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Rohilkhand Medical College Campus, Pilibhit Bypass Road, Bareilly-243006 (U.P.) INDIA
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Email: info@rmchbareilly.com, info@biu.edu.in Website: www.biu.edu.in

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CHAPTER - 1

INTRODUCTION

1.1 BACKGROUND OF STUDY

A needle stick injury is the entrance of the skin by a hypodermic needle or other pointed item that has been in contact with blood, tissue or other body liquids before the openness.1 Despite the fact that the intense physiological impacts of needlestick injury are for the most part immaterial, these wounds can prompt transmission of blood-borne illnesses, putting those uncovered at expanded danger of contamination from infection causing microorganisms, for example, the hepatitis B infection (HBV), hepatitis C infection (HIV) and human cytomegalovirus (HCV). Among medical care laborers and research center staff around the world, in excess of 25 blood-borne infection diseases have been accounted for to have been brought about by needle stick wounds Recent experiences with SARS have demonstrated the vulnerability of HCWs to occupationally acquired infectious viral diseases. Worldwide, about 320,000 workers die of communicable diseases every year, some 5000 of them in the European Union. The estimated periodic death rate for Health care Worker from work-related incidents, such as infections, ranges from 17 to 57 per million workers; in total, 9 to 42 healthcare workers per million pass away from work-related infections per year2.

The Administration for the Promotion of Workplace Health and Safety states that between 1992 and 2002, 28 HCWs died in the USA from complications due to NSIs Not withstanding needlestick wounds, transmission of these infections can likewise happen because of tainting of the mucous layers, for example, those involving the eyes, blood, or other body fluids, even though over 80% of all percutaneous exposures result from needlestick injuries events in the United States.3

Different occupations are additionally at expanded danger of needlestick harm, including legal authorization, workers, tattoo specialists, food preparers, and horticultural laborers4 Furthermore, antiviral medication used to manage HIV exposure at work has resulted in severe hepatitis necessitating a liver transplant. 5

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This study investigated the effectiveness of intervention education for preventing NSIs/SIs among nursing students. The evaluation was based on 107 students who had been licensed as nurses after their graduation. These nurses were similar to the original student population in baseline demographic characteristics, frequencies of incidence of NSIs/SIs and encountering contaminated NSIs/SIs. The departments that study subjects practiced nursing work in hospitals either in internship or in work after graduations were not significantly related to the occurrences of NSIs/SIs. When nursing students graduated, they could choose their workplace; therefore, it seems unlikely that the subjects would have continued working in the same departments as those during their internship. In spite of the subjects working in different departments, compared to pre-test outcomes, the reported occurrences of NSIs/SIs in all departments declined post-test. Interestingly, we supposed that individuals working in the surgery department would have more opportunities to use needles or sharps and thus be involved in NSIs/SIs; but in fact, after our educational intervention, injuries.6

Approximately 35% 6.4% are nurses of assistants suffered at least one pointed injury when at home care careers; the comparable figures for other blood and bodily fluid exposures were respectively 15.1% and 6.7%. Sharps injuries occurred annually in 5.1 out of every 100 full-time equivalent nurses and 1.0 out of every 100 helpers. Medical procedures that cause sharps injuries include injecting drugs, piercing fingers and heels, and drawing blood. Other factors include sharps disposal, exposure to waste, and patient handling. Sharps with safety features are generally not used The estimate is that workplace-based surveillance systems under report sharps injuries by approximately 50%.7

Surgeons are among the people most prone to 6 needlestick injuries in the workplace. This study's objective was to determine the frequency and reporting of needlestick injuries among surgical patients. doctor at Kermanshah Medical University in the first six months of 2012. In a cross-sectional survey for descriptive analysis, 29 surgeons were examined using the census method. Use a reliable and valid questionnaire as a research tool to collect data. Using SPSS version 16 and analyzing data based on descriptive and

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inferential statistics Among 29 recruited surgeons, Five (17.2%) had a needlestick injury within 6 months, of which only 1 followed established reporting and follow-up guidelines. The most common damage tool is a sewing needle (60%). There were notable variations between the injured and uninjured groups with respect to gender (X2 = 5.612, P = 0.003) and number of patients (Z = 2.40, P = 0.016). and daily working hours (Z=2.85, P=0.04). Given the relatively high and underreported prevalence of injuries from needlesticks among surgery doctor, careful adherence to operating room safety guidelines is recommended. In addition, safer surgical instruments should be used8

A large percentage (79.5%) of HCWs reported had one or more NSIs in their career. The average number of NSIs ever it was discovered to be 3.85 per Health Care Worker (range 0-20). Seventy-two (22.4%) reported receiving an NSI within the past month. More than half (50.4%) attributed fatigue to the cause of their injury. Most injuries (34.0%) occurred during restatement. In response to the previous NSI, 60.9% washed the injured area with Water and soap, while 38 (14.8%) did nothing. Only 20 (7.8%) of the healthcare professional received HIV/AIDS post-exposure prophylaxis (PEP) after injury. Avoidable practices like needle resealing led to injury. Medical care facility prevention program must include the prevention of NSI, and training HCWs on safety procedures must be a regular hospital activity.9

In hospital settings, needlestick injuries are a common occurrence and can result in life-threatening consequences. Despite a decrease in 5 needlestick injuries due to universal preventives and safety-conscious needle designs, they still occur. Soon after HIV was discovered in the early 1980s, awareness of needlestick injuries began to grow. Still, hepatitis B or C pose a greater concern than HIV after a needlestick injury. To assist healthcare organisations in managing needlestick injuries and determining when to initiate post-exposure HIV prevention. Healthcare practitioners can use a model created by the center for disease control for prevention to determine when to begin antiretroviral treatment. This effort stresses role of the inter-professional platoon in refining care for impacted cases and discusses the evaluation and treatment of needlestick injuries.

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Needlestick accidents are a potential workplace concern for millions of health-care workers. Although the occurrence of needlestick injuries has dramatically decreased in the last 30 years 5 as a result of the implementation of global guidelines, these incidents continue to occur. Surgeons are among healthcare workers., ER staff, lab technicians, and nurses are the most vulnerable to needlestick injuries. Despite hospitals having policies in place regarding the proper use, storage, and The disposal of needles 5 as well as the most recent models of safety-conscious needles, needlestick injuries are nevertheless more common. This is because using needles in healthcare is essential. Emergency department personnel and surgeons are examples of healthcare workers. Majority of the time, the negligent acts and risky behaviours of medical staff members are to blame for There were 525 798 HCWs involved in 113 research. NSIs occurred at a rate of 43%.11 The WHO's 26 African Region had the highest incidence of these injuries (52%), while Africa had the highest prevalence (51%). Women were more likely to be NSIs than men, which is concerning. The most common NSI-transmitted disease was hepatitis C virus infection (21). Nurses, general wards, needle capping, and septic waste disposal were the causes, sanitarium locations, professions, and processes linked to the highest occurrence of NSIs.12

A large number (79.5%) of the workers reported having an NSI during their career This is a concerning figure. In a study conducted in rural North India, a similar frequency of NSI in a working lifetime was observed to be 73%. Several previous studies have indicated that a relatively high number of HCWs have suffered needlestick injuries while performing their duties. Work, both in India and internationally. In our analysis, there were 93 cases of NSI among 322 healthcare workers in previous month in the previous month, for a yearly occurrence rate of roughly 3.47%. Pournaras et al. estimated the frequency of NSI to be 2.4% annually, however they acknowledge that this figure may have been underreported because they only took reported events into account.. A comprehensive, international WHO research on the global burden of sharps injury estimated that 31 the average number of injuries per health care worker was between 0.2 and 4.7 per year. [illegible]

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showed that the average number of NSIs ever documented for a healthcare worker was 3.85 (or 4.5 if we include 3 HCWs who had worked for at least a year), compared to the 4.2 seen in other studies. Kermode, et al. Gloves are acknowledged as an important first line of defence, however many healthcare workers (HCWs), particularly nurses and technicians, were harmed while not wearing them. Self-inflicted mistake was responsible for 84.4% of the injuries. a figure consistent with previous research findings. As mentioned before, a large number of injuries in the current study.13

During the research period, 9775 NSIs 12 were reported in the hospitals. Most NSIs was reported by nurses (72.6 percent, p 0.01). Among all professional categories, the needle produced the highest number of NSIs (79.5%, p 0.01). Hospital registrations serve as the basis for the average yearly NSI rates. Out of a thousand persons, there were 16.8 paramedics, 20.5 nurses, and 16.0 doctors. In total, 45.2% of NSIs were not recorded. We calculated that hospital carers in Poland most likely sustain 13,567 NSIs annually.14

Globally 3 The prevalence of needlestick injuries among healthcare workers (occurrence of at least 1 NSI within the previous year) was assessed in 87 studies conducted in 31 countries. It was discovered that estimates for 6 the prevalence of NSIs among all HCWs ranged from 3.5% to 100%. The random effects approach found that 44.5% of 50,916 health care workers were affected by NSIs. Subgroup analysis with the WHO as a basis The EMRO has the greatest 7 rate of NSIs among nurses, whereas the American and Western regions have the lowest overall prevalence. The total prevalence in the EMRO was 1.9 times higher than in America (52.0 vs. 26.7), showing a significant disparity. The combined frequency 15

A yearly of 600,000 to 1,000,000 medical services laborers experience wounds brought about by sharp articles16

Hepatitis B virus, HIV, and HCV are the infectious agents that are most concerning in this regard. These three viruses are the causes of parenterally transmitted non-A and non-B hepatitis17.

However, the majority of research on preventative methods for injuries caused by

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objects has been theoretical in nature. A few writers have considered using the health belief model to better understand how to implement preventative methods to reduce the risk of sharp injuries. 18

Globally, there are over 350 million HBV infections, while the WHO calculates that there are about 170 million HCV infections. A sizable share of liver illnesses is caused by HBV and HCV infection worldwide. Due to the shared routes of transmission between the two hepatotropic viruses, co-infection with both viruses is widespread, particularly in regions with high rates of HBV infection and among persons who are at increased risk for parenteral infection. It is unknown how many people have both HCV and HBV infections..19

79.5 percent of HCWs said they have sustained one or more needle stick injuries over their tenure. The historical median for NSIs per HCW was 3.85, with a range of 0 to 20. 72 people (22.4%) reported receiving an NSI within the preceding month. Fatigue was the reason for more than half of the group's injury reports. Recapping was when the majority of mistakes (34%) occurred. According to the results of their most recent NSI, 60.9% of respondents washed the damaged area, while 38 (14.8%) chose to do nothing and the other respondents used water and soap. Only 20 (7.8%) of the wounded healthcare workers received post-exposure prophylaxis (PEP) for HIV/AIDS..20

79.5 percent of HCWs acknowledged suffering at least one needle stick injury throughout their tenure. 3.85 NSIs per with a range of 0 to 20, HCW were determined to be the historical median. Of the participants, 72 (22.4%) reported receiving an NSI in the preceding month. Fatigue was cited as a reason for injury reports in 50.4 percent of cases. The majority of errors (34.0%) occurred while recapping. According to the results of their most recent NSI, 60.9% of participants bathed the affected region, 38 (14.8%) remained silent, and the remainder used water and soap. Only 20 (7.8%) of the affected healthcare workers received post-exposure prophylaxis (PEP) for HIV/AIDS..21

According to statistics, there are 100,000 attendant wounds produced by sharp objects every year in the United Kingdom.21.116 Patients Enrolled in this study, Table

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time from injury to interview was 3 days (range 0-15). The majority of the subjects (73%) were female nurses or trainees. Over the course of their employment, 79.5 percent 3 of health care workers reported at least one needlestick injury. On average, 3.85 NSIs per health care worker (range of 0 to 20) were discovered to have occurred. 72 people (22.4%) claimed to have suffered a needlestick injury in the recent month. Over half (50.4%) of those surveyed blamed their injuries on weariness. Recapping was the primary cause of injuries (34.0%). In reaction to22

11 Most commonly reported reason for NSIs was administering medication and collecting blood (42%) followed by two-handed recapping of needle (37%). Only 34% of the trial participants received hepatitis B vaccine. Overall, HCWs did not follow recommended practices when it came to common safety measures, such as making sure protective gear like gloves and clothing is readily available in their workplaces (10%) and (40%).23 Infections including HIV, HBV, and HCV can spread via at least 20 distinct NSIs. Every 3 year, hundreds of thousands of healthcare personnel are exposed to contaminated needlesticks and sharp injuries, which increases their risk of developing HIV, HBV, and HCV. Furthermore, the probability of obtaining an infection from NSIs is 3.0% to 10% for HCV, 40% for HBV, and 0.2% to 0.5% for HIV..24

By and large, attendants include the gathering of medical services laborers that experience the most elevated pace of wounds brought about by sharp articles25

This descriptive-Analytic study was completed in the university's hospitals. A questionnaire with the necessary information was created and distributed to hospital workers. Census sampling was used. The questionnaires were completed by 847 people. SPSS statistical software was used to analyse the acquired data. Results: According to the result of study, the majority of the subjects (73.7%) were female. 29 The average age was (36.17.07) years. The highest of the individuals (47.9%) has bachelor's degree (74.5%) and were nurses, midwives, 3.3% anesthetists, 7.7% laboratory professionals, and 9% radiology staff. Approximately 57.5% of the participants had blood or fluids splashed into their mouths or eyes. In 43.77% and 35.3% of the cases, respectively, needles and

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catheters were responsible for injuries.26

The study utilized structured questionnaire to assess experiences of NSIs, associated activities with injury and documentation. The 520 questionnaires that were recovered were sufficient for analysis. 290 (55.7%) of the HCWs—including 77.6% physicians, 68.3% nurses, 51.4% laboratory personnel, and 30.0% health attendants—reported having NSIs. 68.5% of injuries were caused by syringe needles. Giving intramuscular injections was the activity most frequently linked to injuries (52.4%). The majority of injuries (51.4%) happened during usage, whereas 23.4% had to do with disposal. 93 (32.1%) of the injury-causing items had been used before. Just 25% of those hurt reported their injuries to the proper authorities. 27

According to prospective studies, the risk of contracting 22 HIV from a hollow-bore needle delivering blood from a known source of HIV seropositive patients ranges between 0.2% and 0.5%..28

Two hundred and fifty appropriate responders file out the survey (86 %). The two professions with the largest percentages of NSSIs during the previous year were anaesthesia 59 (27.4%) as well as operating room personnel 55 (25.6%). The group of inhabitants had a noticeably weaker understanding of local protocol. The most common excuses for not adhering to local protocols established by the NSSI were a lack of comprehension (42.4%) and lengthy operations that prevented patients from leaving the operating table (37.3%).29

The prevalence of NSI, SIs, and BBFEs, respectively, was 23.7%, 9.8%, and 40.0%. Training without practice (OR: 1.67; 95% CI: 1.29-2.17), rushing (OR: 4.81; 95% CI: 3.41-6.79), ignorance (OR: 1.36; 95% CI: 1.04-1.77), insufficient staffing (OR: 1.60; 95% CI: 1.21-2.11), and out-of-date guidelines (OR: 1.69; 95% CI: 1.04-2.74) were the danger element for NSIs. Haste was one of the risks for NSIs (OR, 2.43; 95% CI, 1.57-3.76). Long working hours per week were associated with BBFEs (OR, 2.07; 95% CI, 1.06-4.04), training without practice was associated with BBFEs (OR, 1.54; 95% CI, 1.22-1.95), lack of awareness was associated with BBFEs (OR, 1.54; 95% CI, 1.26-2.06), and [illegible]

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staffing was linked with BBFEs (OR, 1.63; 95% CI, 1.26-2.11).30

1.2 NEED OF THE STUDY

The most at risk population to occupational injuries brought on by exposure to needlestick accidents are nurses. In Kirkpatrick's opinion, the suggestions, This study evaluated the effectiveness of a continuous education programme for nursing staff focused at preventing needlestick injuries on the job injuries model..31

The danger of occupationally acquired illnesses is an unavoidable part of regular patient care. Healthcare practitioners who contract occupational infections frequently get sick or even pass away. To increase adherence to tried-and-true infection control methods, additional research is required. The risk of and expenses associated with occupationally acquired infections must be considered as health care reform proceeds. considered.32

Study investigated the effectiveness of intervention education intervention for preventing NSIs/SIs among nursing students. The evaluation was based on 107 students who had been licensed as nurses after their graduation. These nurses were similar to the original student population in baseline demographic characteristics, frequencies of incidence of NSIs and encountering contaminated NSIs/SIs. The departments where subjects practiced nursing in hospitals, either as an internship or after graduation, were not substantially connected to the occurrences of NSIs/SIs. When nursing students graduated, they could choose their workplace; therefore, it seems unlikely that the subjects would have continued working in the same departments as those during their internship. Despite the subjects working in different departments, compared to pre-test outcomes, the reported occurrences of NSIs/SIs in all departments declined post-test. Interestingly, we supposed that individuals working in the surgery department would have more opportunities to use needles or sharps and thus be involved in NSIs/SIs; but in fact, after our educational intervention, injuries.33

Health care workers reported having one or more needle stick injuries at some point in their careers in 79.5 percent of cases. There was discovered to be an historical average of 3.85 NSIs per HCW (within a range of 0-20). 72 persons (22.4%) reported having

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hurt by a needle in the previous month. Weariness was mentioned for 50.4 percent of injuries reported. The bulk of accidents (34.0%) occurred when recapping. In contrast to 3zsxeft8 (14.8%) who did nothing following their most recent needle stick injury, 60.9% of respondents cleansed the afflicted area with water before going shopping. Twenty (7.8%) of the injured medical workers received post-exposure prophylaxis (PEP) against HIV/AIDS..34

5 A needlestick injury is the most common occupational injury sustained by student nurses. Such an injury can be quite serious and dangerous. Injured student nurses are at danger of developing infections and perhaps blood-borne illnesses. Ninety percent 21 of needlestick injuries to healthcare workers occur in underdeveloped countries. According to the World Health Organization's most recent estimates, approximately three million cases are reported each year. Student nurses are thought to have a high rate of 5 needlestick injuries due to their inexperience, poor technique, and inadequate use of universal precautions..35

A cross-sectional research study with 322 interns and resident physicians, nurses, nursing students, and technicians was carried in a Delhi tertiary care hospital. 6 The results of the investigation revealed that a sizable percentage of HCWs (79.5%) said they had experienced one or more NSIs during their careers. It was discovered that there were, on average, 3.85 needlestick injuries per healthcare worker (with a range of 0 to 20). Twenty-seven people (22.4%) reported receiving an NSI in the preceding month. Over 50% of those surveyed (50.4%) attributed injuries to fatigue. An injury's rate of 34.0% was caused by recapping. When it came to their most recent needlestick injury, 38 respondents (14.8%) 3 took no action, while 69 percent cleaned the wound with soap and water. only following their injury.36

According to estimates from the World Health Organisation (WHO), Globally, needlestick injuries produce 16,000, 66,000, and 1,000 cases of HIV and HCV among healthcare professionals, respectively.. Teaching health care workers about safety practices is a crucial ongoing activity within a program because percutaneous exposure accounts

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roughly 37.0% of HBV, 39.0% of HCV, and 4.4% of HIV cases among healthcare workers participating in workplace programmes.. 37

Needlestick and pointed injuries, which affect health care workers globally, are especially common in China. The purpose of study were to describe the risk factors and prevalence for NSIs among nurses employed by a Chinese educational facility. 402 completed surveys were collected from 463 nurses. 261 nurses in all (64.9%) reported having been hurt by needles or sharp objects. NSIs was more prevalent in female nurses junior nurses, new nurses, nurses who do surgery, and nurses. Logit regression research 25 suggests that age and place of employment are separate Risk Factors for NSI. Syringe needles caused the greatest needlestick injuries (59%), followed by glass objects (22%), trocar core/catheter wires (4%), and other device types. 38

In India, the majority of healthcare professionals (79.5%) reported receiving one or more needlestick wounds during their careers. There was a historical average of 3.85 NSIs per HCW (ranging from 0 to 20). 72 persons (22.4%) reported having been hurt by a needle in the previous month. 50.4 percent of those who reported an injury blamed it on tiredness.. The majority of accidents (34.0%) happened when recapping. When it came to their recent NSI, 38 (14.8%) of the respondents did nothing, while 60.9% cleaned the damaged area with shop and water The number of HCWs who received HIV/AIDS post-exposure prophylaxis (PEP) was just 20, or 7.8%. injury.39

Sharma R, et. al. this study looks into the incidence and treatment 3 of needlestick injuries among medical staff in a tertiary care setting in Delhi, IndiaThe Indian Association of Preventive and Social Medicine publishes "Community Medicine" as its official journal. January, 2010.40

The 12 study was conducted in the postgraduate Department of Surgery at the District Hospital and ART Centre of Rohilkhand Medical College, Bareilly, Uttar Pradesh, India, in cooperation with the Department of Microbiology. The time frame of the prospective trial is December 2017–May 2018.41

The study included all patients who were admitted to the surgical department for the

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emergency surgery, as well as for conservative care. The returning guests were sent away. According to the results, the department of surgery tested 1577 hospitalised patients for HIV, HCB, and HBV. The most common infections were HBV and HCV, however HIV and confections were occasionally found. The most usually affected age group was 21 to 50, with a male to female ratio of 2.3:1. Testing for HIV, HBV, and HCV.41 In India, it is unknown how many occupational-related injuries occur each year, and because information is scarce, it is impossible to estimate a yearly rate. The EPI net framework recommends that.42

All above study revealed that there is lack of knowledge regarding needle stick injury so this study is very helpful for nurses for the purpose of preventing needle stick injuries

1.3 TITLE

Effectiveness of Educational intervention on Knowledge Regarding Needlestick Injury and its prevention among the staff nurses

AIM

To assess Effectiveness of Educational intervention on Knowledge Regarding Needlestick Injury and its prevention among the staff nurses

OBJECTIVES

1. To assess the level of knowledge score regarding needlestick injury among the staff Nurses.

2. To assess the effectiveness educational intervention on knowledge score regarding needlestick injury among the staff Nurses.

3. To associate the Pre- test knowledge score among the experimental and control group with the selected demographic variables.

1.4 HYPOTHESIS

1. There will be significance difference between the pre test or post test knowledge score in the experimental.

2. There will be significance association between the knowledge score with in the control and experimental group with selected demographic variable.

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1.5 OPERATIONAL DEFINITION

Effectiveness:

Effectiveness is the capability of producing the result desire or ability to put desire result when something is deemd effective it mean it has intended to produce deep or vivid impression43

In this study it refers to the way of finding the level of knowledge of staff nurses on needlestick injury education intervention regarding needlestick injury by Structure Knowledge Questionnaire.

Educational intervention:

An organised activity staged by the teacher, using concepts and material from books or other sources, leading to a stated set of learning objectives44

Educational interventions provide staff nurse's with the support needed to acquire the skills being taught by the lesson plan & PPT and should address functional skills, academic, cognitive, behavioral, and social skills that directly affect the nurse's ability an education.

Needlestick Injury:

5 A hypodermic needle or other sharp instrument touches blood, tissue, or another bodily fluid without causing a needle stick injury45.

Staff Nurses: Staff Nurse, gives a comprehensive overview the function of a Staff Nurse, detailing the main duties, career opportunities and challenges of the role.46

In this study GNM, B.Sc (N) Post Basic (N) & NPCC nurses are participating in the study.

