Effect of point-of-care RNA and dried blood spot testing on initiation of treatment among people with hepatitis C infection attending needle and syringe programs (TEMPO): a cluster randomised controlled trial

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Background: Point-of-care HCV RNA testing may increase testing and treatment, but there are few randomised trials. We compared treatment initiation following offer of point-of-care HCV RNA, dried-blood-spot (DBS), or standard of care (SOC) testing among people with recent injecting and current HCV attending needle and syringe programs (NSP).

Methods: In this practice-level, cluster randomised controlled trial, we recruited participants reporting recent injecting drug use from 16 NSPs in Australia. Sites were randomised to offer HCV testing via 1) SOC (referral for venepuncture-based phlebotomy or DBS HCV RNA); 2) DBS HCV RNA; and 3) point-of-care HCV RNA. The primary outcome treatment initiation within 12 weeks of enrolment among those with current HCV infection (detectable and quantifiable HCV RNA). Efficacy analyses included a comparison of SOC versus both interventions combined and point-of-care testing compared to SOC or DBS.

Results: Sixteen NSP clusters were randomised to HCV testing by SOC (n=5), DBS HCV RNA (n=5), or point-of-care HCV RNA (n=6). From Aug 08, 2022 to May 30, 2025, 1,801 participants were screened and 205 enrolled (11% current HCV infection). The proportion initiating HCV treatment within 12 weeks was 14% (8/59) with SOC, 13% (7/56) with DBS HCV RNA, and 38% (34/90) with point-of-care HCV RNA testing. There was no difference in treatment initiation within 12 weeks in the combined intervention arms compared to SOC [OR 1.97, 95% CI (0.49, 7.97), p=0.343]. There was a difference in the proportion initiating treatment within 12 weeks between point-of-care and SOC [OR 3.96, 95% CI (1.40, 11.20), p=0.010] and point-of-care and DBS [OR 4.40, 95% CI (1.44, 13.43), p=0.009].

Conclusion: Point-of-care HCV RNA testing increased initiation of HCV treatment within 12 weeks of enrolment compared to SOC or DBS testing among people reporting recent injecting drug use and current HCV infection attending NSPs, supporting its use as an intervention to enhance HCV treatment initiation.

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