Vitamin A Supplementation in children aged 12 to 59 months in Amajuba Health District in 2016.

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SOUTH AFRICA

Submitted in partial fulfilment of the academic requirements for the degree:

Master of Public Health in the Discipline of Public Health Medicine,

School of Nursing and Public Health

University of KwaZulu-Natal.

The dissertation contributes 50% of the MPH qualification

This dissertation is presented in the

The Journal Article Manuscript Format

BY

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Dates and Registration Number with Research Ethics Committee: 19 January 2016 BE 368/15

Date of Current Version of Dissertation: 29 March 2017

ABSTRACT

Background:

Vitamin A is required for normal development, defence of the immune system and for maintaining good eye health in infants and children. Vitamin A deficiency is a major public health problem globally and in South Africa. Routine supplementation with high-dose Vitamin A has been a strategy employed to reduce the burden of Vitamin A deficiency in children aged from six to 59 months. Coverage of vitamin A supplementation (VAS) however remains low in older children in South Africa particularly in Amajuba Health District.

Objectives:

The objectives of this study were to measure VAS coverage and factors associated with poor VAS uptake in this District.

Methods

An analytic cross sectional study design was used. A two-stage cluster-sample method was used to select the participants. The study population involved mothers and caregivers of children aged 12 to 59 months residing in Madadeni, a township in the District. The study sample of 198 participants was obtained from 33 randomly selected clusters within each of which 6 households were approached. Data was collected using a field-worker administered structured questionnaire. The study received ethical approval (BE 368/15) and was conducted with participant's consent.

Results

The coverage of VAS amongst these children was 57% (95% CI: 49 - 63). Younger children (18 to 23 months) had better (Prevalence Ratio (PR) 1.2 (95% CI: 0.8 - 1.6) coverage than older children. Children who were up to date with VAS coverage were significantly more likely to have received a measles vaccine ($p<0.01$). A significant association was found between VAS status of children and caregivers being able to identify the blue capsules as the 6 to 11-month dose and the red capsules as the 12 to 59-month Vitamin dose capsule. There was a non-

significant but positive association of a child having received VAS and higher level of education of the caregivers, shorter distance from health facilities, living in an urban area and having received information about VAS from a health worker

Conclusion and Recommendations

Amajuba Health District had a VAS coverage of 57%, which is below the national target of 65%. The low levels of knowledge about Vitamin A among caregivers is a concern, despite knowledge being weakly associated with VAS uptake in children. Health workers need to provide better education for caregivers about Vitamin A. Focus should also be placed on accessing older children as they are more likely miss VAS doses. (385 words)

Dissertation Format:

This dissertation is presented in the Journal Article Manuscript Format approved by the University of KwaZulu-Natal. In place of presenting a 'Results' chapter, a Journal Article Manuscript, ready for submission to the South African Medical Journal for peer review is presented

DECLARATION

I ...Mbalenhle Luthando Mdlalose..... declare that

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ACKNOWLEDGEMENTS

I would like to thank my supervisor Dr Stephen Knight for his guidance and his continuous support and encouragement during every stage of my research. I would like to thank the research assistants who gave of their time to assist me. I would also like to thank all the participants of this research who welcomed myself and the research assistants into their homes and agreed to answer our questions. I would also like to thank the UKZN CHS Masters scholarship department for providing funding for the running expenses of this research.

ACRONYMS AND ABBREVIATIONS

BREC	Biomedical Research Ethics Committee
CI	Confidence Interval
DHS	District Health System
EPI	Expanded Programme on Immunization
ECD	Early Childhood Development Centres
IMCI	Integrated Management of Childhood Illness
IU	International Units
MDG	Millennium Development Goal
MICS	Multiple Indicator Cluster Surveys
PHC	Primary Health Care
PHREC	Provincial Health Research & Ethics Committee
UNICEF	United Nations Children's Fund
VAD	Vitamin A deficiency
VAS	Vitamin A supplementation
WHO	World Health Organization

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1 CHAPTER I: INTRODUCTION

1.1 BACKGROUND

In this introductory chapter, a background on the state of vitamin A deficiency globally and in South Africa is presented along with the state of vitamin A supplementation in South Africa and more specifically in Amajuba Health District. This chapter presents a picture of what is known so far about Vitamin A supplementation coverage and what still needs to be known. This then leads us to the purpose and importance of the current study; a statement of a problem and how this study will solve this problem.

1.1.1 What is known so far?

Vitamin A is an important nutrient required for normal growth and development of infants and children, for integrity of the immune system and for good eye health. [(1)] Vitamin A is a fat-soluble substance. Vitamin A is made up of the building blocks retinol, retinaldehyde and retinoic acid. There are two forms of vitamin A, preformed (animal sources) and provitamin A (plant sources). Children normally get vitamin A from food sources such as breastmilk, green leafy vegetables, yellow and orange fruits and vegetables, eggs, cheese and liver. Signs of vitamin A deficiency include xerophthalmia, anaemia and growth retardation. Vitamin A deficiency is most common in young children, particularly pre-school aged children. Young children are more susceptible to the deficiency because they are more prone to dietary deprivation either through poor breastfeeding or weaning practices. Young children are also more susceptible to diarrhoea, common infections and malnutrition which are all risk factors for VAD[(2)]. Vitamin A deficiency (VAD) is a major public health problem, worldwide, but also in South Africa with many children being affected. [(3)] Vitamin A supplementation (VAS) is one of strategies employed by the South African Department of Health to reduce VAD, thus improving child health and moving towards achieving sustainable development goal 3 which is about ensuring healthy lives and promoting well-being for all ages. [(4, 5)] Coverage of routine VAS tends to be higher among the younger age groups (6 to 11 months) in comparison to the older age groups (12 to 60 months)[(6)], mainly due to children in the older age group accessing health services less often.[(7)] The current national coverage of VAS at 52% is below the national target of 65%. [(7)] Amajuba Health District is also one of districts which is underperforming and is below the national target of 65% as

well as the national average of 52%.[7] Current information on national, provincial and district coverage of VAS is based on administrative measures of coverage; that is; it is based on tally sheet data collected at points of service where vaccines and VAS is administered. [8] Other strategies to improve VAS status include the food-based interventions through the promotion of dietary diversification which can target infants, young children and lactating mothers. This involves encouraging the consumption of vitamin A rich foods and establishing food gardens. Food fortification is also a strategy to improve VAS status.[9] Recommendations on the use of VAS in children aged 6 to 59 months arose from two WHO technical consultations to review scientific evidence for the reduction of child morbidity and mortality. This consultative group consisted of 46 experts including ministries of health, Food and Nutrition Research Institute. VAS guidelines were developed based on two Cochrane systematic reviews looking at the effect and safety of VAS in children.[2]

1.1.2 What needs to be known?

As coverage is routinely measured at Health District level by administrative means, community-based measures of coverage need to be explored, which will allow us to compare VAS coverage estimates determined using both measures. The knowledge, attitudes and practices of caregivers of children from different age groups about VAD and VAS also need to be known so that we may be able to determine whether these are associated with children either receiving or not receiving vitamin A.

1.1.3 What is the importance of this study?

Investigating the problem of low VAS coverage is important because low coverage can lead to increased prevalence of vitamin A deficiency in children; leading to increased child morbidity and mortality. [1]Understanding why some children have not had VAS could help influence policy and practice of this component of the Expanded Programme on Immunization. The main importance of this study is that it will be a step towards improving vitamin A status and coverage in the study area.

1.1.4 How the study will solve the problem?

The study investigated VAS coverage and possible causes of low coverage in Amajuba Health District by comparing characteristics of caregivers of children who are up to date in receiving Vitamin A doses

with children who are not. Through identifying factors which possibly contribute to not receiving Vitamin A, it allows for better planning of interventions and for programme enhancement .[1]

1.2 STATEMENT OF THE PROBLEM

The problem at hand is the low coverage of Vitamin A supplementation in children aged from 12 to 59 months despite the health service being freely available at all primary health care facilities in South Africa. Coverage is stated as 'being low' based on Amajuba Health district coverage being below the national and provincial targets.

1.2.1 Research Hypothesis

The null hypothesis of this study is that there is no difference between the demographic and other characteristics of mothers and caregivers of children who are up to date in receiving VAS and those of children who are found not to be up to date in receiving VAS.

1.2.2 Research Questions

This study aims to answer the following research questions:

- What is the coverage of VAS among children aged 12 to 59 months in Amajuba Health District in 2016?
- Is there an association between VAS status in children aged 12 to 59 months and caregiver and child characteristics such as age, race, area of household, education level, income level, access to media and information, knowledge on Vitamin A, immunization status?

1.3 PURPOSE OF THE RESEARCH

The purpose of this research is to find possible ways to improve vitamin A status and coverage in Amajuba Health District and to investigate the reasons for low uptake of Vitamin A supplementation in children aged 12 to 59 months in 2016, in order to inform policy and practice.

1.4 SPECIFIC OBJECTIVES

The specific objectives of this research were:

- To measure coverage of Vitamin A supplementation in Amajuba Health District; and
- To compare the characteristics of children who are up to date with VAS with those who are not up to date with receiving VAS and identify associations.

1.5 OPERATIONAL DEFINITIONS USED IN THE STUDY

Children who are **up to date** in receiving VAS in this study refers to children who are found to have received a dose of VAS within the previous six months and children who are **not up to date** are defined as those children who have not received a dose of VAS within the previous six months. **Vitamin A status** is also used to refer to this concept in this report.

Routine Vitamin A supplementation coverage: Proportion of children aged 12 to 59 months receiving at least one dose of Vitamin A capsule (100 000IU if 0 to 11 months) or 200 000IU (if between 12 to 60 months) in the past six months.

Household: A household is a group of persons who live together and provide themselves jointly with food and/or other essentials for living, or a single person who lives alone.[10]

Urban: A classification based on dominant settlement type and land use. Cities, towns, townships, suburbs, etc., are typical urban settlements. Enumeration areas comprising informal settlements, hostels, institutions, industrial and recreational areas, and smallholdings within or adjacent to any formal urban settlement are classified as urban. A formal urban settlement is structured and organised. Land parcels (plots or erven) make up a formal and permanent structure. A local council or district council controls development in these areas. Services such as water, electricity and refuse removal are provided roads are formally planned and maintained by the council. This category includes suburbs and townships.[10]

Rural: Any area that is not classified urban. Rural areas are subdivided into tribal areas and commercial farms.