1.6 CONCEPTUAL FRAME WORK

A conceptual framework is a method of analysis. that comes in variety of forms and circumstances It can be applied to many different fields where an overall image is needed. It is employed for organizing concepts and arranges ideas. Strong conceptual frameworks do this way that is simple to recall and captures something real apply.47

THEORITICALFRAMEWORK

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The theoretical framework is presented in the early section of a dissertation and provides the rationale for conducting research to investigate a particular research problem48

The present study aim 1 to assess the effectiveness of educational intervention on knowledge regarding needlestick injury among Nurses. The Investigator adopted General System's Model developed by Ludwig Von Bertalanffy (1968).

OPEN SYSTEM

Experimental group served as an open system. It functions and interacts with its environment and receives input through the boundaries. It consists of four parts:

(i) Input

In this research, the input is educational intervention on needle stick injury to staff nurses. The questionnaire used is the questionnaire includes 40 items. Each item consists of a information on avoiding needlestick injuries.

(ii) Through put

Transformation inside the system refers to the process of teaching staff nurses on how to avoid needlestick injuries.

(iii) Out put

It is the product returned of the knowledge to staff nurses on prevention of needlestick wound. The outcome of 6 this study will be an increased level of understanding about needlestick injuries.

(iv) Feedback

Feed back is evaluation or response of system, here feedback might be either favourable or unfavourable. In this study feedback emphasize to strengthen of knowledge. The investigator develops awareness among staff nurses by analysing demographic data and administering a pre-test.

CLOSED SYSTEM

The Control Group served as closed system, which does not interact with this and no educational intervention was administered. So there will not be any change in the knowledge level in the post-test.

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1.7 SUMMARY:

This chapter discusses the introduction, background of the investigation, problem description, study objectives, hypotheses, operational definition, and theoretical framework.

FIGURE 1: CONCEPTUAL FRAME WORK BASED ON THE MODIFIED GENERAL SYSTEM MODEL (VON LUDWIG BERTTALANFFY

CHAPTER - 2

REVIEW OF LITERATURE

INTRODUCTION

Review of literature is a key step in research process & significant role in development of research project in order develop a deeper in side in to the problem area. A The purpose of this literature review was to assess the effectiveness of instructional initiatives targeted at preventing needlestick injuries among staff nurses.

So, the extensive review of literature done by the investigator to elicit factual information. The literature review was based on an extensive survey of published and unpublished research studies, Journal articles and non research literature related to the present study. The research-related literature was reviewed and arranged in the following sections.

Section 1: Literature related to knowledge related to Needlestick injury

Section 2: Literature related to educational interventions on Needlestick injury

Section 3: Literature related to causes and Prevalence of Needlestick injury

SECTION 1: Literature related to knowledge related to needlestick injury

T. segaye Amlak B, et al.49 conducted a cross sectional research study on Needlestick injury and factors that contribute to them among healthcare professional in Southern Ethiopia. The study's goal was to analyzed needlestick injury and their associated characteristics among healthcare employees. The study's sample consisted of 341 healthcare employees who were chosen using a stratified sampling technique. The data was gathered through the use of standardized structured questionnaires. These st

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were analyzed using SPSS version 26, and the findings revealed that 30.6% of healthcare professionals suffered needlestick injury in the workplace. Healthcare professionals who have not taught on needlestick injury safety measures, working in the labor unit adjusted odds ratio: 3.394-14.749).

So, above study reveled that nurses are more prone to get 1 needle stick injury so education intervention is very effective for prevention of needlestick injury.

Ziqubu L, et al.50 conducted a A descriptive cross-sectional study was conducted in rural South Africa to determine the knowledge, attitude, and practice of sharp waste disposal among diabetic patients who self-inject at home in the remote uMzinyathi District Municipality. The study sample consisted of 308 diabetic patients, these sample were selected by using the Consecutive sampling, the data were collected by using the knowledge questionnaire, these data were analyzed by using the inferential and descriptive statistics, the result of study were shows that the majority of respondents (62.3%) lacked knowledge regarding proper sharps waste disposal. The highest majority of respondents (90.6%) recognized that sharps waste should be separated from general waste. 53.3% of people who admitted that someone in their home had been hurt by a needle said they were motivated to modify how they disposed of sharps waste. According to the study's findings, most respondents lacked understanding about how to dispose of pointed waste because they weren't given the required instruction. Diabetic patients were generally unaware of how to dispose of pointed waste in a domestic setting to provide diabetes patients with pertinent information on pointed waste disposal, the study advised healthcare professionals to emphasize correct sharps waste disposal awareness more.

G Adhikari, Yadav KK51 conducted a descriptive survey research design on study to evaluate understanding 1 of needlestick injury among nurses in tertiary care Hospital at Jhapa Nepal, the aim of study was to evaluate the knowledge regarding needle stick injury among the nurses, the sample of study was nurses theses are 100, were selected by using convenient sampling method, the data were collected by using the knowledge questionnaire, the data were analyzed by using version 20, This study results show

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73% had average knowledge, 7% had good knowledge and 20% had poor knowledge respectively. Chi–square value revealed that there was significant association between knowledge with demographic variables of educational qualification and working experiences, where p value was lower than 0.05 ($p<0.05$).

Above study revealed that there is lack of knowledge This study serves to increase staff nurses' knowledge of needlestick injuries.

Bharti PP, et al.52 conducted a study Regarding the Frequency and Professional Health care providers' awareness of needlestick injuries professional, A Tertiary Healthcare based Study from North India. The aim of study was to estimate the incidence along with the awareness regarding NSIs, among the health care workers of Lady Hardinge Medical College & Associated Hospitals. The sample of study were health care workers, the total sample of study was 400 these sample were selected by using the simple random sampling, the data were collected by using the questionnaire, these data was analyzed by using the inferential or descriptive statistics the result of study was Scores of 70 percent or more were regarded as acceptable awareness, 50 to 70 percent as fifty percent or less reported having inadequate awareness. Only 38.8% of physicians, 23% of nurses, and 8% of technicians knew enough about injuries caused by sharp objects. Only 4% of technicians, 18.4% of doctors, and 9% of nurses reported having an adequate degree of PEP awareness. There was a substantial disparity in acceptable levels of post-exposure prophylaxis (PEP) and NSI awareness among different categories of healthcare personnel.Therefore, the mentioned study revealed the necessity of ongoing training program to increase NSI reporting and awareness.

Celikkalp U, Irmak AY53 conducted a study on workplace exposures of aspiring health professional during clinical practice needlestick injuries and knowledge of occupations level in turkey hospitals in 2021. The study sought to determine the knowledge and attitudes of injured or uninjured students towards occupational hazards as well as needle stick injuries sustained by medical faculty, nursing students, and laboratory programme students during clinical practice. The study included 452 students from the School of Medici

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Internships in Hospitals for University Health, and Associate Degree students. The structured questionnaire method was employed 6 to collect the data. Both 1 descriptive and inferential statistics were used to investigate the data. The study discovered that 206 students (47.4%) were injured by needlesticks while participating in clinical practice. The learners' average 30 occupational risk information score was found to be 18.76 + 5.64. 1 The study revealed that medical students had the greatest knowledge score (22.784.52), whereas nursing students

Newmai C, et al.54 conducted research on cross-sectional nursing personnel's understanding, perspectives, and behaviours pertaining to the responsible management of sharps in 2021. The study's goal was to analyse nursing staff's knowledge, attitudes, and procedures when handling sharp objects. The easy sampling strategy was used to pick a sample of 45 nursing personnel for this study. Some of the Christian Institute of Medical Sciences and Research's wards in Dimapur, Nagaland, served as the location for the event. The data was gathered using self-administered questionnaires, and were evaluated using a Likert scale and an observational checklist, respectively. According to the study's findings, the majority of participants (38%) were in the 26–30 age range, had their education at private institutions (67%) and had an average of fewer than three years of work experience (44%) overall. When sharps handling expertise was evaluated, it was discovered that 5% of people had excellent knowledge, 53% had very good knowledge, 13% had good knowledge, 22% had fair knowledge, and 7% had bad knowledge. 98% of people had a positive view, and 2% had a neutral attitude, according to a survey on the safe handling of pointed.

So above study revealed that lack of knowledge Therefore, educational interventions are beneficial in increasing the staff nurses' understanding of needlestick injuries.

Shil R, Upashe SP55 conducted a study Nursing students' understanding of needlestick injuries: effectiveness of systematic education method, The study sought to measure student nurses' understanding of needlestick injury. The study included 30 nursing students as a sample. The study's sample was selected at random using the simple

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random procedure. Data were acquired using a structured knowledge questionnaire. The data were analysed using both inferential and descriptive statistics. The findings of the investigation were Based on the study's findings, Six students (20%) knew very little about needlestick injuries, while 24 students (80%) knew a little amount. Neither group grasped the topic. The study's findings revealed that 6 students (20%) had insufficient knowledge regarding needlestick injuries, while 24 students (80%) knew something about them.

Vardhini H, et al.56 conducted a cross-sectional study in 2020, a South Indian hospital assess the behavior and knowledge of the staff nurses or paramedical staff about post-exposure prophylaxis for the HIV. The purpose of 9 study is to evaluate and compare staff nurses' and paramedical workers' knowledge of and use of PEP to prevent HIV. There were 66 paramedical and 339 nurse's professionals in the study's overall sample. The data was collected by using the structured questionnaire. These data were analysed using SPSS version 24. The study's conclusions show that, out of the 405 participants, 339 (83.7%) were nurses and 66 (16.3%) were paramedics. Between the ages of 21 and 44, 29 the average age was 34.2 + 8.6. Participants between the ages of 20 and 30 represented the majority (72.3%), which included paramedical workers and nurses.. A significant portion of paramedical personnel (74.8%) and staff nurses (74.9%) were in their initial one to five years of employment.

So, the above study demonstrated that lack of information. The instructional session helps staff nurses better comprehend needlestick injuries, which is advantageous.

Yadav S57 Conducted a research study on Anesthesiologists' evaluation of safety procedures for preventing needlestick injuries at Maharashtra. The study's goal was to analyse the occurrence of 5 needlestick injuries as well as anesthesiologists' understanding of safety practices for preventing them. The study included a total of 403 anesthesiologists from Maharashtra. These samples were chosen using the survey approach. 12 The data were collected using an 18-item questionnaire that had been pre-validated and evaluated. Data were analysed using descriptive and inferential statistics. .The finding of study was The occurrence of needlestick wound in anesthesiologist

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73.7% (n = 403), with males accounting for 71.1% (n = 235) and females accounting for 77.4% (n = 168Medical school anesthesiologists were 75.0% (n = 148), private practice anesthesiologists were 72.7% (n = 216), and those working in both medical school and private practice were 74.4% (n = 39). Those who worked for longer amount of time was more likely affected.

Tshering K, et al.58 conducted a study on Assess of HIV post exposure prophylaxis knowledge, attitude, and practice among nurses at Jigme Dorji Wanghuck National Referral Hospital, Bhutan 2020. The study's objective was to evaluate nurses' post-exposure prophylactic HIV-related knowledge, attitudes, and behaviours A total of 221 registered nurses made up the study's sample. Data was gathered through the use of a self-administered structured questionnaire. The SPSS version 21 was used to analyse the data. 14 The findings of the investigation were 221 nurses filled out the questionnaire; 125 (56.6%) of them were female. The mean age of the nurses was 28.265 years (range: 22–42 years), with the majority (44.1%) falling between 26 and 30 years of age. The most common degree held by nurses (67.4%) is a diploma in general nursing. Over half (55.7%) of the participants has worked in wards, while the majority (70.1%) had worked in hospitals for one to four years. One hundred and thirteen

The above survey demonstrated a dearth of expertise among staff nurses hence teaching programs are successful in raising staff nurses' awareness of Needlestick injuries.

A. Madhavan, et al.59 conducted a cross-sectional study on A comparison of health care providers' understanding, attitudes, and behaviours surrounding needlestick injuries. The study's goals included identifying the 4 prevalence of needlestick injuries among nurses and interns, as well as the knowledge, attitudes, and preventative techniques used by individuals who had received one. Staff nurses comprised the study's sample. Purposive sampling was employed to choose this sample, which included 100 staff nurses and 100 house surgeons in total. A self-structured questionnaire with 27 multiple-choice items 18 was used to collect data on HCWs' KAP for NSIs. The data were then examined 4 using SPSS version 20, and the study concluded that NSI occurred at a rate of 24.4% in

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nurses and 75.6% among interns. Interns had the most expertise with two clinical procedures: blood withdrawal

So, above study indicates that there lack of knowledge among the staff 1 nurse regarding needlestick injury.

Bharati M, Natekar DS60 Conducted A study was conducted to evaluate staff nurses' knowledge about needlestick injuries in order to create a booklet on how to prevent. 27 The research was conducted in a few Bangalore hospitals. The study aimed to assess participants' awareness 7 of needlestick injuries. A total of 30 samples were chosen for the inquiry utilising the continent sampling technique. The data were analysed using a self-administered, structured, closed-ended questionnaire. The data were analysed using descriptive or inferential statistics. The study concluded that the sample distribution, stated as a percentage, revealed that 56% of the respondents were between the ages of 26 and 30, 34% between the ages of 22 and 25, 8% between the ages of 31 and 35, and the remaining 2% between the ages of 36 and 40. 40% were men, whereas 60% were women. 88% of them had

SECTION 2: Literature related to educational interventions on needlestick injury

Aljaloud J Ohoud61 We out a quasi-experimental study to determine how a needlestick injury education programme affected the competency of nursing interns. The purpose of the study was to evaluate how developing an educational programme affected nursing interns' capacity to stop needlestick injuries. The study included 68 nursing interns as a sample. The Awareness and Observation The data was gathered via a self-administrated questionnaire. Statistics that are both descriptive and inferential were used to analyze data. According to the study's findings, 79.4% of the participants was women. Age-wise, 88.2% of them were in the 21–23 age range. Less than a quarter (16.2%) of participants had GPAs ranging from 4.5 to 5.0, whereas 5.9% had GPAs between 3.30 and 3.49. Also, every single

The above study establishes that an NSI prevention education program is success

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enhancing nursing interns' knowledge of NSI incidence prevention and post-exposure therapies.

D. Gopi, GR. Savitha62 The study's purpose was to evaluate how well an organised instruction programme worked on carried a research on how a structured teaching programme affected students' knowledge of general precautions and the prevention of blood-borne infections. B.Sc. Nursing Students of Selected Nursing Colleges the knowledge regarding universal precautions and the prevention of blood borne infections among the final 9 year B.Sc. Nursing students, The sample of study was the final year B.Sc. Nursing students, and the total sample of study was 60 samples, which 11 were selected by simple random sampling, Data were collected by using the, knowledge questionnaire, and the data were analysed by inferential and descriptive statistics, The study's conclusion demonstrates that final-year B.Sc. nursing students' knowledge is reflected in their results on general precautions and avoiding blood-borne infections. The mean difference was 5.52 between the pre-test and post-test means, which were 15.42 and 20.94, respectively. It is significant at 0.05 with a standard deviation of 3.35 in the pretest, 8.17 in the post-test, and a calculated "t" value of 13.3. There is a substantial and noteworthy difference in the knowledge scores from the pre- and post-tests.

So, it indicates that a structured teaching program is effective for final year B.Sc. nursing students.

Mostafa Eldosoky Ibrahim Amina, et al.63 conducted an interventional study on a health education programme on protecting healthcare personnel in the Fakous region of the Sharqia Governorate from suffering needlestick injuries. 3 The study aimed to assess primary healthcare practitioners' knowledge, attitudes, and behaviours about needle stick injuries. The study has a sample size of 104 healthcare professionals. These samples were chosen using simple random selection, data was collected via a questionnaire, and the findings were analysed using inferential and descriptive statistics. The study revealed that there was a strong statistically significant link between 5 having a needlestick injury and obtaining three doses of the Hepatitis B vaccine, which was related with a lower

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history of needlestick injuries. With the exception of waste disposal, study participants' understanding of standard infection prevention practices improved dramatically following intervention.

The study revealed that the effect of health education is remarkable in improving knowledge levels and increasing awareness of health-care professionals infection

Abalkhail Adil, et al.64 conducted A cross-sectional survey research on Needle-Stick Injuries among Hospital worker in saudi Arabia, The goal of this cross-sectional survey in Saudi Arabia was to determine the annual incidence of NSIs and analyse their causes among healthcare workers. In total, 361 healthcare professionals from around Saudi Arabia took part in the poll, which was conducted using the purposive sample approach. The survey was administered online via Google Form, and the results were analysed using SPSS version 20 (IBM, Armonk, NY, USA). According to the study's findings, our participants included medical technologists (24.9%), nurses (19.1%), medical professionals (13.9%), dentists (6.6%), chemists (6.1%), volunteers (10.8%), dentistry or health science students (16.1%), and housekeeping workers (2.5%). The majority of the participants were female (70.6%) and Saudi (83.1%), with 41.6% being young (20-25 years old). Only 45.2 percent of the participants got The rate was 28.3% for men and 19.6% for women. The prevalence rates were 36% among doctors, 34.8% among nurses, 29.2% among dentists, 21.1% among medical technologists, 13.6% among chemists, and 11.1% among housekeepers. Healthcare practitioners from various nations The Aaboveresearch study concluded that the high incidence and low reporting rate of NSIs highlight the need for education and awareness-raising programmes aimed at healthcare professionals.

ME. Ibrahim Amina, et al.65 conducted a research study on a health education programme on the Preventing needlestick injuries among medical personnel in Fakous district, Sharqia governorate. The study aims to evaluate primary health-care practitioners' knowledge, attitudes, and behaviours regarding needle stick injuries. 104 employees work in primary health care centres (PHCs). These samples were selected using a

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multistage sampling approach, and data were collected using a variety of standardised questionnaires. The data was analysed using SPSS version 22 for Windows. The results of the study show that an independent sample t-test was employed to compare two independent groups of properly distributed variables (parametric data). P values < 0.05 were considered significant.Needlestick injuries are primarily caused by unsafe injections. Increased working hours, night shifts, and disregard for universal measures were all independent NSI risk factors.

Al Mostafa66 conducted a research study on a health education Program on the prevention of Health workers in Fakous district, Sharqia governorate, suffered needlestick injuries. The study sought to assess primary healthcare practitioners' knowledge, attitudes, and practices about needlestick injuries. The study sample consisted of 104 healthcare personnel. Data were obtained using a structured questionnaire, and the sample was chosen using a multistage sampling mechanism. The data were examined with SPSS version 22. The study's conclusions were A positive history of needlestick injuries was substantially related with a positive history of HBV immunisation (three doses). Participants' comprehension of routine infection control practices improved statistically significantly after the intervention, with the exception of trash disposal. Before intervention, the overwhelming

Ibrahim S67 conducted in a cross-sectional study on The study aimed to analyse nursing students' knowledge of injection techniques and needlestick injury at Mansoura University. The study had a total sample size of 240 nursing students. Samples were chosen using the convenient sampling strategy. The data was acquired via a self-administered questionnaire. The data were examined with SPSS version 20. The study's findings show that, with an average age of 21.88 (0.64), 57.7% of the students under inquiry were 22 years old, whereas 80.4% of the group The subject under investigation was a female. 62.6% of the students lived in rural areas, whereas 82.2% did not work in private hospitals. In terms of socioeconomic status, 5.5% of students were from low-income homes, while 87.1% came from middle-class families. Only 12.3% and 9.8%

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study's students went through infection control and safe injection procedures training sessions, respectively.

Khurshid Anjum, et al.68 conducted a research study to evaluate first-year B.Sc. nursing students at Syed Mantaqi Memorial College of Nursing were knowledgeable about preventing needlestick injuries 12 The purpose of this study was to see how a structured teaching curriculum affected the comprehension of needlestick injury prevention among first-year B.Sc. nursing students in Awantipora Kashmir. These samples were picked using purposive sampling, which is 40 in number. A questionnaire was used to collect data, which was then analysed using inferential and descriptive statistics. The study's findings suggest that improvement mean percentage 29.43% with t value 27.1124, P 0.05 significance criterion., which shows there is an enhancement of there is structured teaching program. Based on above results it accept the hypothesis which claims that a substantial difference between the pretest and posttest knowledge scores.

The results of study revealed that teaching program was very educational and would aid them in learning about preventing needlestick injuries.

George Fatethin69 at the MOSC nursing college in Kolenchery, researchers looked at the usefulness of a systematic training programme in improving nursing students' comprehension 4 of needlestick injury prevention. The 7 study sought to determine how a structured education curriculum influenced nursing students' awareness of managing and preventing needlestick injuries. The study's participants were nursing students. The stratified random sampling method was utilised to choose these nursing candidates. A total of 100 student nurses comprised the sample. Multiple-choice questions were utilised to collect data. The data were analysed using both differential and inferential statistics. The study's findings revealed that, based on pre-test results, around 5% of participants had high knowledge, 44% had low knowledge, and 51% had average understanding 4 of needlestick injury prevention. The pretest knowledge score was proven to be important.

Singh Sudhir70 1 A pre-experimental study was conducted at a selected nursing college in Faridabad, Haryana, to assess the effectiveness of a structured training pro

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nursing students' awareness of needlestick injuries and how to prevent them. The study aimed to see how well-structured training courses increased nursing students' understanding of needlestick injuries and how to avoid them. After examining the data with both descriptive and inferential statistics, the study discovered that the overall mean score was 5.41 with a 3.29 SD before the exam and increased to 14.10 with a 3.71 SD after the exam. The mean difference in scores between the pretest and posttest was 8.69. The calculated 't' value was 35.58.

This shows that a systematic training program was successful in raising nursing students' knowledge levels.

Mohammed MU, KV KR71 conducted A cross-sectional study on the knowledge and behaviors of the nursing staff regarding the prevention of needlestick injuries was carried out In a tertiary care teaching hospital in South India. The study aimed to examine the general public's understanding of needlestick injuries. The study's sample size was 100 nurses. The data were gathered using a series of structured multiple-choice surveys, and the findings were analysed with Minitab 19. The study's findings reveal that, while 90% of nurses were aware of the pathogens conveyed, 85% were uninformed of the "no-recapping" disposal process, and 90% were unaware of infection transmission, just 24% were familiar with the concept of NSI. Eighty percent of respondents responded, and the NSI incidence was

Düzgöl M, et al.72 conducted a study on risk groups for needlestick injury Among the healthcare personnel at Children's Hospital A cross-sectional study was conducted to investigate the risk group for needlestick injury among health care workers, as well as potential risk groups, activities, and prevention methods. The survey involved 249 healthcare personnel. The data was gathered using a questionnaire and analysed using influential and descriptive statistics.

The study's findings revealed that nurses were at the highest risk.

El-Hay, et al.73 conducted a investigation into how a training module's implementa-

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affected internship nursing students' performance in terms of needlestick injury safety. The study's objective was to ascertain how implementing a training module affected nursing interns' performance with regard to safety concerns surrounding needlestick injuries. 75 internship nursing students made up the study's total sample, which was chosen using a simple random sampling. Information was gathered utilising Tool II, the Structure Questionnaire Sheet, an observation checklist, and the students' actual use of the NSI safety procedures. Problems that influence utilising subsequent safety precautions Structure: A questionnaire sheet called "Checklist for Monitoring Pupils' Practice with NSI Safety Measures" contains information on NSI's safety protocols. 3 The study found that night shifts and a lack of training were the most significant issues affecting their follow-up safety measures.

