

Hepatitis B Vaccination Program at Two Tertiary Hemodialysis Centres



Lindsay Kufta, B.Sc.(Pharm); Wynnie Lau, Pharm.D., ACPR; Karen Shalansky, Pharm.D., ACPR, FCSHP; Jacek Jastrzebski, MD, FRCP(C); Mercedeh Kiaii, MD, FRCP (C), Departments of Pharmacy and Nephrology

Background

- Hemodialysis (HD) patients at higher risk of hepatitis B infection:
 - Potential exposure due to improper disinfection of fomites
 - Chair/bed, blood splashes on clothes, dialysis machine
 - Frequent diagnostic and therapeutic procedures
 - Immune dysfunction
 - Reduced vaccination response rate (55-88%) vs general population (95-100%)
- Hepatitis vaccine recommendations for HD patients (Table 1):
 - Higher dose vaccine plus repeat second series or booster if Hepatitis B surface antibody (Anti-HBs) < 10 mIU/mL

Table 1: Recombivax-HB Vaccination Schedule

	Adult	Dialysis/CKD
Series 1	10mcg at 0,1,6 mos	40 mcg at 0,1, 6 months
Series 2	None	Repeat series if Anti-HBs<10 after series 1
Booster	None	Annual if anti-HBs<10, with prior response to series 2

Objectives

- Primary Outcomes**
 - Capture response rate to Hepatitis B vaccination in HD patients following vaccination series 1, 2, and booster
 - Examine factors associated with responders vs non-responders to hepatitis vaccine (from series 2 or booster)
- Secondary Outcomes**
 - Examine factors associated with responders vs non-responders to hepatitis vaccine after series 1, 2 or booster
 - Determine adherence to vaccine protocol:
 - Vaccine # 2: given 4-6 weeks post vaccine # 1
 - Vaccine # 3: given 4.5-5.5 months post vaccine # 2
 - Anti-HBs level: 1-2 months post vaccine # 3 or booster

Methods

- Retrospective chart review (PROMIS database)
- Inclusion:** All HD patients receiving hepatitis vaccination since implementation of the new Hepatitis B provincial protocol:
 - St. Paul's Hospital: Dec 2015-July 2017
 - Vancouver General Hospital: Mar 2016-July 2017
- Exclusion:**
 - Hepatitis B positive
 - Anti-HBs ≥ 10 mIU/mL
 - Known non-responders prior to study or vaccine refusal