FORMAT OF THIS DISSERTATION

The following chapters are included in this report, which is presented in the Journal Article Manuscript format

Chapter 1: Includes an introduction to the report, laying out the research topic at hand, a problem statement is presented as well as the purpose and objectives of the study.

Chapter 2: Includes a review of the literature focusing on vitamin A supplementation, vitamin A deficiency, vitamin A supplementation coverage nationally, provincially and at district level, it also explores methods previously used to measure VAS coverage as well as barriers to VAS.

Chapter 3: Journal article manuscript

Chapter 4: Additional findings, discussion and limitations, presenting a synthesis of findings and expanding on limitations in the study.

1.6 SUMMARY OF CHAPTER

This chapter provided a statement of the problem, which was low VAS coverage in the 12 to 59 month age group. The chapter also presented what is currently known about VAS, which included the health benefits of vitamin A, the status of VAS coverage in South Africa and in Amajuba Health District. The chapter also outlined what still needs to be known, namely community-based estimates of VAS coverage and caregiver knowledge, attitudes and practices. This chapter provided a background upon which this research is based.

2 CHAPTER II: LITERATURE REVIEW

2.1 INTRODUCTION

In this literature review, the burden of VAD is reviewed both globally and in South Africa, along with its consequences. The various strategies which are implemented in order to reduce VAD are visited in this review. Focus is then drawn on one of these strategies; that being VAS; which is the focus of this study. More specifically, the vitamin A supplementation program of the South African Department of Health is defined and reviewed. Furthermore, various methods of measuring coverage of VAS are explored, including administrative-based methods and population-based surveys. In addition, the two-stage cluster sampling method in measuring coverage is also explored. Finally, the literature review looks at barriers to VAS programs as reported by various studies which have also explored VAS.

2.2 SCOPE OF LITERATURE REVIEW

The literature for this research was acquired through various sources including electronic journals, web references and government documents. Search terms included words such as: “vitamin A deficiency, vitamin A supplementation in children, vitamin A supplementation coverage in South Africa, in Amajuba Health District, causes of low vitamin A supplementation coverage, methods for measuring immunisation coverage”

2.3 LITERATURE REVIEWED

2.3.1 Vitamin A deficiency

Vitamin A deficiency, according to the World Health Organization (WHO), is globally a significant public health issue in 96 countries. [(3)] A reported 190 million (95% Confidence Interval (CI): 170 - 202) or 33% of preschool children are estimated to have VAD (serum retinol <20µg/Dl).[(11)]; which is particularly a significant public health issue in many middle-income countries, including South Africa. [(4)] The South African National Food Consumption Survey reported in 2005, that the prevalence of VAD in children aged 1 to 9 years was 63.6%, based on a survey sample of 3120 children. [(4)] The South African National Health and Nutrition Examination Survey (SANHANES) more recently in 2013 reported that the national VAD prevalence for South Africa was (43.6% 95% CI: 36 - 51) for

children under the age of five years. [12] Data from the South African Vitamin A Consultative Group (SAVACG) reported a VAD prevalence of 34% in the year 2000 for children under 4 years.[13] The SANHANES and SAVACG studies assessed VAD within different but close age groups and looking at the data reported between 2000 and 2013, it appears there has hardly been a reduction in VAD prevalence in SA.VAD prevalence in SA is still a significant public health issue because according to the WHO, a country is considered to have a significant public health problem of VAD if the prevalence is higher than 20%. [12] This can have dire consequences on the health of the individual as discussed in the next section.

2.3.2 Consequences of Vitamin A deficiency

Vitamin A is a crucial nutrient for normal growth and development, for a strengthened immune system and for eye health.[14] Vitamin A deficiency is the consequence of diets which are insufficient in vitamin A, leading to low body stores of the micronutrient. This deficiency can lead to compromised physiological functions such as tissue growth and resistance to infections.[15] Thus, children with VAD have increased vulnerability to childhood illnesses and infections including measles and diarrhoeal diseases, and are at an increased risk of developing nyctalopia (night blindness).[3] More severe VAD is a risk for xerophthalmia and blindness. [14] The WHO estimates VAD contributes to 6% of under-five child deaths in Africa [16], while VAS can lead to a 23% reduction in all-cause mortality among children.[4] Strategies thus need to be in place to reduce the burden of VAD.

2.3.3 Strategies to reduce the burden of Vitamin A deficiency

There are a number of approaches which are implemented in different countries to reduce the burden of VAD.[3] Such approaches include the promotion of breastfeeding, food fortification, improving dietary behaviour as well as VAS.[3] Of these interventions, routine supplementation with high dose vitamin A capsules has been shown to be the highest-impact intervention and is cost-effective.[3] Vitamin A supplementation for children aged 6 to 59 months can contribute to reducing child morbidity and mortality, thus moving towards achieving moving towards achieving sustainable development goal number 3 which is about ensuring healthy lives and promoting well-being for all ages, in countries where VAD is a significant public health concern.[5, 17]

2.3.4 Vitamin A supplementation programme in South Africa Measuring Vitamin A coverage

VAS is indeed one of strategies which have been adopted by South African Department of Health with the aim of preventing VAD.[4] The VAS program was first introduced in South Africa in 2001.[4] In South Africa, vitamin A is given routinely to children aged 6 to 59 months, every 6 months, the first dose given at 6 months of age.[3] A dose of 100 000IU (blue capsule) is given to children aged 6 to 11 months and a dose of 200 000IU (red capsule) is given to children aged 12 to 59 months.[3] The VAS program in South Africa is primarily delivered through health facilities together with the EPI and IMCI programmes.[4]

The indicator for VAS coverage as defined by UNICEF is the percentage of children aged six to 59 months who have received two age appropriate VAS capsules at six month intervals in the past 12 months.[11] The denominator is multiplied by 2 as children routinely should receive 2 doses annually.[4] The integration of the VAS program with other child health services such as EPI has been found to be very successful in achieving good coverage in children under the age of one year but has been less successful in achieving the same coverage among the 12 to 59 month age group.[18] This can mainly be attributed to reduced clinic attendance of children after 18 months of age where the immunization schedule stops until children reach the age of five years.[18] As a strategy to address this issue, ward based outreach teams have been deployed to administer vitamin A supplementation at household and community level.[7] Despite this effort, South Africa is among many countries which face challenges with regard to achieving good Vitamin A coverage among the 12 to 59 month age group.[19]

The United Nations Children's Fund (UNICEF) reported global coverage of VAS in 2011 was 75% for children receiving at least two VAS doses annually. [20]Although national coverage has been increasing steadily over the past decade from 12.8% in 2004/05 to 44% in 2013/14, which was still below the then national target of 60% in 2013/14.[19] National VAS coverage further improved to 52% in 2014/2015, which was still below the new national target of 55% for 2014/2015.[7] KwaZulu-Natal has improved from a VAS coverage of 49% in 2013/2014 to 55% in 2014/2015.[7] Amajuba Health District which is the setting of the proposed study is one of districts in South Africa with the lowest Vitamin A 12 to 59

months coverage which was a low 35% in 2013/14 and improved to 50% in 2014/2015.[7, 19] Coverage for 2015/16 in Amajuba District is 54% and is still below the national target of 65%.[1]

2.3.5 Barriers to achieving good Vitamin A supplementation coverage

A number of studies have been conducted with the aim of identifying possible challenges and barriers to achieving optimal Vitamin A coverage. One such study was a cross sectional study conducted in Nepal which sought to identify demographic and other differences between children aged 12 to 59 months who received vitamin A and those who did not receive vitamin A.[1] This was a countrywide survey involving a sample of 4013 children.[1] This particular study was based on data already collected during the 2011 Nepal Demographic and Health Surveys and Vitamin A was not the primary information being collected.[1] This study reported a strong association between children not receiving a dose of vitamin A in the previous 6 months and lower levels of education in mothers as well as living in a rural area.[1] For instance children with mothers who had less than a year of education had higher odds ratios of not receiving vitamin A (OR 1.7; 95% CI: 1.0 -2.7) compared to children who had mothers with higher levels of education.[1] Odds of not receiving vitamin A also decreased with increasing levels of education.[1] The odds ratio of children not receiving vitamin A was higher in rural areas (OR 1.7; 95% CI: 1.2-2.6) than in urban areas.[1]

Slightly differing findings were reported in a similar cross sectional study conducted in Tanzania in 2013.[21] This study had a sample of 1203 children aged 6 to 59 months.[21] In this study it was reported that children living in rural areas had significantly higher odds ratio (OR 3.3; 95% CI: 1.5-7.0)of receiving vitamin A than those children living in urban areas.[21] No significant relation was found between maternal education and receipt of vitamin A by children in this study.[21] In addition, this study

[1] Data from district health information system 2015/16

reported that children with more siblings had higher odds of receiving vitamin A than children with no siblings. [21]

Another cross sectional study was conducted in India in 2013 , which was based on existing data from India's National Family Health Survey conducted between 2005 and 2006.[14] This was a cross sectional survey involving a sample of 20 802 children aged between 12 and 35 months.[14]This study reported increased likelihood of vitamin A receipt in children with mothers who had higher levels of education (OR 2.4; 95% CI: 2.0-2.8), higher income and socio-economic status.[14] The study found higher levels of vitamin A receipt in rural than urban areas in an adjusted logistic regression model (OR 1.2; 95% CI: 1.1-1.3) (14). It was also found that younger children (12 to 23 months) were more likely to receive vitamin A than older children (24 to 35 months).[14] A positive association between children receiving vitamin A and a higher level (more than 10 years) of maternal education (Prevalence Ratio 1.1, 95% CI 1.0-1.1) was also found in a 2010 cross sectional study.[22] The study was based on a national survey conducted in Bangladesh in 2004 on a sample of 3745 children aged 18 to 59 months.

