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A Study Protocol on: Evaluate the Awareness Program on Selected Vaccinations among Chronic Kidney Disease Patients

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Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Background: "Chronic Kidney Disease" also known as a chronic renal failure, is one of the major health problems today. And infection is the second leading cause of morbidity and mortality in patients with chronic kidney disease, contributing around 30–36% of deaths among patients on dialysis. Overall, this condition is a threat to the life of the patients, hence to improve in the patient's condition on dialysis and renal replacement therapy is a must. Here, early vaccination becomes must as primary treatment modalities to prevent the patients from communicable diseases like Hepatitis-B, Influenza, Pneumococcal diseases.
Aim: To evaluate the effectiveness of the awareness program on selected vaccinations among chronic kidney disease patients.
Methodology: Quasi experimental one group pre-test post-test research design will be used in this study and samples will be chronic kidney disease patients. Non probability purposive sampling technique will be used to select the samples. This research study included 100 chronic kidney

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disease patients of selected hospitals in Vidarbha region. Samples must select according to requirements for inclusion and exclusion criteria. For this study, Age between 18 to 65 years above, both male and female, Chronic kidney disease patients attending Nephrology and Medicine OPD/IPD and admitted patients in selected hospitals in Vidarbha region, able to read and write Marathi or Hindi, Willing to participate in study, available during data collection.
Expected Results: 1. To access this information for educating and change the attitude of patients regarding selected vaccination among chronic kidney disease patients. And understand the importance of vaccination before the onset of dialysis and renal transplantation.
Conclusion: Conclusion will be drawn from the statistical analysis.

Keywords: Chronic kidney disease; hospital-acquired infection; hepatitis B; influenza; pneumococcal; patient; vaccination.

1. INTRODUCTION

Infection is the second major common cause of morbidity and mortality among patients with chronic kidney disease in India, contributing up to 30–36% of deaths among patients on dialysis**,** these patients are very susceptible to any kind of infection, which results in patient's low immunity power and patients came in immune deficiency stage. Such patients show manifestations like abnormal phagocytosis, T and B lymphocytes, they mostly suffer from septicemia and pulmonary infectious diseases. In chronic kidney disease, most of the patients died because of an infection, the mortality is high in chronic kidney disease population due to Hepatitis-B, pulmonary infection and influenza as compared to general population [1- 5].

Immunization is a must against common infectious disease like Hepatitis-B, pneumococcal diseases and influenza. Influenza spreads every year, but in different strength and hence every year vaccination is needed in chronic kidney disease patients and also should be taken by healthy individuals for avoiding further risk. Chronic kidney disease patients having low antibody response to vaccine indicate the degree of renal failure [6-8].

So, this highlights that these vaccines are must needed for chronic kidney disease population as compared to other medical intervention. Vaccination in chronic kidney disease population saves more lives; hence the practice of vaccination for chronic kidney disease patients in hospital is necessary. Infections increase hospital stay among patients. Nephrologists, health care professionals are taking the initial step to participate in awareness programs and create awareness among chronic kidney disease population regarding vaccination by using educational methods and media. All these steps are very essential for the good prognosis of patients with chronic kidney disease [9-15].

1.1 Objective

1. To assess the existing level of knowledge on selected vaccinations among chronic kidney disease patients.
2. To assess the level of attitude on selected vaccinations among chronic kidney disease patients.
3. To evaluate the effectiveness of awareness program on knowledge and attitude on selected vaccinations among chronic kidney disease patients.
4. To associate the post-test knowledge score on awareness program on selected vaccinations among chronic kidney disease patients with selected demographic variables
5. To associate the post-test attitude score on awareness program on selected vaccinations among chronic kidney disease patients with selected demographic variables

1.2 Research Hypothesis

H_1- There is a significant difference between pre-test and post-test knowledge and attitude scores on selected vaccinations among chronic kidney disease patients.

