MMED RESEARCH PROJECT

Paediatric Pain Assessment and Management Survey within the Rahima Moosa Mother and Child Hospital.

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Declaration

I Dr Lindiwe Mabaso declare that this Research Report is my own, unaided work. It is being submitted for the Degree of M MED (Paediatrics) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

(Signature of candidate)

15th day of March 2021 in Boksburg

Dedication

We are a product of our environment. It is with that in mind that I dedicate this to my mother and sisters, who with God's blessing upon our lives, created an environment which nurtured me into the person I am today.

Thank you to my husband for seeing me. Thank you for being my inspiration to reach even greater heights. Each day I look forward to the miraculous destiny we forge towards together as we bear witness to each other's growth and to the growth of our family.

My stars, Agrinneth Mabaso, Ntsakisi Mabaso, Mathabo Segkobela, Nyikiwe Mabaso, Ngonyama Shamase and Fisokuhle Shamase.

Acknowledgements

The completion of this work would not have been possible without the patient guidance of Dr Anisa Bhettay and Dr Despina Demopoulos. The hours you have invested in my professional and personal growth are appreciated. And finally, Dr Tim De Mayer, thank you for selflessly giving of your time and expertise at a moment's notice. May God bless you.

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Abbreviations

The following definitions and abbreviations will be used in the documentation of the study.

CHBAH	Chris Hani Baragwanath Academic Hospital
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
NIPS	Neonatal Infant Pain Scale
Paediatric doctor	a paediatrician, registrar or medical officer who belongs to the Department of Paediatrics.
PMI	Pain Management Index. A score, ranging from negative three to positive three, used to quantify the pharmacological management of pain. Pain severity is subtracted from analgesic used[1] Severe pain = three, moderate pain =two, mild pain = one and no pain = zero. Strong opioid = three, weak opioid = two, non-opioid analgesic = one, no analgesia = zero
rFLACC	Revised Faces, Legs, Activity, Cry and Consolability
RMMCH	Rahima Moosa Mother and Child Hospital
SAMJ	South African Medical Journal
WAHC	Wits Academic Hospital Complex

Wits	University of the Witwatersrand
WHO	World Health Organisation

Submissible paper

Paediatric Pain Assessment and Management Survey within the Rahima Moosa Mother and Child Hospital.

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Abstract

Background

Painful experiences are prevalent within the paediatric inpatient population. Immaturity and cognitive impairment may preclude competent expression of such experiences, and the need for analgesia. Methods of pain assessment and guidelines for treatment in the paediatric population are well established but are not widely used around the world. Limited data suggests that the situation is similar in South Africa. The study aims to review the assessment and management of pain in South African medical paediatric inpatients.

Objectives

The primary objective was to determine the proportion of children who receive analgesia where indicated. The secondary objectives were to determine the incidence of pain at presentation, the prevalence of pain amongst admitted patients, if pain evaluations are done and if pain is treated, and the adequacy of such treatment.

Methods

The study was a prospective cross-sectional survey of medical paediatric inpatients at Rahima Moosa Mother and Child Hospital. The tool used for data collection was designed uniquely for this study, with sections for demographic data, patient or caregiver interview and review of the patient chart. Pain assessments were done using the revised Faces, Legs, Activity, Cry and Consolability score and the Neonatal/Infant Pain Scale. The analysis consists of descriptive statistics of epidemiological data and comparative statistics using grouped variables with significance level set at $p < 0.05$.

Results

The sample consisted of 74 participants aged three days to four years old and 58% were male. The incidence of pain at admission was found to be 73% (53 participants). Eight percent (six participants) of the study sample had pain evaluation at admission, and only one patient was evaluated for pain within the 24 hours preceding study participation. Of the 74 patients reviewed, seven (9.5%) received appropriate analgesia. Paracetamol was given to 23 (31%) patients, either for pyrexia, or the indication was not documented. More than half of the study sample - 44 (59.5%) - received no analgesia .

The presence of pain, both by caregiver report ($p = 1$) and by pain score ($p = 0.096$), was not associated with the administration of analgesia.

Conclusion

Pain in the paediatric population at RMMCH is common, it is seldom assessed, and validated pain scores are rarely used. The result is pain management which is inadequate in all three domains of assessment, treatment and re-evaluation.

Key words

Paediatric pain, pain assessment tools, analgesia

Word count

387

Background and introduction

Pain, defined as an unpleasant physical or emotional experience which is associated with actual or potential tissue damage, is a personal and subjective experience[1] [2]. It is prevalent in the paediatric population, both surgical and medical conditions[3] [4] [5]. Extensive research has been done worldwide which proves that young children, and even neonates, experience pain.

The gold standard of pain assessment is by self-report[2]. This method proves difficult in certain children, whose neurodevelopmental immaturity precludes coherent description of painful experiences and competent requests for analgesia when needed. Cognitively impaired patients are a particularly vulnerable group. Depending on their level of ability, some depend only on non-verbal communication. This unique set of circumstances has led to the development of several validated pain assessment tools for children of all ages, as well as for children with cognitive impairment.

The use of a pain score allows the selection of appropriate analgesia for the severity of pain present. Reassessment and regular documentation after initiating management indicates efficacy of interventions for pain. This allows adjustments to be made where necessary[6] [7]. Despite the availability of this wealth of knowledge, and tools with which to manage pain well in children, pain remains poorly understood, rarely assessed and inadequately treated within paediatric clinical practice worldwide. South Africa is no exception.

Studies conducted in Canada, the United States of America, New Zealand, and Australia, have shown that documentation of pain scores is poor, with rates varying from 27% to 48%[4] [8] [9]. Nurses use and document pain scores more frequently than physicians, but analgesia is more often given without the use of a pain score. Despite the existence and cognizance of protocols for pain management in these settings, analgesia was found to be inadequate or infrequent in many cases and resulted in breakthrough pain.

In Brazil, a three-day pain audit in a paediatric teaching hospital showed that the majority of patient records lacked any documented pain assessment[10]. Additionally, no non-pharmacological pain relief was recorded, and there was poor knowledge of protocols, guidelines and policies regarding pain assessment and management. Self-reporting of pain prevalence was higher than caregiver, nurse and physician reporting. Of note, 90% of children older than 24 months of age reported their pain, usually to their caregivers, with precise descriptors of site, intensity, and quality. This indicates that self-report, the gold standard for pain assessment, may be used successfully in preschool children.

Research on the subject within the African continent is limited with only two published studies on the epidemiology of paediatric pain and its treatment in South Africa [11] [12]. Both studies show that paediatric management could use improvement, and similar results were reported in Kenya [2]. Pain is common worldwide in the paediatric population and the management of this pain is inadequate. Additionally, diagnosis and management may require painful procedures.

The barriers to adequate pain management are vast and often regionally unique. Some of the known barriers to appropriate pain management in paediatrics identified in the literature are: difficulties with accurate assessment and quantification of pain in children as they may be unable to self-report; lack of knowledge of how to treat pain well amongst all health professionals looking after children; the misconception that children, especially infants, lack the ability to feel or experience pain; the failure of health professionals to assess for pain at all; the misconception that pain management is difficult; and fear of side effects and addiction[13]. Health professionals' personal beliefs and attitudes toward pain can also interfere with pain evaluation and management[14]. A barrier that is important in our setting is one identified by N Nortjé et al[15]. The influence of culture on the expression and derived meaning of painful experience. The expression of pain is not encouraged in South African Nguni and Sesotho cultures, particularly for men[15]. Traditional medicine is more accessible and widely accepted as the first place from which to seek help, except for children, for whom western medicine should be sought first[15]. The cultural meaning of pain (unappeased ancestors or witchcraft) may also limit its expression in the medical setting[15].

Poor pain management has both acute and chronic consequences. Acute consequences of unrelieved pain are anxiety, fear and sleep disturbances[14]. Physiological consequences are tachycardia and increased metabolic demand, tachypnoea and splinted breathing which cause hypoxia and alkalosis in a child who may have low reserve due to their illness[14]. Raised cortisol levels, which can cause impairment of immune function and delay wound healing and lastly reduced gut and genitourinary motility which cause nausea, ileus and urine retention[14].

Early pain experiences have been linked to neurodevelopmental abnormalities, decreased cortical brain volumes and axonal disturbances, heightened behavioural responses and an increased risk for anxiety-related psychiatric illness later in life[16, 17]. Untreated or inadequately treated acute pain results in central sensitization which causes increased central nervous system responsiveness to painful and nonpainful stimuli[18]. This contributes to the development and maintenance of chronic pain. It is vital that pain is adequately managed to prevent these short- and long-term consequences.

The study aims to review the assessment and management of pain of medical paediatric inpatients. The primary objective is to describe the prevalence of pain among medical paediatric in patients.

The secondary objectives are:

1. To determine the incidence of pain at presentation and the prevalence of pain amongst admitted patients
2. To determine if pain evaluations are done
3. To determine if pain is treated, and the adequacy of such treatment.

Methods

This was conducted as a prospective cross-sectional survey. It consisted of a survey, patient evaluation for pain at the time of the survey and a chart review. The study was conducted at the Rahima Moosa Mother and Child Hospital (RMMCH). It is a secondary academic hospital affiliated with the University of Witwatersrand which services women and children. All medical patients under the age of twelve years admitted to the general paediatric medical department at RMMCH were included. Patients with surgical diagnoses and those admitted to the intensive care unit and the neonatal unit were excluded. Data was collected prospectively by convenience sampling in the paediatric wards at RMMCH on three days in September 2018 and four days in April 2019.

A target sample size of 64 patients was determined using the Fischer's Formula for Prevalence studies[19]. The expected prevalence of pain was 78%, as taken from the study "Prevalence severity and initial management of pain among children admitted in Kenyatta National Hospital general paediatric wards"[2]. This study is selected because it is an African study and at the time of protocol development, there were no South African studies of pain prevalence amongst medical paediatric patients.

The tool used for data collection was a "Pain management and Assessment Audit Form" developed uniquely for this study. It was designed based on the information required to achieve the objectives set out above. It consisted of three sections, one for demographic data, one for an interview of the patient, parent or caregiver and finally a section for the review of the patient's file for evidence of pain assessment and adequacy of pain management. The adequacy of the analgesia was assessed using the prescription chart with reference to the level of pain at the time of the interview as perceived by the caregiver or patient.

The tool was written in English, however, the language used when interviewing was that which was most comfortable and common to the interviewee and data collector. The languages used were English and isiZulu. The assistance of a translator was not needed for any of the caregivers interviewed.

The objective assessment of pain at the time of data collection was done using the Neonatal Infant Pain Scale (NIPS) and the Revised Faces, Legs, Activity, Cry and Consolability (R-FLACC) score.

The NIPS is designed to assess six behavioural indicators of pain response in preterm (less than 37 weeks) and term neonates up to 6 weeks of age[20]. It is a non-invasive and validated measurement which assesses cry, motor activity, facial expression, state of arousal and breathing patterns, and is scored out of seven[20, 21] The patient is assessed as having no pain if the score is zero, mild pain for a score of one to three, moderate to severe pain for a score of four and above[20].

The R-FLACC score uses five behavioural parameters to assess for pain, each scored between zero and two[22]. The five categories are facial expression, leg movement, activity, cry and consolability[22]. A total score of zero means no pain, one to three is mild pain, four to seven is moderate pain, and eight to ten is severe pain[23]. The score can be used for post-surgical, trauma related, malignant and other painful disease processes[22].

Both scales are well validated to accurately determine pain severity and are selected for ease of use and because they are the tools recommended by the Clinical Guideline for Paediatric pain management at the RMMCH[24].

Self-report was to be used for patients above the age of eight years because this is the age above which self-report scales like the numerical rating scale and the visual analogue scale are validated for use[7]. For the purposes of this review, the Wong-Baker FACES scale[25] was selected as it is already part of the pain guidelines that exist at RMMCH. The scale is currently validated for use from the age of three years. Children are asked to select from cartoon type faces, which are designed to indicate escalating severities of pain, that which best matches the pain they are experiencing.