On a different perspective, a South African study conducted in 2011 investigated the opinions and knowledge of mothers of small children on the VAS program at primary health clinics as well as the opinions of staff members at these clinics.[23] The study was conducted in the Western Cape Province of South Africa; in the rural Overberg District Municipality and the urban Cape Town Metropolitan Municipality.[23] A total sample of 176 mothers of children below the age of five years were interviewed.[23] In this study, it was found that a higher proportion of children in living in rural areas had received vitamin A than children living in urban areas.[23] It was also reported that a relatively low proportion of mothers who were part of the study had knowledge of why their children were receiving vitamin A and an even smaller proportion had been given written information on vitamin A.[23] Missed opportunities for vitamin A supplementation were also identified at primary health clinics in this study. [23] Challenges which were brought up by staff members who were interviewed in the study included shortage of vitamin A Capsules and insufficient staff training on the Vitamin A program.[23]

Similar findings were reported by another South African study with a similar design. In this study conducted in 2007 by in the Boland area of the Western Cape; missed opportunities for VAS were also reported.[24] Low levels of maternal knowledge on vitamin A were also reported by this study. In this

study, unavailability of vitamin A capsules at facilities was reported as a barrier to implementation but staff training was not reported as a barrier.[24] Both of the latter studies may have some limitations of having small sample sizes as well as being prone to selection bias due to only looking at those children who attended primary health clinics. However, they do provide some valid suggestions of possible challenges which may contribute to lower than optimal vitamin A coverage.

2.3.6 Two-stage cluster sampling

The common way of estimating VAS coverage is through the administrative process of reviewing tally sheets at points of administration which generate data on supplementation.[8] The advantage of this method is that it is simple and time-efficient. This method has shortcomings as it may be characterized by human error in recording or incorrect calculations.[8] The quality of such data is often influenced by the quality of a country's health information system.[18]

Population-based surveys provide another method of measuring vitamin A supplementation coverage.[18] This is when data on VAS coverage is collected from country-wide surveys, for example, from demographic and health surveys.[18] These surveys can be useful in verifying tally sheet coverage estimates but have a limitation of being prone to recall bias.[18]

Another method of measuring coverage is through post-event coverage surveys.[8] These are conducted at household level with caregivers of children aged 6 to 59 months.[8] This method may be used to estimate VAS coverage, verifying it against tally sheet data, and can also be used as an opportunity to gather data on enablers and obstacles to high coverage.[8] Through these surveys, knowledge of caregivers and health care workers on the VAS program can be assessed.[8] The strength of these surveys is a reduction in recall bias, since they are usually conducted a short while after vitamin A campaigns or activities.[8] During such surveys, caregivers are usually shown vitamin A capsules to facilitate memory and to avoid confusion with other interventions.[8] Post-event coverage surveys can serve as a useful way of balancing out inconsistencies which may be inherent in tally sheet reports.[8] Such surveys can be conducted using the standard WHO EPI cluster sampling methodology.[8]

2.4 SUMMARY OF CHAPTER

The importance of vitamin A and the consequences of its deficiency were described in this literature review. Two-stage cluster sampling was highlighted as a highly effective method of measuring coverage. It is apparent from this literature review that there are a number of common themes suggested by different studies in terms of barriers to children receiving VAS. These include education levels of caregivers, whether caregivers live in rural or urban setting, and income levels of caregivers as well as knowledge levels on vitamin A. Further research is needed to establish whether similar patterns are seen in the South African context, and more specifically, in the context of Amajuba Health District. Health system factors which may influence VAS coverage according to cited literature includes shortage of vitamin A capsules, missed opportunities for VAS at clinics as well as lack of training of health care workers.

3 CHAPTER III: JOURNAL ARTICLE MANUSCRIPT

In this chapter, I am presenting a Journal Article Manuscript which describes the new research that I completed as part of my Master of Public Health degree at the University of KwaZulu-Natal. I have prepared the article to be submitted to the South African Medical Journal. In the appendices (Annexure E) I have included a summary of the Instructions to Authors for this journal. The type of article is an original research article and should be between 3000 and 4000 words. Although this article has not yet been published, it should be ready to be sent off to the editors for peer review.

I have numbered the lines to assist you if you have comments to make. I have included the Tables and Figures where I think they could be included in the final published article – as opposed to being submitted separately as required by the editors.

There are some additional results, discussion and limitations, which were not included in the article in Chapter 4 of this dissertation.

Title page:

Full Title: Vitamin A Supplementation in children aged 12 to 59 months in Amajuba Health District in 2016.

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Biography

Mbalenhle Luthando Mdlalose is an MPH student in the discipline of Public Health Medicine; she is a registered Nutritionist with experience in community nutrition and working at primary health care level.

Word count:

Abstract

Background:

Vitamin A is required for normal development, defence of the immune system and for maintaining good eye health in infants and children. Vitamin A deficiency is a major public health problem globally and in South Africa. Routine supplementation with high-dose Vitamin A has been a strategy employed to reduce the burden of Vitamin A deficiency in children aged from six to 59 months. Coverage of vitamin A supplementation (VAS) however remains low in older children in South Africa particularly in Amajuba Health District.

Objectives:

The objectives of this study are to measure VAS coverage and factors associated with poor VAS uptake in this District.

Methods

An analytic cross sectional study design was used. A two-stage cluster-sample method was used to select the participants. The study population involved mothers and caregivers of children aged 12 to 59 months residing in Madadeni, a township in the District. The study sample of 198 comprised six participants from 33 randomly selected clusters. Data was collected using a field-worker administered structured questionnaire. The study received ethical approval (BE 368/15) and was conducted with participant's consent.

Results

The coverage of VAS amongst these children was 57% (95% CI: 49 - 63). Younger children (18 to 23 months) had better (Prevalence Ratio (PR) 1.2 (95% CI: 0.8 - 1.6) coverage than older children. Children who were up to date with VAS coverage were significantly more likely to have received a measles vaccine ($p<0.01$). A significant association was found between VAS status of children and caregivers being able to identify the blue capsules as the 6 to 11-month dose and the red capsules as the 12 to 59-month Vitamin dose capsule. There was a non-significant but positive association of a child having received VAS and higher level of education of the caregivers, shorter distance from health facilities, living in an urban area and having received information about VAS from a health worker.

Conclusion and Recommendations

Amajuba Health District had a VAS coverage of 57% which is below the national target of 65%. The low levels of knowledge about Vitamin A among caregivers is a concern, despite knowledge being weakly associated with VAS uptake in children. Health workers need to provide better education for caregivers about Vitamin A. Focus should also be placed on the caregivers of older children as they are more likely miss VAS doses.

Word count: 385 words

Key words: Community-based coverage survey; South Africa;

Introduction

Vitamin A is an important nutrient required for normal growth and development of infants and children, for integrity of the immune system and for good eye health. [1] Vitamin A deficiency (VAD) is a major public health problem, worldwide, but also in many middle-income countries, including South Africa (SA) with many children being affected. [2] According to the World Health Organisation (WHO), a country with a VAD prevalence of greater than 20% has a public health problem that can impact child health. [3] Globally it is estimated that 190 million (95% Confidence Interval (CI): 170 - 202) or 33% of preschool children are estimated to have VAD (serum retinol <20µg/Dl). [4] [5] The South African National Food Consumption Survey (NFCS) in 2005 reported that the prevalence of VAD in children aged 1 to 9 years was 64% in a representative sample of 3120 children. [5] The prevalence of VAD reported in the 2013 South African National Health and Nutrition Examination Survey (SANHANES) was 44% (95% CI: 36 - 51) for children under the age of five years. [3] Data from the South African Vitamin A Consultative Group (SAVACG) reported a VAD prevalence of 34% in the year 2000 for children under 4 years. [6]

Vitamin A is a crucial nutrient for normal growth and development, for a strengthened immune system and for eye health. [7] Thus, children with VAD have increased vulnerability to childhood illnesses and infections including measles and diarrhoeal diseases. One of the earliest signs of VAD is nyctalopia (night blindness). More severe VAD is a risk for xerophthalmia and blindness. [7] Globally, in 2013, it was estimated that 4 million children under the age of 5 years were affected by xerophthalmia. [7] The WHO estimates VAD contributes to 6% of under-five child deaths in Africa [8], while vitamin A supplementation (VAS) can lead to a 23% reduction in all-cause mortality among children. [5] Strategies thus need to be in place to reduce the burden of VAD.

Globally, advocacy initiatives to implement VAS in many countries as a strategy to improve child survival began in 1997. [9] Vitamin A supplementation is one of approaches employed by the SA Department of Health (DoH) to reduce VAD, thus improving child health and moving towards achieving Sustainable Development Goal number 3 which is about ensuring healthy lives and promoting well-being for all ages. [5] [10]

The indicator for VAS coverage as defined by UNICEF is the percentage of children aged six to 59 months who have received two age appropriate VAS capsules at six-month intervals in the past 12 months. [11] The denominator is multiplied by 2 as children routinely should receive 2 doses annually.[5] Routine VAS tends to be higher among the younger age groups (6 to 11 months) in comparison to the older age groups (12 to 59 months),[8] mainly due to children in the older age group accessing health services less often. [12]

The United Nations Children's Fund (UNICEF) reported global coverage of VAS in 2011 was 75% for children receiving at least two VAS doses annually. [13] The 2016 national coverage of VAS in SA is 52%, which is below the national target of 65%. [12] The coverage in Amajuba Health District (AHD) is 54% and the coverage is lower in children aged from 12 to 59 months despite the health service being freely available at all primary health care facilities in SA.[5] Most national, provincial and district VAS coverage information in SA is calculated from routine administrative data. Tick register data collected at service points where vaccines and VAS is administered is used together with data from ward-based outreach teams who also administer Vitamin A when they visit homesteads as part of the 'Reengineering Primary Health Care' policy in the country. [14] There are no community-based surveys of VAS coverage reported from SA.

As VAS coverage indicators are routinely calculated in AHD by administrative means, community-based measures of coverage as well as the knowledge, attitudes and practices of caregivers of children from different age groups about VAD and VAS is not known. Accurate measures of the prevalence of VAS coverage and understanding the reasons some children have not had VAS could help influence policy and practice of this component of the Expanded Programme on Immunization in SA. [1]

The purpose of this study was to measure community-based VAS coverage in children aged 12 to 59 months in 2016 in AHD and to investigate the understanding of VAD and VAS by mothers and caregivers of VAD and VAS, in order to inform policy and practice.

