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The impact of haemophilus influenzae type b (hib) vaccine on pneumonia and meningitis among children under the age of 1 year in the Klerksdorp district of the North West Province

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THE IMPACT OF HAEMOPHILUS INFLUENZAE TYPE B (HIB) VACCINE ON PNEUMONIA AND MENINGITIS AMONG CHILDREN UNDER THE AGE OF 1 YEAR IN THE KLERKSDORP DISTRICT OF THE NORTH WEST PROVINCE

RESEARCH REPORT SUBMITTED

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BY

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****

Supervisor: Mr Caesar Vundule

Declaration

I, Otsile Calvinia Sebekedi declare that this research report is my own, unaided work. It is being submitted in partial fulfillment of the requirements of the degree of Master of Public Health (MPH) in the university of the Witwatersrand, Johannesburg, Republic of South Africa. This work has not been submitted before for any degree or examination at this or any other university.

Signature: 

Date: 07 November 2000

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EXECUTIVE SUMMARY

The purpose of this study was to determine the impact of Hib vaccine on pneumonia and meningitis in children under the age of 1 year in the Klerksdorp district of the North West Province.

A record review was done to select cases under the age of 1 year admitted at Tshepong hospital with either pneumonia or meningitis. Two similar periods were compared in respect of the incidence of both conditions.

The study has shown a decline in the incidence of both pneumonia and meningitis after introduction of the vaccine. While the decline in the incidence of pneumonia was statistically significant, that of meningitis was shown to be insignificant.

The significant decline in the incidence of pneumonia is suggestive of the positive impact of the Hib vaccine.

It is recommended that:

- A similar study be conducted in the North West Province after 3 years of the introduction of the vaccine.

- The impact of the Hib vaccine be measured on an ongoing basis using surveillance data.
- Other studies be conducted in the province and in the country to determine factors that may affect effectiveness of the immunisation programme and the impact of HIV/AIDS on the programme respectively.

CHAPTER 1

INTRODUCTION AND ORIENTATION

1.1 Background

Communicable diseases remain one of the major health problems in developing countries today. These diseases are responsible for high rates of morbidity and mortality in the countries affected. The situation has been compounded by the HIV/AIDS pandemic which emerged in the past two decades, whereby these diseases take opportunities of compromised immune systems of individuals infected with HIV.[1] Other compounding factors include the poor living conditions in which most people in less developed countries live. Countries experiencing civil wars and other forms of internal strife are at increased risk because of displacement of communities to over-crowded slum areas.[2]

Infections from Haemophilus Influenzae Type B (Hib) bacteria are among the major causes of severe bacterial diseases in unimmunised infants and young children under the age of 5 years in both developed and developing countries. Infection with Hib bacteria can cause pneumonia, meningitis, septicaemia, septic arthritis, osteomylitis, cellulitis, pericarditis and epiglottitis. Some of the children who survive the Hib disease suffer permanent disabilities such as blindness, deafness, and paralysis due to neurological impairment.[3]

In South Africa a Cape Town study estimated that 1 in 250 children under the age of 5 years become seriously ill from Hib disease and most children need hospitalisation to be treated.[3]

Pneumonia and meningitis due to Hib are common in children under the age of 1 year and mortality from meningitis is high.[4] In developed countries about 5% of children with Hib meningitis die, while the case fatality rate in developing countries may be up to 47%. In South Africa the Cape Town study also established that 1 in 11 children who become infected with Hib will die and the case fatality rate may differ between provinces.

According to Children's Vaccine Initiative 1998 [5], the first modern Hib vaccine, appeared in the health scene about a decade ago. This Hib conjugate vaccine, unlike its unconjugated predecessors has proven to be effective and efficacious against Hib disease in both developed and developing world settings. Mulholland et al 1997 [4] also maintain that "protein polysacccharide conjugate vaccines have been highly effective in reducing Hib disease and carriage in industrialised countries". In 1974 the World Health Organisation (WHO) introduced a successful programme known as the "Expanded Programme on Immunisation" (EPI), with the

objective of expanding immunisation services beyond smallpox, with the emphasis of providing these services for children in developing countries.[6] At the beginning of the programme, six vaccine preventable diseases were included in the EPI: tuberculosis, diphtheria, pertussis, tetanus, polio and measles. Subsequently two more vaccines were included in the routine EPI schedule during the 1990s. These were yellow fever and hepatitis B vaccines. Yellow fever vaccine was introduced in the EPI programme in countries where this disease posed a risk. Hepatitis B vaccine was introduced gradually with a target date of 1997 for its incorporation in the immunisation programme of all countries.[6] In countries where neonatal tetanus is an important cause of infant mortality, immunisation of women of child bearing age, especially pregnant women is recommended. The policy for neonatal tetanus elimination in South Africa is in line with this recommendation.[7]

WHO/EPI/Gen 1993 [6] further states that the immunisation schedule in each country is consistent with epidemiology of diseases against which immunisation is provided, and within the capacity of the vaccine delivery system. It is thus important for immunisation programmes considering inclusion of additional vaccines as part of their routine immunisaton schedules to evaluate the epidemiological patterns of the target diseases in their country, as well as additional resources required for the introduction of the new vaccine to ensure cost effectiveness and sustained

supply and distribution respectively. The first priority for routine immunisation programme is to ensure that infants are immunised against the target diseases with appropriate primary immunisation at the youngest age possible.

In South Africa, hepatitis B vaccine was introduced as part of the immunisation programme in 1995, but yellow fever vaccine has never been part of the programme since it is not endemic in the country.[7]
South Africa therefore currently provides eight vaccines in its EPI programme.

The lastest vaccine to be introduced in the South African EPI programme is Haemophilus Influenzae Type B (Hib) vaccine, on 1 July 1999. Three doses are given to each child at the age of 6, 10 and 14 weeks. Reconstitution of the Hib vaccine with diphtheria, tetanus and pertussis (DTP) vaccine takes place at the point of immunisation so as to administer DTP-Hib combined vaccine in one injection to every eligible child. The vaccine is given at the same time with Hepatitis B and polio vaccines.

The North West province in South Africa also participated in the national initiative of Hib implementation which started on 1 July 1999 in all the public sector health clinics. The vehicle for Hib implementation is the EPI programme.

The EPI is a vertical programme at provincial level, headed by the programme manager (EPI Coordinator) at an Assistant Director level. The EPI unit is located in the Sub-Directorate: Communicable Diseases Control, which is in turn located in the Directorate: Health Programmes.

Policies for the EPI programme are developed at national level with inputs from provinces. Implementation takes place at provincial level within the District Health System structures. The actual immunisation thus takes place as an integral part of primary health care activities in each clinic. Participation of hospitals in the EPI is confined to immunisation with BCG and polio drops at birth as well as catch up immunisations for admitted children and those consulting at out-patient departments.

The provincial EPI Coordinator champions the whole process of policy implementation at all levels and provides technical support to district coordinators in the 18 health districts of the province. At district level EPI uses Communicable Disease Control Coordinators (CDCs) for policy implementation at facility (clinic and hospital) level. Each district has a

CDC who is not only responsible for the EPI, but for all communicable diseases in the district. The role of CDCs in the EPI include, among others, training and technical supervision of vaccinators, EPI disease surveillance, outbreak response and ad hoc projects such as measles and polio campaigns and introduction of new vaccines.

Primary Health Care services in the Klerksdorp district where the study site is located are rendered by 18 fixed clinics, 16 of which belong to the local authorities and 2 to the province. The local authority thus plays a pivotal role in Primary health Care service delivery in this district. There are seven mobile teams serving mainly the farming areas of Klerksdorp. Of the seven mobile teams, four belong to the local authority and depart from three fixed local authority clinics every morning. Three of the seven teams belong to the province and are accountable to the Assistant Director of Community Health Services at the Klerksdorp district office where they converge every morning before leaving for their various stations.

Vaccine logistics and related functions are handled by the Directorate of Pharmaceutical Services. The function of procurement, management and distribution of drugs including vaccines up to district depots was outsourced to a private company: Vuna Health Care Logistics (VHL) since October 1999. The Department is thus still responsible for management

and distribution of vaccines from hospitals which are the current distribution points for clinics.

1.2 Study site

The study was conducted in the North West province (map1).[8] The province comprises areas of the former Western Transvaal, Bophuthatswana and part of the Cape Province. According to the 1996 population census, the population is 3,4 million (table 1).[9] There were 75 124 (2.2%) children under the age of 1 year in 1996. This number constitutes the target population for primary vaccine series in immunisation. About 70% of the population live in rural areas where distances from health facilities are vast, and transport poses one of the major problems.

The economy of the province relies heavily on mining, with resultant migration to towns for job seeking. Continuous migration and the seasonal movement of farm workers make it difficult to maintain and assess the effectiveness and efficacy of health services including immunisation.[10]

The Department of Health established its new boundaries after 1994. According to these boundaries, the province was divided into five regions, but have been recently reduced to four, with the merge of two regions of the Eastern side of the province (Odi and Rustenburg).[11] The regions were

sub-divided into 18 districts. Boundaries of the health districts were coterminous with those of magisterial districts, the only difference being that Christiana and Schweizer-Reneke magisterial districts formed one health district.[8] These boundaries are expected to change in the near future with the implementation of the new boundaries resulting from the demarcation process presently taking place in the country. A list of regions and districts in those regions is as follows:

A. Mafikeng

Mafikeng

Lichtenburg

Zeerust

Delareyville

B. Klerksdorp

Klerksdorp

Potchefstroom

Ventersdorp

Wolmaransstad

C. **Rustenburg**

Rustenburg

Mogwase

Odi

Moretele

D. **Vryburg**

Vryburg

Kudumane

Taung

Ganyesa

Schweizer-Reneke

Map 2 shows the location of primary health care facilities in the Klerksdorp region.[8]

The Klerkdorp district has the third largest population after Moretele and Rustenburg according to the 1996 population census.[9] About 10% of the population (334 497) live in this district. Children under the age of 1 year constitute 2% (6362) of the district population. Using the 2.3% provincial growth rate, the population under the age of 1 year was estimated at 6811 in 1999 and 6968 in the year 2000 (table 2). [9]

The facility where the study was conducted is Tshepong hospital. This is one of the two public sector hospitals in the district. The other hospital, Klerksdorp is a provincial hospital and serves as a referral point for the entire Klerksdorp region and in some instances for the province. Tshepong is a district hospital situated in a small township of Jouberton just in the outskirts of town. Before 1994, Klerksdorp was a whites only hospital while Tshepong served mainly black patients. The two hospitals are, however, under the same management and are known as Klerksdorp/ Tshepong complex. Rationalisation of services in these institutions took place in May 1999, when Tshepong was identified as a district hospital and Klerksdorp as a provincial hospital both serving all racial groups. During the process of rationalisation paediatric wards of both hospitals were merged and the responsibility of paediatric medical care for the entire district given to Tshepong hospital. The implication is that there is no paediatric ward at Klersdorp hospital presently, and Tshepong caters for all medical care needs of all children in the district who require level 1 medical care in the public sector. As this happened in the middle of the study it may have had substantial impact on results in terms of accessibility to paediatric care.

