Evaluating a patient-centred intervention to increase disclosure and promote resilience for children living with HIV in Kenya

Rachel C. Vreeman[a,b,c], Winstone M. Nyandiko[c,e], Irene Marete[c,e], Ann Mwangi[c,f], Carole I. McAteer[d,c], Alfred Keter[c,f], Michael L. Scanlon[a,b,c,g], Samuel O. Ayaya[c,e], Josephine Aluoch[c] and Joseph Hogan[h]

Objective: We evaluated the impact of a patient-centred, culturally and age-appropriate disclosure counselling intervention on HIV disclosure rates among Kenyan children living with HIV.

Design: A prospective, clinic-cluster randomized trial.

Methods: We followed 285 child–caregiver dyads (children ages 10–14 years) attending eight HIV clinics (randomized to intervention or control) in Kenya. Participants at intervention clinics received intensive counselling with trained disclosure counsellors and culturally tailored materials, compared with control clinics with standard care. Disclosure was treated as a time-to-event outcome, measured on a discrete time scale, with assessments at 0, 6, 12, 18 and 24 months. Mental health and behavioural outcomes were assessed using standardized questionnaires.

Results: Mean age was 12.3 years [standard deviation (SD) 1.5], 52% were girls, with average time-on-treatment of 4.5 years (SD 2.4). Between 0 and 6 months, disclosure prevalence increased from 47 to 58% in the control group and from 50 to 70% in the intervention group. Differences in disclosure were not sustained over the following 18 months. The prevalence of depression symptoms was significantly higher in the intervention than in the control group at 6 months (odds ratio 2.07, 95% confidence interval 1.01–4.25); however, there was no evidence that these differences were sustained after 6 months.

Conclusion: The clinic-based intervention increased disclosure of HIV status to children living with HIV in the short-term, resulting in earlier disclosures, but had less clear impacts longer-term. Although well tailored interventions may support disclosure, children may still experience increased levels of depression symptoms immediately following disclosure.

AIDS 2019, **33** (Suppl 1):S93–S101

Keywords: children and adolescents, disclosure of HIV status, intervention, Kenya, resilience, resource-limited setting

[a]Department of Health Systems Design and Global Health, Icahn School of Medicine at Mount Sinai, [b]Arnhold Institute for Global Health, NY, NY, USA, [c]Academic Model Providing Access to Healthcare (AMPATH), Eldoret, Kenya, [d]Ryan White Center for Pediatric Infectious Disease and Global Health, Department of Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana, USA, [e]Department of Child Health and Paediatrics, [f]Department of Behavioral Sciences, School of Medicine, College of Health Sciences, Moi University, Eldoret, Kenya, [g]John W. McCormack Graduate School for Policy and Global Studies, University of Massachusetts, Boston, MA, and [h]Department of Biostatistics, Brown University School of Public Health, Providence, Rhode Island, USA.

Correspondence to Rachel C. Vreeman, Arnhold Institute for Global Health, 1216 Fifth Avenue, Rm 556, NY, NY 10029, USA; Tel: +1 212-824-7950; e-mail: rachel.vreeman@mssm.edu
Received: 20 March 2018; revised: 8 February 2019; accepted: 11 February 2019.

DOI:10.1097/QAD.0000000000002183

Introduction

For the world's 2.1 million children under the age of 15 who are living with HIV, over 90% of whom live in sub-Saharan Africa, disclosure is a critical step in the transition to adolescence and adulthood [1,2]. Disclosure of HIV status to children refers to a child learning about his or her HIV infection and its treatment and management [3]. The WHO recommends that all school-age children (i.e. children 6–12 years of age) be informed of their HIV status, but studies suggest that most children 6–12 years of age are not fully disclosed [4,5]. Moreover, children in resource-limited settings may be less likely to know their status and more likely to learn it at later ages compared to children in high-income settings [6]. Caregivers of HIV-infected children delay disclosure for a variety of reasons, including being afraid of negative psychological effects for the child (e.g. depression and suicidality), feeling the child is unready to learn his or her HIV status, feeling unprepared to answer the child's questions and fearing subsequent HIV-related stigma and discrimination [7–11].

Disclosure to children living with HIV is essential for adherence to treatment [8,12], retention in HIV care [13] and transition to adult care settings [14]. Disclosure also has important yet underexplored implications for children's mental health and psychosocial development; relationships with caregivers, healthcare providers and friends; and access to social support networks [15–17]. HIV-infected children may be at a greater risk for mental and behavioural health challenges that affect all aspects of HIV prevention and treatment, but there are insufficient data, particularly in sub-Saharan Africa, on the prevalence of mental and behavioural health issues, their impact on HIV care and disclosure of HIV status, and services and interventions [18,19]. Several disclosure models to promote and improve disclosure have been proposed, but few have been rigorously evaluated, particularly for their impact on mental and psychosocial outcomes, and the potential for their adaptation to different contexts is unclear [3,4,20,21].

The concept of resilience may be useful for conceptualizing the potential risk *and* protective factors for mental and behavioural health among HIV-infected children and the mediating role disclosure of HIV status can play. In their review of mental health and resilience in HIV-infected and affected children, Betancourt *et al.* [22] defined resilience within a social-ecological framework as 'the attainment of desirable social and emotional adjustment, despite risks due to HIV'. The authors identified factors at various social-ecological levels associated with resiliency, including coping strategies, self-esteem, positive child-caregiver relationships, access to educational resources and social and peer support. Disclosure is likely integral to these factors. Only one study in their review focused on disclosure; a qualitative study of HIV-affected orphans and caregivers in Uganda found that disclosure and openness about HIV were associated with resilience and self-efficacy, while secrecy and stigma were tied to low self-esteem, anxiety and hopelessness [23].

