Impact of Rapid Testing and Self-Administered Risk Questionnaires on Hepatitis C Screening Rates

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BACKGROUND

Underdiagnosis remains a major barrier to Hepatitis C (HCV) elimination.

The aim of this study is to evaluate if providing rapid HCV testing (RT) at Primary Care Centers (PCC) —either by itself or with a digital risk-assessment questionnaire (RT+Q) to guide HCV testing—can improve screening rates and boost the detection of cases.

CONTEXT



Hospital Ramon y Cajal is the reference of *The 4th Healthcare area* served 520,713 individuals (16 years old) across 20 Primary Care Centers.











METHODS (I)

This is a cluster-randomized, stepped-wedge trial conducted across eight Primary Care Centers (PCC) between July 2023 and February 2025. An initial 4-month observation phase (July–October 2022) was implemented in all centers, followed by 4-month intervention periods:

- Control (standard practice after training on HIV screening)
- Rapid hepatitis C testing (RT)
- Combined intervention: RT + self-administered risk questionnaire (RT+Q)

Randomization — Present analysis

	4 month (m) Jul-Oct/2022	4m Jul-Oct/2023	4m Nov-Feb/2024	4m Mar-Jun/2024	4m Jul-Oct/2024	4m Nov-Feb/2025	12M
PCC	Period 0	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6
C-1 C-2	Observational	** Control	Control	Control	* RT	* RT + Q	RT + Q
C-3 C-4	Observational	** Control	Control	* RT	* RT + Q	RT + Q	RT + Q
C-5 C-6	Observational	** Control	* RT	* RT + Q	RT + Q	RT + Q	RT + Q
C-7 C-8	Observational	** RT	* RT + Q	RT + Q	RT + Q	RT + Q	RT + Q

* Training Session's on HIV/HCV, PreP indications and Atenea Study design to the PCC

METHODS (II) Outcomes. Rates x 10^5 patients assigned of: 1. Screening tests. 2.HCV positive tests. 3. Newly HCV diagnosed persons.

Intervention type was modeled as a categorical variable with four levels, using the observation phase as the reference. Poisson regression models, adjusted for period and clustering by center, were fitted to estimate incidence rate ratios (IRRs) with 95% CI.

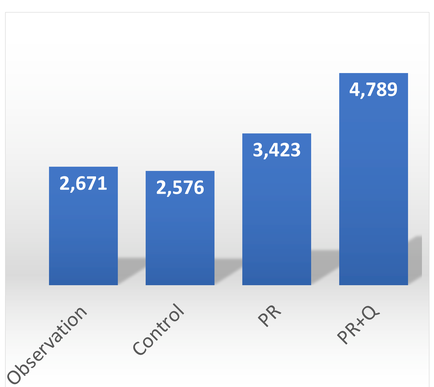
In Primary Care Centers, both the addition of Rapid HIV tests, or these tests alongside a with a Self-administered HCV Risk Questionnaire significantly improved screening coverage and enhanced HCV case detection

RESULTS. A total of 48 observations (6 time periods across eight primary care centers) were included in the analysis. The study population included 476,201 individuals, with 17,614 HCV tests performed, yielding 257 positive results (29 newly diagnosed).

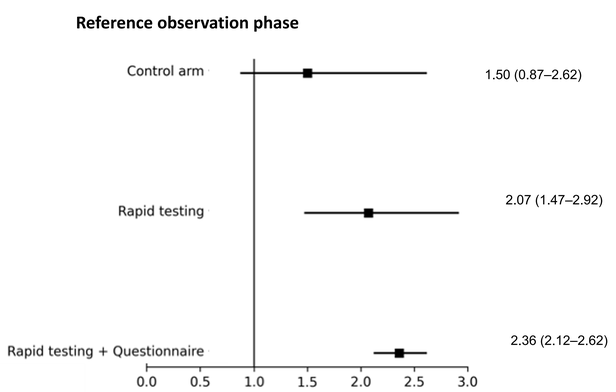
Intervention	HCV Tests	HCV Positive	New HCV	HCV Test x100k	HCV Positive x100k	New HCV x100k	Nº Risk questionnaires
Observation	2,120	24	4	2,671	30.24	5.04	N/A
Control	2,827	39	2	2,576	35.54	1.82	N/A
PR	2,717	40	4	3,423	50.39	5.04	N/A
PR+Q	9,950	154	19	4,789	74.13	9.15	851
TOTAL	17,614	257	29	13,459	190.3	21.05	851

Compared with the observation phase (2,120 HCV tests were conducted with 24 positives), HCV Screening rates increased by 136% in the RT+Q phase (IRR = 2.36; 95% CI: 2.12–2.62; p < 0.001) and by 107% in the RT phase (IRR = 2.07; 95% CI: 1.47–2.92; p < 0.001), while Control phase demonstrated a non-significant increase (IRR = 1.50; 95% CI: 0.87–2.62; p = 0.146). The Prevalence of Anti-HCV significantly increased in the RT+Q phase (IRR = 2.75; 95% CI: 1.94–3.89; p < 0.001), the rapid HCV testing alone (PR) was associated with an increase in the rate of HCV-positive results (IRR = 2.14; 95% CI: 0.99–4.60; p = 0.052) and Control phase revealed no differences (IRR = 1.05; 95% CI: 0.31–3.64; p = 0.933).

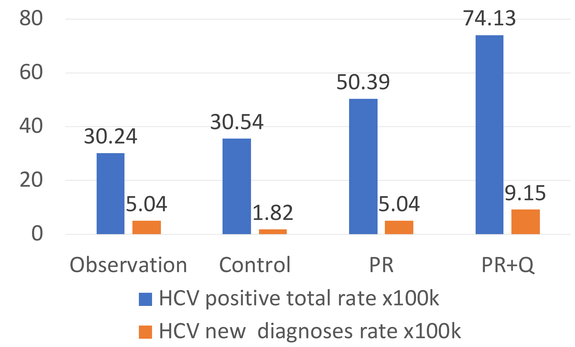
Overall HCV Screening Rate x100K



Adjusted IRR Overall HCV Screening Rate



HCV positive tests and New HCV infections Rate x100K



New Hepatitis C virus diagnoses

The implementation of rapid testing alone (PR) was associated with an almost threefold increase in the rate of new HCV diagnoses compared with the observation phase (IRR = 2.98; 95% CI: 0.97–9.13; p = 0.055). Similarly, the combined strategy of rapid testing plus a risk assessment questionnaire (PR+Q) was associated with a 2.75-fold higher rate of new HCV diagnoses (95% CI: 0.94–7.99; p = 0.063).

Adjustment for calendar periods

The magnitude and statistical significance of the intervention effects remained largely unchanged after accounting for period, supporting the conclusion that the observed increase in HCV detection activity was mainly due to the implementation of rapid testing strategies and not solely to temporary trends or the confounding effect of other screening programs outside ATENEA.

CONCLUSIONS

The implementation of rapid hepatitis C testing combined with self-administered risk questionnaires in Primary Care significantly enhances screening activity.

ADDITIONAL KEY INFORMATION

Ethics. Study was approved by Hospital Ramon y Cajal ethical committee and Madrid Primary Care Research Unit. All materials used with patients were also review and approved (clinicaltrials.gov ID: NCT06528626)

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In a study carried out in primary care centers, we compared usual care with the use of rapid hepatitis C tests, with and without a short self-completed risk questionnaire. Using rapid testing, especially together with the questionnaire, helped test more people and identify more hepatitis C cases, which could reduce missed diagnoses and support elimination efforts.