

Meeting WHO Goals for HCV Elimination: **The role of Micro-elimination**

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Disclosures

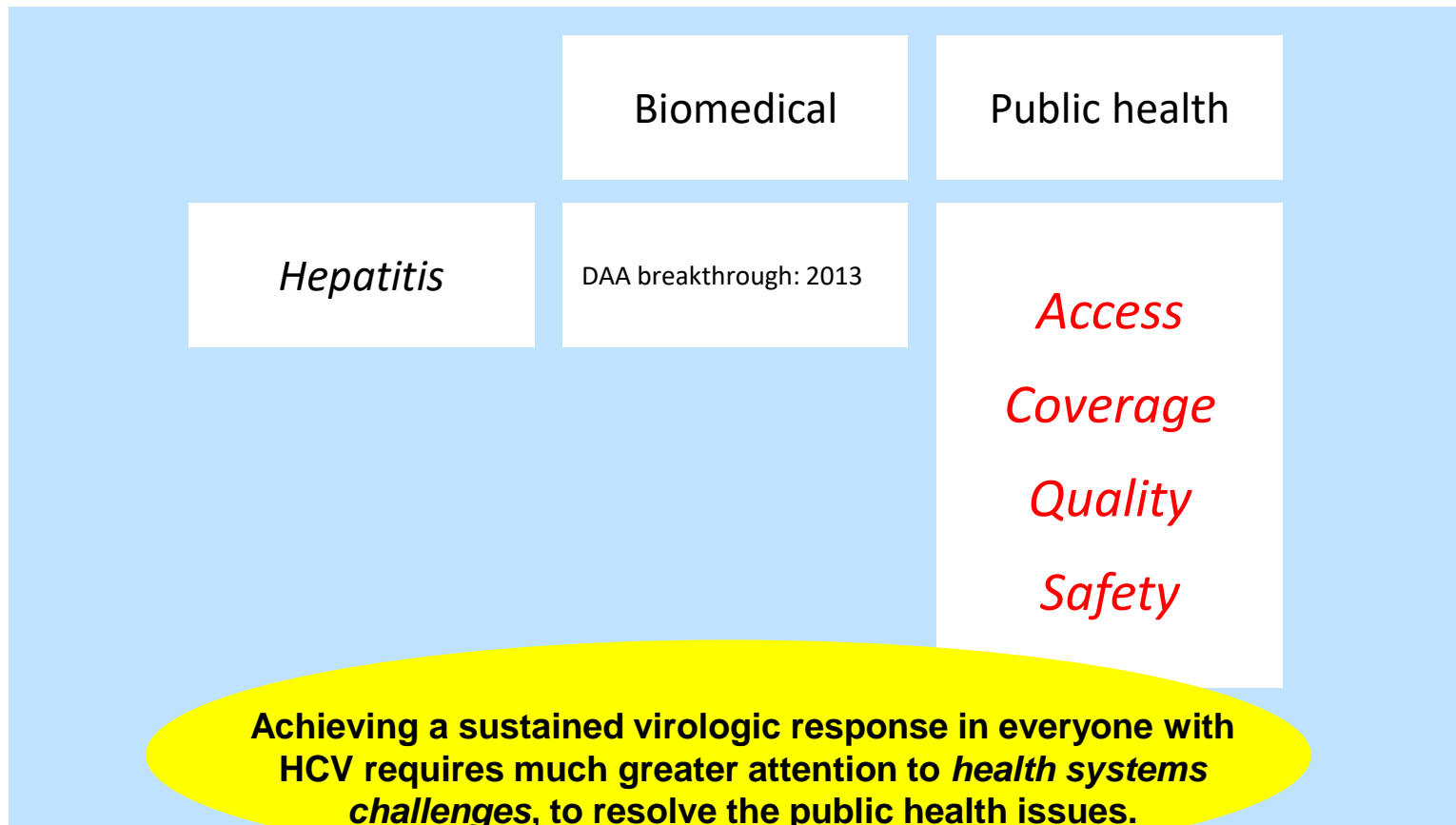
Research grants and speaker fees from AbbVie, Gilead Sciences, MSD. Speaker fees from Abbott, CEPHEID, Janssen and Intercept.

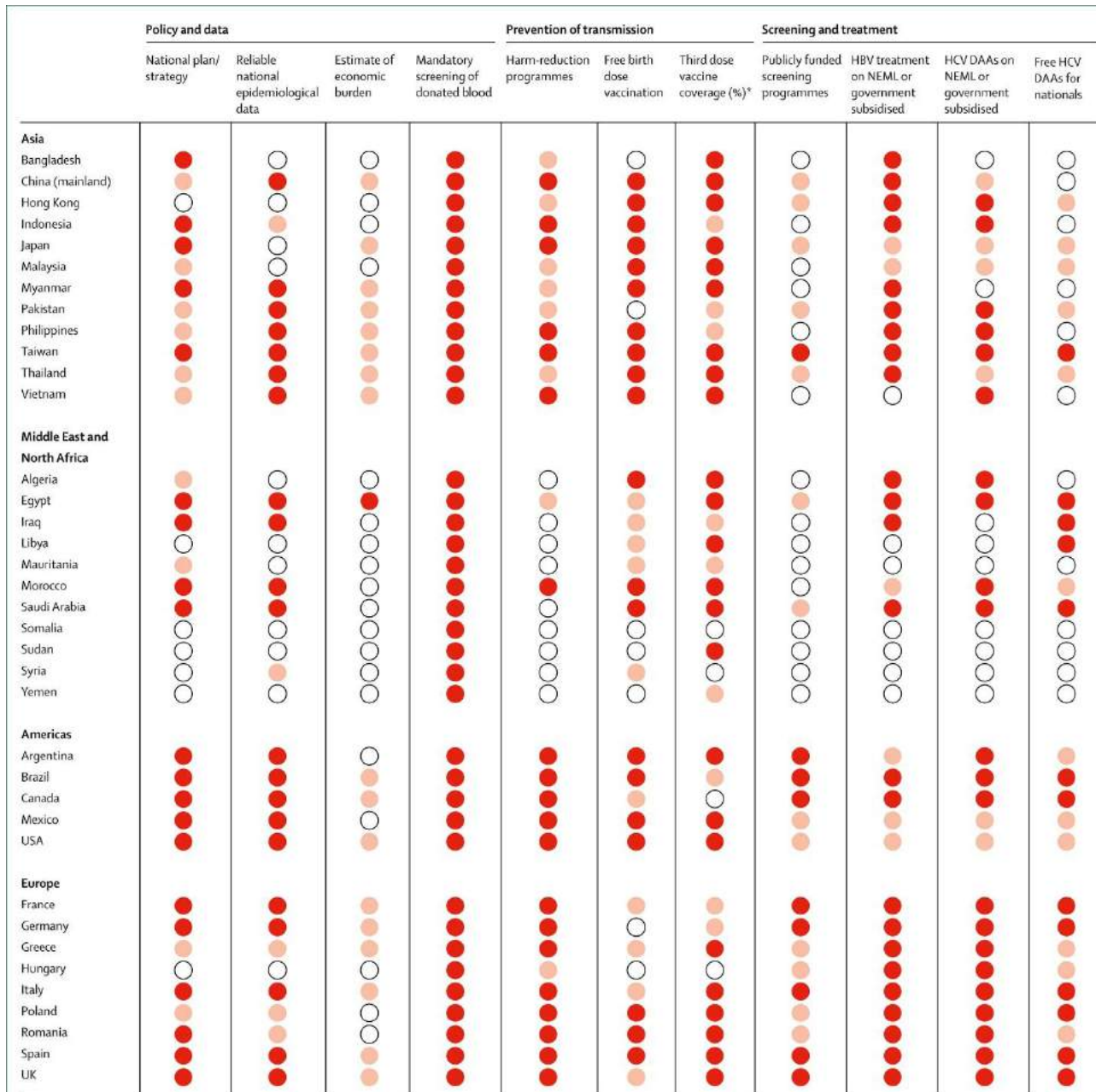
The question in the field of hepatitis C...

Translating good biomedical tools into
good health outcomes for people living
with hepatitis C –

what will it take?

Meeting two types of challenges to eliminate HCV

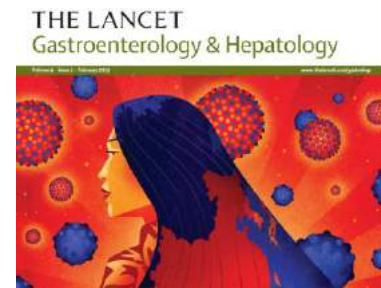




Red circles denote the existence of a policy.

