Effect of point-of-care RNA and dried blood spot testing on initiation of treatment among people with HCV attending needle and syringe programs: a practice-level cluster randomised controlled trial

Authors:
Grebely J[1], Cunningham EB[1], Payne J[1], Tu E[1], Barault M[1], Mounsey D[1], Martinello M[1], Law M[1], Cunningham P[1,2], Read P[1,3], Shih STF[1], Guy R[1], Maher L[1], Applegate TL[1], Gray RT[1], Degenhardt L[4], Wiseman V[1,5], Treloar C[6], Doumany J[7], Matthews S[8], and Dore GJ[1] on behalf of the TEMPO Study Group

[1]The Kirby Institute, UNSW, [2]New South Wales State Reference Laboratory for HIV, St Vincent's Centre for Applied Medical Research, [3]Kirketon Road Centre, South Eastern Local Health District, NSW Health, [4]National Drug and Alcohol Research Centre, UNSW, [5]Department of Global Health and Development, London School of Hygiene & Tropical Medicine, [6]Centre for Social Research in Health, UNSW, [7]Australian Injecting and Illicit Drug Users League, [8]Flinders University International Centre for Point-of-Care Testing, Flinders Health and Medical Research Institute, Flinders University.

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

Methods: This practice-level cluster randomised controlled trial (TEMPO Study) compared linkage to HCV treatment by screening strategy: 1) point-of-care HCV RNA testing; 2) DBS testing; and 3) SOC (referral for venepuncture-based phlebotomy or DBS testing), among people with recent injecting drug use attending NSPs in Australia. NSP clusters were randomised, stratified by geographic region. Cluster allocation and data collection were masked; trial statisticians were unmasked for this analysis. The primary outcome was initiation of treatment within 12 weeks among those with detectable HCV RNA at screening. The primary analysis compared SOC versus both interventions combined. Secondary analyses compared each intervention to SOC and point-of-care RNA testing to SOC/DBS testing.

Results: In total, 16 NSP clusters were randomised to point-of-care RNA testing (n=6), DBS testing (n=5), or SOC (n=5). Overall, 1,793 participants were enrolled at the time of analysis. Overall, 207 had current HCV infection (12%): 89 (13%) in point-of-care, 55 (10%) in DBS, and 63 (12%) in SOC arms. Treatment initiation within 12 weeks was 33% (point-of-care), 12% (DBS), and 11% (SOC). Treatment initiation was similar in the intervention arms (point-of-care/DBS) compared to SOC (odds ratio [OR], 1.93, 95% CI: 0.40-9.39) and in the point-of-care RNA testing arm compared to SOC (OR, 3.75, 95% CI: 0.94-14.95). Treatment initiation was greater in the point-of-care RNA testing arm compared to SOC/DBS (OR, 3.80, 95% CI: 1.19-12.12).

Conclusion: Point-of-care HCV RNA testing was associated with increased initiation of HCV treatment within 12 weeks of testing compared to those receiving SOC/DBS among people with recent injecting drug use attending NSPs.

Disclosure of Interest Statement: This study has received funding from the NHMRC, Gilead Sciences, and Cepheid. JG is a consultant/advisor and has received research grants from Abbott, Abbvie, bioLytical, Cepheid, Gilead Sciences, Hologic, and Roche.