THE IMPACT OF DISCLOSURE ON HEALTH OUTCOMES IN HIV-INFECTED NIGERIAN CHILDREN

Angela Odiachi

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Approved by:

Harsha Thirumurthy

Edward Brooks

John E. Paul

Carol Golin

Vicki Tepper

ABSTRACT

Angela Odiachi: The Impact of Disclosure on Health Outcomes in HIV-Infected Nigerian Children
(Under the direction of Harsha Thirumurthy)

AIM: The study aimed to determine the prevalence, age and main agent of disclosure among Nigerian children on antiretroviral treatment. The study also sought to elicit barriers to, and facilitators of disclosure, and the context and process of disclosure. **METHODS:** In this cross-sectional, facility-based study, a semi-structured questionnaire was administered to 110 parents/caregivers of children ≥ 6 years, to determine child's disclosure status. This was followed by a more detailed interview with 15 parent/caregivers of disclosed children. CD4, viral load, opportunistic infections and adherence information were also extracted from medical records for all 110 children. **RESULTS**: The mean age (SD) of the children in the study was 10.15 (2.97) years, with a median (range) of 9.50 (6 – 18) years. According to parents/caregivers' accounts 34 (30.9%) children knew they were living with HIV, while 74 (67.3%) did not know. Mean age (SD) at disclosure was 10.47 (2.62) years, with a median (range) of 10.00 (6 - 17) years. Most of the children (79.4%) were disclosed at home by their parent(s)/caregiver. The rest were disclosed at the hospital: five were disclosed by a health care provider, while two were accidental disclosure. The most common reasons for disclosure were related to adherence issues – either to help prepare the children to take their medicines or that the child had refused to take his/her medicines (39.4%). This was followed by the child asking a lot of questions related to his/her health, frequent visits to the hospital, or why s/he was taking a lot of medicines even though s/he did not feel ill (27.3%). Most parents/ caregivers did not disclose because the child was considered too young (84.0%) or will not be able to keep their HIV status a secret (10.7%). Disclosure was mostly unplanned and a one-off event. Children’s reaction to disclosure ranged from no reaction to shock and crying. Multivariate logistic regression showed that only child’s age was a statistically significant predictor of status disclosure (OR 1.69, p=0.002; 95% CI 1.21 – 2.34). The study did not show any association between disclosure and other child and parent/caregiver characteristics. There was no association between disclosure and self-reported adherence (p=0.615).

To Dika

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Except the LORD build the house, they labor in vain that build it.

Psalm 127: 1

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TABLE OF CONTENTS

LIST OF TABLES……xi

LIST OF FIGURES……xii

LIST OF ABBREVIATIONS……xiii

CHAPTER 1: INTRODUCTION……1

Nigeria……2

HIV in Nigeria……3

Institute of Human Virology Nigeria……4

Structure of this dissertation……5

References……6

CHAPTER 2: THE IMPACT OF DISCLOSURE ON HEALTH OUTCOMES IN HIV-INFECTED CHILDREN: A LITERATURE REVIEW……8

Introduction……8

Method……10

Results……13

Discussion……18

Conclusion……29

References……………………………………………………………………………………………………….30

CHAPTER 3: METHODOLOGY……………………………………………………………………………………….33

Study design and Methods………………………………………………………………………………….33

IRB and Ethical Considerations……………………………………………………………………………44

Data Analyses……………………………………………………………………………………………………47

References……………………………………………………………………………………………………….49

CHAPTER 4: PATTERNS, PREVALENCE AND PREDICTORS OF PEDIATRIC DISCLOSURE AMONG HIV-INFECTED NIGERIAN CHILDREN ON TREATMENT……………………………50

Introduction………………………………………………………………………………………………………50

Methods………52

Results……55

Discussion……64

Conclusion……67

Acknowledgments………………………………………………………………………………………………67

References……68

CHAPTER 5: THE CONTEXT AND PROCESS OF PEDIATRIC HIV DISCLOSURE…………………70

Introduction………………………………………………………………………………………………………70

Methods………71

Results……73

Discussion……84

Conclusion……87

Acknowledgments……………………………………………………………………………………………………….87

References……….89

CHAPTER 6: PLAN FOR CHANGE……………………………………………………………………………………………91

Introduction…….91

Study Recommendation…………………………………………………………………………………………….93

Moving from research to policy guidelines: The Advocacy Planning Framework……………………….93

Advocacy planning for the development of pediatric HIV disclosure guidelines ………………………95

References………...100

APPENDIX 1: QUESTIONNAIRE PARENTS/CAREGIVER OF PEDIATRIC ART PATIENTS……………………………101

APPENDIX 2: PATIENT DATA EXTRACTION FORM………………………………………………………………………107

APPENDIX 3: INTERVIEW GUIDE FOR PARENTS/CAREGIVERS OF DISCLOSED CHILDREN………………… ……108

APPENDIX 4: UNIVERSITY OF ABUJA TEACHING HOSPITAL INSTITUTIONAL REVIEW BOARD LETTER OF APPROVAL……………………………………………………………………………………………110

APPENDIX 5: UNIVERSITY OF NORTH CAROLINA INSTITUTIONAL REVIEW BOARD LETTER OF APPROVAL……………………………………………………………………………………………………111

LIST OF TABLES

Table

2.1 Overview of studies included in the literature review……………………………………………….19

3.1 Overview of study design……………………………………………………………………………………….39

4.1 Respondent characteristics…………………………………………………………………………………..55

4.2 Child characteristics……………………………………………………………………………………………..57

4.3 Child’s knowledge of HIV status………………………………………………………………………..….58

4.4 Reasons for disclosure of child’s status to child……………………………………………………….58

4.5 Reasons for non-disclosure of child’s status to child…………………………………………………59

4.6 Multivariate logistic regression of HIV disclosure to child (n=108)……………………………..60

4.7 Multivariate logistic regression of HIV disclosure to child (n=110)……………………………..61

4.8 Multinomial logistics regression of HIV disclosure to child…………………………………………62

4.9 Relationship between disclosure and adherence……………………………………………………..64

5.1 Characteristics of caregivers and disclosed children………………………………………………..75

5.2 Characteristics of caregivers and disclosed children………………………………………………..79

6.1 Key activities for advocating for the development of pediatric HIV disclosure guidance………98

6.2 Tailored messages for advocacy audiences………………………………………………………………99

LIST OF FIGURES

Figure 2.1 Flowchart of the identification of studies included in the literature review………12

Figure 6.1 The Advocacy Planning Framework……………………………………………………………………………94

LIST OF ABBREVIATIONS

ACTION	AIDS Care and Treatment in Nigeria Program
ACTIONplus	AIDS Care and Treatment in Nigeria (ACTION) Follow-on Program
APF	Advocacy Planning Framework
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral drug
CLHIV	Children Living with HIV
CSO	Civil Society Organization
HIV	Human Immunodeficiency Virus
IHVN	Institute of Human Virology Nigeria
MTCT	Mother to Child Transmission
NACA	National Agency for the Control of AIDS
PACTG	Pediatric AIDS Clinical Trial Group
PEPFAR	(US) President’s Emergency Plan for AIDS Relief
PI	Principal Investigator
PMTCT	Prevention of Mother to Child Transmission
PSD	Paediatric Spectrum of Disease
QoL	Quality of Life
SDQ	Strengths and Difficulties Questionnaire
SOP	Standard Operating Procedures or Protocols
SRH	Sexual and Reproductive Health
SSA	Sub Saharan Africa
TWG	Technical Working Group
UATH	University of Abuja Teaching Hospital
UNICEF	United Nations Children’s Fund
WHO	World Health Organization

CHAPTER 1
INTRODUCTION

Ninety percent of the 2.5 million children infected with HIV live in Sub-Saharan Africa (SSA) [1]. Despite significant increases in access to antiretroviral drugs (ARV) Prevention of Mother-to-Child (PMTCT) programs in resource-limited countries are fraught with major challenges and coverage is not complete. Consequently, many children continue to be infected perinatally with HIV. However, as a result of ARV access, these children are living longer [2]. Thus, a generation of children living with HIV (CLHIV) is coming of age. As these children approach adolescence, many of them have not been disclosed to, i.e. they have not been told they are living with HIV. The term *disclosure*, in this context, refers to informing children that they have HIV. World Health Organisation *Guideline on HIV Counselling for Children up to 12 years of Age* recommends that children of school age (6-12 years) be told they have HIV [3]. The American Academy of Pediatrics also recommends HIV status disclosure to school aged children [4].

Disclosure prevalence from four studies in developing countries ranged from 29% to 62 % [2]. Vaz et al. [2] reported only 3% pediatric disclosure in their study in the Democratic Republic of Congo, while Vreeman et al. [5] also reported almost 100% non-disclosure. More recent studies on SSA have similarly reported low disclosure rates - 13.5% (Nigeria), 21% (Ghana), 17.4% and 39.5% (Ethiopia), 19% and 26% (Kenya), and 32.6% (Cote d'Ivoire) [6-12]. Factors that influence pediatric disclosure include child's age and cognitive development, concerns around antiretroviral treatment (ART) adherence, imminent onset of sexual activity, and the need to protect others from infection. Benefits of pediatric disclosure include improved adherence to ART, and psychosocial well-being and mental health. Despite these benefits of disclosure, nondisclosure remains high because disclosure carries with it a negative exposure due to the association of HIV positive status and sex (promiscuity). Disclosure of HIV status to children living with HIV, or to partners, remains ‘navigation in a moral field’ [13]. Therefore to protect the family name and one’s reputation, and avoid rejection and discrimination, many choose not to disclose HIV status to children.

Literature on disclosure suggests that when disclosure does happen, it is not done in a systematic way [2]. The process remains largely context dependent. It is also not clear whether there are policies and guidelines on pediatric disclosure in many countries. Yet, disclosure could be a potent force in the prevention and control of HIV infection to those not infected, and for those who are already infected it provides an opportunity for improved quality of life for the HIV infected and their families, and slowing of disease progression.

This study, therefore, aimed to explore the association between pediatric disclosure i.e. disclosure of child’s seropositive HIV status, and health outcomes among children living with HIV in Nigeria: Is there any correlation between HIV disclosure and improved or worsened health – physical, psychological, or other dimensions of health? The study also aimed to assess the prevalence, patterns and predictors of HIV status disclosure to children. The study also looked at non-disclosure to determine if there were any relevant ethical issues to consider in pediatric disclosure, and how these would be applicable to the SSA context; and how disclosure policies and guidelines would facilitate or support HIV control measures.

While the literature review looked at pediatric HIV disclosure in all contexts, particular interest was on SSA, since most CLHIV reside in this part of the world. As much as possible, the literature review also attempted to tease out any regional differences, if any, on health outcomes and HIV disclosure.

Nigeria

Nigeria is the most populous country in Africa with a 2013 projected population of over 170 million people. Situated in West Africa, Nigeria is bordered by Niger Republic, Chad, Benin Republic, Cameroun, and the Atlantic Ocean. Its 36 states and Federal Capital Territory Abuja are further divided into 774 local government areas in six geopolitical zones (South east, South south, South west, North central, North east and North west). The main religions in the country are Christianity, Islam and Traditional religions.

HIV in Nigeria

With an estimated 3.4 million people (including 430,000 children under 15 years) living with HIV [1], Nigeria has the second highest number of persons living with HIV in the world, after South Africa. The first HIV case in Nigeria was reported in 1986. Since then the HIV prevalence rate has changed from 1.8% in 1991 to 5.8% in 2001, then 4.4% in 2005 and 4.1% in 2010. HIV prevalence is highest in urban areas. Each year, 215,130 persons die from AIDS, and 56,681 children are born with HIV [14]. The main route of HIV transmission in Nigeria is heterosexual sex. Low risk heterosexual sex contributes almost 50% of new infections [14]. Other modes of infection are injecting drug use, female sex workers and men who have sex with men, which contribute almost 25% of new infections. Illiteracy, poverty, sexually transmitted infections, low condom use and a lack of perceived personal risk have been identified as drivers of the HIV epidemic in Nigeria.

The HIV response in Nigeria was established in 1986, and was health sector driven. In 2000, a multi-sectoral response commenced. Antiretroviral therapy (ART) in Nigeria began in 2002, with a free ART program introduced in 2006. By December 2012, there were 566 ART facilities in Nigeria (up from 20 sites in 2002) providing treatment to 491,021 of the about 1.66 million persons in need of treatment [15].

The PMTCT program started in 2002 with six sites. By 2013, 5622 sites provided PMTCT services [16]. Guidelines to prevent perinatal transmission of HIV include providing prophylaxis of three antiretroviral medicines to pregnant women who test positive. The key strategies of the PMTCT program include testing women who are pregnant for HIV; providing antiretroviral drugs to women who are identified during pregnancy, or delivery, followed by ARV to the infant from birth and up to 6 weeks after birth, to prevent HIV transmission. Early infant diagnosis also ensures that children who are exposed (i.e. children born to HIV positive women) are identified early, and if HIV positive, are started on ART immediately.

In 2013 only 58,000 (or 27%) HIV-positive pregnant women received ARV prophylaxis to prevent transmitting the virus to their unborn or breastfeeding children [16]. Yet, 10% of new infections in Nigeria are due to mother to child transmission (MTCT) [15]. Spectrum modeling suggests that MTCT accounted for 24.5% of new infections in 2011. The main challenge to PMTCT service delivery is that only 35.8% of women deliver in health facilities where these services are provided, even though up to 60.6% of pregnant women attend antenatal clinics [17]. Also of the many women who are tested for HIV, fewer receive their HIV results, and far fewer commence ARV to prevent HIV transmission to their infants during pregnancy, delivery or breastfeeding.

Institute of Human Virology Nigeria

The Institute of Human Virology Nigeria (IHVN) is an indigenous nongovernmental organization, which until 2010 was affiliated with the University of Maryland Baltimore USA to implement the AIDS Care and Treatment in Nigeria (ACTION) program that was funded by the US President's Emergency Plan for AIDS Relief (PEPFAR). IHVN's pediatric ART program started in 2006. As at January 2012 IHVN's follow-on ACTIONPLUS pediatric ART program supported 36 health facilities in 18 of the 36 states in Nigeria and the FCT. Of the 89,509 persons on ART in 2012 the IHVN supported sites, 5,265 were children (0- 14 years).

Structure of this dissertation

The findings from this study are presented as follows in this dissertation: Chapter 2 presents the studies included in the literature review. Chapter 3 describes the study methods, while Chapter 4 presents the findings from the quantitative component of the study. These include the prevalence, patterns and predictors of HIV disclosure to children at the pediatric clinic at the University of Abuja Teaching Hospital (UATH). Chapter 4 also presents the limited analyses that could be done on the relationship between disclosure and health outcomes. (There were limited data on patient CD4 count, viral load and opportunistic infections in the patient paper and electronic medical records). Chapter 5 contains the findings from the qualitative component of the study. It presents the context and process of HIV disclosure to children. Chapter 6 – the plan for change - is a summary of the proposed strategies for disseminating the findings from the study in order to influence policy on pediatric HIV disclosure in Nigeria, and sub Saharan Africa, as well as programming for children living with HIV. The study instruments used in the study are contained in the appendices.

This dissertation adopted the three paper format. The following are the three papers presented in the dissertation:

1. The impact of disclosure on health outcomes in HIV-infected children: A literature review (Chapter 2). The target journal for publishing this paper is *AIDS Care: Psychological and Socio-medical Aspects of AIDS/HIV.*
2. Patterns, prevalence and predictors of pediatric disclosure among HIV-infected Nigerian children on treatment (Chapter 4). The target journal for publishing this paper is the *Journal of the International AIDS Society.*
3. The context and process of pediatric HIV disclosure among HIV-infected Nigerian children on treatment (Chapter 5). The target journal for publishing this paper is *AIDS Care: Psychological and Socio-medical Aspects of AIDS/HIV.*

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CHAPTER 2
THE IMPACT OF DISCLOSURE ON HEALTH OUTCOMES IN HIV-INFECTED CHILDREN: A LITERATURE REVIEW

INTRODUCTION

Ninety percent of the 2.5 million children infected with HIV live in Sub-Saharan Africa (SSA) [1]. Despite significant increases in access to antiretroviral drugs (ARV), Prevention of Mother-to-Child (PMTCT) programs in resource-limited countries are fraught with major challenges and coverage is not complete. Consequently, many children continue to be infected perinatally with HIV. In 2014, there were 220,000 new HIV infections in children 0-14 years globally. Of these, 190,000 were in SSA [2], and Nigeria contributed 60,000 of these in 2012 [3]. However, as a result of ARV access, these children are living longer [4]. Thus, a generation of children and children living with HIV (CLHIV) is coming of age. As these children approach adolescence, many of them have not been disclosed to, i.e. they have not been told they are living with HIV. The term *disclosure*, in this context, refers to informing children that they have HIV. World Health Organisation *Guideline on HIV Counselling for Children up to 12 years of Age* recommends that children of school age (6-12 years) be told they have HIV [5]. The American Academy of Pediatrics also recommends HIV status disclosure to school aged children [6].

Disclosure prevalence from four studies in developing countries ranged from 29% to 62 % [4]. Vaz et al. [4] reported only 3% pediatric disclosure in their study in the Democratic Republic of Congo, while Vreeman et al. [7] also reported almost 100% non-disclosure. More recent studies on SSA have similarly reported low disclosure rates - 13.5% (Nigeria), 21% (Ghana), 17.4% and 39.5% (Ethiopia), 19% and 26% (Kenya), and 32.6% (Cote d'Ivoire) [8-14]. Factors that influence pediatric disclosure include child's age and cognitive development, concerns around antiretroviral treatment (ART) adherence, imminent onset of sexual activity, and the need to protect others from infection. Benefits of pediatric disclosure include improved adherence to ART, and psychosocial well-being and mental health. Despite these benefits of disclosure, nondisclosure remains high because disclosure carries with it a negative exposure due to the association of HIV positive status and sex (promiscuity). Disclosure of HIV status to children living with HIV, or to partners, remains “navigation in a moral field” [15]. Therefore to protect the family name and one’s reputation, and avoid rejection and discrimination many choose not to disclose HIV status to children.

Literature on disclosure suggests that when disclosure does happen, it is not done in a systematic way [4]. The process remains largely context dependent. It is also not clear whether there are policies and guidelines on pediatric disclosure in many countries. Yet, disclosure could be a potent force in the prevention and control of HIV infection to those not infected, and for those who are already infected it provides an opportunity for improved quality of life for the HIV infected and their families, and slowing of disease progression.

This literature review, therefore, aimed to explore the association between pediatric disclosure i.e. disclosure of child’s seropositive HIV status, and health outcomes among children living with HIV: Is there any correlation between HIV disclosure and improved or worsened health – physical, psychological, or other dimensions of health? The review also aimed to assess the prevalence, patterns and predictors of HIV status disclosure to children. The literature review also looked at non-disclosure to determine if there were any relevant ethical issues to consider in pediatric disclosure, and how these were applicable to the SSA context; and how disclosure policies and guidelines could facilitate or support HIV control measures.

While the literature review looked at pediatric HIV disclosure in all contexts, particular interest was on SSA, since most CLHIV reside in this part of the world. As much as possible, the review also attempted to tease out any regional differences, if any, on health outcomes and HIV disclosure.

METHOD

Search Process: A multi-stage process was used to search for data on disclosure of HIV status to children living with HIV in 2011. First, the ISI Social Science website database was searched for relevant articles. This was followed by a search in the bibliography sections of these articles for other publications that were relevant i.e. pursuing references of references. Articles pertinent to the research question, "The Impact of Disclosure on Health Outcomes for HIV-Infected Children," were searched for in the ISI Web of Science database, using the terms arrangement as follows:

((Child* OR adolescent OR p*diatric OR perinatal*) AND (HIV OR status) AND (Diclos*))

Child(ren) OR Pediatric OR Paediatric OR Adolescent OR Perinatal(ly)	AND	HIV OR Status	AND	Disclosure OR Disclosing

The search strategy was repeated in 2014 for additional peer reviewed articles that may have been published since the last search. This second search was limited to studies conducted on SSA.

