIVE ANTIRETROVIRALS

"NO-CO-INFECTION PROJECT" IN HIV ITALIAN POPULATION

- HCV TEST FOR ALL PATIENTS
- RETEST HCV EVERY YEAR IF NEGATIVE
- RETEST HCV IF NEW RISK FACTORS

Population targets

HCV in PWID
HCV in jail population
HIV/HCV population
HCV in "high risk" MSM

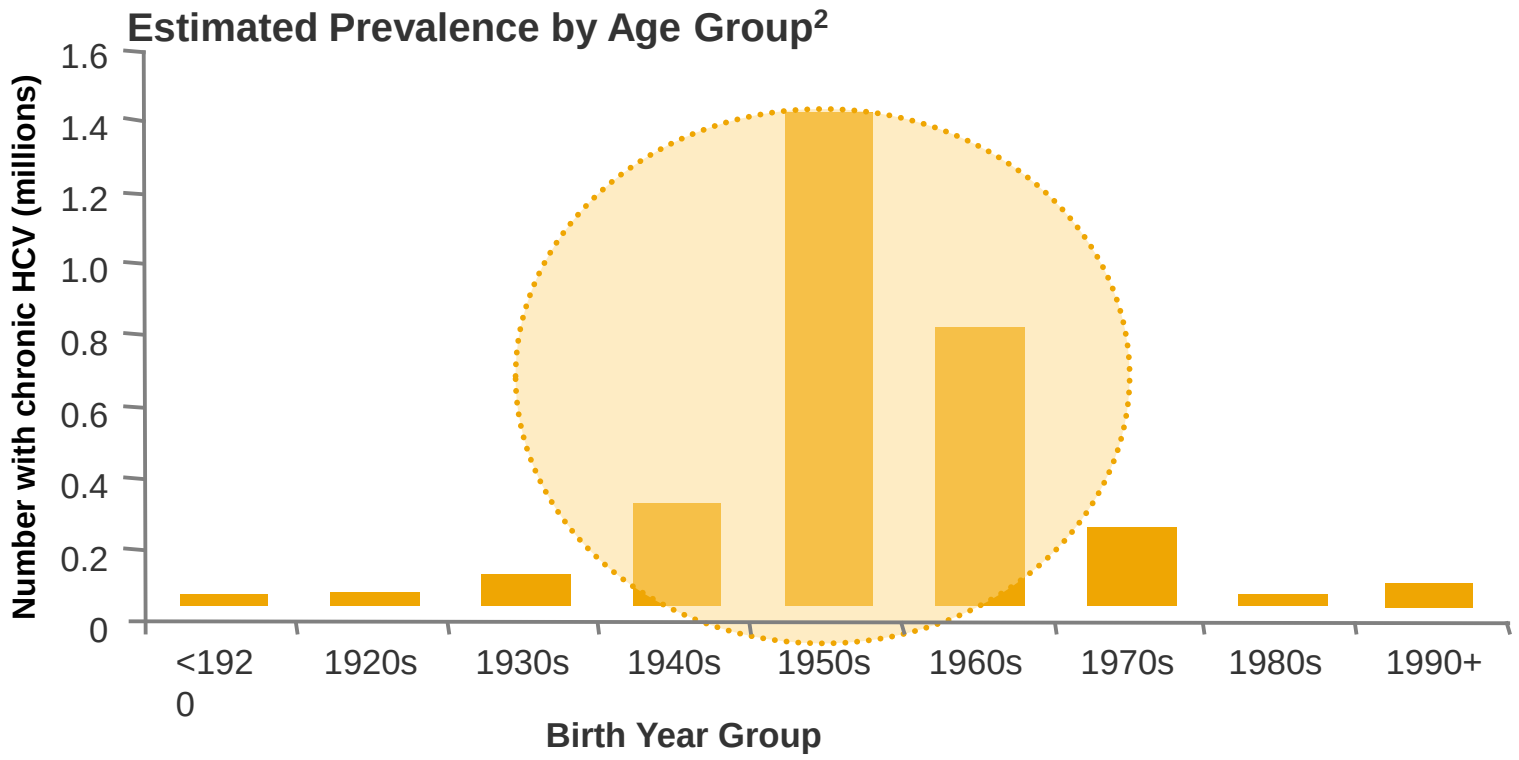
Relative small numbers but
high risk of HCV transmission

HCV in "other" population

- "Baby boomers"
- Patients with comorbidities

Large numbers but
very low risk of HCV transmission

Baby Boomers (Born in 1945–1965) Account for 76.5% of HCV in the US[1]