The objective of this study was to design and rigorously evaluate the impact of a 2-year disclosure intervention to increase the proportion of children who know their HIV status, and support their clinical, mental and behavioural health – that is their *resilience* – through the disclosure process.

Materials and methods

Study design

We conducted a cluster randomized controlled trial of Kenyan children and their caregivers (Vreeman 1R01MH099747–01, 'Patient-Centered Disclosure Intervention for HIV-Infected Children') to evaluate the effectiveness of a culturally adapted, multicomponent intervention to support disclosure of HIV status to HIV-infected children in western Kenya. Randomization was conducted at the level of health facility, with four facilities receiving the intervention programme and four facilities continuing with usual care. The eight clinics for randomization were selected primarily due to their large paediatric and adolescent population but were diverse in other ways, including their location in urban, semi-urban or rural settings as well as the ethnicity of their patients. The intervention components, referred to cumulatively as the HADITHI ('Helping AMPATH Disclose Information and Talk about HIV Infection') intervention, centre on participants' access to intensive counselling sessions (group and one-on-one) with trained counsellors and culturally tailored materials such as pamphlets and videos designed locally (http://www.indiana.edu/~hadithi/home.php). Children and their caregivers were followed for 2 years, with intensive clinical and psychosocial assessments conducted at baseline and at 6-month intervals thereafter.

This study was approved by the Institutional Review Board at Indiana University School of Medicine in Indianapolis, Indiana, USA, and by the Institutional Research Ethics Committee at Moi University School of Medicine in Eldoret, Kenya. Informed consent was required from all of the participants' parents or guardians, with assent also required from child participants.

Setting and population

This study was conducted at eight health facilities of the Academic Model Providing Access to Healthcare (AMPATH) in western Kenya. AMPATH is a collaboration between Moi University School of Medicine, Moi Teaching and Referral Hospital in Eldoret, Kenya, the Kenyan Ministry of Health and a number of North America universities led by Indiana University School of

Medicine [24,25]. AMPATH currently cares for over 5000 HIV-infected children under the age of 15 years on antiretroviral therapy (ART) across 58 health facilities and satellite clinics. Disclosure protocols at AMPATH recommend initiating disclosure to children at age 10 and implementing full disclosure before age 14, which is when children are transferred from the paediatric to adult care system.

Convenience sampling was employed to recruit 35–36 eligible children at each of the eight facilities between April and June of 2013. Random sampling was not feasible due to the small number of children in the targeted age group at each facility. Eligibility for participation in the intervention included the child being 10–14 years of age, HIV-infected and in active care at one of the eight study clinics. The child's disclosure status (i.e. whether or not the child knew his/her HIV status) was not considered as an inclusion or exclusion criteria. The only inclusion criteria for caregivers was that they reported significant involvement in the child's medical care.

Measures

Trained study staff administered a set of questionnaires to each child and caregiver at baseline and then every 6 months for 2 years. To assess disclosure status, child and caregiver versions of a disclosure questionnaire were developed in this setting from previous qualitative work [11,26], and administered separately to all children and caregivers, that is the child was not present when their caregiver was responding to questions and *vice versa*. Disclosure questionnaires were administered in private by a study research assistant familiar with disclosure. Caregivers were asked whether the child knew that they had HIV and that HIV was the reason that they came to clinic, took medication, and had an illness. If a caregiver responded 'yes' to any of these questions, the child was considered disclosed by caregiver-report. To prevent accidental disclosure, children were asked open ended questions about whether they knew why they came to clinic, why they took medication and what their illness was called. Research assistants were trained to probe further if needed to assess disclosure status. If a child responded 'HIV' to any of these questions, the child was considered disclosed by child-report.

Depression symptoms were measured by the Patient Health Questionnaire nine-item depression instrument (PHQ-9) and overall emotional and behavioural symptoms were measured by the Strengths and Difficulties Questionnaire – Youth Version (SDQ). Scores on the PHQ-9 were first categorized as 'no depression' (score of 0–4), 'minimal symptoms' (score of 5–9), 'mild major depression' (score of 10–14), 'moderate major depression' (score of 15–19) and 'severe major depression' (score of >20), as done elsewhere [27]. Due to very low frequencies of children reporting mild major, moderate or severe major depression, the scale was transformed, leaving three depression severity categories: 'no depression' (score of 0), minimal symptoms (score of 1–4) and moderate/severe depression (score 5–19). Scores on the SDQ were categorized into three categories: normal (score of 0–15), borderline (score of 16–19) and abnormal (score of 20–40), as done elsewhere [28,29]. Questionnaires were administered in the same order for all participants and were given in Swahili or English depending on the child's and caregiver's preference. Child reports are analysed here. Study personnel recorded the participants' answers on a paper form, which was then entered into a study database using REDCap electronic data capture tools [30]. Additional demographic and clinical characteristics of the participants were extracted by the study team from the child's medical file using a standardized paper clinical extraction tool and entered into REDCap.

