RISK FACTORS FOR NEONATAL SEPSIS, ITS EFFECT ON MATERNAL POST PARTUM DEPRESSION, MATERNAL SATISFACTION ABOUT THE CARE RECEIVED AND ADHERENCE TO INFECTION CONTROL STANDARDS BY HEALTH CARE WORKERS IN GOVERNMENT SECONDARY AND TERTIARY CARE HOSPITALS IN THE DISTRICT OF GAMPAHA.

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ABSTRACT

Neonatal sepsis is one of the major contributory factors that cause neonatal morbidity and mortality. As very little is known about the risk factors for neonatal sepsis the present study was carried out to determine the risk factors for neonatal sepsis and its association on maternal post partum depression. It also describes the maternal satisfaction regarding the neonatal and maternal care received through government health services and the adherence of infection control standards by health care workers in the hospital setup.

The study was carried out in the District of Gampaha in Sri Lanka during the period of August 2010 to January 2011.

A case control study to determine the risk factors for neonatal sepsis was conducted among the mothers of diagnosed neonatal sepsis babies and mothers of non sepsis babies. A sample of 240 cases and 240 controls were enrolled. The cases were recruited according to the clinical features of WHO strategy in Integrated Management of Childhood Illness. The information was gathered from the interviewer administered questionnaire and by the data extraction sheets. To find out risk factors for neonatal sepsis and to control confounders multiple logistic regression analysis was applied. The results were expressed as Odds ratios and their 95% confidence intervals.

A descriptive cross sectional study design was used to assess the maternal post partum depression due to neonatal sepsis of their newborn. The study instruments were self administered validated Sinhala version of Edinburg Postpartum Depression Scale and the interviewer administered questionnaire.

Maternal satisfaction regarding neonatal care and maternal care received through government health services were assessed by using a 20 item satisfaction scale among the mothers of sepsis neonates.

The adherence to infection control standards by health care workers in selected procedures carried out in labour rooms, neonatal intensive care units, postnatal wards and operation theatres has been observed directly according to the check lists. Designs of buildings and physical facilities were observed in the same units according to the check lists relevant to infection control guide lines.

The maternal risk factors for neonatal sepsis were registration of pregnancy in the antenatal clinic after eight weeks of gestation (OR=1.91;95% CI: 1.07-3.44); total antenatal clinic visits ≤4 (OR=7.18; 95% CI: 2.10-24.49); having a bad obstetric history of mothers namely abortions, still births and early neonatal deaths (OR=6.78; 95% CI: 3.21-14.32); history of maternal fever during the last one week of delivery (OR=2.74; 95% CI: 1.25-6.02); dribbling more than 18 hours before delivery of neonate (OR=10.00; 95% CI: 2.12-47.44); total number of vaginal examination >3 times before delivery of neonates (OR=3.28; 95% CI: 2.10-24.49); meconium stained amniotic fluid when delivering the neonate (OR=10.57; 95% CI:3.75-29.74); and mode of delivery by caesarean section, forceps or vacuum (OR=2.33; 95% CI=1.40-3.86). The neonatal risk factors were time of birth of the neonate between 4 pm to 8 am of following day. (OR=2.12; 95% CI: 1.29-3.47), being a male neonate (OR=1.74; 95% CI: 1.09-2.78.44) and birth weight < 2500g (OR=5.17; 95% CI: 2.79-9.57).

The post partum depression among mothers of sepsis neonates was 78% whereas among controls were 28%. Neonatal sepsis was a risk factor (OR=14; 95% CI: 8.6-22.8) for maternal post partum depression.

The overall maternal satisfaction regarding the received neonatal care was 90% and maternal care was 84.6%. The diet and drinking water provided from the hospital were taken only by 6.7% and 8.3 % of mothers respectively.

Out of observed procedures for infection control standards the compliance of hand washing among the labour room staff, neonatal intensive care units and post natal wards were 57.1%, 80% and 82% respectively.

Conclusions and Recommendations

Eight maternal factors and three neonatal factors were identified as risk factors for neonatal sepsis. Among those, six of the maternal factors and two of the neonatal factors were modifiable. Therefore preventive strategies should be contemplated with relevant authorities. Post partum depression was very high (78%) among the mothers of sepsis neonates. It is extremely crucial to arrange screening for postpartum depression and counselling sessions while in the hospital for all mothers of neonates with neonatal sepsis. Although the overall satisfaction of care was satisfactory it is needed to pay attention on deficient areas like sanitary facilities and communication skills. It is of importance to pay regular attention to the adherence of infection control

standards among all categories of health care workers and carry out regular in-service training programmes regarding this need.

It is advisable to establish routine clinical audits to improve the services and share experiences to minimize the neonatal infections and other adverse outcomes.

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LIST OF ABBREVIATIONS

ANC	Antenatal Clinic
APGAR	APGAR score
BHT	Bed Head Ticket
CI	Confidence Interval
CNTH	Colombo North Teaching Hospital
CRP	C- Reactive Protein
CSF	Cerebro Spinal Fluid
DGH	District General Hospital
DHS	Demographic and Health Survey
EOS	Early Onset Sepsis
EPDS	Edinburg Postnatal Depression Scale
GCE (A/L	General Certificate of Examination (Advanced Level)
GCE (O/L)	General Certificate of Examination (Ordinary Level)
HAI	Healthcare Associated Infection
IAQ	Interviewer Administered Questionnaire
IMCI	Integrated Management of Childhood Illnesses
IMR	Infant Mortality Rate
LBW	Low Birth Weight
LMP	Last Menstrual Period
LOS	Late Onset Sepsis
LR	Labour Room
LSCS	Lower Segment Caesarean Section
MDG	Millennium Development Goals
MOH	Medical Officer of Health
NNICU	Neonatal Intensive Care Unit
NNMR	Neonatal Mortality Rate

NVD	Normal Vaginal Delivery
OFC	Occipito frontal Circumference
OR	Odds Ratio
OT	Operation Theatre
PHM	Public Health Midwife
PHOO	Paediatric House Officers
PI	Principal Investigator
PNW	Post Natal Wards
POG	Period Of Gestation
PPD	Postpartum Depression
PPE	Personal Protective Equipment
PROM	Premature Rupture of the Membrane
RDHS	Regional Director of Health Services
SLMA	Sri Lanka Medical Association
SPHM	Supervising Public Health Midwife
SPSS	Statistical Package for Social Sciences
UK	United Kingdom
USA	United State of America
VOG	Visiting Obstetric and Gynaecologist
WHO	World Health Organization

1. INTRODUCTION

Neonatal sepsis is a leading cause of neonatal morbidity and mortality. It has been seen as a major preventable cause of neonatal deaths.

Mortality during infancy is taken as an important indicator measuring the health status and quality of life in a country. As under-five mortality is decreasing in almost all countries, neonatal mortality emerges as an increasingly prominent component of under-five mortality. Therefore it receives additional attention.

According to World Health Organization (WHO) estimates, there are about five million neonatal deaths per year. Out of those, 98% occur in developing countries. Infections, prematurity and birth asphyxia are the main causes of neonatal deaths (Vergnano, 2005). According to findings, of the estimated 8.9 million deaths in children younger than five years worldwide in 2008, infectious diseases were the cause for 68% of deaths. Out of those 41% of deaths occurred in neonates and the most important causes were preterm birth complications (12%), birth asphyxia (9%), sepsis (6%) and pneumonia (4%), (Robert et al., 2010). World Health Organization in 2000 -2003 report estimated that neonatal sepsis and pneumonia are responsible for about 1.6 million deaths annually, which occursmainly in resource poor countries (Boyce, 2005). Khalid et al revealed that the similar conditions that are responsible for neonatal deathswere the most important causes of neonatal morbidity (Khalid et al., 2004).

The achievement of Millennium Development Goal 4 (MDG), developed at the Millennium Summit in 2000 is two thirds reduction of 1990 child mortality levels by the year 2015. An acceleration of the decline in mortality is possible with the expansion of key effective, affordable interventions targeting the important causes of neonatal mortality. In view of the short time left to meet MDG 4, there is greater demand for frequently updated national data on the cause of child mortality to guide national and global programmatic priorities and researches (Jones et al., 2003).

1.1 Child mortality and neonatal mortality

1.1.1. Global situation

At the WHO Regional Forum in 2003, it was highlighted that each year around nine million young children in low and middle-income countries die before they reach their fifth birthday. Out of that, neonatal and perinatal mortality amounts to around six million. Neonatal death for the same period was around four million with a neonatal death rate of 31 per 1000 live births. The least developed countries accounted for 98% of perinatal and neonatal deaths. Seventy percent of these deaths were due to preventable and treatable causes. The most common causes of death were diarrhoea, malaria, neonatal infections, pneumonia and preterm delivery at birth. A child's risk of dying is highest in the first month of life, where safe childbirth and effective neonatal care are essential (WHO Regional Health Forum, 2003).

1.1.2 Sri Lankan situation

Sri Lanka has a population of 20 million and around 364565 (2009) babies are born annually. The GNP for 2006 was 2790 billion Rupees and the total health expenditure amounts to 7.6% of national expenditure (Annual Health Statistics 2006). The Infant Mortality Rate (IMR) in the country is 9.0 per 1000 live births and the Neonatal Mortality Rate (NNMR) is 6.2 per 1000 live births (Annual Health Statistics, 2008). This means that around 3240 neonates die before they reach their first month of life. Therefore, if a significant impact on the reduction of infant mortality is to be achieved, attempts to reduce infant death in the country should target on reducing neonatal deaths. The Millenium Development Goals (MDG) states that all countries should commit to reduce under-five mortality in children by two-thirds between 1990 and 2015.

According to the observation of the DHS 2006, neonatal deaths are most likely to occur at birth and if not, during the first week of life and early neonatal deaths account for one third of infant deaths. The following table gives the mortality for infants and neonates since 1990 to 2008 in Sri Lanka.

Table 1.1: Infant and neonatal mortality rates from 1990 to 2008

Year	IMR	NNMR	Year	IMR	NNMR
1990	19.3	13.0	1999	13.8	10.6
1991	17.7	12.8	2000	13.3	9.9
1992	17.9	13.0	2001	12.2	9.6
1993	16.3	12.8	2003	11.3	8.4
1994	16.9	12.9	2004	9.8	7.2
1995	16.5	12.5	2005	11.2	7.2
1996	17.3	13.0	2006	10.0	7.4
1997	16.3	12.8	2007	8.5	5.9
1998	14.3	10.5	2008	9.0	6.2

Source: Annual Health Statistics 2006, 2008

The above table shows that more than three quarter of infant deaths are due to neonatal deaths which emphasizes that the interventions for reduction of infant mortality should mainly focus on the neonatal period (Annual Health Bulletin 2006, 2008). The common causes of infant deaths in Sri Lanka were congenital abnormalities (39%), prematurity (24%), asphyxia (15%), sepsis (8%), and othercauses (14%)(FHB, Annual report of family health, 2007).However having a NNMR far better than most of the neighbouring and developing countries, has given a false assurance to health policy makers in Sri Lanka.

1.2. Neonatal sepsis

The neonatal period is defined as from birth to 28 days of life. The first seven days of life is defined as the early neonatal and the latter part as the late neonatal period. Newborn babies are more vulnerable to be infected from bacteria, viruses and fungi than older children because their defence mechanism is immature and some non-pathogenic organisms alsocan cause serious infection in the neonatal period. Neonatal sepsis is defined as a clinical syndrome of bacteremia with systemic signs and symptoms of infection in the first four weeks of life (Vergano et al 2005). The reported incidence of neonatal sepsis ranges from 7.1 to 38 per 1000 live births in the world. In Asia it is from 6.1 to 23 per 1000 live births and in Africa from 3.5 to 8.9 per 1000 live births. Inthe United States and Australia, it ranges from 1.5 to 6 per 1000 live births (Vegnanno et al., 2005). In Sri Lanka the incidence of neonatal sepsis is around 24.9 per 1000 live births (Karunasekara et al., 1999).

1.2.1. Diagnosis of neonatal sepsis

Early diagnosis of neonatal sepsis is extremely important to start treatment to prevent mortality. However diagnosis of neonatal sepsis either by laboratory or from clinical signs is difficult.The clinical features of sepsis are non-specific in neonates and a high index of suspicion is required for timely diagnosis of sepsis. Laboratory evaluation assists in the diagnosis and confirmation of infection. It needs the positive culture of blood, cerebro spinal fluid, or urine to confirm the sepsis. But it takes at least more than 48 hours to get positive culture reports. Some research identified that only 30% of blood cultures are positive in clinically diagnosed sepsis babies (Rashid et al., 2006).

To overcome the problem of diagnosis of neonatal sepsis, WHO recommended to diagnose severe bacterial infection of neonates by a positive single clinical signs. This strategy is now practiced more than 75 countries (WHO, IMCI 2005).These clinical features adopted by Family Health Bureau with expert opinion to practise in Sri Lanka (FHB, IMCI, 2006).

1.3. Neonatal sepsis and under five child mortality

A systematic analysis carried out by Robert and group to identify global, regional and national causes of under-five child mortality in 2008. From this research they found out that in Africa 29% of child deaths occurred during the neonatal period and of that 5% were due to neonatal sepsis. Pneumonia caused another 3% of deaths. In USA 48% of child deaths occur during the neonatal period and of that 5% were due to neonatal sepsis. Pneumonia caused another 2% of death. In Europe there were 53% of child deaths during the neonatal period and neonatal sepsis caused 3% of deaths whereas pneumonia caused another 3 % of deaths. In the South East Asian region 54% of child deaths occurred in the neonatal period. Neonatal sepsis caused 7% of deaths and pneumonia caused another 8% of deaths. In the Western Pacific region 52% of child deaths occurred in the neonatal period and 2% were due to neonatal sepsis. Pneumonia caused another 2% of deaths (Robert et al., 2010).

1.3.1. Early Onset Sepsis (EOS) and Late Onset Sepsis (LOS)

Neonatal sepsis may be classified according to the time of onset of the disease - early onset (EOS) and late onset (LOS). The distinction has a clinical relevance, as EOS disease is mainly due to bacteria, acquired before and during delivery. However, in the literature, there is little consensus as to what age limits apply, with EOS ranging from 48 hours to 6 days after delivery (Vergnano, et al., 2005), from birth to 72 hours

(Sangavi et al., 1996) and as some literature describe, the presence of infection in the first 5-7 days of life (Aggarwal, 2001). Late onset sepsis frequently reflects the infections acquired nosocomiallyor from community sources after delivery (Aggarwal, 2001).

1.4. Risk factors for neonatal sepsis

There were number of researches (Piaczek & Whitelaw 1983; Yancey et al.,; 1996; Oddie et al., 2002; Dutta et al., 2010) carried out to identify risk factors for neonatal sepsis. Several proven maternal and neonatal risk factors for neonatal sepsis are described in literature. The maternal risk factors that were identified was, lack of antenatal clinic attendance OR=2.39 (95%CI: 1.05-5.49) (Mugalu et al., 2006), clinical chorioamnionitis OR=4.4 (95% CI:1.2-16.1), mother being in the labour room for more than 12 hours OR=4.29 (95% CI: 1.4-13.1) (Yancey et al., 1996), vaginal examination more than 3 times OR=9.5 (95% CI: 3.0-31.0) before delivery of neonates(Dutta et al., 2010), dribbling more than 18 hours OR=7.8 (95% CI:5.2-11.6), caesarean section delivery OR=2.4 (95% CI:1.7-3.5), intra partum maternal fever OR=7.2 (95% CI:4.3-12.2) (Staphine et al., 2006), and meconium stained amniotic fluid OR1.5 (95% CI: 1.7-3.4) (Leal et al., 2012).

The neonatal risk factors were male sex of neonate OR=2.7 (95% CI: 2.0-5.0), gestational age less than 30 weeks OR=2.9 (95% CI: 1.0- 4.0)birth weight less than 1500g OR=2.8 (95% CI:2.0-5.0)(Dutta et al., 2010), gestational age less than 34 weeks OR=5.2 (3.0-9.0),(Staphine et al., 2006). Khalid and the group also showed maturity less than 30 weeks OR=11.6 (95% CI: 7.1-19.1), and birth weight less than 1500g OR=9.7 (95% CI: 5.8-16.0) as risk factors for neonatal sepsis.

1.5. Maternal psychological status

Unpleasant psychological nature of the parents especially the mothers of sick neonates is well documented (Miles et al., 1993, Shields et al., 1997) in literature. Some authors measured it as stressors (Chourasia et al., 2012,Miles et al 1991, Jopek et al., 2009) whereas others measured it as depressions (Aduwuya et al., 2005, Tamaki et al., 1997). There were researchers who measured it as anxiety (Carter et al., 2005). Identifying these psychological statuses is important to improve theability of mothers to meet the needs of their babies and to develop skills required to fulfil their role. Mothers in postpartum period are a special group and their psychological changes can be measured as postpartum depression. Recent studies done in Sri Lanka showed a high prevalence (Rowel, 2004, Rathnayake, 2011) of postpartum depression among mothers. It is important to findout the association between postpartum depression and neonatal sepsis andwhether neonatal sepsis could be a risk factor for postpartum depression. This would be useful to improve the management of neonatal sepsis and be proactive in identifying women at risk and provide appropriate counselling.

1.5.1. Postpartum depression

The non-psychiatric depression that the women experienced during the first four weeks of the postpartum period is overall referred to as postpartum depression (American Psychiatric Association, 2000).Risk factors for postpartum depression have been examined indicating that the strongest predictors for PPD include depression or anxiety during pregnancy, personal and family history of depression, lack of social support and stressful life event (Beck, 2001; Rowel 2004; Roberston, 2004). However, most women who were depressed did not necessarily have personal and family histories of depression. It is important to consider causes that occur more commonly such as stressful life events including sickness of the neonates.

Studies carried out to find out the prevalence of depression among postpartum mothers showed 10% in UK (Pitt, 1968), 15.9%in Italy (Benvenuti et al., 1990), and 24.5% in Portugal (Areias et al., 1996). Among Asian countries the prevalence in India was 23% (Patel et al., 2002) while in Sri Lanka it was32.1% (Rowel, 2004). The illness of the new born baby was a significant correlate both for prevalent cases (OR=1.98, 95% CI: 1.30-3.10) and incident cases OR= 2.2, (95% CI: 1.2-3-8) of PPD in Sri Lanka (Rowel, 2004). The studies carried out to asses PPD of mothers whose neonates were in neonatal intensive care units found out that the rate of PPD increased by 70% in USA (Mount, 2009), 35.6% in California (Shaw et al., 2014), and 70% in Ghana (Gold et al., 2013).

1.6.Patient satisfaction

The non medical aspect has also been much emphasised in relation to patient centred health care. The main concern on the part of the health care service providers is to provide the best available medical services from the technical point of view (WHO, 2000a). On the other hand the patients, while expecting the best technical services, are also concerned about the manner in which the services are delivered as well as the setting in which the services are provided (Donabedian, 1980, Emmanuel & Emmanuel 1996). The health care service they receive is judged primarily by these non medical aspects of service delivery. The dignity and other interpersonal aspects of the service delivery practice is the vehicle by which technical care is implemented and on which its success depends (Donabedian, 1980).

Satisfaction, like many other psychological concepts, is easy to understand but hard to define. Patient satisfaction captures client perception of the quality of care delivered by a health provider or the system (Murray and Evans, 2001). Satisfaction is not some pre-existing phenomenon that can be measured. It is a judgment of people form over a period of time as they reflect on their experience. A simple and practical definition of satisfaction would be the degree to which desired goals have been achieved (Browns et al., 1993). It is an attitude of a person's general orientation towards one's total experience of health care. Satisfaction comprises both cognitive and emotional facets and relate to previous experiences, expectations and social network. It can be achieved when perception of the quality of care and services that they receive in the health care setting has been positive, satisfying and meet their expectations (Browns et al., 1993).

1.7. Infection control in health care setting

Infection control is a series of procedures and guidelines carried out to prevent health care associated infections (HAI). There are infections that are acquired by patients during their stay in hospital or infections that are acquired by health care workers while working in the hospital. Health care associated infections are also known as nosocomial infections or hospital acquired infections. The patients who require treatment for HAI have to stay longer in hospitals and are treated with expensive antibiotics and have a high mortality. HAI may be transmitted by health care workers to patients, from patient to patient, and from patient to health care workers (Hospital Infection Control Manual, 2005). Health Care Associated Infections (HAI) occurs worldwide and affects both developed and developing countries. In developed countries 5-10% of patients acquire one or more infections and 15-40% of patients admitted to critical care are affected (Lazzario et al., 2004). It is estimated that at any time, more than 1.4 million people worldwide are suffering from infections acquired in hospital (WHO, safety solution, 2009).

1.8. Standard precautions

Many of these HAI can be prevented by following a set of very simple guidelines called standard precautions. These standard precautions should be followed by all health care workers at all times when attending to all patients regardless of their diagnosis or presumed infectious status. Infections in special care units may need a few more specialized guidelines for infection control in addition to the standard precautions. It consists of hand washing procedures, use of personal protective equipment, environment control, management of blood and body fluids spills and management of sharps (SLMA, National Guidelines, SLCM, 2007).

Hand washing is considered to be the most effective measure to reduce infections acquired in hospitals. Therefore it is important that health care workers maintain meticulous standards of hand care. The researches carried out to observe hand washing compliance revealed poor compliance. In Georgia, overall compliance was 51.6% in surgical intensive care units and 47.2% in medical intensive care units (Gilbert et al., 2010) and hand hygiene compliance among doctors was 16% and among nurses 40%. Another study in Italy found 7.7% of doctors and 19.3% of nurses were compliant with hand washing (Marito et al., 2011).

1.9. Arrangement of government health care setting for pregnant mothers until delivery

Following diagram shows that the routine procedure carried out in government hospitals when mother admitted for the delivery. After admission to the hospital she might undergo blood drawings, intra venous access, vaginal examinations, speculum examinations, shavings, staying in the general ward, staying in the labour room, undergoing vaginal delivery, caesarean section, forceps deliveries or vacuum extraction. While providing all these services she is intervened by all categories of health care workers namely consultants, senior doctors, junior doctors, nursing officers, midwifes and health care assistants. In any instances if those service providers are not adhere to the infection control guidelines, protocols including hand hygiene procedures all these mothers and neonates are at risk of getting infections.

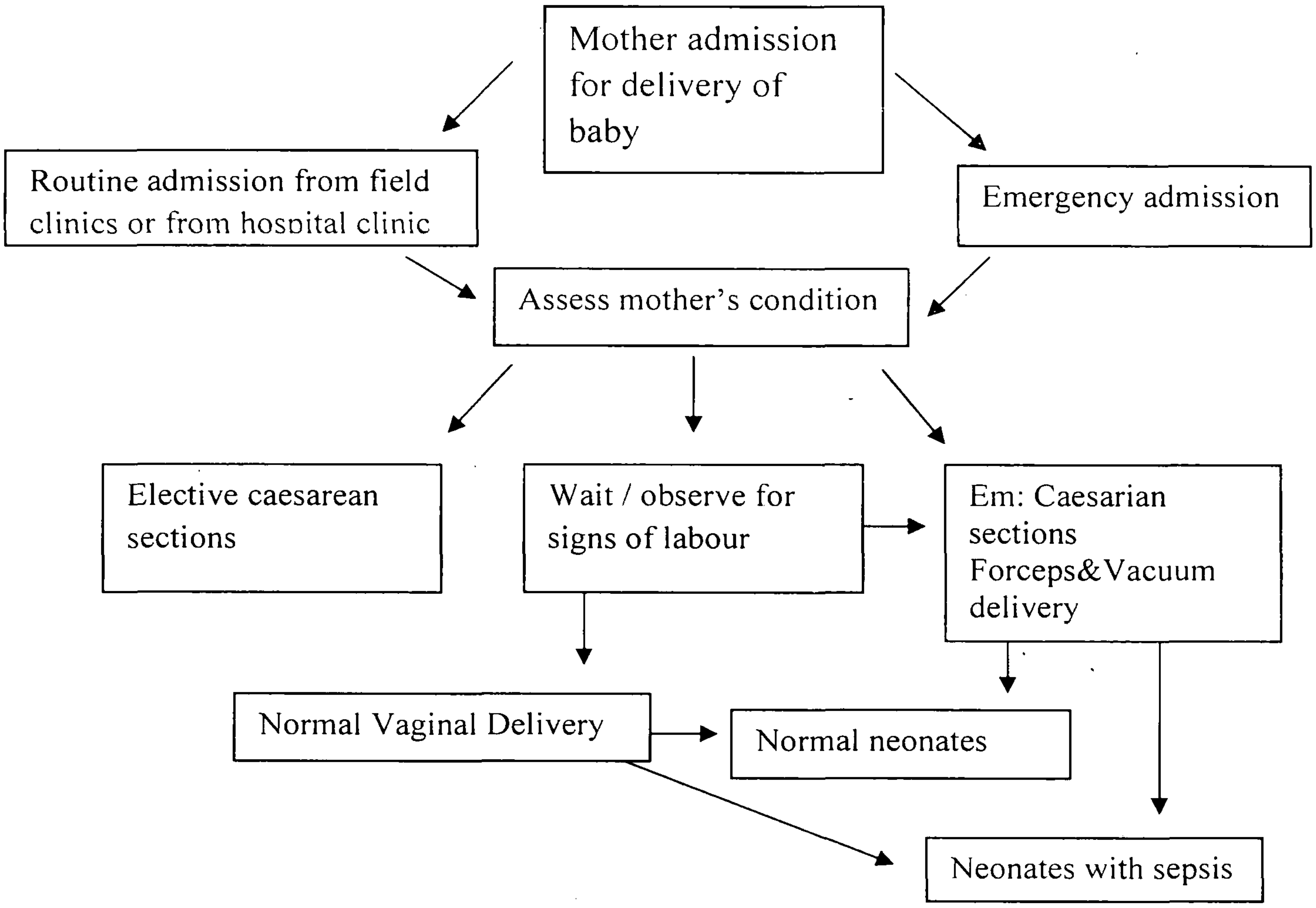

Fig: 1. Flow chart to demonstrate the routine procedure practiced in government health sector when mothers admitted for delivery

1.10. Justification

Although neonatal sepsis is a leading cause of mortality and morbidity among infants in Sri Lanka, the magnitude of the problem is still uncertain. So far, only a limited research has been carried out to assess the risk factors for neonatal sepsis. As Sri Lanka is a country with limited resources, it is important to identify preventable risk factors and focus on early attention to prevent the sepsis and improve the neonatal mortality and morbidity. If necessary data were available it would help immensely to address these issues to ensure that the majority of neonates become productive members of the next generation.

Mothers' mental health is crucial when their neonates are sick because of the importance of attachment and bonding with the baby; their participation in care; and long term infant development. The birth of a critically ill infant may cause crisis for the family. Most of them have some difficulty in adapting to both the hospital environment and especially the neonatal intensive care unit (NNICU) environment. Both these environments are stressful for the parents. Therefore it is important to find out if there is an association between neonatal sepsis and postpartum depression of mothers. This would be useful for the management of mothers by including counselling to prevent PPD and intern improve the neonatal health. Targeting parental mental health in the hospital and the NNICU with effective intervention improved parental function and bonding, as well as improved parent physician communication (Susan et al., 2011).

As explained by the health outcome indicators, Sri Lanka has achieved high standards of health status and health care services (Ministry of Health, Annual Health Bulletin, 2008). In an era where the public considers nonmedical needs as equally important, patient satisfaction surveys are important to further enhance the quality of health services. Dissatisfaction of the services could lead to poor utilisation of services. Improving the satisfaction rarely creates a strain on the available budget and resources. Only minimal finances are necessary to improve the satisfaction on various components of the health system. It is the awareness of the service providers that need to be addressed in order to improve the way the patients are treated and the setting in which they are treated.

There has been an increasing emphasis on the use of patient satisfaction surveys to gather information providing consumer views which can be used to influence policy and service development. In the public sector, quality measures function as a direct measure of accountability as well as providing information to hospitals about areas for improvement.

There are guidelines on procedures such as hand washing, infrastructure developments, protocols related to prevent sepsis as well as there are in-service training programmes to prevent sepsis. However there has not been an assessment to perceive the effectiveness of these interventions in relation to reduction of neonatal sepsis. Therefore it is important to find out the current situation on infection control practices among health care workers for further reduction neonatal sepsis.

As described above, this research examines several aspects related to areas of neonatal sepsis, associated maternal postpartum depression and neonatal sepsis, patient satisfaction with neonatal and maternal care provided through government health care services, and adherence of infection control standards by health care workers in selected procedures.

The following conceptual diagram further describes the possible connection of all those areas of study in relation to Sri Lankan government hospital settings.

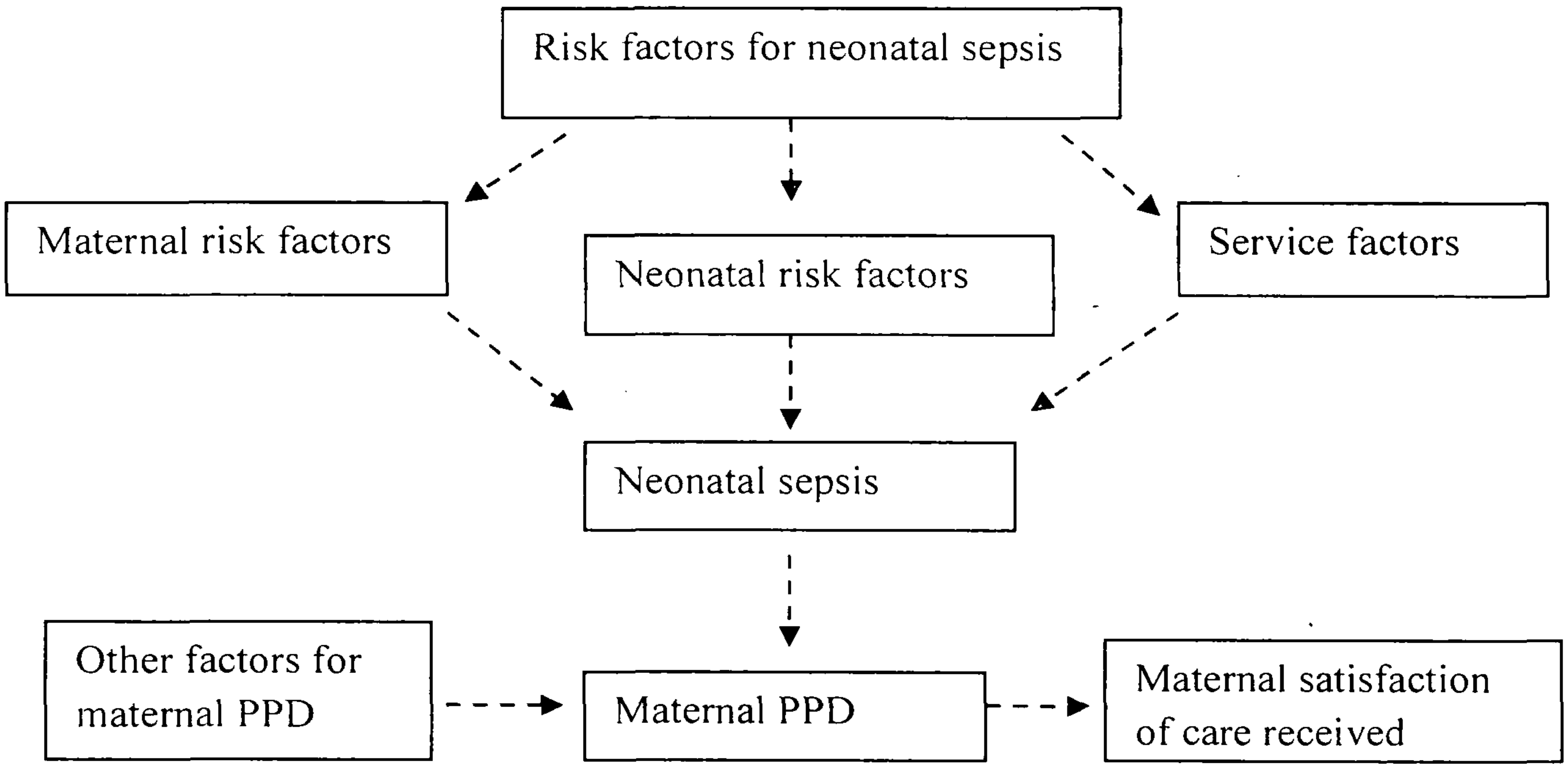

Fig: 2. The conceptual frame work to reflect interconnection between study areas

These above mentioned areas have received very little attention in our country. Therefore, the lack of evidence pertaining to the local setting hinders identification and application of appropriate interventions which would certainly benefit the mother, her family, the community and the country at large. Therefore this research was carried out to achieve the following objectives.

1.11. Objectives

1.11.1. General objectives:

1. To determine the risk factors for neonatal sepsis and its effect on the postpartum depression of the mothers in secondary and tertiary care hospitals in the District of Gampaha.

2. To describe the maternal satisfaction on the care received by both mother and neonate and the adherence of infection control standards by health care workers in secondary and tertiary care hospitals in the District of Gampaha.

1.11.2. Specific objectives:

1. To determine the risk factors for neonatal sepsis among newborn babies receiving care in the secondary and tertiary care hospitals in the District of Gampaha.

2. To determine the effect of neonatal sepsis on the postpartum depression of the mothers in secondary and tertiary care hospitals in the District of Gampaha.

3. To describe the maternal satisfaction on care received by the mother and neonate from the government health services during the hospital stay in secondary and tertiary care hospitals in the District of Gampaha.

4. To describe the adherence of infection control standards by health care workers in selected procedures in the labour rooms, neonatal intensive care units, postnatal wards and operation theatres in secondary and tertiary care hospitals in the District of Gampaha.

1. REVIEW OF LITERATURE

2.1. Global scenario of Neonatal Mortality

Every year, nearly 40% of all under-five child deaths have been among new born infants in their first 28 days of life namely the neonatal period. Three quarters of all new born deaths occur in the first week of life. In developing countries, nearly half of all mothers and newborns do not receive the skilled care that is expected during and immediately after birth. Up to two thirds of new born deaths can be prevented if known effective health measures are provided at birth and during the first week of life (Zupan & Abmon, WHO, 2006).

Table 2.1: Causes of neonatal deaths in the world

Cause	Percentages (%)
Premature and low birth weight babies	30
Neonatal infections	25
Birth asphyxia and birth trauma	23
Congenital anomalies	7
Diarrhoeal diseases	3
Neonatal tetanus	3
Other causes	9

Source: The Global Burden of Diseases: 2004 update: WHO Geneva 2008.

Among the 3.1 million deaths that occurred among babies during 0-28 days of life, approximately one third was due to infections (including pneumonia, sepsis, neonatal tetanus and diarrhoea). Preterm birth complications caused another one million deaths and birth asphyxia was the third major cause of deaths in this early period of life. Therefore the risk of dying from neonatal conditions can be mitigated with quality care during pregnancy; safe and clean delivery by a skilled attendant and immediate postnatal care including resuscitation; extra care of LBW babies; attention to baby warmth; treatment of neonatal sepsis; and early initiation of breast feeding (WHO, The Global Burden of Diseases: 2008).

Neonatal mortality has been declining worldwide. The number of deaths among babies 0-28 days of life decreased from 4.4 million in 1990 to 3.1 million in 2010. There was also a reduction of 28% in neonatal mortality rates (NNMR) over the same period from an estimated 32 deaths per 1000 live births to 23 deaths per 1000 live births. However it is a slow progress and while some advancement has taken place and NNMR has declined in all WHO regions of the world, its progression seem unequally distributed. While NNMR were halved in the European and Western Pacific regions, the reduction observed in the African region was only 19%. Here the progress has been generally slow and it is the slowest in the region with the highest NNMR (WHO, World Health Report, 2011). The following figure shows the trends in neonatal mortality rates at global and regional levels.

Trends in neonatal mortality rates at global and regional levels 1990-2010

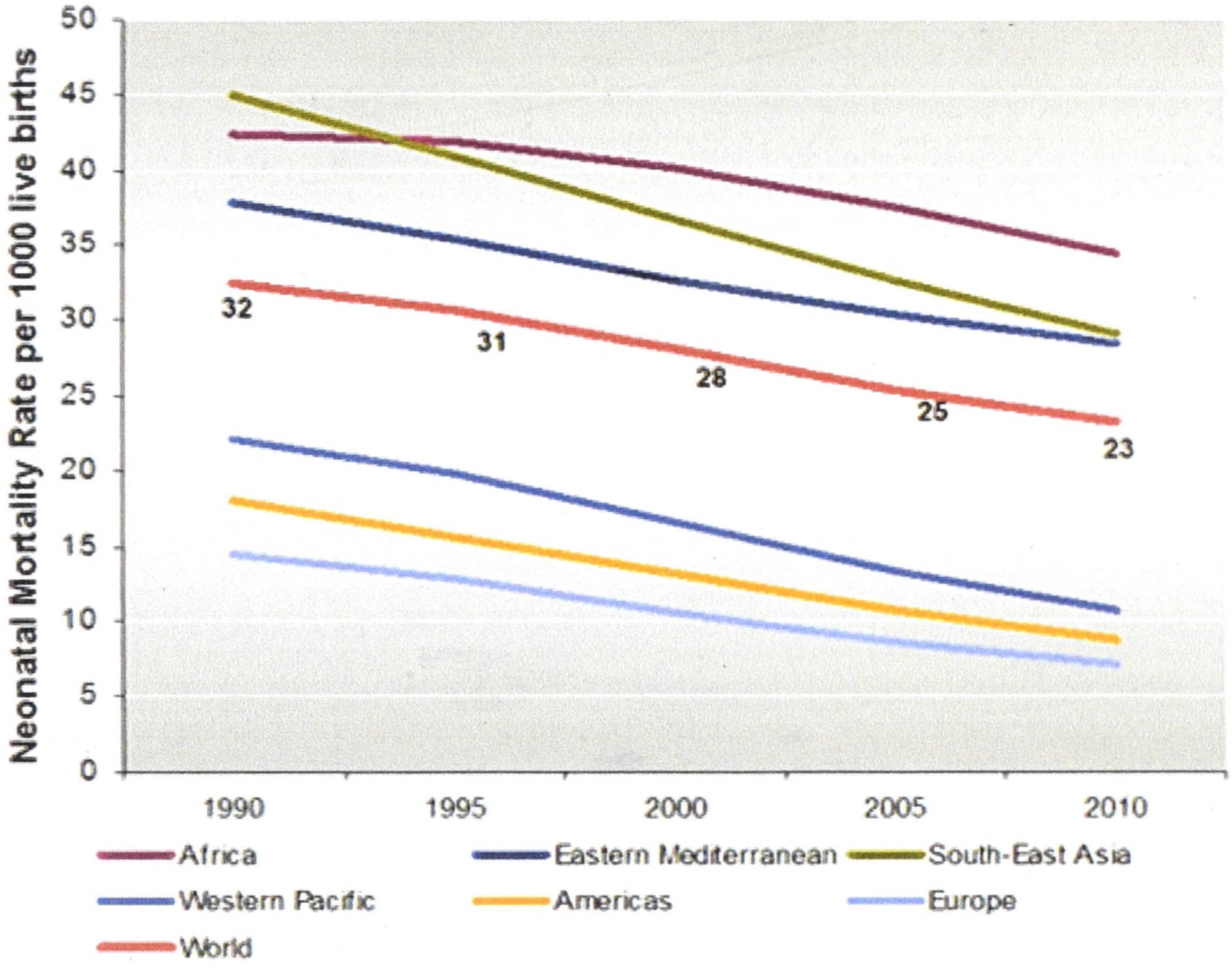

Chart data from: UN-IGME. *Levels & trends in child mortality*. Report 2011

Fig : 3 Trends in NNMR at global and regional level from 1990-2010.

2.1.1. Neonatal sepsis and neonatal mortality

When considering the contribution of sepsis towards neonatal deaths, the estimated world figure for neonatal deaths caused by infections was 36% in 2005, (Lawn et al., 2005). In Pakistan infection contributes to 62% of neonatal deaths (Tazer et al., 2007). The case fatality rate due to neonatal sepsis differs from country to country. In Korea it was 9% (Shin et al., 2010), Sweden 15% (Tessin et al., 2004),Yale 12%, Australia 14% (Berger et al., 1998), India 19.4% and Sri Lanka 11% (Karunasekara et al., 1999). In another study carried out by analysing neonatal deaths during the five-year period from 1997 to 2001 in Sri Lanka showed that neonatal infections led to 20 % of neonatal deaths (Rajindrajith et al., 2009). A study carried out by Fonseka and others in Galle District revealed that 44% of neonatal deaths were due to neonatal sepsis (Fonseka et al., 1994). Lucas and Ediriweera found that 41% of neonatal deaths at the Castle Street Hospital for Women in Colombo were due to neonatal sepsis (Lucas & Ediriweera, 1996).

2.1.2. Neonatal infections

Throughout pregnancy and until the membranes rupture, the foetus is relatively protected from the microbial flora of the mother by the chorioamniotic membranes, the placenta and amniotic fluid. However there are many ways in which infectious agents can reach the foetus or newborn to cause infection. Procedures disturbing the integrity of the uterine content, such as amniocentesis, cervical cerclage, transcervical chorionic villus sampling or percutaneous blood sampling can permit entry of skin or vaginal organisms, causing amnionitis and secondary foetal infection (Gibbs et al., 1981).

Initial colonization of the neonates usually takes place after rupture of the maternal membranes particularly when it is more than 24 hours and the ascent of vaginal bacteria will cause neonatal infections. Other main routes of infections are aspiration of infected amniotic fluid, infection of the mother at the time of birth, and transplacental haematogenous infection during or shortly before delivery. Finally bacteria can be introduced after birth from the environment surrounding the baby, either in the community or at home (Claudio et al., 2004).

Sophisticated equipment for respiratory and nutritional support combined with invasive techniques providing life support to ill infants, arterial and venous umbilical catheters, central venous catheters, peripheral arterial and venous cannulae, urinary indwelling catheters, hyper alimentation infusions, and assisted ventilation provide enormous opportunities for relatively non virulent pathogens to establish infection and to invade the host (Claudio et al., 2004).

2.2. Neonatal sepsis

Neonatal sepsis is normally defined both clinically and microbiologically by positive blood or Cerebrospinal Fluid (CSF) culture (Vergnano et al., 2005). In some literature neonatal sepsis is defined as a positive blood culture in combination with systemic inflammatory response syndrome (Vergnano et al., 2005). A problematic diagnostic situation exists for neonatal sepsis as simply there is no available diagnostic test that can detect or exclude neonatal sepsis with acceptable sensitivity and specificity. Therefore the neonatologists have to initiate antibiotic treatment on the slightest suspicion of sepsis (Ohlin et al., 2010). There was also a lack of consensus on the definition of neonatal sepsis. Therefore it was very difficult to find an accepted definition either for clinical use or for scientific studies. In earlier studies a wide variety of definitions have been used (Haque, 2005).

2.2.1. Early Onset Sepsis (EOS) and Late Onset Sepsis (LOS)

Neonatal sepsis may be classified according to the time of onset of the disease as early onset sepsis (EOS) and late onset sepsis (LOS). The distinction has clinical relevance as early onset disease is mainly due to bacteria acquired before and during delivery and late onset disease is due to bacteria acquired nosocomialy or from community sources (Khalid et al., 2004; Vergnano et al., 2005). Some literature state that early onset refers from birth to 72 hours, (Sangavi et al., 1996) and others refer birth to one week to be considered as early onset sepsis. Some studies categorized that early onset occurs in the first 48 hours (Placzek & Whitelaw, 1983).

Placzek & Whitelaw (1983) analyzed 1000 admissions to NNICU at Hammersmith Hospital, London for a three-year period starting from 1979. They reviewed clinical records and bacterial isolates of all 1000 consecutive admissions to the neonatal intensive care unit. All positive cultures were divided into two groups those occurring in the first 48 hours of life were grouped as EOS and those occurring after 48 hours were grouped as LOS. Out of that 17 (26%) had EOS and 74% had LOS.

Khalid and group (2004) categorized the blood culture positive neonatal sepsis cases in a tertiary care hospital in the UK as EOS and LOS. There were 124 culture positive neonates during the five-year period starting from 1996. The onset of sepsis less than 72 hours was considered as early onset and there were 24 (20%) neonates with EOS and 100 (80%) neonates with LOS (Khalid et al., 2004).

A study was carried out in Taiwan by recruiting a total of 270 patients of blood culture positive sepsis during January 1992 to December 2001. They categorized early onset as during the first week of life and late onset as after the first week. In the early onset group there were 76 (28.1%) patients and in the late onset group there were 194 (71.9%) patients. The clinical presentation was mostly non specific in LOS. There were more premature and VLBW infants in the late onset group (Jiang et al., 2004)

2.2.2. Incidence of neonatal sepsis

The reported incidence of neonatal sepsis varies from 7.1 to 38 per 1000 live births in Asia, 6.5 to 23 per 1000 live births in Africa and 3.5 to 8.9 per 1000 live births in South America. When compared to rates reported in USA and Australia ranges from 1.5 to 6 per 1000 live births (Hyde et al., 2002). Khalid and others revealed that in UK the incidence of neonatal sepsis were 8.4 per 1000 live births (Khalid et al., 2004). In Sweden the incidence was 2.8 per 1000 live births (Tessin et al., 2008). In South East Asia the rate of blood culture confirmed neonatal sepsis ranged from 4 to 20 per 1000 live births and clinically diagnosed sepsis from 16 to 38 per 1000 live births (Tazer et al., 2007).

In Sri Lanka the incidence of neonatal sepsis was 24.4 per 1000 live births (Karunasekara et al., 1999) among NNICU admissions. In India the incidence was 37.2 per 1000 live births (Betty Chacko & Inderprech Sohi, 2007). In Taiwan it was 40.6% of incidence among NNICU admissions (Jiang et al., 2004). In South Korea it was 30.5 per 1000 live births (shin et al., 2009). In Mexico the incidence was 4.3 per 1000 neonates (Leal et al., 2012).

2.2.3. Pathogens of neonatal sepsis

A variety of microorganisms cause neonatal sepsis. Over time the causative organism of neonatal sepsis has changed. Regional differences of the specific organisms of neonatal sepsis have been reported (Vesikari, 1985; Bizzarro et al., 2005). Pathogens may be changed whether it is early onset sepsis or whether it is late onset sepsis (Jiang et al., 2004).

In the UK, they analyzed 78 blood culture positive neonates during a six-year period from 1999. The microorganisms they found were as follows. *Enterobacteria Spp* 28%, *Esherichia Coli* 26%, *Klebsiella Spp* 26%, *Acenetobactor Spp* 10% and *Psedomonas* 4 % (Stefania et al., 2011). Shin et al., (2011) analyzed 502 blood culture positive neonates with sepsis. They found gram positive organisms 43.6%, Gram negative organisms 37.6%, and fungus 18.8% as causes of infections in neonates. Gram positive organisms were *staphylococcus aureus* 25%, Coagulace- negative staphylococcus 8%, and group b streptococcus 2% and gram negative bacteria were *Klebsiella pneumonia* 12.8%, *Escherichia Coli* 8.7%, Enterobacteriseae 2%, and Acenetobactor 2% (Shin et al., 2009).

The causative pathogens can be categorized according to the onset of sepsis as early onset or late onset sepsis. In Taiwan, Jiang et al., (2004) analyzed 270 neonates with 325 episodes of sepsis for a 10-year period from 1992. They found that Gram negative bacteria were common for both early and late onset sepsis. In early onset sepsis, Coagulase negative (13%), Group B streptococcus (18%) and *Staphylococcus aureus* (3%) were among Gram positives whereas *Escherichia Coli*(21%),Pseudomonas (6%) and *Klebsiella pneumonia* (3%) were among gram negatives.For late onset sepsis, Coagulase-negative staphylococcus 22%, *Staphylococcus aureus* 15% and group B streptococcus 1% were among Gram positive organisms and *Escherichia Coli* 9%, Acenetobactor 9%, *Klebsiella* 8% and *Pseudomonas* 6% were among Gram negative bacteria (Jiang et al., 2004).

In France a prospective study was carried out to see the pattern of pathogens that causes neonatal sepsis. They recruited 217 neonates with blood culture positive neonatal sepsis during a one-year period in tertiary care hospitals. Those pathogens were group B streptococcus 58.5%, *Escherichia Coli* 22%, Non Group B streptococcus 5.5%, coagulase-negative staphylococcus 2.4%, and *Staphylococcus aureus* 1.8% (Kuhn et al., 2008).

Mathew and others analyzed 647 infants of neonatal sepsis for their causative organisms in Yale. They found Coagulase-negative staphylococcus (29%), *Escherichia Coli* 12%, group B streptococcus 10%, and *Staphylococcus aureus* 8% (Mathew et al., 2005).