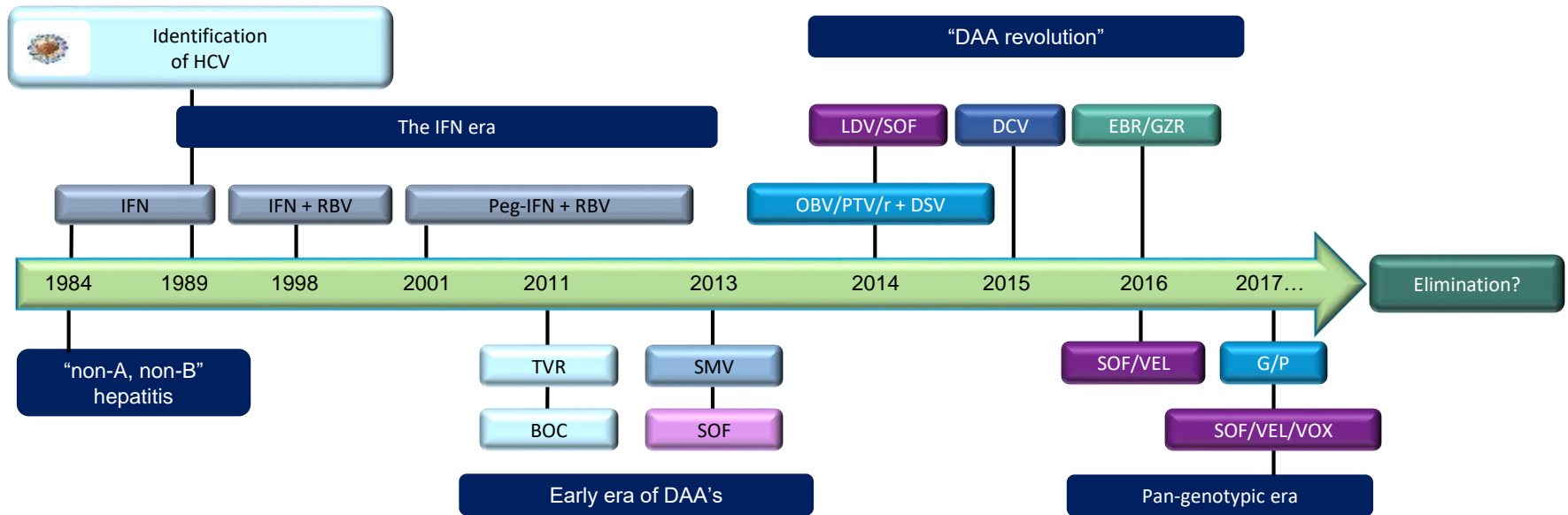
Pink circles denote that a policy is in development, is not well applied, or is in place for specific subpopulations;

White denotes the absence of a policy.



Source: Cooke G et al. Lancet Commission: Accelerating the Elimination of Viral Hepatitis, *The Lancet Gastroenterology & Hepatology*, 2019; 4: 135–84. @JVLazarus

HCV treatment timeline



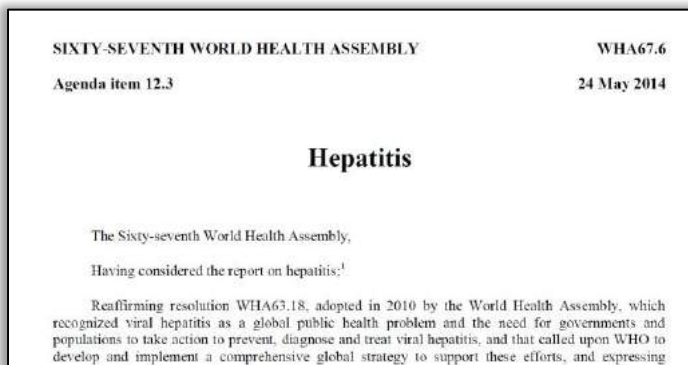
Sources: Pawlotsky JM, et al. *J Hepatol* 2016; 62: S87–99; Manns M, et al. *Nat Rev Dis Primers* 2017;3:1–19.



New global political will to eliminate HCV

World Health Assembly resolutions (2010, 2014)

Patient community delivers NOhep (2016)



Hepatitis C Elimination in Europe (2016 + 2018) 'Our vision for a Hepatitis C-free Europe'



First World Hepatitis Summit (2015)

84 countries represented – repeated in 2017



Sources: World Hepatitis Summit 2015 meeting report. Available at: <http://www.worldhepatitisalliance.org/sites/default/files/resources/documents/World%20Hepatitis%20Summit%20Report.pdf>; Elimination manifesto. Available at: <http://www.hcvbrusselssummit.eu/elimination-manifesto> (both accessed January 2017)



WHO Global Health Sector Strategy on Viral Hepatitis 2016–2021



28 May 2016: The first of its kind, WHO publishes a global strategy aiming for elimination of viral hepatitis as a public health threat by 2030



Source: WHO Global Health Sector Strategy on viral hepatitis. Available at: http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_32-en.pdf?ua=1 (Accessed August 2016)

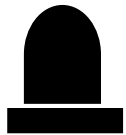
Global Health Sector Strategy

HCV targets at a glance



Incidence targets

- **30%** reduction in new HCV infections by 2020
- **80%** reduction in new HCV infections by 2030



Mortality targets

- **10%** reduction in mortality by 2020
- **65%** reduction in mortality by 2030



Harm reduction

- Increase in sterile needle and syringes provided per PWID/year from **20** in 2015 to:
 - **200** by 2020
 - **300** by 2030



Testing targets

- **90%** of people aware of HCV infection by 2030



Treatment targets

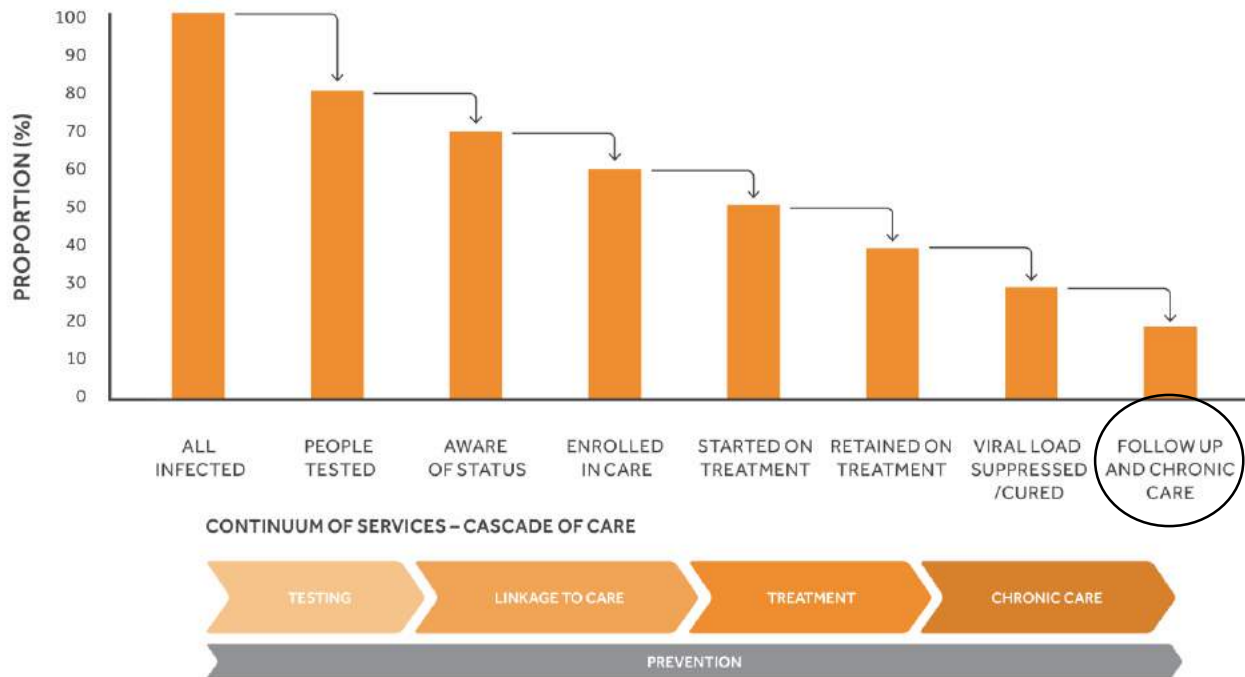
- **80%** of people treated by 2030

Source: WHO GHSS. http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_32-en.pdf?ua=1 (Accessed August 2016).



The continuum of viral hepatitis services and the retention cascade

- WHO goal: eliminate HCV as a public health threat by 2030
- The HCV Cascade of Care: a key element of monitoring progress

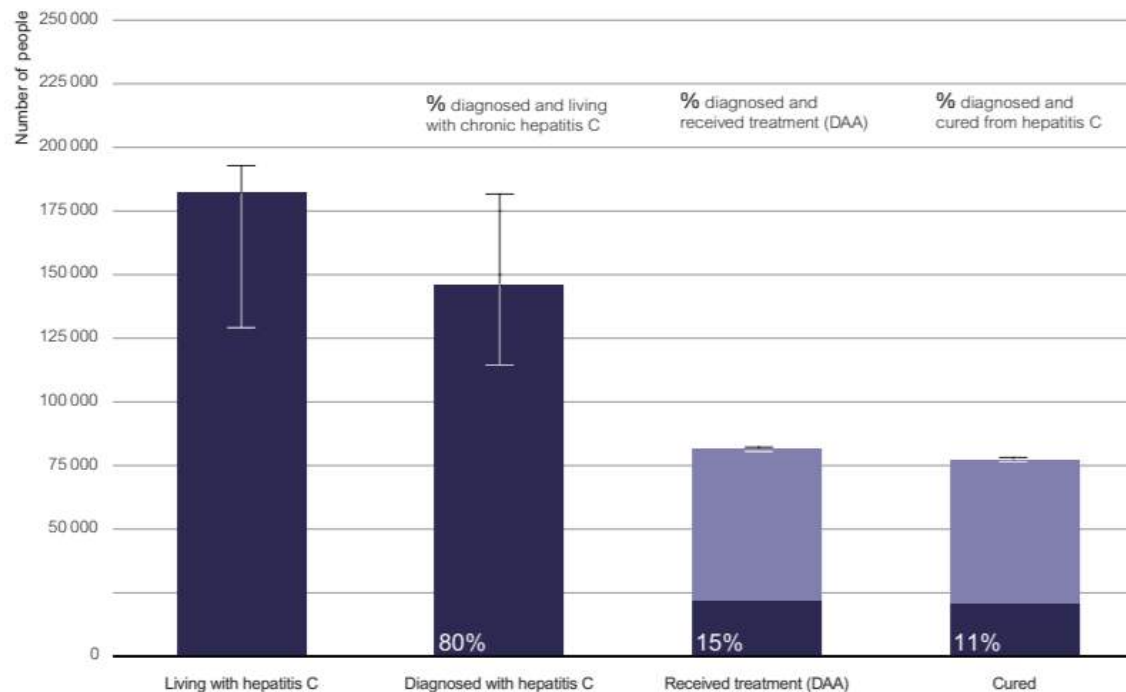


Source: WHO Global Hepatitis Report, 2017. Available at www.who.int/hepatitis/publications/global-hepatitis-report2017/en/ (accessed May 2017).

