

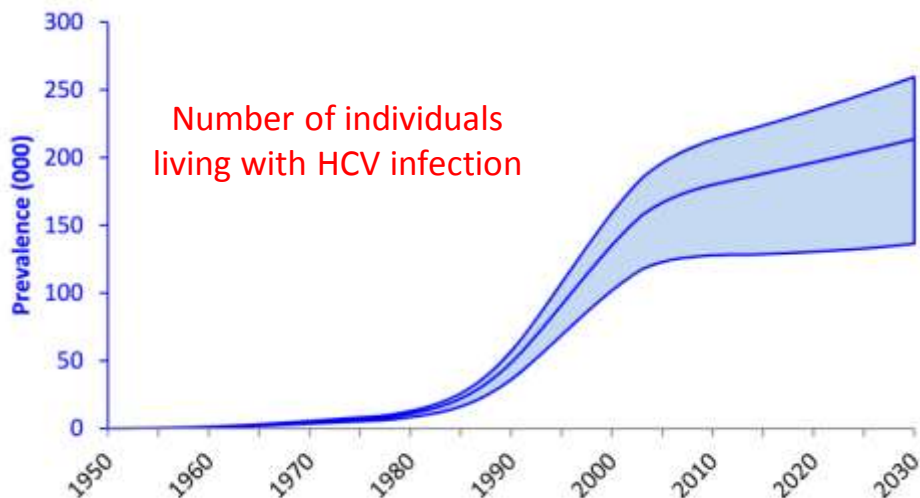


Diagnosis and Point of Care Testing of Hepatitis C

Heidar Sharafi, PhD

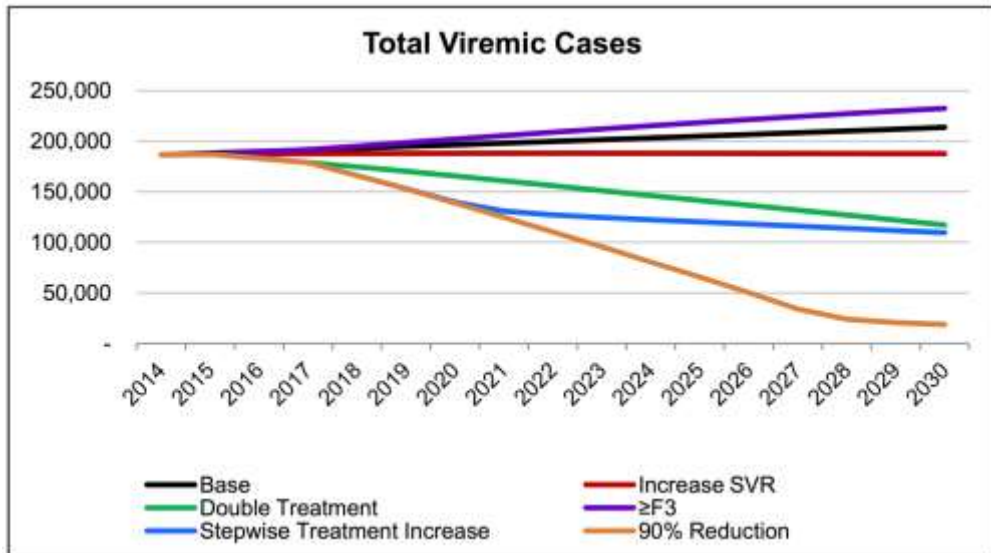
Iran Hepatitis Network

Where are we going with the current strategies?



