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Clinical Practice Patterns in Hepatitis B Vaccination for Patients with Chronic Kidney Disease

Casey Light [a,b*], Karen Heslop [a] and Hemant Kulkarni [b]

[a] Curtin School of Nursing, Curtin University, Bentley, Western Australia, Australia.
[b] Armadale Renal Service, Armadale Hospital, Armadale, Western Australia, Australia.

Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Clinical Practice Article

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ABSTRACT

Aim: To investigate the clinical practice patterns among renal professionals regarding hepatitis B vaccination in chronic kidney disease and to identify potential barriers affecting early initiation.
Background: Optimal hepatitis B vaccination requires a rigorous 6-month schedule for protective seroconversion. However, seroconversion rates are suboptimal in dialysis populations with declining immunity due to disease progression. While early vaccination is recommended, global consensus on the ideal stage of chronic kidney disease for initiation is lacking.
Study Design: A cross-sectional study, clinical practice pattern survey using the on-line "Qualtrics" platform.
Place and Duration of Study: On-line survey conducted from July 2023 to February 2024 across Australasia.
Method: A 14-question web-based survey was disseminated to renal professionals via the regular newsletters of the professional renal organizations and emails to the renal unit managers. Participation was anonymous, voluntary with informed consent.

**Corresponding author: E-mail: casey.light@health.wa.gov.au, casey_light@hotmail.com;*

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Results: 125 responses (25 medical, 78 nurses, 22 either) from 133 received were eligible after eight exclusions without consent, with highest representation from Western Australia, New South Wales, and Victoria (28.42%, 22.11%, 22.11% respectively). Majority were nurses (62.41%) in the satellite settings (33.68%). A significant portion of respondents only initiate the vaccine at the start of dialysis: medical 21.74%, n=5; nursing 45.00%, n=27 (p=0.048). Lack of designated staff (35.34%) and established guidelines (15.52%) were major barriers for not commencing vaccination pre-dialysis, additionally, a total of 13.8% of the respondents demonstrated limited awareness of the "need" or "benefits" of pre-dialysis vaccination (6.90%, 6.90% respectively).
Conclusion: This pilot survey revealed diverse clinical practice patterns, highlighting barriers that influence the vaccination timing. Findings support the need for determining the optimal stage of chronic kidney disease to commence the hepatitis B vaccination and standardized management strategies as well as promoting staff awareness and understanding of the importance of initiating the hepatitis B vaccination earlier before reaching dialysis requirement.

Keywords: Chronic kidney disease; clinical practice pattern; haemodialysis; hepatitis B vaccination.

1. INTRODUCTION

1.1 Background and Significance

Infection poses significant morbidity and mortality risks and has been recognized as the second most important cause of death among patients with chronic kidney disease (CKD) [1-3]. The bloodborne Hepatitis B virus (HBV) is particularly concerning, leading to acute hepatitis, liver fibrosis and liver cancer [4, 5]. While effective treatment is limited, preventative vaccination is crucial in minimizing the impact of the Hepatitis B virus [6].

Despite the HBV vaccination availability since 1982 [7], as a result following the fatal HBV infection outbreaks in the haemodialysis units of two Edinburg hospitals in 1969-1970 [8], infection remains prevalent in the general population and especially among haemodialysis (HD) patients over the past decades [1], including in recent year of 2017 in a Victoria HD unit in Australia despite rigorous precaution measures [9]. HD patients face elevated risk due to frequent blood exposure, skin breaches from needling, and hospitalizations for vascular access procedures [1, 10]. Hepatitis B vaccination remains an essential factor for protection and prevention of the transmission of the HBV infection in the HD units [2].

The rigorous hepatitis B vaccination schedule consists of three (H_B_VAX II®) or four doses (Engerix B®) spanning over a 6-month course [2, 11, 12]. On completion of this primary course, follow-up serology of anti-HBs titers of > 10mIU/mL is classified as seroconversion and >100mIU/mL as seroprotective, for those who showed anti-HBs titer of < 10 mIU/mL post course completion are considered non-responders and a booster course repeating the primary regime is required [11]. Annual serology follow-ups are recommended to determine the need for further booster requirement if anti HBs titer remains <10mIU/mL [13].