There are three private hospitals in the district. According to a report of Centre for health Policy of the university of the Witwatersrand 1997 [12], 21 percent of the population in the Klerksdorp district belong to medical aid

schemes. This implies that about 21 percent of the population in this district obtain their health services from the private sector.

1.3 Statement of the problem

It is estimated that 1 in 250 (5 729) children under the age of 5 years in South Africa become seriously ill from Hib disease every year. Most of these children are treated in hospital. Data from the Cape Town study suggests that 20% of survivors have permanent brain damage, mainly from Hib meningitis.[3]

Death from Hib disease is especially common in children under the age of 1 year. Most deaths occur as a result of Hib meningitis, pneumonia or septicaemia.[3]

Immunisation with Hib vaccine is the only way of protecting children against Hib disease. Until 1 July 1999, only those parents who could afford to pay their private practitioners for the expensive vaccine were able to protect their children from Hib disease in South Africa. From 1 July 1999, the Hib vaccine was introduced as part of the routine immunisation schedule for all public clinics participating in immunisation. The vaccine is given to all children visiting those clinics at 6, 10 and 14 weeks.[13]

The impact of Hib vaccine in South Africa is not known. The aim of this study was to determine the impact of this vaccine on the incidence of pneumonia and meningitis in children under the age of 1 year in the Klerksdorp district of the North West Province.

1.4 Rationale for the study

This study sought to determine the impact of Hib vaccine on clinical cases of pneumonia and meningitis in the Klerksdorp district. Based on the information gained from the literature review, the researcher made an assumption that the Hib vaccine should result in a decline on the overall incidence of clinical pneumonia and meningitis as the number of Hib specific cases decline.

Intervention strategies for disease control require that effective surveillance systems be put in place so as to determine the impact of these interventions.

Hib disease was made notifiable in South Africa since 1994.[14] The current notification system, however, relies solely on the notification of a clinical diagnosis by a health worker without taking the laboratory component into consideration. In diseases such as Hib, this is quite questionable, as the clinical diagnosis of for example, Hib pneumonia would not differ from the

clinical diagnosis of other acute bacterial pneumonia. This has caused formidable underreporting of Hib disease in the notification system.[15]

A laboratory surveillance system for Hib meningitis in South Africa was introduced in 1994 when the disease was made notifiable.[15] The system was, however not well established in most parts of the country until 1999 after the Hib vaccine implementation. Hib diseases have thus been under-reported. The result is that there is no reliable baseline data against which comparison can be made since the laboratory surveillance system is now in place. Furthermore, the surveillance system is only for Hib meningitis, but there are other forms of Hib infections such as Hib pneumonia for which laboratory confirmation is not available.

In the absence of a comprehensive laboratory surveillance system, Hib vaccine was introduced as part of routine immunisation on 1 July 1999. It became advisable for the researcher to use other means on a small scale of determining the impact of this vaccine within a short period after its implementation. Pneumonia and meningitis were chosen because they are the most common Hib diseases in South Africa. It was found, during the process of the study that Tshepong hospital was one of the few that had established laboratory surveillance of Hib meningitis before 1999. Although this study sought to compare clinical cases of pneumonia and meningitis before and after introduction of the Hib vaccine, laboratory

surveillance was used to confirm Hib specific meningitis cases, as it provided an accurate picture of the disease incidence for periods under review (see annexure). Clinical diagnosis was solely used for cases of pneumonia.

1.5 Ethical considerations

Following approval of the research protocol by the post graduate and ethics committees of the university, permission and approval to conduct the study was sought from the Deputy Director General of the Department of Health in the North West Province. Permission was also obtained from the Tshepong hospital management (see annexures).

The staff in the paediatric ward at Tshepong hospital was orientated about the study with regard to its rationale, the time frames and their role in the process. It was further explained that no staff member would be punished in any way as a result of the study.

Since secondary data was used in the form of records, no individuals were interviewed and thus no consent was obtained from individuals participating in the study. Names of patients were not included at any stage of this study. Patient admission numbers were used solely to ensure that duplication of reporting does not occur.

1.6 Aim and objectives

The aim of this study was to determine the impact of the Hib vaccine on the incidence of hospitalised cases of clinical pneumonia and meningitis among children under the age of 1 year in the Klerksdorp district of the North West Province.

The study objectives were as follows :

1 .6.1 To determine the demographic (age) characteristics of children admitted with either clinical pneumonia or meningitis at Tshepong hospital in Klerksdorp district.

1.6.2 To compare the number of incident cases of clinical pneumonia under the age of 1 year admitted at Tshepong hospital for a period of 6 months before and 6 months after the introduction of the vaccine.

1.6.3 To compare the number of incident cases of clinical meningitis under the age of 1 year admitted at Tshepong hospital for a period of 9 months before and 9 months after introduction of the vaccine.

1.6.4 To determine the Hib immunisation status of children admitted with either pneumonia or meningitis.

1.6.5 To determine the number of doses and interval between doses for immunised children admitted with either pneumonia or meningitis.

CHAPTER 2

LITERATURE REVIEW

Hib immunisation is provided through the Expanded Programme on Immunisation (EPI). EPI is one of the eight components of Primary Health Care (PHC). Primary Health Care thus formed the point of departure for literature that was reviewed, so as to get a broader perspective of the field in which immunisation in general, and specifically Hib immunisation and its impact on target diseases take place. Reports and articles on primary Health Care, Expanded Programme on Immunisation and Hib diseases and the vaccine, and studies on the impact of Hib were investigated to establish commonalities and differences, but most importantly to determine previous studies done on the topic being researched and relationships of the findings of those studies with this one.

2.1 International perspective of primary health care.

Dennill et al 1995 [16] state that the concept of primary health care was developed as a means to urge governments of several countries to rationalise their highly technical approach to health care and to broaden their coverage by providing better basic services. Despite this move, health care throughout the world continued to have fragmented systems with trends towards expensive treatment for a few ill people rather than

preventive and promotive health care for many. These inequalities were found in both developed and developing countries worldwide.

In response to the international sense of despair regarding inadequate health care, an international conference on Primary Health Care, jointly sponsored by the World Health Organisation (WHO) and the United Nations Children's Fund (UNICEF) was hosted by the government of USSR at Alma-Ata in 1978. At the end of the conference a declaration of intent was drawn up. The declaration succinctly outlined the principles and components through which any primary health care service can be universally established.[16]

2.1.1 Principles underlying a successful primary health care strategy

According to Denill et al 1995 [16], a successful primary health care strategy is underpinned by six principles: access, equity, affordability, availability, effectiveness and efficiency.

There should be a comprehensive access to primary health care services which involves geographical, financial and functional access. Services should be within a reasonable distance from where the people using them live. WHO recommends 5 – 10 km and transport should be available. Costs should be in such a manner that users of services are able to pay

for them, and the services rendered must be appropriate to the health needs of the population as well as being culturally acceptable.[16]

People should have equal access to basic health care and social services. Emphasis should be placed on the disadvantaged such as people in rural areas, poor people and others who are at greatest risk for health problems.[17] Of greater importance is the fact that primary health care services should be aligned with what the community and the country can afford. No person should be denied health care because of their inability to pay.

There should be sufficient and appropriate services to meet the health care needs of each community. The services provided must do what they were intended to do, and the results attained should be proportionate to the input, in terms of effort expended, money, time and other resources.[16]

2.1.2 Other important concepts for a successful primary health care strategy.

Community involvement and participation.

The key concept in primary health care is the involvement of the community in needs assessment, plans to address identified needs, implementation of plans and evaluation of the whole process. The global polio eradication initiative has a good example of the real sense of

community participation and its benefits. For example, the independent commission (Taylor Commission), established in 1992 by the Pan American Health Organisation found that the greatest positive impact of polio eradication was on social mobilisation and intersectoral collaboration.[18] Social mobilisation strategy involved strengthening existing community organisations, the widespread use of education campaigns involving the mass media and political and community leaders. The approach ensured that communities were not only motivated to bring their children to be immunised during national immunisation days, but they also became actively involved in the campaign by helping to deliver the vaccine and maintain the cold chain, often making available their own vehicles, refrigerators and ice boxes. The business community heavily supported the National Immunisation Days in the Phillipines from 1993 to 1996, through funding, allowing establishment of immunisation posts in fast food outlets, petrol stations, shopping malls, radio and television stations, bus and railway stations, government offices, schools and hundreds of company clinics.[18]

Of importance as well is the findings of the Taylor Commission on the impact of polio eradication campaign on health systems in the Americas. The Taylor Report pointed out that the polio eradication campaign established a culture of immunisation and served to improve

communication between health services staff and local communities, which in turn enhanced community participation.[18]

Intersectoral collaboration.

Primary health care, according to Lancaster 1988, [17] recognises that the health of a community cannot be improved by interventions within the health sector alone. Other sectors are equally important, and, in some cases more so, in promoting the community's health and self reliance. For example, education, environment, industry, housing and nutrition are interrelated with health. These sectors need therefore to work together in a coordinated manner to ensure that they contribute to the health of the population and to avoid conflicting or duplicating efforts.

Intersectoral collaboration and community participation were found to be the twin pillars of primary health care and two strategies that had proved very difficult to implement in the Latin American countries before the polio eradication campaign which provided a base for development and implementation of these strategies.[18]

Disease prevention and health promotion

Emphasis in primary health care is on disease prevention and health promotion rather than curative services. Programmes such as

immunisation form the pillar of preventive services, while provision of health information provide a good measure for health promotion.[17]

Appropriate technology.