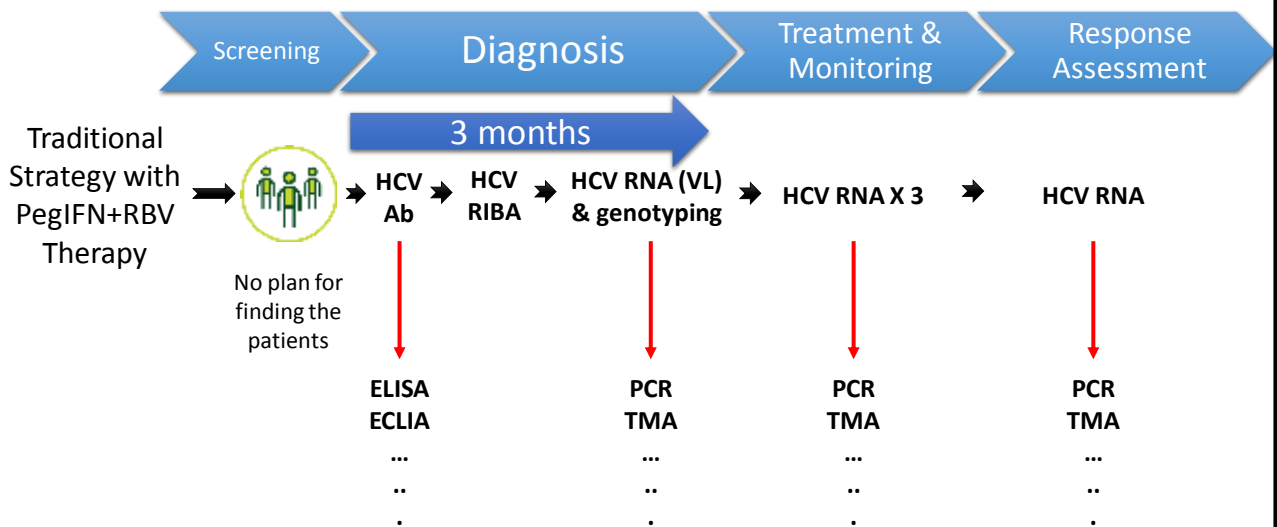
Hajarizadeh et al. Hepat Mon. 2016.

What is the Solution?

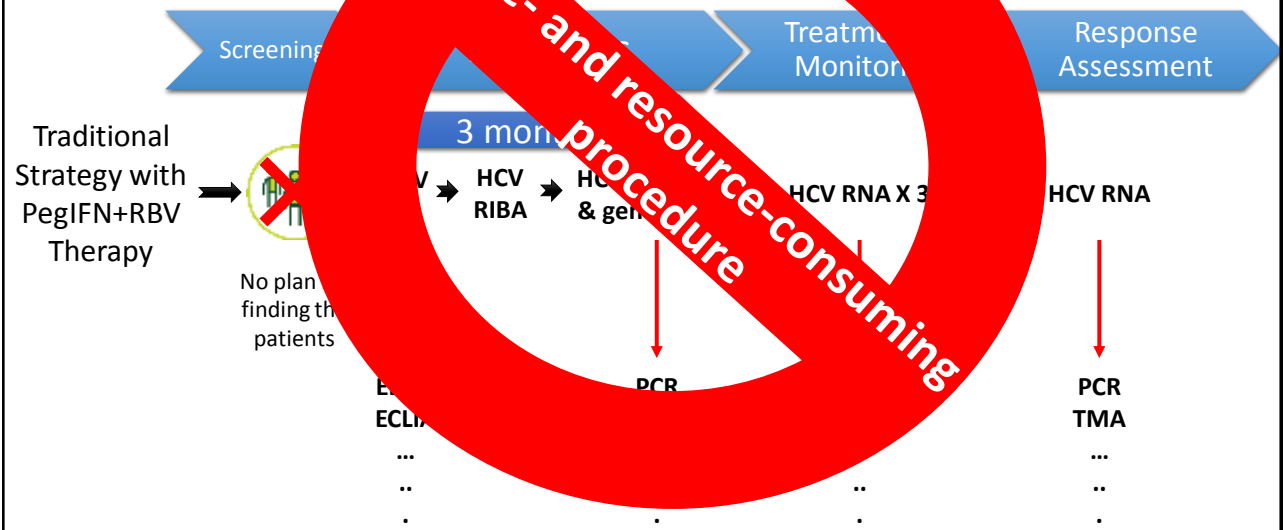


Hajarizadeh et al. Hepat Mon. 2016.