While HBV vaccination has become a standard of practice for all HD units, the seroconversion rate remains suboptimal of 44.3% in the HD population [14, 15], with various studies demonstrating the compromised immune response in HD patients, leading to reduced vaccine efficacy [16-20]. Further emerging studies also link declining immunological response to diminishing renal functions [21,22], as they showed response rate of 66% in non-dialysis dependent stage 5 CKD (eGFR <15 mL/min/1.73m ^{2}) [23], 69% at stage 4 CKD (eGFR <29 mL/min/1.73m^2) [4], with one study exploring as early as stage 3 CKD (eGFR < 59 mL//min/1.73m ^{2}) showing response rate of 89 % comparing to a response rate of 96.2% in healthy individuals [24,25]. These findings highlighted the HBV vaccine response in different stages of CKD in correlation with the declining renal functions, leading to the advocacy to have the HBV vaccination for patients with CKD before they reach end stage kidney failure at dialysis initiation [5]. However, the optimal and beneficial CKD stage for vaccination lacks definitive consensus through large, randomized control trials [5]. Vaccination protocols and policies continue to exhibit international variation [26,27]. Moreover, failure to complete the full course may lead to poor response to the vaccine [28,29]. Thus further investigations would be of benefit to promote positive influence and standardized practice

Our survey study aims to investigate the national professional practice patterns relating to the hepatitis B vaccination timing in CKD patients, and to uncover potential barriers hindering vaccination management. A "Clinical Practice Pattern" survey was selected as it has proven effectiveness in fields like hypothyroidism [30], IgA nephropathy [31] and physician practice [32]. This online survey facilitates rapid, anonymous response across the renal community, revealing current practice patterns, variations and barriers.

Survey findings will illuminate clinical practice guidelines availability and highlight barriers impeding unified practice. Moreover, results may guide future research to pinpoint the optimal CKD stage for hepatitis B vaccination and promote standardized management and avoiding the failure to complete the full course that may lead to poor response to the vaccine [2, 5].

1.2 Aim

To explore the clinical practice patterns amongst the renal professionals in managing hepatitis B vaccination in patients with chronic kidney disease, and the barriers that may impact on the initiation and continuity of the vaccination course.

1.3 Objectives

The objectives of the survey are to explore:

- Staff awareness of the impact of hepatitis B infection and vaccination
- Clinical practice patterns
- Stage of CKD for vaccination commencement
- Availability and adherence of clinical practice guidelines
- Management, continuity of hepatitis B vaccination program
- Barriers to the implementation of the vaccination management
- Barriers for not commencing the vaccination pre dialysis

2. MATERIALS AND METHODS

2.1 Study Design

A cross-sectional, anonymous web-based survey was conducted from July 2023 to February 2024 using the "Qualtrics" platform. The 14-question survey aimed to investigate the clinical practice patterns and barriers related to hepatitis B vaccination management in CKD patients.

2.2 Recruitment and Sampling

The survey was disseminated nationally to all members of prominent renal organizations, including the Renal Society of Australasia (RSA), The Australian and New Zealand Society of Nephrology (ANZSN), the Australian New Zealand Dialysis and Transplant (ANZDATA) and Kidney Health Australia.

Participation was invited through regular newsletters of these organizations. Additionally, direct emails were sent to renal unit managers for distribution to their staff. An introductory letter outlined the purpose of the survey. Contents of the survey questionnaire are shown in Appendix 1.