Public health problem

Lack of standardisation in HCV CoC monitoring hampers efforts to tack progress toward WHO elimination goals

Figure 2.6.1 The hepatitis C diagnosis and care cascade, 2017



Source: Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia: annual surveillance report 2018. Sydney: Kirby Institute, UNSW Sydney; 2018.

Outcome: the Consensus HCV CoC

Box 1. Definitions for the Consensus Hepatitis C Cascade of Care for a given year

The 2017 calendar year is used to illustrate these definitions, which can be applied to any 12-month period.

Infected = Number of people estimated to have viremic HCV infection on 1 January 2017.

Diagnosed = Number of people who received a diagnosis of viremic HCV infection before or during 2017, were still infected at the beginning of 2017 and were still alive at the end of 2017. This number excludes people whose HCV infection was cured (spontaneously or through treatment) before 2017, but includes those whose HCV infection was cured over the course of 2017. (People who have only had an antibody-based diagnosis are excluded.)

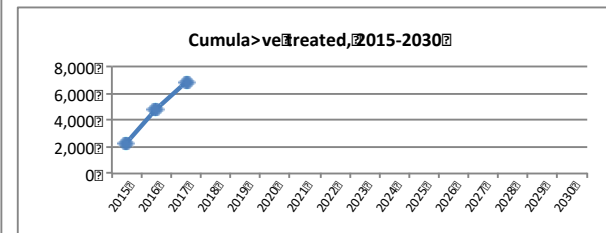
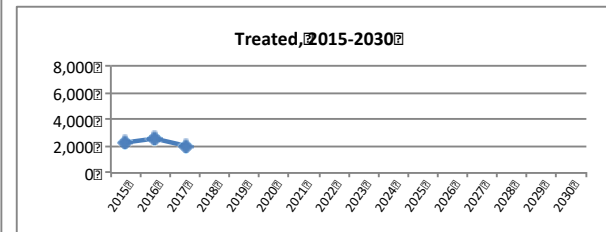
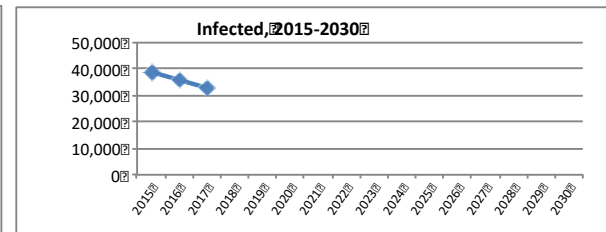
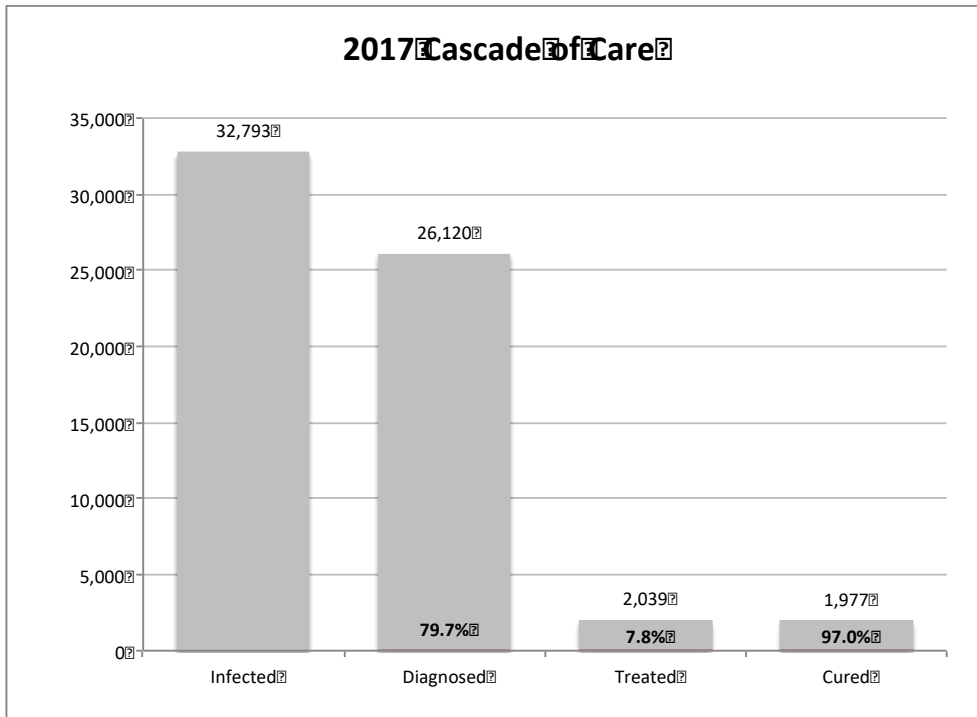
Treated = Number of diagnosed people (as defined above) who initiated HCV treatment at any time during 2017 (all types of treatment, including interferon-based regimens).

Cured = Number of treated people (as defined above) who attained a sustained virologic response (SVR)*, including people who initiated treatment in 2017 and underwent SVR testing within the first six months of 2018.

*SVR is defined according to the latest clinical practice guidelines that are relevant for the country of interest, e.g., guidelines from a national clinical society or from the World Health Organization, the European Association for the Study of the Liver or the American Association for the Study of Liver Diseases.

Source: Safreed-Harmon *et al.* [Clin Infect Dis.](#) 2019 Jul 28. pii: ciz714. doi: 10.1093/cid/ciz714. [Epub ahead of print]


CoC – Sweden



A useful tool for comparison among countries and over time.

Source: Safreed-Harmon *et al.* The Consensus Hepatitis C Cascade of Care: standardized reporting to monitor progress toward elimination. [Abstract] ILC2019.



The continuum of viral hepatitis services and the retention cascade – example from Canada



BC Centre for Disease Control
An Agency of the Government of British Columbia

Hepatitis C cascade of care among people who inject drugs in British Columbia in 2017

Sofia Bartlett¹, Amanda Yu¹, Stanley Wong¹, Zahid Butt¹, Carmine Ross¹, Hasina Sami¹, Terri Butler-Taylor¹, Maria Alvarez², Margo Pearce¹, Maryam Darvishian¹, Jason Wong¹, Mark Gilbert¹, Mark Tyrinda¹, Mel Krajden¹, Naveed Jarjuu¹
¹BC Centre for Disease Control, Vancouver, British Columbia

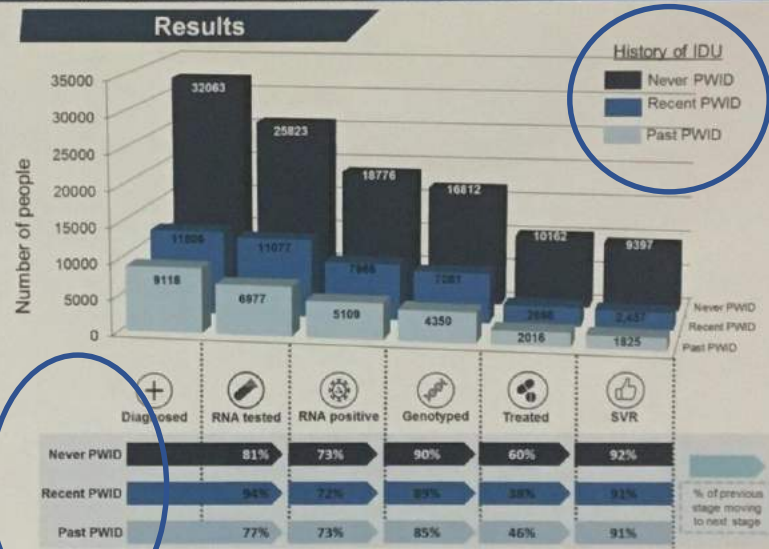



British Columbia
Hepatitis Testers Cohort

Background & Aims

- Direct acting antivirals (DAAs) with high cure rates, shortened treatment duration and high tolerability are expected to increase treatment rates among people living with hepatitis C virus (HCV).
- People Who Inject Drugs (PWID) are disproportionately affected by HCV infection compared to other groups at risk of infection, and they frequently have multiple other comorbidities.
- To assess progression through HCV care and treatment among PWID, we constructed the HCV cascade of care among people diagnosed with hepatitis C virus infection living in British Columbia (BC), Canada in 2017, stratified by history of injecting drug use.

Results



History of IDU

- Never PWID
- Recent PWID
- Past PWID

Diagnosed **RNA tested** **RNA positive** **Genotyped** **Treated** **SVR**

Group	Diagnosed	RNA tested	RNA positive	Genotyped	Treated	SVR
Never PWID	8118	81%	73%	90%	60%	92%
Recent PWID	11006	94%	72%	89%	38%	91%
Past PWID	6977	77%	73%	85%	46%	91%

Key Findings

- Integration of provincial testing, treatment, mortality, medical visit and hospitalization datasets makes assessment of HCV care cascades possible at both population and sub-population levels.
- HCV treatment uptake remains lower among both recent and past PWID, compared to those with no history of injecting drug use, despite equivalent progression through the testing stages of the HCV care cascade among all three groups.
- These analyses could be used to monitor progress toward HCV elimination goals and guide strategies to reduce disparities in health among PWID.

Method




Figure 1. British Columbia Hepatitis Testers Cohort (BC-HTC) data sources.