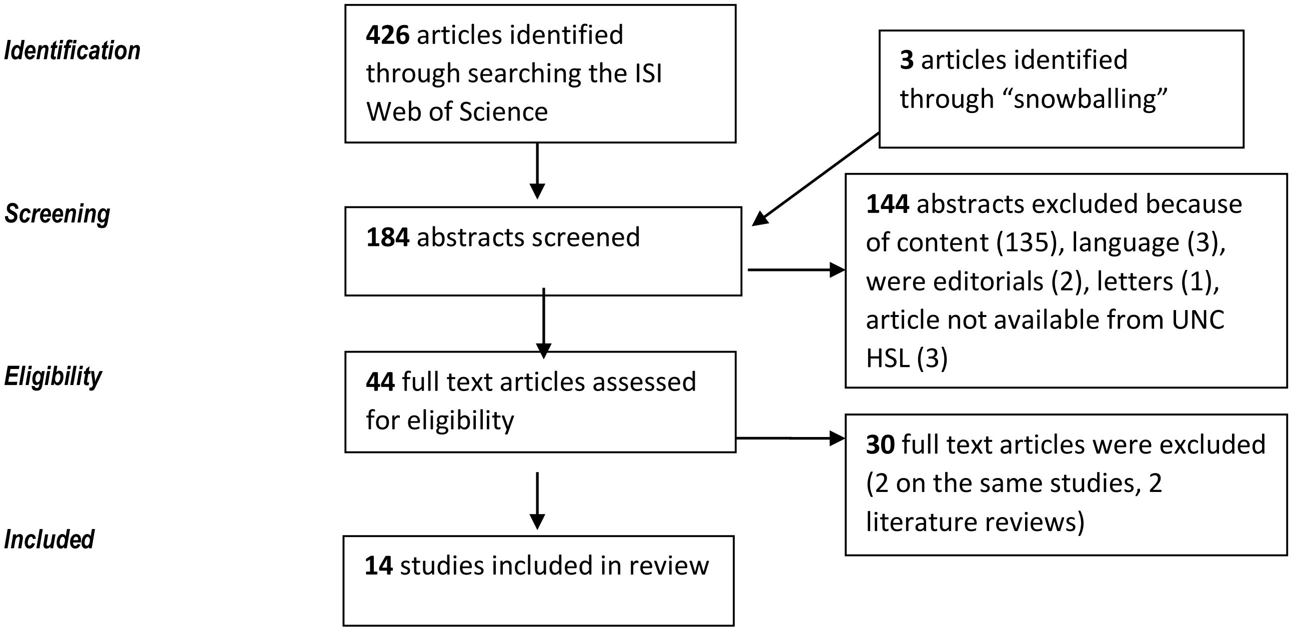
Inclusion criteria: Only articles on studies published in peer-reviewed journals were included in the review. Articles had to focus on disclosure of HIV status to children (persons under 18 years) living with HIV, and be based on primary data collection. Since it was anticipated that there would be a wealth of available primary data on the subject (and there were) secondary data (systematic reviews or meta-analyses) were not included in the review. Commentaries were also not included in the review. Studies could be qualitative or quantitative, or mixed methods. However, they had to contain an explicit definition of the term disclosure or a clear indication that children knew their positive HIV serostatus, and the consequences and outcomes of such disclosure as a dependent or independent variable. Studies could include reasons for disclosure, the process of disclosure and by whom. Studies could also focus on only children to whom their status had been disclosed to them, or also contain a control group whose status was not disclosed to them. The most important element was that studies were limited to those where full disclosure of HIV status was done. In other words, children knew they were HIV positive. “A child was considered to be fully informed of his or her status if the term HIV, AIDS, or any local term specifically associated with HIV/AIDS has been used in a discussion with the child about the child’s health” [4]. Reviewed articles also had to include a clear description of the population size, data collection process, the independent and dependent variables, and how data were analyzed.

Exclusion criteria: Studies on disclosure of other childhood illnesses other than HIV were not included. Also disclosure studies of status of others – adults, parents, and so on - were not included. Only studies where disclosure was by a parent, caregiver or health care provider were included. Studies where children learned of their serostatus inadvertently through sources other than parents, caregivers or health care providers were not included in the review, as it is believed that the effect of such disclosure may be different from that through a controlled environment through a parent/caregiver or health provider.

Studies where there was only partial disclosure i.e. discussing with children about the child’s health in general terms, without specific mention of HIV or AIDS, and non-English language articles were not included. There was no time limit or country or regional restriction to the studies or publications included in the review.

Identified studies: The 2011 search yielded a total of 426 articles. After a review of the article titles, 242 articles that were not relevant to the research question were eliminated from further search. Abstracts for the remaining 184 articles were reviewed, after which a further 144 articles were excluded because of content (135), three were in French, and the rest were editorials, articles and letters. Another three articles could not be retrieved from the UNC library. Full text of the 44 articles that appeared relevant to the research question was then reviewed for eligibility. Fifteen articles met the inclusion criteria, but two articles were publications on the same study, so one was eliminated from further review.

Figure 2.1: Flow Chart of the Identification of Studies included in the Review



An additional eight studies were identified from the 2014 search. While all reported disclosure rates and factors that affected status disclosure, only one study assessed the association between disclosure and health outcomes, namely ART adherence, and stigma and depression [13], and was included in the review.

Due to the limited number of studies that met the inclusion criteria, the inclusion of articles did not focus on their internal validity based on the study approaches, strong statistical power, or an experimental approach. Nor were the external validity of articles a limiting factor in terms of a large study population, random sample, and explicit analysis of context and intervention factors for which generalization is possible. (The impact is discussed under the Discussion section, as a limitation of the studies in this review).

Data extraction: The following data were then extracted from the studies that met the inclusion criteria. In addition to information on authors, year of article, and country where study was conducted, participant characteristics (study participants, children's age), and study characteristics (sample size, study type and design, type of analysis, dependent and independent variables, results, statistics, significance and study validity information), and the health outcomes of disclosure were extracted from the studies.

RESULTS

Five major health outcomes emerged from children's knowledge of their seropositive status (Table 2.1): Disease progression (CD4 count, death) and other physical outcomes; Adherence to antiretroviral treatment (ART); Self-esteem, mental, emotional and other psychosocial outcomes; and Sexual and reproductive health, including HIV prevention outcomes. The latter was particularly relevant to another theme that emerged from the results, that was not in the original review conceptualization – disclosure of status by the children to friends and sexual partners.

Physical outcomes

Three studies described the physical health outcomes of status disclosure in children living with HIV (CLHIV). The first, a comparison study of 325 Romanian children 5 – 17 years on antiretroviral treatment, some of whom had been told their serostatus and others who were non-disclosed, showed a significant difference in disease progression as measured by decline in CD4 % and death [16]. A Kaplan Meier survival analysis showed that non-disclosed children were more likely to die (p=0.03). Although there was no significant difference in CD4 decline, the trend was the same, with a greater proportion of non-disclosed children experiencing CD4 decline (p=0.26), and were more likely to experience death or CD4 decline than children who knew their status (p=0.03).

A 1997 multicenter Pediatric Spectrum of Disease (PSD) active surveillance study of 100 American school CLHIV in Massachusetts, however, did not show any association between clinical severity of children's symptoms (CDC clinical stage of mild, moderate or severe) with whether a child was told of his or her disease status [17]. Forty-eight percent of children with severe symptoms had been told of their status compared to 39% of children with mild to moderate symptoms. Similarly, Vreeman et al. did not find any associations between disclosure status and clinical indicators like CD4 count and WHO disease stage in their study of 792 caregiver-child dyads in Kenya [13].

Adherence to treatment

One would have expected more studies on the effect of disclosure on treatment adherence, since this is the reason most often given for promoting status disclosure. However, only three studies focused on the effect of disclosure of child's status to the child and treatment adherence. The quasi experimental study of disclosure's effect on 40 children on ART in Puerto Rico showed that over half (58%, 95% CI 41% - 73%) self-reported that knowing their status had helped them develop better adherence to their medicines [18]. All 25 adolescents and their caregivers in the South African qualitative study reported good adherence as a result of the children knowing their status [19]. In the Kenya study by Vreeman et al., disclosure status was not associated with adherence as reported on the clinical encounter form or by caregivers. However, disclosure was associated with child-reported adherence (p= .03), and disclosed children reported more non-adherence than non-disclosed children [13].

Mental and Psychosocial outcomes

Understandably, majority of the studies reviewed focused on the mental, emotional and other psychosocial effects of disclosure, since this is one of the reasons often cited for both disclosure and non-disclosure to children. Nine articles, four of which were on SSA, focused on this health outcome. While two of the articles were on the same Pediatric AIDS Clinical Trials Group (PACTG) 219 C prospective cohort study, the authors and foci of the two articles were different, and were therefore included as separate studies in this review. The first PACTG 219 C study focused on the effect of HIV disclosure on the quality of life (QoL) based on 2423 study visits by 395 CLHIV in USA [20]. The study showed that there were no statistically significant differences between pre-disclosure and post-disclosure quality of life domains (general health perception, symptom distress, psychological status, health care utilization, physical functioning, and social/role functioning). Disclosure was not significantly associated with QoL in crude or adjusted mixed effects model analyses, indicating that QoL did not change because of disclosure of HIV infection status. Caregivers reported lower QoL scores after disclosure for all domains except social/role functioning, although these differences were not significant. The other PACTG 219C study, however, reported that CLHIV were at increased risk of psychiatric hospitalization than the general pediatric population, and knowledge of seropositive status was significantly associated with increased risks of admission in this population [21]. Multivariate analysis showed that CLHIV who were aware of their status were six times more likely to be hospitalized because of psychiatric illnesses compared to those who were not, mostly for depression and behavioral disorders – which are precursors for more severe pathologic conditions, such as bipolar disorder and suicide.

The progression of patients' self-reported emotions after disclosure ranged from sadness immediately after disclosure to normalcy by most youth (70%, N=40, $p<0.05$) after six months of disclosure. However, one patient remained depressed six months after depression [18]. Lester et al., however, showed that disclosure of status may not necessarily minimize emotional distress, as HIV disclosure was associated with increased parent-rated anxiety in HIV-infected children ($p=.04$) [22]. This points to the need for further studies on the appropriate timing and type of disclosure of pediatric HIV [22].

A UK study of CLHIV [23] did not show any statistical difference in psychological (emotional and behavioral) adjustment than the general population, as measured by the Strengths and Difficulties

Questionnaire (SDQ score of 0.56 which approaches acceptability levels). However, a similar study in Zambia using the same SDQ methodology [24] showed increased mental health problems (OR = 2.1), especially emotional symptoms (OR = 3.6) and peer problems (OR = 7.1). Univariate analysis showed no difference between children who knew their HIV status and those who were aware of their status. However, the non-disclosure group was twice as likely to experience emotional difficulties (OR=2.63, 95% CI: 1.11 to 6.26).

The South African study by Petersen et al. [19] showed similar emotional difficulties for children who received a positive HIV diagnosis. Thirty-six percent (N=9) reported withdrawing from their friends and social activities, and over 50% reported internalized stigma. But for the eight children in an exploratory study in the Democratic Republic of Congo who knew their status, despite the negative emotions experienced at the time of disclosure, there were no (subsequent) negative effects of knowing their status [4]. Instead the benefits of knowing their status included no longer worrying so they could avoid being sicker, as well as being able to protect others from HIV infection.

The Kenya study of 792 caregiver-CLHIV dyads found that disclosed children experienced higher rates of HIV-related stigma and depression symptoms although only depression symptoms were significantly associated with disclosure in multivariate regression (OR =2.6, 95% CI 1.1-6.2) [13].

Sexual and reproductive health

Young CLHIV receive health services under pediatric care, and are often not being adequately prepared for adult life. Only one study focused on sexual and reproductive health (SRH) issues for CLHIV. In terms of SRH services, especially in relation to preventive practices, such as condom or contraceptive use among sexually active CLHIV, only 37% (N=236) of CLHIV in a Population Council study in Uganda reported using a condom at time of first sex [25]. Only 50% used any form of contraception in current or previous relationships, and 47% reported current condom use (All figures were statistically significant,

$p<0.05$). These are relatively high use rates compared to the general population, and especially for adolescent population [25].

Disclosure of status to others by children

Research has shown that self-disclosure of traumatic or secretive information produces observable health benefits [26]. In this regard, the focus is on whether self-disclosure influences health outcomes such as the immune response, psychological well-being and other health outcomes. Four studies on this issue met the inclusion criteria. Sherman et al. observed a small but significant increase in CD4 percent - a predictor for disease progression (mean = +1.78, SD =5.03, $t(63)=2.83$, $p<0.01$) in children who had self-disclosed to friends. This increase was still significant even when child's age was controlled in the analysis. An ANOVA for these data were also significant ($F(2,60)=4.28$, $p<0.05$). Psychological well-being as measured by self-concept did not approach significance ($F(2,60)=0.56$, $p>.15$). Similar ANOVA analysis for changes in behavioral problems also did not approach significance ($F(2, 5) = 0.69$, $p>0.15$).

Battles and Weiner [27] examined the psychosocial factors associated with long-term survival of pediatric HIV in 80 parent-child dyads of disclosed children. Pearson product moment correlations showed that disclosure was positively related to social support ($r=.35$, $p<0.05$), self-competence ($r=.35$, $p=.08$), and decreased problem behavior ($r= -.21$, $p<=.08$) except for public disclosure (i.e. disclosure to the media), where the Student's t-test showed a negative association with self-competence ($F=3.5$, $p<0.05$).

A small scale qualitative study of six program participants at a transition to adulthood program embedded in the National Health Service family clinic in the UK showed that participation in the transition program facilitated a positive attitude towards medication, and hope for the future. However, respondents reported not disclosing their status to others, including sexual partners [28].

DISCUSSION

Findings

The first major finding from this review is that HIV disclosure to children living with HIV has an effect on disease progression in terms of clinical severity of symptoms, CD4 percent and ultimately death. While the Romanian comparison study showed that HIV disclosure led to a slowing down of disease progression through higher CD4 percent [16], the US study did not show any impact of HIV disclosure on clinical severity of disease symptoms [17], nor did the Kenya study show any association with CD4 count [13]. It may be argued that the US study used a limited sample size, and no information on the statistical significance of the results was presented, compared to the more rigorous analysis of the Romanian study, which included adjusting for confounders. All the same, more prospective studies

Table 2.1: Overview of studies included in the literature review

	Authors	Study Goal	Country	Sample size	Study Type	Study Design	Type of analysis	Independent variable	Dependent variable	Results
A	**A: Physical outcomes**									
1	Ferris et al., 2007 [16]	Disclosure effect on disease progression	Romania	325	Quantitative and Qualitative	Comparison groups - disclosed versus non-disclosed; retrospective database analysis	Student t tests, chi square test, Fischer's Exact test, Cox regression models	HIV disclosure	Death, CD4 decline, combined, time to HIV disease progression	Death =4.9% vs 11.0%; CD4 17.3% vs 21.3%; Cox regression Hazard ration 0.60 (p=0.03). no statistical significant difference in CD4 decline between disclosed and non-disclosed children (p=0.26); non-disclosed children more likely to experience disease progression through death or CD4 decline (p=0.03). non-disclosed children were more likely to die ()
2	Cohen et al., 1997 [17]	Issues related to school attendance and HIV disclosure	USA	100	Surveillance	Abstraction of medical records	Logistic regression, using SAS, X^2,	HIV disclosure	Clinical severity of symptoms	49% of children with severe symptoms have been told compared with 39% of children with mild and moderate symptoms. Clinical severity of child's symptoms not associated with child's knowledge of status or not
3	Vreeman et al., 2014 [13]	Association between disclosure and key child level demographic, clinical, and psychosocial characteristics	Kenya	792 caregiver-child dyads	Cross – sectional, quantitative	Comparison groups – disclosed and non-disclosed children, medical chart review	Pearson's chi-squared test, multivariate logistic regression with odds ratio	HIV disclosure	Clinical characteristics – adherence, CD4 count, CD4 %, WHO staging	No association between disclosure and WHO staging (p=0.079), and CD4 count
	B: Adherence to treatment									
1	Blasini et al., 2004 [18]	Disclosure model	Puerto Rico	40 CLHIV	Quantitative	Quasi experimental, before after,	Fisher's exact test, report p values for two-tailed test	HIV disclosure	Sadness, worry, insecurity and other psychosocial outcomes	42% CLHIV felt sad immediately after disclosure. At 6 months, 70% youth reported normalcy. One patient reported depression after 6 months. 58%, 95% CI reported better adherence

2	Petersen et al., 2010 [19]	Examine psychosocial challenges and protective factors	South Africa	25	Qualitative		thematic using NVivo8	HIV disclosure	Identity, psychosocial issues, internalised stigma	22 CLHIV knowing status emotionally difficult; 36% (9) withdrew from friends; >50% showed internalised stigma; 100% good adherence
3	Vreeman et al., 2014 [13]	Association between disclosure and key child level demographic, clinical, and psychosocial characteristics	Kenya	792 caregiver-child dyads	Cross – sectional, quantitative	Comparison groups – disclosed and non-disclosed children, medical chart review	Pearson's chi-squared test, multivariate logistic regression with odds ratio	HIV disclosure	Clinical characteristics – adherence, CD4 count, CD4 %, WHO staging	Disclosure was associated with child reported adherence (p=0.03) with disclosed children reporting more non-adherence than non-disclosed children
	C: Mental and Psychosocial outcomes									
1	Vaz et al., 2010 [4]	Explore events before, during and after disclosure	Democratic Republic of Congo	8	Qualitative			HIV disclosure	Worry; protect others from infection	Children felt sad immediately after disclosure; but later did not state any negative effect of knowing their status; benefits included not being worried and avoid being sicker; being able to protect others.
2	Sopena et al., 2011 [23]	Psychological adjustment	United Kingdom	30	Quantitative	Correlational design,	Pearson correlations	HIV disclosure	Psychological adjustment (behavioural and emotional); disclosure to others	Psychological adjustment score = -1.03. p>0.05, no significant differences btw CLHIV and general UK population
3	Menon et al., 2007 [24]	Relationship between disclosure and mental health	Zambia	127	Quantitative, Qualitative	Cross sectional survey	Mann Whitney U test, Spearman, content analysis	HIV disclosure	Emotional, conduct, hyperactivity, peer relations, pro-social behaviour	Difficulties 29.1% (N=37) OR2.1 (CI 95%); increased mental problem OR=2.1), peer problem (OR=7.1), emotional symptoms (3.6). Those whose status not disclosed more likely to score abnormal range for emotional difficulties (OR=2.63, 95% CI). Disclosure did not have negative impact on mental health

4	Gaughan et al., 2004 [21]	Examine long term outcomes among CLHIV and nonCLHIV	USA	2298 CLHIV, 1021 nonCLHIV	Quantitative	Prospective cohort study (PACTG) 219C	Relative risks using Poisson rate parameters; Cox proportional hazards regression techniques	HIV disclosure	Psychiatric hospitalisation	CLHIV incidence of 6.17 cases per 1000 person years (CI 95%) versus 1.7 cases per 1000 person years for non CLHIV.CLHIV aware of their status were 6 times more likely to be hospitalised due to psychiatric illnesses, compared to CLHIV not aware of their status (hazard ratio 6.13). Depression and behavioural disorders were most common reasons for hospitalisation. knowledge of HIV status significantly associated with increased risk of psychiatric hospitalisation
5	Butler et al., 2009 [20]	Impact of disclosure on quality of life	USA	395 CLHIV (2423 study visits)	Quantitative	Prospective cohort study	Spearman's, Pearson's, Wilcoxon signed rank tests	HIV disclosure	QoL (general health perception; symptom distress; psychological status, physical functioning; social/role functioning, health care utilisation	Health perception 0.410 (P=.70); symptom distress 0.588 (P=.31), psych status 0.005 (P>0.999), physical functioning 0.536 (P=0.79); social/role functioning 0.380 (p=0.69); health care use -0.275 (p=.61). No statistically significant difference between pre and post disclosure quality of life; caregivers reported lower QoL scores after disclosure, though not stat significant
6	Lester et al., 2002 [22]	Explore factors associated with emotional distress in CLHIV	USA	51	Quantitative and Qualitative		Content data analysis; Kaplan Meier survival curves, multiple linear regression	HIV disclosure	Child's parent rated anxiety level	Higher anxiety significantly associated with HIV disclosure; (t=2.15, p=.04). Child rated depression or anxiety showed no association with HIV disclosure. Disclosure does not necessarily minimise emotional distress
7	Blasini et al., 2004 [18]	Disclosure model	Puerto Rico	40 CLHIV	Quantitative	quasi experimental, before after,	Fisher's exact test, report p values for two-tailed test	HIV disclosure	Sadness, worry, insecurity and other psychosocial outcomes	42% CLHIV felt sad immediately after disclosure. At 6 months, 70% youth reported normalcy. One patient reported depression after 6 months. 58%, 95% CI reported better adherence
8	Petersen, et al., 2010 [19]	Examine psychosocial challenges and protective factors	South Africa	25	Qualitative		Thematic using NVivo8	HIV disclosure	Identity, psychosocial issues, internalised stigma	22 CLHIV knowing status emotionally difficult; 36% (9) withdrew from friends; >50% showed internalised stigma; 100% good adherence