2.3 Survey Instrument

The survey comprised the following sections:

- Respondent Characteristics (Q1 to Q4): Captured the professional background and practice settings
- Practice Patterns (Q5 to Q13): Examined the vaccination initiation timing, availability of clinical practice guidelines, and staff coordination for managing the complete vaccination course.
- Early Vaccination and Barriers (Q14): Explored awareness of early vaccination benefits and experience in addressing the barriers to pre-dialysis vaccination.
- Comments Section: Provided an optional space for respondents to express additional insights or concerns.

2.4 Participation and Data Collection

Participation was voluntary and required informed consent from the medical and nursing staff within the renal services, including clinics and dialysis units. Responses were collected and managed through the "Qualtrics" platform.

2.5 Data Analysis

Data were analyzed using the built-in capabilities of the "Qualtrics" survey tool. Results were obtained directly from the "Qualtrics" summary and report views, with findings presented in both absolute numbers (n) and percentages (%) for

clarity. The Excel CHISQ.TEST program was used to calculate the statistical significance of the data on respondents who only commence the HBV vaccination at initiation of dialysis. A *p*-value of <0.05 is considered statistically significant.

3. RESULTS

A total of 133 responses were received. After excluding eight non-consented responses, 125 completed and consented responses comprised the Survey Population (N=125). The breakdown of the Survey Population was as follows:

- medical staff: 20.00% (n=25),
- nursing staff: 62.40% (n=78),
- either: 17.60% (n=22).

The following Tables 1 to 3 provided survey results and key observations described as below:

- Table 1: Geographical regions of the respondents and their area of practice.

Responses were received from all major Australian States and Territories, as well as New Zealand, with the highest representation from Western Australia (28.42%), New South Wales (22.11%) and Victoria (22.11%). Most respondents were nurses, particularly those working in satellite dialysis settings (33.68%).

- Table 2: Survey questions responses.

A significant portion of respondents only initiate Hepatitis B vaccination at dialysis commencement (Medical n=5, 21.74%; Nursing n=27, 45.00%) (*p*=0.048) despite having a unit-based vaccination protocol (77.91%), this could be related to 52.27% reported a lack of staff coordinator in the area to manage the vaccination programme.

- Table 3: Barriers for not commencing the Hepatitis B vaccination pre-dialysis.

Lack of designated staff (35.34%) and no established guidelines were identified as primary barriers to pre-dialysis vaccination. Additionally, 6.90% responded not aware of the need and another 6.90% responded they were not aware of the benefits of initiating the vaccine before dialysis commencement.

Table 1. Regions and Area of practice

Category	n	Percentage (%)
Geographic region		
ACT	0	0.00
NT	2	2.11
NSW	21	22.11
QLD	15	15.79
SA	4	4.21
TAS	0	0.00
VIC	21	22.11
WA	27	28.42
NZ	2	2.10
Not stated	3	3.16
Area of Practice		
Renal Clinic (Medical)	13	13.68
CKD Clinic (Nursing)	13	13.68
In Centre dialysis	26	27.37
Satellite dialysis	32	33.68
Home Therapies	3	3.16
Not stated	8	8.42

ACT, Australian Capital Territory; NT, Northern Territory; NSW, New South Wales; QLD, Queensland; SA, South Australia; TAS, Tasmania; VIC, Victoria; WA, Western Australia; NZ, New Zealand.

Table 2. Survey questions responses

Survey questions (Q5-Q13)						
Do you identify the patients for Hepatitis B vaccination?	**Medical**		**Nurse Practitioners**		**Nurses**	
	n	(%)	n	(%)	n	(%)
Yes	24	(72.73)	17	(89.47)	57	(74.03)
No	9	(27.27)	2	(10.53)	20	(25.97)
If "**Yes**", what stage CKD do you commence hepatitis B vaccination?	**Medical**		**Nurse Practitioners & Nurses**			
Stage 2 CKD	3	(13.04)	0	(00)		
Stage 3 CKD	2	(8.70)	0	(00)		
Stage 4 CKD	7	(30.43)	12	(20.00)		
Stage 5 CKD	6	(26.09)	21	(35.00)		
Only at initiation of dialysis	5	(21.74)	27	(45.00)		
If "**No**", do you only commence hepatitis B vaccination at the initiation of dialysis?	**Medical** ("No" =9)		**Nurse Practitioners & Nurses** ("No" 2+20=22)			
Only at initiation of dialysis	7	(77.78)	19	(86.36)		
Do you have a unit-based hepatitis B vaccination clinical practice guideline?	**Medical, Nurse Practitioners, Nurses**					
Yes	67	(77.91)				
No	19	(22.09)				
Is there a staff member or coordinator in your area to manage the full primary and booster hepatitis B vaccination regime?	**Medical, Nurse Practitioners, Nurses**					
Yes	42	(47.73%)				
No	46	(52.27%)				

