



WE ARE SEARCHING FOR HEPATITIS



Poster ID: 357

Hepatitis C RNA reflexive testing utilising a single blood sample collected in the Australian emergency department setting can be done

Julia Di Girolamo^{1, 2}, David Prince^{1, 2, 3}, Robert Porritt⁴, Kiran Thapa⁴, Alexander Prudence¹, Melissa Bagatella¹, Sicha Manadhar¹, Hong Foo⁴, Michael Maley⁴, Alexander Mackey⁵, Gregory Dore³, 6 Miriam T Levy^{1, 2, 3}
¹ Department of Gastroenterology and Liver, Liverpool Hospital, Sydney, Australia, ² Ingham Institute for Applied Medical Research, Sydney, Australia, ³ The University of New South Wales, Sydney, Australia, ⁴ NSW Health Pathology, Sydney, Australia, ⁵ Emergency Department, Liverpool Hospital, Sydney, Australia, ⁶ The Kirby Institute, UNSW, Sydney, Australia.

Background and Aim

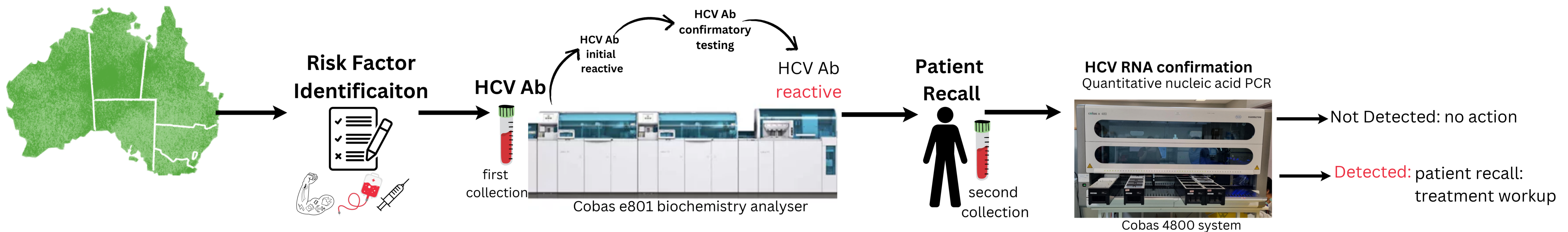
- Case detection remains a challenge for hepatitis C virus (HCV) elimination.
- Plateauing of testing and diagnosis rates suggest the need for universal screening programs, however HCV diagnostic testing methods may be a barrier.
- Australian Guidelines recommend an initial hepatitis C antibody (HCV Ab) serology assay, followed by molecular confirmation of hepatitis C RNA. The latter requires patient recall and new specimen collection.
- This multi-step process is complicated by instances of loss to follow up and introduces inefficiencies as many recalled patients may not have active infection.
- Laboratories may, at first blood collection, reserve a second blood tube however this is not a practical solution in the context of large-scale automated universal hepatitis screening programs.
- Automatic universal Screening Emergency Admissions at Risk of Chronic Hepatitis (SEARCH) is effective and now we describe the outcomes of a novel hepatitis C RNA reflexive testing process.

Methods

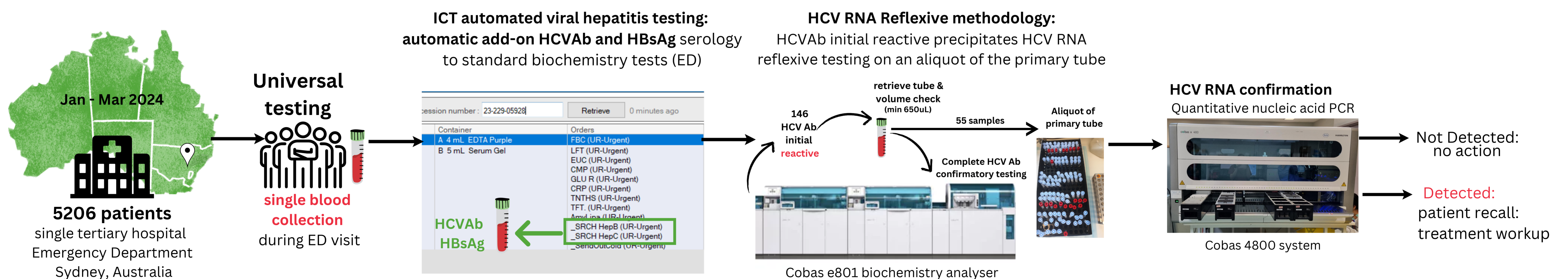
Reflexive testing process at a single tertiary hospital site in Sydney, Australia:

1. A computer algorithm automatically added HCVAb tests when an adult underwent routine biochemistry testing in the Emergency Department (ED). Initial positive HCV Ab serology results were identified and if sufficient volume available (minimum 650µL), specimens were retrieved from the Cobas e801 biochemistry analyser and aliquoted
2. Polymerase chain reaction (PCR) testing of HCV quantitative nucleic acid on Cobas 4800 instrument.
3. Patients were recalled for a dedicated collection to confirm the validity of the HCV RNA results obtained by reflexive testing.

Standard sequent HCV RNA testing



SEARCH 3X Reflexive HCV RNA testing on a single ED tube



Results

- SEARCH 3X tested 5206 emergency adult patients for HCVAb yielding 146 (2.8%) HCVAb positive samples eligible for reflexive RNA testing
- The proportion successfully tested by the reflexive HCV RNA methodology was 55 (38%) of which 7 (13%) were positive, 47 (85%) were negative and 1 invalid.
- Testing could not be performed on 91 (62%) specimens due to insufficient blood sample volume remaining after the ED biochemistry testing and automated viral hepatitis serology testing was completed.
- Of the 54 with valid results, 40 (75%) to date, have been recalled for a subsequent formal laboratory HCV RNA test on a dedicated tube.
 - Six of the 7 RNA positives were confirmed (1 patient died).
 - Of the 47 RNA negative, 34 (72%) were confirmed and 9 (19%) are being followed-up.
 - Two were lost to follow up and two declined further testing.
- No false positive or false negative results were identified using the reflexive HCV RNA single tube method.
- 100% concordance between reflexive RNA and laboratory RNA result (for cases where both results available).

Table 1. Comparison of reflexive and formal laboratory (dedicated tube) HCV RNA results

		Reflexive RNA result	
		Positive	Negative
Formal laboratory RNA result	Positive	6	0
	Negative	0	34
	Not available	1	13

Conclusion

- Reflexive HCV RNA single tube methodology was efficient in establishing a complete HCV diagnosis in 54 patients, without the need for a second blood collection.
- Insufficient sample volume may be overcome by education of ED staff to collect a full blood tube.
- This methodology appears to be accurate method to diagnose hepatitis C viraemia (100% concordance in RNA results) however further studies are needed.

References:

- Prince DS, Pipicella JL, Fraser M, et al. Screening Emergency Admissions at Risk of Chronic Hepatitis C (SEARCH) to diagnose or 're-diagnose' infections is effective in Australia. *J Viral Hepat.* 2021; 28: 121– 128. doi: 10.1111/jvh.1339
- Jacob R, Prince DS, Pipicella JL et al. Routine screening of emergency admissions at risk of chronic hepatitis (SEARCH) identifies and links hepatitis B cases to care. *Liver Int.* 2023 Jan;43(1):60-68. doi: 10.1111/liv.15414.
- Prince DS, Girolamo JD, Pipicella JL et al. Finding Cases of Hepatitis C for Treatment Using Automated Screening in the Emergency Department is Effective, but What Is the Cost? *Can J Gastroenterol Hepatol.* 2022 Oct 14;2022:3449938. doi: 10.1155/2022/3449938