9	Vreeman et al., 2014 [13]	Association between disclosure and key child level demographic, clinical, and psychosocial characteristics	Kenya	792 caregiver-child dyads	Cross – sectional, quantitative	Comparison groups – disclosed and non-disclosed children, medical chart review	Pearson's chi-squared test, multivariate logistic regression with odds ratio	HIV disclosure	Clinical characteristics – adherence, CD4 count, CD4 %, WHO staging	caregiver-reported depression symptoms (OR 2.63, 95%CI 1.12–6.20) were significantly associated with knowing one's status
	D: Sexual and reproductive health outcomes									
1	Birungi, et al., 2009 [25]	Sexual expressions of CLHIV	Uganda	740	Qualitative and Quantitative		Quantitative - cross tabs, chi square, significance tests of proportions; Qualitative - content analysis	HIV disclosure	Condom use, contraceptive use; status disclosure to others	Condom use 37%; contraception 50%; disclosure to partner 38%, p<0.05; condom use 37%; contraception 50%; disclosure to partner 38%
	E. Child's disclosure of status to others									
1	Sherman et al., 2000 [26]	Physiological and psychological consequences of children's self-disclosure	USA	64 CLHIV-caregiver dyads	Quantitative	Before-after, comparison groups	Univariate ANOVA, $X^{2,}$ Tukey's Honestly Significant Difference test,	Child's self-disclosure	CD4% (disease progression), self-concept, behavioural problems	Disease progression: CD4% showed small but significant increase (mean =+1.78, SD=5.03); t(63)=2.83, p<.01); ANOVA data significant: F(2,60)=4.28, p<.05; Self-concept did not approach significance, F(2,60)=0.56, p>.15; Behavioural problems also did not approach significance, F(2,57)=0.69, p>.15. Even with child's age controlled, self-disclosure to friends was associated with significantly greater CD4% change
2	Campbell et al., 2010 [28]	Impact of transition program	UK	6	Qualitative		Thematic approach	HIV disclosure	Disclosure to others; hopes for the future	100% difficulty disclosing to others; hopeful about future # not included)

3	Battles et al., 2002 [27]	Examine psychosocial factors associated with long term survival of pediatric HIV.	USA	80 parent-CLHIV dyads	Quantitative	Descriptive. Longitudinal study	Pearson product moment relations, Chi-square, Student's t	HIV disclosure	Child behaviour, self-perception,	Disclosure significant positive association with peer social support (r=.35, p<.05), marginally negatively associated with aggressive behaviour (r=-.21, p=.08, marginally positively associated with perceived social self-competence (r=.35, p=.08. Pearson product-moment correlations showed disclosure was positively related to social support, self-competence, decreased problem behaviour, except for public disclosure, where Student t showed negative association with global self-competence.
4	Birungi, et al., 2009 [25]	Sexual expressions of CLHIV	Uganda	740	Qualitative and Quantitative		Quantitative - cross tabs, chi square, significance tests of proportions; Qualitative - content analysis	HIV disclosure	Condom use, contraceptive use; status disclosure to others	Condom use 37%; contraception 50%; disclosure to partner 38%; p<0.05; condom use 37%; contraception 50%; disclosure to partner 38%

CLHIV = Children living with HIV

on larger sample CLHIV populations are needed to draw any definitive conclusions on the effects of HIV disclosure on disease progression and severity.

The second major health outcome of HIV disclosure was ART treatment adherence. Since ART is life long, one recurring challenge for caregivers and CLHIV is how to maintain treatment adherence. With ART, a high adherence level of up to 95% or more is necessary to avoid drug resistance and its very serious consequence of treatment failure. As such ART adherence is a critical factor in managing HIV infection. One would, therefore, have expected more studies on the effect of disclosure on CLHIV treatment adherence, since this is the reason most often given for promoting status disclosure. However, only three studies focused on the effect of disclosure of child's status to the child and treatment adherence [13, 18, 19]. As expected, the children and their caregivers reported improved adherence to treatment as a result of the children knowing their HIV status. Incidentally, the small sample sizes (40 and 25) and the less than rigorous analyses limit any broad conclusions on the impact of disclosure on treatment adherence. This review, therefore, calls for more studies considering the importance of adherence on HIV treatment.

Understandably, majority of the studies focused on the mental, emotional and other psychosocial effects of disclosure, since this is one of the reasons often cited for both disclosure and non-disclosure to children. Five of the nine studies in the review reported a negative impact of disclosure on some aspect of mental health, while four did not. Only three of the studies (two in the US, and from the same PACTG 219C prospective study and one from Kenya) had sufficiently large sample sizes, but both US studies reached differing conclusions. While Butler's 2009 study [20] of 2423 visits of 395 CLHIV did not show any statistically significant difference between pre and post HIV disclosure on QoL (general health perception; symptom distress; psychological status, physical functioning; social/role functioning, health care utilization), Gaughan et al. [21] showed in their study of 2298 CLHIV and 1021 children not living with HIV that knowledge of HIV status was significantly associated with increased risk of psychiatric hospitalization, with CLHIV who were aware of their status being six times more likely to be hospitalized due to psychiatric illnesses, compared to CLHIV not aware of their status (hazard ratio 6.13). It is not clear what the reasons could be for the different conclusions from the two studies. A possible explanation for the different conclusions could be that while Butler et al. measured pre and post disclosure QoL changes in the same CLHIV, Gaughan's study compared psychiatric hospitalization in HIV disclosed CLHIV to children not living with HIV. The experience of a significant life event (such as death in the family, beginning school) also contributed to the positive correlation between disclosure and hospitalization, and may partly explain the contrasting conclusions from the studies. Although the Kenya study by Vreeman [13] had a large sample of 792, and reported higher rates of depression and stigma among disclosed children, the study was not designed to assess the impact by pre- and post-disclosure characteristics.

The only study on the impact of disclosure on SRH outcome showed a positive and statistically significant correlation between disclosure and condom use and contraceptive use rates that are even much higher than the general population rates for adolescents, in addition to status disclosure to partners [25]. Obviously, this is a less well researched area and further studies are needed [25].

Finally, a child's knowledge of their HIV status, and the child's subsequent disclosure of their status to others (friends and sexual partners) had an effect on child's health outcomes. Three of the four studies showed a positive correlation between child's disclosure of their status on the child's health outcome, such as increase in CD4 percent [26], increased self-competence and decrease in problem behaviour [27]. The UK study of six children showed none of the children disclosed their status to sexual partners [28].

Implications and Recommendations

Disclosure of a child's HIV status to the child has value in terms of positive health outcomes for the child, such as better adherence and slower disease progression [16]. Yet, there does not seem to be a systematic or coherent system for child disclosure. One recommendation from this review, therefore, is the need for government and program policies and guidelines that will promote child HIV disclosure in order to address the current low rates of disclosure in SSA. To date, no SSA country has developed detailed disclosure guidelines. However, WHO has published *Guideline on HIV Counselling for Children up to 12 years of Age* for adaptation in countries [5]. As more CLHIV are of school age, such policies and guidelines also need to include disclosure to education personnel in the school environment, as well as how to build capacity in the school environment to limit stigma and facilitate support for CLHIV in schools. Although the decision to inform schools of the child's HIV status should remain a family decision, providers and program managers can facilitate the process and help build family capacity to do this [17].

Disclosure may not always be beneficial, as negative effects may manifest both in the short and longer term, such as precipitated psychiatric issues [21]. While it is not clear how much of a challenge this is in SSA, or whether the resulting psychiatric illness is due to HIV or other psychosocial factors, clinicians need to set up systems to monitor and identify warning signs of psychiatric illness, and establish systems for referrals for mental health services [21]. Programs that not only address clinical needs of children but other aspects of child well-being, including psychosocial, life skills, for instance., self-competence, and SRH needs, as well as psychosocial support programs for caregivers are also needed.

Programs that adequately address the SRH needs of CLHIV are a clear need from this review, especially as many CLHIV are growing into adolescence and beginning sexual activity. It is critical to reorient health care providers to address their ability and willingness to provide services for HIV prevention, and contraceptives to CLHIV. They also need to emphasize status disclosure, especially in discordant relationships (where one partner is not living with HIV), and encourage consistent condom use to prevent further infection of CLHIV and others [25].

Research gap

Only five of the 15 studies included in this review were conducted in sub-Saharan Africa (none in West Africa), two of which had very small sample size of 8 and 25, and limited the ability to perform rigorous analyses that will also focus on causality, and not just correlations. However, currently 90% of CLHIV live in SSA, with ~15% of them living in Nigeria alone [1]. Clearly, therefore, a major recommendation is the need for more studies on SSA, especially as the different cultural, social and economic environment in SSA may (or may not) influence health outcomes and HIV disclosure differently. Another recommendation is for more studies of larger sample size, and more rigorous analyses – not only for studies on SSA, but also for studies from other regions (the US and elsewhere), as nine of the 15 studies reviewed were of sample size 100 or less.

Studies in this review focused mostly on children infected perinatally. However, it is not clear if there will be differences in health outcomes between perinatally acquired HIV and non-parental transmission (such as, blood transfusion, and sexual transmission) and differences in disclosure and health outcomes. Experiences of youth who learn of their status accidentally (outside of their families or health providers) also need to be studied. Programs also need a better understanding of disclosure on school attendance and performance, and to study the complex social needs of HIV positive children, as these relate to the school environment [17].

Current studies have limited information on the disclosure process and context. There is need for a better understanding of the appropriate process, context, and child's age for disclosure of status, and how these impact on health outcomes [4]. The WHO pediatric disclosure guidance also recommends further research on who is best positioned to disclose to the child; and what factors can promote or act as barriers to disclosure [5]. Such studies could provide important information for policy development and guidelines on pediatric HIV disclosure. Studies of physical health outcome also need to include other markers of HIV disease progression, such as viral load, clinical status and/or growth velocity [16]. Furthermore, more studies adapted for SSA are needed that use standardized measures to assess emotional health.

Limitations

This review and the interpretation of the findings presented here have several limitations. First, only one database was searched. It is likely that widening the study search to additional databases, such as PubMed, would have yielded other relevant studies. Also, with only one reviewer, the study review process did not benefit from a second opinion where there were uncertainties on whether to include a study or not. The third limitation is the very small sample size of most of the studies. This limited the sophistication of analyses that could be performed by the researchers, including adjusting for confounders. As such, very limited conclusions can be drawn from the studies. Fourth, most of the studies were cross sectional. Therefore, only correlational inferences between disclosure and health outcomes could be made, without establishing causality.

Fifth, key terms were not defined in most studies. While a few studies used standard tools developed and tested for psychometric studies [20], [21], [23], [24], in majority of the studies, it was up to the investigator to determine how anxiety, depression, and other key terms were defined and conceptualized in the studies. While CD4 count (and percent) was used as a key indicator for disease progression, inclusion of other indicators, such as the number and severity of adverse health events as stronger indicators of HIV disease progression, would have made the studies better [16]. Finally, most of the studies included in the review were conducted outside sub-Saharan Africa. It is not clear if similar findings will be obtained if the studies are repeated within the SSA context.

CONCLUSION

This review highlights that HIV disclosure to CLHIV does have an effect on health outcomes – physical, psychological, treatment adherence, SRH, and status disclosure to others - albeit the different studies did not always reach the same conclusions. There is a very clear need for more studies on SSA, the region where the majority of CLHIV resides, as well as more rigorous and longitudinal studies, with larger study samples that will allow for more sophisticated analyses that can establish causality. Information from these studies would also be valuable to countries and program managers to develop HIV disclosure policies and guidelines, and programs that improve the well-being of CLHIV and their caregivers.

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CHAPTER 3
METHODOLOGY

STUDY DESIGN AND METHODS

The cross-sectional, facility-based study consisted of (1) a quantitative evaluation that used a combination of primary data collection and secondary data analysis to characterize *pediatric disclosure* (defined as disclosure of child's seropositive HIV status to the child or informing the child that s/he has HIV) and explored its association with health outcomes in Nigerian children; and (2) a qualitative component to determine the context and process of disclosure to children.

The central research question for the quantitative component was: *"Is there any association between pediatric HIV serostatus disclosure and the child's health?* In other words, "*Does HIV disclosure have any association with improved or worsened child's physical (clinical) health outcomes?"* The study also aimed to describe the rates and context of disclosure in a cohort of children in Nigeria.

The main study objectives were the following: In Nigerian children on ART,

1. Determine the rate and nature of HIV status disclosure, and identify the main agent (family, healthcare worker, religious leader, school staff) of disclosure to these children
2. Determine and document the age at HIV disclosure among disclosed children
3. Investigate locally pertinent barriers to, and facilitators of disclosure among disclosed and non-disclosed children
4. Investigate associations between disclosure, and health outcomes, namely: CD4 count, opportunistic infections, adherence to ART, and viral load.

The independent variable was HIV status disclosure (disclosed or not disclosed). Key dependent variables that were examined were the following health outcomes: changes in CD4 count (CD4 decline), frequency of opportunistic infections, treatment adherence, and viral load. Due to the cross-sectional design of the study, it was not possible to establish causality. The focus of the study was, therefore, to determine if there was any association between key dependent variables and disclosure.

Study setting

This study was conducted at the pediatric antiretroviral treatment (ART) clinic of the University of Abuja Teaching Hospital (UATH) in the Federal Capital Territory Abuja, Nigeria, between February and July 2015. This ART program is supported by the US President's Emergency Plan for AIDS Relief (PEPFAR) through the AIDS Care and Treatment in Nigeria (ACTION) program of the Institute of Human Virology Nigeria (IHVN). At the time of the study, a total of 401 children were currently receiving ART at the clinic. Of these, 35 (8.7%) were 0 – 5 years; 177 (44.1%) were 6 – 9 years; 139 (34.7%) were 10 – 14 years; and 50 (12.5%) were ≥ 15 years.

The pediatric clinic runs an "adolescent clinic" for older children, once every month. During this clinic, nurses and adherence counsellors provide health talks to the older children and their parents, before they meet with the doctor for consultation. The adherence counsellors also assess patient adherence, and provide counselling, as part of each patient's visit to the clinic. Clinic staff (doctor, nurses and counsellors) also assist parents/caregivers with status disclosure to the children when necessary. However, there is no set pattern or procedure for how disclosure takes place. Some of these older children come unaccompanied to the clinic for their visits.

Sample size calculation

Previous studies on disclosure in Nigeria showed very low rates of HIV disclosure to children. Therefore, the sample size that could capture a sufficient number of disclosed children, based on the proportion of children expected to be disclosed, was determined as follows:

$n = (Z/MoE)^2 * p * (1-p)$

Where

n = sample size

z = 1.96 (95% CI)

MoE = margin of error = 5%

p = disclosure rate (= average 10% based on two studies in Nigeria: Brown et al. at 13% [1] and Tepper et al, – personal communication, at 7%)

$n = (1.96 * 1.96 * 0.10 * 0.90)/(0.05 * 0.05)$

=138.2976

= 140

The study therefore, sought to sample a total of 140 children.

Study participants

Study participants were CLHIV ≥ 6 years currently prescribed antiretroviral medications for treatment of HIV disease based upon relevant Nigerian Guidelines for ART [2], regardless of time of enrollment, or adherence to regimen, with no planned treatment interruptions at the study site. A total of 110 parents/caregivers of these current pediatric ART patients at the clinic were selected for the study. The principal investigator (PI) did not have any direct contact with the CLHIV. The quantitative component of the study involved administering a questionnaire (Appendix 1) to the 110 parents/caregivers of pediatric ART patients; and also extracting health data on the children from their medical records, using a data extraction form (Appendix 2). The qualitative component consisted of in-depth interviews by use of an interview guide (Appendix 3) with a total of 15 parents/caregivers of disclosed children to determine the context and process of disclosure to the children. Only families receiving pediatric ART were in this clinic. It was not expected that a family will be in the clinic for any other reason besides HIV treatment, as this was a pediatric ART clinic.

Participant recruitment and study procedure

Parents/ caregivers of every eligible pediatric ART patient who visited the clinic for their regular consultation were invited to participate in the study. After the medical consultation with the medical provider (doctor), the doctor read out information from the study recruitment form pre-approved by both the University of North Carolina at Chapel Hill, USA and the UATH institutional review boards to the parents/ caregivers. The doctor asked those who agreed to participate in the study to meet with the PI. The PI then presented more detailed information about the study to potential participants. Thereafter, the PI consented the respondents who agreed to participate, and administered the study tools. Participants were informed they could terminate the discussion at any time.

A: Quantitative component: The PI interviewed those who agreed to participate in the study by administering a semi-structured questionnaire. The questionnaire format was in sections – icebreaker, disclosure status (whether child had been disclosed, or not), and socio-demographic data. In closing, the participants were invited to ask any questions they had.

If child was disclosed, the questionnaire asked for age at disclosure, who disclosed the child's status, where status disclosure took place, and the reasons for disclosure. For parents/caregivers who had not disclosed to their children, the PI obtained reasons for nondisclosure and other concerns. The questionnaire also captured socio-demographic data about the caregiver and the child, including relationship of respondent to child (i.e. if biological parent or other relative), and other characteristics of the family. The administration of each questionnaire lasted about 20 - 25 minutes (including consent time). The interviews were conducted in the absence of the children to prevent accidental disclosure. Questionnaires were administered in English, Pidgin English, or Hausa through an interpreter. The PI continued with participant recruitment until the end of June 2015 when 110 participants had been recruited, and interviewed.

For each completed questionnaire, secondary data on dependent variables – CD4 count, opportunistic infections, WHO staging, viral load, and treatment adherence - were later extracted from patient’s paper charts for all 110 children. Extracted data spanned the period 2013 to 2015. Other extracted data included patient age, date ART was started, and ART regimen. Not all patient paper medical records were available. For the eight missing paper files, patient data were extracted from electronic medical records (which often contained less data required for the study than paper records). The data extraction process did not involve any direct contact with the children or their parents/caregivers.

B: ***Qualitative component*****:** A total of 15 parent/caregivers of children who reported their child had been disclosed to during the administration of the study questionnaire (described above) were also interviewed using an interview guide, to determine the context of HIV disclosure to the child, in order to more fully understand how the disclosure process happened – how, where, who, and when, and other pertinent issues arising from the interview. The interview, was designed to be conversational and used probes to explore unexpected themes, and elicit a description of the process by which parents/ caregivers made the decision to disclose, and disclosed to the child, and what terms were used to explain the illness to the child, including whether terms “HIV”, “AIDS” or any local term was specifically mentioned to the child during the disclosure process. The interview also explored parent/caregiver perceptions of the effects that disclosure had on the child, including but not limited to the child's emotional reaction to the diagnosis. For a child to be determined as fully disclosed, the term HIV or AIDS or a local equivalent term must have been used in discussion with the child about the child's health by parent/caregiver, or healthcare worker [3].

The PI took notes during the interviews. No participant agreed to be audiotaped, so the interviews were not recorded on a voice recorder. Each interview lasted for 20 – 25 minutes.

Pre-test: The survey questionnaire and interview guide were pretested with two parents/caregivers at the ART site. These were not included among the final 110 parents/caregivers in the study analyses. The main aim of the pretest was to enable the PI fine-tune the study instruments, if necessary. The pretest also involved linking the questionnaire responses to the data extraction form. At this point, patient identifier coding modalities were finalized to ensure confidentiality of data and protection against deductive disclosure of participant identity through linking the questionnaire and medical data to the patient.

The questionnaire and interview were administered in the subject's language of choice, and where this was different from the interviewer's language, with the help of an interpreter, who was a health care worker at the clinic. Since there are many Nigerian languages, the questionnaire was not translated into Nigerian languages. Since many of the parents/caregivers were themselves HIV-positive and receiving treatment at the adjoining adult ART clinic, it was usual for parents to leave their children in the pediatric clinic, while they consulted with the doctor at the adult clinic.

In all, a total of 298 participants (not unique patients) were recruited for the study (Table 3.1). Patient's name and other personal identifiers were not collected on the data collection instruments (questionnaire, interview guide or patient data extraction form). Instead, the patient's file/chart number were noted in a notebook that was kept separately from the completed questionnaires. This enabled the PI to later retrieve information on child's CD4 count, adherence, opportunistic infection, WHO staging and viral load.

Table 3.1: Overview of Study Design

Study Focus	Study component	Study Tool	Participant Type	Max. # participants
Disclosure status	Quantitative	Questionnaire (Appendix 1)	Parents/caregivers of CLHIV	140
	Quantitative	Data Extraction Form (Appendix 2)	CLHIV	140
Disclosure context	Qualitative	Interview Guide (Appendix 3)	Parents/caregivers of CLHIV	15
Pre-test of Study tools	Pre-test	Questionnaire Data extraction form Interview Guide (Appendix 1, 2, 3)	Parents/caregivers	3
			TOTAL	**298***

* Not unique patients

The study then sought to compare the group of disclosed children with non-disclosed children in terms of differences in health outcomes – CD4 count, number and frequency of opportunistic infections, viral load, and ART adherence during the three year study period. Below is the sequencing of the study components:

Step 1: A recruitment letter with information on the study was read out by the doctor to each parent/caregiver of an eligible child at the end of their medical consultation.