Methods

A community-based observational, analytic cross sectional study design was used for this implementation research. The study population was mothers and caregivers of children aged 12 to 59 months in Madadeni, a predominantly urban township with some rural sections in the Newcastle sub-district of AHD of KwaZulu-Natal (KZN). A two-stage cluster-sample method was used to select the sample. Selection of the 33 clusters was done using a 1:8000 scale map of Madadeni. A 2cm by 2cm grid was drawn on the map resulting in 450 numbered $4cm^2$ squares that covered the study area. Each square was a cluster. A random sample of 33 clusters was selected. In each cluster (square), a random starting point was identified as the house closest to the centre of the square and the next six houses to the right were sequentially visited similar to the methods described in the Expanded Programme of Immunisation 30 X 7 Coverage Survey method. [15] The 33 X 6 two-stage cluster sampling method used in this study yielded a total of 198 participants. The sample size of 198 was calculated using EPIINFO. The study population was assumed to be more than 1000; the coverage used was 50%; with 10% variability; and with 95% confidence limits. More clusters than the standard 30 in the EPI 30 X 7 method were used, as accessing clusters in the township was relatively easy.

In this present study, the VAS coverage reported was an indication of the proportion of children aged 12 to 59 months receiving one dose of VAS within a period of 6 months, thus the denominator was not multiplied by two.

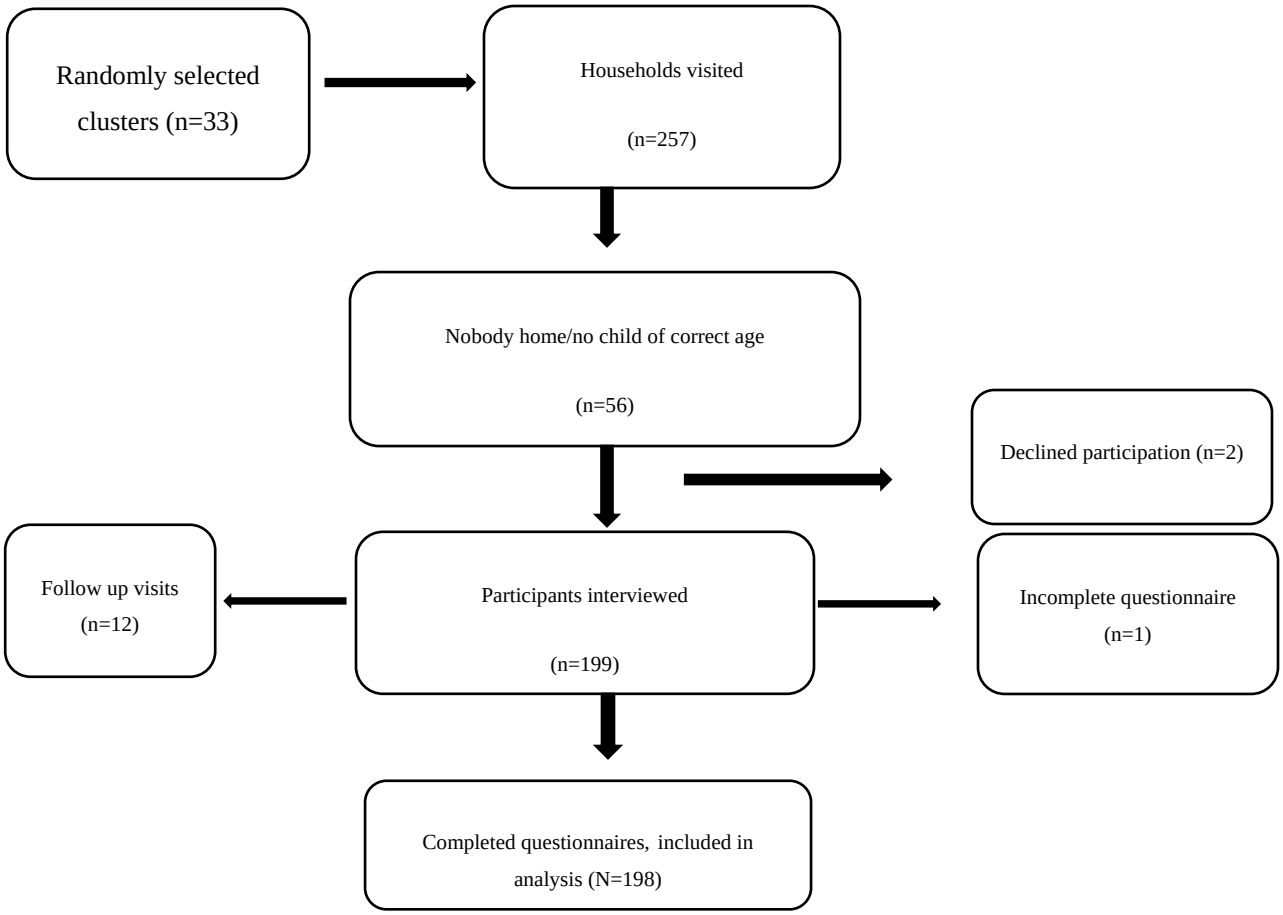

Figure 1: Process of final sample selection for VAS coverage survey

A total of 106 households had more than one child under 5 years, however no household had more than one child sampled for the study. Data was collected using a field-worker administered structured questionnaire at household level. The questionnaire is based on the UNICEF Multiple Indicator Cluster Survey (MICS).[15] To improve content and face validity the questionnaire was translated into *isiZulu* and pilot tested on 10 mothers at a clinic.

In order to minimize interviewer bias, the two field workers received standardised training on the content and administration of the questionnaires and uniform collection and recording of data. The data collection forms were checked by the principal investigator (PI) on a daily basis. The importance of maintaining the confidentiality of participant information was communicated to the participants to

ensure that there was limited respondent bias or likelihood of participants responding in a socially desirable manner. To minimize recall bias, participants were shown a Vitamin A capsule to aid memory with regard to questions on VAS. Coverage of VAS was verified by checking Road to Health Booklet (RtHB) entries, in addition to subjective caregiver reports.

Data was entered into Microsoft Excel and analysed using STATA statistical software. Analytic statistics were used to measure associations and compare differences between children who had or had not received VAS. The null hypothesis stated that there is no difference in characteristics between the two groups and the significance level was set at 0.05. The two-independent samples t-test was used to test for equality of means of numeric continuous variables between the two groups of children. Pearson Chi-squared tests were used to test for equality of proportions for different categorical variables between the two groups.

The study was approved by University of KwaZulu-Natal Biomedical Research Ethics Committee (BE 368/15) and the KZN DoH Research Committee. Both written and verbal informed consent was obtained from participants at the time of the interview. The purpose of the survey was explained to participants and included in the participant information sheet in *isiZulu*. The appropriate Vitamin A capsule dose was offered to children who were eligible.

Results

Sample demographic characteristics

The mean age of the 198 children aged 12 to 59 months included in the study investigating VAS coverage and understanding in Madadeni was 33 months (Standard Deviation (SD) 15) and that of the child's caregivers was 33 years (SD 13) - range 11 to 88 years. Most of the caregivers were single (170, 86% - 95% CI: 80 - 90), African (196, 98% - 95% CI: 96 - 99) females (194, 97% - 95% CI: 95 - 99), and lived in an urban area (157, 79% - 95% CI: 73 - 84). Two thirds (130, 66% - 95% CI: 56 - 72) were unemployed and social grants or pensions were the main source of income (161, 81% - 95% CI: 75 - 86). The majority of caregivers (120, 60%) had 12 or more years of education. Most of the respondents (117, 59% 95% CI: 52 - 66) reported an average household monthly income of between R1000 and R5000. Most caregivers reported that the household they lived in was "very close" to a health facility (108, 54% - 95% CI: 47 – 61) while (30, 15% - 95% CI: 10 - 20) reported living "very

far" from a health facility. Most of the caregivers reported that their mode of transport for travelling to clinics was walking (126, 64% 95% CI: 57 - 70) and it took them less than an hour to travel to the clinic (168, 85% - 95% CI: 79 - 89). A median of eight people lived in a household with two being children under five years. More than two-thirds (135, 68% - 95% CI: 61 - 74) of the children were not attending any early child development (ECD) centre and those that did attend an ECD centre (44, 69% 95% CI: 57 - 80) spent one to seven hours per day at the centre.

Vitamin A supplementation coverage

Community-based VAS coverage was assessed by determining the proportion of the 198 children between 12 and 60 months in the study sample who had received a single dose of VAS within the previous six months. One hundred percent of participants 'data on coverage was determined by Road to Health Booklet and none was determined by verbal report. The overall VAS coverage (prevalence) in children in this study population was 57% (95% CI: 49 - 63). Children aged 18 to 23 months had the highest VAS coverage (71%, 95% CI: 65 - 76) and this decreased with increasing age. It was 65% in the 24 to 35-month age group, 49% in the 36 to 47-month age group and a low of 44% in children aged 48 to 59 months.

The children of mothers and caregivers older than 35 years had the best VAS coverage (79%, 95% CI: 76 - 82). This was 72% and significantly higher relative to the youngest group of caregivers (Prevalence Ratio (PR 1.27, 95% CI: 1.15 - 2.13).

A child who had received their first dose of Vitamin A even one day after 6 months and not at 6 months; and/ or subsequent doses after more than 6 months was classified as having received vitamin A late. The majority (111, 56% - 95% CI: 49 - 62) of the children had received their first dose of vitamin A late, a trend was observed with the second dose of VAS as well (112, 56% - 95% CI: 49 - 63). Most children, (127, 64% - 95% CI: 57 - 70) in the study had received their last dose of vitamin A at a health facility during a routine Well-Baby Clinic visit, while (32, 16% 95% CI: 11 - 22) had received their last dose during an immunization campaign, which are usually held at ECD centres in the district. Only one child had received a VAS dose at home from a community caregiver and the rest (16, 8% 95% CI: 5 - 13) had received a VAS dose when they had attended the health facility for an illness.

The majority of caregivers interviewed (151, 76% - 95% CI: 69 - 81) were sure their children had received at least one vitamin A capsule, 43 (21% - 95% CI: 16 - 27) were not sure their child had received VAS and 6 (3% - 95% CI: 1 - 7) were sure their child had never received VAS. However, on review of the RtHBs, it was confirmed that only 5 (2% - 95% CI: 1 - 5) children had never received vitamin A supplementation before. Most (146, 73% - 95% CI: 67 - 79) of the caregivers did not know when the last dose of vitamin A was given.