The use of non-pharmacological methods for pain management was not included in the data collection tool because the survey did not include the observation of an interaction between health workers and patients, for the evaluation of procedural pain, which is when such tools are likely used. These tools can and are often applied without prescription and therefore the review of patient records would unlikely give accurate reflection of their use, or the lack there-of.

This study was approved prior to collection of data by the University of Witwatersrand Human Research Ethics Committee (Clearance certificate number M180116). Participation was subject to the signing of an informed consent form.

Data was captured in REDCap (hosted by the University of the Witwatersrand) and the data exported to MS Excel (Microsoft, USA) for use. Analysis was done using Stata release 15 (StataCorp, USA). Categorical variables were expressed as frequencies and percentages, and continuous data presented using means and standard deviation (SD). Comparative analysis was done using Chi-square tests of association, and odds ratios were calculated using logistic regression for significant variables. P-values of less than 0.05 were considered significant.

Results

On all the days used to collect data, there were a total of 268 patients in the four paediatric wards. However, not all patients in the ward were eligible for interview as they may have taken part in the study on the previous day. A total of 80 patients were approached, five refused to participate and one was excluded as the patient was above the age of 12 years. A diagram showing patient selection and participation is seen in Figure 1.

The complete data set consisted of a total of 74 patients. Their ages ranged from three days to four years and three months with a mean age of eleven months (SD twelve months). *Table 1* shows patient characteristics, demographics, and diagnoses. All participant surveys were conducted by caregiver report as all participants were under the age of eight years.

Table 1: Patient characteristics and diagnoses

Characteristic	Frequency (percent) n (%)
Gender	
Male	43 (58)
Female	31 (42)
Race	
Black African	63 (85)
White African	3 (4)
Asian	3 (4)
Mixed race	5 (7)
Diagnosis	
Respiratory only	25 (34)
Neonatal sepsis	9 (12)
Respiratory and gastrointestinal	7 (10)
Cardiac	7 (10)
Nutritional	7 (10)
CNS*	4 (5)
GIT	4 (5)
Hepatic	3 (4)
Infectious disease	3 (4)
Other	5 (6)
Key informant	
Mother	68 (92)
Father	6 (8)

**CNS-Central nervous system, GIT-Gastrointestinal system.*

Pain epidemiology

The incidence of pain as part of the presenting complaint was 73% (95% CI = 60% to 82%) by caregiver report. Age was not a significant determinant of pain (p = 0.070).

The prevalence of pain later in the diagnosis by caregiver report was 31% within the twenty-four hours preceding the interview. At the time of the interview, pain prevalence by caregiver report was 15%. When assessed using a pain score, it was found that the prevalence of pain at the time

of interview was double that determined by care givers at 30% of the sample. While this finding failed to meet statistical significance (p = 0.051), it remains a clinically significant finding. There was no significant difference in pain score between sexes (p = 0.8). Full details contained in Table 2, which shows the overall pain prevalence and severity at different times of the admission.

Table 2: Pain epidemiology

	Frequency (percent)
Pain present at admission N=73	53 (73)
Worst pain within preceding 24hours (caregiver report) N = 23	
Mild	14 (19)
Moderate	5 (7)
Severe	4 (5)
Pain at time of interview by caregiver report N = 11	
Mild	8 (11)
Moderate	2 (3)
Severe	1 (1)
Pain at time of interview by pain score N = 22	
Mild	19 (26)
Moderate	3 (4)
Severe	0 (0)

Pain assessment

At admission, six of the 74 (8%) patients were assessed for pain according to patient record. Of the 53 patients who reportedly had pain as part of their presenting complaint, four of those had their pain evaluated in some way at admission according to patient record. Subsequent pain evaluations were also low, with only one patient having had two pain reviews documented within the 24 hours preceding the interview. The rest had no documented pain reviews in their patient files. Table 3 bellow shows the frequency of pain assessment at admission and within the 24 hours preceding interview.

Table 3: Pain assessment

	Frequency (percent)
Pain assessment N=73	
Pain assessed at admission	6 (8)
Pain not assessed at admission	67 (92)
Frequency pain evaluation within 24hrs of interview N =74	
None	73 (99)
Once	0 (0)
Twice	1 (1)

Pain treatment and adequacy of treatment

Analgesia given was adequate for level of pain severity for only seven (9.5%) of the 74 participants at some point in their care. Almost 60% of the patients reviewed had no analgesia during their admission up to the time of review. Almost a third were given paracetamol. The paracetamol was either given for pyrexia and indicated as such, or the indication was not specified. Frequencies of pain treatment and its adequacy are contained in *Table 4* below, and associations between pain and its management are detailed in *Table 5* using Fishers Exact testing.

In Table 5, only two of the eight analysed parameters show an association which is statistically significant. Those are the association between the assessment of pain at admission and the receipt of analgesia ($p = 0.004$), and between the presence of pain before admission by parent report and the receipt of analgesia ($p = 0.033$).

Table 4: Pain treatment and adequacy of treatment

	Frequency (percent)
Analgesia received N = 74	
Appropriate analgesia received	7 (10)
Received paracetamol – indication not stated	23 (31)
No analgesia received	44 (59)
Analgesia amongst patients with pain at admission N = 53	
Appropriate analgesia received	5 (9)
Received paracetamol-indication not stated	21 (40)
No analgesia received	27 (47)
Analgesia amongst patients with pain by pain score N=22	
Appropriate analgesia received	0 (0)
Received paracetamol-indication not stated	12 (55)
No analgesia received	10 (45)
Prescription adequacy (to pain by caregiver report) N = 74	
Appropriate analgesia	13 (18)
Analgesia not appropriate to pain severity	17 (23)
N/A (no analgesic or no pain)	44 (59)
Timed analgesia N = 73	
Yes	55 (75)
No	18 (25)

Table 5: Comparison of analgesia administration and pain status

	Present	Absent	P-value♠	Odds ratio	95% Confidence interval
Received no analgesia or paracetamol only vs received appropriate analgesia					
PBA*	53	20	1.00	-	-
Pain assessed at admission	6	67	0.004	7.59	0.88 – 4.67
Pain reported at time of interview	11	63	1.00	-	-
Measured pain	22	52	0.096	-	-
No analgesia received vs any analgesia received (paracetamol and/or other appropriate drug)					
PBA	53	20	0.033	3.85	1.14 – 13.06
Pain reported at time of interview	11	63	0.749	-	-
PBA vs no PBA					
Timed analgesia	18	54	0.762	-	-
Pain assessed	6	67	0.73	-	-

*PBA- Pain Before Admission

♠ Fishers Exact test

Discussion

The paediatric population at RMMCH has pain incidence that is similar to findings in institutions around the world and other areas of South Africa. Pain is seldom assessed, validated pain scores are rarely used, and the result is poor pain management.

Pain incidence at RMMCH at the time of admission mirrors that reported at the Red Cross War Memorial Children's Hospital trauma unit[11]. This is an important finding, because the patients reviewed in this study all had medical illnesses, as opposed to surgical diagnoses. This finding challenges the general assumption made by health care workers that surgical patients experience more pain than do medical patients, as was shown by Cardona et al[12] and EA Cummings et al[4] in their studies. It also highlights a potential for increased vulnerability of medical patients to poor pain management as a result.

The pain incidence at admission found in this study is as high as found in studies from around the world from as far back as 1996. No improvement has been achieved in all these years of reviews despite availability of guidelines [3,4,5,9,11,12].

The declining prevalence of pain later in the admission, both by caregiver report and by pain score, can possibly be attributed to the use of paracetamol for pyrexia, or by routine prescription without

actual assessment of a child's analgesic needs as based on pain severity. It is also likely due to the management and subsequent resolution of pathology.

At the time of the interview, the prevalence of pain by caregiver report is half of what was found by pain score. Other studies found better agreement between caregiver and objective pain score[26] [27]. Although not specifically evaluated in this study, this disparity in reported pain between caregiver and pain score could be explained by the cultural nuances of our diverse society, by language differences and by historical power dynamics associated with South Africa's political past[15]. These potential influences require further study and awareness amongst clinicians.

Pain is rarely assessed at RMMCH. The best opportunity for pain assessment for patients was found to be at admission. Pain assessments in the days following admission rarely occurred. Investigational and therapeutic procedures carried out during a hospital admission are known to be painful. Although not specifically investigated in this study, the absence of subsequent pain evaluations exposes a period of risk where procedural pain is unlikely to be addressed.

The low rate of pain evaluation correlates, unsurprisingly, with inadequate analgesic use and pain management. More than half of patients did not receive any analgesia despite it being indicated. Most patients were inappropriately given single agent analgesia (paracetamol), even where moderate or severe pain necessitated stronger agents and a multimodal approach.

Of the patients who had pain at admission, only seven percent received analgesia that was appropriate for their pain. When paracetamol is included, the odds ratio of receiving analgesia when pain is present at admission is 3.85 ($p = 0.033$), however when paracetamol is removed, there is no significant association between the presence of pain at admission and the receipt of analgesia. It is likely that many patients benefit from the routine use of paracetamol for fever without formal pain evaluation with a validated pain score.

There is no statistically significant association between the presence of pain by caregiver report and the receipt of analgesia. However, when pain is clinically evaluated, there is statistically and clinically significant evidence that analgesia is more likely to be given.

The study population did not include anyone over the age of eight years. Therefore, none of the study participants were the primary informant. The study relied on caregiver assessments and pain scores without the use of self-report, which is the gold standard for pain assessment. This study population reflects that of RMMCH and therefore the reality of pain assessment and management in this institution.

The barriers to pain assessment and management specific to this institution should be explored in future studies. They could provide useful insight and a great starting point toward quality improvement if identified.

This study enriches the currently sparse body of knowledge with regards to the epidemiology of paediatric pain and its management in South Africa. It provides South African paediatric clinicians of all disciplines insight into their own behaviour and an opportunity for a deliberate effort toward improvement.

Study Limitations

While an enquiry into the presence of pain at admission took place, the severity of that pain was not documented, making comparison of progression difficult.

The exact analgesics prescribed were not recorded at the time of data collection. This was an unfortunate error in study design. Therefore, a pain management index could not be calculated. This may have made analysis of adequacy of care more accurate. The Pain Management Index a score, ranging from negative three to positive three, used to quantify the pharmacological management of pain. Pain severity is subtracted from the analgesic used[27].

The study was conducted in a single centre with a relatively small sample size.

The study design allowed for the primary respondent to be the patient only if older than 8 years of age because that was the age from which assent was to be acquired from the child and the RMMCH paediatric pain protocol was designed for self-report above the age of 7years. Therefore, none of the pain evaluations was by self-report.

Conclusion

Pain in the paediatric population at RMMCH is common and its management is poor, in all three domains of assessment, treatment and re-evaluation. This is despite the wealth of knowledge, tools and guidelines on the management of pain in the paediatric population and the presence of a pain management guide written specifically for use at RMMCH. This finding is not unique to this hospital and is likely similar in many South African healthcare institutions.

These findings suggest that more than a written protocol is needed to improve pain management.

Recommendations

Training of medical staff on pain assessment and management may raise awareness. The training should begin with consultants as they are the drivers of behaviour amongst junior staff, and because they remain constant in an academic environment with high trainee doctor turn over. This high turnover would necessitate regular training every few months. Nurses, who spend the most time with patients, should be placed at the forefront for training opportunities.

Visible pain assessment posters may prompt use by health professionals and may prompt caregivers to speak up when they feel that their child's pain is not being managed. Perhaps the inclusion of a section for pain score evaluation in both the nurses triage form and the doctor's

admission file template may encourage accurate and regular documentation of results, interventions and reassessments.