Step 2: Questionnaires were administered by the PI to 110 consented parents/caregivers of current pediatric ART patients.

Step 3*:* Interview Guide was administered to 15 parent/caregivers of children who reported their child had been disclosed to during the administration of the study questionnaire (Step 2 above).

Step 4: For each completed questionnaire, information on patient's CD4 count, treatment adherence, viral load, WHO staging and opportunistic infections was extracted from the patient's paper charts or electronic records, using a data extraction form.

Definition of key terms and variables

Children living with HIV: For this study, this was limited to children ≥ 6 years enrolled in the pediatric ART program at UATH. Enrollment for ART was deemed sufficient evidence of positive HIV sero-status.

Pediatric disclosure: Defined as informing the child that s/he had HIV, regardless of whether it was intentional or accidental.

Disclosure status: Children were categorized as disclosed or non-disclosed depending on whether they knew of their HIV positive status or not – as reported by the parent/caregiver. Information on disclosure status was gathered through the questionnaire that was administered to parents/ caregivers. A "Yes" response by the parent/caregiver to any of the questions: (1) Does child know s/he has HIV?; (2) Does child know s/he comes to clinic for HIV care?; (3) Does child know that the name of his/her sickness is HIV?; or (4) Does child know that s/he is taking medicine for HIV? was taken as evidence of child's disclosure, while a "No" was considered non-disclosure [4].

Parent/caregiver: Defined as an adult aged 18 years and over who was responsible for the day-to-day care of the minor (pediatric ART patient), including biological parents identified through eligibility screening by health care providers at the study site.

CD4 decline: CD4 count (or CD4% if child is less than 5 years of age) is a measure of the body's immune system response to HIV, with higher CD4 values suggesting a stronger immune response. A CD4 count taken before or within the first six months of ART initiation were defined as the baseline CD4 count. Changes in subsequent CD4 were measured against this baseline to determine if CD4 count had declined. In the case of untreated HIV infection CD4 cell count may decline, but a rebound may be observed with good adherence to ART. Therefore, CD4 measurement is important because it is a practical sign of both disease progression and adherence to ART [2]. Since CD4 count is expected to remain stable, or increase when on ART, when a decline in CD4 is observed, it is often an indication of poor adherence. A CD4 count of ≥500 cells/ml is associated with good viral suppression, while a CD4 count of 200 to 499 cells/ml is considered moderate viral suppression. Counts below 200 cells/ml are considered severe immune suppression. A minimum of two valid CD4 counts taken during the three year study period were required for inclusion in the analysis. CD4 decline was considered to have occurred if, for any two consecutive CD4 counts (or between baseline and subsequent CD4 count), the later CD4 count was lower by a value of up to 50 cells/ml and crossed between the various thresholds (severe, moderate or no immune suppression) [5]. The requirement for the difference in CD4 value of 50 cells/ml was to ensure that the decline was clinically significant [5]. Data on CD4 count were extracted from the patient's paper or electronic medical records. CD4 counts were measured every three months at UATH.

Frequency of opportunistic infections: Data on incidents of opportunistic infections in pediatric ART patients were limited to those available in patient paper or electronic medical records. Opportunistic infections of interest were limited to serious ones (WHO stage 3 and 4) such as tuberculosis, esophageal candidiasis, and cryptococcal meningitis. Opportunistic infections that had occurred or were treated outside of the ART clinic and/or not recorded in the patient treatment records were not included in the analyses. The study sought to compare the average number of times patients received treatment to manage opportunistic infections at the study site (proxy for number of episodes) for disclosed versus non-disclosed children.

ART (Treatment) adherence: Treatment adherence meant not missing doses of prescribed medication. Patient medical records on ART adherence are updated during patient visits based on patient reported missed doses. Antiretroviral drugs (ARV) are dispensed to patients on a monthly basis at the commencement of ART. Thereafter, ARV is dispensed on a two-monthly basis. Treatment adherence is measured in percent, with a minimum of 95% adherence (i.e. not missing more than three doses per month or one dose in ten days, of a twice daily regimen) required to prevent drug resistance [6]. The average of all adherence data for the three year study period that was available in the paper or electronic medical records were calculated for each patient. Non-adherence was therefore missing doses in the past 30 days [4]. Average adherence rates less than 95% were considered non-adherence. Average adherence ≥95% was considered adherence.

Viral Load: Viral load is a measure of viral burden in the blood. The more HIV reproduces in the body, the higher the viral load. Viral load is measured as number of copies of viral particle per milliliter of blood. It is an objective assessment of how the body is fighting HIV, and of the efficacy of, and adherence to, HIV treatment. Viral load together with CD4 count provide a good picture of how the body is fighting HIV. Monitoring CD4 counts and viral loads during treatment helps the doctor assess how well the patient responds to their prescribed treatment. Low viral load indicates successful adherence to treatment. Under optimal conditions, administration of ART should lead to rapid and sustained suppression of viral load. Usually by week 24 following initiation of treatment, a patient's viral load should be at the least < 400 copies/ml. The ideal is sustained viral suppression at 50 copies/ml for as long as possible to halt, prevent or delay disease progression [2]. Ideally, in the treatment-naive patient viral suppression to <50 copies/ml should be achieved and sustained by 16-24 weeks following commencement of ART. Therefore, virologic failure is described as viral load not suppressed to undetectable levels (<400 copies/ml) after 6 months on ART; and viral load not suppressed to undetectable levels (<50 copies/ml) after 12 months on ART. Viral load measurements were taken every six months for each patient at UATH.

For the purposes of this study, therefore, patients on treatment for up to six months, but less than 12 months, were expected to have viral load suppressed to undetectable levels (<400 copies/ml), to be considered adherent. Patients on treatment for ≥ 12 months were expected to have viral load suppressed to undetectable levels (<50 copies/ml) to be considered adherent. Patients with viral load measures greater than these values were considered non-adherent. Average values for disclosed children were then compared with those for non-disclosed children.

Subject inclusion and exclusion criteria

Children who met all the following criteria were eligible for enrollment in the study, if:

- Child was confirmed with HIV-infection in accordance with the Nigerian National Testing algorithm [2].
- Child was ≥ 6 years of age and was receiving HIV care and medication at the pediatric ART clinic at UATH
- Child was currently prescribed antiretroviral medications for treatment of HIV disease based upon relevant Nigerian Guidelines [2], regardless of time of enrollment, or adherence to regimen, with no planned treatment interruptions. However, patient records had to provide at least two CD4 readings for the patient to be included in the study (estimated to be at least a minimum of three months).
- Child was with at least one biological parent or caregiver at the study site, who was able to act as the child's agent under Nigerian law and local practice, and who provided informed consent.

Children and their parent/caregivers were not eligible to enroll in the study if:

- Child shared the same parent/caregiver or lived in the same household as an already-enrolled child
- Parent/caregiver of child did not speak or understand English, Hausa, Igbo, Yoruba, or Pidgin English

- Child had severe developmental impairment that would impact understanding of disclosure of status

Study Limitations: Disclosure information was based solely on information provided by parents/caregivers. This was subject to recall bias, as respondents may not recall actual date/period of disclosure. This ultimately affected categorization of pediatric patients as disclosed or non-disclosed. A targeted convenience sample of participants was taken rather than a random sample. Only participants who “volunteered and agreed” to participate in the study were included. This self-selected sample may be different from the rest of patients, and thus may not be fully representative of pediatric patients at the study site. Only opportunistic infections managed at the study site and entered in the medical charts were included in the study. This may not fully represent all episodes of opportunistic infection as some may be self-managed, or managed elsewhere. Finally, the current study design could allow for only correlations between variables to be made, and no causal inferences.

IRB AND ETHICAL CONSIDERATIONS

Study on vulnerable population: Although this study was on children living with HIV, the PI had no contact/direct interactions with these children. Only the parents/caregivers were interviewed. Children were also not in the room during the interviews with their parents/caregivers, to prevent any accidental disclosure of their HIV status.

Psychological risk of accidental status disclosure to child participants: Children may cry, feel sad or be depressed when they learn they have HIV. Measures were taken to ensure there was no inadvertent disclosure of HIV status to children who did not know their status. This included not having children in the room during interviews with parents/caregivers, not mentioning HIV when parents/caregivers were informed about the study after their medical consultation with the doctor, as the children were with them in the consultation room; and not assenting/consenting the children for the study. No child inadvertently learned about their HIV status in the course of the study.

Privacy and confidentiality: To ensure confidentiality of participation, all instruments and forms were coded with a unique subject identifier that rendered the data anonymous to persons outside the study. Patient names were not used on any study instrument. Data were kept in a locked cabinet. Research records were kept confidential to the level allowed by law. Records with identifying information, such as consent forms, were stored separately from survey information.

Informed consent: The PI obtained written consent from parents/caregivers of pediatric ART patients at enrollment. Consent and enrollment took place at the UATH after permission had been received from the potential participant to hear about the study. All study procedures were described in detail such that the participant was fully informed of their requirements while in the study. During this consent process, the study subjects were reminded they were completely free to choose to take part in the research or not, and that their decision would not affect their care at the clinic. Potential study subject agreed or declined to participate in the study. Those who consented to participate in the study were enrolled. The consent form was reviewed orally by the PI and the participant was invited to ask detailed questions about the study. Study participants were consented and interviewed in their language of choice. Most parents/caregivers at the clinic spoke English or Pidgin English. Only a few parents/caregivers did not speak or understand English or Pidgin English, and spoke only Hausa. In these few cases, where the subject was non-English speaking, the consent form was read out in the local language (Hausa) via an interpreter, who was a health care worker at the clinic. Such interviews were also done in the local language with the assistance of an interpreter who is fluent in the written and spoken local language. Since there are many Nigerian languages, the questionnaire was not translated. All participants were informed that the information they provided through interviews was confidential (i.e., not shared with anyone outside of the research team) and voluntary (i.e., they were not obliged to answer any question). Interviewees were told that they were free to take breaks and/or terminate the interview at any time.

Duration and participant time commitment: This study lasted for seven months (February – August 2015), which included time for both data collection and analyses. Parent/caregiver surveys were completed via a one-time visit with no subsequent contact following the initial contact. Each contact time with the parent/caregiver lasted approximately 20 – 25 minutes, including time for consent for the questionnaire, and an additional 20 – 25 minutes for the 15 parents/caregivers of disclosed children selected for the qualitative component of the study. Both study instruments were administered at the same one-time contact. Parents/caregivers and their children did not receive any incentives or payments for their participation in the study, beyond verbal gratitude expressed by the PI for their participation.

Linking questionnaire to patient medical records: The questionnaire and patient extraction form received a unique identifier for each child. No names appeared on these two instruments. After each interview with a parent/caregiver, the patient’s medical file number and questionnaire unique identifier were noted in a separate notebook, which was stored in a safe place and separately from completed questionnaires and data extraction forms. Information in the notebook enabled the PI to retrieve patient medical paper or electronic records in order to retrieve the necessary information on the patient extraction form.

Data security considerations: The survey was mostly paper-based, and required only minimal additional electronic data. There was no personally identifiable information in/on any of the study instruments. The PI used a notebook to note down patients' chart numbers, in order to later retrieve patient information from their charts. This notebook was the only medium that contained identifiable information (I.e. medical record number). The PI stored the notebook separately and securely from the study instruments, under lock and key when not in use. As soon as the PI retrieved the needed patient information (which did not include any identifiable information) the notebook will be destroyed. No identifiable information was stored electronically.

DATA ANALYSES

Quantitative data: A data dictionary was constructed for the questions in the survey questionnaire and the applicable values. Questions in the survey questionnaire were also pre-coded before administration to facilitate easy data entry. Data were analyzed using SPSS statistics version 20 and STATA version 12 software packages. Descriptive statistics sought to determine the distribution of key variables within the sample and respondent characteristics, such as numbers of respondents by gender, socio-demographic characteristics of parents/caregivers, age of patients, and disclosure status, age at disclosure, who disclosed, and setting of disclosure. Means, medians, ranges, percentages and standard deviations were calculated as appropriate. Some data grouping was done for patient age (6 – 9 years, 10 – 14 years, ≥ 15 years), age at disclosure, and patient family socio-demographic data. The second level of analyses involved bivariate analyses that compared the relationship between observed health outcomes, namely, ART adherence, for disclosed and non-disclosed children, and if this difference was statistically significant. Chi square tests were calculated to test any associations between disclosure status (categorical variable) and other categorical variables.The next level of analyses used multivariate logistic regression and multinomial logistic regression models to determine the relationship between disclosure and socio-demographic characteristics of the patients, and the parents/caregivers, in order to determine the predictors of disclosure. Explanatory variables for each model were retained based on statistical significance, and conceptual relevance. Odds ratios with 95% confidence intervals were estimated from each explanatory model. Statistical significance was set at p value ≤ 0.05.

Qualitative data: The PI typed up the handwritten notes from the interview with each parent/caregiver. This was followed by a line-by-line analysis of the notes, in order to sort and code information from these interviews. Responses to each question were then gathered together and reviewed to check for any emerging themes. Ideas were sorted into similar themes, and codes were developed based on the themes. The emerging themes were then aggregated to provide a fuller picture of why disclosure takes place, how, when and by whom.

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CHAPTER 4

PATTERNS, PREVALENCE AND PREDICTORS OF PEDIATRIC DISCLOSURE AMONG HIV-INFECTED NIGERIAN CHILDREN ON TREATMENT

INTRODUCTION

In 2014 there were 36.9 million people living with HIV globally [1]. Of these, 25.8 million lived in sub Saharan Africa (SSA), including 2.3 million children (or 90% of all infected children 0 -14 years in the world) [1]. This implies that SSA continues to bear the largest burden of the global HIV epidemic. There has been considerable progress in preventing perinatally transmitted new infections in children through prevention of mother to child transmission programs. However, new infections in children 0- 14 years have remained largely unchanged in Nigeria. There were 220,000 new HIV infections in children 0-14 years globally in 2014. Of these, 190,000 were in SSA [1], and Nigeria contributed 60,000 of these in 2012 [2]. With 430,000 children 0-14 years living with HIV in Nigeria in 2014, the country accounts for almost one-fifth of all children living with HIV (CLHIV) in the world [3].

These children are growing into adolescence (10 – 19 years) - a period of life involving significant physical, physiological and psychological changes that mark the transition to adulthood [3]. For CLHIV, they bear the added challenge of a life-long illness. Adolescence is also a period marked with experimentation, and for many adolescents, this phase of their lives will mark their sexual debut. It becomes important, therefore, that CLHIV know their HIV status – not only to protect themselves from reinfection, but also to protect their sexual partners.

In 2011 WHO published the *Guideline on HIV disclosure counselling for children up to 12 years of age*, which recommends that children of school age (6 – 12 years) should be told their HIV positive status, and younger children should be told their status incrementally to accommodate their cognitive skills and emotional maturity, in preparation for full disclosure [4]. The Nigeria *Integrated National Guidelines for HIV Prevention, Treatment and Care* highlights the importance of HIV disclosure to children [5]. It recommends the following steps for pediatric HIV disclosure:

- Evaluate the child and family for readiness-including child's age and maturity. Five to seven years are earliest recommended ages for disclosure, and all [children] should be disclosed by age 12 years.
- Ascertain a child's and caregiver's understanding of HIV infection
- Explain the benefits of early awareness of HIV infection to the child and caregiver/family
- Provide ongoing psychosocial support.

However, a recent study conducted in Nigeria showed only 13.5% disclosure rate [6]. Other recent studies on SSA have similarly reported low disclosure rates - 21% (Ghana), 17.4% and 39.5% (Ethiopia), 19% and 26% (Kenya), and 32.6% (Cote d'Ivoire) [7-12].

Factors that influence pediatric disclosure include child's age and cognitive development, concerns about antiretroviral treatment (ART) adherence, imminent onset of sexual activity, and the need to protect others from infection. Benefits of pediatric disclosure include improved adherence to ART, and psychosocial well-being and mental health. Despite these benefits of disclosure, nondisclosure remains high because disclosure carries with it a negative exposure due to the association of HIV positive status and sex (promiscuity). Disclosure of HIV status to children living with HIV, or to partners, remains "navigation in a moral field" [13]. Therefore to protect the family name and one's reputation, and avoid rejection and discrimination many choose not to disclose HIV status to children. Clearly, therefore, there is a need to understand the factors that promote or hinder pediatric HIV disclosure.

This study, therefore, sought to determine the following in Nigerian children on ART:

1. The rate and nature of HIV status disclosure, and identify the main agent (family, healthcare worker, religious leader, school staff) of disclosure to these children
2. The age at HIV disclosure to children who have been disclosed to
3. Locally pertinent barriers to, and facilitators of disclosure among disclosed and non-disclosed children
4. Associations between disclosure, and health outcomes, namely: CD4 count, opportunistic infections, adherence to ART, and viral load.

METHODS

Study setting

This study was conducted at the pediatric antiretroviral treatment (ART) clinic of the University of Abuja Teaching Hospital (UATH) in the Federal Capital Territory Abuja, Nigeria between February and July 2015. This ART program was supported by the US President's Emergency Plan for AIDS Relief (PEPFAR) through the AIDS Care and Treatment in Nigeria (ACTION) program of the Institute of Human Virology Nigeria (IHVN). At the time of the study, a total of 401 children were currently receiving ART at the clinic. Of these, 35 (8.7%) were 0 – 5 years; 177 (44.1%) were 6 – 9 years; 139 (34.7%) were 10 – 14 years; and 50 (12.5%) were ≥ 15 years.

The paediatric clinic runs an "adolescent clinic" for older children once every month. During this clinic, nurses and adherence counsellors provide health talks to the older children and their parents, before they meet with the doctor for consultation. Some of these older children come unaccompanied to the clinic for their visits. The adherence counsellors also assess patient adherence, and provide counselling, as part of each patient's visit to the clinic for consultation. Clinic staff (doctor, nurses and counsellors) also assist parents/caregivers with status disclosure to the children when necessary. However, there is no set pattern or procedure for how disclosure takes place.

Study participants, recruitment and design

Study participants were CLHIV ≥ 6 years currently prescribed antiretroviral medications for treatment of HIV disease based upon relevant Nigerian Guidelines [14], regardless of time of enrollment, or adherence to regimen, with no planned treatment interruptions at the study site. Parents/caregivers of every eligible pediatric ART patient who visited the clinic for their regular consultation were invited to participate in the study. Parents/caregivers who agreed to participate in the study were consented by the Principal Investigator (PI) and interviewed, using a semi-structured questionnaire. The questionnaire sought, among other things, information on child's disclosure status. If child was disclosed, the questionnaire also asked for age at disclosure, who disclosed the child's status, where status disclosure took place, and reasons for disclosure. For parents/caregivers who had not disclosed to their children, the reasons for nondisclosure and concerns were obtained. The questionnaire also captured socio-demographic data about the caregiver and the child, including relationship of respondent to child (i.e. if biological parent or other relative), and other characteristics of the family. The administration of each questionnaire lasted about 20 - 25 minutes (including consent time). The interviews were conducted in the absence of the children to prevent accidental disclosure. Questionnaires were administered in English, Pidgin English, or Hausa through an interpreter. The PI continued with participant recruitment until end June 2015 when 110 participants had been recruited and interviewed.

For each completed questionnaire, secondary data on CD4 count, opportunistic infections, WHO staging, viral load, and treatment adherence were later extracted from patient's paper charts (and where these were missing, from the electronic medical records) for all 110 children, using a data extraction form (Appendix 2). Extracted data spanned the period 2013 to 2015. Other extracted data included patient age, date ART was started, and ART regimen. The data extraction process did not involve any direct contact with the children or their parents/caregivers.

Definition of key terms and variables

Children living with HIV: For this study, this was limited to children ≥ 6 years enrolled in the pediatric ART program at UATH, Abuja Nigeria. Enrollment for ART was deemed sufficient evidence of positive HIV serostatus.

Pediatric disclosure: Defined as informing the child that s/he had HIV.

Disclosure status: Children were categorized as disclosed or non-disclosed depending on whether they knew of their HIV positive status or not – as reported by the parent/caregiver. Information on disclosure status was gathered through the questionnaire that was administered to parents/caregivers. A “Yes” response by the parent/caregiver to any of the questions: (1) Does child know s/he has HIV?; (2) Does child know s/he comes to clinic for HIV care?; (3) Does child know that the name of his/her sickness is HIV?; or (4) Does child know that s/he is taking medicine for HIV? was taken as evidence of child’s disclosure, while a “No” was considered non-disclosure [11].

