Factors Associated With Developing Ophthalmia Neonatorum in Harare City, 2013

By

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DECLARATION

I, Vengere Calvin, certify that this dissertation is my original work and submitted for the Master in Public Health Programme. It has not been submitted in part or in full to any other university and/or any publication.

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I, having supervised and read this dissertation, am satisfied that this is the original work of the author in whose name it is being presented. I confirm that the work has been completed satisfactorily for presentation in the examination.

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ABSTRACT

Factors Associated With Developing Ophthalmia Neonatorum in Harare City, 2013

Introduction: Ophthalmia neonatorum is defined as any conjunctivitis with discharge from the eyes during the first 28 days of life. Ophthalmia neonatorum is preventable. Gonococcal ophthalmia, if untreated, may progress rapidly to corneal ulceration, perforation, corneal opacification, staphyloma formation and eventually blindness. Globally the prevalence of ophthalmia neonatorum has been on the decline. In Harare Province alone, the cases increased by a massive 65% from 1023 cases in 2010 to 1688 cases in 2011 although the total number of deliveries increased by only 8%. This study was conducted in order to determine the factors associated with developing ophthalmia neonatorum in Harare City.

Materials and Methods: An unmatched 1:1 case-control study was conducted. A case was defined as any newly born baby with eye discharge in the first 28 days of life in Harare City while a control was any newly born baby in Harare City who did not develop eye discharge in the first 28 days of life. Pretested questionnaires were used to collect data and antenatal records were reviewed. 22 eye swabs were collected and analysed in the laboratory.

Results: 77 cases and 75 controls were recruited into the study. Independent factors associated with developing ophthalmia neonatorum were being born to HIV positive mother AOR 0.35 (CI 0.13-0.92), having received Tetracycline Eye Ointment (TEO) prophylaxis at birth AOR 0.21 (CI 0.07-0.50) and being born of a planned pregnancy AOR 0.38 (CI 0.17-0.87). Only 43 (28%) study participants received TEO prophylaxis. On thirteen (62%) of the eye swabs collected the microorganism isolated was resistant to tetracycline. Sixteen (73%) of the isolated microorganisms were staphylococcus species, with 8 (50%) of the staphylococcus species being resistant to tetracycline.
**Conclusion:** The huge increase in the cases of ophthalmia neonatorum was partly because the majority of health workers were not giving prophylaxis and treatment according to national guidelines, and partly due to widespread resistance to tetracycline. We recommended therefore that the Ministry of Health and Child Welfare in Zimbabwe consider replacing TEO with ciprofloxacin eye ointment for use as prophylaxis against ophthalmia neonatorum.

**Key Words:** Ophthalmia neonatorum, resistant, susceptible, Harare City
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University of Zimbabwe, August 2013
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LIST OF ABBREVIATIONS

ANC: Antenatal Care
AOR: Adjusted Odds Ratio
ARI: Acute Respiratory tract Infection
BBA: Born Before Arrival
CHC: Child Health Card
CI: Confidence Interval
c/s: Caesarean Section
DHE: District Health Executive
DMO: District Medical Officer
EGA: Estimated Gestational Age
GCON: Gonococcal Ophthalmia Neonatorum
HIV: Human Immunodeficiency Virus
HSO: Health Studies Office
JREC: Joint Research Ethics Committee
MRCZ: Medical Research Council of Zimbabwe
NLFC: Non Lactose Fermenting Coliforms
NVD: Normal Vaginal Delivery
OR: Odds Ratio
PNO: Principal Nursing Officer
PPNG: Penicillinase Producing Neisseria Gonorrhoea
PROM: Preterm Rupture of Membranes
Q1: First Quartile
Q3: Third Quartile
STI: Sexually Transmitted Infection
TB: Pulmonary Tuberculosis
TEO: Tetracycline Eye Ointment
USPSTF: United States Preventive Services Task Force
UTI: Urinary Tract Infection
WHO: World Health Organization
X²: Chi square
Ophthalmia neonatorum is defined as any conjunctivitis with discharge from the eyes during the first month of life\textsuperscript{1,2,5}. The causes of ophthalmia may be gonococcal or non-gonococcal, and Chlamydia trachomatis is the most important cause in the latter group. The risks of ophthalmia neonatorum due to gonococci and chlamydia in infants born to an infected mother ranges from 30\% to as high as 50\%, respectively. Gonococcal ophthalmia, if untreated, may progress rapidly to corneal ulceration, perforation, corneal opacification, staphyloma formation and eventually blindness. Chlamydial ophthalmia usually follows a less severe progression course. Ophthalmia neonatorum is preventable through: 1) the mother and father avoiding risky sexual behaviour thus avoid sexually transmitted infections (STIs); 2) routine screening for and treatment of STIs during antenatal clinic visits; and 3) disinfection of the infant's conjunctivae at birth by use of prophylactic eye treatment such as: a) 1\% aqueous
silver nitrate solution into each conjunctival sac; b) benzyl penicillin solution into the infant's eyes; or c) tetracycline 1% or erythromycin 0.5% eye ointment ².

A host of other possible causative organisms of ophthalmia neonatorum include Staphylococcus aureus, Streptococcus pneumoniae amongst different other micro-organisms. Less frequently viral causes, notably the herpes simplex virus have been identified as causes. Ophthalmia neonatorum can also occur as a result of chemical irritants, in which case it will usually be self-limiting, resolving within 24 to 36 hours. Ophthalmia neonatorum due to infective causes however requires drug therapy ³.

Ophthalmia neonatorum is among the commonest infectious diseases that occur in the first month of life with the prevalence of 1.6 to 66.5%. The clinical signs and symptoms include hyperaemic conjunctivae, tearing, discharge, keratoconjunctivitis, blepharitis, and pseudomembrane formation. The common organisms that cause neonatal conjunctivitis include Staphylococcus aureus, Haemophilus influenza, Streptococcus pneumonia, gonococcus, Pseudomonas aeruginosa, and Chlamydia trachomatis. The prevalence rates, natural history and medical management of the condition differ from one community to the other. Credé prophylaxis by 1% silver nitrate was found to be useful against gonorrhoeal ophthalmia, however for inclusion blennorrhoea or herpetic infection silver nitrate may not be effective. Silver nitrate may cause some slight chemical conjunctivitis which resolves spontaneously after a few days. Risk factors for ophthalmia neonatorum such as premature rupture of membranes (PROM) and urinary tract infections (UTI) in mother or gestational age, birth weight, gender, prematurity, sepsis, pulmonary infection, or dermatitis in the neonate have been associated with the occurrence of ophthalmia neonatorum ⁴.
Treatment for ophthalmia neonatorum is based on clinical signs and laboratory analysis results. Systemic antibiotics and topical eye preparations can be used to treat the condition. In Zimbabwe the national guidelines on management of sexually transmitted infections (STIs) recommend the use of tetracycline eye ointment (TEO) for prophylaxis against ophthalmia neonatorum and kanamycin injection in combination with oral erythromycin for treatment of the condition.

The occurrence of neonatal conjunctivitis dropped significantly in the developed world following the discontinued use of silver nitrate as prophylaxis against the condition. Recently, the prevalence of neonatal conjunctivitis in the developed world was thought to be less than 0.5%. In some parts of the world however, the incidence of neonatal conjunctivitis remains high, especially in the developing countries. In Pakistan, for instance 17% of about 1000 babies had ophthalmia neonatorum. In Africa new cases of neonatal conjunctivitis continue to be recorded in high numbers.

In Zimbabwe the number of cases of ophthalmia neonatorum increased from 4260 in 2005 to reach a peak of 5772 by 2007 then fell gradually to 5338 by 2011. In Harare City, ophthalmia neonatorum cases increased from 810 cases in 2010, to 1645 cases in 2011 and to 1658 cases in 2012. Although the cases of ophthalmia neonatorum were on the rise, the number of total deliveries in Harare City during the same period increased by a smaller margin from 26 933 deliveries in 2010 to 29 099 deliveries in 2011. The total deliveries then fell down to 27 135 in 2012.
1.2 Problem Statement

In Zimbabwe ophthalmia neonatorum (neonatal conjunctivitis) has been always by far the commonest STI in the 0-4 year age group averaging 87% since 2005. The number of cases of ophthalmia neonatorum increased by 20.7% between 2010 (4421 cases) and 2011 (5338 cases). In Harare province alone, the cases increased by a massive 65% from 1023 cases in 2010 to 1688 cases in 2011, decreasing slightly to 1668 in 2012 although the total number of deliveries increased by only 8% from 26 933 deliveries in 2010 to 29 099 deliveries in 2011.

Figure 2: Number of Cases of Ophthalmia Neonatorum by Province, 2010 and 2011

This huge increase in cases could be a result of health care providers not following the national guidelines to give tetracycline prophylaxis to all new born babies, or due to resistance to tetracycline ointment. Ophthalmia neonatorum is preventable. If not prevented, its occurrence leads to an increase in disease burden and can be complicated by corneal perforation, cataracts and irreversible blindness to the young child.
Chapter 2: Literature Review

2.10: Introduction

Literature review was done on the prevalence of ophthalmia neonatorum, spectrum of causative microorganisms of the condition, clinical presentation and complications associated with the condition. The review of literature was also aimed at drugs used for prophylaxis against ophthalmia neonatorum, laboratory tests and treatment of the condition. Factors associated with the condition were also unravelled as well as microbial resistance to drugs used for both treatment and prophylaxis against ophthalmia neonatorum.