2. MATERIALS AND METHODS

An information evaluator research approach with a quasi-experimental one group pre-test and post-test research design will be used for this study. After getting the Institutional ethics committee permission, [Ref.No.DMIMS (DU)/IEC/Dec-2019/8688] as well as from chief medical superintendent from AVBR Hospital from Sawangi (m) Wardha. By using purposive sampling technique, 100 samples will be selected based on the calculation [16].

2.1 Sample Size will be Calculated on the basis of Cochran's Formula

$$n = \frac{Z \propto/2^2 . P . (1-p)}{e^2}$$

Where; $Z\propto/_2$ is the level of significance at 5% i.e. 95% confidence interval = 1.96, P = Prevalence of chronic kidney failure = 17% = 0.17, e = Error of margin = 8% = 0.08 [8]. the sample size will be calculated to include 84 samples in research study. However, the researcher decided to include 100 samples.

2.2 The Inclusion Criteria Were

(i) Patients who will be of Age 18 to 65 years and above, (ii) Both male and female included (iii) Chronic kidney disease patients attending Nephrology and Medicine OPD/IPD and admitted patients in selected hospital in Vidarbha region. (iv) Have willing to give consent (v) Able to read and write English, Marathi or Hindi (vi) willing to participate in study. (vii) Patients who will be available during data collection period.

2.3 The Exclusion from the Study Criteria Was

(i) Age below 18 years (ii) Severe respiratory problems (iii) Severe Cardiac problems (iv) Critically ill (v) Autoimmune related diseases. (vi) Patients who will be participated in similar kinds of study.

Demographic variables will be collected in terms of age, gender, education, occupation, monthly family income. A structured knowledge questionnaire and attitude scale will be used to assess level of knowledge and attitude score.

2.4 Scoring Method

- If answer is correct score 1 was given
- If answer is wrong score 0 was given
- The knowledge score was graded from poor knowledge to excellent knowledge score.

2.5 Attitude Scale

The Likert- type attitude scale consists of 15 items. The items belong to attitude on selected vaccinations among chronic kidney disease patients. Patient's responses were marked as 5 for those who strongly agreed, 4 for those who agreed, 3 for neutral, 2 for those who disagreed and 1 for those who strongly disagree. The subjects responded to each item by choosing one of the five alternative - strongly agree, agree, neutral, disagree and strongly disagree based on the statement [16].

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Positive Item	5	4	3	2	1
Negative Item	1	2	3	4	5

Table 1. Scoring method to assess knowledge on selected vaccinations among chronic kidney disease patients

Sr.no	Level of knowledge Score	Score Range
1.	Poor	0-3
2.	Average	4-6
3.	Good	7-9
4	Very good	10-12
5.	Excellent	13-15

Table 2. Scoring method to assess the attitude regarding selected vaccinations among chronic kidney disease patients

Sr.no	Level of attitudescore	Score Range
1.	Strongly disagree	0-15
2.	Disagree	16-30
3.	Neutral	31-45
4.	Agree	46-60
5.	Strongly agree	61-75