A policy which allows nurses to initiate pain management by a predetermined algorithm both at admission triage and in the wards while they await review by a doctor, could minimise pain agony while waiting to be seen in busy academic and public hospitals where waiting times are often long.

Conflict of Interest

None to report

Author Contributions

LM: primary investigator and author

AB: co-author, thesis supervisor. Involved in study design and manuscript review.

DD: thesis supervisor. Involved in manuscript review.

Funding sources

Fully self-funded.

Word count

4440

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Figure 1:

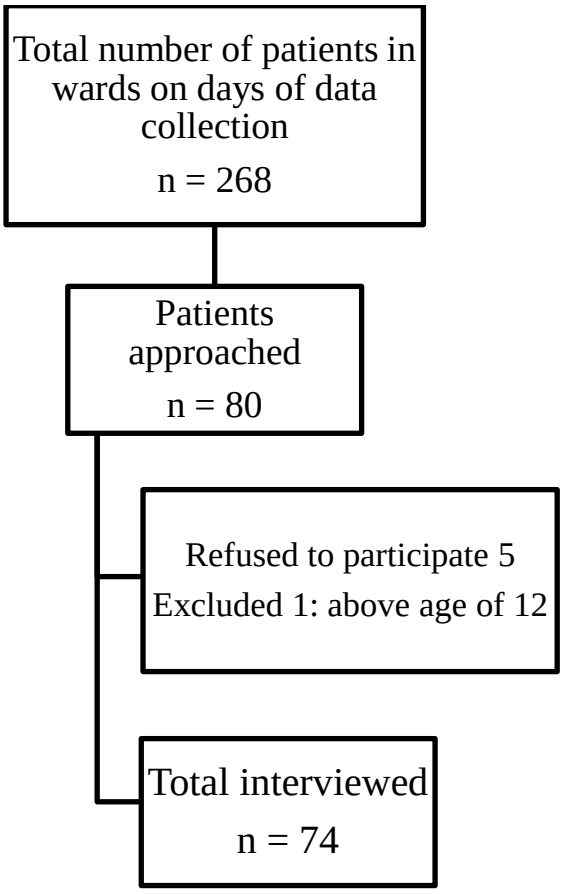


Figure 1: flow diagram of patient selection and participation

Appendix 1: Pain Assessment and Management Audit Tool

Pain Assessment and Management Audit Tool

Section A: Demographics

1. Pt identification (hospital number)	
2. Study number	
3. Hospital	
4. Unit and ward	
5. Age	
6. Sex	
7. Race	
8. Diagnosis	
9. Day of admission	

Section B: Patient/caregiver interview

10. Key informant	
11. Reason for above	Neonate/pt cognitive impairment/no parent/immaturity(<7yrs)/NA
12. Pain before admission	Yes/No
13. Worst pain in last 24hr as perceived by patient or care giver.	
14. Pain now as perceived by patient or care giver?	
15. Current pain score (FLACC OR NIPS)	
16. Patient or care giver aware of analgesia being given if pain present?	Yes/No/NA
17. If yes above, was it adequate?	Yes/Partially/No/NA

Section C: Patient record analysis

18. Record of pain assessment/score at admission	Yes/No
19. Number pain scores done last 24hr	None/Once/Twice/More
20. Analgesia ever given?	Yes/None/Paracetamol-indication pyrexia or not indicated
21. Analgesia prescribed as needed only (prn)	Yes/No

22. Was prescribed analgesia appropriate for level of pain as perceived by the patient or caregiver? *see analgesia guide bellow	Yes/No
23. Analgesia prescribed by the clock	Yes/No

**Question 22: Analgesia guide*

Mild pain	Score 1-3	Non-pharmacological methods AND simple analgesic (Paracetamol and/ or NSAID)
Moderate pain	Score 4-7	Non-pharmacological methods AND simple analgesic AND opioid
Severe pain	score8-10	Non-pharmacological methods AND simple analgesics AND opioid

NIPS: Neonatal Infant pain Scale

NEONATAL INFANT PAIN SCALE			
NPS	**0 POINT**	**1 POINT**	**2 POINTS**
FACIAL EXPRESSION	RELAXED	CONTRACTED	
CRY	ABSENT	MUMBLING	VIGOROUS
BREATHING	RELAXED	DIFFERENT THAN BASAL	
ARMS	RELAXED	FLEXED/STRETCHED	
LEGS	RELAXED	FLEXED/STRETCHED	
ALERTNESS	SLEEPING/CALM	UNCOMFORTABLE	

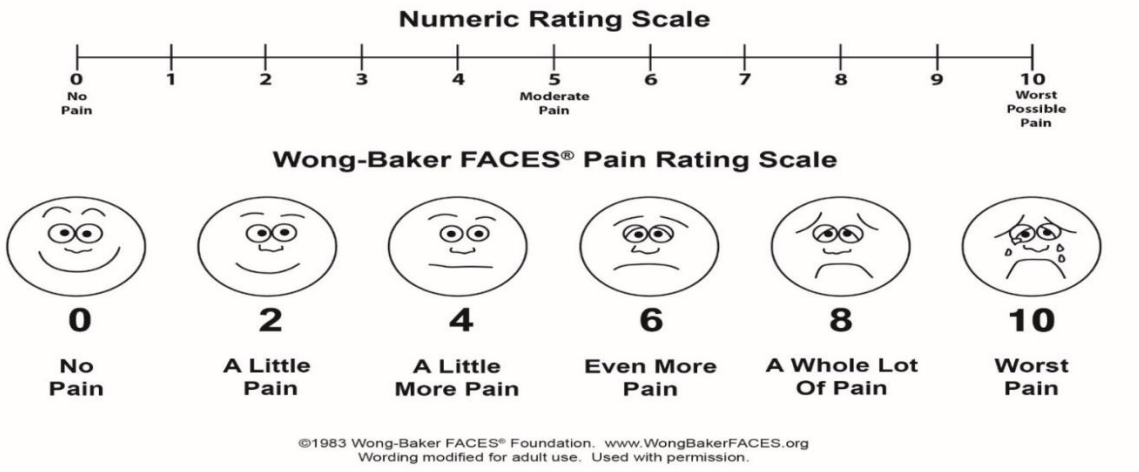
PAIN ASSESSMENT TOOL - BEHAVIOURAL: R-FLACC SCORE - 2 MONTHS OLD – 16 YEARS

	0	1	2
FACE	No particular expression or smile	Occasional grimace/frown: withdrawn or disinterested [appears sad or worried]	Constant grimace or frown: frequent or constant quivering chin, clenched jaw. [Distressed looking face: expression of fright or panic]

LEGS	Normal position or relaxed	Uneasy, restless, tense [occasional tremors]	Kicking or legs drawn up [marked increase in spasticity, constant tremors or jerking]
ACTIVITY	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense [mildly agitated (e.g. head back and forth, aggression); shallow splinting respirations, intermittent sighs]	Arched, rigid or jerking [severe agitation head banging; shivering (not rigors), breath holding, gasping or sharp intake of breath; severe splinting]
CRY	No cry [awake or asleep]	Moans or whimpers, occasional complaint [occasional verbal outburst or grunt]	Crying steadily, screams or sobs, frequent complaints [repeated outbursts, constant grunting]
CONSOLABILITY	Content, relaxed	Reassured by occasional touching, hugging, or "talking to"; distractible	Difficult to console or comfort [pushing away caregiver, resisting care or comfort measures]
Revised descriptors for children with disabilities shown in brackets			

<u>Numeric rating scale and Wong Baker FACES Scale for self-report. (>7years)</u>

To be used for questions 12 and 13. Numeric rating scale for care giver opinion, and Wong baker for self-report.



Appendix 2: Ethics clearance certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

Office of the Deputy Vice-Chancellor (Research & Post Graduate Affairs)

TO: Dr LNM Mabaso
School of Clinical Medicine
Department of Paediatrics and Child Care
Medical School
University

E-mail: lmnmabaso11@gmail.com

CC: Supervisor: Dr A Bhettay <anisabhettay@gmail.com>
and <HREC-Medical.ResearchOffice@wits.ac.za>

FROM: Iain Burns
Human Research Ethics Committee (Medical)
Tel: 011 717 1252

E-mail: Iain.Burns@wits.ac.za

DATE: 14/05/2018

REF: *R14/49*

PROTOCOL NO: **M180116** *(This is your ethics application study reference number. Please quote this reference number in all correspondence relating to this study)*

PROJECT TITLE: *Paediatric pain assessment and management survey within the Rahima Moosa Mother and Child Hospital*

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to the Government funding of the University.

MSWorks2000/Iain0007/Clearscan.wps

Appendix 3: SAMJ (South African Medical Journal) author guidelines

General article format/layout

Accepted manuscripts that are not in the correct format specified in these guidelines will be returned to the author(s) for correction, which will delay publication.

General:

- Manuscripts must be written in UK English.
- The manuscript must be in Microsoft Word format. Text must be single-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes).
- Please make your article concise, even if it is below the word limit.
- Qualifications, ***full*** affiliation (department, school/faculty, institution, city, country) and contact details of ALL authors must be provided in the manuscript and in the online submission process.
- Abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.
- Include sections on Acknowledgements, Conflict of Interest, Author Contributions and Funding sources. If none is applicable, please state 'none'.
- Scientific measurements must be expressed in SI units except: blood pressure (mmHg) and haemoglobin (g/dL).
- Litres is denoted with an uppercase L e.g. 'mL' for millilitres).
- Units should be preceded by a space (except for % and ºC), e.g. '40 kg' and '20 cm' but '50%' and '19ºC'.
- Please be sure to insert proper symbols e.g. µ not u for micro, a not a for alpha, b not B for beta, etc.
- Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160.
- Quotes should be placed in single quotation marks: i.e. The respondent stated: '...'
- Round brackets (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.
- If you wish material to be in a box, simply indicate this in the text. You may use the table format –this is the *only* exception. Please DO NOT use fill, format lines and so on.

SAMJ is a generalist medical journal, therefore for articles covering genetics, it is the responsibility of authors to apply the following:

- Please ensure that all genes are in italics, and proteins/enzymes/hormones are not.

- Ensure that all genes are presented in the correct case e.g. TP53 not Tp53.

**NB: Copyeditors cannot be expected to pick up and correct errors wrt the above, although they will raise queries where concerned.

- Define all genes, proteins and related shorthand terms at first mention, e.g. '188del11' can be glossed as 'an 11 bp deletion at nucleotide 188.'

- Use the latest approved gene or protein symbol as appropriate:

- Human Gene Mapping Workshop (HGMW): genetic notations and symbols
- HUGO Gene Nomenclature Committee: approved gene symbols and nomenclature
- OMIM: Online Mendelian Inheritance in Man (MIM) nomenclature and instructions
- Bennet et al. Standardized human pedigree nomenclature: Update and assessment of the recommendations of the National Society of Genetic Counselors. J Genet Counsel 2008;17:424-433: standard human pedigree nomenclature.

Preparation notes by article type

Research

Guideline word limit: 4 000 words

Research articles describe the background, methods, results and conclusions of an original research study. The article should contain the following sections: introduction, methods, results, discussion and conclusion, and should include a structured abstract (see below). The introduction should be concise – no more than three paragraphs – on the background to the research question, and must include references to other relevant published studies that clearly lay out the rationale for conducting the study. Some common reasons for conducting a study are: to fill a gap in the literature, a logical extension of previous work, or to answer an important clinical question. If other papers related to the same study have been published previously, please make sure to refer to them specifically. Describe the study methods in as much detail as possible so that others would be able to replicate the study should they need to. Results should describe the study sample as well as the findings from the study itself, but all interpretation of findings must be kept in the discussion section, which should consider primary outcomes first before any secondary or tertiary findings or post-hoc analyses. The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

Select figures and tables for your paper carefully and sparingly. Use only those figures that provided added value to the paper, over and above what is written in the text.