2.11: Prevalence and Causative Organisms for Ophthalmia Neonatorum

A study done in Tehran showed relatively high numbers of cases of ophthalmia neonatorum among hospital-born babies. A total of 170 cases of ophthalmia neonatorum (5.4%) were recorded. Laboratory analysis of eye specimens showed 20.6% gram positive cocci, 8.8% gram negative bacilli and 1.8% gram negative cocci. No growth was recorded in 68.8% of the specimens. The commonest microbes isolated after cultures were: coagulase positive staphylococci (15.3%), Staphylococcus epidermidis (13.5%), E. coli (7.6%), and Staphylococcus aureus (5.9%), and no growth in 48.2% of the specimens. In ten cases (5.9%), DIF samples showed Chlamydia trachomatis. Speaking of public health, ophthalmia neonatorum due to gonococcus (GCON) becomes the significant form because it can quickly progress to blindness. The prevalence of GCON is related directly to the cases of maternal gonococcal infections. In the majority of the developed countries the frequency of gonorrhoea in expecting mothers no more than 1%; whereas in the developing world the incidences range from 3% to 15%, greater than half resulting from penicillinase producing Neisseria gonorrhoeae strains (PPNG).
2.12: Risk Factors for Ophthalmia Neonatorum

In one study, the majority (62.4%) of infected neonates were of male sex, with greater than three quarters being delivered via normal vertex delivery (NVD). Premature rupture of membranes (PROM) came out as the commonest maternal risk factor occurring in 10% of the deliveries. Gul and Jamal found that infants born to mothers who had meconium stained liquor, and those delivered through Caesarean section were at increased risk of contracting ophthalmia neonatorum. Other risk factors for the development of ophthalmia neonatorum included maternal gestational urinary tract infection, maternal fever during pregnancy and meconium aspiration syndrome intrapartum. Isernberg also singled out maternal vaginal tract infections in pregnancy as a major predisposing factor to development of ophthalmia neonatorum. Chemical conjunctivitis has been identified as another cause of the condition. Mundia et al in Kenya conducted a study to determine whether prolonged labour led to an increase in the rate of exposure of the neonate’s eyes to the mother’s vaginal commensals, and whether this exposure resulted in greater risk of contracting ophthalmia neonatorum. They concluded that prolonged labour will lead to an increase in the rate of transmission of mother’s vaginal commensals to the eyes of the neonates and eventually ophthalmia neonatorum.

2.13: Prevention of Ophthalmia Neonatorum

The mother- to-child transmission rates for ophthalmia neonatorum ranges from 30% to 50%. A multi-faceted approach is required to control gonococcal ophthalmia neonatorum and control measures include (a) preventing gonococcal infections in women of childbearing age, (b) screening and appropriate treating of gonococcal infections in expecting mothers, (c) topical prophylaxis in the neonates soon after delivery, and (d) prompt diagnosis and correct management of gonococcal ophthalmia neonatorum.
administration soon after delivery of either 1% silver nitrate eye drops or 1% TEO has been found to work very well \(^5,10\), leading to reduction of new cases of gonococcal ophthalmia neonatorum by margins between 80% and 95%. In high risk areas prophylactic treatment has been deemed highly cost-effective \(^10\).

In a study done by Ghotbi N et al in 2012, comparison of the effect of tetracycline 1% and erythromycin 0.5% ophthalmic ointments for prophylaxis against ophthalmia neonatorum was conducted. Twenty two (20%) of those in the tetracycline group developed ophthalmia neonatorum, whereas 16 (14.5%) of those in the erythromycin group developed the condition and 25 (22.7%) of the control group also had ophthalmia neonatorum. It was concluded that prophylaxis against ophthalmia neonatorum using erythromycin or tetracycline topical eye ointments were effective and essential \(^11,14\).

2.14: Treatment of Ophthalmia Neonatorum

In Zimbabwe the national guidelines on management of sexually transmitted infections (STIs) recommend the use of tetracycline eye ointment (TEO) within 6 hours of delivery for prophylaxis against ophthalmia neonatorum and ceftriaxone/kanamycin injection in combination with oral erythromycin for treatment of the condition \(^5\).

Ophthalmia neonatorum is deemed an ophthalmic emergency; therefore every case must be admitted. The clinical presentation and laboratory analysis results then guide the medical management of each case. Every case of ophthalmia neonatorum should be treated with systemic drugs \(^5,12\) (parenteral penicillin, erythromycin, kanamycin, spectinomycin or ceftriaxone) instead of eye ointments to avert systemic spread of the causative micro-organism. Since the aetiological agent is an STI, it becomes always necessary to also treat the mother and her sexual partner/partners. World Health Organisation guidelines on management of STIs provide for the syndromic management of all cases of ophthalmia
neonatorum, covering for both Neisseria gonorrhoea and chlamydia trachomatis. Both infections occur together in about 2% of all the cases of STIs. Chemical conjunctivitis is generally self-limiting; with symptoms resolving in two to three days and therefore no particular drug therapy may be required. Specific treatment for ophthalmia neonatorum due to infective causes depends on the clinical symptomatology and the laboratory analysis results on Gram, Giemsa, and Papanicolaou stains.

2.15: Complications of Ophthalmia Neonatorum

Ophthalmia neonatorum can be complicated by corneal ulceration, followed by corneal perforation, corneal opacification, staphyloma formation and eventually blindness. Assessment for the complications of ophthalmia neonatorum is based on clinical signs, symptoms and assessment of visual function. The assessment of visual function should be done as a component of the neurological examination for the new born although often times it only ends with examination of movements around the eye, fixing the gaze and following a moving object. In a study that was done to come up with a simple set of testing items for evaluating the various elements of vision, Ricci D. et al in 2007 found that the simple tests can be put to use two days from the delivery of the neonate. The test items were used on fifty normal birth weight babies, and consisted of nine pieces of equipment for determining eye movements, both reflex and with focus on an object, fixation and following (in the horizontal, vertical and in an circular directions), being able to distinguish colour bands of various spatial frequencies, and attending at far objects. These test items were simple to conduct and did not need any special course. The assessment itself would not need any special environment and was simple to use even for children in incubators. The items used were small and could be cleaned easily. They concluded that simple tests, which can be
completed between five and ten minutes, could be easily applied and gives useful information on several aspects of visual function in new-borns.  

2.16: Laboratory Tests for Ophthalmia Neonatorum

Eye swab laboratory analysis is important for appropriate diagnosis and treatment of neonatal conjunctivitis. Firstly culture on chocolate agar or a Thayer-Martin test for *N. gonorrhoeae* can be done together with blood agar for other microorganisms. Chlamydial infection can be tested for with a conjunctival scraping Giemsa stain for intracytoplasmic inclusion bodies or direct immunofluorescent antibody assay. In ophthalmia due to herpes, gram stain can show multinucleate giant cells or Papanicolaou smear can yield eosinophilic intranuclear inclusions in epithelial cells. Culture for herpes simplex virus can be required if a corneal epithelial defect exists or the diagnosis is difficult from clinical assessment alone when vesicular lesions are presence. Table 1 below highlights some of the aspects herein articulated.
Table 1: Time of onset, aetiology and laboratory tests for ophthalmia neonatorum

<table>
<thead>
<tr>
<th>Day of Onset after Delivery</th>
<th>Causative Organism (Signs and Symptoms)</th>
<th>Eye Scrapings</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–2</td>
<td>Chemicals (mild lid swelling with watery exudate)</td>
<td>Minimal reactive cells to few PMN</td>
</tr>
<tr>
<td>2–7</td>
<td>Gonococci (severe lid oedema with purulent discharge)</td>
<td>A lot of reactive cells with Gram negative intracellular diplococci</td>
</tr>
<tr>
<td>3–10</td>
<td>Chlamydia (variable lid oedema with serous or purulent discharge)</td>
<td>Many reactive cells with Giemsa stain for basophilic cytoplasmic inclusion bodies or direct immunofluorescent assay</td>
</tr>
<tr>
<td>4–7</td>
<td>Other bacteria (<em>Staphylococcus, Streptococcus, Haemophilus</em>) purulent discharge</td>
<td>Gram stain for bacteria</td>
</tr>
<tr>
<td>3–14</td>
<td>Herpetic (serous exudate with dendritic keratitis or geographic ulceration)</td>
<td>Varying reactive cells with multi-nucleated giant cells</td>
</tr>
</tbody>
</table>

2.17: Antimicrobial Resistance in Ophthalmia Neonatorum

In a study conducted by Raucher et al in 1983, silver nitrate, which was the most commonly used drug for prophylaxis against neonatal conjunctivitis especially due to gonococci, did not work against chlamydia. Moreover, penicillinase producing strains of gonococci which were resistant to penicillin were increasing in some regions of the United States and Europe. These developments resulted in newer drugs for prophylaxis and treatment of ophthalmia.
neonatorum namely intramuscular penicillin and topical tetracycline ointment (1%) for eye prophylaxis\textsuperscript{9, 16, 17}.

In 2011 Zuppa et al concluded that the use of 1% tetracycline solutions was more effective despite the prospect of drug resistance from some bacteria. None of the used drug combinations proved effective enough to warrant their use on a large scale\textsuperscript{18}. In 2013 Peymaneh et al recommended performing eye discharge culture before antibiotic treatment after finding that the most widespread drug resistance occurred with Ampicillin, Penicillin, Cefixime, and Ceftazidime (100% resistance)\textsuperscript{15, 19}.