SECTION 3: Literature related to prevalence and cause of needlestick injury

Alam Muhammad, et al.74 conducted a cross-sectional investigation at the Hayatabad Medical Complex in Peshawar on the incidence and treatment of needlestick injuries. The study's objective was to determine how common needlestick injuries are in medical facilities. There were 190 people in the study sample, including paramedics, doctors, medical students, Nurses, including student nurses. Convenient These samples were chosen through sampling, and the data was gathered using predefined performa. The data were examined with SPSS 23.0, a statistical analysis application. The statistical significance was calculated using 10 a P value of 0.05. The survey found that 60 (31.1%) medical staff members sustained needle stick injuries.

Nine (15%) of the injuries happened when the patients interacted with other high-risk patients, and 51 (85%) occurred when the individuals were not classified as high-risk.

B Tsegaye Amlak, et al.75 conducted a cross-sectional study Investigating the 3 factors that lead to needlestick injuries The purpose of this research was to investigate medical personnel in southern Ethiopia. A stratified 9 sampling technique was used to select a sample of 341 healthcare workers, data were collected using standardised structu

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questionnaires, and data were analysed using SPSS version 26 to investigate needlestick injuries and the factors associated with them among healthcare professionals. The study discovered that working in an emergency room (5.718 (4.326-6.398), an operating room (2.359 (1.781-4.430), an inpatient unit (3.278 (1.804-5.231)), a medical laboratory technician (1.070 (1.432-3.304), and a paediatrics unit (adjusted odds ratio: 3.394 (1.775-7.126) According to the findings from the previous studies, needlestick

DS Alameer, et al.76 conducted an analytic cross-sectional 3 study on the prevalence and determinants of work-related injury among health workers in Jeddah, Saudi Arabia, The study aimed 13 to determine the frequency and risk factors for workplace injuries. The study's sample, which included all of the social research statistics software, excluded HCW. The statistical package for the sample included 387 social studies students. Data were collected using a validated, self-administered questionnaire, and SPSS version 26 was used for analysis. The investigation's findings revealed that 12 the majority of the 387 participants in this study were female (n = 283, 73.1%). The most common age group was 31-35 years old, accounting for 149 individuals (38.5%). Saudi nationals made up 24 the vast majority of participants (n = 372; 96.1%). with 223 (57.6%) holding a B.Sc. in nursing. The guy supposedly had more than a decade of experience.

N Elisa, et al.77 conducted a cross-sectional study on injuries from needlesticks among medical students at an eastern Ugandan tertiary hospital; the sample of study was clinical students. These students were chosen using simple random sampling, with participants assigned numbers ranging from one to thirty until the sample size was reached, data were collected using soft copy questionnaires, and convenient sampling was used, with questionnaire links sent to children whose social media accounts we had access to. These data were processed with STATA version 14. According to the poll, 160 (55.2%) clinical students self-reported having experienced a sharp injury in the previous year, with 46.6% occurring during clinical practice. Ninety-nine percent of the students received numerous cuts. Fingers (83.1%) and solid needles (72) (45%) were the most commonly affected locations. 124 students (42%) reported working with 15 or more patients every day.

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compared to 197 students.than clinical students did. Students who saw more than fifteen patients in a single day were more likely toThe aforementioned research indicate that needlestick injuries occur frequently among clinical students.

J Yun, et al.78 conducted a National Survey of Sharp Injury Incidence Among Healthcare Professionals in the United States: To better understand medical reporting procedures and causes of underreporting, an online poll designed with poll Monkey and disseminated via MailChimp intends to build on previous research by projecting sharps injury rates across the country.The study's sample included of doctors, fellows, residents, medical professionals, and nurses from various backgrounds. The data was collected using a survey, and the sample was picked at random. Following the survey, 460 persons (15.3%) answered, with 13 deemed ineligible due to incomplete or inconsistent answers. The final study includes data from 447 participants. 59%, according to statistics (n = 263).

A Abalkhail, et al.79 conducted an incidence study of health care workers' knowledge, attitude, and practises regarding needlestick injuries. A Cross-Sectional Research Study in Saudi Arabia's Professional City This study set out to ascertain how frequently medical workers sustain needlestick injuries. A stratified multistage cluster of 786 people was chosen for the sample using a sampling method. Data was collected using a standardised questionnaire, and the analysis was performed using SPSS version 25.0. According to the study's findings, 115.57%, or 91/786, of medical workers sustained needlestick injuries in the previous year. Saudis, women, and nurses were the most commonly injured groups. 52.7% of all injuries were not recorded. Ticks and needles cause approximately 0.7% of all wounds.

M Li, L Huo, et al.80 conducted a longitudinal investigation of the prevalence, emotional impact, and long-term consequences of insulin injection needlestick injury among clinical nurses Shaanxi is a western Chinese province. The purpose of a cross-sectional study was to determine the frequency, psychological tool, and long-term effects of insulin-induced needlesticks on clinical nurses. Nurses comprised the study's sample. These nurses were chosen via random cluster selection, and the study's total sample size

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5389. SPSS version 18.0 was used to evaluate the data collected through the online questionnaire. According to the study's findings, wounds caused 18.7 infections per 1000 nurses. When nurses recapped the needle, the most injuries (42.4%) occurred. In 98.4% of cases, injured nurses acted quickly and responsibly. Only 30.3% of nurses reported their injuries to administrative staff, while 43.2% rejected or ceased the suggested follow-up.

PP Bharti, et al.81 conducted a cross-sectional in a secondary Researchers examined The prevalence of needlestick injuries, their features, and nursing staff awareness in a hospital in North India. The study's objectives were to establish the frequency of needlestick injuries and to assess staff nurses' knowledge of these injuries and the risk factors that accompany them. The study's sample included nurses. A questionnaire was used to collect information from the study's 456 staff nurses, who made up the entire sample. This data was analysed using SPSS statistical software, version 24. According to the study's findings, 66.7% of the hospital's staff nurses were exposed to NSIs while at work. Multivariate binary logistic regression demonstrated a substantial relationship between nursing staff education, needlestick injuries, and

I Deshpande, et al.82 conducted a cross-sectional research to find out how frequently critical care nurses employed in remote tertiary care facilities get needle stick accidents. The study sought to determine the prevalence of needlestick injuries among staff nurses working in rural care units in London. The study's sample comprised of 76 nursing staff members selected using the stratified sampling technique. A survey was used to collect data, which was then examined using descriptive and inferential statistics to arrive at the final conclusion of 76 nursing staff members. In total, 27 (35.5%) of the nursing staff had NSIs. According to 14 (18.4%) nursing staff members, routine medicine administration is the leading cause of needlestick injuries.Above research study concludes that nursing professionals are the key players in both elective and emergency situations. Critical care nurses get needlestick injuries much more frequently than other nurses. Creating awareness and training appropriately is mandatory for critical care nurses.

MA Eltahir, et al.83 conducted a descriptive cross-sectional research study [illegible]

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Researchers investigated the prevalence of needlestick injuries among dentistry students at Qassim University, focusing on their knowledge and attitudes. The study's objective was to analyse common knowledge, attitudes, and needlestick injuries among Qassim University dental students. The study's sample consisted of dental students selected using the total enumeration method. The study used a total sample size of 98 students. Data were acquired using surveys., and SPSS version 23 was utilised for data analysis. The study found that students in different classes were never hurt, injured once, and injured twice in their third year, whereas students in their fourth year were not harmed, injured once, injured twice, and not recalled. The intern dentists reported.

The above study shows that needlestick injuries occur often but are not common among students at Qassim University, and students' knowledge of protective measures is low. The amount of information about risk of NSI cross infection was high.

Z Berhan, et al.84 conducted a cross-sectional study on the study's objective was to evaluate the prevalence of needlestick injuries among healthcare professionals. The study's sample consisted of 318 health care workers recruited using a two-stage selection process.

Data were collected using the self-administered questionnaire, and these data were analysed. The study's outcome was 29.5% (95% CI: 24.2–35.5%) in the one year preceding the survey. 46.0% reported mild injuries, 33.3% reported superficial injuries, and 20.7% reported serious injuries. A suture needle was used.

Düzgöl M, et al.85 conducted a study a cross-sectional study on risk groups for injuries from needlesticks among Children's Hospital medical personnel. The study sought to classify the risk of needlestick injuries among healthcare workers, as well as to identify potential risk groups, protective measures, and prevention techniques. The study's sample size included 249 healthcare practitioners. The data was collected by a standardised questionnaire and evaluated using descriptive and inferential statistics. According to the survey results, nurses were the most likely to get needlestick injuries, followed by those working in the cleaning industry. Healthcare staff are not following the recommended

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safety protocols. Needlestick injuries can be avoided by raising awareness, encouraging education, implementing safe work processes for handling needles and related items, and using safety-featured equipment.

Düzgöl M, et al.85 conducted a study a cross-sectional study on risk groups for injuries from needlesticks among Children's Hospital medical personnel. The study's goal was to identify which healthcare practitioners are more vulnerable to needlestick injuries.Possible risk groups, protection measures, and prevention tactics. The study's sample size included 249 healthcare practitioners. The data was collected by a standardised questionnaire and evaluated using descriptive and inferential statistics. According to the survey results, nurses were the most likely to get needlestick injuries, followed by those working in the cleaning industry. Healthcare staff are not following the recommended safety protocols. Needlestick injuries can be avoided by raising awareness, encouraging education, implementing safe work processes for handling needles and related items, and using safety-featured equipment.

Vaz FS, Salelkar S 86 conducted A cross-sectional study of the knowledge and behaviours of staff nurses in a tertiary care hospital in South India regarding the prevention of needle sticks Finding out how much the general public knew about needlestick injuries was the aim of rearch study. One hundred members of the nursing staff made up the study's sample. The data was collected using a multiple-choice structured questionnaire comprising both open-ended and multiple-choice items, and the analysis was performed using Minitab software, version 19.. The study's conclusions showed that NSI had an 80% response rate and was 45% widespread. Just 24% of the nurses had heard of NSIs, but 90% had heard of how infections spread and 85% had no idea how properly dispose of trash without recapping.

Nesreen Helmy, et al.87 The incidence of needlestick injuries among health ministry nurses in hospitals was evaluated. The research study sought to determine the prevalence of needlestick or sharp stick injuries among nurses working for the Health Ministry and Population. The total sample size for the study was 364 nurses from

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in Dakhlia Governorate. A standardised 18 questionnaire was used to collect data, which participants completed on their own. The data was examined with SPSS (Standards for Statistical Product and Service Solution) version 20.0. The study's findings revealed that 304 (83.6%) of the nurses who were tested had suffered needlestick injury, and that younger nurses had much higher average knowledge scores about needlestick injuries, but their average practice scores were

.

CHAPTER - 3

AIM AND OBJECTIVES

3.1 Aim

 To assess effectiveness on knowledge regarding prevention 3 of needlestick injury among the staff nurses.

3.2 Objectives

1. To assess level of knowledge score regarding needlestick injury among the staff Nurses.

2. To assess effectiveness of educational intervention on knowledge score regarding needlestick injury among the staff Nurses.

3. To associate Pre- test knowledge score among the experimental & control group with their selected demographic variables.

CHAPTER - 4

MATERIAL AND METHODS

A 23 systematic, diligent, scientific, evidenced based method to pursue research in any discipline is called as research methodology. In simple words, it is called as a plan for the research. This chapter consist with the research methodology, the research approach, designs, study setting, population, development and explanation of the tool, development of the online course, technique for gathering data and statistical techniques were used for analyzing the data.

4.1 RESEARCH APPROACH:

The research approach is the broad basic procedure for collecting data in a scientific

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research institute. The research is the vehicle for hypothesis testing or answering research questions. The research approach tells the researcher what and how to collect data, how to analyze the data. To achieve the study's objectives a “Quantitative research approach” was considered most effective.

FIGURE 2: SCHEMATIC PRESENTATION OF STUDY DESIGN.

4.2 RESEARCH DESIGN:

The research design is concerned with overall framework for conducting the study. It helps the investigator in selection of the subjects, manipulation of independent variables, Observation to be made and type of statistical analysis to be used to interpret data. Selection of research design depend upon the condition under with the experiment may be conducted.

According to Pilot and Beck, “Research design is a researcher’s overall plan for answering research questions”, the research design selected for present study is True/classical experimental research design, 1 pre test post test only design will be used to assess how well an educational intervention is working regarding needlestick injury.

Quantitative research design

Group

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Pre-test

Intervention

Post-test

Experimental

√

√

√

Control

√

X

√

4.3 RESEARCH SETTING:

Setting is the physical location and condition in which data collection takes place in the study. The study was carried out in a particular Uttar Pradesh hospital. Varun Arjun Medical College and Hospital in Shahahanpur, Uttar Pradesh, and Rohilkhand Medical College and Hospital are the chosen hospitals. The practicality of completing the research study and availability of samples will determine which hospital is chosen for the investigation.

4.4 STUDY DURATION:

The duration of study was one year which is used for the collecting of data, evaluation and presentation of findings.

4.5 RESEARCH SAMPLE:

Population refers to totality of all the subjects that conform to set of population.

Nurses working Rohilkhand Medical College & Hospital Bareilly, U.P., Nurses working in Varun Arjun Medical College & Hospital Shahjahanpur, U.P. hospital of U.P was selected as sample.

4.6 SAMPLE SIZE:

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The size of sample for the this study was calculated using following formula

N= ( )2 Z1- /2+Z1- 2

(m1 – m2)2

where z=1.96 at 95% confidence, required sample size will be192.16. 220 sample calculated with 20% attrition rate which will be divided into experimental & control group (100 sample in each group).

4.7 SAMPLING TECHNIQUE:

Simple Random Sampling Technique is use in the study, Lottery method were used in the study.

4.8 SAMPLING CRITERIA

Inclusive Criteria:

1. Staff Nurses working in selected hospitals in Bareilly U.P.

2. Staff Nurses willing to take part in a research project.

Exclusive Criteria:

1. Staff Nurses who are working in MRD.

2. Staff Nurses whose age not more than 35 years.

Study Population:

The study population includes staff nurses working in the Rohilkhand Medical College & Hospital & Varun Arjun Medical College & Hospital.

4.9 VARIABLES OF STUDY:

Independent Variable: Educational Intervention regarding needle stick injury & its prevention Among the staff nurses.

Dependent Variable: Knowledge regarding needlestick injury and its prevention Among the staff nurses.

4.10 ETHICAL CONSIDERATION:

1. Before conducting the study, ethical clearance were obtained from institutional ethical committee, Bareilly international university.

2. Permission obtained from the Medical Superintendents of hospitals.

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3. Data collection procedure explained to the subjects and got informed consent, assent and told about the data will be kept confidential and will be used for the research purpose.

4. The subjects were told about the freedom of withdrawing from the study at anytime.

4.11 DATA COLLECTION TECHNIQUE:

The data were collected by using the structured and pre test questionnaire.

4.12 DESCRIPTION OF RESEARCH TOOL

The structured questionnaire consisted of three parts.

Part 1: Demographic tool

Part 2: Structured Knowledge Questionnaire is Discover the knowledge on prevention & management of Needlestick injury.

Tool 1: This section consisted of 7 items on socio-demographic variables with an instruction to participants to put a tick mark (√) against the appropriate choice closely representing their answers.

Demographic variable such as age in year, Gander, Marital Status, working area, Professional Education, Experience, have ever attended any in service education program regarding needlestick injury & Area in which you are working.

Section A: Demographic Data-it includes age, Gender, marital status, working area Professional Education, Experience, you have ever espouse with the needlestick injury.

SECTION A: DEMOGRAPHIC DATA:

Demographic Features of Staff Nurses

Variable

Distribution

1.Age in years

a) 22-25

b) 26-29

c) 30-33

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d) >35

2.Gender

a) Male

b) Female

3.Marital status

a) Married

b) Unmarried

4.Working area

a) ICU

b) Emergency

c) General ward

d) Other

5.Professional Education

c) G.N.M

d) B.SC Nursing

e) M.SC Nursing

a) NPCC

6.Experience

a) 0-2 Years

b) 3-5 Years

c) 6-8 Years

d) >8 Years

7.Have you attended any in service education program regarding needlestick injury? If yes then describe

a) Yes

b) No

Description……

8.Area in which you are working.

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a) Emergency ward

b) Operation theatre

c) Pre & Post operative ward

d) Other

Tool 2: Structured questionnaire contains the knowledge on needlestick injury & its prevention in 6 Aspect. Which is General Item related to Needlesticks injury, Items related to causes of needlesticks injury, Item related to clinical feature, Item related to prevention of needlestick injury, Item related to management of needlestick injury, Item related to follow up care.

BLUE PRINT

Section	Content area	Items on knowledge	No. of questions	Percentage (%)
1	General Item related to Needlesticks injury.	1,2,3,4,5	5	12.5%
2	Items related to causes of Needlestick injury	6,7,8,9,10,	5	12.5%
3				

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Items related to

Clinical feature

11,12,13,14,15,

5

12.5%

4

Items related to 4 prevention of needlestick injury

16,17,18,19,20,21,22,

23,24,25,

10

25%

5

Items related to management of needlestick injury

26,27,28,29,30

5

12.5%

6

Items related to follow up care

31,32,33,34,35,36,37,

38,39,40

10

25%

Total

40

100%

SCORING INTERPRETATION:

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Tool 2: Knowledge questionnaire has 40 multiple choice questions with 4 alternative choices for each. Among them only one choice is right. The correct response is given the score of “One” and for the wrong response “Zero” score is given. The interpretation is those who scores 27 to 40 marks and above in the test is considered adequate knowledge and who scored 14 to 26 marks is considered moderate knowledge and 13 and less than 13 is having inadequate knowledge.

PHASES OF STUDY:

The 12 study was conducted in following phases.

Phase 1: Development of knowledge questionnaire on needlestick injury was done in language English. Reliability of the tool and validity was established.

Phase 2: Pilot study were carried out. Based on this exercise, tool was finalized.

Phase 3: Pre assessment 1 of Knowledge Regarding Needlestick injury among staff nurse in experimental or control group.

Phase 4: Implementation of educational intervention program on needlestick injury & its prevention in experimental group.

Phase 5: Post assessment 1 on knowledge regarding needlestick injury & its prevention in both Experimental & control group was done after 15 days. Assessment of knowledge on needlesticks injury in experimental group by post test.

Phase 6: Analysis of data was done

Step involve in development of knowledge questionnaire were as follows.

a. Review of literature:

Books, journals, articles and published research studies were reviewed to obtain adequate content for Knowledge Questionnaire Needlestick injury & its prevention. There were so many studies conducted about 1 Knowledge Regarding Needlestick injury earlier but no specific tool was available. Hence it has decided to develop a questionnaire to assess the knowledge regarding needlestick wound among staff nurses.

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b. Review of textbooks and online content:

Their search reviewed various text books of needlestick injury& its prevention content to develop questionnaire on needlestick injury& its prevention among staff nurses.

c. Consultation with experts:

Discussion with the expert so emergency management, educator helped their researcher to formulate and includes various it in knowledge questionnaire on needlestick injury & its prevention.

d. Dimensions of knowledge questionnaire on needlestick injury & its prevention:

The following dimensions were addressed in the questionnaire

e. Finalization of items to be incorporated in the questionnaire:

A blue print was made to distribute the items on needlestick injury & its prevention. After obtaining the experts "suggestions and advice the questionnaire was finalized.

f. Content validity of tool:

To ensure the content validity of tool developed by the researcher on 4 prevention of needlestick injury, it was submitted to the experts were requested to give their opinion regarding accuracy, relevancy and appropriateness of items under various dimensions of the tool. The suggestions from the experts were incorporated in the knowledge questionnaire and thus got finalized. The list of experts who validated the tool is placed in the appendix.

Phase 2: Development of module was done.

The step involves in development of lesson plans on needlestick injury & its prevention.

4.13 VALIDATION OF TOOL:

To ensure content validity of the lesson plans they were submitted to experts in area of education, Emergency and nursing. The experts were requested to give their opinion regarding accuracy, relevancy and appropriateness for the content on needlestick injury & its prevention. The corrections given by the experts were incorporated. The item level content validity index (CVIs) ranged from 0.80 - 0.95 & the scale level CVI using

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averaging approach was 0.85

4.14 PRE TESTING OF TOOL:

Pretesting of tool was done on 10 participants to check the difficulty in comprehending the study tool and the finding regarding tool was self –explanatory, simple language and time taken 20 minutes.

4.15 RELIABILITY OF TOOL:

The reliability of tool was determined by split half method and r-value of knowledge questionnaire was 0.87 which shows tool is highly reliable.

Phase 3: Pilot study is to be carried out. Based on this exercise, tools, were finalized. Staff nurses of two hospitals was selected for the pilot study and they were not included for the final study. The pilot study were conducted from 19th June 2021 to 3 July 2022 staff nurses were selected by sampling random technique. Feasibility of tool administration and method of data collection were tested out and found suitable.

The purpose of the pilot study was

To find the feasibility of conducting the final research study.

 To assess the Effectiveness of data collection plan.

 To identify the inadequacies of the plan and make the modification required.

 To determine the method of statistical analysis.

 To find out clarity of tool, education intervention program and time requirement for tool administration.

Pilot study revealed that

 In experimental group majority 80% of the participants has adequate knowledge and in control group none was having adequate knowledge.

Phase 4: Pre assessment of Knowledge Negarding needlestick injury & its prevention among the staff nurse in experimental & control group. Before conducting the study ethical clearance and permission were obtained from institutional ethical committee, Bareilly international university. Permission is obtained from Medical superintendent of

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college & hospital. Informed consent and assent taken from the individual sample and the data were kept confidential and only used for the research purpose. The subjects were told about the freedom of withdrawing from the study at any time. Quantitative data was collected through structured pretested questionnaire for both groups. The total duration given for test is 45 minutes

Phase 5: Implementation of educational intervention program on needlestick injury & its prevention in experimental group

The timing for administering educational intervention is fixed according to the convenience of hospital authorities. Educational intervention is administered only to experimental group. It consist of PPT related to needlestick injury Incidence, infection are caused by needlestick injury, how does needlestick injury is occur, who are the risk if needlestick injury, where the needlestick injury occur, management of needlestick injury, Type of infection is spread by needlestick injury.

Phase 6: Post test knowledge regarding needlestick injury & its prevention in both Experimental & control group was done with an interval of 15 days

4.16 DATA COLLECTION PROCEDURE:

The final study were conducted among the staff nurses from august 2022 to May 2023. Written informed consent were obtained from each study participants by explaining the purpose of study and assuring confidentiality. Data were collected by using a structured and pre-tested 40 knowledge questionnaire, in experimental Group and control group. 100 staff nurses. who were, selected in control group followed by next 100 staff nurses selected in experimental group. Data was collected using a structured and pre-tested 40 knowledge questionnaire in the experimental and control group. Educational intervention implemented through verbal discussion, demonstration, and poster to experimental group only and same was withheld from the control group. Post test were conducted after 7 to 14 days after intervention among both the groups. The average time to complete the session was 20-25 minutes. Descriptive statistics includes frequency, percentage, mean, mean difference and standard deviation was used to describe result. Inferential statistics

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paired t test, unpaired t-test, Chi square test, were used for find the effectiveness and association.

DATA COLLECTION SCHEDULE:

S. No.

Group

Setting

Number of Staff Nurses

Period of Conducting Study

1.

Experimental

Group

(Pilot Study)

Keshalata Hospital Bareilly

10

Permission from the hospitals Authorities- 20/06/2022

Screening:

Pre Test:21/06/2022

Post Test:06/07/2022

(15 Day Gap)

2.