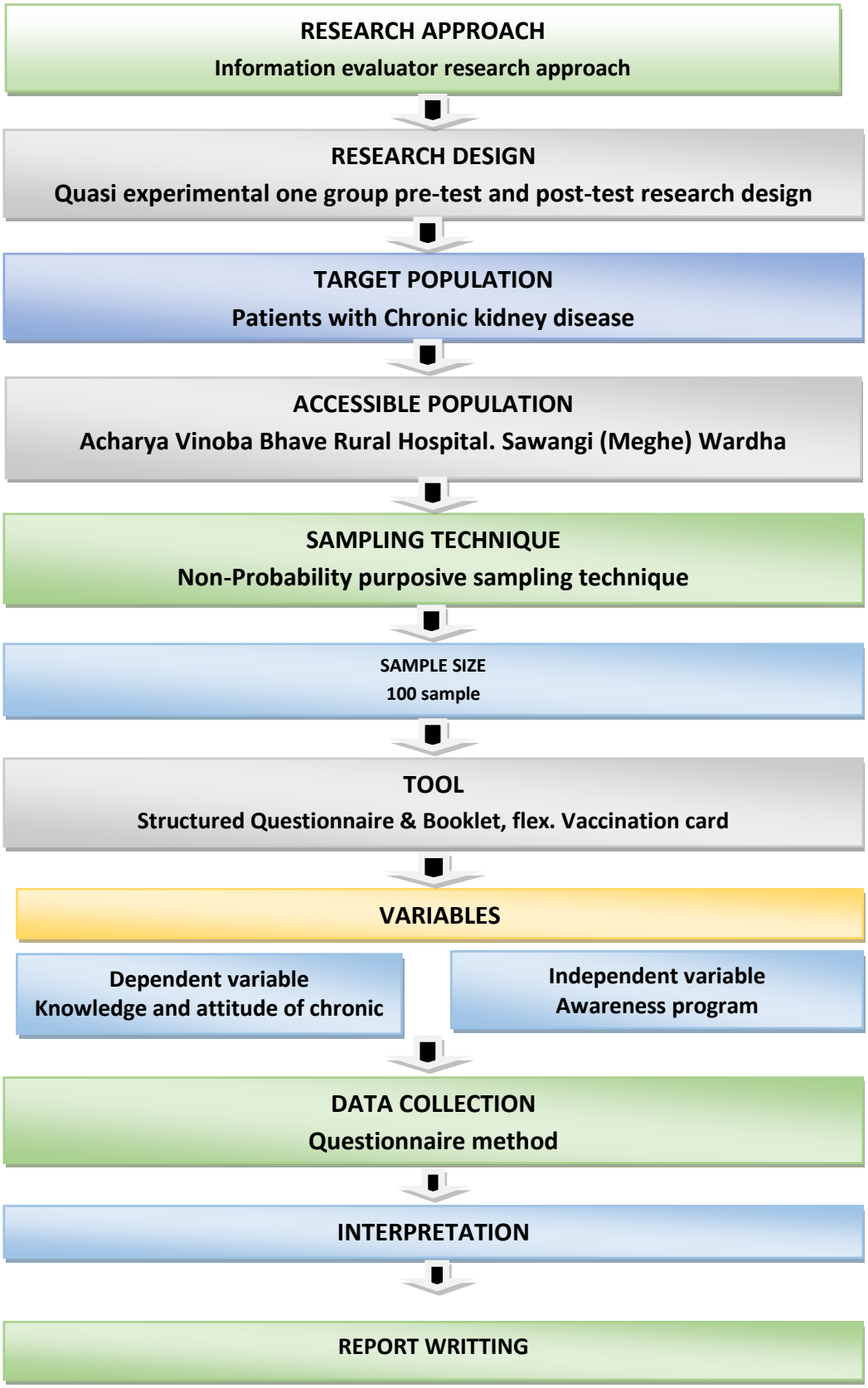

Fig. 1. Schematic presentation of quasi experimental one group pre-test post-test research design for the present study

2.6 Outcome Measures

2.6.1 Primary outcome

1. To access this information for educating and change the attitude of patients towards selected vaccination among chronic kidney disease patients. And understand the importance of vaccination before the onset of dialysis and renal transplantation.

2.6.2 Secondary outcome

2.To suggests that, this vaccine should be available at various private and government hospitals at low prices than its original price.

2.6.3 Data management and monitoring

Data collection will be conducted for a single month span. This research will be carried out

After receiving authorization from the authorities concerned.

2.6.4 Tool for data Collection

Section A – Demographic Variables

A demographic information which gives baseline information obtained from patients such as Age, gender, educational , occupation, monthly family income,.

Section B –I- Self developed structure questionnaire.