2.2 Justification for Conducting the Study

Ophthalmia neonatorum is preventable by screening all pregnant women for sexually transmitted infections during antenatal care and treating all those that have infections. Use of prophylactic treatment helps to further prevent the condition. Globally, ophthalmia neonatorum has been reduced significantly and is as low as 0.5% prevalence in developed countries. In Zimbabwe, the increase in the cases of ophthalmia neonatorum is a cause for concern particularly in Harare Province where there was a 65% increase in the condition between 2010 and 2011. This huge increase certainly called for investigation to find out whether the standard antenatal care and tetracycline eye ointment (TEO) prophylaxis was no longer effective or whether the said standard care was not being practised by health care workers in Harare City. This study was designed to determine the risk factors for contracting the condition. Recommendations drawn from the study would guide the next step of action to reverse the huge increase in morbidity due to ophthalmia neonatorum and its attendant complications especially irreversible blindness.
2.3: The Conceptual Framework

Figure 3: Conceptual framework for factors associated with developing ophthalmia neonatorum in Harare City

Maternal health factors
- Vaginal discharge
- Preterm rupture of membranes
- Prolonged labour
- HIV positive status
- Extremes of parity

Neonatal health factors
- Prematurity
- Low birth weight
- Ocular malformations
- Other neonatal infections
- Meconium stained liquor

Health services factors
- Antenatal care
  - Not screened for STIs during pregnancy
  - Not treated of gestational STIs
- Delivery
  - Poor infection control during delivery
  - Mode of delivery assisted
- Prophylaxis not given
- Prophylaxis not effective

Socio-economic factors
- Mother’s age in the extremes
- Mother’s marital status single
- Place of residence
- Home delivery
- Mother’s level of education low
- Sex of baby boy
- Unbooked pregnancy
Chapter 3: Research Question and Study Objectives

3.1 Research question

What are the factors associated with ophthalmia neonatorum in Harare City?

3.2 Broad objective:

- To determine the factors associated with developing ophthalmia neonatorum in Harare City.

3.3 Specific objectives:

- To describe the socio-demographic characteristics of cases of ophthalmia neonatorum
- To determine the risk factors associated with ophthalmia neonatorum in Harare City
- To assess the prophylaxis used for ophthalmia neonatorum in Harare City
- To determine the drug sensitivity patterns of micro-organisms associated with ophthalmia neonatorum in Harare City
- To assess the treatments given to cases of ophthalmia neonatorum in Harare City
Chapter 4: Methods

4.1 Study Design
An unmatched 1:1 case control study was conducted

4.2 Definition of cases and controls
A case of ophthalmia neonatorum was defined as any newly born baby in Harare City with mucopurulent eye discharge, hyperaemia and conjunctival oedema in the first 28 days of life. A control was any newly born baby in Harare City with no eye discharge or swelling in the first 28 days of life.

4.3 Inclusion criteria
All newly born babies in their first 28 days of life in Harare City were considered for enrolment in the study as a case or control. Born before arrivals (BBAs) were also included in the study.

4.4 Exclusion criteria
All babies born outside Harare and those that had evidence of congenital malformations of the ocular regions or swelling due to trauma were not included in the study. Babies that develop conjunctivitis after 28 days of life were also not included in the study.

4.5 Selection of cases and controls
Cases were selected amongst babies attending the postnatal clinics at selected health facilities in Harare City and developed discharging eyes in their first 28 days of life. Controls were selected amongst babies attending the postnatal clinics at selected health facilities in Harare City and did not develop discharging eyes in their first 28 days of life. (Also see sampling procedure in the next few paragraphs below). The researcher conducted physical examinations on all the study participants. Where possible for all cases, conjunctival swabs were collected for microscopy culture and sensitivity testing.
4.6 Study setting
The study was conducted at six randomly selected polyclinics in Harare City and at homes of selected cases and controls.

4.7 Study Population
All babies born in Harare City during the study period were considered for enrolment into the study as either a case or a control. Mothers or caregivers of cases and controls were interviewed. All antenatal and postnatal records for the cases and controls were reviewed. Selected health workers in the maternity departments were interviewed as key informants.

4.8 Sample size determination
In a study done by Ernest S. K. et al in Nigeria in 2000, babies born to mothers with maternal age less than 20 years were 4.27 times more likely to develop neonatal conjunctivitis. Using Epi Info StatCalc at 95% Confidence Interval for an unmatched 1:1 case-control study, assuming 80% power and 10% expected frequency of exposure in the control group, a sample size of 61 cases and 61 controls were determined. Assuming a 10% non-response rate, the minimum sample size calculated is 136 study participants (68 cases and 68 controls).

4.9 Sampling Procedure
Six polyclinics in Harare City were randomly sampled using the lottery method for inclusion into the study. At each selected clinic systematic sampling was then done from the list of babies seen at the postnatal clinics in the preceding two months to come up with 20 cases and 20 controls from each selected polyclinic, making up to a total of 120 cases and 120 controls were systematically selected initially. The first case on the sampling frame was randomly selected using the lottery method and subsequent participants determined form the predetermined sampling interval.
4.10 Permission to conduct the study

Permission to conduct the study was sought and granted from the Health Studies Office, Harare City Health Department, UZ- Parirenyatwa Joint Research Ethics Committee (JREC) and Medical Research Council of Zimbabwe.

4.11.0 Ethical Considerations

Informed written consent was sought from all mothers/guardians of study participants. A standard Medical Research Council of Zimbabwe (MRCZ) consent form was adapted for use in the study. The study protocol was explained in full to all study participants in Shona, a language they understand with complete details of all procedures to be done.

4.11.1 Informed Consent

A written informed consent was obtained from all study participants. All study participants were given consent forms to sign after the purpose of the study and procedures were explained to them and that signing meant that they agree to take part in the study knowingly and freely. It was also explained to them that study participants were allowed to terminate their participation at any time they felt like doing so without any consequences even after signing the consent form. Copies of the consent forms are included in appendices 3 and 4. The consent form included information on research process, purpose and objectives, benefits of the study.

4.11.2 Right to Confidentiality

Respondents were assured that information they availed to the researcher was not going to be divulged to anybody else other than for the only purposes of the study. This was done to protect participants’ confidentiality. Anonymity was maintained throughout the study by not recording any names of the participants on the questionnaires. Completed questionnaires were kept under lock and key. Electronic data was secured by use of passwords and codes for
access. No unauthorised persons were allowed access to laboratory specimens and results since they were labelled with participants’ names for tracking purposes.

4.11.3 Beneficence

All babies found to be affected by ophthalmia neonatorum or any other conditions were routinely managed at the health facilities. Appropriate referrals were also done for those that needed to be referred.

4.12 Data collection

Data was collected using interviewer administered questionnaires and checklists. Physical examinations were done by the researcher and cotton-tipped conjunctival swabs collected and sent for microscopy culture and sensitivity testing for all cases with visible eye discharge at the time of the interview. Key informant interviews were done with sisters-in-charge of the maternity departments and some midwives found on duty on the day of the study.

4.13 Study variables

Study variables are as outlined in table 2 below. The sources of the information were mainly the Child Health Card (CHC), the Antenatal Care (ANC) card, history from the mother/caregiver as outlined in the interviewer administered questionnaire and the physical examination by the health workers which was then substantiated by the researcher as necessary
Table 2: Study variables in the determination of factors associated with ophthalmia neonatorum in Harare City

<table>
<thead>
<tr>
<th>Variable</th>
<th>Indicator</th>
<th>Source of information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case status</td>
<td>Case, Control</td>
<td>CHC, mother</td>
</tr>
<tr>
<td>Age</td>
<td>Age in days</td>
<td>CHC, mother</td>
</tr>
<tr>
<td>Sex</td>
<td>Sex</td>
<td>CHC, mother</td>
</tr>
<tr>
<td>Place of delivery</td>
<td>Home, facility name</td>
<td>CHC, ANC card</td>
</tr>
<tr>
<td>Maternal education level</td>
<td>None, primary, secondary, tertiary</td>
<td>CHC, mother</td>
</tr>
<tr>
<td>Birth weight</td>
<td>Weight in kilograms</td>
<td>CHC</td>
</tr>
<tr>
<td>Mode of delivery</td>
<td>NVD, Assisted delivery, C/S</td>
<td>CHC, ANC card</td>
</tr>
<tr>
<td>Booking status</td>
<td>Booked, Unbooked</td>
<td>CHC, ANC card</td>
</tr>
<tr>
<td>Duration of labour</td>
<td>Duration in hours</td>
<td>CHC, ANC card</td>
</tr>
<tr>
<td>EGA at delivery</td>
<td>EGA in weeks</td>
<td>CHC, ANC card</td>
</tr>
<tr>
<td>Maternal HIV status</td>
<td>Code 0, code 1</td>
<td>CHC, ANC card</td>
</tr>
<tr>
<td>Comorbidity</td>
<td>ARI Yes, ARI No</td>
<td>CHC, physical examination</td>
</tr>
<tr>
<td>Parity</td>
<td>P0, P1, P2</td>
<td>ANC card</td>
</tr>
<tr>
<td>Maternal VDS</td>
<td>Yes, No</td>
<td>CHC, ANC card</td>
</tr>
<tr>
<td>Membranes</td>
<td>PROM yes, PROM no</td>
<td>CHC, ANC card</td>
</tr>
<tr>
<td>Liquor status</td>
<td>Meconium stained yes/no</td>
<td>CHC, ANC card</td>
</tr>
<tr>
<td>TEO prophylaxis</td>
<td>Yes, No</td>
<td>CHC, ANC card</td>
</tr>
<tr>
<td>Conjunctival swab</td>
<td>Name of microorganism isolated</td>
<td>Laboratory results</td>
</tr>
</tbody>
</table>
4.14 Pre-test
Pretesting of the data collection tools was done at a satellite clinic in Harare City.

4.15 Data analysis
Epi Info version 3.5.1 was used for entering data, generate frequencies, means, proportions and odds ratios. Stratified analysis was done to assess for effect modification and control for confounding on the relationship between planning pregnancy and developing ophthalmia neonatorum as stratified by booking the pregnancy. Multivariate logistic regression analysis was also done using the back-wise elimination method to control for confounding and determine independent factors associated with the development of ophthalmia neonatorum in Harare City. Microsoft Excel was used to generate graphs.