A study was carried out at the De Soysa Hospital for Women, Colombo, over a period of 24 months (1995-1997) to identify the causative organism for neonatal sepsis. It was found that *E.coli* (52%) and *Klebsiella* (22%) were responsible for over 70 % of neonatal sepsis cases (De Silva et al., 1998).

2.2.4. Diagnosis of neonatal sepsis

Bacterial sepsis is one of the most common diagnostic challenges in new born medicine. The identification and treatment of newborns with infection is weak in many developing country settings, because a majority of sick newborns present with non specific signs and symptoms. Therefore diagnosing of neonatal sepsis is difficult even in the most sophisticated settings (WHO, 2009). A definitive diagnosis based on culture of blood, cerebro spinal fluids, or urine is usually reached only after a delay of a day or two, yet rapid progression of untreated infection may greatly increase morbidity or mortality for neonates.

2.2.4.1. Laboratory diagnosis

Laboratory diagnostic tests have poor or indeterminate accuracy and are often not universally available. Obtaining blood cultures from neonates can be difficult as sample volumes are small and a substantial number are negative or contaminated. Many studies found that blood cultures were positive only around 30-40% of the clinically diagnosed sepsis (Mondale et al., 1991; Rashid et al., 2006; Mugalu et al., 2006). Another study shows that only 20.7% of blood cultures were positive with clinical diagnosis of sepsis neonates (Ohlin et al., 2010). Due to antibiotic use and small sample volumes, blood cultures may give false negative results. Conversely, many positive blood cultures may be contaminants. This is particularly true for Coagulase-Negative Staphyloccoci (CoNS), which account for about 70% of all positive blood cultures in neonates, though only about half of these represent true infection (Modi et al., 2009).

C - reactive protein (CRP) test is an acute phase protein measurement which is widely used in sepsis diagnosis. Opinions on the diagnostic usefulness of CRP vary. C-Reactive Proteins increases over the initial day of life, with correspondingly increasing diagnostic sensitivity at 24 and 48 hours based on the ROC curve analyses (Carrigan et al., 2004). The cut-off point for CRP also varies. Some authors have considered a CRP value of >10 mg /L to start antibiotic therapy (Chiesa et al., 2004).

There are various biomarkers namely procalcitonin (PCT), Tumour necrosing factor (TNF), Inter Leukin 6 (IL6) and Inter Leukin 8 (IL 8). Among all markers associated with sepsis contradictory results have been reported (Chiesa et al., 2004). These tests are not perfect. Some real cases of infection will produce negative test results whereas some neonates without infection will show positive test. The potential usefulness of the test will depend on the clinical condition of the neonate. If the neonate is extremely sick the test will not give much additional information (Chiesa et al., 2004).

Newborn infants, especially premature infants, are prone to fulminant bacterial sepsis because of their immature immune system. A decreased interferon–gamma production by T lymphocytes, deficient immunoglobulin production by B lymphocytes and lower opsonization potential due to decreased function of complements contribute to this relative immune deficiency state. Although a reliable test for early diagnosis of sepsis has not been identified for the research, it is defined as follows. They were clinical suspicion, a positive blood culture or CSF culture and having at least three of the following haematological findings. Those are total leucocytes count ≤5000/µl or ≥20000µl, total neutrophil count ≤1750 µl or ≥5400µl, immature neutrophil counts ≥600/µl, immature/ total neutrophil ratio ≥0.02, platelet counts ≤150000/µl (Kalayci et al., 1997).

2.2.4.2. Clinical Diagnosis of neonatal sepsis

Various countries use clinical features to diagnose neonatal sepsis as delayed treatment produces drastic results for the neonates. Integrated Management of Childhood illness (IMCI) is a new strategy developed by the Child Health and Development Division of the WHO to address common childhood health conditions. IMCI has shown proven benefits in the setting where it was implemented. It includes the clinical signs of sepsis in young infants aged less than two months. The strategy focuses on systematically addressing major childhood illnesses. More than 75 countries successfully adopted this strategy for their countries (WHO, IMCI, 2000).

World Health Organization states that identification of infants who are severely ill and in danger of dying within the first week of life is of major public health importance in the world. Therefore to clarify signs and symptoms of neonatal sepsis, WHO conducted a large multicentre study of the clinical features and causes of serious bacterial infections from 1990 to 1992 among infants less than two months. The study centres were located in Ethiopia, Gambia, Papua New Guinea and Philippines. Infants were selected on the basis of the clinical findings. Fifty one individual clinical signs and symptoms were selected at the beginning and later clustered into groups. A total of 8418 infants less than 90 days were triaged in the four sites and 4552 infants were satisfied for criteria to be enrolled into the study. Out of the 4552 infants 2398 infants met the pre-specified criteria for laboratory evaluation, blood cultures, and chest radiographs. Following this, they developed the clinical prediction rule and simplified the model to be used in the clinical setting. Twelve clinical signs were finalized. These included temperature more than 37.5^0C and less than 36.5^0C, presence of convulsions, fast breathing more than 60/minutes, severe chest in-drawing, nasal flaring, grunting, presence of bulging fontanel, pus drawing from the ear, red umbilical stump, pustules, lethargy, unconsciousness, and less than normal movement (FHB, Integrated Management of Childhood Illness [IMCI] 2006).

However, this guideline did not cover the illnesses among newborns in the first week of life. A recent study was conducted to provide evidence to support the IMCI referral check list for 0-7 days of life. They recruited 3177 neonates from age 0-6 days and 5712 neonates aged 7- 59 days. The study was conducted in Bangladesh, Bolivia, Ghana, India, Pakistan and South Africa aiming at providing evidence to support an IMCI referral check list for sick neonates in the first week of life. From seven intervention studies they found out that the most common diagnoses requiring hospitalization was severe infection namely sepsis, pneumonia and meningitis. The initial signs revealed, history of difficulty in feeding [OR=10.0;95% CI:6.9-14.5], history of convulsions [OR=15.4; 95% CI: 6.4-37.2], lethargy [OR=3.5; 95%CI:1.7-7.1], movement only when stimulated [OR= 6.9;95% CI:3.0-15.5], respiratory rate >60 beats per minute or more [OR=2.7;95% CI:1.9-3.8], grunting [OR=2.9;95% CI:1.1-7.5], severe chest in-drawing [OR=8.9;95% CI:4.0-20.1], temperature of 37.5^0C or more [OR=3.4;95%CI:2.4-4.9]or below35.5^0C [OR=9.2 95%CI:4.6-18.6], prolonged capillary refilling time [OR=10.5;95% CI:5.1-21.7], cyanosis [OR=13.7;95% CI:1.6-116.5] and stiff limbs [OR=15.1;95% CI:2.2-105.9]. The presence of any single sign of these showed 87% and 74% ofsensitivity and specificity respectively. Thereafter even when three signs namely, prolonged capillary refill, cyanosis and stiff limbs were removed; the sensitivity (85%) and specificity (75%) were still the same. Therefore finally seven signs were selected for severe blood stream infection of neonates aged 0-7 days. They were, history of difficulty in feeding, history of convulsions, movement only when stimulated, respiratory rate of 60 breaths per minute or more, severe chest in-drawing, grunting, and temperature of 37.5 ^{0}C or more or below 35.5 ^{0}C. The presence of even one of these signs was considered for the diagnosis of neonatal sepsis (Sandra et al., 2009, WHO, IMCI 2001, WHO, The Young Infants Clinical Signs Study Group 2008).

The clinical features which were originally in the WHO IMCI were adopted by the Family Health Bureau of Sri Lanka with experts' opinion in 2006 and a single sign was considered as severe disease of the neonates (FHB, Integrated Management of Childhood Illness (IMCI) 2006, Weber, 2008).

The following table shows the evidences for use of single clinical sign to diagnose of neonatal sepsis.

Table: 2.2. Summary of the evidences that use single clinical sign to diagnose neonatal sepsis

WHO (IMCI)* **Single sign of any infant considered as severe blood stream infection**	**WHO**The Young Infants Clinical Signs Study Group.** **Single signs of the following considered as severe blood stream infection**	**FHB***** **Adopted WHO IMCI criteria** **Single signs of the following considered as severe disease**
Temperature more than 37.5 ^{0}C and less than 36.5^{0}C	Temperature of 37.5^{0}C or more or below 35.5^{0}C	Temperature of 37.5^{0}C or more or below 35.5^{0}C
Presence of convulsions	Presence of convulsions	Presence of convulsions
Fast breathing more than 60/minutes,	Fast breathing more than 60/minutes,	Fast breathing more than 60/minutes or slow breathing less than 30 per minute
Severe chest in-drawing	Severe chest in-drawing	Severe chest in-drawing
Nasal flaring	History of difficulty in feeding,	Pallor,mottling or dusky skin
Grunting	Grunting	Grunting
Presence of bulging fontanel	Movement only when stimulated	Floppy or stiffness
Pus drawing from the ear		More than 10 skin pustules
Umbilical redness extending to the skin		Umbilical redness extending to the skin or bleeding from umbilical stump
More than 10 skin pustules		Central cyanosis
Lethargy, unconsciousness, less than normal movement		

*WHO - Integrated Management of Childhood Illness (IMCI) 2006,**WHO - The Young Infants Clinical Signs Study Group 2008.**FHB - Adopted WHO IMCI criteria, 2006

In Uganda, Mugalu and others carried out a case control study to find out risk factors for neonatal sepsis by using a single clinical sign in IMCI strategy for case definition for neonatal sepsis. Then the clinically diagnosed sepsis neonates were categorised into two groups as blood culture positives and negatives. There were 37% of positive blood cultures (Mugalu et al., 2006).

Ohlin and others (2010) have conducted a study to identify which clinical signs at presentation are most predictive of sepsis in neonates. Newborn infants ≤28 day of age admitted to the NNICU at Orebro University Hospital (Sweden) during a period of eight years from September 1997 to November 2005 were prospectively and consecutively enrolled into the study. Nine clinical signs known to be associated with sepsis were prospectively studied together with medical history and laboratory values. The infants were closely monitored and the followingclinical signs were taken in: feeding intolerance; tachypnoea, apnoea; bradycardia (heart rate<100); irritability; blood pressure, feeding intolerance, distended abdomen; and hypotension or impaired peripheral circulation. There were 401 neonates with suspected sepsis. A total of 83 (20.7%) samples were positive for blood culture. Five of the nine clinical signs (bradycardia, apnoea, blood pressure, feeding intolerance, and distended abdomen) were significantly associated ($p<0.05$) with a positive blood culture (Ohlin et al., 2010).

A population based prospective study was carried out in France over a period of one year from March in 2004. The study population included all preterm and term neonates with confirmed or probable EONS who were treated with antibiotics for at least five days. They classified the subjects as having confirmed EONS defined by positive blood and/or CSF cultures, probable EONS defined as clinical and biological signs of sepsis with positive gastric aspirates or positive peripheral cultures or possible EONS defined by clinical or biological signs with negative cultures. According to the French guidelines clinical signs of neonatal infection includes fever or hypothermia, grayish skin colour, tachycardia, bradycardia, poor capillary refilling time, hypotension or shock, grunting, tachypnoea or apnoea, respiratory distress, bulged fontanel, lethargy and seizures (Kuhn et al., 2010).

2.2.5. Risk factors for neonatal sepsis

2.2.5.1. Socio demographic factors

In Canada a case control study was carried out by recruiting 70 cases and 470 controls during five-year periods from 1993 to find out maternal, neonatal and socio demographic risk factors for group B streptococcal neonatal sepsis. Maternal age, maternal residencies, marital status, maternal education, paternal education, and income levels were studied as socio demographic factors. This study disclosed that maternal age less than 20 years was an associate factor (OR=2.38; 95% CI: 1.06-5.36) for neonatal group B infections (Adair et al., 2003).

2.2.5.2. Maternal risk factors for neonatal sepsis

A cohort study was carried out in a tertiary care hospital in India to assess the risk factors for neonatal sepsis. Six hundred and one neonates of less than 34 weeks of gestation without neonatal malformations were recruited for the study. Eighty five neonates were diagnosed as blood culture positive. Ten maternal and neonatal risk factors were assessed for neonatal sepsis. and bivariate analysis showed the associated maternal factors were per vaginal examination three or more than three times (OR=5.85; 95% CI:2.0-17.2), clinical chorioamnionitis (OR=4.7; 95% CI: 0.82-25.28), PROM >18 hours (OR=1.52; 95% CI:0.8-2.8), duration of labour more than 18 hours (OR=0.62; 95% CI: 0.2-1.7), maternal fever (OR=0; 95% CI: 0-5.74), and foul smelling liquor (OR=0; 95% CI: 0-24.96). After multiple logistic regression analysis the number of vaginal examinations more than three (OR=9.5; 95% CI: 3-31), and clinical chorioamnionitis (OR=8.8; 95% CI: 2-430) were found as maternal risk factors for neonatal sepsis (Dutta et al., 2009).

Mugalu and others (2006) carried out a research in Uganda to find out risk factors for neonatal sepsis. They recruited 290 neonates prospectively. The WHO case definition for neonatal sepsis in the Integrated Management of Childhood Illness (IMCI) was used to select subjects for their study. They discovered lack of antenatal clinic attendance (OR=2.39; 95% CI: 1.05-5.49, p=0.02) as a significant maternal risk factor for neonatal sepsis. Premature rupture of the membranes more than 18 hours before delivery (OR=1.56; 95% CI: 0.82-2.96, p=0.14), meconium stained liquor (OR=2.42 95% CI:0.67-9.04; p=0.11), foul smelling liquor (OR=1.49; 95% CI: 0.75-2.95; p=0.21), and maternal pyrexia in perinatal period (OR=1.65; 95% CI: 0.93-2.93; p=0.06) were not found as significant risk factors for blood culture positive neonatal sepsis (Mugalu et al., 2006).

A case control study was carried out to find out the risk factors for *Escherichia coli* sepsis in neonates in Georgia, California and Connecticut (Stephanie et al., 2005). They recruited 132 culture confirmed neonatal sepsis babies and 1212 controls retrospectively for a five-year period from1997. The study revealed that the maternal risk factors for neonatal sepsis were caesarean section delivery (OR=2.4; 95% CI: 1.7-3.5), Intrapartum fever (OR=7.2; 95% CI: 4.3-12.2) and premature rupture of the membranes more than 18 hours before the delivery of neonate (OR=7.8 (95% CI: 5.2-11.6) (Stephanie et al., 2005).

Oddie et al., (2002) carried out a case control study to find out risk factors for early onset group B streptococcal sepsis in the UK. They recruited neonates of 24 weeks of gestation or more, in whom group B streptococcus was isolated from a normally sterile site (blood or CSF) in the first week of life. Thirty six live born babies developed group B streptococcal sepsis in the first week of life during the study period of two years (April 1998 to April 2000). They revealed that the prematurity (OR= 10.4; 95% CI: 3.9-27.6), dribbling more than 18 hours before delivery (OR= 25.8; 95% CI: 10.2-64.8), dribbling before onset of labour (OR=11.1; 95% CI: 4.8-25.9), and intrapartum fever of the mothers (OR=10.0; 95% CI: 2.4-40.8) were significant associated factors for neonatal sepsis. Multiple logistic regression, showed dribbling >18 hours (OR=13.7, 95% CI: 4.8-39.5) and intrapartum fever (OR+10.0; 95% CI: 1.7-60.7) as statistically significant risk factors for neonatal sepsis (Oddie et al., 2002).

Karunasekara and Pathirana (1999) have conducted a cross sectional descriptive study on neonatal sepsis at a tertiary care hospital in Sri Lanka. Ninety eight neonates were recruited for the study on clinical evidence of sepsis and 3005 neonates recruited as controls during a one year study period in 1999. Gestational age, birth weight and mode of delivery were evaluated as risk factors for neonatal sepsis. They found out instrumental deliveries (χ^2 =31.04, p=<0.0001) as a significant associated maternal factor for neonatal sepsis (Karunasekara et al., 1999).

A cohort study was carried out in the USA to find out risk factors for neonatal sepsis by recruiting 823 mothers. Clinical and culture proven neonatal sepsis were diagnosed in 116 neonates. The maternal risk factors they found out for neonatal sepsis were that the mother was in the labour room for more than 12 hours (OR=7.2; 95% CI: 1.6-32.2), chorioamnionitis (OR=4.4; 1.2-16.1), and endometritis (OR=6.4; 95% CI: 1.2-34.2) (Yancey et al., 1996).

In South Korea, Shin et al., (2009) carried out a retrospective cohort study for a three-year period starting from 1999 to find out risk factors for neonatal sepsis. They analyzed 868 neonates diagnosed with the disdease. Out of these, 689 neonates were clinically diagnosed whereas 179 neonates were diagnosed by positive blood or cerebro spinal fluid cultures. Next, they compared the early onset neonatal sepsis with the late onset neonatal sepsis for risk factors. Dribbling for more than 18 hours (p<0.001), was found as a maternal risk factor for neonatal sepsis in both clinically diagnosed or culture positive neonates (Shin et al., 2009).

A case control study was carried out in Canada by recruiting 70 cases and 470 controls for a 5-year period from 1993. They were analyzed for socio demographic factors, maternal risk factors and neonatal risk factors for group B streptococcal sepsis. Socio demographic factors were not associated with neonatal sepsis. As shown in the multiple logistic regression model, the maternal risk factors for neonatal group B streptococcus sepsis were monitoring of labour for more than 10 hours (OR=2.24 95% CI: 1.22-4.13), maternal intrapartum fever >37.5^{0}C (OR=2.64; 95% CI: 1.34-5.23), and duration of labour for more than 10 hours(OR=1.84; 95% CI: 1.06-3.18) (Adair et al., 2003).

In Pakistan, Muhammad et al., (2014) retrospectively conducted a cohort study to follow up neonates with history of maternal dribbling for more than 18 hours over a period of 5 years from 2007 to 2011 in a tertiary care hospital. In this study they recruited 428 neonates with history ofmaternal dribbling. Seventeen neonates were diagnosed as culture positive neonatal sepsis. They revealed that maternal fever (OR=37; 95% CI: 3.4-93.3) was a significant risk factor for culture positive neonatal sepsis (Muhammad et al., 2014).

In Mexico, a retrospective cohort study was carried out to identify risk factors for neonatal sepsis by recruiting 514 neonates with sepsis, in a tertiary care hospital during a four-year period from 2004. They followed up 11790 neonates and 514 were clinically diagnosed with sepsis during the study period. The identified maternal risk factors were meconium stained amniotic fluid RR=1.5 (95% CI; 1.1-1.9: p<0.0001), and dribbling more than 24 hours RR=3.5 (95% CI: 1.8-6.6; p<0.0001) (Leal et al., 2012).

2.2.5.3. Neonatal risk factors for neonatal sepsis

In India a cohort study carried out by recruiting 601 neonates by clinical diagnosis of sepsis in a tertiary care hospital found that associated neonatal factors for neonatal sepsis were maturity of less than 30 weeks of gestation (OR, 3.4;95% CI: 2.1-5.8), birth weight of less than 1500g [OR 3.6; 95% CI: 2.1-6.1], being male sex (OR=2.15; 95% CI:1.3-3.7), small for gestational age [OR=1.7; 95% CI: 0.9-2.8] and Apgar score less than four at five minutes (OR=1.2; 95% CI: 0.3-4.3). Multiple logistic regression showed that birth weight < 1500 g [OR=2.8; 95% CI: 2-5], male sex (OR=2.7; 95% CI:2-5) and maturity of neonates less than 30 weeks (OR=2 9; 95% CI: 1-4) were the neonatal risk factors for sepsis (Dutta et al., 2010).

Mugalu and others (2006), in Uganda found that being a male sex (OR=1.96; 95% CI: 1.17-3.29, p=0.01) is a risk factor for blood culture positive neonatal sepsis than clinically diagnosed neonatal sepsis.

A case control study carried out in three countries namely Georgia, California and Connecticut showed that maturity of neonate less than 34 weeks (OR=42.2 ;95% CI:25.4-69.8) and 34 to 36 weeks (OR=5.2 ;95% CI:3.0-9.0) were risk factors for neonatal sepsis with *Escherichia coli* among neonates (Stephanie et al., 2005). Karunasekara, (1999) also found that low birth weight (χ^2 = 25.2, p=<0.0001) and prematurity were neonatal factors significantly associated with neonatal sepsis (χ^2= 37.68, p=<0.0001) in Sri Lanka (Karunasekara et al., 1999).

In South Korea a retrospective cohort study revealed that birth weight of neonates less than 2500 g (p<0.001), Apgar score less than seven at five minutes (p<0.001), and prematurity of less than 37 weeks were significant (p< 0.001) neonatal risk factors both in clinically and culture confirmed neonatal sepsis. In this study more male neonates developed sepsis than female neonates. But it was not statistically significant (p<0.85) (Shin et al., 2009). It was found that maturity of neonates less than 37 weeks (OR=5.11; 95%CI: 2.54-10.28) was a risk factor for beta streptococcus neonatal sepsis in Canada (Adair et al., 2003).

A retrospective cohort study was carried out by recruiting 1612 of neonates to find out risk factors for neonatal sepsis in a tertiary care hospital in the UK from 1996 for a five-year period. Blood cultures were positive for 124 neonates. The neonatal factors that were discovered as risk factors for neonatal sepsis were maturity less than 30 weeks (OR= 11.6; 95% CI: 7.1-19.1), and birth weight less than 1500g (OR= 9.7; 95% CI: 5.8 - 16.0) (Khalid et al., 2004). In Pakistan from a retrospective cohort study it was found that the low birth weight ≤1500 (OR=9.8; 95% CI: 1.5-65.7)] was a significant risk factor for blood culture positive neonatal sepsis (Muhammad et al., 2014).

Makhoul and others (2009) carried out a prospective cohort study in Israel to determine early onset Group B streptococcus sepsis among high risk neonates born after prolonged rupture of the membranes during a one year period from February 2006, all neonates born beyond 35 weeks of gestation with maternal premature rupture of the membranes ≥18 hours were recruited for the study. Neonates were followed up for 48-72 hours for clinical signs suggestive of sepsis. Of the 3616, live born 212 (5.9%) met the inclusion criteria and were enrolled in this study. Only 12 (5.6%), of the neonates presented with one or more clinical signs suggesting of sepsis. The independent neonatal risk factors for sepsis were the lower five minutes Apgar score and maturity less than 37 weeks which remained as significant ($p< 0.0002$ and $p= 0.01$) respectively (Makhoul et al., 2009).

Leal et al., (2012) carried out a retrospective cohort study by recruiting clinically diagnosed neonates with sepsis to find outany risk factors. The identified neonatal risk factors for sepsis were low birth weight <2500 RR=1.1 (95% CI: 1.1-1.2; p<0-0001) and prematurity less than 37 weeks of gestation (RR=2.4; 95% CI: 1.7-3.4, p<0.0001), (Leal et al., 2012).

2.3. Maternal postpartum depression

The postpartum period is generally a time of happiness and bonding between the mother and the newborn but complicated pregnancies can alter this. Postpartum depression (PPD) is a common complication of child birth occurring in approximately 10% to 20 % of women worldwide. One of the Meta analysis showed prevalence of non psychotic postpartum depression was 13% (O' Hara et al., 1996, Frideman et al., 2001). PPD is a diagnostic term used to describe a moderate to severe depressive disorder occurring in the postpartum period. PPD may be detected at any time during the first postnatal year but it generally commences within the first six weeks after delivery (Cox, 1982). Among the mothers of infants in the NNICU, rates of PPD increased up to 25% in Turkey (Akman et al., 2006) and up to 70 % in the USA (Mount, 2009). The strongest risk factors for PPD are a personal or family history of depression; disturbed relationship; unfavourable socio economic factors; illness of the neonates and stressful life events. Obstetric risk factors include multiple births, VLBW infants, conception via assisted reproductive technologies and experiencing stillbirths. In Sri Lanka it was found out that lack of support from the husband, abuses by the husband or relatives, illness of the neonate, recent unexpected life events, normal vaginal deliveries, and prematurity of neonates were significant correlates for PPD (Rowel, 2004).

Several instruments such as the Edinburg Postnatal Depression Scale (EPDS), Beck Depression Inventory (BDI), Delusions-Symptoms-States Inventory, General Health Questionnaire (GHQ), Pitt Depression Scale, Hospital Anxiety and Depression Scale, and Postpartum Depression Screening Scale (PDSS) have been used to assess depression during ante partum and postpartum periods. Among these, the most widely used screening tool developed for the postpartum period was the EPDS. It focuses on cognitive and affective symptoms, which avoids the inflation of prevalence compounded by the presence of physical symptoms (such as fatigue and physical discomfort) typical in normal pregnancy and the postpartum period (Regmi et al., 2002). This self reported scale consists of 10 questions that can be completed at the mother's convenience. Each of the 10 questions is scored from 0 to 3, making the overall range between 0 and 30. Although the original validation was made with a cut-off score of 12 for a positive screen, subsequent studies have identified increased sensitivity and specificity in high risk population using a cut off score of nine (Chandran et al., 2010, Rowel, 2004).

There were several studies (Tamaki et al., 1997; Neilson et al., 2000; Davis et al., 2003; Drewett et al., 2004; Adewuya et al., 2005) that used EPDS to measure postpartum depression among postpartum mothers of premature neonates. Some studies used cut-off level as ≥9 (Adewuya et al., 2005, Tamaki et al., 1999) and some used cut-off score as ≥ 12 (Drewell et al., 2004). Tamaki et al., (1999) in Japan found that 25% of them depressed among mothers of preterm neonates while control group it was only 17.2% percent. Therefore the level of depression varies according to the cut off point. Adewuya et al., (2005) in Nigeria found that from his study, 33% of mothers of preterm neonates in NNICU were depressed whereas 10.8% of mothers were depressed in the control group. There were 15.4% of mothers who were depressed in the UK when the premature neonate was admitted to NNICU while 9.4% mothers were depressed among the control group (Drewett et al., 2004). According to Davis et al., (2003) in Australia, it was revealed that 40.3% of mothers with preterm neonates were depressed.

The psychological reactions of parents when their babies are in the NNICU were assessed (Shaw et al., 2009) in USA. After the neonate was hospitalized in the NNICU it was a highly stressful event for parents. They examined the symptoms of acute stress disorder (ASD) immediately after their infant's birth. It shows that 9% of mothers were depressed due to the admission of the neonates to the NNICU (Shaw et al., 2009).

A cross sectional descriptive study was carried out to assess post traumatic stress disorder, depression and anxiety of mothers whose neonates were in the NNICU. The study was carried out ina tertiary care hospital in California by recruiting 135 mothers. To assess post traumatic stress disorder, depression and anxiety; Stress Reaction

Questionnaires (SASRQ), the Beck Depression Inventory (BDI) and Beck Anxiety Inventory (BAI) were used respectively. Their findings were as follows; 71.1% of mothers met screening criteria for acute stress disorders, 47.4% of mothers were positive for anxiety symptoms and 35.6% of mothers were depressed. Out of the sample screened 77.8% of mothers were positive for symptoms of depression (Shaw et al., 2014).

A case control study was carried out by Yurdakule and others (2009) in Turkey to find out maternal psychological problems associated with neonatal intensive care admissions. They recruited 100 mothers whose infants were admitted to NNICU as cases and 100 mothers who delivered a healthy full term baby. Their study instrument was the EPDS to measure maternal PPD with cut off value of ≥ 13. The number of mothers with depression was 29.5% whereas in control group it was 13.6%. It was statistically significant ($p < 0.005$). There were no significant difference between socio demographic factors namely maternal age ($p<0.09$), education level of mothers ($p<0.30$), working status of mothers ($P< 0.82$), parity of mothers ($P<0.54$), type of delivery ($P< 0.41$), gender of the baby ($p<0.82$), and preterm of the neonate ($P<0.82$) with maternal postpartum depression (Yurdakul et al., 2009).

Gold et al., (2013) carried out a cross sectional descriptive study to find out depression and it'sriskfactors, among mothers ofsick infants in a tertiary care hospital in Ghana. Mothers of infants hospitalized in the neonatal unit were recruited. Translated version of the Patient Health Questionnaire (PHQ-9) was used among 153 mothers to assess depression. Out of those 70% of mothers with hospitalized infants had PHQ-9 score indicating depressive symptoms (Gold et al., 2013).

A case control study was conducted in a tertiary care hospital in New Zealand to find out the parental response when their neonates were in NNICU. They recruited 447 parents with neonates admitted to NNICU and 189 parents of neonates without admitted to NNICU during a one year period in 2001. Both mothers and fathers were assessed for anxiety and depression. They used the EPDS questionnaire to assess depression and the Hospital Anxiety and Depression Scale (HADS) to assess anxiety. The total score of 12.5 was considered as the cut-off point for EPDS. According to the EPDS 22% of NNICU mothers were depressed whereas 12% of controls were depressed. In this study cut-off point for EPDS (12.5) may underestimate the cases of depression. There was no significant difference in socio demographic features such as age, marital status and education status between NNICU mothers and the control group (Charter et al., 2005).

Postpartum emotional distress among mothers of preterm infants was evaluated among 60 postnatal women. Beck Depression Inventory (BDI) and the GHQ 30 questionnaire were used for the assessment. Thirty three mothers of preterm neonates and 27 mothers of full term neonates were invited for the study. More of mothers with preterm neonates (27.3%) had GHQ 30 scores which categorized them as having significant emotional distress than mothers of full term normal infants (3.7%). Similarly more of mothers having preterm neonates (15.1%) were depressed than mothers of full term infants (3.7%) (Ukpong et al., 2003).

In France a cross sectional descriptive study was carried out to evaluate the postpartum depression predictive value at three days of postpartum period and to determine a cut-off score for major depression. They recruited 859 postpartum mothers at day three and 722 mothers within four to six weeks of postpartum period. Thirty percent of mothers had an EPDS score of nine. The sensitivity and specificity at day three postpartum were 0.88 and 0.50 respectively at a cut-off value of nine. They concluded that the EPDS scale can be used in the first week of postpartum period of mothers (Teissedre et al., 2004).

A prospective study for the presence of depression was carried out in South India by recruiting 270 mothersby using the EPDS scale. Mothers who had their infants admitted to the hospital (RR=4.5; 95% CI: 3.2-6.4) and infants who had fever (RR=1.7; 95% CI: 1.1-2.8) were significant factors associated with PPD assessed by EPDS scale (Patel et al., 2002). The mothers of babies with health problems had a higher risk (OR=1.7; CI: 1.3-2.2) of depression, even after a one year period of postpartum (Inandi et al., 2002).

In Sri Lanka, a community based prospective study was carried out to validate the translated Sinhala version of EPDS and to find out the prevalence and incidence of antenatal and postpartum depression. Translation of the EPDS was done with "translation and back translation technique" with the help of bilingual experts. Content validity of the EPDS was examined by a panel of three consultant psychiatrists based on ICD 10 diagnostic criteria as the "gold standards". The cut-off score of nine with a sensitivity of 90.7% and a specificity of 86.8% were found to detect depression in antenatal mothers. The same cut-off score was found to detect depression in post natal mothers at sensitivity of 89.9% and a specificity of 78.9%. By using the above cut-off point of EPDS, the prevalence of postpartum depression in the District of Puttalam was 32.1% and the incidence was 23.9%. From the multivariate analysis, nine factors were identified as significant correlates of prevalent cases of postpartum depression and six factors for incident cases. Three factors were common to both prevalent and incident cases: the recent death of a close friend, having a normal vaginal delivery, and sick neonates. Other significant factors for prevalent cases were an unplanned pregnancy (OR=1.6; 95% CI: 1.1-2.3), conflict with the husband (OR=1.3; 95% CI: 1.1-2.0), subject to physical abuse (OR=5.3; 95% CI: 1.6-16.1) and harsh words by husband (OR=2.1; 95% CI:1.3-3.1), death of a friend (OR= 2.2; 95% CI: 1.3-3.7), normal vaginal delivery (OR=1.7; 95% CI: 1.1-2.6), low birth weight (OR=1.6; 95% CI: 1.01-2.4) and illness of the neonate (OR=2.1; 95% CI: 1.2-3.4). The significant correlates for incident cases were death of a friend (OR=2.6; 95% CI: 1.4-4.9), argument with family members (OR=2.7; 95% CI: 1.1-6.8), normal vaginal delivery (OR=2.2; 95% CI: 1.3-3.8), prematurity (OR=2.2; 95% CI: 1.3-3.6), and condition of the baby (OR=5.8; 95% CI: 1.6-21.6). The EPDS scale was recommended as a reliable and valid instrument to screen the postpartum depression in the Sri Lankan context and cut-off scores were identified as nine with sensitivity of 90.7% and specificity of 86.7% for antenatal and post natal mothers (Rowel, 2004).

Rathnayake, (2011), carried out a descriptive cross sectional research to find out the prevalence of postpartum depression among postnatal mothers in the Gampaha District. For this study, 500 post natal mothers were recruited and PPD was assessed by using the validated EPDS. This study revealed that the prevalence of PPD was 31.6% (95% CI: 27.6-35.8). From this study it was found that the independent risk factors for PPD included loss of employment of head of house hold (OR=2.8; 95% CI: 1.2-6.9), debt beyond means of repayment (OR=2.6; 95% CI:1.5-4.3), not having support from the husband (OR=4.5; 95% CI:1.5-13.5), conflicts with the husband (OR=1.9; 95% CI:1.1-3.3), and handicapped child in the family (OR= 4.1; 95% CI: 1.3-12.4 p=0.02) (Rathnayake, 2011).

2.4. Maternal satisfaction with care provided to neonates and mothers

Patient satisfaction has become an accepted indicator of quality of care today. Parent satisfaction with the medical care of their children has been the subject of a number of studies (Lewis et al., 1986; Budreau and Chase 1994; Ygge, and Arnetz 2001). Several have focused on neonatal care (Conner, 1999, Saigal et al., 1999). There are evidence that increased knowledge and information about medical treatment result in more confident parents, who in turn make their children, feel more secure. Conversely, parental anxiety can have reverse effects resulting in fearful and anxious patients (Edwinson et al., 1998).

A sixty three item questionnaire was validated to measure parental satisfaction on paediatric care in Sweden. The instruments measure quality of care from the parent's perspective by means of eight domains. Information on illness; information on routines; accessibility; medical treatment; care processes; staff attitude; participation; and staff work environment, together, aim at achieving a total picture of the quality of care (Ygge, & Arnetz, 2001).

Measures of satisfaction of care allows one to obtain information about specific attributes of technical care, organizational structure and the outcomeand satisfaction with overall care. The satisfaction with care is both a measure of care and a reflection of the respondent's perceptions (Ware et al., 1983).

Out of available questionnaires, the Picker Institute Inpatient NICU was developed to measure parent satisfaction with the NICU experiences. Before the infant is admitted to the NICU it goes on to cover the admission process, caring of the infant after the birth, discharge and follow up care. The other questionnaire NICU_PSF (J.M.C.) was developed to measure parent perception of care, targets, areas that need improvement and evaluate the quality of care (Jeanetti et al., 1999). Both the above questionnaires include assurance, caring, communication, consistent information, education and environment, follow up care, pain management, support (emotional, physical and spiritual), participation in care and proximity (Jeanetti et al., 1999).

It was very difficult to measure the satisfaction of care because people tend to give a very positive response to questions that asked about their views on medical care. Browns and Lumley, (1998) in Australia revealed that in surveys, more than 80% state that they are satisfied when asked and for overall rating of care as well. The majority of women 71.4 % stated their care was very good and a further 21.1% described it as good. Those who said their experience of care was mixed was 6.3%, and 1.2 % described that the care was poor or very poor. Ninety three (93.3%) percent of mothers agreed with the statement that midwives and doctors were very reassuring and encouraging (Browns and Lumley, 1998).

A randomized control trial was conducted in England to observe maternal satisfaction regarding routine examination of newborns. They recruited 826 mothers into two groups. One group of neonates was examined by a Senior House Officer (SHO) and the other group was examined by a midwife. The mothers of neonates who were examined by the midwives were more satisfied (OR=0.49; CI: 0.39-0.75; p, 0.001) than the mothers of neonates examined by the SHO. Discussion of healthcare issues like feeding, sleeping and skin care by examiner (OR=0.49; CI: 0.34-0.70; p<0.001) were related to enhanced satisfaction. Parity of the mother (OR=1.11; CI: 0.80-1.55) and mode of delivery (OR=1.04; CI: 0.70=1.53) were not related to maternal satisfaction in the examination (Wolk et al., 2002).

A cross sectional descriptive study was carried out in a tertiary care hospital in Sri Lanka to find out client satisfaction on paediatric care in 1994. The author interviewed 222 bystanders of paediatric patients when discharged from the hospital. Majority 203 (91.4%) of participants were mothers of the children. Out of the participants 91.9% were satisfied with the treatment they received. Ninety eight percent of them were satisfied with the doctor's attitude. Only 26% were satisfied regarding all aspects of advice given (De Silva et al., 1996).

The mothers' satisfaction with the care they received during the hospital stay for delivery of their neonates was assessed in one of the districts of Sri Lanka. For this study, 446 pairs (mother/ baby) who delivered their babies in selected hospitals either in a district hospital or base hospital in the Puttalam District were recruited. The level of satisfaction was measured by using a five point Likert scale. The satisfaction regarding interpersonal care, technical aspect of care and physical facilities were assessed. It was found that satisfaction regarding cleanliness of ward was high (70.4%) and satisfaction regarding sanitary facilities including water, toilets etc., was poor (35%). The proportion of mothers satisfied with the physical environment was 28.7%.

More than 80% of mothers expressed their satisfaction with the availability of medical facilities and the competency of care providers. Forty seven percent (47.9%) expressed their satisfaction regarding the opportunity given to them to clarify their doubts about the care of the newborn. A high degree of satisfaction was reported with regard to the courtesy of the health care providers - medical officers (95.1%), nurses (92.6%) and midwives (83.9%) in that order. Multiparous mothers were twice (OR=2.14; 95% CI: 1.38-3.32) more likely to be satisfied with inter personal aspects of care than primi mothers. Socio demographic variables were not found to be associated with this interpersonal aspect of care. The type of hospital was strongly associated with the level of satisfaction. Mothers who delivered in district hospitals (OR=5.78; 95% CI: 2.74-12.28) and base hospitals were more satisfied than those at general hospitals. Those mothers with low birth weight babies were more satisfied with the interpersonal aspect than mothers with normal birth weight babies (OR=2.11; 95% CI: 1.19-3.77). Being multiparous (OR= 2.14; 95% CI: 1.38-3.32) and the type of hospital being a district or base, were found to be independent variables for satisfaction on the technical aspect of care. Socio demographic factors were not found to be associated with the satisfaction on technical aspect of care. Regarding the physical environment, mothers who were Moor (OR=1.84; 95% CI: 1.04-3.24) or of Tamil (OR=2.43 95% CI: 1.13-5.22) ethnicity were more satisfied than the Sinhalese. Those with family income of less than 7000 rupees (OR=1.65; 95% CI: 1.04-2.63) were more satisfied than those with higher income. Other socio demographic factors were not found to be associated with satisfaction with the physical environment. Satisfaction regarding breast feeding assistance given by the health care providers was 12.3% of mothers (Senarath, 2004).

It has been found that different levels of satisfaction may indicate the perspectives of the quality of care. The patients with lower expectations are generally more satisfied although there may be a confounding variable involved. Socio-demographic characteristics have been described as inconsistent predictors with satisfaction. Greater education attainment has been found to show lesser satisfaction (Stzia and Wood, 1998).

An assessment of the satisfaction of care received by cancer patients in the Colombo District was carried out in (2006) by recruiting 418 cancer patients (Jayasekera, 2006). The questionnaire used was the Quality of Life and Satisfaction with Care Questionnaire. He found a relatively low satisfaction in tertiary care hospitals in Sri Lanka, with the mean score of availability of information provisions (43.88) and interpersonal skills among nurses (56.43). The interpersonal skills of doctors scored (60.05), and information provision was (51.58.). There was an apparent lack of satisfaction (47.74) with regard to the personnel and kindness, helpfulness and information provisions by other hospital persons. Age, sex, marital status and education with the dimension on general satisfaction did not yield any significant ($p< 0.05$) results. The only noticeable feature was the marginal higher satisfaction in those with a lower level of education ($f=0.46$, $P=0.71$) (Jayasekera, 2006).

Goonawardena, (2001) carried out a research on the quality of intrapartum and postpartum care in primary health care institutions inKalutara District. This study revealed that the majority of mothers (98.4%) felt that provision of care by hospital staff was very satisfactory. Regarding the facilities available in the hospital and cleanliness of the wards 98.4% and 96.8% were satisfied respectively. Majority of mothers, (90%), had mentioned that care received during the delivery was satisfactory. With regard to the satisfaction in the monitoring of the postpartum period, 71.3% were satisfied. In the same study, 64.6% of mothers mentioned that midwives helped to breast feed the baby whereas a high proportion of mothers (98.9%) had given breast milk as the first feed (Goonawardena, 2001).

A cross sectional descriptive study was carried out in Serbia to find out about maternal satisfaction regarding perinatal care of government health services. A self administered questionnaire was administered among the 34431 mothers in 2009. The questionnaire measures the environmental factors, communications, interpersonal care, technical care and professional aspect of care. Fifty six percent of mothers were satisfied regarding the sanitary facilities and foods served by the hospital. Communication and interpersonal satisfaction was 74.4%. The kindness of nursing staff was 82%. Regarding the breast feeding advice, 65.4% of mothers were satisfied (Mategic et al., 2014).

Mahapatra et al., carried out a cross sectional descriptive study in India, by interviewing 1139 persons and 237 attendants of hospital workers. They studied accessibility, availability, communication, and interpersonal aspects, time spent by the doctor, financial aspect, technical quality, and certain other general aspects such as utility and hygiene. The questionnaire was a rated scale from 1 to 5 based on the satisfaction. Overall satisfaction found for communication was 72%, for technical quality 63%, and time spent by doctor 60% (Mahapatra et al., 2001).

A descriptive cross sectional study was carried out by using the Swedish Pyramid Questionnaire (SPQ) in Greece to find out parental satisfaction regarding paediatric care. They recruited 206 parents whose children were admitted for more than three days. This questionnaire consisted of eight domains namely accessibility, staff attitudes and the care process, information about the child's state of health, information about routine, medical treatment, parental participation, and staff work environment. They found out following results; politeness of doctors was 94.7%, and nursing personnel it was 89.3%, satisfaction of nursing care 87.4%, respect shown to them when necessary 90.3%, willingness to support by nurse 82.5%, and worked under stress 78.6%. Personal contact with the nurses was 52.4% and with doctors it was 43.7%. Work with heavy work load was 78.2%, information about child illness 79%, information of child's treatment and illness 80%, understanding of information received85.4%, and opportunity to ask questions 83% (Matziouv et al., 2011).

2.5. Infection control in the health care setting

Infection control has been identified as a model for the emerging patient safety movement. Infection control is a series of procedures and guidelines to prevent hospital-associated infections. There are infections that are acquired by patients during their stay in hospital. About 10- 25% of patient acquired infection were neither present nor incubating at the time the patient was admitted to the healthcare facility and may appear even after the patient is discharged. Hospital associated infections may be transmitted by health care worker to patient, from patient to patient and from patient to health care workers. An important route of transmission is from the hands of health care workers, droplets and through air and dust (Hospital Infection Control Manual, 2005).

2.5.1. Health care associated infections (HAI)

It is estimated that at any time, more than 1.4 million people worldwide are suffering from infections acquired in hospitals. Health care associated infections occur worldwide and affect both developed and developing countries. In developed countries, between 5% and 10% of patients acquire one or more infections and 15% - 40% of patients admitted to critical care are thought to be affected. In a setting where resources are poor, infection can exceed 20% but the WHO declares that available data are scanty and more research is urgently needed to assess the burden of disease in developing and transitional countries (WHO, Patient Safety Solutions 2007).

There are various guidelines to achieve maximum control of hospital acquired infections - the guidelines prepared by WHO and the Centre for Diseases Control and some have local guidelines for infection control in health care settings. These guidelines mainly addressed subjects such as hand hygiene, use of personal protective equipment, management of sharps, and management of blood spills and handling of blood and body fluids and specimens.

2.5.2. Standard precautions

Standard Precautions, Universal Precautions (UP) and Body Substance Isolation (BSI) combined into a set of simple standardized guidelines to prevent transmission of all types of pathogens in the hospital setting. Universal Precautions was first recommended in 1987 to prevent the transmission of blood borne pathogens to healthcare personnel. In 1996, the application of the concept was expanded and renamed "Standard Precautions." Standard Precautions are intended to prevent the transmission of common infectious agents to healthcare personnel, patients, and visitors in any healthcare setting. During the care for any patient, one should assume that an infectious agent could be present in the patient's blood or body fluids, including all secretions and excretions except tears and sweat. Therefore appropriate precautions, including use of PPE, must be taken (Krein et al., 2006).

Standard Precautions are a set of guidelines, which should be followed to reduce the transmission of HAI in hospitals. They should be used by all healthcare workers at all times when attendingallthe patients, regardless of their diagnosis or presumed infectious status. They are designed to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection in hospital. Standard precautions combine universal precautions (UP), which were developed to reduce the risk of blood borne infections. In the protocol of standard precautions, hand washing, personal protective equipment (gloves, masks, gown, apron, goggles, boots and caps) and patient care equipment, cleaning of equipment and environmental controls and management of blood and body fluid spills are included (Hospital Infection Control Manual, 2005).

A cross sectional descriptive study was carried out to asses self reported compliance with universal precautions and its determinants, and to describe the occupational exposures to blood and body fluids among health care workers in secondary care hospital in Sri Lanka. It revealed that medical officers reported lower compliance rate (46%) than nurses (62%), (Senarath & De Silva, 2002). The study population comprised 239 HCWs comprising of medical officers, nurses, midwives and medical laboratory technicians. According to the findings, nurses frequently reported a high level of compliance with the disposal of needles into the sharp bins (88.9%), hand washing immediately after contamination (73.8%) and taking precautions to prevent injuries when using sharp objects (68.3%). Medical officers reported lower compliance rates than nurses. Compliance for wearing PPE was lower among all categories of HCWs (Senarath & De Silva, 2002).

2.5.3. Hand hygiene practices

Transfer of pathogens from patient to other patients or to environmental surfaces occurs most commonly via the contaminated hands of health care workers. Hand hygiene is the single most important standard precaution for infection control. These bacteria are transient and can be greatly reduced in numbers by effective hand washing with soap and water. To prevent the transfer of microorganisms it is essential to wash hands before contact with any patient and after hands have become contaminated with micro organisms. The first description of the impact of hand washing on reducing sepsis in health care settings was made by Holmes in 1843 followed by Semmelweiss in 1846. It gradually became accepted as one of the most important measures for preventing transmission of pathogens in health care facilities. Systematic reviews on hand washing shows that hand antisepsis reduces the incidence of HAI (WHO, Guideline for Hand Hygiene, 2008).

An interventional study was carried out to control an outbreak of *Klebsiella pneumonia* in a neonatal intensive care unit in Australia. They had controlled the outbreak from 56/1000 patient's days to zero by preventing cross infection by strict attention to hand washing. The importance of hand washing was stressed during in-service and unit nursing education. Each nurse was given the responsibility to act on behalf of the babies under his or her care and to insist that all attending personnel wash hands before and after handling the babies. Following this no further episodes of sepsis occurred (Jennifer et al., 1999).

Hand hygiene practices were observed among the birth attendants of the labour room in the government hospitals of a district in Sri Lanka. After observing 48 deliveries it was revealed that 64.6% of birth attendants practiced hand washing before they assisted in deliveries in the labour rooms. Out of those birth attendants, application of soap was observed in 93.5%, washing finger tips 19.4%, washing thumbs 29.0% and washing inter digital spaces 22.6%. Hand washing practice after delivery was 95.8%. Almost all of them wiped their hands with unsterile towels (Senarath, 2004).

Ariyarathna et al., carried out a cross sectional descriptive study to observe knowledge, attitude and practices of hand hygiene in tertiary care hospitals in Sri Lanka. They recruited 289 of study participants from final year medical and nursing students. They found out knowledge regarding hand washing among medical students was 69% whereas among nursing students it was 83%. Among them, overall practices of hand washing were poor and it was responded as 67% (Ariyarathna et al., 2011).

Knowledge, attitude and practices of hand hygiene were assessed at intensive care units of Anuradapura teaching hospital with eighty one health care workers including doctors, nurses and paramedical staff. The study identified that 10 % of participants had overall good practice, 27.5% had moderate practice. A percentage of 62.5% had poor practice of hand hygiene. A sufficient amount, 60% had good knowledge and 47.5% of them had good attitude. Out of all participants 92.5% knew of the importance of hand hygiene (Kudawidanage, et al., 2011).

In Italy Marito et al., (2011) carried out an interventional study to find out compliance of hand hygiene among doctors and nurses in the intensive care unit of tertiary care hospitals. Total of 420 observations were made among 23 nurses and 18 doctors. Overall hand hygiene before the intervention was 14.3%. Among doctors it was 7.7% and among nurses it was 19.3%. After the intervention for improving hand washing, 456 observations were conducted immediately. The compliance among the doctors was 50.5% whereas among the nurses it was 40.7% percent. A year later the intervention, observations were made among the same group. It was found that nurses had improved up to 49.8% and in doctors it had decreased to 36.5%. Overall compliance of hand washing immediately after intervention was 44.9%, and after one year of the intervention it was 45.2% (Marito et al., 2011).