Control Group

(Pilot Study)

Medcity Hospital Bareilly

10

Permission from the hospitals Authorities- 19/06/2022

Screening:

Pre Test:20/06/2022

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Post Test:05/07/2022

(15 Day Gap)

1.

Experimental

Group

RMCH Bareilly

Morning50

Permission from the hospitals Authorities- 05/11/2023

Screening:

Pre Test:06/11/2023

Post Test:04/12/2023

(28 Day Gap)

Evening50

2.

Control Group

Varun Arjun Medical College & Hospital, Shajhanpur

Morning50

Permission from the hospitals Authorities- 07/11/2023

Screening:

Pre Test:08/11/2023

Post Test:06/12/2023

(28 Day Gap)

Data analysis and Interpretation of data

Evening50

4.17 DATA ANALYSIS PROCEDURE:

Objective

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Data collection

Data scoring & analysis

1. To assess level of knowledge regarding needlestick injury Among the staff nurses.

The Knowledge level will be assessed through structured questionnaire in Experimental and control group.

Interpretation

- 0 -13 Inadequate
- 14 -26 Moderate
- 27 -40 Adequate

2. To assess effectiveness on knowledge regarding needlestick injury Among the Nursing staff.

Education intervention will be imparted through the video, and demonstration & and post test conducted in both group.

Un Paired 't' test will be use to check the effectiveness between experimental & control group of score reducing Needlestick injury.

3. To associate pre test knowledge among the experimental & control group with their selected demographic variable.

Pre test knowledge of Experimental & control group will be associated with selected demographic variable such as age, sex, marital status, professional education, experience.

Chi square test will be used for association of level with selected demographical variables.

4.18 SUMMARY OF THE CHAPTER

This chapter deals with the methodology was use for the study. Research approach,research design, study duration, research setting, sample, sample size, sampling technique, sampling criteria, ethical consideration, data collection technique, data collection tool, content validity of tool, pretesting and reliability of the tool, pilot study, Procedure for data collection, Prepare a strategy for interpretation & data analysis.

CHAPTER - 5

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OBSERVATION AND RESULTS

This chapter consists 2 with analysis and interpretation of data gathered from 200 Staff nurses experimental group, control group respectively.

5.1 OBJECTIVES

1. To Assess the level of knowledge score regarding needlestick injury Among the staff Nurses.

2. To evaluate the effectiveness of educational intervention on knowledge regarding prevention of needlestick injury Among the staff nurses.

3. To associate the Pre- test knowledge score Among the experimental and control group with their selected demographic variables.

Quantitative Analysis:

Section A: Description of the demographic variable.

Section 20 B: Effectiveness of Educational Intervention on Knowledge Regarding needlestick injury among the staff nurses.

Section C: Association of demographic characteristics with pre-test knowledge scores in experimental group.

SECTIONA: DESCRIPTIONOFTHEDEMOGRAPHICVARIABLE

Table 1: Description of sample characteristics in term of frequency and percentage (n=100+100)

DEMOGRAPHIC VARIABLE

2 EXPERIMENTAL GROUP

CONTROL GROUP

F

%

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F

%

Age in years

22-25

49

49

46

46

26-29

18

18

21

21

30-33

24

24

16

16

>35

9

9

17

17

Gender

Male

18

18

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33

33

Female

82

82

67

67

Marital Status

Married

14

14

39

39

Unmarried

86

86

61

61

Professional Education

G.N.M

66

66

78

78

B.Sc. Nursing

29

29

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13

13

Post Basic Nursing

4

4

8

8

NPCC

1

1

1

1

Experience

0-2 Years

38

38

37

37

3-5 Years

31

31

27

27

6-8 Years

12

12

25

25

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>8 Years

19

19

11

11

Any in-service education program regarding needle stickinjury?

Yes

31

31

39

39

No

69

69

61

61

Area in which you area working.

Emergency ward

18

18

16

16

Operation Theatre

12

12

13

13

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Post-operative ward

26

26

10

10

Other ward

44

44

61

61

Table 1 depicts that in experimental group, 49% of the participant were belongs to 22-25 years age group and 24 % of the participant were belong to 30-33 years and 18% were belong to 26-29 years age group & 9% belong to more than 35 years.

In control group, 46 % of the participant were belongs to above 22-25 years of age, 21% were belongs to 26-29 years, 17 % of the participant were above 35 years and remaining 16% was belong to 30-33 years.

Figure 3: Percentage distributions of participant according to their age in experimental & control group.

14 Table 1 shows that Experimental Group, majority of the participants.e.82% was female and remaining 18% were male.

In control group, 67 % of the participant were female & 33% of the male.

Figure 4: Percentage distributions of participant according to their gender in experimental & control group

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Table 1 depicts that in experimental group, 86 % of the participant were unmarried, 14% of the participants 14 % were married.

In control group, 61% of the participant were unmarried, 39% were married.

Figure 5: Percentage distributions of participants according to their marital status in experimental & control group

Table 1 depicts that in experimental group, 66% were having GNM qualification, 29% were having B.Sc. nursing degree and 4% were having post basic nursing degree and the remaining 1% having NPCC degree.

In control group, 78% of the participants having GNM qualification, 13% were having B.Sc. nursing degree and 8% We have a post-basic nursing degree and the rest 1% having NPCC degree.

Figure 6: Percentage distributions of participants according with their Professional education in experimental & control group

Table 1 depicts that in experimental group, 38% were having 0-2 years experience, 31% were having 3-5 years experience and 19% were having more then 8 years experience and remaining 12% having 6-8 years experience.

In control group, 37% of the participant were having 0-2 years of experience, 27% were having 3-5 Years of Experience and 25% were having 6-8 year of experience and remaining 11% having more then 8 year of experience.

Figure 7: Percentage distributions of participants according with their Experience in experimental & control group.

Table 1 indicates that. in experimental group, majority of the participant are staff n

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were not participated in any in service educational program and remaining 31% were participated in in-service educational program.

In control group, 61 % of the participant were not participated in any service educational program & 39% of participants are participated in in-service educational program.

Figure 8: Percentage distributions of participants according with their in-service educational program participation status in experimental & control group

Table 1 shows that in experimental group, largest number of participants are that is.44% were working in others wards and remaining 26% were working in post operative ward and 18 % working in emergency & remaining 12% working in operation theater.

In control group, 61% of the participant were working in other wards &16% of participants are working in emergency and 13% were working in operation theater and remaining 10% were working in post operative wards.

Figure 9: Percentage distributions of participants according with their area of Working in experimental & control group

SECTION B: EFFECTIVENESS OF EDUCATIONAL INTERVENTION PROGRAM ON KNOWLEDGE REGARDING NEEDLESTICK INJURY AND ITS PREVENTION AMONG THE STAFF NURSE.

Table 2: Comparison of mean pre-test and post-test knowledge scores of the experimental group. (n= 100)

Test

Range

Mean±SD

Mean

Difference

df

t- value

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(p-value)

Pre-test

38-7=31

13.39 ± 3.635

9.89

99

4.82(0.000)

Post-test

39-10= 29

23.28 ± 4.636

t(99)= 1.99, p<0.05

Table 2 interpreted the mean post test knowledge score (23.28 ± 4.636) of the experimental group was greater than the mean pre-test knowledge score (13.39 ± 3.635) of the experimental group with mean difference of 9.83. The calculated t value was (t=4.82) more than the tabled value (t99=1.99). Hence forth the finding denoted there is significance difference of mean post-test knowledge scores.

Figure 10: Comparison of mean Pre-test and Post-test knowledge scores of the experimental group.

Table 3: Comparison of post-test score of the experimental and control group.

(n=100+100)

Post-test

Range

Mean±SD

Mean

Difference

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DF

t- value

(p-value)

Experimental

Group

39-10= 29

21.22 ± 6.49

11.17

198

4.30(0.00001)

Control

Group

37-8= 29

17.25 ± 6.54

t(198)= 1.99, p<0.05

Table 3 explicated average mean post-test knowledge score (21.22 ± 6.49) of the experimental group were higher than the post test knowledge score (17.25 ± 6.54) of control group with the mean difference was 11.17. The calculated t value was (t=4.30) greater than the tabled value (t198= 1.99). Indicating there is significance difference in average mean post-test knowledge scores.

Figure 11: Comparison of mean post-test knowledge scores of the experimental and control group

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SECTION C: ASSOCIATION OF DEMOGRAPHIC CHARACTERISTICS WITH PRE-TEST KNOWLEDGE SCORES.

Table 4: Association of demographic characteristics of experimental group with pre-test knowledge scores

S.

No.

Socio-

demographic

Variable

Total

Sample

(n)

Level of Knowledge

Chi

Square

Table

Value,

Df

Chi

Square

Value,

(p) Value

Adequate

Moderate

Inadequate

F

%

F

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%

F

%

1.

Age

22-25 years

26-29 years

30-33 years

>35 years

49

18

24

9

6

4

4

2

6

4

4

2

27

10

14

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5

27

10

14

5

16

4

6

2

16

4

6

2

12.59,

6

1.90,

(0.050)NS

2.

Gender

Male

Female

18

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82

5

11

5

11

5

51

5

51

8

20

8

20

5.99,

2

7.145,

(0.050)

3.

Marital Status

Married

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Unmarried

14

86

4

12

4

12

7

49

7

49

3

25

3

25

5.99,

2 NS

1.96,

(0.050)NS

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4.

Professional Education

G.N.M.

B.Sc. Nursing

Post Basic Nursing

NPCC

66

29

4

1

12

4

0

0

12

4

0

0

37

16

2

1

37

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12.59,

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2.64,

(0.050)NS

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Experience

0-2 Years

3-5 Year

6-8Year

> 8 Year

38

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5.99,

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Area In Which You Are Working

Emergency Ward

Operation Theatre

Post operative ward

Other Ward

18

12

36

44

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Table 4 depicts that association of socio-demographic characteristics of Experimental group with pre-test knowledge score. The analysis revealed the there was statistical significant association established with the gender and no association established with rest of the selected socio-demographic variables.

Table 5: Association of demographic characteristics of control group with 1 the pre-test knowledge score.

S.

No.

Socio-

demographic

Variable

Total

Sample

(n)

Level of Knowledge

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Chi

Square

Table

Value,

Df

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Value,

(p) Value

Adequate

Moderate

Inadequate

F

%

F

%

F

%

1.

Age

22-25 years

26-29 years

30-33 years

>35 years

46

21

16

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2.

Gender

Male

Female

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67

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Marital Status

Married

Unmarried

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Professional Education

G.N.M.

B.Sc. Nursing

Post Basic Nursing

NPCC

78

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5.

Experience

0-2 Years

3-5 Year

6-8Year

> 8 Year

37

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6.

Inservice Education Program Regarding Needlestick Injury

Yes

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Area In Which You Are Working

Emergency Ward

Operation Theatre

Post operative ward

Other Ward

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Table 5 depicts that association of socio-demographic characteristics of control group with pre-test knowledge score. The analysis showed 14 that there was statistically significant association established with the Marital status and no association established with rest of the selected socio-demographic variables.

SUMMARY:

This chapter deals with gathering, analysis was done for determining the effectiveness of educational intervention 1 on knowledge regarding needlestick injury among staff nurses and its prevention (In experimental & control group).

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CHAPTER - 6

DISCUSSION

This chapter presents a discussion with similar studies, conclusion, implications, limitations, recommendations and summary.

DISCUSSION

The findings of present study discussed with other related study and organized under following sections:

6.1 SECTION A: DESCRIPTION OF THE SAMPLE CHARACTERISTICS:

Majority of the staff nurses in experimental group i.e. 49 % were belongs to age group of 22 – 25 years and in control group 46 % of the participant were belong to 22-25 years of age. In experimental group majority 82 % were female and in control group also 67 % of participant was female. In experimental group majority of 86% of the participants were unmarried and in control group 61 % of participants were also unmarried. In experimental group,66% of the participants were GNM and in control group majority i.e 78% were also GNM. In the experimental group majority of staff nurses 38% were having 0-2 year of experience and in control group 37 % of the participants were also having 0-2 years of experience. In experimental group,69% of participant were not participants in in-service education program and in control group majority i.e 61% were also were not participated in in-service education program. In experimental group vast of staff nurses 44 % were working in another wards and in control group 61 % of participants working in other ward. Findings of present study in similar with study conducted by Shil R, Upashe SP88, (2020) to assess the impact of structure teaching program (STP) on nursing students' understanding of needlestick injuries. The study's findings show that pre-test total mean score was 5.41 with a standard deviation of 3.29, and the post-test score found to be higher. With standard deviation of 3.71, the total mean score increased to 14.10. Between pre-test and post-test, there was an average difference of 8.69. At the p>0.05 level, the calculated "t" value of 35.58 is significant. This shows that structured education program was successful in raising nursing students' knowledge level regarding needlestick

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6.2 SECTION B: EFFECTIVENESS OF EDUCATIONAL INTERVENTION PROGRAM ON KNOWLEDGE REGARDING NEEDLESTICK INJURY AND ITS PREVENTION AMONG THE STAFF NURSES.

Present study shoes that the mean post test knowledge score (21.22 ± 6.49) of experimental group was greater than mean post-test knowledge score (17.25 ± 6.54) the control group with mean difference of 7.56. The calculated t value was (t=4.30) more than tabled value (t198 = 1.99). Hence there is significance difference in mean post-test knowledge scores. So, it revealed that the educational intervention was effective in enhancing knowledge of staff nurses regarding needlestick injury and its prevention. Findings of the present study in similar with study conducted by Shil R, Upashe SP, (2020)88 to assess the impact of a structured education program on nursing students' awareness of needle stick injuries. According to the study's findings, the pre-test total mean score was 5.41 with a 3.29 standard deviation, while the post-test total mean score improved to 14.10 with a 3.71 SD. Pre- and post-test results had an average difference of 8.69. At the p>0.05 level, the calculated 't' value of 35.58 is significant. This shows that structured education program was successful in raising nursing students' understanding of needlestick injuries.

6.3 CONCLUSION:

The present study concluded that structured teaching program was effective in enhancing the knowledge, regarding prevention of Needlestick injury among the staff nurses. Awareness was created among the staff nurses. The nursing educator can use the results of study and can improve the knowledge level and can create awareness regarding prevention of Needlestick Injury among the staff nurses. In order to prevent needlestick injuries, nurses can increase their knowledge. Future researchers can use the study's findings to assist them conduct qualitative research. The same study can be carried out in college of nursing area. A comparison between medical and paramedical fields can be made, and the same study can be duplicated on large samples, allowing results to be generalized.

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6.4 IMPLICATIONS OF THE STUDY:

NURSING EDUCATION

As the society is highly technologically develop than ever before, and no indication that this tendency will abate., prevention Needlestick injuries are quite important. So, curriculum in nursing should consist of subject related to which will enhance the knowledge of staff nurse regarding needlestick injury and its prevention. Nurse educator with certification on needlestick injury can help in planning the ideal way of implementing educational intervention on needlestick injury to the nurses in hospitals.

NURSING PRACTICE

In areas of nursing practice nurses:

- Should be trained regarding prevention of needlestick injury.
- Should conduct special lectures, in-service education and continuing education on knowledge on prevention of needlestick injury
- Should involve courses related to prevention of needlestick injury.
- Nurses must realize and accept the teaching role, as the members of the society are aware that it is their right to be informed and they need to know more about prevention of needlestick injury.
- Screening for victims of needlestick injuries.
- and proper counseling to be given to them.
- By recognizing the health problems of needlestick injury the nurse should assisted focus on therapy.
- Needle stick injury reporting could overcome the problem of issues.

NURSING ADMINISTRATION

- The nurse administrator should conduct on educational program regarding needlestick injury and its prevention to safe.
- The nurse administrator should plan, organize and conduct IEC activities to motivate nurses in conducting awareness program Regarding Needle stick injury & its Prevention.

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 The nurse administrator should organize seminars, workshop and other educational program for staff nurses as a part of in-service education program.

 School/ College educational program should conduct to educate about needlestick safety.

NURSING RESEARCH

 Nursing students should do extensive research in this area to find out effectiveness of educational intervention program regarding needlestick injury and its prevention as there is very less research conducted in this area.

 More number of nurses researches on needlestick injury and prevention and its management to been courage for nurses students.

 Many such research studies could be conducted in large scale.

6.5 LIMITATIONS

 Due to the constraint, there searcher has selected only Nurses.

 The study limited to 200 samples.

 Investigator had no control on the answer given by the sample since data collection. However, the presence of control group who also had equal chance of getting such information helped to overcome such biases.

6.6 RECOMMENDATIONS FOR FUTURE RESEARCH AND SUGGESTION

Future Research is needed to determine

 Authenticated survey to be done in India to find out real statistic so impact on health effect related to Needlestick injury and its Prevention.

 A study should be conducted to evaluate effectiveness of educational intervention program on large sample.

 A study should be done to explore factors contributing to needlestick injury.

 Large scale prevalence study on needlestick injury can be done at national level and worldwide.

 A study should be done for find out the prevalence needlestick injury.

 Similar study should be done between different levels of college level.

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 Similar study should be conducted by taking samples from two different settings like, government hospitals and private hospitals and compare them.

 A study should be done to explore the factors contributing of needlestick injury.

CHAPTER - 7

SUMMARY AND CONCLUSION

SUMMARY

It includes systematic activities carried out throughout the study. The goal of the current study was to Evaluate the impact of an educational intervention on staff nurses' understanding of Needlestick Injuries and how to prevent them.

To achieve this investigator formulated the objectives as follows

1. To assess the level of knowledge needle stick injury Among the staff Nurses.
2. To assess the effectiveness of educational intervention on knowledge regarding needle stick injury Among the staff Nurses.
3. To associate the Pre- test knowledge among the experimental and control group with their selected demographic variables.

The investigator reviewed the literatures to support the study as well as result of the study. It was in 3 parts

Section 1: Literature related to knowledge related to needlestick injury

Section 2: Literature related to educational interventions related to needlestick injury

Section 3: Literature related Causes & Incidence related to needlestick injury

The conceptual framework chosen for study were based on general system Model of course evaluation. The concepts of these models were modified and utilized for present study. The research approach chosen for study was quantative research approach, Explanatory. In this study200 samples was selected from the hospitals.

The prepared tool was in 2 parts.

Part 1: Demographic tool.

Part 2: Structured questionnaire to find out knowledge on needlestick injury &

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prevention.

Content validity was obtained from 10 experts. The reliability of tool was determined by test-retest method and r-value of knowledge questionnaire was 0.79, which showed the tool was highly reliable.

Pilot study was done on ten percent of the samples. The pilot study showed feasibility in conducting the study. Few modifications were done in the study with expert's suggestions.

The primary purpose of the study was to assess the efficacy of an educational intervention aimed at increasing staff nurses' knowledge of needlestick injuries and how to prevent them. The gathered information was coded, and both inferential and descriptive statistics were used for analysis.

The findings of study was in experimental group,

AGE: 49% of participants was belong to 22-25 years age group, 24 % were belongs to 30-33years, 18%of the participants were belong to 26-29years or 9 % participants belong to more than 35 years.

GENDER: 82% participants are female and 18% participants are male

MARRITAL STATUS: 86% Participants' was Unmarried and remaining 14% participants' was married.

PROFESSIONAL EDUCATION: 66% Participants' was GNM, 29% participants weas B.Sc. Nursing or 4% participants was Post Basic Nursing and 1% were NPCC.

EXPERIENCE: 38%Participants having 0-2 year of exprience,31% having 3-5 years of experience 19% participants' having more than 8 year of experience and remaining 12% having 6-8 years of experience.

INSERVICE EDUCATION PROGRAM REGARDING NEEDLE STICK INJURY: 69% Participants does not participated in service educational program regarding Needlestick Injury and remaining 31% participants were participated in in-service educational program related to needlestick injury.

AREA IN WHICH YOU ARE WORKING

44% Participants were working in other ward, 26% participants were working in ICU

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operative wards,18% participants were working in emergency ward and remaining 12% participants were working in operation theatre.

In Control group:

AGE: 46% of the participant were belong to 22-25 years age group21 %of the participants were belong to 26-29years, 17% participant belong to more than 35 years, 16 % were belongs to 30-33years.

GENDER: 67% participants are female and 33% participants are male

MARRITAL STATUS: 61% Participants' are Unmarried and remaining 39% participants' are married.

PROFESSIONAL EDUCATION: 78%Participents were GNM, 13% participants were B.Sc. Nursing or 8% participants were Post Basic Nursing and 1% were NPCC.

EXPERIENCE: 37%Participants having 0-2 years of experience,27% having 3-5 years of experience and11 % participants' having more than 8 years experience and remaining 25% having 6-8 years of experience.

INSERVICE EDUCATION PROGRAM 9 REGARDING NEEDLE STICK INJURY: 61% Participants does not participated in any in service educational program related to needlestick injury and remaining 39% participants were participated in in-service educational program related to needlestick injury.

AREA IN WHICH YOU ARE WORKING

61% Participants were working in other ward, 10% participants were working in post operative wards,16% participants were working in emergency ward and remaining 13% participants were working in operation theatre.

1 To assess the Effectiveness of educational intervention program on knowledge regarding needlestick injury Among the staff nurses.

The mean post test knowledge score (23.28 ± 4.63) 2 of the experimental group was greater than mean pre test knowledge score (13.39 ± 3.63) of the experimental group with mean difference of 9.53. The calculated t value was (t=4.82) more than tabled value (t99=1.98). The average 9 mean post-test knowledge score (21.22 ± 6.49) of the

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experimental group was higher than mean post-test knowledge score (17.25±6.54)of the control group with them difference of 10.89.The calculated t value was(t=4.30)greater than the tabled value (t198=1.99)

Association of demographic characteristics with pre-test knowledge scores.

 Among all demographic variables was no 33 Significant Association with pre-test knowledge score at p = 0.004* in experimental group.

 Among all the demographic variable 2 there was No significant association with the pre-test knowledge scores at p=0.006 in control group

CONCLUSION

The following conclusions were drawn on the basis of finding of study. The comparison of pre & post tests knowledge, in experimental & control group showed that, in experimental group 15 the post test scores were increased and its was supported by Findings of the qualitative study revealed that the staff nurses got benefited by educational intervention as their knowledge on 4 Prevention of Needlestick Injury were increased. It proved that the educational intervention about the prevention of needlestick injury effective. It was also seen that these was Statistically Significant association between selected socio demographic variable 2 in experimental group and in control group. It could be concluded that educational intervention was useful for developing knowledge as they perceived by educational intervention regarding 4 prevention of needlestick injury.

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I. INTRODUCTION

Diarrheal diseases continue to be a major concern for developing countries. An estimated 248 million episodes of diarrhea occurs every year in children under 5 years [2]. Viruses are the major cause of acute diarrhea in both developed and developing nations.

Acute diarrheal disease is among the leading cause of mortality in children under 5-year accounting 13% of the mortality.

A diversity wide enough, these diarrheal agents include non-infectious (e.g., toxins) and infectious agents (bacterial, protozoal, and viral). (Elliott, 2007; Nawaz et al., 2012). Globally, the commonest bacterial pathogens causing gastroenteritis are Campylobacter spp (especially Campylobacter jejuni), Vibrio cholerae (the cause for cholera), Salmonella spp, including Salmonella typhi (typhoid fever), Shigella spp, Yersinia enterocolitica, and a variety of enteropathogenic Escherichia coli strains, including the enterotoxigenic E. coli i.e. ETEC strain (Elliott, 2007).