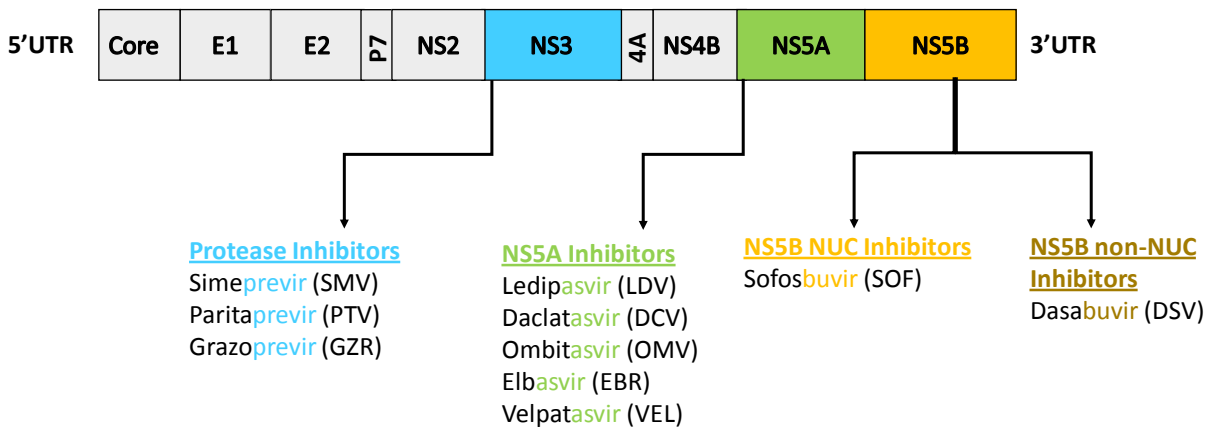
Strategies for Screening and Diagnosis 1



Strategies for HCV Diagnosis 1



Approved HCV Direct-acting Antiviral (DAA) Agents



Bertino G. *World Journal of Hepatology*. 2016;8(2):92-106.

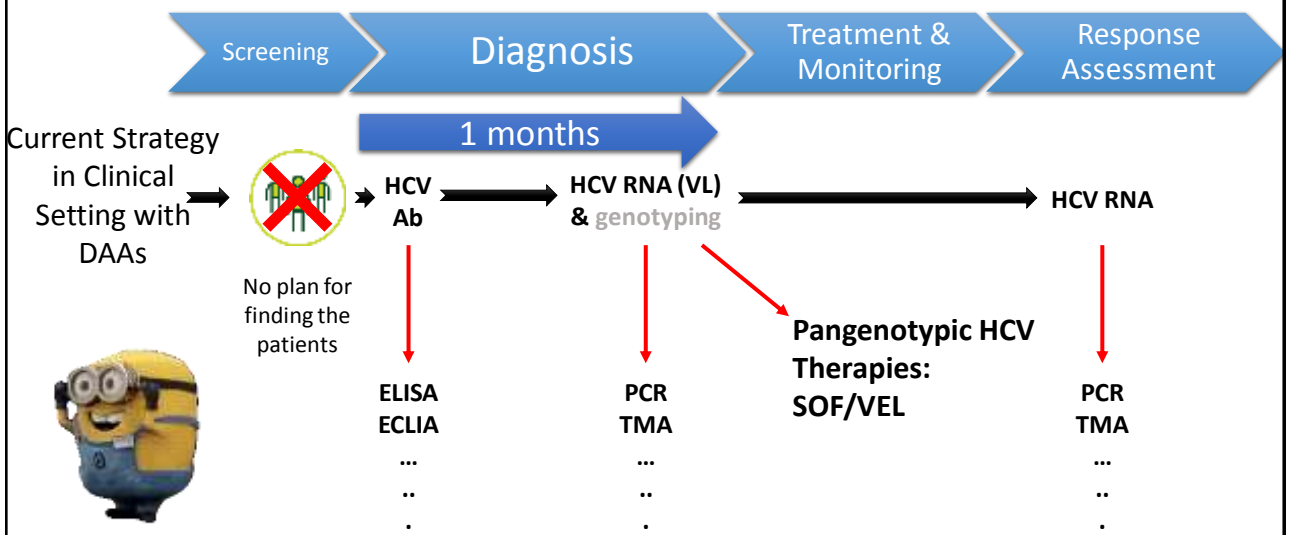
Approved HCV Direct-acting Antiviral (DAA) Agents

>95% efficacy, short 12-week treatment duration, low side-effects (Feasible therapy)

Grazoprevir (GZR) (OMV)
 Sofosbuvir (SOF) (EBR)
 Velpatasvir (VEL)

Bertino G. *World Journal of Hepatology*. 2016;8(2):92-106.

