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Impact of pharmacist-led interventions on influenza vaccination rates in high-risk populations

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ABSTRACT

Two pandemic outbreaks of H1N1 influenza have occurred in the past century: the Spanish flu in 1918 and the swine flu in 2009. It has been the most common human influenza virus subtype, causing a considerable amount of illness and mortality on a global scale. Antiviral prophylaxis is used in the event of unexpected influenza outbreaks to immediately stop the virus's spread. However, the effectiveness of antiviral medications in treating influenza appears questionable because drug-resistant strains are becoming more prevalent. Additionally, currently existing influenza vaccinations are strain-specific and need to be periodically reformulated to incorporate a combination of the strains of the influenza A and B viruses that are now in circulation. The development of a humoral immune response against the extremely changeable hemagglutinin protein is the issue with these vaccines. Furthermore, in the event of an unexpected epidemic, it is challenging to ensure their timely and sufficient availability. Therefore, the development of a more effective vaccine strategy that can provide universal or at least broad protection against the constantly evolving influenza virus strains in the global population is urgently needed.

Keywords: *Pharmacy, vaccination, medicine, healthcare delivery systems.*

1. INTRODUCTION

The conjugate vaccination known as the Haemophilus influenzae type B (HIB) vaccine was created to prevent invasive diseases brought on by the Haemophilus influenzae type B bacteria. The Hib vaccine is advised by the Centers for Disease Control and Prevention (CDC). The frequency of invasive Hib disease has dropped from 40–100 per 100,000 children to 1.3 per 100,000 as a result of the Hib vaccine's widespread usage in the United States between 1980 and 1990 [1]. Early childhood meningitis has been considerably reduced in industrialized and, more recently, developing nations by vaccinations against Haemophilus influenzae (Hib). Nearly all cases of meningitis, severe pneumonia, and other invasive infections in children under five are caused by the bacterium Haemophilus influenzae type b (Hib). It spreads from infected to vulnerable people via the respiratory system [2]. According to estimates, Hib caused 386 000 deaths in young children and two to three million cases of serious illness, including meningitis and pneumonia, in 2000. Although Hib illness is seen worldwide, it is challenging to prove because it necessitates quick laboratory testing in people who have never taken antibiotics.[15]. More than 100 countries currently include the vaccine in their regular vaccination schedules, and the World Health Organization advises all nations to use Hib conjugate vaccines. The vaccine can be administered alone or in combination with DTP and other vaccines, such as inactivated polio and hepatitis B vaccines [3]. Following immunization of over 100,000 newborns, the safety and effectiveness of a polyribosylribitol phosphate (polysaccharide)-tetanus protein conjugates vaccine (PRP-T) against Haemophilus influenzae type b (Hib) were assessed. There were no significant adverse effects linked to the vaccination. Within the first six months of life, immunogenicity tests revealed that 70% to 100% of newborns had an antibody response after two doses, and 98% to 100% after three doses. 90% of recipients still had antibodies, and after receiving a booster dosage at 18 months of age, they experienced notable anamnestic reactions. After three doses, PRP-T produces mean titers that are equal to or greater than those of other Hib vaccinations now on the market. Even though controlled effectiveness trials were halted by the licensure of other vaccines, no Hib disease has been documented in the more than 100,000 vaccinated children who have gotten multiple doses of PRP-T, and five occurrences of Hib disease had occurred among placebo recipients in those trials up until that point [13].[5]. Therefore, PRP-T induced immunologic memory in addition to immunogenicity early in infancy. Over 80% of cases of Hib occur in children between the ages of 4 and 18 months, making it primarily a juvenile disease with a high global case fatality rate.[4]. Since invasive illness is nearly solely limited to type B organisms and antipolysaccharide antibodies are crucial for natural immunity, the type B polysaccharide capsule appears appealing as a vaccine antigen [11].

2. METHODOLOGY

In accordance with WHO TRS 897, the polysaccharide poly ribosyl ribitol phosphate (PRP) was conjugated with tetanus toxoid to create the Haemophilus type B conjugate. Both fermentation and synthetic basal media were used to cultivate Haemophilus influenzae type B [6]. Purified polysaccharide (PRP) was prepared after the fermented Haemophilus type B was permitted to go through a subsequent step of inactivation and cell separation. Tetanus Toxoid mass was conjugated with purified polysaccharide (PRP).[9]. The cost and unsuitability of Hib conjugate vaccines for long-term storage have hampered the use of the Haemophilus influenzae type b (Hib) vaccine in low- and middle-income nations.[12]. To increase the Hib conjugate vaccine's applicability in countries where the H [17]. influenzae problem was developing, a novel, low-cost, and non-infringing production method was required.The burden of Hib disease has been significantly reduced by protein–polysaccharide conjugate vaccines, which were the first to be routinely used in a community.[7]. Prior to mass production and sale, the produced vaccine must undergo stability testing. Thus, a study on stability is proposed.[14].