Do not replicate data in tables and in text .

Structured abstract

- This should be 250-400 words, with the following recommended headings:
    - **Background:** why the study is being done and how it relates to other published work.
    - **Objectives:** what the study intends to find out
    - **Methods:** must include study design, number of participants, description of the intervention, primary and secondary outcomes, any specific analyses that were done on the data.
    - **Results:** first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.

    - **Conclusion:** must be supported by the data, include recommendations for further study/actions.
- Please ensure that the structured abstract is complete, accurate and clear and has been approved by all authors.
- Do not include any references in the abstracts

Main article

All articles are to include the following main sections: Introduction/Background, Methods, Results, Discussion, Conclusions.

The following are additional heading or section options that may appear within these:

- Objectives (within Introduction/Background): a clear statement of the main aim of the study and the major hypothesis tested or research question posed
- Design (within Methods): including factors such as prospective, randomisation, blinding, placebo control, case control, crossover, criterion standards for diagnostic tests, etc.
- Setting (within Methods): level of care, e.g. primary, secondary, number of participating centres.
- Participants (instead of patients or subjects; within Methods): numbers entering and completing the study, sex, age and any other biological, behavioural, social or cultural factors (e.g. smoking status, socioeconomic group, educational attainment, co-existing disease indicators, etc)that may have an impact on the study results. Clearly define how participants were enrolled, and describe selection and exclusion criteria.
- Interventions (within Methods): what, how, when and for how long. Typically for randomised controlled trials, crossover trials, and before and after studies.
- Main outcome measures (within Methods): those as planned in the protocol, and those ultimately measured. Explain differences, if any.

Results

- Start with description of the population and sample. Include key characteristics of comparison groups.
- Main results with (for quantitative studies) 95% confidence intervals and, where appropriate, the exact level of statistical significance and the number need to treat/harm. Whenever possible, state absolute rather than relative risks.
- Do not replicate data in tables and in text.
- If presenting mean and standard deviations, specify this clearly. Our house style is to present this as follows:
- E.g.: The mean (SD) birth weight was 2 500 (1 210) g. Do not use the ± symbol for mean (SD).
- Leave interpretation to the Discussion section. The Results section should just report the findings as per the Methods section.

Discussion

Please ensure that the discussion is concise and follows this overall structure – sub-headings are not needed:

- Statement of principal findings
- Strengths and weaknesses of the study
- Contribution to the body of knowledge
- Strengths and weaknesses in relation to other studies
- The meaning of the study – e.g. what this study means to clinicians and policymakers
- Unanswered questions and recommendations for future research

Conclusions

This may be the only section readers look at, therefore write it carefully. Include primary conclusions and their implications, suggesting areas for further research if appropriate. Do not go beyond the data in the article.

Illustrations/photos/scans

- If illustrations submitted have been published elsewhere, the author(s) should provide consent to republication obtained from the copyright holder.
- Figures must be numbered in Arabic numerals and referred to in the text e.g. '(Fig. 1)'.
- Each figure must have a caption/legend: Fig. 1. Description (any abbreviations in full).
- All images must be of high enough resolution/quality for print.
- All illustrations (graphs, diagrams, charts, etc.) must be in PDF or jpeg form.
- Ensure all graph axes are labelled appropriately, with a heading/description and units (as necessary) indicated. Do not include decimal places if not necessary e.g. 0; 1.0; 2.0; 3.0; 4.0 etc.
- Scans/photos showing a specific feature e.g. *Intermediate magnification micrograph of a low malignant potential (LMP) mucinous ovarian tumour. (H&E stain).* –include an arrow to show the tumour.
- Each image must be attached individually as a 'supplementary file' upon submission (not solely embedded in the accompanying manuscript) and named Fig. 1, Fig. 2, etc.

Tables

- Tables should be constructed carefully and simply for intelligible data representation. Unnecessarily complicated tables are strongly discouraged.
- Large tables will generally not be accepted for publication in their entirety. Please consider shortening and using the text to highlight specific important sections, or offer a large table as an addendum to the publication, but available in full on request from the author

- Embed/include each table in the manuscript Word file - do not provide separately as supplementary files.
- Number each table in Arabic numerals (Table 1, Table 2, etc.) and refer to consecutively in the text.
- Tables must be cell-based (i.e. not constructed with text boxes or tabs) and editable.
- Ensure each table has a concise title and column headings, and include units where necessary.
- Footnotes must be indicated with consecutive use of the following symbols: * † ‡ § ¶ ‖ then ** †† ‡‡ etc.

Do not: Use [Enter] within a row to make 'new rows':

Rather:

Each row of data must have its own proper row:

Do not: use separate columns for *n* and %:

Rather:

Combine into one column, *n* (%):

Do not: have overlapping categories, e.g.:

Rather:

Use <> symbols or numbers that don't overlap:

References

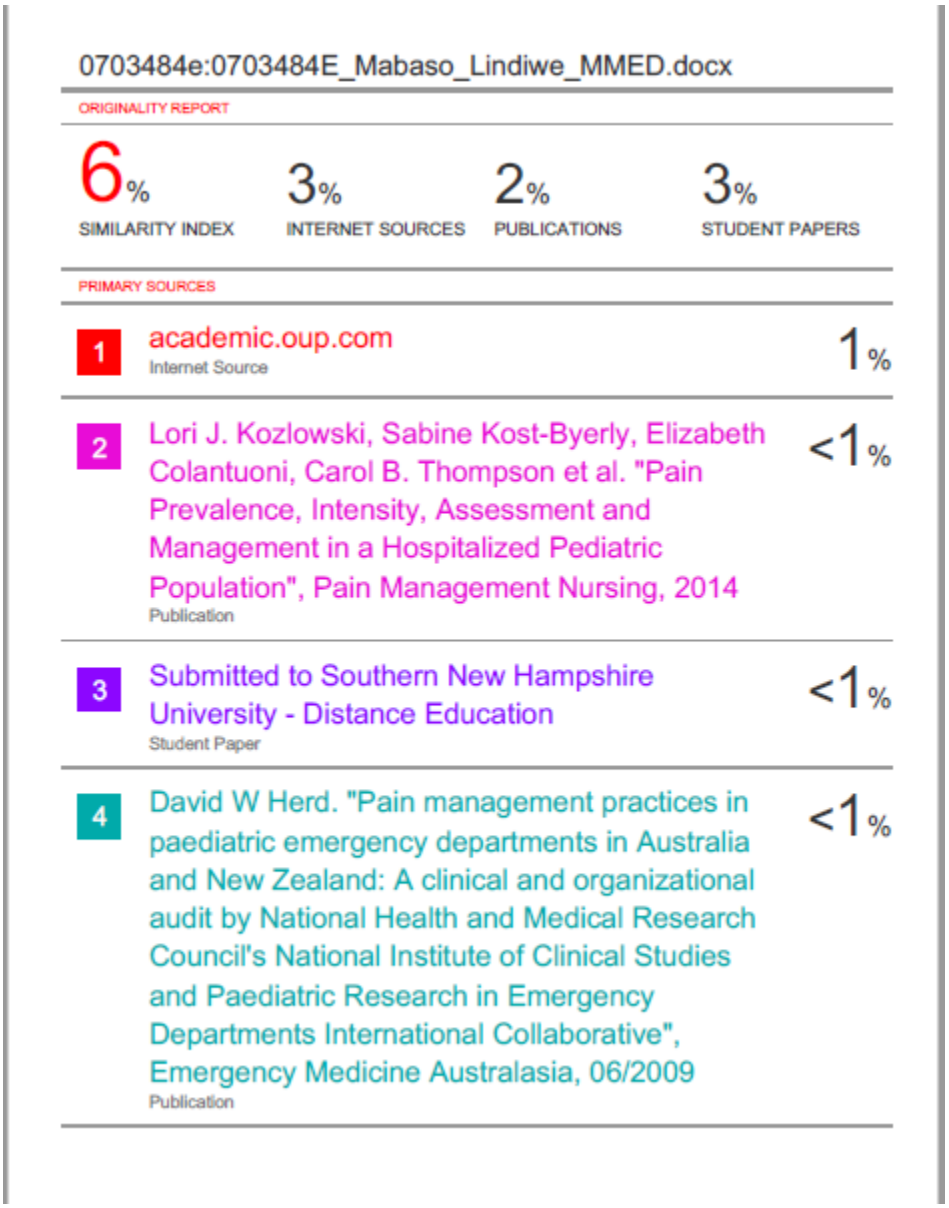
NB: *Only complete, correctly formatted reference lists in Vancouver style will be accepted. Reference lists must be generated manually and not with the use of reference manager software. Endnotes must* ***not*** *be used.*

- Authors must verify references from original sources.
- Citations should be inserted in the text as superscript numbers between square brackets, e.g. These regulations are endorsed by the World Health Organization,[2] and others.[3,4-6]
- All references should be listed at the end of the article in numerical order of appearance in the Vancouver style (not alphabetical order).
- Approved abbreviations of journal titles must be used; see the List of Journals in Index Medicus.
- Names and initials of all authors should be given; if there are more than six authors, the first three names should be given followed by et al.
- Volume and issue numbers should be given.
- First and last page, in full, should be given e.g.: 1215-1217 **not** 1215-17.

- Wherever possible, references must be accompanied by a digital object identifier (DOI) link). Authors are encouraged to use the DOI lookup service offered by CrossRef:
    - On the Crossref homepage, paste the article title into the ‘Metadata search’ box.
    - Look for the correct, matching article in the list of results.
    - Click Actions > Cite
    - Alongside 'url =' copy the URL between { }.
    - Provide as follows, e.g.: https://doi.org/10.7196/07294.937.98x

Appendix 4: Turnitin report

(Full report attached as PDF file)



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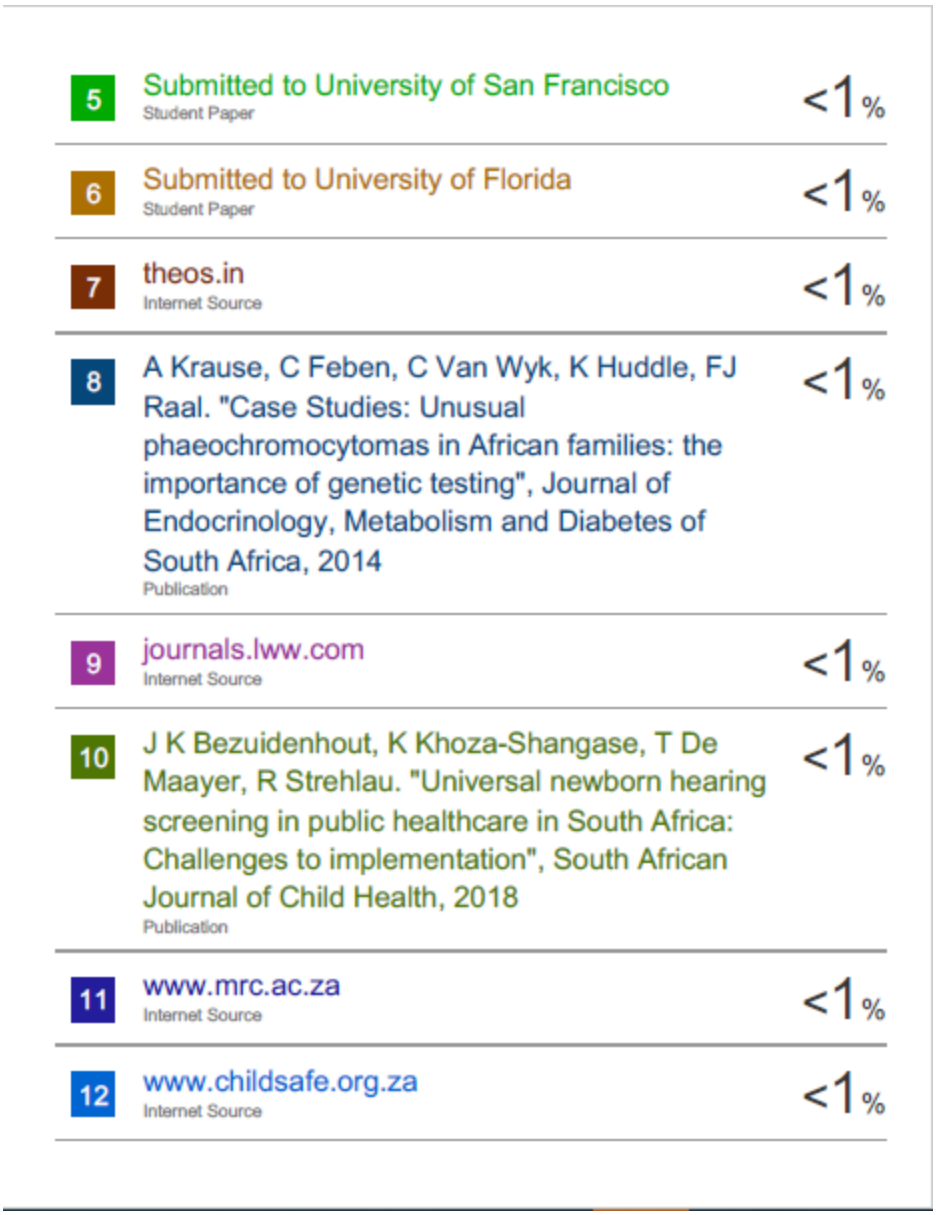