Caregivers knowledge about Vitamin A was assessed and most (141, 71% - 95% CI: 64 -77) reported having never been informed by a health worker of the importance for their children to receive VAS. As a result, most (150, 75% - 95% CI: 69 - 81) did not know the VAS dose frequency of vitamin A, and very few (33, 16% 95% CI: 12 - 22) knew that VAS should be given six monthly. There was very little knowledge among the caregivers on identifying and differentiating between the different doses of the vitamin A capsules. Only 14 (7% 95% CI: 4 - 12) correctly identified the 'blue' (6 to 11 month) VAS dose capsule and 32 (16% 95% CI: 12 – 22) identified the 'red' (12 to 60 months) dose Vitamin A capsule. Most also were unaware when the first dose of VAS should be given, (146, 73% - 95% CI: 67 - 79), and only (28, 14% - 95% CI: 9 -19) correctly stated that the first dose should be at six months of age. There was also very little knowledge about the side effects of VAS among the caregivers. Only 23 (12%) of the mothers and caregivers were able to list side effects of VAS and 49 (35%) were aware of the benefits of VAS. The reduction of childhood illness was the most frequently mentioned benefit (38, 19% 95% CI: 14 – 25) among those caregivers who could list some benefits. Health facilities were the most frequently reported place where caregivers heard about vitamin A, where 139 (70% 95% CI: 63 - 76) of the caregivers reported that they usually hear about vitamin A at health facilities.

Immunization and weight

Assessing the nine and 18-month measles immunisation status among children in the study population and relating this with VAS coverage was also analysed as part of the study. Most (184, 93% - 95% CI: 88 - 96) of the 198 children had been vaccinated for measles at least once according to what was recorded on the RtHB. The majority (124, 63% 95% CI: 54 - 72) had received both doses of measles vaccine, (53, 27% 95% CI: 24 - 30) only the 9-month dose and 4 (2%) had only received measles vaccine at 18 months. Sixty-one (97% 95% CI: 74 - 119) of the 63 children aged 12 to 23 months had

received the 9-month dose of measles vaccine. There was a statistically significant association ($p<0.01$) between children having been immunised for measles and receiving VAS. Children who had VAS were 2.7 times more likely to have had measles vaccination. Children who had received no measles vaccination were 0.88 times less likely to receive VAS (95% CI: 0.80 – 0.96).

Caregiver knowledge of their children's growth patterns was assessed through questions about their child's previous weight recording. It was found that only 27% (95% CI: 21 - 34) correctly recalled their child's previous weight.

Associations between VAS status and respondent characteristics

The association between VAS coverage and a number of independent variables was assessed. Caregivers with less than 10 years of education had the best VAS coverage (61%) and although the coverage was slightly lower with increasing education levels, this was not statistically significant ($p=0.93$). Children with caregivers who were pensioners had with the highest VAS coverage (62%) followed by those unemployed (58%) and children of employed care givers had the lowest coverage (40%) ($p=0.18$). The best coverage (62%) was in those with a reported monthly income of less than R1000.

No significant association was found between marital status of caregivers and VAS status of children ($p=0.25$). No significant association was found between whether children lived in an urban or rural area.

Statistically significant associations were found between VAS status of children and the ability of caregivers to correctly identify and differentiate the blue capsules of Vitamin A ($p=0.03$) and the red capsules of Vitamin A ($p=0.03$).

No significant association was found between VAS status of children and the ability of caregivers to correctly recall their child's previous weight ($p= 0.08$).

In testing hypotheses of association between VAS status of children and some numerical variables such as caregiver age in years and children's age in months, the independent samples t-test was used, with the significance level also set at 0.05. No significant association was found between VAS status of

children and age of their caregivers (p=0.98). No significant association was found between VAS status of children and number of people living in one household (p=0.10) as well as the number of children living in the same household (p=0.34). However, there was a significant association found between VAS status of children and age of children (p=0.03). The mean age of those children who were found to be up to date in VAS was 31 months (95% CI: 28 - 33) and the mean age of those who were not up to date with VAS was 35 months (95% CI: 32 - 38).

Table 1: Relationship between respondent characteristics of caregivers of children aged 12 to 59 months and VAS receipt in 2016

Independent variable category	Sub-variable	Number of Children		Prevalence	Prevalence Ratio PR	95% CI
		Vit A given	Vit A not given			
Age of Child (months)	12-17	23	15	60.5%	Reference	
	18-23	22	9	71.0%	1.17	0.83 to 1.65
	24-35	24	13	64.9%	1.07	0.76 to 1.52
	36-47	25	26	49.0%	0.81	0.55 to 1.18
	48-60	18	23	43.9%	0.73	0.47 to 1.12
Age of Caregiver (years)	<=24 years	37	25	62.7%	Reference	
	25 to 35 years	42	32	50.8%	0.81	0.61 to 1.08
	>=36	33	29	72.1%	1.15	0.84 to 1.57
Current Occupation	Unemployed	75	55	57.7%	Reference	
	Scholar	16	13	55.2%	0.96	0.67 to 1.37
	Employed	13	13	50.0%	0.87	0.57 to 1.31
	Pensioner	8	5	61.5%	1.07	0.68 to 1.68
Source of Income	Salary/wage	8	12	40.0%	Reference	
	Grant	96	65	59.6%	1.49	0.86 to 2.59
	Other	8	9	47.1%	1.18	0.70 to 1.98
Education Level	< 10 years	30	19	61.2%	Reference	
	10 -12 years	58	43	57.4%	0.94	0.71 to 1.24
	Higher	24	24	50.0%	0.82	0.57 to 1.17
Area of Household	Urban	90	67	57.3%	Reference	
	Rural	22	19	53.7%	0.94	0.68 to 1.28
Average household income	< R1000	33	20	62.3%	Reference	
	between R1000 & R5000	66	51	56.4%	0.91	0.70 to 1.18
	>R5000	13	15	46.4%	0.75	0.48 to 1.17
Measles immunisation	9 + 18 months	75	49	60.5%	Reference	
	9 months	31	22	58.5%	0.97	0.74 to 1.26
	Other time	4	3	57.1%	0.94	0.49 to 1.93
	No immunisation	2	12	14.3%	0.24	0.06 to 0.86
Measles immunisation	Yes	110	74	59.8%	Reference	
	No	2	12	14.3%	0.24	0.07 to 0.87
	Total	**112**	**86**	**56.6%**		

Discussion

In 2015/16, the VAS coverage was reported as 54% which was well below the 2015/16 national target of 65%.[2] The community-based VAS coverage in this study of 57% (95% CI: 49 - 63), which is not substantially different to that reported.

The community-based and administrative methods for measuring coverage in this District are very similar suggesting that monitoring the coverage using administrative methods gives a good indication of the actual coverage. Previous studies comparing community based and administrative methods of monitoring coverage have found differences in the results of the two methods.[16] Although there was little difference shown in this study between community-based and administrative methods, it is necessary to have community-based surveys as a validation method and this might be done at least once a year.

The district coverage of 57% as found in this study was not very different compared to the reported KZN provincial coverage of 55% in 2014/15 as well as the national coverage of 52% in 2014/15. The coverage of 57% for Amajuba Health District was higher than other districts in KZN including UMkhanyakude Health District which had VAS coverage of less than 40% in 2014/15. The Amajuba District coverage of 57% however is still lower than the coverage in better performing districts such as UMzinyathi which had coverage of above 58% in 2014/15.

A number of previous studies reported a strong association between lower levels of caregiver education and children not being up to date in receiving Vitamin A.[1] The findings of the current study were similar to a study done in Tanzania which also found no significant association between caregiver education levels and VAS status of children.[16] The Tanzania study was also community-based and used the EPI cluster sampling methodology with a considerably larger sample size than the current study (30 by 40 clusters, n=1200). Although not significant, a higher education and income was associated with not receiving vitamin A. This may be attributed to a tendency of caregivers in this

[2] Data obtained from district health information system 2016

category to make less use of public health facilities and rather use private facilities such as private doctors.

While a strong association between children receiving vitamin A and a higher caregiver income was reported by a 2013 study in India, the present study found no significant association between caregiver income level and receipt of vitamin A by children. Findings of the study in India was from a cross-sectional study of 20 802 children aged 12 to 35 months whose mothers participated in a national survey thus was more representative.[7]

The 2012 study conducted in Nepal found a strong association between children not being up to date with VAS and living in a rural area, while no such association was found between VAS status of children and area of household in the present study. The Nepal study however was a nationally representative survey with a sample of 4013 children aged 12 to 59 months.[1] The present study however had unequal representation of participants living in urban area and rural areas, and the majority lived in urban areas.

Similar to findings reported by a 2011 study in the Western Cape SA, the present study found that a low percentage of mothers and caregivers had knowledge of why children receive vitamin A supplementation and very few mothers had been informed by a health worker on vitamin A. Caregivers in this study had very little knowledge on the health benefits of receiving VAS and on how often their children should receive a dose. A majority of the caregivers reported health facilities as the place where they heard about vitamin A, yet a majority also reported they had not been informed by a health worker on why vitamin A is given to children. This may be an indication that health workers do share with caregivers that they are giving vitamin A, but are not sharing important information on why vitamin A is given. However, there was no significant association found in the present study between caregiver knowledge on VAS and receipt of vitamin A by children.

The majority of caregivers reported living very close to a health facility, with most reporting that it usually took them less than an hour to travel to the nearest health facility, however this was found not to be associated with children receiving vitamin A. This is an indication that caregivers can have close access to health facilities yet not take their children to receive VAS. The responses for this question

were very subjective however, as how close or far a health facility was reported depended on the opinions and perceptions of respondents.

Study Limitations

This study had a relatively small sample size in comparison to previous studies referred to in the literature. Data could only be aggregated and the sample of 198 did not allow for a great deal of inference. Once a cluster was obtained; sequential / convenience sample of 6 households in the cluster was used. This was a limitation since children within the same cluster are likely to have similar characteristics, such as proximity to a health facility and access to services. This may have presented a form of selection bias. There was a race and gender imbalance in the study sample, which also presented a form of selection bias, with African female caregivers having the highest representation. This may have led to great similarity in characteristics. There was also a limitation in the design of the study, since this was a cross sectional study, exposures and outcomes were measured at the same time thus a strong case for causality could not be established. Since the principal investigator was introduced as both a research student and as a Department of Health worker, some information bias may have been introduced as participants may have felt a need to give favourable responses. The study was conducted in one area within the sub-district of Newcastle and this area is mostly urban. This was a limitation since the data may not be generalizable to the whole of AHD, particularly areas that are more rural. Despite these limitations, the findings of this study may not be sufficient to warrant a change of policy and but they may be used as a basis for improving current practice and some valuable recommendations can arise from the findings.