2.1 Study Design

In accordance with WHO TRS 897, the polysaccharide poly ribosyl ribitol phosphate (PRP) was conjugated with tetanus toxoid to create the Haemophilus type B conjugate. Both fermentation and synthetic basal media were used to cultivate Haemophilus influenzae type B. Purified polysaccharide (PRP) was prepared after the fermented Haemophilus type B was permitted to go through a subsequent step of inactivation and cell separation. Tetanus Toxoid mass was conjugated with purified polysaccharide (PRP) [8-10].

3. DATA ANALYSIS

The product was added to the lyophilizer at a positive shelf temperature after the vials were filled. HIB/001A/13, HIB/002A/13, and HIB/003A/13 are the names assigned to the vials. The samples underwent both an accelerated stability assay and a real-time stability assay. The product underwent real-time stability testing as well as stress stability testing. A tray of the Hib-formulated vaccine was used for the first experimental run. About 1000 vials of batch HIB/001A/13 were kept at 2–8 degrees for 24 months as part of that real-time stability research.

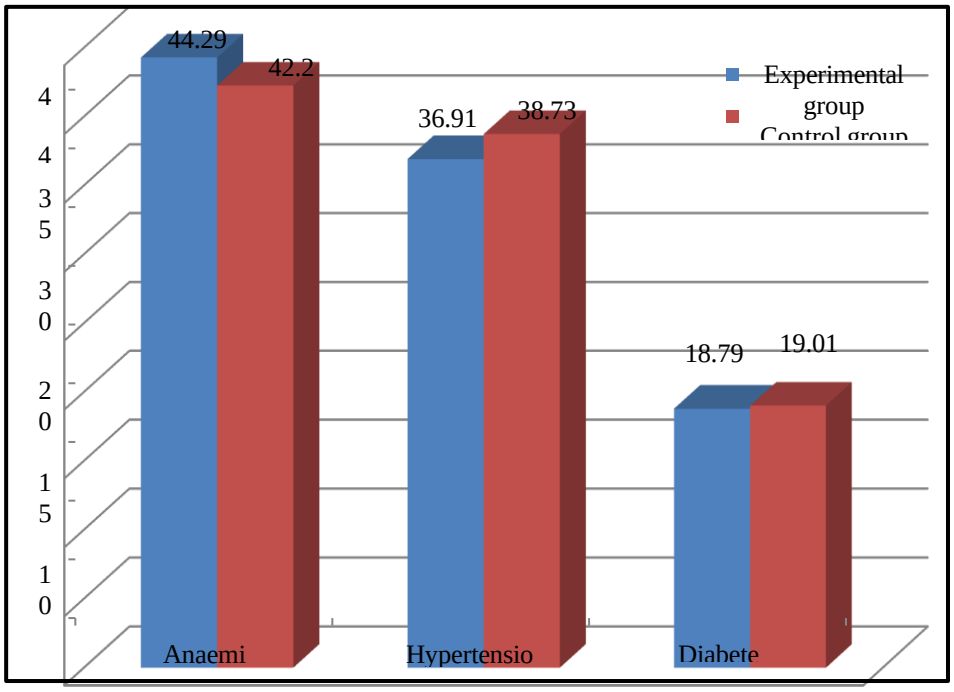

Figure 1: Resources used by survey respondents

PRP content and moisture percentage are two of the most important test factors for the preservation and storage of the Hib conjugated vaccine. As a result, both factors are thoroughly analyzed for every study.

Table1: Real time Stability study Testing details for HIB/001A/13

Product Name	*Haemophilus influenzae* Type b Conjugate Vaccine
Pharmacopoeia reference	B.P.
Presentation	0.5 mL

Dose	Single dose 0.5 mL
Batch No(s).	Hib Vaccine Final lot – HIB/001A/13
Testing frequency	Day 0 and 1,2,3,4,5,6,9,12, 15, 18 & 24 months
Storage temperature during the study	2-8° C
FINAL LOT TEST	
S. No.	**Test Parameters**
1	PRP Content
2	Molecular size
3	Visual inspection
4	Sterility
5	pH
6	Endotoxin
7	Abnormal toxicity
8	Protein
9	Free PRP
10	PRP: Protein
11	Moisture %

A tray of Hib-formulated vaccine was used for the second experimental run. Approximately 1000 vials of batch HIB/002A/13 were kept at 2–8 degrees for 24 months as part of that real-time stability research.