Doebbling and others (1992) reported baseline hand washing rates by intensive care unit medical staff was only 12.4% before and 10.6% after patient contact and it was only 4.3% percent. The rates increased to about 1 in 3 occasions when the doctors knew they were being observed. However with education, feedback, reinforcement and further observations the rates rose to 68.3% before, 64.8% after and 55.2% both before and after contact (Doebbling et al., 1992).

In Georgia, Gilbert et al., (2010) observed doctors and nurses working on surgical and medical intensive care units. They made 506 and 345 of hand hygiene observations in surgical ICU and medical ICU respectively. Overall compliance was 51.6% in surgical ICU and 47.2% in medical ICU. In surgical ICU nurses were 40% of compliance before contact with the patient and 75% after contact with the patient. Among doctors it was 16% before contact with the patient and 34% after contact with the patient. The gown and glove compliance among doctors was 40% whereas among nurses it was 68% in surgical ICU. In medical ICU it was 84% among nurses and 70% among doctors (Gilbert et al., 2010).

A cross sectional descriptive study was conducted to observe the diurnal variation of hand washing compliance among health care workers in tertiary care ICU in India. They observed hand hygiene opportunities in the day time from 8 a.m. to 2 p.m. and as the night time from 2 p.m. to 8 a.m. the following day. Total of 5639 hand hygiene opportunities were observed among doctors, nurses and paramedical staff. The overall compliance among doctors was 39.9%, nurses 60.7% and paramedical staff 38.6%. Among all, no hand washing was practiced 27% in the day time and 55% in the night shifts. In the night shifts, doctors' compliance was 46% whereas in nurses and paramedical staff it was 55% and 31% respectively (Sahay et al., (2010).

Another cross sectional study in Philippines found that average compliance of hand washing among doctors was 43%, nurses 31% and other healthcare workers 28% (Rambaue et al., 2004). In Taiwan it was found that after improving hand washing from 43% to 80%, the rate of nosocomial infection reduced from 15.1 per 1000 patient days to 10.6 per 1000 patient days, especially for respiratory tract infections as reduced 3.3% per 1000 patient days to 1.06% per 1000 patient days (Won et al., (2004) An observational study was carried out in a tertiary care hospital of NNICU in Argentina which observed 4347 hand hygiene opportunities. After increasing compliance of hand hygiene from 23% to 64 % the reduction of nosocomial infections were 45.5% per 1000 patient days to 27.9% per 1000 patient days (Rosenthal et al., 2008).

2.5.4. Personal protective equipment (PPE)

The primary role of PPE is to reduce the risk of transmission of microorganisms between patient, healthcare workers and environment. All clothes and equipment are intended to be worn or held by a person to protect them from risk to health and safety while at work. PPE provides a protective physical barrier that reduces contamination of clothes, skin and the mucous membranes of the eyes, nose and mouth. PPE includes gloves mask, gown, apron, goggles, boots and caps. Items of PPE should be selected by the health care worker according to the risk of exposure (Infection Control Guideline, 2005). Glovesshould be used when touching blood, body fluids, secretions, excretions or contaminated items and when touching mucous membranes and non-intact skin. A gownshould be used during procedures and patient care activities when contact of clothing and/or exposed skin with blood, body fluids, secretions, or excretions is anticipated. Aprons are sometimes used as PPE over scrubs, such as in haemodialysis centres when inserting the needles. Masks andgoggles or face shields should be used during patient care activities that are likely to generate splashes and sprays of blood, body fluids or secretions (CDC guideline on PPE, 2008).

The use of personal protection equipment was observed among the birth attendants when assisting the normal deliveries in the labour rooms. The PPE such as aprons and gloves were used by everyone when attending to delivery but none of them changed their foot wear at entry or wore a sterile gown or a mask (Senarath, 2004).

2.5.5. Infection control standards in newborn care practices

Cross sectional descriptive study was carried out to observe essential new born care practices in Puttalum district of Sri Lanka and observed 48 normal vaginal deliveries in four selected labour rooms in the district. The observed practices were drying of neonates immediately after birth, wrapping of the neonate after birth and skin to skin contact with the mother. There were 95.8% neonates dried thoroughly soon after birth, 77.1% were wrapped with a dry towel and 41.7 % neonates were given to the mother immediately after birth to keep skin to skin contact. In breast feeding practices, only one mother did not initiate breast feeding within one hour of delivery. Breast feeding was started on 62.5% (30) neonates within half an hour whereas 35.4% neonates were started on breast feeding within half an hour to one hour. Assistance in positioning of the neonates was given to 83% of mothers and assistance in correct attachment was given to 68.1% of mothers by the health care providers (Senarath, 2004).

2.5.5.1. Neonatal infections and breast feeding practices

The newborn starts to be colonized in the upper respiratory tract and gastrointestinal tract as well as on the skin directly from birth onwards. Human milk contains protein secreting antibodies, lactoferin, Lacto albumin, oligosaccharides, numerous hormones, cytokines, and growth factors. Some of these factors were able to kill certain bacteria and viruses. Protection against neonatal septicaemia, meningitis and necrotizing enterocolities has been demonstrated (Hanson, 2006).

A matched case control study was carried out in Lahore, Pakistan, in 1987 to find out the protection of breast fed babies from neonatal infection. The study recruited 42 cases of clinically diagnosed neonates with sepsis and 270 controls. They found out that even the partially breast fed neonates were protected from sepsis and it was significant (OR=18, 95% CI: 7.9-37.7) (Ashrof et al., 1991).

A prospective study was carried out in Jerusalem by recruiting 274 women to find out breast feeding practices and illnesses of their neonates. The women were interviewed on breast feeding practices and signs and symptoms of diseases and episodes of diseases. Infants exclusively breast fed had significantly lower incidence of illness than the bottle fed and partially breast fed neonates. Among the breast fed group, 52% had no episodes of illness whereas only 15% had no illness among the non breast fed group (Patti et al., 1984).

A prospective study was carried out in Greece to investigate the effect of breast feeding on the frequency and severity of infections in neonates. The study recruited 926 neonates and closely monitored all infective episodes. Infants with exclusive breast feeding had fewer infection episodes than the partially breast fed or non breast fed infants. Prolonged exclusive breast feeding was associated with fewer infection episodes (p=0.019) and less admissions to hospital due to such episodes (p=0.037) than partially breastfed or non breast fed infants (Ladomenon et al., 2010).

In Ghana, a prospective cohort study was carried out to find out the early infant feeding practices on infection specific neonatal mortality. The study recruited 10942 neonates. The risk of death as a result of infection was taken as an outcome variable. There was a 2.6-fold increased risk of infection-associated death among those who were delayed in initiation of breast feeding (Edmond et al., 2010).

A study was done in Netherland to find out the association of duration of exclusive breast feeding with infection in infancy. The study was a population based prospective study by recruiting 4164 of neonates who were exclusive breast fed, partially breast fed and never breast fed. The study found out that those who were exclusively breast fed until the age of four months had a lower risk of infection than the never breast fed infants. The findings were statistically significant for upper respiratory tract infection OR=0.65 (95% CI: 0.51-0.83) and OR= 0.50 (95% CI: 0.32-0.79) for lower respiratory tract infection (Duijts et al., 2010).

2.5.6. Handling of sharps and body fluids

The handling of body fluids and sharps when assisting in the normal vaginal deliveries were observed by Senarath in his study carried out in the District of Puttalam. It identified that spilled blood and body fluids were cleaned with disinfectant by 41.7% and sharps were discarded in to sharp bins at 56.3% of deliveries. Majority (97.9%) of health care workers avoided recapping of needles (Senarath, 2004).

2. METHODOLOGY

This study consisted of four components.

Component I

This component addressed the specific objective No.1, a case control study to determine the risk factors for neonatal sepsis in District of Gampaha.

Component II

This component addressed the specific objective No. 2 which was a descriptive cross sectional analytical study to assess the effects of neonatal sepsis on maternal postpartum depression.

Component III

This component achieved specific objective No. 3 which was a descriptive cross sectional study to describe the mother's satisfaction regarding the services provided through the government health services to neonates and mothers.

Component IV

This was a descriptive cross sectional study to describe the adherence of infection control standards by health care workers in selected procedures carried out in labour rooms, neonatal intensive care units, post natal wards and operation theatres.

3.1 Component I

A case control study was carried out to determine the risk factors for neonatal sepsis in the tertiary and secondary care hospitals of Gampaha District.

3.1.1. Study design

A case control study

3.1.2. Study setting

The study was conducted in the District of Gampaha, one of the three districts in the Western Province of Sri Lanka. The selected district ranges from highly urbanized to rural areas and consists of a population of diverse socioeconomic and ethnic composition. Gampaha district is one of the highly populated districts in Sri Lanka. Its population in 2008 was 2,291,341 and the total births for the same year were 36,510 (Planning Division, RDHS office, Gampaha 2009). The total land area is 1386.6 km^2 and population density is 1595 per km^2. It consists of 15 Medical Officer of Health (MOH) areas and 538 Public Health Midwives (PHMM) areas.

Government curative patient care services in the district are provided by eleven Primary Medical Care Units(PMCU), eleven Divisional Hospitals (DH), three Base Hospitals (BH), two District General Hospitals (DGH) and one Teaching Hospital (TH).The Doctor: Population ratio of the district is 1:1788 (Annual Health Bulletin, 2006).

The study setting included hospitals where there are neonatal intensive care units (NNICU/ mother/baby centres). Therefore the Colombo North Teaching Hospital (CNTH), the District General Hospital Gampaha, the District General Hospital Negombo and the Base Hospital Wathupitiwala were included in the study. In CNTH there were three labour rooms (LR), two (NNICUs), three post natal wards (PNWs) and two operation theatres (OTs). In the District General Hospital Gampaha there were two LRs, one NNICU, two PNWs, two OTs and one mother baby centre. In the District General Hospital Negombo there was one LR, one NNICU, two PNW, one OT and one mother baby centre. In Base Hospital Wathupitiwala there was one LR, one NNICU, one PNW and one OT. Septic neonates were managed by a Consultant Paediatrician in all four hospitals.

The controls were selected from all the MOH areas of the Gampaha District. Therefore the study setting for controls was also from the administrative district of Gampaha. The vital statistics of Gampaha District and details of maternal care provided in year 2009 is given in Annexure I.

3.1.3. Study period

This study was carried out from July 2010 to February 2011.

3.1.4. Study population

The study population was mothers and their neonates who were diagnosed of having neonatal sepsis as cases and the control population was mothers and their neonates who were not diagnosed of having neonatal sepsis.

3.1.4.1. Working definition for selection of cases

The purpose of this was to arrive at an accurate checklist to filter out neonates with sepsis from neonates without sepsis. The clinical features for the checklist for selection of neonatal sepsis cases were initially gathered following a review of literature (Rennie, 2008; Modi et al., 2009; Integrated Management of Childhood Illness (IMCI, WHO 2005); Integrated Management of Childhood Illnesses [IMCI] programme by Family Health Bureau, Ministry of Health, 2006; Weber, 2003; Sandra, et al., 2009). Following the review, the decision was made to select the signs from the WHO case definition for severe bacterial infection of neonates used in the Integrated Management of Childhood Illness (IMCI) for the present study. The same clinical features which were published in the IMCI from the WHO study were adopted adapted to Sri Lanka by the Family Health Bureau with expert opinion.

Following this a consensus was sought by the PI from three experts in paediatrics and two community physicians with regard to the checklist.

Finally, the presence of a one of the below clinical feature from the list in a neonate was considered as neonatal sepsis case.

- Temperature <35.5 C or Temperature ≥37.5
- Respiratory rate more than 60/minutes
- Severe chest in-drawing
- Presence of convulsion
- Grunting
- Bulging fontanels
- Pus draining from the ear
- Red umbilical stump extending to the surrounding skin
- Lethargy/ less than normal movement/unconsciousness
- Inability to attach well to the breast/inability to suckle or feed
- More than 10 skin pustules or bullae

Inclusion criteria

Neonates less than 28 days of completed age who were diagnosed of having neonatal sepsis based on the presence of:

1. One of the above clinical signs or
2. Positive blood culture or cerebro- spinal fluid (CSF) culture

Exclusion criteria for cases

1. Neonates with congenital abnormalities
2. Neonates whose mothers were not residing in the Gampaha District
3. Mothers who cannot read and write the Sinhala language

3.1.4.2 Selection of cases

A total of 25 Paediatric House Officers (PHOO) were employed in all four hospitals where the data collection was carried out. They were all grade medical officers and had completed six weeks of training on neonatology. All of them had been working in the neonatology units for more than three months when the data collection commenced. These PHOO are usually involved in examining all the babies born in particular hospitals studied. The Principal Investigator initially briefed the PHOO on the present study and the clinical signs in the checklist (Annexure II). Then they were asked to fill the check list if they find a neonate with any clinical sign mentioned in the check list. When the PI or data collectors visited the hospitals, the neonates with those clinical features were taken as neonatal sepsis cases. These signs were cross checked with the Bed Head Ticket (BHT)and history from the mother was also taken before recruiting a neonate as a case. The neonates who fulfilled the definition of case were recruited for the study during the study period. All the mothers who were eligible and willing to participate were recruited for the study from all neonatology units of Gampaha District from the commencement of the study until the sample size was fulfilled.

3.1.4.3. Definition of controls

A control is defined as neonates born during same period the cases were born and had not been diagnosed as having sepsis according to the above criteria. These controls were selected randomly from the same MOH area where relevant cases arose.

Exclusion criteria for controls

1. Neonates with congenital abnormalities
2. Neonates whose mothers were not residing in Gampaha District
3. Mothers who cannot read and write Sinhala language
4. Mothers who did not deliver their neonates in hospitals of Gampaha District

3.1.4.4. Selection of controls

When a case was recruited for the study on a particular day,the permanent residence of the mother was inquired into. Then the controls were selected from the same MOH area as the case. Controls were selected within two weeks of recruiting the cases. Those controls were the neonates born during the same period as the cases and not diagnosed of having neonatal sepsis according to the case definition. If there were more than one case recruited to the study from the same MOH area per day, the same numbers of controls were selected from that MOH area. The neonates selected as controls were followed up until they completed 28 days of life.

The procedure carried out to select the controls

The Principal Investigator addressed the monthly conferences held in all the MOH areas in the Gampaha District before initiation of the data collection. All the MOOH were informed about the objectives of the study and briefed on the procedure of the data collection. All PHMM were asked to keep the relevant information (name of the mother, date of birth of the neonate, address or the directions leading to the relevant mother's house) regarding the reported births during the study period. All possible contact numbers were collected from the PHMM in the district. The PI and three data collectors collected data for this study. A single data collector was allocated to collect data from the cases at the Colombo NorthTeaching Hospital Ragama and District General Hospital Negombo. Once a case was recruited from one of these hospitals, the data collector allocated to collect data from the controls for relevant MOH areas was informed. The data collector for controls of that particular MOH area in turn, randomly selected 10 PHHM areas from the same MOH area. Then all 10 PHMM were contacted over the phone. Following this, inquiries were made for a list of new born babies for that relevant time period. If there was a single neonate, that neonate was taken as a control for that particular case. If there were more than one neonate for the same period, control was selected randomly. Once the relevant control was identified either the PI or allocated data collector visited their residence. Then questionnaires were administered to them same as for cases. The Bed Head Ticket (BHT) of controls was traced from the hospital where they delivered the neonate. Record sheet I and II were filled according to the information in the BHT.

3.1.5. Sample size calculation

Sample size for the case control study with one control per case was calculated using the following formulae (Schlesselman, 1982).

1. The relative frequency of exposure among cases in the target population (P_1)
2. The relative frequency of exposure (proportion exposed) among controls in the target population(P_0)
3. A hypothesized relative risk associated with exposure that would have sufficient biologic or public health importance to warrant its detection (R)
4. The desired level of significance (α)
5. Probability of type II error (β)
6. The desired study power (1- β)

$$n = \frac{[Z_\alpha\sqrt{2pq}+Z_\beta\sqrt{(p_1q_1+ p_0q_0)}]^2}{(p_1-p_0)^2}$$

$$n = \frac{2 \times(Z\alpha+Z\beta)^2 \times p(1-P)}{(p_1-p_0)^2}$$

$$P_1 = \frac{p_0 R}{[1 + P_0(R - 1)]}$$

R = Odds Ratio = 1.9 Risk factor for low birth weight (Khalid et al., 2004)

$\alpha = 0.05$, $\beta = 0.021-\beta = 0.08$

$Z\alpha = 1.96$ (e)$Z\beta = 1.28$

P_0 = anticipated proportion of exposure among controls is 0.17. Exposure rate in controls,i.e.,

low birth weight percentage is (17%) in Sri Lanka (Annual Health Bulletin, 2007).

Specification of values for, α and β is a matter of judgment.

According to the above calculation a minimum of 225 cases and 225 controls were needed to detect the smallest Odds Ratio that would have sufficient public health importance.After adding 5% for the non-responders, it was decided to recruit 240 cases and 240 controls.

3.1.6. Sampling technique

The consecutive recruiting of cases and controls were done until the required sample size was achieved.

3.1.7. Study instruments:

Three types of study instruments were developed for the first component of the study.

1. Interviewer administered questionnaire –I [IAQ I (Annexure III)]
2. Record sheet – I (Annexure IV)
3. Record sheet – II (Annexure V)

3.1.7.1. Interviewer administered questionnaire (IAQ I)

The Interviewer administered questionnaire was grouped into three parts. The first group of questions was to gather information on personal identification and socio demographic information of the mothers and their neonates. Second group of questions were there to gather information on past obstetric history. Third group of questions comprised of details on present obstetric history of the mother. Similar research carried out locally, [Senarath 2004, Goonewardena 2001, Rowell 2004, Karunasekara, 1999) were reviewed before preparing the IAQ I(Annexure III)].

The questions for personal identification included name, age, address, MOH area and PHM area of the mother. For identification of the neonates, the questionnaire included the date, time, sex and place of birth of the neonates.Basic socio demographic data such as ethnicity, education, religion, occupation and monthly income of family, mother's and spouses marital status etc., were gathered.

Details about past obstetric history such as abortions, stillbirths, history of early or late neonatal deaths and its possible causes, age and sex of the living children, selected details on present pregnancy which could not be obtained from record sheet 1 and II, past and present medical history of this pregnancy such as pregnancy induced hypertension, gestational diabetes mellitus, heart disease complicated pregnancies, history of any psychiatric diseases, any other significant diseases and drug history were obtained. Family history of diabetes, hypertension, and psychiatric diseases were also inquired into.

The items to be included in the second and third part of the questionnaire were selected following a review of risk factors proven or suspected to be associated with neonatal sepsis. Similar studies (Mugalu et al., 2006, Oddie et al., 2002, Khalid et al., 2004, Jiang et al., 2004, Ladfors et al., 1998, Plaizek and Whitelaw 1983, Karunasekara et al., 1999) carried out to find out risk factors for neonatal sepsis were reviewed before preparing the third section of the questionnaire. The draft questionnaire was discussed with three paediatricians who were working in the NNICU. Review was done by two obstetricians and three consultant community physicians. Following the experts' opinion, changes were made for the final version of the questionnaire. The changes made were that the diagnosis for clinical chorioamnionitis should be made by a consultant, and the meconium stained liquor need to be documented by a doctor after vaginal or speculum examinations. The questionnaire was designed with the sequence of simple to complex questions to get the best line of flow. The questions were worded in simple language that could be understood by anyone irrespective of their level of education. These were prepared in a culturally sensitive and acceptable way to the participants. The questionnaire was prepared in English and translated into Sinhala and subsequently back to English by a third person to ensure accuracy of the translation. Guidelines were (Annexure XI) made for the interviewers to maintain the uniformity of the administration.

3.1.7.2. Record sheet –I to extract the relevant data from the mother's BHT

Record sheet I was developed by the PI to extract the relevant data from the mother's BHT, Ante Natal Records, and from previous diagnosis cards. This record sheet was developed in English. (Annexure IV) and the following details were included.

- Period of gestation (POG) when registering in ANC
- Number of routine field antenatal clinic visits, number of visits to the government hospital clinic, number of private sector attendance, any medication given, and any documented interventions such as amniocentesis, cervical circlarge, chorionic villous sampling or percutaneous blood sampling during ante natal period
- Date and time of admission to the hospital
- Medical disorders during the gestational period of this pregnancy
- Rupture of the membranes and hours of dribbling- spontaneous or artificial rupture of the membranes, confirmed dribbling by medical officer after vaginal

examination. Colour of liquor, odour of liquor, stain of liquor (the written documentation by the medical officer was considered)

- Number of vaginal examinations done after and before rupture of the membranes. Numbers of vaginal examinations were counted according to the documentation in the BHT.
- Period of Gestation (POG) when baby was delivered (counted according to mother's last menstrual period. Failing that, ultra sound scan date was considered as accurate).
- Number of hours stayed in the labour room. (Total hours counted according to the documentation in the BHT).
- Signs of infection/fever or duration of fever in mother (fever considered only when there was a documented temperature chart or documented notes)
- Results of the relevant investigations (blood cultures, white blood cell count /differential count, C-Reactive proteins, urine examinations) considered as correct according to the documented reports in the BHT.
- The mode of delivery - indications for lower segment Caesarean sections (LSCS) or instrumental deliveries such as vacuum and forceps deliveries (extracted according to the BHT).

3.1.7.3. Record sheet II to extract the relevant data from the neonate's BHT

Record sheet II was designed to extract data from the neonate's BHT or from the neonatal formats. It was developed in English. This record sheet was basically used to extract the following data: (Annexure V)

- Date and time of birth, sex of the neonate
- Birth weight, length, Occipitofrontal circumference (OFC),
- APGAR score, history of resuscitation and steps of resuscitation
- Signs and symptoms of neonate when admitted to the NNICU and complaints by the mother in the postnatal ward.
- Investigations done and its results (e.g., white blood cell count/differential count, C-Reactive proteins, blood culture, urine culture, urine full report, lumbar puncture reports)
- Type of organism when blood cultures were positive
- Type of antibiotics given

- Details of breast feeding, time of initiation of breast feeding, and whether formula milk was given
- Number of days stayed in the hospital
- Outcome of the neonate / diagnosis /live discharge or death

After formulation of English version of IAQ I, record sheet I and II, face and content validity was assessed by the same experts involved in reviewing the questionnaire. All questions were assessed for its validity based on relevance to the local context and appropriateness of wording used. In this part, the content validity was assessed by observing whether all the aspects to be studied under the objectives have been included in the questionnaire. The questions that all experts agreed were included for the final version of IAQ I, record sheet I and record sheet II.

3.1.8. Pre-testing the data collecting instruments

The questionnaire was pre-tested among 10 mothers having neonates with neonatal sepsis at Awissawella Base Hospital in Colombo District. The main purpose of pre-testing the questionnaire was to assess the time taken to complete it and the comprehensibility. The selected mothers were informed about the purpose, procedure and the objectives of this activity and requested to answer the questionnaire. If the mothers had answered only some of the questions or had misunderstood the questions, or had irrelevant answers, they were asked the regarding the clarity of the questions. Following the administration of the pre-test, the mothers were asked how they understood the questions in order to determine whether the wording used were appropriate and to find out whether the questions could have been asked in a different way. Modifications were made on the basis of their answers. Five mothers did not correctly understood, "any complaint during present pregnancy". It was changed to "any diseases or illness during this pregnancy". Thus according to the suggestions the final version of IAQ I, Record sheet I and II were finalized.

3.1.8.1. List of variables and operational definitions

The variables included in the IAQ I related to the personal identification and socio demographic features listed below with their operational definitions where applicable.

Personal identification for mother and neonates

Name: First name and surname

Age: Age in completed years as at last birthday

Address of the mother: Postal address of the house, (place of residence during the last one year period considered as residence)

Date of birth of neonate: Birth day of neonate

Sex of neonate: Male or female

Place of birth: The hospital where the neonate was delivered

Disc number: The disc number given to mothers and neonates at the hospital

Socio demographic features

Ethnicity: Sinhalese, Sri LankanTamil, Indian Tamil, Muslim or any other ethnicity

Religion: Buddhist, Christian or Catholic, Islam or any other religion

Education level: Highest grade completed or highest examination passed was assessed as:Never schooled, Grade 1-5, Grade 6-11, passed GCE O/L, Passed GCE A/L,and degree and above

Civil status: Whether legally married or customarily married was considered as married, unmarried, widowed, divorced or separated

Occupation: Whether they were in any paid employment and if so current designation of employment. Later it was categorized according to the "Annual employment return sent to the Commissioner of Labour" (Annexure XII).

Total family income:

Total income from occupation, businesses, cultivation, or from any other property in rupees

Number of pregnancies:

Total number of pregnancies counted according to the previous pregnancy records

Period of gestation at first visit to ANC:

Calculated according to the present pregnancy records

3.1.9. Methods of data collection

Data collection was carried out from August 2010 to December 2010. It was performed by the Principal Investigator and three pre intern doctors. Data collectors were trained for the purpose of the study by the PI (3.1.11). Data collectors visited the NNICUs, post natal wards and mother baby units of the selected hospitals daily. Cases were recruited according to selection criteria. If there were neonatal sepsis cases, the relevant mothers were informed about the purpose of the study. They were explained the necessity of voluntary participation and the requirement of consent for the participation to the study. Mothers found to be suitable were invited to participate. The fact that participating or not participating is not going to affect them or their neonate in any way was clearly stressed. Following this explanation the Sinhalese version of consent form was distributed. Written consent was obtained from each mother. Thereafter the IAQ I was administered to the mothers who were selected for that particular day for the study. Mothers were informed that they are free to ask for any clarification when necessary. Record sheet I was filled from the mother's BHT and record sheet II was filled from the neonates BHT on the same day. Minimal disturbances for the routine activities of the NNICU due to data collection procedures were ensured.

Interviews were conducted during a convenient time for mothers. Mothers were handed over their sick neonates around 8 a.m. Then the mothers were asked to extract breast milk for their neonates. The timing of interviews was made flexible for the participants according to their role with neonates. In order to minimize the refusal of participation, subjects were made aware of the study by explaining the details about the study. In addition to that, confidentiality was maintained throughout the data collection. Questionnaires were subjected to checks for completeness of data at different times by the PI. At the end of the data collection the mothers who participated in the study were thanked for their contribution.

Once a case had been recruited for the study the data collector of controls for the relevant MOH area was informed in order to be able to find the control for the particular case.

3.1.10. Assessment of reliability of the data

The reliability of data was assessed employing the test retest reliability in order to examine the level of agreement between the PI and three data collectors.

One week after starting data collection, the same questionnaire was re-administered by the PI among 12 mothers who participated in the study. Results of test re-test reliability of the selected categorical variables that were included in the questionnaire were assessed using kappa coefficient and results were given in Annexure XIII. The reliability between the PI and the data collectors were found to have good reliability with minimum kappa coefficient of 0.60 for any variable included.

3.1.11. Training of data collectors

Three pre intern doctors were recruited to assist the PI for data collection. They had received basic knowledge and field experiences on paediatrics, neonatology, obstetrics and gynaecology during their undergraduate training. Also they had acquired exposure in dealing with post partum mothers, neonates and infants while they were undergoing field community appointments.

The PI uniformly trained the data collectors for two days prior to the commencement of the study. Since this data collection involved several aspects it was crucial to train data collectors to the highest standard possible. This was done by a programme with two sessions.

Session I

Three pre intern doctors were trained by the PI to collect information listed in the IAQ 1, and II, Record sheet I, and Record sheet II. The training programme included lectures with practical sessions at the Faculty of Medicine, Ragama. The following were explained to the trainees by the PI:

- Brief overview of the objectives of the research project
- Outline of the research methodology and data collection procedure
- Adherence to guidelines and protocols when entering NNICUs

- Application of the selection criteria for cases according to the definition case definition.
- Obtaining informed consent and other ethical issues involved
- Administration of the IAQ I,IAQ II, IAQ III, and EPDS
- Ensuring confidentiality of data and privacy of the patients
- Minimizing non responses rate by explaining the research
- Obtaining reliable and accurate data

Neonatal Intensive Care Units are arranged in such a way to prevent infection from any source. Therefore the data collectors were thoroughly advised to adhere to the protocols and guidelines set by NNICUs. At the same time they were informed to respect all the staff of the hospitals and the mothers and not to disturb any routine work at those places. Interviewers were trained to summarize the data by themselves without any reporting errors. They were also trained to ask the questions in a natural manner and record the gathered data without interpreting them. The interviewers were thoroughly advised not to show their emotions by facial expressions or any other manner and not to divulge any information regarding neonates without getting permission from the relevant staff.

Session II

The PI and data collectors first visited the NNICU of the Colombo North Teaching Hospital. There they were instructed on how to enter the NNICU by the nursing sister in-charge of the NNICU. They were explained about how to find the neonates as a case and to trace the relevant mother. Demonstration of data collection was done by the PI. Next, the three pre interns were instructed to conduct two interviews with mothers. The PI closely supervised the procedures they carried out.

The following day they were taken to the Ragama MOH office to demonstrate the collection of data from controls. They were addressed by the Supervising Public Health Midwife and explained how to trace the post partum mothers with the help of the relevant PHMM. Then the PI and all data collectors visited two post partum mothers in the field. They were shown how to collect data from controls. The SPHM explained and demonstrated collection of data without disturbing mothers' routine work.

Thereafter, a single data collector was allocated for the CNTH and District General Hospital Negombo for the collection of data from cases of the said hospitals. The same person was allocated to the Ragama MOH area to collect data from the controls. The second data collector was allocated for data collection from controls from the MOH areas of Negombo, Ja-ela, Seeduwa, Katana, Wattala and Minuwangoda. The third data collector was allocated for data collection from the cases of Base Hospital Wathupitiwala and adjacent MOH areas namely Attanagalla, Meerigama, and Divulapitiya. The PI collected data from the District General Hospital Gampaha and controls from the adjacent MOH areas namely Dompe, Mahara, Biyagama, Kelaniya and Gampaha.

On the first day the PI accompanied each interviewer to the relevant hospitals and introduced them to the staff. Then the PI supervised the data collection by them and assessed the effectiveness of the initial training they received. Problems encountered in data collection was discussed and clarified. Thereafter, the data collectors met the PI and handed over the completed questionnaire once a week.

3.1.12. Data entry and analysis

Questions were coded after finalizing the questionnaire. Data entry was carried out by the PI through the software package Statistical Package for Social Science (SPSS) version 16. Statistical analysis was performed by the PI using the SPSS 16 version under the guidance of the supervisor. Following the data entry, the frequency distributions of variables were examined and incompatible entries were identified and corrected by referring to the original questionnaire. Basic characteristics of the study population were described using frequency distributions. Bivariate analysis was performed to see the strength of association between neonatal sepsis and associated factors. The strength of association expressed as odds ratios (OR) with the relevant 95% confidence interval and p values were calculated for each association.

Multivariate logistic regression analysis was performed to identify the risk factors for neonatal sepsis controlling for the effect of confounding factors. Variables that showed a probability value of <0.25 in the bivariate analysis of this study were included in the multiple logistic regression analysis. Then risk factors expressed as odds ratio (OR) with relevant 95% confidence interval and p values were calculated. The Hosmer and Lemeshow test was used to test the statistical significance of the overall regression model. Results were expressed as OR with the respective 95% CI to quantify the strength of association between neonatal sepsis and risk factors.

3.2. Component II

Component II determines the effect of neonatal sepsis on the post partum depression of the mothers whose babies were diagnosed of having neonatal sepsis and mothers of neonates without neonatal sepsis.

3.2.1. Study design

Descriptive cross sectional study

3.2.2. Study setting

All four hospitals which were already selected for Component I of the study namely Colombo North Teaching Hospital, the District General Hospital Gampaha, the District General hospital Negombo and the Base Hospital Wathupitiwala were selected for this component of the study.

All the controls from the relevant MOH areas were assessed in the community.

3.2.3. Study population and control population

The same mothers who participated in Component I were invited to this component of the study too. The mothers were selected as cases after three days (Tiessedre et al., 2004) of diagnosis of neonatal sepsis in their neonates. Comparison group was the same group of mothers who were selected as controls in Component I of the study.

3.2.4. Sample size calculation

The sample size was calculated using WINPEPI Version 2.3.8. (Abramson, 2004).

R = Odds Ratio associated with the exposure that would have sufficient biological or public health importance to warrant its detection or the relative risk corresponding to thesmallest increase or decrease in risk of interest. OR taken as 1.98 (post partum depression for sick neonates (Rowel, 2004).

α = Desired level of significance / probability of Type I error was taken as 0.05

β = Probability of Type II error was taken as 0.02

$1-\beta$ = the desired study power was taken as 0.08

p = anticipated proportion of exposure among controls 0.32, Rowel 2004)

$Z\alpha$ = corresponds to 1.96 (desired level of significance)

$Z\beta$ = corresponds to 1.28

To compare the post partum depression of two groups of mothers a minimum of 184 cases and 184 controls were needed. After adding 5% of nonresponse rate the sample size will be 193 post partum mothers.

As Component I of the study included 240 cases and 240 controls, the final sample size for this component was taken as 240 mothers with septic neonates and 240 mothers of non septic babies as it was decided to include all the cases and all the controls of Component I of this study for Component II as well.

3.2.5. Study instruments

Data collecting instruments were the Edinburgh Postnatal Depression Scale (EPDS) and the Interviewer Administered Questionnaire II (IAQ II)

Part A: Sinhala version of EPDS was used to screen for post partum depression. It is a self administered questionnaire (Annexure VII)

Part B: IAQ II

Interviewer administered questionnaire was designed to get the other associated factor and correlates which were already found in previous local studies (Rowel, 2004) and international studies (Patel et al., 2002) in relation to post partum mothers(Annexure VIII).

3.2.5.1. Edinburgh Postnatal Depression Scale (EPDS)

The Edinburgh Postnatal Depression Scale (EPDS) has been widely evaluated in many countries and cultures around the world. It has been validated in the western countries such as Netherlands (Pop et al., 1992), USA (Roy et al., 1993), and Sweden (Lundh and Gullang, 1993). It has shown remarkable stability and comparability (Victoria et al., 2009). It is a self administered questionnaire and validated in Sri Lankan context and recommended for use in Sri Lanka (Rowel, 2004). It has already been used to assess the prevalence of post partum depression in the Puttalam District (Rowel, 2004) and Gampaha District (Rathnayake, 2011). A cut off score of nine would detect depression with a sensitivity of 90.7% and specificity of 86.7% in antenatal mothers. A cut off score of nine would detect postpartum depression with sensitivity of 89.9% and a specificity of 78.9%.

3.2.5.2. Interviewer administered questionnaire II (IAQII)

Development and designing of IAQ II

The draft study questionnaire was designed to cover factors and correlates of post partum depression in mothers. The main risk factors already found from previous studies (Rowel, 2004) were emphasized when preparing this IAQ II. In literature review it was revealed that many correlates have been identified by other researchers (Cox et al., 1993; Patel, 2004). The correlates which have been already identified as significant correlates for prevalent cases of post partum depression were unplanned pregnancy OR=1.6 (1.1-2.3), Conflict with husband OR=1.5(1.1-2.0), physical abuse during pregnancy OR= 5.2 (1.6-16.1), use of harsh words by husband OR=2.1 (1.3-3.1), death of a friend OR=2.2 (1.3-3.7), normal vaginal delivery1.7 (1.1-2.6), low birth weight OR=1.6 (1.01-2.4, and illness of the baby OR=2.1 (1.2-3.4). A Significant correlates for incident cases of post partum depression was found from the local study. Those were, death of a friend OR= 2.6 (1.4-4.9), argument with family members OR=2.7 (1.1-6.8), normal vaginal delivery OR= 2.2 (1.3-3.8), condition of the baby OR=5.8 (1.6-21.1), prematurity OR=2.2 (1.3-3.6), and illness of the baby OR=2.1 (1.1-3.8). There were three significant associations included in the questionnaire although those were not significant correlates from multiple logistic regressions. The three factors were lack of family support OR=2.5 (1.7-3.6), lack of support from husband OR=1.8 (1.2-2.7), and economic hardships OR=1.9 (1.3-2.6).

Questions were included in the IAQ II to cover the risk factors both for incidence and prevalence cases. Some information was already obtained from IAQ I and record sheet I and II. Those were, unplanned pregnancy, low birth weight, mode of delivery of the neonates, illness of the newborn and prematurity of the newborn. Those factors were not repeated in the IAQ II. It consisted of information regarding lack of family support, conflict with the husband and relatives, any form of abuse from anyone, and whether they faced economic hardships or unexpected events or recent death of close relatives (Annexure VIII).

The questions were designed in a simple way and worded in simple language that could be understood by the participants.

3.2.6. Assessing the validity of the data collecting instrument:

The EPDS questionnaire was already validated and recommended to use in Sri Lankan context with the cutoff point of ≥9. With this cut off its sensitivity was 90.7% and specificity was 86.8% for antenatal mothers. With the same cut off point there was 89.9% sensitivity and 78.9% specificity for the postpartum mothers to detect post partum depression. Therefore using the same scale to measure the post partum depression of post partum mothers did not cause a significant validity issue.

Following the formulation of questions relevant to the correlates, their face and content validity was assessed by two community physicians who were involved in the researches of post partum depression. At the same time the operational definition that has been used to obtain the information was assessed. Relevant questions were assessed for its validity based on appropriateness and the relevance in local context. The following changes were made based on their recommendations. Instead of asking direct questions such as "Did you get abused by husband?" the question was worded as "Did you have experiences of being abused by following persons?"– Husband, Mother-in-law, Mother, Sister-in-law, Any other person (specify). Finally experts agreed on face and content validity of both EPDS and IAQ II.

3.2.7. Pre test of Questionnaire

Pre testing of the IAQ II was done among the 10 mothers whose babies were diagnosed as having neonatal sepsis in the Awissawella Base Hospital. At the same time the EPDS was also distributed among the mothers. Non-septic controls were selected from the relevant MOH areas. During the pre-test, the acceptability, comprehension and ease of administration of questionnaire were assessed. Special attention was given to the time taken to complete the questionnaire and difficulties in posing and responding to questions on sensitive issues. After pre testing no changes were made to the IAQ II. It was decided to carry extra pencils and file covers for mothers to answer the self administered EPDS questionnaire.

3.2.7.1. List of variables and their operational definitions

EPDS contains 10 questions. Each question had four answers to be marked by the participants. Scoring system for each of the responses given in Annexure VII. According to the total score, the participants were categorized as depressed or not depressed. Cut-off mark for the depression was aggregation of nine or more than nine. Less than nine was considered as not depressed.

Variables in IAQ II

Support for day-to-day work - was assessed by inquiring whether someone was helping in routine activities at home such as cooking, washing and cleaning.

Someone to look after other children - was assessed by asking about the people caring for the other kids at home when she was attending to the newborn baby.

Experiences of abuses - meant any kind of abuses including physical, mental, and sexual harassments, and verbal abuses either by husband or any other family members.

Suffering of major illnesses - anyone in the list faced major accidents, recent strokes, broken bones, underwent surgery, was newly diagnosed with a cancer or had handicapped children

Major economic hardships - loss of occupation of husband, herself, loss of big property, faced any major disasters during the last one year and difficulty in repayment of loans.

3.2.8. Training of data collectors

The same data collectors for Component I collected data for this component too. Training procedure was the same as 3.1.11. Same dates were used to train on this component of the study. The purpose of the study was carefully explained to the data collectors by the PI. A brief overview of the objective, the psychological aspect of post partum mothers and medical aspect of post partum mothers were explained. It was stressed that this component of the study should be carried out after three days of recruiting neonates as cases. Tiessedre et al., found that it will take at least 72 hours to change the psychological status of the mother after sickness of the neonates (Tiessedre et al., 2004).

3.2.9. Methods of data collection

The same data collectors for Component I, also collected data for Component II. As mentioned in section (3.1.11), pre intern medical officers carried out the data collection. Once the neonates were recruited as neonatal sepsis cases for component I of the study, the mothers of neonates were already known by the data collectors. As it would take some time for the mother to have a psychological effect due to sickness of the baby, this IAQ II was administered five days after the diagnosis of neonatal sepsis. It has been decided to distribute the self administered EPDS questionnaire after administration of IAQ II after taking informed verbal consent. Therefore the EPDS questionnaire was given after completion of IAQ II. Mothers were explained the objective of that questionnaire, the purpose of the information and the importance of answering by themselves. They were provided a file cover and a pencil to mark the answers. The answer papers were collected once completed.

3.2.10. Assessment of reliability of data

The reliability was assessed employing test re-test methods. Same questionnaire was re-administered among selected mothers who participated for Component I and II of the study two to three days after Component II of the study. Results of the test retest reliability of the categorical variables that included were assessed using kappa coefficient and results are in Annexure XIII.

3.2.11. Data entry and analysis

Data entry was carried out by the PI by using the SPSS software package version 16 (SPSS). Following data entry, the frequency distribution of variables was examined and incompatible entries were identified and corrected by referring to the original questionnaire. Statistical analysis was conducted employing the software package SPSS (version 16).

From the EPDS scale a cut off score of nine or more than nine was considered as post partum depression. All the mothers were categorized into two groups as depressed or non depressed. Bivariate cross tabulation was done to identify the association of post partum maternal depression with selected socio demographic factors, maternal factors and neonatal factors. Odds Ratios (OR), 95% confidence interval and the p value were calculated. The factors that showed associations >0.25 in the bivariate analysis were entered into the multivariate logistic regression model. Results were expressed in terms of exact OR and 95% CI.

3.3. Component III

To describe the mother's satisfaction with care provided by government health services to the neonate and mother during the hospital stay.

3.3.1. Study design

Descriptive cross sectional study

3.3.2. Study setting

All the four hospitals which were already selected for Component I of the study, namely, Colombo North Teaching Hospital, District General Hospital Gampaha, District General Hospital Negombo and the Base Hospital Wathupitiwala were selected for this component of the study.

3.3.3. Study population

Mothers with neonates diagnosed of having sepsis were invited for this component of the study. Median duration of hospital stay after diagnosis of neonatal sepsis was around 7 to 10 days (local data from the NNICU of CNTH). It was decided to collect data for this component, on the day of the discharge of the mother and neonate from the hospital.

3.3.4. Study period

Study period was August 2010 to 31st of January 2011

3.3.5. Sample size

All the mothers who participated as cases in Component I were invited for this component of the study to assess the satisfaction regarding care provided by the government health care services to their neonates and the mother herself. Therefore, total sample size for this component was 240 mothers.

3.3.6. Sampling technique

The mothers who participated in Component 1 as cases were recruited as participants.

3.3.7. Study instruments

Interviewer administered questionnaire (IAQ III) with sections A-C

Section A - A five point Likert scale questionnaire with 20 items referring to the satisfaction of mothers on neonatal care (Annexure IX)

Section B - A five point Likert scale questionnaire with 20 items regarding the care received by mothers after admission to the hospital for delivery of the neonates (Annexure X).

Section C - Two open ended questions to give three suggestions to improve satisfaction regarding care provided to neonates and mothers (IX_A and X_A respectively).

3.3.7.1 Development of the IAQ III

After an extensive literature search based on similar studies (Jeanetti et al., 1999, Goonewardena, 2001, Senarath, 2004, Drapher et al., 2001, Waldenstrom et al., 2006, Ygge and Arnetz, 2001) several important components were identified regarding satisfaction on neonatal care. Those components were assurance, caring, communication, information, education, and environment, follow up care, pain management, participation, proximity, and support. Considering the local set up and relevance to this study, it was decided to include the satisfaction questionnaire to cover the following domains.

1. Information given/obtained regarding the neonates and mothers' illness, investigations and treatment.
2. Time spent on the neonates, mothers and the skills of the staff
3. Communication skills with mothers and relatives
4. Courtesy of various category of staff including consultants, medical officers, nurses and minor staff
5. Sanitation, cleanliness and other facilities in the hospital
6. Respect given by the staff to the neonates and mothers and recommendation of the same hospital for another episode of illness of the same neonates or to another patient

An interviewer administered questionnaire was developed by the PI to obtain the information on the above areas. The draft questionnaire was prepared by reviewing the same kind of studies in local and international level (Drapher et al., 2001; Goonewardena, 2001; Ygge & Arnetz, 2001; Senarath, 2004; Waldenstrom et al., 2006,). The original questionnaire was prepared in English and translated into Sinhala. The draft questionnaire was discussed with two administrators who were interested in patient satisfaction surveys. The final correction was made then and there while discussing the questionnaire. Each statement on satisfaction had a 5 point Likert scale for the mothers to indicate a range from highly satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied and highly dissatisfied.. Marks were allocated from 5-1 according to the descending degree of satisfaction for each statement. Then the experts and PI agreed to assess the satisfaction component when the mother and neonates were discharged from the hospital.

3.3.7.2. Assessment of validity of the IAQ III

Assessment of content validity was carried out by the same administrators who participated to finalize the IAQ II. It was decided earlier to make five suggestions to improve satisfaction of care. But after reviewing for content validity it was reduced to three suggestions. Therefore, all the experts agreed upon appropriateness of content to measure the satisfaction of care, relevance in the local context, and appropriateness of the words used.

3.3.8. Pretesting the IAQ III

The questionnaire was pre tested at the Base Hospital Awissawella for feasibility and appropriateness. Following the pre-test the wording of two questions was changed to make it more user friendly.

3.3.9. Training of data collectors

The same data collectors for component I and II collected data for this component too. Training procedures were same as 3.1.11 and same dates and sessions were used to train on this component of the study too.

3.3.10. Methods of data collection

Data collectors already knew these mother/new-born pairs when they were recruited for Component I and II of the study. Once they discharged from the hospital the IAQ III was administered after taking informed verbal consent from the mothers. Mothers were given enough time to think and answer the questions. Explanations were given when necessary. Confidentiality was maintained throughout the process.

3.3.11. Assessment of reliability of data

The reliability was assessed employing test re-test method. As IAQ II was administered when the mother and neonates discharged from the hospital, it was decided to visit randomly selected 10 mothers who participated for the main study at their residence after one week of discharge. Then the PI re-administered the IAQ III among those selected mothers. Results of test re-test reliability of the selected variables were assessed using kappa and results given in annexure XIII. It shows minimum score of 0.60 and good agreement.

3.3.12. Data entry and analysis

Data entry and analysis were done by the PI by using a SPSS statistical software package version 16. The entered data were rechecked for accuracy.

The individual satisfaction was calculated as a proportion of each item of satisfaction. The answers of highly satisfied and satisfied were amalgamated as satisfied for this purpose. Then neither satisfied nor dissatisfied, dissatisfied and highly dissatisfied answers were amalgamated as dissatisfied and each proportion was calculated.

The cut off point for satisfaction and non satisfaction for each domain were taken at third quartile. The bivariate cross tabulation was done with selected socio-demographic factors, neonatal factors and maternal factors. Odds ratios and 95% CI were calculated to assess the significant association. The factors that showed association > 0.25 in the bivariate analysis were entered into the logistic regression model to perform multivariate analysis to see the significant factors for maternal satisfaction of care provided to neonates and mothers.

3.4. Component IV

This component was designed to observe the infection control methods adopted and adherence of health care workers for selected infection control standards in the labour rooms (LR), postnatal wards and NNICU and operation theatres.

3.4.1. Study design

Descriptive cross sectional study

3.4.2. Study setting

All four hospitals, which were already selected for Component 1 of the study namely the Colombo North Teaching Hospital, District General Hospital Gampaha, District General Hospital Negombo and the Base Hospital Wathupitiwala were selected for this component of the study.

3.4.3. Study population

In component IV of the study, two reference populations were identified.

Part A: This part was designed to collect data regarding the structure of the LR, post natal wards, NNICU and operation theatres regarding infection control standards. This included all labour rooms; all post natal wards; all NNICU; and all operation theatres (OT) conducting caesarean sections in all four hospitals which have been mentioned above. Therefore there were total of seven labour rooms; nine post natal wards; five NNICUs; and six operation theatres.

Part B:

This part was designed to gather information regarding adherence to infection control standards by health care workers in selected procedures. The observations were carried out in LRs, NNICUs, PNWs and OTs. Health care workers in the relevant units were doctors, nursing sisters, nursing officers and midwives.

3.4.4. Sampling

3.4.4.1. Part A:

This included all LRs, all NNICUs, all PNWs and all OTs which conduct caesarean sections in the four hospitals to observe the adopted infection control standards.

3.4.4.2. Part B

It was decided to observe selected procedures from each unit in randomly selected dates. One particular health care provider was observed only once.