4.16: Laboratory tests
Conjunctival eye swabs were collected from all study participants where eye discharge or scrapings could be obtained. The samples were sent to the laboratory within 72 hours of collection and microscopy, culture and sensitivity testing done on the individual specimens.
Chapter 5: Results

5.1 Socio-demographic Characteristics of Participants

Table 3: Socio-demographic Characteristics of Participants in the Study to Determine Risk Factors for Ophthalmia Neonatorum in Harare City

<table>
<thead>
<tr>
<th>Variable</th>
<th>Case (%)</th>
<th>Control (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=77</td>
<td>n=75</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>48(62.3)</td>
<td>33(44.0)</td>
<td>0.01</td>
</tr>
<tr>
<td>Female</td>
<td>26(37.7)</td>
<td>42(56.0)</td>
<td></td>
</tr>
<tr>
<td>Median age (days)</td>
<td>14(Q1=9;Q3=20)</td>
<td>6(Q1=3;Q3=10)</td>
<td>0.00</td>
</tr>
<tr>
<td>Mean birth weight (grams)</td>
<td>3214 (variance=206951)</td>
<td>3050 (variance=218305)</td>
<td>0.03</td>
</tr>
</tbody>
</table>

There was a significant difference for sex, age and birth weight between the cases and the controls. Cases had a median age of 14 days whereas controls had a median age of 6 days. The age was recorded on the day of the interview. The difference in the median age was because controls were interviewed soon after sampling, whereas cases were interviewed after the controls. The significant difference between cases and controls on sex and mean birth weight suggest that sex and birth weight are factors associated with the development of ophthalmia neonatorum. Selection procedures may possibly have resulted in the non-comparability of the cases and controls.
5.20: Factors Associated with Ophthalmia Neonatorum

5.21: Socio-Economic Factors

Table 4: Socio-Economic Factors Associated with Ophthalmia Neonatorum in Harare City

<table>
<thead>
<tr>
<th>Variable</th>
<th>Case (%)</th>
<th>Control (%)</th>
<th>OR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=77</td>
<td>n=75</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother single</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2(2.6)</td>
<td>2(2.7)</td>
<td>0.97</td>
<td>0.14-7.49</td>
<td>0.68</td>
</tr>
<tr>
<td>No</td>
<td>75(97.4)</td>
<td>73(97.3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>48(62.3)</td>
<td>33(44.0)</td>
<td>2.11</td>
<td>0.25-0.91</td>
<td>0.01</td>
</tr>
<tr>
<td>Female</td>
<td>29(37.7)</td>
<td>42(56.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home delivery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>6(7.8)</td>
<td>4(5.30)</td>
<td>1.50</td>
<td>0.18-2.46</td>
<td>0.28</td>
</tr>
<tr>
<td>No</td>
<td>71(92.2)</td>
<td>71(94.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother’s level of education</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary or less</td>
<td>3(3.9)</td>
<td>6(8.0)</td>
<td>0.47</td>
<td>0.11-1.94</td>
<td>0.23</td>
</tr>
<tr>
<td>Secondary or better</td>
<td>74(96.1)</td>
<td>69(92.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age of mother &lt;20 yrs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>10(13.0)</td>
<td>9(12.0)</td>
<td>1.09</td>
<td>0.42-2.87</td>
<td>0.43</td>
</tr>
<tr>
<td>No</td>
<td>67(87.0)</td>
<td>66(88.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Planned pregnancy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>43(55.8)</td>
<td>57(76.0)</td>
<td>0.40</td>
<td>0.12-0.80</td>
<td>0.00</td>
</tr>
<tr>
<td>No</td>
<td>34(44.2)</td>
<td>18(24.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy booked</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>67(87.0)</td>
<td>67(89.3)</td>
<td>0.80</td>
<td>0.30-2.15</td>
<td>0.33</td>
</tr>
<tr>
<td>No</td>
<td>10(13.0)</td>
<td>8(10.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Socio-economic factors significantly associated with developing ophthalmia neonatorum in this study were male sex (OR 2.11, 95% CI 0.25-0.91) and planning pregnancy (OR 0.40, 95% CI 0.12-0.80). Being delivered at home was found to be a risk factor for developing ophthalmia neonatorum (OR 1.50, 95% CI 0.18-2.46) but however was not statistically
significant. Booking a pregnancy was found to be protective against ophthalmia neonatorum (OR 0.80, 95% CI 0.30-2.15)

### 5.22: Maternal and Neonatal Factors

**Table 5: Maternal and Neonatal Factors Associated with Ophthalmia Neonatorum in Harare City**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Case (%)</th>
<th>Control (%)</th>
<th>OR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=77</td>
<td>n=75</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 or &gt;4</td>
<td>35(45.5)</td>
<td>41(54.7)</td>
<td>0.69</td>
<td>0.36-1.31</td>
<td>0.13</td>
</tr>
<tr>
<td>2 to 4</td>
<td>42(54.5)</td>
<td>34(45.3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delivery term</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2(2.6)</td>
<td>4(5.3)</td>
<td>0.47</td>
<td>0.08-2.67</td>
<td>0.33</td>
</tr>
<tr>
<td>No</td>
<td>75(97.4)</td>
<td>71(94.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comorbidity present</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>13(16.9)</td>
<td>7(9.3)</td>
<td>1.97</td>
<td>0.74-5.26</td>
<td>0.09</td>
</tr>
<tr>
<td>No</td>
<td>64(83.1)</td>
<td>68(90.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother HIV status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>+ve</td>
<td>9(12.9)</td>
<td>16(22.9)</td>
<td>0.50</td>
<td>0.82-4.91</td>
<td>0.07</td>
</tr>
<tr>
<td>-ve</td>
<td>61(87.1)</td>
<td>54(77.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meconium stained liquor at birth</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5(6.5)</td>
<td>4(5.3)</td>
<td>1.23</td>
<td>0.21-3.15</td>
<td>0.52</td>
</tr>
<tr>
<td>No</td>
<td>72(93.5)</td>
<td>71(94.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother had vaginal discharge:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>11(14.3)</td>
<td>6(8.0)</td>
<td>1.92</td>
<td>0.07-5.48</td>
<td>0.12</td>
</tr>
<tr>
<td>No</td>
<td>66(85.7)</td>
<td>69(92.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PROM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1(1.3)</td>
<td>5(6.9)</td>
<td>0.18</td>
<td>0.02-1.55</td>
<td>0.09</td>
</tr>
<tr>
<td>No</td>
<td>76998.7</td>
<td>67(93.10)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prolonged labour</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>11(14.3)</td>
<td>5(6.7)</td>
<td>2.33</td>
<td>0.77-7.08</td>
<td>0.07</td>
</tr>
<tr>
<td>No</td>
<td>66(85.7)</td>
<td>70(93.3)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Maternal and neonatal risk factors for developing ophthalmia neonatorum included having a comorbid condition (OR 1.97, 95% CI 0.74-5.26), meconium stained liquor (OR 1.23, 95% CI 0.21-3.15) and being born to a mother who had vaginal discharge (OR 1.92, 95% CI 0.07-5.48). All the maternal and neonatal factors were not significantly associated with developing ophthalmia neonatorum in Harare City.

5.23: Health Service Factors

Table 6: Health Service Factors Associated with Ophthalmia Neonatorum in Harare City

<table>
<thead>
<tr>
<th>Variable</th>
<th>Case (%)</th>
<th>Control (%)</th>
<th>OR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caesarean section</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5(6.5)</td>
<td>1(1.3)</td>
<td>5.14</td>
<td>0.59-4.51</td>
<td>0.11</td>
</tr>
<tr>
<td>No</td>
<td>72(93.5)</td>
<td>74(98.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Received TEO prophylaxis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>11(14.3)</td>
<td>32(42.7)</td>
<td>0.22</td>
<td>0.10-0.49</td>
<td>0.00</td>
</tr>
<tr>
<td>No</td>
<td>66(85.7)</td>
<td>43(57.3)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The risk factors for developing ophthalmia neonatorum in Harare City found in this study were having been delivered at home (OR 1.5, 95% CI 0.18-2.46), prolonged labour (OR 2.33, 95% CI 0.77-7.08), meconium stained liquor at delivery (OR 1.23, 95% CI 0.21-3.15) and mother having vaginal discharge in pregnancy (OR 1.92, 95% CI 0.07-5.48). However these risk factors were not statistically significant in this study. Protective factors found in the study included being born from a planned pregnancy (OR 0.40, 95% CI 0.12-0.80), mother
having booked the pregnancy (OR 0.80, 95% CI 0.30-2.15) and having received tetracycline eye ointment (TEO) prophylaxis at birth (OR 0.22, 95% CI 0.10-0.49). A statistically significant protective factor for developing ophthalmia neonatorum was receiving TEO prophylaxis at birth (OR 0.22, 95% CI 0.10-0.49). It is also notable that only 43(28%) of the 152 study participants received TEO prophylaxis against a target of 100% in accordance with national guidelines on prevention of sexually transmitted infections.
5.24: Logistic Regression Analysis

Table 7: Independent Factors Associated with Developing Ophthalmia Neonatorum in Harare City

<table>
<thead>
<tr>
<th>Variable</th>
<th>Adjusted OR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mother HIV positive</td>
<td>0.35</td>
<td>0.13-0.92</td>
<td>0.03</td>
</tr>
<tr>
<td>TEO prophylaxis</td>
<td>0.21</td>
<td>0.09-0.50</td>
<td>0.00</td>
</tr>
<tr>
<td>Planned pregnancy</td>
<td>0.38</td>
<td>0.17-0.87</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Babies born to mothers who were HIV positive (OR 0.35, CI 0.13-0.92), babies that received tetracycline eye ointment on the day they were born (OR 0.21, CI 0.09-0.50) and those that were born from a planned pregnancy (OR 0.38, CI 0.17-0.87) were less likely to develop ophthalmia neonatorum after controlling for possible confounding.
5.25: Laboratory Results

Table 8: Laboratory Results of Microorganisms Isolated From Eye Swabs and their Resistance Patterns to Tested Drugs in the Study on Ophthalmia Neonatorum

<table>
<thead>
<tr>
<th>Organism Isolated</th>
<th>Total</th>
<th>Tetracycline</th>
<th>Erythromycin</th>
<th>Ciprofloxacin</th>
<th>Cefuroxime</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Staphylococcus species</td>
<td>16</td>
<td>8</td>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2. Staphylococcus aureus</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>3. Escherichia coli</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4. Klebsiella species</td>
<td>2</td>
<td>2</td>
<td>-</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>5. NLFC</td>
<td>6</td>
<td>2</td>
<td>-</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>6. No growth</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

A total of 22 eye swabs were collected and microscopy, culture and sensitivity tests done on the specimens. Sixteen (73%) of the eye swabs yielded staphylococcus species after culture whilst 6 (27%) yielded non-lactose fermenting coliforms (NLFC), 2 (9%) had Klebsiella species and one (5%) had Escherichia coli. One eye swab specimen had no growth after 48 hours of incubation. Only six (29%) of the different microorganism species isolated were fully susceptible to tetracycline with 13(62%) being resistant to tetracycline.