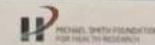

- The BC Testers Cohort (BC-HTC) used for analysis. BC-HTC includes all individuals tested for HCV in BC since 1990, linked to data on all prescription drugs, medical visits, hospitalizations and mortality data.
- Six cascade of care stages defined: 1) anti-HCV positive (diagnosed); 2) RNA tested; 3) RNA positive; 4) genotyped; 5) initiated treatment; and 6) achieved post-treatment sustained virologic response (SVR).
- People diagnosed with HCV infection stratified by history of injecting drug use using previously validated algorithm (recent PWID, people who injected drugs <3 years; past PWID, >3 years ago; or never PWID) and progression through care cascade compared among these groups.

Next Steps

- Uptake may increase among PWID after removal of fibrosis restrictions on DAA treatment eligibility in BC in early 2018
- However, factors associated with treatment uptake among this sub-population should be investigated to help identify strategies to enhance HCV treatment uptake among this group.

For more information, please contact:
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Barriers: late presentation

Mauss et al. *BMC Medicine* (2017) 15:92
DOI 10.1186/s12916-017-0856-y

BMC Medicine

CORRESPONDENCE

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Late presentation of chronic viral hepatitis for medical care: a consensus definition

Stefan Mauss^{1,2}, Stanislas Pol^{2,9}, Maria Buti^{2,3}, Erika Duffell⁴, Charles Gore⁵, Jeffrey V. Lazarus⁶, Hilje Logtenberg-van der Grient⁷, Jens Lundgren⁶, Antons Mozalevskis^{6,8}, Dorthe Raben^{6,10*}, Eberhard Schatz¹¹, Stefan Wiktor¹², Jürgen K. Rockstroh^{10,13} and on behalf of the European consensus working group on late presentation for Viral Hepatitis Care

Abstract

Introduction: We present two consensus definitions of advanced and late stage liver disease being used as epidemiological tools. These definitions can be applied to assess the morbidity caused by liver diseases in different health care systems. We focus is on hepatitis B and C virus infections, because effective and well tolerated treatments for both of these infections have greatly improved our ability to successfully treat and prevent advanced and late stage disease, especially if diagnosed early. A consensus definition of late presentation with viral hepatitis is important to create a homogenous, easy-to-use reference for public health authorities in Europe and elsewhere to better assess the clinical situation on a population basis.

Methods: A working group including viral hepatitis experts from the European Association for the Study of the

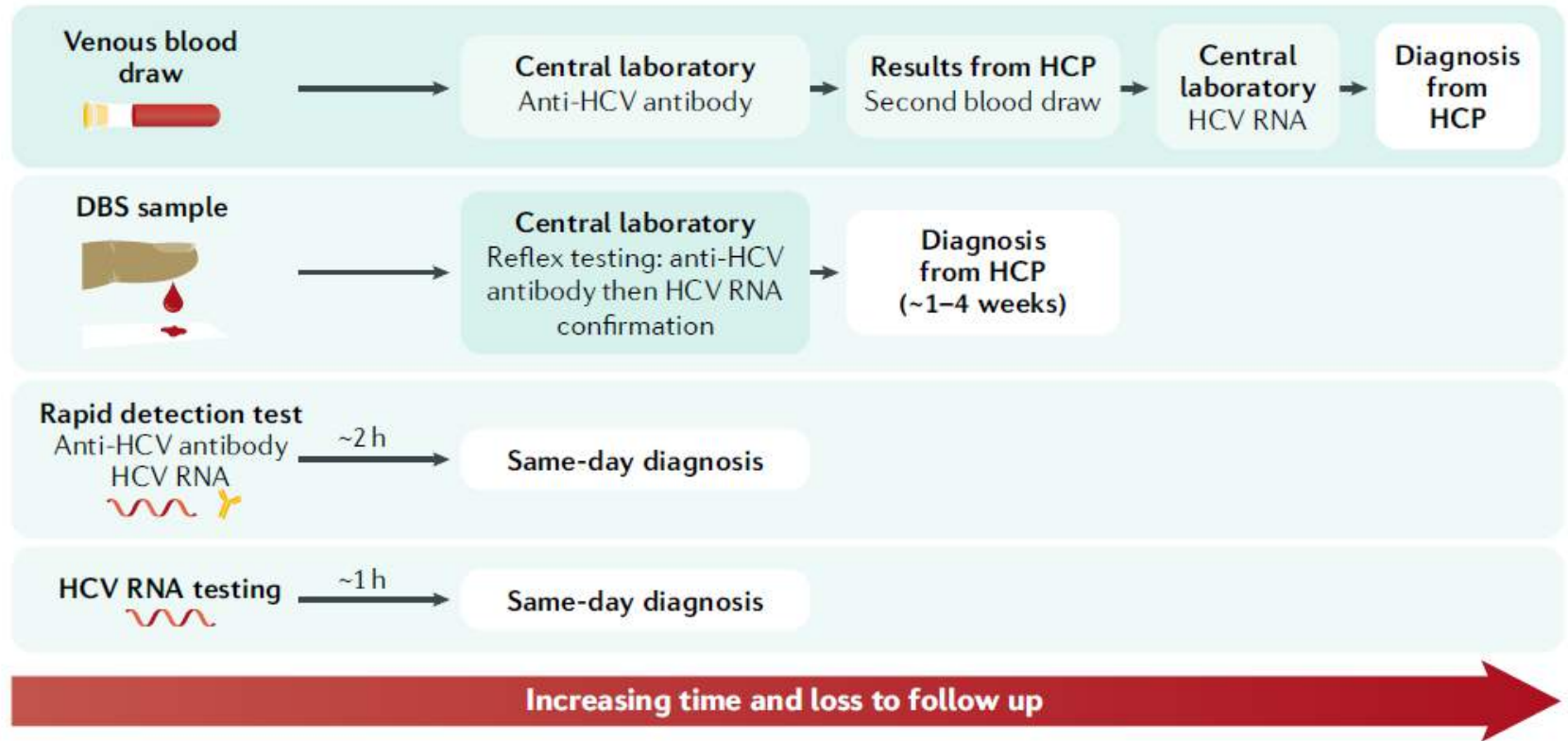
Source: Mauss et al. *BMC Med*, 2017.

Tracking late presentation

HCV and HBV LATE PRESENTATION STUDY											
Name of center and contact person											
HCV											
CENTER				PATI							
Subject	Type of Center	Service/Department	Origin of referral	Gender	DOB	Country of Origin	Previously tested for HCV?	Year of last test	Year of diagnosis	RNA at first assessment	
1											
2											
3											

Source: Lazarus JV et al. Too many people with viral hepatitis are diagnosed late – with dire consequences. *Nature Reviews GastroHep*, 2019 In press.

Fewer visits please...

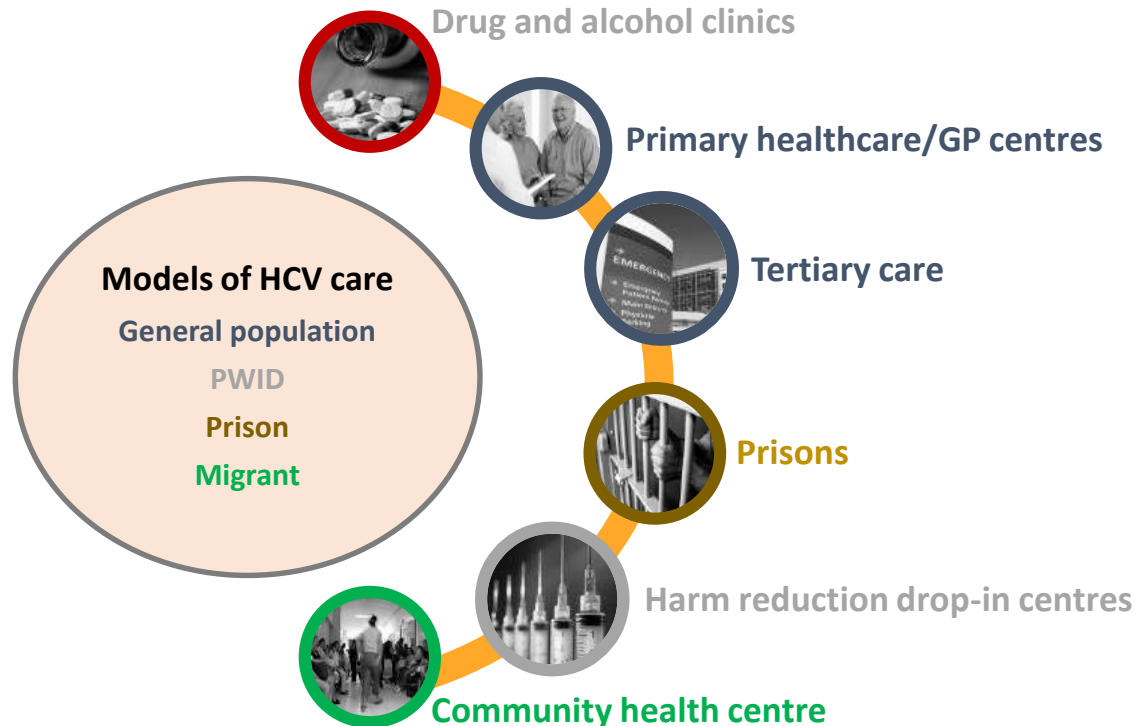


Sources: Lazarus et al. Too many people with viral hepatitis are diagnosed late – with dire consequences. *Nature Rev*, Aug 2019.

Grebely et al. Hepatitis C point-of-care diagnostics: in search of a single visit diagnosis. *Expert Review of Molecular Diagnostics*. 2017;1473-7159.

Different models of HCV care are needed for different HCV subpopulations for testing and treatment

Multiple models essential



Source: Bruggmann P, Litwin AH. *Clin Infect Dis* 2013;57(Suppl 2):S56–61.
Lazarus JV et al. We know DAAs work, so now what? Simplifying models of care to enhance the hepatitis C cascade. *J Int Med* 2019 In press.