During the period of the study, routine viral load testing was being incorporated into AMPATH clinical procedures for the first time. Because viral loads were not yet routinely available, viral load testing for study participants was done as part of the study investigations for each participant at the conclusion of the study, at the 24-month visit. Viral load testing was done at the AMPATH Reference Lab in Eldoret, Kenya, using Abbott's RealTime assay with the Molecular *m*2000*sp* for sample preparation and *m*2000*rt* for real-time amplification/detection (Abbott Molecular Inc., Des Plaines, Illinois, USA). Viral load was categorized in two ways: undetectable ($\leq$40 copies/ml vs. detectable and suppressed ($\leq$1000 copies/ml) vs. unsuppressed (>1000 cop-copies/ml).

Analyses

We defined disclosure as a binary response of 'disclosed' vs. 'not disclosed'. We analysed disclosure by caregiver-report, by child-report, and a 'composite' measure of disclosure defined by either the child or caregiver reporting positive disclosure. Disclosure was treated as a time-to-event outcome, measured on a discrete time scale in line with the study visits (0, 6, 12, 18, 24 months). Hence, each individual has a time of disclosure or, if never disclosed, has a duration of follow-up time without disclosing. Discrete-time random-effects hazard models of the form $\text{logit}\{h(t)\} = u + \alpha(t) + \beta(t)G$ were fit to characterize the rate of new disclosure, where h (t) is the probability of a new disclosure at time *t* among those who have not yet disclosed. The group indicator is G (= 0 or 1); $\beta(t)$ is the time-specific effect of group on log odds of new disclosure; $\alpha(t)$ is a time-specific intercept term, and u is a clinic-specific random effect assumed *to* follow a normal distribution with mean zero and unknown variance. The random effect accounts for variation in disclosure rates between clusters. Standard error calculations were carried out using bootstrap resampling, with 1000 bootstrap draws using individual participant as the

sampling unit. Consistent with the study design, we resampled with replacement within each clinic. Models were fit using maximum likelihood as implemented in the glmer package in R (Version 3.3.1). Results are summarized using two measures: time-specific hazard ratio and time-specific cumulative prevalence of disclosure. The time-specific hazard ratio compares probability of new disclosure at each time point, where the denominator is those who have not yet disclosed. Time-specific cumulative prevalence compares cumulative proportion disclosed at each time point postbaseline.

Clinical, mental and behavioural outcomes were summarized using mean (standard deviation), frequency (frequency percentage) or medians (interquartile range), depending on whether the normality assumption is satisfied for the variable. Continuous variables were assessed for Gaussian assumptions using Shapiro–Wilk test. Independent-sample *t*-test was used to compare normally distributed continuous variables and two-sample Wilcoxon rank-sum test was used to compare nonnormally distributed variables. Comparison of proportions between the intervention and control groups was done using the Wald test for proportions. The effect of the intervention on depression (score on the PHQ-9 indicating no symptoms of depression < mild depression < moderate/severe depression), and on emotional and behavioural symptoms (score on the SDQ indicating normal < borderline < abnormal) were assessed using a mixed effects ordinal logistic regression model. We included clinic-specific and individual-specific random effects with participants nested within clinics. The treatment arm and the time variable, as well as the interaction of the two, were included as the main effects. We report the odds ratios (ORs) and corresponding 95% confidence intervals (95% CIs) for ordinal regression results.

Sample size for the study was sufficient to detect, with 80% power, a difference in proportion disclosed of 20%, with an assumption of 90% disclosure in the intervention arm and 70% in the control arm at month 24. Our calculation assumed a two-sided hypothesis test with type I error rate (alpha) set at 5%; loss to follow up of 15%; and within-cluster (intraclass) correlation of 0.1.

Results

Child and caregiver participant characteristics

A total of 285 Kenyan caregiver–child dyads were enrolled at baseline. The mean age of child participants was 12.3 years and 52% were girls (Table 1). The children from the control clinics were significantly more likely to have been orphaned ($P = 0.011$), but otherwise the demographic and

Table 1. Baseline demographic and clinical characteristics.

			Control	Intervention	Total	
Variable		*n*	Mean ± SD or Median (IQR) or *n* (%) (*n* = 142)	Mean ± SD or Median (IQR) or *n* (%) (*n* = 143)	Mean ± SD or Median (IQR) or *n* (%) (*n* = 285)	*P*
Age (years)		285	12.3 ± 1.5	12.3 ± 1.5	12.3 ± 1.5	0.990[c]
Male		285	65 (45.8%)	73 (51.1%)	138 (48.4%)	0.373[a]
Attend school		285	141 (99.3%)	142 (99.3%)	283 (99.3%)	1.000[b]
Orphaned (both parents dead)		283	81 (57.5%)	60 (42.3%)	141 (49.8%)	0.011[a]
Sibling Has HIV		265	27 (19.9%)	25 (19.4%)	52 (19.6%)	0.923[a]
WHO clinical stage:	1	282	48 (34.3%)	42 (29.6%)	90 (31.9%)	
	2		49 (35.0%)	41 (28.9%)	90 (31.9%)	0.234[a]
	3		40 (28.6%)	52 (36.6%)	92 (32.6%)	
	4		3 (2.1%)	7 (4.9%)	10 (3.6%)	
On ART		285	122 (85.9%)	128 (89.5%)	250 (87.7%)	0.355[a]
Duration on ART (years)		250	4.4 ± 2.1	4.6 ± 2.6	4.5 ± 2.4	0.400[c]
Regimen:	First line		116 (95.9%)	121 (93.8%)	237 (94.8%)	
	Second line	250	5 (4.1%)	8 (6.2%)	13 (5.2%)	0.489[a]
$CD4^+$ percentage		259	28.0 (21.0 to 33.0)	28.0 (19.0 to 34.0)	28.0 (20.0 to 33.0)	0.880[d]
BMI-for-Age *Z* scores		195	−0.82 ± 1.05	−1.06 ± 1.17	−0.95 ± 1.12	0.137[c]
Height-for-age *Z* scores		195	−1.69 ± 1.32	−1.95 ± 1.21	−1.83 ± 1.27	0.155[c]
Caregiver:	Mother	285	54 (38.0%)	56 (39.2%)	110 (38.6%)	0.844[a]
	Father	285	9 (6.3%)	4 (2.8%)	13 (4.6%)	0.1521[a]
	Sibling	285	10 (4.9%)	1 (0.7%)	8 (2.8%)	0.036[b]
	Grandparent	285	10 (7.0%)	7 (4.9%)	17 (6.0%)	0.444[a]
	Aunt/Uncle	285	20 (14.1%)	20 (14.0%)	40 (14.0%)	0.981[a]
	None	285	39 (27.5%)	53 (37.1%)	92 (32.3%)	0.083[a]
	Other	285	3 (2.1%)	2 (1.4%)	5 (1.8%)	0.684[b]