Figure 1: Trial Flow Diagram

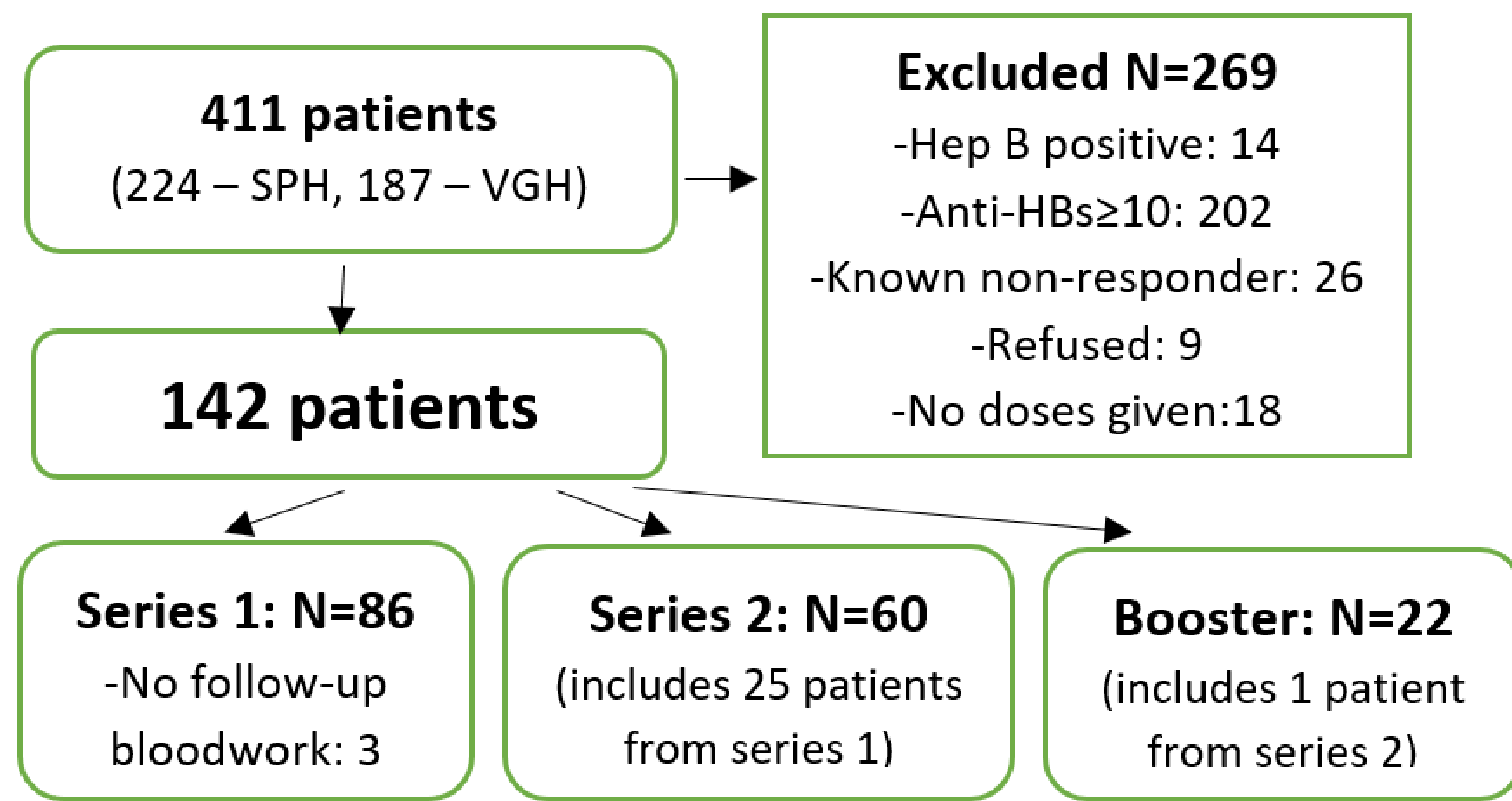


Table 2: Baseline demographics

Variable	N=142
Dialysis Site, n (%)	SPH 82 (57.7%) VGH 60 (40.3%)
Age, mean (SD)	68.9 (13.9)
Gender, Male, n (%)	92 (64.8%)
Ethnicity, n (%)	Caucasian 49 (34.5%) East Asian 47 (33.1%) South Asian 19 (13.4%) Filipino 12 (8.4%)
Co-morbidity, n (%)	Diabetes 88 (62%) Cancer 23 (16.2%) Immunosuppressants 14 (9.9%) Previous Transplant 9 (6.3%)
Dialysis Vintage, mean months (SD)	22.9 (38.7)
Urea Reduction Ratio, mean (SD)	77.8 (0.31)

Table 3: Primary Outcome: Factors Affecting Response (Series 2/booster)

Variable	Response (N=52)	No Response (N=29)	p-value
Dialysis Site, n (%)	SPH 35 (67.3%) VGH 17 (32.7%)	14 (48.3%) 15 (51.7%)	0.096
Age, mean (SD)	71.8 (13.0)	68.4 (13.4)	0.267
Gender, Male, n (%)	37 (71.2%)	18 (62.1%)	0.402
Ethnicity, n (%)	Caucasian 16 (30.8%) East Asian 19 (36.5%) South Asian 7 (13.5%) Filipino 5 (9.6%)	18 (62.1%) 5 (17.2%) 2 (6.9%) 2 (6.9%)	0.253 0.668 0.772 0.270
Co-morbidity, n (%)	Diabetes 36 (69.2%) Cancer 9 (17.3%) Immunosuppressants 3 (5.8%) Previous Transplant 2 (3.8%)	16 (55.2%) 7 (24.1%) 4 (13.8%) 2 (6.9%)	0.208 0.461 0.231 0.549
Dialysis Vintage, mean months (SD)	38.4 (48.2)	28.5 (43.1)	0.367
Adherence, n (%)	29 (55.8%)	9 (31.0%)	0.035

Table 4: Primary Outcome: Vaccination Response Rates

Vaccine Response (Anti-HBs ≥ 10)	n (%)
Series 1 (N=83)	51 (61.4%)
Series 2 (N=60)	35 (58.3%)
Booster (N=22)	18 (81.8%)

Table 5: Multivariate Analysis: Age, Site, Adherence

Factor	Primary Outcome N=81 (Series 2, booster)	Secondary Outcome N=140 (Series 1, 2, booster)
Age, OR (95%CI)	1.12 (0.94 to 1.35) p=0.22	0.99 (0.92-1.07); p=0.856
Adherence, OR (95%CI)	2.41 (0.89 to 6.80) p=0.08	2.2 (1.4-3.4); p=0.0005
Dialysis Site, OR (95%CI)	0.54 (0.20 to 1.45) p=0.22	0.61 (0.40-0.93); p=0.02

Table 6: Secondary Outcome: Adherence to protocol

Interval	Series 1 (N=86)	Series 2 (N=60)	Booster (N=22)
Vaccine 1→2 (4-6 weeks)	75 (87.2%)	46 (76.7%)	N/A
Vaccine 2→3 (4.5-5.5 months)	59 (68.6%)	38 (63.3%)	N/A
Follow-up anti-HBs level (1-2 months)	49 (57%)	38 (63.3%)	14 (63.6%)
Missed Doses (1 or 2)	8 (9.3%)	5 (8.3%)	N/A

Discussion

- Vaccine response rates for HD patients similar to literature
 - Series 1: 61.4%; Series 2: 58.3%
- Factors affecting vaccination response:
 - Adherence
 - Dialysis site
 - Lower response with less adherent site

Limitations

- Small numbers, limited numbers within subgroups
- Retrospective design
 - Possibility of missed documentation
 - Unable to assess circumstances of missed/late doses (eg. acute hospitalization)

Conclusions

- Adherence to regimen associated with better response to vaccine
- Recommendations to increase adherence:
 - Increase evaluation of hepatitis vaccine records (quarterly)
 - Annual nursing in-servicing
 - Improve documentation