Of the sixteen specimens that yielded staphylococcus species, eight specimens (50%) showed resistance to tetracycline and only one showed resistance to ciprofloxacin. Erythromycin resistance was also high with 4 (25%) of the staphylococcal species being resistant to erythromycin.
5.26: Treatments Prescribed to Cases of Ophthalmia Neonatorum

Figure 4: Pie chart showing proportion of cases given treatment

Fifty two (67%) of the cases received tetracycline eye ointment as part of treatment for ophthalmia neonatorum. The total number of cases of ophthalmia neonatorum that were prescribed at least kanamycin injection and oral erythromycin as per national guidelines on treatment of ophthalmia neonatorum was only 22 (29%).
5.27: Drug Stock Status at Harare City Clinics

Table 9: Drug Stock Status at Harare City Clinics During the Study to Determine Factors Associated With Ophthalmia Neonatorum in Harare City

<table>
<thead>
<tr>
<th>Name of Clinic</th>
<th>TEO</th>
<th>Kanamycin injection</th>
<th>Erythromycin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mabvuku</td>
<td>Out of stock</td>
<td>In stock</td>
<td>In stock</td>
</tr>
<tr>
<td>Edith Opperman</td>
<td>Out of stock</td>
<td>Out of stock</td>
<td>In stock</td>
</tr>
<tr>
<td>Rutsanana</td>
<td>In stock</td>
<td>In stock</td>
<td>In stock</td>
</tr>
<tr>
<td>Budiriro</td>
<td>Low stock</td>
<td>Out of stock</td>
<td>Out of stock</td>
</tr>
<tr>
<td>Rujeko</td>
<td>In stock</td>
<td>In stock</td>
<td>In stock</td>
</tr>
<tr>
<td>Hatcliffe</td>
<td>In Stock</td>
<td>In stock</td>
<td>In stock</td>
</tr>
</tbody>
</table>

Tetracycline eye ointment is the recommended medicine for use as prophylaxis against ophthalmia neonatorum in Harare City whilst kanamycin injection and oral erythromycin in combination are the recommended drugs for the treatment of the condition. Of the eighteen key informants interviewed all (100%) of them indicated that three drugs are sometimes out of stock. On the day of the interviews, 2 out of 6 clinics visited did not have TEO in stock whilst one clinic did not have kanamycin and oral erythromycin in stock.
Review of records showed that 57% of all the study participants delivered at Harare City clinics did not receive TEO prophylaxis whilst at Harare and Mbuya Nehanda Maternity hospitals almost all the study participants delivered there did not get TEO prophylaxis.
Chapter 6: Discussion, Conclusion & Recommendations

6.1: Discussion

The use of topical eye prophylaxis is one of the key strategies in the prevention against ophthalmia neonatorum\textsuperscript{2, 10, 13, 21, 29}. In this study the use of TEO as prophylaxis was again found to be protective against the development of ophthalmia neonatorum despite the emergency of resistance to tetracycline. These findings are in keeping with those obtained by Zuppa et al in 2011 who concluded that there was enough evidence to suggest better outcomes using 1\% tetracycline solutions\textsuperscript{3, 11, 18, 22} even if there is the risk of selecting drug resistant bacteria\textsuperscript{18}.

The proportion of home deliveries, which is one of the risk factors for ophthalmia neonatorum found in this study, was less than 10\%. These findings are in contrast to findings by Montagu D. et al who found out that in sub-Saharan Africa, South Asia, and Southeast Asia, more than 70\% of all births in the lowest two wealth quintiles occurred at home and 54.1\% of the richest women reported using public facilities for deliveries\textsuperscript{23}. The main reasons for home deliveries are unaffordable user fees for booking the pregnancy and religious beliefs. User fees in Harare City were reduced from US $50.00 to $35.00 and when coupled with the dollarization of the Zimbabwean economy in 2009, this could have led to the decline in proportion of home deliveries from high national figures of 69\% documented by the United Nations in Zimbabwe in 2009\textsuperscript{24} to less than 10\% local home deliveries found in this study in 2013. The decline in the proportion of home deliveries is a positive development since it is associated with better pregnancy outcomes including the incidence of ophthalmia neonatorum.

In this study the age of the mother was not significantly associated with the development of ophthalmia neonatorum. These findings are consistent with findings by Dannevig L. et al
who found out that male babies in northern Norway were more often affected by ophthalmia neonatorum than girls 10, 19, 25 whilst the age of the mother did not significantly influence the occurrence of neonatal conjunctivitis 25. The relationship between sex of the child and development of ophthalmia may however have been confounded by some factors since after controlling for possible confounding the relationship was no longer statistically significant. The biggest risk factor for developing ophthalmia neonatorum is a maternal infection or sexually transmitted infections (STIs) at the time of delivery 26. Delivering at home, prolonged labour and maternal vaginal discharge during pregnancy were found to be risk factors for the development of ophthalmia neonatorum in the study. In a study done by Olatunji F. O. et al in Nigeria on ophthalmia neonatorum in Kaduna, maternal vaginal discharge during pregnancy, prolonged labour and place of delivery were also found to be risk factors for the development of ophthalmia neonatorum 27. When the mother has vaginal discharge during pregnancy, they may infect the baby during delivery when the baby comes in contact with the maternal vaginal fluids, and if the labour is prolonged there is increased duration of exposure of the baby to the infections in the maternal perineum during the delivery thereby increasing the chances of contracting ophthalmia neonatorum. These findings are similar to those by Mundia D. et al who found out that the longer the duration of labour, the higher the rate of development of neonatal conjunctivitis 11. Being delivered through a Caesarean Section came out as a risk factor contracting ophthalmia neonatorum in this study. The findings are consistent with those by Gul et al who found out that in Pakistan being delivered through Caesarean Section was a significant risk factor for ophthalmia neonatorum 28.

Planning the pregnancy and booking the pregnancy were found to be protective against developing ophthalmia neonatorum in this study. In Harare City the planned pregnancy
would more often than not be booked as well since resources for the pregnancy would be sourced during the planning phase of the pregnancy. Subsequently booking the pregnancy would increase the likelihood of receiving comprehensive antenatal care. Antenatal care services include screening for and treating STIs thereby reducing the risk of developing ophthalmia neonatorum.

The United States Preventive Services Task Force (USPSTF) has recommended that all newborns receive prophylaxis. Prophylaxis should be provided within 24 hours after birth. The USPSTF concluded that there is high certainty that the net benefit is substantial for topical ocular prophylaxis for all newborns for the prevention of gonococcal ophthalmia neonatorum. In this study on ophthalmia neonatorum in Harare City prophylaxis was given to only 28% of the 152 study participants. This is against the provisions of the national guidelines on management of sexually transmitted infections which recommend the use of TEO for prevention of ophthalmia neonatorum in every new born child in Zimbabwe. Given the fact that the use of tetracycline eye ointment (TEO) as prophylaxis was again found to be protective against the development of ophthalmia neonatorum in Harare City in this study, it may be concluded that the documented increase in cases of ophthalmia neonatorum in Harare City from 2010 to 2012 were partly due to prophylaxis not being used for the prevention of the condition. The reasons for not giving TEO prophylaxis may include stock outs and non-compliance by the health workers in the maternity units in Harare to guidelines on prevention of sexually transmitted infections (STIs). Furthermore the majority of the eye swabs collected revealed widespread resistance to tetracycline, the drug used for prophylaxis against neonatal conjunctivitis in Zimbabwe which may be the other reason for the increase in the cases of ophthalmia neonatorum in Harare City. WHO guidelines for the treatment of malaria recommend that the first line treatment should be changed if total failure rate exceeds 10%,
however, efficacy and failure rates should be considered in the context of their 95% confidence interval.  

The health workers in the maternity units in Harare’s non-compliance to guidelines on prophylaxis for ophthalmia neonatorum coupled with the widespread resistance to TEO will lead to continued increase in the disease burden due to ophthalmia neonatorum.

6.2: Conclusion

In conclusion the reasons for the increase in cases of ophthalmia neonatorum in Harare City include widespread resistance (more than 50% resistance) to TEO by the three commonest microorganisms isolated from the eye swabs as causes of ophthalmia neonatorum and non-use of the TEO by health workers (from 57% to 94% from one health facility to the other).