ART, antiretroviral therapy.
[a]Pearson's Chi-square test.
[b]Fisher's exact test.
[c]Two-sample *t*-test.
[d]Two-sample Wilcoxon rank-sum test.

Table 2. Child reported disclosure prevalence, and incidence by month.

	Prevalence of disclosure			Incidence of new disclosures		
Month	Control freq (%)	Interv freq (%)	Difference (95% CI)	Control (%)	Interv (%)	Hazard ratio (95% CI)
0	42 (30%)	48 (34%)	4.0 (−6.6 to 14.6)	–	–	–
6	48 (34%)	58 (42%)	7.2 (−4.0 to 18.4)	6%	12%	1.90 (0.63–5.74)
12	56 (42%)	63 (48%)	6.8 (−5.0 to 18.6)	12%	13%	1.08 (0.42–2.76)
18	63 (48%)	75 (58%)	10.2 (−1.8 to 22.2)	10%	18%	2.01 (0.71–5.66)
24	76 (58%)	90 (74%)	15.5 (3.7 to 27.3)	19%	37%	2.47 (1.01–6.04)

CI, confidence interval.

clinical characteristics between the groups were not statistically different. The majority of caregiver participants were the biological mother of the child (54%), but there were a significant number of aunt/uncle caregivers (19%) and biological fathers (17%) as primary caregivers. The participants had a mean CD4% of 28.0% and had been on ART for an average of 4.4 years, with 95% of the children on first-line ART regimens. In the course of 24 months of follow-up, 25 patients withdrew from the study and seven patients died, leaving 253 participants who completed all study assessments and follow-up. There were no significant differences in loss to follow-up by treatment group.

Disclosure status

Caregiver and child reports of the child's disclosure status were inconsistent. At baseline, 32% of the children reported that they knew their HIV status already, with 30% of the children in the control group and 34% of the children in the intervention group reported as being disclosed per the child participants at baseline. Using the composite measure of disclosure (i.e. whether either the child or caregiver reported that the child was disclosed), at baseline, 47% of children in the control group and 50% of children in the intervention group were disclosed. At baseline, 19% of the child–caregiver dyads answered differently within the dyad as to whether the child knew his or her HIV status. In the vast majority of cases of disagreement (89%), the caregiver reported that the child's HIV status had been disclosed to the child, while even with probing, the child's knowledge of their HIV status could not be elicited. Additional baseline characteristics of this study population are described in more detail elsewhere [26].

Using child-reported disclosure (Table 2), the prevalence of disclosure increased between the baseline and 24 months of follow-up from 30 to 58% in the control arm and from 34 to 74% in the intervention arm. There was a significant difference in composite disclosure prevalence for the intervention group at 24 months (difference of 15.5%, 95% CI: 3.7–27.3). The intervention group had significantly more new disclosures between the 18-month and 24-month time points than controls (37 vs. 19%, hazard ratio = 2.47, 95% CI: 1.01–6.04). Using a composite measure for positive disclosure (Table 3), disclosure increased during the course of the study from 47 to 84% in the control arm and from 50 to 89% in the intervention arm. The prevalence of disclosure was higher in the intervention group at each time point, but these differences were only significant at the 6-month follow-up, when 70% of children in the intervention arm were disclosed after 6 months in the study, compared with 58% in the control arm ($P = 0.039$).

Mental and behavioural health

Most children scored within normal ranges for the mental and behavioural health measures used. At baseline, a total of 30 children (9.5%) reported moderate/severe depression on the PHQ-9 and 22 children (7.7%) reported abnormal scores on the SDQ, with no significant difference between intervention and control groups (Table 4). The treatment effect, captured by the interaction of the HADITHI intervention and time, showed variable results (Table 5). On the PHQ-9, children in the intervention group had 2.1 times (95% CI 1.01–4.25) the odds of moving from a lower depression category to a higher (i.e. more severe) depression category than children in the control group at month 6, the same timepoint at which disclosures increased significantly. However, at months 12 and 18, children in the intervention group had a reduced odds of moving from

Table 3. Caregiver and child reported (composite) disclosure prevalence, and incidence by month.