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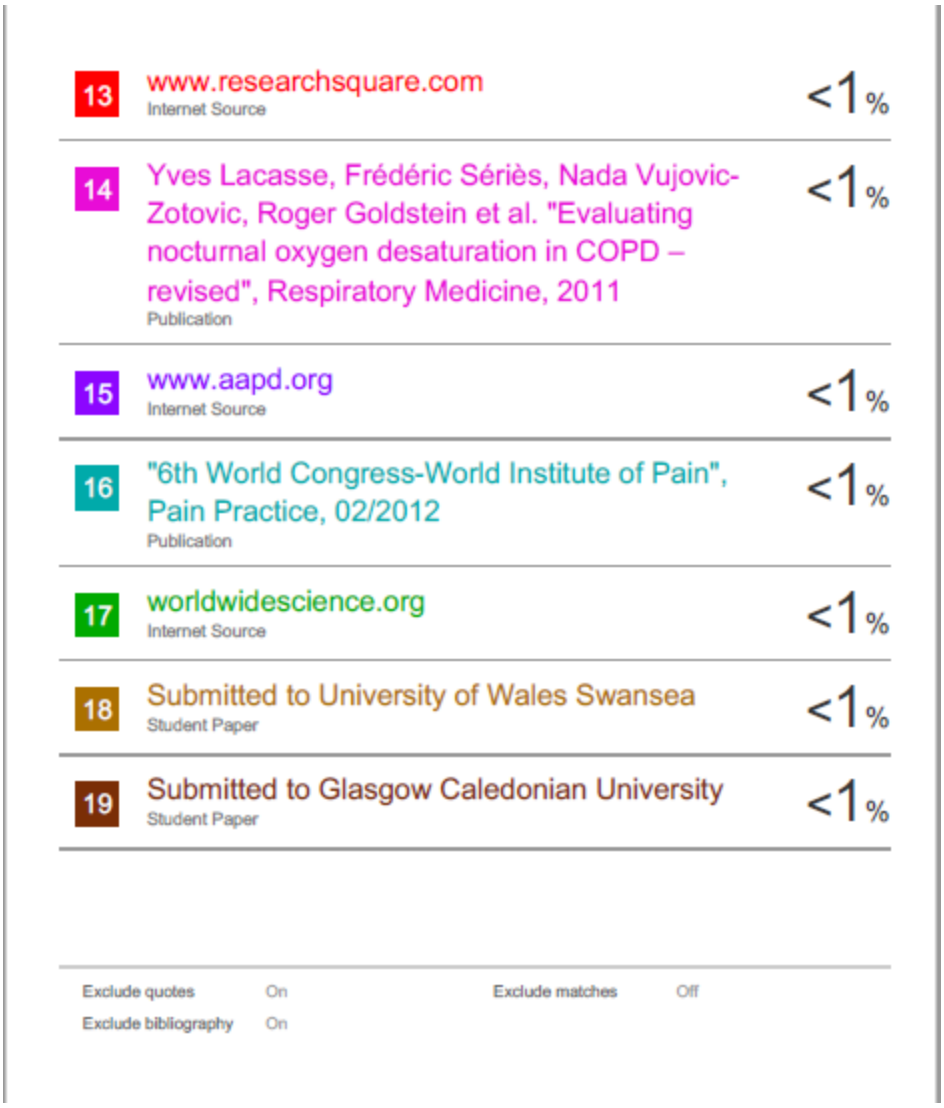

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Exclude quotes	On	Exclude matches	Off
Exclude bibliography	On		

Appendix 5: MMED Proposal

Paediatric Pain Assessment and Management Survey within the Rahima Moosa Mother and Child Hospital.

Researcher: Dr Lindiwe Mabaso

Student number: 0703484E

Degree: Master of Medicine-Paediatrics

University: University of the Witwatersrand

Supervisor 1: Dr Anisa Bhettay

Supervisor 2: Dr Despina Demopoulos

TABLE OF CONTENTS:

11.0 Appendices

12.0 References

INTRODUCTION, BACKGROUND AND RATIONALE FOR THE STUDY

Pain is defined as an unpleasant physical or emotional experience which is associated with actual or potential tissue damage (1). The inability to verbally communicate the experience of pain does not negate its existence, nor the need for treatment (2).

The prevalence of pain in paediatrics is well studied and documented internationally. Much work has been done to validate pain assessment tools and develop pain management protocols. Despite this, pain management remains visibly poor. This is a global phenomenon. The South African context, however, lacks local data in terms of prevalence and management of pain. Few paediatric institutions have established pain management protocols. Only one South African paediatric institution has published data on its pain incidence and management.

A prospective observational study was conducted at the Red Cross War Memorial Children's Hospital trauma unit in the Western Cape in 2008. It showed that 76% of presenting patients experience some level of pain during their hospital stay, 13.3% of whom experienced severe pain. Of these patients, only 37% received analgesics and 6.6% of prescribed analgesics were not or only partially given (3).

An epidemiological study conducted in the African and paediatric context in Kenya revealed an overall pain prevalence of 78% within the first 24 hours of admission. At the time of evaluation, 100% of older children (aged 4 to 12 years) reported experiencing pain in the first 24 hours of their admission. While caregivers reported a 91% prevalence of pain amongst younger children (aged 1 month-4years), an objective evaluation using the FLACC pain score revealed a lower pain prevalence of 69%. The severity of pain by FLACC score assessment amongst the children aged 1 month to 4 years was moderate in 29%, and severe in 2% of participants. In the older group, moderate pain severity was reported by 69% of participants. Severe pain was reported by 5% of the participants. Particularly significant is the finding that clinical procedures accounted for 99% of pain experienced, whereas disease accounted for a comparatively lower, but still independently significant, pain prevalence of 79%. Their findings regarding level of pain management were mixed. When based on pain score findings, 88% of older children and 85% of younger children received analgesia for admission diagnosis. However, only 2% of older children and 4% of younger children were provided with procedural analgesia. When evaluated using the Pain Management Index, only half of patients who received analgesia were adequately managed, and only 25% were receiving analgesia regularly. Non-pharmacological interventions were not used for any of the patients evaluated (4).

A study conducted in 2004 at the Hospital for Sick Children, a Canadian quaternary paediatric hospital, showed that only 27% of patients had pain prior to their admission. A further 77% of patients experienced pain during admission, which, although not specifically evaluated in this study, suggests a significant amount of pain is procedural. Analgesics were given intermittently, and pain was not documented during the preceding 24 hours for 73% of patients (5).

As early as 1996, epidemiological studies were indicating inadequacies in paediatric pain management. A study conducted in IWK-Grace Health Centre in Canada, revealed an unacceptably high prevalence of pain. There was no significant difference in pain levels

experienced by surgical and medical patients. This highlights the need to assess pain adequately for all patients (6).

Pain assessment and management in South African hospitals seems similarly poor, based on the one local study available(3), and anecdotally. Paediatric pain epidemiology has only been studied in one South African institution, the Red Cross War Memorial Children's Hospital, in their Trauma unit. In South Africa, there exists no data on the epidemiology of pain amongst medical paediatric patients.

At a national level, guidelines for pain assessment and management are included in the Hospital-level Paediatrics Standard Treatment Guidelines and Essential Medicines List, published in 2017(7). They include guidelines for the assessment of pain, and for management of procedural, acute and chronic pain. These guidelines largely conform to the World Health Organisation's approach. This is an approach which enjoys consensus among many experts and organisations worldwide.

The WHO principals of pain management in children still adhere to those first introduced in 1986, but with the addition of one new concept (2).

- ✓ "By the mouth"

  The simplest and least painful route of administration possible for the clinical situation should be selected. The intravenous route is used where immediate relief is needed and if regional routes are unavailable or inappropriate

- ✓ "By the clock"

  Dosing intervals must be regular as pain is a consistent entity in most disease processes. Analgesics must be given regularly to prevent pain re-emergence. Breakthrough pain must be monitored for and treated appropriately with additional medication or doses. The total daily dose should then be recalculated for the following day based on total amount of analgesia used. The exception is pain that is clearly episodic and unpredictable in nature or is procedural.

- ✓ "By the individual"

  Adapt treatment to the needs of the patient and to their tolerance of specific drugs used.

- ✓ "Using a two-step strategy"

  This is the new WHO principal of paediatric pain management. The WHO no longer recommends the three-step pain ladder for children. This was done in order to eliminate weak opioids, for which there exists considerable genetic variability in enzyme activity amongst children (2).

Management is based on whether pain is assessed to be mild, or moderate to severe (2).

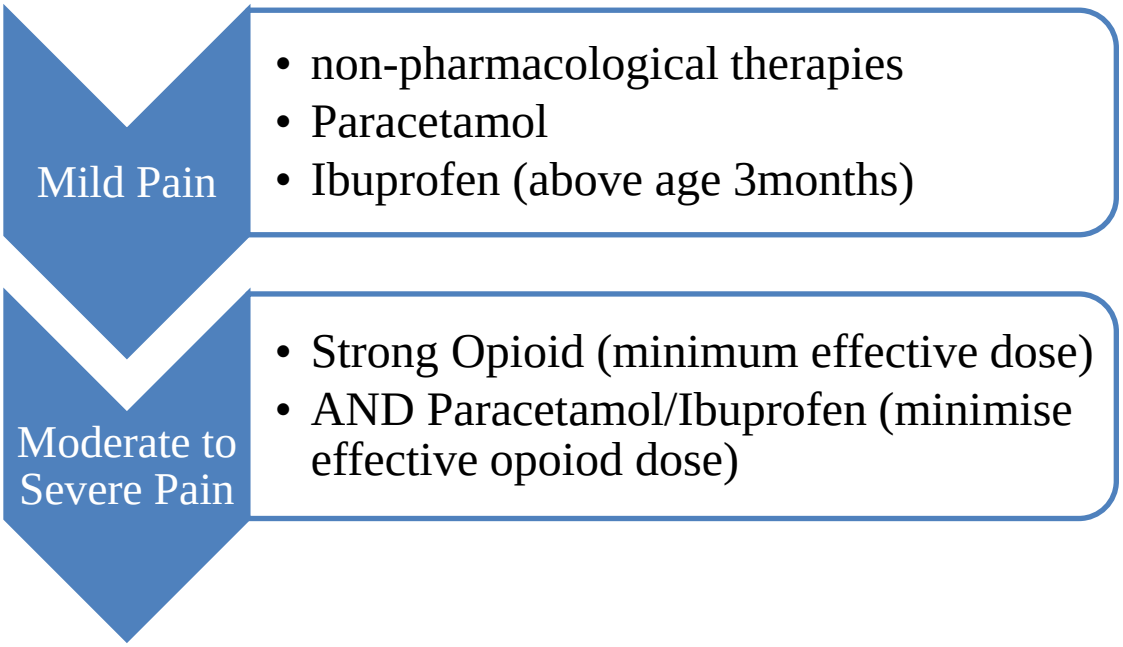
Once an initial assessment of the severity of pain has been made, treatment can commence. Mild pain is treated with non-pharmacological strategies like play, swaddling and non-nutritive suck and with a simple analgesic like panado or ibuprofen. Moderate and severe pain are treated with a strong opioid together with a simple analgesic and non-pharmacological measures.