GP: general practitioner

@JVLazarus

Models of care – definition

A model of care (MoC) signifies a setting-specific framework that outlines how to provide the relevant services and interventions throughout the HCV cascade of care.

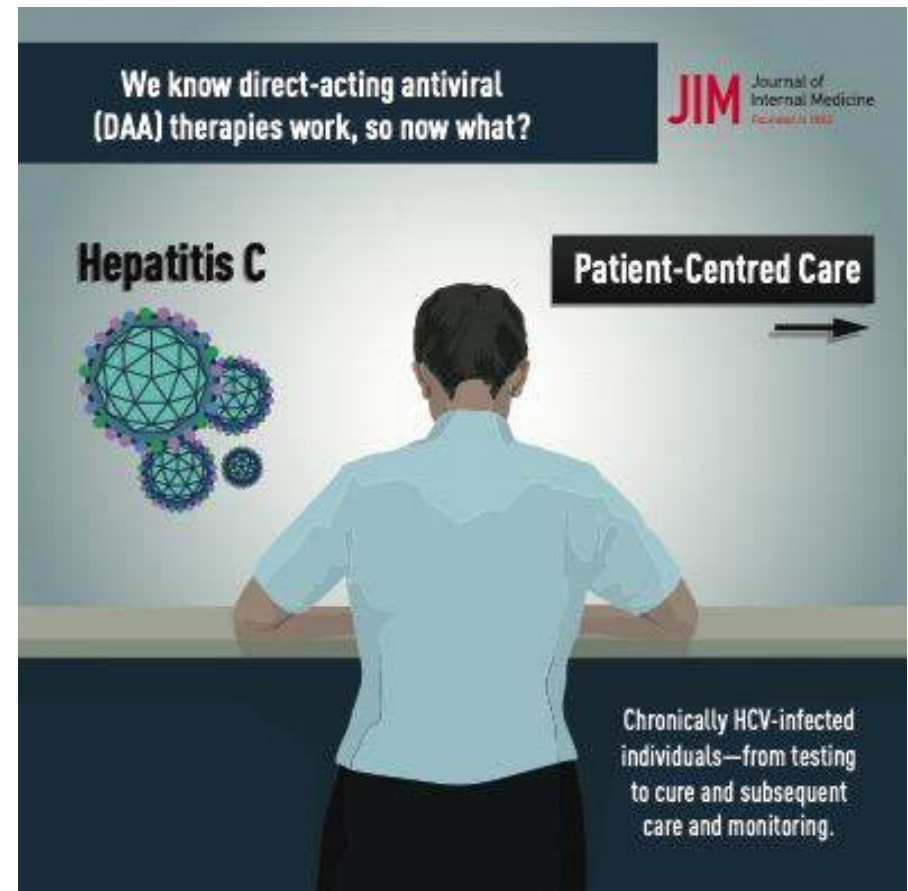
An MoC should address four key questions:

1. *where* to provide the services
2. *what* services to provide
3. *who* to provide them and
4. *how* to integrate them.

Source: Lazarus JV et al. We know DAAs work, so now what? Simplifying models of care to enhance the hepatitis C cascade. *J Int Med* 2019 Nov;286(5):503-525.

What is an ideal MoC for HCV?

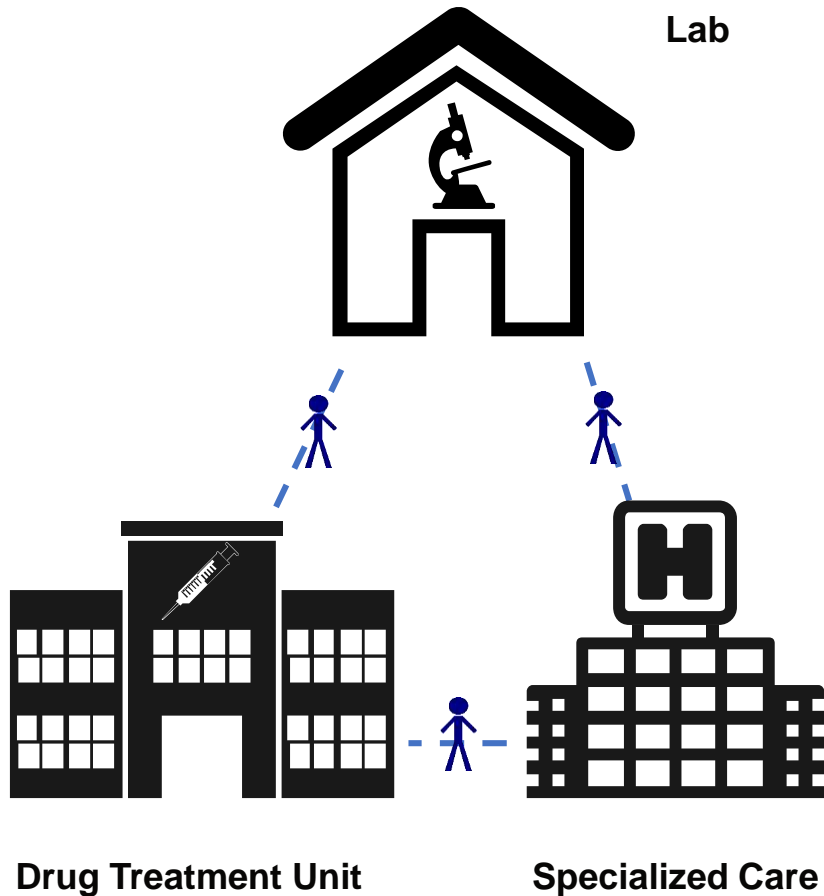
- Much can be learned from examining innovative MoCs, which suggest that *an effective MoC for HCV infection should be:*
 - Simple
 - Targeted
 - Multidisciplinary
 - Scalable
 - Integrated
 - Patient-centred and affordable.



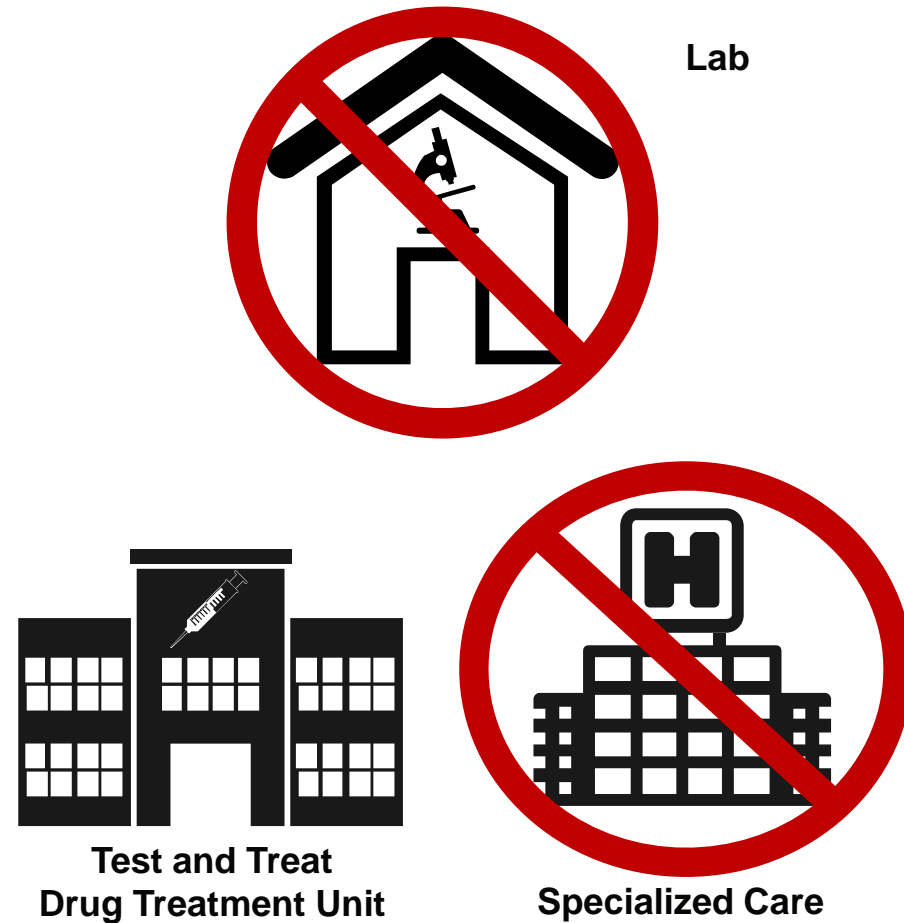
Source: Lazarus JV et al. We know DAAs work, so now what? Simplifying models of care to enhance the hepatitis C cascade. *J Int Med* 2019 In press.

Case 1. Where Would You Want To Be Tested and Treated?

**Former Organization:
Patient travelled**



**Future Organization: The
sample and meds travel**



Source: Shared Addiction Care Copenhagen (SACC) Report 2017.
Available at: <http://www.chip.dk/Collaborations/SACC> (accessed July 2018).