Appropriate technology is defined by National Science foundation in Lancaster 1988 [17] as "health care that is relevant to the needs and concerns of people, as well as being acceptable to them". Costs, affordability of services within the context of existing resources such as number and type of health professionals and other workers, equipment, supplies and their distribution patterns through the community are all essential elements of appropriate technology.

GOBI – FFF

Three years after Alma-Ata the United Nations Children's Fund introduced a programme called "Child Survival Revolution". The objective was to reduce the high morbidity and mortality of infants and children in the developing world, since the improvement in the welfare of children was very limited despite the introduction of primary health care. Four activities were recommended to accomplish the child survival revolution strategy:

- G – Growth monitoring
- O – Oral rehydration
- B – Breastfeeding
- I – Immunisation

Subsequently, UNICEF and interested parties agreed that the emphasis first be placed on immunisation, to be followed by oral rehydration and other phases as soon as possible. This agreement was expanded by the introduction of three more activities additional to the original four. These were:

- F – Food supplementation
- F – Female literacy
- F – Family planning

Despite the wide criticism of this programme it was universally accepted as an integral part of primary health care.[16]

2.1.3 Trends in the Global Strategy of Primary Health Care

Many of developed countries have made substantial progress in bringing health services to their people. An ageing population has emerged in these countries because of an increased life expectancy, resulting in a shift in health problems to more chronic conditions. Rapid urbanisation has also affected health needs, with problems related to new lifestyles, high risk behaviour and deteriorating environments. The emphasis of the services in these countries is to meet these new needs and to reduce socio-economic disparities.[16]

Dennill et al 1995 [16] further state that developing countries have also made significant progress in establishing a health infrastructure based on

primary health care. As the programme evolves and needs are met, new health needs similar to those in developed countries emerge, and these need to be addressed, often under constraints of resources. Some developing countries continue to struggle with very high infant and maternal mortality rates and alarming morbidity rates. Socio-economic conditions are poor, resources are scarce and the philosophy behind primary health care is still, to a certain extent, misunderstood in some countries. The situation is often compounded by natural and man-made disasters. These countries require both technical and financial support from the international community to aid them in their national development and health policies for them to attain optimal primary health care for all.

2.2 South African perspective of primary health care

Until 1994, health care in South Africa comprised a system that was highly fragmented, biased towards curative care and the private sector, inefficient and inequitable. Although the concept of primary health care was acknowledged in most literature locally, there were no policies to address its implementation in line with the contents of the Alma-Ata declaration. [19]

The need for transformation of the health sector in South Africa saw the African National Congress (ANC) initiating development of an overall National Health Plan based on Primary Health Care approach in 1994.

The plan was linked with the Reconstruction and Development Programme which involved all other sectors. Health was therefore viewed from a development perspective, as an integral part of socio-economic development plan in South Africa.[19]

Implementation of the National Health Plan for South Africa started in 1994. Three levels of government are identified in the plan: national, provincial and district levels, each with its own responsibilities and shared common goal: health care provision for the people of South Africa. Health care delivery takes place in a decentralised manner, with the district health system as a vehicle for the decentralisation process. Primary health care facilities are clinics and they serve as the point of entry into the health care system. A comprehensive package of services: preventive, promotive, curative and rehabilitative are provided for individuals, families and communities at clinic level.[20]

The services provided by primary health care workers include: immunisation, communicable and endemic disease prevention, maternity care, screening of children, integrated management of childhood illnesses (IMCI) and child health care, health promotion, youth health services, counselling services, chronic diseases, diseases of older persons, rehabilitation, accident and emergency services, family planning, and oral health services. Patients visiting primary health care services are treated

mainly by primary health care nurses. Patients with complications are referred to higher levels of care such as hospitals if the conditions cannot be treated at primary health care level.[21]

2.2.1 Primary health care services in the North West Province

The North West Province has adopted Primary Health Care as a national strategy to address the basic health care needs of the population. The primary health care strategy is also pursued as part of socio-economic development.[22]

Primary health care services are brought nearer to the people through a decentralised system of district health. The district health system encourages participation of local communities. This has been strengthened by the launching of governance structures in the form of district committees, clinic committees and hospital boards.[23]

The province is also engaged in a continued process of forging partnerships with other sectors and other Departments that impact on health. This strategy ensures a holistic approach to primary health care and health care in general. It is hoped that the partnership against HIV/AIDS which is currently being strengthened will in the long run benefit other programmes such as immunisation.[24]

2.3 International perspective of Haemophilus Influenzae Type B .

Children represent the most vulnerable segment of the population in any society. Promoting children's good health is one vehicle through which social development can be achieved.[25] Immunisation has proven to be the most cost effective way of preventing childhood communicable diseases responsible for high morbidity and mortality particularly in developing countries.

One of the major causes of morbidity and mortality haunting developing world today is Haemophilus Influenzae Type B disease. This comprises a variety of serious and potentially life threatening diseases among which are Hib pneumonia and meningitis in infants and children under the age of 5 years. [7] It is reported that safe and effective conjugated vaccines have been developed and licensed for use in several industrialised countries where they have dramatically reduced the incidence of Hib disease especially meningitis.[13]

According to a Summary of Notifiable Diseases of USA 1997 [26] an estimated 20 000 cases of Hib invasive diseases among children occurred annually prior to Hib vaccine licensure in 1987 in the United States of America. The dramatic decline was attributed to the introduction of the Hib vaccine to children of pre-school age. To that effect, a total of 260 cases of Haemophilus invasive disease among children aged less than 5

years were reported in 1997. Of the 260 children, 82 (41%) for which serotype was known were type B. Forty-two (51%) were aged less than 6 months, which means they were too young to have completed a three dose primary Hib vaccination. However, 27 (68%) of the 40 children who were old enough (6 months and above) to have completed a three dose primary series before they developed Hib invasive disease were incompletely vaccinated or their vaccination status were unknown. These cases might have been prevented with age appropriate vaccination.[26]

According to WHO Global Programme for Vaccines and Immunisation Report, priorities for research and development related to prevention of Hib disease in developing countries were addressed in March 1996. Subsequently the possibility of introducing Hib vaccine into the EPI schedule formed the main discussion of an international meeting held in Bali, Indonesia in December 1996. The results from two clinical trials performed in the Gambia and Chile showed 80% to 100% efficacy of conjugated Hib vaccine against Hib pneumonia and 90% to 95% against all types of invasive Hib diseases. The findings also showed a significant reduction in nasopharyngeal carriage. "These findings have fuelled interest in the wider introduction of Hib conjugate vaccine into routine immunisation programmes in developing countries" .[25]

While the vaccine was shown to be efficacious in the prevention of Hib pneumonia according to The Gambian trial, it was also interesting to reveal that it had an impact on the overall incidence rate of pneumonia as an indirect measure of the true incidence of Hib pneumonia in the community.[4]

Kim Mulholland, leader of the study team, is reported to have been excited by the results of the trial, that the vaccine reduced the incidence of all forms of pneumonia by 21%. This, according to him tells us not only that the vaccine works, but for the first time gave an indication that in a third world setting, one case in five of pneumonia could be due to Hib.[4] The Gambia trial conducted in the even more difficult conditions of a poor African country, according to Mark Steinhoff of Johns Hopkins University, strengthened the case for not delaying the introduction of routine Hib immunisation in developing world. In the Gambia, deliberations on key issues regarding the introduction of the vaccine in the national immunisation programme started in October 1996 in a meeting held with all Hib conjugate vaccine producers.[4]

2.4 South African perspective of Haemophilus Influenzae Type B.

In South Africa, like in other developing countries, little was known about the epidemiology of the Hib infections until 1993, when two studies were conducted in Cape Town, one on carriage of Hib in Cape Town [3] children

and the other one on epidemiology of Hib infections in Cape Town.[27] The conclusion drawn from the Hib carriage study was that carriage of Hib in normal children in Cape Town is similar to that reported from other developing countries.[3]

The study on the epidemiology of Hib generated information necessary for decision making with regard to the introduction of routine Hib immunisation in Cape Town. National extrapolations were made from this study to the fact that about 5 729 children in South Africa suffer from Hib diseases annually and 1 in 11 with Hib die. This prospective study documented that invasive Hib infections is a significant problem in Cape Town with Hib infections accounting for 86.5% of invasive cases.[27]

The observation of the overall clinical disease patterns in South Africa suggests that Hib infection accounts for 70% of pneumonia cases, 24.2% of meningitis cases, 2.9% of septicaemia cases and 2.9% of other Hib diseases. Available data from the notification system indicate that a total of 262 cases of Hib disease was reported during the period 1994 to 1998 to the national Department of Health (table 3). 14 deaths were reported over the same period.[28]

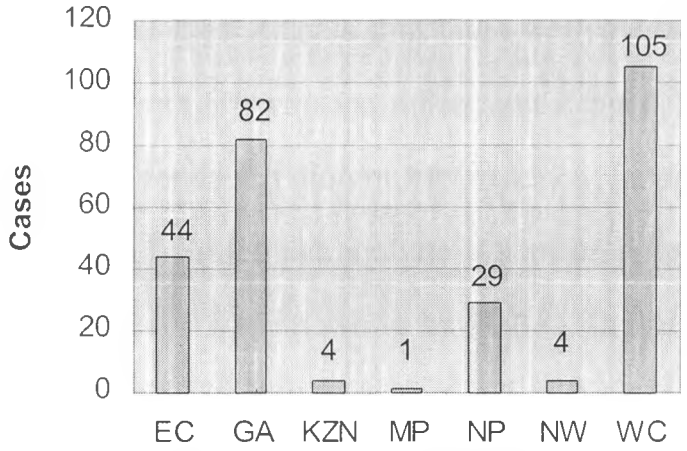
Table 3: Number of Hib disease cases notified in South Africa: 1994-1998.

Year	Number of cases
1994	43
1995	52
1996	65
1997	49
1998	53
Total	262

Source: Epidemiological Comments 1999;1(13):3.

The provincial breakdown is shown in figure 1. No cases were reported from the Free State and Northern Cape Provinces.