Eight categories of procedures namely use of PPE, hand washing practices, provision of neonatal care, umbilical cord care, immediate post natal care, breast feeding practices, handling of sharps and management of blood spills were observed in the labour rooms and there were seven labour rooms in the studied hospitals. From each procedure ten observations were made in each labour room. Therefore 70 observations were made for each category of procedure.

The selected procedures which are important for the control of infections inside the NNICU and to prevent cross infections among sick neonates were observed from the five NNICUs of all four hospitals. The selected procedures were use of PPE, hand washing, drawing of blood for blood cultures, handling of sharps and handling of samples with blood and body fluids. Ten observations were made for each procedure from one NNICU. Therefore total of 50 observations were made for a selected procedure.

The selected procedures from the PNWs were hand washing and the BCG vaccination. Ten observations were made for each procedure. There were eight post natal wards in the four hospitals studied. Therefore atotal of 80 observations were made for each procedure.

The selected procedures from the OTs were hand scrubbing, use of theatre cloths, immediate neonatal care, umbilical cord care and hand washing. There were six operation theatres belonging to the studied four hospitals. As ten observations were made for each procedure, there were a total of 60 observations made for each procedure from all operation theatres.

3.4.5. Study instruments

3.4.5.1. Part A (for observation of LRs, NNICUs, PNWs and OTs)

There were 4 check lists to observe the structure and the availability of other minimum facilities for infection control in the LRs, NNICUs, PNWs and OTs.

Check list 1- to assess the physical structure of the LRs (Annexure XIV),

Check list 2—to assess the physical structure of the NNICU (Annexure XV),

Check list 3 – to assess the physical structure of the PNWs (Annexure XVI)

Check list 4 – to assess the physical structure of the OTs (Annexure XVII).

3.4.5.2. Part B Study instruments

There were 4 check lists to observe the infection control standards carried out in the above units by health care workers.

Check list 5- Procedures carried out in LR (Annexure XVIII)

Check list 6 – Procedures carried out in NNICU (Annexure XIX)

Check list 7- Procedures carried out in PNWs (Annexure XX)

Check list 8- Procedures carried out in OTS (Annexure XXI)

3.4.6. Development of the study instruments

3.4.6.1. Part A:

This check list consisted of relevant basic facilities, which should be necessarily there in the LR, NNICUs, PNWs and OTs according to the current guidelines. Draft check lists were prepared by the PI according to the LR management guidelines of the Ministry of Health; instructions given in the Building and other Guidelines for Neonatal Intensive Care Units; Special Care Baby Units and Mother Baby Care Units; Ministry of Health; Family Health Bureau; Perinatal Society of Sri Lanka;Central Engineering Consultancy Bureau (2007); Hospital infection control manual; WHO guidelines; and SLMA Guidelines for infection control.

3.4.6.2. Part B:

This check list was developed by the PI to assess the adherence of selected procedures carried out by different kinds of health care workers concerned with infection control of the LR, NNICU, PNW and OT. The check lists were prepared using the same guidelines as mentioned in 3.4.6.1. and the Guideline for Hand Hygiene by WHO, 2008.

Basically, check list B was included to assess the use of personal protective equipment (PPE) by health care workers; adherence of infection control standards when performing normal vaginal deliveries and Caesarean sections; hand hygiene and management of sharps; provision of newborn care including cord care and breast feeding management and practices; management of blood spills; examination of newborn babies; blood drawing/IV cannulations for neonates; and management of specimens such as blood and urine samples and procedures when performing BCG vaccinations.

Both check lists A and B were discussed and reviewed by a group of experts including Consultant Paediatricians, a Consultant Microbiologist, Consultant Community Physicians and Gynaecologists. The final versions of the check lists were prepared according to their comments. All the experts decided to observe the procedures and decide on their accuracy. Incomplete procedures were considered as incorrect.

3.4.7. Assessing the validity of the data collecting instruments

Parts A and B of the check list were assessed for face and content validity. The same experts who participated in finalizing of the check lists assessed the validity and its appropriateness as a measure of infection control designs and procedures. They also assessed the appropriateness of the items measured in both parts A and B. Finally they all agreed on the content validity of the items included in Part A and B check lists.

3.4.8. Pretesting the data collecting instruments

The check lists were pretested at the Base Hospital Awissawella for feasibility and appropriateness. Physical facilities were assessed by observation of all four sections namely LR, NNICU, PNW and OT. At times, the help of nursing officers in charge was needed to get information. The PI directly observed the procedures carried out according tocheck list B.

3.4.9. Method of data collection

3.4.9.1. Part A.

The data collection was conducted by the PI with other components of the study simultaneously. The structure and the availability of facilities listed in the check lists were assessed on randomly selected days. Altogether five to six random days per institution over a period of six months were observed. The institutions were visited without prior notice on the selected days. The LRs, NNICUs, PNWs and OTs were personally checked by the PI on each of the selected days. Information regarding the structure and availability of the items according to the check lists were observed. The check lists were filled in once the observation was completed. Assistance and clarifications were obtained from the nursing sister or in-charge nursing officer of the relevant sections.

3.4.9.2. Part B.

The PI visited the labour rooms of the institutions according to the previously selected random days. Out of mothers awaiting delivery, the PI selected a mother who is going to deliver next in line as indicated by cervical dilatation. Then the PI observed one of the health care personnel who were engaged with the delivery. Observation of the selected procedures (3.4.6.2) was done according to the check lists. The check list was filled by the PI shortly after the procedure was over. A different health care worker was observed during each delivery. Likewise all the selected procedures were observed according to the check lists in the relevant sections. In each shift only one or two procedures were observed from the same unit. Therefore 70 deliveries were observed from the seven labour rooms. Staff in the institution was unaware of the dates the observations were carried out. Ten such observations were made for each selected procedure from each institution. Procedures were selected to represent all relevant categories of staff. All relevant units were visited according to the roster prepared in advanced.

3.4.10. Data entry and analysis

Data entry and analysis was done by the PI through the SPSS version 16. Variables of check lists included only two responses (Yes or No) and descriptive analysis was carried out and results presented accordingly.

3.5. Measures to ensure quality of data

1. All possible measures were undertaken to ensure the quality of data both at design and implementation stages of the study. The clinical features recommended by WHO were included for the case definition of neonatal sepsis with the consensus of local experts in Component I of the study.

2. The main objective was to construct the questions in IAQI, IAQII and IAQIII in a simple manner and free of ambiguity, to encourage accurate and honest responses without embarrassing the respondents. Therefore clear and specific questions were included in the questionnaire. Questions were worded in an unpretentious manner that

conveyed the intent and no technical terms were used. Special attention was paid to avoid any confusion that may arise when answering. The questions were arranged in a sequence of simple to complex and general to specific. There were only two open ended questions to facilitate easy answering and minimal variations.

3. Items for the data collecting instrument were generated following a scientific process. In order to identify the variables included in the questionnaire for risk factors, an extensive scientific search of literature was done for case definition of neonatal sepsis, post partum depression, patients' satisfaction and infection control standards. Expert opinion was obtained to finalize the data collecting instruments. All the data collecting tools were reviewed by experts to assess the content, face and consensual validity. All instruments were pretested and corrections were made accordingly.

4. All the data collectors were trained before the data collection was initiated. The interviewers were trained for the purpose of the study and interviewer guide were given. The importance of assessing the eligibility criteria, taking informed consent, ensuring confidentiality and minimizing non-response were emphasized during the training. The steps in the data collection were explained. It was particularly emphasized that necessary precautions be taken in order to obtain reliable and accurate data. The data collectors were trained to ask questions in a neutral manner and note down the respondent's answers without interpreting them (see section 3.1.11).

5. Study participants were informed of the purpose of the study, nature of the study and the confidentiality of data. The fact that data would not be analyzed at individual level or published at individual level was clearly explained and it was also clearly stressed that their participating or not participating is not going to affect them in any way. A place with minimal disturbances was selected for administering the questionnaire. Other staff were not present at the place of data collection, in order to ensure confidentiality. The PI randomly checked the accuracy of the data collection by interviewing the subsample of mothers. Its reliability was assessed with test re-test method and reliability was found to be good.

6. All check lists for infection control standards were developed according to the acceptable guidelines, WHO standards, Ministry of Health regulations, and recommendations by expert committees and by reviewing the previous researches.

7. The PI was the sole observer for the available physical facilities for infection control and adherence of infection control standards by healthcare workers. This minimized the inter-observer bias. The PI was involved in the data collecting procedure as well as supervising the relevant activities of the data collectors. The questionnaires were checked for its completeness once in two days and clarified and the incomplete answers were refilled.

8. Selection bias is minimized in this study as the outcome occurs subsequent to the arising of the risk factor (in dribbling leading to neonatal sepsis, recall bias does not arise as the risk factors have been recorded in the BHT). Confounding bias has been controlled at the analysis stage. The Principal Investigator did the data entry followed by cross checking. Any inconsistent or missing responses were traced back to the original questionnaire and were corrected.

3.6. Ethical and administrative considerations

At the onset of the study ethical clearance was obtained from the Ethical Review Committee of the Faculty of Medicine, University of Kelaniya (Annexure XXX). Administrative clearance for the data collection was obtained from, Regional Director of Health Services of the Gampaha District, Directors of the relevant hospitals and from all the MOOH of the Gampaha District prior to data collection (Annexure XXXI). The PI visited all the MOH offices on the day of the monthly conferences and MOHs and all PHMs were addressed and explained about the study and data collecting procedure. Prior approval was obtained from the consultants in charge of the Gynaecological wards, Paediatric wards, Post Natal Wards and the NNICU.

As pre testing of the questionnaire was done at the Base Hospital Awissawella, written permission from the Medical Superintendent was obtained (Annexure XXIV).There were no invasive procedures carried out either on the baby or the mother. The PI and data collectors adhered to all the protocol for infection control in the NNICUs and OTs, PNWs and LRs when collecting data. All sensitive questions and problematic questions were removed after pre testing.

Informed written consent was obtained from all the participants. Only the mothers who had given consent and were willing to participate were enrolled for the study. The objectives of the study were explained and each mother was interviewed separately to assure the confidentiality of the participants. If any mother was found to be having any postpartum depression, the relevant authorities were informed and follow up was arranged.

The directors of the hospitals and in-charge nursing officers were informed regarding the observational part of the study. In assessing the physical environment, permission was obtained from the nursing officer in-charge or ward sister of the LR, NNICU, PNW and OTs. The staff members were also informed regarding the observational part of the study but the particular day of the observation was not informed.

The paper based records were kept with the PI with no access to outsiders and the computer entries were given a unique identification number so that the individuals cannot be traced.

Data entry and analysis was done by the PI. Electronic version of data base was password secured and the data sheet was kept under lock and key.

4. RESULTS

The study was carried out with the aim of determining the risk factors for neonatal sepsis, its association on maternal postpartum depression, satisfaction of mothers regarding neonatal and maternal care provided and adherence of infection control standards by health care workers in selected procedures of neonatal care in secondary and tertiary care hospitals of Gampaha District. As mentioned in the methodology, the study included the following components:

1. Case control study to determine the risk factors for neonatal sepsis.
2. Descriptive cross sectional study to determine the association of neonatal sepsis on maternal postpartum depression.
3. Descriptive cross sectional study to describe the maternal satisfaction regarding the neonatal and maternal care provided through government health care services.
4. Descriptive cross sectional study to describe the adherence of infection control standards by health care workers in selected procedures in hospital settings.

4.1. Component I

4.1.1 Study sample

Two hundred and forty mothers and neonates who (in hospital) were diagnosed as having neonatal sepsis and 240 mothers and neonates (from the community) who were not having neonatal sepsis were included for Component I of this study.

Out of the 240 mothers, one mother died while in hospital. Four mothers did not respond to the postpartum depression scale in Component II and patient satisfaction questionnaire in Component III. Hence the response rate for the case control study was 98.8% and for the Component II and III were 99.2% and 98.4% respectively.

The distribution of Medical Officer of Health (MOH) area of mothers for cases is given in Table 4.1. There were no mothers representing Biyagama and Kelaniya MOH areas.

Table 4.1 Distribution of cases of the study population according to their residing MOH areas

MOH area	Number of cases	Percentage (%)
Gampaha	32	13.3
Negombo	30	12.5
Attanagalla	24	10.0
Minuwangoda	23	9.6
Katana	22	8.8
Mahara	21	8.8
Seeduwa	20	8.3
Divulapitiya	16	6.7
Dompe	16	6.7
Ja-Ela	12	5.0
Meerigama	11	4.6
Wattala	09	3.8
Ragama	05	2.1
Kelaniya	0	0.00
Biyagama	0	0.00
Total	240	100.0

The same numbers of controls were recruited from the same MOH areas as the cases and thereby the total study population including both cases and controls were 480 mothers and neonates.

The majority of sepsis babies (n=32, 32.2%) represented the Gampaha MOH area and the next two areas with high representation were from Negombo MOH area (n= 30, 12.5%) and Attanagalla (n=24, 10.0) MOH area respectively (Table No.4.1). There were only 05 (2.1%) neonatal sepsis babies from Ragama MOH area.

The following table shows the distribution of the cases by their institutions of treatment for neonatal sepsis.

Table 4.2 Distribution of cases according to their institutions of treatment

Institutions of treatment	**Number of cases**	**Percentage (%)**
CNTH Ragama	77	32.0
DGH Gampaha	73	30.3
DGH Negombo	54	22.5
BH Watupitiwala	36	15.2
Total	**240**	**100.0**

DGH-District General Hospital,CNTH-Colombo North Teaching Hospital, NNICU- Neonatal Intensive Care Unit, BH-Base Hospital.

The majority of neonatal sepsis cases 72 (30.0%) were reported from the CNTH. The second highest number 73 (30.3%) of neonatal sepsis cases was reported from DGH Gampaha. The next highest numbers 54 (22.5%) and 36 (15.2%) cases of neonatal sepsis were reported from DGH Negombo and BH Watupitiwala respectively.

4.1.2. Socio demographic characteristics of the study participants

Basic socio demographic factors such as age groups, ethnicity, religion, educational achievements, occupation, marital status and basic family income of the study population were studied and results are given in Table 4.3.

Table 4.3 Distribution of socio demographic characteristics of the cases and controls (n=480)

Socio demographic factors	**Cases**	**Controls**	**Total**
Age category of mothers	**Number (%)**	**Number (%)**	**Number (%)**
< 20 years	14(5.8)	15(6.3)	29 (6.0)
20-25 years	68(28.3)	54(22.5)	122(25.4)
26-30 years	89(37.1)	102(42.5)	191(39.8)
31-35 years	45(18.8)	47(19.6)	92(19.2)
>35 years	24(10.0)	22(9.6)	46 (9.6)
Total	240(100.0)	240(100.0)	480(100.0)
Ethnicity			
Sinhalese	224(93.3)	222(92.9)	446(93.1)
Muslim	9(3.8)	10(4.2)	19(4.0)
Sri Lankan &IndianTamil	6(2.5)	7(2.9)	13(2.5)
Burgher	1(0.4)	0(0)	1(0.2)
Total	239(99.8)	240(100.0)	479*(99.8)
Religion			
Buddhist	194(81.3)	181(75.5)	375(78.3)
Catholic	32(14.6)	46(19.2)	78(16.0)
Islam	9(3.8)	10(4.2)	19(4.0)
Hindu	4(1.7)	3(1.3)	7(1.5)
Total	239(99.8)	240(100.0)	479*(99.8)
Education status of the mothers			
Up to Grade 5	8(3.3)	3(1.3)	11(1.9)
Grade 6 - Grade 10	35(14.6)	19(7.9)	54(11.3)
Passed O/L	103(42.9)	130(54.2)	233(48.7)
Passed A/L	75(31.3)	76(31.7)	151(31.5)
Degree and above	18(7.5)	12(5.0)	30(6.4)
Total	239(99.8)	240(100.0)	479*(99.8)
Education status of spouses			
Up to Grade 5	4(1.6)	4(1.6)	8(1.6)
Grade 6 - Grade 10	31(12.9)	23(11.3)	54(11.3)
Passed O/L	114(47.5)	139(57.9)	253(52.7)
Passed A/L	78(32.5)	67(27.9)	145(30.2)
Degree and above	12(5.0)	7(2.9)	19(4.0)
Total	239(99.8)	240(100.0)	479*(99.8)

Continuation of distribution of socio demographic characteristics of the study participants (n=480)

Socio demographic factors	Cases	Control	Total
Occupation of the mothers**	**Number**	**Number**	**Number (%)**
Professionals and administrators	17 (7.1)	11 (5.1)	299(6.0)
Clerical and supervisors	9 (3.8)	9 (3.7)	18(3.8)
Skilled	16 (6.7)	13 (5.4)	29(6.0)
Unskilled	12 (5.0)	8 (3.3)	20(4.2)
House wife	185(77.1)	198 (82.5)	384(80.0)
Total	239(99.8)	240(100.0)	480(99.8)
Occupation of the spouses**			
Professionals and administrators	24((10.0)	20(8.3)	44(9.2)
Clerical and supervisors	22(9.2)	11(4.6)	33(6.9)
Skilled	123(51.3)	108(45.0)	231(48.1)
Unskilled	70(29.2)	100(41.7)	170(35.4)
Unemployed	0(0)	1(0.4)	1(0.2)
Total	239(99.8)	240	479*(99.8)
Marital status of mothers			
Currently married	237(98.8)	236(98.2)	473(98.6)
Unmarried	1(0.4)	1(0.4)	2(0.4)
Separated	0(0)	3(1.3)	3(0.6)
Widowed	1(0.4)	0(0)	1(0.2)
Total	239(99.8)	240(100.0)	479*(99.8)
Total family income			
<5000	0 (0)	2(0.8)	2(0.4)
5001-10000	10(4.2)	19(7.9)	29(6.0)
10001-15000	39(16.3)	46(19.2)	85(17.7)
15001-20000	77(32.1)	70(29.2)	147(30.6)
>20000	113(47.1)	103(42.9)	216(45.0)
Total	239(99.7)	240(100.0)	479*(99.7)

*Maternal death, **Occupations were categorized according to the classification of occupational categories as used in the Annual Employment Return to the Commissioner of Labour

Age:

Twenty nine (6.0%) mothers were below 20 years. Out of those 14 (5.8%) mothers were among cases and 15 (6.3%) mothers were among controls. The highest proportion (39.8%, n=191) of study participants belonged to 26-30 years of age. There were 89 (37.1%) mothers among cases and 102 (42.5%) mothers among controls. Of the total, 46 (9.6%) mothers were more than 35 years of age. The mean age of the study participants were 28 years (SD=5 years).

Ethnicity

As shown in Table 4.3, the majority of mothers (n=446, 93.1%) were Sinhalese and the rest of the population, 4% (n=19) were Muslims and 2.5 % (n=13) were Tamils. There were 224 (93.3%) Sinhalese mothers among cases and 222 (92.9%) were among controls.

Religion:

The majority of the mothers (n=375; 78.3%) were Buddhist whereas Catholics (n=78, 16.0%), Hindus (n=7; 1.5%) and Islam (n=19; 4%) represented the minority (Table 4.3). There were 195 (81.3%) mothers among cases and 181 (75.5%) among controls.

The highest educational level achieved:

Mothers

The majority of mothers (n=233; 48.7%) had passed the GCE O/L. Thirty mothers (6.3 %) had an educational level of a degree or above and there were. 11 (1.9%) mothers with education level less than grade five (Table 4.3). The majority of mothers (n=103; 42.9%) among cases had passed O/L and there were 130(54.2%) mothers among controls with the same qualification.

Spouses

The majority of total participants had attained (n=253; 52.7%) more than ≥GCE O/L and 8 (1.6%) fathers had educational level less than grade five. There were 145 (30.2) fathers of neonates passed A/L whereas 19 (4.0%) were degree and above. There were 114(47.5%) fathers had passed O/L among cases and 139 (57.9%) fathers with the same qualification among controls.

Marital Status:

Among the study participants the number currently married was 473 (98.6%). Of the remaining five, there were two (0.4%) unmarried participants two were separated and one (0.2%) widowed.

There were 237(98.8%) married women among cases whereas 236 (98.2%) among controls.

Total family income:

The highest proportion (n=216, 45%) of study sample belonged to the monthly family income of more than 20,000 rupees. There were 113 (47.1) mothers among cases and 103 (42.9) mothers among controls. Only two (0.4%) families of the study population had an income of ≤5000 rupees (Table 4.4).

Occupation:

Mother's occupation

Out of total study population the highest proportion (n=384, 80%) of mothers were not on paid employment whereas 29 (6.0%) mothers were professionals and administrators and 185(77.1%) mothers were housewives among cases and 198 (82.5%) mothers were housewives among controls.

Spouse's occupation

The majority 479 (99.8%) of the spouses were employed among study population. A higher proportion (n=231; 48.1%) of spouses were skilled employees. There were 123 (51.3%) fathers as skilled workers among cases and 108 (45.0) among controls.

4.1.3. Description of the cases and controls

The following table demonstrates the institutions where the cases and controls delivered their neonates.

Table 4.4 Distribution of cases and controls (n=480) according to the institutions of delivery of their neonates

Institution of delivery	Cases		Controls	
	Number	**Percentage%**	Number	**Percentage%**
CNTH WD 23/25	42	17.5	33	13.8
CNTH WD 18	40	16.7	42	17.5
DGH GampahaWD 12	34	14.2	25	10.4
DGH Gampaha WD 10	33	13.8	36	15.0
BH Wathupitiwala	30	12.5	36	15.0
DGH Negombo WD 12	29	12.1	19	7.9
DGH Negombo WD10	17	7.1	17	7.1
CNTH WD 17	15	6.2	32	13.3
Total	240	100.0	240	100.0

The majority of neonates (N=42; 17.5%) who suffered from neonatal sepsis were delivered in ward 23/25 of the CNTH hospital and the majority 42 (17.5%) of controls were delivered in ward 18 of the same hospital. Out of all deliveries, 97 (40.4%) cases and 107 (44.6%) controls were delivered in the CNTH hospital (Table 4.4).

4.1.4. Description of the cases of neonatal sepsis

Distribution of clinical features among cases

There were 240 cases of neonatal sepsis from the above mentioned four hospitals of Gampaha District. The neonates were recruited as cases according to the WHO criteria mentioned in the IMCI (Integrated Management of Childhood Illness) strategy for severe blood stream infection. The following table depicts the distribution of clinical features among neonatal sepsis cases.

Table 4.5 Distribution of clinical features among cases

Clinical feature	Present Number (%)		Absent Number (%)		Total Number (%)	
Temperature >37.5	127	52.9	113	47.1	240	100.0
Respiratory rate >60	59	24.6	181	75.4	240	100.0
Grunting	56	23.3	184	76.7	240	100.0
Convulsions	40	16.7	200	83.3	240	100.0
Not sucking/Not attached to the breast/ Not able to feed	28	10.4	215	89.6	240	100.0
Reduced movement/lethargy /unconsciousness	16	6.7	224	93.3	240	100.0
More than 10 skin pustules	6	2.5	234	97.5	240	100.0
Temperature <35.5	3	1.2	237	98.8	240	100.0
Severe chest in drawing	3	1.2	237	98.8	240	100.0
Bulging fontanel	1	0.4	239	99.6	240	100.0
Red umbilicus, redness extending to abdominal skin or bleeding from stump	1	0.4	239	99.6	240	100.0
Pus from ear	0	0.0	240	100.0	240	100.0

The most common [n=127 (52.9%)] clinical feature was fever. Fifty nine neonates (24.6%) presented with respiratory rate more than sixty and 56 (23.3%) neonates presented with grunting. There were 40 (16.7%) neonates who presented with convulsions. Not a single neonate presented with pus from ear.

Distribution of number of clinical signs at the time of diagnosis among the cases of neonatal sepsis

Although a single clinical sign was taken for the diagnosis of neonatal sepsis, the numbers of presenting clinical features were analysed. The following table shows the distribution of number of clinical features among the diagnosed neonatal sepsis cases.

4.6. Distribution of number of clinical signs of the neonatal sepsis cases.

Number of clinical signs	Number	Percentage (%)
Single sign	115	47.9
Two signs	91	37.9
Three signs	18	7.6
Four signs	3	1.2
Zero clinical signs but blood cultures were positive	13	5.4
Total	240	100.0

There were 115 (47.9%) neonates who presented with a single clinical sign whereas 91 (37.9%) of neonates presented with two clinical signs. There were 18 (7.5%) neonates who presented with three clinical signs. Thirteen neonates (5.4%) did not show any clinical signs but they were recruited for the study as their blood cultures were positive.

Although these 240 neonates were recruited into the study as neonatal sepsis, the individual neonate was given a diagnosis at the time of discharge or expiring. The following table depicts the given diagnosis from the hospitals for these neonates with neonatal sepsis at the time of discharge or death.

Table 4.7. Distribution of cases according to the diagnosis given on discharge (n=240)

Diagnosis	Number	Percentage (%)
Treated as sepsis/neonatal sepsis	95	40.3
Meningitis/treated as meningitis	56	23.3
Septicaemia	29	13.1
Congenital pneumonia	17	7.1
Birth asphyxia/Hypoxic Ischemic Encephalopathy	14	5.9
Meconium aspiration syndrome	10	4.2
Pneumonia	7	2.9
Investigated for fever	6	2.4
Necrotising Entero Colitis	2	0.8
Abscess	2	0.8
Dandy walker syndrome	1	0.4
Herpes simplex infection	1	0.4
Total	**240**	**100.0**

The majority of neonates were treated as sepsis or had neonatal sepsis (n=95; 40.3%) whereas the next higher proportion had meningitis or was treated as meningitis (n=56; 23.3%). Septicaemia was reported in 29 (13.1%) babies. Meanwhile pneumonia or congenital pneumonia were reported from 24 (10%) of neonates (Table 4.7).

With regard to the age of onset of neonatal sepsis neonates were categorized into two groups. In the present study neonates were diagnosed as having sepsis before 72 hours of birth, i.e., Early Onset Sepsis (EOS) and after 72 hours of birth, i.e., Late Onset Sepsis (LOS). The distribution among cases is depicted in Table 4.8.

Table 4.8 Distribution of cases according to the age of onset of neonatal sepsis (n=240)

Age of onset of sepsis	Number	Percentage (%)
≤ 72 hours of age (EOS)	165	68.8
>72 hours of age (LOS)	75	31.2
Total	240	100.0

There were 165 (68.8%) neonates with EOS whereas 75 (31.2%) of cases were LOS (Table 4.8).

Table 4.9 Distribution of cases according to the length of hospital stay (n=240)

Number of days in the hospital	Number of cases	Percentage (%)
5-7 days	60	25.0
8 - 14 days	89	37.1
15 - 21 days	71	29.6
>21 days	20	8.3
Total	240	100.0

Mean=13.67 SD ±6.64

The majority (n=89; 37.1%) of neonates were treated for 8 to 14 days. The range of stay was 5-41 days and the mean length of hospital stay was 13.67 (SD= 6.64 days) days (Table 4.9). There were 20 (8.3%) neonates who were treated for more than 21 days.

Table 4.10. Distribution of status of blood cultures among cases (n=240)

Blood culture results	Number of cases	percentages
Positive	69	28.8
Negative	171	71.2
Total	**240**	**100.0**

There were 69 (28.8%) blood cultures reported as positive among the diagnosed neonatal sepsis cases (Table 4.10).

Table 4.11. Distribution of microorganisms in positive blood cultures (n=69) of neonatal sepsis cases

Micro organism	**Number**	**Percentage (%)**
Staphylococcus aureus	18	26.4
Coagulase-Negative Staphylococus	15	21.8
MRSA*	10	14.6
Coliform	8	11.6
Mixed growth	7	10.1
Areobic sporebarers	3	4.3
Viridans *streptococcus*	2	2.8
Pseudomonas spp	2	2.8
Acinetobacterspp	2	2.8
Enterobacterspp	1	1.4
Group B *Streptococcus*	1	1.4
Total	69	100.0

*MRSA= Methicillin Resistant *Stapylococcusaureaus*

Out of all positive blood cultures *Staphylococcus aureus*(n=18; 27%) and Cogulase-negative *Staphylococcus* (CoNS) (n=15; 22.5 %) were the commonest organisms isolated. *Methicillin Resistant Staphylococcus aureus* (MRSA) were found among 15% (n=10) of the neonates (Table 4.11). Group B *streptococcus* was isolated only from one (1.5%) neonate. The microorganisms that were isolated from blood cultures namely *Staphylococcus aureus,* Cogulase- negative *Staphylococcus* and MRSA are usually not found in normal vaginal flora and are suggestive of acquired infection from the external environment.

The following table shows the lumbar punctures performed among the neonatal sepsis babies.

Table 4.12. Distribution of lumbar punctures performed among diagnosed neonatal sepsis cases (n=240)

Lumbar puncture	Number of lumbar punctures	Percentage%
Not performed	150	62.5
LP positive	43	17.9
LP negative	47	19.6
Total	**240**	**100.0**

Out of all neonatal sepsis cases 150 (62.5%) neonates did not undergo the LP examination. Out of the total cases of neonatal sepsis, 43 (17.9%) lumbar punctures were positive.

Although the blood test for C Reactive Proteins (CRP) was not performed in the government health sector, there were neonates who were requested for test to be performed in the private sector. The results of CRP test given in the Table no 4.13.

Table 4.13. Distribution of C -Reactive Proteins levels (CRP) among cases (n=240) of neonatal sepsis

C-Reactive Proteins levels	Number	Percentage %
<6 mg	80	33.3
≥6 mg	85	35.4
Not performed	75	31.2
Total	**240**	**100.0**

Among the total neonatal sepsis cases CRP was not performed for 75 (31.2%) of neonates. Out of the total cases 85 neonates (35.4%) showed the value similar or more than six which is taken as suspicious of infection in Sri Lanka. But out of 165 performed CRP tests, only 85(51%) cases were positive.

The basic blood test carried out in government health sector to diagnose sepsis was White Blood Cell (WBC) counts. The distribution of WBC counts among cases of neonatal sepsis is given in table 4.14.

Table 4.14. Distribution of total WBC counts among cases of neonatal sepsis. (n=240)

Total WBC count	Number	Percentage (%)
<4000	8	3.3
4001-11000	87	36.2
11001-20000	103	42.9
>20001	42	17.5
Total	**240**	**100.0**

The majority (n=103; 42.9%) of neonates with neonatal sepsis had a high total WBC count (≥ 11001-20000) whereas 8 (3.3%) neonates reported neutropenia (<4000).

The outcome of neonatal sepsis cases were measured either as live discharge or death. The following table shows the outcome of neonatal sepsis cases.

Table 4.15. Distribution of outcome of neonatal sepsis babies

Outcome	Number (n)	Percentage (%)
Live discharge	232	96.7
Death	8	3.3
Total	**240**	**100.0**

There were 232 (96.7%) neonates who recovered from neonatal sepsis after treatment. Eight neonates (3.3%) died due to neonatal sepsis. Therefore case fatality rate for neonatal sepsis was 3.3%.

Table 4.16. Distribution of feeding with formula milk among cases and controls (n=480)

Formula milk	Cases n=240		Controls n=240	
	No	%	No	%
Given	20	8.3	6	2.5
Not Given	220	91.7	234	97.5
Total	**240**	**100.0**	**240**	**100.0**

Out of 240 cases 20 (8.3%) neonates were given formula milk while in the hospital whereas 2.5% (n=6) of the control group were given formula milk after they were discharged from the hospital (Table 4.16).

4.1.5. Bivariate analysis of risk factors for neonatal sepsis

4.1.5.1 Association of socio demographic characteristics of mothers of neonatal sepsis cases and controls

The comparison of occurrence of neonatal sepsis with some selected socio demographic factors of mothers among cases and controls are given below.

Table 4.17. Association between socio demographic factors of mothers among cases and controls

Socio demographic factor	Cases		Controls		Odds Ratio (95% CI)	P value
	No	%	No	%		
Age of the mother						
<20 years	14	5.8	15	6.2	0.92	0.861
≥20 years	226	94.2	225	93.8	0.44-1.97	
Age of the mother						
>35 years	24	10.0	22	9.1	1.10	0.751
≤35 years	216	90.0	218	90.9	0.59-2.02	
Ethnicity						
Non Sinhalese	16	6.7	17	7.1	0.93	0.857
Sinhalese	224	93.3	223	92.2	0.46-1.90	
Mothers' Religion						
Non Buddhist	45	18.8	59	24.6	1.41	0.121
Buddhist	194	81.2	181	75.4	0.91-2.19	
Family income (Rs)						
≤20000	126	52.9	137	57.1	0.84	0.359
>20001	113	47.1	103	42.9	0.59-1.21	
Education level						
<O/L	44	18.3	22	9.2	2.22	0.004
≥O/L	195	81.7	218	90.8	1.28-3.84	
Civil status						
Unmarried, separated or divorced	3	1.2	4	1.7	0.74	0.703
Currently married	236	98.8	236	98.3	0.165-3.37	
Mothers' occupation						
Housewives	185	77.5	198	82.5	0.73	0.171
On paid employment	54	22.5	42	17.5	0.46-1.15	

Mothers of neonates with an educational level of < O/L were 2.2 times (p= 0.004) more prone to get neonatal sepsis than mothers of neonates ≥ O/L and the association was statistically significant (p<0.005). All the other socio demographic characteristics of mothers were not significantly associated with neonatal sepsis of their neonates (Table 4.17.).

4.1.5.2. Association of selected maternal factors and neonatal sepsis

The association of selected maternal factors namely parity of the current pregnancy, history of abortions, still births and history of neonatal deaths and the being first born neonate or subsequent child were compared between cases and control of neonatal sepsis. The results depicts in Table 4.18.

Table 4.18. Association of selected maternal factors among cases and controls

Selected maternal factor	**Cases** No	%	**Controls** No	%	**Odds Ratio (95% CI)**	**P value**
Parity						
Parity one	122	50.8	101	42.1	0.80	0.055
Second or more than second	118	49.2	139	57.9	0.49-1.00	
History of abortions / still birth / neonatal death						
Yes	56	82.4	12	17.6	5.78	0.001
No	184	44.7	228	55.3	3.01-11.1	
Being first born or subsequent born						
Being a first child	139	57.2	104	42.8	1.80	0.001
Subsequent child	101	42.6	136	57.4	1.25-2.5	

Being a first born child carries a 1.8 time risk of having neonatal sepsis (OR=1.8; p=0.001) than subsequent birth. History of abortions, still births and history of early neonatal deaths were significantly higher (OR= 5.78; p=0.001) among cases than controls. Numbers of pregnancies (parity) was not an associated factor with neonatal sepsis (Table 4.18).

The weeks of gestation when registration in ANC, Number of field clinic visits, number of hospital clinic visits, number of private clinic visits and total number of ANC visits were compared between cases and controls of neonatal sepsis. The results are given in Table 4.19.

Table4.19. Association of ANC care received among mothers of neonatal sepsis cases and controls (n=480)

Antenatal clinic attendance	Cases		Controls		Odds Ratio (95% CI)	P value
	No	%	No	%		
Week of first registration in ANC						
>8week	60	25.8	33	13.8	2.17	0.001
≤8 week	173	74.2	207	86.2	1.36-3.48	
No: of visit to field clinic at MOH						
≤4 visits	37	15.4	4	1.7	10:75	0.001
>4visits	203	84.6	236	98.3	3.76-30.68	
No: of visits to Govt. hospital clinic						
<4 visits	236	98.3	215	89.6	6.86	0.001
≤4 visits	4	1.7	25	10.4	2.35-20.03	
No: of visits to a private sector VOG						
≤4 visits	118	49.2	140	58.3	0.60	0.044
>4 visits	122	50.8	100	41.7	0.48-0.99	
Total No: of antenatal visits						
≤4 visits	17	7.1	2	0.8	9.07	0.001
>4 visits	223	92.9	238	99.2	2.07-39.71	

MOH=Medical Officer of Health, VOG = Visiting Obstetrician and Gynaecologist

There was a statistically significant difference between cases and controls according to the gestational age at registration at ANC. The risk of getting neonatal sepsis was 2.17 times higher in those who registered in the antenatal clinic after eight weeks of pregnancy than those who registered before eight weeks of pregnancy.

There was a significant difference between antenatal clinic attendances either to field or government hospitals. Those who attended more than four visits in the field clinics were less likely to get neonatal sepsis (OR =10.5; 95% CI: 3.76-30.68) than those who had four or less ANC visits. But there was no difference regarding occurrence of neonatal sepsis and the number of attendance to the private sector clinics. However there was a significant difference (OR= 9.07; 95% CI: 2.07-39.71) between any type of clinic attendance which is four or less clinic visits to more than four clinic visits with regard to occurrence of neonatal sepsis.

The presence of antenatal diseases such as epilepsy, bronchial asthma, Thalasemia, hypo/hyper thyroidism, GDM, PIH and presence of maternal fever were studied among cases and controls of neonatal sepsis and results are given below.

Table 4.20. Association of maternal antenatal diseases among cases and controls

Maternal antenatal diseases	Cases No	Cases %	Controls No	Controls %	Odds Ratio (95% CI)	P value
Presence of ante natal diseases						
Yes	49	20.5	41	17.1	1.25	0.338
No	190	79.5	100	82.9	0.79-1.98	
Presence of GDM+PIH						
Yes	40	16.7	34	14.2	2.22	0.437
No	199	83.3	206	85.8	0.74-2.00	
Maternal fever						
Yes	39	16.2	12	5.0	3.68	0.001
No	201	83.8	228	95.0	1.89-7.24	

GDM- Gestational Diabetes Mellitus, PIH- Pregnancy Induced Hypertension

There was no significant difference (p=0.338) between the presence of antenatal diseases (epilepsy, bronchial asthma, Thalasaemia minor, hypo/hyper thyroidism, GDM and PIH) or absence with neonatal sepsis cases and controls. When calculated for PIH and GDM separately there were no significant (OR=2.22 p=0.437) difference between cases and controls of neonatal sepsis. Mothers having fever during last one week prior to delivery was a significant factor (OR=3.68; 95% CI: 1.89-7.24; p=0.001) for neonatal sepsis.

Comparisons were done with regards to mother's admission time to the hospital and number of hours of dribbling among cases and controls (Table 4.21).

Table 4.21 Association of selected maternal factors before delivery of neonates among cases and controls (n=480)

Maternal factors	Cases		Controls		Odds Ratio (95% CI)	P value
	No	%	No	%		
Mothers' admission time						
On call hours (4 pm up to 8 am of following day)	120	50.0	79	39.7	2.04	0.001
Normal working hours (8 am to 4 pm)	120	50.0	161	67.1	1.41-2.95	
Hours of dribbling						
>18 hours	33	13.8	1	1.2	12.59	0.001
≤18 hours	207	86.2	237	98.8	3.81-41.67	

The babies of mothers who were admitted during the on call hours (from 4 pm to 8 am the following day) were more likely (OR 2.04; 95% CI:1.41-2.95) to get neonates with sepsis than those who got admitted during the normal working hours (from 8 am to 4 pm).There was a significantly higher (OR=12.59; 95% CI: 3.81-41.67;p= 0.001) association of neonatal sepsis among cases than controls when there was history of more than eighteen hours of dribbling.

Several variables related to interventions before delivery of neonates were examined for a difference between cases and controls. The associations are given in Table 4.22.

Table 4.22. Association of some selected interventions before delivery of neonates among cases and controls

Variables related to interventions	Cases No	Cases %	Controls No	Controls %	Odds Ratio (95% CI)	P value
Number of VE before rupture of the membranes						
>3	84	35.0	45	18.8	2.33	0.001
⩽3	156	65.0	195	81.2	1.54-3.55	
Number of VE after rupture of the membranes						
>3 times	63	26.2	31	12.9	2.40	0.001
⩽3 times	177	73.8	209	87.1	1.49-3.87	
Rupture of the membranes						
Yes (ARM/spontaneous)	188	78.3	182	75.8	1.15	0.515
Non rupture of the membranes	52	21.7	58	24.2	0.75-1.76	

VE= Vaginal Examinations, ARM= Artificial Rupture of the Membranes

More than three vaginal examinations before the rupture of the membranes (OR=2.33; 95% CI: 1.54-3.55; p=0.001) or after rupture of the membranes (OR=2.40; 95% CI: 1.49-3.87;p=0.001) was highly significant causing neonatal sepsis for cases than controls.

The cases and controls were categorized into two groups depending on whether the rupture of the membranes was spontaneous or artificial. Both spontaneous rupture and artificial rupture of the membrane groups were compared with the non rupture of the membrane group. There is no significant difference (OR 1.15;95% CI: 0.75-1.76;p= 0.510) between cases and controls according to the rupture of the membranes (Table 4.22).

Selected variables namely gestational period of amenorrhea **(POA)**, colour of liquor when delivery of neonate, mode of delivery, number of hours in the labour room before and after delivery of neonates were compared between cases and controls and results are given below.

Table 4.23 Association of gestational period of amenorrhea (POA), number of hours in the labour rooms, colour of amniotic fluid and mode of delivery of the neonates among cases and controls

Variables	Cases		Controls		Odds Ratio (95% CI)	P value
	No	%	No	%		
POA						
<36	45	18.9	2	0.4	55.75	0.001
⩾36	193	81.1	232	99.6	7.61-407.93	
Colour of liquor*						
Meconium stained	37	15.6	5	2.1	8.70	0.001
Not stained	200	84.4	233	97.9	3.35-22.54	
Mode of delivery						
LSCS/Forceps/Vacuum deliveries	115	47.9	76	31.7	1.98	0.001
Normal Vaginal deliveries	125	52.1	164	68.3	1.36-2.88	
No. of hours in the LR before delivery						
>10 hrs	34	14.2	14	5.8	2.66	0.002
⩽10 hrs	206	85.8	226	94.2	1.39-5.10	
No of hours in the LR after delivery						
>5 hrs	46	19.2	28	11.7	1.795	0.023
⩽5hrs	194	80.8	212	88.3	1.08-2.98	

*3 cases of home deliveries do not know the colour of liquor, POA= Period of Amenorrhoea, LR=Labour room, LSCS= Lower Segment Caesarean Section

The group of neonates of less than 36 weeks (OR=55.75; 95% CI: 7.61-407.93) of POA have a higher possibility of getting neonatal sepsis than their comparable control groups. It is demonstrated that more than 10 hours in the LR before delivery of neonates has a 2.66 (95% CI: 1.39-5.10) times higher possibility of getting neonatal sepsis than less than 10 hours in the LR. There was a significantly higher occurrence of neonatal sepsis (OR 1.79; 95% CI: 1.08-2.98) among the neonates who were in the LR for more than 5 hours after delivery than the neonates who were less than five hours in the LR. Mean hours of stay in the LR for the cases were 3.9 (SD=4.4 hours) hours and for the controls were 3.4 (SD= 3.2 hours) hours. There was a significantly higher occurrence (OR 8.70; 95% CI: 1.36-2.88) of neonatal sepsis with meconium stained liquor when delivering the baby than clear amniotic fluid. Caesarean sections, vacuum deliveries, and forceps deliveries were 1.96 times more likely (OR 1.98; p=0.001) to get neonatal sepsis than normal vaginal deliveries.

Selected variables regarding the delivery namely number of days in the hospital, place of delivery, whether assisted or non assisted and time of delivery were compared between cases and controls to explore the differences and results depicts in Table 4.24.

Table 4.24.Associations of number of days in the hospital before delivery, place of the delivery, assisted or non assisted delivery and time of delivery of neonates among cases and controls

Variable	Cases		Controls		Odds Ratio (95% CI)	P value
	No	%	No	%		
No. of days in the hospital before delivery						
>10 days	14	5.8	10	4.2	1.42	0.402
⩽10 days	226	94.2	230	95.8	0.82-3.27	
Place of birth of the neonates						
Secondary care	147	61.2	131	54.6	1.31	0.139
Tertiary care	93	38.8	109	45.4	0.92-1.89	
Assisted or non assisted delivery						
Non assisted delivery (Home delivery)	3	1.7	0	0.0	2.01	0.045
Assisted delivery by skilled person	237	98.3	240	100.0	1.84-2.08	
Time of delivery of neonates						
On call hours (between 4 pm to 8 am of following day)	121	50.4	93	38.8	1.60	0.010
Normal working hours (8 AM -4PM	119	49.6	147	61.2	1.11-2.30	

There was no significant difference (OR= 1.42; 95% CI: 0.82-3.27) for occurrence of neonatal sepsis between cases and controls regarding the length of stay in the hospital before delivery. The comparison of deliveries in the secondary and tertiary care hospitals in Gampaha District did not show any significant difference between two types of hospitals in the occurrence of neonatal sepsis (OR=1.31; 95% CI:0.92-1.89). Non assisted births were 2.01 (95% CI: 1.84-2.08; p=0.045) times more likely to get neonatal sepsis than assisted deliveries. But it is not statistically significant. Time of delivery i.e. during on call hours (4 pm to 8 am of following day) were more likely (OR 1.60; 95% CI: 1.11-2.30; p=0.010) to get neonatal sepsis than which took place during normal working hours (8 am to 4 pm).

4.1.5.3. Association of neonatal factors and neonatal sepsis

Table 4.25. Association of neonatal factors among cases and controls (n=480)

Neonatal factors	Cases N=240		Controls = 240		Odds Ratio (95% CI)	P value
	No	%	No	%		
Birth weight of neonates						
<2500	74	30.8	23	9.6	4.21	0.001
⩾2500	166	69.2	217	90.4	2.52-7.00	
Length of the neonates						
<49cm	52	22.6	26	10.8	2.40	0.001
⩾50cm	178	77.4	214	89.2	1.44-4.00	
Sex of the neonates						
Male	137	42.9	113	47.1	1.48	0.028
Female	103	57.1	127	52.9	1.04-2.14	
APGAR score (at 5 min)						
≤ 7	54	22.8	0	0.4	70.52	0.001
10	183	77.2	239	99.6	9.66-514.57	
Resuscitated at birth						
Resuscitated	43	17.9	0	0.0	2.22	0.001
Not resuscitated	197	82.1	240	100.0	2.00-2.46	

There was statistically significant difference between low birth weight (<2500g) and normal birth weight babies with regard to neonatal sepsis. Low birth weight babies were 4.20 (95% CI: 2.52-7.00) times more likely to get neonatal sepsis than normal birth weight babies. If the length of the babies were less than 50 cm there was a 2.40 (95% CI: 1.44-4.00) times higher chance of getting sepsis than babies more than 50 cm length. Being a male baby carries a 1.47 (95% CI: 1.04-2.14) times possibility of getting sepsis than being a female baby. APGAR score of less than seven at five minutes of delivery was 70.52 (OR=70.52: 95% CI; 9.66-514.57) times higher to get neonatal sepsis among cases than controls. Neonates who were resuscitated at birth were 2.46 (95% CI: 2.00-2.46) times likely to develop neonatal sepsis than non resuscitated babies (Table 4.26).

Table4.26. Summary of the variables those were significant in bivariate analysis

	Variable	OR	95% CI	P value
	Socio-demographic factors			
1	Education level of the mother	2.22	1.28-3.84	0.004
	Maternal factors			
2	History of abortions, stillbirth and neonatal deaths	5.78	3.01-11.10	0.001
3	Time of registration of pregnancy > 8 weeks of gestation	2.17	1.36-3.48	0.001
4	Number of field clinic visits	10.75	3.76-30.68	0.001
5	Total number of ANC clinic attendance	9.07	2.07-39.71	0.001
6	History of maternal fever during last one week	3.68	1.89-7.24	0.001
7	Mothers' admission time to the hospital during on-call hours	2.04	1.41-2.95	0.001
8.	Number of hours of dribbling > 18 hours	12.59	3.81-41.67	0.001
9	Meconium stained amniotic fluid	8.70	3.36-2.88	0.001
10	Number of hours in the labour room before delivery of the neonate > 10 hours	2.66	1.39-5.10	0.023
11	Total number of vaginal examinations >3 times	2.40	1.49-3.87	0.001
12	Mode of delivery either instrumental or caesarean sections	1.98	1.36-5.10	0.001
	Neonatal factors			
13	Time of delivery of the neonate during on-call hours	1.60	1.11-2.30	0.010
14	Being a first born infant	1.8	1.25-2.5	0.001
15	Birth weight of neonates less than 2500g	4.21	2.52-7.00	0.001
16	Maturity of neonate less than 36 weeks	55.75	7.61-407.93	0.001
17	Length of the neonate less than 50 cm	2.40	1.44-4.00	0.001
18	Sex of the neonate being a male	1.48	1.04-2.14	0.021
19	APGAR score less than 7 at 5 min	70.52	9.66-514.57	0.001
20	Resuscitated at birth	2.22	2.00-2.46	0.001

4.1.6. Determinants of risk factors for neonatal sepsis

As shown in Table 4.26, the bivariate analyses found 20 variables which were significantly associated with ($p < 0.05$) occurrence of neonatal sepsis. This included one socio demographic factor, 13 maternal factors and seven neonatal factors. Multivariate logistic regression model identified the following variables as significantly associated risk factors for neonatal sepsis (Table 4.27). However education level of the mother, number of field clinic visits, mother's admission time to the hospital, number of hours in the labour room, being a first born neonate, maturity of the neonate, length of the neonate, APGAR score less than 7 at 5 minutes and being resuscitated at birth were not statistically significant factors in multiple logistic regression analysis.