The intestinal protozoan like Giardia intestinalis, Cryptosporidium and Entamoeba histolytica also known to cause diarrheal illness (Elliott, 2007; Einarsson et al., 2016; Squire and Ryan, 2017).

In high- income countries, viruses account for the majority of gastrointestinal infections, with about 70% of disease reported to be of viral origin (Elliott, 2007; Kotloff et al., 2013). Among the viral agents, rotaviruses and noroviruses, together with adenoviruses, astroviruses, and sapoviruses are the major etiological agents of viral gastroenteritis in children (Iturriza- Gomara et al., 2008).

Whereas, in low and middle-income countries, bacterial and protozoal pathogens also play an important role (Elliott, 2007). The 20 Global Enteric Multicenter Study (GEMS) conducted in sub-Saharan Africa and south Asia, found most cases of severe diarrhea were associated with one of four pathogens: rotavirus, Cryptosporidium, ETEC producing heat stable toxin (ST-ETEC; with or without co- expression of heat-labile enterotoxin) along with Shigella (Kotloff et al., 2013). Cryptosporidium was second only to rotavirus as

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contributor to moderate-to-severe diarrheal disease in their particular study.

India has an estimated 457,000-884,000 hospitalizations and 2 million outpatients visits for diarrhea. Annually around 334,000 death happens in children due to diarrhea of which 98,000 is for rotavirus alone.

I.A. ROTAVIRUSES

Rotaviruses were discovered originally in the intestinal tissue of mice in 1963. In 1973, Ruth Bishop and her colleagues published a paper in the Lancet stating virus particles in epithelial cells of the duodenum mucosa of children with acute non-bacterial gastroenteritis.

Ian Holmes, an electron microscopist saw round wheel like structure among the samples provided by Bishop after a period of two years. He met Minnie Mathan in south of India and taught her to identify these viruses at Christian Medical College (CMC), Vellore .The first paper of Rotavirus was published in Indian in the year 1977, as the virus was linked with 26% of the viral gastroenteritis. Shortly Dr Paniker in Calicut contacted Dr Mathan for analyzing samples against an outbreak from gastroenteritis, where they identified the causative agent to be Rotavirus which was seasonal.

I.A.a. Rotavirus Characteristics

I.A.a.i. Morphology

The Rotavirus genus belongs to the family Reoviridae. The virus particles are 70 nm in diameter which has non-enveloped icosahedral structures, and a triple-layered capsid. When visualized by electron microscopy they have the appearance of a 'wheel' (Figure 1). The genome of the virus constitutes 11 segments of double-stranded RNA, which codes for six structural (VP1, 2,3, 4, 6, and 7) and six non-structural proteins (NSP1–6) (Wilhelmi et al.,2003).

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Fig 1. Structure of Rotavirus

The segmented genome of rotavirus readily reassorts during coinfection, a property that has been used in developing vaccines and undoubtedly portrays virus evolution.

The capsid proteins of the virus are responsible for the major antigenic properties of rotaviruses. It comprises of seven major groups (A-G). Majority of the strains causing infection in humans are from group A. Occasional cases of groups B and C rotavirus causing human infection has been linked. GS6 in Group-A rotaviruses encodes VP6. This VP6 is the major viral protein and also the major target of common diagnostic tools. The outer capsid proteins, VP7or G-protein and VP4 or P-protein decides serotype specificity and also the basis of the binary classification (G and P type) of rotaviruses. G and P proteins induces neutralizing antibodies and perhaps involved in protective immunity.

I.A.a. ii. Strains of Rotavirus

Fourteen G serotypes of rotavirus, 10 of which occur in humans, have been defined by cross-neutralization studies

Eight P serotypes of human rotaviruses have been characterized. Also there have been other variants of VP4 gene that has been detected which makes the number of P serotypes more than 20.

Theoretically, a total of 80 different strains could result by combining the known 10 G and 8 P serotypes od rotavirus found in human. For vaccine development purposes, it is fortunate that only four common strains G1 P[8]; G3 P[8]; G4 P[8]; and G2 P[4] of rotavirus predominate globally.

However, the strains of rotavirus and its prevalence varies considerably from one geographic area to another. Unusual strains have been frequent 11 in many of the developing countries.

I.A.a.iii. Viability of Rotavirus

The virus remains viable in the environment, hence can survive and remain infectious on non-porous materials (glass, stainless steel, a smooth or rough plastic) at least 10 days at 4 and22 °C, 9 and at least 6 days at 36°C.

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I.A.a.iv. Transmission of Virus

3 Rotavirus is shed in large quantities in stools during episodes of rotavirus-associated diarrhea. Transmission of the virus is majorly by the fecal–oral route, mainly by close person-to-person contact, and few virions are needed to cause disease in susceptible hosts. Fomites leads to transmission of rotavirus in day care centers and hospitals.

I.A.b. Epidemiology

Rotaviruses are ubiquitous; 95% of children worldwide are infected by 3 to 5 years of age and high infection rates were documented in newborns.

The frequency of clinical illness is high among children in the age group of 4 to 36 months. The risk of this age group being hospitalized are also high due to severe rotavirus infection. In temperate climates, fall and winters seems to have 1 the highest number of rotavirus associated diarrhea; in developing countries and tropics, infection are less marked by seasonality. The activity of Rotavirus infections 2 in the United States is at its peak and starts at the Southwest in autumn i.e. (October through December) and ends in Northeast during spring i.e. (March through May). The reason behind this pattern is unknown. Rotaviruses shedding in stool is high during episodes of diarrhea. Detection of Rotavirus is usually done through antigen enzyme immunoassays (EIA) till onr week after infection. Detection beyond 30 days can be done in the immunocompromised patients.

I.A.c. Pathogenesis and Immunity

Infection of Rotaviruses is of the upper 2/3rd of small intestine along the absorptive villous epithelium After replication in the upper small intestine, infectious particles are released into the intestinal lumen and undergo further replication in the distal areas of the small intestine. Despite rotaviruses being present in the lamina propria and the regional lymphatics, replication is absent at these sites. Systemic spread in immunocompetent persons are rare.

In infants and young children, neutralizing antibodies directed primarily against the G serotype of the infecting strain (homotypic response) develop after primary infection with rotavirus. Repeat rotavirus infections elicit both a homotypic and heterotypic [illegible]

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different strains of G serotypes) antibody response. The rise in serum antibody titre due to natural infection in young children is protective against rotavirus diarrhea. Titre against similar G serotype are more protective against similar infection rather that a different G serotype. [2] A protective role of placentally transferred maternal antibody among infants < 3 months of age has also been speculated since rotavirus disease is rare in this age group. However, the neutralizing antibody among vaccine recipients have sometimes been poorly correlated with disease protection; therefore, serum antibody's exact role in disease protection remains unclear and doubtful.

I.B. ROTAVIRUS VACCINES

WHO recommends routine rotavirus vaccination to all infants against the vaccine preventable infectious disease. These rotavirus vaccines aim to mimic natural rotavirus infection, and to provide partial immunity for protecting [2] against moderate to severe disease.

I.B.i. Human-Animal Reassortant Rotavirus Vaccine

1. Human-rhesus reassortant Vaccine: RotaShield® (Wyeth Laboratories, Marietta, PA, USA), the first vaccine licensed for rotavirus, was developed by coinfecting cell cultures with rhesus rotavirus strain (MMU18006) (G3) and human rotavirus strains D (G1), DS-1(G2), and ST3 (G4) (Estes and Cohen, 1989). It contains three reassortant viruses expressing human serotypes G1, G2, and G4 combined with rhesus rotavirus serotype G3, which is immunologically similar to human G3 (Bines, Patel, & Parashar, 2009). In a vaccine trial conducted in Venezuela, the efficacy of RotaShield was 48% against a first episode of rotavirus diarrhoea. However, it gave 88% protection against severe diarrhoea, 75% protection against dehydration, and produced a 70% reduction in hospital admissions. Unfortunately, RotaShield was withdrawn withing 9 months into the national vaccination program in the USA because of an unexpected strong association with intussusception (about 1 in 12,000 vaccine recipients) in 1999 (Bines, Patel, & Parashar, 2009

2. Human-bovine reassortant vaccine: RotaTeq® (Merck and Co, Whitehouse Station, NJ, USA) is a live, oral multivalent human- bovine reassortant vaccine that contains five

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attenuated reassortant rotaviruses. Four different rotaviruses express the most common human rotavirus A G-types, 1 G1, G2, G3 and G4, and the fifth variant of the virus expresses the single most common human rotavirusa P-type, P[8]. Licensed first in the USA in 2006, it consists of three doses, which are administered beginning at 6-12 weeks of ages, followed by the subsequent doses at a 4-10 weeks interval, and with the last dose administered before 32 weeks. During 2001- 2004, over 70,000 healthy infants were randomized in a Rotavirus Efficacy and Safety Trial conducted in 11 countries. The data showed that the efficacy of RotaTeq vaccine in preventing severe disease of rotavirus was 98% (95%CI 88-100), and 74% (95%CI 67-79) against rotavirus disease of any severity (Vesikari et al., 2006). 2 This vaccine was licensed in the U.S. in 2006.

I.B.ii. Live Attenuated Human Vaccine

Rotarix® (Glaxo-SmithKline Biologicals, Rixensart, Belgium) is a single-strain live, attenuated human G1P[8] vaccine. This vaccine was first licensed globally in Mexico in 2005 and in the USA in 2008. The Rotarix vaccine is administrated as a two-dose oral series, which is given to infants beginning at 6-weeks of age, followed by the second dose administered after a minimum 4 weeks interval and before 24-weeks of age. 2 An efficacy trial of approximately 4,000 infants in six European countries showed a vaccine efficacy of 87.1% (95% confidence interval (CI) 80–92) against rotavirus disease of any severity, and 90% (95% CI 85–94) against severe disease (Vesikari et al., 2007).

I.B.a Effectiveness of Live rotavirus vaccine, RotaTeq and Rotarix

Both RotaTeq and Rotarix are available internationally and recommended by the WHO for all infants worldwide to decrease the global burden of rotavirus disease (WHO, 2013). By the end of 2020, rotavirus vaccination was implemented in national vaccination programs in 106 (44.8%) countries (Figure 2). It has been reported that Rotarix and RotaTeq exhibit similar effectiveness against the homotypic as well as heterotypic rotavirus strains (Leshem et al., 2014). Since the introduction of rotavirus vaccines into national

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immunization programs from 2006, substantial reductions have been seen in the number of children having severe and fatal diarrhea in low-middle to high income countries (Patel et al., 2011). India became the first Asian country to implement the Rotavirus vaccination on April, 2016.

Multiple nations have introduced rotavirus vaccination in their national programs, January 2020 [54]. Global Alliance for Vaccines and Immunization (GAVI) is the organisation that supports immunization projects in countries thought the world

Fig 2. Global Status of Rotavirus Vaccination

I.B.b Progress for new vaccines

I.B.b.i. Indigenous human-bovine reassortant vaccine

ROTAVAC uses the strain 116 which has been produced Bharat Biotech International Ltd., located in Hyderabad, India. This strain is derived from a natural bovine-human reassortant strain (G9P[11]), which was isolated from Indian neonates. This vaccine is licensed in India after showing an efficacy of 55% among severe cases of rotavirus diarrhea. This vaccine is licensed in India after showing 55% efficacy against severe rotavirus diarrhea, and was included in the Indian universal immunization programme in 2015 as a 3-dose schedule

Lamb vaccine: Lanzhou lamb rotavirus vaccine (LLR-85, Lanzhou Institute of Biological Products) is an attenuated monovalent lamb rotavirus (G10P[12] strain) vaccine (Bai et al., 1994). This vaccine licensed in China is available in the Chinese private market.

I.B.b.ii. Human neonatal rotavirus vaccine

A monovalent vaccine (BRV3-BB, neonatal G3P[6] strain) was developed by Bilsh

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his colleagues (Dennehy et al., 2008). This strain was isolated originally from naturally infected neonates in Melbourne neonatal nurseries. It appears to be attenuated naturally, and provides protection for asymptomatically infected infants against any furthert rotavirus disease (Bishop et a l.,1983). The intention is for BRV3 vaccine to be administrated at birth. A recent phase II study of this vaccine among New Zealander infants demonstrated that it was both immunogenic and well-tolerated when administered as 3 dose schedules, beginning within the first 5 days of life (Bines et al., 2015). Recently, this vaccine underwent further field trials in Indonesia where it was found to have a vaccine efficacy of 75% when administered within the first 5 days of life (Bines et al., 2018; Kirkwood et al., 2017).

I.B.b.iii. Other vaccines

Non-replicating rotavirus vaccines have been considered to avoid the possible rare, yet severe adverse events like intussusception, of live attenuated oral vaccines. For example, monovalent P2-P8 (non-replicating G1P[8] VP8 subunit parenteral rotavirus, PATH) vaccine showed better tolerance and immunogenicity against homologous strains in infants of South African, although it induced only modest or no neutralising antibodies against heterologous group P[4] and P[6] bearing strains respectively (Groome et al., 2017). Importantly, it did not interfere with subsequent immune responses to Rotarix, implying there may be a role for mixed parenteral and oral schedules. Further phase I/II trials of a candidate trivalent P2-VP8 (P[4], P[6], and P[8] are now underway in South Africa. Other approaches such as a heat inactivated human rotavirus (G1P[8] strain) vaccine (CDC, USA) and virus-like particles (VLPs, Baylor college of Medicine, USA) are under development (Velasquez et al., 2015; Kirkwood et al., 2017).

I.C. VIRUSES THAT CAUSE GASTROENTERITIS

I.C.i. Caliciviruses (including Noroviruses and Sapoviruses)

The viruses in the Caliciviridae family are single-stranded, positive-sense RNA viruses

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There are five genera described in this family, in which two (Norovirus and Sapoviruses) infect humans (karst, 2015). Both can cause acute gastroenteritis with varying combinations of diarrhea and vomiting; however, Norovirus causes more disease than Sapoviruses. (Wilhelmi et al., 2003)

I.C.ii. Noroviruses

There are two sizes of viral particles of norovirus observed, with diameters of 30 to 38 nm and 20 to 23 nm were found under EM (Someya, 2011; Lou, 2012). Their genome contains three open reading frames (ORFs 1-3). Norovirus can be separated into six genogroups (I– VI) based on the sequence of the major capsid protein VP1 (which is encoded by ORF-2 and -3) (Robilotti et al., 2015). Within these genogroups, genogroup I, II, and IV (GI, GII and GIV) cause gastroenteritis in humans (Karst et al., 2015). Norovirus was first described by Kapikian et al. in 1972, after an outbreak of gastroenteritis in a school in Norwalk, Ohio (Kapikian et al., 1972).

Norovirus is highly infectious, as exposure to minute amounts of virus carries a high risk of infection (Approximately 50% for a single infectious virus particle) (de Graaf et al., 2016). Transmission is primarily through the fecal–oral route, direct or indirect contact, while airborne spread following vomiting has been associated in some outbreaks. Transmission also happens through ingestion of contaminated food and water . (de Graaf et al., 2016; Patel et al., 2009).

Clinical symptoms include nausea, vomiting, abdominal cramps, myalgia, fever, and non- bloody diarrhoea (Patel et al., 2009). Norovirus infections are generally self-limiting.

I.C.iii. Sapoviruses

Sapovirus was named after Sapporo, Japan where it was first identified by EM in an outbreak of gastroenteritis in a home for infants in 1977 (Chiba et al., 1979). The viral particles are about 30 to 38 nm in diameter, and have icosahedral structures and cup-shaped depressions on the surface (Oka et al., 2015). There are eight sapovirus genogroups (GI- GVIII) reported, and four (GI, GII, GIV and GV) genogroups

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detected among humans (Oka et al., 2015). Sapoviruses has been an infectious agent causing acute gastroenteritis among children and adults worldwide (Oka et al., 2015; Chiba et al., 2000).

Transmission occurs through the fecal-oral route. Clinical symptoms of Sapoviruses infection frequently include diarrhea and vomiting; other symptoms, such as nausea, stomach/abdominal cramps, chills, headache, myalgia, or malaise, are also not uncommon (Oka et al., 2015).

I.C.iii. Adenoviruses

Adenoviruses were first identified from adenoid issue cell culture in the year 1953 by Wallace Rowe and colleagues (Rowe et al., 1953). They belong to the family Adenoviridae. Adenoviruses are non-enveloped DNA viruses, about 70 nm in diameter in size and have an icosahedral symmetrical structure (Wilhelmi et al., 2003; Okitsu-Negishi et al., 2004).

Novel adenoviruses continue to be described, and there are now over 60 different adenovirus types in six species (A-F) described in humans (Matsushima et al., 2013). The two types that are most frequently associated with gastroenteritis are types 40 and 41.

I.C.iv. Astroviruses

Human Astroviruses are within the genera of Mamastrovirus, which belong to the family of Astroviridae. They were initially identified in 1975 in the faeces of children with acute diarrhoea (Wilhelmi et al., 2003; Clark and Mckendrick 2004).

The viral particles were described as 28-41nm in diameter, non-enveloped, and have a five or six-pointed star structure (Bosch, 2014). The genome of Astroviruses is a single-stranded positive sense RNA molecule containing three open reading frames (ORFs): ORF1a, ORF1b, and ORF2 (Clark and Mckendrick 2004).

Astroviruses are transmitted via the fecal oral route (Dennehy,2011). Symptoms associated with astroviruses infections include a mild and watery diarrhea that lasts for 2 to 3 days along with vomiting, fever, anorexia, and abdominal pain. While astroviruses may not cause as severe disease as other viruses (i.e. rotavirus, noroviruses), they are

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recognized as endemic pathogens worldwide.

I.D. OTHER VIRUSES, INCLUDING RESPIRATORY VIRUSES FOUND IN FECES

I.D.i. Enteroviruses

Enteroviruses are a genus of the Picornaviridae family. They are positive-sense ssRNA viruses and comprise a large group of immunologically distinct serotypes belonging to four species; polioviruses, coxsackie viruses, echoviruses and the enteroviruses (Christensen et al., 2003; Hsiung and Wang., 2000; Murray and Baron, 2003). Enterovirus infections can range from subclinical disease, febrile illnesses with a rash or mild upper respiratory symptoms through to meningitis, encephalitis, hepatitis, myocarditis and severe sepsis-like illness with multi-organ failure (Christensen et al., 2003).

The bowel is the main site of enterovirus replication, and protracted detection of enterovirus in stool for several weeks is well recognized (Cinek et al., 2006). However, although enteroviruses may persist in the bowel, it is considered that they do not produce significant amounts of diarrheal illness in humans (Cukor and Blacklow, 1984).

I.D.ii. Bocaviruses

The recently discovered human bocaviruses (HBoV) have been classified into the bocavirus genus. HBoV was first discovered by Allanderin 2005 from pooled nasopharyngeal aspirate from children with acute respiratory tract infections. In 2009-2010, there were three other species of human bocaviruses (HBoV2, 3, 4) identified, expanding this genus to four species (Jartti et al., 2012).

Human bocaviruses have been detected from a variety of specimens. Contrary to HBoV1, which is typically found in respiratory samples, other species (HBoV2-4) have been mainly detected in human stool (Nawaz et al., 2012; Arthur et al., 2009; Kapoor et al., 2010). However, these viruses are usually co-detected with other potential pathogens and whether they are genuine enteric pathogens, facilitate infection by other viruses or simply are shed asymptomatically remains to be accessed (Melamed et al., 2017).

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I.D.iii. Coronaviruses

Coronaviruses are medium-sized, lipid-containing, enveloped RNA viruses (Kahn & McIntosh, 2005). The traditional thinking was that the coronavirus family only caused the common cold (up to a third of all coryzal illness in humans), with HCoV-OC43 and 229E only occasionally associated with 16 gastroenteritis among young children from low and middle-income countries and the immunocompromised.

In the year 2002-2003, this changed when the 23 severe acute respiratory syndrome coronavirus (SARS-CoV) emerged in the Guangdong province of China (Walker et al., 2013); in addition to severe respiratory disease, this new coronavirus also caused significant gastrointestinal symptoms.

The above section has described the various viral etiological agents found in the Gastro-intestinal tract, where these viruses may be co-present with other potential pathogens. Majorly the diarrheal disease organism include rotavirus, noroviruses, AdV- F, astrovirus and sapovirus. However, other viruses (Eg., enterovirus) and respiratory viruses are also found in feces (eg., HBoV and HCoV). These viruses may also be responsible for acute gastroenteritis.

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II. REVIEW OF LITERATURE

One of the major upliftment that 21st century faced was the increase in life expectancy from 40 years in the 19th-20th century to around 70 years.

Survival does have a link to economic status, health care, education, level of income the country accompanying war and civil unrest. Often the health care system is inflicted with health care problems which affects the population at large. Two of the extreme population are at the receiving side i.e., the Pediatrics and the Geriatric. The pediatric population being vulnerable to infections due to microorganism, majority of mortality among children is by diarrhea and Rotavirus being the common infective agent.

A morphology similar to Rotavirus was reported in the dairy claves at 1969.Few years later Ruth Bishop's publication in Lancet about a virus in the children at duodenal mucosa which caused non-bacterial gastroenteritis was a remarkable finding in the year 1973. After a couple of years, Ian Holmes (electron microscopist) who discovered the round wheel structure provided by Bishop in his visit to South India at Christian Medical College taught Dr. Minnie Mathan to detect these distinctive structures.

North American countries constitutes around 23 countries where USA, Mexico and Canada absorb the maximum population. USA was the first few countries to bring 28 in the Rotavirus vaccine.

Before 2006, every U.S. child got infected with rotavirus around 4 the age of 5 years. [1-3]. Majority of the cases of severe gastroenteritis among U.S. children in this age group, as was a result of Rotavirus Infection. This resulted an estimated 205,000–272,000 emergency department (ED)visits, 55,000–70,000 hospitalizations, and 20–60 deaths annually [2–8]. An average estimated cost was estimated to cost around US$ 1 billion annually due rotavirus gastroenteritis [9].

A survey done between the period of 2005-2008 i.e., pre and post vaccination era. Multiple sites were involved in sample collection, during 2005–2006 and 2006–2007 seasons. In the year 2005–2006, positive samples of 438 of 479 (91.4%) were confirmed as W

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of 562 (87.7%), 2006–2007, 179 of 207 (86.5%) in 2007–2008 in the consecutive years respectively, with turn over of a total of 1110 EIA confirmed positive specimens for rotavirus. This suggests a decline in the Rotavirus infection among children.

Even though in the 2007–2008 season, G1 dominated, G3 was the most frequent strain to be seen. [12] The common four genotypes detected in every season were G1P [8], G2P [4], G3P [8], and G9P [8]. Some uncommon strains were also observed during the study period and those are G2P [8], G1P [6], G2P [6], G4P [6], G1P [4], G3P [9], G12P [6], and G12P [8]. The mean age of rotavirus cases was increased notably in patients < 3 years old in the 2007–2008 season compared to earlier two seasons. The increased overall prevalence of G3P [8] strains in 2007–2008, the first rotavirus season with reasonable rotavirus vaccine coverage, was consistent with Australian reports of G3 dominance following RotaTeq introduction.

However, the changing strains in both the countries have prevailed with large declines in the severity of rotavirus disease. A continual post vaccine study was suggested for a continual monitoring of the different strains and its emergence.