Figure 1: Reported cases of Hib disease by province: 1994-1998



Source: *Epidemiological Comments 1999,1(13):3.*

On the basis of the international experience with regard to safety, efficacy and effectiveness of the Hib vaccine, South Africa undertook to introduce it routinely as part of the Expanded Programme on Immunisation (EPI) schedule. The Hib vaccine was thus introduced nationwide in the immunisation schedule with effect from 1 July 1999.[13]

2.5 Hib vaccine efficacy

A double blind randomised trial was conducted in the Gambia to assess the efficacy of the Hib conjugate vaccine for the prevention of meningitis, pneumonia and other invasive diseases due to Hib. The efficacy of the vaccine for the prevention of all invasive diseases after 3 doses was 95%. For the prevention of Hib pneumonia after two or three doses it was 100%.[4]

In the United States the protective efficacy of two or more doses of Hib vaccine among children aged 2 to 18 months was 86%.[29] Other serological studies indicate that there are several serological parameters associated with Hib vaccine efficacy in infants. They also state that the immune response to different Hib vaccines varies both quantitatively and qualitatively.[30] In the study of the Valencian community of Spain, the Hib vaccine efficacy was shown to be 90.6%. The Australian study estimated the vaccine efficacy at 80% for Aboriginal children.[31]

2.6 Vaccine identification and handling

The formulation used is that of DTP-Hib combined vaccine which is given as part of primary vaccination series at 6, 10 and 14 weeks at the same time with polio and hepatitis B vaccines. No catch up of older children was done. Thus a child having had received all the three doses of DTP of the primary series was regarded as old.[13]

The Hib component of the vaccine is a white powder which contains Hib particles conjugated to a protein. The DTP component is a liquid which contains diphtheria, tetanus toxoid and killed pertussis. The DTP-Hib combined vaccine is obtained by reconstituting the lyophilised Hib component with the liquid DTP component. The type of formulation used may change from time to time depending on what is available on tender. Studies have, however, shown that different formulations have similar effects.[13]

In order for the vaccine to maintain its scientifically proven properties, namely, safety, efficacy and effectiveness certain procedures need to be adhered to. With regard to safety it is necessary to ensure that only the vaccine is given to the child and not micro-organisms. Aseptic techniques therefore need to be adhered to during vaccine administration process.[32] According to the "guidelines for vaccine handling at all levels 1997 [33] only a potent vaccine can be effective. Introducing new and expensive vaccines is unlikely to be worthwhile unless we can assure the maintenance of potency and quality. The DTP-Hib vaccine, like any other vaccine is heat sensitive and should always be stored at a temperature of between 2 and 8 degrees celsius.[33]

The vaccine components or reconstituted vaccine must not be frozen according to the cold chain and immunisation operations manual 1997. [33] The Expanded Programme on Immunisation policy guidelines require that the temperature of every vaccine refrigerator be read and recorded twice daily on the temperature chart so that any deviations from the normal can be detected timeously and appropriate action be taken. Cold boxes should be used as an alternative cold chain maintenance measure in cases of power failure.[33]

The EPI/SA 1999 [13] policy stipulates that a reconstituted vial of DTP-Hib vaccine may be used in subsequent immunisation session for a maximum period of 7 days provided that the vaccine has not expired, it is stored under the correct temperature and is not contaminated.

In the North West province all vaccinators were trained on all requirements for handling the vaccine as discussed. The new vaccine is thus expected to perform well like it did in other developing countries (The Gambia, Chile and Uruguay). The reason for bringing in handling of the vaccine is because the whole situation as discussed may obscure the impact of the vaccine. The potential confounders in this study such as cold chain were thus controlled.

CHAPTER 3

METHODOLOGY

3.1 Study design

A descriptive study with an analytic component involving retrospective record review was conducted. Comparison was made with regard to the incidence of both clinical pneumonia and meningitis before and after introduction of the Hib vaccine. The periods compared were 1 November 1998 to 30 April 1999 and 1 November 1999 to 30 April 2000 for pneumonia. For meningitis they were 1 November 1998 to 31 July 1999 and 1 November 1999 to 31 July 2000.

3.2 Study population.

The study population was all children under the age of 1 year whose place of residence was in the Klerksdorp district at the time of the study. The reason for recruiting children under the age of 1 year was that Hib disease is reported to be more common in this age group than others.

3.3 Study sample

Children recruited to the study were those under the age of 1 year admitted at Tshepong hospital, which is a public hospital serving the whole population using level 1 public sector health services in the Klerksdorp district. The reason for choosing this district was that it is one

of the districts in which good quality of care has been ascertained. Therefore all factors which could impact negatively on effectiveness of the Hib vaccine such as cold chain maintenance were well under control in this district. Hib disease causes serious illness and in most cases children have to be hospitalised for treatment. However, since patients on medical aid did not participate in the study, the sample size may not be representative of the entire population of less than 1 year in the district.

The sample consisted of all children aged less than 1 year with a clinical diagnosis of either pneumonia or meningitis, admitted at Tshepong hospital during the chosen 6 and 9 months periods respectively before or after implementation of the Hib vaccine .

3.4 Pilot study

A pilot study was conducted in February 2000 following receipt of the letter of permission from the management of Tshepong hospital to conduct the study at the site. Different periods from those chosen for the study were used. The pilot study aimed at checking the adequacy of the checklist, availability and completeness of records and the time schedule for data collection.

Three months were reviewed during the pilot study. These were 01 July to 30 September 1998 and 01 July to 30 September 1999. In addition to

data collection for the pilot study, availability of the admission registers to be reviewed during the study was checked. Recording of the immunisation status was also checked for the period November 1999 to February 2000.

The pilot study revealed that a total of 123 cases of pneumonia under the age of 12 months were admitted at the hospital during the 3 months in both periods. 58 (41.1%) cases were admitted in 1998 and 65 (52.8) cases in 1999. Regarding meningitis there was a total of 4 cases, 3 (75%) of whom occurred in 1998 and 1 (25%) in 1999. Age was missing in the records for 2 cases of pneumonia and meningitis cases had all the ages recorded. All other variables were recorded for all cases in both conditions.

The pilot study further revealed that until May 1999, both Tshepong and Klerksdorp hospitals were running paediatric units. The process of rationalisation had since combined the two to form one unit at Tshepong hospital. It therefore became reasonable for the researcher to review registers of both hospitals for a complete picture of the incidence of pneumonia and meningitis before introduction of the Hib vaccine for the period under review.

The checklist was found to be adequate, admission registers of both hospitals were available for the period 01 November 1998 to 31 July 1999. The register for the period after the Hib vaccine implementation was also

available and was completed on a daily basis in respect of personal details of children admitted to the ward. The immunisation status was being recorded in cases where the immunisation card was available and the report from the ward nursing sister revealed that mothers were encouraged on a continuous basis to bring along the immunisation cards whenever a child was admitted to the hospital. . The original time schedule for data collection was adhered to since it was found to be reasonable. No adjustment was thus made either in the data collection tool or time frames for data collection.

3.5 Measurement

Measurement tools

A checklist was designed to collect data from variables that were investigated.

Variables

The variables investigated were: age, diagnosis, date of admission, immunisation status, number of Hib doses received and the dates doses were given.

Data collection techniques

Preparations for data collection were done within the context of EPI management since the researcher is the manager of the EPI programme

in the province. An existing system of presenting a child's immunisation card with every consultation or admission to hospital was strengthened at the facility after the Hib vaccine implementation. This system only requires screening of the immunisation card so that the child can be immunised on discharge if there are missing immunisations. An additional requirement of documenting the immunisation status of Hib and the dates of immunisation was temporarily introduced at Tshepong hospital paediatric ward and it was not without limitations. Other variables from which data collection was intended were readily available from the admission register.

Data collection process

The data collection process was undertaken during the period May to July 2000. All data were collected by the researcher. The nursing sister in charge of the paediatric ward was requested to oversee documentation of the required information on the Hib immunisation status of every child under the age of 1 year admitted to the ward. Ward admission registers were accessed from the paediatric ward at Tshepong hospital. A data collection sheet was used to collect data from each patient admitted at the hospital during periods under review (see annexure A). Records were reviewed retrospectively to identify required variables.

The admission registers were reviewed for the periods 1 November 1998 to 30 April 1999 and 1 November 1999 to 30 April 2000 for pneumonia.

Periods were extended to 31 July 1999 and 31 July 2000 for meningitis. Based on the previous years admissions of both pneumonia and meningitis, it was likely to get enough cases of pneumonia within 6 months whereas more time was needed for meningitis cases because of few numbers of cases in the previous years. This is the reason why the period for meningitis was extended by 3 months.

Validity and reliability

The data collection was done by the researcher and measures were taken to minimise errors. Cross checking was done in all cases of doubtful information. Patient registration (hospital) numbers were used to check for duplications.

3.6 Data capturing and analysis

The data entry screen was designed in EpiInfo 6 according to each variable. Data was captured and later frequency tables were generated for each category of variables. Excel was used to produce tables and graphs for presentation. Incidence rates, relative risks, and p values were calculated for various categories of data using the stata programme.

The denominators used to calculate the incidence rates were the 1996 population census for children under the age of 1 year in the Klersdorp district. Projections were made for 1999 and 2000. These projected

figures were adjusted for 6 months and 9 months for pneumonia and meningitis respectively. The 1999 and 2000 projected and adjusted population figures were thus used as the denominators for the periods before and after the Hib vaccine implementation respectively.

The incidence rate of pneumonia was expressed per 1000 population while that of meningitis was expressed per 10 000 population due to the small number of cases in meningitis.

CHAPTER 4

RESULTS

4.1 Age distribution of cases

Pneumonia

There were 323 cases of pneumonia under the age of 12 months. Of these, 185 (57.3%) cases were admitted before the Hib vaccine implementation and 138 (42.7%) were admitted after implementation of the vaccine (table 4).

Table 4: Age distribution of pneumonia cases under the age of 12 months before and after Hib vaccine implementation: Klerksdorp district

	1998/99		1999/2000	
Age in months	Number of cases	Percentage	Number of cases	Percentage
0	10	5.4	7	5.1
1	24	13.0	19	13.8
2	19	10.3	22	15.9
3	41	22.2	24	17.4
4	15	8.1	18	13.0
5	20	10.8	10	7.2
6	13	7.0	8	5.8
7	10	5.4	6	4.3
8	5	2.7	9	6.5
9	8	4.3	7	5.1
10	13	7.0	4	2.9
11	7	3.8	4	2.9
Total	**185**	**100**	**138**	**100**

Meningitis

There were 53 cases of meningitis under the age of 12 months. Of this total, 31 (58.5%) cases were admitted before and 22 (41.5%) cases were admitted after the vaccine implementation. Table 5 shows the age distribution of cases.