Table 4.27. Determinant of risk factors for neonatal sepsis in multivariate regression model analysis

	Risk Factors	**B**	**S.E.**	**Wald**	**Sig.**	**OR**	**95.0% C.I.**	
		Lower	**Upper**	**Lower**	**Lower**	**Upper**	**Lower**	**Upper**
	Maternal factors							
1	>8 weeks of POG when registered in ANC	.649	.299	4.709	.030	1.914	1.065	3.439
2	History of abortions, still births and neonatal death	1.913	.382	25.147	.000	6.777	3.208	14.316
3	Total Number of ANC visits ≤ 4	1.971	.626	9.900	.002	7.175	2.102	24.486
4	History of maternal fever during last one week	1.008	.401	6.299	.012	2.739	1.247	6.016
5	Dribbling for more than 18 hours before delivery	2.303	.794	8.405	.004	10.001	2.108	47.441
6	Number of total vaginal examination before delivery >3	1.189	.266	19.912	.000	3.283	1.948	5.534
7	Mode of delivery by LSCS, Vacuum or Forceps	.845	.258	10.725	.001	2.327	1.404	3.857
8	Meconium stained amniotic fluid	2.358	.528	19.934	.000	10.565	3.753	29.738
	Neonatal factors							
9	Sex of the neonate being male	.555	.238	5.423	.020	1.741	1.092	2.777
10	Time of birth of the neonate (between 4 pm to 8 am of following day)	.750	.251	8.933	.003	2.118	1.295	3.465
11	Birth weight of neonate <2500g	1.643	.314	27.354	.000	5.171	2.793	9.570
	Constant	2.583	.310	69.607	.000	.076		

None of the socio demographic variables were, found to be risk factors for the neonatal sepsis. Registration at ANC after 8 weeks of gestation is significantly (OR=1.91; CI =1.06-3.44) associated with neonatal sepsis than at or before 8 weeks of gestation. The mothers who had a history of abortions, stillbirths and early neonatal deaths were a significant (OR= 6.77; CI 3.20-14.31) risk factor for neonatal sepsis than those without the history of same factors. Mothers who did not attend the antenatal clinics less than≤ 4 times were significantly associated (OR=7.18; CI 2.10-24.49) with occurrence of neonatal sepsis in their neonates. History of maternal fever during the last one week prior to delivery was also significantly (OR=2.74; CI 1.24-6.02) associated with neonatal sepsis. Mothers who had a history of dribbling for more than 18 hours before delivery of their neonates were 10 times more likely to get (OR=10.01; CI= 2.10-47.44) neonatal sepsis than those babies whose mothers had less than 18 hours of dribbling. Having a history of meconium stained liquor had a 10.57 (CI: 3.75-29.14) times more risk for occurrence of neonatal sepsis than those who did not have meconium stained liquor. When the number of vaginal examinations were more than three times there was approximately threefold risk (OR= 3.28; CI =1.95-5.53) of getting sepsis for their neonates than those who had less than three times of vaginal examinations. Those who experienced interventional deliveries (Caesarean sections, forceps deliveries and vacuum deliveries) were 2.3 times at risk (OR= 2.33 (CI= 1.40-3.86) of getting neonatal sepsis than normal vaginal deliveries.

Neonate being male baby carried a 1.74 times (CI= 1.09-2.73) risk of getting neonatal sepsis than female babies. Neonates delivered during the on-call hours (from 4 pmto following day 8am) were more at risk (OR= 2.12; CI 1.29-3.41) of getting neonatal sepsis than those who were born during the routine working hours (from 8 am to 4 pm). Birth weight of neonates, less than 2500g were five times at risk (OR=5.1; CI= 2.79-9.57) to get neonatal sepsis than normal birth weight babies.

Hosmer and Lemeshow test was performed to examine the prediction capacity of the residuals of the model (Hosmer and Lemeshow, 2000). The chi-square value of the residuals of the final model was 0.716 with p value of 0.915. This indicates that the overall significance of risk factors was statistically significant ($\chi 2$ =0.516; p=0.915) and final model explains it in a statistically significant manner.

4.2. Component II

4.2.1. Distribution of postpartum depression among study population

The association between maternal postpartum depression and neonatal sepsis was measured by using self administered EPDS questionnaire. The EPDS scale was validated for Sri Lanka and has been used in several studies (section 3.2.5.1). The cut off point for depression was taken as score of nine. Those mothers taken as score of nine or more were considered as depressed. Those who were taken a score below nine were considered as non-depressed.

Table 4.28. Distribution of maternal depression among the study population (n=480)

Characteristics	Maternal depression Present No	%	absent No	%	Total	Odds Ratio 95% CI	P value
Neonatal sepsis							
Present	185	78.4	51	21.6	236 (100.0 %)	13.44	0.001
Absent	51	21.2	189	78.8	240 (100.0 %)	(8.68-20.83)	
Total	236*	49.2	240	50.5	476 (100.0%)		

*4 participants did not answered for the questionnaire

There were 185 (78.4%) depressed mothers among the cases of neonatal sepsis and 51 (21.2%) depressed mothers among the controls neonatal sepsis. Four mothers (0.8%) did not answer the EPDS questionnaire. Out of these four mothers there was one maternal death. The association between maternal postpartum depression and neonatal sepsis was statistically significant (OR= 13.44; 95% CI: 8.68-20.83).

4.2.2. Socio demographic factors and maternal post partum depression

The comparison between the socio demographic factors and maternal postpartum depression were made to see any association between those two factors. The results depicted in Table No .4.29.

Table 4.29 Association of post partum depression with socio demographic factors of mothers (n=386)

Characteristics	Maternal depression				Odds Ratio 95% CI	P value
	Present		absent			
	No	%	No	%		
Age of mothers						
<20 years	14	48.3	15	51.7	0.95	0.885
⩾20 years	222	49.7	225	50.3	0.45-2.01	
Ethnicity						
Non Sinhalese	15	45.5	18	54.5	0.84	0.623
Sinhalese	221	49.9	222	50.1	0.41-1.70	
Religion						
Non Buddhist	44	42.3	60	57.7	0.69	0.093
Buddhist	192	51.6	180	48.4	0.44-1.07	
Educational level						
< O/L	36	55.4	29	44.6	1.31	0.314
⩾O/L	200	48.7	211	51.3	0.77-0.22	
Mothers occupation						
Housewives	186	48.9	194	51.1	0.88	0.583
Paid occupation	50	52.1	46	47.9	0.56-1.38	
Income(Rupeese)						
⩽ 10000	11	35.5	20	64.5	0.54	0.104
>10001	225	50.6	200	49.4	0.25-1.15	
⩽20000	126	48.3	135	51.7	0.89	0.531
>20001	110	51.2	105	48.8	0.62-1.28	

The socio demographic factors were not significantly associated with the mothers postpartum depression status (Table 4.29).

4.2.3. Maternal post partum depression and selected maternal and neonatal factors

The following selected maternal and neonatal factors were compared between the depressed and non depressed mothers (Table 4.30).

Table 4.30. Association of post partum depression and selected maternal and neonatal factors

Maternal and neonatal factors	Maternal depression Present No	%	Absent No	%	Odds Ratio 95% CI	P value
POA						
<36 weeks	38	84.4	7	15.6	6.27	0.001
≥36 weeks	199	46.4	230	53.3	2.74-14.36	
Presence of bad Obstetric history						
Present	42	62.5	25	37.3	1.86	0.015
Absent	194	47.4	215	52.6	1.09-3.17	
Gender of the neonates						
Male	129	52.0	119	48.0	1.23	0.268
Female	107	46.9	121	53.1	0.85-1.76	
First born or subsequent born						
Being a First born	128	53.3	111	46.4	1.38	0.081
Subsequent children	108	45.6	129	54.4	0.96-1.98	
Birth weight						
<2500	62	64.6	34	35.4	2.61	0.001
⩾2500	174	45.8	206	54.4	1.36-3.44	
Age of onset of sepsis						
≥72 hours	54	72.0	21	28.0	1.69	0.100
<72 hours	131	81.4	30	18.6	0.89-3.24	
Type of the hospital						
Tertiary care hospital	136	49.3	140	50.7	1.05	0.790
Secondary care hospital	101	50.5	99	49.5	0.73-1.51	

Maturity of the neonates and the birth weight were significantly associated with maternal postpartum depression. Mothers of babies whose maturity was less than 36 weeks of gestation were significantly (OR=6.27; P 0.001) depressed than mothers whose neonates were 36 weeks or more weeks of gestation. Mothers having neonates with a birth weight less than 2500g were two times (OR= 2.61: 95% CI: 1.36- 3.44) more likely to be depressed than mothers with neonates of a birth weight of more than 2500g.

4.2.4. Maternal depression and some selected social factors

The available literature shows that maternal depression occurred due to various social factors such as lack of social support, major life events, history of abuses, major illnesses of a family member and economic hardships. The following table shows the association of above variables and postpartum depression among mothers.

Table 4.31. Association of social support, major life events, economic hardship, and abuses among depressed and non depressed mothers

Characteristics	Maternal depression				Odds Ratio 95% CI	P value
	Present		Absent			
	No	%	No	%		
Social support						
Absent	3	60.0	2	40.0	1.51	0.650
Present	234	49.8	236	50.2	0.25-9.14	
Support during hospital stay						
Yes	3	60.0	2	40.0	1.51	0.650
No	234	49.8	236	50.2	0.25-9.14	
Abuse of mother						
Yes	3	100.0	0	0.0	0.49	0.081
No	234	49.5	239	50.5	0.45-0.54	
Major illness among family members						
Yes	2	50.0	2	50.0	1.01	0.99
No	235	49.8	237	50.2	0.14-7.22	
Having economic hardship						
Yes	6	100.0	0	0.0	0.49	0.013
No	230	49.0	239	51.0	0.45-0.54	
Experience of unexpected events						
Yes	5	71.4	2	28.6	2.57	0.246
No	231	49.4	237	50.6	0.49-13.35	

There were no significant association of maternal depression and selected factors such as social support, abuses, major life events, economic hardship and unexpected events in their life in this sample.

4.2.5. Determinants of maternal depression

The variables that had a probability level of 0.25 and less in the bivariate analysis were included in the logistic regression model as independent variables for better control of confounding factors to determine the risk factors for maternal depression.

Table 4.32. Multivariate logistic regression model for maternal depression and significant variables from bivariate analysis

Variables	B	S.E.	Wald		95.0% C.I.		
	Lower	Upper	Lower	OR	Lower	Upper	P value
Birth weight of the neonate <2500	-.195	.337	.335	0.82	0.43	1.59	0.563
Maturity of neonate <36 weeks	.746	.508	2.159	2.12	0.78	5.70	0.142
Bad obstetric history (history of abortions, still birth, neonatal death)	-.494	.334	2.184	0.61	0.31	1.18	0.139
Presence of neonatal sepsis	2.641	.248	113.740	14.03	8.64	22.80	0.001
Constant	-1.250	.160	61.366	.286			.000

Maternal postpartum depression was significantly (OR=14.03; 95% CI: 8.64-22.80) associated with neonatal sepsis. Therefore neonatal sepsis was a risk factor for maternal postpartum depression. Other significant factors in bivariate analysis such as birth weight of the neonate, maturity of neonates, and bad obstetric history of the mothers were not found significant in multivariate logistic regression analysis.

4.3. Component III

4.3.1. Maternal satisfaction regarding care received to neonates and mothers

Maternal satisfaction with various aspects of care provided through the government health services were assessed at the discharge of the mothers and neonates from the hospital. It consisted of two parts. One was the maternal satisfaction regarding the care received for their neonates after delivery and while in the NNICU and the other was the care received by the mothers themselves since admission to the hospital until delivery. Satisfaction was assessed by a 20 items scale. The responses were marked using a 5 point Likert type Scale: (i) Highly satisfied, (ii) Satisfied, (iii) Neither satisfied or dissatisfied, (iv) Dissatisfied, and (iv) Highly dissatisfied as described in section (3.3.7.1) in methodology. The individual satisfaction was calculated by amalgamating (i) and (ii) as satisfied and (iii),(iv) and (v) as dissatisfied.

4.3.2. Maternal satisfaction regarding the care received for their neonates

The total satisfaction was categorized according to five domains. They were, information they received regarding their neonate's illness; skills of the staff and the time they spent with the neonate; communication with mothers; kindness of the various category of staff when providing services; and mothers' recommendation of the institution they stayed for future admission for a another episode of illness (Table 4.33).

Table 4.33. Distribution of maternal satisfaction and selected aspect of services received to neonates during the hospital stay (n=235)

Description of the services	Satisfied		Not satisfied	
	No	%	No	%
Information regarding neonates				
1. Information given about neonate's illness	203	84.6	32	13.3
2. Information given about neonate's investigation	196	81.7	39	15.2
3. Information given about neonate's treatment	205	85.2	30	12.4
4. Treatment received by the neonate	227	94.6	8	3.3
Skills and time spent				
5. Confidence and competence/skills of staff	212	88.4	23	9.1
6. Counselling, explanation and reassurance	215	89.3	23	8.4
7. Introduction of staff by themselves	5	2	230	95.8
8. Willingness to help by the staff when neonate needed	223	92.9	12	5
9. Love & respect towards neonate	225	93.8	10	3.7
10. Willingness to help by the staff when mother needed	227	94.6	8	3.3
11. Time spent to answer the questions	215	89.6	20	8.3
Communication				
12 Opportunity to ask questions	227	94.5	8	3.3
13. Understanding of explanation	217	90.4	18	7.5
Courtesy of Staff				
14. Kindness of Consultant	193	80.4	42	17.6
15. Kindness of medical officer	216	90.0	19	8.6
16. Kindness of nursing officer	226	94.0	9	3.5
17. Kindness of minor Staff	222	92.9	13	4.9
Respect and recommendations				
18. Love & respect towards mother	222	92.6	13	5.4
19. Return to same institution for the next episode of illness of my child	227	94.6	8	3.3
20. Recommendation for another child as favourable place	225	93.8	10	4.1

Five mothers did not respond

A majority of 227 (94.6%) mothers were satisfied regarding the treatment their neonates received whereas 39 (15.2%) mothers were dissatisfied regarding the information provided about their neonates. The practice of introducing of staff by themselves to the patients was not familiar in our country; 230 (95.8%) mothers mentioned it as dissatisfied. The satisfaction regarding the support given to baby and the mother when they needed was 93.8% and 95.4% respectively. The overall communication also scored a 95.4% for opportunity to ask questions and understanding of explanations given by the staff. Hundred and ninety three (80.4%) mothers were satisfied regarding the kindness of the consultant whereas junior medical officers, nursing staff and minor staff were rated 90.0%, 94.0% and 92.9% respectively. The majority of mothers (95.8%) recommended the stay in the unit for another child whereas 94.6% of them preferred to return to the same unit for future episode of illness.

4.3.2.1. Maternal satisfaction regarding the neonatal care according to the identified domains

The findings of mother's satisfaction were presented in two ways. The level of satisfaction of mothers with each individual item (Table 4.33) and the proportion of mothers satisfied with given domains. The identified domains were information received regarding neonates illness and investigations, time spent and skills of staff, communication between staff and mothers, kindness of staff towards the mother and regarding the respect to the mothers and recommendation of same institution for another episode of illness. According to the domains the responses were amalgamated and a total score of more than 75% was taken as satisfaction for each domain. The total satisfaction according to each domain was as follows.

Table 4.34. Distribution of total satisfaction score according to the identified domains (n=235)

Domains of satisfaction	Satisfied		Not satisfied	
	No	%	No	%
Information regarding illness, investigation and treatment	201	83.8	34	14.2
Time spent and skills of staff	191	79.6	44	18.3
Communication between staff and mothers	218	90.8	17	7.1
Kindness of staff	222	92.5	13	5.4
Respect to the mothers and recommendation of the institution for future illness	224	93.3	11	4.6

5 (2.5%) not responded

As indicated in table 4.33 the item 1, 2, 3 and 4 were amalgamated to find out their satisfaction regarding the information they got from health care workers about their neonate's illness, investigations and treatments. Two hundred and one (83.8%) mothers were satisfied regarding the information received about their neonates from the staff. Hundred and ninety one mothers (79.6%) expressed their satisfaction about the competency and skill of the staff and time spent by them on their neonates during hospital stay. A high degree of satisfaction (n=218, 90.8%) was reported about the communication aspect of staff with the mothers. Ninety two percent (n=222) of mothers were satisfied regarding the kindness of care given by the various categories of staff. More than 93.3% (n=224) of mothers expressed their satisfaction with the respect shown by the staff towards them, and recommended the same hospital for the treatment of another neonate.

4.3.3. Association of socio demographic factors and maternal satisfaction regarding neonatal care

The total satisfaction score was compared with socio demographic factors of mothers (Table 4.35) and the results were as follows.

Table 4.35. Association of selected socio demographic factors and maternal satisfaction regarding neonatal care (n=235)

Socio demographic factor	Satisfied		Not satisfied		Odds Ratio (95% CI)	P value
	No	%	No	%		
Age of the mother						
≤25 years	119	76.8	36	23.2	1.10	0.76
>25 years	60	75.0	20	25.0	0.59-2.07	
Ethnicity						
Non Sinhalese	13	81.3	3	18.8	1.38	0.62
Sinhalese	166	75.8	53	24.2	0.38-5.04	
Mothers' Religion						
Buddhist	148	77.9	42	22.1	1.59	0.20
Non Buddhist	31	68.9	14	31.1	0.78-3.26	
Family income (rupees)						
≤20000	94	76.4	29	23.6	0.97	0.92
>20001	85	47.5	27	48.2	0.53-1.77	
Education level						
<O/L	36	83.7	7	16.3	1.70	0.19
≥O/L	143	74.5	49	25.5	0.74-4.22	
First born/subsequent						
Subsequent child	73	72.3	28	27.7	0.78	0.22
Being a first born	106	79.1	28	20.0	0.38-1.26	
Mothers' occupation						
Paid employment	40	74.1	14	25.9	1.16	0.68
Not on employment	139	76.8	42	23.2	0.58-2.33	

There was no significant association with selected socio demographic factors namely age, ethnicity, religion, occupation, family income, and the mother's occupation and maternal satisfaction regarding neonatal care.

4.3.4. Association of maternal satisfaction on neonatal care received and some selected maternal and neonatal factors

The total satisfaction score was compared with selected maternal factors like type of the hospital delivered, presence of bad obstetric history, type of delivery and the number of days in the hospital. The neonatal factors considered were maturity of the neonates, birth weight, gender of the neonates and early onset sepsis and late onset sepsis of the neonates.

Table 4.36 Association of maternal satisfaction regarding neonatal care and some selected maternal and neonatal factors (n=235)

Maternal and neonatal factors	**Satisfied**		**Not satisfied**		**Odds Ratio (95% CI)**	**P value**
	No	**%**	**No**	**%**		
Type of the hospital						
Tertiary care	67	74.4	23	25.6	0.86	0.62
Secondary care	112	77.2	33	22.8	0.47-1.58	
Presence of bad obstetric history						
Present	40	72.7	15	27.3	1.27	0.49
Absent	139	77.2	41	22.8	0.64-2.53	
Mode of delivery of the baby						
NVD	97	78.2	27	21.8	1.27	0.43
Instrumental delivery and caesarean sections	82	73.9	29	26.1	0.70-2.32	
Number of days in the hospital						
<10 days	80	77.7	23	22.3	1.16	0.63
≥10 days	99	75.0	33	25.0	0.63-2.13	
Maturity of the neonates						
≥36 weeks	148	78.3	41	21.7	1.68	0.15
<36 weeks	30	68.2	14	31.8	0.82-3.47	
Sex of the neonates						
Male	104	77.6	30	22.4	1.20	0.55
Female	75	74.3	26	25.7	0.66-2.2	
Birth weight of baby						
≥2500	124	76.5	38	23.5	1.07	0.84
<2500	55	75.3	18	24.7	0.56-2.03	
Age of onset of the sepsis of neonates						
Early onset<72 hours	121	75.6	39	24.4	0.91	0.77
Late onset ≥72 hours	58	77.3	17	22.7	0.48-1.74	

The selected maternal and neonatal factors were not significantly associated with maternal satisfaction on neonatal care (Table 4.36).

4.3.5. Maternal satisfaction regarding the care received for mothers themselves

As described in section 4.3.1 individual maternal satisfaction regarding the maternal care received were assessed.

Table 4.37. Distribution of maternal satisfaction with selected aspect of services received to the mothers themselves during the hospital stay

Description of services	Satisfied		Dissatisfied	
Physical and sanitary facilities	No	%	No	%
1. Sleeping facilities provided	188	78.4	47	19..6
2. Toilet facilities provided	167	69.9	68	28.3
3. Cleanliness of the floor of the wards	194	80.8	41	17.1
4. Other facilities provided	180	75.0	55	22.9
5. Physical appearance of the wards	207	86.3	28	11.7
Diet and drinking water				
6. Regarding the diet provided	16*	6.7	0	0.0
7. Regarding the drinking water	20**	8.3	1	0.4
Kindness of staff				
8. Kindness of Consultant	222	92.5	13	5.4
9. Kindness of medical officer	224	93.3	11	3.8
10. Kindness of nursing officers	220	91.6	13	6.0
11. Kindness of midwives	229	95.5	6	2.7
12. Kindness of other staff	208	86.7	27	13.3
Breast feeding counselling				
13. Explanation on breast feeding	224	93.3	11	3.8
Information and communication				
14. Opportunity to ask questions	228	95.4	7	3.1
15. Understanding of explanation given	219	91.3	14	6.3
16. Time spent on explanation	230	95.8	5	2.3
17. Reassurance, counselling and management	216	90.8	18	7.1
Respect and recommendation				
18. Respect shown towards mother	230	95.8	5	2.3
19. Return to same ward and hospital for next episode of illness	224	93.3	11	3.8
20. Recommendation to another mother as a favourable place	225	93.8	10	3.5

*219 mothers did not take diet provided by the hospital; **214 mothers did not take water provided from the hospital

Out of 240 mothers 219 (91.2%) mothers had not taken the diet supplied by the hospital. Those who got the diet from the hospital were 100% satisfied with it. The mothers who were entitled for a diabetic diet and other specified diet have taken hospital diet. Only 20 (8.3%) mothers had taken drinking water provided for them by the hospital. All of them were satisfied regarding the water provided. Majority of mothers 224 (93.3%) were satisfied regarding the breast feeding counselling and management whereas 11 (4.6%) mothers were not satisfied.The proportion of mothers satisfied with information provided and communication aspect was 91.2% (n=219).

More than 89.2% of (n=214) mothers were satisfied with the kindness of the various categories of staff. The satisfaction of mothers on the kindness of the consultant (92.5%), junior doctors (92.6%), nursing officers (92.5%) and minor staff (86.7%) was in that order (Table 4.38).

There were 212 (n=88.3%) mothers satisfied with their obstetric unit and they recommended the same unit for others as a favourable place.

4.3.6. Maternal satisfaction regarding the care provided to mothers from their obstetric units according to the domains

The total score of maternal satisfaction was calculated and more than 75% of the total score was taken as cut off point for satisfaction. Then the total satisfaction score according to the domains were calculated. The results depicted in the following table (Table 4.38).

Table 4.38. Distribution of total satisfaction of mothers according to the domains

Domains of satisfaction	**Satisfied**		**Not satisfied**	
	No	**%**	**No**	**%**
Sanitation and other facilities	183	76.2	52	21.7
Diet*	16	6.7	0	0.0
Drinking water**	20	8.3	0	0.0
Breast feeding counseling	224	93.3	11	4.6
Information and communications between mother and staff	219	91.2	16	6.7
Kindness of staff	214	89.2	21	8.8
Respect to the mother and recommendation of the institution	212	88.3	23	9.6

Five participants-Missing, * n=219 (91.2%) not taken diet from the hospital, **n=214 (89.2%) not taken drinking water from the hospital

The total satisfaction regarding the sanitation provided for mothers were high (76.2%). Sanitary facilities included toilet facilities, cleanliness of the wards and toilets and physical environment of the wards. Total satisfaction regarding the information and communication between the staff and the mothers were 91.2% and the kindness of the staff were 89.2%.

4.3.7. Maternal satisfaction regarding maternal care and socio demographic factors

Total maternal satisfaction score on maternal care and socio demographic factors were analyzed to see whether there were any association and results are given below.

Table 4.39 Association of selected socio demographic factors and maternal satisfaction regarding maternal care

Socio demographic factor	Satisfied		Not satisfied		Odds Ratio (95% CI)	P value
	No	%	No	%		
Age of the mother						
≤25 years	76	95.0	4	5.0	1.89	0.27
>25 years	141	91.0	14	9.0	0.60-5.93	
Ethnicity						
Non Sinhalese	15	93.8	1	6.3	1.26	0.83
Sinhalese	202	92.2	17	7.8	0.16-10.14	
Mothers' Religion						
Buddhist	175	92.1	15	7.9	1.20	0.78
Non Buddhist	42	93.3	3	6.7	0.33-4.33	
Family income (rupees)						
≤20000	116	94.3	7	5.7	1.81	0.24
>20001	101	90.2	11	9.8	0.67-4.83	
Education level						
<O/L	42	97.7	1	2.3	0.25	0.15
≥O/L	175	91.1	17	8.9	0.32-1.90	
First or subsequent child						
Being a first child	125	93.3	9	6.7	1.35	0.53
Being a subsequent child	92	91.1	9	8.9	0.52-3.56	
Mothers' occupation						
Housewives	167	92.3	14	7.7	0.95	0.94
Paid employment	50	92.6	4	7.4	0.33-3.03	

There is no significant association between maternal satisfaction and socio demographic factors of mothers.

4.3.8. Maternal satisfaction and selected maternal and neonatal factors

Maternal satisfaction on maternal care was compared with some selected maternal and neonatal factors.

Table 4.40 Association of maternal satisfaction regarding maternal care with selected maternal and neonatal factors (n=235)

Maternal and neonatal factors	Satisfied No	Satisfied %	Not satisfied No	Not satisfied %	Odds Ratio (95% CI)	P value
Type of the hospital						
Tertiary care	90	100.0	0	0.0	1.14	0.01
Secondary care	127	87.6	18	12.4	1.07-1.25	
Presence of bad obstetric history						
Present	48	87.3	7	12.7	2.24	0.11
Absent	169	93.9	11	6.1	0.82-6.09	
Maturity of the neonates						
≥36 weeks	178	94.2	11	5.8	3.02	0.02
<36 weeks	37	84.1	7	15.9	1.11-8.42	
Mode of delivery of the baby						
NVD	119	96.0	5	4.0	3.16	0.27
Instrumental and caesarean sections	98	88.3	13	11.7	1.09-9.17	
Sex of the neonates						
Male	125	93.3	9	6.7	1.36	0.53
Female	92	91.1	9	8.9	0.52-3.56	
Birth weight of neonate						
≥2500	151	93.2	11	6.8	1.46	0.45
<2500	66	90.4	7	9.6	0.54-3.92	
Age of onset of the sepsis						
Early onset<72 hours	72	96.0	3	4.0	2.48	0.15
Late onset ≥72 hours	145	90.6	15	9.4	0.69-8.85	
Number of days in the hospital						
<10 days	125	93.3	9	6.7	1.31	0.53
≥10 days	92	91.1	9	8.9	0.52-3.56	

As shown in Table 4.40, out of all selected factors regarding maternal satisfaction in bivariate analysis, mothers who delivered at tertiary care hospitals were more satisfied than mothers delivered at secondary care hospitals and it was significantly associated (OR=1.14; 95% CI: 1.07-1.25). The mothers of more than 36 weeks of gestation were more satisfied (OR= 3.02; 95%:1.11-8.42) with the maternal care they received than mothers of less than 36 weeks of gestation.

4.3.9. Determinants of maternal satisfaction regarding maternal care

The p value of less than 0.25 variables in bivariate analysis were analyzed in the logistic regression model to verify any confounding factors and to determine the association of significant factors for maternal satisfaction.

Table 4.41. Multivariate analysis to determine the maternal satisfaction regarding maternal care with significant associated factors in bivariate analysis

	B	S.E.	Wald		95.0% C.I		
	Lower	Upper	Lower	OR	Lower	Upper	P value
1.Type of the hospital being tertiary care	-.159	.318	.249	0.85	0.46	1.59	0.62
2.Maturity of the neonates ≥36 weeks	.654	.381	2.937	1.92	0.91	4.06	0.09
3.Level of education of mother≥ O/L	-.653	.462	1.999	0.52	0.21	1.29	0.16
Constant	-1.111	.258	18.538	.329			.000

Place of birth, whether it is tertiary care or secondary care, maturity of neonates more than 36 weeks or less than 36 weeks and mothers' education level less than O/L or more than O/L were not significantly associated with mothers' satisfaction of maternal care provided from the government institutions.

4.3.10. Suggestions given by mothers to improve neonatal care in the hospitals

All the mothers who participated in the satisfaction component of the study were asked to offer three suggestions to improve neonatal care in the hospital. It was an open ended question. The answers given were clustered under the following categories.

1. To improve the facilities which are not available currently such as investigations like CRP, and availability of medicine which are expensive.
2. Further improvement of available services in small hospitals for deliveries and availability of medical officers
3. To improve the physical facilities

The following suggestions were made by mothers to improve the neonatal care and there by improve the mother's satisfaction.

Table 4.42 Suggestions made by mothers to improve the neonatal care by introducing the currently non available facilities

Suggestions	Number	Percentage
Improve the facilities for investigations like CRP	106	44.2
Increase the availability of high cost medicine	73	30.4
Increase facilities to spend more time by fathers with their neonate	33	13.8
Increase facilities for LBW/premature neonates	10	4.1
Increase the facilities to get information regarding the neonate's condition (keep a receptionist during visiting hours)	8	3.3
Not given suggestions	10	4.1
Total	240	100.0

The majority of mothers (n=106; 44.2%) of neonatal sepsis babies mentioned that facilities for investigations should be improved as some investigations were done at the private sector. As an example almost all CRP investigations were done at the private sector. A large proportion of mothers (30.4%) mentioned to increase the availability of medicine as they had to buy some of the antibiotics out of pocket. Thirty three mothers (13.8%) suggested increasing facilities for the fathers to stay with their neonates for a longer time.

Table 4.43. Suggestions given by mothers to improve neonatal care by improving the currently available services

Suggestions	No	Percentages (%)
Regular mechanism for mothers to train on infection control/at least on hand washing	84	35.0
Increase availability of medical officers	44	18.3
Staff should get more precautions on infection control	41	17.1
Small hospitals should develop more for deliveries	27	11.2
Not given suggestions	16	6.6
Medical students should train before handling mothers and babies	12	5.0
Special training to staff on premature and LBW babies	8	3.3
Increase number of minor staff in the LRs	8	3.3
Total	240	100.0

The majority of mothers (n=84; 35%) suggested regular training for mothers regarding infection control practices and health education talks were insufficient for some mothers. Therefore it is necessary to demonstrate and promote hand washing regularly in the maternity wards. Forty four mothers suggested increasing the number of junior medical officers. Five percent (n=12) of mothers suggested proper training of medical students before handling mothers and babies.

Table 4.44. Suggestions given by mothers to improve physical facilities in neonatal care (n=235)

Suggestion	No	Percentages
Arrange to reduce the distance to NNICU from post natal wards or provide more beds for PN mothers closer to NNICU	104	43.4
Keep mother and baby together as far as possible/improve mother baby units	48	20.0
Establish a dining area/room for mothers	31	12.9
Arrange the sitting space for feeding mothers	22	9.2
Evacuate the mosquito breeding sites from the hospital	11	4.6
Improve the cleanliness of NNICU	5	2.1
Limit visitors to NNICU/Mother baby units	5	2.1
Supply of mosquito nets for mothers in the NNICU room	3	1.2
Not given suggestions	6	2.4
Total	240	100.0

A large proportion of mothers (n=104; 43.4%) mentioned that the NNICU is not situated close to the post natal wards. Therefore they found it difficult to walk the distance from the postnatal wards to the NNICU. Forty eight mothers (20%) suggested establishing mother baby units to keep mother and baby together when they are sick.

4.3.11. Suggestions made by mothers to improve maternal care and thereby maternal satisfaction in the hospital

As mentioned above suggestions were taken from mothers to improve maternal care in the hospital. The suggestions were categorized as follows:

1. To improve sanitary facilities such as toilet facilities and the number of dust bins
2. To improve the service facilities like increase availability of essential equipment, and medicine like prostaglandin pessary
3. Suggestions to improve non sanitary physical facilities such as mosquito nets and adequate space for breast feeding

Table 4.45. Suggestions made by mothers to improve sanitary facilities in order to improve maternal care and thereby maternal satisfaction

Suggestions	Number	Percentages
Improve the cleanliness of toilets/number of toilets	85	35.4
Clean the postnatal wards more frequently	49	20.4
Increase the number of dust bins in the toilets	44	18.3
Regular training of mothers on discarding sanitary pads	43	17.9
Increase no. of commodes / showers	10	4.2
Not responded	9	3.7
Total	240	100.0

The majority, 35.4% (n=85) of mothers mentioned to improve the cleanliness of toilets and number of toilets, whereas 20.4% (n=49) of mothers recommended to improve the cleanliness of the post natal wards.

Table 4.46 Suggestions made by mothers to improve the service facilities in order to improve maternal care and thereby maternal satisfaction

Suggestion	Number	Percentages
Increase availability of essential equipment like cannulae/urinary catheters	80	33.3
Train minor staff to care for patients	67	27.9
Regular visits to postnatal section by Consultants to increase care of post natal mothers	50	27.9
Increase availability of medicine like prostaglandins	16	6.7
Not given suggestions	8	3.3
Total	240	100.0

The majority of mothers (n=80; 33.3%) mentioned increasing the availability of medicine and equipment like cannulae. Sixty seven (27.9) mothers suggested training the minor staff regarding patient care. Fifty mothers (27.9%) mentioned that the visit to the post natal wards by the consultants should be improved.

Table 4.47 Suggestions made by mothers to improve non sanitary physical facilities in order to improve maternal care and thereby maternal satisfaction

Suggestions	Number	Percentages
Need solution for the problem of stray dogs and cats	75	31.3
Insufficient number of beds in the wards	55	22.9
Post natal wards / mother and baby wards are too warm	43	17.9
Flies are all over the wards	19	7.9
Mosquito problems and the supply of mosquito nets	11	4.6
Breast feeding place is not adequate /privacy is not maintained	11	4.6
Beds are too high in the post natal wards	9	3.8
Not responded	15	6.2
Total	240	100.0

Seventy five mothers (31.3%) mentioned of nuisance from the stray dogs and cats while in the wards. A large proportion of mothers (22.9%) mentioned that the number of beds were not enough in the post natal wards.

4.4. Component IV

Part A:

The building design and physical facilities were observed in relation to infection control guidelines. Observations were done according to the check lists in the LR, NNICU, PNW and OT. The results were displayed in annexure XXII, XXIII, XXIV and XXV.

Part B

Observations of the adherence of infection control standards by health care workers in selected procedures in the Labour Rooms (LRs), Neonatal Intensive Care units (NNICUs), Post Natal Wards (PNWs) and Operation Theatres (OTs).

Direct observations were made by the PI according to the check-lists to observe the adherence of infection control standards by health care workers in selected procedures. This component was carried out in LRs, NNICUs, PNW and OTs.

4.4.1. Observation of the adherence of infection control standards by health care workers in selected procedures in the labour room

Thirteen categories of procedures namely use of PPE, hand washing practices, provision of neonatal care, umbilical cord care, immediate post natal care, breast feeding practices, handling of sharps and management of blood spills were observed in the labour rooms and there were seven labour rooms in the studied hospitals. From each procedure ten observations were made in each labour room. Therefore 70 observations were made for each category of procedure.

The following table depicted the usage of PPE and adherence of hand hygiene procedures by the health care worker who attended to the normal delivery procedure.

Table 4.48 Distribution of practices of usage of Personal Protective Equipment (PPE)and hand washing by the birth attendants when attending in the labour room (n=70)

Practices	Yes		No	
	Number	Percentage	Number	Percentage
Changed the shoes	44	62.9	26	37.1
Wore masks	9	12.9	61	87.1
Wore apron	56	80.0	14	20.9
Wore gown	9	12.9	61	87.1
Hand washed before wearing gloves	40	57.1	30	42.9
Wore sterile gloves	70	100.0	0	100.0

All birth attendants (100.0%) wore sterile gloves before attending deliveries whereas only 40 (57.1%) birth attendants washed their hands before attending deliveries. Change of shoes were practiced by 44 (62.9%) birth attendants before entering the labour room and aprons were worn by 80% (n=56) of birth attendants before attending deliveries in the labour room.

Table 4.49. Distribution of adherence of steps in hand washing by birth attendants who washed hands before attending the delivery (n=40)

Steps of hand washing	Yes	
	Number	Percentage (%)
Removed all bangles, rings and watches or did not wear	21	52.5
Used soap or liquid soap	40	100.0
Used running water	40	100.0

All (100.0%) the hand washers used either soap or liquid soap for the hand washing. Removal of bangles rings and watches were practiced by 52.5% of health care workers.

Table 4.50. Distribution of adherence to steps in hand washing procedure among birth attendants who washed hands before delivery (n=40)

Steps	Yes		No	
	Number	Percentage %)	Number	Percentage (%)
Over the surfaces	40	100.0	0	0.0
Back of the hands	39	97.5	1	2.5
Inter digital spaces	31	77.0	9	22.5
Back of the fingers	30	75.0	10	25.0
Thumbs separately	25	62.5	5	37.5
Tip of the fingers	28	70.0	12	30.0

One hundred percent (n=40) of birth attendants washed over the surface when they washed their hands. Those who washed their thumbs separately were 62.5% (n=25) and tip of the fingers 70.0% (n=28).

Table 4.51. Distribution of type of towels used to wipe the hands by the birth attendants after washing their hands (n=40)

Type of towels	YES		NO	
	Number	Percentage	Number	Percentage
Disposable towel	0	0.0	40	100.0
Single use sterile towel	37	95.7	3	4.3
Common towel	0	0.0	40	100.0
Separate towel	0	0.0	40	100.0

The majority (n=37; 95.7%) of birth attendants used the single use sterile towels to wipe out their hands after washing whereas three (4.3%) did not wipe their hands after washing.

Table 4.52. Distribution of selected practices of neonatal care performed by the birth attendants while delivering the baby (n=70)

Practice	Yes		No	
	No	%	No	%
Delivered the neonate over the mothers abdomen	29	41.4	41	58.6
Dried the baby immediately	65	92.9	5	7.1
Wiped eyes and mouth	60	85.7	10	14.3
Applied antimicrobial to eyes	0	0.0	70	100.0
Discarded wet cloths immediately	61	87.1	9	12.9

The majority (n=65; 92.9%) of birth attendants dried the baby immediately but only 41.4 % (n=29) of babies were delivered over the abdomen for skin to skin contact.

Table 4.53. Distribution of infection control practices while providing umbilical cord care by birth attendants (n=70)

Practice	Yes		No	
	Number	Percentage	Number	Percentage
Changed or washed the gloves before cord was cut	54	77.1	16	22.9
Clamped and cut the cord	65	92.9	5	7.1
Used sterile instruments	70	100.0	0	0.0
Observed for oozing	53	75.7	17	24.3
Application of any substances over the stumps	0	0.0	70	100.0

All (100%) birth attendants used sterile instruments to cut umbilical cords whereas five umbilical cords (7.1%) were cut without proper clamping of the cords. Umbilical cord stump observation for oozing was done for 75.7% of deliveries.

Table 4.54. Distribution of practices of neonatal care performed by the birth attendant just after birth of neonate

Practice	Yes		No	
	Number	Percentage (%)	Number	Percentage(%)
Left the baby on mother's chest for skin to skin contact after delivery	27	36.8	42	61.4
Covered the baby well	65	92.9	5	7.1
Covered the head of the baby	44	62.9	26	37.1
Did not remove the vernix	66	94.3	4	5.7

Leaving the baby over the mothers abdomen was done in 36.8% (n=27) of deliveries and covering the baby well was observed in 65 (92.9%) deliveries. Although the removing of vernix is not practiced now, in four neonates (5.7%) this was practised.

Table 4.55. Distribution of breast feeding practices within the labour rooms by the birth attendants

Breast feeding practices	Yes		NO	
	Number	Percentage	Number	Percentage
Initiation of breast feeding within ½ hour to 1 hour	46	65.7	24	34.3
Help in positioning of the neonates	57	81.4	13	18.6
Help in attachment of the baby	54	77.1	16	22.9
Any other substances given other than breast milk	0	0.0	70	100.0

Although the best breast feeding practice was to initiate breast feeding within ½ an hour to one hour period, only 65.7% (n=46)of neonates were started on breast feeding during that period. More than 80% of mothers were helped to position the neonates for breast feeding by health staff.

At the antenatal clinics mothers are advised to bring the caps and socks for their newborn when they come to the hospital for the delivery. Mothers are expected to bring clean items after washing at home. Those things are important to protect the temperature of the newborn. The frequency distribution of mothers who brought those things is displayed in Table 4.56.

Table 4.56. Distribution of caps and socks brought by the mothers to the hospital for their neonates (n=70)

Description	Yes		No		Total
	Number	Percentage	Number	Percentage	
Caps and socks brought by mother	44	62.9	26	37.1	70 (100.0%)
Washed the caps and socks before use	28	63.0	16	37.0	44(100.0%)

There were 44 (62.9%) of the mothers brought the caps and socks for their neonates. Out of those 28 (63%) mothers washed the caps and socks before use on their neonates.

Table 4.57. Distribution of practices of handling sharps by birth attendant while assisting for deliveries (n=70)

Practice	YES		NO	
	Number	Percentage	Number	Percentage
Recap before disposal of syringes	13	18.6	57	81.4
Disposing the syringes without separating the needle	66	94.3	4	5.7
Sharps disposed in to sharp bins	63	90.0	7	10.0
Change of sharps from person to person	2	2.9	68	97.1

The used sharps were disposed in to the sharp bins in 90% (n=63) of the occasions whereas recap before disposing was done by 13 (18.6%) birth attendants. Two person (2.9%) changed sharps from person to person before disposal.

Table 4.58. Distribution of practices taken to prevent cross infection by the birth attendant following deliveries

Practice	Yes		No	
	Number	Percentage (%)	Number	Percentage (%)
Apply TCL and keep it for 30 minutes over the blood spilled floor	8	11.4	62	88.6
Use separate mop to wipe out the contaminated places	50	71.4	20	28.6
Change the mackintosh for the delivery of a new mother	69	98.6	1	1.4
Keep the contaminated materials in the separate bins	69	98.6	1	1.4

TCL on blood spilled floor was applied only 11.4% (n=8) times. Separate mops to wipe out the contaminated places were used 71.4% (50) times.

4.4.2 Observation of the adherence of infection control standards by health care workers in selected procedures in NNICUs

The selected procedures which are important for the control of infections inside the NNICU and to prevent cross infections among sick neonates were observed from the five NNICUs of all four hospitals. The selected procedures were use of PPE, hand washing, drawing of blood for blood cultures, handling of sharps and handling of samples with blood and body fluids. Ten observations were made for each procedure from one NNICU. Therefore total of 50 observations were made for a selected procedure.

Table 4.59. Distribution of use of PPE and adherence to infection control practices when entering the NNICU by the staff (n=50)

Practice	Yes		No	
	Number	Percentage	Number	Percentage
Change the shoes	48	96.0	2	4.0
Wear sterile masks	2	4.0	48	96.0
Wear sterile gown	17	34.0	33	66.0
Wear sterile caps	0	0.0	50	100.0
Wash hands before entering the NNICU	30	60.0	20	40.0

The majority (n=48; 96.0%) of health care workers changed their shoes when entering the NNICU. Only 60% (n=30) of health care workers washed hands before entering the NNICU. No one wore the sterile caps while in the NNICU.

Table 4.60. Distribution of adherences to infection control practices by health care workers when handling the neonates in the NNICU (n=50)

Practice	Yes		No	
	Number	Percentage	Number	Percentage
Washed hands before handling the neonates	41	80.0	10	20.0
Already nails cut short	46	92.0	4	8.0
Washed hands after touching the neonates	50	100.0	0	0.0

There were 41 (80%) health care workers who washed their hands before touching the sick neonates in the NNICU whereas all (100.0%) health care workers washed their hands after touching the sick neonates.

Table 4.61. Distribution of adherence to steps in hand washing by the health care workers in the NNICU (n=41)

Steps	Number	Percentage	Number	Percentage
Used soap/liquid soap	41	100.0	0	0.0
Used running water	41	100.0	0	0.0
Wiped hands	41	100.0	0	0.0

All health care workers (100.0%) who washed their hands used either soap or liquid soap, and running water and wiped hands.

Table 4.62. Distribution of adherence to steps in hand washing by the health care workers in the NNICU (n=41)

Steps	Yes		No	
	Number	Percentage	Number	Percentage
Over the surfaces	41	100.0	0	0.0
Back of the hands	39	94.7	2	5.3
Inter digital spaces	36	87.5	5	12.5
Back of the fingers	34	81.6	7	18.4
Thumbs separately	32	76.8	9	23.2
Tip of the fingers	32	76.8	9	23.2

As seen in Table 61 there were 81.6% (n=34) of health care workers who washed the back of the fingers whereas only 76.8% (n=32) workers washed the thumbs separately. All of them washed over the surfaces of their hands.

Table 4.63. Distribution of the type of towels used to wipe hands among the health care workers who washed the hands (n=41)

Type of towel	Number	Percentage
Disposable towel	9	21.9
Single use sterile towel	32	78.1
Common towel	0	0.0
Separate towel	0	0.0
Total	41	100.0

There were 78.1% (n=32) of health care workers who wiped their hands by using a single use sterile towel whereas nine (21.9%) health care workers wiped their hands by using disposable towels.

Table 4.64. Distribution of adherence to infection control procedures by health care workers when performing venepunctures on the neonates (n=50)

Practice	Yes		No	
	Number	Percentage	Number	Percentage
Wash hands before inserting the cannulae	43	86.0	7	14.0
Wear a pair of sterile gloves before commencing the puncture	25	50.0	25	50.0
Use of 70% alcohol to clean the skin	50	100.0	0	0.0
Documentation of date on the BHT/dressing	26	52.0	24	48.0

All (n=50; 100.0%) of the health staff performed the cannulation after disinfection of the skin by 70% alcohol. Hands were washed by 43 (86.0%) of them before insertion of cannulae whereas 50.0% of them wore sterile gloves before the insertion.

Table 4.65 Distribution of adherence to infection control procedures in selected procedures by the health care workers when drawing blood samples for blood cultures (n=50)

Practice	Yes		No	
	Number	Percentage	Number	Percentage
Cleaning of skin with70% alcohol	50	100.0	0	0.0
Allow to dry	36	72.0	14	28.0
Use of Betadine for cleaning	34	68.0	16	32.0
Wash hands before drawing blood samples	48	96.0	2	4.0
Use of sterile gloves	49	98.0	1	2.0
Use of sterile syringes and needles	50	100.0	0	0.0

All the health care workers used 70% alcohol for skin disinfection and sterile needles before drawing of blood for blood culture. There were 48 (96.0%) of health care workers who washed their hands prior to wearing sterile gloves for drawing of blood for cultures.

Table 4.66 Distribution of adherence to infection control practices by health care workers when handling the sharps and disposal of sharps in the NNICU (n=50)

Practice	Yes		No	
	Number	Percentage	Number	Percentage
Recap before disposing syringes	9	18.0	41	82.0
Disposed syringes without separating the needle	50	100.0	0	0.0
Sharps disposed to sharp bins	50	100.0	0	0.0
Change of sharps from person to person	0	0.0	50	100.0
Sharp bins not filled more than 3/4	41	82.0	9	18.0

Hundred percent 100.0% (n=50) of health care workers disposed the sharps in to the sharp bins and all of them did not separate the needles from the syringes. No one (0%) changed the sharps from person to person whereas nine (18.0%) workers did the recapping of needles.

Table 4.67 Distribution of adherence to selected infection control practices in the NNICU (n=50)

Practice	Yes		No	
	Number	Percentage	Number	Percentage
Advice mother to hand wash before handling the baby	27	54.0	23	46.0
Supervision of hand washing of mothers	5	10.0	45	90.0
Advice mothers to hand wash after handling the babies	12	24.0	38	76.0
Supply of clean sterile cup for breast milk extraction	50	100.0	0	0.0

Twenty seven mothers (54.0%) were advised by nurses to wash their hands before handling their sick neonates in the NNICU. Only five mothers (10.0%) were supervised by the health care workers for hand washing.