Case 2. T'n'T, Copenhagen Denmark



Source: Lazarus 2019

Case 2. T'n'T in a van, Copenhagen Denmark

- Running from April 2019.
- Peer-led by Brugernes Akademi, Denmark, with on-site nurses.
- Rapid antibody PoC tests and GeneXpert machine in the van.
- Linkage to care at hospital – medicine can be delivered to the van.
- Parked behind the main train station in Copenhagen, Denmark's largest open drug scene

Case 3. Background: HCV testing at pharmacies project

- Running from April 2018-April 2019.
- Based on original model of community pharmacy testing piloted by the London Joint Working Group.
- 8 GeneXpert machines based in the top 8 needle exchange pharmacies in Birmingham and Manchester (not all sites yet active in the two locations).
- Live from mid-July 2018

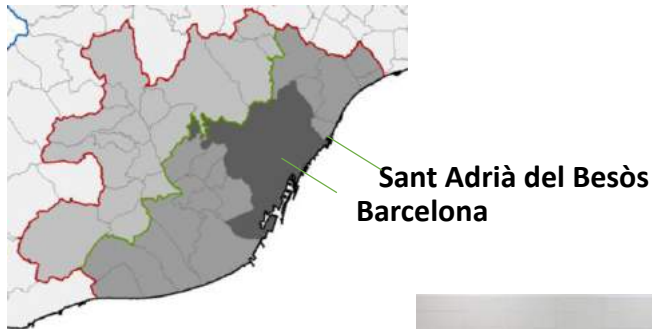


Source: Ahmed Elsharkawy, Birmingham, UK. Personal communication, Oct 2018.

Case 4: Decentralised testing - Barcelona

Harm reduction center “El Local”

Metropolitan area of Barcelona



“La Mina”
neighbourhood
important drug
trafficking area in
Spain



“El Local”

2,700 different users in 2017
86,400 inj. drug consumes
182,800 syringes distributed
110,800 syringes returned



- Distribution of needles, syringes and paraphernalia
- Drug consumption room
- Outreach-street work
- Breakfast/snacks
- Showers and clean clothes
- Screening (HCV, HIV, TB)
- Vaccination (HAV, HBV, tetanus)
- Educational sessions

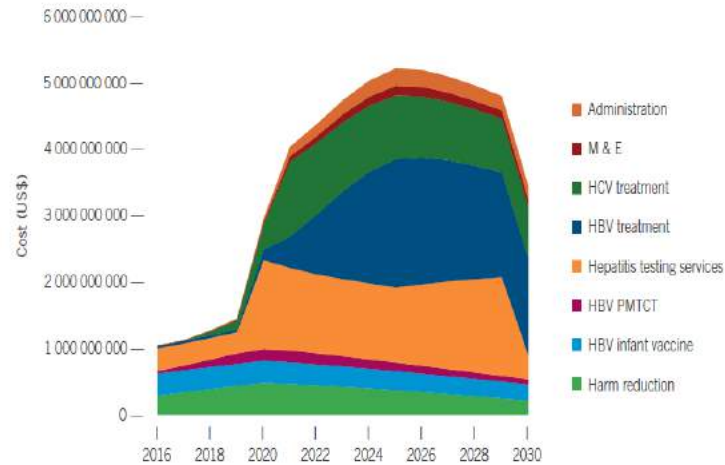
Source: Courtesy of Elisa Martó, Microbiology Service of Germans Trias Hospital, Spain, April 2019.

Elimination is Daunting for the Health System

Cost of implementing the WHO global health sector strategy on viral hepatitis, 2016–2030



Challenging



HBV, hepatitis B virus; HCV, hepatitis C virus; M&E, monitoring and evaluation; PMTCT, prevention of mother-to-child transmission.

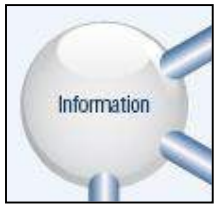
Costly




Complex



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HCV (micro-) elimination in certain populations is also feasible in the short-to-medium term

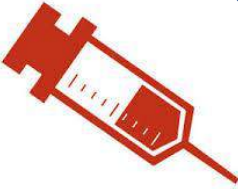

Decompensated cirrhotics



Veterans

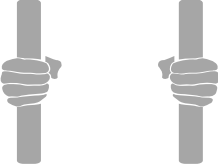

Patients with haemophilia


Patients with chronic kidney disease


Transplant patients


PWID


HIV/HCV co-infected


Incarcerated individuals

Sources: Lazarus JV *et al.* The micro-elimination approach to eliminating hepatitis C: strategic and operational considerations. *Seminars in Liver Disease*, 2018; 38(03): 181-192.

Lazarus JV, Wiktor SZ, Colombo M, Thursz M. Micro-elimination – a path to global elimination of hepatitis C. *Journal of Hepatology*, July 2017.

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Micro-elimination approach

Generally speaking, micro-elimination approaches should meet the following criteria, although these criteria may need to be adapted to different epidemiologic situations and geographic settings:

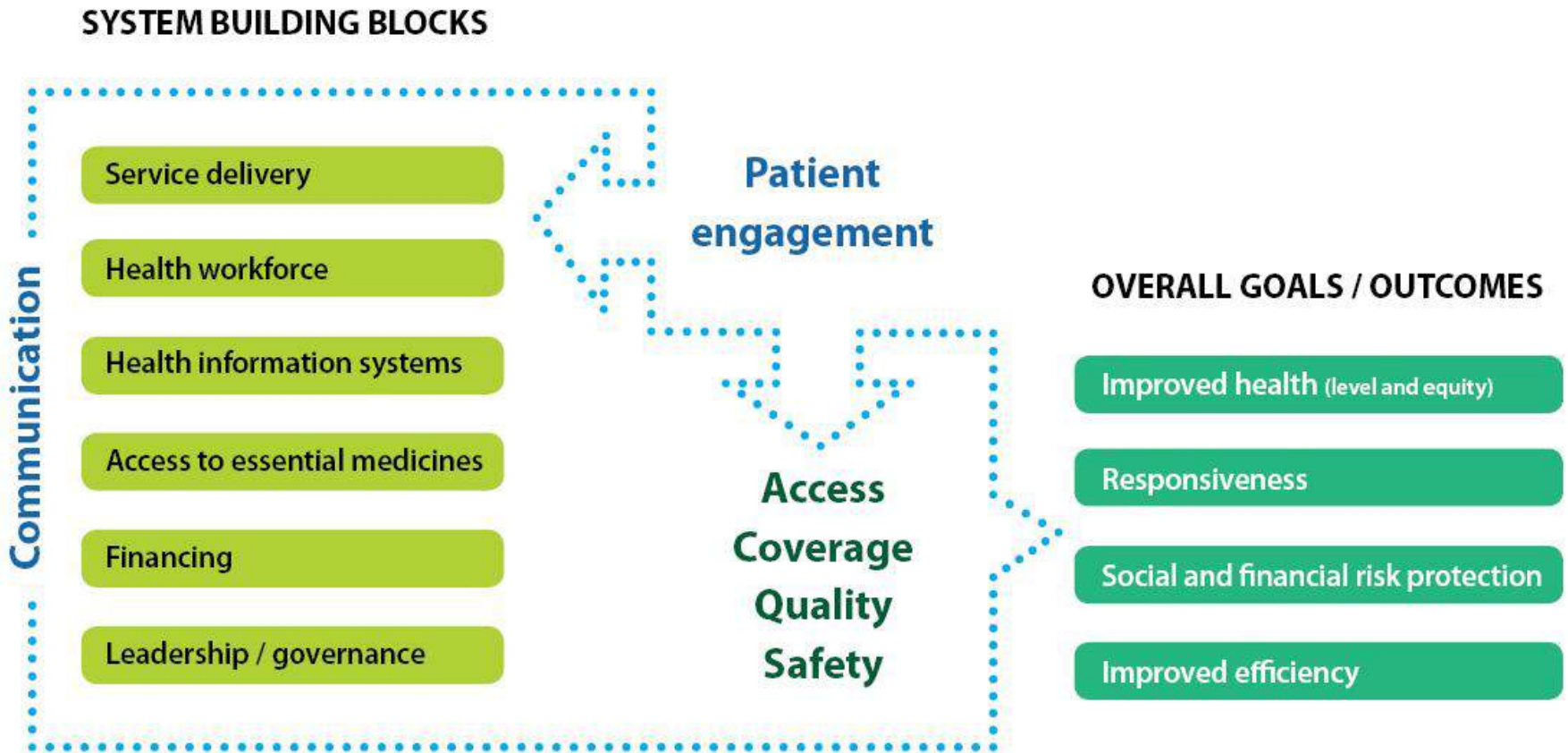
- There is a **plan** for how to tailor health resources and services to overcome known barriers and achieve high levels of HCV diagnosis and treatment in one or more clearly definable populations of interest within a specified timeframe.
- The plan sets forth achievable annual **targets**, basing these on mathematical modeling when relevant to determine the levels of diagnosis and treatment required to progress to the plan's ultimate elimination targets.
- The plan is developed and implemented through a **multi-stakeholder** process, with essential participants including government officials, health service providers, and civil society representatives.
- Progress and outcomes are **monitored** and publicly reported using indicators selected at the outset of the process.

Sources: Lazarus JV *et al.* The micro-elimination approach to eliminating hepatitis C: strategic and operational considerations. *Seminars in Liver Disease*, 2018 ; 38(03): 181-192..