Table 5: Age distribution of meningitis cases under the age of 12 months before and after Hib vaccine implementation: Klerksdorp district

	1998/99		1999/2000	
Age in months	**Number of cases**	**Percentage**	**Number of cases**	**Percentage**
0	5	16.1	0	0
1	1	3.2	0	0
2	3	9.7	2	9.1
3	5	16.1	4	18.2
4	3	9.7	1	4.5
5	3	9.7	3	13.6
6	2	6.5	3	13.6
7	0	0	1	4.5
8	1	3.2	2	9.1
9	1	3.2	3	13.6
10	3	9.7	1	4.5
11	4	12.9	2	9.1
Total	**31**	**100**	**22**	**100**

4.2 Incidence rates

Pneumonia

The incidence rate of pneumonia cases in the period before Hib vaccine implementation was 54.3 per 1000 population compared to 39.6 per 1000

in the period after implementation of the vaccine. (P value=0.0048) The relative risk was 1.37 (confidence interval:1.09 – 1.72). The monthly incidence rates for both periods under review are compared in table 6.

Table 6: Monthly incidence rates of pneumonia cases under the age of 12 months: Klerksdorp district: 1998/99 and 1999/2000.

	1998/99		1999/2000	
Month	**Number of cases**	**Incidence rate per 1000**	**Number of cases**	**Incidence rate per 1000**
November	37	65.2	20	34.4
December	30	52.9	33	56.8
January	26	45.8	20	34.4
February	21	37.0	26	44.8
March	30	52.9	16	27.6
April	41	72.2	23	39.6
Total	**185**	**54.3**	**138**	**39.6**

Meningitis

The incidence rate for meningitis was 60.7 per 10 000 population in the period prior to Hib vaccine implementation as compared to 42.1 per 10 000 in the period after the vaccine implementation. (P value=0.19). The relative risk was 1.44 (95% confidence interval: 0.81 – 2.61). Table 7 shows the monthly incidence rates.

Table 7: Monthly incidence rates of meningitis cases under the age of 12 months: Klerksdorp district: 1998/99 and 1999/2000.

Month	1998/99		1999/2000	
	Number of cases	Incidence rate per 10000	Number of cases	Incidence rate per 10000
November	5	88.1	4	68.9
December	2	35.2	3	51.7
January	7	123.3	1	17.2
February	3	52.9	1	17.2
March	4	70.4	2	34.4
April	5	88.1	1	17.2
May	5	88.1	6	103.3
June	0	0	2	34.4
July	0	0	2	34.4
Total	**31**	**60.7**	**22**	**42.1**

4.3 Laboratory confirmed cases of Hib meningitis

During the period under review, 580 specimens from patients of all ages were submitted to Tshepong hospital laboratory for meningitis test before the Hib vaccine implemention. After implementation of the vaccine, 1 100 specimens were submitted to this laboratory. 15 (2.6%) specimens were positive for all types of meningitis for the period before Hib implementation as compared to 28 (2.5%) positives after Hib implementation.

Of the 15 positive specimens before Hib implementation, 4 (26.7%) were positive for Hib meningitis. Of the 4 cases, 3 were under the age of 1 year, and 1 was 6 years old. In the period after Hib vaccine implementation the number of positive Hib meningitis cases were also 4 (14.3%). There was no case under the age of 1 year among them (see annexure).

The substantial increase in the number of tests sent to the laboratory before vaccine implementation and after implementation was due to merging of the former Klerkdorp hospital laboratory and the Tshepong hospital laboratory into one laboratory based at Tshepong hospital since April 1999. It was difficult to obtain information for the age under review as the system could only generate individual patient information and not a summary of age groups of specimens sent to the laboratory.

4.4 Hib immunisation status of children under the age of 12 months.

Of the 160 children under the age of 12 months admitted with pneumonia and meningitis (138 & 22 respectively) after implementation of the Hib vaccine, 17 were not immunised with the Hib vaccine and the immunisation status of 14 children was not known because their immunisation cards were not available for screening at the time of their admission. A total of 129 (80.6%) children under the age of 12 months had received all the dose(s) of the Hib vaccine required by their ages. Table 8

shows the immunisation status of children with pneumonia and meningitis for all doses combined.

Table 8: Immunisation status of children under the age of 12 months admitted at Tshepong hospital after introduction of the Hib vaccine.

Age group in months	Frequency	Number of children immunised	Number of children not immunised	Immunisation status not known
0 – 2	50	42	6	2
3 – 5	60	49	4	7
6 – 8	29	23	3	3
9 –11	21	15	4	2
Total	**160**	**129 (80.6%)**	**17 (10.6%)**	**14 (8.8%)**

4.5 The number of doses and interval between doses for immunised children admitted with either pneumonia or meningitis.

The number of doses received were as follows:

64 (49.6%) children received 1 dose each.

10 (7.8%) children received 2 doses each and

55 (42.6%) children received 3 doses each. The immunisation coverage for children who received all the three doses was 34.4%.

The interval between doses was 4 weeks in all cases of immunised children.

4.6 Commonly encountered variable

4.6.1 HIV status of cases

Although there was no plan in the protocol to collect data on the HIV status of children admitted with either pneumonia or meningitis, this variable appeared frequently during the process of data collection and the researcher thought it was not only interesting, but it would assist in arriving at conclusions as it was considered to be one of the confounding factors. Since the data was readily available it was collected.

It was interesting to note that 40 (18.5%) of the 216 cases of pneumonia and meningitis combined during the period 01 November 1998 to 31 July 1999 were HIV positive. During the period 01 November 1999 to 31 July 2000, there were 58 (36.3%) HIV positive cases of all the 160 cases of pneumonia and meningitis combined.

CHAPTER 5

DISCUSSION

Pneumonia

This study has shown a significant difference between the two periods compared with regards to the clinical incidence of pneumonia cases under the age of 1 year admitted at Tshepong hospital (P value = 0.0048). The difference showed a decline in the number of cases after implementation of the Hib vaccine.

The results showed that before the Hib vaccine implementation, children under the age of 1 year had 1.37 chances of contracting pneumonia than in the period after Hib vaccination.

The results of this study on pneumonia are consistent with those of the Gambia study on assessment of the efficacy of a Hib conjugate vaccine for the prevention of pneumonia, meningitis, and other invasive diseases due to Hib. The Gambia study showed that the Hib vaccine was highly effective in preventing pneumonia and meningitis due to Hib after the three doses are given in infancy. The second and third doses provided 100% protection efficacy for pneumonia cases. The protection efficacy was 95% for all other invasive diseases. There was a 21% reduction in the radiologically defined pneumonia. Good immunogenicity was associated with efficacy, as had been found in industrialised countries.[4]

Despite the consistent results, the methodology used in this study, however, differs from the one used in the Gambia study, and the objectives were also different. The other important difference is that the Gambia study was conducted countrywide while this study was conducted in only one district. The researcher is not aware of any previous study similar to this one globally including South Africa.

Other studies which showed consistent results with this one are trials of two developing countries, Gambia and Chile which showed 80% to 100% efficacy of conjugated Hib vaccine against pneumonia and 90% to 95% against all types of invasive Hib diseases.[4]

Meningitis

In respect of meningitis this study has also shown a difference in the number and incidence rate of meningitis in the two periods compared. The statistical test (p value = 0.19), however, showed that the observed difference was not significant. This means that the observed decline in the incidence of cases was a result of chance.

The results of this study on meningitis were therefore not consistent with those of the Gambia and Chile. The researcher is not aware of any studies that are consistent with this one regarding the impact of Hib on the incidence of meningitis. Other factors which might have played a role are

not known. The impact of HIV infection was considered. Could it be due to the limitations in the methodology? This needs further investigation.

The available literature does not comment on the impact of HIV on seroconversion or incidence of vaccine preventable diseases. However, the study conducted at Chris Hani Baragwanath hospital revealed that paediatric HIV infection has changed the profile of paediatric admission diagnoses and increased hospital mortality. HIV negative children on the other hand showed declining rates of vaccine preventable diseases.[34]

According to the USA study the clinical efficacy of the currently used vaccines in the HIV infected individuals is not well defined. It, however, appears that patients in the earlier stages of infection are more likely to mount a protective antibody response than those in the later stages.[35]

Immunisation coverage

The immunisation coverage for children who received all the three doses of the vaccine was 34.4%. The cumulative proportion of children immunised with 1st 2nd and 3rd doses was 80.6%. It is believed that this immunisation status provided significant protection against pneumonia.

Comparison of laboratory confirmed meningitis cases

Further consideration was given to the laboratory confirmed Hib meningitis cases during the periods under review. The results showed that before Hib vaccine implementation there were 3 cases of laboratory Hib confirmed meningitis cases under the age of 1 year. After implementation of the vaccine no cases under the age of 1 year were reported.

If one was to use the argument of the laboratory confirmed Hib meningitis, it is more likely that the Hib vaccine had similar impact on meningitis as it had on pneumonia.

5.1 Limitations

The limitations in this study were as follows:

Validity and reliability

Though the researcher collected the data and cross checked all entries, the extent of accuracy of records reviewed could not be ascertained.

Timing of the study

The first cohort of children who were six weeks old and entered the Hib immunisation on 1 July completed their third dose in September or end of August. The data collection process started on 1 November. This was about one month after the first cohort had completed their third dose. This period is considered to be short given that there was only one cohort of children who received the required three doses of the vaccine when the data collection process started. As a result of this, not all children had completed their three doses at the time of the study and the findings were based on different number of doses received instead of three doses

Sample size

The sample size for meningitis was small, 31 cases and 22 cases before and after implementation of the vaccine respectively. The small sample size of clinical meningitis cases made it difficult to draw conclusions.

Generalisation

As stated in the introduction, about 21% of the population in the Klerksdorp district belong to the medical aid schemes. This proportion of private patients were not included in the study. Secondly, the study was conducted in a public sector facility which mainly caters for patients not on medical aid, predominantly blacks. The implication is that other racial groups were underrepresented in the study and the researcher might have

lost on a number of other important unique features such as incidence of pneumonia and meningitis among whites and their compliance with immunisation.