Table 3. Barriers for not commencing hepatitis B vaccination pre-dialysis

	Survey question (Q14) What are the barriers for not commencing hepatitis B vaccination pre-dialysis (early CKD) in your area? (Tick all that apply)	(n)	(%)
1	Not aware of the need to commence hepatitis B vaccination pre-dialysis	8	6.90
2	Not aware of the benefits of commencing hepatitis B vaccination pre-dialysis	8	6.90
3	There are no established clinical practice guidelines for pre-dialysis hepatitis B vaccination	18	15.52
4	There is no designated staff to manage hepatitis B vaccination pre-dialysis	41	35.34
5	Do not see the need to start hepatitis B vaccination pre-dialysis	2	1.72
6	Wait until the patient commences dialysis to start hepatitis B vaccination	14	12.07
7	No barriers, my service has the facility to commence hepatitis B vaccination pre-dialysis	25	21.55

4. DISCUSSION

This survey was distributed nationally over a period of 7 months, elicited a strong response from the renal medical and nursing staff across a diverse practice setting. Notably, satellite dialysis units, In-Centre units, medical renal clinics, and the renal nursing CKD clinics were well represented.

A majority of the respondents (medical staff =72.73%, nurse practitioners= 89.47% and nurses =74.03%) actively identify the patients requiring hepatitis B vaccination. However, the survey revealed a lack of consensus regarding the optimal CKD stage for vaccination initiation**,** with medical reporting starting at stage 4 CKD (30.43%) and stage 5 CKD (26.09%) and some clinics as early as stage 2 (13.04%,) and Stage 3 CKD (8.70%), while a significant portion of the respondents (medical n=5,21.74%; nursing n=27,45.00%) (p=0.048) only initiate the vaccine at dialysis commencement. These combine findings highlight a critical need for standardized guidelines.

Hepatitis B vaccination poses unique challenges with rigorous steps of baseline serology screening and duration for an effective full vaccination course over six months [2,11]. There is the added complexity in vaccine response from the CKD population as immunity declines correspondently to the degree of renal failure [16,17]. Such complexities likely contributes to the varied practice patterns observed in the survey.

When exploring the factors for not commencing the vaccination pre-dialysis in the survey, the major barriers identified were lack of designated staff (35.34%) and established guidelines (15.52%) for pre-dialysis vaccination commencement. Additionally, a total of 13.8% of the respondents demonstrated lack of knowledge of early vaccination pre-dialysis: 6.90% not aware of the “need” and the other 6.90% were not aware of the “benefits” of commencing the vaccination pre-dialysis. These findings underscore the importance of promoting knowledge about pre-dialysis hepatitis B vaccination benefits. This is supported by the scoping review in our previous study, highlighting the importance for vaccination before dialysis initiation due to diminishing immune response [23].

5. CONCLUSION

To our knowledge, this is the first survey investigating the hepatitis B vaccination clinical practice patterns in CKD populations. It exposes a lack of standardized guidelines and multiple barriers hindering timely vaccinations and completion of the 6-month regimen.

We advocate for the development of standardized guidelines, including a definitive CKD stage for vaccination initiation, and the establishment of dedicated coordinator roles to improve successful vaccination rates which is crucial for infection control in this vulnerable population.