Table 4.68. Distribution adherence to infection control practices by the health care workers when handling the blood and specimens with body fluids (n=50)

Practice	Yes		No	
	Number	Percentage	Number	Percentage
Place specimens in a leak proof container	50	100.0	0	0.0
Do not contaminate the outside of the container	41	82.0	9	18.0
Store specimen away from food and drinks	50	100.0	0	0.0
Transport specimens securely to prevent spillage	21	42.0	29	58.0

All (100%; n=50) placed the specimens in the leak proof container whereas nine (18.0%) specimens were contaminated outside the container. Only 42% (n=21) specimens were transported securely to prevent spillage.

4.4.3. Observation of the adherence to infection control standards by health care workers in selected procedures in the post natal wards (PNW)

The observation of the adherence to infection control standards by health care workers in selected procedures were carried out in each PNWs. The selected procedures were hand washing and the BCG vaccination. Ten observations were made for each procedure. There were eight post natal wards in the four hospitals studied. Therefore atotal of 80 observations were made for each procedure.

Table 4.69 Proportion of HCW who washed their hands before attending to the neonates (n=80)

Hand washing practice	Yes		No		Total	
	Number	(%)	Number	(%)	Number	(%)
Hand wash before attending to the neonates	66	(82.5)	14	(17.5)	80	(100%)

There were 66 (82.5%) health care workers who washed their hands before attending the neonates in the postnatal wards.

Table4.70. Distribution of selected aspects of practices in hand washing among those who washed hands before attending to the neonates in the post natal wards (n=66)

Practice	Yes		No	Total
	Number	(%)	Number (%)	Number (%)
Removed bangles	17	23.8	49	76.2
Used soap/liquid soap	40	60.8	26	39.2
Used hand rubs	26	39.2	40	60.8
Closed the tap (elbow operated/someone else)	35	49.0	31	51
Wiped hands after washing	38	84.0	28	16.0

Those who used hand rubs did not need to wipe out their hands. From those who washed their hands (n=40) two persons did not wipe their hands. Out of the 40 workers who used tap water for hand washing, 35 closed the tap by using their elbow or through someone else.

Table4.71 Distribution of adherence to hand washing steps among those who washed/applied hand rubs before handling the neonates in Post Natal Wards (n= 66)

Steps	Number	Percentage%
Over the surfaces of the hands	47	71.4
Back of the hands	61	92.7
Back of the fingers	48	72.9
Inter digital spaces	47	71.4
Thumbs separately	42	63.8
Tip of the fingers	40	60.8

Out of the 66 observations of hand washing and hand rubs 63.8% (n=42) did not wash thumbs separately and 60.8%, (n=40) did not wash the tips of the fingers.

Table 4.72 Distribution of adherence to infection control practices by health care workers when performing BCG vaccinations (n=80)

Practice	Yes Number	(%)	No Number	(%)
Hand washing before vaccination	62	77.4	18	22.6
Use of disposable needles	80	100.0	0	0.0
Discarding of needles without recapping	25	68.8	55	31.2
Dispose without separating needles	80	100.0	0	0.0
Dispose in to sharp bins	77	96.2	3	3.8
Change sharps from person to person	0	0.0	0	0.0
Washed hand after vaccination	80	100.0	0	0.0

Out of 80 observations, 62 (77.4%) of workers had practiced hand washing before starting BCG vaccinations whereas 100% of them washed hands after vaccination. Only 25 (68.8%) workers practiced to discard without recapping of needles. Sharps disposed into sharp bins done by 77 (96.2%) of the health care workers.

4.4.4. Observations of the adherence to infection control practices by health care workers in selected procedures in relation to neonatal care carried out in the operation theatres (OT)

The theatres where the caesarean sections were carried out were observed for selected procedures in relation to neonatal care. The selected procedures were hand scrubbing, use of theatre cloths, immediate neonatal care, umbilical cord care and hand washing. There were six operation theatres belonging to the studied four hospitals. As ten observations were made for each procedure, there were a total of 60 observations made for each procedure from all operation theatres.

Table 4.73 Distribution of adherence to infection control practices in selected procedures by health care workers before attending the caesarean section

Practice	Yes		No	
	Number	Percentage	Number	Percentage
Used nail brushes for the first hand scrub	50	83.3	10	16.7
Applied antiseptic solutions	60	100.0	0	0.0
Removed or did not wear jewellery	46	76.7	14	23.3
Hand held high while washing	56	93.3	4	6.7

The majority (n=50; 83.3%) of the health care workers have used nail brushes for the first time for the scrub. All workers used antiseptic solutions for hand washing. Out of those 46 (76.7%) removed or did not wear jewellery such as rings.

Table4.74. Distribution of adherence to infection control practices by health care workers in the following selected procedures before attending to the caesarean sections (n=60)

practice	Yes		No	
	Number	Percentage	Number	Percentage
Completely changed in to the theatre clothes	52	86.7	8	13.3
Caps properly covered the hair	55	91.7	5	8.3
Masks completely covered the nose and mouth	44	73.3	16	26.7
Wore double gloves	41	68.3	19	31.7
Masks changed after each operation	10	16.7	50	83.3

Fifty two (86.7%) health care workers had completely changed into the theatre clothes when they carried out caesarean sections. Fifty five (91.7%) and 44 (n=73.3) workers properly wore caps and masks respectively while carried out caesarean sections.

Table 4.75. Distribution of adherence to infection control practices by birth attendants when entering the Operation Theatre (n=60)

Practice	Yes		No	
	Number	Percentage	Number	Percentage
Completely changed into the theatre clothes	0	0.0	60	100.0
Changed the shoes when entering the theatre	60	100.0	0	0.0
Caps properly covered the hair	45	75.0	15	25.0
Masks completely covered the nose and mouth	41	80.3	19	31.7
Washed hands before wearing the gloves	20	33.3	40	66.7
Wore sterile gloves	60	100.0	0	0.0

All the birth attendants were public health midwives from the relevant wards. None of the birth attendants changed their uniforms when entering the surgical theatre. All (100.0%) the birth attendants changed their shoes when entering the theatre. Only 20 (33.3%) birth attendants washed their hands before wearing sterile gloves for handling the neonates.

Table4.76. Distribution of adherence to infection control practices by theatre nursing officers when assisting the caesarean sections (n=60)

Practice	Yes		No	
	Number	Percentage	Number	Percentage
Wiped eyes of the neonates immediately	46	76.7	14	23.3
Wiped mouth of the neonates immediately	50	83.3	10	16.7
Dried the baby immediately	49	81.7	11	18.3

As mentioned in Table 76 above, 76.7% (n=46) of assisting nursing officers wiped the eyes of neonates immediately and mouth was wiped immediately by 50 (83.3%) nurses. Baby was dried immediately by 49 (81.7%) nursing officers.

Table 4.77. Distribution of adherence to infection control practices by birth attendants when performing the neonatal care in the operation theatre (n=60)

Practice	Yes		NO	
	Number	Percentage	Number	Percentage
Changed or washed the gloves before cutting the umbilical cord	19	31.7	41	68.3
Clamped and cut the cord	59	98.3	1	1.7
Observed for oozing	43	71.7	17	28.3
Used sterile instrument	60	100.0	0	0.0
Application of substances over the stump	0	0.0	60	100.0
Discarded wet clothes immediately	52	86.7	8	13.3
Application of antimicrobials to the eyes	0	0.0	60	100.0

Only 19 (31.7%) birth attendants changed or washed their hands before cutting the umbilical cords. An observation for oozing was done by 43 (71.7%) birth attendants. Discarding of wet clothes was done immediately by 52 (86.7%) birth attendants.

Table 4.78. Proportion of neonates who received the following care practices from birth attendants (n=60)

Practice	Yes		No	
	No	%	No	%
Place the baby on the mothers abdomen or in her arms for skin to skin contact	6	10.6	54	90.0
Started breast feeding in the theatre itself	60	100.0	0	0.0
Brought caps and socks by mothers	38	63.3	22	36.7
Dressed neonates with - caps and socks washed before	26	43.3	34	56.7

All the neonates (100.0%) were started on breast feeding in the theatre itself whereas only six (10.6) of the neonates were kept in contact with the mothers skin inside the theatre. Thirty eight mothers (63.3%) had brought caps and socks for their neonates but only 26 (43.3%) of them had washed those before dressing up the neonates.

1. DISCUSSION

5.1. General

Scientific progress during the 20th century was responsible to reduce overall mortality rates, increase life expectancy, and decrease infant mortality rates. During this period, percentage decrease in rates of mortality has been highest for infants and children. The WHO studies reveal that more than two thirds of all new born deaths occur in term, well developed babies. Ensuring their survival does not require expensive technology but mere simple, cost effective preventive measures and prompt extra care which helps to reduce perinatal and neonatal morbidity and mortality. Developed countries enjoy better health indices.For example, the IMR in developed countries is low, being less than 10 per 1,000 live births compared with a range of 100 per 1,000 live births and greater in developing countries (WHO, World Report 2006). IMR in developed countries have dropped dramatically during the last few decades but not so in the developing countries. It is estimated that as many as 50% of such infant deaths could be prevented through simple interventions (Martines et al., 2005).

Therefore it is timely to identify the preventable causes for neonatal deaths and thereby reduce the infant mortality rates which would enable to achieve the MDG 4 in 2015. To achieve this, it is of utmost importance to receive accurate and current information on the causes of neonatal morbidity and mortality and thus reduce the adverse outcome. Out of the preventable causes of neonatal mortality, neonatal sepsis is one for which simple interventions are available. Therefore, it is important to find out the risk factors in local settings for neonatal sepsis. Although several studies (De Silva et al., 1998; Karunasekara et al., 1999; Rajindrajith et al., 2009) have been done previously on neonatal sepsis, and limited studies have been carried out in Sri Lanka to find out the risk factors for neonatal sepsis. Rajandrajith et al., (2009) analysed the causes for neonatal deaths during the period of five years from 2003 to 2007 and revealed that 20% of neonatal death were due to neonatal sepsis. Another study carried out by Fonseka et al., (1994) in the district of Galle found that 44% of infants died due to sepsis. The annual report of the Family Health Bureau mentions that 9% of infant deaths were due to sepsis and 70% of infants died during the neonatal period (Annul Report, FHB 2009). This study was undertaken as it is an important area which has not received much attention. The present study addressed the risk factors for neonatal sepsis, association between maternal postpartum depression and neonatal sepsis, maternal satisfaction of care provided through government health services and adherence of infection control standards by health care workers when performing procedures with neonates. The study contributes the evidence for health sector improvement to achieve MDG 4.

The study comprised of four components. The first component was a case control study and the other three components were descriptive cross sectional studies. Component II was designed to compare the postpartum depression of mothers of sepsis and mothers of non sepsis neonates. Component III was to assess the satisfaction of mothers with maternal and neonatal care provided through government health services. Component IV was designed to observe the adherence of infection control standards by health care workers when performing neonatal care.

5.2. Component I

Risk factors for neonatal sepsis

The methodology selected was a case control study to determine the risk factors for neonatal sepsis. There are different epidemiological approaches to identify the risk factors, namely, case control study, cross sectional analytical, cohort and experimental studies. When considering the different study designs they have both advantages and disadvantages unique to their methodology. The selected method was easy to perform and had the ability to examine a large number of predictor variables making it highly cost effective. It is less time consuming than the experimental and cohort studies. In the present study, one control per case was selected. The controls were selected from the same MOH areas as the cases, the main prerequisite of a case control study being that the controls should be representative of the population from which the cases arose. The other important aspect is that it is easy to eliminate the confounding factors by performing multivariate analysis. It also has the advantage of identifying risk factors with the optimal use of limited resources (Schlesselman, 1982). As both neonatal sepsis and risk factors had already occurred at the time the interviews were carried out there might be temporal relationships in case control studies. But in this study it was minimal as neonatal sepsis occurred during a short period of time and only the incident cases were recruited for the present study.

The risk factors can be detected by performing the cohort study design too. The cohort study takes longer time. It needs to follow up a large number of pregnant mothers until delivery to find out the risk factors of neonatal sepsis. The design needs a lot of resources and financial support too. Therefore the PI preferred the case control study tothe cohorts study.

There were several reasons for selecting Gampaha district for the present study. It has five neonatal intensive care units representing both tertiary and secondary care hospitals. Although there are many neonatal intensive care units in the Colombo District, they mostly attend to neonates transferred from other parts of the country. Therefore the residence of the mothers would be from various parts of Sri Lanka and it might be very difficult to find controls for those neonatal sepsis cases. The other favourable factor was that nearly 10% of the total deliveries in Sri Lanka occurred in the Gampaha District. In the year 2007, out of 380,000 total deliveries in Sri Lanka 36,000 births took place in the Gampaha District (Census and Statistics, 2007) The district of Gampaha was familiar and easily accessible to the PI which enabled to optimally monitor and supervise all activities. This played a vital role in the successful completion of the research project. All these reasons would have improved the quality of data. For the study, cases were selected from the hospitals and controls were selected randomly from the community enabling to enhance the external validity and the generalization of the study findings to the entire district of Gampaha.

The ethnic distribution of the Gampaha District - 91.0% Sinhalese, 3.6% Tamil, 3.8% Moors and 1.7% of others - was fairly represented in the sample selected being 93.1% Sinhalese, 2.7%, Tamils 4.0% Moors and 0.2% of others. It may be noted that as the instrument EPDS scale was in Sinhalese, one of the exclusion criteria for the participants was the inability to understand the Sinhala language. Despite this, there were 32 non Sinhalese mothers who understood the Sinhala language and therefore participated in the study. Although it was possible to obtain a sample with an ethnic distribution comparable to that of the district, non-Sinhalese participants might have answered the questions in the EPDS questionnaire differently. Therefore it was one of the limitations of the study.

There was a scarcity of similar kind of studies conducted locally to obtain a realistic Odds Ratio to calculate the sample size for the risk factors in the current literature. Therefore, Odds Ratio for risk factor of low birth weight from a similar kind of study conducted in the UK was taken to calculate the sample size for this study (Khalid et al., 2004). The prevalence of LBW which is a relative frequency of exposure among controls was taken from the Sri Lankan figures. The sample size with a confidence level of 95% and a power of 80% was selected as appropriate (Lawanga and Lemeshow, 1991). The adequacy of the sample size was reflected in the present study by the narrow 95% CI of interval of risk factor of LBW (OR=4.21; 95% CI=2.52-7.00) for neonatal sepsis. The sample size was calculated using the standard formula for the case control study (Schlesselman, 1982).

Initially, a comprehensive literature review was conducted to gather information on different forms of definitions for neonatal sepsis. The gold standard for the diagnosis of neonatal sepsis is either a positive blood culture or CSF culture (Vergano et al., 2005). But it is very difficult to take one laboratory as the reference laboratory and do all the blood cultures of neonates in a uniform way. It is very costly and involves a lot of logistic issues and beyond the scope of this type of study at this stage. The other important matter is that in clinical practice there were neonates with negative blood culture reports with severe sepsis and vice versa (Rashid et al., 2006).

It was difficult to find out a case definition for neonatal sepsis as practices are different in the clinical setup. In clinical practice, neonatal sepsis is diagnosed clinically by consultant paediatricians after clinical assessment of the neonates. However in research, there might be subjective variations on clinical diagnosis among the paediatricians. Therefore the necessity for a uniform method to recruit the neonates as cases was highlighted. This issue was overcome by using the WHO strategy on Integrated Management of Childhood Illness (IMCI)for diagnosis of neonates with severe bacterial infections. The Integrated Management of Childhood Illness was prepared after conducting multicentre study by WHO (section 2.2.3) on clinical features to diagnose severe bacterial infection. The same clinical features were adopted by the Family Health Bureau to use in Sri Lanka through an expert panel (WHO, IMCI, 2005; FHB, IMCI 2006). The sensitivity and specificity of the tool was 85% and 75% respectively. The IMCI strategy was adopted by more than 75 countries and is being used successfully (WHO Hand book of IMCI, 2005). With these criteria the present study showed that 47.9% of neonates with sepsis presented with a single sign and 37.9% of neonates with sepsis presented with two clinical signs. As a significant proportion of neonates presented with a single clinical sign it was appropriate to identify a case by one clinical sign.

Paediatric house officers who examined the neonates for clinical features had completed their internship and had also received training on neonatology. These doctors were not involved in the data collection of the research. Therefore the selection bias that could occur with selection of cases was minimized.

In the present study cases were selected from the hospital and controls were selected randomly from community from the same MOH area of the case. According to Rothman & Greenland the external validity of the study could be strengthened by selecting cases as similar as controls in all characteristics except for the outcome (Rothman & Greenland, 1996).

Non response which is a type of selection bias also affects the external validity of the study. The non response rate for cases was (0.4%) as one mother was in a critical state when recruited for the study and died later. Three more mothers (1.2%) did not answer the satisfaction questionnaire and depression scale as their babies died while being treated, whereas five mothers who had lost their babies participated in the study. Therefore non participation of this small number of mothers would not have been a significant effect. All selected controls (100%) participated in the study. The sample size incorporated an allowance for non response and because of the low non response (0.4%) rate no additional recruitment of respondents was required. This ensured the external validity of the study enabling the results to be generalized.

The inquired risk factors and other information from mothers were obtained within a short period of time. That is, the events that happened during the pregnancy period and perinatal period. Both pregnancy and perinatal periods were same for controls too. The majority of risk factors could be cross checked with the documented data. The data were extracted from the documents such as pregnancy records, diagnosis cards and BHTs. Therefore recall bias of the participants were minimized.

Interviewer bias has been eliminated in the manner in which the study was conducted. In this respect, all data collectors were pre-intern doctors from the same medical faculty. The data collectors were given prior training on the important aspects of data collection and they were provided with written guidelines (Annexure XI) to ensure uniform administration of the questionnaire that were interviewer administered. An IAQ was considered preferable to a SAQ because respondents were from different socio demographic categories and the way they understood the questions may have differed depending on their socio economic status. Therefore the response rate and completeness of the responses were enhanced with the IAQ than the SAQ. The IAQ has a further advantage of allowing the respondent an opportunity to clarify doubts if needed. The IAQ I, which was developed after extensive literature review and socio demography was drawn from the questionnaires used in other studies including the Demographic Health Survey 2006/2007. The draft questionnaire was reviewed by experts in the field for relative appropriateness of wording used and acceptability to the local context. The majority of questions were close-ended which made the provision of responses and the analysis of data easy. As data collectors were pre interns, they were familiar with BHT, and it was easy to gather correct data. Some of the relevant data was also cross checked with the mother's information such as time of admission to the hospital, number of vaginal examinations, and hours of staying in the labour rooms.

The three data collectors being female was an additional advantage as they had to interact with the mothers. When considering the mothers of sepsis neonates, there was enough time to get information leisurely once the mothers finished the breast feeding and milk extraction and also they remained in the hospital for more than 6-7 days. When considering the controls, the mothers were at home and data collection was done leisurely. Even if the data collectors happened to miss any information, there was time to get the relevant data filled. The data collectors and PI residing in Gampaha District was an additional advantage in data collection.

Data collection was done under the close supervision of the PI. Interviewer bias was minimized by training interviewers to ensure uniformity in eliciting and recording of data. All instruments were pretested and thereby enhanced the smooth collection of data by refining questions and minimizing ambiguous wording and sorting out practical problems in its applications.

A comparison of data collection by data collectors and the PI was carried out. The inter observer variability was measured by Kappa coefficients and the range of Kappa from 0.65-1.0 confirmed good reliability among data collectors.

Informed consent was taken prior to data collection which is an important ethical requirement in terms of autonomy. Each respondent was briefed by data collectors on the purpose of the study. Confidentiality of information was also ensured. The contact details of the PI were issued to each respondent in case they wished to seek clarification.

Bivariate analysis followed by multivariate regression analysis to adjust for confounding was used to identify the risk factors for neonatal sepsis. The reduction of number of significant variables of the case control study from 20 in the bivariate to 11 in the multivariate analysis showed the degree of systematic error (bias) that would have effected due to the presence of confounding factors. In addition the magnitude of four ORs were reduced during the multivariate analysis, which also showed the ability of multivariate analysis to take control of distorted effect measures that occurs due to the presence of confounding. In the multivariate analysis the final model was able to predict 71.6% of the variance of neonatal sepsis which indicate that the majority of the variables determining the neonatal sepsis have been identified after controlling the confounding factors.

5.2.1. Maternal risk factors for neonatal sepsis

5.2.1.1 Antenatal risk factors

The antenatal clinic registration after eight weeks of gestation

In Sri Lanka pregnant mothers are being registered in field antenatal clinics before eight weeks of gestation since 2007. Prior to 2007 the antenatal clinic registration was done before 12 weeks of gestation. It was identified that the early registration for antenatal care was beneficial for both mother and baby. This study revealed that those mothers being registered after eight weeks of gestation in the antenatal clinics was a risk factor (OR=1.91; 95% CI: 1.07-3.44) for neonatal sepsis in their neonates. The Family Health Bureau data revealed that more than (66%) of antenatal mothers were registered in the ANC before eight weeks of pregnancy (FHB, Annual Report on Family Health, 2007). However there were mothers registered in the private clinics and followed up at private clinics. These categories of mothers were not included in the present study. Data regarding this group might not be included in the FHB data. In the UK, Adair et al., found that lack of adequate prenatal care was not a significant risk factor (OR=0.91; 95% CI: 0.26-3.16) for neonatal sepsis. In their study they considered only the group B streptococcus sepsis of neonates and the adequacy of prenatal care was measured by the number of antenatal clinic visits, the time of registration at antenatal clinic and the type of hospital served (Adair et al., 2003) while this study considered the all types of neonatal sepsis and the time of registration and total number of antenatal clinic visits. This difference may have caused prenatal care as an insignificant result for risk factor (OR= 0.91, 95% CI; 0.26-3.16) for neonatal sepsis.

Lack of antenatal clinic attendance

Eight maternal risk factors for neonatal sepsis were found after multiple logistic regression analysis. Out of those the lack of antenatal clinic visits four or less than four times, was a significant risk factor OR= 7.17; 95% CI: 2.10-24.49) for neonatal sepsis. In Sri Lanka for the majority of mothers the main source of antenatal care was the field antenatal clinics. The number of average ANC attendance was seven visits (FHB, Annual Report of Family Health 2007). Mothers who failed to attend to antenatal care are likely to miss the routine screening tests for infections such as urinary tract infections. Diseases like diabetes will not be diagnosed early nor would they get health education regarding delivery and early neonatal care. All these reasons may increase the risk for neonatal sepsis of their neonates. In Uganda, Mugalu et al., (2006) also found the same risk factor as a significant risk factor (OR=2.39; 95% CI: 1.05-5.49) for neonatal sepsis by a case control study. In that particular study cases for neonatal sepsis were recruited according to the WHO strategy of IMCI.

Bad obstetric history

Bad obstetric history namely, history of abortions, stillbirths and early neonatal deaths were risk factor (OR= 5.78; 95% CI =3.01-11.10; p=0.001) for neonatal sepsis than those who did not have a bad obstetric history. Frequency distribution of data also showed 56 mothers with history of abortions, neonatal deaths and still birth among the cases whereas only 12 mothers were among the controls. As post mortems were not performed for all still births and neonatal deaths, causes for previous neonatal deaths and still births were not identified. There might be some recurrent infections associated with these events. A case control study carried out in Canada by Adair et al also studied those factors with group B neonatal sepsis and did not find significant association with history of therapeutic abortions OR=0.04 (0.08-1.30), still births OR=0.49 (0.01-3.48) and spontaneous abortions OR=1.34 (0.76-2.35) (Adair et al., 2003). Their study was confined to the culture positive group B streptococcal sepsis and not on clinical neonatal sepsis.

History of maternal fever

In the present study it was found that the mother having a history of fever during the last one week of delivery of neonate or while delivering the neonate was a risk factor (OR=2.74; 95% CI: 1.25-6.02) for neonatal sepsis. This shows that indication of active disease by fever that was manifest during labour or before labour is a significant risk factor. In Staphine et al (2005) found that intra partum fever was a significant (OR=7.2; 95% CI: 4.3-12.2) risk factor for neonatal sepsis in his case control study. Adair et al also found that maternal fever was a significant risk factor in Canada (OR= 2.64; 95% CI: 1.34-5.23) for neonatal sepsis for group B streptococcal sepsis in neonates. Maternal fever may be due to various reasons such as chorioamnionitis, endometritis and urinary tract infections. Current study also revealed similar results which the other studies have previously discovered.

Vaginal examinations more than three times

The number of total vaginal examinations being more than three times before delivery was a risk factor (OR= 3.28; 95% CI: 1.95-5.53) for neonatal sepsis in spite of whether the membranes were ruptured or not. This is consistent with finding of Dutta et al (2009) and found that per vaginal examination more than three times was a risk factor (OR=9.52; 95% CI: 2.96-30.53) for neonatal sepsis in India. It was a prospective cohort study conducted in tertiary care hospitals in India. In this study there were 601 cohorts of neonates were followed up and 85 were diagnosed of having neonatal sepsis. Once labour was started the vaginal examination carried out once in four hours and assessed the progression of labour by cervical dilatations. Repeated vaginal examinations increase the chance of introducing bacteria from the external environment into the birth canal and thereby cause neonatal infection. The number of vaginal examinations can be minimized by adhering to standard protocols and guidelines.

Meconium stained amniotic fluid

The present study revealed that the meconium stained amniotic fluid was a risk factor (OR=10.57; CI=3.75-29.74) for neonatal sepsis. Experiences on chronic hypoxia, by foetus may result in the passage of meconium in utero. At the time of delivery, gasping by the foetus or newborn infant can cause aspiration of amniotic fluid contaminated by meconium and cause meconium aspiration syndrome. Analysing the 301 of meconium aspirated neonates in Castle Street hospital, found out that 1/6th of them developed neonatal sepsis (Lucas & Rankothge, 1995). In Mexico Leal et al., (2012) in cohort study revealed that the meconium stained amniotic fluid caused a three times risk of neonatal sepsis than clear liquor (RR =3.5; 95% CI: 1.1-1.9). Once the meconium is aspirated into the lung tissues it irritates the lung tissues and will cause pneumonitis. This condition will lead to secondary bacterial infection and cause pneumonia for the neonates.

Premature rupture of the membranes

Premature rupture of the chorionic membranes more than 18 hours before delivery of neonate was one of the important risk factors for neonatal sepsis (OR=10.0; CI: 2.12-47.44) p=0.004). Throughout pregnancy and until membranes rupture the foetus is relatively protected from the microbial flora of the mother by the chorioamniotic membranes, placenta and the antibacterial factors in amniotic fluids. Once the integrity of the membranes is disturbed, it can permit skin or vaginal organisms to ascend and produce inflammation of the foetal membranes causing secondary foetal infections. This same finding was supported by Oddie et al (2002) in UK. They showed that the rupture of the membranes for more than 18 hours before delivery was a significant (OR=13.7; CI: 4.8-39.5) risk factor for neonatal sepsis. Another study carried out in Israel (Shah et al., 2006) found out that dribbling >18 hours was a significant (p=0.019) risk factor for neonatal sepsis. Staphinie et al (2005) in California, Georgia and Connecticut find out from a retrospective case control study that rupture of the membrane > 18 hours was significant (OR=7.8; 95% CI: 5.2-11.6) risk factor for neonatal *E.coli* sepsis. In a retrospective cohort study conducted in Mexico by Leal et al (2012) also found that PROM more than 24 hours was a risk factor (RR=3.5; 95% CI: 1.8-6.6) for neonatal sepsis. Initial colonization of the neonates usually take place after rupture of the maternal membranes and the ascending of vaginal bacteria will cause neonatal infections (Claudio et al., 2004). Although the previous studies were done on bacteriological confirmed cases of neonatal sepsis, and the current study was done on clinical diagnosis of neonatal sepsis, dribbling was found as a common risk factor.

Mode of delivery of neonates

In the present study the mode of delivery other than the NVD, such as vacuum, forceps deliveries and caesarean sections was a risk factor (OR=2.33; CI: 1.40-3.86) for occurrence of neonatal sepsis. In government hospital setting (Fig 2) vacuum extractions, forceps deliveries and emergency Caesarian sections are usually carried out in an emergency situation. Therefore the indications for those deliveries need to be analysed to find out the true association with neonatal sepsis. Sample size for this particular study might not be adequate for individual analysis of those factors as the objective of present study was different. In a previous study carried out in a tertiary care hospital of Sri Lanka also revealed that the instrumental deliveries were significantly ($\chi2=31.04$; $p<0.0001$) associated with neonatal sepsis (Karunasekara et al., 1999). Though it was stated the significant factors as "risk factors" the credibility of the results are low as it was a cross sectional descriptive study. Staphanie et al also concluded that in a case control study delivery by caesarean section was a risk factor OR=2.4; 95% CI: 1.7-3.5) for neonatal *E. coli* sepsis (Staphani et al., 2005). However mode of delivery per se is difficult to interpret as a risk factor for neonatal sepsis without analysis of indication for forceps, vacuums and caesarean section deliveries separately.

Socio demographic factors

Mother's age, ethnicity, religion, education level, civil status, occupation and total family income were studied as socio demographic factors for present study.

The bivariate analysis showed that the neonates of mothers with education level less than O/L is 2.22 (OR=2.22; 95% CI 1.28-3.84) times more prone to get neonatal sepsis than those who got through O/Ls and above qualifications (Table 4.17). But the same variable was not a significant risk factor with multivariate analysis. Other socio demographic factors such as teenage pregnancy, elderly mothers, ethnicity, religion, family income, civil status and mothers' occupation were not found as significant associations with neonatal sepsis from the present study. Same findings were there by Adair et el who found that socio-demographic factors were not risk factors for neonatal group B streptococcus infection in a case control study in Canada (Adair et al., 2003). In Isreal, Salam et al found that advanced maternal age was a significant risk factor for neonatal sepsis (p=0.017). The present study did not show significant association with both variables - for advanced maternal age OR=1.10 (0.59-2.02) and teenage mothers OR=0.92 (0.44-1.97) as a significant risk factor for neonatal sepsis. The absence of a relationship with socio demographic factors and neonatal sepsis could be most likely due to relatively homogeneous study group in the present study and the universal availability of free health care in Sri Lanka.

5.2.2. Neonatal risk factors for neonatal sepsis

Low birth weight of neonate

Low birth weight was also found to be a risk factor for sepsis in new born babies. In Sri Lanka any neonate less than 2500 g is considered as low birth weight. The neonates with less than 2500 g birth weight were five times at risk of getting sepsis than neonates with more than 2500 g of birth weight (OR=5.17; 95% CI: 2.79-9.57). In India it was found that birth weight of less than 1500 g was a risk factor (OR=2.79; 95% CI: 1.54-5.09) for neonatal sepsis. The results are similar to observations of Karunasekara et al (1999) in her study which also found that birth weight less than 2500 g was a significant risk factor (χ^2 =25.2;$p< 0.0001$) for neonatal sepsis (Karunasekara et al., 1999). Khalid et al (2004) in their study in the UK also concluded that neonates with birth weight of less than 2500 g had more risk OR=2.2; 95% CI:1.1-4.6) in getting sepsis. Birth weight is a basic biological determinant of neonatal outcome. The low birth weight is associated with poor immune system and may cause neonatal sepsis than in normal birth weight neonates.

Being a male neonate

Male gender was another significant risk factor for neonatal sepsis. In the present study being a male neonate was a risk factor (OR=1.7; 95% CI: 1.09-2-78) for neonatal sepsis than a female neonate. Dutta et al in their research also found that the male sex was a risk factor (OR=2.70; CI: 1.55-4.70) in India for neonatal sepsis. Mugalu et al (2006) also concluded that male sex was a risk factor OR=1.96; (95% CI: 1.17-3.29) for neonatal sepsis in Uganda. Although not a significant risk factor, there were a number of studies with male predominance in which a male:female ratio for neonatal sepsis was 1.27:1 (Isaacs, 2003) 1.4:1 in Taiwan (Jiang et al., 2004) and 11:6 in UK (Placzek and Whitelaw, 1983). Sepsis associated deaths are also high in the USA among male neonates than female neonates (Stoll et al., 1998).Although many studies shown an association between male sex and neonatal sepsis a valid hypothesis was not revealed among them.

Time of birth of neonates

Considering the time of birth of the neonate, between 4 p.m. to 8 am of following day was a risk factor (OR=2.12; 95%CI: 1.29-3.47) and more likely to get neonatal sepsis than those born during the day. Patho-physiological explanations for this association are not found in literature. Only favorable finding was diurnal variation of hand washing practices among health care workers. In a study carried out in ICU of tertiary care hospital in India, observed diurnal variation of hand washing compliance among health care workers. In this study it was shown the hand washing practices in day and night shift was different. In the night shifts they had poor compliance. During the day time no hand washing was practiced by 27% of health care workers and in the night shifts no hand washing was practiced by 55% of the staff (Sahay et al., 2010).

The manpower allocation was not equal in the day, evening and night shifts. The normal working hours are considered to be from 8 a.m. to 4 p.m. daily for the doctors, and 4 p.m. onwards was considered as on-call hours. For the nursing officers, midwives and minor staff there were three shifts for a day. However during evening and night shifts it was observed that manpower allocation was less than day shifts. This was also being an added factor for the present study finding. It needs more detail research to find out whether the emergencies were attended at correct time by the service providers after 4 pm.

In the current study Staphylococcus aureus dominated the blood culture isolates (62.8%) including Staphylococcus *aureus* (26.4%), Methicillin Resistant *Staphylococcus aureus* [MRSA, (14.6%)], and Coagulase negative staphylococcus (21.8%). These organisms invade from the environment rather than the maternal normal vaginal flora. Therefore it indicates that the majority of infections can be prevented from practices of proper hand washing by adherence to infection control standards and guideline by all health care workers. Mugalu et al (2002) had the similar finding in a study carried out in Uganda by recruiting neonatal sepsis cases according to IMCI strategy. They also found that *Staphylococcus aureus* (62.7%)was the most common organism that caused neonatal sepsis in their neonates.

The majority 233 (97.2%) of cases identified as neonatal sepsis in current study were diagnosed as neonatal sepsis 95 (40.3%), meningitis 56 (23.3%), septicaemia 29 (13.1%) and pneumonia. 24 (10.0%) which could be ultimately considered as neonatal sepsis. This finding confers with the case definition of "single clinical sign" for identifying neonatal sepsis. Out of those neonates one neonate presented with convulsions and was diagnosed as Dandy Walker Syndrome and six (2.4%) more neonates were investigated for fever and not given a proper diagnosis.

5.3. Component II

Maternal postpartum depression

The second component of the study aims to identify any association between the maternal postpartum depression and sepsis of their neonates. The descriptive cross sectional design was used for this component. Cross sectional studies can also be used for examining associations. "The choice of which variables to label as predictors and which as outcomes depends on the cause and effect hypotheses of the investigation" (Hulley et al., 2001). The mother's mental status might be affected due to their newborn's illness. It was found that the prevalence of postpartum depression is around 32% in Sri Lanka in district of Puttalam (Rowel, 2004) and 31.6% in Gampaha (Rathnayake, 2011). Both researchers used the Sinhala version of validated EPDS scale to assess the postpartum depression. The known prevalence of current depression in adult women in the primary health care setting was 10.4% (WHO, 2001). One Meta analysis showed the prevalence of non psychotic postpartum depression was 13 % (O' Hara et al., 1996; Frideman et al., 2011).

The available scales or tools to assess the psychological status or depression levels in the population are the Mini Neuro Psychiatric Interview, Structured Interview Guide for the Hamilton Depression Scale (HDS), Beck Depression Inventory (BDI), Centre for Epidemiological Scale - Depression (CES-D), Brief Symptom Inventory (BSI), Hospital Anxiety and Depression Scale (HAD) and Montgomery Aspers Depression Rating Scale (MADRS). None of these scales were validated to use in postpartum mothers in Sri Lankan culture and context. Therefore the translated and validated Sinhala version of EPDS (Rowel, 2004) which had gained wide acceptance in other cultures too, was used to assess the status of depression of individual postpartum mothers. It is simple and less time consuming. The cut off value chosen by Rowel was ≥9 with sensitivity of 90%, specificity of 79% and intra class correlation coefficient of 0.96.

Sample size was calculated according to the Sri Lankan prevalence study. Maternal depression for sick neonates was (OR=2.1; 95% CI: 1.2-3.4) taken from Rowel's study.

As the Sinhalese translation of EPDS was validated the same tool was used in present study too. As it was a self administered questionnaire, the interviewer bias which occurred in administration was excluded. The already found risk factors (Rowel, 2004, Rathnayake, 2011) and correlates for postpartum depression were evaluated for the same group of mothers by using IAQ II. Therefore IAQ II was prepared to assess the other well known correlates or risk factors for postpartum depression of this particular group of mothers. The draft IAQ II consisted of significant correlates for postpartum depression found by other studies (Chandran, 2002; Rowel, 2004). Two experts of psychiatry and two experts in community medicine reviewed the IAQ II to ensure the content and face validity. To minimize the recall bias the variables included in the IAQ II were limited only for the pregnancy period. Only four mothers did not answer to the EPDS scale and IAQ II. Out of four, one mother passed away and in the other three mothers their neonates passed away. There were four mothers who lost their neonates during the study period but they volunteered the IAQ II and EPDS. Therefore the mothers who responded were not different from the non-responded group of mothers.

By performing multiple logistic regression analysis the confounders were controlled and the internal validity of the study was enhanced. Out of five significant associations in bivariate analysis only one factor, neonatal sepsis was found as the risk factor for maternal postpartum depression.

In the present study it was revealed that the presence of maternal depression among the mothers of neonatal sepsis neonates was 78.4% whereas postpartum depression among the control group was 21.6%. It was statistically significant (OR=14.03; 95% CI: 8.64-22.80: p=0.001). Shaw et al 2014 revealed in a study carried out at a California tertiary care NNICU that 77.8% mothers were positive for symptoms of depression, anxiety and trauma. Another study carried out in Turkey revealed using the same EPDS that 29.5% of NNICU group mothers were depressed whereas in control group it was 13.6% (Yurdakul et al., 2009). It was statistically significant ($p< 0.005$). But in this study the cut off level for EPDS score was 13. The difference of PPD among the mothers observed could be due to different cut off values used in EPDS in different studies.

By using another study instrument called Patient Health Questionnaire (PHQ- 9) in Ghana, among the mothers of hospitalized infants in NNICU it was found that 70% of mothers had postpartum depression (Gold et al., 2013). The PHQ-9 was widely used in Ghana to assess postpartum depression (Weobong et al., 2009; Foster et al., 2008).

Postpartum depression assessed by using the Beck Depression Inventory (BDI) among mothers who deliveredpremature neonates in Nigeria found that 15.1% of mothers were depressed with preterm neonates in NNICU than the term neonates (3.7%). (Ukpong et al., 2003)

It was not found the association between socio demographic factors and postpartum depression of the mothers from this study. The factors studied were the age of mother (OR=0.95; 95% CI:0.45-2.01,p=0.88)), Ethnicity (OR=0.84; 95% CI:0.41-1.70, p=0.0.62), religion [OR=0.69; 95% CI:0.44-1.07,p=0.09), education level of the mother (OR=1.31; 95% CI:0.77-0.22,p=0.31), occupation status of the mother (OR=0.88; 95% CI:0.56-1.38,p=0.58) and income status (OR=0.89; 95% CI:62-1.28,p=0.53) of the family. Similar findings (Yurdakul et al., 2009) revealed that there were no significant association between socio demographic factors namely maternal age (p<0.09), education level of mothers (p<0.30), and working status of mothers (P< 0.82), (Yurdakul et al., 2009) and the postpartum depression of mothers of neonates admitted to NNICU. Charter et al (2005) also in his case control study carried out in New Zealand found that maternal depression with NNICU admitted neonates was 22%. He also used the EPDS questionnaire to assess postpartum depression. The total score of 12.5 was used as cut off point for depression. The difference between cut off point for EPDS scale may underestimate the cases of depression when compared to the present study.

The significant correlates for prevalence of postpartum depression revealed by Rowel namely lack of social support (OR=1.51 (0.25-9.14; p<0.65), lack of support from the husband (OR=1.51 90.25-9.14; p<0.65), history of abuses by husband or other persons (OR=0.49 (0.45-0.54p< 0.08), having economic hardship (OR=0.49 (0.45-0.54); p<0.03) and death of close relatives (OR=2.57[(0.49-13.35) p< 0.25) were not found as significant correlates for present study group. Only the neonatal sepsis was a highly significant (OR=14.03; 95% CI: 8.64-22.80 p= 0.001) independent risk factor for maternal depression. The difference in findings may be due to study settings in which they were carried out; Rowel's carried out a descriptive study among postpartum mothers in the community whereas present case control study was carried out for cases in hospital and from controls in community. Other main differences between the two studies were the time of administration of the EPDS questionnaire. In Rowel's study the EPDS questionnaire was administered after six week of post natal period where as present study EPDS administered within two weeks of delivery to postpartum mothers.

In India, also it was revealed that infants admitted to hospitals (RR=4.5; 95% CI: 3.2-6.4) and infants who had fever (RR=1.7; 95% CI: 1.1-2.8) were significant factors associated with postpartum depression of mothers. Inandil et al (2002) in that study also revealed that mothers whose babies were having health problems had a higher risk (OR=1.7; 95% CI; 1.3-2.2) of being depressed.

The actual proportions of depressed mothers were difficult to compare in different studies due to use of different scales and tools. Even with the same scale like EPDS, the cut off scores to define depression were different in various studies. Nevertheless there was sustained evidence in literature to support the present study findings.

5.4. Component III

Maternal satisfaction on care provided to mother and neonate

Patient satisfaction is considered to be a vital component in the evaluation of the quality of care provided to the client (Goodman et al., 2004). Therefore parent satisfaction with health care can be used as a good proxy measure for quality of care provided for their neonate. Although there has been delivery of free health care to every person in the country by successive governments since independence, it is important to evaluate the satisfaction of service delivery from time to time. But it seems to be lacking in government health care settings. However we have creditable health indices in comparison with other countries with relatively low per capita income.

Parent satisfaction on health care was associated with improvement in their child's clinical status and, understanding of information given by health care workers (Matziou et al., 2011). However in the current study only mothers were involved instead of both parents, therefore only mothers were interviewed regarding the satisfaction of care received by them and their neonates.

A descriptive cross sectional study was carried out among the mothers of neonates who were diagnosed with neonatal sepsis. It was decided to interview all mothers of neonatal sepsis cases regarding neonatal care and maternal care they received once decided to discharge from the hospital. At this stage a mother would have been exposed to all service components and is in a better position to provide accurate responses. Therefore satisfaction regarding care provided to their sick neonates and care provided to the mothers at the time of discharge from the hospital were assessed. Level of satisfaction is subjective and that is sensitive to the external factors and thus likely to fluctuate within short periods of time.

There were very few studies that have assessed various aspects of patient satisfaction in the government hospital setting in Sri Lanka. It was difficult to find a validated instrument to measure patient satisfaction among those limited studies (De Silva and Darmage, 1996; Senarath et al., 2004; Goonawardena, 2002) carried out in Sri Lanka. In literature there were three instruments mainly used for patient satisfaction namely, SERVQUAL; Validated Patient Satisfaction Scale by the Picker Institute; and other tools designed or validated by the respective authors. Basically all these instruments will assess accessibility, convenience, information, communication, empathy, cleanliness, and satisfaction with regards to food, medical and nursing care and hospital environment (Dayasiri et al., 2010). Senarath and Gunawardena, (2011) validated a questionnaire to measure patient perception of the quality of nursing care and related hospital services. The validated instrument consisted of interpersonal care, efficiency in service provision, competency, physical environment, cleanliness and provision of personalized information. The items used in a study by Senarath, (2004), included the interpersonal aspect, technical aspect and availability of physical facilities.

The study instruments for the present study was designed and adopted by the PI according to the questionnaire used in other studies for patient satisfaction both in local setting (Senarath 2004, Goonawardena, 2002) and international setting (Ygge and Arnetz, 2001). The questionnaire was a simple version which can be administered easily. It covers the information, competencies and skills, communication, courtesy of staff and recommendation of the institution in future episodes of illness. The questionnaire was an interviewer administered and consisted of twenty items with five point Likert type scale. Its face validity, content validity and comprehensiveness were ensured by experts, involved in the same type of studies.

The interview was conducted when the mother and neonate were decided to be discharged from the hospital. That was better practical situation to assess the mothers' satisfaction. As these interviews were conducted in the hospital premises, mothers may have reported more positive perceptions of the services and greater satisfaction than they actually felt. This is because they might believe that while in hospital positive comments are more appropriate and they are reluctant to express dissatisfaction to a certain degree. Therefore it leads to a degree of underreporting of deficiencies and their dissatisfaction regarding care. This issue was highlighted by the previous authors (Sitzia and Wood, 1997). This underreporting was minimized in the present study by carrying out an exit interview. These biases were minimized by explaining the purpose of the study and ensuring the anonymity and confidentiality of the information provided. Furthermore interviews were carried out in a place where there was no access to health care workers.

The data collectors were the same pre-intern doctors and trained for the purpose as described above in the case control section (section 3.1.11). Clarifications of questions were done for the participants when required. Bivariate analyses were carried out to clarify whether the satisfaction of mothers were due to some other factors such as socio demographic, maternal and neonatal factors or purely due to the services provided by the health system.

5.4.1. Maternal satisfaction regarding neonatal care

The satisfaction component of the present study shows that the overall satisfaction of the mothers regarding neonatal care was 90%. Health staff introducing themselves before corresponding with patient is not usually practiced in Sri Lanka. Therefore the satisfaction in that item was indicated as a highly dissatisfied (92%) score. Eighty six percent of mothers were satisfied with the information received regarding their neonate's illness and investigations. The information given was understood by 92% of mothers. In Greece a cross sectional descriptive study by recruiting 214 parents carried out a satisfaction survey. For that study they used Pyramid Questionnaire and shown that provision of information about child's illness 94.8%, understanding of given information 85.4% and maternal satisfaction on the treatment received by neonates was 94.6% (Matziou et al, 2011). According to De Silva & Darmage, (1996), maternal satisfaction for treatment they received in the tertiary care hospital in Sri Lanka was 91.1% (De Silva & Darmage, 1996). Satisfaction with the opportunity to ask questions when they provide paediatric care in the present study was 95%.Whereas Senarath, (2004) found that 47.9% of mothers expressed their satisfaction regarding the opportunity given to them to clarify their doubts regarding the care of the newborn which was a low figure compared to other studies.

The proportion of mothers satisfied regarding the kindness of doctors was 90.0%. De Silva in his study carried out in 1999 revealed that 98.6% were satisfied with the doctor's attitude towards their sick child. Total satisfaction regarding information and communication of neonatal care were 83.8% and 90.8% respectively. Overall satisfaction on the kindness of staff was 92.5% whereas kindness of consultants, medical officers, nursing officers and minor staff were 80.4%, 90.9%, 94.6% and 92.9% respectively. In Senarath's study it was 95.1% for medical officers and 92.6% for nursing officers in Puttlam district. Even in England the mothers were satisfied ($p<0.001$) more when their neonates were examined by midwives rather than senior house officers (Wolk et al., 2002).

In the present study 94.6% mothers said that they will come back to the same institution for any future episodes illness of their children. This showed the confidence on the government health services by the clients. According to De Silva's finding, 77% of mothers mentioned that they will come back to the same institution for any future episodes illness of the child.

5.4.2. Maternal satisfaction regarding maternal care

Maternal overall satisfaction regarding the care provided to mothers while they were staying in the obstetric wards was 84.6%. Goonawardena, (2002) found that in Kalutara District there were 98.4% satisfied with the total maternity care provided by the hospital while altogether 76.2% were satisfied regarding the sanitary facilities provided during their hospital stay. Goonawardena carried out her study in primary care hospitals of Kalutara district wheras present study conducted in secondary and tertiary care hospitals of Gampaha district. Senarath, (2004) found that only 35% of mothers were satisfied regarding the toilets and water supply of the maternity wards in Puttlam district. In the present study the satisfaction of mothers regarding toilet facilities were69.9%. The proportion of mothers satisfied with the cleanliness of the wards was 86.3% and in Senarath's study the satisfaction on cleanliness of wards was 70.4% and in the Kalutara District by Goonawardena, (2002), 96.8% mothers were satisfied on cleanliness of the maternity wards. The present study revealed that the satisfaction on the physical environment of the wards was 86.3%. In Senarath's study it was 28.7%. It was revealed by Mategic et al (2014)in the public hospitals of Serbia by inquiring 34431 postpartum mothers found out that maternal satisfaction on sanitary facilities was 44%. The differences of satisfaction between local studies regarding cleaning, appearances and cleanliness of the wards may be due to the current policy of sanitation in health institutions. At present, almost all government hospital cleaning activities are done by private sector cleaning services. In the past it had been done by the government sanitary workers. According to the experiences of the PI, private cleaning services were more efficient and supervised than the government sanitary workers. This might be the reason for the improvement of satisfaction on sanitation and cleaning than the earlier studies.