Further, the study relied on admitted cases only. This means that not all cases of pneumonia and meningitis have been detected. Although this does not affect the proportion of cases in the two groups, it gives a false impression of the number of cases in the population.

CHAPTER 6

CONCLUSIONS

The proportion of children who received at least one dose of the vaccine was 80.6% among admitted children with pneumonia and meningitis at Tshepong hospital. It is believed that the decline in the incidence of pneumonia was due to the impact of the Hib vaccine.

While the decline in the incidence of meningitis was not statistically significant, the impact of the Hib vaccine in reduction of cases of meningitis cannot be excluded at this level. Other important factors that might have hindered the impact of the vaccine on the incidence of meningitis need further investigation. These factors include, among others, the possibility of a small sample size bias and the impact of HIV infection.

Further, the absence of laboratory confirmed Hib meningitis cases under the age of 1 year after Hib implementation against 3 cases of the same age group before implementation of the vaccine strengthens the argument in favour of the Hib vaccine for meningitis.

On the basis of the significant decline in the incidence of pneumonia, it is concluded that the new Hib vaccine reduced the incidence of pneumonia

by 14.7 percent in the Klerksdorp district within a period of 10 months after its implementation. Its positive impact on meningitis could, however, not be detected in this study, probably due to other confounding factors.

While the findings of this study are not conclusive, they are suggestive that the Hib vaccine had a significant decline on the incidence of pneumonia in the Klerksdorp district. Regarding the incidence of meningitis, further research is needed to investigate the impact of the Hib vaccine on this disease.

Limitations in the methodology and the possibility of confounding factors are acknowledged.

Despite these limitations, it is believed that this research project has generated important information which provides the basis for future research in this phenomenon. Against this background, it is important to make recommendations that may form the basis of further research.

RECOMMENDATIONS.

It is recommended that:

- A similar study be conducted in the North West province after 3 years of implementation of the Hib vaccine when there will be enough population to

form the basis of comparison in respect of the immunisation status and exposure to Hib disease.

- The impact of Hib vaccination be measured on a routine and continuos basis using laboratory surveillance for Hib meningitis and other available information.
- Studies be conducted in South Africa to identify the vaccination and programme factors that may hinder the impact of the Hib vaccine.
- Given that there was no significant decline in the incidence of clinical meningitis cases, studies be conducted in South Africa to determine the impact of HIV infection on the success of the immunisation programme with main emphasis on the possibility of its adverse effects on seroconversion rates.

DISSEMINATION OF FINDINGS

Copies of this report will be distributed to all stakeholders including, managers in the provincial and district offices of the North West Department of Health, Tshepong hospital management and staff at Tshepong paediatric ward.

Presentation of results will also be made in provincial research conferences planned to be held annually.

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REFERENCES

1. Picket G, Hanlon J. Public Health: Administration and practice. 9th ed. Boston: Times Mirror/ Mosby College Publishing;1990.

2. Polio News: Countries in conflicts. WHO/EPI/PN 1999; (4):5

3. Hussey G D, Coetzee G, Hitchcock J, Van Schalkwyk H, Kibel M. Carriage of Haemophilus Influenzae in Cape Town Children. *S A Med J 1994;84:155.*

4. Mulholland K, Hilton S, Adegbola R, Usen S, Oparango A, Omosigho C, et al. Randomised trial of Haemophilus Influenzae type –b tetanus protein conjugate for prevention of pneumonia and meningitis in Gambian infants. Lancet 1997 Apr;349:1191.

5. Hib – Who's using it, who isn't and why not. CVI forum 1998;(16):13.

6. Galazka A. The Immunological Basis for Immunisation: General Immunology. Geneva, WHO; 1993.

7. Immunisation that Works. The Vaccinator's Manual of the Expanded Programme on Immunisation in South Africa : EPI(SA). Pretoria: Department of Health; 1995.

8. Vundule C. Health and Welfare in the North West Province: Implications for Planning. Durban: Health Systems Trust & Department of Health; 1996.

9. Statistics South Africa. The People of South Africa Population Census. Pretoria: Statistics South Africa; 1996.

10. National Review of the Expanded Programme on Immunisation in South Africa (EPI[SA]): National Report. Republic of South Africa: Pretoria; 1994.

11. Municipal Dermacation Board. Report on category B municipality (draft). North West Province; 1999.

12. Center for Health Policy. The use of norms and guidelines in planning of primary health care services. Johannesburg: University of the Witwatersrand.

13. Department of Health. Health Worker pamphlet for Haemophilus Influenzae Type B. Pretoria; 2000.

14. Department of Health. Notification of medical condition book. Health Act, 1977 (Act 63 0f 1977). Pretoria : Department of Health; 1994.

15. Laboratory surveillance of Hib, Meningococcal and Pneumococcal Disease. Proceedings of a meeting; 1999 Apr 9; South Africa, Johannesburg Airport Conference Centre.

16. Denill K, King L, Lock M, Swanepoel T. Aspects of Primary Health Care: Community Health Care in Southern Africa. Halfway House: Southern Block Publishers (pty) Ltd; 1995.

17. Stanhope M, Lancaster J. Community Nursing. Process and Practice for Promoting Health. 2nd ed. Washington DC: The C. V. Mission Company; 1998.

18. World Health Organisation. Polio. The beginning of the end. Geneva, WHO; 1997.

19. African National Congress. A National Health Plan for South Africa. Johannesburg; 1994.

20. Department of Health. Health Sector Strategic Framework. Pretoria; 1999.

21. Primary Health Care. SA: An overview. Available from SA-Webs: http://www.gov.za/yearbook/health.htm.

22. African National Congress. The Reconstruction and Development Programme. A policy framework. South Africa, Johannesburg; 1994.

23. Provincial Gazette. North West Health, Developmental Social Welfare and Hospital Governance Institutions Act, 1997 (Act 2 of 1997).

24. North West Province. Provincial Council on AIDS. Working document. Department of Health; 2000.

25. World Health Organisation. It's "all systems go for the Hib vaccine. Vaccine & Immunisation News: The Newsletter of the Global Programme for Vaccine and Immunisation. GPV/97.02 1997; (4):1.

26. United States Department of Health and Human Services. Morbidity and Mortality Weekly Report: Summary of Notifiable Diseases. US 1997; 46:viii.

27. Hussey G, Hitchcock J, Schaaf H, Coetzee G, Hanslo D, Van Schalkwyk E, et al. Epidemiology of invasive Haemophilus influenzae infections in Cape Town, South Africa. *Ann Trop Paediatr 1994; 14:97-103.*

28. Department of Health. Notified cases of Haemophilus influenzae type b in South Africa. Epidemiological comments 1999;1(13):3

29. Jafari HS, Adams WG, Robinson KA, Plikaytis BD, Wenger DJ. Efficacy of Haemophilus Influenzae type b conjugate vaccines and persistence of disease in disadvantaged populations. The Haemophilus Influenzae Study Group. Am J Public Health 1999 Mar; 89(3):364-8.

30. Madore DV. Characterization of immune response as an indicator of Haemophilus Influenzae type b vaccine efficacy. Paediatr Infect Dis J 1998 Sept;17(9 suppl):S207-10.

31. Bower C, Condon R, Rayne J, Burton P, Watson C, Wild B. Measuring the impact of conjugate vaccines on invasive Haemophilus Influenzae type b infection in Western Australia. Aust NZ j Public Health 1998 Feb;22(1)62-72.

32. World Health Organisation. Reducing the Risk of unsafe injections in immunisation programmes: The role of injection equipment. Geneva, WHO/EPI/LHIS/94.02; 1996.

33. Department of Health. Cold Chain and Immunisation. Operations Manual: Guidelines for vaccine handling at all levels. Pretoria:EPI/SA;1998.

34. Zwi KJ, Pettifor JM, Soderland N. Paediatric hospital admissions at a South African urban regional hospital: the impact of HIV, 1992-1997. Ann Trop Paediatr 1999 Jun;19(2):135-42.

35. Pau Ak, McNicholl IR, Pursell KJ. Active immunization in HIV-infected patients. Pharmacotherapy 1996 Mar-Apr;16(2):163-70.

ANNEXURE A

The South African Institute for Medical Research
Die Suid-Afrikaanse Instituut vir Mediese Navorsing

1038
JOHANNESBURG 2000
SOUTH AFRICA · SUID-AFRIKA

(011) 489-9000
4-22211
BACTERIA
(011) 489-9001

PR 5200296

Stats printed for period 1-11-98 → 31-7-99

SAIMR LABORATORY SYSTEM 14/09/00 10:2

Positive Test Results

Reviewed tests only
Region: All Location: All Ward/s ALL Test Code: CSF Param: CSFGR From labno WTS0337462 to WTS0393454 Race: All
Results = HAEIN

Lab No	Anonymous	Loctn	Ward	Age	Sex	Race	Received	Result
WTS0347084		TSH	2	0			21/12/98	HAEIN
WTS0349967		TSH	2	0	F	B	04/04/99	HAEIN
WTS0350833		TSH	CAS	6		C	21/04/99	HAEIN
WTS0354147		TSH	2	0	M		05/05/99	HAEIN

Tests from labno WTS0337462 to WTS0393454

Total: 930 Positive: 4 0.69%

***** End of Positive Test Results *****

The South African Institute for Medical Research
Die Suid-Afrikaanse Instituut vir Mediese Navorsing

1038
JOHANNESBURG 2000
SOUTH AFRICA · SUID-AFRIKA

(011) 489-9000
4-22211
BACTERIA
(011) 489-9001

PR 5200/96

Stats printed for period 1-11-99 → 31-07-2000.