An estimated 35% of undiagnosed baby boomers with HCV currently have advanced fibrosis (F3-F4; bridging fibrosis to cirrhosis)[3]

1. Centers for Disease Control and Prevention. *MMWR*. 2012;61:1-32; Adapted from Pyenson B, et al. *Consequences of Hepatitis C Virus (HCV): Costs of a baby boomer Epidemic of Liver Disease*. New York, NY: Milliman, Inc; May 18, 2009. http://www.milliman.com/expertise/healthcare/publications/rr/consequences-hepatitis-c-virus-RR05-15-09.php Milliman report was commissioned by Vertex Pharmaceuticals; 3. McGarry LJ et al. *Hepatology.* 2012;55(5):1344-1355.

Address All Stakeholder for HCV testing

- Primary care providers
  - General Practitioners
  - Nurses
  - Other Point of care (STI, antidiabetic centers, etc)
  - Specialists who also do primary care
- Emergency rooms (rapid test for combined HCV/HIV)
- Specialists in the hospital
- Lab directors
    - Map anti-HCV reactive tests
    - Reflex HCV RNA testing for all anti-HCV reactive tests

Electronic medical record alert improves HCV testing for baby boomers in primary care setting: adults born during 1945–1965

screening test rate for HCV increased from a baseline of 30% to a 55% during the nine-month project period