In Mexico, group A rotavirus (RVA) infections remain the most common cause of severe dehydrating diarrhea in children. [13] Studies from Mexico has suggested that the most prevalent combination was G1P [8] with 57.85% and G2P [4] genotype was detected in a small proportion (2.86%) of the specimens tested. Uncommon strains like G1P[4], G2P[8], G3P[4] were also present in the population among children.[14] Emergence of G12P[8] an uncommon strain has been spotted in Samora, Mexico. [15].

Did the vaccination lead to the reduction in the number of hospitalization and death in children after the vaccination? A study does reflect a portion of the same done along three years of introduction of rotavirus vaccination. About 10,993 diarrheal-related hospitalizations occurred each prevaccine rotavirus season from 2003 to 2006 among children <5 years of age. In 2008 the rate of decline in diarrhea-related hospitalizations was 11% (N = 9836) and continued as 40% (N = 6597) in the year 2009. The greatest declines occurred in infants of age <12 months during 2008 was 25% followed by

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2009, with single dosage of rotavirus vaccination covering 74% and 89%, respectively. A 43% decline was also noted among children 12 to 23 months of age during the 2009 season. No declines were noted during either 2008 or 2009 among unvaccinated children >24 months of age during the study period.

The first ever multicentric study done by Andrew McDermid et al on Rotavirus genotypes in Canada, published their research and it estimated that 1300–1800 days of hospitalization at tertiary care of Canadian pediatric hospitals annually was called for in children with gastroenteritis due to rotavirus infection. [16]

Of the 348 samples that were screened for rotavirus in hospital, 246 (71%) were found to be positive. Overall, the most common genotype encountered in this study was G1P[8], being present in 67% of the specimens. The other common genotypes were G3P[8] (18%) and G2 P[4] (8.5%). The study stated that the current genotyping data indicate that the available vaccines should be serologically well-matched to the prevalent strains of rotavirus, based on the genotype prevalence at these sites. Further continued surveillance is required for an emergence of a newer strain.

In late May 2003, the Jamaican Ministry of Health (MoH) identified a sharp increase in the number of acute gastroenteritis (AGE) cases reported throughout the country, accompanied by increases in AGE-associated hospital admissions and deaths among children. The greatest increase in AGE cases was observed among children aged <5 years in the southeastern parish of Kingston and St. Andrew. [17]. Their detection was mostly based on ELISA and hence genotypes present across could not be found. . Furter after the trials of Rotavirus vaccine among 1804 Jamaican infants, further efficacy data could not be found and neither the prevalent genotype of Rotavirus in that area.

Rotavirus infections gauged for 32% of hospitalizations & 9% of ambulatory visits for diarrhea at Department of Santa Rosa (Guatemala). Thus, resulting in year-long modification of 36 hospitalizations and 372 ambulatory visits per 10,000 children. It was noted that the numbers were, 91% of hospitalizations and 81% of ambulatory visits among the age group of children < 2 years. During 2007-08 & 2008-09 seasonal occurred

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rotavirus, G1P8 genotype constituted for 71% and 95%, respectively.

Things were critical when an outbreak of cholera began in Haiti in October of 2010. In 2012, at Haiti, 3 departments under 4 hospitals started laboratory-enhanced surveillance for diarrheal disease so as to be aware of the progression of epidemic cholera. They tested 1,616 stool samples from 2012 (April) till 2013 (March), Vibrio cholerae-1,030 (63.7%); Shigella-13 (0.8%); Salmonella-6 (0.4%); and Rotavirus-63 (3.9%) of specimens tested positive The rate 10 of positive samples tested among children < 5 years old for rotavirus accounted upto13.5%. Another study, 7173 stool sample were collected, 6257 (87.2%) of them were screened for RVA antigen, out of which 980 (15.7%) tested positive for RVA antigen. Looking at these two different studies, it's obvious that the infection by Rotavirus in this area is lesser as contrasted with the other countries in the continent of North America. [19]

Brazil which falls under South American continent had a review article prior to the initiation of Rotavirus vaccine regarding the morbidity and mortality of children below 5 years. The study found out Rotavirus infections caused and average of 3,525,053 episodes of diarrhea, 655,853 outpatient visits, 92,453 hospitalizations with 850 deaths of children 3 years of age annually in Brazil.[20]

The incorporation of the G1P [8] rotavirus vaccine named Rotarix GlaxoSmithKline-line Biologicals, Belgium by the country Brazil in its 2006 immunization program, led to marked decrease in diarrhea-related morbidity and mortality. The studies that were conducted immediately after the commencement of vaccine outlined that G2P [4] which was a heterotypic strain having lower efficacy in correspondence to the vaccine was the genotype responsible for a high proportion in rotavirus–diarrhea. [21,22] The annual variation of causative genotypes of rotavirus may be reason behind G2[4] strains being as raised shareholder, coupled with selection of heterotypic genotypes for which the vaccine has lower efficacy. [23]

In all regions of Brazil, ante-vaccination and post-vaccination G1P [8] genotype was widely recorded. Since 2000 G5P [8] genotype ceased to appear that was predominantly

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year 1995. Starting from 1996-2000, commonly in Southeast and West-Central regions of Brazil G9 with P [8], P [6] or P [4] was documented which was later found to be found in multiple region subsequently from 2001. G4 with P [6] and P [8] was the often-noted variant from all regions prior to 1995, followed by the Southeast through 1996-2000 and the thereafter since 2001 at South/Southeast & West Central regions. G12P [8] was found to be prevalent in the region of South during 2001-06 and ensuing 2006-15 at the regions of North and Northeast. Out of 5 regions, 4 recorded the occurrence of G2P [4] prior to the vaccination and entirely noted in every 5 region post-vaccination.[24]

Even as their disposition of disease-causing ability changed over time, recurrent combinations observed were G2P [4] (53%), G1P [8] (20%), G9P [8] (10%). G1P [8] was the most frequent strain with 43% ante-vaccination while low frequencies of G9P [8] (22%); G2P [4] (7%) was seen. 8% of all genotypes in 2007-10 and 23% during the course of 2011-16 was accounted by G1P [8]. In the year 1995, ante-vaccination G9P [8] raised from 0%-9; 32% at 1996–2000 & 2001–2006, respectively. The downhill trend post-vaccination to 6% through 2007–10 & 1% in 2011–15 was reported. Earlier to 1995 prevalence of genotype G2P [4] reduced from 19% to 12% & 1% among 1996–2000 & 2001–06 and then contrasted by shooting up to 74% in 2007–10 and plummeted to 45% in 2011–15.

G & P types of Rotaviruses in Brazil have changed significantly in recent decades, with major changes occurring after the rotavirus vaccine introduction. Divergence of genotypes causing infection was recorded efficiently even prior to the introduction of vaccination which showed the changing trends among strains in the time frame of 1-2 years. [6,7] Natural ecology of the disease-causing rotavirus was the foundation for this variation trend. In Europe, e.g., per annum, amidst the peak and nadir rotavirus seasons variations was observed in genotype distributions. [7] Extensively around the globe through the years 1973-2003, 88% of rotavirus infections were brought about by 4 combinations of G & P genotypes viz., G1P [8], G2P [4], G3P [8] and G4P [8], which were counted with varied proportions in generating the disease. To illustrate, North America, Europe and Australia > 70% of cases were instigated by G1P [8], but diminished count of 23%–30% in USA

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like Africa, South America and Asia. Throughout 1990-2006, G9P [8] and G12P [8] rose up to existence universally and this changing trend exemplifies that significant and persistent changes were made out naturally even ante-vaccination in addition to the fact that they were not equivalent geographically. [8]

Another study had genotype G3P [8] was the most prevalent during the two years (83.7% in 2018 and 65.5% in 2019), and nucleotide sequencing of some strains demonstrated that they belonged to the emergent equine-like G3P [8] genotype. The obligation for continual epidemiological surveillance assessing the impact of mass RVA immunization together with observation the raise of new genotypes was necessitated by the prevalence of a dominant potential genotype causing AGE was the implication of the study.

Argentina falling in the same continent introduced Rotarix™ monovalent vaccine for global dispensing and it resulted in steep lowering of all causative cum confirmed rotavirus cases along with prompt majority in the prevalence of the G2P [4] genotype.

In the year 2017-18, where prevalence was equally distributed within various age groups 1183 cases of Rotavirus (13.2%) were identified. Weekly distribution of high positive cases was recorded by end of July and starting of August. The G2P [4] and G3P [8] genotype dominated all through 2007. However, G12P [8] genotype increased during 2018. The identification of seldom visible G9P [4] and G8P [8] strains (that bears DS-1-like genetic backbones) were observed at limited numbers, which was notable. [27,28]

The occurrence of rotavirus in the group of children < 5 years significantly attaining peaks during early spring was seen to be diminished with subsequent universal vaccination for 4 years. Not the emergence of local strain reassortment but newer strains posed as the reason for uncommon genotypes. [27,28]

Colombia recorded 18% reduction in diarrhea-related mortality in children <5 years old in the wake of vaccination programme. [29]. A study in 2002 along the Colombian northern coast about the various genotypes of Rotavirus prevalent in the area. 67.9% of the strains could be typed. G1 (57.9%), was the most predominant VP7 genotype, followed by G3 (21.1%), G9 (15.8%) and G2 (5.3%). 49.1% of P [4] genotype ranked first in strains

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the VP4 genotypes, next off with 36.4% of P [6] & down the line with 14.5% of P [8]. The genotypes which were not detected was G4; G8 and P [9]. 8.8% of G3P [4] & 7.0% of G9P [6] were the frequent G-P combinations, latterly 5.3% of each G1 P [4] and G1 P [8]. The genotypes G3 P [4] and G9 P [6] differed from remaining by displaying the long and short patterns simultaneously of RNA profiles, wherein, all G1 P [8] strains showed only long RNA profiles. 21.0% of strains were associated with mixed infections. The novel strain of G9 along with unconventional combinations of both the 3 G and P genotypes as G9 P [6] and G3 P [4], was collected with striking heterogenicity in strains.

Ten years later in 2014, a multicentric study was done on the effectuality of Rotavirus vaccine those are monovalent in nature. The adjusted effectiveness was 79.19% (95% CI, 23.7 to 94.32) among children with age of 6-11 months & -39.75% (95% CI, -270.67 to 47.24) among those >12 months of age. Against overnight rotavirus hospitalizations, RV1 provided protection of 84.42% (95% CI, 22.68 to 96.86) among children with age of 6-11 months, and -79.49% (95% CI, -555.8 to 51.08) among those >12 months. The strains observed were, 57% were G2P [4], 9.8% G9P [8], 6% G9P [6]. [31].

In 2019, a study based on vaccinated children (86.2%) showed the prevalence of infection by Rotavirus-A of about 30.53%.[32] G3 strains accounted for 11 the vast majority of cases (82.8%), followed by G12 strains (13.8%) and G3/G9 coinfections (3.4%). In P genotypes, P [8] being the dominant with 69%, P [9] falls next with 31%. G3P [8] with subsequent G3P [9] strain is the commonest combination of G[P] genotype. In Colombia, the study concluded that even post-vaccination Rotavirus emerged to be the chief source of infection 12 in children < 5 years of age. [32]

The year 2021 showed the importance concerning the alarming increase of worldwide reports in humans about raising 34 equine-like G3P [8] DS-1-like strains. [33]. It is responsible for around 25% of gastroenteritis (GE) cases, 33% of hospitalized GE cases, and an annual mortality rate of 113.4/100,000 in children < 5 years of age in Peru.[34] Ehrenkranz and team calculated a decade's burden of rotavirus among Peruvian children through multiple published and unpublished reports during ante-vaccination period.

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Peruvian National Immunization Program. The study claimed over 63% of children in Peru would have gone through a spell of diarrhea because of rotavirus; where 1 among 10 would be in need of visitation to clinics; while 1 in 20 may have a compelling need of hospitalization and finally, 1 in 375 may face mortality. [35]

In another study it was stated that Norovirus being the primary, Rotavirus followed it as the major secondary cause for diarrhea. The strain most commonly found was G12P [8] which was about 67% of overall strains found in that area [36]. To the contrary another study has a reversal of results where Rotavirus was responsible for 41.03% of the diarrhea cases followed by Norovirus.[37]

African nations have also been an epicenter of Rotavirus infection among the children population. The African Rotavirus Surveillance Network has stated that the burden of the disease is high being around 49.1% in 2006. [38]

Great variability in circulating rotavirus strains has been observed across African countries from year to year. During 2009–12, the most prevailing rotavirus of all the ones that were common with the range of 14% to 31% was strain G1P [8], along with 12-14% of usual presence of mixed G and P strains were also found. Africa differed from developed nations by having lower frequency of strains, such as G2P [4], G3P [8] and G4P [8]. In defiance, Africa comes across various strains like G1P [6], G2P [6], G3P [6], G1P [4], G9P [4], G12P [6] and G12P [8], as responsible for 27–40% of circulating strains per annum that are found in scarce at developed countries. The dominant P [8], followed by P [6] and P [4] were the notable genotypes. [39]

In Enugu State of Nigeria, prevalence of infection between 0-12 months was 60.9% and overall prevalence of 31.5% among children smaller than 5 years. [39] In a study from 2011-16, a count of 1242 children (46%) were positively tested for rotavirus among the total of 2694 children with acute gastroenteritis. The aforementioned results, 66% were of < 1 year and 94% were < 2 years of age. [40] In Nigeria, Zaria district Ahmadu Bello University Teaching Hospital, displayed the viral load of Rotavirus of 66.7%. [41]

Ethiopia having the second largest population among the African nation. In the year

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population among children the positivity rate of Rotavirus infection was 21%. Children between 6-12 months had an infectivity rate of (36%) followed by children < 6 months i.e. around (23%). [42] Among < 5 years of children with acute diarrhea the positivity rate of Rotavirus was 43.7% and a mortality rate of 4.4%. [43] Alongside the dominant strain was changing every year which was G12P [8] in 2011 (36%) and in 2012 (27%), G2P [4] (35%) in 2013, G9P [8] (19%) in 2014, G3P [6] and G2P [4] (19% each) in 2015, and G3P [8] (29%) in 2016. [44]

Egypt is demarcated as most populous countries among the African nations. The burden of the disease is high across few regions which goes up to 69.2% of the symptomatic patients with age < 5 years. [45] With 3.9% mortality in children having Rotavirus infection, majority of the infection (85.7%) happens during the time of 12-24 months of age. The most common genotypes identified during this study were G3P [8] (37.7%) and G1P [8] (19.5%), but there were uncommon genotypes G1P [6] (3.9%), G9P [6] (1.3%), G8P [14] (1.3%), and G12P [6] (2.6%) were also detected. [46] Recent studies suggest children with gastroenteritis being infected with rotavirus to 58%. [47]

South Africa, in 2009 reported 46% prevalence of Rotavirus-A infection among < 5 years of age in children. There have been lesser studies on the viral genotyping where the most frequent of it was G2P [4] (466/2038; 23%); G1P [8] (42½038; 21%), G12P [8] (384/2038; 19%), G9P [8] (254/2038; 12%); G2P [6] (179/2038; 9%) and G8P [4] (113/2038; 6%. [48] A study also concluded that ante-vaccination the estimate of rotavirus infection was 24% and was meagerly reduced by 1% i.e., to 23% post-vaccination in the pooled national prevalence. However, post-vaccination in the regions of KwaZulu-Natal and Western Cape the raise in cases were recorded for 21-28% and 18-24%, respectively. The genotypes of G1P [8], along with by G2P [4], G3P [8], and G1P [6] were found to be most widespread ante-vaccination. However, post-vaccine, a multi variance in genotypes diversity with G9P [8] emerging as the significant, followed by G2P [4], G12P [8], and G1P [8] were observed. [49]

England introduced the Rotarix vaccine on June 2013. Preceding the routine vaccin

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time period in England and Wales, rotavirus gastroenteritis had huge burden on healthcare resources, as it was accountable for an estimate of 750,000 incidents of diarrhea; 80,000 episodes of clinical consultations [50], and 14,300 hospitalizations per annum of 4 children aged <5 years. [51] There was also exclusive cases of rotavirus gastroenteritis in children who were diagnosed with co-occurrence of encephalopathy.[52]

The G1P [8] was the most prevalent ranging from 39%-74%. But introduction of vaccine has changed the scenario where the genotypes have been diverse where G2P [4], G3P [8], G12P [8] and G4P [8] significantly increased relative to G1P [8]. [53] Vaccine associated diarrhea was also detected. G1P [8] genotypic strain clusters which were derived by Rotarix vaccine was found during time of vaccination and held liable for positivity among infants of 2 months with 82% in 107 cases out of 130 total; consecutively amounting to 68% in 36 cases out of 53 in total of 3 months old. Although, a time period of 7 weeks after the last vaccination date was noted when 13 samples were collected. [54] Germany accounted for 72% of all notified RV patients were 1 children <5 years of age. The highest rate of occurrence per annum which approximates up to, 200/10,000 was in children of age < 2 years. About 50% of patients under the age group of 5 years reported were in the need of hospitalization and 9% of those obtained the infection through nosocomial source.[55] While G1P [8] was predominant (45.8%), G9P [8] has emerged as the second most frequent genotype combination (37.7%). Furthermore, a few human rotavirus G10P [6] and G10P [8] infections were observed. [56]

Annual rotavirus infection cases in Italy sums up to around 15,000. [57] Finding suggests that 10% of the infection are nosocomial in nature. [58] Study from Umbria identified the genotypes G1P [8], G4P [8], and the novel strain G12P [8] caused a large community- and hospital-acquired outbreak. Another study from the Northern part of Italy showed 82.4% prevalence of frequently observed RotavirusA strains such as G3P [8], G1P [8], G9P [8] and G2P [4]. [59]

Rotavirus infection was accountable for 300,000 cases of acute diarrhea per annum, 138,000 episodes of visits to general practitioners, 18,000 cases which needed

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hospitalizations, and eventually 9 cases of deaths. [60] Dijon, France reported 61% of the diarrheal cases to be from Rotavirus A infection followed by human caliciviruses, astroviruses, and adenovirus types “40” and “41”. [61] The predominance of P9G [8] up to 77.3% has been ascertained in parts of France. [62] As depicted in another study about children attending Pediatrics emergency department due to diarrhea, rotavirus infections were found as the cause in the age group lesser than 2 years (83.9%). A clear predominance of G1P [8] strains (62.2%; 54.3%–73.1%) associated with heterogeneous circulation of secondary major strains, i.e., G9P [8] (11.5%; 7.3%–22.0%), G3P [8] (10.4%; 1.5%–19.3%), G2P [4] strains (6.6%; 1.1%–17.5%) and G4P [8] (2.7%; 0.8%–7.3%), depending on season. The five major genotype combinations accounted for 93.3% (92.3%–96.2%) of strains, showing a relatively stable detection rate from season to season. [63] The study further issued continual monitoring for newer strains that might reduce the potency of the vaccines.

On observing the diversity of Rotavirus infection, 5 the number of children having diarrhea associated with Rotavirus were around 44%.[64] The common genotypes found were G1P [8] followed by G9P [8]. Around 114.5 cases per 1000 9 in children younger than 5 years were treated in primary care and 11.8 children per 1000 were hospitalized with gastroenteritis annually. [65]

Indonesia has a highest 3 prevalence of Rotavirus infection in children younger than 5 years. The prevalence of RVA in South Sumatra (55.4%) and West Papua (54.0%) showed higher level of infections whereas East Java (31.7%) has a slightly lower prevalence rate.[66] Of all age groups, children aged 6-11 and 12-23 months had the highest prevalence of rotavirus caused diarrhea in all years (54.2% and 50.6%, respectively).[67] Multiple genotypes were seen where the most common were G1P[8] (18, 45%), G3P[8] (14, 35%), G3P[6] (4, 10%), G3P[9] (2, 5%), G2P[4] (1, 2.5%).

Japan recorded Rotavirus A infection as high as 44% among children having diarrhea. In the year of 2014-2015 but with the post-vaccination it has come down to 34.5 % on the year 2018-2019. There has been a mixed variation in the major genotype circulated

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basis where G1P [8] and G1P [8] in 2014-15, G2P [4] and G9P [8] in 2015-16, G1P [8] and G8P [8] in 2017-2018, and G8P [8] in 2018-19. [68]

South Korea has reported a massive 43.5% Rotavirus A infection of children in the NICU (Neonatal Intensive Care Unit) which gave an insight of how Rotavirus vaccination did not affect the incidence of RV infection in new born and preterm infants in the NICU where the dominant genotype was G4P [6]. [69] Close to 76.7% of total identified strains, genotypes G1P [8], followed by G3P [8], G4P [6], and G2P [4], were accounted for along with more recent, strain of G9P[8] which rose to the rank of fifth most common among all genotype due to its marked increase. [70]

The positivity of Rotavirus A among children in Bangladesh has ranged from 20.3% to 32.0%. [71, 72] This is an unusual trend where the positivity of the Rotavirus A infection has surged over the years. 50% of the total no.of children who accounted to be positive for the Rotavirus A infection were lesser than the age of 2 years [72] G1P[8] (27%) was the prevalent strain which was followed by G12P[8] (15%) and G9[P4] (9%). Rare genotypes like G1P[4], G1P[6], G2P[6], G2P[8], G9P[6] were also observed. Mixed infections were detected in 14.2% of the samples. [73]

Infection of 4 children younger than 5 years in the country of Nepal ranged from 21.1% to 28.0%. Both the studies were conducted in the capital city of Kathmandu where the former was in the year 2021 whereas the later in the year 2019. Rotavirus A infection was found more in the age group of less than 2 years old. In either of the studies G12P[6] and G2P[4] was considered to be the predominant genotype. The other genotypes found were G1P[8] , G12P[6] and G9P[8]

The Indian Saga: Infection among Indian 9 children under 5 years with Rotavirus A has a diverse number ranging from 4.6% in Kolkata to 89.8% in Manipur, among hospitalized children, and from 4% in Delhi to 33.7% in Manipur in community among stool samples. Identifying it to be a cause of nosocomial infection ranges from 5.2 to 80.5%. [74]

14 In a community-based cohort, done in Vellore on the southern part of the country, rotavirus an infection among children was found to be 18% on the first month. The

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of the infection was due to G10P[11] strain. The seasonal trend was from October to March. Four common G types - G1 (26.8%), G2 (16%), G10 (11.2%) and G9 (9.6%) were seen [75]

Aurangabad, Maharashtra showed an infectivity rate of 11% with significant amount of infection was due to G1P[8]. [76] Hospital in Southern Haryana in an observational study found 11.02% infectivity rate among admitted patients younger than 5 years for acute diarrhea. [77] There was no genotyping done to find the strains responsible.