In this study ophthalmia neonatorum was found to be less prevalent amongst those newly born babies that received TEO prophylaxis, as well as amongst those children born to mothers who planned and booked their pregnancies than those who did not plan or book their pregnancies. Ophthalmia neonatorum was more prevalent amongst newly born boys than newly born girls. There was no significant association between being born to a mother less than 20 years old and developing ophthalmia neonatorum.
6.3: Recommendations

- To conduct similar follow up studies on a national scale to determine the susceptibility patterns to TEO of microorganisms causing ophthalmia neonatorum –
  
  *Director AIDS and TB Unit, MoHCW*

- To ensure the use of eye ointment for prophylaxis against ophthalmia neonatorum in all maternity units in Harare through refresher courses on prevention and management of STIs – *Director of Nursing Services, Harare City, PNO Mbuya Nehanda Maternity and Harare Central Hospitals.*

- To ensure correct treatment of ophthalmia neonatorum at all clinics in Harare City –
  
  *Sisters in Charge, Harare City Council clinics*

6.4: Study Limitations

Only 22 eye swab specimens were collected and analysed in the laboratory because the most of the cases of ophthalmia neonatorum did not have eye discharge at the time of the interview. This small number of specimens limits the power of the study.

The study depended on the clinical diagnosis made by the health workers in Harare City. There is possible misclassification (most likely non-differential) of cases and controls.
References


2013.


Appendix 1: Shona Questionnaire

Mibvunzo yokuongororwa kwezvikonzero zvinechekuita nechirwere chekupupira maziso kuvana vacheche muguta reHarare, gore ra 2013

Zita rekiriniki_________________________      Date ______________

Chikamu chekutanga

1. Zuva rekuuzvarwa kwemwana _________________ 2. Zera remwana (mazuva) ______

3. Rudzi rwomwana Mukomana [ ] Musikana [ ] 4. Nhumbu yechingani__________

5. Kwakazvarirwa mwana _________________ 6. Uremu pakuzvarwa (kgs) _______

7. Pamunogara______________________________________________________________

8. Zvekuroorwa kwaamai vemwana

Vari voga [ ] Vakarooora [ ] Vakarambana [ ] Vakafirwa [ ] Vanogara nechikomba [ ]

9. Zera ramai vomwana (makore) ________

Chikamu chechipiri: Zvikonzero zvinechekuita nekupupira maziso kwevana vacheche

10. Mwana akazvarirwa kupi?

    Pakiriniki/ chipatara [ ] Mumba [ ]

    Zvimwe (jekesa) __________________________

11. Makasunungutswa nani?

    Mukoti/chiremba [ ] Mbuya nyamukuta [ ]

    Vamwewo (jekesa) __________________________
12. Makadzidza kusvika papi?

Hapana [ ]    Puraimari [ ]    Sekondari [ ]    Kumakoreji [ ]

13. Maive makaronga kuita pamuviri pomwana uyu here?

Hongu [ ]    Kwete [ ]

14. Makanyoresa pamuviri here?

Hongu [ ]    Kwete [ ]

15. Pamuviri paive pakura zvakadini pamakanyoresa? ________

16. Makafambira kukiriniki kangani nenyaya yepamuviri musati masununguka? ________

17. Makaita nguva yakareba zvakadini muchirwadziwa pakusununguka mwana? ________

18. Mwana akasunugutswa nenzira ipi?

Zvakanaka nemutovo wemazuva ose [ ]    Neoparesheni [ ]

Mwana akadhonzwa [ ]    Zvimwe (jekesa) ________

19. Pamuviri panga pave nemwedzi mingani pamakazosununguka mwana? ________

20. Pane zvimwe zvirwere zvine mwana here parizvino? (Kana pasina endai kumubvunzo 19)

Hongu [ ]    Kwete [ ]

21. Kana zviripo ndezvi pipi zvirwere zvacho?

Mabayo [ ]    Chokosoro [ ]    Manyoka [ ]

Muviri wose [ ]    Zvimwe (jekesa) ______________________________
22. Makaongororwa utachiona hwe HIV muropa menyu here? (Kana musina endai kumubvunzo 24)
   
   Hongu [ ] Kwete [ ]

23. Zvakabuda muongororo ye HIV yeropa renyu ndezvipi?
   
   HIV yakanzi irimo muropa [ ] HIV yakanzi haimo muropa [ ]

24. Mwana akanzi aitira tsvina mudumbu here pamakasununguka?
   
   Hongu [ ] Kwete [ ]
   Zvimwe (jekesa) __________________

25. Makamboita chirwere chepabonde here muine pamuviri? (Kana musina endai kumubvunzo 27)
   
   Hongu [ ] Kwete [ ]

26. Makarapwa here chirwere chepabonde chamakaita?
   
   Hongu [ ] Kwete [ ]

27. Ko shupa yakaputika sei pamaive nepamuvisi?
   
   Yakaputika pamuviri pasati pasvika [ ] Yakaputika yoga pakusununguka [ ]
   Yakaputitswa nevaisunungutsa mwana [ ] Handizivi [ ]

Chikamu chechitatu: Mushonga wokudzivirira chirwere chokupupira kwemaziso

28. Mwana akapiwa mushonga wokudzivirira chirwere chokupupira kwemaziso here? (Kana asina endai kumubvunzo 30)
   
   Hongu [ ] Kwete [ ]

29. Mushonga wokudzivirira waakapiwa waive werudzi rupi? (Tarisa makadhi omwana)
   
   Tetracycline [ ] Erythromycin [ ] Chloramphenicol [ ] Handizivi
   
   Zvimwewo (jekesa) ____________________________________________
**Chikamu chechina: Kurapwa kwakaitwa chirwere chokupupira maziso kwemuchache**
*(pane avo vakaita chirwere chete)*

30. Mwana akamboita cherwere chokupupira maziso here kubva paakazvarwa?

| Hongu [ ] | Kwete [ ] |

31. Akatanga kupupira maziso ava nemazuva mangani kubva pakuzvarawa? ______

32. Akarapwa maziso aipupira here? *(Kana asina endai kumubvunzo 33)*

| Hongu [ ] | Kwete [ ] |

33. Akapiwa mushonga wemhando ipi? *(Tarisa kadhi romwana)*

| Tetracycline [ ] | Mushonga wokunwa [ ] |
| Akabaiwa majekiseni [ ] | Zvimwe (jekesa) ________________________________ |

**Chikamu cheshanu: Matambudziko emaziso akazokonzerwa nechirwere chekupupira maziso (pane avo vakaita chirwere chete)**

34. Mwana akazomboita mamwe matambudziko emaziso akakonzerwa nekupupira maziso kwaaiwe amboita here?  Hongu [ ]  Kwete [ ]

35. Kana aripo matambudziko akazouya tsanangurai *(Ongorora maziso owana kuti pane urema here)*

| Kupofomara meso [ ] | Kuita rutara [ ] | Kuvhurika kwenyama dzepaziso [ ] |
| Zvimwewo (jekesa) ________________________________ |

Tatenda chose
Appendix 2: English Questionnaire

Questionnaire to determine the factors associated with ophthalmia neonatorum in Harare City, 2013

Health facility name____________________________     Date _____________

Section A: Socio-demographic information

1. Date of birth (dd/mm/yyyy) __________________  2. Age (days) ______

3. Sex of child   male [  ]   female [  ]     4. Parity____

5. Place of birth______________________________  6. Birth weight (kgs) ______

7. Physical address ______________________________________________________

8. Marital status of mother

   Single [ ]   Married [ ]   Divorced [ ]   Widowed [ ]   Cohabiting [ ]

9. Age of mother (years) ______

Section B: Risk Factors

10. Where was the child born?

    Health facility [  ]   Home [  ]

    Other (specify) __________________________

11. Who attended to the delivery of the baby?

    Trained health worker [  ]   Traditional birth attendant [  ]

    Other (specify) __________________________

12. What is your highest level of education?

44
13. Was your pregnancy planned?
   Yes [ ]  No [ ]

14. Where you booked?
   Yes [ ]  No [ ]

15. What was the gestational age at booking? ______

16. How many antenatal visits did you make before delivery? ______

17. How long did you take to deliver your baby from the time you started having labour pains? ______

18. How was the baby delivered?
   Normal Vaginal Delivery [ ]  Assisted delivery [ ]  Ceasarian Section [ ]

19. How many weeks was the pregnancy when you delivered? ______

20. Does your child currently suffer from any other diseases? (If No, skip question 21)
   Yes [ ]  No [ ]

21. If yes, what other disease is the baby suffering from?
   Pneumonia [ ]  ARI [ ]  Diarrhoea [ ]  Sepsis [ ]
   Other (specify) __________________________________________

22. Were you tested for HIV? (If No skip question 23)
   Yes [ ]  No [ ]

23. If yes, what were the results of the HIV test?
   Code 0 [ ]  Code 1 [ ]

24. During delivery of the baby, what was the state of the liquor?
   Meconium stained [ ]  Clear [ ]

Other (specify) ________________________________________________________________

25. Did you have any vaginal discharge during pregnancy? *(If no skip question 26)*

    Yes [ ]  No [ ]

26. If yes, were you treated?

    Yes [ ]  No [ ]

27. How were the membranes ruptured during delivery?

    Preterm rupture (PROM) [ ]  Spontaneous rupture during labour [ ]
    Artificial rupture [ ]  Do not know [ ]

Section C: Tetracycline Eye Ointment Prophylaxis

28. Was your child given any eye ointment soon after birth? *(If no, skip question 29)*

    Yes [ ]  No [ ]

29. If yes, what is the name of the ointment given?

    Tetracycline eye ointment [ ]  Erythromycin eye ointment [ ]
    Chloramphenicol [ ]
    Other, specify______________________________________________________________

Section D: Treatment of Ophthalmia Neonatorum (for cases only)

30. Did your child ever have any eye discharge?

    Yes [ ]  No [ ]

31. If yes, how old was the baby when discharge started? ____

32. If yes, was the child treated? *(If No skip question 33)*
33. If yes, what was the treatment given?

- Tetracycline eye ointment [  ]
- Oral antibiotics [  ]
- Parenteral antibiotics [  ]
- Other (specify) ____________________________

Section E: Complications of ophthalmia neonatorum (for cases only)

34. Did the child have any further eye problems related to the eye discharge?

- Yes [  ]
- No [  ]