The next step is to re-evaluate if the choice of analgesic has been sufficient and step up if needed. Re-evaluation is also vital to look for and manage any side effects that may occur.

Morphine and other opioids are titrated to analgesic dose with minimal acceptable and / or manageable side effects. No standard dose ceiling exists(2)

Known common side effects of opioids are, nausea and vomiting, constipation, sedation, euphoria, bradycardia and postural hypotension. An uncommon and yet notorious side effect is respiratory depression. However, this is dose related and rare if doses are titrated as is advised. Another common excuse for inadequate opioid use is fear of addiction. Tolerance is what happens when the body becomes accustomed to a particular dose, necessitating a higher dose to achieve the same effect. This is a physiological phenomenon which is not to be confused with dependence. Dependence is a behavioural and cognitive phenomena, inciting a strong desire to take the psychoactive drug, persistently using it despite harmful effects and prioritising its use above other activities and obligations(2)

Opioid withdrawal does occur with prolonged use if opioid analgesics are suddenly stopped. This is also a physiological phenomenon which need not be feared and is avoided by tapering doses(2)



(2)

Within the University of Witwatersrand Academic Hospitals, Rahima Moosa Mother and Child Hospital (RMMCH) is the only of the four main public hospitals with an established paediatric pain management team on call 24 hours a day. This service is rendered by the Department of Anaesthesia, and was started in September of 2016, with the introduction of a clinical guideline for paediatric pain assessment and management (Appendix 1).

The division of neonatology at the Chris Hani Baragwanath Academic Hospital (CHBAH) includes a section on “Sedation and Analgesia” and “Assessing Sedation and Analgesia needs” in

its neonatal guidelines (last updated in 2015). It includes both assessment and treatment, with doses provided. While the focus is on patients in the Neonatal Intensive Care Unit who are being ventilated or have undergone surgical procedures, the guidelines clearly outline a protocol that covers all neonatal patients adequately(8) (Appendix 2). The Paediatric Protocols guideline, published in 2016, does not have any guidelines for the assessment or management of pain(9)

The Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) does not have a paediatric guideline. Their neonatal guideline booklet, last updated 2016, has a section on sedation and analgesia. This section does not include how pain or agitation is to be evaluated (Appendix 3).

Some of the known barriers to appropriate pain management in paediatrics identified in the literature are: difficulties with accurate assessment and quantification of pain in children as they cannot self-report; lack of knowledge of how to treat pain well; the misconception that children, especially infants, lack the ability to feel or experience pain; the failure of health professionals to assess for pain at all; the misconception that pain management is difficult; and fear of side effects and addiction (10). Health professionals' personal beliefs and attitudes toward pain can also interfere with pain evaluation and management (11). Lastly, not using pain scores can result in pain being underestimated or overlooked entirely.

The cornerstone of managing pain well is recognising its existence and quantifying it in order to guide its treatment.

The gold standard for evaluating the presence and severity of pain is by self-report (12). This relies on intact verbal skills, and the cognitive development to understand the measurement of a pain experience and then communicate this using a continuum scale (13). A significant proportion of paediatric patients will lack the cognitive ability to use these scales meaningfully. This is either due to age, or because of neurodevelopmental disability. To address these challenges, behavioural observational scales have been developed. Below is a table taken from a systematic review of observational tools comparing utility of scales based on clinical condition (Appendix 3) (14)).

Not only are children able to experience pain, but they also suffer lasting consequences secondary to pain experiences. Links have been made between early pain experiences and neurodevelopmental abnormalities, heightened behavioural responses and an increased risk for anxiety-related psychiatric illness later in life (15,16). Acutely, the psychological consequences of unrelieved pain include anxiety, fear and sleep disturbances (11). Some of the physical/physiological effects are (11):

Rapid, shallow and splinted breathing which may cause hypoxia and alkalosis

Poor lung expansion and reluctance to cough causing retention of secretions and atelectasis

Increased heart rate and blood pressure secondary to pain increases cardiac oxygen demand which may contribute to cardiac ischaemia and morbidity

An increase in stress hormones like cortisol and adrenaline which increase metabolic demand and impede healing and immune function

Reduced gut and genitourinary motility leading to urine retention, ileus, nausea and/or vomiting.

Correct pain management has far reaching benefits for children, both in the short and long term. It should form part of basic patient evaluation and care. This study aims to begin to address the lack of epidemiological data on pain and its management in the South African context, particularly amongst the medical patients. This study could inform policy review and behavioural change within the University of the Witwatersrand's Department of Paediatrics.

2.0 AIM OF THE STUDY

Research Question:

To review the management of pain amongst medical paediatric patients under the age of twelve years at Rahima Moosa Mother and Child Hospital, a University of the Witwatersrand Academic institution.

3.0 OBJECTIVES OF THE STUDY

3.1 Primary objective

1. To determine the proportion of children who receive analgesia where indicated.

3.2 Secondary objectives

1. To determine the incidence of pain as part of the presenting complaint in paediatrics.
2. To determine the prevalence of pain amongst paediatric medical patients.
3. To determine if pain is evaluated and if such evaluation is documented.
4. To determine if pain is treated and how well it is treated.

4.0 RESEARCH ASSUMPTIONS:

The following definitions and abbreviations will be used in the documentation of the study.

CMJAH: Charlotte Maxeke Johannesburg Academic Hospital

CHBAH: Chris Hani Baragwanath Academic Hospital

Paediatric doctor: a paediatrician, registrar or medical officer who belongs to the Department of Paediatrics.

Minor: "Children under the age of 18 are legal minors and, accordingly, have limited legal capacity to act independently without the assistance of an adult." (13).

RMMCH: Rahima Moosa Mother and Child Hospital

WAHC: Wits Academic Hospital Complex

WHO: World Health Organisation

Wits: University of the Witwatersrand

5.0 DEMARCATION OF THE STUDY FIELD

The study will be carried out at the Rahima Moosa Mother and Child Hospital, one of the University of Witwatersrand three main academic hospitals.

6.0 ETHICAL CONSIDERATIONS

Ethical conduct when undertaking "Non-Therapeutic Research" on minors is governed by the National Health Act Section 71(3)(a)(ii). It stipulates that consent must be obtained from the Minster of Health for "Non Therapeutic Research" on minors (17). The Minister has now delegated this responsibility to grant ethical approval for all non-therapeutic research to registered Research Ethics Committees.

Therefore, Ethics approval will be acquired from the University of Witwatersrand Ethics Committee.

I believe that they will agree that this proposed research fulfils the stipulated prerequisites in the National Health Act.

Informed consent will be acquired from guardians prior to getting informed assent from minors between the ages of eight and twelve using the forms attached (Appendices 5 and 6).

Confidentiality will be maintained by not using names when capturing data.

7.0 RESEARCH METHODOLOGY

7.1 STUDY DESIGN

This will be conducted as a present prospective cross-sectional survey based on the methodology employed by the "Pain in hospitalized children: a prospective cross-sectional survey of pain prevalence, intensity, assessment and management in a Canadian paediatric teaching hospital." published in 2008. Data collection will take place once ethics and site-specific approval is acquired.

7.2 STUDY POPULATION

All medical patients under the age of twelve admitted to the general paediatric medical department at Rahima Moosa Mother and Child Hospital.

7.3 STUDY SAMPLE

All medical patients under the age of twelve admitted in paediatric wards at Rahima Moosa Mother and Child Hospital.

7.3.1 SAMPLE SIZE

The target sample size is 64 patients.

This was determined using the Fischer's Formula for Prevalence studies(18):

$$N = \frac{Z^2P(1-P)}{d^2}$$

$$N = \frac{1.96^2 \times 0.78 \times (1-0.78)}{0.10^2}$$

$$N = 64$$

Z = A constant determined by confidence interval (CI)

N = Sample size

P = Expected prevalence or proportion, i.e. 78% is 0.78

d = Precision

For a 95% confidence interval, Z is 1.96.

P was taken from the prevalence of pain as determined in the study "Prevalence severity and initial management of pain among children admitted in Kenyatta National Hospital general paediatric wards" (4). This study is selected because it is an African study and there are no South African Studies of pain prevalence amongst medical paediatric patients.

D, the precision was set at 10% or 0.10. The precision of 10% was selected for the following reasons: it falls within the accepted range of precision for descriptive epidemiological studies with a P (expected prevalence) value of 0.6 or more, and it accounts or adjusts for the scale of research possible of a Masters degree without compromising the quality the study.

7.3.2 SAMPLING METHOD

Non-probability convenience sampling will be used to select the study population. All patients admitted to the general paediatric medical wards at RMMCH at the time of data collection.

7.3.3. INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria:

All patients under the age of 12, admitted to the identified hospital's paediatric units at the time of data collection may be included.

Exclusion criteria:

1. Patients lodging/admitted in medical wards for surgical units or diagnoses.

7.4 DATA COLLECTION

7.4.1 DATA COLLECTION INSTRUMENT

Each participant will have data collected using a pain management and assessment audit form developed uniquely for this study (Appendix 7).

The tool is not based on any one tool from another study. Rather it was developed based on the information required to make meaningful conclusions about the state of pain management in our hospitals. It consists of a section for basic demographic data, a section for an interview of the patient or caregiver and a section for the analysis of the patient record or file. It is designed in English, however the language used when speaking to participants will be that which is most comfortable for the participant.

Assessment of pain at the time of the interview will be done using the revised FLACC score for children aged 2 months to 12 years (Appendix 8) and the Neonatal Infant Pain Scale (NIPS) for neonates up to 2 months of age (Appendix 9). Both scales are well validated to accurately determine pain severity and are selected for ease of use and because they are the tools recommended by the Clinical Guideline for Paediatric pain management at the Rahima Moosa Mother and Child Hospital.

7.4.2 DATA COLLECTION METHOD

Data collection will take place at the RMMCH in wards one, two and four, preferably on consecutive days, and will be done by the lead investigator (myself) and one research assistant. The time for evaluation of one patient with acquisition of consent is approximately 15min. This is based having piloted the process on a patient in the ward.

The research assistant is Dr Caolom Abrahams, currently an intern at CHBAH with interest in paediatrics. Participation is voluntary and there will be no payment.

The audit form may be completed electronically or on paper. Each participant's identity will be protected by assigning each participant a study number for identification.

7.5 DATA ANALYSIS

Primary outcome measure:

The prevalence of pain among medical inpatients at Rahima Moosa Mother and Child Hospital under the age of 12.

Secondary outcome measures:

1. The proportion of patients who received analgesia where indicated.
2. The incidence of pain as a part of the presenting complaint.
3. The prevalence of pain amongst paediatric medical patients
4. How often pain is evaluated and if documented in patient records.

Reporting of data

The assistance of a statistician will be sort for complete and accurate analysis of data where needed.

Microsoft Excel will be used for capturing of data.