Conclusion

The low levels of knowledge among caregivers regarding Vitamin A found in this study were concerning, despite there being no significant association found between VAS status of children and knowledge levels of caregivers. Thus, it is recommended that emphasis be placed on focusing training of health workers on the importance of educating caregivers on the reasons for giving Vitamin A. Focus should also be placed on the older age groups of children as they are more likely miss VAS doses. This can be done by scaling up community outreach activities aimed at finding children at community level and providing them with the service of VAS. ECD and household visits should assist in reaching children of the older age group who may not be accessing health facilities regularly. Such outreach activities should also include an element of providing health education to mothers and caregivers informing them of the importance of VAS along with other essential child health services such as immunisations and growth monitoring.

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4 IV: ADDITIONAL FINDINGS, DISCUSSION AND LIMITATIONS

4.1 INTRODUCTION

This study focused on vitamin A supplementation in children aged between 12 to 59 months in Amajuba Health District and aimed to measure coverage of VAS in the district as well as to assess whether there an association between VAS status in children aged 12 to 59 months and caregiver and child characteristics. In this chapter, additional findings of the study will be discussed along with a discussion on the methods used to ensure validity of the study as well as a discussion on limitations of the study.

4.2 ADDITIONAL FINDINGS

Table 1 shows the additional findings of the study. Most caregivers reported that the household they lived in was “very close” to a health facility (108, 54% - 95% CI: 47 – 61) while (30, 15% - 95% CI: 10 - 20) reported living “very far” from a health facility, however this was found not to be associated with children receiving vitamin A. This is an indication that caregivers can have close access to health facilities yet not take their children to receive VAS. Most of the caregivers reported that their mode of transport for travelling to clinics was walking (126, 64% 95% CI: 57 - 70) and it took them less than an hour to travel to the clinic (168, 85% - 95% CI: 79 - 89). No significant association was found between VAS status and: distance of respondent household from the nearest health facility (p=0.27); the mode of transport used to reach health facilities (p=0.93); the time it takes to travel from home to a health facility (p=0.47). It was concerning to find low levels of knowledge on vitamin A supplementation among mothers and caregivers and very few mothers had been informed by a health worker on vitamin A, (141, 71% - 95% CI: 64 -77) reported having never been informed by a health worker of the importance for their children to receive VAS. Most caregivers were also unaware when the first dose of VAS should be given, (146, 73% - 95% CI: 67 - 79), and only (28, 14% - 95% CI: 9 -19) correctly stated that the first dose should be at six months of age. There was also very little knowledge about the side effects of VAS among the caregivers. Only 23 (12%) of the mothers and caregivers were able to list side effects of VAS and 49 (35%) were aware of the benefits of VAS. No significant association

was found between VAS status of children and whether caregivers had the correct knowledge on how often children should receive VAS (p=0.27) and knowledge on the correct age of receiving the first dose of VAS (p=0.81). No significant association was found between a caregiver having ever been informed by a health worker on why children received VAS and the VAS status of children (p=0.81). No significant association between VAS status of children and caregiver knowledge on the benefits of receiving vitamin A (p=0.99) and knowledge on the possible side effects of vitamin A (p=0.65). The reduction of childhood illness was the most frequently mentioned benefit (38, 19% 95% CI: 14 – 25) among those caregivers who could list some benefits. A majority of the caregivers reported health facilities as the place where they heard about vitamin A, yet a majority also reported they had not been informed by a health worker on why vitamin A is given to children. This may be an indication that health workers do share with caregivers that they are giving vitamin A, but are not sharing important information on why vitamin A is given. However, there was no significant association found in the present study between caregiver knowledge on VAS and receipt of vitamin A by children. There was also no significant association found between VAS status of children and the place where caregivers heard about Vitamin A (p=0.59).

Table 2: additional characteristics of caregivers of children aged 12 to 59 months in Amajuba Health District 2016 and VAS receipt.

Independent variable category	Sub-variable	Number of Children		Prevalence	Prevalence Ratio PR	95% CI
		Vit A given	Vit A not given			
Mode of transport to health facility	Private car/public transport	40	32	55.6%	Reference	
	Walking	72	54	57.1%	1.03	0.83 to 1.65
Time to reach health facility	< 1 hour	94	74	56.0%	Reference	
	>=1 hour	18	12	60.0%	1.07	0.78 to 1.48
Informed by health worker	Yes	33	24	57.9%	Reference	
	No	79	62	56.0%	0.97	0.74 to 1.26
Caregiver knowledge on first dose of VAS	At 6 months	16	12	57.1%	Reference	
	Do not know	96	74	56.5%	0.99	0.70 to 1.40
Caregiver knowledge on side effects of VAS	Correct side effect named	16	7	69.6%	Reference	
	Do not know/incorrect answer	96	79	54.9%	0.79	0.58 to 1.07
Caregiver knowledge on health benefits of VAS	correct benefit named	35	25	58.3%	Reference	
	Do not know/incorrect answer	77	61	55.8%	0.96	0.74 to 1.24
Place of hearing about vitamin A	Health facility	82	57	59.0%	Reference	

Radio/television/newspaper	13	14	48.1%	0.82	0.54 to 1.24
Family/friends	5	5	50.0%	0.85	0.45 to 1.60
Other	10	6	62.5%	1.06	0.71 to 1.59
Never heard of vitamin A	2	4	33.3%	0.69	0.21 to 2.29
Total	**112**	**86**	**56.6%**		

4.3 BIAS, LIMITATIONS OF RESULTS AND STUDY DESIGN

4.3.1 Measurement validity

Measurement validity is the extent to which an assessment measures what it is intended to measure. Defining household distance from the nearest health facility was determined subjectively based on participants' perceptions of what is "near" "far" and "not so far". This was a limitation as it would have been more objective to measure actual distance of each household from the nearest facility and have a standard definition of what is considered far and near.

4.3.2 Statistical conclusion validity

Statistical conclusion validity is the extent to which conclusions about the relationship among variables based on data are correct. Pearson- Chi tests were used to measure associations between categorical data and two sample t-tests were used to test for association of numerical data with the independent variable. Significance level was set at 0.05. The coverage of VAS amongst children was 57% (95% CI: 49 - 63). Younger children (18 to 23 months) had better (Prevalence Ratio (PR) 1.2 (95% CI: 0.8 - 1.6) coverage than older children. Children who were up to date with VAS coverage were more likely to have received a measles vaccine and this was statistically significant ($p<0.01$). The association between receiving measles vaccine and receiving VAS is however not surprising as the EPI programme is designed such that children are given VAS during immunisation visits. A significant association was found between VAS status of children and caregivers being able to identify the blue capsules as the 6 to 11-month dose and the red capsules as the 12 to 59-month Vitamin dose capsule. There was a non-significant but positive association of a child having received VAS and higher level of education of the caregivers, shorter distance from health facilities, living in an urban area and having received information about VAS from a health worker. A larger sample size may have given the study more power and rendered some of the findings statistically significant.

4.3.3 Internal validity

Internal validity is the extent to which the findings of a study are due to the exposure being measured and not some other cause. Data collectors were given uniform training on how to administer the

questionnaires to ensure that there is limited variation in the mode of data collection which can threaten internal validity. There was a limitation in the design of the study, since this was a cross sectional study, exposures and outcomes were measured at the same time thus a strong case for causality could not be established. Since the principal investigator was introduced as both a research student and as a Department of Health worker, some information bias in the form of the Hawthorne effect may have been introduced as participants may have felt a need to give favourable responses. Data collectors also had a tendency of asking leading questions by mentioning some of the possible responses to questions instead of just letting the participants respond. A pilot test of the questionnaire was conducted to improve reliability of the questionnaire and adaptations were made based on findings. Lack of multivariate analysis and attempt to control for clusters was a key weakness of the study design and this compromised the value of conclusions drawn.

4.3.4 External validity

External validity refers to the extent to which the results of a study can be generalized to a wider population. This study had a relatively small sample size in comparison to previous studies referred to in the literature. Data could only be aggregated and the sample of 198 did not allow for a great deal of inference. The study setting was mostly urban thus, the results of the study may not be able to be generalizable to more rural areas. Once a cluster was obtained; sequential / convenience sample of 6 households in the cluster was used. This was a limitation since children within the same cluster are likely to have similar characteristics, such as proximity to a health facility and access to services. This may have presented a form of selection bias. There was a race and gender imbalance in the study sample, which also presented a form of selection bias, with African female caregivers having the highest representation. This may have led to great similarity in characteristics.

4.4 SUMMARY OF CHAPTER

This chapter summarised the additional findings arising from the research, as well as limitations and bias of the study.

5 CHAPTER V: CONCLUSIONS AND RECOMMENDATIONS

5.1 INTRODUCTION

This study focused on investigating VAS coverage in children aged 12 to 59 months in Amajuba Health District as well as comparing the characteristics of children who were up to date with VAS with children who were not up to date with VAS. In this final chapter, findings of the study; in line with the study aims and objectives; will be discussed and interpreted. This chapter will also present recommendations for practice and policy as well as recommendations for further studies in the topic.

5.2 CONCLUSIONS

The District Health Barometer reported a VAS 12 to 59 months coverage of 50% in Amajuba District in 2014/15 which was below the then national target of 55%. The present study estimated a VAS coverage of 57% in Amajuba District for 2016, indicating that the district has still not reached the target of 65% for 2016.

A number of studies have been conducted previously to compare the characteristics of children who are up to date in receiving VAS with those of children who are not up to date. Some of these studies have found associations between some of these characteristics and VAS status of children. For instance, some studies found a strong positive association between lower caregiver education levels and children not receiving VAS. Other studies found a significant association between children residing in rural areas and not receiving VAS. The present study however found no significant association between children receiving VAS and many of these characteristics; including caregiver education level, income level, and caregiver age, area of household and even proximity to health facilities. No significant associations were found between VAS status of children and caregiver access to media and information, to caregiver being informed by a health worker on VAS and knowledge of caregivers on VAS benefits and side effects.

The study did find a strong association between VAS status of children and age of children; where it was found that older children were more likely to not be up to date with VAS than younger children. This trend has also been reported by other studies. A significant association was also found between

VAS status of children and having received a measles vaccine. A significant association was also found between VAS status of children and whether caregivers could correctly identify the different Vitamin A doses.