	Prevalence of disclosure			Incidence of new disclosures		
Month	Control freq (%)	Interv freq (%)	Difference (95% CI)	Control (%)	Interv (%)	Hazard ratio (95% CI)
0	67 (47%)	72 (50%)	3.2 (-8.4 to 14.8)	–	–	–
6	81 (58%)	96 (70%)	11.5 (0.5–22.5)	42	64	2.43 (1.12–5.29)
12	94 (70%)	100 (76%)	6.6 (-3.6 to 16.8)	29	24	0.75 (0.28–2.06)
18	98 (74%)	108 (84%)	8.9 (-0.3 to 18.1)	15	30	2.44 (0.66–8.98)
24	110 (84%)	109 (89%)	5.5 (-2.3 to 13.3)	40	41	1.06 (0.30–3.66)

CI, confidence interval.

Table 4. Mental and psychosocial outcomes.

Month		N	PHQ-9 depression severity (n, %)		
			No depression (score of 0)	Minimal symptoms (score of 1–4)	Moderate/severe depression (score of 5–19)
0	Control	141	87 (61.7%)	41 (29.1%)	13 (9.2%)
	Intervention	143	68 (47.6%)	58 (40.6%)	17 (11.9%)
6	Control	139	90 (64.7%)	37 (26.6%)	12 (8.6%)
	Intervention	138	62 (44.9%)	64 (46.4%)	12 (8.7%)
12	Control	134	75 (56.0%)	42 (31.3%)	17 (12.7%)
	Intervention	131	65 (49.6%)	45 (34.4%)	21 (16.0%)
18	Control	132	63 (47.7%)	55 (41.7%)	14 (10.6%)
	Intervention	127	60 (47.2%)	45 (35.4%)	22 (17.3%)
24	Control	131	80 (61.1%)	40 (30.5%)	11 (8.4%)
	Intervention	122	52 (42.6%)	53 (43.4%)	17 (13.9%)
			SDQ behavioural health (n, %)		
			Normal (score of 0–15)	Borderline (score of 16–19)	Abnormal (score of 20–40)
0	Control	141	109 (77.3%)	22 (15.6%)	10 (7.1%)
	Intervention	143	112 (78.3%)	19 (13.3%)	12 (8.4%)
6	Control	139	107 (77.0%)	21 (15.1%)	11 (7.9%)
	Intervention	138	102 (73.9%)	28 (20.3%)	8 (5.8%)
12	Control	134	105 (78.4%)	17 (12.7%)	12 (9.0%)
	Intervention	130	103 (79.2%)	16 (12.3%)	11 (8.5%)
18	Control	132	97 (73.5%)	25 (18.9%)	10 (7.6%)
	Intervention	127	95 (74.8%)	17 (13.4%)	15 (11.8%)
24	Control	131	103 (78.6%)	14 (10.7%)	14 (10.7%)
	Intervention	122	93 (76.2%)	24 (19.7%)	5 (4.1%)

PHQ-9, Patient Health Questionnaire nine-item depression instrument; SDQ, Strengths and Difficulties Questionnaire – Youth Version.

a lower to higher depression category (though not statistically significant), and at month 24, the odds between intervention and controls were similar. On the SDQ, children in the intervention group had 1.2 times (95% CI 0.55–2.55) the odds of moving from a normal to borderline or borderline to abnormal category at 6 months. At months 12, 18 and 24, children in the intervention group had reduced odds (ORs between 0.80 and 0.87), though these were also not statistically significant.

Viral load

At the 24-month final study visit, 251 participants had viral load measures drawn. Of these, 118 participants (47%) had a detectable viral load (>40 copies/ml) and 91 participants (36%) were defined as virally unsuppressed (>1000 copies/ml). Individuals in the intervention arm had a higher odds of achieving viral suppression (OR = 2.29, 95% CI 0.89–5.39), but this was not statistically significant. This comparison was adjusted for baseline $CD4^+$ cell count to alleviate potential imbalances in treatment groups due to missing observations. The unadjusted comparison yielded an OR of 1.48 with 95% CI (0.89–5.39).

Table 5. Effect of intervention on mental and psychosocial outcomes.

	Odds ratio (95% confidence interval)
PHQ-9, Intervention vs. control	
Month 6	2.07 (1.01–4.25)
Month 12	0.62 (0.31–1.25)
Month 18	0.56 (0.28–1.13)
Month 24	1.06 (0.52–2.17)
SDQ, Intervention vs. control	
Month 6	1.18 (0.55–2.55)
Month 12	0.80 (0.33–1.90)
Month 18	0.87 (0.38–2.02)
Month 24	0.81 (0.34–1.94)

PHQ-9, Patient Health Questionnaire nine-item depression instrument; SDQ, Strengths and Difficulties Questionnaire – Youth Version.

Discussion

Disclosure is a critical milestone for HIV-infected children, as it is necessary for the transition of responsibility for medication-taking and disease management to move from parent (or guardian) to child and for care transitions between paediatric and adult clinical care services. This study provides preliminary evidence for a clinic-based counselling intervention to increase disclosure of HIV status to perinatally HIV-infected children and adolescents. At baseline, about one-third of this cohort of Kenyan children ages 10-15 years reported that they knew their HIV status. This low prevalence is consistent with estimates from other resource-limited settings [4]. This also provided evidence that the protocols in place within the clinical system, which called for HIV disclosure to children to be done at age 10, were either not effective or not fully implemented. This points to the need to improve strategies to facilitate disclosure within a resource-limited clinic setting.

