

CLINICAL PRACTICE PATTERNS IN HEPATITIS B VACCINATION FOR PATIENTS WITH CHRONIC KIDNEY DISEASE

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.

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 (21.74 % medical, 45.00% nursing) only initiate the vaccine at the start of dialysis. Lack of designated staff (35.34%) and established guidelines (15.52%) were major barriers for not commencing vaccination pre-dialysis, additionally 6.90% of the respondents indicated limited awareness of the need or benefits of pre-dialysis vaccination.

Conclusion: This pilot survey revealed diverse clinical practice patterns, highlighting barriers influencing vaccination timing. Findings support the need for determining the optimal chronic kidney disease stage for hepatitis B vaccination initiation 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.

(288 words)

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 in chronic kidney disease (CKD) [1, 2]. The Hepatitis B virus (HBV) is particularly concerning, leading to acute hepatitis, liver fibrosis and liver cancer [3, 4]. While effective treatment is limited, preventative vaccination is crucial in minimizing the impact of Hepatitis B virus [5].

Despite HBV vaccination availability since 1982, infection remains prevalent in the general population and especially among haemodialysis (HD) patients. HD patients face elevated risk due to frequent blood exposure, skin breaches from needling, and hospitalizations for vascular access procedures [1, 6].

Research indicates compromised immune response in HD patients, leading to reduced vaccine efficacy [7, 8]. Emerging studies link declining immunological response to diminishing renal functions [9], advocating for

vaccination prior to dialysis initiation dialysis [4]. However, the optimal CKD stage for vaccination lacks definitive consensus through large, randomized control trials[4].

The rigorous hepatitis B vaccination schedule spans over 6 month with 3 doses [2, 10], failure to complete the full course may lead to poor response to the vaccine [2, 4]. Vaccination protocols and policies exhibit international variation [11, 12].

This study aims to investigate 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 [13], IgA nephropathy [14] and physician practice [15] . 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.

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 might 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 percentage (%) for clarity.

2.6 Ethics

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.

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=21).

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 WA (28.42%), NSW (22.11%) and Victoria (22.11%). The majority of respondents were nurses, particularly those working in satellite dialysis settings (33.68%).

- Table 2: Survey questions responses.

A significant portion of respondents initiate Hepatitis B vaccination only at dialysis commencement (Medical 21.74%, Nursing 45.00%) 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.

- 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 the benefits of commencing the vaccine before dialysis commences.

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)
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 (72.73% of medical staff, 89.47% of nurse practitioner and 74.03% of nurses) 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 (21.74% medical, 45% nursing) initiating only at dialysis commencement. These combine findings highlight a critical need for standardized guidelines.

Hepatitis B vaccination poses unique challenge with rigorous steps of baseline serology screening and duration for an effective full vaccination course over six months [2, 10]. There is the added complexity in vaccine response from the CKD population as immunity declines correspondently to degree of renal failure[7, 8]. Such complexity 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, 6.90% of the respondents indicated limited awareness of the need or benefits of pre-dialysis vaccination. 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 recommendations for vaccination before dialysis initiation due to diminishing immune response [16].

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 vaccination 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 vaccination rates. Successful vaccination is crucial for infection control in this vulnerable population.

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)

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UNDER PEER REVIEW

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

- Yes
-

Q1. Are you a medical staff

- Yes

Q2. Are you a nursing staff?

- Yes

Q3. Where is your location of practice?

- ACT
- NT
- NSW
- QLD
- SA
- TAS
- VIC
- WA
- Other (please specify) _____

Q4. What is your area of practice?

- Renal Clinic (Medical)
- CKD Clinic (Nursing)
- In Centre Dialysis
- Satellite Dialysis
- Home Therapies
- Remote country
- Other (please specify) _____

Q5. (For Medical Staff)

Do you identify the patients at the renal clinic for hepatitis B vaccination?

- Yes – please go to Q6
- No – please go to Q7

Q6. (For Medical staff answered "Yes" for Q5)

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

Q7. (For Medical staff answered "No" to Q5)

Do you only commence hepatitis B vaccination at initiation of dialysis?

- Yes

Q8. (For renal nursing staff)

Do you identify and obtain medication order to commence hepatitis B vaccination?

- Yes -- Please go to Q10
- 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

UNDER PEER REVIEW