II- Modified five point likert scales for attitude.

2.7 Statistical Analysis

2.7.1 Descriptive method

For analysis of demographic data will be going used frequency and mean, mean percentage and standard deviation will be used for assessing the awareness regarding selected vaccination among chronic kidney disease patients.

2.7.2 Inferential statistics

Effectiveness of awareness program will be measure by using student paired‘t’ test. And association of post knowledge score and post attitude score with demographic variables by using ONE WAY ANOVA.

2.8 Ethics and Dissemination

This study will approve by the Institutional Ethics Committee of DMIMS (DMIMS. All participants will ask to read and sign the informed consent. Proper explanation about purpose of study and then knowledge questionnaire and attitude scale will be given to the samples. Information about the samples will handle properly so that confidentiality and anonymity will maintain. Information will not use or release outside the terms of the agreement.

3. EXPECTED OUTCOMES/RESULT

In this present study, output includes many patients belonging to lower socioeconomic status cannot afford this costly vaccine and many patients are not aware of this vaccination needed in chronic kidney disease before starting of dialysis, because of lack of education or no any such information received from health care professionals. Hence it’s essential to create awareness regarding vaccination among chronic kidney disease patients to reduce morbidity and mortality.

4. DISCUSSION

A study will be conducted to evaluate the awareness program on selected vaccinations among chronic kidney disease patients. This is a cross sectional descriptive study. Quasi experimental one group pre- test post-test research design will be selected for this study.

There will be 100 samples going to selected for this study from selected hospitals in Vidarbha region. The purposive samples will be selected for this study. The Samples will be randomly selected, the self -developed structure questionnaire on knowledge and modified five point likert scale used to assess attitude of patients towards selected vaccination. And obtained data will be analyzed using descriptive, inferential statistics and will be interpreted in terms of objective of the study. As an evidence another study suggested that, a cross-sectional observational study was conducted in the Department of Nephrology, Pakistan Institute of Medical Sciences, Islamabad, from December 2015 to May 2016. A total of 451 patients were included in the study, 57.43% were male and 42.57% were female. Mean age was 43.76±17.12 years. About 69% of the patients were from low socioeconomic class, 31% from the middle or higher middle class. Most of the

patients were either uneducated (32.59%) or only had eight years of school education (33.04%). Only 19.9% of patients were vaccinated against hepatitis B virus. Status of vaccination against hepatitis B virus in chronic kidney disease patients is not satisfactory. It is strongly associated with socioeconomic class [17].

A study was conducted on Influenza vaccine delivery and effectiveness in end-stage renal disease. Influenza vaccination rates in the general population improve the good outcome than the end stage renal disease patients. Need little attention towards end stage renal disease patients vaccination rates in the end stage renal disease population were less than 50% for each season. Influenza vaccine was associated with a lower risk for hospitalization and death. Vaccination is an important part of preventive treatment modalities for chronic kidney disease patients. Ideally, it should be received by chronic kidney disease patients before the onset of hemodialysis [18].

Even though patients have not received it before the onset of dialysis, they can receive it afterwards but it necessary to complete the vaccination schedule as recommended by Indian journal of nephrology [18]. If patients are immunized early risk of infection will reduce in patients and patients response will be good for dialysis and ultimately it will result in a reduction in morbidity and mortality of a chronic kidney disease patients. After renal transplantation influenza vaccination is a must for these patients for preventing them from epidemic or pandemic diseases.

For example in today's COVID -19 pandemic, a patient with chronic kidney disease, if not immunized with influenza then patients may have chances of pulmonary problems like pneumonia, septicemia and hence to prevent them from all such critical issues patients should receive all vaccines.

5. CONCLUSION

Conclusion will be drawn from the statistical analysis.

CONSENT

As per international standard or university standard, patient's written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

Ethics approval was obtained from (IEC-ref. No. DMIMS (DU)/IEC/Dec-2019/8688).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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