The micro-elimination evidence base

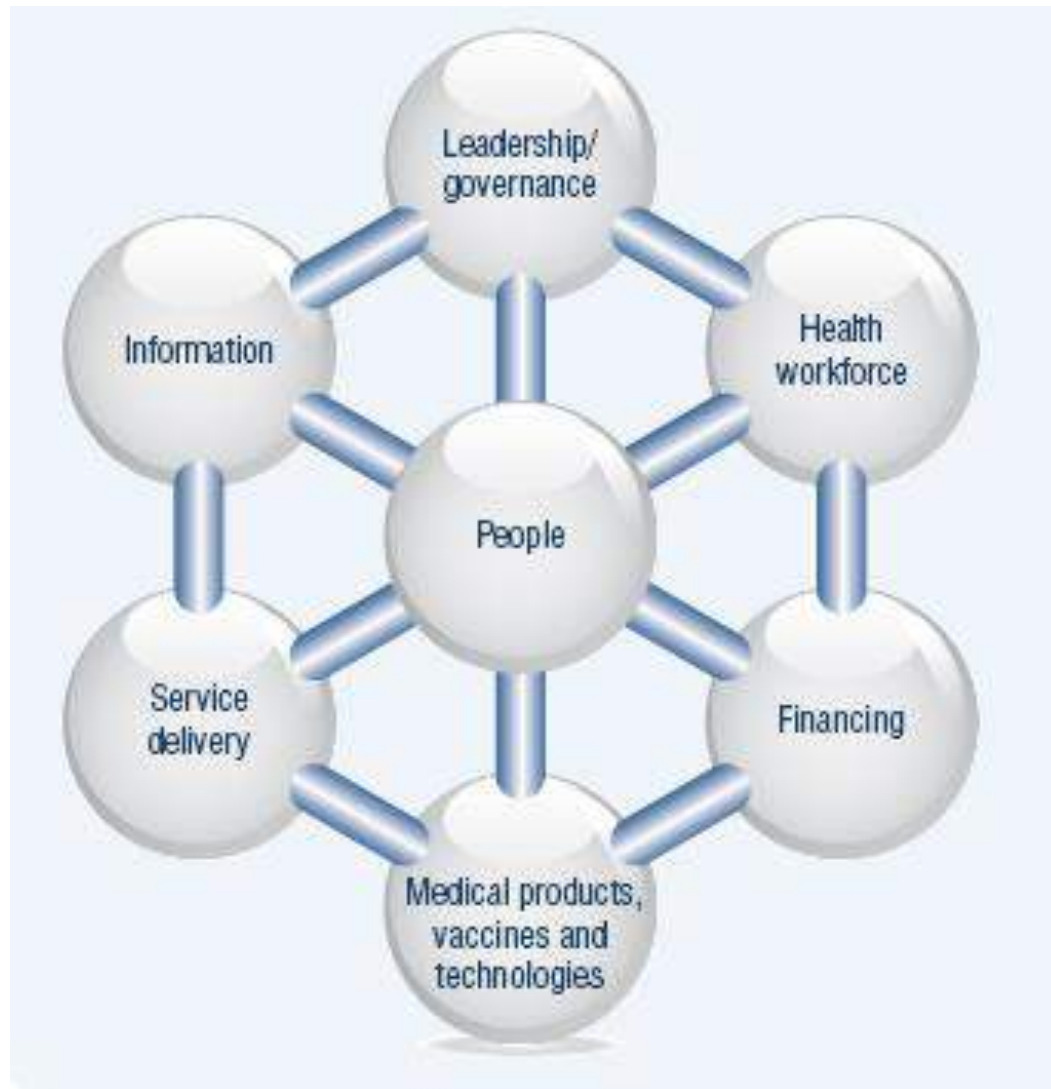
1. To what extent do initiatives reported to date follow the criteria proposed for a micro-elimination approach to HCV?
 2. What evidence exists to support the effectiveness of the micro-elimination approach?
- 7 studies from: Australia, Canada, Iceland, the Netherlands, Spain (n=3) + conf abstracts: Georgia Slovenia + Ireland (haemophilia)

A paradigm change: The central role of people and communication



Source: Lazarus and France. A new era for the WHO health system building blocks? 2014.

People-centred health systems

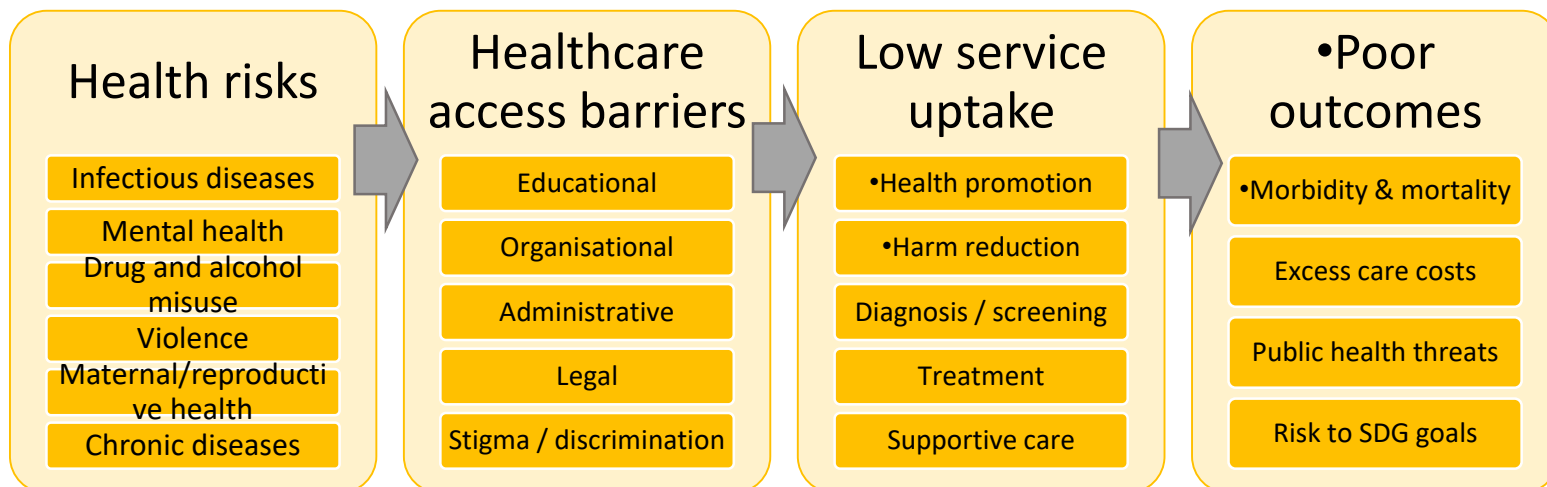


See: WHO. <http://www.who.int/servicedeliverysafety/areas/people-centred-care/en/>

Healthcare access challenges among marginalized people

Marginalized groups at high risk of vulnerability:

- Homeless
- LGBTI
- People who use drugs
- Prisoners
- Sex workers
- Undocumented migrants



Source: Lazarus *et al.* Nobody Left Outside (NLO) Checklist: Improving access to healthcare for vulnerable and underserved Groups. ICIC 2019 Oral presentation 621.

Lazarus *et al.* Leaving nobody outside our healthcare systems—in Europe or elsewhere. *BMJ Opinion*, 25 Nov 2019.

<https://blogs.bmj.com/bmj/2019/11/25/leaving-nobody-outside-our-healthcare-systems-in-europe-or-elsewhere/>.

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Service design innovation - NLO Service Design Checklist

NOBODY LEFT OUTSIDE

Service Design Checklist

Version 1, June 2019

Purpose

This Checklist is intended for use by service providers and policymakers to design and deliver targeted health and social services that are accessible to the following underserved, marginalised people: homeless, migrants, sex workers, prisoners, people who inject drugs (PWID) and LGBTI communities. It is also intended for use by community representatives to help them advocate for improved access to health and social care services for underserved people and their community.

The sections in this Checklist are not expected to be equally relevant to users of service providers and policymakers. An indication of the expected direct relevance of each section to these stakeholders is given as follows:

- Possibly relevant
- ✓ Relevant
- ✓✓ Very relevant

The items in this Checklist may apply to services designed for any of the aforementioned communities. The accompanying Guidance Document provides further explanation and guidance regarding most items, including on specific considerations for particular communities.

This Checklist is structured according to the World Health Organization [Health Systems Framework](#)¹. It is intended as a guide and is not necessarily exhaustive.

¹ [World Health Organization. \(2010\). Health systems framework: building resilience to crises. *Health Affairs*, 29\(12\), 2010-2012.](#)

NLO		Yes	No	Not relevant / Comments
A. Service delivery				
Also Present and address the following and secure a follow-up to address the service.				
Relevant: Providers ✓✓ Policy-makers ✓				
DESIGN STAGE				
A1. Were community representatives involved in the design of the service?				
Has the design of the service taken into account that:				
A2. Health and social care needs of the community?				
A3. Existing facilities to access care for the community, identified by the community and/or service users?				
A4. Existing facilities identified by health care staff in delivering services to the community?				
A5. Existing services and staff skills to the community?				
A6. Relevant clinical practice guidelines and/or best practice?				
SERVICES PROVIDED				
A7. Does the service provide access (integrated or linked) to the range of health and social services needed by the community?				
A8. Are the needs of each service user met on an individualised basis?				
ACCESSIBILITY AND ADAPTATION				
Is the service made easy to access and use by the community by:				
A9. Providing items only based on/for mobile devices?				
A10. Having convenient opening hours?				
A11. Providing child-friendly writing forms?				
A12. Providing physical accessibility for people with reduced mobility?				
A13. Being provided in an accessible or confidential location?				
A14. Not requiring users to provide personal identification to access the service?				
A15. Being free of charge to users?				
A16. Providing user-friendly information about the available health and social services and users' rights to access these (translated into several languages)?				
A17. Providing users with sufficient information and explanation to allow them to make informed choices about their healthcare?				
A18. Being readily tailored to be sensitive to users' culture, faith, gender, housing status and literacy?				
A19. Offering users the option to choose to see a male or female staff member?				
A20. Providing translated interpreters for relevant languages during consultations?				
A21. Offering users assistance with completing forms or other documents?				
A22. Being presented and signposted effectively within the community?				
A23. Providing incentives for users to use the service?				
A24. Using digital tools to help link people to care?				
PEER SUPPORT				
A25. Does the service use peer care and support by community members?				
A26. Are peer support workers adequately compensated for their services?				