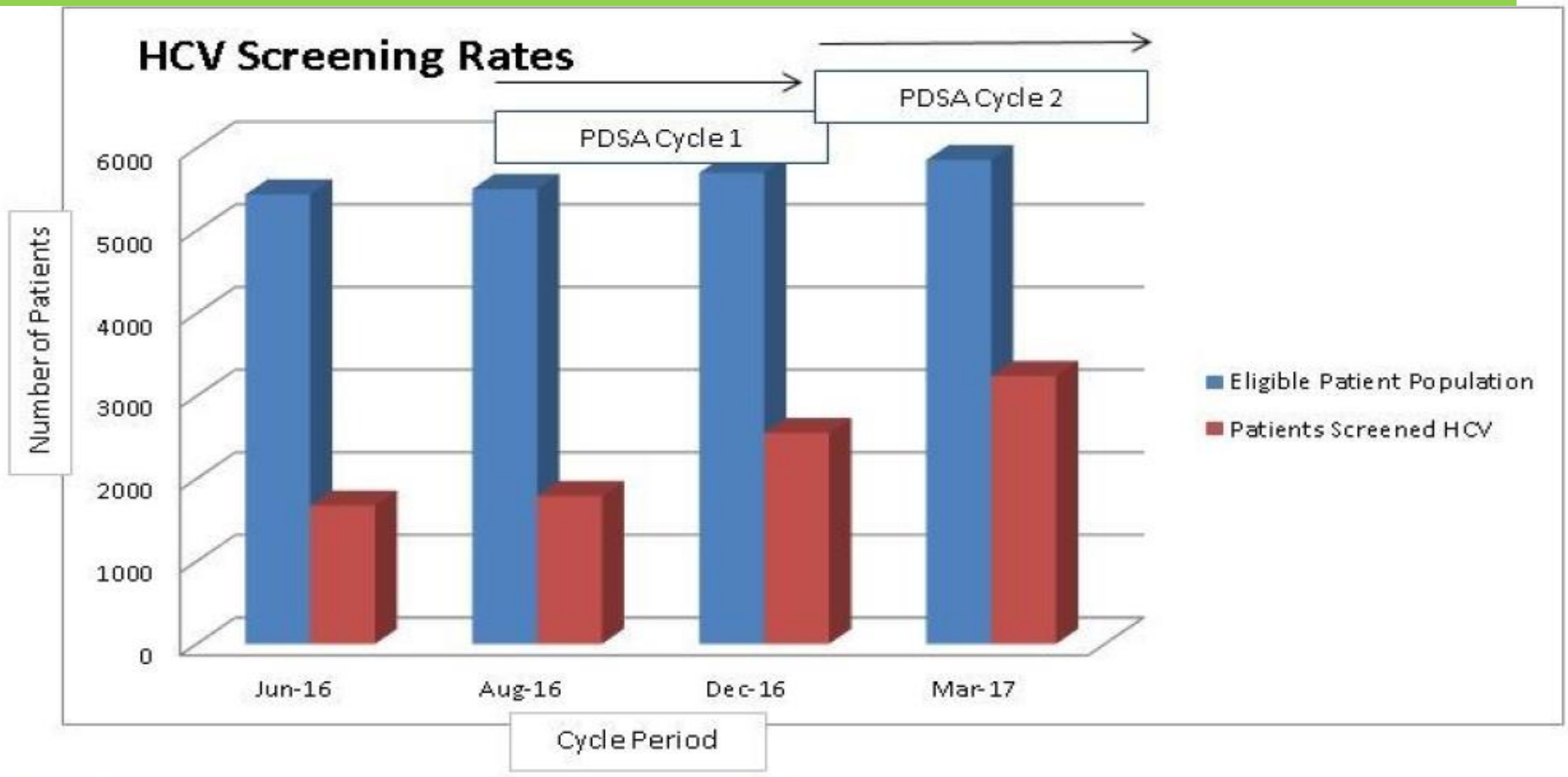


Figure 1 HCV screening rates. HCV, hepatitis C virus; PDSA, Plan-Do-Study-Act.

BMJ Open Quality 2017;6:e000084.

Overcoming Barriers to HCV Testing

- Identify *what* would convince people responsible for doing HCV testing that testing helps solve *their* problem
- Convince these testers that it is urgent to test people now
- Identify misconceptions and fears and address them or help develop solutions
- Show case successes

Misconceptions

Misconception: My patients don't have undiagnosed hepatitis C

Hepatitis C is common and uniform testing of baby boomers plus risk based testing can identify them

Misconception: Hepatitis C is slowly progressive so I have time to identify patients

25% of baby boomers already have cirrhosis

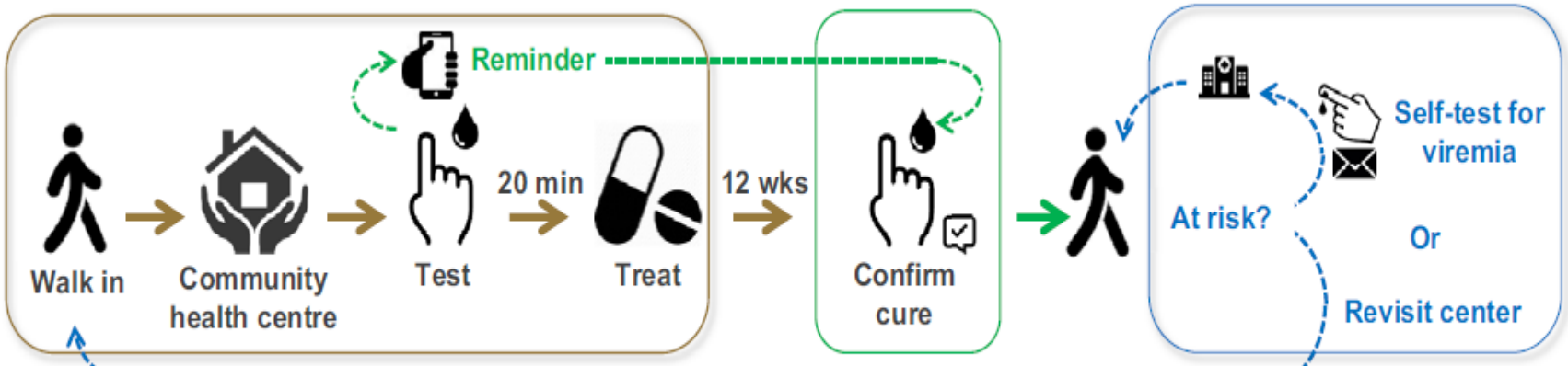
If we find all of these undiagnosed people it will overwhelm our system

It takes time to bring people into care

There are too many prompts already and I don't have time to deal with this

For baby boomers this is a one-time, inexpensive blood test that can be done with other routine labs

The holy grail: the ideal point-of-care test for active hepatitis C virus (HCV) infection



In Italy, now, not tomorrow implementation of multiple " microelimination" projects may accelerate HCV containment

Key points

- Innovative strategies to provide access to HCV diagnostic assays are an immediate priority
- An integrated program of hepatitis C virus diagnosis, staging, and treatment will help more hepatitis C virus-infected adults achieve cure
- Innovations to close gaps along the hepatitis C virus cascade of care will contribute to progress in disease eradication
- May decentralized models of care to diagnose HCV infection and confirm cure within community health care settings be crucial to achieve HCV elimination by 2030?

Grazie per l'attenzione