Parent/caregiver: Defined as an adult aged 18 years and over who was responsible for the day-to-day care of the minor (pediatric ART patient), including biological parents identified through eligibility screening by health care providers at the study site.

Ethical considerations

The study was approved by the Institutional Review Board of the University of North Carolina at Chapel Hill and the University of Abuja Teaching Hospital Medical Advisory Committee, Nigeria.

Data analyses

Data were analyzed using SPSS statistics version 20 and STATA version 12 software packages. Descriptive statistics sought to determine the distribution of key variables within the sample and respondent characteristics, such as numbers of respondents by gender, socio-demographic characteristics of parents/caregivers, age of patients, and disclosure status, age at disclosure, who disclosed, and setting of disclosure. Means, medians, ranges, percentages and standard deviations were calculated as appropriate. Some data grouping was done for patient age (6 – 9 years, 10 – 14 years, ≥ 15 years), age at disclosure, and patient family socio-demographic data. The second level of analyses involved bivariate analyses that compared the relationship between observed health outcomes, namely, ART adherence, for disclosed and non-disclosed children, and if this difference was statistically significant. Chi square tests were calculated to test any associations between disclosure status (categorical variable) and other categorical variables.The next level of analyses used multivariate logistic regression and multinomial logistic regression models to determine the relationship between disclosure and socio-demographic characteristics of the patients, and the parents/caregivers, in order to determine the predictors of disclosure. Explanatory variables for each model were retained based on statistical significance, and conceptual relevance. Odds ratios with 95% confidence intervals were estimated from each explanatory model. Statistical significance was set at p value ≤ 0.05.

RESULTS

Parent/caregiver characteristics

A total of 110 questionnaires were administered in English (n=78), Pidgin English (n=25), and Hausa through an interpreter (n=7). Thirty-four (30.9%) of the respondents were male and 76 (69.1%) were female. Sixty-seven (60.9%) of respondents were child's mother, and 26 (23.6%) were the father. The majority (n=105, 95.5%) were child's primary caregiver. Most parents/caregivers had ever been to school. Only five respondents (4.5%) had never been to school. Table 4.1 shows other respondent characteristics.

Table 4.1: Respondent characteristics (N=110)

Respondent Characteristic	n (%)
Gender	
• Male	34 (30.9)
• Female	76 (69.1)

Age	
≤ 19 years	1 (0.9)
20 – 29 years	9 (8.2)
30 – 39 years	39 (35.4)
40 – 49 years	47 (42.8)
50 – 59 years	10 (9.1)
≥ 60 years	4 (3.6)
Relationship to child	
Mother	67 (60.9)
Father	26 (23.6)
Sibling	4 (3.6)
Uncle	3 (2.7)
Aunt	7 (6.4)
Grandparent	1 (0.9)
Other	2 (1.8)
Respondent is child's caregiver	
Yes	105 (95.5)
No	5 (4.5)
Level of education	
Primary school	25 (22.7)
Secondary school	39 (35.5)
Post-secondary/Higher	41 (37.3)
No education	5 (4.5)
Tribe	
Hausa/Fulani	9 (8.2)
Igbo	16 (14.5)
Yoruba	4 (3.6)
Gwari/Gbagi	15 (13.6)
Tiv	7 (6.4)
Idoma	4 (3.6)
Igala	4 (3.6)
Edo (Bini, Ishan, Akoko-Edo)	13 (11.8)
Others	38 (34.5)
Religion	
Christian	82 (74.5)
Muslim/Islam	28 (25.5)

Child characteristics

There were 60 male (54.5%) and 50 female (45.5%) children (Table 4.2). The mean age (SD) of the children was 10.15 (2.97) years, with a median (range) of 9.50 (6 – 18) years. All the children were in school: 6.4 % in kindergarten; 70.9% in primary school, 22.7% in secondary school. Fifty-five children were 6 – 9 years; 45 were 10 – 14 years; and ten were 15 – 18 years. There was limited information on mode of transmission in the medical records or from information volunteered by respondents (n=27, 24.5%). The questionnaire did not seek to elicit the mode of HIV transmission. However, some respondents gave this information in the course of the interview. Majority of the children were infected perinatally (n=24, 88.9%). Two children were infected through blood transfusion, and one child was infected from sexual assault.

Table 4.2: Child characteristics (N=110)

Child characteristics	n (%)
Gender	
• Male	60 (54.5)
• Female	50 (45.5)
Age (completed years)	
• 6 – 9 years	55 (50.0)
• 10 – 14 years	45 (40.9)
• 15 – 18 years	10 (9.1)
Class	
• Kindergarten	7 (6.4)
• Primary school	78 (70.9)
• Secondary school	25 (22.7)
Tribe	
• Hausa/Fulani	11 (10.0)
• Igbo	15 (13.6)
• Yoruba	10 (9.1)
• Gwari/Gbagi	14 (12.7)
• Tiv	8 (7.3)
• Idoma	3 (2.7)
• Igala	5 (4.5)
• Edo (Bini, Ishan, Akoko-Edo)	12 (10.9)
• Others	32 (29.1)
Mode of HIV transmission	
• MTCT	24 (88.9)
• Blood transfusion	2 (7.4)
• Sexual transmission	1 (3.7)
• Total	27

Prevalence of HIV Disclosure

According to parents/caregivers' accounts 34 (30.9%) of the children knew they were living with HIV, while 74 (67.3%) did not know the name of their sickness was HIV (Table 4.3). There was a statistically significant difference between 6-9 year olds and 10 – 18 year olds who were disclosed, with more of the latter knowing their status: 9.1% versus 52.7% (Pearson chi-square tests: X^2 = 25.482, df=2, p=0.000). Three (30%) of the 10 children in the study aged ≥ 15 years had not been disclosed to. Two respondents could not tell if child knew or not. One of these respondents was a 37-year old mother and caregiver of a 7-year old boy. The other respondent was a 20-year old aunt (and not caregiver) of an 8-year old boy.

Table 4.3: Child's knowledge of HIV status

Child's age/ Child's knowledge of status, n (%)	**Disclosed**	**Non-disclosed**	**Don't know**	**Total**
6 -9 years	5 (9.1)	48 (87.3)	2 (3.6)	55 (100)
10 – 18 years	29 (52.7)	26 (47.3)	0 (0.0)	55 (100)
Total	34 (30.9)	74 (67.3)	2 (1.8)	110 (100)

Chi-Square Tests	**Value**	**df**	**Asymp. Sig. (2-sided)**
Pearson Chi-Square	25.482	2	.000

Disclosure characteristics

Mean age (SD) at disclosure was 10.47 (2.62) years, with a median (range) of 10.00 (6 - 17) years and mode of 10 years. The most common reasons for disclosure were related to adherence issues – either to help prepare the child to take his/her medicines or that the child had refused to take his medicines

Table 4.4: Reasons for disclosure of child's status to child

Reasons for disclosure	**n (%)**
To help child take medicine/child refused to take medicine	13 (39.4)
Child was asking a lot of questions	9 (27.3)
Child is now mature/old enough	3 (9.1)
So child can protect him/herself	1 (3.0)
Child was sexually assaulted	1 (3.0)
Doctor said I should tell her	1 (3.0)
Other reasons	5 (15.2)
Total	33

(Table 4.4). This was followed by the child asking a lot of questions related to his/her health, frequent visits to the hospital, or why s/he was taking a lot of medicines even though s/he did not feel ill, or why s/he was the only child in the family taking medicines.

Most parents/caregivers did not disclose because the child was considered too young (84.0%) or will not be able to keep a secret (10.7%) (Table 4.5). Among parents/caregivers who cited child being too young as a reason for non-disclosure, 11 further explained that as a result of child's age, child will not be able to keep their positive sero-status a secret – not realising the import of a positive sero-status and the resultant stigma and discrimination that could ensue. Three respondents gave other reasons for non-disclosure: One 37-year old mother said she did not have any particular reason for not disclosing to her 12-year old daughter. A 35 -year old mother's reason for not disclosing to her 15-year old son was that she did not know how the child would react to disclosure; and one 26-year old female respondent, who cares for her 16-year old brother, did not disclose because she felt the health care workers should be the ones to disclose.

Table 4.5: Reasons for non-disclosure of child's status to child

Reasons for non-disclosure	**n (%)**
Child is too young	63 (84.0)
Child will not be able to keep it a secret	8 (10.7)
It will make child sad	1 (1.3)
Other reasons	3 (4.0)
Total	75

Of the 34 disclosed children, 27 (79.4%) were disclosed at home by their parent(s)/caregiver. The rest were disclosed at the hospital. Of these, five were disclosed by the health care provider, while two were accidental disclosure: one child, an 11-year old boy, overheard the health care provider talking to his mother about his illness. The other child, an 8-year old boy, figured out his status because he used to sit in for the health talks his mother used to receive at the hospital. Both his parents were HIV-positive. The father insisted that neither he nor his wife had any talks with the boy about his HIV status. However, he said the boy "has always known" he was positive.

Predictors of disclosure

The next level of analyses used logistic regression models to determine the relationship between disclosure and socio-demographic characteristics of the children and the parents/caregivers, in order to determine the predictors of disclosure. This was a multivariate logistic regression of knowledge of status against the following variables: child's gender (male, female), age (in completed years), class at school (kindergarten, primary or secondary), child's tribe (Hausa/Fulani, Igbo, Yoruba, Gwari/Gbagyi, other) and

Table 4.6: Multivariate logistic regression of HIV disclosure to child (n=108)

Know status |	Odds Ratio	Std. Err.	z	P>|z|	[95% Conf. Interval]
Child's gender					
Reference	Male				
Female	2.93	2.03	1.55	0.121	.75 - 11.40
Child's age	1.69	.28	3.12	0.002	1.21 - 2.34
Child's school class	1.69	1.42	0.62	0.536	.32 - 8.79
Child's tribe					
Reference	Hausa/Fulani, Kaduna				
Igbo	.00	.01	-1.46	0.145	.79e-07 - 8.496
Yoruba	3.16	9.69	0.38	0.707	.01 - 1283.41
Gwari/Gbagyi	2.01	3.96	0.35	0.723	.04 - 95.65
Other	.03	.09	-1.12	0.265	.00 – 13.60
Respondent's relationship to child					
Reference	Father				
Mother, Other	.94	.62	-0.10	0.924	.26 - 3.42
Respondent's religion					
Reference	Christian				
Muslim/Islam	1.09	.79	0.12	0.908	.26 - 4.54
Respondent's language	1.20	.42	0.52	0.606	.60 - 2.38
Respondent's tribe					
Reference	Hausa/Fulani, Kaduna				
Igbo	40.15	164.40	0.90	0.367	.01 - 122792
Yoruba	.07	.25	-0.75	0.454	.00 - 69.24
Gwari/Gbagyi	.34	.67	-0.54	0.586	.01 - 16.31
Other	20.98	64.84	0.98	0.325	.05 – 8960.58
Respondent's Age	1.05	.03	1.76	0.079	.99 - 1.12

respondent relationship to child (mother, father, sibling), age, tribe (Hausa/Fulani, Igbo, Yoruba, Gwari/Gbagyi, other), language and religion (Christianity and Islam). There were three categories of children – children who knew their positive HIV status; children who did not know their HIV status; and a third category of children whose parents/ caregivers responded they did not know if the children knew their status. Since the number of children under the "Don't know" category was only two, two sets of multivariate logistic regression analyses were run: First, with the "Don't know" category dropped from the analysis (Table 4.6); and secondly with the "Don't know" category coded together with the no

Table 4.7: Multivariate logistic regression of HIV disclosure to child (n=110)

Know status	Odds Ratio	Std. Err.	z	P>|z|	[95% Conf. Interval]
Child's gender					
Reference	Male				
Female	2.94	2.04	1.55	0.121	.75 - 11.44
Child's age	1.70	.28	3.16	0.002	1.22 - 2.35
Child's class	1.67	1.41	0.61	0.543	.32 - 8.71
Child's tribe					
Reference	Hausa/Fulani, Kaduna				
Igbo	.00	.01	-1.46	0.146	4.40e-07 - 8.71
Yoruba	3.20	9.83	0.38	0.706	.01 - 1323.99
Gwari/Gbagyi	2.01	3.97	0.35	0.725	.04 - 96.80
Others	.03	.10	-1.12	0.264	.00 – 13.64
Respondent's relationship to child					
Reference	Father				
Mother, others	.93	.61	-0.11	0.912	.25 - 3.40
Respondent's religion					
Reference	Christian				
Muslim/Islam	1.10	.80	0.12	0.901	.26 - 4.58
Respondent's language	1.20	.42	0.52	0.601	.60 - 2.40
Respondent's tribe					
Reference	Hausa/Fulani, Kaduna				
Igbo	40.89	168.56	0.90	0.368	.01 - 131922.9
Yoruba	.07	.25	-0.75	0.453	.00 - 69.56
Gwari/Gbagyi	.34	.66	-0.55	0.581	.01 - 16.20
Others	21.17	65.65	0.98	0.325	.05 – 9229.53
Respondent's age	1.06	.03	1.79	0.073	.99 - 1.12

disclosure category (Table 4.7). In both cases, only child's age was a statistically significant predictor of status disclosure (OR 1.69, p=0.002; 95% CI 1.21 – 2.34), and (OR 1.70, p=0.002, 95% CI 1.22 – 2.35) respectively. Other child characteristics (gender, class in school, tribe) and parent/caregiver characteristics (religion, relationship to child, tribe, language and age) were not statistically significant.

Multinomial logistic regression was also done, as a test of sensitivity. This was also a logistic regression of knowledge of status against child's gender (male, female), age (in completed years), class at school (kindergarten, primary or secondary), child's tribe (Hausa/Fulani, Igbo, Yoruba, Gwari/Gbagyi, other) and respondent relationship to child (mother, father, sibling). The analyses also tested parent/caregiver

Table 4.8: Multinomial logistic regression of HIV disclosure to child

	Child's knowledge of HIV status	**Coef.**	**Std. Err.**	**z**	**P>z**	**95% Confidence Interval**
Yes						
	Child's gender	0.38	0.54	0.7	0.481	-0.68 – 1.45
	Child's age	0.36	0.13	2.84	0.005	0.11 – 0.60
	Child's class in school	0.67	0.71	0.94	0.345	-0.72 – 2.06
	Child's tribe	0.07	0.27	0.26	0.793	-0.46 – 0.60
	Parent/caregiver relationship to child	0.45	0.58	0.77	0.439	-0.69 – 1.60
	Parent/caregiver religion	0.54	0.66	0.81	0.417	-0.76 – 1.84
	Parent/caregiver level of education	-0.07	0.34	-0.19	0.846	-0.73 – 0.60
	Parent/caregiver tribe	0.10	0.12	0.87	0.386	-0.13 – 0.33
	Parent/caregiver age	0.05	0.03	1.66	0.098	-0.01 – 0.12
	Constant	-10.66	2.75	-3.88	0	-16.05 - -5.27
No	(Base outcome)					
Don't know						
	Child's gender	34.29	12178.34	0	0.998	-23834.82 – 23903.40
	Child's age	-32.65	6743.69	0	0.996	-13250.05 – 13184.74

	Child’s class in school	184.18	34534.36	0.01	0.996	-67501.93 - 67870.28
	Child’s tribe	54.20	14224.29	0	0.997	-27824.89 - 27933.29
	Parent/caregiver relationship to child	56.03	12196.57	0	0.996	-23848.81 - 23960.86
	Parent/caregiver religion	-59.03	21074.66	0	0.998	-41364.61 - 41246.55
	Parent/caregiver level of education	-93.29	12331.29	-0.01	0.994	-24262.18 - 24075.59
	Parent/caregiver tribe	-23.44	8111.85	0	0.998	-15922.37 - 15875.50
	Parent/caregiver age	-3.89	699.05	-0.01	0.996	-1374.00 - 1366.22
	Constant	-70.62	114523.30	0	1	-224532.10 - 224390.90

N= 108

characteristics, such as age, education (no school, primary, secondary, post-secondary/higher), and tribe (Hausa/Fulani, Igbo, Yoruba, Gwari/Gbagyi, other). Again, only child’s age (in completed years) was a statistically significant predictor of pediatric disclosure: coefficient = 0.36 (p value 0.005, CI 0.1-0.6) (Table 4.8). The study did not show any association between disclosure and other child characteristics, such as gender, class in school or tribe, nor any association with parent/caregiver religion, level of education, tribe or age.

HIV disclosure and child’s physical (clinical) health outcomes

Almost all the patients (n=90, 80%) had several self-reported adherence data in their paper medical records. However, only two of these 90 children were recorded as non-adherent (Table 4.9). Analysis of the relationship between disclosure and adherence using Pearson chi-square tests showed no statistically significant difference in adherence between disclosed and non-disclosed children (X^2= 0.972, df=2, p=0.615). There were limited data on patient CD4 count, and hardly any data on viral load, and opportunistic infections in the patient paper or electronic medical records. One hundred patients had at least one CD4 reading in their records. However, at least two readings were required to determine if there had been a CD4 decline, or not. Fifteen children had at least one viral load measure. Only four children were reported to have had an opportunistic infection (pulmonary tuberculosis). As such, this dissertation does not present any findings on association between disclosure and child's CD4, viral load or opportunistic infections.

Table 4.9: Relationship between disclosure and adherence

Disclosure status/ Adherence status, n (%)	Adherent	Non-adherent	Total
Disclosed	27 100.0 30.0	0 0.0 0.0	27 100.0 30.0
Non-disclosed	59 96.7 65.6	2 3.3 2.2	61 100.0 67.8
Don't know	2 100.0 2.2	0 0.0 0.0	2 100.0 2.2
Total	88 97.8	2 2.2	90 100.0
Chi-Square Tests	**Value**	**df**	**Asymp. Sig. (2-sided)**
Pearson Chi-Square	.972	2	.615

DISCUSSION

Disclosure prevalence from this study was 30.9 %, with more 10 – 18 year olds significantly knowing their status than 6-9 year olds: 52.9% versus 9.1% (X^2 = 25.482, df=2, p=0.000). The overall disclosure prevalence of 30.9% was much higher than the 13.5% reported from another study in Nigeria [6], and other studies from SSA: 17.4 % in Ethiopia [8], 19% in Kenya [10], 21% in Ghana [7]; and 26% in Kenya [11]. But it was similar to the 39.5% reported in Ethiopia [9], and 32.6% in Cote d'Ivoire [12]. The mean age (SD) at disclosure from this study was 10.47 (2.61) years. It was higher than the 8.7 (2.2) years reported from the earlier cited Nigeria study, but similar to the Ethiopia study of 10.7 (2.3) years. One could speculate that the lower disclosure rates in some of the SSA studies could be because these studies were conducted a while ago (mostly in 2008 and 2009), even though the studies were on children of comparable age (usually 5 – 16 years). Since then, access to ART has expanded, possibly leading to relatively higher disclosure rates.

As in other studies in the SSA region, reasons for disclosure were related to child's adherence to medication, as well as repeated questioning from child on their illness and/or medication [6], [7], [9], [10]. Parents/caregivers in this study cited child's young age and, therefore, inability to fully understand the import of a positive HIV serostatus (84.0%), and child's inability to keep a secret (10.7%), with the resultant fear of stigma and discrimination that may arise from revealing their status to others, as major reasons for not disclosing child's status. This result was not different from what other studies in the region have reported. In Brown's Nigeria study [6], 63.9% parents/caregivers reported child's inability to understand; and 41% reported fear of disclosure to other children; and 33.7% cited fear of disclosure to family/friends, as reasons for non-disclosure. Kallem [7] also reported that over half of parents/ caregivers (29 of 56 parents/caregivers) who had not disclosed gave fear that child would tell others as a reason for non-disclosure; and 26 of 56 parents felt their children were too young to be informed of their status. The analysis of parents citing child's young age as a reason for non-disclosure in this study uncovers two underlying factors. First, the child is too young and therefore will not understand the import of an HIV diagnosis, predicated on child's cognitive ability. Second, the child is too young and will not be able to keep a secret, not appreciating that HIV status could invite negative reactions, will expose themselves to stigma and rejection from their fellow children or the adults around. Unlike other studies [6], parents/caregivers in this study did not cite fear of blaming parents as a reason for non-disclosure.