NLO		Yes	No	Not relevant / Comments
B. Health workforce				
Also Present and address the following and secure a follow-up to address the service.				
Relevant: Providers ✓✓ Policy-makers ✓				
Health workforce recruitment and training plan				
B1. Health workforce recruitment and training plan:				
B2. User input in health workforce plan, and program objectives/strategy and staff?				
B3. Training regarding education about health systems and health care delivery care users and staff?				
B4. Community staff including non-care workers?				
B5. Staff management?				
B6. Staff development?				
B7. Incentives and other strategies to attract the necessary services providers to rural and remote?				
B8. Incentives, neither or self-care staff, essential in primary and secondary care?				
B9. Incentives to attract the necessary staff to the staff?				
Service delivery programmes include and address the:				
B10. Community engagement?				
B11. Physical access (transport)?				
C. Support to the community system				
Also Present and address the following and secure a follow-up to address the service.				
Relevant: Providers ✓✓ Policy-makers ✓				
C1. The community represented in leadership of the service is essential?				
Are reliable systems in place to monitor the:				
C2. Long-term success of the service?				
C3. Quality and safety of the service?				
C4. User defined goals to measure user feedback on service delivery?				
C5. The health system supports research and innovation and health data to improve the quality?				
C6. Are the digital health services in the programme and/or support the service delivery?				
C7. Does the service support user feedback?				
D. Financial				
Also Present and address the following and secure a follow-up to address the service.				
Relevant: Providers ✓✓ Policy-makers ✓				
D1. Do the providers, health and social care providers, have the capacity to deliver the service?				
D2. Are the providers, health and social care providers, able to deliver the service?				
D3. Do the providers, health and social care providers, have the capacity to deliver the service?				
D4. Do the providers, health and social care providers, have the capacity to deliver the service?				

NLO		Yes	No	Not relevant / Comments
F. Leadership & governance				
Also Present and address the following and secure a follow-up to address the service.				
Relevant: Providers ✓✓ Policy-makers ✓				
F1. Is community representation included in the leadership and governance of the program?				
F2. Do the community representation activities regarding health rights, equity, and the health and social care?				
F3. Are there ongoing health promotion and public consultation?				
F4. Is there a formal policy/strategy, health and social care development, developed with the community?				
F5. Is the community and health authorities involved in the service or the health system?				
F6. Do the health and social services, health and social care services, collaborate with the community?				
F7. Do the health and social services, health and social care services, collaborate with the community?				
F8. Do the health and social services, health and social care services, collaborate with the community?				

Source: Lazarus et al. Nobody Left Outside (NLO) Checklist: Improving access to healthcare for vulnerable and underserved Groups. ICIC 2019 Oral presentation 621.

Focusing on service design and delivery

Involve community
in design

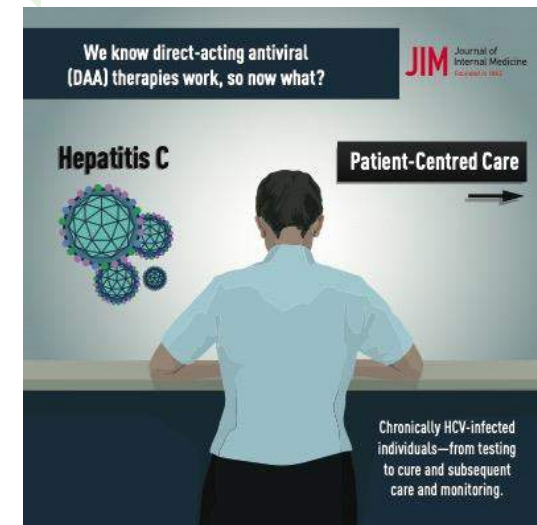
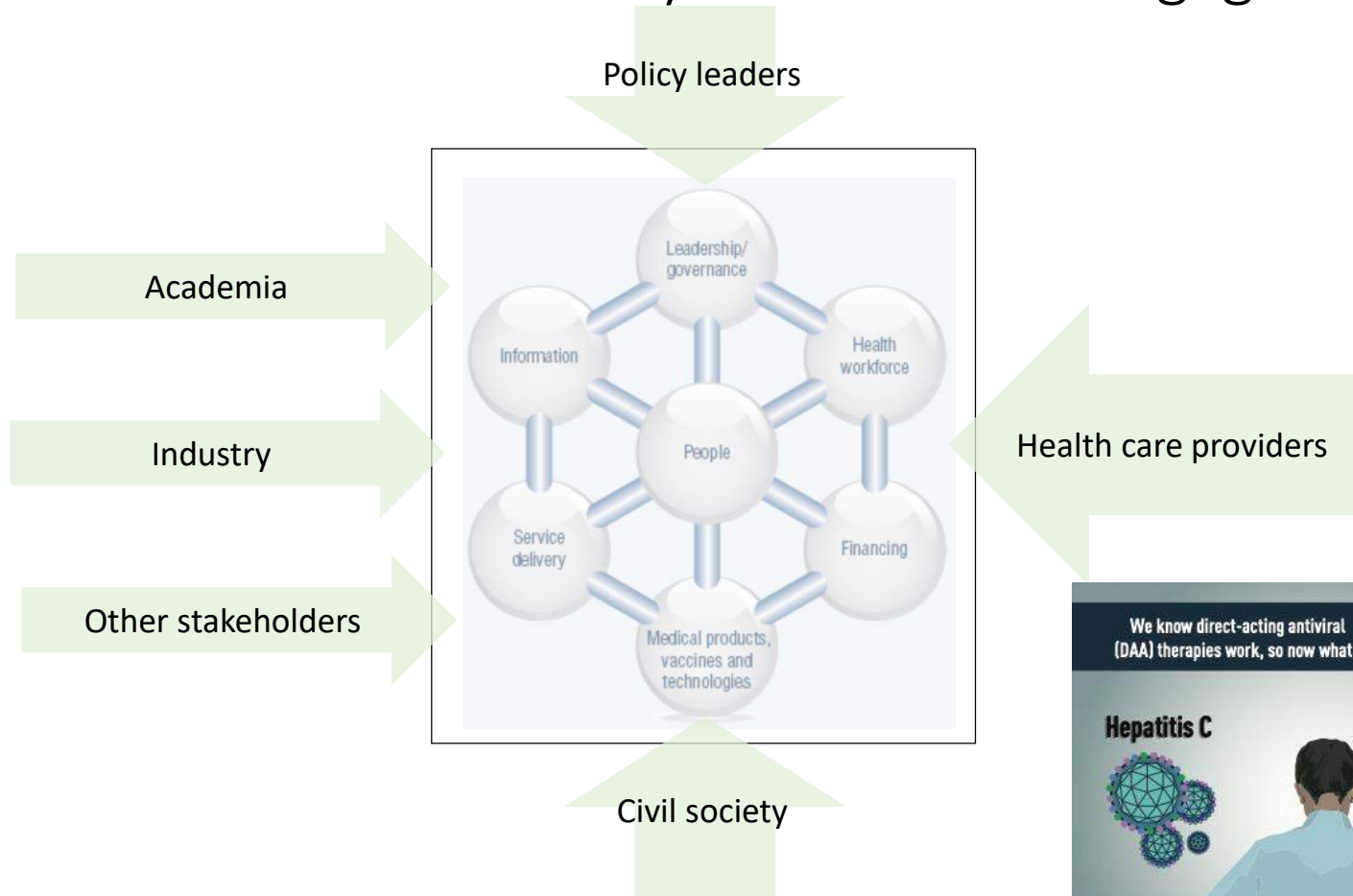
Design
considerations

A. Service delivery		Yes	No	Not relevant / Comments
Aim: Design and deliver an easily accessible service that meets the needs of the communities for whom it is intended.				
Relevance: Providers ✓✓ Policy makers ✓				
DESIGN STAGE				
A1. Were community representatives involved in the design of the service?				
Has the design of the service taken into account the:				
A2. Health and social care needs of the community?				
A3. Existing barriers to service access for the community, identified by the community and/or service users?				
A4. Existing barriers identified by healthcare staff in delivering services to the community				
A5. Existing resources and skills within the community				
A6. Relevant clinical practice guidelines and/or best practices?				

Source: Lazarus *et al.* Nobody Left Outside (NLO) Checklist: Improving access to healthcare for vulnerable and underserved Groups. ICIC 2019 Oral presentation 621.

Putting it all together ...




A people-centred health systems approach to HCV elimination with all key stakeholders engaged



12 Countries on Track to Achieve WHO HCV Elimination Targets

HCV Elimination Targets
2017



-  On track for WHO elimination targets
-  Working towards elimination
-  Not on track: elimination unachievable given present policy

2017 data.

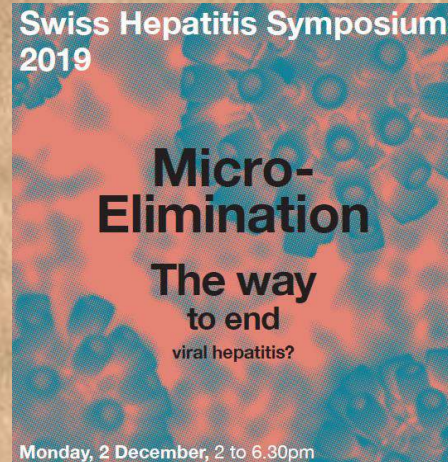
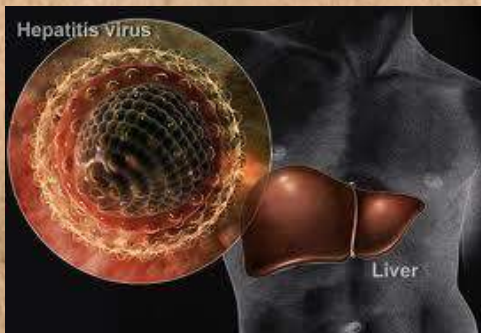
Source: CDA Foundation. POLARIS Observatory. Available at: <http://cdfound.org/Polaris/> (accessed July 2018).

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--BREAKING NEWS-- Switzerland has eliminated hepatitis C



Multistakeholder effort
and health system
reforms leads to HCV
elimination.

From **micro-elimination** in
2019 to HCV elimination as a
public health threat in 2025

HCV Elimination Strategy
a success!

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