Strategies for Screening and Diagnosis 2



HCV RNA Assessment

- HCV RNA detection (qualitative) should be tested **before initiation** of treatment and **12 or 24 weeks after treatment** completion. SVR12 and SVR24 are **99%** concordance.
- HCV RNA detection should be made by a reliable **sensitive assay**.

HCV Core Ag (cAg) Evaluation

- Attractive alternative to molecular methods
- Advantages over molecular methods
 - **Cheap** (50% to 70% less expensive)
 - **Stability** of the marker at RT for 96 hours
 - **Easy to perform** through various methods even ELISA
- New HCV treatment monitoring tool, well suited to IFN-free regimens

HCV cAg and HCV RNA

(A) Sensitivity and specificity of HCVcAg in diagnosing quantifiable HCV RNA

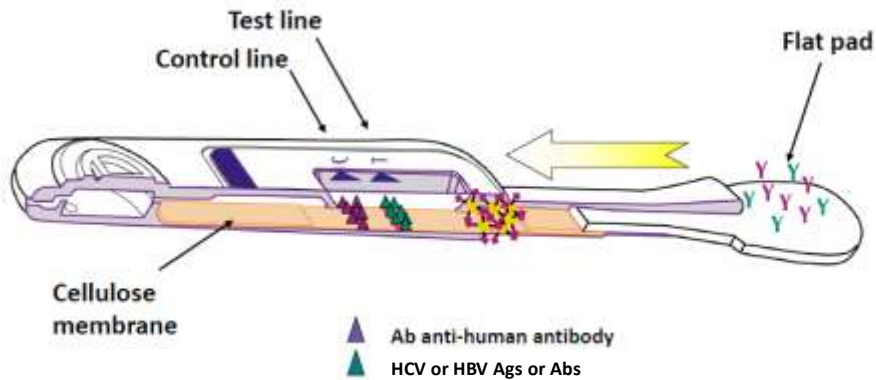
Treatment	Visit	Samples (n)	Sensitivity% (95% CI)	Specificity% (95% CI)
Pre-treatment	BSL/SCR	92	94 (88, 98)	100
On-treatment	Week 4	85	31 (14, 55)	98 (91, 100)
	Week 12	16	100	100
	ETR	75	56 (21, 86)	100
Post-treatment	SVR12/24	65	100	100

Lamoury et al. J Clin Virol. 2017.

Strategies for Screening and Diagnosis 3



Rapid Diagnostic Test (RDT)