Ninety one percent (91.2%) of mothers were satisfied regarding the communication with the health staff. In Goonawardena's study 99.45% of mothers mentioned that they discussed and communicated their problems with the midwives. In the present study with regard to the opportunity to ask questions 93.4% stated that they had the opportunity. These differences of satisfaction may be the difference in institutions that carried out the research. The present study was carried out in secondary and tertiary care hospitals whereas Goonawardena,(2002) carried out his study in primary care settings of a district. In tertiary care hospitals all the staff are usually busy and there are considerable workload whereas in the primary care setting they have time to talk to the patients as there may be less number of patients.

Maternal satisfaction regarding breast feeding promotion and counseling in present study was 93.3%. According to Senarath, (2004) study, assistance given to breast feeding was 12.3% indicating poor satisfaction. The vast difference between breast feeding and counselling may be due to the Ministry of Health carrying out more training programmes on breast feeding promotion and counselling for midwives and nursing officers during the last five to six years with the implementation the policy of exclusive breast feeding for six months. In Serbia by a cross sectional study found that 65.4 % of mothers were satisfied regarding breast feeding assistance and counselling (Matejic et al., 2014).

Regarding the kindness of care of health staff in relation to the staff category, consultants were (92.5%),doctors (93.6%), nursing officers (92.5%), midwives (95.8%) and minor staff (86.7%). In Greece, the study found the politeness of doctors and nurses were 94.6% and 89.3% respectively (Matziou et al). In Senarath's study, satisfaction regarding midwives was 83.9%. In the Browns and Lumley study in Australia, 93.3% mothers agreed that doctors and midwives were reassuring and encouraging the mothers (Browns and Lumley, 1998).

The majority of mothers had not taken meals served by the hospitals. Only 6.7% (16) of mothers consumed the diet provided by the hospital and 8.3% of mothers took drinking water provided by the hospitals. The mothers have obtained diet from hospital only when they were supposed to have special diet such as a diabetic diet or a high protein diet. Therefore it is time to reorganize the provision of diet to the maternity wards.

The overall satisfaction of care regarding neonatal care and maternal care was not different according to the socio demographic factors. The same findings was revealed by Jayasekara (Jayasekera, 2006) in his study (p=0.71) that the socio demographic factors were not associated with satisfaction of care. Patient's expectation had been considered as primary importance in determining the level of satisfaction. Patients with lower expectations were more easily satisfied (Sitzia and Wood 1997).

5.5. Component IV

Adherence of infection control standards by health care workers

Infections may be transmitted from health care workers to patients, patients to health care workers or patient to patients directly or indirectly. These infections impose a great burden on hospital resources. Many of these infections could be prevented by following simple, cost effective practical guidelines on infection control. Therefore adherence of these infection prevention guidelines is of paramount importance to prevent infections in hospital settings.

Although the government health services were provided by trained health care personnel (doctors, nurses and PHMM) in Sri Lanka their performances needed to be evaluated from time to time. As there is no continuous professional development or continuous medical education concept in our country, it is important to assess the adherence of guidelines periodically. Out of those, infection control is the most vital aspect. It is important to evaluate and arrange the necessary training programmes to update their knowledge, compliance and skills. Usually among health care workers compliance for some aspects of infection control would decline with time. Standard precautions and universal precautions are important to practice correctly daily by all health care workers. In spite of regular reminders it is difficult to maintain good compliance on infection control practices (Sharma et al., 2011).

Due to feasibility and the availability of time it was decided to make ten observations from each selected procedure from LRs, NNICUs, PNWs and OTs. As an example, ten hand washing procedures were observed from one labour room. As there were seven labour rooms, a total of 70 hand washing procedures were observed collectively. Likewise the observations were made on selected procedures namely use of PPE, hand washing , neonatal care , umbilical cord care , breast feeding initiation, handling of sharps, management of blood spills and BCG vaccinations. Observations were made for all categories of health care workers irrespective of their designation as it is important for all of them to adhere with infection control standards. The observed procedures and places were selected according to a schedule prepared using random numbers in order to avoid any selection bias. Inter observer bias was minimized as all observations were made only by the Principal Investigator. The observations were made according to a check list to strengthen the accuracy of data. Direct observations using check lists were common practice in similar kind of studies (Goonawardena 2002, Senarath 2004, Vidal et al., 2001). The presence of an observer while carrying on procedures may have influenced the practice of the health care provider towards favorable direction. To minimize this issue at the beginning of the study only the nursing officer in-charge was explained regarding the observation of the procedures but the health care providers were unaware of the particular day the observations were carried out. Therefore the potential for observation bias under study was minimized.

To improve the quality of data the minimum infection control standards required for procedures were obtained from the following documents; WHO Essential Newborn Care Course; Integrated Management of Pregnancy and Child birth; Guide for the Labour Room Management; Building and other Guideline for NNICU, SCBU and Mother baby centres; Infection Control Manual by the College of Microbiologists; and SLMA Guideline for Standard Precautions. By WHO and local expert panels have recommended that all the above standards been put to practice in Sri Lanka. The face and content validity of the check lists were ensured by the experts in the field of infection control.

It is a well known factor that HAI spread due to cross infection from poor hand hygiene of health care workers. A simple hand washing procedure is very important to prevent HAIs. In the present study, the frequency distribution of hand washing practices observed among health care workers in LR, NNICU, PNW and OT were 57.1%, 80%, 82.5% and 33.3% respectively. Although there were facilities in each NNICU for hand washing, only 60% health care workers washed their hands before entering the NNICU. The low rates of hand washing reported from the operation theatres by PHMM might be due to lack of facilities for the hand washing in the theatres other than scrubbing area. Senarath (2004) also found that hand washing practices before assisting in the delivery was 65% among the birth attendants. Goonawardena (2002) also revealed that percentage of hand washing practices among labour room midwives were 85.3%. In previous studies the quality of hand washing not being evaluated but the present study the quality of hand washing found to be poor. The proportion of workers who adhere to steps of hand washing correctly was different in various settings. When considering the step of washing thumbs separately, the practices in LR was 67%, NNICU 70% and PNW 40%. Almost all had used either soap or disinfectant for the hand washing whereas 7.5% from LR and 16% from PNW did not wipe their hands after washing.

According to Kudavidanage (2011), only 10% of the health care workers had overall good practice of hand washing in the ICU set up of the teaching hospital, Anuradhapura (Kudavidanage et al., 2011). Doebbling, in the UK found that the hand washing rate by ICU medical staff was 12.4% before contact with the patient and 10.65% after contact (Doebbling, et al., 1992). Marito et al in Italy also revealed that for hand washing in the NNICU, even after intervention, the compliance among doctors was 50.5% whereas among nurses it was 40.7% (Marito et al., 2011).

In the use of PPE when entering the LR, 80% of them wore aprons and 12% wore masks. In the NNICU 34% of them wore sterile gowns and 4% wore masks. In Georgia the gown and glove compliance in the surgical ICU among doctors was 40 % whereas among nurses it was 68%. In medical ICU it was 84% among nurses and 70% among doctors (Gilbert et al., 2010).

When considering the management of sharps and disposal of sharps, recapping of needles were done by 18.6%, 18.0% and 31.3% in LR, NNICU and post natal wards respectively. Disposal of sharps to the sharp bins were done by 94.3%, 100% and 96.2% in the LR, NNICU and PNW respectively. Senarath (2004) also found that 21% of HCW practiced recap of needles. The practices were different when the place was specialized and there were more availability of trained staff. Therefore the NNICU staff was better than other staff most of the time.

Drawing of blood for cultures was also important when managing the sepsis babies. Eighty percent of samples were drawn by nursing officers whereas 20 % of samples were drawn by medical officers. When considering the steps in drawing blood, 100% of them used 70% alcohol to disinfect the skin, 72% of them allowed to dry and povidone iodine was used only by 68%.

Skin to skin contact of mothers and early initiation of breast feeding were two more important practices to prevent infection among newborns. In the present study it was revealed that 65.7% of neonates were started on breast feeding within the first hour of delivery and health care workers helped to position the baby 81.4% and helped with attachment 77.1%. Goonawardena (2001) in her study found that 98.9% commenced breast feeding within the labour room and 64.6% of HCW helped the mothers to breast feed.

After evaluating of the results of all these component of the study it was evident that there were modifiable and non modifiable risk factors for neonatal sepsis. Majority of neonatal sepsis could be prevented by implementing proper infection control standards as those were due to gramme positive organism. It was identified that the need of screening programmes to identify the postpartum depression of mothers of neonatal sepsis babies is mandatory.

5.6. Generalization of the research findings

This research consisted of four main components with two study designs namely a case control study, three descriptive studies. The sample size was calculated according to the available ORs and prevalence data. There was a minimum of non response and volunteering with regard to the descriptive and case control studies. Although the cases and risk factors had already occurred at the time of data collection for the case control component of this study, the majority of cases occurred after exposed to the risk factors. Therefore selection bias was minimal. Hence the selection of study samples was devoid of selection bias with respect to all components of the study and therefore it may be considered that this study has satisfactory external validity which enables the finding to be generalized.

With regard to the internal validity the interviewer bias was minimized. Confounding was addressed through the use of multiple logistic regressions. Hence it is considered that this study has satisfactory internal validity as well. The precision of most of the effect measures were evident through the narrow 95% confidence interval derived.

For the study findings to be generalized (external validity to the source population from which samples arose) it is imperative that the study results are valid (internal) and precise. As both internal and external validity have been achieved to a satisfactory degree, the results of this study can be generalized to the whole of Gampaha District.

5. CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

1. The identified risk factors for neonatal sepsis in the District of Gampaha were as follows:

   Maternal risk factors

   a) Registration of mothers in the antenatal clinics after 8 weeks of gestation
   b) Total number of antenatal clinic visits by mother being ≤ 4 times
   c) Bad obstetric history of mothers namely, history of abortions, still births and neonatal deaths
   d) Presence of maternal fever during the last one week before delivering the neonate
   e) Dribbling for more than 18 hours before delivery of the neonate
   f) Total number of vaginal examinations being>3 before delivery of the neonate
   g) Presence of meconium stained liquor when delivering the neonates
   h) Mode of delivery of the neonates by vacuum, forceps or caesarean sections

Neonatal risk factors

   a) Birth weight < 2500 g
   b) Being a male neonate
   c) Time of delivery of the neonates between 4 pm to 8 am of following day

2. Maternal depression among mothers of neonates with neonatal sepsis was 78% and the mothers of non sepsis babies were 28% in the District of Gampaha
3. The total maternal satisfaction regarding the neonatal care provided was 90% whereas satisfaction for maternal care provided was 84.6%.
4. The design and the available physical facilities in the labour rooms, neonatal intensive care units, post natal wards and operation theatres with regards to infection control standards were not according to the guidelines.
5. The adherence to infection control standards by health care workers in observed procedures were not up to the standards. Especially hand washing practices among health care workers in LR, NNICU and PNW were 57.1%, 80% and 82% respectively.

RECOMMENDATIONS

1. The Family Health Bureau of Ministry of Health which is the relevant national authority in taking policy decisions regarding maternal and neonatal care should be informed of the risk factors for neonatal sepsis.

2. Strengthening of home visits by PHMM to improve the early registration and to motivate mothers for ante natal clinic visits.

   According to the Family Health Bureau guidelines all mothers should be registered in the ante natal clinic before eight weeks of pregnancy and antenatal mothers should attend a minimum of seven antenatal clinic visits. It is recommended to find out the obstacles for home visits of PHMM. All supervising officers of PHMM should be made aware of this issue and improve the close supervision of PHMM duty.

3. Awareness of antenatal mothers regarding hand washing practices

   The routine health education talks in antenatal clinics could be used to emphasize the importance of hand washing practices and its effectiveness regarding reduction of neonatal sepsis and other co-morbidities. Therefore PHMM should be made aware through in-service training programmes regarding the above matter.

4. Availability and adherence to guidelines

   It is essential to emphasize on proper adherence to guidelines on dribbling, number of vaginal examinations after admission to ward and prophylactic antibiotic policy. It is the responsibility of the consultant to supervise the adherence to guidelines by junior staff.

5. Strengthening the monitoring of labour

   Special attention should be made to enhance the use of partogram and improve fetal monitoring to ensure early diagnosis of meconium stained liquor. Thereby interventions can be done promptly.

6. Establishment of routine clinical audit within the units for monitoring and evaluation of each specialized units.

   It is time to introduce a mechanism to analyse all the indications for instrumental deliveries and caesarean sections for each specialized unit. Then the consultants, medical officers, nurses and PHMM will get the opportunity to learn from their own experiences to minimize the unfavourable effect on mother and neonate.

7. Regular screening programmes to detect postpartum depression among mothers of neonates with neonatal sepsis.
   It is time to introduce a screening programme to detect postpartum depression among mothers whose neonates are at neonatal units. Then the curative, supportive and counselling services for them can be arranged. Routine psychiatric support services should be improved for these mothers. It is recommended to train institutional staff in postnatal wards and neonatal intensive care units regarding maternal postpartum depression.

8. Improvement of soft skills among government health care workers.
   New strategies of customer services which are used in private sector institutions for better public relations are to be introduced among government health care workers. Short training courses for the undergraduates and nursing students as well as in-service training for all categories of staff regarding soft skills such as communications and empathy are to be introduced.

9. Planned infrastructure facilities
   Infrastructure facilities to be improved on infection control practices for almost all labour rooms, neonatal intensive care units, post natal wards and operation theatres enabling them to control infections.
10. Establishment of continuous professional development programmes
   During the basic training period it is necessary to stress on infection control standards for all categories of health staff namely medical students, nurses, public health midwives and minor staff. At the same time it is compulsory to introduce regular in-service programmes like continuous professional development and conduct routine reviews and evaluations for all type of staff categories regarding infection control.

Limitations

1. In component II of the study IAQ II required responses like social support, physical and mental abuses etc. All those variables are subjective. Therefore the quality of information obtained would depend on the extent to which respondents interpret the questions. Although efforts were made to minimize the variation, this inherent deficiency could still exist.

2. When assessing the postpartum depression, the mothers who stayed at home might be less depressed than those in hospital. Therefore it might be an overestimation of postpartum depression among mothers who stayed in hospital.

3. Thirteen of Tamil and 19 of Muslim mothers recruited for the study might have not understood the Sinhala language as Sinhalese mothers. Therefore the EPDS questionnaire which was administered in Sinhala medium might not have been answered equally byboth groups. This might result in underestimation or overestimation of depression among the two groups.

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Annexure

Annexure I

Number of live births, neonatal deaths and infant death according to MOH area-- in year 2009

MOH area	Estimated new year population	Number of live births	Number of neonatal deaths	Number of late neonatal deaths	Total infant deaths
1.Ragama	84487	1103	03	05	08
2.Wattala	177787	2202	13	04	17
3.Ja-ela	151399	1866	06	08	14
4.Seeduwa	154979	1600	10	10	20
5.Negambo	172223	2345	10	06	16
6.Katana	110770	1725	05	04	09
7.Minuwangoda	181293	2645	16	10	26
8.Divulapitiya	152382	1980	12	08	20
9.Meerigama	171261	2328	07	03	10
10.Attanagalla	183907	2631	12	11	23
11.Dompe	155119	2210	09	09	18
12.Mahara	210666	2894	13	09	22
13.Gampaha	202888	2680	14	06	20
14.Keleniya	160353	1807	11	06	17
15.Biyagama	192102	2838	15	02	35
Total	**2461615**	**32854**	**153**	**122**	**275**

Number of delivaries live birth and neonatal death according to the institutions Year 2010 in Gampaha district

Type of the institution	Institution	Number of deliveries	Number of total live birth	Neonatal deaths
TH	CNTH	9278	9299	49
DGH	Gampaha	5558	5608	13
DGH	Negambo	5042	4979	31
BH	Wathupitiwala	3990	3984	14
BH	Meerigama	16	16	0
BH	kiribathgoda	6	6	0
DH	Minuwangoda	26	26	0
DH	Divulapitiya	23	23	0
DH	Dompe	15	15	0
DH	Akarragama	33	33	0
DH	Pamunugama	4	4	0
DH	Radawana	25	24	0
RH	Biyagama	9	8	
RH	Bokalagam	0	0	0
RH	Udupila	0	0	0
RH	MalwatuH'ipitiy	0	0	0
RH	Ja Ela	5	5	0
	Total	**24052**	**24030**	**107**

Annexure II

The following clinical feature to be marked by the PHO when she/he admit the neonates to the NNICU or when keep observation of neonates in the PNW

Fast breathing (respiratory rate more than 60 per minute)

Severe chest in-drawing

Not suckling

Not attachment at all

Grunting

Convulsion

Fever temperature more than 37.5^0 C

Hypothermia temperature less than 35 ^{0}C

Lethargic, less than normal movement or unconsciousness

Bulging fontanel

Bleeding from umbilical stump, pus drainage from umbilicus or redness of umbilicus extending to the abdominal wall

More than ten skin pustules, bullae,

Annexure- III

Confidential

Serial No:

Interviewer administered questionnaire I (IAQ - I)

(To be filled by the data collectors)

The objective of this questionnaire is to obtain the socio demographic information and risk factors for neonatal sepsis from the mothers of neonates who are diagnosed of having neonatal sepsis.

Fill in the blanks or mark with most appropriate answers.

Identification of the participant

(Relevant information to be rechecked from the mother's card or CHDR*)

1. Name of the mother : ....
2. Date of birth of mother : ....
3. What is your age at the last birthday : ....
4. Date of birth: Year............... Month .... Date ....
5. Address of the mother (residence during last one year) :

   ....
   ....
   ....
6. Telephone Number : ....
7. Brief description about the direction to reach your residence

   ....
   ....
   ....
8. MOH area which mothers residence belongs to: ....
9. PHM area which mothers resides: ....
10. Date of birth of the neonate: ....
11. Place of birth: ....
12. Time of birth: ....
13 Name of the baby (If present):...

***CHDR =Child Health development Record**

14 To which ethnic group do you belong?

Sinhala	
S L- Tamil	
Indian Tamil	
Muslim	
Others	

15. To which does your husband belong?

Sinhala	
S L- Tamil	
Indian Tamil	
Muslim	
Others	

16. To which religion do you belong?

Buddhist	
Catholic	
Hindu	
Muslim	
Others	

17. To which religion does your husband belong?

Buddhist	
Catholic	
Hindu	
Muslim	
Others	

18. What is the highest education level you have achieved?

Never schooling	
1-5	
6-10	
Passed GCE O/L	
Passed GCE A/L	
Degree and above	

19. What is the highest education level your husband has achieved?

Never schooling	
1-5	
6-10	
Passed GCE O/L	
Passed GCE A/L	
Degree and above	

20. What is your present civil status?

Currently Married	
unmarried	
widowed	
divorce	
separated	

21. What is your occupation? (write the current occupation)

22. What is your husband's occupation? (write the current occupation)

23. What is your total family income in rupees per month?

<2000	
2001-5000	
5001- 10000	
10001-15000	
15001-20000	
>20000	

24. How many pregnancies (irrespective of the outcome) and including this pregnancy have you gone through? Give me the detail of each).

No of pregnancy	Place of delivery	Abortion	stillbirth	sex	Age to date

- **Detail regarding current pregnancy and delivery**

I would like to ask you some more detail about this pregnancy

25. Was it a planned pregnancy?

Yes	
NO	

26. LMP:

Year	Month	Date

27. EDD:

Year	Month	Date

28. Has the POA been confirmed by ultra sound scan?
   i. Yes
   ii. No

29. At which POA did you first visit the ANC for this pregnancy? (Re check with pregnancy record)

   ....

30. How many times did you visit the VOG for this pregnancy?

At Gov hospital	At private centre	At what POA

31. How many times did you attend routine ANC in the field/hospital?
   (Data can be extracted from the mother cards)

At what POA did you attend	By whom did you examine

32. Did you have any complication during presant pregnancy? Or in previous pregnancies

i. Yes	
ii. No	

If Yes,

Complication	For how long	In previous pregnancies
GDM		
PIH		
Heart dis: complicating		
Psychiatric diseases		
Others (specify)		

33. Did you take any medicine/drugs for long time other than vitamins given?

1. Yes ☐
2. No ☐

34. If yes, what is / are the medicine/drug / drugs

....

....

....

35. Do you have any family history of following illnesses?

Disease	Yes / No
Diabetes	
Hypertensions	
Psychiatric illness	
Others	

36. What is the POA when deliver this baby

By her dates:..........................
By USS date (if dates are not certain): ....

37. Did you undergo any of the following intervention during this pregnancy?

1. Amniocentisis ☐
2. Cervical cerclage ☐
3. Chorionic villus sampling ☐
4. Percutaneous blood sampling ☐

38.Did you have any illnesses during last one month of this pregnancy?

Illness	How many days	Did you get the treatment/ what are the treatment
UTI		
Fever		
Foul smelling vaginal discharge		
Other (specify)		

39. Did you have dribbling before delivery of the baby? YES/NO
If yes,

1. Spontaneous ☐
2. After ARM* ☐

40. Were you in the labour room

If Yes, How many hours before delivery? ....

How many hours after delivery? ....

41. What is the mode of delivery of this baby?

Mode of delivery	Yes/ No	What is the indication
Normal vaginal		
Forceps		
Vaccum		
Caesarian section	EM/EL	
Any other (specify)		

EM- Emergency LSCS, EL- Elective LSCS

***ARM= Artificial Rupture of the Membrane**

ඇමුණුම 1

රහසිගතයි.

ප්‍රශ්නාවලිය 1

(දත්ත එකතු කරන්නන් විසින් එකතු කළ යුතුයි.)

මෙම ප්‍රශ්ණාවලියේ අරමුණ වන්නේ නව ජන්මයන් ආසාදනය වීම සඳහා වූ අවදානම් සාධක සොයාගැනීමයි. මේ සඳහා තොරතුරු රැස්කරනු ලබන්නේ නව ජන්ම ආසාදනය වූ නව ජන්ම දරුවන්ගේ මව්වරුන්ගෙනි. ඔබගේ කාරුණික දායකත්වය බලාපොරොත්තු වන අතර එමඟින් අනාගතයේදී ඇතිවන නව ජන්ම ආසාදන අඩුකර ගැනීමට පියවර ගත හැකියි.

හඳුනාගැනීම

අදාල දත්ත මව් කාඩ්පතෙන් ඇඳ ඉහ වාර්තාවෙන් හෝ ළමා වර්ධන සටහනෙන් උපුටා ගන්න.

1. මවගේ නම ....
2. මවගේ උපන් දිනය ....
3. මවගේ වයස (පසුගිය උපන් දිනයට) ....
4. මවගේ ලිපිනය ....
5. මවගේ දුරකථන අංකය (තිබේනම්) ....
6. අවශ්‍ය වුවහොත් නිවසට පැමිණීමට හැකි වන ලෙස මාර්ගය සටහන් කරගන්න.

7. මවගේ ස්ථිර පදිංචි නිවස අයත් සෞ. වෛ. නි. කොට්ඨාශය
....
8. පවුල් සෞඛ්‍ය නිලධාරී කොට්ඨාශය ....
9. නව ජන්මයාගේ උපන් දිනය ....
10. නව ජන්මයා උපන් ස්ථානය (රෝහල) ....
11. උපන් වේලාව ....
12. නව ජන්මයාගේ නම (තිබේනම්) ....
13. නව ජන්මයාගේ ඩිස්ක් අංකය ....
14. ඔබගේ ජාතිය කුමක්ද ?

සිංහල	
ශ්‍රී ලංකා දෙමළ	
ඉන්දියානු දෙමළ	
මුස්ලිම්	
වෙනත්	

15. ඔබගේ ස්වාමිපුරුෂයාගේ ජාතිය කුමක්ද?

සිංහල	
ශ්‍රී ලංකා දෙමළ	
ඉන්දියානු දෙමළ	
මුස්ලිම්	
වෙනත්	

16. ඔබගේ ආගම කුමක්ද?

බෞද්ධ	
කතෝලික	
හින්දු	
ඉස්ලාම්	
වෙනත්	

17. ඔබගේ ස්වාමිපුරුෂයාගේ ආගම කුමක්ද?

බෞද්ධ	
කතෝලික	
හින්දු	
ඉස්ලාම්	
වෙනත්	

18. ඔබ ලබා තිබෙන ඉහළම අධ්‍යාපන සුදුසුකම කුමක්ද?

පාසැල් ගොස් නැත	
1-5 දක්වා	
6-10 දක්වා	
අ.පො.ස. (සා.පෙ.)	
අ.පො.ස. (උ.පෙ.)	
උපාධි හෝ ඉහළ	

19. ඔබගේ ස්වාමිපුරුෂයා ලබා තිබෙන ඉහළම අධ්‍යාපන සුදුසුකම කුමක්ද?

පාසැල් ගොස් නැත	
1-5 දක්වා	
6-10 දක්වා	
අ.පො.ස. (සා.පෙ.)	
අ.පො.ස. (උ.පෙ.)	
උපාධි හෝ ඉහළ	

20. ඔබගේ වර්තමාන විවාහක අවිවාහක බව?

විවාහක	
අවිවාහක	
වැන්දඹු	
නීතියෙන් වෙන්වූ	
වෙන්වූ	

21. ඔබගේ වර්තමාන රැකියාව කුමක්ද

22. ඔබගේ ස්වාමිපුරුෂයාගේ වර්තමාන රැකියාව කුමක්ද?

23. ඔබගේ පවුලේමසකට සම්පූර්ණ ආදායම කොපමණද?

රුපියල් 2000 ට අඩු	
රුපියල් 2001-5000	
රුපියල් 5001-10000	
රුපියල් 10001-15000	
රුපියල් 15001-20000	
රුපියල් 20000 ට වැඩි	

24. කරුණාකර ඔබගේ පසුගිය ගැබ්ගැනීම් සහ ප්‍රසූතයන් පිළිබඳව පහත විස්තර ලබාදෙන්න.

කීවෙනි ගර්භයද	ප්‍රසූත කළ ස්ථානය	ගබ්සා වීම්	මළදරු උපත්	දරුවාගේ ගැහැණු පිරිමි බව	දැනට වයස

කරුණාකර ඔබගේ වර්තමාන ගර්භනීභාවය පිළිබ!දව පහත විස්තර ලබාදෙන්න.

25. මෙය සැළසුම් සහගත ගර්භයක්ද?

ඔව්	
නැත	

26. අවසන් ඔසප් දිනය කුමක්ද?

වර්ෂය	මාසය	දිනය

27. දරුවා ප්‍රසූත කිරීමට බලාපොරොත්තු වන දිනය

වර්ෂය	මාසය	දිනය

28. ඔබගේ ගර්භනී කාලය ස්කෑන් පරීක්ෂාවක් මගින් තහවුරු කළාද?

ඔව්	
නැත	

29. මෙම ගර්භනී භාවය ස!දහා පළමුවෙන්ම පූර්ව ප්‍රසව සායනයට යනවිට ගර්භයට වයස (සති/මාස)
කියද?

....

30. මෙම ගර්භනී කාලය තුල නාරි හා ප්‍රසව විශේෂඥ වෛද්‍යවරයා කොපමණ වාරයක් ඔබව පරීක්ෂා කලේද?

රජයේ රෝහලේ දී	පෞද්ගලික ආයතනයක දී	ගර්භයට වයස (සති/මාස)

31. මෙම ගර්භනී කාලයේදී පූර්ව ප්‍රසව සායනයට (ප්‍රදේශයේ/රෝහලේ) කොපමණ වාරයක් සහභාගි වුයේද?

ගර්භයට වයස (සති/මාස)	පරීක්ෂා කරනලද නිලධාරියා

32. මෙම ගර්භනී සමයේදී හෝ පෙර ගර්භනී අවස්ථාවලදී ඔබට යම් සංකුලතාවයක් තිබුණේද?

ඔව්	
නැත	

පිළිතුර ඔව් නම්,

සංකූලතාවය	වර්තමාන ගර්භනි සමයේදී	පෙර ගර්භනි අවස්ථාවකදී	කොපමණ කලක්ද
ගර්භනී සමයේ දියවැඩියාව			
ගර්භනී සමයේ අධි රුධිර පීඩනය			
හෘද රෝග			
මානසික රෝග			
වෙනත්			

33. ගර්භනී සමයේ ලබාදෙන විටමින් හැර ඔබ වෙනත් බෙහෙත් හෝ ඖෂධ වර්ග භාවිතා කලේද?

ඔව්	☐
නැත	☐

34. ඉහත (33) ප්‍රශ්නයට පිළිතුර ඔව් නම්, එම බෙහෙත් මොනවාද

....

....

....

....

35. ඔබගේ පවුලේ සාමාජිකයනට (මව/පියා/සහෝදර සහෝදරියන්) පහත ස!දහන් අසනිප තිබේද?

රෝගය	ඔව්/නැත
දියවැඩියාව	
අධික රුධිර පීඩනය	
ඔානසික රෝග	
වෙනත්	

36. වර්තමාන නව ජන්මයා ඉපදෙන විට ගර්භයට වයස කියද?

මවගේ දින අනුව	
ස්කෑන් පරීක්ෂණ දින අනුව	

37. මෙම ගර්භනී කාලය තුල පහත ස!දහන් ක්‍රියාමාර්ග ස!දහා යොමුවී තිබේද?
(ඔව් නම් ලකුණද නැත නම් ✗ ලකුණද යොදන්න.)

ගර්භ තරලය ලබාගැනිම	
ගැබ් ගෙලට මැහුම් දැමීම	
ගර්භ පටක ලබාගැනිම	
ගරභයේ රුධිරය පරිඩාවට ගැනිම	

38. මෙම ගර්භනී කාලයේ අවසාන මාසයේ ඔබට කුමන හෝ රෝගයක් වැළ!දුනේද?

රෝගය	කොපමණ දින ගණනක්ද	එයට ප්‍රතිකාර ලබාගත්තේද? ප්‍රතිකාරය කුමක්ද?
මුත්‍රා ආසාදන		
උණ		
දුග!ද හමන යෝනි ස්‍රාවයක්		
වෙනත්		

39. මෙම ජන්මයා ප්‍රසූත කිරීමට පෙර ගර්භ තරලය පිටවූවාද?

ඔව්	
නැත	

පිළිතුර ඔව් නම් එය සිදුවූවේ,

ස්වාභාවිකව	
කෘත්‍රිමව පටල බි!දීමෙන් (වෛද්‍යවරුන්)	

40. ප්‍රසූතියට පෙර ගර්භ තරලය පැය කීයක් පිටවූවාද?

....

41. ප්‍රසූත කාමරයේ ප්‍රසූතියට පෙර පැය කීයක් ගතකලේද?

....

ප්‍රසූත කාමරයේ ප්‍රසූතියට පසු පැය කීයක් ගතකලේද?

....

42. මෙම ජන්මයා ප්‍රසූත කළ ක්‍රමය කුමක්ද?

ප්‍රසූත කළ ක්‍රමය	ඔව් / නැත	මැදිහත් වීමට හේතුව
සාමාන්‍ය යෝනි		
අ!ඩු මගින්		
ඇකියුම් මගින්		
සීසර් සැත්කමකින්	සාමාන්‍ය/ හදිසි	

Annexure IV

Record sheet I

(These data to be extracted from the mothers BHT by the data collectors).

1. Date of admission to the hospital? ....
2. Time of Admission: ....
3. Mothers BHT No: ....
4. Mothers blood group: ....
5. Any medical disorders during gestational period?
   ....
   ....
   ....
   ....

6. Previous child with Group B Streptococcus infections:

iii. Yes	
iv. No	

7. Rupture of membranes

Spontaneous	
ARM	

8. How many hours the rupture of membranes has occurred before delivery of the baby? ....Hrs
9. Number of vaginal examinations done before and after rupture of the membranes before delivery

Before	
After	

10. Status of Liquor (Amniotic fluid)

Colour	Clear			
Odour	Normal		Offensive	
Meconium	Thin		Thick	

11. History of chorioamnionitis? (should be diagnosed by specialist)

1. Yes	
2. No	

12. If Yes, How many days before delivery? ....

13. History of Fever (written document should be available)

1. Yes	
2. No	

14. If Yes, Duration of fever How many days: ....

15. Antibiotics given

Antibiotics	How long

16. Date and time of the delivery of the baby: Date: ....
Time:....................

17. What are the investigations done during antenatal and postnatal period:

	At what POA	In postnatal period	Results of the investigations
UFR			
Urine for culture and ABST			
WBC/DC			
Blood Sugar			
VDRL			
CRP			
Vaginal swabs & culture			
Others (specify)			

Annexure V

Record sheet II

(These data should be extracted from the neonates BHT / Neonatal examination formats/CHDR of the neonate)

1. Name of the mother/ baby: .... Disc No: ....
2. Sex: Male / Female
3. Date of birth: ....
4. Time of birth: .... am/pm

40. Date and time of Admission to the NNICU: ...Date:
Time:....................

Birth weight	
Length	
OFC	
APGAR score At birth At 5 min 10 min	

41. Resuscitation at birth:

1. Yes	
2. No	

7. Signs and symptoms of the baby when admitted to the (**mark √ or ×**)

Signs /symptoms	**√ or ×**	**Signs/symptoms**	**√ or ×**
Convulsion		Lethargic or unconscious	
Respiratory rate >60 breath/min		Crepitations	
Severe chest in drawing		Reduced movement	
Severe chest in drawing		Temperature >37.7 (or feel hot) or <35.5 C (or feels cold)	
Nasal flaring		Not able to feed	
Grunting		Reduced capillary refilled time	
Bulging fontanel		Not attaching to the breast	
Pus draining from the ear		Cyanosis	
Redness around umbilicus extending to the skin		No suckling at all	

8. What are the investigations done for the neonate?

Investigation done	**Results**	
WBC/DC		
Blood culture		
UFR/ Urine culture		
Umbilical swabs		
Others (specify)		

9. Details about investigations done

Investigations	**Date**	**Organisms**	**ABST**	
Blood culture				
Urine culture				
CSF culture				
Others				

10. Was the baby given antibiotics

1. Yes	
2. No	

11. What are the antibiotics given and how many days?

Antibiotics given	**How many days**

12. What are the details about breast feeding?

Time of the first feed		
Colostrums given or not	Yes	No
On demand feeding	Yes	No
Keep mother baby together	Yes	No
Suckling	Yes	No

11. If expressed Breast Milk,

Mode of feeding	Gavarge/Cup
frequency	

12. If given formula milk, fill the following details

Type	
Mode of feeding	
Frequency	

13. How many days in the hospital? ....

14. What is the outcome of neonate : (circle the answer)

i. Live discharge

ii.Death

15. What is the diagnosis given when discharge: ....

....

16. If neonatal death occurred,

Date and time of death	
Post mortem	Done/ Not done
Cause of death given	

Annexure VI

Edinburgh Postnatal Depression Scale (EPDS) (Self administered questionnaire)

Annexure VIII Edinburgh Postnatal Depression Scale(to be filled by the participants)

Num.	In the past week	Coding column
1	I have been able to laugh and see the funny side of things	
	As much as I always could	0
	Not quiet so much now	1
	Definitely not so much now	2
	Not at all	3
2	I have looked forward with enjoyment to things	
	As much as I ever did	0
	Rather less than I used to	1
	Definitely less than I used to	2
	Hardly at all	3
3	I Have blamed myself unnecessarily when things went wrong	
	Yes most of the time	3
	Yes some of the time	2
	Not very often	1
	No never	0
4	I have been anxious or worried for no good reason	
	No not at all	0
	Hardly ever	1
	Yes some time	2
	Yes very often	3
5	I have felt scared or panic for no good reason	
	Yes quiet a lot	3
	Yes some times	2
	No not much	1
	No not much at all	0
6	Things have been getting on top of me	
	Yes most of the time I haven't been able to cope at all	3
	Yes some times I haven't been coping as well as usual	2
	Most of the time I have coped quiet well	1
	No I have been coping as well as ever	0

	In the past	**Coding column**
7	I have been so unhappy that I have had difficult sleep Yes most of the time Yes some time Not very often No not at all	3 2 1 0
8	I have felt sad or miserable Yes most of the time Yes quiet often Not very often No not at all	3 2 1 0
9	I have been so unhappy that I have been crying Yes most of the time Yes quiet often Only occasionally No never	3 2 1 0
10	The thought of harming myself has occurred to me Yes quiet often Some times Hardly ever Never	3 2 1 0

එඩින්බරෝ පසුප්‍රසව අවපීඩන මාපකය

පසුගිය සතිය තුල ඔබට කුමන ආකාරයේ හැගම ඇති වූවාද යන්න පහත සඳහන් වගන්ති කියවා ඔබට සිතෙන අන්දමෙ ඉතාම කිටටු උත්තරයට යටින් ඉරක් අඳින්න.

මෙන්න උදාහරණයක්;

පසුගිය සතිය තුලදී ඔබ කොතෙක් දුරට ප්‍රීතියෙන් කල් ගත කලෙහිද?
සැමවිටම
බොහෝ විට
බොහෝ විට නැත
කිසිවිටක නැත
මෙයින් තේරුම යන්නේ පසුගිය සතිය තුල ඔබ බොහෝ විට ප්‍රීතියෙන් කල්ගතකල බවය.

1	පසුගිය සතිය තුල ඔබට සිනාසිමටත් යමක සිනහ උපදවන සුළු පැත්ත දැකිමටත් කොපමණ දුරට හැකිවූවාද? 1 මට මීට පෙරත් හැකිවූ පමණින්ම 2 ඉස්සර තරමට හැකි වූයේ නැත 3 කොහෙත්ම ඉස්සර තරම් හැකි වූයේ නැත 4 නැත කිසිසේත්ම හැකිවූයේ නැත	0 1 2 3
2	යම් යම් දේවල් ගැන සතුටු සිතින් පුල පුලා බලා සිටිමට පසුගිසියතුලදී ඔබට කොපමණ දුරට හැකිවූයේද? 1 මා මීට පෙර සිටි තරමටම 2 වෙනදාට වඩා අඩුවෙන් 3 ස්ථිරවම වෙනදාට වඩා අඩුවෙන් 4 නැත කොහෙත්ම නැති තරම්	0 1 2 3
3	පසු ගිය සතිය තුලදී යම් කිසිවක් වැරදුන විට ඔබ අනවශ්‍ය ලෙස ඔබටම දොස් පවරා ගත්තෙහිද? 1 ඔවු සැමවිටම වාගේ 2 ඔවු සමහර විටකදී 3 කලාතුරකින් පමණක් 4 නැත කිසිවිටෙක නැත	3 2 1 0
4	පසුගිය සතිය තුල ඔබ හේතුවක් නොමැතිව හිත කරදර කරගනිමින් හෝ කුමක් වෙයිදෝ යන සැකයෙන් පසුවුනෙහිද? 1 නැත කිසිවිටෙක නැත 2 බොහෝම කලාතුරකින් පමණි 3 ඔවු සමහර විට 4 ඔවු නිතරම පාහේ	0 1 2 3
5	පසුගිය සතිය තුල ඔබ කිසිම සැලකිය යුතු හේතුවක් නොමැතිව බියටත් කලබලයටත් පත් වූයෙහිද? 1 ඔවු විශාල වශයෙන් 2 ඔවු සමහර විටකදී 3 නැත එතරම් නැත 4 නැත කිසිවිටෙක නැත.	0 1 2 3

	ආකාරය ගැන ඔබට කුමක් කිව හැකිද? 1 බොහෝ විට ඒවාට සාර්ථකව මුහුණ දිමට හැකි වී නැත 2 සමහර විට වෙනදා තරම් හොඳින් මා ඒවාට මුහුණ දුන්නේ නැත 3 මම බොහෝ විට ඒවාට හොඳින් මුහුණ දුන්නෙමි 4 මම වෙනදා මෙන්ම හොඳින් ඒවාට මුහුණ දුන්නෙමි	3 2 1 0
7	පසුගිය සතිය තුල ඔබ නින්දටවැටිමට පවා අපහසු වන තරමට අසතුටෙන් පසුවුයෙහිද? 1 ඔවු බොහෝ විට 2 ඔවු සමහර විට 3 ඔවු ඉදහිට අවස්ථාවලදී පමණක් 4 කිසිවිටෙක එසේ සිදුවුයේ නැත	3 2 1 0
8	පසුගිය සතිය තුල ඔබ දුකෙන් හෝ සිත්තැවුලෙන් සිටියේද? 1 ඔවු නිතරම පාහේ 2 ඔවු බොහෝ විට 3 කලාතුරකින් පමණක් 4 නැත කිසිවිටෙක නැත	3 2 1 0
9	පසුගිය සතිය තුල ඔබ අසතුටින් නිසා හැඩු අවස්ථා තිබුනේද? 1 ඔවු නිතරම පාහේ 2 ඔවු බොහෝ විට 3 ඉදහිට පමනක් 4 නැත කිසිවිටෙක නැත	3 2 1 0
10	ඔබට හානියක් කර ගැනිම්මේ සිතුවිලි පසුගිය සතිය තුලදී ඔබට කොතෙක් දුරට ඇති වුයේද? 1 ඔවු නිතරම පාහේ ඇති විය 2 ඔවු සමහර විට පමනක් ඇති විය 3 ඉතා කලාතුරකින් පමණක් ඇති විය 4 නැත කිසිවිටෙක ඇති වුයේ නැත	3 2 1 0

Annexure VIII
Interviewer Administer questionnaire
To be filled by interviewers.

1. **Do you have someone to support for day today work?**

1	Husband	
2	Mother	
3	Mother in law	
4	Sister	
5	Others (specify)	

2. **Do you have someone to look after other children when you attend to the newborn baby**

1	Husband	
2	Mother	
3	Mother in law	
4	Sister	
5	Others (specify)	

3. **Do you have any experiences of abuse (physical, verbal, sexual) during last one year?**

1	Husband	
2	Mother	
3	Mother in law	
4	Sister	
5	Others (specify)	

4. **Do you have any close relatives suffering from major illnesses?**

1	Husband	
2	Mother	
3	Mother in law	
4	A child	
5	Others (specify)	

5. **Do you have major economic hardship?**

1	Loss of occupation of your husband	
2	Loss of your occupation	
3	Loss of any property	
4	None	
5	Others (specify)	

6. **Did you face any unaccepted events recently (during last one year)?**

1	Husband	
2	Mother	
3	Mother in law	
4	A child	
5	Others (specify)	

බී කොටස

1. ඔබගේ එදිනෙදා වැඩ කටයුතු ස!දහා සහාය වීමට කවුරු හෝ සිටිද?

සැමියා	
මව	
නැන්දම්මා	
ෂහෝදරියන්	
වෙනත් (ස!දහන් කරන්න)	

2. ඔබ නව ජන්මයා බලාගනිද්දී අනෙකුත් දරුවන් රැක බලාගැනිමට කවුරුන් හෝ සිටිද?

සැමියා	
මව	
නැන්දම්මා	
සහෝදරියන්	
වෙනත් (ස!දහන් කරන්න	

3. ඔබගේ ල!ගම ඥාතින් විසින් ඔබව අයුතු යොදවා ගැනිම් (භෞතික මානසික ලිංගික) වලට හසුකරගෙන තිබේද?

සැමියා	
මව	
නැන්දම්මා	
සහෝදරියන්	
වෙනත් (ස!දහන් කරන්න	

4. ඔබගේ ල!ගම ඥාතින් සුවකළ නොහැකි / භයානක රෝගාබාධ වලින් පෙලෙයිද?

සැමියා	
මව	
නැන්දම්මා	
දරුවෙකු	
වෙනත් (ස!දහන් කරන්න	

5. ඔබ බලාපොරොත්තු නොවූ ආර්ථික අපහසුතා වලට මුහුණ දුන්නාද?

1. සැමියාගේ රැකියාව අහිමි වීම	
2. ඔබගේ රැකියාව අහිමි වීම	
3. කිසියම් දේපොලක් අහිමි වීම	
4. කිසිවක් නැත	
5. වෙනත් (ස!දහන් කරන්න	

6. ඔබ මෑත කාලයේදී බලාපොරොත්තු නොවූ අවස්ථාවකට මුහුණ දුන්නේද?

1. සැමියාගේ මරණය	
2. ළමයෙකුගේ මරණය	
3. මවගේ / පියාගේ අභාවය	
4. කිසිවෙක් නැත	
5. වෙනත් (ස!දහන් කරන්න	

Annexure IX

Interviewer administered questionnaire I (Part A) Serial No:

To assess the satisfaction of mothers regarding the care provided for their neonates while in the ward
Please circle best possible response.

Description	Highly satisfied	Satisfied	Neither satisfied or dissatisfied	Dissatisfied	Highly dissatisfied
1. Regarding the information concerning your neonate's illness	5	4	3	2	1
2. Regarding the information concerning your neonate's investigations	5	4	3	2	1
3. Regarding the information concerning your neonate's treatment	5	4	3	2	1
4. Regarding the treatment received to your neonate's	5	4	3	2	1
5. Regarding the confidence of competence /skills of the staffs	5	4	3	2	1
6. Regarding the counseling ,explanations and reassurance	5	4	3	2	1
7. Regarding the introduction of staff by themselves to you	5	4	3	2	1
8. Regarding the support given by the staff when your neonate's need it	5	4	3	2	1
9. Regarding the love and respect to the neonate	5	4	3	2	1
10. Regarding the support by the staff when mother need it	5	4	3	2	1
11. Regarding the time spend to attend questions	5	4	3	2	1
12. Regarding the opportunity to ask questions about your neonates illness	5	4	3	2	1
13. Regarding the understanding of explanation given	5	4	3	2	1
14. Regarding the kindness of consultants	5	4	3	2	1
15. Regarding the kindness of doctors	5	4	3	2	1
16. Regarding the kindness of the nursing staff	5	4	3	2	1
17. Regarding the kindness of minor staff	5	4	3	2	1
18. Regarding the love and respect to you	5	4	3	2	1
19. Regarding the return to same institution for the next time	5	4	3	2	1
20. Regarding the recommendation to another child as a favorable place	5	4	3	2	1

ඇමුණුමෂඩ
තෘප්තිමත්භාවය බැලීමේ ප්‍රශ්නාවලිය
(දත්ත සපයන්නන් විසින් පිරවිය යුතුයි.)
කොටස

මෙම ප්‍රශ්නාවලියේ අරමුණ වන්නේ ඔබගේ නව ජන්ම දරුවාට ලබාදුන් ප්‍රතිකාර සහ සත්කාර පිළිබ!දව ඔබගේ තෘප්තිය විමසීමයි. ඔබ සපයන සියලුම තොරතුරු රහසිගත බව කරුණාවෙන් සලකන්න.

වඩාත්ම සුදුසු පිළිතුර රවුම් කරන්න.

විස්තරය	බොහොමයක් තෘප්තිමත්	තෘප්තිමත්	තෘප්තිමත් හෝ අතෘප්තිමත් නැත	අතෘප්තිමත්	බොහෝ අතෘප්තිමත්
නව ජන්මයාගේ රෝගය සහ පරීක්ෂණයන් පිළිබ!දව					
1. ඔබගේ දරුවාගේ අසනීපය සම්බන්ධව ලැබුණු තොරතුරු පිළිබ!දව	5	4	3	2	1
2. ඔබගේ දරුවාගේ අසනීප ස!දහා වූ පරීක්ෂණවල තොරතුරු පිළිබ!දව	5	4	3	2	1
3. ඔබගේ දරුවාට ලැබෙන ප්‍රතිකාර වල තොරතුරු පිළිබ!දව	5	4	3	2	1
4. ඔබගේ දරුවාට සුදුසු ප්‍රතිකාර ලැබීම පිළිබ!දව	5	4	3	2	1
කාර්ය මණ්ඩලයේ කුසලතාවය සහ වේලාව වෙන්කිරීම පිළිබ!දව					
5. සේවකයන්ගේ කුසලතාවය හෝ නිපුනතාවය පිළිබ!දව	5	4	3	2	1
6. ආතතිය අඩුකිරීම, විස්තර කිරීම සහ සහනයන් ලබාදීම පිළිබ!දව	5	4	3	2	1
7. කාර්ය මණ්ඩලය විසින් ඔවුන් ඔබට හ!දුන්වාදීම පිළිබ!දව	5	4	3	2	1
8. ඔබගේ දරුවාට අවශ්‍ය විට කාර්ය මණ්ඩලය සහයෝගය දීම පිළිබ!දව	5	4	3	2	1
9. ඔබගේ දරුවාට ආදරයෙන් සහ ගෞරවයෙන් ප්‍රතිකාර කිරීම් පිළිබ!දව	5	4	3	2	1
10. ඔබ කාර්ය මණ්ඩලය ඇමතූ විට ඔබට උදව් කිරීමට වූ කැමැත්ත පිළිබ!දව	5	4	3	2	1
11. ප්‍රශ්න වලට පිළිතුරු දීමට කාලය වැය කිරීම පිළිබ!දව	5	4	3	2	1

තොරතුරු හුවමාරුව පිළිබඳව					
12. ඔබගේ දරුවාගේ අසනීපය සම්බන්ධව ප්‍රශ්න කිරීමට ඔබට අවස්ථාවක් ලැබීම පිළිබඳව	5	4	3	2	1
13. ඔබගේ දරුවාගේ අසනීපය සම්බන්ධව සපයන තොරතුරු අවබෝධ කරගැනීම පිළිබඳව	5	4	3	2	1
කාර්ය මණ්ඩලයේ කරුණාව පිළිබඳව					
14. ඔබගේ දරුවාගේ අසනීපය සම්බන්ධව විශේෂඥ වෛද්‍යවරයාගේ කරුණාව පිළිබඳව	5	4	3	2	1
15. කණිෂ්ට වෛද්‍යවරයාගේ කරුණාව පිළිබඳව	5	4	3	2	1
16. හෙද කාර්ය මණ්ඩලය විසින් ඔබගේ දරුවාට දක්වන ලද කරුණාව පිළිබඳව	5	4	3	2	1
17. කණිෂ්ට කාර්ය මණ්ඩලයේ කරුණාව පිළිබඳව	5	4	3	2	1
ගෞරවය සහ ආයතනය අනුමත කිරීම පිළිබඳව					
18. ඔබට දක්වන ලද ආදරය සහ ගෞරවය පිළිබඳව	5	4	3	2	1
19. ඔබගේ දරුවාට අසනීපයක් වූ විට නැවත මෙම රෝහලට පැමණීම පිළිබඳව	5	4	3	2	1
20. තවත් මවකට ඔවුන්ගේ දරුවන්ගේ අසනීප සඳහා ප්‍රතිකාර ලබාගැනීමට මෙම වාට්ටුව අනුමත කිරීම පිළිබඳව	5	4	3	2	1

Annexure X

Interviewer administered questionnaire III Serial No:

To assess the satisfaction of mothers regarding the care provided for the mother while in the ward

Please circle the best possible response.