DISCLAIMER (ARTIFICIAL INTELLIGENCE)

Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc) and text-to-image generators have been used during writing or editing of manuscripts.

CONSENT

This “Clinical Practice Pattern” survey was conducted as a Quality Assurance (QA) project and did not involve direct patient interaction thus without patient consent requirement. All medical and nursing staff responding to the survey were required to complete the “Consent” tick box before able to proceed further in the survey. (Appendix 1).

ETHICAL APPROVAL

This “Clinical Practice Pattern” survey was conducted as a Quality Assurance (QA) project and did not involve direct patient interaction. As such, formal ethics approval was obtained from the Public Health Service Safety Quality Education and Innovation Committee within the Governance Evaluation Knowledge Outcomes (GEKO) system (Approval Number 50168 granted July 2023). This approval underscores the study’s adherence to responsible research practices and its focus on improving patient care within established ethical boundaries.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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APPENDIX 1 - SURVEY QUESTIONS

CONSENT

I consent to complete the following survey and give permission to the researcher to use the data for research purpose

- o Yes

Q1. Are you a medical staff
- o Yes

Q2. Are you a nursing staff?
- o Yes

Q3. Where is your location of practice?
- o ACT
- o NT
- o NSW
- o QLD
- o SA
- o TAS
- o VIC
- o WA
- o Other (please specify) _____

Q4. What is your area of practice?
- o Renal Clinic (Medical)
- o CKD Clinic (Nursing)
- o In Centre Dialysis
- o Satellite Dialysis
- o Home Therapies
- o Remote country
- o Other (please specify) _____

Q5. (For Medical Staff)
Do you identify the patients at the renal clinic for hepatitis B vaccination?
- o Yes – please go to Q6
- o No – please go to Q7

Q6. (For Medical staff answered "Yes" for Q5)
What stage CKD do you commence hepatitis B vaccination?
- o Stage 2 CKD
- o Stage 3 CKD
- o Stage 4 CKD
- o Stage 5 CKD
- o Only at initiation of dialysis

Q7. (For Medical staff answered "No" to Q5)
Do you only commence hepatitis B vaccination at initiation of dialysis?
- o Yes

Q8. (For renal nursing staff)
Do you identify and obtain medication order to commence hepatitis B vaccination?
- o Yes -- Please go to Q10
- o No -- Please go to Q11

Q9. (For Renal Nurse Practitioners)
Do you identify and prescribe medication order to commence hepatitis B vaccination?
- Yes - Please go to Q10
- No - Please go to Q11

Q10. (For renal nursing staff or nurse practitioners answered "Yes" to Q8 or Q9)
What stage CKD do you commence hepatitis B vaccination?
- Stage 2 CKD
- Stage 3 CKD
- Stage 4 CKD
- Stage 5 CKD
- Only at initiation of dialysis

Q11. (For renal nursing staff or nurse practitioners answered "No" to Q8 or Q9)
Do you only commence hepatitis B vaccination at initiation of dialysis?
- Yes

Q12. Do you have a unit-based hepatitis B vaccination Clinical Practice Guideline?
- Yes
- No

Q13. Is there a staff member or coordinator in your area to manage the full primary and booster hepatitis B vaccination regimes?
- Yes
- No

Q14. **What are the barriers for not commencing hepatitis B vaccination pre-dialysis (early CKD) in your area? (Tick all that apply)**
- Not aware of the need to commence hepatitis B vaccination pre-dialysis
- Not aware of the benefits of commencing hepatitis B vaccination pre-dialysis
- There are no established clinical practice guidelines for pre-dialysis hepatitis B vaccination
- There is no designated staff to manage hepatitis B vaccination pre-dialysis
- Do not see the need to start hepatitis B vaccination pre-dialysis
- Wait until the patient commences dialysis to start hepatitis B vaccination
- No barriers, my service has the facility to commence hepatitis B vaccination pre-dialysis

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