Overall, there was very little knowledge amongst the caregivers on vitamin A, including its benefits and when it should be given. A high percentage of caregivers also reported not being informed by health workers on the reasons that their children receive vitamin A.

5.3 RECOMMENDATIONS

1. Although in this study no significant association was found between VAS status of children and caregiver knowledge on vitamin A as well as whether caregivers were informed by health workers on vitamin A; the low levels of knowledge on VAS among caregivers is concerning and should be addressed. It is recommended that health workers in direct contact with caregivers are trained and encouraged to place more emphasis on sharing information with parents on why vitamin A is given to children. The intended outcome of this recommendation would be to raise awareness among caregivers on VAS and hopefully increase their behavior of seeking this health service. To achieve this health care workers need to be invested and committed to advocacy for the service.
2. Anecdotal accounts indicated some caregivers thought that children should only be taken to health facilities when they are sick or for immunisations and most were not aware of the six-month intervals of receiving VAS. It is thus recommended that caregivers are informed of the importance of children receiving VAS, this should motivate them to take their children to health facilities to receive this service. It has been shown in previous studies that educating caregivers increases their likelihood of practicing beneficial caregiving health behaviours.[(1)] There have been great successes in emphasizing and promoting the importance of immunisations to caregivers as can be seen in the high immunisation coverage shown in previous studies and the present study. The same efforts should be put into promoting vitamin A supplementation. There has also been great success in combining vitamin A supplementation with EPI services and in this study a strong association was found between children being up to date with VAS and having received their measles immunisations. However it is not sufficient to merely

combine the two services but education on both services should be given to caregivers. In addition to informing caregivers on the importance of VAS it is also recommended that they are educated on dietary diversification and consuming Vitamin A rich foods.[2]

3. This study found that lack of VAS was found more in older children thus emphasis needs to be placed on older children, particularly those older than 18 months as this is when the immunisation schedule stops until they are six years old. It is recommended that more campaigns are conducted to target this age group at Early Childhood Development Centres as well as awareness campaigns targeting parents to educate them on dose schedules and the importance of receiving VAS up until the age of five years. The intended outcome of this recommendation would be to increase the number of older children accessing this service. To achieve this, resources will have to be dedicated to providing outreach services, including human resources and transport.

5.4 RECOMMENDATION FOR FURTHER STUDY

This study has attempted to estimate VAS coverage and compare characteristics of caregivers of children aged 12 to 59 months in Amajuba District, however, sampling was done in only one of the three sub-districts. A suitably sized random selection of participants across the district might improve the power of the study. The South African Department of Health has deployed ward based outreach teams as an effort to improve vitamin A supplementation coverage, however there is little information on the impact of this on coverage and it is difficult to assess whether this is being implemented sufficiently.[7] Therefore, more research is needed to explore the level and impact of VAS given by outreach teams. Furthermore, research is needed to investigate the integration of data of outreach teams with data of primary health care facilities to see if there is some data loss or under-reporting.

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ANNEXURES

ANNEXURE A: ETHICAL APPROVAL

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

19 January 2016

MS ML Mdlalose (206514449)
Discipline of Public Health
School of Nursing and Public Health Medicine
mbaleeh@gmail.com

Protocol: Vitamin A supplementation in children aged 12 - 60 months in Amajuba Health District: investigating vitamin A supplementation coverage in 2016.
Degree: M-PH
BREC reference number: BE368/15

EXPEDITED APPLICATION

The Biomedical Research Ethics Committee has considered and noted your application received on 08 August 2015.

The study was provisionally approved pending appropriate responses to queries raised. Your responses dated 14 January 2016 to queries raised on 16 October 2015 have been noted and approved by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval.

This approval is valid for one year from **19 January 2016.** To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2015), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be RATIFIED by a full Committee at its meeting taking place on 09 **February 2016.**

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

Professor J Tsoka-Gwegweni
Chair: Biomedical Research Ethics Committee

cc supervisor: knights@ukzn.ac.za
cc postgrad: zamla.m@ukzn.ac.za

ANNEXURE B: DEPARTMENT OF HEALTH PERMISSION LETTER

health
Department:
Health
PROVINCE OF KWAZULU-NATAL

330 Langalibalele street
Private Bag X9051 PMB, 3200
Tel: 033 395 2805/3189/3123 Fax: 033 394 3782
Email: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

DIRECTORATE:
Health Research & Knowledge Management (HKRM)

Reference: **HRKM010/16**
KZ_2016RP32_976

20 January 2016

Dear Miss M L Mdlalose
(University of KwaZulu-Natal)

Subject: Approval of a Research Proposal

1. The research proposal titled '**Vitamin A Supplementation in children aged 12 to 60 months in Amajuba Health District: Investigating Vitamin A supplementation coverage in 2016**' was reviewed by the KwaZulu-Natal Department of Health (KZN-DoH).

   The proposal is hereby **approved** for research to be undertaken at the selected Amajuba district and in the selected schools.

2. You are requested to take note of the following:
   a. Make the necessary arrangement with the identified facility before commencing with your research project.
   b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.

3 Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Ms G Khumalo on 033-395 3189.

Yours Sincerely

E Lutge

Dr E Lutge
Chairperson, Health Research Committee
Date: 21/01/16.

Fighting Disease, Fighting Poverty, Giving Hope

ANNEXURE C: QUESTIONNAIRE

QUESTIONNAIRE FOR CAREGIVERS OF CHILDREN AGED 12 TO 59 MONTHS

UNDER-FIVE CHILD INFORMATION PANEL	**UF**
☐ *This questionnaire is to be administered to all mothers or caretakers who care for a child that lives with them and is under the age of 5 years.* ☐ *A separate questionnaire should be used for each eligible child.*	
UF1. Cluster number: ___ ___ ___	**UF2**. Child number: ___ ___
UF7. Interviewer's name and number: Name_____ ___ ___	**UF8**. Day / Month / Year of interview: ___ ___ /___ ___ / 2 0 1 ___

☐ *Repeat greeting if not already read to this respondent:*

WE ARE FROM THE UNIVERSITY OF KWAZULU-NATAL AND DEPARTMENT OF HEALTH WE ARE CONDUCTING A SURVEY ABOUT THE HEALTH OF CHILDREN, FAMILIES AND HOUSEHOLDS. I WOULD LIKE TO TALK TO YOU ABOUT (*child's name*)'S HEALTH AND WELL-BEING. THE INTERVIEW WILL TAKE ABOUT ***30*** MINUTES. ALL THE INFORMATION WE OBTAIN WILL REMAIN STRICTLY CONFIDENTIAL AND ANONYMOUS.

MAY I START NOW?

- ☐ *Yes, permission is given ⇨ Go to UF12 to record the time and then begin the interview.*
- ☐ *No, permission is not given ⇨ Circle '03' in UF9. Discuss this result with your supervisor.*

UF9. Result of interview for children under 5 ☐ *Codes refer to mother/caretaker.*	Completed ..... 01 Not at home ..... 02 Refused ..... 03 Partly completed ..... 04 Incapacitated ..... 05 Other (*specify*) _____ 96

UF10. Field editor's name and number: Name_____ __	**UF11**. Main data entry clerk's name and number: Name_____ __ __ Hour and minutes……..___ ___: ___

UF12. Record time	___

MOTHER/CAREGIVER INFORMATION		MC
Demographic and socioeconomic information		
☐ **MC1.**IN WHAT MONTH AND YEAR WERE YOU BORN? ☐ AGE IN YEARS	DOB of caregiver: Day/Month/Year ___ ___ / ___ ___ / ___ ___ ___ ___ _____	
☐ **MC2.** GENDER OF CAREGIVER	Female……1 Male……2	
☐ **MC3.** ETHNICITY OF CAREGIVER	African……1 White……..2 Indian……3 Coloured ……..4 Other (specify)……..5	
☐ **MC4.** MARITAL STATUS	Married……..1 Single……2 Divorced……3 Widowed……4	
☐ **MC5.** CURRENT OCCUPATION OF CAREGIVER	Employed ……1 Scholar/student……...2 Pensioner……3 Unemployed……4 Other (specify) ……5	
☐ **MC6.** MAIN SOURCE OF INCOME	Salary/wage……..1 Social grant/pension……2 Other ……3	
Education		
☐ **MC7.** HAVE YOU EVER ATTENDED SCHOOL?	Yes……1 No ……2	
☐ **MC8.** WHAT IS THE HIGHEST LEVEL OF SCHOOL YOU ATTENDED: PRIMARY, SECONDARY, OR HIGHER	<7 years.....0 7 years.....1 10 years.....2 12 years……..3 Higher……4 None……5	
• *Access to media and use of information technology*		
MC9. HOW OFTEN DO YOU READ A NEWSPAPER OR MAGAZINE: ALMOST EVERY DAY, AT LEAST ONCE A WEEK, LESS THAN ONCE A WEEK OR NOT AT ALL?	Almost every day ..... 1 At least once a week ..... 2 Less than once a week ..... 3 Not at all 4	
MC10. WHICH MAGAZINE OR NEWSPAPER DO YOU		

READ?		
MC11. DO YOU LISTEN TO THE RADIO ALMOST EVERY DAY, AT LEAST ONCE A WEEK, LESS THAN ONCE A WEEK OR NOT AT ALL?	Almost every day ..... 1 At least once a week ..... 2 Less than once a week ..... 3 Not at all 4	
MC12. WHICH RADIO STATION DO YOU LISTEN TO?		
MC13. HOW OFTEN DO YOU WATCH TELEVISION: WOULD YOU SAY THAT YOU WATCH ALMOST EVERY DAY, AT LEAST ONCE A WEEK, LESS THAN ONCE A WEEK OR NOT AT ALL?	Almost every day ..... 1 At least once a week ..... 2 Less than once a week ..... 3 Not at all 4	

HOUSEHOLD CHARACTERISTICS		HC
HC1. AREA OF HOUSEHOLD	Urban……..1 Rural……...2	
HC2. TOTAL NUMBER OF HOUSEHOLD MEMBERS:	_____	
HC3. NUMBER OF CHILDREN UNDER AGE 5:	_____	
HC4. WHAT IS THE AVERAGE HOUSEHOLD MONTHLY INCOME?	Less than R1000…….1 Between R1000 and R5000……...2 Between R5000 and R10 000……3 Between R10 000 and R15 000…….4 >R15 000	
HC5. HOW FAR IS THE HOUSEHOLD FROM THE NEAREST HEALTH FACILITY?	Very close…….1 Not so far……..2 Very far……..3	
HC6. MODE OF TRANSPORT USED TO REACH HEALTH FACILITY	Private car……1 Public transport (bus, taxi)…..……...2 Walking…….3 Other (specify)	
HC7. USING THIS TRANSPORT HOW LONG DOES IT TAKE YOU FROM HOME TO THE CLINIC?	Less than an hour……..1 1 hour……2 2 hours……..3 More than 2 hours……4	

