

Introduction

Chronic hepatitis C virus (HCV) infection is an important problem in hemodialysis (HD) patients. In the Dialysis Outcomes and Practice Patterns (DOPPS) population, for example, the mean prevalence rate is 13.5%.¹

KDIGO, KDOQI, and CDC recommendations each specify screening seronegative patients every 6-12 months for the surveillance of HCV infection in HD facilities. However, the clinical utility of recommended tests has not been examined in large populations.

Methods

- Baseline and annual or semi-annual surveillance was conducted among 104,129 in-center HD patients for the presence of antibodies to HCV using a screening chemiluminescent immunoassay (Table 1).
- Screening results followed serum signal/cutoff ratios:
 - <0.8 **nonreactive** and presumed negative
 - ≥11 **reactive** and presumed positive without recommendation for supplemental testing and
 - 0.8 to <11.0 **equivocal** (0.8 to <1.0) or reactive (1.0 to <11). Results in this range prompted reflex, same-sample use of recombinant immunoblot assay (RIBA) to confirm or exclude the presence of anti-HCV antibody.
- RIBA results were reported as positive (confirmatory), negative, or indeterminate. For the period of the current report, 11/2009 to 4/2011, we tested new patients and those previously found to be HCV negative.

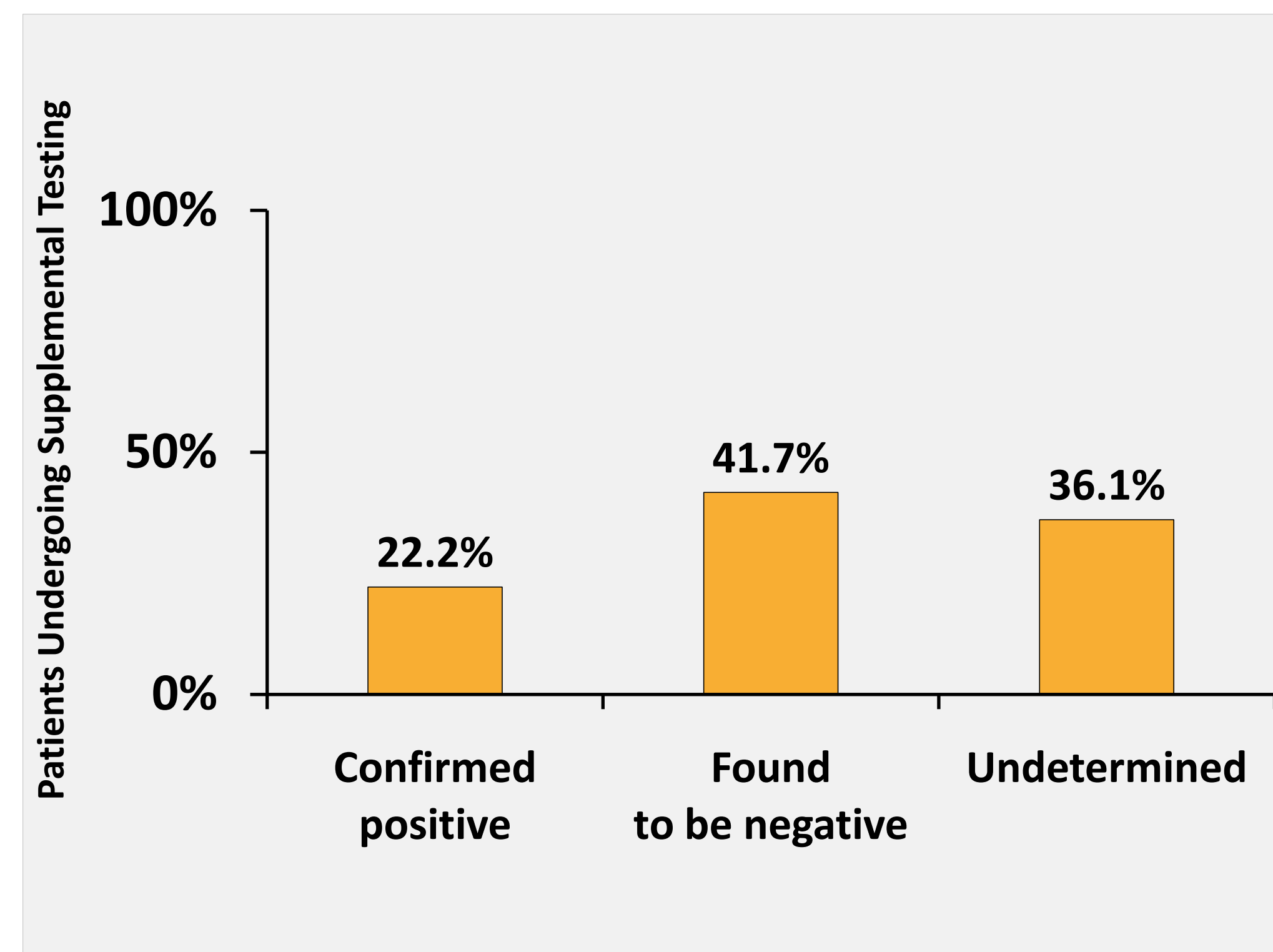
Results

Table 1. Demographics

	Mean ± SD
N	104,129
Mean age ± SD (yr)	61.7 ± 15.3
% Male	56.2%
Race and Ethnicity	
% African-American	34.4%
% Hispanic	15.8%
% Asian, Pacific Islander	4.0%
% Native American	1.1%
% Unknown	0.2%
% with Diabetes	43.9%
Mean vintage ± SD (yr)	3.2 ± 3.7
Mean BMI ± SD	27.8 ± 7.2

- Overall, 7.4% of patients showed reactive results by HCV immunoassay screening.
- 1.4% of patients evidenced screening results in the equivocal range and therefore underwent reflex testing for RIBA (Figure 1). Of those:
 - 22.2% were confirmed positive,
 - 41.7% were found to be negative, and
 - 36.1% returned indeterminate results.
- No previously nonreactive patient was found to be positive by RIBA supplemental testing.

Figure 1. Reflex Testing for RIBA



- Among patients with baseline reactive screening results (ratio ≥11), 1,200 patients were later rescreened. Among those,
 - 0.078% were nonreactive (<0.8) on follow-up and
 - 0.223% showed equivocal results the 1.0 to <11 range.
- Among patients previously nonreactive for HCV by screening, 0.099% showed reactive results (≥11) on follow-up surveillance testing.

Conclusions

- Among HCV-positive patients, we found evidence that reactivity in HCV screening antibody assays wanes or fluctuates.
- Since the pre-test probability of new-negative results in previously seropositive patients approaches that of new-positive results in those previously seronegative, our findings suggest that, when expected seroconversion rates are low:
 - HCV surveillance in seronegative patients should be conducted no more frequently than annually, and
 - new positive screening results in HD patients should be interpreted with caution and should undergo case-by-case clinical adjudication.

References

- Fissell RB, Bragg-Gresham JL, Woods JD, Jadoul M, Gillespie B, Hedderwick SA, Rayner HC, Greenwood RN, Akiba T, Young EW. *Kidney Int.* 2004 Jun;65(6):2335-42.

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Correspondence: david.vanwyck@davita.com

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