SAIMR LABORATORY SYSTEM 14/09/00 10

Positive Test Results

Reviewed tests only
Region: All Location: All Ward/s ALL Test Code: CSF Param: CSFGR From labno WTS0413887 to WTS0479891 Race: All
Results = HAEIN

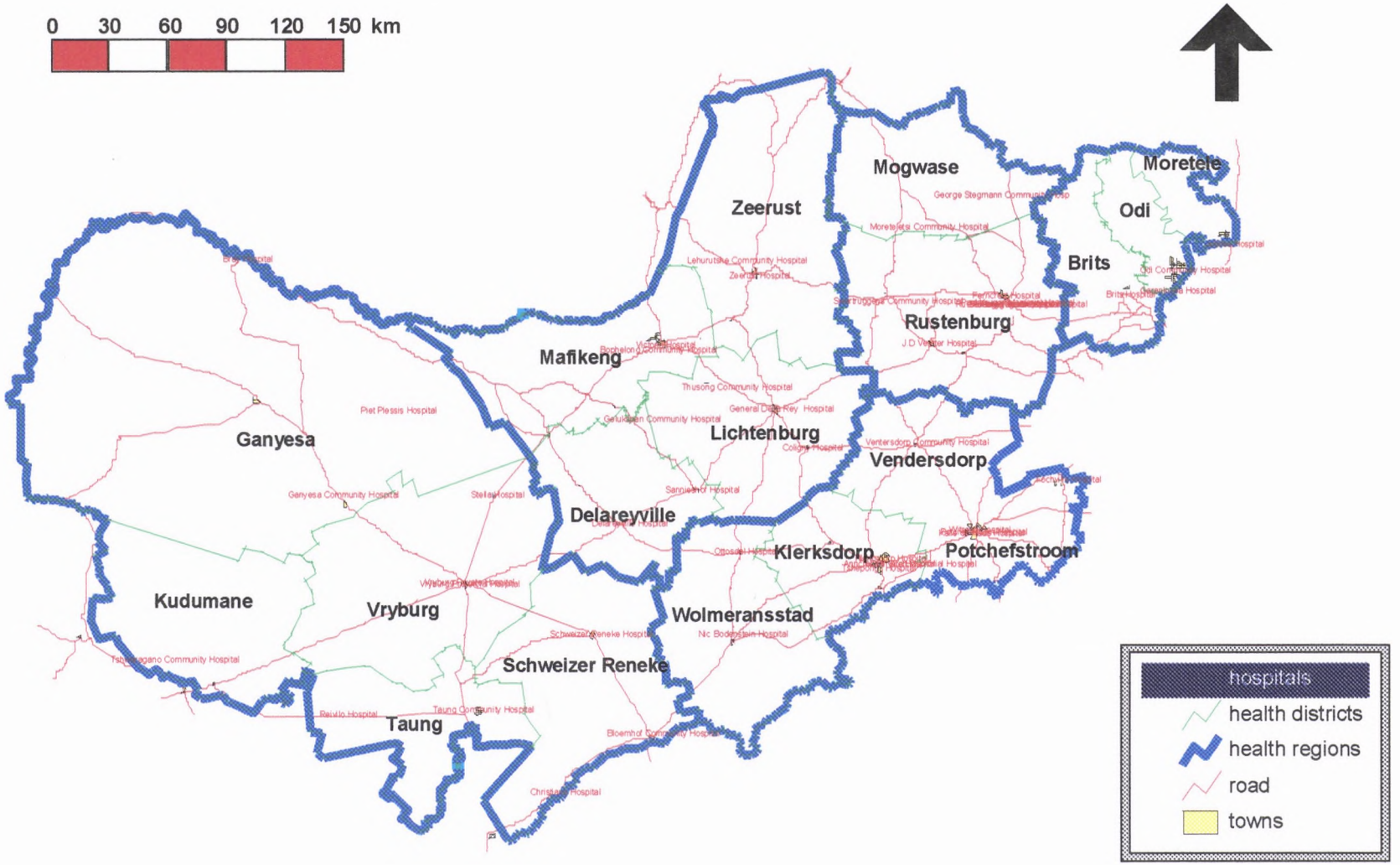
Lab No	Anonymous	Loctn	Ward	Age	Sex	Race	Received	Result
WTS0438807		TSH	CAS	26	M		03/01/00	HAEIN
WTS0476548		TSH	3	1	F		05/02/00	HAEIN
WTS0479585		TSH	3	3			16/02/00	HAEIN
WTS0465383		TSH	CAS	2	F	B	31/05/00	HAEIN

Tests from labno WTS0413887 to WTS0479891

Total: 1001 Positive: 4 . 0.40%

***** End of Positive Test Results *****

MAP OF THE HEALTH DISTRICTS AND REGIONS, NORTH WEST PROVINCE



MAP 2 KLERKSDORP REGION: ACCESSIBILITY OF CLINICS AND HEALTH CENTRES

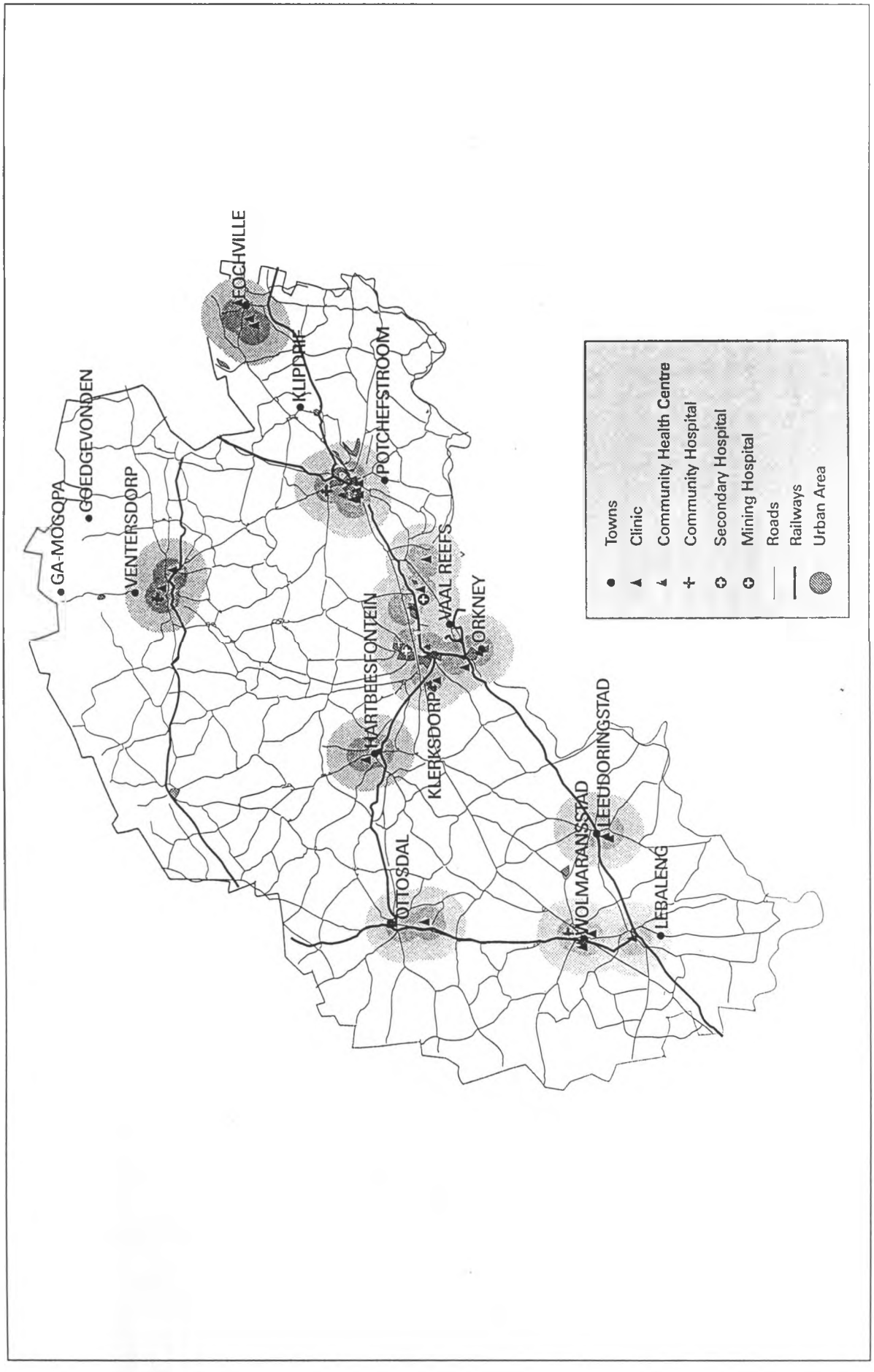


Table:1

Statistics South Africa
Census 96:Community profile - Descriptive
Table 1
MD by 5year group
for Weighted Person