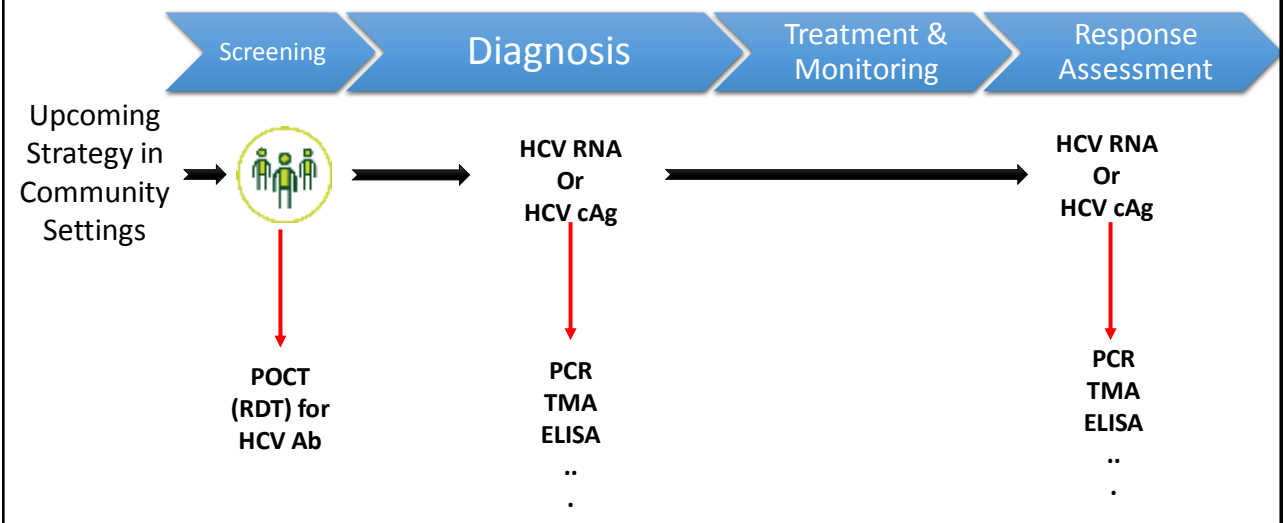


Rapid Diagnostic Test (RDT)

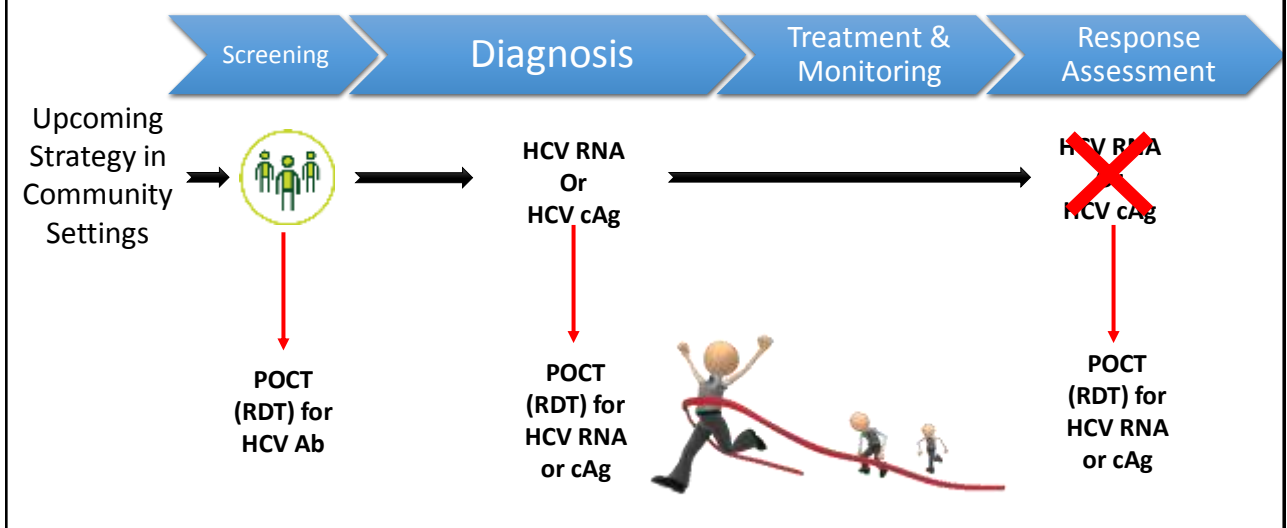
- Can be used at the site of patient care
 - Prison
 - DIC, MMT, VCT
 - Rural areas
- Can use original specimen matrices in addition to serum and plasma
 - Oral fluid
 - **Fingerstick whole blood**



Strategies for Screening and Diagnosis 3



Strategies for Screening and Diagnosis 3



Dried Blood Spots (DBS)

- Feasible and reliable alternative to point-of-care assays for viral hepatitis
- HCV RNA Detection
- Solves the problem of storage and shipment of samples
- Can be stored for weeks at ambient temperature without clinically significant degradation of nucleic acids
- Use of DBS is limited by the small amount of plasma per blood spot and less efficient nucleic acid extraction, which gives a reduced sensitivity in samples with low-level viremia.
- With regard to hepatitis C, this rarely has any practical consequences, as most untreated patients have viral loads (far) above 1000 IU/ml.