The HADITHI intervention package, which was informed by rigorous and culturally grounded qualitative work in this setting, provided one such strategy, although the results were mixed. Although the intervention group had a significantly higher incidence of disclosure in the short-term, the cumulative proportion disclosed at subsequent periods of follow-up was not significantly different between intervention and controls. Nonetheless, because disclosure typically accumulates in this population over time, the earlier and accelerated rates of disclosure with the intervention provide evidence that the intervention package catalyzed this important step in adolescents' transition to adulthood and management of their own medical care. A recent review revealed seven unique disclosure models in peer-reviewed literature, of which five included some structured process for disclosure, counselling and follow-up, as well as a diversity of resources such as books and toolkits in the nonpeer-reviewed, 'gray' literature [20]. As the majority of these resources have not been rigorously evaluated, the randomized design and grounded intervention components of this study contribute important data to the complex and underexplored issues of disclosure of HIV status to children and adolescents in sub-Saharan Africa.

Previous work around the concept of resilience among HIV-infected and affected youth offers important insights into disclosure, but there are few studies employing this concept in empirical work on disclosure. We provide preliminary evidence for how resilience might be measured in relation to a disclosure intervention. In our cohort, we found that between 8 and 17% of children had moderate to severe depression symptoms on the PHQ-9, while between 4 and 12% of children has abnormal behavioural scores on the SDQ. During the study, we observed a general pattern of increased depression symptoms in the intervention cohort at month 6 when disclosures increased significantly in this group. Clinically, this could be understood as children initially having a negative reaction to disclosure, as it is undoubtedly a traumatic experience for some, but then readjusting to more positive emotional and behavioural levels. This hypothesis is supported by our qualitative work in this setting on disclosure that finds caregivers are particularly worried about the immediate negative psychological effects of disclosure, but that caregivers who had already disclosed generally reported that negative psychological effects were short-term and outweighed by long-term benefits such as improved adherence to treatment [11,31]. Moreover, the intervention components included significant postdisclosure mental health support, including access to study counsellors and materials as well as referral to more comprehensive mental health services available through the AMPATH clinical system. A quasi-experimental study of a disclosure intervention among 40 children in Puerto Rico found that most children (70%) achieved feelings of normalcy 6 months postdisclosure [32]. More broadly, if resilience requires integration of one's disease status into a positive self-conception, as well as accessing educational and support resources, knowing one's disease status is a necessary first step towards these goals. For this young cohort, the prevalence of negative mental and behavioural health symptoms also underscores the importance of continually evaluating mental health as youth move through adolescence and investigating mental health support interventions for this vulnerable population in resource-limited settings.

Although this study was not powered to examine differences in the potential impact of the intervention on viral load suppression, the trend suggested that the intervention group may have had more viral suppression. Without more frequent measures to correlate more closely with the potential timing of disclosure, it is difficult to know whether disclosure is associated with virologic outcomes; however, this is a positive trend. A recent study of children in Namibia found that disclosed children had significantly lower viral loads than nondisclosed children and that adherence among disclosed children increased over time [33]. Increased resilience, including mental and behavioural health, may play an important role in supporting HIV treatment outcomes such as adherence and viral suppression.

This study has several limitations that merit discussion. First, we found some discrepancy between caregivers' reports of child disclosure and children's reports of disclosure. However, we used the more conservative composite reports of caregiver and child reporting on disclosure status for the analyses, and these indicated significant increases in disclosure among the intervention group participants, with both caregiver and child reports trending in the same directions. We have not found validated, standardized assessments of disclosure status for use for children in settings such as Kenya [4]; however, our measurement tools were developed from prior qualitative work in this setting and tested through cognitive interviewing techniques for face validity and acceptability [11,26,34]. There are also few studies of the reliability and validity of mental and behavioural assessment tools (including those used in this study) among this specific population [19], and we found anecdotal evidence from study counsellors that these tools might underestimate children's psychological distress. Second, we checked baseline covariates for balance between the intervention and control arms and orphan status was found to be more prevalent in the control arm. This evidence of differential distribution is a potential limitation in respect to orphan status and disclosure, which warrants further study.

Finally, the control group participants were exposed to much more detailed, regular questioning about disclosure than other patients in the control clinics. The true standard of care at AMPATH does include a disclosure protocol with guidelines on the age at disclosure initiative

and disclosure process. AMPATH staff, including clinical officers and nurses, participate in annual disclosure trainings. Still, it is possible that the repeated disclosure questioning as part of the study protocols may have led more families in the control group to engage in the disclosure process with their children than in a true standard of care group. This intervention was tested in only one country in sub-Saharan Africa. There may be language and cultural content challenges if implementing it in another setting. Nonetheless, the AMPATH programme in Kenya is representative of many in sub-Saharan Africa [13,35,36], and the study sites included both urban, peri-urban and rural clinical sites. Moreover, the freely available and manualized curricula can be adapted for a particular setting. This trial evaluated a set of clinic-based interventions; it is not possible to distinguish whether individual components were effective. Because implementation strategies cannot be used or tested without a full description of their components and how they should be used, we have made available on the website precise descriptions that enable measurement and reproducibility.