Table 2: Real time Stability study Testing details for HIB/002A/13:

Product Name	*Haemophilus influenzae* Type b Conjugate Vaccine
Pharmacopoeia reference	B.P.
Presentation	0.5 mL
Dose	Single dose 0.5 mL
Batch No(s).	Hib Vaccine Final lot – HIB/001A/13
Testing frequency	Day 0 and 1,2,3,4,5,6,9,12, 15, 18 & 24 months
Storage temperature during the study	2-8° C
FINAL LOT TEST	
S. No.	**Test Parameters**
1	PRP Content
2	Molecular size
3	Visual inspection
4	Sterility
5	pH
6	Endotoxin
7	Abnormal toxicity
8	Protein
9	Free PRP
10	PRP: Protein
11	Moisture %

PRP content and moisture percentage are two of the most important test factors for the preservation and storage of the Hib conjugated vaccine. As a result, both factors are thoroughly analyzed for every study.

Table 3: Real time Stability study Testing details for HIB/003A/13

Product Name	*Haemophilus influenzae* Type b Conjugate Vaccine
Pharmacopoeia reference	B.P.
Presentation	0.5 mL
Dose	Single dose 0.5 mL
Batch No(s).	Hib Vaccine Final lot – HIB/001A/13
Testing frequency	Day 0 and 1,2,3,4,5,6,9,12, 15, 18 & 24 months
Storage temperature during the study	2-8° C
FINAL LOT TEST	
S. No.	**Test Parameters**

1	PRP Content
2	Molecular size
3	Visual inspection
4	Sterility
5	pH
6	Endotoxin
7	Abnormal toxicity
8	Protein
9	Free PRP
10	PRP: Protein
11	Moisture %

A tray of Hib-formulated vaccine was used during the third experimental run. Approximately 1000 vials of batch HIB/003A/13 were kept at 2–8 degrees for 24 months as part of that real-time stability research. PRP content and moisture percentage are two of the most important test factors for the preservation and storage of the Hib conjugated vaccine. As a result, both factors are thoroughly analyzed for every study. The product will be more effective and retain the necessary residual moisture levels if the hold time of primary drying is changed rather than the ramp time.

Table 4: Tests performed on Final Lot of Hib Vaccine

Tests performed on Final Lot of Hib Vaccine	
S.No.	**Title**
1	Determination of free PRP content in GPC fractions of PRP-TT conjugate
2	Estimation of EDC content in Hib-TT sterile bulk conjugate using UV-Vis Spectrophotometry
3	To perform sterility test on Hib-TT sterile conjugate Bulk.
4	To estimate Protein content in Tetanus toxoid bulk
5	To perform SDS-PAGE analysis of the Tetanus toxoid bulk samples to check the purity of the bulk.
6	To check the purity of the Tetanus toxoid bulk by HPLC method

Following the successful conclusion of the lyophilization cycle, the final lot vials were examined for every test listed in table 4.7 below. This new technique produced a lyophilized vaccine that was good and free of dried product aggregation. [16]. In the main and secondary drying stages, reduction was used to shorten the lyophlization cycle. Additionally, shorter cycle times lower lyophilization costs.

4. CONCLUSION

This study illustrates the manufacturing of the Hib vaccine and the qualities of the finished freeze-dried product, including sterility, potency, and efficacy. Additionally, it looks into protein-polysaccharide immunology, polysaccharide immunobiology, and antigen properties. This further demonstrates that the timing of the lyophilization cycle and moisture affect the product's effectiveness. A more thorough knowledge of how vaccines interact with herd immunity, illness, and natural immune responses is slowly coming to light. Although there are numerous epidemiological and immunobiological parallels, protein-polysaccharide conjugate vaccines are advised for Hib. The long period of time that surveillance must be conducted to track the outcomes of such research is highlighted by experience with Hib conjugate vaccines. Nonetheless, such surveillance can offer assurance regarding the capacity of vaccinations to lessen the burden of these severe diseases as well as important insights into vaccine immunobiology. Although the WHO has made providing Hib a priority, distribution challenges are still mostly related to cost and logistics. Furthermore, some places lack basic epidemiological data, and by identifying disease burdens and expanding the use of these extremely effective vaccines, important steps may be taken right now.

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