A positivity rate of 36.9% with majority of it belonging to the age group of 6 months to 2 years was observed in Odisha. Majority of them had severe dehydration. Rotavirus gastroenteritis exhibited a single peak from November to February. 21 The common genotype combination was G3P[8] (46%) followed by G1P[8] (19%), G2P[4] (5%), and G9P[4] (3%). [78]

In an unusual finding in West Bengal Evolutionary, it was analyzed that out of all the predominant genotypes 1 (G1, G2, G3, and G9) the fact revealed was that they were as depicted in the phylogenetic dendrogram mostly phylogenetically distant to the rotavirus vaccine strains. [79]

The sub-Himalayan belt in north India showed incidence of Rotavirus A infection in children showed as high as 40.43% in 2016 where G3P[8] was most common genotype (46.94%) found, followed by G1P[8] (13.78%), [80] Bareilly showed 45.5% of positivity rate among children. [81]

III. MATERIALS AND METHODS

a) Study Setting: Hospital Based study (Tertiary care hospital)

b) Study design: Cross sectional study

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c) Study population: 9 Children under 5 years with diarrhea / acute gastroenteritis n coming in as OPD or IPD patients in Mayo 10 Institute of Medical Sciences will form the study population from the institutional committee.

d) Study period: Two years (August 2019-August 2021)

e) Sample size: 196 30 =226

Sample size calculation by the formula Z2pq/d2, where

Z = Standard normal deviate (1.96)

p = prevalence

q = 1-p

d = degree of accuracy (0.05 or 5%)

Taking the prevalence as 15%

1.96 x 1.96 x 0.15 x 0.85 0.05 x 0.05 = 195.92

f) Selection of sample:

i) Inclusion criteria

 1 Children under 5 years with acute gastroenteritis

 Children under 5 years with diarrhea alone

ii) Exclusion criteria

 Children under five years with bloody diarrhea

 Parents or children not accepting to participate

Parents were instructed to collect stool specimen of the child in a sterile wide mouthed screw capped plastic container (15-20 ml) provided to them and submit it in the laboratory within an hour of collection.

III. A. SAMPLE PROCESSING

Freshly passed patients stool sample was sent to microbiology laboratory in central lab. The sample was divided into two parts:

 One part of the sample was stored at -20 degrees with buffer for further investigation of rotavirus antigen.

 The second part was used for further: routine microscopic / macroscopic exam

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pus cells and for detection of parasites directly from the specimen and also by formol ether sedimentation technique

III.A.a Detection of Rotavirus

III.A.a.i ELISA

Rotavirus antigen was detected in stool sample using EDI Fecal Rotavirus ELISA kit.

 Assay Principle: This ELISA is designed, developed and produced 15 for the qualitative and quantitative measurement of rotavirus antigen in test specimen.

It uses the enzyme immunoassay (microplate-based) process. It is coated with highly purified antibody across the wall in the microtiter well. Assay controls along with fecal specimen, along with HRP-conjugated monoclonal antibodies that are specific to 15 the inner capsid protein in rotaviruses is added to microtiter wells of microplate. These wells coated with a highly purified polyclonal anti-rotavirus antibody on the wall. Following the incubation, an immunocomplex of “Anti-Rotavirus Antibody – Rotavirus Antigen – HRP-conjugated Anti rotavirus Tracer Antibody” are formed in the presence if there is a presence of rotavirus antigen in tested sample.

Tracer antibody that are unbound along with protein or buffer are removed during the washing step. The HRP-conjugated tracer antibody which binds to the well was incubated with substrate solution and then measured in a

ELISA reader. Enzymatic activity of the

tracer antibody bound on the microtiter well is directly proportional to the antigen level of rotavirus in each of the test specimen. A double antibody sandwich ELISA test will be performed using a polyclonal anti-Rotavirus antibody to capture the antigen from the stool sample.

 Reagents: This test was stored at 2 – 8°C upon receipt. Regents were used once it attained room temperature.

1. Anti-Rotavirus Antibody Coated Microplate

One microplate having 12 x 8 strips (96 wells total) and coated with highly purified anti-rotavirus antibody.

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This reagent was stored at 20 to 8°C.

2. Anti-Rotavirus Tracer Antibody

A vial has 12 mL of concentrated horseradish peroxidase (HRP) conjugated monoclonal anti-rotavirus tracer antibody within a stabilized protein matrix. This reagent was stored at 2 –8°C.

3. ELISA Wash Concentrate

One bottle contained 30 mL of 30-fold concentrate. The contents were diluted before use with 870 mL of demineralized water and mixed well. Upon dilution this yielded a working wash solution. The diluted wash buffer was stored at room temperature.

4. ELISA HRP Substrate

One bottle contained 12 mL of tetramethylbenzidine (TMB) along with hydrogen peroxide. This reagent was stored at 2 – 8°C.

5. ELISA Stop Solution

One bottle contained 12 mL of 0.5 M sulfuric acid. This reagent was stored at 20 to 8°C.

6. Rotavirus Antigen Calibrator 6

1 vial contained 1.5 mL of Rotavirus Antigen Calibrator 6. This calibrator is in a liquid bovine serum albumin-based matrix with a non-azide preservative.

7. Concentrated Patient Sample Diluent

One bottle contained 30 mL of 10-fold concentrated buffer matrix with protein stabilizers and preservative. This reagent was stored at 20 to 8°C. Before use the concentrated buffer was diluted with 290 mL of distilled water and mixed well. Upon dilution this worked as a working like calibrator 6 matrix buffer, NC and also diluent for patient sample. It was stored at 20 to 8°C.

III.B. SPECIMEN COLLECTION & STORAGE

1.Stool specimens can be collected at all times of the day.

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2. Collection a sample of feces was done in universal container.

3. It was required to collect minimum 0.1 mL liquid stool sample or 0.1 g solid sample.

4. The specimen was stored at -20ºC.

III.C. REAGENT PREPARATION

(1) Prior to use all the reagents were made to come at room temperature.

(2) ELISA Wash Concentrate was diluted to working solution prior use.

(3) Concentrated Patient Sample Diluent was diluted to working solution prior use.

(4) Prepare 1:3 serially diluted calibrators using Rotavirus Ag Calibrator Level 6 and 1x Patient Sample Diluent as the dilution buffer was Prepared. The unused part was stored at -20ºC for long term storage.

III.D. PATIENT SAMPLE PREPARATION

18 For manual weighing procedure only: Patient samples was diluted 1:11 with 1x Patient Sample Diluent before being measured.

(1) A 2 ml plastic vial was labelled.

(2) In case of solid stool sample, about 90mg i.e., size of a green pea) with a spatula or a disposable inoculation loop was suspended with 1 mL 1x Patient Sample Diluent and mixed well on a vortex mixer.

(3) It was then centrifuged at 3000 rpm (800- 1500 g) for 5-10 minutes. The supernatant was directly used in the assay.

(4) The remaining sample was stored at -20ºC.

III.E. SAMPLE ADDITION

(1) Sufficient number of anti-rotavirus antibody-coated microwell strips were placed in a holder to run rotavirus controls and unknown samples in duplicate.

(2) Test Configuration

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(3) 100 µL of working calibrators (or controls) and diluted patient stool sample was added into
each designated microwell.
(4) It was then incubated at room temperature for 1 hour.
(5) After an hour, the plate sealer was removed. The contents of each well were aspirated. Each
well, was washed 5 times by dispensing 350 µL to 400
µL of working wash solution into each well and then completely aspirating the contents by an
automated microplate washer can be used.
(6) 100 µL of tracer antibody solution was added in the micrototre wells.
(7) The plate was covered with the plate sealer. Further it was totally covered with an aluminum foil to prevent any exposure to light.
(8) The plate was incubated at the room temperature for 30 min.
(9) The plate sealer was removed. The contents in the microtitre well were aspirated and washed for 5 times by dispensing around 350 µL to 400 µL of wash buffer solution into each well and aspirating the contents by the automated microplate washer.
(10) 100 µL of ELISA HRP Substrate was added.
(11) The plates were covered with plate sealer and also aluminum foil from above to avoid exposure to light.
(12) It was next incubated for 20 minutes at room temperature.
(13) The aluminum foil and plate sealer was removed. 100 µL of Stop Solution was added in each microtiter well and mixed gently.
(14) The absorbance was read at 450 nm within 10 minutes in the ELISA reader.

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III.F. INTERPRETATION OF RESULTS

III.F.i. Qualitative Measurement

1. Positive or reactive: Any sample well that is obviously more yellow than the negative control well.

2. Negative or non-reactive: Any sample well that is not obviously more yellow than the negative control well.

Note: The negative control, as well as some patient samples, may show some slight yellow color. A sample well must be obviously darker or more yellow than the negative control well, when it is interpreted as a positive result.

 ELISA Reader:

1. Calculation of the average absorbance for each pair of duplicate test results.

2. Calculation of the cut-off: The positive and the negative cut-off are done by using following formula.

Positive Cut-Off = 1.1 x (mean extinction of negative control + 0.08)

Negative Cut-Off = 0.9 x (mean extinction of negative control + 0.06)

3. Interpret test result

 Positive: If patient sample value is greater than the Positive Cut-Off

 Negative: If patient sample value is less than the Negative Cut-Off

 Equivocal: If patient sample value is between the Positive Cut-Off and the Negative Cut-Off.

4. Assay quality control

 Positive control must show an average OD reading greater than 0.8.

 Negative control should show an average OD reading less than 0.1.

III.G. REAL TIME PCR DETECTION OF ROTAVIRUS A

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 Helini Rotavirus -A Realtime PCR kit was used for Rotavirus A detection from stool sample. Initial sample preparation was done using Helini Purefast stool processing buffer.

1. 2ml of Stool Processing buffer was transferred into 5ml centrifuge tube.
2. About 100mg to 150mg of stool samples was Transferred and Vortex thoroughly for 2 to 5min. it was Made sure that stool sample has mixed thoroughly in Stool processing buffer

 It was then Incubated for 5 minutes at room temperature and stored at -20C for future use.

 Next it was thawed and inverted multiple times. Then it was centrifuged at 13000 RPM for 5 minutes.

 The supernatant i.e., around 350µl is pipetted in 2ml centrifuge tubes.

 The 350µl of supernatant was used for RNA purification

III.G.i. RNA purification/ Nucleic acid

 The HELINI Purefast viral nucleic acid mini spin prep kit was used for RNA purification.

 The component of the kit was as follows: Carrier RNA, Proteinase K, Lysis buffer, Elution buffer, Wash buffer 1 and 2.

 Before the initiation of procedure, the working areas were cleaned with 70% ethanol and RNAse Zap. Utmost care was taken for the flow of work to be in a unidirectional way.

 Wash buffer preparation: Both wash buffer 1 and 2 were made according to the company recommendation. Around 150 µL of sample is required for the purification process.

Wash buffer-1

Wash Buffer-2

Concentrated Buffer

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52ml

24ml

Ethanol [96 – 100%] to add

36ml

64ml

Total volume

88ml

88ml

 Procedure for Nucleic acid extraction:

1. 20µl of Proteinase K was added in a fresh 1.5ml centrifuge tube.

2. 150µl of sample was then pipetted.

3. 250µl of Lysis Buffer was added and mixed well by pulse vortexing for 10 seconds.

4. 5µl of Carrier RNA was added along with 5µl of Internal control template as an internal control.

5. It was followed with a brief vortexing and centrifugation for few seconds to bring down drops to the bottom of the tube.

6. Incubation at 56ºC for 10min was done.

7. 250µl of [100%] ethanol was mixed well by vortex for 10seconds. Then the component was spinned down to bring drops to the bottom of the tube.

8. The entire sample was then transferred into the Purefast® spin column. Centrifugation was done at 8000rpm for 1 min. the collection tube containing filtrate was discarded. The spin column was put into fresh collection tube.

9. 600µl of Wash buffer-1 [Ethanol added] was then added to Purefast® spin column. It was Centrifuged at 8000rpm for 1min. Collection tube containing filtrate was discarded. The spin column was put into fresh collection tube.

10. 600µl of Wash buffer-2 [Ethanol added] was added to Purefast® spin column and centrifuged at 10000rpm for 1min. The collection tube containing filtrate was

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discarded. Spin column was put into fresh collection tube.

11. Centrifugation at 12000rpm for 2 min was done [Empty spin]. This step is essential to avoid residual ethanol. Collection tube containing filtrate was discarded.

12. The Purefast® spin column was transferred to fresh 1.5 ml micro- centrifuge tube.

13. Around 60µl of Elution Buffer was added to the center of spin column membrane. Incubation for 2 minutes at room temperature was done.

14. Centrifugation at 10000rpm for 1 min was done. The Purefast spin column was discarded. Centrifuge tube now had the eluted nucleic acid. It was stored at -80 degrees for further evaluation.

III.G.ii. Detection of Rotavirus A with Helini Rotavirus-A Realtime PCR Kit

HELINI Rotavirus-A [19] Real-time PCR is an in vitro nucleic acid amplification test, based on real-time PCR technology, for the detection and quantification of human Rotavirus-A in human biological samples

HELINI Rotavirus-A Real-time PCR Kit constitutes a ready-to-use system for detecting Rotavirus-A specific RNA using [2] polymerase chain reaction (PCR). It amplifies the specific conserved region of the Rotavirus-A genome, and direct detection of specific amplicon in the FAM channel. Alongside, it also contains an internal control amplification system that identifies any possible PCR inhibition and RNA purification efficiency. External positive control is supplied, which can be used simultaneously for qualitative and quantitative to determination the amount of viral load.

 Specificity: Rotavirus-A primer and probe have been designed for the specific and exclusive in vitro quantification of Rotavirus-A. The target sequence (NSP3) is highly conserved and sequences in this kit have 100% homology with a broad range of clinically relevant reference sequences based on a comprehensive bioinformatics analysis.

 The kit constituted of the following components: One step RT-PCR Master Mix, RT-Taq enzyme mix, Rotavirus-A Primer Probe Mix [Rotavirus PP Mix], Internal control [Ri

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Probe Mix [IC PP Mix], Internal control template [IC template], Rotavirus -A Positive control [QS1] lyophilized, PCR grade water. The kit was stored at -20°C for storage. Before initiating the PCR process, the following materials and instruments required were checked for:

 Real-time PCR instrument having FAM & HEX channels

 Centrifuge with a rotor for PCR strips/tubes and 96 well plates

 Optical cap qPCR tubes or strips

 Micro Pipettes (variables)

 Micro Pipette tips with filters (disposable)

 Powder-free gloves (disposable)

 Preparation of consumable for PCR:

a) Preparation of Positive Control and standard curve dilution series: Positive control is diluted before use.

b) The vials were centrifuged at 10000 rpm for 3min.

c) 245µl of PCR grade water was added and the vial was closed

d) It was then Incubated at room temperature for 10min.

e) Gentle vortexing for 5 seconds was done.

f) Incubation for 5min at room temperature was done.

g) Gentle jetting with pipette was done for 5 seconds.

h) It was Centrifuged again at 1000 - 2000rpm for 5seconds.

i) It was then ready for use.

j) Dilution the positive control (standard) for preparation of Standard curve dilution series the following was done:

- Pipette 90µl of PCR grade water into three 1.5ml micro centrifuge tubes and label as QS2 to QS4.

- Pipette 10µl of PC (Positive control) -QS1 into tube QS2.

- Vortex thoroughly. Then spin down for a brief time .

- Change pipette tip and pipette 10µl from tube QS2 into tube QS3.

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- Vortex thoroughly and spin down briefly.

- Repeat steps 4 and 5 to complete the dilution series.

- Use 10µl per reaction.

STANDARDS

COPIES PER µL

QS-1

QS-2

QS-3

QS-4

1000000

100000

10000

1000

- The detection protocol is as follows: All components to be thawed totally. Mixing of products to be done by gentle inversion of a tubes followed by a short spin.. The following volume of components are 26 to be used for each of the reaction.

COMPONENTS

VOLUME PER REACTION

One step RT-PCR Master Mix

8µl

RT-Taq enzyme mix

2µl

Rotavirus-A PP Mix

2.5µl

IC PP Mix

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2.5µl

15µl

Purified RNA

10µl

Final reaction volume

25µl

- Negative Control setup [NTC]: Add 10µl of PCR grade water.

- Qualitative Positive Control (PC) setup: 10µl of the PC to be added. [any one from QS1 to QS4]

 Programming Thermal cycler

Sample volume

25µl

Fluorescence Dyes

FAM & HEX

Passive reference

None

Ramping rate

Default

 Thermal Profile

Step

Time

Temp

Reverse transcriptase

20min

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50ºC

Taq enzyme activation / Hold

15min

95ºC

45

cycles

Denaturation

20sec

95ºC

Annealing

20sec

56ºC

Extension

20sec

72ºC

Data collection/Acquisition

Targets

FAM

Rotavirus-A

HEX

Internal control

 Interpretation of Result of PCR

Step 1 Internal control Validation

- Select the test samples alone for the internal control analysis. Select HEX dye and view the graph of internal control amplification. A successful amplification Ct value must

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within Ct 21 +/- 10.

- This range indicates there NO PCR inhibition following the reaction. Any sample value beyond Ct 31 indicates sample having an issue in the purification or inhibiting PCR reaction.

- Internal control will not get amplified in the negative and positive controls. 24 Ignore a late noise HEX amplification graph in the NTC and Positive control wells.

Step 2 8 FAM - Negative and Positive control validation

- Select the NTC and Positive control [Qualitative] or Standards wells [Quantitative], select FAM channel, and view the graph of amplification.

- The NTC must be flat with no Ct value. Adjustment of the threshold value can be done just above the NTC if required. The PC or Standards must be amplified as per their copy numbers.

- NTC justifies NO contamination in the reagent as well as fine pipetting and its environment. PC validates that the storage of reagents and reaction parameters which are done as prescribed.

Step3 FAM - Test Sample status

- In FAM channel, test samples were selected one by one, analyze the graph/amplification.

 Qualitative interpretation of results:

Test Sample

Negative control

Positive control

Internal Control

Interpretation

Positive

Negative

Positive

Positive

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Rotavirus-A specific RNA detected

Negative

Negative

Positive

Positive

No Rotavirus-A specific RNA Detected. Sample does not contain detectable amounts of ROTAVIRUS-A specific RNA.

Negative

Negative

Negative

Negative

Experiment fails

Positive

Positive

Positive

Positive

Experiment fails

All the samples found to be positive for Rotavirus -A were further genotyped.

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III.G.iii. 13 Genotyping of Rotavirus A

The initiation for the process of Genotyping of Rotavirus A was done by choosing appropriate primers for the process. The oligonucleotides were received from Eurofins Genomics India Pvt Ltd. Bangalore.

S.No.

Gene/

Genotype

Primer name

Primer details (positions)

Annealing temp (C)

Product size (bp)

1

VP7

Rota 1 – F

GATCCGAATGGTTGTGTAATCCAAT (nt 531-550)

55

304

Rota 2 – R

AATTCGCTACGTTTTCTCTTGG (nt 824-808)

2

VP4

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Con 3 – F

TGGCTTCGCTCATTTATAGACA (nt 11-32)

53

876

Con 2 – R

ATTTCGGACCATTTATAACC (nt 868-887)

3

VP7

Beg 9 – F

GGC TTT AAA AGA GAG AAT TTC CGT CTG G (nt 1-28)

52.5

1062

End 9 – R

GGT CAC ATC ATA CAA TTC TAA TCT AAG (nt 1062-1036)

4

G1

9T1-1

TCTTGTCAAAGCAAATAATG (nt 176 to 195)

42

158

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5

G2

9T1-2

GTTAGAAATGATTCTCCACT (nt 262 to 281)

42

244

6

G3

9T-3P

GTCCAGTTGCAGTGTTAGC (nt 484 to 503)

42

466

7

G4

9T-4

GGGTCGATGGAAAATTCT (nt 423 to 440)

42

403

8

G5

FT5

CATGTACTCGTTGTTACGTC (nt 779-760)

55

780

9

G6

DT6

CTAGTTCCTGTGTAGAATC (nt 499-481)

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55

500

10

G8

HT8

CGGTTCCGGATTAGACAC (nt 273-256)

55

274

11

G9

9T-9B

TATAAAGTCCATTGCAC (nt 131 to 147)

42

110

12

G10

ET10

TTCAGCCGTTGCGACTTC (nt 714-697)

55

715

13

G11

BT11

GTCATCAGCAATCTGAGTTGC (nt 336-316)

55

337

14

[P1]

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pNCDV

CGAACGCGGGGGTGGTAGTTG (nt 269-289)

55

622

15

[P4]

2T-1

CTATTGTTAGAGGTTAGAGTC (nt 474 to 494)

48

483

16

[P5]

pUK

GCCAGGTGTCGCATCAGAG (nt 336-354)

55

555

17

[P6]

3T-1

TGTTGATTAGTTGGATTCAA (nt 259 to 278)

48

423

18

[P7]

POSU

CTTTATCGGTGGAGAATACGTCAC (nt 389-412)

55

502

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19

[P8]

1T-1

TCTACTTGGATAACGTGC (nt 339 to 356)

48

345

20

[P9]

4T-1

TGAGACATGCAATTGGAC (nt 385 to 402)

48

391

23

[P11]

pB223

GGAACGTATTCTAATCCGGTG (nt 574-594)

55

314

 The primers were activated by adding the requisite amount of nuclease free water as follows:

- Primer + dH20 i.e. (Yield n mole * 10 approx.)

- This is around a dilution of 1:10

- The extracted RNA was then used for G and P genotyping.

 G Rotavirus genotyping:

Preparation of cDNA

The PCR Reaction Mixture constituted the following components (Total volume: 20 µL)

Extracted RNA:3 µL

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Forward Primer (Con 3 – F): 0.5 µL

Reverse Primer (Con 2 – R): 0.5 µL

MINT-O Precision PCR Master Mix: 10 µL

Nuclease free water: 6 µL

The following PCR cycle was used for amplification

Hold temperature1: 950C for 5 min

Cycling: 950C for 30 sec

460C for 30 sec

720C for 1 minute

Holding temperature 2: 720C for 7 minutes

Total number of cycles: 35

The cDNA at the end was used for the Rotavirus-A Genotyping

The primers having similar annealing temperature were kept in one batch.

Batch 1: 3 G1, G2, G3, G4, G9

Batch 2: G5, G6, G8, G10, G11

Primers having similar annealing temperature was made into a single mix.

The PCR Reaction Mixture constituted the following components (Total volume: 20 µL)

Extracted RNA:2 µL

Forward Primer (Con 3 – F): 0.5 µL

Reverse Primer (G1, G2, G3, G4, G9): 1 µL

MINT-O Precision PCR Master Mix: 10 µL

Nuclease free water: 6.5 µL

The following PCR cycle was used for amplification

Hold temperature1: 950C for 5 min

Cycling: 950C for 30 sec

420C for 30 sec

720C for 1 minute

Holding temperature 2: 720C for 7 minutes

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Total number of cycles: 35

A similar cycle was also processed for the Batch 2 primers.

This end product was then used for Electrophoresis.

 P Rotavirus genotyping:

The PCR Reaction Mixture constituted the following components (Total volume: 20 µL)

Extracted RNA:3 µL

Forward Primer (Beg 9 – F): 0.5 µL

Reverse Primer (End 9 – R): 0.5 µL

MINT-O Precision PCR Master Mix: 10 µL

Nuclease free water: 6 µL

The following PCR cycle was used for amplification

Hold temperature1: 950C for 5 min

Cycling: 950C for 30 sec

530C for 30 sec

720C for 1 minute

Holding temperature 2: 720C for 7 minutes

Total number of cycles: 35

The cDNA at the end was used for the Rotavirus-A Genotyping

The primers having similar annealing temperature were kept in one batch.

Batch 1: P1, P5, P7, P11

Batch 2: P4, P6, P8, P9

Primers having similar annealing temperature was made into a single mix. The PCR

Reaction Mixture constituted the following components (Total volume: 20 µL)

Extracted RNA:2 µL

Forward Primer (Beg 9 – F): 0.5 µL

Reverse Primer (P1, P5, P7, P11): 1 µL

MINT-O Precision PCR Master Mix: 10 µL

Nuclease free water: 6.5 µL

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The following PCR cycle was used for amplification

Hold temperature1: 950C for 5 min

Cycling: 950C for 30 sec

470C for 30 sec

720C for 1 minute

Holding temperature 2: 720C for 7 minutes

Total number of cycles: 35

A similar cycle was also processed for the Batch 2 primers.