35. If yes, please explain the problem (Do physical examination of the eyes to check for complications)

- Blindness [  ]
- Corneal opacity [  ]
- Ectropion [  ]
- Other (specify) [  ] ____________________________

Thank you
Appendix 3: Shona Consent

MEDICAL RESEARCH COUNCIL OF ZIMABWE

GWARO REMVUMO YEMUBEREKI WEMWANA

MUSORO WETSVAKURUDZO: Zvikonzero zvinechekuita nechirwere chekupupira maziso kwevana vacheche muguta reHarare

Nhungamiri yetsvakurudzo: Vengere Calvin [MBChB, UZ]

Vamwe varimutsvakurudzo: J. Mberikunashe [MBChB, MPH, UZ]

G. Shambira [MBChB, MPH, UZ]

Nharembozha: +263 712 878 906

Zvamunofanira kuziva pamusoro petsvakurudzo iyi:

- Tinokupayi gwaro remvumo iri kuti muverenge zvinangwa, njodzi kana zvakanakira tsvakurudzo iyi.
- Kurapwa kwamazuva ose kunobva paruzivo ruripo nechakare rwezvemishonga inozikanwa kubatsira kwayo pamurwere woga woga. Chinangwa chikuru chetsvakurudzo dzezvuita ndechokutsvaka zivo inozobatsira varwere vacha yawo mazuva ari mberi.
- Hativimbisi kuti tsvakurudzo iyi ichawana chainobatsira mwana wenyu.
- Mune kodzero yokuramba kuti mwana wenyu apinde mutsvakurudzo iyi, uyewo munotenderwa kubvuma iye zvino asi moz HANDURE pfungwa
- Chero chipi zvacho chamafunga, hachikanganisi kurapwa kwemwana wenyu kwaagara achiitwa.
- Tarisisai gwaro remvumo iri zvakanaka. Bvunzai mibvunzo yanumayo musati maita sarudzo.
- Sarudzo yenyu yamuchaita kuti mwana wenyu apinde mutsvakurudzo iyi haimanikidzwi.

CHINANGWA


ZVINOITWA
Kana masarudza kutendera mwana wenyu kuti apinde mutsvakurudzo, mwana uyu achaongororwa maziso ake kuti onopupira here kana zvimwewo zvirwere zvemaziso. Akaonekwa kuti anopupira maziso achatorwa tsvina inopupira pamaziso ake kuti inoongororwa umhutu hurimo.

NJODZI KANA KURWADZISWA

Pachange pasina njodzi kana kurwadziswa kwomwana pane zvose zvichaitwa zvakanangana netsvakurudzo iyi.

MUBAYIRO KANA MUBHADHARO

Hatingavimbisi kuti pachange paine mumwe mubhadharo kana mubairo unopiwa mwana apinda mutsvakurudzo iyi, kunze kokutariswa zvirwere zvamaziso nachiremba arikuita tsvakurudzo iyi.

MIKANA YOKURAPWA

Mwana wenyu acharapwa samazuva ose zvisineyi kuti mabvuma here kana kuramba kuti apinde mutsvakurudzo iyi.

KUCHENGETWA KWEZIVO

Kana mwana wenyu akapinda mutsvakurudzo iyi, zvichazikanwawo neveHarare City Health Department neveUniversity of Zimbabwe Community Health Department. Ruzivo rwose rwuchawanikwa patsvakurudzo iyi rungangodaro rwuchifumura mwana wenyu rwuchachengetwa rwusingazikanwi pachena uyewo rungangoziviswa koga kana imi kana mwana wenyu atenderana nazvo.

DZIMWE MARI DZINODIKANWA

Pachange pasina dzimwe mari dzinodikanwa kubva kwamuri maererano nekupinda kwemwana wenyu mutsvakurudzo iyi.

KUKUVARA

Kuri kokuti mwana wenyu akuvara nekuda kwetsvakurudzo iyi, anogona kurapiswa netsvakurudzo iyi. Nzwisisi kuti mari dzekurapwa uku dzinobhadharwa netsvakurudzo iyi.

KUSUNUNGUKA KUPINDA MUTSVAKURUDZO

Kupinda mutsvakurudzo iyi hakumanikidzwi. Kana masarudza kuti mwana wenyu apinde mutsvakurudzo iyi, zvamasarudza hazvikanganisi hukana hwemwana wenyu nekiriniki, vashandi veutano kana zvipatara kwete. Kana masarudza kutendera mwana wenyu kupinda mutsvakurudzo, imi pamwe nomwana wenyu makasununguka kubuda mutsvakurudzo iyi nguva ipi zvayo pasina kurapiswa.

MIBVUNZO
Musati mabaya taratadzo yezita renyu pagwaro iri, sunungukayi kubvunza kana mune zvamisina kunzwisisa. Munogona kutora zvenyu nguva yamungada muchifunga nezvavo.

**MVUMO**

**MAVA KUITA SARUDZO YOKUTENDERA KANA KURAMBA KUTI MWANA WENYU APINDE MUTSVAKURUDZO IYI. KUBAYA TARATADZO YEZITA RENYU KUNOREVA KUTI MAVERENGA MUKANZWISISA ZVAKANYORWA MUGWARO RINO, MUKAWANA MHINDURO PAMIMVUNZO YENYU YOSE, MUKASARUDZA KUTENDERA KUTI MWANA WENYU APINDE MUTSVAKURUDZO IYI.**

Zuva ramunobaya zita renyu pagwaro rino kuti mwana wenyu apiinde mutsvakurudzo iyi, kunova nhasi, rinofanira kuva pakati pamazuva akaratidzwa pachidhindo chiri pashizha roga roga. Mazuva awa anoratidza koga mazuva anotenderwa kuti mwna wenyu apiinde mutsvakurudzo iyi asi haataridzi mazuva acharamba mwana wenyu arimutsvakurudzo iyi. Shizha roga roga rinechidhindo chinoratidza tender yeveMRCZ.

__________________________________________
**ZITA ROMUBEREKI (namavara makuru)**

Zuva

__________________________________________
**Taratadzo yezita romubereki kana mumiririri aripamutemo**

Nhambo

__________________________________________
**Hukama neapinda mitsvakurudzo**

__________________________________________
**Taratadzo yezita reChapupu**

Taratadzo yezita revetsvakurudzo

*(Optional)*

**MUCHAPIWA GWARO RAKAFANANA NEGWARO REMVUMO KUTI MUCENGETE**
Kana mune mibunzo maererano netsvakurudzo ino kana gwaro rino pamusoro peiyo mibunzo yamapindurwa nenhungamiri yetsvakurudzo ino, kana kuti muchiona sokuti hamuna kubatwa zvakana, kana kuti muchinzwa kuda kukurukura nomumwe asiri pakati peava varimutsvakurudzo iyi, sunungukayi kubata ve Medical Research Council of Zimbabwe panhare dzinoti 791792 or 791193.
Appendix 4: English Consent

MEDICAL RESEARCH COUNCIL OF ZIMABWE

INFORMED CONSENT FORM

FOR PARENTAL CONSENT

PROJECT TITLE: Factors associated with developing ophthalmia neonatorum in Harare City

Principal Investigator: Vengere Calvin [MBChB, UZ]
Co-Investigator(s) J. Mberikunashe [MBChB, MPH, UZ]
G. Shambira [MBChB, MPH, UZ]

Phone number +263 712 878 906

What you should know about this research study:

- We give you the consent form so that you may read on the purpose, risks, and benefits of the research study.
- Routine care depends on the best known medical management and is given with the aim of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients.
- We are not promising that the research is going to benefit your child.
- You reserve the right to refuse to allow your child to take part, or agree for your child to take part now and change your mind later.
- Your decision will not affect your child’s usual care.
- Please review the consent form carefully. You may ask any questions before you decide.
- Your choice to allow your child to participate is voluntary.

PURPOSE

You are being asked to allow your child to participate in a research study to determine factors associated with developing ophthalmia neonatorum in Harare City. The aim of the study is to find out some of the reasons why newly born children in Harare develop eye discharge in the first 28 days of their life. The study is also done in partial fulfilment of a master degree in Public Health with the University of Zimbabwe. Your child was selected to participate in this study because he/she was born in Harare in 2013.

PROCEDURES AND TIME PERIOD

Once you decide to allow your child to participate, your child will undergo routine physical examination to look for eye discharge and any other eye problems. A swab may be collected from the eyes if there is some eye discharge.
RISKS AND DISCOMFORTS
There is no risk of injury or pain to the child.

BENEFITS AND/OR COMPENSATION
We cannot and do not guarantee or promise that your child will receive any benefits from this study.

ALTERNATIVE PROCEDURES OR TREATMENTS
The child will receive the standard health care whether you agree or not for your child to participate in the study.

CONFIDENTIALITY
If you indicate your willingness for your child to participate in this study by signing this document, we plan to disclose to Harare City Health Department and University of Zimbabwe in partial fulfilment of a public health degree. All the information that will be obtained from with this study and can be identified with your child will be kept confidential and will be disclosed only with permission from you or when appropriate, your child.

ADDITIONAL COSTS
There are no additional costs that will result from your child’s participation in the study.

IN CASE OF INJURY
If your child's participation in this study causes any injury, treatment will be given by the study. The costs of such treatment will be the study’s responsibility.

FREE WILL PARTICIPATION
Taking part in the study is voluntary. If you decide not to allow your child to take part in the study, that decision does not affect your own or your child's future relations with this institution, its personnel, and associated hospitals. If you decide to allow your child to participate, you and your child are allowed to withdraw your consent and discontinue participation any time without being penalised.

QUESTIONS AND ANSWERS
Before you append your signature on this form, please ask any questions on any aspects of this study that is still not clear to you. You can take as much time as you wish to think it over.