As more and more HIV-infected children in sub-Saharan Africa reach adolescence, we must support these youths and their families through the process of disclosure in a manner that maximizes their resilience to achieve optimal physical, mental, emotional and social health. This study provides evidence that an intervention including strategic, tailored health support services within a clinical setting in western Kenya was associated with greater rates of disclosure in the early phases of follow-up. Although there is some evidence that, at the population level, depression increases concomitantly in the intervention arm in the early part of follow-up, this study is not designed to investigate a causal link between disclosure and increased risk of depression. Nonetheless, our findings suggest that further exploration of the links between mental health and the complexity of the disclosure process in adolescence are important next steps.

Acknowledgements

RCV, WMN, IM, SOA and JH were responsible for the study concept and design. CIM, MLS and JA led the implementation of the study and collection of data. AM, AK and JH led the management and analysis of data. RCV and MLS led the drafting of the initial draft of the manuscript and all authors contributed to the revision of the manuscript and approved of the final version.

This research was supported by the National Institute for Mental Health, Bethesda, Maryland, USA through a grant entitled 'Patient-Centered Disclosure Intervention for HIV-Infected Children' (1R01MH099747–01), and by Providence/Boston Center for AIDS Research, Providence, Rhode Island, USA (P30AI042853). The authors acknowledge the diligent work by the HADITHI counsellors and research assistants, as well as the invaluable contribution of time from the cohort of families who participated in this study and the healthcare workers involved in their routine care.

The views expressed in this article are those of the authors and do not necessarily represent the view of the Indiana University School of Medicine, Icahn School of Medicine at Mount Sinai, or the Moi University School of Medicine. The authors have no conflicts of interest to disclose. The primary author had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of interest

The authors of this manuscript have no competing interests to report.

References

1. Cervia JS. **Easing the transition of HIV-infected adolescents to adult care.** *AIDS Patient Care STDS* 2013; **27**:692–696.
2. UNAIDS. Fact sheet: World AIDS Day, 2017. Geneva: UNAIDS; 2017.
3. Wiener L, Mellins CA, Marhefka S, Battles HB. **Disclosure of an HIV diagnosis to children: history, current research, and future directions.** *J Dev Behav Pediatr* 2007; **28**:155–166.
4. Vreeman RC, Gramelspacher AM, Gisore PO, Scanlon ML, Nyandiko WM. **Disclosure of HIV status to children in resource-limited settings: a systematic review.** *J Int AIDS Soc* 2013; **16**:18466.
5. WHO. Guidelines on HIV disclosure counseling for children up to 12 years of age. Geneva: WHO; 2011.
6. Pinzon-Iregui MC, Beck-Sague CM, Malow RM. **Disclosure of their HIV status to infected children: a review of the literature.** *J Trop Pediatr* 2013; **59**:84–89.
7. Gyamfi E, Okyere P, Enoch A, Appiah-Brempong E. **Prevalence of, and barriers to the disclosure of HIV status to infected children and adolescents in a district of Ghana.** *BMC Int Health Hum Rights* 2017; **17**:8.
8. Inzaule SC, Hamers RL, Kityo C, Rinke de Wit TF, Roura M. **Long-term antiretroviral treatment adherence in HIV-infected adolescents and adults in uganda: a qualitative study.** *PLoS One* 2016; **11**:e0167492.
9. Kiwanuka J, Mulogo E, Haberer JE. **Caregiver perceptions and motivation for disclosing or concealing the diagnosis of HIV infection to children receiving HIV care in Mbarara, Uganda: a qualitative study.** *PLoS One* 2014; **9**:e93276.
10. Mburu G, Hodgson I, Kalibala S, Haamujompa C, Cataldo F, Lowenthal ED, *et al*. **Adolescent HIV disclosure in Zambia: barriers, facilitators and outcomes.** *J Int AIDS Soc* 2014; **17**:18866.
11. Vreeman RC, Nyandiko WM, Ayaya SO, Walumbe EG, Marrero DG, Inui TS. **The perceived impact of disclosure of pediatric HIV status on pediatric antiretroviral therapy adherence, child well being, and social relationships in a resource-limited setting.** *AIDS Patient Care STDS* 2010; **24**:639–649.
12. Nichols J, Steinmetz A, Paintsil E. **Impact of HIV-status disclosure on adherence to antiretroviral therapy among HIV-infected children in resource-limited settings: a systematic review.** *AIDS Behav* 2017; **21**:59–69.
13. Arrive E, Dicko F, Amghar H, Aka AE, Dior H, Bouah B, *et al*. **HIV status disclosure and retention in care in HIV-infected adolescents on antiretroviral therapy (ART) in West Africa.** *PLoS One* 2012; **7**:e33690.