In this study, child's age was the only factor associated with disclosure. Multivariate logistic regression of child's age and status disclosure showed a statistically significant association (OR 1.68, p=0.002, 95% CI 1.21 – 2.34) and (OR 1.70, p=0.002, 95% CI 1.22 – 2.35). Multinomial logistic regression also showed a similar statistically significant association between child's age and status disclosure (p=

0.005). Other studies in SSA also reported a similar association. Kallem's study in Ghana reported age of child was a significant predictor of disclosure (Wilcoxon rank sum test, p=0.01) [7]. In Ethiopia, Biadgilign reported that children 10 – 14 years were more likely to be disclosed than younger children [(aOR = 0.11; 95% CI = 0.03–0.34) and (aOR = 0.19; 95% CI = 0.10–0.37, respectively)] [8]. Similarly, Vreeman reported that in Kenya older age (OR 1.49, 95% CI 1.35–1.63) was significantly associated with disclosure [11]. Another study from Kenya showed that disclosed children had a higher median age than those who were not (13 years versus 8 years; $p < 0.001$) [10]. In Cote d'Ivoire, Meless reported that disclosure increased significantly with age (> 18 years vs. 13 - 15 years; aOR (22.1; 95% CI: 5.2 - 93.5; $p < 0.0001$).

Unlike the Kenya study by John-Stewart [10], which reported an association between caregiver age and disclosure (40 vs. 35 years; p = 0.009), this study did not find any such association. This study also did not find any correlation between disclosure and child's level of education or class, nor the parent/caregivers' level of education. However, Kallem reported that disclosure was significantly associated with child's level of education (Fisher's exact test, $P < 0.01$) [7]. Biadgilign reported that children whose caregivers were educated up to primary level or higher were less likely to be disclosed compared to children whose caregivers were illiterate [8].

This study did not show any relationship between child's knowledge of his/her status and self-reported adherence (X^2= 0.972, df=2, p=0.615). However, Vreeman's Kenya study showed mixed results, with children reporting more adherence than caregivers [11]. There continues to be a need for more objective and reliable measures of adherence, such as viral load, since self-reports may not be reliable. Incidentally, there were limited viral load data in patients' medical files at UATH for analysis. Only 15 patients had any viral load readings in their files, even though viral load measurements were supposed to be taken every six months.

This study had several limitations. A targeted convenience sample of participants was taken rather than a random sample. Only participants who volunteered and agreed to participate in the study were included. This self-selected sample may be different from the rest of the patients, and thus may not be fully representative of pediatric patients at the study site.

Some older adolescents came unaccompanied for their consultations. They were, therefore, not interviewed as part of the study, since the study was designed to only interview parents/ caregivers and not the children themselves. It is possible that this group of older children were disclosed. Therefore, it is likely that the actual disclosure rate for this site could be higher than the 30.9% reported from this study.

Finally, the current study design could only allow for correlations between variables to be made, and no causal inferences.

CONCLUSION

The HIV disclosure rate for CLHIV seen at UATH was low, similar to rates reported by other studies in SSA. Child's age was the only predictor of HIV disclosure to the child. Child's young age was the major reason given by parent/caregivers for not disclosing child's positive HIV status to the child. Parents/caregivers who disclosed child's status to child did so mostly for reasons related to child's adherence to medication. The study did not find any association between disclosure and self-reported adherence.

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CHAPTER 5
THE CONTEXT AND PROCESS OF PEDIATRIC HIV DISCLOSURE

INTRODUCTION

Improved access to antiretroviral therapy (ART) in sub-Saharan Africa (SSA) has meant that more children living with HIV (CLHIV) are growing into adulthood. With a 2013 population of 170 million people, Nigeria is Africa's most populous country. In 2012 there were over 3.4 million people living with HIV in Nigeria, including an estimated 430,000 children under 15 years of age [1].

The World Health Organisation (WHO) recommends pediatric disclosure, defined as disclosure of a child's seropositive HIV status to the child or informing the child that s/he has HIV, to children of school age (6 – 12 years) [2]. However, despite the reported benefits of disclosure, many studies in SSA report low disclosure rates to children. A 2013 national survey of Nigerian adolescents aged 10 to 19 years showed that >80% of adolescents did not know their HIV status, and up to 6% of parents of CLHIV admitted to not disclosing the children's status [3]. Only 13 (13.5%) children in a Nigeria HIV Care program had been disclosed to [4]. Other recent studies in SSA also show low disclosure rates: 21% (Ghana), 17.4% and 39.5% (Ethiopia), 19% and 26% (Kenya), and 32.6% (Cote d'Ivoire) [5-10]. Given the high number of children living with HIV in Nigeria, the culture of non-disclosure to these children, especially as they approach sexual debut, is likely to have negative consequences.

Many issues surround disclosure, such as: Who should disclose to the child – the parent or the health care worker? Where should disclosure take place – at home or the health facility? At what age should the child be disclosed? How should disclosure take place – as a one-off discrete discussion or a gradual process consisting of several discussions over a period of time? [2].

Parents/caregivers of CLHIV often cite many reasons for not disclosing to their children. These include concerns around how the children would react, if told they were living with HIV [5] [7]; children's young age, and therefore inability to understand the implications of an HIV diagnosis [4] [7]; and the fear of children being stigmatised in their communities if their positive HIV status were disclosed by the children to others in the community [7]. Many parents/caregivers also report they lack the skills to disclose to their children [11]. For parents/caregivers who disclose, their reasons for disclosure include repeated questioning by the children regarding their continuing taking of medications, the need to promote medication adherence, and the perception that the children were now mature enough to understand their HIV-positive diagnosis [4], [5], [12]. Where disclosure happens it is often unplanned, and does not take place in a systematic way. The process remains largely context dependent [12]. WHO has, therefore, provided some guidance on how country programs could address many of these issues, in order to increase disclosure to children [2].

This study on children who have been told they are living with HIV, therefore, sought to elicit the process and context of disclosure, the reasons for disclosure, who disclosed to the children, when and where disclosure took place, and other emerging themes. It is hoped this will contribute to the body of Nigeria-specific knowledge on pediatric HIV disclosure, and help shape the development of HIV disclosure guidance in Nigeria, and elsewhere in the SSA region.

METHODS

This qualitative study was nested in a larger study that also included a quantitative component. In this study, respondents who explained that they had disclosed to their children in the quantitative component were further interviewed by administering an interview guide (Appendix 3).

Setting

The study was conducted at the pediatric clinic of the University of Abuja Teaching Hospital (UATH), Abuja, Nigeria. As at June 2015, there were 401 children receiving ART at this clinic. The Institute of Human Virology Nigeria (IHVN) supports the provision of ART services at the clinic, through its AIDS Care and Treatment in Nigeria (ACTION) program, with funding from the US President's Emergency Plan for AIDS Relief (PEPFAR). IHVN is an indigenous nongovernmental organization, which until 2010 was affiliated with the University of Maryland Baltimore USA to implement the ACTION program. IHVN's pediatric ART program started in 2006. As at January 2012 IHVN's follow-on ACTIONPLUS pediatric ART program supported 36 health facilities in 18 of the 36 states in Nigeria and the FCT. IHVN sites provided ART to 89,509 persons, including 5,265 children (0- 14 years).

Study design and participants

In the course of the larger study, 34 parents/caregivers reported that their children knew of their positive HIV status during the administration of the study questionnaire. Of these, the interview guide was administered to 15 of them, to more fully elicit the process of disclosure to their children. The aim of the study was to determine the context of HIV disclosure to the child, in order to more fully understand how the disclosure process happened: how was the decision made to disclose to the child; what was the setting for disclosure; and what were the parents/caregivers concerns regarding disclosure. The interview also explored parent/caregiver perceptions of the effects of disclosure on the child, especially child's emotional reaction to disclosure. The interview was designed to be conversational and used probes to elicit a description of the process, who disclosed to the child, where, when and how disclosure took place. The interviews also sought to clarify if the terms "HIV", "AIDS" or any local term was specifically mentioned to the child during the disclosure process. For a child to be determined as disclosed, the term HIV or AIDS or a local equivalent term must have been used in discussion with the child about the child's health by parent/caregiver, or healthcare worker [12].

Data collection and analysis

Data collection took place between February and June 2015. Data collection continued until 15 parents/caregivers had been interviewed. The principal investigator (PI) took notes by hand during the interviews. No parent/caregiver consented to being audiotaped during the interviews. Thereafter, the PI typed up the notes from the interview with each parent/caregiver. This was followed by a line-by-line analysis of the notes, in order to sort and code information from these interviews according to disclosure themes, such as, reasons for disclosure, who disclosed, where, when and how disclosure took place, and other emerging themes.

Ethics

The Institutional Review Boards at the University of North Carolina at Chapel Hill USA, and the University of Abuja Teaching Hospital approved this research.

RESULTS

Process of disclosure

Descriptions provided by parents/caregivers of the disclosure process suggest that this was usually a discrete, one-off event that was unplanned. There was often no scheduled discussion to disclose to the child.

> One morning we were about to come to hospital. Then I told him about the reason why we were coming. I asked him first of all, then I told him. Do you know the reason for your [coming to hospital?] I asked him what is called HIV? He said No [he didn't know]. That's what the doctor says is your sickness. It is what we are going for.
>
> There was a day he kept asking me. After school we will discuss topic of the drugs. So when they were teaching them about drugs in Social Studies [in school], he asked for HIV, what it means. I now explained the drugs he is taking is ART, to kill HIV in the system.

Disclosure was, also sometimes triggered by an event, for instance, exasperation with child for refusing to take their medicine.

> It was in the morning. It is not because I planned it. But because he refused to take his medicine…That's why I told him that the sickness will kill him.

Even when it was the health care worker who disclosed, there did not appear to be any prior preparation of the parent/caregiver or child. There was also limited follow on disclosure sessions. However, some parents mentioned they reinforced the information health care workers had provided, or vice versa.

> When I came for appointment they asked me if I had told her. They told me why now? I don't know how to explain it. It was that very day they told him. It was that very day.

In one instance, where the child probably got infected via sexual assault/transmission, the disclosure process was also unplanned and a discrete event.

> Doctor called and informed me. So I asked her. I don't have it. So how comes you have it. That's when she opened up and told me that a man came across her.

On the one occasion when it appeared disclosure was planned, it took place the same day. There were no subsequent, deliberate, follow-on discussions on disclosure. It was usually that one conversation.

> It was at midnight. I did not want anybody to hear me. I'd been telling her that day to remind me [that there is something I wanted to tell her]. She kept reminding me. Then I told her. Do you know why we are forcing you to take medicine? It's because you have HIV. Don't let anybody know.

The conversation about the child's HIV status often took place in private between the child and parent(s). Other siblings or persons were usually not around.

> It was after evening devotion [prayers]. I asked the other children to go to bed. Then it was just me and the mother. Then I told him.
>
> It was me and my wife. I decided to tell him at that time. There was a seminar here [the hospital]. He was invited. I wanted him to know before then.

There were a number of families at the hospital where several children were living with HIV. In such cases, parents/caregivers would usually disclose to the children at the same time, rather than individually.

> It was at night in the house. The step mom was not around. It was private time. I told him and his brother at the same time.

Table 5.1 Characteristics of caregivers and disclosed children

Case #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Parent/caregiver characteristics															
Age (years)	32	47	42	50	55	40	48	30	45	38	63	45	37	62	60
Gender	Female	Male	Male	Male	Male	Female	Female	Female	Male	Female	Male	Female	Female	Male	Female
Relationship to child	Mother	Father	Father	Father	Father	Mother	Mother	Mother	Father	Mother	Father	Mother	Mother	Father	Aunt
HIV status	Positive	Positive	Negative	NA	Negative	Positive	Positive	NA	Negative	Positive	NA	Negative	NA	Positive	Positive
Child characteristics															
Gender	Female	Male	Male	Female	Female	Female	Female	Male	Male	Female	Male	Female	Male	Male	Male
Age at interview (years)	11	10	13	16	11	9	13	11	18	12	16	15	9	13	11
Age at diagnosis (years)	6 mo	3.5	11	7	9	8 mo	12	6	3	10	13	8	2	5	8 mo
Age at disclosure (years)	11	4	12	14	10	7	12	7	15	12	13	13	8	13	10

NA = Not available mo = months

Reasons for disclosure

By far the most common reason parents/caregivers gave for disclosure was related to the children taking their drugs. Children complained of being tired of constantly taking medicines, even when well, and were refusing to take their drugs. Another related reason, as one parent put it, was that parents felt the children needed to know why they were taking drugs, especially before the children started taking prescribed medicines, in order to prepare them. Yet other parents felt children needed to take more responsibility for taking their drugs, even when their parents were not around. These parents felt disclosure would ensure such responsibility for medication adherence.

> They are asking me they are tired of taking the drugs. So I had to tell them.
>
> So he can take his medicines because sometimes he refuses to take his medicine. That's why I told him that the sickness will kill him. Since I told him he became consistent in taking the drugs.
>
> I want her to take her medicine… let her know her status…let her know her condition so she can take care of herself.
>
> I prepare him to take the medicine properly, so he can take his drugs even when I am not around. I am not always around when he takes the drug.
>
> Because when she comes here [the hospital] she will be given drugs. So she should know why she should be given the drugs.

Some parents also spoke of feeling the children were now cognitively developed to understand what being diagnosed with HIV meant. The parents felt the children were now mature, and ought to know their status. For other parents, children being mature meant they could now keep their status a secret, if told, without disclosing it to others.

> At that age I didn't tell him. But when I know he can understand I told him.
>
> By now she's matured. By 12 years I can explain a little bit to her. She's having maturity now.
> I hide it from him so he will not expose himself. But as I see he is getting matured I decided to speak with him. He is going to age of reason, wanting to understand reason for his drugs. I was waiting for when he is able to understand.

Knowing their status would also enable the children to be discreet with their ARV drugs, and not inadvertently expose their status to others.

> I wanted him to know before other people will embarrass him, kind of. It is possible somebody will see him with the drugs and begin to ask him questions.

One parent described her dismay that her son would take his box of pills outside the house to show his playmates. Since the child did not understand what illness the medicines were meant for. This parent had experienced discrimination from her neighbours at home and in church when they learnt she was living with HIV. She did not want her son to go through the same experience with his playmates.

> *Dis medicine no be everybody for carry am go outside. You know say de medicine e go dey carry am show people. Em say e no know. Now e dey take medicine for inside house*

One parent disclosed only because the doctor had asked him to.

> If doctors had not asked me to tell her I will not have told.

Person who disclosed, and where

Disclosure happened either at home or in hospital. Majority of the children were disclosed to at home by their parents/caregivers (Table 5.2). This was either the mother, father or both parents. Parents chose to be the ones to disclose for a variety of reasons – either because they felt it was their duty, and therefore they should be responsible for disclosing to the child; or they felt it would be good for the children if they disclosed. In other cases, they simply disclosed because at the time of disclosure, it was the parent the child asked the reason for taking drugs.

> I felt it was my duty to tell him
>
> It is good for me to tell them. No need for somebody else to tell them
>
> At that time, it was me she asked. That's why I told her.

Two children were disclosed to at the hospital by a health care worker – the doctor, in one instance, and by the nurse (chief matron) at the pediatric clinic. One 13-year old girl was diagnosed with HIV while on admission in hospital. The doctor then disclosed her status to her. One parent felt he did not have the skills to disclose to his child so requested for the health care worker's help.

> For me to tell her I may not express myself the way she can know it better. That's why I told doctor they are the people who can explain it better.

There were no reported cases of disclosure by clergy in church or the school environment, or elsewhere.

Children's reaction to disclosure

Children's immediate reactions ranged from no reaction, calmness, and being quiet, as reported by four parents, to sadness in two children, shock or mild shock for two children, anger by one child, and crying by two children. In one case, both parents and the child cried at the time of the disclosure.

> There was no reaction – no tears, nothing.
>
> He's still junior. He didn't feel anything.
>
> He became cold. He listened to me. When I finished, he remained quiet. He was reflecting on it. We lost two of his sisters. I had to tell him it is the reason [i.e. his sisters died from AIDS]
>
> It's like he knew already what I was saying. He was not terribly shocked.
>
> She was shocked.
>
> We all shed tears, wondering how this sickness came into being

The parents were, however, quick to add that the children's reactions were only immediate, and quickly passed.

> She became sad somehow, [but] only that day.
>
> She was very sad. But now she does not talk about it.

Table 5.2 Characteristics of disclosure

Case #	Who disclosed	Where	When	Others present during disclosure	Reasons for disclosure	Child's reaction to disclosure
1	Mother	Home	At night	No	Child refused to take his medicines	No reaction
2	Accidental disclosure	Hospital	During health talks with mother at the clinic	Mother	Not applicable	Not available
3	Father	Home	At night, after evening prayers	Mother	So child can take his medicines even when his father was not around	Cry
4	Father	Home	In the morning	No	Child was asking when she would stop taking her medicines	No reaction
5	Health care worker	Hospital	During regular clinic visit	Father	Doctor asked that the child be disclosed	Not available
6	Mother	Home		Sister who was also HIV-positive	Child was complaining that she was tired of taking medicines	Shock
7	Health care worker	Hospital	Child was admitted in hospital	Mother and sister who were both also HIV-positive	So they will know how to live their lives	No reaction (probably because child was too sick). But the other sibling cried.
8	Mother	Home	morning	No	Child refuses to take his medicines	No reaction
9	Father	Home	At night	Brother who was also HIV-positive. Step mother was not around	Child was now mature	"He became cold"
10	Mother	Home	Not available	Father	She is mature now	"She was very sad"
11	Father	Home	In the morning as they were about to come to the hospital	Not available	So child can know why he is taking medicines	"He is still junior. He did not feel anything"
12	Mother	Home	Not available	Not available	Child was complaining she was tired of taking medicines	Anger (child was infected through blood transfusion)

13	Mother	Home	When child came back from school	Not available	Child was asking questions	“He was somehow”
14	Father	Home	Not available	Not available	So child can be discreet with his medicines	“He was not terribly shocked. It was as if he knew already”

In one instance, an older sibling (not living with HIV) overheard her mother (who is also HIV-positive) disclosing to the younger sister who is living with HIV. She started crying, perhaps thinking her mother would soon die.

> The senior girl [older daughter] heard and started crying. I had to ask her, "Did you see anybody dying? Do I look like I am going to die? I am not going to die. See, I am healthy."

Conversations with the children

Prior to disclosure, the most common question children asked was why they had to continue taking medication, even when they did not feel sick. They also wanted to know when they would stop taking the medicines. Where the child was the only infected child in the family, they would ask why their other siblings did not have to take medicines all the time. Two children asked if they could share their medicines with their other siblings when they were sick.

> She kept asking why she is taking medicine. When will she stop?
>
> Why this too much drugs every day like this. He say how long he will take it before stopping?
>
> Why only me taking these drugs? My younger ones are not taking.
>
> *Wen my broda sick make I give am?*

One child also asked why he was not allowed to go to boarding school, since it was common in Nigeria for children in secondary schools to live in boarding schools.

> Why no boarding school? Every sibling has gone to boarding school. Now he knows why.

After disclosure, seven parents reported that their children had stopped asking any questions about their health, or the reason for continuing to take drugs. One child also asked how he became infected, and wondered if his parents were also infected. Two children still continued to ask when they will stop taking their drugs.

> She has not asked any questions since then. She is content with the answer I gave her.

> He always ask about how come [he got infected]? Are his parents infected?

Child's refusal to accept a positive HIV-diagnosis

There was a case of an 11-year old boy who was told by his 60 year old aunt, who was also his caregiver, that he was living with HIV. But he refused to accept his status. It seemed so improbable to him that he would be infected with HIV.

> *E dey ask from where HIV come wey em catch am.*

Challenges parents face with disclosure

Most parents described the difficulties and stress they felt with disclosure – either not feeling they had the right skills to disclose, or they worried about how the child would feel and react to the news of their HIV-positive status.

> I didn't tell her then because I found it difficult. How would she feel? But that night I told her. Even me myself I was relieved. I did not find it easy. I found it difficult to tell her. If she had been taking her medicine I would not have told her.

Some parents broke down in tears as they shared their experiences and concerns about their children, and their future, and how they would cope with living with HIV.

> I just had to tell him. I feel he can't be taking drugs without knowing. Though I found it so difficult to tell him, I as a father, I don't have it. Even the mother and the other children. He is the only one. [Father broke down when narrating the experience]

One parent, however, felt his vocation as a preacher prepared him to disclose to his child.

> I was prepared through religion- preaching every morning, prayers.

Parents' concerns for their children

While much needed attention is now being focused on how children experience living with HIV, it is important to remember that parents also find caring for CLHIV distressful. At the end of the interviews, the PI invited parents to ask any questions. Most parents appreciated the opportunity to talk with somebody, not just about medicines and medical issues, but the struggles they were having with HIV as an illness in the family. Parents' concerns went beyond medical issues, to other challenges with life, in general. Some of these concerns become more poignant when cast in the context of HIV. Such fears included concern for the other siblings being inadvertently infected with HIV by the CLHIV. One father of two girls sent the younger, non-infected child, to live with the child's grandmother. He was concerned that the older girl, who was living with HIV, could infect the younger one. He felt since they were both young children, they may not be careful while playing with sharp objects, and may inadvertently infect the younger child.