UNDER 5 CHILD INFORMATION		UF
UF1. ON WHAT DAY, MONTH AND YEAR WAS (NAME) BORN? Probe: WHAT IS HIS / HER BIRTHDAY? *If the mother/caretaker knows the exact birth date, also enter the day; otherwise, circle 98 for day.* *Month and year must be recorded.*	Date of birth Day __ DK day.....8 Month.....__ __ Year.....2 0 __ __	
UF2. HOW OLD IS (NAME)? PROBE: HOW OLD WAS (NAME) AT HIS / HER LAST BIRTHDAY? RECORD AGE IN COMPLETED YEARS. RECORD '0' IF LESS THAN 1 YEAR. COMPARE AND CORRECT UF1 AND/OR UF2 IF INCONSISTENT.	Age (in completed years) .....__	
UF3. DOES (NAME) ATTEND ANY ORGANIZED LEARNING OR EARLY CHILDHOOD EDUCATION PROGRAMME, SUCH AS A PRIVATE OR GOVERNMENT FACILITY, INCLUDING CRÈCHE OR COMMUNITY CHILD CARE?	Yes.....1 No .....2 DK 8	
UF4. WHAT IS THE NAME OF THIS FACILITY?		
UF5. HOW MANY HOURS PER DAY DOES HE/SHE SPEND AT THIS FACILITY?	1-7 hours…….1 8-10 hours……2 12 hours……..3	

VITAMIN A		**VA**
VA1.DO YOU HAVE A RTHB OR IMMUNIZATION CARD FOR (NAME) If yes: MAY I SEE IT PLEASE?	Yes, seen.....1 Yes, not seen.....2 No card 3	
VA2. DATE OF VITAMIN A (FIRST DOSE) DATE OF VITAMIN A (SECOND DOSE) *Check RTHB*	dd/month/year ____ / ____ / ____ (a) dd/month/year ____ / ____ / ____ (b)	
VA3. HAS (NAME) EVER RECEIVED A VITAMIN A CAPSULE (SUPPLEMENT) LIKE THIS ONE? - *Show capsule or dispenser for different doses – 100,000 IU for those 6-11 months old, 200,000 IU for those 12-59 months old.*	Yes……..1 No ……...2 DK……....3	
VA4. HOW MANY MONTHS AGO DID (NAME) TAKE THE LAST DOSE? (CONFIRM BY CHECKING RTHB)	Months ago (based on caregiver recall).....__ __ (a) Based on RTHB……..__ __ (b) DK.....3	
VA5. WHERE DID (NAME) GET THIS LAST DOSE?	On routine visit to health facility .....1 Sick child visit to health facility ….2 National Immunization Day campaign.....3 Other (specify) _____ 4 5	
VA6. HAVE YOU EVER BEEN INFORMED BY A HEALTH WORKER WHY (NAME) RECEIVES VITAMIN A	Yes…….1 No……..2	
VA7. HOW OFTEN SHOULD CHILDREN RECEIVE VITAMIN A?	Every 6 months……1 Other (specify)…….2 DK……..3	
VA8. AT WHAT AGE SHOULD CHILDREN RECEIVE THEIR FIRST DOSE OF VITAMIN A?	Every 6 months…….1 Other (specify)……2 DK…….3	
VA9. WHAT IS THE VITAMIN A DOSAGE FOR 6 TO 11 MONTHS?	Blue capsule…….1 Red capsule……..2 DK……3	
VA10. WHAT IS THE VITAMIN A DOSAGE FOR 12 TO 60 MONTHS?	Blue capsule…….1 Red capsule……..2	

	DK……3	
VA11. DO YOU KNOW THE BENEFITS OF VITAMIN A? IF SO PLEASE LIST A FEW	Eye health…….1 Immune system……2 Reduce childhood illness……3 Do not know……..4 Other (specify)……..5	
VA12. CAN YOU LIST AT LEAST 3 FOODS WHICH CONTAIN VITAMIN A?	_____ DK……1	
VA9. WHERE DID YOU HEAR ABOUT VITAMIN A?	Health facility…….1 Radio/Television/newspaper…...…2 Family/friends…….3 Other (specify)……...4	
EP11. WAS YOUR CHILD GIVEN MEASLES VACCINE?	Yes ……1 No ……..2 DK……..3 Age…….4 Age DK……..5	
EPI2. CHECK RTHB IF AND WHEN MEASLES VACCINE WAS GIVEN	Yes…….1 No……2 Age _____	
EPI 3. WHAT WAS YOUR CHILD'S LAST RECORDED WEIGHT? AT WHAT AGE	Correct recall……..1 Incorrect recall……2 DK…….3	

ANNEXURE D: CONSENT FORM AND PARTICIPANT INFORMATION SHEET

CONSENT FORM

This Informed Consent Form is for caregivers of children participating in the research titled: ***Vitamin A Supplementation in children aged 12 to 59 months in Amajuba District: Investigating Low Coverage***

Name of Principle Investigator: Mbalenhle Luthando Mdlalose

Name of Organization: University of KwaZulu Natal

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 to participate)

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

PART II: Certificate of Consent

Certificate of Consent

I have been asked to give consent for my participation in this research study which will involve completing one questionnaire I have read the foregoing information, 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 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 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_____ **AND** **Thumb print of participant**

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

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

A questionnaire will be read out to the participant and researcher will record responses on behalf of the participant.

I confirm that the participant 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.

A copy of this Informed Consent Form has been provided to the participant ____

Print Name of Researcher/person taking the consent_____

PARTICIPANT INFORMATION SHEET

Part I: Information Sheet

Introduction

My name is Mbalenhle Luthando Mdlalose. I am a part-time student at the University of KwaZulu Natal and also I work for the Department of Health in Amajuba District. I am currently doing research on Vitamin A which is given to children by the Department of Health. Before doing any research it is important that we obtain your permission to take part in it. If there are any words or concepts that you do not understand, please stop me and these will be explained to you as we go along and you may ask questions at any time.

Purpose

This research is being conducted in order to find out how the program of Vitamin A is going in the district, how many children are receiving Vitamin A as well as to find possible reasons that some children do not receive Vitamin A. Results from this research may help to improve child health as it can help the department to find better ways of providing this service.

Type of Research Intervention

This research will be conducted through a structured questionnaire which will be filled in by the researcher while interviewing you.

Selection of Participants

You were selected because we want to talk to mothers or caregivers of children aged 12 to 59 months living in this area

- *Do you know why we are asking you to take part in this study? Do you know what the study is about?*

Voluntary Participation

You do not have to agree to talk to us. You can choose to say no and any services that you and your family receive at health facilities will not change. You can ask as many questions as you like and we will take the time to answer them. You do not have to decide today. You can think about and tell me what you decide later.

- *If you decide not to take part in this research study, do you know what the options are? Do you know that you do not have to take part in this research study, if you do not wish so? Do you have any questions?*

Procedure

You will be participating in a questionnaire which will take place here in your household. The researcher will be reading out questions to you and recording your responses in the questionnaire. If there are questions which you do not want to answer we may skip them and move on to the next question. The answers recorded will be confidential and only the researcher will have access to them. The questionnaires will be destroyed after a year.

Duration

Completing of this questionnaire will take about 30 minutes of your time.

- *If you decide that you can take part in the study, do you know how much time will the questionnaire take? Where will it take place? If you agree to take part, do you know that you can stop participating? Do you know that you may not respond to the questions that you do not wish to respond to? Do you have any more questions?*

Risks and Discomforts

Some questions may ask for information which is confidential or which you do not feel comfortable to answer. If you do not wish to answer a certain question that is fine and you do not have to provide an explanation as to why you do not wish to respond.

Benefits

There will be no direct and immediate benefit for participating in the research but your participation is likely to improve how health services are delivered for children in your community in the future. Your child will also be given Vitamin A if it is found that he/she is due for a dose. Please note that this is not dependent on your participation.

Reimbursements

You will not be provided with any payment for participating in this research.

- *Can you tell me if you have understood correctly the benefits of your participation in the research? Do you have any other questions?*

Confidentiality:

Because something out of the ordinary is being done through research in your community it will draw attention. If you participate you may be asked questions by other members of the community. We will not be sharing personal information about you outside of the research team. The information that we collect from this research project will be kept confidential. Information about you will be put away and no-one but the researchers will be able to see it. Any information shared through reporting of this research will only have generalized information with no specific reference to you personally.

- *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about your child will remain confidential? Do you have any more questions?*

Sharing of Research Findings

At the end of the study, we will be sharing what we have learnt with the participants and with the community. Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. A written report will be given to the participants which can be shared with their families. We will also publish the results in order that other interested people may learn from our research

Right to refuse or withdraw

You may choose not to participate in this study. Choosing to participate or not will not affect your treatment at any health facility in any way. You and your child will still have all the benefits that would otherwise be available at any health facility. You may stop participating in this research at any time you wish without losing any of your rights.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact: **[Mbalenhle Luthando Mdlalose, Cell: 0837520492, Email: mbaleeh@gmail.com].** This proposal has been reviewed and approved by BREC which is a committee whose task is to make sure that research participants are protected from harm. If you wish to find out more about BREC, please contact (……..)

- *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study?*

ANNEXURE E: INSTRUCTIONS TO AUTHORS

Preparing an article for anonymous review

To ensure a fair and unbiased review process, all submissions are to include an anonymised version of the manuscript. The exceptions to this are Correspondence, Book reviews and Obituary submissions.

Submitting a manuscript that needs additional blinding can slow down your review process, so please be sure to follow these simple guidelines as much as possible:

An anonymous version should not contain any author, affiliation or particular institutional details that will enable identification.

Please remove title page, acknowledgements, contact details, funding grants to a named person, and any running headers of author names.

Mask self-citations by referring to your own work in third person.

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 or RTF document 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)'.

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.

Preparation notes by article type

Research

Guidelines

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.

Review process

The guest editor reviews the articles and returns them to the CME editor for review and final approval.

rds about your current fields of interest.