A description of participants will be provided outlining eligible patients, number of patients approached, confirmed /included participants and reasons for not taking part.

Descriptive analysis will be used for the characteristics of study participants such as age, sex and diagnosis.

Epidemiological frequency measures will be used to describe prevalence of pain, the incident of pain as part of the presenting complaint and the proportion of patients who receive analgesia where indicated. Continuous variables which are normally distributed, will be described with means and standard deviations, and continuous non-parametric data will be described with median and interquantile range. Frequency and percentages will be used for categorical variables.

8.0 SIGNIFICANCE OF THE STUDY

Adequate pain management is an essential component of holistic patient care. Poor management of pain leaves any institution and health care practitioner lagging far behind the world's currently accepted minimum standards for adequate care. It subjects patients to unnecessary suffering with acute and chronic consequences. This study strives to offer the paediatric departments of the University of Witwatersrand an opportunity to improve pain management by describing the incidence and prevalence of pain, and the adequacy of its management currently. This study will also contribute to the currently lacking data on epidemiology of pain and its management amongst children treated in South African hospitals.

9.0 POTENTIAL LIMITATIONS

1. Having only two investigators collect data may lengthen the period of data collection.

2. A potentially long period of data collection may result in peer awareness of an upcoming audit within their unit, potentially eliciting change in behaviour which may skew results.

3. Precision of 10% used in sample size calculation may limit power of statistics and make inference of findings to the general paediatric population difficult.

10.0 PROJECTED OUTLINE

10.1 TIMEFRAME

	2017					2018							
	August	Sept	Oct	Nov	Dec	Jan	Feb	Mar	April	May	June	July	Aug
Protocol	X	X	X	X									
Submission to post-grad committee					X	X							

Application for institutional permission					x	x							
Submission for ethics Approval						x	x						
Data collection								x	x	x	x		
Data Analysis											x	x	
Write-up											x	x	X
Submission												x	X

10.2 BUDGET FOR THE STUDY

Total budget is estimated at R7390.

	Pages per document	**Number of units**	**Cost per unit in Rands**	**Total**
Printing of parental consent forms	6	220	0.50	660
Printing of minor assent forms	8	220	0.50	880
Printing of pain audit tool	2	220	0.5	220
Stapling into patient packs	16	220	0.50	110
Printing of research report	Estimated at 60	2	1.0	120
Binding of report	Estimated at 60	2	200	400
Statistician consult	N/A	1	5000	5000
			Total	**7390**

The cost of the study will be funded privately by the researcher.

10.3 PUBLICATION PLAN

The final report will first be submitted to the University of Witwatersrand post graduate research office for assessment. Thereafter, publication can be considered.

11. APPENDICES

Appendix 1

Clinical Guideline for Paediatric pain management. Rahima Moosa Mother and Child Hospital. Department of Anaesthesia.

Appendix 2

Neonatal protocols CHBAH:" Sedation and Analgesia" and "Assessing Sedation and Analgesia needs"

Appendix 3

Neonatal protocols CMJAH 2016/2017: Sedation and Analgesia

Appendix 4

"Scales recommended by intended context of measurement, with source, age of child for which each tool is intended, metric, rationale, and level of evidence" (12).

Appendix 5

Information letter and consent form for parents

Appendix 6

Information letter and assent form for child

Appendix 7

Data collection tool: The Pain Assessment and Management Audit sheet.

Appendix 8

Revised FLACC scale (18)

Appendix 9

NIPS score (17)

12.0 REFERENCES

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Appendix 1

CLINICAL GUIDELINE FOR PAEDIATRIC PAIN MANAGEMENT

RAHIMA MOOSA MOTHER & CHILD HOSPITAL

DEPARTMENT OF ANAESTHESIA

Compiled by: Dr Anisa Bhettay Date: 1 September 2016

Authorized by: Dr Thomas Kleyenstuber Date: 1 September 2016Authorized by: Mrs S Jordaan Date: 1 September 2016

Review date: 1 June 2018

CLINICAL GUIDELINE FOR PAEDIATRIC PAIN MANAGEMENT

RAHIMA MOOSA MOTHER & CHILD HOSPITAL

This clinical guideline aims to:

- Improve the management of pain in children by:
    - Reducing the time to administration of analgesia
    - Promoting safe administration of appropriate analgesia
    - Encouraging escalation of management where necessary

Key points to remember:

- Children are only able to verbalize ‘pain’ at 5 years, and their self-report is still unreliable.
- Know the pharmacokinetics and pharmacodynamics of the drugs that you are prescribing.
- The best route of administration is IV or Intranasal>PR>PO.
- Even if patients are being starved for theatre they can get oral analgesia.

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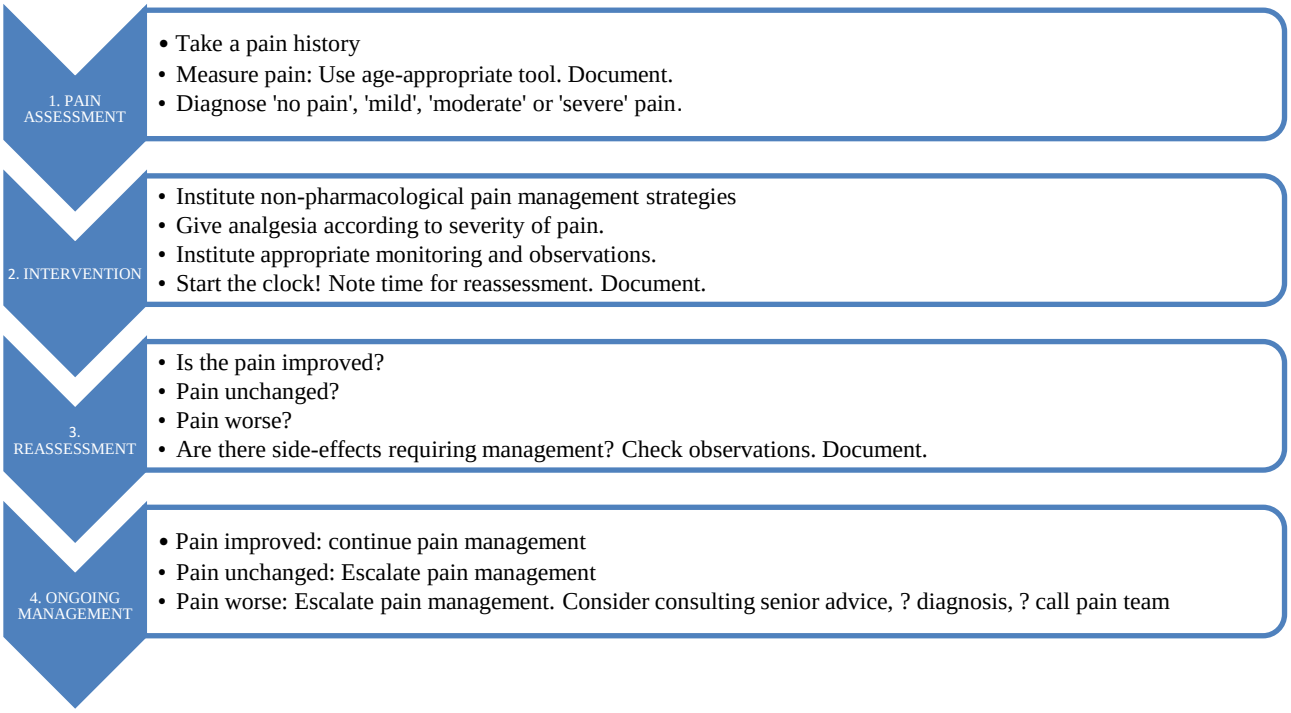


Non-pharmacological pain management strategies: physical & psychological

PHYSICAL:

- Neonates: swaddling, breastfeeding, sucrose, sucking
- Heat/cold
- Cuddling
- Immobilise/splint fractures
- Dress burns or bleeding wounds that may cause distress
- Child-friendly environment

PSYCHOLOGICAL:

- **Explanation –** explain what is happening, what is about to happen, and reassure child & parent
- Distraction – play, music, TV, reading

PAIN ASSESSMENT TOOLS:

- Use a pain assessment tool (see below) to diagnose no pain, mild, moderate or severe pain:

- 0 = NO PAIN
- 1 - 3 = MILD pain
- 4 - 7 = MODERATE pain
- 8 - 10 = SEVERE pain

- Once the assessment has been made, document the pain 'score' and initiate the appropriate level of treatment.

PAIN ASSESSMENT TOOL – BEHAVIOURAL: NIPS SCORE - NEONATES

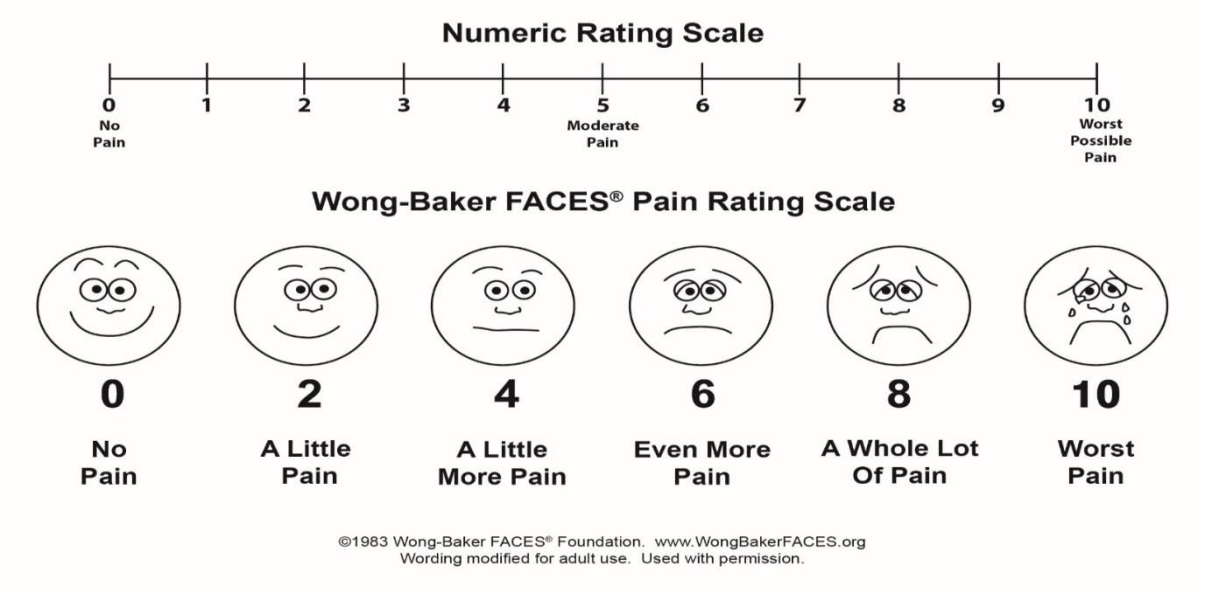
NEONATAL INFANT PAIN SCALE			
NPS	0 POINT	1 POINT	2 POINTS
FACIAL EXPRESSION	RELAXED	CONTRACTED	
CRY	ABSENT	MUMBLING	VIGOROUS
BREATHING	RELAXED	DIFFERENT THAN BASAL	
ARMS	RELAXED	FLEXED/STRETCHED	
LEGS	RELAXED	FLEXED/STRETCHED	
ALERTNESS	SLEEPING/CALM	UNCOMFORTABLE	

PAIN ASSESSMENT TOOL - BEHAVIOURAL: R- FLACC SCORE - 2 MONTHS OLD – 16 YEARS

	0	1	2
Face	No particular expression or smile	Occasional grimace/frown; withdrawn or disinterested [Appears sad or worried]	Consistent grimace or frown; frequent/constant quivering chin, clenched jaw [Distressed-looking face; expression of fright or panic]
Legs	Normal position or relaxed	Uneasy, restless, tense [Occasional tremors]	Kicking, or legs drawn up [Marked increase in spasticity, constant tremors or jerking]
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense [Mildly agitated (e.g., head back and forth, aggression); shallow, splinting respirations, intermittent sighs]	Arched, rigid, or jerking [Severe agitation head banging; shivering (not rigors); breath holding, gasping or sharp intake of breath; severe splinting]
Cry	No cry (awake or asleep)	Moans or whimpers, occasional complaint [Occasional verbal outburst or grunt]	Crying steadily, screams, or sobs; frequent complaints [Repeated outbursts, constant grunting]
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or "talking to"; distractible	Difficult to console or comfort [Pushing away caregiver, resisting care or comfort measures]

*Revised descriptors for children with disabilities shown in *brackets*.