HCV RNA POCT

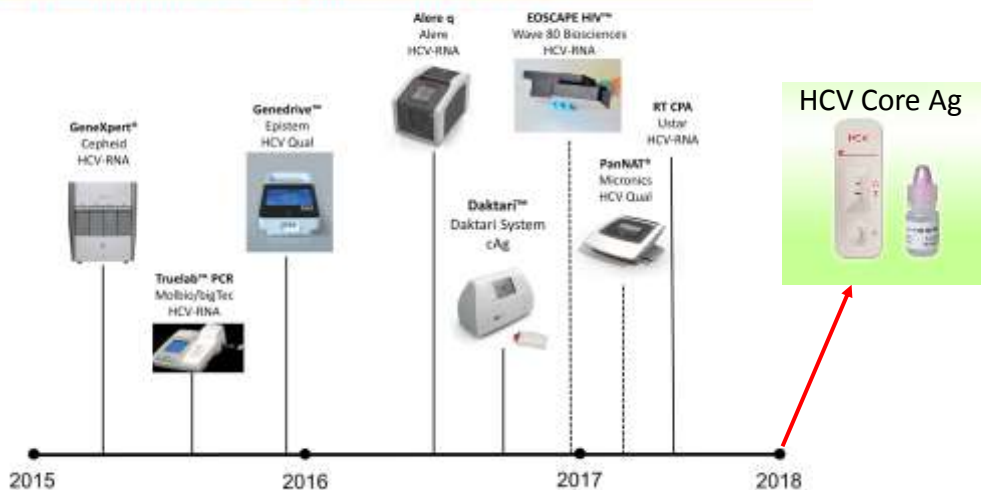
- Xpert HCV Viral Load quantifies HCV genotypes 1–6 over the range of 10 to 100,000,000 IU/mL
- 1 minute hands-on time
- No requirements for PCR room settings
- 105 minutes run time with a viral load report
- Run daily or on-demand



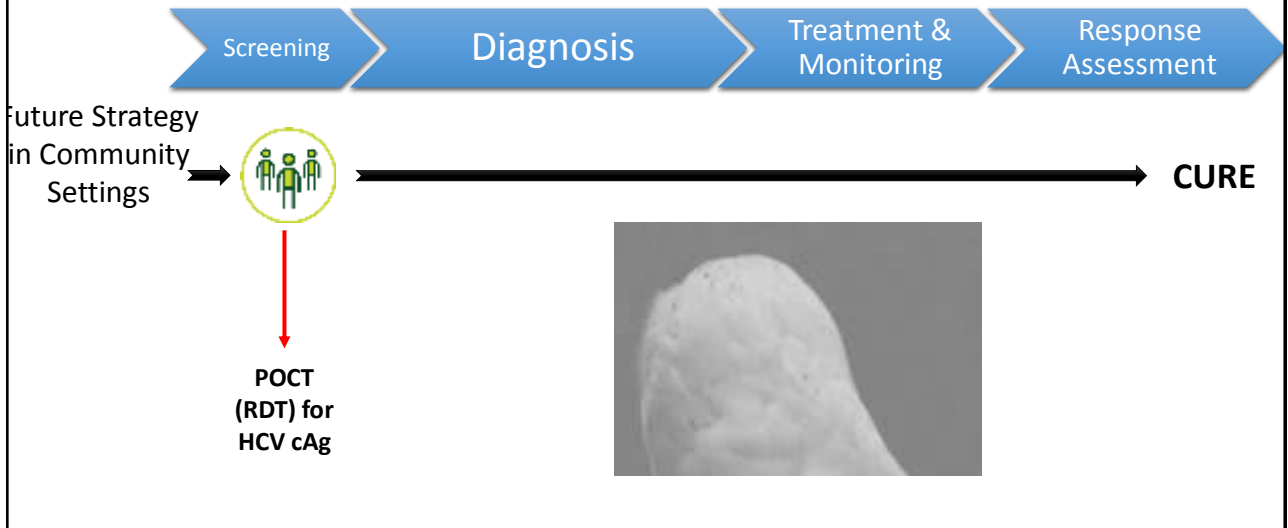
Point-of-care Tests in the Pipeline

Hepatitis C virus point-of-care diagnosis and treatment monitoring platforms: pipeline*

UNITAID



Strategies for Screening and Diagnosis 4



**Thank You
Very Much**