This end product was then used for Gel Electrophoresis.

 Preparation of Gel for electrophoresis:

1. Preparation of buffer: 50 X TAE buffer by Gene to Protein Pvt Ltd was used. Approximately 500 ml of TAE was prepared by adding 490ml of distilled water with 10 ml of TAE buffer concentrate. This mixture can be used both in preparation of agar and electrophoresis tank.

2. Preparation of agar:

- 1% agar was prepared by mixing 100 ml of buffer solution with 1 gm of Agar-agar. Microwave was used to help dissolve the agar with the buffer adjusting each cycle of microwave to 30 seconds and whirling the conical glass beaker with every cycle till it dissolves perfectly.
- It was then cooled to around 45 degrees, GreenR DNA Gel stain was added which is a substitute of Ethidium bromide. It was added in a concentration of 5 l per 100 ml of agar. It was ten poured into Mini caster by avoiding formation of any bubbles. The comb was placed for the formation of well in the gel.
- Once the Gel solidified, it was then put inside the electrophoresis tank and filled with the diluted TAE buffer. Once filled with TAE buffer, the comb was pulled out and the gel was ready for pipetting of sample.

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- The first well was pipetted with 1KB ladder while the other was loaded with samples.

- Once samples were loaded in the well, voltage was fixed at 90V for 45 minutes.

- Once the run was over the caster was pulled up slowly and the gel was then put over an UV plate.

- The UV place was put inside the Gel Doc EZ Imager and image was observed with the help of Image Lab software on the computer screen.

- Based on the position of the DNA band over the gel, the size of the band was determined keeping the ladder as a control band.

- Genotyping was determined by the band size.

IV. RESULTS

A total of 323 stool samples were collected of children till 5 years with diarrhea during the study period. All the samples were subjected to ELISA for Rotavirus detection and further subjected to RT-PCR for conformation where the number of positive samples was around 143.

 AGE WISE DISTRIBUTION OF GASTROENTERITIS

- A total of 323 stool samples from children with gastroenteritis were collected which comprises of both OPD and IPD cases. Among the children suffering from gastroenteritis 174 were boys and 149 were girls.

- Majority of the children suffering gastroenteritis were from the age group of 6-12 (38.1%) months followed by 13-24 (29.1%) months and the least from 25-60 months (14.2).

- Infection among the age group of 6-12 months was higher among boys ie 40.8% and lower among the girls i.e. 34.9%.

AGE

MALE

FEMALE

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TOTAL

(In Months)

Number (%)

Number (%)

Number (%)

0-6 Months

32(18.4)

28(18.8)

60(18.6)

6-12Months

71(40.8)

52(34.9)

123(38.1)

13-24 Months

53(30.5)

41(27.5)

94(29.1)

25-60 Months

18(10.3)

28(18.8)

46(14.2)

Total

174(100)

149(100)

323(100)

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 DISTRIBUTION OF ROTAVIRUS CASES WARD WISE

- Of the 323 cases of gastroenteritis, majority of the patients were from OPD i.e., 231 whereas IPD constituted of 92 patients.
- Among the 231 OPD patients, Rotavirus positive 6 cases were found to be 95 (41.1%) and non-Rotavirus A cases were 136 (58.9%).
- Of the 92 IPD patients, children infected with Rotavirus A were 48 (52.2%) whereas the number of non-Rotavirus A infection were 44 (47.8%).

WARD

NUMBER OF CASES

NUMBER 6 OF ROTAVIRUS POSITIVE CASES

NUMBER OF ROTAVIRUS NEGATIVE CASES

Number (%)

Number (%)

Number (%)

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OPD

231

95(41.1)

136(58.9)

IPD

92

48(52.2)

44(47.8)

Total

323

143(44.3)

180(55.7)

 AGE WISE DISTRIBUTION OF ROTAVIRUS A INFECTION:

- Infection due to Rotavirus A showed a similar inclination as corresponding to the overall cases of gastroenteritis among children.

- Positive cases were high among 7 the age group of 6-12 months followed by 13-24 months and lowest among 0-6 months.

- The negative cases represent gastroenteritis patient other than Rotavirus A infection. Non-Rotavirus A infection had a similar trend which was higher between 6-12 months (60 cases) followed by 13-24 months (53 cases) and least among 25-60 Months (26 cases).

AGE

NUMBER OF CASES

NUMBER OF POSITIVE CASES

NUMBER OF NEGATIVE CASES

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(In Months)

Number

Number (%)

Number (%)

0-6 Months

60

19(31.7)

41(68.3)

6-12Months

123

63(51.2)

60(48.8)

13-24 Months

94

41(43.6)

53(56.4)

25-60 Months

46

20(43.5)

26(56.5)

Total

323

143(44.3)

180(55.7)

 GEOGRAPHICAL DISTRIBUTION OF ROTAVIRUS A INFECTION:

- Though the hospital caters the need of both urban and rural population, the c

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the cases of Rotavirus A infection was from the rural area.

- The number of cases from rural area was 126 () whereas it was 17() across urban area.

GEOGRAPHICAL AREA

NUMBER OF CASES

NUMBER OF ROTAVIRUS POSITIVE CASES

NUMBER OF ROTAVIRUS NEGATIVE CASES

Number

Number (%)

Number (%)

URBAN

62

17(27.4)

45(72.6)

RURAL

261

126(48.3)

135(51.7)

Total

323

143(44.3)

180(55.7)

 SEASONAL DISTRIBUTION OF RVGE CASES:

- The highest number of cases were seen in winters and gradually decreased

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the summer. The majority of the Rotavirus A infection was during the month of January followed by November and December and least being in the month of July.

MONTH

NUMBER OF CASES

NUMBER OF POSITIVE CASES

NUMBER OF NEGATIVE CASES

Number (%)

Number (%)

Number (%)

APRIL

5

4(80)

1(20)

MAY

5

2(40)

3(60)

JUNE

8

4(50)

4(50)

JULY

1

1(100)

0(0)

AUGUST

7

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3(42.9)

4(57.1)

SEPTEMBER

12

5(41.7)

7(58.3)

OCTOBER

21

12(57.1)

9(42.9)

NOVEMBER

72

33(45.8)

39(54.2)

DECEMBER

75

29(38.7)

46(61.3)

JANUARY

78

31(39.7)

47(60.3)

FEBRUARY

25

13(52)

12(48)

MARCH

14

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6(42.9)

8(57.1)

Total

323

143(44.3)

180(55.7)

 GENOTYPE DISTRIBUTION OF ROTAVIRUS

- There were six different genotype that were identified during the study which is descending order were G9P[4] , G1P[8] , G3P[8] , G3P[11] , G2P[4] & G9P[8]. Two of the samples could not be genotyped.

- G9P[4] constituted 1 the majority of the genotype (31.5%) followed by G1P[8] (31.5%) and least being G9P[8] (4.2%).

GENOTYPE

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Number of SAMPLES (%)

G1P[8]

32(22.4)

G2P[4]

12(8.4)

G3P[11]

17(11.9)

G3P[8]

29(20.3)

G9P[4]

45(31.5)

G9P[8]

6(4.2)

UN-TYPABLE

2(1.4)

 CO-INFECTION OF ROTAVIRUS AAND PARASITES

- Parasites were found be in 44 patients suffering from gastroenteris where the number pf boys were 26 and the girls were 18 in number.

- The parasites detected were Giardia, Entamoeba histolytica, Taenia and Ascaris.

- Entamoeba hystolytica constituted of 21 patients followed by Giardia which was 17 in number. Taenia and Ascaris were 3 each .

- Co-infection with parasites were found in six patients (4 Giardia , 2 Entamoeba histolytica)

- The genotype G3P[8] constituted 1 the majority of the co-infection (3 Giardia and 1 Entamoeba hytolytica) followed by G1P[8] (1 Giardia, 1 Entamoeba histolytica)and G9P[4] (1 Giardia)

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V. DISCUSSION

Rotavirus vaccination was introduced in the National Vaccination Schedule (2016), by the Government of India. In the global arena, Rotavirus is accountable for the leading cause of diarrhea and is associated with 453,000 deaths in children globally. [1]

India alone accounts for 457,000 – 884,000 hospitalizations and 2 million visits for diarrhea. [2] AGE has a wide number of pathogens which includes virus, bacteria and parasites.[4] Virus is the major source of infection with 70% cases of AGE and rotavirus being the forerunner followed by norovirus.[5]

The rate of infection due to virus in both developed as well as developing nations are similar.[6] Diarrhea alone attributes to about 334,000 deaths in India alone and Rotavirus infection leads to 98,000 deaths in children <5 years of age.[3]

Studies in Indian health care facilities on children have found that around 26% of all hospitalisations related to diarrhoea is caused by rotavirus. Owing to its genetic diversity across the country, determining the serotypes would help in determining the antigen makeup in the vaccines.

Prevalence of Gastroenteritis

Our study shows a prevalence of gastroenteritis higher among boys (53.86%) than in girls (46.13) in the age < 5 years. A similar trend was noticed by Khan et al in his study, where prevalence was around 61.4% among boys and 38.6 among girls [7] Study conducted by Kazi et al also had higher percentage among boys (57%) and significantly lower among girls (43%). [8] In Ukraine, Chernyshova et al conducted a surveillance program in parts of Kyiv and Odesa where too gastroenteritis was higher among boys (57%) and lower in girls (43%). [9] but study conducted by Sreekant P et al in the slums of southern India showed higher prevalence of gastroenteritis among females (52.1%) than in males (47.9%). [10]

Our study showed higher prevalence among the age of 6-12 months (38.1%), [11]

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by 13-24 months (28.1%) and among 0-6 months (14.2%). A similar age distribution was unavailable for gastroenteritis. Study by Saha J et al showed an overall prevalence of diarrhea of 14.4% among the age of 0-11 months followed by 12-23 month (13.89) and lowest being 48-59 months (4.75%). [11] Similar conclusion was drawn by Paul P where prevalence of diarrheal patients was high in 0-11 months (14%), followed by 12-23 months (13.4%) and least among 48-59 months (4,6%) of age. [12] Adding to the above Ghosh K et al showed higher prevalence of diarrhea among 0-11 month (14.01%), followed by 12-35 months (10.97%) and least among the age of 36-59 months (5.25).[13]

Prevalence of Rotavirus A

The variation in stool sample positivity for Rotavirus infection swerve from 4.6% in the region of Kolkata [14] to 89.8% in the north eastern state of Manipur [15], among children who are hospitalised and 4% in the capital i.e. Delhi [16] to 33.7% in Manipur [17] among community.

The study shows prevalence of Rotavirus at 44.3% which is close to study conducted by Arun, P at Chennai where the prevalence rate was 41.64%. [18] Higher prevalence among IPD (53.4%)0and OPD (47.5%) patients were found by Mullick, S et al in her study at Kolkata which is in pertinence with our study [19]

Bijnor district of Western Uttar Pradesh showed a prevalence of Rotavirus infection of 39.5% which is still on a higher side and close to our prevalence rate of 44.3%. [20] Vashishtha, V et al in their study showed 30.5% of RVA infection in areas of Maharastra [21] followed with 28.7% in Assam. [22]

In the eastern zone of the country ie Odisha, prevalence of RVA was around 36.4%. [23] Nepal being in proximity to India has a prevalence of 28% for RVA infection. [24] In lower income country like Nigeria RVA shows a prevalence of 25.5% [25]

RVA infection among different age group

In our study, proportion of children having high rotavirus infection were among the age of 6-12 months (44.05%) followed by 13-24 months (28.67%) and least among the 36

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months (18.6%).

The age group between 6-12 months, where infection with RVA is high i.e., 44.05% is proportionate with the study of Ranjitha S et al where similar age group has a prevalence of 45.2% [26]. Girish Kumar, C et al also had similar outcomes based on age which was 40.7% between the age of 6-11 months. [27] Another study discussing the Indian National Rotavirus Surveillance (INRS) programme showed 44.3% prevalence in the similar age group.[28]

Pattern of infection among 7-12 months in Chennai was 31.3% for male and 28.6% in females which was still on a higher side, followed by 13-18 (male-27%, female-22%) months and 19-24 months (male-16%, female-12%), cumulatively showing similar trend in our study. Population from 0-6 months shows Rotavirus positivity of 14% and 10% respectively showing close resemblance to our study.

Study from Meerut by has contrasting results to our study where RVA infection are higher among 13-24 months (22.72%) children followed by 6-12 months (15.49%). Our study population has higher infection rates among 6-12 months followed by 13-24 months. Low prevalence rate at the age group of 0-6 months is shared by both the studies which is 18.8% in our study and 6.25% in the above. [29]

Yet a study from Karnataka by Shetty, R. S et al showed similar pattern of infection based on age where the age betwen 7-12 months has high prevalence of 31.3% followed by 13-24 months (29.8%) and lower in the age group of 0-6 months (18.75). This study shares a fair resemblance to our study between the age group of 13-24 months (29.1%) and 0-6 months (18.6%) [30]

Two neighbouring countries follow the similar pattern of infection by Rotavirus A i.e., Nepal and Bangladesh where infection by RVA in higher during the first 24 months . [31,32] In Nepal prevalence rate are higher in the first 24 months, where 0-11 months shares 30% and 12-24 months shares 27% of RVA infection. Similarly, Bangladesh has high prevalence rates of RVA infection from 6-24 months (77%) followed by 0-5 months (14.9%) and lest in the age group of 24-59 months (8.1%). Higher frequency of

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among 6-12 months of age because of child's weaning from breast milk to artificial food products. This might be associated with the loss of protective antibodies the child has due to breast feeding. 13-24 months are second to the age group of 6-12 months that has RVA infection. This can be due to contact with people having subclinical infection or through fomites as RVA are contagious and viral load of <100 is enough to cause infection

From 0-6 months, maternal antibody (IgA anti Rotavirus antibody) from mother passed through breast milk provides initial protection among children.

The decline in RVA infection after 2 years is due to present of protective antibodies from initial infection. An episode of diarrhoea by Rotavirus infection in every child below the age of 5 years.

Rotavirus infection among Rural and Urban population

Cases of RVA infection among children were higher for rural areas (48.3%) and lower among urban population (27.4%).

Studies which consent to the same is by Paul, P et al [12], Saha J [11], Shetty, A. [33] where rural population was highest among RVA infestation which was 76.1%, 59.89% and 71.43%.

Multiple reasons may quantify RVA infection among rural population. Most importantly is the unavailability of sanitation or toilet facility ultimately leading to unsafe stool disp

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Water from unimproved sources contaminated with faecal matter also adds to the major source of infection among the population. Rural areas had limited hygiene practice which too acts as a source of infection.

Seasonal Distribution of Rotavirus A infection

This study showed majority of the infection during the winter season. Highest number of cases were found during the month of January followed with November and December. Least number of cases were found during the month July and May respectively.

Studies conducted by Girish Kr et al [27], Shetty R S [30], Pradhan S K [35] and Giri S [35] also shows similar trend where majority of the infection by RVA is during winters starting from November to February.

A possible explanation to this seasonal trend can be that the virus survives at low temperature and low humidity. Rainfall also adds to the higher incidence of Rotavirus A infection.

Rotavirus and its Genotypes

The four G genotypes identified were G9, G3, G1 and G2 whereas the P genotype identified were P8, P4 and P11.

Six different genotypes identified in our study were G9P[4] , G1P[8] , G3P[8] , G3P[11] , G2P[4] & G9P[8].

Giri S and his colleagues [36]in their study showed prevalence of G1P[8](56.3%), G2P[4](9.1%), G9P[4](7.6%), G9P[8](4.2%), and G12P[6](3.7%) across southern India and G1P[8](36%), G9P[4](11.4%), G2P[4](11.2%), G12P[6](8.4%), and G3P[8](5.9%) across northern India in a multicentric study. Across both the sides G1P[8] is the major genotype found which is the second most common genotype in our study. G9P[4], the prevalent genotype of our stands third across southern India and second across northern India. G3P[8], which is third in the list of our study wasn't found in southern India and

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least presence in the northern side of the country. Genotype G2P[4] has its presence in northern India whereas G9P[8] has its presence in southern India. Genotype G3P[11] was found neither in the southern or northern part of the country.

A study across four centres across north India [37] showed the genotypes G1P[8] (27.73%), G12P[6] (13.28%), G9P[4] (7.23%) and G1P[6] (6.75%). This study only had one strain common to our study i.e. G1P[8]. All the other genotypes have no resembles with our study.

Girish Kumar, C. P et al [27] had prevalence of G1P[8] (52.9%) which is second on our list, followed by G9P4 (8.7%) which showed maximum presence in our area and G2P4 (8.4%).

Study by Ranjitha S. et al showed presence of genotype G1P [8] and G2P[4] strains, followed by G2P[6] (6.5%) , G2P [8] and G9P[8].

Spain has higher prevalence of G9P[8] followed by G1P[8].[39] The predominantly common strains in Iran were were G2P[4] (18.8%), followed by G1P[8] (9.4%) and G4P[8] (9.4%).[40]

In Angola, most prevalent genotype was G1P[8] (47.2%), followed by the uncommon G1P[6] (29.2%), and G2P[4] (12.5%).[41] G9P[6] and G1P[8] were the major Genotypes seen in Ghana.[42] In Tunisia, predominant combination was G1P[8] (37.5%), followed by G3P[8] (25%), G2P[4] (16.7%), G4P[8] (12.5%), G9P[8] (1.7%). Unusual combination G9P[9] was also observed.[43]

Nepal 9 On the basis of molecular analysis of Rotavirus A, G12P[6] (46.39%) was the major genotype genotype followed by G1P[8] (35.05%), G3P[8] (7.21%) and G1P[6] (5.15%). [44]

Majority of the studies in India found G1P[8] as the major genotype in Rotavirus A infection. [27,36,37, 38] whereas our study has G9P[4] as the major genotype.

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VI. SUMMARY AND CONCLUSION

This study shows higher prevalence of Rotavirus A infection (44.3%) among children suffering from gastroenteritis.

Prevalence of Rotavirus A infection was higher in male (53.86%) than in females (46.13).

Our study showed higher prevalence of gastroenteritis among the age group between 6-12 months (38.1%), followed by 13-24 months (28.1%) and among 0-6 months (14.2%).

In our study, proportion of children having high rotavirus infection were from the age group of 6-12 months (44.05%) followed by 13-24 months (28.67%) and least among the age of 0-6 months (18.6%).

G9P[4] was the commonest of (31%) genotype among Rotavirus A followed by G1P[8] (22.4%). In India, the major cause of Rotavirus A infection is the genotype G1P[8]

Cases of RVA infection among children were higher for rural areas (48.3%) and lower among urban population (27.4%).

The trend during this study showed winter season having the majority of infection. Highest number of cases were found during the month of January followed with November and December. Least number of cases were found during the month of July and May respectively.

The four G genotypes identified were G9, G3, G1 and G2 whereas the P genotype identified were P8, P4 and P11.

Six genotypes prevalent in our study were G9P[4] , G1P[8] , G3P[8] , G3P[11] , G2P[4] & G9P[8].

A leading cause of death is diarrhoea among children under five years, making it is an important issue pertaining to human health in our country. These results of our study is an evidence of Rotavirus being the prevalent cause of infection among children that causes diarrhoea.

Rotavirus with its complex epidemiology which is common for a virus with multitudinous variation in transmission is amplified in studies from India, demonstrating the diversity

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of the virus in different settings.

These findings necessitate stringent efforts for improving coverage of vaccination, sanitation, proper water supplies and sanitation, and access to and quality of medical care. The diversity among Rotavirus circulating among the current population 6 in the study area encourages continuous prospective monitoring of circulating strains of rotavirus. Any changes in their distribution required prompt observation to determine the effectiveness of active immunization programs.

Figure 3: Addition of Stop Buffer in Microtiter plate

Figure 4: Programming of ELISA Reader

Figure 5: Reading of results

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Figure 6: Master Mix Preparation for Rotavirus A

Quantitation Report

Experiment Information

Run Name

09-07-2022 ROTAVIRUS RUN 6 CHANDRIM

Run Start

09-07-2022 13:33:40

Run Finish

09-07-2022 15:44:49

Operator

chandrim sengupta

Notes

rotavirus a detection pcr 6

Run On Software Version

Rotor-Gene 2.3.5.1

Run Signature

The Run Signature is valid.

Gain Green

6.67

Gain Yellow

8.

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Quantitation Information

Threshold

0.0719

Left Threshold

1.000

Standard Curve Imported

No

Standard Curve (1)

conc= 10^(-0.263*CT + 10.400)

Standard Curve (2)

CT = -3.801*log(conc) + 39.531

Reaction efficiency (*)

(* = 10^(-1/m) - 1) 0.83267

M

-3.80106

B

39.53088

R Value

0.99912

R^2 Value

0.99823

Start normalising from cycle

1

Noise Slope Correction

No

No Template Control Threshold

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% 0

Reaction Efficiency Threshold

Disabled

Normalisation Method

Dynamic Tube Normalisation

Digital Filter

Light

Sample Page

Page 1

Imported Analysis Settings

Messages

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www.qiagen.com

Message

Profile

Cycle

min secs Hold@50°,200

Cycle Point

min secs Hold 2@95°,150

(repeats) Cycling 45

Step 1@95°, hold20secs

Step 2@56°, hold20secs, acquiring toCycling A([Green][1][1],[Yellow][2][2])

Step 3@72°, hold20secs

Raw Data For Cycling A.Green

Quantitation data for Cycling A.Green

Standard Curve

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No

.

Colou r

Name

Type

Ct

Ct Comment

Given Conc (copies/ul)

Calc Conc (copies/ul)

1

QS1

Standard

16.5

5

1,000,000

1,110,408

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2

QS2

Standard

20.8

2

100,000

83,428

3

QS3

Standard

24.2

5

10,000

10,494

4

QS4

Standard

28.0

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1,000

1,029

5

NC

Negative Control

6

SAMPLE 1

Unknown

7

SAMPLE 2

Unknown

31.0

5

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170

8

SAMPLE 3

Unknown

32.5

5

69

9

SAMPLE 4

Unknown

30.6

222

No

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1

10

SAMPLE 5

Unknown

31.5

4

127

11

SAMPLE 6

Unknown

32.1

2

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89

12

SAMPLE 7

Unknown

29.5

1

432

13

SAMPLE 8

Unknown

30.5

4

232

14

SAMPLE 9

Unknown

18.8

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0

283,889

15

SAMPLE 10

Unknown

19.9

0

146,239

16

SAMPLE 11

Unknown

28.1

1

1,010

17

SAMPLE 12

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Unknown

23.2

4

19,342

18

SAMPLE 13

Unknown

26.5

3

2,634

19

SAMPLE 14

Unknown

28.0

7

1,033

20

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SAMPLE 15

Unknown

27.5

8

1,391

21

SAMPLE 16

Unknown

26.9

5

2,038

22

SAMPLE 17

Unknown

19.6

6

169,297

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23

SAMPLE 18

Unknown

27.7

9

1,227

NEG (NTC) - Sample cancelled due to NTC Threshold. NEG (R. Eff) - Sample cancelled as efficiency less than reaction efficiency threshold. Legend:

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Figure 7: RT PCR Run file

Figure 8: Preparation of Agar

Figure 9: Gel Preparation for electrophoresis

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Figure 10: Addition of samples in wells for Electrophoresis

Figure 11: Bands of Genotype P for Rotavirus A

Figure 12: Bands of Genotype G for Rotavirus A

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