The major concern another mother had was about her two teenage girls getting married. According to her, the church they attended would not allow the children to be married in church, even to another person who was HIV-positive. Their church would not wed them. A widower and father of four children, who had already lost two children to AIDS, and the surviving two boys were living with the virus was concerned with how he would keep the surviving children alive. He was very grateful for the free treatment program at the clinic, and the work by health workers to keep patients alive. He had been tested and found negative, but his late wife was positive.

The role of schools in HIV disclosure

No parent reported disclosure happening in schools, or about teachers or other school personnel being involved in disclosure. However, some parents mentioned that the lessons provided in schools on HIV helped them disclose to their children. Many respondents mentioned that knowing their children were already learning about HIV helped them to disclose. They felt it was easier to disclose because the children had some knowledge about HIV.

The main concern parents mentioned in relation to schools, was how to deflect the children's questions about not going to boarding school. It is common practice in Nigeria for children to live in boarding schools while attending secondary school (from 9 - 10 years or above). Due to concerns about disclosure of status, and medication adherence, many parents of CLHIV chose for their children to attend secondary school from home. However, these children felt they were missing an important experience compared to their mates.

> He's the last [child]. Why no boarding school? Every sibling has gone to boarding school. I told him a lie. I told him he was my last child, so I wanted him around me. He accepted it. Now he knows why.

DISCUSSION

The findings from this study are consistent with those reported in similar qualitative studies in SSA. Children are often disclosed because of repeated questioning from the children [4] [5] [13], and the parents' perception that children are cognitively mature to understand their diagnosis [4] [7]. As has been reported in other studies, this study showed that fear of inadvertent disclosure and child's young age are main barriers to disclosure [4] [5] [7] [8] [13]. Similarly, this study also showed that the disclosure process is often a one-off event that is often unplanned [12], even though WHO guidance on pediatric disclosure encourages that disclosure should involve a series of discussions.

Children's reactions to disclosure in this study were similar to those reported by other studies. They included no reaction, to shock, and crying. Many parents in this study attributed their children's lack of reaction to the children's young age and lack of understanding of the news. This has been observed in other studies [12]. However, some of these studies that also included interviews with the children, showed the children had a different experience of the disclosure process/news than their parents. They were quiet, not because they were too young and did not understand the news, but chose not to ask questions or react to the news, despite the questions and concerns they had about the news of their diagnosis [12].

Although this study showed that both parents and health care workers disclosed to children, it was outside the scope of this study to determine which was better, and therefore, who should disclose – parents or health care workers, or where disclosure should take place – the hospital or home, or which had more benefits. The study also did not systematically seek information on parents/caregivers' own HIV status and how that affected or did not affect disclosure, although some parents/caregivers volunteered information on their HIV status (positive or negative) in the course of the discussions.

This study suggests that schools already play an important role in disclosure by providing basic HIV education to children, as part of the school curriculum. Schools could also play an even bigger role by providing an additional and alternative environment for disclosure. Some parents reported their concerns around their children being able to go to boarding school, like other children, due to concerns with medication adherence and disclosure. Most children in Nigeria go on to live in boarding schools when in secondary school from age 9 to 12 years. As WHO notes in its pediatric disclosure guidance document, this and many other school-related issues for children suggest that this is an important area for study [2]. School personnel could prove to be other "safe" persons outside the family who could assist with pediatric disclosure [2].

Health care workers already play an important role in pediatric disclosure by encouraging parents to disclose to their children, and also helping to disclose when necessary. Some parents mentioned they would not have disclosed if they had not been asked by health care workers to disclose to their children. But some parents still report their lack of skills to disclose, despite their desire to disclose. Health care workers could, therefore, facilitate more disclosure by building parents' skills to disclose. The PI's conversations with health care workers at UATH did not show that this was happening systematically or in a structured way.

This study noted two cases of inadvertent disclosure. It is not clear how this compares with children who were intentionally disclosed. In any case, parents and health care workers need to ensure such inadvertent disclosure is prevented.

One child refused to accept his HIV diagnosis, asking where HIV “came from” that he could have been infected. This could be an indication of the quality of the disclosure process, and the inadequacy of the information provided to the child by his parent/caregiver during disclosure. This 11-year old boy, who was disclosed to by his 60 year old aunt (caregiver), was perinatally infected. This example makes a case for ensuring that the disclosure process is structured in terms of how it happens and that adequate information is provided during the process. A disclosure guidance could, therefore, be a helpful document for parents and health care workers on how to disclose to children living with HIV.

Stigma and discrimination remain an important barrier to pediatric disclosure [7] [13]. Some parents explained their concerns about being seen at the paediatric clinic – especially by health care workers from other departments who they knew, since being seen at the clinic would indicate that their child was HIV positive. One female respondent mentioned how she always prayed on each clinic day that nobody they knew would see them in the clinic. This study highlights how such concerns also contributed to non-disclosure of status to children, as parents want to wait until children are older and would not divulge information about their status.

Religion plays an important role in life in Nigeria. It was therefore, surprising that religious leaders were not playing a more visible role in disclosure. One parent described how her pastor stepped in when she was experiencing stigma and discrimination from other church members. Due to the pastor’s intervention, the discrimination stopped. However, the church and mosque could play a more active role in disclosure. More studies are needed to describe if, and how, religious leaders are involved in disclosure, and in addressing stigma and discrimination. They are already actively involved in the larger HIV response, and could be effective agents in disclosure.

Most respondents were themselves HIV-positive, and many would come to the clinic both for their own clinic consultations with the doctor at the adjoining adult ART clinic, and for their child's. Due to the very high patient volume and long queues at the adult ART clinic many kept shuttling between the adult clinic and the pediatric clinic. As such, they could not spare too much time for the interview and questionnaire. This, therefore, limited the amount and scope of probing that the PI could undertake. Visiting parents in their homes was not a viable option due to concerns about stigma and the related cost of this option. Neither, was scheduling another time for parents to return to the clinic for the interview an option, due to the cost implications – for parents and the PI. No respondent agreed to be audio-taped. The PI, therefore, had to rely on taking as much notes by hand as possible. This limited the amount of information that could be gathered.

CONCLUSIONS

By far the most common reason parents/caregivers gave for disclosure was related to the children taking their drugs. The disclosure process suggest that this was usually a discrete, one-off event that was unplanned. Children's immediate reaction ranged from no reaction, to sadness, ange and crying. Some parents described their difficulties with disclosure, including not feeling they had the right skills to disclose. Health care workers could therefore facilitate more disclosure by building parents' skills to disclose. Religious leaders could be more actively involved in disclosure, and the reduction of stigma and discrimination against persons living with HIV. Schools could also provide an additional environment for disclosure.

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CHAPTER 6
PLAN FOR CHANGE

INTRODUCTION

Key findings from this study include a low pediatric HIV disclosure rate at 30.9%, with 10.19 years as the mean age at disclosure, and three (30%) of the 10 children in the study aged ≥ 15 years not knowing they are HIV positive. The study also showed that most children (79.4%) were disclosed to at home by their parents/caregivers. The process of disclosure was not usually planned – neither by health care workers nor parents. Some parents/caregivers expressed they lacked the skills to disclose to their children. Health care workers at UATH – the study site - did not have any detailed guidance or manual on how to work systematically with CLHIV and their parents/caregivers to ensure disclosure. While the study did not interview children directly, some parents/caregivers reported that their children were affected emotionally, albeit in the short term, by learning their HIV status.

These findings stand in stark contrast to the World Health Organisation guideline on pediatric disclosure. WHO published the *Guideline on HIV disclosure counselling for children up to 12 years of age* in 2011 [1]. The guideline provides definitive and evidence based guidance to health care workers and pediatric HIV program managers on when, who and how to inform children of their own and caregivers' HIV status. The following are some of the key WHO recommendations on pediatric HIV disclosure:

1. Children of school age (6 – 12 years) should be told their HIV positive status. Younger children should be told their status incrementally to accommodate their cognitive skills and emotional maturity, in preparation for full disclosure.

2. The decision on who will disclose to the child should be guided by the intent to improve/ promote the child's welfare and minimize the risk to his or her well-being and to the quality of the relationship between child and parent/caregiver.
3. Initiatives should be put in place to enforce privacy protection and institute policy, laws and norms that prevent discrimination and promote tolerance and acceptance of people living with HIV. This can help create environments where disclosure of HIV status is easier.

Even though this guideline has been in the public domain for four years now, as far as is known, no country in SSA, including Nigeria, has developed its own detailed national pediatric HIV disclosure guidelines. The Nigeria *Integrated National Guidelines for HIV Prevention, Treatment and Care* includes half a page of information on the importance of HIV disclosure to children [2]. It proposes the following steps for pediatric HIV disclosure:

- Evaluate the child and family for readiness-including child's age and maturity. Five to seven years are earliest recommended ages for disclosure, and all [children] should be disclosed by age 12 years.
- Ascertain a child's and caregiver's understanding of HIV infection
- Explain the benefits of early awareness of HIV infection to the child and care giver/family
- Provide ongoing psychosocial support.

This, however, is a far cry from the guidance that health care workers require – as findings from this study show - to be able to appropriately and effectively counsel and guide CLHIV and their parents/caregivers on disclosure.

STUDY RECOMMENDATION

The one recommendation from this study is, therefore, for the ***Government of Nigeria to develop national <u>standard operating procedures or protocols</u> and a <u>training manual</u> for health care workers and parents/caregivers of children living with HIV that will promote child HIV disclosure*** *in order to address the current low rate of disclosure in the country.*

One objective of this study is for its findings to add to the existing body of scientific knowledge in the field of care and treatment for children living with HIV, and further the understanding of the factors that facilitate and hinder HIV disclosure to children in resource limited settings. It is expected that this body of knowledge will be useful in developing guidelines for HIV disclosure to children – in Nigeria and elsewhere on the continent.

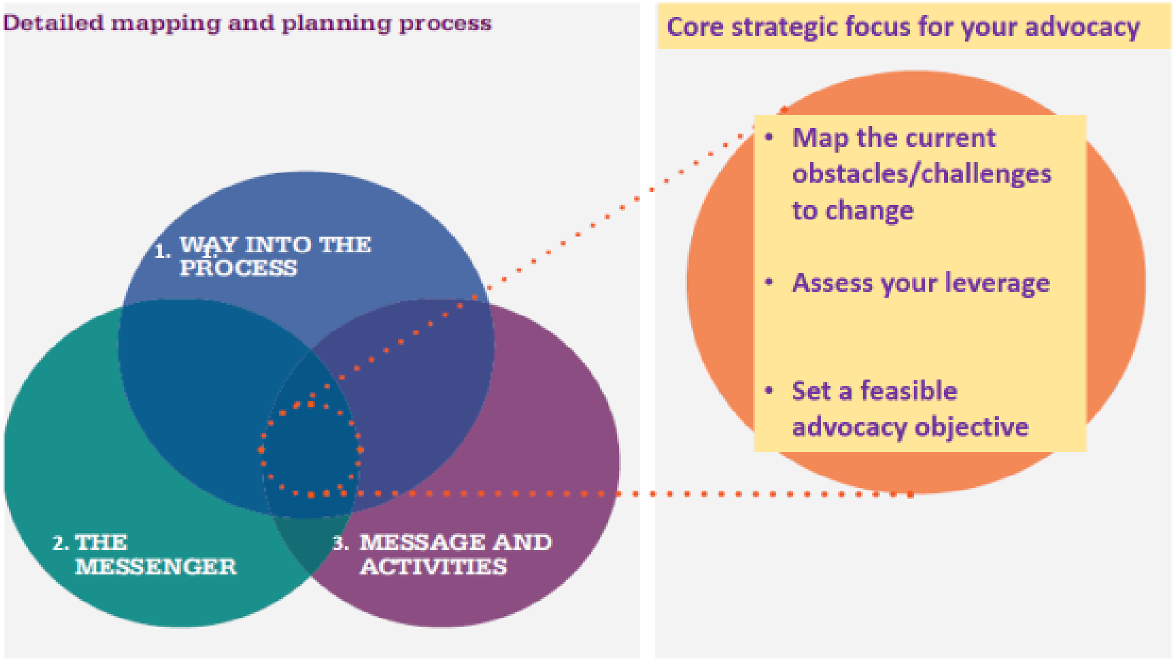
Study findings will also be useful in designing HIV related guidelines in the education setting. As more CLHIV reach school age, such guidelines also need to include disclosure to education personnel in the school environment, and how to build capacity in the school environment to limit stigma and facilitate support for CLHIV in schools. Although the decision to inform schools of the child's HIV status should remain a family decision, providers and program managers can facilitate the process and help build family capacity to do this.

MOVING FROM RESEARCH TO POLICY AND GUIDELINES: THE ADVOCACY PLANNING FRAMEWORK

This chapter presents an implementation plan for how the findings from this study will be used to advocate for the development of standard operating procedures or protocols (SOPs) and a training manual for pediatric HIV disclosure in Nigeria, using an adaptation of the Advocacy Planning Framework (APF) [3] . First, is the presentation of the strategic focus and the three pillars of the APF, followed by how the APF will be applied in advocacy efforts to move the policy development process for pediatric HIV disclosure in Nigeria.

According to Young and Quinn [3] policy advocacy focuses on influencing decisions of public policy. They define "*successful advocacy as a process through which the main target audiences, including decision makers, need to build ownership of the ideas and proposals put forward, which will then direct them in leading any upcoming decision*" (page 56). The APF is a simple tool for advocacy that consists of a core strategic focus and three pillars (Figure 6.1). These three pillars are: (1) **Way into the Process** – which seeks to determine the best approach to get one's issue into the policy debate, and who should be the target audience(s) for advocacy; (2) **The messenger** – which seeks to determine who should lead or be the face of the advocacy efforts; and (3) **The message and activities** – which seeks to determine the messages and activities that will be effective in reaching the target audience(s). Three strategic questions that will help to build these three pillars are: (1) Map out the current obstacles and challenges to the policy initiative. That is, the barriers that are blocking the policy making process from

Figure 6.1 The Advocacy Planning Framework



Adapted from Young & Quinn (2012)

moving forward; (2) Assess what leverage one can bring to the advocacy process; and (3) Set a feasible advocacy objective or endpoint for the advocacy initiative. This should focus on the change one seeks to see, and how far one thinks the advocacy process can be moved forward, and not necessarily on the policy outcome.

ADVOCACY PLANNING FOR THE DEVELOPMENT OF PEDIATRIC HIV DISCLOSURE GUIDELINES

A. Strategic focus for advocacy

Mapping the current obstacles and challenges*:* It is not envisaged that there will be substantial opposition to developing SOPs or a training manual for pediatric HIV disclosure. The main challenge will be to gather enough momentum from civil society organization (CSO) stakeholders to trigger the process, amidst the competing program and funding priorities in these organizations. The usual practice for developing national tools, is for a CSO or coalition of CSOs to spearhead the process, by developing draft protocols and training manuals for use in their own programs. It is then often easier to follow up with adopting or adapting these documents for national use, thereafter. Recent discussions indicate that at least one CSO is already developing pediatric disclosure related documents. The PI will work closely with this CSO and government focal persons in the two key government ministry and agency – the National Agency for the Control of AIDS (NACA), and the National AIDS/STIS Control Programme (NASCP) - as well as UNICEF to move this issue into the national discourse.

A key opportunity for the advocacy process is the publication of the WHO guideline [1]: What Young and Quinn [3] term the “policy spillover,” or an international trend that can catalyse policy discussion in many countries. PEPFAR also requires disclosure as an element of the package of care provided to CLHIV by PEPFAR supported programs. These two opportunities already “soften up” the process for advocating for the development of Nigeria-specific guidance documents [3, page 125].

Assessing leverage for advocacy: This study is one of few studies on pediatric disclosure in Nigeria. To date, there is only one published peer-reviewed work on pediatric HIV disclosure on Nigeria [4]. Therefore, the findings from this study will be welcome. The PI has also worked in the adolescent and reproductive health arena for over a decade. The stakeholder network that has been developed in-country in these fields and familiarity with key government and civil society stakeholders will help in advocating for the proposed change/development in the country.

Setting a feasible objective for advocacy: The objective of this advocacy effort will be to move forward the process of developing national SOP, and training manuals for health care workers and parents/caregivers on pediatric HIV disclosure. The country recently moved towards the consolidation of HIV guidelines. Instead of having separate guidelines for HIV prevention, treatment and care, the separate existing documents were consolidated into one document in 2014 [2]. Therefore, advocating for a separate pediatric HIV disclosure guideline will likely meet with stiff opposition from many stakeholders. However, it is clear that SOP, and training manuals are needed by stakeholders, especially program managers and health care workers, as these documents will facilitate the practical implementation of the recommendations in the consolidated guidelines. One sub-objective of this advocacy initiative will, therefore, be to get the discussion of the development of the SOP and training manuals on the agenda for the next pediatric HIV technical working group (TWG) meeting. The TWG is where most program managers and health care workers meet regularly to discuss technical issues.

B. Detailed mapping and planning process

Way into the process: The main aim of this APF pillar is a detailed mapping of the policy landscape in order to understand the key policy actors and their influence. Key information from this stakeholder analysis will include mapping the key policy decision makers that should be influenced; clarifying the position of these key actors in relation to the proposed advocacy intervention; understanding the policy or guideline making process; and identifying the opportunities and best timing for this advocacy effort.

The main strategy for this stakeholder mapping will be one-on-one meetings with pediatric HIV focal persons at government ministries and agencies, such as the Federal Ministry of Health, NACA, CSOs and UNICEF.

The messenger*:* This will be the key stakeholder who will lead the advocacy efforts, and be the champion and "face" for this advocacy. Young and Quinn suggest identifying such a champion from within or close to the government sector [3]. However, considering that the process of developing guidelines, SOPs and training manuals is often initiated by program implementing partners that need such guidance documents for their program implementation, the PI may choose a champion from an implementing partner or a multilateral organisation, such as UNICEF. In view of the very hierarchical structure of the government sector, a champion from within the government sector would need to be high up the ladder to be influential. Incidentally, the program focal persons are often lower cadre officers in the ministry, who will not be able to rock the boat.

Implementing partners and UNICEF have the financial resources to fund national meetings and workshops for developing, adapting and adopting national guidance documents. This is an important consideration, as the lack of funds can sometimes hinder the policy development process. Such a champion will have to be credible, and reputable among stakeholders. Beyond identifying a champion for the advocacy efforts, it will be helpful to identify other supporters of this effort from among the identified stakeholders and build a coalition of support around this issue.

Activities**:** Key advocacy activities will include one-on-one meetings with key stakeholders, such as focal persons at key government ministries and agencies, UNICEF and program implementing partners. The PI will focus on two implementing partners – IHVN and FHI 360 – that are key players in the pediatric HIV arena. Other activities will include participating in technical working group meetings, and presentations at conferences – local and international, and at TWG meetings. Publication of study findings in peer reviewed journals will also enhance the value of the study findings for advocating for the development of the guidance documents. Table 6.1 summarizes the key activities for advocating for the development of national pediatric HIV disclosure SOP and training manuals.

Table 6.1 Key activities for advocating for the development of pediatric HIV disclosure guidance

S/N	Key Activities	Objectives/Comments	Timeline
1	Finalise and submit three manuscripts on the study findings to peer reviewed journals	This will increase the advocacy value of the study findings	Nov 2015
2	Map the actors, network, and power centers: - Who they are - What is their current thinking and position on pediatric HIV disclosure guidance	The focus will be on these actors: - NASCP, NACA (Government) - UNICEF (multilateral) - IHVN, FHI 360 (CSO/IPs) - Others	Nov 2015
3	Clarify the process for the development of national standard operating procedures and training manuals	The aim will be to determine the current opportunities and how to align advocacy efforts through TWG and other national level meetings and events	Nov 2015
4	Choose the face of the advocacy efforts	The aim is to identify which stakeholder is best positioned to lead the broader advocacy/ guidance development process	Nov - Dec 2015
5	Mobilize other support	Identify and mobilize other supporters of pediatric HIV disclosure	Nov - Dec 2015
6	Select and implement advocacy activities and communication tools and channels	Mostly publication and other literature	Oct 2015 – Mar 2016
7	Plan for challenges and responses	This will be ongoing – developing responses as challenges emerge	Oct 2015 - Mar 2015

Message: Different messages will be tailored to the different audiences, as shown in Table 6.2. Suggestions for crafting appropriate messages include providing arguments to the various audience segments, “how seen from their perspective, it makes sense to change” [3, page 118]. Also including a mix of carrots (incentives) – what they stand to gain from developing the guidance documents; and sticks (sanctions) – what they stand to lose if the guidance documents are not developed, are useful hints for effective messages [3, page 118].