Description	**Highly satisfied**	**satified**	**Neither sas or nor dissdissatis**	**Dissatified**	**Highly dissatisfied.**
1. Regarding the sleeping facilities provided to you	5	4	3	2	1
2. Regarding the cleanliness of the toilets	5	4	3	2	1
3. Regarding the cleanliness of the floor of the ward	5	4	3	2	1
4. Regarding the other facilities provided for you	5	4	3	2	1
5. Regarding the appearance of the ward	5	4	3	2	1
6. Regarding the diet provided to you	5	4	3	2	1
7. Regarding the of drinking water provided to you	5	4	3	2	1
8. Regarding the kindness of consultants	5	4	3	2	1
9. Regarding the kindness of medical officers towards you.	5	4	3	2	1
10. Regarding the kindness of nursing officers towards you.	5	4	3	2	1
11. Regarding the kindness of midwives.	5	4	3	2	1
12. Regarding the kindness of minor staff towards you					
13. The explanation given to you regarding breast feeding	5	4	3	2	1
14. Regarding the opportunity to asking questions about your conditions	5	4	3	2	1
15. Regarding the understanding of explanations given	5	4	3	2	1
16. Regarding the time spend on explanation	5	4	3	2	1
17. Regarding reassurance, counseling and management	5	4	3	2	1
18. Love and respect to you	5	4	3	2	1
19. Regarding the return to this ward for another episode of illness of you.	5	4	3	2	1
20. Regarding the recommendation of this ward to another mother as a favorable place	5	4	3	2	1

නව ජන්මයාට දෙනලද ප්‍රතිකාර හා රැකවරණය පිළිබ!ද තෘප්තිමත්භාවය බැලීමේ ප්‍රශ්නාවලිය

මෙම ප්‍රශ්නාවලිය මගින් ජන්ම ආසාදනයට ලක්වූ දරුවන්ගේ මව්වරුන් වාට්ටුව තුල ඇතුලු වී සිටි කාලය ඇතුලත දී තෘප්තිමත්භාවය මනිනු ලැබේ.
වැඩිපුරම ගැලපෙන පිළිතුර රවුම් කරන්න.

විස්තරය	බොහොමයක් තෘප්තිමත්	තෘප්තිමත්	තෘප්තිමත් හෝ අතෘප්තිමත් නැත	අතෘප්තිමත්	බොහෝ අතෘප්තිමත්
සනිපාරක්ෂක සහ අනෙකුත් පහසුකම් පිළිබ!දව					
1. නිදාගැනීමට සැපයූ පහසුකම් පිළිබ!දව	5	4	3	2	1
2. වැසිකිළිවල පවිත්‍රතාවය පිළිබ!දව	5	4	3	2	1
3. වාට්ටු බිමේ පවිත්‍රතාවය පිළිබ!දව	5	4	3	2	1
4. ඔබට සපයන ලද අනෙකුත් පහසුකම් පිළිබ!දව	5	4	3	2	1
5. වාට්ටුවේ භෞතික පෙනුම පිළිබ!දව	5	4	3	2	1
ආහාර සහ බීමට සපයන වතුර පිළිබ!දව					
6. ඔබට සපයන ලද ආහාර පිළිබ!දව	5	4	3	2	1
7. බීමට සපයන ලද වතුර පිළිබ!දව	5	4	3	2	1
කාර්ය මණ්ඩලයේ කරුණාව පිළිබ!දව					
8. ඔබට ප්‍රතිකාර කිරීමේදී විශේෂඥ වෛද්‍යවරයාගේ කරුණාව පිළිබ!දව	5	4	3	2	1
9. වෛද්‍යවරුන්ගේ කරුණාව පිළිබ!දව	5	4	3	2	1
10. හෙද කාර්යමණ්ඩලය ඔබට දක්වන කරුණාව පිළිබ!දව	5	4	3	2	1
11. පවුල් සෞඛ්‍ය නිලධාරිනීන්ගේ කරුණාව පිළිබ!දව	5	4	3	2	1
12. කණිෂ්ට කාර්ය මණ්ඩලය ඔබට දක්වන කරුණාව පිළිබ!දව	5	4	3	2	1
මව්කිරි දීම පිළිබ!දව					
13. මව්කිරි දීම සම්බන්ධයෙන් කළ විස්තරය පිළිබ!දව	5	4	3	2	1

තොරතුරු හුවමාරුව සහ දැනගැනිම පිළිබඳව					
14. ඔබගේ අසනීප තත්වයන් සම්බන්ධව ප්‍රශ්න කිරීමට ඇති අවස්ථාවන් පිළිබඳව	5	4	3	2	1
15“ ඔබට පැහැදිලි කළ තොරතුරු වටහා ගැනිම පිළිබඳව	5	4	3	2	1
16. ඒවා විස්තර කිරීමට ගත් කාලය පිළිබඳව	5	4	3	2	1
17. ආතතිය අඩුකිරීම, විස්තර කිරීම සහ සහනයන් ලබාදීම පිළිබඳව	5	4	3	2	1
ගෞරවය සහ ආයතනය අනුමත කිරීම පිළිබඳව					
18. ඔබට දක්වන ලද ගෞරවය පිළිබඳව	5	4	3	2	1
19. ඔබගේ අසනීපයක් සඳහා නැවත මෙම රෝහලට පැමිණීම පිළිබඳව	5	4	3	2	1
20. තවත් මවකට ප්‍රතිකාර ලබාගැනීමට මෙම වාට්ටුව අනුමත කිරීම පිළිබඳව	5	4	3	2	1

Annexure IX $_A$

Part C:
What are the things to be done to improve satisfaction regarding neonatal care? Please suggest three suggestions.

1.

2.

3.

Annexure X $_A$

What are the things to improve the mother's satisfaction regarding mothers care? Please suggest three suggestions.

1.

2.

3.

Annexture XI

A study on risk factors for neonatal sepsis in Gampaha district

Interviewer guide –I

Instructions for interviewer of mothers at institutions

Contents

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1. About the study
2. How to select participant at the hospital
3. Consent
4. How to administer the questionnaire

1. About the study

The aim of this study is to assess the risk factors for neonatal sepsis in Gampaha district. The value of the study is dependent on the quality of data collected by interviewers. The study will be conducted in four components

Component I

To determine the risk factors for neonatal sepsis. The data will be collected from mothers of newborn with neonatal sepsis. Mothers will be interviewed with IAQ I,data will be extracted from record sheet I from maternal BHT and record sheet II from neonatal BHT.

Component II

The self administered EPDS questionnaire and IAQ II will be administered to the same mothers on component I of the study to assess the post partum depression and causative factors for it. It is administered on day fifth of diagnosis of neonatal sepsis.

Component III

Maternal satisfaction regarding the government health services about care provided to the neonates and to the mother during their hospital staying. Interviewer administered satisfaction questionnaire will be administered on discharge of mother and the neonate from the hospital.

Component IV

To describe the adherence of infection control standards by health care workers in selected procedures in of neonatal intensive care units, labour room, post natal wards and operation theatres. These data will be collected only by the P.I.

You must ensure the confidentiality of information provided by mothers very strictly. This activity should be carried out independent of the health staffs of the unit concerned.

Your role as an interviewer is to select mother new-born pairs and interview them.

2. How to select the participants from the hospital

Please visit the NNICU and post natal wards and Mother Baby Care units daily and identify the following mothers and neonates who are eligible for the study

The neonates who are having single sign from following or blood culture positive will be recruited as neonatal sepsis cases. The clinical signs are:

Fast breathing (respiratory rate more than 60 per minute)

Severe chest in-drawing

Not suckling

Not attachment at all

Grunting

Convulsion

Fever temperature more than 37.5^0 C

Hypothermia temperature less than 35 ^{0} C

Lethargic, less than normal movement or unconsciousness

Bleeding from umbilical stump, pus drainage from umbilicus or redness of umbilicus extending to the abdominal wall

Skin pustules more than ten

These annexure will be with the neonatal BHT with green colour printed papers. Then clinical features cross check with neonatal BHT. Then you identify the relevant mother from the name and disc number of the neonates.

Those who could not communicate in Sinhalese should be excluded from the study.

3. Consent

Be polite to the respondent. She should be informed about the survey. Inform to the participant that she and her neonate have been selected as an eligible participant to be interviewed in the study on the factors regarding the neonatal sepsis. Inform to the respondent that the survey is confidential and the results will be used to improve the future planning for neonatal health. Interview will take about 20-30 minutes and you have freedom to attend yourself and baby at any time. The information given by you will not affect subsequent services provided to you or your neonate. You have the option in participate or withdrawn at anytime during the interview. Once she agreed to participate, hand over the consent form provided and get the written consent.

4. How to administer the questionnaire

You are responsible to complete all parts of the questionnaire. IAQ I consisted of 1-37 of questions. There are open ended and close ended questionnaire. When there is open ended question, you have to write the answer in the blank space. When there is close ended you have to mark (tick off) the correct answer.

Question number 19 – write the kind of job done during last one year period. If the mother has done several occupations write the main one. If house wife mention as house wife. From 22 to up to 31 questions you verify with the mother's pregnancy records.

Then you start to fill the Record sheet I. For this part you have to use mothers BHT. The question numbers 32 to 37 have to verify with the mother's BHT. Then data should be extracted from neonates BHT.

At the end of the task thank her for participating in the study.

Then your duty is to inform the MOH areas of the case neonate to the data collector for controls of that MOH area.

Then on the 5th-6th day you have to contact the same previous mothers and welcome them. When you tell today I would like to get some information from you. One questionnaire you have to mark the answers. Then after getting verbal consent for that you deliver the EPDS questionnaire with pencil and file cover to the relevant mothers. You first explain what to do. If necessary you can explain to the mother the example question and show what to do. Then mothers will do it. After completion you collect the questionnaire. Then administer the IAQ II questionnaire. Before you leave the NNICU you have to calculate the total marks for EPDS scale. If it is more than nine you have to check the question number 10 whether the mother has suicidal ideas. If so you have to inform the one of the doctor working in the NNICU or nursing officer in- charge of nursing sister in- charge of NNICU.

When the mother is discharge from the hospital you have to contact the mother and tell her "Today I would like to know about your satisfaction regarding the services provided to you and your neonate during hospital stay. Please tell the truth. The information provided by you, are very confidential and will not divulge to others or hospital staff. Then the IAQ II part A and part B will be administered.

Then thanks to the mother about participation to the study. Do not remember to give contact number of P.I to the mothers to contact for any clarifications.

Part B:

Interviewer guide for data collection from controls

How to select the participants

Once a case recruited from the one of the hospital mention above, the data collector for the controls for that particular MOH area will be informed. Then you have o give a call 10 of the randomly selected PHM s working in that particular MOH area. If there is one neonate during that period he/She will be recruited as a control. But if more than one neonate for that particular case, one selected randomly. Then the address of the mother and small guide to find the place for that mother were taken from the area PHM. Then the data collector visits the mother and neonate at their residence.

Then after explaining the study to the mother of control, take the consent for the study. Then you administer the IAQ I and IAQ II. Then EPDS questionnaire to be given to the mother to fill. Then ask for pregnancy record of mother and CHDR of neonate. Then the relevant data for record sheet I and record sheet II to be extracted from the pregnancy record (date of registration at ANC, POG when deliver the neonate, past obstetric history, details of ultra sound scan, and the medication taken during pregnancy period and the hospital where neonates delivered). Then from the CHDR the relevant data for record sheet II (look for date of birth, birth weight, APGAR score and OFC).

Once finished the data collection thanks the mother for participating in the study and give the contact number of P.I. to clarify any issues. While carry out these entire thing you should not disturb the routine work of neonate and house work. Then according the name of mother , date of admission to the hospital, ward of the hospital and date of birth of neonate, the BHT of the mother to be traced and other information of record sheet I and II to be filled.

Annexure XII

Classification of occupational categories

Classification if occupational categories as used in annual employment return to commissioner of labour

1. Administrative and managerial workers

Persons who decide on policies and participate in their interpretation and execution and those who as directors and managers plan, organize coordinate and direct activities of private or public enterprise or one or more of their department

Eg: General managers
Production managers
Other senior managers
Estate supirindentans
Senior administrative officers

2. Professionals, Technical and related workers

Persons who carry out professional functions in scientific, Engineering, Technological, economic, social, medical, legal, teaching, literary, cultural and other fields. Also included are technicians who generally work under the supervision of the more highly qualified professional workers and perform allied functions.

Eg: Accountants
Legal officers
Personal Officers
Doctors and qualified medical staff
Engineers
Architects
Qualified technologists and technicians
Tea tasters
Commercial artists
Designers

3. Clerical and related fields

Persons who carry out what are what are commonly thought of as "office job" and also ticket collectors and conductors on passenger's vehicles, and postman delivery services. Supervisory occupants related to office work and transport and communication services operations are also included.

Eg: Junior executive

Chief clerks
Stenographers
Typist
Book keepers
Cashiers
Store Keepers
Telephone operators
Calculating and business machine operators
Bus conductors
Clerks of all description

4. Sales workers

Persons engaged in or directly associated with buying and selling of goods and property and services of all kinds. Also included in state supervisors and those managing small retail shops.

Eg: Sales supervisors
Managers of small shops and boutiques
Salesman and sales women
Shop assistants Canvassers
Auctioneers
Brokers
Petrol service attendants

5, 6, 7, All other workers

Persons who supervise or render catering, housekeeping, personal protective and related services and also persons connected with agricultural, animal husbandry, forestry, fishing, hunting, mining, manufacturing, construction, maintenance, repair, handling and transportation activities, Persons in this category are to be divided into three groups as follows.

5. Supervisors including foreman

All supervisors connected with activities mention against "all other workers' are to be included. Also persons running small service establishments like restaurants, bars, boarding houses etc. Who may go under the name of 'managers' are also included.

Eg: Kanganies
Field assistants
Foreman
Production Supervisors
Construction gang supervisors
Managers of small restaurants, bars and similar service establishment

6. Skilled and semiskilled

Persons who are not foreman or supervisors and also a not unskilled workers as defined later should all be included here. Eg: spinners, dyers, weavers, plumbers, Fitters, Electricians and carpenters. Tailors Hair Dressors, Shoe makers, bakers, waiters, Bar keepers, motor mechanics, Printers, Brick layers, Drivers, Toddy trappers, ect. And all apprentices and trade learners.

7. Unskilled workers

Workers who perform manual tasks of a simple and routine nature, requiring mainly physical effort and little or no previous training or experiences. EG: Labourers, Watches, Sweepers, Cleaners, Peons and other minor employees

Annexure XIII

Inter- observer reliability between Principal investigator and interviewers for selected variables in the questionnaire

Variable	**Reliability measure**	**Value**
Number of field clinic visits	0.80	**0.000**
Highest education attained	**0.72**	**0.000**
Mothers occupation	**0.58**	**0.000**
Experiences of abuses by relatives	**0.76**	**0.000**
Politeness of consultants	**0.66**	**0.000**
Respect given to mother	**0.69**	**0.000**
Regarding the understanding of explanations	**0.71**	**0.000**

Annexure XIV

Check list for observation of building design and physical facilities in relation to infection control standards in the labour rooms

Serial no	Description	Yes	No
1.	Building designated for the LR		
2.	Waste disposal site near by/ not near by to the labour room		
3.	Water supply for 24 hours/ separate storage tanks		
4.	Availability of elbow operated water taps		
5.	Door of the toilets directly open to the LR		
6.	Cleaners can go to the toilets without going through the LR		
7.	Floor tiled if yes large tiled (24x24 or 36 x 36) / small tile		
8.	Wall tiled		
9.	Separate place to wash surgical instrument		
10.	Separate place to wash and dry mackintosh / linen		
11.	Separate storage room		
12.	Place to change of shoes at the entrance		
13.	Separate place for receptions		
14.	Place to change the patient from trolly to trolley		
15.	Separate place to change the clothes		
16.	Dress the sterile clothe supplied by LR		
17.	Availability of foot operated dust bin		
18.	Piece of soap (with good draining of water) available in each sink		
19.	Stores for sterilized equipment		
20.	Stores for sterilized packs		
21.	Washing rooms		
22.	Separate door to dispose biohazard		
23.	Separate dirty utility room		
24.	General stores		
25.	Cleaners room		
26.	Duty rooms for staffs		

Source : Building and other guide line for NICU/ SCBU/ MBC prepared by Family Health Bureau ,Ministry of health, perinatal society of Sri Lanka and Central Engineering consultancy Bureau (2007), Infection control manual, College of Microbiologists ,Sri Lanka,(2005).

Annexure XV

Check list for observation of building design and physical facilities in relation to infection control standards in the NNICU

S. No:	Description	Yes	No
1.	Building designated for NNICU		
2.	Garbage disposal site near by		
3.	24 hour water supply/separate reservoir tank		
4.	Availability of facility for hand washing before entry		
5.	Separate place for changing of cloths		
6.	Separate place for changing of shoes		
7.	Availability of elbow operated water tap		
8.	Availability of soap/liquid soap		
9.	Availability of towels		
10.	Pictorial display of hand washing		
11.	Availability of separate stethoscope for each cot		
12.	Walls tiled up to 5 feet /not		
13.	Floor tiled up large tile (2x2) / small tile		
14.	Incubator washing and drying area		
15.	Sterilization room		
16.	Sterilized goods stores		
17.	Pantry		
18.	Store rooms for drugs and surgical equipment		
19.	Linen washing room		
20.	Cleaners room		
21.	Dirty utility rooms		
22.	Mother baby units		
23.	Breast feeding room		
24.	Counseling room		
25.	Staff rooms		
26.	Separate areas for low dependency		
27.	Separate areas for high dependency		
28.	Separate areas for procedures		
29.	Separate areas for duty station		
30.	Separate areas for isolation room		
31.	Availability of staff rooms		

Annexure XVI

Check list for observation of building design and physical facilities in relation to infection control standards in the PNW

	Discription	Yes	NO
1	Availability of sink and taps		
2	Pictorial display of hand washing		
3	Availability of colour coded dust bins		
4	Overcrowding of PNW		

Annexure XVII

Check list for observation of building design and physical facilities in relation to infection control standards in the OT

S. No:	**Description**	**Yes**	**No**
1	There is a designated place for dressing		
2	There is a cabinet or box with well fitting lid to keep sterile packs		
3	Doors keep close while operating		
4	Restrict conversations while surgery		
5	There are separate trolleys for theatre and wards		
6	There are detergent fluids for scrub		
7	There are brushes for nail brush		
8	There are either elbow operated or foot operated taps for scrub		
9	There are no infectious foci next to the theatre		

Annexure -XVIII

Part B-Check list for observation of procedures carried out in the labour room

1. When the birth attendant preparing for delivery,

		Yes	No
1.	Change the shoes before enter to the LR		
2.	Wear the mask before enter to the LR		
3.	Wear sterile gown		
4.	Wash hands before wear the gloves		
5.	Wear sterile gloves		

2. The following things has been done by the birth attendant while delivering the baby

		Yes	No
1.	Place the baby on mothers abdomen or in the arms		
2.	Thoroughly dry the baby immediately		
3.	Wipe eyes		
4.	Put anti microbial to the eyes		
5.	Discard wet cloths immediately		

3. Which of the followings Y /N regarding the umbilical cord care provided by the birth attendant?

		Yes	No
1.	Change the gloves /wash the gloves before cut the umbilical cord		
2.	Clamp and cut the cord		
4.	Used sterile instrument		
5.	Observe for oozing blood		
6.	Application of any substances over the stump		

4. Does the birth attendant give the following care to the baby just after delivery?

		Yes	No
1.	Leave the baby on mothers chest in skin to skin contact		
2.	Cover the baby		
3.	Cover the head of the baby		
4.	Did not remove the vernix		
5.	Initiate of breast feeding with in one hour		

5. Does the birth attendant help to the mother to start breast feeding?

		Yes	No
1.	Initiation of breast feeding within 30 min to 1 hour		
2.	Any other feeding given other than breast feeding		
3.	HCW promote breast feeding		
4.	HCW help for positioning of the baby		
5.	HCW help for attachment of the baby		

6. Does the birth attendant adhere to the following things when wash the hands.

		Yes	No
1.	Remove all bangles, rings, watches		
2.	Cut nail short		
3.	Use soap/liquid soap		
4.	Use running water		
5.	Wipe out hands		

7. Does the birth attendant wash the following parts of the hand when hand washing?

		Yes	No
1.	Over the surface		
2.	Back of the hands		
3.	Inter digital spaces		
4.	Back of the fingers		
5.	Thumbs separately		
6.	Tip of the fingers		

8. What are the items used by the birth attendant to wipe out hands.

		Yes	No
1.	Disposable towels		
2.	Single use sterile towels		
3.	Common towel		
4.	Separate towel		

9. Does the birth attendant does the following things when dispose the sharps.

		Yes	No
1.	Recap before dispose		
2.	Dispose without separating the needle		
3.	Dispose to the sharp bin		
4.	Change of sharps from persons to persons		

10. Does the birth attendant take necessary action to get done following things?

		Yes	No
1.	Put TCL and keep for 30 min over the blood spilled floor		
2.	Use separate mop to wipe out the contaminated places		
3.	Change the mackintosh for the delivery of a new mother		
4.	Keep the contaminated materials in a separate bin		

Annexure XIX

Part B-Check list for the adherence of infection control practices of the NNICU staff

1. The following things has been done by the health care worker when examination/ cleaning of the sick neonates.

1	Change the shoes when enter to the unit		
2	Wear sterile gown provided		
3	Wear sterile mask provided		
4	Wear sterile caps provided		
5	Wash hands before touch the baby		
6	Wash the hands after touching the baby		

2. Does the health care worker adhere to the following things when wash the hands.

		Yes	No
1.	Remove all bangles, rings, watches		
2.	Cut nail short		
3.	Use soap/liquid soap		
4.	Use running water		
5.	Wipe out hands		

3. Does the health care worker wash the following parts of the hand when hand washing?

		Yes	No
1.	Over the surface		
2.	Back of the hands		
3.	Inter digital spaces		
4.	Back of the fingers		
5.	Thumbs separately		
6.	Tip of the fingers		

4. What are the items used by the health care worker to wipe out hands.?

		Yes	No
1.	Disposable towels		
2.	Single use clean towel		
3.	Common towel		
4.	Separate towel		
5.	Did not wipe out		

5. When health care worker doing the peripheral venous cannulation

		Yes	No
1.	Wash the hands before starts the procedure		
2.	Wear pair of disposable clean gloves		
3.	Selected site disinfected with 70% alcohol and allowed to dry		
4.	The date of insertion documented in the BHT / on the dressing		

6. When health care worker collect blood for blood culture the following things has been done.

		Yes	No
1.	Clean with 70% alcohol over and around the selected site		
2.	allowed to dry		
3.	Clean with 10% povidone iodine and allow at least 2 min to act		
4.	Wash the hands before the procedure		
5.	Wear the pair of sterile gloves		
6.	Use sterile needle and syringes to draw blood		

7. Does the birth attendant does the following things when dispose the sharps.

		Yes	No
1.	Recap before dispose		
2.	Dispose without separating the needle		
3.	Dispose to the sharp bin		
4.	Change of sharps from persons to persons		
5.	Sharp bin is not filled up to ¾ of the bin		

8. When extraction of breast milk is carried out by a mother

		Yes	No
1.	Advise mother to wash hands before squeeze the breast milk		
2.	Give a boiled / immersed in Milton solution milk cup		
3.	Advise mother to wash hands before handling the baby		
4.	Advise mother to wash the hands after handling the baby		
5.	Wear the pair of sterile gloves		
6.	If use syringes for feeding does it discard after each use		

9. When the health care worker manage the blood spills

		Yes	No
1.	Wear heavy duty gloves		
2.	Soak up fluids using absorbant material (gauze,wadding,papers)		
3.	Pour 1% hypoclorite solutions and keep for 10 min		
4.	Clean area with detergent		
5.	Wear the pair of sterile gloves wash hands		
6	Discard gloves as clinical waste		

10. Collection and transport of specimens

		Yes	No
1.	Place specimens in a leak proof container		
2.	Donot contaminate the out side of the container		
3.	store specimen away from food and drink		
4.	Transport securely to prevent spillage		

Annexure XX

Check list for the adherence of infection control standards by health care workers in **Post natal wards**

1. Does the health care worker who examine the newborn ,practices the hand washing,

		Yes	No
1.	Remove all bangles, rings, watches		
2.	Cut nail short		
3.	Use soap/liquid soap		
4.	Wipe out hands		
5.	Close the tap by elbow/some one else		

2. Does the health care worker follow the following steps in hand washing

1	Over the surface		
2	Back of the hands		
3	Interdigital spaces		
4	Back of the fingers		
5	Thumbs separately		
6	Tip of the fingers		

3. The health care worker who attend to the BCG vaccinations

1	Wash the hands before attend to the BCG vaccination		
2	Clean the skin with antiseptics		
3	Use disposable needle and syringe		
4	Wash the hands after attending the vaccination		
5	Keep the neonates on the clean surface		

4. Disposal of sharps after BCG vaccination

1	Recap before dispose		
2	Dispose without separating the needle		
3	Dispose to the sharp bin		
4	Change of sharps from persons to persons		
5	Hand washing after BCG vaccination		

Annexure XXI

Part B: Observation of adherence of infection control standards by health care workers of operation theatre in selected procedures

1. Before attending to the caesarian section the health care worker

		yes	no
1.	Remove all jewelers, watches before scrubbing		
2.	Use nail brushes for the first hand wash		
3.	Apply 3-5 ml of antiseptic detergent		
4.	Rub all surfaces of hands and foreams3-5 minutes		
5.	Hands held high while washing with water		

2. Before attending to the caesarian section the health care worker

		yes	no
1.	Completely change into theatre clothing		
2.	Caps properly covering hair		
3.	Mask completely cover the nose and mouth		
4.	Put double gloves during surgery		
5.	Mask change after each operations		

3. Patient who come for the caesarian section

		yes	no
1.	Wear clean cloths		
2.	Wear light coloured cloths		
3.	Wear cap		
4.	Wear leggings		

4. Does the birth attendant of the theatre

		yes	no
1.	Completely change into theatre cloths		
2.	Change the shoes when enter to the theatre		
3.	Caps properly covering hair		
4.	Mask completely cover the nose and mouth		
5.	Hand washed before wear the gloves		
6.	Wear sterile gloves		

5. Does the birth attendant did the following things after delivery

		yes	no
1.	Change the gloves /wash the gloves before cut the umbilical cord		
2.	Clamp and cut the cord		
3.	Used sterile instrument		
4.	Observe for oozing blood		
5.	Application of any substances over the stump		

6. Does the birth attendant did the following things after delivery

		yes	no
1.	Thoroughly dry the baby immediately		
2.	Wipe eyes		
3.	Put anti microbial to the eyes		
4.	Discard wet cloths immediately		
5.	Place the baby on mothers abdomen or in the arms		
6.	Starts breast feeding in the theatre with in one hour		

Annexure XXII

Part A;

Observations of the building designs and physical facilities in relation to infection control standards were made. Availability of the facility marked as yes and if not marked as no. The total results were presented as percentages. Total of seven labour rooms belongs to the study institutions. The availability of facilities given as a percentages below.

Results or observation of building design and physical facilities in relation to infection control standards in the NNICU

Serial No.	Decription	No	%
1.	Building designated for the LR	7	100
2.	Waste disposal site near by/ not near by to the labour room	1	14
3.	Water supply for 24 hours/ separate storage tanks	4	57
4.	Availability of elbow operated water taps	3	42
5.	Door of the toilets directly open to the LR	2	14
6.	Cleaners can go to the toilets without going through the LR	6	85
7.	Floor tiled if yes large tiled (24x24 or 36 x 36) / small tile	6	85
8.	Wall tiled	5	71
9.	Separate place to wash surgical instrument	4	57
10.	Separate place to wash and dry mackintosh / linen	4	57
11.	Separate storage room	5	71
12.	Place to change of shoes at the entrance	4	57
13.	Separate place for receptions	1	14
14.	Place to change the patient from trolley to trolley	1	14
15.	Separate place to change the clothes	3	42
16.	Dress the sterile clothe supplied by LR	0	0
17.	Availability of foot operated dust bin	3	57
18.	Piece of soap (with good draining of water) available in each sink	7	100
19.	Stores for sterilized equipment	7	100
20.	Stores for sterilized packs	6	85
21.	Washing rooms	4	57
22.	Separate door to dispose biohazard	4	57
23.	Separate dirty utility room	3	42
24.	General stores	4	71
25.	Cleaners room	1	14
26.	Duty rooms for staffs	1	14

All labour rooms from the beginning, design for labour rooms. Out of seven labour rooms, the proper staff rooms available only (14%) in one labour room.

Annexure XXIII

Obsevation of the NNICU were made according to the check list given below. The results were present as percentages. There were total of five NNICU belongs to the study hospitals.

observation of building design and physical facilities in relation to infection control standards in the NNICU

Serial No	Description	Number	%
1.	Building designated for NNICU	3	60
2.	Garbage disposal site near by	1	20
3.	24 hour water supply/separate reservoir tank	2	40
4.	Availability of facility for hand washing before entry	3	60
5.	Separate place for changing of cloths	1	20
6.	Separate place for changing of shoes	2	40
7.	Availability of elbow operated water tap	4	80
8.	Availability of soap/liquid soap	5	100
9.	Availability of towels	2	40
10.	Pictorial display of hand washing	3	60
11.	Availability of separate stethoscope for each cot	3	60
12.	Walls tiled up to 5 feet /not	3	60
13.	Floor tiled up large tile (2x2) / small tile	3	60
14.	Incubator washing and drying area	3	60
15.	Sterilization room	4	80
16.	Sterilized goods stores	4	80
17.	Pantry	1	20
18.	Store rooms for drugs and surgical equipment	4	80
19.	Linen washing room	3	60
20.	Cleaners room	0	0
21.	Dirty utility rooms	3	60
22.	Mother baby units	3	60
23.	Breast feeding room	3	60
24.	Counseling room	1	20
25.	Availability of Staff rooms	1	20
26.	Separate areas for low dependency	4	80
27.	Separate areas for high dependency	4	80
28.	Separate areas for procedures	4	80
29.	Separate areas for duty station	4	80
30.	Separate areas for isolation room	5	100

Two of the buildings were not originally design for NNICU. All NNICU has a facility to hand wash before entering. Majority 4 (80%) of units donot have separate staff rooms.

Annexure XXIV

Observations of the post natal wards were made for availability of basic facilities according to the infection control standards. There were nine post natal wards included to the institutions.

S. No:	Description	No	%
1	Availability of sink and taps (at least one / ward)	7	77%
2	Pictorial display of hand washing	4	44%
3	Availability of colour coded dust bins	1	14
4	Overcrowding of PNW	9	100

There was only one post natal ward using colour coded dust bins. All (100%) post natal wards were overcrowded.

Annexure XXV

The operation theatres were observed only in relation to neonatal care. Observations carried out in the theatres that performed caesarian sections. There were six operation theatres that are performing caesarian sections.

Serial no	Description	No	%
	There is a designated place for dressing	6	100
	There is a cabinet or box with well fitting lid to keep sterile packs	6	100
	Doors keep close while operating	4	66
	Restrict conversations while surgery	4	66
	There are separate trolleys for theatre and wards		
	There are detergent fluids for scrub	6	100
	There are brushes for nail brush	6	100
	There are either elbow operated or foot operated taps for scrub	5	83
	There are no infectious foci next to the theatre	1	16

Annexure XXVI $_A$

Patient's information sheet

I Dr. ...., currently attached to wish to carry out a study on risk factors and preventive practices for neonatal sepsis, its effect on maternal post partum depression and adherence to infection control standards by health care workers for selected procedures in neonatal care. Mean while in this study it is also plan to assess the patient's satisfaction regarding neonatal care and maternal care provided through government health services.

In this study mother of neonates who were diagnosed of having neonatal sepsis suppose to be answered three interviewer administered questionnaire and single self administered questionnaire in three occasions. First one will be at the beginning of the diagnosis, second one will be while in the ward and third one will be at discharge from the hospital. Each one will be approximately take 15 to 20 minutes.

Your new born baby will not be subjected to any form of physical examinations and no blood or other specimen collected for this study. Participation for the study will be completely voluntary and refusing to take part will not affect the care provided to your child. In spite of giving consent you can withdraw from the study at any time from the study.

There will not be any potential risk or benefits to your child by participating in this study and you will not be entitled any form of financial benefits. If you wish to participate to the study there will not be any cost of participation.

When interviewing you will be given maximum privacy and the confidentiality of the information will be ensured. The data sheet will be kept under lock and key and electronic version of data base will be pass word secured.

If you have any doubts about this study you are free to get them clarified from the principal investigator.

Dr. ....

Contact number 071..............

Annexure XXVII

Consent form to be completed by the participants

Description	**Yes**	**No**
I have read the information sheet		
I was explained about the study by the investigator		
I had the opportunity to discuss the problems and clarify my concerns regarding the study		
I understand my participation is voluntary and I know I can withdraw from the study at any time.		
I had sufficient time to come to a decision		

I here give my consent to take part in the study.

Participant signature: ....

Date: ....

Name: ....

Sheet to be completed by the investigator

I have explained to the study to above volunteer. She had indicated her wiliness to participate in the study.

....

Signature of the investigator:

Date:

ඇමුණුම

සහභාගි වන්නන් සඳහා උපදෙස් පත්‍රිකාව

වෛද්‍ය .... වන මම වර්තමානයේ .... ට අනුයුක්තව සේවය කරන අතර, නව ජන්ම ළදරුවන් ආසාදනය වීමට හේතු සාධක සොයා බැලීමටත් ඒවා වළක්වාලීමට කළහැකි ආරක්ෂණ ක්‍රම පිළිබඳවත් අධ්‍යනයක් කරමි. තවද නම ජන්මයන් ආසාදනය වූ විට ඇතිවන මව්වරුන්ගේ ආතතිය සහ නව ජන්මයන් ආසාදනය වූ පසු නව ජන්මයාට සහ මවට ලබාදුන් ප්‍රතිකාර සහ රැකවරණයේ තෘප්තිය පිළිබඳව ද මෙයින් අධ්‍යනය කිරීමට බලාපොරොත්තු වෙමි.

මෙම අධ්‍යනයේදී ආසාදිත නව ජන්මියාගේ මව්වරු විසින් ප්‍රශ්නාවලි තුනකට පිළිතුරු සැපයිය යුතය. ඉන් පළමු වැන්න සඳහා ආසාදිත තත්ත්වය හඳුනාගත් විගසමද, දෙවැන්න සඳහා ප්‍රතිකාර ලබන අතරතුර ද තුන්වැන්න සඳහා ප්‍රතිකාර ලබා රෝහලෙන් පිටවන අවස්ථාවේදී ද පිළිතුරු ලබාගැනීමට බලාපොරොත්තු වෙමි. එක් ප්‍රශ්නාවලියකට පිළිතුරු දීමට සාමාන්‍යයෙන් විනාඩි විස්සක් පමණ ගතවේ.

ඔබගේ දරුවා කිසිම භෞතික විභාග කිරීමකට හෝ සාම්පල එකතු කිරීමකට ලක් කරනු නොලැබේ. මෙම අධ්‍යනයට සහභාගි වීම සම්පූර්ණයෙන්ම ස්වේච්ජාවෙන් කළ යුතු දෙයක් වන අතර ඔබ මෙයට සහභාගි නොවීම හේතුවෙන් ඔබගේ ළදරුවාට ලැබෙන ප්‍රතිකාර වල කිසිඳු වෙනසක් සිදුනොවේ. එමෙන්ම මේ සඳහා ඔබ මුලින්ම කැමැත්ත ලබා දුන්නද ඕනෑම අවස්ථාවක මෙම අධ්‍යනයෙන් ඉවත් විය හැකිය.

ඔබ මෙම අධ්‍යනයට සහභාගි වීමෙන් ඔබගේ දරුවාට හානියක් හෝ විශේෂ වාසියක් සිදු නොවන බව අවධාරනය කරන අතර මෙයට සහභාගි වීම නිසා ඔබට කිසිඳු ගෙවීමක් ද නොලැබේ. එසේම මෙයට සහභාගි වීමට ඔබට අමතර වියදමක් දැරීමට සිදුනොවේ. දත්ත රැස් කිරීමේදී ඔබගේ පෞද්ගලිකත්වය උපරිමයෙන් ආරක්ෂාකරන අතර ඔබගේ තොරතුරුවල රහස්‍යභාවය ආරක්ෂා කිරීමටද පොරොන්දු වෙමි. මෙම තොරතුරු යතුරැලා ආරක්ෂා කරන අතර පරිගණක කරන ලද දත්ත සුරක්ෂිත කරනු ලැබේ.

ඍමම සමීක්ෂණය සම්බන්ධයෙන් මොනයම් හෝ පැහැදිලි කිරීමක් හෝ ගැටලුවක් නිරාකරණය කරගැනීම පිණිස දත්ත එකතු කරන්නාගෙන් විමසීමට ඔබට නිදහස ඇත. එසේම අවශ්‍ය ඕනෑම මොහොතක ප්‍රධාන සමීක්ෂකව ඇමතීමට ඔබට අවස්ථාව ඇත.

දුරකථන අංක ....

Anexure XXVII$_B$

Annexure XXVIII

National Guidelines for hand hygiene and patient care device management:

Hand washing procedure

1. Soap and water is used for routine hand washing to remove transient microorganisms.
2. Nails must be clean and short
3. Remove watches, bangles and rings
4. Wet hands and apply soap on all surfaces of hands.
5. Rub hand systematically for 10-15 seconds covering all surfaces especially the tips of fingers, the thumbs and the finger webs.
6. Rinse hands thoroughly
7. Dry hands thoroughly using a single use clean towel which is then send to the laundry for washing
8. Use towel to turn off the tap if it is not elbow operated

. Hand Hygiene products

1. Plain soap: Hand washing with plain soap and water for 15 seconds reduces bacterial counts of the skin
2. Alcohols: Alcohol based hand antiseptics containing 60%-95% alcohol are the most effective. The application should last for 20 seconds after rubbing hands together. The drying effect of alcohol can be reduced by adding 1%-3% glycerol.
3. Chlorhexidine: The effective percentage of chlorhexidine gluconata is 2-4%.

4 Iodine and iodophors : The formulation used for hand hygiene should contain 7.5%-10% povidone iodine.

Indications for hand washing and hand antisepsis

- When hands are visibly dirty
- If hands are not visibly soiled either wash hands with soap and water or use an alcohol hand rub.
- Decontaminate hands before having direct contact with patients
- Before wearing sterile gloves
- After contact with body fluids
- Even after contact with a patient's intact skin

- When moving from a contaminated body site to a clean body site
- After contact with inanimate objects
- After removing gloves.

Insertion of peripheral venous cannulae

- Observe proper hand hygiene- Wash hand with conventional antiseptic containing soap and water or with waterless alcohol based gel or foams and wear gloves.
- Disinfect clean skin with an appropriate antiseptic before cannulae insertion (2% chlorhexidine based preparation or 70% alcohol or 10% povidone iodine) Allow the antiseptic to remain in the insertion site to air dry (povidone iodine to remain on the skin for at least for 2 minutes) before inserting the cannulae.
- Use of gloves does not substitute for hand hygiene.

Management of spills

Blood and body fluid spills

i. Wear heavy duty gloves
ii. Soak up fluid using absorbent material (paper towels, gauze, wadding)
iii. Pour 1% hypochlorite solution (10,000 ppm of available chlorine 0 till it is well soaked. Leave for at least 10 minutes.
iv. Remove the absorbent material and discard as clinical waste.
v. Clean area with detergent and water and dry.
vi. Discard gloves as clinical waste.
vii. Wash hands.

Precautions to prevent blood borne infections

Handling of sharps

i. Avoid using sharps unnecessarily
ii. Sharps should be disposable (single use only)
iii. Take care to prevent injuries while using, handling after procedures, cleaning and disposing of sharps.
iv. Avoid recapping used needles. As far as possible avoid removal of used needles from disposable syringes by hand.

v. Discard sharps directly into the 'sharps bin' which should be located as close as practical to the area in which the items were used. Discard used sharps immediately and never leave them lying around.

vi. Dispose the sharps bin when it is ¾ full. Never let the sharp bin fill up more than ¾ full.

vii. Sharps must not be passed directly from hand to hand.

Place reusable glass syringes and needles in a puncture resistant container for transport to the decontamination area.

viii. Use clean gloves during phlebotomy.

Procedure for collection and transport of specimens

i. Place specimens in a leak proof container

ii. The outside of the container should not be contaminated.

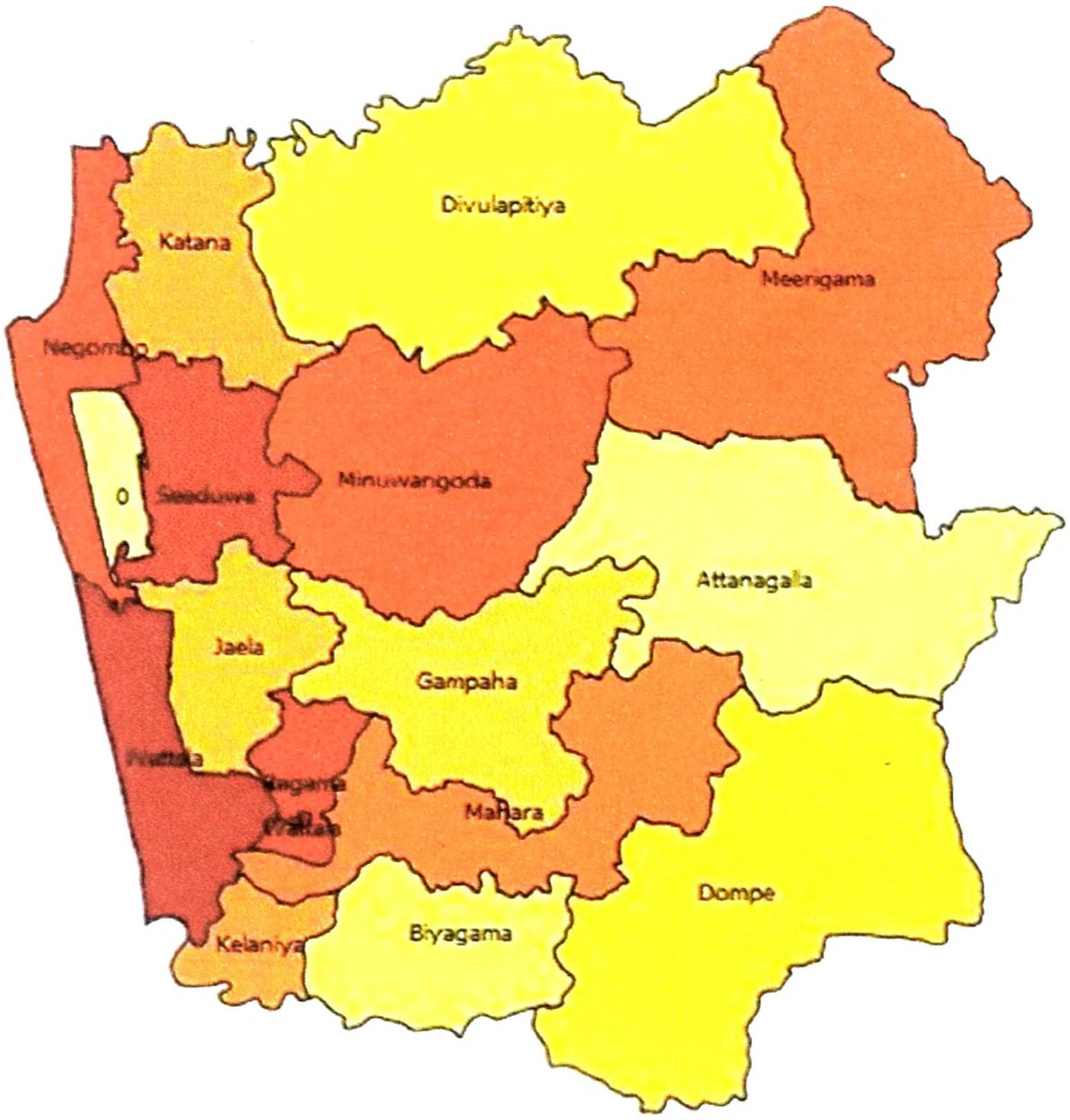
iii. Place the request forms in a plastic bag or separately from the specimen to prevent contamination.

iv. Store specimens away from food and drink.

v. Transport securely to prevent spillage (Mannual of infection control, Ministry of health 2000).

Annexure XXIX

MOH areas in Gampaha District



UNIVERSITY OF KELANIYA, SRI LANKA
FACULTY OF MEDICINE
ETHICS REVIEW COMMITTEE

Ref: P72/07/2010

20.07.2010

Dr. DUCJ Jayasinghe,
No 174, Malani Sewana,
Keragala,
Henegama.

Risk factors,preventive practices for neonatal sepsis & its effect on maternal psychological status & satisfaction of care among mothers in secondary & tertiary care hospitals of Gampaha district

Authors: DUCJ Jayasinghe, HTCS Abeysena

Thank you for submitting the above research proposal for ethical clearance. I am pleased to inform you that the Ethics Review Committee which met on 20.07.2010 has granted ethical clearance to the above study.

The following documents were reviewed

- Protocol Version 1, dated June 2010
- Questionnaire Version 1, dated June 2010
- Information sheet and Consent Form Version 1, dated June 2010

With best wishes,

P. Jayaw

Prof. Pushpa Jayawardana
Chairperson / ERC

PO Box 6, Thalagolla Road, Ragama, Sri Lanka
Telephone: (00 94 11) 2958166, 2958219, 2958037
Fax: (00 94 11) 2958251 & 2958337

සෞඛ්‍ය සේවා අධ්‍යක්ෂ කාර්යාලය - ගම්පහ දිස්ත්‍රික්කය
කච්චේරි සංකීර්ණය, කොළඹ පාර, ගම්පහ, ශ්‍රී ලංකාව
சுகாதார சேவைகள் பணிப்பாளர் காரியாலயம் – கம்பஹா மாவட்டம்
கச்சேரி கம்ப்ளெக் கொழும்பு வீதி கம்பஹா ஸ்ரீ லங்கா.
OFFICE OF THE REGIONAL DIRECTOR OF HEALTH SERVICES – GAMPAHA DISTRICT
Kachcheri Complex, Colombo Road, Gampaha, Sri Lanka.

මගේ අංකය: My No: GM/EPID/GN/2010 எனது இல :	ඔබේ අංකය: Your No: உமது இல :	දිනය: Date: 2010.08.11 திகதி :

Dr. D. U. C. J. Jayasinghe
Department of Public Health
Faculty of Medicine
University of Kelaniya

<u>Research Project on " Risk factors, preventive practices for neonatal sepsis and its effect on maternal psychological status and satisfaction of care among mothers in secondary and tertiary care hospitals of Gampaha District"</u>

With reference to your letter dated 10th August 2010, I would like to grant permission to you for the above study to do in the District of Gampaha.

2. Please be kind enough to send your recommendations, relevant data & findings after completion of the study.

Thank You

Dr. A. L. A. L. Padmasiri
Regional Director of health Services
Gampaha District

Regional Director of Health Services
Gampaha District

Copy

1. All Heads of the Health Institutions in Gampaha District - for your kind support

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