PAIN ASSESSMENT TOOLS – SELF REPORT: > 7 YEARS OLD



PAIN MANAGEMENT ACCORDING TO SEVERITY: See below for dosing.

MANAGEMENT OF MILD PAIN:

- Non-pharmacological pain management strategies
- Simple analgesia: Paracetamol

  +/- NSAID: Ibuprofen

  Or Diclofenac

MANAGEMENT OF MODERATE PAIN:

- Non-pharmacological pain management strategies
- Simple analgesia: Paracetamol

  + NSAID: Ibuprofen

  Or Diclofenac
- **+** Opioid: S/L: Tilidine

  OR PO: Morphine syrup

  OR Intranasal: Fentanyl

  OR Tramadol IV

MANAGEMENT OF SEVERE PAIN:

- Non-pharmacological pain management strategies
- Simple analgesia: Paracetamol

  + NSAID: Ibuprofen

  Or Diclofenac
- **+** Opioid IV: Morphine

  OR Opioid Intranasally (no IV access): Fentanyl

AND ASK…?

- Is the pain ongoing or expected to last > 12 hours?
- Consider PCA or opioid infusion – call on-call pain anaesthetist.
- Consider calling on – call pain anaesthetist to provide regional anaesthesia where appropriate.

FORMULARY:

Sucrose 25%:

- Administer 0.2-0.5ml onto the front of the neonate/infant's tongue
- If using a pacifier, apply to the pacifier.
- Give 2 minutes prior to a painful procedure
- Analgesic effect lasts 5-8 minutes

Paracetamol:

- PO: 20mg/kg 4-6 hourly (max 90mg/kg/day)
- PR: 30mg/kg 6 hourly
- IV: Neonates or < 10kg – 10mg/kg 6 hourly

  Older – 15mg/kg 6 hourly

NSAIDs:

- Ibuprofen syrup: 7.5-10mg/kg 8 hourly (>3 months old)
- Diclofenac PR: 1mg/kg 8 hourly (>6 months old)

Opioids:

- Tilidine:
  - 1mg/kg/dose 4-6 hourly. 1 drop = 2.5mg
  - Weight / 2.5 = number of drops.
  - Decant dose into a syringe. Don't 'pour' into the child's mouth.
- Morphine:
  - Per Os: Morphine syrup 0.2-0.4mg/kg/dose 4-6 hourly.
  - IV: < 6 months old: Morphine 0.02mg/kg/dose
  - > 6 months old: 0.04mg/kg/dose
  - > 50kg: 2mg
  - Can be dosed at 0.1mg/kg BUT the safety of titration is lost
  - Titrate at 15 minute intervals until comfortable then dose 4-6 hourly.

- Intranasal Fentanyl:
    - 1st Dose: 1.5mcg/kg
    - 2nd Dose: 0.5mcg/kg after 10 minutes
    - Technique: Use 1ml syringe + MAD (Mucosal Atomiser Device)
    - The patient should be reclining at 45 degrees and the syringe should be held horizontally and the contents expelled into the nares in one rapid dose.
    - Do not ask patient to sniff.
    - Doses of 1 mL (50 micrograms) or more should be divided between nares.
    - Observe in Casualty for 20 minutes after dose.
    - Suitable for discharge one hour after dose if responding appropriately

- Tramadol:
    - IV: 1mg/kg 4-6 hourly

MONITORING:

- All patients receiving opiates MUST have the following monitored AND documented:
    - Heart rate
    - Oxygen saturation via CONTINUOUS saturation monitoring for 1st 15 minutes.
    - Respiratory Rate
    - Level of consciousness
    - Pain score
- Frequency of monitoring: Observe closely for 15 minutes after administering opioid dose. Then do observations every 30 mins for the 1st hour. Thereafter, observations can be documented 2 hourly.
- There must be a nurse available to respond to the monitor, initiate management and escalate care appropriately.
- Resuscitation equipment should be readily available, checked and in working order.

Appendix 2
To be attached as a PDF file

Appendix 3
To be attached as a PDF file

Appendix 4
To be attached as PDF file

Appendix 5

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

INFORMATION DOCUMENT AND INFORMED CONSENT FORM
For parents of children who are to participate in the study titled:

"Paediatric Pain Assessment and Management Survey within the Rahima Moosa Mother and Child Hospital."

Name of Principle Investigator: Dr Lindiwe Mabaso
Name of Organization: University of the Witwatersrand

This Informed Consent Form has two parts:

- Information Sheet (to share information about the study with you)
- Certificate of Consent (for signatures if you agree that your child may participate)

You will be given a copy of the full Informed Consent Form

Part 1: Information Sheet.

Greeting:

Kind greetings to you and thank you for your time.
I am Dr Lindiwe Mabaso. I am currently a registrar specializing in Paediatrics at the University of Witwatersrand. I am the principal investor for the above-named study.

Introduction:

I, Dr Lindiwe Mabaso am doing research on how well pain is assessed and managed in the paediatric units of the University of Witwatersrand.

Research is the process of in collecting information in a systematic way to answer a question.

In this study, we want to find out if pain is being looked for and treated by doctors and other health care providers when caring for patients in paediatrics

During this study, the investigator will not be interfering with patient care in any way. I am only observing what is already being done.

Invitation to participate:

I am asking you to please give me permission to include your child in this research study. Should you agree and give us signed consent, we will then explain the study to your child, if he or she is old enough to understand, in order to get their agreement as well (assent). We will only go ahead if both of you agree to take part.

Selection of Participants:

The aim is to evaluate as many children admitted in the children's wards as possible. There are no special characteristics about any child in particular that makes one more likely than another to be asked to take part.

What is involved in the study?

This study is a present prospective cross-sectional survey.

Should you (and your child if old enough to assent) kindly grant me permission for your child to take part, I will assess if they have any pain at the moment and grade the pain using a scoring system. Then I will be asking you or your child if they are old enough, a series of questions about their pain experiences, and finally look through their medical file to see if pain was looked for and or treated before.

I am the only investigator. I am a South African citizen and no one from another country will be taking part as an investigator.

I estimate that the whole process will take about 15 to 25min of your time.

The participant will be given pertinent information on the study while involved in the project and after the results are available.

Risks

There are no foreseeable risks to participating in this study.

Benefits:

There are no direct benefits to choosing to participate in this study. The study aims to improve pain management in the future. So, the potential benefits are in the long-term improvement of care provided to children.

Alternative:

There are no alternative treatments or procedures as this study will not involve treatments or procedures. The study involves an interview and patient record review.

Participation is voluntary:

Should you choose not to take part in this study, there will be no penalty or loss of treatment for your child. You may also change your mind about taking part in the study at any time during the interview. All that is required is for you to inform the investigator and for your withdrawal of participation be recorded on the consent form and data collection form.

Any new findings acquired during the research which may affect any future participant's willingness to take part will be communicated during the process of acquiring consent.

Reimbursements:

There is no reimbursement offered for participating in this study.

Confidentiality:

All reasonable efforts will be made to keep personal information confidential. Only members of the research team will have access to any information we gather. Your child will be identified using a participant number. Therefore, all personal information cannot be traced back to your child's name. Once the study is done and all our findings have been analysed, our conclusions may be published in medical journals. This information will hopefully help institutions that care for children to improve their service.

Absolute confidentiality cannot be guaranteed. Personal information may be disclosed if required by law. There are organizations like the University of Witwatersrand Research Committee, which may inspect research records for quality assurance. If the results of the study are published, this may lead to individual identification.

Contact details of researcher/s:

For further information / reporting of study related adverse events.

Dr Lindiwe Mabaso
07814400124
Lmnmabaso11@gmail.com

Contact details of REC administrator and chair – for reporting of complaints / problems.

Ms. Zanele Ndlovu zanele.ndlovu@wits.ac.za – 011 717 1252/2700/1234/2656

Part 2: Certificate of Consent

I have read the information about the study, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.

Print Name of Parent or Guardian _____
Signature of Parent of Guardian _____
Date _____
Day/month/year

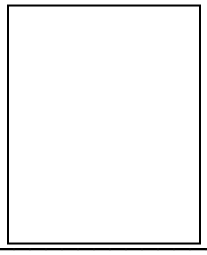
If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness: _____ ***Signature of witness:*** _____

AND

Thumb print of participant:



***Date*:** _____
Day/month/year

Statement by the researcher/person taking consent:

I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the following will be done:

1. An evaluation will be done using a pain scoring chart will be done to see if the child is experiencing pain at the time of the interview and if so how severe it is.

2. An interview will be conducted with the parent/guardian, or with the child if he or she is old enough to understand.

3. The child's file will be reviewed to determine if pain was previously assessed for and if it was treated.

I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

The research team reserves the right to terminate participation at any point should the need arise. Other than sudden deterioration in clinical condition of a participant requiring urgent care during the collection of data, there are few foreseeable circumstances that would necessitate this. Should this happen, the reasons for termination of data collection will be communicated by the data collector to the guardian.

A copy of this Informed Consent Form has been provided to the parent or guardian of the participant.
Print Name of Researcher/person taking the consent: _____

Signature of researcher: _____
Date: _____
Day/month/year

An Informed Assent Form will ____ OR will not ____ be completed.

Appendix 6

Informed Assent Form for children aged 8 to 12 years who are invited to participate in the study:

"Pain Assessment and Management Survey within the University of Witwatersrand Academic Hospitals"

Hello. I am Dr Lindiwe Mabaso. I am a doctor working in the children's wards. I am trying to find out something about the care provided for you in the hospital.

I am doing research on how well pain is looked for and how well it is taken care of in the children's wards. During this study, I will not be changing how the doctors are helping you for your sickness.

I am going to explain my research to you and invite you to take part. If you do not understand anything written in this form or that I say, please feel free to ask me at any time.

I want to find out if pain is being looked for enough when children, like yourself, are being helped in hospital. I also want to see if something is being done for pain when it is there. I am asking you to please give me permission to include you in this research study.

If you say yes to the study, I will check if you have pain now. Then I will ask you some questions. The last step is for me to look at your patient file to see what was done for your pain if you had any. I think that this will take about 15 to 20 minutes.

You will not get anything for taking part in the study. We hope to use the information we find to make us better at taking care of children. You can also change your mind at any time.

I will not tell anyone that you took part in this research. Also, the information we get from you will not be given to anyone who is not part of this research team.

If you would like to find out the results of this research, we can provide an explanation to you and your parent when we are finished.

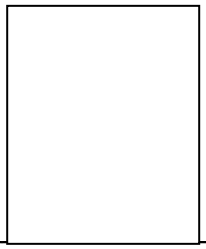
If you have questions, please ask me. If you want to ask me questions later, you can call me at: Dr Lindiwe Mabaso: 078 1440 124

If you agree to take part in the research, please sign here:

Print name of child: _____

Signature of child: _____ **Date:** _____

Print name of witness (not a parent): _____ **Signature of witness:** _____
AND
Thumb print of participant



Date: _____

Day/month/year

Appendix 7
See appendix 1 of main article

Appendix 8
To be attached as PDF file

Appendix 9
To be attached as PDF file