14. Dahourou DL, Gautier-Lafaye C, Teasdale CA, Renner L, Yotebieng M, Desmonde S, *et al*. **Transition from paediatric to adult care of adolescents living with HIV in sub-Saharan Africa: challenges, youth-friendly models, and outcomes.** *J Int AIDS Soc* 2017; **20 (Suppl 3)**:21528.
15. Boon-Yasidhi V, Naiwatanakul T, Chokephaibulkit K, Lolekha R, Leowsrisook P, Chotpitayasunond T, *et al*. **Effect of HIV diagnosis disclosure on psychosocial outcomes in Thai children with perinatal HIV infection.** *Int J STD AIDS* 2016; **27**:288–295.
16. Gyamfi E, Okyere P, Appiah-Brempong E, Adjei RO, Mensah KA. **Benefits of disclosure of HIV status to infected children and adolescents: perceptions of caregivers and healthcare providers.** *J Assoc Nurses AIDS Care* 2015; **26**:770–780.
17. Mutumba M, Musiime V, Tsai AC, Byaruhanga J, Kiweewa F, Bauermeister JA, *et al*. **Disclosure of HIV status to perinatally infected adolescents in urban Uganda: a qualitative study on timing, process, and outcomes.** *J Assoc Nurses AIDS Care* 2015; **26**:472–484.
18. Mellins CA, Malee KM. **Understanding the mental health of youth living with perinatal HIV infection: lessons learned and current challenges.** *J Int AIDS Soc* 2013; **16**:18593.
19. Vreeman RC, McCoy BM, Lee S. **Mental health challenges among adolescents living with HIV.** *J Int AIDS Soc* 2017; **20 (Suppl 3)**:21497.
20. Wright S, Amzel A, Ikoro N, Srivastava M, Leclerc-Madlala S, Bowsky S, *et al*. **Talking to children about their HIV status: a review of available resources, tools, and models for improving and promoting pediatric disclosure.** *AIDS Care* 2017; **29**:1019–1025.
21. Butler AM, Williams PL, Howland LC, Storm D, Hutton N, Seage GR 3rd, *et al*. **Impact of disclosure of HIV infection on health-related quality of life among children and adolescents with HIV infection.** *Pediatrics* 2009; **123**:935–943.
22. Betancourt TS, Meyers-Ohki SE, Charrow A, Hansen N. **Annual research review: mental health and resilience in HIV/AIDS-affected children: a review of the literature and recommendations for future research.** *J Child Psychol Psychiatry* 2013; **54**:423–444.
23. Daniels M, Malinga Apila H, Bj Rgo R, Therese Lie G. **Breaching cultural silence: enhancing resilience among Ugandan orphans.** *Afr J AIDS Res* 2007; **6**:109–120.
24. Einterz RM, Kimaiyo S, Mengech HN, Khwa-Otsyula BO, Esamai F, Quigley F, *et al*. **Responding to the HIV pandemic: the power of an academic medical partnership.** *Acad Med* 2007; **82**:812–818.
25. Inui TS, Nyandiko WM, Kimaiyo SN, Frankel RM, Muriuki T, Mamlin JJ, *et al*. **AMPATH: living proof that no one has to die from HIV.** *J Gen Intern Med* 2007; **22**:1745–1750.
26. Vreeman RC, Scanlon ML, Marete I, Mwangi A, Inui TS, McAteer CI, *et al*. **Characteristics of HIV-infected adolescents enrolled in a disclosure intervention trial in western Kenya.** *AIDS Care* 2015; **27 (Suppl 1)**:6–17.
27. Kroenke K, Spitzer RL, Williams JB. **The PHQ-9: validity of a brief depression severity measure.** *J Gen Intern Med* 2001; **16**:606–613.
28. Goodman R, Meltzer H, Bailey V. **The Strengths and Difficulties Questionnaire: a pilot study on the validity of the self-report version.** *Eur Child Adolesc Psychiatry* 1998; **7**:125–130.
29. Goodman R, Renfrew D, Mullick M. **Predicting type of psychiatric disorder from Strengths and Difficulties Questionnaire (SDQ) scores in child mental health clinics in London and Dhaka.** *Eur Child Adolesc Psychiatry* 2000; **9**:129–134.
30. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. **Research electronic data capture (REDCap): a metadata-driven methodology and workflow process for providing translational research informatics support.** *J Biomed Inform* 2009; **42**:377–381.
31. Vreeman RC, Scanlon ML, Inui TS, McAteer CI, Fischer LJ, McHenry MS, *et al*. **'Why did you not tell me?' Perspectives of caregivers and children on the social environment surrounding child HIV disclosure in Kenya.** *AIDS* 2015; **29 (Suppl 1)**:S47–S55.
32. Blasini I, Chantry C, Cruz C, Ortiz L, Salabarria I, Scalley N, *et al*. **Disclosure model for pediatric patients living with HIV in Puerto Rico: design, implementation, and evaluation.** *J Dev Behav Pediatr* 2004; **25**:181–189.
33. Beima-Sofie KM, Brandt L, Hamunime N, Shepard M, Uusiku J, John-Stewart GC, *et al*. **Pediatric HIV disclosure intervention improves knowledge and clinical outcomes in HIV-infected children in Namibia.** *J Acquir Immune Defic Syndr* 2017; **75**:18–26.
34. McHenry MS, Nyandiko WM, Scanlon ML, Fischer LJ, McAteer CI, Aluoch J, *et al*. **HIV stigma: perspectives from Kenyan child caregivers and adolescents living with HIV.** *J Int Assoc Provid AIDS Care* 2017; **16**:215–225.
35. **International Epidemiologic Database to Evaluate AIDS (IeDEA). A survey of paediatric HIV programmatic and clinical management practices in Asia and sub-Saharan Africa: the International epidemiologic Databases to Evaluate AIDS (IeDEA).** *J Int AIDS Soc* 2013; **16**:17998.
36. Leroy V, Malateste K, Rabie H, Lumbiganon P, Ayaya S, Dicko F, *et al*. **Outcomes of antiretroviral therapy in children in Asia and Africa: a comparative analysis of the IeDEA pediatric multiregional collaboration.** *J Acquir Immune Defic Syndr* 2013; **62**:208–219.