District	0	1-4	5-9	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85-89	90-94	95-99	100-104	105-109	110-114	115-119	Unspecified	Total
Brits	3427	13566	17022	15560	15094	16065	15895	14482	13034	10661	7944	5925	4432	3476	2755	1944	1347	696	385	171	53	3	2	0	0	1478	**165417**
Delareyville	4133	16431	22017	21894	18540	13664	8775	7409	6744	6007	4689	4438	3713	3439	2926	2480	1592	826	429	188	86	2	4	0	1	1017	**151444**
Ganyesa	2912	11866	14713	14150	11791	8931	6451	5682	4835	3965	3130	2718	1972	1857	1609	1235	959	451	254	103	59	4	2	0	0	381	**100030**
Klerksdorp	6362	23635	30054	29942	28960	31413	34362	35222	31376	23415	16943	12232	9305	6517	4752	3060	2072	1013	385	190	35	8	1	1	1	3241	**334497**
Kudumane	4006	15928	20333	19845	17680	13241	9360	8311	7403	6034	4608	3852	3054	2864	2368	1657	1287	577	284	118	49	5	1	0	0	1002	**143867**
Lichtenburg	2799	11271	14819	15967	15203	12903	10383	9175	8079	6607	4940	4323	3483	2713	2229	1684	1040	560	278	169	63	6	5	4	0	1275	**129978**
Mafikeng	6732	25331	29818	29585	27584	27886	23189	19007	15898	11682	8504	7106	5691	4452	3795	3223	1938	1045	558	276	169	5	2	1	0	2181	**255658**
Mogwase	4590	18562	25112	24309	21845	18268	15946	14231	12823	10014	7338	6359	5190	4665	4075	2890	2607	1429	796	392	173	6	1	1	0	1596	**203218**
Moterele	8027	31221	38170	38588	34499	32641	26832	22279	18688	15946	12355	10208	7925	6840	5894	4044	3340	1448	843	391	171	14	7	5	4	1634	**322014**
Odi	9059	36636	47705	43975	41029	45295	39941	33695	28372	23727	18074	14400	11132	8874	6917	4641	3584	1658	975	364	158	15	6	8	2	3069	**423311**
Potchefstroom	3019	11385	14855	15576	17185	19624	16201	14694	12808	10083	7836	6179	4762	3578	2778	1866	1373	759	404	139	51	0	0	0	0	1617	**166772**
Rustenburg	6560	27382	33561	30423	29610	34600	40846	41409	35392	25808	17655	12762	9321	6798	5185	3692	2727	1507	790	353	144	17	4	3	0	4361	**370910**
Schweizer-Reneke	1618	7121	10434	10401	9950	7789	5947	5249	4654	3835	3240	2764	2236	1869	1559	1125	748	408	225	70	25	0	0	0	0	584	**81851**
Taung	5468	21993	27953	28047	24774	17443	12322	10712	9366	7772	6636	6045	5323	4777	3879	3330	2305	1113	514	183	89	4	1	0	0	1227	**201276**
Ventersdorp	482	2573	3886	4011	3676	3330	2433	2029	1743	1516	1214	1159	884	778	620	457	315	166	83	33	13	0	0	0	0	325	**31726**
Vryburg	1389	5537	6626	6631	6242	6005	5137	4754	4268	3698	2790	2227	1572	1170	872	588	399	247	110	57	17	0	0	0	0	184	**60520**
Wolmaransstad	1470	6880	10080	10405	9676	7960	6163	5185	4547	3685	3089	2529	2015	1628	1399	1017	600	324	129	56	19	4	0	0	0	1053	**79913**
Zeerust	3071	12607	17207	16923	16479	13365	9381	7811	6488	5523	4412	3985	3182	2901	2752	1961	1782	979	535	202	73	2	2	0	0	1270	**132893**
Total	**75124**	**299925**	**384365**	**376232**	**349817**	**330423**	**289564**	**261336**	**226518**	**179978**	**135397**	**109211**	**85192**	**69196**	**56364**	**40894**	**30015**	**15206**	**7977**	**3455**	**1447**	**95**	**38**	**23**	**8**	**27495**	**3355295**

data with age 0 as seperate item

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Space-Time Research Online support: support@str.com.au

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Table 2: PROJECTIONS OF THE 1996 CENSUS DATA

			Under 1	Under 1	Under 1	**Under 1**	1-4	1-4	1-4	**1-4**
	0	**1-4**	**1997**	**1998**	**1999**	**2000**	**1997, 1-4**	**1998**	**1999**	**2000**
Ganyesa	2912	11866	2979	3047	3118	**3189**	12139	12418	12704	**12996**
Kudumane	4006	15928	4098	4192	4289	**4387**	16294	16669	17053	**17445**
Vryburg	1389	5537	1421	1454	1487	**1521**	5664	5795	5928	**6064**
Taung	5468	21993	5594	5722	5854	**5989**	22499	23016	23546	**24087**
Mafikeng	6732	25331	6887	7045	7207	**7373**	25914	26510	27119	**27743**
Zeerust	3071	12607	3142	3214	3288	**3363**	12897	13194	13497	**13807**
Lichtenburg	2799	11271	2863	2929	2997	**3066**	11530	11795	12067	**12344**
Delareyville	4133	16431	4228	4325	4425	**4527**	16809	17196	17591	**17996**
Schweizer-Reneke	931	4170	952	974	997	**1020**	4266	4364	4464	**4567**
Wolmaransstad	1470	6880	1504	1538	1574	**1610**	7038	7200	7366	**7535**
Christiana (add to..	687	2951	703	719	736	**752**	3019	3088	3159	**3232**
Klerksdorp	6362	23635	6508	6658	6811	**6968**	24179	24735	25304	**25886**
Ventersdorp	482	2573	493	504	516	**528**	2632	2693	2755	**2818**
Potchefstroom	3019	11385	3088	3159	3232	**3306**	11647	11915	12189	**12469**
Mogwase	4590	18562	4696	4804	4914	**5027**	18989	19426	19872	**20330**
Rustenburg	6560	27382	6711	6865	7023	**7185**	28012	28656	29315	**29989**
Brits	3427	13566	3506	3586	3669	**3753**	13878	14197	14524	**14858**
Odi	9059	36636	9267	9481	9699	**9922**	37479	38341	39222	**40125**
Moterele	8027	31221	8212	8400	8594	**8791**	31939	32674	33425	**34194**
Total	**75124**	**299925**	**76852**	**78619**	**80428**	**82278**	**306823**	**313880**	**321099**	**328485**

data with age 0 as seperate item

Created on 8/5/99

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ANNEXURE B

ANNEXURE 1

IMPACT OF HIB VACCINE

CHECKLIST

1. Hospital number:

2. Residential address: ----------

---

3. Date of birth :

D	D	M	M	Y	Y

4. Age in months:

5. Date of admission:

D	D	M	M	Y	Y

6. Diagnosis ----------

7. Hib immunisation status:

Immunised	Not immunised

8. Date(s) immunised and interval between doses:

	Date dose received	Age in weeks	Interval between doses in weeks
1 dose			-
2 doses			
3 doses			

ANNEXURE 2

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

COMMITTEE FOR RESEARCH ON HUMAN SUBJECTS (MEDICAL)
Ref: R14/49 Sebekedi

CLEARANCE CERTIFICATE **PROTOCOL NUMBER** M990941

PROJECT	The Impact of Haemophilus Influenzae Type B (Hib) Vaccine On Pneumonia And Meningitis Among Children Under The Age if 1 Year In Klerksdorp District of The North West Province
INVESTIGATORS	C Sebekedi
DEPARTMENT	Community Health, North West Dept of Health
DATE CONSIDERED	991001

DECISION OF THE COMMITTEE *

Approved unconditionally

DATE 991014 CHAIRMAN.....(Professor P E Cleaton-Jones)

* Guidelines for written "informed consent" attached where applicable.

c c Supervisor: Mr C Vundile
Dept of ,

Works2\Iain0015\HumEth97.wdb\M 990941
==========
DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and ONE COPY returned to the Secretary at Room 10001, 10th Floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee.

DATE 25/10/99 SIGNATURE .....

PROTOCOL NO.: M 990941

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

ANNEXURE 3

Faculty of Health Sciences

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

7 York Road PARKTOWN Johannesburg 2193 Telegrams WITSMED Telex 4-24655.SA
FAX 643-4318 TELEPHONE 647-2075
E-MAIL jmainwa@chiron.wits.ac.za

MRS OC SEBEKEDI
P O BOX 4524
MMABATHO
2735

APPLICATION NUMBER 9813073A
STATUS (DEG 39) (MM816) PZZ

1999-12-18

Dear Mrs Sebekedi

Approval of protocol entitled 'The impact of Haemophilus Influenzae B (Hib) vaccine on pneumonia and meningitis among children under the age of 1 year in the Klerksdorp district of the North West Province

I should like to advise you that the protocol and title that you have submitted for the degree of Master Of Public Health (Part-Time) have been approved by the Postgraduate Committee at its recent meeting. Please remember that any amendment to this title has to be endorsed by your Head of Department and formally approved by the Postgraduate Committee.

Mr C Vundule has/have been appointed as your supervisor/s. Please maintain regular contact with your supervisor who must be kept advised of your progress.

Please note that approval by the Postgraduate Committee is always given subject to permission from the relevant Ethics Committee, and a copy of your clearance certificate should be lodged with the Faculty Office as soon as possible, if this has not already been done.

Yours sincerely

J.O Mainwaring (Mrs)
Faculty Officer
Faculty of Health Sciences

Telephone 647-2075/2076

Copies - Head of Department____Supervisor/s

ANNEXURE 4

Republic of South Africa

Deputy Director General for Health and Developmental Social Welfare
NORTH WEST PROVINCE

26 November 1999

Private Bag X2068
Mmabatho
2735

Tel.: (018) 387-5284 / 5
Fax: (018) 387-5334
e-mail: mmanong_ntoane@nwpg.org.za

Ms Calvinia Sebekedi
Department of Health
North West

Dear Ms Sebekedi,

RE: PERMISSION TO CONDUCT RESEARCH IN THE NORTH WEST PROVINCE

The Departmental Research Committee recently reviewed your research proposal entitled ***The impact of haemophilus influenzae type B (Hib) vaccine on pneumonia and meningitis among children under the age of 1 year in Klerksdorp district of the North West province,*** and wishes to inform you that permission has been granted to conduct the study, subject to the following conditions:

i. The Ethics/Research Review Committee of your academic institution has approved your proposal,

ii. The Department will not be responsible for any costs associated with the research project,

iii. That on completion of the research project, a copy of the research report (or dissertation or thesis) will be submitted to the Department.

Attached are comments from the Departmental Research Committee that you should address before conducting your research project.

Any enquiries and correspondence regarding the research should be addressed to Mr Caesar Vundule or Mrs Rebone Gcabo (tel. (018) 3875213/6).

Yours sincerely,

M.C. NTOANE
Deputy Director General

ANNEXURE 5

NOORDWES PROVINSIE/NORTH WEST PROVINCE
DEPARTEMENT VAN GESONDHEID EN
ONTWIKKELENDE MAATSKAPLIKE WELSYN
DEPARTMENT OF HEALTH ANDDEVELOPMENTAL SOCIAL WELFARE

Klerksdorp/Tshepong Hospitaal Kompleks
Hospital Complex

Tel: 018 462 4400 - Klerksdorp
Fax: 018 462 4048

Privaatsak/Private Bag A14
KLERKSDORP 2570

Tel: 018 406 3111 - Tshepong
Fax: 018 465 5160

Alle korrespondensies moet gerig word aan die Superintendent
All correspondence to be directed to the Superintendent.

Ms.Calvinia Sebekedi,
Department of Health,
North West Province

Re:Ethics Committe approval for your research on the efficacy of Hib vaccine.

The ethics committee of the complex met on 7/01/2000 and considered your application. The committee decided to approve your application. The study is approved for a period of 3 months from the date of approval. A report of your study should be submitted to the ethics committee at the end of 3 months.
All relevant patient files used for the study can be accessed from archives after following the procedures of the department. The files should be returned and may not be taken out of the hospital.

Dr.A.H.Wadee
Hospital Manager
Chairman,Ethics Committee

07/01/99