AUTHORIZATION
NOW YOU ARE MAKING THE DECISION WHETHER OR NOT TO ALLOW YOUR CHILD TO PARTAKE IN THE STUDY. IF YOU SIGN IT MEANS THAT YOU HAVE READ AND UNDERSTOOD ALL THE CONTENTS OF THIS DOCUMENT, HAVE
HAD ANSWERS TO ALL YOUR QUESTIONS, AND HAVE FREELY ALLOWED YOUR CHILD TO TAKE PART.

The day you sign this document to enroll your child into the study, that is, today’s date, MUST be between the dates written on the approval date stamp on all the pages. These dates show that this form is valid at the time you allow your child to take part in the study but do not show how long your child will participate in the study. Every page of the Informed Consent Form is stamped to show the form’s validity as approved by the MRCZ.

_________________________ ______________
Name of Parent (please print) Date

_________________________ ______________
Signature of Parent or legally authorized representative Time

_________________________
Relationship to the Study Participant

_________________________ __________________
Signature of Witness Signature of Research Staff

(Optional)

YOU SHALL BE PROVIDED WITH A COPY OF THIS CONSENT FORM TO KEEP.

If you wish to ask any questions about this study or consent form above those answered by the investigator, including questions about the research, your rights as a research Participant or research-related injuries; or if you feel that you may have been treated unfairly and wish to talk to an alternative person, please feel free to call the Medical Research Council of Zimbabwe on telephone 791792 or 791193.
Appendix 5: Key Informant Interviewer Guide

Key informant questionnaire to determine the factors associated with ophthalmia neonatorum in Harare City, 2013

Health facility name__________________________ Date _____________

Section A: Socio-demographic information

1. Age (years) __________  2. Years in service ____

3. Sex  male [    ]  female [    ]  4. Designation__________________________

Section B: Risk Factors

5. Where are the majority of babies in your catchment area born?
   Health facility [    ]  Home [    ]
   Other (specify) ______________________

6. How prevalent is the problem of home deliveries in your catchment area?
   Less than 10% [    ]  Less than a quarter [    ]
   Less than half the deliveries [    ]  More than half the deliveries [    ]
   More than 3 quarters of deliveries [    ]  Other (specify) __________

7. Who attends to the deliveries of the babies in your catchment area?
   Midwives [    ]  Other nurses [    ]
   Traditional birth attendants [    ]  Other (specify)
   ______________________

8. Is the number of midwives adequate enough to attend to all deliveries at the facility?
   Yes [    ]  No [    ]
9. If no, how many midwives are in post out of how many required?

In post ________ Required (Establishment) ________

10. How common is the problem of unbooked pregnancies in your catchment area?

   Less than 10% [ ] Less than a quarter [ ]
   Less than half the deliveries [ ] More than half the deliveries [ ]
   More than 3 quarters of deliveries [ ]

   Other (specify) ________________________________

11. What are the main reasons for the unbooked pregnancies that you come across in your area?

   High booking fees [ ] Apathy [ ] Religious beliefs [ ]
   Lack of awareness amongst the mothers [ ] Poor health services [ ]

   Other reasons (specify) ________________________________

12. Which Sexually Transmitted Infections (STIs) do you routinely screen for and treat during antenatal care?

   Gonorrhoea risk assessment [ ] Chlamydia risk assessment [ ]
   Syphilis tests [ ] HIV tests [ ]
   Genital ulcers [ ]

   Other (specify) ________________________________

13. Do you have any challenges maintaining good infection control standards during deliveries at your clinic? (If no, skip question 15)

   Yes [ ] No [ ]
14. If yes, what are the challenges?

- Poor lighting due to electricity blackouts [ ]
- Inadequate delivery packs [ ]
- Lack of proper linen for the delivery beds [ ]
- Unreliable autoclaving machines [ ]
- Water shortages [ ]
- Inadequate disinfectants [ ]
- Shortage of cleaners (Cos) [ ]
- Other (specify)

__________________________________________________________

15. What do you think should be done to improve infection control at your clinic?

___________________________________________________________________________

___________________________________________________________________________

Section C: Tetracycline Eye Ointment Prophylaxis

16. At your clinic, do you give TEO prophylaxis routinely? (If no, skip question 14)

- Yes [ ]
- No [ ]

17. If yes, is it being given these days at your clinic?

- Yes [ ]
- No [ ]

18. If no, what are the reasons for not giving TEO prophylaxis?

- Stock outs of TEO [ ]
- Lack of knowledge by health staff [ ]
- Lack of supervision of health staff [ ]
Section D: Treatment of Ophthalmia Neonatorum

19. How common is ophthalmia neonatorum in your area?

Rare [ ] Common [ ] Very common [ ]

20. How is ophthalmia neonatorum treated at your clinic?

Tetracycline eye ointment [ ] Erythromycin [ ]

Kanamycin injection [ ] Treatment of father and mother of child [ ]

Other (specify) ________________________________

Section E: Complications of ophthalmia neonatorum

21. Have you ever recorded any complications of ophthalmia neonatorum at your clinic?

Yes [ ] No [ ]

22. If yes, what complications of ophthalmia neonatorum have you ever seen at your clinic?

Blindness [ ] Corneal opacity [ ] Ectropion [ ]

Other (specify) [ ]

Thank you
Appendix 6: MRCZ Approval Letter

Medical Research Council of Zimbabwe
Josiah Tongogara / Mazoe Street
P. O. Box CV 573
Causeway
Harare

APPROVAL LETTER

Ref: MRCZ/B/535

23 July, 2013

Calvin Vengere
University of Zimbabwe
Department of Community Medicine
P.O. Box A1/78
Avondale
Harare

RE: Factors Associated with Developing Ophthalmia Neumatargam in Harare City.

Thank you for the above titled proposal that you submitted to the Medical Research Council of Zimbabwe (MRCZ) for review. Please be advised that the Medical Research Council of Zimbabwe has reviewed and approved your application to conduct the above titled study. This is based on the following documents that were submitted to the MRCZ for review:

a) Study Proposal
b) English and Shona Informed Consent Forms version 1.1 dated 15 June 2010

• APPROVAL NUMBER: MRCZ/B/535
  This number should be used on all correspondence, consent forms and documents as appropriate.

• TYPE OF MEETING: Expedited Review
• APPROVAL DATE: 23 July, 2013
• EXPIRATION DATE: 22 July, 2014
  After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the MRCZ Offices should be submitted one month before the expiration date for continuing review.

• SERIOUS ADVERSE EVENT REPORTING: All serious problems having to do with subject safety must be reported to the Institutional Ethical Review Committee (IERC) as well as the MRCZ within 3 working days using standard forms obtainable from the MRCZ Offices.

• MODIFICATIONS: Prior MRCZ and IERC approval using standard forms obtainable from the MRCZ Offices is required before implementing any changes in the protocol (including changes in the consent document).

• TERMINATION OF STUDY: On termination of a study, a report has to be submitted to the MRCZ using standard forms obtainable from the MRCZ Offices.

• QUESTIONS: Please contact the MRCZ at Telephone No. (04) 791792, 791193 or by e-mail on mrcz@mrcz.org.zw.

Mr. Chinenge

Your Faithfully,

MRCZ SECRETARIAT
FOR CHAIRPERSON
MEDICAL RESEARCH COUNCIL OF ZIMBABWE

PROMOTING THE ETHICAL CONDUCT OF HEALTH RESEARCH

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Appendix 7: JREC Approval Letter

Joint Parirenyatwa Hospital
And College of Health Sciences
Research Ethics Committee

Date: 3rd July 2013
JREC Ref: 152/13

Name of Researcher: Dr Calvin Vengere
Address: University of Zimbabwe, Department of Community Medicine

Re: Factors Associated With Ophthalmia Neonatorium In Harare City.

Thank you for your application for ethical review of the above mentioned research to the Joint Research Ethics Committee. Please be advised that the Joint Research Ethics Committee has reviewed and approved your application to conduct the above named study.

- APPROVAL NUMBER: JREC/152/13
- APPROVAL DATE: 3rd July 2013
- EXPIRATION DATE: 2nd July 2014
- TYPE OF MEETING: Expedited Review

This approval is based on the review and approval of the following documents that were submitted to the Joint Ethics Committee:

a) Completed application form
b) Full Study Protocol
c) Informed Consent in English and/or appropriate local language
d) Data collection tool version:

After this date the study may only continue upon renewal. For purposes of renewal please submit a completed renewal form (obtainable from the JREC office) and the following documents before the expiry date:

a. A Progress report
b. A Summary of adverse events.
c. A DSMB report

- MODIFICATIONS:
Prior approval is required before implementing any changes in the protocol including changes in the informed consent.
• TERMINATION OF STUDY:

On termination of the study you are required to submit a completed request for termination form and a summary of the research findings/results.

Yours Faithfully,

Professor MM Chidzonga
JREC Chairman
Appendix 8: Approval Letter from Harare City

CITY OF HARARE

Director of Health Services
DR STANLEY MUNOFA
MD (Cuba) MPH (Zim)

29 May 2013

Dr C Vengere
3686 Mainway Meadows
Prospect, Waterfalls
HARARE

Dear Doctor

RE: PERMISSION TO CONDUCT A STUDY ON NEONATAL CONJUNCTIVITIES IN HARARE CITY

I acknowledge receipt of your letter dated 23 May 2013 in connection with the above.

Permission is granted for you to carry out the above study at six polyclinics in Harare City.

You will be required to pay USD50.00 administration fee prior to commencement of the study. The fee is payable to City Health Department, 6th floor, Rowan Martin Building.

Please be also advised that it is -our institutional policy that written permission should be sought from the department prior to any presentation or publication of research findings.

For further assistance please liaise with the Sisters In Charge of the Clinics.

Yours faithfully

DIRECTOR OF HEALTH SERVICES
IM/rn

c.c. Ethics Committee
Sister In Charge - Clinics