Table 6.2 Tailored messages for advocacy audiences

Audience	Message
Government	• There are already Nigeria-based studies - including this one – that show very low rates of disclosure, and the desire by parents/caregivers to learn skills on how to disclose. In other words, there is a "consumer" need for the guidance. • Nigeria will be seen internationally as being a frontrunner to develop national pediatric HIV guidance documents ("carrot") • WHO has published the pediatric HIV guideline that will be useful in the Nigeria process
UNICEF	• WHO has published disclosure guideline that could be useful • UNICEF will be seen as promoting conformity with WHO (a sister body) recommendation ("carrot")
Implementing partners (CSO)	• As PEPFAR partners, implementing partners are already required to develop disclosure guidance and provide disclosure services, as part of the package of care for HIV-infected children ("carrot") • Many infected adolescents may be starting sexual activity, and if not disclosed may infect others ("stick").

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APPENDIX 1: QUESTIONNAIRE FOR PARENTS/CAREGIVERS OF PEDIATRIC ART PATIENTS

(Complete the following)	1. Date of interview_________________________________ 2. Location_______________________________ 3. Respondent – Male/Female---------------------------------- 4. Child – Male/Female---------------------------------- 5. Interviewer-- 6. Language of interview-- 7. Questionnaire Ref. No_____________________________
Introduction and Consent	My name is Angela Odiachi. I am a University student conducting research on health. This study has been reviewed and granted permission by both my University Research Ethics Committee, and the University of Abuja Teaching Hospital Ethics Committee. I would very much appreciate your participation in this study. This information will help both governments and program managers to plan health services. The survey usually takes between 20 and 25 minutes to complete. Whatever information you provide will be kept strictly confidential and will not be shown to other persons. Should you have any questions, please feel free to call any of the following contact person(s): **UATH Contact Person: (designation)---------------; Email:------------- Phone**: **UNC Contact Person: (designation)--------- Email: --------------- Phone: ---------** All of the answers you give will be confidential. Participation in the survey is completely voluntary. If I should come to any question you do not want to answer, just let me know and I will go on to the next question; or you can stop the interview at any time. However, I hope you will participate in the survey since your views are important. At this time, do you want to ask me anything about the survey? May I begin the interview now?
A: Ice breaker	1. Can you tell me why you came to the hospital today? ____ 2. What year did child start receiving treatment at this health facility? -----Year -----------------
B: Disclosure	*I am now going to ask you some questions about child's health* *3.* What year did child start taking ART medicine**?** **Year _________** **Month___________** **Don't know________________**

	4. What year was child diagnosed with HIV? **Year _________** **Month___________** **Don't know________________** 5. Does child know s/he has HIV? (1) Yes (2) No (8) Don't know 6. Does child know s/he comes to clinic for HIV care? (1) Yes (2) No (8) Don't know 7. Does child know that the name of his/her sickness is HIV? (1) Yes (2) No (8) Don't know 8. Does child know that s/he is taking medicine for HIV? (1) Yes (2) No (8) Don't know **If No to Question 5 to 8, skip to Q 14**
C: Disclosure Context - **When diagnosed** - **Setting** - **By whom**	*I am now going to ask you some questions about child's health* 9. Who informed child that s/he had HIV? (1) Parent/caregiver (2) Health care provider (3) Pastor/Imam/Clergy (4) School personnel (4) Child was told by a relative (5) Child was told by _______--(someone else, *please specify*)

	(6) Child saw his/her health report (7) Other method ___________(*specify*) (8) I don’t know 10. Where was child told he had HIV? (1) At home (2) At the hospital (3) At school (4) At church (5) Other, specify________________ (8) Don’t know 11. Why was child told s/he had HIV? (1) To help him/her take his/her medicines regularly/ Child refused to take medicines (2) To improve their health (3) Child is now mature/old enough (4) Child was asking a lot of questions about his/her illness/medicines (5) Child was about to start school (6) Child refused to come to hospital (7) So they do not infect others (8) Child may become sexually active (9) So child can protect him/herself (10) Other, specify________________ (88) Don’t know 12. What year did child learn that s/he had HIV? Year___________ Month_______________ 13. How old was child when s/he was told s/he had HIV? ___________________________ years (8) Don’t know
D: Non-disclosure	14. Why have you not told child s/he has HIV? (1) It will make them sad

(2) It will make them angry
(3) they will not be able to keep it a secret
(4) Child is too young
(5) Child will blame parent
(6) Child will refuse to take his/her medicines
(7) Child will refuse to come to clinic
(8) Do not know how to disclose to child his/her status
(9) Other people may find out
(10)The child may be afraid they might die and give up
(11) Other, specify_____________________________________
(88) Don't know

15. Do you have any suggestions on what will help you disclose child's status to him/her?

E: Sociodemographics

I am now going to ask you some questions about child and his/her family

16. In what month and year was child born?

Year __________________ (9998) Don't know Year
Month__________________(98)___Don't know month

17. How old was child at last birthday?
---------------------------- (AGE IN COMPLETED YEARS)

COMPARE AND CORRECT Q.16 AND/OR Q.17 IF INCONSISTENT

18. Is child in school?

(1) Yes
(2) No
(8) Don't know

IF NO, SKIP TO Q 20

19. During this school year, what level of school is child attending?
(1) Kindergarten

(2) Primary
(3) secondary
(4) Post-secondary/Higher
(5) Other, specify________________________
(8) Don’t know

20. What is child’s tribe?
(1) Hausa
(2) Igbo
(3) Yoruba
(4) Other, specify------------------------------------
(8) Don’t know

21. How are you related to the child?
(1) Mother
(2) Father
(3) Sibling
(4) Uncle
(5) Aunt
(6) Grandparent
(7) Other, specify______________________________
(8) Don’t know

22. Are you child’s caregiver?
(1) Yes
(2) No
(8) Don’t know

23. How old were you at your last birthday?

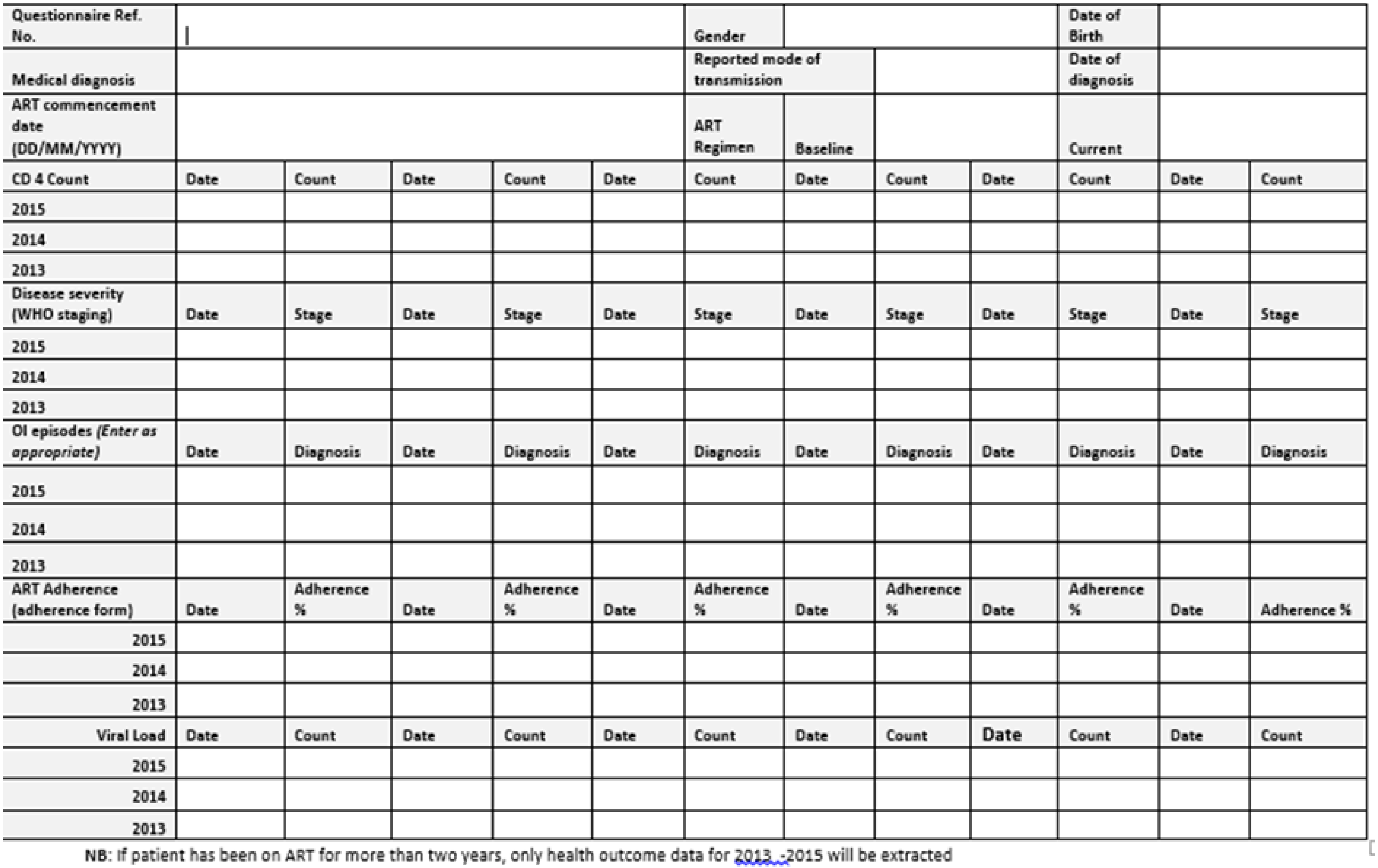
----------------------------AGE IN COMPLETED YEARS

24. Have you ever attended school?
(1) Yes
(2) No
(8) Don’t know

25. What is the highest level of school you attended:
(1) Primary
(2) secondary
(3) Post-secondary/Higher
(4) Other, specify________________________

	(8) Don't know 26. What is your religion? (1) Christian (2) Muslim/Islam (3) Traditionalist (4) Others, specify_________________ 27. What is your tribe? (1) Hausa (2) Igbo (3) Yoruba (4) Others, specify-----------------------------------
Conclusion	I have come to the end of my questions. Do you have any questions for me? Thank you for your time.

APPENDIX 2: PATIENT DATA EXTRACTION FORM



Questionnaire Ref. No.						Gender				Date of Birth		
Medical diagnosis						Reported mode of transmission				Date of diagnosis		
ART commencement date (DD/MM/YYYY)						ART Regimen	Baseline			Current		
CD 4 Count	Date	Count	Date	Count	Date	Count	Date	Count	Date	Count	Date	Count
2015												
2014												
2013												
Disease severity (WHO staging)	Date	Stage	Date	Stage	Date	Stage	Date	Stage	Date	Stage	Date	Stage
2015												
2014												
2013												
OI episodes *(Enter as appropriate)*	Date	Diagnosis	Date	Diagnosis	Date	Diagnosis	Date	Diagnosis	Date	Diagnosis	Date	Diagnosis
2015												
2014												
2013												
ART Adherence (adherence form)	Date	Adherence %	Date	Adherence %	Date	Adherence %	Date	Adherence %	Date	Adherence %	Date	Adherence %
2015												
2014												
2013												
Viral Load	Date	Count	Date	Count	Date	Count	Date	Count	Date	Count	Date	Count
2015												
2014												
2013												

NB: If patient has been on ART for more than two years, only health outcome data for 2013 -2015 will be extracted

APPENDIX 3: INTERVIEW GUIDE FOR PARENTS/CAREGIVERS OF DISCLOSED CHILDREN

INTRODUCTION: I know you have answered some of the questions I am about to ask you. But I want you to feel free to discuss some of the questions in more detail.

You have mentioned that child was disclosed when s/he was ---- years, and it was ----- who disclosed to him/her.

1. **(HOW)** Can you describe **how** child found out s/he was HIV positive?
   (Probe for where, when, disclosed by whom?)

2. **(WHY)** Can you explain more why was child told s/he had HIV?
   (Probe: what helped you or your family/or made it easier to disclose to child?)

3. (**WHO**) You mentioned that child was told by ……Why was it this particular person (and not someone else)?

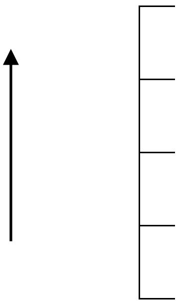
4. **(WHEN)** You mentioned that child was -----old when she was told. Can you explain why it was this particular age – not earlier or later?

5. **(HOW MUCH)** How much do you think child knows about her sickness? Do you think child knows s/he has HIV?

(**Probe: Has the word HIV or AIDS or local equivalent been used by anyone in any conversation with child about their sickness**? **If local equivalent term was used, which specific term?)**

6. **(VISUAL)** If you were to show on a scale like the one below, the bottom mark being the child does not know at all, and the top mark being child knows she has HIV, where would you place how much child knows on the scale?

Highest (child knows s/he has HIV)



Lowest (child does not know s/he has HIV)

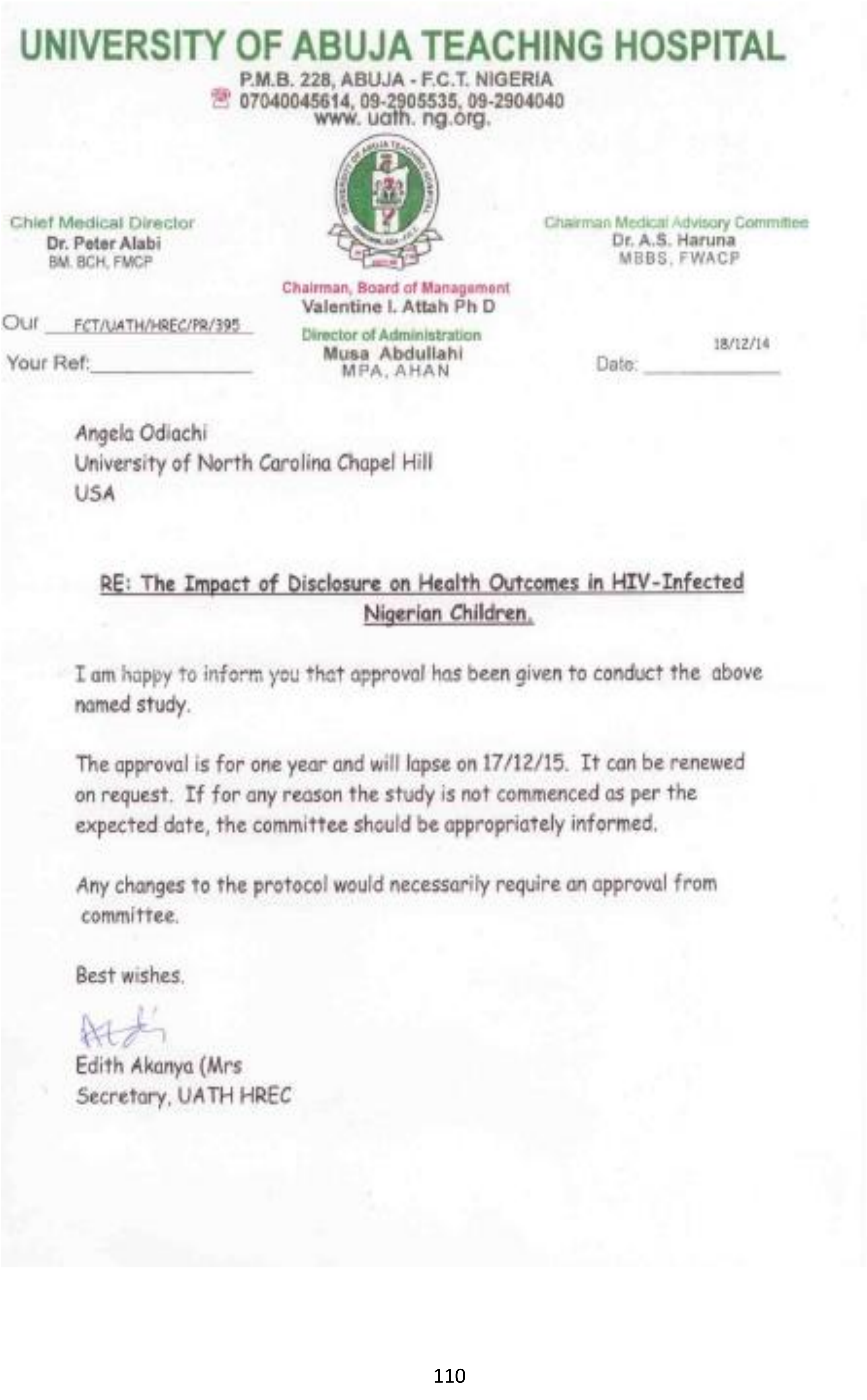
7. Can you explain why you have chosen this point?

8. Can you describe some conversations you have had with child about his/her health. (**Probe**: What questions has child asked about his/her health? Who child asked; when; where?)

9. What answers was s/he given?

Thank you for your time. I appreciate your participation in the study

APPENDIX 4: UNIVERSITY OF ABUJA TEACHING HOSPITAL INSTITUTIONAL REVIEW BOARD LETTER OF APPROVAL



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Chief Medical Director
Dr. Peter Alabi
BM. BCH, FMCP

Chairman, Board of Management
Valentine I. Attah Ph D

Director of Administration
Musa Abdullahi
MPA, AHAN

Chairman Medical Advisory Committee
Dr. A.S. Haruna
MBBS, FWACP

Our FCT/UATH/HREC/PR/395
Your Ref:
Date: 18/12/14

Angela Odiachi
University of North Carolina Chapel Hill
USA

RE: The Impact of Disclosure on Health Outcomes in HIV-Infected Nigerian Children.

I am happy to inform you that approval has been given to conduct the above named study.

The approval is for one year and will lapse on 17/12/15. It can be renewed on request. If for any reason the study is not commenced as per the expected date, the committee should be appropriately informed.

Any changes to the protocol would necessarily require an approval from committee.

Best wishes.

Edith Akanya (Mrs
Secretary, UATH HREC

APPENDIX 5: UNIVERSITY OF NORTH CAROLINA INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

To: Angela Odiachi
Health Policy and Management

From: Non-Biomedical IRB

Approval Date: 2/04/2015
Expiration Date of Approval: 1/12/2016
RE: Notice of IRB Approval by Full Board Review
Submission Type: Initial
Study #: 11-2033

Study Title: The Impact of Disclosure on Health Outcomes in HIV-Infected Nigerian Children

This submission has been approved by the IRB for the period indicated.

Study Description:

Purpose: This study aims to explore the association between *pediatric disclosure* (defined as disclosure of child's seropositive HIV status to the child or informing the child that s/he has HIV) and health outcomes in a cohort of HIV-infected children in Nigeria. The study will: (1) Determine the rate and nature of HIV status disclosure, and identify the main agent of disclosure; (2) Determine age at HIV disclosure (3) Investigate locally pertinent barriers to, and facilitators of disclosure and (4) Investigate associations between disclosure, and health outcomes (adherence, viral load, CD4, and Opportunistic infections).

Participants: These will be 140 parents/caregivers of children living with HIV at the Pediatric ART clinic, of the University of Abuja Teaching Hospital, Abuja, Nigeria

Procedures (methods): The study is in two parts: (1) Quantitative component that explores the association between pediatric disclosure and health outcomes. This will involve administering a questionnaire to 140 parents/caregivers of paediatric ART patients; and also extracting health data on the children from their medical records (2) Qualitative component that consists of indepth interviews with a minimum of 10 parents/caregivers of disclosed children to determine the context and process od disclosure to children.

Regulatory and other findings:

This research, which involves children, meets criteria at 45 CFR 46.404 and/or 21 CFR 50.51 (research involving no greater than minimal risk). Permission of one parent or guardian is sufficient.
The IRB has determined that assent of the children may be waived according to 45 CFR 46.408(a) and/or 21 CFR 50.55(c)(1). The capability of some or all of the children (based on age, maturity or psychological state) is so limited they cannot reasonably be consulted about their willingness to participate. For the children six and below.

The IRB has determined that assent of the children may be waived according to 45 CFR 46.408(a) and/or 21 CFR 50.55(c)(2) because the intervention or procedure(s) involved, available only in the context of the research, offers a prospect of direct benefit that is important to the health or well-being of the children.

Investigator's Responsibilities:

Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

Your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/irb_event.cfm?actn=info&irbid=11-2033.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented. Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at http://irbis.unc.edu.

Please be aware that approval may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records).

The current data security level determination is Level III. Any changes in the data security level need to be discussed with the relevant IT official. If data security level II and III, consult with your IT official to develop a data security plan. Data security is ultimately the responsibility of the Principal Investigator.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:
Harsha Thirumurthy, Health Policy and Management IRB Informational Message - please do not use email REPLY to this address